

Protection of persons in mobile radio electromag

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Introduction

The project, commissioned by the Federal Ministry of Economy and Labour [10], investigated whether persons with cardiac pacemakers and defibrillators are impaired by electromagnetic fields emitted by GSM mobile radio, DECT, UMTS, Power Line Communication and induced current radio systems. The aim of the study was to provide a preventive assessment of effects from electromagnetic interference with cardiac pacemakers and defibrillators, with special focus on the types of modulation used and accumulated field sources in the case of multiple use of sites. In a further step, the results, which were determined theoretically and in experiment, were verified via practical tests with volunteers.

This article will present the results on disturbing effects on cardiac pacemakers from GSM and UMTS mobile radio signals. As shown in figure 1, a “structured method” approach was used, based on the combination of two part models. The coupling model on the one hand implies the mechanism of the transformation of an electromagnetic field outside the body into an interfering voltage at the input of the implant. The compatibility model indicates the interfering voltage above which implant failures are to be expected. The combination of both part models allows for a qualified assessment of effects on implants in electromagnetic radio frequency fields. The structured method has been successfully used in several studies commissioned by the Forschungsgemeinschaft Funk for the investigation of this issue (see [6], [7], etc.).

The investigation of the coupling model is based on numerical simulations using the Finite Difference Time Domain Method. The compatibility model is deter-

with cardiac pacemakers netic fields

mined by immunity measurements. For this, different mobile radio interfering signals are produced by adequate RF sources and sent to the tested implant via a conductor.

Construction and functioning of cardiac pacemakers

A cardiac pacemaker is an implantable electric pulse generator establishing and maintaining a normal heart rate. The design of a cardiac pacemaker is shown in figure 2.

The pacemaker's electronics, consisting of a stimulator and an analyser part, are housed by a bio-compatible metal case together with a long-duration battery. Electric pulses are conducted to the heart for stimulation via one or several electrodes that are connected to the heart, and an existing heart signal (if so) is perceived.

Depending on the site of the stimulation, cardiac pacemakers can be subdivided into two main groups:

- single-channel pacemakers, which stimulate/sense only in the upper chamber (atrium) or the lower chamber (ventricle) of the heart, and
- multi-channel pacemakers, which stimulate/sense both in the atrium and the ventricle.

Furthermore, there is a difference between unipolar and bipolar pacemakers:

- Unipolar pacemakers use the pacemaker's case as one pole and the pacemaker's electrode as the antipole; thus, the stimulating current flows between two spatially separated points.
- Bipolar pacemakers generally use a coaxial electrode array, the stimulating current flowing only between internal and external conductor directly inside the heart. But modern models may also be operated in unipolar mode.

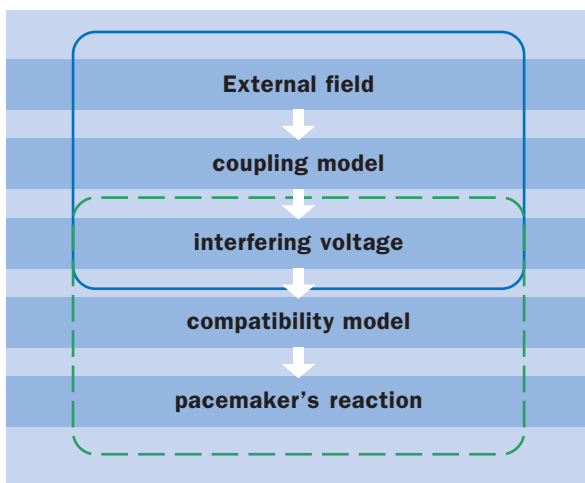


Figure 1: The combination of coupling model and compatibility model, and the significance of the interfering voltage at the input of the implant



Figure 2: Design of a cardiac pacemaker

State of standardization

The standard DIN EN 50061/A1 (VDE 0750 part 9/A1):1996-07 [2] for the protection of persons with active electronic implants is applicable until September 2005. However, since it is not harmonized, DIN EN 50061/A1 is not mandatory for pacemaker manufacturers. It covers only a limited frequency range of 20 Hz to 30 MHz. Moreover, the central immunity requirements are optional, i.e. if they are not complied with, it is sufficient to indicate this in the manual.

