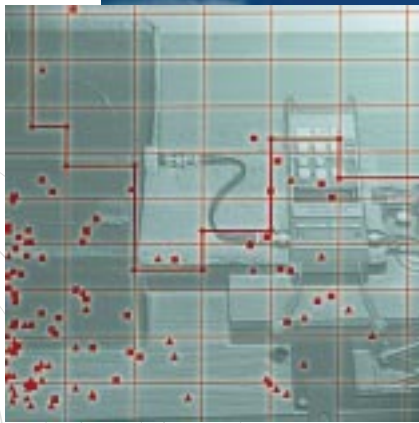


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Electromagnetic Interference of Pacemakers by Mobile Phones

W. Irnich, L. Batz, R. Müller and R. Tobisch

Edition
Wissenschaft



Forschungsgemeinschaft Funk

Editorial

Dear Readers,

with this issue of „Electromagnetic Interference of Pacemakers by Mobile Phones“ the Forschungsgemeinschaft Funk continues to publish their studies in English language. The original study was published in German in 1996 as Edition Wissenschaft No. 7. In 1997 the American medicine journal „PACE“ published it as an off-print.

An increasing number of people is in need of a cardiac pacemaker. On the other hand more and more people enjoy the comfort of a mobile phone. Therefore, the question if this vital aid can be influenced by mobile phones is increasingly a topic of great interest.

This study was the first in the world which examined a big number of pacemakers – covering about 80% of the equipment on the market – under severe conditions using the three mobile nets existing in Germany: C-net (450 MHz, analogue), D-net (900 MHz, GSM) and E-net (1800 MHz, GSM).

The German Federal Association for Radiation Protection advises patients with pacemakers to observe a distance of 20 cm to a mobile phone (Infoblatt 5/97).

Gerd Friedrich

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Electromagnetic Interference of Pacemakers by Mobile Phones

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Summary

The topic interference of pacemakers by mobile phones has evoked a surprisingly strong interest, not only among pacemaker patients, but also in the public opinion. The latter is the more surprising, as in the past, the problem of interference has scarcely found the attention that it deserves in the interest of the patient.

It was the intention of our investigation to test as many pacemaker models as possible to determine whether incompatibility with mobile phones of different modes may exist, using an in vitro measuring setup. We had access to 231 different models of 20 manufacturers. During the measurements, a pulse generator together with a suitable lead was situated in a 0.9 g/L saline solution and the antenna of a mobile phone was positioned as close as possible. The gap in which interference occurred was defined as "maximum interference distance". All three nets existing in

Germany, the C-net (450 MHz, analogue), the D-net (900 MHz, digital pulsed), and the E-net (1,800MHz, digital pulsed) were tested in succession.

Out of 231 pulse generator models, 103 pieces corresponding to 44.6% were influenced either by C- or D-net, if both results were totaled. However, this view is misleading as no patient will use C- and D-net phones simultaneously. Separated into C- or D-net interference, the result is 30.7% for C or 34.2% for D, respectively, of all models tested. The susceptible models represent 18.6% or 27% of today's living patients respectively. All models were resistant to the E-net. With respect to D-net phones, all pacemakers of six manufacturers proved to be unaffected. Eleven other manufacturers possessed affected and unaffected models as well. A C-net phone only prolonged up to five pacemaker periods within 10 seconds during dialing without substantial impairment to the patient. Bipolar pacemakers are as susceptible as unipolar ones.

The following advice for patients and physicians can be derived from our investigations: though 27% of all patients may have problems with D-net phones (not C- or E-net), the application should generally not be questioned. On the contrary, patients with susceptible devices should be advised that a distance of 20 cm is sufficient to guarantee integrity of the pacemaker with respect to hand held phones. Portables, on the other hand, should have a distance of about 0,5 m. Pacemaker patients really suffering from mobile phones are very rare unless the phone is just positioned in the pocket over the pulse generator. The contralateral pocket or the belt position guarantees, in 99% of all patients, undisturbed operation of the pacemaker. A risk analysis reveals that the portion of patients really suffering from mobile phones is about 1 out of 100,000. Nevertheless, it would be desirable in the future if implanting physicians used only pacemakers with immunity against mobile phones as guaranteed by the manufacturers.

1 Introduction

The topic of electromagnetic interference (EMI) due to mobile phones has evoked a strong interest not only among physicians but also in the public opinion. This is surprising, as the topic of EMI has been in the public eye since the first report was published in 1968 by Furman and coworkers.¹

Numerous investigations of interference have been published since then (for references, see Moberg and Strandberg²). The reported cases were regarded as anecdotal and rare, without severe clinical relevance. This brings up the question as to what clinical relevance means, and whether interference is only critical if life-threatening. How many casualties are necessary to give reasons for "relevance"?

The latest interest in EMI due to mobile phones has its justification

in the fact that there is no producer of electromagnetic fields (EMF) as mobile as mobile phones, and no EMF source may come so close to an implanted pacemaker if, for instance, put in the pocket just over the pacemaker. Moreover, it is estimated that up to 15% of the population may possess mobile phones in the near future, at least in Europe.

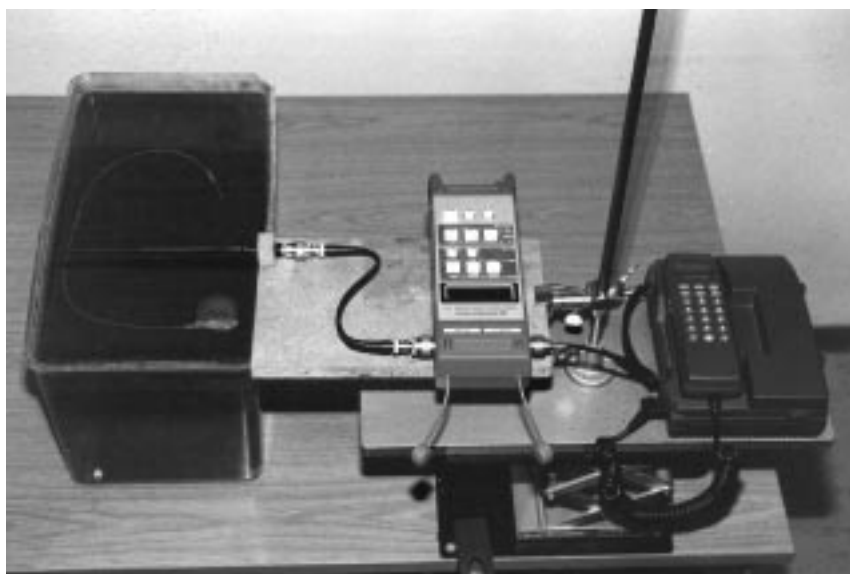
The investigators of this problem of mobile phones so far have mostly stated that there are pacemakers that are susceptible and added that pacemaker patients should be cautious in using them.³⁻¹¹ As no author so far has named horse and horseman – as if susceptibility to mobile phones is physically inevitable and not related to brands or models – it was our goal to investigate as many models as possible in an in vitro trial to see whether differences between brands and models exist with respect to mobile phone in-

terference.¹² If only one or more manufacturers produced only resistant pacemaker models, the proof would be furnished that it is technically possible to protect pacemakers from being interfered with by mobile phones. On the other hand, such an investigation would yield an insight of which and how often pacemakers are concerned, what their reaction to EMI would be, and what preventive measures could be pursued.

2 Methods

2.1 Simulation of an Implanted Pacemaker

To electrically realize the situation of a pacemaker placed inside a patient, the pacemaker and its electrode were installed in a saline solution, with a resistivity corresponding to that of the low frequency range of muscle tissue. Detailed calculations and considerations of how to simulate the situation of an implanted pacemaker for low and high frequencies have been previously described.¹² Briefly, a 0.9 g/L saline solution has been used. Its conductivity of 170 mS/m (5.9 Ω m correspondingly) was chosen to simulate the low frequency behaviour of tissue. The high frequency conductivity of 500 to 1,000 mS/m is so high that it would nearly short circuit the pacemaker output, thereby possibly altering the sensing behaviour due to excessive burdening of the battery and of the pacemaker input. The difference in penetration depth was taken into consideration by an in-



Top view on the measuring set up: the pacemaker with its electrode is in the tank on the left, above that the antenna of a portable D-net device and in the middle between antenna and portable device there is the measuring device.

