



BSI Standards Publication

Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices

Part 2-1: Specific assessment for workers
with cardiac pacemakers

National foreword

This British Standard is the UK implementation of EN 50527-2-1:2016. It supersedes BS EN 50527-2-1:2011 which will be withdrawn on 4 July 2019.

The UK participation in its preparation was entrusted to Technical Committee GEL/106, Human exposure to low frequency and high frequency electromagnetic radiation.

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English Version

**Procedure for the assessment of the exposure to
electromagnetic fields of workers bearing active implantable
medical devices - Part 2-1: Specific assessment for workers with
cardiac pacemakers**

Procédure pour l'évaluation de l'exposition des travailleurs
porteurs de dispositifs médicaux implantables actifs aux
champs électromagnétiques - Partie 2-1: Spécification
d'évaluation pour les travailleurs avec un simulateur
cardiaque

Verfahren zur Beurteilung der Exposition von
Arbeitnehmern mit aktiven implantierbaren medizinischen
Geräten (AIMD) gegenüber elektromagnetischen Feldern -
Teil 2-1: Besondere Beurteilung für Arbeitnehmer mit
Herzschrittmachern

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Europäisches Komitee für Elektrotechnische Normung

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Contents

Page

European foreword.....	5
1 Scope.....	6
2 Normative references.....	6
3 Terms and definitions.....	6
4 Specific assessment.....	8
4.1 Description of the assessment process.....	8
4.1.1 General.....	8
4.1.2 Equipment consideration.....	11
4.1.3 Patient warning consideration.....	11
4.1.4 Cases for additional investigation.....	11
4.1.5 Choice of investigative method.....	14
4.2 Clinical investigation.....	15
4.3 Non-clinical investigation.....	15
4.3.1 General.....	15
4.3.2 Non-clinical investigation by <i>in vitro</i> testing.....	16
4.3.3 Non-clinical investigation by comparative study.....	17
5 Documentation.....	20
Annex A (normative) Pacemaker specific replacement of EN 50527-1:2016, Table 1.....	21
Annex B (informative) Clinical investigation methods.....	27
B.1 External ECG monitoring.....	27
B.2 Assessment of pacemaker compatibility using stored data and diagnostic features.....	27
B.3 Real time event monitoring by telemetry.....	27
Annex C (informative) <i>in vitro</i> testing/measurements.....	29
C.1 Introduction.....	29
C.2 EM phantom.....	29
C.2.1 General.....	29
C.2.2 EM phantom design.....	29
C.3 Basic procedure for cardiac pacemaker <i>in vitro</i> testing.....	30
C.4 References.....	31
C.5 Literature.....	32
Annex D (informative) Modelling.....	33
D.1 General.....	33
D.2 Analytical techniques.....	33
D.3 Numerical techniques.....	33
D.4 Field modelling or calculations.....	33
D.5 Modelling the human body and implant.....	34
D.6 References.....	34
Annex E (informative) Derived worst case conversions for frequencies below 450 MHz.....	35
E.1 Introduction.....	35
E.2 Functionality of implanted pacemaker leads.....	35
E.3 Conversion based on known field strength.....	36
E.3.1 General.....	36
E.3.2 Low frequency range (below 5 MHz).....	36
E.3.3 Pure magnetic field (16 Hz to 5 MHz).....	37
E.3.4 Pure electric field (16 Hz to 150 kHz).....	39
E.3.5 Field with electric component (16 Hz to 150 kHz).....	42
E.3.6 Field with electric and magnetic component (150 kHz to 5 MHz).....	43
E.3.7 Range between low and high frequency ranges (5 MHz to 30 MHz).....	44

