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Research Report

Electromagnetic fields at workplaces:

Safety of workers wearing active and passive implants during exposure to electromagnetic fields

Legal information

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1 Introduction

On 26 June 2013, the European Parliament and the Council adopted Directive 2013/35/EU [4] on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields), repealing the original Directive 2004/40/EC [3]. Directive 2013/35/EU, commonly referred to as the EMF Directive, lays down minimum requirements for the safety and health of workers against risks arising from exposure to static and time-varying electric, magnetic and electromagnetic fields (EMF) with frequencies up to 300 GHz.

Directive 2013/35/EU requires employers to conduct an assessment of the risks posed by electric, magnetic and electromagnetic fields at workplaces and, if necessary, to take appropriate measures to eliminate or minimize such risks. Article 4(5)d of Directive 2013/35/EU explicitly requires that, in the course of determination of the exposure and assessment of the associated risk, special consideration to be given to workers who wear active implants such as pacemakers or defibrillators or passive implants such as implanted medical devices, or who wear medical devices on the body, such as insulin pumps. Article 5(4) of Directive 2013/35/EU states that measures to prevent or reduce risks shall, where applicable, be adapted to the needs of workers "*who have declared the use of active or passive implanted medical devices (. . .) or the use of medical devices worn on the body*".

However, Directive 2013/35/EU makes no further statements regarding the exposure levels at workplaces above which workers who wear active and passive implants are likely to be at risk.

Based on the current state of scientific knowledge, the present background paper concerning electromagnetic fields specifies threshold values for electromagnetic fields at workplaces. Compliance with these values ensure the safety and health of workers wearing active and passive implants, even under the least favourable exposure conditions. The provisions for passive implants are also applicable to other metallic/conductive foreign bodies embedded in body tissue.

Like Directive 2013/35/EU, this report addresses the exposure of workers to static and low-frequency electric and magnetic fields and to radiofrequency electromagnetic fields with frequencies up to 300 GHz. It gives particular consideration to possible interaction of static, low-frequency electric and magnetic fields and radiofrequency electromagnetic fields with passive implants, and to the impact of unintentional interference with the operation of active implants caused by static, low-frequency and radiofrequency electromagnetic fields.

2 Active and passive implants

The cardiac pacemaker is probably the best-known active implant. However, a wide variety of further active and passive implants have been developed and used for over 100 years which may also be of interest in connection with the subject matter to be discussed here. Therefore, it is advantageous to begin with an overview of the various implants and their function.

2.1 Passive implants

Historically, passive implants were the first type of implants to be used. They serve as a substitute for parts of the body that have been destroyed or damaged by illness or external influences, e.g. accidents, in full or in part, so that the mechanical function is restored as far as possible.

The main passive implants are:

- Endoprostheses (artificial hip, knee and shoulder joints)
- Splints and stabilizers, and nails and screws for bone fractures
- Stents
- Artificial heart valves
- Cranial Plates.

These implants continue to be manufactured primarily from metal (stainless steel, titanium, gold). Increasingly, plastics, ceramics or composite materials are being used that have been specially developed for this purpose and combine high mechanical strength with excellent compatibility with the tissue of the human body.

2.2 Active implants

Active implants, first developed and used in the 1950s, have their own energy source and monitor, support and/or replace body functions. The active implants most frequently used are cardiac pacemakers and defibrillators. However, a wide range of implants for other organ functions have been developed in recent years and are growing in significance.

In order of importance and frequency of use, the following functional principles are applied in active implants for monitoring, supporting and replacing body functions:

1. Electrical signals (pulses, e.g. from cardiac pacemakers), corresponding in their form and energy content to the body's natural intrinsic signals, control organs and muscles.
2. High-energy electrical pulses (e.g. from defibrillators) resynchronize the cardiac rhythm.
3. Electrical signals from acoustic or optical sensors partially replace the function of a sensory organ, such as the ear (cochlear implants, auditory brainstem implants) or eye (retina encoders).
4. Electrical signals (pulses, e.g. from neurostimulators) mask pathological intrinsic signals from the body, in order to render them ineffective.
5. Electronically controlled insulin pumps which inject insulin on demand can be implanted in diabetics or worn externally on the body.
6. Measurement and transmission of the body's intrinsic bioelectric signals, for example for diagnostic purposes and to control electromechanical prostheses.

At present, the prevalence of implantations in Germany is estimated as follows [6]:

- Over 100,000 cardiac pacemakers and defibrillators are implanted every year [18]. Of these, around 10% of implant recipients are aged significantly under 60. Owing to medical and technical progress and the associated expansion of the scope of applications of implants and their therapeutic uses, the age of first-time recipients of implants is continually decreasing.
- The next-largest group are wearers of electronic inner ear prostheses (cochlear implants), accounting for around 2,500 new implants per year.
- The number of patients fitted with electronic insulin pumps is in the same order of magnitude.
- Stimulators for the stomach, bowel, bladder and other organs, as well as neurostimulators, are implanted in much lower numbers.

3 Influence of electric, magnetic and electromagnetic fields on active and passive implants

3.1 Electric fields

The relationship between the external, disturbance-free electric field strength E_0 and the resulting electric field strength in the body tissue E_i is determined by the condition that the normal component of the displacement current at the surface boundary of the human body must remain steady [19, 20].

For a simple homogeneous ellipsoid model of the body, this is expressed by the following equation:

$$E_0 \cdot k \cdot \varepsilon_0 \cdot 2\pi \cdot f = \kappa \cdot E_i \qquad (3.1)$$

Where:

k field distortion factor; for human beings, $k \approx 13 \ldots 18$

ε_0 Dielectric constant of the free space (vacuum);

$$\varepsilon_0 = \frac{1}{\mu_0 \cdot c_0^2} \approx 8.854 \cdot 10^{-12} \frac{A^2 \cdot s^4}{kg \cdot m^3}$$

f Frequency of the field

κ (mean) conductivity of the body tissue(s)

In principle, Equation 3.1 continues to be valid for more natural and anatomically correct body models. However, the variables k and κ then become parametric functions.

3.1.1 Static electric fields

It follows directly from Equation 3.1 for static electric fields ($f = 0$) that the electric field strength in the body tissue E_i is constantly (almost) zero, irrespective of the electric field strength of the external static electric field E_0. The external static electric field breaks down completely at the surface of the human body; the interior of the body is (almost) field-free and thus shielded from any effect of the external static electric field. Therefore, external static electric fields cannot influence active implants or interact with passive implants.

In principle, this also holds true for medical devices worn on the body, such as insulin pumps, provided they are worn under clothing. In this case, the residual conductivity of the clothing, which is always present, is sufficient for effective shielding against the electric field.

Static electric fields can, however, give rise to discharge processes and associated electric shocks. These occur either when the person becomes charged within the external static electric field and is discharged by touching an earthed conductive object, or when the earthed person touches a conductive object charged by the external static electric field and thus discharges. Depending on the discharge currents and energies, the function of active implants may be affected. Further information can be found in Section 6.1.4.

3.1.2 Low-frequency electric fields

External low-frequency electric fields generate internal electric fields within the tissue. With reference to Equation 3.1, the relationship between the external and internal electric field strength can be expressed as follows:

$$E_i = \frac{k \cdot \varepsilon_0 \cdot 2\pi \cdot f}{\kappa} \cdot E_0 \qquad (3.2)$$

Since, in the low-frequency range, the term $k \cdot \varepsilon_0 \cdot 2\pi \cdot f$ is very small compared to the value of κ, a shielding effect for the interior of the human body with respect to the exterior remains. However, in contrast to static electric fields, this effect is not an (almost) complete shielding anymore.

Particularly in the case of power engineering frequencies with external electric field strengths of several kV/m, the electric field strength in the tissue is in the order of only a few mV/m. However, these electric field strengths within the tissue may be sufficient to interfere with the intended functioning of active implants such as cardiac pacemakers or defibrillators, or to interact unfavourably with passive implants.

3.2 Magnetic fields

Magnetic fields can only exert a physical force on electrical charges if these charges are moving. There are three physical effects of magnetic fields on biological tissue:

- Electrodynamic forces and magnetic induction
- Magnetomechanical effects
- Electron spin interaction.

The main effect of a magnetic field, the Lorentz force $\vec{F}$ on a point charge q moving at velocity $\vec{v}$, can be described by the following equation:

$$\vec{F} = q \cdot (\vec{v} \times \vec{B}) \qquad (3.3)$$

These forces give rise to charge displacements in biological tissue. They generate electrical potential differences and thus electric field strengths in the tissue of the human body. The relationship between the electric field strength and the magnetic flux density is described by Faraday's law of induction [19]:

$$\oint \vec{E} \cdot d\vec{l} = -\frac{d}{dt} \int \vec{B} \cdot d\vec{A} \qquad (3.4)$$

The left-hand side of Equation 3.4 is the line integral over a closed curve; the right-hand side is the time derivative of the surface integral of the normal component of the

magnetic induction. Equation 3.4 yields an average electric field over the geometric dimensions of the loop when the integral varies over time. For a loop with fixed dimensions, several scenarios are possible:

- The magnetic field itself varies over the time. This is the typical situation in many field studies in which a spatially homogeneous field is modulated, e.g. with a sine wave.
- By motion in a field with spatial changes, i.e. when a person moves within a field exhibiting strong spatial gradients.
- The relative orientation between the loop and the field vector is changed. This is the case when the loop rotates within a static field, i.e. a person changes their orientation relative to the field vector.

Spatial and temporal field gradients are therefore decisive and can amplify the induction effect. Irrespective of whether a person is stationary in a field that varies over time or is moving within a constant magnetic field. In both cases the effect is the same: An electric field is induced.

3.2.1 Static magnetic fields

Static magnetic fields penetrate the biological tissue of the human body without being significantly altered. They exert forces, particularly on ferromagnetic implants. Force effects on a conductive implant also occur when a person moves within a static magnetic field.

In addition, the functioning of magnetically actuated electrical switches in active implants, such as reed contacts or Hall effect switches, can be influenced by static magnetic fields.

3.2.2 Low-frequency magnetic fields

Low-frequency magnetic fields also penetrate the biological tissue of the human body without being significantly altered.

Magnetically actuated electrical switches in active implants, such as reed contacts or Hall effect switches, can also be influenced in their function by low-frequency magnetic fields with frequencies of up to several 10 Hz. Low-frequency magnetic fields also exert forces on conductive implants.

However, the main effect of low-frequency magnetic fields is the induction of electric field strengths as per Equation 3.4, both in the body tissue and in the implants themselves. This can directly or indirectly disrupt the functioning of active implants or cause temperature rises in conductive implants.

In addition, depending on the shape of the implant, local electric field strengths in the body tissue in the immediate vicinity of the implant may increase.

3.3 Radiofrequency electromagnetic fields

The direct effect of radiofrequency electromagnetic fields is that they penetrate the human body, and that energy is absorbed in the body tissue or in the material of the implant. Energy absorption causes a rise in temperature, which can increase the temperature of the body tissue or the implant.

If, for example, a passive implant warms up, the resulting expansion and subsequent cooling may, possibly only after several such cycles, cause the implant to lose its firm bond in the surrounding body tissue.

The penetration depth of the electromagnetic field into the biological tissue depends on the frequency and the body tissue's dielectric properties. The higher the frequency of the electromagnetic field and the dielectric constant of the tissue, the lower the penetration depth. With continuous-wave exposure to electromagnetic fields of several gigahertz, the penetration depth is already so low that undesired interaction with active and passive implants can be ruled out, provided the permissible values for occupational exposure are observed.

