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**TNO report**

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**Influence of Mobile Terminals for GSM, GPRS  
and UMTS on 22 Medical Apparatuses**

|                      |                                                                               |
|----------------------|-------------------------------------------------------------------------------|
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## Summary

This interference study was performed on 22 medical apparatuses selected by the St. Antonius Hospital at Nieuwegein, The Netherlands. The selected medical apparatuses were seen as critical for patient safety. The medical apparatuses were tested at susceptibility for GSM, GPRS and UMTS signals. These signals were transmitted close to the medical apparatuses at maximum power levels as applicable according to the GSM, GPRS and UMTS standards. The medical apparatuses were placed in the hospital environment. They were fully active during testing but they were not connected to patients for obvious reason. The tested medical apparatuses were 4 Monitors, 3 Pumps, 3 Incubators, 2 Dialys Machines, 2 External (Temporary) Cardiac Pacemakers and others.

All medical apparatuses were tested when functioning. Where relevant, tests were performed both with an apparatus powered from the mains and powered from its internal accumulator. The separation distance was determined. This is the distance to the point in space most far from the apparatus where it could just be disturbed. At a found disturbance position, transmission was realised during several tens of seconds.

Five test signals were used. Four of them were GSM/GPRS signals. Two GSM/GPRS signals had 903.2MHz as their carrier wave frequency; two others 1737,6MHz. At both frequencies one signal was a GSM/GPRS signal with one time slot filled. At both frequencies the other GSM/GPRS signal had two consecutive time slots filled. The fifth test signal was a continuous UMTS signal at 1947, 2MHz. Disturbance reactions by the medical apparatuses were classified according to their possible hazardous consequences for the patient.

For the GSM/GPRS signals the biggest distance at which ca. 3% of the 22 medical apparatuses tested could be disturbed was 50cm. Due to the restricted number (22) of medical apparatuses tested, the uncertainty in this separation distance if used for a bigger collection of medical apparatuses is about 50%.

For the UMTS signal one disturbance was found (at 15cm) despite of the low power of the UMTS signal.

### Remarks:

- If in this report for a certain model of medical apparatuses no interference is reported one must not conclude that the apparatus fulfils all EMC requirements. The reason for this is that tests were limited and had a typical (restricted) purpose. A conclusion of this type belongs to the responsibility of the manufacturer and must be based on more elaborate testing.
- The GPRS system in this research transmits over the European GSM system that has a power of 2W in active timeslots in the GSM 900 MHz band and 1W in the GSM 1800 MHz band (root mean square value during transmission in a time slot). When comparing results from this research with publications from the US, one must realise that mobile GSM phones ("Cell phones") in the US often transmit at a lower power level: 0,6W.
- GSM, GPRS and UMTS signals have not been transmitted with variable power during the interference tests. However in practice UMTS power will be variable according to a power control scheme determined by the system. The power of

GSM/GPRS signals in practice is controlled by the telecommunication network system as well.

The number of 22 tested medical apparatuses is bigger than in some international studies. However TNO published in 2007 together with the AMC results of identical interference tests on 61 medical apparatuses <sup>1)</sup>.

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<sup>1)</sup> Interference by new-generation mobile phones on critical care medical equipment. In Magazine: *Critical Care* May 2007, 11:R98. E.J. van Lieshout, S. N. van der Veer, R. Hensbroek, J. C. Korevaar, M. B. Vroom and M. J. Schultz. See website <http://www.ccforum.com/content/11/5/R98> (visited 2009-09-01).

# Contents

|          |                                                             |           |
|----------|-------------------------------------------------------------|-----------|
|          | <b>Summary .....</b>                                        | <b>2</b>  |
| <b>1</b> | <b>Introduction.....</b>                                    | <b>5</b>  |
| 1.1      | Description of the test .....                               | 5         |
| <b>2</b> | <b>Choice and number of medical apparatuses tested.....</b> | <b>7</b>  |
| <b>3</b> | <b>Test signals .....</b>                                   | <b>9</b>  |
| <b>4</b> | <b>Test set-up and test protocol .....</b>                  | <b>11</b> |
| <b>5</b> | <b>Results.....</b>                                         | <b>12</b> |
| 5.1      | Classification of disturbances .....                        | 12        |
| 5.2      | Results per medical apparatus.....                          | 12        |
| 5.3      | Detailed reactions of the medical apparatuses tested.....   | 14        |
| 5.4      | Results analysed.....                                       | 18        |
| 5.5      | Discussion of results .....                                 | 20        |
| <b>6</b> | <b>Signature.....</b>                                       | <b>22</b> |
|          | <b>Appendices</b>                                           |           |
|          | A Photographs                                               |           |
|          | B The set-up for generating test signals                    |           |
|          | C Literature                                                |           |

**Note:** Bold symbols between brackets [ ] indicate hyperlinks in the e-version of this report.

# 1 Introduction

This interference study was performed on 22 medical apparatuses selected by the St. Antonius Hospital at Nieuwegein, The Netherlands. The hospital considered to introduce GSM/GPRS technology and/or UMTS technology and needed to know the interference behaviour of specific in-house medical apparatuses. Therefore selected medical apparatuses (see below) were tested for possible susceptibility for UMTS and GSM/GPRS signals from mobile terminals (Uplink) <sup>2)</sup>.

Both GSM/GPRS and UMTS were included in the tests because in the absence of UMTS coverage, the communication will take place through GPRS. GPRS uses the GSM 900 MHz system or the GSM 1800 MHz system with 1 or two time slots filled (see below). The GSM, GPRS and UMTS signals came from a suitable generator. The signals were fed into balanced measuring antennas via amplifiers and power meters. Modulation and amplitude were set at a laptop PC. This PC had been programmed by Agilent (HP) to have a choice between about 20 different testing signals. This allowed for testing independently from the GSM/GPRS/UMTS telecommunication network. In this way the signals could be transmitted at maximum specified power. And the precise moments of transmission could be determined by the testing procedure because there were no (network related) connection delays. (In network mode the network would have determined the power level and the precise connection moment. This would have introduced uncertainty in the testing process. Especially the power at which tests took place would have been unknown). Transmitting through balanced measurement antennas has been proved a reliable method earlier <sup>3)</sup>. Transmitting with balanced antennas is attractive mainly because of easy manipulation of antennas. Additionally the influence of the person holding the antenna can be neglected - and this does not apply to a person that must manipulate a mobile terminal (a pda / mobile phone / cell phone / handy).

## 1.1 Description of the test

In order to test possible susceptibility of medical apparatuses 22 of them were set upon their own in the hospital environment and subjected to GSM, GPRS and UMTS signals. These medical apparatuses could in principle be positioned in the vicinity of GSM, GPRS or UMTS terminals in the hospital practice. Where relevant, the medical apparatuses were tested both powered from the mains and powered from the internal accumulator. During testing the point in space most far from a medical apparatus was determined where it could just be disturbed. From this the so-called separation distance resulted. At a found disturbance position, transmission was realised during several tens of seconds. Testing was done with five test signals. In the next paragraphs the following is presented:

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<sup>2)</sup> Also named “mobile hand terminals”. They can have the same appearance as “traditional” mobile phones. The “Uplink” is the signal path from hand terminal to telecommunication network.

<sup>3)</sup> See TNO report **Literature** [4] in which the disturbing effect of balanced measurement antennas is compared to the effect of mobile phones operating in the 900MHz band and in the 1800MHz band.

- The choice of the medical apparatuses tested,
- The choice and generation of the GSM/GPRS and UMTS test signals,
- The way of testing,
- The test results and their interpretation.