E.3.8	High frequency range (above 30 MHz).....	44
E.4	Conversion based on known compliance with basic restrictions.....	46
E.4.1	General	46
E.4.2	Short survey on the direct effects of human exposure (induced current density)	46
E.4.3	Short survey on induced voltages on an implanted lead.....	48
E.4.4	A simple model to analyse the possible voltages at pacemaker terminations generated from induced current density equivalent the basic restrictions of Council Recommendation 1999/519/EC.....	48
E.5	References	50
Annex F	(informative) Interference from power-frequency magnetic and electric fields from transmission, distribution and use of electricity	52
F.1	Sensitivity of pacemakers to interference.....	52
F.2	Immunity requirements	52
F.3	Voltage induced in the leads by magnetic fields	53
F.4	Voltage induced in the leads by electric fields.....	54
F.5	Values of 50 Hz magnetic and electric field that may cause interference	56
F.6	Factors that affect the immunity from interference	57
F.6.1	Reasons for improved immunity	57
F.6.2	Adjustment for pacemaker sensitivity	58
F.7	Application to exposure situations	59
F.7.1	Public exposures.....	59
F.7.2	Beneath high voltage power lines.....	59
F.7.3	Occupational settings.....	60
F.7.4	Temporary exposure above the interference levels	61
F.8	References	61
Annex G	(informative) Determination of the pacemaker immunity and guidelines provided by pacemaker manufacturers – Determination method.....	62
G.1	Introduction	62
G.2	EMC and pacemakers – General guidelines	62
G.3	Induced voltages, fields and zones	65
G.3.1	Induced voltage test levels	65
G.3.2	Magnetic field amplitudes producing test limits	65
G.3.3	Induced voltage zones.....	67
G.3.4	Magnetic field zones	67
G.4	References	68
G.5	Literature.....	69
Bibliography		70

Figures

Figure 1	— Overview of the assessment process.....	9
Figure 2	— Pacemaker specific assessment process	10
Figure 3	— Additional investigation process	13
Figure 4	— Comparison process	18
Figure C.1	— Example of <i>in vitro</i> procedure for EM interference at low frequency using planar electrodes, bipolar lead and ECG and data recording	31
Figure E.1	— Typical implantations of cardiac pacemakers (abdominal implantation with prolonged lead is used in clinical environment only).....	36
Figure E.2	— Effective induction area of an open wire loop inside a conductive medium	37
Figure E.3	— Schematic representation of bipolar pickup of interference in an infinitely extended homogeneous conducting medium	39
Figure E.4	— Induced voltage on the implanted lead in a pure <i>E</i> field	41
Figure E.5	— Schematic graphs of the same voltage on the lead for different layouts.....	43
Figure E.6	— Eddy-current inside a conductive medium induced by varying magnetic flux	47

Figure E.7 — Voltage induced on a lead inside conductive body tissue	48
Figure E.8 — Voltages on an implanted lead.....	50
Figure F.1 — How the immunity ratio affects magnetic field that may result in interference	58
Figure F.2 — How the immunity ratio affects electric field that may result in interference	59
Figure G.1 — Induced voltage test levels	65
Figure G.2 — Magnetic field amplitudes, for frequencies below 5 000 kHz, producing test limits in unipolar configurations	66
Figure G.3 — Induced voltage zones for unipolar configurations	67
Figure G.4 — Magnetic field zones, for frequencies below 5 000 kHz and for unipolar configurations	68

Tables

Table A.1 — Compliant workplaces and equipment with exceptions	21
Table F.1 — Amplitude of the immunity test signal applied	53
Table F.2 — Values of 50 Hz electric and magnetic field (r.m.s.) that might, under unfavourable circumstances, cause interference in a pacemaker.....	56
Table F.3 — Summary of typical maximum field values beneath high-voltage overhead lines at 1 m above ground	60

European foreword

This document (EN 50527-2-1:2016) has been prepared by CLC/TC 106X "Electromagnetic fields in the human environment".

The following dates are fixed:

- latest date by which this document has to be implemented (dop) 2017-07-04
at national level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with (dow) 2019-07-04
this document have to be withdrawn

This document supersedes EN 50527-2-1:2011.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

EN 50527 is currently composed with the following parts:

- EN 50527-1, *Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices — Part 1: General*;
- EN 50527-2-1, *Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices — Part 2-1: Specific assessment for workers with cardiac pacemakers*;
- prEN 50527-2-2, *Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices — Part 2-2: Specific assessment for workers with implantable cardioverter defibrillators*¹⁾.

1) Currently at drafting stage.

1 Scope

This European Standard provides the procedure for the specific assessment required in EN 50527-1:2016, Annex A, for workers with implanted pacemakers. It offers different approaches for doing the risk assessment. The most suitable one will be used. If the worker has other Active Implantable Medical Devices (AIMDs) implanted additionally, they need to be assessed separately.

The purpose of the specific assessment is to determine the risk for workers with implanted pacemakers arising from exposure to electromagnetic fields at the workplace. 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.

NOTE 1 This standard does not address risks from contact currents.

The techniques described in the different approaches may also be used for the assessment of publicly accessible areas.

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 are not exceeded.

