



IFA

Institut für Arbeitsschutz der
Deutschen Gesetzlichen Unfallversicherung

Risk assessment for workers with CIEDs exposed by electromagnetic fields

**in the context of the German Ordinance on the protection of workers against
hazards caused by electromagnetic fields (EMFV)**

Dr. Carsten Alteköster

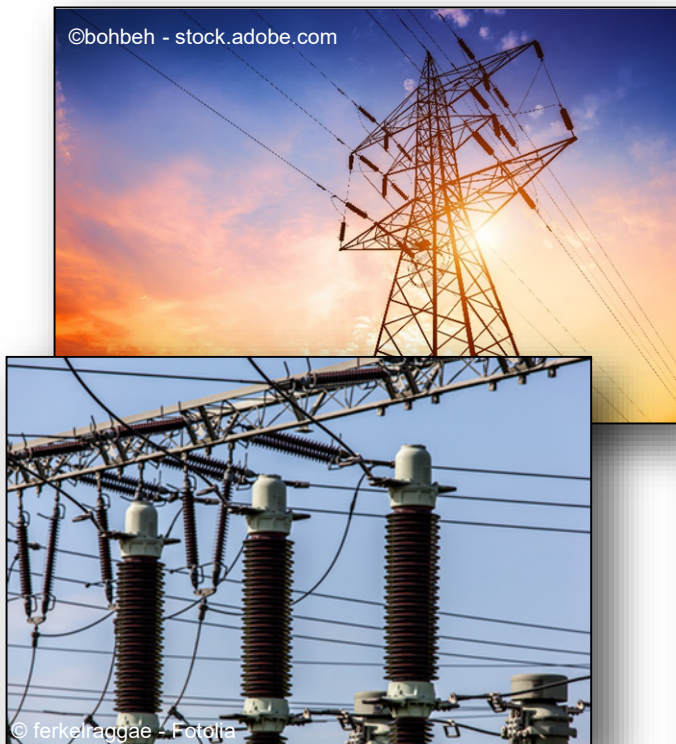
Institute for Occupational Safety and Health of the German Social Accident Insurance



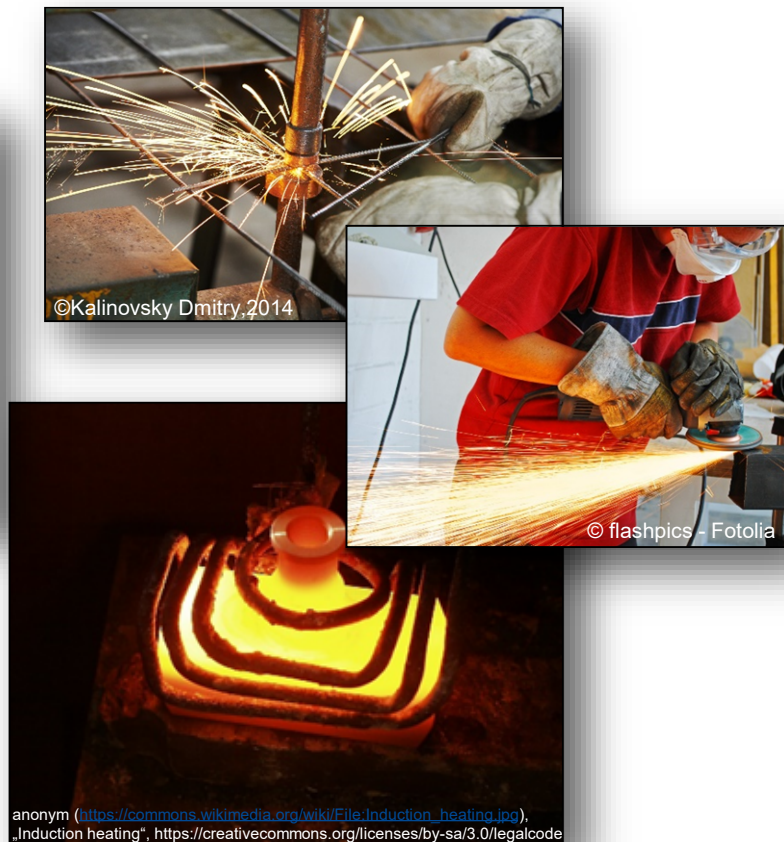
Section Machine and system safety
Webinars on "Digital manufacturing - Research results from occupational safety and health"
10.06.2024

Electromagnetic fields (EMF) at industrial workplaces

electric fields



magnetic fields

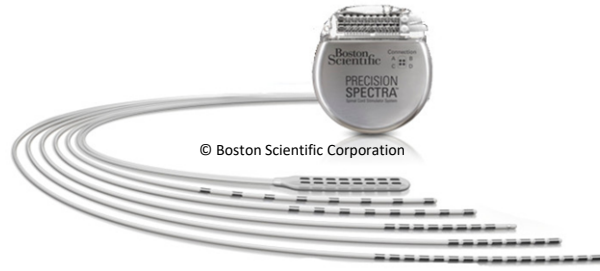


electromagnetic fields



Examples of active and passive medical implants

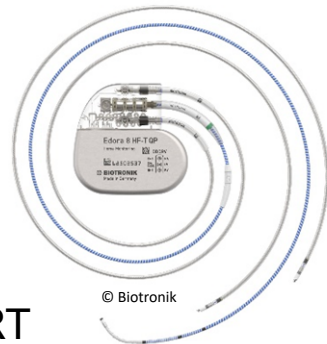
SCS (Spinal Cord Stimulation)



