SLOVENSKI STANDARD
SIST EN 50527-2-1:2011

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Postopek ocenjevanja izpostavljenosti delavcev z aktivnimi medicinskimi vsadki elektromagnetnim poljem - 2-1. del: Specifično ocenjevanje pri delavcih s srčnimi spodbujevalniki

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

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

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

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EUROPEAN STANDARD

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English version

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Foreword

This European Standard was prepared by the Technical Committee CENELEC TC 106X, Electromagnetic fields in the human environment.

The text of the draft was submitted to the formal vote and was approved by CENELEC as EN 50527-2-1 on 2011-05-02.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2012-05-02
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2014-05-02

This European Standard has been prepared under Mandate M/351 given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 2004/40/EC.

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1 Scope

This European Standard provides the procedure for the specific assessment required in Annex A of EN 50527-1:2010 for workers with implanted pacemakers. It offers different approaches for doing the risk assessment. The most suitable one shall be used. If the worker has other AIMDs implanted additionally, they have 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 to workers bearing a pacemaker 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 Clause 5 of ANSI/AAMI PC69:2007.

2 References

2.1 Normative references

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

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 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 (IEC 62226-3-1:2007)

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

2004/40/EC: 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), Official Journal L 159, 30/07/2004, p. 1–26

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 50527-1:2010 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 For 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 and lead(s)

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

3.7
pacemaker-Employee
worker with an implanted pacemaker

NOTE For this worker, EN 50527-1 has revealed that a specific assessment following Annex A of EN 50527-1:2010 has to be done. If this worker bears additionally other AIMD, they have to be assessed separately.

3.8
transient exposure
exposure to electromagnetic fields that is acceptable for pacemaker-Employee because it fulfils the following requirements:

- the exposure is not constant: it comes to an end or reduces to non influential levels
- the exposure does not damage the pacemaker
- the exposure only leads to acceptable response of the pacemaker based on the advice from the responsible physician (for example by general guidance or by a specific warning) and/or described in the documentation accompanying the pacemaker

NOTE Such exposure may be caused by the electromagnetic field being temporary or by the exposed person moving within, or through, an electromagnetic field. The duration of transient exposure varies widely and can only be determined as the result of the risk assessment, based on the expected response of the pacemaker to the exposure and the physician's advice on the acceptability of the response

3.9
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

3.10
Holter monitor
Holter ECG monitor
device that continuously records the heart's rhythms

NOTE 1 The monitor is usually worn for 24 h – 48 h during normal activity.

NOTE 2 The above definition was adopted from NIH (U.S. 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).

3.11
EM phantom
physical model containing tissue-equivalent material used to simulate the body in an experimental dose measurement (from World Health Organisation)

NOTE EM phantoms are sometimes also referred to as torso simulator or phantom.

4 Specific assessment

4.1 Description of the assessment process

The risk assessment is based on the approach that, according to EN 45502-2-1, 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 Clause 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:

   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 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 4.1.1 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.