Modulated or pulsed radiofrequency electromagnetic fields require particular consideration. The low-frequency signal components of modulated or pulsed signals may be decoded in circuit-related non-linearities of active implants and, in the same way as the interference voltages of corresponding low-frequency field components, adversely affect intended functioning of the implant.

4 Risk assessment for persons wearing active implants

Current figures show cardiac pacemakers and defibrillators to be by far the most frequently implanted active implants [18]. The risk assessment below will therefore focus essentially on these two types of implant and develop a safety concept for persons who wear them. The same approach is applicable by analogy to other active implants.

Knowledge of the basic functions of these systems is required for an understanding of the potential risks to wearers of cardiac pacemakers and defibrillators when they are exposed to electromagnetic fields.

4.1 Cardiac pacemakers

4.1.1 Purpose of the cardiac pacemaker

In a healthy heart, the cardiac processes, i.e. contractions of the individual muscle groups, are controlled largely autonomously by the heart's intrinsic pacemaker, the sinoatrial node. Should the sinoatrial node be impaired or fail, for example as a result of a disease, this leads to cardiac arrhythmia and, in the worst case, to the death of the affected person.

For this type of heart disease, which ranges from an extremely low heart rate to a serious cardiac arrhythmia, implantation of a cardiac pacemaker has proved to be a suitable treatment. The number of cardiac pacemaker types is large, and each type can be adapted (programmed) over a wide range to the specific needs of the individual patient.

4.1.2 Design of the cardiac pacemaker

A cardiac pacemaker system consists of the pacemaker itself, which generates the electrical stimulation pulses, and one or more highly flexible, insulated leads connecting the pacemaker to the heart by means of electrodes at the end of a lead, which make galvanic contact to the body tissue. A distinction is drawn between unipolar and bipolar leads. Unipolar leads consist of a single conductor with one electrode located at the tip; bipolar leads consist of two separate conductors, which are insulated from each other and from the body tissue, and have two electrodes (tip and ring). The cardiac pacemaker is connected to the heart by one or more leads, depending on whether the heart is stimulated and/or the intracardiac ECG recorded only in a single chamber of the heart, or in multiple chambers (ventricle/atrium, one or both sides).

A cardiac pacemaker essentially comprises the following function groups:

- a programmable input amplifier
- a microprocessor system for analysing the received signals, controlling the pulse generator and storing data and events
- a pulse generator for generating the stimulation pulses
- a telemetry/programming unit
- a battery.

These function groups are enclosed in a titanium enclosure with connectors for the leads.

4.1.3 Function of the cardiac pacemaker

The main functions of a cardiac pacemaker are to monitor cardiac function and to deliver suitable electrical stimulation pulses on demand to ensure that the heart is functioning adequately as a pump. This "demand mode" of the cardiac pacemaker permits low energy consumption and in turn savings on the battery charge, and as a result, a long implant lifetime of the pacemaker. Stimulation pulses are delivered only when the heart's intrinsic rhythm is insufficient or lacking. With sufficient autonomous control, stimulation by the pacemaker does not occur. Depending on the disease, however, continuous stimulation may be necessary. Most implant systems are also capable of recognizing a range of pathologies and providing appropriate therapy for them.

The intracardiac electrocardiogram is recorded continuously via the electrodes to determine whether the heart's intrinsic rhythm is sufficient. The sensing electrodes are also used for stimulation of the heart on demand. Where unipolar leads are used, stimulation occurs by closing the electrical circuit between the electrode tip in the heart and the enclosure of the cardiac pacemaker. With bipolar electrodes, current flows only between the two electrodes (tip and ring) located in the heart.

4.2 Defibrillators

Defibrillators (ICD: implantable cardioverter-defibrillator; PCD = pacemaker cardioverter-defibrillator) are very similar in design to cardiac pacemakers, but feature significantly extended therapeutic functions. These additional functions enable implants of this type to treat life-threatening ventricular fibrillation, as well as – in most cases – providing cardiac pacemaker therapy. To treat ventricular fibrillation, the defibrillator senses the heart's condition via a bipolar lead. If ventricular fibrillation is

detected, a further, specialized electrode, e.g. a shock coil, delivers a high-energy pulse (shock) directly to the heart muscle after a programmable delay. The shock usually resynchronizes the cardiac rhythm.

4.3 Possible mechanisms of electromagnetic interference with cardiac pacemakers and defibrillators and their significance for the wearer of the implant

The functioning of cardiac pacemakers and defibrillators can be affected as follows by low-frequency electric fields, static and low-frequency magnetic fields, and by the low-frequency demodulation products of modulated or pulsed radiofrequency fields:

- Firstly, an interference may be caused by uptake within the cardiac pacemaker, as the enclosure of implantable cardiac pacemakers is almost “transparent” for static and low-frequency magnetic fields. Human body tissue has no attenuating effect on static and low-frequency magnetic fields. The magnetic field strength within the human body is therefore the same as would be measured at the same location in the absence of the body.
- The second risk for interference with the cardiac pacemaker arises from electrical signals of sufficient duration and voltage and relevant signal forms reaching the input of the cardiac pacemaker via the sensing lead, i.e. the lead registering the intracardiac electrocardiogram. Such a signal can, for example, be coupled into the implanted cardiac pacemaker lead by electric field strengths in the tissue caused by external low-frequency electric and magnetic fields. The interference voltage depends essentially on the type of leads used, the location of the implanted leads in the body, and in the case of magnetic fields, the effective area of the induction loop and the direction, amplitude and modulation of the external field.

Examples of typical failures of cardiac pacemakers and defibrillators are listed below with reference to the implanted system (cardiac pacemaker or defibrillator), the condition of the heart and associated requirements regarding therapy, and the strength, duration and temporal waveform of the interfering signal.

4.3.1 Cardiac pacemakers

- The heart is executing its “normal”, intrinsic rhythm, free of cardiac arrhythmias, and the cardiac pacemaker should not deliver any stimulation pulses. However, caused by uptake of external low-frequency electric and magnetic fields or by low-frequency demodulation products of modulated or pulsed radiofrequency fields, the cardiac pacemaker measures an abnormal input signal, and switches as programmed to its interference mode.Depending on the pacemaker model and how it is programmed, asynchronous stimulation of the heart and influencing of the cardiac rhythm may occur. The transition to interference mode is usually not noticed by the wearer of the cardiac pacemaker. Brief cardiac discomfort may occasionally be felt. In very rare cases, the switching itself may cause false triggering of the heart, potentially leading to serious impairment of the cardiac rhythm (bradycardias, tachyarrhythmias). In such cases, the consequence for the cardiac pacemaker’s wearer is prolonged discomfort or reduced performance.
- The heart is executing its “normal”, intrinsic rhythm, free of cardiac arrhythmias, and the cardiac pacemaker should not deliver any stimulation pulses. However, distortion of the input signal of the cardiac pacemaker due to the interference voltage caused by external low-frequency electric and magnetic fields or by the low-frequency demodulation products of modulated or pulsed radiofrequency fields is sufficiently severe to prevent the pacemaker from detecting a beat (undersensing). In this case, the pacemaker delivers stimulation pulses (asynchronously) after a programmable delay. The wearer of the cardiac pacemaker may then experience situations similar to those described above when a transition to interference mode occurs.
- The heart’s intrinsic rhythm is inadequate or lacking. Under these circumstances, the cardiac pacemaker should deliver stimulation pulses. However, the pacemaker interprets the distortion of its input signal as an intrinsic cardiac rhythm (oversensing) and suppresses its stimulation function (inhibition). The duration of inhibition is determined essentially by the duration and the time course of the distortion of the cardiac pacemaker’s sensing signal. Prolonged inhibition in combination with considerably reduced intrinsic cardiac activity can lead to dizziness or unconsciousness, and in the event of no intrinsic activity, even to death.

- On a dual-chamber cardiac pacemaker, distortion of the pacemaker's input signal can also be interpreted as a natural cardiac rhythm in the atrium. This results in the ventricle being stimulated at the rhythm of this signal, or even at a higher rate (treatment of atrial fibrillation). Situations may then arise for the wearer of the cardiac pacemaker similar to those described above for a transition to interference mode. Depending on the frequency of stimulation, however, considerable cardiac discomfort and tachycardia may also occur.
- Static magnetic fields can trigger the magnetically actuated switch in the cardiac pacemaker, e.g. a reed contact or Hall effect switch. This switches the pacemaker to programming mode, whereby it stimulates at a fixed, preset frequency, possibly asynchronously to existing cardiac activity. The wearer of the cardiac pacemaker may then experience situations similar to those for a transition to interference mode.

Study of cardiac pacemakers has revealed that some devices switch to interference mode even when the amplitude of the distortion of the input signal, particularly at power frequency, is still substantially lower than that of the physiological cardiac signal and the latter can still be detected with sufficient reliability. This behaviour of cardiac pacemakers, together with the associated occasional switch to interference mode and including the accompanying risks, is tolerated by the medical profession, as it enables avoidance of the far more frequent and hazardous effect of inhibition [26].

In the presence of external electric and magnetic fields with frequencies of up to around 1000 Hz, the use of bipolar leads can lead to lower interference voltages at the input of the cardiac pacemaker than with unipolar leads. The decisive factor for the interference voltage amplitude at the input of the cardiac pacemaker in the presence of external electric fields is the geometric distance in the direction of the field between the two contact surfaces of the stimulation circuit (enclosure of the pacemaker and tip electrode in the heart for unipolar lead configurations; between the two (tip and ring) electrodes in the heart, i.e. the "ring-tip distance", for bipolar lead configurations). In the presence of external magnetic fields, the decisive factor is the actual effective loop area in consideration of the lead configuration.

In the scenario of exposure to highly inhomogeneous magnetic fields limited in their extent, like for example, when magnetic field sources of small geometric dimensions are used close to the body, it should be noted that, owing to the smaller effective loop area, bipolar lead configurations are much more capable of sensing the maximum magnetic inductions that arise than are unipolar lead configurations, in which the integration over the greater effective loop area always results in the magnetic induction being averaged. This means that in particular cases, bipolar lead configurations may be more susceptible to interference than unipolar lead configurations when exposed to local, inhomogeneous magnetic fields of this kind.

Although the use of bipolar leads usually leads to lower interference voltages at the input of the cardiac pacemaker at frequencies up to around 1000 Hz than is the case with unipolar configurations, it should be noted that the use of bipolar leads also reduces the amplitude of the intracardiac electrocardiogram, thereby necessitating greater amplification of the input signal, resulting in turn in the pacemaker having a higher sensing threshold and thus also a larger susceptibility to interference. The advantage of bipolar leads over unipolar configurations is thus fully or at least partly reduced when the immunity to interference of the overall "lead/cardiac pacemaker" system is considered.

4.3.2 Defibrillator

The malfunctions listed under 4.3.1 may also occur on defibrillators featuring cardiac pacemaker functionality.

However, the following particular aspects must be considered for defibrillators:

- Where, on defibrillators featuring signal interference detection, the distortion of the input signal caused by the external low-frequency electric and magnetic fields or the low-frequency demodulation products of modulated or pulsed radiofrequency fields results in the defibrillator being switched to its interference mode, detection and treatment of ventricular fibrillation is not possible.
- When oversensing by the defibrillator occurs frequently, interference voltages at the defibrillator input, caused by external low-frequency electric and magnetic fields or the low-frequency demodulation products of modulated or pulsed radiofrequency fields, may be misinterpreted by the defibrillator as ventricular fibrillation, and lead to unwanted triggering of a shock stimulus.