Pacemaker (PM)



subcutaneous ICD

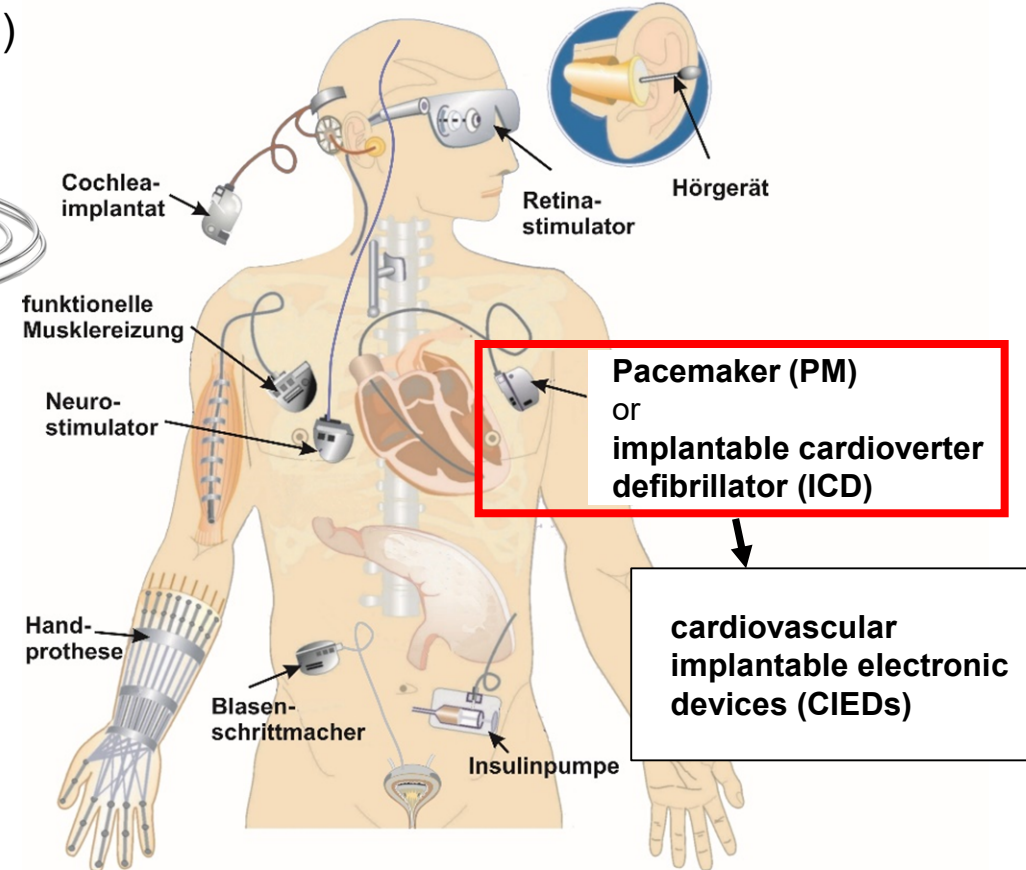


CRT (Cardiac Resynchronization Therapy)

leadless PM



Stents

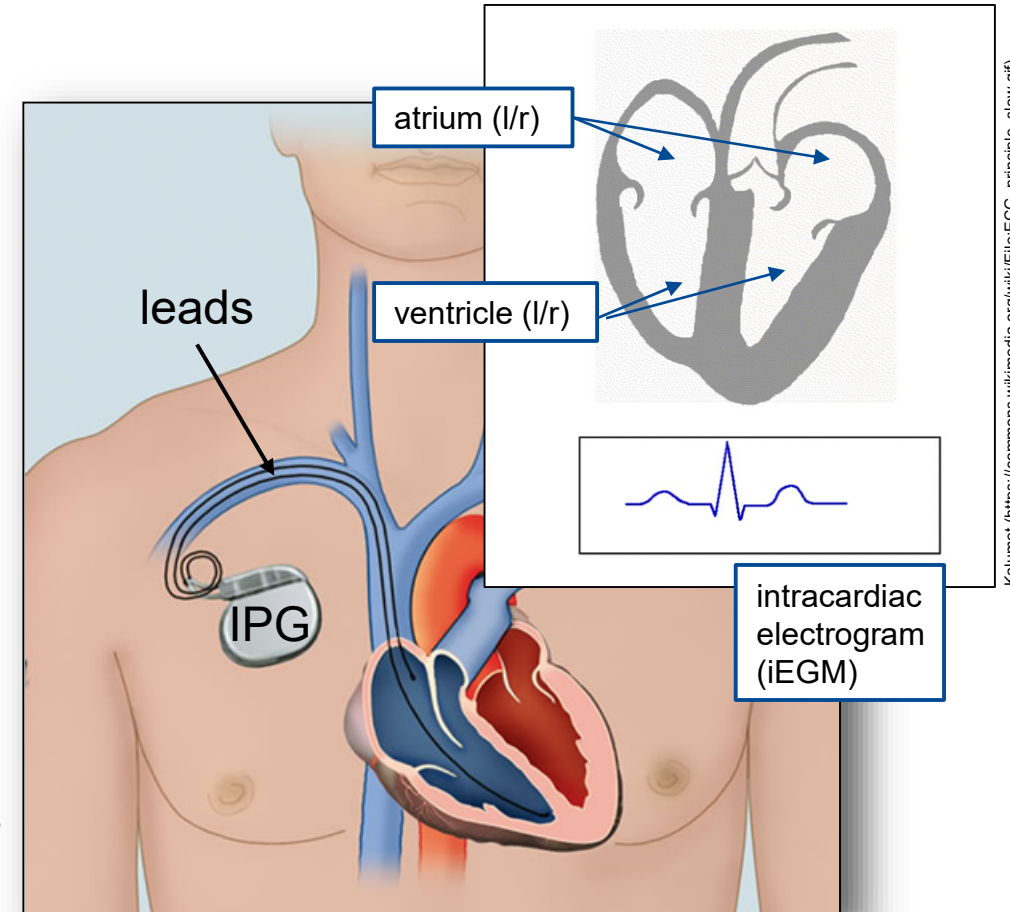


Potential Effects of Electromagnetic Fields on cardiovascular implantable electronic devices (CIEDs)

