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TNO report

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**96 Medical Apparatuses tested for interference by
WLAN/WiFi signals**

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Summary

This research describes the influence of WLAN¹ signals on medical apparatus in hospitals. The results in this report were obtained during an educational project by TNO and 14 SME companies (TNO MKB-grant). The project was supported by 4 hospitals.

At 10cm distance 3% of 96 tested medical apparatuses were disturbed. At 0cm distance (WLAN antenna against medical apparatus) 10% of the apparatuses were disturbed. The WLAN signals were transmitted at 100mW, which is the standardised power in the 2,4 and 5GHz frequency bands. The character of the disturbances was at 0cm distance unsafe at half (5%) of the (10%) of the 96 disturbed medical apparatuses; the maximum distance at which interference was found was 50cm. The character of the disturbances varied between light and unsafe, equally distributed over the distances 0-50cm.

The number of medical devices tested (96) can be considered large enough to formulate the following general expectation: As long as WLAN antennas are kept away more than 10cm from medical apparatuses during normal use in hospitals, hardly interferences and/or unsafe disturbances are expected. At shorter distances in special situations some disturbances are expected (half of which unsafe).

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

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

Remarks

- 1: The test method minimized the dependency from the environment where the tests took place.
- 2: If in this report for a certain type of medical apparatus no interference is reported one must not conclude that the apparatus is not susceptible. The reason for this is that tests were limited, had a typical (restricted) purpose and were not intended to cover the standard IEC 60601-1-2 for EMC of Medical Equipment. A conclusion about the complete EMC behaviour of a medical apparatus is the responsibility of the manufacturer and must be based on more elaborate testing.
- 3: The number of medical apparatuses included in the immunity testing was limited. The medical apparatuses were carefully selected to cover the actual situation in the rooms at the hospitals. The medical apparatuses and the WLAN systems are believed to represent a certain collection as can be found in more hospitals. However no strict

¹⁾ WLAN = Wireless Local Area Network (In Netherlands language: Draadloos lokaal netwerk), also called WiFi = Wireless Fidelity.

general conclusions about other medical apparatuses can be drawn from this report without careful judgment and comparison. In case of doubt additional testing may be needed (as international standards advise generally as well).

Samenvatting

Dit rapport beschrijft de invloed van WLAN² signalen op medische apparatuur in ziekenhuizen. De resultaten in dit rapport zijn verkregen tijdens een educatief project van TNO met 14 MKB-bedrijven (TNO MKB-regeling). Aan het project werkten vier ziekenhuizen mee.

Op 10cm afstand trad bij 3% van 96 onderzochte medische apparaten storende invloed op. Op 0cm afstand (WLAN antenne tegen medisch apparaat) ondervond 10% van de apparaten storing. De WLAN signalen hadden het gebruikelijke vermogen van 100mW in de 2,4 en 5GHz frequentiebanden. Het karakter van de storingen was bij 0cm afstand onveilig bij de helft (5%) van de (10%) van de 96 verstoorde medische apparaten; de maximale afstand waarop storende invloed werd gevonden was 50cm. Het karakter van de invloeden varieerde van licht tot onveilig, willekeurig verdeeld over de afstanden 0-50cm.

Het aantal onderzochte medische apparaten (96) kan groot genoeg worden geacht om de volgende algemene verwachtingen uit te spreken: Zolang WLAN antennes op meer dan 10cm afstand van medische apparaten blijven tijdens normaal gebruik in ziekenhuizen zijn nauwelijks storende en/of onveilige invloeden te verwachten. Op kortere afstand zullen in bijzondere gevallen enkele storingen kunnen optreden (waarvan ca. de helft onveilig).

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

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

Opmerkingen

- 1: De testmethode minimaliseerde de afhankelijkheid van de omgeving waar de test plaats vond.
- 2: Wanneer in dit rapport van een bepaald apparaat geen verstoring wordt gemeld mag daar niet de conclusie aan worden verbonden, dat dit apparaat dus niet gevoelig is. Het apparaat is immers slechts beperkt getest en met een zeer bepaald (beperkt) doel. De norm IEC 60601-1-2 voor EMC van medische apparatuur was zeker niet afgedekt. Een dergelijke uitspraak behoort tot de competentie en

²⁾ WLAN = Wireless Local Area Network (Draadloos lokaal netwerk), ook wel aangeduid met WiFi = Wireless Fidelity.

verantwoordelijkheid van de fabrikant van het betreffende apparaat en moet worden gestoeld op uitvoeriger onderzoek.

- 3: Het aantal onderzochte medische apparaten was beperkt. De apparaten zijn zorgvuldig geselecteerd met het oog op de toepassingsituaties in ziekenhuizen. Zowel de medische apparaten als WLAN systemen kunnen als representatief worden beschouwd voor meerdere ziekenhuizen. Echter, er kunnen geen strikte algemene conclusies voor andere medische apparaten worden gebaseerd op dit rapport zonder zorgvuldige beoordeling en vergelijking. In geval van twijfel kan het nodig zijn om aanvullend te testen (zoals internationale normen in het algemeen ook adviseren).

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1 Introduction

This research describes the influence of WLAN³ signals on medical apparatus in hospitals. The results in this report were obtained during an educational project by TNO and 14 SME companies (TNO MKB – grant). The project was supported by 4 hospitals. A selection of the medical equipment of the 4 hospitals was tested for susceptibility to WLAN signals. This report presents the tests and the results. These results are formulated in such a way that the hospitals and the SME companies can base management strategies and/or technical measures on them to consider introduction of WLAN systems in hospitals. The aim was to test whether selected medical apparatuses (see below) were susceptible to WLAN signals and if so at what distance. The character of possible reactions (hazardous or not) was also of interest.

1.1 Description of the tests

In order to test possible susceptibility of medical apparatuses, 96 of them were set upon their own in the hospital environment and subjected to the WLAN signals. Medical apparatuses were selected that could in principle be positioned in the vicinity of the WLAN antennas⁴ during normal functioning of the operating room, the intensive care unit, etc. Where relevant, the medical apparatuses were tested both powered from the mains and powered from their internal accumulator. If a medical apparatus was found that could be disturbed, the point in space most far from the medical apparatus was determined where the disturbance just started to occur. This distance is usually called the separation distance **d**. This name indicates that possible sources of interference should be kept away from this medical apparatus more than this “separation distance”. At a found disturbance position, transmission of the WLAN signal was realized during several tens of seconds (typically 30 seconds). Testing was done according to a predefined testing program with predefined WLAN test signals. In the next paragraphs the following is presented:

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

³⁾ WLAN = Wireless Local Area Network (In Netherlands language: Draadloos lokaal netwerk), also named WiFi = Wireless Fidelity.

⁴⁾ Not the antennas of Access Points (A.P.s) of installed WLAN systems were considered relevant in this study. On the contrary: As relevant were considered: The antennas of hand-held devices with which users may move around medical apparatus. (In WLAN terminology these hand-held devices are called “clients”). In this study the antennas of these hand-held devices were “simulated” by using Access Points.

2 Choice of Medical Apparatuses tested

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

In Table 2.1 below an overview is presented how many medical apparatuses of a certain type were tested within the total of **88** tested medical apparatuses. Within one type / model / function of medical apparatus, more than one make was tested in a number of cases; never the same type / model was tested twice; no research was done on the variations within one type / model. As the last column indicates **8** medical apparatuses were tested that were connected to a medical apparatus that was tested as well (These connected apparatus were tested as medical apparatuses as well).

Table 2.1: Type and number of medical apparatuses tested.