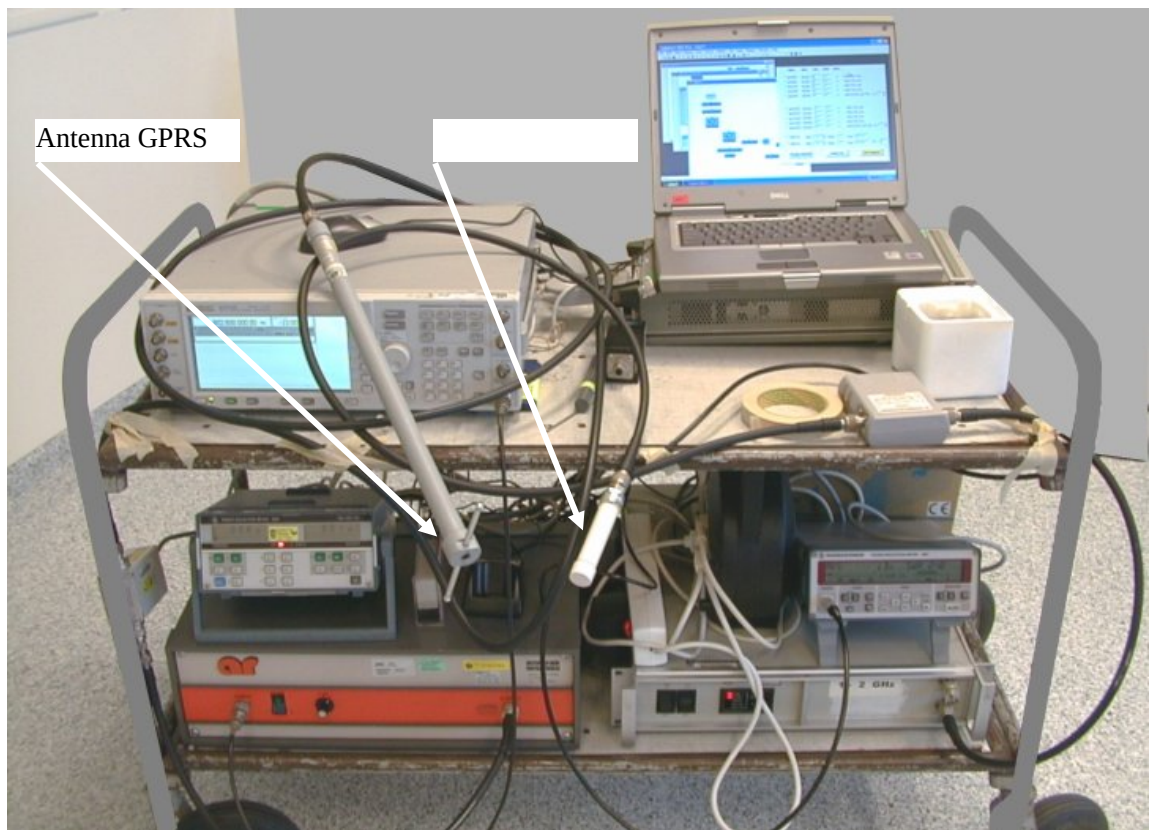


Figure 1: Test set-up to generate the GSM/GPRS and UMTS test signals

## 2 Choice and number of medical apparatuses tested

The selected medical apparatuses were seen by the hospital as critical for patient safety. The hospital choice was also based on the set of 61 medical apparatuses tested earlier by TNO together with the AMC. Apparatuses already tested at the AMC needed not be tested again.

By specifying the medical apparatuses tested in detail in this report, other hospitals is given the opportunity to decide whether the collection of apparatuses tested represents the situation at other places.

In the table below the 22 medical apparatuses tested in this study at the Antonius are presented together with the 61 medical apparatuses tested at the AMC. In total group of  $22 + 61 = 83$  within one type / function of medical apparatus, more than one make was tested in most cases; never the same model was tested twice however (no research was done on the variations within one make or model because this was not seen as important for the purpose of the study).

### Numbers of medical apparatuses tested:

Notation: "Number tested at AMC" + "Number tested at the St. Antonius"

| Type / function of medical apparatus | Number of models tested<br>" AMC" + "St. Antonius" |
|--------------------------------------|----------------------------------------------------|
| Critical Care Monitor                | 12 + 4                                             |
| ICU Ventilator                       | 9                                                  |
| Syringe Pump                         | 7 + 1                                              |
| Volumetric Infusion Pump             | 4 + 1                                              |
| Hemofiltration / Dialysis            | 5 + 2                                              |
| Temporary External Cardiac Pacemaker | 4 + 2                                              |
| Defibrillator/AED                    | 3                                                  |
| Forced-air Warming Unit              | 3                                                  |
| Fluid Warmer                         | 2                                                  |
| Blood Warmer                         | 0 + 2                                              |
| Critical Care Bed                    | 2                                                  |
| Enteral Feeding Pump                 | 2 + 1                                              |
| Intra-aortic Balloon Pump            | 2 + 1                                              |
| Telemetry System                     | 2 + 3                                              |
| ECG 12 Leads                         | 1                                                  |
| Mobile Suction Unit                  | 1                                                  |
| Continuous-airflow Mattress          | 1                                                  |
| Air Humidifier                       | 1                                                  |
| Anaesthesia Ventilator               | 0 + 1                                              |
| Heart-Lung Machine                   | 0 + 1                                              |
| Incubator                            | 0 + 3                                              |
| Total number of apparatuses tested   | 61 + 22                                            |

The photographs in **Appendix A** show details of five of the 22 medical apparatuses tested at the St. Antonius Hospital.

The 22 medical apparatuses tested and their functional details are given in the table below. The “No.” (First column) relates to the sequential order in which the apparatuses were tested and registered during testing.

**Medical apparatuses:** Functions tested, Settings and other details (For test results see other tables).

| No.                                           | Medical apparatus tested                                                                                   | Functions tested, Settings and other details                                                                                                                                                                       | Battery / Mains |
|-----------------------------------------------|------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| <b>Syringe Pump</b>                           |                                                                                                            |                                                                                                                                                                                                                    |                 |
| 1                                             | Asena GH, Alaris Medical Systems                                                                           | 20ml/hour resp.200ml/hour; Syringe: BD Plastipak 50                                                                                                                                                                | Battery + Mains |
| <b>Volumetric Infusion Pump</b>               |                                                                                                            |                                                                                                                                                                                                                    |                 |
| 2                                             | Asena/GW, Alaris Medical Systems                                                                           | 100 ml/hour                                                                                                                                                                                                        | Battery + Mains |
| <b>Enteral Feeding Pump</b>                   |                                                                                                            |                                                                                                                                                                                                                    |                 |
| 3                                             | Kangaroo ePump, Sherwood                                                                                   | 200ml/hour                                                                                                                                                                                                         | Battery + Mains |
| <b>Intra-Aortic Balloon Pump</b>              |                                                                                                            |                                                                                                                                                                                                                    |                 |
| 11                                            | CS300, Datascope                                                                                           | Normal settings                                                                                                                                                                                                    | Mains           |
| <b>Patient Monitor/Meter</b>                  |                                                                                                            |                                                                                                                                                                                                                    |                 |
| 9                                             | IntelliVue MP70, Philips;<br>With Monitor IntelliVueX2                                                     | <b>Parameters:</b> ECG, ABP, HF, SpO <sub>2</sub> , NiBP                                                                                                                                                           | Mains           |
| 10                                            | IntelliVueX2, Philips                                                                                      | <b>Parameters:</b> ECG, ABP, HF, SpO <sub>2</sub> , NiBP                                                                                                                                                           | Battery         |
| 7                                             | AS3, Datex Ohmeda [Incl Mainframe, Multiparameter, Anesthesia Gas Module and coupled to ADU A-Auf (No.8) ] | <b>Parameters:</b> ECG, Invasive Press. P1, Temp. T1, SpO <sub>2</sub><br><b>Anesthesia Gases:</b> O <sub>2</sub> , CO <sub>2</sub> , N <sub>2</sub> O, Sevoflurane, Spirometric Measurement + Damp Identification | Battery + Mains |
| 14                                            | Infinity Delta, Dräger;<br>[Incl. Multimed 12 and HemoMed.]                                                | <b>Parameters:</b> ABP, HF (80 from Fluke Simulator MPS 450)                                                                                                                                                       | Battery + Mains |
| <b>Anaesthesia Ventilator</b>                 |                                                                                                            |                                                                                                                                                                                                                    |                 |
| 8                                             | ADU A-Auf, Datex-Ohmeda                                                                                    | Volume controlled; 1 l/min O <sub>2</sub> ; 7 l/min Min.Vol                                                                                                                                                        | Mains           |
| <b>Dialysis</b>                               |                                                                                                            |                                                                                                                                                                                                                    |                 |
| 4                                             | Prismaflex, Gambro                                                                                         | 200ml/min;<br>Tested with complete set + artificial kidney                                                                                                                                                         | Mains           |
| 6                                             | Dialog <sup>+</sup> , B. Braun                                                                             | 300ml/min. HDF = Hemo Dia Filtration;<br>Tested with complete set + artificial kidney                                                                                                                              | Mains           |
| <b>Blood Warmer</b>                           |                                                                                                            |                                                                                                                                                                                                                    |                 |
| 5                                             | Autocontrol 3XPT, Barkey<br>Connected to Dialysis Prismaflex                                               | Patient line was placed in Warmer. Warmer was set at 41°C fixed (not actively controlling the temperature)                                                                                                         | Mains           |
| 19                                            | Level 1, Sims Industries                                                                                   | Set at 41°C                                                                                                                                                                                                        | Mains           |
| <b>Temporary (External) Cardiac Pacemaker</b> |                                                                                                            |                                                                                                                                                                                                                    |                 |
| 12                                            | EV 4543, Pace Medical Inc.<br>Single Chamber VVI                                                           | <b>A: Synchron. Pacing:</b> 4V; <b>Sensitivity:</b> 1 resp. 2 mV<br><b>B: Asynchronous:</b> Pacing rate: 210                                                                                                       | Battery         |
| 13                                            | 4570, Pace Medical Inc.<br>Dual chamber                                                                    | <b>A: Pacing :</b> DDD-mode : <b>Sense Arterial:</b> 1 mV<br>and <b>Sense Ventricular:</b> 2 mV<br><b>B: Static pacing:</b> DDI: <b>Output pulse:</b> 10 V                                                         | Battery         |
| <b>Heart-Lung Machine</b>                     |                                                                                                            |                                                                                                                                                                                                                    |                 |
| 15                                            | HL 30 (Nr.22 for Thoracic Surgery)                                                                         | Several components included: Among others:<br>OR-computer Maquet                                                                                                                                                   | Mains           |
| <b>Incubator</b>                              |                                                                                                            |                                                                                                                                                                                                                    |                 |
| 16                                            | 8000 SC, Dräger                                                                                            | Set at 33°C                                                                                                                                                                                                        | Mains           |
| 17                                            | Isolette TI 500, Dräger / Airshields                                                                       | Normal setting                                                                                                                                                                                                     | Battery + Mains |
| 18                                            | Isolette C 2000, Hill-ROM/Air Shields                                                                      | Normal setting                                                                                                                                                                                                     | Mains           |
| <b>Telemetry</b>                              |                                                                                                            |                                                                                                                                                                                                                    |                 |
| 20                                            | Transmitter 7496263E5604, Dräger                                                                           | F = 203,450MHz,                                                                                                                                                                                                    | Battery         |
| 21                                            | Monitor Fujitsi/Siemens, Monitor only                                                                      | Normal screen settings                                                                                                                                                                                             | Mains           |
| 22                                            | Antenna Winegard-Bublington LA                                                                             | Actively receiving in system                                                                                                                                                                                       | From system     |