Electromagnetic interference (EMI)

Components and functions of CIEDs

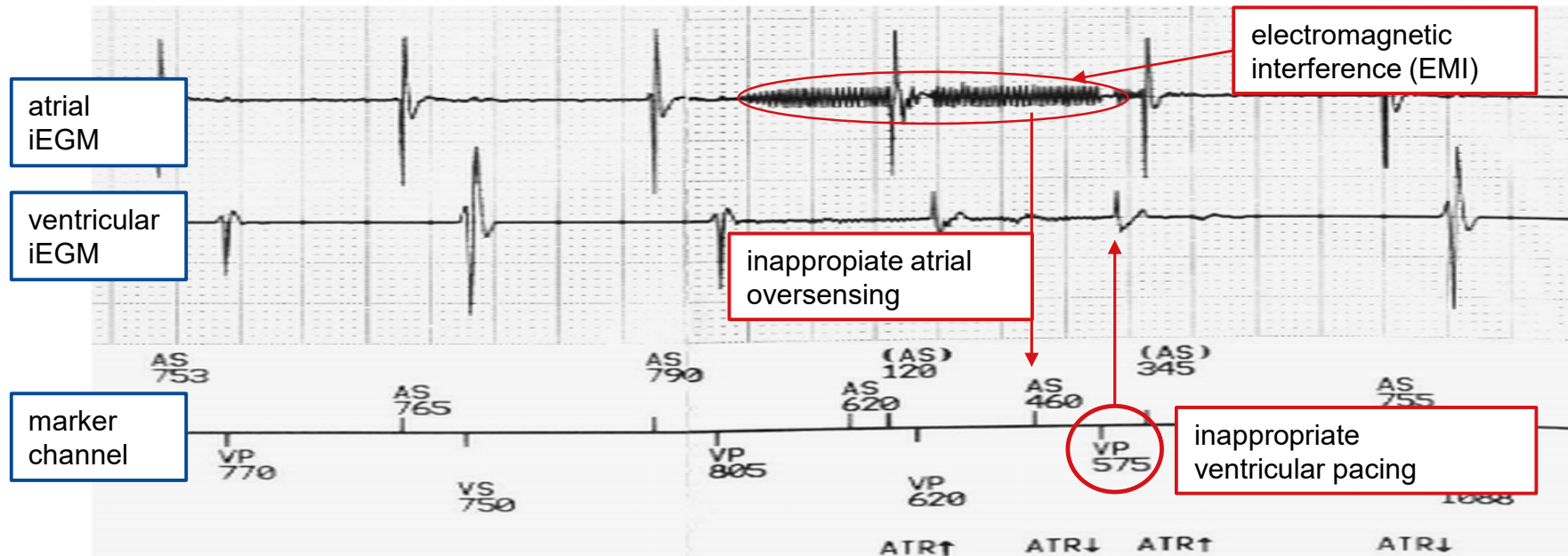
- Implantable pulse generator (IPG) (power source and circuitry that controls CIEDs operations)
- Lead(s) (thin, flexible, electrically insulated wires) are connected to the IPG on one end, and placed within the heart's chamber with the other end
- The cardiac depolarization is sensed through the electrodes (poles) at the end of the leads **(SENSING FUNCTION)**
- Evaluation of the sensed cardiac depolarization (intracardiac electrogram (iEGM))
- If necessary, the IPG sends electrical impulses or shocks through the lead to stimulate the heart



Kalunet (https://commons.wikimedia.org/wiki/File:ECG_principle_slow.gif),
 „ECG principle slow“, https://creativecommons.org/licenses/by-sa/3.0/legalcode

Potential consequences of EMI on CIEDs

- Low-frequency EMF can induce electric fields and currents within the human body and the leads of the CIED
 - ➔ atrial or ventricular oversensing
 - ➔ pacing inhibition, inappropriate mode switch, inappropriate shock delivery, ...

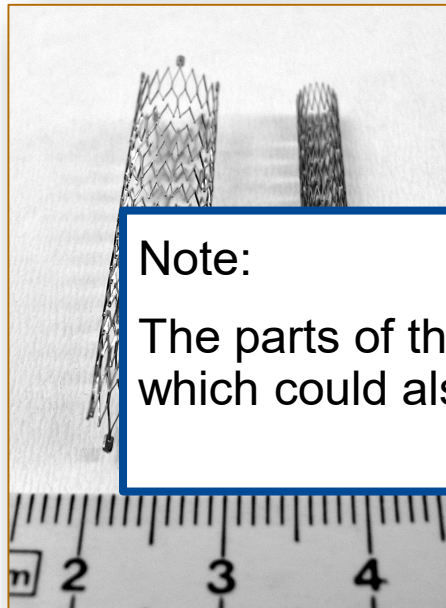


© Artur Golbert - Fotolia

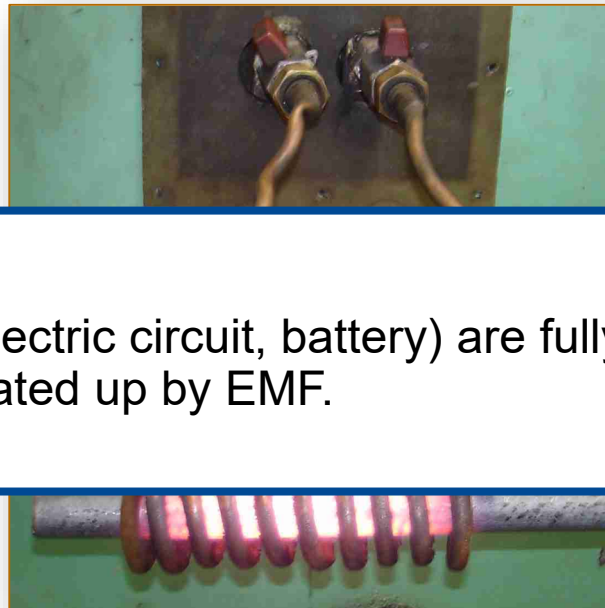
Source: Research Report 2010, Research Center for Bioelectromagnetic Interaction (femu), Institute of Occupational Medicine, University Hospital, RWTH Aachen University, Aachen, Germany; <https://www.ukaachen.de/kliniken-institute/institut-fuer-arbeits-sozial-und-umweltmedizin/femu.html>