Medical Apparatuses tested (type)	Number of medical apparatuses tested	Number of medical apparatuses connected
Ventilator	13	
Syringe Pump	9	1
Infusion Pump	4	1
Enteral Feeding Pump	3	
Balloon Pump	2	
Monitor (patient, transport, cardiac output)	9	
Meter (BP, pulsoxymeter, temp, etc.)	7	
Telemetry Cardiology	2	1
Pacemaker Programmer	1	
Blood warmer	1	
EEG Electroencephalograph	1	
ECG Electrocardiograph	2	
CTG Cardiotocograph	2	
ERG Electroretinograph	1	
Defibrillator	6	
Electrosurgery	3	
Dialysis	4	2
Anaesthesia	3	
Ultrasound (US)	4	
Infant Incubator	2	
LVAD Left ventricle assist device	1	1
HLM Heart lung machine	1	1
Heating Device	1	
Surgical Navigation	1	1
Endoscopy	1	
Angiographic Table	1	
Gamma Probe	1	
UPS Uninterruptible power supply	1	
O ₂ Regulator	1	
Total 96 =	88 +	8

In **Chapter 5** of this report the medical apparatuses tested are specified further. In the photographs in **Appendix B** two of the medical apparatuses tested are shown.

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

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

Medical apparatuses were tested according to a protocol that was settled before testing.

Medical apparatuses were tested in normal use modes.

3 WLAN Test signals

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

The test signals of the WLAN systems are summarized in the next paragraphs. The test signals were chosen with the intention to have included in the testing as many normal use signals from the WLAN systems as possible. WLAN signals can differ strongly depending on carrier frequency, data rate, package size and transmission conditions. All test signals fulfilled the international standard IEEE 802.11X with X being a, b or g (n was not tested because this standard was still a draft at the time of testing). As indicated in Table 3.1, the power level of some test signals could be or was increased up to 500mW. For the final conclusions in this report only the results with 100mW were counted and separated from results with higher power.

In Table 3.1 summarizes the WLAN signals used to test medical apparatuses for possible influence.

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

802.11.X	Frequency	Data rates **)	Channel	Power [mW] *)
X = b	b: 2,4GHz	b: 11Mbit/s	b: Ch1	b: 100mW
X = a + g	g: 2,4GHz	g: 54Mbit/s	g: Ch11	g: 100mW or 200mW or 500mW
	a: 5GHz	a: 54Mbit/s	a: Ch36 and: a: Ch64	a: 500mW, provided with an 18dBi antenna a: 100mW

*) The output power at the antenna connector was set in such a way that the power radiated from the antenna was at the level indicated in this column (EIRP). For the final conclusions in this report only the results with 100mW counted and results with higher power were neglected.

) Possible data rates for 802.11 **b are: 1, 2, 5.5 or 11Mbit/s according to the standard. Possible data rates for 802.11 **g** and **a** are: 6, 12, 24, 32 or 54Mbit/s according to the standard.

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

- Ch1 (100mW/2,4GHz/11Mbit/s);
- Ch11 (500mW/2,4GHz/54Mbit/s) could also be switched to 200mW and 100mW;
- Ch36 (500mW/18dBi/5GHz/54Mbit/s);
- Ch64 (100mW/5GHz/54Mbit/s).

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

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

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

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

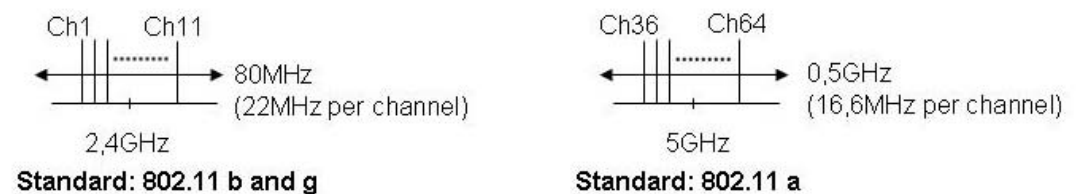


Figure 3.1 Channels 1, 11, 36 and 64 in their respective frequency bands at 2,4GHz and 5GHz according to the IEEE 802.11 standards.

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

Table 3.2 Overview of routine testing practices.

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

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

4 Test Protocol

The interference tests were performed at 4 hospitals. Most of the testing took place in a technical location at medical departments. Some tests were performed in an operating room at the hospital. Test rooms facilitated enough space around the medical apparatuses (typically 2m). Before testing started it was verified that at locations around, under and above the testing location, no interference issues could arise in the hospital practice. The test practices as described below were followed.

Test practices

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

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

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

Remarks

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

5 Results

5.1 Introduction

In **Paragraph 5.3** below the results of interference tests are presented in detail. At first in **Paragraph 5.2** a classification of possible disturbances is presented. In **Paragraph 5.4** the results are summarized and presented graphically.

5.2 Classification of disturbances

Disturbances and/or interferences at the medical apparatuses were classified according to Table 5.1 below. The classifications only apply to the interference at the specific apparatus. The classification **U (Unsafe)** is not restricted to life threatening situations for the patient. The importance of interference must be seen in the right perspective: in a way every disturbance is unacceptable during treatment of patients⁵.

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

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

5.3 Detailed results

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

⁵⁾ 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, using sense organs, movability, alertness, etc. Therefore the safety philosophy for medical apparatus is totally different from the safety philosophy for household or industrial equipment for example, that is used by healthy persons being not patients.

Legend to Table 5.2 below

Column 1: The **No. in test** refers to the testing order of the medical apparatuses as recorded during the interference testing. Photos of some medical apparatuses are placed in **Appendix B** to this report.

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

Column 3 and 4: In these columns the separation distance is given for those medical apparatuses that were influenced by WLAN signal(s). Column 3 and 4 belong to 500mW and 100mW transmitted power respectively.

In columns 3 and 4 the letter **N** means that no interference occurred at any distance from the medical apparatus including distance 0cm (=WLAN antenna against the medical apparatus). The footnotes in columns 3 and 4 refer to details of the interferences found. In columns 3 and 4 the influences found are classified according to the **N/L/S/U** scheme ⁶ as described in **Paragraph 5.2** of this report.

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

No. in test	Medical Apparatuses tested	Separation distance d	
		At 500mW	At 100mW
	Ventilator		
4	Servo Ventilator 300, Siemens	N	N
19	SERVO I, Maquet	N	N
15	Evita XL, Dräger	N	N
56	Evita 2 Cap, Dräger	N	N
18	Demonstration apparatus, General Electric	N	N
14	Oscillatory Ventilator Model 3100 A, Sensormedics	1cm ⁷ U	1cm ⁸ U
9	Babylog 8000 HFV, Dräger	N	N
34	Infant Flow Sipap, Viasys	40cm ⁹ U	10cm ¹⁰ U
75	Neonatal Stephanie, Stephan	N	N
24	Homecare Ventilator Integra, Saime VS	N	N
70	Homecare Ventilator 150, Saime Elisée	5cm ¹¹ L	1cm ¹² L
71	Homecare Ventilator Bipap Synchrony, Respirationics	N	N
80	Transport Ventilator Oxylog 3000, Dräger	N	N

⁶) **N/L/S/U** = **No/Light/Significant/Unsafe** disturbance or interference. In Netherlands language: = **N/L/S/O** = **Nee/Lichte/Significante/Onveilige** verstoring of interferentie.

⁷) At one location at the center of the upside plane of the housing: Ch11 at 100 and 500mW: Incorrect measurement of pressure resulted in level alarms (optical and acoustical) and sometimes also in stopping of ventilator.

⁸) See previous note.

⁹) Separation distance from the transducer interface 677-002. Note that real influences only occurred at a few cm from the transmitter.

¹⁰) See previous note.

¹¹) Separation distance from the pressure measuring head. Pressure curve and P_{peak} and the motor speed are influenced.

¹²) See previous note.

