## **TNO Quality of Life**

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### **TNO report**

#### KvL/P&Z 2010.094

97 Medical Apparatuses tested at the Academic Medical Center (AMC) Amsterdam for interference by WLAN/WiFi signals

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# Summary

This research describes the influence of WLAN <sup>1</sup> signals on medical apparatuses in the Academic Medical Center (AMC) Amsterdam. The results in this report were obtained by testing medical equipment with WLAN signals. A comparable research was reported earlier. See TNO report KvL/P&Z 2007.117 dated September 2007, **Literature** [1].

At 20cm distance 3% of 97 tested medical apparatuses were disturbed. At 0cm distance (WLAN antenna against medical apparatus) 7% of the apparatuses were disturbed. The WLAN signals were transmitted at 100mW, which is the standardised power in the 2,4 and 5GHz frequency bands. The character of the disturbances was at 0cm distance unsafe at about half (4%) of the (7%) of the 97 tested medical apparatuses; the maximum distance at which interference was found was 30cm. The character of the disturbances varied between significant and unsafe, equally distributed over the distances.

These results are comparable to the results in the TNO study from 2007 – although the 10cm found in the 2007-study as the 3% border (instead of the 20cm found at AMC) is a difference. The 50cm found in the 2007-study as the maximum distance where interference occurred (instead of the 30cm found at AMC) is another difference.

The number of medical apparatuses tested (97) can be considered large enough to formulate the following general expectation: As long as WLAN antennas are kept away more than 20cm from medical apparatuses during normal use in hospitals, hardly interferences and/or unsafe disturbances are expected. At shorter distances in special situations some disturbances are expected half of which unsafe.

Attention for this interference aspect is important if (non medical) apparatus with WLAN antennas are (as normal use) placed on medical apparatus, or if WLAN antennas are built into medical apparatuses that are placed on top of or under other medical apparatuses. In these cases the distance can be 0cm and some disturbances are expected. Special measures maybe needed to prevent this.

During this research signals were transmitted at the extra strong power level of 500mW as well. This was done to facilitate finding possible disturbances quicker than normal. These results are not included in the above conclusions because WLAN systems will not be used at that strong power level in hospitals. No patients were involved in the research; where necessary, input signals for the medical apparatuses were generated with simulators. The medical apparatuses were set up fully functional. They were powered from the mains and in some cases from built-in accumulators.

#### Remarks

- 1: The test method minimized the dependency from the environment where the tests took place.
- 2: If in this report for a certain type of medical apparatus no interference is reported one must not conclude that the apparatus is not susceptible. The reason for this is that tests were limited, had a typical (restricted) purpose and were not intended to cover

<sup>&</sup>lt;sup>1)</sup> WLAN = Wireless Local Area Network (In Netherlands language: Draadloos lokaal netwerk), also called WiFi = Wireless Fidelity.

- the standard IEC 60601-1-2 [4] for EMC of Medical Equipment. A conclusion about the complete EMC behaviour of a medical apparatus is the responsibility of the manufacturer and must be based on more elaborate testing.
- 3: The number of medical apparatuses included in the immunity testing was limited. The medical apparatuses were carefully selected to cover the actual situation in the rooms at the hospitals. The medical apparatuses and the WLAN systems are believed to represent a certain collection as can be found in more hospitals. However no strict general conclusions about other medical apparatuses can be drawn from this report without careful judgment and comparison. In case of doubt additional testing may be needed (as international standards advise generally as well).

# Samenvatting

Dit rapport beschrijft de invloed van WLAN<sup>2</sup> signalen op medische apparaten in het Academisch Medisch Centrum (AMC) te Amsterdam. De resultaten in dit rapport zijn verkregen door medische apparatuur te testen met WLAN-signalen. Een vergelijkbaar onderzoek is eerder gepubliceerd. Zie TNO report KvL/P&Z 2007.117 dd. september 2007, **Literature [1]**.

Op 20cm afstand trad bij 3% van 97 onderzochte medische apparaten storende invloed op. Op 0cm afstand (WLAN antenne tegen medisch apparaat) ondervond 7% van de apparaten storing. De WLAN signalen hadden het gebruikelijke vermogen van 100mW in de 2,4 en 5GHz frequentiebanden. Het karakter van de storingen was bij 0cm afstand onveilig bij de helft (4%) van de (7%) van de 97 geteste medische apparaten; de maximale afstand waarop storende invloed werd gevonden was 30cm. Het karakter van de invloeden varieerde van significant tot onveilig, willekeurig verdeeld over de afstanden.

Deze resultaten zijn vergelijkbaar met de resultaten in de TNO studie uit 2007 – hoewel de 10cm in de 2007-studie als 3% grens (in plaats van de 20cm gevonden bij het AMC) niet hetzelfde is. De 50cm gevonden in 2007-studie als maximum afstand waarop interferentie op trad (in plaats van de 30 cm gevonden bij AMC) is een ander verschil.

Het aantal onderzochte medische apparaten (97) kan groot genoeg worden geacht om de volgende algemene verwachtingen uit te spreken: Zolang WLAN antennes op meer dan 20cm afstand van medische apparaten blijven tijdens normaal gebruik in ziekenhuizen zijn nauwelijks storende en/of onveilige invloeden te verwachten. Op kortere afstand zullen in bijzondere gevallen enkele storingen kunnen optreden (waarvan ca. de helft onveilig).

Aandacht voor deze stoorproblematiek is belangrijk wanneer (niet medische) apparaten met WLAN antennes <u>op</u> medische apparaten worden gebruikt, of wanneer WLAN antennes worden ingebouwd in medische apparaten, die op of onder andere medische apparaten "gestapeld" kunnen worden. In deze gevallen kan de afstand 0cm worden en zijn enkele storingen te verwachten. Speciale maatregelen kunnen nodig zijn om dit te voorkomen.

Bij het onderzoek werd ook met de "bovennormale" sterkte van 500mW gezonden om gemakkelijker eventuele storingen op het spoor te komen. Die resultaten zijn niet in bovenstaande conclusies meegenomen, want WLAN systemen zullen niet op die sterkte in ziekenhuizen worden bedreven. Bij het onderzoek waren geen patiënten betrokken; er werd waar nodig gewerkt met simulatoren die de ingangssignalen leverden aan de medische apparatuur. De medische apparatuur was volledig functioneel opgesteld en werd gevoed vanuit het net en in sommige gevallen uit de ingebouwde batterij.

#### **Opmerkingen**

1: De testmethode minimaliseerde de afhankelijkheid van de omgeving waar de test plaats vond.

<sup>&</sup>lt;sup>2)</sup> WLAN = Wireless Local Area Network (Draadloos lokaal netwerk), ook wel aangeduid met WiFi = Wireless Fidelity.

- 2: Wanneer in dit rapport van een bepaald apparaat geen verstoring wordt gemeld mag daar niet de conclusie aan worden verbonden, dat dit apparaat dus niet gevoelig is. Het apparaat is immers slechts beperkt getest en met een zeer bepaald (beperkt) doel. De norm IEC 60601-1-2 [4] voor EMC van medische apparatuur was zeker niet afgedekt. Een dergelijke uitspraak behoort tot de competentie en verantwoordelijkheid van de fabrikant van het betreffende apparaat en moet worden gestoeld op uitvoeriger onderzoek.
- 3: Het aantal onderzochte medische apparaten was beperkt. De apparaten zijn zorgvuldig geselecteerd met het oog op de toepassingsituaties in ziekenhuizen. Zowel de medische apparaten als WLAN systemen kunnen als representatief worden beschouwd voor meerdere ziekenhuizen. Echter, er kunnen geen strikte algemene conclusies voor andere medische apparaten worden gebaseerd op dit rapport zonder zorgvuldige beoordeling en vergelijking. In geval van twijfel kan het nodig zijn om aanvullend te testen (zoals internationale normen in het algemeen ook adviseren).

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- A Functional modes of all tested medical apparatuses
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## 1 Introduction

This research describes the influence of WLAN signals on medical apparatus in the Academic Medical Center (AMC) Amsterdam. The results in this report were obtained by testing medical equipment with WLAN signals. A selection of the medical equipment of the AMC was tested for susceptibility to these signals. This report describes the tests and presents the results. These results are formulated in such a way that the AMC can base management strategies and/or technical measures on them to consider introduction of WLAN systems. The aim was to test whether selected medical apparatuses (see below) were susceptible to WLAN signals and if so at what distance. The character of possible reactions (hazardous or not) was also of interest.

## 1.1 Description of tests

In order to test possible susceptibility of medical apparatuses, 97 of them were set upon their own in the hospital environment and subjected to the WLAN signals. Medical apparatuses were selected that could in principle be positioned in the vicinity of the WLAN antennas <sup>3</sup> during normal functioning of the intensive care unit, the operating room, etc. Where relevant, the medical apparatuses were tested both powered from the mains and powered from their internal accumulator. If a medical apparatus was found that could be disturbed, the point in space most far from the medical apparatus was determined where the disturbance just started to occur. This distance is usually called the separation distance d. This name indicates that possible sources of WLAN signals should be kept away from this medical apparatus more than this "separation distance". At a found disturbance position, transmission of the WLAN signal was realized during several tens of seconds (typically 30 seconds). Testing was done according to a predefined testing program with predefined WLAN test signals. In the next paragraphs the following is presented:

- The chosen medical apparatuses tested;
- The choice and generation of the WLAN test signals;
- The way interference testing was performed;
- The test results and their interpretation (tables with descriptions of disturbances found at specified distance).