Potential consequences of EMI on metallic objects

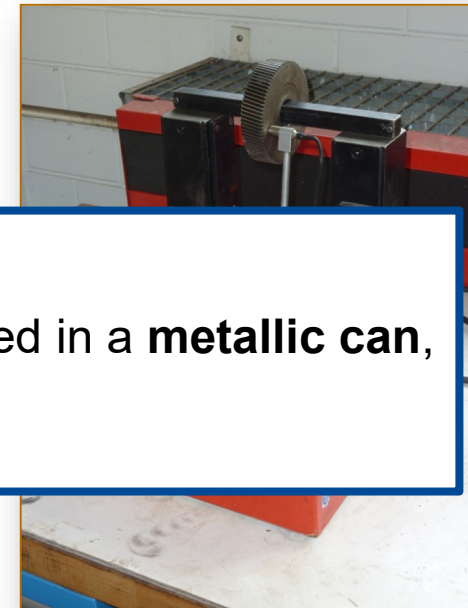
Example: Heating of a stent in the carotid artery by inductive heating



Quelle: Frank C. Müller
https://commons.wikimedia.org/wiki/File:Stent4_fcm.jpg, „Stent4 fcm“,
<https://creativecommons.org/licenses/by-sa/2.5/legalcode>



Quelle: taken by en:User:Vector1 nz, cropped by User:Tokino
https://commons.wikimedia.org/wiki/File:Induction_heating_of_bar_crop.jpg, „Induction heating of bar crop“,
<https://creativecommons.org/licenses/by-sa/3.0/legalcode>



Quelle: Institut für Arbeitsschutz (IFA)

Note:

The parts of the IPG (electric circuit, battery) are fully enclosed in a **metallic can**, which could also be heated up by EMF.

Some potential consequences of EMI on CIEDS

- Low-frequency EMF can induce electric fields and currents within the human body and the leads of the CIED
 - ➔ atrial or ventricular oversensing
 - ➔ pacing inhibition, inappropriate mode switch, inappropriate shock delivery, ...

- High-frequency fields can heat up tissue and metal-made objects
 - ➔ Heating of the implant
 - ➔ Harm of the tissue surrounding the CIED
 - ➔ dislocation of the CIED

- Static magnetic fields exert force on ferromagnetic objects
 - ➔ Reed switch activation
 - ➔ asynchronous pacing, temporary suspension of tachyarrhythmia therapy (ICD)

Factors for EMI and potential clinical consequences

Characteristics of the EMF exposure

- relevant part of the EMF (electric field, magnetic field , electromagnetic field)
- frequency (static, low-frequency, high-frequency)
- field strength
- temporal characteristic of the EMF (sinusoidal, exponential, arbitrary,...)
- exposure duration

Characteristics of the CIED and implant wearer

- device settings (filter characteristics, sensing threshold, mode)
- sensing configuration (unipolar-/bipolar)
- lead configuration and position
- physical body characteristics

Risk assessment

Legislative framework

is based on

EU Directive 2013/35/EU
 („EMF-Directive“)

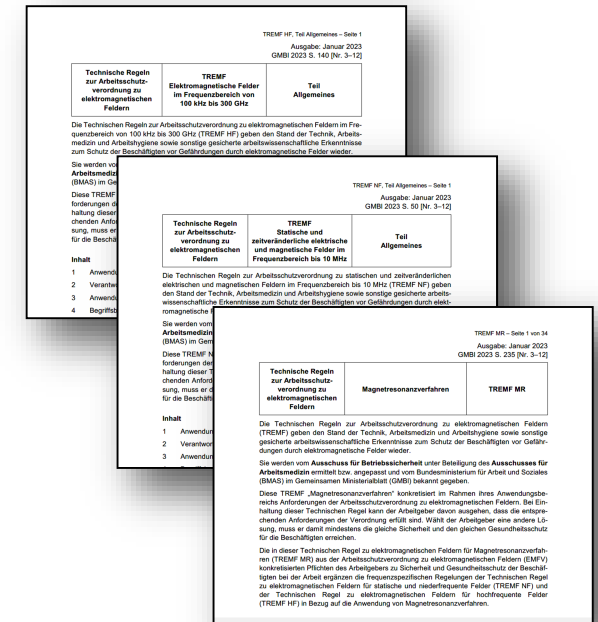


German Ordinance on the protection of workers against hazards caused by electromagnetic fields (EMFV)



is specified in more detail by

Technical rules (TREMFF)



Technical Rules for the EMFV (TREMFM)

Directive and Ordinance point out the particular risk of implant wearers when they are exposed to EMF and require that they be given special attention but do not provide any threshold values or procedures for risk assessment.

The Technical Rules are therefore of great value, because they

- can be seen as a more detailed formulation of the requirements of the German Ordinance on the protection of workers against hazards caused by electromagnetic fields (**EMFV**)
- they reflect the **state of the art** in the assessment of the risk caused by exposure to electromagnetic fields.
- contain numerous information, flowcharts and tables to help the employer to fulfill the requirements of the EMFV,
- **contain frequency-dependent threshold values, flowcharts for risk assessments of workers at particular risk, examples of risk assessments and much more information.**

Precondition for a risk assessment for workers with CIEDs

The employer must have notice of workers with CIEDs in the company.