No. in test	Medical Apparatuses tested	Separation distance d	
		At 500mW	At 100mW
Syringe Pump			
1	GH MK III, Alaris Asena	N	N
10	Perfusor fm, B. Braun	N	N
32	Perfusor compact, B. Braun	N	N
27	TCI & TIVA, IVAC	N	N
28	PCAM, IVAC	N	N
64	P2000 Alaris, IVAC	N	N
78	P6000/TIVA, IVAC	N	N
53	Pilot C NL Leiden, Fresenius Vial	N	N
74	Module DPS, Fresenius Vial	N	N
74a	Base Unit, Fresenius Vial	N	N
Infusion Pump			
2	Graseby 3000	N	N
20	Infusomat fmS, B. Braun	N	N
21	fm Computer, B. Braun (for Infusomat fmS, No.20)	N	N
57	Volumed μ VP7000, Arcomed	N	N
62	Volumetric Pump μ VP 5005, Arcomed	N	N
Enteral Feeding Pump			
22	Applix Smart, Fresenius Kabi	N	N
54	Kangaroo 224, Sherwood Medical	N	N
92	Flocare 800, Nutricia	N ¹³	N
Balloon Pump			
5	Autocat 2 Wave, Arrow	N	N
51	System 98, Datascope	N	N
Monitor / Meter			
8	Patient Monitor SC 9000 XL, Siemens	N	N
67	Patient Monitor IntelliVue MP50, Philips	N	N
68	Patient Monitor S/5 (differs from No. 47), Datex Ohmeda	N	N
90	Patient Monitor Eagle 4000, General Electric (Marquette)	N	N
47	Transport Monitor S/5 (differs from No. 68), Datex Ohmeda	N	N
11	Transport Monitor IntelliVue MP 30 Neonatal, Philips	N	N
91	Transport Monitor Pro, General Electric	N	N
29	OK Monitor “Merlin/CMS”, HP	N	N
52	Cardiac Output Monitor Vigilance Monitor VGS2, Edwards	N	N
55	NO _x Monitor Sensor, Sensormedics	N	N
61	Blood Pressure Meter Pro 100 V2, General Electric	N	N
30	Blood Pressure Meter Dinamap PRO 100V2, Critikon	N	N
86	Blood Pressure Meter Monitor 300-serie, Welch Allyn	N	N
31	Pulsoxymeter N-595, Nellcor	N	N
35	Oxygen measurement Oxydig, Dräger	N	N
60	Ear Thermometer First Temp Genius M3000 A, Sherwood-Davis&Geck. Functionally tested in test unit Tyco Healthcare.	0cm ¹⁴ L	0cm ¹⁵ L

¹³⁾ With Ch11 (500mW/2,5GHz) a disturbance occurred when the antenna was held against the housing on one specific location. Acoustic alarm occurred together with the message "set". Because this disturbance was very difficult (but not impossible) being reproduced, the influence was recorded but not counted as "interference".

¹⁴⁾ At 0cm from Thermometer (500mW): The indicated temperature was 0,5°C too high. At 5cm: No influences.

No. in test	Medical Apparatuses tested	Separation distance d	
		At 500mW	At 100mW
Telemetry			
7	Transmitter, Dräger	10cm ¹⁶ U	0cm ¹⁷ U
7a	Central Station Infinity Telemetry, Siemens (Belonging to No.7)	N	N
63	Transmitter 5200899E510U, Siemens	2cm ¹⁸ U	2cm ¹⁹ U
Pacemaker programmer			
82	EPR 1000 plus, Biotronik	N ²⁰	N
Blood warmer			
40	41°C Autocontrol, Barkey	N	N
EEG			
13	Brainlab, OSG	N	N
ECG Electrocardiograph			
65	MAC 5500, General Electric	5cm ²¹ L	5cm ²² L
66	Marquette MAC 5000, General Electric	10cm ²³ L	10cm ²⁴ L
CTG Cardiotocography			
79	Avalon FM20, Philips	N ²⁵	N ²⁶
87	Model 259 A, General Electric Medical Systems	N	N
ERG Electroretinograph			
50	VEP-ERG Multiliner Vision, Jaeger	N	N

¹⁵⁾ At 0cm from Thermometer (100mW): The indicated temperature was 0,3⁰C too high. At 5cm: No influences.

¹⁶⁾ At 10cm from Transmitter (500mW): No trace received at central desk. Also no trace returned after removal of the WLAN antenna. Two right LEDs on Transmitter blinked permanently. Transmitter had to be switched off and on to return to normal functioning.

¹⁷⁾ At 0cm (100mW): No trace received at central desk. However: Trace returned when WLAN antenna was removed. No blinking LEDs.

¹⁸⁾ At 0cm from Transmitter (500mW and 100mW): No trace received at central desk. Also no trace returned after removal of the WLAN antenna. Two LEDs on Transmitter blinked permanently. Transmitter had to be switched off and on to return to normal functioning. At 2cm (500mW and 100mW): No trace received at central desk. However: Trace returned when WLAN antenna was removed. No blinking LEDs. At 3cm (500mW and 100mW): No influences.

¹⁹⁾ See previous note.

²⁰⁾ With Ch11(500mW) at 20cm from the programming head the communication between the programmer and the pacemaker was blocked. The Internal EMI TEST function (built-in in the pacemaker programmer) detected that external interference was present (from Ch11=500mW, Ch1=100mW and Ch64=100mW; Ch36 was not detected by the internal EMI TEST). Therefore the communication failure was not counted as “interference”.

²¹⁾ Influences on ECG traces. At 0cm: An incorrect message about muscle tremors appeared.

²²⁾ Influences on ECG traces.

²³⁾ Influences on ECG traces.

²⁴⁾ Influences on ECG traces.

²⁵⁾ At 10cm from CTG transducer acoustic noise occurred from the WLAN signal; however, the heartbeat could still be heard. Therefore this was not counted as “interference”.

²⁶⁾ See previous note.

No. in test	Medical Apparatuses tested	Separation distance d	
		At 500mW	At 100mW
Defibrillator			
3	Heartstart XL, M4735A	N	N
45	Lifepak 12, Physio Control	N	N
46	CodeMaster, HP	N	N
69	Lifepak 9, Physio Control	N	N
81	Responder 3000(Mono phase), General Electric Marquette	N	N
83	M-Series (Bi phase), Zoll	N	N
Electrosurgery			
36	Force FX, Valleylab	N	N
44	ICC 300, ERBE	N	N
89	ICC 80, Erbe	N	N
Dialysis			
16	with Citrate-option (future), Edwards Aquarius	N	N
17	Alarm (installed for Dialysis, No. 16), NIRA	N	N
39	Prismaflex, Gambro	N	N
41	Hemodialysis AK 200, Gambro	N	N
42	Laptop Latitude (for Hemodialysis AK 200, No. 41), Dell	N	N
85	Aquarius (CVVH), Edwards	N	N
Anaesthesia			
23	Anaesthesia Physioflex, Physio Medical Systems	N	N
25	Cato, Dräger	N	N
43	Primus, Dräger	N	N
Ultrasound (US)			
26	US Scanner Flex Scan T57S System Five, General Electric	20cm ²⁷ S	8cm ²⁸ S
72	Sono 5500, HP	N	N
73	iE33, Philips	N	N
84	Technos MP, Esaote	N ²⁹	N
Infant Incubator			
76	Isolette C2000, Dräger	N	N
77	Weyer83	N	N

²⁷⁾ At 20cm from monitor and also 20cm from cable near the Ultrasound element:
Ch11(500mW): trembling of the monitor screen.

²⁸⁾ At 8cm from monitor and also 8cm from cable near the Ultrasound element: Ch1, Ch11, Ch36(500mW), Ch64(100mW): an incorrect vertical “beam” appeared on the monitor.

²⁹⁾ With Ch11 (500mW/2,5 GHz) at 20cm from the buttons under the monitor screen, some text on the screen fluttered. This was not counted as “ interference”.

