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TNO report

2016 | Final report

A binder with EMC Reports from TNO on EMI in Medical Equipment.

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INTRODUCTION

This collection of “medical EMC reports” from TNO covers the years 1995-2010. The orderers of these reports permitted publication. If a report is in Dutch language, an English summary is included. The Dutch report can generally be understood from its technical nature (tables and figures). Most reports also are separate available on the TNO repository **http://repository.tudelft.nl/search/tno/?q=hensbroek** (search on the author’s name) where this binder is available as well.

Note: This binder with a collection of EMC reports from TNO was prepared in conjunction with the 2016 white paper “A Model for Interference(…)” which is also available on the repository.

Appendix 1

SUMMARY of Research report TNO TG/95.044: Influence of 2-Watt GSM pocket phones on 205 medical apparatus - field measurements (1 August 1995)

Field measurements conducted with 205 apparatus and systems revealed that 101 apparatus/systems exhibited a certain sensitivity to signals transmitted by a 2-Watt GSM pocket phone. During this research no measurements were performed with 8-Watt GSM (in-car) phones. The group of 205 apparatus/systems consisted of 200 apparatus/systems used mainly in hospitals and 5 apparatus also used outside hospitals.

The following equipment was examined:

17	analysers
5	anaesthetic machines
14	lung ventilators
7	blood pressure meters
10	incubators
6	external pacemakers
17	infusion pumps
22	patient monitors
26	syringe pumps
76 + 5	various electronic (medical) apparatus
205	

The following results were obtained:

1 It was necessary to transmit very close to the apparatus/systems (within about 1 metre) in order to find interference. The only exceptions found to this '1 - metre rule' were nine apparatus which reacted at a distance of between 1 and 5 metres already, including five apparatus connected directly to patients which reacted at distances of between 1 and 4 metres already.

2 With 69 of the 101 apparatus/systems which reacted, the reaction took place at distances less than or equal to 10 centimetres.

3 With 14 of the 101 apparatus/systems which reacted, a dangerous situation to patients was observed. The dangerous reactions consisted of:

- 2 analysers which gave incorrect values without giving an alarm (indirect danger). (0.5 and 3 m)
- 5 lung ventilators and 1 anaesthetic machine stopped working without giving an alarm or abruptly changed their stroke volume. (0 - 0.25 m)
- 1 external pacemaker stopped giving stimulation pulses. (0.25 m)
- 1 O_2 concentration meter in an incubator stopped giving acoustic alarms. (0.05 m)
- with 2 paging systems, calls could not be received from the exchange (indirect danger). (0 - 0.3 m)
- with 1 syringe pump, the setting was erased from the memory (with an alarm). (0.05 m)
- with 1 water mattress used in an operating theatre, the regulation was disrupted. (0.10 m)

One dangerous reaction occurred at a distance of about 3 metres (with an analyser/osmometer). The other dangerous reactions all occurred within one metre of the 2-Watt GSM pocket phone. (End of summary)

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TNO-rapport

Invloed van 2 Watt GSM-zaktelefoons op 205 medische apparaten - praktijkmetingen

1 augustus 1995, onderzoeksrapport TG/95.044

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Aantal tabellen : 2

Aantal figuren : 1

Nederlandse organisatie voor toegepast-natuurwetenschappelijk onderzoek

De missie van TNO Preventie en Gezondheid is vooral het bevorderen van het aantal gezonde levensjaren van de mens. Het onderzoek richt zich op verbetering van gezondheid en gezondheidszorg in alle levensfasen: jeugd, arbeidende mens en ouderen.

SAMENVATTING Onderzoeksrapport TNO TG/95.044: Invloed van 2 Watt GSM-zaktelefoons op 205 medische apparaten - praktijkmetingen (1 augustus 1995)

Uit praktijkmetingen aan 205 apparaten en systemen bleek, dat 101 apparaten/systemen een zekere gevoeligheid vertoonden voor het door een 2 Watt GSM-zaktelefoon uitgezonden signaal. Er is tijdens dit onderzoek niet gemeten met 8 Watt GSM-(auto)telefoons. De groep van 205 apparaten/systemen was opgebouwd uit 200 apparaten/systemen die voornamelijk toegepast worden in het ziekenhuis en 5 apparaten die ook buiten het ziekenhuis worden gebruikt.

Onderzocht zijn:

17	Analysers
5	Anesthesie apparaten
14	Bademings apparaten
7	Bloeddrukmeters
10	Couveuses
6	Externe pacemakers
17	Infuuspompen
22	Patiëntmonitoren
26	Spuitpompen
76 + 5	Diverse elektronische (medische) apparaten
205	

De volgende resultaten zijn gevonden:

1 Er moest erg dicht bij de apparaten/systemen worden gezonden (binnen circa 1 m afstand) om invloeden te vinden. De enige gevonden uitzonderingen op deze " 1 meter - regel " waren: 9 apparaten, welke al reageerden op afstanden tussen circa 1 en 5 m, waarvan 5 direkt aan patiënten gekoppelde apparaten, welke al reageerden op afstanden tussen circa 1 en 4 m.

2 Bij 69 van de 101 apparaten/systemen die reageerden vond de reactie plaats op afstanden kleiner dan of gelijk aan 10 cm.

3 Bij 14 van de 101 apparaten/systemen die reageerden werd een voor een patiënt "gevaarlijke" reactie geconstateerd. De gevaarlijke reacties bestonden uit:

- 2 Analysers, die verkeerde waarden aangaven zonder alarm (indirekt gevaar). (0,5 en 3 m)
- 5 Bademings apparaten en 1 Anesthesie apparaat stopten zonder alarm of wijzigden abrupt hun slagvolume. (0 - 0,25 m)
- 1 Externe pacemaker stopte met afgeven van stimulatiepulsen. (0,25 m)
- 1 O_2-Concentratiemeter in een couveuse gaf geen akoestisch alarm meer. (0.05 m)
- Bij 2 Personen oproep systemen kon geen oproep van de centrale worden opgevangen (indirekt gevaar). (0 - 0,3 m)
- Bij 1 Spuitpomp werd de instelling uit het geheugen gewist (met alarm). (0,05 m)
- Bij 1 Watermatras, gebruikt op de ok, werd de regeling verstoord. (0,10 m)

Eén gevaarlijke reactie ontstond op circa 3 m afstand (bij een Analyser/osmometer); de overige gevaarlijke reacties deden zich alle voor binnen 1 m van de 2 Watt GSM-zaktelefoon.

INHOUDSOPGAVE

1 INLEIDING[1]

Het voorliggende rapport maakt deel uit van een serie van drie rapporten, respectievelijk betrekking hebbend op de volgende drie digitale telefoniesystemen met zaktelefoons:
- GSM
- DECT
- CT-2

De internationale omschrijving van deze drie digitale telefoniesystemen is opgenomen in Bijlage 4 van dit rapport. De geteste medische apparaten zijn in Bijlage 1 van alle drie de rapporten vermeld op alfabetische volgorde van het type apparaat. Alle apparaten hebben ook een volgnummer gekregen, dat eveneens is vermeld. Omdat de tests met de drie bovengenoemde systemen niet geheel parallel konden lopen, komen sommige apparaten niet in alle drie de rapporten voor. De reeds in rapport TG/95.010[2] vermelde resultaten zijn voor de volledigheid opnieuw in bovengenoemd GSM-rapport opgenomen. Dit is ook gedaan met de beschrijving van de GSM-metingen uit rapport TG/95.010.

In landen waar zaktelefoons reeds enige tijd in gebruik zijn, wordt regelmatig gewag gemaakt van storing op medische apparatuur die door die telefoons wordt veroorzaakt. Tevens is het vermoeden geuit, dat de mate waarin storingen op kunnen treden niet voor alle systemen hetzelfde is. Omdat bovengenoemde systemen ook in Nederland naar verwachting op grote schaal gebruikt zullen gaan worden, is het belangrijk om inzicht te verwerven in de omvang en de aard van de problematiek. Zaktelefoons zenden via de ether signalen naar een basisstation. Dit zendsignaal is met name bij het GSM-systeem in principe voldoende sterk om medische apparatuur, die zich in de buurt bevindt, te kunnen storen. Echter, niet alle medische apparatuur is even storingsgevoelig en niet alle drie de systemen zenden hetzelfde soort signaal. Dit rapport beschrijft in de ziekenhuispraktijk uitgevoerde stoorexperimenten inclusief de reacties, die apparaten vertoonden en de afstand waarop storing optrad.

2 DOEL VAN HET ONDERZOEK

Doel van het uitgevoerde onderzoek was het verzamelen van ervaringen met een groot aantal medische apparaten en het zodanig rapporteren van deze ervaringen, dat het toelatingsbeleid voor zaktelefoons in Nederlandse ziekenhuizen er op kan worden gebaseerd.

3 ONDERZOEKSMETHODE

3.1 ALGEMEEN

Een GSM-zaktelefoon en een simulatie-opstelling werden gebruikt als potentiële "stoorbronnen". In praktijksituaties in vijf ziekenhuizen werden deze stoorbronnen geactiveerd in de nabijheid van medische apparatuur. Er is naar gestreefd om vooral die apparatuur te onderzoeken, waarbij veiligheidsaspecten een rol spelen. Ten opzicht van

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[1] De tekst van deze inleiding is in alle drie de rapporten, waarover in deze inleiding wordt gesproken, identiek.

[2] "Invloed van 2 Watt GSM-telefoons op medische apparatuur - oriënterende metingen; 20 januari 1995, onderzoeksrapport TG/95.010.", TNO Preventie en Gezondheid, Leiden

rapport TG/95.010 is nieuw, dat nu ook operatiekamer apparatuur ("ok-apparatuur") in het onderzoek is betrokken. Rekening houdend met de mogelijkheden van de afdelingen en met de beschikbare tijd is een zo representatief mogelijke groep apparaten onderzocht. Er is niet speciaal naar oude of nieuwe apparaten gezocht; de leeftijd van de onderzochte apparaten is ook niet geregistreerd. De indruk bestaat, dat de apparaten gemiddeld circa 5 jaar oud waren en dat er vrijwel geen apparaten zijn onderzocht, die ouder waren dan 10 jaar. Er is in de ziekenhuis-praktijk gemeten omdat het noodzakelijk was om de apparatuur realistisch in werking te hebben. In risico situaties, waarbij een patiënt nadelige gevolgen zou kunnen ondervinden, is met een gezonde proefpersoon gewerkt. Op diverse apparaten is middels een technische "dummy" onafhankelijk van patiënt of proefpersoon gewerkt. Om redenen van efficiency en veiligheid en om de betrokken ziekenhuisorganisaties niet onnodig te belasten, is vooraf een beproevingsprotocol opgesteld en uitgetest in een technische ruimte van een ziekenhuis. Het beproevingsprotocol is opgenomen in Bijlage 3.

3.2 GEBRUIKTE STOORBRONNEN

Er werd bij het onderzoek gebruik gemaakt van een GSM-zaktelefoon en van een simulatie-opstelling, die nagenoeg hetzelfde signaal opwekte als een GSM-zaktelefoon. De reden om naast de GSM-zaktelefoon ook een simulatie-opstelling te gebruiken was de volgende: of GSM-zaktelefoons hun maximum vermogen (2 Watt) ook daadwerkelijk zenden of niet, wordt vanuit het GSM-netwerk geregeld. Daardoor kan een GSM-zaktelefoon tijdens stoorexperimenten niet dienen als "constante stoorbron". Van de simulatie-opstelling kon het zendvermogen op 2 Watt worden ingesteld. In een aantal gevallen kon wegens praktische omstandigheden niet met beide stoorbronnen worden gemeten, maar alleen met de simulatie-opstelling, Zie Bijlage 1. Zie Bijlage 4 voor nadere gegevens over GSM-systemen.

3.3 TOEPASSING EN AANTAL ONDERZOCHTE APPARATEN

Er zijn 205 apparaten onderzocht. De onderzochte apparaten kunnen als volgt worden ingedeeld:

		aantal:
MI	= Medisch apparaat bInnen (In) het ziekenhuis	192
N	= Niet medisch apparaat	8
MU	= Medisch apparaat bUiten (Uit) het ziekenhuis	5
		205

Zoals uit deze getallen blijkt, lag de nadruk bij het onderzoek geheel op medische apparatuur, die in het ziekenhuis wordt toegepast (MI). De acht N-apparaten waren communicatie- en toegangscontrôlemiddelen, die voor de bedrijfsvoering van het ziekenhuis noodzakelijk zijn. De vijf MU-apparaten waren hoortoestellen, die ter oriëntatie zijn gemeten.

In Bijlage 1 zijn alle geteste apparaten alfabetisch gerangschikt en voorzien van een volgnummer. Dit volgnummer is vermeld in kolom 1 van Bijlage 1.

De tabel in Bijlage 1 geeft een overzicht over de onderzochte apparatuur. Uit die tabel is bijvoorbeeld af te lezen, dat onderzocht zijn:

- 17 Analysers
- 5 Anesthesie apparaten
- 14 Beademings apparaten

-	7	Bloeddrukmeters
-	10	Couveuses
-	6	Externe pacemakers
-	17	Infuuspompen
-	22	Patiëntmonitoren
-	26	Spuitpompen
-	81	Diverse elektronische apparaten
	205	

Diverse keren zijn apparaten van hetzelfde fabrikaat en type, maar met verschillend serienummer onderzocht. De volgnummers van deze apparaten zijn in de eerste kolom van de tabel in Bijlage 1 in één doorlopend vak weergegeven. Zo waren bijvoorbeeld de apparaten Nr. 18 en 19 (zie de tabel van Bijlage 1) van hetzelfde fabrikaat en type. Een open vak onderaan de pagina heeft dezelfde betekenis. Zo waren ook de apparaten Nr. 35 t/m 38 van hetzelfde fabrikaat en type. In paragraaf 4.2 wordt ingegaan op de laatste kolom van de tabel in Bijlage 1.

4 UITKOMSTEN VAN HET ONDERZOEK

4.1 DE AFSTAND WAAROP APPARATEN REAGEERDEN

In Bijlage 1 zijn alle geteste apparaten alfabetisch gerangschikt en voorzien van een volgnummer. In Bijlage 2 zijn de geteste apparaten gesorteerd op de afstand waarop zij reageerden. Deze afstand is te vinden in de laatste kolom van Bijlage 2. Er is in die laatste kolom eerst gesorteerd op "ja" (wel storing) en "nee" (geen storing). Vervolgens is binnen elk van de groepen "ja" en "nee" gesorteerd op afstand. Het volgnummer van elk apparaat is ook in Bijlage 2 opgenomen (eerste kolom). Middels dit volgnummer kan in Bijlage 1 worden nagezocht wat precies de aard van de reactie van een gestoord apparaat was.

Van de 205 onderzochte apparaten vertoonden 101 apparaten een zekere gevoeligheid voor het door een GSM-zaktelefoon uitgezonden signaal. De figuur op de volgende pagina geeft per afstand weer hoeveel apparaten reacties vertoonden. Hierbij wordt opgemerkt:

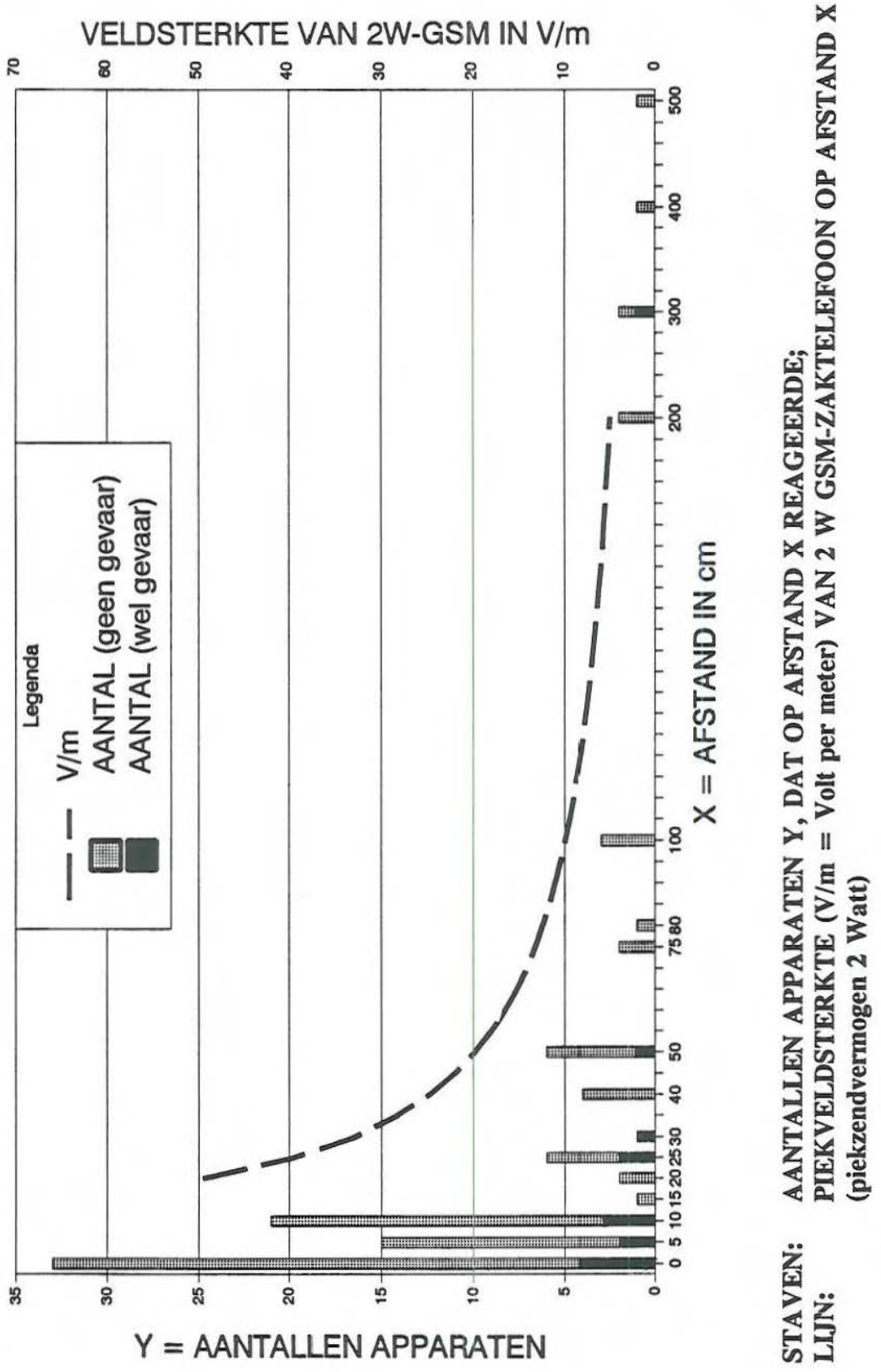
- De hoogte van de staven = Y = het aantal apparaten, dat op afstand X reageerde. Alle staven gesommeerd hebben de "hoogte" 101 - het totale aantal apparaten, dat reageerde.
- De staven zijn op de goede afstand op de X-as geplaatst, maar boven 200 cm is wel een andere schaal toegepast. De staven bij 300, 400 en 500 cm zijn feitelijk vertekend weergegeven.
- In de figuur is met een gebogen lijn aangegeven: de veldsterkte (in Volt per meter, V/m) van een 2 Watt GSM-zaktelefoon als functie van de afstand tot die telefoon.

Laatstgenoemde veldsterkte-lijn is gebaseerd op de benaderingsformule:

$$E = 7 \cdot (\sqrt{W}) / d \quad V/m$$

Voorbeeld: op 1 m afstand (d=1) van een 2 Watt GSM-zaktelefoon (W=2) is de veldsterkte: E = circa 10 V/m.

In de praktijk varieert de veldsterkte doordat een fabrikagemarge ten aanzien van het gespecificeerde vermogen geldt, maar vooral ook doordat reflecterende voorwerpen locale verhogingen en verlagingen van de veldsterkte kunnen veroorzaken. Bij de praktijkmetingen aan apparatuur werd dit effect gecompenseerd door de GSM bron op veel locaties rond het te testen apparaat te activeren.



STAVEN: AANTALLEN APPARATEN Y, DAT OP AFSTAND X REAGEERDE;
LIJN: PIEKVELDSTERKTE (V/m = Volt per meter) VAN 2 W GSM-ZAKTELEFOON OP AFSTAND X (piekzendvermogen 2 Watt)

Samenvattend: Van de 205 onderzochte apparaten/systemen bleken er 101 een zekere gevoeligheid te vertonen voor het door een 2 Watt GSM-zaktelefoon uitgezonden signaal.

De volgende resultaten zijn gevonden:

1 Er moest erg dicht bij de apparaten/systemen worden gezonden (binnen circa 1 m afstand) om invloeden te vinden. De enige gevonden uitzonderingen op deze "1 m - regel" waren:
   - 9 apparaten, die bij circa 1-5 m al reageerden. Zie de apparaten Nr. 1, 74, 7 ,17 ,90 ,127 ,8 ,68 en 99 in de tabellen van Bijlagen 1 en 2 (In Bijlage 2 staan de apparaten op afstand in de hier genoemde volgorde bij elkaar; in Bijlage 1 staan ze op nummer),
   - waarvan 5 direkt aan een patiënt gekoppelde apparaten, die al op afstanden van 1 - 4 m reageerden. Zie de apparaten 74, 90 ,127 ,68 en 99.

2 Bij 69 van de 101 apparaten/systemen die reageerden vond de reactie plaats op afstanden kleiner dan of gelijk aan 10 cm (Bij telling in Bijlage 2 apparaat 127 niet meegeteld, want reageerde al op 200 cm).

4.2 AARD VAN DE REACTIES

De gebruikte GSM-bronnen beïnvloedden diverse onderzochte apparaten wanneer zij in de nabijheid van die apparaten werden geactiveerd. De reacties zijn in detail beschreven in de laatste kolom van de tabel in Bijlage 1.

In 14 van de 101 gevallen werd een voor patiënt of gebruiker "gevaarlijke" reactie geconstateerd. De gevaarlijke reacties bestonden uit:

	afstand
- 2 Analysers, die verkeerde waarden aangaven zonder alarm (indirekt gevaar) (Nr. 2 en Nr. 17).	(0,5 en 3 m)
- 5 Beademings apparaten en 1 Anesthesie apparaat stopten zonder alarm of wijzigden abrupt hun slagvolume (Nrs. 33, 34, 35, 37, 38 en 18).	(0 - 0,25 m)
- 1 Externe pacemaker stopte met afgeven van stimulatiepulsen (Nr. 96).	(0,25 m)
- 1 O_2-Concentratiemeter in een couveuse gaf geen akoestisch alarm meer (Nr. 127).	(0.05 m)
- Bij 2 Personen oproep systemen kon geen oproep van de centrale worden opgevangen (indirekt gevaar) (Nr. 128 en Nr. 129).	(0 - 0,3 m)
- Bij 1 Spuitpomp werd de instelling uit het geheugen gewist (met alarm) (Nr. 175).	(0,05 m)
- Bij 1 Watermatras, gebruikt op de ok, werd de regeling verstoord (Nr. 205).	(0,10 m)

Eén gevaarlijke reactie ontstond op circa 3 m afstand (bij een Analyser/osmometer; Nr. 17); de overige gevaarlijke reacties deden zich alle voor binnen 1 m van de 2 Watt GSM-zaktelefoon.

In de overige 87 gevallen (101-14 = 87) betrof het een beïnvloeding (storing) zonder dat

er sprake was van een direkt gevaar voor de patiënt. Hierbij wordt wel opgemerkt dat te veel "ongevaarlijke storingen" wel nadelig kunnen zijn voor de gang van zaken op een ziekenhuisafdeling, waardoor wel van een indirekt gevaar kan worden gesproken als er veel "ongevaarlijke" storingen zijn.

Deze resultaten bevestigen de tendensen, die bij eerder onderzoek waren gebleken. Zie rapport TG/95.010.

4.4 CONSEQUENTIES VOOR 8 WATT TOEPASSING

Een apparaat, dat op 1 m afstand van de 2 Watt GSM-zaktelefoon reageerde, zal theoretisch ook op 2 m afstand van een 8 Watt GSM-(auto)telefoon reageren. Voor de omrekening naar andere vermogens geldt de volgende regel:

Van de apparaten, die reageerden op een afstand van 20 cm of meer, kunnen de resultaten theoretisch worden geëxtrapoleerd naar GSM-telefoons met hogere vermogens:

> Een GSM-telefoon met een 4x zo groot vermogen geeft dezelfde veldsterkte af op een 2x zo grote afstand:
>
> dus: 2 W geeft op 1 m afstand een veldsterkte van circa 10 V/m
> en : 8 W geeft op 2 m afstand een veldsterkte van circa 10 V/m

De apparaten, die reageerden op 5, 10 en 15 cm afstand bevonden zich in het zogenaamde nabije veld van de GSM-stoorbron. Dit is het veld "vlak bij de zendende bron". Omdat dit veld vlak bij de bron zeer van de locale situatie afhankelijk is (geaarde delen, handen gebruiker, antenneconstructie, etc.), is omrekening naar grotere vermogens niet verantwoord. Voor de onderzoeksvraag is die omrekening ook niet zo belangrijk: het zal ook bij 8 Watt GSM-telefoons gaan om afstanden kleiner dan 1 m.

Voor de apparaten, die reageerden op een afstand < 5 cm is betrouwbare omrekening in het geheel niet mogelijk, maar - gezien hun betrekkelijke ongevoeligheid - ook niet erg interessant.

5 AANBEVELING VOOR NADER ONDERZOEK

Het is nodig om medische apparatuur, die buiten het ziekenhuis wordt toegepast, uitvoerig te testen, omdat die aan veldsterkten van autotelefoons kan worden blootgesteld op relatief kleine afstand. Die veldsterkten zijn - zoals bekend - groter dan de veldsterkten van GSM-zaktelefoons. In dat onderzoek zouden ook reeds bestaande systemen (portofoons, analoge autotelefoons e.d.) kunnen worden betrokken.

Het is gewenst om daarbij de theoretische regel voor het omrekenen van de afstand ("apparatuur reageert op 8 Watt telefoon op 2 x zo grote afstand als op 2 Watt zaktelefoon", zie paragraaf 4.4) experimenteel te verifiëren aan de hand van een aantal gevoelige apparaten.

BIJLAGE 1: APPARAATREACTIES

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
1	Analyser HPLC, Elektrochemische detector bij -	MI	500 cm: ja	Op ca. 5 m: GSM-telefoon èn GSM-simulator: onbruikbare uitslagen; gebruikers ondervonden vaker storing (geen gevaar)
2	Analyser, eiwit scanner	MI	50 cm: ja	Op ca. 50 cm afstand: GSM-simulator: verkeerde waarde (zonder foutmelding) (gevaar) Op ca. 25 cm afstand: GSM-telefoon: verkeerde waarde (zonder foutmelding) (gevaar)
3	Analyser, nefelo meter, troebelingstest	MI	0 cm: nee	
4	Analyser, urine-	MI	0 cm: nee	
5	Analyser, multi-	MI	0 cm: ja	GSM-simulator bij apparaat: onterechte foutmelding (meting wordt niet beïnvloed) GSM-telefoon: geen invloed
6	Analyser, bloedgassen	MI	40 cm: ja	Op 40 cm afstand: GSM-simulator: alleen tijdens calibratie invloed Op 20 cm afstand: GSM-telefoon: alleen tijdens calibratie invloed Op 0 cm afstand: GSM-simulator èn GSM-telefoon: geen invloed
7	Analyser, PH/bloedgassen	MI	300 cm: ja	Op 300 cm: GSM-telefoon èn GSM-simulator: onbruikbare metingen; displays verstoord
8	Analyser, hematologische cel analyser	MI	100 cm: ja	Op 100 cm voor apparaat: GSM-telefoon: uitlezing barcodelezer fout, apparaat stopt met correcte foutmelding; GSM-simulator: zelfde als bij GSM-telefoon
9	Analyser, fotome-trische che-mieanalyser	MI	0 cm: nee	
10	Analyser, chemie	MI	40 cm: ja	Op 40 cm: GSM-telefoon: bibberend beeld; Op 15 cm: GSM-simulator: zelfde als bij GSM-telefoon

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
11	Analyser, chemie	MI	0 cm: nee	
12	Analyser, fotometrie dmv vlam	MI	0 cm: nee	
13	Analyser, bloedgassen	MI	0 cm: nee	
14	Analyser, HPLC	MI	0 cm: nee	
15	Analyser, hema-tologische cel analyser	MI	0 cm: nee	
16	Analyser, bloed-cellen	MI	10 cm: ja	Op 10 cm: GSM-telefoon èn GSM-simulator: bibberend beeld
17	Analyser, osmometer	MI	300 cm: ja	Op ca. 300 cm afstand: GSM-simulator èn GSM-telefoon: verkeerde waarde (zonder foutmelding) (gevaar)
18	Anesthesie apparaat	MI	0 cm: ja	GSM-simulator bij apparaat: beademing stopt zonder akoestisch alarm gevaar GSM-telefoon bij apparaat: geen invloed
19	Anesthesie apparaat	MI	0 cm: ja	Bij apparaat: GSM-simulator: O_2-indicator verstoord
20	Anesthesie apparaat	MI	0 cm: ja	GSM-telefoon èn GSM-simulator bij apparaat: apparaat meldt onterecht een technische storing (nr 527). Herstart noodzakelijk
21	Anesthesie apparaat	MI	0 cm: ja	Bij apparaat: GSM-simulator: onterechte foutmelding ("verkeerde druk in supply en in patiënt")
22	Anesthesie apparaat	MI	0 cm: nee	
23	Audiometer	MI	0 cm: nee	
24	Ballonpomp	MI	0 cm: nee	
25	Beademings apparaat	MI	0 cm: nee	

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
26	Beademings apparaat	MI	0 cm: nee	
27	Beademings apparaat	MI	0 cm: nee	
28	Beademings apparaat	MI	0 cm: nee	
29	Beademings apparaat	MI	0 cm: nee	
30	Beademings apparaat	MI	0 cm: nee	
31	Beademings apparaat	MI	0 cm: nee	
32	Beademings apparaat	MI	0 cm: ja	GSM-simulator èn GSM-telefoon bij apparaat: invloed op display-uitlezing; verder geen invloed
33	Beademings apparaat	MI	25 cm: ja	Op 25 cm: GSM-simulator: aantal slagen en slagvolume neemt abrupt toe (gevaar) Op 10 cm: GSM-telefoon: zelfde als bij GSM-simulator (gevaar)
34	Beademings apparaat	MI	10 cm: ja	Op 10 cm: GSM-simulator: aantal slagen en slagvolume neemt abrupt toe (gevaar); akoestisch alarm komt alleen als het goed is ingesteld (gevaar)
35	Beademings apparaat	MI	0 cm: ja	GSM-telefoon èn GSM-simulator: onderdruk-triggering valt weg in de stand SIMV (semi-ondersteunde ademhaling);apparaat stopt en gaat even later in alarm (gevaar !)
36	Beademings apparaat	MI	0 cm: nee	
37	Beademings apparaat met **open deksel** (zo gebruikt)	MI	0 cm: ja	GSM-simulator: stopt; na 2 sec alarm, mits alarm door gebruiker is ingesteld; geen mechanisch alarm (gevaar)

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
38	Beademings apparaat	MI	10 cm: ja	Op 10 cm: GSM-simulator: apparaat stopt meestal; akoestisch alarm komt alleen als het goed is ingesteld (gevaar); soms neemt slagvolume toe of af (gevaar)
39	Bewakingspost met patiëntmonitoren	MI	0 cm: nee	
40	Bloeddrukmeter	MI	0 cm: ja	Bij apparaat: GSM-simulator: 200 Hz hoorbaar
41	Bloeddrukmeter	MI	0 cm: nee	
42	Bloeddrukmeter	MI	0 cm: nee	
43	Bloeddrukmeter	MI	0 cm: nee	
44	Bloeddrukmeter	MI	0 cm: nee	
45	Bloeddrukmeter	MI	0 cm: nee	
46	Bloeddrukmeter	MI	0 cm: nee	
47	Bloedverwarmer	MI	0 cm: ja	Bij apparaat: GSM-simulator: display verstoord
48	Bloedverwarmer op ok	MI	25 cm: ja	Op 25 cm van apparaat: GSM-simulator: regeling wordt verstoord; schakelt soms uit zonder alarm Op 0 cm van apparaat: GSM-telefoon: zelfde als bij GSM-simulator
49	Bloedverwarmer op ok	MI	50 cm: ja	Op 50 cm van apparaat: GSM-simulator: regeling wordt verstoord; schakelt soms uit zonder alarm Op 10 cm van apparaat: GSM-telefoon: zelfde als bij GSM-simulator
50	Brandmelder	N	0 cm: nee	
51	Brandmelder	N	0 cm: nee	
52	Cardio Tocograaf (CTG)	MI	5 cm: ja	Op 5 cm van voorkant en van bedieningspaneel: GSM-telefoon: 200 Hz hoorbaar (modulatiefreq. GSM); GSM-simulator: zelfde als bij GSM-telefoon
53	Couveuse	MI	0 cm: nee	

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
54	Couveuse, open	MI	0 cm: nee	
55	Couveuse	MI	0 cm: nee	
56	Couveuse	MI	0 cm: nee	
57	Couveuse	MI	0 cm: nee	
58	Couveuse	MI	0 cm: nee	
59	Couveuse	MI	0 cm: nee	
60	Couveuse, transport	MI	0 cm: nee	
61	Couveuse	MI	0 cm: nee	
62	Couveuse	MI	0 cm: ja	Bij voorkant: GSM-telefoon: indicatiemeter van "heater" wordt beïnvloed, maar temperatuurregeling niet; GSM-simulator: zelfde als bij GSM-telefoon
63	CT-scanner (bedieningspaneel met monitor achter scherm)	MI	5 cm: ja	Op 5 cm van onderzijde monitor: GSM-telefoon: bibberend beeld. Op 5 cm: GSM-simulator èn GSM-telefoon: 200 Hz hoorbaar op intercom (modulatiefrequentie GSM)
64	Defibrillator tester	MI	0 cm: nee	
65	Defibrillator	MI	0 cm: ja	Bij GSM-simulator èn GSM-telefoon: ECG-signaal wordt verstoord en - als stoorbron ònder apparaat wordt gehouden - on derdrukt; geen SYNChronisatie-fouten
66	Defibrillator	MI	20 cm: ja	Op ca. 20 cm van apparaat: GSM-simulator: bewegende antenne stoort synchronisatie Op 10 cm van apparaat: GSM-telefoon: zelfde als bij GSM-simulator
67	Defibrillator	MI	10 cm: ja	Op 10 cm: GSM-telefoon: tellers en curves verstoord; Bij voorkant: GSM-simulator: synchronisatie van defibrillatie verstoord

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
68	Defibrillator	MI	100 cm: ja	Op ca. 100 cm van apparaat: GSM-simulator: bewegende antenne stoort synchronisatie Op 10 cm van apparaat: GSM-telefoon: zelfde als bij GSM-simulator
69	Dialyse apparaat zonder slangen	MI	0 cm: nee	
70	Dialyse apparaat met slangen	MI	0 cm: ja	GSM-telefoon èn GSM-simulator: luchtbeldetector geeft onterecht alarm
71	Dialyse apparaat zonder slangen	MI	10 cm: ja	Op ca. 10 cm van voorkant: GSM-telefoon èn GSM-simulator: apparaat stopt; geeft alarm; kan weer gestart worden
72	Dialyse apparaat	MI	0 cm: nee	
73	Dialyse apparaat	MI	10 cm: ja	Op 10 cm: GSM-simulator: Arteriële bloedpomp stopt; akoestisch alarm gaat af; display verstoord
74	Doptone: akoestisch "opzoeken" van ader	MI	400 cm: ja	Op ca. 400 cm van apparaat: GSM-telefoon èn GSM-simulator: 200 Hz hoorbaar (modulatiefreq. GSM)
75	Drukmonitor, hersenvat	MI	0 cm: nee	
76	ECG apparaat	MI	5 cm: ja	Op 5 cm van apparaat: GSM-simulator: apparaat stopt
77	ECG apparaat	MI	10 cm: ja	Op 10 cm van apparaat: GSM-simulator: pennen verstoord
78	ECG apparaat	MI	0 cm: ja	GSM-simulator: zeer lichte ruis op ECG-signaal
79	ECG apparaat	MI	0 cm: nee	
80	ECG apparaat	MI	0 cm: nee	
81	Echocardiograaf: UG apparaat (met videorecorder)	MI	40 cm: ja	Op 40 cm: GSM-telefoon: pieptoon (hoger dan 200 Hz) in het UG apparaat bij puls-doppler mode; Op 5 cm: GSM-telefoon: op monitor UG: ECG signaal gestoord en horizontale lijn op monitor

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
82	Echocardio-graaf/UG appa-raat (met video-recorder)	MI	80 cm: ja	Op 50 cm: GSM-simulator: 200 Hz hoorbaar (modulatiefreq. GSM); Op 80 cm: GSM-telefoon: zelfde als bij GSM-simulator
83	EEG apparaat	MI	5 cm: ja	Op 5 cm van de "headbox": GSM-simulator: sterke beïnvloeding basislijn op scherm; Bij kastje voor "flitslichtsturing": GSM-simu-lator: onderdrukking flitslicht
84	EEG apparaat	MI	10 cm: ja	Op 10 cm van apparaat: GSM-simulator: geringe ruis op signaal
85	EEG apparaat	MI	5 cm: ja	Op 5 cm van leidingen naar patiënt en op 5 cm naast apparaat: GSM-simulator èn GSM-telefoon: invloed op signaal ("bewegingsartefacten"); geen gevaar
86	Elektrochirurgie	MI	0 cm: nee	
87	Elektrochirurgie	MI	0 cm: nee	
88	Elektrochirurgie	MI	0 cm: nee	
89	Elektrochirurgie	MI	0 cm: nee	
90	EMG apparaat (ringelektrode)	MI	200 cm: ja	Op ca. 200 cm van apparaat: GSM-simulator: geen beoordeling van spierstimulatiemeting mogelijk; 200 Hz hoorbaar uit luidspreker
91	EMG apparaat	MI	40 cm: ja	Op 40 cm van EMG-naald: GSM-telefoon: geringe storing op signaal; geen gevaar; Op 30 cm van leiding naar patiënt: idem
92	ENG apparaat	MI	0 cm: nee	
93	Ergometer	MI	0 cm: nee	
94	EVP - Optische stimulator	MI	5 cm: ja	Op 5 cm van apparaat: GSM-simulator: lichtbalk toont verkeerde lampjes; scherm van PC bibbert
95	Externe pacemaker	MI	0 cm: nee	

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
96	Externe pacemaker	MI	25 cm: ja	Op 25 cm van kabel en app.: GSM-telefoon: 'sense'-ingang wordt geactiveerd, waardoor geen stimulatie meer wordt gegeven(gevaar). Op 20 cm: GSM-simulator: zelfde als bij GSM-telefoon
97	Externe pacemaker	MI	0 cm: nee	
98	Externe pacemaker	MI	0 cm: nee	
99	Externe pacemaker	MI	100 cm: ja	Op ca. 100 cm: GSM-simulator: gaat pacen omdat hij storing detecteert
100	Externe pacemaker	MI	0 cm: nee	
101	Hart-long machine	MI	0 cm: nee	
102	Hoortoestel (in-het-oor; geen spoel)	MU	10 cm: ja	Op 10 cm: GSM-telefoon en GSM-simulator: 200 Hz hoorbaar (modulatiefreq. GSM) (straalt direkt in op elektronica)
103	Hoortoestel (achter-het-oor)	MU	75 cm: ja	Op 75 cm: GSM-telefoon: 200 Hz hoorbaar (modulatiefreq. GSM). Op 50 cm: GSM-simulator: zelfde als bij GSM-telefoon
104	Hoortoestel (achter-het-oor; geen spoel)	MU	50 cm: ja	Op 50 cm: GSM-telefoon en GSM-simulator: 200 Hz hoorbaar (modulatiefreq. GSM) (straalt direkt in op elektronica)
105	Hoortoestel (achter-het-oor)	MU	75 cm: ja	Op 75 cm: GSM-telefoon: 200 Hz hoorbaar (modulatiefreq. GSM). Op 25 cm: GSM-simulator: zelfde als bij GSM-telefoon. Met uitgeschakelde ontvangstspoel: idem, maar lager niveau
106	Hoortoestel (in-het-oor; geen spoel)	MU	10 cm: ja	Op 10 cm: GSM-telefoon en GSM-simulator: 200 Hz hoorbaar (modulatiefreq. GSM) (straalt direkt in op elektronica)
107	Infuuspomp	MI	0 cm: nee	
108	Infuuspomp	MI	0 cm: nee	

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
109	Infuuspomp	MI	0 cm: nee	
110	Infuuspomp	MI	0 cm: nee	
111	Infuuspomp	MI	0 cm: nee	
112	Infuuspomp	MI	0 cm: nee	
113	Infuuspomp	MI	0 cm: nee	
114	Infuuspomp, luchtbeldetector van een -	MI	0 cm: nee	
115	Infuuspomp	MI	10 cm: ja	Op 10 cm van rechter zijkant **of voorkant** van de pomp: GSM-telefoon: onterechte foutcode (druppelsensor-fout: bijv. lege fles); pomp stopt en geeft akoestisch alarm; Bij druppelsensor: geen reactie; Op 10 cm van rechter zijkant of voorkant pomp of van druppelsensor: GSM-simulator: zelfde als bij GSM-telefoon
116	Infuuspomp	MI	5 cm: ja	Op 5 cm van de rechter zijkant van de pomp: GSM-telefoon: onterechte foutcode (druppelsensor-fout: bijv. lege fles); pomp stopt en geeft akoestisch alarm. Bij druppelsensor: geen reactie; Bij rechter zijkant van pomp **of bij druppelsensor**: GSM-simulator: zelfde als bij GSM-telefoon
117	Infuuspomp	MI	25 cm: ja	Op 25 cm van apparaat: GSM-simulator èn GSM-telefoon: onterecht alarm (code A40); pomp blijft goed werken
118	Infuuspomp	MI	10 cm: ja	Op 10 cm van apparaat: GSM-simulator èn GSM-telefoon: onterecht alarm (code A40); pomp blijft goed werken
119	Infuuspomp	MI	5 cm: ja	Op 5 cm van achterk. pomp: GSM-telefoon: pomp stopt en geeft akoestisch alarm; GSM-simulator: zelfde als bij GSM-telefoon

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
120	Infuuspomp	MI	0 cm: ja	Bij druppelsensor: GSM-telefoon: onterechte foutcode (onvoldoende inloop); pomp stopt en geeft akoestisch alarm; GSM-simulator: zelfde als bij GSM-telefoon
121	Infuuspomp	MI	5 cm: ja	Op 5 cm van rechter zijkant: GSM-telefoon: onterechte foutcode (intern mankement); pomp stopt en geeft akoestisch alarm; Bij druppelsensor: GSM-telefoon: onterechte foutcode (onvoldoende inloop); pomp stopt en geeft akoestisch alarm; GSM-simulator: zelfde als bij GSM-telefoon
122	Infuuspomp	MI	0 cm: ja	GSM-telefoon bij apparaat: pomp stopt en geeft akoestisch en visueel alarm; onterechte foutmelding (tegendruk) GSM-simulator bij apparaat: pomp stopt en geeft akoestisch en visueel alarm
123	Infuuspomp, luchtbeldetector van een -	MI	0 cm: nee	Detector werkt correct
124	Luchtbevochtiger bij beademings apparaat	MI	0 cm: nee	
125	Luchtbevochtiger bij beademings apparaat	MI	0 cm: nee	
126	O_2-Concentra-tiemeter	MI	0 cm: nee	

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
127	O_2-Concentratiemeter in couveuse	MI	200 cm: ja	Op ca. 200 cm: GSM-telefoon èn GSM-simulator: aanwijzing O_2-concentratie stijgt van 20% naar 21% (en op ca. 1 m naar 22 à 23 %) ; Op ca. 5 cm: GSM-telefoon èn GSM-simulator: aanwijzing O_2-concentratie verdwijnt; Daarna geen akoestisch alarm meer bij overschrijden van alarmgrenzen (gevaar !); nog wel optisch alarm (knipperlampje); Bij apparaat (0 cm afstand): GSM-telefoon: apparaat kan soms worden uitgeschakeld zonder permanent alarm (gevaar !)
128	Pager personenbeveiliging (met molesttouwtje)	N	0 cm: ja	GSM-telefoon diagonaal op pager: binnenkomende boodschappen geblokkeerd (ontvanggedeelte) (gevaar!); zendgedeelte: geen invloed
129	Pager oproepsysteem (telefonische oproep met alfanumeriek display)	N	30 cm: ja	Op 30 cm: GSM-telefoon: binnenkomende boodschappen geblokkeerd (ontvanggedeelte) (gevaar!); zendgedeelte: geen invloed
130	Pager oproepsysteem (oud; - telefonische oproep)	N	0 cm: nee	
131	Pager oproepsysteem (alleen telefonische oproep)	N	0 cm: nee	
132	Patiëntbel op bed en knop op doos aan wandgoot	MI	0 cm: nee	
133	Patiëntmonitor (ECG/CVD/SAT/NIBP)	MI	20 cm: ja	Op 20 cm van apparaat: GSM-simulator en GSM-telefoon: ruis op ECG-signaal op scherm en papierstrook; beeld bibbert

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
134	Patiëntmonitor, interface naar beademings apparaat	MI	0 cm: nee	
135	Patiëntmonitor (ECG/SpO_2/ bloeddruk)	MI	0 cm: nee	
136	Patiëntmonitor (CO_2/NIBP)	MI	0 cm: ja	Bij apparaat: GSM-simulator: bewegende antenne veroorzaakt onterechte foutmelding ("NIBP artefact")
137	Patiëntmonitor (SaO_2)	MI	0 cm: nee	
138	Patiëntmonitor (ECG/SpO_2)	MI	50 cm: ja	Op ca. 50 cm: GSM-simulator: BPM telling op scherm wordt nul ("0") en BPM pieptoon valt weg; geen alarmmelding; geen gevaar; Op ca. 5 cm: GSM-telefoon: zelfde als bij GSM-simulator
139	Patiëntmonitor (ECG/SpO_2/ bloeddruk)	MI	5 cm: ja	Op 5 cm: GSM-telefoon: ECG signaal sterk vervormd, waardoor BPM aanwijzing naar 200 stijgt en apparaat in alarm gaat; GSM-simulator: zelfde als bij GSM-telefoon
140	Patiëntmonitor (ECG)	MI	0 cm: ja	Bij apparaat: GSM-simulator: ruis op signaal op scherm en papierstrook
141	Patiëntmonitor (ECG/ademha-ling/bloeddruk)	MI	50 cm: ja	Op 50 cm: GSM-simulator: stoorpiekjes op ademhalingscurve als stoor-bron wordt bewogen; Op 20 cm: GSM-telefoon: zelfde als bij GSM-simulator
142	Patiëntmonitor (ECG/ademha-ling/bloeddruk)	MI	0 cm: nee	
143	Patiëntmonitor	MI	5 cm: ja	Op 5 cm afstand: GSM-telefoon èn GSM-simulator: wegvallen beeld (helderheid naar nul)

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
144	Patiëntmonitor, draagbaar	MI	10 cm: ja	Op 10 cm: GSM-telefoon èn GSM-simulator: sterke ruis op signaal op scherm; nullijn verschuift; QRS-signaal blijft goed
145	Patiëntmonitor (ECG/bloeddruk)	MI	0 cm: ja	Bij linker zijkant: GSM-telefoon: bibberend beeld; Bij ingangsconnektor: GSM-telefoon: ruis op ECG signaal op scherm, maar geen verstoring van metingen en geen alarm; Op zelfde locaties: GSM-simulator: zelfde als bij GSM-telefoon, maar ruis op ECG signaal is kleiner
146	Patiëntmonitor ECG/RESP/SpO_2/ PLETH/Druk + Temp	MI	0 cm: nee (beveiliging tegen storing wordt inge-schakeld)	GSM-simulator bij apparaat: apparaat schakelt automatisch een storingsonderdrukkingsfilter in. GSM-telefoon: geen invloed
147	Patiëntmonitor (ECG/SpO_2/ bloeddruk)	MI	0 cm: ja	GSM-telefoon: zeer sterke ruis op signaal; GSM-simulator: sterke ruis op signaal
148	Patiëntmonitor	MI	0 cm: ja	Bij apparaat: GSM-simulator: ruis ("gras") op ECG signaal op scherm
149	Patiëntmonitor (ECG / SaO_2)	MI	10 cm: ja	Op 10 cm van voor- of rechter zijkant: GSM-simulator: verticale lijn over beeld; Bij linker zijkant en bij gele alarmknop: wegvallen beeld (helderheid naar nul); Op 10 cm van achterkant: toestel 'reset', maar start wel weer goed op
150	Patiëntmonitor	MI	0 cm: nee	
151	Patiëntmonitor (CO_2,SpO_2, $ETCO_2$)	MI	0 cm: ja	Bij sensor SpO_2: GSM-simulator: alarm
152	Patiëntmonitor (respiratie)	MI	0 cm: nee	
153	Patiëntmonitor (ECG/SpO_2/ bloeddruk)	MI	0 cm: nee	

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
154	Patiëntmonitor (ECG/SpO_2/ bloeddruk)	MI	10 cm: ja	Op 10 cm: GSM-simulator: sterke ruis op signalen op scherm; QRS/HR-signaal blijft goed Op 0 cm: GSM-telefoon: ruis op drukcurve op scherm; QRS/HR-signaal blijft goed
155	Pulsoximeter	MI	0 cm: nee	
156	Pulsoximeter	MI	0 cm: nee	
157	Pulsoximeter	MI	0 cm: nee	
158	Pulsoximeter	MI	0 cm: ja	Bij apparaat: GSM-simulator: systeem verstoord; herstelt zichzelf
159	Röntgenapparaat (koppeling naar ontwikkelaar)	MI	0 cm: nee	
160	Röntgenapparaat (bedieningspaneel met monitor achter scherm)	MI	5 cm: ja	Op 5 cm: GSM-telefoon èn GSM-simulator: lijnen op beeld monitor; niet storend
161	Röntgenapparaat (beeldversterker bij patiëntenbed)	MI	15 cm: ja	Op 15 cm: GSM-telefoon: relais in voedingskast schakelen spontaan (geen gevolg waarneembaar); Op 5 cm: GSM-simulator: zelfde als bij GSM-telefoon
162	Röntgenapparaat (monitor bij patiëntenbed)	MI	50 cm: ja	Op 50 cm van kabels: GSM-telefoon: lijnen op beeld; niet storend; Op 20 cm van kabels: GSM-simulator: zelfde als bij GSM-telefoon
163	Röntgenapparaat	MI	0 cm: nee	
164	Spuitpomp	MI	5 cm: ja	Op 5 cm van bovenkant: GSM-simulator: pomp stopt en geeft akoestisch alarm; Bij andere zijden: GSM-simulator: onterecht occlusie alarm
165	Spuitpomp	MI	0 cm: ja	GSM-telefoon èn GSM-simulator: onterecht occlusie alarm; pomp stopt en geeft akoestisch alarm
166	Spuitpomp	MI	0 cm: nee	

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
167	Spuitpomp	MI	0 cm: nee	
168	Spuitpomp	MI	0 cm: nee	
169	Spuitpomp	MI	0 cm: nee	
170	Spuitpomp	MI	0 cm: nee	
171	Spuitpomp	MI	0 cm: nee	
172	Spuitpomp	MI	0 cm: nee	
173	Spuitpomp	MI	0 cm: nee	
174	Spuitpomp	MI	0 cm: nee	
175	Spuitpomp	MI	5 cm: ja	Op 5 cm van apparaat: GSM-simulator: pomp stopt met alarm; geheugen met instellingen gewist (gevaar)
176	Spuitpomp	MI	0 cm: nee	
177	Spuitpomp	MI	10 cm: ja	Op ca. 10 cm: GSM-simulator: pomp stopt met alarm
178	Spuitpomp	MI	10 cm: ja	Op 10 cm van apparaat: GSM-simulator èn GSM-telefoon: onterecht occlusie alarm; pomp blijft goed werken
179	Spuitpomp	MI	10 cm: ja	Op 10 cm van apparaat: GSM-simulator èn GSM-telefoon: onterecht occlusie alarm; pomp blijft goed werken
180	Spuitpomp	MI	0 cm: ja	Op 0 cm: GSM-simulator pomp stopt en geeft akoestisch alarm
181	Spuitpomp	MI	0 cm: ja	Op ca. 0 cm: GSM-telefoon èn GSM-simulator: pomp stopt en geeft akoestisch alarm
182	Spuitpomp, bewakingsfunctie van een -	MI	0 cm: nee	Bewakingsfunctie werkt correct
183	Spuitpomp	MI	0 cm: nee	
184	Spuitpomp	MI	0 cm: nee	

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
185	Spuitpomp	MI	0 cm: ja	Bij apparaat: GSM-simulator: onterechte foutmelding (occlusie-alarm); pomp stopt
186	Spuitpomp	MI	0 cm: ja	Bij apparaat: GSM-simulator: onterechte foutmelding (occlusie-alarm); pomp stopt
187	Spuitpomp	MI	0 cm: ja	Bij bovenkant: GSM-simulator: onterecht occlusie alarm
188	Spuitpomp	MI	10 cm: ja	GSM-simulator: onterechte foutmelding ("volumegrens bereikt"), pomp stopt en geeft akoestisch alarm; GSM-telefoon: zelfde als bij GSM-simulator. Net of accu: maakt geen verschil
189	Spuitpomp	MI	5 cm: ja	Op 5 cm: GSM-telefoon: onterechte foutmelding ("volumegrens bereikt"), pomp stopt en geeft akoestisch alarm; Op 0 cm: GSM-simulator: zelfde als bij GSM-telefoon
190	Sterilisator	MI	0 cm: ja	GSM-telefoon: groene stift van schrijver werd enigszins beïnvloed
191	Stoelweegschaal dialysepatiënten	MI	0 cm: nee	
192	Telemetrie ontvangantenne	MI	20 cm: nee	Antenne aan plafond: niet nodig om dichter bij te gaan
193	Telemetrie ontvangantenne	MI	0 cm: nee	
194	Telemetrie transmitter (ECG)	MI	10 cm: ja	Op 10 cm: GSM-simulator: invloed op basislijn; GSM-telefoon: geen invloed
195	Telemetrie ontvanger (kastje)	MI	0 cm: nee	
196	Telemetrie monitor	MI	0 cm: nee	
197	Telemetrie transmitter	MI	0 cm: ja	Bij kastje: GSM-telefoon en GSM-simulator: ruis op signaal op scherm en papierstrook

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
198	Telemetrie transmitter (ECG)	MI	0 cm: nee	
199	Toegangscontrolesysteem: sluisbediening	N	100 cm: nee	Op 100 cm geen invloed; uit voorzorg niet dichter bij gegaan: de omkasting van de elektronica was er af ivm. onderhoud
200	Toegangscontrolesysteem: deur (kaartlezer)	N	0 cm: nee	
201	Verwarmingsmatras op ok	MI	0 cm: ja	Bij apparaat: GSM-simulator: display wordt beïnvloed
202	Voedingspomp	MI	25 cm: ja	Op 25 cm van apparaat: GSM-simulator: het opraken van de vloeistof wordt niet gedetecteerd; na de test wel Op 10 cm van apparaat: GSM-telefoon: zelfde als bij GSM-simulator
203	Voedingspomp	MI	25 cm: ja	Op 25 cm van apparaat: GSM-simulator: het opraken van de vloeistof wordt niet gedetecteerd; na de test wel Op 10 cm van apparaat: GSM-telefoon: zelfde als bij GSM-simulator
204	Wasmachine okmateriaal	MI	0 cm: nee	
205	Watermatras op ok	MI	10 cm: ja	Op 10 cm van apparaat: GSM-telefoon èn GSM-simulator: regeling wordt verstoord; geen alarm; gevaar mogelijk

BIJLAGE 2: APPARATEN gesorteerd op: afstand (ja/nee) en daarna op: alfabet [3]

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)
1	Analyser HPLC, Electrochemische detector bij -	1 MI	500 cm: ja
74	Doptone: akoestisch "opzoeken" van ader	2 MI	400 cm: ja
7	Analyser, PH/bloedgassen	3 MI	300 cm: ja
17	Analyser, osmometer	4 MI	300 cm: ja (g)
90	EMG apparaat (ringelektrode)	5 MI	200 cm: ja
127	O_2-Concentratiemeter (zie ook: 5 cm: gevaar)	6 MI	200 cm: ja
8	Analyser, hematologische cel analyser	7 MI	100 cm: ja
68	Defibrillator	8 MI	100 cm: ja
99	Externe pacemaker	9 MI	100 cm: ja
82	Echocardiograaf/UG apparaat (met video-recorder)	10 MI	80 cm: ja
103	Hoortoestel (achter-het-oor)	11 MU	75 cm: ja
105	Hoortoestel (achter-het-oor)	12 MU	75 cm: ja
2	Analyser, eiwit scanner	13 MI	50 cm: ja (g)
49	Bloedverwarmer op ok	14 MI	50 cm: ja
104	Hoortoestel (achter-het-oor; geen spoel)	15 MU	50 cm: ja
138	Patiëntmonitor (ECG/SpO_2)	16 MI	50 cm: ja
141	Patiëntmonitor (ECG/ademhaling/bloeddruk)	17 MI	50 cm: ja
162	Röntgenapparaat (monitor bij patiëntenbed)	18 MI	50 cm: ja
6	Analyser, bloedgassen	19 MI	40 cm: ja
10	Analyser, chemie	20 MI	40 cm: ja
81	Echocardiograaf:UG apparaat (met videorecorder)	21 MI	40 cm: ja
91	EMG apparaat	22 MI	40 cm: ja
129	Pager oproepsysteem (telefonische oproep met alfanumeriek display)	23 N	30 cm: ja (g)

[3] Een "g" in de laatste kolom betekent: Voor patient of gebruiker gevaarlijke reactie (direkt of indirekt).

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)
33	Beademings apparaat	24 MI	25 cm: ja (g)
48	Bloedverwarmer op ok	25 MI	25 cm: ja
96	Externe pacemaker	26 MI	25 cm: ja (g)
117	Infuuspomp	27 MI	25 cm: ja
202	Voedingspomp	28 MI	25 cm: ja
203	Voedingspomp	29 MI	25 cm: ja
66	Defibrillator	30 MI	20 cm: ja
133	Patiëntmonitor (ECG/CVD/SAT/NIBP)	31 MI	20 cm: ja
161	Röntgenapparaat (beeldversterker bij patiëntenbed)	32 MI	15 cm: ja
16	Analyser, bloedcellen	33 MI	10 cm: ja
34	Beademings apparaat	34 MI	10 cm: ja (g)
38	Beademings apparaat	35 MI	10 cm: ja (g)
67	Defibrillator	36 MI	10 cm: ja
71	Dialyse apparaat zonder slangen	37 MI	10 cm: ja
73	Dialyse apparaat	38 MI	10 cm: ja
77	ECG apparaat	39 MI	10 cm: ja
84	EEG apparaat	40 MI	10 cm: ja
102	Hoortoestel (in-het-oor; geen spoel)	41 MU	10 cm: ja
106	Hoortoestel (in-het-oor; geen spoel)	42 MU	10 cm: ja
115	Infuuspomp	43 MI	10 cm: ja
118	Infuuspomp	44 MI	10 cm: ja
144	Patiëntmonitor, draagbaar	45 MI	10 cm: ja
149	Patiëntmonitor (ECG / SaO_2)	46 MI	10 cm: ja
154	Patiëntmonitor (ECG/SpO_2/bloeddruk)	47 MI	10 cm: ja
177	Spuitpomp	48 MI	10 cm: ja
178	Spuitpomp	49 MI	10 cm: ja
179	Spuitpomp	50 MI	10 cm: ja

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)
188	Spuitpomp	51 MI	10 cm: ja
194	Telemetrie transmitter (ECG)	52 MI	10 cm: ja
205	Watermatras op ok	53 MI	10 cm: ja (g)
52	Cardio Tocograaf (CTG)	54 MI	5 cm: ja
63	CT-scanner (bedieningspaneel met monitor achter scherm)	55 MI	5 cm: ja
76	ECG apparaat	56 MI	5 cm: ja
83	EEG apparaat	57 MI	5 cm: ja
85	EEG apparaat	58 MI	5 cm: ja
94	EVP - Optische stimulator	59 MI	5 cm: ja
116	Infuuspomp	60 MI	5 cm: ja
119	Infuuspomp	61 MI	5 cm: ja
121	Infuuspomp	62 MI	5 cm: ja
127	O_2-Concentratiemeter (zie ook: 200 cm)	63 MI	5 cm: ja (g)
139	Patiëntmonitor (ECG/SpO_2/bloeddruk)	64 MI	5 cm: ja
143	Patiëntmonitor	65 MI	5 cm: ja
160	Röntgenapparaat (bedieningspaneel met monitor achter scherm)	66 MI	5 cm: ja
164	Spuitpomp	67 MI	5 cm: ja
175	Spuitpomp	68 MI	5 cm: ja (g)
189	Spuitpomp	69 MI	5 cm: ja
5	Analyser, multi-	70 MI	0 cm: ja
18	Anesthesie apparaat	71 MI	0 cm: ja (g)
19	Anesthesie apparaat	72 MI	0 cm: ja
20	Anesthesie apparaat	73 MI	0 cm: ja
21	Anesthesie apparaat	74 MI	0 cm: ja
32	Beademings apparaat	75 MI	0 cm: ja
35	Beademings apparaat	76 MI	0 cm: ja (g)

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)
37	Beademings apparaat met **open deksel** (zo gebruikt)	77 MI	0 cm: ja (g)
40	Bloeddrukmeter	78 MI	0 cm: ja
47	Bloedverwarmer	79 MI	0 cm: ja
62	Couveuse	80 MI	0 cm: ja
65	Defibrillator	81 MI	0 cm: ja
70	Dialyse apparaat met slangen	82 MI	0 cm: ja
78	ECG apparaat	83 MI	0 cm: ja
120	Infuuspomp	84 MI	0 cm: ja
122	Infuuspomp	85 MI	0 cm: ja
128	Pager personenbeveiliging (met molesttouwtje)	86 N	0 cm: ja (g)
136	Patiëntmonitor (CO_2/NIBP)	87 MI	0 cm: ja
140	Patiëntmonitor (ECG)	88 MI	0 cm: ja
145	Patiëntmonitor (ECG/bloeddruk)	89 MI	0 cm: ja
147	Patiëntmonitor (ECG/SpO_2/bloeddruk)	90 MI	0 cm: ja
148	Patiëntmonitor	91 MI	0 cm: ja
151	Patiëntmonitor (CO_2,SpO_2,$ETCO_2$)	92 MI	0 cm: ja
158	Pulsoximeter	93 MI	0 cm: ja
165	Spuitpomp	94 MI	0 cm: ja
180	Spuitpomp	95 MI	0 cm: ja
181	Spuitpomp	96 MI	0 cm: ja
185	Spuitpomp	97 MI	0 cm: ja
186	Spuitpomp	98 MI	0 cm: ja
187	Spuitpomp	99 MI	0 cm: ja
190	Sterilisator	100 MI	0 cm: ja
197	Telemetrie transmitter	101 MI	0 cm: ja
201	Verwarmingsmatras op ok	102 MI	0 cm: ja
3	Analyser, nefelo meter, troebelingstest	103 MI	0 cm: nee

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)
4	Analyser, urine-	104 MI	0 cm: nee
9	Analyser, fotometrische chemieanalyser	105 MI	0 cm: nee
11	Analyser, chemie	106 MI	0 cm: nee
12	Analyser, fotometrie dmv. vlam	107 MI	0 cm: nee
13	Analyser, bloedgassen	108 MI	0 cm: nee
14	Analyser, HPLC	109 MI	0 cm: nee
15	Analyser, hematologische cel analyser	110 MI	0 cm: nee
22	Anesthesie apparaat	111 MI	0 cm: nee
23	Audiometer	112 MI	0 cm: nee
24	Ballonpomp	113 MI	0 cm: nee
25	Beademings apparaat	114 MI	0 cm: nee
26	Beademings apparaat	115 MI	0 cm: nee
27	Beademings apparaat	116 MI	0 cm: nee
28	Beademings apparaat	117 MI	0 cm: nee
29	Beademings apparaat	118 MI	0 cm: nee
30	Beademings apparaat	119 MI	0 cm: nee
31	Beademings apparaat	120 MI	0 cm: nee
36	Beademings apparaat	121 MI	0 cm: nee
39	Bewakingspost met patiëntmonitoren	122 MI	0 cm: nee
41	Bloeddrukmeter	123 MI	0 cm: nee
42	Bloeddrukmeter	124 MI	0 cm: nee
43	Bloeddrukmeter	125 MI	0 cm: nee
44	Bloeddrukmeter	126 MI	0 cm: nee
45	Bloeddrukmeter	127 MI	0 cm: nee
46	Bloeddrukmeter	128 MI	0 cm: nee
50	Brandmelder	129 N	0 cm: nee
51	Brandmelder	130 N	0 cm: nee
53	Couveuse	131 MI	0 cm: nee

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)
54	Couveuse, open	132 MI	0 cm: nee
55	Couveuse	133 MI	0 cm: nee
56	Couveuse	134 MI	0 cm: nee
57	Couveuse	135 MI	0 cm: nee
58	Couveuse	136 MI	0 cm: nee
59	Couveuse	137 MI	0 cm: nee
60	Couveuse, transport	138 MI	0 cm: nee
61	Couveuse	139 MI	0 cm: nee
64	Defibrillator tester	140 MI	0 cm: nee
69	Dialyse apparaat zonder slangen	141 MI	0 cm: nee
72	Dialyse apparaat	142 MI	0 cm: nee
75	Drukmonitor, hersenvat	143 MI	0 cm: nee
79	ECG apparaat	144 MI	0 cm: nee
80	ECG apparaat	145 MI	0 cm: nee
86	Elektrochirurgie	146 MI	0 cm: nee
87	Elektrochirurgie	147 MI	0 cm: nee
88	Elektrochirurgie	148 MI	0 cm: nee
89	Elektrochirurgie	149 MI	0 cm: nee
92	ENG apparaat	150 MI	0 cm: nee
93	Ergometer	151 MI	0 cm: nee
95	Externe pacemaker	152 MI	0 cm: nee
97	Externe pacemaker	153 MI	0 cm: nee
98	Externe pacemaker	154 MI	0 cm: nee
100	Externe pacemaker	155 MI	0 cm: nee
101	Hart-long machine	156 MI	0 cm: nee
107	Infuuspomp	157 MI	0 cm: nee
108	Infuuspomp	158 MI	0 cm: nee
109	Infuuspomp	159 MI	0 cm: nee

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)
110	Infuuspomp	160 MI	0 cm: nee
111	Infuuspomp	161 MI	0 cm: nee
112	Infuuspomp	162 MI	0 cm: nee
113	Infuuspomp	163 MI	0 cm: nee
114	Infuuspomp, luchtbeldetector van een -	164 MI	0 cm: nee
123	Infuuspomp, luchtbeldetector van een -	165 MI	0 cm: nee
124	Luchtbevochtiger bij beademings apparaat	166 MI	0 cm: nee
125	Luchtbevochtiger bij beademings apparaat	167 MI	0 cm: nee
126	O_2-Concentratiemeter	168 MI	0 cm: nee
130	Pager oproepsysteem (oud; telefonische oproep)	169 N	0 cm: nee
131	Pager oproepsysteem (alleen telefonische oproep)	170 N	0 cm: nee
132	Patiëntbel op bed en knop op doos aan wandgoot	171 MI	0 cm: nee
134	Patiëntmonitor, interface naar beademings apparaat	172 MI	0 cm: nee
135	Patiëntmonitor (ECG/SpO_2/bloeddruk)	173 MI	0 cm: nee
137	Patiëntmonitor (SaO_2)	174 MI	0 cm: nee
142	Patiëntmonitor (ECG/ademhaling/bloeddruk)	175 MI	0 cm: nee
146	Patiëntmonitor ECG/RESP/SpO_2/ PLETH/Druk + Temp	176 MI	0 cm: nee
150	Patiëntmonitor	177 MI	0 cm: nee
152	Patiëntmonitor (respiratie)	178 MI	0 cm: nee
153	Patiëntmonitor (ECG/SpO_2/bloeddruk)	179 MI	0 cm: nee
155	Pulsoximeter	180 MI	0 cm: nee
156	Pulsoximeter	181 MI	0 cm: nee
157	Pulsoximeter	182 MI	0 cm: nee
159	Röntgenapparaat (koppeling naar ontwikkelaar)	183 MI	0 cm: nee
163	Röntgenapparaat	184 MI	0 cm: nee
166	Spuitpomp	185 MI	0 cm: nee

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)
167	Spuitpomp	186 MI	0 cm: nee
168	Spuitpomp	187 MI	0 cm: nee
169	Spuitpomp	188 MI	0 cm: nee
170	Spuitpomp	189 MI	0 cm: nee
171	Spuitpomp	190 MI	0 cm: nee
172	Spuitpomp	191 MI	0 cm: nee
173	Spuitpomp	192 MI	0 cm: nee
174	Spuitpomp	193 MI	0 cm: nee
176	Spuitpomp	194 MI	0 cm: nee
182	Spuitpomp, bewakingsfunctie van een -	195 MI	0 cm: nee
183	Spuitpomp	196 MI	0 cm: nee
184	Spuitpomp	197 MI	0 cm: nee
191	Stoelweegschaal dialysepatiënten	198 MI	0 cm: nee
193	Telemetrie ontvangantenne	199 MI	0 cm: nee
195	Telemetrie ontvanger (kastje)	200 MI	0 cm: nee
196	Telemetrie monitor	201 MI	0 cm: nee
198	Telemetrie transmitter (ECG)	202 MI	0 cm: nee
200	Toegangscontrolesysteem: deur (kaartlezer)	203 N	0 cm: nee
204	Wasmachine ok-materiaal	204 MI	0 cm: nee
192	Telemetrie ontvangantenne	205 MI	20 cm: nee
199	Toegangscontrolesysteem: sluisbediening	206 N	100 cm: nee

BIJLAGE 3: BEPROEVINGSMETHODE

Medische apparatuur en zaktelefoons werden als volgt geactiveerd:

* Medische apparatuur in werking:
  - Patiënt, proefpersoon of technische nabootsing daarvan aansluiten op medisch apparaat,
  - Toezicht door en oordeel van afdeling vragen (gebruiker),
  - In overleg met de afdeling ook zelf het apparaat bedienen waar dat verantwoord is.