<sup>&</sup>lt;sup>3)</sup> Not the antennas of Access Points (A.P.s) of installed WLAN systems were considered relevant in this study. On the contrary: As relevant were considered: The antennas of handheld devices with which users may move around medical apparatus. (In WLAN terminology these hand-held devices are called "clients"). In this study the antennas of these hand-held devices were "simulated" by using Access Points.

# 2 Choice of Medical Apparatuses tested

When selecting medical apparatuses to be tested the key criterion was the direct medical safety for the patient at locations in the hospital.

In Table 2.1 below it is presented how many medical apparatuses of a certain type were tested at the AMC within the total of **97** tested medical apparatuses. Within one type / model / function of medical apparatus, more than one make was tested in a number of cases; never the same type / model was tested twice; no research was done on the variations within one type / model. As the last column indicates **7** medical apparatuses were tested that were connected to a medical apparatus that was tested as well (These connected apparatus were tested as medical apparatuses as well).

Table 2.1: Type and number of medical apparatuses tested.

Medical apparatuses tested (Type)	Number of medical	Number of medical
	apparatuses tested	apparatuses connected
Ventilator	7	
Gas Analyser	1	1
Syringe Pump	3	
Volumetric Infusion Pump	2	
Enteral Feeding Pump	1	
Intra-Aortic Balloon Pump	1	
Heart Assist Device	1	
Contrast Medium Pump	1	
Monitor/Meter	9	4
BGM	2	
Blood gas Analyser	5	
Dialysis	2	
EEG	3	
EKG	3	
Blood Warmer	2	
External Defibrillator / Monitor	2	
Infant Incubator	1	
Photo Therapy	1	
Pager System	2	
Patient Bed	1	
Cooling system	2	
Infant Warmer	2	
Patient Warmer (air)	1	
Temporary (External) Pacemaker	2	
Ultrasound Diagnostic Scanner	4	
Weighing Scale	4	
Surgical Microscope	4	2
Endoscopic System	1	
Bronchoscopic System	1	
Surgical Navigation	3	
Anaesthesia Ventilator	4	
Heart Lung Machine	2	

Heater/Cooler			1		
Blood gas Analyser			1		
Centrifugal Control Module			1		
Vitrectomia Unit			1		
Electrosurgery			1		
Ultrasound Surgery			1		
Cryosurgical System			1		
Laser			3		
	Total	97 =	90	+	7

In **Chapter 5** of this report the medical apparatuses tested are specified further. In **Appendix A** more details are given.

The following categories of apparatus were deliberately not included in the tests:

- Medical apparatus not likely used near the WLAN antennas such as implantable pacemakers or hearing aids;
- Electric wheelchairs;
- Medical equipment used at home;
- Non medical apparatus.

Medical apparatuses were tested according to a protocol that was settled before testing. Medical apparatuses were tested in normal use modes.

# 3 WLAN Test signals

Three WLAN systems were tested for their possible interference influence on medical apparatuses. The selection of the WLAN systems was an essential part of the testing process. The WLAN systems had different signal characteristics as can be seen from Table 3.1 below. As can be seen from the table, the carrier frequencies of the WLAN systems were 2,4GHz and 5GHz respectively.

The test signals of the WLAN systems are summarized in the next paragraphs. The test signals were chosen with the intention to have included in the testing as many normal use signals from WLAN systems as possible. WLAN signals can differ strongly depending on carrier frequency, data rate, package size and transmission conditions. All test signals fulfilled the international standard IEEE 802.11X with X being a, b or g. System "n" was not tested because this standard was at draft stage from 2004-2009 and practical implementation will take some more years. However "n" is not expected to result in interferences differing from those found in this research. As indicated in Table 3.1, the power level of some test signals was increased to 500mW. For the final conclusions in this report only the results with 100mW were counted and separated from results with higher power.

Table 3.1 Summary of the WLAN signals	used to test medical apparatuses for possible
influence.	

802.11.X	Frequency	Data rates **)	Channel	Power [mW] *)
X = b	b: 2,4GHz	b: 11Mbit/s	b: Ch1	b: 100mW
X = a + g	g: 2,4GHz	g: 54Mbit/s	g:Ch11	g: 100mW or 500mW
	a: 5GHz	a: 54Mbit/s	a: Ch36 and:	a: 500mW, provided with an extra amplifier
			a: Ch64	a: 100mW

- \*) The output power at the antenna connector was set in such a way that the power radiated from the antenna was at the level indicated in this column (EIRP). For the final conclusions in this report only the results with 100mW were counted and results with higher power were neglected.
- \*\*) Possible data rates for 802.11 **b** are: 1, 2, 5.5 or 11Mbit/s according to the standard. Possible data rates for 802.11 **g** and **a** are: 6, 12, 24, 32 or 54Mbit/s according to the standard.

To summarize the table above: During testing the following WLAN test signals were available:

- Ch1 (100mW/2,4GHz/11Mbit/s);
- Ch11 (500mW/2,4GHz/54Mbit/s) could also be switched to 100mW;
- Ch36 (500mW/5GHz/54Mbit/s);
- Ch64 (100mW/5GHz/54Mbit/s).

Depending on the package size the signal has different "zero-periods" on the radio connection: periods in which the Access Point (A.P.) is "listening". At the data link layer the signal was filled up with packages: short, middle or long packages (in bytes). At the PC the packages could be changed during the testing sessions:

- Short packages (length: 80 bytes),
- Middle length packages (length: 600 bytes),
- Long packages, (length: 1400 bytes)

On a digital oscilloscope signals were registered as typical samples of test signals on time scale of 0,1ms/div., 1ms/div. and 10ms/div. (see photograph in **Appendix C**).

At the AMC only long packages were transmitted because from earlier tests it revealed that long packages resulted in most interference (worst case).

Channels 1, 11, 36 and 64 were used in the testing. These channels are the most outer channels in the two frequency bands (2,4GHz Band and 5GHz Band) as far as indoor use is concerned. In the European Union Channel 13 may be used as well. This channel was not used for the interference tests. Not using this Channel was considered not influencing the relevancy of the results of the interference tests for the European situation – even when Channel 13 would be used. The reason for this being not relevant is that from EMC point of view the frequencies of Channel 11 and 13 hardly differ.

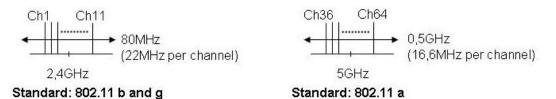


Figure 3.1 Channels 1, 11, 36 and 64 in their respective frequency bands at 2,4GHz and 5GHz according to the IEEE 802.11 standards.

The routine testing practice on every testing day was as shown in Table 3.2.

Table 3.2 Overview of routine testing practices.

Testing	ž.
order	
1	Switch off GSM phones.
2	Every test set-up in a new environment and every new day:
	- Make a spectrum registry of WLAN test signals as proof that test signals /
	field strength had the correct amplitude.
3	Have the medical apparatus functioning at normal settings. Simulate patient input
	signals or organize a volunteering test person to simulate patient signals (e.g. ECG).
4	Test with all transmitting antennas around the medical apparatus at the same time:
	- Testing duration: several tens of seconds (=typically 30s).
	- Start at 0cm from the medical apparatus,
	- Move around the medical apparatus with the Access Points
5	If disturbance occurs: find the separation distance <b>d</b> = biggest distance at which
	disturbance occurs.

Details of the test set-up can be found in **Appendix B** to this report.

## 4 Test Protocol

Most of the interference tests were performed at the Intensive Care department and at the Operating Room department of the AMC. Some tests were performed at other departments. Most of the testing took place in a technical location at these departments. Test rooms facilitated enough space around the medical apparatuses (typically 2m). Before testing started it was verified that at locations around, under and above the testing location, no interference issues could arise in the hospital practice. The test practices as described below were followed.

#### **Test practices**

The medical apparatus was located in such a way that it could be radiated from all sides (no persons or objects in the direct surroundings of the apparatus - especially not a metal testing table). Medical apparatuses were functioning normally; patient simulator or test person and/or patient phantom connected; attention was paid to possible sensitivity of simulators. For ECG apparatuses an ECG simulator was used or a volunteering testing person connected. For defibrillators a defibrillator tester was used. For ventilators an artificial lung was used. The point in space was searched, most far from the apparatus, where it could just be disturbed. When testing for possible susceptibility at a certain position in space, transmission was realized during several seconds. At a found disturbance position, transmission was realized during several tens of seconds before reporting.

The reaction of the medical apparatus (if any) was noted down: flashing lamps, audible alarms, display disturbances, all details. When the apparatus stopped, it was also reported whether it could be restarted by switching it OFF and ON again and whether all settings were lost or not. When disturbances occurred, it was also checked whether memory functions were disturbed.

Some typical test situations can be seen in the photographs in **Appendix C** to this report.