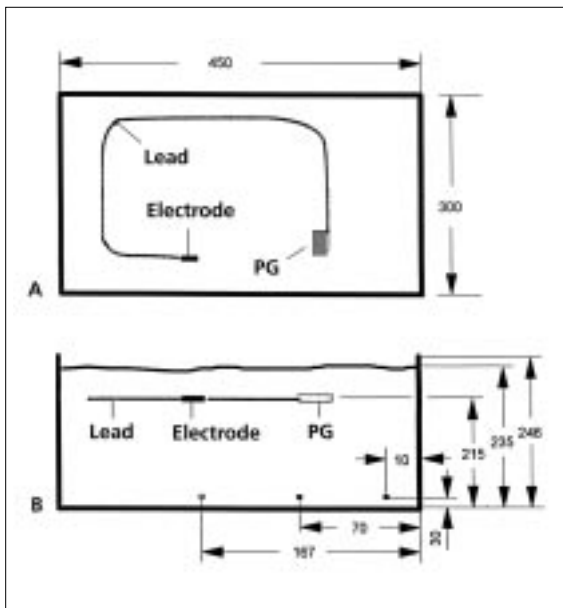


Figure 1.
Tank as simulation model for testing pacemaker behaviour during mobile phone application (all measures in mm).
A = top view; B = side view; PG = pulse generator.

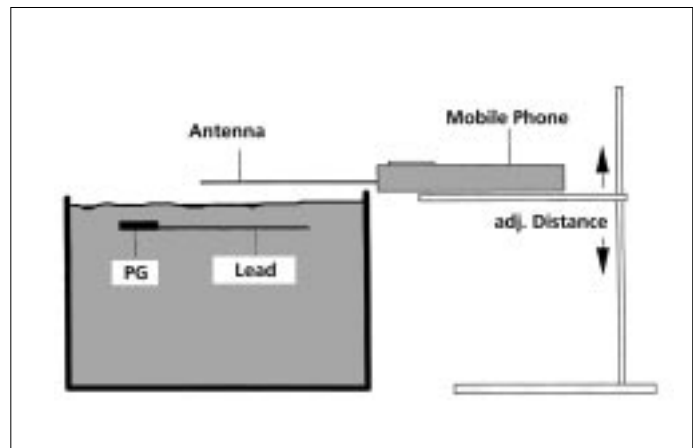


Figure 2.
Determination of the "maximum interference distance": The mobile phone is placed on a wooden plate that can be adjusted vertically so that the height can be measured up to which interference is just existing.

creased layer of water (20 mm instead of 5 mm tissue).

The pacemaker patient model for the test of mobile phones is shown in Figure 1. The minimum distance between surface of water and antenna of a mobile phone reached 10 mm. Pacemaker and electrode were held at a height of 215 mm with the help of foam sponges (used by florists to store water).

Quite low at the bottom of the tank, three pin jacks were placed in a distance of 185 mm from the pacemaker plane (215 to 30 mm) that were in contact with the solution. By these jacks the pacemaker pulse was derived, and an inhibiting signal could be coupled in. In order to prevent additional coupling of radiofrequency, this large distance between the pacemaker plane and the jacks was chosen. Figure 2 shows how the

maximum interference distance was determined.

A block diagram of the measuring setup is shown in Figure 3. The pacemaker pulses are received by an oscilloscope (HP 1201 B) and made visible and acoustical by a device called acoustic pulse control (APC). The maximum distance of interference of pacemakers is determined after switching on mobile phone (Mobpho) and measuring the antenna power by a power meter (CIT). With the help of an attenuator with 100%/200% switching, the pacemaker can be synchronized by the CENELEC¹³ triangular test signal produced by the function generator HP 3312 B. For measuring of interference behaviour the threshold of 100% was increased up to 200%¹³. The transmitting power of the mobile phones could be varied by the transmitter CMD55.

2.2 Characterization of the Different Mobile Phone Modes Investigated

There are three mobile phone nets used in Germany today. As they act differently on pacemakers, they are described in more detail. For simplicity, the different nets are called C-, D-, and E-nets, as they are designated in Germany. Table I summarizes in brief the main characteristics.

The C-net has a carrier frequency of around 450 MHz, the information is coded in FM and analogue mode, the transmission is continuously as "continuous waves". Maximum transmission power is 2 W for hand held phones, also called "handy" in the following, and 15 W for portable phones. During organization of a call, there is a sort of pulsing that yields DC pulses

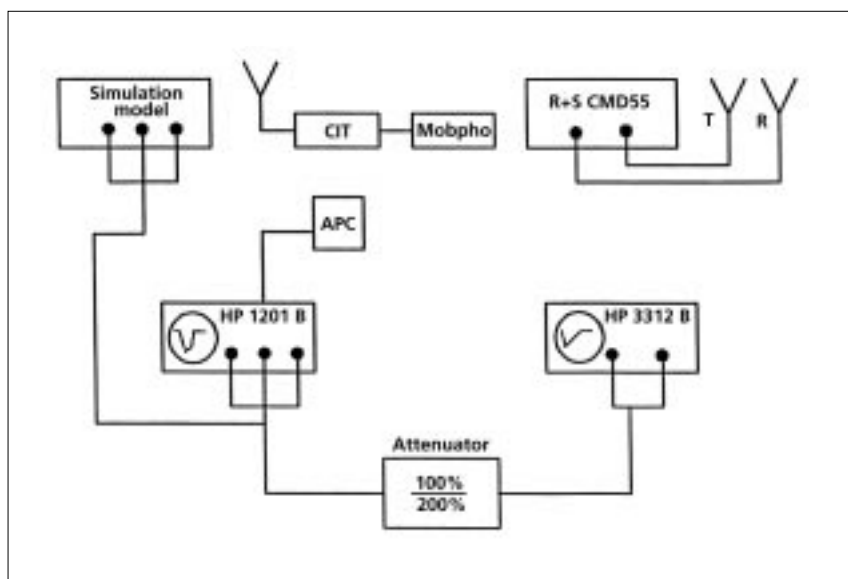


Figure 3.

Measuring setup: the output power of the mobile phone (mobpho) is measured by a powermeter (CIT). The reaction (inhibition or triggering or switching to interference mode) is observed with the aid of an oscilloscope (HP 1201B). An acoustic pulse control (APC) coupled to the output of the oscilloscope amplifier indicates each pacemaker pulse by a beep tone. A triangular test pulse according to EN 50 061¹³ produced by a function generator HP 3312 B is fed into the simulation model via a circuit allowing adjustment of 100% or 200% of the reaction threshold.

of about 0.5-Hz frequency after demodulation within a pacemaker circuitry.

The D-net, according to the European GSM standard, has a carrier frequency of around 900 MHz. The information is digitally coded, the transmission is pulsed with a maximum output power, only during pulses of 2 W for handies and 8 W for portables. Demodulation of the pulsed signal contains 217 Hz and a combination of 2 Hz and 8 Hz during call organization and in DTX mode (the user is listening).

The E-net is completely equal to the D-net, except the carrier frequency is around 1,800 MHz.

2.3 The Mobile Phone as Interference Generator

The mobile phones were placed on a wooden plate (see Fig. 2) in such a way that the antennae were aligned in parallel to the electrode connector. With the

help of pacemakers that reacted sensitively to signals of mobile phones, the localization that ensured maximum coupling could be found.

In the C-net a hand held phone with up to 2 W, and in the D-net, an 8-W device was used. The transmitting power is normally variable and very important for determination of interference threshold. It is automatically adapted to the basic station with which the mobile phone communicates. Therefore, the transmitt-

ing power was protocolled during all measurements.

All possible operating conditions of a mobile phone were tested: call organization; and the normal operation with and without DTX mode (only possible in D- and E-net).

