ROBOTICS FOR HEALTHCARE

Final Report

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Author(s)   Maurits Butter (TNO)
                                Arjan Rensma (TNO)
                                Joey van Boxsel (TNO)
                                Sandy Kalisingh (TNO)
                                Marian Schoone (TNO)
                                Miriam Leis (TNO)
                                Gert Jan Gelderblom (Vilans)
                                Ger Cremers (Vilans)
                                Monique de Wilt (Vilans)
                                Willem Kortekaas (EuroAct, Japan)
                                Axel Thielmann & Kerstin Cuhls (FhG ISI, Germany)
                                Anna Sachinopoulou & Ilkka Korhonen (VTT, Finland)

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Executive Summary

Objective of Study

For the last two decades the European Commission (EC), and in particular the Directorate General Information Society and Media, has been strongly supporting the application of Information and Communication Technologies (ICT) in healthcare. ICT is an enabling technology which can provide various solutions in the healthcare sector, ranging from electronic patient records and health information networks to intelligent prosthetics and robotised surgery. The EC funded the present study with the aim to investigate the potential of robotics in healthcare.

Robotics for healthcare is an emerging field which is expected to grow in the face of demographic change (ageing), expected shortages of healthcare personnel, calls for improving quality of life for the elderly and disabled, and the need for even higher quality care, for example high precision surgery. All these factors stimulate innovation in the domain of Robotics for Healthcare. Several programs and networks dedicated to research on robotics are already focusing part of their efforts on applications in healthcare.

In this study the following definition of robotics has been used:

> Robotics for Medicine and Healthcare is considered the domain of systems able to perform coordinated mechatronic actions (force or movement exertions) on the basis of processing of information acquired through sensor technology, with the aim to support the functioning of impaired individuals, medical interventions, care and rehabilitation of patients and also to support individuals in prevention programmes.

The main aim of this study is to provide key research policy recommendations for the application of robotics in healthcare. Another objective of the study is to raise awareness about these important new developments among a wider audience.

To this extent, a roadmap of promising applications of robotics in healthcare and associated R&D was developed, taking into account the state of the art as well as short and long-term future possibilities with a time horizon ending in 2025.

A number of deliverables have been developed. This document represents the final report of the study. The report describes the research approach, the findings and the conclusions and recommendations for research directions in the EC programs.

The focus of the study is on solutions that support the key objectives of healthcare:
- To contribute to quality, safety and efficiency of care.
- To promote the shift to preventive and personalized care.
- To support the availability of long term care for people in need.

Since the application of robotics in healthcare is not only an issue of technology, but also heavily dependent on societal acceptance, safety and reliability issues as well as regulations, special attention was paid to these aspects.

Contractors and partners

The main contractor of the study was the Innovation Policy group of TNO Quality for Life, focusing on the study methodology and management. The other members of the consortium were "Prevention & Health" (also from TNO Quality of Life), Vilans (the Netherlands), Fraunhofer Gesellschaft-ISI (Germany), VTT (Finland) and EuroAct (Japan).

Methodology

The project methodology was a combination of desk research and expert consultation. According to the EC specifications, the methodologies for this study included literature research, surveys and interviews with experts and stakeholders as well as an evaluative workshop with a representative group of experts and stakeholders for drafting the roadmap. During the project, over 50 internal and external experts have been consulted.

One of the pillars of the study are the concepts of Innovation Themes and Innovation Areas, developed by TNO (Butter & Hoogendoorn, 2003). An Innovation Theme is an innovation subject within which innovation takes place for ca. 20 years. Actors working on an innovation theme share a vision on solving a societal issue (i.e. non fossil based energy). Innovation Themes are made up of Innovation Areas. Innovation Areas are basically categories of Product/Market combinations that they are being innovated during a time period of ca. 10-20 years.

The study was divided into four work packages (diagram below):
- The development of a State-of-the-Art analysis report.
- Development of the Roadmap, consisting of six sub road maps.
- In depth analysis using three Case studies (surgical robots, intelligent prosthetics, robotized motor coordination analysis and therapy)
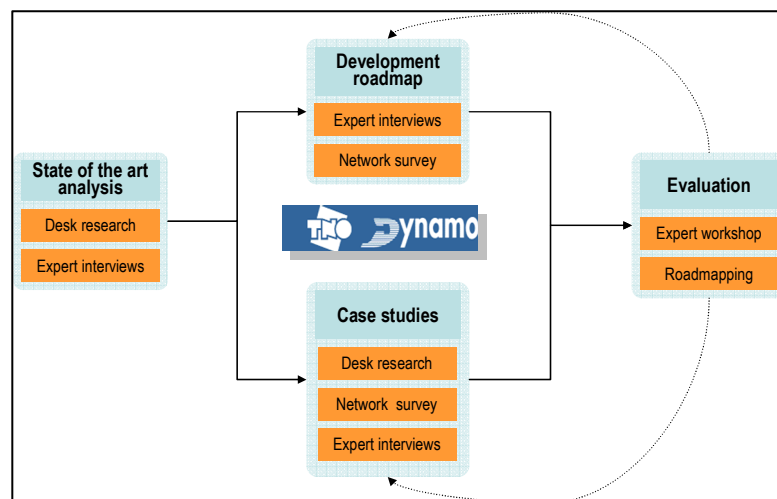- Evaluation of results in an expert workshop.

Figure 1: Overview of the study approach.

The State-of-the-Art report (the SOTA report) presented the state of the art in Robotics for healthcare on a large number of applications and enabling technologies.

The topics for the roadmap were chosen on the following criteria: market and industrial attractiveness and relationship to the eHealth domain.

The three case studies were chosen in close consultation with the EC in order to provide further insights with regard to the driving factors and barriers to the development of robotics for healthcare, the role of the stakeholders and possible ethical and legal issues.

The concluding two-day expert workshop was conducted with 45 experts in order to evaluate the results and the concept roadmaps.

Major findings
This study identified the following five innovation themes:
* Robotics for medical interventions
* Robotics supporting professional care
* Robotics assisted preventative therapies and diagnosis
* Robotic assistive technology
* Robotics for rehabilitation treatment

Within these innovation themes, 21 innovation areas were identified, as shown in Figure 2 below.
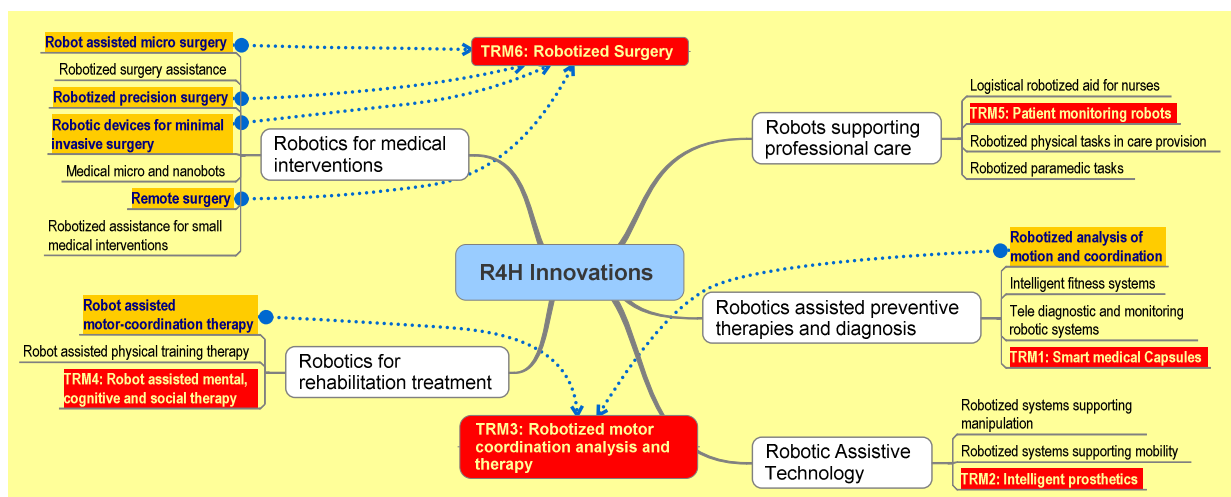
Figure 2: Overview of the innovation areas and relation with the Technology Roadmaps developed.

Based on a survey among stakeholders and in close cooperation with the EC, the six most relevant innovation areas were selected and research roadmaps were prepared for them:

* Smart medical capsules (for endoscopy, biopsy and targeted drug delivery)
* Intelligent prosthetics
* Robotised patient monitoring systems
* Robotised surgery (a combination of the areas related to the facilitation of the surgeon in the operating room)
* Robotised motor coordination analysis and therapy
* Robot assisted mental, cognitive and social therapy

Robotic systems are very complex. They depend on many enabling technologies and challenges. These technologies and challenges require significant amount of R&D, are dependent on each other and progress at different speeds. Human-machine interface designs, sensor systems, mobile energy supply, energy efficiency and biocompatible materials are some of the main topics. The key technologies which were identified are presented in figure 3 and are further elaborated in Chapter 5. The roadmaps of the selected innovation areas are presented in detail in Chapter 6.
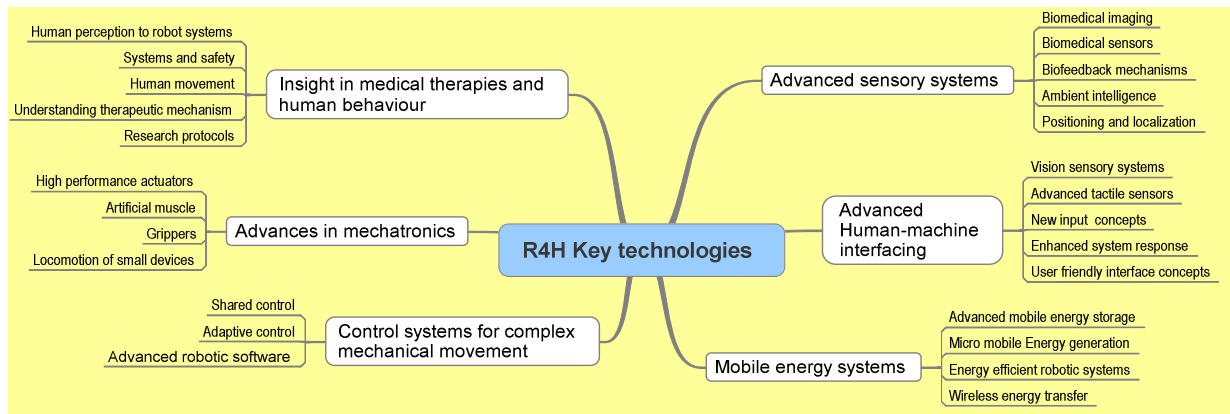
Figure 3: Overview of the identified related key technologies for the domain of the application of robotics in healthcare.

The field of Robotics for Healthcare is driven by the expectation that robots will be able to play an important role in helping societies to cope with a number of the big challenges and trends of the next decades. The study has shown that the application of robotics in healthcare is in many areas a young but promising field with different segments that are progressing at different speeds. Only a few products have reached the stage of large scale market introduction, the real measure for successful innovation. Many applications are still very expensive. In many instances, it is quite difficult to identify the reasons for discontinued and unsuccessful projects, since multi-dimensional factors like legal issues, regulations, enabling technologies, social acceptance and unforeseeable disruptive incidents play key roles.

The first commercial products on the market may serve as a signal for a greater development to follow, as the potential added value of robots in healthcare will be fully recognized. The market is expected to grow, as the following examples indicate. The U.S. market for prosthetics, orthoses and cosmetic enhancement products is expected to increase from $6.8 billion in 2005 to $10.8 billion in 2010, at an AAGR (average annual growth rate) of 9.9%. Powered wheelchairs could reach a market volume of a little over $1 billion by 2013 in the USA and Asia alone. Smart medical capsules may even take over the whole market for classic colonoscopy screenings as prices for smart medical capsules will drop below the current $450 per unit.

Since the overall sector of robotics in healthcare is still an emerging area with successes and failures, a final conclusion about the future trajectory cannot be made at present. Nonetheless, the identification of drivers, barriers and challenges will be helpful for guiding the development into a desired direction for achieving higher quality, safety and availability of care and a shift to prevention.

From the side of the stakeholders, e.g. patients, doctors, hospitals, care institutions, health insurance companies and authorities, it appears that most of them see the developments as very interesting for the future, but very few of them show an urgent drive to switch to these new applications right now.

Suppliers play a rather supporting role, but patient involvement in research and development is (too) little. Although government is not considered a key player in this area, governmental funding for related R&D is crucial.

Key policy recommendations
Given the findings, the main recommendation to the EC is to further develop this area in the Framework Programme. This recommendation is strengthened by the fact that only a few research programmes exist that specifically focus on this area. Further arguments to support this conclusion are:

- The field is still in its infancy, but some products are already commercialised. This supports the conclusion that there is a market, but that this market has just entered its growth phase. It will take a lot of time before important innovations find their way into regular healthcare. Some ideas will not even be realised within the study's time horizon of 2025.

- The "Robotics for Healthcare" network in Europe is relatively small, but the authors believe that it has a critical mass (both within research and industry).

- Robotics is seen to be part of the next potential Kondratiev wave. Therefore further influential developments in the field can be expected. As the potential benefits for healthcare are significant, early application is beneficial.

- Looking at the broad enabling technologies, cooperation with other robotic application fields should be facilitated (e.g. through the EURON network).

- More than the development of new applications, the field also needs the further enhancement of the "Robotics for Healthcare" network to establish a sound multidisciplinary community. Researchers, industry, medical professionals and users themselves should all be included to enhance user oriented research. The fact that there is already a network will be helpful in this.

- The model of innovation used should incorporate not only research, but a combination of research, development and application to ensure actual use of the research. Soft elements of innovation like the analysis of user acceptance should also be included as potentially fundable aspects.

- To be an effective program as a whole (and be more effective than a set of separate innovation projects) it would be advisable to add two "horizontal" lines to the program: one on legal issues and one on ethical issues.

- Because the field is very new, acceptance and implementation will be complicated. To raise awareness and promote involvement of stakeholders, awareness activities should accompany any innovation program.

- Considerable attention should be paid to good communication and cooperation with programmes in related fields.

- Attention should be given to the development of "hard evidence" of the actual benefits of the application of robotics in healthcare. This includes the development of standardized research protocols

- Several ethical issues can be seen in relation to robotics in healthcare, such as privacy, substitution of human contact by machine contact and outcome parameters for therapeutic interactions of robots with patients who have cognitive or mental disabilities. It is important that concerns on ethical issues are translated into design and outcome criteria which are useful during innovation processes.

- Robotic systems are introduced in existing legal and regulatory systems. However, the current methodology, in particular, to prove the effectiveness of medical interventions with robotic systems, seems very burdensome and costly. In their present form, legal and regulatory aspects represent perhaps one of the biggest impediments for innovation in this field. Methodology, like evidence-based medicine, originally designed for medicines, should be adapted to the characteristics of (robotic) devices.

- When an initiative is taken to start a program for robotics in healthcare, much thought must be given to the question of which are the most appropriate criteria for granting proposals in relation to the stage of development. Considering broad application in regular healthcare as the final yardstick for successful innovation, the program must include some mechanism that guarantees that the program not only attracts researchers interested in long term possibilities, but also companies and/or health institutes which have an urgent interest in practical applications. This might take the form of a program with more compartments (each with separate budgets) which have granting criteria optimally geared to the type of development project in that specific compartment and to the type and roles of stakeholders that need to be involved.

1 Introduction to Robotics in Medicine and Healthcare

1.1 Why this study and what will be its use

This study is carried out within the framework of the eHealth activities of the European Commission, which aim to "significantly improve the quality, access and efficiency of healthcare for all citizens".

Research activities related to eHealth in the Seventh Framework Programme aim to support highly interdisciplinary research for:

- Improved productivity of healthcare systems by facilitating patient care at the point of need.
- Continuous and more personalised care solutions, addressing the informed and responsible participation of patients, and responding to the needs of elderly people.
- Savings in lives and resources by focusing on prevention and prediction rather than on costly medical interventions after symptoms and diseases have developed.
- Higher patient safety by optimising medical interventions and preventing errors.

Additionally, the eHealth Action Plan, coordinated by the DG Information Society and Media, is directed towards one of the biggest challenges in the European society:

Continuing the increase in quality, access and efficiency of healthcare against the background of the growing importance of chronic disease (partly due to unwanted lifestyle, but also as a result of the success in combating mortal diseases) and of demographic changes.

Ageing is considered a major challenge within this context. Epidemiologists speak of "double ageing". On one side, the proportion of the population above 65 years is increasing, due to the demographic transitions, which take place as the post World War II baby boom works its way through the population pyramid. The second challenge of ageing is that the average age of the older population is also increasing, due to the ever increasing quality of healthcare. Projections show that this will lead to severe shortages, especially in the nursing professions. On the other hand, all kinds of new developments in healthcare take place, leading to new forms of improved therapy and diagnosis. However, they often also lead to increased costs of healthcare, which cause large budgetary problems for member states.

Against this background, a surge in developments in the field of robotics can be seen. Bill Gates is even speaking about robotics being the next major trend in innovation (Gates, 2007). Stimulated by further miniaturization and increasing intelligence, radical innovations in robotics can be seen leading to new functionalities and areas of application. Research into these possibilities is already going on worldwide. In the Fifth and Sixth Framework Programs for Research of the European Commissions robotics was an important theme. The EURON Network of Excellence has been set up with the ambitious goal to make Europe the leading area for robotics. One of the deliverables of the EURON NoE is a roadmap report on the domain of robotics, including robotics for healthcare (EURON 2004). Also the European Technology Platform on Robotics has been set up with the aim of establishing a consolidated European strategy in robotics.

These developments prove to lead to interesting opportunities for healthcare. Although Robotic technologies are already applied in the healthcare for a number of years, it is evident that the application of robotics has a large new potential to contribute to the aims mentioned before. At the same time, it is also evident that it offers good opportunities for the European industry. A comparison of the involvement of the USA, Far East and Europe regarding the whole domain of robotics, including robotics for healthcare, can be found in the WTEC report (Bekey et.al, 2006).

Considering the potential of this field, the European Commission intends to develop roadmaps of promising applications of robotics in healthcare. These roadmaps will present insight into the expected impact of robotics in healthcare and give direction to the most promising directions for research, development and implementation to bring about these opportunities. The outcomes of this study will be used as input to the further development of the EC Framework Programmes.

1.2   What is Robotics in Medicine and Healthcare

The definition and demarcation of the concept of robotics is not easy, but essential for the study. Looking at the field of robotics today and trying to formulate a definition, it is important to bear in mind the history and the fact that cultural images of robotics are still very influential in directing the present perception of robots. An example of this is the fact that often robots are seen as "artificial humans", due to the image set by science fiction writers like Karel Čapek and Isaac Asimov.

Some history on the development of robotics

The word "robot" was coined in 1920 by Karel Čapek, a Czech writer, well before the first real robots. It is related to the Czech word for work, "robota", and used for a machine that would be used for freeing men of tedious and heavy work.

The field of robotics has a short history if looking at machines that can perform human tasks. However, the concept is much older. Already in ancient times stage machines were used for theatrical effects, although they were operated by men literally behind the stage. An example is a chess machine, which did not play itself but contained a hidden small-sized chess human player.

In the 20th century the development of modern robots proceeded much slower and much less spectacular than expected. The most important mechanical components (e.g. mechanical joints, energy systems, electro motors) of present day robots have evolved over a long period of time, starting from the 1940-ies. The real acceleration in the speed of evolution of robots was brought about by ICT, especially the invention of the "chip". Its increasing calculating power and capacity to perform more complex tasks, makes the use of more complex sensory devices possible.

The latest driver originates from advances in biological sciences. Our knowledge of the human body has increased tremendously and extends to processes like the brain and the nervous system. This knowledge enables mimicking by artificial devices and also shows more possibilities for interaction between humans and robotic devices.

The perception of modern robots heavily leans on developments in computers and mechatronics, but its core function is still the automation of physical work. An

important aspect further demarcating the area of robotics, is its intelligent interaction with the environment.

Systems on a micrometer or nanometer scale are also included in the area of robotics, provided that they perform all three essential functions defining a robot: 1) acting on environmental stimuli in combination with 2) sensing and 3) logical reasoning.

This means that devices without mechatronic actions are not regarded as robots in the modern sense. Examples are all kind of computer and information systems like expert systems, intelligent databases, Artificial Intelligence systems. Complex sensor systems, including pattern recognition or image reconstruction, functioning on their own are also not regarded as robots. They have only effect on their environment through human intervention. It is not necessary for inclusion in this definition of a robot, to be able to move around autonomously in the environment with navigation systems. As in other fields, robots with a fixed position but which perform mechatronic activities in their immediate environment are included.

On the other hand, the field of healthcare must be demarcated. Important to this area is the connection to the patient and the application area of medical healthcare. As the e-Health action plan looks at the increase of quality, access and efficiency of the healthcare system, this is considered an important aspect for demarcation. Prevention is believed to be generally both more effective and less costly than cure and care. For this reason the scope of this study on robotics is extended to preventive and predictive medicine.

Within the scope of the present study, the following definition of Robotics in Healthcare is employed:

> *Definition of robotics in healthcare used in the study*
> *Robotics for Medicine and Healthcare is considered the domain of systems able to perform coordinated mechatronic actions (force or movement exertions) on the basis of processing of information acquired through sensor technology, with the aim to support the functioning of impaired individuals, rehabilitation of patients, care and medical intervention of patients and also to support individuals in prevention programmes.*

The following systems are excluded from this study:
- Robot pets.
- Partly excluded: Robotic systems for transport and logistics or for complicated laboratory procedures. They are only included insofar they are used directly by patients or in the treatment or nursing of patients ("at the bedside").
- Educational robots and robots for logistical purposes in laboratories.

1.3 What are the main objectives of the study

The overall objective of the study is to develop a roadmap of promising applications of robotics in healthcare, encompassing also associated technologies, research directions and expected impact. This roadmap has time horizons of 5 years and 15 years, but also

identifies intermediate key innovations. Important criteria for the selection of "promising applications" are:

- Added value to solving key challenges in healthcare, such as management of chronic diseases, demographical changes, nursing shortages and rising costs.
- Economic indicators such as opportunities for the European industry and European research.
- The possibility of effective and efficient integration in the healthcare system.

The second objective of the study is the identification of the related technological developments (key enabling technologies). Thirdly, a clear overview will be given of the relation of the promising applications with (developments in) user needs. Finally, attention is given to the societal context of the promising applications (e.g. driving forces and barriers).

The promising applications focus on high quality, safety and efficiency of healthcare systems, provision of personalized care, disease prevention, early diagnostics, support of people in the ageing society (including home care and independent living) and support of other people in need of long-term care.

The information is used for both strategy development for the European industry, as well as strategy development for European research (FP7).

1.4 What is the approach

One of the pillars of the study is the Dynamo concept, developed by TNO (Butter & Hoogendoorn, 2003). Part of this concept is the division of Innovation in five levels of abstraction. The levels used for this study are "Innovation Themes" and "Innovation Areas". An Innovation Theme is an innovation subject within which innovation takes place for ca. 20 years. Actors working on an innovation theme share a vision on solving a societal issue (i.e. non fossil based energy). Innovation Themes are made up of Innovation Areas. Innovation Areas are basically categories of Product-Market-Combinations. Innovation areas are further characterised by the fact that they are being innovated during a time period of ca. 10-20 years.
The approach was based on identifying the relevant Innovation themes and Innovation Areas.

The approach to the study is a combination of desk research and expert consultation. During the desk research, both important literature and the internet were analysed. The expert consultation was organized through interviews, a survey, forum discussions and a 2-day expert workshop.
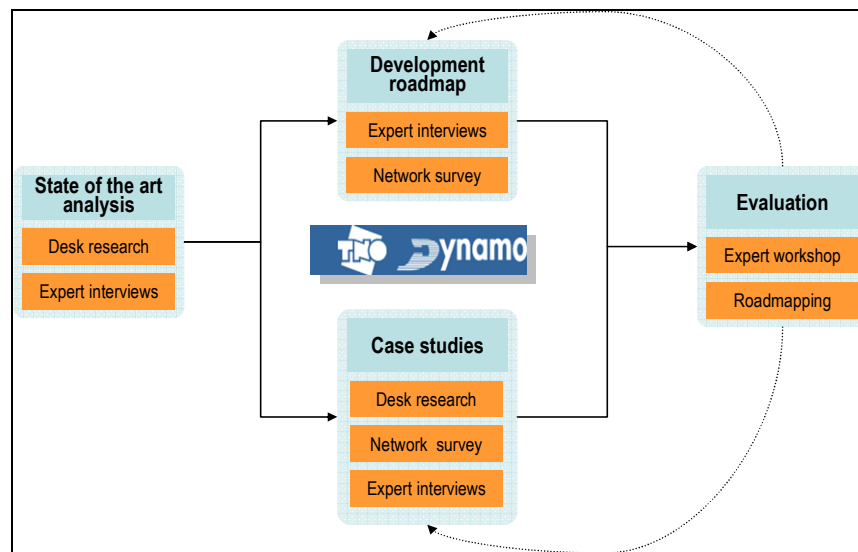
Figure 4: Overview of the study approach.

The following work packages were distinguished:
- The development of a State of the art analysis report
- Development of the Roadmap
- In depth analysis using three Case studies
- Evaluation of results in an Expert workshop

In addition to the "internal" experts of TNO, Fraunhofer, VTT and Vilans, external experts were also consulted (over 50 experts) using interviews, questionnaires and the 2-day evaluation workshop. This group of experts has an international character and a multidisciplinary background in research, business and policy.

As the core of the project aimed at the systematic gathering of information, the TNO data management tool Dynamo was used for collection. In total, some 350 robotic applications and 350 organizations were collected and profiled using innovation and market characteristics.

State of the Art report
The core activities within this work package were internet/literature search, interviews and a questionnaire. Using the results from the internet/literature search, experts were identified to be interviewed. Also the International Conference on Rehabilitation Robotics (ICORR) conference was used as an opportunity to conduct several face-to-face and telephone interviews (39). Next to the local and international network of the partners in Scandinavia, Germany, Japan/Korea and the Benelux, a trip to the USA was made to broaden the geographical coverage. The experts identified are now part of the Robotics for Healthcare network (R4H, currently ca. 85 experts), with which several activities were executed later. The information collected (approx. 400 applications, approx 350 organisations) was transferred to the Dynamo database, which was used to analyse the data. Individual characteristics, like country of origin and innovation area, enhanced the richness of the information. The MERODA database proved to be a valuable source of information (Meroda, 2007). A questionnaire to the R4H expert group provided information about the attractiveness of several innovation areas and their phase of development.

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It proved to be impractical to develop a State-of-the-art analysis report without looking forward into the future. Therefore, the information provided by the experts and the desk research was not limited to the present state of the art, but also gave insight in future activities.

Part of the result of this work package was the development of a **R4H Catalogue**, in which an overview is given about the organisations and R4H applications collected. As this was considered an internal EC document, the report is not publicly available.

Roadmap
The second work package was aimed at the development of the roadmap. A single roadmap was considered impractical and therefore the six most relevant themes were selected for further analysis:
- Intelligent prosthetics.
- Smart medical capsules.
- Robot assisted mental, cognitive and social therapy
- Robotised patient monitoring systems
- Robotised surgery
- Robotised motor coordination analysis and therapy

The criteria for the selection were market and industrial attractiveness and the relationship with the eHealth domain.

The activities in this work package were internet/literature research, interviews and a forum discussion. The forum discussion proved to be of little added value, due to a below average response rate. The results of the work package were presented in the Evaluation work shop and the outcomes of these discussions were fed back into the roadmap development.

Case studies
To further enhance the insight in the driving factors and barriers accompanying the application of robotics for healthcare, three case studies were conducted. They especially needed to elaborate upon the ethical/legal aspects and successes and failures. In close consultation with the EC, three cases were chosen for further elaboration:
- Robotised surgery.
- Intelligent prosthetics.
- Robotised motor coordination analysis and therapy.

The activities conducted in this work package were internet/literature search, a questionnaire and over 10 additional interviews. Also the evaluation workshop proved to be of added value. A scheduled forum discussion was cancelled due to the experience with the first forum discussion (limited response).

The questionnaire conducted within this work package was aimed at the analyis of the stakeholders in the three cases. Using the R4H-network, experts were asked to indicate per case what the "Skills" and "Wills" of the individual stakeholder groups were. This information was used to define a strategy to further develop policy.

Evaluation workshop

An important work package was aimed at the evaluation of the results in a two day workshop (Brussels). The established R4H-network was invited to participate and to comment on the concept roadmaps. There were introductions by experts on the six areas and in depth discussions in specific parallel sessions. Some 45 experts were present, although research and business were overrepresented. All core areas were covered (roadmaps).

The in-depth discussions on the concept roadmaps provided more insight in the specifics of the six areas. Also a timeline of each area was assessed using the experts views.

1.5   The consortium

The main contractor of the study was the TNO-Innovation Policy group, focusing on the study methodology and management. This unit within TNO focuses on the soft side of innovation and the development of policy and strategy. As TNO is the second largest RTO in Europe, TNO-IPg had access to experts in the field to further sharpen the content. A number of those experts came from TNO-Prevention & Health.

The main partner in the consortium was Vilans, who was in charge of daily operational affairs and content development. Vilans is a research and development organisation in the field of long term care.

To complete international coverage and content expertise, also the Fraunhofer ISI unit (Germany), VTT (Finland) and Euro-act (Japan) were part of the consortium. These organisations provided additional content information, conducted a number of interviews with experts (in their geographical region) and participated in the evaluation workshop.

1.6   Note to readers

In the analytical approach, a distinction is made between societal issues, applications and enabling technologies.

At the core of the approach are the applications of robotics for healthcare. These are considered innovations that can become available in the coming two decades (mid term). The societal issues are the pressures on the development of these innovations. The key technologies are enabling and are the results of research into often more general components.

Firstly, the societal issues are described in Chapter 2. Then the focal subjects of the study are described in Chapter 3, the applications of robotics in healthcare. In Chapter 4 on the cases, three of the identified application areas are described in more detail, also giving attention to the actors that have influence on their development. In Chapter 5, the underlying key technologies are described.

Chapter 6 integrates the findings on societal issues, applications and key technologies of 6 prioritized application areas leading to 6 technology road maps. In chapter 7, the final conclusions of the study are presented, including the major policy recommendations.

Part of the final results but provided separately are:
- The annex document, including a more in depth description of the methodology, the interviews, the evaluation workshop and the surveys.
- The R4H catalogue. The catalogue includes a description of some 350 organisations that are involved in the field of R4H. These organizations are also inserted in the project database.

Disclaimer

> The opinions expressed in this study are those of the authors and do not necessarily reflect the views of the European Commission.

2 Societal issues and user needs

2.1 Introduction

This chapter focuses on the societal issues on the demand side of robotics for health care. The aim of the section is to provide more insight into the factors in the environment driving the developments in this sector as well as into user needs. This will enable the development of a more demand driven innovation policy for the stimulation of research in the different areas.

2.2 Societal issues

Factors driving the developments in the environment of R4H can be divided in the following groups according to the DESTEP[1] approach. Although less structured, a similar overview of influences is elaborated in the EURON roadmap report (EURON 2004).

Demographic:
•Population
•Epidemiologic
•Rural vs. urban

Economic:
•General economic trends
•Market characteristics
•International developments

Social:
•Ethical issues
•Social trends
•Technological acceptance

Technological:
•The innovation system
•Technological trends
•Technological limitations

Environmental:
•Resource scarcity
•Waste & Emission
•Environmental security

Political:
•The legal system
•Governmental support
•The political agenda

Figure 5: The DESTEP factors (Fahey, 1986).

As the descriptions will show, these factors sometimes reinforce each other. In the next sections, the factors are described in more detail from the perspective of robotics in healthcare.

2.2.1 Demographic factors

Population
The healthcare system is under pressure. This pressure is caused by an increasing demand for health care in the next decades, attributed mainly to the increasing number of elderly people that need healthcare. Due to the post World War II "baby boom" the

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[1] An instrument for mapping the influence of societal factors on a specific area of interest, in this case the field of robotics for healthcare.

percentage of people above 65 will grow strongly during the period of 2010-2030, with an annual growth rate of 2.8 % (EURON, 2004) and reach a maximum around 2035. Due to increased welfare and better medical procedures (see next section on epidemiologic factors) individuals live longer. These processes reinforce each other during the next decades. This phenomenon is called "double ageing" and occurs in most developed countries. Coinciding with the ageing trend, people strive for, and are able to remain independent till a higher age. Although this counters part of the effect of the ageing problem, the demand for medical and social care is nevertheless strongly increasing.

This challenge is increased by developments on the other side of the population pyramid. The younger age groups (absolute and relative) are decreasing in size during the next decades. The consequence is that the economic basis for paying for the income and the care for the elderly is decreasing. But also the workforce available to deliver the care is relatively decreasing, as well as the availability of informal (family) care providers. This is leading to tensions in the actual availability of healthcare of sufficient quality and quantity in the next decades.

Epidemiological factors

In healthcare, demographic factors are closely connected to epidemiological factors. There are some general trends in developed countries. The first trend is an increasing life expectancy, but the years gained are partly unhealthy years. Men are catching up with women in two respects: the difference in life expectancy between men and women is decreasing. Furthermore the quality of healthy life years gained as compared to unhealthy years gained, is better for men. Many diseases which in the past caused the death of patients have now turned into chronic diseases, often requiring long term care. International comparative research is showing that the burden of disease is shifting from younger age groups to older age groups but it is still inconclusive whether the overall burden of disease is diminishing (Perenboom, 2004).

Despite the progress in medical science there are still many diseases for which no adequate or only a very burdensome or inefficient treatment exists. Large societal costs are involved with the care for incurable diseases. There is large societal demand for new therapeutic or preventive procedures for these diseases.

Rural vs. Urban developments

Geographic density varies greatly within and between countries. A large scale movement can be seen in people leaving rural areas to go to cities and suburban areas, where there is more work and schools, shops and recreational facilities. There are several other economic and social mechanisms causing the development of big cities. Depopulation and urbanisation cause specific problems for healthcare delivery. The healthcare in metropolitan areas changes because of the changing population and "big city problems". This will require social remedies. The problems in the rural areas, however, are caused by a population density that becomes too low for the traditional forms of healthcare delivery. New applications of information technology like telecare (European Commission, 2008) and robotized versions of them (see patient monitoring in chapter 6) are expected to offer solutions, supporting people and preventing further migration to the cities.

2.2.2   *Economic factors*

The most important economic factors in the domain of robotics for healthcare are general economic trends, market characteristics and international developments. These will be discussed in the following sections.

General economic trends

Economic growth proves to be permanent (with conjectural ups and downs). Health is a priority both on the political and the individual level: it is a historical fact that health care spending grows faster than the average economy. Robotic systems can sustain growth of costs where there is purchasing power, but not enough manpower to provide (health) services in the traditional way.

In the era of globalization, continuous innovation is a worldwide phenomenon. Innovation is only for a (small) part a matter of national policies, but countries have to deal, also in healthcare, with a constantly growing offer of new insights, components, materials, products and even services from abroad. A reactive strategy (protectionism) is not seen as the best way: new forms of international cooperation and specialization in high end products seem a more productive strategy. Priority for robotisation fits well in this strategy.

Market characteristics

There are several economic factors driving the developments in healthcare which will have significant specific impact on the area of robotics. The most important is the decreasing financial base. This trend is expected to continue in the coming years because of the rising costs of health care and the decreasing proportion of working people in the population. Traditionally, health in European countries is (unlike the United States of America) for more than half a century paid for by the government directly or by collective systems with a legal basis. When doctors adopted new forms of treatment, this was almost automatically included in reimbursement schemes. These systems were allowed to grow for years without the need to prove their cost-effectiveness. In many countries, the healthcare budget grew faster that the average economic growth.

The last decades, however, debate arose about the burden of the overall health costs for the economy (for figures about the costs of healthcare as percentage of the GNP in European and other OECD countries see OECD, 2008). Governments in European countries have tried to counteract this trend of ever increasing costs by all kinds of policy instruments. Many of them have in common that market incentives are in some way or another introduced both for patients and healthcare providers. There is more room for private clinics and care organizations. In some instances these market incentives are extended to health care insurers. In some countries healthcare insurers have been transformed from organizations executing government policies to real commercial companies. For patients this has taken the form of larger financial risk or contribution but also of more freedom to choose a health insurer. Healthcare providers now have to negotiate sometimes with health insurers about the price of specific interventions (Diagnosis Related Groups). This makes it interesting for private parties to invest in healthcare. Large companies like Microsoft and Philips are intensifying their investments in the (high tech) health sector. This requires from governments quite different responsibilities like the prevention of monopolies or too strong concentration, or guaranteeing that the patient has correct information on the quality and safety of the care delivered by various providers.

There are also other economic factors influencing (innovation in) healthcare.
- An economic factor driving the health care system is the role it plays in the labour market. The effects are mixed. On the one hand productivity growth of the health sector is like other forms of personal service in the collective sector constantly lagging behind other sectors because of the Law of Baumol (Baumol, 1993). On the other hand, the health sector is counter cyclic and this can help to stabilize the economy in times of recession and unemployment.
- Another economic driving factor is the potential for labour reduction. Based on the original concept of robots (Karel Čapek) it can be said that robotics aim at the replacement of human labour. This could cause the reduction of workforce needed and consequently lead to a reduction in labour costs or to delivery of care to an increased number of patients with the same number of professionals.

International developments
The production of medicines and medical devices has been internationalized for many years. This process is still continuing and extending to more types of products. Healthcare itself, however, has for a long time been a matter of almost exclusively national policies. This is changing for several reasons. ICT makes it possible not only to produce goods abroad and guarantee timely supply, but also to deliver services (e.g. evaluation of X-ray pictures, helpdesk service and medical call centres). Another trend is patients undergoing medical treatment abroad, either in emergency situations or for faster access to care. In the EU, developments are underway which make it easier to receive treatment in other Member States, while insured in your own country.

A good healthcare system is internationally seen as a measure of the civilization of a country (cohesion is a priority in the policies of the EU) and is one of the important aspects determining the international competitiveness of a country as a domicile for companies or international organizations. In addition, healthcare is an important international market for selling goods and services and will increasingly be so.

2.2.3   *Social factors*
The most important social factors in the domain of robotics for healthcare are ethical issues, social trends and cultural factors, especially with regards to acceptance of new technologies. These will be discussed in the following sections.

Ethical issues
So far ethical factors do not seem to be a major obstacle for the developments in the field of robotics for healthcare. The experts that were consulted suggested that this is caused by the fact that the stage of development of the area is still too far from practical application with "real" doctors and "real" patients. This has not led to decisions about the introduction of robotics in collective health benefits packages, in health insurance policies or in purchasing decisions of regular hospital and care institutions, and maybe by patients themselves. Ethical issues usually only arise when stakeholder groups disagree about what is right and what is wrong with respect to certain new developments and start a debate about such issues.

Still, a number of emerging ethical issues were identified. These are:
- *The dehumanization argument.* By some it is considered inhumane to deploy a machine to take care of ill/elderly people (concern is greater in Europe than in Japan with the US in the middle). Japan promotes robots as "companions for the

elderly". This is regarded especially a problem where the machine takes over tasks traditionally conducted by humans (communication, activities with physical proximity). (Conservative) social scientists go even a step further and predict that human-machine interactions may replace human-human interactions (Frude's Argument or "Human Replacement Argument"). What will a growing social and "psychological" interaction between humans and machines mean for society? (Knorr Cetina, 1997, Lindemann 2000)

- *Social poverty and dying alone.* In some views the deployment of robots for taking care of ill and elderly is also regarded as "social poverty", meaning the exclusion of elderly and sick from (an increasingly health oriented) society. Also it is sometimes interpreted as getting rid of ones responsibility. Surveys also might suggest that dying alone is a wide-spread concern in society.

- *Experimenting with the ill and vulnerable.* Since robotics in the medical field is applied to ill people, questions may arise whether the ill and vulnerable may be used as guinea pigs for technological experiments (i.e. in the area of prosthetics, neurotechnology, robot surgery). The counter argument is that patients with very slim chances of survival with standard procedures do not have much to lose anyway and could only profit from the experiments. By many this is criticized to be a too utilitarian approach in ethics. (Rodota, 2005)

- *Exploiting human emotions.* Some express concern that building robots, that display communication skills and emotions (although the actual existence of such qualities may remain disputed and hard to evaluate), may deliberately exploit human emotions and that the technology may be used for deceptive purposes. (Lindemann 2000).

- *Dual-use of technology.* Advanced intelligent prostheses, robot technology and neural interfaces (e.g. BCI - Brain Computer Interface) may also be used for military purposes (and are also developed by the military, e.g. DARPA in the USA). How to ethically evaluate medical technology that may also be used for military purposes? (Roco, 2002)

- *Human Enhancement Technology (HET).* This is an emerging question dealing with the possible use of technology originally intended as compensatory measure (prostheses, technology to cure an illness) for means of improving healthy humans (it is still an emerging issue and successes or failures are still uncertain). This not only creates problems with safety, regulations and financing, but also with ethical questions about the definition of (future) human beings and aspects of equality. The question about equality deals with rather pragmatic issues (whether "enhanced humans" have advantages and enhancement is costly, the rich people will have an inherent advantage in society). There is also the question where to draw the ethical and legal threshold between healing and enhancement? What impact may this have on the definition of illness and health? It poses new ethical and legal challenges as in the case of the athlete with a leg prosthesis, Oscar Pistorius, who wants to qualify for the "normal" Olympic Games. (Roco, 2002, Nordmann 2004, Leis, 2006, Warwick, 2007)

- *Defining what is "human" and altering the human condition.* Closely related to the HET debate is the question about defining human beings in view of biomedical

engineering. If applying robots in health care, humans might come into a strange situation where they might be surrounded by machines that try to simulate human behaviour, while themselves being dependent on/partly fused with machines (i.e. ICU machines, artificial organs, prosthesis). The concern about tempering with the natural (life extension, replacement organs) is also an emerging question (Fukuyama 2002).

- *Future questions.* The following questions may not be relevant today, since the crucial technology has not been sufficiently developed, is still in its infancy or may never be feasible. Nonetheless these questions might be worth addressing (cf. Mori 1999, Fukuyama 2002, Mcnally 2001, Leis 2006):
    - Is it ethical to extend the life of humans with the means of technology (already a relevant question in some regard)?
    - Social, legal and human status of a (medical) cyborg: human, machine, partly human-machine: what does this mean for the status of humans and machines?
    - The search for better safety and human-machine-interfaces calls for more intelligent robots and AI systems. How intelligent are they allowed to become, what is ethically acceptable? How to treat them and what status to give them?

- *Affordability.* Developing high tech robot systems able to support, treat or train patients will only live up to its potential when these systems will actually become available to the population. This will depend to a large extent on financing of care and substitution of traditional cure or care by robotised versions. If financing of robotic healthcare systems will not be accommodated the investment of R&D recourses will not render. Furthermore, with the widening of the gap between what can be done and what is actually done, ethical boundaries may be crossed.

These ethical issues may seem very far in the future. However, it is also clear that later in the future several of these issues can cause serious ethical questions. Society has to deal with these questions in an acceptable way to make the innovations a success and collect the potential benefits of robotics in healthcare for society. As the thinking about robotic applications in the far future has already started, it is relevant to also start the discussions about the ethical aspects of them.

Social trends
There are several important categories of socio-cultural factors driving the developments in healthcare. The first category relates to macro level socio-cultural factors. These include solidarity, cohesion and the health status of particular social groups (women, persons with a handicap, immigrants). They also include rising expectations about health. These expectations are the result of sociological and cultural processes, influenced by education and reflected in the media. These rising expectations relate not only to the health services themselves but also to the way they are delivered and the outcome is evaluated (not only with medical parameters but also with indicators like Quality of Life (Aaronson, 1993)). Patient orientation (patient empowerment) has become an important separate criterion. For people with disabilities, it not enough to just give them support with their daily activities, but also to make it possible for them to function and participate as much as possible as normal citizens.

The second category refers to micro level social factors. This category includes patient safety, i.e. in terms of the occurrence of severe incidents with patients in healthcare. In a country like the Netherlands (population of 16 million inhabitants), it was estimated in 2007 that about 1700 patients die each year because of medical errors and a much larger number incurs severe injuries (Bruijne, 2007). Figures in other countries appear to be similar (in percentage terms).

Another micro level factor is the labour conditions in the health sector. This is an important problem especially in the lower qualified nursing and caring professions. Not only the relatively low payment is a problem, but also the labour conditions leading to large short term sickness absence from work and long term incapacity to work. This is reinforced by a relatively unfavourable image of this sector. Another, related, issue is the growing importance of informal care as people want to stay in their own home as long as possible. It is impossible to meet this demand entirely with professional care. This deficit in the availability of care cannot be completely replenished by the availability of informal caregivers. The reasons for this are that some of the elderly are becoming very old and the informal care givers are getting very old too, a higher number of older women (daughters) are working and more adult children live far away or even abroad. For example, it was calculated that in the Netherlands in 1950 there were 140 persons per dementia patient whereas it is expected that in 2050 there will 20 persons per dementia patient (Rosendal, 2006).

Technological acceptance
A crucial factor influencing the application of robotics for healthcare is the acceptance of new technologies. For all technologies, acceptance is determined by the outcome of two mechanisms:
- the way society has dealt with ethical, social (and environmental) issues;
- the way end users have been informed about the new technology (or preferably have had a say in its development) and the opportunity they have got to get accustomed to the new technology.

This is certainly important for the application of robotic systems in healthcare. Specific to the robotics systems is the fact that they can operate as (semi) autonomous actors. This creates completely new acceptance issues. One such issue is the extent to which robots resemble humans. Research with present day robots has shown that people accept robots better if they are similar to humans, but not if they are too similar and cause confusion (the concept of the "uncanny valley" in the acceptance/similarity diagram) (Mori, 1970) (see also section 2.2.3, Social - including ethical - factors).

2.2.4 Technological factors
The most important technological factors in the domain of robotics for healthcare are the innovation system, technological trends and technological limitations. These will be discussed in the following sections.

The innovation system
Identifying and implementing new scientific and technological opportunities and turning them into real innovations often appears to be more difficult than initially thought.

Development of technological applications towards broadly used products proceeds in several stages:
- idea generation
- proof of concept
- field tests
- first introduction in the market
- broad diffusion in the market.

What is typical for healthcare is that these stages do not flow over into each other like in many other sectors, but that the intermediate product has to meet legal criteria to proceed from one stage to the other. Crucial in the healthcare sector are patient trials, varying from small trials which need the approval of an Ethical Review Committee to a large scale randomized controlled clinical trial often necessary for uptake in a collective benefit package.

These processes are reinforced by all kinds of organizational and policy instruments to improve the societal benefit of science and technology. Pure science is not the dominant model anymore. Nowadays the universities have partly been transformed in organizations striving for valorisation of their scientific output and there are many more research organizations which have application of research and promotion of innovation as their official mission. This is complemented by special research and innovation programmes. This is not only going on at national level, but it has become one of the most important goals in the European Union. In the Lisbon Strategy (European Council, 2000) it is stated that the EU wants to become the most competitive economy in the world in 2010 capable of sustainable economic growth with more and better jobs and greater social cohesion, and that innovation is the main instrument to accomplish this (see also the Report from the High Level Group chaired by Wim Kok "Facing the Challenge", European Communities, 2004). Even before the Lisbon declaration was agreed upon, the European Framework Programmes already had a significant impact on technological research and the application of technology in Europe (see also section 1.2.6, Political (and legal) factors). Taken together all these organizations and technology policy instruments form an important driving factor of their own.

Technological trends
Technological developments are an important driver for change in society. Also healthcare has been changed dramatically by new technologies, like new process technologies and new pharmaceuticals. Furthermore, developments in biomedical imaging have led to structural changes and it is impossible to image a life without these technologies.

TNO in the last four years has analysed major technological developments, of which several can prove to have this effect on the application of robotics in healthcare (Dynamo, 2008):
- *Molecular biotechnology*
  This trend has emerged since the discovery of DNA. Although already present for decades, the effects are not yet fully exploited.
- *Neuro-cognitive science*
  In this new trend, neurological insight and understanding the brain converge into a new field of science and technology.

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- *Information and networking technologies*
  Starting with the development of the transistor, the developments of ICT are still an important enabler for new innovations.
- *Advanced materials*
  New developments of nanotechnology and computational tools create opportunities for new materials like functional materials, new catalysts, and bioactive materials.
- *Intelligent mechatronics*
  The emergence of MEMS technology initiated a new wave of possible innovations, due to its consequences on costs and size of mechatronic systems.
- *Smart electric and electronic devices*
  The miniaturization of electronics has changed the field of electronics by demanding the inclusion of information, communication and intelligence in consumer goods.

These technologies can be seen as drivers of innovation.

Technological limitations
In the health sector there is a constant drive to push the limits of what is possible. Despite the great improvements in many types of interventions, there are still many aspects for which improvements will be welcome. When it relates to surgery and other interventions, there is always the wish to perform procedures better, safer, faster, with the ability to work longer without getting tired and to work inside the body where you can not see with your eyes etc. Many devices and procedures are very expensive and the application is therefore restricted to urgent cases.

Redesigning them, or their production processes so that they become cheaper might help to broaden the application area considerably (e.g. for prevention or screening purposes). There is also a constant drive to make it possible that devices are used at less specialized places and by less highly educated professionals. This requires among others, further miniaturization and better energy supply for mobile applications or for internally applied or implantable devices. The ultimate ideal is the use by the patient himself, not only at home but also at other places and "en route". Labour circumstances were and still are an important issue. This is now reinforced by the shortages on the labour market in the healthcare sector, especially in the nursing and caring professions. For all these reasons, the health sector is constantly looking to technologies developed elsewhere (in other sectors) to help improve products and procedures in healthcare.

2.2.5   *Environmental factors*
The most important environmental factors in the domain of robotics for healthcare are resource scarcity, waste and environmental security. These factors will be discussed in the next sections.

Resource scarcity
"Informatisation" of production processes in society (in the widest sense), as was once thought, would lead to more efficient use of energy and scarce materials ("dematerilization"). But for the moment, it is clear that both the traditional sectors and the ICT industry use much energy and rare materials. Large scale use of robots will certainly reinforce this trend. The concomitant resource issues will increase at the same time if no timely action is taken (like including sustainability criteria in the design specifications of robotic systems).

Waste

Traditionally environmental factors are not seen as very important in the development of the health sector. There are a few specific issues relating to dangerous materials (radioactive, toxic and infectious materials) with specific regulations to solve them. No specific waste risks are foreseen for robotics in health care and the possible use of robots to diminish these problems is outside the scope of this study.

Environmental security

The healthcare sector is responsible for about one tenth of the flows of materials, energy usage and waste production. As long term effects of global warming, depletion of rare materials and sustainability become more important, this will also have a large impact on the materials and energy flows in healthcare. As a medium term trend, it may be stated that environmental issues will become much more important criteria for the design of products and processes for health care. However, this is not regarded as a major trend relevant for the application of robots in healthcare.

2.2.6   *Political factors*

The most important political factors in the domain of robotics for healthcare are legislation and regulation, governmental support and the political agenda. The impact of these factors will be discussed in the next sections.

Legal factors and regulation

Legal issues require a large proportion of the efforts to proceed to the later stages of the innovation trajectory. Especially, representatives from companies active in the field of robotics in healthcare are very outspoken in this respect. They state that the methodology to prove that devices are effective and safe enough for starting trials and the methodology to prove the cost-effectiveness in terms of evidence based medicine (to become included in health benefit packages) is in almost every respect unsuitable for devices. Historically speaking this methodology was first developed for medicine and adapted to other medical interventions like the use of devices. But this is seen as so burdensome that it is regarded as perhaps one of the largest barriers to innovation in this field.

During the evaluation workshop there was no time to discuss possible solutions. But because of the importance of this issue, additional research was done to get a closer look at these issues. A number of aspects were found which make clear that solving the legal aspects of development, introduction and use of robotics in healthcare is not simply a matter of applying existing laws and regulations. The most important of these issues are:

- *General note on the aspect of "legal lags"*. There is the general problem that laws and regulations often pose a problem to the freedom of research and innovation. This may be good as a precautionary measure, but when exaggerated, regulations may also hinder technological and economic progress. So the actual challenge is to find a balance between precaution and risking uncertain outcomes and adapt the legal system to the latest developments and even look ahead of time. When looking at emerging technologies (e.g. genetic engineering, advanced ICT/AI, nanotechnology or biomedical engineering) a kind of "legal lag" can be observed, i.e. the existing regulations are actually not suitable for application in many innovative areas of R&D. Often the early experiments and developments even

operate in a legal vacuum, since there is no legal directive that is logically applicable for certain new cases. This situation may cause strong social reactions and often minimizes public acceptance of the new idea.

Special case of robots in healthcare. The central characteristic of a robot distinguishing it from other devices, is its (degree of) autonomy (its ability to react to unpredictable events in a flexible way) (Grunwald, 2002). In the special case of their deployment in healthcare, they are expected to operate in close proximity to humans and even ill and helpless people (this distinguishes the situation from the case of industrial robots). Intelligent prostheses, which are also mentioned in this report, may pose other legal and ethical questions, which may get increasingly relevant in the future as neurotechnology (including brain-computer interface based technologies) and Artificial Intelligence advance.

- *Definition of robots.* Because of their special characteristics, it seems unclear how to classify robots (classification is relevant with regard to the guidelines that apply). Robots share characteristics with common medical devices (some robots, like operation robots or rehabilitation devices, share more characteristics; others, like service robots, share less characteristics). But in contrast to medical devices that are either designed for a specific purpose (e.g. a pacemaker) or are being controlled by a human (e.g. scanning/imaging devices), robots add the potential quality of at least partial autonomy. Also they are intended to be designed in order to react in a situation-dependent manner and testing may be problematic, because not every situation can be foreseen.