### 3 Test signals

Five test signals - four of them named S1, S1a, S2 and S2a for the purpose of identification - were selected from a set of 20 possible test signals that could be generated with the test set-up. Restriction of the number of test signals was a critical planning factor for testing. Total test time during the research was 3 to 4 days.

The following test signals were used:

- S 1: GPRS in the 900MHz band with two time slots filled (2TSL)
- S 1a: GSM in the 900MHz band with one time slot filled (1TSL)
- S 2: GPRS in the 1800MHz band with two time slots filled (2TSL)
- S 2a: GSM in the 1800MHz band with one time slot filled (1TSL)
- UMTS

The timing principals of these signals are outlined in **Figure 2**. As indicated in the figure the signal **GPRS 2TSL** contains two active time slots (TSL = Time Slot) in every frame. Because of the two filled time slots the GPRS 2TSL signal implies a stronger interfering potential than the “ordinary” GSM/GPRS 1TSL signal that has one active time slot in every frame (with same frame duration P).

**Remark:** In the AMC a special “GPRS 1 in 64” signal was used as well as depicted in the figure. This signal was not used at the St. Antonius because it was not relevant there.

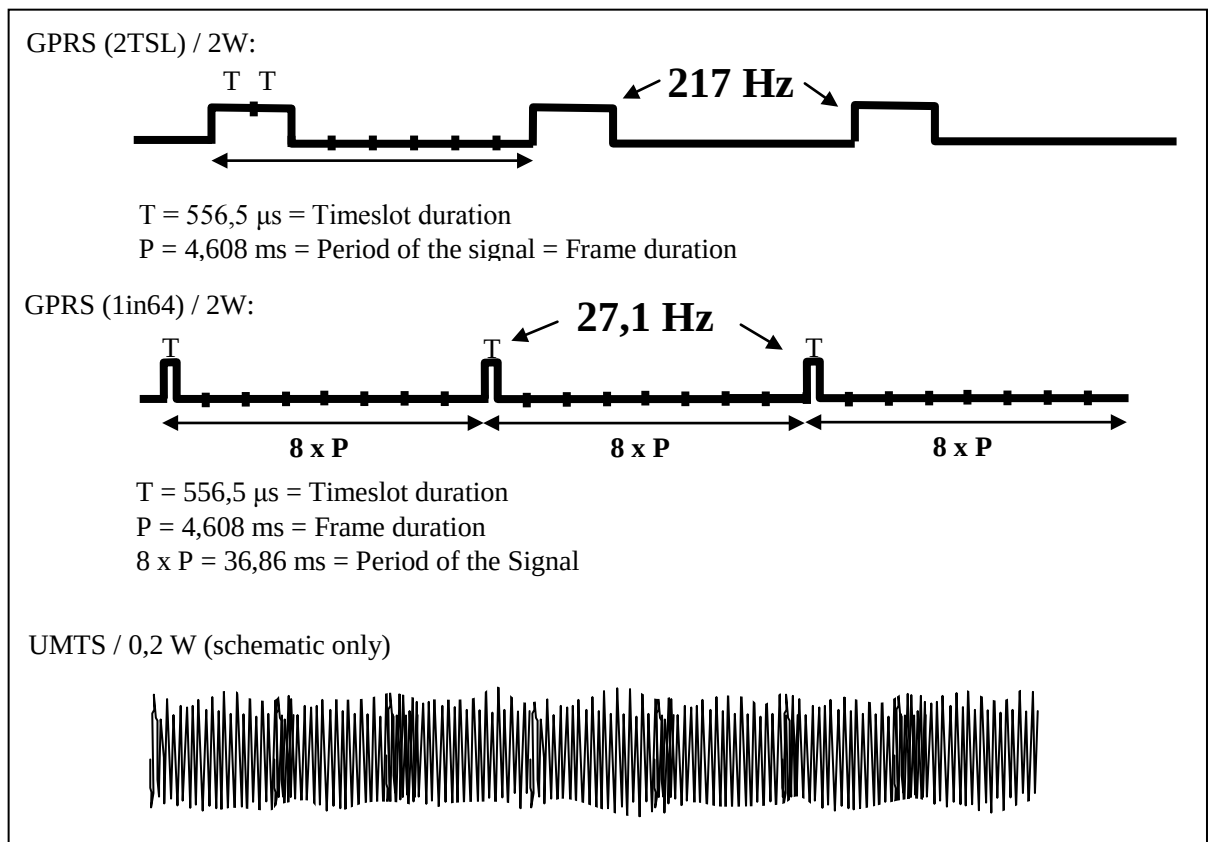


Figure 2: Sketch of the timing principles in the five test signals used in the St. Antonius Hospital

The **UMTS** signal has the character of a noisy signal as indicated in Figure 2. The power difference between GPRS and UMTS is not graphically scaled in Figure 2.

The details about the frequency and the power of the test signals are:

- GPRS was tested in both the 900 MHz band and the 1800 MHz band. Based on earlier research [4] it was expected that signals in the 1800 MHz band would have less interfering potential because of their lower power and their higher carrier frequency. This behaviour was to be verified again in this study.
- The carrier frequencies and the transmitted power of the test signals were:
  - For GSM/GPRS 900 MHz / 2W = 33 dBm: 903,2 MHz  
(= Channel 66 Uplink; Channel Bandwidth 0,2 MHz).
  - For GSM/GPRS: 1800 MHz / 1W = 33 dBm: 1737,6 MHz  
(= Channel 649 Uplink; Channel Bandwidth 0,2 MHz).
  - For UMTS: FDD 1947,2 MHz / 0,2W = 23 dBm  
(Uplink; Channel Bandwidth 4,93 MHz).

The frequencies and powers were specifically allowed for this project by KPN, department Wholesale&Operations Mobile.

In **Appendix [B]** the test set-up providing these five signals is described.

## 4 Test set-up and test protocol

The tests were performed in the hospital environment. Testing took place in a technical room and at some departments in the St. Antonius Hospital. The rooms measured bigger than 5x10 m; the test locations were free from objects in the direct surroundings of the apparatus to be tested. Before testing an inspection took place to verify that at locations around under and above the testing location no interference issues could occur during testing. The next test practices were followed:

Locate the medical apparatus in such a way that it can be radiated from all sides (no persons or metal objects in the direct surroundings of the apparatus - especially not a metal testing table). Have the apparatus functioning normally; test person or simulator and/or patient phantom connected; INsensitivity of the simulator for disturbances is to be proven separately always. For ECG apparatus an ECG simulator is used or a volunteering testing person connected. For ventilators an artificial lung is used. Search for the point in space most far from the apparatus where it can just be disturbed. When testing for possible susceptibility at a position, transmission is realised during several seconds. At a found disturbance position transmission is realised during several tens of seconds before reporting.