2.4 The Electrode as Receiving Antenna

It has been demonstrated that the attenuation of an electrode de-

	C-Net	D-Net	E-Net
Carrier frequency/MHz	450	900	1,800
Information coding	FM	Digital	Digital
Transmission	CW	PW	PW
Maximum Power/W			
Cellular (Handy)	2	2	1
Portable	15	8	-
Frequency of demodulation product/Hz	0.5	2*/8*/217	2*/8*/217

Table I: Main Characteristics of Different Nets

(FM = frequency modulation, CW = continuous waves, PW = pulsed waves)

* DTX mode = user is silent or during call organization.

depends on the kind of material and thickness of insulation between conductor and water.¹⁴ For each of the three frequencies the silicon electrode always had the lowest attenuation. On the contrary, the damping of a thin PVC insulated flex wire is increased by the factor 15.6. The polyurethane insulated electrode is in between both extremes; it makes the pacemaker system less susceptible because of its higher attenuation as compared with silicon insulation.

Whenever possible, the pacemaker was connected with a silicon electrode. The calculated higher sensitivity to interference of the silicon electrode has been proven true in our experiments.

2.5 The Pacemakers Investigated

The pacemaker models used for this investigation came from a collection gathered during the past 10 years. They were mainly explanted from deceased patients for cremation (explantation then is obligatory in Germany). The Department of Medical Engineering is the official collecting point for such devices in the federal state of Hesse in Germany. All units were tested for normal function. The sensitivity settings were left as they were. Therefore, the sensitivity can be regarded as representative for the whole population. The mean value for single channel or the ventricular channel of dual channel generators was $2.15 \text{ mV} \pm 0.70 \text{ mV}$ (minimum: 0.34 mV ; maximum: 5.8 mV) and for the atrial channel $1.08 \text{ mV} \pm 0.46 \text{ mV}$ (minimum: 0.53 mV , maximum: 2.47 mV), tested with the triangular CENELEC¹³ signal.

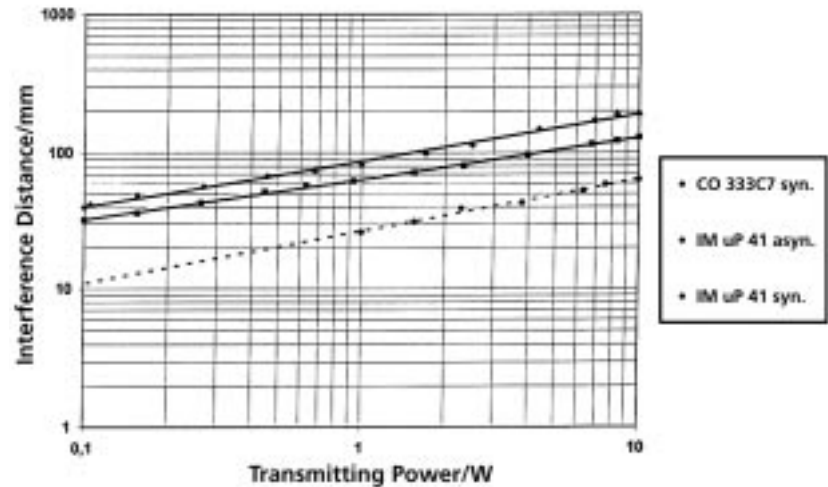


Figure 4.

The "maximum interference distance" for two sensitive pacemakers as a function of transmitting power (the distance in this case is determined from the surface of the pulse generator). Syn means synchronized (inhibited) by the triangular test signal; asyn means free running, the latter having a remarkable lower threshold in the IM $\mu\text{P}41$ pacemaker.

2.6 Procedure of Measuring

First, the pacemaker was checked unsynchronized with a minimum distance between pacemaker and antenna. Then the mobile phone was activated, and attention was paid to the effect produced by the pacemaker being either inhibited, or synchronized, or unaffected, respectively. Interfered by mobile phones, the distance was increased until the test was negative (see Fig. 2). In such a way, the same pacemaker was tested by devices of the C-, D-, and E-net in succession.

Then, the pacemaker was inhibited corresponding to the CENELEC standard¹³ by a negative, asymmetrical triangular signal of 2-ms decay and 13-ms rise time, the amplitude of which was adjusted to twice the threshold. The test as described above was repeated to question whether the synchroniz-

ed pacemaker would change to its interference rate.

For both tests, the maximum interference distance has been registered as the characteristic parameter for interference that will be used for describing possible interference behaviour of a pacemaker.

3 Results

3.1 Calculation of Interference Distance as a Function of Transmitting Power

For two susceptible pacemakers, it was found with the help of our test transmitter CMD55 (Fig. 3) which power corresponds to which maximum interference distance. In double logarithmic scale it turned out to be a straight line

Results

(Fig. 4), the steepness of which, averaged over the three curves, was nearly exactly 0.33 (see Appendix). This means that for a sensitive pacemaker, the maximum interference distance increases with the third root of transmitting power.

As it is improbable that a handy is positioned closer than 10 mm

to the body surface and just in parallel to the electrode, this distance was defined by us as shortest possible distance of a handy. The corresponding distance of 28 mm for an 8-W device cannot be realized because of the dimension and handling of a portable phone. Because of their possible proximity to the body surface, han-

dies are more critical for pacemaker patients than portable phones.

For all further analysis, we assume that a pacemaker must be regarded as resistant, if it is not interfered by a handy, coming as close as 10 mm to the water surface.

3.2 Interference by Demodulation Products

If signals are derived from the pacemaker input in the low frequency range, one can clearly see demodulation of pulsed signals at nonlinearities. If this demodulation product is further filtered by a low pass, which normally exists in pacemakers, the correlation between high frequency radiation and interference is nicely demonstrated (Fig. 5). Especially in the operation mode DTX, it is shown that with a low upper cut-off frequency of a pacemaker, the pulse packets arising every 0.5 seconds look like a rectangular signal of higher amplitudes compared with pulses arising every 0.125 seconds. This result explains why the unsynchronized pacemaker, together with the DTX mode is more sensitive than pacemakers inhibited by test signals. The pulses arising every 8 Hz must reach a higher intensity to switch pacemakers over to "interference rate".

Figure 6 demonstrates the mechanism by which pacemakers are influenced by the C-net. With the help of a dipole antenna and by rectification the envelope of the received voltage (upper curve in Fig. 6) and the output of a susceptible pacemaker (lower curve in Fig. 6), are recorded simultaneously. Call organization starts

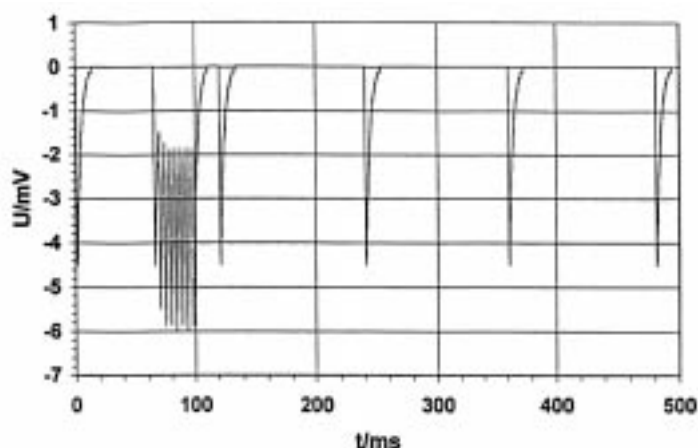


Figure 5. Demodulation product measured at the input of a pulse generator and filtered with a low-pass of 50-Hz upper cut-off frequency during DTX operation of the D-net: The eight spikes every 0.5 seconds closely coupled reach a higher amplitude of about 6 mV as compared to the 8-Hz single spikes. Thus, a pacemaker can either be inhibited (by the 2 Hz spike packet) or is switched to interference mode (by the 8-Hz spikes).