#### Remarks

- 1: The test method minimized the dependency from the environment where the tests took place.
- 2: If in this report for a certain type of medical apparatus no interference is reported one must not conclude that the apparatus is not susceptible. The reason for this is that tests were limited, had a typical (restricted) purpose and were not intended to cover the standard IEC 60601-1-2 for EMC of Medical Equipment. A conclusion about the complete EMC behaviour of a medical apparatus is the responsibility of the manufacturer and must be based on more elaborate testing.
- 3: The number of medical apparatuses included in the immunity testing was limited. The medical apparatuses were carefully selected to cover the actual situation in the rooms at the hospitals. The medical apparatuses and the WLAN systems are believed to represent a certain collection as can be found in more hospitals. However no strict general conclusions about other medical apparatus can be drawn from this report without careful judgment and comparison. In case of doubt additional testing may be needed (as international standards advise generally as well).

## 5 Results

#### 5.1 Introduction

In **Paragraph 5.3** below the results of interference tests are presented in detail. At first in **Paragraph 5.2** a classification of possible disturbances is presented. In **Paragraph 5.4** the results are summarized and in **Paragraph 5.5** presented graphically. In **Paragraph 5.6** the results are compared to interference by GSM phones.

#### 5.2 Classification of disturbances

Disturbances and/or interferences at the medical apparatuses were classified according to Table 5.1 below. The classifications only apply to the interference at the specific apparatus. The classification **U** (**U**nsafe) is not restricted to life threatening situations for the patient. The importance of interference must be seen in the right perspective: in a way every disturbance is unacceptable during treatment of patients <sup>4</sup>.

Table 5.1: Classification of disturbances/interferences in medical apparatus.

	Meaning	Example	
N	No, no disturbance or	- Irrelevant noise or humble from a loudspeaker.	
	interference occurs		
L	Light disturbance occurs	- Small interference on the Video Display/Screen of	fa
		medical apparatus but no disturbance of the	
		functioning of the apparatus.	
		- Relevant noise or humble from a loudspeaker.	
S	Significant but not (yet)	- Disturbance of the functioning of the apparatus bu	ιt
	unsafe disturbance	no safety hazard for patient or user - no indirect	
		safety hazard as well.	
		<ul> <li>Small "spikes" on ECG curves.</li> </ul>	
		<ul> <li>Disturbances on a display without hazard.</li> </ul>	
U	Unsafe disturbance	<ul> <li>Defibrillator with "spikes" on ECG curves</li> </ul>	
		(synchronisation error)	
		- (Correct) failure messages without acoustical alar	m.
		- Disturbance or stopping of an apparatus without	
		(acoustical) alarm.	
		- Disturbing a process or an indication (example: a	
		display) with a safety hazard aspect.	

The standard IEC TR 60513 **Literature [8]** lays down the international safety philosophy for medical apparatus. In this standard the starting point is the "vulnerable patient" who often is restricted partially or totally in reflex actions, using sense organs, movability, alertness, etc. Therefore the safety philosophy for medical apparatus is totally different from the safety philosophy for household or industrial equipment for example, that is used by healthy persons being not patients.

#### 5.3 Detailed results

In this paragraph all tested medical apparatuses are tabulated and all found interferences / disturbances are described in detail. The results are presented for the 100mW and the 500mW signals separately.

In total 97 apparatuses were tested at the AMC in June and October 2009. Nearly all were medical apparatuses (exception: two non-medical apparatuses: pager system and blood gas analyser).

Apparatuses as tested on 18 - 26 June 2009 are numbered 1 to 63. The numbering reflects the order of testing which was determined by practical circumstances like availability of a specific apparatus.

Apparatuses as tested on 19 - 22 October 2009 are numbered 1, 1A to 33 (= 34 apparatuses). The numbering starts with 1 again, but now *cursivated*. Most of the apparatuses 1-33 tested in October 2009 are used in the Operating Room only (Exception: Ear thermometer No. 32). The other apparatuses (tested in June 2009; number not cursivated) were sometimes used in the Operating Room but most of them at other medical departments of the AMC.

In table 5.2 below the separation distance **d** [in cm] can be found in column 4 named **Interference Y/N**. The separation distance **d** was determined for both 100mW and 500mW transmitted power. If interference was found, the WLAN Channel (1/11/36/64) is specified in the column 5 in table 5.1. Details about WLAN Channels can be found in chapter 3 of this report.

### **Legend to Table 5.2 below**

**Column 1**: The **No. in test** refers to the testing order of the medical apparatuses as recorded during the interference testing. Photos which illustrate the testing method can be found in **Appendix C** to this report.

**Column 2**: **Medical apparatus tested** are presented in this column per functional group. The type (name) of each medical apparatus is mentioned as it was indicated on the apparatus itself followed by the name of the manufacturer. Seven medical apparatuses were connected to medical apparatuses tested. They are marked with a ● in column 2. They were tested as medical apparatuses as well.

**Column 3**: The Year of purchase by the AMC. In cases marked with "?" the year of purchase could not be found or there was some doubt about it.

**Column 4**: In these column the separation distance **d** is given for those medical apparatuses that were influenced by WLAN signal(s). The letter **N** means that no interference occurred at any distance from the medical apparatus including distance 0cm (=WLAN antenna against the medical apparatus). The footnotes in columns 4 refer to details of the interferences found. In columns 4 the influences found are classified according to the **N/L/S/U** scheme <sup>5</sup> as described in **Paragraph 5.2** of this report.

**Column 5**: The channel that transmitted the WLAN signal in case of interference.

<sup>&</sup>lt;sup>5)</sup> N/L/S/U = No/Light/Significant/Unsafe disturbance or interference. In Netherlands language: = N/L/S/O = Nee/Lichte/Significante/Onveilige verstoring of interferentie.

Table 5.2 All tested medical apparatuses and description of all interferences found, the separation distance **d** per apparatus and the classification of the interference.

No. in test	p	Year of purchase		Interference Y/N Classific. N/L/S/U 100mW:cm 500mW:cm	Channel No. 1/ 11/ 36/ 64
	Ventilator				
15	Galileo type Gold, Hamilton		01	N	
32	Galileo Type Classic, Hamilton		03	Y <sup>6</sup> ) Classific.: U 100mW: 10cm 500mW: 50cm	1 / 11 11
46	C2, Hamilton		80	N	
52	G5, Hamilton		80	N	
53	Raphael Color, Hamilton		03	N	
58	Raphael XTC, Hamilton		80	N	
17	Babylog 8000, Dräger		95	N	
	Gas Analyser				
16	Printer Nox Bedfont NO meter, Cardin Health	nal	09	Y <sup>7</sup> ) Classific.: U 100mw: 0cm 500mW: 5cm	1/11/36/64 11
31	Evita 4, Dräger		96	N	
	Syringe Pump				
2	Perfusor Space, B.Braun		08	N	
14	Perfusor fm, B.Braun		99	N	
7	Alaris PK		06	N	
	Volumetric Infusion Pump				
1	Infusomat Space P, B.Braun		08	N	
4	Infusomat P, B.Braun		04	N	
	Enteral Feeding Pump				
5	Applix Smart, Fresenius Kabi		07	N	
	Intra-Aortic Balloon Pump				
10	AutoCAT2WAVE, Arrow		05	N	
	Heart Assist Device				
11	Impella - Pump, Abiomed - Impella		05	N	
	Contrast Medium Pump				
20	Mallinckrodt Optivantage DH, Tyco Healtho	care	06	N	
	Monitor/Meter				
6	Patient Monitor MP 90 (Intellivue), Philips		03	N	

<sup>&</sup>lt;sup>6</sup>) **Ch1** 100mW: 10cm from backside and from vertical sides: Flowtriggers occur incorrectly. Photo in **Figure C.4** is taken with antenna at 0cm. At 0cm the Respiration Frequency raises from 25→ 37 cycles/min.

Ch11 at 100mW: 10cm from backside and from vertical sides: Flowtriggers occur incorrectly.

**Ch11** at 500mW: 50cm from backside and from vertical sides: Flowtriggers occur incorrectly. NB: **Ch36** and **Ch64**: No interference.

<sup>&</sup>lt;sup>7</sup>) **Ch1** 100mW: 0cm from specific place on housing: Incorrect steps of ca. 0,5 ppmNO-indication (no alarm).

**Ch11** at 500mW: 5cm from specific place on housing: Incorrect steps of ppmNO-indication. At 0cm: Incorrect indication of ca. 61 ppmNO plus alarm AND: Incorrect steps of more than 5 ppmNO indication PLUS: Spontaneous wrong indication of NOX (which is 0 in reality). Effect starts at 5cm.

**Ch11** at 100mW: 0cm from specific place on housing: Incorrect steps of more than 5 ppmNO-indication (no alarm).

Ch36 at 100(!)mW: 0cm from specific place on housing: Incorrect steps of ca. 0,5 ppmNO-indication (no alarm).