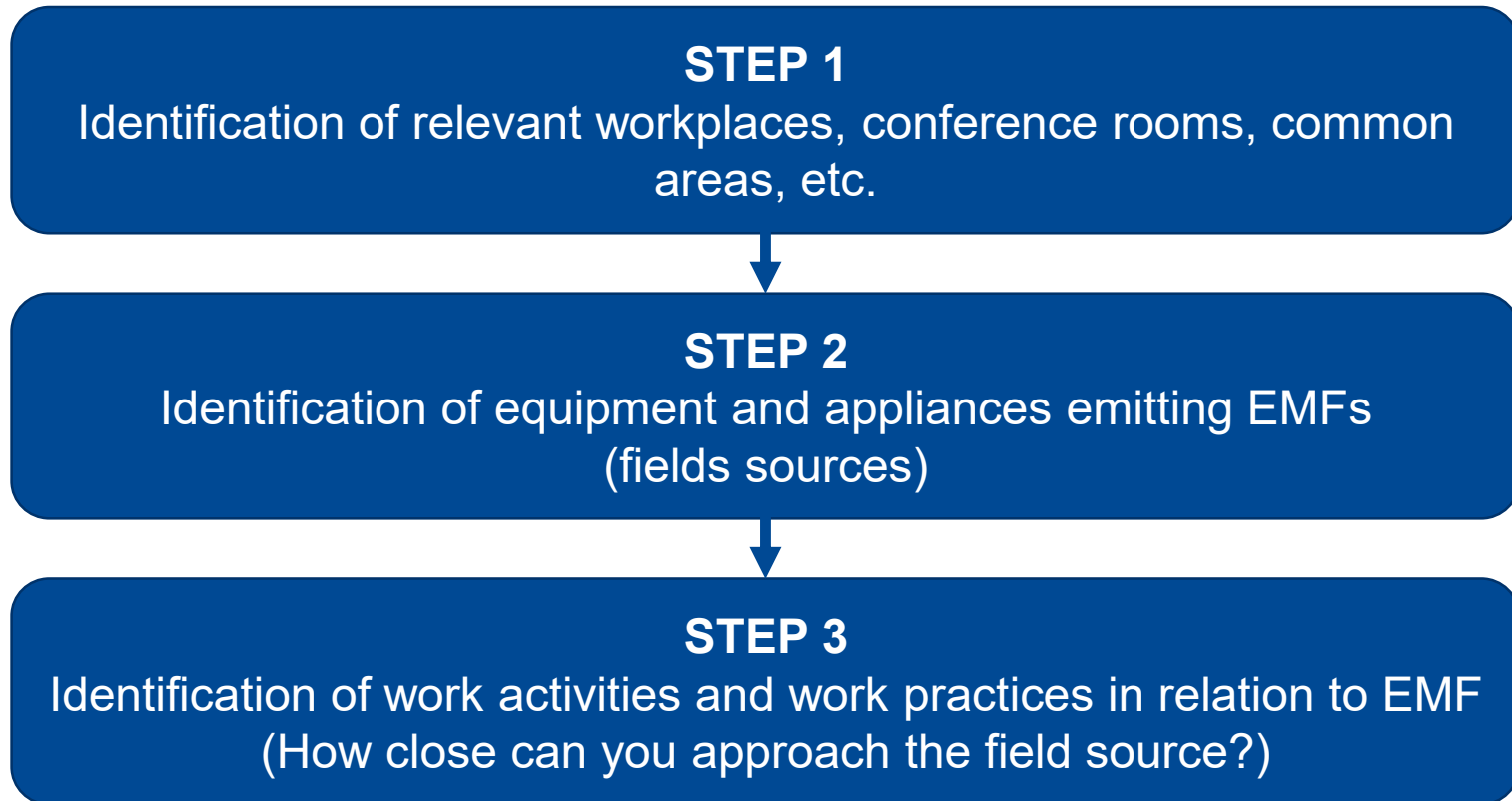
Problem: It is not mandatory for a worker to indicate that he or she is wearing an implant.
(according to the EMFV)

Preventive measure: Worker information Creating awareness of possible risks!!

- providing appropriate information about the nature of the hazards associated with EMF and possible symptoms
- providing specific information for worker with CIEDs (name contact persons for further confidential consultations, e.g. company medical officer)
- provide information about workplaces in your company where high EMF exposure must be expected



Risk assessment for workers with CIEDs (according to EMFV)



Risk assessment for workers with CIEDs (according to EMFV)

STEP 4
 First assessment of the exposure situation using Yes/No tables
 (TREMf, DGUV-Information 203-043)

Tab. A2.1 Bewertung verschiedener Expositionssituationen für besonders schutzbedürftige Beschäftigte

Art der EMF-Quelle	Individuelle Bewertung erforderlich für Träger aktiver Implantate	Individuelle Bewertung erforderlich für Träger passiver Implantate
Öffentlich zugängliche Bereiche		
Geräte am öffentlich zugänglichen Arbeitsplatz, die die Expositionsgrenzwerte nach EU-Ratsempfehlung zu EMF 1999/519/EG einhalten	Nein	Nein
Öffentlich zugängliche Arbeitsplätze, die die Referenzwerte nach EU-Ratsempfehlung zu EMF 1999/519/EG einhalten	Nein	Nein
Bürogebäude/Büroausstattung		
Mobiltelefone, Smartphone (Gebrauch selbiger, Abstände < 15 cm)	Ja	Nein
Mobiltelefone, Smartphone (Arbeitsplätze mit solchen, Abstände > 15 cm)	Nein	Nein
Büroausstattung (z. B. Kopiergeräte, Scanner, Aktenvernichter, elektrisch betriebene Heftapparate) mit drahtgebundenen Kommunikationsmodulen	Nein	Nein
Büroausstattung (z. B. Kopiergeräte, Scanner, Multifunktionsgeräte etc.) mit drahtloser Kommunikation, z. B. WLAN oder Bluetooth (in unmittelbarer Nähe, Abstände < 15 cm)	Ja	Nein
Büroausstattung (z. B. Kopiergeräte, Scanner, Multifunktionsgeräte etc.) mit drahtloser Kommunikation, z. B. WLAN oder Bluetooth (in größerer Entfernung, Abstände > 15 cm)	Nein	Nein