The standard EN 45502-2-1:2003-09 was adopted in September 2003 on the European level [4]. It replaces standard DIN EN 50061/A1, and the central immunity requirements cannot be evaded anymore. This European standard includes interference thresholds for the static magnetic field (as the only external field for securing the functioning of Reed contacts inside the pacemaker!), as well as device-related interference thresholds for the voltage produced at the interface (pacemaker input) in the frequency range between 16 Hz and 450 MHz. For immunity testing, interfering voltages are applied via RC networks at

the pacemaker's input, i.e. there is no discernible relation to the fields affecting the pacemaker's bearer from the outside. For the frequency range of 450 MHz to 3 GHz, the standard refers to the American standard ANSI/AAMI PC69 [1]. The ANSI standard requires irradiation immunity measurements for this frequency range, the pacemaker being exposed inside a fluid-filled phantom to the electromagnetic field of a dipole, similar to the real implant situation.

The draft German standard E DIN VDE 0848-3-1 (VDE 0848 part 3-1):2002-05 [3] shall close existing gaps in the safety of persons at exposure to electric, magnetic and electromagnetic fields. By distinguishing coupling and immunity, both aspects can be considered independently. The draft standard therefore includes conversion methods describing the relationship between the open circuit voltage induced at an implanted electrode and the external fields by which it is produced. The devices themselves are therefore classified into 3 interfering voltage immunity levels:

- Devices of adequate immunity whose bearers are without risk at sites of unlimited public access and at sites where there are no signs indicating a

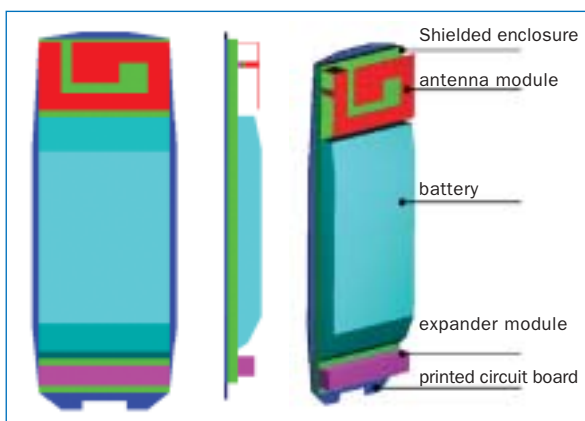


Figure 3: Applied mobile phone with integrated antenna for GSM 900

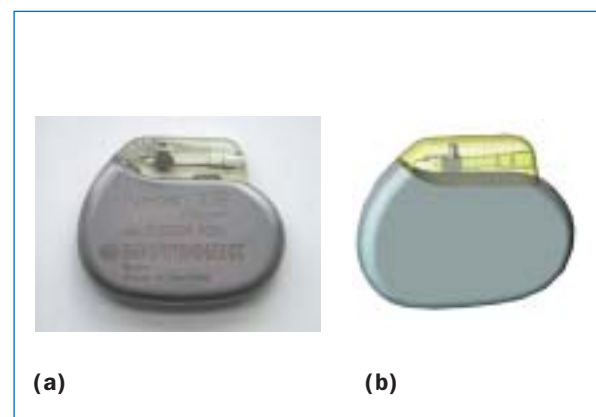


Figure 4: Modern unipolar pacemaker (a) and simulation model (b)

local or short-term exceeding of reference values according to 1999/519/EC [11].

- Devices of limited immunity whose bearers have to heed certain warnings and announcements addressing cardiac pacemaker bearers.
- Devices that are susceptible to interference; their safety can be ensured only by individual case measures.

Based on this classification, the safety in EMF of a precisely defined group of cardiac pacemaker bearers could be ensured in future. However, it is a prerequisite that cardiac pacemaker manufacturers label their devices according to their immunity level. Furthermore, EMF generators would have to indicate the areas where field strengths determining classification are exceeded.

For taking decisions on the professional assignment of cardiac pacemaker bearers to EMF workplaces, it is imperative to keep in mind that the classification as „devices of adequate immunity“ is only valid for field strengths below the reference values of the EU Council recommendation 1999/519/EC. The field strengths set forth in this recommendation can be

distinctly exceeded at workplaces; thus in these cases there has always to be carried out an individual case evaluation.

