1 # Foreword

2 This draft European Standard was prepared by the Technical Committee CENELEC TC 106X,
3 Electromagnetic fields in the human environment. It is submitted to the CENELEC enquiry.

4 _____

5

Contents

Figures

Tables

1 Scope

This European Standard provides the procedure for the specific assessment required in Annex A of EN 50527-1 for AIMD-Employees with a pacemaker.

The purpose of the specific assessment is to determine the risk of workplace exposure for an AIMD-Employee with a pacemaker. The assessment includes the likelihood of clinically significant effects and takes account of both transient and long term exposure within specific areas of the workplace.

The frequency range to be observed is from 0 Hz to 3 GHz. Above 3 GHz no interference with the pacemaker occurs when the exposure limits given in 2004/40/EC are not exceeded.

NOTE The rationale for limiting the observation range to 3 GHz can be found in Clause 5 of ANSI AAMI PC 69:2007

2 References

2.1 Normative references

EN 50527-1:2010, Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices – Part 1: General

EN 45502-2-1:2003, Active implantable medical devices – Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrythmia (cardiac pacemakers)

EN ISO 14155-1:2009, Clinical investigation of medical devices for human subjects – Part 1: General requirements (ISO 14155-1:2003)

EN ISO 14155-2:2009, Clinical investigation of medical devices for human subjects – Part 2: Clinical investigation plans (ISO 14155-2:2003)

2.2 Regulatory references

1999/519/EC, Council Recommendation of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz), Official Journal L 199, 30/07/1999, p. 59 – 70

3 Definitions (additional to the definitions in EN 50527-1)

3.1
implantable pulse generator (IPG)
part of the active implantable medical device, including the power supply and electronic circuit, that produces an electrical output

NOTE For purposes of this Part 2-1, the term implantable pulse generator describes any active implantable medical device that incorporates functions intended to treat bradyarrhythmias.

3.2
pacemaker
active implantable medical device intended to treat bradyarrhythmias, comprising an implantable pulse generator and lead(s)

3.3
electrode
electrically conducting part (usually the termination of a lead) which is designed to form an interface with body tissue or body fluid

3.4
unipolar lead
lead with one electrode

3.5
bipolar lead
lead with two electrodes that are electrically isolated from each other

3.6
reference levels
the reference levels for general public exposure to electric, magnetic and electromagnetic fields as specified in 1999/519/EC

3.7
Table 1
when used in this standard Table 1 or Table 1 equipment means Table 1 of EN 50527-1 or the equipment specified therein together with additional information given in Annex A

4 Specific assessment

4.1 Description of the assessment process

A specific risk assessment for the AIMD-Employee bearing a pacemaker is required when one of the following three conditions exists:

(a) there is equipment present in the workplace which is either not included in, or not used in accordance with Table 1 of EN 50527-1 subject to amendments to Table 1 as noted in Annex A of this document and the pacemaker-bearing employee does not have a history of uninfluenced behaviour in its presence;

(b) all equipment at the workplace is listed in Table 1 of EN 50527-1 subject to amendments to Table 1 as noted in Annex A of this document and is used in accordance with it, but the pacemaker-Employee has received warning(s) from the responsible physician that their pacemaker may be susceptible to electromagnetic interference (EMI), thereby increasing their risk at the workplace. There are two types of warnings that may be given:

   i. patient specific warnings provided by the responsible physician to the pacemaker -employee due to sensitivity settings in effect that may cause changes in pacemaker behaviour in the presence of electromagnetic fields (EMF) that are below the reference levels; or

   ii. general warnings supplied by the pacemaker manufacturer in accompanying documentation about recognized behaviour changes of the pacemaker when it is subjected to EMF generated by specific types of equipment;

(c) there is equipment present in the workplace either not included in, or not used in accordance with Table 1 of EN 50527-1 subject to amendments to Table 1 as noted in Annex A of this document AND for which the pacemaker-Employee does have a history of uninfluenced behaviour while in its presence BUT the pacemaker-Employee has received a specific warning as described above.

In order to minimize the burden placed on the employer and pacemaker -Employee, the assessment should begin with the investigation steps shown in Figure 1. The steps to be taken are based upon whether the specific assessment is the result of an equipment issue or a patient warning issue.

When only condition (a) exists, then 4.1.1 shall apply. When only condition (b) exists, then 4.1.2 shall apply. When condition (c) exists, then both 4.1.1 and 4.1.2 shall apply.

NOTE When a pacemaker is tested according to EN 45502-2-1, the manufacturer is required to provide a warning to the implanting physician in the accompanying technical information as to any sensitivity settings available in the device that if used, afford the device with a reduced immunity to certain types of EMI. A specific warning would only be given to the patient receiving the implant if they were discharged with one of these settings in effect, or if at follow-up, a change to one of these settings was made for clinical reasons.

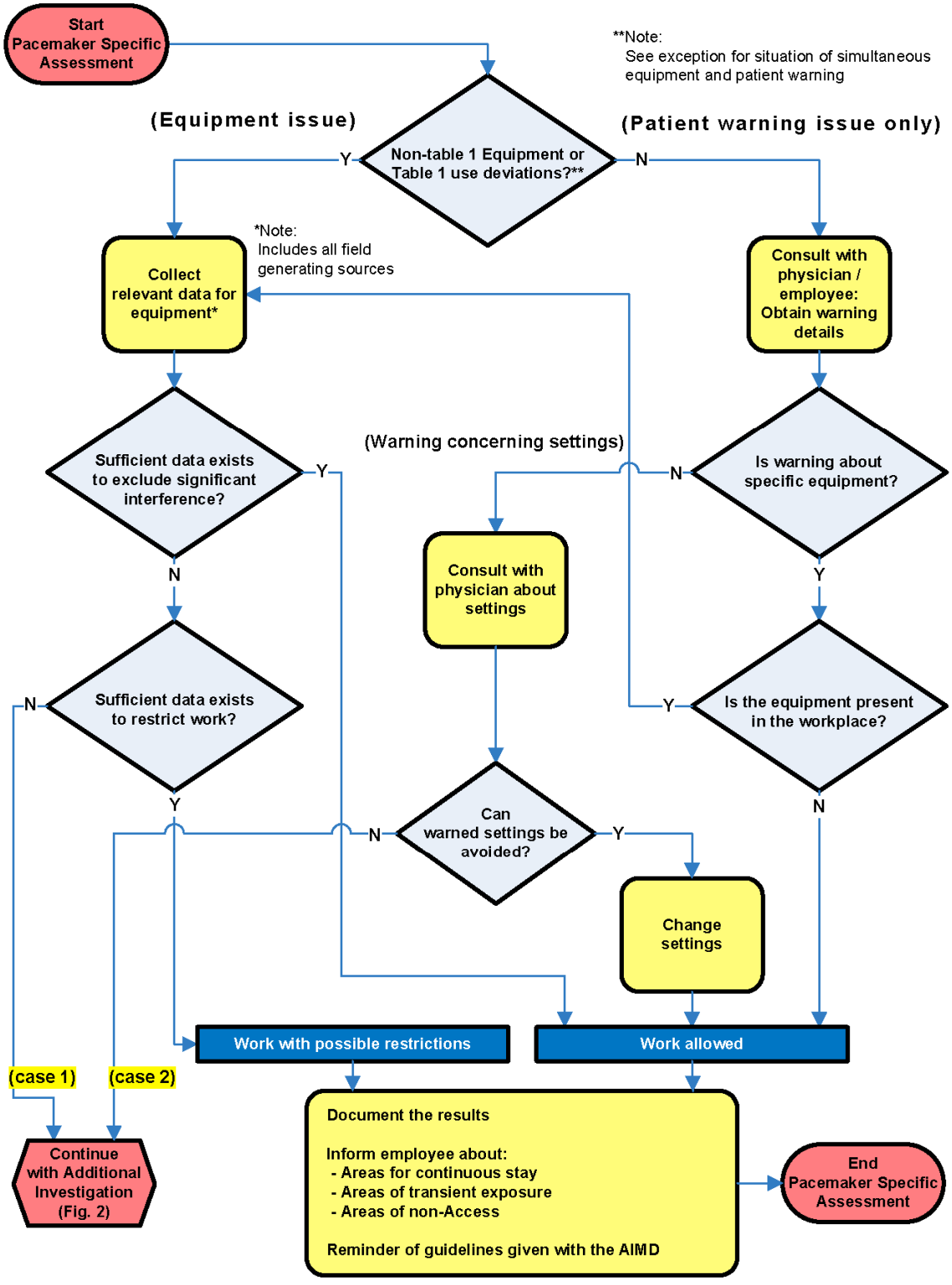


Figure 1 - Pacemaker specific assessment process

4.1.1 Non-Table 1 equipment is present, or listed equipment is not used in accordance with Table 1

Information relevant to the equipment or other field generating sources under consideration shall be collected to sufficiently answer the following two questions:

- can it be determined that clinically significant interference with the AIMD-Employee's pacemaker will not occur as a result of expected exposure to the equipment under consideration? If so, no further assessment is required and documentation of the result can proceed, as required in Clause 5;

- can it be determined that the AIMD-Employee can return to the workplace only with restrictions placed on the work tasks or areas of access? If so, no further assessment is required and documentation of the work restrictions can proceed as required in Clause 5.

When neither of these questions can be answered positively, additional investigation, hereafter referred to as "Case 1", is required as discussed in 4.1.3.

NOTE the intent of this clause is to find and utilize information that may already exist that allows one to conclude the assessment without further, more costly and time consuming effort. It is recommended that experts who are likely to have such information be contacted. Examples of such experts are: the pacemaker manufacturer, equipment manufacturer, employer's technical department, consultants, or others skilled in EMI effects with implanted pacemakers.

4.1.2 AIMD-Employee has received warning(s) from the physician

The responsible physician and AIMD-Employee shall be consulted to determine the type of and details for any EMI warnings applicable to the AIMD-Employee's pacemaker.

If the warning is about behaviour of the pacemaker due to interference from particular types of equipment (see 4.1 (b) (ii)) then it shall first be determined whether that equipment is actually present in the workplace:

- if the equipment is not present the AIMD-Employee is allowed to work without restrictions and the pacemaker specific assessment can be concluded and documented as required in Clause 5.

- if the equipment subject to the warning is present the steps given in 4.1.1 shall be taken.

If the warning is due to settings in effect that may cause reduced immunity (see 4.1 (b) (i)) to EMI that is at or below the reference levels, the responsible physician shall be consulted to determine whether such settings can be changed to avoid those that are associated with the warning, thereby restoring standard immunity levels:

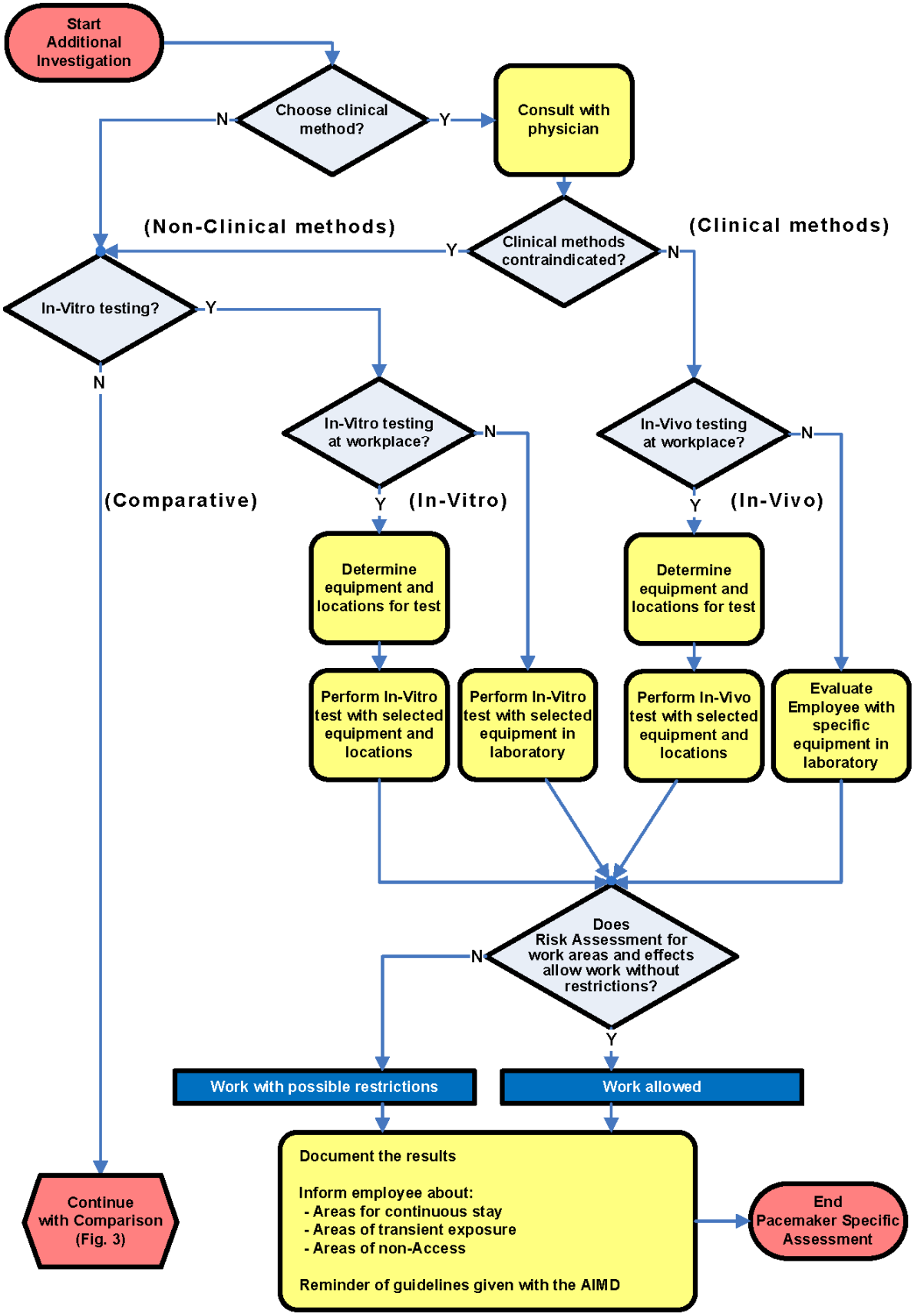
- if it is determined that such a change can be made, the AIMD-Employee shall be advised to arrange, through consultation with the responsible physician, for these changes to be made prior to returning to work. When the setting change has been completed, the AIMD-Employee is allowed to work without restrictions. The results shall be documented as required in Clause 5 and the assessment is concluded.

- if the settings cannot be changed, then additional investigation, hereafter referred to as "Case 2" is required as discussed in 4.1.3.

4.1.3 Cases for additional investigation

When the investigation steps shown in Figure 1 have been followed but fail to mitigate or dismiss risk to the AIMD-Employee from the effects of workplace EMI, then an additional investigation shall be performed as shown in Figure 2. The goal of the investigation is to determine the likelihood of clinically significant response to the EMI at the workplace that is the result of:

- **Case 1**: Equipment is used at the workplace that is
  - either not listed in, or not used in accordance with, Table 1 of EN 50527-1, and for which there is no information available that allows a pre-determination of safe or restricted work for the AIMD-Employee, or
  - capable of emitting fields that may induce pacemaker lead voltages greater than the immunity levels established by conformity with the pacemaker product standard, EN 45502-2-1, or
  - known by the pacemaker manufacturer to potentially cause interference with the AIMD-Employees' pacemaker and there is no applicable safe use guideline available from other sources.
- **Case 2**: The responsible physician has prescribed settings of the AIMD-Employees' pacemaker that make it susceptible to EMI even from equipment listed in Table 1 of EN 50527-1.



233
234

Figure 2 - Additional investigation process

4.1.4 Choice of investigative method

There are two alternative types of investigative method that may be used:

- clinical (or in vivo) methods directly involving the AIMD-Employee who is monitored for interference effects; or
- non-clinical methods based upon a choice of either in vitro or comparative study.

If a chosen method provides insufficient information for the risk assessment further investigation is necessary.

4.1.4.1 Considerations in choosing a clinical method

Prior to choosing to use a clinical method (for examples see Annex B) the responsible physician should be consulted to determine if it is contraindicated. If it is contraindicated, a non-clinical method shall be chosen.

NOTE AIMD-Employees who are pacemaker dependent, or who would otherwise suffer harm from the effects of even temporary EMI are examples of those who would be contraindicated.

When considering the use of a clinical method, a second consideration is the choice of site at which it should be performed. Generally, the preferred site is the AIMD-Employee's workplace, but this may not be feasible for a number of reasons. Consideration should be given to whether one of the methods described in Annex A can be performed while the AIMD-Employee is moving through the workplace or performing the anticipated job function. Limiting factors may include

- harsh or dirty environments,
- confined spaces,
- inability to provide for coincident monitoring by clinical personnel or manufacturer representatives, and their equipment, possibly due to the specific location or the non-availability of personnel or equipment,
- workplaces consisting of many locations physically separated by geography or those which are not accessible to clinicians and / or pacemaker manufacturer representatives,
- workplace situations and equipment that may offer an EMF environment that varies significantly from day to day such that the exposure provided during a single test may not represent the likely worst case, or even typical, exposure values for that AIMD-Employee.

If it is determined that a clinical investigation at the workplace is not feasible, the assessment team may consider the possibility that the method could be applied in a laboratory setting. At a minimum, the following two limiting factors should be considered:

- the additional investigation is Case 2, where it is not known which equipment in the workplace may be a cause of EMI that may be hazardous to the AIMD-Employee In such cases it is therefore impractical to bring all possible workplace equipment to the laboratory for testing;
- the additional investigation is Case 1, involving specific equipment of unknown EMI characteristics, when such equipment cannot be taken to a laboratory due to considerations of any kind.

If a determination is made to perform a clinical investigation, then one of the methods in Annex A may be chosen and carried out. See 4.2.

4.1.4.2 Considerations in choosing a non-clinical method

Alternatively a non-clinical method may be chosen for the additional investigation, for instance when

- the workplace EMF environment is known to fluctuate significantly from day to day, thereby rendering additional uncertainty in a single instance of clinical testing,

- the range of field levels associated with the workplace or specific equipment may already be known. In this case a comparative approach as outlined in 4.3.3 may be readily attempted,

- the clinical approach is impracticable for any of the other reasons given in 4.1.4.1.

If a determination is made to perform a non-clinical method, one of the two methods discussed in 4.3 shall be chosen.

4.2 Clinical investigation

Once it has been decided to perform a clinical investigation and found to be feasible, it should be carried out in accordance with the requirements of EN ISO 14155-1 and EN ISO 14155-2.

NOTE These standards define procedures for the conduct and performance of clinical investigations of medical devices.

This investigation may be performed in either the AIMD-Employee's workplace or in a laboratory setting, as determined in 4.1.4.1.

The assessment team may choose one of the methods described in Annex A. The choice and rationale shall be documented according to Clause 5.