**Ch64** at 100mW: 0cm from specific place on housing: Incorrect steps of ca. 0,5 ppmNO-indication (no alarm).

No. in test		Year of purcha	se	Interference Y/N Classific. N/L/S/U 100mW:cm 500mW:cm	Channel No. 1/ 11/ 36/ 64
7	ICP (Intracranial) Monitor Camino SPM-1, Integra Neurosciences		09(?)	N	
8	<ul> <li>Pressure Monitoring Set (Intra Arteria Sensor), Edwards Lifesciences</li> </ul>	ıl	09	N	
27	Polysomnography Unit N 7000, Embla (Me	edcare)	?	N	
28	Transcutaneous CO2 / O2 meter TCN Radiometer	Л 40,	07	N	
29	Capnograph / Pulsoxymeter Microcap (Microstream), Oridion	Plus	07	N	
21	Pulsoxymeter Oximax N-600, Nellcor		09	N	
22	Pulsoxymeter 3900 Oximeter TruTrak+, D Ohmeda		04	N	
47	Video System (Intubation) Glidescope, Mc Portable GVL, Saturn Biomedical Systems	del s, Inc.	09	N	
1	Monitor CMS, Philips	invis	ible	N	
1A	<ul> <li>Gas Analyser "Airway Gases" M1026</li> <li>Philips</li> </ul>		05	N	
41	Ear Thermometer M 3000A, Tyco Healthc First TempGenius	are /	80	Y <sup>8</sup> ) Classific.: U 100mw: 20cm 500mW: 30cm	1 / 11 / 64 11 / 36
32	Ear Thermometer Genius 2 IR Tympanic Thermometer, Tyco Healthca (New type purchased by AMC)	are	09	Y <sup>9</sup> ) Classific.: U 100mw: No 500mW: 1cm	- 11
	BGM				
45	Bedside BGM B-glucose Analyser, Hemo AB		03	N	
49	Blood Glucose Meter Accu-Check Inform,	Roche	?	N	
	Blood gas Analyser				
48	i-Stat 1 Analyser, Abbott		80	N	
54	Rapidlab 865, CIBA-Corning		95	N	
42	Rapidlab 1265, Bayer Healthcare		06	N	
33	MR 850 AFU, Fisher en Paykel		02	N	
40	MR 730, Fisher en Paykel		96	N	
	Dialysis				
3	Diapact CRRT, B.Braun		97	N	
26	Home Choice Pro Automated PD System (Peritoneal), Baxter		03	N	
	EEG				
55	EEG: osg Brainlab // sw-version 4		02	N	
56	EEG: SD LTM 64 BS, Micromed		09	Y <sup>10</sup> ) Classific.: S 100mW: 30cm 500mW:100cm	1 /11 11

 $<sup>^{8}</sup>$ ) Ch1 100mW: 20cm from Sensor: Temperature is influenced. At 0cm: From 22  $\rightarrow$  23  $^{0}$ C.

**Ch11** at 500mW: 30cm from Sensor: Temperature is influenced. At 0cm: From  $22 \rightarrow 27$  °C.

**Ch11** at 100mW: 10cm from Sensor: Temperature is influenced. At 0cm: From 22  $\rightarrow$  26  $^{\circ}$ C.

**Ch36** at 500mW: 30cm from Sensor: Temperature is influenced. At 0cm: From 22  $\rightarrow$  32  $^{\circ}$ C.

**Ch64** at 100mW: 10cm from Sensor: Temperature is influenced. At 0cm: From 22  $\rightarrow$  24  $^{0}$ C.

<sup>&</sup>lt;sup>9</sup>) **Ch11** at 500mW: 1cm from thermometer housing: Temperature is influenced. At 0cm: 2,4°C too high. NB: **Ch1, Ch36** and **Ch64**: No interference.

<sup>&</sup>lt;sup>10</sup>) **Ch1** 100mW: 5cm from headbox and belonging cables: Interfering voltage on screen. At 0cm: 400micovolt amplitude as measured on screen.

**Ch11** at 500mW: 100cm from headbox and belonging cables: Interfering voltage on screen. At 0cm: 1000micovolt amplitude as measured on screen.

**Ch11** at 100mW: 30cm from headbox and belonging cables: Interfering voltage on screen. At 0cm: 600micovolt amplitude as measured on screen.

NB: Ch36 and Ch64: No interference.

in test	р	ear of urcha		Interference Y/N Classific. N/L/S/U 100mW:cm 500mW:cm	Channel No. 1/ 11/ 36/ 64
	EEG: SAM 32 RFO fc 1, Micromed		09	Y <sup>11</sup> ) Classific.: S 100mw: 10cm 500mW: 20cm	1 / 11 11
	EKG				
61	EKG: Mac 5000 12 Channels, Marquette		02	N	
62	EKG: Mac 5500, General Electric (ex Marc		80	N	
39	EMG: Medelec Synergy, Viasys Healthcare	;	80	N	
	Blood Warmer				
18	Fluido, The Surgical Company		07	Y <sup>12</sup> ) Classific.: U 100mw: 25cm 500mW: 35cm	1 /11 11 / 36
10	Fluid Management System FMS 2000, Belmont		09	Y <sup>13</sup> ) Classific.: U 100mw: No 500mW: 10cm	- 11
	External Defibrillator / Monitor				
59, 60	Lifepak 20, Medtronic		03	N	
	Infant Incubator				
25	Giraffe, Ohmeda		02	N	
	Photo Therapy				
23	Photo Therapy (Lamp) System BiliBlanket I Ohmeda	Plus,	03	N	
	Pager System				
50, 51	Emergency Department ("S.E.H."), Stanley	works	06	N	
	Patient Bed				
63	Total Care Duo 2, Hill-Rom		03	N	
	Cooling system				
30	Cooling blanket Cair Cooler, Pentatherm		05	N	
9	Mattress (water) Blanketroll II, Cincinnati Si Zero	ub-	03	N	
	Infant Warmer				
19	Ohio Warming Table System IWS 4400, Oh			N	
34	Babytherm 8004, Dräger		02	N	
	Patient Warmer (air)				

<sup>11</sup>) **Ch1** 100mW: 0cm from headbox and belonging cables: Interfering voltage on screen. At 0cm(!): 100micovolt amplitude as measured on screen.

Ch11 at 500mW: 20cm from headbox and belonging cables: Interfering voltage on screen. At 0cm: 2000micovolt amplitude as measured on screen.

Ch11 at 100mW: 10cm from headbox and belonging cables: Interfering voltage on screen. At 0cm: 1000micovolt amplitude as measured on screen.

NB: Ch36 and Ch64: No interference.

<sup>12</sup>) **Ch1** 100mW: 0cm from backside: Delta Flow = 65 ml/min. peak-to-peak. Delta T = 0.4 °C. Ch11 at 500mW: 35cm from backside: Influence starts.

At 0cm from backside: Delta Flow = 310 ml/min. peak-to-peak. Delta T = 2  $^{\circ}$ C.

Ch11 at 100mW: 25cm from backside: Influence starts.

At 0cm from backside: Delta Flow = 100 ml/min. peak-to-peak. Delta T = 1  $^{0}$ C.

Ch36 at 500mW: 0cm from backside: Influence starts.

At 0cm from backside: Delta Flow = 100 ml/min. peak-to-peak. Delta T = 0.5  $^{\circ}$ C.

NB: **Ch64**: No interference.

<sup>13</sup> )Ch11 at 500mW: 10cm from locking handle (disposable): Temperature indication is influenced. At 0cm: 2°C.

NB: Ch1, Ch36 and Ch64: No interference.

No. in test	Medical apparatus tested  Year of purchase  Warm Air Hyperthermia System, The Surgical Company			Interference Y/N Classific. N/L/S/U 100mW:cm	Channel No. 1/ 11/ 36/ 64
0.5			00	500mW:cm	
35			02	N	
	Temporary (External) Pacemaker				
12	5348 Single Chamber (Marked "8"), Medtro	onic	04	N	
13	5388 Dual Chamber (Marked "23"), Medtro		04	N	
	Ultrasound Diagnostic Scanner				
43	Vivid 7 Dimension, GE Healthcare		08	N	
44	Model EUB 6500, Hitachi		04	N	
8	Vivid Five, Vingmed Technomlogy / GE		01	N	
19	Site Rite 3, BARD		02	N	
-	Weighing Scale		_	· ·	
36	Model 757, Seca		04	N	
37	Model 376, Seca		07	N	
38	Bedscale 2002, Scale-Tronix		02	Y <sup>14</sup> ) Classific.: S	
30	Bedscale 2002, Scale-1101lix		02	100mw: 5cm	1 / 11
				500mW: 20cm	11
24	Type 7726 Electronic, Soehnle Professiona	al	07	N	
	Surgical Microscope				
18	OPMI Pentero, Zeiss		06	N	
20	NC4, Carl Zeiss Surgical		06	N	
25	F20, Leica		?	N	
26	Monitor Model LMD-2450MD, Sony		09	N	
27	S8, Carl Zeiss Surgical		08	N	
28	Monitor X-17 AV, Neovo		08	N	
	Endoscopic System				
3	Extera II (CV 180 + CLV 180), Olympus		07	N	
	Bronchoscopic System		-		
11	Image 1 + Xenon 300, Storz		06	N	
, ,	Surgical Navigation		00	14	
23	Vector Vision, BrainLAB		05	N	
23 24	Kolibro, BrainLAB		06	N	
2 <del>4</del> 29	StealthStation TREON plus, Medtronic		03	N	
29	Anaesthesia Ventilator		03	IN .	
2			01	N	
2 4	Aestiva/5, Datex-Ohmeda		01	N	
	S/5 Avance, Datex-Ohmeda Julian, Dräger				
15	. 0		00	N	
21	Zeus, Dräger		06	N	
_	Heart Lung Machine		00	N.I.	
5	S5, Stöckert		06	N	1
12	Roller pump, Stöckert		07	N	
	Heater/Cooler		0.0		
6	Coolant Type R134A, Maquet / Jostra		09	N	
	Blood gas Analyser				
17	CDI 500, Terumo		01	N	
	Centrifugal Control Module				
9	3M, Sarns		97	N	
	Vitrectomia Unit				
22	Vitrectomie 25G, Constellation, Alcon		09	N	

Ch1 100mW: 5cm from frontside: Wrong indication.
Ch11 at 500mW: 20cm. from frontside: Wrong indication.
Ch11 at 100mW: 5cm. from frontside: Wrong indication.