* Stoorbron in werking:
  - Begin op circa 1 m afstand
  - Vergroot / verklein deze afstand tot de grens wel / geen storing wordt gevonden. Ga eventueel tot "op" het medische apparaat.
  - Beproevingsduur circa 10 minuten per apparaat (richtgetal)
  - Test ook de patiëntaansluitingen:
    - elektroden, infuuslijnen, etc.,
    - aansluitkastjes, losse delen.

* Beweeg / roteer / etc. de zaktelefoon en varieer de positie in meerdere richtingen ten opzicht van het medische apparaat.

* Noteer de resultaten in de tabel.

BIJLAGE 4: INTERNATIONALE REFERENTIES VAN DE DRIE DIGITALE TELEFONIE SYSTEMEN, WAARMEE IS GETEST

CT-2: 2e generatie Cordless Telephone:

Draaggolffrequentie	:	ca. 900 MHz
Piekvermogen	:	ca. 0,01 Watt
"Modulatie (aan-uit)"	:	ca. 500 Hz

Internationale referentie:
Second Generation Cordless Telephone according prI-ETS 300 131 (1994), FINAL DRAFT June 1994, 2nd Edition, operating in the frequency band 864,1 MHz to 868,1 MHz.

DECT: Digital European Cordless Telephone:

Draaggolffrequentie	:	ca. 1900 MHz
Piekvermogen	:	ca. 0,25 Watt
"Modulatie (aan-uit)"	:	ca. 100 Hz

Internationale referentie:
Digital radio equipment as described in ETS 300 175-2 (1993), I-ETS 300 176 TBR6, operating in the frequency range 1880 to 1900 Mhz.

GSM: Global System for Mobile communication (vnl. Europees):

Draaggolffrequentie	:	ca. 900 MHz
Piekvermogen	:	max. ca.2 Watt
"Modulatie (aan-uit)"	:	ca. 200 Hz

Internationale referentie:
Mobile telephones according prI-ETS 300 033, GSM 02.06 or GSM 05.05 with a maximum peak power of 33 dBm (power class 4 or power control level 5).

Appendix 2

SUMMARY of Research report TNO TG/95.045: Influence of DECT pocket phones on 131 medical apparatus - field measurements (1 August 1995)

Field measurements conducted with 131 apparatus and systems revealed that 19 apparatus/systems exhibited a certain sensitivity to signals transmitted by a DECT pocket phone (transmitting power 0.25 Watt). The group of 131 apparatus/systems consisted of 126 apparatus/systems used mainly in hospitals and 5 apparatus also used outside hospitals.

The following equipment was examined:

11	analysers
2	anaesthetic machines
6	lung ventilators
5	blood pressure meters
2	incubators
6	external pacemakers
8	infusion pumps
16	patient monitors
11	syringe pumps
59 + 5	various electronic (medical) apparatus
131	

The following results were obtained:

1 It was necessary to transmit very close to the apparatus/systems to find influences (within a few decimetres). The only exceptions found to this 'decimetres rule' were:

   a an HPLC analyser which the users knew to be exceptionally sensitive to interference reacted at a distance of about 50 centimetres already;

   b a hearing aid which reacted at about 50 centimetres already (hearing aids were not included systematically in the research; this measurement concerned an investigative measurement);

   c an acoustic apparatus for locating veins reacted at about 3 metres already;

2 12 of the 19 apparatus which reacted were medical apparatus used in the hospital (including those mentioned above in 1 a and 1c).

3 The reaction which occurred with one of the apparatus was indirectly dangerous to patients. It concerned an analyser/osmometer which gave an incorrect value at about 10 centimetres.

(End of summary)

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TNO-rapport

Invloed van DECT-zaktelefoons op 131 medische apparaten - praktijkmetingen

1 augustus 1995, onderzoeksrapport TG/95.045

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Aantal pagina's : 23

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Aantal tabellen : 2

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Nederlandse organisatie voor toegepast-natuurwetenschappelijk onderzoek

De missie van TNO Preventie en Gezondheid is vooral het bevorderen van het aantal gezonde levensjaren van de mens. Het onderzoek richt zich op verbetering van gezondheid en gezondheidszorg in alle levensfasen: jeugd, arbeidende mens en ouderen.

SAMENVATTING Onderzoeksrapport TNO TG/95.045: Invloed van DECT-zaktelefoons op 131 medische apparaten - praktijkmetingen (1 augustus 1995)

Uit praktijkmetingen aan 131 apparaten en systemen bleek, dat 19 apparaten/systemen een zekere gevoeligheid vertoonden voor het door een DECT-zaktelefoon (zendvermogen 0,25 Watt) uitgezonden signaal. De groep van 131 apparaten/systemen was opgebouwd uit 126 apparaten/systemen die voornamelijk toegepast worden in het ziekenhuis en 5 apparaten die ook buiten het ziekenhuis worden gebruikt.

Onderzocht zijn:	11	Analysers
	2	Anesthesie apparaten
	6	Beademings apparaten
	5	Bloeddrukmeters
	2	Couveuses
	6	Externe pacemakers
	8	Infuuspompen
	16	Patiëntmonitoren
	11	Spuitpompen
	59 + 5	Diverse elektronische (medische) apparaten
	131	

De volgende resultaten zijn gevonden:

1 Er moest erg dicht bij de apparaten/systemen worden gezonden (binnen enkele decimeters afstand) om invloeden te vinden. De enige gevonden uitzonderingen op deze " decimeters - regel " waren:

   a een HPLC-Analyser, waarvan de gebruikers zich bewust waren, dat hij buitengewoon storingsgevoelig was en die op circa 50 cm al reageerde,

   b een Hoortoestel dat op circa 50 cm al reageerde (hoortoestellen zijn niet systematisch in het onderzoek betrokken; het betrof een oriënterende meting),

   c een Akoestisch apparaat voor het "opzoeken" van een ader, dat op circa 3 m al reageerde.

2 Van de 19 apparaten die reageerden, waren 12 medische apparaten, die in het ziekenhuis worden toegepast (inclusief de hierboven onder 1a en 1c genoemde apparaten).

3 Bij één van de apparaten die reageerden, betrof het een voor een patiënt indirekt "gevaarlijke" reactie. Het was een Analyser/osmometer, die op circa 10 cm afstand een verkeerde waarde aangaf.

INHOUDSOPGAVE

1 INLEIDING[1]

Het voorliggende rapport maakt deel uit van een serie van drie rapporten, respectievelijk betrekking hebbend op de volgende drie digitale telefoniesystemen met zaktelefoons:
- GSM
- DECT
- CT-2

De internationale omschrijving van deze drie digitale telefoniesystemen is opgenomen in Bijlage 4 van dit rapport. De geteste medische apparaten zijn in Bijlage 1 van alle drie de rapporten vermeld op alfabetische volgorde van het type apparaat. Alle apparaten hebben ook een volgnummer gekregen, dat eveneens is vermeld. Omdat de tests met de drie bovengenoemde systemen niet geheel parallel konden lopen, komen sommige apparaten niet in alle drie de rapporten voor. De reeds in rapport TG/95.010[2] vermelde resultaten zijn voor de volledigheid opnieuw in bovengenoemd GSM-rapport opgenomen. Dit is ook gedaan met de beschrijving van de GSM-metingen uit rapport TG/95.010.

In landen waar zaktelefoons reeds enige tijd in gebruik zijn, wordt regelmatig gewag gemaakt van storing op medische apparatuur die door die telefoons wordt veroorzaakt. Tevens is het vermoeden geuit, dat de mate waarin storingen op kunnen treden niet voor alle systemen hetzelfde is. Omdat bovengenoemde systemen ook in Nederland naar verwachting op grote schaal gebruikt zullen gaan worden, is het belangrijk om inzicht te verwerven in de omvang en de aard van de problematiek. Zaktelefoons zenden via de ether signalen naar een basisstation. Dit zendsignaal is met name bij het GSM-systeem in principe voldoende sterk om medische apparatuur, die zich in de buurt bevindt, te kunnen storen. Echter, niet alle medische apparatuur is even storingsgevoelig en niet alle drie de systemen zenden hetzelfde soort signaal. Dit rapport beschrijft in de ziekenhuispraktijk uitgevoerde stoorexperimenten inclusief de reacties, die apparaten vertoonden en de afstand waarop storing optrad.

2 DOEL VAN HET ONDERZOEK

Doel van het uitgevoerde onderzoek was het verzamelen van ervaringen met een groot aantal medische apparaten en het zodanig rapporteren van deze ervaringen, dat het toelatingsbeleid voor zaktelefoons in Nederlandse ziekenhuizen er op kan worden gebaseerd.

3 ONDERZOEKSMETHODE

3.1 ALGEMEEN

Een DECT-zaktelefoon welke communiceerde met het bijbehorende basisstation werd gebruikt als potentiële "stoorbron". In praktijksituaties in vijf ziekenhuizen werd de stoorbron geactiveerd in de nabijheid van medische apparatuur. Er is naar gestreefd om vooral die apparatuur te onderzoeken, waarbij veiligheidsaspecten een rol spelen.

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[1] De tekst van deze inleiding is in alle drie de rapporten, waarover in deze inleiding wordt gesproken, identiek.

[2] "Invloed van 2 Watt GSM-telefoons op medische apparatuur - oriënterende metingen; 20 januari 1995, onderzoeksrapport TG/95.010." TNO Preventie en Gezondheid, Leiden.

Rekening houdend met de mogelijkheden van de afdelingen en met de beschikbare tijd is een zo representatief mogelijke groep apparaten onderzocht. Er is niet speciaal naar oude of nieuwe apparaten gezocht; de leeftijd van de onderzochte apparaten is ook niet geregistreerd. De indruk bestaat, dat de apparaten gemiddeld circa 5 jaar oud waren en dat er vrijwel geen apparaten zijn onderzocht, die ouder waren dan 10 jaar. Er is in de ziekenhuis-praktijk gemeten omdat het noodzakelijk was om de apparatuur realistisch in werking te hebben. In risico situaties waarbij een patiënt nadelige gevolgen zou kunnen ondervinden, is met een gezonde proefpersoon gewerkt. Op diverse apparaten is middels een technische "dummy" onafhankelijk van patiënt of proefpersoon gewerkt. Om redenen van efficiency en veiligheid en om de betrokken ziekenhuisorganisaties niet onnodig te belasten, is vooraf een beproevingsprotocol opgesteld en uitgetest in een technische ruimte van een ziekenhuis. Het beproevingsprotocol is opgenomen in Bijlage 3.

3.2 GEBRUIKTE STOORBRON

Er werd bij het onderzoek gebruik gemaakt van een DECT-zaktelefoon (zendvermogen 0,25 Watt). Zie Bijlage 4 voor nadere gegevens over DECT-systemen.

3.3 TOEPASSING EN AANTAL ONDERZOCHTE APPARATEN

Er zijn 131 apparaten onderzocht. De onderzochte apparaten kunnen als volgt worden ingedeeld:

		aantal:
MI	= Medisch apparaat bInnen (In) het ziekenhuis	118
N	= Niet medisch apparaat	8
MU	= Medisch apparaat bUiten (Uit) het ziekenhuis	5
		131

Zoals uit deze getallen blijkt, lag de nadruk bij het onderzoek geheel op medische apparatuur, die in het ziekenhuis wordt toegepast (MI). De acht N-apparaten waren communicatie- en toegangscontrôlemiddelen, die voor de bedrijfsvoering van het ziekenhuis noodzakelijk zijn. De vijf MU-apparaten waren hoortoestellen, die ter oriëntatie zijn gemeten.

In Bijlage 1 zijn alle geteste apparaten alfabetisch gerangschikt en voorzien van een volgnummer.Dit volgnummer is vermeld in kolom 1 van Bijlage 1.

De tabel in Bijlage 1 geeft een overzicht over de onderzochte apparatuur. Uit die tabel is bijvoorbeeld af te lezen, dat onderzocht zijn:

-	11	Analysers
-	6	Beademings apparaten
-	6	Externe pacemakers
-	8	Infuuspompen
-	16	Patiëntmonitoren
-	11	Spuitpompen
-	73	Diverse elektronische apparaten
	131	

Diverse keren zijn apparaten van hetzelfde fabrikaat en type, maar met verschillend serienummer onderzocht. De volgnummers van deze apparaten zijn in de eerste kolom van de tabel in Bijlage 1 in één doorlopend vak weergegeven. Zo waren bijvoorbeeld de apparaten Nr. 35, 36 en 37 (zie de tabel van Bijlage 1) van hetzelfde fabrikaat en type.

Een open vak onderaan de pagina heeft dezelfde betekenis. Zo waren ook de apparaten Nr. 26 en 28 van hetzelfde fabrikaat en type.

4 UITKOMSTEN VAN HET ONDERZOEK

4.1 DE AFSTAND WAAROP APPARATEN REAGEERDEN

In Bijlage 1 zijn alle geteste apparaten alfabetisch gerangschikt en voorzien van een volgnummer. In Bijlage 2 zijn de geteste apparaten gesorteerd op de afstand waarop zij reageerden. Deze afstand is te vinden in de laatste kolom van Bijlage 2. Er is in die laatste kolom eerst gesorteerd op "ja" (wel storing) en "nee" (geen storing). Vervolgens is binnen elk van de groepen "ja" en "nee" gesorteerd op afstand. Het volgnummer van elk apparaat is ook in Bijlage 2 opgenomen (eerste kolom). Middels dit volgnummer kan in Bijlage 1 worden nagezocht wat precies de aard van de reactie van een gestoord apparaat was.

Van de 131 onderzochte apparaten vertoonden 19 apparaten een zekere gevoeligheid voor het door een DECT-zaktelefoon uitgezonden signaal. De figuur op de volgende pagina geeft per afstand weer hoeveel apparaten reacties vertoonden. Hierbij wordt opgemerkt:

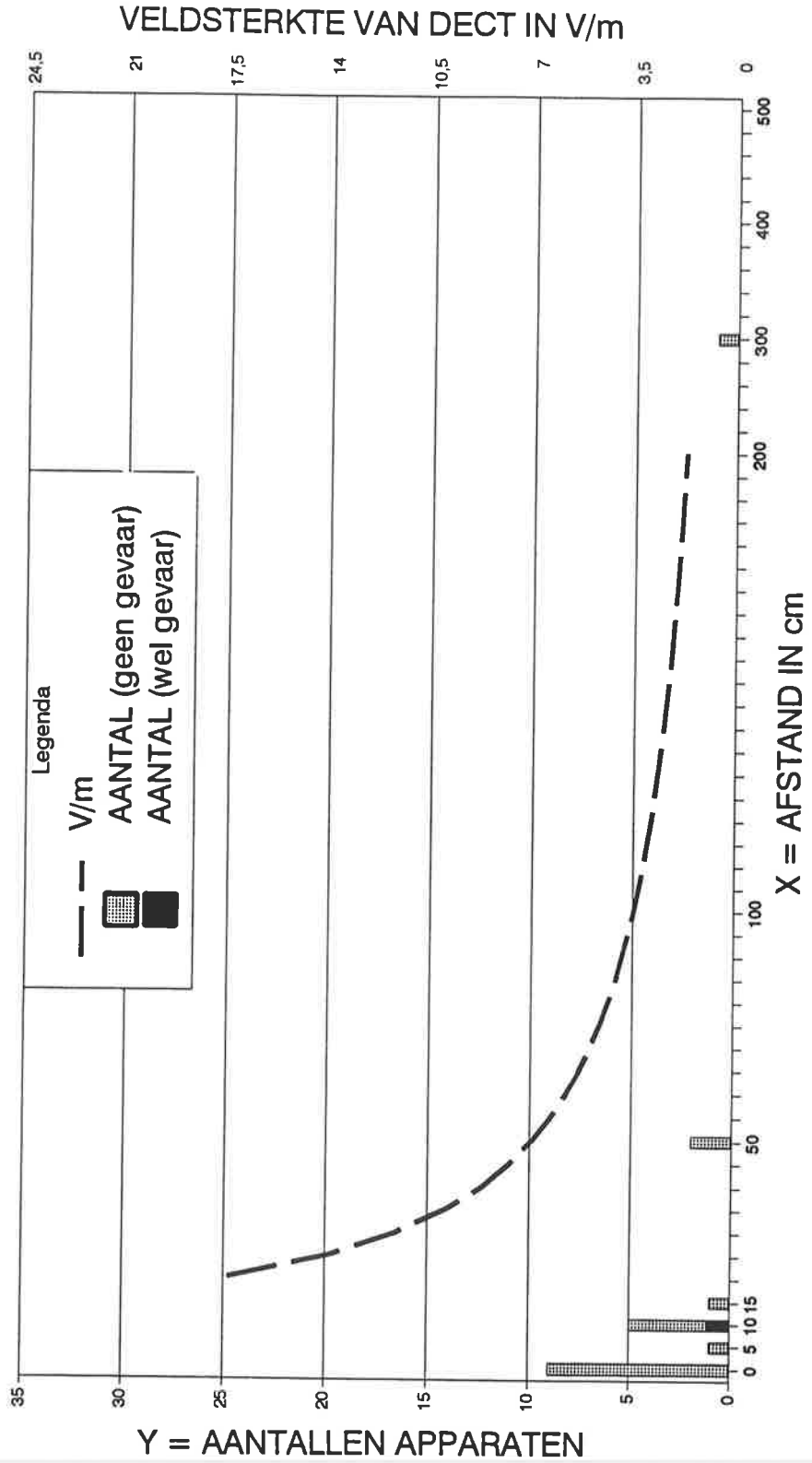
- De hoogte van de staven = Y = het aantal apparaten, dat op afstand X reageerde. Alle staven gesommeerd hebben de "hoogte" 19 - het totale aantal apparaten, dat reageerde.
- De staven zijn op de goede afstand op de X-as geplaatst, maar boven 200 cm is wel een andere schaal toegepast. De staaf bij 300 cm is in die zin vertekend weergegeven.
- In de figuur is met een gebogen lijn aangegeven: de veldsterkte (in Volt per meter, V/m) van een DECT-zaktelefoon als functie van de afstand tot die telefoon.

Laatstgenoemde veldsterkte-lijn is gebaseerd op de benaderingsformule:

$$E = 7 . (\surd W) / d \quad V/m$$

Voorbeeld: op 1 m afstand (d=1) van een DECT-zaktelefoon (W=0,25) is de veldsterkte: E = circa. 3,5 V/m.

In de praktijk varieert de veldsterkte doordat een fabrikagemarge ten aanzien van het gespecificeerde vermogen geldt, maar vooral ook doordat reflecterende voorwerpen locale verhogingen en verlagingen van de veldsterkte kunnen veroorzaken. Bij de praktijkmetingen aan apparatuur werd dit effect gecompenseerd door de DECT-zaktelefoon op veel locaties rond het te testen apparaat te activeren.



STAVEN: AANTALLEN APPARATEN Y, DAT OP AFSTAND X REAGEERDE;
LIJN: PIEKVELDSTERKTE (V/m = Volt per meter) VAN DECT-ZAKTELEFOON OP AFSTAND X (piekzendvermogen 0,25 Watt)

Samenvattend: Van de 131 onderzochte apparaten/systemen bleken er 19 een zekere gevoeligheid te vertonen voor het door een DECT-zaktelefoon uitgezonden signaal. De 19 apparaten, die reageerden zijn te vinden in het begin van de tabel in Bijlage 2.

De volgende resultaten zijn gevonden:

1 Er moest erg dicht bij de apparaten/systemen worden gezonden (binnen enkele decimeters afstand) om invloeden te vinden. De enige gevonden uitzonderingen op deze " decimeters - regel " waren:

- een HPLC-Analyser, waarvan de gebruikers zich bewust waren, dat hij buitengewoon storingsgevoelig was en die op circa 50 cm al reageerde. Zie apparaat 1 in Bijlagen 1 en 2.

- een Hoortoestel dat op circa 50 cm al reageerde (hoortoestellen zijn niet systematisch in het onderzoek betrokken; het betrof een oriënterende meting). Zie apparaat 104 in Bijlagen 1 en 2.

- een Akoestisch apparaat voor het "opzoeken" van een ader, dat op circa 3 m al reageerde. Zie apparaat 74 in Bijlagen 1 en 2.

2 Van de 19 apparaten, die reageerden waren 12 medische apparaten, die in het ziekenhuis worden toegepast. Twee van de onder punt 1 genoemde uitzonderingen bevonden zich onder deze 12.

4.2 AARD VAN DE REACTIES

De gebruikte DECT-zaktelefoon beïnvloedde diverse onderzochte apparaten wanneer de bron in de direkte nabijheid van die apparaten werd geactiveerd. De reacties zijn in detail beschreven in de vijfde kolom van de tabel in Bijlage 1.

Bij één van de apparaten die reageerde betrof het een voor de patiënt indirekt "gevaarlijke" reactie. Deze deed zich voor op 10 cm afstand (bij een Analyser/osmometer; nr 17).

BIJLAGE 1: APPARAATREACTIES

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
1	Analyser HPLC, Electrochemische detector bij -	MI	50 cm: ja	Op circa 50 cm: onbruikbare uitslagen
8	Analyser, hematologische cel analyser	MI	0 cm: ja	Op 0 cm: uitlezing barcodelezer fout, machine stopt met correct alarm
8.1	Analyser: datakoppeling met ZIS (PC)	MI	0 cm: nee	
9	Analyser, fotometrische chemieanalyser	MI	0 cm: nee	
10	Analyser, chemie	MI	0 cm: nee	
11	Analyser, chemie	MI	0 cm: nee	
13	Analyser, bloedgassen	MI	0 cm: nee	
14	Analyser, HPLC	MI	0 cm: nee	
15	Analyser, hematologische cel analyser	MI	0 cm: nee	
16	Analyser, bloedcellen	MI	0 cm: nee	
17	Analyser, osmometer	MI	10 cm: ja	Op 10 cm: verkeerde waarde (zonder foutmelding) (indirekt gevaar)
19	Anesthesie apparaat	MI	0 cm: nee	
21	Anesthesie apparaat	MI	0 cm: nee	
23	Audiometer	MI	0 cm: nee	
24	Ballonpomp	MI	0 cm: nee	
26	Beademings apparaat	MI	0 cm: nee	

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
28	Beademings apparaat	MI	0 cm: nee	
31	Beademings apparaat	MI	0 cm: nee	
35	Beademings apparaat	MI	0 cm: nee	
36	Beademings apparaat	MI	0 cm: nee	
37	Beademings apparaat met **open deksel**	MI	0 cm: nee	(werd met open deksel gebruikt)
39	Bewakingspost met patiëntmonitoren	MI	0 cm: nee	
40	Bloeddrukmeter	MI	0 cm: nee	
41	Bloeddrukmeter	MI	0 cm: nee	
44	Bloeddrukmeter	MI	0 cm: nee	
45	Bloeddrukmeter	MI	0 cm: nee	
47	Bloedverwarmer	MI	0 cm: nee	
50	Brandmelder	N	0 cm: nee	
51	Brandmelder	N	0 cm: nee	
52	Cardio Tocograaf (CTG)	MI	0 cm: nee	
58	Couveuse	MI	0 cm: nee	
62	Couveuse	MI	0 cm: nee	
63	CT-scanner (bedieningspaneel met monitor achter scherm)	MI	0 cm: ja	Op 0 cm: lijnen op beeld monitor; niet storend
64	Defibrillator tester	MI	0 cm: nee	
65	Defibrillator	MI	0 cm: nee	
66	Defibrillator	MI	0 cm: nee	

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
67	Defibrillator	MI	0 cm: nee	
68	Defibrillator	MI	0 cm: nee	
69	Dialyse apparaat zonder slangen	MI	0 cm: nee	
70	Dialyse apparaat met slangen	MI	0 cm: nee	
71	Dialyse apparaat zonder slangen	MI	0 cm: nee	
74	Doptone: akoestisch "opzoeken" van ader	MI	300 cm: ja	Op circa 300 cm van apparaat: 100 Hz hoorbaar (modulatiefreq. DECT)
75	Drukmonitor, hersenvat	MI	0 cm: nee	
76	ECG apparaat	MI	0 cm: nee	
77	ECG apparaat	MI	0 cm: nee	
78	ECG apparaat	MI	0 cm: nee	
79	ECG apparaat	MI	0 cm: nee	
80	ECG apparaat	MI	0 cm: nee	
81	Echocardiograaf:UG apparaat (met videorecorder)	MI	0 cm: nee	
82	Echocardiograaf/UG apparaat (met videorecorder)	MI	0 cm: nee	
83	EEG apparaat	MI	0 cm: nee	
84	EEG apparaat	MI	0 cm: nee	
85	EEG apparaat	MI	0 cm: nee	
89	Elektrochirurgie	MI	0 cm: nee	
90	EMG apparaat (ringelektrode)	MI	0 cm: ja	Op 10 cm van apparaat en bij headbox / front: 100 Hz hoorbaar uit luidspreker

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
91	EMG apparaat	MI	10 cm: ja	Op 10 cm van leiding naar patiënt: DECT-telefoon: geringe storing op signaal
92	ENG apparaat	MI	0 cm: nee	
93	Ergometer	MI	0 cm: nee	
94	EVP - Optische stimulator	MI	0 cm: nee	
95	Externe pacemaker	MI	0 cm: nee	
96	Externe pacemaker	MI	0 cm: nee	
97	Externe pacemaker	MI	0 cm: nee	
98	Externe pacemaker	MI	0 cm: nee	
99	Externe pacemaker	MI	0 cm: nee	
100	Externe pacemaker	MI	0 cm: nee	
101	Hart-long machine	MI	0 cm: nee	
102	Hoortoestel (in-het-oor; geen spoel)	MU	10 cm: ja	Op 10 cm: 100 Hz hoorbaar (modulatiefrequentie DECT). Straalt direkt in op elektronica
103	Hoortoestel (achter-het-oor)	MU	0 cm: ja	Op 0 cm: 100 Hz hoorbaar (modulatiefrequentie DECT)
104	Hoortoestel (achter-het-oor; geen spoel)	MU	50 cm: ja	Op 50 cm: 100 Hz hoorbaar (modulatiefrequentie DECT); Straalt direkt in op elektronica
105	Hoortoestel (achter-het-oor)	MU	10 cm: ja	Op 10 cm: 100 Hz hoorbaar (modulatiefrequentie DECT). Met uitgeschakelde ontvangstspoel: idem, maar lager niveau

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
106	Hoortoestel (in-het-oor; geen spoel)	MU	10 cm: ja	Op 10 cm: 100 Hz hoorbaar (modulatiefrequentie DECT). Straalt direkt in op elektronica
107	Infuuspomp	MI	0 cm: nee	
108	Infuuspomp	MI	0 cm: nee	
113	Infuuspomp	MI	0 cm: nee	
115	Infuuspomp	MI	0 cm: ja	Bij **linker- en** rechter zijkant pomp: onterechte foutcode (druppelsensor-fout: bijv. lege fles); pomp stopt en geeft akoestisch alarm
116	Infuuspomp	MI	0 cm: ja	Bij rechter zijkant van pomp: onterechte foutcode (druppelsensor-fout: bijv. lege fles); pomp stopt en geeft akoestisch alarm
119	Infuuspomp	MI	0 cm: nee	
120	Infuuspomp	MI	0 cm: nee	
121	Infuuspomp	MI	0 cm: nee	
127	O_2-Concentratiemeter in couveuse	MI	0 cm: nee	
128	Pager personenbeveiliging (met molesttouwtje)	N	0 cm: nee	
129	Pager oproepsysteem (telefonische oproep met alfanumeriek display)	N	0 cm: ja	Op 0 cm: soms is boodschap verminkt
130	Pager oproepsysteem (oud; telefonische oproep)	N	5 cm: ja	Op 5 cm: pieper gaat niet over

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
131	Pager oproep-systeem (alleen telefonische op-roep)	N	0 cm: nee	
132	Patiëntbel op bed en knop op doos aan wandgoot	MI	0 cm: nee	
133	Patiëntmonitor (ECG/CVD/SAT/ NIBP)	MI	0 cm: nee	
134	Patiëntmonitor, interface naar beademings apparaat	MI	0 cm: nee	
135	Patiëntmonitor (ECG/SpO_2/ bloeddruk)	MI	0 cm: nee	
136	Patiëntmonitor (CO_2/NIBP)	MI	0 cm: nee	
137	Patiëntmonitor (SaO_2)	MI	0 cm: nee	
138	Patiëntmonitor (ECG/SpO_2)	MI	0 cm: nee	
139	Patiëntmonitor (ECG/SpO_2/ bloeddruk)	MI	0 cm: nee	
140	Patiëntmonitor (ECG)	MI	0 cm: nee	
141	Patiëntmonitor (ECG/ademha-ling/bloeddruk)	MI	0 cm: nee	
142	Patiëntmonitor (ECG/ademha-ling/bloeddruk)	MI	0 cm: nee	
145	Patiëntmonitor (ECG/bloeddruk)	MI	0 cm: nee	

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
147	Patiëntmonitor (ECG/SpO_2/ bloeddruk)	MI	0 cm: nee	
148	Patiëntmonitor	MI	0 cm: nee	
149	Patiëntmonitor (ECG/SaO_2)	MI	0 cm: nee	
151	Patiëntmonitor (CO_2,SpO_2, $ETCO_2$)	MI	0 cm: nee	
153	Patiëntmonitor (ECG/SpO_2/ bloeddruk)	MI	0 cm: nee	
155	Pulsoximeter	MI	0 cm: nee	
158	Pulsoximeter	MI	0 cm: nee	
159	Röntgenapparaat (koppeling naar ontwikkelaar)	MI	0 cm: nee	
160	Röntgenapparaat (bedieningspaneel met monitor achter scherm)	MI	0 cm: ja	Op 0 cm: lijnen op beeld monitor; niet storend
161	Röntgenapparaat (beeldversterker bij patiëntenbed)	MI	0 cm: nee	
162	Röntgenapparaat (monitor bij patiëntenbed)	MI	15 cm: ja	Op 15 cm van bedrading: lijnen op beeld monitor; niet storend
163	Röntgenapparaat	MI	0 cm: nee	
164	Spuitpomp	MI	0 cm: nee	
165	Spuitpomp	MI	0 cm: nee	
169	Spuitpomp	MI	0 cm: nee	
170	Spuitpomp	MI	0 cm: nee	
174	Spuitpomp	MI	0 cm: nee	
175	Spuitpomp	MI	0 cm: nee	

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)	OMSCHRIJVING VAN DE REACTIE
176	Spuitpomp	MI	0 cm: nee	
177	Spuitpomp	MI	0 cm: nee	
187	Spuitpomp	MI	0 cm: nee	
188	Spuitpomp	MI	0 cm: nee	
189	Spuitpomp	MI	0 cm: ja	Bij pomp: onterechte foutmelding ("volumegrens bereikt"); pomp stopt en geeft akoestisch alarm
190	Sterilisator	MI	0 cm: nee	
192	Telemetrie ontvangantenne	MI	20 cm: nee	Antenne aan plafond: niet nodig om dichter bij te gaan
193	Telemetrie ontvangantenne	MI	0 cm: nee	
194	Telemetrie transmitter (ECG)	MI	0 cm: nee	
195	Telemetrie ontvanger (kastje)	MI	0 cm: nee	
196	Telemetrie monitor	MI	0 cm: nee	
197	Telemetrie transmitter	MI	0 cm: nee	
198	Telemetrie transmitter (ECG)	MI	0 cm: nee	
199	Toegangscontrolesysteem: sluisbediening	N	50 cm: nee	Op 50 cm geen invloed; uit voorzorg niet dichter bij gegaan: de omkasting van de elektronica was er af ivm. onderhoud
200	Toegangscontrolesysteem: deur (kaartlezer)	N	0 cm: nee	
201	Verwarmings matras op ok	MI	0 cm: nee	
204	Wasmachine okmateriaal	MI	0 cm: nee	

BIJLAGE 2: APPARATEN gesorteerd op: afstand (ja/nee) en daarna op: alfabet [3]

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)
74	Doptone: akoestisch "opzoeken" van ader	MI	300 cm: ja
1	Analyser HPLC, Electrochemische detector bij -	MI	50 cm: ja
104	Hoortoestel (achter-het-oor; geen spoel)	MU	50 cm: ja
162	Röntgenapparaat (monitor bij patiëntenbed)	MI	15 cm: ja
17	Analyser, osmometer	MI	10 cm: ja (g)
91	EMG apparaat	MI	10 cm: ja
102	Hoortoestel (in-het-oor; geen spoel)	MU	10 cm: ja
105	Hoortoestel (achter-het-oor)	MU	10 cm: ja
106	Hoortoestel (in-het-oor; geen spoel)	MU	10 cm: ja
130	Pager oproepsysteem (oud; telefonische oproep)	N	5 cm: ja
8	Analyser, hematologische cel analyser	MI	0 cm: ja
63	CT-scanner (bedieningspaneel met monitor achter scherm)	MI	0 cm: ja
90	EMG apparaat (ringelektrode)	MI	0 cm: ja
103	Hoortoestel (achter-het-oor)	MU	0 cm: ja
115	Infuuspomp	MI	0 cm: ja
116	Infuuspomp	MI	0 cm: ja
129	Pager oproepsysteem (telefonische oproep met alfanumeriek display)	N	0 cm: ja
160	Röntgenapparaat (bedieningspaneel met monitor achter scherm)	MI	0 cm: ja
189	Spuitpomp	MI	0 cm: ja
8.1	Analyser: datakoppeling met ZIS (PC)	MI	0 cm: nee
9	Analyser, fotometrische chemieanalyser	MI	0 cm: nee
10	Analyser, chemie	MI	0 cm: nee
11	Analyser, chemie	MI	0 cm: nee

[3] Een "g" in de laatste kolom betekent: Voor patient of gebruiker gevaarlijke reactie (direkt of indirekt).

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)
13	Analyser, bloedgassen	MI	0 cm: nee
14	Analyser, HPLC	MI	0 cm: nee
15	Analyser, hematologische cel analyser	MI	0 cm: nee
16	Analyser, bloedcellen	MI	0 cm: nee
19	Anesthesie apparaat	MI	0 cm: nee
21	Anesthesie apparaat	MI	0 cm: nee
23	Audiometer	MI	0 cm: nee
24	Ballonpomp	MI	0 cm: nee
26	Beademings apparaat	MI	0 cm: nee
28	Beademings apparaat	MI	0 cm: nee
31	Beademings apparaat	MI	0 cm: nee
35	Beademings apparaat	MI	0 cm: nee
36	Beademings apparaat	MI	0 cm: nee
37	Beademings apparaat met **open deksel**	MI	0 cm: nee
39	Bewakingspost met patiëntmonitoren	MI	0 cm: nee
40	Bloeddrukmeter	MI	0 cm: nee
41	Bloeddrukmeter	MI	0 cm: nee
44	Bloeddrukmeter	MI	0 cm: nee
45	Bloeddrukmeter	MI	0 cm: nee
47	Bloedverwarmer	MI	0 cm: nee
50	Brandmelder	N	0 cm: nee
51	Brandmelder	N	0 cm: nee
52	Cardio Tocograaf (CTG)	MI	0 cm: nee
58	Couveuse	MI	0 cm: nee
62	Couveuse	MI	0 cm: nee
64	Defibrillator tester	MI	0 cm: nee
65	Defibrillator	MI	0 cm: nee
66	Defibrillator	MI	0 cm: nee

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)
67	Defibrillator	MI	0 cm: nee
68	Defibrillator	MI	0 cm: nee
69	Dialyse apparaat zonder slangen	MI	0 cm: nee
70	Dialyse apparaat met slangen	MI	0 cm: nee
71	Dialyse apparaat zonder slangen	MI	0 cm: nee
75	Drukmonitor, hersenvat	MI	0 cm: nee
76	ECG apparaat	MI	0 cm: nee
77	ECG apparaat	MI	0 cm: nee
78	ECG apparaat	MI	0 cm: nee
79	ECG apparaat	MI	0 cm: nee
80	ECG apparaat	MI	0 cm: nee
81	Echocardiograaf:UG apparaat (met video-recorder)	MI	0 cm: nee
82	Echocardiograaf/UG apparaat (met video-recorder)	MI	0 cm: nee
83	EEG apparaat	MI	0 cm: nee
84	EEG apparaat	MI	0 cm: nee
85	EEG apparaat	MI	0 cm: nee
89	Elektrochirurgie	MI	0 cm: nee
92	ENG apparaat	MI	0 cm: nee
93	Ergometer	MI	0 cm: nee
94	EVP - Optische stimulator	MI	0 cm: nee
95	Externe pacemaker	MI	0 cm: nee
96	Externe pacemaker	MI	0 cm: nee
97	Externe pacemaker	MI	0 cm: nee
98	Externe pacemaker	MI	0 cm: nee
99	Externe pacemaker	MI	0 cm: nee
100	Externe pacemaker	MI	0 cm: nee

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)
101	Hart-long machine	MI	0 cm: nee
107	Infuuspomp	MI	0 cm: nee
108	Infuuspomp	MI	0 cm: nee
113	Infuuspomp	MI	0 cm: nee
119	Infuuspomp	MI	0 cm: nee
120	Infuuspomp	MI	0 cm: nee
121	Infuuspomp	MI	0 cm: nee
127	O_2-Concentratiemeter in couveuse	MI	0 cm: nee
128	Pager personenbeveiliging (met molesttouwtje)	N	0 cm: nee
131	Pager oproepsysteem (alleen telefonische oproep)	N	0 cm: nee
132	Patiëntbel op bed en knop op doos aan wandgoot	MI	0 cm: nee
133	Patiëntmonitor (ECG/CVD/SAT/NIBP)	MI	0 cm: nee
134	Patiëntmonitor, interface naar beademings apparaat	MI	0 cm: nee
135	Patiëntmonitor (ECG/SpO_2/bloeddruk)	MI	0 cm: nee
136	Patiëntmonitor (CO_2/NIBP)	MI	0 cm: nee
137	Patiëntmonitor (SaO_2)	MI	0 cm: nee
138	Patiëntmonitor (ECG/SpO_2)	MI	0 cm: nee
139	Patiëntmonitor (ECG/SpO_2/bloeddruk)	MI	0 cm: nee
140	Patiëntmonitor (ECG)	MI	0 cm: nee
141	Patiëntmonitor (ECG/ademhaling/bloeddruk)	MI	0 cm: nee
142	Patiëntmonitor (ECG/ademhaling/bloeddruk)	MI	0 cm: nee
145	Patiëntmonitor (ECG/bloeddruk)	MI	0 cm: nee
147	Patiëntmonitor (ECG/SpO_2/bloeddruk)	MI	0 cm: nee
148	Patiëntmonitor	MI	0 cm: nee
149	Patiëntmonitor (ECG/SaO_2)	MI	0 cm: nee
151	Patiëntmonitor (CO_2,SpO_2,$ETCO_2$)	MI	0 cm: nee
153	Patiëntmonitor (ECG/SpO_2/bloeddruk)	MI	0 cm: nee

Nr.	APPARAAT	MI/MU/N	AFSTAND X in cm + reactie (ja of nee)
155	Pulsoximeter	MI	0 cm: nee
158	Pulsoximeter	MI	0 cm: nee
159	Röntgenapparaat (koppeling naar ontwikkelaar)	MI	0 cm: nee
161	Röntgenapparaat (beeldversterker bij patiëntenbed)	MI	0 cm: nee
163	Röntgenapparaat	MI	0 cm: nee
164	Spuitpomp	MI	0 cm: nee
165	Spuitpomp	MI	0 cm: nee
169	Spuitpomp	MI	0 cm: nee
170	Spuitpomp	MI	0 cm: nee
174	Spuitpomp	MI	0 cm: nee
175	Spuitpomp	MI	0 cm: nee
176	Spuitpomp	MI	0 cm: nee
177	Spuitpomp	MI	0 cm: nee
187	Spuitpomp	MI	0 cm: nee
188	Spuitpomp	MI	0 cm: nee
190	Sterilisator	MI	0 cm: nee
193	Telemetrie ontvangantenne	MI	0 cm: nee
194	Telemetrie transmitter (ECG)	MI	0 cm: nee
195	Telemetrie ontvanger (kastje)	MI	0 cm: nee
196	Telemetrie monitor	MI	0 cm: nee
197	Telemetrie transmitter	MI	0 cm: nee
198	Telemetrie transmitter (ECG)	MI	0 cm: nee
200	Toegangscontrolesysteem: deur (kaartlezer)	N	0 cm: nee
201	Verwarmings matras op ok	MI	0 cm: nee
204	Wasmachine ok-materiaal	MI	0 cm: nee
192	Telemetrie ontvangantenne	MI	20 cm: nee
199	Toegangscontrolesysteem: sluisbediening	N	50 cm: nee

BIJLAGE 3: BEPROEVINGSMETHODE

Medische apparatuur en zaktelefoons werden als volgt geactiveerd:

* Medische apparatuur in werking:
  - Patiënt, proefpersoon of technische nabootsing daarvan aansluiten op medisch apparaat,
  - Toezicht door en oordeel van afdeling vragen (gebruiker),
  - In overleg met de afdeling ook zelf het apparaat bedienen waar dat verantwoord is.

* Stoorbron in werking:
  - Begin op circa 1 m afstand
  - Vergroot / verklein deze afstand tot de grens wel / geen storing wordt gevonden. Ga eventueel tot "op" het medische apparaat.
  - Beproevingsduur circa. 10 minuten per apparaat (richtgetal)
  - Test ook de patiëntaansluitingen:
    - elektroden, infuuslijnen, etc.,
    - aansluitkastjes, losse delen.

* Beweeg / roteer / etc. de zaktelefoon en varieer de positie in meerdere richtingen ten opzicht van het medische apparaat.

* Noteer de resultaten in de tabel.

BIJLAGE 4: INTERNATIONALE REFERENTIES VAN DE DRIE DIGITALE TELEFONIE SYSTEMEN, WAARMEE IS GETEST

CT-2: 2e generatie Cordless Telephone:

Draaggolffrequentie	:	ca. 900 MHz
Piekvermogen	:	ca. 0,01 Watt
"Modulatie (aan-uit)"	:	ca. 500 Hz

Internationale referentie:
Second Generation Cordless Telephone according prI-ETS 300 131 (1994), FINAL DRAFT June 1994, 2nd Edition, operating in the frequency band 864,1 MHz to 868,1 MHz.

DECT: Digital European Cordless Telephone:

Draaggolffrequentie	:	ca. 1900 MHz
Piekvermogen	:	ca. 0,25 Watt
"Modulatie (aan-uit)"	:	ca. 100 Hz

Internationale referentie:
Digital radio equipment as described in ETS 300 175-2 (1993), I-ETS 300 176 TBR6, operating in the frequency range 1880 to 1900 Mhz.

GSM: Global System for Mobile communication (vnl. Europees):

Draaggolffrequentie	:	ca. 900 MHz
Piekvermogen	:	max. ca.2 Watt
"Modulatie (aan-uit)"	:	ca. 200 Hz

Internationale referentie:
Mobile telephones according prI-ETS 300 033, GSM 02.06 or GSM 05.05 with a maximum peak power of 33 dBm (power class 4 or power control level 5).

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Effects on medical equipment at home of pocket phones and the like – field measurements

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TNO

Summary of TNO report **"Effects on medical equipment at home of pocket phones and the like – field measurements"**, TNO Prevention and Health, TNO Research report PG/TG/00.050, 28 April 2000.

Results summarized

Medical equipment at home is comparably sensitive to fields from pocket telephones as medical equipment in the hospital: within 1 to 2 m, interference can occur. Therefore a warning about the sensitivity of extramural equipment to interference remains to be justified. On the other hand, too much fear for influences of this type is needless. No indications were found for wheelchairs being disturbed by pocket phones carried by passers-by; however, for the sake of security, users of wheelchairs who want to use a hand-held telephone themselves should first switch off their wheelchair. Foreign publications indicate that apnoea monitors must be made less sensitive if this has not been done yet. Warnings against possible interference must be added to pocket telephones and be placed on the Internet (in most cases this already happens on the basis of publications from 1995). Warnings should be added to medical equipment as well.

The new draft second edition of the EMC standard for medical equipment (applicable from around 2001) prescribes manufacturers of medical equipment to specify at how close distances near medical equipment mobile communication devices may be used in relation to their transmitted power. It is therefore necessary that manufacturers of pocket phones and the like indicate this power and that they indicate it as maximum power. Annex C to this report gives examples of this.

Results in figures

A total of 100 medical apparatuses for extramural use were tested. Tests were performed with GSM 2 W, GSM 8 W, DCS 1800, DECT and CT 0. Of the 100 medical apparatuses tested, 42 appeared to be immune to all sources of interference applied. The greatest percentage of disturbance occurred with the GSM 8 W [1] source: 57 medical apparatuses appeared to be sensitive. The greatest distance at which interference could occur was 300 cm (respiratory support device). Of the 57 apparatuses sensitive to GSM 8 W, 19 (33%) reacted in a way that could impair safety. Of the 37 apparatuses sensitive to GSM 2 W, 17 (46%) reacted in an unsafe manner. For DCS 1800 the percentage of sensitive apparatuses was 10%, for DECT (1900 MHz) 4%, and for CT 0 (40 MHz) 3%. With all interference sources unsafe reactions occurred as well. These unsafe reactions occurred at all distances, not primarily at the shortest distances. Respiratory support devices belonged to the most sensitive apparatuses and also mostly elicited unsafe reactions. Several other apparatuses were only unsafe at distances of some centimetres until some decimetres (e.g. blood glucose monitors, infusion pump for medicine, social alarm equipment, wheelchairs and scooters). Of the 34 wheelchairs and scooters tested, 13 reacted, but the transmit-

[1] GSM 8 W is not being used in the Netherlands any more.

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ting antenna of the pocket telephone had to be very close to the electronic circuits of the wheelchair concerned to elicit a reaction.

Other reactions can be described as unpleasant, but it has to be noted that several unpleasant reactions combined may be hazardous because they hide real danger.

Warnings

The new DCS 1800 system results in few interferences. The overall conclusion is that medical equipment for home use is slightly less sensitive to interference than medical equipment in the hospital. However, outside the hospital stronger sources of interference are to be expected, such as vehicles close to the window, and no professional personnel is available if interference problems occur. Therefore, a serious warning statement should be addressed to both manufacturers of pocket phones and producers of medical equipment. That warning statement is that, on the one hand, medical equipment for home use must be made less sensitive to disturbing fields emitted by pocket phones and, on the other, manufacturers of pocket phones should (continue to) include warnings with the phones and on the Internet against using these phones near medical equipment. Medical apparatuses must be accompanied by a warning against possible interference influences. A more or less reassuring conclusion from the investigation is that no high sensitivities were found for wheelchairs: some wheelchairs were sensitive but only if the antenna of the transmitting device was brought very close to the electronic circuits of these wheelchairs.
Unless manufacturers of wheelchairs fully guarantee the insensitivity of their products, wheelchair users should bring their wheelchair in a safe situation (switch it off) before they make phone calls themselves. The results of this study do not indicate that pocket phones that are at a distance of more than a few decimetres, for example in the hands of passers-by, do disturb wheelchairs.

Keywords
pocket phone, mobile phones, interference, GSM, medical equipment, ElectroMagnetic Compatibility (EMC), extramural

(End of summary)

Remark: An English summary has been distributed earlier under full responsibility of TNO. When translating the report in full the above version of the summary resulted, containing editorial changes.

Contents

1 Introduction

1.1 Research questions

The research question can be formulated as follows.

It is increasingly common practice that patients are discharged form the hospital with electromedical equipment for treatment at home. Medical equipment in the hospital is more or less sensitive to disturbances. These facts make it relevant to explore the possibility that electronic medical equipment used at home is influenced by electromagnetic fields. Possible sources of interference include wireless (radio)-communication devices.

At the request of Zorgonderzoek Nederland, TNO conducted the field measurements reported here into possible influences on electromedical equipment used by patients at home. In this context, 'at home' should be taken in a broad sense. The equipment referred to is electromedical equipment that can be used by or for patients outside the hospital. Such equipment may be a wheelchair for outdoor use or an insulin pump carried on the body. The home situation differs from the hospital in that supervision of the use of equipment is lacking at home. The user must be confident that the equipment will function properly under whatever conditions.

The study covered both currently available and foreseeable telecommunication tools, with a specific focus on the target group, the site of use and the extent of penetration.

The following concrete questions were asked.

To what extent is it justified today to have complex medical technological equipment used in the patients' home (for the chronically ill, for example)? To what extent can currently present sources of electromagnetic fields, such as GSM (car) phones and other communication systems operating via the air disturb medical equipment?

What role play mobile means of communication, and what role will such tools anticipated in the foreseeable future play, in the home environment, also in the light of the expected growth of the use of networks operating via the air and soon via satellites?

Do the increasingly complex electronic functions built into medical equipment, in combination with the explosive penetration of mobile communication tools, introduce a real risk of disturbances in medical equipment? To what extent is medical equipment shielded against such disturbances? The coincidence is very hard to trace for lay users, and this will be more problematic as the technology becomes more complex.

The aim of this study was to quantify, by means of laboratory and field measurements, disturbances of medical equipment in extramural care arising from the explosive penetration of pocket phones and similar mobile communication tools in society. The results should yield concrete suggestions for improvement and for new, reproducible testing methods that can be applied for future extramural electromedical equipment.

1.2 Importance of the research

Medical technological provisions are applied in the home situation on an increasingly larger scale because their use is associated with various advantages: they enable patients to be in their own home, a higher level of subjective well-being and, last but not least, lowered costs relative to intramural care. Increasingly complex electronics are built into these provisions, and it is exactly these electronics that help enable their extramural application. When these medical provisions are applied in the home situation, it is rarely explored exhaustively whether such an application is justified with a view on disturbing influences. In evaluating the general infrastructure in the patient's home, the influence of possible sources of interference should be taken into account because they might adversely affect the treatment and care of the chronically ill, for example.

In addition to the well-known disturbance by electronic equipment such as television, radio and the phones referred to above, there are currently other devices such as the fax, the microwave oven or the inductive hot plate. Such equipment as vacuum cleaners, irons and electric heaters are also potential sources of interference. In specific cases, an important factor may also be communication equipment that must generate electromagnetic fields to be able to function, such as broadcasting stations and relay stations of communication systems. Our society is insufficiently aware of the potential hazards, which is reflected in the licences granted to radio amateurs: they are allowed to generate strong fields provided under the condition that they assist their environment in case of disturbances. On a distance of some metres form the transmitting aerial, the field strength may be tens of volts while the standard for insensitivity of medical equipment is only 3 V/m. Moreover, the current standard is confined to frequencies lower than 1000 MHz while many communication devices operate at much higher frequencies[2].

New means of communication are following each other in rapid succession and also come within the reach of private users. The complexity of society and the increasingly lower costs of advanced electronic circuits promote the current boom in mobile means of communication operating via the air. Whether this is a desirable trend is beyond the scope of this study. After all, their introduction occurs on a large scale and involves not one provider but an array of mutually competitive suppliers, for all age categories

[2] The 1st edition of this standard is now in force (reference [9] in Appendix E). The 2nd edition has been issued as a draft (reference [10]).

youngsters included. The best-known forms today are ATF3- and GSM phones[3], both as a pocket phone and as a car-bound variant.

Society is insufficiently aware that pocket phones are also sources of electromagnetic fields that can disturb (medical) equipment. Typical of the Dutch situation is that a high population density combined with an anticipated high degree of penetration of pocket phones result in a high coverage, which might increase the likelihood of 'incidents'.

These facts lead to the reasonable fear that the application of medical technology at home will introduce potential hazards. That this fear is not hypothetical was demonstrated by a TNO field study in health care institutions[4] [5] [6]. That study, which has resulted in precautionary measures in hospitals[7] , revealed that ca. 49% of intramural medical equipment is sensitive to the fields of GSM pocket phones with a transmitting power of 2 W. The effect of the standard 8 W car phone was not covered by that study because their use within care institutions is not a real option. In contrast, the 8 W [8] mobile car phone is potential source of disturbances indeed in the extramural situation because many users of medical equipment are traffic participants and because other traffic participants can be in their close proximity, for example just on the other side of a window. In particular, the intramural study has revealed that patient monitors, sphygmomanometers, respirators, incubators, infusion pumps, syringe pumps and other equipment are sensitive. The sensitivity of pacemakers and hearing aids is sufficiently known[9] [10] [11] to keep them outside the current extramural study.

It should be noted that, besides the risk of life-threatening disturbances, attention must be extended to more commonly occurring harmless but highly annoying disturbances. After all, in the home situation, users have to rely on themselves: in contrast to the

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[3] ATF3 = Auto Telephone, the third channel, was closed in the Netherlands in 1999. It will also be closed in other countries (the UK will close the TACS channel around 2005). GSM stands for Global System for Mobile Communications.

[4] Influence of 2 W GSM pocket phones on 205 medical apparatuses: field measurements. TNO research report TG/95.044. 1 August 1995, Reference [1].

[5] Influence of DECT pocket phones on 131 medical apparatuses: field measurements. TNO research report TG/95.045. 1 August 1995, Reference [2].

[6] Influence of CT 2 pocket phones on 106 medical apparatuses: field measurements. TNO- research report TG/95.046. 1 August 1995, Reference [3].

[7] VIFKA: Recommendations regarding the use of pocket telephones within health care institutions, Reference [4]

[8] GSM 8 W is not used in the Netherlands any more.

[9] Irnich et al., Electromagnetic interference of pacemakers by mobile phones. PACE 19 (October 1996), pp. 1431–1446.

[10] Schlegel et al., Electromagnetic compatibility of the in-vitro interaction of wireless phones with cardiac pacemakers. Biomedical Instrumentation & Technology, November/December 1998, pp. 645–655.

[11] T.L. Fry et al., Impact of CDMA wireless phone power output and puncture rate on hearing aid interference levels. Biomedical Instrumentation & Technology, January/February 2000, pp. 29-38.

situation in institutions, there is no medical or technical staff directly available. Also from a quality point of view and for the user's peace of mind, 'harmless disturbances' are highly undesirable.

Because the cause of disturbances is often irreducible, those involved rarely recognize them as disturbances. It has been established, for example, that certain apnoea monitors do not alert users to the presence of fields generated by broadcasting stations. Split responsibilities hinder a united tackling of this problem by authorities involved: each governmental body is just responsible for part of the problem.

The study reported here aimed at secondary prevention by concentrating on damage due to failing equipment. In particular the expansion of the presence of GSM devices has made clear that a new problem is being introduced in health care. The risk of hazardous interference and annoying disturbances in the patient's home and on the streets will increase. Problems can be anticipated for such equipment as infusion devices, complex wheelchairs and oxygen provision at home.

Two contrasting developments can be noted. First, the industry, encouraged by the success of GSM devices, is working on better and faster communication systems. These systems are characterized by higher frequencies; their signals have greater bandwidths and other transmission characteristics than the currently employed systems. Second, there is opposition from the medical technology industry against new standards with more stringent EMC requirements. This resistance aggravates the EMC problems because standards lag behind new developments by definition. Currently applied transmission signals are not yet covered by standard EMC requirements. They still depart from the field strength threshold of 3 V/m although this threshold is exceeded by far by many transmitting stations. The consequences of these contrasting movements could imply higher risks to patients.

2 Execution of the study

In practical conditions at a number of lessors, sources of disturbances were activated in the vicinity of medical equipment. The aim was to test in particular equipment for which safety aspects are relevant as well as equipment that is hired out on a regular basis. A group of apparatuses as representative as possible were tested, allowing for the facilities of the lessors and available time. Measurements were performed in simulated practical conditions because it was essential to have the equipment operate under realistic conditions. Healthy volunteers were used wherever risks were involved that might evoke adverse consequences for patients. For some apparatuses, a technical 'dummy' was used in place of a patient or a healthy volunteer. If required, the participating companies assisted in operating the equipment, which obviously function more simply than intramural equipment.

2.1 Medical equipment at home

The below table presents an overview of the medical equipment examined. The apparatuses were selected in consultation with, among others, organizations that sell or lend out medical equipment. Care was explicitly taken that specific types of equipment were drawn into the tests, wheelchairs included. Details on the equipment tested and their reactions to interference are listed in Appendix A.

INFUSION PUMPS	
General (volumetric, syringe)	**2**
Drug pumps	**8**
Nutritional pumps	**5**
MONITORING *)	**6**
BEDS	
Electrically operated beds	**2**
Patient hoists	**2**
MISCELLANY	
Wheelchairs	**20**
Scooters	**14**
Drug atomizers	**4**
Respiratory support equipment	**12**
Mucus suction device	**1**
Dialysis equipment	**2**
Blood glucose monitors	**14**
Sphygmomanometers	**2**

Social alarm equipment	3
Insulin pens	2
EMG device	1
Total	**100**

*) In this equipment coronary care (ECG or pulse), respiration (motion or RESP) and blood saturation (SpO2) were built in, in varying combinations.

Medical equipment used in ambulances was left out of this study. Obviously, this equipment is also used outside the hospital and is exposed to fields from the same pocket phones as those evaluated in this study. There are reports warning that some of these apparatuses require improvement because they are used, by definition, in emergency situations[12].

Pacemakers and hearing aids were left out of the study for the reasons given above.

2.2 Pocket phones and similar emitting devices

The behaviour of pocket phones as a source of disturbances is only known for intramural use; this aspect is still in the focus of attention across the world (see recent literature[13]). To the best of our knowledge, until this report was finished, no publications have been devoted to the disturbing behaviour of a bigger variety of types of medical equipment in extramural care.

The study focused on the following types of pocket phones and the like:

- GSM 900 MHz 2 W
- GSM 900 MHz 8 W
- DCS 1800 MHz 1 W
- DECT 1900 MHz 0.25 W
- CT 0 40 MHz 0.01 W

These and other systems are described in detail in Appendix B. In that appendix, also figures from the literature are quoted, which illustrate the great extent of penetration of mobile phones. A look ahead until 2015 is also presented in Appendix B. The following explanation suffices here:

[12] Tobisch and Irnich's book, reference [5].

[13] ECRI publication, reference [7].

1) GSM 2 W was involved in the tests because this system is currently used most of all.

2) GSM 8 W was involved because the version with this transmitting power is found in the extramural situation as a mobile (car-bound) device. The GSM 8 W variant was also used to verify the anticipated correlation between likelihood of disturbances and 'transmitting power'.

3) DCS 1800 1 W is strongly expanding. It is also referred to as GSM 1800 because it will replace/extend the GSM system.

4) DECT 0.25 W was involved in the tests because this system has a fair chance of being applied in buildings.

5) CT 0 was included in the tests as an example of a commonly used system with a very low transmitting power, which is expected to hardly induce disturbances.

For an overview covering many more radiotelephone systems, the reader is referred to Appendix B, which describes why many systems were not included in the study.

Walkie-talkies and the like are beyond the scope of this study for the following reason. It was decided to focus on pocket phones that are or soon will be on the market in large numbers. Therefore, walkie-talkies and the like were not included. Security services, porters, fire brigades, police, etc frequently use these devices. Because of the high transmitting power of these devices (from 1 W to 5 W) and because of their permanent presence in the hospital, they carry a great risk of disturbing medical equipment[14] (more than most pocket phones for all types of medical equipment), but their number will not exceed those of pocket phone now or in the near future. Moreover, the users of walkie-talkies and the like (mostly professionals) can rather simply be informed and instructed with regard to disturbance aspects of these tools. For that reason, pocket phones were considered to carry a greater potential risk than walkie-talkies and the like. This was a point of departure for this study. Another reason was that the risk of disturbances by walkie-talkies and the like is not under dispute: it has been an established fact for years (see, for example, a paper published in 1979[15]).

Analogue pocket phones were not included in the study because they are increasingly losing popularity and have not and will not have the high degree of penetration digital pocket phones have. For that reason, the confusing discussion in the

[14] An MDA publication (UK) in 1997 (reference [8]) reports extensively on the influence on medical equipment of 'two-way radios' with a high transmitting power.

[15] Elektronik im Kraftfahrzeug, VDI Berichte 612, Oktober 1986, ISBN 3-18-090612-X, pp. 502-503.

literature about the question whether or not analogue pocket phones lead to more serious disturbances than do digital ones is not relevant any more[16].