- *A necessity for stricter guidelines.* Because the health care setting adds the component of limited human autonomy, stricter guidelines ought to apply for robots in healthcare than for standard medical devices, industrial robots and household robots. But this raises the question if such machines will ever get sufficient approval since they may not be regarded as absolutely necessary (unlike a pacemaker or ICU equipment) and there exists an intrinsic uncertainty about aspects of their functioning in diverse settings.

- *Liability questions in the context of robots and intelligent prosthesis.* Intelligent prostheses, either with a direct interface to the patient`s nervous system (already in clinical trials) or with the ability to correct/compensate movements or partially autonomously move for the wearer (e.g. with the help of sensors), may also pose legal and liability questions: what if (by accident) a wearer of a prosthesis injures another person. Can it be proven that it was done unintentionally? And if so, who then is responsible for the action? The wearer (it may have been a malfunction causing an unintended movement)? The manufacturer or some of the subcontractors, the programmer, the researchers, testing agencies? Neuronal implants (neurostimulators, deep brain stimulation) which are already in use, e.g. for Parkinson's patients or patients with deep depressions may cause behavioral changes. Also the question arises, in how far existing regulations regarding medication (e.g. anti depressive and mood altering drugs) may or may not apply (Rodota, 2005).
Similar liability problems may occur with robots doing surgery on patients (if they really act at least semi-autonomous and are not just devices controlled by the surgeon) or delivering food and medication (what if the hospital service robot delivers the wrong food or medicine to a patient).

- *Data security*. Interactive robots / medical devices may gather data about their environment and people (patients, personnel), which they might share with other platforms or transfer to other systems or persons even on a global basis. In this regard legal questions about data security and privacy issues have to be addressed. The question is if existing regulations for data security apply and if robotic devices pose a novel situation (e.g. when compared with debates over electronic patient records, RFID tags, DNA screening and databases.)

- *Access and financing*. Another legal aspect concerns access and financing. The use of robots and robot-based prosthesis/orthosis in the healthcare setting is rather new, still costly, in most cases not regarded as essential and therefore generally not or only marginally funded/financed through public insurance. But maybe the use of robots will also cut down costs for health care systems. Who should bear the costs, who will be willing to pay for it and would this lead to a distortion in medical quality and equality? (cf. early adopters and risk discussions).

Necessities and problems with regard to regulations are:
- At least standard safety regulations (as with other medical appliances)
- Additional safety because of the (potential) autonomy of the system
- Aspects relating to direct patient contact / human interaction with device
- Novelty aspect (no long term experience)
- Regulations in different countries differ, making exports/imports difficult.
- Liability of the parties involved.

Parties that may be held responsible for malfunctions are:
- Person being affected (e.g. why go near a robot or person with a prosthesis?)
- End user/patient (naivety – why trust in the system?)
- Doctor/physician/medical advisor (uninformed?)
- State regulations agency (giving too early okay?)
- Testing agency (insufficient testing?)
- Manufacturer/producing company (brought it on market too early?)
- Subcontractors (maybe it's just a malfunctioning part produced by someone else?)
- Programmers/designers (fundamental design/programming flaw?)
- Researchers (error in basic theory?)
- The device itself. (e.g. if running on evolutionary, self improving or adapting software?).

Future questions. Since the technology described in the following chapters is still in its infancy, the concerns/questions expressed in the following may not be of immediate concern, but nonetheless worth to think about from a proactive stance (Leis, 2006).

- *Legal rights of "cyborgs"*. In the future the development of technology that may alter or interfere with natural physiological processes will develop further. Will these technical parts be regarded as an integral part of ones personal identity and what does this mean for the definitory status of "non technologized humans", humans living with technology as integral part of their body/mind and machines that might display human characteristics. Where to draw the hypothetical line between human and machine in a legal and ethical sense. Such questions already arise in the context of bioethics and the question of creating chimera and humanized animals for organ transplant experiments.

- *Questions about legal rights for robots.* Even more far fetched (at least currently) is the question over legal rights for future intelligent robots (equal intelligence to primates, dolphins or even humans). Can an advanced autonomous robot be legally defined as a "person" (with all rights and obligations) and would it be a crime to deactivate it/delete its memory (equivalent to killing) or "force them to work" (this would be quite contradictory to the original idea of creating robots)? Not so far fetched is the question, if damaging a robot to which a human has developed some degree of attachment is to be considered as more than damage to property, maybe similar to injuring/killing a pet? (Mcnally, 2001).

As a result of this analysis three conclusions can be formulated about legal aspects in relation to robotics in healthcare:

- Legal aspects can indeed become major obstacles to innovation in this field. It is of crucial importance to solve these questions and develop legislation more suitable for robotics in healthcare.
- Some of these issues apply to robotic systems that will become reality only far in the future, probably after the time horizon of the year 2025. This applies in particular to fully autonomous robots (cyborgs, android robots). In the next years, attention should be paid to applications more in the domain of "human augmentation" that will become reality much sooner.
- Because so many legal issues possibly will arise, it is very important to set the right priorities for research to solve these issues. (Potential) applications could, e.g., be placed in three categories of increasing concern, related to the possible risks and the levels of uncertainty about the risks and the effectiveness of solutions to cope with them. As a first suggestion:

Minor concerns:
- Cleaning robots (e.g. floor, sanitary installations)
- Devices for rehabilitation assistance (e.g. adaptable walking machines)
- Passive assistance devices with limited adaptability function (e.g. beds that automatically adjust to a patient's ergonomic needs, semi-automated wheelchairs, e.g. with sensor-based obstacle avoidance systems)

Medium concerns:
- Sensor-based prosthesis (not coupled with nervous system)
- Service robots with main interaction with hospital personnel (e.g. for errands, delivery of files and probes)
- Passive monitoring devices with interaction capability under control of humans (e.g. tele-health systems, vital sign monitors with alert function)

High concerns:
- Robots that directly interact with patients (e.g. bringing food and medications, care-robots)
- Robots autonomously or semi-autonomously performing surgery
  (The situation may look differently if the "robot" only serves augmenting system for the surgeon – i.e. providing him with data and skills where humans come to their limits, e.g. overlay of MRI/CT images.

Governmental support

Government support is indispensable for the functioning of health care systems in societies, both in terms of financing and in terms of regulating quality, safety, cost effectiveness and patient orientation. In European countries, about 9 % of the BNP is spent on healthcare (OECD, 2008). This is still for the largest part financed by governments directly or by collective arrangements facilitated by governments. Governments are also responsible for the financing (and the legal basis) of authorities and organizations monitoring quality and safety of the healthcare system (e.g. Health Inspectorates), deciding upon the composition of collective health benefit packages and watching over proper functioning of private health organizations and markets.

Governments are also to a large extent responsible for innovation in the healthcare sector. Governments are sponsoring technological and medical research institutes (universities, academic hospitals, research institutes) and research programs. This varies from programs for additional granting of research primarily based on the excellence criterion to programs dedicated to specific health targets or innovation areas. As the government as a whole, is responsible both for promoting innovation and guarding quality and safety, these roles can sometimes collide. This can be problematic if these antagonistic roles are located in different authorities and agencies. Modern innovation programs therefore try to incorporate safety, social and ethical aspects as design criteria (Rip, 2008).

The European Union is not responsible for organisation and delivery of healthcare. Under the Article 152 of the EC Treaty, EU action must aim to improve public health, prevent human illness and diseases, and identify sources of danger to human health (see the EU health portal, which gives a good overview of all the EU activities in the health field: European Commission, 2008). Through the health policy, the EU plays its part in improving public health in Europe, and in so doing provides added value to Member State actions while fully respecting the responsibilities of the Member States for the organisation and delivery of health care. The EU health policy focuses mainly on strengthening cooperation and coordination, supporting the exchange of evidence-based information and knowledge, and assisting with national decision-making. Further aims are ensuring patient safety and the quality of healthcare to facilitate cross-border healthcare, as well as the mobility of health professionals and patients. There are activities in other policy areas of particular relevance to ensure a high level of health protection, as well as a protection of personal data in health systems. Technological developments and information society programmes include work relevant to health systems and public health. Several specific research projects are designed to provide scientific support to health-related challenges. Relevant programs for the robotics field are eHealth, eInclusion (European Commission 2008), the EURON Network of Excellence (EURON, 2004) and the European Technology Platform EUROP. See also the WTEC report for more relevant research (Bekey, 2006).The evaluation and authorisation of medical products is another key related topic. Particularly relevant for medical robotics is the Medical Device Directive (the MDD). The MDD (European Commission Enterprise and Industry, 2008) contains the arrangements for a single European market for medical devices and the CE conformity marking for admission on the market (Conformité Européenne).

As funding for research and technology development is an important driver for innovation in the field of R4H, an assessment is made within this study to identify international attention to this subject in innovation programs (SOTA, 2008). It can be

concluded that there is little specific focus on the R4H field in international innovation programs. Most programs that facilitate the application of robotics in healthcare are more general in nature. If there is focus, then the areas "Robot assistive technology" and "Robots supporting professional care" receive the most attention. The international programs support mostly public research. Looking at country coverage, most countries have a program that may support the development of R4H, but in most cases will be general.

The political agenda
The political system translates the wishes living in society into actions of the executive part of government. Societal problems related to health may be of an economic kind, like defining solidarity in healthcare in economic terms or the introduction of a new healthcare system with stronger market incentives or the necessity of supporting innovation. For a large part, these discussions lead to decisions about the spending of the government budget. Politics can also translate social and ethical problems or dilemmas into new or revised legislation or into other government instruments. Particularly important is the scientific debate about the cost effectiveness of healthcare interventions. A debate which resulted in the methodology of Evidence Based Medicine (see the sites of the Institute of Medicine in the USA, IOM 2008, and of the Cochrane Collaboration originated in the UK, Cochrane Collaboration, 2008). This approach is now backed by political support, giving it more societal robustness (NICE, 2008; RVZ, 2006). However, this approach hinders the innovation process of Robotics for Healthcare.

Choices that are made by politics can have far reaching consequences such as the choice of the Japanese government not to stimulate Robotics in cure but specifically in care (see Annex A Interviews).

2.3   Needs of the health care sector

In the previous paragraph the environment of the healthcare sector was scanned. The following paragraphs will zoom in on the industry level and more specifically on the demand side of the health care market in general. In later chapters, needs will be discussed more in depth per innovation area.
Generically the demand side consists of users and buyers and can be segmented into:
- Patients and their social environment (especially informal caregivers).
- Professional users (doctors, nurses, paramedical professions like physical therapists)
- Cure and care institutions (such as hospitals, care organisations).
- Other stakeholders (researchers, health insurance companies)

Other stakeholder categories cannot be regarded as users but are necessary to facilitate or regulate the use and the users of healthcare. These are the legislative and regulatory organisations and the largest financiers of the health care system, the insurance companies.

In essence all criteria for good healthcare can be reduced to four general criteria/needs: quality, safety, efficiency and patient orientation. With this last criterion all the aspects are summarized which are not explicitly included in the first three aspects.

Aspects of patient orientation are:
- taking into account the physical, physiological and genetic differences between people;
- the extent to which patients can undergo treatment at a time and place that they wish and by a professional of their choice;
- taking into account the autonomy and the personal preferences of patients;
- taking into account the possibilities and impossibilities of the physical and social environment of the patient;
- the degree in which treatment is painful, invasive, embarrassing, burdensome, causes scars etc.;
- the way patients are treated (information, waiting lists, personal attention, comfort, complaints, handling of incidents).

These criteria can take several forms depending on the specific form of treatment. What is also differing is the relative importance that various user or stakeholders groups assign to each of these criteria or the formal responsibility they have for any of them. In this paragraph the opportunities for application of robotics systems are analyzed along these lines.

2.3.1 Patients and their social environment

From the point of view of the patients and their social environment quality, safety and patient orientation are the most important. Robotics offer plenty of opportunities for better, newer and safer treatments. Furthermore the versatility of the robot opens new avenues for taking the personal characteristics and wishes of the patient into account. Depending on the specific application the emphasis may vary. This will be investigated further in this study.

Some therapies and treatments are very painful or burdensome for patients. Robotic systems can both include more fun elements to the treatments/therapies, as well as make them more efficient and less invasive. This is also beneficial for society as a whole.

Quick recuperation is another need of both patients and doctors. Some medical procedures are less invasive and more efficient using robotic systems, like minimal invasive surgery and robotized motor coordination therapies.

Patients also increasingly want independent living. **Currently,,** disabled people and elderly need to live in a care giving environment, if their limited abilities do not allow them to perform their Daily Activities of Life any longer. Robotic systems can provide both assistance in daily activities as well as monitoring safety, increasing independent living and cost savings at the same time.

Certain categories of patients, such as disabled people and elderly want to participate in society. Participation highly depends on mobility and communication. Robotic systems can improve these social functions.

2.3.2 Healthcare professionals

The category of healthcare professionals is a very diverse category with equally divers needs and desires. Doctors have high professional standards regarding quality and safety. Safety is an important issue not only because of the responsibility for the patient, but also because of his own risks, in the sense of physical risks but certainly in the sense of financial risks and reputation and career damage. Patient orientation is an issue that

has been discussed in relation to the behaviour of doctors for a long time. It is still regarded as an aspect where there is room for improvement. The importance of the efficiency aspect depends on the fact whether the income of the doctor depends directly on his productivity. If this is the case, a contradiction may occur with the efficiency targets of society. If not, the situation is comparable to the situation of the patient; the doctor wants to give the best care independent of the costs. Untill now, making doctors also responsible for the efficiency of the healthcare system has proved to be a very difficult issue. The same holds roughly for other medical and paramedical professionals.

In numbers, by far the most important group of health professionals are the professionals in the nursing and caring professions. They have the most direct contact with the patient and his social environment and the professional ethic is to give the best but also personal care. This wish, however, may create conflicts with efficiency, especially where the norms for efficiency have been quantitatively specified in detail. These professions are often not in a position to change this situation. But there are two more important issues. First is that labour circumstances in the nursing and even more in the caring professions are not very good, from a physical point of view and because of the stress of the work. The image of the professions, which was rather good several decades ago, has deteriorated significantly. This is worsened by a second problem: the imminent shortages on the labour market especially for these professions. Robotics can offer solutions for both of these problems. The development, acceptance and implementation problems for robots assisting (or even replacing) caregivers may be great, the long term benefits can hardly be overestimated.

2.3.3 Cure and care institutions

Hospitals, nursing homes, special clinics and organizations for home care or ambulant care are a very important category because they organize most of the healthcare and employ most of the people working in healthcare. The management is responsible for (large) investments and also formally responsible for quality and safety issues. Normally this is taken care of by installing Quality and Safety Management Systems. In several countries, governments are taking initiatives to make care institutions more responsible for efficiency too, sometimes by creating negotiation situations with health insurance companies (e.g. on the price assigned to Diagnosis Related Groups). These developments increase the need for care institutions to be more responsive to patients and their wishes. The management can also be responsible for special aspects of the strategy such as being a prominent research or teaching hospital or having a leading position in the region. Introduction of robotics can be one of the ways to accomplish this.

2.3.4 Other stakeholders

Researchers and industry have a dual perspective on these issues. **Researchers** regard this area as intellectually very interesting and offering good career opportunities. In principle this could run parallel to the interests of patients, healthcare professionals and other stakeholders. However, the interests of the other parties are not always identical, and the preferences of the parties offering the best financial perspectives for research may become dominant. Researchers may also be reluctant to leave their inventions in the hands of companies when the research has made enough progress to start the next phase, the phase of product development.

The dual perspective of **industry** is to serve the health customer on the one hand whilst aiming for continuity, profitability and growth of the company on the other. Also here

these interests could run parallel to the interests of patients, healthcare professionals and other stakeholders. In reality however, this is more difficult. The most important problem seems to be the risk of investing in completely new technology compared to investing in the improvement of existing products. This is both because of financial reasons and because of high demands on their technological capabilities.

Health insurance companies are traditionally organizations carrying out government regulations and policies. Because of the growing problems with healthcare budgets, governments in many countries are trying to shift part of the responsibility for efficiency to health insurance companies. Although the newly introduced market incentives have visible effects, there is still doubt whether this really will help to control macro-budgets. In some countries, consumers have got more choice in selecting their health insurance company and the preferred type of health insurance policy. It is expected that this will make these companies more responsive towards patient orientation aspects. There is concern that the attention for costs and patient orientation issues may be at the cost of attention for quality and safety issues. Insurance companies are not well equipped to evaluate these aspects either. Hope is placed on the development of indicators to make this feasible (both for insurance companies and patients).

3   Applications of robotics in healthcare

3.1   Introduction

The domain of healthcare is diverse. It includes a range of activities, from prevention and diagnostics, via cure including medical interventions ranging from surgery to therapy, to care, short term care supporting recovery or long term care supporting independence.
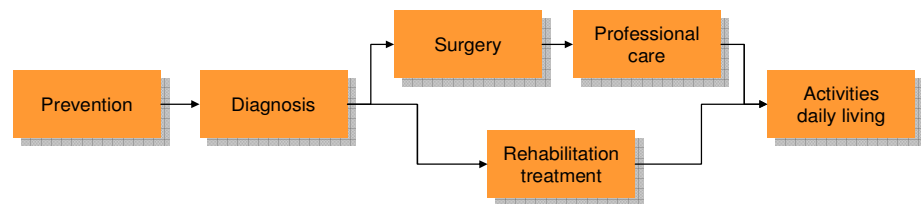

Figure 6: Activities in the R4H value chain.

Within this range many activities are supported by technology including robot technology. Moreover, many additional activities may be effectively supported by robotic systems.
This chapter deals with the possible application of robotics in all activities.

3.2   Major innovation themes

The earliest application of robotics for medicine and healthcare already dates back several decades. An important breakthrough was the PUMA 560, developed at the Imperial College London in 1985. The PUMA placed a needle for a brain biopsy by CT guidance. Much exploratory research has been carried out since, some research lines turned into development projects and some of the resulting products were introduced on the market. This market introduction is a crucial step. From the moment a product enters the market the product cycle enters a new stage. All the expectations about the potential benefits change into real decisions of authorities and real purchasing decisions and experiences of users. These experiences can be turned into new ideas, criteria for improving the devices already on the market, adaptations to make them suitable for other applications and into ideas for new applications.

In general, the study shows that robotic systems can add value to health care in four ways:
- **Reduction in labour costs.** This can be achieved by just replacing specific human activities by robots. An example here is automating logistic activities within professional care.
- **Increasing independence and social participation** of vulnerable people. This can lead to both social and economic benefits, increasing individual independence and self-support in daily life. An example is the ability to feed one self or an increased level of independent living.
- **Increasing the quality of care** that can be provided by robotic systems. Robots can act more precise and can repeat actions as no human can. Automated bone cutters for hip surgery are an example.

- **Performing activities that can not be performed by humans.** Robots can perform activities that cannot be done by surgeons due to limitations of size or precision. Here, the micro capsules for taking internal body tissue samples present an example.

This chapter provides an overview by discussing areas of application, not only by stating the present situation of commercial use, but also by looking at the areas where significant developments take place. It focuses on the actual products that are available on the market.

The categorisation of the domain of Robotics for healthcare is not generally agreed upon. In the EURON roadmap report (EURON 2004) many applications of robotics are listed under the more general term "service robots". Among many other medical robots, healthcare and rehabilitation surveillance and aiding the handicapped and elderly are mentioned. Due to the demarcation of the study as described in Chapter 1, the starting point for discussing applications of robotics in healthcare does not fully cover all service robots (e.g. domestic and industrial service robots). In the selection, the definition of the domain, as explained in the introductory chapter, has been taken into account. This means that educational robots, robot pets, robots for logistical purposes and robots in laboratories are excluded from this overview. A more R4H focused categorization is set up. The WTEC report (Bekey et.al 2006) mentions surgery robotics, diagnosis, artificial components (e.g prosthetics) and rehabilitation robotics ranging from wheelchairs to orthoses. Micro-Nano systems are mainly regarded in research oriented applications. Also here, the categories mentioned are not "one-on-one" used in the R4H categorization.
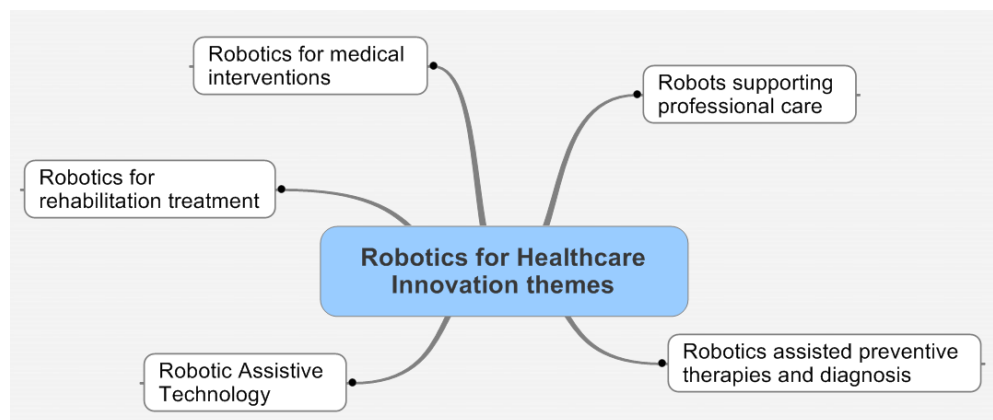

Figure 7: Innovation themes of R4H

Looking at robotics for healthcare, five different innovation themes can be distinguished:
- The first innovation theme includes **the assistance by robots in both prevention and diagnostics.** Using robotics can enhance efficiency and effectiveness in monitoring health as well as diagnostics.
- The second innovation theme includes **the facilitation of disabled or chronically ill in their daily activities**. Examples are robotized mobility and the help of handicapped people in their homes.

- The third innovation theme focuses on **the assistance of professional care giving**. Robots are used to help nurses both in the hospital environment as well as in domestic nursing activities.
- The fourth theme focuses on the **rehabilitation of patients**. Robots may assist the treatment of patients in improving their situation after the conclusion of medical intervention.
- The last innovation theme is **the application of robotics in surgery**. Focal point is the operating room and the assistance a robot can provide, both by the actual surgery as well as related logistical activities in the operating room.

The innovation themes are subdivided into innovation areas. In the following paragraphs, for each of these innovation themes, the innovation areas will be distinguished. Depending on the availability, underlying innovation concepts will also be identified. Finally, a preliminary number of applications and organizations will be provided.

3.3   Robot assisted preventive therapies and diagnosis

3.3.1   *General description*

Preventive and predictive medicine are both included in preventive healthcare programs of public authorities and are aimed at groups of people that are not ill (yet). In Europe there are screening programs to monitor youth health, breast cancer, dental problems etc. and all kinds of public education programs directed at specific groups and specific aspects like physical exercise. In the future a larger part of preventive medicine will be tailored to the individual. Preventive health care is made more specific with predictive healthcare. Predictive healthcare is based on identifying high risk groups on the basis of statistics linking health problems to family background, lifestyle, living area, working conditions, previous health problems etc.

Early recognition of groups at risk needs follow up involving monitoring, screening and eventually diagnosis. Robotics may have a role in these activities gradually evolving from mainstream applications for large sections of the population to applications specifically designed for individual patient assessment.
Specific diagnosis systems will be closely related to treatment devices enabling monitoring of patient progress.

From the prevention point of view, two possible innovation areas can be identified. The first is the connection of diagnostic functionalities to robots already used. These can be robots used for motion or coordination analysis or intelligent fitness robots. The other group of innovation areas are dedicated diagnostic robots, including tele- diagnostic robots and miniaturized robots for internal diagnosis.

To summon up, the following innovation areas can be distinguished:
- **Robotised analysis of motion and coordination**
- **Intelligent fitness systems**
- **Tele-diagnostic and monitoring robotic systems**
- **Smart medical capsules**

3.3.2   Robotised analysis of motion and coordination

In motion and coordination analysis, tedious sequences of movements need to be performed by the patients to scan their motor capabilities. These movements must be registered and analyzed, facilitating precise description and assessment of patient capabilities. Using such procedures, important muscle and coordination dysfunctions can be identified.

Caren consists of a force platform and a virtual environment able to map human movement in controlled conditions

The use of sophisticated screening programs for the motor and coordination system leads to detailed information about occurrence and development of illnesses. In this context, robots can perform complex tests which are tedious and troublesome for paramedical professionals, in very efficient and reproducible ways.

This application area is just surfacing on the field of robotics as a spin-off from the robotic systems that are developed for therapy purposes. This situation could change if governments, health institutions or firms would want to use more sophisticated screening for more people.

Firms and products
Examples of systems are:
- Caren, produced by MOTEK, is a force platform in a virtual surrounding which registers human movement induced by the moving platform.
- POPE, developed by the TU Delft, is capable of measuring complex interrelated muscle activity levels to guide treatment of post traumatic Muscular Dystrophia.

3.3.3   Intelligent fitness systems

Another application area closely related to the previous innovation area could be the use of sophisticated fitness machines for the whole citizen population. Promoting physical exercise has become a very important target in public health programs because of the relation with a number of "affluence diseases" (obesity, diabetes). However individual adjustment to the personal situation and to the progress in fitness still needs improvement. Reinforcing compliance or motivation to persevere for longer periods of time by offering more variable and attractive training programs is also one of the key factors for improving the success of fitness programs. Robots could be included in the next generation of fitness machines.

This application area is not yet under development and no serious experiments have been identified. The potential of this market could be very big. The private UK health club market in 2000 was estimated to be worth over 1.5 billion pound. The commercial fitness equipment sector that year was valued at over £200 million. In 2007 the total UK health and fitness market is expected to increase by 5% in value terms to an estimated peak of £4130 million (Market & Business Development, 2007). In Germany the number of health and fitness clubs increased from 4,750 in 1992 to 6,500 in 2002, an increase of 36.8 percent (Deloitte & Touche, Health Club Management 2003) .

3.3.4   Tele-diagnostic and monitoring robotic systems

Making a diagnosis usually requires the attendance of a doctor. New developments in robotics make remote assessment of patients possible. These systems can include communication functionalities, sensory systems, knowledge management systems and smart Human Machine Interface (HMI) tools. Moreover, monitoring individuals at risk

either after identification as belonging to a high risk sub-population or after treatment could make use of less intensive but similar systems.

The developments in tele-diagnostic or monitoring systems and be divided into the following innovation concepts:

- *Advanced diagnostics*
  Automated sensor systems or imaging systems that can be tele-operated or feature a level of automation
- *Patient consults*
  Remote consultation through a robot including communication functionalities and limited sensory systems for patient examination.
- *Patient monitoring*
  Robotic systems that monitor the vital life signs and other characteristics of patients and report incidents or transmit continuous information.

Firms and products:

- OTELO, developed and produced by Laboratoire Vision & Robotique, IUT de Bourges. This system is a mobile tele-echography and uses an ultra-light robot to remotely diagnose patients (development project finished).
- Robot-Based Tele-Echography II, developed by University Hospital of Grenoble (clinical trails).
- RP-7 tele-diagnostic system for doctors consultation, developed by InTouch Technologies, Inc (commercially available).
- IWARD, developed by Fraunhofer (FhG) and other European partners. This system uses swarming monitoring robots to monitor patients (development phase).

The RP-7 Robot is built on a platform. The RP System Core is comprised of a customer computer, controls and servo system. A multi-level computing system heartbeat and watchdog monitors the safe operation of the RP-7 Robot.

In general, this area of application is well under development but with a limited number of interesting commercial applications available. However, many developments are witnessed to further increase the intelligence of the systems.

3.3.5 Smart medical capsules

Diagnosing illnesses inside a body is often done by an endoscope using sophisticated tools which may include the functionality to take tissue samples. These procedures are regarded as burdensome for the patient. The use of robotics, combined with the further miniaturization of sensors leads to the development of miniature and wireless endoscopic micro capsules. These smart medical capsules were first developed in 2001 as an FDA approved commercial product for inspecting the digestive tract diseases. It was the first promising non-invasive miniature device in the development towards a real robotic micro-capsule.

Endoscopic Micro-Capsules add motion control and cameras to current capsule endoscopes.

Current passive capsule endoscopes are equipped with cameras to image the gastrointestinal tract and provide reliable disease diagnosis in a minimally invasive way. However, because clinicians have no control over the position and orientation of the capsules, there is a chance for missed diagnoses. Allowing the clinician to stop, move and orient the capsule on command would improve diagnostic capabilities by letting the operator take a closer look or backtrack to re-examine a region of interest. Furthermore, once reliable control is obtained and the capabilities of the device have been increased, the

capsule can be equipped with tools for performing tissue biopsy or for cleaning or cauterizing wound sites. Tele-operated and semi-autonomous control of these capsules is thus a new robotic challenge. By developing novel nano-robotic motion and clamping mechanisms, novel surgical micro/nano-manipulators, drug delivery micro-spray devices and biochemical nanosensors, these capsules could evolve into active nano-robotic micro-capsules in the future. These applications would not belong to the current innovation area but they obviously are related developments.

Products and firms:
• The group of Metin Sitti is developing such micro-capsules by using bio-inspired adhesives to stick the capsule to the intestinal lining (under development);
• Olympus Medical Systems Corporation has developed capsule endoscopes and peripheral technologies for further expansion and progress in endoscope applications (commercially available);
• PillCam COLON capsule by Given Imaging is another example of a smart capsule (commercially available).

This application area is still very much under development. However, some high-tech products are already commercially available and the area can be seen as a significant growth market, both from an economic as well as from an innovation point of view. The US market is estimated to grow from $65 million in 2006 to $370 million in 2011 (MRG, 2007).

3.3.6   General conclusions on robot assisted preventive therapies and diagnosis
The costs of application of *Robotised motor coordination* and *Intelligent fitness systems* will probably be an important barrier for widespread use. This argument will count even stronger for applications that are meant for every citizen no matter whether this is financed from public funds or by private consumers. Currently, it seems likely that this whole area of preventive and predictive application of robots, however desirable it may be, needs a long technological evolution. Perhaps pioneer niche markets are necessary to develop into less expensive devices with proven cost-effectiveness. However, these conclusions are based on little data and few available systems.

The development of robotized tele-diagnostic systems is well on its way, but only a limited number of applications are available on the market. Although it can help reduce the costs of healthcare, further development is needed to increase user friendliness and costs. Social acceptance is still a problem, but experiments show this can be solved.

The development of smart medical capsules can be seen as an emerging market, where the number of commercial applications is growing. Furthermore, the innovativeness of this area has strong potential, leading to large markets. Applications must also be seen outside the preventive and diagnostic applications.

3.4   Robotic Assistive Technology

3.4.1   General description
In Europe some 40 million people are disabled or suffer from a chronic illness. A significant number of them live still in a relatively independent situation. To enhance independent functioning and societal participation for disabled and chronic ill people in

their environment of daily living robotics can help by providing individual support. These activities include e.g. personal hygiene, eating and leisure activities.

Traditionally, these activities require support by professional or informal care providers when technological support runs short. Robotics can reduce the professional and informal care in domestic environments by supporting and, in part, replacing it. This may even facilitate increased independent living. As an example, severely motor impaired individuals depend heavily on the support of other individuals in their day to day life. In part, this care is provided by professional caregivers while another, large part of this care is provided by informal caregivers. This situation has two main drawbacks. The costs of providing this type of care are high, clearly with professional caregivers but also, although more indirect, with informal caregivers. In developed societies the availability of care givers is decreasing in general, while the demand is growing due to demographic changes. This makes the provision of care a growing problem in the decades to come. The other drawback is the feeling of lower self reliance. All individuals in society strive for a level of autonomy and independency. Being dependent of human care provision is generally conceived as opposite to this. The provision of technology including robotics could, in part, solve both problems. It can contribute to a lesser demand for human care provision while at the same time it could help restoring independency of the handicapped individual.

The following innovation areas can be distinguished:
- **Robotised systems supporting manipulation**
  These applications support users in using devices in their day-to-day activities (such as eating with the feeding robot).
- **Robotised systems supporting mobility**
  These applications help disabled people with their mobility in daily activities.
- **Intelligent prosthetics**
  These applications are replacements of external parts of the body.

The systems can support or compensate body functions by direct replacement of body functionality by a robot system (prostheses or orthoses). Systems can also provide activity related support (workstations, feeding robot, or smart mobility devices).
In the EURON roadmap report (EURON, 2004) this domain of robot applications is referred to as Care assistant / intelligent homes. A number of currently outdated systems are described but a similar range of functionalities is included. Additional functionalities mentioned are medical robots, a topic which is covered in this report under surgery.

The technology used is diverse, but important drivers are the further miniaturization of sensors and mechatronic systems, high performance materials and the increasing ability to intelligently process information. This is not only creating innovations, but also reducing costs of complex systems.

3.4.2   *Robotised systems supporting manipulation*
This group of applications are personalised, robotized manipulation assistants to help disabled people in their domestic or working environments. These systems support individuals by providing manipulation ability of various types. The aim of these systems is to provide sufficient support to enable handicapped individuals to participate independently in occupational settings or at home. Such manipulation can be provided by sophisticated hand-like devices, by arm like devices fitted with a more basic gripper,

or systems that are designed to perform specific activities of daily living (ADL) tasks optimally. Examples of such activities are eating, brushing teeth, picking up objects, opening doors, filing and paper handling, etc. This can either involve mobile grippers or dedicated devices capable of supporting tasks on specific pre-defined locations.

ARM manipulator arm by Exact Dynamics BV (the Netherlands). Robot manipulator consisting of a mechatronic robot arm mounted on an electrical wheelchair controlled by a joystick and button device mounted on the armchair.

The development of manipulating devices faces the challenge of creating safe systems that can function reliable in direct contact with vulnerable individuals. In addition, the systems must be able to operate fast and effectively. In order to offer real support to their users, the systems should allow to be controlled in an intuitive way that does not create too much mental load. To a certain extent, these requirements are contradictive and lead to delicate design compromises.

From the technological perspective, there are numerous arms available from the space and industry domains, that could be transferred to the care domain (e.g. Bekey et.al, 2006). The adaptation of mainstream technology for this type of application is still elaborate and therefore costly, as is system integration. This elaboration is difficult since severely handicapped people only form a small imperfect market where goods are not financed by the users.

From the technological side, more sophisticated modelling and control technology as well as the further miniaturization of mechatronics, enable new innovations.

This innovation area includes several innovation concepts:
- *Gravity compensation systems*
  Smart systems that can assist disabled people who have limited power or hand-eye coordination.
- *Hand mimicking systems*
  Exogenous static systems connected to objects in homes (wall, tables, etc.), that assist disabled people with daily life activities.
- *Wheelchair mounted personal assistance devices*
  Devices connected to wheelchairs that act as personal assistants to the disabled.

Examples of firms and products in this innovation area:
- Exact Dynamics BV (NL) produces the ARM manipulator (commercial product).
- Secom Ltd (JP) produces the Myspoon feeding robot (commercial product).
- MicroGravity (NL) produces the ARMON (commercially available).
- Alfred I. DuPont Hospital for Children (USA) has developed the WREX (experimental).
- The EC-MATS Consortium (EU) developed MATS (prototype in 2006).

The adaptation of mainstream technology for this type of application is still elaborate and therefore costly as is system integration. This elaboration is difficult since severely handicapped people only form a small imperfect market where financers are others than users. The challenge regarding the work environments lies in the ability to produce a system that is as unobtrusive as possible. So far, systems have not been able to do so. Dedicated systems such as ProVAR or RAID-MASTER met system requirements but have had only limited success in being taken into use on a daily basis.

Concluding it can be said that the hand mimicking devices are mostly seen as research challenges with limited practical application. The development of grippers is somewhat related to the hand like devices but more aimed at practical application. The arm-like devices are found in actual use more often and in an increasing variety. Worldwide several hundred of such systems are in day to day use by end-users. Proving the cost-effectiveness of such systems is still difficult and complex. A range of such system are currently available triggered by an emerging market due to changes in health care reimbursement.

3.4.3   *Robotised systems supporting mobility*
Mobility is a crucial social need for many disabled people. The traditional wheelchair is one of the most important mobility concepts that enable disabled people to meet other people and being part of society. However, a significant group of people is not able to use the traditional wheelchair to achieve the independent movement needed. Blindness, limited muscle power in the arms and limited eye-hand coordination are just some examples of problems that need to be overcome.

The concept of smarter systems has been appealing enough to trigger research projects for decades. The aim of smart wheelchairs is to provide independent mobility for those who cannot make use of traditional power wheelchairs. In 2006, the market for power wheelchairs was $756.5 million in the USA and Asia alone, and is expected to reach a little over $1 billion by 2013. The primary customer is the home medical equipment (HME) provider (Wintergreen Research, 2007). Increasing the functionality of the power wheelchair with robotics, may provide access to independent mobility for a group of users currently excluded by the state-of-the-art power wheelchair. This is one third to half the size of the current power wheelchair user group (Fehr, 2000).

Through sensor technology and navigational abilities users will be enabled to manoeuvre safely and effectively, because technology takes care of the wheelchair control where the abilities of the user run short. Similar are smart walkers which can support individuals with limited standing, walking or balancing ability and who suffer from additional limitations (e.g. blindness). For blind people there are some robot systems that help with navigation and/or obstacle detection. The most important innovations have an already existing non-robotic mobility device as a starting point, e.g. an electric wheelchair or a walker. Innovations are made to extend the manoeuvrability and the areas where the device can be used. In addition, coupling of all kinds of other devices to the robot, for navigation purposes, etc. are researched.

Looking at some important innovation concepts, the following type of products can be given:
- *Robotised wheelchairs*
  Increasing the usability of traditional wheelchairs for disabled people with severe motor limitations. Additional functionality can be added to the wheelchair through robotics, in terms of the ability to cover difficult terrain or the ability to navigate and avoid obstacle collision.
- *Smart walkers*
  Robotic systems that support mobility impaired people while walking who cannot make use of traditional walkers.
- *Exoskeletons for disabled people*
  Devices worn by disabled people that enable movement through EMG sensors.

Products and firms:
- The I-Bot, produced by Independence Now (USA) (commercially available in USA).
- MOVEMENT (Modular Versatile Mobility Enhancement), produced by the EC-MOVEMENT consortium (EU) (under development).
- Guido Haptica (0-series), produced by Haptica (IE).
- GuideCane, produced by the University of Michigan (USA) (under development).
- HAL5 Hybrid Assistive Limb, developed by CYBERDYNE (JP) (under development).
- BLEEX produced by Berkeley UC (USA) (Military version is functional)

Quite a number of smart wheelchair developments were initiated, however, with almost no commercial results up until now. The availability on the market of these systems is very limited. The relative expensive systems are designed for the more severely impaired. This is a relatively small market. Moreover, technology to make effective and safe systems is still relatively expensive (e.g. laser scanner). The one commercial product in this domain is the I-bot which, due to local regulations and reimbursement programs, is not available outside the USA.

Availability of exoskeletons for healthcare is not existent yet. Applications for the handicapped are only experimental so far. Development of systems suitable for day to day use is still underway. Limiting problems are battery power and the unresolved complexity that lies in intuitive control of the system.

The I-Bot wheelchair by Independence Now is capable of balancing on two wheels, climb stairs and manoeuvre safely over very uneven terrain.

Intelligent prosthetics

The loss of a limb is an often recurring source of disability. It can be the result of trauma, war related casualty (i.e. landmines), but also common diseases (e.g. diabetics) or genetic imperfections. People without one or more limbs may benefit from restoring mobility and independence by prostheses. These prostheses mimic human functionality through artificial muscles, joints or skeleton parts. Optimal control over the artificial limb movement provides the user benefit of the prosthesis approaching the use of a natural limb as close as possible. The number of amputations being around 140,000 annually in the USA (Business Wire, 2007) shows the enormous market for this type of product. However, it should be noted that the number of users that would benefit from a robotised prosthesis is only a small part of the total population.

Traditional prostheses are passive artificial limbs without any intelligence. This limits the enhancement of mobility, due to the complexity of human limb movements and control. The developments in active prosthesis focus on several aspects. The first aspect is **imitating the natural movement** of human limbs. Human motion is complex and most artificial limbs are generally able to perform only the simplest movements. An other aspect is the **physical connection** of the prosthesis to the human body. Usually rigid materials are limiting the fit, leading to discomfort and reduction of controllability. A third essential aspect is the **human control** of the prosthesis by the human nervous system. Usually, the connection is not active. A last essential aspect is the **external**

feedback to the user. This includes restoring sensation, as well as feedback of movement to adjust action.

The developments in micro processing, modelling and mechatronics (miniaturization) increases the potential of prosthetics for smart active prosthetics. Important underlying innovations are in the field of smart modelling and processing of movements, mobile energy systems and advanced sensors and other mechatronic technologies. But also new materials are developed that enhance the "fit" of the prosthesis to the human body.

Looking at the developments in this innovation area, the following innovation concepts can be distinguished:
- *Intelligent lower extremities prosthesis*
  These type of products focus on the replacement of feet and legs, and include dealing with the complex movement of walking.
- *Intelligent upper extremities prosthesis*
  These type of products focus on the replacement of fingers, hands and even arms. These include dealing with the complex movement of "grippers".

Products and firms:
- C-leg knee joint, produced by Otto Bock (DE) (commercially available);
- McKibben muscle, developed by Shadow Robot Company (experimental).

Otto Bock C-Leg is a successful development setting new standards in prosthetics.

The successful applications in this innovation area provide an extra functionality in comparison to the more traditional solutions. Revolutionary devices have not made it to commercial exploitation yet. To meet market demand the functionality of the C-leg was even simplified after the successful introduction of the original version. It seems the introduction of high end innovative prosthetics comes in small steps. But to date, only a limited number of smart prostheses have left the experimental stage. Those who did, provide only part of the potential gain offered by artificial control of prosthetics.

3.4.5   *General conclusions on robotic assistive technology*
In today's society there is a substantial number of people with disabilities and their number is growing because of demographic reasons. The empowerment of this segment of society has been increasing over the years leading to a societal acknowledged striving for optimized social participation. At the same time both professional and informal care is becoming scarce. Given the fact that people increasingly prefer to be as independent as possible, this is an application area of very great importance. Much research has been carried out and many experimental devices have become available. The application of relatively complex and expensive systems for rehabilitation purposes, is considered more and more acceptable in light of the severe limitations users are facing.

However, only very few applications have actually made it to commercialization. So far, most applications have been developed for severely disabled persons. These patients are a diverse and relative small part of the potential user population. Furthermore, these robotic systems are still very expensive due to relative high R&D investments. Therefore the size of this market is rather limited and not able to generate enough revenues for companies to further invest in this area. Things would change if

there were also devices suitable for the much larger group of less severe disabilities, but these developments are still in a developmental stage.

3.5 Robots supporting professional care

3.5.1 *General description*

Professional care provision is an important social institution, with a substantial workforce. In Northern European countries, like the Netherlands, Sweden, and UK, this can be 8-10% of all employees. Experts estimate that around 70% of all people aged over 70 are unable to perform at least one or two daily routine activities without support (Eurofound, 2006). Provision of personal care is the traditional answer to such problems, but the increasing ageing of society is feared to lead to a too large societal pressure on professional care. The increasing demand for care services and growing strain on the supply of such services, points to a future imbalance between supply and demand, not in the least because of the increasing age of professional care givers themselves. Severe shortages are expected in the nursing and caring professions, while the image that the sector has in the labour market has already deteriorated during the last decades.

Although there is a growing tendency to provide care to patients living at home as long as possible, much care is and will be provided in care institutions such as hospitals, retirement homes and nursing homes. This innovation theme is limited to the assistance of professional care givers in any of these institutional environments. Assistance to the independence of individuals by means of provision of assistive technology in their daily lives was elaborated in the previous section. Activities of professional care providers that may be supported include transferring and lifting of patients, logistical processes, provision of care in ADL tasks: hygiene, patient nutrition, monitoring of patients, etc.

The introduction of technology in care, including robotics, is generally embraced as a potential solution for the double ageing problem. Many trials have been executed involving many different technologies, but the success and impact seem to be smaller than expected. Implementation and uptake of technology in traditional care provision encounters problems other than mere technological ones. This certainly holds true for robotic applications. Nonetheless, the potential of robotized systems in support of care provision remains an interesting domain. It includes a number of innovation areas:

- **Logistical robotised aid for nurses**
- **Robotised patient monitoring systems**
- **Robotised physical tasks in care provision**
- **Robotised paramedic tasks**

Crucial technological innovation drivers for this innovation theme are the traditional drivers seen in robotics. These include the further miniaturization of sensors which reduce costs and increase the potential intelligence of robotic systems. Also the developments in mechatronic components, as well as ubiquitous ICT enable smart, strong, robotic systems. In Europe the number of robots in professional service support increased within three years (2002 until 2005) from 12,400 to 25,500 (EURON, Technology Roadmaps).

3.5.2 *Logistical robotised aid for nurses*

A large part of the activities of professional care is of logistic nature. It includes both the fulfilment of daily needs of patients (distribution of mail or personal care products, environmental cleaning tasks), as well as the provision of drugs and food to patients.

The TUG system transports a variety of hospital carts. It automates and tracks the delivery of goods in hospitals.

Traditionally, this work is done manually, without much automation. The development of smart systems enables the use of robots to automate the deliverance of e.g. medicines and food. This may enhance security, compliance and reliability while reducing labour costs.

The development of robots to assist care personnel in their logistical activities finds it origin in developments in parallel domains. Many non-patient related logistic tasks in hospitals can already be performed by robotised systems. Although the required technology is available it will require adaptation to the patient environment in order to be effective in this innovation area. Also here, most of the key innovation drivers of robotics play a role (miniaturization, intelligence through ICT, high performance materials).

Looking at this innovation area, the following types of innovation concepts can be distinguished:
- *Cleaning robots for hospital environments*
  Cleaning robots for operating rooms and patient rooms, able to deal with patient encounters and to work in the sensitive environment of hospitals.
- *Automated medicine distribution systems*
  Robotic systems that keep track and distribute medicines to patients, including monitoring compliance.
- *Robotized catering*
  Automated systems for the distribution of food in hospitals and other care institutions.
- *Automated inventory management systems*
  Robotized systems that monitor and refill care supplies, including systems for pharmacy and daily care for patients.

Products and firms:
- IWARD: a swarming robotized electronic nurse system, developed by the Fraunhofer-Gesellschaft (under development);
- TUG and Homer; two products that facilitate smart automated deliverance within hospitals, produced by Aethon (commercial available).

In general, the developments in this field are based on more general technologies also used in other domains. Systems are often adjusted to the environment of the nurse. This means that more general systems are commercially available. High-tech dedicated systems for hospitals are still under development.

Although there is an obvious development going on regarding these systems towards market activity, there is still a rather limited amount of systems active on a day to day basis. Certainly in Europe, systems are rarely available on the commercial market. Intuitive control and smoothing the remote interaction is still a problem as is the effective integration into existing care systems.

3.5.3 *Robotised patient monitoring systems*

Monitoring of patients is an ongoing activity in care rich environments. One of the nursing activities is monitoring of patients and assisting doctors in their daily meetings with patients. Systems can support nurses in nursing homes and elderly homes by remotely monitoring patients and remotely diagnosing occurring problems. Furthermore, robot systems can be used within medical care facilities to support patients consulting a doctor and/or nurse without them being physically present.

Mobile systems depend on their onboard sensor systems to manoeuvre safely and reliably through unstructured areas where they can encounter humans. The first challenge in designing these systems is to do so at competitive costs. Furthermore, the system in itself merely functions as a remote sensor. The follow up of signalling will determine the quality of the overall system. In most cases this will include human involved services. The second challenge is to combine monitoring systems with human involved services into effective care systems.

The following types of innovation concepts can be distinguished:
- *Robots for monitoring patients*
  These relative "simple" robots only monitor vital signs (e.g. absence of movement) and other more easily sensed signals and communicate them to the nurse or doctor. These systems can be applied in the professional environment as well as in households.
- *Advanced robotized monitoring*
  These robotic systems can perform sophisticated analysis of patients remotely, sending back the information to the doctor.
- *Virtual doctor consultation*
  These systems replace the physical presence of a doctor by enabling the patient to consult the doctor via video.

The Mir-H platform provides a mobile system able to monitor safety and activity at home.
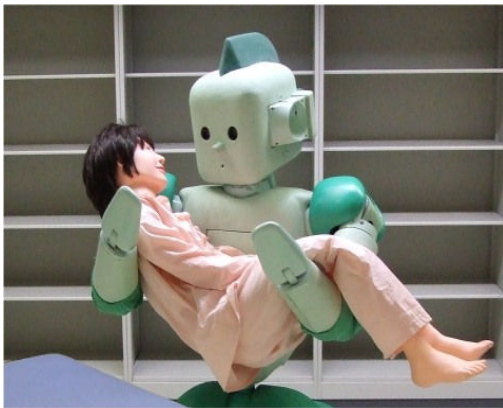
Products and firms:
- Robot doctor RP7, which replaces the doctor and creates a remote connection. This system is developed by InTouch Health (USA) (commercial product)
- Mir-H, which allows remote communication between doctors and patients in the domestic environment. Developed by MOST I TECH (KR) (commercial product)

Although systems are being developed for the market, there is still a rather limited amount of systems active on a day to day basis. Certainly in Europe. Systems are rarely available on the commercial market. Intuitive control and smoothing the remote interaction is still a problem as is the effective integration into the existing care systems. However, some promising results can be seen that show that the acceptance of these robotic systems by patients is not a crucial bottleneck.

3.5.4 *Robotised physical tasks in care provision*

Nursing is labour intensive, also from the physical point view. Taking care of patients includes cleaning patients and changing beds. These activities require lifting (too) much weight or exerting (too) much force. To relieve nurses and prevent work related injury, robotic systems can be used to assist or even replace the nurse for specific tasks.

Systems providing supportive labour in care provision obviously have to be able to handle vulnerable humans with the utmost care. This places high demand on the sensor system and the actuators.

The following innovation concepts can be distinguished:

- *Nurse assisted robotic patient lifting systems*
  Being a labour intensive activity, lifting of patients by nurses can be assisted by robotics systems. These systems do not act independently.

- *Autonomous robotic patient lifting systems*
  Another robotics application is the autonomous lifting of patients. These systems are considered less socially acceptable, due to safety and patient acceptance issues.

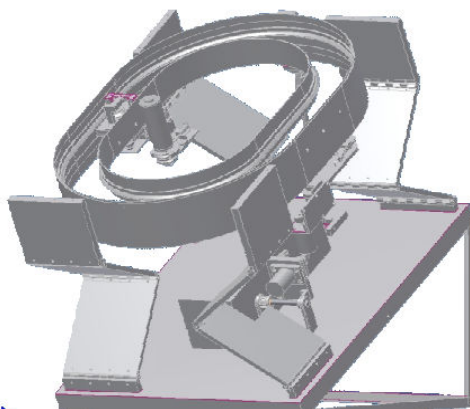RI-MAN is designed for lifting and carrying humans.

Products and firms:
- RIKEN (JP) develops RI-MAN
- University of Tokyo (JP) develops ETL-Humanoid
- Daihen Co. Ltd. (JP) produces the C-PaM, a robotic "Careful patient mover". This is a very simple and effective system to move a patient from one bed to another.

The introduction of these systems in the healthcare system is in itself a challenge. Acceptance of such systems by both care provider and patient highly depends on cultural expectations. Acceptance seems to be better in Asian countries where the origin of these systems lies. For the European situation adaptation will be required. Systems are rarely available on the commercial market. They still need improvement, especially systems to support patient lifting and carrying tasks. Another limiting barrier for practical application is battery power and energy consumption.

3.5.5 *Robotised paramedic tasks*

In the work of healthcare professionals there are a large number of frequently recurring tasks that need to be executed repeatedly and with full attention because of the involvement of humans and potential health risks. Some of these tasks require high level of skills and as such may be open for execution by a robot system. Potential robotised tasks are of non-invasive nature, such as analysis of body samples, blood pressure measurement, injury care, applying bandages etc.

Systems executing paramedic tasks in care provision obviously have to be able to handle vulnerable humans with the utmost care. This place high demand on the sensor system and the actuators. Moreover the system must be equipped with the heuristics that builds expertise in order to perform the tasks at the required quality level while being able to adopt task execution to individual circumstances.

So far, only one bandage applying robot has been identified.

Products and firms:
- Vision Dynamics (NL) develops PERROB.

PERROB: Perrob is a robot system specifically designed to apply bandages around patients leg as part of compression therapy.

The potential of these systems seems to be much larger than the available systems indicate. Development of robot systems in this area is easily feasible with respect to the available technology. The demand for systems may appear smaller than reality while technology requirements are relatively low.

3.4.6. *General conclusions on robots supporting professional care*

Robot systems for care giving support are still in the experimental phase. However, results of experiments in practical situations become more and more available. Opportunities for practical application exist in medical facilities, nursing homes and elderly homes. Systems can support doctors and nurses in remote "patient rounds", delivering meals and medication, lifting and carrying patients and patient monitoring. The potential demand for robotic support in care giving tasks is huge. The market potential is big. Barriers could be the (social) interaction between robot system and user, the acceptance of such systems in practical situations, energy consumption and battery power.

3.6 Robotics for rehabilitation treatment

3.6.1 *General description*

Rehabilitation focuses on the treatment of patients with a physical and mental disability. These treatments aim at the functional restoration, where emphasis is placed on the optimization through the combined use of medication, physical modalities, experiential training approaches and the use of assistive technology. Common conditions that are treated by physiatrists include amputation, spinal cord injury, sports injury, stroke, musculoskeletal pain syndromes such as low back pain, fibromyalgia and traumatic brain injury. But also patients with heart and lung diseases can benefit from rehabilitation treatments.