If the AIMD-Employee's situation is Case 1, involving specific equipment, the assessment team should decide whether to perform the investigation in a provocative or non-provocative manner. The choice shall be documented and a test plan prepared, reviewed and approved by the assessment team:

- a non-provocative test subjects the AIMD-Employee to all exposure situations associated with the equipment that is anticipated to be present during the normal execution of their duties. Such a test should include closest expected distances and orientations relative to the equipment, as well as a duration of exposure sufficient to determine whether clinically significant EMI effects should have occurred. The limitation of this approach is that it may reveal no effects, in which case there may be distances, orientations, or durations for exposure, which while not anticipated, may occur as a result of unusual working conditions. In this case, the residual risk may be higher1 since a boundary of safe exposure has not been determined. If this approach is taken, the instructions to the AIMD-Employee shall include a statement of the higher risk when performing their duties in a manner different from that used in the testing.

- a provocative test subjects the AIMD-Employee to exposure situations that include decreased distances or longer exposure durations than are anticipated during normal execution of their job duties. These exposures must be planned and executed to protect the safety of the AIMD-Employee. The advantage of this approach is that it may reveal a boundary of safe exposure and/or a duration of safe transient exposure. In this case, the residual risk is reduced since the safe exposure conditions are more fully known.

NOTE 1 Where available, information about the known range of field levels compared with the actual levels during the tests can reduce the residual risk.

NOTE 2 If the AIMD-Employee's situation is Case 2, a provocative clinical test may not be recommended when exposure to many items of equipment or areas of access in the workplace would be required.

4.3 Non-clinical investigation

There are two methods to the non-clinical investigation:

- in vitro testing, involving the use of a pacemaker device and lead inserted into a torso simulator that is then exposed to the unknown workplace EM fields;

- comparative study, involving characterization of the workplace EMF and a prediction of the effects on the AIMD-Employee's pacemaker through analysis and comparison with pacemaker immunity levels.

NOTE A model of a portion of the human body that duplicates selected properties of the anatomy for the purposes of testing the influence from external effects.

The following factors may be considered when making the choice of which method of non-clinical investigation to use:

- in vitro testing must be performed using a device and leads of the same make and model as those, implanted in the AIMD-Employee. See 4.3.1. If the In vitro method is chosen it should be performed in accordance with the requirements of 4.3.2;

- comparative study requires the determination of induced voltages, and pacemaker immunity. If the situation is Case 1 and it is found that the field levels are below the reference levels, this method can result in an early determination that the risk to the AIMD-Employee is sufficiently low and that the AIMD-Employee can work without restrictions. The finding shall be documented as required in Clause 5 and the assessment is concluded. Otherwise the comparison according to Figure 3 is necessary. If the Comparative study method is chosen, it should be performed in accordance with the requirements of 4.3.2.

4.3.1 Non-clinical investigation by in vitro testing

4.3.1.1 Determination of in vitro testing feasibility

The following requirements are necessary to perform an in vitro test and should be considered:

- the workplace environment is such that a torso simulator, device programmer, and test personnel can be accommodated for the duration of anticipated testing;

- a fully functional pacemaker and leads of the same make and model as that implanted in the AIMD-Employee can be obtained from the manufacturer or the physician;

- a device programmer compatible with the AIMD-Employee's pacemaker is available and capable of device interrogation with up-to-date programming software;

- the approximate lead layout as implanted in the AIMD-Employee is known and available.

If all requirements can be met, then the in-vitro method may be chosen.

4.3.1.2 Requirements for in vitro testing

The pre-requisites given in 4.3.1.1 shall be met. The pacemaker and leads shall be arranged within a torso simulator so as to approximate the layout of the lead known for the AIMD-Employee. The pacemaker shall be programmed with the same parameters and have the same operating software as that existing for the AIMD-Employee.

A test plan shall be prepared that defines:

- the exposure situations (orientation, distance and duration) to be used for the testing, whether it is to evaluate EMI with specific equipment or within workplace areas;

- methods and configurations for testing to detect effects, such as pacing inhibition, rate tracking, or asynchronous pacing;

- criteria for results observation, recording, and interpretation, including a definition of which effects should be considered clinically significant for the AIMD-Employee in question;

- provisions for monitoring the device behaviour in the presence of unknown field levels. Since the level of applied fields may be higher than those specified in the product test standard EN 45502-2-1, care must be exercised to prevent irreversible damage to the device that would invalidate test results.

NOTE For tests with specific equipment, it is recommended to plan provocative tests as risk to the AIMD-Employee is not a factor. Safety of the personnel conducting the testing must still be considered. It is also recommended that such tests be planned in such a way that the field levels and potential for effects are increased during the assessment up to the point at which it becomes provocative. This will minimize the chance of device damage.

The test plan shall be reviewed and approved by assessment team and where necessary input obtained from the pacemaker manufacturer.

An example for performing an in-vitro test is given in Annex C.

4.3.2 Non-clinical investigation by comparative study

This method of investigation is described in Figure 3 and is based on the comparison of the induced voltages on the leads with the voltage immunity at the connectors of the pacemaker.

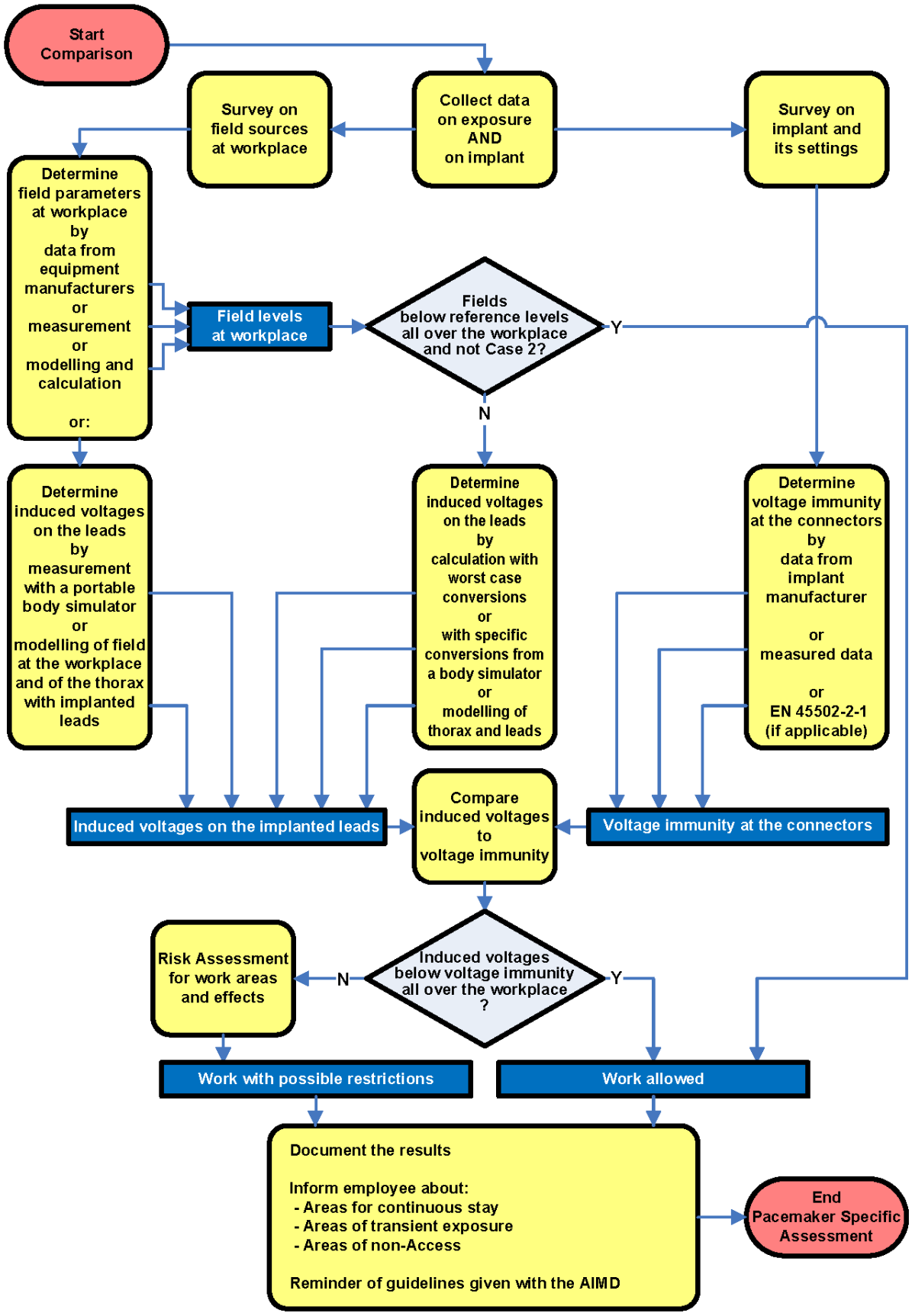


Figure 3 - Comparison process

4.3.2.1 Determination of the induced voltages on the leads

One method is to directly determine the induced voltages by measurement using a body simulator or by modelling the field and the thorax with implanted leads included (see example in Annex C).

Another method is to determine the EMF levels and associated induced lead voltages, either throughout the AIMD-Employee's anticipated work areas (Case 2), or that which is associated with specific equipment (Case 1). In either case, the fields must be determined through measurement, modelling (see example in Annex C) or use of pre-existing information for the equipment of concern:

- for Case 2 situations, the fields must be determined by performing a workplace survey of all non-Table 1 equipment that the AIMD-Employee may reasonably be expected to encounter or work with. The scope of the equipment to be measured, modelled or otherwise assessed may be reduced by application of prior knowledge obtained from experts;

- if the field levels are determined to be below the reference levels and the situation is not Case 2, the AIMD-Employee can work without restrictions. The finding shall be documented as required in Clause 5 and the assessment is concluded;

- if the situation is Case 2 or the fields are found to exceed the reference levels, the next step is to determine the induced voltages on the leads, either by calculations with worst case conversions (see examples in Annex E (all frequencies) and Annex F (specific for power lines) or with specific conversions derived from a body simulator or by modelling of thorax and leads (see example in Annex D).

4.3.2.2 Determination of the voltage immunity

The voltage immunity at the connectors of the IPG may be obtained

1. using data obtained:

    a. from the pacemaker manufacturer, or

    b. from existing measurements (in accordance with EN 45502-2-1), or

    c. from the requirements specified in EN 45502-2-1. The use of the requirements specified in EN 45502-2-1 for obtaining voltage immunity is only possible when it is known that the pacemaker has been tested according to that standard, and the situation is not Case 2.

NOTE EN 45502-2-1 contains the minimum specifications for device immunity. Many devices have a significantly better actual immunity than the minimum requirements at some frequencies. Furthermore, many implanted devices are used at less sensitive settings which will also enhance their immunity. This means there is a greater chance of allowing the AIMD-Employee to work without restrictions if actual data, sourced from the device manufacturer or obtained through additional immunity testing, is used.

2. by performing an immunity test using the methods of EN 45502-2-1. If the waveform of the interfering signal is known, the test may be done using this waveform instead. The waveform used shall be documented.
   Since the level of applied signals will necessarily be higher than those specified for immunity in the pacemaker product test standards, care must be exercised to prevent irreversible damage to the device that would invalidate test results..

NOTE If this assessment is being made specifically for only one or two devices it might be quicker and more convenient to perform a direct in vitro test as in 4.3.1.

Further examples are given in Annex G.

4.3.2.3 Comparison of induced voltages to voltage immunity

Comparing the voltage immunity against the induced voltages at the leads will reveal one of three possible situations:

- the induced voltages at all locations are below the voltage immunity, and work can then be allowed without restrictions;

- the induced voltages are above the voltage immunity only in places which can be clearly identified and exposure can be avoided or a transient exposure duration that does not lead to clinically significant pacemaker interaction is known or can be specified. In this situation, work can be allowed with restrictions;

- in all other cases interference cannot be excluded and work of the AIMD-Employee can not be allowed on the basis of this method of assessment.

5 Documentation

A final report of the investigation shall be completed, even if the investigation is prematurely terminated, that describes the overall risk assessment process, the method chosen with the rationale for the choice, the findings and the drawn conclusions. The risk assessment following this standard offers different options to perform the risk assessment and as the methods are very different a unique form the documentation is not feasible but must be tailored to the approach chosen.

Annex A
(normative)

Pacemaker specific replacement of EN 50527-1, Table 1

This pacemaker-specific Table 1 replaces the Table 1 given in EN 50527-1. The exceptions and remarks have been adopted to reflect the special pacemaker requirements.

NOTE Throughout this table are repetitions of the phrase “recommendations restricting use associated with the pacemaker”. These recommendations are typically available to the pacemaker-bearing employee from their responsible physician, the pacemaker manufacturer, or equipment manufacturer.

Table 1 - Compliant workplaces and equipment with exceptions

Designation of workplace	Examples of equipment	Exceptions and remarks
All places	Lighting equipment	For the case of microwave or RF lighting follow recommendations restricting use associated with the pacemaker or perform a special assessment using one of the methods specified in 4.1.4.
All places	Computer and IT equipment	No restrictions
All places	Computer and ITE equipment *including* wireless communication	If such equipment contains transmitter greater then 40 mW (like Bluetooth Class 1, WiFi or GSM) follow recommendations restricting use associated with the pacemaker or perform a special assessment using one of the methods specified in 4.1.4.
All places	Office equipment	For the case of tape erasers follow recommendations restricting use associated with the pacemaker or perform a special assessment using one of the methods specified in 4.1.4.
All places	Mobile phones, and cordless phones	For pacemakers the interference distance between source and AIMD is 15 cm for peak powers up to 2 W.
All places	Two-way radios	Follow recommendations restricting use received with the AIMD or perform a special assessment using one of the methods specified in 4.1.4.
All places	Base stations for DECT cordless phones and WLAN (e.g. Wi-Fi)	For pacemakers the interference distance between source and AIMD is 15 cm for peak powers up to 2 W.
All places	Non-wireless communication equipment and networks	
All places	Electric handheld and transportable tools	Areas containing such equipment are deemed to comply without further assessment. For the case the pacemaker-bearing employee is to operate the tools, follow recommendations restricting use associated with the pacemaker or perform a special assessment using one of the methods specified in 4.1.4.

442 **Table 1 - Compliant workplaces and equipment with exceptions** *(continued)*

Designation of workplace	Examples of equipment	Exceptions and remarks
All places	Portable heating tools (e.g. glue guns, heat guns)	Areas containing such equipment are deemed to comply without further assessment. For the case the -bearing employee is to operate the tools, follow recommendations restricting use associated with the pacemaker or perform a special assessment using one of the methods specified in 4.1.4.
All places	Battery chargers	Small battery chargers for household use. For the case of large chargers (for professional use) or chargers using inductive coupling or chargers using proximity coupling, follow recommendations restricting use associated with the pacemaker or perform a special assessment using one of the methods specified in 4.1.4.
All places	Electric operated garden appliances	Areas containing such equipment are deemed to comply without further assessment. For the case the pacemaker-bearing employee is to operate the tools, follow recommendations restricting use associated with the pacemaker or perform a special assessment using one of the methods specified in 4.1.4.
All places	Audio & video equipment	If the equipment uses wireless transmission follow recommendations restricting use received with the AIMD or perform a special assessment using one of the methods specified in 4.1.4.
All places	Portable battery powered equipment not including radio frequency transmitters	
All places	Electrical room heating equipment	
All places	All non-electrical equipment	Some non-electrical equipment may include high static magnetic fields (for example permanent magnets). In this case, follow recommendations restricting use associated with the pacemaker or perform a special assessment using one of the methods specified in 4.1.4.
All places	All equipment producing static magnetic fields	Equipment capable of producing static magnetic flux density of $B > 1$ mT, at the region occupied by the pacemaker, may cause influenced behaviour. This 1 mT peak limit also applies for “quasi static“ magnetic fields in the frequency range from 0 Hz up to a few Hz.

443 **Table 1 - Compliant workplaces and equipment with exceptions** *(continued)*

Designation of workplace	Examples of equipment	Exceptions and remarks
All places	Electricity supply networks in the workplace and electricity distribution and transmission circuits passing through or over the workplace. The magnetic and electric field exposure are considered separately. For magnetic field exposures the following are compliant: • any electrical installation with a phase current rating of 100 A or less; • any individual circuit within an installation, with a phase current rating of 100 A or less; • any circuit where the conductors are close together and having a net current of 100 A or less; • all components of the networks satisfying the criteria above are covered, (including the wiring, switchgear, transformers etc.); • any overhead bare conductors of any voltage. For electric fields exposures the following are compliant: • any underground or insulated cable circuit, rated at any voltage; • any overhead bare circuit rated at a voltage up to 100 kV, or overhead line up to 150 kV, above the workplace, or at any voltage where the workplace is indoors.	The criteria given in the middle column here for demonstrating that fields are low enough to avoid interfering with pacemakers are based on demonstrating that the exposures are lower than the reference levels given in the Council Recommendation 1999/519/EC of EMF exposures for the general public. It states that for magnetic fields all overhead lines satisfy this criterion but for electric fields only lines with a rated voltage up to 150 kV satisfy it. However for an overhead line whose voltage is greater than 150 kV the electric field will usually, but not always, be lower than the public reference level. Clause C.2 gives more information about this, and as a result a risk assessment for a workplace with an overhead line passing over is not required if any of the following apply: • if measurements in the workplace have shown that the general public electric field reference level is not exceed; • if computations of the electric field in the workplace from the overhead line (e.g. provided by the operator of the line) have shown that general public electric field reference level is not exceed; • if no part of the line where it passes over the workplace has a clearance to ground that is less than 16 m (291 kV to 420 kV lines), 11 m (226 kV to 290 kV lines), 9 m (151 kV to 225 kV lines) or any height (0 kV to 150 kV lines); • where the workplace is indoors. This applies where a pacemaker bearing employee is at ground level (standing or sitting etc), and not where the employee is above the ground. In the electricity supply industry some work places may be very close to electricity supply equipment, in which case the field may exceed the Council Recommendation general public reference levels. The risk assessment for a pacemaker bearing employee needs to consider the levels fields that could be encountered by the employee and the sensitivity to interference of the particular pacemaker implanted taking account of its type, its sensitivity settings and whether the leads are bipolar or unipolar. Areas where the field exceeds these levels may involve only “transient exposures” (see 4.6 of EN 50527-1) in which case they may be permitted for the pacemaker bearing employee.