- If the defibrillator's internal magnetically actuated switch, e.g. a reed contact or Hall effect switch, is influenced by static magnetic fields, this usually causes the defibrillator's therapeutic function to be deactivated.

Due to the exclusive use of bipolar leads, the interference voltage at the input of defibrillators caused by external low-frequency electric and magnetic fields is in principle significantly lower than that at the input of cardiac pacemakers with unipolar leads, particularly for frequencies below 1000 Hz, provided strongly localized exposure to inhomogeneous magnetic fields does not occur (see 4.3.1). However, it must be noted that defibrillators for the detection of ventricular fibrillation are often set to a higher sensitivity than cardiac pacemakers, and may even feature dynamic adjustment of the input sensitivity (auto-sensing), which likewise may partly or fully cancel out the enhanced interference immunity of the system as a whole (i.e. bipolar leads & defibrillator).

5 Directives, regulations and standards – overview and critical assessment

5.1 General

In accordance with EU Directive 1990/385/EEC [1], all active implants must be designed to operate uninfluenced under all ambient conditions normally encountered in the life of an implant wearer. This means that, provided the limits for the protection of persons applicable in publicly accessible areas are observed, no special measures are required for wearers of active implants. Since the limits in place in the 1990s for the protection of persons in publicly accessible areas were in some cases even higher than those in force today [25], it can be assumed that all active implants approved at that time and placed on the market since then are sufficiently immune to interference.

Unfortunately, the reality is quite different. There were and still are active implants that do not comply with the interference immunity requirements of EU Directive 1990/385/EEC [1]. Contrary to the wording of the EU Directive, it has not been possible to prevent these active implants from entering the market or remove them from it.

Relevant product standards for cardiac pacemakers and defibrillators, such as EN 45502-2-1 [10] and EN 45502-2-2 [11, 12], which, among other things, contain provisions regarding the immunity of active implantable medical devices to interference in electric, magnetic and electromagnetic fields, state only interference threshold values for the static magnetic field and device-specific interference threshold values for the voltage at the lead connector for the frequency range from 16.7 Hz to 3 GHz. However, these product standards do not set out any actual interference immunity requirements, since compliance with the product standards does not require unrestricted compliance with the interference immunity specifications. Instead, a warning notice in the accompanying documentation for the cardiac pacemaker or defibrillator is sufficient if the interference immunity specifications for frequencies up to 1 kHz are not met, in order to still fulfil the requirements of the product standards [10, 11, 12]. Product standards are therefore not sufficient, at the present time, to completely exclude the possibility of active implants being subject to adverse influences.

Recognition is growing of the need for the necessary protection to be assured for wearers of active implants in electric, magnetic and electromagnetic fields, and for the corresponding requirements in EU directives to be implemented. Unfortunately, it has not yet been possible to implement this protection requirement in full because, as already stated, the relevant product standards [10, 11, 12] still fail to specify a binding lower limit for the immunity of cardiac pacemakers and defibrillators to interference.

Whereas the VDE 0848 series of standards "Safety in electric, magnetic and electromagnetic fields" has long recognized the additional need for protection of wearers of active implants and has set out provisions to this effect [16], corresponding regulations at the European level did not exist until recently [13, 14]. The decisive impetus for standardization activities at the European level is due to the many years of effective national standardization activity in Germany, even though further work on the E DIN VDE 0848-3-1 [16] draft standard and its finalization were ultimately halted by the activities at the European level.

EN 50527-2-1 [14] specifies methods for assessing the exposure of workers wearing active implantable medical devices (AIMDs) – in this case cardiac pacemakers – to electromagnetic fields. It adopts the proven method set out in the E DIN VDE 0848-3-1 [16] draft standard of dividing possible interference effects into two independent aspects, enabling these to be assessed separately. These aspects are, firstly, the interference effect exerted on the implanted cardiac pacemaker system, consisting of the cardiac pacemaker device and the necessary leads, by an external electric, magnetic and electromagnetic field to which the person is exposed, and secondly, the actual interference immunity of the cardiac pacemaker.

EN 50527-2-1 [14] assumes that where cardiac pacemakers satisfy the requirements of the EN 45502-2-1 [10] product standard, their function is not influenced by external electric, magnetic and electromagnetic fields below the values permitted by EU Council Recommendation 1999/519/EC [2], with the exception of static magnetic fields and pulsed radiofrequency fields. This means, for example, that for a frequency of 50 Hz at electric field strengths with RMS values of up to 5 kV/m and magnetic flux densities with RMS values of up to 100 μT, no interference with pacemakers is to be expected.

If, for example, the requirements of the EN 45502-2-1 [10] product standard are not met, the attending physician must issue a suitable warning to the patient, stating whether specific electric appliances, machinery and systems – which may also include household appliances and public transport – could disturb the cardiac pacemaker or whether the particular settings of the cardiac pacemaker make it sensitive in general to external electric, magnetic and electromagnetic fields. In both cases, individual consultation with the wearer of the cardiac pacemaker is

essential, as the particular sensitivity of their implant to interference can have far-reaching effects on the wearer's daily life.

However, it should be noted that the EN 50527-2-1 [14] standard contains certain simplifications and inconsistencies. For example, the standard generally assumes for the assessment of bipolar leads that the interference voltage at the input of the cardiac pacemaker caused by external low-frequency electric and magnetic fields is 20 times lower than is the case with unipolar leads. However, not all ring-tip distances on the market are taken into account for bipolar leads nor are all anatomy-specific distances between the cardiac pacemaker and the tip electrode in the heart taken into account for unipolar leads with left or right pectoral implantation [14, 21]. Although some of the studies cited in the standard have significant shortcomings, their results were adopted unchanged. Since the underlying product standard DIN EN 45502-2-1 [10] only contains specific provisions for the frequency range from 16 Hz to 450 MHz, the provisions of standard DIN EN 50527-2-1 [14] are also incomplete with regard to the frequency range under consideration.

5.2 EN 45502-2-1 product standard

Despite its shortcomings (see Section 5.1), the EN 45502-2-1 [10] product standard contains a number of fundamental provisions that are essential for setting threshold values for electromagnetic fields at the workplace. Compliance with these values ensures the safety and health of workers wearing active implants, particularly cardiac pacemakers and defibrillators.

Although unipolar lead configurations are now used only rarely in cardiac pacemaker systems and not at all in defibrillators, they are primarily considered in the following. There are two main reasons for this: On the one hand, almost any bipolar system can continue to operate in unipolar mode, e.g., in the event of a lead failure. On the other hand, the immunity to interference of the lead (s)/cardiac pacemaker system as a whole is usually lower in unipolar mode than in bipolar mode. In the interests of a worst-case analysis, it is therefore appropriate to use the more sensitive unipolar overall system as the basis for the assessment.

The EN 45502-2-1[10] product standard specifies the following essential test requirements in Clause 27, "*Protection of the active implantable medical device from electromagnetic non-ionizing radiation*":

- **Sub-clause 27.4**
  "*The implantable pulse generator shall be designed so that a malfunction of the implantable pulse generator due to unmodulated external magnetic fields during exposure is unlikely*."
  In the frequency range between 16.6 Hz and 167 kHz, immunity to interference from an unmodulated sinusoidal signal with a maximum peak-to-peak value V_{pp} of 1 V is required.
- **Sub-clause 27.5**
  "The implantable pulse generator shall be designed so that a change in the therapeutic behaviour of the implantable pulse generator due to generally encountered modulated electromagnetic fields is unlikely."
  "The implantable pulse generator shall be set to the highest sensitivity in both unipolar and bipolar modes for which the manufacturer claims compliance with this standard (...). For frequencies above 1 kHz, this minimum setting is 2,0 mV in unipolar sensing mode (...) or the sensitivity set at the time of shipment, whichever is the more sensitive."
  In the frequency range between 16.6 Hz and 150 kHz, immunity to interference from a modulated test signal (see **Figure 5.1** for the time curve) with a peak-to-peak value V_{pp} in accordance with **Table 5.1** is required.
  In the frequency range between 150 Hz and 450 kHz, the requirements to be met for immunity to interference in accordance with Table 5.1 apply to a different modulated test signal (see **Figure 5.2** for the time curve). For frequencies above 10 MHz, compliance with the requirements for interference immunity is checked only selectively for the frequencies 20, 100 and 200 MHz. The curve of the peak-to-peak value V_{pp} of the test voltages in accordance with Sub-clauses 27.4 and 27.5 of the EN 45502-2-1 [10] product standard against the frequency (see also Table 5.1) is shown graphically again in **Figure 5.3**.
  For fields with frequencies in the range between 450 MHz and 3 GHz, no further tests are required for "*implantable pulse generators that are equipped with feed-thru filters at the housing for all through-shield connections and whose filters have a proven insertion loss of more than 30 dB (...)*". Compliance shall be confirmed by "*inspection of a design analysis of the feed-thru filters provided by the manufacturer, supported by data and calculations from test studies as appropriate, or the implantable pulse generator complies with the applicable performance criteria in 6.5 of AAMI PC69 at each frequency tested".* During testing according to AAMI PC69, the pacemaker and lead are placed in a model

torso filled with conductive liquid at a distance of 2.5 cm from a dipole which is fed with a continuous wave signal of 120 mW during the test. Further details of the test setup and on how to perform the test can be found in [5].

- **Sub-clause 27.6**
  "The implantable pulse generator shall not be affected by static magnetic fields with a flux density of up to 1 mT."
  The test is performed in a field coil that is "capable of generating a uniform magnetic field with a flux density of up to 1 *mT* ± 0,1 *mT* in the region to be occupied by the implantable pulse generator."

5.3 EN 50527-2-1 standard and E DIN VDE 0848-3-1 draft standard: comparison and evaluation

Although EN 50527-2-1 [14] makes illogical assumptions and contains simplifications and inconsistencies, and finalization of the E DIN VDE 0848-3-1 [16] draft standard was halted by activities at the European level (see also Sub-clause 5.1), both documents nevertheless contain valuable information of essential relevance to the specification of threshold values for electromagnetic fields at the workplace for workers wearing active implants, in particular cardiac pacemakers and defibrillators.