The publication of the draft E DIN VDE 0848-3-1 (VDE 0848 part 3-1):2002-05 elicited a flood of still unresolved objections. Cardiac pacemaker manufacturers reject mandatory labelling indicating immunity levels, and many EMF generators reject the obligatory labelling in cases where reference values of the EU Council recommendation are exceeded.

Germany presented the standard 0848-3-1 to the then TC 211 of CENELEC as a new standards project. As the required number of member countries interested in cooperation did not come forth, work on this project was stopped.

In 2004, a New Work Item Proposal on the issue of active implants was presented to CENELEC. This proposal is pursued further and dealt with by TC106X, the successor of TC 211.

Numerical study of the coupling model

The coupling model describes the relationship between electromagnetic fields emitted by a field source

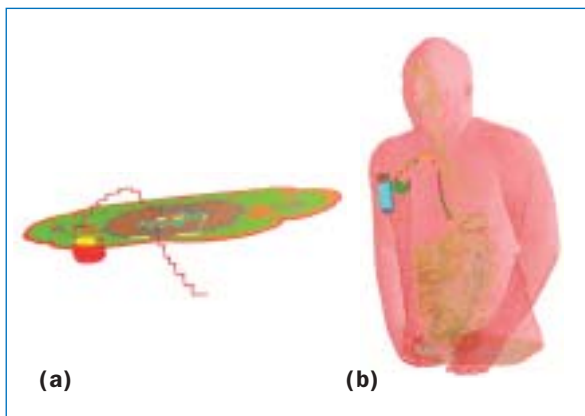


Figure 5: Position of the cardiac pacemaker inside the body model with right-side pectoral implantation. Transversal view of the body model (a), and view with transparent body surface and mobile phone positioned in the area of the breast (b).

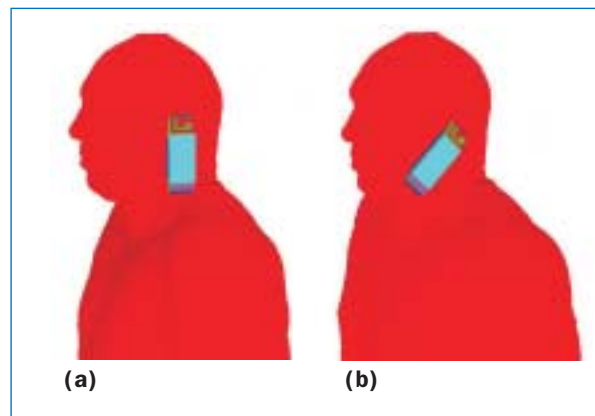


Figure 6: Position of the mobile phone at the left side of the head; vertical orientation (a) and realistic phone position (b).

	Current simulations	
Body model	inhomogeneous, anatomical body model (AFRL) with 40 different tissue typeslayered	human body model with skin, fat and muscle tissue
Cardiac pace-maker (CPM) model	detailed model, based on a commercial model	simple CPM model
Implantation	right-side pectoral, based on the anatomical details of the body model	plane position of the CPM and the electrode inside the layered body model
Field source in the near field	model of a mobile phone with integrated antenna	dipole

Table 1: Differences between simulation models [6]

(e.g. a mobile end device) and the interfering voltage at the pacemaker’s input, based on a realistic implant situation. The following exposure scenarios are considered:

- end device at different distances from the breast,
- end device in phoning position (held to the right or left ear),
- exposure in the far field of a base station antenna.

Model design

The end device model is based on a mobile phone with integrated antenna. Figure 3 shows the applied mobile phone platform with the antenna for GSM 900. For GSM 1800 and UMTS modified antennas, adjusted for the frequency range, are used.

Figure 4 shows the photograph of the modelled unipolar pacemaker and the corresponding simulation model. The metal case with the dielectric header is seen. The connector for a unipolar electrode is located inside the header. The pacemaker case is modelled as an ideally conductive volume. The pacemaker is inserted in the right-side pectoral implantation manner into the body model of the U.S. Air Force

Research Laboratory [9] to examine the coupling model. The model is based on the Visible Human Data Set and has a spatial resolution of 1 mm. It distinguishes approx. 40 different tissue types. The dielectric properties of the biological tissue are determined through the parametric model of Gabriel [5], which is applicable in the frequency range between 10 Hz and 100 GHz. Implantation depth of the pacemaker is 5 mm; figure 5 shows views of the pacemaker integrated into the body model.