444 **Table 1 – Compliant workplaces and equipment with exceptions** *(continued)*

Designation of workplace	Examples of equipment	Exceptions and remarks
All places	Instrumentation, measurement and control equipment	If such equipment contains transmitter greater then 40 mW (like Bluetooth Class 1, WiFi or GSM) follow recommendations restricting use associated with the pacemaker or perform a special assessment using one of the methods specified in 4.1.4.
All places	Household appliances	Professional appliances like cookers, laundry machines, microwave ovens etc. used in restaurants, shops etc. are included. For the case of inductive heating equipment follow recommendations restricting use associated with the pacemaker or perform a special assessment using one of the methods specified in 4.1.4. If such equipment contains transmitter greater then 40 mW (like Bluetooth Class 1, WiFi or GSM) follow recommendations restricting use associated with the pacemaker or perform a special assessment using one of the methods specified in 4.1.4.
All places	Battery driven transmitters	Follow recommendations restricting use received with the AIMD or perform a special assessment using one of the methods specified in 4.1.4.
All places	Base stations antennas	Keep outside the interference distance as described in the assessment following Annex A of EN 50527-1. If an interference distance is specified by a competent authority this has to be used.
Medical workplaces	All medical equipment not using RF sources	If medical workplaces include static or time varying magnetic or electric fields, then operational precautions may be necessary. For equipment used at medical workplaces listed elsewhere in this table look at the appropriate sub(clause).
Workplaces open to the general public (as covered by 4.3 of Directive 2004/40/EC)	Places open to the public and in compliance with the exposure limits given in the European council recommendation 1999/519/EC are deemed to comply without further assessment provided that the compliance was made against the derived reference levels.	It is possible, under certain circumstances, to exceed the reference levels and still comply with the Recommendation basic restrictions. Such circumstances are usually in localised areas, close to EMF emitting equipment, so transient exposure in those areas may be permitted. In case of doubt further guidance may be obtained from device or emitter manufacturers, medical advisors or by the use of the appropriate device specific standard.

445 **Table 1 - Compliant workplaces and equipment with exceptions** *(continued)*

Designation of workplace	Examples of equipment	Exceptions and remarks
All places	CE-marked equipment which has been assessed using one or more of the standards listed in EN 50499:2008, Annex C.	Areas containing such equipment are deemed to comply without further assessment provided that the compliance was made against the derived reference levels. It is possible, under certain circumstances, to exceed the reference levels and still comply with the Recommendation basic restrictions. Such circumstances are usually in localised areas, close to the CE marked equipment, so transient exposure in those areas may be permitted. In case of doubt further guidance may be obtained from device or emitter manufacturers, medical advisors or by the use of the appropriate device specific standard.
All places	Equipment placed on the European market in compliance with the Council Recommendation 1999/519/EC as required by the relevant directives in particular in compliance with their related harmonized standards listed in the Official Journal of the European Union. Examples are provided in EN 50499:2008, Annex C.	Some equipment placed on the European market may also be compliant with the Council Recommendation 1999/519/EC although they have not received the CE marking, for example if it is part of an installation. Areas containing such equipment are deemed to comply without further assessment provided that the compliance was made against the derived reference levels. It is possible, under certain circumstances, to exceed the reference levels and still comply with the Recommendation basic restrictions. Such circumstances are usually in localised areas, close to the CE marked equipment, so transient exposure in those areas may be permitted. In case of doubt further guidance may be obtained from device or emitter manufacturers, medical advisors or by the use of the appropriate device specific standard.

446

Annex B
(informative)

Clinical investigation methods

B.1 External ECG monitoring

External ECG monitoring, which may be performed using Holter monitoring equipment, is an available method for investigating possible interference. It must be a planned action regarding locations and time of stay and must be supervised and the results interpreted by competent persons.

Interference episodes (e.g. asynchronous pacing, missed beats) will be recorded and can be correlated to exposure situations.

NOTE When such examinations are done it must be ensured that the monitoring device is not inadvertently interfered with and that the monitoring results are reliable.

B.2 Assessment of pacemaker compatibility using stored data and diagnostic features

Data storage and diagnostic capabilities are designed into implantable pacemakers and can be used to explore the effects of EMI. They may easily be combined with the external measurement of ECG as in A.1.

Event storage or other diagnostic features (depending on manufacturer and pacemaker model) are well known and have been used in the past to explore interference due to EMF. Event records are useful and accurate both during in vivo and in vitro testing. The results would be specific for the pacemaker model tested.

For example, one state of the art pacemaker model may include additional diagnostic features such as “episode triggers” which could be used to explore potential interference episodes. The“episode trigger function” for example provides means of recording intracardiac signals for a certain period of time as seen by the pacemaker along with event markers and timing information. These recording sessions (episodes) are saved in a dedicated memory inside the pacemaker and can be retrieved through telemetry. For example, an “episode trigger” could be programmed to be initiated by the device entering its “Noise Reversion” mode, or by applying a magnet near the device (Magnet Response) for a short period of time (e.g.1 s - 2 s).

Terminology for these features may differ among pacemaker manufacturers, however all of them provide similar capability.

To select a proper procedure and method for this type of in vivo investigation a thorough consultation with the manufacturer of the pacemaker and with the responsible physician is needed. In most cases it is required to have a representative from the manufacturer on hand to evaluate device performance and to program or to initiate suitable “episode trigger conditions”.

B.3 Real time event monitoring by telemetry

Most pacemakers incorporate the capability for real-time telemetric monitoring using either vendor-specific UHF band broadcasting or the digital ISM band (Industrial, Scientific, and Medical Band) standardized Wi-Fi network technology. Modern telemetry radio transmitters can measure and send multiple physiological parameters like multi-channel ECG.

Virtually all pacemakers today include Event Monitoring functions which allow the capability to monitor the operation of the implanted pulse generator (IPG) in real time through a programming unit using short range inductive telemetry. Inductive telemetry typically provides a communication distance of a few cm. Any EMF interference of the IPG can be observed directly in real time under normal working conditions and under provocative EMF exposure of the worker, provided that the telemetry channel itself is not interfered with by the EMF exposure.

State of the art pacemakers provide communication distances in the range of one or a few meters (e.g. IFM-band or MICS band technology) and thus allows robust and convenient real time event monitoring.

NOTE This method of telemetry monitoring could also be used during in vitro investigations/studies).

Annex C
(informative)

In vitro testing/measurements

C.1 Introduction

The aim of *in vitro* testing is to mimic as close as possible the real in vivo situation. It helps to study without unnecessary risk for the worker his AIMD behaviour in his working places. The goal is to check the possibility of interaction between an implantable cardiac device and an EM source in professional environment.

This is done by placing the device and its probe inside a torso phantom mimicking a patient bearing it. The whole set up could be placed in the vicinity of the EM source of interest or fixed on a mobile support that could be moved at different working places.

C.2 EM phantom

C.2.1 Definition

EM phantom is a physical model containing tissue-equivalent material used to simulate the body in an experimental dose measurement (from World Health Organisation).

C.2.2 General

EM phantom is a low cost tool for non-risky approach *in vitro* experiences to test AIMD susceptibility in a professional environment. By using an experimental body simulator, systematic testing of various degrees of interaction is possible in a professional environment. This simulator could be very simple or more sophisticated.

The human body is mainly heterogeneous. The trunk is composed by muscle, bone and air forming complex shaped boundaries with respect to its anatomy. Adding an electronic biomedical device introduces a high conductivity part for the PM case and at the tip of the probe where electrodes are in contact with the tissue.

This hybrid system is thus difficult to mimic. It remains possible and reasonable as a first approach for bio-EMC studies to consider a homogeneous phantom in which the device is conveniently placed. Use of a homogeneous material contained in one volume for simulating parts of the body has been agreed on by the the IEEE sub-committee on Techniques, Procedures, and Instrumentation (IEEE SCC 34 SC1) and has been used extensively in standardisation and research environments.

C.2.3 EM phantom design

C.2.3.1 General

In reviewing all current and previously published documentation, it is evident that the phantoms used by different teams are not based on a common definition and where such definition exists it is not clearly defined. Human like phantom are commercially available. They are based on a combination of canonical shapes. Easier to build custom made phantom are presented in scientific or technical publications (see literature in C.5).

A physical model containing tissue-equivalent material used to simulate the body must have electrical properties similar to those of human tissues with regards to frequency of interest. Dielectric properties of concern are the relative permittivity (ε_r) and the conductivity (σ).

Geometry and orientation of the AIMD inside the phantom in connection with those of the source are also crucial parameters. The shape of the phantom should allow easy, unmistakable and repeatable coupling between the tissue boundary and the inserted AIMD. Position and geometry of the probe and the contact between the electrodes and the phantom should be repeatable in order to allow comparisons between studies.

C.2.3.2 Commercial phantoms

Many phantoms are commercially available. Some of them are based on the Specific Anthropomorphic Mannequin (SAM) phantom defined in [C.1], [C.2] and [C.3]. They enable the dosimetric evaluation as well as connection of the inserted AIMD inside the phantom to the rest of the measurement experimental set up. Robots are used for a few of them for positioning and measurements. Reference markings on the phantom allow the complete setup of all predefined phantom positions and measurement grids. The parameters are set up according to [C.1], [C.2], [C.3] and [C.4].

C.2.3.3 Custom made phantoms

A simple torso simulator is a plastic box used to represent the human trunk cavity or the total body. This tank could be parallelepipic or cylindrical with dimensions close to a human torso. It is filled with a phantom which simulates human body electromagnetic properties. A plexiglas (or other non conductive translucent material) is designed to fix the pacemaker and the probe in a reproducible manner. The cardiac implant and its probe are placed on a plexiglas support close to the wall of the tank thus allowing telemetry records. The distance between the source and the phantom could be adjusted according to the professional activities of the AIMD employee.

For most accurate results, especially at lower frequencies, the exact geometry of AIMD placement inside the specific AIMD-Employee should be used but this may not be known, or the assessment may be done on a more general basis. In such cases an effective pacemaker lead loop area of 225cm should be used. Practically this can be done by creating a custom lead or by using a standard lead and making one or more small loops behind the AIMD to obtain the correct effective length and overall loop area. This method is used by Irnich in [C.5].

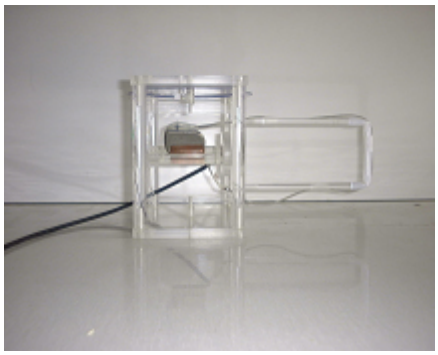
The FDA introduced a single homogeneous bath contained in a simple parallelepipedic volume (flat phantom) to simulate complex, multiple body tissues for EMI evaluations of pacemakers; this simulation has been used by the industry for many years.

C.3 Basic procedure for cardiac pacemaker *in-vitro* testing

Simulation of pacemakers will be accomplished by way of a torso simulator and testing equipment. An ECG signal injection system is used to simulate heart activity and signal monitoring equipment for acquiring pacemaker signals. Telemetry recording could be done in real time or *a posteriori* (Figure C.1). All equipment for the measurement will be placed in and around (or below) the torso simulator in order to avoid any interactions with the EM source.

This ability of the device to respond to both internal and external magnetic and RF signals allows the device to be programmed for optimal clinical benefit as the patient's needs change. In order to perform this test it is necessary to obtain the appropriate programmer and instructions necessary for interrogating and programming the respective pacemaker. The programming features vary widely, but all units provide the control necessary to establish the common parameters needed. Each unit will be programmed according to medical staff advising. It is important to note that pacemaker parameters are typically programmed non-invasively by means of RF signals or pulsed magnetic fields.

The whole set up has to be moved, if necessary, to each of the previously chosen places in the employee's professional environment according to the general procedure.



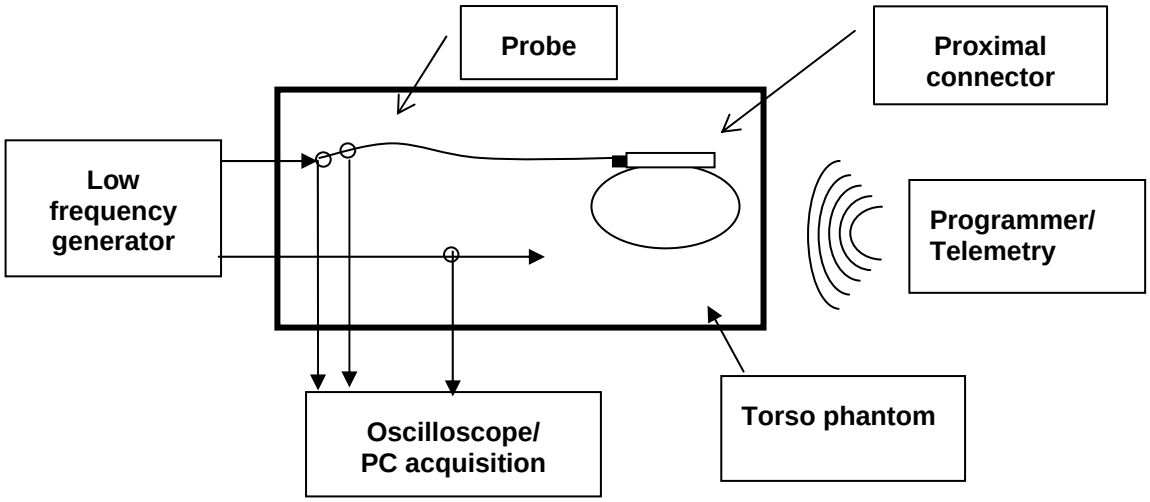


Figure C.1 - Example of basic signal injection and data recordingfor in vitro procedure

NOTE ECG signal injection preferably done through separate electrodes not direct in contact with the electrodes of the pacemaker lead.

C.4 References

[C.1] IEEE 1528:2003, Recommended practice for determining the peak spatial-average Specific Absorption Rate (SAR) in the human head from wireless communications devices: measurement techniques

[C.2] EN 50361:2001, Basic standard for the measurement of specific absorption rate related to human exposure to electromagnetic fields from mobile phones (300 MHz - 3 GHz)

[C.3] EN 62209-2 [1)], Human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices - Human models, instrumentation, and procedures - Part 2: Procedure to determine the specific absorption rate (SAR) for wireless communication devices used in close proximity to the human body (frequency range of 30 MHz to 6 GHz) (IEC 62209-2:2010)

[C.4] FCC OET Bulletin 65 Supplement C

Evaluating Compliance with FCC Guidelines for Human Exposure to Radiofrequency Electromagnetic Fields

Supplement C:2001 "Additional Information for Evaluating Compliance of Mobile and Portable Devices with FCC Limits for Human Exposure to Radiofrequency Emissions"

[C.5] Irnich W. Electronic security systems and active implantable medical devices, Pacing Clin Electrophysiol 2002;25:1235-1258

1) At draft stage.

C.5 Literature

Grant, Hank and Schlegel, Robert E., 1998, In Vitro Study of the Interaction of Wireless Phones with Cardiac Pacemakers, EMC Report 1998-2.

Guy, A.W. ; Analyses of Electromagnetic Fields Induced in Biological Tissues by Thermographic Studies on Equivalent Phantom Models ; IEEE Transactions on Microwave Theory and techniques ; Feb 1968 ; Volume: 19, n°2 ; 205- 214

Trevor W. Dawson, Kris Caputa, Maria A. Stuchly. Pacemaker interference by magnetic fields at power line frequencies. IEEE transactions on biomedical engineering, vol 49, No3 March 2002.

M Nadi, A Hedjiedj, L Joly, P Schmitt, B Dodinot, E Aliot ; Relevance of in vitro studies for the immunity of cardiac implants in an electromagnetic field environment Archives des maladies du coeur et des vaisseaux. 2003 Apr;96 Spec No 3: 22-9

Mariya Lazebnik, Ernest L Madsen, Gary R Frank and Susan C Hagness ; Tissue-mimicking phantom materials for narrowband and ultrawideband microwave applications ; 2005 ; Phys. Med. Biol. **50** 4245-4258

C Marchal, M Nadi, A J Tosser, C Roussey, M L Gaulard. Dielectric properties of gelatine phantoms used for simulations of biological tissues between 10 and 50 MHz. International journal of hyperthermia : the official journal of European Society for Hyperthermic Oncology, North American Hyperthermia Group. 1989 Nov-Dec ;5(6): 725-32

Maria A Stuchly, Robert Kavet Numerical Modeling of pacemaker interference in the electric utility environment. IEEE transactions on device and materials reliability , Vol 5, No. 3, September 2005.

Trevor W.Dawson, Maria A. Stuchly, Kris Caputa, Antonio Sastre, Richard B.Shepard, Robert Kavet. Pacemaker interference and low frequency electric inductions in humans by external fields and electrodes. IEEE transactions on biomedical engeneering ,Vol 47, No 9, September 2000.

Trevor W. Dawson, Kris Caputa, Maria A. Stuchly. Pacemaker interference by magnetic fields at power line frequencies. IEEE transactions on biomedical engineering, vol 49, No3 March 2002.

Giuseppe Della Chiara, Valter Mariani Primiani and Franco Moglie Experimental and numeric investigation about electromagnetic interference between implantable cardiac pacemaker and magnetic fields at power line frequency ; Ann Ist Super Sanità 2007 | Vol. 43, No. 3: 248-253

Annex D
(informative)

Numerical modelling

D.1 General

Human exposure to electric and magnetic fields can be assessed using computational dosimetry. This can be by modelling the exposing field and also by modelling the target implant in an exposing field. There are a variety of analytical and numerical methods that can be used [D.1]. Quasi-static methods (where it is assumed that the phase of the incident field is constant across the body being modelled) are suitable at lower frequencies, where the body dimensions are small in comparison with the wavelength (up to about 5 MHz).

The cardiac device implanted into the human body is generally very complex and simplifying assumptions are necessary. In general, computational methods for analysing EM problems fall into two categories: analytical techniques and numerical techniques. This annex provides guidance on how such techniques may be used.

D.2 Analytical techniques

These techniques apply assumptions to simplify the geometry of the problem in order to apply a closed-form solution. These assumptions depend on the frequency of interest. A quasi-static approach is currently used and the analytical studies on homogeneous models were the main resources of information regarding EM field distribution inside the human body and at the limits of the implanted device. Up to now, these techniques were mainly applied to EM dosimetry and can be extended to the AIMD coupling in a professional environment. One example of this is the model used where the implant in the body is simplified to an open circuit loop with an effective induction area equivalent to that found for real devices in the body. This model is the basis for many of the values and assumption used for standardization work on immunity of devices.

D.3 Numerical techniques

Over the years, different computational methods have been investigated over the past several years [D.2] Well known examples of these are the Method of moments (MoM), finite element method (FEM), finite integration technique (FIT), generalized multipole technique, impedance method, the scaled frequency finite-difference time-domain (FDTD) method, and the scalar potential finite difference (SPFD) method. Software based on these methods is available both commercially and designed in research laboratories. They can be used to model and determine voltages (currents) at the tip of the probe or at the pacemaker input stage according to each professional EM environment and examples of such work can be found in the bibliography [D.3, D.4, D.5]. If such modelling techniques are used, appropriate validation is required. This can be provided by peer review, appropriate published reference citations, comparison against analytical solutions other reviewed or referenced models.

