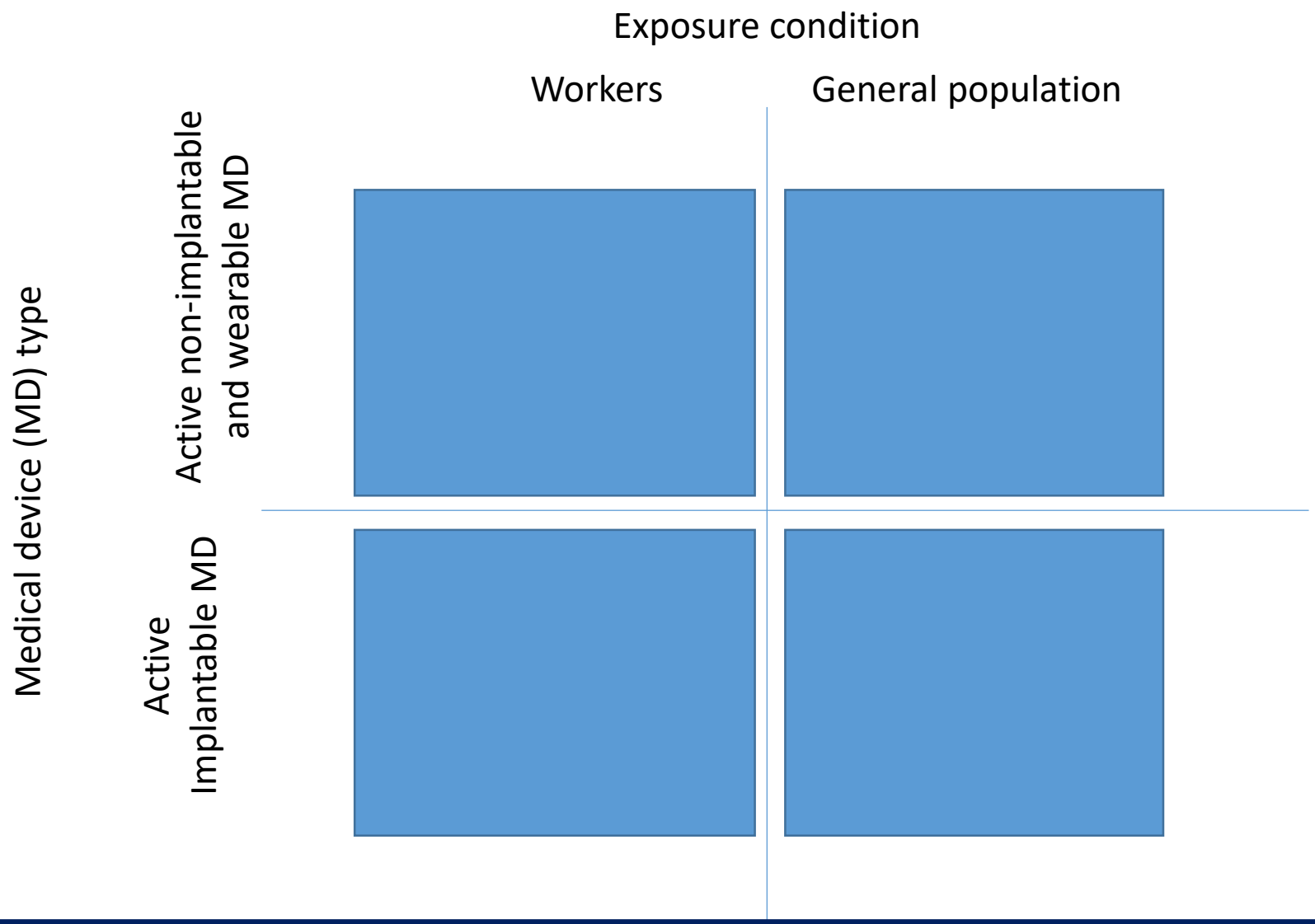
Sessione 1 - Aggiornamenti sul quadro Normativo