NOTE 2 The rationale for limiting the observation range to 3 GHz can be found in ISO 14117:2012, Clause 5.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 45502-2-1:2003²⁾, *Active implantable medical devices — Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)*

EN 50413, *Basic standard on measurement and calculation procedures for human exposure to electric, magnetic and electromagnetic fields (0 Hz - 300 GHz)*

EN 50527-1:2016, *Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices — Part 1: General*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 50527-1:2016 and the following apply.

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 1 to entry: For the purposes of EN 50527-2-1, the term implantable pulse generator describes any active implantable medical device that incorporates functions intended to treat cardiac arrhythmias.

3.2

pacemaker

active implantable medical device intended to treat bradyarrhythmias, comprising an implantable pulse generator with or without lead(s)

2) The EMC requirements within EN 45502-2-1 have been incorporated with updates into ISO 14117 and their use is recommended here.

Note 1 to entry: CRT-P devices (Cardiac resynchronization therapy pacemaker) by their nature behave similar and are covered by this standard. CRT-P devices are sometimes also called multi-channel pacemakers.

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

pacemaker-employee

worker with an implanted pacemaker

Note 1 to entry: For this worker, EN 50527-1 has revealed that a specific assessment following EN 50527-1:2016, Annex A needs to be done. If this worker bears additionally other AIMD, they need to be assessed separately.

3.7

assessment team

team consisting of:

- employer and if applicable, his occupational health and safety experts and/or occupational physician,
- pacemaker-Employee and his responsible physician,
- (technical and medical) experts as necessary, e.g. manufacturer of the pacemaker

3.8

Holter monitor

Holter ECG monitor

device that continuously records the heart's rhythms

Note 1 to entry: The monitor is usually worn for 24 h – 48 h during normal activity.

Note 2 to entry: The above definition was adopted from NIH (US. National Institute of Health). The Holter monitor is named for Dr. Norman J. Holter, who invented telemetric cardiac monitoring in 1949. Clinical use started in the early 1960s. Numerous medical publications can be found referring to “Holter”, “Holter monitoring” or often also called “Holter ECG monitoring” (see e.g. PubMed at <http://www.ncbi.nlm.nih.gov/pubmed>).

3.9

EM phantom

physical model containing tissue-equivalent material used to simulate the body in an experimental dose measurement (from World Health Organization)

Note 1 to entry: EM phantoms are sometimes also referred to as torso simulator or phantom.

3.10

uninfluenced behaviour

behaviour for which conditions are provided in EN 50527-1:2016, 4.1.3

4 Specific assessment

4.1 Description of the assessment process

4.1.1 General

The risk assessment is based on the approach that, according to EN 45502-2-1 and ISO 14117, pacemakers are expected to work uninfluenced as long as the General Public Reference levels of Council Recommendation 1999/519/EC are not exceeded (except for static magnetic fields and for pulsed high frequency electromagnetic fields) (see also F.7).

Further risk assessment is not necessary if a history of uninfluenced behaviour at the workplace exists and a responsible physician has confirmed that this history is sufficient to exclude severe (clinically significant) interaction.

A specific risk assessment for the pacemaker-Employee is required when there is history of influenced behaviour or one of the following three conditions is fulfilled:

- a) there is equipment present in the workplace that is neither included in, nor used in accordance with Table A.1;
- b) all equipment at the workplace is listed in Table A.1 (see Annex A) and is used accordingly, but the pacemaker-Employee has received warning(s) from the responsible physician that the pacemaker may be susceptible to electromagnetic interference (EMI), thereby increasing the risk at the workplace. There are two types of warnings that may be given:
 - 1) 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
 - 2) 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 that is neither included in, nor used in accordance with Table A.1 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 4.1.2 shall apply. When only condition (b) exists, then 4.1.3 shall apply. When condition (c) exists, then both 4.1.2 and 4.1.3 shall apply.

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.

For equipment included in and used per Table A.1				
		History		
		Influenced Behaviour	Un-influenced Behaviour	No History available
Warning from responsible Physician	Yes	2	3	2
	No	2	1	1
For Equipment not included in or not used per Table A.1				
Specific risk assessment for the pacemaker-Employee is required				

Legend	
1	Further risk assessment is not necessary
2	Specific risk assessment for the pacemaker-Employee is required
3	Further risk assessment unnecessary if responsible physician has confirmed that this history is sufficient to exclude clinically significant interaction