511 BGI/GUV-I 511
 DGUV Deutsche Gesetzliche Unfallversicherung Spitzenverband

Gerät	Beeinflussung von Herzschrittmachern		Bemerkung
	nicht wahrscheinlich	möglich	
Bürogeräte			
Beleuchtung (Decken- u. Tischleuchten)	X	-	
IT-Geräte (z.B. PC)	X	-	
Telefon/FAX-Gerät	-	-	
Lüfter, Heizlüfter	X	-	
Elektrische Bürogeräte (z.B. Kopierer, Schreibmaschine, Aktenvernichter, Hefter)	X	-	
Multimedia (Audio/Video)	X	-	in Implantatnähe möglich
Dauermagnete (Magnetklammern, Namensschilder, Plaketten)	X	-	in Implantatnähe möglich

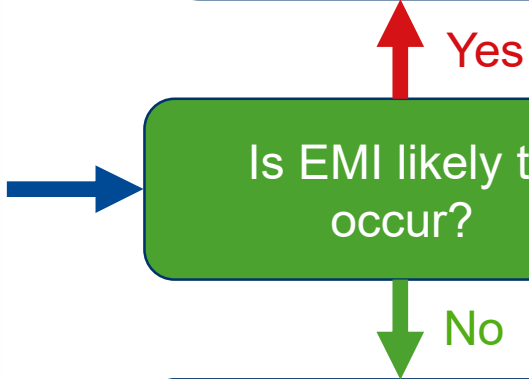
Information
 Beeinflussung von Implantaten durch elektromagnetische Felder
 Eine Handlungshilfe für die betriebliche Praxis
 Juni 2009 aktualisierte Fassung März 2012

under revision

Go to STEP 5
 or
 implement
 protective measures
 (furthermore documenting,
 monitoring and reviewing)

Is EMI likely to occur?

Documentation
 (furthermore monitoring and reviewing)

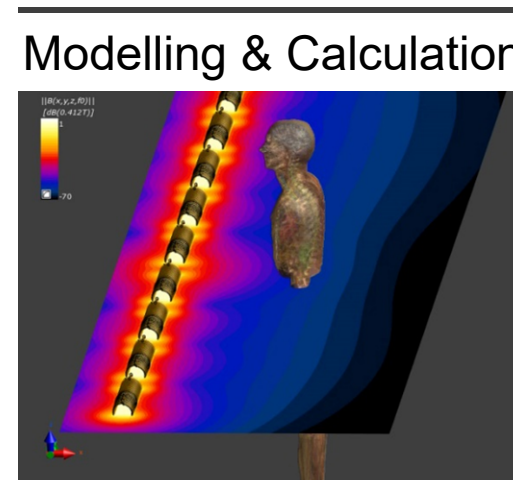


Risk assessment for workers with CIEDs (according to EMFV)

STEP 5

Detailed survey of the EMF exposure

physical quantity of interest (magnetic field, electric field, both),
frequency and amplitude, spatial characteristics, temporal characteristics



Risk assessment for workers with CIEDs (according to EMFV)

STEP 6 Assessment against worst-case threshold levels

TREMF NF/HF; ANNEX A1.7
„Thresholds for ensuring the safety of workers with active implants”

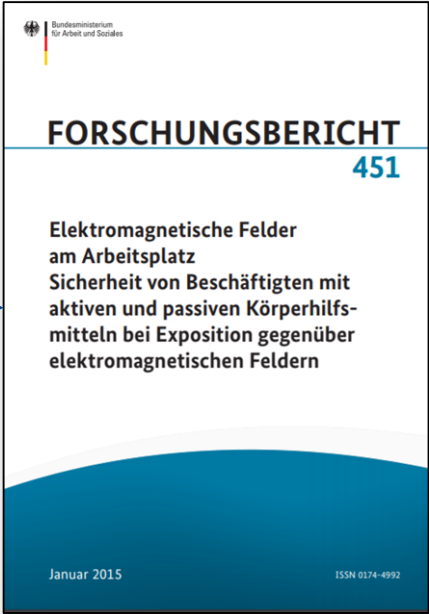
Annex contains threshold values for exposure of workers with active and passive implants to magnetic or electric fields

TREMF NF, Teil 2 – Seite 119

Tab. A1.26 Schwellenwerte der externen magnetischen Feldstärke H und Flussdichte B, die die Sicherheit von Personen mit aktiven medizinischen Implantaten im Sinne des Forschungsberichts FB 451 gewährleisten (nach Tabelle 6.4 FB 451), mit $B = \mu_0 \cdot \mu_r \cdot H$; $\mu_r = 1$; $\mu_0 = 4\pi \cdot 10^{-7} \frac{Vs}{Am}$

Frequenzbereich	Spitzenwert der externen magnetischen Feldstärke $H \left(\frac{A}{m}\right)$	Spitzenwert der externen magnetischen Flussdichte $\vec{B} \text{ (T)}$
0 Hz < f ≤ 9,97 Hz	555	$697 \cdot 10^{-6}$
9,97 Hz < f ≤ 1000 Hz	$5555 \cdot \frac{1}{f}$	$6,97 \cdot 10^{-3} \cdot \frac{1}{f}$
1000 Hz < f ≤ 3000 Hz	$5,55 \cdot 10^{-3} \cdot f$	$6,97 \cdot 10^{-9} \cdot f$
3 kHz < f ≤ 167 kHz	16,7	$21 \cdot 10^{-6}$
167 kHz < f ≤ 1 MHz	$2778 \cdot 10^3 \cdot \frac{1}{f}$	$3,5 \cdot \frac{1}{f}$
1 MHz < f ≤ 5,33 MHz	2,78	$3,5 \cdot 10^{-6}$
5,33 MHz < f ≤ 10 MHz	$14,8 \cdot 10^6 \cdot \frac{1}{f}$	$18,6 \cdot \frac{1}{f}$
10 MHz < f ≤ 16,0 MHz	1,48	1,86

for a detailed discussion of the threshold values see [Research Report 451](#) (German Federal Ministry of Labour and Social Affairs)