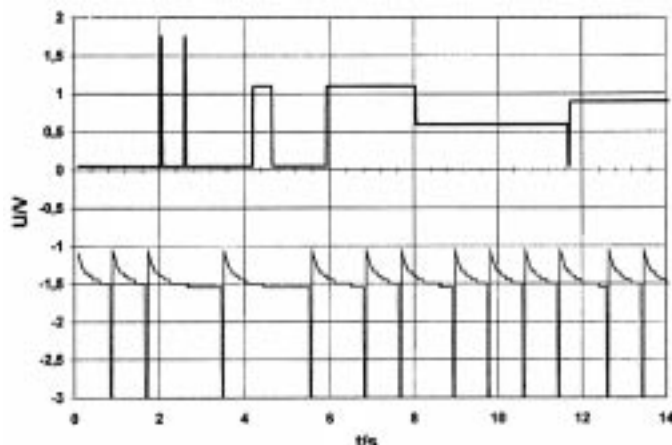
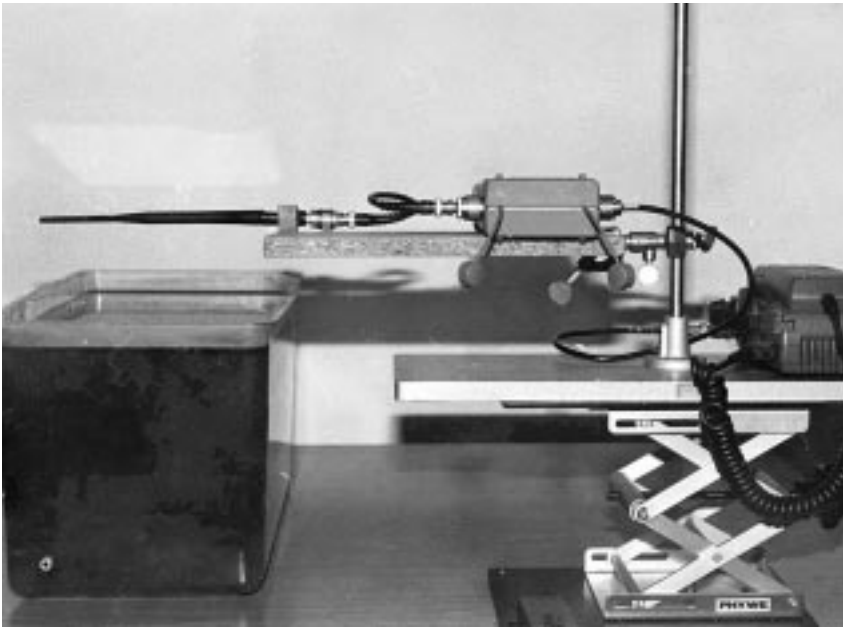


Figure 6. Demodulation product and pacemaker interference during call organization of the C-net: with the help of a dipole antenna and by rectification, the envelope of the received voltage (upper curve) is compared with the output of a sensitive pacemaker (lower curve). Within the period of call organization of about 10 seconds, there are five prolonged pulse intervals. Upstrokes and downstrokes of the envelope can influence the pacemaker (see prolongation at $t = 6s$ and $t = 8s$).



Side view on the setup as it was used to measure the "maximum interference distance".

with two strong pulses at $t = 2$ seconds, followed by a 450-ms pulse at $t = 4.2$ seconds and a longer lasting amplitude that is reduced to half its value at $t = 8$ seconds. At $t = 11.7$ seconds call organization can be regarded as finished. During 10 seconds there have been five prolonged intervals. Normally, depending on rate and refractory period, the number of prolonged intervals were < 5 . Instead of 72.5 ppm, the rate during the 14 seconds was reduced to 51.4 ppm, or, averaged over 1 minute, the rate was 67.6 ppm.

3.3 Transmitting Power and Programmed Sensitivity

Three susceptible pacemakers have been checked with regard to the change in maximum interference distances in relation to their sensing thresholds. For all three pacemakers, the correlation between distance and interference threshold was a straight

line in double logarithmic scale, but the steepness was negative and about 0.33 (see Appendix). We have learned from this finding that the maximum interference distance is in inverse proportion to the third root of the sensing threshold.

Based on the assumption, that the maximum interference distance at constant threshold is proportional to the third root of the transmitting power, and the distance at constant power is proportional to the reciprocal value of the third root of the sensing threshold, it can be concluded that the maximum interference distance is proportional to the third root of the ratio of power to interference threshold (see Appendix).

This result is of importance as, if interference of a pacemaker exists with < 2 W, its sensing threshold can be increased to the same extent to render it insensitive (see Appendix).

3.4 Measurement of 231 Pacemakers

Tables II and III show the most important results of the measurement of 231 different models of pacemakers. The maximum interference distances for C-net phones were directly measured, and that of the D-net for a power of 2 W was calculated on the basis of the results at 8 W to achieve higher accuracy. In the C-net, the pacemakers were interfered only during dialing period or call organization, as demonstrated by Figure 6, and not by the small amplitude modulation still existing during call. In the E-net, no pacemaker was affected. The reason is not only the lower power and the reduced penetration depth at 1.8 GHz, but also an increased reflection at the surface and a higher attenuation along the lead. Presumably at that frequency, the voltage produced at the input of a pacemaker is twice damped by capacities as compared with the D-net. By registering of the demodulation product in the E-net we found that the amplitudes of the demodulation product are 10 to 20 times lower as in the D-net.

The results of our measurement are assigned to the model of the pacemaker (Table II) and to the maximum interference distance with respect to D-net (Table III). The rightmost column in both tables shows the number of patients estimated by us, who might still live with this model in Germany at the end of 1994.

Seventy-one (30.7%) of the 231 tested models can be interfered with by C-net, and 79 (34.2%) by D-net (see Table III). A total of

Results

No.	MFC	Model	Age	Dc	Dd	Patients
1	AL	11	12		10	8
2	AL	20	12	81	59	
3	AL	21	12		6	62
4	AL	24	12		17	5
5	AL	25	11		13	19
6	AL	35	12		28	
7	AL	RDP2	12	43		
8	AL	RDP3	11	48		6
9	BI	Diplos 04(V)	11	86	85	1
10	BI	Diplos 05	11	91		325
11	BI	Diplos M05	6	33	104	525
12	BI	Ergos TC 03(V)	1		9	297
13	BI	Kalos 03-1	12	81	13	
14	BI	Kalos 03-2	12	86	18	31
15	BI	Kalos 04	10		45	920
16	BI	Kalos 05	5	29	22	492
17	BI	Leios 03	12	81	18	
18	BI	Leptos 01-1	12			1046
19	BI	Leptos 01-2	12			
20	BI	Leptos M01-1	10			232
21	BI	Leptos M01-2	10			
22	BI	Leukos 03-1	12	75	20	4
23	BI	Metros TC 01	1			391
24	BI	Mikros 02	8		13	1027
25	BI	Nanos 01	5		29	2731
26	BI	Neos 01-1	12			5675
27	BI	Neos 01-2	12			
28	BI	Neos 02	6			2281
29	BI	Neos LP01	7		13	505
30	BI	Neos LP01-2	7			
31	BI	Neos M01	7			1919
32	BI	Neos MLP01	7			678
33	BI	Physios	3			1191
34	BI	Physios TC 01(V)	1			6
35	BI	Pikos 01	3			3301
36	BI	Trios 01	8			2217
37	BI	Trios M01	8			880
38	BT	877	12	56	52	
39	BT	979	8			4
40	BT	Giotto 85M	7	74	21	460
41	CF	227	12			
42	CK	115	12			
43	CK	215	12			
44	CO	188A7	12	55		
45	CO	190F	12	445	45	
46	CO	217A	12	301	35	210
47	CO	237A	12	182		2
48	CO	242A7	12	116	17	0
49	CO	331A	10	126	68	123
50	CO	333C7	12	103	189	1
51	CO	334A	12	108	156	134
52	CO	337A	11	68	108	33
53	CO	342A7	12	79	80	
54	CO	402B	11			292
55	CO	415A(V)	10			15
56	CP	439	7	49		66
57	CP	443	6			320
58	CP	444	4			1265
59	CP	445	7			745
60	CP	446	4			6