In the disturbance tests, various types of pocket phones and the like were used. The following precautions were taken to guarantee that these tests were representative and could proceed smoothly:

GSM:
Two GSM arrangements were used in the study, one of which was designed as a dipole antenna configuration. That arrangement could be adjusted to both 2 W and 8 W. The other simulator had a fixed transmitting power of 2 W. Earlier trials had convincingly shown that the simulation arrangements produced a similar disturbing action as a regular GSM phone. The reason for not using a regular GSM phone was that the GSM network determines whether or not a GSM phone transmits at its maximum power (2 W). For that reason, a GSM phone could not serve as a 'constant source of disturbances' in the disturbance experiments because no reproducible results would be obtained. Reproducible results were achieved indeed with the simulation arrangements.

DCS 1800:
Use was made of a pocket phone set by the manufacturer to the required constant transmitting power (30 dBm = 1 W) through intervention in its electronic circuit.

DECT:
Use was made of a DECT pocket phone with its corresponding base station.

CT 0:
Use was made of a CT 0 pocket phone with its corresponding base station.

2.3 Patterns in the likelihood of disturbances

Relationship between likelihood of interference and transmitting power
It was examined whether more powerful pocket phones cause disturbances at a greater distance than do less powerful ones. Although this relationship seems to be obvious, it is important to explore whether in practice the distance at which interference occurs increases with increasing transmitting power of pocket phones and, if so, what pattern underlies this relationship. The theoretical formula $E = 7(\sqrt{W})/d$ is thus tested against practice. Tests of this nature are useful and are usually conducted. They may yield surprising results. For example, Segal et al. recently found

[16] Tobisch and Irnich's book (reference [5], p. 97) states (erroneously in the opinion of TNO) that analogue phones lead to stronger disturbances and that apparently the average transmitting power determines the risk of disturbances. The draft 2nd edition of standard IEC 60 601-1-2 (reference [10], p. 66) mentions the opposite, namely that digital pocket phones produce stronger disturbances than do analogue ones. This controversy (which is no longer very relevant anyhow) might be solved by means of the two rules of thumb in the next chapter of this report.

that the field strength of pocket phones in hospital rooms does not fit the theoretically expected curve but is higher under specific conditions, and lower under other conditions, than could be expected on the basis of the above 'free field' formula.

Relationship between likelihood of interference and transmission frequency
Another envisaged result of these practical tests was to find a rule of thumb for the frequency dependence of the disturbance threshold. A strong suspicion existed that higher frequencies exert less disturbing actions than lower frequencies. This assumption could be tested by systematically comparing interference phones operating at 1800 MHz with those operating at 900 MHz. The outcome has to be corrected for power differences in order to compare just the effect of differences in transmission frequency.

3 Results of the study

The results are summarized here and described in greater detail in Appendix A.

3.1 Sensitivity of medical equipment at home

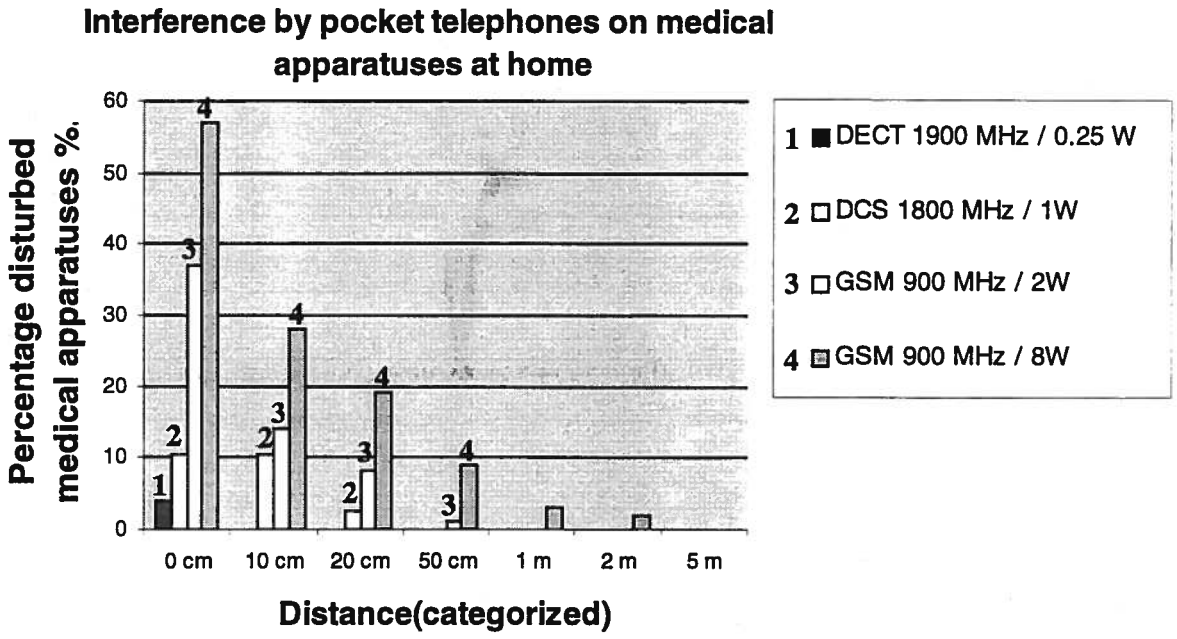
The results showed the following picture of the sensitivity to interference of extramural medical equipment.

Of the 100 medical apparatuses tested, 42 appeared to be immune to all sources of interference applied. The greatest percentage of disturbance occurred with the GSM 8 W source: 57 medical apparatuses appeared to be sensitive. The greatest distance at which interference could occur was 300 cm (respiratory support device). Of the 57 apparatuses sensitive to GSM 8 W, 19 (33%) reacted in a way that could impair safety. Of the 37 apparatuses sensitive to GSM 2 W, 17 (46%) reacted in an unsafe manner. For DCS 1800 the percentage of sensitive apparatuses was 10%, for DECT (1900 MHz) 4%, and for CT 0 (40 MHz) 3%. With all interference sources unsafe reactions occurred as well. These unsafe reactions occurred at all distances, not primarily at the shortest distances. Respiratory support devices belonged to the most sensitive apparatuses and also mostly elicited unsafe reactions. Several other apparatuses were only unsafe at distances of some centimetres until some decimetres (e.g. blood glucose monitors, infusion pump for medicine, social alarm equipment, wheelchairs and scooters). Of the 34 wheelchairs and scooters tested, 13 reacted, but the transmitting antenna of the pocket telephone had to be very close to the electronic circuits of the wheelchair concerned to elicit a reaction.

The below figure summarizes all results and can be clarified as follows. On the horizontal axis the distances are plotted at which interference with medical equipment was observed. The vertical bars indicate what percentage of medical equipment was disturbed at that particular distance or above. For example, 28% of the medical apparatuses tested were disturbed by GSM 900 MHz/8 W at a distance of 10 cm or above. Appendix A presents the results for each source of interference separately (also in tables and in graphs). That appendix also describes in detail the reactions of medical equipment.

Interference of intramural equipment by GSM 900 MHz 2 W has been tested before[17]; 49% of the intramural equipment were found to react. Comparison of these figures with the 37% found in this study for extramural equipment suggests that the extramural equipment tested in the present study is ca. 20% less susceptible to interference by GSM 2 W than the intramural equipment tested previously.

[17] Influence of 2 W GSM pocket phones on 205 medical apparatuses: field measurements. TNO research report TG/95.044. 1 August 1995.(Dutch Language only), Reference [1].



3.2 Rules of thumb for the likelihood of disturbances

The following two empirical rules of thumb reasonably describe the results obtained, as explained below. In the frequency range of 400–1800 MHz the likelihood of interference:

- increases with the square root of the transmitting power (for example, 4-fold higher power results in a 2-fold higher likelihood of interference).
- decreases in an inversely proportional fashion with increasing frequency (for example, when the frequency is doubled, the likelihood is halved).

The data presented in the histogram show that these rules of thumb fairly fit into the interference results found in this study.

According to the first rule of thumb, GSM 8 W would interfere $4^{1/2} = 2$ times as strongly as GSM 2 W. The results (see histogram) show a factor of ca. 1.7.

Comparison of GSM 2 W and DCS 1800/1 W results in the following picture. DCS 1800 transmits with a power of 1 W, 2-fold less than GSM 2 W. Hence (first rule of thumb), the likelihood of interference will be $2^{1/2}$ = ca. 1.4 times lower for DCS 1800 than for GSM 2 W. DCS 1800 transmits with a frequency twice as high as that of GSM, hence (second rule of thumb) the likelihood of interference will be twice as low. The product of these factors is 1.4 x 2 = 2.8. The results show that GSM 2 W and DCS 1800 differed in interference by a factor of ca. 3.5. It should be

noted, however, that the number of disturbances by DCS 1800 was small (4 apparatuses), so no smooth curve for this analysis could be obtained.

Appendix A shows that these two rules of thumb also reasonably hold for recent results reported in the literature and for previous results reported by TNO. The first rule of thumb can be readily explained intuitively considering that the field strength is a function proportional to $(P)^{1/2}$. The plausibility of the second rule of thumb is demonstrated in Appendix A.

CAVEAT. These rules of thumb can only be used for policy making after being further tested. It has to be tested, for example, whether the relationship between likelihood of interference and frequency is also inversely proportional for the IMT-2000 system (also referred to as UMTS), as would be expected on the basis of the second rule of thumb. The frequency of IMT-2000 is 2.1 GHz, i.e. far above the range to which the rules of thumb provisionally apply. Moreover, it should be noted that they are rules of thumb indeed, based on the 'average likelihood', so the interference behaviour of a specific medical apparatus may appreciably deviate from these rules of thumb.

3.3 Regulations for extramural equipment

Many hospitals across the world have issued a ban on the use of pocket phones. Obviously, such a ban is meaningless in the extramural situation: the use of pocket phones is more or less fact. The only decision that can be made for the extramural situation is whether or not to issue a warning that the use of pocket phones can cause disturbances. It could also be considered to formulate requirements for medical equipment to be used at home, whether or not on a voluntary basis.

Because a hospital ban on the use of pocket phones is sort of warning signal for the public at large that pocket phones may disturb medical equipment, it is useful to briefly discuss the intramural situation with a view on the extramural situation.

The argument that pocket phones pose no problem because there are no reports of incidents is not very convincing because incidents in general tend to be reported only rarely. Moreover, the disturbances referred to in this report are EMC interference incidents, which are very hard to identify and are usually not recognized by users as an EMC problem. Even if users report an incident, they will report, for example, that the apparatus failed to work but worked again soon after. It may be exactly attributable to the ban on pocket phones in many hospitals that there are few reports of accidents. As an (inadvisable) experiment, one could consider to raise the ban just to see whether incidents would occur. The possibility of disturbances in practice has convincingly been demonstrated to react seriously to them. If one wants to recognize reports, there are incidents indeed, albeit they are not always well documented as disturbances. Finally, another aspect taken into consideration is that many 'harmless' disturbances still may contribute to hazardous situations because the attention of attending personnel is needlessly diverted.

For the intramural situation, ECRI[18] and others state that the restrictive measures described above could be relaxed (but not abolished!). The ECRI advice is based, partly on Irnich and Tobisch[19]. The following points relevant to the extramural situation as well can be derived from Irnich and Tobisch findings:

- At distances ≥1 m, 10 out of 224 (predominantly intramural) medical apparatuses (4.5%) were sensitive to interference by pocket phones with a transmitting power of 0.5 W and a transmission frequency of 450 MHz.

  Note: ECRI analysed data from Irnich and Tobisch incorrectly, quoting that of the 224 apparatuses, 4 (2%) were affected at distances greater than 1 m. The number of 4 mentioned by Irnich and Tobisch referred just to the apparatuses that underwent 'realistic dangerous' interference; taking 'realistic dangerous' and 'harmless' disturbances together, Irnich and Tobisch found 10 disturbed apparatuses. This confusion was verified with the authors (see also the next item).

- For 4 of the 10 apparatuses, the interference was qualified as 'realistic dangerous'. In other words, for these 4 apparatuses, the susceptibility to interference by 0.5 W/450 MHz pocket phones was 'realistic dangerous' at a distance of ≥1 m. Two of these 4 apparatuses were apnoea monitors.

- At a distance of ≥1 m, 5 of the 224 apparatuses (2.2%) were sensitive to pocket phones with a transmitting power of 2 W and a transmission frequency of 900 MHz. The interference was not hazardous for any of these 5 apparatuses.

3.4 Apnoea monitors

A special aspect of some apnoea monitors is that the monitors detect electromagnetically whether the patient is still breathing. The monitors must not warn when there is a slowly varying electromagnetic signal really representative of the respiratory rhythm. In some apnoea monitors, the alarm in case of apnoea could be suppressed when a pocket phone was slowly moved up and down. Hence, when the patient does not breath any more and there is still a slowly varying electromagnetic signal induced by a pocket phone, such monitors do not alert as they should do.

In this study, two of the apnoea monitors tested proved to be sensitive at a distance of ≤50 cm (Nos. 6 and 7 in the table in Appendix A). Both reacted in a hazardous manner, at a distance of 5 cm and 50 cm respectively.

Tobisch and Irnich[20] tested four apnoea monitors, all of which reacted, for example to GSM 900 MHz 8 W at distances of 400, 200, 200 and 50 cm. Three monitors were qualified as 'hazardous', (See the table in Appendix D derived from Tobisch and Irnich's book.)

[18] ECRI publication 1999, reference [7].

[19] Paper 'Mobile phones in hospitals', January/February, reference [6].

[20] Tobisch en Irnich's book, reference [5].

3.5 Wheelchairs

Users of electrical wheelchairs should be warned in the instructions for use that, as a precaution, they better switch off their wheelchair before using a mobile phone. Such warnings are already common practice. The 'separation distance' prescribed in the 2nd edition of IEC 60 601-1-2 should be specified as well. Sensitive electronics should not be present on places on which luggage can be transported in the wheelchair because luggage may encompass a pocket phone which is in contact with the network and can be called up, thus potentially exerting a disturbing action. For wheelchairs that are fully unsusceptible, it should be mentioned to what pocket phones this applies (as to power and frequency; see examples in Appendix C).

3.6 Warnings for pocket phones

The Internet site http://www.gsmworld.com/technology/tech_faq.html alerts to the potential influence of pocket phones on medical equipment as follows (the last sentence refers to the medical equipment in the domestic situation):

> ***Why are there so many restrictions on using mobile phones in hospitals?*** At short range, the radio signal from a mobile phone may cause interference with electronic medical devices. At distances greater than 2 m the possibility is substantially reduced. It is possible for mobile phones to be used in designated areas of hospitals; however, you should obey any warning signs and the instructions of hospital staff. If you use electrical medical equipment in your home, we recommend that you seek the advice of your doctor or equipment supplier.
>
> **For more information please contact:**
>
> GSM Association
> Avoca Court, Temple Road, Blackrock, Co. Dublin, Ireland.
> Tel: +353 1 269 5922
> Fax: +353 1 269 5958
> Email: info@gsmworld.com
> GSM Association world wide web site address:
> http://www.gsmworld.com/

3.7 Warnings for medical equipment

In the draft second edition of IEC 60 601-1-2, the EMC standard for medical equipment, a number of requirements are formulated that did not apply yet in the first edition. For example, the documentation of medical equipment shall specify

the 'separation distance' to pocket phones of a specified power. Pocket phones should not be closer than that distance to medical equipment. The separation distance must be specified by means of a formula in which the power of the pocket phone can be filled in. If users know the transmitting power of a pocket phone, they can calculate at what distance from the equipment it may be used. It seems to be an improvement compared to the first edition of the standard because this amendment solves the problem of specification of the sensitivity to interference of new equipment. Experience must learn whether it works out satisfactorily in daily practice. The draft second edition takes 2.5 GHz as the highest frequency with the argument that, for the time being, few sources of interference will operate at frequencies higher than that. The draft second edition of IEC 60 601-1-2 explains that the modulation method is to be chosen on the basis of the properties of the apparatus to be tested. If that apparatus registers very low frequencies, for example, the field of interference should be modulated with those very low frequencies.

Moreover, the draft second edition requires an immunity threshold of 10 V/m for vital equipment, called 'life-supporting equipment' in the draft. For other equipment (including much of the equipment for home care), the threshold remains 3 V/m. The 'separation distance' is based on this threshold of 3 or 10 V/m. However, specific standards apply for specific medical apparatuses with other field strengths, including wheelchairs.

By introducing the 'separation distance', the draft second edition passes over the fact that about half of all medical equipment is insensitive to interference by pocket phones, even if the antenna is held against that medical equipment, i.e. at a 'separation distance' of 0 cm. This shortcoming in the draft could be simply circumvented by claiming explicitly in the manual for such equipment that it is insensitive to the electromagnetic fields of pocket phones. For equipment for which a situation in which a pocket phone is held against it is real (for wheelchairs, for example), this appears to be a recommendable option. On the other hand, it may be advisable to make some reservation for equipment for which the close proximity of a pocket phone is not a likely situation by specifying a minimal separation distance in the manual even if the equipment is fully insensitive to interference.

4 Conclusion

Results summarized

Medical equipment at home is comparably sensitive to fields from pocket telephones as medical equipment in the hospital: within 1 to 2 m, interference can occur. Therefore a warning about the sensitivity of extramural equipment to interference remains to be justified. On the other hand, too much fear for influences of this type is needless. No indications were found for wheelchairs being disturbed by pocket phones carried by passers-by; however, for the sake of security, users of wheelchairs who want to use a hand-held telephone themselves should first switch off their wheelchair. Foreign publications indicate that apnoea monitors must be made less sensitive if this has not been done yet. Warnings against possible interference must be added to pocket telephones and be placed on the Internet (in most cases this already happens on the basis of publications from 1995). Warnings should be added to medical equipment as well.

The new draft second edition of the EMC standard for medical equipment (applicable from around 2001) prescribes manufacturers of medical equipment to specify at how close distances near medical equipment mobile communication devices may be used in relation to their transmitted power. It is therefore necessary that manufacturers of pocket phones and the like indicate this power and that they indicate it as maximum power. Annex C to this report gives examples of this.

Warnings

The new DCS 1800 system results in few interferences. The overall conclusion is that medical equipment for home use is slightly less sensitive to interference than medical equipment in the hospital. However, outside the hospital stronger sources of interference are to be expected, such as vehicles close to the window, and no professional personnel is available if interference problems occur. Therefore, a serious warning statement should be addressed to both manufacturers of pocket phones and producers of medical equipment. That warning statement is that, on the one hand, medical equipment for home use must be made less sensitive to disturbing fields emitted by pocket phones and, on the other, manufacturers of pocket phones should (continue to) include warnings with the phones and on the Internet against using these phones near medical equipment. Medical apparatuses must be accompanied by a warning against possible interference influences. A more or less reassuring conclusion from the investigation is that no high sensitivities were found for wheelchairs: some wheelchairs were sensitive but only if the antenna of the transmitting device was brought very close to the electronic circuits of these wheelchairs.
Unless manufacturers of wheelchairs fully guarantee the insensitivity of their products, wheelchair users should bring their wheelchair in a safe situation (switch it off) before they make phone calls themselves. The results of this study do not indicate that pocket phones that are at a distance of more than a few decimetres, for example in the hands of passers-by, do disturb wheelchairs.

5 Signatures

Author(s)	Signature
R. Hensbroek, M.Sc. Manager, Safety and EMC	Was signed

Internal evaluation by	Signature
R.G.M. van Melick, Pharm.D. Manager Testing and Inspections	Was signed

Appendix A Behaviour of the equipment tested

This appendix describes all reactions of the medical equipment tested. The distance at which the reactions occurred is also mentioned. Finally, the results found are analysed.

A.1 All results in one table

The table on the next pages summarizes all results of the study: all apparatuses tested are listed as well as the sources of interference applied. For every medical apparatus tested and for each source of interference applied, the interfering effects are mentioned. The table mentions the distance from the transmitting antenna in centimeters at which the disturbance described in the footnotes occurred. No interference at all is indicated by an **n** (for no interference). A dash (–) in the table means that the equipment in question was not tested against that particular source of interference. Disturbances giving rise in practice to an unsafe situation is indicated by an **U** (for unsafe). Footnotes describe the nature of the disturbance in further detail.

Note: If no interference occurred, the test was obviously also performed at a distance of 0 cm; however, because there was no interference, no distance is mentioned. As a matter of course, if interference was only found at a distance of 0 cm, **'0 cm'** is mentioned.

Note: If interference only occurred at a short distance from the apparatus tested (relative to the dimensions of the apparatus), the site on the apparatus at which interference occurred during the study was recorded as well. For brevity sake, however, that site has not been included in this report.

Note: The footnotes apply to all influences found on the equipment as listed in every row of the table. In the few cases that the influences differed among sources of interference, multiple footnotes refer to that row, i.e. one footnote for each source involved.

No.	Medical equipment	GSM sim 2 W	GSM dipole 2 W	GSM dipole 8 W	DCS 1800 1 W	DECT 0.25 W	CT 0 0.01 W
1	Respiration/H_2O[1]	20 cm: U	20 cm: U	50 cm: U	–	n	n
2	Respiration/H_2O[2]	30 cm: U	30 cm: U	200 cm: U	–	n	n
3	Respiration/H_2O[3]	30 cm: U	2 cm: U	10 cm: U	–	n	n
4	Respiration/H_2O[4]	20 cm: U	20 cm: U	100 cm: U	–	n	0 cm: U
5	Respiration/H_2O[5]	50 cm: U	100 cm: U	300 cm: U	–	0 cm: U	10 cm: U
6	Respiration monitoring[6]	n	n	5 cm: U	–	n	n
7	Respiration monitoring[7]	0 cm: U	10 cm: U	50 cm: U	–	n	n
8	Monitoring SpO_2[8]	n	n	0 cm	–	n	n
9	Monitoring SpO_2 / respiration	n	n	n	–	n	n
10	Monitoring SpO_2 / respiration	n	n	n	–	n	n
11	Monitoring SpO_2 / respiration[9]	0 cm: U	0 cm: U	10 cm: U	–	n	n
12	Sphygmomano-meter[10]	n	n	5 cm	n	n	n
13	Sphygmomano-meter	n	n	n	n	n	n
14	Blood glucose meter	3 cm[11]	3 cm: U[12]	30 cm[13]	–	n	n
15	Blood glucose meter	30 cm: U[14]	20 cm[15]	55 cm[16]	10 cm[17]	n	n
16	Blood glucose meter[18]	1 cm	1 cm	10 cm	–	n	n
17	Blood glucose meter[19]	n	n	3 cm	–	n	n
18	Blood glucose meter[20]	3 cm	n	n	–	n	n
19	Blood glucose meter[21]	5 cm	5 cm	5 cm	–	n	n

[1] Very brief or no alarm; functioning is affected.
[2] Very brief or no alarm; functioning is affected.
[3] Very brief or no alarm; functioning is affected.
[4] Very brief or no alarm; functioning is affected.
[5] Very brief or no alarm; functioning is affected.
[6] No alarm in the presence of a moving pocket phone.
[7] Very brief or no alarm; functioning is affected.
[8] Acoustic and/or visual alarm; functioning or set-up is influenced; switching off and on usually required.
[9] Functioning disturbed; alarm is not switched on.
[10] No measurement; error message on display.
[11] Error message or display disturbed; user has to repeat the measurement.
[12] Faulty measured value.
[13] Error message or display disturbed; user has to repeat the measurement.
[14] Faulty measured value.
[15] Error message or display disturbed; user has to repeat the measurement.
[16] Error message or display disturbed; user has to repeat the measurement.
[17] Error message or display disturbed; user has to repeat the measurement.
[18] Error message or display disturbed; user has to repeat the measurement.
[19] Error message or display disturbed; user has to repeat the measurement.
[20] Error message or display disturbed; user has to repeat the measurement.
[21] Error message or display disturbed; user has to repeat the measurement.

No.	Medical equipment	GSM sim 2 W	GSM dipole 2 W	GSM dipole 8 W	DCS 1800 1 W	DECT 0.25 W	CT 0 0.01 W
20	Blood glucose meter[22]	10 cm	10 cm	40 cm	–	n	n
21	Blood glucose meter[23]	10 cm	10 cm	50 cm	–	2 cm	n
22	Blood glucose meter[24]	3 cm	2 cm	5 cm	–	n	n
23	Blood glucose meter[25]	3 cm	3 cm	8 cm	–	n	n
24	Blood glucose meter[26]	5 cm	5 cm	10 cm	–	n	n
25	Blood glucose meter[27]	5 cm	n	12 cm	–	n	n
26	Blood glucose meter[28]	n	n	3 cm	–	n	n
27	Blood glucose meter[29]	n	n	10 cm	–	n	n
28	Dialysis device	n	n	n	–	n	n
29	Dialysis device[30]	10 cm	10 cm	25 cm	–	0 cm	n
30	EMG device	n	n	n	n	n	n
31	Elec.operated bed[31]	0 cm	0 cm	15 cm	n	n	n
32	Elec.operated bed[32]	0 cm	0 cm	30 cm	n	n	n
33	Infusion pump	n	0 cm[33]	5 cm[34]	–	n	n
34	Infusion pump[35]	10 cm	10 cm	30 cm	–	0 cm	n
35	Infusion pump (drugs)	n	n	n	–	n	n
36	Infusion pumps (drugs)	n	n	n	–	n	n
37	Infusion pump (drugs)	n	n	n	–	n	n
38	Infusion pump (drugs)	n	n	n	–	n	n
39	Infusion pump (drugs)	n	n	n	–	n	n
40	Infusion pump (drugs)[36]	n	n	5 cm	–	n	n
41	Infusion pump (drugs)[37]	n	n	0 cm	–	n	n

[22] Error message or display disturbed; user has to repeat the measurement.
[23] Error message or display disturbed; user has to repeat the measurement.
[24] Error message or display disturbed; user has to repeat the measurement.
[25] Error message or display disturbed; user has to repeat the measurement.
[26] Error message or display disturbed; user has to repeat the measurement.
[27] Error message or display disturbed; user has to repeat the measurement.
[28] Error message or display disturbed; user has to repeat the measurement.
[29] Error message or display disturbed; user has to repeat the measurement.
[30] Functioning stops; acoustic + visual alarm + error message; equipment has to be switched off and on and readjusted/restarted.
[31] No longer operable; acoustic alarm.
[32] No longer operable; no alarm, but a relay is flapping audibly.
[33] False alarm; functioning unaffected.
[34] Acoustic and/or visual alarm; functioning or adjusting is influenced; switching off and on usually required.
[35] Acoustic and/or visual alarm; functioning or adjusting is influenced; switching off and on usually required.
[36] Functioning stops; acoustic + visual alarm + error message; equipment has to be switched off and on and readjusted/restarted.

No.	Medical equipment	GSM sim 2 W	GSM dipole 2 W	GSM dipole 8 W	DCS 1800 1 W	DECT 0.25 W	CT 0 0.01 W
42	Infusion pump (drugs)[38]	n	n	5 cm: U	–	n	n
43	Insulin pen	n	n	n	n	n	n
44	Insulin pen	n	n	n	n	n	n
45	Humidifier[39]	n	n	5 cm	–	n	n
46	Drug atomizer	n	n	n	–	n	n
47	Drug atomizer	n	n	n	–	n	n
48	Drug atomizer[40]	n	n	10 cm	–	n	n
49	Drug atomizer[41]	n	n	0 cm	–	n	n
50	Patient hoist	n	n	n	n	n	n
51	Patient hoist	n	n	n	n	n	n
52	Social alarm equipment[42]	20 cm: U	30 cm: U	35 cm: U	15 cm: U	n	n
53	Social alarm equipment[43]	20 cm: U	20 cm: U	30 cm: U	10 cm: U	n	n
54	Social alarm equipment[44]	40 cm: U	20 cm: U	50 cm: U	30 cm: U	n	n
55	Wheelchair	n	n	n	–	n	n
56	Wheelchair	n	1 cm[45]	2 cm: U[46]	–	n	n
57	Wheelchair	n	n	n	n	n	n
58	Wheelchair	n	n	n	n	n	n
59	Wheelchair	n	n	n	n	n	n
60	Wheelchair	n	n	n	n	n	n
61	Wheelchair	n	n	n	n	n	n
62	Wheelchair	n	n	n	n	n	n
63	Wheelchair	0 cm[47]	0 cm[48]	5 cm: U[49]	n	n	n
64	Wheelchair	n	n	n	n	n	n
65	Wheelchair	n	n	n	n	n	n
66	Wheelchair	n	n	n	n	n	n
67	Wheelchair	n	n	n	n	n	n

[37] Functioning stops; acoustic + visual alarm + error message; equipment has to be switched off and on and readjusted / restarted.
[38] Very brief alarm or no alarm; functioning is affected.
[39] Display is disturbed; equipment produces a bleep and readjusts itself; functioning is not impaired.
[40] Acoustic and/or visual alarm; functioning or adjusting is influenced; switching off and on usually required.
[41] Acoustic and/or visual alarm; functioning or adjusting is influenced; switching off and on usually required.
[42] No talking/listening connection due to a strong buzz. When the disturbance is made undone, the aid station is called after all.
[43] No talking/listening connection due to a strong buzz. When the interference source is taken away.
[44] No talking/listening connection due to a strong buzz.
[45] Slight speed reduction and/or influence on lights, direction indicator or indicators for the user.
[46] Brakes are released in the standstill position.
[47] Slight speed reduction and/or influence on lights, direction indicator or indicators for the user.
[48] Slight speed reduction and/or influence on lights, direction indicator or indicators for the user.
[49] Strong increase in speed and/or change of direction.

No.	Medical equipment	GSM sim 2 W	GSM dipole 2 W	GSM dipole 8 W	DCS 1800 1 W	DECT 0.25 W	CT 0 0.01 W
68	Wheelchair	n	n	n	n	n	n
69	Wheelchair[50]	n	n	3 cm: U	–	n	n
70	Wheelchair[51]	n	n	1 cm	–	n	n
71	Wheelchair[52]	n	n	1 cm	-	n	n
72	Wheelchair[53]	n	n	2 cm: U	-	n	n
73	Wheelchair[54]	1 cm	2 cm	5 cm	–	n	n
74	Wheelchair[55]	n	n	2 cm	–	n	n
75	Scooter	n	n	n	n	n	n
76	Scooter	n	n	n	n	n	n
77	Scooter	n	n	n	n	n	n
78	Scooter	n	n	n	n	n	n
79	Scooter	n	n	n	n	n	n
80	Scooter	n	n	n	n	n	n
81	Scooter	5 cm: U[56]	5 cm[57]	20 cm: U[58]	n	n	n
82	Scooter	n	n	n	n	n	n
83	Scooter	n	n	n	n	n	n
84	Scooter	5 cm: U[59]	5 cm[60]	5 cm: U[61]	n	n	n
85	Scooter[62]	1 cm	1 cm	1 cm	n	n	n
86	Scooter[63]	n	2 cm: U	15 cm: U	n	n	n
87	Scooter[64]	n	0 cm: U	25 cm: U	n	n	n
88	Scooter[65]	n	n	0 cm	n	n	n
89	Mucus suction device (nasal tube)	n	n	n	–	n	n
90	Pump (nutrition)	n	n	n	–	n	n
91	Pump (nutrition)[66]	n	n	0 cm	–	n	n
92	Pump (nutrition)[67]	n	n	0 cm	–	n	n
93	Pump (nutrition)[68]	0 cm	0 cm	0 cm	–	n	n

[50] Strong increase in speed and/or change of direction.
[51] Slight speed reduction and/or influence on lights, direction indicator or indicators for the user.
[52] Slight speed reduction and/or influence on lights, direction indicator or other indicators for the user.
[53] Motor stops.
[54] Slight speed reduction and/or influence on lights, direction indicator or indicators for the user.
[55] Slight speed reduction and/or influence on lights, direction indicator or indicators for the user.
[56] Strong increase in speed or change of direction.
[57] Slight speed reduction and/or influence on lights, direction indicator or indicators for the user.
[58] Strong increase in speed or change of direction.
[59] Strong increase in speed or change of direction.
[60] Slight speed reduction and/or influence on lights, direction indicator or indicators for the user.
[61] Strong increase in speed or change of direction.
[62] Slight speed reduction and/or influence on lights, direction indicator or indicators for the user.
[63] Strong increase in speed or change of direction.
[64] Strong increase in speed or change of direction.
[65] A relay connects; no consequences for the user.
[66] Acoustic and/or visual alarm; functioning or adjusting is influenced; switching off and on usually required.
[67] Acoustic and/or visual alarm; functioning or adjusting is influenced; switching off and on usually required.
[68] Acoustic and/or visual alarm; functioning or adjusting is influenced; switching off and on usually required.

No.	Medical equipment	GSM sim 2 W	GSM dipole 2 W	GSM dipole 8 W	DCS 1800 1 W	DECT 0.25 W	CT 0 0.01 W
94	Pump (nutrition)[69]	n	n	0 cm	–	n	N
95	O_2 concentrator	n	n	n	–	n	n
96	O_2 concentrator	n	n	n	–	n	n
97	O_2 concentrator	n	n	n	–	n	n
98	O_2 concentrator	n	n	n	–	n	n
99	O_2 concentrator[70]	0 cm	5 cm	20 cm	–	n	n
100	O_2 concentration meter[71]	15 cm	15 cm	50 cm	–	n	15 cm

[69] Acoustic and/or visual alarm; functioning or adjusting is influenced; switching off and on usually required.
[70] Acoustic and/or visual alarm; functioning or adjusting is influenced; switching off and on usually required.
[71] Display is disturbed.

A.2 Results ordered per source of interference by distance at which the reaction occurred

In this section all medical apparatuses tested are ordered by source of interference and by the distance at which a reaction was found. Like in the above collective table, an 'n' indicates that the equipment did not react at all. Each of the below tables is a copy of one column of the collective table. In the tables the apparatuses are ranked by distance at which an influence was found, with the most susceptible apparatus ranking first. For example, apparatuses 5 and 2 were the most sensitive to both GSM 2 W and GSM 8 W (see the collective table above). Therefore, these apparatuses rank first in the below tables for GSM 2 W and GSM 8 W ranked by their interference distance. The numbers in the third column indicate how many apparatuses reacted at or above the particular distance mentioned in the second column. These numbers are also presented graphically below the tables. The graphs fully represent the results listed in the corresponding tables. The exponential curves are the best-fitting curve through the bars, with the digits 0, 1, 2, 3, 4, 5 and 6 being taken to represent the respective distances on the horizontal axis: for example, the '0 cm' bar corresponds with exp(0). The exponential curves are merely illustrative, for visual support, and were not used for calculations.

GSM 900 MHz/2 W

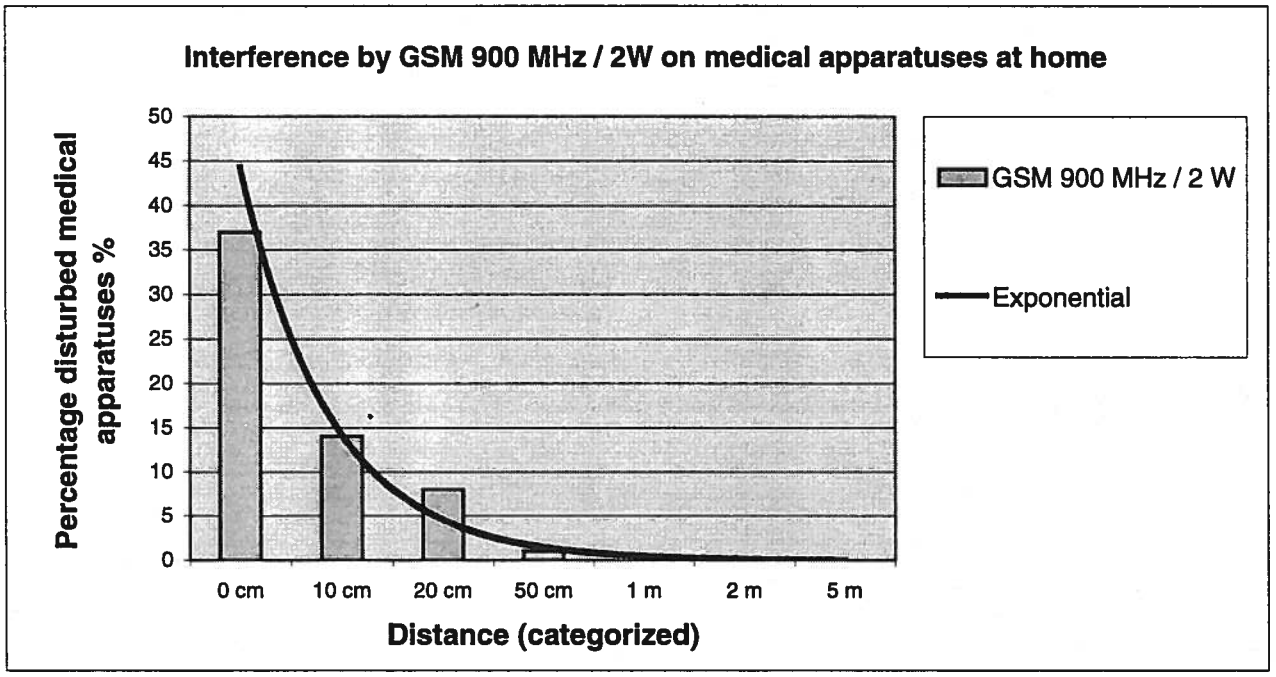
For GSM 2 W, the average distance for the two applied simulators was taken, i.e. the 2 W GSM simulator and the 2 W GSM dipole. The distances were practically equal for the two simulators. The (small) differences found are shown in the first two columns of the collective table above.

GSM 900 MHz/2 W		
5	75 cm: U	1
2	30 cm: U	
54	30 cm: U	
15	25 cm: U	
52	25 cm: U	
1	20 cm: U	
4	20 cm: U	
53	20 cm: U	8
3	15 cm: U	
100	15 cm	
20	10 cm	
21	10 cm	
29	10 cm	
34	10 cm	14
7	5 cm: U	
19	5 cm	
24	5 cm	
25	5 cm	
81	5 cm: U	
84	5 cm: U	
14	3 cm	
18	3 cm	
22	3 cm	
23	3 cm	
99	3 cm	

73	2 cm	
86	2 cm: U	
16	1 cm	
56	1 cm	
85	1 cm	
11	0 cm: U	
31	0 cm: U	
32	0 cm: U	
33	0 cm	
63	0 cm	
87	0 cm: U	
93	0 cm	37
6	n	
8	n	
9	n	
10	n	
12	n	
13	n	
17	n	
26	n	
27	n	
28	n	
30	n	
35	n	
36	n	

37	n	
38	n	
39	n	
40	n	
41	n	
42	n	
43	n	
44	n	
45	n	
46	n	
47	n	
48	n	
49	n	
50	n	
51	n	
55	n	
57	n	
58	n	
59	n	
60	n	
61	n	
62	n	
64	n	
65	n	
66	n	

67	n	
68	n	
69	n	
70	n	
71	n	
72	n	
74	n	
75	n	
76	n	
77	n	
78	n	
79	n	
80	n	
82	n	
83	n	
88	n	
89	n	
90	n	
91	n	
92	n	
94	n	
95	n	
96	n	
97	n	
98	n	



GSM 900 MHz/8 W

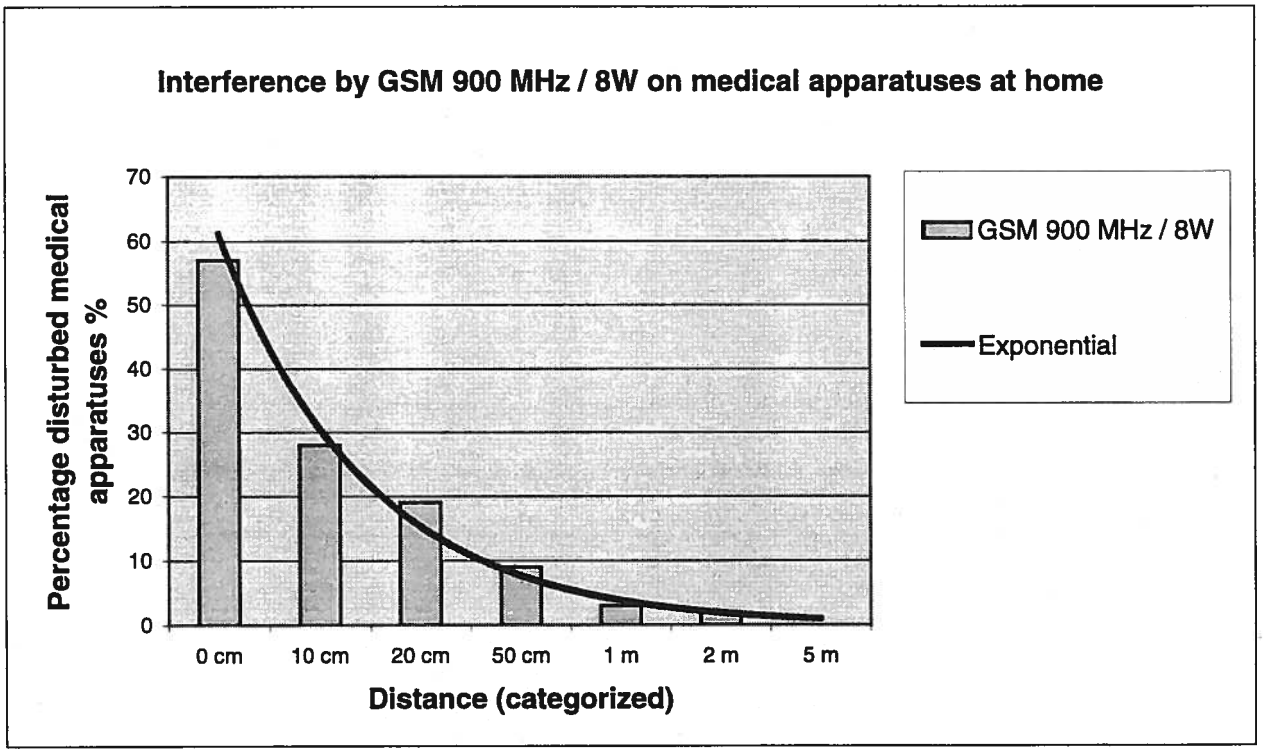
GSM
900 MHz/8 W

5	300 cm: U	
2	200 cm: U	2
4	100 cm: U	3
15	55 cm	
1	50 cm: U	
7	50 cm: U	
21	50 cm	
54	50 cm: U	
100	50 cm	9
20	40 cm	
52	35 cm: U	
14	30 cm	
32	30 cm	
34	30 cm	
53	30 cm: U	
29	25 cm	
87	25 cm: U	
81	20 cm: U	
99	20 cm	19
31	15 cm	
86	15 cm: U	
25	12 cm	
3	10 cm: U	
11	10 cm: U	
16	10 cm	

24	10 cm	
27	10 cm	
48	10 cm	28
23	8 cm	
6	5 cm	
19	5 cm	
22	5 cm	
33	5 cm	
40	5 cm	
42	5 cm: U	
45	5 cm	
73	5 cm	
63	5 cm: U	
84	5 cm: U	
12	5 cm	
17	3 cm	
26	3 cm	
69	3 cm: U	
56	2 cm: U	
72	2 cm: U	
74	2 cm	
70	1 cm	
71	1 cm	
85	1 cm	
8	0 cm	

41	0 cm	
49	0 cm	
88	0 cm	
91	0 cm	
92	0 cm	
93	0 cm	
94	0 cm	57
9	n	
10	n	
13	n	
18	n	
28	n	
30	n	
35	n	
36	n	
37	n	
38	n	
39	n	
43	n	
44	n	
46	n	
47	n	
50	n	
51	n	
55	n	

57	n	
58	n	
59	n	
60	n	
61	n	
62	n	
64	n	
65	n	
66	n	
67	n	
68	n	
75	n	
76	n	
77	n	
78	n	
79	n	
80	n	
82	n	
83	n	
89	n	
90	n	
95	n	
96	n	
97	n	
98	n	



DCS 1800 MHz/1 W

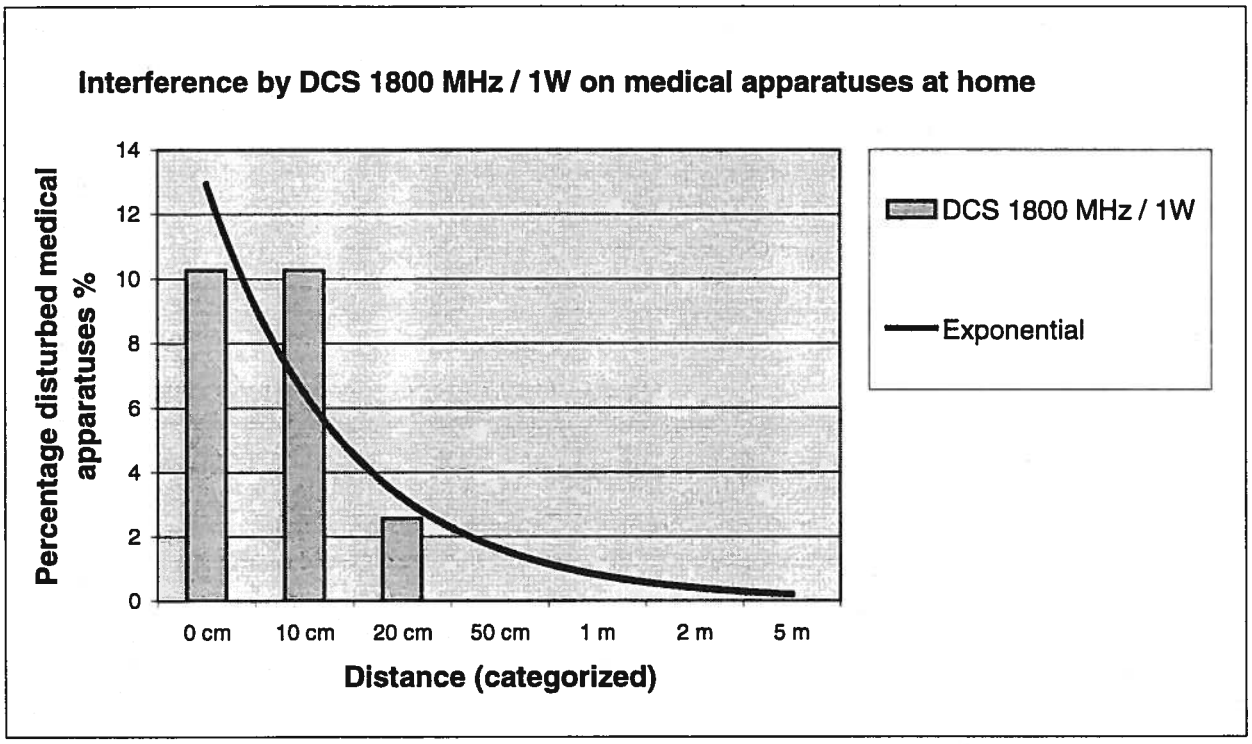
DCS 1800
1800 MHz/1 W

54	30 cm: U
52	15 cm: U
15	10 cm
53	10 cm: U
12	n
13	n
30	n
31	n
32	n
43	n

44	n
50	n
51	n
57	n
58	n
59	n
60	n
61	n
62	n
63	n

64	n
65	n
66	n
67	n
68	n
75	n
76	n
77	n
78	n
79	n

80	n
81	n
82	n
83	n
84	n
85	n
86	n
87	n
88	n



DECT 1900 MHz/0.25 W

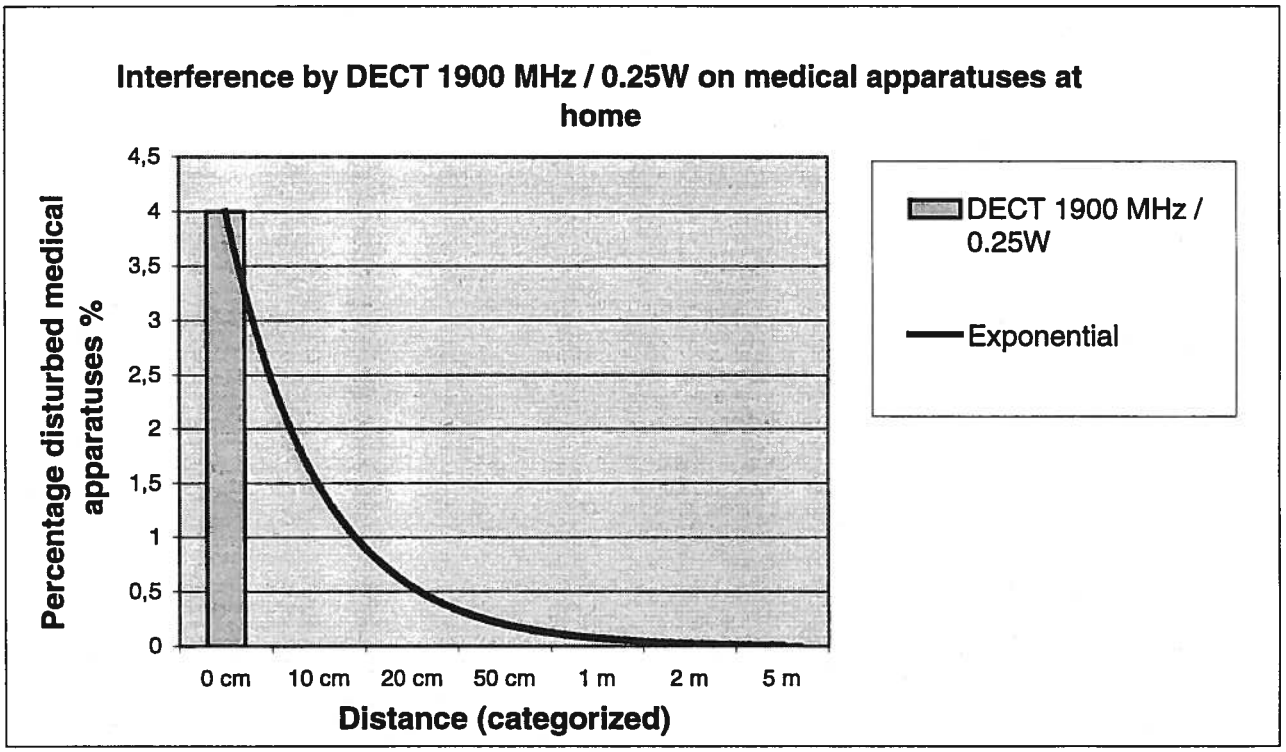
DECT
1900 MHz/0.25 W

21	2 cm
5	0 cm: U
29	0 cm
34	0 cm
1	n
2	n
3	n
4	n
6	n
7	n
8	n
9	n
10	n
11	n
12	n
13	n
14	n
15	n
16	n
17	n
18	n
19	n
20	n
22	n
23	n

24	n
25	n
26	n
27	n
28	n
30	n
31	n
32	n
33	n
35	n
36	n
37	n
38	n
39	n
40	n
41	n
42	n
43	n
44	n
45	n
46	n
47	n
48	n
49	n
50	n

51	n
52	n
53	n
54	n
55	n
56	n
57	n
58	n
59	n
60	n
61	n
62	n
63	n
64	n
65	n
66	n
67	n
68	n
69	n
70	n
71	n
72	n
73	n
74	n
75	n

76	n
77	n
78	n
79	n
80	n
81	n
82	n
83	n
84	n
85	n
86	n
87	n
88	n
89	n
90	n
91	n
92	n
93	n
94	n
95	n
96	n
97	n
98	n
99	n
100	n



CT 0 40 MHz/0.01 W

CT 0
40 MHz/0.01 W

100	15 cm
5	10 cm: U
4	0 cm: U
1	n
2	n
3	n
6	n
7	n
8	n
9	n
10	n
11	n
12	n
13	n
14	n
15	n
16	n
17	n
18	n
19	n
20	n
21	n
22	n
23	n
24	n

25	n
26	n
27	n
28	n
29	n
30	n
31	n
32	n
33	n
34	n
35	n
36	n
37	n
38	n
39	n
40	n
41	n
42	n
43	n
44	n
45	n
46	n
47	n
48	n
49	n

50	n
51	n
52	n
53	n
54	n
55	n
56	n
57	n
58	n
59	n
60	n
61	n
62	n
63	n
64	n
65	n
66	n
67	n
68	n
69	n
70	n
71	n
72	n
73	n
74	n

75	n
76	n
77	n
78	n
79	n
80	n
81	n
82	n
83	n
84	n
85	n
86	n
87	n
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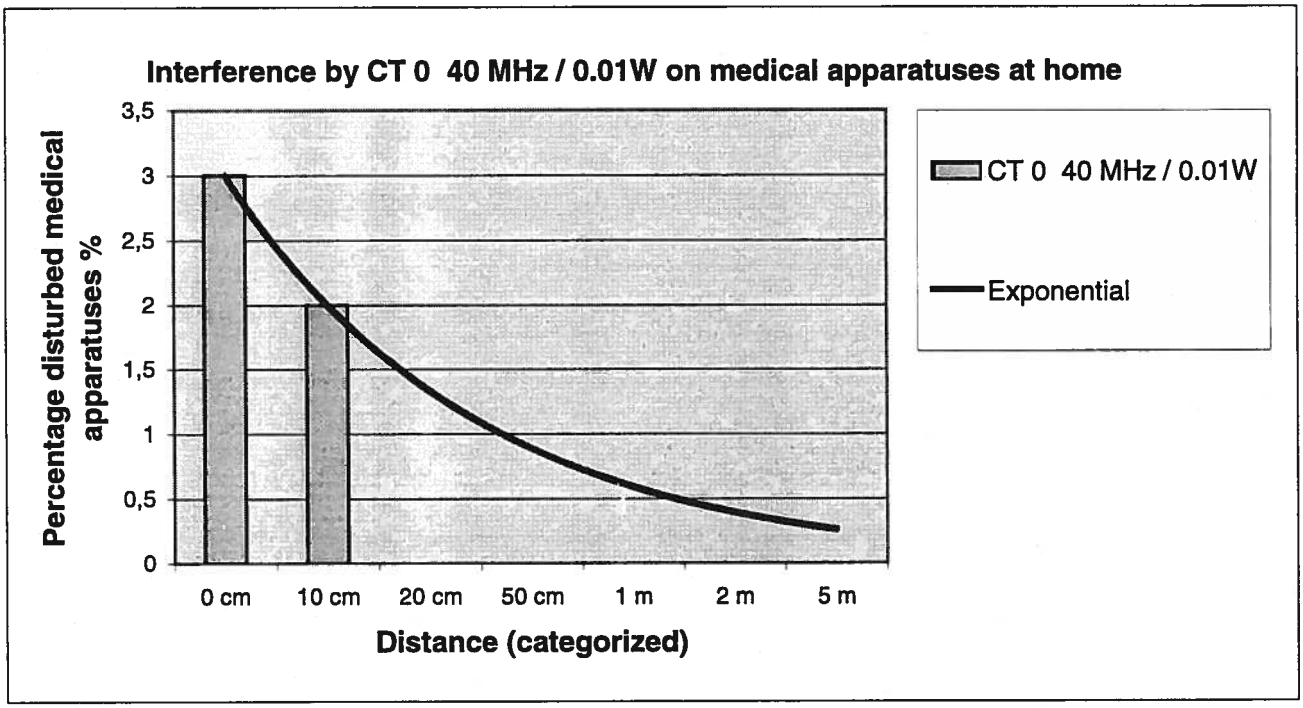
93	n
94	n
95	n
96	n
97	n
98	n
99	n



A.3 Analysis of previous results

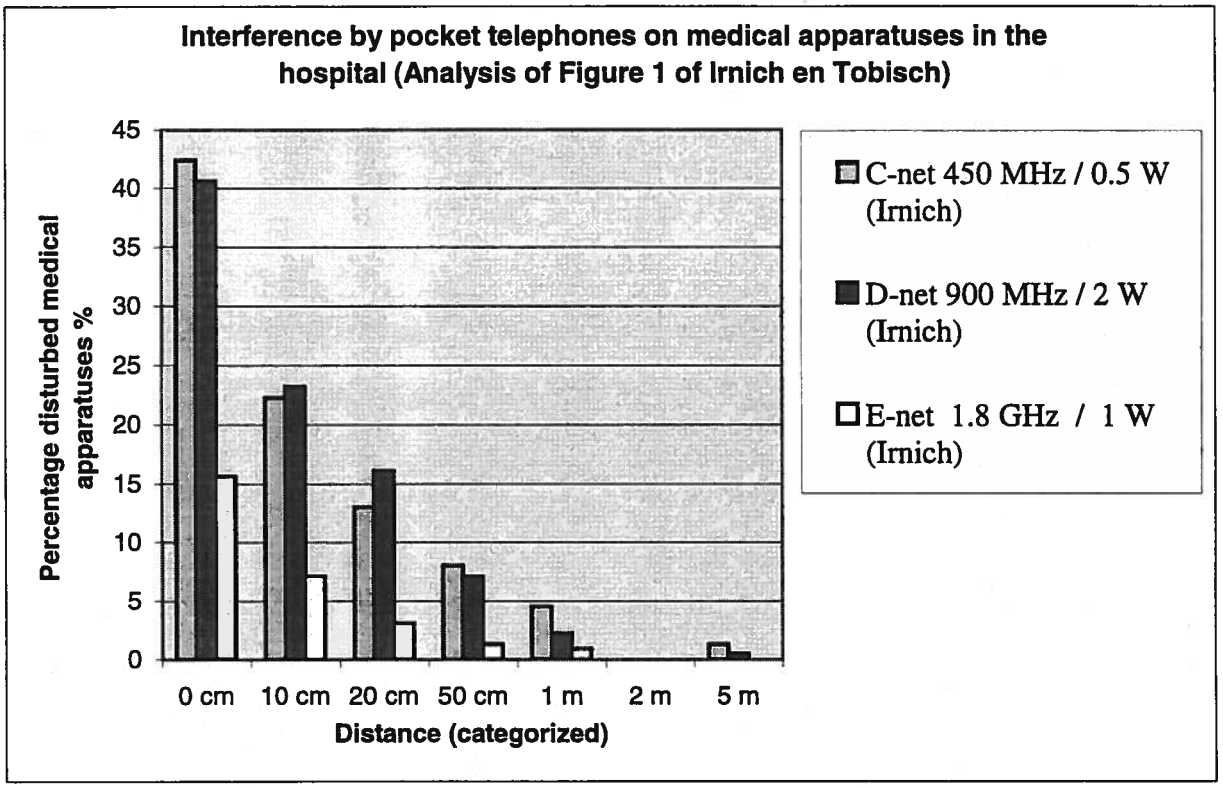
ECRI[72] notes that, on average, Irnich en Tobisch[73] found a 3-fold higher influence ('likelihood of interference') for 900 MHz than for 1800 MHz pocket phones, but do not elaborate this analysis. If one does, the results found provide more insight than they do at first sight.

This section elucidates the following two empirical rules of thumb that help explain interference outcomes published independently of one another.

These rules of thumb are as follows. In the frequency range of 400–1800 MHz the likelihood of interference:

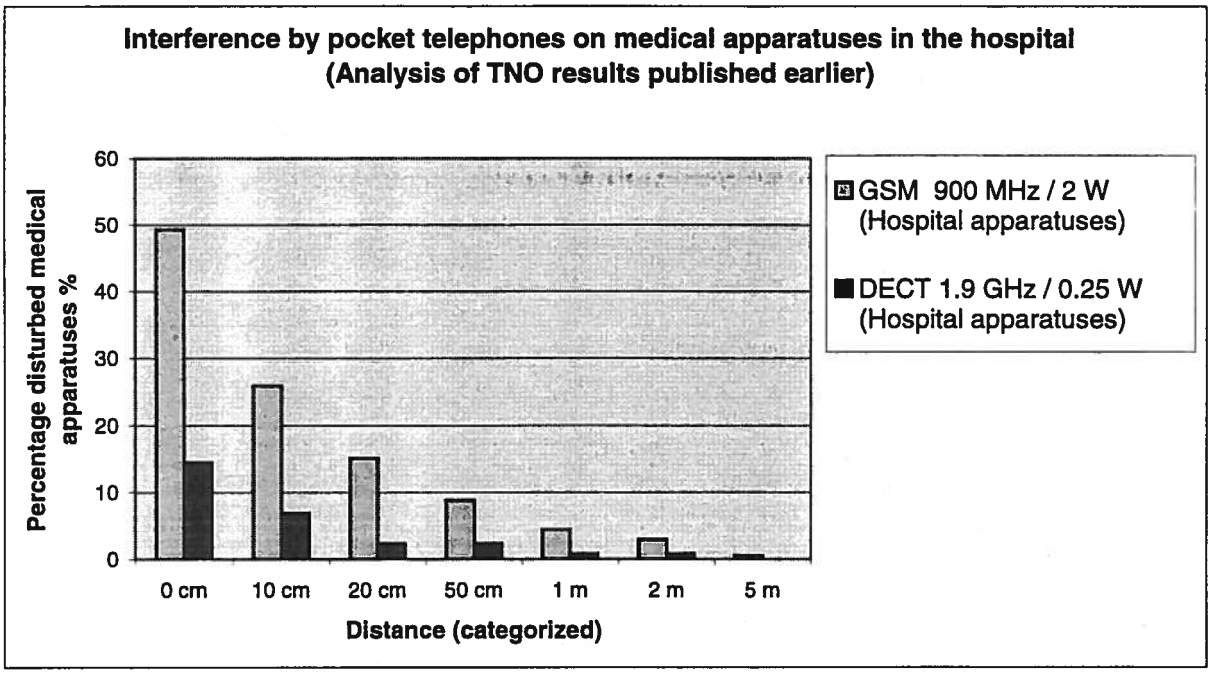
- increases with the square root of transmitting power (for example, a 4-fold higher power results in a 2-fold higher likelihood of interference).
- decreases in an inversely proportional fashion with increasing frequency (for example when the frequency is doubled, the likelihood is halved).

These rules of thumb help explain the results found by Irnich and Tobisch as follows (presented below again). The proportion of disturbed apparatuses was similar for C-net and D-net. Relative to C-net, D-net operates at a two-fold higher frequency (thus, a halved likelihood of interference) and a four-fold higher power (thus, a doubled likelihood of interference). The combined result is a similar likelihood of interference (proportion of disturbed apparatuses) for C-net and D-net. Similarly, relative to D-net, E-net has a two-fold higher frequency (thus, a halved likelihood of interference) and a two-fold lower power (thus, a $2^{1/2}$ lower likelihood of interference). The combined result is a ca. 3-fold lower likelihood of interference. This relationship can be seen in the below histogram: roughly, for each distance category the rightmost bar is three-fold smaller than the other two bars.



[72] ECRI publication 1999, reference [7].
[73] Tobisch en Irnich's book, reference [5].

The results previously found by TNO [74] [75], too, reasonably fit in with the two rules of thumb, as shown in the below histogram. DECT operates at 1.9 GHz and hence has a 2.1-fold lower likelihood of disturbance than GSM 900 MHz (1900/900). DECT has a power (0.25 W) 8-fold lower than that of GSM 900 MHz/2 W and hence 2.8-fold lower likelihood of interference ($8^{1/2}$). Thus, the combined likelihood of interference is ca. 6-fold lower likelihood of interference for DECT 1.9 GHz/0.25 W than for GSM 900 MHz/2 W. The histogram roughly shows a ratio of 4, which fairly approximates the hypothesized ratio of ca. 6.



The results of a study by MDA (UK)[76] can also be explained quite well with these rules of thumb.

Intuitively, the first rule of thumb is easily explained from the notion that the field strength is proportional to $P^{1/2}$.

The second rule of thumb can be explained plausibly by assuming that the antenna efficiency with which the circuits of medical equipment unintentionally receive the interfering signal halves when the frequency is doubled. This relationship can be explained as follows: frequencies of 400–1800 MHz correspond with wavelengths of 75–15 cm. The unintended antenna action often involves resonance on ¼ of the wavelength, i.e. 19–4 cm for frequencies of 400–1800 MHz. Apparently, sensitive circuits with a length of 19 cm are more common that those 4 cm long. According to this reasoning, smaller medical apparatuses should be less susceptible than larger ones. On average, this is probably the case, but there is no scientific proof for this proposition.

Finally, it should be noted that these rules are rules of thumb indeed and that they apply to the 'average likelihood'. The interference behaviour of a specific apparatus may deviate appreciably from these rules of thumb.

[74] Reference [1].
[75] Reference [2].
[76] MDA publication (UK) of 1997, reference [8].

Appendix B Overview of mobile radiotelephony systems

This appendix describes systems that are currently used or will be used in the foreseeable future in the Netherlands and abroad. Comparison of systems in different countries often leads to confusion because different countries are using different systems and different national (sales) names which are used liberally in the international literature without stating explicitly national designations are used. For example, the DCS 1800 system is called 'PCN' (personal communication network) in the UK and 'E-Netz' in Germany, and GSM is usually called 'D-Netz' in Germany. In the UK, an analogue system operating at 900 MHz has been introduced ('TACS'), while the analogue system in Germany ('C-Netz') operates at 450 MHz. In the USA, 900 MHz 'handheld cell phones' transmit with a power of 0.6 W, while 900 MHz (GSM) pocket phones in Europe transmit with a power of 2 W. Different powers lead to differences in the likelihood of interference with medical equipment. Such differences are reason enough to order in this appendix all systems involved. Its should be noted in this context that new standards are set or provisional standards become in force practically every year

1. General characteristics

In mobile telephony, six main groups can be distinguished each of which constitutes a specific network:

1 Cellular mobile radio systems
2 Cordless telephone systems, CT
3 Private/professional mobile radio, PMR
4 Radio local area networks, RLANs
5 Flight telephones
6 Satellite systems

1.1. Cellular mobile radio systems

A cell is an area with a diameter of, for example, some kilometres, in which a telephone communicates with a base station at a frequency different from the frequencies for adjacent cells. More distant cells can

use the same frequency (efficient use of the ether). When a cell border is passed, the system is switched automatically to a different frequency. Cellular systems use different frequencies for 'uplink' (from mobile phone to base station) and 'downlink' signals (form base station to mobile phone). Users of cellular systems are connected with the public telephone network.