D.4 Field modeling or calculations

For well-defined sources, magnetic flux densities can be calculated accurately depending on the quality of the model. It may also be possible to model a more complex source with multiple simpler sources, provided the resultant fields can be shown to be representative or more conservative. Electric fields can also be calculated, but because the fields are perturbed by conducting objects, calculations may be of limited value unless the perturbations by such objects can also be modelled. Electric-and magnetic-field calculations, when properly performed, can also help to complete measurements (and similarly measurements can be used to complete or validate modelled field results).

For many workplace environments, it can difficult to determine the specific currents and voltages that could occur at the tip of the probe or at the pacemaker input stage as a function of the external EM source. In such cases it may be possible to use a simpler model to characterise the relationship or the transfer function between the electromagnetic (EM) fields emitted by a given device and a cardiac implant and thus use that relationship to calculate the eventual interfering voltage.

D.5 Modeling the human body and implant

Such modelling involves the use of a representative model of the human body. The model can be as simple or complex as necessary for the required accuracy and in some cases approximate uniform solid phantom shapes are used. In many cases sophisticated millimetre resolution body models (with resolutions of the order of 1 mm to 6 mm) are used. These models are often derived from MRI data or from photographs of the anatomical sectional diagrams, and include accurate tissue conductivities for different body tissues.

A model of the implanted medical device and lead then has to be inserted accurately into the body model. Again the model need only be as accurate as required for the accuracy of the required results. For example a pacemaker device model may only need a representative outer case and the connections for the implant lead (with a suitable input impedance) to be sufficient.

D.6 References

[D.1] “Electromagnetic Dosimetry for models of humans and animals : A review of theoretical and numerical techniques”, Durney, C.H., Proceedings of the IEEE 68(1), pp.33-40, 1980

[D.2] “Advanced Modeling in Computational Electromagnetic Compatibility”, Dragan Poljak; ISBN: 9780470036655 ; 2007 John Wiley & Sons, Inc.

[D.3] “The investigation of electromagnetic field influence generated by mobile phones on cardiac pacemakers with the anatomically based human model” Arkadiusz Miaskowski & al. ; COMPEL: The International Journal for Computation and Mathematics in Electrical and Electronic Engineering; 2008; Volume: 27 – 4

[D.4] “Realistic modelling of interference in pacemakers by ELF magnetic fields”; Augello, A.; De Leo, R.; Moglie, F.; Applied Electromagnetics and Communications, 2005. ICECom 2005. 18th International Conference on Volume , Issue , 12-14 Oct. 2005 Page(s):1 – 4

[D.5] “Active medical implants and occupational safety – measurement and numerical calculation of interference voltage” , F. Gustrau, A. Bahr, S Goltz & S Eggert, ", Biomedizinische Technik (Ergänzungsband 1, Teil 2), 47: 656-659, 2002

Annex E
(informative)

Derived worst case conversions

E.1 Introduction

Using a non-clinical method comparing induced voltages on the implanted leads with voltage immunity of the pulse generator, the induced voltages are to be determined. This applies to frequencies up to 450 MHz. Above 450 MHz the induced voltages may be calculated but the assessment is not compatible with the determination of voltage immunity following pacemaker product standards.

On the one hand this could be done by using a body simulator (Annex C) or by modelling of thorax and leads (Annex D). Both investigations could be specific to the AIMD-Employee under question.

On the other hand the induced voltages are limited in general by size and conductivity of the human body. There are many publications dealing with such worst case conversions to estimate maximum voltages induced at a given external field. This annex summarises findings of those publications.

This approach is based on worst case situations and neglects the specifics of the AIMD-Employee under question. Therefore the conversions rather result that the induced voltage will be below a value than saying it will ever take it. Consequently this approach is able to exclude interference technically but it is not able to predict occurrence of any interference. For that, using worst case conversions will provide a huge safety margin.

E.2 Functionality of implanted pacemaker leads

The implanted cardiac pacemaker consists of a pulse generator in a metallic case and one or multiple implanted leads. The lead provides connection between the pulse generator implanted near the collarbone and the heart.

The lead is used twofold, to deliver the stimulation pulses to ventricle or atrium and to enable the pulse generator sensing heart beat. The lead is enclosed by and partly connected to the body tissue. When the person is exposed to electromagnetic fields, the device receives both, physiological potentials (heart beat) and interference induced on the lead.

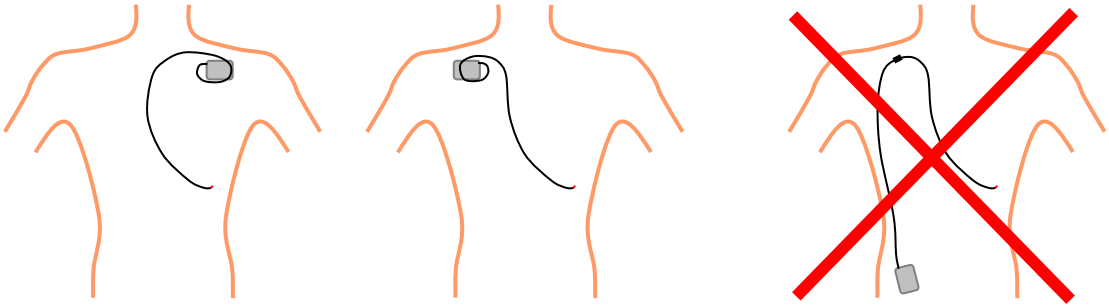


Figure E.1 - Typical implantations of cardiac pacemakers
(abdominal implantation with prolonged lead is used in clinical environment only)

The cardiac lead is insulated but entirely enclosed by conductive body tissue. At the end nearest the heart a unipolar lead makes galvanic contact to the body tissue with one tip electrode. At the end connected to the device, a large area of the cardiac pacemaker case makes galvanic contact with the body tissue. When unipolar sensing, the cardiac pacemaker detects the voltage between the conductor of the lead and the pulse generator case.

A bipolar lead has two electrodes (tip and ring) with a distance between them of some cm at its heart end to contact both, inner and outer conductors with the body tissue. For bipolar sensing, the cardiac pacemaker detects the differential mode voltage between the two conductors only. But nevertheless a bipolar sensing cardiac pacemaker has to suppress the common mode interference voltage induced between any connector and case.

E.3 Conversion based on known field strength

E.3.1 General

Conversion from exposure field strength to induced voltage on an implanted lead depends upon frequency and direction of the field and upon the shape of the implanted lead. The AIMD-Employee can move around and therefore may encounter any direction of exposure field vector. For safety reasons, the conversion should be based on the most sensitive orientation. Each AIMD-Employee has its individual shape of implanted lead and consequently shows its individual conversion factor. It is very sumptuous to derive conversions factors for an individual constellation and consequently it is desirable to avoid this in most cases. For safety reasons in these cases the conversion should be based on the maximum realistically achievable shape of implanted leads delivering some additional safety margin in most applications (see Figure E.2 in E.6). The conversion tools for maximum shaped pacemaker leads are described here and need not be derived during every risk assessment individually.

E.3.2 Low frequency range (below 5 MHz)

At low frequencies wavelength is much larger than the human body and the far field condition ($\boldsymbol{E}/\boldsymbol{H}$ = 377 Ohms) does not apply. Consequently it is necessary to look for both field components independently. In some cases one of the field components ($\boldsymbol{E}$ or $\boldsymbol{H}$) predominates and the other is effectively negligible.

Without the enclosing body tissue, the lead equals an open loop providing some sensitivity for electric fields but no sensitivity for magnetic fields. Implanted into the thorax, the lead gets shielded by the conductive body tissue, reducing the sensitivity for electric fields. On the other hand, the conductive body tissue provides no shielding against magnetic fields. Additionally the connection of lead and case to the body tissue close the loop and cause sensitivity for magnetic fields.

Substantial electric fields only can be found next to railway supplies (16 Hz or 50 Hz) and power lines (50 Hz or 60 Hz) and in the surrounding of radio or broadcast transmitters (> 150 kHz). Most low frequency field sources at the workplace produce magnetic fields without substantial electric field components. Therefore in most cases the conversion can be restricted to E.3.3 (Pure magnetic field) and ignore E.3.4 and E.3.5 (Fields with electric and magnetic component).

E.3.3 Pure magnetic field (16 Hz to 5 MHz)

For frequencies below about 5 MHz plain induction law applies. The only problem is that the implanted lead itself doesn't compare to a closed loop directly; but because it is embedded in a conductive medium and connected to it at both ends, it is effectively closed via a virtual back path through this medium.

In case a lead is placed in an infinitely extended conductive medium, the loop can be thought being closed by a straight wire form tip connector of the lead to the non-insulated case of the pulse generator. The induction area $\boldsymbol{A}$ for a lead of given length $\boldsymbol{L}$ will be maximal with a semicircle layout: $\boldsymbol{A} = \boldsymbol{L}^2 / 2\pi$.

This is still true within a finite space (as in the thorax) in case the virtual straight line is centred. Real implantations are shifted towards the wall of the thorax, reducing the effective induction area. Theoretical field calculations and measurements both confirm this reduction. Figure E.2 shows a unipolar lead in a semicircle layout schematically:

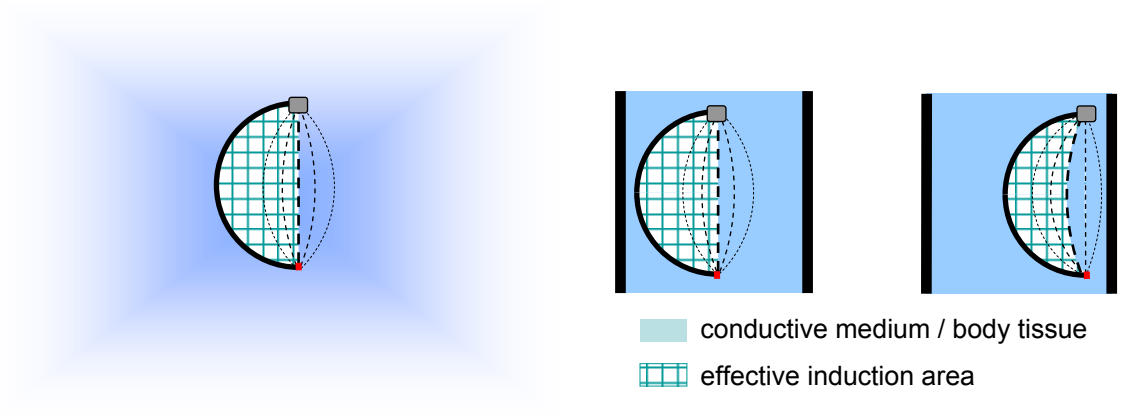


Figure E.2 - Effective induction area of an open wire loop inside a conductive medium

The current path in the conductive medium is spread over a volume rather than concentrated on a one-dimensional line. Therefore it is shown as a set of dashed lines in Figure E.2.

In the left picture the conductive medium is unlimited. In the middle picture the medium is restricted to the size of the thorax in such a way, that the virtual back path (dashed lines from tip to case) is symmetrical to the centre of the thorax. In both cases the effective induction area to be used for the induction law equals the area of the semi circle as shaded in the picture and the back path can be thought to be a straight wire from tip to ring.

In the right picture the lead is shifted in such a way, that tip and case are nearer to the border of the thorax than to its centre line. Approaching the wall of the thorax, the spread volume of the current back path is deformed and displaced. This causes a reduction of the effective induction area, which is no more as large as the geometrical loop area as described above. The quantity of this decrease depends upon the inhomogeneity of the conductive body tissue too.

Additionally it is impossible to implant a cardiac lead with a semicircle shape, which solely would represent the maximum achievable geometrical loop area. Examination of X-rays show, that maximum geometrical loop areas result with left pectoral implantation of the pulse generator. With the usual cardiac lead length of about 50 cm, the maximum achievable geometrical loop area is about 315 cm². Taking into account the above mentioned reduction effects, the maximum achievable effective induction area A_{ind}^{max} is about 225 cm² only. This means that the maximum sensitive implanted unipolar cardiac lead delivers the same induced interference voltage as an equivalent closed wire loop with 225 cm² loop area:

$$A_{ind}^{max} = 225\ \mathrm{cm}^2 \qquad [E.1]$$

Most pacemaker-Employees will have a much smaller individual effective induction area. Even using this maximum effective induction area of 225 cm² with any pacemaker-Employee bearing a unipolar pacemaker provides a substantial safety margin.

NOTE ANSI AAMI PC69 uses an average loop area of 200 cm² and assumes a maximum geometric loop area of 289 cm². The 225 cm² mentioned above represent the maximum achievable effective induction area.

Two different sensing modes of pacemakers can be used. In unipolar sensing mode, the lead has only a single conductor and gives contact to the heart tissue through a single electrode only. In unipolar sensing mode the pulse generator senses the cardiac potential between one connector and the pulse generator case. In bipolar sensing mode, the lead has two conductors and contacts the heart tissue through two separate electrodes, spaced apart by some cm. In bipolar sensing mode the pulse generator senses the cardiac potential between the two connectors. The case of the pulse generator is not involved in bipolar sensing mode.

With a unipolar lead both the wanted cardiac potential and any induced interference, are sensed between the single connector and case of the pulse generator. With a bipolar lead the induced interference voltage feeds between any connector and the case but the wanted cardiac potential feeds between both connectors. If the pulse generator provides sufficient common mode rejection, it should not be confused by the interference.

Application of the induction law (Equation E.19) to the maximum effective induction area of unipolar leads (Equation E.1) gives the maximum induced open loop voltage achievable with any unipolar lead:

Unipolar: $$V_{pp}^{ind,max} = 3{,}6 \cdot 10^{-7} \cdot H_p \cdot f \qquad 16\ Hz \le f \le 5\ MHz \qquad [E.2]$$

where

$V_{pp}^{ind,max}$ is the maximal induced voltage on a unipolar lead (open loop) measured peak-to-peak and expressed in V;

H_p is the amplitude of the magnetic field strength measured peak and expressed in A/m;

f is the frequency expressed in Hz.

NOTE The voltage is measured peak-to-peak according to the requirements of EN 45502-2-1, but the magnetic field strength is measured as peak only. Thus the induction law uses the area of 225 cm² and an additional factor of 2.

The spacing between both cardiac electrodes also acts as a smaller antenna.

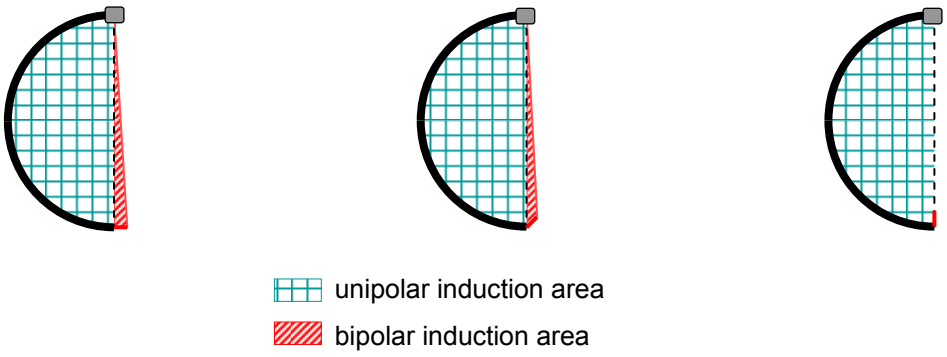


Figure E.3 - Schematic representation of bipolar pickup of interference

In an infinitely extended homogeneous conductive medium the maximum induced bipolar interference voltage is achieved with the ring to tip segment oriented tangential to the end of the lead. But the conductivity is not homogeneous inside the human body, the thorax has a limited extension and the shape of the implanted lead is not semicircle. Therefore the optimum orientation of the ring to tip segment varies. Calculations and measurements show, that the maximum achievable bipolar induced interference voltage for every bipolar lead is about 20 times smaller than the maximum achievable induced interference voltage amongst all unipolar leads for separations of tip to ring electrode below or equal to 2 cm.

NOTE This was derived at 16 Hz to 50 Hz with standard leads of 50 cm to 52 cm length and applies to spacing of tip to ring up to 2 cm.

Applying the factor 20 into Equation E.2, gives the maximum induced open loop voltage achievable with any bipolar lead amongst tip and ring connector:

Bipolar: $V_{pp}^{ind,max} = 1{,}8 \cdot 10^{-8} \cdot H_p \cdot f$ *16 Hz ≤ f ≤ 60* Hz [E.3]

where

$V_{pp}^{ind,max}$ is the maximal induced voltage on a bipolar lead (open loop) measured peak-to-peak and expressed in V;

H_p is the amplitude of the magnetic field strength measured peak and expressed in A/m;

f is the frequency expressed in Hz.

NOTE There is no published study for this factor at frequencies above 60 Hz. It can be assumed that the factor changes with frequency. Development of EN 45502-2-1 was based on the assumption that the factor is at least 10 for all frequencies below 150 kHz and consequently the threshold for bipolar immunity was set to 1/10 of the unipolar threshold. Above 150 kHz it was assumed that the factor is high enough to neglect bipolar interference voltages completely. Theoretical estimations suggest that the factor of 20 could be valid up to 60 kHz.

E.3.4 Field with electric and magnetic component (16 Hz to 60 Hz)

In case of simultaneous electric and magnetic fields both voltages, electrically influenced and magnetically induced, are to be added. Because no phase shift inside the body may occur at these frequencies, both voltages may be added according the relative phase of the fields.

At frequencies 16 Hz to 60 Hz the implanted lead doesn't act as an antenna itself for electric fields. The external electric fields influence currents inside the body tissue. In case of electric fields this currents are rather straight than circular. Due to the limited conductivity of the body tissue this currents generate potentials inside the tissue. Equipotent surfaces arise inside the thorax. The voltage on an implanted unipolar lead equals the difference between the potentials at the locations of tip and of case. In contrast to a short Hertzian dipole this potential drop has considerably low impedance.

Some publications cover the voltages influenced on the implanted lead by electric fields at 50 Hz. Measurements and calculations with simplified models as well as with sophisticated whole body models containing the implanted lead show comparable results. The influence is maximized when the person stands upright on a conductive plane grounded at its feet and raises the arm upwards on the implanted side. The findings of [E.1], [E.2], [E.3] and [E.4] are:

0,10 to 0,14 μV_{pp} @ 1 V_p/m for an isolated person standing upright in a vertical electrical 50 Hz field
0,28 to 0,30 μV_{pp} @ 1 V_p/m for the same person grounded with raised arm on the implanted side. The findings are summarized in Figure E.4.

It seems not to be a typical situation at the workplace, that an AIMD-Employee with 2 m height stands upright in a homogeneous vertical electric field, being grounded at its feet (barefoot) and raising its arm on the implanted side straight upwards. Therefore the published values are reduced for the purpose of this standard to 0,22 μV_{pp} @ 1 V_p/m. This value will cover a homogeneous vertical field at the workplace and an AIMD-Employee which is 2 m high, standing either barefoot on a metal plate but not raising its arm straight upwards or bearing shoes and raising its arm as much as can.