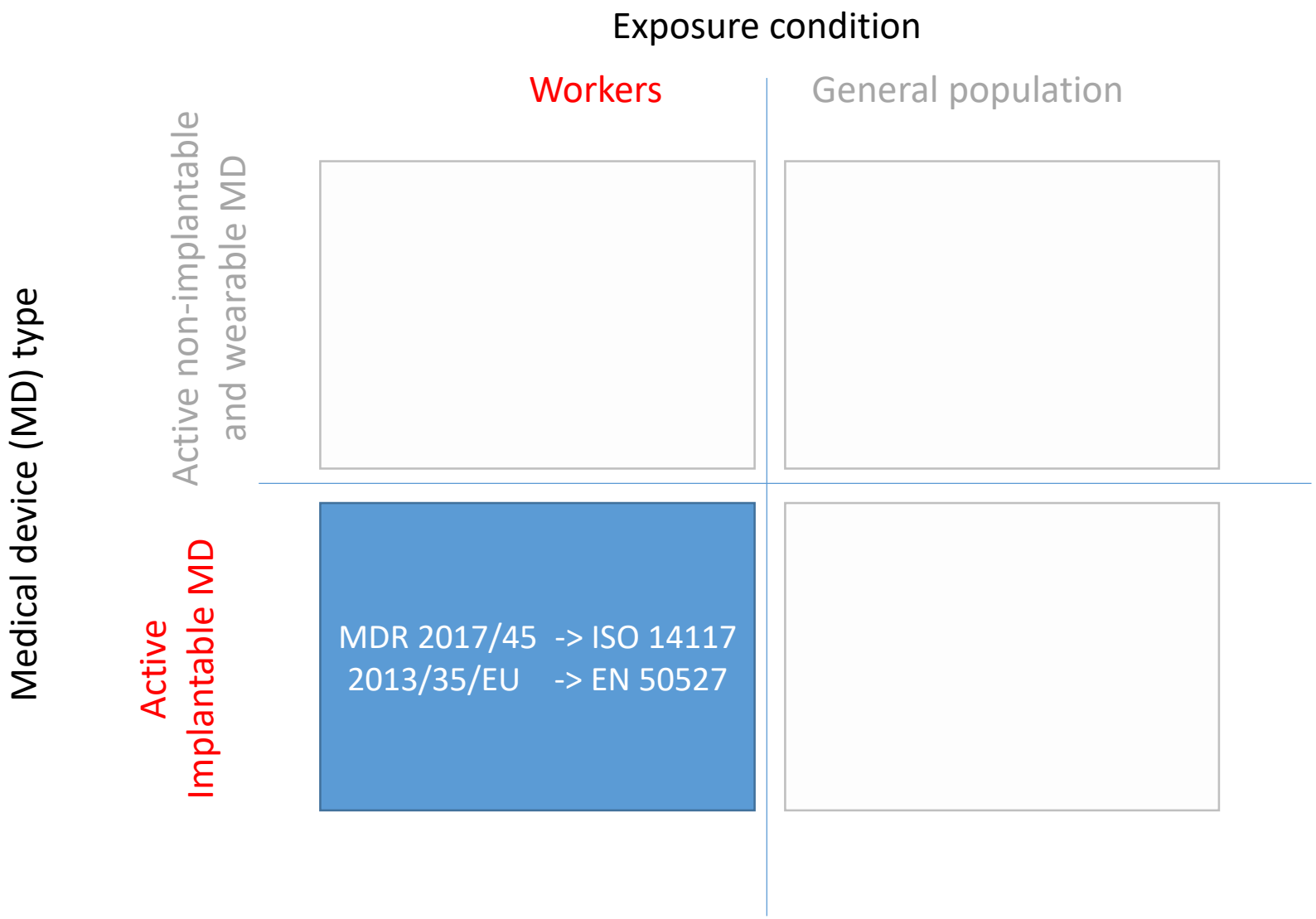
Moderatore: R. Falsaperla – INAIL – DIMEILA

10:00	La compatibilità elettromagnetica dei dispositivi medici indossabili Ing. Federica Censi - ISS
10.20	La compatibilità elettromagnetica dei dispositivi medici impiantabili attivi Ing. Eugenio Mattei - ISS
10:40	Metodologie per la valutazione del rischio per lavoratori con dispositivi impiantabili o indossabili Ing. Giovanni Calcagnini – ISS

Inquadramento generale (1)



Inquadramento generale (2)



La famiglia di norme CEI EN 50527

N O R M A I T A L I A N A C E I

Norma Italiana — *Data Pubblicazione*

CEI EN 50527-1 — **2017-09**

La seguente Norma è identica a: EN 50527-1:2016-12.

Titolo

Procedura per la valutazione dell'esposizione ai campi elettromagnetici dei lavoratori con dispositivi medici impiantabili attivi
Parte 1: Generalità

N O R M A I T A L I A N A C E I

Norma Italiana — *Data Pubblicazione*

CEI EN 50527-2-1 — **2017-09**

La seguente Norma è identica a: EN 50527-2-1:2016-12.