No. in test	Medical Apparatuses tested	Separation distance d	
		At 500mW	At 100mW
	Several		
6	LVAD Left Ventricle Assist Device Heartmate XVE,Thoratec	N	N
6a	Fixed station (read-out) for LVAD (part of No. 6), Thoratec	N	N
12	HLM Heart Lung Machine (“Ecmo-system“), Stöckert	N	N
12a	Blood Clotting Meter (Installed for HLM Stöckert, No.12)	N	N
33	Heating Device (mattress/blood) Norm-O-Temp, CSZ	N	N
37	Surgical Navigation system Stealth Station Treon Plus	N ³⁰	N
	Infrared controlled, Medtronic		
38	Idem: system Electromagnetic (EM)	N	N
48	Endoscopy, LEMKE	N	N
49	Angiographic Table, Triumph Jupiter	N	N
88	Gamma Probe Model: Europrobe, Manufacturer: Eurorad	50cm ³¹ U	50cm ³² U
58	UPS Uninterruptible Power Supply Model ABCE...IEC, Powervar	N	N
59	O ₂ Regulator Infant Flow System, Viasys	N	N

³⁰) With Ch11(500mW) at 10cm: Acoustic noise could be heard from a loudspeaker. This was not counted as "interference".

³¹) With Ch11 (2,5 GHz) at 500 and 200 and 100mW: At 50cm from the cable connector: Incorrect indication on apparatus (between 0 and 2000 cps). With **no** cable connected: **no** influences. Near the detector head: no influences. So, the disturbances enter via the cable. Ch1 and Ch64: same influences; Ch36(18dBi): No influence. Long and short packages had the same effect.

³²) See previous note.

5.4 Summary of results

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

Table 5.3: Summary of all tested medical apparatuses that were influenced and the separation distance d per apparatus (at 500mW and 100mW).

No. in test	Medical Apparatuses tested	Separation distance d			
		At 500mW		At 100mW	
	Ventilator				
14	Oscillatory Ventilator Model 3100 A, Sensormedics	1cm	U	1cm	U
34	Infant Flow Sipap, Viasys	40cm	U	10cm	U
70	Homecare Ventilator 150, Saime Elisée	5cm	L	1cm	L
	Monitor / Meter				
60	Ear Thermometer First Temp Genius M3000 A, Sherwood-Davis&Geck. Functionally tested in test unit Tyco Healthcare.	0cm	L	0cm	L
	Telemetry				
7	Transmitter, Dräger	10cm	U	0cm	U
63	Transmitter 5200899E510U, Siemens	2cm	U	2cm	U
	ECG Electrocardiograph				
65	MAC 5500, General Electric	5cm	L	5cm	L
66	Marquette MAC 5000, General Electric	10cm	L	10cm	L
	Ultrasound (US)				
26	US Scanner Flex Scan T57S System Five, General Electric	20cm	S	8cm	S
	Several				
88	Gamma Probe Model: Europrobe, Manufacturer: Eurorad	50cm	U	50cm	U

5.5 Graphical presentation of results

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

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

From Figure 5.1 for example it can be concluded that at distances above 10cm about 3% of the medical apparatuses tested was disturbed by the WLAN signal 100mW. The continuous graphs are the theoretical field strength at distance d from WLAN antennas according to the basic formula $E = 7 \times (\sqrt{W}) / d$ in which W is power in watt (See **Literature [4]**). This field strength must be taken from the right vertical axis in the graphs of Figure 5.1 and Figure 5.2. Two examples:

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

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

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

At 100mW			At 500mW		
No. in test	Separation distance d		No. in test	Separation distance d	
	At 500mW	At 100mW		At 500mW	At 100mW
7	10cm U	0cm U	60	0cm L	0cm L
60	0cm L	0cm L	14	1cm U	1cm U
14	1cm U	1cm U	63	2cm U	2cm U
70	5cm L	1cm L	65	5cm L	5cm L
63	2cm U	2cm U	70	5cm L	1cm L
65	5cm L	5cm L	7	10cm U	0cm U
26	20cm S	8cm S	66	10cm L	10cm L
66	10cm L	10cm L	26	20cm S	8cm S
34	40cm U	10cm U	34	40cm U	10cm U
88	50cm U	50cm U	88	50cm U	50cm U

Conclusions from the graphs in Figure 5.1 and Figure 5.2:

- For **100mW** the distance at which 3% of the tested medical apparatuses was influenced is: 10cm;
- For **500mW** the distance at which 3% of the tested medical apparatuses was influenced is: 20cm;
- As mentioned above already the 3% point for 100mW is at 10cm. As can be seen from Figure 5.2 the 3% point for 500mW is at about 20cm. This shift in distance (about a factor 2) is very close to what the formula $E = 7 \times (\sqrt{W}) / d$ would imply (from 100mW to 500mW implies a shift of $\sqrt{5} = 2,24$);
- The characterisations of the disturbances (**L**, **S**, **U**) are indicated in both diagrams. As can be seen the letters **L**, **S** and **U** are equally distributed over the distances 0-50cm. So unsafe disturbances occur at all distances 0-50cm.

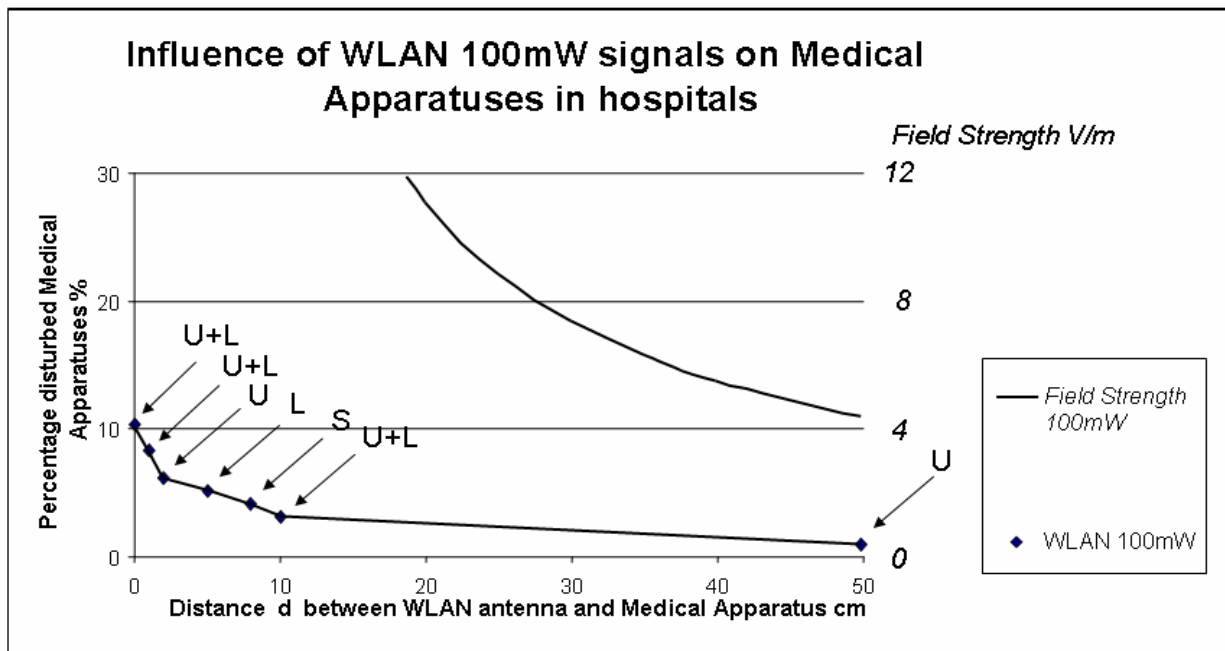


Figure 5.1: Influence of WLAN 100mW signals on medical apparatuses in hospitals.