Table 5.1:
Peak-to-peak value V_{pp} of the test signal amplitude according to EN 45502-2-1 [10] in the frequency range between 16.6 Hz and 450 MHz

Frequency f	Peak-to-peak value V_{pp} of the test signal amplitude [mV]
16.6 Hz ≤ *f* ≤ 1 kHz	2
1 kHz ≤ *f* ≤ 3 kHz	2 · (*f* / 1 kHz)^2
3 kHz ≤ *f* ≤ 150 kHz	6 · (*f* / 1 kHz)
150 kHz ≤ *f* ≤ 167 kHz	6 · (*f* / 1 kHz)
167 kHz ≤ *f* ≤ 1 MHz	1000
1 MHz ≤ *f* ≤ 10 MHz	1000 · (*f* / 1 MHz)
20 MHz	10000
100 MHz	10000
200 MHz	10000

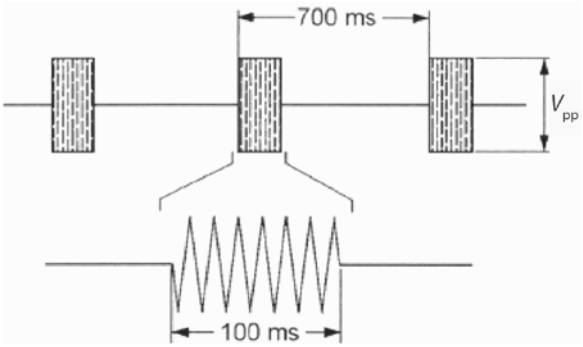

Figure 5.1:
Test signal according to EN 45502-2-1 [10] for frequencies in the range between 16.6 Hz and 150 kHz

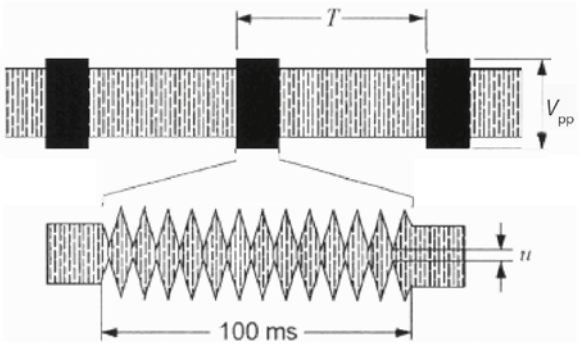

Figure 5.2:
Test signal according to EN 45502-2-1 [10] for frequencies in the range between 150 kHz and 450 MHz

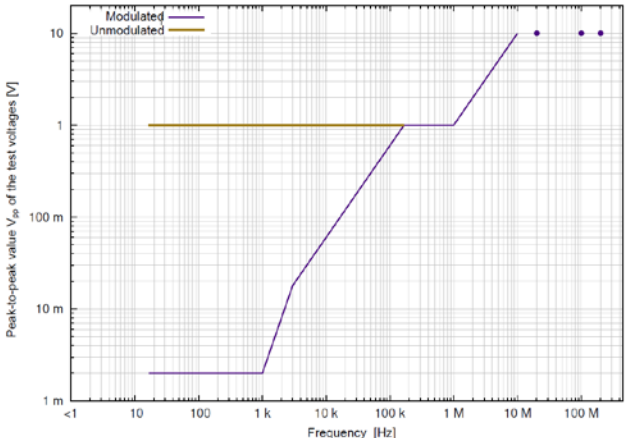

Figure 5.3:
Curve of the peak-to-peak value V_{pp} of the test signal amplitude according to Sub-clauses 27.4 and 27.5 of the EN 45502-2-1 [10] product standard as a function of frequency

In particular, both the EN 50527-2-1 [14] standard and the E DIN VDE 0848-3-1 [16] draft standard contain formulae that establish the relationship between the interference voltages V_{pp} at the input of the cardiac pacemaker and the external electric and magnetic field strengths. Consistent with a worst-case consideration, only unipolar lead configurations or sensitivity settings/cardiac pacemakers with limited interference immunity (Category 1) in accordance with draft standard E DIN VDE 0848-3-1 [16] are considered.

Unless specified to the contrary, the frequency f in Hertz [Hz] and the respective peak values of the external electric and magnetic field strengths $\hat{E}_0$ and $\hat{H}_0$ in V/m and A/m are to be used in all formulae. The result is the respective peak-to-peak value V_{pp} in volts of the maximum interference voltage to be anticipated at the input of the cardiac pacemaker.

5.3.1 EN 50527-2-1 standard

EN 50527-2-1 [14] contains the following formulae for converting the peak values of the external electric and magnetic field strengths $\hat{E}_0$ and $\hat{H}_0$ to the maximum interference voltages V_{pp} to be anticipated at the input of the cardiac pacemaker.

- **Magnetic field in the frequency range between 16 and 5 MHz**
  The standard assumes that the loop area spanned by the lead is no greater than 225 cm^2. Applying the law of induction yields the equation:

$$V_{pp} = 3.6 \cdot 10^{-7} \cdot f \cdot \hat{H}_0 \qquad (5.1)$$

- **Electric field in the frequency range between 16 and 60 Hz**
  Although most of the studies cited in the standard consider only a frequency of 50 or 60 Hz, the following conversion formula is considered valid for the frequency range between 16 and 60 Hz:

$$V_{pp} = 4.4 \cdot 10^{-9} \cdot f \cdot \hat{E}_0 \qquad (5.2)$$

It can be seen from Figure E.4 of EN 50527-2-1 [14] that this curve does not correspond to any of the studies cited and does not represent the worst case. As already explained in 5.1, not all anatomy-specific distances between the cardiac pacemaker and the tip electrode in the heart for unipolar leads with left or right pectoral implantation were taken into account, and the results of some studies cited in the standard, despite considerable shortcomings, were adopted unchanged [21].

- **Electric field in the frequency range between 60 and 150 kHz**
  The standard does not contain a conversion formula for this frequency range.
- **Fields with electric and magnetic field components in the frequency range between 16 and 60 Hz**
  If electric and magnetic fields are present simultaneously, the maximum interference voltage occurring at the input of the cardiac pacemaker is estimated as the sum of the effects of both fields:

$$V_{pp} = f \cdot \max(4.4 \cdot 10^{-9} \cdot |E_0(t)| + 3.6 \cdot 10^{-7} \cdot |H_0(t)|) \qquad (5.3)$$

Instead of the peak values, the instantaneous absolute values of the external electric and magnetic field strengths $|E_0(t)|$ and $|H_0(t)|$ in V/m and A/m, respectively, are to be used in the equation.

- **Fields with electric and magnetic field components in the frequency range between 60 Hz and 150 kHz**
  The standard does not contain a conversion formula for this frequency range.
- **Fields with electric and magnetic field components in the frequency range between 150 kHz and 5 MHz**

$$V_{pp} = 3.6 \cdot 10^{-10} \cdot f \cdot \sqrt{\hat{E}_0^2 + 10^6 \cdot \hat{H}_0^2} \qquad (5.4)$$

- **Electric, magnetic and electromagnetic fields in the frequency range between 5 MHz and 30 MHz**
  EN 50527-2-1 [14] states that in this frequency range, the electric and magnetic field components can occur both independently of each other as well as in combination (see Equation 5.4). Depending on the type of field source, certain field components will dominate and make a significant contribution to the interference voltage at the input of the cardia pacemaker.
  The equation below is produced solely by interpolation at the limits of the frequency range. This is also reflected in the fractional exponents.

$$V_{pp} = \max \begin{cases} 6.55 \cdot 10^{-10} \cdot f^{1.4} \cdot \hat{H}_0 \\ 3.6 \cdot 10^{-10} \cdot f \cdot \sqrt{\hat{E}_0^2 + 10^6 \cdot \hat{H}_0^2} \\ 3.17 \cdot 10^{-16} \cdot f^{1.9} \cdot \hat{E}_0 \end{cases} \qquad (5.5)$$

Close examination of the individual elements of Equation 5.5 shows that the term in the middle for both the electric and magnetic field components cannot be transferred to the other two expressions by setting of one selected field quantity to zero. This is questionable from both a physical and a mathematical perspective and raises considerable doubts about the underlying model and interpolation method.

The statement in EN 50527-2-1 [14] that the middle term keeps the curve continuous at the 5 MHz point and at 30 MHz leads to lower values of the interference voltage V_{pp} at the input of the pacemaker than those resulting from Equation 5.6 also provides little reassurance. At the given interference voltages, this approach allows for excessively high permissible external electric and magnetic field strengths. This conflicts with the consideration of a worst-case scenario, and under circumstances may jeopardize the safety and health of workers wearing active implants who are exposed to electromagnetic fields at work.

- **Electromagnetic fields in the frequency range between 30 MHz and 450 MHz**
  For all exposures in this frequency range far-field conditions, i.e. a constant ratio of $\frac{E_0}{H_0} = Z_0 = 120\pi\Omega \approx 377\Omega$ are assumed. While this assumption is generally permissible for exposures in publicly accessible areas, in the specific field of occupational safety and health, near-field exposures are usually the rule. Before applying the formulae below, especially for the conversion of the magnetic field component, it must therefore always be verified whether far-field conditions do in fact apply.

In the **frequency range between 30 and 200 MHz**, whole-body and partial-body resonances may occur. The relationship between the maximum interference voltage V_{pp} at the input of the cardiac pacemaker and the peak value of the external electric and magnetic field component of the electromagnetic field is given by EN 50527-2-1 [14]:

$$V_{pp} = 5.1 \cdot 10^{-2} \cdot \max\begin{Bmatrix} 377 \cdot \hat{H}_0 \\ \hat{E}_0 \end{Bmatrix} \quad (5.6)$$

In the **frequency range between 200 and 400 MHz**, partial-body resonances occur more frequently. For this frequency range, EN 50527-2-1 [14] specifies the following relationship between the maximum interference voltage Vpp occurring at the input of the cardiac pacemaker and the peak value of the external electric and magnetic field component of the electromagnetic field:

$$V_{pp} = 4.1 \cdot 10^{23} \cdot \frac{1}{f^3} \cdot \max\begin{Bmatrix} 377 \cdot \hat{H}_0 \\ \hat{E}_0 \end{Bmatrix} \quad (5.7)$$

In the **frequency range between 400 and 450 MHz**, the maximum interference voltage V_{pp} occurring at the input of the cardiac pacemaker can be described by the coupling of the external electric and magnetic field component of the electromagnetic field into the lead, whose electrical length decreases steadily with increasing frequency, and, due to its constant mechanical length, also acts as a variable low-pass filter. The result is independent of frequency and is specified in EN 50527-2-1 [14] as follows:

$$V_{pp} = 6.37 \cdot 10^{-3} \cdot \max\begin{Bmatrix} 377 \cdot \hat{H}_0 \\ \hat{E}_0 \end{Bmatrix} \quad (5.8)$$

- **Electromagnetic fields with frequencies above 450 MHz**
  EN 50527-2-1 [14] contains no conversion formulae for these frequencies.

5.3.2 E DIN VDE 0848-3-1 draft standard

The E DIN VDE 0848-3-1 draft standard [16] contains the following formulae for converting the peak values $\hat{E}_0$ and $\hat{H}_0$ or the instantaneous values $|E_0(t)|$ and $|H_0(t)|$ of the external electric and magnetic field strengths into the maximum interference voltages Vpp to be anticipated at the input of the cardiac pacemaker.

- **Frequency range between 0 Hz and 25 kHz**

$$V_{pp} = f \cdot \max(4.45 \cdot 10^{-9} \cdot |E_0(t)| + 3.6 \cdot 10^{-7} \cdot |H_0(t)|) \quad (5.9)$$

- **Frequency range between 25 and 300 kHz**

$$V_{pp} = 3.6 \cdot 10^{-7} \cdot \sqrt{9 \cdot 10^4 \cdot \hat{E}_0^2 + f^2 \cdot \hat{H}_0^2} \quad (5.10)$$

- **Frequency range between 300 kHz and 5.33 MHz**

$$V_{pp} = 3.6 \cdot 10^{-10} \cdot f \cdot \sqrt{\hat{E}_0^2 + 10^6 \cdot \hat{H}_0^2} \quad (5.11)$$

- **Frequency range between 5.33 MHz and 16.9 MHz**

In this frequency range, the maximum interference voltage V_{pp} occurring at the input of the cardiac pacemaker is composed of the sum of the peak values of the electric and magnetic field components, unless one of the two field components dominates.

$$V_{pp} = \max\begin{Bmatrix} 6.76 \cdot 10^{-14} \cdot f^2 \cdot \hat{H}_0 \\ 3.6 \cdot 10^{-10} \cdot f \cdot \sqrt{\hat{E}_0^2 + 10^6 \cdot \hat{H}_0^2} \\ 1.29 \cdot 10^{-22} \cdot f^{2.85} \cdot \hat{E}_0 \end{Bmatrix} \quad (5.12)$$

Here, too, close examination of the sub-elements of Equation 5.12 shows that the term in the middle for both the electric and magnetic field components cannot be transferred to the other two terms by one field quantity being set selectively to zero in each case. This is questionable from both a physical and a mathematical perspective and raises considerable doubts about the underlying model and interpolation method.