Titolo

Procedura per la valutazione dell'esposizione ai campi elettromagnetici dei lavoratori con dispositivi medici impiantabili attivi
Parte 2-1: Valutazione specifica per lavoratori con stimolatore cardiaco (pacemaker)

N O R M A I T A L I A N A C E I

Norma Italiana — *Data Pubblicazione*

CEI EN 50527-2-2 — **2018-11**

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Titolo

Procedura per la valutazione dell'esposizione ai campi elettromagnetici dei lavoratori con dispositivi medici impiantabili attivi
Parte 2-2: Valutazione specifica per lavoratori con defibrillatori cardiaci impiantati (ICD)

N O R M A I T A L I A N A C E I

Norma Italiana — *Data Pubblicazione*

CEI EN 50527-2-3 — **2022-07**

La seguente Norma è identica a: EN 50527-2-3:2021-10.

Titolo

Procedura per la valutazione dell'esposizione ai campi elettromagnetici dei lavoratori portatori di dispositivi medici impiantabili attivi
Parte 2-3: Valutazione specifica per lavoratori con neurostimolatori impiantabili

La famiglia di norme CEI EN 50527

N O R M A I T A L I A N A C E I

Norma Italiana

CEI EN 50527-1

La seguente Norma è identica a: EN 50527-1:2016-12.

Data Pubblicazione

2017-09

Titolo

Procedura per la valutazione dell'esposizione ai campi elettromagnetici dei lavoratori con dispositivi medici impiantabili attivi

Parte 1: Generalità

CEI EN 50527 – 1: premesse e scopo

This European Standard provides a procedure to assess the risk to workers bearing one or more active implantable medical devices from exposure to electric, magnetic and electromagnetic fields at a workplace.

It describes how a general risk assessment should be performed and determines whether it is necessary to carry out a detailed risk assessment.

CEI EN 50527 – 1: razionale

The risk assessment is based on the approach that AIMDs are expected to function as described in their product standards as long as the General Public Reference levels of Council Recommendation 1999/519/EC (except for static magnetic fields) are not exceeded [Directive 2007/47/EC] and where no specific warnings have been issued to the AIMD-Employee.

CEI EN 50527 – 1: filosofia

This risk assessment therefore checks both for fields present at the workplace that exceed these levels and for AIMD-Employees that are subject to lower immunity of their AIMD due to clinical reasons.

The risk assessment continues by checking the equipment present at the workplace. Equipment listed in Table 1 may be assumed to produce fields that do not exceed the General Public reference levels of Council Recommendation 1999/519/EC.

If there is equipment present that is not listed in Table 1 or is not used as specified in the remarks in Table 1 it needs to be assumed that the electric, magnetic or electromagnetic field levels may be too high to ensure uninfluenced behaviour of the AIMD. In this case a specific assessment following Annex A shall be performed.

If all equipment at the workplace is listed in Table 1 and is used as specified in the remarks in Table 1 it is necessary to find out whether the AIMD-Employee has received specific warnings from the responsible physician. Such specific warnings are based on the fact that the immunity of the implant under the condition of implantation and parameter setting is not compatible with General Public reference levels.