The reaction of the apparatus (if any) is noted down: lamps that are flashing, audible alarms, display disturbances, all details. When the apparatus is stopping also report whether it can be restarted by switching it OFF and ON again and whether all settings were lost or not. When disturbances occur also check whether memory functions were disturbed. Classify the behaviour of the apparatus.

### Remarks:

- If in this report for a certain model of medical apparatuses no interference is reported one must not conclude that the apparatus fulfils all EMC requirements. The reason for this is that tests were limited and had a typical (restricted) purpose. A conclusion of this type belongs to the responsibility of the manufacturer and must be based on more elaborate testing.
- The GPRS system in this research transmits over the European GSM system that has a power of 2W in active timeslots in the GSM 900 MHz band and 1W in the GSM 1800 MHz band (root mean square value during transmission in a time slot). When comparing results from this research with publications from the US, one must realise that mobile GSM phones ("Cell phones") in the US often transmit at a lower power level: 0,6W.

## 5 Results

### 5.1 Classification of disturbances

Disturbances at the medical apparatuses caused by the five interference signals were classified according to the principle described below. The classifications only apply to the interference at the specific medical apparatus. The classification **H** (**Hazardous**) is not restricted to life threatening situations for the patient. The importance of classification should not be over emphasized: in a way every disturbance is not acceptable during treatment of patients <sup>4</sup>).

H = Hazardous: direct physical influence on patient by unintended change in equipment function  
 S = Significant: influence on monitoring with significant level of attention needed causing substantial distraction from patient care  
 L = Light: ....without significant level

### 5.2 Results per medical apparatus

The results are summarised below as follows:

- The “No. in test” (first column) relates to the sequential order in which the apparatuses were tested and registered during testing. The number corresponds to table 1 and has the only purpose to identify the apparatus within this report,
- The last 5 columns specify the **Separation distance**: the biggest distance in cm at which the apparatus could be disturbed with each of the five interfering signals mentioned above. In this column also the classification **H**, **S**, **L** or **n** is presented with meaning as explained above,
- The **Reactions** of the apparatuses are detailed in the table in the next paragraph,
- In the column **Ye**. the year of purchase is presented.

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<sup>4</sup>) The standard IEC 60513 **Literature** [7] 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, in using sense organs, in movability, in 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 a patients.

**Legend for Reactions:** H=Hazardous; S=Significant; L=Light (does not occur in this report); n=no Reaction.

**Last 5 Columns:** S 1 = GPRS 900MHz (2TSL), S 1a=GPRS 900MHz (1TSL),

S 2 = GPRS 1800MHz (2TSL); S 2a=GPRS 1800MHz (1TSL).

| No. in Test                                   | Medical apparatus tested                                                                             | Year of Purchase | Remarks and Administrative Numbers                                           | For each Interference Signal: Separation Distance in cm + Reaction Class H,S,L,n |      |      |     |      |
|-----------------------------------------------|------------------------------------------------------------------------------------------------------|------------------|------------------------------------------------------------------------------|----------------------------------------------------------------------------------|------|------|-----|------|
| No.                                           | Medical Apparatus tested                                                                             | Ye.              | Remarks                                                                      | UMTS                                                                             | S 1  | S 1a | S 2 | S 2a |
| <b>Syringe Pump</b>                           |                                                                                                      |                  |                                                                              |                                                                                  |      |      |     |      |
| 1                                             | Asena GH, Alaris Medical Systems                                                                     | 04               | 002352                                                                       | 15 H                                                                             | 50 H | 15 H | n   | n    |
| <b>Volumetric Infusion Pump</b>               |                                                                                                      |                  |                                                                              |                                                                                  |      |      |     |      |
| 2                                             | Asena/GW, Alaris Medical Systems                                                                     | 02               | 1959                                                                         | n                                                                                | 2 H  | 2 H  | 5 H | 2 H  |
| <b>Enteral Feeding Pump</b>                   |                                                                                                      |                  |                                                                              |                                                                                  |      |      |     |      |
| 3                                             | Kangaroo ePump, Sherwood                                                                             | 06               | 005151                                                                       | n                                                                                | n    | n    | n   | n    |
| <b>Intra-Aortic Balloon Pump</b>              |                                                                                                      |                  |                                                                              |                                                                                  |      |      |     |      |
| 11                                            | CS300, Datascope                                                                                     | 08               | 25505                                                                        | n                                                                                | n    | n    | n   | n    |
| <b>Patient Monitor</b>                        |                                                                                                      |                  |                                                                              |                                                                                  |      |      |     |      |
| 9                                             | IntelliVue MP70 + Mainframe, Philips; [Monitor IntelliVueX2 was connected]                           | 09               | MP70: 49978; Mainfr.:50016; Monitor IntelliVueX2: 50739                      | n                                                                                | 20 H | 15 H | n   | n    |
| 10                                            | IntelliVueX2, Philips                                                                                | 09               | Tested As Transport Monitor                                                  | n                                                                                | 15 H | 5 H  | n   | n    |
| 7                                             | AS3, Datex Ohmeda [Incl.Mainframe, Multiparameter, Anaesthesia Gas Module; Coupled to No.8 ADU A-Auf | 04               | AS3: 003529; F-CU8-09, (...).00-027: M-ESTPR-00-03 An.Ga.:000852: M-CAIOV 03 | n                                                                                | 5 H  | 5 H  | 5 S | 5 S  |
| 14                                            | Infinity Delta, Dräger; [Incl. Multimed 12 and HemoMed.]                                             | 08               | 51898                                                                        | n                                                                                | n    | n    | n   | n    |
| <b>Anaesthesia Ventilator</b>                 |                                                                                                      |                  |                                                                              |                                                                                  |      |      |     |      |
| 8                                             | ADU A-Auf, Datex-Ohmeda                                                                              | 04               | 003263 (Construction year:'99)                                               | n                                                                                | n    | n    | n   | n    |
| <b>Dialysis</b>                               |                                                                                                      |                  |                                                                              |                                                                                  |      |      |     |      |
| 4                                             | Prismaflex, Gambro                                                                                   | 08               | 25523                                                                        | n                                                                                | n    | n    | n   | n    |
| 6                                             | Dialog <sup>+</sup> , B. Braun                                                                       | 07               | 25236                                                                        | n                                                                                | n    | n    | n   | n    |
| <b>Blood Warmer</b>                           |                                                                                                      |                  |                                                                              |                                                                                  |      |      |     |      |
| 5                                             | Autocontrol 3XPT, Barkey Connected to Prismaflex (No.4)                                              | 08               | 25528; Tested while at fixed setting 41°C                                    | n                                                                                | n    | n    | n   | n    |
| 19                                            | Level 1, Sims Industries                                                                             | 01               | 000662                                                                       | n                                                                                | 5 H  | 5 H  | 0 S | 0 S  |
| <b>Temporary (External) Cardiac Pacemaker</b> |                                                                                                      |                  |                                                                              |                                                                                  |      |      |     |      |
| 12                                            | EV 4543, Pace Medical Inc.                                                                           | 07               | 24542                                                                        | n                                                                                | 10 H | 5 H  | 5 H | 10 H |
| 13                                            | 4570, Pace Medical Inc.                                                                              | 08               | 47576                                                                        | n                                                                                | n    | n    | n   | n    |
| <b>Heart-Lung Machine</b>                     |                                                                                                      |                  |                                                                              |                                                                                  |      |      |     |      |
| 15                                            | HL 30 (Nr.22 for Thoracic Surgery)                                                                   | 04               | 003135                                                                       | n                                                                                | 5 H  | 2 H  | 5 H | 5 H  |
| <b>Incubator</b>                              |                                                                                                      |                  |                                                                              |                                                                                  |      |      |     |      |
| 16                                            | 8000 SC, Dräger                                                                                      | 94               | 4-.21.01.00-011                                                              | n                                                                                | n    | n    | n   | n    |
| 17                                            | Isolette TI 500, Dräger / Airshields                                                                 | 07               | 005969                                                                       | n                                                                                | 0 H  | 0 H  | 0 S | n    |
| 18                                            | Isolette C 2000, Hill-ROM/Air Shields                                                                | 03               | 1261                                                                         | n                                                                                | n    | n    | n   | n    |
| <b>Telemetry</b>                              |                                                                                                      |                  |                                                                              |                                                                                  |      |      |     |      |
| 20                                            | Transmitter 7496263E5604, Dräger                                                                     | 06               | 005391                                                                       | n                                                                                | 2 H  | 2 H  | 5 S | 5 S  |
| 21                                            | Fujitsu/Siemens, Monitor only                                                                        | 07               | 005752 Only Monitor tested                                                   | n                                                                                | n    | n    | n   | n    |
| 22                                            | Antenna Winegard-Bublington LA                                                                       | 06?              | Stickered as A58                                                             | n                                                                                | n    | n    | n   | n    |