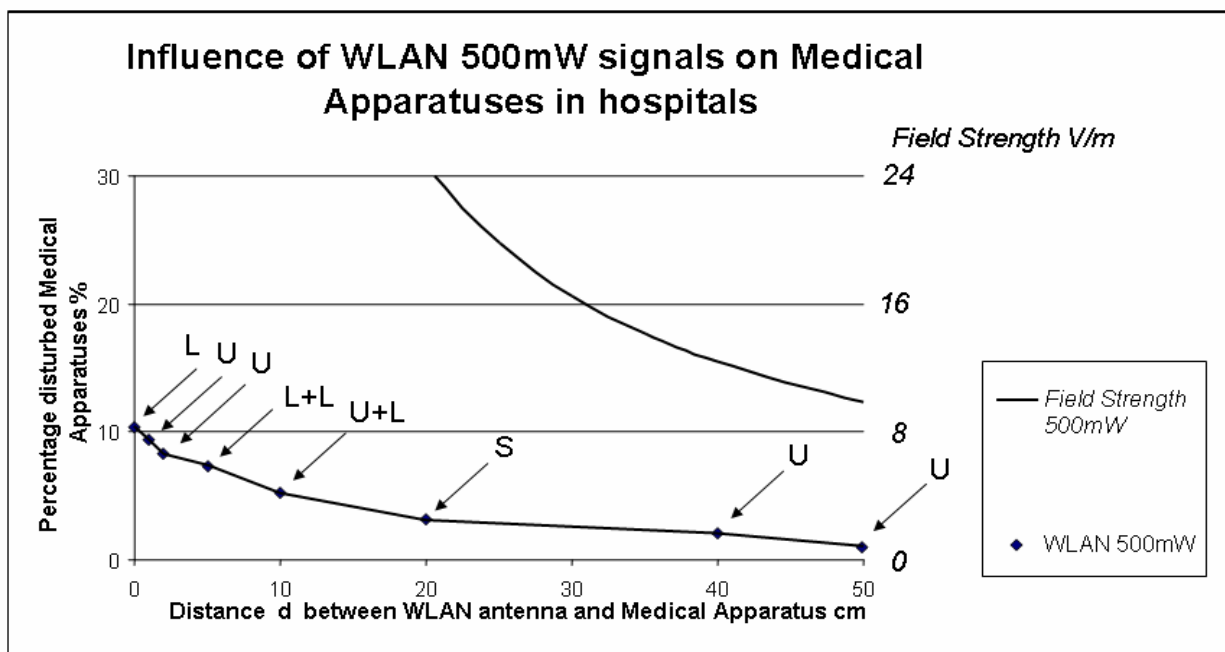


Figure 5.2: Influence of WLAN 500mW signals on medical apparatuses in hospitals.

5.6 Number influenced apparatuses per type

In Table 5.5. below the number of tested apparatuses per type is given and the number of apparatuses per type that were influenced.

Table 5.5: Number of tested apparatuses per type and the number of apparatuses per type that were influenced.

Medical Apparatuses tested (per type)	Number of medical apparatuses tested (+ number connected)	Number of medical apparatuses influenced by the tests
Ventilator	13	3 (at 500 and at 100mW)
Syringe Pump	9 (+1)	0
Infusion Pump	4 (+1)	0
Enteral Feeding Pump	3	0
Balloon Pump	2	0
Monitor (patient, transport, cardiac output)	9	0
Meter (BP, pulseoxymeter, temp, etc.)	6	1 (at 500 and at 100mW)
Telemetry Cardiology	2 (+1)	2 (at 500 and at 100mW)
Pacemaker Programmer	1	0
Blood warmer	1	0
EEG Electroencephalograph	1	0
ECG Electrocardiograph	2	2 (at 500 and at 100mW)
CTG Cardiotocograph	2	0
ERG Electroretinograph	1	0
Defibrillator	6	0
Electrosurgery	3	0
Dialysis	4 (+2)	0
Anaesthesia	3	0
Ultrasound (US)	4	1 (at 500 and at 100mW)
Infant Incubator	2	0
LVAD Left ventricle assist device	1 (+1)	0
HLM Heart lung machine	1 (+1)	0
Heating Device	1	0
Surgical Navigation	1 (+1)	0
Endoscopy	1	0
Angiographic Table	1	0
Gamma Probe	1	1 (at 500 and at 100mW)
UPS Uninterruptible power supply	1	0
O ₂ Regulator	1	0
Total	88 (+ 8 connected) tested	10 influenced

5.7 Comparison of results to GSM results

Interpretation of WLAN results as presented in the **Paragraph 5.5** is possible by comparing them with results from comparable research on GSM mobile phones. In Figure 5.3 the results from research on GSM mobile phones are depicted (copied from **Literature [4] and [5]**).

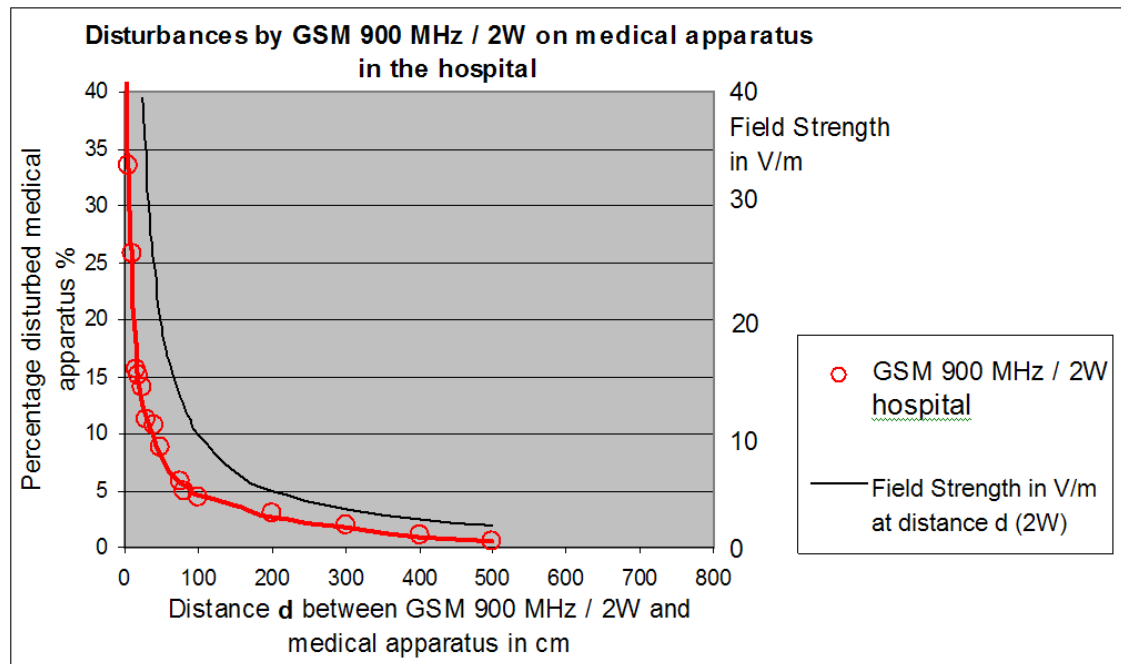


Figure 5.3: Disturbances by GSM 900 MHz / 2W on medical apparatus in the hospital (copied from Literature [4] and [5]).

From the graph in Figure 5.3 it can be seen that at 150cm distance from GSM phones about 3% of the medical apparatus is disturbed. The distance at which 3% apparatus are disturbed is internationally advised as the separation distance to be kept³³. As concluded in **Paragraph 5.5** the 3% point for WLAN 100mW lies at 10cm. From this comparison it concludes that the ratio between the separation distances for GSM and WLAN is a factor of 15.

³³⁾ It is generally advised not to have GSM phones transmitting within this distance from a medical apparatus (in hospital and in home environment). See for example:

- 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: V-ICTN Recommendations **Literature [6]** based on **Literature [4]** and referring to **Literature [2]**.