Figure 1 — Overview of the assessment process

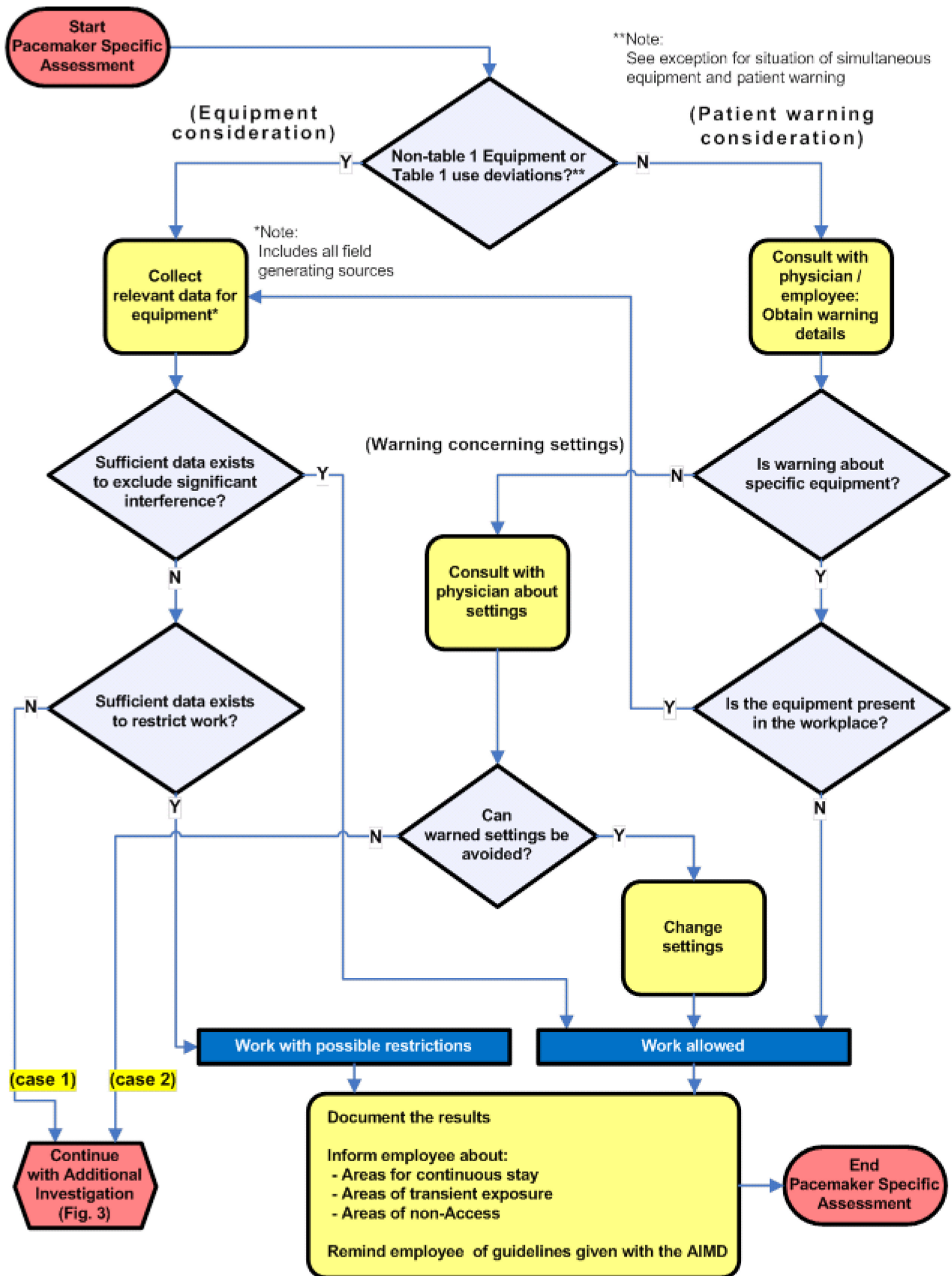


Figure 2 — Pacemaker specific assessment process

4.1.2 Equipment consideration

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

- can it be determined that clinically significant interference with the 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 pacemaker-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 specified in 4.1.4.

The intent of this clause is to find and utilize information that may already exist and that allows the assessment to be completed 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.

4.1.3 Patient warning consideration

The responsible physician and pacemaker-Employee shall be consulted to determine the type of and details for any EMI warnings applicable to the 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 pacemaker-Employee is allowed to work without restrictions and the pacemaker specific assessment can be completed and documented as required in Clause 5;
- if the equipment subject to the warning is present, the steps given in 4.1.2 shall be taken.