The mobile phone is positioned parallel to the pacemaker in front of the breast, as is seen in figure 5b. This leads to a minimum distance of 5.5 cm between pacemaker case and mobile phone.

Figure 6 shows the positioning of the mobile phone close to the head. Two configurations are examined: (a) The phone axis is parallel to the body axis. (b) The phone has a realistic phoning position.

Results

The results for the exposure scenario „mobile phone positioned in front of the breast“ for the frequencies 900 MHz, 1750 MHz and 1950 MHz are depicted in

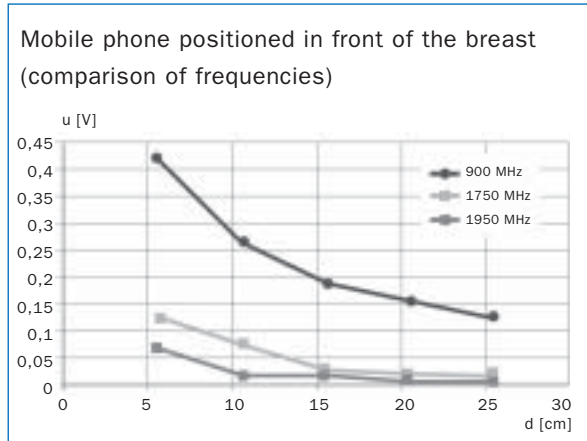


Figure 7: Graphic depiction of the interfering voltage (amplitude) for different distances and frequencies between pacemaker case and mobile phone positioned in front of the breast (P = 1 W).

figure 7. It is seen clearly that the interfering voltage for 900 MHz is higher by more than 10 dB than for the other two frequencies.

These results shall be discussed in more detail against the backdrop of results found in literature [6]. The evaluation of results must consider the essential differences between the setup examined in [6] and the configuration examined here. These differences are summed up in table 1.

Figure 8 shows for near field exposure that current simulation results, when using a detailed body model, all the same are in the same order of magnitude as the results in [6], where a simplified layered model of the human body was applied. But figure 8 also shows the variation in interference to be expected due to the varying distances between field source and cardiac pacemaker, the implantation manner and the type of field source.

Figure 9 lists the results for the scenario “Mobile phone positioned at the ear” for the frequencies 900 MHz, 1750 MHz and 1950 MHz. It becomes clear that the maximum interfering voltages are more than 20 dB below the ones for the exposure scenario „Mo-

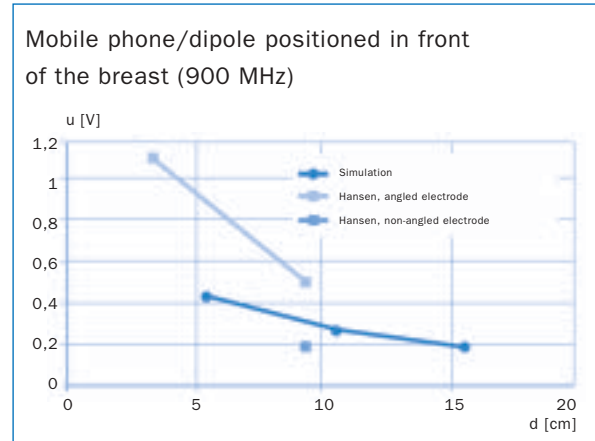


Figure 8: Comparison of interfering voltages determined for different distances between pacemaker case and mobile phone positioned in front of the breast with the results in [6] for a frequency of 900 MHz.

bile phone positioned in front of the breast“. If the radiation source is far away from the pacemaker, like e.g. with a base station, environmental influences can be neglected and, for simplification, a homogeneous plane wave can be assumed for the purpose of describing spatial field distribution. Figure 10 graphically depicts the results of calculations with a horizontally and a vertically oriented homogeneous plane wave of an amplitude $E = 1 \text{ V/m}$. It shows again that the highest interfering voltages occur in the 900 MHz frequency range.