61	CP	447				4			81
62	CP	538				7			270
63	CP	539				7	31		915
64	CP	938				4			57
65	EA	1370				7			196
66	EA	3003				5	100		246
67	EA	6035				3	57		222
68	EA	6530				12	122		
69	EA	7034(V)				3			152
70	IM	uP 20				8			93
71	IM	uP 30				8	60	93	166
72	IM	uP 41				7	106	74	90
73	IM	uP 61				7		51	330
74	IM	uP 71				4	83	58	71
75	IN	223				12		10	
76	IN	227				12		20	5
77	IN	229-01				12			
78	IN	233-05				12	45	21	
79	IN	235-01				10			91
80	IN	251-02				11	13		3
81	IN	253-04				12		19	4
82	IN	253-05				12	50	28	24
83	IN	253-07				12	26	8	4
84	IN	253-09				12			33
85	IN	253-19				11			603
86	IN	253-23				9			707
87	IN	253-25				7			1304
88	IN	254-31				3		15	1141
89	IN	259-01(V)				12			
90	IN	281-05				7	60	18	774
91	IN	283-01(V)				10			414
92	IN	284-05				6			1438
93	IN	294-03				4		16	1148
94	MC	403				12		40	
95	MD	5923				12			169
96	MD	5925				12			
97	MD	5927				12			
98	MD	5941				12			2919
99	MD	5966				10			0
100	MD	5967				12			298
101	MD	5983				12			21
102	MD	5985				12			1484
103	MD	5995				12			
104	MD	8320				7			37
105	MD	8329				7			501
106	MD	8330				4			776
107	MD	8331				5			1454
108	MD	8340				5			1253
109	MD	8341				5			2061
110	MD	8412				6		26	130
111	MD	8413				6		14	394
112	MD	8416				5			433
113	MD	8419				4			1068
114	MD	8420				10	21		309
115	MD	8423				12			3044
116	MD	8424				3		13	1232
117	MD	8426				2		14	29
118	MD	8437				9			731
119	MD	5940LP				10			332
120	MD	5984LP				11			86
121	MD	5989L				12			16
122	MD	7000A(V)				12			22

Results

123	MD	7005C	10		8	382
124	MD	7006(V)	10			128
125	MD	7027(V)	5	83		121
126	MD	7071(V)	6	58	38	129
127	MD	7071M(V)	4	36		282
128	MD	7075(V)	4		11	276
129	MD	7077(V)	4		10	1060
130	MD	7084(V)	2	25	13	162
131	MD	7085(V)	2			47
132	MD	7100(V)	?			
133	MD	7107(V)	2	51	33	178
134	MD	7108(V)	3			1906
135	MD	8341M	5	41		1896
136	MD	8423M	4		13	650
137	MD	SP1010	9			29
138	OS	Acculith 100	7	61	33	76
139	OS	Acculith 102	9	73	31	101
140	OS	Acculith 104	9		21	104
141	OS	Acculith 3	12		113	221
142	OS	Acculith 51	12	37	76	65
143	OS	Acculith 52	12		73	314
144	OS	VITACOR	1	59	44	44
145	OS	VITACOR-E	1	54	155	74
146	PA	2008T	4			551
147	PA	2016T(V)	4			3059
148	PA	2022T(V)	3			1346
149	PA	225-6	12			
150	PA	241-6	10		38	1473
151	PA	AFP	11	35	34	29
152	PA	GENISIS 285K(V)	8			1303
153	PA	GENISIS(V)	8		18	
154	PA	PHOENIX	5			
155	PL	FP 05	10		38	13
156	PL	S 01	10	10	158	4
157	SO	610/A	10	103	20	30
158	SO	630/A	12	83	21	19
159	SO	LIT216	12			
160	SO	LIT222	12			
161	SO	ORION 30/A	10			532
162	SO	ORION 35	6			387
163	SO	Swing 100B	3			22
164	SP	629	12			378
165	SP	657	12	35	14	
166	SP	659	12			10
167	SP	668	12			688
168	SP	669	12			131
169	SP	674	12			22
170	SP	678	12			140
171	SP	686	11			1716
172	SP	689	9			336
173	SP	698	9			371
174	SP	718	11			290
175	SP	748	8		48	1476
176	SP	2033T	5			823
177	SP	2034K	5			810
178	SP	2037K	5	55		2174
179	SP	2037T	5			
180	SP	2038K	4			1461
181	SP	2040T	2			1151
182	SP	2049K	3			878
183	SP	608K	4			172
184	SP	658K	4		15	

185	SP	658M	4			610
186	SP	703S	7	69		380
187	SP	748k	8		28	1476
188	SP	MP688	11			1344
189	TE	158	9			1139
190	TE	161	12			
191	TE	174	12			681
192	TE	1202	7			366
193	TE	1204	4			198
194	TE	1206	1			165
195	TE	1210	1			
196	TE	1254	1			154
197	TE	8218	2			607
198	TE	8230	4			932
199	TE	1250H	1			27
200	TE	1256(A)	1	57		
201	TE	1256D	1			
202	TE	158B	8			395
203	TE	158C	7			398
204	TE	5281 A	9			161
205	TE	5281 C	6			144
206	TE	6291(V)	6			72
207	TE	8222(V)	4			186
208	TE	8224(V)	3			418
209	TE	9221(V)	5			435
210	TR	LCP201	?			
211	TR	MCP 201	?			
212	VI	Ceryx 111	7			101
213	VI	Ceryx 121	7	86	34	905
214	VI	Ceryx 123	5	88	23	267
215	VI	Ceryx 311	7	45		242
216	VI	Ceryx 321	7	68	23	2047
217	VI	Ceryx 323	5	61	75	2523
218	VI	Ceryx 323p	2	101	12	
219	VI	Ceryx 611	11	33		337
220	VI	Ceryx 614	9	46		19
221	VI	Ceryx 621	7	66	40	621
222	VI	Ceryx 623	5	81	41	623
223	VI	Ceryx 623p	2	101	36	
224	VI	Diamond 800(V)	1			170
225	VI	Finesse 201p	2	99	18	1675
226	VI	Onyx 101	8			416
227	VI	P4122	12			609
228	VI	PRIMO 205	2	78	15	295
229	VI	Quintech 911	11	67		88
230	VI	Quintech 915	9	188		188
231	VI	Topaz 515	2		46	525
231	20					111.811

**Table II: Results of Measurements
(By Model of Pacemaker)**

(Age = maximum age of the model; AL = Alpha; BI = Biotronik; BT = Biotec; CF = Cardiofrance; CK = Cook; CO = Cordis; CP = Cardiac Pacemakers; Dc = maximum interference distance in mm with measured 2W transmitting power, C-net; Dd = maximum interference distance in mm with calculated 2W transmitting power, D-net; EA = L'Electronic Appliquee; IM = Implantronik; IN = Intermedics; MC = Medcor/Haig; MFC = manufacturer's code (see Table IV); MD = Medtronic; OS = Osypka; PA = Pacesetter; Patients = estimated no. Of patients living with the model at the end of 1994 in Germany; PL = Pacelab; SO = Sorin; SP = Siemens-Pacesetter; TE = Teletronics; TR = TuR Transformatoren & Röntgenwerk; VI = Vitatron.)