Robotic systems are believed to be able to play an important role in therapy activities within rehabilitation treatment. Systems can be used in clinical situations as well as at home. Especially in home situations robot therapy can support the client in execution of therapy independently, especially in case of repetitive activities. Such systems must be seen as supportive of existing therapy practice and not as replacing the therapist. Besides dealing with physical motor related therapy, interest is growing for robot support in mental and social related therapy. Robotics in physical therapy can be divided in motor-coordination therapies and muscle sustaining therapies. Robot assisted therapies for mental and cognitive diseases are mostly based on role playing concepts.

This innovation theme can be divided in the following innovation areas:
- **Robot assisted motor-coordination therapy**
- **Robot assisted physical training therapy**
- **Robot assisted mental, cognitive and social therapy**

3.6.2 *Robot assisted motor-coordination therapy*

Damage to the brain or nervous system can result in impairment in coordination of motor behaviour. A very well known example is of persons suffering from one sided impaired motor-control, following recovery from stroke. Therapies are focussed on regaining the motor control in the brain or restoration of functional performance. The mechanisms behind the restoration of function on the basis of brain plasticity are not

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fully understood yet. However, the general conception is that repeated movement eventually will lead to restoration of brain functioning for control of this movement. Spinal cord injuries are the cause of another familiar group of patients. Depending on the nature of the lesion recovery of control may be possible but the focus of therapy is mostly on the restoration of functional performance on the basis of regaining control. Robot therapy systems have been developed for training of both the upper extremities and lower extremities.

Hocoma's Locomat is a system designed to support the patient in restoring gait patterns while taking away the body weight on the patients legs.

The use of robotic systems focuses on guided movement of limbs in order to have an optimal effect from a therapeutic and functional perspective. The positive aspect of robotized therapies is that force feedback to the patient can be regulated, increasing the effect of the therapy, and robotized therapies offer options for functionalities introduced for stimulating patients to increase compliance to the therapy. Given the number of annual patients the (diverse) group of CVA (stroke) patients forms an interesting market. But differences between patients within this group can be large, making it difficult to develop widely applicable systems. So far, systems encountered seem to have been developed from a technological perspective rather than on the basis of demand from therapy. But for some of these systems the therapeutic effectiveness is currently under investigation.

The following innovation concepts can be distinguished:
- *Arm movement controlling systems*
  Robotic assistance with therapies that train the restoration of motor-coordination for upper extremities.
- *Gait training robotic systems*
  Robotized assisted therapies for the training of lower extremities.

Products and firms:
- EC-GENTLE/S consortium (EU) developed an arm support system making use of the Haptic Master (experimental).
- Hocoma (CH) brings Lokomat to the market, a gait training system that is being sold to rehabilitation centers and hospitals.
- Stanford University (USA) develops the MIME, Mirror-Image Movement Enabler. It facilitates the mirroring of movement abilities of the healthy body side to the affected body side. (experimental)

The detailed control of arm movement is challenging because not only the movement of the hand is relevant but also the optimization of the movement of shoulder, elbow and wrist needs to be taken into account. A system capable of doing this soon becomes very large and unusable for therapy purposes (certainly at home). Force feedback to the arm provides major learning advantages and should preferably be added to the arm movement control system. Strong, reliable and precise force feedback systems are still under development. The restoration of the role of propriocepcis is a not to be neglected area in the development of extremity movement control. However, the technology is hardly available at the moment.

3.6.3   *Robot assisted physical training therapy*

Robot systems can especially be useful for muscle sustaining therapies. This is somewhat comparable with the use of fitness systems. For stimulating the muscles these sustaining therapy robot systems are very much based on fundamental and repetitive motor activities. To exert these activities clinical settings with continuous therapeutic supervision is not necessary. Therefore it is also possible to exert these therapies in home situations. For home environments there is a great need for simple and inexpensive robotic systems integrated with standard PC. Playing a computer game as part of the therapy can be very stimulating for the client.

Systems able to perform the required functionality are not necessarily complex systems. Technologies available from other domains (e.g. gaming industry) are suited for application in this domain. Combinations of technologies can result in effective innovations. The challenge lies in providing functionality that appeals to the therapist, motivate the patient and is effective in its results.

Products and firms:
- Rutgers University (USA) develops Rutgers Ankle (prototype)
- BerkelBike (NL) by BerkelBike (commercially available).

The Rutgers Ankle allows movement of the ankle for therapy purposes in all three degrees of freedom. Capable of supplying low and high forces in all directions, permitting a large variety of exercises. For use at home.

Successful systems in this domain make effective use of available technologies while being innovative in the offered functionality and answering a market demand. Technology driven systems (innovative technology) often have a difficult task in convincing the market.

In general the rehabilitation therapy industry in the US consists of about 20,000 practices with a combined annual revenue of about $11 billion. The industry is highly fragmented. No company has more than 5 percent market share and the top 50 companies have less than 25 percent.

3.6.4   *Robot assisted mental, cognitive and social therapy*

Social interaction can be severely hampered because of cognitive or mental impairment. The advantage of robot systems in support of therapy aimed at restoration of social skills, lies in the controllable behaviour of robots and their ability to repeat actions. Robot systems are designed for interaction with humans in various types of social behaviour such as communication and cooperative play. Emotional bonding may have advantages over human social interaction because of the typical robot characteristics. Communication between persons with mental and/or cognitive diseases and other persons often is very problematic. It has been shown that children with communication disorders (e.g. autistic children) and elderly persons (e.g. demented persons) can benefit from interaction with robot systems. In addition robots have characteristics that human, pets or dolls do not possess (hour-rate, need for cleaning and caring, passiveness).

Some robotic systems designed for simulation of human social interaction are already commercially available. In most cases these systems are regarded as toys or mechanical pets (Bekey et.al, 2006). The therapeutic potential is recognised and is being

researched. Further development is as complex as human social interaction and will require addition research.

Products and firms:
* Intelligent System Co., Ltd. (JP) produces Paro (commercial product).
* Arcs (AT) developed the PlayROB, a system enabling physical impaired children to play with LEGO
* Massachusetts Institute of Technology (USA) developed Leonardo Robot (experimental).

Covered in soft white antibacterial fur, **Paro's** artificial intelligence means it can mimic animal behavior and over time, develop its own character.

Although the technology itself may not be complex, designing systems that appeal to human emotions on exactly the right level require delicate design iterations. The success of most of these systems illustrate that robotics have a large potential in this domain, maybe even one of the most promising of all domains. This impact will however be easily underestimated by public financers and may be regarded as just childs play. Therapeutic impact may be substantial however.

The challenge lies in appealing to the patients by providing the right functionality with the right technology. Certainly children with cognitive disorders can be easily over-stimulated resulting in counterproductive effects. The Japanese take up of robot technology resulted in the development of interactive pets to counter the effect of growing solitude among elderly with dementia. The subtle interaction offered by the pets triggers emotional behavior in both elderly and children, not only in Japan. First European trials proved to be very promising as well.

Analysis of the market size of traditional toys in the US has shown a decrease from $43800 million in 2006 to $29300 million in 2010, while the market for high tech toys will increase from $24000 million in 2006 to $34800 million in 2010. The application of toys for healthcare will be only a very small part in this but the development of healthcare applications can highly benefit from mainstream developments.

3.6.5   General conclusions on robotics for rehabilitation treatment
There are several robotic systems on the market for supporting physical as well as mental and cognitive therapy. Systems must support therapy activities, not replace the therapist. Furthermore, the effectiveness of the systems during therapy situations is not known. Special therapy concepts for robotic therapy must be developed for effective use in clinical as well as home application.

Although several robot systems for therapy support are already commercially available on the market, there is still little evidence for the effectiveness of the therapy concepts both in clinical and in home application.

3.7   Robotics for medical interventions

3.7.1   Introduction

One of the major activities in the healthcare system is the performance of medical interventions. This includes surgery but also minor interventions like taking a biopsy. These activities are performed by doctors as well as by nurses. In the USA alone, there are over 7,000 hospitals, indicating a significant potential market.

Research in the area of *robotics for support of medical intervention* started around fifteen years ago and is very active today. In this area, robots being used to support the surgeon are starting to take over some tasks of the surgeon. In fact, the very first examples can be found of whole new tasks a surgeon was not able to perform, which can be performed by robots. Robotic support of medical intervention can help accomplish tasks that doctors by themselves cannot accomplish because of the precision, endurance and repeatability of robotic systems. Besides, robots are more able to operate in a contained space inside the human body. For these reasons robotic systems are considered an important factor in the future of surgery. Today, the first robotic systems are already being used. Specifically, robots are contributing to improvement of non-invasive or minimally invasive surgery and to better outcomes of surgery. With robotic surgical systems it is possible to do open surgery, minimally invasive surgery, remote tele-surgery, preoperative planning, surgical rehearsal, intra-operative navigation (image-guided surgery) and surgical simulation all from one place. Today, robots in this domain have been demonstrated and are in actual use in the surgery of the brain, heart, spinal cord, knee, throat, kidney and eye. Since the robotic surgical system improves consistency and quality, it is becoming more and more popular.

In this domain the following innovation areas can be distinguished:

- **Robot assisted micro surgery**
- **Robotised precision surgery**
- **Robotic devices for minimal invasive surgery**
- **Medical micro and nanobots**
- **Remote surgery**
- **Robotised assistance for small medical interventions**
- **Robotised surgery assistance.**

3.7.2   Robot assisted micro surgery

Part of surgery focuses on small and delicate tissues. At this moment, surgeons are much better in soft tissue surgery than robots because they can adapt more easily to the behaviour of the tissue. But surgeons can be assisted by robots for precision and micro surgery. They can scale the movements of the surgeon, filter out tremor in the movement of the surgeon and stop the surgeon from accidentally cutting there where he is not supposed to. The relevant medical practice includes eye, ear, nose, throat, face, hand and cranial surgeries.

Products and firms:
- The Acrobot Company Ltd (UK) develops The ACROBOT
- Johns Hopkins University (USA) develops Steady Hand Robot (In development)
- Hansen Medical Inc. (USA) developed the Sensei Robotic Cather System and Artisan Control Catheter for commercial use.
- Intuitive Surgical Inc. (USA) developed the Da Vinci® Surgical System (on the market).

To facilitate further progress in this domain surgery has to become even less invasive, provide access to deep structures and greater magnification. The control of the systems needs to be improved; better interfaces including dexterity enhancement, haptic feedback, smaller force sensors and 3-D navigation. To improve performance in soft tissue, better models and enhanced tool-tissue interaction are required. To improve safety, sterilization requires progress, but also compatibility with other surgical equipment and the application of inexpensive materials. Robots in this domain can make new procedures possible and increase precision. On top of that, robot assisted surgery can decrease trauma.

Making a one-centimeter keyhole incision to perform the operation, the Da Vinci surgical system enables the surgeon to engage in minimally invasive surgery while he is situated at a console several feet away from the operating table.

In general, the most successful applications will be those which make use of the strong points of a robot as a replacement of the weak points of the human surgeon . These are endurance, precision, repeatability and reliability. The conclusion can be that although a few commercial systems are available on the market, this area is still to be considered experimental and needs additional developments in order to mature.

The need to perform delicate surgical procedures, safely, in narrow spaces where the surgeon cannot see directly, has created a growing market for devices that act as extensions of the surgeon's eyes and hands (surgeon robot support). The US market for medical robotics and computer-assisted surgical equipment (MRCAS) was worth an estimated $564 million dollars in 2005. The market is projected to reach $2.8 billion by 2011. The total worldwide market for MRCAS devices and equipment is expected to be $1.3 billion in 2006 and $5.7 billion by 2011.

3.7.3 *Robotised surgery assistance*

In the operating room, the surgical nurse provides essential assistance to the surgeon. They provide care and support to patients before, during, and after surgery. Different positions include scrub nurses (who pass sterile instruments and supplies to surgeons and assist them with the actual surgery), circulating nurses (who work outside the sterile field), and RN first assistants (who deliver direct surgical care to patients).
Robots can assist the surgeon with passing the sterile instruments and supplies. But the system can also provide the surgeon with one or more extra arms to hold something: a patient's limb, an instrument or a camera. This arm can be controlled through foot pedals en stays perfectly still.

Products and firms:
• Robotic Systems & Technologies Inc. (USA) develops Penelope, a robot surgical instrument server.

There are only a few of these robotic systems under development. There are even less systems commercially available. But some outstanding individual products are developed and already in use. In the future, these type of products will be further developed and their commercial application is promising.

3.7.4   Robotised precision surgery

Some procedures in surgery are well suited for robotic assistance. These procedures (in "hard material"), such as replacing hips, are well defined and can be planned beforehand in a 3-D model of the patient. Also in hard material, a robot can work automatically and more easily due to its static and predictive nature. However in soft material, the tissue can change between making the 3-D model and the operation. Furthermore, in soft material, the tissue might react during the procedure differently than expected.

The RoboDoc surgical system uses Computer Tomography to obtain structural information of the surgical object pre-operatively. The OrthoDoc allows the surgeon to construct a pre-operative bone-milling procedure

Autonomous surgery robots were being developed after it was possible to make a precise 3-D model of a patient. The rest of the technology was already available for industrial purposes. These robots are very useful for executing pre-planned tasks in hard materials like bones. They will become even more precise, more versatile and faster.

These autonomous robots are already used in orthopaedic surgery. A surgeon can prepare and optimize the size and position of for example, a hip implant in the 3-D model based on CT-scan data. After the task is defined, the system has to be "registered" so the 3-D model in the computer is perfectly aligned with the real patient, robot and tools. Once everything is set up, a robot can manipulate and position tools like drills, knifes, saws or needles very precisely according to plan.

Products and firms:
• Integrated Surgical Systems (USA) developed ROBODOC®
• Johns Hopkins University (USA) develops PAKY Needle Driver.

At this moment, the use of robotised precision surgery is well in its development phase and some commercial products are readily available on the market. However, the application is limited to operating upon static materials like bone. To improve these robots, it would be better not to use industrial robots anymore but rather design robots that are better suited for surgery. Then it is possible to make robots that are smaller, more precise, have improved dexterity can be used with intra-operative imaging and can be used for a number of different procedures.

3.7.5   Robotic devices for minimal invasive surgery

Minimal invasive surgery (MIS) is getting more popular because it causes less trauma for the patient and patients recover faster. For the surgeon MIS is often more demanding and complicated because everything has to be done through a few small holes. MIS surgery often takes longer, the surgeon cannot see what he is working on directly (he has to look through an endoscope or on a display), he cannot feel what he is doing and the use of instruments is less intuitive.

Minimal invasive surgery allows only instruments and not the hands of the surgeon to enter the patient's body. Making this type of surgery possible requires the development of specialized tools and instruments for minimal invasive surgery. Cameras, mechanics, orientation support and intra-operative imaging systems are examples. Some of these systems meet the definition of a robot.

Robots help by providing a more ergonomic and user friendly, intuitive interface for those instruments, thereby increasing precision. This user interface does not have to be above the operating table. The surgeon can sit in a comfortable position, control all the instruments through special ergonomic handles and see a 3-D image which is logically oriented. Difficult or rare procedures can be done remote controlled by specialized surgeons.

Products and firms:
- Intuitive Surgical Inc. (USA) developed the Da Vinci® Surgical System (on the market) (commercially available).

Like systems for micro surgery, this group of robotic surgery systems is still highly under development. Often the systems for minimal invasive surgery are overlapping with systems for micro surgery, like the well known Da Vinci surgical robot.

Each year, approximately 4 million minimally invasive procedures are performed worldwide that are candidates for use with a robot. Approximately 17,000 robots are needed to meet the current MIS case load. Currently, less than one-third of the market potential for MIS is being performed with this patient-friendly technique. The market opportunity for robots continues to grow as more traditional "open" procedures evolve toward a less invasive surgical approach. (http://www.smallcapreview.com/rbot.htm)

3.7.6 *Medical micro and nanobots*

Traditionally, technology has been an essential element in surgery. However, the introduction and development of robot technology opens complete new possibilities.

Micro medical Robot aims to minimize the need for surgery, this surgical micro robot can affix diverse kind of medical devices such as micro camera, micro manipulators, various sensors and drug delivery injector.

Entering the human body for monitoring, diagnosis or even intervention while the person can stay awake and keep functioning normally becomes possible with micro- or nanotechnology.

The potential of nanotechnology in health care and medicine will include the development of nano particles for diagnostic and screening purposes, the manufacture of unique drug delivery systems, gene therapy applications and the enabling of tissue engineering, including the future of nanorobot construction.

Today, surgical nanobots are already moving closer to the mainstream. With capabilities "coordinated by an on-board computer," they will almost certainly be built through some form of molecular manufacturing.

Nano machines are largely in the research-and-development phase, but some primitive devices have been tested. An example is a sensor having a switch approximately 1.5 nanometers across, capable of counting specific molecules in a chemical sample. The first useful applications of nano machines, if such are ever built, might be in medical technology, where they might be used to identify cancer cells and destroy them.

True nanorobots (nanosize is smaller than 100 nm, 1 nm $=10^{-9}$ metres) are still hypothetical. The first primitive robots that can work on miniature scale have been tested. These are rather called microrobots.

Products and firms:
- University of Nebraska Medical (USA), miniature in vivo robots (in development).
- Ritsumeikan University (JP) micro medical robot, (prototype)
- Technion (IL) Swimming Micro Robot, (prototype)
- Carnegie Mellon University (USA) is developing Endoscopic Micro-Capsules

The potential of NanoRobotics for healthcare and medicine could be very large. Possibilities are envisioned that can form a major contribution to the improvement of medicine by providing alternatives to surgery or contribute substantially to minimal invasive surgery. However, the current state of this technology is still far away from actual application in surgery. Most potential is still only theoretical. The first rather simple applications on micro scale are being developed and being tested. People involved or most active in the field are from Canada (e.g. Sylvain Martel), the USA (e.g. Metin Sitti, Aristides Requicha), Brazil (e.g. Cavalcanti) and from Switzerland (e.g. Bradley Nelson). The most promising micro/nanorobotics applications in the near future can be expected in the fields of robot (externally) controlled and navigated small scale particles/systems and miniature/micro autonomous capsules/systems.

3.7.7 Remote surgery

Some surgeries are complicated and need highly skilled surgeons. These experts are sometimes not available in a hospital, or even in a region. Remote surgery can enable the possibility for these procedures by using a robotic system. One of the earliest remote surgeries was conducted on 7 September 2001 across the Atlantic Ocean, with a surgeon in New York performing a gallbladder operation on a patient 6,230 km away in Strasbourg, France.

These systems are often not much different from the robotic systems for micro surgery and minimal invasive surgery, as these also have a disconnected platform on which the surgeon is controlling the robot.

For now, remote surgery is not a widespread technology. Before its acceptance on a broader scale, many issues will need to be resolved. For example, established protocols and global compatibility of equipment must be developed in order for such procedures to occur in spite of communication problems such as linguistic differences. Also, there is still the need for an anaesthetist and a backup surgeon to be present in case there is a disruption of communications or a malfunction in the robot (Kay, 2007).

3.7.8 Robotised assistance for small medical interventions

Besides surgery, other small medical interventions take place too. These can be done by a skilled nurse or by doctors. Examples are taking blood samples, biopsies and the performance of punctures. As these are normally more or less routine small interventions, they often can be robotised. Robotic end-effectors are being developed to facilitate image-guided minimally invasive needle-based procedures, such as tumour ablation, biopsy, thoracentesis and blood sampling.

A robotic system can take blood samples autonomously from the forearm. Force/position profiles while pressing a flat-headed probe against the surface of the skin, enable the determination of a vein's location to within 1 mm on a phantom. When a needle is inserted, the characteristic force/position profile, on puncturing the vein wall, is distinctive enough to implement automatic needle withdrawal to prevent overshoot (Zivanovic, 2000).

A novel mechanical end-effector addresses the challenges associated with any major needle-based procedure, focusing on liver biopsy and ablation. In this end-effector embodiment, the distal end of a single articulating arm can grip needles and instruments and allows a fairly high number of degrees of freedom of movement during the complex motions associated with positioning and driving needles, as well as correcting the periodic motions associated with breathing. Tightening a cable that runs through the articulations fixes the arm in a rigid state, allowing insertion of the gripped needle (Sun et al, 2006).

The development of these systems is still more or less experimental, although some clinical testing takes place. Problems with safety and costs still prevent general use.

3.7.9   *General conclusions on robotics for medical interventions*
The use of robotised medical interventions is a dynamic and promising field. Practical examples can be seen, but are still limited. But these examples have already proven commercial potential. The increasing procedures performed by the Da Vinci system, as well as the increasing number of competitive systems are showing this. The potential benefit of robotics supporting medical intervention is widely accepted. It is embraced not only by the technological side, but also by the healthcare (cure) side. The new possibilities and potential gains such as improved working conditions, improved effectiveness of health care, increased precision and reliability (certainly regarding Minimal Invasive surgery), have been appealing enough to initiate projects for the introduction of robotics for medical intervention. Up to date, this has resulted in the introduction of systems that are able to support the current practice in surgery. Although this is obviously beneficial much more is foreseen. This has not been realized yet but can be expected to emerge in the coming years.

Many systems have an integrative approach to robotics in surgery. Although the fields of application are different, many robotic systems have some of the same functionalities. A simple example is the connection between remote surgery and micro surgery. As micro surgery needs a disconnected HMI to translate activities to the micro level, this can be seen as remote surgery as such. Also the technological components between minimal invasive robotized surgery are overlapping with micro surgery. In the future it is predicted by experts that the differences will diminish and systems will be integrated. Minimal invasive will be combined with precision and micro surgery. The Da Vinci system clearly shows the integrative approach. To use autonomous robots for soft tissue surgery, the robot has to be able to predict soft tissue movement and adapt its procedure to the unforeseen. This requires the modelling of tissue behaviour and the robot should understand what is happening from intra-operative imaging. It will take a long time before robots can do this better than human surgeons. Also the steep learning curve to the actual use these systems prohibits the large use of the systems.

A different perspective can be seen in the field of micro and nanobots for surgery. Although quite a large number of scientists is working in the field of micro- and nano robotics, there are only a few groups combining miniature and robotics concepts for concrete medical applications. Apart from communities working in the specific fields of nano medicine (including monitoring, diagnosis, and treatments by making use of lab-on-chip systems, nano particles for (targeted) drug-delivery, etc.) and synthetic biology (including biologically inspired or functionalized biological systems, such as flagella motors, motor proteins, etc.), the community of medical micro- and nano robotics consists of a few groups only.

4   Cases

4.1   Introduction

The final goal of the project is to formulate a roadmap for research in the field of robotics in healthcare on the basis of six roadmaps for important innovation areas. First, draft roadmaps were made on the basis of the literature search and the first round of interviews and surveys. However to gain more insight in the underlying mechanisms of innovation in this field, especially in the roles stakeholders play or should play and in their mutual relations to realize the promises in this field, these areas have been studied in more detail in the form of case studies. Because more work is involved with doing a case study, the number of case studies was restricted to three. These areas were selected in consultation with the EC, based on broad coverage of the field and applicability for DG-Information Society and Media. These three selected cases are:

- **Robotised surgery[2];**
- **Intelligent prosthetics;**
- **Robotised motor-coordination analysis and therapy.**

The case studies also pay attention to the history of the innovation areas and give a picture of successes and failures and the drivers and barriers responsible for them. The case studies try to extrapolate and synthesize all this information into scenario's about the optimal interplay of the various stakeholders which will give the best guarantee that the promises in the roadmaps will be turned into reality.

This chapter will start with the methodological framework and approach to the case studies. Then the three cases will be described and the chapter will finish with the more general conclusions that can be drawn for the integral field of robotics for healthcare.

4.2   Methodological framework and approach

As outlined above, the objective of the case studies was to get more detailed information about the field, with special attention to the stakeholders and driving forces and barriers. The following underlying issues were addressed:

- Successes and failures in the areas from a historical point of view, in order to identify "lessons learned";
- Identification of driving forces and barriers, with special attention to ethical and legal issues;
- A stakeholder assessment, including the possible roles of stakeholder groups in the innovation chain.

The approach to the case studies can be divided into the following elements:

- Internet and literature survey;
- Expertise of the consortium;
- Specific interviews with experts in the field;
- Discussions during the evaluation workshop;
- Questionnaire on Skills and Wills of stakeholders.

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[2] **Including minimally invasive surgery, assisted micro surgery, precision surgery, tele-surgery**

The analysis of driving forces and barriers was based on a predefined set of category of factors that influence innovation processes. This set of factors is given in the following table. This table was the starting point for discussions with experts.

Driving forces and barriers

- Conservatism in users
- Conservative market structure
- Cooperation in development
- Cooperation in sales
- Critical mass
- High competition
- High initial costs
- High variable costs
- Integration in existing environment
- Intellectual property rights

- Limited benefits
- Market uncertainty
- Political attention
- Regulation
- Scientific and/or technological barriers
- Societal acceptance
- Sunk costs
- Technological maturity
- User awareness
- Lack of R&D funding

Figure 8: Generic drivers and barriers.

In addition to the interviews conducted in an earlier stage of the study, additional focused interviews with experts were conducted to enhance the quality of the case studies.

Part of the study was the evaluation of results in an international expert workshop. The workshop focused on six innovation areas (see Chapter 6: Roadmaps), which had overlap with the three cases. In the discussions during the workshop, much valuable information was collected that enriched the case studies.

An important focal point of the case studies was the analysis of the stakeholders. To assess the role of the stakeholders in the innovation process, a Skill/Will analysis was conducted using a questionnaire. The R4H expert network was used to get information about the capacities of the stakeholders, as well as their attitude towards innovation. The method used is based on the assumption that the actual participation of organisations is influenced by two major aspects:

- The skills to act on the strategy
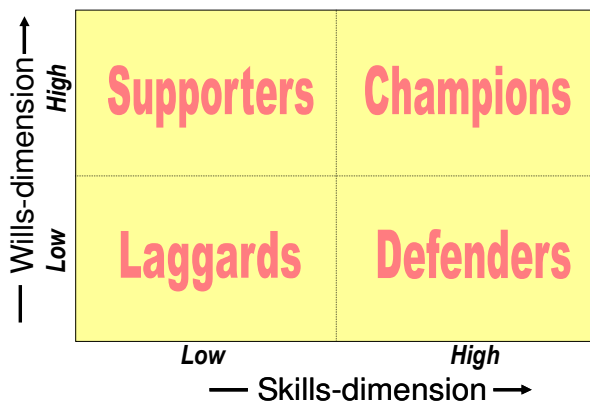- The will to participate

Figure 9; Skill-will matrix.

The two dimensions can be plotted in a scheme, leading to four strategic quadrants:

- **Laggards**
  Organizations that lack the skills to participate and also are not willing to participate, will be reluctant to get involved in the strategy. They will act as followers to the strategy and should not be involved.
- **Defendants**
  These organizations will have an interest in participation, but their objective is to preserve the present situation. Special attention should be given to counteract eventual opposition.
- **Supporters**
  Organizations that are willing to participate to enable the innovation, but are lacking the skills (e.g. financial capacity), should be involved in the strategy as supporters.
- **Champions**
  The organizations that are the most important to participate in the strategy and can even have a leading role, are organizations that are positive to the innovation suggested and have the skills to make the change happen.

It is clear that the position of the stakeholder in the Skill/will matrix offers information on how the stakeholder should be involved in the innovation trajectory.

The Skills dimension focuses on the existing capital of organizations to make the actions needed operational and participate in the innovation strategy. The fundamental factors of influence can be based on production factors stated by Porter (Porter, 1992):

- Present human capital on R&D
- Access to financial capital
- Organizational strategy
- Available technological capital
- Access to external networks

The organizational willingness to participate in an innovation strategy is determined by their attitude to innovation and factors from their environment. The following factors can be distinguished (Montalvo, 2002):

- Market opportunities
- Economic risks
- Societal and institutional pressure
- Customer pressure

A semi-quantitative five value approach is used to position the stakeholder group on a specific indicator. The results are based on the average of the responses. For further information about the approach, see Annex C.

4.3   Case 1: Robotised surgery

4.3.1   *History and future*

The assistance to surgeons by robotic systems in the operating room has been under development for some decades now. The assistance or even total replacement of the surgeon by robotic systems is potentially beneficial, because of improved accuracy, increased stability (tremor reduction), scale motion, 3D vision, increased patient recovery, sterilization and resistance to radiation and infection (Lanfranco et al, 2004).

The PUMA 560 was one of the first applications of robotics in the surgical field and was used to guide a needle using CT guidance for brain biopsy (Lanfranco et al, 2004). This robotic system was of industrial origin and adjusted to perform the operation by Kwoh and Young. The system was only used on 22 patients (Dombre, 2007). Three years later, Davies et al performed a resection of the prostate using the Puma 560 system (Davies. 2000). This was the start of the development of Surgical robots, but were still highly experimental and for research purposes only. The results showed that there were advantages in precision, but the systems were still very crude.

In 1992 Integrated Surgical Systems developed the ROBODOC that performed orthopaedic surgeries (hip replacements). This system was the first robotic surgical system approved by the FDA. Over 70 systems were manufactured and over 10,000 patients were operated upon using the system. However, recent experiences show that although the precision of the orthopaedic operation is high, movement of patients lead to unexpected complications. Therefore, the ROBODOC system is no longer available on the market. However, there are some further developments on the system.

In the mid 1990-ties, a new step was made, integrating the opportunities of computer motion. This led to the further development of Minimal Invasive Surgery (MIS)

systems. In 1994 the AESOP3 system, made by Computer Motion Inc., was one of the first systems that incorporated these functionalities in order to gain experience with the concept. The system was a spin-off from military developments. This concept was later integrated in the ZEUS robotic system of the same company. The ZEUS system is one of the few robotic surgery systems that have gained the approval from the FDA (Meadows, 2002). A second system is the Da Vinci robot (Intuitive Surgical, Inc.), which is a sophisticated robotic platform designed to enable complex surgery using minimally invasive approach. The Da Vinci system consists of an ergonomic surgeon's console, a patient-side cart with four interactive robotic arms, a high-performance vision system and proprietary EndoWrist instrument. Due to a patent discussion, Computer motion was taken over by Intuitive Surgical and the two systems were more or less integrated.

Although some hundreds of systems are already commercially installed, the actual use of the systems is limited. The successes can be found in the teleoperating approach and the minimally invasive element. Furthermore, the continuous improvement of new instruments has a positive effect on its success. In general however, the large size of these systems, the still limited use and the steep learning curve are considered problematic. Also, the operating time is generally longer than using traditional approaches. In addition, success is strongly related to the level of embedding of the robot in the planning process of surgery (EURON, 2004)

Alongside with these developments within the medical field, the NASA and the U.S. Army developed concepts around telesurgery. These applications were obviously aimed at performing surgery on soldiers in a war zone by surgeons situated in a safe region. This army system is known as MASH4 and is still in a pre-testing stage. This system has been successfully demonstrated on animal models but has not yet been tested or implemented for actual battlefield casualty care (Lanfranco et al, 2004).

Besides robots actually performing surgery, robots are also developed to perform supporting activities in the operation room. Examples are the suture robot, dynamic arm supports, dynamic patient supports, the scrub nurse robot (SNR, Penelope) or microsurgical manipulation (Steady Hand Robot). In "Operating Room of the Future" initiatives several robot systems are brought together to create a testing or training facility.

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[3] Automated Endoscopic System for Optimal Positioning Robotic System
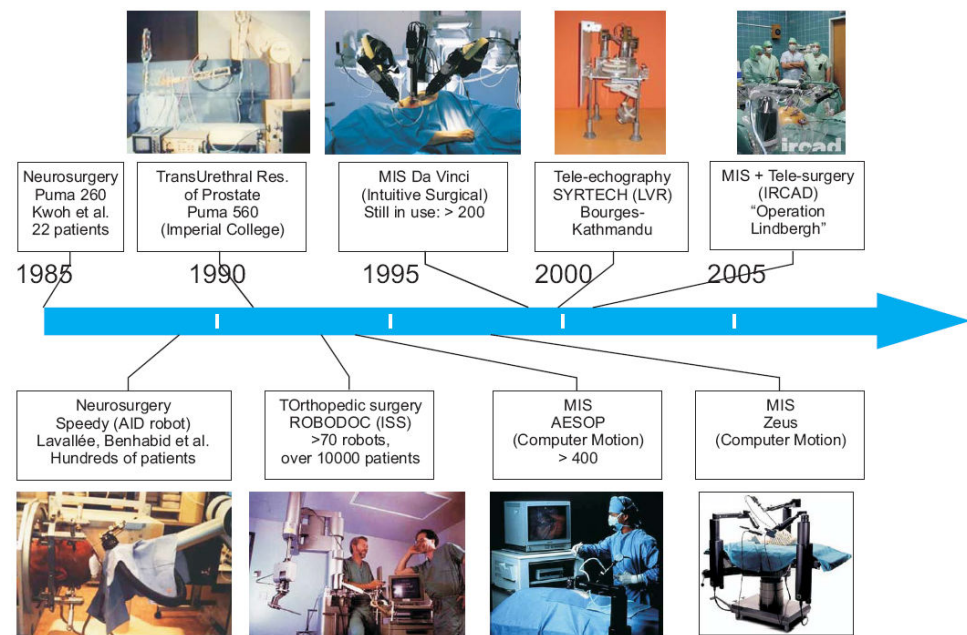[4] Mobile Advanced Surgical Hospital

Figure 10: An overview of some milestones in the development of surgical robots (Dombre, 2007).

Future oriented developments to enable further innovation are: Image Guided surgery, Haptic Feedback, MRI compatible robots, Human Adaptive Mechatronics. An important outcome of the R4H workshop was that the development of these systems will be shifted towards more simple and dedicated functionalities. The large physical size of e.g. the Da Vinci robot proves to be an issue for many hospitals.

Surgical robot systems are mainly still in testing and even pre-testing phase and only a few are taking their first steps into real life of the operation room. At this moment, although some commercial systems are already on the market, the phase of development of these systems is considered still in its infancy (both functionalities and market). Potential further developments and also their added value are high. But the number of manufacturers (commercial and academic) is still very limited.

4.3.2 *Major barriers and driving forces*
The driving forces and barriers that influence the development and implementation of surgical robots are diverse. Based on the desk research, interviews and evaluation workshop these influences can be described.

Barriers
An important barrier is still the **technological** capabilities for user-friendly operation of the systems. Some technological challenges are reducing the actual added value, like sound forced feedback on the activities of the surgeon. This limits the usability of the systems. Also, the "run time" positioning of the system towards the patients has proven to be a hazard to the quality of the intervention and is therefore inhibiting the use of the systems. Another important technological factor is the size of the systems. The commercial systems now on the market need significant reconfiguration of the operating room, even increasing its size. For many hospitals this is not possible.

From the healthcare professional's point of view, there are some additional more practical barriers. A first important aspect is the lack of trust in the technology, this is

crucial because of the medical perspective. Next to this, getting used to the systems takes quite some time and is time consuming (learning curve). Together with the increase in operating time needed, this reduces the added value of the systems. Also the systems hinder the access to the patients when emergency occurs (e.g. removal of the robot while still attached to the patient). Using the systems long distance (Trans-Atlantic), is accompanied by time delays in signal, leading to unacceptable inaccuracy. Individual preferences of surgeons, hospital staff and management for the degree of robotisation of their operating room are not in favour of the robotic systems. In Europe personal contact in healthcare is preferred. Personal confidence is given to the responsible physician/surgeon and his physical presence is important. The current generation of surgeons does not accept robot surgery in full (Healthcare is waiting for doctors of the "Nintendo generation").

Legislation can also be an important barrier. Normally, it takes the legal system a decade to accept medical devices; e.g. the approval of the Da Vinci robot took over a decade. This barrier is slowing down innovation and time is consuming. Clinical trials are mandatory, but can only be started after meeting all the applicable rules. But also the financing mechanisms for the use of these exclusive and expensive techniques are slowing innovation down. As evidence for reduction of costs or other added value of the systems is not yet scientifically proven, acceptance by the insurance agencies is limited.

In **financial, economic** terms, the systems are expensive. The two commercial systems mentioned earlier (Da Vinci and ZEUS) cost about $ 1,000,000. Often these systems are not based on mass production principles, increasing their costs. Due to the fact that approval is so time consuming, the market for these systems has a "lead market" character. Also today the basis for the systems is originating from more industrial basis (e.g. the PUMA 560), but the further evolution of the systems need a healthcare foundation. Funding from governmental institutions is needed to create a "grown market". The basis for the systems is industrial, but the further evolution to healthcare is needed, as adjustment of industrial concepts is limiting the added value. This will take large investments. Development depends on financing structures of cooperating market and research parties. Funding programmes start to emerge, but the field is highly technological and therefore capital intensive.

Drivers

On the other hand, there are also some drivers to be seen. From the **technological** side, new developments in MEMS, feedback systems, location systems, IT-hardware and software are creating new opportunities for further development of surgical robots. The spin-in from other adjacent robotic markets is still increasing opportunities of surgical robots (e.g. haptic feedback). The field is still to be considered in its technological infancy, so much is to be gained.

From the **social** perspective, more and more systems are used in hospitals and for medical personnel it has an "image", or "status" component. Also some elements of added value are considered important to the practical situation, like precision, scale of motion, and reduction of tremor. Also our society is shifting towards the robotic "hype", where the application of robots is expected, even demanded. Experience in other innovation areas show that robotized patient monitoring is received very positively.

Standardization of hardware (toolkit for robotics) and software (cf. Bill Gates on robots for everyday use) present the available components in a sort of database, leading to an improvement of the economic side of the systems. This will stimulate the use and re-use of pieces of technology instead of reinventing the same thing more than once. This will also stimulate the exchange of knowledge in the field. When larger numbers of robots are produced, this will quickly diminish costs for technology (hardware and software). Also the economic success of e.g. the Da Vinci robot (stock value of Surgical Intuitive Inc. increased multiple times over the last few years) will stimulate others to invest in the systems. Furthermore, new governmental funding programs explicitly give attention to Surgical robots (e.g. the Dutch Point One program).

4.3.3   *The innovation system: stakeholders and their relations*

The primary stakeholder in the innovation system concerning the development of surgical robots are still research organizations. Due to the fact that the development of these systems are still in its infancy, the major developments are not yet to be found in business "at large". But some companies are producing commercial applications, thus producers of surgical systems are also a stakeholder. As the surgical robots still have high linkages with other robotic markets (e.g. industrial and domestic), suppliers of components are considered a third stakeholder group. Next to these more supplier oriented stakeholders, there is a strong interaction with hospitals and their medical specialists. Research and development is highly done in cooperation with them. Two less connected (due to phase of development) stakeholder groups are "Health insurance" and governmental regulation. Both are in the end stage of crucial importance for societal acceptance, but of lower importance in the present phase of the development. Governmental funding programmes (when available) form an important, even indispensable accelerator.

The **manufacturers** of systems are limited. A recent market study identified some 40 companies that were involved in the manufacturing of surgical systems, including suppliers of components. Intuitive Surgical Inc., Endovia Medical, Inc., In Touch Health and Microdexterity Systems, Inc. (Robotics) are renowned examples of system manufacturers. Most of the companies in this stakeholder group have connections to the defence industry or research (spin-off). The huge budgets needed for the development of these systems make the shift to a full open market hard to realize.

Independent **research organizations** (university groups and public or private research institutions) play an important role in the further development of these systems. As robotic surgery today can be characterized as an innovation area in the early stage of its development, universities play an important role in its development. Often, the relationship with university hospitals proves to be essential, due to its applied scientific character. Looking at the institutes (e.g. Johns Hopkins University, Harvard – Boston, University of Cataluna, Washington University, NASA, LIRMM, Fraunhofer) often limited size departments are involved.

The **suppliers** of components are divided into software and hardware companies. Hardware companies design and produce components, materials, semi-finished products, software, technical services or production machines and supply these to the manufacturers of the final products. But as the robotic character is often based on more general technologies (e.g. mechatronic components, ICT components, imaging) more general suppliers will play an important role in the innovation of surgical robotics. However, it is not expected that they will play an active role, as the market for them is

relative small. The development of software is often done by the system developers. On the other hand, some shifting towards more medical suppliers can be seen, which focus on the development of navigational systems, surgical equipment and intelligent operating rooms (4navitec GmbH, B. Braun Aesculap, Siemens Medical Solutions, Stryker Corp.). Large multinationals like Siemens, Johnson & Johnson, Philips are also actively involved.

University **hospitals** are suppliers of knowledge and are also involved in the design and manufacture of prototypes. The assembly of complete robotic systems and the distribution of these systems (directly or by means of importing or marketing & sales firms) is done by manufacturers. University hospitals are at the front-end of development, integrating the views of medical professionals and technical experts. They also do scientific research, as is clearly to be seen by the involvement of university hospitals among which are Johns Hopkins, Washington University and Harvard. The medical specialists and other medical, paramedical and nursing professionals play an important role, as they will be the ones operating the systems. Hospitals and other medical, preventive or care institutions, purchase and/or use this category of robotic systems; these organizations represent medical professionals and institutions.

An important stakeholder group are **Government** bodies and organizations working under the auspices of government. These regulate the admission on the market, admission in health care and inclusion in collective health benefit schemes of robotic systems and treatments in which these systems are used. As their main mission is patient safety, and they have a formal responsibility to this, they have high reactive impact on the innovation in this field. The US FDA is an important example of a governmental body that is involved.

Another stakeholder group are the public and private health **insurance** companies (or other organizations that finance healthcare activities). Big health insurance companies also finance research & innovation in surgical robotics. Their agenda focuses mainly on: cost issues, patient demands, hospital demands and quota. In principle, reducing risk is an important aspect of their philosophy. Robotized surgery is still in its infant stage, which needs risky investments. However, some characteristics of the innovation field are in line with this philosophy. Only limited insurance companies are strategically involved in the high risk developments of these systems.

The linkage between research, development and application in this field is strong. The further development of these systems often takes place in the medical environment (e.g. hospitals). Public and private health insurance companies and governmental regulation are involved in the later stages of the innovation process, looking at the clinical trials and evaluating its societal benefits (cost reduction, increasing quality, safety). In the heart of the "innovation system" are the university hospitals, who together with the industry are performing research and development.

4.3.4   *Skill/will of the stakeholders*

The Skill/Will concept is used as tool to assess which stakeholder can be involved in the further innovation within the Surgical Robots area. Here, the outcomes of the Questionnaire[5] are combined with the information collected in the interviews, desk research and Evaluation workshop.

The first stakeholder group are the **manufacturers of surgical robots**. In the figure below, an overview is given of the skills and will-elements of this group, based on the questionnaire sent.
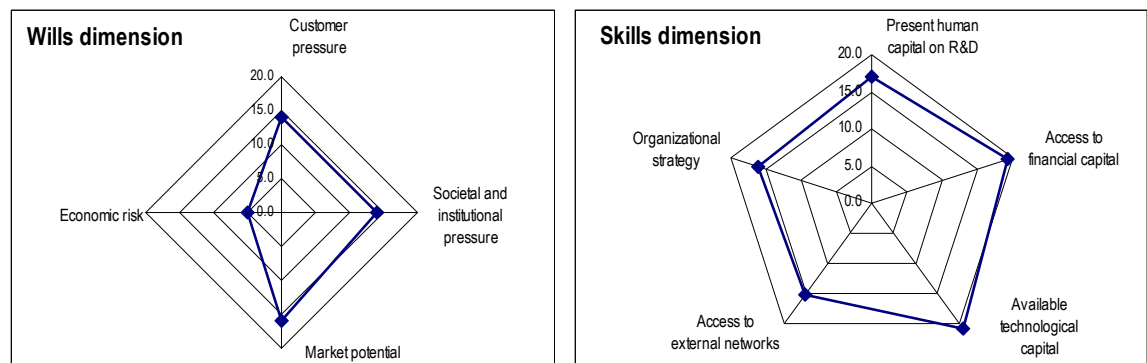

Figure 11: Wills and skills of manufacturers of surgical robots.

It is clear that the overall Skills of this group are to be considered positive. Especially the technological capital is a strong point as most actors have their origin in research. Because of the still "young" market, their access to the commercial external network is still underdeveloped. But from the Will perspective, there an aspect gives some concerns. Although in general the Will of this stakeholder group is positive, the economic risks are reducing the overall opportunities. From the interviews and workshop it became clear that because of e.g. the still early stage of the area, the added value, final system concepts, technological enhancements reduce the predictability of the market highly.

The second stakeholder group are the **Suppliers of robotic components**. In the figure below, an overview is given of the skills and will of this group, based on the questionnaire sent.

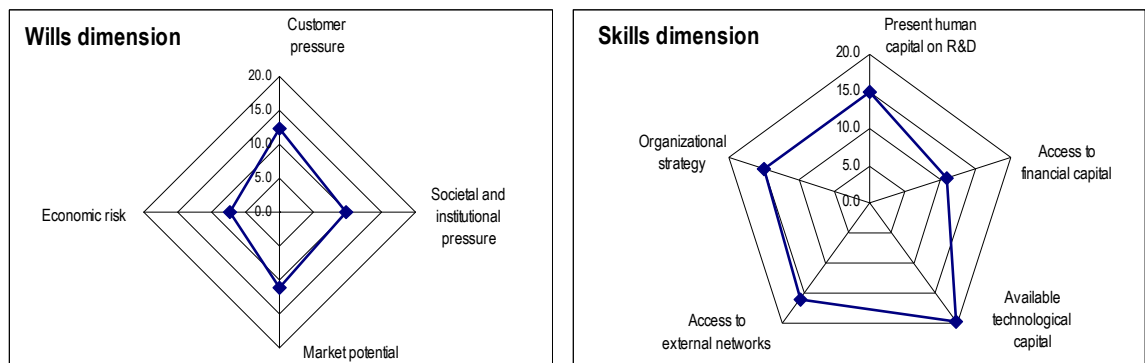[5] For further information about the questionnaire: See annex C.

Figure 12: Wills and skills of suppliers of surgical robots.

The diagrams show that this stakeholder group looks almost as qualified as the manufacturers to play an important role in the further development of the area. The fact that they also supply to other domains will surely have a positive effect and perhaps has a positive effect on economic risks and available technological capital. But also all other factors are positive, although access to financial capital is considered relative the weakest. But looking at the Will side, Societal and institutional pressure is somewhat reduced, so actual Will is also reduced. This is confirmed by the interviews and workshop where their role they normally was more one as "supporters" and not as "champion".

The third stakeholder group is **Research**. Academia, together with research departments of large companies and hospitals, or even research oriented SMEs are part of this group. In the figure below, an overview is given of the skills and wills of this group, based on the questionnaire sent.
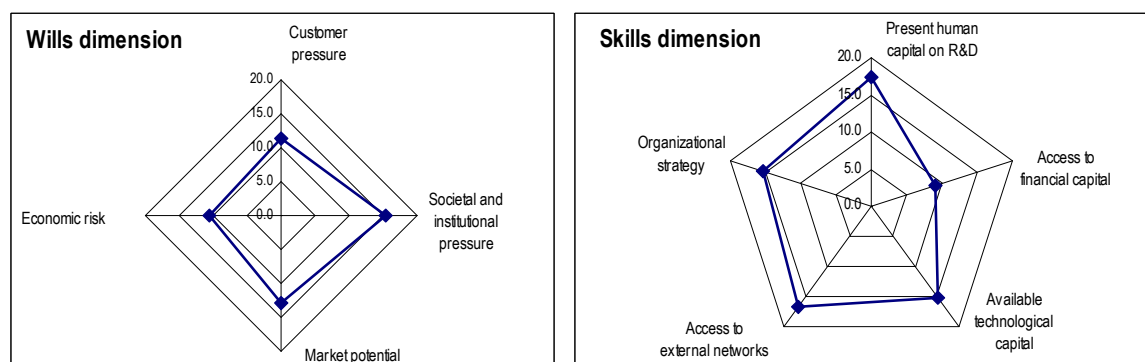

Figure 13: Will and skills of research organisations of surgical robots.

The Skill side of this stakeholder group is strong, although the overparticipation of the stakeholders in the questionnaire can cloud the results somewhat. Slightly off is the access to financial capital, which weakens their possible "champion" role. The Will side is overall somewhat weaker than the groups discussed before. Customer relation is under pressure, which is validated by the expert workshop. Research tend to give too little attention to the customer needs. Also economic risks have a negative impact on the

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Will of Research. This perhaps finds its origin in the highly uncertain technological evolution and/or the short term public grants (normally 4 years).

The fourth stakeholder group to be discussed is **Hospitals and Medical specialists**. This group is heterogeneous and the results should be looked at critically. In the figure below, an overview is given of the skills and wills of this group, based on the questionnaire sent.
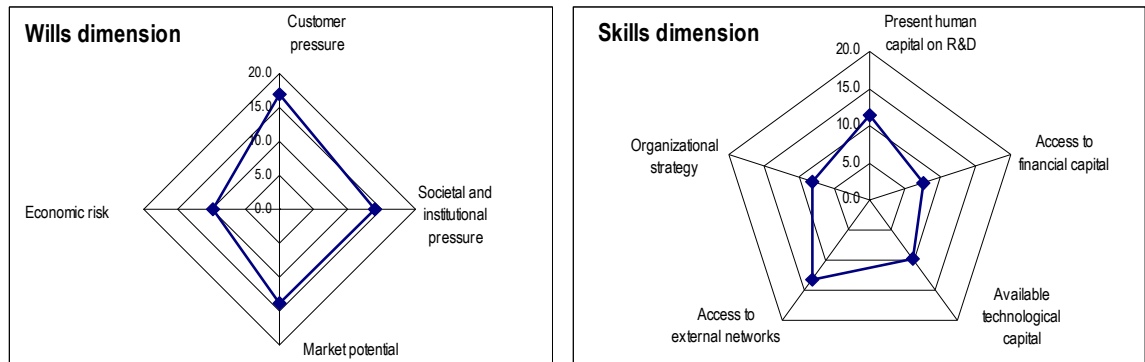

Figure 14: Wills and skills of hospitals and medical specialists of surgical robots.

Looking at the Skill side, it is clear that this group has a diverse profile. Although the access to the external networks is high, the organizational strategy towards the area is (in general) limited. Also access to financial capital is limited, which can be explained because of the financial pressure of the healthcare sector. The Will side is much stronger, leading to opportunities for cooperation. But the involved economic risks can jeopardize actual involvement (which is clearly needed from the user side).

The fifth stakeholder group is the **Health Insurers**. This group includes the major financing agencies to hospitals and other healthcare providers. In the figure below, an overview is given of the skills and wills of this group, based on the questionnaire sent.
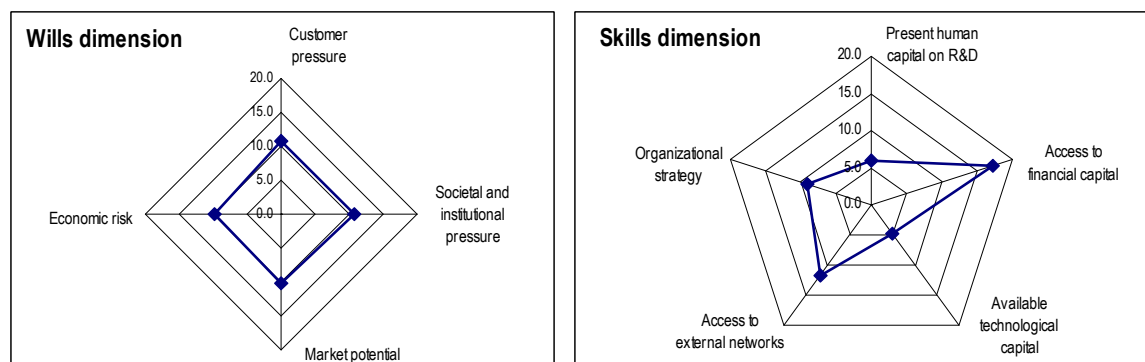

Figure 15: Wills and skills of health insurers of surgical robots.

The Skill side of this stakeholder group clearly shows that they are not well equipped to initiate and participate in the development of surgical robots. Although access to financial capital is strong, the other elements severely limit their potential involvement.

And also the Will side can be considered weak. Although customer and institutional pressure are high, the economic risks are reducing their focus on the field. These conclusions are confirmed by the interviews and workshops. Although asked to participate, many insurance organizations did not. Discussions showed that their view on the area is limited and that they will become more important in the future. At this moment, the area is too much in its infancy for this group to be involved. However, in a later phase they can be crucial.

The last stakeholder group is **Governmental regulation**. As this is considered crucial in the implementation of innovations in this area, the Skill/Will matrix can show a potential role. In the figure below, an overview is given of the skills and wills of this group, based on the questionnaire sent.
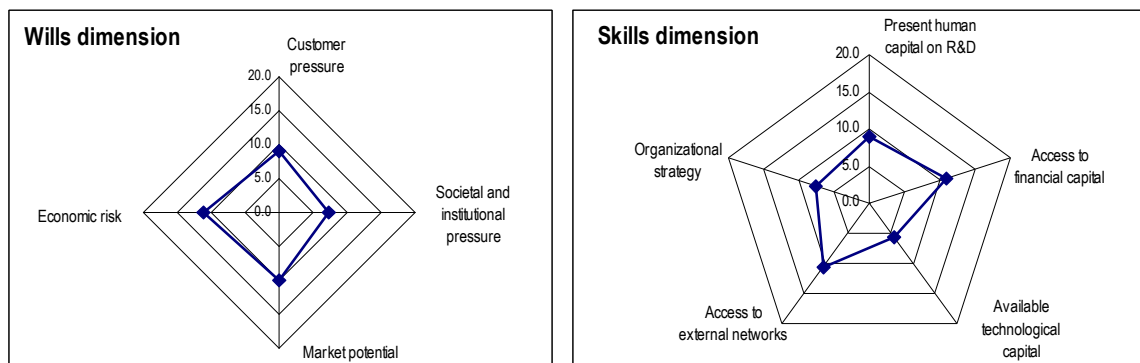

Figure 16: Wills and skills of governmental regulators of surgical robots.