If the warning is due to the applied settings of the pacemaker that may cause reduced immunity (see 4.1.1 b) 1)) to EMI that is at or below the reference levels, the responsible physician shall be consulted to determine whether the settings can be changed to avoid settings that are associated with the warning, thereby restoring standard immunity levels:

- if it is determined that such a change of settings can be made, the pacemaker-Employee shall be advised to arrange, through consultation with the responsible physician, for these changes of settings to be made prior to returning to work. When the change of setting has been completed, the pacemaker-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 4.1.4.

4.1.4 Cases for additional investigation

When the investigation steps shown in Figure 2 have been followed but fail to mitigate or to dismiss risk to the pacemaker-Employee from the effects of workplace EMI, then an additional investigation shall be performed as shown in Figure 3 and described in 4.1.5. The goal of the investigation is to determine the likelihood of a clinically significant response of the pacemaker to the EMI at the workplace that is the result of the following:

a) **Case 1:** Equipment is used at the workplace that is:

- 1) neither listed in, nor used in accordance with, Table A.1, and for which there is no information available that allows a pre-determination of safe or restricted work for the pacemaker-Employee, or

- 2) capable of emitting fields that may induce pacemaker lead voltages exceeding the immunity levels established by conformity with the pacemaker product standard, EN 45502-2-1,
 - 3) known by the pacemaker manufacturer to potentially cause interference with the pacemaker and there is no applicable safe use guideline available from other sources.
- b) **Case 2:** The responsible physician has prescribed settings of the pacemaker that make it susceptible to EMI even from equipment listed in Table A.1.

If one of these cases is valid, an additional investigation as shown in Figure 3 and described in 4.1.5 shall be performed.