At frequencies 16 Hz to 60 Hz the maximum open loop voltage $V_{pp}^{ind,max}$ into a unipolar lead can be described as the maximum instantaneous value of the sum of both partial voltages due to both the magnetic and electric field effects:

Unipolar: $$V_{pp}^{ind,max} = 4{,}34 \cdot 10^{-9} \cdot \max\left(83 \cdot \left|H(t)\right| + \left|E(t)\right|\right) \cdot f \qquad 16\ Hz \le f \le 60\ Hz \qquad [E.4]$$

where

$V_{pp}^{ind,max}$ is the maximum open loop voltage a unipolar lead can deliver, measured peak-to-peak and expressed in V;

$E(t)$ is the instantaneous value of the electric field strength outside the human body at time t expressed in V/m;

$H(t)$ is the instantaneous value of the magnetic field strength at time t expressed in A/m;

f is the frequency expressed in Hz; applicable range is 16 Hz to 60 Hz;

max() is the maximum value over time of the sum of two time varying terms.

NOTE The phase angle between electric and magnetic field component is to be taken into account. The voltage $V_{pp}^{ind,max}$ is measured peak-to-peak according to the requirements of EN 45502-2-1, but the electric field strength is measured as instantaneous amplitude (reaching single peak at its maximum only). This is taken account of in the factors used in this equation.

This means that at 50 Hz an electrical field of 1 V/m peak (= 0,707 V/m r.m.s.) induces a maximum voltage of 0,22 µV peak to peak on the lead and a magnetic field of 1 A/m peak (= 0,707 A/m r.m.s.) induces a maximum voltage of 18 µV peak to peak on the lead.

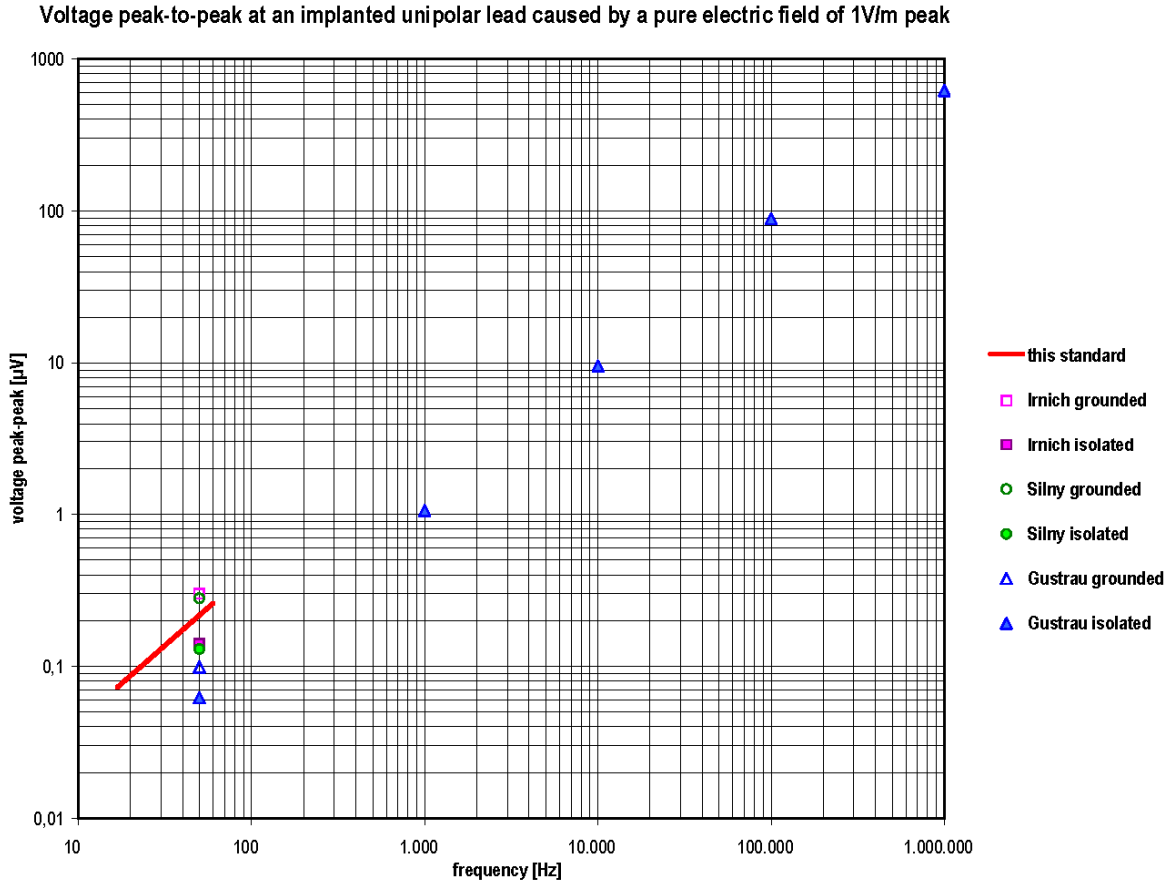


Figure E.4 - Induced voltage on the implanted lead in a pure *E* field

In Annex F another theoretical estimation of the voltage induced by a pure $\boldsymbol{E}$ field is given (calculation method from Dimbylow et al.) which results voltages comparable to those found by Irnich and Silny [E.2], [E.3].

The voltage picked by a bipolar lead between tip and ring in a pure electric field is substantially smaller, because the distance between tip and ring is much smaller than 25 cm. For common bipolar leads with length of 50 cm and spacing between tip an ring of maximum 2 cm, the maximum achievable interference voltage between tip and ring for every bipolar lead is at least 20 times smaller than the maximum achievable interference voltage between tip and case amongst all unipolar leads. Therefore a factor of 20 can be assumed for each of electric and magnetic term and consequently for the sum of both too.

Applying the factor 20 gives the maximum open loop voltage achievable with any bipolar lead amongst tip and ring connector:

Bipolar: $$V_{pp}^{ind,max} = 2{,}17 \cdot 10^{-10} \cdot \max\left(83 \cdot \left|H(t)\right| + \left|E(t)\right|\right) \cdot f \qquad \textit{16 Hz} \le f \le \textit{60 Hz} \qquad \text{[E.5]}$$

where

$V_{pp}^{ind,max}$ is the maximum open loop voltage a bipolar lead can deliver, measured peak-to-peak and expressed in V;

$E(t)$ is the instantaneous value of the electric field strength outside the human body at time t expressed in V/m;

$H(t)$ is the instantaneous value of the magnetic field strength at time t expressed in A/m;

f is the frequency expressed in Hz; applicable range is 16 Hz to 60 Hz;

$\max()$ is the maximum value over time of the sum of two time varying terms.

E.3.5 Field with electric component (60 Hz to 150 kHz)

No reliable studies are published up to now. Therefore no worst case conversions can be used if an electric field of above 60 Hz and below 150 kHz may contribute to the exposure significantly.

E.3.6 Field with electric and magnetic component (150 kHz to 5 MHz)

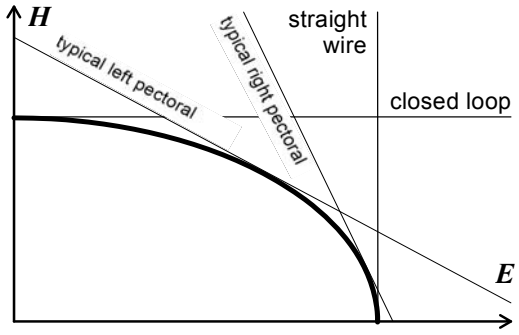
At frequencies above 150 kHz the linear addition of the maximum achievable voltage for magnetic component and electric component makes no sense, because it is impossible to achieve them with the same lead arrangement.

The closed wire loop has maximum sensitivity to the magnetic field but minimum sensitivity to the electric field. For the assessment of voltages on such a lead, a single formula covering *magnetic* field only would be sufficient. With a straight wire it is exactly the reverse: A single formula covering *electric* field only would suffice in practice.

Apart from these two ideal cases, there is a whole range of other lead shapes. In these cases, it will be necessary to establish formulae for both field components. If two separate formulae are used, one for the magnetic and one for the electric field, and if these formulae are to provide a blanket coverage of all conceivable leads, the magnetic property of a wire loop and the electric property of an extended conductor would be assumed for each lead layout at the same time. This would result in a considerable overestimation.

The further the tip electrode and the case of the pulse generator are placed apart, the longer the comparable electric dipole will be, but the less closed it will be too. This relationship can be exploited with a combined formula for both electric and magnetic fields. From the calculations for the four constellations E1, E2, E3 and E4 in [E.7], [E.8] and [E.9] it can be assumed that a quadratic addition formula is practicable.

961



962 **Figure E.5 - Schematic graphs of the same voltage on the lead for different layouts**
963 Ellipse: envelope to all configurations (real leads are outside)

964 The quadratic addition in the combination formulae is a pragmatic combination for the common blanket
965 description of very different forms of antennae in the frequency range 150 KHz to 5 MHz.

966 At frequencies above 150 kHz measurements and calculations proved that the lead inside the tissue
967 can be approximated by a short electrically extended dipole for the electrical field component. This
968 simplification matches to the results of calculations in [E.7], [E.8] and [E.9].

969 Thus the maximum achievable induced voltage on any unipolar lead can be described as the square
970 sum of the magnetic and an electric term:

971 $$V_{pp}^{ind,max} = 3{,}6 \cdot 10^{-7} \cdot \sqrt{10^6 \cdot H_p{}^2 + E_p{}^2} \cdot f \qquad 150\ kHz \le f < 5\ MHz \qquad [E.6]$$

972 where

973 $V_{pp}^{ind,max}$ is the maximum induced voltage on a unipolar lead (open loop), measured peak-to-
974 peak and expressed in V;

975 E_p is the electric field strength outside the human body, measured peak and expressed in
976 V/m;

977 H_p is the magnetic field strength measured peak and expressed in A/m;

978 f is the frequency expressed in Hz; applicable range is from 150 kHz to 5 MHz.

979 NOTE The ratio of E and H conversion factors are derived from numerical field calculations [E.7], [E.8] and are compatible with
980 the findings of other publications referenced to in this annex.

981 ### E.3.7 Range between low and high frequency ranges (5 MHz to 30 MHz)

982 Below 5 MHz, ***H*** and ***E*** field are independent from each other and superposition of electric and
983 magnetic effects has to be taken into account. Above 30 MHz, ***H*** and ***E*** field can not be assumed to be
984 independent and ***H*** or ***E*** field is to be regarded, which ever is higher with respect to far field condition.
985 Between 5 MHz and 30 MHz either method might apply. No definitive model is published so far.
986 Therefore this range is considered as intermediate and the numerical transformation is interpolated
987 between both known parts outside this range.

$$V_{pp}^{ind,max} = \max\left\{\begin{array}{l} 6{,}55\cdot 10^{-10}\cdot H_p\cdot f^{1{,}4} \\ 3{,}6\cdot 10^{-7}\cdot\sqrt{10^6\cdot {H_p}^2+{E_p}^2}\cdot f \\ 3{,}17\cdot 10^{-16}\cdot E_p\cdot f^{1{,}9} \end{array}\right\} \qquad 5\ MHz \le f < 30\ MHz \qquad [E.7]$$

where

$V_{pp}^{ind,max}$ is the maximum induced voltage on a unipolar lead (open loop), measured peak-to-peak and expressed in V;

E_p is the electric field strength outside the human body measured peak and expressed in V/m;

H_p is the magnetic field strength outside the human body measured peak and expressed in A/m;

f is the frequency expressed in Hz; applicable range is from 5 MHz to 30 MHz;

$\max\{\}$ is the maximum value out of the three independent terms.

The broken exponents 1,4 and 1,9 arise from interpolation effects. The upper term (H only) and the lower term (E only) connect to the numerical transformation valid above 30 MHz steadily. At the lower end at 5 MHz these terms are less than or equal to the numerical transformation valid below 5 MHz. The middle term (H and E) prolongs the numerical transformation valid below 5 MHz. At 30 MHz this term is less than the numerical transformation valid above 30 MHz, avoiding any conflict at this corner frequency. The frequency at which one term takes over depends upon the local wave impedance of the exposure field that is the ratio E/H at the area of the implanted lead.

E.3.8 High frequency range (above 30 MHz)

Starting at 30 MHz whole body resonance (due to the effects on a grounded large person in a vertical E field) might occur. Under such conditions the local field impedance ($Z = E/H$) of the exposing field does not matter, because the conductive body tissue forces its own field impedance inside the body. Consequently it makes no sense to look for H and E field additionally, it is sufficient to determine one of them. In this case either H or E is to be observed, which ever results the higher induced voltage in Equation E.8. This assumes far field condition ($E = Z_0 H$ where Z_0 = 377 Ohms). No addition of components is required. The range of partial body resonance rolls out smoothly above 200 MHz.

$$V_{pp}^{ind,max} = 5{,}1\cdot 10^{-2}\cdot\max\left\{\begin{array}{l} 377\cdot H_p \\ E_p \end{array}\right\} \qquad 30\ MHz \le f < 200\ MHz \qquad [E.8]$$

where

$V_{pp}^{ind,max}$ is the maximum induced voltage on a unipolar lead (open loop), measured peak-to-peak and expressed in V;

E_p is the electric field strength outside the human body measured peak and expressed in V/m;

H_p is the magnetic field strength outside the human body measured peak and expressed in A/m;

$\max\{\}$ is the maximum out of two terms.

NOTE The conversion factor is derived from numerical field calculations [E.7], [E.8] and compares with the findings of other publications referenced to in this annex.

Also at frequencies above the body resonance the local impedance of the exposing field does not matter, because wavelength is shorter than the size of the human body. The effects of partial body resonance get attenuated increasingly with frequency. Above 400 MHz resonance effects are predominant no more.

$$V_{pp}^{ind,max} = 4{,}1 \cdot 10^{23} \cdot \max\left\{\begin{matrix} 377 \cdot H_p \\ E_p \end{matrix}\right\} \cdot f^{-3} \qquad 200\ MHz \le f < 400\ MHz \qquad [E.9]$$

where

$V_{pp}^{ind,max}$ is the maximum induced voltage on a unipolar lead (open loop), measured peak-to-peak and expressed in V;

E_p is the electric field strength outside the human body measured peak and expressed in V/m;

H_p is the magnetic field strength outside the human body measured peak and expressed in A/m;

f is the frequency expressed in Hz; applicable range is from 200 MHz to 400 MHz;

$\max\{\}$ is the maximum out of two terms.

In the frequency range 400 MHz to 450 MHz the interference is dominated by the induction on a very short segment of the lead on the connector side. On the one hand the field strength deep inside the thorax (at the heart end of the lead) is low with respect to that near the pulse generator. On the other hand, the lead itself acts like a low pass filter attenuating the signal flow from the tip electrode towards the pulse generator. In this frequency range the numerical transformation can be described as constant.

$$V_{pp}^{ind,max} = 6{,}37 \cdot 10^{-3} \cdot \max\left\{\begin{matrix} 377 \cdot H_p \\ E_p \end{matrix}\right\} \qquad 400\ MHz \le f \le 450\ MHz \qquad [E.10]$$

where

$V_{pp}^{ind,max}$ is the maximum induced voltage on a unipolar lead (open loop), measured peak-to-peak and expressed in V;

E_p is the electric field strength outside the human body measured peak and expressed in V/m;

H_p is the magnetic field strength outside the human body measured peak and expressed in A/m;

$\max\{\}$ is the maximum out of two terms.

NOTE The conversion factor is derived from numerical field calculations [E.10] and is compatible with the findings of other publications referenced to in this annex.

E.4 Conversion based on known compliance with basic restrictions

E.4.1 General

The induction law is not applicable directly in case the field strength is not known. Some devices and installations do not comply with the reference levels (for general public) or with the action values (occupational) but comply with the basic restrictions nevertheless.

Reference levels and action values were field strengths derived from the basic restrictions using simplified numerical modelling providing substantial safety margin. These simplified models fairly well cover far field situations and/or homogeneous whole body exposures. There are many known field sources neither providing far field nor homogeneous whole body exposure.

One of these known situations the derived reference levels do not suite for are localized magnetic fields in the low frequency range (below 5 MHz). For such fields the derived reference levels are much too restrictive and a local magnetic field strength at reference level induces eddy currents in the human body far below the acceptable current densities allowed in basic restrictions. In the exposure guidelines issued by ICNIRP, and those issued by Recommendation and Directive in the European Union, exceeding the reference levels is allowed provided the basic restrictions are not exceeded.

Induced current density in the human body and voltage induced in an implanted lead are closely connected to one another. If the induced current density is known (e.g. it is below the basic restriction), than the maximal induced voltage on an implanted lead can be derived without determination of the according magnet field. For this “shortened” derivation two things are needed, understanding of direct effects of human exposure and induction on a non closed lead inserted in a dissipative medium.

The following subclauses describe a simple analytical model which is based on the H-field induction. It demonstrates the possibility of transient exposure and also the use of the transient voltage test levels in the Pacemaker standard EN 45502-2-1. It cannot cover every situation, but the transfer equations can cover the more complex ones if comparison is made with the voltages in 27.3 of EN 45502-2-1.

E.4.2 Short survey on the direct effects of human exposure (induced current density)

The theoretical dosimetric model for induced current density assumes a closed circular current path orthogonal to an incident magnetic field [E.13] as shown in Figure E.6 below.

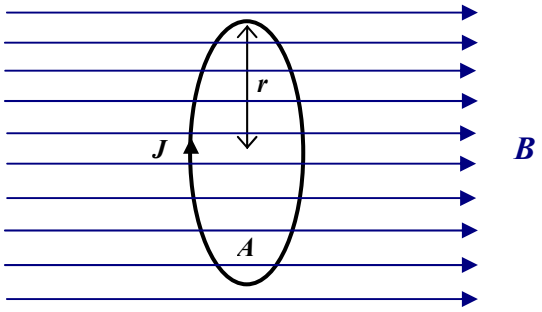


Figure E.6 - Eddy-current inside a conductive medium induced by varying magnetic flux

In general it can be shown that a good approximation for the current induced in a circular cross section is

$$J = \frac{\sigma \cdot r}{2} \frac{dB}{dt} \qquad \text{[E.12]}$$

where

J is the current density;

σ is the conductivity of the path;

r is the radius of the path; and

B is the magnetic field strength.

For a uniform magnetic field with a single frequency component, this simplifies to:

$$J = \pi \cdot r \cdot f \cdot B \cdot \sigma \qquad \text{[E.13]}$$

and

$$B = \frac{J}{\pi \cdot r \cdot f \cdot \sigma} \qquad \text{[E.14]}$$

The electric field inside body tissue is different from that measured in the absence of a body. It is related to the induced current in the tissue by the following equation:

$$J = \sigma \cdot E \qquad \text{[E.15]}$$

where

J is the current density (in A m^{-2});

σ is the conductivity of body tissue (in S m^{-2});

E is the in-situ electric field (in V m^{-1}).