| Patient Monitor                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                              |  |   |      |      |     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|--|---|------|------|-----|
| 9                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | IntelliVue MP70 + Mainframe, Philips;<br>[Monitor IntelliVueX2 was connected]                                |  | n | 20 H | 15 H | n   |
| Description of interference reactions:<br><b>UMTS:</b> At 0cm: No reaction.<br><b>Signal 1:</b> At 20cm from the small monitor X2: At the MP70 an <u>Incorrect</u> message appeared “ECG electrodes?” + Acoustic Alarm was given. Also EKG traces disappeared on the MP70 screen. On the small monitor X2 a visual alarm indication appeared as well.<br><b>Signal 1a:</b> At 15cm from the small monitor X2: Same reaction as for <b>Signal 1</b> above.<br><b>Signal 2:</b> At 0cm: No reaction.<br><b>Signal 2a:</b> At 0cm: No reaction.<br><b>After the interference tests:</b> Apparatus functioned normal.                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                              |  |   |      |      |     |
| 10                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | IntelliVueX2, Philips                                                                                        |  | n | 15 H | 5 H  | n   |
| Description of interference reactions:<br><b>UMTS:</b> At 0cm: No reaction.<br><b>Signal 1:</b> At 15cm from the small monitor X2: an <u>Incorrect</u> message appeared “ECG electrodes?” + Acoustic Alarm was given. Also the EKG traces disappeared on the small monitor X2.<br><b>Signal 1a:</b> At 5cm from the small monitor X2: an <u>Incorrect</u> message appeared “ECG electrodes?” + Acoustic Alarm was given. Also the EKG traces disappeared on the small monitor X2.<br><b>Signal 2:</b> At 0cm: No reaction.<br><b>Signal 2a:</b> At 0cm: No reaction.<br><b>After the interference tests:</b> Apparatus functioned normal.                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                              |  |   |      |      |     |
| 7                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | AS3, Datex Ohmeda [Incl. Mainframe, Multiparameter, Anaesthesia Gas Module and coupled to ADU A-Auf (No.8) ] |  | n | 5 H  | 5 H  | 5 S |
| Description of interference reactions:<br><b>UMTS:</b> At 0cm: No reaction.<br><b>Signal 1:</b> <b>A:</b> At 5cm from the Anaesthesia Gas Module: <u>Incorrectly</u> the indication of Sevoflurane disappeared (empty indicator) + <u>Incorrect</u> message “Failure in Damp Identification”. After moving away the test antenna the indication of Sevoflurane became “0” and after some seconds it raised to normal (1,8%).<br><b>B:</b> At 0cm from the connector for Arterial Pressure P1: At the trace on the monitor screen a “ <b>band of interference</b> ” ca. 4mm in height was observed.<br><b>Signal 1a:</b> Same reactions <b>A</b> and <b>B</b> at the same distances as for <b>Signal 1</b> above.<br><b>Signal 2:</b> Same reaction <b>B</b> (no A) at the same distance as for <b>Signal 1</b> above.<br><b>Signal 2a:</b> Same reaction <b>B</b> (no A) at the same distance as for <b>Signal 1</b> above. In P2 some interference as well.<br><b>After the interference tests:</b> Apparatus functioned normal. |                                                                                                              |  |   |      |      |     |
| 14                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Infinity Delta, Dräger;<br>[Incl. Multimed 12 and HemoMed.]                                                  |  | n | n    | n    | n   |
| Description of interference reactions: No reactions (including distance 0cm between apparatus and antenna).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                              |  |   |      |      |     |
| Anaesthesia Ventilator                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                              |  |   |      |      |     |
| 8                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | ADU A-Auf, Datex-Ohmeda                                                                                      |  | n | n    | n    | n   |
| Description of interference reactions: No reactions (including distance 0cm between apparatus and antenna).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                              |  |   |      |      |     |
| Dialysis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                              |  |   |      |      |     |
| 4                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Prismaflex, Gambro                                                                                           |  | n | n    | n    | n   |
| Description of interference reactions: No reactions (including distance 0cm between apparatus and antenna).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                              |  |   |      |      |     |
| 6                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Dialog <sup>+</sup> , B. Braun                                                                               |  | n | n    | n    | n   |
| Description of interference reactions: No reactions (including distance 0cm between apparatus and antenna).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                              |  |   |      |      |     |

| Blood Warmer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                            |  |   |      |     |     |      |     |      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|--|---|------|-----|-----|------|-----|------|
| 5                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Autocontrol 3XPT, Barkey<br>Connected to Prismaflex (No.4) |  | n | n    | n   | n   | n    | n   | n    |
| Description of interference reactions: No reactions (including distance 0cm between apparatus and antenna).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                            |  |   |      |     |     |      |     |      |
| 19                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Level 1, Sims Industries                                   |  | n | 5 H  | 5 H | 0 S | 0 S  | 0 S | 0 S  |
| Description of interference reactions:<br><b>UMTS:</b> At 0cm: No reaction.<br><b>Signal 1:</b> <b>A:</b> At 5cm from display: <u>Incorrect</u> blinking red indicator lamp (meaning: “water level too low” while the water level was fully correct) and an acoustic alarm occurred and the heating switched OFF. Temperature indication went down. After switching OFF an ON: Apparatus functioned normal again.<br><b>B:</b> At 5cm from ON/OFF switch and from the display the sound of a flapping relais (?) could be heard.<br><b>Signal 1a:</b> At 5cm: Same reactions <b>A</b> and <b>B</b> as described above for <b>Signal 1</b> .<br><b>Signal 2:</b> At 0cm from display: the sound of a flapping relais (?) could be heard. (Only near the display; not near the ON/OFF switch and no reaction A as described for Signal 1 above).<br><b>Signal 2a:</b> At 0cm: Same reaction as described above for <b>Signal 2</b> .<br><b>After the interference tests:</b> Apparatus functioned normal. |                                                            |  |   |      |     |     |      |     |      |
| Temporary (External) Cardiac Pacemaker                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                            |  |   |      |     |     |      |     |      |
| 12                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | EV 4543, Pace Medical Inc.                                 |  | n | 10 H | 5 H | 5 H | 10 H | 5 H | 10 H |
| Description of interference reactions:<br><b>UMTS:</b> At 0cm: No reaction.<br><b>Signal 1:</b> At 10cm:<br><b>A:</b> During synchronous Pacing: Pace rhythm incorrectly slowed down from 70 to 30 and Sense Indication lighted up. This occurred while pacing at both 1 mV and 2 mV sensitivity setting. Pulse width was influenced as well.<br><b>B:</b> During asynchronous pacing (set at 210): No pace pulses any more and pace indication permanently lighted up.<br><b>Signal 1a:</b> At 5cm: During synchronous Pacing: Pace rhythm slowed down and Sense Indication lighted up. Pulse width was influenced as well.<br><b>Signal 2:</b> At 5cm: During synchronous Pacing: Pace rhythm slowed down and Sense Indication lighted up.<br><b>Signal 2a:</b> At 10cm: During synchronous Pacing: Pace rhythm slowed down and Sense Indication lighted up.<br><b>After the interference tests:</b> Pacemaker functioned normal.                                                                     |                                                            |  |   |      |     |     |      |     |      |
| 13                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 4570, Pace Medical Inc.                                    |  | n | n    | n   | n   | n    | n   | n    |
| Description of interference reactions: No reactions (including distance 0cm between apparatus and antenna).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                            |  |   |      |     |     |      |     |      |
| Heart-Lung Machine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                            |  |   |      |     |     |      |     |      |
| 15                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | HL 30 (Nr.22 for Thoracic Surgery)                         |  | n | 5 H  | 2 H | 5 H | 5 H  | 5 H | 5 H  |
| Description of interference reactions:<br><b>UMTS:</b> At 0cm: No reaction.<br><b>Signal 1:</b> At 5cm from level detector in venous reservoir: <u>Incorrect</u> visual (Orange buttons on touch screen) and acoustic alarm and arterial flow stops <u>incorrectly</u> .<br><b>Signal 1a:</b> At 2cm: Same reaction as for <b>Signal 1</b> above.<br><b>Signal 2:</b> At 5cm: Same reaction as for <b>Signal 1</b> above.<br><b>Signal 2a:</b> At 5cm: Same reaction as for <b>Signal 1</b> above.<br><b>After the interference tests:</b> Apparatus functioned normal.                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                            |  |   |      |     |     |      |     |      |