NB: Ch36 and Ch64: No interference.

No. in test	Medical apparatus tested	Year of purchase		Interference Y/N Classific. N/L/S/U 100mW:cm 500mW:cm	Channel No. 1/ 11/ 36/ 64
	Electrosurgery				
13	Force Triad, Valleylab		09	N	
	Ultrasound Surgery				
14	Ultracision, Ethicon / Johnson&Johnson		07	N	
	Cryosurgical System				
33	Precise, Galil Medical		80	N	
	Laser				
16	Ultra Pulse Laser CO <sub>2</sub> , Lumenis		09	N	
30	Versapuls, Lumenis		02	N	
31	Calculase HoYAG (2080nm) Class 4, Pilo (635nm) Class 2, Carl Storz Endoscope	ot	09	N	

#### 5.4 Summary of results

A summary of all medical apparatuses tested that were influenced is given in Table 5.3 below.

Table 5.3: Summary of all tested medical apparatuses that were influenced and the

separation distance **d** per apparatus (at 500mW and 100mW).

No. in	Medical apparatuses tested Year purc	of hase	Separation distance d [cm] and Classification: L / S / U			/ Ū
test			At 100m	W	At 500	0mW
	Ventilator					
32	Galileo Type Classic, Hamilton		10cm <b>U</b>		50cm	U
	Gas Analyser					
16	Printer Nox Bedfont NO meter, Cardinal Health (Coupled to Ventilator No. 17)		0cm <b>U</b>		5cm	U
	Monitor/Meter					
41	Ear Thermometer M 3000A, Tyco Healthcare / First TempGenius		20cm <b>U</b>		30cm	U
32	Ear Thermometer Genius 2 IR Tympanic Thermometer, Tyco Healthcare (New type purchased by AMC)		No interfer	ence	1cm	U
	EEG					
56	EEG: SD LTM 64 BS, Micromed		30cm <b>S</b>	;	100cm	S
57	EEG: SAM 32 RFO fc 1, Micromed		10cm <b>S</b>		20cm	S
	Blood Warmer					
18	Fluido, The Surgical Company	07	25cm <b>U</b>		35cm	U
10	Fluid Management System FMS 2000, Belmo	nt 09	No interfer	ence	10cm	U
	Weighing Scale					
38	Bedscale 2002, Scale-Tronix	02	5cm <b>S</b>		20cm	S

Full details about the interference reactions and the WLAN Channels are given in Table 5.2.

#### 5.5 Graphical presentation of results

The test results are presented in the tables and graphs on the following page. Table 5.4 is directly copied from the summary of results in Table 5.3 in **Paragraph 5.4**. In the graphs of Figures 5.1 and 5.2 the following is depicted:

• The percentage of medical apparatuses that was disturbed at a distance **d** or higher. This percentage (%) is along the vertical axis; the distance **d** (in cm) is along the horizontal axis. The curves with the black dot markings belong to the results in Table 5.4 for 100mW and 500mW respectively.

From Figure 5.1 for example it can be concluded that at distances above 20cm about 3% of the medical apparatuses tested was disturbed by the WLAN signal 100mW. The continuous graphs are the theoretical field strength at distance **d** from WLAN antennas according to the basic formula  $E = 7 \times (\sqrt{W}) / d$  in which W is power in watt (See **Literature** [5]). This field strength must be taken from the right vertical axis in the graphs of Figure 5.1 and Figure 5.2. Two examples:

- Example 1 (Figure 5.1): At 50cm from a WLAN 100mW antenna (dipole) the field strength is about 4,4 V/m.
- Example 2 See Figure 5.2.: At 50cm from a WLAN 500mW antenna (dipole) the field strength is about 9,9 V/m.

In the Table 5.4 below the disturbances found are listed in order according to the separation distance **d** at which influence occurred by **100mW** and **500mW** WLAN signals respectively. Note that the two lists contain the same information, however in different order.

Table 5.4: The found disturbances listed in order of separation distance at 100mW and 500mW respectively (The two lists contain the same information, however in different order).

At 100mW				
No. in	Separa	tion dist	ance d [	cm]
Test	At 100m	ıW	At 500mW	
32	No inter	ference	1cm	U
10	No inter	No interference		U
16	0cm	U	5cm	U
38	5cm	S	20cm	S
57	10cm	S	20cm	S
32	10cm	U	50cm	U
41	20cm	U	30cm	U
18	25cm	U	35cm	U
56	30cm	S	100cm	S

			At 500n	nW
No. in	Separa	ation dis	tance d	[cm]
Test	At 100	mW	<b>At 500</b> n	nW
32	No inte	rference	1cm	U
16	0cm	U	5cm	U
10	No inte	rference	10cm	U
38	5cm	S	20cm	S
57	10cm	S	20cm	S
41	20cm	U	30cm	U
18	25cm	U	35cm	U
32	10cm	U	50cm	U
56	30cm	S	100cm	S

Conclusions from the graphs in Figure 5.1 and Figure 5.2:

- For **100mW** the distance at which 3% of the tested medical apparatuses was influenced is: 20cm;
- For **500mW** the distance at which 3% of the tested medical apparatuses was influenced is: 35cm;
- As mentioned above already, the 3% point for 100mW is at 20cm. As can be seen from Figure 5.2 the 3% point for 500mW is at about 35cm. This shift in distance (about a factor 2) is comparable to the figure that the formula  $E = 7 \times (\sqrt{W}) / d$  would imply (from 100mW to 500mW implies a shift of  $\sqrt{5} = 2,24$ );
- The characterisations of the disturbances (**S** and **U**) are indicated in both diagrams. As can be seen the letters **S** and **U** are equally distributed over the distances. So unsafe disturbances generally occur at all distances.

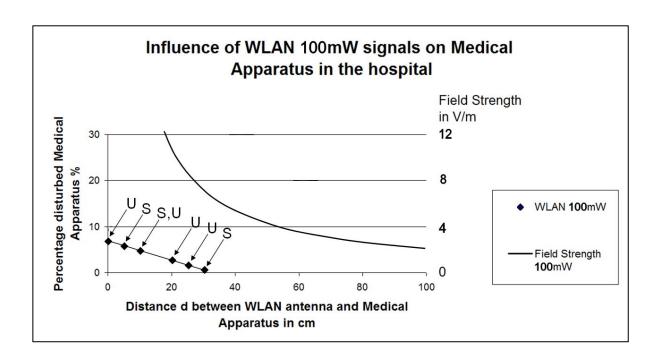


Figure 5.1: Influence of WLAN 100mW signals on medical apparatuses in hospitals.

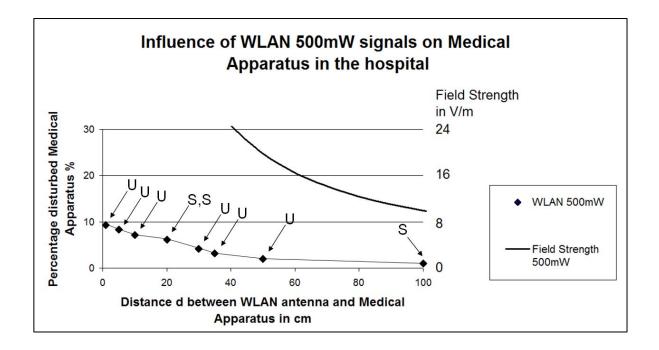


Figure 5.2: Influence of WLAN 500mW signals on medical apparatuses in hospitals.

## 5.6 Comparison of results to GSM results

Interpretation of WLAN results as presented in the **Paragraph 5.5** is possible by comparing them with results from comparable research on GSM mobile phones. In Figure 5.3 the results from research on GSM mobile phones are depicted (copied from **Literature [5] and [6]**).

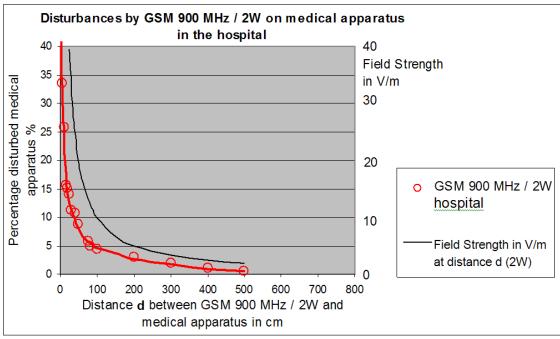


Figure 5.3: Disturbances by GSM 900 MHz / 2W on medical apparatus in the hospital (copied from Literature [5] and [6]).