Results

No.	MFC	Model	Age	Dc	Dd	Patients
50	CO	333C7	12	103	189	1
156	PL	S 01	10	10	158	4
51	CO	334A	12	108	156	134
145	OS	VITACOR-E	1	54	155	74
141	OS	Acculith 3	12		113	221
52	CO	337A	11	68	108	33
11	BI	Diplos M05	6	33	104	525
71	IM	uP 30	8	60	93	166
9	BI	Diplos 04(V)	11	86	85	1
53	CO	342A7	12	79	80	
142	OS	Acculith 51	12	37	76	65
217	VI	Ceryx 323	5	61	75	2523
72	IM	uP 41	7	106	74	90
143	OS	Acculith 52	12		73	314
49	CO	331A	10	126	68	123
2	AL	20	12	81	59	
74	IM	uP 71	4	83	58	71
38	BT	877	12	56	52	
73	IM	uP 61	7		51	330
175	SP	748	8		48	1476
231	VI	Topaz 515	2		46	525
45	CO	190F	12	445	45	
15	BI	Kalos 04	10		45	920
144	OS	VITACOR	1	59	44	44
222	VI	Ceryx 623	5	81	41	623
221	VI	Ceryx 621	7	66	40	621
94	MC	403	12		40	
126	MD	7071(V)	6	58	38	129
150	PA	241-6	10		38	1473
155	PL	FP 05	10		38	13
223	VI	Ceryx 623p	2	101	36	
46	CO	217A	12	301	35	210
213	VI	Ceryx 121	7	86	34	905
151	PA	AFP	11	35	34	29
138	OS	Acculith 100	7	61	33	76
133	MD	7107(V)	2	51	33	178
139	OS	Acculith 102	9	73	31	101
25	BI	Nanos 01	5		29	2731
82	IN	253-05	12	50	28	24
6	AL	35	12		28	
187	SP	748k	8		28	1476
110	MD	8412	6		26	130
214	VI	Ceryx 123	5	88	23	267
216	VI	Ceryx 321	7	68	23	2047
16	BI	Kalos 05	5	29	22	492
158	SO	630/A	12	83	21	19
40	BT	Giotto 85M	7	74	21	460
78	IN	233-05	12	45	21	
140	OS	Acculith 104	9		21	104
157	SO	610/A	10	103	20	30
22	BI	Leukos 03-1	12	75	20	4
76	IN	227	12		20	5
81	IN	253-04	12		19	4
225	VI	Finesse 201p	2	99	18	1675
14	BI	Kalos 03-2	12	86	18	31
17	BI	Leios 03	12	81	18	

90	IN	281-05	7	60	18	774
153	PA	GENISIS(V)	8		18	
48	CO	242A7	12	116	17	0
4	AL	24	12		17	5
93	IN	294-03	4		16	1148
228	VI	PRIMO 205	2	78	15	295
88	IN	254-31	3		15	1141
184	SP	658K	4		15	
165	SP	657	12	35	14	
111	MD	8413	6		14	394
117	MD	8426	2		14	29
13	BI	Kalos 03-1	12	81	13	
130	MD	7084(V)	2	25	13	162
5	AL	25	11		13	19
24	BI	Mikros 02	8		13	1027
29	BI	Neos LP01	7		13	505
116	MD	8424	3		13	1232
136	MD	8423M	4		13	650
218	VI	Ceryx 323p	2	101	12	
128	MD	7075(V)	4		11	276
1	AL	11	12		10	8
75	IN	223	12		10	
129	MD	7077(V)	4		10	1060
230	VI	Quintech 915	9	188		188
47	CO	237A	12	182		2
68	EA	6530	12	122		
66	EA	3003	5	100		246
10	BI	Diplos 05	11	91		325
125	MD	7027(V)	5	83		121
186	SP	703S	7	69		380
229	VI	Quintech 911	11	67		88
67	EA	6035	3	57		222
200	TE	1256(A)	1	57		
44	CO	188A7	12	55		
178	SP	2037K	5	55		2174
56	CP	439	7	49		66
8	AL	RDP3	11	48		6
220	VI	Ceryx 614	9	46		19
215	VI	Ceryx 311	7	45		242
7	AL	RDP2	12	43		
135	MD	8341M	5	41		1896
127	MD	7071M(V)	4	36		282
219	VI	Ceryx 611	11	33		337
63	CP	539	7	31		915
83	IN	253-07	12	26		4
114	MD	8420	10	21		309
80	IN	251-02	11	13		3
103	17					38016

**Table III: Results of Measurements
(Maximum Interference Distance)**

(AL = Alpha; BI = Biotronik; BT = Biotec; CF = Cardiofrance;
CK = Cook; CO = Cordis; CP = Cardiac Pacemakers; EA = L'Electronic
Appliquee; IM = Implantronik; IN = Intermedics; MC = Medcor/Haig;
MD = Medtronic; OS = Osypka; PA = Pacesetter; PL = Pacelab;
SO = Sorin; SP = Siemens-Pacesetter; TE = Teletronics; TR = TuR
Transformatoren & Röntgenwerk; VI = Vitatron. See Table III for
other abbreviations.)

Model	Distance/mm	Model	Distance/mm
5966	-	5967	-
8330	-	8331	-
8340	-	8341	-
8412	26	8413	14
7084	13	7085	-

Table IV: Sensitivity in Bipolar and Unipolar Units

Programmed Rate/min ⁻¹	Interference Duration/s	Interference Rate 1/min ⁻¹	Interference Rate 2/min ⁻¹
72	9.6	63	70
70	10.5	46	66
60	10.8	44	57

Table V: Interference Durations and Rates Due to C-Net

Rate 1 = no. of pm-pulses is related to interference duration;
Rate 2 = related to 1 minute.

103 models is interfered with either by C- or D-net. It is remarkable that the most sensitive pacemaker, with a maximum distance of 334 mm by interference of the C-net, ranges in the D-net with 45 mm only at place 22. On the other hand, the most susceptible D-net pacemaker – with an interference distance of 189 mm – was in the C-net, with 103 mm at place 9. Thirty-two pacemakers have been interfered by D-net, but not by C-net; conversely 24 pacemakers by C-net, but not by D-net (see Table III).

None of the mobile phones, even the portable 8-W C- and D-phones, could permanently affect pacemakers. Therefore, mobile phones cannot, as is sometimes argued, change the program of pacemakers.

3.5 Lead Configuration and Mobile Phones

It has been argued that bipolar pacemakers would be resistant to mobile phone interference⁶. One can make physically plausible that a co-axial lead shields the inner conductor, and that the current injected at the tip electrode is completely attenuated along the 60-cm conductor so that the different conductor has the potential zero at its generator input. The outer conductor, how-

	all		1 - 6 years*		7 - 12 years**	
Tested pacemakers	231		83		148	
Corr. patient numbers**	111,811		55,877		55,934	
	SM	Pat	SM	Pat	SM	Pat
1. By C-phone alone	10.4 %	7.0 %	8.4 %	8.8 %	11.5 %	5.2 %
2. By C-phone alone	15.2 %	15.4 %	14.5 %	16.7 %	13.5 %	14.1 %
3. By C + D phone	20.4 %	11.6 %	18.1 %	12.6 %	21.6 %	10.6 %
4. Sum 1 + 3	30.7 %	18.6 %	26.5 %	21.5 %	33.1 %	15.8 %
5. Sum 2 + 3	34.2 %	27.0 %	32.5 %	29.3 %	35.1 %	24.8 %

Table VI: Breakdown of Interference Samples

* of function time estimated

** of living patients with these models estimated

ever, acts as antenna with respect to the can. This means that bipolar systems with differential input stage (programmable lead configuration) must be similarly sensitive as unipolar ones, if the sensitivity is the same. As bipolar systems are usually more sensitive, they should be more affected by mobile phone interference according to our hypothesis.

As we investigated 44 Medtronic (Medtronic Inc., Minneapolis, MN, USA) models with five couples of bipolar (even number) and unipolar (subsequent uneven number) models, it was easy to demonstrate the correctness of our physical plausibility: 5 (18.5%) out of 27 unipolar systems; whereas 4 (23.5%) out of 17 bipolar units were susceptible. Table IV demonstrates, moreover, that two bipolar units out of five couples were more sensitive than the

corresponding unipolar units. With equation A3, one can calculate that model 8413 needs 5 W, instead of 2 W in model 8412, to be interfered in 26-mm distance. Both models 8412 and 8413 were programmed to and possessed the same sensing threshold of 2.5 mV.

4 Discussion

4.1 Risks for Pacemaker Patients by Mobile Phones

E-Net

As already mentioned, no pacemaker was influenced by mobile phones of the E-net, either during call organization or during normal operation including DTX mode.

C-Net

With devices of the C-net, an asynchronous pacemaker occasionally showed up to five prolonged intervals between two stimulation pulses during call organization (Fig. 6). Depending upon the period of the pacemaker and the refractory period, pauses up to 2.5 times the period can arise. Calculations demonstrate that in the most unfavourable case, the rate can be decreased down to 44 min^{-1} over a period of up to 10.8 seconds (Table V). If the rate is not related to the duration of interference, but, as usually in medicine, to 1 minute, the rate is decreased by not more than 5 ppm.