First-generation cellular systems are analogue (e.g. NMT 450 introduced in 1981, TACS and ETACS in 1985, and NMT 900 in 1986). They operate at frequency bands around 150, 200, 450 and 900 MHz. In the first years of this century, analogue cellular systems will be replaced by digital cellular systems. The transition from analogue to digital will take place because the capacity (number of channels) of analogue systems has reached its limit. Digital systems have a greater capacity than analogue ones.

The first European digital system (GSM, 1991) consists in pocket phones with a peak transmitting power of 2 W, while the peak transmitting power for the first American digital system (NDAC/D-AMPS, 1991) is only 0.6 W. For the second American digital system (NADC / IS – 95) the peak transmitting power of the handheld telephones is even only 0.2 W. For that reason, there are fewer concerns about interference with medical equipment in the Americas than elsewhere. The European DCS 1800 system, which was established in 1993 and gradually implemented since 1998, works at a frequency of 1.8 GHz, while the peak transmitting power of these pocket phones is 1 W. (See below sections for more details on GSM ~~en~~ and DCS 1800.)

1.2. Third-generation mobile communication system

Digital systems are usually called 'second-generation' system as distinct from the 'first-generation' systems, the analogue cellular systems. The 'third-generation' system is now called IMT-2000 (International system for Mobile Telecommunication) for 3G (for 3rd generation). Talks about this system in the International Telecommunication Union (ITU) will probably result in a combination of two systems with internationally the strongest position world-wide, the time multiplex technology (Time Division Multiple Access, TMDA), the European standard technology currently applied in GSM, DCS 1800, CT 2, DECT and TETRA, and the code multiplex technology (Code Division Multiple Access, CDMA), which is predominantly applied in the USA in some variants. The result for the user could be a pocket phone capable of automatically switching from one technology to another and also fitting in with currently used second-generation systems. At the time of measurements in the current study, too little was known about third-generation systems to include them in practical tests.

1.3. Cordless telephony systems, CT

A cordless telephone (CT) is connected to a telephone line in place of a standard, fixed telephone. The 'mouthpiece' is a cordless device designed as sort of mobile phone and can communicate over a limited distance (within a building, for example) with the base telephone via the air. The user has access to the public telephone network. If required, multiple cordless phones can communicate with one and the same base telephone. A limited transmitting power suffices as the distance form the base apparatus is limited.

The first-generation CT systems (CT 0 en CT 1) are analogue systems for use at home. The second-generation, digital CT systems (CT 2, DECT, PHS, with a peak transmitting power ≤250 mW) have been designed as cellular systems with a transmission range limited, for example, to buildings or premises.

Cordless systems are less expensive than mobile systems because of their limited transmission range and because less facilities/functions have been built in than in mobile systems.

1.4. Private/professional mobile radio, PMR

PMR systems are systems for communication among vehicles in a fleet or among individuals provided with a 'hand unit'. Usually there is a base station through which all communication takes place. Communication is restricted to the phones included in the network; there is no connection with the public network. Examples are walkie-talkies and phones of taxis, ambulances, police, fire brigades and security services. Peak transmitted power may be appreciably higher than 2 W and may be even amount to some tens of watts for mobile phones built into vehicles and the like. In the TETRA system defined for Europe in 1997, also a hand-held phone with a peak transmitting power of 1 W is defined, but some hand-held units within the TETRA system may transmit at higher power. The TETRA system is a digital PMR system that, like GSM, DCS 1800, CT 2 and DECT, is based on a number of time slots (see below).

Some PMR systems transmit speech, some transmit data, and some transmit both. PMR systems that only transmit data are also called 'wide area networks' (WANs) as distinct from LANs (see below).

1.5. Radio local area networks, RLANs

Local area networks (LANs) are cable systems that connect computers with one another or with a central server. Computers are rendered mobile by means of a radio connection. For example, they can be placed on a lorry. A synonym of RLAN is 'wireless LAN' (WLAN). RLANs have hardly been standardized thus far. These systems have a great potential, among other reasons because the likelihood of interference is limited because of their relatively low transmitting power (see, for example, Dempsey[1], who has evaluated a 2.4 GHz WLAN with a transmitting power of 100 mW on interference and health effects.

1.6. Flight telephony

Phones of terrestrial analogue or digital cellular systems are banned in aeroplanes because of their potentially hazardous effect on (navigation) systems aboard. These cellular systems have not been designed anyhow for pocket phones switching from one cell to another with flying speed. Therefore, special flight telephone systems have been developed that are safe to aeroplane systems and connect with special ground stations providing access to the public telephone network.

1.7. Satellite systems

Satellite systems allow of communication in areas in the world with a very low population density or where ground stations cannot be built for whatever reason (sea, desert, some mountainous areas). Systems like INMARSAT and IRIDIUM have mobile/portable transmitters/receivers with a peak transmitting power of 7 W or more. In the GLOBALSTAR system a 'pocket phone' with a peak transmitting power of 1 W is being planned.

[1] M.K. Dempsey: The Physiological Effects of 2.4 GHz Frequency Hopping Radios. WLI Forum, Wireless LAN Interchangeability Forum, Sunnyvale, CA, http://www.wlif.com. The publication is accessible on: http://www.wlif.com/pdfs/physio.pdf

2. Aspects covered by this study

2.1. Cellular mobile radio systems

The digital cellular systems **GSM** and **DCS 1800** were included in this study because an explosive growth in the use of pocket phones in Europe is anticipated. No analogue system was included because analogue cellular systems will be replaced by other systems in the next few years.

2.2. Cordless telephony systems, CT

Cordless telephony systems were included in the study because the use of large numbers of such systems at home is anticipated. An analogue (**CT 0**) and digital CT system (**DECT**) were included in order to verify whether these systems do not interfere indeed with medical equipment, as may be expected on the basis of the low peak transmitting power of CT phones.

2.3. Private/professional mobile radio, PMR

PMR systems were not included in the study because such systems are not going to be used in or around private houses in large numbers. Although it cannot be excluded that medical equipment at home is disturbed by some equipment within PMR systems transmitting outside the house due to the high transmitting power of some of these systems, it will not occur frequently enough to justify inclusion of such equipment in this study. Besides, it is an established fact that strong transmitters of the PMR type can interfere with electronics.

2.4. Radio local area networks, RLANs

RLANs were not involved in the study because no large numbers of these systems will be used and because no interference with medical equipment at home is to be expected.

2.5. Flight telephony

These systems were not included because no interference with medical equipment at home is to be expected.

2.6. Satellite systems

Satellite systems were not included because, for the time being, no large numbers of 'satellite pocket phones' were to be expected and because they still do not function well within houses (only close to a window and in 'sight' of the satellite).

3. Characteristics of signals transmitted by pocket phones

Prior to describing in more detail the systems included in this study, we will first explain three important concepts related to the characterization of signals (and hence fields) transmitted by pocket phones, viz. the concepts of 'time multiplex', 'automatic adjustment of the transmission level' and 'spectrum'.

3.1. Time multiplex, a special mechanism in some systems

In the GSM system, for example, a particular channel is shared by 8 phones which transmit by turns: when one phone transmit, the other seven remain silent. The turns are changes at so rapid succession that the users do not notice it. This process is named 'time multiplex', with multiple phones 'multiplexing' in time. Every phone has its own 'time slot' during which it transmits, e.g. with 2 W peak power. Subse-

quently, the phone is 'silent' for 7 time slots. Thus, the average transmitting power of phones with a peak power of 2 W is 0.25 W Ave (2:8). As the time multiplexing process proceeds through microprocessors it is a digital system. Time multiplex is applied in various systems including GSM, DCS 1800, CT 2, DECT and TETRA.

3.2. Automatic adjustment of the transmitting power of pocket phones

If the base station receives well the signal of the pocket phone, the power of the phone is automatically down-tuned in order to safe battery capacity and to reduce the risk of interference between pocket phones in different cells. This 'adaptive power control' is done by the system without the user noticing any effect on the speech connection.

3.3. Spectrum

Systems based on time multiplex (such as GSM, DCS 1800, CT 2, DECT and TETRA) operate with frames containing the time slots. The repeat frequency of the frames depends on frame length, which is determined on its turn by the number of time slots. For GSM and DCS 1800, the frame length is 4.615 ms, hence the frame repeat frequency is 217 Hz. A GSM or DCS 1800 frame contains 8 time slots of 0.577 ms each. The frame repeat frequency is 100 Hz for DECT and 500 Hz for CT 2. Thus, the spectrum of these systems also encompasses frequencies of 217, 100 and 500 Hz and, in addition, their harmonics (i.e. multiples of 217, 100 and 500 Hz).

Because, in some communication systems, there are periods in system control longer than those of the time slots and frames, the signal spectrum of GSM, DECT, DCS 1800 and TETRA also encompass low frequencies (e.g. 2 and 8 Hz and their multiples for GSM and DECT).
Because GSM, DECT, DCS 1800, CT 2 and TETRA are pulsed systems, magnetic fields are formed in the close vicinity of the telephones. Linde and Mild (in an EC report) and Andersen et al. (in an EC rapport) measured low-frequency magnetic flux densities up to 1.8 μT rms.

3.4. GSM

The Global System for Mobile communications, GSM (in French: Groupe Special Mobile) is a European standard designed to function worldwide via 'roaming agreements' among network operators. It is a cellular system. Initially, the base stations were built primarily along motorways – hence the designation 'mobile'. With ever more base stations, also in cities, the percentage of cover of GSM improves and its character shifts from 'mobile' towards 'hand-held/pocket'. The frequency bands are close to those of TACS/NMT systems in order to facilitate the gradual transition of these analogue systems to GSM.

The bands of the older systems, which will be replaced by GSM on the long run, lie 'in between' the GSM bands:

- CT 1: 914–915 MHz and 959–960 MHz,
- TACS/NMT: 890–905 MHz and 935–950 MHz,
- CT 2+: 944 and 948 MHz.

3.5. DCS 1800

The Digital personal Communication System, operating at 1800 MHz, is the successor and extension of the GSM system. Its technical configuration bears strong resemblance with the GSM system. Like GSM, it has 8 time slots and its frame frequency is 217 Hz.

3.6. DECT

The Digital Enhanced (European) Cordless Telecommunication system has been designed for cordless communication with PABX telephone exchanges, a specific type of switchboards, and for cordless communication in a wireless LAN. It is a cellular, digital system with a low transmitting power (a low range, ca. 200 m). It is used predominantly within offices. Its technical configuration bears strong resemblance with the GSM system. Like GSM, it has 8 time slots and a repeat frequency of 217 Hz.

4. Characteristics of systems

The characteristics of the most common systems are listed in the below table.

CELLULAR ANALOGUE	
TACS / NTACS / ETACS	**Total Access Communication Systems (ETACS = Extended TACS, with 7% more channels than TACS)** ANALOGUE/CELLULAR; frequency bands between 860 and 960 MHz In the UK, it is named Vodafone analogue network or Cellnett analogue network
	E.g. UK, Ireland, Austria, Italy, Spain, 1985 (will disappear in 2005). Highest peak transmitting power for pocket phones 0.6 W (ETACS also higher) Transmitting power of TACS pocket phones is not adjusted automatically, in contrast to ETACS Definition document: MPT 1324 (1987), TACS Spec. (1991)
NMT 450	**Nordic Mobile Telephone, operating at ca. 450 MHz** ANALOGUE/CELLULAIR; 453–458 MHz and 463–468 MHz In the Netherlands, NMT 450 was also named ATF2 = AutoTeleFoon 2
	E.g. western Europe, 1981 Highest peak transmitting power of pocket phone 1.5 W Transmitting power is not adjusted automatically The Dutch ATF2 network was closed in 1995. The German C-net is an NMT 450 system working with 'handies' of 0.5 W[2]. There were also C-net portable devices working on a big battery and operating at 2.5 W. In the literature, the latter devices are sometimes referred to as 'C-net 2.5 W'.
NMT 900	**Nordic Mobile Telephone** ANALOGUE/CELLULAR; 890–915 MHz and 935–960 MHz In the Netherlands, NMT 900 was also called ATF3 = AutoTeleFoon 3
	In the Netherlands, Scandinavia, Switzerland, etc., 1986. The Dutch ATF3 network was closed in 1999. Highest peak transmitting power for pocket phone: 1 W. Transmitting power is adjusted automatically.

[2] Tobisch and Irnich's book, reference [5]

AMPS	**Advanced Mobile Phone Service** ANALOGUE/CELLULAR; 824–849 MHz and 869–894 MHz
	North America, for example. Highest peak transmitting power for pocket phones: 0.8 W Transmitting power of pocket phones is not adjusted automatically.
CELLULAR DIGITAL	
GSM	**Global System for Mobile Communications** DIGITAL/CELLULAR; 880–888 MHz, 890–915 MHz, 925–933 MHz, 935–960 MHz
	Europe, Asia, Pacific, etc., 1991 Frame frequency 217 Hz Highest peak transmitting power for pocket phone: 2 W peak ± 2 dB (–37%/+58%) Average transmitting power for pocket phone: 0.25 W Ave ± 2 dB (–37%/+58%) Vehicle set: up to 20 W Transmitting power of pocket phones is adjusted automatically. NOTES: • The '910 MHz' version of the GSM standard is currently in use in Europe; the standard defines various other bands. • In the UK, the commercial names of GSM are Vodafone digital network and Cellnett digital network. • The German D-net is a GSM system. Definition document: ETS 399 577 (ETSI GSM 05.05)
DCS 1800	**Digital personal Communication System, operating at ca. 1800 MHz** DIGITAL/CELLULAR; 1710–1785 MHz, 1805–1880 MHz
	Europe, 1993 (gradually implemented in the Netherlands from 1998) Frame frequency 217 Hz Highest peak transmitting power for pocket phone: 1 W peak ± 2 dB (–37%/+58%) Average transmitting power for pocket phone: 0.125 W Ave ± 2 dB (–37%/+58%) Vehicle set: up to 20 W Transmitting power of pocket phones is adjusted automatically. NOTES: • Is also named 'GSM 1800' because its modulation is comparable to that of GSM. • In the UK, it is called PCN (Personal Communication Network), with the commercial names Orange DCS 1800 and One 2 One DCS 1800. • The German E-net is a DCS 1800 system. Definition document: ETS 399 577 (ETSI GSM 05.05)

NADC/D-AMPS	**North American Digital Cellular/Digital Advanced Mobile Phone Service** DIGITAL/CELLULAR; 824–849 MHz and 869–894 MHz
	North America, for example, 1991 Frame frequency 50 Hz Highest peak transmitting power for pocket phone: 0.6 W Transmitting power of pocket phones is adjusted automatically. Definition document: IS 54, IS 55, IS 56, IS 136
NADC/IS-95	**North American Digital Cellular** DIGITAL/CELLULAR; 824–849 MHz and 869–894 MHz
	North America, for example, 1995 Frame frequency 50 Hz Highest peak transmitting power for pocket phone: 0.2 W Transmitting power of pocket phones is adjusted automatically Definition document: IS 95
PCS	**Personal Communication Systems (Services?)** DIGITAL/CELLULAR; 1850–1910/1930–1990 MHz
	E.g. USA, 1996 Open system which includes several other systems (e.g. a type of DCS 1800 operating at 1900 MHz, a type of IS-95, a type of PHS and a type of DECT) NOTE • See also 'PCN' under DCS 1800. PCS and PCN are highly similar.
IMT-2000	**International Mobile Telecommunications 2000.** Worldwide standard for how third-generation mobile telecommunication systems will develop[3]. See UMTS for details.
UMTS	**Universal Mobile Telecommunications System.** The European CEPT standard for IMT-2000. Will operate in Europe in the bandwidths 1900–1980 MHz, 2010–2025 MHz and 2110-2170 MHz for terrestrial systems. In Europe, the bands 1980–2010 MHz and 2170-2200 MHz are reserved for mobile satellite services, UMTS included. Definition document: CEPT/ERC/DEC(99)25 dd. 29 November 1999. This document does not specify transmitting power[4]. UMTS will start in 2002. On the longer run (possibly in 2008) the GSM network will merge into UMTS.
CORDLESS ANALOGUE	
CT 0	ANALOGUE; 31 and 40 MHz (frequencies in the Netherlands and Spain) E.g. in Europe, USA, Australia, Asia Highest peak transmitting power for pocket phone: 10 mW. Transmitting power of pocket phones is not adjusted automatically.
CT 1 CT 1+	ANALOGUE; 914/959 MHz ANALOGUE; 885/932 MHz
	Highest peak transmitting power for pocket phone: 10 mW Transmitting power of pocket phones is not adjusted automatically.

[3] http://www.itu.int/imt/vision.html
[4] European Radiocommunications Committee (ERC), http://www.ero.dk

CORDLESS DIGITAL	
CT 2 CT 2+	DIGITAL/CELLULAR; 864.1–868.1 MHz DIGITAL/CELLULAIR; 944–948 MHz
	Defined worldwide in 1989; popular in Australia and the Far East. Frame frequency: 500 Hz (2:1 time multiplex) Highest peak transmitting power for pocket phone 10 mW peak; Ave 5 mW. Transmitting power of pocket phones is adjusted automatically. Definition document: ETS 300 131
DECT	**D**igital **E**nhanced (**E**uropean) **C**ordless **T**elecommunications DIGITAL/CELLULAR; 1880–1900 MHz
	Europe, 1994 Frame frequency 100 Hz Highest peak transmitting power for pocket phone: 0.250 W peak Average transmitting power for pocket phone: 0.01 W Ave Transmitting power of pocket phones is not adjusted automatically. NOTES • Channels are shielded against tapping by means of a Cyclic Redundancy Code (CRC). • Definition document: ETS 300 175-2 (1993), I-ETS 300 176 TBR6 • Blue tooth is a new technology for WLAN communication between apparatuses over a distance of 10–100 m. This technology will possibly enter the market in 2001. It bears resemblance to DECT but operates at 2.45 GHz. It is a worldwide free band, which enhances the likelihood of worldwide standardization. The bandwidth is 80 MHz. The transmitting power will probably be ca. 10–100 mW but might be higher.
PHS	**P**ersonal **H**andy phone **S**ystem DIGITAL/CELLULAR; 1895–1918 MHz
	Japan, 1994 Frame frequency 200 Hz Highest peak transmitting power for pocket phone: 80 mW Transmitting power of pocket phones is not adjusted automatically. Definition document: RCR Spec. Std 2B (TBA)
PRIVATE/PROFESSIONAL MOBILE RADIO (PMR)	
TETRA	**T**rans **E**uropean **T**runked **Ra**dio system; professional applications DIGITAL; 380–385 MHz and 390–395 MHz
	Defined for Europe in 1997 Frame frequency 17.65 Hz Highest peak transmitting power for pocket phone: 1 W and higher Transmitting power of pocket phones is adjusted automatically. Definition document: ERC/DEC/(99)04 dated 10 March 1999 (this document does not specify transmitting power).

RADIO LOCAL AREA NETWORKS (RLANs)	
HIPERLAN 1)	**High-Performance European Radio Local Area Network** DIGITAL; bands around 5.2 GHz (in 1996)
	Defined world-wide in 1996 (?) Highest peak transmitting power of pocket phone: 1 W. Definition document: prETS 300 652
HIPERLAN 2)	**High-Performance European Radio Local Area Network** DIGITAL; 17.1–17.3 GHz
	Defined world-wide in 1996 (?) Highest peak transmitting power for pocket phone: 0.1 W. Definition document: prETS 300 652
WLAN	See under DECT
FLIGHT TELEPHONY	
INMARSAT AERO	**International MARitime SATellite, AERO version** DIGITAL/CELLULAR; frequency bands around 1.6 GHz
	Defined world-wide Highest peak transmitting power for mobile unit: 25.5 dB W Transmitting power of mobile units is adjusted automatically.
SATELLITE SYSTEMS	
INMARSAT	**International MARitime SATellite** Various CELLULAR systems, both ANALOGUE and DIGITAL ones; frequency bands around 1.6 GHz
	Most systems have a worldwide coverage except for the poles. Highest peak transmitting power for mobile unit: 33–36 dB W Transmitting power of mobile units is adjusted automatically in some IMMARSAT systems but not by others.
IRIDIUM draft specification	Frequency bands near 1.6 GHz Highest peak transmitting power for mobile units: 7 W Transmitting power of mobile units is adjusted automatically. The 70 satellites of the IRIDIUM network will be destroyed in default of buyers (source NRC Handelsblad newspaper of 1 April 2000)
GLOBALSTAR draft specification	Frequency bands near 1.6 and 2.5 GHz Highest peak transmitting power for mobile units: 1 W and higher. Transmitting power of mobile units is adjusted automatically.

PR 27	Radio amateurs 26.960–27.410 MHz 4 W

5. Extent of penetration

Early in 2000, ca. 40% of all Europeans was in the possession of a mobile telephone. The Fins ranked first, with 70%. In 1999, a total of 284 million mobile phones were sold across the world.[5] In the same year, also the 200 millionth GSM telephone was sold.[6] According to the GSM Association[7], an industrial organization, 4 new GSM customers joined the ranks every second in the beginning of 2000. This means an annual increase in number of GSM customers of 63 million ('angle of inclination' of early 2000).

According to Dutch TV newscast, there were some 6 million Dutch mobile callers on 6 April 2000. According to NRC Handelsblad newspaper, there were slightly over 15 million mobile callers on that date in the UK.

The expected worldwide expansion of mobile telephony is reflected in the below table.[8] As can be read from the table, markets in North America and Europe will be the first to reach the saturation point. Even in 2015, the markets in Asia, Africa and South America will still be far away from that point, even if population growth is not allowed for. These figures were also cited in the magazine "Elektronica" of November 1999.

Customers in millions at year end	1995	2000	2005	2010	2015
EU 15	22	113	200	260	300
North America	36	127	190	220	230
Asia Pacific	22	149	400	850	1400
Rest of world	7	37	150	400	800
Total	87	426	940	1730	2730

It is anticipated that mobile telephones will outnumber fixed phones by 2010.

6. Concepts

Some frequently used concepts in mobile telephony are listed below.

Analogue system	A system in which speech signals directly modulate a carrier wave, just like in frequency-modulated (FM) and amplitude-modulated (AM) radio signals. Consequently, the communication signal is analogous to the speech signal.
Digital system/digital network	The speech signal is converted to ones and zeros (on and off), which modulate the carrier wave.

X

klein beetje?

[5] NRC Handelsblad newspaper, 14 March 2000.
[6] Elektronica monthly, November 1999
[7] http://www.gsmworld.com/technology/tech_faq.html
[8] http://www.siriuscomm.com/umts_regdirect.htm :

Cellular system/cells	A cell is an area within which a telephone communicates with a base station at a frequency that cannot be received in adjacent cells. In contrast, telephones in cells further away can transmit at the same frequency (efficient use of the ether). When passing a cell boundary, the system switches automatically to a different frequency. Both the older analogue (NMT) systems and the newer systems GSM, DECT, CT 2, DCS 1800 and TETRA are cellular systems.
Base station/fixed station	A fixed antenna usually aimed at (part of) a cell via which mobile or pocket phones communicate. The base station gives the phone access to the telephone network in which exchanges regulate the traffic.
Percentage of cover	A figure reflecting the percentage of a given area in which a mobile or pocket phone can be reached
Mobile phone	A phone intended for use in a vehicle. It can be used outside the vehicle after being charged in the vehicle.
Pocket phone/Handy	Intended to be carried in a jacket pocket. It must be charged in a charger and/or by changing the battery.
Portable device	Device in a bag or case that also contains a powerful battery to prolong the capacity. Often a charger is built in to charge the battery from the 230 V electricity grid or form the car battery. Application: communication in the absence of electricity.
Amateur band/Citizen's Band (CB) '27 Mc rig'	In a frequency range around 27 MHz, users may transmit without a licence but under specific conditions (e.g. the transmitting power may not exceed 4 W, and only the FM modulation may be used). In the USA, this frequency is called the 'amateur band' or the 'Citizen's Band' (CB). In the Netherlands, it is often referred to as '27 Mc', where 'c' stands for cycle, as a synonym of Hz (hertz). This band is frequently used illegally, often with too high a transmitting power. Worldwide, radio amateurs have been allocated frequency bands other than 27 MHz, in which transmission is subject to fairly stringent restrictions. Amateurs who fail to meet these conditions are banned from radio ham societies and may lose their broadcasting licence.
Pager	A device that can receive messages which are displayed on a small screen and/or can be listened in. The messages are usually entered via the telephone. Some pagers are also able to send a return message.

Power (in W = watt)	Energy (in joule, J) per second.
Average (Ave) power	For example, a system transmitting for 1 second at a power of 2 W followed by 7 seconds of 'silence', 1 second of transmission, and so on, transmits with an average power of 2:8 = 0.25 W Ave. In that case, the average transmitting power is 0.25 W Ave.
Peak transmitting power	In the above example, the system transmits at its peak power in each transmission period of 1 second. Consequently, its peak transmitting power is 2 W.
LAN and RLAN	Local Area Network (see description in the section about RLANs (1.5 in this Appendix).

7. Units and quantities

ms	= 0.001 second	
mV	= 0.001 V	
W	= watt = joules per second	
mW	= 0.001 W	
Hz	= cycles per second	
kHz	= 1000 Hz	
MHz	= 1000,000 Hz	1 MHz = 1000 kHz
GHz	= 1000,000,000 Hz	1 GHz = 1000 MHz
dB	20 log(A/B) ['voltage dB'] = = 10 log (C/D) ['power dB']	A/B is a voltage ratio; C/D is the corresponding power ratio.
dBm	10 log(P/0.001)with P in W	0.001 W = 1 mW; hence the 'm' in dBm.
dBW	10 log(P) with P in W Often written dB (with the W omitted) if it is clear from the context that the unit referred to is dBW.	dBW = dBm – 30

Appendix C Peak power of various types of pocket phones and the like

Type	A/D	Peak power[21]	Average power	Frequency
GSM European, e.g. D-net (D)	D	2 W (handy) 8 W (mobile)	0.25 W (handy) 1 W (mobile)	900 MHz „
Cell(ular) phone e.g. D-AMPS (USA)	D	0.6 W (hand-held) 3 W (mobile)	0.2 W (hand-held) 1 W (mobile)	900 MHz
Cell(ular) phone e.g. AMPS (USA)	A	0.8 W (hand-held)	0.8 W (hand-held)	band around 860 MHz
NMT analogue e.g. C-net (D)	A	0.5 W (handy) 2.5 W (portable) 15 W (mobile)	0.5 W (handy) 2.5 W (portable) 15 W (mobile)	450 MHz „ „
NMT 900 e.g. ATF3 (NL)	A	1 W	1 W	band around 900 MHz
TACS, NTACS, ETACS (until 2005) e.g. Vodafone (UK) and Cellnett (UK)	A	0.6 W	0.6 W	band around 900 MHz
DCS 1800, GSM 1800 e.g. E-net (D) and PCN (UK)	D	1 W	0.125 W	1800 MHz
DECT	D	0.25 W	0.01 W	1.9 GHz
FHSS LAN	D	0.1 W	0.1 W	2.4 GHz
CT 0	A	10 mW	10 mW	31 and 40 MHz
CT 1	A	10 mW	10 mW	900 MHz band

[21] 'Handy' is the term commonly used in Germany for pocket phones, 'portable' for portable equipment which used to be carried as 'shoulder bag', and 'mobile' for equipment built in in a vehicle.

CT 2	D	10 mW	5 mW	900 MHz band
Walkie-talkie	A	2.5 W	2.5 W	435 MHz
CB (citizen band in USA and UK)	A	4 W	4 W	27–28 MHz
UHF walkie-talkie (USA: business band)	A	5 W	5 W	450/465 MHz
Mobile radio (USA)	A	20 W	20 W	465 MHz
Amateur radio (USA)	A	5 W	5 W	465 MHz

Appendix D Apnoea monitors listed in reference [5]

Distances in cm to apnoea monitor

Producer	Device type	Serial number	C 0.5 W	C 2.5 W	D 2 W	D 8 W	E 1 W	DECT	Notes
GeTeMed	VG 100 IMP	01 95442	5	150	10	200			Respiration and cardiac rhythm are detected falsely. The equipment resets and restarts automatically.
Graseby	MR10S	820		10	5	50	1		The equipment resets and restarts automatically or must be switched on by hand. Heart frequency is falsely detected
Osypka	Baby Guard BS 1000	8901493	150	400	70	200	7		Movement of child is falsely detected.
Siss	Babycontrol AÜW 1	BC 7569	800	1400	40	400	3		Respiration and cardiac rhythm are falsely detected.

Remark (not from [5]):

C = NMT 450 MHz (analogue)

D = GSM 900 MHz

E = DCS 1800

Appendix E References

[1] Influence of 2 W GSM pocket phones on 205 medical apparatuses: field measurements. TNO research report TG/95.044. 1 August 1995 (Dutch Language only).

[2] Influence of DECT pocket phones on 131 medical apparatuses: field measurements. TNO research report TG/95.045. 1 August 1995 (Dutch Language only).

[3] Influence of CT 2 pocket phones on 106 medical apparatuses: field measurements. TNO- research report TG/95.046. 1 August 1995 (Dutch Language only).

[4] Recommendations regarding the use of pocket telephones within health care institutions, VIFKA, 1 September 1995 (VIFKA is now called Netherlands ICT Association). This report has been distributed worldwide and contains abstracts of references [1], [2] and [3].

[5] Tobisch, Rolf: Mobilfunk im Krankenhaus – Einfluβ von Mobiltelefonen auf lebensrettende und lebenserhaltende Medizintechnik [Mobile phones in hospitals: the influence of mobile phones on life saving and life sustaining medical equipment]. Rolf Tobisch, Werner Irnich. Situation January 1999; Schiele & Schön, Berlin. ISBN 3-7949-0640-3.

[6] Irnich, W. and R. Tobisch: Mobile phones in hospitals. Biomedical Instrumentation & Technology, January/February 1999, pp. 28-34. This paper is a summary of the book, Reference [5].

[7] Paper in ECRI's journal Health Devices of October 1999 entitled "Cell Phones and Walkie-Talkies, Is it Time to Relax Your Restrictive Policies", pp. 409–413.

[8] Medical Device Agency (UK): Electromagnetic Compatibility of Medical Devices with Mobile Communications. MDA Devices Bulletin DB 9702 dated March 1997. MDA Room 1207, Hannibal House, Elephant & Castle, London SE1 6TQ.

[9] Standard IEC 60601-1-2 entitled "Medical electrical equipment – Part 1: General requirements for safety. 2 Collateral standard: Electromagnetic compatibility - Requirements and tests". First edition, 1993-04.
See [10] as well.

[10] Draft second edition of the IEC 60601-1-2 standard entitled "Medical electrical equipment – Part 1: General requirements for safety. 2. Collateral standard: Electromagnetic compatibility - Requirements and tests".
Document Number: 62A/308/CDV, dated 2000-02-11.

Errata (integrated in this version)

TNO research report PG/TG/00.050 of 28 April 2000, "Effects on medical equipment at home of pocket phones and the like – field measurements".

- The ISBN of this report is: 90-5412-064-9.
- Page 2 and page 7: For GSM/8 W, add the following footnote:
  GSM 8 W is not being used in the Netherlands any longer.
- Page 15: The vertical axis of the histogram starts with 0, not with 01.
- Page 15 and page 34: First of the two points: 'the transmitting power squared' should read 'the square root of the transmitting power'. (The example illustrates this relationship.)
- Page 17: The note in smaller font says that '4 of the 224 apparatuses include 4...'. This should read 'of the 224 apparatuses, 4 (2%)...'.

Nederlandse Organisatie voor toegepast-natuurwetenschappelijk onderzoek / Netherlands Organisation for Applied Scientific Research

Susceptibility of 90 medical apparatuses for TETRA portophones – practical measurements

TNO-Report PG/TG/2004.076E, dated 30 March 2004

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SUMMARY [1])

In near future ambulance personnel will be using TETRA portophones. The susceptibility of medical apparatuses in the hospital for TETRA portophones has been investigated. This study was a base for a code of practice for ambulance personnel as regards the use of TETRA portophones. Out of 90 apparatuses tested 49 apparatuses exhibited a certain reaction at a certain distance (including distance 0 cm, meaning that the antenna of the portophone was positioned against the apparatus) of TETRA 1W. The most susceptible apparatus was disturbed at about 8m distance.

13 reactions of apparatuses had a hazardous character and 25 reactions had a significant but not hazardous character. The reactions of 11 apparatuses were considered light.
Among the 90 apparatuses tested 3 (ca. 3%) exhibited disturbances at a distance of 5m or more. The distance at which 3% of the apparatuses can be disturbed is internationally seen as a safe separation distance for GSM 2W. Thus for TETRA 1W the 3% safe separation distance based on the results in this report is 5m. To be on the safe side this 5m was calculated by considering all reactions of medical apparatuses as not allowed [2]).
It must be envisaged that medical apparatuses can be susceptible for radio signals from TETRA portophones with which calls are made or which transmit autonomous messages. Ambulance personnel must receive instructions about how to use TETRA portophones. At this stage of the research the measurement results justify a warning against the use in hospitals of TETRA portophones by others than emergency services. A serious warning against the use in hospitals of TETRA portophones with more power than 1W by anybody is justified as well [3]).

Autonomous messages can disturb medical apparatuses. This revealed from a restricted test on about 30 medical apparatuses. The disturbances by portophones transmitting autonomous messages (AUM) are less probable than the disturbances by portophones that transmit calls in the direct mode (DMO). However, autonomous messages appeared to be not short enough in time to never disturb. External pacemakers, defibrillators and some lung ventilators can pose a risk not only with DMO, but also with AUM because they appeared not free from disturbances by AUM. Some disturbances can result in hazards for the patient. Many medical apparatuses however are immune for AUM.

Remark 1: Based on some explorative tests it is not expected that TETRA portophones will disturb implants in patients like pacemakers.

Remark 2: In a further investigation to be ordered by the ministries VWS/BZK the results as presented in this report will be compared to results from other studies and will be theoretically founded.

--- end of summary ---

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1) The full report can be ordered from the above address. Price: € 110,-- exl V.A.T.

2) Of course distances have to be balanced against the medical importance of TETRA.

3)The C2000 network in The Netherlands restricts the transmitting power of the portophones to 1W. Therefore this warning does not apply to C2000, but it applies to any possible civil use of TETRA. In case of a disaster in a hospital (fire and the like) it may be justified to use higher transmitting power – for example in the so called direct mode (DMO). This study does not cover that kind of disaster situations.

Nederlandse Organisatie voor toegepast-natuurwetenschappelijk onderzoek / Netherlands Organisation for Applied Scientific Research

Gevoeligheid van 90 medische apparaten voor C2000/TETRA portofoons – praktijkmetingen

TNO-Rapport PG/TG/2004.076, 30 maart 2004

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SAMENVATTING [1])

Ambulancepersoneel zal in de nabije toekomst gebruik gaan maken van TETRA portofoons. De gevoeligheid van medische apparatuur in het ziekenhuis voor TETRA portofoons werd onderzocht. Het onderzoek is bedoeld om er praktische gedragsregels voor ambulancepersoneel uit af te leiden. Van de 90 geteste apparaten vertoonden er 49 een vorm van storing op een zekere afstand (inclusief afstand 0 cm, dwz. antenne van portofoon tegen het apparaat) van TETRA 1W. Het gevoeligste apparaat reageerde op ca. 8m afstand.

Van de reacties hadden er 13 een gevaarlijk karakter en 25 een significant maar ongevaarlijk karakter. 11 reacties werden als licht bestempeld.
Van de 90 geteste apparaten vertoonden er 3 (ca. 3%) op een afstand van 5m of meer verstoring. De afstand waarbij 3% apparaten storing vertoont wordt bij GSM 2W internationaal als “adviesafstand” aangehouden. Bij TETRA 1W ligt de vergelijkbare afstand op basis van de bevindingen in dit rapport dus op 5m. Deze afstand is er veiligheidshalve op gebaseerd dat alle reacties van medische apparaten als ongewenst worden beschouwd [2]). Er dient rekening mee gehouden te worden dat medische apparatuur gevoelig kan zijn voor de radiogolven van TETRA portofoons waarmee gesprekken worden gevoerd of die autonoom berichten versturen. Ambulancepersoneel dient op een nader te bepalen wijze geïnstrueerd te worden ten aanzien van het gebruik van TETRA portofoons. Gezien de meetresultaten lijkt een waarschuwing voor het gebruik in ziekenhuizen van TETRA portofoons door anderen dan de hulpdiensten in deze fase van het onderzoek op zijn plaats. Een ernstige waarschuwing tegen het gebruik in ziekenhuizen van TETRA portofoons met een groter vermogen dan 1W door wie dan ook is eveneens op zijn plaats [3]).

Ook Autonome Berichten kunnen medische apparaten storen. Dit bleek bij een beperkte test aan ca. 30 medische apparaten. De storende werking van portofoons die Autonome Berichten (AB) verzenden is minder dan van portofoons die in de direct mode (DMO) gesprekken verzenden. Maar de autonome boodschappen zijn dus niet zo kort, dat ze nooit storen. Externe pacemakers, defibrillatoren en sommige beademingsapparaten vormen niet alleen bij DMO, maar ook bij AB een probleem in die zin, dat ze niet altijd storingsvrij zijn bij AB. Bij sommige verstoringen zouden patiënten gevaar lopen. Veel medische apparatuur is echter wel immuun voor AB.

Opmerking 1: Op grond van enkele oriënterende testen wordt niet verwacht dat TETRA portofoons implantaten van patiënten zoals pacemakers e.d. verstoren.

Opmerking 2: In vervolgopdracht van VWS/BZK zullen de resultaten die in dit rapport worden gepresenteerd vergeleken worden met resultaten uit ander onderzoek en theoretisch worden onderbouwd.

--- einde samenvatting---

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[1]) Dit rapport kan worden besteld op bovenstaand adres. Prijs: € 110,-- ex. BTW.

[2]) Afstanden moeten uiteraard worden gewogen tegen de achtergrond van het medisch belang van TETRA.

[3]) Het C2000 netwerk begrenst het zendvermogen van portofoons op 1W waardoor deze waarschuwing niet op C2000 van toepassing is, maar wel op eventueel civiel gebruik van TETRA. Bij calamiteiten in een ziekenhuis zoals brand e.d. kunnen de omstandigheden wellicht rechtvaardigen dat wel met sterkere zendvermogens wordt gewerkt – bijvoorbeeld in zogenaamde direct mode (DMO). Het verrichte onderzoek heeft geen betrekking op dat soort afwegingen.

TNO Preventie en Gezondheid

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Gevoeligheid van 90 medische apparaten voor C2000/TETRA portofoons - praktijkmetingen

Datum 30 maart 2004

Auteur Ir. R. Hensbroek

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Opdrachtgever Projectbureau C2000, CPA
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Samenvatting

Ambulancepersoneel zal in de nabije toekomst gebruik gaan maken van TETRA portofoons. De gevoeligheid van medische apparatuur in het ziekenhuis voor TETRA portofoons werd onderzocht. Het onderzoek is bedoeld om er praktische gedragsregels voor ambulancepersoneel uit af te leiden. Van de 90 geteste apparaten vertoonden er 49 een vorm van storing op een zekere afstand (inclusief afstand 0 cm, dwz. antenne van portofoon tegen het apparaat) van TETRA 1W. Het gevoeligste apparaat reageerde op ca. 8m afstand.

Van de reacties hadden er 13 een gevaarlijk karakter en 25 een significant maar ongevaarlijk karakter. 11 reacties werden als licht bestempeld.
Van de 90 geteste apparaten vertoonden er 3 (ca. 3%) op een afstand van 5m of meer verstoring. De afstand waarbij 3% apparaten storing vertoont wordt bij GSM 2W internationaal als "adviesafstand" aangehouden. Bij TETRA 1W ligt de vergelijkbare afstand op basis van de bevindingen in dit rapport dus op 5m. Deze afstand is er veiligheidshalve op gebaseerd dat alle reacties van medische apparaten als ongewenst worden beschouwd **1)**. Er dient rekening mee gehouden te worden dat medische apparatuur gevoelig kan zijn voor de radiogolven van TETRA portofoons waarmee gesprekken worden gevoerd of die autonoom berichten versturen. Ambulancepersoneel dient op een nader te bepalen wijze geïnstrueerd te worden ten aanzien van het gebruik van TETRA portofoons. Gezien de meetresultaten lijkt een waarschuwing voor het gebruik in ziekenhuizen van TETRA portofoons door anderen dan de hulpdiensten in deze fase van het onderzoek op zijn plaats. Een ernstige waarschuwing tegen het gebruik in ziekenhuizen van TETRA portofoons met een groter vermogen dan 1W door wie dan ook is eveneens op zijn plaats **2)**.

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2) Het C2000 netwerk begrenst het zendvermogen van portofoons op 1W waardoor deze waarschuwing niet op C2000 van toepassing is, maar wel op eventueel civiel gebruik van TETRA. Bij calamiteiten in een ziekenhuis zoals brand e.d. kunnen de omstandigheden wellicht rechtvaardigen dat wel met sterkere zendvermogens wordt gewerkt – bijvoorbeeld in zogenaamde direct mode (DMO). Het verrichte onderzoek heeft geen betrekking op dat soort afwegingen.

Inhoudsopgave

1 Inleiding

Het in dit rapport beschreven onderzoek is uitgevoerd als onderdeel van het project dat de invoering van het mobiele communicatienetwerk C2000 behelst. C2000 gaat door alle hulpverleners van OOV-diensten gebruikt worden voor de mobiele communicatie van spraak en data. C2000 is gebaseerd op de zogenaamde TETRA standaard [7] [3]).

Alle mobiele communicatiesystemen die functioneren op basis van het zenden en ontvangen van radiogolven kunnen elektrische en elektronische apparaten in enigerlei mate beïnvloeden. Dit verschijnsel wordt wel aangeduid met de term elektromagnetische interferentie. Als medische apparatuur wordt beïnvloed kan dit consequenties hebben voor de gezondheidstoestand van de patiënt bij wie behandeling of diagnose met die apparatuur plaats vindt; als er beïnvloeding optreedt, dan kan deze variëren van licht hinderlijk tot gevaarlijk.

Door de opdrachtgever is bij TNO Preventie en Gezondheid de vraag neergelegd om de gevoeligheid van medische apparatuur voor signalen van C2000/TETRA portofoons te onderzoeken en de uitkomsten zodanig te presenteren dat er een gedragscode voor ambulancepersoneel op kan worden gebaseerd.

Het plan van de opdrachtgever is om deze door hem op te stellen gedragscode vervolgens in de praktijk te laten toetsen door ambulancemedewerkers teneinde de bruikbaarheid ervan en de medische risico's bij het hanteren van de gedragscode in de praktijk te evalueren. Het doel van de opdrachtgever daarbij is om te komen tot een door landelijke organisaties gedragen en in de praktijk goed te hanteren gedragscode, die door alle ziekenhuizen in Nederland wordt toegepast.

Dit rapport beschrijft de uitkomsten van technische tests met medische apparatuur, welke zijn gericht op het gebruik van C2000/TETRA portofoons door Nederlandse ambulancemedewerkers in de ziekenhuisomgeving.

Om de onderzoeksvraag te beantwoorden is een projectteam samengesteld. Dit rapport is het resultaat van de inspanningen van dit projectteam waarin de volgende organisaties participeerden met de taken zoals aangegeven:

Organisatie	Taak
BZK	Algemene ondersteuning
VWS	Algemene ondersteuning
ITO	Communicatie deskundigheid en beschikbaar stellen van portofoons
AMC	Initiële projectopzet, Inbreng medisch-technische deskundigheid, Coördinatie van testprogramma's in de ziekenhuizen.
VUmc	
Projectbureau C2000, CPA en Ambulance Hulpverlening, Startregio	Projectcoördinatie
TNO Preventie en Gezondheid	Advisering, Coördinatie en uitvoeren van metingen, Rapportage

[3]) Zie literatuurlijst in bijlage L

TNO garandeert volledig de wetenschappelijke juistheid van de uitgevoerde experimenten en van de voorliggende rapportage.

In bijlage A is algemene informatie over TETRA opgenomen die relevant is in verband met de storende werking van TETRA portofoons. In hoofdstuk 2 is informatie opgenomen over de portofoons waarmee getest is. De tests vonden plaats in 2003.

2 Testprocedure en testomstandigheden

Om een beeld te krijgen van de mogelijke beïnvloeding van medische apparatuur zijn 90 medische apparaten in een ziekenhuis los opgesteld en blootgesteld aan radiogolven van zendende C2000/TETRA portofoons. Het betreft medische apparaten, waar een ambulancemedewerker in principe bij in de buurt kan komen tijdens het afleveren/ophalen van een patiënt in een ziekenhuis. Alle onderzochte medische apparaten zijn functionerend getest. Waar relevant werd apparatuur zowel getest bij voeding uit het net als bij voeding uit de interne batterij. Steeds is het verste punt rondom het apparaat opgezocht waar het nog juist in storing kon worden gebracht. Op een eventueel gevonden stoorpositie is enkele tientallen seconden gezonden. De portofoons zijn in de zogenaamde direct mode (DMO) bedreven waardoor zij op hun maximum vermogen zonden. Daarnaast vond een onderzoek plaats aan een beperkt aantal medische apparaten waarbij de invloed werd nagegaan van portofoons die Autonome Boodschappen (AB) zenden. De resultaten van dat beperkte onderzoek zijn vermeld in Bijlagen F en G. Als passages in dit rapport betrekking hebben op AB, dan is dat uitdrukkelijk in die passages vermeld. Als er niets is vermeld hebben passages in dit rapport betrekking op “spreken in normale mode (DMO)”.

Hieronder volgt een verkorte weergave van het testprotokol **[4)]** :

Opstelling en wijze van testen

De tests zijn uitgevoerd in een ziekenhuisomgeving. De volgende aanwijzingen golden:

Plaats het te testen medische apparaat zo dat het van alle kanten kan worden aangestraald (geen personen en objecten in de directe omgeving van het apparaat – met name geen metalen testtafel). Het apparaat in normaal bedrijf brengen; proefpersoon of simulator en/of fantoom van patiënt aangesloten; storingsONgevoeligheid van simulator steeds apart vaststellen. Bij ECG apparatuur een ECG simulator gebruiken of een proefpersoon aansluiten. Bij defibrillatoren een defibrillatortester gebruiken. Bij beademingsapparatuur een kunstlong gebruiken. Zoek het verste punt rondom het apparaat waar het nog juist in storing kan worden gebracht. Dit punt vinden door rondom het apparaat te zenden onder alle mogelijke richtingen. Tijdens het opzoeken van mogelijke storingsgevoeligheid per positie enkele seconden zenden; op een eventueel gevonden stoorpositie enkele tientallen seconden zenden alvorens te rapporteren.

De eventuele reactie van het apparaat noteren: lampjes die knipperen, toontjes, schermverstoringen, alle bijzonderheden. Bij uitval van het apparaat ook noteren of het apparaat middels net UIT en AAN schakelen weer op kan starten en of daarna alle instellingen wel of niet opnieuw moeten worden gedaan. Bij verstoring ook nagegaan of eventueel aanwezige geheugenfuncties nog in tact zijn. De eventuele reactie van het apparaat beoordelen - indien gewenst met hulp van in het ziekenhuis aanwezige deskundigen – waar nodig ook met medici. Het verstoren van een display en het verstoren van de werking van apparatuur alleen als gevaarlijk klassificeren als het tot gevaar kan leiden.

---

4) Het volledige testprotokol is op te vragen bij de auteur.

Opmerking 1: De testmethode is er op gericht om de invloeden van de omgeving van het medische apparaat op de testuitkomst zo klein mogelijk te maken. Bij stoorafstanden groter dan enkele meters zal er wel invloed van de omgeving zijn, waardoor in die afstanden een grotere onzekerheid zit. Deze onzekerheid kan geschat worden op 25%.

Opmerking 2: Door een groot aantal verschillende apparaten in de test mee te nemen: wordt het nadeel gecompenseerd, dat het gedrag van een bepaald apparaat in de uitkomst van de test overheerst. Tevens wordt hiermee voorkomen dat het bij een korte observatie van een apparaat (enkele minuten) missen van een functioneel detail in de einduitkomst van de tests overheerst.

Opmerking 3: 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 (zie vorige opmerking) en met een zeer bepaald (beperkt) doel. Een dergelijke uitspraak behoort tot de competentie / verantwoordelijkheid van de fabrikant van het betreffende apparaat en moet worden gestoeld op uitvoeriger onderzoek.

TETRA portofoons [5]):

Er is getest met de volgende portofoons:

- MOTOROLA 1W: Is de meest gebruikte portofoon; heeft de vermoedelijk storende eigenschap van de zogenaamde linearization burst; Het vermogen van het TETRA signaal van de Motorola portofoon is 1W.
- SEPURA (Secret Public Radio): geen linearization burst; levert 3W in de direct mode (= DMO = simplex mode); Is gebruikt om zo af en toe ook met dit toegelaten hogere vermogen te testen.
- De portofoons zijn in de direct mode (DMO) bedreven (niet met het TETRA netwerk verbonden), want het netwerk zou de sterkte van de portofoons gaan regelen en dan zou het vermogen waarmee is getest dus niet stabiel en ook nog onbekend zijn.

De MOTOROLA 1W portofoon is als hoofdbron gebruikt bij alle testen; met de SEPURA 3W portofoon is slechts een deel van de medische apparaten getest.

Opmerking: De internationale TETRA standaard staat portofoons met grotere vermogens dan 1W uitdrukkelijk toe **[6])**. Er is echter vooral met de 1W versie getest omdat 1W het niveau gaat worden waarop de portofoons door het Nederlandse C2000 netwerk automatisch worden begrensd. Als de stoorkans van een groot aantal medische apparaten bij 1W bekend is, dan kan de stoorkans bij 3W worden voorspeld [8].

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[5]) In Bijlage B zijn zendpatronen van een portofoon weergegeven.

[6]) Het is dus niet uitgesloten dat een keer in een ander netwerk dan C2000 wordt besloten om bijvoorbeeld vanwege ontvangstkwaliteit toch naar die optie te grijpen. Het heeft dus weldegelijk zin om ook met 3 W te testen.

3 Testresultaten

3.1 Aantallen geteste medische apparaten per soort

Bij het selecteren van de te testen medische apparatuur is nadrukkelijk gelet op het belang voor de direkte medische veiligheid van de patiënt op ziekenhuisafdelingen waar ambulancepersoneel kan komen. Door de apparatuur in het rapport te vermelden wordt het voor andere ziekenhuizen mogelijk om zelf af te wegen hoe representatief de geteste apparatuurverzameling is voor elders aanwezige apparaten.

De verzameling geteste medische apparatuur is qua functionaliteit representatief voor ziekenhuisafdelingen waar ambulancepersoneel kan komen.

Hieronder is een overzicht gegeven van de geteste soorten en aantallen medische apparaten. Per soort apparaat zijn meerdere fabrikaten getest; nooit is hetzelfde type apparaat twee maal getest; er is geen onderzoek gedaan naar de spreiding per fabrikaat of type.

Soort medisch apparaat	Aantal getest
Infusie pomp etc.	9
Anesthesie / Beademing	15
Bevochtiger	3
Patiënt monitor	17
Couveuse	6
Externe defibrillator	6
Dialyse	8
Cardiologische apparatuur	16
Ultrageluid	4
Overig	6
In totaal getest:	90

In Bijlage C die in paragraaf 3.3 van dit rapport uitvoerig wordt toegelicht, is de geteste medische apparatuur nader gespecificeerd.

Er is voor gezorgd dat apparatuur die veel in ambulances wordt gebruikt in de tests werd betrokken.

De volgende categorieën apparaten werden weloverwogen niet in de test betrokken:

- Vast in de ambulance aangebrachte elektronische apparatuur zoals computers met voertuiggegevens of voor motormanagement en analoge mobilofoon- en portofoon apparatuur zijn niet in de test betrokken.
- Medische apparatuur die normaliter niet gebruikt wordt in aanwezigheid van ambulancepersoneel zoals bijvoorbeeld elektrochirurgie apparatuur, is niet in de test betrokken.

3.2 Implantaten

In het TNO laboratorium werden drie soorten implantaten getest: een pacemaker, een implanteerbare defibrillator en een implanteerbare neurostimulator. Zie de foto's in Bijlage K. De implantaten werden getest in een fysiologisch zoutoplossing en waren volledig functioneel. Functionaliteit werd bereikt door de leads (draden) van de implantaten op een representatieve wijze in de oplossing te leggen. Bij de pacemaker en de defibrillator werd een hartsignaal door de oplossing geleid door twee elektroden in de oplossing te plaatsen en daar de geschikte stroompulsen door te leiden. De stroompuls werd opgewekt met een speciale simulator (zie foto). De door de implantaten afgegeven signalen werden waargenomen op twee andere in de oplossing geplaatste elektroden en op de programmeerapparatuur. Met deze programmeerapparatuur (zie foto) werden de implantaten ook ingesteld (gevoeligheid, signaalsterkte, etc.).

3.3 Resultaten per medisch apparaat

In de Bijlage C zijn alle verkregen resultaten samengevat. De resultaten zijn als volgt gepresenteerd:

In Bijlage C:
- bevat de eerste kolom een volgnummer dat alleen dient voor identificatie van het betreffende medische apparaat binnen dit rapport,
- bevat de kolom ***Functie*** de aanduiding van het soort medisch apparaat. In de bijlage zijn de medische apparaten gegroepeerd volgens de indeling van paragraaf 3.1,
- bevat de kolom ***Verstoringsafstand d*** de grootste afstand waarop het betreffende medische apparaat verstoord kon worden door 1W respectievelijk 3W portofoons. In deze kolom is ook de klassificatie N, L, S of H weergegeven welke in onderstaande tabel nader is toegelicht. Een liggend streepje betekent: niet getest. Deze afkortingen zijn ook vermeld in de legenda onder de tabel,
- bevat de kolom ***Reactie*** een korte omschrijving van de verstoring die plaats vond,
- bevat de kolom ***Jaar*** het bouwjaar van het medische apparaat.

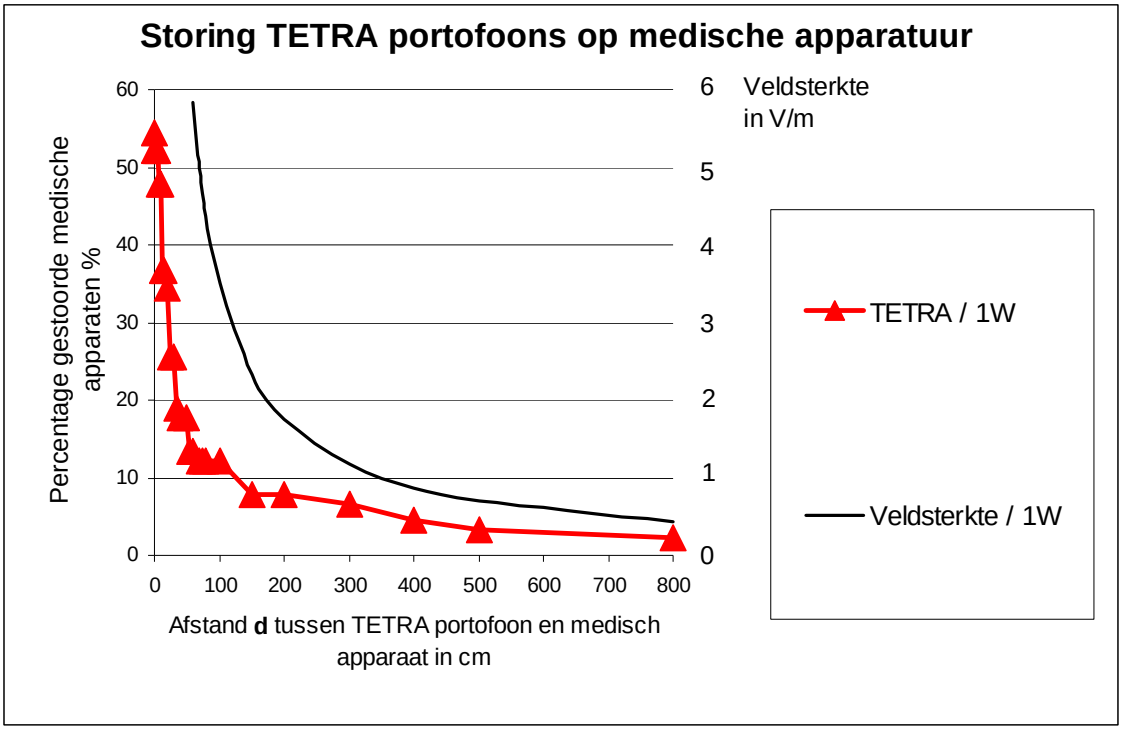
Klassificatie van verstoringen

Verstoring en/of interferentie die optrad door invloed van de TETRA portofoons op de medische apparaten is geklassificeerd zoals in onderstaande tabel is aangegeven op basis van technische deskundigheid. De klassificaties in Bijlagen C, D en G gelden alleen voor de verstoring van het specifieke apparaat. De klassificatie "Gevaarlijk" is ruimer dan alleen levensgevaar voor de patiënt.

	Omschrijving	Voorbeeld
N	**Nee,** geen verstoring of interferentie aanwezig	
L	**Licht**e verstoring aanwezig	- Kleine beweging van de Video Display /het scherm van een medisch apparaat
S	**Significant**e maar (nog) niet gevaarlijke verstoring	- Kleine stoorpulsen op een getoonde ECG curve - Verstoring van een display zonder gevaar
H	**Gevaarlijk**e verstoring (Engels: H = Hazard)	- Defibrillator met stoorpulsen op de ECG curve (synchronisatiefout), - (Terechte) foutmelding zonder akoestisch alarm, - Het ontregelen of stoppen van een apparaat zonder (akoestisch) alarm, - Verstoren van een proces of uitlezing (bijvoorbeeld een display) met gevaar aspect.

3.4 Resultaten samengevat

De resultaten van de stoortests met medische apparaten zijn in Bijlage D gesorteerd op verstoringsafstand **d** in de kolom voor de 1W portofoons. De testresultaten zijn samengevat in figuur 1. Deze figuur is de grafische weergave van de tabel aan het eind van Bijlage D.



Figuur 1: Storing door TETRA portofoons op medische apparatuur

In figuur 1 is het percentage medische apparaten weergegeven dat verstoord werd door TETRA portofoons op een afstand groter of gelijk aan **d**. Het percentage (%) is uitgezet langs de linker vertikale as; de afstand **d** (in cm) is uitgezet langs de horizontale as. De curve met driehoekige markeringen () geeft het percentage weer. Uit de grafiek kan bijvoorbeeld worden afgelezen, dat boven ca. 150 cm afstand ca. 8% van de geteste medische apparaten verstoord raakte door een 1W TETRA portofoon. De doorgetrokken curve in de figuur geeft de theoretische veldsterkte weer op de afstand **d** van de 1W TETRA portofoon volgens de formule $E = 3{,}5 \times (\sqrt{W}) / \mathbf{d}$ [4] waarbij W het vermogen is. Deze veldsterkte moet worden afgelezen op de rechter vertikale as van de figuur. Bijvoorbeeld: op 100 cm van een 1W portofoon is de veldsterkte ca. 3,5 V/m.

Ander voorbeeld: uit figuur 1 kan worden afgelezen, dat op 1m ca. 12% van de geteste medische apparaten storing vertoont. Dit betekent, dat op die afstand 88% van de geteste apparaten geen storing vertoont. Op 0,5m bedraagt het percentage dat geen storing vertoont 82%.

De aantallen opgetreden verstoringen volgens de klassificatie van par. 3.3 zijn als volgt:

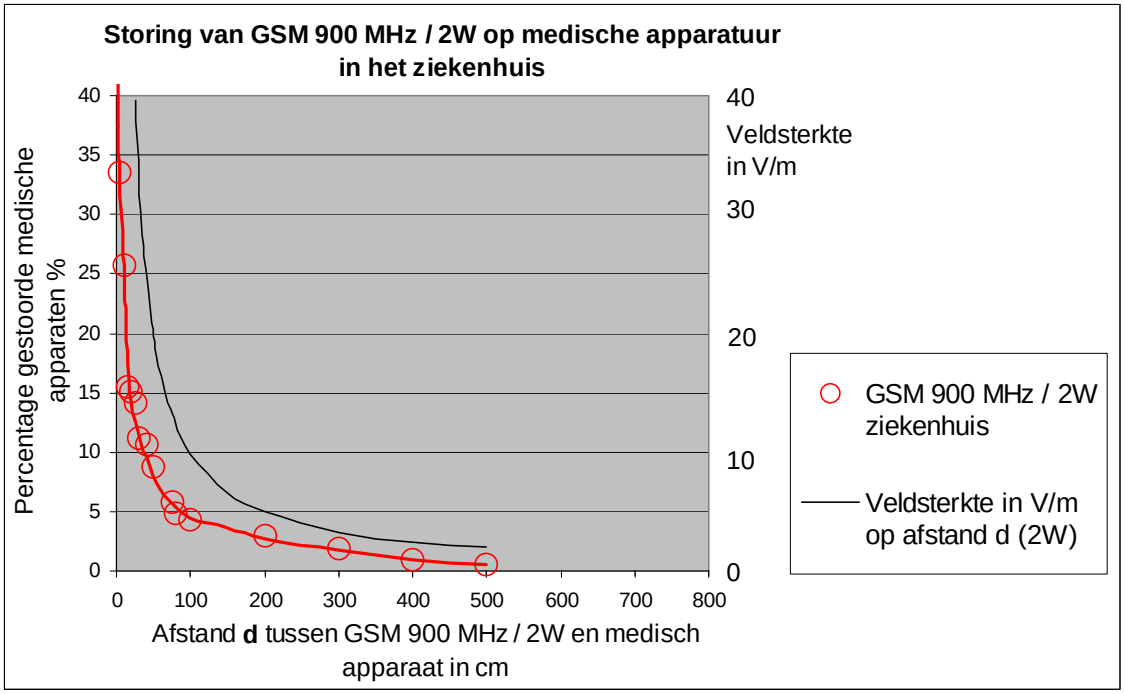
		1W
N	Nee	41
L	Licht	12
S	Significant	24
H	Gevaarlijk	13
	Totaal	90

Tabel 1

Bij de tests zijn geen medische apparaten irreversibel defect geraakt. Na het wegnemen van de stoorbron(nen) functioneerden de meeste apparaten weer normaal. Bij 9 apparaten was het wel nodig om ze uit en weer aan te zetten om ze te laten terugkeren naar normaal functioneren (apparaten nummers 1, 4, 6, 7, 9, 18, 48, 61 en 64).

3.5 Interpretatie van de testresultaten

Interpretatie van de testresultaten zoals weergegeven in de vorige paragraaf is mogelijk door ze te vergelijken met de resultaten die zijn gevonden bij soortgelijk onderzoek met GSM telefoons. De resultaten van onderzoek met GSM telefoons zijn te vinden in referentie [2] van de literatuurlijst in Bijlage L en zijn weergegeven in figuur 2.



Figuur 2: Storing door GSM 900 MHz / 2W op medische apparatuur in het ziekenhuis. Gegevens ontleend aan [2].

Uit figuur 2 kan worden afgelezen, dat op 150 cm afstand van GSM telefoons ca. 3% van de medische apparaten verstoord wordt. De afstand waarbij 3% apparaten storing vertoont wordt bij GSM 2W internationaal als "adviesafstand" aangehouden **[7)]**. Uit figuur 1 kan worden afgelezen dat de vergelijkbare afstand bij TETRA op 5m ligt.
Er dient dus rekening mee gehouden te worden dat medische apparatuur gevoelig kan zijn voor de radiogolven van C2000/TETRA portofoons waarmee gesprekken worden gevoerd.

In Bijlage E zijn de resultaten van de tests met de 3W portofoon vergeleken met de resultaten van de 1W portofoon. De uitkomst is dat medische apparatuur voor de 3W portofoons gevoeliger is dan voor de 1W. Een ernstige waarschuwing tegen het gebruik in ziekenhuizen van TETRA portofoons met een groter vermogen dan 1W door wie dan ook is daarom op zijn plaats **[8)]**.

---

7) Er wordt geadviseerd niet met zendende GSM telefoons binnen deze afstand van medische apparatuur (in ziekenhuis en in de thuisomgeving) te komen. Bron: VIFKA Aanbevelingen [5] en [6].

8) Het C2000 netwerk begrenst het zendvermogen van portofoons op 1W waardoor deze waarschuwing niet op C2000 van toepassing is, maar wel op eventueel civiel gebruik van

Bij het beoordelen van de opgetreden verstoringen volgens de klassificatie L, S en H dient bedacht te worden, dat een verstoring van een lichtere klasse kan wijzigen in een verstoring van een zwaardere klasse als de stoorbron dichter bij het medische apparaat komt. Bij het testen is veelal niet dichterbij gestoord nadat een zekere storingsgevoeligheid werd vastgesteld. Deze werkwijze was vooraf afgesproken. Verder kunnen veelvuldig optredende verstoringen van een lichtere klasse gezamenlijk het karakter krijgen van een zwaardere verstoring omdat ze niet allemaal of niet allemaal gelijktijdig aandacht kunnen krijgen van het medisch personeel.