From the graph in Figure 5.3 it can be seen that at 150cm distance from GSM phones about 3% of the medical apparatus is disturbed. The distance at which 3% apparatus are disturbed is internationally advised as the separation distance to be kept <sup>15</sup>. As concluded in **Paragraph 5.5** the 3% point for WLAN 100mW lies at 20cm. From this comparison it concludes that the ratio between the separation distances for GSM and WLAN is about a factor of 7.

<sup>&</sup>lt;sup>15)</sup> It is generally advised not to have GSM phones transmitting within this distance from a medical apparatus (in hospital and in home environment). See for example:

<sup>-</sup> Hanada et al in IEEE Trans on EMC November 2000 Literature [9],

<sup>-</sup> Health Devices November 2001 (ECRI) Literature [10].

<sup>-</sup> Morrissey et al, Health Physics (2002) 82: pp 4 - 51 Literature [11].

<sup>-</sup> A Netherlands regulation is: V-ICTN Recommendations **Literature** [7] based on **Literature** [5] and referring to **Literature** [3].

# 6 Signatures

Author	Signature
R. Hensbroek, M.Sc.	Remodensbrock
Project manager	
Approved by	Signature
Drs. R.A. Bezemer	THE
Peer review	

# A Functional modes of all tested medical apparatuses

In Table A.1 below details can be found about the functions that the medical apparatuses performed during interference testing. Details about the power situation are given as well (powered from the mains and/or from the internal battery if present). Apparatuses are tabulated in the same order as in the other tables in this report.

Table A.1: Functional modes of all tested medical apparatuses and specification of the

power source (mains or battery).

	power source (mains or batter		
No.		ear of	Functional modes of medical
in test	P	urchase	apparatuses and specification of the power source (mains or battery)
lesi	Ventilator		the power source (mains or battery)
4.5		0.4	Maria OMAN / IIN / alarga a saggil /
15	Galileo type Gold, Hamilton	01	Mode: CMV "Volwassenen" (= grown- ups)
32	Galileo Type Classic, Hamilton	03	Powered from the mains;
			Mode: (S)CMV // 25 cycles/min //
L			500 ml // 10 cmH2O // 50 % O2
46	C2, Hamilton	08	(S)CMV // 500 ml // 3 cmH2O // 21 % O2 // Flowtrigger 3l/min
52	G5, Hamilton	08	P-CMV Infant // 40 c/min // 20 cmH2O // 21 % O2 // Peep 3 cmH2O
53	Raphael Color, Hamilton	03	(S)CMV // c=20 b/min // 9 l/min //
55	Ixaphael Color, Hamilton	03	VT=500ml // 50 % O2 // PEEP 5 cmH2O
58	Raphael XTC, Hamilton	08	(S)CMV // c=20 b/min // VT=500ml //
56	Rapriaei XTC, Hamilton	08	Trigger 6I/min // 50 % O2 // PEEP
			5cmH2O
17	Babylog 8000, Dräger	95	Mode: IMV (PEEP 3,4); Gas Analyser
			16 was connected to 17
	Gas Analyser		
16	Printer Nox Bedfont NO meter, Card	inal 09	Coupled to <b>Ventilator</b> 17 (Babylog
	Health		8000)
31	Evita 4, Dräger	96	Mode: IPPV Autoflow V; f=20; V=0,4
	Syringe Pump		
2	Perfusor Space, B.Braun	08	Mode: Functioning
14	Perfusor fm, B.Braun	99	20 ml/hr
7	Alaris PK	06	Empty syringe; normal delivery
			settings
	Volumetric Infusion Pump		
1	Infusomat Space P, B.Braun	08	Mode: Functioning
4	Infusomat P, B.Braun	04	Mode: Functioning
	Enteral Feeding Pump		
5	Applix Smart, Fresenius Kabi	07	Mode: Functioning
	Intra-Aortic Balloon Pump		
10	AutoCAT2WAVE, Arrow	05	Synchronised with EKG (Simulator)
	Heart Assist Device		
11	Impella - Pump, Abiomed - Impella	05	Measured with UP - Impella Testplug Pump (Not measured with Catheter)
	Contrast Medium Pump		
20	Mallinckrodt Optivantage DH, Tyco	06	Set at 2 ml/sec; Data Connection Box
	Healthcare		and Console included in test set-up
	Monitor/Meter		
6	Patient Monitor MP 90 (Intellivue), Philips	03	Mode: Functioning. App. No.8 was connected
7	ICP (Intracranial) Monitor Camino SPM-1	, 09(?)	
ľ	Integra Neurosciences	,   (.)	(App. No. 6) via Pressure Unit ("Druk")

No.	Medical apparatus tested Y	ear of		Functional modes of medical
in		ourchas		apparatuses and specification of
test				the power source (mains or battery)
8	Pressure Monitoring Set (Intra Arteri	ial 0	9	Connected to MP 90 (App. No. 6) via
	Sensor), Edwards Lifesciences			Measurement Server ("broodje")
27	Polysomnography Unit N 7000, Embla	?		Mode: Functioning
28	(Medcare)  Transcutaneous CO2 / O2 meter TC	M 0	7	See also App. No. 28 and 29 Connected to App. No. 27; Also tested
20	40, Radiometer	JIVI U	,	separately with SpO2
29	Capnograph / Pulsoxymeter Microca	0 ag	7	Connected to App. No. 27; Also tested
	Plus (Microstream), Oridion			separately. Tested while measuring
				Capnography EtCO2 and with SpO2.
21	Pulsoxymeter Oximax N-600, Nellcor	0:		Alarm levels were set active
22	Pulsoxymeter 3900 Oximeter TruTrak+,	04	4	Alarm levels were set active
47	Datex - Ohmeda Video System (Intubation) Glidescope, M	ladal O	0	Dowered from mains only (Potters was
47	Portable GVL, Saturn Biomedical System		9	Powered from mains only (Battery was empty)
	Inc.	13,		Chipty)
1	Monitor CMS, Philips	in	ıvi-	ECG, SaO <sub>2</sub> /Pleth, IBP, Vue Link;
		si	ible	Connected tot "Computerbox" Agilent
				M1046B / CE0366 (2001).
1A	Gas Analyser "Airway Gases" M1020	6B. 0	5	Gas Analyser 1A was connected.  Top-box on Monitor CMS (App. No. 1)
174	Philips	ов, U	5	Top-box on Monitor Civis (App. No. 1)
41	Ear Thermometer M 3000A, Tyco Healtho	care 0	8	Mode: Surface Measurement (During
	/ First TempGenius			this continuous measurement
				influence could be detected easier
22	For Thormometer Conius 2	- 0	0	than before)
32	Ear Thermometer Genius 2 IR Tympanic Thermometer, Tyco Healtho	osre 0	9	Mode: This version has 1 mode only. It can not measure continously.
	(New type purchased by AMC)	Jaic		Therefore detecting influence was
	( ton type parenassa by time)			more difficult than before
	BGM			
45	Bedside BGM B-glucose Analyser, Hemo	Cue 0	3	Mode: Functioning
	AB			
49	Blood Glucose Meter Accu-Check Inform	ı, ?		Glucose measurement performed after
	Roche Blood gas Analyser			Calibration
48	i-Stat 1 Analyser, Abbott	08	Ω	Mode: Functioning
	, ,	9:		
54	Rapidlab 865, CIBA-Corning			Mode: Functioning
42	Rapidlab 1265, Bayer Healthcare	0	ь	Siemens Automatic QC included in test.
33	MR 850 AFU, Fisher en Paykel	0:	2	Indicating 39 °C
40	MR 730, Fisher en Paykel	9(		Mode: Indicating Air Temperature
70	Witt 750, Fisher erri ayker	3	U	39 °C
	Dialysis			
3	Diapact CRRT, B.Braun	9	7	CVVH 150 ml/hr
26	Home Choice Pro Automated PD System	n 0:	3	Functional with complete set and
	(Peritoneal), Baxter			artificial belly
	EEG			
55	EEG: osg Brainlab // sw-version 4	0:	2	5 Channels electrodes placed on
			_	human arm
56	EEG: SD LTM 64 BS, Micromed	09		Electrodes placed on human arm
57	EEG: SAM 32 RFO fc 1, Micromed	0	9	Electrodes placed on human arm
	EKG			
61	EKG: Mac 5000 12 Channels, Marquette	0:	2	Powered from internal battery
				(=normal use);
62	EKC : Mag 5500 Conoral Floatria (av.	0	0	ECG simulator: Fluke MPS 450
62	EKG : Mac 5500, General Electric (ex Marquette)	0	O	Powered from internal battery (=normal use);
	, and quotio,			ECG simulator: Fluke MPS 450
39	EMG: Medelec Synergy, Viasys Healthca	are 0	8	Mode: Tested while stimulating Nervus
				Medianus (Distal Right
				10 mA Impulses)