It is clear that this group is not the most important group in the research, development and implementation phase. Both the present Skill side and the Will side are weak and will lead to a "laggard" role. Important to notice is that the Social institutional pressure is low, which can be a danger to the area. Image building to the civilians could be of importance to increase societal pressure.

4.3.5 *Conclusions*

The most significant conclusion of the case study is that the area is still in its infancy. The technology base is often still of industrial nature and application is small. Research is almost always a core element of the applications. But there is much development and activities seen. Also the societal benefits of the area are in potential considered significant, although the hard evidence of added value is not fully clear. The number of organizations involved is mostly a combination between research, industry and hospitals; their number is significant, but limited. However, especially in Europe, "Research" is the most important stakeholder group involved. Commercial output is still small and used in niche markets, however strong economic growth is seen and further growth is to be expected.

Major barriers are of technological nature. Being in their infancy, the applications are not yet fully developed to a level that the economy of scale is reached. But significant developments in adjacent areas are to be seen, and are expected to have high impact on the further development. Society is not yet ready for full acceptation, but experiments show that progress is made and patients are accepting robotic surgery. Also the "innovators" in the medical healthcare are involved in development. Legislation proves to be an important barrier, because of the long time and high investments needed. This

reduces commercial will to engage in this economically risky business. And the required investments are still significant.

On the other hand, some drivers can be seen that stimulate the market. Perhaps the most important is the commercial success of a few systems. Technology also here is a major driver, but the potential positive effects of surgical robots are stimulating. Futhermore increased funding from public administration focuses on the area.

Looking at the stakeholders, the assessment of potential roles of stakeholders in the further research and development of the area is of importance. The overview of all Skill/Will profiles of the stakeholder groups is shown in the figure below.
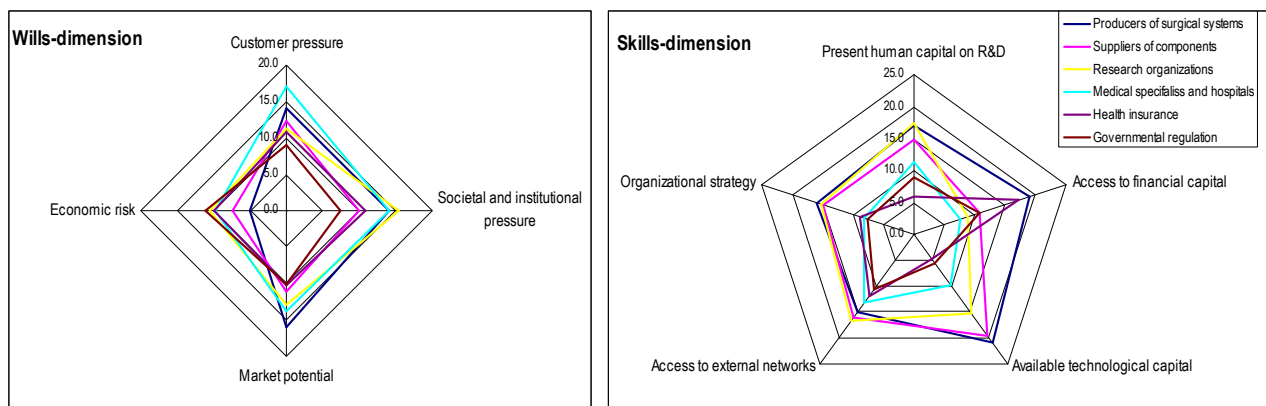

Figure 17: Combined overview or the wills and skills of stakeholders of surgical robots.

As the field is still in its infancy, the major players are research and development. However, due to uncertainties there are major economic risks.
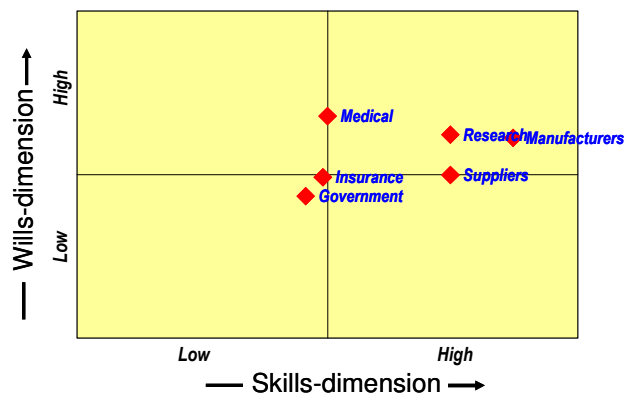

Figure 18: Skill-will matrix of Robotised surgery.

Positioning these stakeholder groups in a Skill/Will matrix, shows the importance of both business and research. Both can be considered potential champions and need to engage in joint research and development. Also the medical world (e.g. hospitals) is expected to be strongly supportive. Although Governmental regulation and Insurance companies are important players in the area, the analysis shows that it is perhaps too soon to include them in research and development in this area. The problem is however, that the formal acceptance is a key barrier.

4.4 Case 2: Intelligent prosthetics

4.4.1 History and future

The loss of a limb is a source of disability of which the general public is well aware. The frequency of occurrence is relatively low in comparison to other sources of disability, i.e. stroke. It can be the result of trauma, (traffic, labour accidents), war related casualty i.e. landmines, but also common diseases (e.g. diabetics) or genetic imperfections. People without one or more limbs may benefit from prosthetics through restoring of mobility and increased independence. Prosthetics mimic human functionality through artificial muscles, joints or skeleton parts. Optimally, control over the artificial limb movement provides the user a level of benefit approaching the functionality of a natural limb as close as possible. However, prosthetics able to perform at the level of natural limbs will require much improvement beyond the traditional mechanical domain. The introduction of robotics in the domain of prosthetics provides considerable opportunities to improve functionality. The challenge that comes with this new generation of prosthetics is to combine the expanding system potential with comfort and control. Products can be divided into prostheses for the upper limbs (hand, arm) and prostheses for the lower limbs (leg, feet). Products lacking intelligence and activity (like passive hip and knee prosthesis) will not be included in this investigation.

Traditional prostheses are passive artificial limbs without any on board intelligence. This limited the enhancement of mobility, due to the complexity of human limb movements and control. Intelligent prosthetics began with the addition of sensors and actuators in prosthetic devices. Some remarkable milestones for upper limb and lower limb prosthesis will be described.

Upper limb prosthesis

In 1964 the first functional myoelectric prostheses to be manufactured in bulk were fabricated in the United Kingdom (Russian Arm, Hanger Limb Factory) based on a Russian design (B. Popov, 1965). Not long after that, other countries followed. Initial development however already started in the 1950's (EURON, 2004). Research prototypes and commercially available prostheses have gradually improved ever since.

The Elektrohand 2000 was developed in 1988 by Otto Bock (Germany). This is a myoelectric controlled hand prosthesis, especially developed for children from 18 months – 13 years old (Otto Bock, www.ottobock.com). With a 300mm per second opening/closing speed and enhanced EMG signal processing, the myoelectric Sensorhand from Otto Bock (1997) has excellent speed and responsiveness (Otto Bock, www.ottobock.com). The unique autograsp feature keeps held objects from slipping by monitoring and changing grip force as needed. The iLimb Hand was developed in 2007 by Touch Bionics (Touch Bionics, www.touchbionics.com). It is another myoelectric controlled hand prosthesis. A built-in detection system tells each individual finger when it has sufficient grip to avoid crushing objects. The RIC Neurocontrolled Bionic Arm is an example of the next generation bionic prosthesis (Ben McGrath, 2007). This arm is under investigation but is planned to be developed and marketed in 2010. It is a system which replaces the entire arm or even both arms.

Lower limb prosthesis

The S-N-S Mauch leg system was developed in 1962 by Mauch Inc (www.mauchinc.com). This hydraulic knee control offers proven reliability, a smooth natural gait and a high level of flexibility for more active lifestyles. Otto Bock's C-Leg was marketed in 1997 (www.ottobock.com). This lower limb prosthesis is a microprocessor-controlled knee. The design gives good stability and is very reliable. Power is delivered by easy-to-charge lithium ion batteries with 40-45 hours of power.

In 2005, Össur introduced the Powerknee (www.ossur.com). It works as an integrated extension of its user. The Powerknee synchronizes motion with that of the sound leg. When walking on level ground, the user is gently propelled forward, allowing greater distances to be covered without becoming as tired as before. On stairs and inclines, the knee actively lifts the user up the next step.

Össur's Propriofoot was marketed in 2006 (www.ossur.com). The Propriofoot responds to changing terrain and transforms the approach to stairs and slopes, as well as level-ground walking. By angling itself appropriately, it also helps amputees to sit and stand up easily and more naturally. It gives a feeling of improved proprioception with a more balanced, symmetric and confident gait with reduced wear and tear on the back, hips and knees. MIT Media Lab has developed the Powered ankle-foot prosthesis in 2007 (Emily Singer, 2007) and plans to commercialise the system in the summer of 2008. The prosthesis is capable of propelling the wearer forward and varying its stiffness over irregular terrain, successfully mimicking the action of the ankle.

From applications of the described systems in the market, it can be noted that systems have been especially successful when they are robust, very reliable, make individual fitting and adaptation possible. Furthermore, it is important that they should have a cosmetic look similar to the natural limb (EURON, 2004). Whether specific prosthetic systems have really been successes or failures is hard to say. In general, it can be noted that only a small part of research and development results are or have been really used in practical situations by end users. However, results of research and development, which were not practically implemented, were used for new versions of development products. Knowledge gathered by failures of earlier products will be of advantage to make successors more successful.
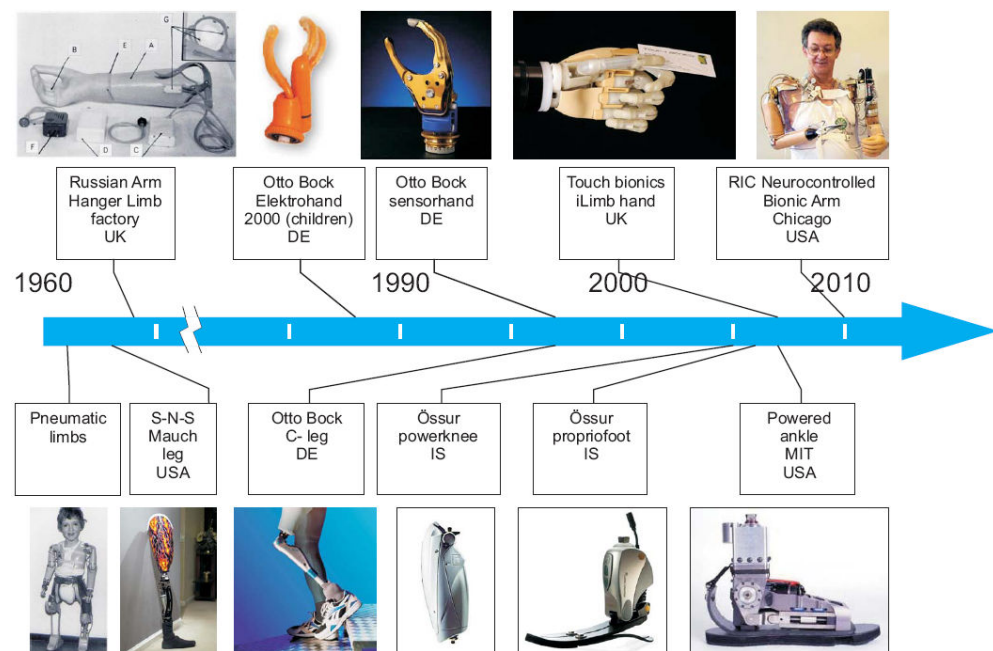
Figure 19: Milestones in the development of Intelligent Prosthetics.

Currently there are some intelligent lower limb prosthetics on the market offering dynamic interactive action with the users behaviour. These prostheses can actively lock its joint or change the resistance of the knee joint and thus support the active extension or flexion of joints (knee or ankle) synchronizing the users gait pattern. Some can adapt their behaviour to various terrains and variations in walking styles of users. In general the prosthesis functionality is aimed to support the users gait and standing functions and only performs such relative easy tasks, static or repeating movement cycles (WTEC, 2006).

For upper limbs the situation is different, there is no standard movement repertoire for upper limbs. This requires the user to be in control continuously. Most complex is the functional use of the hand and fingers (WTEC, 2006). There are a number of myoelectric hand prostheses on the market. These are mostly user controlled, by contraction of specific muscles which trigger prosthesis movement through EMG signals.

Future developments in smart prosthesis should focus on several aspects.
Improvement of technology: mechanics, actuators, sensors, and energy supply. Currently not all the mechanical possibilities can be used ("underactuation"). To create a mechanical system with more degrees of freedom the mechanics need to be smarter, better actuators are required and sensors need to improve so that the user can get more feedback.

Physical connection of prosthesis to the human body. Usually rigid materials are limiting the fit, leading to discomfort and reduction of controllability. New materials should be lighter, stronger, increase wearing comfort and should improve attachment of the prosthesis (fitting) preventing decubitus. Furthermore, using new materials, more attention for aesthetic aspects should be taken care of.

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Imitating the natural movement of human limbs. Human motion is complex and most artificial limbs are generally able to perform only the simplest movements. Currently single joint movement is the best available option, but it results in unnatural movement. To decrease the mental load of controlling a limb with many DOFs a control concept will be required, requiring from the user control on the higher level of intention ("task control": grasping a glass, using fork or knife) while lower levels of control (coordination and steering) will be handled at the peripheral (device) level.

Human control of the prosthesis. Human prosthesis interfacing can be indirect (using the different sensory-motor capabilities of the person) or direct (reading/stimulating the nervous system activity) To make a prosthesis that feels and is controlled like a natural limb, researchers are heading in the direction of brain-machine interfaces, working in both directions (sending actuator signals, receiving sensory information). These interfaces will probably evolve from an advanced EMG based interface via non-invasive CNS (central nervous system) and invasive PNS (peripheral nervous system) to an invasive CNS interface.

External feedback to the user. This includes restoring sensations such as pressure and movement, both through propriocepcis and skin sensations (artificial skin and artificial muscle), as a means of feedback on movement to adjust action.

4.4.2 *Barriers and driving forces*
Barriers

Technological. Crucial technology development can be a barrier as well as a challenge. A possible barrier lies in the availability of control systems facilitating natural movement of the prosthesis. Furthermore the operation of prosthetics needs to be as intuitive as possible and preferably even as subconscious as the control of natural limbs. Energy management, failsafe solutions, attachment and wearing comfort of the prosthesis for the users, ethical aspects and social factors all need attention for optimization. Current solutions are not able to meet the desires of the users. This for example results in amputees not using their artificial controllable hand. They take often refuge to a purely cosmetic prosthesis.

Social. Limiting forces may be the decrease of public awareness of war victims after the end of war activities in the Middle East in the near future. Landmine casualties worldwide could be an important beneficiary group of intelligent prosthetics but the nations giving residence to most victims cannot sustain a healthcare system capable of providing expensive intelligent prosthetics.

Economical. Regardless of the large amount of potential users at the moment there is no economical basis for a market for tailored systems for landmine victims. This could only become possible if major technological developments make smart prostheses much cheaper (programs for effective but low cost prosthesis).
Barriers will be the absence of demonstrated added value and increased cost effectiveness ratios of developed systems in comparison with traditional systems. However, in the sense of drug related controlled clinical trials this is virtually impossible. New methodology has to be developed for the establishment of evidence based value of prosthetics.

Legal and ethical. Funding of clinical research and development of prostheses, especially in Europe, is difficult. The development of innovative prostheses by

companies can be hampered by safety legislation and ethical issues concerning the involvement of users as test persons. This prevents effective user centred design. Furthermore, the reimbursement of robotic prostheses as healthcare provisions is also problematic; even more, because of the differences in legislation on healthcare insurance in the various countries. As commercial healthcare insurance seems to be introduced in a growing number of countries, there is a risk that the focus of healthcare provisions will be on short term financial effects rather than on longer term quality aspects. Intelligent prostheses that will bring high initial costs will have difficulty being admitted in those systems.

Especially for prosthetic products, aesthetical aspects are also very important. Systems should mimic the look of the human body part they replace. Furthermore, again for aesthetical aspects, the system should imitate the natural movement of the human limb.

Driving forces

Technological. Availability of new technologies and social acceptance of technology and higher expectations regarding independence will be driving forces. Developments in technology and increasing prosthetic functionality will provide a challenge.

The options are increasing system self governance (peripheral control) and the application of brain interfacing. More specifically, for lower limb prosthetics there is a need to execute standard motion patterns which will be less demanding for the user in terms of control. Knowledge of walking robots and exoskeleton technologies will be of advantage. For upper limb prosthetics, the natural movement is more challenging because of the high dexterity and small size of the human hand. Challenges are optimizing grippers, the use of artificial muscles (small strong, energy efficient) and lightweight and strong materials for mechanics. For aesthetic and sensory improvement there is a need for elastic, human like skin with tactile and heat sensors.

Social. This development process may be reinforced by the demand of patients and victims of (war) violence. Currently the US military combat victims are a driving force for fast improvement of prosthetics, but also the increasing number of diabetics (aging society) , and possibly improved healthcare in 2nd and 3rd world countries. In any case patients from 1st world countries will demand improved prosthetics as the technology becomes available.

Economical. The driving forces in Europe for the introduction of intelligent prosthetics is the mechanism that people who are kept independent longer through innovative assistive technology will introduce a number of advantages to the individual as well as society in terms of financial, social and subjective wellbeing. In the long run this will bring an increased level of participation to the individual. Europe and other parts of the world will profit from the advances made in the USA due to programs initiated because of war victims.

4.4.3 *The innovation system: stakeholders and their relations*

Important stakeholders are: government, financers, healthcare providers, research organizations, manufacturers/suppliers, users

Government: The availability of appropriate support for impaired citizens is a concern for any government. When the cause of a highly visible part of these disabilities lies partially in the activities of the same government the stress on the government to compensate increases. This can be witnessed in the extensive research that is being performed in the USA funded by the DARPA program: "Revolutionizing Prosthetics

2009". In general however, the number of people needing smart prostheses is hardly big enough to rely on commercially sound development of innovative systems. Governments should step in and support development in order to achieve the needed improvement of prosthetic systems.

Financers: A distinction must be made between financers of innovations and financers of provision of prosthetics through healthcare systems, Financing of prosthetics development is of eminent importance, because the size of the potential market is relatively small and will not be able to support high end product development. An important driving force is the current USA funding program aimed at revolutionizing prosthetics.
After prototype development there must be options for field study research to demonstrate effectiveness. Effective systems must be developed into commercial products which will require investments and will attract companies besides the traditional prosthetics companies. The investments must be retrieved through provision of systems financed by the healthcare reimbursement structures in countries. This mechanism will facilitate further R&D which will lead to gradual improvement and cost reduction of the available prostheses.

Healthcare providers: The healthcare organizations involved in the provision of prostheses may be general hospitals but when intelligent prosthetics are involved, more likely, specialized institutions such as rehabilitation clinics are involved with dedicated medical professionals (orthopaedic surgeons, physical therapists, occupational therapists) and fitting experts (LIVIT Orthopaedic). Innovative systems will require funding for users during the selection, personal adaptation and early use. Such support can not only be provided by the system suppliers. Also medical staff needs to be involved into rehabilitation with the new prosthetic device.

Research: Main players in the innovation system are still the research institutes. Veterans Affairs Palo Alto, Applied Physics Laboratory (APL) of John Hopkins University, MIT Biomechatronics Group, SSSUP ARTS Lab are some examples of well known research centres in this area. As the development of technology is complex, specialized research will be required. The funding of this research can hardly be on the basis of private or corporate funding. Due to the relative small market size the need for public financial support and specialized funds will be required. After the technology development there will be a need for product development. The largest target groups will be addressed first, specialized products for niche markets will not be first priority and may require additional research funding.

Manufacturers/suppliers: Following the research progress, companies need to step in to actually bring the innovative technology to the market. Important manufacturers are Otto Bock, Össur, Motion Control Inc. In doing so, they must have an eye for both the users and the medical profession. Suppliers of parts, for instance micromotors by Faulhaber and robotic arms/hands by Festos, will need to bring the actual technology close to their market, the manufacturers of the complete robotic systems. Local suppliers play an important role in bringing the technology to users and ensuring system functioning to its maximum capacity.

Users: Users will demand optimal support. The exact nature of this optimal support is to be determined in individual cases and highly depends on individual characteristics and expectations, moreover the context of use and the type of intended activities will be

determine the type of system required but also the added value of advanced systems in individual cases.

An important remark related to robotics in healthcare is that lots of research and development is going on worldwide, however only few products are really used in practical situations by end users. In general this also counts for intelligent prosthetics. To discus this problem we will make a subdivision into Technology (innovation, research, development), Products (manufacturing, supplying) and Practical Application (regulations via government, indication by medical professionals, financing by health care providers, practical use by end users)

As already stated technology is not the main problem. Lots of innovation, research and development is going on in all kind of research centres resulting in new ideas, concepts and prototypes. So why are only few products really manufactured and supplied? When manufacturers and suppliers see an investment opportunity leading to a market for intelligent prosthetics with a regular ROI (return on investment) they will produce and deliver. An important conclusion is that the demand for products for practical application is limited. Medical professionals will indicate and support the practical use of prosthetics when this is of advantage in practical use and the end user will use the systems when they gain functionality by means of the intelligent prosthesis. The problem therefore lies mainly in financing. Healthcare providers are very reluctant in providing users with new and often expensive assistive devices as they are not forced to do so. Regarding funding of research, politics (government) plays a very important role in the development and especially in the implementation of new technologies and products related to healthcare solutions.

4.4.4 *Skill/Will of the stakeholders*

The Skill/Will concept is used to assess the stakeholders involved in the further innovation within the Intelligent Prosthetics area. The outcomes of the Questionnaire[6] are combined with the information collected in the interviews, desk research and Evaluation workshop.

Manufacturers are the first stakeholder group. In the figure below an overview is given of the Skills and Wills of this group based on the questionnaire sent. Only a small number of manufactures are the main market driven stakeholders. Important players are Otto Bock and Össur and both already have intelligent prosthetics on the market. These products are presented in the spotlight under the header "Bionics". Both see potential and have included intelligent prosthetics as a main item in their strategy.

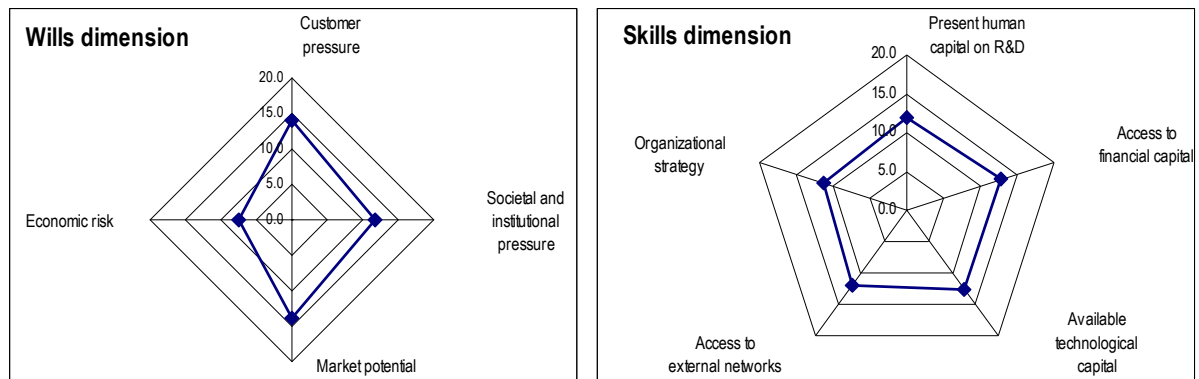[6] For further information about the questionnaire: See annex C.

Figure 20: Wills and skills of manufacturers of intelligent prosthetics.

From the Skills diagram it can be concluded that skills potentially can and should be improved on all mentioned issues. As can be noted from the will-dimension, the producers are kept back by the perceived economic risk. In comparison to the development cost, the demand for practical systems is small, despite enough customer pressure and estimated market potential. This leads to high economic uncertainties. Healthcare providers are reluctant to pay for new expensive products.

Suppliers of robotic components are the second stakeholder group. In the figure below an overview is given of the Skills and Wills of this group based on the questionnaire sent. The diagrams show that suppliers have almost the same qualifications as the manufacturer stakeholder group. Skills can be improved on all items. Also for suppliers of components, the perceived economic risk is an important drawback, however less than for the manufacturers.
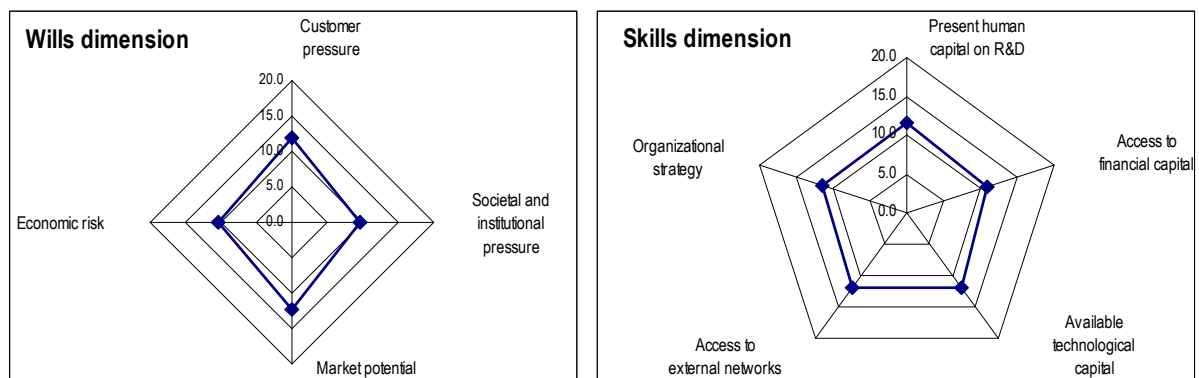

Figure 21: Wills and skills of suppliers of intelligent prosthetics.

Suppliers also deliver to other domains and this will also diminish economic risk in the prosthetic area. Customer, Societal and Institutional pressure is less than for the manufacturers group. Suppliers deliver to manufacturers. They are less directly involved in the realization of the final prostheses systems.

Research organizations like Technical Universities, Rehabilitation Research Institutes, Research Departments of companies and hospitals have been traditional developers of innovative systems on prosthetics. On the basis of scientific modelling new concepts for mimicking human movement are developed. More and more this concerns mechatronic

systems, which are in essence innovative intelligent prosthetics. Unfortunately, the development of promising concepts into commercial smart prosthesis is rarely taken up by academia or Research and Technology Organisations (RTOs). Because of this, only a very small amount of smart prostheses has actually become available for end users. In the figure below an overview is given of the Skills and Wills of this group based on the questionnaire sent.
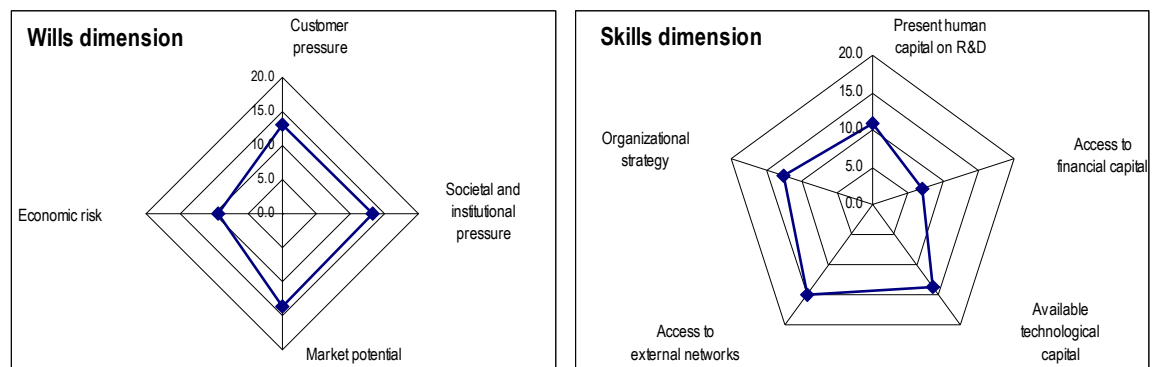
Figure 22: Wills and skills of research organizations in intelligent prosthetics.

From the skill-will-dimension it appears that the economic risk is an important factor, probably because access to financial capital is difficult. On the other hand there is a lot of societal and institutional pressure for new research and developments. Funding of this research will require government support. Knowledge exchange between research organisations seems not a big problem according to the score on access to external networks. Basic research and implementation of its results will be required to gradually move to prosthetics closing to the biological examples or beyond.

Medical profession is another important stakeholder group. The demand of the medical profession for intelligent prosthetics is driven by the professional wish to improve health care to patients. The acceptance of novel systems will therefore depend on the availability of proven effectiveness of the systems. Related to this is the availability of funding. Smart systems will be more expensive than traditional prosthetics and the added value may find support from financers once it is not only proven effective but also cost effective. Besides functionality, durability, safety and reliability are all part of this required effectiveness evaluation. In the figure below an overview is given of the Skills and Wills of this group based on the questionnaire sent.
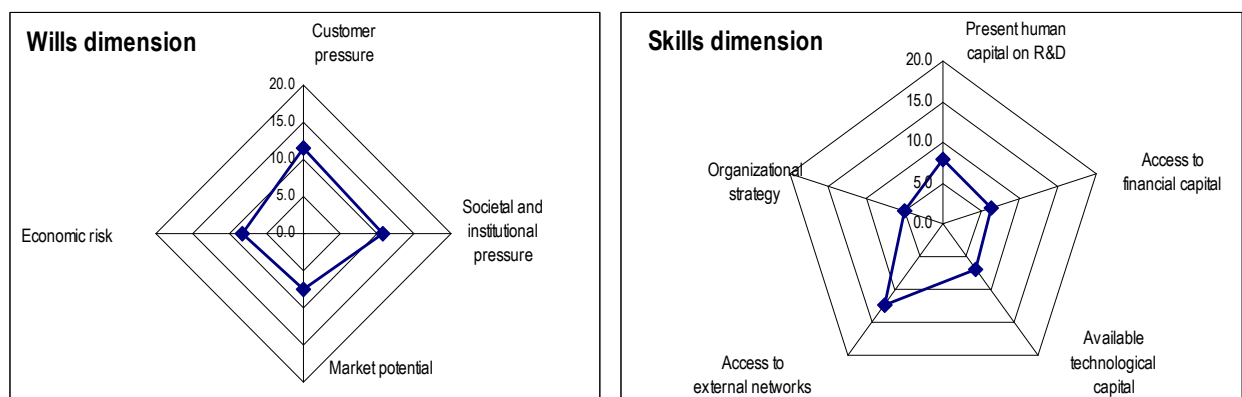
Figure 23: Wills and skills of medical organizations in intelligent prosthetics.

As can be noted from the score of market potential and economic risk, intervention of government for financial support will be required. The skill-dimension diagrams show an important lack of influence from medical sspecialist which can be concluded from very low organizational strategy, low human capital on R&D, lack of access to financial capital, technological capital. Access to external networks is far better. Related to their education, experience and working environment the medical profession has a broad, also external, network.

End users and patient organisations only play a very small role in this development. At best, they are included in the assessment of user needs but only rarely as stakeholder. As prosthetics are intended for individual users the voice of only one user is seldom heard. But also patient organisations representing end users play only a minor role in initializing developments. In the figure below, an overview is given of the Skills and Wills of this group based on the questionnaire sent.
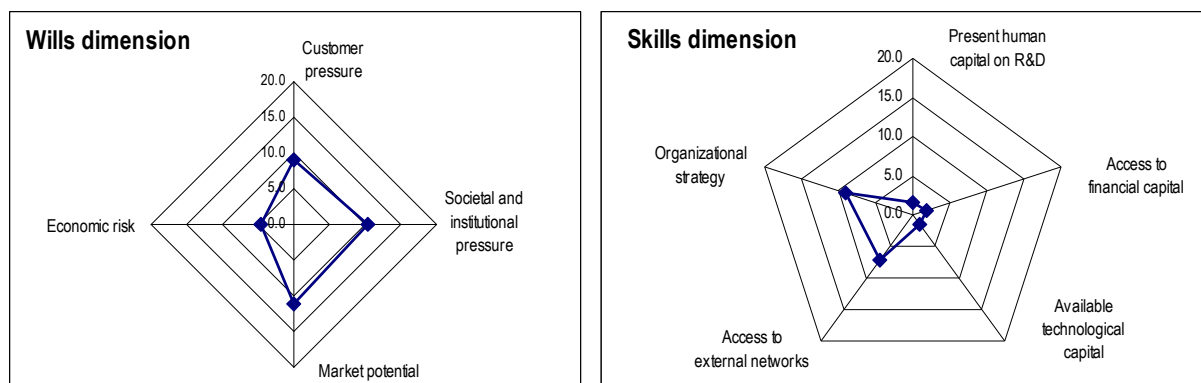
Figure 24: Wills and skills of end users and patient organisations of intelligent prosthetics.

The Skills diagram shows the minor impact from users and patient organisations on all five aspects, but especially on available technological capital, access to financial capital and human capital on R&D. Therefore, the influence on important items such as development and provision of prosthetics is very minor. Since financers of this type of healthcare provisions are not the end users, the commercial market mechanism fails regarding the development of prosthetics. The economic risk is an important drawback. Governmental support is essential.

Figure 25: Wills and skills of health insurers concerning intelligent prosthetics.

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Health insurers are the main financing parties in providing prosthetic systems to the end users although there are of course differences between countries in the willingness to deliver and the concept to support the provision of systems to their citizens. In the figure below an overview is given of the Skills and Wills of this group based on the questionnaire sent.
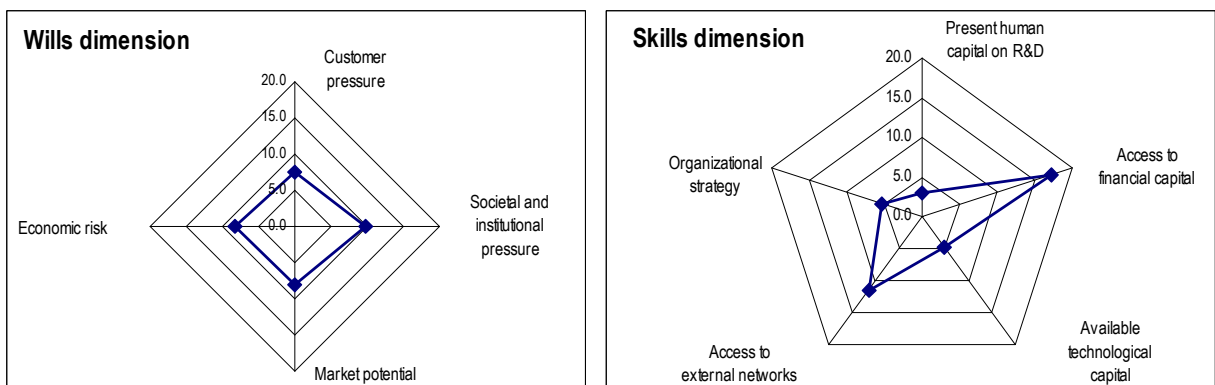
The skill-will dimensions for health insurance show low scores on all aspects of skill and will. From this, it can be concluded that their knowledge, interest, efforts and striving related to aspects like development and provision of prosthetics, is still rather low. There is only one exception. Health insurers, of course, have access to huge financial capital.

Governments of different countries have, of course, great differences in the willingness to support the development and provision of prosthetic systems to their citizens. The example of the development coordinated by DARPA in the US is an example of how development can be boosted. The systems that will become available are likely to find their way in other countries including the Member States of the EC. The development of other prosthetics for different target groups will also follow from the results of the DARPA initiated systems. In the figure an overview is given of the Skills and Wills of
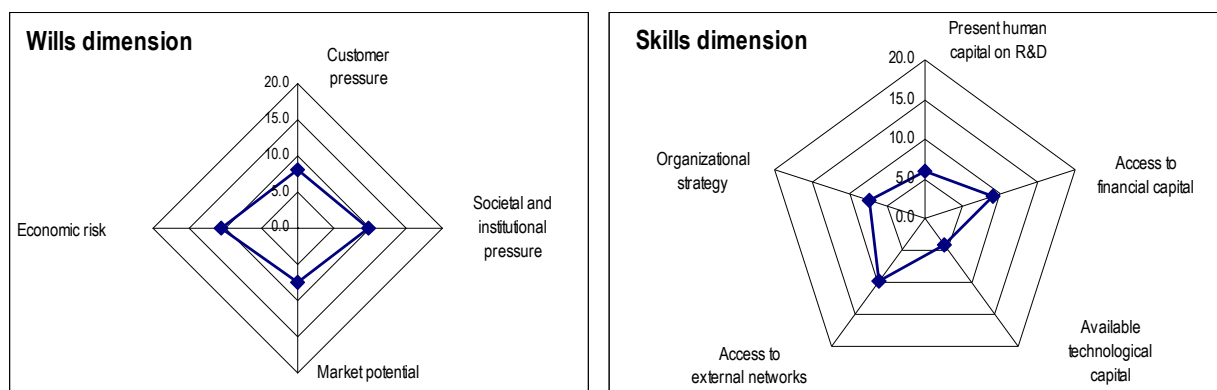

Figure 26: Wills and skills of governmental regulation concerning intelligent prosthetics.

this group based on the questionnaire sent. The skill-will dimensions for government show low scores on all aspects of skill and will. From this, it can be concluded that their knowledge, interest, efforts and striving related to aspects like development and provision of prosthetics is still rather low.

4.4.5 *Conclusions*

The overview of Skill/Will profiles of all stakeholders is given in the diagram below. The major players are research and development. Due to the uncertain financial structure for research, development and provision, the economic risk is the most important aspect in the Will diagram. From the Skills diagram, the minor impact from users and patient organisations, especially on available technological capital, access to financial capital and human capital on R&D can be noted.

The Skill/Will matrix below shows even better the minor impact of the patient organisations. Also government, medical professionals and health insurance play a minor role. Government and health insurance could play a more important role through regulation and financial support of research, development and provision.

Medical professionals and patient organisations should be more involved for aspects related to effectiveness and aesthetics.
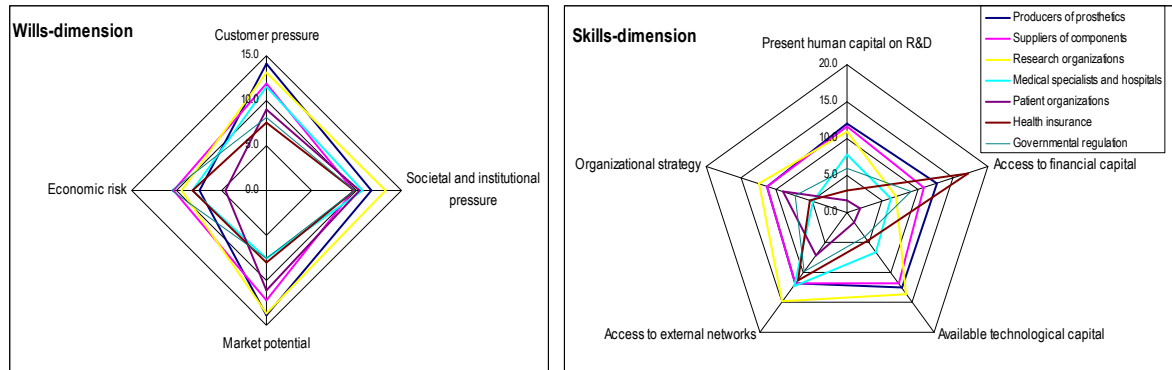

Figure 27: Overview of the different stakeholders on intelligent prosthetics.

From the case study it can be concluded that the main goal for upper limb as well as lower limb prosthesis are the development of more intelligent prosthesis with focus on improvement of performance and usability.

For aspects related to technology, social and economics the following can be noted: innovative aspects for the future should especially focus on physical connection of the prosthesis to the human body, imitating natural movement and look of the human limb, more intuitive control and external feedback to the user.

Innovations in this field will be driven by a number of key technologies including interfacing, intuitive interaction, improved device control of many DOFs, the development of sensory systems with effective feedback to the user and the integration of smart mechanical systems with improved aesthetic quality. Altogether, the systems should approximate the human limbs much closer than they do today, with individual adjustment possibilities.
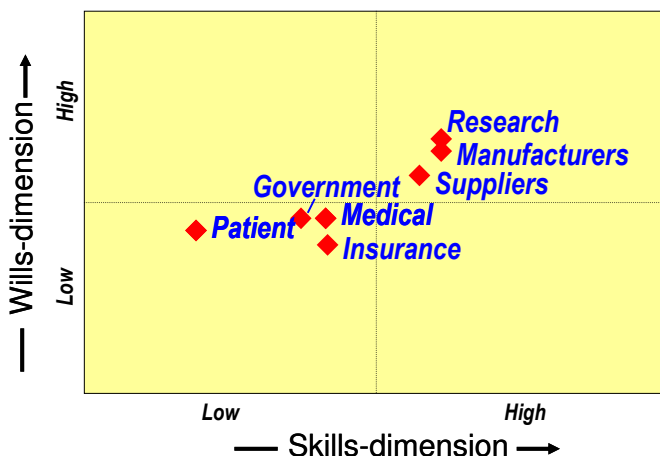
Figure 28: Skill-will matrix of Intelligent Prosthetics.

Technology is not the main problem. Innovation leads to new ideas, concepts and prototypes. However, only few products are really marketed. The main problem is financing. Healthcare providers are reluctant to provide users with new expensive devices and they are hardly forced to do so. Government can play an important role in legislation on healthcare insurance.

In general, social attitude towards disability and technological fixes are influencing factors for acceptance of prosthetic devices. If the benefits of intelligent prosthetics outweigh their negative consequences (discomfort, stigmatisation and aesthetics), then acceptance will be less of a problem.

The economic risk for manufacturers and suppliers to produce and deliver prosthetic devices is high, because healthcare providers are reluctant to pay for new and expensive products. The development of promising concepts by research organizations into commercial products is rarely taken up by manufacturers. As a result, only a small amount of intelligent prostheses has actually become available for end users. At the moment research for new concepts is only possible by governmental financial support.

For the successful introduction and acceptance of intelligent prosthetic systems by financers, medical professionals and of course users, proven (cost) effectiveness will be required. This effectiveness should not only concern medical functionality but also more social aspects as quality of life, increased independence and user satisfaction. Clinical trials so far have focussed on the mere functional aspects and more attention to the social aspects is required. However the medical profession and patient organization are hardly involved in specifying and developing new concepts. They are willing to do so but often, especially patient organizations and end users, lack the skills necessary for effective involvement. For future research and development medical professionals, patient organizations and end users should play a more important role.

Final conclusion
In the future, prosthetic devices will have to function more and more like natural limbs. Systems will react, feel, look and weigh the same as the natural limb. Moreover, system functioning will be controlled only at higher cognitive levels ("task control": grasping a glass, using fork or knife) while the required more basic control loops will be executed by the system internally (like the subconscious functioning of the cerebellum in unaffected limb movement). Finally, systems will be able to provide flexible sensory feedback to its users.

4.5 Case 3: Robotised motor coordination analysis and therapy

4.5.1 *History and future*
Due to acquired damage to brain or nervous system people can have resulting impairments in coordination of motor behaviour. A very well known example is of persons, who after recovering from stroke, suffer from one sided impaired motor-control.

Treatment of such impairment focuses on restoring lost motor control in the brain and/or restoration of functional performance. However, the mechanisms behind the restoration of function on the basis of brain plasticity are not fully understood yet (Johnson, 2006). In general the conception is that repeated movement will eventually lead to restoration of brain functioning for control of this movement. Robot therapy systems have been developed for training of motor control of both the upper extremities and lower extremities. Such systems offer controlled support of movement, for therapy purposes by either helping the human in making the movement or straining the movement and for assessment purposes.

Robotised therapy of motor coordination
In general, two basic types of systems can be distinguished;
- Robotic assistance with therapies that train the restoration of motor-coordination for upper extremities,
- Gait training robotic systems; robotized assisted therapies for the training of lower extremities.

For *upper extremities*, the first systems were developed in the nineties mainly in the USA. Examples are the MIT-manus (MIT) 1992 (Fasoli et.al, 2003), designed to permit stroke survivors to practice two-dimensional (2-D) point-to-point movements, and the MIME system developed at PaloAltoVA/Stanford University 1993 (Burgar et.al., 2000). The system registers the movement of the unaffected arm and through a robotic arm the affected arm makes the same, mirrored, movement. The ArmGuide (Rehabilitation Institute of Chicago) 1999, (Kahn et.al., 2004) is another major example. It aims at not only providing therapy in 2D motion support but also at offering, in the same movement range, diagnostic options. In Europe, also in the nineties, a first system was developed in Germany (Bi-Manu-Track) 1998, later followed by the Gentle/s project resulting in the Gentle/S system (University of Reading, coordinator) 2005 (Loureiro et.al., 2003). It makes use of the HapticMaster FCS (NL) (Moog/FCS, 2008) as device for haptic feedback. Therapy robots permit stroke survivors to practice three-dimensional (3D) point-to-point reaching movements occurring in a haptic virtual environment or in the real world. Typically, to practice these movements, the stroke survivor's impaired arm is supported against gravity while he/she is asked to use the impaired hand to hold the handle of the robot and move it or permit the impaired arm to be moved through reaching exercises.

The positive aspect of robotized therapies is that force feedback to the patient can be regulated, increasing the effect of the therapy, and robotized therapies offer options for functionalities introduced for stimulating patients to increase compliance to the therapy (Johnson, 2006).

The Gentle/S system was developed and tested in an EC funded project. It aims at offering force feedback guidance in moving the affected arm in order to effectively train its control.

Given the number of annual patients the (diverse) group of CVA (stroke) patients forms an interesting market. But differences between patients within this group can be large, making it difficult to develop widely applicable systems. So far, systems encountered seem to have been developed from a technological perspective rather than on the basis of demand from therapy. But for some of these systems the therapeutic effectiveness has already been proved by clinical trials (MIME, MIT-Manus) (Kwakkel et.al, 2008).

For restoration of walking and *gait training* an early German system was developed in Berlin in the early nineties (Uhlenbrock et.al., 1997). Later, work in Balgrist University Hospital, Zurich, Switzerland, led to the founding of the LOCOMAT system, now brought to the market (rehabilitation centres and hospitals) by HOCOMA AG (CH) (Colombo, 2001). These systems simulate the phases of gait and modify key gait parameters such as stride length and walking speed. Often these systems are used in the rehabilitation of non-ambulatory patients, such as those with SCI, and partially ambulatory patients, such as those with stroke, and as such they often support some percentage of a patient's body-weight. First clinical trials show favourable results (Husemann et.al, 2007).

The detailed control of limb movement is challenging because not only the movement of foot is relevant but also the optimization of the movement of the joints in the whole limb needs to be taken into account. A system capable of doing this soon becomes very large and unusable for therapy (at home) purposes. Force feedback to the arm provides

major learning advantages and should preferably be added to the (arm) movement control.
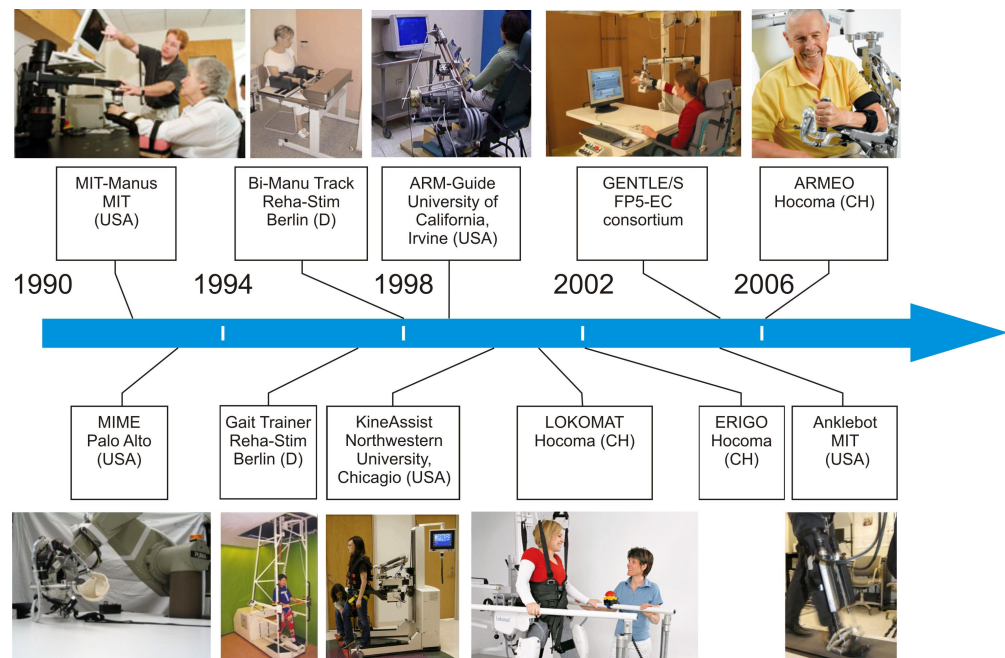

Figure 29: Milestones in the development of Robotized motor coordination analysis and therapy.

Robotised analysis of motor coordination
The treatment of patients with impaired patient motor coordination needs to be guided by precise description and assessment of patient capabilities. For this, patients would need to perform elaborate sequences of movements to map their motor capabilities. Using such procedures, important muscle and coordination dysfunctions can be identified.

However, because of the complexity of these procedures most assessments are currently made on the basis of expert, yet subjective, interpretation by healthcare professionals.
An important improvement could be reached by means of the use of robotized systems. For this purpose, robots can perform complex tests in very efficient and reproducible ways. This area of application is just surfacing to the field of robotics, as a spin-off from the robotic systems that are developed for therapy purposes. First systems are under development and seem to emerge in technical development environments with strong links to the medical profession.

A first example of such systems is the Caren system brought to the market by MOTEK. Caren offers multiple ways to provide perturbations and dual tasking, capture measurements and provide feedback. With this use, gait becomes easier to objectify, quantify and categorize (Fung et.al., 2004). Other examples include the Rutgers Ankle (Rutgers University) 2001 (Deutsch et.al., 2001) and KINARM 2006 (BKIN Technologies, 2008) Canada. These systems assess the dynamic range of movement of body parts or the whole body and balance control. Also the earlier mentioned Arm Guide system (Kahn et.al., 2004) offers assessment functionality besides its therapeutic application. The POPE developed by TU Delft (NL) 2005 (Schouten et.al 2006) is

capable of measuring complex interrelated muscle activity levels to guide treatment of post traumatic dystrophia. This systems mainly serves important research purposes.

As only a small number of systems are actually introduced in the market it is difficult to determine the success of the many experimental systems that have been developed. Even systems that failed in reaching the market they aimed at, may have offered important insights during the process and may re-emerge at a later stage, maybe in another form (e.g. Gentle/S). The early work reported above on robot mediated rehabilitation had a important impact on the development of the market. The substantial clinical evaluation of the MIT-Manus and MIME systems became available many years after their first introduction but form now an important landmark in the development of the systems towards application in regular healthcare (Kwakkel et.al, 2008).
The development of these prototyped systems also provided important apparatus for fundamental research into the underlying mechanisms governing human motor coordination.

Commercial successes so far, are the HOCOMA systems. Not only the initial LOKOMAT system is currently offered, but also the arm rehabilitation system ARMEO and variants to the gait training systems ERIGO and a paediatric version of LOKOMAT are available. Nevertheless, results of trials are ambivalent as to the effectiveness of the robotic systems in comparison to human intermediated therapy. MIT-manus and MIME system have proved their effectiveness in trials and must be regarded as successful pioneer systems. The road to market implementation seems to be long, as clinical studies have to prove the effectiveness of systems. The Pope system is an example of a successful system which may not make it to the market but the research it enables will most likely result in spin off systems.

As systems develop, the applications will become more effective. The experimental nature of both the systems and the underlying modelling of human motor behaviour recovery will evolve. This will pave the way to more specific development but also to more specific patient applications. Currently, systems under development are either aimed at diagnosis or therapy. More and more, systems will evolve either combining both aspects in one system or sharing an expert system using the diagnosis as outset for therapy goal determination and subsequently for monitoring patient progress. The therapy system will be able to provide specific targeted therapy guided by the same expert system. This will not only cover compatible systems but also advancement in modelling of human motor control therapy. As a consequence, systems will be able to provide personalized therapy as soon as they recognize their user. Supervision by a therapist will remain necessary but systems could extend therapy beyond the constraints of available human intermediated therapy. Home application of systems could be conceivable because of this capability. Increased motivation to comply with therapy may be reached through application of Virtual Reality and haptic feedback technology. Next, it can also be expected that through more precise monitoring of both diagnosis and progress, the effects of therapy could be much better monitored leading to increased understanding of human motor control and demonstration of cost effectiveness of the provided therapy. Both issues are driving forces for the application of robotized support of impaired motor control interventions.

The future development of therapy systems will aim towards integrated effective systems. Personalized systems capable of providing movement support that suit the needs of the user in order to maintain fitness, detect problems or provide focused

therapy. This would be done in a way that would be both effective and self motivating through the use of sensor technology and additional technologies such as virtual reality and haptic feedback. The main innovation will therefore be system integration and development of algorithms that define personalized effective systems.

The future developments will focus on three Product-Market combinations (PMC's):

- Intramural diagnosis and treatment of motor coordination related problems
- Extramural (home) treatment of motor coordination related problems
- Prevention and initial treatment of problems through mainstream service driven fitness-like environments.