Immunity measurements

Conduction-related measurements are performed for 88 explanted pacemakers without altering the preset sensitivity. With regard to their introduction to the market, the devices covered the years 1980 to 2003. 5 pacemakers are programmed bipolar, the rest is operated with unipolar sensing.

Interfering signals

The pulsed RF carriers shown in figure 11 are defined as interfering signals for the two GSM variants at

900 MHz and 1800 MHz. Pulse length of the bursts is 550 ms.

The envelope depicted in figure 11a occurs at an active speech connection between mobile unit and base station and is defined as GSM interfering signal 1.

During lulls in conversation the mobile unit resp. the base station can transmit in the DTX mode. In order to save energy and minimize interference, the respective transmitter is off over longer time periods. This DTX signal is defined as GSM interfering signal 2 and shown in figure 11b.

Notably, GSM base stations transmit at maximum power in the first channel and in all eight time slots. The first two time slots are reserved for signalling, time slots three to eight can be allocated to connections to a mobile unit. If there is no connection to a mobile unit, dummy bursts are transmitted. This leads to the GSM interfering signal 3 depicted in figure 11c.

Besides the aforementioned GSM signals, which mainly occur during speech connections, there are special GSM data signals, such as HSCSD (High Speed Circuit Switched Data) or GPRS (General Packet Radio

Services). HSCSD or GPRS compatible end devices and mobile radio networks are needed for this.

HSCSD allows the allocation of several time slots for higher data rates. This can be done separately for uplink and downlink. As an example of such signals the GSM interfering signal 4 is depicted in figure 11d.

Two QPSK modulated interfering signals are defined for UMTS, whose envelope is shown in figure 12. The UMTS interfering signal 1 is part of the UMTS test signal for the performance of bio-electromagnetic experiments proposed in [8]. The end device transmits at maximum power in an undersupplied area. The variation of levels by 3 dB shown in figure 12a is typical.

In addition, the UMTS interfering signal 2 is defined, whose repetition rate as a worst case lies in the range of the normal heart rate. The UMTS interfering signal 2 depicted in figure 12b has a period length of 700 ms; power varies by about 30 dB. This signal could occur in well-supplied areas with periodically arranged obstacles the mobile radio user moves between.

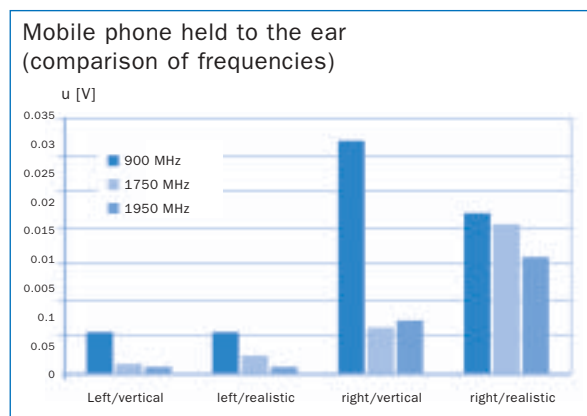


Figure 9: Graphic depiction of interfering voltages (amplitude) for different positions of the mobile phone at the right and the left ear of the user at 900 MHz, 1750 MHz and 1950 MHz (P = 1 W).

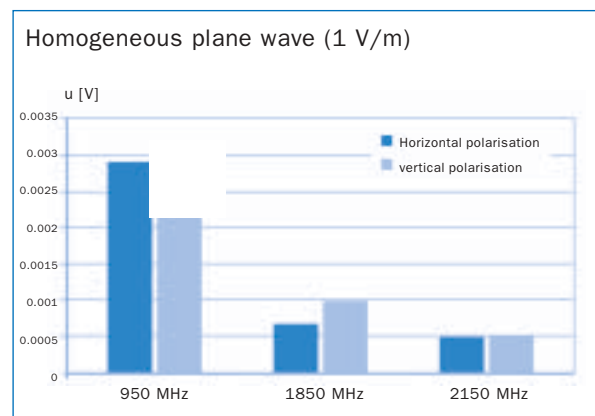


Figure 10: Graphic depiction of interfering voltages (amplitude) at frontal incidence of a homogeneous plane wave (HPW, E = 1 V/m).



Measurement setup

The measurement setup shown in figure 13a permits the input of conducted interfering signals of different mobile radio standards, also possibly of simulated heart signals, and allows the measurement of the pacemaker's behaviour under different conditions.