1) EMC fields vs Immunity

2) General Public Reference Level

3) Simplified vs specific assessement

4) Specific warnings

CEI EN 50527-1: procedura per la valutazione del rischio

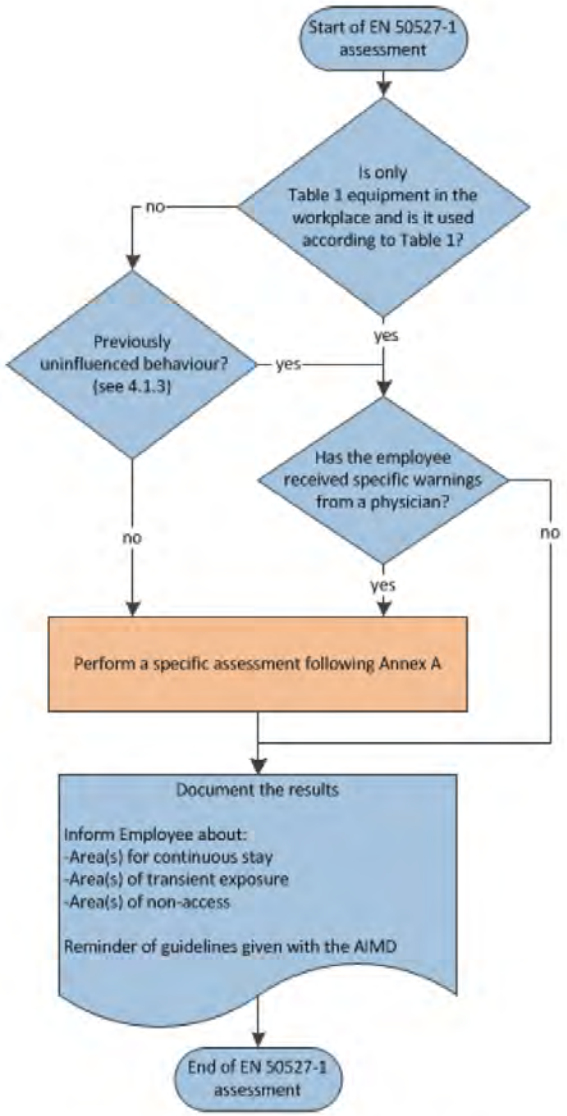

Figure 2 — Risk assessment process

Tabella 1: ‘‘whitelist’’

È stata compilata sulla base della tabella della EN50499, ma con alcune eccezioni

Un utile supporto nella decisone può essere trovato nella Guide Pratiche

CEI EN 50527-1: Table 1 (whitelist) example 1

Designation of workplace	Examples of equipment	Exceptions and remarks
All places	Mobile phones, smart phones and cordless phones	See 5.2.1 As example for pacemakers and defibrillators the interference distance between source and AIMD is 15 cm for peak powers up to 2 W.
All places	Two-way radios	See 5.2.1.
All places	Base stations for DECT cordless phones and WLAN (e.g. Wi-Fi)	See 5.2.1 As example for pacemakers and defibrillators the interference distance between source and AIMD is 15 cm for peak powers up to 2 W.

5.2.1 General recommendations

In all cases where recommendations restricting use of workplace equipment are given with the AIMD, they should be identified and taken into account as part of the risk assessment. Where these recommendations cannot be taken into account at the workplace, a specific risk assessment following Annex A is required. Such recommendations are normally in the form of a minimum separation distance between the equipment and the AIMD. Those recommendations are given in the patients manual the AIMD-Employee receives from the implanting institution or by the suppliers of the specific equipment in the workplace.

CEI EN 50527-1: Table 1 (whitelist) example 2

Designation of workplace	Examples of equipment	Exceptions and remarks
Medical workplaces	All medical equipment not using electromagnetic field emitters for therapeutic or diagnostic purposes	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 section.
Workplaces open to the general public (as covered by Article 4.6 of Directive 2013/35/EU)	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 localized 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.

CEI EN 50527-1: Specific Risk Assessement

CEI EN 50527-1: Specific Risk Assessement

A.1 General

This annex provides a method for the specific assessment of AIMD-Employees where there is no particular standard. If there is a standard for a specific AIMD in the EN 50527-2-x series, then the provisions given in that standard take precedence over the methods in this annex.

The risk assessment should involve input from:
— employer and if applicable his occupational health and safety experts and/or occupational physician,
— AIMD-Employee and his responsible physician,
— experts (technical and medical), e.g. manufacturer of the AIMD.

CEI EN 50527-1: Non-clinical Approach

A.2 Non-clinical approach

A.2.1 Assessment of the exposure situation

The maximum continuous and transient field strength at the workplace shall be known or determined. Information about peak field strength, modulation, etc. shall be collected. Plain R.M.S. measurement results are not sufficient for non-sinusoidal field sources. Weighted peak measurements may need additional considerations on the peak values.
The determination may be done by one or more of the following options:

- measurement;
- calculation;
- information provided by the supplier of the equipment.

Measurements shall follow an appropriate standard such as EN 50413 or applicable product or measurement standard.

In the absence of a specific warning an assessment following Subclauses A.2.2 to A.2.4 is not necessary, when the General public reference levels (without time averaging) are not exceeded.

A.3 Clinical approach

The clinical approach could be used to assess the risk for the AIMD-Employee. The AIMD-Employee is exposed under clinical supervision for a significant duration in the workplace to the foreseeable exposure situations or in a laboratory simulating the workplace exposure situation. The behaviour of the AIMD is then checked by the the responsible physician or under his responsibility by e.g. telemetry during and after the exposure.

The AIMD-Employee may be exposed to the foreseeable exposure levels investigating occurence or absence of interference with the AIMD (non-provocative test) or may be exposed and the exposure level raised until interference with the AIMD is observed (provocative test).