| Incubator                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                       |  |   |   |   |   |   |   |   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--|---|---|---|---|---|---|---|
| 16                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 8000 SC, Dräger                       |  | n | n | n | n | n |   |   |
| Description of interference reactions: No reactions (including distance 0cm between apparatus and antenna).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                       |  |   |   |   |   |   |   |   |
| 17                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Isolette TI 500, Dräger / Airshields  |  | n | 0 | H | 0 | H | 0 | S |
| Description of interference reactions:<br><b>UMTS:</b> At 0cm: No reaction.<br><b>Signal 1:</b> <b>A:</b> At 0cm from temperature indicator in front panel: temperature indication <u>incorrectly</u> influenced ( e.g. from 37 <sup>0</sup> C → 22,4 <sup>0</sup> C).<br><b>B:</b> At 0cm from heating indicator in front panel: Heating element <u>incorrectly</u> activated (power current from the mains was measured: it raised with 400mA)<br><b>Signal 1a:</b> At 0cm: same reactions <b>A</b> and <b>B</b> as for <b>Signal 1</b> above.<br><b>Signal 2:</b> <b>A:</b> At 0cm from temperature indicator in front panel: temperature indication <u>incorrectly</u> influenced (E.g. from 36,1 <sup>0</sup> C → 37,7 <sup>0</sup> C).<br><b>B:</b> No activation of heating element occurred (no <b>B</b> ).<br><b>Signal 2a:</b> At 0cm: No reaction.<br><b>After the interference tests:</b>                                                                                                             |                                       |  |   |   |   |   |   |   |   |
| 18                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Isolette C 2000, Hill-ROM/Air Shields |  | n | n | n | n | n |   |   |
| Description of interference reactions: No reactions (including distance 0cm between apparatus and antenna).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                       |  |   |   |   |   |   |   |   |
| Telemetry                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                       |  |   |   |   |   |   |   |   |
| 20                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Transmitter 7496263E5604, Dräger      |  | n | 2 | H | 2 | H | 5 | S |
| Description of interference reactions:<br><b>UMTS:</b> At 0cm: No reaction.<br><b>Signal 1:</b> At 2cm from transmitter: <u>Incorrect</u> indication (on the monitor Fujitsu/Siemens) of detection of pacemaker pulses. At 0cm: Incorrect detection of many pacemaker pulses, sometimes resulting in Visual + Acoustical alarm + Beeper (Sein): Asystolic alarm (Three Stars-alarm). Sometimes the curve (trace) disappears from the Fujitsu/Siemens monitor.<br><b>Signal 1a:</b> At 2cm: Same reactions as described above for <b>Signal 1</b> .<br><b>Signal 2:</b> At 5cm: Sometimes all curves (traces) disappear from the Fujitsu/Siemens monitor. When the curves disappeared then a visual + acoustical alarm + message occurred: “Transmitter Interference”. It could not be experimentally verified whether the alarm was generated at the transmitter or at the receiver.<br><b>Signal 2a:</b> At 5cm: Same reactions as described above for <b>Signal 2</b> .<br><b>After the interference tests:</b> |                                       |  |   |   |   |   |   |   |   |
| 21                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Monitor Fujitsu/Siemens, Monitor only |  | n | n | n | n | n |   |   |
| Description of interference reactions: No reactions (including distance 0cm between apparatus and antenna).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                       |  |   |   |   |   |   |   |   |
| 22                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Antenna Winegard-Bublington LA        |  | n | n | n | n | n |   |   |
| Description of interference reactions: No reactions (including distance 0cm between apparatus and antenna).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                       |  |   |   |   |   |   |   |   |

## 5.4 Results analysed

The summarizing table below has been prepared to allow for some general conclusions from the tests on the 22 medical apparatuses at the St. Antonius.

| No. | Medical Apparatus tested                                                                                    | Ye. | Remarks                                                                         | UMTS | S 1 | S 1a | S 2 | S 2a |   |   |    |   |
|-----|-------------------------------------------------------------------------------------------------------------|-----|---------------------------------------------------------------------------------|------|-----|------|-----|------|---|---|----|---|
| 1   | Asena GH, Alaris Medical Systems                                                                            | 04  | 002352                                                                          | 15   | H   | 50   | H   | 15   | H | n | n  |   |
| 2   | Asena/GW, Alaris Medical Systems                                                                            | 02  | 1959                                                                            | n    | 2   | H    | 2   | H    | 5 | H | 2  | H |
| 3   | Kangaroo ePump, Sherwood                                                                                    | 06  | 005151                                                                          | n    | n   | n    | n   | n    | n | n | n  |   |
| 11  | CS300, Datascope                                                                                            | 08  | 25505                                                                           | n    | n   | n    | n   | n    | n | n | n  |   |
| 9   | IntelliVue MP70 + Mainframe,Philips; [Monitor IntelliVueX2 was connected]                                   | 09  | MP70: 49978; Mainfr.:50016; Monitor IntelliVueX2: 50739                         | n    | 20  | H    | 15  | H    | n | n | n  |   |
| 10  | IntelliVueX2, Philips                                                                                       | 09  | Tested As Transport Monitor                                                     | n    | 15  | H    | 5   | H    | n | n | n  |   |
| 7   | AS3, Datex Ohmeda [Incl.Mainframe, Multiparameter, Anaesthesia Gas Module and coupled to ADU A-Auf (No.8) ] | 04  | AS3: 003529: F-CU8-09, (...).00-027: M-ESTPR-00-03<br>An.Ga.:000852: M-CAIOV 03 | n    | 5   | H    | 5   | H    | 5 | S | 5  | S |
| 14  | Infinity Delta, Dräger; [Incl. Multimed 12 and HemoMed.]                                                    | 08  | 51898                                                                           | n    | n   | n    | n   | n    | n | n | n  |   |
| 8   | ADU A-Auf, Datex-Ohmeda                                                                                     | 04  | 003263 (Construction year:'99)                                                  | n    | n   | n    | n   | n    | n | n | n  |   |
| 4   | Prismaflex, Gambro                                                                                          | 08  | 25523                                                                           | n    | n   | n    | n   | n    | n | n | n  |   |
| 6   | Dialog <sup>+</sup> , B. Braun                                                                              | 07  | 25236                                                                           | n    | n   | n    | n   | n    | n | n | n  |   |
| 5   | Autocontrol 3XPT, Barkey Connected to Prismaflex (No.4)                                                     | 08  | 25528; Tested while at fixed setting 41 <sup>0</sup> C                          | n    | n   | n    | n   | n    | n | n | n  |   |
| 19  | Level 1, Sims Industries                                                                                    | 01  | 000662                                                                          | n    | 5   | H    | 5   | H    | 0 | S | 0  | S |
| 12  | EV 4543, Pace Medical Inc.                                                                                  | 07  | 24542                                                                           | n    | 10  | H    | 5   | H    | 5 | H | 10 | H |
| 13  | 4570, Pace Medical Inc.                                                                                     | 08  | 47576                                                                           | n    | n   | n    | n   | n    | n | n | n  |   |
| 15  | HL 30 (Nr.22 for Thoracic Surgery)                                                                          | 04  | 003135                                                                          | n    | 5   | H    | 2   | H    | 5 | H | 5  | H |
| 16  | 8000 SC, Dräger                                                                                             | 94  | 4-.21.01.00-011                                                                 | n    | n   | n    | n   | n    | n | n | n  |   |
| 17  | Isolette TI 500, Dräger / Airshields                                                                        | 07  | 005969                                                                          | n    | 0   | H    | 0   | H    | 0 | S | n  |   |
| 18  | Isolette C 2000, Hill-ROM/Air Shields                                                                       | 03  | 1261                                                                            | n    | n   | n    | n   | n    | n | n | n  |   |
| 20  | Transmitter 7496263E5604, Dräger                                                                            | 06  | 005391                                                                          | n    | 2   | H    | 2   | H    | 5 | S | 5  | S |
| 21  | Monitor Fujitsu/Siemens, Monitor only                                                                       | 07  | 005752 Only Monitor tested                                                      | n    | n   | n    | n   | n    | n | n | n  |   |
| 22  | Antenna Winegard-Bublington LA                                                                              | 06? | Stickered as A58                                                                | n    | n   | n    | n   | n    | n | n | n  |   |