The measurement equipment consists of the following components:

- CPM with adapter to coaxial cable,
- ECG signal generator according to [4],
- interfering signal generation using an RF source and a modulation source,
- coupling network for the coupling of interfering signals and for the separation of pacemaker signals, interfering signals and ECG signals,
- devices for the processing and display of the separated signals,
- PC for the recording and evaluation of the signals using an appropriate software.

All devices are synchronized and linked to the PC via a bus system. This enables automation to a large extent allowing the efficient measurement of properties.

The block diagram of the measurement setup is shown in figure 13b. An amplitude shift keyed CW generator is applied for generating the GSM interfering signals. For UMTS interfering signals a vector signal generator is used, modulated by appropriate UMTS test signal sequences. For combined measurements, a preset UMTS signal is overlaid with a GSM interfering signal of variable amplitude.

Measurement procedure

Before and after the actual immunity measurements, a function test of the examined pacemaker takes place in order to determine potential device failures. Immunity measurements are conducted for the two cases "ECG signal present/not present"; the level of interference is changed each time by 1 dB steps. The measurement is completed as soon as a disturbance of the pacemaker is detected, or the maximum interference level is reached without the appearance of effects.

A pacemaker disturbance is defined for the two cases ECG signal present/not present:

- 1 ECG signal present

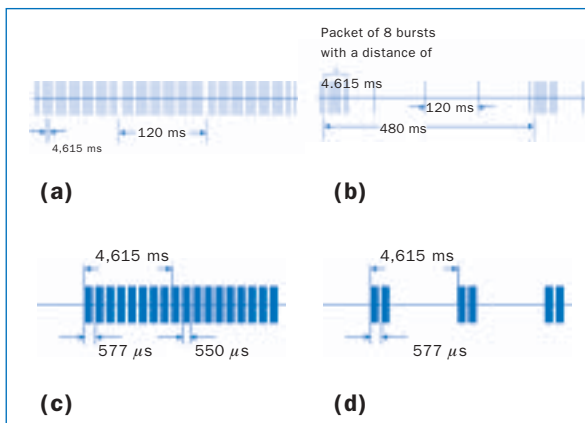


Figure 11: Schematic diagram of GSM interfering signals 1 to 4 as pulsed carriers

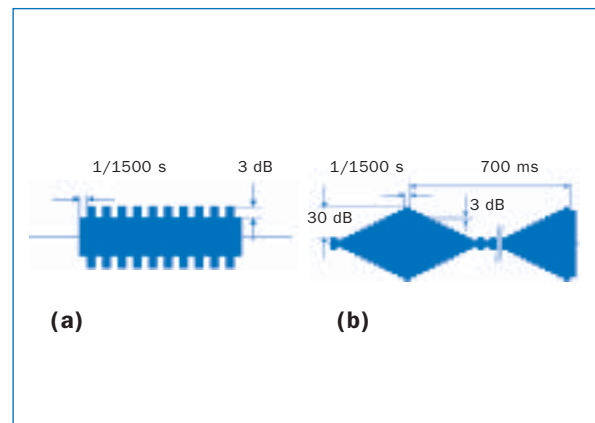


Figure 12: Schematic diagram of the UMTS interfering signal 1 (a) and UMTS interfering signal 2 (b) with fast power control