It should be considered that this approach may not identify a safety margin unless a provocative test is undertaken.

Details of such clinical investigation cannot be standardized but the responsibility and the required depth of investigation shall be determined with the responsible physician and the physician supervising the tests.

La famiglia di norme CEI EN 50527

NORMA ITALIANA CEI

Norma Italiana — *Data Pubblicazione*

CEI EN 50527-1 — **2017-09**

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Titolo

Procedura per la valutazione dell'esposizione ai campi elettromagnetici dei lavoratori con dispositivi medici impiantabili attivi
Parte 1: Generalità

NORMA ITALIANA CEI

Norma Italiana — *Data Pubblicazione*

CEI EN 50527-2-1 — **2017-09**

La seguente Norma è identica a: EN 50527-2-1:2016-12.

Titolo

Procedura per la valutazione dell'esposizione ai campi elettromagnetici dei lavoratori con dispositivi medici impiantabili attivi
Parte 2-1: Valutazione specifica per lavoratori con stimolatore cardiaco (pacemaker)

NORMA ITALIANA CEI

Norma Italiana — *Data Pubblicazione*

CEI EN 50527-2-2 — **2018-11**

La seguente Norma è identica a: EN 50527-2-2:2018-05.

Titolo

Procedura per la valutazione dell'esposizione ai campi elettromagnetici dei lavoratori con dispositivi medici impiantabili attivi
Parte 2-2: Valutazione specifica per lavoratori con defibrillatori cardiaci impiantati (ICD)

NORMA ITALIANA CEI

Norma Italiana — *Data Pubblicazione*

CEI EN 50527-2-3 — **2022-07**

La seguente Norma è identica a: EN 50527-2-3:2021-10.

Titolo

Procedura per la valutazione dell'esposizione ai campi elettromagnetici dei lavoratori portatori di dispositivi medici impiantabili attivi
Parte 2-3: Valutazione specifica per lavoratori con neurostimolatori impiantabili

CEI EN 50527-2-1: Pacemaker

N O R M A I T A L I A N A C E I

Norma Italiana

CEI EN 50527-2-1

La seguente Norma è identica a: EN 50527-2-1:2016-12.

Data Pubblicazione

2017-09

Titolo

Procedura per la valutazione dell'esposizione ai campi elettromagnetici dei lavoratori con dispositivi medici impiantabili attivi Parte 2-1: Valutazione specifica per lavoratori con stimolatore cardiaco (pacemaker)

Under revision. Expected 2025

CEI EN 50527-2-1: Pacemaker

Recepita come CEI EN 50527-2-1:2017-09

EN 50527-2-1:2016 (E)

4 Specific assessment

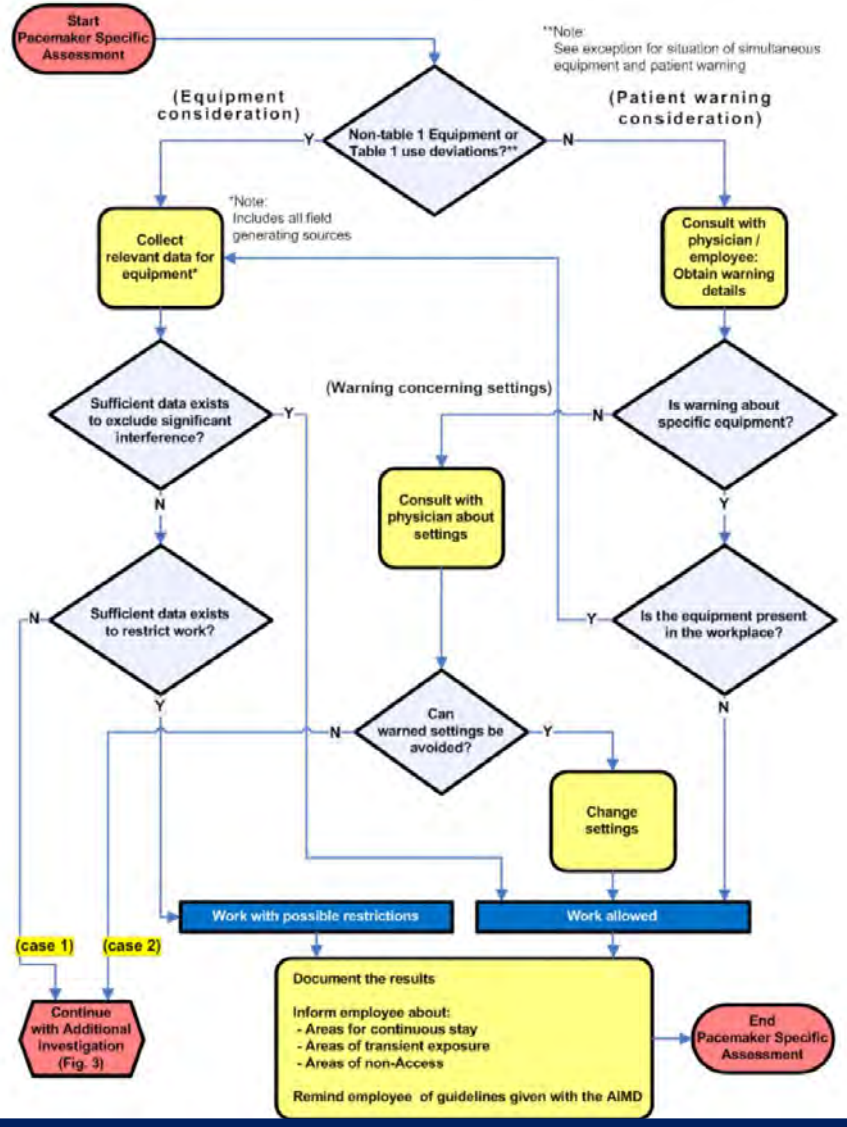
4.1 Description of the assessment process