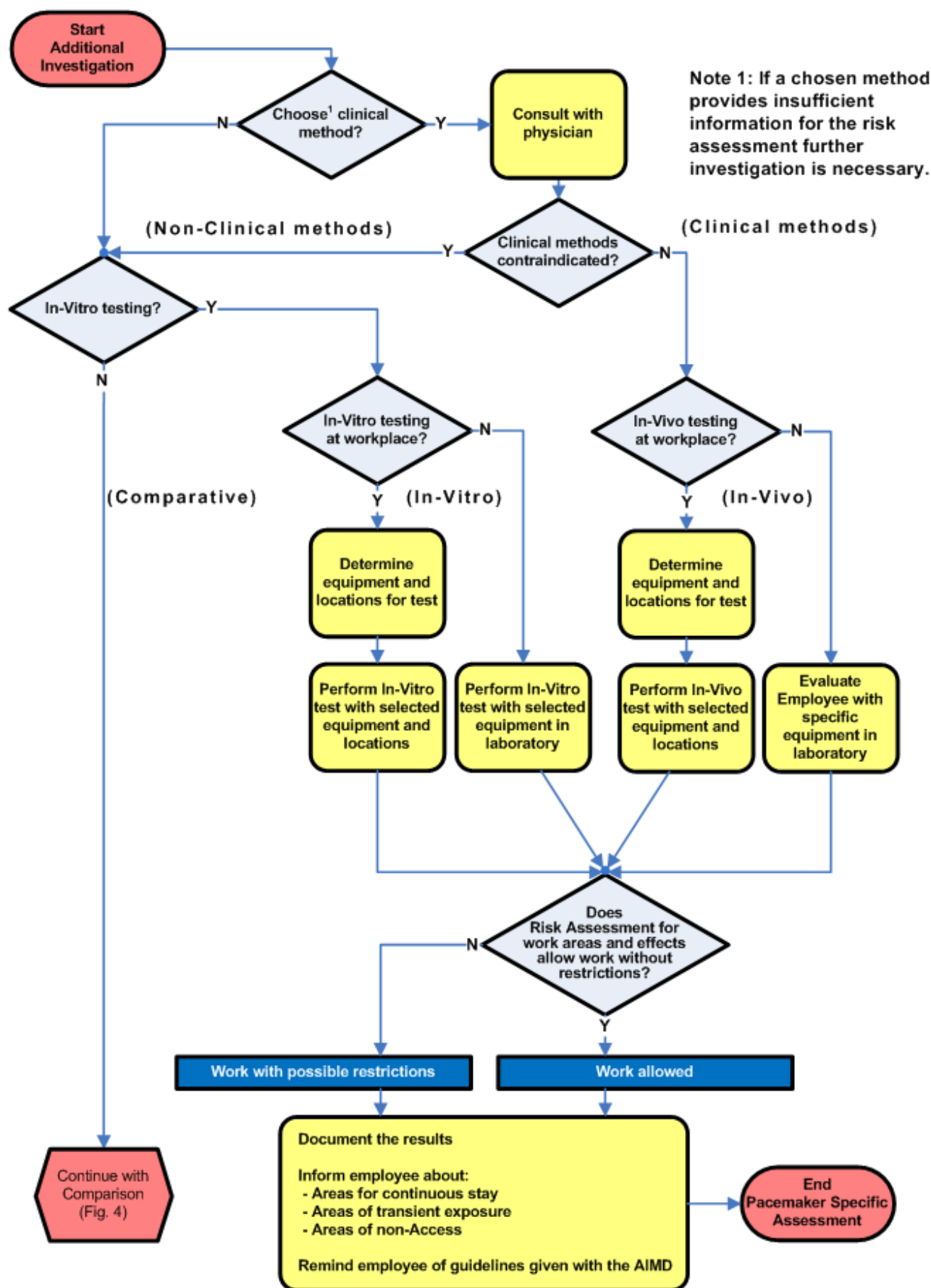


Figure 3 — Additional investigation process

4.1.5 Choice of investigative method

4.1.5.1 General

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

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

For leadless pacemaker systems only clinical and non-clinical *in vitro* methods shall be used as comparative study methods have not yet been established.

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

4.1.5.2 Considerations in choosing a clinical method

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

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

A clinical method can only be started with consent of the pacemaker-Employee according to national regulation. 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 pacemaker-Employee's workplace, but this might not be feasible for a number of reasons. Consideration should be given to whether one of the methods described in Annex B can be performed while the pacemaker-Employee is moving through the workplace or performing the anticipated job function. Limiting factors can include

- harsh or dirty environments,
- confined spaces,
- inability to provide 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 different locations separated geographically or those which are not accessible to clinicians and / or pacemaker manufacturer representatives,
- workplace situations and equipment that might offer an EMF environment that varies significantly from day to day such that the exposure provided during a single test might not represent the likely worst case, or even typical, exposure values for that pacemaker-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 the cause of hazardous EMI to the pacemaker-Employee. In such cases it is 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, where the 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 B may be chosen and carried out as described in 4.2.

4.1.5.3 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 4.1.5.2.

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 national regulation, or else with the requirements of EN ISO 14155.

NOTE 1 These standards define procedures for the conduct and performance of clinical investigations of medical devices.

This investigation may be performed either in the pacemaker-Employee's workplace or in a laboratory setting, as determined in 4.1.5.2.

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

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

NOTE 2 Where available, information about the known range of field levels compared with the actual levels during the tests can reduce the residual risk.

NOTE 3 If the pacemaker-Employee's situation is Case 2, a provocative clinical test might 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

4.3.1 General

There are two methods for the non-clinical investigation:

- *in vitro* testing, involving the use of a pacemaker device and lead inserted into an EM phantom suitable for e.g. the frequency range under consideration that is then exposed to the EMF at the workplace;

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

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

- *in vitro* testing shall be performed using an IPG and leads of the same make and model as those implanted in the pacemaker-Employee. If the *in vitro* method is chosen, it should be performed in accordance with the requirements of 4.3.2;
- a comparative study requires the determination of induced voltages and pacemaker immunity. If the Comparative study method is chosen, it should be performed in accordance with the requirements of 4.3.3 and shown in Figure 4.

4.3.2 Non-clinical investigation by *in vitro* testing

4.3.2.1 Determination of *in vitro* testing feasibility

The following requirements are necessary to perform an *in vitro* test:

- the workplace environment is such that an EM phantom, device programmer, and test personnel can be accommodated for the duration of anticipated testing;
- a fully functional pacemaker and leads, if applicable, of the same make and model as that implanted in the pacemaker-Employee can be obtained from the manufacturer or the physician;
- a device programmer compatible with the pacemaker-Employee's pacemaker is available and capable of device interrogation with up-to-date programming software;
- the approximate lead layout as implanted in the pacemaker-Employee is known and available.

General information may be available from *in vitro* studies about the behaviour of a variety of pacemaker types and settings in specific types of electromagnetic fields. These may contain useful information about the exposure under consideration. It may be possible to use these results to make conservative judgements about particular exposure situations. Care should be taken as the specific implantation of the pacemaker-Employee is not necessarily included in the studies.

4.3.2.2 Requirements for *in vitro* testing

The pre-requisites given in 4.3.2.1 shall be met. The pacemaker and leads, if applicable, shall be arranged within an EM phantom so as to approximate the layout known for the pacemaker-Employee. The pacemaker shall be programmed with the same parameters and have the same operating software as that existing for the pacemaker-Employee.