E.4.3 Short survey on induced voltages on an implanted lead

A pacemaker implantation can be considered as an open circuit loop in a magnetic field.

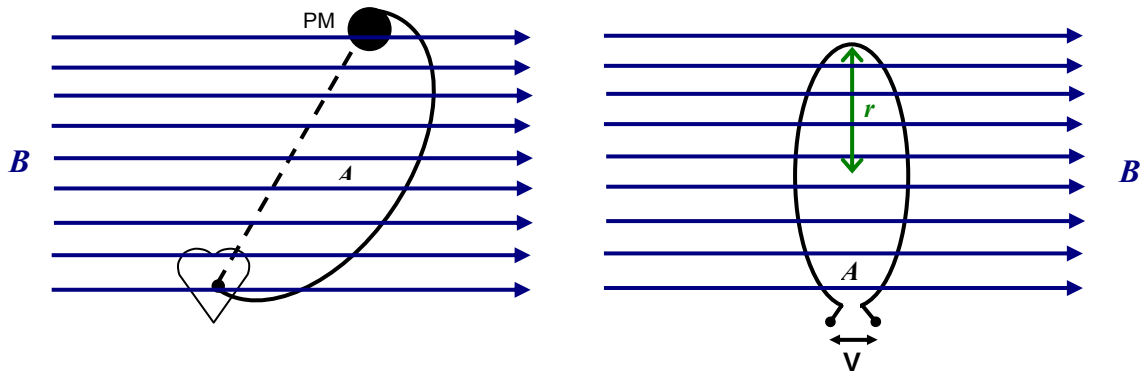


Figure E.7 - Voltage induced on a lead inside conductive body tissue

For the voltage, v, induced across the open ends of a loop in a uniform field (from Maxwell's Equations):

$$v = \oint E dl = -\int_s \frac{dB}{dt} ds \qquad \text{[E.16]}$$

Substituting the value for a sinusoidal field $\boldsymbol{B} = \boldsymbol{B}_0 \cos\omega \boldsymbol{t}$ and integrating over the area gives:

$$v = -\int_s \omega \cdot B_0 \cdot sin(\ \omega t\ ) ds = -A \cdot \omega \cdot B_0 \cdot sin(\ \omega t\ ) \qquad \text{[E.17]}$$

For sinusoidal fields this is equivalent to:

$$V = A \cdot \omega \cdot B \qquad \text{[E.18]}$$

Substituting for $\omega=2\pi f$ and $\boldsymbol{B} = \mu \boldsymbol{H}$ gives the "induction equation" (or the Faraday Equation)

$$V = -2 \cdot \pi \cdot \mu \cdot f \cdot A \cdot H = -2 \cdot \pi \cdot f \cdot A \cdot B \qquad \text{[E.19]}$$

where

$\boldsymbol{V}$ is the induced voltage;

$\boldsymbol{f}$ is the frequency;

$\boldsymbol{A}$ is the loop area;

$\boldsymbol{\mu}$ is the permeability (free space);

$\boldsymbol{H}$ is the magnetic field.

NOTE Using the value for loop area of 225 cm² for A, and allowing for the difference between peak and peak-peak values, in Equation E.19 provides the same result as Equation E.2.

E.4.4 A simple model to analyse the possible voltages at pacemaker terminations generated from induced current density equivalent the basic restrictions of 1999/519/EC

If the theoretical induced current loop and the effective open circuit pacemaker loop are defined as having the same area, with the same B-field, then the two equations E.14 and E.19 can be combined.

Substituting for B provides the following:

$$V = -2 \cdot \pi \cdot f \cdot A \cdot B = -\frac{2 \cdot \pi \cdot f \cdot A \cdot J}{\pi \cdot r \cdot f \cdot \sigma} = -\frac{2 \cdot A \cdot J}{r \cdot \sigma} = -\frac{2 \cdot \pi \cdot r \cdot J}{\sigma} \qquad \text{[E.20]}$$

NOTE While it looks at first that the formula has no frequency dependencies, this is not so because both J and σ vary differently with frequency.

This induced voltage V (open loop), can be compared with the values provided in EN 45502-2-1 to provide some information about the possible levels of voltage at pacemaker terminals when there are fields producing induced body currents equivalent to the maximums in 1999/519/EC.

The normal units for $\boldsymbol{J}$ are in r.m.s., and those for pacemaker terminal voltages are in peak-peak. Thus a multiplying factor of 2.828 must also be applied to normalise the units.

$$V_{pp} = -\frac{5.66 \cdot \pi \cdot r \cdot J_{rms}}{\sigma} \qquad \text{[E.21]}$$

Substituting in values of J from 1999/519/EC and values for σ based on the Brain and Nerve tissues over a range of frequencies gives the following graph, Figure E.8. This shows the possible voltage induced at pacemaker terminals, as compared against some of the values provided in the EN 45502-2-1. This graph exemplifies that human beings (without implants) are much more immune against pure magnetic fields in the frequency range up to 5 MHz than are patients with implanted pacemakers. At the moment, the threshold values against sensing of interference required in EN 45502-2-1 for pacemakers are derived from the reference levels of 1999/519/EC rather than from the Basic Restrictions. But at least the damage thresholds for pacemakers generally correspond to the Basic Restrictions of 1999/519/EC as compared using E.21.

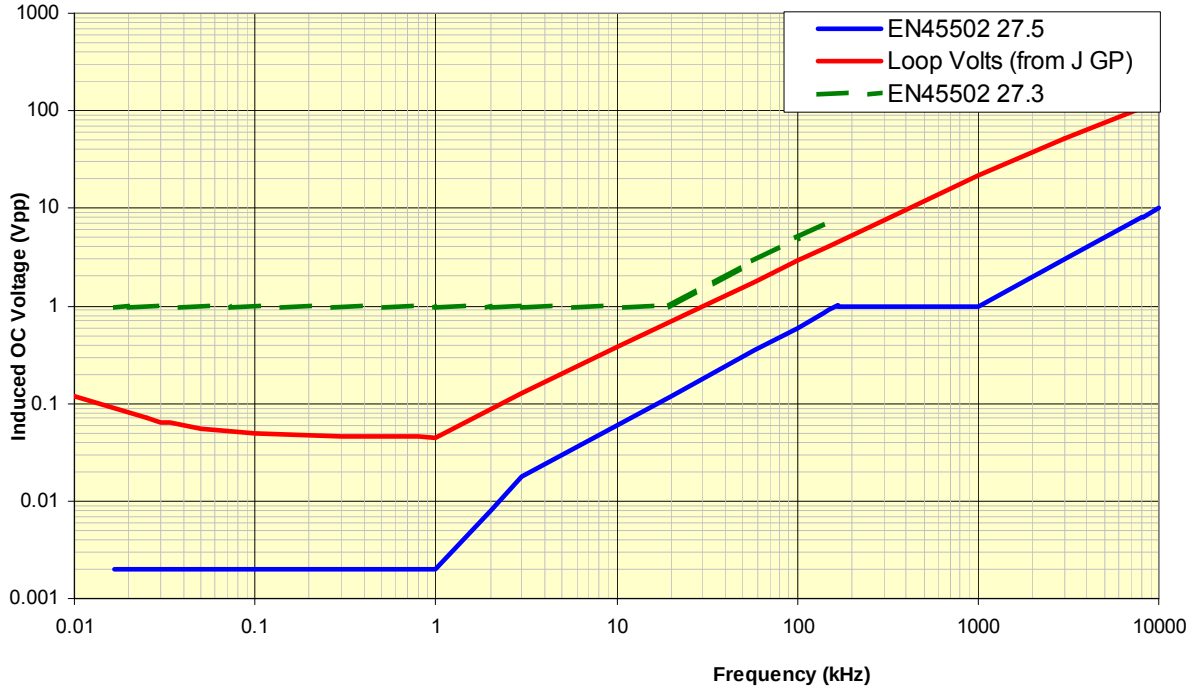


Figure E.8 - Voltages on an implanted lead (peak-to-peak sensing thresholds of unipolar pacemakers according to EN 45502-2-1 (blue), derived from magnet field corresponding to basic restrictions of 1999/519/EC (red) and damage threshold of pacemakers according to EN 45502-2-1 (green dashed)

This model does indicate that for exposure situations, where the fields are above the reference levels but the induced current is not above the general public basic restrictions, the induced voltage on an exposed pacemaker implantation is likely to be below the damage test levels of the pacemaker devices. In such cases it can be possible for transient exposure of persons with implanted pacemakers from field levels above the reference levels. When this occurs the device may go into one of the protective modes of operation such as fixed rate pacing or may be briefly inhibited during the exposure. Thus long term exposure is not recommended.

NOTE This is a simplified model and there could be specific exposure situations to which the assumptions behind the model do not apply or in which the level of non-uniformity and complexity of the exposure could make the induced current mode too conservative. In such cases the total model would not be conservative. Especially this simplified model covers pure magnetic field exposure only. In case of pure electric or combined electric and magnetic field exposure, the superposition of both influences is to be observed.

E.5 References

Literature referencs which where taken into account for deriving the conversions. None of these reference cover the whole frequency range and some of them cover special field situations such as pure magnetic or pure electric fields only.

Some of the studies are not commonly found in libraries. They can be accessed at DKE Deutsche Kommission Elektrotechnik Elektronik Informationstechnik im DIN und VDE.

[E.1] Irnich W., Herzschrittmacherpatienten unter Hochspannungsleitungen, Herzschr. Elektrophys 10 (1999) 164-169

[E.2] Irnich W., Berechnung der inneren aus der äußeren elektrischen Feldstärke und ihr Einfluß auf Herzschrittmacherpatienten, Biomed. Technik, 44 (1999), 232-236

[E.3] Scholten A., Silny J., Grenzwerte für moderne Herzschrittmacher in elektrischen 50 Hz-Feldern, FEMU-Forschungsbericht 2000, 47-50

[E.4] F. Gustrau, A. Bahr, S. Goltz, S. Eggert: "Active medical implants and occupational safety - measurement and numerical calculation of interference voltage", Biomedizinische Technik (Ergänzungsband 1, Teil 2), 47: 656-659, 2002. (ISBN 0939-4990)

[E.5] Irnich, W.: Electronic Security Systems and Active Implantable Medical Devices. – In: Journal of Pacing and Clinical Electrophysiology, PACE, Futura Publishing Company 2002, Vol. 25 No. 8, P. 1235-1258

[E.6] Bossert, T.; Dahme, M.: Beeinflussung von Herzschrittmachern durch leistungsstarke Funksender. – In: Elektromagnetische Verträglichkeit, Tagungsband EMV'88, Hüthig-Verlag (1988), S. 545 - 554

[E.7] Hansen, V.; Xu, X.; Kammerer, H.; Eibert, T.: Elektromagnetische Felder im Nahbereich im freien Raum und im biologischen Körpergewebe, 30 kHz bis 100 MHz, HF-Störspannungen an Herzschrittmachern. – Bericht der Ruhr-Universität Bochum im Auftrag der Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, Fb 733 (1995)

[E.8] Xu, X.: Störbeeinflussung implantierter Herzschrittmacher durch elektromagnetische Nahfelder. – Dissertation an der Ruhr-Universität Bochum (1997)

[E.9] Hansen, V.; Streckert, J; Xu, X.: Rechenprogramm zur Unterstützung und Auswertung von betrieblichen Messungen des elektromagnetischen Nahfeldes, 30 kHz bis 50 MHz. – Bericht der Bergischen Universität Wuppertal im Auftrag der Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, Ergänzender Nachtrag zur Schrift Fb 733 (1997)

[E.10] Hansen, V.; Vaupel, T.: Numerische Berechnung der Eingangsimpedanz von Herzschrittmachern und der durch einen externen Dipol am Herzschrittmachereingang erzeugten Störspannung. – In: Newsletter Edition Wissenschaft (1996), Nr.6, S. 9 - 22

[E.11] Hansen, V.; Streckert, J.: Simulationsrechnung zur Ermittlung der Störspannung am Eingang implantierter Herzschrittmacher im Fernfeld einer Mobilfunk-Basisstation des D-Netzes. – Bericht der Bergischen Universität Wuppertal im Auftrag von Mannesmann Mobilfunk (1997)

[E.12] Landstorfer, F. M.; Geisbusch, L.; Jakobus, U.; Maier, M.; Ruoß, H.-O.; Spreitzer, W.; Waldmann, J.: Development of a model describing the coupling between electrodes of cardiac pacemakers and transmitting antennas in their close vicinity in the frequency range from 50 MHz to 500 MHz. – Final Report second edition des Instituts für Hochfrequenztechnik Universität Stuttgart im Auftrag der Forschungsgemeinschaft Funk (10.1999)

[E.13] Occupational exposure to electromagnetic fields: practical application of NRPB guidance, P.J. Chadwick, NRPB-R301, National Radiological Protection Board, Chilton, Didcot, Oxfordshire, UK, 1998

Annex F
(informative)

Interference from power-frequency magnetic and electric fields from transmission, distribution and use of electricity

F.1 Sensitivity of pacemakers to interference

Pacemakers are potentially susceptible to interference from magnetic and electric fields arising from electricity transmission and distribution systems and from the use of electricity, but this only occurs if the fields are strong enough. This interference arises primarily because both magnetic and electric fields can induce voltages in the leads between the pacemaker and the heart.

Pacemakers fulfilling the requirements of EN 45502-2-1 will not suffer interference from the fields from electrical equipment in situations where the electric and magnetic fields are lower than the reference levels specified for the general public in the Council Recommendation 1999/519/EC [F.1] about EMF exposures to the general public where the time of exposure is significant. Therefore any member of the general public with a pacemaker should not normally experience interference from power frequency sources of fields unless they have received a specific warning from their physician that their pacemaker implantation is exceptionally susceptible to interference. However there are situations where the field can be larger than public exposure reference levels. For the general public these are where the exposure exceeds the reference level but not the basic restriction and where period of exposure is not significant, and for occupational exposure situations higher exposure levels are permissible (currently set out in the Directive 2004/40/EC [F.2] which is due to apply from April 2012). It is therefore necessary to be able to understand whether or not interference takes place.

The purpose of this Annex is to draw together information that will assist with assessing the likelihood of interference to their pacemaker, for workers with pacemakers who work in environments where the magnetic and electric fields at the power frequency of 50 Hz exceeds the public exposure reference levels.

This annex summarises the induced voltage immunity requirements for pacemakers at power frequencies (F.2), the voltages induced in the leads by magnetic fields (F.3), the voltages induced in the leads by electric fields (F.4) and then this information is combined to show the field levels for which pacemakers are required to be immune from interference (F.5). There are several reasons why in practice, immunity from interference is better than these minimum requirements, and these are discussed in F.6.

Finally in F.7 consideration is given about the possibility of interference from power frequency fields in different exposure situations, general public, under power lines and occupational.

F.2 Immunity requirements

Tests to ensure pacemakers offer reasonable immunity to electromagnetic interference are given in Clause 27 of EN 45502-2-1. Tests to check that the voltages induced in leads are unlikely to cause persistent malfunction, transient malfunction, or unacceptable changes in therapeutic behaviour of the device are given in 27.3, 27.4 and 27.5 respectively. The last of these is the most demanding and is therefore the one used here.

The tests of 27.5.1 cover the frequency range that includes power frequencies of 50 Hz and its harmonics. A test signal is applied to the terminals of the pacemaker which is required to continue operating unaffected throughout the tests. The test signal comprises of intermittent voltage sine waves (100 ms on and 600 ms off) of frequencies throughout the frequency range under test. The amplitudes of the test signals for the relevant frequency range 16,6 Hz to 1 kHz are given in Table F.1.

Table F.1 - Amplitude of the immunity test signal applied. These are for the test under 27.5.1 of EN 45502-2-1 for the frequency range 16.6 Hz to 1 kHz

	Unipolar pacemaker	Bipolar pacemaker
Test signal	2 mV peak-to-peak	0,2 mV peak-to-peak

Provided that the voltage induced in the leads by the field is less than the immunity test voltages in Table F.1, the pacemaker should be immune from interference.

It may be noted that it is specified in EN 45502-2-1 that the immunity tests are carried out for sensitivity settings of 2 mV peak to peak for unipolar pacemakers and 0,3 mV peak to peak for bipolar pacemakers or, if the device does not have settings this sensitive, the tests must done at the most sensitive settings available on the device. If the tests show that the pacemaker does not achieve immunity at these settings, a warning is included in the documentation. When pacemakers are implanted in a patient it is common to use a lower sensitivity (i.e. a higher numerical value of the sensitivity setting) than those used for the immunity test. This means the pacemaker is also less sensitive to interference voltages and therefore they have a greater immunity to interference from magnetic and electric fields.

EN 45502-2-1 also contains tests to ensure, when the interference voltage reaches 1 V_{pp}, that there is no transient or persistent malfunction of the device.

F.3 Voltage induced in the leads by magnetic fields

The r.m.s. voltage induced in the leads by a changing magnetic field is found using Faraday's law:

$$V = B \cdot A \cdot 2 \cdot \pi \cdot f \qquad [F.1]$$

where

V *is the induced voltage in Volt;*

B *is the r.m.s. magnetic flux density in Tesla;*

A *is the area of the inductive loop in m^2;*

f *is the frequency in Hz.*

Annex E provides information about the effective area of loop to use and concludes that it is 225 cm² for unipolar leads and a factor of 20 less (11,25 cm²) for bipolar leads. These are the maximum areas, corresponding to when the field direction relative to the body is horizontally from front to back.

NOTE This area of 225 cm² applies for unipolar pacemakers implanted in the left pectoral position. Implantation in the right pectoral results in a significantly smaller loop area (say 135 cm²) because of the S-shaped path taken by the lead, which results in a lower induced voltage. For a loop area of say 135 cm² the induced voltage would be reduced by a factor of 0,6 and so the immunity would be correspondingly higher.

The sensitivity settings of pacemakers are expressed in mV peak to peak, and the loop area is expressed in cm^2. The peak to peak voltage for 50 Hz therefore becomes

$$V_{pp} = B \cdot A \cdot 8{,}89 \cdot 10^{-8} \qquad [F.2]$$

where

V_{pp} *is the induced peak to peak voltage in Volt;*

B *is the r.m.s. magnetic flux density in μT;*

A *is the area of the inductive loop in cm^2;*

F *is the frequency in Hz.*

And for frequency components other than 50 Hz it is

$$V_{pp} = B \cdot A \cdot N \cdot 8{,}89 \cdot 10^{-8} \quad \text{[F.3]}$$

where

N is the frequency factor (or harmonic number).

$$N = f / 50$$

Thus for a unipolar device in the left pectoral position

$$V_{pp} = 20{,}0 \cdot 10^{-6} \cdot B \cdot N \quad \text{[F.4a]}$$

where

V_{pp} *is the induced peak to peak voltage in Volt;*

B *is the r.m.s. magnetic flux density in μT.*

and for a unipolar device in the right pectoral position

$$V_{pp} = 12{,}0 \cdot 10^{-6} \cdot B \cdot N \quad \text{[F.4b]}$$

where

V_{pp} *is the induced peak to peak voltage in Volt;*

B *is the r.m.s. magnetic flux density in μT.*

For a bipolar device

$$V_{pp} = 1{,}0 \cdot 10^{-6} \cdot B \cdot N \quad \text{[F.5]}$$

where

V_{pp} *is the induced peak to peak voltage in Volt;*

B *is the r.m.s. magnetic flux density in μT.*

Note that these induced voltages correspond exactly to those given in Equations E.4 and E.5 for magnetic field. Thus the voltage induced in bipolar leads by a 50 Hz magnetic field of 200 μT is 0,20 mV_{pp} and the voltage induced in unipolar leads by a 50 Hz magnetic field of 100 μT is 2,0 mV_{pp}.