Er is geen verband tussen storingsgevoeligheid en bouwjaar van de medische apparatuur. De geteste medische apparaten dateren van de jaren 1990 tm. 2002.

Opmerking 1: In Bijlage J worden een aantal factoren besproken, die niet onderwerp van onderzoek waren, maar die wel een rol kunnen spelen bij de kans dat een TETRA portofoon van een ambulancemedewerker in de praktijk een medisch apparaat stoort. De volgende factoren worden in die bijlage besproken:
- Zendvermogen,
- Linearization burst,
- Keying,
- Absorptie door de gebruiker,
- Trefkans.

Opmerking 2: De in het voorliggende onderzoek gevonden gevoeligheid van medische apparatuur voor C2000/TETRA portofoons lijkt groter dan door de Engelse MDA is gevonden [1]. Het theoretisch onderbouwen van de gevonden praktijkresultaten was geen onderdeel van het huidige onderzoek evenmin als het vergelijken van de uitkomsten met die van ander onderzoek. Op basis van de gerapporteerde bevindingen zal in een vervolgopdracht van VWS/BZK worden nagegaan of de gevonden afstanden van beïnvloeding inderdaad beduidend groter zijn dan bij ander onderzoek gerapporteerd. Dit is van belang omdat VWS/BZK daarop specifiek of in zijn algemeenheid oplossingen of (beleids)maatregelen kan baseren.

TETRA. Bij calamiteiten in een ziekenhuis zoals brand e.d. kunnen de omstandigheden wellicht rechtvaardigen dat wel met sterkere zendvermogens wordt gewerkt – bijvoorbeeld in zogenaamde direct mode (DMO). Het verrichte onderzoek heeft geen betrekking op dat soort afwegingen.

4 Conclusies

De gevoeligheid van medische apparatuur in het ziekenhuis voor TETRA portofoons werd onderzocht. Het onderzoek is bedoeld om er praktische gedragsregels voor ambulancepersoneel uit af te leiden. Van de 90 geteste apparaten vertoonden er 49 een vorm van storing op een zekere afstand (inclusief afstand 0 cm, dwz. antenne van portofoon tegen het apparaat) van TETRA 1W. Het gevoeligste apparaat reageerde op ca. 8m afstand.

Van de reacties hadden er 13 een gevaarlijk karakter en 25 een significant maar ongevaarlijk karakter. 11 reacties werden als licht bestempeld.
Van de 90 geteste apparaten vertoonden er 3 (ca. 3%) op een afstand van 5m of meer verstoring. De afstand waarbij 3% apparaten storing vertoont wordt bij GSM 2W internationaal als “adviesafstand” aangehouden. Bij TETRA 1W ligt de vergelijkbare afstand op basis van de bevindingen in dit rapport dus op 5m. Deze afstand is er veiligheidshalve op gebaseerd dat alle reacties van medische apparaten als ongewenst worden beschouwd **[9)]**. Er dient rekening mee gehouden te worden dat medische apparatuur gevoelig kan zijn voor de radiogolven van TETRA portofoons waarmee gesprekken worden gevoerd of die autonoom berichten versturen. Ambulancepersoneel dient op een nader te bepalen wijze geïnstrueerd te worden ten aanzien van het gebruik van TETRA portofoons. Gezien de meetresultaten lijkt een waarschuwing voor het gebruik in ziekenhuizen van TETRA portofoons door anderen dan de hulpdiensten in deze fase van het onderzoek op zijn plaats. Een ernstige waarschuwing tegen het gebruik in ziekenhuizen van TETRA portofoons met een groter vermogen dan 1W door wie dan ook is eveneens op zijn plaats **[10)]**.

Ook Autonome Berichten kunnen medische apparaten storen. Dit bleek bij een beperkte test aan ca. 30 medische apparaten (Bijlagen F en G). De storende werking van portofoons die Autonome Berichten (AB) verzenden is minder dan van portofoons die in de Direkt Mode (DMO) gesprekken verzenden. Maar de autonome boodschappen zijn dus niet zo kort, dat ze nooit storen. Externe pacemakers (Nr 70, 72, 73), defibrillatoren (Nr 53, XXXX, YYYY) en sommige beademingsapparaten (Nr 18, 26)vormen niet alleen bij DMO, maar ook bij AB een probleem in die zin, dat ze niet altijd storingsvrij zijn bij AB. Bij sommige verstoringen zouden patiënten gevaar lopen. Veel medische apparatuur is echter wel immuun voor AB.

Opmerking 1: Het onderwerp van dit rapport moet niet worden verward met het onderwerp GSM telefoons die door het algemene publiek worden gebruikt en die medische apparatuur kunnen verstoren. TETRA portofoons worden niet door het algemene publiek gebruikt; het personeel dat TETRA portofoons gebruikt werkt onder verantwoordelijkheid van professionele organisaties (ambulance en andere

---

9) Afstanden moeten uiteraard worden gewogen tegen de achtergrond van het medisch belang van TETRA.

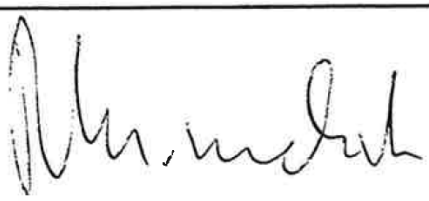
10) Het C2000 netwerk begrenst het zendvermogen van portofoons op 1W waardoor deze waarschuwing niet op C2000 van toepassing is, maar wel op eventueel civiel gebruik van TETRA. Bij calamiteiten in een ziekenhuis zoals brand e.d. kunnen de omstandigheden wellicht rechtvaardigen dat wel met sterkere zendvermogens wordt gewerkt – bijvoorbeeld in zogenaamde direct mode (DMO). Het verrichte onderzoek heeft geen betrekking op dat soort afwegingen.

hulpdiensten) en daardoor kan dat personeel geïnstrueerd worden over hoe te handelen als portofoons worden gebruikt. Bovendien zal het aantal TETRA portofoons veel kleiner zijn dan het aantal GSM- en andere telefoons en ook zal het veel gemakkelijker zijn om TETRA portofoons te traceren en te identificeren dan GSM- en andere telefoons.

Opmerking 2: Op grond van enkele oriënterende testen wordt niet verwacht dat TETRA portofoons implantaten van patiënten zoals pacemakers e.d. verstoren.

Opmerking 3: In vervolgopdracht van VWS/BZK zullen de resultaten die in dit rapport worden gepresenteerd vergeleken worden met resultaten uit ander onderzoek en theoretisch worden onderbouwd.

5 Ondertekening

Auteur	Handtekening
Ir. R. Hensbroek Projectleider	
Drs. R.G.M. van Melick, Apotheker Manager Testen en Beoordelen	

A Informatie over TETRA

TETRA (Terrestrial Trunked Radio) is een Europese telecommunicatie standaard [7]. Deze open standaard is primair ontwikkeld voor de onderlinge communicatie tussen OOV diensten. Echter de TETRA standaard kan ook gebruikt worden door private diensten. TETRA is een goed beveiligd systeem voor digitale communicatie. De frequenties 380-395 MHz zijn voor de OOV diensten en er zijn andere frequenties voor civiele toepassingen binnen TETRA.

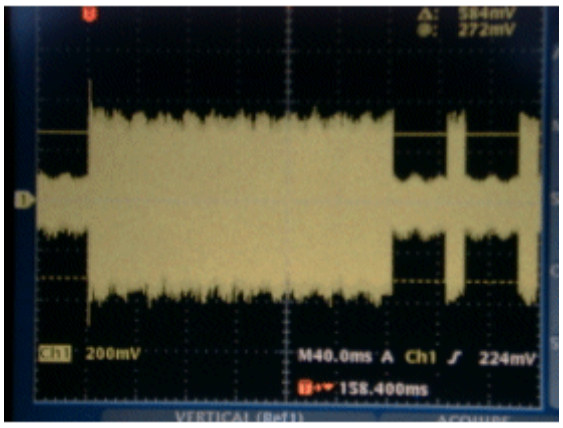
De informatie wordt niet continu verzonden, maar in tijdsloten op bepaalde frequenties. Een tijdslot duurt ongeveer 14 ms en heeft een herhalingsfrequentie van ca 18 Hz. Het kanaal ofwel de uitgezonden frequentie wisselt bij iedere transmissie. Hierdoor wordt de frequentieruimte efficiënter verdeeld onder de gebruikers. Dit mechanisme staat ook wel bekend als trunking (de tweede T van TETRA). Het wisselen van frequentie wordt Frequency Division Multiple Acces (FDMA) genoemd en het verzenden in verschillende tijdsloten staat bekend als Time Division Multiple Acces (TDMA). TETRA is dus een combinatie van TDMA en FDMA. TETRA lijkt qua structuur veel op GSM.

Een mobiel station (mobilofoon, portofoon, radio data randapparaat) zendt gedurende één tijdslot. Een tijdslot heeft de duur van een kwart van een zogenaamd frame. Het vermogen gedurende een tijdslot is 1W bij een 1W portofoon. Gedurende de overige tijdsloten van het frame zendt het mobiele station niet. Het resultaat is een hoogfrequent signaal (380-395 MHz) met een pulsvormige omhullende. Deze omhullende kan worden beschouwd als een 18 Hz pulstrein met een duty cycle van 25%. Zie de foto's in Bijlage B.

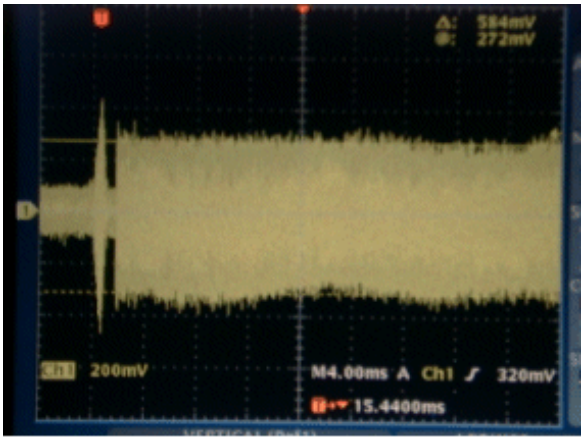
Ter vergelijking: een 2W GSM 900 mobiele telefoon werkt met een 217 Hz pulstrein met een duty cycle van 12,5% (1 van 8 tijdsloten). Europese GSM telefoons zenden met 2W in hun actieve tijdslot; In het Amerikaanse systeem NADC zenden mobiele telefoons met 0,6W.

Algemene informatie: http://www.astrid.be/NL/tetra/tetra_01_normes.htm

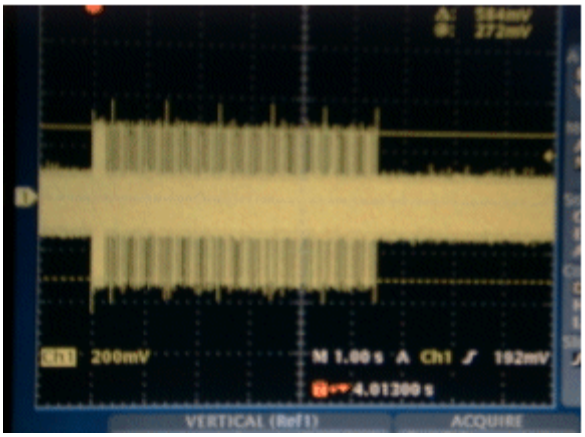
B Foto's TETRA signaal (Alles DMO)



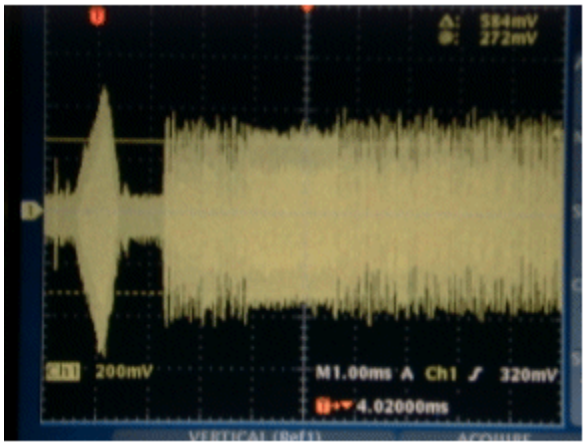
Tijdbasis: 40 ms per hokje
Foto toont de 240 ms burst na indrukken spreeksleutel. Daarna zijn twee 56 ms frames te zien, elk met een 14 ms tijdslot er in. Aan het begin van de 240 ms burst zit een "klein naaldje": de linearization burst [zie ETS 300 396-3 subclause 4.3.2]. Zie ook volgende foto:



Tijdbasis: 4 ms per hokje
Foto toont het kleine naaldje van de vorige foto op een iets uitgerekte schaal. Dit verschijnsel zit dus vóór de 240 ms burst die helemaal op de vorige foto staat. Hiernaast is het kleine naaldje nog verder uitgerekt.



Tijdbasis: 1 s per hokje.
Foto toont een signaal bij ca. 6,5 seconden lang indrukken spreeksleutel. Het "kleine naaldje" herhaalt zich om de ca. 1 seconde (hoorbaar op de radio).



Tijdbasis: 1 ms per hokje
Foto toont "klokvormige linearization burst" direkt na indrukken spreeksleutel. Daarna is een stuk te zien van de 240 ms burst.

Meer informatie over de opbouw en timing van het DMO TETRA signaal is te vinden in ETS 300 396-3

C Verstoringen van medische apparaten in DMO

	Functie	***Verstorings-afstand d:***		***Reactie***	***Jaar***
		1W	***3W***		
		cm	***cm***		
	Infusion pumps, etc.: 9 items				
1	Syringe pump	10 S	-	Pump stops with alarm	93
2	Syringe pump	N	N		00
3	Syringe pump	N	10 L	Acoustic beeps heard	01
4	Syringe pump system	20 H	-	Microprocessor disturbed	99
5	Volumetric pump	N	N		91
6	Volumetric pump	50 S	-	Pump stops with alarm	93
7	Volumetric pump	50 S	-	Pump stops with alarm	99
8	Syringe pump	N	N		00
9	Feeding pump	5 S	20 S	Low battery alarm	98
	Anesthesia / Lung ventilation: 15 items				
10	Anesthesia machine	30 L	60 L	Display jitter	97
11	Patient monitor	20 S	-	1W: 20 cm: Interference on ECG curve. 1W: 0 cm: Out of control	99
12	Lung ventilator	10 L	-	Electromagn.valve influenced	90
13	Lung ventilator	N	20 S	Interference on curves	00
14	Lung ventilator	10 L	50 L	Display disturbed	97
15	Lung ventilator	N	N		94
16	NO controller for lung ventilator	10 H	-	NO out of control (too much)	98
17	Transport Lung ventilator	10 S	20 S	Minute Volume Display disturbed	97
18	Lung ventilator	300 H	-	1W: 300 cm: Unmeant beat 1W: 100 cm: Ventilator stops	02
19	Lung ventilator	50 S	-	LED's + display disturbed	02
20	Lung ventilator	N	N		99
21	Lung ventilator	30 S	-	Display disturbed	93
22	NO Analyzer for Lung ventilator	200 H	-	Read-out disturbed	93
23	NO Injector for Lung ventilator	300 H	-	Display disturbed	93
24	Lung ventilation	0 H	8 H	False ventilation trigger + displayed digits disturbed	01

	Humidifiers: 3 items

25	Humidifier	N	N		97
26	Respiratory humidifier	15 S	-	Detection alarm heating wire	93
27	Respiratory humidifier	N	0 S	Temperature out of control	02

	Patient monitors: 17 items

28	Patient monitor System	500 L	-	1W: 500 cm: Jitter on VDT 1W: 200 cm: Interference on ECG curve	92
29	Patient monitor System	60 S	-	Interference on ECG curve	99
30	Patient monitor System	30 S	100 S	Interference on ECG curve	99
31	Patient monitor System	20 S	100 S	Interference on ECG curve	01
32	Patient monitor	30 S	-	Interference on ECG curve	01
33	Patient monitor	N	15 S	CO2 curve influenced	97
34	Patient monitor	N	50 S	Plethysmogramm and SpO2 influenced	95
35	Patient monitor	10 L	30 L	Display jitter	91
36	Patient monitor	10 L	-	Display jitter	97(?)
37	Patient module for Patient monitor	N	N		91(?)
38	Rack for Patient monitor	N	N		95(?)
39	Rack for Patient monitor	N	N		95
40	Patient monitor	100 S	150 S	Interference on ECG curve	00
41	Patient monitor	35 S	-	Interference on ECG curve	96
42	Patient monitor	N	N		97
43	Patient Monitor	N	0 S	Measurement sometimes disturbed	98
44	Batterycharger	800 L	-	Ventilator speed changes	00

	Infant incubator: 6 items

45	Infant warmer	15 L	50 S	1W: Display jitter 3W: Measurement influenced	02
46	Infant warmer	20 S	30 S		88
47	Infant incubator	N	N		02
48	Infant incubator	5 S	-	1W: 5 cm: acoustic alarm 1W: 2 cm: total reset	91
49	Transport incubator	N	N		86
50	CO2/SpO2 Monitor	N	5 S	False alarm on CO2 measurement	97

	External defibrillators: 6 items

51	Defibrillator	N	10 H	Internal discharge of capacitor	90
52	Defibrillator/ Monitor	N	N		02
53	Defibrillator	800 H	-	Interference on ECG curve + Heart Frequency (HF) digits disturbed	99
54	Defibrillator	N	N		01
55	Defibrillator	N	20 S	Interference on ECG curve	95
56	Defibrillator	N	N		02

	Dialysis: 8 items

57	Peritoneal Dialysis Cycler	20 S	30 S	Temperature indication disturbed	91
58	Dialysis	N	N		?
59	Apheresis System	N	N		01
60	Dialysis	N	N		00
61	Dialysis	10 H	-	System hang-up	02
62	Dialysis CVVH	5 S	10 S	Alarms (e.g. venous air in line)	99
63	Dialysis	N	N		95
64	Peritoneal Dialysis	N	10 H	System error	98

	Cardiac other: 16 items

65	ECG Recorder	N	10 L	Interference on ECG curve	02
66	ECG trolley	100 S	-	Interference on ECG curve	99
67	ECG monitor	N	0 L	Interference on ECG curve through sync input	95
68	ECG monitoring	N	10 L	Interference on ECG curve	95
69	Intra aortic balloonpump	N	0 L	Interference on ECG curve	00
70	External pacemaker	20 H	-	TETRA signal interpreted as heart activity	96
71	External pacemaker	20 H	-	TETRA signal interpreted as heart activity	97
72	External pacemaker	400 H	-	TETRA signal interpreted as heart activity	85
73	External pacemaker	50 H	-	TETRA signal interpreted as heart activity	01
74	External pacemaker patient system analyzer	N	N		98
75	Telemetry transmitter	20 S	100 S	Interference on ECG curve at central post	95
76	Telemetry transmitter	5 S	-	Interference on ECG curve at central post	98
77	Telemetry transmitter	10 S	-	Interference on ECG curve at central post	?
78	Cardiac Telemetry	N	N		?

79	Cardiac flow velocity doppler	100 S	-	Disturbances on displayed doppler signal	96
80	Cardiac X-Ray	100 L	-	Interference on VDT	86/92

	Ultrasound: 4 items

81	Ultrasound scanner	N	N		00
82	Ultrasound scanner	N	10 L	Display unstable	01
83	Ultrasound scanner	30 L	-	Display jitter	00
84	Ultrasound scanner	30 L	150 L	Display unstable	95

	Other: 6 items

85	Bed	N	N		02
86	WLAN	N	-		00?
87	Liquid Oxygen Container (Trans-portable + separate portable unit)	10 L	-	Display influenced	99
88	Implantable Pacemaker	0 H	-	Into interference mode	95?
89	Implantable Cardioverter Defibrillator	N	N		98?
90	Implantable Neurostimulator	N	N		98?

LEGENDA

	Omschrijving	**Toelichting**
N	Nee	Nee, geen verstoring of interferentie aanwezig
L	Licht	Lichte verstoring aanwezig (Engels: L = Light)
S	Significant	Significante maar (nog) niet gevaarlijke verstoring (Engels: S = Significant)
H	Gevaarlijk	Gevaarlijke verstoring (Engels: H = Hazard)
-	niet getest	In kolom ***Verstoringsafstand d: 3W***

D Verstoorde medische apparaten gesorteerd op afstand

NR	***Functie***	***Verstorings-afstand d:***	
		1W	***3W***
		cm	***cm***
24	Lung ventilation	0 H	8 H
88	Implantable Pacemaker	0 H	-
48	Infant incubator	5 S	-
62	Dialysis CVVH	5 S	10 S
76	Telemetry transmitter	5 S	-
9	Feeding pump	5 S	20 S
1	Syringe pump	10 S	-
12	Lung ventilator	10 L	-
14	Lung ventilator	10 L	50 L
16	NO controller for lung ventilator	10 H	-
17	Transport Lung ventilator	10 S	20 S
35	Patient monitor	10 L	30 L
36	Patient monitor	10 L	-
61	Dialysis	10 H	-
77	Telemetry transmitter	10 S	-
87	Liquid Oxygen Container	10 L	-
26	Respiratory humidifier	15 S	-
45	Infant warmer	15 L	50 S
4	Syringe pump system	20 H	-
11	Patient monitor	20 S	-
31	Patient monitor System	20 S	100 S
46	Infant warmer	20 S	30 S
57	Peritoneal Dialysis Cycler	20 S	30 S
70	External pacemaker	20 H	-
71	External pacemaker	20 H	-
75	Telemetry transmitter	20 S	100 S
10	Anesthesia machine	30 L	60 L
21	Lung ventilator	30S	-

NR	***Functie***	***Verstorings-afstand d:***	
		1W	***3W***
		cm	***Cm***
30	Patient monitor System	30 S	100 S
32	Patient monitor	30 S	-
83	Ultrasound scanner	30 L	-
84	Ultrasound scanner	30 L	150 L
41	Patient monitor	35 S	-
6	Volumetric pump	50 S	-
7	Volumetric pump	50 S	-
19	Lung ventilator	50 S	-
73	External pacemaker	50 H	-
29	Patient monitor System	60 S	-
40	Patient monitor	100 S	150 S
66	ECG trolley	100 S	-
79	Cardiac flow velocity doppler	100 S	-
80	Cardiac X-Ray	100 L	-
22	NO Analyzer for Lung ventilator	200 H	-
18	Lung ventilator	300 H	-
23	NO Injector for Lung ventilator	300 H	-
72	External pacemaker	400 H	-
28	Patient monitor System	500 L	-
44	Batterycharger	800 L	-
53	Defibrillator	800 H	-
2	Syringe pump	N	N
3	Syringe pump	N	10 L
5	Volumetric pump	N	N
13	Lung ventilator	N	20 S
15	Lung ventilator	N	N
20	Lung ventilator	N	N
25	Humidifier	N	N
27	Respiratory humidifier	N	0 S
33	Patient monitor	N	15 S
34	Patient monitor	N	50 S
37	Patient module for Patient monitor	N	N
38	Rack for Patient monitor	N	N
39	Rack for Patient monitor	N	N

NR	***Functie***	***Verstorings-afstand d:***	
		1W	***3W***
		cm	***Cm***
42	Patient monitor	N	N
47	Infant incubator	N	N
49	Transport incubator	N	N
50	CO2/SpO2 Monitor	N	5 S
51	Defibrillator	N	10 H
52	Defibrillator/ Monitor	N	N
58	Dialysis	N	N
59	Apheresis System	N	N
60	Dialysis	N	N
63	Dialysis	N	N
65	ECG Recorder	N	10 L
81	Ultrasound scanner	N	N
82	Ultrasound scanner	N	10 L
69	Intra aortic balloonpump	N	0 L
67	ECG monitor	N	0 L
68	ECG monitoring	N	10 L
43	Patient Monitor	N	0 S
54	Defibrillator	N	N
55	Defibrillator	N	20 S
85	Bed	N	N
78	Cardiac Telemetry	N	N
86	WLAN	N	-
8	Syringe pump	N	N
56	Defibrillator	N	N
64	Peritoneal Dialysis	N	10 H
74	External pacemaker patient system analyzer	N	N
89	Implantable Cardioverter Defibrillator (ICD)	N	N
90	Implantable Neurostimulator	N	N

Legenda: Zie aan het eind van Bijlage C en zie ook paragraaf 3.3

Samenvatting van de voorgaande tabel voor 1W portofoons:

Afstand d [cm]	**Aantal verstoord door 1W**	**Cumulatief**	
		Aantal	%
800	2	2	2
500	1	3	3
400	1	4	4
300	2	6	7
200	1	7	8
100	4	11	12
60	1	12	13
50	4	16	18
35	1	17	19
30	6	23	26
20	8	31	34
15	2	33	37
10	10	43	48
5	4	47	52
0	2	49	54
	Totaal 49		

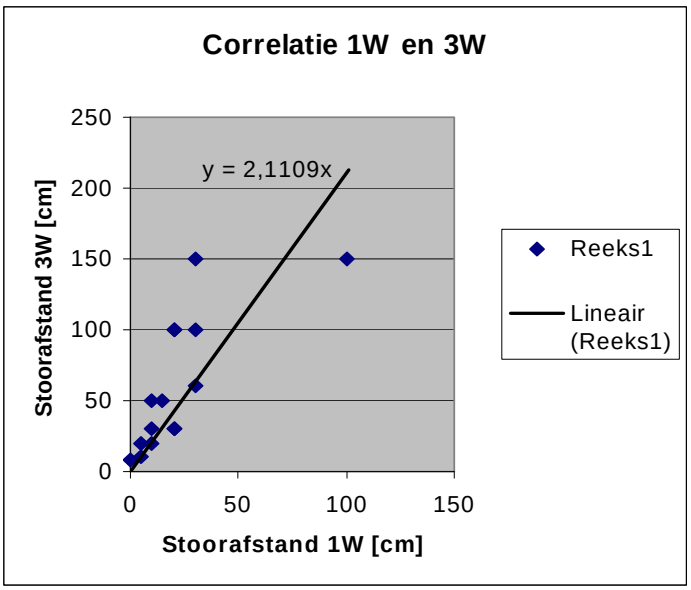
Figuur 1 in paragraaf 3.4 is de grafische weergave van de getallen in bovenstaande tabel.

Opmerking: Het aantal medische apparaten dat met 3W is getest is bewust beperkt gehouden. Daardoor is het niet verantwoord om op de tests met 3W de cumulatieve percentages te berekenen zoals in bovenstaande tabel voor 1W is gedaan. Zie verder Bijlage E.

E Correlatie 1W en 3W

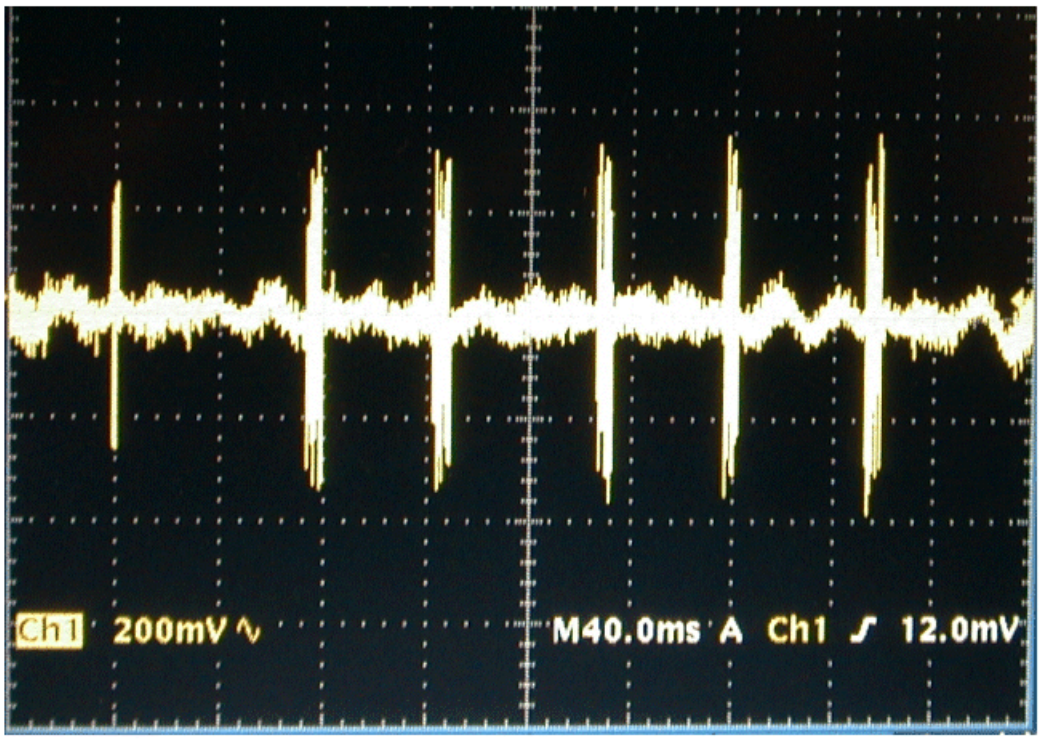
In onderstaande figuur zijn de stoorafstanden uitgezet van die apparaten die zowel voor 1W als voor 3W gevoelig waren. Niet alle medische apparaten zijn met beide vermogens getest. Dit is gedaan om tijd te winnen. Als een medisch apparaat niet gevoelig was voor 1W is vaak wel ook getest met 3W om na te gaan of het betreffende apparaat voor 3W wel gevoelig was. Van alle apparaten die gevoelig zijn voor 1W kan gevoeglijk worden aangenomen dat ze ook voor 3W gevoelig zijn. Bij een aantal willekeurig gekozen medische apparaten is dat ook getoetst tijdens de tests. De figuur is de illustratie van die toetsing. De verhouding van de stoorafstanden op 1W versus die op 3W is gemiddeld een factor 1 / 2,1 = ca. 0,5. Op grond van theoretische overwegingen zou men verwachten dat deze verhouding gelijk is aan de wortel uit de vermogensverhouding: $(1/3)^{1/2}$ = ca. 0,6. Gezegd kan dus worden dat de medische apparatuur volgens verwachting gevoeliger is voor de 3W portofoon dan voor de 1W portofoon.

1W [cm]	3W [cm]
0	8
5	10
5	20
10	50
10	20
10	30
15	50
20	100
20	30
20	30
20	100
30	60
30	100
30	150
100	150



F Autonome Berichten (AB)

De test “autonoom zenden” is apart uitgevoerd in oktober 2003 met het type standaard SRP2000 portofoon, zoals dat bij de GG&GD Amsterdam aanwezig was op dat moment [11]. Het onderzoek concentreerde zich op de eventuele storende werking van door de portofoons uitgezonden autonome boodschappen (hier “AB” genoemd) op een selecte verzameling medische apparaten [12]. Ter verificatie van eerder verkregen resultaten werd ook in de DMO mode gezonden. Het vermogen van de portofoons waarmee getest is, is voor en na de test gecontroleerd en in orde bevonden (Zie Bijlage I).



AB bij uitschakelen van de TI mode. De AB begint met een linearization burst (het smalle pulsje). De SRP2000 zendt om de 28 sec zo’n linearization burst. Dan volgen vijf informatie-pulsen in halve tijdsloten (duur van elke puls: ca. 7 ms). AB worden gezonden in halve tijdsloten (ca. 7 ms) en op maximaal vermogen (1 W).

FIGUUR 1: Een voorbeeld van een door een portofoon uitgezonden Autonome Boodschap (“AB”)

---

[11] Portofoons genummerd 3-434 en 4-434

[12] Door middel van **Autonome boodschappen (**AB) houdt een C2000 portofoon contact met het C2000 netwerk zonder dat de gebruiker dit merkt. AB duren kort (fracties van een seconde). AB worden bijvoorbeeld gezonden als een portofoon onderweg automatisch (“autonoom”) op een andere zendmast over gaat. De gebruiker merkt hier niets van en kan ononderbroken communiceren.

De portofoons hadden op de testlocaties in AMC en VUmc voldoende ontvangst [13] om met het C2000 netwerk te kunnen communiceren. De portofoons zonden op hun maximale vermogen.

De wijze van zenden van AB

Er zijn op twee manieren AB gezonden:

Manier I: "*AB bij uitschakelen van de TI mode (Transmit Inhibit mode)"*
- Portofoon staat aan
- Transmit Inhibit (T.I.) inschakelen.
- Uit de T.I. halen d.m.v. rode toets. Op dit moment komt een pulstrein van ca. 6 pulsen (hoorbaar op radio). Geschikt voor de test "autonoom zenden". Werkt snel en eenvoudig, want connectie met netwerk blijft bestaan.

Manier II: "*AB bij inschakelen portofoon*"
- Zet portofoon uit (lang drukken op modetoets). De portofoon verlaat de T.I. mode en zendt kort voor het uitschakelen een AB naar het netwerk.
- Zet portofoon aan (lang drukken op modetoets). Op dit moment komt pulstrein (hoorbaar op radio). Geschikt voor test. Pulstrein is langer dan bij Manier I.

In Bijlage G bevat de kolom ***Verstoringsafstand d bij AB*** de resultaten van de tests met gezonden AB volgens Manier I en Manier II. De resultaten voor de twee manieren verschillen niet.

De geteste medische apparaten

In totaal zijn 28 apparaten met AB getest. Het aantal geteste medische apparaten met een bepaalde functie is in onderstaande tabel weergegeven. De nummers in de derde kolom verwijzen naar Bijlage F, waarin de gedetailleerde testresultaten zijn vermeld.

Aantal	Functie	Nr in tabel van Bijlage G
3	Pumps	4, 6, 7
4	Lung ventilator / Anesthesia	10, 18, 19, 26
9	Patient monitors incl. Telemetry	11, 28, 29, 30, 31, 32, 40, 41, 75
1	Battery charger	44
2	Infant warmers	45, 46
3	Defibrillators	53, XXXX, YYYY
1	Dialyser cycler	57
1	ECG recorder	66
3	External pacemakers	70, 72, 73
1	Ultrasound scanner	83
Totaal: 28		

NB: In het AMC werd alleen de Telemety transmitter (Nr 75) niet in de in de noot genoemde bedkamer gemeten, maar op de cardiologieafdeling.

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[13] In ruimte "Bedkamer F.3-222" van het AMC bedroeg het ontvangstniveau bijvoorbeeld –85 à –75 dBm (RSSI). In ruimte 3A14 (oude VKC in VUmc) was het ontvangstniveau (mast 103) eveneens –85 à –75 dBm (RSSI).

Gevonden resultaten

De resultaten van alle geteste medische apparaten zijn vermeld in Bijlage G. De volgende resultaten zijn opvallend (niet àlle resultaten uit Bijlage G worden hier uitgelicht):

1. De externe pacemaker Nr 70 was nu (bij de tweede test) in DMO gevoelig op 150 cm (destijds bij de eerste test gevoelig voor DMO op 20 cm). Nu ook op 150 cm gevoelig voor AB. De externe pacemaker pulst verkeerd: niet waar het wel moet en wel waar het niet moet.
2. De Externe pacemaker Nr 72 was nu in DMO gevoelig op 20 cm (destijds op 400 cm). Ook op 150 cm gevoelig voor AB. De externe pacemaker pulst verkeerd: niet waar het wel moet en wel waar het niet moet.
3. Bij veel ECG apparatuur veroorzaakte de DMO mode veel stoorsignaal ("gras"). In zulke gevallen gaven AB veelal een paar "artefacten", die veel minder storend zijn omdat de gebruiker aan (bewegings)artefacten is gewend. "Gras" en "artefacten" worden door gebruikers veelal herkend als zijnde niet fysiologisch van oorsprong. Vaak maakt "gras" de juiste interpretatie van het signaal geheel onmogelijk en belemmeren de "artefacten" die interpretatie slechts gedeeltelijk.
4. De Lung Ventilator Nr 18 gaf onbedoelde slagen bij AB op 20 cm. (Bij DMO op enkele m afstand).
5. Nu bij de tweede test waren vaak niet precies de medische apparaten met hetzelfde inventaris- en serienummer beschikbaar als bij de eerste test onderzocht werden. Als wel precies hetzelfde apparaat beschikbaar was, zaten er vaak niet dezelfde modules op. Als wel dezelfde modules aanwezig waren, lag de stoorgrens op enkele uitzonderingen na op ongeveer dezelfde afstand als de vorige keer. De stooreffecten waren over het algemeen hetzelfde. Bij enkele apparaten was de stoorafstand (DMO mode) bij de tweede test heel anders dan bij de eerste test. Soms was er sprake van een ander inventaris-/serienummer; soms betrof het precies hetzelfde apparaat.
6. De Battery Charger Nr 44 was ongevoelig voor DMO en ongevoelig voor AB. Was bij eerdere test gevoelig op 8 m! (Was nu wel ander serienummer dan vorige keer).
7. Bij de Defibrillator Nr 53 lag de DMO-stoorgrens nu op 9m (vorige keer 8m). Voor AB lag de stoorgrens op 1m. Op 1m kon met AB een stoorpuls worden geïntroduceerd waarop een door de gebruiker gestarte defibrillatie-actie niet werd uitgevoerd. Zie storingsregistratie in Bijlage H.
8. De AED (Nr XXXX in de tabel van Bijlage G) behandelde niet het ventrikel fibrilleren als op ca. 50 cm afstand werd gezonden met een TETRA portofoon in de DMO mode. De automatische stem adviseerde "no shock" waar wel een shock had moeten worden geadviseerd (zo'n shock wordt dan door de gebruiker gestart). Er is niet met AB gezonden. De DMO-verstoring van een AED wordt extra gevaarlijk geacht als daarbij sprake is van een minder deskundige gebruiker.
9. De resultaten voor de twee manieren van zenden van AB verschillen niet. Hoewel de AB bij de twee manieren van zenden niet exact hetzelfde zijn, zijn de verschillen kennelijk niet groot genoeg om tot verschillend test-/stoorresultaat te leiden.

Samenvattend:

Autonome berichten kunnen medische apparaten storen. Dit bleek bij een beperkte test aan ca. 30 medische apparaten. De storende werking van portofoons die Autonome Berichten (AB) verzenden is minder dan van portofoons die in de direct mode (DMO) gesprekken verzenden. Maar de autonome boodschappen zijn dus niet zo kort, dat ze nooit storen. Externe pacemakers (Nr 70, 72, 73), defibrillatoren (Nr 53, XXXX, YYYY) en sommige beademingsapparaten (Nr 18, 26)vormen niet alleen bij DMO, maar ook bij AB een probleem in die zin, dat ze niet altijd storingsvrij zijn bij AB. Bij sommige verstoringen zouden patiënten gevaar lopen. Veel medische apparatuur is echter wel immuun voor AB. Het zal niet mogelijk zijn om op basis van de gevonden verstoringen te voorspellen wat de kans op een incident in de praktijk is.

De gevonden soort storingen zijn representatief voor dit soort testen. Dat betekent dat bij vergelijkbare tests aan andere apparaten wel andere uitkomsten gevonden kunnen worden. Steeds zullen ze echter ongeveer lijken op de in dit onderzoek gevonden uitkomsten. Voldoende reden om actie te ondernemen.

Leiden, februari 2004

G Verstoringen van medische apparaten met AB

In onderstaande tabel zijn de resultaten van de test met Autonome Boodschappen (AB) samengevat. De kolom ***Verstoringsafstand d bij AB*** bevat de afstand d in cm waarop een eventuele verstoring van een medisch apparaat werd geconstateerd. In onderstaande tabel zijn bij elk apparaat de inventaris-/serienummers vermeld van de eerste test in DMO (begin 2003) en van de tweede test met AB (eind 2003). In de tabel is gesorteerd op volgnummer van het apparaat in Bijlage C. De geselecteerde apparaten waren gebaseerd op die bijlage: het waren alle beschikbare apparaten met d=15 cm en hoger (DMO mode; 1W-portofoon) staan in onderstaande lijst. In totaal zijn 28 apparaten getest . Voor de test met AB is geprobeerd zo veel als mogelijk dezelfde apparaten te testen als bij de eerste test in DMO mode. Vaak waren echter niet dezelfde apparaten beschikbaar. Voor de uitkomst heeft dit geen grote gevolgen. In de voetnoten zijn de reacties van de medische apparaten kort toegelicht.

MEDISCHE APPARATUUR gesorteerd op Nr uit Bijlage C:

Nr	***Functie***	***Verstorings-afstand d in DMO mode*** [14]	***Verstorings-afstand d bij AB*** [15]
		1W	***1W***
		cm	***cm***
4	Syringe pump system	20 H / 20 H	N
6	Volumetric pump	50 S / 50 S	0 S [16]
7	Volumetric pump	50 S / 50 S	N
10	Anesthesia machine	30 L / 30 L	N
11	Patient monitor	20 S / 100 L	N
18	Lung ventilator	300 H / 500 H	20 H [17]
19	Lung ventilator	50 S / 50 S	N
26	Respiratory humidifier	15 S /15 S	5 S [18]
28	Patient monitor System	500 L / 100 L [19]	0 L [20]
29	Patient monitor System	60 S / 50 S	50 L [21]
30	Patient monitor System	30 S / 15 S	15 L [22]
31	Patient monitor System	20 S / 20 S	15 L [23]

[14]) Er zijn twee waarden genoteerd, gescheiden door een schuine streep. Voor de schuine streep staat de waarde die bij de eerste test in DMO is gemeten en in Bijlage C is vastgelegd. Achter de schuine streep staat de waarde, die bij de tweede test (met AB) werd gevonden in DMO mode. Die meting in DMO mode werd verricht voorafgaand aan de AB meting. Achter de afstand is middels een letter N, L, S of H aangegeven hoe ernstig de verstoring werd beoordeeld.

[15]) AB = Autonome Boodschap. AB gezonden bij UIT schakelen van de TI mode. Bij IN schakelen van de portofoon: zelfde resultaten.

[16]) Acoustisch alarm + Foutmelding (error message)

[17]) Bij AB: Onbedoelde slag; Op gevoeliger stand treedt dit al op 2 m op (gevoeliger stand niet gedaan in DMO mode).

[18]) Detectie alarm als op 15 cm van de verwarmingsdraad werd gezonden.

[19]) Stond bij tweede test los opgesteld en bij eerste test op pendel (andere loop van voedingskabels).

[20]) Beeld springt eenmalig, maar dit zal niet door de gebruiker worden opgemerkt; geen gevaar.

[21]) Artefacten;Herkenbaar als zijnde niet fysiologisch van oorspong; Niet gevaarlijk.

[22]) Artefacten; Herkenbaar als zijnde niet fysiologisch van oorspong; Niet gevaarlijk.

Nr	***Functie***	***Verstorings-afstand d in DMO mode*** [14] ***)***	***Verstorings-afstand d bij AB*** [15] ***)***
		1W	***1W***
		cm	***cm***
32	Patient monitor	30 S / N	N
40	Patient monitor	100 S / 10 S	N
41	Patient monitor	35 S / 0 S	N *24*
44	Batterycharger	800 L / N *25*	N
45	Infant warmer	15 L / 15 L	N
46	Infant warmer	20 S / 5 S	N
53	Defibrillator	800 H / 900 H *26*	100 H *27*
57	Peritoneal Dialysis Cycler	20 S / 10 S	N
66	ECG trolley	100 S / 100 S *28*	N
70	External pacemaker	20 H / 150 H	150 H *29*
72	External pacemaker	400 H / 20 H	150 H *30*
73	External pacemaker	50 H / 200 H	50 H *31*
75	Telemetry transmitter	20 S / 0 S	N *32*
83	Ultrasound scanner	30 L / 30 L	10 L *33*
XXXX	Automatic External Defibrillator (AED)	- / 50 H *34*	-
YYYY	Defibrillator	- / 0 cm *35*	-
NB: Nr XXXX en YYYY zijn ten tijde van de test met AB ter informatie toegevoegd, maar alleen in DMO getest.			

LEGENDA

	Omschrijving	**Toelichting**
N	Nee	Nee, geen verstoring of interferentie aanwezig
L	Licht	Lichte verstoring aanwezig (Engels: L = Light)
S	Significant	Significante maar (nog) niet gevaarlijke verstoring (Engels: S = Significant)
H	Gevaarlijk	Gevaarlijke verstoring (Engels: H = Hazard)
-	niet getest	In twee rechter kolommen

23) Artefacten op ECG; Herkenbaar als zijnde niet fysiologisch van oorspong (geen artefacten op respiratie); Bij 0 cm zijn artefacten wel groot, maar zijn het bij AB nog steeds geïsoleerde gebeurtenissen.

24) Kleine artefacten op 0 cm van scherm niet meegeteld.

25) Ander serienummer dan bij vorige DMO test.

26) Op 2m onderdrukt de storing de schokken als ze er wel hadden moeten zijn of genereert extra schokken als ze er niet hadden moeten zijn.

27) Gestarte defibrillatie-actie werd niet uitgevoerd of een defibrillatie-actie werd onterecht op gang gebracht. Zie storingsregistratie in Bijlage G.

28) Zie storingsregistratie in Bijlage G.

29) Pacemaker pulst verkeerd (wel waar het niet moet en niet waar het wel moet).

30) Pacemaker pulst verkeerd (wel waar het niet moet en niet waar het wel moet).

31) Pacemaker pulst verkeerd (wel waar het niet moet en niet waar het wel moet).

32) Kleine artefacten; geen gevaar; zullen nauwelijks worden opgemerkt.

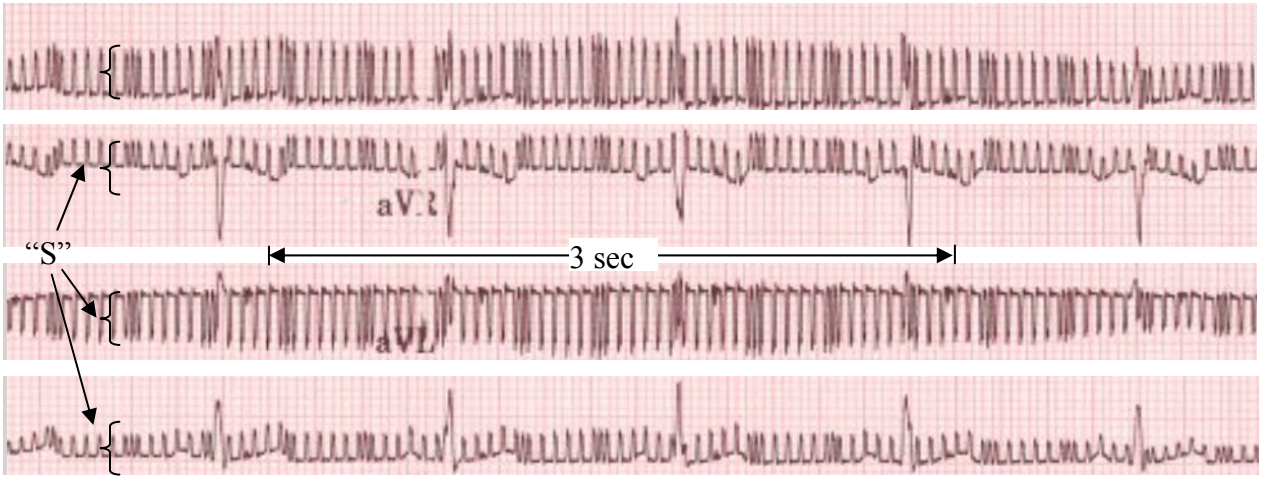
33) Colourbox positie verstoord op het scherm (Effect in DMO en bij AB gelijk).

34) Behandelde op 50 cm niet het ventrikel fibrilleren waar dit wel had gemoeten. Alleen bij de tweede test onderzocht ter informatie; Alleen in DMO getest; Geen AB getest.

35) Alleen bij de tweede test onderzocht: Gaf in DMO mode in 1 van de 8 keer een onnodig advies om niet te schokken (door de storing). Het effect is dus moeilijk te reproduceren (1 van de 8 keer). Omdat het effect moeilijk te reproduceren is, is er niet getest met AB.

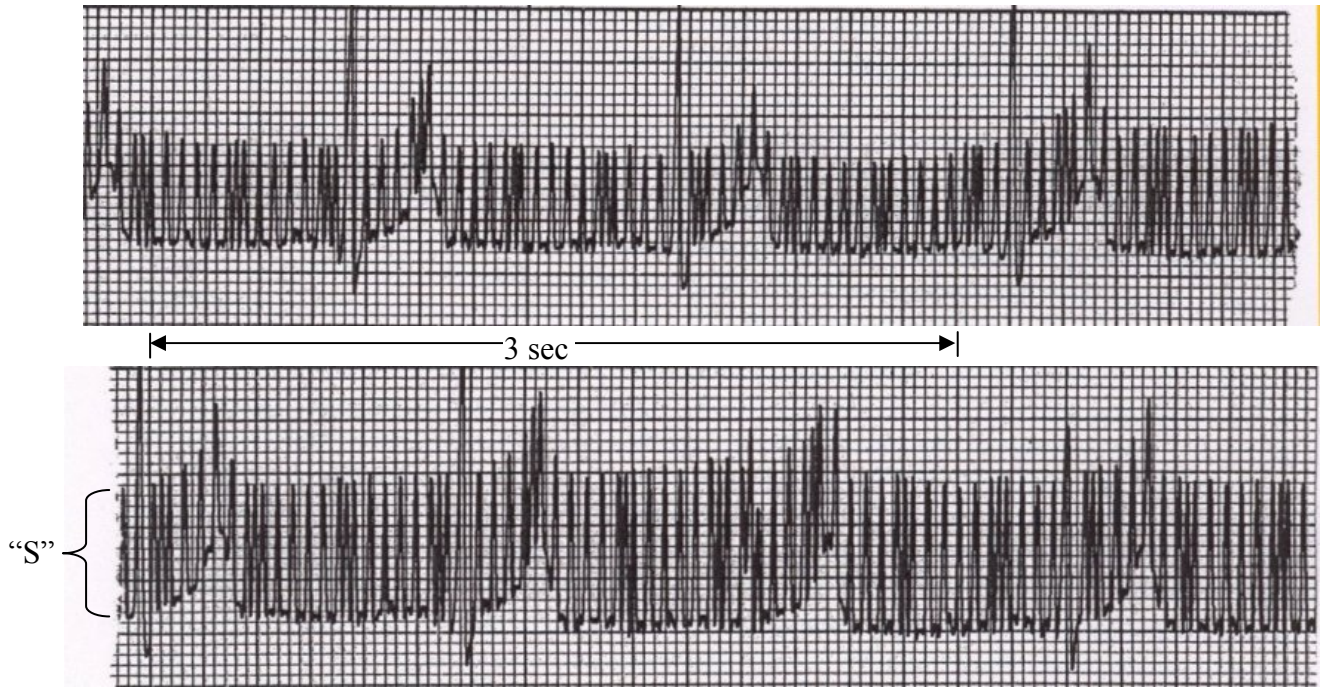
H Voorbeelden van storingsregistraties

1. ECG recorder (Nr 66 in de tabel):

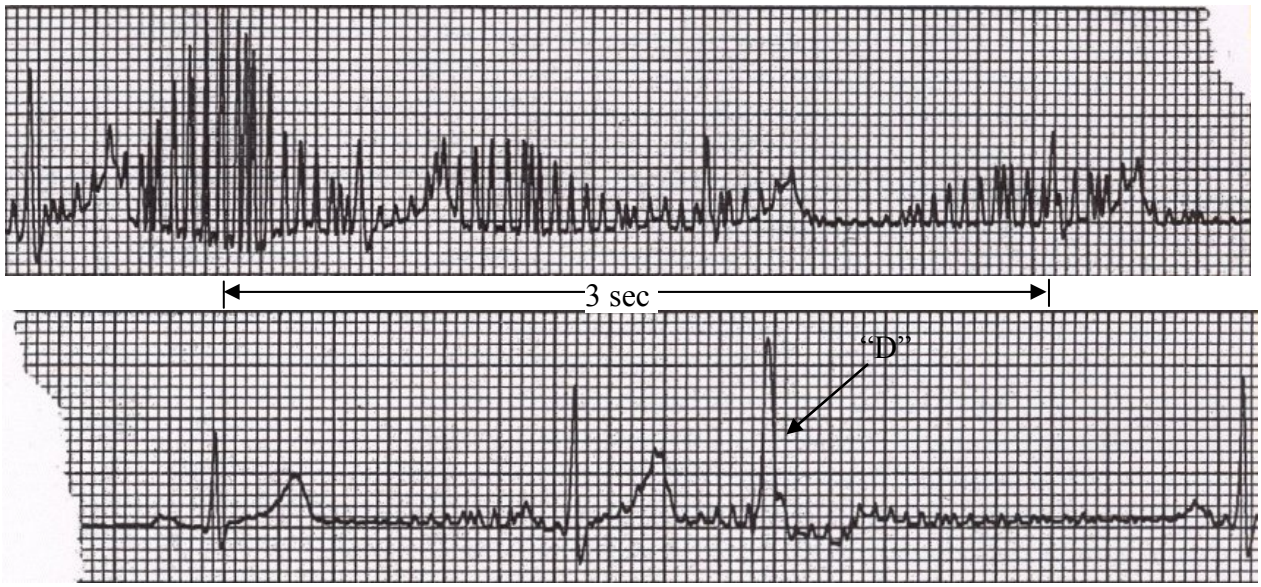


DMO mode op 20 cm afstand. Portofoon vrijwel stil gehouden. Op de ECG signalen is permanent storing "S" aanwezig ("gras"). Tussen de storing door is nog wel het van een simulator afkomstige hartsignaal te herkennen (de regelmatige pulsen). NB: Uiteraard is vastgesteld, dat het niet de simulator was, die storingsgevoelig was. De gebruiker herkent het signaal als zijnde niet fysiologisch. De storing maakt juiste interpretatie van het signaal onmogelijk.

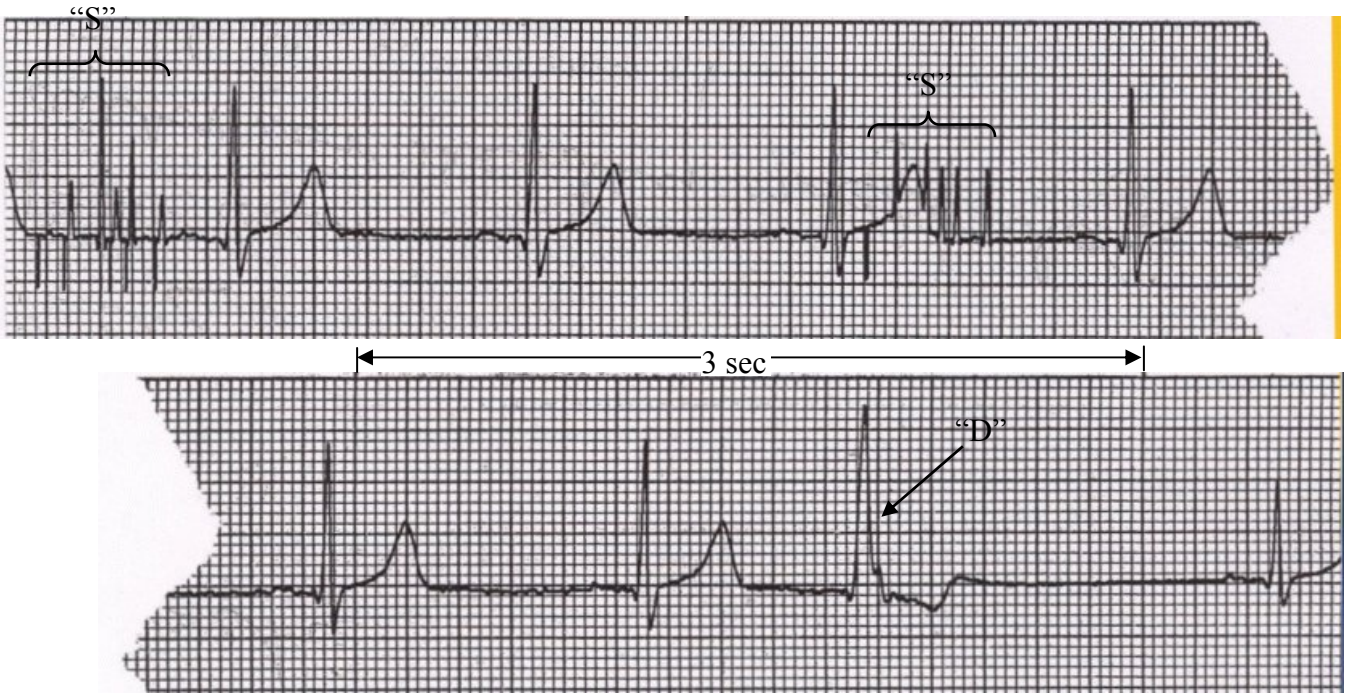
2. Defibrillator (Nr 53 in de tabel):
Achtereenvolgend worden hieronder getoond:
- registratiestroken van DMO mode op 2m afstand; portofoon min of meer stil gehouden,
- registratiestroken van DMO mode op 2m afstand; portofoon bewogen,
- registratiestroken van AB op 1m afstand.



DMO mode op 2m afstand; portofoon min of meer stil gehouden. Op het ECG-signaal is permanent storing "S" aanwezig ("gras"). Een door de bedienaar gestarte defibrillatie-actie werd door deze storing niet uitgevoerd. Tussen de storing door is nog wel het van een simulator afkomstige hartsignaal te herkennen (de regelmatige pulsen). NB: Uiteraard is vastgesteld, dat het niet de simulator was, die storingsgevoelig was.



DMO mode op 2m afstand. Portofoon bewogen. Daardoor nemen de stoorpieken toe en af . De storing bewerkstelligt een onterechte defibrillatie-actie "D".



AB op 1m afstand. Storing "S" bewerkstelligt een onterechte defibrillatie-actie "D".

I Controle van het zendvermogen van de gebruikte TETRA portofoons

Informatie en Communicatie Technologie Organisatie

Datum
16 oktober 2003

Afdeling
Kenniscentrum

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Van De Bont T.W.M. ICT-specialist Kenniscentrum	
MEMO	**Onderwerp** Zendvermogen SEPURA terminals

Reden meting

Controleren of de TETRA terminals die gebruikt worden tijdens de testen voldoen aan de ETS specificaties. Deze meting is uitgevoerd voor en na de testen (autonoom zenden) in het AMC op 30 september en 1 oktober 2003.

Testapparatuur

IFR 2968 TETRA Testset serienummer 296501/708.

Gemeten terminals

Sepura SRP2000 software versie 4.09
Vermogen gemeten met door fabrikant aangeleverde testkabel.

CPA nummer 4- 434 serie nummer 2PN530303E9E44E
zendvermogen 28,1 dBm voor en 28,3 dBm na testen

CPA nummer 3- 434 serie nummer 2PN430243E9D88EE
zendvermogen 28,4 dBm voor en 28,5 dBm na testen

J Factoren die de stoorkans in de praktijk beïnvloeden

Er zijn diverse factoren aan te wijzen die de stoorkans in de praktijk beïnvloeden. Voor alle duidelijkheid: de kans, dat een medisch apparaat door een TETRA portofoon van een ambulancemedewerker wordt gestoord. In onderstaande paragrafen worden een aantal van deze factoren besproken zonder ze overigens te kwantificeren. Het kwantificeren van elk van deze factoren apart vereist een apart onderzoek per factor en zelfs als men de factoren zou kennen heeft men er niet veel aan, want het bepalen van de stoorkans zelf is een vrijwel onmogelijke opgave. En het moge duidelijk zijn dat men aan verhogende of verlagende factoren niet veel heeft als men de kans zelf niet eens kent…. Is het dan wel zinvol om deze factoren te bespreken? Ja, dat is wel zinvol, want er wordt bij het lezen van rapporten zoals het voorliggende rapport veel over al deze factoren gediscussieerd. Om die discussies te begeleiden is het zinvol onderstaande paragrafen bij de hand te hebben.

J.1 Zendvermogen

Er is bewust getest in de zogenaamde direct mode (DMO) omdat in deze mode de portofoons op hun maximale vermogen zenden. In de andere mogelijke mode, de Trunked Mode (Trunked = geschakeld, dwz. opgenomen in het communicatienetwerk), wordt het vermogen van de portofoons door het netwerk geregeld: als de ontvangstcondities gunstig zijn dan gaat in de Trunked mode het zendvermogen naar beneden omdat daardoor de batterij minder snel leeg raakt. Bij slechte ontvangstcondities wordt in de Trunked mode het zendvermogen wel naar maximum geregeld. Die “slechtste” ontvangstcondities kunnen zich binnen een ziekenhuisgebouw tijdens normaal gebruik van een portofoon zeer wel voordoen, bijvoorbeeld als de portofoon zich “wat dieper” in het gebouw bevindt en de dempende werking van de gebouwconstructie (metalen delen – o.a. vlechtwerk van de betonbewapening) zich doet gelden. Dus ook in de Trunked Mode kan bij normaal gebruik in een ziekenhuis het maximum zendvermogen door de portofoons worden gezonden. De belangrijkste reden om in de direct mode (DMO) te zenden is echter dat daardoor het zendvermogen waarbij een actuele test is uitgevoerd bekend is. Zou de test in Trunked Mode zijn uitgevoerd, dan zou het actuele zendvermogen niet bekend zijn geweest wat zeer onhandig zou zijn bij het interpreteren van cq. het rapporteren over de stoorgevoeligheid van een medisch apparaat.

In principe zou het (theoretisch) mogelijk moeten zijn om uit een schatting van het feitelijke zendvermogen gedurende het actuele gebruik van een portofoon binnen een ziekenhuis door een ambulancemedewerker een factor te berekenen voor stoorkansvermindering ten opzichte van de uitgevoerde test bij vast maximaal vermogen. Deze berekening is niet uitgevoerd omdat genoemde schatting niet voorhanden is.

J.2 Linearization burst

Er is gezonden met portofoons die werken met de zogenaamde Linearization burst. Dat is een door de TETRA standaard toegelaten voorziening waarmee het zendvermogen van de portofoon wordt gekalibreerd: regelmatig wordt een vast pulsvormig signaal uitgezonden.

Bij de test is niet separaat onderzocht wat het effect van de linearization burst op medische apparatuur is. Dit kon ook niet separaat worden onderzocht omdat de beschikbare 1W portofoon met linearization burst was uitgevoerd. Tijdens de test is niets gebleken waaruit een indicatie voor deze invloed zou kunnen volgen.

J.3 Keying

Tijdens het testen is niet bewust onderzocht wat het effect van keying is. Keying is het feit, dat direkt na het indrukken van de zendknop ("transmit **key**") de portofoon gedurende ca. 0,25 seconde een ander signaal zendt dan daarna. Tijdens de tests is regelmatig op de zendknop gedrukt – ook terwijl de portofoon vlak bij de medische apparatuur werd gehouden. Keying is dus impliciet meegetest zonder het effect van keying apart er uit te lichten tijdens de tests. Een onderzoek naar Keying zou een veel uitvoeriger test aan veel meer medische apparaten vereisen dan in het voorliggende onderzoek mogelijk was. Tijdens het testen is de indruk ontstaan dat de meeste medische apparaten niet gevoelig zijn voor Keying. Het betreft echter slechts een indruk.

J.4 Absorptie door de gebruiker

Een deel van de uitgezonden energie van een portofoon wordt geabsorbeerd door "objecten" in de omgeving. Hoofd en lichaam van de gebruiker zullen meestal de dichtstbijzijnde objecten zijn en er zal sprake zijn van absorptie van energie door hoofd en lichaam van de gebruiker. Daardoor zal er sprake zijn van een zekere "schaduwwerking". Hoe sterk de schaduwwerking is is niet bekend.

Anderzijds zullen hoofd en lichaam van de gebruiker ook een deel van de energie reflecteren naar de zijde waar de gebruiker de portofoon houdt. Dit zal voor die zijde een verhoging van de veldsterkte tot gevolg hebben. Hoeveel is niet bekend.

In eerste benadering kan gezegd worden dat beide effecten (absorptie en reflectie) in de tests zijn "meegenomen" doordat de portofoons in de hand werden gehouden – zij het dat ze zich niet helemaal in de normale gebruikspositie bevonden.

J.5 Trefkans

Om tijdens normaal bedrijf van het ziekenhuis een verstoring van medische apparatuur te bewerkstelligen, veroorzaakt door een TETRA portofoon van een ambulancemedewerker moet aan de volgende condities zijn voldaan:

- een medisch apparaat met een bepaalde storingsgevoeligheid moet zich op een bepaalde plaats bevinden, èn:
- een ambulancemedewerker moet zijn portofoon gebruiken èn:
- zich op die plaats bevinden èn:

- onder de juiste (“gevoelige”) hoek ten opzichte van het medische apparaat zenden.

Bij de uitgevoerde stoorgevoeligheidstests speelden bovengenoemde factoren geen rol omdat per onderzocht apparaat de stoorgevoeligheid van het apparaat werd “opgezocht”.