For the first two PMC's, elderly will be the largest target group, but also younger patients of trauma related injuries. There may also be a link to recovery from sports injuries. For the third PMC any health oriented individual may be part of the target group, becoming more apparent when motor coordination related problems emerge to some extent. Again, for the first two PMC's, regular healthcare financing will be the prime funding source. Therefore, consumer markets of the systems need to be developed. For the third PMC individual financing will be the logical way to fund development directly through sale of systems or indirectly through sale to service providers.

4.5.2 *Major barriers and driving forces*
Driving forces

Technological drivers: The technology developments have been, and will continue to be, driving forces for the development of systems. Key technologies important for robotized motor coordination therapy and analysis are:

• *Force feedback*

Haptics play a key role in the development of systems. The availability to give force or movement feedback to users is an essential element in developing a therapy system as patients need to improve their function on the basis of gradual improving motor coordination. It plays an eminent role in the ability to transfer the skills acquired in therapy to day to day life.

• *Virtual reality(VR).*

To further improve feedback but also to stimulate compliance VR can be a decisive factor. Not only will patients better integrate bodily and sensory cues but also acquired skills can be projected in real life environments through the application of VR.

• *Sensor technology for feedback.*

Sensor technology will enable systems to tailor its behaviour on the performance of the patients thus providing a tailored behaviour to optimize the therapeutic behaviour of the system.

• *Dynamic imaging techniques (e.g. MRI while moving).*

These techniques are necessary to better understand the underlying mechanisms but also to monitor patient behaviour not only on the level of physical performance but also on the level of cerebral activity. The monitoring of internal activity simultaneously with physical performance will greatly enhance system effectiveness.

• *Mobile therapy systems (in the home or worn on the body)*

Available robot therapy systems tend to be large and bulky requiring the patient to come to the systems instead of vice versa. Mobile systems including solutions for enduring power supply will change this situation. Systems could incorporate therapy but more importantly monitoring of behaviour in daily life, making it less cumbersome. This will lead to increased effectiveness and less impact on the social participation of patients.

Social drivers: As the number of patients will keep increasing for the coming decades, the demand for motor coordination monitoring and therapy will continue to increase as well. This represents, in combination with the decrease in the amount of human care and the demand for increased effectiveness, a positive change for technology in this domain. System development so far gives way to the expectation that adequate technology is available and continued improvement of functioning is to be expected. This will certainly be true for human motor coordination research.

Less certain is the emergence of a commercial market for this type of systems. So far this has not been established on a significant scale and systems have been too expensive to actually reach this state. It is to be witnessed whether valid business cases will be developed, paving the way to market development.

Economical drivers: Until recently a small number of research centres were dominant in this domain. However, in recent years system development seems to widen over many sites following the initial success of the early systems and the growing demand caused by increasing numbers of stroke patients and further predicted increase. Initially, systems were developed from technical perspective and were challenged to prove their value in therapy setting. This critical point seem to have been taken with success opening up for a diversity of systems with an increasing functional offer to support therapists. The initially small sales numbers are likely to increase with the ongoing demonstration of effectiveness of available systems. Testing the pioneer systems in clinical trial conditions has been a major step towards recognition of added value of the robotised systems.

Ongoing research on human motor coordination will be a driving force for these systems. Controlled motor behaviour in combination with increased facilities for coordinating activities will provide rich material for theoretical progress. Following this, improvement of therapies and systems can be expected.

Barriers

Technological barriers: Technological barriers exist mainly in the absence of understanding of knowledge on human motor behaviour and recovery. This is essential to the development of effective therapy systems. The current generation of systems will help in acquiring improved understanding and this will in turn lead to better systems. The dimensions of systems will be a barrier of expanding therapy beyond the clinic. Portable or even wearable systems will require mobile power supply and much lighter designs.

Social barriers: The acceptance of robots as medical intervention replacing the traditional physical therapists will meet objection, both with patients and the medical professionals. Although there is no indication of this being the purpose of the systems under development these sentiments form a barrier. Even the shortage of therapists which is an increasing problem has not been able to change the attitude towards robotics. The absence of proven effectiveness and even mentioning of reverse effects plays an important role in this. What will complicate the introduction of systems is the need for individualized training as patient requirements will grow highly individual with increased precision. But also on group level, differentiation between systems intended for various target audiences can be expected; for example, the development of systems for elderly focusing on balance and fall prevention.

Economical barriers: An important barrier will be the adoption of systems within the existing care provision. Large scale application of systems requires seamless

incorporation of systems within the existing healthcare provision. So far this has not been achieved up to satisfactory level. In addition, health care financers have not been convinced regarding the cost effectiveness of systems making the acceptance of robotized therapy as a product more difficult.

Legal and ethical aspects: The legal and ethical issues relevant for the development and uptake of these systems relate to the development process and the procurement process. Development of these systems requires involvement of patients. Legal protection of patients may hamper experimentation and system evaluation. This also relates to ethical issues since being subjected to experimental systems will imply not (immediately) undergoing traditional treatment which may be less or more effective. For stroke therapy it is generally accepted that the first 12 weeks after stroke are decisive for the further recovery. This makes is disputable to spent precious time on non proven effective systems.

A further legal issue is that the financing of these systems must become part of the procurement system. This may not be allowed due to increased initial costs, even though improved effects may occur. Substitution of human involved therapy may lead to ethical objections in patients but also in therapists.

4.5.3 The innovation system: stakeholders and their relations

Government: This stakeholder group includes all the government bodies and organizations that regulate the financing of healthcare, the conditions under which health interventions are included in the health benefit system and the quality, safety and cost-effectiveness of the health system. There is discussion about the possible tension between the goal of a cost-effective healthcare on the one hand and costly innovations which need room for experimentation on the other hand. There could be a risk that the introduction of new technologies is slowed down because new technologies cannot meet the required conditions as easily as interventions that are regularly used. Governmental funding could also be a driving force for research leading to the development of innovative systems and this already happens, happens on national level but also on EC level. But there is not always a logical link between the funding of innovations and the acceptance of the same innovations in healthcare financing.

Financers: Commercial robotic motor coordination systems are applied within the context of hospitals and other healthcare providers. Through investments of private organizations, systems used are finally financed by the applying healthcare institution. Through the delivery of care to patients using the apparatus, the investment costs can be retrieved. Healthcare provision is financed by either (local) government, healthcare insurers or private parties depending on the organization on national level. The quest for improved care and control over budgets will cause them to choose for systems that will improve effective care provision but only if this will simultaneously improve cost-effectiveness. In 2007 the Dutch National Council on Healthcare Insurance (CVZ) advised the Dutch Minister of Healthcare to allow the application of LOKOMAT in Healthcare insurance financed rehabilitation therapy, but financing should be located at healthcare providers such as a Rehabilitation centre and not in individual healthcare insurance (CVZ, 2007).

Healthcare providers: The healthcare providers are in part the same as the parties eventually financing in the systems under discussion. These could be hospitals, clinics or rehabilitation centres for intramural care provision. For extramural care provision,

including preventive health services national or regional health institutions could be involved. Systems could be applied through home care providers or independent therapists. Providing standard care for their patients with increased potential for compliance and effectiveness is appealing to healthcare institutions. Moreover, due to improved monitoring functions, increased understanding of the rationale behind interventions will evolve. This makes the application of provisional systems mainly interesting for experimentation and research.

Users: Primary users are therapists (e.g. occupational or physical therapists). Systems are aimed at supporting or extending their work. Day to day operation will be in the hand of qualified (paramedic) care personnel. In the case of domestic use of the systems (extending therapy to the home environment) it will be mainly patients and their informal caregivers who will use the systems. But ultimately the benefit of using the systems lies with the patient. These end-users will accept the systems when they provide the best options for care and recovery. An increased role of technology may have to face initial scepticism but with demonstrated effects the benefits will eventually be embraced.

Manufacturers: Systems need to be brought to the market after initial prototype development. So far, most systems originate from an academic research environment and only slowly diffuse to more commercial organizations. As system effectiveness matures, this will improve. Commercial organizations (SMEs) are already taking up activities and first systems are entering the market. However, this concerns less than a dozen companies so far (e.g., Kinetic Muscle, BKIN Technologies). As research organizations tend to have difficulty in transferring prototypes into market products, the involvement of SMEs is needed for further development of the field. However, it can be expected that in 5 to 10 years these kinds of devices can be found in all major clinics and rehabilitation hospitals in the developed world, and even in patients' homes. (Krebs, 2007). Stimulating SMEs to get involved will largely depend on market potential. The availability of funding options and the demonstration of system effectiveness will be key factors in this process.

Research: For the initial R&D activities regular funding and science funding through academia will be required. The development of functioning prototypes will pave the way to product development but also to the development of the understanding of underlying mechanisms of human motor control. The role of research in this process is therefore crucial to the further development of the field. This concerns both the conceptualization of functional therapy systems but also the demonstration of effectiveness. In the USA, the MIT and the Veteran Affairs in collaboration with academia (Stanford, Rice University) were the first to start this research. Currently, a large number of research organisations and academic groups are working on these types of systems; in total this may concern over 100 organisations. In many academic centres, systems are under development (e.g. RUPERT (Jiping H., 2005), HOWARD (Reinkensmeyer. et. al. 2004). In Europe, this involved, at first, mainly technological development but more and more medical and social elements are under investigation in projects, resulting in an increase of research groups focussing on this.

4.5.4 *Skill/will of the stakeholders*
The experts view on the skill – will distribution over the stakeholders concerning shows some interesting features.

The **manufacturers** are seen to score well on both the skill and will dimensions but are kept back by the perceived economic risk and to a lesser extend by the absence of customer pressure. This corresponds to other outcomes of the study. In the workshop it became clear that development is executed by R&D organisations and the uptake by companies has high potential, but this is only just emerging.
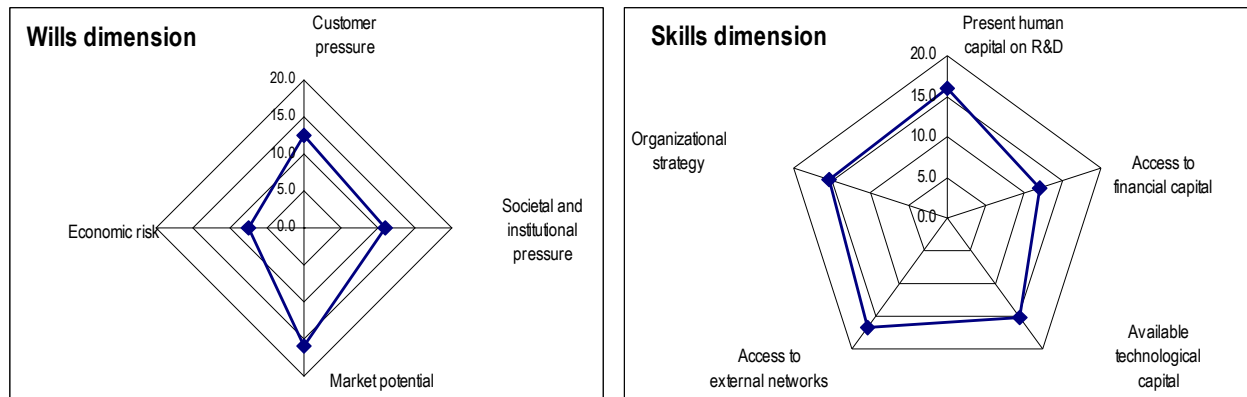

Figure 30: Wills and skills of manufacturers of Robotised motor coordination analysis and therapy systems.

This matches the fact that the number of **supplying companies** is still small. Availability of technology and parts is high, as is the access to technological capital, but here the will dimensions is similar to the manufacturers while the market potential scores are even lower. The suppliers are able to step in but economic reasons keep them reluctant. This is in line with findings from the workshop discussion and the interviews.
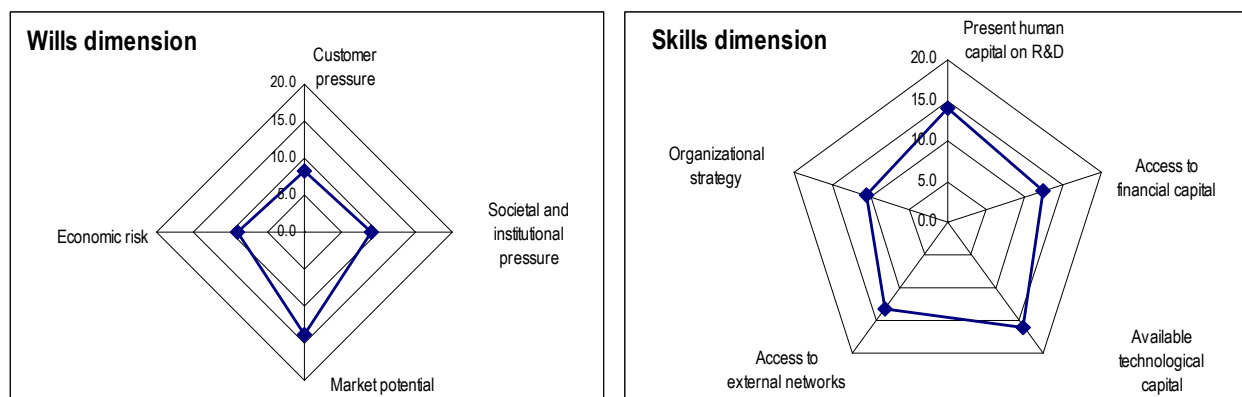
Figure 31: Wills and skills of suppliers of robotised motor coordination analysis and therapy systems.

The **research** organisations score high on both the skill and will dimensions. This matches the availability of many experimental systems. This does not only concern the technology developing institutes, but more and more medical centres as well. In the USA, there has been a number of trials performed aiming at demonstrating effectiveness.

The research organisation, highly visible in the workshop and represented in the interviews agreed to this viewpoint. The current status of the market shows that there is reluctance for entering the market due to lack of potential financing sources. Besides, it is not the prime activity of researcher to commercialise products. Funding of technical

research was not reported to be too little but funding of research into effectiveness was reported to be difficult.
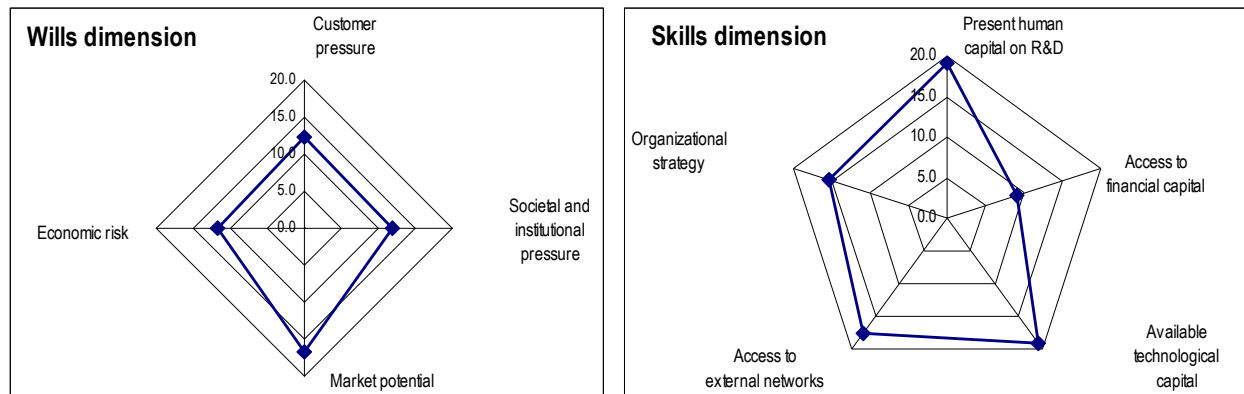
Figure 32: Wills and skills of research organisations in robotised motor coordination analysis and therapy systems.

The involvement of **medical specialists and hospitals** is different from the medical research centres. Economic risks keep them back; but also because there is not ample proof of effectiveness and because systems are expensive. However, consumer pressure and the external network are relatively high. This provides favourable conditions once the economic constraints can be solved.
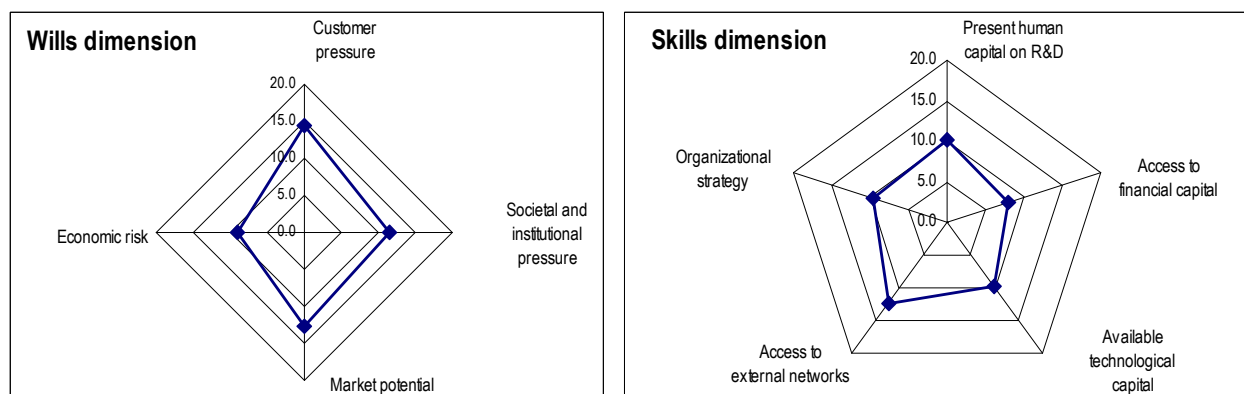
Figure 33: Wills and skills of medical organisations in robotised motor coordination analysis and therapy systems.

By means of the interviews, it became indeed clear that the public awareness of the potential of robot mediated therapy will have to increase before the economically sound application of robot systems reaches a larger scale. In the workshop, the attending pioneer researcher expressed the need for clinical trials as a solution to this barrier.

The other user group, the **patients,** have very little influence on the introduction of systems. Their skill dimensions score low, but of course they form the market potential for the systems and an important argument at societal level.

This result is typical for the position of patients during the introduction of technology in rehabilitation. They are dependent on the innovative power of the healthcare professionals and given the complex financing structure of healthcare provision in Europe, it is impossible to influence this development by consumer-like behaviour. At the same time, all the activity in healthcare is warranted both in the justification of
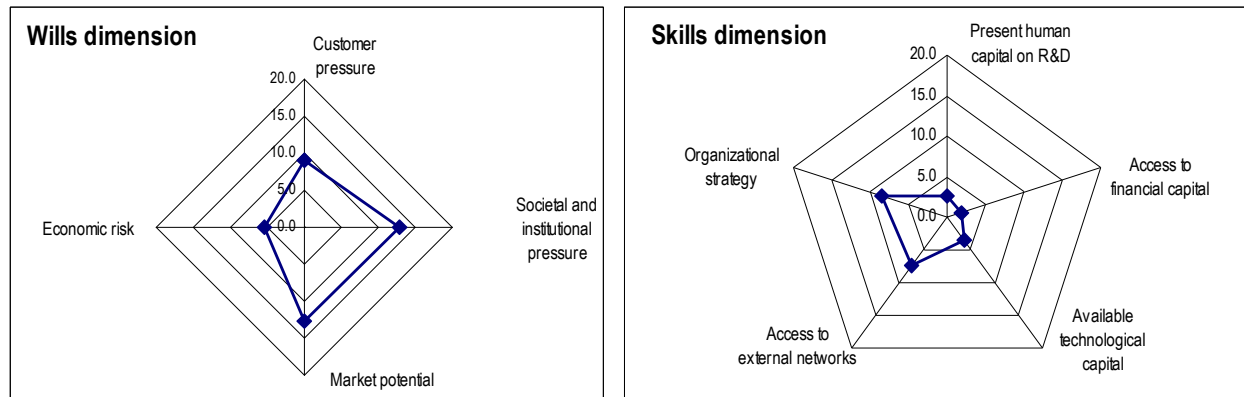
Figure 34: Wills and skills of patient and patient organisations in robotised motor coordination analysis and therapy systems.

actions but also in the reality of day to day practice. Lack of public awareness and the absence of overwhelming evidence for (cost-) effectiveness of robot mediated therapy, were reported as the reasons for this status quo.

The **healthcare financing organizations**, either private (insurance companies) or governmental are seen to have their skills mainly high on the access to financial capital and take a intermediated position concerning their will dimension. They have very little involvement in the development of systems which is holding back the development in general as the potential financial benefit lies with them. The lack of participation of healthcare financers in the workshop underlined these findings. Currently, the involvement of these stakeholders was regarded to be limited and this is in full correspondence with the above results.
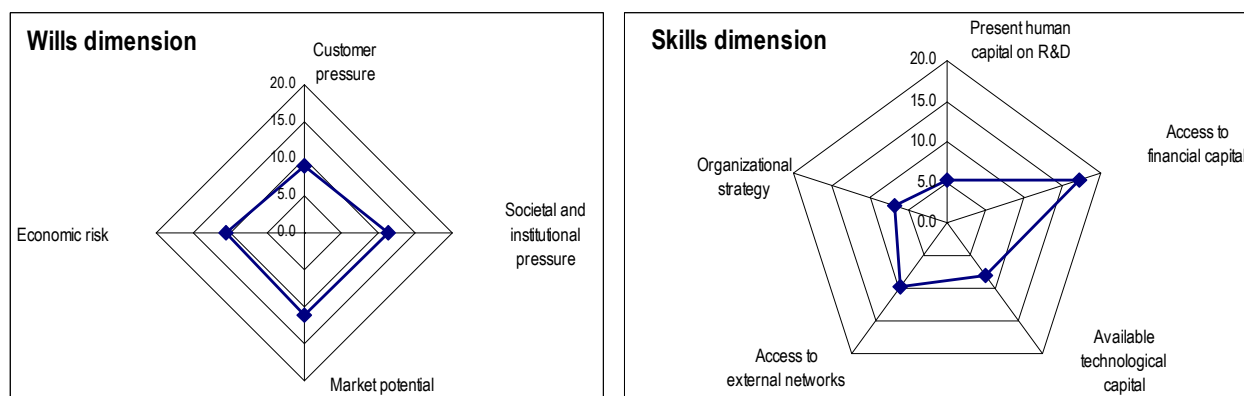

Figure 35: Wills and skills of healthcare financing organisations of robotised motor coordination analysis and therapy systems.

The involvement of the **government** as societal stakeholder, leading in many policy and funding issues and mostly in regulation, is judged to be restricted to raising issues but surprisingly low on funding issues. Governments can be leading in policy and legislation and therefore play a key role in the promotion of innovative healthcare interventions but are not seen to do so up to a noteworthy level.
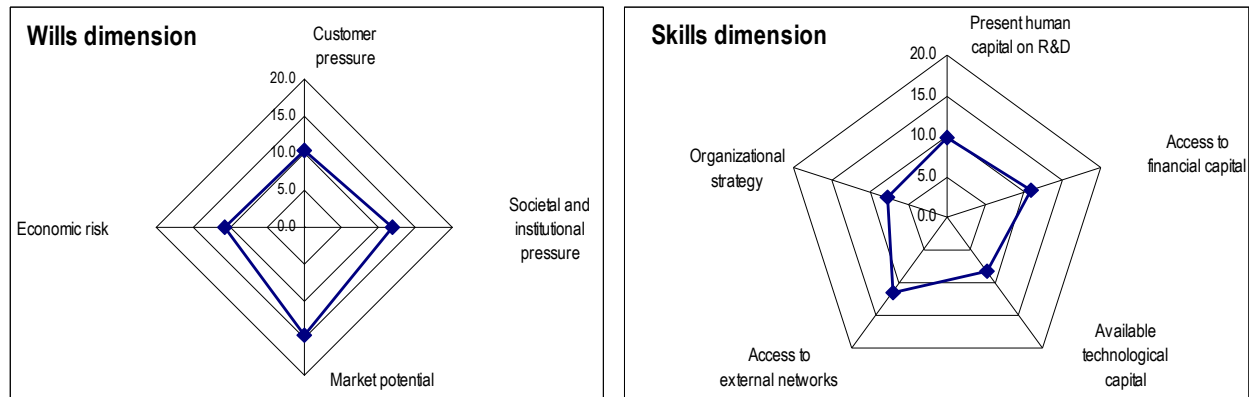
Figure 36: Wills and skills of governmental regulation of robotised motor coordination analysis and therapy systems.

The results of the interviews, and certainly the workshop, are in line with these findings. The current trend in Europe towards privately financed healthcare in some form, explains the lack of funding related involvement.

Preventive services have only a very limited role in this domain as systems are far from actual application. Their skills dimension scores overall low but once effective systems become available the market potential is high due to the societal impact and with that the economic impact.
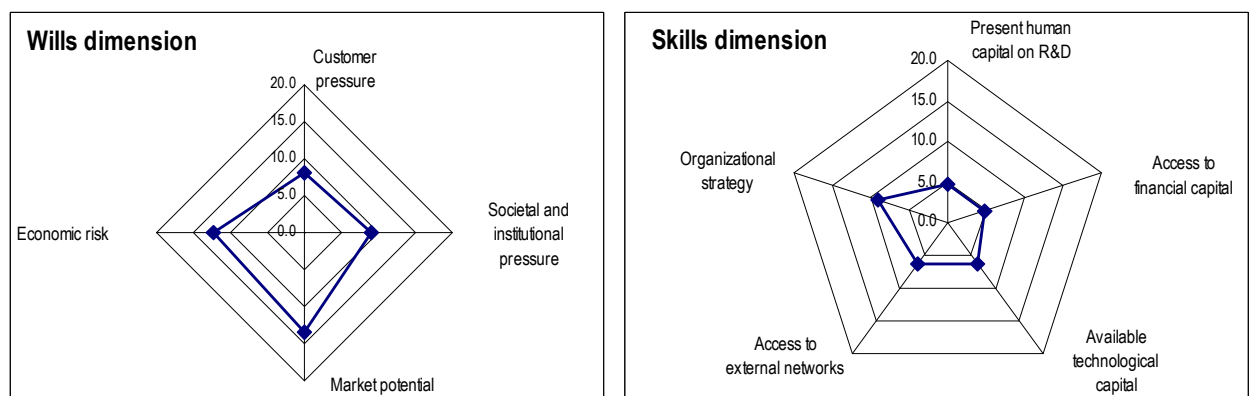

Figure 37: Wills and skills of preventive services involved in robotised motor coordination analysis and therapy systems.

In the workshop, the importance of preventive application of this type of systems was denied, given the current state of the art. Potentially, larger importance may develop when technical progress makes systems less obtrusive and definitely much cheaper.

4.5.5   Conclusions

Overall, it was stated in the workshop that functional systems are the first goal to be reached. Following this, the effectiveness is to be demonstrated before wider application is witnessed. In addition, diversity in robot systems can be expected, systems suitable for specific rehabilitation, e.g. balance training for frail elderly or systems providing intelligent gravity compensation. A final expected innovation is a major increase in systems' automated technological adaptation to the individual patient, offering tailored therapy.

A shortage of available physical therapists can be expected and the workload for the available physical therapists needs to be decreased. But there is also more intrinsic benefit in therapy robots. Improved effects for patients through the combination of human given therapy and robot mediated therapy are expected. In the long run, the robots may even out-perform human therapists; an example mentioned was stumble training, not feasible with a human therapist but certainly in a future robot's repertoire.

For the further development of the robotized diagnosis of motor coordination functioning, key developments will be *Dynamic imaging techniques* and *Mobile monitoring systems.* The effectiveness of systems can be greatly enhanced by combining sources of information. In this case, brain activity monitoring will provide valuable insights in understanding motor coordination deficiencies. To be able to make proper use of this, wearable systems will be required to monitor human movement during everyday functioning. The link with everyday functioning will improve transfer of effects to patient performance and consequently social participation.

For the further development of motor therapy, the combination of therapy with virtual reality and haptic feedback will improve the quality of therapy and stimulate patient motivation and compliance. This is then likely to improve the effect of therapy. The availability of exoskeletons may make systems mobile and open the possibility of offering therapy in everyday environment. However, the added value of this is to be demonstrated.

Although a number of systems are already functional on the market, further technical improvement will increase effectiveness. These improvements can be expected in the coming years. Nonetheless this will not be the main barrier to the adoption of systems in healthcare provision. The adoption of robot systems in regular healthcare will be a more problematic issue. Adaptation of healthcare provision to make room for this kind of therapy and diagnosis will require adaptation of the current organization of healthcare provision. To convince healthcare institutions to accept robotized diagnosis and therapy, demonstrated cost effectiveness will be required.

The decision on involving robot diagnosis and therapy systems will lie with healthcare institutions. In principle there is no barrier for the admittance of these systems as soon as it meets regulations and added value has been demonstrated. The problem connected to this is that a low number of sales will prevent the much needed effectiveness improvement from being realized in next generation products. In contrast, healthcare providers will be looking for the most effective systems and will wait until they are available on the market.

In figure 38 the diagrams of all stakeholders are brought together into one overview.
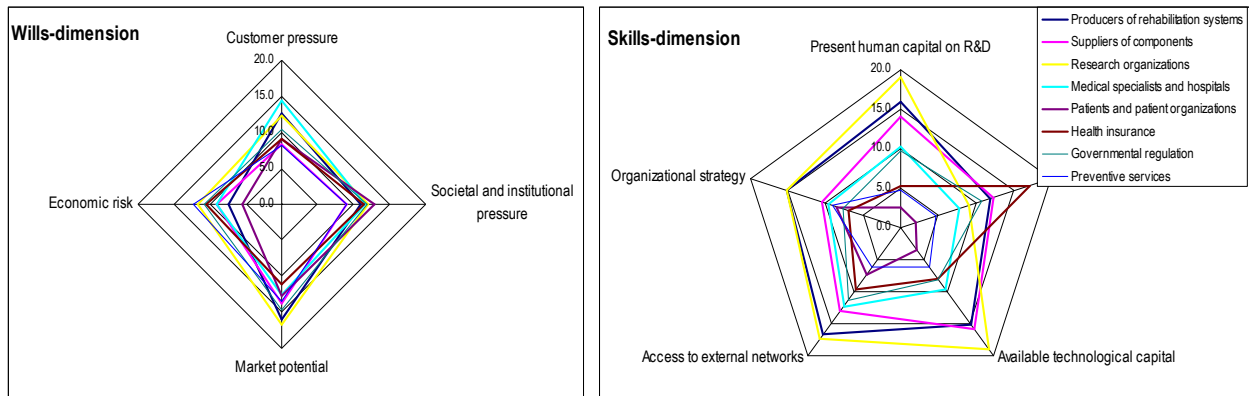
Figure 38: Overview of the stakeholders involved in robotized motor coordination therapies and analysis.

The prominent skill role of research is clear; so is the overall lack of access to funding for all stakeholders apart from the health insurers. Intriguing is the similarity in scores on the will dimension. There is no clear driving stakeholder seen in this domain. This may correspond to the current initial state but from interviews it became clear that there is large potential is to be gained and this will profit patients mostly; to a lesser extent, the healthcare providing institutions and most certainly the private companies bringing effective systems to the market. Finally, it was reported that with the growing demographic change, the healthcare professionals may also have a large potential gain, as there will be shortage of human therapists.

The combination of skill and will data results in the final diagram (fig. 39). It shows the leading position of research organizations so far, leading both in will and skill, closely followed by the manufacturers who are indeed entering the arena with the first generation of commercial products.
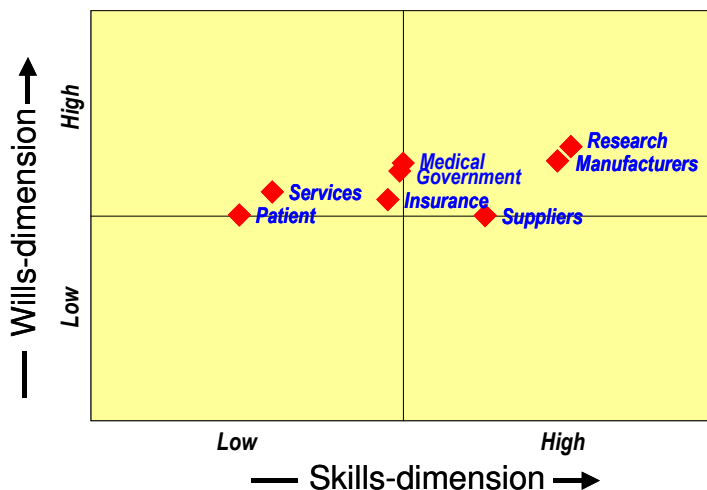
Figure 39: Skill-will matrix Robotised motor coordination therapies and analysis.

The successes of this, will initially be modest as the medical professionals, the insurers and the governmental may be positive on introduction but have to meet the financial and legislative constraints attached to the introduction. Patients have a passive role according to the experts. The predictive component in this case is still under developed but already the will is seen to be at average level. Most striking is the trailing role of the patients. As their prominence increases, other stakeholders will follow them towards application of robotic mediated therapy. As this application depends on involvement of all stakeholders, insures and medical professionals will then need to improve their skills and can be expected to do so.

4.6   General conclusions of the cases

The information presented in this chapter shows that the three selected innovation areas have commonalities. All three are young fields (1980s), although there was some mentioning of research in the 1960-ties on intelligent prosthetics. But there are some differences in the maturity and the potential market volume of the three areas. It appears that in all three areas much progress has been made in the earlier stages of the innovation process (invention, research). But very few products have actually reached the stage of large scale market introduction. It is striking however, that few individual success are to be seen in all three cases.

In the perspective of these complicated innovation trajectories, it appears rather difficult to qualify examples of innovation projects as successes or as failures. Very few examples have reached the stage of broad diffusion into regular healthcare, the ultimate criterion for a healthcare innovation. On the other hand a number of projects have been stopped for reasons for which it has become clear that no easy answers can be found. However, for other cases the qualification "success" or "failure" could not easily be made and seems to depend on the stage of the development it is judged to be in.

All cases contain promises for the future. During the search for stakeholders such as doctors, hospitals, care institutions, health insurance companies and patients, it appeared that most of them see the developments as very interesting for the future, but very few of them show an urgent drive to jump on the bandwagon right now. And although there are some technological barriers, there are disruptive new developments to be expected that will change the landscape of the areas.

Looking at the stakeholders, it is clear that manufacturers and researchers need to join forces to increase the momentum in innovation. Both are considered "champions", but commercialization is a major barrier because of the weak cooperation between "supply and demand". Suppliers play a more supporting role and patient involvement in research and development is (too) little.
Government funding is important for the momentum of the field. Although government is not considered an active player, financial funding of research and development is crucial. But some institutional barriers are slowing down the innovation process, like for example, the approval of systems for human use. The ethical problems are limited.

A remark on the conclusions is that the roles of stakeholders, in relation with the consecutive stages of the development of the healthcare product and intervention, change during their lifecycle. Because of the formal aspects of several of these phases, the role of a stakeholder may have to change when moving to the next phase, or the role of another stakeholder may become more important for formal reasons. In these situations it can be part of the analysis to investigate how these skill/will patterns change over time.

The preliminary conclusions in this chapter are the best result one can get with the methodology used for the case studies. Therefore it was very important that these preliminary conclusions were discussed at the evaluation workshop with a variety of stakeholders around the table. The insights gained from the case studies, complemented with the results of the workshop, have been used to finalize the draft roadmaps which are presented in chapter 6.

5 Enabling technologies

5.1 Introduction to enabling technologies

In the previous chapter, robotic systems were categorized in five application domains based on the research. These descriptions can be seen as end user applications that have added value to society. In this chapter, the more technology oriented side of robotics for healthcare is described. Technologies can be seen as the underlying components that enable the development of the robotic systems. An overview of the state of the art in these technologies also provides insight in the technological bottlenecks of further development of robotic applications.
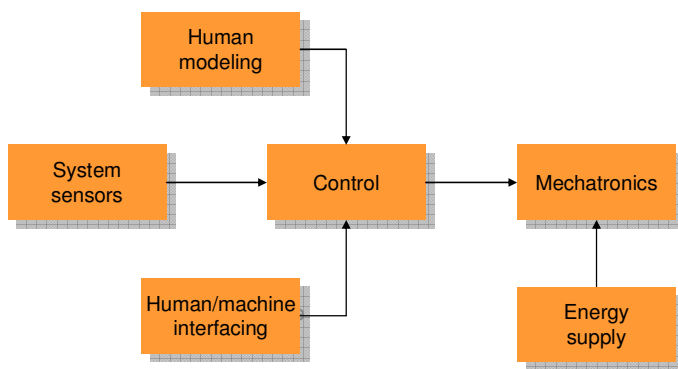
Figure 40: Modular elements of a robotic system.

In general, a robot is build up from different crucial components. One component focuses on the interface between the environment and the machine itself (**system sensors**). Information about the environment is integrated with personal information from the user into a **control** unit. This control unit uses information about **human modelling** to convert it into **mechatronic actions**, which are powered by an **energy supply** unit.

Next to these robotics technologies, improvements in the body of the robot are important to the further development of robotics for healthcare. These crucial elements of a robotic system are also the point of departure for a discussion on the essential technology fields for robotics in healthcare.
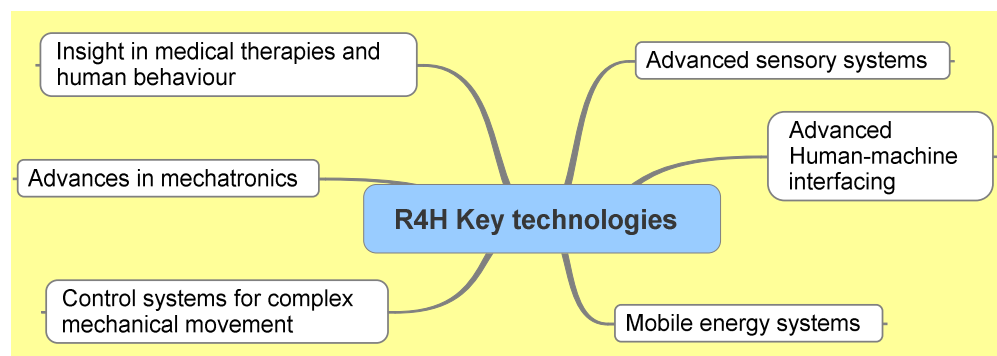
Figure 41: Key technologies in R4H.

Looking at the major developments in technologies that are linked to robotics, the following technological themes can be distinguished:
- **Advanced sensory systems**
  In the field of healthcare, specific sensory systems are needed, especially where the interaction with (biological) environment is crucial.

- **Advanced Human-machine interfacing**
  The interaction between humans and robotic systems is essential to its usability. Technologies like feedback mechanisms, HMI approaches, and input control concepts are important developments.
- **Efficient mobile energy systems**
  The development of new energy systems to provide robots with power to perform independently from the electricity grid, in a efficient way. Miniaturization and the increase of energy capacity are important.
- **Control systems for complex movements**
  Further developments of control mechanisms that enable the efficient and effective translation of information to activity.
- **Advances in mechatronics**
  New energy efficient, highly responsive, miniaturized systems where mechanical and electronic aspects of robotics are integrated.
- **Insight in medical therapies and human behaviour**
  New insights in the human movements and behaviour, also scientific insights in therapeutic approaches are needed to improve the effect of robotic systems.

These technology themes will be discussed in the following sections. This will be less elaborative than the previously described application areas, because these themes are often object of research related to the more general research community of robotics.

5.2 Advanced sensory systems

5.2.1 General description
To be able to function in an optimal way, robot systems need information coming from the human object and/or information coming from the operating environment. When an increase in independence and autonomous operation of the robot system is more desirable, information on the environment becomes very important. It is clear that advances in sensory systems are driving this kind of applications, especially in healthcare. Not only further miniaturization of sensors enabling its use (costs and size), but also further improvements in e.g. chemical, optical and biochemical sensing make new input and feedback mechanisms possible.

Main developments in sensor technologies important to the field of robotics for healthcare are:
- **Biomedical imaging**
- **Positioning and localization**
- **Biomedical sensors**
- **Biofeedback mechanisms**
- **Ambient intelligence**

5.2.2 Biomedical imaging
As the knowledge on the internal structure of a human body is important for surgery, biomedical imaging is an important technological area for R4H. Biomedical imaging is a broad specialization within biomedical engineering that involves the application of quantitative science and engineering to detect and visualize biological processes. Important sub-areas in biomedical imaging are the development of new imaging technologies and the application of these tools and knowledge to the study of diseases with the ultimate goal of aiding medical intervention.

- The development of new imaging technologies in this area is quite significant, because of the more general use of biomedical imaging in large medical systems. Well known examples are scans with radiography, magnetic resonance, computed tomography and nuclear medicine. Especially the integration of several techniques and computer processing is of importance.
- For the R4H domain, these developments are of importance because of their guiding opportunities. Both run time guidance of surgery, as well as guided robotised surgery benefit from these developments. An example is guided brain surgery where a surgeon uses virtual images, to make the best plan to enter the brain and remove the tumour, avoiding important brain structures and blood vessels. (National Cancer Institute, 2007).

In the robotic domain, robots are also developed to operate in MR environments.

5.2.3 Positioning

For many robotic systems, the localization of the system is of crucial importance. For mobile robots it is important that they can find their way in their environment. Nowadays we are watching the breakthrough of navigation systems for cars, bicycles and walking. Outdoor navigation systems are mostly based on the GPS (Global Positioning System) while the new Galileo system will significantly improve accuracy. However, most applications will be used inside buildings (hospitals, in-house, in a room) and in the vicinity of buildings. GPS based systems are not well suited for these applications because of distortion and loss of signal in buildings. Research for inside navigation focuses on intelligent systems having pre programmed knowledge of the environment. New developments in this area are (A. Huhtala1, 2007):

- WLAN devices
- 'Pseudolite' Global positioning systems
- RFID tags
- Radio trackers
- Blue tooth
- Video tracking/image analysis

Most of the systems are not yet fully optimized and enhancement of resolution and counteracting distortion of systems are key challenges.

Another crucial research area is the localization of devices in the body. Small devices inserted in human objects (e.g. the endoscopic capsules) need to be localized to build up a systematic image of the object. This localization is difficult due to the resolution needed and signal distortion. A system like GPS has a resolution of about one meter and can hardly penetrate the human body. This area is still very much under development. Some technologies mentioned are MRI based and use high frequency-band radio telemetry.

5.2.4 Biomedical sensors

Implanted biomedical sensor devices have the potential to revolutionize medicine. Smart sensors, which are created by combining sensing materials with integrated circuitry, are already being considered for several biomedical applications. Important research areas are the development of micro sensor systems for biomedical artificial prostheses and micro-machine nano-robot systems. These devices require the capability to communicate with an external computer system (base station) via a wireless interface.

- A current version of the artificial retina prosthesis and cortical implant is under development. The development team is assembled by a variety of disciplines: Ophthalmology, Neurosurgery, Computer Networking, VLSI, and Sensors to develop the novel solutions needed to make artificial vision for the visually-impaired a reality. A novel approach was adopted to providing a complete system for restoring vision to visually-impaired persons – from the signals generated by an external camera to an array of sensors that electrically stimulate the retina via a wireless interface. (Schwiebert et al, 2002)
- Autonomous micro machines that can explore the interior of organisms without being physically connected to the outside world are developed. The efforts integrate the past research in robot control using computer vision feedback, MEMS, deposition of permanent magnetic materials for the fabrication of microsystems, and the manipulation of deformable objects into wireless, magnetically guided microrobots (microsystems). The goal for this kind of applications is to perform delicate microsurgery and drug delivery in difficult to reach locations, such as the eye, brain or other organs (Institute of Robotics and Intelligent Systems, 2007).

The limited power and computational capabilities of smart sensor based biological implants present research challenges in several aspects of wireless networking due to the need for bio-compatible, fault-tolerant, energy-efficient and scalable design. Furthermore, embedding tele-sensors in humans adds additional requirements. For example, the wireless networking solutions should be ultra-safe and reliable, work trouble-free in different geographical locations (although implants are typically not expected to move: they shouldn't restrict the movements of their human host), and require minimal maintenance. This necessitates application-specific solutions which are vastly different from traditional solutions.

5.2.5 Biofeedback mechanisms

The feedback of the consequences of robotic activities to the user enhances its control. In the healthcare, biological feedback is important because it is essential input for robotic systems. Some examples of parameters that are needed as feedback information are temperature, muscle activity, movement, chemical & biochemical concentrations and other life signs.

Developments in this area can be seen as a result of nanotechnology, both from the perspective of nano-electronics and MEMS, as well as nanotechnology based chemicals for e.g. catalysts and smart materials. Also important are the increasing knowledge about the human body and its properties and fast processing of information due to computer power and software developments. The main developments in biofeedback systems are:
- Increased speed and accuracy in biofeedback
- Materials with integrated electronic sensors (wearable sensors in textiles)
- Use of new polymers and polymer materials with sensor functionalities

5.2.6 Ambient intelligence

For mobile robots it is important that they can find their way in their environment. For a number of robot applications it is necessary that the robot can recognize objects in its environment: walls of and objects in a room, persons, etc. Obstacle detection and object identification are important areas for ambient intelligence.

- Obstacle detection for avoiding is based on reflection concepts with infrared sensory systems, ultrasound sensory systems, etc..
- Object identification. In a number of instances it is not enough to recognize the type of object but also the identity (the person, the number of a room or of a product). Robot recognition can be facilitated greatly if the environment and objects in the environment contain easy recognizable clues. A number of technologies have already been developed mostly for other goals like bar-codes. At this moment a completely new generation of "smart tags" is being introduced like Radio Frequent Identification (RFID). Object identification by robots for healthcare can benefit from these new technologies.

5.3 Advanced Human-machine interfacing

5.3.1 General description

The connection between the human user and the device (robotic system), often referred to as the HMI (human machine interface), is a crucial part of robotic systems. The added value depends highly on the operation of this connection. It is clear that if a keyboard of a computer is not responding quickly enough to the keystrokes of a user, the computer does not work properly.

From the system perspective the HMI provides input coming from the user, and from the user perspective it enables the user to get feedback from the robot system. Input can be discrete (switches, keypad, speech commands) and proportional (joystick, turning knobs, steering wheels, muscle signals, brain signals). Of course, input signals can also be generated from sensors mounted on the robot system, however we will regard these as part of the robot system itself. Examples of feedback are: the actions of the system (response), displays (text, graphical), generated sound (e.g. speech), tactile feedback or haptic feedback.

The developments in HMI are one of the most important part of the overall developments in Robotics. Like in other innovations, societal acceptance and user friendliness of the system are crucial to the actual use. In other words, the technology can be as sophisticated as can be, but the actual use is often dominated by barriers in the HMI. The major developments aim at:

- **Vision sensory systems**
- **Advanced tactile sensors**
- **New input concepts**
- **Enhanced System responses**
- **User friendliness of interface concepts**

5.3.2 Vision sensory systems

As humans rely heavily on their vision system in daily functioning, the outside world contains numerous visual cues suitable for steering operation. However, the human vision system is a very complex system relying heavily on cervical processing of incoming visual information. Artificial vision systems will need to be able to perform comparable processing of visual information in order for visual sensors to be effective. Matching human processing is today not the aim of vision sensors. Effective combinations of different types of visual sensing in combination with processing capacity are under development. Areas under investigation are artificial stereo vision and more "classical" 3-D camera systems.

- *Artificial stereo vision*. In human vision, spatial information in general is based on two methods – analysis of the content of the seen scene as well as comparison of the two images by the right and left eye. For "artificial" stereo vision, the above mentioned analysis of images is hard to realize. For such an algorithm, the image system would have to support stable and fast object recognition in a first step which is not realistic with current available calculation performance. The second method – using stereo disparity effect – is the basic strategy for computational stereo vision.
- The group of *3-D TOF camera systems* can be seen as interesting alternative to "classical" stereo imaging – offering high-resolution 3-D image data in real time. These systems are based on the time-of-flight (TOF) principle and work with a modulated infrared light source. The emitted light pulses are reflected by the objects in a scene and travel back to the camera, where their precise time of arrival is measured locally in each "smart" pixel of a custom image sensor. In contrast to conventional cameras, such a camera thus not only determines the local brightness in the scene, but also the complete distance map, i.e. the 3-D model of its environment.

5.3.3   Advanced tactile sensors

Tactile sensors are important devices within the robotics industry. They provide the linkage between "touch" of the user and the device. Robotics are expanding to minimally invasive surgery applications and the lack of tactile feedback in the currently available endoscopic and robotic tele-manipulation systems represents a significant limitation. A need has arisen for the development of surgical instruments with integrated sensors for tactile feedback. These developments will for example be used to improve minimally invasive surgery in cases where physicians rely on endoscopes. It could also help robots grip objects by allowing them to "feel" an object with great sensitivity.

The underlying technological elements are often based on MEMS, opto-electronic systems, nano particle polymers, or piezo-electro systems. Some examples are:

- Advanced tactile sensors with high spatial resolution can be efficiently fabricated using micromachining technology (MEMS). Micro-Electro-Mechanical Systems (MEMS) is the integration of mechanical elements, sensors, actuators and electronics on a common silicon substrate through micro fabrication technology. MEMS based tactile sensors are already applied in surgical instruments, such as sophisticated endoscopic tools.
- Nano particle film could guide surgeons' tools and help robots grip. Researchers have created a thin-film tactile sensor that, in some ways, is as sensitive as the human finger. When pressed against a textured object, the film creates a topographical map of the surface, by sending out both an electrical signal and a visual signal that can be read with a small camera. The spatial resolution of these "maps" is as good as that achieved by human touch.

5.3.4   Input concepts

Connecting humans to the robotic system is usually done by external devices, like a computer screen or joysticks and data gloves. However, the use of biomedical sensors introduces a more direct way of connecting the user to the robotic device. Several principles are researched at this moment, but two in particular; EMG control and brain-computer interfaces (BCI).

EMG signals are often used as interface between the user and his/her upper or lower limb prosthetic device. The purpose is to interface and interact with the nervous system to improve control of a powered prosthesis and provide sensory feedback to the user. This new high performance interface results in more natural movements of existing myo-electric prostheses. EMG recordings are possible by surface sensors or by implanted technology. The use of implanted technology will greatly simplify system donning by the user and overcome the inherent limitations of surface EMG recordings. The use of 4-8 EMG recordings and a more sophisticated pattern detection algorithm can provide a much more transparent and effortless control interface for the user that will allow at least three degrees of freedom to be controlled simultaneously.

Brain Computer Interfaces (BCI) have been developed. Cerebral electric activity is recorded via the electroencephalogram (EEG). Electrodes, attached to the scalp, measure the electric signals of the brain. These signals can be amplified and transmitted to a computer, which transforms them into device control commands. The crucial requirement for the successful functioning of the BCI is that the electric activity on the scalp surface already reflects motor intentions, i.e. the neural correlate of preparation for hand or foot movements. The BCI detects the motor-related EEG changes and uses this information, for example, to control arm and leg prosthesis. Besides achieving prosthesis by this means, it is also possible to operate all kind of devices which are connected to the computer. Such a communication can even be realized via the internet.

Recently, Man-Machine-Interfaces connecting the nervous system to the technical system, gain more and more in importance (PNSC: Peripheral Nervous System Control; CNSC: Central Nervous System Control).

5.3.5 *System response*

New developments in interface tools focus on opportunities for new system response. Haptic and tactile feedback systems are often mentioned.

An innovative example of a haptic feedback concept uses the so called CyberGrasp, a lightweight, force-reflecting exoskeleton that fits over a CyberGlove® and adds resistive force feedback to each finger. With the CyberGrasp force feedback system, users are able to feel the size and shape of computer-generated 3-D objects in a simulated "virtual world." Grasp forces are produced by a network of tendons routed to the fingertips via the exoskeleton. There are five actuators, one for each finger, which can be individually programmed to prevent the user's fingers from penetrating or crushing a virtual solid object. The device exerts grasp forces that are roughly perpendicular to the fingertips throughout the range of motion, and forces can be specified individually. The CyberGrasp system allows full range-of-motion of the hand and does not obstruct the wearer's movements.

To correctly master a system, the user needs an uninterrupted flow of feedback. This feedback is usually delivered through the visual channel. When the visual channel is highly loaded during the control of a complex task, the benefits of simultaneous vibrotactile feedback can be of advantage. Vibrotactile response can function as a valuable feedback modality with reliability comparable to the classical visual feedback. It feels very natural for control purposes. As studies have shown that our ability to manipulate objects heavily relies on the contact, haptic and tactile feedback systems prove to be of high importance for the use of robotic systems. Building a user-transparent tactile feedback system is a difficult research problem, since current and

near-term actuator technologies do not provide the fidelity needed to produce realistic sensations. E.g. the use of vibrotactile feedback is research for further use

5.3.6   User friendly interface concepts

A very important part of the interface is the interface control concept. This is the concept for interaction between user and system: the way the system has to be controlled (input) and the way the system responds (feedback). Interface control concepts can be optimized by applying intuitive control and individual adaptability. Not only for specialists and care persons, making use of robot systems, but especially for persons with motor as well as cognitive problems, user friendly interfacing is a field of investigation and important progress is still being made. Important new concepts can be seen both in the field of software approaches and new interface tools.

- *new interface tool*
  An example of a new interface tool is surface computing. It is a major advancement that moves beyond the traditional user interface to a more natural way of interacting with digital content. Microsoft Surface™, Microsoft Corp's first commercially available surface computer, breaks down the traditional barriers between people and technology to provide effortless interaction with all forms of digital content through natural gestures, touch and physical objects instead of a mouse and keyboard.
  Although surface computing is a new experience for consumers, over time Microsoft believes there will be a whole range of surface computing devices and the technology will become pervasive in people's lives in a variety of environments. As form factors continue to evolve, surface computing will be in any number of environments (schools, businesses, homes) and in any number of form factors (part of the countertop, the wall or the refrigerator).