No. in		ear of urchase	Functional modes of medical apparatuses and specification of
test	Blood Warmer	1	the power source (mains or battery)
10	Fluido, The Surgical Company	07	Mode: 150 ml/min./ 38°C
18 10	Fluid Management System FMS 2000,	07	Settings: 200 ml/min; 37,2°C
10	Belmont  External Defibrillator / Monitor	09	Settings, 200 mi/min, 37,2 C
		00	D 16 0 : D 51 31 0
59, 60	Lifepak 20, Medtronic	03	Powered from the mains; Defibrillation was done Synchronous + Asynchronous; No 60: built-in pacemaker
	Infant Incubator		·
25	Giraffe, Ohmeda	02	Set at 37 °C; Photo Therapy Light activated also; Tested with skin sensor in and not in control loop
	Photo Therapy		
23	Photo Therapy (Lamp) System BiliBlanke Plus, Ohmeda	t 03	Mode: Functioning
	Pager System		
50,	Emergency Department ("S.E.H."),	06	Pager: Model APG 5 + Group-call
51	Stanleyworks Patient Bed		AHHA (Acute Hersen Hulp -11 pagers)
63	Total Care Duo 2, Hill-Rom	03	Mode: Functioning
03	Cooling system	03	Mode. Full clioning
20		0.5	Cooling from 22 40 °C and
30	Cooling blanket Cair Cooler, Pentatherm	05	Cooling from 22 → 10 °C and from 17 → 22 °C
9	Mattress (water) Blanketroll II, Cincinnati Zero	Sub-03	Settings: Both Servo + Hand control
	Infant Warmer		
19	Ohio Warming Table System IWS 4400, Ohmeda	80	Set at 35,3 °C
34	Babytherm 8004, Dräger	02	Warming + Light activated; Manual control + control by skin temperature sensor
	Patient Warmer (air)		
35	Warm Air Hyperthermia System, The Sur	gical 02	Set at 43,3 °C
	Temporary (External) Pacemaker		
12	5348 Single Chamber (Marked "8"), Medtronic	04	Synchronous and Asynchronous
13	5388 Dual Chamber (Marked "23"), Medtr	onic 04	DDD and Asynchronous Atrial
	Ultrasound Diagnostic Scanner		
43	Vivid 7 Dimension, GE Healthcare	08	Mode: Functioning
44	Model EUB 6500, Hitachi	04	Mode: Functioning
8	Vivid Five, Vingmed Technomlogy / GE	01	Mode: Functioning
19	Site Rite 3, BARD	02	Mode: Functioning
	Weighing Scale		3
36	Model 757, Seca	04	Mode: Powered form mains + On + Hold
37	Model 376, Seca	07	Mode: Functioning
38	Bedscale 2002, Scale-Tronix	02	Powered from internal battery (scale does not have a mains connection)
24	Type 7726 Electronic, Soehnle Profession	nal 07	Mode: Functioning
	Surgical Microscope		
18	OPMI Pentero, Zeiss	06	Mode: Functioning
20	NC4, Carl Zeiss Surgical	06	Mode: Functioning
25	F20, Leica	?	Mode: Functioning. No. 26 was connected
26	Monitor Model LMD-2450MD, Sony	09	Connected to Surgical Microscope No. 25

No. in test		ear of ourchase	Functional modes of medical apparatuses and specification of the power source (mains or battery)
27	S8, Carl Zeiss Surgical	08	Mode: Functioning. No. 28 was connected
28	Monitor X-17 AV, Neovo	08	Connected to Surgical Microscope No. 27
	Endoscopic System		
3	Extera II (CV 180 + CLV 180), Olympus	07	Mode: Functioning
	Bronchoscopic System		
11	Image 1 + Xenon 300, Storz	06	System parts: Image 1, Xenon 300, Storz, Monotor PVM-20M2MDE
	Surgical Navigation		
23	Vector Vision, BrainLAB	05	Tested in start-up configuration (marker-check)
24	Kolibro, BrainLAB	06	Mode: functioning
29	StealthStation TREON plus, Medtronic	03	Mode: Functioning
	Anaesthesia Ventilator		
2	Aestiva/5, Datex-Ohmeda	01	Mode: Volume controlled, F=12 min <sup>-1</sup> , Tidal Volume = 0,5ltr, I:E=1:2,
4	S/5 Avance, Datex-Ohmeda	04	Mode: Tidal Volume=0,5 ltr, F=12 min <sup>-1</sup> , I:E=1:2 , Flow=6 ltr/min, O <sub>2</sub> =100%
15	Julian, Dräger	00	Mode: Tidal Volume = 0,6 ltr, F=12 min <sup>-1</sup> , Flow=3 ltr/min, O₂=100%, Pmax=25cmH₂O
21	Zeus, Dräger	06	Mode: Tidal Volume = 0,4 ltr, F=12 min <sup>-1</sup> , Flow=6 ltr/min, $O_2$ =100%
	Heart Lung Machine		
5	S5, Stöckert	06	System parts: Console, 3 Pump Units,S5 Gas Blender, Clamp(Okkluder from 2008)
12	Roller pump, Stöckert	07	Mode: Several speeds observed; no fluid line in pump
	Heater/Cooler		
6	Coolant Type R134A, Maquet / Jostra	09	Mode: Normal Functioning
	Blood gas Analyser		
17	CDI 500, Terumo	01	Monitor blood gas
	Centrifugal Control Module		
9	3M, Sarns	97	pom = ca. 2800 r.p.m. (No flow through the flow sensor)
	Vitrectomia Unit		
22	Vitrectomie 25G, Constellation, Alcon	09	Functioning with disposables connected
	Electrosurgery		
13	Force Triad, Valleylab	09	Mode: Monopolar Cut and Coagulation
	Ultrasound Surgery		
14	Ultracision, Ethicon / Johnson&Johnson	07	SonoSurg Generator tested without scissors
	Cryosurgical System		
33	Precise, Galil Medical	08	Mode: Start-up screen only (No instruments available; no cryogenic procedure)
	Laser		
16	Ultra Pulse Laser CO <sub>2</sub> , Lumenis	09	Setting: 1 Watt
30	Versapuls, Lumenis	02	Mode: Activated; 5Hz; 3,2 Joule
31	Calculase HoYAG (2080nm) Class 4, Pile (635nm) Class 2, Carl Storz Endoscope	ot 09	Mode: Activated; 6Hz; 0,5 Joule

## B WLAN test set-up

- 1. Measurement Equipment to monitor testing
  - o Spectrum analyser: fsh manufactured by Rohde & Schwarz;
  - o Attenuator 20dB.
- 2. Hardware in the test set-up:
  - o 2 PC's / 8 AP's (in this way combining 802.11 a, b, g in one test);
  - o Amplifiers at 2,4GHz and at 5 GHz to start testing on every medical apparatus with 2 channels at higher power levels than normal;
  - o Medical Apparatuses were placed on a wooden cart.

**Note**: 4 Access Points simulated 4 clients. These 4 A.P.s were brought close to the medical equipment. 4 other A.P.s communicated with the "client-simulating-A.P.s". The A.P.s were Lancom A.P.s (Lancom L-54 dual wireless) with Atheros Chipsets (=Printed Circuit Boards). The A.P.s fulfilled the requirements of IEC/EN 60601-1-2 (for EMC on medical equipment). The results of the interference tests (**Paragraph 5**) are considered independent from the make of the A.P.s.

**Note**: Antennas were normalized antennas. No directional antennas were used. Within a distance of 15cm from the antennas far field conditions do not apply for 2,4GHz. Within a distance of 8cm from antennas far field conditions do not apply for 5GHz. Testing at distance 0cm means that the antenna is held against the medical apparatus. At this distance no far field conditions occur. In the near field it is not possible to apply the (simple) standard far field formulas that relate field strength to radiated power at a certain distance. In the far field however such calculations can be performed in principle.

The diagram in Figure B.1 below depicts the test set-up. See also the photographs in **Appendix C** to this report.

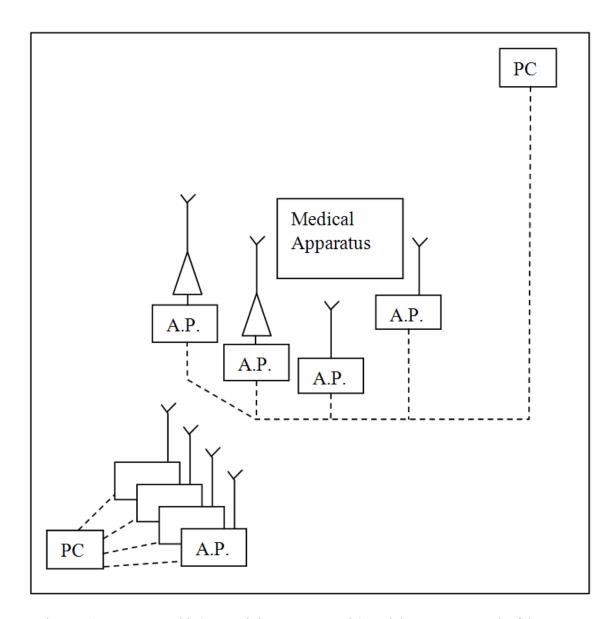


Figure B.1: Test set-up with 4 transmitting antennas and 4 receiving antennas. Each of these groups of antennas was connected to a separate PC.