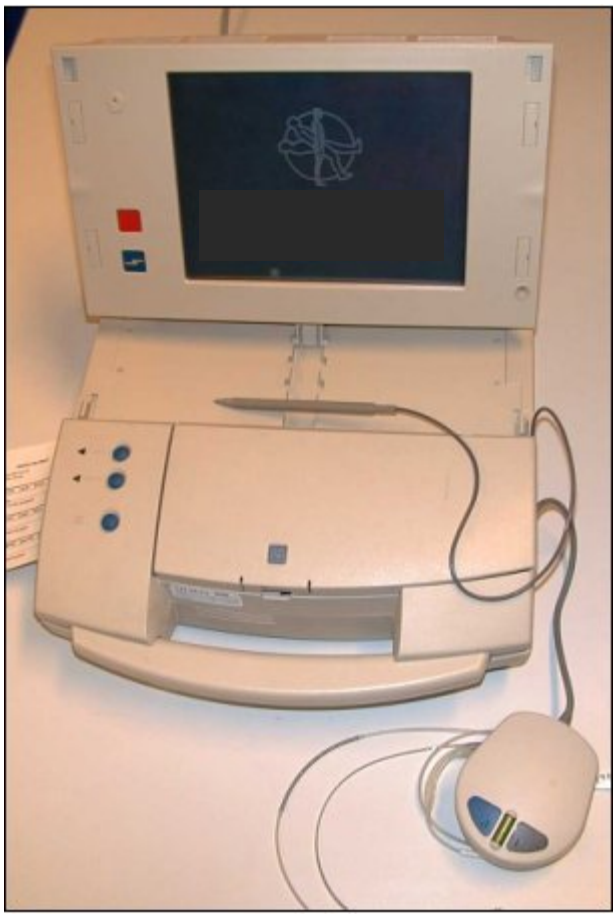
Omdat de kans op bovengenoemde condities niet bekend is, is de echte stoorkans per apparaat niet te berekenen. Wel kan over de echte stoorkans het volgende worden gezegd:

- Tijdens rondlopen met een portofoon zal een 10 keer zo kort gesprek een 10 keer zo kleine kans op storing opleveren,
- De stoorkans door het uitzenden van een automatisch signaal door de portofoon naar het netwerk is veel kleiner dan de stoorkans door het voeren van een gesprek,
- De meeste storingen zijn van het type S (= Significant maar ongevaarlijk) en niet van het type H (= Gevaarlijk / Hazard). De storing “Interference on ECG” is de meest voorkomende storing. In veel gevallen zal een storing dus bestaan uit een “Interference on ECG”, die meestal het karakter S (= Significant) zal hebben. Deze storing zal in een aantal gevallen door het ziekenhuispersoneel kunnen worden opgemerkt. Als dit gebeurt tijdens een gesprek van een ambulancemedewerker via zijn portofoon, dan zal er in veel gevallen een aanmerking in de richting van deze ambulancemedewerker worden gemaakt.

K Foto’s van enkele medische apparaten en portofoons

Implanteerbare defibrillator met twee leads/wires/electroden.

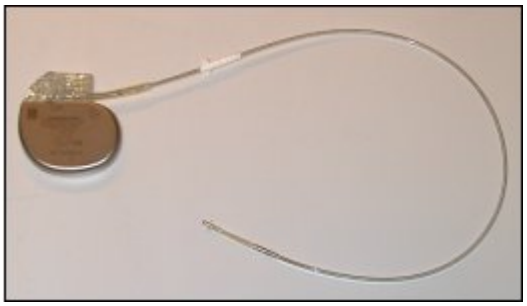
Programmeerapparaat voor defibrillator.



Defibrillator in zoutoplossing ter simulatie van het menselijk lichaam.

Implanteerbare neurostimulator.

Implanteerbare pacemaker met lead/wire/electrode.



Simulator voor het genereren van hartsignalen.

TETRA portofoons.

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TNO report

KvL/P&Z 2007.117

96 Medical Apparatuses tested for interference by WLAN/WiFi signals

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Number of appendices	3

Summary

This research describes the influence of WLAN [1] 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

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[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 WLAN[2] 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).

Contents

1 Introduction

This research describes the influence of WLAN [3] 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 antennas [4] 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).

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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: Ch**36** 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.

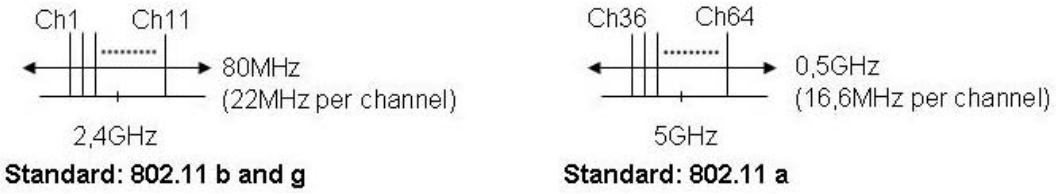


Figure 3.1 Channels 1, 11, 36 and 64 in their respective frequency bands at 2,4GHz and 5GHz according to the IEEE 802.11 standards.

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** (**U**nsafe) is not restricted to life threatening situations for the patient. The importance of interference must be seen in the right perspective: in a way every disturbance is unacceptable during treatment of patients [5].

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. - Relevant noise or humble from a loudspeaker.
S	**Significant** but not (yet) unsafe disturbance	- Disturbance of the functioning of the apparatus but no safety hazard for patient or user - no indirect safety hazard as well. - Small “spikes” on ECG curves. - Disturbances on a display without hazard.
U	**Unsafe** disturbance	- 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, Respironics	N	N
80	Transport Ventilalor Oxylog 3000, Dräger	N	N

6) **N**/**L**/**S**/**U** = **N**o/**L**ight/**S**ignificant/**U**nsafe disturbance or interference. In Netherlands language: = **N**/**L**/**S**/**O** = **N**ee/**L**ichte/**S**ignificante/**O**nveilige 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 µVP7000, Arcomed	N	N
62	Volumetric Pump µVP 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 $0{,}5^0$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	41ºC 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 $0{,}3^0$C 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 Infrared controlled, Medtronic	N [30]	N
38	Idem: system Electromagnetic (EM)	N	N
48	Endoscopy, LEMKE	N	N
49	Angiographic Table, Trumph 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

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

At 500mW

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

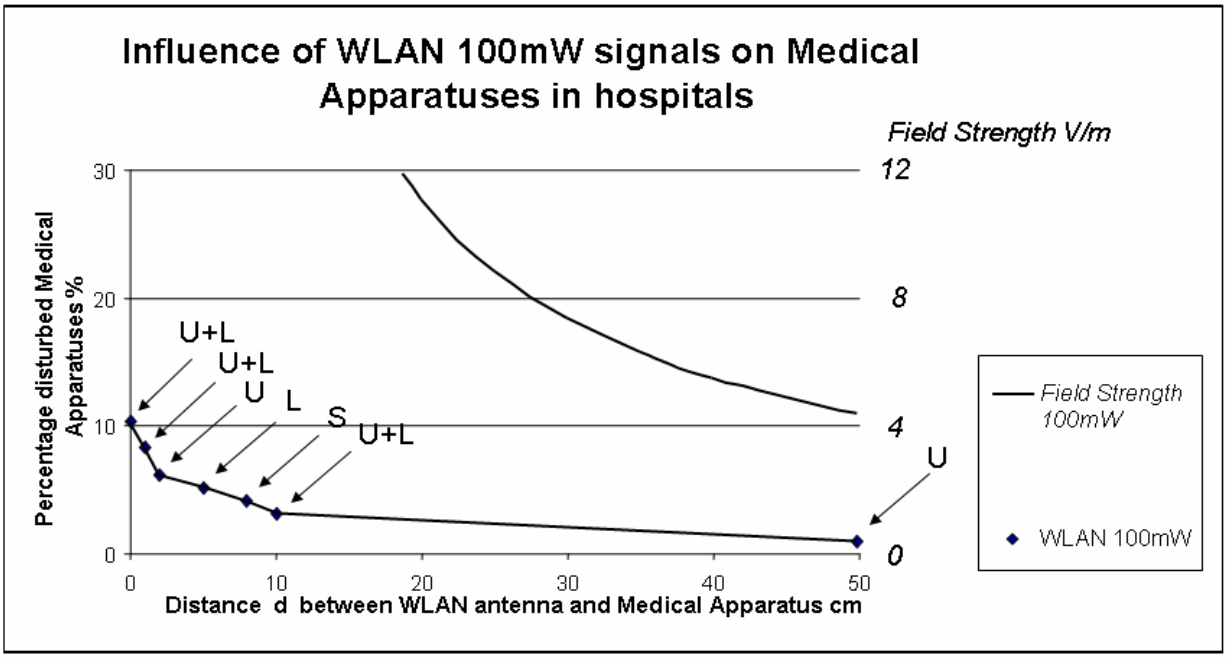


Figure 5.1: Influence of WLAN 100mW signals on medical apparatuses in hospitals.

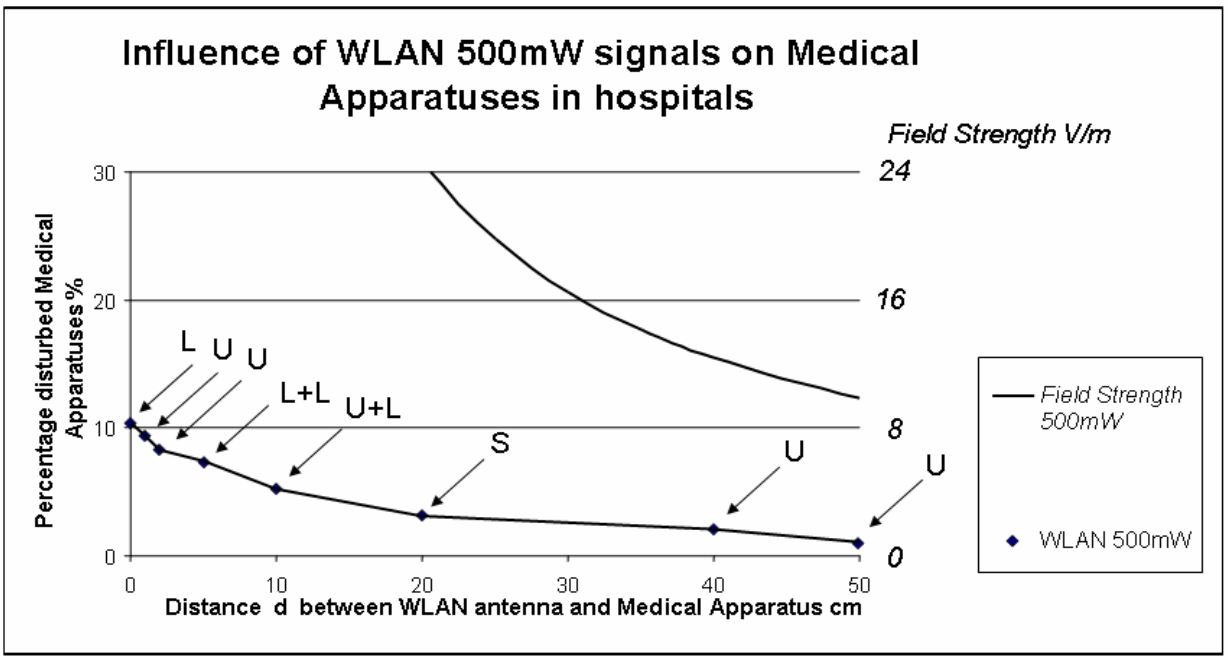


Figure 5.2: Influence of WLAN 500mW signals on medical apparatuses in hospitals.

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, pulsoxymeter, 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]**).

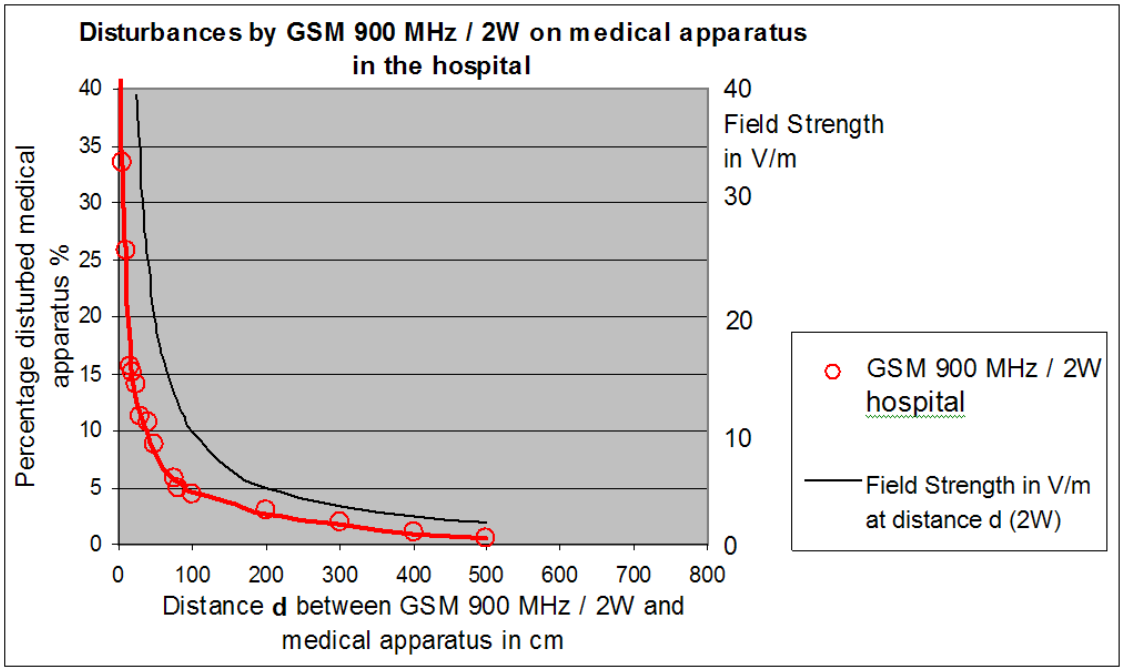


Figure 5.3: Disturbances by GSM 900 MHz / 2W on medical apparatus in the hospital (copied from Literature [4] and [5]).

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 kept [33]. 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

During this research TNO was assisted by an excellent crew of people who prepared, organized, initiated, coordinated, assisted and realized and just helped on many aspects.

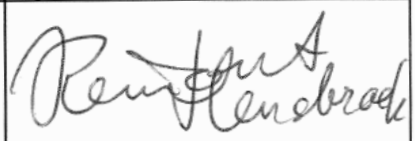
The hospitals mentioned below supported the project. They provided medical apparatuses and supported intensively in operating them and explaining their functionality including the related risks; also in case disturbances occurred.

- Erasmus MC University Medical Center Rotterdam;
- 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
   - Spectrum analyzer: fsh manufactured by Rohde & Schwarz;
   - Horn antenna: Double Ridged Guide Horn Antenna, Manufacturer: EMCO;
   - Model: 3115, Serial No. 9104 3649;
   - Attenuator 20dB.

2. Hardware in the test set-up:
   - 2 PC's / 8 AP's (in this way combining 802.11 a, b, g in one test);
   - 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;
   - 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.

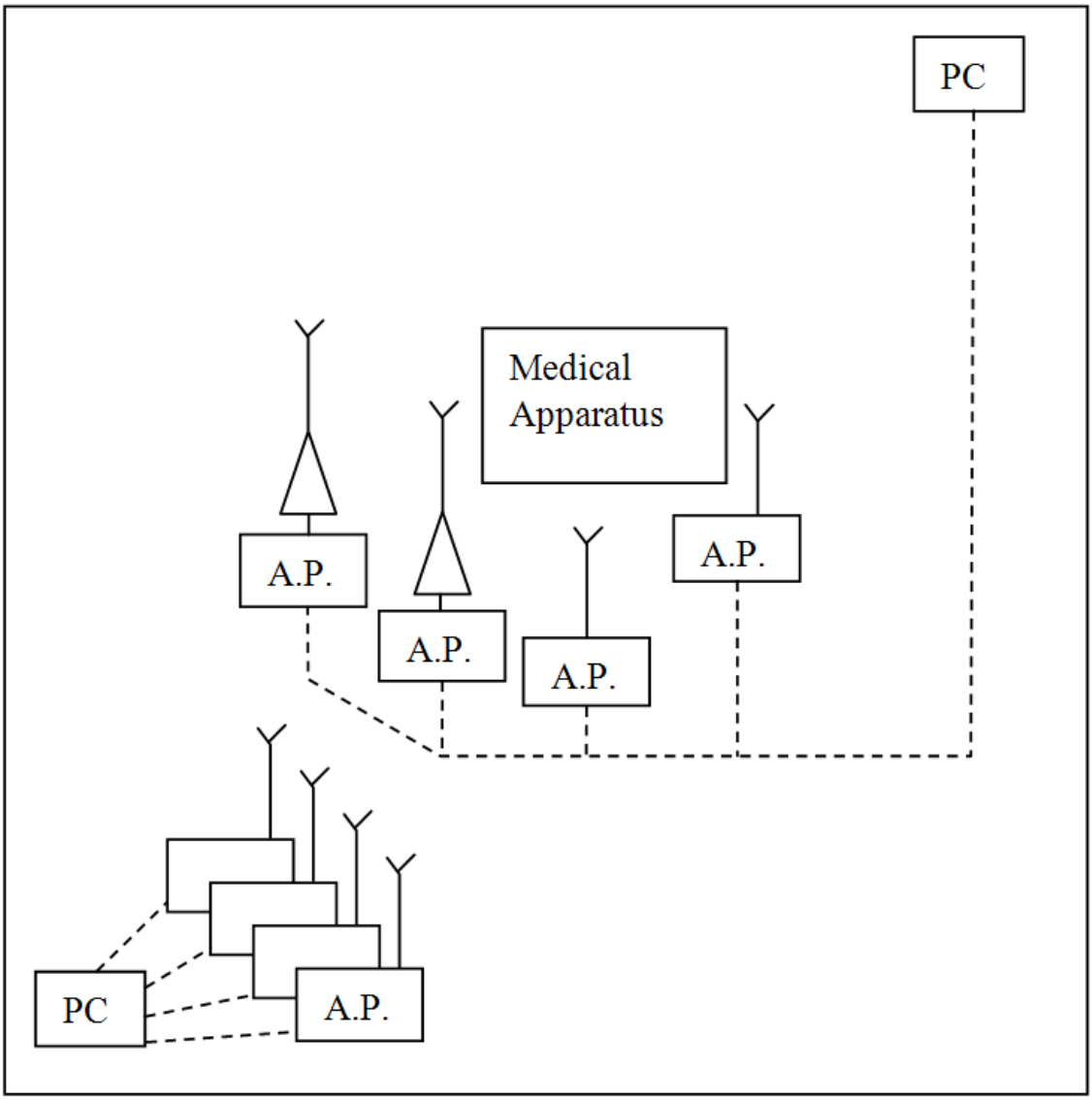


Figure B.1: Test set-up with 4 transmitting antennas and 4 receiving antennas. Each of these groups of antennas was connected to a separate PC.

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.

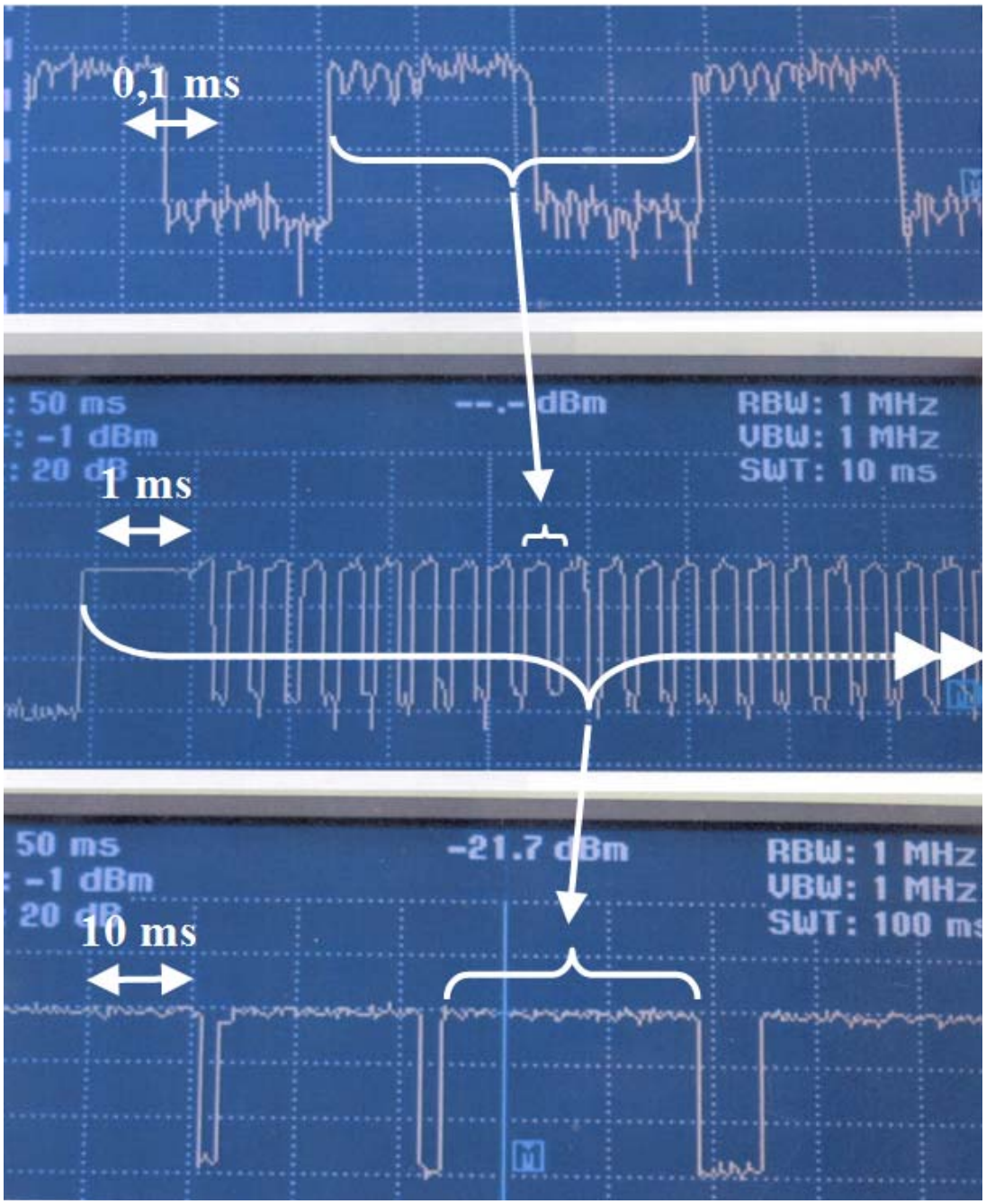


Figure B.2: Test signal of Ch1 with short packages. The time base: 0,1ms/division (upper trace), 1ms/div (middle trace) and 10ms/div (lower trace).

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).

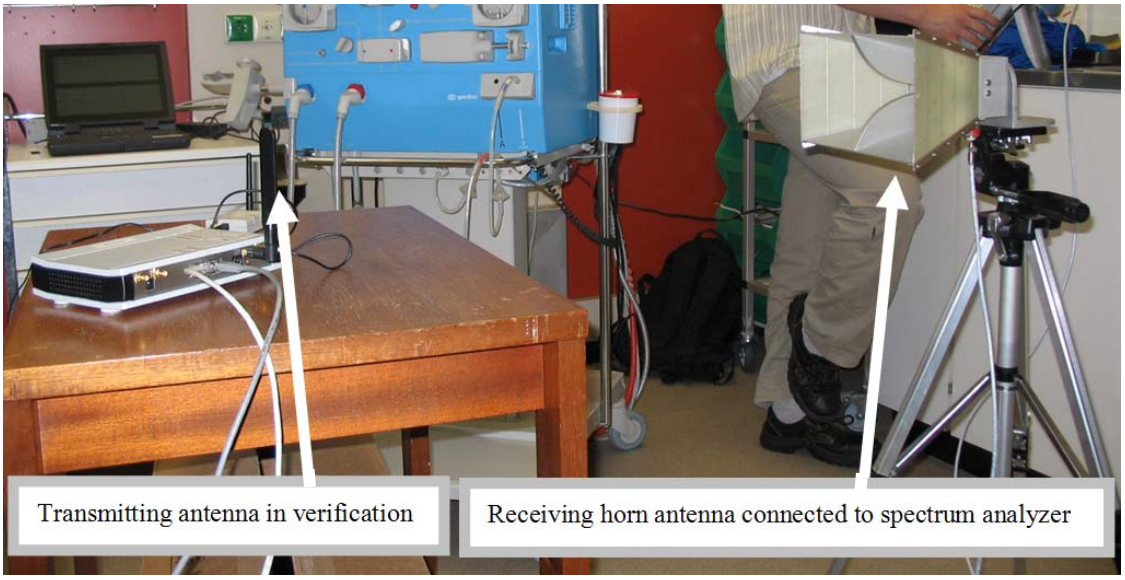


Figure B.3.

Figure B.4.

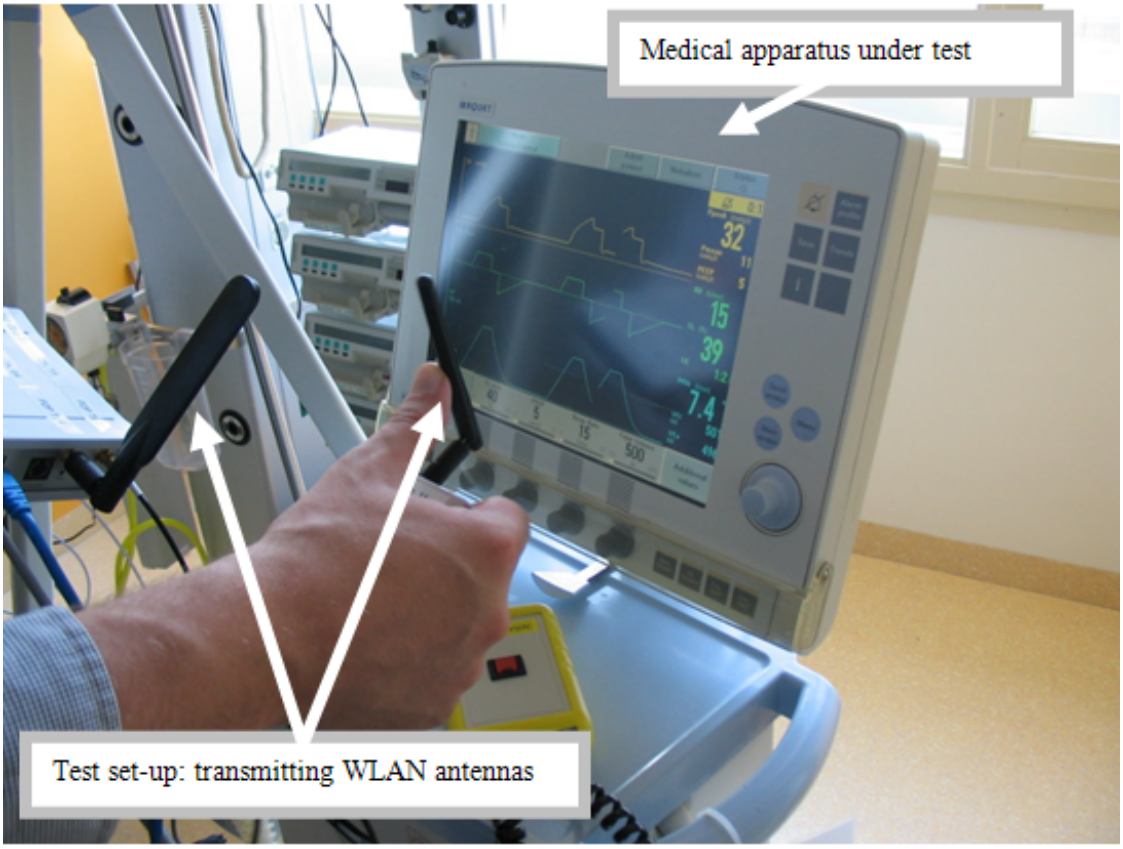


Figure B.5.

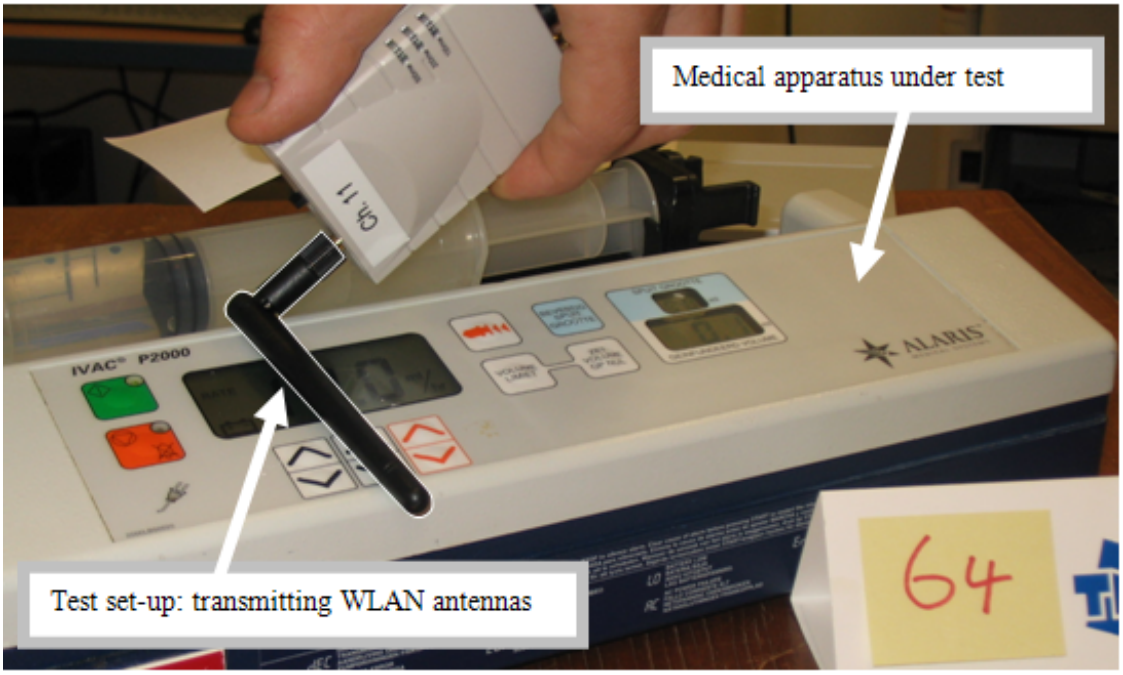


Figure B.6.

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”).
3. IEC 60601-1-2: 2001 Medical electrical equipment – Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests. Second edition 2001-09
4. TNO report “Effects on medical equipment at home of pocket phones and the like – field measurements”, TNO Prevention and Health, TNO Research report PG/TG/00.050 (28 April 2000)
   For medical apparatus this report refers to:
   Influence of 2W GSM pocket phones on 205 medical apparatuses: field measurements. TNO report TG/95.044. 1 August 1995 (NL Language).
5. R. Hensbroek, Interference by handheld telephones on medical equipment (NL language). In magazine: “Klinische Fysica”. December 2000.
6. Recommendations for the use of GSM and cordless telephones near electronic medical equipment for home care, 25 October 2000. This document has been drawn up by the Telecommunication branch of the Netherlands Association for Information and Communication Technology (V-ICTN). It is published on the internet site of the Netherlands Ministry of Welfare, Health and Sports.
   Those recommendations refer to the still applicable recommendations in **Literature [2]:** Recommendations regarding the use of pocket telephones within health care institutions 1995, VIFKA, 1 September 1995 (VIFKA is now called “Vereniging ICT Nederland”).
7. IEC 60513 (1988): Safety Philosophy for Testing of Medical Electrical Equipment.
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.
9. ECRI Health Devices 30 (11), November 2001: Wireless Communication Devices and Electromagnetic Interference, pp. 403-409.
10. Morrissey et al: Characterization of Electromagnetic Interference of Medical Devices in the Hospital due to Cell Phones. Health Physics, January 2002, Volume 82, Number 1, pp 45-51.

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

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Number of appendices	3

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 [1]).

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[1]) 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

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) [2]).

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 [3]). 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 form the mains and powered form 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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[2]) 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.

[3]) 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.

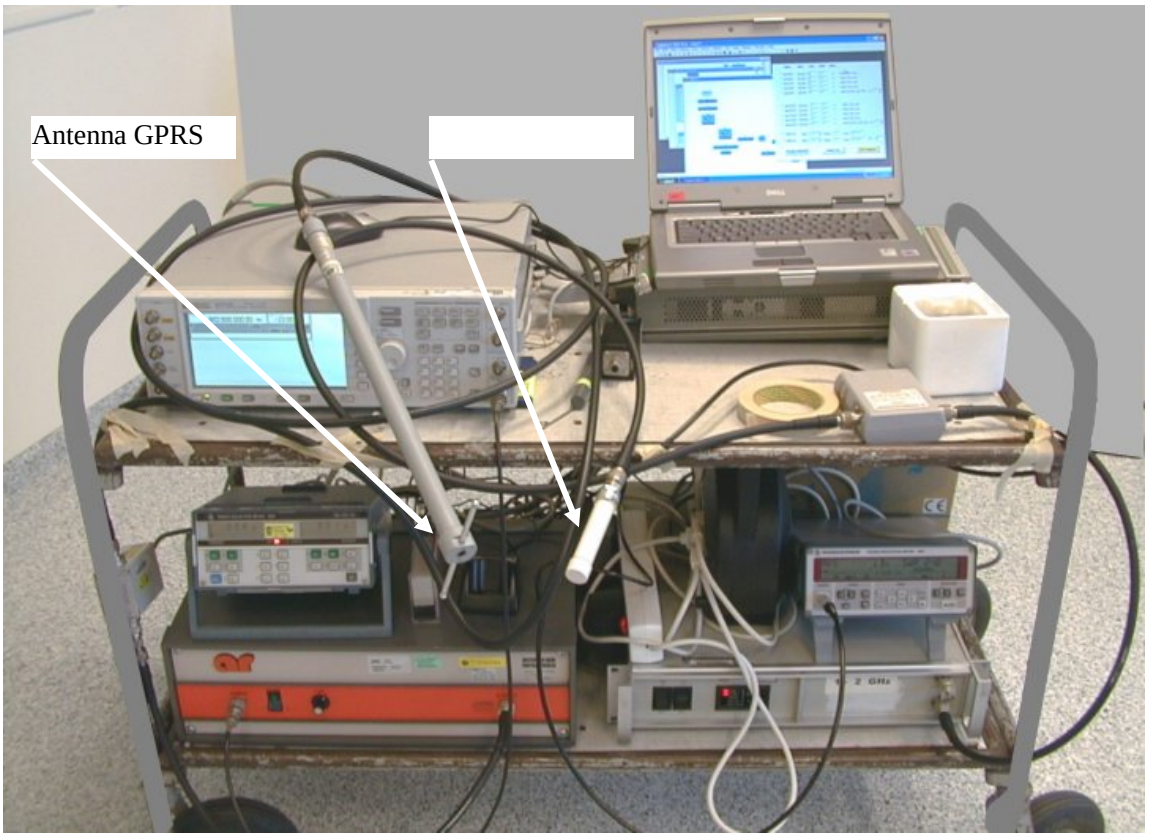

Figure 1: Test set-up to generate the GSM/GPRS and UMTS test signals

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** “ 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
Syringe Pump			
1	Asena GH, Alaris Medical Systems	20ml/hour resp.200ml/hour; Syringe: BD Plastipak 50	Battery + Mains
Volumetric Infusion Pump			
2	Asena/GW, Alaris Medical Systems	100 ml/hour	Battery + Mains
Enteral Feeding Pump			
3	Kangaroo ePump, Sherwood	200ml/hour	Battery + Mains
Intra-Aortic Balloon Pump			
11	CS300, Datascope	Normal settings	Mains
Patient Monitor/Meter			
9	IntelliVue MP70, Philips; With Monitor IntelliVueX2	**Parameters**: ECG, ABP, HF, SpO_2 , NiBP	Mains
10	IntelliVueX2, Philips	**Parameters**: ECG, ABP, HF, SpO_2 , NiBP	Battery
7	AS3, Datex Ohmeda [Incl Mainframe, Multiparamer, Anesthesia Gas Module and coupled to ADU A-Auf (No.8)]	**Parameters**: ECG, Invasive Press. P1, Temp. T1, SpO_2 **Anesthesia Gases**: O_2, CO_2, N_2O, Sevoflurane, Spirometric Measurement + Damp Identification	Battery + Mains
14	Infinity Delta, Dräger; [Incl. Multimed 12 and HemoMed.]	**Parameters**: ABP, HF (80 from Fluke Simulator MPS 450)	Battery + Mains
Anaesthesia Ventilator			
8	ADU A-Auf, Datex-Ohmeda	Volume controlled; 1 l/min O_2 ; 7 l/min Min.Vol	Mains
Dialysis			
4	Prismaflex, Gambro	200ml/min; Tested with complete set + artificial kidney	Mains
6	Dialog$^+$, B. Braun	300ml/min. HDF = Hemo Dia Filtration; Tested with complete set + artificial kidney	Mains
Blood Warmer			
5	Autocontrol 3XPT, Barkey Connected to Dialysis Prismaflex	Patient line was placed in Warmer. Warmer was set at 41^{0}C fixed (not actively controlling the temperature)	Mains
19	Level 1, Sims Industries	Set at 41^{0}C	Mains
Temporary (External) Cardiac Pacemaker			
12	EV 4543, Pace Medical Inc. Single Chamber VVI	**A: Synchron. Pacing**: 4V; **Sensitivity**: 1 resp. 2 mV **B: Asynchronous**: Pacing rate: 210	Battery
13	4570, Pace Medical Inc. Dual chamber	**A: Pacing** : DDD-mode : **Sense Arterial**: 1 mV and **Sense Ventricular**: 2 mV **B: Static pacing**: DDI: **Output pulse**: 10 V	Battery
Heart-Lung Machine			
15	HL 30 (Nr.22 for Thoracic Surgery)	Several components included: Among others: OR-computer Maquet	Mains
Incubator			
16	8000 SC, Dräger	Set at 33^{0}C	Mains
17	Isolette TI 500, Dräger / Airshields	Normal setting	Battery + Mains
18	Isolette C 2000, Hill-ROM/Air Shields	Normal setting	Mains
Telemetry			
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.

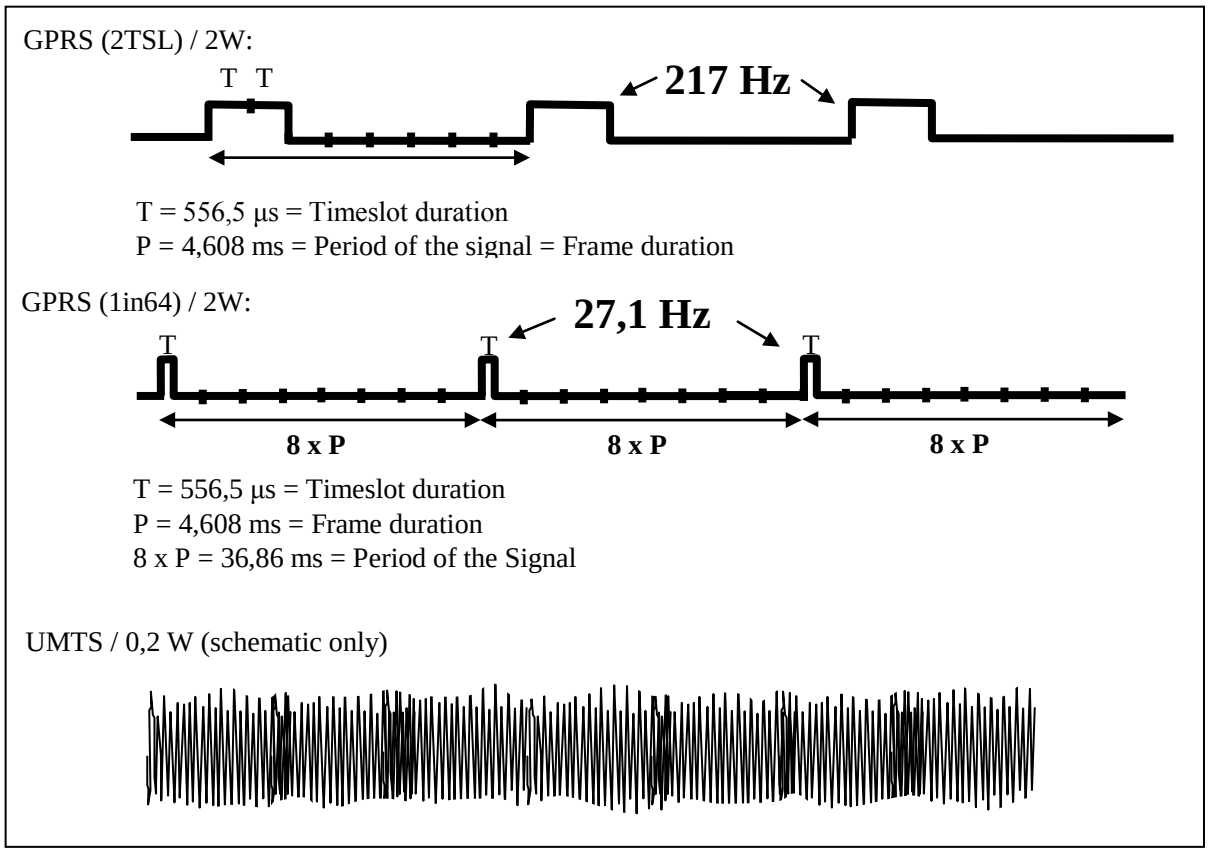

Figure 2: Sketch of the timing principles in the five test signals used in the St. Antonius Hospital

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** (**H**azardous) 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 [4]).

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.

[4]) 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**
Syringe Pump								
1	Asena GH, Alaris Medical Systems	04	002352	**15 H**	**50 H**	**15 H**	n	n
Volumetric Infusion Pump								
2	Asena/GW, Alaris Medical Systems	02	1959	n	**2 H**	**2 H**	**5 H**	**2 H**
Enteral Feeding Pump								
3	Kangaroo ePump, Sherwood	06	005151	n	n	n	n	n
Intra-Aortic Balloon Pump								
11	CS300, Datascope	08	25505	n	n	n	n	n
Patient Monitor								
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
Anaesthesia Ventilator								
8	ADU A-Auf, Datex-Ohmeda	04	003263 (Construction year:'99)	n	n	n	n	n
Dialysis								
4	Prismaflex, Gambro	08	25523	n	n	n	n	n
6	Dialog^{+}, B. Braun	07	25236	n	n	n	n	n
Blood Warmer								
5	Autocontrol 3XPT, Barkey Connected to Prismaflex (No.4)	08	25528; Tested while at fixed setting 41^{0}C	n	n	n	n	n
19	Level 1, Sims Industries	01	000662	n	**5 H**	**5 H**	**0 S**	**0 S**
Temporary (External) Cardiac Pacemaker								
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
Heart-Lung Machine								
15	HL 30 (Nr.22 for Thoracic Surgery)	04	003135	n	**5 H**	**2 H**	**5 H**	**5 H**
Incubator								
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
Telemetry								
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

5.3 Detailed reactions of the medical apparatuses tested

Table with detailed description of the interference reactions per medical apparatus
In the table below the interference reactions are described for each apparatus tested. The table below contains basic information of each apparatus with the described interference reactions added per apparatus. The table is following the same principles as in the previous paragraphs.

Legend for Reactions: **H**=Hazardous; **S**=Significant; **L**=Light (does not occur in this report); n=no Reaction.
Results Columns: **S 1** = GPRS 900 (2TSL), **S 1a**=GPRS 900 (1TSL), **S 2** = GPRS 1800 (2TSL); **S 2a**=GPRS 1800 (1TSL) .

No.	Medical Apparatus tested		UMTS	S 1	S 1a	S 2	S 2a
Syringe Pump							
1	Asena GH, Alaris Medical Systems		**15 H**	**50 H**	**15 H**	n	n
Description of interference reactions: **UMTS**: At 15cm from the centre of the front-side of the pump: ACOUSTIC ALARM occurred + the Message "AANDRIJVING ONTGRENDELD" incorrectly appeared on the front panel of the pump. **Signal 1**: At 50cm from the pump: The pressure bar on the front panel of the pump incorrectly indicated that the PRESSURE ROSE while in reality the pressure did not raise. No alarm at 50cm. However around 25cm the message "OBSTRUCTIE" occurred incorrectly + acoustic alarm after some seconds. At ca.0cm also other incorrect messages appeared (mentioning "A/D convertor" or "Ref.Voltage"). **Signal 1a**: At 15cm from the centre of the front-side of the pump: Acoustic Alarm occurred + the Message "AANDRIJVING ONTGRENDELD" appeared incorrectly. **Signal 2**: At 0cm: No reaction. **Signal 2a**: At 0cm: No reaction. **After the interference tests**: the internal Event log and Service Log in the pump could be read: they contained events that apparently related to the above alarms and messages (no detailed investigation was performed).							
Volumetric Infusion Pump							
2	Asena/GW, Alaris Medical Systems		n	**2 H**	**2 H**	**5 H**	**2 H**
Description of interference reactions: **UMTS**: At 0cm: No reaction. **Signal 1**: At 2cm before the front screen of the pump: Incorrect message "Err" (meaning: Internal Error) + Acoustical Alarm and pump stopped. Switching OFF and ON was necessary. After power ON the setting (100 ml/hr) was lost (changed into 0 ml/hour) . Pump could be set at 100 ml/hour again. Pump operated normal again after this. **Signal 1a**: At 2cm: Same reaction as for **Signal 1** above. **Signal 2**: At 5cm from small lid: Incorrect message "Err" (meaning: Internal Error) + Acoustical Alarm (less sharp tune than with **Signal** 1 above!) and pump stopped. Switching OFF and ON was necessary. After power ON the setting (100 ml/hour) was still present and the pump functioned normal again. **Signal 2a**: At 2cm: from small lid: Incorrect message "Pressure High". Pump could be brought to normal function without switching OFF and ON. **After the interference tests**: the internal Event log and Service Log could be read (through infrared): they contained events apparently relating to the above alarms and messages (no detailed investigation was performed).							
Enteral Feeding Pump							
3	Kangaroo ePump, Sherwood		n	n	n	n	n
Description of interference reactions: No reactions (including distance 0cm between apparatus and antenna).							
Intra-Aortic Balloon Pump							
11	CS300, Datascope		n	n	n	n	n
Description of interference reactions: No reactions (including distance 0cm between apparatus and antenna).							

Patient Monitor							
9	IntelliVue MP70 + Mainframe,Philips; [Monitor IntelliVueX2 was connected]		n	**20 H**	**15 H**	n	n
Description of interference reactions: **UMTS**: At 0cm: No reaction. **Signal 1**: At 20cm from the small monitor X2: At the MP70 an Incorrect 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. **Signal 1a**: At 15cm from the small monitor X2: Same reaction as for **Signal 1** above. **Signal 2**: At 0cm: No reaction. **Signal 2a**: At 0cm: No reaction. **After the interference tests**: Apparatus functioned normal.							
10	IntelliVueX2, Philips		n	**15 H**	**5 H**	n	n
Description of interference reactions: **UMTS**: At 0cm: No reaction. **Signal 1**: At 15cm from the small monitor X2: an Incorrect message appeared "ECG electrodes?" + Acoustic Alarm was given. Also the EKG traces disappeared on the small monitor X2. **Signal 1a**: At 5cm from the small monitor X2: an Incorrect message appeared "ECG electrodes?" + Acoustic Alarm was given. Also the EKG traces disappeared on the small monitor X2. **Signal 2**: At 0cm: No reaction. **Signal 2a**: At 0cm: No reaction. **After the interference tests**: 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**	**5 S**
Description of interference reactions: **UMTS**: At 0cm: No reaction. **Signal 1**: **A**: At 5cm from the Anaesthesia Gas Module: Incorrectly the indication of Sevoflurane disappeared (empty indicator) + Incorrect 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%). **B**: At 0cm from the connector for Arterial Pressure P1: At the trace on the monitor screen a "**band of interference**" ca. 4mm in height was observed. **Signal 1a**: Same reactions **A** and **B** at the same distances as for **Signal 1** above. **Signal 2**: Same reaction **B** (no A) at the same distance as for **Signal 1** above. **Signal 2a**: Same reaction **B** (no A) at the same distance as for **Signal 1** above. In P2 some interference as well. **After the interference tests**: Apparatus functioned normal.							
14	Infinity Delta, Dräger; [Incl. Multimed 12 and HemoMed.]		n	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	n
Description of interference reactions: No reactions (including distance 0cm between apparatus and antenna).							
Dialysis							
4	Prismaflex, Gambro		n	n	n	n	n
Description of interference reactions: No reactions (including distance 0cm between apparatus and antenna).							
6	Dialog^{+} , B. Braun		n	n	n	n	n
Description of interference reactions: No reactions (including distance 0cm between apparatus and antenna).							

Blood Warmer							
5	Autocontrol 3XPT, Barkey Connected to Prismaflex (No.4)		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**
Description of interference reactions: **UMTS**: At 0cm: No reaction. **Signal 1**: **A**: At 5cm from display: Incorrect 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. **B**: At 5cm from ON/OFF switch and from the display the sound of a flapping relais (?)could be heard. **Signal 1a**: At 5cm: Same reactions **A** and **B** as described above for **Signal 1**. **Signal 2**: 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). **Signal 2a**: At 0cm: Same reaction as described above for **Signal 2**. **After the interference tests**: Apparatus functioned normal.							
Temporary (External) Cardiac Pacemaker							
12	EV 4543, Pace Medical Inc.		n	**10 H**	**5 H**	**5 H**	**10 H**
Description of interference reactions: **UMTS**: At 0cm: No reaction. **Signal 1**: At 10cm: **A**: 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. **B**: During asynchronous pacing (set at 210): No pace pulses any more and pace indication permanently lighted up. **Signal 1a**: At 5cm: During synchronous Pacing: Pace rhythm slowed down and Sense Indication lighted up. Pulse width was influenced as well. **Signal 2**: At 5cm: During synchronous Pacing: Pace rhythm slowed down and Sense Indication lighted up. **Signal 2a**: At 10cm: During synchronous Pacing: Pace rhythm slowed down and Sense Indication lighted up. **After the interference tests**: Pacemaker functioned normal.							
13	4570, Pace Medical Inc.		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**
Description of interference reactions: **UMTS**: At 0cm: No reaction. **Signal 1**: At 5cm from level detector in venous reservoir: Incorrect visual (Orange buttons on touch screen) and acoustic alarm and arterial flow stops incorrectly. **Signal 1a**: At 2cm: Same reaction as for **Signal 1** above. **Signal 2**: At 5cm: Same reaction as for **Signal 1** above. **Signal 2a**: At 5cm: Same reaction as for **Signal 1** above. **After the interference tests**: 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**	n
Description of interference reactions: **UMTS**: At 0cm: No reaction. **Signal 1**: **A**: At 0cm from temperature indicator in front panel: temperature indication incorrectly influenced (e.g. from 37^0C → $22,4^0$C). **B**: At 0cm from heating indicator in front panel: Heating element incorrectly activated (power current from the mains was measured: it raised with 400mA) **Signal 1a**: At 0cm: same reactions **A** and **B** as for **Signal 1** above. **Signal 2**: **A**: At 0cm from temperature indicator in front panel: temperature indication incorrectly influenced (E.g. from $36,1^0$C → $37,7^0$C). **B**: No activation of heating element occurred (no **B**). **Signal 2a**: At 0cm: No reaction. **After the interference tests**:							
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**	**5 S**
Description of interference reactions: **UMTS**: At 0cm: No reaction. **Signal 1**: At 2cm from transmitter: Incorrect 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. **Signal 1a**: At 2cm: Same reactions as described above for **Signal 1**. **Signal 2**: 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. **Signal 2a**: At 5cm: Same reactions as described above for **Signal 2**. **After the interference tests**:							
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
11	CS300, Datascope	08	25505	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
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 and coupled to ADU A-Auf (No.8)]	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
8	ADU A-Auf, Datex-Ohmeda	04	003263 (Construction year:’99)	n	n	n	n	n
4	Prismaflex, Gambro	08	25523	n	n	n	n	n
6	Dialog^{+} , B. Braun	07	25236	n	n	n	n	n
5	Autocontrol 3XPT, Barkey Connected to Prismaflex (No.4)	08	25528; Tested while at fixed setting 41^{0}C	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
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
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
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
22	Antenna Winegard-Bublington LA	06?	Stickered as A58	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, 5, 5, 0, 0 cm
S 2a:	6 out of 22 apparatuses were influenced at distances:	10, 5, 5, 5, 2, 0 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]**.

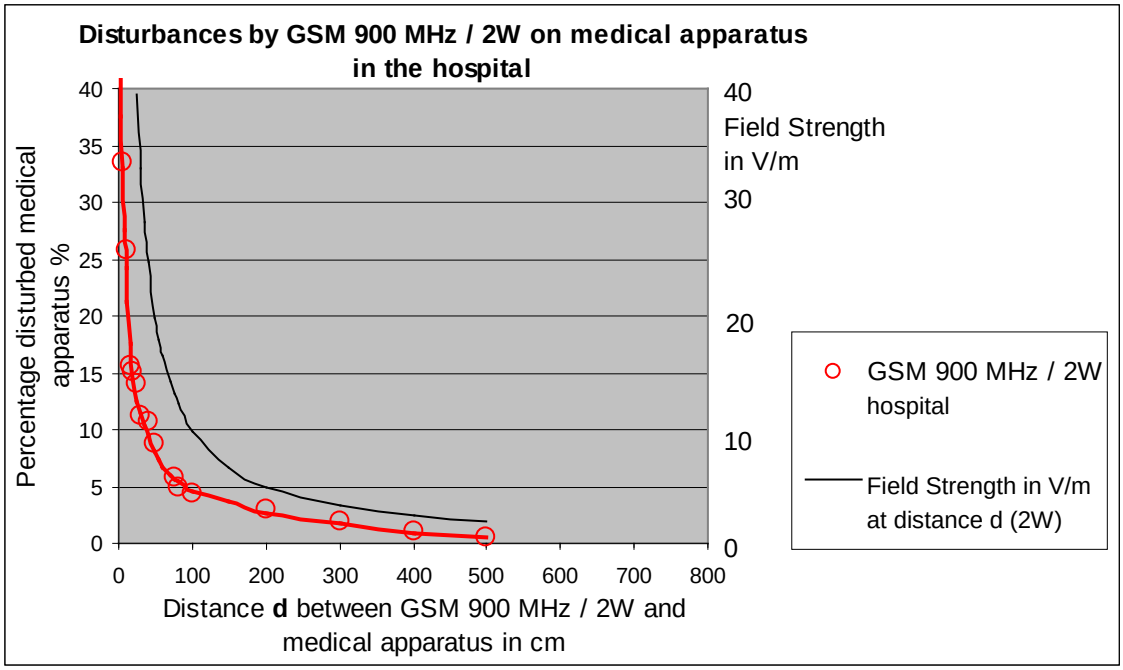

Figure 3: Disturbances by GSM 900 MHz / 2W on medical apparatus in the hospital. Figure copied from **Literature [4] and [5]**

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 [5]). 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

[5]) 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 (≤ 20 cm) some disturbances were still found both at the AMC and at the St. Antonius. This was against expectations in some literature [6]). 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.

[6]) 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 ≤ 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

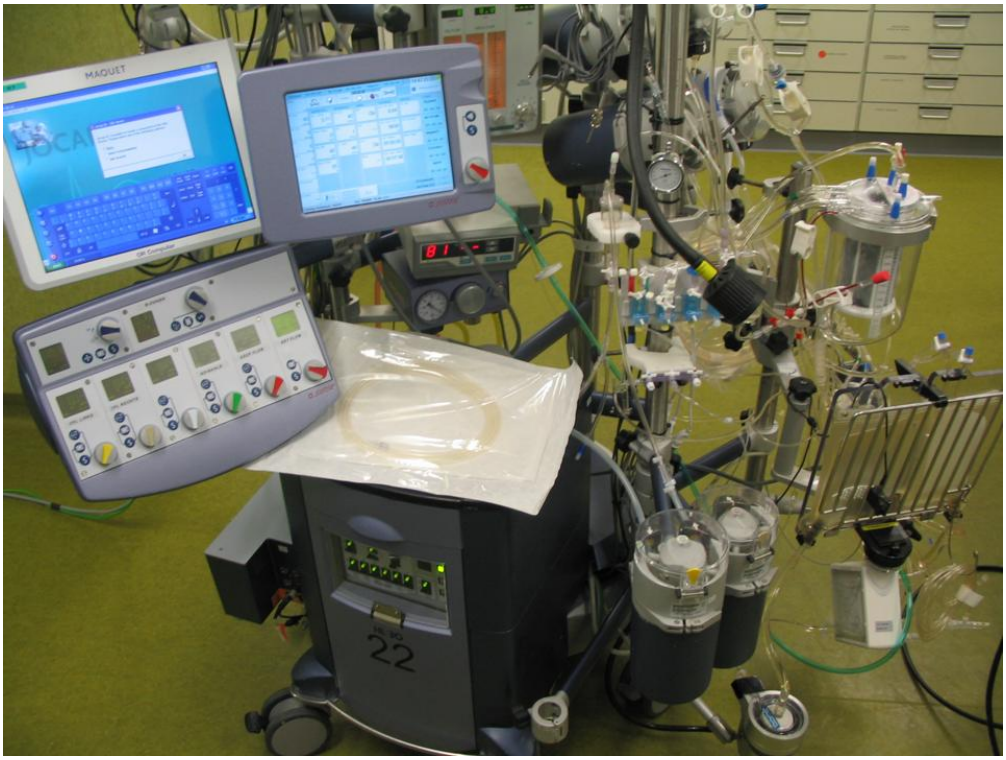

Figure 4: HLM: Apparatus No. 15

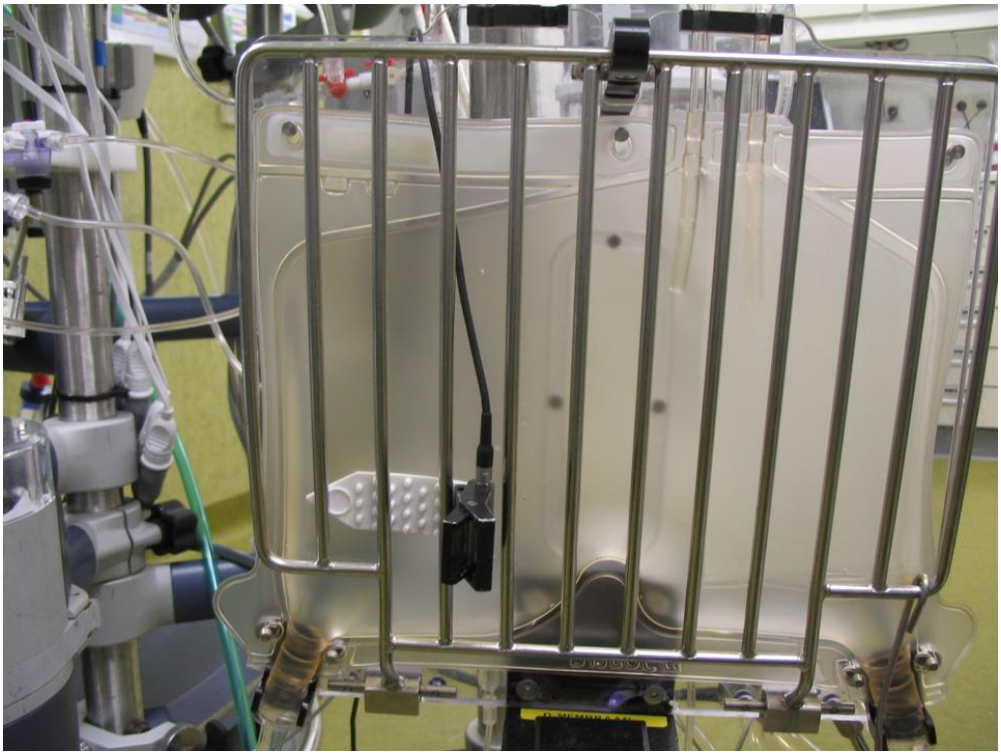

Figure 5: Detail of HLM : Apparatus No.15

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

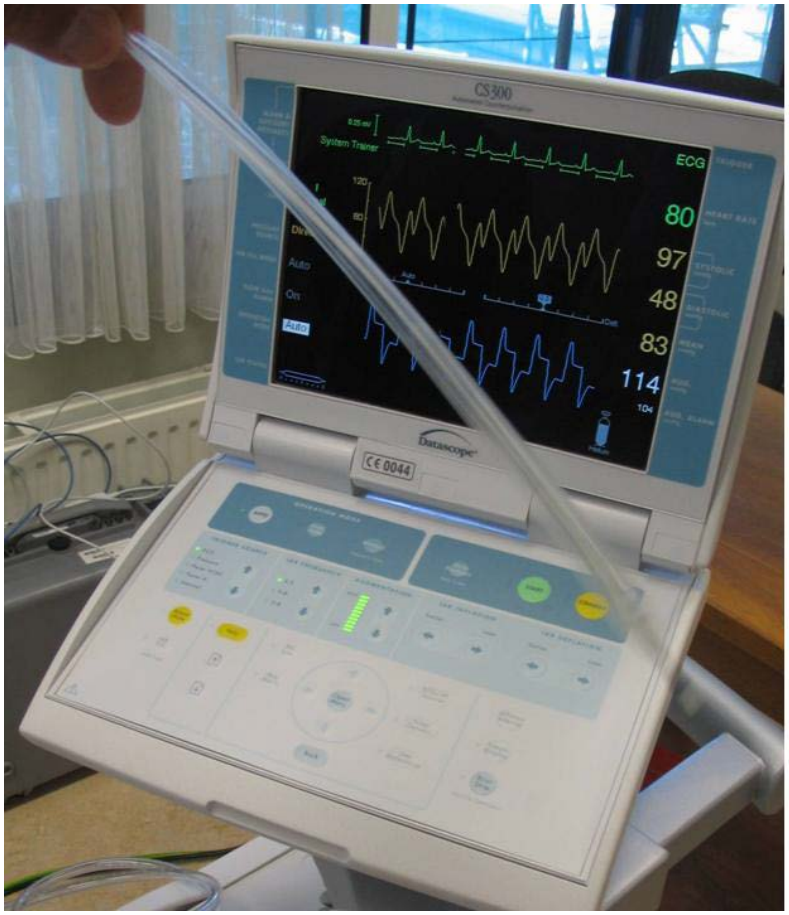

Figure 7: Intra-Aortic Balloon Pump CS300: Apparatus No. 11.

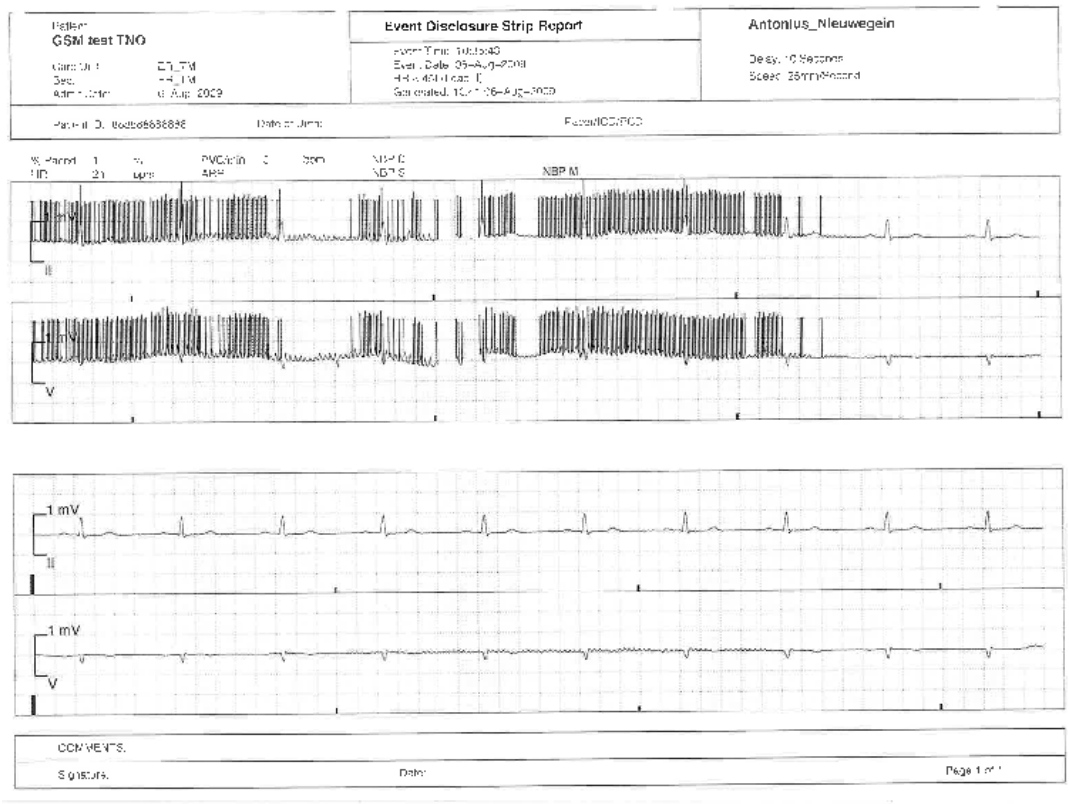

Figure 8: Interference on Telemetry: Apparatus No. 20.

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.