- *software approaches*
  New software approaches focus on the increase of simple interactive programs. Mostly the user has to select from command structures (often menu's) and/or give control signals to force the system to generate a certain action. Developers strive for user friendly interfacing concepts, like more intuitive, intelligent and flash oriented interfaces. Less information is presented and the software will be smart and assist choosing. An important development is the introduction of gaming elements to increase the "fun" factor in treatments. From the surgical side, 3-D is further developed.

The main challenge for advanced Human Machine interfaces is to deal with user acceptance in the use situation. Use of supporting technical systems in daily life can be difficult to accept and the need to use "extravagant" interface system will be a serious threshold. It can be reason enough for users to reject a system all together, regardless of its added value. Certainly when systems are developed for small user groups e.g severely impaired users, production series will be very small and as a consequence costs will be enormous.

Although interface development has a long tradition it is still a developing field in which intuitive control concepts need to be developed or optimized. Developments will be accelerated once mainstream developments will emerge that can be adopted to healthcare applications.

5.4   Mobile energy systems[7]

5.4.1   General description
One of the essential elements of a robot is the power unit. Next to enabling mechanical movement, a robust power supply is needed for the sensory and information processing systems. With static robots, this power supply can be organized using a static energy network, like our electricity grid. However, advances in miniaturization and the increasing need for supporting mobile functions are demanding mobile energy systems (including storage and generation of energy). The number of robots that can freely move, is increasing, but there can be also other reasons why connection to the main electricity grid is not feasible. The availability of mobile energy systems has proven to be a bottleneck in the actual use of robotics in general, and especially robotics for healthcare.

In the case of mobile robotics, advances in energy generation and storage systems (e.g. batteries) or a comparable solution are necessary. The consequence of using the current technology is that the energy consuming tasks can be carried out only for a short while before the robot needs to return to a charging station to recharge or replace/change its battery. Changing batteries requires extra batteries which can be costly or may not be feasible due to their operating area. For some tasks, the operation can become too short to be useful. For instance, robots are developed which can move and find their way in rough terrain, but walks into rough terrain are by nature not (meant to be) very short. Similar problems are encountered with other applications, like the energy provision of smart medical capsules or implanted devices.

For these reasons the availability of energy generation and storage systems (e.g. batteries) with a high ratio of energy content to weight or size can be crucial for the viability of specific robot applications. However, there are many other applications with probably much larger markets, where there is also a strong market demand for better energy systems.

Looking at the main innovation theme on mobile energy systems, there are several important areas:
- **Advanced mobile energy storage**
- **Micro energy generation systems**
- **Wireless energy transfer**
- **Energy efficient robotic systems**

The development of mobile energy systems is a more general technology area, as the technologies developed are also of use for e.g. the automotive industry (electric/hybrid cars) and the ICT industry (e.g. battery systems for laptops). However, these technologies are crucial for the development of mobile robotic systems. In the next sections, a global description of technologies which can stimulate the development in robotics is given.

5.4.2   Advanced mobile energy storage
The energy storage systems used in robots are often batteries. Looking at full electric cars, the driving range (and therefore use) is limited by the battery system. But also for robotic systems like exoskeletons, the actual use is limited by the amount of stored

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[7] In consultation with Menno Ros of ECN.

energy and is one of the most crucial bottlenecks. New generation energy storage systems are needed to enhance the use of robotic systems.

Much research is carried out in this field. The main types of energy storage systems are electric batteries, but also other technologies can be used to store electric energy, like ultra-capacitors. The development of these electric storage systems highly benefits from developments in nano-technology, leading for example to the Toshiba lithium-ion nano-battery, which is charged to 80% in 60 seconds and has an extended lifetime (99% after 1000 discharges). But also paper based ultra-conductors enable flexible batteries with fast energy charging/discharging properties.

In this field, the following developments can be considered of high importance to the R4H domain:
- Fast charging systems
- Next generation batteries (e.g. nano Lithium-Ion batteries)
- Ultra-capacitors;
- Paper batteries
- Hydrogen storage systems.

It is save to say that the developments of these technologies that are crucial to a large part of the field of R4H, will not take place in this domain. The developments will mainly take place within the framework of the developments of electric/hybrid cars and mobile ICT equipment.

5.4.3 Micro mobile Energy generation

Next to the storage of energy, the on site, mobile generation of electricity and direct mechanical energy is a sound alternative for the provision of energy to robots. Important developments in this area can be found in the automotive and adjacent industries, like hybrid systems and fuel cells, but the adaptation to the R4H domain still requires different needs (e.g. smaller and light weight systems). Therefore, also the computer industry is an important driving force towards micro mobile energy generation. Traditionally, the development of robotic systems will make use of these advancements and adjust them to their own special needs.

In this area, many different developments can be seen. On one hand, the development of the hybrid car stimulates new systems based on combustion engines (e.g. hydrogen combustion engines). On the other hand, the fuel cell seems like an interesting alternative for batteries, although the weight of the storage tank for hydrogen and the safety (perception) are still problems (reliability, durability, etc.). Next to these relatively large energy systems, a new field is emerging to provide relatively low energy outputs based on energy harvesting, or scavenging, using light, thermal energy (wrist), biochemical energy and/or in vivo power generation.
The following developments can be seen as important to the field of robotics:
- Micro fuel cell systems, also developed for mobile phones and laptops;
- Energy scavenging/harvesting, especially for stand alone sensory systems;
- Thin Film Solar Cells, to provide cheap solar energy;
- Micro turbines, for small mobile vehicles;
- Pneumatic energy systems (e.g. based on gas generating liquids like hydrogen peroxide);
- Hydraulic systems, for heavy duty robotic systems.

As most of these developments are also needed in more extensive markets (billion dollar markets), they will not be developed in the field in R4H.

5.4.4 *Energy efficient robotic systems*

The use of energy by robotic systems can be reduced using different technologies and approaches. This will enhance the working lifetime of mobile robotic systems, so the functionality is increased.

The opportunities for the reduction of energy usage by robotic systems is divers. On one hand, the software can be adjusted to minimize energy consumption using more efficient procedures. Also the communication can be optimized from the perspective of power consumption. Another approach is the (re)generation of energy using the movement of the robot. These examples show some of the opportunities for the reduction of energy consumption to enhance usage.

The following technological developments are considered of importance to this technological theme:
- Software optimization for reduction of power consumption of the processing unit;
- Adjustment of the control wiring of the robotic system, using digital and one wire systems
- The use of low energy consumption external communication;
- Assessment of optimal navigational routes (optimal planning and movements) for movement using enhanced data imaging and GPS
- (Re)generation of energy using gravitational energy during movement.

5.4.5 *Wireless energy transfer*

A way to deal with the limited power of mobile robotic systems, is to wireless recharge the batteries constantly. The developments in this area are still insufficient for robotic systems, but the recharging of electrical toothbrushes shows practical possibilities.

In this field, the following developments can be considered of high importance to the R4H domain:
- Electromagnetic resonators (Witricity)
- Electro magnetic induction
- Power beaming, using light
- Focused electromagnetic beams.

The use of these technologies is still in the early stages, although some important breakthroughs are made in the field of Witricity (by MIT). At this moment, it is possible to wireless transfer around 60W by this technology, enabling completely wireless computing.

5.5 Control systems for complex mechanical movement

5.5.1 *General description*

An essential part of robots is the mechanical movement of the system in a controlled manner. In general two types of control are possible. Supervised control of the robot is possible by input signals coming from a human operator and automatic control by signals coming from sensors scanning the environment. Robot movements in healthcare are mostly a combination of both types. Mechanical robot movements contain lots of

automatic pre-programmed control, however often under supervision of a human operator.

This division of control functions well as long as the human operator has the required control abilities. Applications in which the movement to be controlled is too complex for a human operator or the abilities of specific operators are too limited additional types of control are required. The contribution of the robot system increases to the level in which the systems can overrule the human operator in specified circumstances. This concept introduces not only engineering challenges regarding smooth operation and safety but also ethical and liability issues. These developments were introduced in many types of transportation (i.e. aviation, railways, large sea vessels and the automotive industry) and today there is an ongoing discussion on how to implement this.

Especially related to robotics for healthcare two major developments will be further described:

- **Advanced software for robotics**
- **Shared control**
- **Adaptive control**

5.5.2 *Advanced software for robotics*

Software, or more specifically Artificial Intelligence, can be regarded as a major enabler for robotic systems as well as for intelligent prosthesis. Important capabilities for mobile robots like data acquisition, information processing (e.g. of sensor data), orientation/navigation, pattern and speech recognition, action planning, safety mechanisms and the control of actuators and effectors are all guided by software. As robots in healthcare interact with humans, especially disabled and ill persons, such platforms have to operate safely in noisy environments and need to "anticipate" possible changes in the environment. In 2006, the first unmanned robotic heart surgery was performed in Italy under human surveillance by Carlo Pappone, head of Arrhythmia and Cardiac Electrophysiology at Milan's San Raffaele University. This robot was fitted with learning software and gathered its 'knowledge' from the input of 10000 operations and several human experts. However, this, as well as other such applications, still represent single trials and are far from mainstreaming. Software design and development still presents a bottleneck problem for robotics. As Bill Gates also mentioned, there does not exist a standard operating system for robots yet, which would allow applications to run on different devices.

Main developments in software development and design, important to the field of robotics for healthcare, are:

- Programming languages for robots
- Algorithms based on biological data processing for pattern recognition (images, speech)
- Open Source software projects for robotics and medical data analysis
- Algorithms especially designed for neuroprosthetics and BCIs
- Learning algorithms

Software development itself necessitates many different steps for development and testing, and robots performing such specialized tasks like surgery often need customized software. As the history of Artificial Intelligence suggests, many of the predictions and promises have not been fulfilled. Artificial Intelligence has still not

been successful in providing robots with human-like understanding and flexibility, whereas learning algorithms and pattern recognition software make visible progresses.

Software development is an extremely complex and error-prone task, but especially in the area of robotics in healthcare, securely running software is crucial for safety. This fact may add an additional barrier towards the broad diffusion and acceptance of robots in this area and still provides an advantage for humans. Because of this, most robotic systems used in the medical field still necessitate human controllers which are superior in flexibility, pattern recognition as well as foresight, planning and experience.

Software innovations, i.e. innovations with regard to how computers are programmed (e.g. programming languages for robots, special algorithms for neuroprosthesis and BCIs etc.) should get more attention in general evaluations and innovation policy.

Advances in neuroscience and neurobiology have also influenced the approaches to software design by increasingly shifting attention towards biological concepts, e.g. by developing genetic algorithms or imitating neuronal processing for improving pattern recognition and data analysis.

More and more software is developed in open source projects, where the public gets involved in modifying and improving freely distributed software. The open-source and open-platform approach is even supported by large companies like Microsoft and Apple as well as by the 5th and 6th EC Framework Program. For managing medical records and data administration, the open source medical record software GNUmed has been distributed. Also for robot development in general, there is a huge array of open source software available and even the Japanese home-/care-robot "Wakamaru" is Linux-based.

Software and Artificial Intelligence are so important for the development of Robotics, that these technologies would merit a separate research. This section is confined to some of the major issues in these technologies.

5.5.3 *Shared control*

Controlling devices can be challenging because of a mismatch between user ability and the required system control. One way of dealing with this complexity is to share the control between the user and the system. The user makes the strategic operating decisions and the system takes care of the execution of this strategy on task level. Because of the limited abilities of their users, powered wheelchairs and other motorized mobility aids could benefit from shared control. However also in surgery and rehabilitation training shared control can be applicable.

- *Shared control, estimating user desires*
  Several research groups have equipped existing mobility devices with additional sensing and computing power in order to ease navigation and to reduce the number of accidents. To do so the computer should know which manoeuvre the user desires to execute. Traditional wheelchair interfaces provide no cue on user strategic intention only on task level. Consequently, the user's navigation plans are uncertain and should be estimated. Based on the estimated plans, the computer decides to which degree users should be assisted. In effect user and computer share control over the assistive robot. For example in the European MOVEMENT project shared control is being developed within a modular mobility concept up to prototype level. (K.U. Leuven, 2006)

- *Shared control between haptic devices and human operators*
  Virtual environment-based robotic training systems with haptic (force) feedback have not fully exploited the capabilities of haptic display devices. The simulators primarily focus on displaying the physical laws of equivalent real-world systems in order to re-create realistic environments for tasks. Recent research efforts at Rice University have focused on the design of perceptual overlays in virtual environments that are active rather than passive. Passive virtual fixtures have been the primary perceptual overlay in haptics, and have been used extensively as "virtual rulers" in tele-operation environments to improve operator performance of pick-and-place tasks. Active assistance in the form of shared control between the haptic device and the human operator has the potential to elicit even better performance in virtual and remote environment interactions, and also has implications for improving training effectiveness. The intended applications include stroke rehabilitation and training for pilots, manufacturing, and surgery. (Rice University, 2006)

Shared control may serve as a tool to facilitate control task difficult for human operators. Since safety, liability and ethical issues are of utmost importance here commercial exploitation of such systems will require further development.

5.5.4 Adaptive control
The most recent class of control techniques to be used are collectively referred to as adaptive control. Although the basic algorithms have been known for decades, they have not been applied in many applications because they are calculation-intensive. However, the advent of special-purpose digital signal processor (DSP) chips has brought renewed interest in adaptive-control techniques. The reason is that DSP chips contain hardware that can implement adaptive algorithms directly, thus speeding up calculations.

- *Adaptive control for compensating environmental variations*
  The main purpose of adaptive control is to handle situations where loads, inertias, and other forces acting on the system change drastically. Adaptive control can help deliver both stability and good response. The approach changes the control algorithm coefficients in real time to compensate for variations in the environment or in the system itself. In general, the controller periodically monitors the system transfer function and then modifies the control algorithm. It does so by simultaneously learning about the process while controlling its behaviour. The goal is to make the controller robust to a point where the performance of the complete system is as insensitive as possible to modelling errors and to changes in the environment. Adaptive control concerns modification of the control rules on the basis of changing parameters or conditions. For example, as an aircraft flies, its mass will slowly decrease as a result of fuel consumption: control rules need to adapts by itself to such changing conditions. Adaptive control contrasts robust control since it does not need a priori information about the bounds on these uncertain or time-varying parameters: robust control guarantees that if the changes are within given bounds the control rules need not be changed, while adaptive control is precisely concerned with control rule changes.
- *Adaptive haptic feedback*
  In healthcare such control systems are rare. Adaptation to haptic feedback on the controls during tele-surgery is an example with the tele-surgeon (human) included in the system (John Hopkins University, 2004). A system requiring adaptive

control is the manipulator arm that is ordered to pick up a bottle without
information on the content of the bottle. It could be empty or full, light or heavy.
Force execution of the arm needs to be adapted to sensed feedback on the weight
of the bottle (IUT, 2006).

As with shared control systems, adopting this kind of control within the realm of
healthcare robotics needs to be developed up to a level of exceptional acceptable
reliability.

5.6 Advances in mechatronics

5.6.1 *General description*

Mechatronics is the synergistic integration of mechanical systems, electronic systems,
control systems and computers through the design process, from the very start of the
design process. Integration is the key element in mechatronic design, as complexity has
been transferred from the mechanical domain to the electronic, control and computer
software domains. Mechatronics is an evolutionary design development that demands
horizontal integration among the various engineering disciplines as well as vertical
integration between design and manufacturing. It is the best practice for synthesis by
engineers driven by the needs of industry and human beings. It is clear that robots
include many mechatronic components, as these provide the functionality to translate
information into action.

Horizontal integration in mechatronics concerns the overlap of the four engineering
disciplines resulting in three research themes: electro mechanics, control/drive
electronics and digital control systems. Control/drive electronics will be part of
"Energy saving systems" and digital control electronics will be part of "Control
systems for complex mechanical movements". The electro mechanic theme will be
discussed in more detail in this section and will, related to robotics, be subdivided into
the following technological areas:
- **High performance actuators**
- **Artificial muscles**
- **Grippers**
- **Locomotion of small devices**

5.6.2 *High performance actuators*

Actuators are (by definition) essential for the functioning of robots. They actuate or
drive the different movable parts of the robot by exerting forces on them. They make
the system move and force it to perform actions. Although electric rotary actuators like
DC motors and step motors are most frequently applied in robot systems, also research
is carried out on pneumatic and hydraulic powered actuators. Research is especially
concentrating on the actuators getting higher velocity, more accurate, lightweight, more
effective, smaller and cheaper.

Some examples of new high performance actuators relevant in connection to robotics
are:
- *High Power Permanent magnet DC Motor*
  Permanent Magnet DC Motors offer good efficiencies and a high peak load
  through the use of premium ferrite materials and optimized magnet systems. The
  steel tube housing with externally accessible brushes provides for a rugged, high-
  quality design.

- *Pneumatic Step Motors*
  Directional rotary motion of discrete displacement is achieved by sequentially pressurizing the three ports of this type of motor. Pulsed pressure waves are generated by a remote pneumatic distributor. The motor assembly includes a motor, gearhead, and incremental position encoder in a compact, central bore construction. A special electronic driver is used to control the new motor with electric stepper indexers and standard motion control cards.
- *Polymer based actuators*
  Electroactive polymer based actuators can be used to develop human-like facial expressions in sociable robots. They could reduce the mechanical complexity of the robots and the robots' weight and power requirements, potentially leading to robots that are more robust, more easily manufactured and ideal for autonomous mobility (Hanson, 2003)
- *MEMS based actuators*
  The production of micro electronic mechanical systems through chips technology based manufacturing methods, create the opportunity to on one hand further miniaturize the actual actuators and on the other hand reduce costs.

Actuators play several roles in research. Actuators can be bought as ready made components (as an embodied result of earlier technological research) and used both for building robots for the market and for experimental robotic systems. At the same time, however, the present generation of actuators is also an object of research to obtain new generations of actuators with higher performance or higher price-performance or weight-performance ratio.

5.6.3 Artificial muscles
Robots have been the topic of fantasy for decades as walking, talking, even running humanoids materialized in books and on the screen. But while robots reached the broadest potential in manufacturing, one major impediment has remained for robots penetrating the service and personal markets - the cost and energy inefficiencies of conventional robots. While the industrial market made significant strides in transitioning from the early hydraulic driven arms to electric motors in the 1980's (fixed position, connected to the electricity mains), heavy and inefficient electromagnetic actuation remains the convention not only for robots but for mobile devices in general.

A new research topic is the field of artificial muscle which in principle is a new actuator which aims to fill this gap. The applications for electro artificial muscles are nearly endless. Virtually all existing electromagnetic actuators are targets for replacement with lighter, smaller, lower cost and more power efficient actuators. The initial applications are focused on the smaller, lower stroke and lower force applications than what will be needed for true humanoid robotic applications.

Examples of artificial muscles are:
- *Universal Muscle Actuator (UMA)*
  UMA is the basic building block for generation of EPAM (Electrostrictive polymer Artificial Muscle) actuators. The basic EPAM architecture is made up of a proprietary dielectric elastomer that is coated on both sides with another expandable film of a conducting electrode. When voltage is applied to the two electrodes a Maxwell pressure is created upon the dielectric layer. The elastic dielectric polymer acts as an incompressible fluid expanding in the planar directions. Electrical force is converted to mechanical actuation and motion.

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A significant advantage EPAM has over electromagnetic actuators is energy density, that is, more energy created per unit mass of the actuator itself. (Artificial Muscle Incorporated, 2007)

- *Artificial robot system driven by soft actuators*
  The annelid (worm) provides a biological solution of effective locomotion adaptable to a large variety of unstructured environmental conditions. The undulated locomotion of the segmented body in the annelid is characterized by the combination of individual motion of the muscles distributed along the body, which has been of keen interest in biomimetic investigation. To mimic the unique motion of the annelid, a novel actuation method employing dielectric elastomer is developed. The proposed actuation method provides advantageous features of reduction in size, fast response and ruggedness in operation. By serially connecting the actuator modules, a micro-robot mimicking the motion of the annelid is developed and its effectiveness is experimentally demonstrated. (Kwangmok Jung et al, 2007)

This category of devices is not yet incorporated in robots for healthcare related end-users. Expectations for practical applications are high, but with a long time horizon.

5.6.4 Grippers

The most critical aspect of any robotic arm is in the design of the manipulator or gripper. A robotic arms usefulness and functionality is directly related to the arms ability to sense and successfully manipulate its immediate environment. Robotic end effectors are quick-change mobile robotic systems that can deploy tools. They are also known as robotic accessories, robotic peripherals, robotic tools, or end of arm tooling (EOA). A robotic end effector is an object which when connected to a robot flange, such as a wrist, serves the desired functions of the wrist. It is used to pick up items and can be customized for specific applications.

Some examples of types of robot grippers, which are the result of recent research are:

- *End-Of-Arm-Tooling*
  A wide variety of standard modular EOAT components is available on the market today. This makes assembling of an EOAT reasonable and cost justified. Costs can be saved by buying components and building an EOAT for the simpler applications. EMI-EOAT offers a full line of robotic End of arm tooling components as well as free engineering Design Assistance. Products include framing, Quick Changers, grippers, vacuum cups, suspensions, actuators, nippers, sensors, pneumatic valves and more, from a wide range of popular manufacturers
- *Cyberhands*
  Cyberhands mostly contain five fingers. In order to improve the hand grasp functionality and its anthropomorphism, all the phalanges have a cylindrical shape without sharp edges. Their dimensions are close to the anthropomorphous ones.

This technology area is still largely under development. Although there are examples of products commercially available on the market, their functionality is limited. Of more advanced products some first demonstration models are available, but no actual commercial products are on the market that can perform to the complex demands given in the R4H domain.

Mechatronics form the traditional basis of robotics. The areas of research described in this paragraph comprise the traditional elements that distinct robots from ICT systems.

Being at the core of robot development evolved with other research domains such as advanced materials, miniaturalization and manufacturing methods. Many developments resulting from this tradition were never intended for implementation but did serve the development of the domain. This process is still ongoing and will remain a source of inspiration and a facilitator for future development of robot systems actually implemented.

5.6.5 *Locomotion of small internal devices and micro grippers*

Especially in the field of encapsuled endoscopy, the movement of devices in the body is important. Together with the tools for these miniature devices, the development intra body devices are important to increase the functionalities of the capsules towards biopsy and even surgical procedures.

Some interesting developments can be seen in:
- Making use of the peristaltic movement of the intestines
- External magnetic fields
- The use of micro paddles.

In the field of the micro surgical instruments for capsules some developments can also be seen. These include highly adaptive multi-actuator systems, driven by numerous identical single actuators connected in parallel and in series, a micro gripper for handling and assembling of complex hybrid micro systems and a micro actuator system in medical tools for the percutaneous resection of aortic valves. Especially in the manufacturing side of these tools some important developments are crucial, like laser cutting and wet chemical etching. Also an important technological challenge lies in the simulation of both manufacturing and functioning (Leester-Schädel, 2008).

5.7 Insight in medical therapies and human behaviour

5.7.1 *General description*

Many robotic systems have straight forward procedures embedded in the control unit. However, for robotic applications in healthcare, often a more fundamental knowledge is needed to develop these procedures. Specific robot functionalities for diagnosis, medical intervention, rehabilitation treatment, professional care and individual assistance require a more theoretical base from the medical perspective. The benefit of humans is the ultimate goal of development of medical robotics. Potential users of these systems are patients, handicapped individuals, surgeons, medical staff, caregivers, etc. Unfortunately, the benefit of the user does not mean that robot system development in the healthcare sector will lead to actual application. Only a small portion of all developments enters the phase of testing and evaluation against use-related criteria. The evidence based evaluation of systems needs standardized protocols for evaluation of the application.

More specific it concerns:
- **Human perception of robot systems**
- **Systems and safety**
- **Human movement**
- **Understanding therapeutic mechanism**
- **Research protocols**

5.7.2 *Human perception to robots*

One of the major barriers to the actual use of robotics is their acceptance. This field is still not fully explored and is hindering the optimal use of robots to society. An example is the use of robot assisted remote diagnosis, where the replacement of a physical doctor by a robotic system is considered unwanted.

When people interact with robots in daily life, each individual has different attitude and emotion toward the robots, which cause different behaviour toward them. Thus the influences of attitudes and emotions into human–robot interaction, in particular, those of negative attitudes and anxiety which may directly affect behaviours toward robots should be investigated.

The following scientific challenges are examples that are considered important:
- What are the factors that influence the acceptance of patients for robotic systems?
- Which functionalities will be accepted by patients and which are not?
- How do these factors influence the shape of actual robotic systems?

5.7.3 *Systems and safety*

Safety is an issue in robotics because of the partial autonomy systems are supposed to have according to the definition. Robots systems operating autonomous in the direct environment or even in humans have a clear potential danger for the humans involved. Actions of the robot may be unintended harmful for human or simply contra-productive. Failure of the system or a discrepancy between actions required on the basis of the system senses and what is actually required may lead to dangerous behaviour of the system. In the design of systems a different approach must be taken regarding safety for industrial robots which operate in an human-restricted zone and for healthcare robots which operate in an environment with vulnerable humans per se. Many systems are therefore designed to do nothing unless specifically triggered to do something by a human operator (e.g. dead man switch). This makes, for instance, voice control potentially dangerous since it is not possible to keep on instructing the system continuously.

Existing standards for design of medical devices or assistive technology concerns device safety on a general level. There is no specific healthcare robot standardization yet. Specific safety issues coming with robotic devices are therefore not explicitly addressed (yet).

5.7.4 *Human movement*

As robotic systems are often connected to human mobility and movement, computer modelling and simulation of these aspects plays an increasingly important role in sport and rehabilitation. Applications are ranging from sport equipment design to understanding pathologic gait. Robotic systems like exoskeletons and intelligent prostheses make use of these models. The complex dynamic interactions within the musculoskeletal and neuromuscular systems make analyzing human movement with existing experimental techniques difficult but computer modelling and simulation allows for the identification of these complex interactions and causal relationships between input and output variables.

5.7.5 *Understanding therapeutic mechanism*

An important element to the use of robotic systems in rehabilitation is knowledge about therapeutic mechanisms. What procedures can have which effects on the patient?

However, often these mechanisms are not fully understood, leading to suboptimal use of robotic systems. Further knowledge will increase efficiency and effectiveness of robotized treatments.

An example of an investigated therapeutic mechanism is stroke. Stroke kills 150,000 Americans each year and is the third leading cause of death in the United States. In stroke, severe, irreversible brain tissue destruction occurs which results from extensive neuronal cell death. There are two types of cell death, necrosis and apoptosis. Apoptosis is an inducible process of gene-directed cellular self-destruction. Accumulated evidence shows that apoptosis plays an important part in neuronal cell death found in stroke. It is becoming increasingly clear that many cells display surface molecules known as receptors, some of which act to trigger apoptosis. Such apoptosis-inducing receptors play important roles in many disease processes, including possibly stroke. Therefore, determining the mechanism(s) by which such receptors induce apoptosis, and identifying novel apoptosis-inducing receptors, is likely to lead to more effective treatments for stroke.

5.7.6 *Research protocols*

Determining the effects of robots in healthcare is a complex issue. Evidence for actual added value of the systems is considered crucial and is presently a strong barrier for research and developments. Key is that systems can not be evaluated or compared to other systems.

Measuring the costs is clear as far as the unit of measurement is concerned but it can be difficult to quantify all costs or savings in monetary units (e.g. savings of reduced informal care). Also an integral, methodological approach to the analysis of benefits of the systems is important: research protocols are an important part.

In general, care technology is a developing field of expertise. Consensus on which outcomes to consider and how to relate this to costs is to be developed. For the robot related outcomes in this domain (such as QoL, social participation, satisfaction, independence, functional improvement, activity level and ADL task execution) it is a research domain requiring much progress before methodological sound outcome measurement can be performed.

5.8   Conclusions

In the introduction of this chapter a number of expectations were presented about the collection of research topics about the application for robotics for healthcare. By and large, these expectations have been confirmed.

After the project organization was set up and the data collection started, a large amount of data was collected on research topics which claimed relevance for the field of robotics in health care. A lot of the information could not be related to specific applications or even application domains.

Furthermore, most of these data were restricted to the technological aspects. Not much information was found about the way the later phases of the development trajectory would be carried out, which aspects would become crucial and the involvement of which stakeholder groups would become necessary. As a result, not much information was found on the overall feasibility of the applications in regular healthcare. Therefore,

it was not possible from this information to evaluate the importance of a specific research topic for the field of robotics for healthcare.

6   Roadmaps

6.1   Introduction: what is Technology Road Mapping?

Technology Road Mapping (TRM) is widely used in industry for planning technological research. Because of its success in industrial sectors, this methodology is also applied in other sectors nowadays. The basic idea of Technology Road Mapping is to develop a milestone planning to reach a specific destination (product, service, etc.). However, the destination could also be the solution to a societal issue, as is often the case in policy making.

In this study, an important aspect of TRM is that the actual final result is an ***application area*** that is to be developed within a ***societal context*** and is based on some crucial ***key technologies***. Therefore, the road maps distinguish between three layers:

- The final applications, or innovations, where the application of robotics in healthcare finds its practical use.
- The societal context that influences the shape of these innovations on the demand side. This is important because being an input to EU-policy, the societal needs of the Community should be addressed;
- The key technologies, being the (technical) supply side of innovations. This is important because the results of this study can be used in the further development of policy within the Framework Programme for Research and Technology.
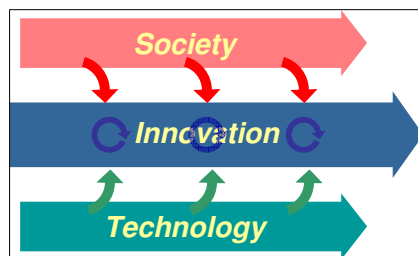
Figure 42: Road map layers.

These three layers make up the roadmap. Elements in the three layers are connected when one element needs another element at a lower layer to be realized. The various products and technologies can be prioritized and estimations are made of the periods (time-paths) when products could become available on the market and the periods when technologies have to be ready for incorporation in a robotic system.

The construction of the roadmaps was carried out in iterative rounds. The first material for the roadmaps was collected with desk research and a first round of interviews. The development of the first roadmaps was done in an interactive process with interviews, an internet forum discussion (see annex C) and an expert network survey. The analysis was elaborated more in depth in several case studies, in particular to analyze the role of the stakeholders, to get a grip on the factors that make an innovation a success or a failure and investigate ethical and legal issues. The final evaluation of the draft roadmaps was carried out during the evaluation workshop. Experts were invited to present keynote speeches and parallel sessions were held on several innovation areas. During these sessions also a roadmap diagram was constructed. In an interactive way the elements for the roadmap diagram were selected and the timing of the various elements was estimated. All the information and opinions collected during this whole process is synthesized in the roadmaps in the next paragraphs.

6.2   Selection of the innovation areas

Based on the research carried out, the field of robotics for healthcare was divided into five different innovation themes, linking them to the different activities in healthcare. Within these themes, 21 innovation areas were identified that can be regarded as important product/market combinations. The innovation themes and innovation areas are presented in figure 43.
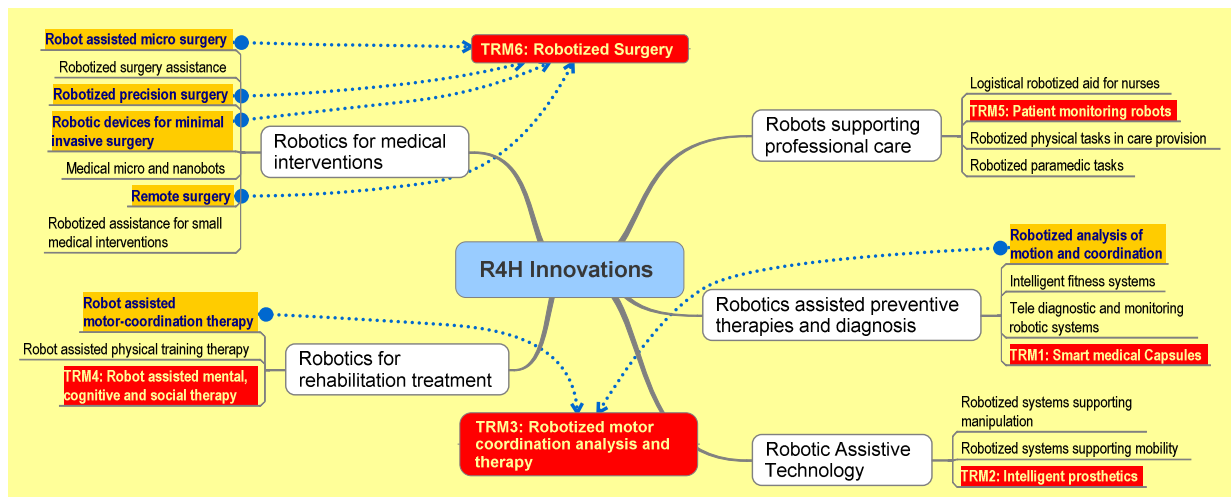
Figure 43: Innovation themes and Innovation areas in Robotics for Healthcare.

Robots supporting professional care addresses the support of professional care with logistical aid, monitoring patients, assisting medical personnel with physical tasks and small paramedical activities. Central in this area are the non-surgical and medical professionals.

Robotics assisted preventive therapies and diagnosis addresses the area of prevention and diagnostics, including innovation areas in pure medical environments as well as the private environment. Its focus is on using smart and intelligent systems for diagnosis, therefore also linking it to robotized assessment tools.

Robotic assistive technology focuses on the use of robots for the support of the disabled persons in their daily activities. This theme includes both robotized systems for support in working and domestic environments, as well as support for mobility. Another important innovation area is the field of intelligent prosthetics, replacing limbs.

The next innovation theme focuses on *Robotics for rehabilitation treatment*, dealing with the disabled through robot assisted therapies. Both physical and mental illnesses are covered.

Surgery is the central objective of the last innovation theme; *Robotics for medical interventions*. Here, the operation room is the focal area. Robotic systems can provide assistance with activities in this healthcare application.

The complexity of the field of Robotics for Healthcare makes it clear that it is not very productive to construct one roadmap for the entire field. It is much more informative to do this for more homogeneous subfields. In agreement with the EC a selection was made. The criteria were threefold:

- for pragmatic reasons, a relatively small number was chosen: six areas
- the six areas together should present a fairly representative picture of the whole field, but no effort was made to produce an exhaustive overview
- a good fit with the core mission of DG Information Society and Media.

The following innovation areas were finally selected (these are the areas in the red ovals in figure 43 on the previous page):

- **Smart medical capsules**
- **Patient monitoring robots**
- **Robotised motor coordination analysis and therapy**
- **Intelligent prosthetics**
- **Robot assisted mental, cognitive and social therapy**
- **Robotised surgery**

In the following paragraphs, road maps for these innovation areas will be discussed. After an introduction, the discussion will focus on the three key building blocks of a road map; innovation and application areas, their enabling technologies and the need for the innovations and applications. These building blocks were already discussed shortly in the previous chapters. In this chapter, we will look into them much more in depth. Developments in these elements are influenced by factors and by actors. Therefore driving forces and barriers (*factors*) will also be discussed as well as relevant *actors*.

6.3 Smart medical capsules

6.3.1 Introduction

Endoscopy is often used to assess the interior surfaces of an organ by inserting a tube into the body. The traditional approach is based on bringing a camera inside the body by using a (rigid or flexible) endoscope. The procedure is accompanied by considerable discomfort for the patient. New developments in miniaturization of sensors and actuators have lead to the development of miniature and wireless endoscopic micro capsules. Based on this platform, other functionalities can be developed, including the collection of bio samples, targeted drug delivery and even the performance of small operating procedures. The results are medical procedures with almost no discomfort for the patient, reduced efforts for medical professionals, improved medical information and less risk.

In figure 44 an overview of the innovation area is given, including the societal demand and related key technologies.
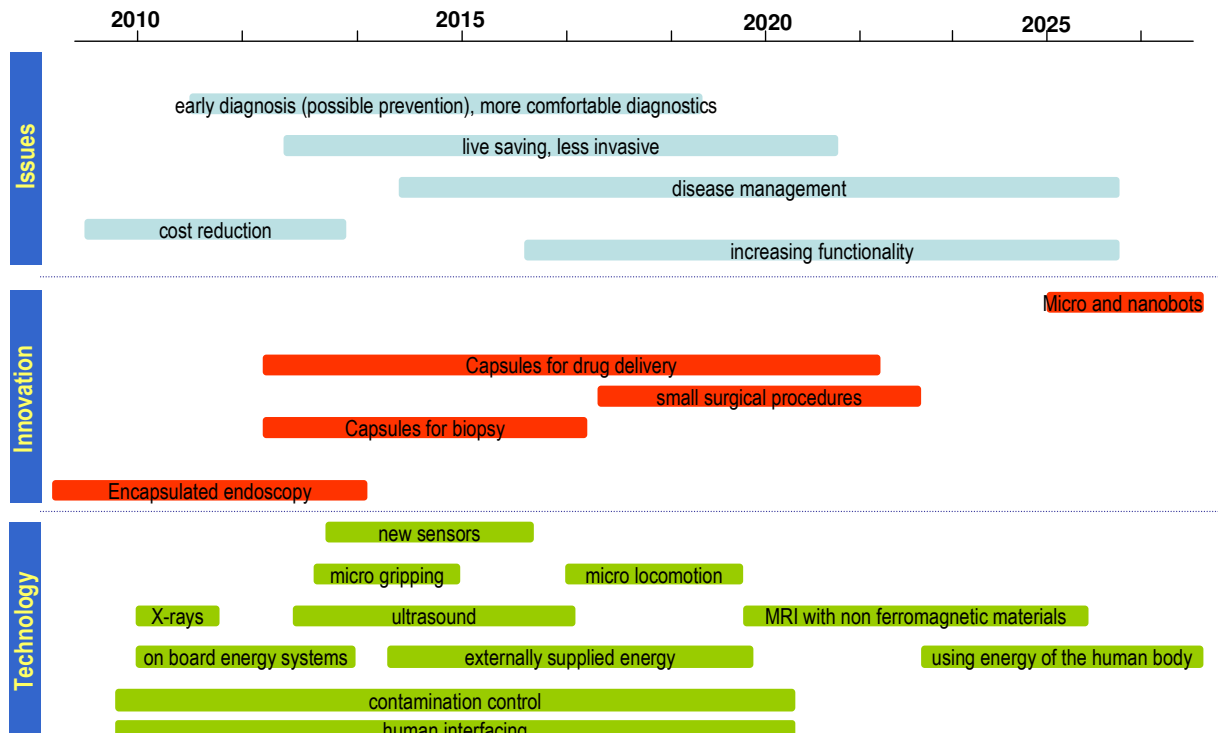
Figure 44: Road map of Smart medical capsules

In the following paragraphs, the applications will be explored and enabling technologies and societal needs will be identified. Besides these *factors*, the innovation area is also driven by a number of *actors*. These will be discussed in a paragraph on stakeholders.

6.3.2 *Innovation and application areas*

At the moment, the innovation area of smart capsules is still in its embryonic stage. Presently, there are only endoscopic capsules on the market. These capsules are equipped with small cameras and/or sensors that record data while travelling through the gastrointestinal tract (for instance pressure, temperature and pH). However, the early signs of new functionalities can be seen, including small medical procedures and drug delivery.

An important development which can be foreseen in the near future is the control of the movement of the capsule. Different techniques are being researched; giving the smart pill little hooks so it can clamp itself to a certain spot, moving it by an external magnetic force field or giving the capsule its own propulsion. To decide where the pill should go, the position, images and measurements of the pill should be available to the operator in real-time. As the functionalities of the "millibot" increase, it will be able to measure and be manipulated more and more. At first this will only be possible in the gastrointestinal tract. However the technique to move magnetic elements by an external force field and further miniaturization will at some point in the future also be available for the use of capsules in other body parts like blood vessels. For the immediate future, no robots are expected to be small enough to go there, but drugs and radiotherapy

elements with a little bit of magnetic material and a coating that dissolves could be delivered and activated at exactly the right spot.

The innovation area of smart medical capsules is basically divided into the following functional sub-areas:

- *Encapsulated endoscopy*
  This area focuses on setting a diagnosis using small capsules that include sensory devices to make images of the intestines. At this moment (2008), it can be considered an emerging market where some players are already commercially present.
- *Capsules for drug delivery*
  Drug delivery today is mainly based on taking pills, whose contents are fully spread throughout the body. Using smart capsules, the drug delivery can be targeted and more personalized. First, some relative large devices are expected for this smart drug delivery, but in the future, micro and nanobots will also enhance the functionality.
- *Capsules for small surgical procedures*
  Already, some capsules are being developed that can take small tissue samples. These micro-gripper facilitated micro-instruments enhance the functionalities of the endoscopic capsules. They will be able to perform small surgical tasks like taking a biopsy or removing unwanted tissue. In the future, this will be further developed towards more complex operations.

Micro and nanobots
Even further in the future, "microbots" and "nanobots" will become available. Because they operate on an entirely different scale they could change medicine rigorously. Individual cells could be examined and if necessary destroyed and DNA could be repaired. For the time being, however, these applications border on science fiction. Furthermore, they could experience serious competition from biotechnological techniques like genomics, proteomics and metabolomics.

The speed of the innovations in this area will be limited by the time it takes to implement and adjust to changes in a highly complex and a high risk field like medicine and healthcare. Once the technology is developed, it will take time to achieve a complete, usable and marketable product. Even after trials and approval, it will also take time for hospitals and medical staff to get used to simultaneously using a combination of different new products.

6.3.3   *Key technologies and research challenges*
Concerning enabling technologies, some challenges are to be met as well. Current "passive" capsule endoscopes are equipped with cameras to make images of the gastrointestinal tract and provide reliable disease diagnosis in a minimally invasive way. However, because clinicians have no control over the position and orientation of the capsules, there is a chance for missed diagnoses. In addition, the actual vital body signs that can be measured are limited (e.g. temperature, pH). Furthermore, some discomfort is still an issue because of the size. Further miniaturization is important.

Due to their required small size, the development of smart medical capsules, requires a combination of powerful technologies, some already available, others requiring further research and development. The most important key technologies and research challenges are:

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- *Advanced sensory systems*
  An important enabling technology for the smart capsules is **biomedical imaging**. The further miniaturization of imaging, together with multi-spectral imaging and scanning of the full body are important challenges. Together they can produce images, echoes, or maps with views made from inside the body (full body scan). In addition, the use of capsules inside MR scanners will create new functionalities. Part of these developments will focus on mobile data processing units that can be used in combination with the capsules. Furthermore, special software to process sensory information is crucial.
  An essential requirement for the full use of the smart capsules is the **localization** of the devices inside a human body. This will require new technology, with high resolution and low human impact. Ultrasound, WiFi and Bluetooth are some examples of technologies that need to be explored. Positioning will enable better diagnostic images and enhance the directed movement of the devices inside the human body. Very small and energy efficient **biomedical sensors** are needed inside smart capsules. These are not only limited to imaging and traditional acquisition of biomedical information (e.g. temperature, pH), but also include more sophisticated characteristics that are currently developed within the field of lab-on-a-chip. These new sensory systems will increase diagnostic capabilities and enhance the functionalities of medical procedures of the smart capsules.

- *Advanced human-machine interfacing*
  Directing the devices needs sophisticated interfaces between the surgeon and the capsule. Systems response is to be enhanced, and **user friendly interface** concepts will become important as soon as it is possible to control the small robots manually from the outside.

- *Mobile energy systems*
  As the capsules need some energy supply, many different **micro mobile energy generation** approaches are being researched to supply these small, wirelessly operating, in-body robots with enough energy for their voyage. Developments are also directed at energy harvesting and use of the energy sources within a body (e.g. fuel cells based on biomaterials). Also, wireless energy transfer and small battery systems are researched.

- *Advances in mechatronics*
  The smart capsules will be equipped with **micro actuators based on MEMS** to enhance their functionality. These will **include micro-grippers** (e.g. for biopsy), but also instruments for **locomotion** (e.g. pedals).

It may be expected that it will take a rather long time to develop these new devices to a complete new health procedure ready for use in everyday health care. It may also be expected that experiences collected with the first generation of smart medical capsules about the best ways of applying these devices and the best application areas, will provide ample feedback for the development of the next generations of smart capsules.

6.3.4 Societal issues and market developments

From the user and societal perspective, this innovation area is facing some interesting challenges. Macro challenges that smart capsules can address, concern the increasing pressure on the healthcare system. Today an endoscopic or surgical procedure is still complicated and time consuming. The costs of operating rooms and surgeons are high. Also the costs of the operating and recuperation time of the patient are ever increasing, leading to a demand for more efficient and effective procedures. These challenges can be addressed by smart medical capsules because they decrease the invasiveness of the

medical procedure. At the same time, the effectiveness of the procedure will be increased. The further pressure on costs and labour due to ageing are also addressed by these smart capsules. In conclusion, it can be said that full use of these devices will reduce costs both on the healthcare system and patient side.

Development of cheaper and easier to handle devices may also open the way for new forms of prevention by using these devices for screening. However, one must realize that for screening programs additional criteria have to be applied regarding the cost-effectiveness of the entire program. In addition, the false positives problem has to be addressed. For this category of devices, large improvements in acceptability compared to the presently used procedures, are expected.

An important issue in this area is the increasing demand for evidence based practice in healthcare, expanding to care and involved technology. because of the widening gap between the needs and available collective means for health care. New medical procedures based on smart capsules and their smaller and more intelligent successors will have to meet stringent criteria for the uptake in the health care benefit packages.

Smart capsules will probably take over the entire market for colonoscopy screenings as soon as they can be manipulated from the outside. It is recommended that everybody over 45 has a colonoscopy every 10 years. This means more than 12.000.000 colonoscopy screenings a year in the USA alone, costing approx. $1800 each (BioRetriever Feasibility Report, Chang et al.). Smart capsules cost about $300-400 each at the moment. As the price per screening drops due to mass production of smart medical capsules, the recommended screening rate could very well rise because of the potential for prevention.

This market will also grow due to the increasing number of elderly and the rising prices for colonoscopy. With increasing functionality such as for taking biopsies, the market for smart medical capsules will expand beyond the colonoscopy market. Smart medical capsules will be used in the diagnosis and treatment of most diseases of the digestive system. The total number of hospital stays for these diseases is already over 1.300.000 a year in the USA alone.

The important exporting countries are at the moment Japan, Israel, and the United States. The importing countries are mostly developed countries. As soon as the costs go down and the quality of care goes up, other countries will follow.

6.3.5   *Drivers and barriers*
One of the main driving forces in this area is the ongoing miniaturization of smart capsules, even up to the level of micro robots. Interdisciplinary research in domains such as nanotechnology, microsystems and mechatronics, being conducted by chemists, physicists, engineers, etc. influences the topic and may lead to further accelerated development and breakthroughs of miniaturized robots for the healthcare sector. But these are the driving forces on the technology "push side"; they will only lead to useful innovations if they make concrete connections with driving forces in society on the demand side. The demand side requires cost effective, efficient procedures for which smart capsules can provide the answer.

At the moment the main barriers are mainly of technical nature. Present products fit relatively easy in the existing system. At a later stage, potential products could require

much more change in medical practice and acceptance by patients and health insurances. The adjustment speed of these domains could then be a major barrier. By a careful choice of products and application areas, and by attention for implementation, this barrier can be lowered. Next to the technical barrier, the clinical trials required to accept new innovations also limit the actual use. Another barrier may also be the complex development trajectories, in which a number of technologies has to be combined and the evidence based approval procedures to prove that the new interventions are more cost-effective than the present ones.

6.3.6   *Key stakeholders and their motivations*
Developments in the area of smart medical capsules are also influenced directly by the actors involved. The most important actors will be discussed in this section.

Government. This includes all government bodies and organizations that regulate the financing of healthcare, the conditions under which health interventions are included in the health benefit system and the quality, safety, cost-effectiveness and patient orientation of the health system. There is discussion on the possible tension between the goal of a cost-effective healthcare and innovation, which needs room for experimentation and allowing failures. There is a risk that the introduction of new technologies is slowed down because new technologies cannot meet the required conditions as easily as interventions that are already regularly used.

Financers. These include health insurance companies and private financers. These organisations are interested in providing efficient healthcare within (increasingly difficult) constraints of consistent quality. They are not especially interested in funding innovative new technologies, unless it regards new interventions with strongly improved cost-effectiveness. At this moment, it is not clear to them that smart medical capsules and their more powerful successors will be important enough in this respect to justify specific funding from their part. Another point of interest is patient orientation. A major advantage is the limited invasive nature of these systems, which is less burdensome for patients.

Healthcare providers. Hospitals will have to accommodate for these innovative types of treatment. However, adjustment of current practice in healthcare is known to be very slow. It may require a whole new generation of physicians before systems are truly adopted in the healthcare provision. Given the fact that currently only the first generation of systems is available, adaptation of the healthcare system to these revolutionary systems will require patience.

Professional users. These include hospital personnel, doctors, paramedics, general practitioners and technicians. They will need to be trained and convinced to adopt the new systems. Given the increasing revolutionary nature of the treatment, a new branch of medical science has to be developed. This in turn needs to be taught to healthcare staff. It is likely that the acceptance of this new type of treatment will be slow.

Patients. Patients are primarily interested in good, safe and patient oriented treatments. This category of devices has potentially much to offer to patients. However, there is no direct link between any patient interest in these devices and the decision of hospitals or professionals to purchase and use these devices.

Manufacturers/suppliers*: Systems are still in a very early phase of development. Although in theory many applications seem feasible, there is still a long way to go before they really become accepted in the market. The entering of entrepreneurs looking for profitable markets will enhance this process and speed up developments. Not only will return on investment facilitate further development, but also field experience with current systems will accelerate the development and application of future systems.

Research (Universities, R&D and Evaluative Research). Currently these are the stakeholders with the highest involvement. Their main interest is continuity and growth of their organizations and excellence in their scientific field. In this field of science, it is a long term interest of researchers that new technologies are actually used in healthcare and that the experiences with these devices create new lines of research. As many applications still only exist in conceptual form it will require much effort and creativity to make these systems become reality. Mainly technology driven developments will have to prove their effectiveness in the context of the growing awareness of the need for evidence based interventions.

6.3.7   *Conclusion: the challenges*
It is certain that these devices will and can be used for important categories of intestinal diseases and that their number will grow. However, especially the development towards micro devices opens a very wide area of other applications. It is not certain whether all these possibilities will be realized in the end and certainly not in what timeframes these possibilities will become reality.

Important driving forces are the increasing number of people suffering from diseases for which these devices can be used and the lower burden for the patient. An important driver is also the number of technologies and scientific disciplines that constantly produce new knowledge and ideas for application in the health field. The main societal barrier is the institutional acceptance of new devices (clinical trials). In addition, further technological developments are needed to make full use of its potential.

To summarise, the expectations for this area for the short term are good and for the very long term perhaps great; both from the economic, as well as from the societal perspective. It is also clear that not only the development of new functionalities is required, but also that the increase of cost-effective and easy to use interventions requires a lot of attention and research.

6.4 Patient monitoring robots

6.4.1 Introduction

Monitoring patients is an essential part of the medical profession, including periodic diagnostics and monitoring of vital life signs. Applications for monitoring patients are already available on the market, like heart and breathing rate monitoring equipment.
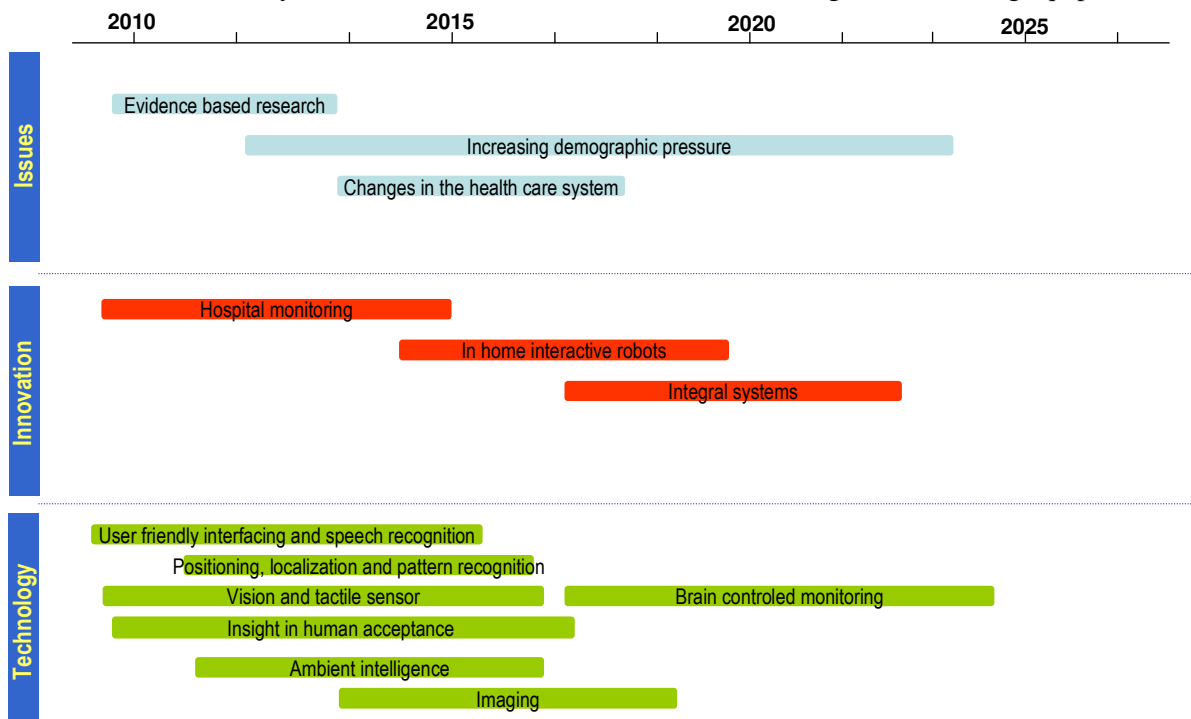
Figure 45: Road map of Patient monitoring robots

The applications however, hardly include commercial use of robotics in this field. The advantage of robotic applications in this field is that a more interactive approach can be established. Using ambient intelligence and mobile robotic systems not only patients can be monitored, but also communication can be established. Robotised patient monitoring systems can remotely monitor and diagnose patients. They can also be mobile and can actively establish more complex contact with a patient in case of calamity (house and hospital).