From the table above the following conclusion can be drawn about distances and about the type of reactions: See next page:

### Distances at which the medical apparatuses reacted

For the 5 interfering signals used in the tests the apparatuses reacted at the following distances:

|       |                                                             |                                                       |
|-------|-------------------------------------------------------------|-------------------------------------------------------|
| S 1:  | 10 out of 22 apparatuses were influenced at distances:      | 50, 20, 15, 10, 5, 5, 5, 2, 2, 0 cm                   |
| S 1a: | Same 10 out of 22 apparatuses were influenced at distances: | 15, 15, 5, 5, 5, 5, 2, 2, 2, 0 cm                     |
| S 2:  | 7 out of 22 apparatuses were influenced at distances:       | 5, 5, 5, <u>5</u> , <u>5</u> , <u>0</u> , <u>0</u> cm |
| S 2a: | 6 out of 22 apparatuses were influenced at distances:       | 10, 5, <u>5</u> , <u>5</u> , 2, <u>0</u> cm           |
| UMTS: | 1 of 22 apparatuses were influenced at distance:            | 15 cm                                                 |

From this overview the following conclusions follow:

- From all test signals used, Signal 1 produces most interference at the biggest distances. The order in which the other interference signals follow is as listed above.
- Whereas Signal 1 and 2 only differ in frequency it can be concluded from these measurements that a carrier wave frequency at the 1800MHz band produces less interference than a carrier wave frequency in the 900MHz band.
- The same conclusion follows for Signals 1a and 1b: These signals only differ in carrier wave frequency.
- Signal 1a has half of the transmit power of Signal 1. Therefore it is understandable that it interferes less.
- The same applies to Signals 2a and 2. Signal 2a has half of the power of Signal 2. Signal 2a produces less interference than Signal 2.
- The UMTS Signal has another character than the other signals. The biggest difference is the power of the UMTS signal. Therefore it is understandable that it interferes less than the other signals.

### Types of reactions from the medical apparatuses

For the 5 interfering signals used in the tests the reactions of the medical apparatuses sorted per distance were:

|       |                                           |
|-------|-------------------------------------------|
| S 1:  | The 10 reactions that occurred: all H     |
| S 1a: | The 10 reactions that occurred: all H,    |
| S 2:  | H at 5, 5, 5 cm and S at 5, 5, 0, 0 cm,   |
| S 2a: | H at 10, 5, 2 cm and S at 5, 5, 0 cm,     |
| UMTS: | The 1 reaction that occurred: H at 15 cm. |

The “S”-reactions have been underlined in the schedule for the **Distances** (in the square above). The conclusion is that de S-reactions occur generally at smaller interfering distances (which means at the less sensitive equipment). This tendency has never been observed at bigger collections of tested medical apparatuses. Therefore this tendency may result from the fact that the collection of medical apparatuses is not very big (only 22). It is noted that no physical mechanism would explain this tendency.

## 5.5 Discussion of results

Interpretation of results as presented in the previous paragraph is possible by comparing them with results from comparable research on GSM mobile phones and the study performed at the AMC. Results from research on GSM mobile phones can be found in **Literature [4] and [5]** and are presented in **Figure 3**. The results from the AMC study can be found in the Critical Care Magazine **[14]**.

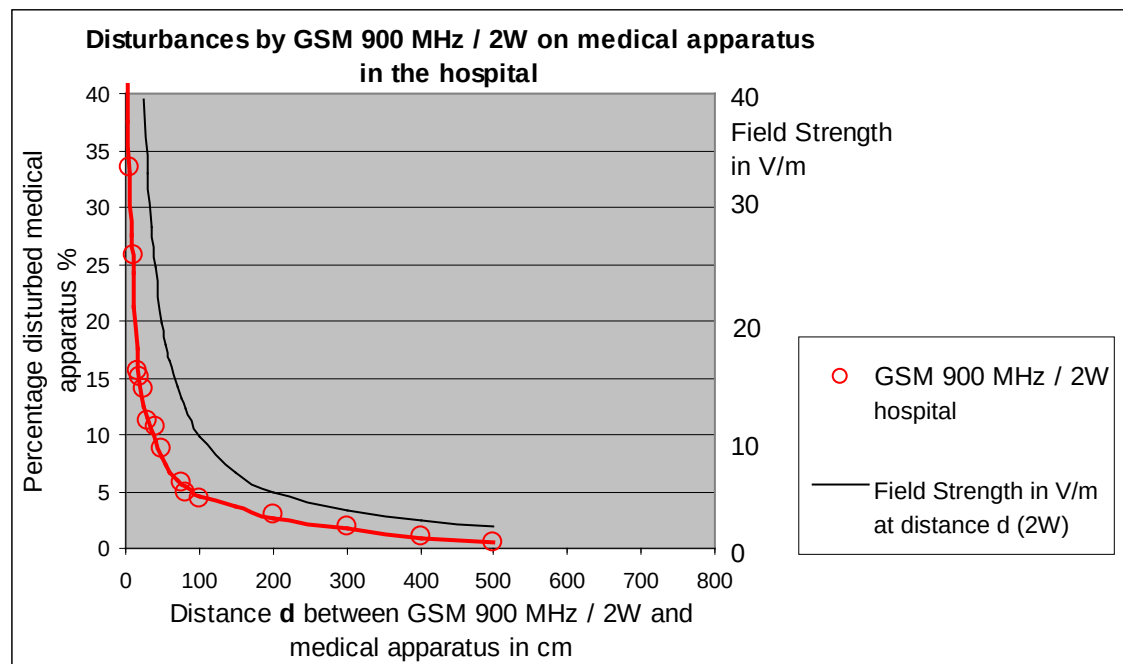


Figure 3: Disturbances by GSM 900 MHz / 2W on medical apparatus in the hospital. Figure copied from **Literature [4] and [5]**

### Comparison with results from other studies:

#### GSM/GPRS 900MHz (1TSL) / 2W:

From **Figure 3** it can be seen that at 150 cm distance from GSM 900MHz (1 TSL!) phones about 3% of the medical apparatuses is disturbed. This is the separation distance as internationally advised to be kept <sup>5)</sup>. The biggest interference distance of 15cm at the Antonius for signal S 1a (1 TSL!) is not an alarming result on one hand, but it still reveals that interference can occur (22 apparatus is a too small number for statistical conclusions).

**GSM/GPRS 900MHz (2TSL) / 2W:** In the AMC study the separation distance was 3,5m. Compared to this 3,5m the biggest interference distance of 50cm at the Antonius for signal S 1 (2 TSL!) is also not an alarming result on one hand, but it also

<sup>5)</sup> It is advised not to have GSM phones transmitting within this distance from a medical apparatus (in hospital and in home environment). See for example:

- Hanada et al in IEEE Trans on EMC November 2000 **Literature [8]**,
- Health Devices November 2001 (ECRI) **Literature [9]**.
- Morrissey et al, Health Physics (2002) 82: pp 4 - 51 **Literature [10]**.
- A Netherlands regulation is: VIFKA Recommendations **Literature [6]** based on **Literature [4]**.

reveals that interference can occur (Again 22 apparatus is a too small number for statistical conclusions).

**UMTS / 0,2W:** With UMTS at very short distances ( $\leq 20$  cm) some disturbances were still found both at the AMC and at the St. Antonius. This was against expectations in some literature <sup>6)</sup>. The little number (and little percentage) of apparatus interfering with UMTS precludes estimating a separation distance so far. The separation distance to be advised will have to be more than the 15 to 20 cm below which the disturbances occurred at AMC and St. Antonius.

### **Classification of the disturbances**

When judging the disturbances that appeared according to the classification **H**, **S** or **L** one must realise that a disturbance of a lower classification can change in a higher class if the interference source moves towards the medical apparatus. During testing the interference source was not always moved more close after having found interference. Further, frequently occurring disturbances of a lower class can all together have the effect of a higher class disturbance because not all of them can get attention from the medical personnel.

### **Year of construction**

The apparatus tested date from the years 1984 to 2004 (AMC) and 1994 – 2009 (St. Antonius). No conclusion can be drawn about a (possible?) relationship between susceptibility and the year of the medical apparatus.

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<sup>6)</sup> Several references indicate this expectation. For example **Literature** [10] reports tests on medical apparatus with CDMA 1900 MHz with 600-630 mW and states that “reduction of power (to 200 mW) would be expected to eliminate EMI (...)”. ECRI **Literature** [2] states that “devices with a power  $\leq 200$  mW have not been found to cause medical device interference”.