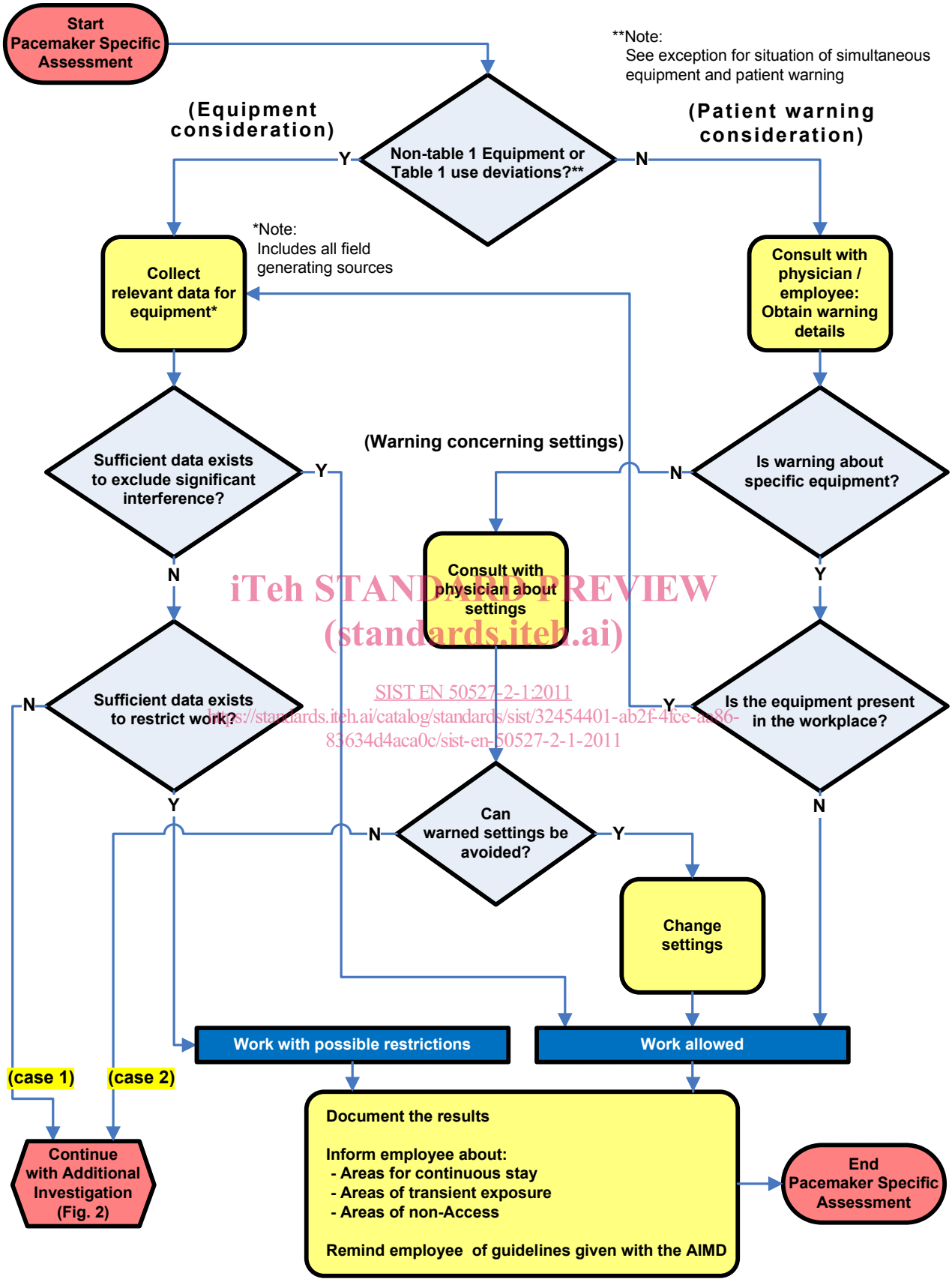

Figure 1 – Pacemaker specific assessment process

4.1.1 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 4.1.3.

NOTE The intent of this clause is to find and utilize information that may already exist and that allows 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 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 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 of the pacemaker 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 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 4.1.3.

4.1.3 Cases for additional investigation

When the investigation steps shown in Figure 1 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 2 and described in 4.1.4. 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.

- **Case 1**: Equipment is used at the workplace that is:
  - 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

- 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,

- known by the pacemaker manufacturer to potentially cause interference with the pacemaker and there is no applicable safe use guideline available from other sources.

- **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 2 and described in 4.1.4 shall be performed.

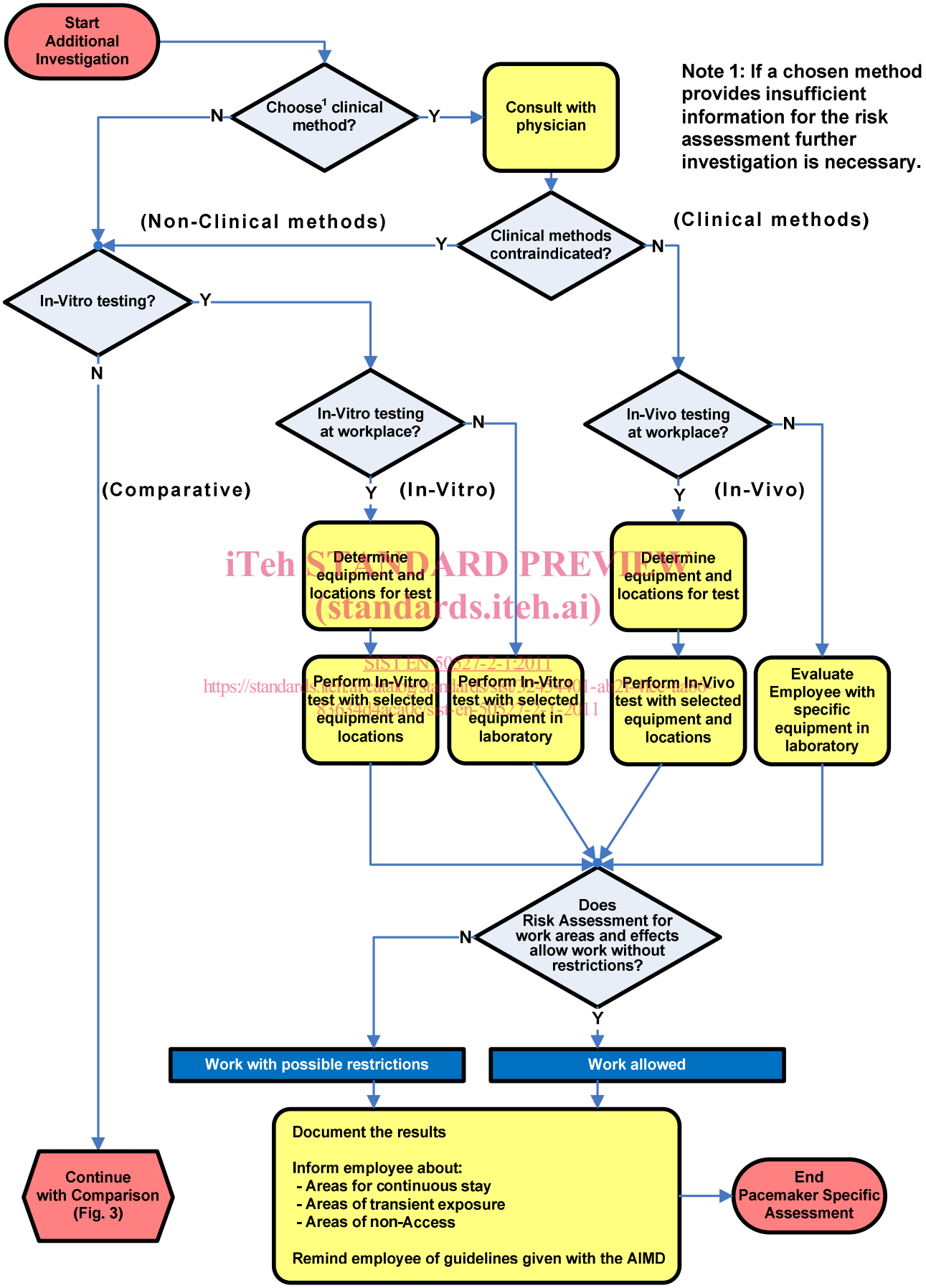

Figure 2 – Additional investigation process

4.1.4 Choice of investigative method

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.

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 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.

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