An inhibited pacemaker was not influenced by this phenomenon. Therefore, interference of pacemakers by C-net is possible, but not worth mentioning as was demonstrated by 24-hours ECG. Bethge et al.¹⁵ found, for example, that intervals were prolonged by muscle signals up to 3 seconds, without being noticed by the patient.

D-Net

Interference of pacemakers by D-net mobile phone was possible during call organization or in the DTX mode (the user is listening, the pulse frequency is reduced from 217 to 8 Hz with 2 Hz superimposed). The prerequisite for a risk of a pacemaker patient is, besides being pacemaker dependent, that he or she brings a handy closer than 20 cm to the pacemaker system and is only listening. In this case, dizziness or syncope is possible.

4.2 Risk and Safe Distance

No pacemaker tested could be interfered above 20 cm by handies with a maximum transmitting power of 2 W in the D-net (Table III). From this it follows for pacemaker patients that they are out of the interference region of handies, if the distance between antenna and pacemaker is $> 20 \text{ cm}$. A corresponding safety distance for portable D-net devices would be approximately 40 cm.

4.3 Number of Pacemaker Models and Patients Interfered by Mobile Phone

To avoid distortion of the figure of interference, our results were weighed by introducing the



Most of the mobile phones interfered during the trial were no longer interfered at a distance of at least 10 cm between pacemaker and mobile phone. Prof. Irnich is showing such a distance which does not allow neither to dial nor to speak on the mobile phone.

probability of how many patients are still alive with this specific model (see last column in Tables II and III). This data was derived from the corresponding implantation numbers multiplied with the survival rate (as a function of patient gender and age). For instance: a male patient receiving a pacemaker in 1985 at age of 73 years (mean age) has a probability of survival in 1995 of 0.18. Thus, this patient's probability is summed up with that of the patients with the same model, provided that its service life is > 10 years. This weighing procedure allows for judging how often interference probability in patients really exists.

Table VI shows how the C- and D-net differ in interference. The following difference is interesting: 10.4% of the tested pacemakers were interfered only by C-net; and 13.9% only by D-net devices. Most of all susceptible pacemakers (20.4%), however, were interfered by C-net and by D-net as well. Lines 4 and 5 and the first column of Table VI show, respectively, how many pacemakers are interfered with, either by C-net or D-net. 30.7% of the tested pacemakers are interfered by C-net, corresponding to 18.6% of the patients, and 34.2% of the pacemakers are interfered by D-net, corresponding to 27% of the patients.

To answer the question whether the interference is dependent upon the age of the pacemakers, the whole sample was divided into "young" (1-6 years implantation period) and "old" samples (7 years and more). Table VI

shows the size of the sample and the numbers of patients represented by it, and the pacemakers being interfered by C- and D-net devices (expressed as percentage). One hundred forty-eight "old" as opposed to 83 "young" models demonstrate that our sample is mainly determined by "old" pacemakers. Again, to prevent distortion of the results caused by this unbalance in age, it is convenient to introduce the patients represented by the models. Under this viewpoint, both, "old" and "young" patient samples are of the same size (just 56,000). As shown in Table VI, the older types were more influenced, but the number of patients representing them is always smaller. Two conclusions can be drawn from this finding: (1) Older types of pacemakers are more susceptible to mobile phones than the newer types; and (2) the oldest of the "old types" were obviously the most sensitive. Thus, their influence on the numbers of patients was largely reduced due to long implantation times, thereby decreasing the percentage of the old sample below those of the young one.

Manufacturers have often made the statement that "those types would be obsolete". Our investigation shows that this statement cannot be interpreted as if new pacemakers behaved much better. As the immunity to interference of mobile phones is obviously no design criterion, the slight improvement in pacemaker numbers shown in Table VI might originate from the reduction in size of the pacemakers during the last 12 years.



If the mobile phone is used properly the distance between antenna and pacemaker immediately amounts to at least 20 cm, which means that pacemakers can no longer be interfered by the D-net.

4.4 Interference and Pacemaker Brands

A detailed analysis of the models and brands affected by D-net shows:

1. Six out of 20 brands are without affected pacemakers with 40 models altogether.
2. Most of the models of six further brands are unaffected.
3. Pacemakers of 11 brands were affected and unaffected.
4. All types of 3 from 20 manufacturers are affected.
5. Only 7 of 79 models are affected by 2-W handies in a distance between 10 and 20 cm, but 72 models between 1 and 10 cm are affected. If the output power is increased to 7 W

or more, only six additional pieces are affected, demonstrating that the borderline between susceptible and non-susceptible behaviour is rather stable.

6. The seven models with a maximum interference distance between 10 and 20 cm represent 990 patients, just 0.9% of all patients in Germany.

As described before, 6 out of 20 investigated brands were immune to D-net mobile phones, but only 3 of them (CF, CK, and TR) were also immune to C-net mobile phones. However, only one or two pacemaker models of these three brands could be investigated.

If all sensitive pacemakers in Tables II or III were eliminated in the past, no real disadvantage for the patients would have emerged. A broad range of all types of pacemakers can be found among the nonsusceptible models. The statement that improvement of interference behaviour means a reduction in pacemaker quality, as is sometimes indicated by manufacturers, proves to be wrong in the light of our results.

4.5 Advice for Doctor and Patient

As previously mentioned, a pacemaker patient is regarded as safe from interference by a handy if the distance is 20 cm or more. For a portable device, the safe distance is 40 cm or more. Therefore, the patient is reasonably safe, as this kind of interfering transmitter can be clearly identified unless

it is in the pocket of his neighbour. Is it necessary to prohibit the use of mobile phones from pacemaker patients? In our opinion, it is more meaningful to inform each patient whether or not his or her pacemaker is susceptible. More than two-thirds of all patients might use a mobile phone without any complications if carrying it at any site of the body. Ninety-nine percent would be undisturbed if the mobile phone was not positioned just over the pacemaker.

A doctor should be familiar with those types of pacemakers that were interfered by mobile phones of the D-net (see Table II). Even if this meant allowing certain patients but not others to use mobile phones, this would be the best way to solve the problem. Above all, the 0.9% of patients with an interference distance of 10 cm or more should know that they have to hold a handy only at their ears and not to the thorax, or they could change to a device of the C- or E-net.

We found that a shirt woven with fine metallic threads provides sufficient shielding so that even the shortest distance between device and implant is possible. Such garments are commercially available.

A step toward eliminating the problem would be if physicians asked for pacemakers non-susceptible to mobile phones. No manufacturer should have real difficulty in supplying such models today, thus guaranteeing in the future that all new productions would be state of the art.

4.6 Risk Assessment

If it is asked how often a risk really exists for pacemaker patients, an assessment has to be made, which is, by the way, very typical for any EMI risk estimation. There are several particular probabilities that form the global probability of a risk by multiplication. In Table VII, for instance, an estimation is given for D-net under the assumption that 27% of all pacemaker patients can be influenced. If the phone distance is between 10 and 20 cm the probability of being influenced is reduced to 0.9%. Furthermore, the probability of being pacemaker dependent so that pacemaker inhibition by mobile phone can pose a problem is estimated at 37%. In Germany in 1995, the probability of owning a mobile phone of the D-net was about 3% (2.5 million users out of 80 million inhabitants). The probability that call organization and ringing phase will exceed 3 seconds is assumed to be 50%. Similarly, the probability of having the mobile phone antenna in parallel with the lead connector is estimated to 50% (as an angle between lead and antenna of 90° would yield no interference). As mobile phones are controlled in their transmitting power by the base station in relation to their distance, a reduction to 1 W or be-

low would reduce the probability of being influenced to 40% or less.

If pacemaker patients are taught not to carry their D-net phones just over the pacemaker, the global risk probability is:

$$0.9\% \cdot 37\% \cdot 3\% \cdot 50\% \cdot 50\% \cdot 40\% = 10 \cdot 10^{-6}$$

or exactly 1 out of 100,000 pacemaker patients (in Germany, about 2). If there were no instructions and no warnings at all, the global probability would increase to 3×10^{-4} or 1 out of 3,300 patients (60 patients in Germany are affected).