A test plan shall be prepared that defines the following:

- 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 pacemaker-Employee in question;
- provisions for monitoring the IPG behaviour in the presence of the fields. Since the level of applied fields may be higher than those specified in the product test standard EN 45502-2-1, care shall be exercised to prevent irreversible damage to the IPG that would invalidate test results.

For tests with specific equipment, provocative testing is recommended as the risk to the pacemaker-Employee is not a factor. Safety of the personnel conducting the testing shall 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.

4.3.3 Non-clinical investigation by comparative study

4.3.3.1 General

This method of investigation is described in Figure 4 and is based on the comparison of the induced voltages on the leads with the voltage immunity at the connectors of the pacemaker.

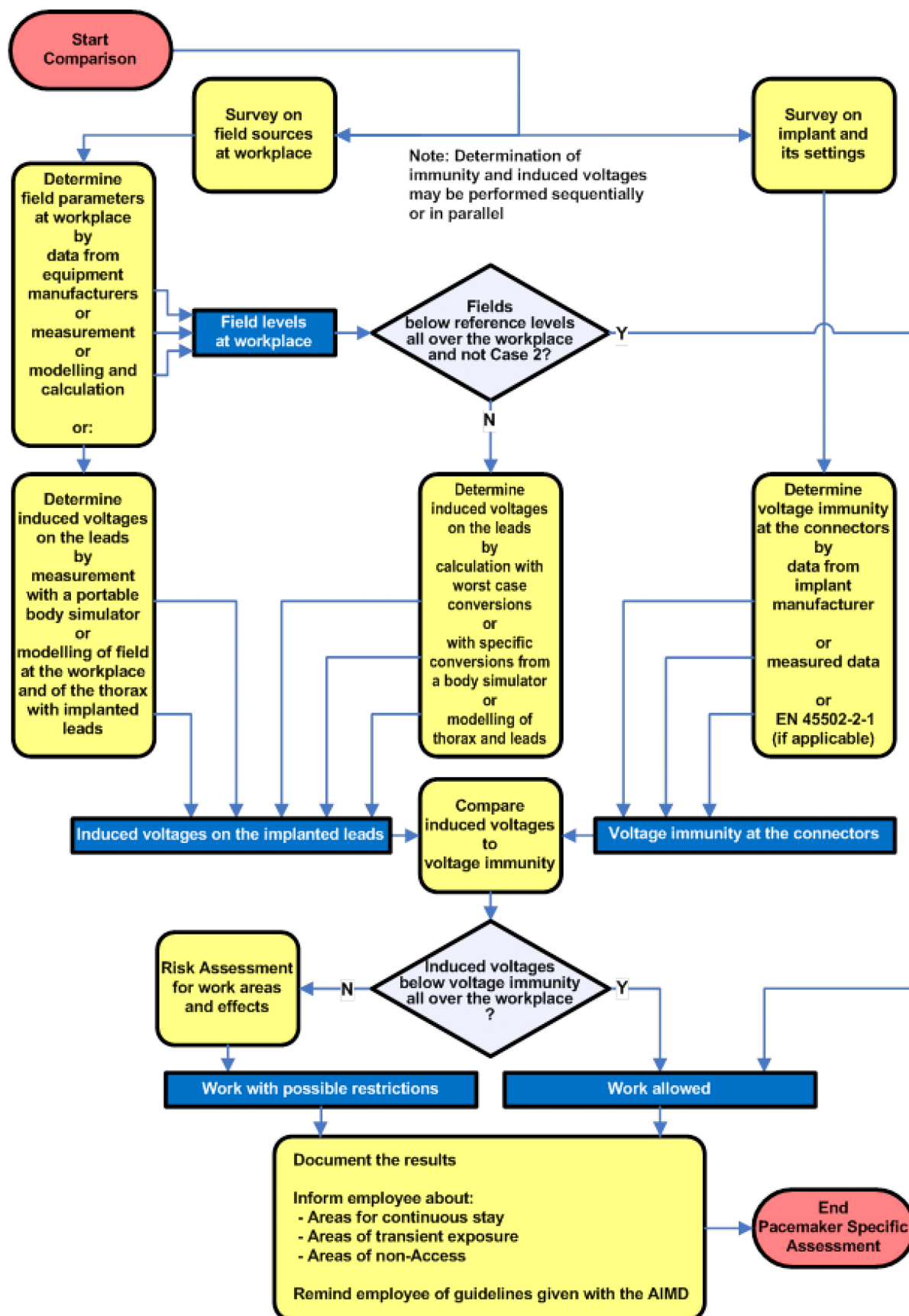


Figure 4 — Comparison process

4.3.3.2 Determination of the induced voltages on the leads

One method is to determine directly the induced voltages by measurement using an EM phantom or by modelling the field and the thorax with implanted leads included (see example in Annexes C and D).