# C Photographs

Figure C.1 shows the test signal of Channel 1 with short packages. The photo is obtained with a spectrum analyzer at zero span. The time base was 0,1ms/division (upper trace), 1ms/div (middle trace) and 10ms/div (lower trace). As indicated in the montage by accolades, the upper trace can be recognized as being a part of the middle trace, etcetera.

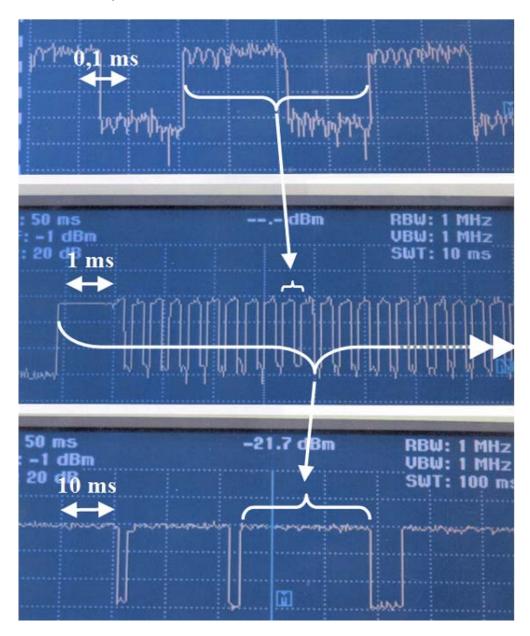


Figure C.1 Test signal of Ch1 with short packages. The time base: 0,1ms/division (upper trace), 1ms/div (middle trace) and 10ms/div (lower trace).

In the photographs following below a transmitting antenna in verification is shown (Figure C.2), interference effects on medical apparatuses (Figure C.3, C.4), the cart with receiving antennas (Figure C.6) and typical test situations with medical apparatuses (Figures C.5, C.7 and C.8).

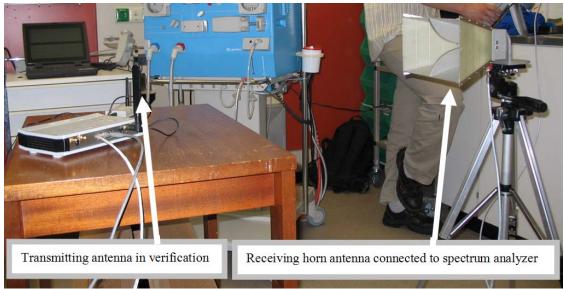


Figure C.2. Transmitting antenna in verification.



Figure C.3. Interference effect on Ventilator Galileo Type Classic (Apparatus No. 32).

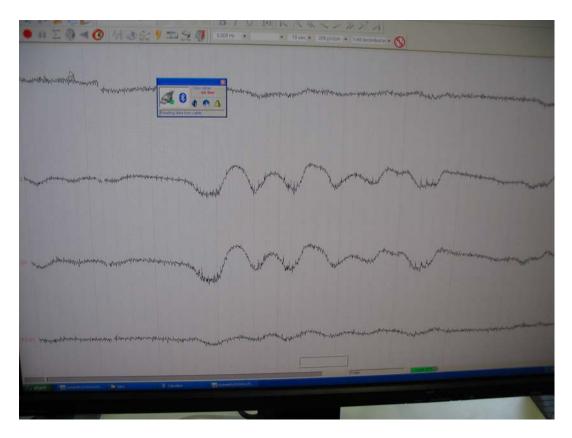


Figure C.4. Interference effect on EEG apparatus SD LTM 64 BS, Micromed (Apparatus No. 56).



Figure C.5. WLAN antenna Ch. 11 near Printer  $NO_X\,$  (Apparatus No. 16).

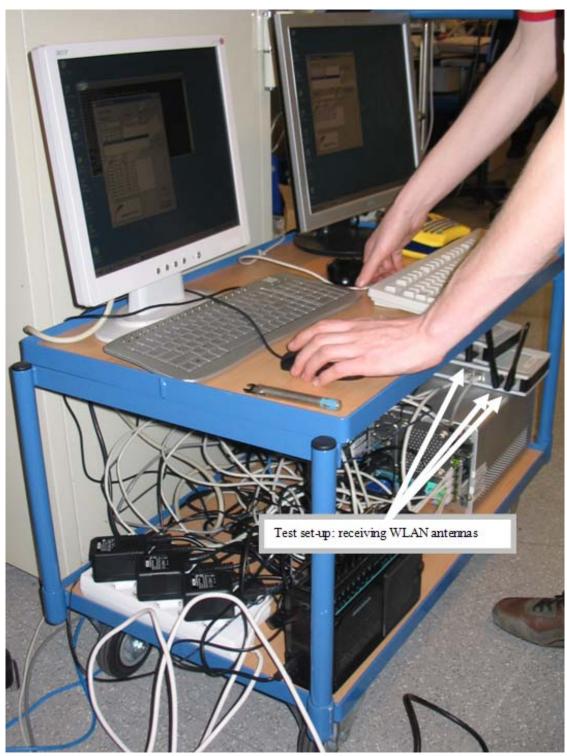


Figure C.6.

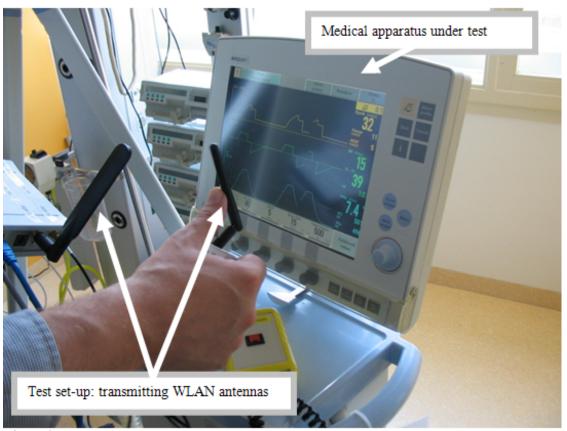


Figure C.7.

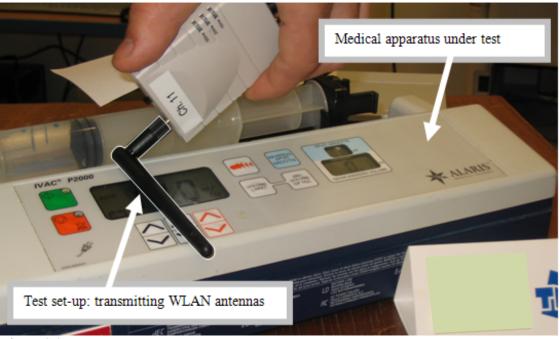


Figure C.8.

## D Literature

- 1. TNO report "96 Medical Apparatuses tested for interference by WLAN/WiFi signals" R. Hensbroek, TNO Quality of Life, Report Number: KvL/P&Z 2007.117 dated September 2007. See: <a href="http://www.TNO.nl/WLAN-Zorg">http://www.TNO.nl/WLAN-Zorg</a>
- 2. Magazine "Technologie in de Gezondheidszorg" (NL language). April 2005, Number 4, 21st Issue, pp.5-6
- 3. Recommendations regarding the use of pocket telephones within health care institutions 1995, VIFKA, 1 September 1995 (VIFKA is now called "Vereniging ICT Nederland").
- 4. IEC 60601-1-2: 2007 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance Collateral standard: Electromagnetic compatibility Requirements and tests. Third edition.
- 5. TNO report "Effects on medical equipment at home of pocket phones and the like field measurements", TNO Prevention and Health, TNO Research report PG/TG/00.050 (28 April 2000) For medical apparatus this report refers to:
  Influence of 2W GSM pocket phones on 205 medical apparatuses: field measurements. TNO report TG/95.044. 1 August 1995 (NL Language).
- 6. R. Hensbroek, Interference by handheld telephones on medical equipment (NL language). In magazine: "Klinische Fysica". December 2000.
- 7. Recommendations for the use of GSM and cordless telephones near electronic medical equipment for home care, 25 October 2000. This document has been drawn up by the Telecommunication branch of the Netherlands Association for Information and Communication Technology (V-ICTN). It is published on the internet site of the Netherlands Ministry of Welfare, Health and Sports. Those recommendations refer to the still applicable recommendations in Literature [3]: Recommendations regarding the use of pocket telephones within health care institutions 1995, VIFKA, 1 September 1995 (VIFKA is now called "Vereniging ICT Nederland").
- 8. IEC TR 60513 (1994) Fundamental Aspects of Safety Standards for Medical Electrical Equipment.
- 9. Hanada et al: Electromagnetic Interference on Medical Equipment by Low-power Mobile Telecommunication Systems. IEEE Transactions on Electromagnetic Compatibility, Vol. 42, No. 4, November 2000, pp. 470-476.
- 10. ECRI Health Devices 30 (11), November 2001: Wireless Communication Devices and Electromagnetic Interference, pp. 403-409.
- 11. Morrissey et al: Characterization of Electromagnetic Interference of Medical Devices in the Hospital due to Cell Phones. Health Physics, January 2002, Volume 82, Number 1, pp 45-51.