Risk assessment for workers with CIEDs (according to EMFV)

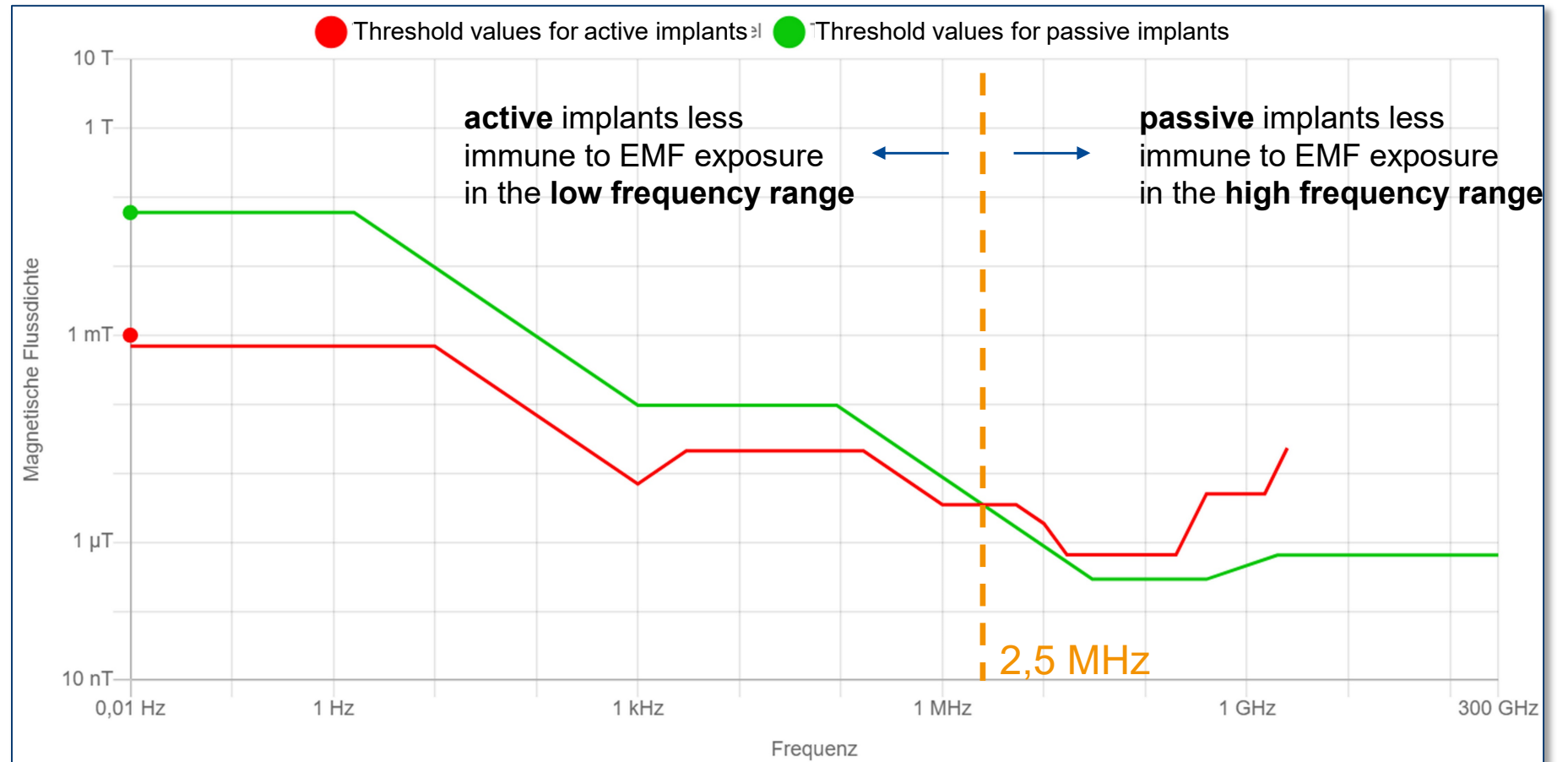
Threshold values (magnetic field, peak values)

Graph created with:

**Limit Info Tool for
Electromagnetic Fields
(EMF-LIT)**

<https://emflit.ifa.dguv.de/default>

- free of use IFA Online-Tool
- english version available



Risk assessment for workers with CIEDs (according to EMFV)