## 6 Signature

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

## A Photographs



Figure 4: HLM: Apparatus No. 15

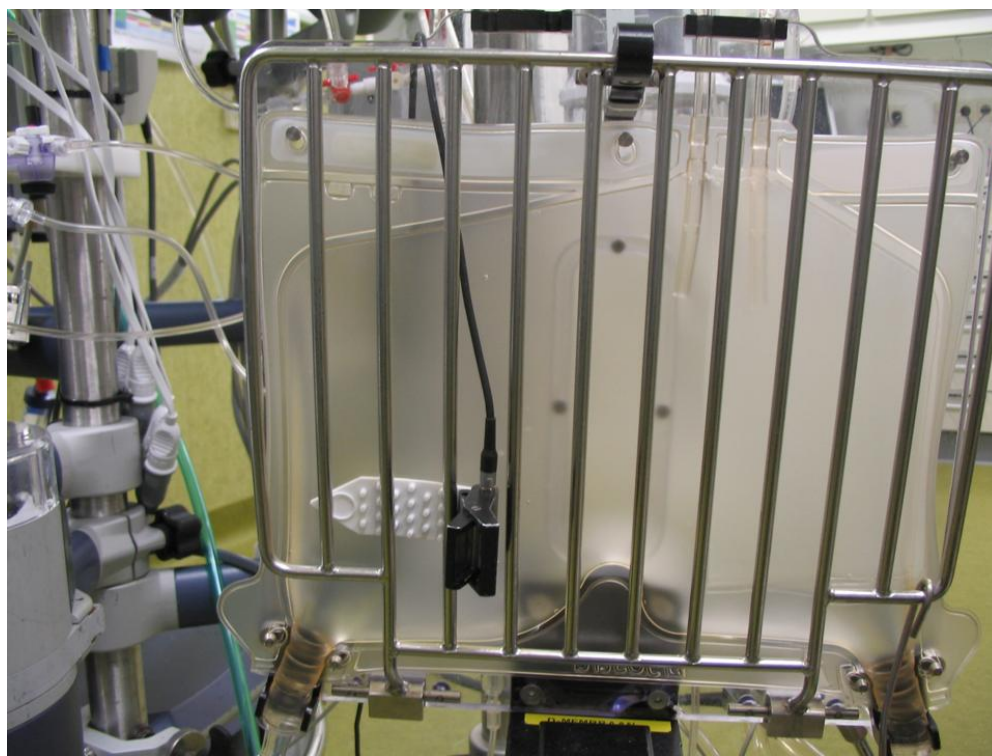


Figure 5: Detail of HLM : Apparatus No.15





Figure 6: Incubator Isolette TI500: Apparatus No. 17.



Figure 7: Intra-Aortic Balloon Pump CS300: Apparatus No. 11.



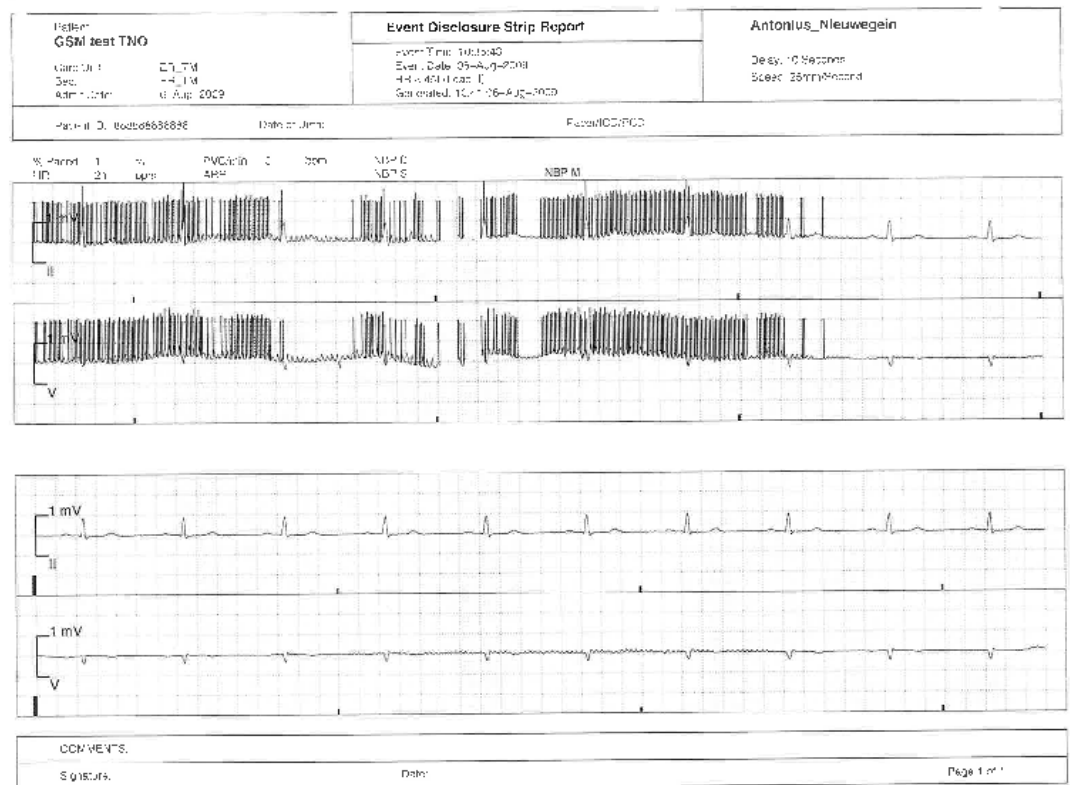


Figure 8: Interference on Telemetry: Apparatus No. 20.



Figure 9: Syringe pump: Apparatus No.1.

## B The set-up for generating test signals

- **Test antenna GPRS:** Rohde & Schwarz Measurement Set
- **Test antenna UMTS:** Kathrein 738 454 2.47 C31
- **UMTS/GPRS generator:** HP/Agilent E4433B **ESG-D** Digital RF Signal Generator, 250 kHz - 4GHz. The generator is provided with a GSM module and a W-CDMA module.
- **Pulse generator:** Pulse / Function Generator HP **8116A** 50 MHz. The output of this secondary generator was connected to the TRIGGER IN input of the Generator ESG-D.
- Laptop with **HP - VEE software**. Via a USB/GPIB converter the ESG-D and the 8116A were controlled from the laptop.

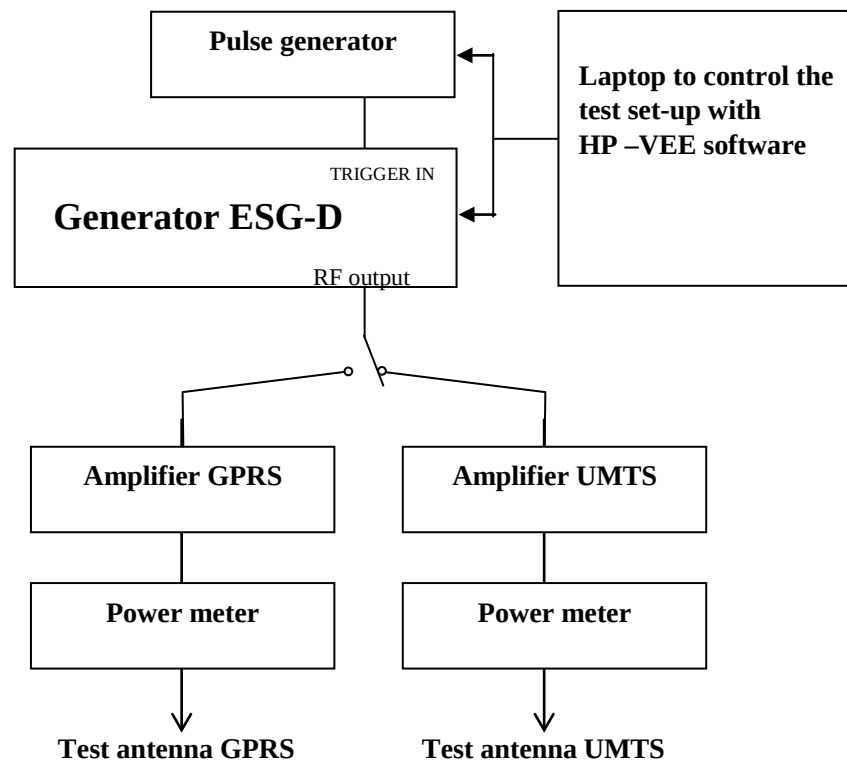


Figure 10: Test set-up for generating the five test signals at the St. Antonius Hospital in Nieuwegein, The Netherlands.

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