F.4 Voltage induced in the leads by electric fields

For electric fields the r.m.s. voltage V induced on an insulated wire within conductive tissue is the voltage in the tissue between the two ends of the wire which is

$$V = L \cdot \cos(\theta) \cdot E_{\text{int}} \quad \text{[F.6]}$$

where

L *is the distance between the ends of the wire, in m;*

θ *is the angle between the straight line joining the ends of the wire and the electric field vector;*

E_{int} *is the r.m.s. value of the internal electric field in the tissue, in V/m.*

The electric field in the tissue is related to the current density in the tissue and to its conductivity by

$$E_{\text{int}} = J / \sigma \qquad \text{[F.7]}$$

where

J *is the average r.m.s. current density in the tissue in A/m^2;*

σ *is the average conductivity through the same tissue in S/m.*

This current density may be calculated numerically however the calculation of current density is also amenable to analytical evaluation using the method set out in EN 62226-3-1 [F.3].

The total current that flows in a body depends on the shape and posture of the body and is proportional to the unperturbed external electric field, and the distribution of that current in the body is affected by the conductivity distribution. Thus

$$J = k \cdot E_{ext} \qquad \text{[F.8]}$$

where

the coefficient k gives the ratio of current density to external electric field.

Combining the above three equations gives

$$V = L \cdot \cos(\theta) \cdot k \cdot E_{ext} / \sigma \qquad \text{[F.9]}$$

where

L *is the distance between the ends of the wire in m;*

θ *is the angle between the wire and the electric field vector;*

k *is the r.m.s. current density in the tissue per kV/m of applied external field;*

E_{ext} *is the r.m.s. value of the external electric field in kV/m;*

σ *is the average conductivity through the same tissue in S/m.*

We now consider each of the parameters.

In accordance with Annex E, for unipolar leads, for the vertical distance between the tip and case we use 0,25 m (L cos(θ) = 0,25 m). For bipolar leads the maximum pin to tip distance is 2 cm and the maximum value for L cos (θ) is one twentieth of the value for unipolar leads (i.e. L cos(θ) = 0,012 5 m).

For σ we use the average conductivity of the body of 0,2 as used by ICNIRP (1998) [F.4].

For k we refer to IEC 62226-3-1 which gives the induced current for a person, standing with arms at their sides. The current density per kV/m of external unperturbed electric field (i.e. k) is just under 0,055 mA/m^2 in the upper chest; increasing downwards in the body until at the waist the values is about 0,09 mA/m^2 or 0,1 mA/m^2. Since the analysis relates to the voltages induced between the heart and pacemaker mounted in the upper chest, it would be reasonable and practical to take an average across the height of the chest of say 0,075 mA/m^2. In fact the slightly higher value of 0,087 mA/m^2 is taken so as to result in the same value for induced voltage as is obtained in Annex E.

NOTE The current density is proportional to frequency; these are values for 50 Hz. Values for third and fifth harmonic for example would be 3 and 5 times greater.

The immunity test voltages for pacemakers are expressed in mV peak to peak. The peak to peak voltage for 50 Hz therefore becomes

$$V_{pp} = 2 \cdot \sqrt{2} \cdot E_{ext} \cdot L \cdot \cos(\theta) \cdot k \,/\, \sigma \qquad \text{[F.10]}$$

where

V_{pp} *is the induced peak to peak voltage in Volt;*

E_{ext} *is the r.m.s. value of the external electric field in kV/m;*

L *is the distance between the ends of the wire in m;*

θ *is the angle between the wire and the electric field vector;*

k *is the r.m.s. current density in the tissue per kV/m of applied external field;*

σ *is the average conductivity through the same tissue in S/m.*

And for frequency components other than 50 Hz it is

$$V_{pp} = 2 \cdot \sqrt{2} \cdot E_{ext} \cdot L \cdot \cos(\theta) \cdot k \cdot N \,/\, \sigma \qquad \text{[F.11]}$$

where

N is the frequency factor (or harmonic number).

$$N = f \,/\, 50$$

Thus for unipolar leads

$$V_{pp} = 0{,}307 \cdot 10^{-3} \cdot E_{ext} \cdot N \qquad \text{[F.12]}$$

where

V_{pp} *is the induced peak to peak voltage in Volt;*

E_{ext} *is the r.m.s. value of the external electric field in kV/m.*

And for bipolar leads

$$V_{pp} = 0{,}015\,4 \cdot 10^{-3} \cdot E_{ext} \cdot N \qquad \text{[F.13]}$$

where

V_{pp} *is the induced peak to peak voltage in Volt;*

E_{ext} *is the r.m.s. value of the external electric field in kV/m.*

NOTE 1 These induced voltages correspond exactly to those given in Equations E.4 and E.5 for electric field, which was achieved by selection of a value of k to slightly higher than was suggested by the data.

NOTE 2 For a non-sinusoidal electric field it is the peak-to-peak value of the induced voltage wave that should be considered.

At elevated electric fields it is also necessary to consider contact currents that arise from touching conducting objects that are a different potential, though this is not addressed here.

F.5 Values of 50 Hz magnetic and electric field that may cause interference

Now we are in a position to bring this together to determine the magnetic and electric fields that may cause interference. Table F.2 shows the 50 Hz magnetic and electric fields that can, under pessimistic assumptions, produce a voltage induced in the leads equal to the immunity test voltage given in Table F.1.

At frequencies other than 50 Hz, the voltage induced by both electric and magnetic fields is proportional to their frequency, whereas according to Figure G.3 the voltage that may cause interference is constant up to 1 kHz. Therefore the field that causes interference is inversely proportional to the values in Table F.1.

Table F.2 - Values of 50 Hz electric and magnetic field (r.m.s.) that might, under unfavourable circumstances, cause interference in a pacemaker

Type of leads	Unipolar	Unipolar	Bipolar
Position of implant	Left pectoral	Right pectoral	Left or Right
Immunity test voltage, [mV_{pp}]	2,0	2,0	0,2
Electric field, [kV/m] r.m.s.	6,5	6,5	13
Magnetic field, [µT] r.m.s.	100	167	200

As stated in EN 45502-2-1 the objective in setting the immunity requirements for pacemakers was to ensure they are immune to interference from fields at the reference levels specified in the Council Recommendation [F.1] about exposures to the general public (100 µT and 5 kV/m). Table F.2 shows that for 50 Hz that is achieved for both unipolar and bipolar pacemakers. For pacemaker models where this is not achieved a warning has to be given in the documentation for the pacemaker.

F.6 Factors that affect the immunity from interference

F.6.1 Reasons for improved immunity

There are several reasons why the immunity to interference from power frequency fields is likely to be better than is given in Table F.2:

a) *Additional filtering in the pacemaker input circuits*

The immunity tests referred to above are designed to ensure that the pacemaker can withstand the specified test signal over a wide range of frequencies, whereas the sensitivity of the input circuitry of a pacemaker varies with frequency. This means that to pass the test for the more sensitive frequencies, at other frequencies the input circuits will be more immune to interference than is required by the standard. Furthermore, because it is known that fields at power frequencies are especially likely to be encountered in the environment, it is common for additional filtering to be included to increase the immunity at 50 Hz and 60 Hz. The extent of this effect will vary from one pacemaker design to another and cannot be quantified without access to specific pacemaker information.

b) Location of implantation

Where the implantation is in the right pectoral position the lead follows more of an S shape which has a lower effective area and results in an increase in immunity.

c) Orientation relative to the field

For magnetic field interference, the calculation of induced voltage assumes the field vector is in the optimal direction for linking to the loop formed by the leads (horizontal, front to back). For electric fields, the field vector is assumed to be parallel with the body. When the relative orientations are different the interference will be reduced.

d) *Use of a lower sensitivity (i.e. higher sensitivity setting)*

When the pacemaker is used with a higher numerical value of sensitivity setting than the one used for the interference tests it will be less sensitive to interference voltages. Subclause F.5.2, provides a method for anticipating the increase in immunity.

e) *Bipolar or unipolar*

Interference is less with bipolar leads than with unipolar leads. It is the bipolar type that is now most commonly used especially in North America and at least part of Europe. Many years ago unipolar was the only type used. Now they tend to be reserved for situations where a stronger pacing signal is required, and therefore it is unlikely that the person in which it is implanted will be employed to work in high exposure situations.

f) Electric fields

For electric fields it has been assumed that the person is standing with arms at their side and electrically grounded. If they are wearing non-conducting footwear, the interference field will be higher and if they crouch or lie down, the interference field will also increase. If they reach upwards with one or both arms then the interference field will decrease.

F.6.2 Adjustment for pacemaker sensitivity

Pacemakers have adjustable sensitivity settings to allow the physician to optimise the implantation for each patient. The immunity tests ensure that the pacemaker is immune to external interference at the most sensitive settings of the pacemaker, whereas in practice pacemakers are used with a less sensitive setting. This means they would also be less sensitive to interference voltages and therefore they have a greater immunity to interference from magnetic and electric fields than is given in Table F.2.

To illustrate this we define a factor, referred to as the immunity ratio, IR, which is the ratio by which the immunity is increased relative to the immunity test conditions. To a first approximation the immunity ratio will be similar in value to the ratio of sensitivity settings:

$$IR \approx \frac{V_S\ (in\ use)}{V_S\ (imunity\ tests)} \qquad [F.14]$$

where

Vs (in use) *is the sensitivity setting that has been set for the patient;*

Vs (immunity tests) *is the most sensitive sensitivity setting for which the pacemaker complied with the immunity tests, which would normally be 2 mV_{pp} (unipolar) or 0,3 mV_{pp} (bipolar) or higher.*

The immunity ratio will be ≥ 1 except for the situation where there is a sensitivity setting in use that is associated with a warning in the accompanying documentation. This is also referred to as “Case 2” in the normative Clause 4 of this standard.

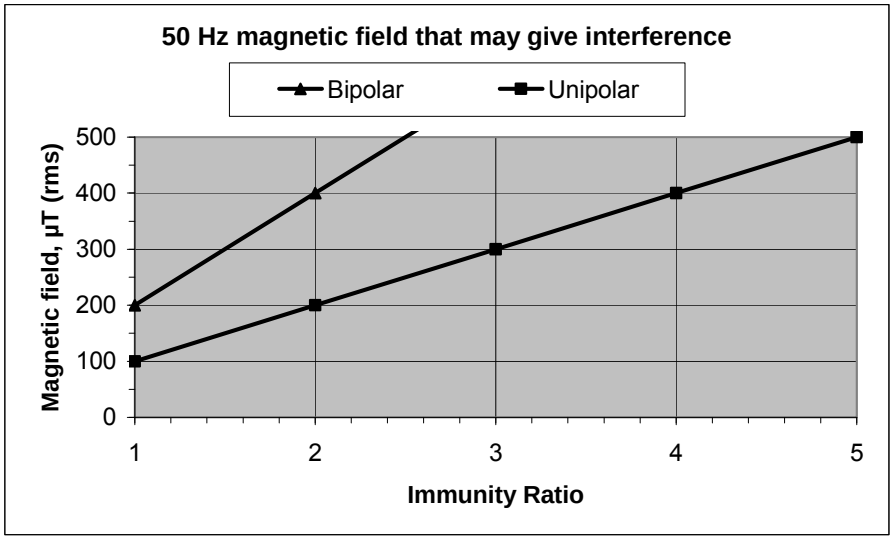


Figure F.1 - How the immunity ratio affects magnetic field that may result in interference

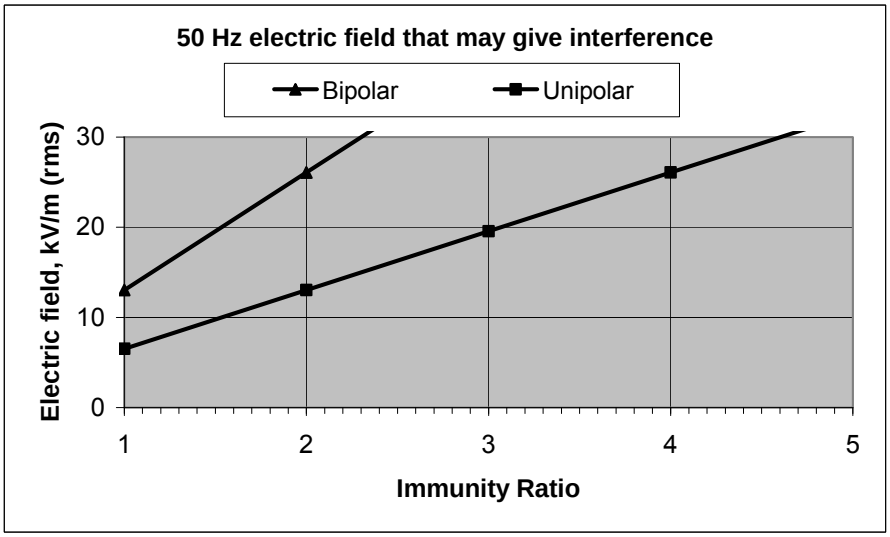


Figure F.2 - How the immunity ratio affects electric field that may result in interference

F.7 Application to exposure situations

F.7.1 Public exposures

Pacemakers fulfilling the requirements of EN 45502-2-1 will not suffer interference from the fields from electrical equipment in situations where the electric and magnetic fields are lower than the reference levels specified for the general public in the 1999 Council Recommendation [F.1] where the time of exposure is significant. Therefore any member of the general public with a pacemaker should not normally experience interference from power frequency field sources unless they have received a specific warning from their physician that their pacemaker implantation is exceptionally susceptible to interference. However there are occasional situations where public exposures can be larger than public exposure reference levels. These are where the exposure exceeds the reference level but not the basic restriction and where period of exposure is not significant.

F.7.2 Beneath high voltage power lines

Table C.1 of EN 50527-1 gives typical maximum and extreme maximum fields beneath high voltage overhead lines. The extreme fields only occur where the height of the conductors above ground is at the lowest permitted. The induced voltages in the leads of a pacemaker for these field levels calculated using Equations F.4a, F.5, F.12 and F.13, which correspond to Equations E.4 and E.5, and are given in Table F.3. The interference voltages are given for magnetic and electric fields separately and together. In the latter case the voltages have been simply added although in practice the phase sum will be less.

Table F.3 - Summary of maximum field values beneath high-voltage overhead lines

Maximum possible 50 Hz interference	Electric field (kV/m r.m.s.)	Magnetic field (μT r.m.s.)	Maximal possible interference at the connector of the device (mV peak-peak)	
			Unipolar (left pectoral position) mV pp	Bipolar mV pp
Test voltage			2,0	0,2
Typical maximum fields (1 m above ground)	≤ 3,0	≤ 40	For B ≤ 0,80 For E ≤ 0,92 For both ≤ 1,72	For B ≤ 0,040 For E ≤ 0,046 For both ≤ 0,086
Occasional maximum fields (1 m above ground)	6,0 – 9,0	45	For B 0,90 For E 1,84 to **2,75** **For both 2,74 to 3,65**	For B 0,045 For E 0,092 to 0,138 For both 0,137 to 0,183
Theoretical maximum (though unlikely to arise) fields (2 m above ground.)	13	125	**For B 2,54** **For E 3,97** **For both 6,51**	For B 0,127 For E 0,199 **For both 0,326**
NOTE Entries exceeding the immunity test voltage are shown in **bold**.				

Table F.3 shows that bipolar pacemakers are immune to fields from high voltage power lines even when the fields exceed the public reference levels by a large margin.

Unipolar pacemakers are immune from fields from high voltage power lines for all but the most extreme and unlikely situations.

It can be concluded that for most sensing parameters of pacemakers, influence from high-voltage overhead lines can be excluded, with the possible exception of unipolar pacemakers with the most extreme sensitivity settings.

F.7.3 Occupational settings

The action values given in 2004/40/EC [F.2] (corresponding to reference levels) at 50 Hz for occupational exposures are higher than for public exposures (500 µT and 10 kV/m), and higher fields still are permissible, though in most occupational situations fields are much lower.

For workers, whose exposures exceed the general public reference levels it is necessary to carry out a risk assessment in accordance with the normative part of this standard, to determine the likelihood of interference occurring. This would take into account the location of implantation, the type of leads used, the model of pacemaker, and the sensitivity setting used. The information contained in this annex suggests that it is only in occasional situations where a person with a pacemaker would not be able to work.

Bipolar configurations are immune to interference at higher levels of field than unipolar, and are therefore to be preferred for patients who need to work in areas where exposures exceed the public exposure reference levels.

For a worker with an implanted bipolar pacemaker with a numerical sensitivity setting greater than the minimum that was used for the immunity tests will also be more immune to interference. For example, consider a patient with a bipolar pacemaker that passed the immunity tests with a sensitivity setting of 0,3 mV_{pp}, is implanted with a sensitivity setting of 0,9 mV_{pp}. The estimated immunity ratio (from Equation F.14) is 3 which means that it would be expected that the patient will be free from interference from induced voltages at up to at 600 µT.

Similarly the same pacemaker should be free from interference from induced voltages from electric fields at values higher than would normally be encountered even in occupational situations. However, and great care must be taken to ensure contact currents arising from touching ungrounded conducting objects in a high electric field do not cause pacemaker interference.

F.7.4 Temporary exposure above the interference levels

We have seen that there can be field levels which will generate voltages above the interference test voltage thresholds given in Table F.1. EN 45502-2-1 also contains tests to ensure that, at voltages above the interference thresholds, there is a controlled behaviour and that there is no malfunction of the device. In the intermediate region, above the field which causes interference, but below the field that causes malfunction, the duration of the temporary exposure should be considered. While the pacemaker tests of EN 45502-2-1 specify either uninfluenced behaviour or transition to a manufacturer specified “interference mode” (usually some form of asynchronous pacing), this mode may not be suitable for long term operation with certain patients. In this situation, input from the responsible physician should be obtained in addition to the assessment of the exposure level.

F.8 References

[F.1] 1999/519/EC, Council Recommendation of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz)

[F.2] Directive 2004/40/EC of the European Parliament and of the Council of 29 April 2004 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (18th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)

[F.3] EN 62226-3-1:2007, Exposure to electric or magnetic fields in the low and intermediate frequency range, methods for calculating the current density and internal electric field induced in the human body - Part 3-1 Exposure to electric fields - analytical and 2D numerical models (62226-3-1:2007)

[F.4] ICNIRP, 1998, Guidelines for limiting exposure to time-varying electric, magnetic, and electromagnetic fields (up to 300 GHz), Health Physics April 1998, Volume 74, Number 4.