At the given interference voltages, this approach allows – as already explained with respect to Equation 5.5 – for excessively high permissible external electric and magnetic field strengths. This conflicts with the consideration of a worst-case scenario, and under circumstances may

jeopardize the safety and health of workers wearing active implants when exposed to electromagnetic fields at work.

- **Frequency range between 16.9 MHz and 2.5 GHz**

In this frequency range, the maximum interference voltage Vpp occurring at the input of the cardiac pacemaker is determined by the contribution of the respective dominant peak value of the electric or magnetic field component.

As already explained in Section 5.3.1, far-field conditions are again assumed for all exposures in this frequency range, i.e., a constant ratio of $\frac{E_0}{H_0} = Z_0 = 120\pi\Omega \approx 377\Omega$.

While this assumption is generally permissible for exposures in publicly accessible areas, in the specific field of occupational safety and health, near-field exposures are usually the rule. Before the formulae below are used, especially for the evaluation of the magnetic field component, it must therefore always be verified whether far-field conditions do in fact apply.

For the **frequency range between 16.9 MHz and 200 MHz**, the E DIN VDE 0848-3-1 draft standard [16] specifies the following equation:

$$V_{pp} = 5.1 \cdot 10^{-2} \cdot \max\begin{Bmatrix} 377 \cdot \hat{H}_0 \\ \hat{E}_0 \end{Bmatrix} \quad (5.13)$$

In the **frequency range between 200 MHz and 400 MHz**, the following applies:

$$V_{pp} = 1.3 \cdot 10^{23} \cdot \frac{1}{f^{2.94}} \cdot \max\begin{Bmatrix} 377 \cdot \hat{H}_0 \\ \hat{E}_0 \end{Bmatrix} \quad (5.14)$$

E DIN VDE 0848-3-1 [16] specifies the following equation for the **frequency range between 400 MHz and 1.5 GHz**:

$$V_{pp} = 6.63 \cdot 10^{-3} \cdot \max\begin{Bmatrix} 377 \cdot \hat{H}_0 \\ \hat{E}_0 \end{Bmatrix} \quad (5.15)$$

In the **frequency range between 1.5 and 2.5 GHz**, the maximum interference voltage Vpp occurring at the input of the cardiac pacemaker is calculated according to the E DIN VDE 0848-3-1 draft standard [16] as:

$$V_{pp} = 2.24 \cdot 10^{25} \cdot \frac{1}{f^{3}} \cdot \max\begin{Bmatrix} 377 \cdot \hat{H}_0 \\ \hat{E}_0 \end{Bmatrix} \quad (5.16)$$

6 Safety of workers wearing active and passive implants and exposed to static and low-frequency electric and magnetic fields and radiofrequency electromagnetic fields at work

The primary objective of Directive 2013/35/EU [4] is to assure the safety and health of workers. This means that all direct and indirect effects of exposure to electromagnetic fields must be limited in such a way that they pose no risk to the safety and health of workers.

While both exposure limit values and action levels are explicitly stated in Directive 2013/35/EU for the "*direct biophysical effects*", such values are missing in whole or in part for the "*indirect effects*".

In particular, with regard to the prevention of "*interference with medical electronic equipment and devices, including cardiac pacemakers and other implants or medical devices worn on the body*", Directive 2013/35/EU [4] contains information only on permissible flux densities for static magnetic fields.

In the sections below, threshold values for workers wearing active and passive implants and exposed to static and low-frequency electric and magnetic fields as well as radiofrequency electromagnetic fields at work, are developed based the current state of scientific knowledge.

Compliance with these threshold values assures the safety and health of workers wearing active and passive implants during occupational exposure to static and low-frequency electric and magnetic fields and radiofrequency electromagnetic fields, even under the least favourable exposure conditions. With respect to active implants, it should be noted, however, that the threshold values were determined only for implanted transvenous cardiac pacemakers and defibrillators that fully comply with the interference immunity specifications of the EN 45502-2-1 [10] product standard. Other active implants, particularly those that are program-controlled only and do not possess sensors for measuring physiological parameters or the body's intrinsic signals, may in some cases exhibit considerably higher interference immunity. However, binding provisions for such implants still do not exist. Considerably lower interference immunity was also observed in some cases, particularly on experimental or new types of implant or those still undergoing clinical trials. Only a specific risk assessment can provide the necessary clarity in these cases.

The introduction of threshold values is intended to support employers in fulfilling their obligations when determining exposure and assessing risks and when taking measures to prevent or reduce risks, particularly with regard to workers wearing active and passive implants.

The threshold values do not obviate the requirement for a risk assessment for the worker concerned that takes into account the specific exposure situations and the worker's implant data. This is particularly the case where the threshold values are exceeded.

The threshold values are not exposure limit values but largely serve as an action level. Should they be exceeded, further measures are required, specific to the case concerned.

6.1 Active implants

Comparison of Sections 5.3.1 and 5.3.2 shows that the formulae for converting the peak values $\hat{E}_0$ and $\hat{H}_0$ or the magnitudes of the instantaneous values $|E_0(t)|$ and $|H_0(t)|$ of the external electric and magnetic field strengths to the maximum anticipated interference voltages V_{pp} at the input of the cardiac pacemaker are largely consistent between EN 50527-2-1 [14] and E DIN VDE 0848-3-1 [16]. Differences are mainly explained by different limits of the frequency ranges, the interpolation methods used, and the choice of sampling points in the entire frequency range.

As assumed in Section 6, the interference immunity requirements of the EN 45502-2-1 product standard [10] serve as a basis for further considerations.

The interference threshold values specified in draft standard E DIN VDE 0848-3-1 [16] for cardiac pacemakers will no longer be used, for a number of reasons. These values are based in part on measurements conducted on cardiac pacemakers in the 1980s and 1990s. Such cardiac pacemakers are by now unlikely to be encountered implanted in patients. Since, in the majority of cases, measurements were performed on explanted cardiac pacemakers, they were not generally reset to factory settings before performance of measurement. It is therefore unclear what influence patient-specific programming of the pacemakers had on the measurement results obtained. Furthermore, the values for interference immunity stated in the E DIN VDE 0848-3-1 draft standard [16] often represent the lower envelope of a collective of measurements, or are based on discrete cases.

A concept for determining the threshold values for workers who are exposed to static and low-frequency electric and magnetic fields and radiofrequency electromagnetic fields at the workplace and are wearing active implants is described below. The concept is developed with reference

to the interference immunity requirements of the EN 45502-2-1 product standard [10] and the formulae for conversion of the peak values $\hat{E}_0$ and $\hat{H}_0$ or the magnitudes of the instantaneous values $|E_0(t)|$ and $|H_0(t)|$ of the external electric and magnetic field strengths to the maximum interference voltages Vpp to be anticipated at the input of the cardiac pacemaker in accordance with the EN 50527-2-1 standard [14] and E DIN VDE 0848-3-1 draft standard [16].

6.1.1 Static electric fields

As discussed in Section 3.1.1, an external static electric field is not able to penetrate the surface of the body. The interior of the body is virtually field-free and thus shielded from any effect of the external static electric field. External static electric fields cannot therefore directly influence active implants.

For this reason, it is irrelevant that the EN 45502-2-1 product standard [10] contains no requirements for immunity to interference DC voltages at the input of the cardiac pacemaker and that the conversion formulae discussed in Section 5.3.2 for a frequency $f = 0$ Hz do not provide a solution for the permissible field strengths for a given interference voltage Vpp at the pacemaker's input.

However, discharge processes and the associated electric shocks can occur in static electric fields. These arise either when a person becomes charged in the static electric field and this charge is discharged when they touch an earthed conductive object, or when the person, whilst themselves earthed, touches a conductive object charged by the static electric field, causing this charge to be discharged through them. Depending on the currents and energy that are discharged, the function of active implants may be affected. Since these discharge processes depend on the geometric dimensions of the charged object and other parameters as well as the static electric field strength, they cannot be limited effectively solely by limiting of the external static electric field strengths. Further observations can be found in Section 6.1.4.

As described in the FB400 research report published by the German Federal Ministry of Labour and Social Affairs [8], the permissible static electric field strength is limited only by way of the anticipated indirect effects. In the report, an exposure limit for static electric fields is stated in the form of a maximum value of 30 kV/m for the external electric field strength [8]. However, the report also states that contact currents may give rise to further limitations if the worker is able to touch an earthed or unearthed object.

Directive 2013/35/EU [4] neither specifies values for exposure limits nor for action levels for limiting the exposure to external static electric fields. However, at a frequency of 1 Hz, a root-mean-square value of 20 kV/m is stated as the low and high action levels for the electric field strength [4]. If the curve is assumed to be sinusoidal and this root-mean-square value is converted to a peak value, this yields a numerical value of 28.3 kV/m, which is only marginally below the exposure limit value for static electric fields determined in the FB400 research report [8].

In the course of further discussion, this peak value of 28.3 kV/m then serves as the threshold value for workers wearing active implants and exposed at the workplace to static electric fields, provided no further limitations arise due to contact currents where the worker is able to touch an earthed or unearthed object (see Section 6.1.4).

6.1.2 Static magnetic fields

Although the EN 45502-2-1 product standard [10] explicitly states in Sub-clause 27.6 that "*the implantable pulse generator shall not be affected by static magnetic fields of flux density of up to 1 mT*", it also permits, the use of test equipment with a tolerance of 1 mT ± 0.1 mT for the magnetic flux density in the region to be occupied by the device under test. A possible influence on the active implant can therefore no longer be ruled out with sufficient certainty at a magnetic flux density from 0.9 mT upwards.

Directive 2013/35/EU [4] states an action level of 0.5 mT for the magnetic flux density of static magnetic fields for "*interference with active implanted devices, e.g. cardiac pacemakers*". Experts consider this value too restrictive.

The permissible value of 0.7 mT for the magnetic flux density of static magnetic fields stated in BG Rule BGR B11 (electromagnetic fields) [7] for wearers of cardiac pacemakers, which has been in force now for over ten years, has proved effective.

This value of 0.7 mT will as the threshold value for workers wearing active implants and exposed at the workplace to static magnetic fields serve in further discussion.

6.1.3 Low-frequency electric and magnetic fields and radiofrequency electromagnetic fields

As can be seen from Table 5.1 and Figure 5.3, the requirements set out in the EN 45502-2-1 product standard [10] for immunity to interference for frequencies of $0 < f \leq 300$ GHz are incomplete. In particular, the frequency ranges $f < 16.6$ Hz and $f > 10$ MHz must be examined more closely.

The immunity requirements for 16.6 Hz are extrapolated as a constant value in the frequency range $0 < f < 16.6$ Hz. This is permissible since, owing to the characteristics of the cardiac pacemakers' input circuits, it can be assumed that the interference threshold values for frequencies $f < 16.6$ Hz increase again and lie above the value stated in the EN 45502-2-1 product standard [10] for the frequency range $16.6\ \text{Hz} \leq f \leq 1$ kHz [17].

The immunity to interference V_{pp} valid at the 10 MHz point can be continuously extrapolated in the frequency range $f > 10$ MHz without limitation as a constant value up to at least 450 MHz, even though EN 45502-2-1 [10] requires verification of compliance with the interference immunity requirements only at specific frequencies in this frequency range.