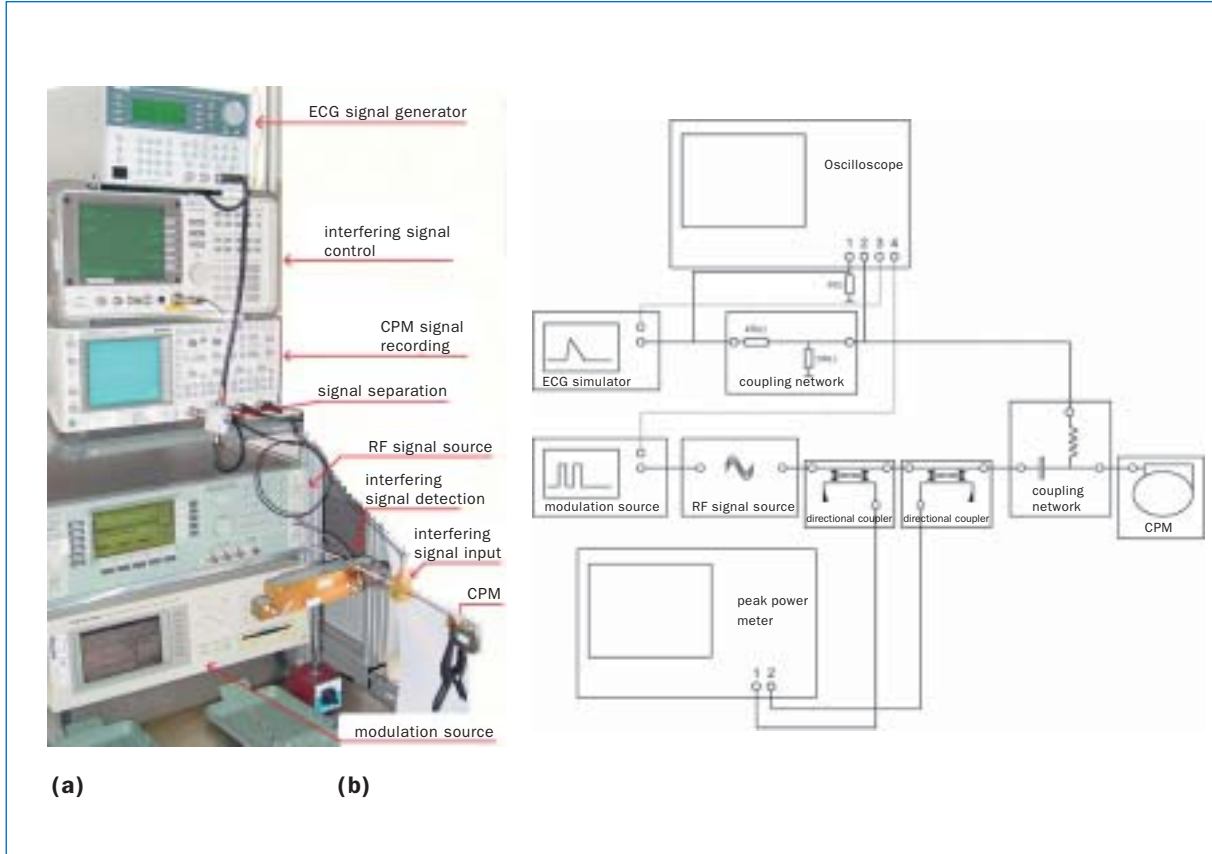


Figure 13: Measurement setup (a) and block diagram (b) for the determination of the influence of interfering signals on the CPM

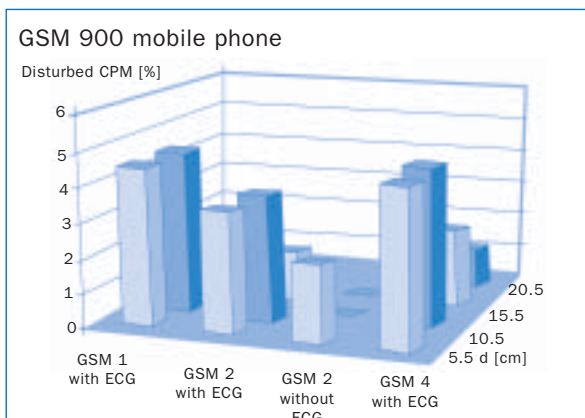


Figure 14: Disturbed cardiac pacemakers at exposure to a GSM 900 mobile phone positioned in front of the user's breast, as a function of the distance between pacemaker case and mobile phone, with the applied interfering signal as parameter.

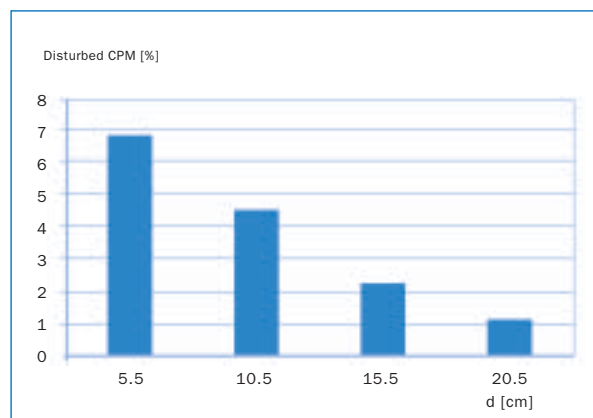



Figure 15: Disturbed cardiac pacemakers at exposure to a GSM 900 mobile phone positioned in front of the user's breast, as a function of the distance between pacemaker case and mobile phone.