Annex G
(informative)

Determination of the pacemaker immunity and guidelines provided by pacemaker manufacturers - Determination method

Pacemaker immunity to electromagnetic interference (EMI) that exceeds the reference levels for the general public given in 1999/519/EC may be determined in several ways:

a) obtain values of the immunity directly from the pacemaker manufacturer. For certain types of interference not addressed by the pacemaker product standards (see EN 45502-2-1 and [G.1]), specific information about the type of EMI signal will be required for them to assess immunity. This information may be obtained during the source characterization of 4.4.1, and may include

- whether the signal is continuous or modulated,
- the continuous or carrier frequency,
- the type of modulation (amplitude, phase, frequency),
- Characteristics of the modulating signal (continuous, pulse, duty cycle, duration, modulation depth),
- for multiple EMI signals, the amplitude relationship between them.

b) perform an immunity test using in-vitro or benchtop methods. If this approach is chosen, all of the following requirements must be met:

- testing must be performed using a device and lead(s) identical to that implanted in the pacemaker bearer;
- the device must be programmed with the software revision and settings identical to those of the worker in question.

Testing must be performed in accordance with the methods of the pacemaker product standards given in EN 45502-2-1 and [G.1]. Since the level of applied signals will necessarily be higher than those specified for immunity in the pacemaker product test standards, care must be exercised to prevent irreversible damage to the device that would invalidate test results.

G.1 EMC and pacemakers – General guidelines

The purpose of this annex is to provide general information on pacemakers' susceptibility to electromagnetic fields (EMF).

Implantable pacemakers are particularly sensitive to peak signals. Emitted fields, whether intentional or not, with frequency components that are similar to those found in a cardiac signal can be problematic. These emitted frequency components can be either from the carrier signal or modulation of the carrier signal. Implantable pacemakers are designed to sense low-level cardiac electrogram signals . As such, the devices can be thought of as very sensitive receivers of low frequency signals. It is important to understand that pacemakers operate by detecting peak voltages, which could also result from a magnetic field coupling with the implanted lead system.

While device filtering in the medium and high frequencies can attenuate interference up to certain levels, it should be noted that high amplitude, modulated or pulsed signals may contain artifacts that fall within the bandpass of the implantable pacemaker and potentially be demodulated and detected, causing undesirable device operation. This latter behaviour may be caused by a number of phenomena dependent on device design including voltage dependent linearity limitations in circuitry, which must be ahead of the filtering.

The potential for interference with implantable pacemakers is a complex topic and is dependent on several factors, such as (but not limited to)

- frequency of the emitted field,
- strength of emitted field,
- modulation format,
- duration of exposure,
- proximity to the patient,
- position of the patient,
- patient characteristics: pacemaker dependency, susceptibility to asynchronous pacing, susceptibility to high pacing rate,
- pulse generator parameters, programmable and nonprogrammable,
- lead coupling factors.

When a worker with an implantable pacemaker is exposed to electromagnetic interference above the interference threshold, the implanted pacemaker may exhibit one or more of the following responses:

- missed pacing beats / stop pacing (pacemaker inhibition);
- reversion to asynchronous pacing;
- high pacing rate (tracking of the EMI by dual chamber devices);
- current induced into the lead system that can trigger an arrhythmia (for higher field levels);
- activation of the magnetic switch (static fields).

An intentional or inadvertent emitter that produces field levels that are at or below human safety exposure standards, national telecommunication regulations or EU recommendation or regulation (such as EC Recommendations 1999/519/EC, EMF Directive 2004/40/EC) could still interfere with an implantable pacemaker. These standards and regulations are intended to avoid biological effects from electromagnetic fields. They are not intended to ensure electromagnetic compatibility (EMC) between emitting equipment and pacemakers.

The human safety EMF exposure guidelines may allow for duty cycle and R.M.S. time averaging of the emitted signal. Pacemakers' circuits are unable to handle these time-averaged large signals. To ensure the safety of pacemaker patients, it is advisable that their exposure be limited to the frequencies (either as a carrier or modulation) and field levels shown in Figure G.1 and Figure G.2.

For surgical implantation, pacemakers must be small in size, lightweight, and provide a long battery life. These combined constraints limit the degree of filtering that can be incorporated into the devices to reject EMI sources, especially at the lower frequencies. Pacemaker immunity basically follows the ICNIRP Public Reference Levels [G.2].

Correlation of pacemaker interference input voltages with radiated electric fields is a very complex subject. Such RF input voltages depend upon coupling factors that vary in each frequency band. For example, lower frequency electric fields induce circulating currents in body tissue, which can be detected by pacemaker circuits as voltage differentials. At higher frequencies, the leads can act as an antenna. At even higher frequencies (like mobile telephone frequency bands), the EMI coupling is primarily into the short lead lengths of the pacemaker header connector block (the rest of the lead wire system is decoupled due to its high impedance and the dampening effect of body tissue). Frequencies above 3 GHz are very unlikely to interfere with pacemakers due to the reflection and absorption of body tissue.

Figures G.1 to G.4 illustrate the correlation between the voltage test levels in 27.3, 27.4 and 27.5 of EN 45502-2-1:2003 pacemaker product standard and electromagnetic field strength levels in A/m peak to peak. This correlation uses an equation based on Faraday's law and reflects an effective induction loop area of 225 cm² considered worst case for left pectoral implants . It should be noted that the largest geometrical implantation loop areas exceed 300 cm² for special cases, e.g. large patients or older implanted systems. The maximum effective electrical induction loop area of 225 cm² however, as used in this standard, is reduced compared with the equivalent geometric lead loop area. Theoretical field calculations and measurements both confirm this reduction effects [G.3] [G.4] [G.5].

Figure G.1 shows the voltage at the input terminals of the pacemaker while Figure G.2 shows the magnetic field that produces this voltage. This assumes the effective induction area of 225 cm², as used in EN 45502-2-1. Figures G.3 and G.4 designate operations that may occur at levels above those shown in Figures G.1 and G.2:

1. EMF levels below filter response (Zone 1): In this region, continuous exposure to an EMI source is unlikely to have an effect on implantable pacemaker operation and is of nominal concern for emitter manufacturers. Zone 1a is as provided in EN 50527-1 and Zone 1b is an additional uninfluenced region for pacemakers as provided in this standard. Both are part of Zone 1;

2. EMF level above filter response (Zone 2a): In this region the EMI source may cause reversion to asynchronous pacing in implantable pacemakers. While asynchronous pacing at a fixed rate is clinically acceptable, it should be understood that it may result in competitive rhythms with intrinsic cardiac activity and long-term use of this modality is not always clinically appropriate. Exposures to these levels should be infrequent and transient or short term. While longer exposures of pacemakers are not necessarily unsafe, they may deny the patient the optimal therapy and such exposures should, therefore, be minimized. In the case of rate responsive pacemakers, such exposures can cause the device to switch to the upper tracking rate. The generally accepted recommendation for Zone 3a is for the patient to pass through the electromagnetic field at a normal rate, without lingering in the field. Exposure to Zone 3a emitting equipment should be minimized and informational signage may be posted to inform workers with implanted pacemakers of the existence of an electromagnetic field to allow them to minimize their exposure time;

3. EMF level above filter response (Zone 2b): In this region the operation of the device is unknown, but no permanent malfunction will affect the implantable pacemakers. In this region exposure should again be infrequent and short term. It should be noted that when the field is removed the device would function as prior to exposure without further adjustment of the device;

4. EMF level above tested limits (Zone 3): In this region the EMI levels are significantly above the maximum exposure levels to which pacemakers are typically designed and tested. Thus, the device response is not generally known and there are no guarantees as to any level of performance. There is also a small but very real possibility that reprogramming or permanent damage to the implantable pacemaker could occur. Should such Zone 3 emitter systems exist, appropriate warning signage is recommended to inform workers with implanted pacemaker so they can take appropriate avoidance actions.

G.2 Induced voltages, fields and zones

G.2.1 Induced voltage test levels

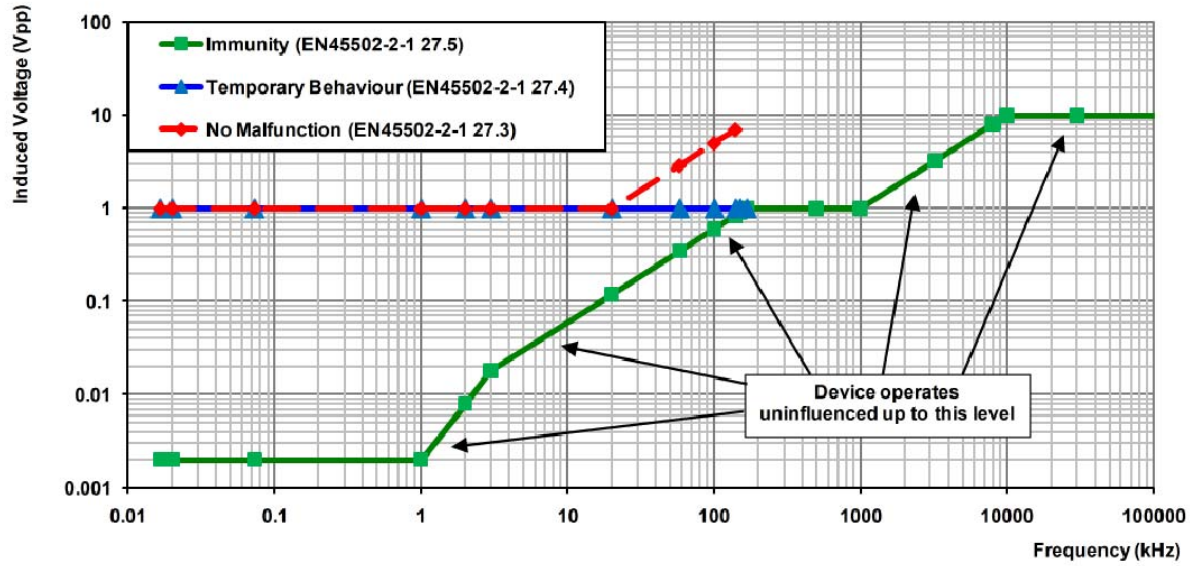


Figure G.1 - Induced voltage test levels

G.2.2 Magnetic field amplitudes producing test limits

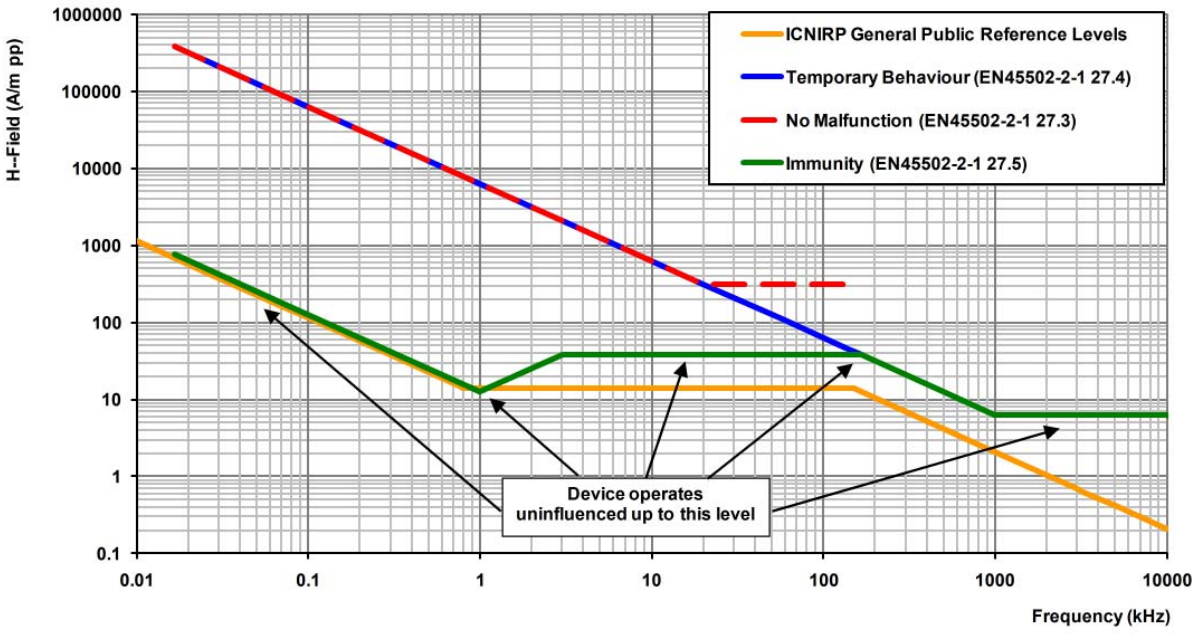


Figure G.2 - Magnetic field amplitudes producing test limits

G.2.3 Induced voltage zones

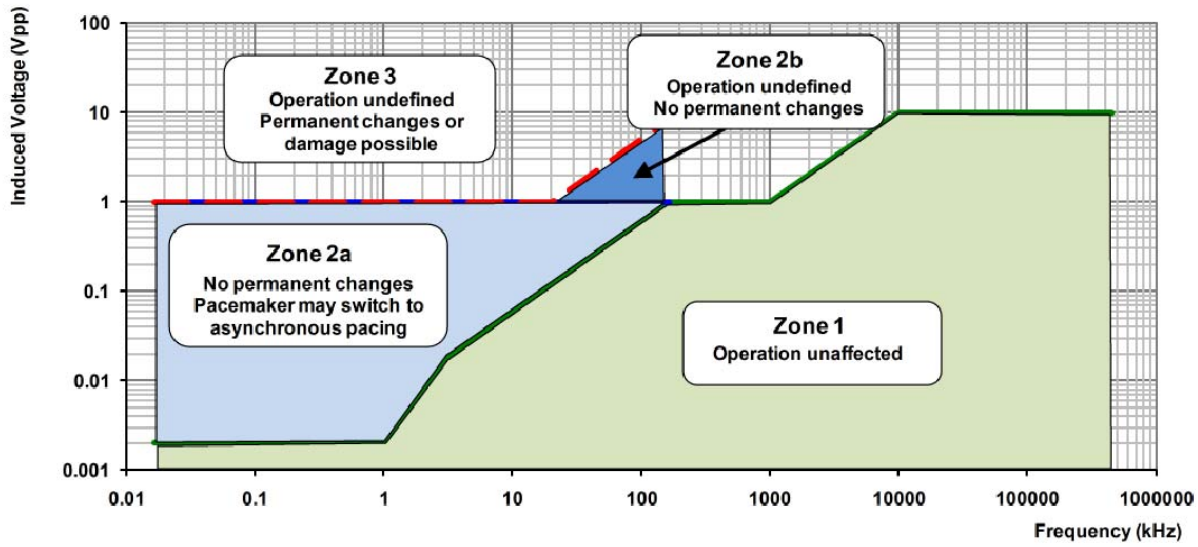


Figure G.3 - Induced voltage zones

G.2.4 Magnetic field zones

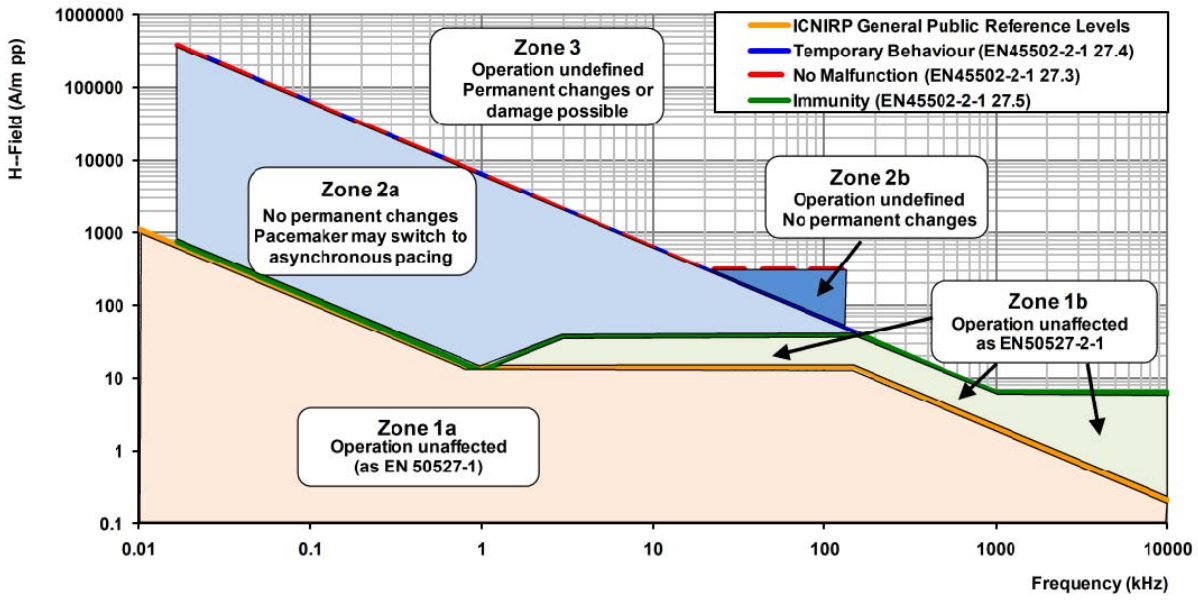


Figure G.4 - Magnetic field zones

G.3 References

[G.1] ANSI/AAMI PC69:2007, Active implantable medical devices – Electromagnetic compatibility – EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators

[G.2] ICNIRP, 1998, Guidelines for limiting exposure to time-varying electric, magnetic, and electromagnetic fields (up to 300 GHz), Health Physics April 1998, Volume 74, Number 4

[G.3] Scholten A. and Silny J. The interference threshold of unipolar cardiac pacemakers in extremely low frequency magnetic fields. *Journal of Medical Engineering & Technology* 25(5):185–194, 2001

[G.4] Gustrau F, Bahr A, Goltz S, Eggert S. “Active Medical Implants and Occupational Safety-measurements and numerical calculation of interference voltage “ in Biomed Rech (Berl) 2002; 47 Suppl1 Pt2: 656-9

[G.5] Irnich W. „Herzschrittmacherpatienten unter Hochspannungsleitungen, Herzschrittmachgertherapie & Elektrophysiologie“, 1999; 10, 164-169

G.4 Literature

Bronzino, Joseph D., editor – The Biomedical Engineering Handbook, 1995, p 1189, Figure 72.3

Webster, John G., editor – Medical Instrumentation and Design, Application and Design, 1992, pp 10-11, Table 1.1

Barr, R., Spach, M. – Sampling rates required for digital recording of intracellular and extracellular cardiac potentials, Circulation vol. 55, no.1 January 1977

Pinski, Sergio L., Trohman, Richard D. – Interference in implanted cardiac devices, Pace, vol.25, No. 9 &10