The requirement, also set out in the EN 45502-2-1 product standard [10], for immunity to interference in the frequency range between 16.6 Hz and 167 kHz from an unmodulated sinusoidal signal is irrelevant in practice, as the movement of the worker wearing an active implant in the low-frequency electric and magnetic field or radiofrequency electromagnetic field can always give rise to "modulation". For consideration of a worst-case scenario, the requirements for immunity to interference from an unmodulated sinusoidal signal as set out in EN 45502-2-1 will therefore not be applied further.

The extrapolated peak-to-peak values Vpp of the test signal amplitude in the frequency range $0 < f \leq 450$ MHz which result from these considerations are compiled in **Table 6.1** and presented graphically in **Figure 6.1**.

If the formulae stated in the EN 50527-2-1 standard and the E DIN VDE 0848-3-1 draft standard for conversion of the peak values $\hat{E}_0$ and $\hat{H}_0$ or the magnitudes of the instantaneous values $|E_0(t)|$ and $|H_0(t)|$ of the external electric and magnetic field strengths to the maximum interference voltages V_{pp} to be anticipated at the input of the cardiac pacemaker (see Sections 5.3.1 and 5.3.2 of this document) are solved for the external electric and magnetic field components and the extrapolated peak-to-peak values Vpp of the test signal amplitude in the frequency range $0 < f \leq 450$ MHz as per Table 6.1 are substituted, the curves shown in **Figures 6.2** and **6.3** are obtained for the external electric and magnetic field strengths and flux densities. The dashed parts of the curves are taken from formulae containing both the electric and magnetic field components. To obtain the maximum permissible peak values of the external electric field strength, the influence of the magnetic field component is set to zero ($H = 0$) and vice-versa.

Table 6.1:
Extrapolated peak-to-peak values Vpp of the test signal amplitude in the frequency range between 0 Hz and 450 MHz

Frequency f	Peak-to-peak value V_{pp} of the test signal amplitude [mV]
$0\ \text{Hz} < f \leq 1$ kHz	2
$1\ \text{kHz} \leq f \leq 3$ kHz	$2 \cdot (f / 1\ \text{kHz})^2$
$3\ \text{kHz} \leq f \leq 150$ kHz	$6 \cdot (f / 1\ \text{kHz})$
$150\ \text{kHz} \leq f \leq 167$ kHz	$6 \cdot (f / 1\ \text{kHz})$
$167\ \text{kHz} \leq f \leq 1$ MHz	1000
$1\ \text{MHz} \leq f \leq 10$ MHz	$1000 \cdot (f / 1\ \text{MHz})$
$10\ \text{MHz} \leq f \leq 450$ MHz	10000

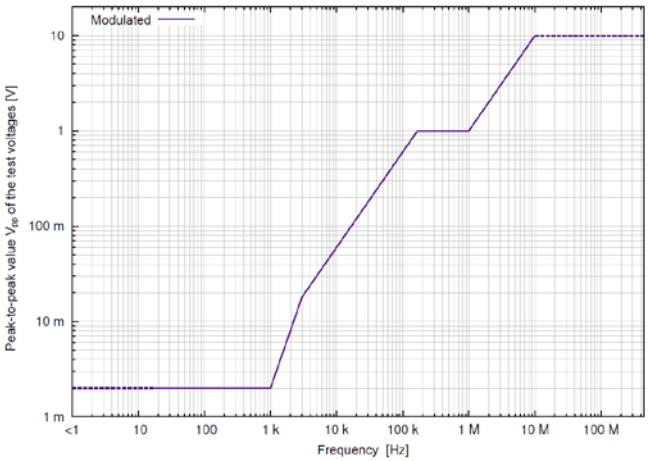

Figure 6.1:
Extrapolated curve of the peak-to-peak value V_{pp} of the test signal amplitude in the frequency range $0 < f \leq 450$ MHz (extrapolated parts of the curve are shown as dashed lines)

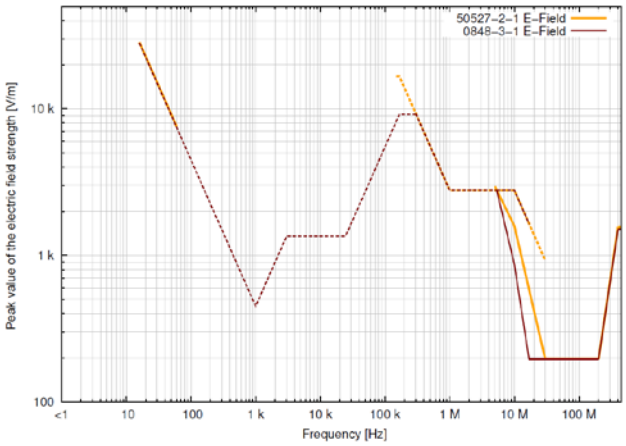

Figure 6.2:
Maximum permissible peak values of the external electric field strength in the frequency range $0 < f \leq 450$ MHz that do not lead to any influenced behaviour of the active implant

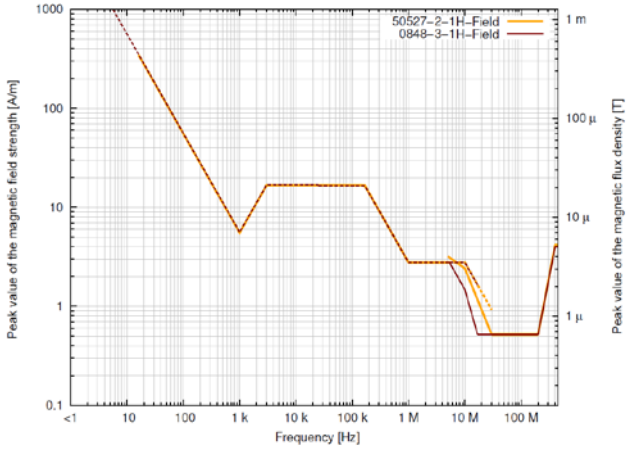

Figure 6.3:
Maximum permissible peak values for the external magnetic field strength in the frequency range $0 < f \leq 450$ MHz that do not lead to any influenced behaviour of the active implant

If the maximum permissible peak values of the external electric field strength in Figure 6.2 are considered more closely, the major gap in the provisions of EN 50527-2-1 [14] in the frequency range between 60 Hz and 150 kHz is particularly evident. The deviations, sometimes considerable, from the provisions of E DIN VDE 0848-3-1 [16] are also immediately apparent. Particularly in the frequency ranges 150 to 300 kHz and 5 to 30 MHz the differences are in some cases considerable.

In EN 50527-2-1 [14], the scope of Equation 5.4 is extended to include lower frequencies down to 150 kHz, although the original approach in the E DIN VDE 0848-3-1 draft standard [16] (see Equation 5.11) applied only at 300 kHz and above, and yielded a different curve (see Equation 5.10) for lower frequencies. Since EN 50527-2-1 [14] provides neither robust studies supporting this extension, nor a rationale or a steady continuation of the curve to lower frequencies, this data will not be discussed further below.

As already explained in the discussion of equations 5.5 and 5.12, the terms containing both field components overestimate the permissible external electric or magnetic field strengths at a given interference voltage Vpp, and cannot be converted to the other expressions that each are valid for only one of the field components. As can be seen from Figure 6.2, although both equations extend the curves steadily at their lower frequency point – 5 MHz for the EN 50527-2-1 standard [14], 5.33 MHz for the E DIN VDE 0848-3-1 draft standard [16] – the values in the continuation of the curve are considerably higher than those which consider only the electric field component (see equations 5.5 and 5.12). Owing to the uncertainties associated with the overall approach, these parts of the curve and the terms on which calculation is based will not be used for further evaluation for the purposes of a worst-case scenario.

Whereas, in the frequency range between 30 and 450 MHz, both EN 50527-2-1 [14] and E DIN VDE 0848-3-1 [16] show – minor rounding deviations aside – a consistent picture, greater deviations are still found in the frequency range between 5 and 30 MHz. EN 50527-2-1 [14] states that the curve in this frequency range is determined solely by interpolation between the two corner frequencies, and that no physical calculation model or test data are known. From Annex E of E DIN VDE 0848-3-1 [16], it can be seen that the curve in the frequency range between 5.33 and 16.9 MHz is determined by interpolation between the corner frequencies. The latter approach, however, yields more conservative values and takes better account of whole-body and partial-body resonances, which mathematically are to be anticipated upwards of around 10 MHz. For this reason, the provisions of E DIN VDE 0848-3-1 [16] in the frequency range from 5.33 to 450 MHz will be used for the purpose of further discussion.

Closer examination of the maximum permissible peak values for the external magnetic field strength in Figure 6.3 shows that the curves of EN 50527-2-1 [14] and E DIN VDE 0848-3-1 [16] match very closely, aside from rounding deviations.

Here too, major differences exist in the frequency range between 5 and 30 MHz. The reasons have already been discussed in detail with respect to Figure 6.2 and can be

applied by analogy to the magnetic field component. The conclusions are the same as for the electric field:

- The terms used in equations 5.5 and 5.12 that include both field components will not be used for further discussion.
- In the frequency range between 5.33 MHz and 450 MHz, only the provisions of the E DIN VDE 0848-3-1 draft standard [16] will be used for further evaluations.

Whereas the EN 50527-2-1 standard [14] lacks conversion formulae for frequencies above 450 MHz, the E DIN VDE 0848-3-1 draft standard [16] contains such formulae for frequencies up to 2.5 GHz.

However, it should be noted that the absorption in human tissue of the energy of a radiofrequency electromagnetic field is highly frequency-dependent. The penetration depth is defined here as the path length in matter at which the electric or magnetic field strength has decreased to $\frac{1}{e} \approx 37\%$ of its initial value. If, for the sake of simplicity, a homogeneous body model is assumed, the penetration depths as a function of the frequency are those shown in **Table 6.2**. The average tissue conductivities used for calculation of the penetration depths, which are stated in Table 6.2, were taken from EN 62209-2 [15].

Table 6.2:
Penetration depth of a radiofrequency electromagnetic field in a homogeneous body model, as a function of the frequency

Frequency [MHz]	Conductivity [S/m]	Penetration depth [mm]
30	0.75	106
300	0.87	31
450	0.87	25
900	0.97	17
1800	1.4	10
2000	1.4	9.5
2450	1.8	7.6

Analyses of X-ray images show that cardiac pacemaker leads are generally implanted at a depth of over 2 cm beneath the skin. Table 6.2 shows that the field components of all electromagnetic fields with frequencies above around 900 MHz are attenuated at least to 1/e, equating to around 37% of their initial value, before they reach the leads. With rising frequency, it therefore becomes increasingly improbable that significant interference voltages are coupled into the leads by the external radiofrequency electromagnetic field.

For frequencies above 2.5 GHz, if the permissible values for occupational exposure are observed and pulsed radiofrequency applications with a peak power considerably higher than the mean power, such as radar, are also excluded, and undue influence on active implants no longer needs to be anticipated, owing to the low penetration depth of the electromagnetic fields.

In the absence of any other source at the present time, the conversion formulae of the E DIN VDE 0848-3-1 draft standard [16] are used in the frequency range between 450 MHz and 2.5 GHz.

6.1.4 Contact currents

Should a worker touch a charged object, or come into contact with an earthed object while themselves being charged by exposure to a static electric field or triboelectricity, a contact current flows. The same can occur when the worker closes an induction loop by touching a conductive object in a time-variable magnetic field or by discharging radiofrequency energy through their body by touching components of an installation.

In general, a distinction can be drawn between two different phases of a contact current event:

- an initial discharge current pulse, e.g. a spark discharge
- a continuous contact current.