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.

CEI EN 50527-2-1: methods



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

CEI EN 50527-2-1: specific risk assessment: when?

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.

CEI EN 50527-2-1: specific risk assessment: how?

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.

CEI EN 50527-2-1: clinical vs nonclinical methods

METODI CLINICI:

- **Monitoraggio tramite ECG o Holter;**
- **Valutazione dei dati memorizzati dal pacemaker (elettrogrammi);**
- **Monitoraggio in tempo reale tramite telemetria;**

Vantaggi:

- ✓ **semplicità del set-up (es. monitoraggio ECG del paziente).**
- ✓ **situazioni realistiche di esposizione;**
- ✓ **Possibilità di studiare molti pazienti / modelli di device;**
- ✓ **Risposte «personalizzate» per casi specifici;**

Limiti:

- ✓ **Potrebbe sollevare questioni etiche;**
- ✓ **Non consente di studiare tutte le funzioni/programmazioni del device;**
- ✓ **Non consente di definire margini di sicurezza;**

METODI NON CLINICI

- **Prove in-vitro;**
- **Studi comparativi;**

Vantaggi:

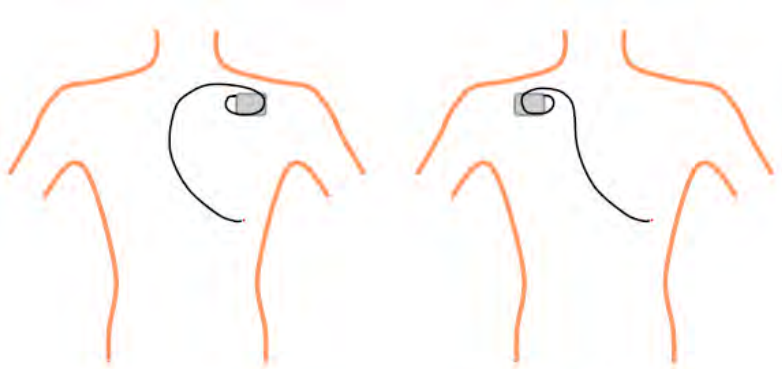
- ✓ **Sicuri (non c'è il paziente);**
- ✓ **Consentono test provocativi e definizione di caso-peggiore;**
- ✓ **Consentono di definire distanze di sicurezza;**
- ✓ **Consentono di studiare molte funzioni/parametri del dispositivo;**

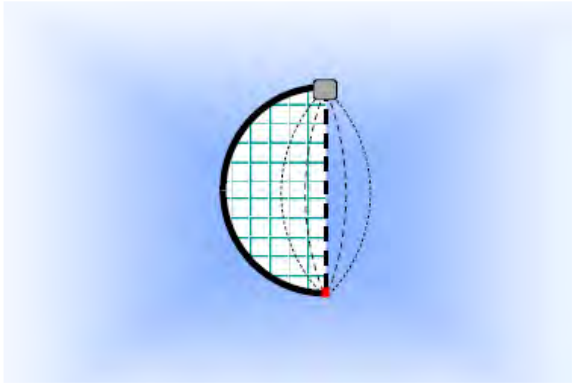
Limiti:

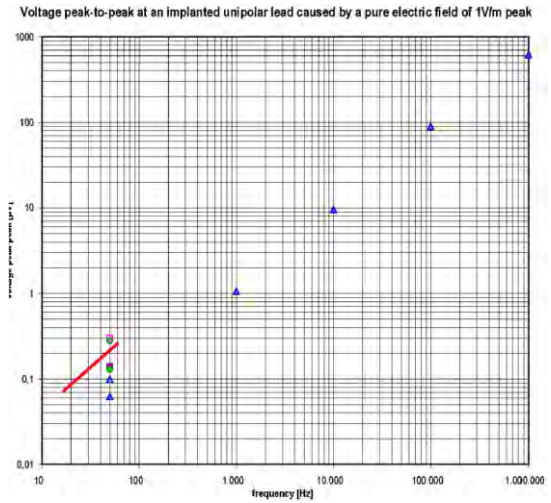
- ✓ **Richiedono una conoscenza e modellizzazione accurata della sorgente EM.**
- ✓ **Lo stesso set-up non si adatta a tutte le frequenze. Per alcune sorgenti (es. RFID) la forma del simulatore di tronco è ancora oggetto di discussione**
- ✓ **In alcuni casi il set-up di generazione dei campi può risultare complesso e costoso**

CEI EN 50527-2-1: informative annexes

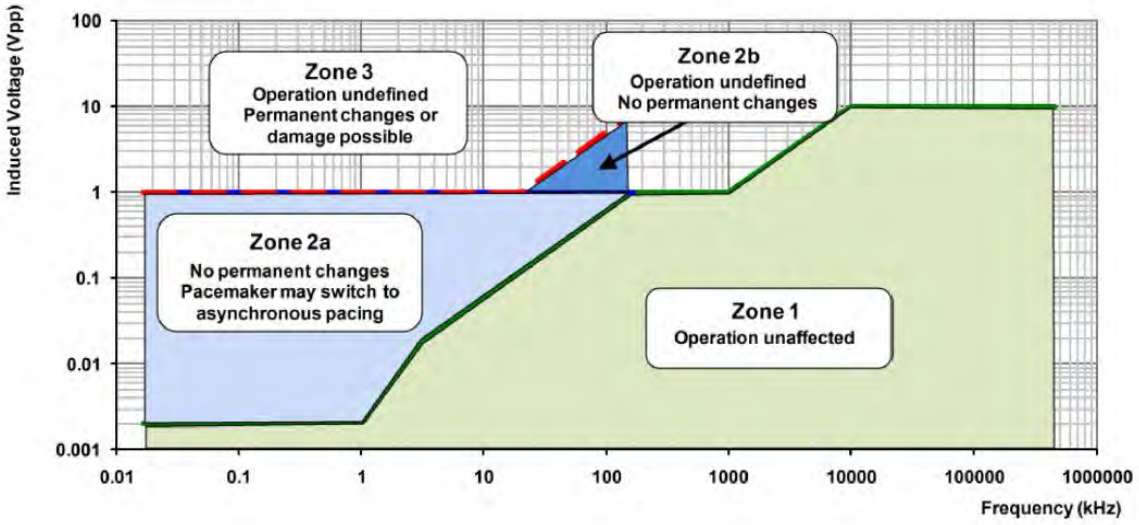
CEI EN 50527-2-1: informative annexes







G.3.3 Induced voltage zones

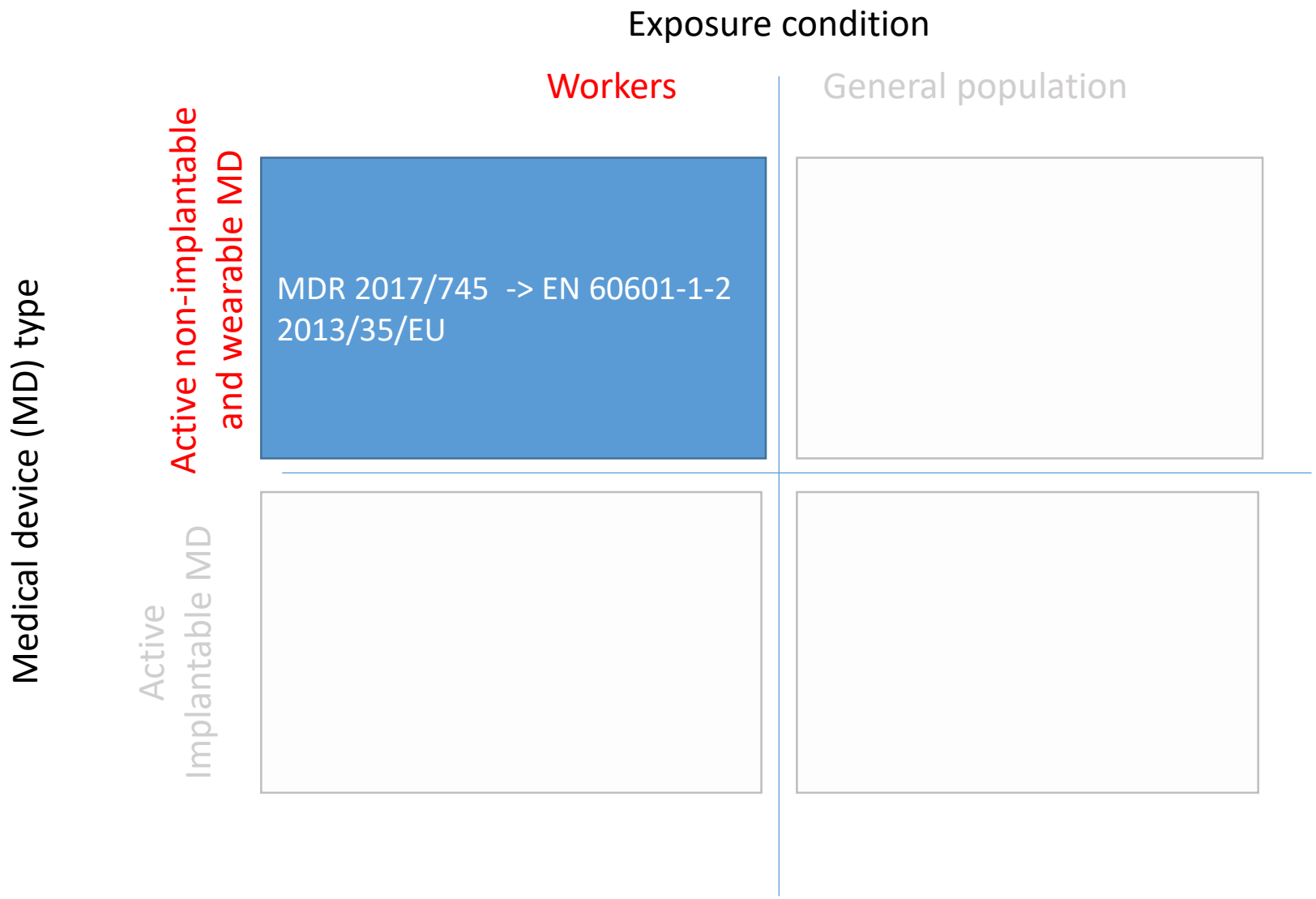


$$V_{pp}^{ind,max} = \max \left\{ \begin{array}{l} 6,55 \times 10^{-10} \times H_p \times f^{1,4} \\ 3,6 \times 10^{-10} \times \sqrt{10^6 \times H_p^{\,2} + E_p^{\,2}} \times f \\ 3,17 \times 10^{-16} \times E_p \times f^{1,9} \end{array} \right\}$$

Take home message

- La famiglia di norme CEI EN 50527 fornisce metodi standardizzati per la valutazione del rischio in lavoratori portatori di DMIA.
- Alcuni «casi» possono essere risolta facilmente utilizzando le informazioni della whitelist.
- In altri casi è necessaria una valutazione specifica, che può essere documentale, in-vitro od in-vivo.

Non-implantable active devices and wearables



Non-implantable active devices and wearables

- Non esiste una norma tecnica per la valutazione del rischio specifico di interferenze elettromagnetiche associato a lavoratori con dispositivi medici attivi non-impiantabili o indossabili

- La norma sulla compatibilità elettromagnetica (EN 60601-1-2) demanda al fabbricante:
  - l'analisi dei rischi ed eventualmente l'esclusione di particolari ambienti o sorgenti
  - Le informazioni da riportare sui manuali dei dispositivi relativamente a livelli di immunità e/o distanze di sicurezza

NON ESISTE UN LEGAME FRA LIVELLI DI IMMUNITA' E LIVELLI DI ESPOSIZIONE ICNIRP!

Modello concettuale per la valutazione del rischio