Monitoring of patients will be an ongoing activity in care intensive environments. Important nursing activities are monitoring of patients and assisting doctors in their daily meetings with patients. In the near future, systems can support nurses in nursing homes and elderly homes by remotely monitoring patients and diagnosing problems. Furthermore, robot systems will be used within medical care facilities to support patients consulting a doctor and/or nurses without them physically being in the same room. In the future, the systems can be integrated with other robotic assistive technologies.

6.4.2   Innovations and applications

Currently, *robotic* patient monitoring systems are essentially used for research purposes only. Although there is an obvious development going on regarding these systems towards market activity, there still is a rather limited number of systems actually in use, especially in Europe. Research is focussing on practical application possibilities; which practical care situations can be supported by robot monitoring, what will be the effect and how can this be implemented in care and care organization concepts.

There are a number of trends in innovation which will accelerate the broad introduction of robots in the care environment, both at home and in institutions. The external trend can be summarized as ambient intelligence. It stands for a variety of technologies which make it possible that not only every person but also every object can be recognized and identified by electronic means (e.g. with RFID tags) and that humans and objects can communicate with each other. The use of robots for care can be combined with other types of use. This will help the acceptability. A second trend is the expected growth of tele monitoring and tele care. A whole series of new applications is in various stages of development and testing. There are two important features for the functionality of these systems: can the system come near the patient everywhere in the house and is it possible to detect from a distance whether professional care is necessary. Robots will give great additional functionally in these respects.

The innovation area of robotic patient monitoring systems is basically divided into the following functional sub-areas:

*   *Mobile systems for hospital monitoring*
    Mobile monitoring systems can be used to reduce the need for doctors and nurses to physically visit patients periodically. These systems are evolving into devices that combine remote monitoring with making complex diagnoses. Advances in time efficiency and automated diagnosis will reduce costs and enhance quality of monitoring.
*   *Home care monitoring systems for elderly and disabled*
    The use of robotic systems in home care enables more reliable monitoring because of their mobility. In case of an alarm, the robotic system can locate the subject and assess visually or by other means the actual situation. This will increase the independence of the patients.
*   *Integral assistive robotic systems*
    The development of robotic assistive systems will include monitoring and diagnosis creating a more integral approach to care and facilitation of elderly and disabled. Apart from providing higher quality care, costs will also be reduced. In the longer run, monitoring robots could evolve into mobile platforms for assistive robotics devices like robot arms.

In the near future, mobile monitoring systems will become more common in hospitals. Some experimental applications show that acceptance by patients is positive. Also the combination with other applications like robotized delivery of drugs is to be expected. In home care, these developments are not expected in the short term, as costs are still high. This also has influence on the development of more integral systems. One of the most important challenges is to combine monitoring systems with human involved services into effective systems. This requires organizational changes at a certain scale in order to become cost-effective.

6.4.3   Key technologies and research challenges

Mobile systems depend on their onboard sensor systems to manoeuvre safely and reliably through unstructured areas where they can encounter humans. The first challenge in designing these systems is to obtain results at competitive costs. Furthermore, the system itself only serves as a remote sensor. The follow up of signalling will determine the quality of the overall system.

Key technologies in robotised patient monitoring systems are:

- *Advanced sensory systems*
  An important added value of robotic patient monitoring systems is the possibility of (tele-)diagnosing the patient situation. Therefore new mobile **imaging** technologies are needed to further develop the area. Ultrasound and other ways to analyse the human body are researched. Another important aspect of the mobile systems is the **positioning and localization** of the systems in buildings (both at home and in hospitals). GPS can not be used. New wireless technologies are researched. Also **ambient intelligence** is important to enable the robot systems to find their way through the environment. The system should have on line knowledge of the environment. This includes obstacle detection and avoidance as well as object identification. The use of RFID is researched in this context. Autonomous driving of mobile monitoring systems should be possible. Sensor systems, especially **vision sensors**, are very important. **Tactile sensors** would be important for the monitoring system to be able to sense and/or pick up objects remotely.

- *Human-machine interfacing*
  A positive human attitude to patient monitoring systems is of utmost importance. The robot system should act in a very **friendly** way, especially in relation to the patient. Controlling the monitoring robot should be very intuitive and user friendly. Furthermore, the emotional side of the interaction is important. Research has pointed out that for acceptability, robots should not be confused with human beings by resembling them too close. Progress is also made with more sophisticated forms of control/interface possibilities (i.e. **brain control**), more refined movements of the robots (through mechanical and electrical controls) and a more **human appearance** of the robot (without running the risk of confusion).

- *Mobile energy systems*
  As energy is necessary for driving, new mobile energy systems are needed. Both new **advanced battery systems** (small, light weight, fast charging, with high energy capacity and (**wireless**) energy transfer are researched to enable better use of the robotic systems. However, these technologies will be developed outside the R4H domain.

- *Advances in mechatronics*
  Actuators are necessary for the mobile monitoring system to be able to drive. One should strive for light weight actuators with low energy consumption. Miniaturization by **MEMS based actuators** can reduce size. **Polymer based actuators** will enhance the human touch to these actuators (e.g. grippers).

- *Insight in medical therapies and human behaviour*
  More scientific and soft "technologies" also play a crucial role in the further developments of the area. First, insight is required in **human acceptance** of robotic systems, which is clearly key to the implementation of robotic monitoring. But also usability and efficiency of robot patient monitoring systems should be demonstrated in practical settings. This means **evaluation** of the whole organizational set up including the call centre, technical maintenance etc.

- *Control systems for complex mechanical movement*
  New **advanced software for robotic systems** is needed for the enhanced communication between the patient and the robotic system. This includes software for speech recognition and software facilitating advanced movement in crowded environments.

Most of these challenges do not only focus on the actual functionality, but also on the reduction of the cost of these systems. Many pilot applications are already present, but commercially not feasible due to costs and lack of patient acceptance.

6.4.4   *Societal issues and market developments*
The aged population is growing. The need for care is already very large and it is forecasted that the need for care will grow further in the future. Therefore, shortage of personnel will raise big problems. To address these problems, robot monitoring systems to support care personnel will be of great advantage. Another trend is the one towards the shift from institutional care to home care. This is caused by budgetary problems and by the cultural phenomenon that older people become more autonomous and individualistic and want to live as long as possible in their own home. Patient monitoring robots can assist in this development. Usability and user-friendliness of the robots are a prerequisite. The third trend is the one towards disease management or continuous care. Although it might also be a more efficient way of organizing care, the most important reasons are the increased quality of care and the resulting increased quality of life.

On the other hand, the acceptance of robots in care concepts could raise, and has already raised, problems. With regard to the patient, privacy and safety are very import concerns. Acceptance by professionals is influenced by the clarity on the division of tasks and responsibilities between the machine and the professional (the status aspect plays an important role too). To improve acceptability, one should not strive for total replacement of doctors, nurses and care personnel by robots (right away or in all situations). A monitoring robot system should start as a care support device to improve the communication between nurse and patient. Acceptance would also increase when the monitoring robot increased individual independence in private home situations. Acceptance will need time, starting with a small group of technology-minded patients and caregivers and from there spreading through society, becoming part of everyone's day to day life. This is a normal innovation diffusion mechanism.

Up till now there hardly exists a market for robot monitoring care support. More knowledge is needed for effective practical applications of robot support in care concepts. Existing robot systems are still very much experimental. Few systems are used in practical care settings. But because of the growing demand for care and lack of available care personnel, a growing market for robot monitoring care support will develop. In the beginning, the applications will mainly be in hospitals, nursing homes and elderly homes. However, a potentially much larger market for the use of robot monitoring systems could emerge: private households.

Japan, Korea, USA and European Community are the most important markets where significant amount of research is conducted in the application of robotic systems in practical care situations. Japan, Korea and USA are focussing on replacement of the doctor and specialist. Systems can be remotely controlled by the doctor to create remote communication between doctor and patient. The European Community is focussing

more on support by such robotic systems to nurses and care personnel for monitoring patients and alternative care concepts.

6.4.5   *Drivers and barriers*

Although the overall technological feasibility of the systems is still not optimal, the acceptance of the systems by hospitals and patients can be considered more important in hospitals. This reluctance to implement the systems (or create a demand) is linked to the acceptability of replacing humans by robots (nurses/doctors, patients). Reliability and safety are important factors too.

The possibility of accidents caused by the use of robots, makes manufacturers reluctant to launch new products. Therefore the patient monitoring robots are still expensive. They cannot as yet compete with the cheaper and easy to use health monitoring devices that are available as (mass) consumer products. Also, the benefits from the use of robots are not yet clear enough to convince healthcare professionals. An important consideration for clinical acceptance is the reliability and accuracy of the measurements. Interoperability and data management are issues that are already countered by the development of protocols and standards like the Vena platform and HL-7.

From the technical perspective, intuitive control and smoothing the remote interaction is still a problem as is the effective integration into the existing care systems. And although some promising results have shown that the acceptance of these robotic systems by nurses will not be a crucial bottleneck, privacy and safety of the patients can be important limiting forces.

From the overall picture of robotics for patient monitoring, however, it can be derived that the growing acceptance of intelligent systems that surround us will continue and this will make such systems for health monitoring in our private surroundings more acceptable too. Information from studies on economical evaluation of substitution of care is showing that intelligent systems for monitoring and patient support can replace effectively the real presence of the caregiver in specific cases, i.e. digital home care with video monitoring.

6.4.6   *Key stakeholders and their motivations*

Research organisations. Research on mobile robot monitoring systems, with onboard sensor capacity, independent automatic driving control and intuitive interaction possibilities between user and robot is an ongoing activity. The effectiveness and safe application of these systems have to be evaluated in practical situations. Important research areas to explore for robot patient monitoring are intuitive robot interaction, sensor technology and navigation control and the development of evaluation methods. Results on these items will have spin off to other areas. An important problem is the step from research prototypes and pilots to product development by companies and introduction into regular healthcare. Who should be taking the initiative: the researcher or the company (or another stakeholder)?

Manufacturers/suppliers. Only very few systems are practically available on the market. All are still very much in an experimental phase. Manufacturers and suppliers of robot monitoring devices are more or less involved in the research for optimization and practical application.

Healthcare providers/institutions. Application environments of robot monitoring systems will be hospitals, elderly and nursing homes and the private home environment. Applying such systems needs structuring of care and development of new care concepts. This opens new possibilities for more qualitative and more effective care even with less man power. Lack of care personnel, improvement of care quality and economic aspects will be important driving forces for patient monitoring robot systems.

Professional users. Real end users will be the doctors, nurses, care personnel and the patients. The arguments for the introduction of robots by the providers might not be the same as for medical professionals. Personal contact with the patient is still an important part of the professional ethic. Efficiency is not their main concern, but soon a situation may occur in which the lack of new colleagues deteriorates the working conditions and this might change the attitude of medical professionals.

Patients. For patients the acceptability is the crucial criterion. In two respects: do they feel that they can interact with the robot in a pleasant and safe way, and do they accept the necessity that they cannot be helped constantly by a human being.

Informal caregivers. For informal caregivers, about the same applies as for patients. It depends on the situation of who interacts most with the robot. Sometimes the importance of the opinion of the informal caregiver is higher than that of the patient (e.g. with patients with dementia).

Financing institutions. Government and health insurers will be mostly interested from an economical point of view. From this perspective important items are: growing lack of nurses and care personnel, saving doctor consulting time, saving on travelling time, structuring care concepts, etc.

6.4.7 Conclusion

Challenges in research areas to explore for robot patient monitoring are intuitive robot interaction, sensor technology and navigation control. Results on these items will also have spin off to other areas. Gathering more knowledge on effective applications of robot monitoring systems in practical care concepts, by means of evidence based practical evaluations, is another important challenge. Finally, research is needed on what makes this new technology more acceptable as a replacement of the human.

Increasing ageing of the population, lack of care personnel, improvement of care quality and economic aspects will be important driving forces for patient monitoring robot systems. A barrier for future applications is the resistance of healthcare financers and providers against this new technology; mainly because of unfamiliarity with this technology and lack of evidence of effective robot monitoring support in practical care situations. Furthermore, these stakeholders are accountable for patient privacy and the challenges of this aspect have not been completely resolved yet.

6.5 Robotised motor coordination analysis and therapy

6.5.1 Introduction

Robotised motor coordination analysis and therapies aim to analyse and support the treatment of patients who acquired problems in motor behaviour due to peripheral or central trauma. The combination of analysis and treatment is relevant because diagnosis directly after the trauma can result in more successful rehabilitation therapies. Ideally, systems could even be used for the early assessment of motor coordination difficulties by means of screening programmes. The latter would not concern traumatic injury but early coordination difficulties resulting from progressive illness.

So far the diagnosis of impaired human motor control has been a complex issue. Caused by the absence of standardised and objective measurement, automated assessment of dynamic movement was virtually impossible. Traditionally, the treatment of impaired motor control patients is executed through intensive involvement of physical therapy, either by manually making a patient move or by monitoring the use of training devices.

The innovation area of robotized motor coordination analysis and therapies can be divided into the following sub-areas (Product-Market Combinations):

- *Intramural diagnosis and treatment of motor coordination related problems*
  Treatment in hospitals and medical centres uses highly professional systems that are equipped to analyse and treat multiple patients. Both analysis and treatment are highly sophisticated, enabling full diagnosis and "custom made" therapies. These systems will be relatively expensive.
- *Extramural (home) treatment of motor coordination related problems*
  More downsized, smaller systems which are better equipped to provide treatment of motor coordination trauma. Limited functionalities for analysis will be included. These systems will be less expensive and can be used by patients on a daily basis.
- *Prevention and initial treatment of problems*
  Through mainstream service-driven fitness-like environments, analysis and treatment of motor coordination trauma can be addressed within the more recreational setting of e.g., a fitness centre. Although the core activity will be focused on the improvement of a condition, additional smaller functionalities can be included that analyse motor coordination and have preventive outputs "on the side".

Currently therapy systems have been developed much further as diagnostic or screening systems. The most common type of trauma is stroke; due to a CVA (Cerebro Vascular Accident), part of the brain is damaged and may cause patients to have impaired motor control. Other neurological diseases (like brain tumours) cause similar problems. In the treatment of such impairments, the natural plasticity of the brain is exploited to reinstall motor coordination, either in the affected brain tissue or in nearby unaffected tissue. Facilitating the recovery of motor control is achieved through training programmes as soon as possible after the incident. The shared mechanisms of the training programs involve the execution of movement of the affected muscle groups, either actively or passively. There is no unitary view on the exact nature of these movement programmes, but the importance of moving is generally acknowledged.

For the first two sub-areas, elderly patients will be the largest target group, but also younger patients of trauma related injuries. There may also be a link to recovery from sports injuries. For the third Product-Market Combination (PMC), prevention and initial treatment, any health oriented individual may be part of the target audience, becoming more apparent when motor coordination related problems emerge to some extent. Again, for the first two PMCs, regular healthcare financing will be the prime funding source. Therefore, consumer markets need to be developed for these systems. For the third PMC, individual financing will be the logical way.

The development of robotic systems capable of training affected patients, may also pave the way for the development of assessment systems and procedures. Using such procedures, important muscle and coordination dysfunctions can be identified. Currently only experimental systems exist, mainly in academic environments. These systems are capable of detailed mapping of dynamic motor coordination capabilities. Since the last decade, robotised systems have emerged which can offer additional support besides the training executed by a physical therapist. These systems evoke preinstalled movements or mirror movements for which unaffected control is still available. The development of these systems is still in progress and the first successful clinical trials have been concluded recently (Kwakkel et al, 2008).

The available systems are a combination of therapeutic knowledge and robotized systems that intelligently monitor and direct movements of limbs. Precision/controlled movement, miniaturisation and medical insight in motor coordination trauma, stimulate the development of these systems. Lately, the demonstrated increase in motivation to comply with therapy through application of Virtual Reality and haptic feedback technology is an additional driver to innovation in this area.

Based on desk research, interviews with experts and a two-day expert workshop the most important Societal Issues, Innovations and Key technologies & research challenges were identified. These are presented in the road map of figure 46.
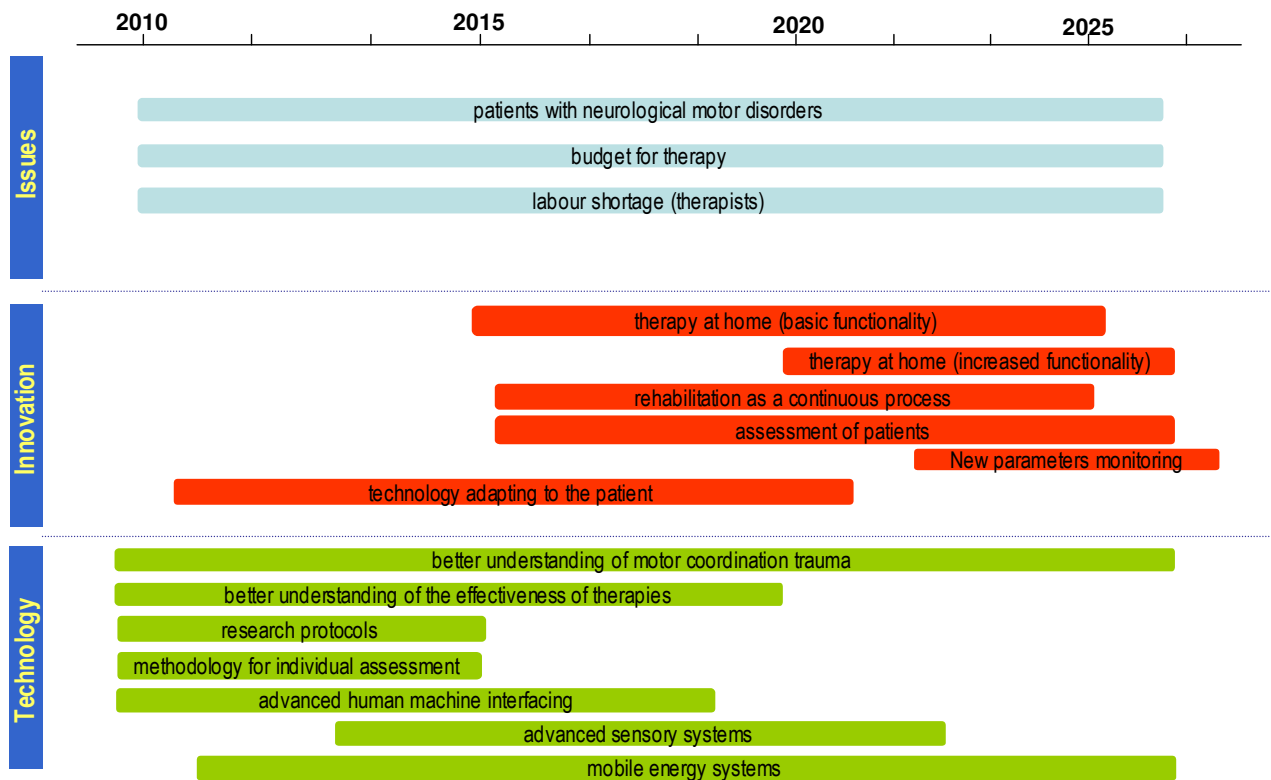
Figure 46: Road map of Robotised motor coordination analysis and therapy

6.5.2 *Innovation and application*

As systems develop, applications will become more effective. The experimental nature of the systems and the underlying modelling of human motor behaviour recovery will evolve. This will pave the way to the development of more specific systems but also to development for specific patient applications. Currently, systems under development are either aimed at diagnosis or therapy. More and more, systems will evolve either combining both aspects in one system or sharing an expert system using the diagnosis as outset for therapy goal determination and subsequently for monitoring patient progress. As a consequence, systems will be able to provide personalised therapy as soon as they recognise their user. Home application of therapy systems could be conceivable because of this capability. The first generation of these systems will provide basic functionality; later more extended systems can be expected.

When home-based systems become available, the range of therapies can also be extended. Therapy is now mainly provided in medical settings starting shortly after the acute phase. The duration of the therapy is limited and focussed on the period with the best recovery potential. With new options for therapy, this period can be extended allowing for a more continuous therapy process. The availability of progress monitoring through the assessment of patients adds to this possibility.

As described in the next section on research challenges, the scientific knowledge in this application domain is likely to deepen as a consequence of technological advancement. This will result in extension of parameters to be assessed by robotised systems for monitoring patient status and progress.

The future will also include personalised systems capable of providing movement support that suits the needs of the user in order to maintain fitness, detect problems or provide focussed therapy. This will be done in a way that is both effective and self motivating through the use of sensor technology and additional technologies such as virtual reality and haptic feedback. The main innovation will therefore be system integration and development of algorithms that define personalised effective systems.

6.5.3   *Key technologies and research challenges*

Important technologies for robotized motion and coordination analysis relate in general to the improvement of the **system hardware**. More specifically the following topics should be mentioned:

- *Advanced human-machine interfacing*
  Haptic feedback plays a key role in the development of these systems. The possibility to provide force or movement feedback to users is an essential element in developing a therapy system, as patients need to improve their function on the basis of gradual improving motor coordination. It plays an important role in the ability to transfer the acquired skills in therapy to daily life. Better sensors and **more precise and lighter hardware** constructions are essential to enable haptic feedback. In addition, further improved feedback compliance by **user friendly interface concepts** can be a decisive factor. Not only will patients better integrate bodily and sensory cues but they will also acquire skills that can be projected in real life environments through e.g. the application of Virtual reality.
- *Advanced sensory systems*
  Biomedical sensors are needed to enable systems to tailor their behaviour to the performance of the patients thus providing a tailored therapy plan to optimize the effectiveness of the system. Also **biomedical imaging** is needed to better understand the underlying mechanisms and to monitor patient behaviour not only on the level of physical performance but also on the level of cerebral activity. The monitoring of internal activity simultaneously with physical performance will greatly enhance system effectiveness.
- *Mobile energy systems*
  At present, robot therapy systems tend to be large and bulky requiring the patient to come to the systems instead of vice versa. Further **miniaturization of the hardware** will increase usability. Such mobile systems require efficient mobile energy storage technology. This will lead to increased effectiveness and less impact on the social participation of patients.

Furthermore, there are a number of research challenges:

- *Insight in medical therapies and human behaviour*
  Perhaps the major research challenge in this area is the **better understanding** of motor coordination trauma and the effectiveness of therapies. The normal human motor control processes are still not completely understood. How they are affected by trauma, disease or ageing and how they can recover is still being researched.
- *Research protocols*
  Closely related to the first issue, is the further development of research protocols to enable evidence based research on the effectiveness of therapies. With increased capabilities to monitor progress, it is possible to better study the effectiveness of the systems and the mechanism underlying human motor coordination, both in the sense of recovery from trauma and human motor coordination in general.

- *Individual assessment*
  With improved sensors and better understanding of motor control processes it will be possible to develop better methodologies for individual assessment.

6.5.4 Societal issues

Main societal drivers of the development of robot systems for motor coordination interventions are the demographic changes in the coming decades. The health problems relevant in this domain are the earlier mentioned CVA and other neurological disorders. These will lead to increased numbers of patients suffering from mobility problems caused by impaired motor control. As the workforce to treat all these patients in traditional sense will not be available, new options need to be looked for. In the domain of motor therapy, robots seem to fit in rather well. The ability to repeat, precisely and interactively, actions supporting patients matches the growing demand. Furthermore, the preventive character and the increase in efficiency of therapies are also addressing these societal issues.

Stroke is the main source of patients requiring intensive therapy shortly after the incident and continued therapy in the following period. According to the WHO estimates, the number of stroke events in EU countries is likely to increase from 1.1 million per year in 2000 to more than 1.5 million per year in 2025 solely because of the demographic changes. Other potential beneficiary patient groups are trauma patients, tumour patients, and possibly patients with brain located diseases such as Parkinson's and Multiple Sclerosis (MS). As with stroke, incidence of these problems/diseases correlates with age and given the demographic changes increase of patients is expected. It is expected that the market size will increase until 2030 keeping pace with changing demographics. In addition to this, growing consumerism and demand for sustained independence will trigger initiatives developing tailored systems capable of providing patient specific monitoring and support and maintenance of motor coordination functions.

But as the advancement of consumerism in care and health related prevention progresses, the systems need to be attractive and effective for patients and cost effective for healthcare providers. If this is achieved, further acceptance of technology not only in cure but also in care can be expected. One can even imagine that technology will emerge as driving force for competition in the care provision market, like it is in the current consumer market. Likewise, a growing demand for an increased level of care throughout Europe can be expected, certainly when systems will mature into high effective and affordable products. In the home care domain, the application of technology may feed the continued demand for sustained independence despite decreasing body functions with increasing age.

The slow progress in modelling and understanding brain damage (i.e. as a result of stroke) limits the development of these systems and the subsequent development of the cure of traumatic damage. Futuristic developments such as stem-cell therapy or neuro-surgery may provide a competitive contribution to the traditional treatment of motor control impairments. Also, increased ability to predict and prevent stroke will reduce the number of patients.

But the demographic changes do not only result in an increase of demand for care but also in the decrease of the availability of medical staff and care personnel. This shortage

of human resources for therapy will increase the demand for alternatives. The most promising alternative is technological systems and, specifically, the robotised systems.

A final societal issue to be mentioned here is the pressure on healthcare budgets, resulting in limitations in financial resources for therapy systems. This places a challenge on any technological development aiming to add to the recovery of affected human motor control.

6.5.5   *Drivers and barriers*
Some technological barriers are key to the further development of the systems. In the paragraph on "key technologies", these are described. In short, good technology for force feedback, better and more efficient therapy, (combination with) imaging techniques and improved human machine interfaces are crucial.

The cost is also considered a barrier for the implementation of the systems. The availability of devices suitable for use in the home and (the accompanied) relatively small market limit further development.

One of the main barriers is also the lack of acceptance or even the resistance of therapists against these innovative systems. Large scale application of systems requires their seamless incorporation within the existing healthcare provision. So far this has not been achieved up to satisfactory levels. Conversely, this is of course related to the absence of proof of effectiveness of robotized therapy. Complicating this, is the long standing absence of proof of effectiveness of traditional therapy. A comparison between traditional and robotized therapy is therefore not easy to make. Evidence based systems are therefore required, not only for assessing the effectiveness of the therapy but also for assessing the safety and absence of any negative consequences of therapy.

However, the number of patients is increasing rapidly. As traditional analysis and therapies are very labour intensive and tedious, this creates demand for these systems. In the future, cost reductions are expected. Demographic developments are the most obvious driving force, leading to an increasing number of patients and a possible shortage of therapists. An increase in therapy-on-demand is expected; the availability of therapy beyond the hours the therapist has available and at a moment when this suits the patient. This will be beneficial to both patient and therapist. In a similar line of reasoning, an increasing demand for therapy in (virtual) social environment is expected; this may enhance motivation and, related to this, effectiveness.

6.5.6   *Key stakeholders and their motivations*

Government.
The role of governments in this domain generally concerns legislation and regulation and possibly also funding. Governments are also involved in the facilitation and coordination of research.

The legislation and regulation may concern the way healthcare is organised and financed. National healthcare systems tend to become more and more governed by commercial oriented organisations but the national governments play a roll in the overall structure of these systems and the development of policy on maintaining the required level of healthcare for the citizens. Part of this involvement concerns the regulation for acceptance of novel interventions. This involves criteria such as public safety but also cost-effectiveness. Given the goal for cost-effective healthcare on the

one hand, and costly innovations which need room for experimentation on the other hand, there could be a risk that the introduction of new technologies is slowed down because new technologies cannot meet the required conditions as easily as the interventions that are already regularly used.

A final role of national governments, and one of the roles of the EC, is to invest in the development of healthcare innovations. One of the main instruments for this is the funding of research. In the past, the development of robotised systems has been financed by national governments but also by the EC (e.g. Gentle/s). Through targeted support of specific types of interventions, national governments can steer the development of innovation. The Japanese government has a policy of support to the introduction of technology in care, and does not support the further introduction of technology in the cure sector.

Local governments have a more direct role in the provision of healthcare. The way this is organised may vary from country to country, but local municipalities can have a large say in the financing and or execution of healthcare provision to their citizens. For instance, in Scandinavian countries local municipalities decide on providing interventions to their inhabitants.

Financers. Parties who finance healthcare vary from county to country. The national organisation of healthcare comprises very complex structures with equally complex financial structures. Healthcare insurers or public organisations may be financing healthcare. But also local municipalities or national governments may be involved as financing bodies. In most countries, combinations of financing parties can be found, contributing to the complexity.

Commercial robotic motor coordination systems are applied within the context of hospitals and other healthcare institutions. In general, financers of these organisations will be interested in providing cost-effective healthcare within increasingly difficult constraints and of consistent quality. The quest for improved care and control over budgets will cause them to choose systems that will improve effective care provision but only if this will simultaneously improve cost-effectiveness. The innovations in the area of motor coordination will be of moderate importance to them.

The financing of research that stimulates the development of these systems takes place in most cases separately from the financing of healthcare provision. Different public organisations put national or regional policy regarding research and development into effect. As mentioned before, the EC is also an active player in this domain and has supported developments mentioned elsewhere. In the USA, much national significant research is funded by NIDDR and in Japan research policy is supported by Ministerial programmes.

Healthcare providers. Healthcare providers will be seeking for quality interventions that are proven effective. Providing standard care for their patients with increased potential for compliance and effectiveness is appealing to healthcare institutions. Moreover, due to improved monitoring functions, increased understanding of the rationale behind interventions will evolve. The medical professionals working for healthcare providing organisations will strive for optimising care provision, and will direct their employing organisations towards this. However, this does not automatically lead to embracing technological innovations. The organisations have to deal with limited budgets and regulations regarding the provision of therapy and will have to take a position regarding technical innovations in the light of this.

Users. Primary users are therapists (e.g. occupational or physical therapists). Systems are aimed at supporting or extending their work. Day to day operation will be in the hands of qualified (paramedic) care personnel. In the case of domestic use of the systems (extending therapy to the home environment) it will be mainly patients and their informal carers who will use the systems (of course under the supervision of the therapist).

However, in the end it is of course the patient who will be using the system, it seems however more appropriate to refer to this type of use as secondary use. These users will be looking for their best options for care and recovery for themselves or relatives. An increased role of technology may have to face initial scepticism but with demonstrated effects the benefits will eventually be embraced. Individual patients have very little influence on the choice of medical therapy, let alone on the development of innovative new systems. But user representations and specific disease related organisations can have an influence on research policy.

Manufacturers. Systems need to be brought to the market after initial prototype development. So far, most systems originate from an academic research environment and only slowly diffuse to more commercial organisations. As system effectiveness increases, the diffusion of the systems will increase as well. Commercial organizations (SMEs) are already taking up activities and first systems are entering the market (i.e. LOKOMAT, MIME). Partly, this is an evolution of presently manufactured training systems. As research organizations tend to have difficulty in transferring prototypes into market products, the involvement of SME's is needed for further development of the field. Stimulating SME's to get involved will largely depend on market potential. The availability of funding and the demonstration of effectiveness of systems will be key factors in this process.

As the systems are still in development, current activities concentrate on research and product development. Only in a very small number of countries, systems are actually sold. Currently, important countries for Robot assisted motor-coordination therapy are: Belgium, France, Germany, Hungary, Italy, Japan, the Netherlands, Sweden, Switzerland (also system supplier), United Kingdom and the United States (also system supplier).

Research organisations. Because the understanding of the underlying mechanisms for motor coordination assessment and therapy still needs to be developed much further, the role of research is crucial to the further development of the field. This concerns both the conceptualisation of functional therapy systems and the evidence based demonstration of effectiveness.

6.5.7 Conclusion

As the number of patients will keep increasing for the coming decades the demand for motor coordination monitoring and therapy will continue to increase. Combined with the decrease in the amount of human care available and the demand for increased effectiveness, the chances for technology development in this domain are very positive. System development so far gives way to the expectation that adequate technology is available and continued improvement of functioning is to be expected. This will certainly be true for human motor coordination research.

However, the emergence of a commercial market for these types of systems is less certain. So far this has not been established on a significant scale, also because systems

have been too expensive. It is to be seen whether valid business cases will be developed, paving the way to market development. The development of a commercially viable market will also be influenced by possible competing solutions.

Ongoing research on human motor coordination will be a driving force for these systems. Controlled motor behaviour in combination with increased facilities for coordinating activities will provide rich material for theoretical progress. Following this, improvement of therapies and systems can be expected.

6.6   Intelligent prosthetics

6.6.1   *Introduction*

The loss of a limb is a source of disability of which the general public is well aware. The frequency of occurrence is relatively low in comparison to other sources of disability, i.e. stroke. The loss of a limb can be the result of trauma or war related violence, but also common diseases (e.g., diabetes) or genetic imperfections can cause a disability.
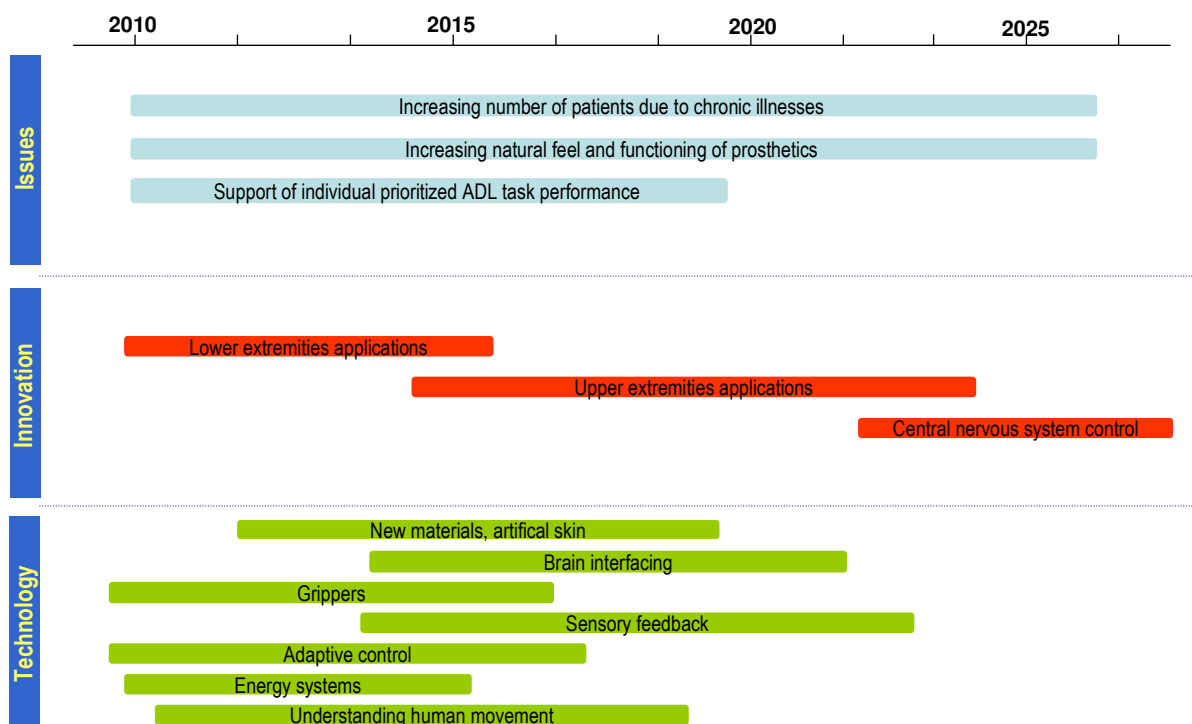
Figure 47: Road map of for intelligent prosthetics

People without one or more limbs may benefit from the restored mobility and independence which prosthetics offer. The concept of prosthetics was already known to ancient Egyptians, although those were passive prostheses. Cybernetic concepts were often mentioned in science fiction, but it took until the late 1980s to develop usable prosthetic systems that include robotic features. Initiated by developments in ICT, high performance materials and improvements in the connection to the human nerve system,

new concepts are developed where the prosthetics are intelligent (including mechatronics and connection to the human body).

6.6.2   *Innovations and applications*
The area of Intelligent prosthetics can be divided into two major sub-areas, the first being the prosthetics for the upper extremities and the second being prosthetics for lower extremities. Both sub-areas use essentially different technologies and also differ in market size (upper: 10%; lower: 90% of the market).

Currently, there are some intelligent *lower extremities* prosthetics on the market offering dynamic interaction with the user. These prostheses can actively lock their joint or change the resistance of the knee joint and thus support the active extension or flexion of joints (knee or ankle) synchronising with the users gait pattern. Some can adapt their behaviour to various terrain and user variation in walking. In general, the functionality of the prosthesis is aimed to support the users gait and standing functions and only performs relative easy tasks (static or repeating movement cycles). Future lower extremity prosthetics will be able to adapt to variations in terrain, imitate natural limb characteristics and support variations in walking, stair climbing or running. Rigid motion patterns will be replaced with dynamically controlled movement performed on the basis of intuitive control by the user. This will facilitate natural motion and application in various types of human activity. For high performance applications (e.g. sports) the provided functionality may even surpass the level of natural functioning.

For *upper extremities* the situation is different, as there is no standard movement repertoire for upper limbs. This requires the user to be in control continuously. The functional use of the hand and fingers is most complex. For this, the remaining muscles in the residual limb may be used, or alternatively nerve signals triggering muscle activation can be diverted into triggering activation of the prosthesis. In this way, it is possible to control a limited set of prosthesis movements such as opening and closing the hand or wrist rotating. Nevertheless, the most sophisticated arms on the market have three degrees of freedom while the human arm has seven (not counting the finger functionality). Future prostheses for replacing hands and arms will make use of the further developments in control software and miniaturization of components. The complexity of the several degrees of freedom in the natural hand will be made available, as well as the connection to the human body (physically and to the nerve system). Sensory feedback systems will also enable the patients to make the connection to the environment, enriching their use. The result will be prosthetics of a more bionic nature.

Future prosthetics will function more and more like natures' original. Systems will react, feel, look and weigh the same as the natural limb. Moreover, system functioning will be controlled only at higher cognitive levels while the required more basic control loops will be executed by the system internally. Finally systems will provide sensory feedback to its users.

6.6.3   *Key technologies and research challenges*
Some innovations are general to both sub-areas mentioned above. The key research challenges focus on improving the connection between the human user and the prosthesis, as well as the better functioning of the device. The aim is to make the prosthesis as good as, or even better than the human limb. Almost all key technology themes are important:

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- *Advanced sensory systems*
  To make the prosthesis functional and portable, lightweight design, **micro actuator** based biosensory systems are needed that can sense heat and small movements and translate this back to the patient. **Feedback** mechanisms are crucial to this.

- *Advanced human-machine interfacing*
  There are a number of myoelectric hands on the market. These are user controlled by contraction of specific muscles triggering prosthesis movement through electromyographic (EMG) signals. The control of the prosthesis is crucial for good performance. **Brain-machine interfacing** (BMI) proves to be one of the key research areas aiming at this objective. Relocation of nerves may be a fascinating option but it will result in too large a complexity for the user with increasing complexity of the prosthesis functioning. Brain interfacing may provide a solution, but the chances will increase with simultaneous shifting of lower level control to the prosthetic device. This will leave only the high level control to the user. For upper extremity prosthetics sensory feedback is more important and will enrich system functioning for the user significantly. In the intermediate run, developments will be seen in invasive connection with the peripheral nervous system (PNS) and non-invasive connection with the central nervous system (CNS). In the long run, it is expected that an invasive connection with the brain can be made. These systems can then also be used in lower extremity prostheses.

- *Materials with natural look and better connection*
  Aesthetics is an important part of prosthesis. Developments in new materials will lead to prosthetics that look like human skin. The connection between the prosthesis and the body will also be further improved. With these technical improvements, mainly in fabrics and materials, the physical contact and connection to the user's remaining extremity will improve. For aesthetic and sensory improvement there is thus a need for elastic, human like skin (artificial skin)

- *Mobile energy systems*
  Both for upper and lower extremities, small, mobile and efficient energy storage systems will be required. These include all underlying key technologies from this research theme. Advances in **energy storage** can be used to have longer use of the systems, but this issue can also be addressed by improvements in **energy generation**. Increasing the **energy efficiency** of the movement of lower extremities can also help longer use of the prosthetics. Furthermore, **wireless energy** transfer can charge the systems without the need to take them off or connect to an external power supply.

- *Control systems for complex mechanical movement*
  The movement of both upper and lower limbs is complex. New control systems are needed for enabling the user to make effective use of the prosthetic device (**adaptive control**). Options include the increase of system self governance (control systems for complex mechanical movement). More specifically, for lower limb prosthetics there is a need to execute standard motion patterns which will be less demanding for the user in terms of control. **Advanced software** is needed to efficiently and actively control the complex movements of an artificial hand.

- *Advances in mechatronics*
  The capability of designing complex prosthetics is getting within reach (i.e., for achieving as many degrees of freedom as the natural hand). Challenges refer to optimizing **grippers**, the use of artificial muscles (small, strong, energy efficient and lightweight) and to strong materials for mechanics.

- *Insight in human behaviour*
  For lower limb prosthetics, the **natural movement** is challenging. Understanding

movement (gait) is still a challenge and needs to be modelled, so that it can be processed into the control unit.

6.6.4   *Societal issues and market developments*
The demand for intelligent prosthetics is currently coming from patients and victims of (war) violence. Currently, the increasing number of US military combat victims is a driving force for fast improvement of prosthetics. But also the increasing number of diabetics, and possibly the need for improved healthcare in the developing world, are driving the developments. In any case, patients from developed nations will demand improved prosthetics as the technology becomes available.

Limiting forces may be the decrease of public awareness of war victims if war activities in the Middle East end. Another limiting force could be declining economy as it will lead to lowering of funding for vital research. Another unexpected limiting force for intelligent prosthetics may be the progress in medical science. As cures may be found for frequent diseases such as diabetes, the number of new patients requiring prosthetics will decrease. This may also be true for other innovative medical interventions making the use of prosthetics less necessary, including a healthier lifestyle. But even with increasing demand, still the (cost) effectiveness of robotised prosthetics needs to be demonstrated over traditional prosthetics. As the new prostheses will be more expensive than their traditional competitors, the additional costs will have to be justified.

Directly, the demand for prosthetics is independent from societal developments. Application will follow the incidence of patients loosing part of their limb(s). Nevertheless, amputations may occur more frequently as more patients suffering from venous system threatening diseases survive longer. Loss of limbs as a consequence of war violence will only affect the need for prosthetics in developed countries, as costs of smart systems will be initially out of reach for smaller economies. Nevertheless, rich countries should finance improvements which in due time will result in improvement of products in the more basic segments of the market.

The U.S. market for prosthetics, ortheses and cosmetic enhancement products is expected to increase from $6.8 billion in 2005 to $10.8 billion in 2010, at an AAGR (average annual growth rate) of 9.9%. Of all applications of prosthetics in the US 90 % concerns lower limbs, 7% concerns lower arm, hand and fingers and a final 2 % concerns the shoulder or upper arm.

The total number of demand for prostheses due to diseases will increase in the future following demographic changes. However, this increase will be relatively small compared to other technology applications. The need for prosthetics due to violence related trauma cannot be predicted. This will depend largely on the occurrence of major war conflicts. Such estimation is beyond the scope of this study.

Many systems are initially developed in research environments at institutes such as the US Veterans Affairs, Palo Alto, the MIT - Biomechatronics Group and in Europe the SSSUP - ARTS lab in Italy. They are making important progress and should be mentioned here. In Europe, two companies are active in Germany and Iceland. The other main country very active in this domain is the US. Both development of concepts and development of products is performed here. More concrete, the main actors are medical devices manufacturer such as Otto Bock, Össur, Endolit and Seattle Systems. Suppliers for these developments are organisations like the Shadow Robotics (UK)

(robotic hand, artificial muscles), the National Institute of Aerospace's (artificial skin) (USA) and Festos (robotic arm and hand).

Sales of smart prostheses can be seen in developed countries, but account only for relative small numbers. More traditional prosthetics are applied in the majority of cases.

6.6.5   *Drivers and barriers*
Generally speaking, the main barrier is that current solutions are still not able to meet the desires of the users. For example, surveys on the use of artificial hands revealed that 30 to 50% of amputees do not use their controllable prosthetic hand regularly, but take often refuge to a purely cosmetic prosthesis.

For the advancement of intelligent prosthetics, the establishment of evidence on the effectiveness of prosthetics is required (evidence based medicine). However, this is virtually impossible in the sense of drug related controlled clinical trials. New methodology for the establishment of evidence based prosthetics has to be developed. In addition to what is stated in the concept roadmap, not only the funding of clinical research, but also the funding of prostheses development is difficult. The development of innovative prostheses by companies can be hampered by legislation concerning the involvement of user as test persons. This prevents effective user centred design.

Furthermore, the reimbursement of robotic prostheses as healthcare provisions is also problematic; even more because of the differences in legislation on healthcare insurance in the various countries. As commercial healthcare insurance seems to be introduced in a growing number of countries, there is a risk that the focus of healthcare provision will be on short term financial effects rather than on longer term quality aspects. Intelligent prostheses that bring high initial costs will have difficulty being admitted in those systems.

In Europe, the driving forces for the introduction of intelligent prosthetics are related to keeping people independent longer, through innovative assistive technology. This will introduce a number of advantages to the individual as well as society in terms of financial, social and subjective wellbeing, and in the long run it will bring an increased level of participation to the individual. Europe and other parts of the world will profit from the advances made in the USA due to programs initiated because of war victims.

6.6.6   *Key stakeholders and their motivations*
Government. The availability of appropriate support for impaired citizens is a concern for any government. When the cause of part of these disabilities lies partially in the activities of the same government the pressure is on the government to compensate the consequences. This can be witnessed in the extensive research that is being performed in the USA funded by the DARPA program: "Revolutionizing Prosthetics 2009". In general, the number of people needing intelligent prosthetics is hardly big enough to rely on purely economically driven development of innovative systems. Governments should step in and support development in order to achieve the needed improvement of prosthetic systems.

Financers. A distinction must be made between financers of innovations and financers of provision of prosthetics through healthcare systems. Financing of prosthetics development is of eminent importance, because the size of the potential market is

relatively small and will not be able to support high end product development. An important driving force is the current DARPA Revolutionizing Prosthetics program.

After prototype development there must be options for field studies to demonstrate effectiveness. Effective systems must be developed into commercial products which will require investments and will attract companies besides the traditional prosthetics companies. The investments must be retrieved through provision of systems financed by the healthcare reimbursement schemes in countries. This mechanism will facilitate further R&D which will lead to gradual improvement of the available prostheses.

Healthcare providers. The healthcare organisations involved in the provision of prosthesis may be general hospitals but when intelligent prosthetics are involved, more likely specialised institutions such as (military) rehabilitation clinics are involved. Innovative systems will require funding for users during the selection, personal adaptation and early use. Such support can not only be provided by the system suppliers. Also medical staff needs to be involved into rehabilitation with the new prosthetic device.

Users. Users will demand optimal support. The exact nature of this optimal support is to be determined in individual cases and highly depends on individual characteristics and expectations. Moreover the context of use and the type of intended activities will be determining the type of system required but also the added value of advanced systems in individual cases.

Manufacturers/suppliers. Following the research progress, companies need to step in to actually bring the innovative technology to the market. In doing so they must have an eye for both the users and the medical profession.

Research. Main players in the innovation system are still the research institutes. This research can hardly be funded by private or corporate parties. Due to the relative small market size the need for public financial support and specialised funds is required.
After the technology development there will be a need for product development. The largest target groups will be addressed first, specialised products for niche markets will not be first priority and may require additional research funding.

6.6.7   *Conclusions*

Technology for the development of traditional prosthetics is by and large available. The development of more and improved intelligent systems can be expected with a large degree of certainty. Less certain is the admission of the more expensive systems in healthcare schemes in developed countries. This is required to increase market volume.

Availability of required technology, social acceptance of technology and higher expectations regarding independence will be driving forces. Barriers will be the absence of demonstrated added value, i.e. improved cost-effectiveness of developed systems in comparison with traditional systems. Improved treatment of diseases previously causing amputation of limbs could be another barrier for the further development of smart prostheses.

It can be expected that intelligent prosthetics will continue to be developed in the coming decades and the increase of applications for patients will follow the state of the

art in product development. The market will increase due to the increasing number of war victims, as well as increased ageing and accompanied diseases.

6.7 Robot assisted mental, cognitive and social therapy

6.7.1 *Introduction*

Social interaction can be severely hampered because of cognitive or mental impairment or deterioration. To compensate negative effects of impaired social skills, patients
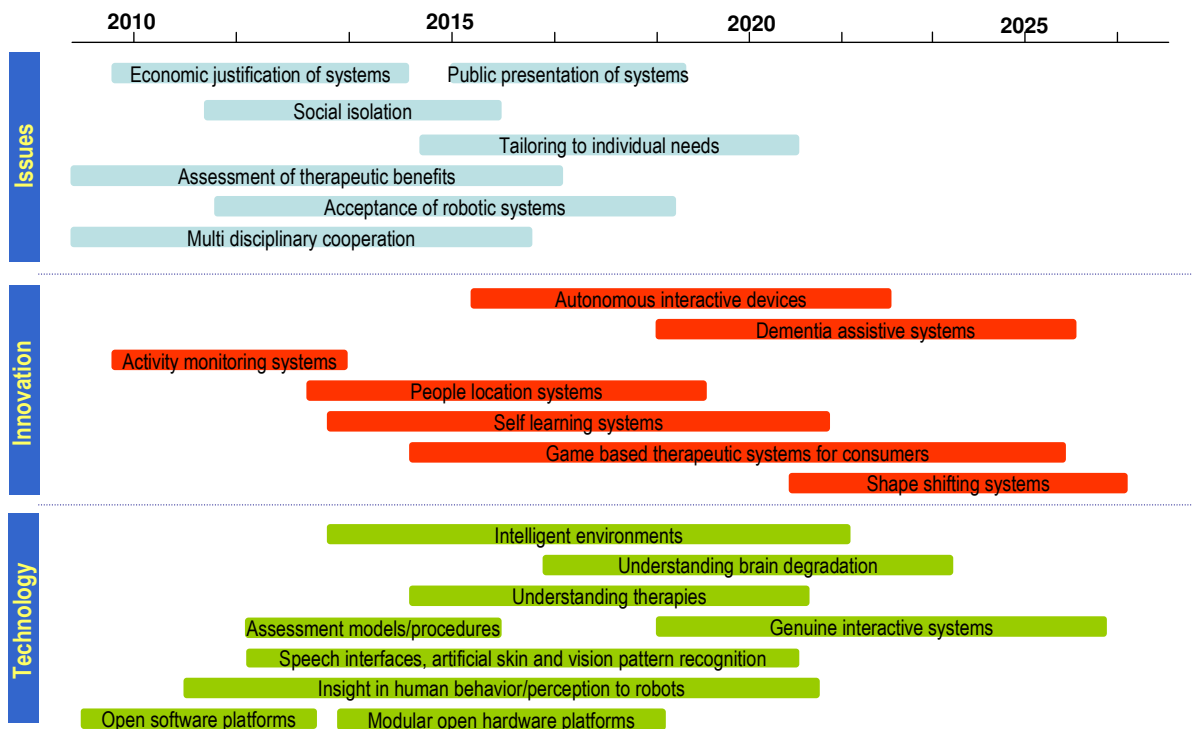

Figure 48: Road map of Robot assisted mental, cognitive and social therapy

receive therapy or care. Typical examples of such patients are children suffering from Autistic Spectrum Syndrome (autism) and elderly suffering from dementia. Both groups may (like any human being) benefit from improved social abilities and social interaction. Treating impaired social abilities is traditionally done through human intermediated therapy, social skill training or social (re-)activation. But, just as any human mediated therapy, this is limited in length and duration due to recourse constraints. However, social interaction is so essential to human functioning that the aim of social activation beyond therapy will easily align with basic human needs for social contact. Means to support social interaction should be seen on a continuum ranging from medical devices to consumer products (entertainment). To avoid confusion, the systems addressed in this section primarily concern healthcare related interventions aimed at restoring or improving human social skills through therapy.

Robot systems designed for interacting with humans in various types of social behaviour, such as communication, cooperative play and emotional bonding, may have advantages over human social interaction because of typical robot characteristics as repeatability and predictability. It has been shown that autistic children and demented elderly can benefit from interaction with robot systems. Moreover, major disadvantages

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of human intermediate therapy (personnel costs), pets (need for cleaning and care) or dolls (passiveness) can be overcome by robot systems.

6.7.2   *Innovations and applications*

There are only a few commercially available robotic systems designed for simulation of human social interaction. Most systems are experimental and mainly used for research purposes. Robotic toy systems, commercially available on the toy market, lack essential capabilities to effectively support social skills. Suitable systems are being prepared with specific sensors and electronic intelligence.

Future innovations in this domain will be the growing interaction possibilities between user and robot and the growing intelligence of the systems. The robot systems will act more and more like electronic buddies compatible with human behaviour and capable of intervening in social skills development. And although the focus in this section is on therapy systems, the link of such robot systems to the toy and entertainment market should not be neglected since it will be a major driving force for reduction of costs and development of supporting technology (e.g. low cost sensors).