Depending on the exposure scenario one phase of the contact current event or both phases may be present. Normally, an initial discharge current with a duration of less than one millisecond occurs only in exposure situations where either a static or time-variable electric field is present. A continuous contact current generally occurs in connection with time-variable electric, magnetic or electromagnetic fields. It can, however, also occur in connection with sustained triboelectric processes.

Whereas the physiological effects are relatively well studied [8, 9, 22, 23, 24, 28], robust data on the effects of contact currents on active implants are still lacking. EN 50527-2-1 [14] states explicitly in its scope that: "*This standard does not address risks to workers who wear a pacemaker from contact currents.*"

Owing to the lack of data, no further details can be provided here, as development of a suitable model, calculation of permissible threshold values and concluding validation of the approach by means of measurements would exceed the scope of this scientific paper.

6.1.5 Threshold values

Summarizing the results of Sections 6.1.1, 6.1.2 and 6.1.3 yields the curves of the threshold value against the frequency shown in **Figures 6.4** and **6.5** and **Tables 6.3** and **6.4**.

The threshold values stated in Figure 6.5 and Table 6.4 for magnetic fields in the frequency range 16.9 MHz < f ≤ 2.5 GHz relate to far-field conditions, as already discussed in Section 5.3.2. Before these values are used, it must be determined whether the exposure to be assessed does in fact relate to far-field conditions.

The threshold values shown in Figures 6.4 and 6.5 and Tables 6.3 and 6.4 represent the maximum peak values in the region of the active implant or the worker's torso and must not be exceeded. Any measurement uncertainties must be taken into account such that they cannot lead to the specified threshold values being exceeded.

Comparing these thresholds with the low and high action levels for non-thermal effects and the action levels for thermal effects in Directive 2013/35/EU [4] yields **Figures 6.6** and **6.7**. Closer examination of Figure 6.6 shows that the low and high action levels for non-thermal effects and the action levels for thermal effects of Directive 2013/35/EU [4] in the frequency ranges 0 Hz ≤ f ≤ 15.9 Hz, and between 1254 Hz and 2.5 GHz for the low action level and 1774 Hz and 2.5 GHz for the high action level, also ensure protection in the first instance for workers wearing implanted active implants. Only in the frequency range between 15.9 Hz and 1254 Hz/1774 Hz the action levels of Directive 2013/35/EU [4] do not guarantee protection for workers wearing implanted active implants when they are exposed to electric fields. In this frequency range, application of the threshold values developed in this document is absolutely essential in order to ensure the safety and health of workers wearing implanted active implants.

Occupational exposure to magnetic fields presents a completely different situation to that of electric fields, as is shown by a more detailed analysis of Figure 6.7. In this case, protection for workers wearing implanted active personal implants is assured only by the action levels for thermal effects of Directive 2013/35/EU [4] and only in the frequency range of approximately 150 kHz <= f <= 2.5 GHz.

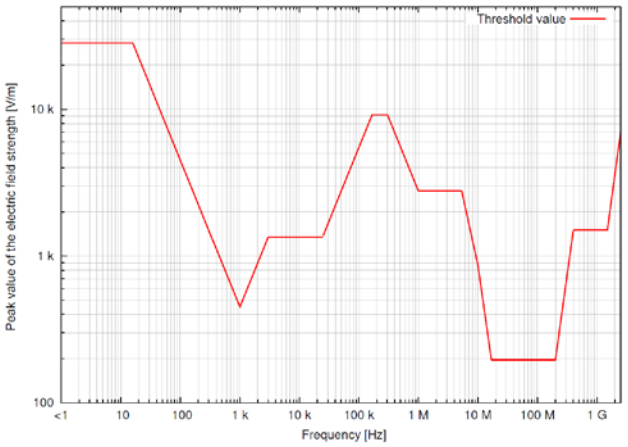

Figure 6.4:
Threshold values of the external electric field strength that do not lead to an influenced behaviour of the active implant

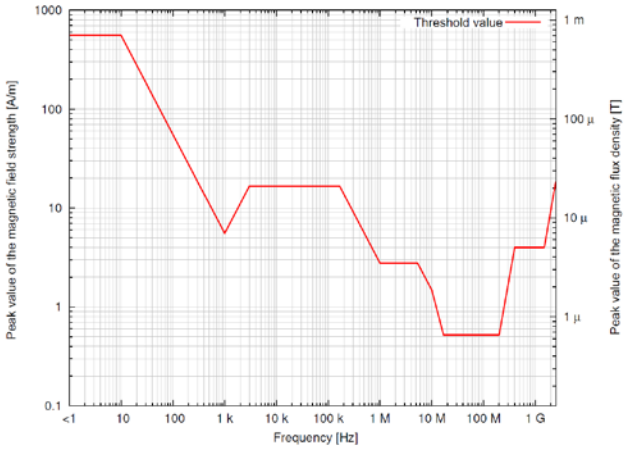

Figure 6.5:
Threshold values of the external magnetic field strength that do not lead to an influenced behaviour of the active implant

Table 6.3:
Threshold values of the external electric field strength that do not lead to an influenced behaviour of the active implant

Frequency f	Peak value of the external electric field strength [V/m]
0 Hz < f ≤ 15.9 Hz	28300
15.9 Hz < f ≤ 1000 Hz	$4.5 \cdot 10^5 / \frac{f}{Hz}$
1 kHz < f ≤ 3 kHz	$450 \cdot \frac{f}{kHz}$
3 kHz < f ≤ 25 kHz	1350
25 kHz < f ≤ 167 kHz	$55 \cdot \frac{f}{kHz}$
167 kHz < f ≤ 300 kHz	9185
300 kHz < f ≤ 1 MHz	$2.77 \cdot 10^6 / \frac{f}{kHz}$
1 MHz < f ≤ 5.33 MHz	2770
5.33 MHz < f ≤ 10 MHz	$6.16 \cdot 10^4 / \left(\frac{f}{MHz}\right)^{1.85}$
10 MHz < f ≤ 16.9 MHz	$6.16 \cdot 10^5 / \left(\frac{f}{MHz}\right)^{2.85}$
16.9 MHz < f ≤ 200 MHz	195
200 MHz < f ≤ 400 MHz	$3.36 \cdot 10^{-5} \cdot \left(\frac{f}{MHz}\right)^{2.94}$
400 MHz < f ≤ 1.5 GHz	1500
1.5 GHz < f ≤ 2.5 GHz	$446 \cdot \left(\frac{f}{GHz}\right)^3$

Table 6.4:
Threshold values of the external magnetic field strength that do not lead to an influenced behaviour of the active implant

Frequency f	Peak value of the external magnetic field strength [A/m]
0 Hz < f ≤ 9.97 Hz	555
9.97 Hz < f ≤ 1000 Hz	$5555 / \frac{f}{Hz}$
1 kHz < f ≤ 3 kHz	$5.55 \cdot \frac{f}{kHz}$
3 kHz < f ≤ 167 kHz	16.7
167 kHz < f ≤ 1 MHz	$2778 / \frac{f}{kHz}$
1 MHz < f ≤ 5.33 MHz	2.78
5.33 MHz < f ≤ 10 MHz	$14.8 / \frac{f}{MHz}$
10 MHz < f ≤ 16.9 MHz	$148 / \left(\frac{f}{MHz}\right)^2$
16.9 MHz < f ≤ 200 MHz	0.52
200 MHz < f ≤ 400 MHz	$8.9 \cdot 10^{-8} \cdot \left(\frac{f}{MHz}\right)^{2.94}$
400 MHz < f ≤ 1.5 GHz	4
1.5 GHz < f ≤ 2.5 GHz	$1.18 \cdot \left(\frac{f}{GHz}\right)^3$

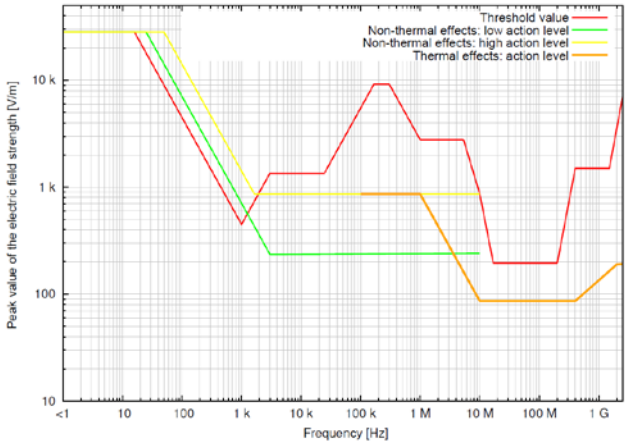

Figure 6.6:
Threshold values of the external electric field strength that do not lead to an influenced behaviour of the active implant, in comparison with the low and high action levels for non-thermal effects and the action levels for thermal effects of Directive 2013/35/EU [4]

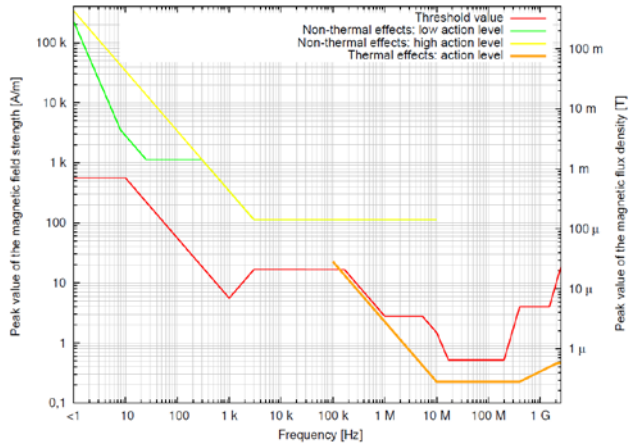

Figure 6.7:
Threshold values of the external magnetic field strength that do not lead to an influenced behaviour of the active implant, in comparison with the low and high action levels for non-thermal effects and the action levels for thermal effects of Directive 2013/35/EU [4]

As can be seen in Figure 6.7, in the frequency range 0 Hz ≤ *f* ≤ 150 kHz, and in consideration of the high action levels for non-thermal effects up to 10 MHz, the peak values lie significantly above the threshold values for implanted active implants. Where workers wearing active implants are exposed to magnetic fields, application of the threshold values developed in this document is therefore absolutely essential in the frequency range 0 Hz ≤ *f* ≤ 150 kHz to assure the workers' safety and health.

6.2 Passive implants

Article 4(5)d of Directive 2013/35/EU [4] explicitly requires that special consideration be given during exposure assessment and risk assessment to workers wearing passive implants, but then specifies only a single action level (see Table B4 of Directive 2013/35/EU [4]) for the "*Interference with active implanted devices, e.g. cardiac pacemakers*". Binding European or international provisions by which the safety and health of workers wearing passive implants can be assured still do not exist.

In Germany, protection for workers wearing passive implants has been regulated for some time in accident prevention regulation BGV B11 (electromagnetic fields) [27], which is supported by the BGR B11 rules for safety and health at work (electromagnetic fields) [7]. Section 3.10.3 of BGR B11 [7] concerning workers with passive implants states that for insured persons wearing passive implants, such as artificial joints or skull plates, access restrictions are generally not required, provided the values permissible for exposure area 1 (area of elevated exposure or hazard area) are complied with; access by such insured persons to areas of elevated exposure must be regulated on a case-by-case basis. The validity of this requirement has been reviewed several times by calculations performed on anatomically correct body models since accident prevention regulation BGV B11 [27] came into force in 2001.

