**BEMER THERAPY IN PATIENTS WITH IMPLANTED PACEMAKERS OR DEFIBRILLATORS**

1. **Introduction**

Cardiac pacemakers and defibrillators are equipped with sensitive electrical amplifiers that detect the intracardiac EKG. The implants can malfunction if the body’s own signals are overridden by interference signals.

Interference signals are usually generated by electromagnetic fields. Such fields are encountered under high tension lines or in the vicinity of high-powered radio stations, for example. These fields induce electrical potentials in a coil in a manner similar to radio reception.

Cardiac pacemakers and defibrillators consist of an electronic impulse generator and electrodes. The electrodes are attached to wires and fed into the heart, where they pick up the intracardiac signal. These electrode probes together with the impulse generator and a return line through the body tissue constitute a coil. If this coil encounters an electromagnetic field, signals are generated in the coil that can interfere with the implant. The greater the area of this „coil“ (illustrated in yellow in the figures) is, the greater the interference signals become.

The induction surface ($F$) is considerably reduced with a bipolar electrode arrangement (i.e., both electrodes are in close proximity to the heart). For this reason only a bipolar arrangement may now be used with any new implant.

Defibrillators generally have a bipolar configuration.

The doctor must therefore choose an implant position in which the coil area is small. For this reason an abdominal implant position is not permissible.
Pacemakers and defibrillators have electronic circuits for filtering out undesired signals. But the only way to say for sure whether an interference field can affect the implant is if the filtering properties are known. The effect, i.e., the filtering properties, that the implant should have are described in the harmonized European standards EN 45502-2-1 for pacemakers and EN 45502-2-2 for defibrillators. However, these standards are not binding.

According to European Council Directive 90/385/EEC of 20 July 1990 as amended by Directive 2007/47/EG of 05 September 2007, implants designated with a CE symbol must fulfill fundamental safety requirements. According to Article 5, it shall be presumed that devices that are compliant with the harmonized standards also fulfill the fundamental requirements. However, this does not mean that devices that do not comply explicitly with the harmonized standards may not also be classified as safe by the bodies responsible for approval and affixed with a CE symbol if the safety thereof can be plausibly demonstrated by other means.

Even if pacemakers or defibrillators fulfill the aforementioned harmonized standards, these devices are not necessarily identical in terms of their electrical interference protection features. Under 27.5.1 of this standard, it states explicitly that the requirements of the standard in the frequency range of up to 1 kHz may still be considered as fulfilled even if the devices are interfered with. In this case the manufacturer must only provide a warning that the pacemaker may be interfered with at this setting, or else state the sensitivity setting at which the device will no longer be interfered with. What this actually means is that a pacemaker or a defibrillator may be more sensitive to electrical interferences than to the intracardiac signal that it is supposed to detect.

![Filtration curve of a typical defibrillator with a perceptual sensitivity of 0.3 mV](image1)

A 50 Hz interference signal with 0.2 mV is just under the detection threshold.  

![A 50 Hz interference signal with 0.2 mV is just under the detection threshold](image2)
In order for a 0.2 mV interference signal not to be detected, in this case the perceptual sensitivity must be programmed to 0.3 mV. In order to make units comparable with one another (i.e., to come up with a uniform measurement for assessing interference potential), a standard factor must be applied. In this case the standard factor is $0.3 \text{ mV} : 0.2 \text{ mV} = 1.5$.

Cardiac pacemakers or defibrillators react indirectly to the voltages induced by electromagnetic fields rather than directly to the fields themselves. A transfer equation is required for converting field strengths (A/m) to voltage (mV) at the unit input. These transfer equations were developed in VDE 0848-3-1 and adopted in the European Standard EN 50527-2-1.

2. Interference resistance

Certain fundamental conditions must be met in order to assess the interference resistance of an implant.

- The implant must have specific filtering properties (EN 45502-2-x).
- The standard factor must be known.
- The induction surface (implant position) must be known.
- The sensitivity setting must be known.
- The strength of the interfering electromagnetic fields must be known.
- The field/voltage transfer equations must be applied.

Thus it comes down to interplay among generators of electromagnetic fields, device manufacturers, and doctors inserting and adjusting implants. The goal is to enable a patient with a pacemaker or a defibrillator to move about in normal surroundings just as safely as a person without such an implant. For industrial operations in which electromagnetic fields are generated and in the interests of doctors and patients, the standardization committee responsible for the safety of active surgical implants in the Federal Republic of Germany, VDE GUK 812.5 „Active surgical implants“, drafted the application guide VDE-AR-E 2750-10 „Rules for the technically optimized application of implantable cardiac pacemakers, defibrillators, and CRT devices“. This standard ensures that the generators of electromagnetic fields can be sure that implanted cardiac pacemakers and defibrillators will be applied by doctors in such a way that in normal surroundings, no interferences from electromagnetic fields can occur.
3. Doctors' responsibility
An underlying principle of this standard is that no doctor can be expected to perform an analysis for each patient based on the induction law and using complex mathematical equations in order to adjust the implant so as to eliminate any hazards due to electromagnetic fields. The doctor is therefore likewise not expected to warn the patient about such hazards, nor to suggest any specific behavioral measures.

However, the responsible doctor can be expected to choose a product that complies with the standard, to implant it in keeping with good medical practice, and to adjust the sensitivity with the standard factor in mind so that interferences are no longer possible. Every doctor is required to do this, regardless of any national standard or convention.

The considerations involved are complex and not easily implemented. The standardization committee responsible for the safety of active surgical implants in the Federal Republic of Germany has therefore calculated the most sensitive settings for which the implants remain unaffected on behalf of the doctor under worst case scenarios. The doctor must take these threshold values into account. This means that only the doctor is able to ensure that an implant remains unaffected in normal surroundings. „Normal surroundings“ is understood to mean compliance with the electromagnetic field threshold values according to the 26th German Federal Emission Protection Ordinance (26. BfmSchv) and/or the corresponding ICNIRP reference values.

4. Safety of the implants
An implant is safe from electromagnetic fields if the doctor chose the proper device and implanted and programmed it correctly. Specifically, this means:

- Pectoral implant position
- Standard-compliant implant
- Sensitivity value set with the standard factor taken into account
- unipolar > 6.8 mV
- bipolar > 0.34 mV

5. Concise statement:
No electromagnetic field-induced interference of implanted cardiac pacemakers or defibrillators can occur in BEMER therapy if the implant is compliant with the European Standard for these implants and if the doctor applies the device in a competent manner.