4.7 Comparison with Other Investigations

Table VIII, to our knowledge, lists all comparable investigations on mobile phones published. Most of them are abstracts, thus demonstrating that these are preliminary results. Joyner et al.³ reported that radiation of 25 W in a distance of 20 cm had no influence on implanted pacemakers. How many patients and which models were engaged was not reported. The EMI probability of the seven other publications⁴⁻¹⁰ reporting on patient investigation ranged from 0%-100%. The largest investiga-

	Portion of Patients Concerned
1. Mobile phone just over PM	27%
2. Mobile phone distance $10 \text{ cm} \leq d \leq 20 \text{ cm}$	0.9%
3. Patient pacemaker dependent	37%
4. Probability of using a mobile phone	3%
5. Probability of inhibition $> 3 \text{ s}$	50%
6. Probability of maximum coupling	50%
7. Probability of transmission power $\leq 1 \text{ W}$	40%

Table VII: Probability of Risk Due to D-Net

Authors	Year	Source	Result
Joyner et al. ⁴	1994	BEMS Abstract Book; 1-1-11	0 (25 W, 20 cm)
Hayes et al. ⁴	1995	PACE 18; Abstract 270	16/30 = 53,3%
Carillo et al. ⁵	1995	PACE 18; Abstract 269	21/59 = 35,6%
Wilke et al. ⁶	1995	Hertzschrittmacher 15; 72-74	2/50 = 4%
Barbaro et al. ⁷	1995	PACE 18; 1218-1224	26/101 = 25,7%
Naegeli et al. ⁸	1995	Eur Heart J 16; Abstract 100	7/39 = 18,0%
Aydin et al. ⁹	1995	Eur Heart J 16; Abstract 101	3/122 = 2,5%
Yesil et al. ¹⁰	1995	PACE 18; 1963	1/1 = 100%
Ehlers et al. ¹¹	1995	Eur Heart J 16; Abstract 99	79/231 = 34,2%
Moberg and Strandberg ²	1995	Eur JCPE 5; 146-157	0/3 = 0%

Table VIII: Preliminary Results: PM & GSM Mobile Phones

*in vitro results. Of 402 patients, 75 are influenced = 18,7%!

tion of Aydin et al.⁹ contained 122 patients with 39 different models of 9 manufacturers; only 2 models (3 patients) were interfered. Hayes et al.⁴ produced the highest interference rate with 16 (53,3%) out of 30 patients. These striking discrepancies in results can be explained in several ways:

1. The selection of brands and their models is decisive.
2. Coupling of EMF into the pacemaking system requires careful positioning of the antenna with respect to lead connector (proximity, angle, and antenna position, three degrees of freedom).
3. Some investigators programmed the pacemakers to the highest sensitivity, others left it as individually set.
4. Most patients will have the redundant lead conductor curled behind the metallic case of the pacemaker within the pocket so that the last 10-15 cm of the conductor are shielded. As the very last part of the lead only acts as antenna, the contribution of that portion of the lead > 15 cm is

damped away, the influencing voltage is largely reduced. We found that one curl may remarkably reduce interference as only 5% of the transmitting power (-13 dB) would be present (only 22% of the electric field). As most patients have such a curl normally in the shadow of the can, the probability of interference and the maximum interference distance will be reduced as compared with our experiments.

Combining all results with patients, we found 75 (18.7%) influenced pacemaker wearers out of 402. This figure is remarkably lower than our 27%, proving that our investigation is more pessimistic than optimistic. This makes our risk assessment still more reassuring.

The in vitro results of three groups^{2,11,12} are also diverging between 0% and 57.1%. These discrepancies are, however, easy to explain. Moberg and Strandberg² used just three modern models that equally proved to be nonsusceptible in our investigation. Their conclusion, that pacemakers are resistant to mobile phone interference, must be res-

tricted to their modern models investigated and cannot be generalized¹⁶. The results of Ehlers et al.¹¹ can simply be explained by the fact that the group investigated the pacemakers together with leads in air, thereby neglecting attenuation, reflection, and penetration depth of the conductive medium, which normally surrounds an implanted pacemaker.

Though our investigation may have produced unfavorable results, it does have its benefits, as it guarantees reproducible and equal conditions for all models tested for susceptibility, without endangering patients¹⁰. This test can easily be repeated by pacemaker manufacturers wishing to improve their products. We believe that only minor changes within the capsule of a pacemaker are necessary to render it nonsusceptible with respect to all sorts of mobile phones. Physicians should request for such resistance.

4.8 Concluding Remarks

Our results and the corresponding considerations allow for the following conclusions:

1. The analog system (C-net) or the digital GSM system (D-net) are capable of influencing up to 27% of all implanted pacemakers at the present time.
2. The only really endangered patients are those that use mobile phones of the digital GSM D-net at 900 MHz.
3. An influence of pacemakers by the digital, 1.8-GHz mobile phone system (E-net) was not found at all.

4. All affected pacemakers started into normal operation after interference ended. Their program was never altered.
5. Possible interference of pacemakers is excluded if the minimum distance between pacemaker and a 2-W handy is 20 cm, and 40 cm between pacemaker and a portable 8-W device.
6. Pacemakers are most sensitive if the digital mobile phone of the D-net is operating in the mode "call organization" or "DTX" (2-Hz switched mode).
7. The possibility of interference or influence is not dependent on the complexity and/or the quality of a pacemaker.
8. Bipolar pacemakers do not possess a higher protection against mobile phone interference than unipolar units.
9. A general warning to pacemaker patients about mobile phones is not expedient, as three-quarters of all patients are unaffected. Rather, the patients should be instructed, if they are wearing a pacemaker that can be interfered with, how they ought to handle such a situation.
10. There is no reason for panic. Pacemaker patients really suffering from digital mobile phones coming into the immediate vicinity of the pulse generator are very rare. Though rare, it would be beneficial if future generations of pacemakers were compatible with all mobile phone systems.

5 Appendix

5.1 Theoretical Considerations: The Distance-Power Relationship

If a linear log-log relationship of distance and power exists, as is indicated in Figure 4:

$$\log D = A + B \log P \quad (A1)$$

D = distance, P = power
 A = constant mainly influenced by pacemaker sensitivity
 B = constant characterizing the spread of the electromagnetic field,

one can derive:

$$D = C \cdot P^B \quad (A2)$$

C = constant determined by 10^A

The three straight lines in Figure 4 possess a slope B which was very close to one-third, with a high correlation coefficient of $r = 0.98$. Thus, if for a given power P_1 the distance is known D_1 , but another distance D_2 is requested for a known power P_2 , one can deduce from equation:

$$\frac{D_2}{D_1} = \left(\frac{P_2}{P_1}\right)^{1/3} \quad (A3)$$

D in equation A3 is the distance between surface of the pacemaker can and farthest point of interference. The results of Tables II and III for D-net were derived from Equation A3 by measuring D_1 with a transmitting power of 8 W and then calculating D_2 with 2 W assumed [$(P_2/P_1)^{1/3} = 0.63$].

5.2 The Distance-Sensitivity Relationship

If the power is kept constant, but the sensitivity is altered, the relation between distance and sensing threshold proved to be nicely linear in a log-log description, but now it has a negative slope of one-third ($r = 0.97$). Thus, a similar ratio to Equation 3 can be formulated:

$$\frac{D_2}{D_1} = \left(\frac{U_2}{U_1}\right)^{-1/3} \left(\frac{U_1}{U_2}\right)^{1/3} \quad (A4)$$

with U_1 and U_2 sensing thresholds of a programmable pacemaker.

Increasing the sensing threshold of a susceptible pacemaker by a factor of 2 will reduce the ratio of distance by $2^{-1/3} = 0.79$. Pacemakers with maximum interference distance of up to 18 mm in Table III can be rendered nonsusceptible (26 pieces), if the sensing threshold is elevated by a factor of 2. A factor of 3 would reduce the number of susceptible pacemakers from 79 (53%) to 42.

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