To ensure the safety and health of workers wearing passive implants, i.e. to avoid impermissible forces acting on the implant, the undesirable increase in electric field strength in the tissue in the region of the implant and an impermissible temperature rise of the implant or the tissue in direct proximity to it, the values permissible for exposure area 1 stated in the BGV B11 accident prevention regulation [27] are adopted below, with a small number of exceptions, as threshold values for passive implants. The exceptions concern static electric and magnetic fields and are described in the following sections.

The provisions also ensure the safety and health of workers with other metallic/conductive foreign objects embedded in their body tissue.

6.2.1 Static electric fields

As discussed in Section 3.1.1, an external static electric field is not able to penetrate the surface of the body. The interior of the body is virtually field-free and thus shielded from any effect of the external static electric field. A mutual influence between external static electric fields and passive implants is therefore not possible.

However, as already described, static electric fields can give rise to discharge processes and the associated electric shocks (see Section 6.1.1.). The permissible static electric field strength, however, is limited only by way of the anticipated indirect effects.

To avoid unnecessary complexity, the threshold value of 28.3 kV/m introduced in Section 6.1.1 for workers wearing active implants and exposed at the workplace to static electric fields is also applied to persons with passive implants, subject to no further limitations arising due to contact currents where the worker is able to touch an earthed conductive or unearthed object (see Section 6.2.4.).

6.2.2 Static magnetic fields

The forces exerted by static magnetic fields on ferromagnetic objects are analysed in the "Projectile risk" section of research report FB400, published by the German Federal Ministry of Labour and Social Affairs (BMAS) [8]. These results can also be applied to the protection of workers wearing passive implants and exposed to static magnetic fields.

Whereas a minimum magnetic flux density value of around 60 mT is required before "normal" (i.e. not actively shielded) static field sources lead to undesirable interaction with passive implants, the minimum magnetic flux density leading to such interaction for actively shielded superconducting magnets, which are used in particular in modern magnetic resonance imaging, is only around 30 mT [8].

These two values are introduced below as threshold values for static magnetic fields.

6.2.3 Low-frequency electric and magnetic fields and radiofrequency electromagnetic fields

As already discussed in Section 6.2, the permissible values for exposure area 1 set out in the BGV B11 accident prevention regulation [27] have for the most part been adopted as threshold values for passive implants. Necessary adjustments are made to the corner frequencies in the low-frequency range to achieve a continuous transition to the values specified for static electric and magnetic fields.

Since the sites of implantation may differ widely and the passive implants are located in some cases only a few millimetres beneath the skin, threshold values must be specified for the entire frequency range from 0 Hz ≤ f ≤ 300 GHz, even though significant interaction for frequencies of the acting fields beyond more than a few 10 GHz may be expected only for a small number of passive implants.

6.2.4 Contact currents

The physical principles for the incidence of contact currents when persons are exposed to static electric, low-frequency electric and magnetic and radiofrequency electromagnetic fields have already been described in Section 6.1.4. No data is available on the interaction between the electric tissue field strengths/body currents caused by contact currents and passive implants as yet.

Since substantiated model studies are also not yet available, no further information on this aspect can be provided in this document, as the studies required for this purpose would exceed the scope of this scientific paper.

6.2.5 Threshold values

Combining the results of Sections 6.2.1, 6.2.2 and 6.2.3 yields the curves for the threshold value against the frequency shown in **Figures 6.8** and **6.9** and **Tables 6.5, 6.6** and **6.7**.

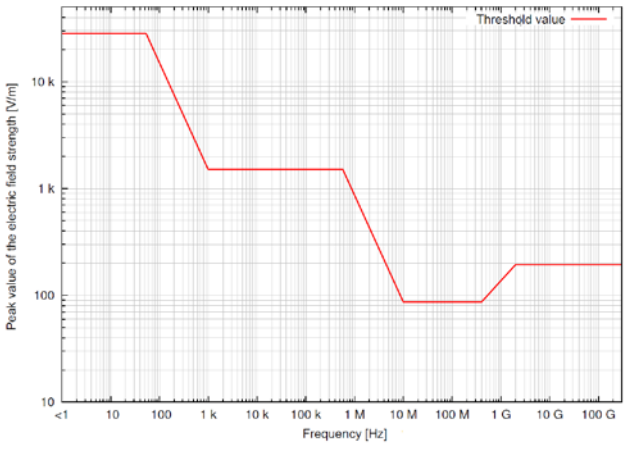

Figure 6.8:
Threshold values for the external electric field strength that ensure the safety of workers wearing passive implants

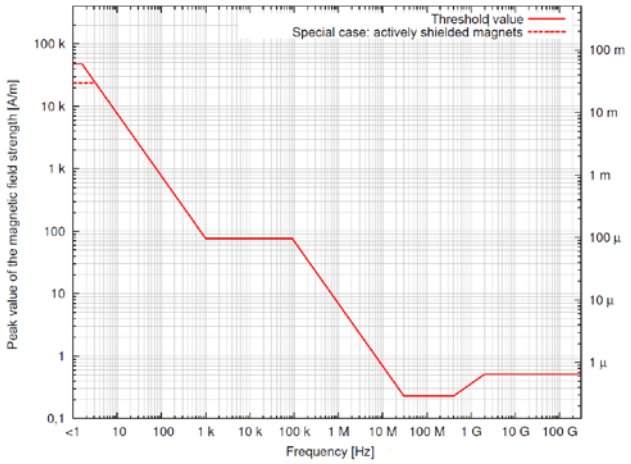

Figure 6.9:
Threshold values for the external magnetic field strength that ensure the safety of workers wearing passive implants

Table 6.5:
Threshold values for the external electric field strength that ensure the safety of workers wearing passive implants

Frequency f	Peak value of the external electric field strength [V/m]
0 Hz < f ≤ 53.3 Hz	28300
53.3 Hz < f ≤ 1000 Hz	$1.51 \cdot 10^6 / \frac{f}{Hz}$
1 kHz < f ≤ 576 kHz	1510
576 kHz < f ≤ 10 MHz	$8.68 \cdot 10^5 / \frac{f}{kHz}$
10 MHz < f < 400 MHz	86.8
400 MHz < f ≤ 2 GHz	$4.34 \cdot \sqrt{\frac{f}{MHz}}$
2 GHz < f ≤ 300 GHz	194

Table 6.6:
Threshold values for the external magnetic field strength that ensure the safety of workers wearing passive implants

Frequency f	Peak value of the external magnetic field strength [A/m]
0 Hz < f ≤ 1.6 Hz	47750
1.6 Hz < f ≤ 1000 Hz	$76400 / \frac{f}{Hz}$
1 kHz < f ≤ 91 kHz	76.4
91 kHz < f ≤ 30 MHz	$6.93 / \frac{f}{MHz}$
30 MHz < f ≤ 400 MHz	0.231
400 MHz < f ≤ 2 GHz	$11.5 \cdot 10^{-3} \cdot \sqrt{\frac{f}{MHz}}$
2 GHz < f ≤ 300 GHz	0.515

Table 6.7:
Threshold values for the external magnetic field strength that ensure the safety of workers wearing passive implants when exposed to actively shielded magnets

Frequency f	Peak value of the external magnetic field strength [A/m]
0 Hz < f ≤ 3.2 Hz	23875
3.2 Hz < f ≤ 1000 Hz	$76400/\frac{f}{Hz}$
1 kHz < f ≤ 91 kHz	76.4
91 kHz < f ≤ 30 MHz	$6.93/\frac{f}{MHz}$
30 MHz < f ≤ 400 MHz	0.231
400 MHz < f ≤ 2 GHz	$11.5 \cdot 10^{-3} \cdot \sqrt{\frac{f}{MHz}}$
2 GHz < f ≤ 300 GHz	0.515

The threshold values shown in Figures 6.8 and 6.9 and Tables 6.5, 6.6 and 6.7 represent the maximum peak values in the region of the worker's active implant and must not be exceeded. Any measurement uncertainties must be taken into account such that they do not result in the threshold values stated being exceeded. For the special case of exposure to actively shielded magnets, the values stated in Table 6.7 and Figure 6.9 apply. Figures 6.10 and 6.11 show the results of comparison between these threshold values and the low and high action levels for non-thermal effects and action levels for thermal effects of Directive 2013/35/EU [4].

Where persons are exposed to electric fields, the action levels stated in Directive 2013/35/EU [4] also ensure the safety of persons wearing passive implants, provided the lower of the two values is always applied in ambiguous cases, particularly where action levels exist for thermal and non-thermal effects in the same frequency range. This significantly simplifies the assessment procedure for persons wearing passive implants.

The threshold values shown in **Figure 6.10** can also be used for exposure assessment in the frequency range between 1 kHz and around 1 MHz if necessary, should the action levels stated in Directive 2013/35/EU [4] be exceeded.

Closer analysis of **Figure 6.11** shows that the action levels stated in Directive 2013/35/EU [4] can only be used for the protection of persons wearing passive implants who are exposed to magnetic fields at the workplace in the area of thermal effects for frequencies of 100 kHz and more. The low action levels for non-thermal effects can also be used in the frequency range between around 3 and 70 Hz to assess the exposure of persons wearing passive implants.

In all other frequency ranges, application of the threshold values developed in this document is essential for ensuring the safety and health of workers wearing passive implants.

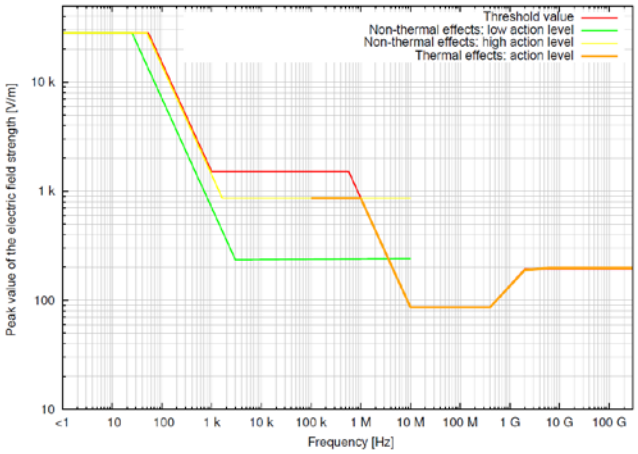

Figure 6.10:
Threshold values for the external electric field strength that ensure the safety of workers wearing passive implants, compared to the low and high action levels for non-thermal effects and the action levels for thermal effects of Directive 2013/35/EU [4]

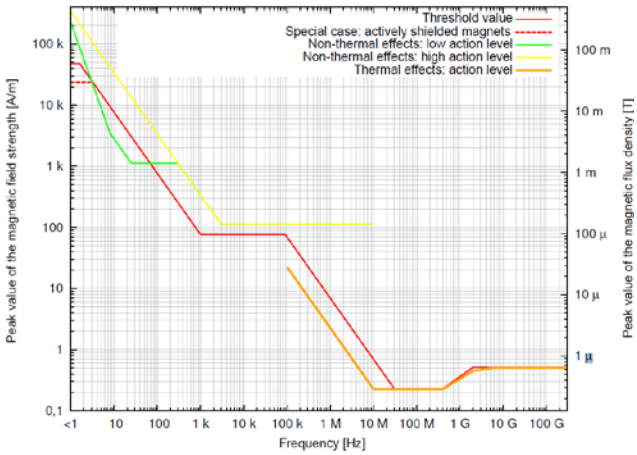

Figure 6.11:
Threshold values for the external magnetic field strength that ensure the safety of workers wearing passive implants, compared to the low and high action levels for non-thermal effects and the action levels for thermal effects of Directive 2013/35/EU [4]

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