The innovation area of Robot assisted mental, cognitive and social therapy is basically divided into the following subareas:

- *Robotized activity monitoring systems*
  In the field of mental and cognitive therapies, monitoring patients is an essential element. New devices will enable the automated monitoring of patients, e.g., in cases where the patients may use the robots as pets, or play-mates. The medical expert can then analyse the collected information.
- *Self learning systems*
  An important development in the area will be the increase of self learning capacities in robotic systems. Today, all behaviour is static, but in the future, this will be more dynamic so that new, more unpredictable situations can be addressed.
- *Game based therapeutic systems for consumers*
  A large potential market is related to robot pets. Although robot pets are not included in this study, the distinction between robot pets and more therapeutic robots is not clear. In the future, both areas will grow even closer.
- *Dementia assistive systems*
  New robot pets are expected for addressing dementia in the elderly. These pets are developed to address certain elements of this disease and by doing this are delaying its progression.
- *Autonomous interactive systems*
  In the long term, robots in this field will include characteristics of artificial intelligence. This will enable the use of the systems in a full autonomous and interactive way, so that support from medical experts is reduced.

The robotic systems in this area are still in their infancy. All present systems, even those in the research phase, are just scratching the surface of the potential of this domain.

6.7.3   *Key technologies and research challenges*

The research challenges are of a multi-disciplinary nature. The combination of more medical research and research in robotics is required, but not easy to realise. The required technologies and underlying research challenges concern a number of robot system elements.

- *Insight in medical therapies and human behavior*

  A better understanding of **brain degradation** and, based on that, an improved understanding of therapy concepts will be required as justification of these systems. Therefore, an important research challenge concerns the insight in **underlying therapeutic mechanisms** governing the mental, cognitive and social disorders. Behind this understanding lies the therapy concept that can be materialized in robot systems and will lay the foundation for effective therapy intervention. Effective human-robot interaction will depend on human-human interaction concepts, especially related to mental and cognitive impaired persons and the nature of each of the impairments.

- *Advanced human machine interfacing*

  Two major elements in this respect are the development of **speech interfaces** and the development of **genuine interactive systems**. This should be based on improved insight in human behaviour and understanding of robots. In order for systems to demonstrate convincing 'personality', they must offer automated, stable behaviour. For social interaction, this requires complex **behaviour patterns** to be able to interact with human communication partners. Automated, dynamic **adaptation of system performance** will be a major research challenge aiming at being convincing in real life interactions. A positive human perception of the robot system is of utmost importance. The robot should act in a very **friendly** manner, especially in relation to the patient. Interaction with the robot should be very intuitive. In the future the robot should be able to recognize, and even understand, human speech, and should also be able to ask questions and give answers.

- *Evidence based practical evaluations*

  Based on the improved assessment of impaired human behaviour not only individual monitoring will improve, but also effectiveness of the systems should be demonstrated. In practical settings the usability and efficiency of robot systems supporting mental, cognitive and social therapy should be verified. Given the ethical constraints effective methodology needs to be developed paving the way to research into system effectiveness. The resulting insights will not only support system development but may also serve as arguments to accept the developed systems within health care systems.

- *Advances in mechatronics*

  Actuators are necessary for systems to be able to drive, move and respond in interaction. Systems should feature **light weight actuators** with efficient energy consumption. But robots should also feature systems to express and convey communication, mimicking emotions through facial expression. New materials may provide changing forms and appearance (colours, patterns, surface touch etc.) and even artificial skin may be adopted. Finally, systems may have to be able to move or pick up objects requiring arms and or **grippers**.

- *Advanced sensory systems*

  Autonomous driving and moving should be possible. The systems should be able to interact on line with the environment. Sensor systems such as laser, infrared and especially **vision sensors** are very essential to this. For support of communication, tactile, audio and most importantly vision sensorial capacities are needed. The vision system should be able to perform on a high level of abstraction; recognizing facial expression, detecting various human movements, identifying persons etc**. Tactile sensors** would be important for the robot system to be able to sense and/or pick up objects. Safety and robustness are prime issues. Autonomous driving requires highly developed control systems. **Ambient intelligence** will further boost the potential of the systems. The behaviour of the robot and the quality of the

provided functionality/therapy will increase when robot behaviour takes the status of the environment into account. This concerns the control of the environment as part of the support to the user in engaging in activities of daily life, but also as support to the patient in coping with the "here and now".

- *Control systems for complex mechanical movement*
  As experimentation is essential to the further development of this type of robots facilitation of development will be required. Regarding both the **advanced robotic software** and the hardware, it should be avoided that each new robot needs to be developed from scratch. The availability of open software platforms as well as **open hardware development** platforms will need to be further supported (e.g. Microsoft robotics platform and LEGO mindstorms).

6.7.4   *Societal issues and market developments*
In the next decades, the ageing problem will, by definition, result in persons becoming older and it can be forecasted that as a result the number of patients suffering from dementia will grow significantly. But also more in general elderly persons will be lonely and socially under stimulated which will have an increasing effect on the occurrence of dementia. Therefore, besides a growing need for robotic therapeutic support for demented elderly, these systems can also serve as private buddy or even as preventive monitoring systems. The witnessed positive effects for communication impaired children may offer a lifelong lasting benefit for these individuals, which will also lead to reductions in costs for care. These driving forces for robots supporting mental, cognitive and social support will even be stronger because of shortages of health professionals in the near future.

Improving research in robot technologies and their acceptance will speed up the practical applications of robot systems for mental, cognitive and social therapies. Acceptance will increase with the growing application of robot interacting systems in the mainstream robotic toy market. However, there will be an increasing demand for evidence based effectiveness of applying robot systems in therapy and care.

Currently, there is hardly a market for robots supporting mentally, cognitively and socially impaired communication. Systems currently applied in research in this domain are still very much experimental. However, initial results show there is potential for these systems. When effective systems become available, the potential market could be seen in elderly care and special education facilities.

In Europe, approximately 20.000 special schools exist of which part may be interested in purchasing a system. Of course this will highly depend on the match between the children's needs and the offered functionality. The number of children diagnosed with autism is increasing, although this is in part related to standardised diagnostic protocols. The second main market concerns the group of elderly suffering from dementia. Due to increasing age the prevalence of dementia is increasing substantially, it is even referred to as an epidemic in relation to the size of the societal problem. Robot systems will not be able to counter this development but will be able to limit the negative societal effects. When more applicable robot systems with functionality for mental, cognitive and social disorders will become available there will be an interesting market size: Furthermore, the broader application area to be expected in the commercial very interesting toy market will serve as a boost for development of systems.

Japan, the USA and the European Union are the most important markets were developments are started on application of robot support in mental, cognitive and social disorders. Japan is currently mainly focussing on robots acting like normal persons with intelligent human interaction possibilities, and pets and dolls with human like personalities. A well known example is of course Paro, the white robot seal. In the USA and European Community, research has started on gathering knowledge on social interaction concepts for mental and cognitive retarded persons (demented elderly, autistic children) and how intelligent robot systems could support therapies. In general, many more systems are introduced, like the Kaspar, Probo, Huggable, Keepon, Roball and PlayRob. which may be an inspiration for therapy systems but as such will require adaptation and further complexity in order to provide effective therapy contributions.

6.7.5   *Drivers and barriers*

Awareness of the potential of these systems is low. This is also reinforced by the lack of scientific evidence on their benefits. A barrier is possibly the fact that in healthcare, therapy has to be evidence-based and this can happen only when sufficient clinical trials are made. But in the cognitive therapy field, this can last very long. It is not possible to demonstrate the effects within a short period. This is still quite a new field and the longer term effects are not yet known.

Companies that can be involved in making products in this field need to examine the same issues as in every field; demonstrated market need , safety, quality and opinions of the funding actors (who pays for it). Researchers and medical people may consider that proven treatment is beneficial but the companies require more. First, there is the need for the system has to be demonstrated, then safety, quality, technology and market need to be analyzed. Following these steps, a company can then find the appropriate solution for the product taking into account that the end customer has to be keen on the product, probably cooperate with researchers in the creation of more expensive prototypes and then try to make a lower-cost product and provide tailor made solutions for the various user groups.

An interesting path to commercialization could be to bring service provision into business e.g. provide the robot for free but receive payment for the use of it. Also, two types of markets could be defined. There are large user groups such as the elderly people and small niches such as the autistic children.

6.7.6   *Key stakeholders and their motivations*

Government. There could be a risk that the introduction of new technologies is slowed down because new technologies in therapy concepts cannot meet the required conditions as easily as therapies that are regularly used.

Financers. Health insurers will be interested in these developments for economic reasons. Treatment should be effective without taking more manpower; on the contrary, it should be effective with even less manpower because lack of care personnel. Health insurers are not especially interested in funding innovative new therapy concepts, unless they concern new therapies with strongly improved cost-effectiveness

Healthcare providers. Healthcare providers will be mainly nursing homes and elderly homes, especially for elderly demented persons, and rehabilitations centres for children with mental and cognitive disorders (autistic children). They will be interested in more effective therapy concepts.

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Professional users. Nurses in elderly homes can be supported by the new technology. Robot technology can support social interaction with demented elderly, asking less constant attention from the care personnel for individual patients. Therapists will be very interested in applications of new therapy concepts for children with mental and cognitive disorders (autistic children).

Patients. Support of attention and social interaction by robot systems will be interesting for patients. Especially elderly and children with mental, cognitive and social disorders can profit from robot supported treatments and give better quality.

Manufacturers/suppliers. Manufacturers and suppliers are looking for economic opportunities. Only very few products are practically available on the market and these are still very much in experimental phase. Manufacturers and suppliers of robot monitoring devices are involved in the research for optimisation and practical application. There can be a strong relation with toys which is a very interesting market.

Research organisations. At the moment much research is going on in the field of mental, cognitive and social disorders related with robot application support. Growing interaction possibilities will mainly be based on developments in sensor technology and electronic intelligence.

6.7.7   *Conclusion: the challenges*
Further development is as complex as human social interaction and will require additional research. Although the technology itself may not be complex, designing systems that appeal to human emotions on exactly the right level require delicate design iterations. The success of the few preliminary systems illustrates that robotics have a large potential in this domain. This impact may however be underestimated by public financers and may be regarded as just child's play, whereas therapeutic impact may be substantial. In the coming years more knowledge will be gained on mental, cognitive and social human interaction concepts. By implementing this knowledge in robot systems these systems will act more and more like human beings and will be more and more able to support the development of skills. In this way, humans will be able to participate up to their potential in daily life.

Growing application of robot interacting systems in the mainstream robotic toy market will certainly lead to increasing acceptance of robot supported therapies for social interactions. Also developments in sensor technology and interaction concepts with growing mimicking of human like interaction will increase possibilities and acceptation of this technology. Demographic changes will lead to more elderly people with dementia and persons becoming lonelier. These persons need attention and social contact. Children with autism, mental and cognitive disorders will have a growing need for attention and therapy. Growing lack of therapists and care personnel will increase the demand for robot systems supporting attention, social interaction and therapy. An important uncertainty will be the acceptance of these robot systems, especially by patients (autistic children and demented elderly), care personnel and therapists.

Key research challenges in this domain are intuitive robot interaction, sensor technology and navigation control. Results with these items will also have spin offs to other areas. Gathering more knowledge on effective applications of robot systems in practical therapy concepts by means of evidence based practical evaluations is another important challenge. A barrier for future applications could be resistance of healthcare

financers and therapists against this new technology; mainly because of unfamiliarity with this technology, and lack of evidence for effective robot support by mental, cognitive and social therapy. People might even express ethical concerns with these applications.

The challenge lies in appealing to the patients by providing the right functionality with the right technology. Certainly children with cognitive disorders can be easily over-stimulated resulting in counterproductive effects. Robot technology will result in the development of interactive pets to counter the effect of growing solitude among elderly with dementia. The subtle interaction offered by the pets will trigger emotional behaviour in both elderly and children. The systems will specifically be used for therapeutic purposes, but can at the same time serve as a private buddy.

6.8 Robotised surgery

One of the major activities in healthcare systems is the performance of medical interventions. These include surgery, but also minor interventions such as taking a biopsy. These activities are performed by doctors as well as by nurses and paramedics.

Robotic support of medical intervention started around fifteen years ago and is an active field today. In general terms, robots which are being used to support the surgeon, are starting to take over tasks of the surgeon. Because of their precision, endurance and repeatability, robotic systems can also automate surgical tasks and do them more precisely. With robotic surgical systems it is possible to do open surgery, minimally invasive surgery (MIS), remote tele-surgery, preoperative planning, surgical training, intra-operative navigation (image-guided surgery) and surgical simulation all from one place. Today, robots in this domain have been demonstrated and are in actual use in surgery of brain, heart, spinal cord, knee, throat, kidney and eye. The use of robotic systems can reduce the need for medical staff, decrease complications and lead to quicker patient recovery.
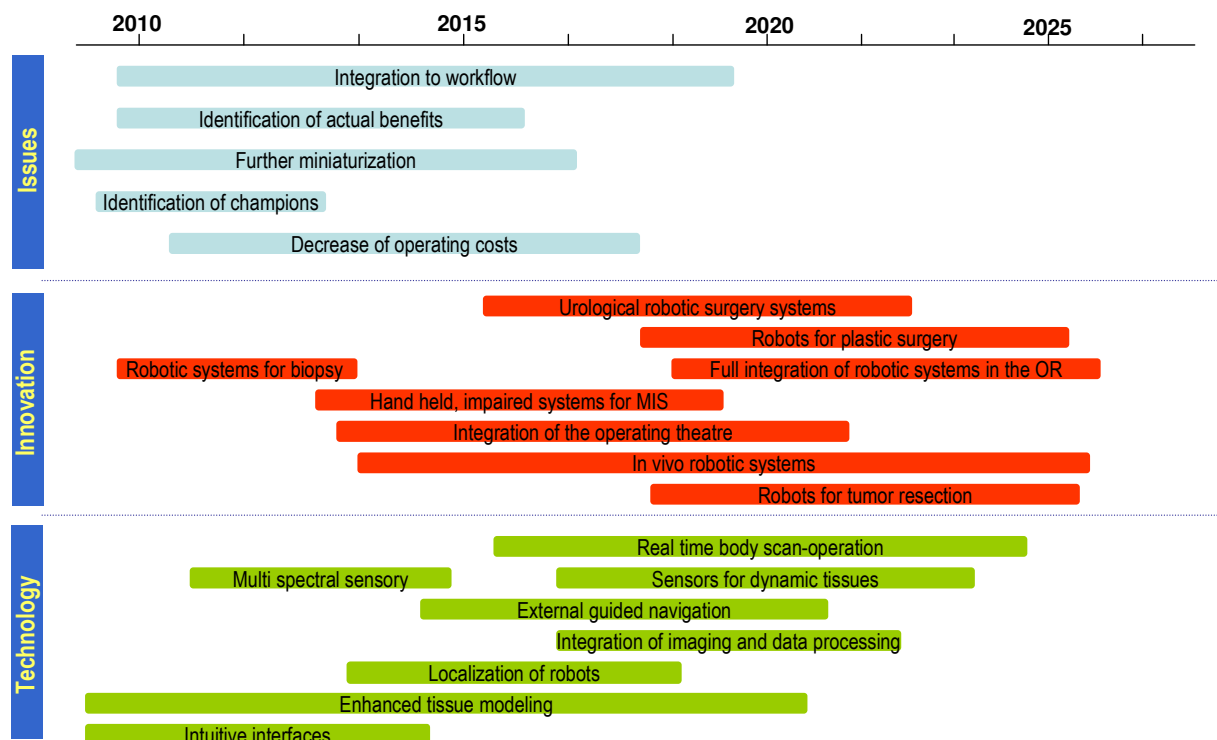

Figure 49: Road map of Robotic surgery

In the following paragraphs the applications will be explored, and enabling technologies and societal needs will be identified. Next to these factors driving the innovation area, the area is also driven by actors. These will be discussed in a paragraph on stakeholders.

6.8.1 *Innovations and applications*
Although surgical robots used to be based on industrial robots, nowadays the development of dedicated surgical robots is taking place. Smaller systems, with

dedicated functionalities are gaining importance. In addition, multi-disciplinary research is boosting the development of new functionalities.

Technological improvements will increase the potential use of robotics in surgery, as its use is now limited to specific surgical procedures in an experimental setting. Robots will be smaller and will integrate minimally invasive, precision and microsurgery functionalities. Furthermore, physical and instrumental assistance to operating room assistants (e.g. as "instrument server") will be further developed. An example of this is the counting of used instruments and logistic feedback, leading to an increase in patient safety and efficiency.

There are two main areas of surgical applications. The first area focuses on autonomous robotised surgery, where the robot is following a pre-operative plan based on CT and MRI scans. Because the robot cannot change its plan, the application area is presently limited and such robots are primarily used for surgery in hard tissue, i.e. bone surgery (orthopaedic surgery). Despite the large improvements in the functionality of imaging devices, it will require major breakthroughs before autonomous robots can be used for soft tissue surgery. The second area and most widely used form of robotised surgery, is tele-manipulation. In this case, the robot is augmenting the surgeon, who stays fully in charge and can immediately react to a new situation. Information about the surgeon's movements is fed into a computer and this computer performs refining, compensating or assistive tasks.

More specifically, the innovation area of Robotised surgery can be basically into the following subareas:
- *Robotic systems for biopsy*
  Today, biopsy is a frequently used functionality of the robotic systems. Further development in this field is to be expected. Enhancements to smaller systems and more dedicated systems are under development, especially in areas where precision and tremor compensation are needed.
- *Hand held improved systems for MIS*
  Minimally invasive surgery is one of the most beneficial functionalities of robotized surgery. However, systems are still large. In the future, these systems will become smaller, even hand held.
- *Integrated systems for the operating theatre*
  The full integration of robotic systems in the operating theatre is to be expected. This includes logistical, assistive and other functionalities that are usually facilitated by operating nurses. These systems will become smaller and more an integrative part of the operating room with even ambient intelligence elements.
- *Robots for tumour resection and urological surgery*
  Today, the use of robotic systems is limited. In the future, automated resection of tumours is also to be made by robotic systems. Precision, MIS and micro surgical functionalities will be integrated towards more dedicated systems.
- *Robots for plastic surgery*
  As plastic surgery is becoming more and more common, surgical robots focussing on performing plastic surgery are expected. However, the unpredictable behaviour of soft tissue is still an important barrier.
- *Robots for orthopaedic surgery*
  These are robots that perform pre-planned procedures on bone tissue (e.g. hip replacement). In this way, the precision of surgical robots can be used to enhance the quality of the operating procedure.

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In the future, the domain of surgical robots can also include micro- and nanobots. This is not considered a part of this roadmap, as the technologies needed and long term future orientation is non characteristic to the area of surgical robots.

6.8.2   *Key technologies and research challenges*

An essential element is the further development of models for different (human) tissues, as this limits use of the robotic systems. In addition, developments in medical imaging will enhance usability (3-D-imaging, image guided surgery). Today, 2-D is standard except for some specific systems, but within 5 years this will shift to 3-D. The next level of imaging will be analyzing the health situation of the tissue/organs to be able to diagnose disease in tissue/organ. Today the standard is navigation with MRI. The future is real time navigation. Improvements in haptic feedback in short term will enhance patient safety by reducing tissue damage (e.g. minimal invasive). Mimic surgery will enable specific training and pre-operative and intra-operative try-out of surgery (simulation), which will reduce unexpected incidents. The current situation is a simple body scan, but within 15 years it will be possible to make small very simple treatments/operations during surgery. So, in the future the different robotic systems will merge in broader platforms that can assist surgeons and even perform surgery autonomously.

The following key technologies are identified:

- *Advanced sensory systems*
  The analysis of tissue and the human body is an important aspect in robotized surgery. Characterizing the object is crucial. Important challenges in the near future are (run time) enhancement of resolution and the use of **medical imaging** within an MRI[8]. Translation to 3-D modelling and mathematical frameworks for analysis will further enhance these images and make them easier to interpret. This includes the **multi-spectral analysis** of the human body. Another crucial technology is the **real time positioning** of the body with respect to the system, as this will reduce problems associated with small changes in the body position.

- *Tissue modelling*
  Related to this key technology is the modelling of human tissue. Currently, this is limited because the robotic system can not operate in soft tissues autonomously (limited prediction of behaviour). In the future, further insight in this domain will enhance the usability of robotic surgery in other areas.

- *Advances in mechatronics*
  At this moment, robotized surgical systems are still large. The further development of Micro Electronic Mechanical Systems (MEMS) based **sensory systems** and high **performance actuators** will decrease the size of the systems and enhance their usability and costs. These MEMS will enable low cost miniaturized sensors (bio, touch, temperature, pressure, etc.), feedback mechanisms, electronic motors, etc. This is crucial for further development of robotics in general.

- *Advanced human-machine interfacing*
  Information transfer from the robot to the surgeon is one of the most essential elements in robotized surgery. Therefore, man-machine interfaces need to be further enhanced. **User friendly interfaces**, like image fusion, ergonomic organisation of information and dealing with information overflow are just a few examples of the challenges in this field. Virtual Reality is also interesting, but still in its early stages of development. New **feedback devices** are developed that

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[8] Magnetic Resonance Imaging

enhance feedback, for instance the magnetic untethered systems. The challenge is to increase the "resolution" and decrease the lag time of these systems. New sensory and mechanical systems are developed that give force feedback to the operator. Furthermore, ergonomically well-designed operating tools may improve working conditions for the surgeon and assisting nurses, who now suffer from RSI[9] and other strain injuries related to minimally invasive static operation techniques.

6.8.3 *Societal issues and market developments*

The robotization of surgery will change the profession of a surgeon, increasing both the efficiency of surgery as well as enhancing the quality. And this is needed because an increase in the number of patients can be expected due to ageing. In addition, societal demand for better quality healthcare will exert pressure on these systems. Robotic surgery can reduce medical errors and increase the speed of recuperation of patients. Dealing with liability of medical interventions (especially in the US) will also increase demand for these robotic systems. From a cultural point of view, robotic systems will enable surgery with no actual human touch, which is becoming a more and more important issue.

The acceptance of robotic systems can be a problem. As in airplanes, removing human intervention entirely will be hard to accomplish although experience shows that resistance to change can be overcome (Penelope) and sometimes a system is surprisingly acceptable. When the proof of concept is there (e.g. the Da Vinci), the path to further development of these systems is open. Societal needs will develop further. As robotized surgery will initiate new possible medical procedures, demand will increase. This will be stimulated by the decreasing costs of robotic systems (e.g. economies of scale and low cost technologies like MEMS). Also the experimental character of the use of surgical robots will disappear, leading to better acceptance by patients, surgeons and hospitals.

Today, the market for surgical robots is still limited. Only the most innovative hospitals consider buying these systems, but the market is increasing. Also commercial production can be seen, with high end equipment in limited numbers. But demand is growing and also new players in the field are surfacing.

The potential market is significant. In the USA alone, there are over 7,000 hospitals. In the short run, full market penetration of the systems is not to be expected due to high cost of purchase as well as the training of personnel and limited use. This will change in the mid term. Robotized systems will be less costly thanks to technological developments and their functionalities will increase. Also, due to more advanced man-machine interaction, training will be less intensive.

It can be seen that the introduction of the Da Vinci surgical robot has opened up the market; it is a commercial proof that will enable the market to grow.

6.8.4 *Drivers and barriers*

Although some commercial applications are to be seen, important barriers still reduce the development and use of surgical robots. First, there is little scientific evidence that the systems are economically beneficial. But the uncertainty about long term effects is also important, as previous robotised surgical procedures have been shown to lead to

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[9] Repetitive Strain Injury

medical complications. The increasing costs of liability of surgeons (especially in the US) may at some point in the future cause robots to become an alternative to "human surgery".

Healthcare professionals in general, and especially surgeons, are conservative and reluctant to accept quickly the new surgical robot systems. They want to see proof of effectiveness and efficiency before applying these systems in practical situations. There should be clear medical benefit. Furthermore, applying robotised surgery systems will raise management problems related to the surgical protocol. This also needs attention.

The clinical trials are also creating an institutional barrier. Long term investments are needed to reach the commercialization phase.

Before starting new developments, a more critical approach and far more knowledge from many surgeons are needed. The development from prototype to product and its implementation are very difficult, especially in the healthcare market. More competitive research could lead to more qualitative results and could speed up development and implementation.

However, there are also some drivers for these systems. Some doctors and hospitals have a positive attitude towards these developments, initiating the market. Furthermore, governmental and societal attention is given to the field and it is becoming part of the political agenda. Funds for research and developments are created.

6.8.5 *Key players and their motivations*

Government. Government bodies and organizations working under the auspices of government have patient safety as their main mission and they have a formal responsibility to this. They have high reactive impact on the innovation in this field.

Health insurance companies. Large health insurance companies sometimes finance research and innovation in healthcare. An example is the Dutch Achmea insurance company. Their agenda focuses mainly on: cost issues, patient demands, hospital demands and quota.

Manufacturers. University hospitals are suppliers of knowledge. They also design and manufacture prototypes. The assembly of complete robotic systems and the distribution of these systems (directly or by means of importing or marketing & sales firms) is done by manufacturers such as Intuitive Surgical, Hansen Medical and In Touch Health. They are at the front-end of development, integrating the views of medical professionals and technical experts. They also do scientific research, as is clearly seen by the involvement of university hospitals among which are Johns Hopkins, Washington University and Harvard.

Suppliers of components. The suppliers of components are divided into software and hardware companies. Hardware companies design and produce components, materials, semi-finished products, technical services or production machines and supply these to the producers of the final products. But as the robotic character is often based on more general technologies (e.g. mechatronic components, ICT components, imaging), more general suppliers will play an important role in the innovation of surgical robotics as well. However, it is not expected that they will play an active role, as the market for

them is relatively small. The development of software is often done by the system developers.

Research. Independent research organizations (university groups and public or private research institutions) play an important role in the further development of these systems. As robotic surgery today can be characterized as an innovation area in the early stage of its development, universities play an important role in its development. Often, the relationship with university or top class hospitals proves to be essential, due to its applied scientific character.

Medical professionals. The medical specialists and other medical, paramedical and nursing professionals play an important role, as they will be the ones operating the systems. Hospitals and other medical, preventive or care institutions, especially those who have an important say in the prescription, purchase and/or use of this category of robotic systems; organizations representing medical professionals and institutions.

6.8.6   *Conclusion: the challenges*
In general, it can be said that some important challenges are of technological nature. The key technologies stated are crucial to the further development, both from a cost perspective as well as from a functionality perspective. As this innovation area is still in the starting phase, improvements are crucial.

On the other hand, the expectation of these systems by society, both formal and informal, are major barriers in the full exploitation of robotics in the field of surgery. Admission on the market is hampered by very strict regulation because of possible claims, patient safety and social acceptance. Specific regulatory environments are needed while currently clinical trial regulations are reducing innovation. The gap between prototype and market is large because of difficulty in clinical trials (no test material).

6.9   General conclusions

6.9.1   *Introduction*
In this chapter roadmaps are presented for quite different types of application of robotics in health care. For each innovation area specific conclusions were drawn.

The size and importance of the markets for the six areas is not the same. Three of the areas will be of relatively limited size although on a global scale they still offer a big market potential. This applies to areas for specialized procedures like analysis of motion and coordination and applications for relatively small target groups like people with amputations or people with mental disabilities.

Very large markets, already at national levels, may be expected, certainly at longer time horizons for new generations of procedures or forms of care which are at this moment very broadly spread and very labour intensive. Applications in surgery will start with specialized operations but will diffuse to the entire field of specialized and general surgery. The same goes for robotic systems for patient monitoring, in the hospital, in care institutions and at home. It will start with patients with special needs or risks but have the potential to grow to an application for every ward and every home. For the area of smart medical capsules a long evolution is foreseen. It is now taking off with

specialized applications, but once the applications which are now on the border of science fiction have become reality, these could revolutionize the image of medical science.

6.9.2 *Certainties and uncertainties*

The following trends are relatively certain:

- the continuous growth of the older population in most countries and the growing scarcity of workers for the cure and especially the care sector;
- the continuous growth of the need and demand by large proportions of the world population to get the best care available;
- the continuous growth of medical science, constantly creating new insights into the cause of diseases and therefore new ideas for new forms of cure and prevention.

Relative uncertain are the following trends:

- The demand for the best healthcare and the possibilities are constantly growing, but it is neither certain that societies remain willing to pay for the growing cost of health care with collective arrangements nor is it certain that the economies will prosper in such ways that less solidarity can be compensated by people from their own means.
- Most trajectories for the development of new robotic applications are rather complex and depend on many separate developments in science and technology. Delays or disappointments in one single field can delay development of the entire application (area). Underlying fundamental research is still needed in many areas before more applied research can start.
- Official health policy in most developed countries tends towards more rational decisions about healthcare. This means, for instance, decisions relying on evidence based medicine procedures. However, this methodology is not yet suited for evaluation of all existing and new procedures, medicines and devices. When it becomes necessary to control health budgets, it might be that innovative technologies are at a disadvantage in decisions for inclusion in health benefit packages.

6.9.3 *Key challenges*

Looking at the field of medical applications of robotics as a whole, and especially looking at general patterns in success and failures, it is possible to see – apart from all the specific situations - a general trend. On the one hand it is a field that makes a very vivid impression. Many scientific and technological developments are taking place and these have raised high expectations with the public about the benefits of a large variety of robotic applications in healthcare. Furthermore many of these development trajectories have been linked to important challenges in health care.

But looking more closely at the development of devices that seem very promising in their early stages, it appears that many of them have great difficulty in reaching the broad diffusion that was envisioned originally. Many devices have been developed up to the stage that functional systems have been produced by companies, successful trials with patients have been done and experimental introduction in research hospitals has started. But many of the systems seem to get stuck in this phase.

There may be several reasons for this. It may be that the systems are still too expensive for regular use or are too difficult to operate on a routine basis. It may also be that there are still doubts that the new application is a more cost-effective replacement of the older

procedures. And finally, it might be that in the laboratories, companies and research hospitals where the new devices are developed there is a general positive attitude toward these new devices, but that in the regular health care in regional hospitals, care institutions and in home care there is still an acceptance issue related to care ethics, work habits or the feeling of being threatened in professional status.

The best way to proceed is therefore to take the roadmaps as a starting point and take a closer look at what is really going on, what the development phases are after the first introduction and find creative solutions to improve the throughput of the innovation system in this field.

ROBOTICS FOR HEALTHCARE
Final report

@Health

7 Vision, conclusions & recommendations

7.1 Vision on the application of robotics in healthcare

The objective of the study is:

to produce a roadmap of promising applications of robotics in healthcare, also encompassing associated technologies, research directions and expected impact.

This roadmap should provide an overview of the state of the art and future potential of the application of robotics in the field of healthcare. A requirement is that the results need to be in line with the core activities of the DG Information Society and Media of the European Commission.

Looking at all the information and opinions in this report, a clear picture emerges of what robotics in healthcare could mean for Europe and how this potential can be realized.

We believe that the field of robotics for healthcare brings a future promise. Although some commercial products are already on the market, this can be considered just the first signal of the potential added value robotics can bring to solving some of the problems in our present healthcare system. But these promises are not yet clear and strong evidence is yet to be delivered. The Da Vinci robot, the most well known surgical robot, is commercially available, but still has high potential for an increase in functionalities. This is characteristic for the early stages in which the development of the domain of robotics for healthcare is in. Full exploitation of the opportunities will still take some decades of research and development.

The opportunities of robotics lie in the reduction of labour, although the successes are still limited and to be found in niche markets. An important aspect is the increase in patient wellbeing (e.g. fast recuperation, patient safety). Concerning ageing, the field of R4H gives opportunities for longer independence. But these opportunities are not limited to ageing. Overall there is a significant potential for contributing to solving some important societal issues.

The study shows that the field of robotics for healthcare is diverse. Twenty one innovation areas are identified, grouped into five themes. In consultation with the client, six innovation areas have been considered important for DG Information Society and Media:
- **Smart medical capsules**
- **Intelligent prosthetics**
- **Patient monitoring robots**
- **Robotised motor coordination analysis and therapy**
- **Robot assisted mental, cognitive and social therapy**
- **Robotised surgery.**

Next to these six selected innovation areas, the study also shows the potential of robotics in **assisting nursing and paramedical care**. As important pressures in labour

market are expected, and some interesting examples are identified, this area is considered to be interesting for further investigation.

From the technological and scientific side, it can be concluded that the field is enabled by several developments that are not dedicated to healthcare. Joint cooperation with developments in energy technologies, sensory systems, medical insight in disease mechanisms and therapies, and in human-machine interfaces are just some examples of the multi-disciplinary and trans-sectoral nature of the field.

As the field is still in its infancy, the market is still open for new and growing organisations. The WTEC report specifically mentions EU funding as one of the driving forces for advancing the robotics domain in Europe (Bekey et.al 2004). It is also clear that although USA and Japan are strong in the field, Europe has excellent researchers in the field. The R4H-network is still limited but very much "alive". The critical mass is considered large enough to facilitate further evolution of the field in Europe. But the combination between research and commercialization is of importance. Examples show that prototypes are often not (yet) commercialized.

Looking at legal issues, the most important barrier to innovation are the clinical trials. Perhaps a restructuring of the institutional system can be discussed, but the fact that the core objects are human beings is prohibiting easy solutions. Equally challenging are the liability issues. As the autonomous character of robots is an essential element, the question is who is liable in case of an accident: the original designer, or the doctor?

In summary, it can be stated that the potential for application of robotics in healthcare is strong. It is to be expected that, although in the short term full exploitation of the potential benefits is unlikely, robots will form a significant part of the healthcare system in the longer term, with large economic and social benefits.

7.2 Societal challenges and user needs

Innovation is the commercial application of new technologies. This implies that social challenges and user needs are addressed. So what are important societal issues and user needs that the application of robotics can address in the field of healthcare?

The first conclusion of the study is that robotics can have a significant added value to the challenges and user needs in healthcare. Besides potential reduction in labour (costs and workforce demand), the increase of quality, safety, efficiency and patient orientation in healthcare is an important impact to consider. The main contributions of robotics to the **challenges** in healthcare are:
- Growth of labour productivity
- Increase in quality of medical interventions and safer medical procedures
- New medical procedures for insufficiently treatable diseases
- Quick recuperation of patients
- Increase in independent living and increasing participation in society
- Higher acceptance of diagnostic procedures and therapies
- More opportunities for personalized care
- New opportunities for prevention and diagnosis.

From the of view point of the **user needs**, two different user groups must be distinguished; the various categories of medical professionals and the patients and their social environment. For the medical professional, enhancing the technical potential of robotics is needed to increase the added value to the level that can be acceptable. This includes both increasing medical functionalities, as well as enhancing the human machine interface, but also the safe and motivating labour circumstances. From the patient's point of view, the most important aspect is the human-machine interface of the robotic device, where the intrusive character can be a barrier. Patient acceptance of robotic systems is key but it should always be kept in mind that the robotic device is embedded in a healthcare procedure and is often used in a social environment. The procedure in the context of the social environment is the unit of analysis to determine the quality of life gained with the new robotic device.

7.3   21 innovation areas, 6 ½ priorities and many enabling technologies

The study shows that the field of robotics for healthcare is diverse. Twenty one innovation areas are identified, grouped into five themes.
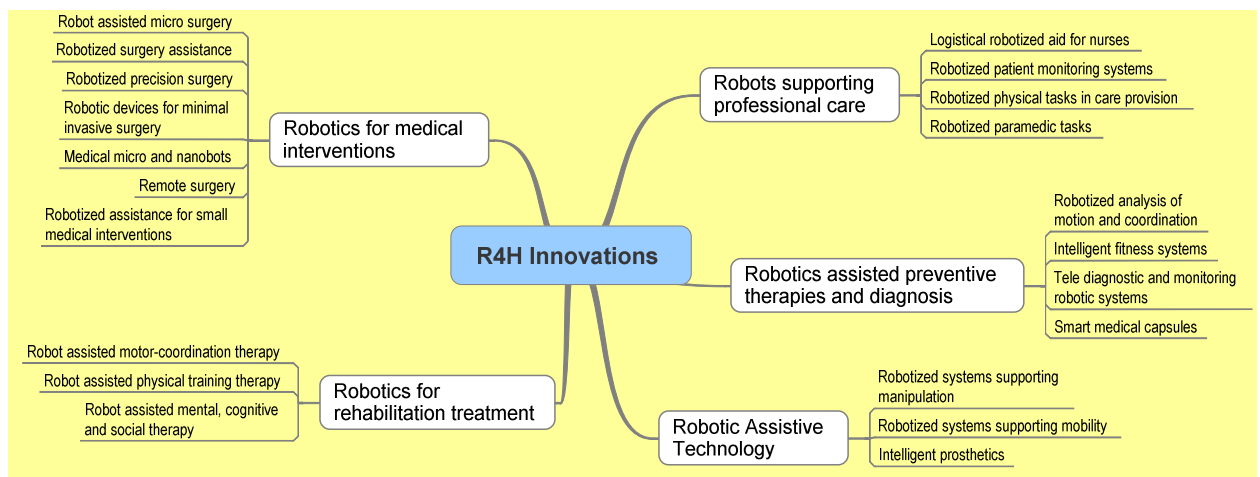

Figure 50: Innovation themes and innovation areas in R4H.

Demarcation of the innovation areas was not easy. During the study it became clear that there is a large degree of interdependence between the areas, such as the relationship between Surgical robots and Medical micro and nano bots. It is also clear that the field is highly multi-disciplinary and has a high connection to robotic systems in other fields of application.

Based on a questionnaire sent to experts in the field and later confirmed in the evaluation workshop, the study also shows that all innovation areas are still in their early stages of development. This is presented in figure 51 on the next page.

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	Invention	Research	Innovators	Early adopters	Early majority
Intelligent fitness systems			X		
Robotized motion and coordination analysis		X			
Tele diagnostic and monitoring systems			X		
Smart Medical Capsules			X		
Systems supporting manipulation			X		
Systems supporting mobility			X		
Intelligent prosthetics			X		
Robotized physical tasks in care taking			X		
Robotized paramedic tasks		X			
Logistical robotized support for nurses			X		
Patient monitoring robots			X		
Robot assisted physical training therapy			X		
Robotized motor coordination therapy			X		
Robot assisted mental, cognitive and social therapy			X		
Robot assisted micro surgery			X		
Robots for surgery assistance			X		
Robots for precision surgery			X		
Robots systems for minimal invasive surgery			X		
Medical and micro nanobots		X			
Remote surgery robots			X		
Robots for assisting small medical interventions			X		

Figure 51: Innovation phases of different innovation areas.

The time of adoption is considered to be mostly medium term, sometimes even long term. Although there are some commercial products on the market, one can not speak of a mature market yet. Many opportunities are just starting to "scratch the surface" and the field still has a strong research character, depending mostly on a high involvement of the academic world. However, it is to be advised that participation of industrial partners is promoted, because this will enhance the much needed further commercialization of the field.

Not all innovation areas are equally relevant. A questionnaire was distributed among experts, asking their judgement on the "Market Attractiveness" of the innovation areas and the "Business position" in relation to the innovation area (the ability of the health care sector to pick the fruits of the innovation area). The results are presented in figure 52 on the next page.
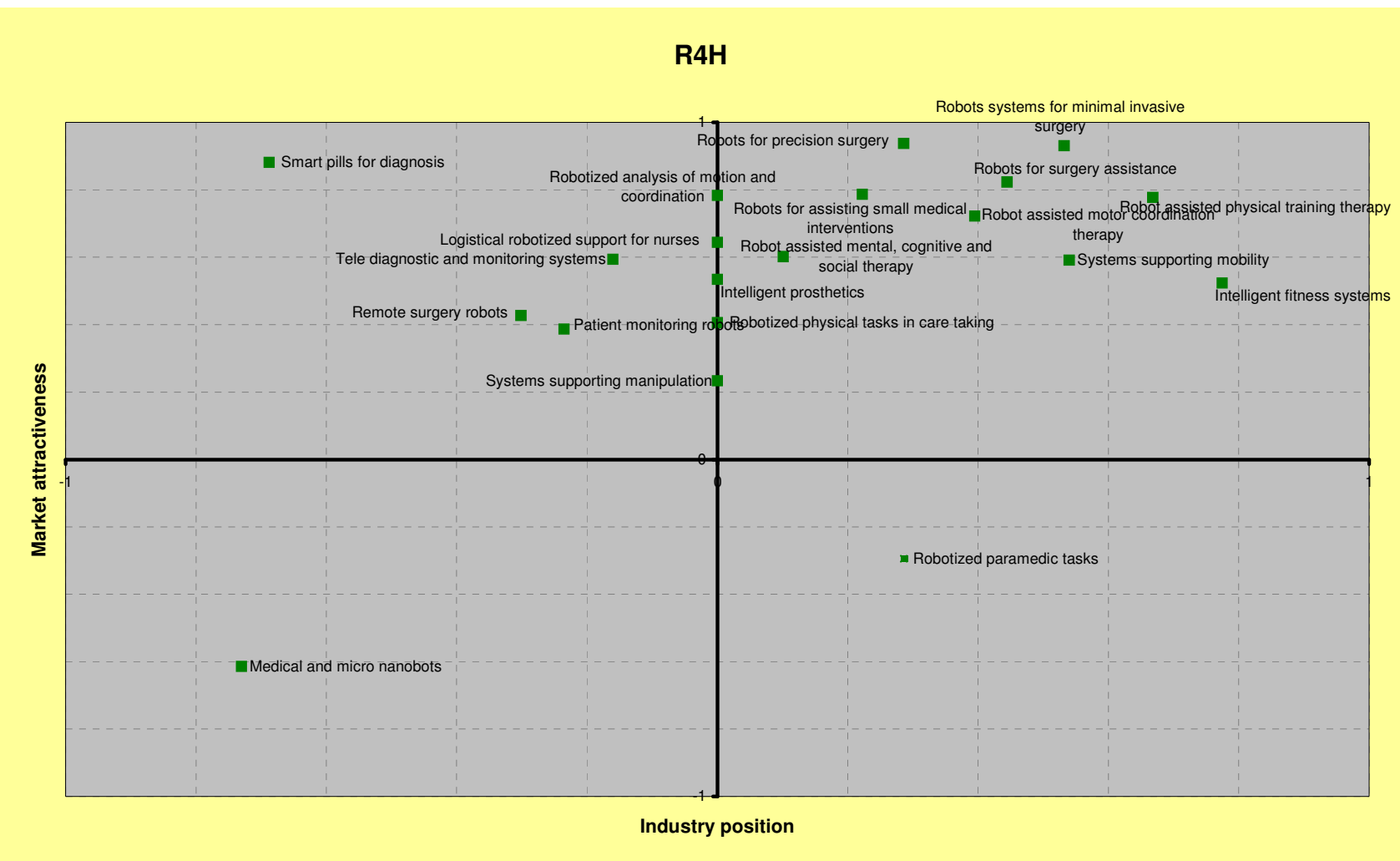
Figure 52: Market attractiveness – Industry position matrix of the innovation areas.

ROBOTICS FOR HEALTHCARE

Final report

As the study is an input to the further development of policy of the Directorate General Information Society and Media, and especially of the future work programmes of the Research Framework Programme, in discussions with the client six innovation areas have been considered important for DG Information Society and Media:

- **Smart medical capsules**. In the coming years, the diagnostic specialties will also experience great developments by the evolution of constantly more capable endoscopic capsules.
- **Intelligent prosthetics**. Incorporating smart functionalities (e.g. based on ICT) into prosthetics will increase the use of robotic systems to support patients with loss of limbs.
- **Robotised patient monitoring systems**. The monitoring of patients in hospitals can be automated with the use of robotic systems. This will increase the quality and potentially reduce labour costs. This can also be integrated with the use of other systems in the home.
- **Robotised motor coordination analysis and therapy**. The automated, or facilitated rehabilitation of motor coordination can enhance effectiveness and efficiency of therapies. Also smart ways to make preventive diagnosis can reduce actual trauma and enhance therapies.
- **Robot-assisted mental, cognitive and social therapy**. The use of small robot devices can assist social therapies and also postpone and prevent psychological problems of elderly, like dementia and loneliness.
- **Robotized surgery:** In the long term, surgery will be revolutionized by all kinds of robotic systems.

Next to these six selected innovation areas, the study also shows the potential of Robotics in **assisting in nursing and paramedical care**. As important pressures in labour market are to be expected, and some interesting examples are identified, this area is considered to be interesting for further investigation.

Concerning the developments of these innovation areas, the following key enabling technologies were identified:
- Advances in sensory systems are needed to create more effective feed back loops and in this way increase the smart interaction with the environment;
- New human-machine interfaces include both human factors in HMI and new technological interfaces that can directly connect the systems to the human user;
- More efficient energy use and increased energy capacity in mobile energy systems are needed to power stand alone robots;
- Control systems for complex mechanical movements are needed to increase the functionality of the robots;
- Advances in mechatronics are needed to miniaturize systems and increase functionality;

• Increased insight in disease mechanisms, medical therapies and human behaviour is needed to increase the effectiveness of medical interventions and robotic actions.
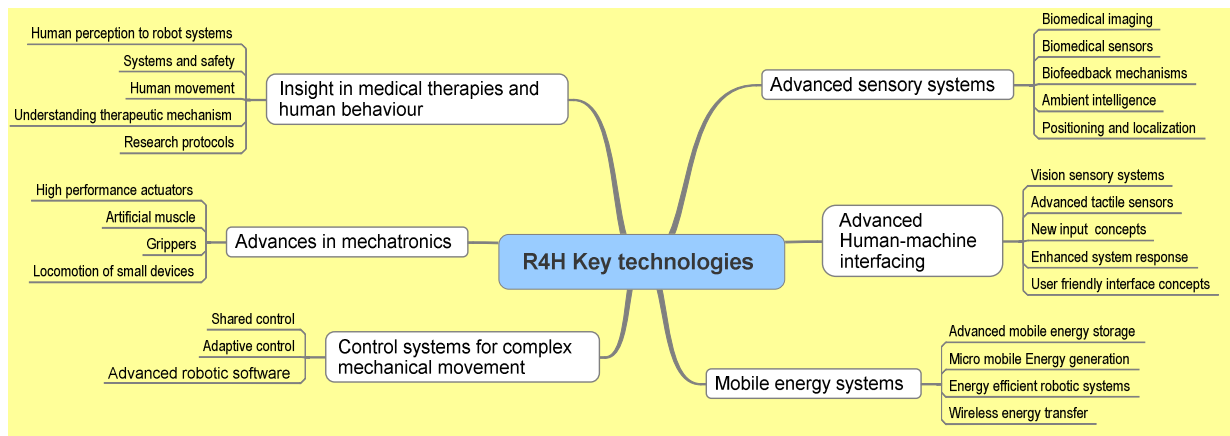

Figure 53: Key technologies for R4H.

An important conclusion is that many of these research areas are not confined to the field of robotics for healthcare, but are applicable to other robotic domains as well. An important conclusion is that in research, band wagon effects are to be included in policy, so policy for specific societal domains can make use of research in other domains.
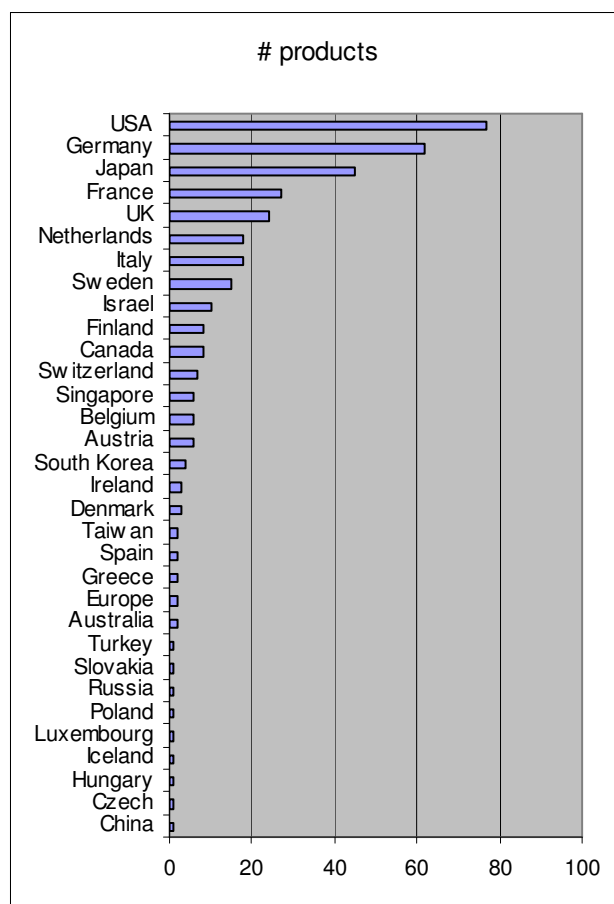

Figure 54: Number of R4H applications per country.

7.4 Country perspective

Based on the research during the project, we can give an overview of the way countries are involved in the field of robotics for healthcare. Information on both organizations and robotic systems was collected. They provide different overviews. Figure 54 presents the overview of robotic applications per country.

In total, 339 products (robotic systems) are identified and mapped for analysis (area and country). Of those, 125 are mapped in more detail in e.g. development phase. In total 328 organizations are identified and 73 are mapped for analysis. Looking at the distribution of the organizations between companies and universities, this is more or less even.

Figure 54 provides an overview of the distribution of the products concerning countries of origin.

It is clear that this overview is not a representative overview of the present situation on robotics in healthcare. The Netherlands can be considered over represented, as well as

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Sweden. But some tentative conclusions can be drawn.

The first is that it that the USA seems to be focusing on the field. The approach did not give more attention to the USA than to other countries, so the high number of systems and organizations shows the relative high emphasis on robotics for healthcare. This is confirmed by the interviews. However, it must be kept in mind that the USA market is comparable with the European Union and not with the individual Member States.

Also Japan seems to be highly active in this field. However, this is not fully confirmed by the interviews. Although robotics can be considered a major research topic, its application to healthcare is limited. Other countries are involved in the application of robotics for healthcare in a limited way, with the exception of Germany. This is also confirmed by the interviews.

7.5   Ethical and legal aspects

Ethical aspects

During the study and the workshop it appeared that only remarks of a very general character were made about ethical aspects. Several ethical issues like privacy, replacement of human care by mechanical care, and concerns of a philosophical nature about the differences between humans and robots were mentioned. However, no information was provided about any specific device with which an ethical issue had arisen *and had been solved* in one way or another (e.g. redesign or formulating rules for application). Probably this is caused by the fact that the stage of development is still too far away from practical application and the "real" doctors and the "real" patients are not yet active stakeholders. An additional study showed that many ethical issues may be expected in the future and that these will raise serious barriers if not solved in time. Ethical aspects should therefore be an indispensable part of research programs in this field.

Legal aspects

Quite the contrary was the case with legal aspects. Especially the representatives from companies active in the field of robotics in healthcare or, more general, with medical devices in healthcare, were very outspoken in this respect. It was stated that the methodology to prove that devices are effective and safe enough for starting trials and the methodology to prove the cost-effectiveness in terms of evidence based medicine (to become included in health benefit packages) was in almost every respect unsuitable for devices. Historically speaking this methodology was first developed for medicines and adapted to other medical interventions like the use of devices. But this is seen as so burdensome that it is regarded as perhaps one of the largest barriers to innovation in this field. An additional study on specific legal problems that might be expected in the future showed that many more legal issues may arise that were not yet identified in the cases investigated in this study. Therefore, legal aspects should also be an indispensable part of research programs in this field.

7.6   Policy recommendations for EC research

As concluded before, the application of robotics has large potential benefits for healthcare systems. The main recommendation to the EC is therefore to further develop this area in the Framework Programme. This recommendation is enhanced by the fact

that few research programmes exist that are specifically focused on the field. Other arguments to support this conclusion are:

- The field is still in its infancy, but some real, commercial products can be found. This supports the conclusion that there is a market, but this market has just entered its growth phase.

- The R4H-network in Europe is small, but the authors believe that it has a critical mass (both research and industry).

- As robotics is seen to be part of the next potential Kondratiev wave (like biotechnology), further developments in robotics can be expected. As the potential benefits for healthcare are significant, early application in this field is beneficial.

- Looking at the broad enabling technologies, cooperation with other fields of application should be facilitated (e.g., through the EURON network). Connection to other domains should be ensured (e.g. defence, domestic and industry). This also includes cooperation with other funding schemes.

- More than the development of new applications, the field also needs the further enhancement of an R4H network to establish a sound multidisciplinary R4H community. Research, industry, medical professionals and users themselves should be included to enhance user oriented research.

- The model of innovation used should incorporate not only research, but a combination between research, development and application to ensure actual use of the research. Soft elements of innovation like the analysis of user acceptance should also be included as potentially fundable aspects.

- To be an effective program as a whole (and be more effective than a set of separate innovation projects) it would be advisable to add two "horizontal" program lines to the program: one on legal issues and one on ethical issues.

- Because the field is very new, acceptance and implementation will be complicated: to raise awareness and promote involvement of stakeholders, awareness activities should accompany any innovation program.

- Attention should be given to the development of "hard evidence" on the actual benefits of the application of robotics in healthcare. This includes the development of standardized research protocols.

- When an initiative is taken to start a program for robotics in healthcare, much thought must be given to the question of which are the most appropriate criteria for granting proposals in relation to the stage of development. Considering broad application in regular healthcare as the final yardstick for successful innovation, the program must include some mechanism that guarantees that the program not only attracts researchers interested in long term possibilities, but also companies and/or health institutes which have an urgent interest in practical applications. This might take the form of a program with more compartments (each with separate budgets) which have granting criteria optimally geared to the type of development project in

that specific compartment and to the type and roles of stakeholders that need to be involved.

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