6 Acknowledgements

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The hospitals mentioned below supported the project. They provided medical apparatuses and supported intensively in operating them and explaining their functionality including the related risks; also in case disturbances occurred.

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- Leiden University Medical Center, LUMC;
- University Medical Center Utrecht, UMCU;
- Diaconessenhuis Leiden.

The following SMEs participated: Auxilium, Colubris Networks, Elspec, EsperantoXL, Geodan Mobile Solutions, Lancom Systems, Lumiad Telecommunication, PHI DATA, Proxim Wireless, Smart Future, Trapeze Networks, Verkerk Service Systemen, VierC and Vosko Networking. A number of SMEs is a WLAN manufacturer. These companies supported the project technically and provided application knowledge as well. The organization Syntens supported the project and consulted the participating SMEs.

A word of special thanks goes to Wim Bos and his company Lumiad. Wims personal flair highly influenced the success of the project.

7 Signature

Author	Signature
Reinout Hensbroek, M.Sc.	
Project manager	
Approved by	Signature
Dr.Ir. A.C.M. Dumay	
Head Department Technology in Healthcare	

A WLAN test set-up

1. Measurement Equipment to monitor testing
 - o Spectrum analyzer: fsh manufactured by Rohde & Schwarz;
 - o Horn antenna: Double Ridged Guide Horn Antenna, Manufacturer: EMCO;
 - o Model: 3115, Serial No. 9104 3649;
 - o Attenuator 20dB.
2. Hardware in the test set-up:
 - o 2 PC's / 8 AP's (in this way combining 802.11 a, b, g in one test);
 - o An amplifier at 2,4GHz and an 18dBi antenna at 5GHz to start testing on every medical apparatus with 2 channels at higher power levels than normal;
 - o Medical Apparatuses were placed on a wooden cart.

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

Note: Antennas were normalized antennas. No directional antennas were used. One exception was made to this: A directional antenna was used (18dBi) in order to produce higher field strength as a means to speed up the searching for possible susceptible medical equipment. Of course, this antenna and this higher field strength was not incorporated in the final counting of influence for the 100mW power level. Within a distance of 15cm from the antennas far field conditions do not apply for 2,4GHz. Within a distance of 8cm from antennas far field conditions do not apply for 5GHz. Testing at distance 0cm means that the antenna is held against the medical apparatus. At this distance no far field conditions occur. In the near field it is not possible to apply the (simple) standard far field formulas that relate field strength to radiated power at a certain distance. In the far field however such calculations can be performed in principle.

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

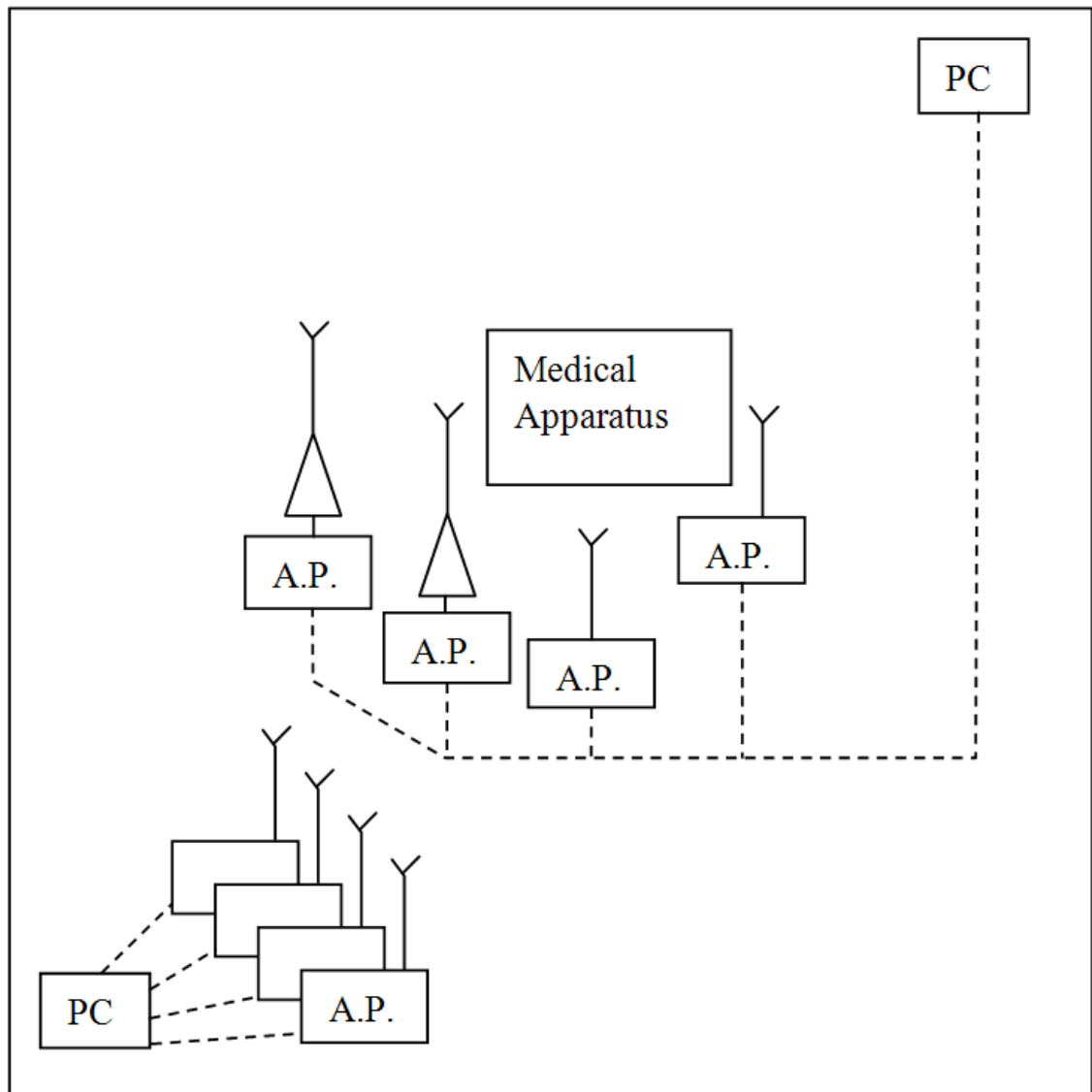


Figure B.1: Test set-up with 4 transmitting antennas and 4 receiving antennas. Each of these groups of antennas was connected to a separate PC.

B Photographs

Figure B.2 shows the test signal of Channel 1 with short packages. The photo is obtained with a spectrum analyzer at zero span. The time base was 0,1ms/division (upper trace), 1ms/div (middle trace) and 10ms/div (lower trace). As indicated in the montage by accolades, the upper trace can be recognized as being a part of the middle trace, etcetera.