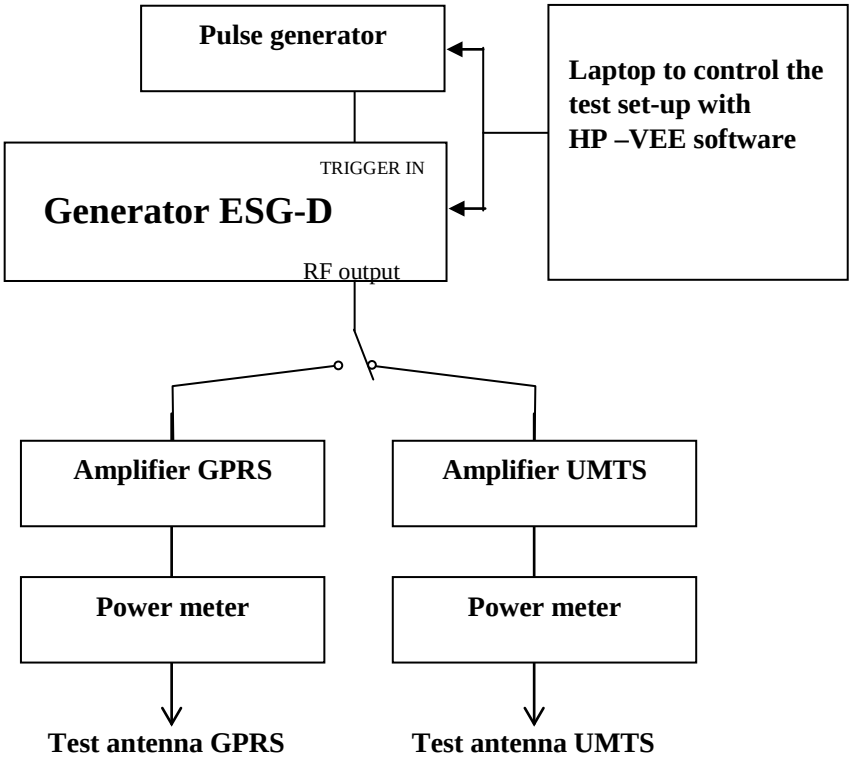

Figure 10: Test set-up for generating the five test signals at the St. Antonius Hospital in Nieuwegein, The Netherlands.

C Literature

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TNO report

KvL/P&Z 2010.094

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

Date	December 2009
Author(s)	R. Hensbroek, M.Sc.
Principal	AMC Amsterdam, The Netherlands
Project number	031.14641
Number of pages	36(incl. appendices)
Number of appendices	4

Summary

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

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

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

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

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

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

Remarks

1: The test method minimized the dependency from the environment where the tests took place.

2: If in this report for a certain type of medical apparatus no interference is reported one must not conclude that the apparatus is not susceptible. The reason for this is that tests were limited, had a typical (restricted) purpose and were not intended to cover

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

the standard IEC 60601-1-2 **[4]** for EMC of Medical Equipment. A conclusion about the complete EMC behaviour of a medical apparatus is the responsibility of the manufacturer and must be based on more elaborate testing.

3: The number of medical apparatuses included in the immunity testing was limited. The medical apparatuses were carefully selected to cover the actual situation in the rooms at the hospitals. The medical apparatuses and the WLAN systems are believed to represent a certain collection as can be found in more hospitals. However no strict general conclusions about other medical apparatuses can be drawn from this report without careful judgment and comparison. In case of doubt additional testing may be needed (as international standards advise generally as well).

Samenvatting

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

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

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

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

Aandacht voor deze stoorproblematiek is belangrijk wanneer (niet medische) apparaten met WLAN antennes 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 kunnen nodig zijn om dit te voorkomen.

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

Opmerkingen

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

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

2: Wanneer in dit rapport van een bepaald apparaat geen verstoring wordt gemeld mag daar niet de conclusie aan worden verbonden, dat dit apparaat dus niet gevoelig is. Het apparaat is immers slechts beperkt getest en met een zeer bepaald (beperkt) doel. De norm IEC 60601-1-2 **[4]** voor EMC van medische apparatuur was zeker niet afgedekt. Een dergelijke uitspraak behoort tot de competentie en verantwoordelijkheid van de fabrikant van het betreffende apparaat en moet worden gestoeld op uitvoeriger onderzoek.

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

Contents

1 Introduction

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

1.1 Description of tests

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

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

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

Table 2.1: Type and number of medical apparatuses tested.

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

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

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

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

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

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

3 WLAN Test signals

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

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

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

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

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

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

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

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

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

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

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

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

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

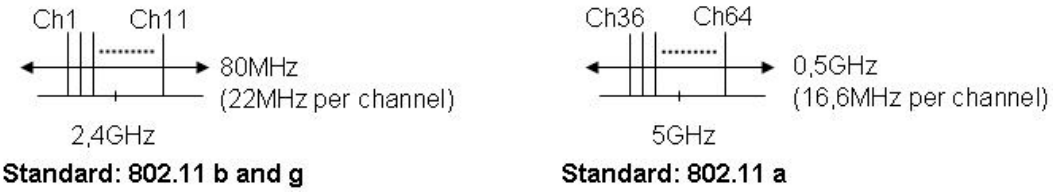

Figure 3.1 Channels 1, 11, 36 and 64 in their respective frequency bands at 2,4GHz and 5GHz according to the IEEE 802.11 standards.

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

Table 3.2 Overview of routine testing practices.

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

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

4 Test Protocol

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

Test practices
The medical apparatus was located in such a way that it could be radiated from all sides (no persons or objects in the direct surroundings of the apparatus - especially not a metal testing table). Medical apparatuses were functioning normally; patient simulator or test person and/or patient phantom connected; attention was paid to possible sensitivity of simulators. For ECG apparatuses an ECG simulator was used or a volunteering testing person connected. For defibrillators a defibrillator tester was used. For ventilators an artificial lung was used. The point in space was searched, most far from the apparatus, where it could just be disturbed. When testing for possible susceptibility at a certain position in space, transmission was realized during several seconds. At a found disturbance position, transmission was realized during several tens of seconds before reporting.
The reaction of the medical apparatus (if any) was noted down: flashing lamps, audible alarms, display disturbances, all details. When the apparatus stopped, it was also reported whether it could be restarted by switching it OFF and ON again and whether all settings were lost or not. When disturbances occurred, it was also checked whether memory functions were disturbed.

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

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

5 Results

5.1 Introduction

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

5.2 Classification of disturbances

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

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. - Relevant noise or humble from a loudspeaker.
S	**Significant** but not (yet) unsafe disturbance	- Disturbance of the functioning of the apparatus but no safety hazard for patient or user - no indirect safety hazard as well. - Small “spikes” on ECG curves. - Disturbances on a display without hazard.
U	**Unsafe** disturbance	- 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.

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

5.3 Detailed results

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

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

Apparatuses as tested on 18 – 26 June 2009 are numbered 1 to 63. The numbering reflects the order of testing which was determined by practical circumstances like availability of a specific apparatus.
Apparatuses as tested on 19 - 22 October 2009 are numbered *1*, *1A* to *33* (= 34 apparatuses). The numbering starts with 1 again, but now *cursivated*. Most of the apparatuses *1-33* tested in October 2009 are used in the Operating Room only (Exception: Ear thermometer *No. 32*). The other apparatuses (tested in June 2009; number not cursivated) were sometimes used in the Operating Room but most of them at other medical departments of the AMC.

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

Legend to Table 5.2 below
Column 1: The **No. in test** refers to the testing order of the medical apparatuses as recorded during the interference testing. Photos which illustrate the testing method can be found in **Appendix C** to this report.
Column 2: **Medical apparatus tested** are presented in this column per functional group. The type (name) of each medical apparatus is mentioned as it was indicated on the apparatus itself followed by the name of the manufacturer. Seven medical apparatuses were connected to medical apparatuses tested. They are marked with a ● in column 2. They were tested as medical apparatuses as well.
Column 3: The Year of purchase by the AMC. In cases marked with "?" the year of purchase could not be found or there was some doubt about it.
Column 4: In these column the separation distance **d** is given for those medical apparatuses that were influenced by WLAN signal(s). The letter **N** means that no interference occurred at any distance from the medical apparatus including distance 0cm (=WLAN antenna against the medical apparatus). The footnotes in columns 4 refer to details of the interferences found. In columns 4 the influences found are classified according to the **N/L/S/U** scheme [5] as described in **Paragraph 5.2** of this report.
Column 5: The channel that transmitted the WLAN signal in case of interference.

[5)] **N**/**L**/**S**/**U** = **N**o/**L**ight/**S**ignificant/**U**nsafe disturbance or interference. In Netherlands language: = **N**/**L**/**S**/**O** = **N**ee/**L**ichte/**S**ignificante/**O**nveilige verstoring of interferentie.

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

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

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

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

Ch11 at 500mW: 50cm from backside and from vertical sides: Flowtriggers occur incorrectly.

NB: **Ch36** and **Ch64**: No interference.

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[7]) **Ch1** 100mW: 0cm from specific place on housing: Incorrect steps of ca. 0,5 ppmNO-indication (no alarm).

Ch11 at 500mW: 5cm from specific place on housing: Incorrect steps of ppmNO-indication.

At 0cm: Incorrect indication of ca. 61 ppmNO plus alarm AND: Incorrect steps of more than 5 ppmNO indication PLUS: Spontaneous wrong indication of NOX (which is 0 in reality). Effect starts at 5cm.

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

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

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

No. in test	Medical apparatus tested	Year of purchase	Interference Y/N Classific. N/L/S/U 100mW: …cm 500mW: …cm	Channel No. 1/ 11/ 36/ 64
7	ICP (Intracranial) Monitor Camino SPM-1, Integra Neurosciences	09(?)	N	
8	• Pressure Monitoring Set (Intra Arterial Sensor), Edwards Lifesciences	09	N	
27	Polysomnography Unit N 7000, Embla (Medcare)	?	N	
28	• Transcutaneous CO2 / O2 meter TCM 40, Radiometer	07	N	
29	• Capnograph / Pulsoxymeter Microcap Plus (Microstream), Oridion	07	N	
21	Pulsoxymeter Oximax N-600, Nellcor	09	N	
22	Pulsoxymeter 3900 Oximeter TruTrak+, Datex - Ohmeda	04	N	
47	Video System (Intubation) Glidescope, Model Portable GVL, Saturn Biomedical Systems, Inc.	09	N	
1	Monitor CMS, Philips	invisible	N	
1A	• Gas Analyser "Airway Gases" M1026B, Philips	05	N	
41	Ear Thermometer M 3000A, Tyco Healthcare / First TempGenius	08	**Y [8]) Classific.: U 100mw: 20cm 500mW: 30cm**	**1 / 11 / 64 11 / 36**
32	Ear Thermometer Genius 2 IR Tympanic Thermometer, Tyco Healthcare (New type purchased by AMC)	09	**Y [9]) Classific.: U 100mw: No 500mW: 1cm**	**- 11**
	BGM			
45	Bedside BGM B-glucose Analyser, Hemo Cue AB	03	N	
49	Blood Glucose Meter Accu-Check Inform, Roche	?	N	
	Blood gas Analyser			
48	i-Stat 1 Analyser, Abbott	08	N	
54	Rapidlab 865, CIBA-Corning	95	N	
42	Rapidlab 1265, Bayer Healthcare	06	N	
33	MR 850 AFU, Fisher & Paykel	02	N	
40	MR 730, Fisher & Paykel	96	N	
	Dialysis			
3	Diapact CRRT, B.Braun	97	N	
26	Home Choice Pro Automated PD System (Peritoneal), Baxter	03	N	
	EEG			
55	EEG: osg Brainlab // sw-version 4	02	N	
56	EEG: SD LTM 64 BS, Micromed	09	**Y [10]) Classific.: S 100mW: 30cm 500mW:100cm**	**1 /11 11**

[8]) **Ch1** 100mW: 20cm from Sensor: Temperature is influenced. At 0cm: From 22 → 23 ^{0}C.
Ch11 at 500mW: 30cm from Sensor: Temperature is influenced. At 0cm: From 22 → 27 ^{0}C.
Ch11 at 100mW: 10cm from Sensor: Temperature is influenced. At 0cm: From 22 → 26 ^{0}C.
Ch36 at 500mW: 30cm from Sensor: Temperature is influenced. At 0cm: From 22 → 32 ^{0}C.
Ch64 at 100mW: 10cm from Sensor: Temperature is influenced. At 0cm: From 22 → 24 ^{0}C.

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[9]) **Ch11** at 500mW: 1cm from thermometer housing: Temperature is influenced. At 0cm: 2,4^{O}C too high.
NB: **Ch1, Ch36** and **Ch64**: No interference.

[10]) **Ch1** 100mW: 5cm from headbox and belonging cables: Interfering voltage on screen. At 0cm: 400micovolt amplitude as measured on screen.
Ch11 at 500mW: 100cm from headbox and belonging cables: Interfering voltage on screen. At 0cm: 1000micovolt amplitude as measured on screen.
Ch11 at 100mW: 30cm from headbox and belonging cables: Interfering voltage on screen. At 0cm: 600micovolt amplitude as measured on screen.
NB: **Ch36** and **Ch64**: No interference.

No. in test	Medical apparatus tested	Year of purchase	Interference Y/N Classific. N/L/S/U 100mW: …cm 500mW: …cm	Channel No. 1/ 11/ 36/ 64
57	EEG: SAM 32 RFO fc 1, Micromed	09	**Y [11]) Classific.: S 100mw: 10cm 500mW: 20cm**	**1 / 11 11**
	EKG			
61	EKG: Mac 5000 12 Channels, Marquette	02	N	
62	EKG : Mac 5500, General Electric (ex Marquette)	08	N	
39	EMG: Medelec Synergy, Viasys Healthcare	08	N	
	Blood Warmer			
18	Fluido, The Surgical Company	07	**Y [12]) Classific.: U 100mw: 25cm 500mW: 35cm**	**1 /11 11 / 36**
10	Fluid Management System FMS 2000, Belmont	09	**Y [13]) Classific.: U 100mw: No 500mW: 10cm**	**- 11**
	External Defibrillator / Monitor			
59, 60	Lifepak 20, Medtronic	03	N	
	Infant Incubator			
25	Giraffe, Ohmeda	02	N	
	Photo Therapy			
23	Photo Therapy (Lamp) System BiliBlanket Plus, Ohmeda	03	N	
	Pager System			
50, 51	Emergency Department ("S.E.H."), Stanleyworks	06	N	
	Patient Bed			
63	Total Care Duo 2, Hill-Rom	03	N	
	Cooling system			
30	Cooling blanket Cair Cooler, Pentatherm	05	N	
9	Mattress (water) Blanketroll II, Cincinnati Sub-Zero	03	N	
	Infant Warmer			
19	Ohio Warming Table System IWS 4400, Ohmeda	08	N	
34	Babytherm 8004, Dräger	02	N	
	Patient Warmer (air)			

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

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

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

NB: **Ch36** and **Ch64**: No interference.

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[12]) **Ch1** 100mW: 0cm from backside: Delta Flow = 65 ml/min. peak-to-peak. Delta T = 0,4 ^{0}C.

Ch11 at 500mW: 35cm from backside: Influence starts.

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

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

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

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

At 0cm from backside: Delta Flow = 100 ml/min. peak-to-peak. Delta T = 0,5 ^{0}C.

NB: **Ch64**: No interference.

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[13])**Ch11** at 500mW: 10cm from locking handle (disposable): Temperature indication is influenced. At 0cm: 2^{O}C.

NB: **Ch1, Ch36** and **Ch64**: No interference.

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

[14]) **Ch1** 100mW: 5cm from frontside: Wrong indication.
Ch11 at 500mW: 20cm. from frontside: Wrong indication.
Ch11 at 100mW: 5cm. from frontside: Wrong indication.
NB: **Ch36** and **Ch64**: No interference.

No. in test	Medical apparatus tested	Year of purchase	Interference Y/N Classific. N/L/S/U 100mW: …cm 500mW: …cm	Channel No. 1/ 11/ 36/ 64
	Electrosurgery			
13	Force Triad, Valleylab	09	N	
	Ultrasound Surgery			
14	Ultracision, Ethicon / Johnson&Johnson	07	N	
	Cryosurgical System			
33	Precise, Galil Medical	08	N	
	Laser			
16	Ultra Pulse Laser CO_2, Lumenis	09	N	
30	Versapuls, Lumenis	02	N	
31	Calculase HoYAG (2080nm) Class 4, Pilot (635nm) Class 2, Carl Storz Endoscope	09	N	

5.4 Summary of results

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

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

No. in test	Medical apparatuses tested	Year of purchase	Separation distance d [cm] and Classification: L / S / U At 100mW	At 500mW
	Ventilator			
32	Galileo Type Classic, Hamilton	03	10cm **U**	50cm **U**
	Gas Analyser			
16	• Printer Nox Bedfont NO meter, Cardinal Health (Coupled to Ventilator No. 17)	09	0cm **U**	5cm **U**
	Monitor/Meter			
41	Ear Thermometer M 3000A, Tyco Healthcare / First TempGenius	08	20cm **U**	30cm **U**
32	Ear Thermometer Genius 2 IR Tympanic Thermometer, Tyco Healthcare (New type purchased by AMC)	09	No interference	1cm **U**
	EEG			
56	EEG: SD LTM 64 BS, Micromed	09	30cm **S**	100cm **S**
57	EEG: SAM 32 RFO fc 1, Micromed	09	10cm **S**	20cm **S**
	Blood Warmer			
18	Fluido, The Surgical Company	07	25cm **U**	35cm **U**
10	Fluid Management System FMS 2000, Belmont	09	No interference	10cm **U**
	Weighing Scale			
38	Bedscale 2002, Scale-Tronix	02	5cm **S**	20cm **S**

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

5.5 Graphical presentation of results

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

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

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

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

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

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

At 100mW

No. in Test	Separation distance d [cm] At 100mW		At 500mW	
32	No interference		1cm	**U**
10	No interference		10cm	**U**
16	0cm	**U**	5cm	**U**
38	5cm	**S**	20cm	**S**
57	10cm	**S**	20cm	**S**
32	10cm	**U**	50cm	**U**
41	20cm	**U**	30cm	**U**
18	25cm	**U**	35cm	**U**
56	30cm	**S**	100cm	**S**

At 500mW

No. in Test	Separation distance d [cm] At 100mW		At 500mW	
32	No interference		1cm	**U**
16	0cm	**U**	5cm	**U**
10	No interference		10cm	**U**
38	5cm	**S**	20cm	**S**
57	10cm	**S**	20cm	**S**
41	20cm	**U**	30cm	**U**
18	25cm	**U**	35cm	**U**
32	10cm	**U**	50cm	**U**
56	30cm	**S**	100cm	**S**

Conclusions from the graphs in Figure 5.1 and Figure 5.2:

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

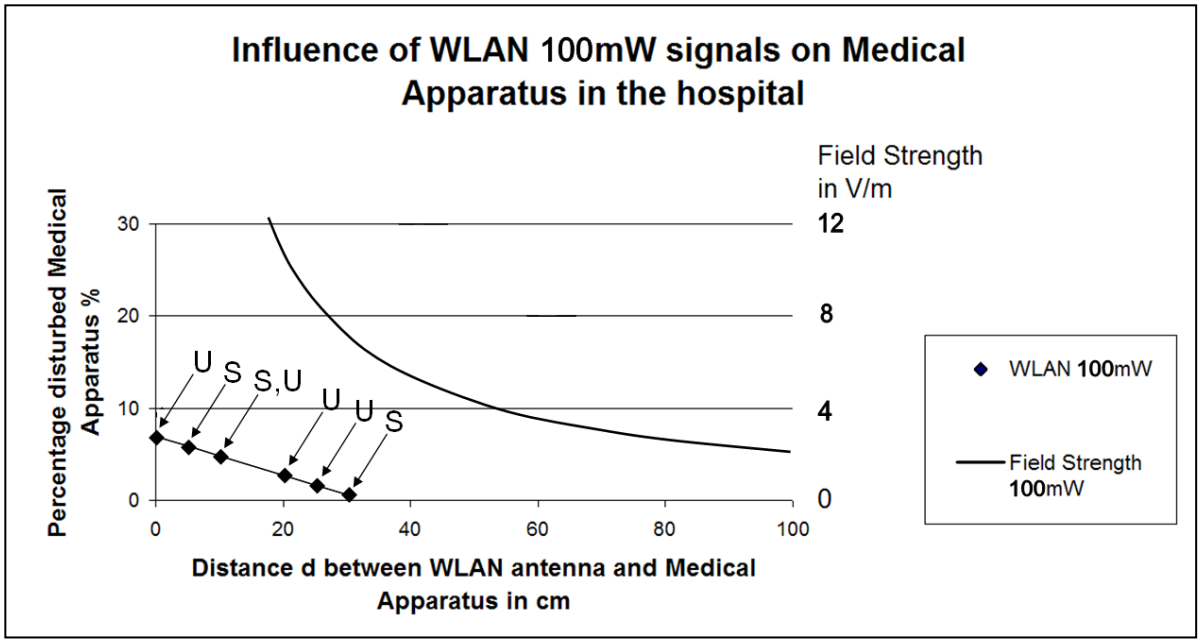

Figure 5.1: Influence of WLAN 100mW signals on medical apparatuses in hospitals.

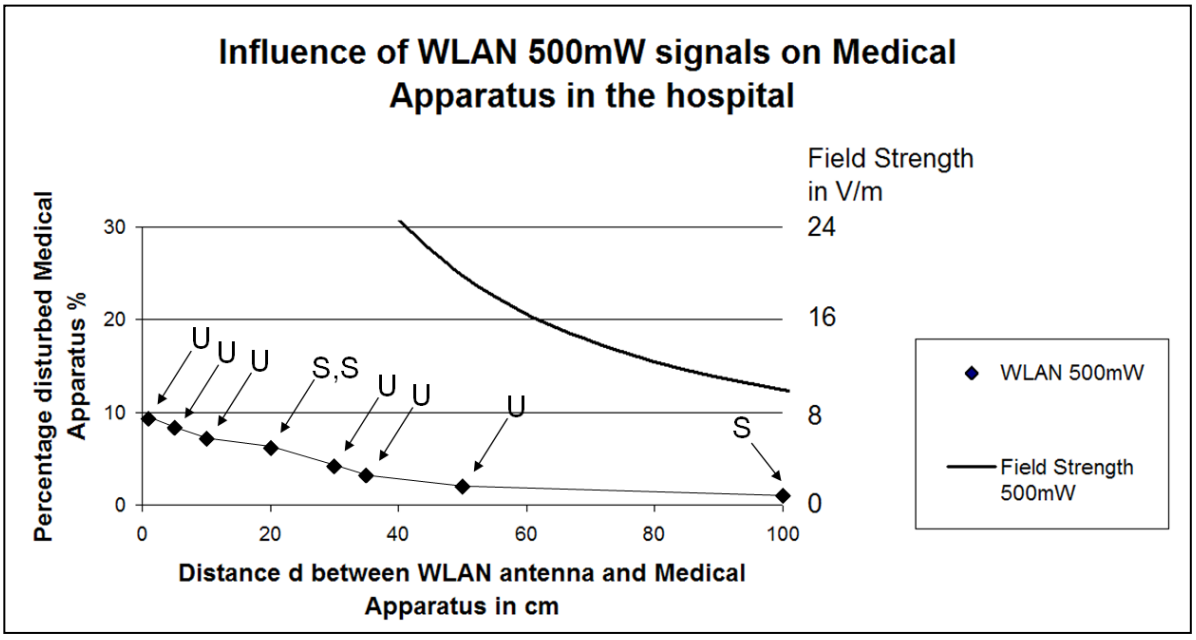

Figure 5.2: Influence of WLAN 500mW signals on medical apparatuses in hospitals.

5.6 Comparison of results to GSM results

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

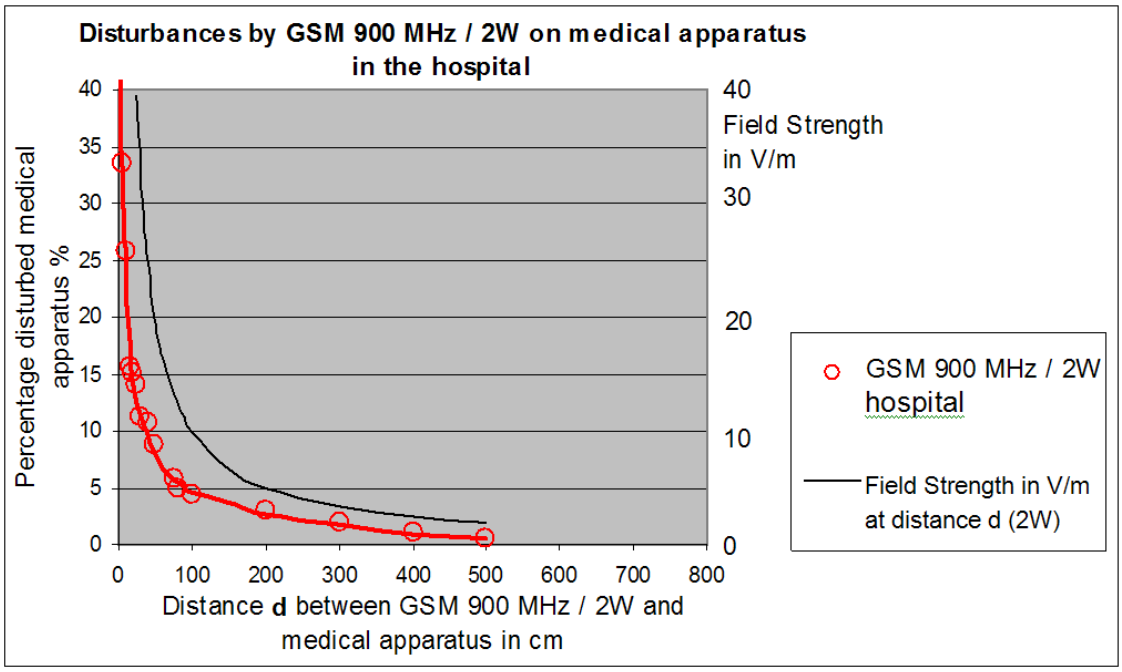

Figure 5.3: Disturbances by GSM 900 MHz / 2W on medical apparatus in the hospital (copied from Literature [5] and [6]).

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

[15] 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 [9]**,
- Health Devices November 2001 (ECRI) **Literature [10]**.
- Morrissey et al, Health Physics (2002) 82: pp 4 - 51 **Literature [11]**.
- A Netherlands regulation is: V-ICTN Recommendations **Literature [7]** based on **Literature [5]** and referring to **Literature [3]**.

6 Signatures

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

A Functional modes of all tested medical apparatuses

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

Table A.1: Functional modes of all tested medical apparatuses and specification of the power source (mains or battery).

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

No. in test	Medical apparatus tested	Year of purchase	Functional modes of medical apparatuses and specification of the power source (mains or battery)
8	• Pressure Monitoring Set (Intra Arterial Sensor), Edwards Lifesciences	09	Connected to MP 90 (App. No. 6) via Measurement Server ("broodje")
27	Polysomnography Unit N 7000, Embla (Medcare)	?	Mode: Functioning See also App. No. 28 and 29
28	• Transcutaneous CO2 / O2 meter TCM 40, Radiometer	07	Connected to App. No. 27; Also tested separately with SpO2
29	• Capnograph / Pulsoxymeter Microcap Plus (Microstream), Oridion	07	Connected to App. No. 27; Also tested separately. Tested while measuring Capnography EtCO2 and with SpO2.
21	Pulsoxymeter Oximax N-600, Nellcor	09	Alarm levels were set active
22	Pulsoxymeter 3900 Oximeter TruTrak+, Datex - Ohmeda	04	Alarm levels were set active
47	Video System (Intubation) Glidescope, Model Portable GVL, Saturn Biomedical Systems, Inc.	09	Powered from mains only (Battery was empty)
1	Monitor CMS, Philips	invi-sible	ECG, SaO_2/Pleth, IBP, Vue Link; Connected tot "Computerbox" Agilent M1046B / CE0366 (2001). Gas Analyser *1A* was connected.
1A	• Gas Analyser "Airway Gases" M1026B, Philips	05	Top-box on Monitor CMS (App. No.*1*)
41	Ear Thermometer M 3000A, Tyco Healthcare / First TempGenius	08	Mode: Surface Measurement (During this continuous measurement influence could be detected easier than before)
32	Ear Thermometer Genius 2 IR Tympanic Thermometer, Tyco Healthcare (New type purchased by AMC)	09	Mode: This version has 1 mode only. It can not measure continously. Therefore detecting influence was more difficult than before
	BGM		
45	Bedside BGM B-glucose Analyser, Hemo Cue AB	03	Mode: Functioning
49	Blood Glucose Meter Accu-Check Inform, Roche	?	Glucose measurement performed after Calibration
	Blood gas Analyser		
48	i-Stat 1 Analyser, Abbott	08	Mode: Functioning
54	Rapidlab 865, CIBA-Corning	95	Mode: Functioning
42	Rapidlab 1265, Bayer Healthcare	06	Siemens Automatic QC included in test.
33	MR 850 AFU, Fisher & Paykel	02	Indicating 39 °C
40	MR 730, Fisher & Paykel	96	Mode: Indicating Air Temperature 39 °C
	Dialysis		
3	Diapact CRRT, B.Braun	97	CVVH 150 ml/hr
26	Home Choice Pro Automated PD System (Peritoneal), Baxter	03	Functional with complete set and artificial belly
	EEG		
55	EEG: osg Brainlab // sw-version 4	02	5 Channels electrodes placed on human arm
56	EEG: SD LTM 64 BS, Micromed	09	Electrodes placed on human arm
57	EEG: SAM 32 RFO fc 1, Micromed	09	Electrodes placed on human arm
	EKG		
61	EKG: Mac 5000 12 Channels, Marquette	02	Powered from internal battery (=normal use); ECG simulator: Fluke MPS 450
62	EKG : Mac 5500, General Electric (ex Marquette)	08	Powered from internal battery (=normal use); ECG simulator: Fluke MPS 450
39	EMG: Medelec Synergy, Viasys Healthcare	08	Mode: Tested while stimulating Nervus Medianus (Distal Right 10 mA Impulses)

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

No. in test	Medical apparatus tested	Year of purchase	Functional modes of medical apparatuses and specification of the power source (mains or battery)
27	S8, Carl Zeiss Surgical	08	Mode: Functioning. No. *28* was connected
28	• **Monitor** X-17 AV, Neovo	08	Connected to Surgical Microscope No. *27*
	Endoscopic System		
3	Extera II (CV 180 + CLV 180), Olympus	07	Mode: Functioning
	Bronchoscopic System		
11	Image 1 + Xenon 300, Storz	06	System parts: Image 1, Xenon 300, Storz, Monotor PVM-20M2MDE
	Surgical Navigation		
23	Vector Vision, BrainLAB	05	Tested in start-up configuration (marker-check)
24	Kolibro, BrainLAB	06	Mode: functioning
29	StealthStation TREON plus, Medtronic	03	Mode: Functioning
	Anaesthesia Ventilator		
2	Aestiva/5, Datex-Ohmeda	01	Mode: Volume controlled, F=12 min^{-1}, Tidal Volume = 0,5ltr, I:E=1:2 ,
4	S/5 Avance, Datex-Ohmeda	04	Mode: Tidal Volume=0,5 ltr, F=12 min^{-1}, I:E=1:2 , Flow=6 ltr/min, O_2=100%
15	Julian, Dräger	00	Mode: Tidal Volume = 0,6 ltr, F=12 min^{-1}, Flow=3 ltr/min, O_2=100%, Pmax=25cmH_2O
21	Zeus, Dräger	06	Mode: Tidal Volume = 0,4 ltr, F=12 min^{-1}, Flow=6 ltr/min, O_2=100%
	Heart Lung Machine		
5	S5, Stöckert	06	System parts: Console, 3 Pump Units,S5 Gas Blender, Clamp(Okkluder from 2008)
12	Roller pump, Stöckert	07	Mode: Several speeds observed; no fluid line in pump
	Heater/Cooler		
6	Coolant Type R134A, Maquet / Jostra	09	Mode: Normal Functioning
	Blood gas Analyser		
17	CDI 500, Terumo	01	Monitor blood gas
	Centrifugal Control Module		
9	3M, Sarns	97	pom = ca. 2800 r.p.m. (No flow through the flow sensor)
	Vitrectomia Unit		
22	Vitrectomie 25G, Constellation, Alcon	09	Functioning with disposables connected
	Electrosurgery		
13	Force Triad, Valleylab	09	Mode: Monopolar Cut and Coagulation
	Ultrasound Surgery		
14	Ultracision, Ethicon / Johnson&Johnson	07	SonoSurg Generator tested without scissors
	Cryosurgical System		
33	Precise, Galil Medical	08	Mode: Start-up screen only (No instruments available; no cryogenic procedure)
	Laser		
16	Ultra Pulse Laser CO_2, Lumenis	09	Setting: 1 Watt
30	Versapuls, Lumenis	02	Mode: Activated; 5Hz; 3,2 Joule
31	Calculase HoYAG (2080nm) Class 4, Pilot (635nm) Class 2, Carl Storz Endoscope	09	Mode: Activated; 6Hz; 0,5 Joule

B WLAN test set-up

1. Measurement Equipment to monitor testing
   - Spectrum analyser: fsh manufactured by Rohde & Schwarz;
   - Attenuator 20dB.

2. Hardware in the test set-up:
   - 2 PC's / 8 AP's (in this way combining 802.11 a, b, g in one test);
   - Amplifiers at 2,4GHz and at 5 GHz to start testing on every medical apparatus with 2 channels at higher power levels than normal;
   - Medical Apparatuses were placed on a wooden cart.

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

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

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

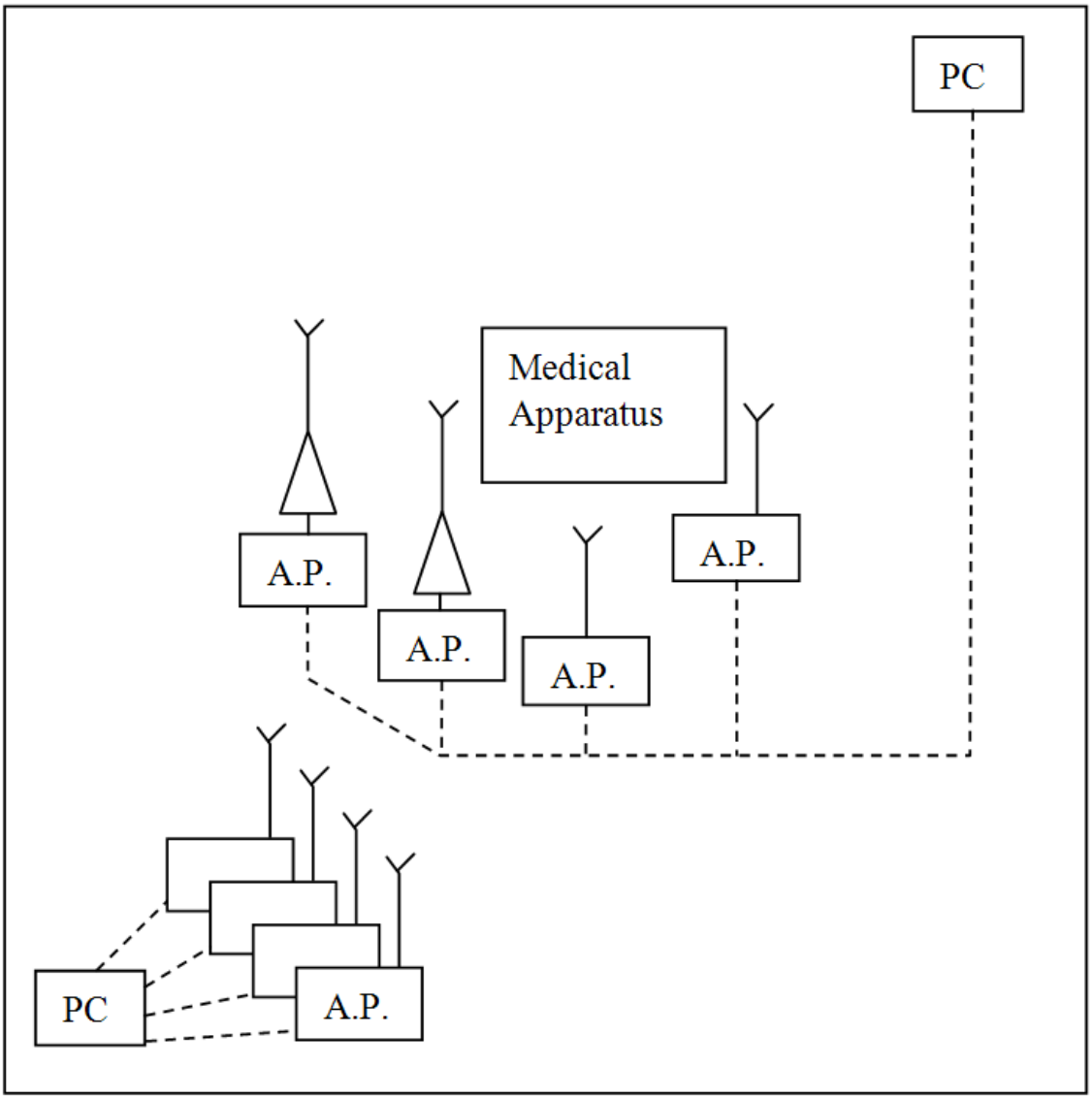

Figure B.1: Test set-up with 4 transmitting antennas and 4 receiving antennas. Each of these groups of antennas was connected to a separate PC.

C Photographs

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

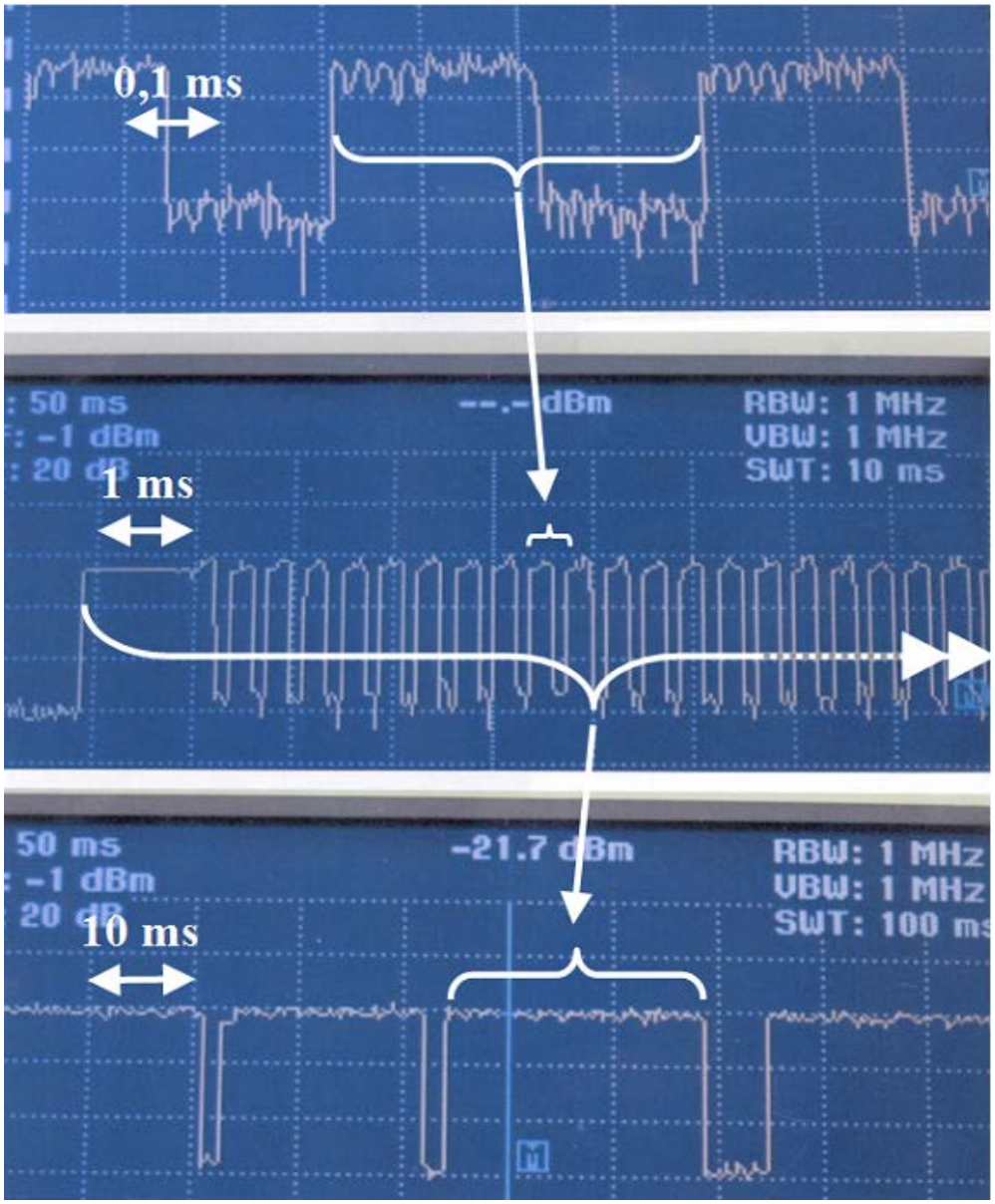

Figure C.1 Test signal of Ch1 with short packages. The time base: 0,1ms/division (upper trace), 1ms/div (middle trace) and 10ms/div (lower trace).

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

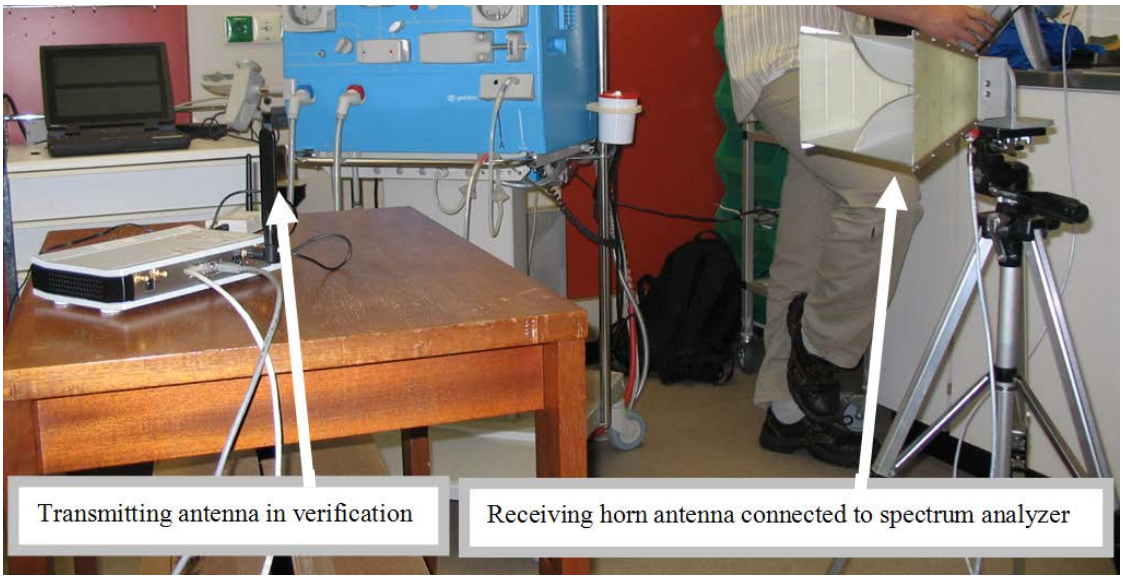

Figure C.2. Transmitting antenna in verification.

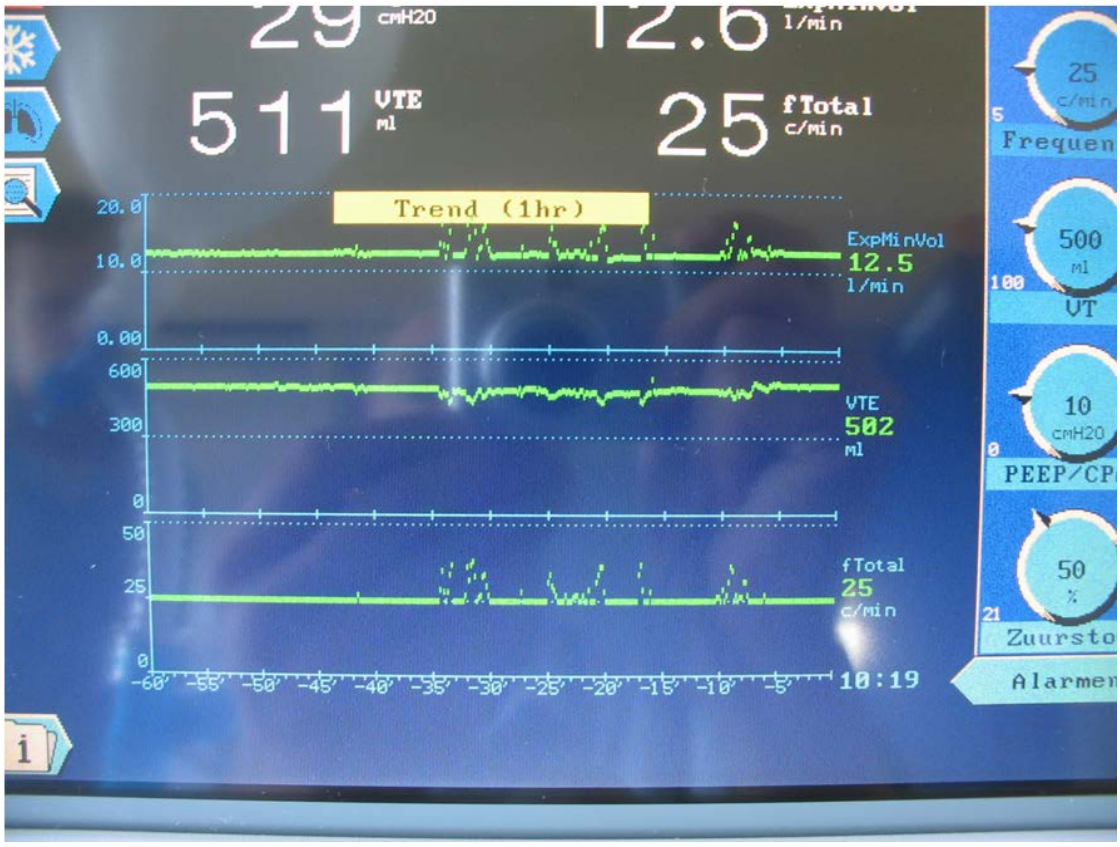

Figure C.3. Interference effect on Ventilator Galileo Type Classic (Apparatus No. 32).

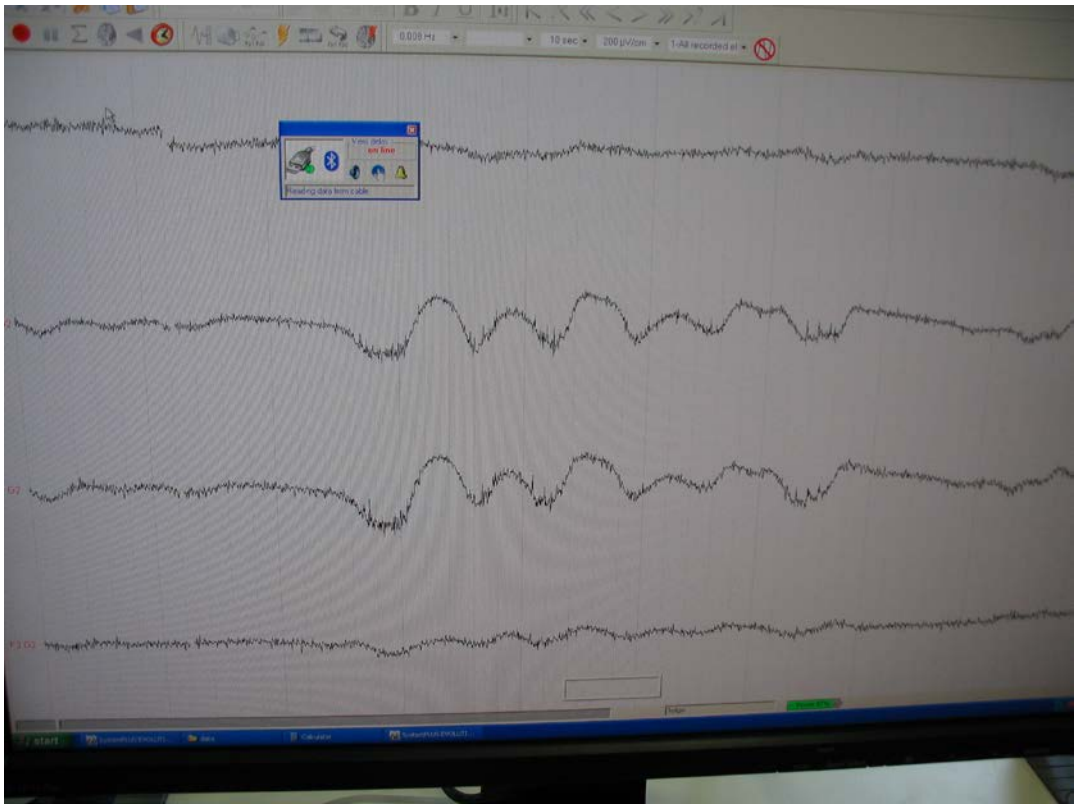

Figure C.4. Interference effect on EEG apparatus SD LTM 64 BS, Micromed (Apparatus No. 56).

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

Figure C.6.

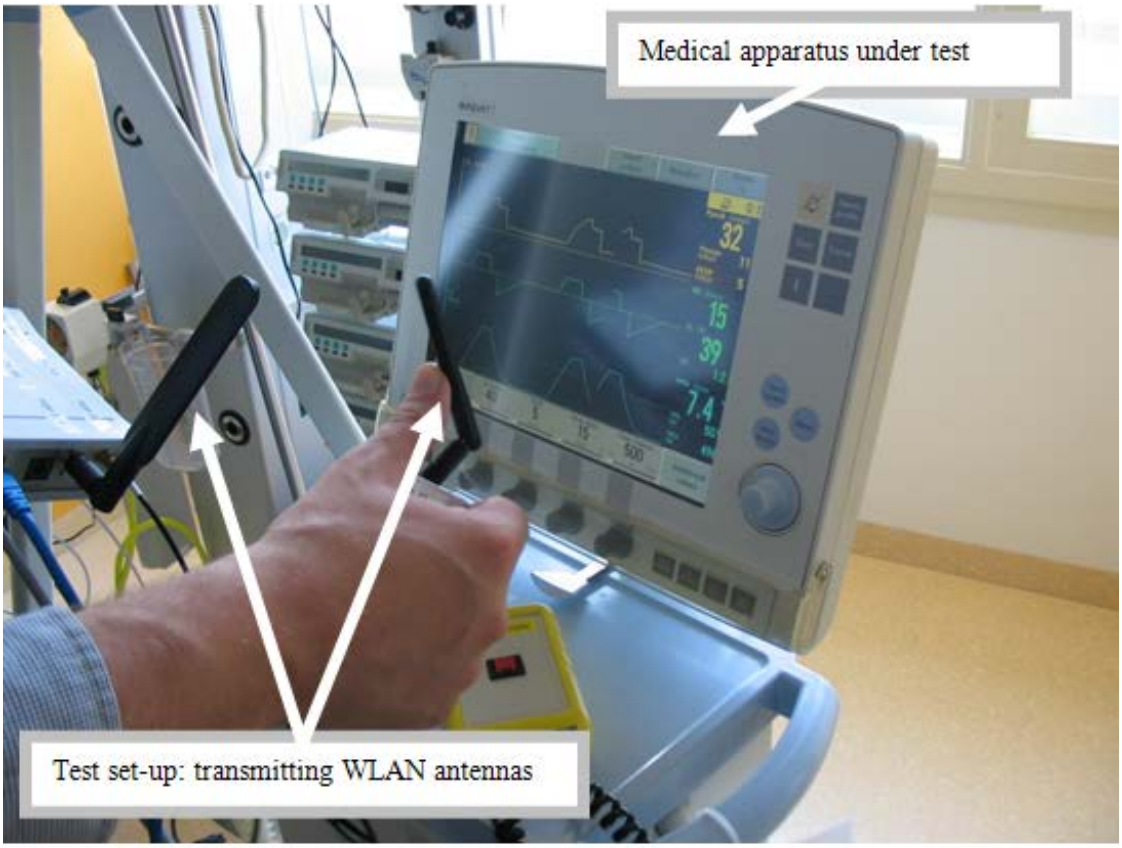

Figure C.7.

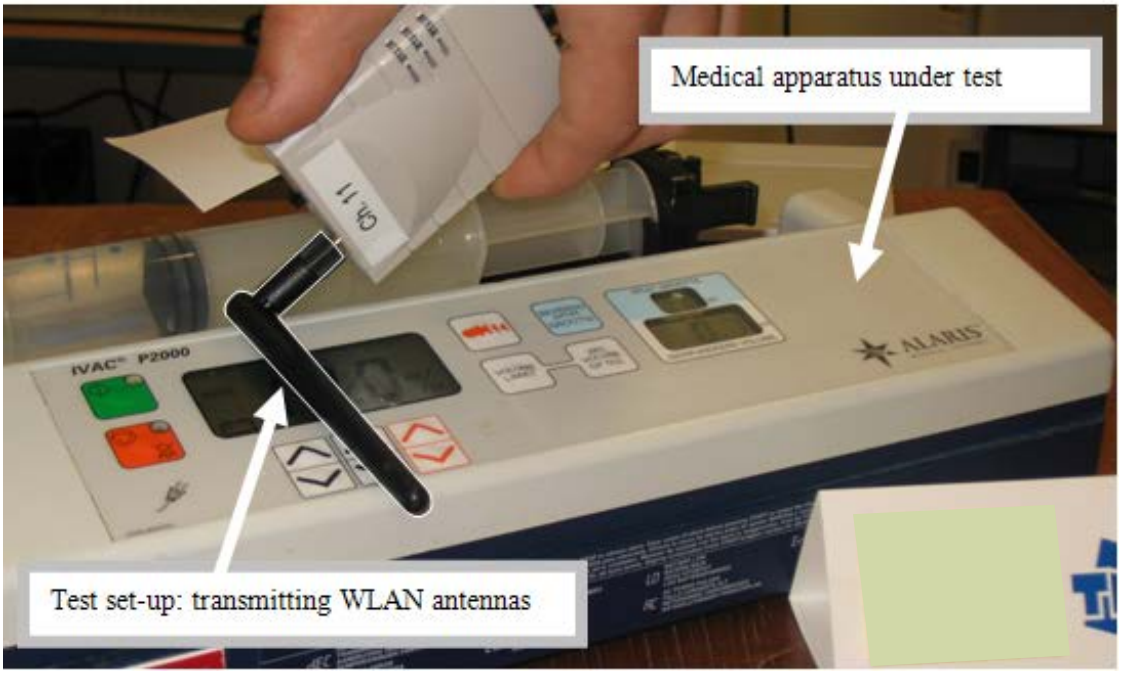

Figure C.8.

D Literature

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

KvL/P&Z2010

93 Medical Apparatuses tested at a Hospital for interference by WLAN/WiFi signals

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Summary

This research describes the influence of WLAN [1)] signals on medical apparatuses in a Hospital. The results in this report were obtained by testing medical equipment with WLAN signals. A comparable research was reported in 2007: See TNO report KvL/P&Z 2007.117 dated September 2007, **Literature** [**1**].

At 15cm distance 3% of 93 tested medical apparatuses were disturbed. At 0cm distance (WLAN antenna against medical apparatus) 4% 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 all (of the 4% of 93) found interferences was unsafe for the patient; the maximum distance at which interference was found was 150cm.

These results are comparable to the results in the TNO study from 2007 – The 3% border now at the present hospital (15cm) is somewhat bigger than the border in 2007 (10cm). Another small difference is the maximum distance where interference occurred: 150cm now versus 50cm in 2007.

The number of medical apparatuses tested (93) can be considered large enough to formulate the following general expectation: As long as the distance between WLAN antennas and medical apparatuses is more than 20cm during normal use in hospitals, hardly interferences and/or unsafe disturbances are expected. At shorter distances in special situations disturbances are expected.

Attention for this interference aspect is important if non medical apparatus (e.g. PDA's) with WLAN antennas are (in 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. Testing and special measures may be needed to prevent this.

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

Remarks

1: The test method minimized 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, the conclusion that the apparatus is not susceptible is not warranted because tests were limited, had a typical (restricted) purpose and were not intended to cover the standard IEC 60601-1-2 [**4**] for EMC of Medical Equipment. A conclusion about

[1)] WLAN = Wireless Local Area Network (In Dutch Language: Draadloos lokaal netwerk), also called WiFi = Wireless Fidelity.

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 hospital. The medical apparatuses and the WLAN systems are believed to represent a collection as can be found in more hospitals. No strict general conclusions about other medical apparatuses can be drawn from this report without careful judgment and comparison. In case of doubt additional testing may be needed (as international standards advise generally as well).

Samenvatting

Dit rapport beschrijft de invloed van WLAN [2)] signalen op medische apparaten in een ziekenhuis. De resultaten in dit rapport zijn verkregen door medische apparatuur te testen met WLAN-signalen. Een vergelijkbaar onderzoek is in 2007 gepubliceerd: Zie TNO report KvL/P&Z 2007.117 dd. september 2007, **Literature** [**1**].

Op 15cm afstand trad bij 3% van 93 onderzochte medische apparaten storende invloed op. Op 0cm afstand (WLAN antenne tegen medisch apparaat) ondervond 4% van de apparaten storing. De WLAN signalen hadden het gebruikelijke vermogen van 100mW in de 2,4 en 5GHz frequentiebanden. Het karakter van alle (4% van 93) gevonden storingen was onveilig voor de patiënt; de maximale afstand waarop storende invloed werd gevonden was 150cm.

Deze resultaten zijn vergelijkbaar met de resultaten in de TNO studie uit 2007 – De 3% grens bij het huidige ziekenhuis (15cm) is wat groter dan de grens uit 2007 (10cm). Een ander klein verschil is de grootste afstand waarbij interferentie optrad: 150cm bij het huidige ziekenhuis tegen 50cm in 2007.

Het aantal onderzochte medische apparaten (93) kan groot genoeg worden geacht om de volgende algemene verwachtingen uit te spreken: Zolang WLAN antennes op meer dan 20cm afstand van medische apparaten blijven tijdens normaal gebruik in ziekenhuizen zijn nauwelijks storende en/of onveilige invloeden te verwachten. Op kortere afstand zullen in bijzondere gevallen storingen kunnen optreden.

Aandacht voor deze stoorproblematiek is belangrijk wanneer niet medische apparaten (bijvoorbeeld PDA's) 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 soms storingen te verwachten. Testen en het nemen van speciale maatregelen kunnen nodig zijn om dit te voorkomen.

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

Opmerkingen

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

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, **Literature [4]**, voor EMC van medische apparatuur

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

was zeker niet afgedekt. Een dergelijke uitspraak behoort tot de competentie en verantwoordelijkheid van de fabrikant van het betreffende apparaat en moet worden gestoeld op uitvoeriger onderzoek.

3: Het aantal onderzochte medische apparaten was beperkt. De apparaten zijn zorgvuldig geselecteerd met het oog op de toepassingssituaties 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).

Contents

1 Introduction

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

1.1 Description of tests

In order to test possible susceptibility of medical apparatuses, 93 of them were set upon their own in the hospital environment and subjected to the WLAN signals. Medical apparatuses were selected that could in principle be positioned in the vicinity of the WLAN antennas [3]) during normal functioning of the intensive care unit, the operating room, etc. Where relevant, the medical apparatuses were tested both powered from the mains and powered from their internal accumulator. If a medical apparatus was found that could be disturbed, the point in space furthest away from the medical apparatus was determined where interference starts. This is the separation distance **d**. The name indicates that possible sources of WLAN signals should be kept away from this medical apparatus more than this “separation distance”. At a found disturbance position, transmission of the WLAN signal was realized during several tens of seconds (typically 30 seconds). Testing was done according to a predefined testing program with predefined WLAN test signals. In the next paragraphs the following is presented:

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

[3]) 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. Some selected laboratory instruments are considered “medical apparatus” as well in this report.

In Table 2.1 below it is presented how many medical apparatuses of a certain type were tested at the hospital within the total of **93** 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 **17** medical apparatuses were tested that were connected to a medical apparatus that was tested as well. These connected apparatuses were tested and reported as separate apparatuses in this study.

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	5	
Syringe Pump	2	
Volumetric Infusion Pump	1	
Monitor/Meter	8	
Ultrasound Diagnostic Scanner	1	
Dialysis	1	1 (No. 8b)
EKG	1	
External Defibrillator / Monitor	1	
Neonatal (infant) Incubator	1	
Infant Warmer	2	
Fluid Warmer	1	
Hypohyperthermia	1	
Cell Saver	1	
Surgical Navigation	2	
Heart Lung Machine	1	
Heater/Cooler	1	
Insufflator	3	
Electrosurgery	1	
RF Lesion Generator (Pain Management)	1	
RF Generator for Endovenous Ablation	1	
Laser	4	
Bone densitometer	1	
Mammography/Biopsy	2	
Bucky room	2	9 (No. 32 b-e and 33 b-f)
X-Ray Chest system	1	
Stereotaxis system	1	
Cardiac Stimulator (EP)	1	
Angiographic contrast Injector	1	
Pacemaker Programmer	3	
Breath Analysis	1	

Medical apparatuses tested (Type)	Number of medical apparatuses tested	Number of medical apparatuses connected
UV-B cabin	1	
IR – Spectral Photometer (Laboratory Pharmacy)	1	
Medicine Analyser (Laboratory Pharmacy)	1	
Microplate Reader (Laboratory Pharmacy)	1	
Mass Spectrometer (Laboratory Pharmacy)	1	
Automated Hematology Analyzer	1	3 (No. 57 b-d)
Blood Glucose Meter	1	
Blood Gas Meter / Analyser	2	
Clinical Chemistry System (Dep. HKCL)	1	3 (No. 60 b-d)
Microbalance	2	
Handheld Contamination Monitor	1	
Radiation Monitor	1	
Radiation Dose Kalibrator	1	1 (no. 74 b)
Quality Control System	1	
Well Meter (Put Kristal)	1	
Chromatogram Scanner	1	
Hand/Foot Radiation Contamination Detector	1	
Endoscope drying cabinet	1	
Endoscope washer / disinfector	1	
RF wireless sensorsystem (Lab Microbiology)	1	
Oxygen Detection	1	
Total 93 =	76 +	17

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

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

- Medical apparatus not likely used near the WLAN antennas such as implantable pacemakers or hearing aids;
- Electric wheelchairs;
- Medical equipment used at home;
- Most 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 interfering 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 normally used signals from WLAN systems as possible. WLAN signals can differ strongly depending on carrier frequency, data rate, package size and transmission conditions. All test signals fulfilled the international standard IEEE 802.11X with X being a, b or g. The presently upcoming system "n" can be considered to be included in the tests because from interference point of view on the radio communication channel "n" has the same power and frequency characteristics as a, b and g [4)]. As indicated in Table 3.1, the power level of some test signals was increased to 500mW. For the final conclusions in this report only the results at 100mW were used.

Table 3.1 Summary of the WLAN signals used for interference testing.

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

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

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

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

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

Depending on the package size the WLAN signal has different "zero-periods" on the radio connection: periods in which the Access Point (A.P.) is "listening". At the data

[4]) We omit that at 5GHz the allowed power is 200mW (ETSI EN 301 893 v.1.5.1 dd. 2008-12). We tested at 100mW because all manufacturers specify 100mW for in-house applications of their access points. For information we also tested at 500mW.

link layer the signal was filled up with packages: short, middle or long packages (in bytes). At the PC the packages could be changed during the testing sessions:

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

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

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

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

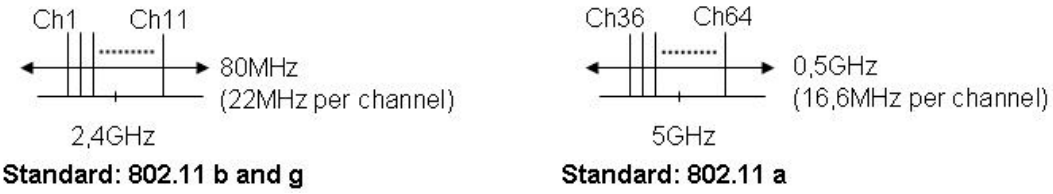


Figure 3.1 Channels 1, 11, 36 and 64 in their respective frequency bands at 2,4GHz and 5GHz according to the IEEE 802.11 standards.

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

Table 3.2 Overview of routine testing practices.

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

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

4 Test Protocol

Interference tests were performed at several departments of the hospital: IC, OR, Laboratory, etc. Test locations 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 positioned 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 – unless this table was the permanent location of the medical apparatus). 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 ventilators an artificial lung was used. The point in space was searched, most far from the apparatus, where it could just be disturbed. When testing for possible susceptibility at a certain position in space, transmission was realized during several seconds. At a found disturbance position, transmission was realized during several tens of seconds before reporting.
The reaction of the medical apparatus (if any) was noted down: flashing lamps, audible alarms, display disturbances, all details. When the apparatus stopped, it was also reported whether it could be restarted by switching it OFF and ON again and whether all settings were lost or not. When disturbances occurred, it was also checked whether memory functions were disturbed.

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

Remarks
1: The test method minimized 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, the conclusion that the apparatus is not susceptible is not warranted because tests were limited, had a typical (restricted) purpose and were not intended to cover the standard IEC 60601-1-2 **[4]** for EMC of Medical Equipment. A conclusion about the complete EMC behaviour of a medical apparatus is the responsibility of the manufacturer and must be based on more elaborate testing.
3: The number of medical apparatuses included in the immunity testing was limited. The medical apparatuses were carefully selected to cover the actual situation in the rooms at the hospital. The medical apparatuses and the WLAN systems are believed to represent a collection as can be found in more hospitals. No strict general conclusions about other medical apparatuses can be drawn from this report without careful judgment and comparison. In case of doubt additional testing may be needed (as international standards advise generally as well).