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

General information on measurement is given in EN 50413. For magnetic induction measurements, a circular measurement coil with an area of 225 cm² will result in realistic values whereas the use of a standard 100 cm² coil and averaging over an area of 225 cm² may result in higher values. The distance between the measuring coil and the surface of the emitting source shall be realistic taking into account that the implanted lead is buried in the body so that direct contact with the source is not possible.

- for Case 2 situations, the fields shall be determined by performing a workplace survey of all non-Table A.1 equipment that the pacemaker-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;
- if the field levels are determined to be below the reference levels and the situation is not Case 2, the pacemaker-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 (for frequencies up to 450 MHz) and Annex F (specifically for power frequencies)) or with specific conversions derived from a body simulator or by modelling of thorax and leads (see example in Annexes C and D).

4.3.3.3 Determination of the voltage immunity

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

a) using data obtained:

- 1) from the pacemaker manufacturer, or
- 2) from existing measurements (in accordance with EN 45502-2-1), or
- 3) 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 1 EN 45502-2-1 contains the minimum specifications for IPG immunity. Many IPG have a significantly better actual immunity than the minimum requirements at some frequencies. Furthermore, many implanted IPG are used at less sensitive settings which will also enhance their immunity. This means there is a greater chance of allowing the pacemaker-Employee to work without restrictions if actual data, sourced from the device manufacturer or obtained through additional immunity testing, is used.

b) 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 shall be exercised to prevent irreversible damage to the device that would invalidate test results.

NOTE 2 If this assessment is being made specifically for only one or two IPG, it might be quicker and more convenient to perform a direct *in vitro* test as described in 4.3.2.

Further examples are given in Annex G.

4.3.3.4 Comparison of induced voltages to voltage immunity and conclusion

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 be allowed without restrictions;
- the induced voltages are above the voltage immunity only in places that 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 presence of the pacemaker-Employee cannot be allowed in that specific workplace on the basis of this method of assessment.

5 Documentation

The risk assessment following this standard offers different options to perform the risk assessment and as the methods are very different, a unique form of the documentation is not feasible but shall be tailored to the approach chosen.

Following national regulation, a final report of the investigation shall be completed and be in the possession of the employer, even if the investigation is prematurely terminated. It shall contain:

- the overall risk assessment process,
- the method chosen,
- the rationale for the choice,
- the findings and
- the conclusions.

Annex A (normative)

Pacemaker specific replacement of EN 50527-1:2016, Table 1

This pacemaker-specific Table A.1 replaces EN 50527-1:2016, Table 1. The exceptions and remarks have been adopted to reflect the special pacemaker requirements. In all rows of Table A.1 where the named equipment uses wireless communication, refer additionally to the lines where this kind of communication device is described.

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

Table A.1 — Compliant workplaces and equipment with exceptions

Designation of workplace	Examples of equipment	Exceptions and remarks
All places	Lighting equipment	Excluding specialized lighting for industrial purposes where the energy is deployed by microwave or radio frequency fields.
All places	Computer and IT equipment not containing wireless communication	No restrictions. Hard disks (other than solid state hard discs) of portable computers and external hard disks should be treated as equipment producing static magnetic fields and be used only with minimum distance of 15 cm between the hard disk and the pacemaker.
All places	Computer and ITE equipment <i>including</i> wireless communication using Bluetooth Class 1 or WiFi (both typically 100 mW)	If such equipment contains RF-transmitters operating at frequencies greater than 450 MHz with peak power radiation greater than 120 mW either follow recommendations associated with the pacemaker restricting their use or perform a special assessment using one of the methods specified in 4.1.2.
All places	Office equipment	For tape erasers, either follow recommendations associated with the pacemaker restricting their use or perform a special assessment using one of the methods specified in 4.1.2.
All places	Mobile phones, smart phones and cordless phones	For pacemakers the interference distance between a mobile phone and pacemaker is 15 cm for radiated peak powers up to 2 W. For DECT phones (250 mW), it is lower.
All places	Two-way radios peak transmitter power up to 120 mW regardless of the distance or peak power higher than 120 mW up to 2 W not closer than 15 cm to the pacemaker	For other two way radios, manufacturers may have recommendations for use.