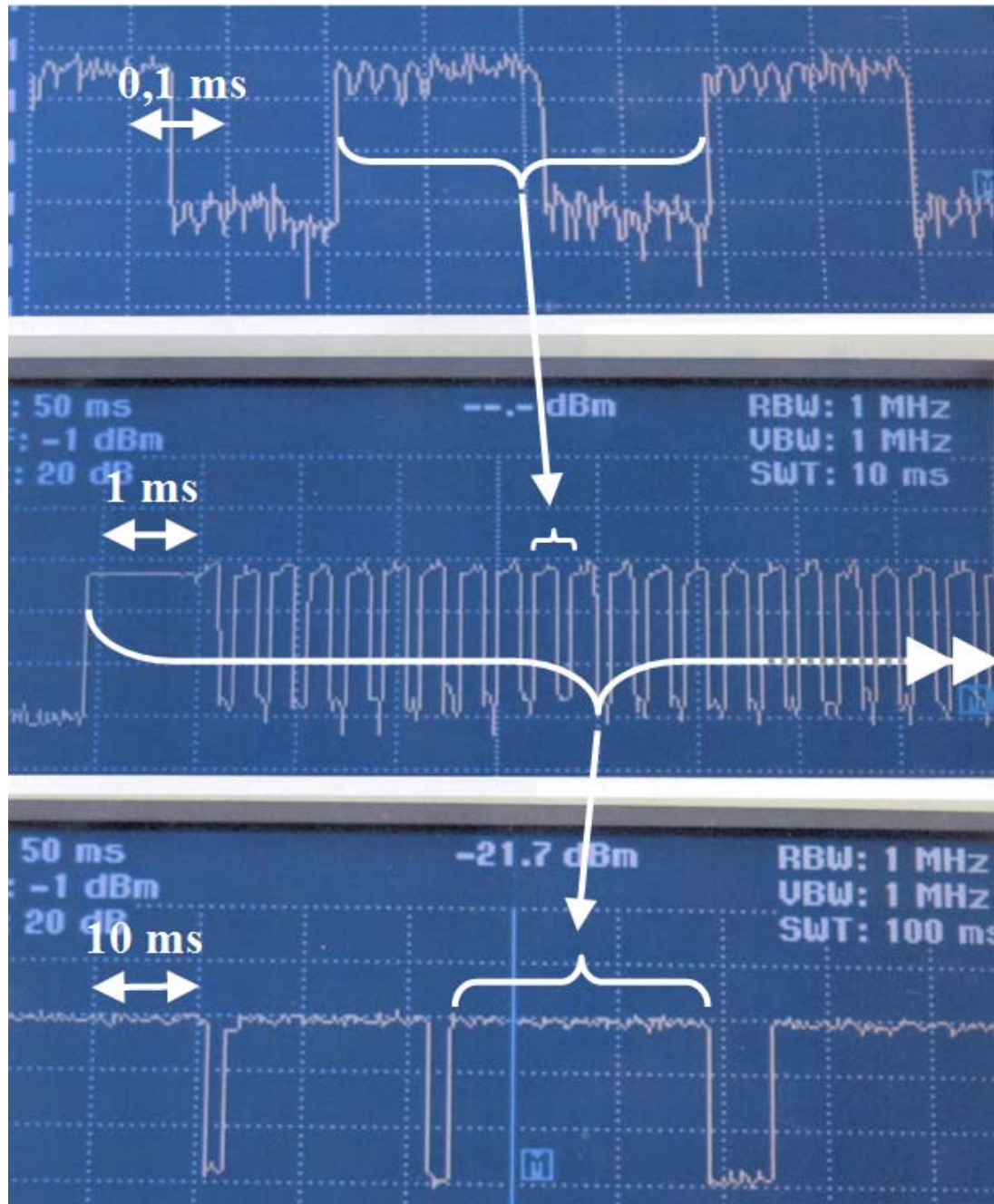


Figure B.2: Test signal of Ch1 with short packages. The time base: 0,1ms/division (upper trace), 1ms/div (middle trace) and 10ms/div (lower trace).

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

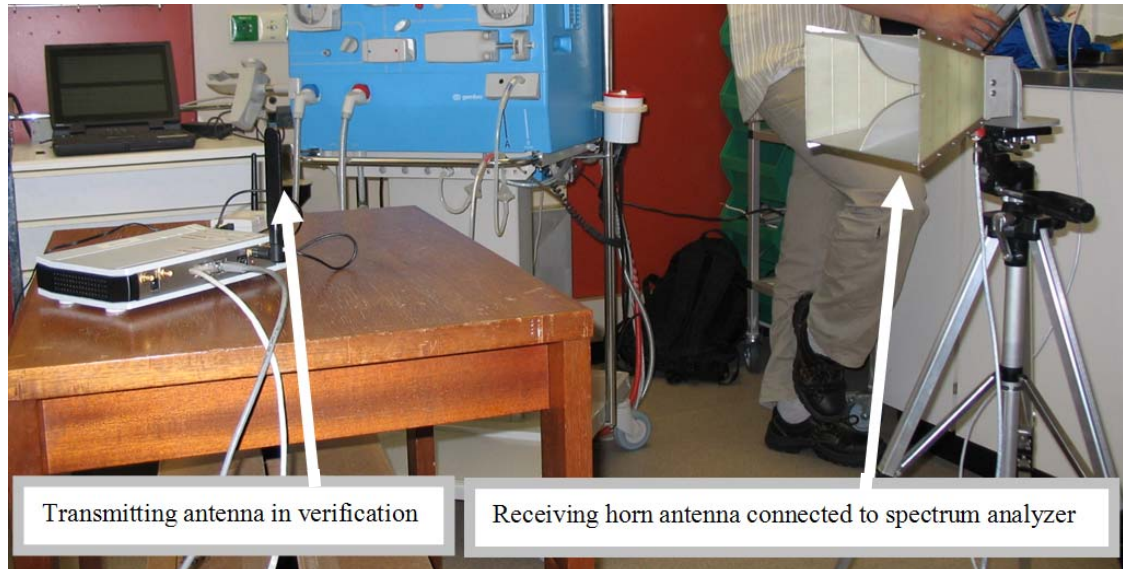


Figure B.3.

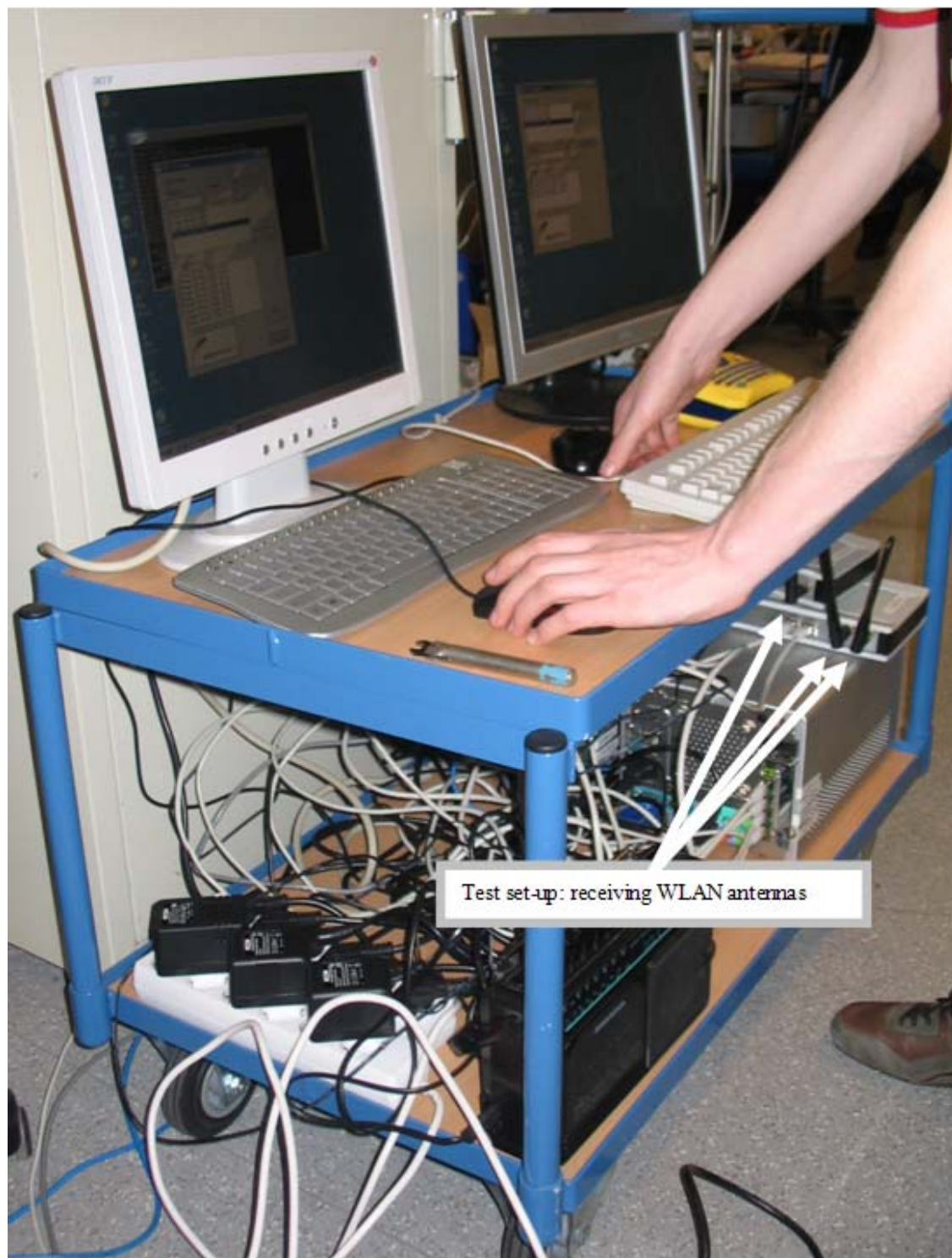


Figure B.4.