In this case the pacemaker is disturbed, if there are one or several pulses emitted during the observation period in spite of the inhibiting pulses.

2 ECG signal not present

In this case the pacemaker is disturbed, when the regular detected pulse frequency deviates by more than 10% from the basic frequency of the cardiac pacemaker during the observation period.

Combination of coupling model and immunity measurements

Immunity measurement results will not be presented separately here. Instead, an overall evaluation also considering the results from the coupling model will follow.

It is shown that the 88 examined pacemakers, with the exception of GSM mobile phone exposure in the 900 MHz range, cannot be disturbed. Interference is particularly not expected from GSM 1800 and UMTS mobile phones. With regard to GSM and UMTS base stations, interference can generally be excluded when the 1999/519/EC reference values [11] for the general public are complied with.

An overlay of GSM and UMTS interfering signals does not result in a change of the pacemaker's interference behaviour. This means that potential disturbances are solely caused by GSM mobile phones at 900 MHz.

No disturbances are expected at exposure to GSM 900 mobile phones in a real phoning situation where the end device is positioned at the user's head, regardless of the side of the head to which the end device is held.

At exposure to GSM 900 mobile phones sporadic disturbances can occur, if the end device is positioned in front of the user's breast, on the side of the pacemaker. Figure 14 shows the devices that are interfered with in this case, as a function of the distance between pacemaker case and mobile phone, with the examined interfering signal as a parameter. All disturbed pacemakers are of older date and were commercially introduced at least 10 years ago. Fig-

ure 15 lists the pacemakers disturbed at exposure to a GSM 900 mobile phone – considering all GSM interfering signals – as a function of the distance between pacemaker and mobile phone. As was expected, the number of disturbed pacemakers decreases with increasing distance.

Volunteer tests

For the validation of performed simulations and conduction-related measurements, 8 volunteers with the pacemaker model Sorin Elect XS Plus are tested. The pacemaker was selected due to immunity measurements which showed this model to be susceptible. Moreover, it is a device from the manufacturer's current catalogue.

The test took place at the Internal Medicine Ward I of the Hospital Unstrut-Hainich-Kreis Krankenhaus, Mühlhausen. Pacemaker sensitivity is in all cases 2 mV and is, when necessary, reprogrammed prior to the test. Two pacemakers are programmed in unipolar, six in bipolar mode. Test results are determined via continuous 3-channel ECG recording. Applied mobile radio devices are the model G60 of Panasonic and U15 of Siemens. The devices are operated with the base station simulator CMU200 of Rohde & Schwarz, at maximum power, and are positioned directly in front of the volunteer's pacemaker during measurements. The GSM device G60 is operated at 900 MHz in channel 38, using the GSM interfering signals 1 and 2. The device U15 transmits in the UMTS mode in channel 9750. It is operated with the UMTS interfering signal 1 – the level varies by 2 dB due to the rapid power control – and a UMTS interfering signal without power control.

Pacemaker disturbances are shown to occur in 50% of the volunteers, when applying the GSM 900 mobile phone, whereas there are no disturbances for UMTS. With regard to GSM 900, disturbances occur both with bipolar and unipolar programming. Furthermore it can be observed that GSM 900 disturbances concentrate on stimulations in the presence of a natural ECG. In one case, however, disturbance occurred in



the form of missing stimulation when there was a pacemaker ECG. The disturbance vanished in all cases when the mobile phone was several centimetres removed from the pacemaker.

The disturbances observed in 50% of the tested volunteers show that the pacemaker is in a state between disturbed and undisturbed operation for the tested interference scenario. The interference behaviour then basically depends on physiological conditions, especially the pacemaker's implantation depth. The fact that the observed disturbances are mostly found in the GSM 900 mode and that there are no disturbances for the UMTS corresponds precisely with the results found in the coupling model and conduction-related immunity measurements.

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