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 possible classification of disturbances is presented. In **Paragraph 5.4** the results are summarized and in **Paragraph 5.5** presented graphically. In **Paragraph 5.6** the results are compared to interference by GSM phones.

5.2 Classification of disturbances

Disturbances and/or interferences at the medical apparatuses were classified according to Table 5.1 below. The classifications only apply to the interference at the specific apparatus. The classification **U** (**U**nsafe) is not restricted to life threatening situations for the patient. The importance of interference must be seen in the right perspective: in a way every disturbance is unacceptable during treatment of patients [5)].

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

	Meaning	Example
N	**No**, no disturbance or interference occurs	- Irrelevant noise or rumble 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. - Relevant noise or rumble from a loudspeaker.
S	**Significant** but not (yet) unsafe disturbance	- Disturbance of the functioning of the apparatus but no safety hazard for patient or user - no indirect safety hazard as well. - Small “spikes” on ECG curves. - Disturbances on a display without hazard.
U	**Unsafe** disturbance	- 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)] The standard IEC TR 60513 **Literature [8]** lays down the international safety philosophy for medical apparatus. In this standard the starting point is the “vulnerable patient” who often is restricted partially or totally in reflex actions, using sense organs, movability, alertness, etc. Therefore the safety philosophy for medical apparatus is totally different from the safety philosophy for household or industrial equipment for example, that is used by healthy persons being not patients.

5.3 Detailed results

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

In total 93 apparatuses were tested at the hospital in June and July 2010. Nearly all were medical apparatuses or laboratory apparatuses (exceptions: an RF radio sensor system and an oxygen level alarm system).

The numbering of the medical apparatuses reflects the order of testing which was determined by practical circumstances like availability of a specific apparatus.

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

Legend to Table 5.2 below
Column 1: The **No. in test** refers to the testing order of the medical apparatuses as recorded during the interference testing. Some photos which illustrate the testing method can be found in **Appendix C** to this report.
Column 2: Medical apparatus tested are presented in this column per functional group. The type (name) of each medical apparatus is mentioned as it was indicated on the apparatus itself followed by the name of the manufacturer. The functional mode during testing of each apparatus is described in **Appendix A**. Seventeen medical apparatuses were connected to medical apparatuses tested. They were tested as medical apparatuses as well.
Column 3: The Year of purchase by the hospital. In cases marked with "?" the year of purchase could not be found or there was doubt about it.
Column 4: In this column the separation distance **d** is given for those medical apparatuses that were influenced by WLAN signal(s). The letter **N** means that no interference occurred at any distance from the medical apparatus including distance 0cm (=WLAN antenna against the medical apparatus). The footnotes in columns 4 refer to details of the interferences found. In columns 4 the influences found are classified according to the **N/L/S/U** scheme [6] as described in **Paragraph 5.2** of this report.
Column 5: The channel that transmitted the WLAN signal in case of interference.

6) **N**/**L**/**S**/**U** = **N**o/**L**ight/**S**ignificant/**U**nsafe disturbance or interference. In Netherlands language: = **N**/**L**/**S**/**O** = **N**ee/**L**ichte/**S**ignificante/**O**nveilige verstoring of interferentie.

Table 5.2 Overview of all tested medical apparatuses and description of all interferences found, the separation distance d per apparatus and the classification (N/L/S/U) of the interference.

No. in test	Medical apparatus tested	Year of purchase	Interference Y/N Classific. N/L/S/U 100mW: …cm 500mW: …cm	Channel No. 1/ 11/ 36/ 64
	Ventilator			
4	Savina (Transport Ventilator), Dräger	10	N	
36	Bipap Knight Star 335, Nellcor Puritan Bennett	00	N	
37	Bipap Harmony, Respironics, Inc.	10	N	
42	Babaylog 2000, Dräger In transport Incubator 5400 together with No. 43	04	N	
66	Leoni 2 Neonatal ventilator, Heinen und Löwenstein (Accutronic)	10	N	
	Syringe Pump			
2	Argus 600 Green Stream SY-P, Argus Medical	05	N	
12	Orchestra NL Module DPS, Fresenius Vial Tested in Orchestra Base Primea	04	N	
	Volumetric Infusion Pump			
20	Model 598, Ivac	03	**Y [7] Classific.: U 100mW: 20cm 500mW: 30cm**	 **11** **11**
	Monitor/Meter			
18	Patient Monitor Intellivue MP5, Philips	09	N	
1	Patient Monitor MP70 (Intellivue M8007A),Philips	09	N	
38	FMS Flexible Module Server, Philips; Tested with MP70 (No, 1)	04	N	
17	ST Analysis: STAN S31 Fetal Heart Monitor, Neoventa Medical AB	07	N	
21	ST Analysis: STAN S21 Fetal Heart Monitor, Neoventa Medical AB	04	N	
19	Fetal Monitor Viridia Series 50XM, M1350B, Hewlett Packard	99	N	
43	Oxygen Monitor MaxO2, Ceramatec In transport Incubator 5400 together with No. 42	97	N	
69	Cardiac Output Meter Vigilant Vig 2E, Edwards **Restricted test (no measurements on screen)**	09	**N** [8]	

[7]) **Ch11** 500mW: 30cm from right side: Acoustic alarm + Error message on screen: P7.
Ch11 at 100mW: 20cm from right side: Acoustic alarm + Error message on screen: E n.
The pump could not be brought back to normal functioning: the error message stayed on. However, after four (4) hours (another pump: 24 hours) the error message disappeared and the pump could be used again. The hospital personnel recognized this error behaviour as occurring already several years (gsm?).

[8]) Restricted test due to failing test features: Only temperature indication was active; no curves on screen; no cardiac output measurement was running.

No. in test	Medical apparatus tested	Year of purchase	Interference Y/N Classific. N/L/S/U 100mW: …cm 500mW: …cm	Channel No. 1/ 11/ 36/ 64
	Ultrasound Diagnostic Scanner			
30	Xario XG, Toshiba; Tested with probe 12L5	09	N	
	Dialysis			
8	5008 Fresenius Medical care	07	N	
8b	Aqua Uno Reverse Osmosis, Fresenius Medical care; Tested with 5008 (No 8)	08	N	
	EKG			
50	Electrofysiologic System Labsystem Pro, C.R. Bard, Inc. Incl.: 2 Monitors in HCK, 2 Monitors + PC on Desk, EKG-amplifier, IC Module	00	N	
	External Defibrillator / Monitor			
5	Heartstart MRx M3535A, Philips	10	N	
	Neonatal (infant) Incubator			
15	Vita Thermocare, Weyer	09	N	
	Infant Warmer			
16	Babytherm 8010, Dräger	01	N	
41	BabyWarmer 50W, KanMed	06	N	
	Fluid Warmer			
3	Buddy, Belmont	10	N	
	Hypohyperthermia			
11	Medi-Therm II MTA 4702, Gaymar Industries,Inc.	04	N	
	Cell Saver			
10	Electa, Sorin Group Tested while restricted functioning	05	N	
	Surgical Navigation			
23	Vector Vision compact, BrainLAB	06	N	
67	DigiPointeur 6200 (Facial + Skull Surgery), Collin	09	N	

No. in test	Medical apparatus tested	Year of purchase	Interference Y/N Classific. N/L/S/U 100mW: …cm 500mW: …cm	Channel No. 1/ 11/ 36/ 64
	Heart Lung Machine			
13	S5, Stöckert; Tested with Heater Cooler (No.14)	09	**Y [9] Classific.: U** **100mW: 2cm** **500mW: 10cm**	 **11** **11**
	Heater/Cooler			
14	Heater Cooler 3T,Stöckert;Tested with S5(No.13)	09	N	
	Insufflator			
24	Pneumo Sure XL High Flow Insufflator, Strijker	09	N	
25	Abdominal CO2 Insufflator 16 ltr, Olympus	95	N	
27	CO2 Insufflator UHI-3, Olympus	06	**Y [10] Classific.: U** **500mW: 25cm**	 11
	Electrosurgery			
26	ForceTriad Z25393, Valleylab	07	N	
	RF Lesion Generator (Pain Management)			
9	System Model RFG – 3c Plus, Radionics	98	N	
	RF Generator for Endovenous Ablation			
63	RF Generator RFG 2, VNUS, Inc.	08	N	
	Laser			
22	Sharplan 1055, Laser Industries	91	N	
34	Eye laser Novus Omni, Coherent	05	N	
35	Eye laser Tango, Ellex	08	N	
39	Dermatology Laser V-beam, Candela	03	N	
	Bone densitometer			
56	Lunar Prodigy, General Electric	02	N	
	Mammography			
28	Lorad Selenica, Hologic Company	06	N	
29	Breast Biopsy Stereotactic Multicare Platinum, Hologic Company	06	N	

[9]) **Ch11** 100mW: 2cm from Flowprobe TX50 of Centrifugal Blood Pump System (make Biomedicus - Medtronic): The registration by the Flowprobe is incorrect (display flashes).
Ch11 at 500mW: 10cm from Flowprobe TX50: same behaviour.

[10]) **Ch11** 500mW: 25cm form frontside: Influence on “pressure” and “Flow”.
Ch11 500mW: 1cm from front side: fast beep: Alarm 5/sec. After switching off and on the apparatus returns to normal functioning. Other Channels and other powers; No interference.

No. in test	Medical apparatus tested	Year of purchase	Interference Y/N Classific. N/L/S/U 100mW: …cm 500mW: …cm	Channel No. 1/ 11/ 36/ 64
	Bucky room			
32 a-e	Bucky system Digital Diagnost, Philips; Includes: Bucky, Tube, Detector, Table, Controldesk, Phosphor system	08	N	
33 a-f	Triathlon Bucky Room (SEH), Oldelft (Canon) Includes: Bucky, Tube, 2 Detectors, Table, Controldesk, PC, Phosphor system	06	N	
	X-Ray Chest system			
48	Allura Xper FD-10, Philips Incl.: Table AD 5 Tilt Angio Diagnost, Operating Console, Electronic control cabinett	06	N	
	Stereotaxis system			
49	Navigant Stereotaxis, Inc. NZA25, Niobe Incl.: Monitor, Operating console, Electronic control cabinet	06	N	
	Cardiac Stimulator			
51	Micropace PTY Ltd EPS 320, Cardiac Stimulator, Bona Computech Light Incl.: Amplifier at HCK, Monitor + PC on Desk, Monitor EKG (No. 50)	09	N	
	Angiographic contrast Injector			
52	Mark V ProVis, Medrad	06	N	
	Pacemaker Programmer			
53	Type Vitatron, Medtronic 2090 (loan) **RF-connection not activated / not available**	90 (?)	N	
54	Merlin Patient Care System, Model 3650, St. Jude Medical **RF-connection not activated / not available**	09	N	
55	Zoom Latitude Programming System, Guidant 3120 (loan) Incl.: RF connection at 350 a 500 MHz	08 (?)	**Y [11] Classific.: U 100mW: 150cm 500mW: 150cm**	**1,11 11**

[11]) **Ch 1**: 100mW: At 150cm A Rate and V Rate not detected via RF connection. Programming head not disturbed at 0cm.
Ch 11: 100mW: At 150cm A Rate and V Rate not detected via RF connection. Programming head not disturbed at 0cm.
Ch 11: 500mW: At 150cm A Rate and V Rate not detected via RF connection. Programming head not disturbed at 0cm.
Ch 36: 500mW: No interference on RF connection and programming head.
Ch 64: 100mW: No interference on RF connection and programming head.

No. in test	Medical apparatus tested	Year of purchase	Interference Y/N Classific. N/L/S/U 100mW: …cm 500mW: …cm	Channel No. 1/ 11/ 36/ 64
	Breath Analysis			
64	MicroLyzer DP Plus, Quintron	06	**Y [12] Classific.: U** **100mW: 1cm** **500mW: 20cm**	 **11** **11**
	UV-B cabin			
40	UV 7001 (UV-B), Waldmann Medizintechnik	05	N	
	IR – Spectral Photometer (Laboratory Pharmacy)			
44	Avatar 370 DIGS, Nicolet	04	**Y [13)] Classific.: U** **500mW: 0cm**	 **36**
	Medicine Analyser (Laboratory Pharmacy)			
45	Medicine Analyser, Dade Behring.	09	N	
	Microplate Reader (Laboratory Pharmacy)			
46	Microplate Reader EL 808, BioTek	07	N	
	Mass Spectrometer (Laboratory Pharmacy)			
47	Discovery Max Finnigan Quantum, Thermo Together with Autosampler Plus	06	N	
	Automated Hematology Analyzer			
57	Sysmex Incl.: Cell Counter, Slide Preparation Unit, Automated Sedimentation Measurement	03	N	
	Blood Glucose Meter			
58	Accu-Check Inform II, Cobas, Roche	10 (?)	N	

[12]) **Ch 11**: 100mW: 1cm from the meters on the front side: Interference: 104mV is changed into 107mV.
Ch 11: 500mW: 20cm from the meters on the front side: Interference. At 0cm 104mV is changed into 1**1**7mV. **Note** that the required accuracy is ± 2mV (information from Internet).
Other Channels: No Interference.

[13]) **Ch 1** 100mW: 5cm from left side: Interference on successive spectra. Match over 10 spectra = 36% which is not acceptable for photometry. However: this is acceptable as interference protection.
Ch11 100mW: 0cm from left side: Interference on successive spectra. Match over 10 spectra = 30% which is not acceptable for photometry. However: this is acceptable as interference protection.
Ch 36 500mW: 0cm from left side: Interference on successive spectra. Match over 10 spectra results in wrong material (NaCl). This effect starts at 150cm (500mW is not a requirement: see report introduction).
Ch 64 100mW: 0cm from left side: Interference on successive spectra. Match over 10 spectra = 94% which is acceptable for photometry.

No. in test	Medical apparatus tested	Year of purchase	Interference Y/N Classific. N/L/S/U 100mW: …cm 500mW: …cm	Channel No. 1/ 11/ 36/ 64
	Blood Gas Meter / Analyser			
59	ABL800 Flex, Radiometer (Dep. HKCL) Incl.: PC-terminal and IT-Network Port	09	N	
62	Rapidlab 845, Bayer	03	N	
	Clinical Chemistry System (Dep. HKCL)			
60	Modular Analytics, Roche Incl.: ISE 900, P 800, E 170	06	N	
	Microbalance			
70	Microbalance AG 204 Delta Range, Mettler Toledo	03	**Y [14] Classific.: U 100mW: No Interf. 500mW: 0cm**	**--- 11**
71	Microbalance XP 204, Mettler Toledo	05	N	
	Aseptic Preparation Laboratory ABA (Pharmacy)			
72	Handheld Contamination Monitor UMo LB123, Berthold	97	N	
73	Radiation Monitor RTD Series 900 mini-monitor, Mini-Instruments, Ltd.	91	N	
74	Radiation Dose Kalibrator VIK 202, Veenstra Incl.: Ionisation chamber, PC, Screen,	05	N	
76	Quality Control System VCS-103 connected with Scanner VCS-101 (No. 77), Veenstra	06	N	
75	Well Meter (Put Kristal) VDA-101 Connected to VCS-103 (No.76), Veenstra	06	N	
77	Chromatogram Scanner VCS-101 Connected to VCS-103 (No.76), Veenstra	06	N	
78	Hand/Foot Radiation Contamination Detector VLB-202, Veenstra	06 (?)	N	
	Endoscope drying cabinet			
6	GV 700, Van Vliet	05	N	
	Endoscope washer / disinfector			
7	WD 440, Wassenburg	03	N	
	RF wireless sensorsystem (Lab Microbiology)			
65	WiSensys (868MHz?)	09 (?)	N	

[14]) **Ch 11** 500mW: 0cm from display: 1microgramm deviation.
Ch 11 200mW: 0cm from display: 0,1microgramm deviation.
Ch 11 100mW: 0cm from display: No deviation; No Interference.
Other Channels: No Interference

No. in test	Medical apparatus tested	Year of purchase	Interference Y/N Classific. N/L/S/U 100mW: …cm 500mW: …cm	Channel No. 1/ 11/ 36/ 64
	Oxygen Detection			
61	Airmaster II, Linde Gas	08	N	

5.4 Summary of results

A summary of all influenced medical apparatuses is given in Table 5.3 below.
Table 5.3 is a summary from table 5.2

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

No. in test	Medical apparatuses tested	Year of purchase	Separation distance d [cm] and Classification: L / S / U	
			At 100mW	At 500mW
	Volumetric Infusion Pump			
20	Model 598, Ivac	03	**20cm U**	**30cm U**
	Monitor/Meter			
69	Cardiac Output Meter Vigilant Vig 2E, Edwards	09	**N 15)**	
	Heart Lung Machine			
13	S5, Stöckert; Tested with Heater Cooler (No.14)	09	**2cm U**	**10cm U**
	Insufflator			
27	CO2 Insufflator UHI-3, Olympus	06	**N**	**25cm U**
	Pacemaker Programmer			
55	Zoom Latitude Programming System, Guidant 3120 (loan) Incl.: RF connection at 350 a 500 MHz	08 (?)	**150cm U**	**150cm U**
	Breath Analysis			
64	MicroLyzer DP Plus, Quintron	06	**1cm U**	**20cm U**
	IR – Spectral Photometer (Laboratory Pharmacy)			
44	Avatar 370 DIGS, Nicolet	04	**N**(acceptable interference)	**0cm U**
	Microbalance			
70	Microbalance AG 204 Delta Range, Mettler Toledo	03	**N**	**0cm U**

[15]) Restricted test due to failing test features: Only temperature indication was active; no curves on screen; no cardiac output measurement was running.

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

5.5 Graphical presentation of results

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

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

From Figure 5.1 for example it can be concluded that at distances above 15cm about 3% of the medical apparatuses tested was disturbed by the WLAN signal 100mW. The continuous graphs are the theoretical field strength at distance **d** from WLAN antennas according to the basic formula $E = 7 \times (\sqrt{W}) / d$ in which W is power in watt (See **Literature [5]).** This field strength must be taken from the right vertical axis in the graphs of Figure 5.1 and Figure 5.2. Two examples:

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

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

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

At 100mW

No. in Test	Separation distance d [cm] At 100mW	At 500mW
55	150cm **U**	150cm **U**
20	20cm **U**	30cm **U**
13	2cm **U**	10cm **U**
64	1cm **U**	20cm **U**
27	-	25cm **U**
44	-	0cm **U**
70	-	0cm **U**
69	-	-

At 500mW

No. in Test	Separation distance d [cm] At 100mW	At 500mW
55	150cm **U**	150cm **U**
20	20cm **U**	30cm **U**
27	-	25cm **U**
64	1cm **U**	20cm **U**
13	2cm **U**	10cm **U**
44	-	0cm **U**
70	-	0cm **U**
69	-	-

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 about 15cm;
- For **500mW** the distance at which 3% of the tested medical apparatuses was influenced is about 25cm;

- As mentioned above already, the 3% point for 100mW is at about 15cm. As can be seen from Figure 5.2 the 3% point for 500mW is at about 25cm. This shift in distance (about a factor 2) is comparable to the figure that the formula E = 7 x (√W) / d would imply (from 100mW to 500mW implies a shift of √5 = 2,24);
- The characterisations of the disturbances (in this study all U) are indicated in both diagrams.

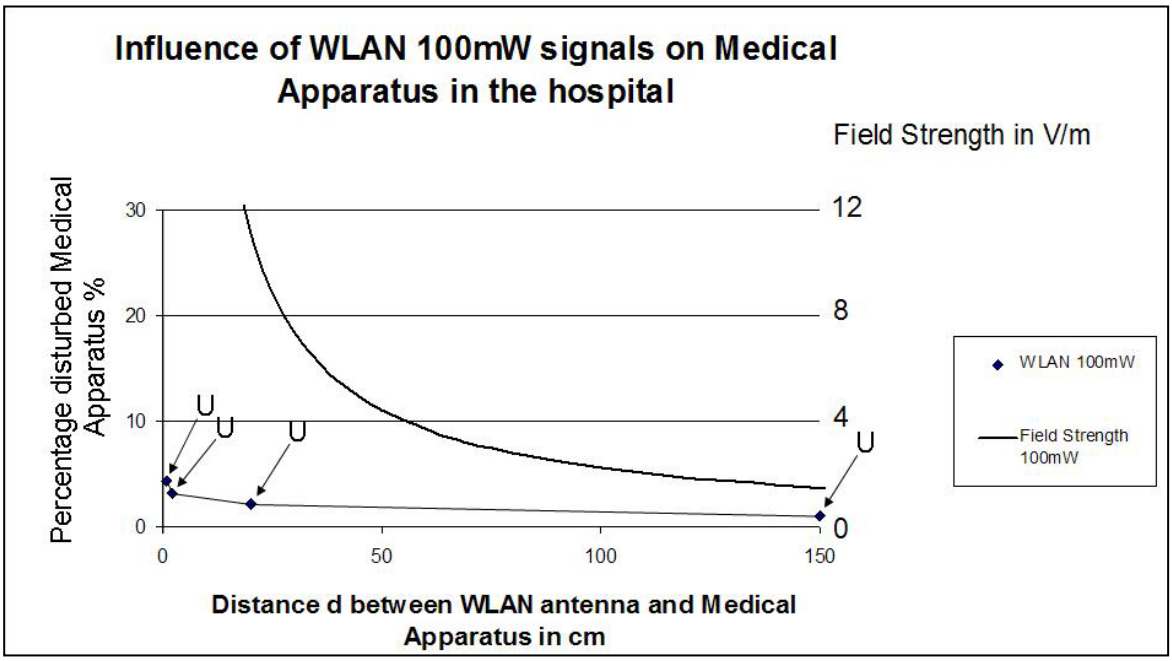


Figure 5.1: Influence of WLAN 100mW signals on medical apparatuses in the hospital.

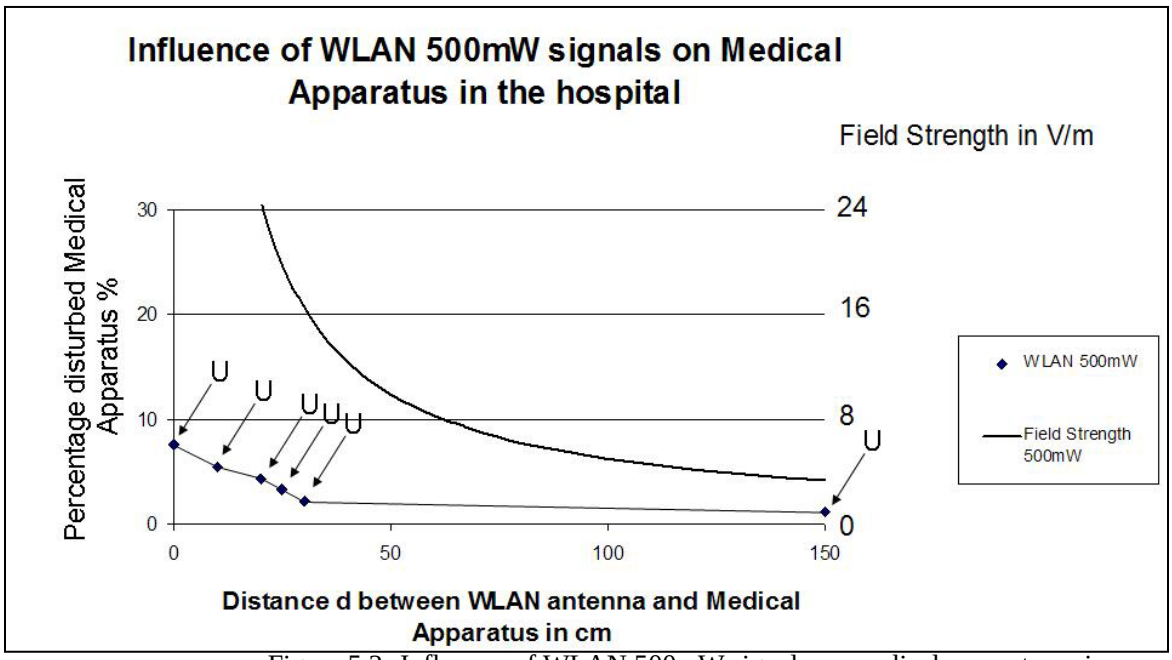


Figure 5.2: Influence of WLAN 500mW signals on medical apparatuses in the hospital.

5.6 Comparison of WLAN results to GSM results

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

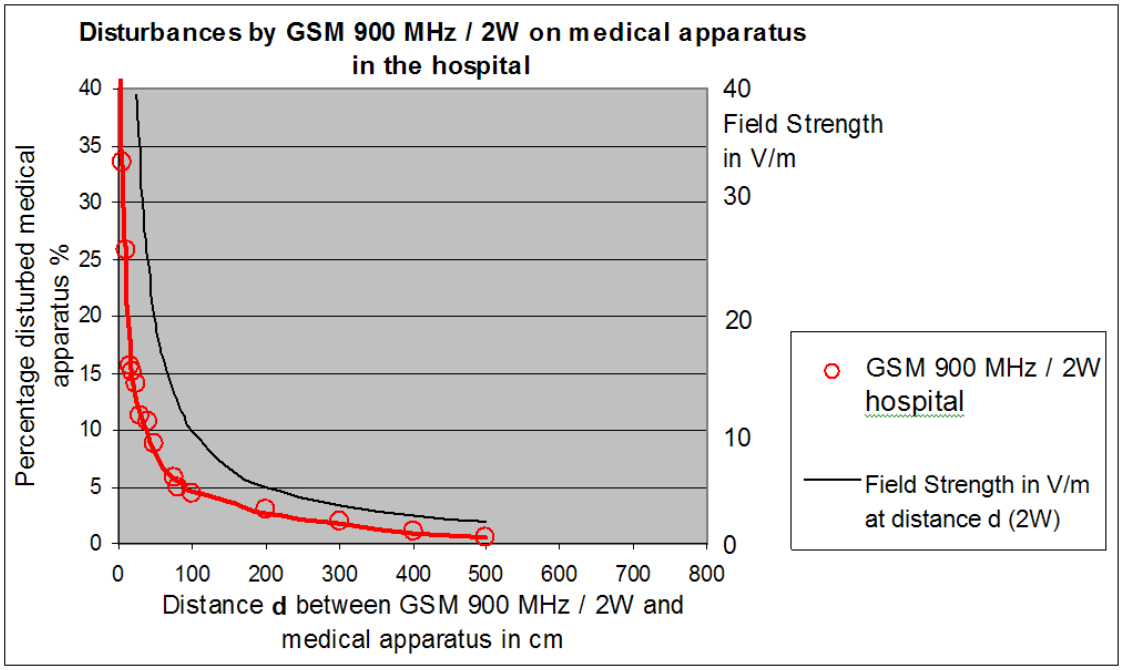


Figure 5.3: Disturbances by GSM 900 MHz / 2W on medical apparatus in the hospital (copied from **Literature [5]** and **[6]**).

From the graph in Figure 5.3 it can be seen that at 150cm distance from GSM phones about 3% of the medical apparatus is disturbed. The distance at which 3% apparatus are disturbed is internationally advised as the separation distance to be kept [16]. As concluded in **Paragraph 5.5** the 3% point for WLAN 100mW lies at about 20cm. From this comparison it concludes that the ratio between the separation distances for GSM and WLAN is about a factor of 10.

[16]) 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 [9]**,
- Health Devices November 2001 (ECRI) **Literature [10]**.
- Morrissey et al, Health Physics (2002) 82: pp 4 - 51 **Literature [11]**.
- A Netherlands regulation is: V-ICTN Recommendations **Literature [7]** based on **Literature [5]** and referring to **Literature [3]**.

6 Signature

Author
R. Hensbroek, M.Sc.
Project manager

Signature

Approved by
R.A. Bezemer M.Sc. MTD
Peer review

Signature

A Functional modes of all tested medical apparatuses

In Table A.1 below details can be found about the functions that the medical apparatuses performed during interference testing (including power situation as far as relevant). Apparatuses are tabulated in the same order as in the other tables in this report.

Table A.1: Functional modes of all tested medical apparatuses and specification of the power source (mains or battery).

No. in test	Medical apparatus tested	Year of purchase	Functional modes of medical apparatuses
	Ventilator		
4	Savina (Transport Ventilador), Dräger	10	SIMV Autoflow, VT=500ml, f=16, PEEP = 5mbar.
36	Bipap Knight Star 335, Nellcor Puritan Bennett	00	Functioning; Normal use settings.
37	Bipap Harmony, Respironics, Inc.	10	Functioning; Normal use settings.
42	Babaylog 2000, Dräger In transport Incubator 5400 together with No. 43	04	Functioning; Normal use settings.
66	Leoni 2 Neonatal ventilator, Heinen und Löwenstein (Accutronic)	10	Tested with testlung. Mode: SIPPV = Synchronous Inspirative Positive Pressure Volume.
	Syringe Pump		
2	Argus 600 Green Stream SY-P, Argus Medical	05	Mounted in docking station; 60 ml/h.
12	Orchestra NL Module DPS, Fresenius Vial Tested in Orchestra Base Primea	04	Functioning in Orchestra Base Primea.
	Volumetric Infusion Pump		
20	Model 598, Ivac	03	Normal use infusion rate.
	Monitor/Meter		
18	Patient Monitor Intellivue MP5, Philips	09	Powered from mains and from internal battery. Tested with ECG simulator.
1	Patient Monitor MP70 (Intellivue M8007A),Philips	09	ECG, ABP (120/80), NiBP, HF (80), CO2, Temp, SpO2 (98), SaO2/Pleth, CVD (0). EKG-Simulator Lionheart 3, Biotek. SpO2 simulator Index 2, Biotek .
38	FMS Flexible Module Server, Philips; Tested with MP70 (No, 1)	04	

No. in test	Medical apparatus tested	Year of purchase	Functional modes of medical apparatuses
17	ST Analysis: STAN S31 Fetal Heart Monitor, Neoventa Medical AB	07	US Transducer, Cardiotocography-transducer (CTG), IUP. Tested with ECG simulator.
21	ST Analysis: STAN S21 Fetal Heart Monitor, Neoventa Medical AB	04	2 x US Transducer, Cardiotocography-transducer (CTG).
19	Fetal Monitor Viridia Series 50XM, M1350B, Hewlett Packard	99	2 x US Transducer, Cardiotocography-transducer (CTG). Tested with SpO2 simulator.
43	Oxygen Monitor MaxO2, Ceramatec In transport Incubator 5400 together with No. 42	97	Functioning.
69	Cardiac Output Meter Vigilant Vig 2E, Edwards. **Restricted test (no measurements on screen)**	09	Restricted test due to failing test features: Only temperature indication was active; no curves on screen; no cardiac output measurement was running.
	Ultrasound Diagnostic Scanner		
30	Xario XG, Toshiba; Tested with probe 12L5	09	Functioning at normal use settings; Tested with probe 12L5.
	Dialysis		
8	5008 Fresenius Medical care	07	Bloodflow 30 ml/min.
8b	Aqua Uno RO = Reverse Osmosis, Fresenius Medical care; Tested with 5008 (No 8)	08	Display: 8 microseconds.
	EKG		
50	Electrofysiologic System Labsystem Pro, C.R. Bard, Inc. Incl.: 2 Monitors in HCK, 2 Monitors + PC on Desk, EKG-amplifier, IC Module	00	Functioning at normal use settings; Tested with simulator Fluke MPS 450.
	External Defibrillator / Monitor		
5	Heartstart MRx M3535A, Philips	10	Performing defibrillations, EKG-Simulator Lionheart 3, Biotek. SpO2 simulator Index 2, Biotek.
	Neonatal (infant) Incubator		
15	Vita Thermocare, Weyer	09	Functioning, Normal use settings.
	Infant Warmer		
16	Babytherm 8010, Dräger	01	Functioning, Normal use settings.
41	BabyWarmer 50W, KanMed	06	Functioning; Normal use settings.

No. in test	Medical apparatus tested	Year of purchase	Functional modes of medical apparatuses
	Fluid Warmer		
3	Buddy, Belmont	10	Functioning.
	Hypohyperthermia		
11	Medi-Therm II MTA 4702, Gaymar Industries,Inc.	04	Warming up and Cooling down.
	Cell Saver		
10	Electa, Sorin Group **Tested while restricted functioning**	05	Tested during short start-up runs, Patient set Dideco CE 0123.
	Surgical Navigation		
23	Vector Vision compact, BrainLAB	06	Detecting three marker balls.
67	DigiPointeur 6200 (Facial + Skull Surgery), Collin	09	Tested during marking at the skull with the “pen”.
	Heart Lung Machine		
13	S5, Stöckert; Tested with Heater Cooler (No.14)	09	Functioning at normal use settings.
	Heater/Cooler		
14	Heater Cooler 3T,Stöckert;Tested with S5(No.13)	09	Functioning: 38.0 0C.
	Insufflator		
24	Pneumo Sure XL High Flow Insufflator, Strijker	09	Functional: Normal use settings: 0,3 l/min CO2.
25	Abdominal CO2 Insufflator 16 ltr, Olympus	95	Functional: Normal use settings.
27	CO2 Insufflator UHI-3, Olympus	06	Functional: Normal use settings.
	Electrosurgery		
26	ForceTriad Z25393, Valleylab	07	Modes: Cut & Coagulating; “Ligasure” electrodes not connected.
	RF Lesion Generator (Pain Management)		
9	System Model RFG – 3c Plus, Radionics	98	Catheter immersed into saline solution. Tested in three modi: measurement/test, burning/treatment, Tip temperature controlled.

No. in test	Medical apparatus tested	Year of purchase	Functional modes of medical apparatuses
	RF Generator for Endovenous Ablation		
63	RF Generator RFG 2, VNUS, Inc.	08	Tested with electrode in saline solution: RF endovenous ablation: 15W phase 1 and 25W phase 2.
	Laser		
22	Sharplan 1055, Laser Industries	91	Tested in functional standby (laser at a low level). All electronics functioning.
34	Eye laser Novus Omni, Coherent	05	Functioning; Normal use settings.
35	Eye laser Tango, Ellex	08	Functioning; Normal use settings.
39	Dermatology Laser V-beam, Candela	03	Tested during calibration: 4 J/cm2 during 40msec.
	Bone densitometer		
56	Lunar Prodigy, General Electric	02	Tested during built-in quality control.
	Mammography		
28	Lorad Selenica, Hologic Company	06	Image taken from a phantom; Vertical movement included in test.
29	Breast Biopsy Stereotactic Multicare Platinum, Hologic Company	06	Functioning at normal use settings
	Bucky room		
32 a-e	Bucky system Digital Diagnost, Philips; Includes: Bucky, Tube, Detector, Table, Controldesk, Phosphor system	08	Normal use settings. Images taken.
33 a-f	Triathlon Bucky Room (SEH), Oldelft (Canon) Includes: Bucky, Tube, 2 Detectors, Table, Controldesk, PC, Phosphor system	06	Normal use settings. Images taken.
	X-Ray Chest system		
48	Allura Xper FD-10, Philips Incl.: Table AD 5 Tilt Angio Diagnost, Operating Console, Electronic control cabinett	06	Normal use settings. Images taken.
	Stereotaxis system		
49	Navigant Stereotaxis, Inc. NZA25, Niobe Incl.: Monitor, Operating console, Electronic control cabinet	06	Functioning at normal use settings.

No. in test	Medical apparatus tested	Year of purchase	Functional modes of medical apparatuses
	Cardiac Stimulator		
51	Micropace PTY Ltd EPS 320, Cardiac Stimulator, Bona Computech Light Incl.: Amplifier at HCK, Monitor + PC on Desk, Monitor EKG (No. 50)	09	Functioning at normal use settings.
	Angiographic contrast Injector		
52	Mark V ProVis, Medrad	06	Functioning at normal use settings; Tested while injecting.
	Pacemaker Programmer		
53	Type Vitatron, Medtronic 2090 (loan) RF-connection not activated / not available	90 (?)	Tested with pacemaker EnTrust (DDE-DDDR); Read-out(EKG) and programmed via programming head.
54	Merlin Patient Care System, Model 3650, St. Jude Medical **RF-connection not activated / not available**	09	Tested with ICD Promote RF (S/N 397678); Read-out(EKG) and programmed via programming head.
55	Zoom Latitude Programming System, Guidant 3120 (loan) Incl.: RF connection at 350 a 500 MHz	08 (?)	Tested with ICD Guidant Renewal 4 RF (DDDR – Mode H 230 S/N 202342); Read-out(EKG) and programmed.
	Breath Analysis		
64	MicroLyzer DP Plus, Quintron	06	Functioning; Normal use settings.
	UV-B cabin		
40	UV 7001 (UV-B), Waldmann Medizintechnik	05	Functioning; Normal use settings; Tested during Countdown.
	IR – Spectral Photometer (Laboratory Pharmacy)		
44	Avatar 370 DIGS, Nicolet	04	Analysing a polystyrene sample.
	Medicine Analyser (Laboratory Pharmacy)		
45	Medicine Analyser, Dade Behring.	09	Analysing E2 Theophylline (control liquid). 20 min.
	Microplate Reader (Laboratory Pharmacy)		
46	Microplate Reader EL 808, BioTek	07	Microplate filled up with white and yellow test liquid.

No. in test	Medical apparatus tested	Year of purchase	Functional modes of medical apparatuses
	Mass Spectrometer (Laboratory Pharmacy)		
47	Discovery Max Finnigan Quantum, Thermo Together with Autosampler Plus	06	Masses: 182, 508, 997.
	Automated Hematology Analyzer		
57	Sysmex Incl.: Cell Counter, Slide Preparation Unit, Automated Sedimentation Measurement	03	Tested during full processing of 3 test samples.
	Blood Glucose Meter		
58	Accu-Check Inform II, Cobas, Roche	10 (?)	Tested during full processing of test-strip and testliquid. No mains power.
	Blood Gas Meter / Analyser		
59	ABL800 Flex, Radiometer (Dep. HKCL) Incl.: PC-terminal and IT-Network Port	09	Tested during full measurement process including database (network).
62	Rapidlab 845, Bayer	03	Tested during full processing of quality control sample.
	Clinical Chemistry System (Dep. HKCL)		
60	Modular Analytics, Roche Incl.: ISE 900, P 800, E 170	06	Tested during full measurement process.
	Microbalance		
70	Microbalance AG 204 Delta Range, Mettler Toledo	03	Weighing 8,7113g.
71	Microbalance XP 204, Mettler Toledo	05	Weighing.
	Aseptic Preparation Laboratory ABA (Pharmacy)		
72	Handheld Contamination Monitor UMo LB123, Berthold	97	Functional (switched on).
73	Radiation Monitor RTD Series 900 mini-monitor, Mini-Instruments, Ltd.	91	Functional (switched on).
74	Radiation Dose Kalibrator VIK 202, Veenstra Incl.: Ionisation chamber, PC, Screen,	05	Measuring: 105,5 MBq.
76	Quality Control System VCS-103 connected with Scanner VCS-101 (No. 77), Veenstra	06	Measuring: Cobalt 57: 122 keV.
75	Well Meter (Put Kristal) VDA-101 Connected to VCS-103 (No.76), Veenstra	06	Measuring: Cobalt 57: 122 keV.

No. in test	Medical apparatus tested	Year of purchase	Functional modes of medical apparatuses
77	Chromatogram Scanner VCS-101 Connected to VCS-103 (No.76), Veenstra	06	Measuring: Cobalt 57: 122 keV
78	Hand/Foot Radiation Contamination Detector VLB-202, Veenstra	06 (?)	Contamination simulated with Cobalt 57: 6,1 Bq/cm2.
	Endoscopes drying cabinet		
6	GV 700, Van Vliet	05	Functioning.
	Endoscope washer / disinfector		
7	WD 440, Wassenburg	03	Functioning: washing / disinfecting.
	RF wireless sensorsystem (Lab Microbiology)		
65	WiSensys (868MHz?)	09 (?)	Three transmitters and a base station were tested while functioning normally.
	Oxygen Detection		
61	Airmaster II, Linde Gas	08	Tested while O2 concentration was reduced with N2.

B WLAN test set-up

1 Measurement Equipment to monitor testing
- Spectrum analyser: fsh manufactured by Rohde & Schwarz;
- Attenuator 20dB.

2 Hardware in the test set-up:
- 2 PC's / 8 AP's (in this way combining 802.11 a, b, g and n in one test);
- Amplifiers at 2,4GHz and at 5 GHz to start testing on every medical apparatus with 2 channels at higher power levels than normal;
- Medical Apparatuses were placed on a wooden cart.

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

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

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

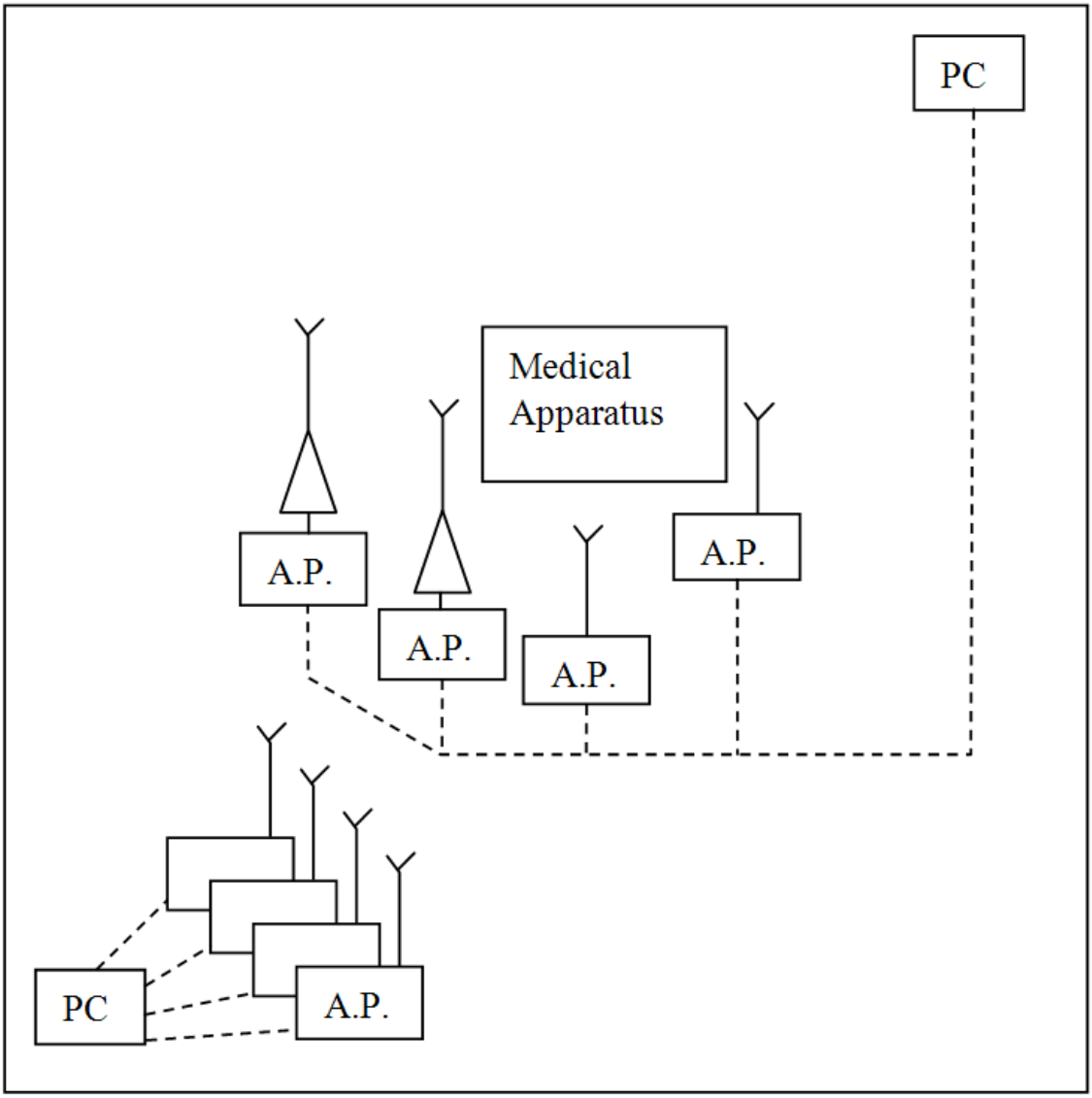


Figure B.1: Test set-up with 4 transmitting antennas and 4 receiving antennas. Each of these groups of antennas was connected to a separate PC.

C Photographs

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

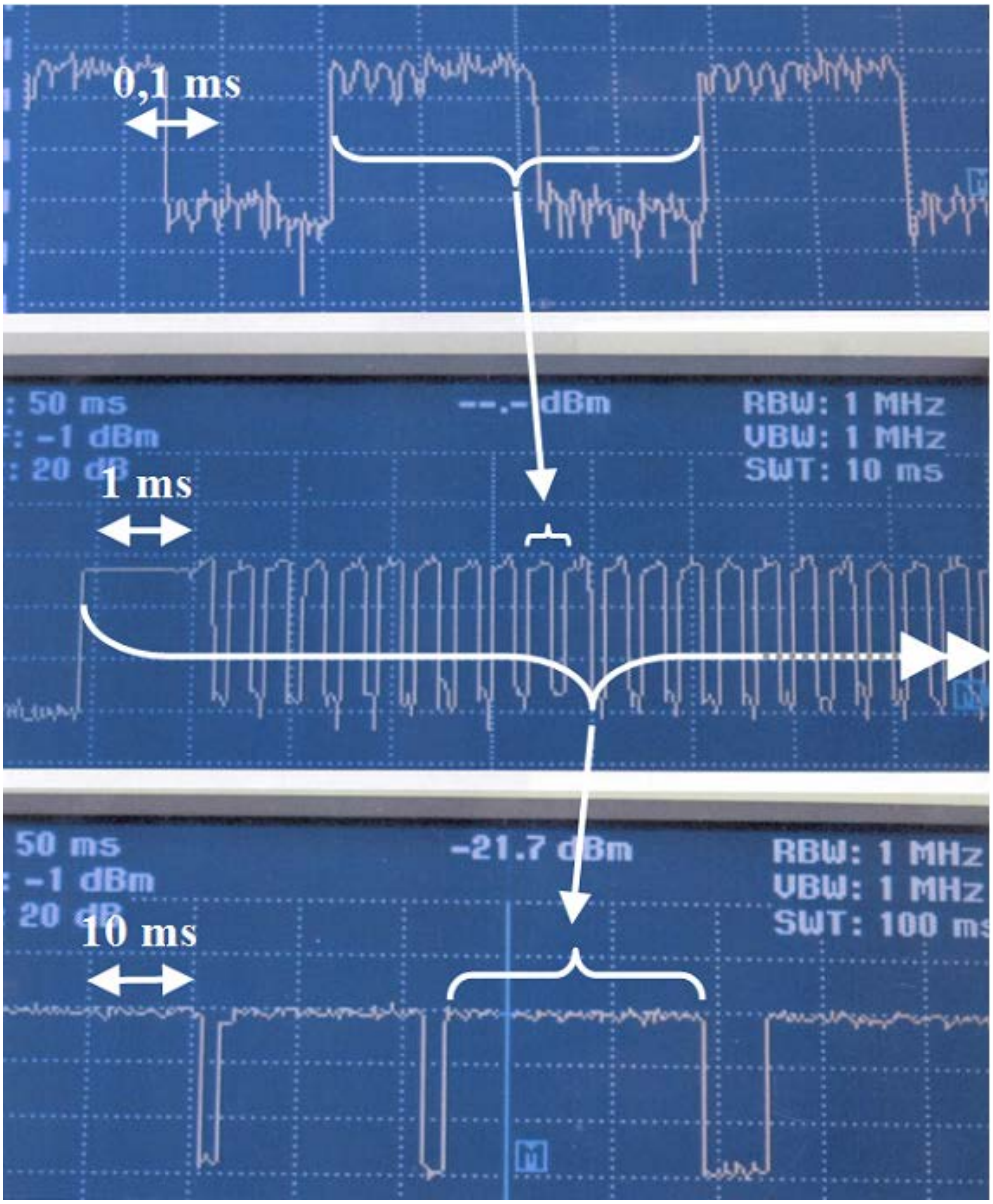


Figure C.1 Test signal of Ch1 with short packages. The time base: 0,1ms/division (upper trace), 1ms/div (middle trace) and 10ms/div (lower trace).

In the photographs following below a transmitting antenna in verification is shown (Figure C.2), two test set-ups for medical apparatuses (Figure C.3, C.4), the cart with receiving antennas (Figure C.6) and typical test situation examples with laboratory apparatus and medical apparatuses (Figures C.5, C.7 to C.10).

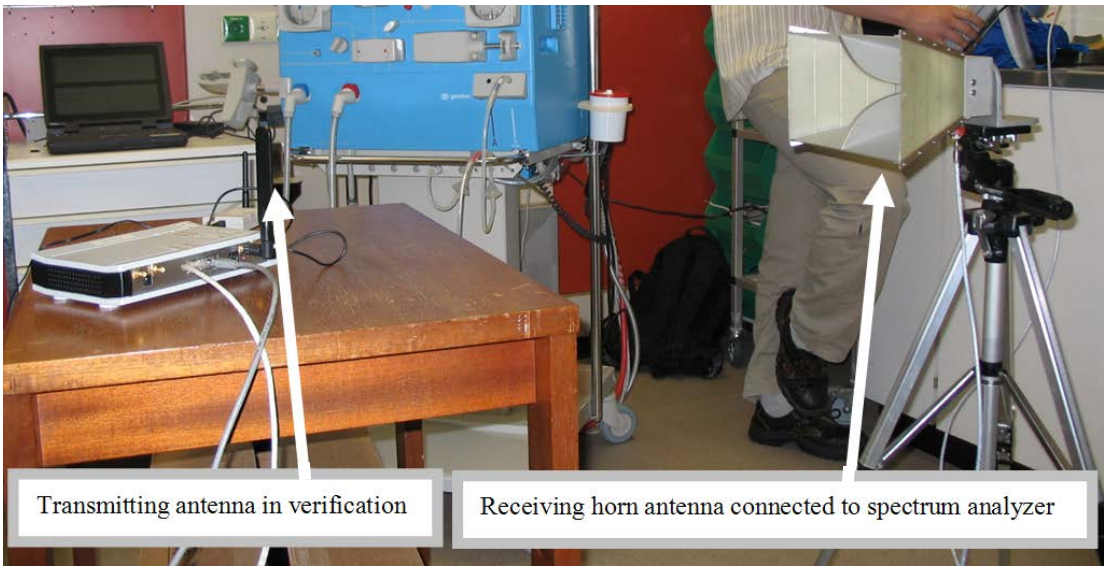


Figure C.2. Transmitting antenna in verification.

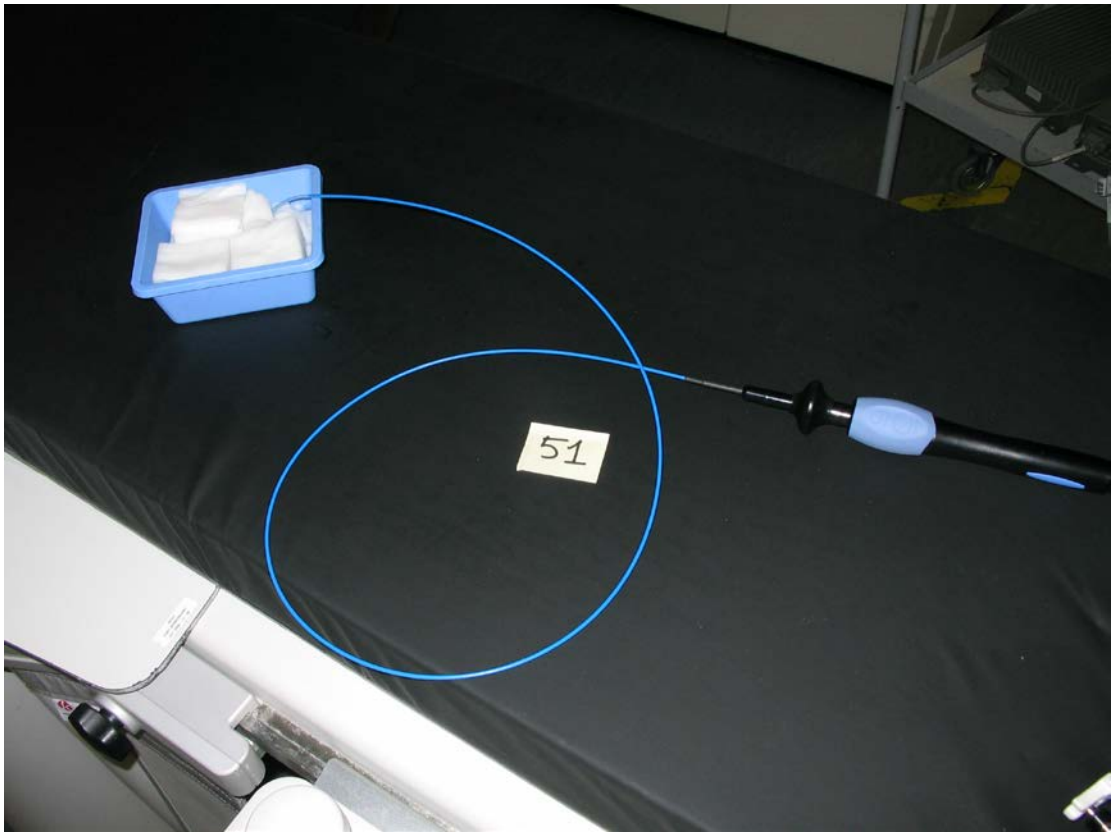
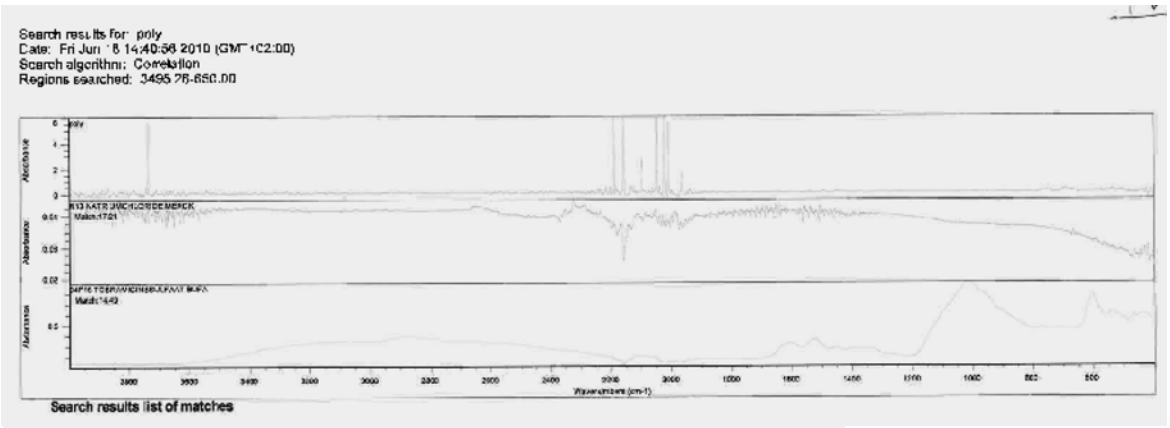


Figure C.3. Test set-up: Loop-electrode for Electrophysiological measurements inserted in saline (Apparatus No. 51).



	Index	Match	Compound Name
1	71	17.21	N13 NATRIUMCHLORIDE MERCK
2	19	14.49	04F16 TOBRAMICINESULFAAT BUFA
3	6	11.47	05H34 AMINOHYDROXYPROPYLIDEENDIFOSFONAAT (APD) APOTHEEK HAAG
4	141	10.46	NITROUS OXIDE GAS (GAS CELL)
5	225	9.58	06D17 TOBRAMYCINESULFAAT
6	61	9.47	04F25 SORBISTERIT PDR FRESENIUS
7	91	8.49	OCTANE-D18,98+ ATOM % D
8	266	5.88	clioquinol placebo
9	235	5.81	Methylcellulose
10	286	5.67	amlipharm emulsie 6%

Figure C.4. Interference: Spectrophotometer identifies Polystyrene incorrectly as Natriumchloride. The low Match (17.21) warns the user that the result is suspect. (Apparatus No. 44)

Figure C.5 Test set-up Laboratory apparatus.

Figure C.6.

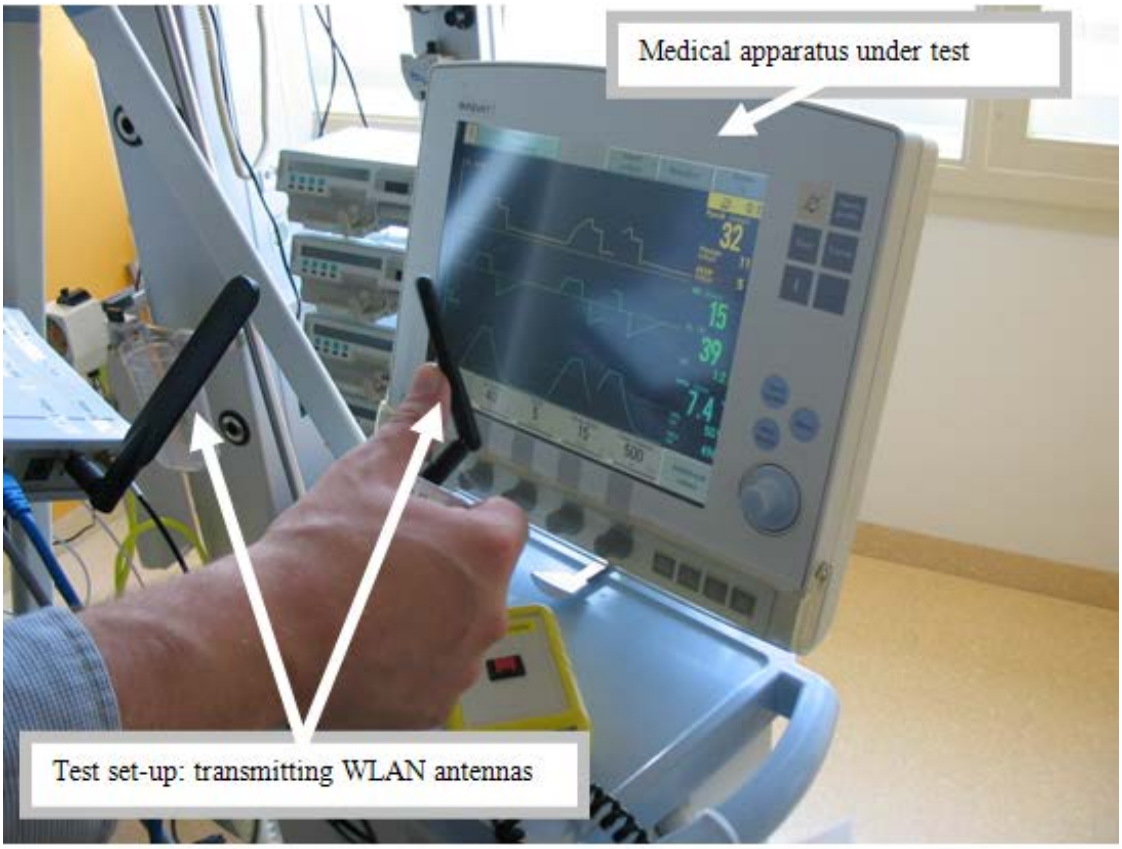


Figure C.7.

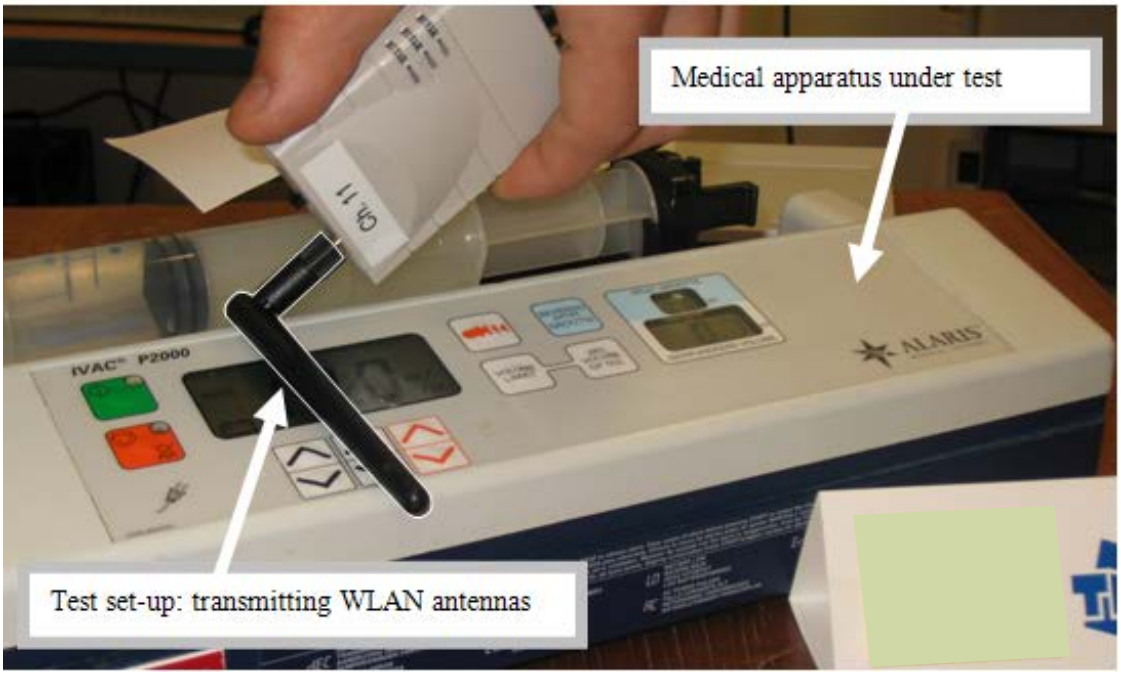


Figure C.8.

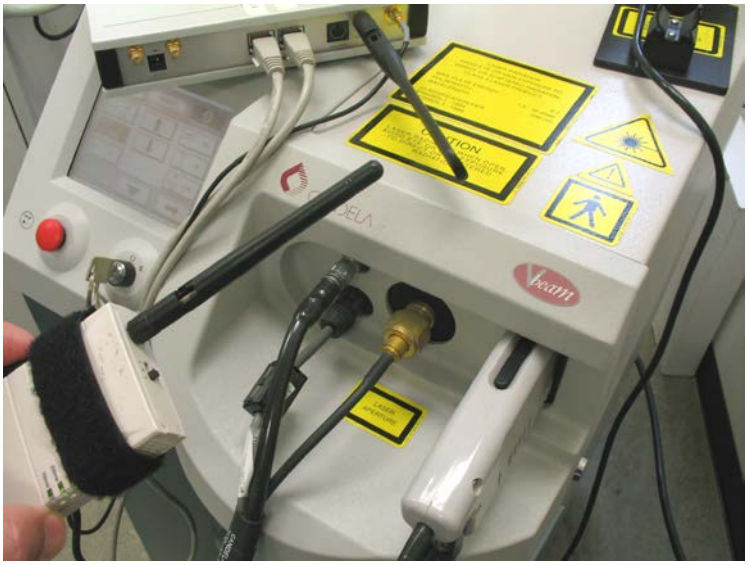


Figure C.9

Figure C.10

D Literature

1 TNO report “96 Medical Apparatuses tested for interference by WLAN/WiFi signals” R. Hensbroek, TNO Quality of Life, Report Number: KvL/P&Z 2007.117 dated September 2007. See: http://www.TNO.nl/WLAN-Zorg

2 Magazine “Technologie in de Gezondheidszorg” (NL language). April 2005, Number 4, 21st Issue, pp.5-6

3 Recommendations regarding the use of pocket telephones within health care institutions 1995, VIFKA, 1 September 1995 (VIFKA is now called “Vereniging ICT Nederland”).

4 IEC 60601-1-2: 2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests. Third edition.

5 TNO report “Effects on medical equipment at home of pocket phones and the like – field measurements”, TNO Prevention and Health, TNO Research report PG/TG/00.050 (28 April 2000)
For medical apparatus this report refers to:
Influence of 2W GSM pocket phones on 205 medical apparatuses: field measurements. TNO report TG/95.044. 1 August 1995 (NL Language).

6 R. Hensbroek, Interference by handheld telephones on medical equipment (NL language). In magazine: “Klinische Fysica”. December 2000.

7 Recommendations for the use of GSM and cordless telephones near electronic medical equipment for home care, 25 October 2000. This document has been drawn up by the Telecommunication branch of the Netherlands Association for Information and Communication Technology (V-ICTN). It is published on the internet site of the Netherlands Ministry of Welfare, Health and Sports.
Those recommendations refer to the still applicable recommendations in Literature **[3]:** Recommendations regarding the use of pocket telephones within health care institutions 1995, VIFKA, 1 September 1995 (VIFKA is now called “Vereniging ICT Nederland”).

8 IEC TR 60513 (1994) Fundamental Aspects of Safety Standards for Medical Electrical Equipment.

9 Hanada et al: Electromagnetic Interference on Medical Equipment by Low power Mobile Telecommunication Systems. IEEE Transactions on Electromagnetic Compatibility, Vol. 42, No. 4, November 2000, pp. 470 476.

10 ECRI Health Devices 30 (11), November 2001: Wireless Communication Devices and Electromagnetic Interference, pp. 403-409.

11 Morrissey et al: Characterization of Electromagnetic Interference of Medical Devices in the Hospital due to Cell Phones. Health Physics, January 2002, Volume 82, Number 1, pp 45-51.