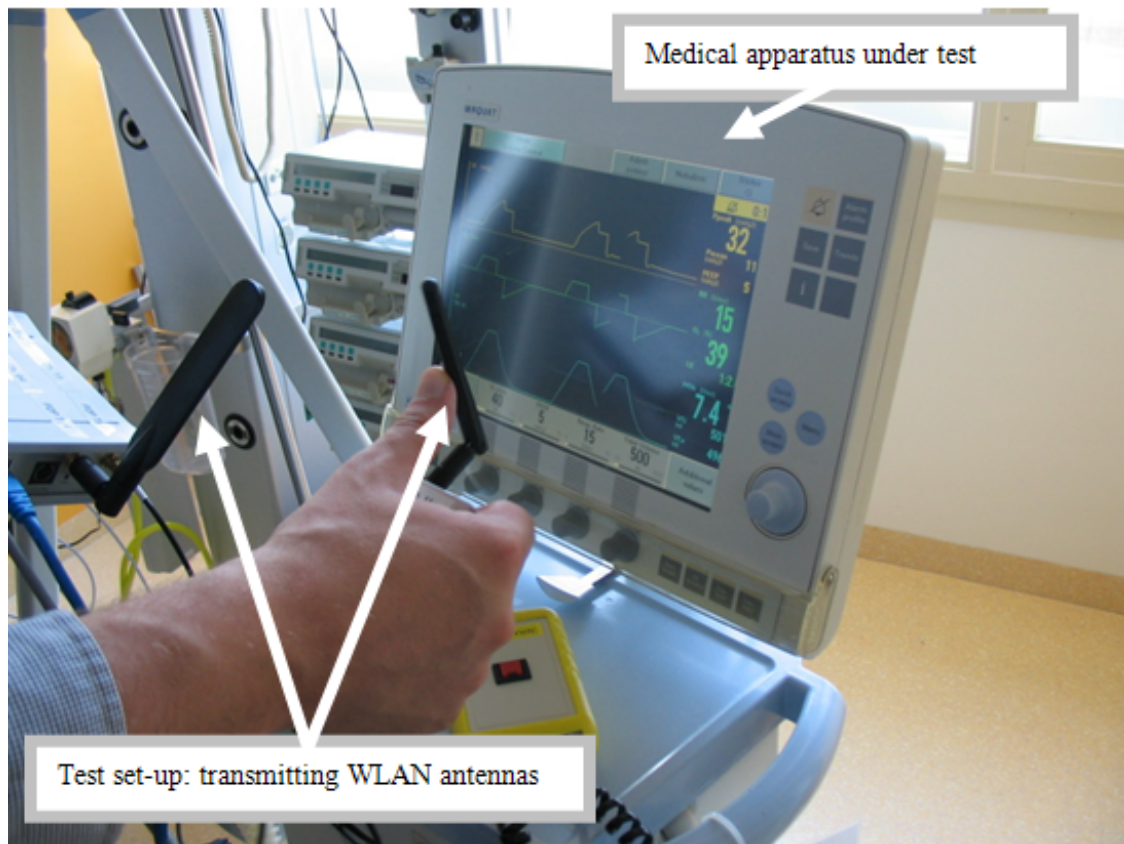


Figure B.5.

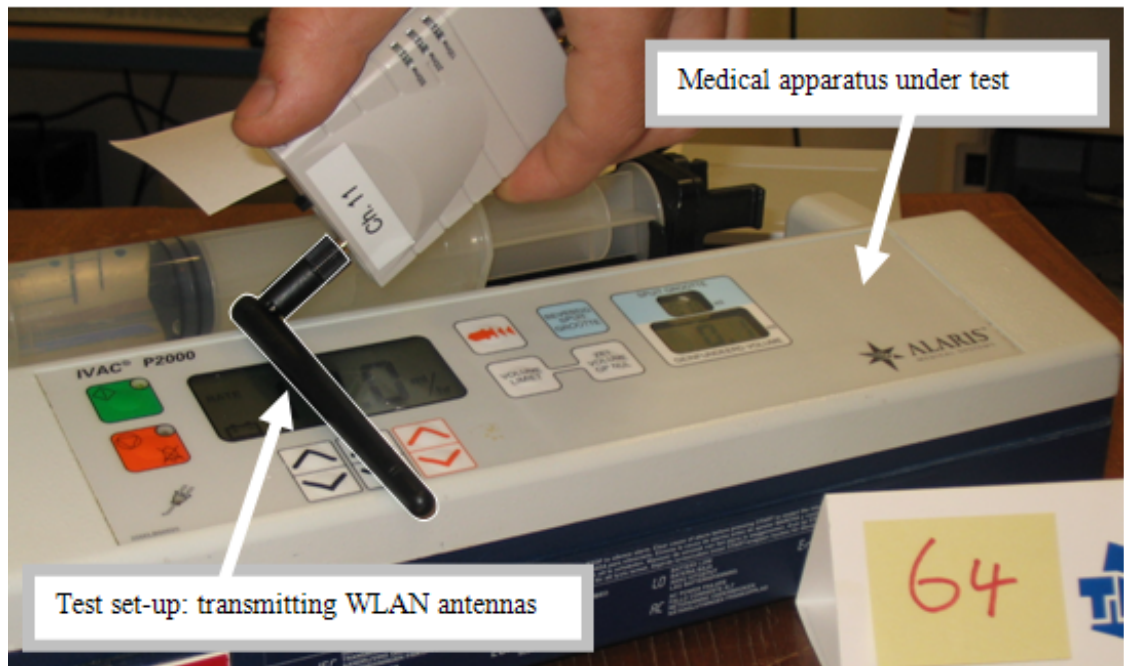


Figure B.6.

C Literature

1. Magazine “Technologie in de Gezondheidszorg” (NL language). April 2005, Number 4, 21st Issue, pp.5-6
2. Recommendations regarding the use of pocket telephones within health care institutions 1995, VIFKA, 1 September 1995 (VIFKA is now called “Vereniging ICT Nederland”).
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For medical apparatus this report refers to:
Influence of 2W GSM pocket phones on 205 medical apparatuses: field measurements. TNO report TG/95.044. 1 August 1995 (NL Language).
5. R. Hensbroek, Interference by handheld telephones on medical equipment (NL language). In magazine: “Klinische Fysica”. December 2000.
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Those recommendations refer to the still applicable recommendations in Literature [2]: Recommendations regarding the use of pocket telephones within health care institutions 1995, VIFKA, 1 September 1995 (VIFKA is now called “Vereniging ICT Nederland”).
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8. Hanada et al: Electromagnetic Interference on Medical Equipment by Low-power Mobile Telecommunication Systems. IEEE Transactions on Electromagnetic Compatibility, Vol. 42, No. 4, November 2000, pp. 470-476.
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