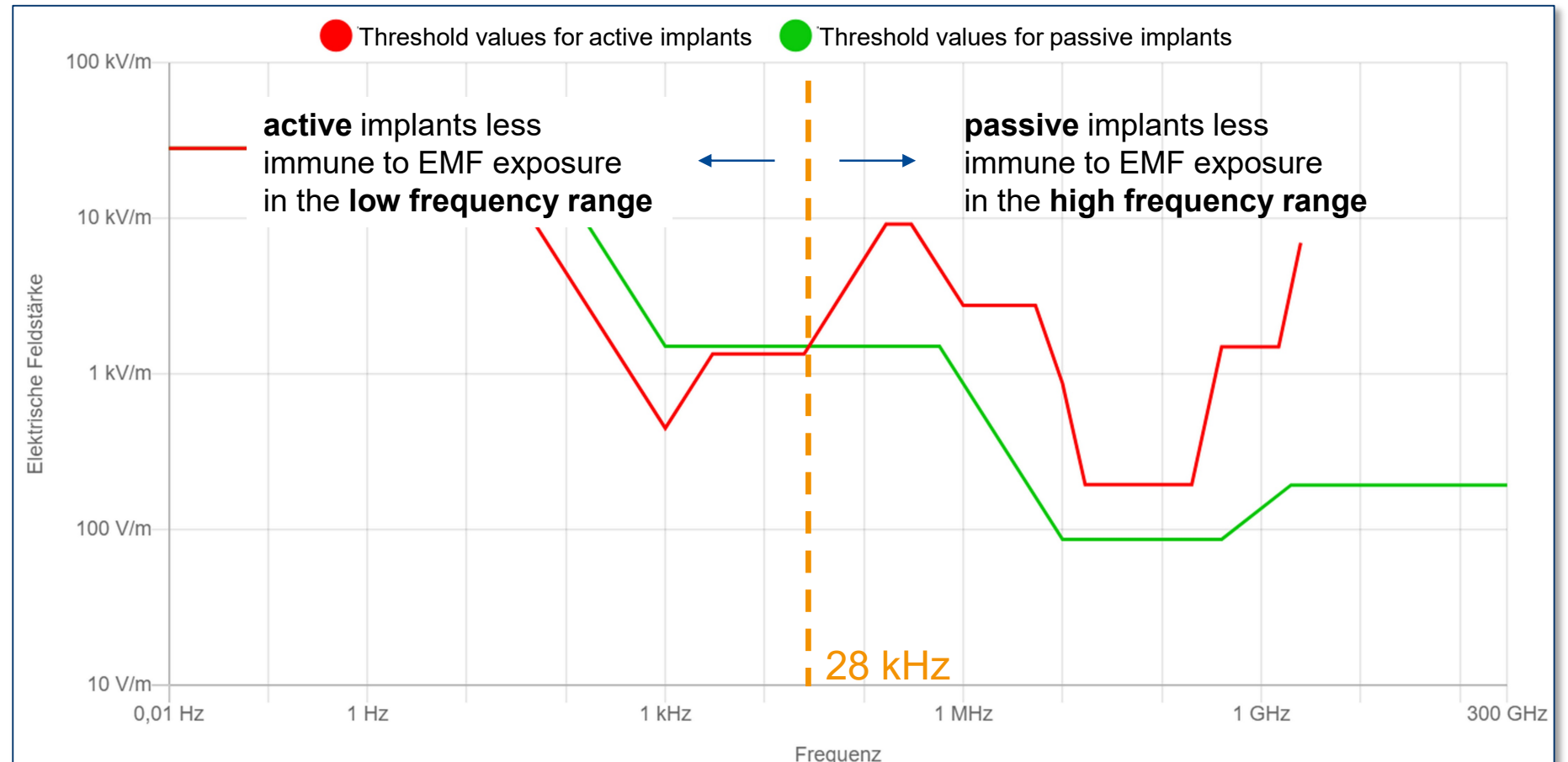
Threshold values (electric field, peak values)

Graph created with:

**Limit Info Tool for
Electromagnetic Fields
(EMF-LIT)**

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- free of use IFA Online-Tool
- english version available



Risk assessment for workers with CIEDs (according to EMFV)

STEP 6 Assessment against worst-case threshold levels

TREMF NF/HF; ANNEX A1.7
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10 MHz < f ≤ 16,0 MHz	$14,8 \cdot 10^2$	$18,6 \cdot 10^8$

Go to STEP 7
or
implement
protective measures
(furthermore documenting,
monitoring and reviewing)

Is EMI likely to occur?

Documentation
(furthermore monitoring and reviewing)

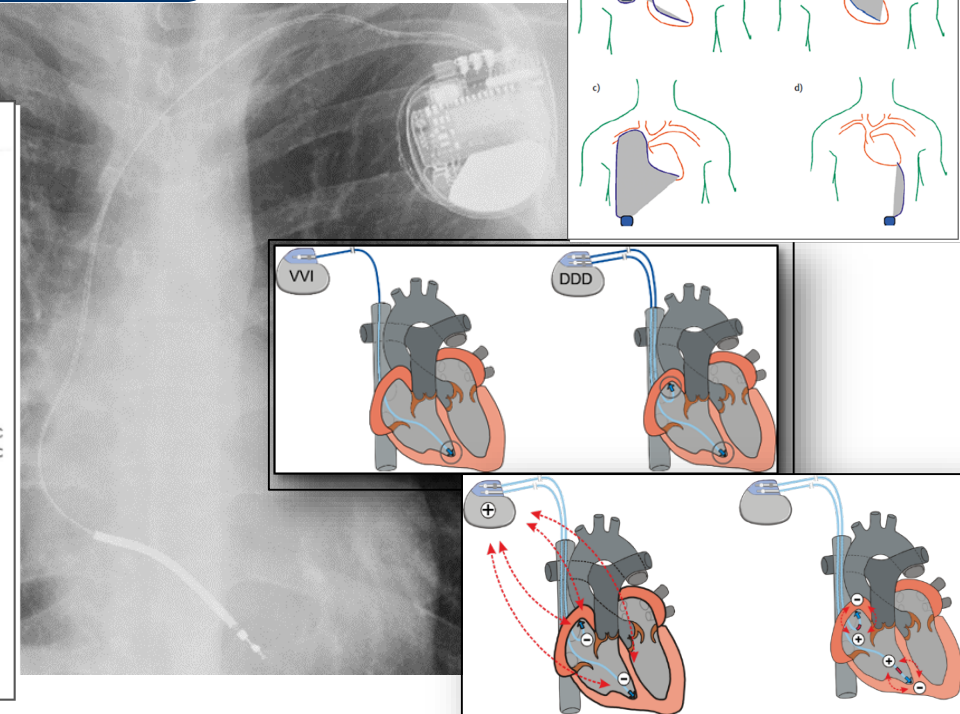
Risk assessment for workers with CIEDs (according to EMFV)

STEP 7 Consideration of the individual factors

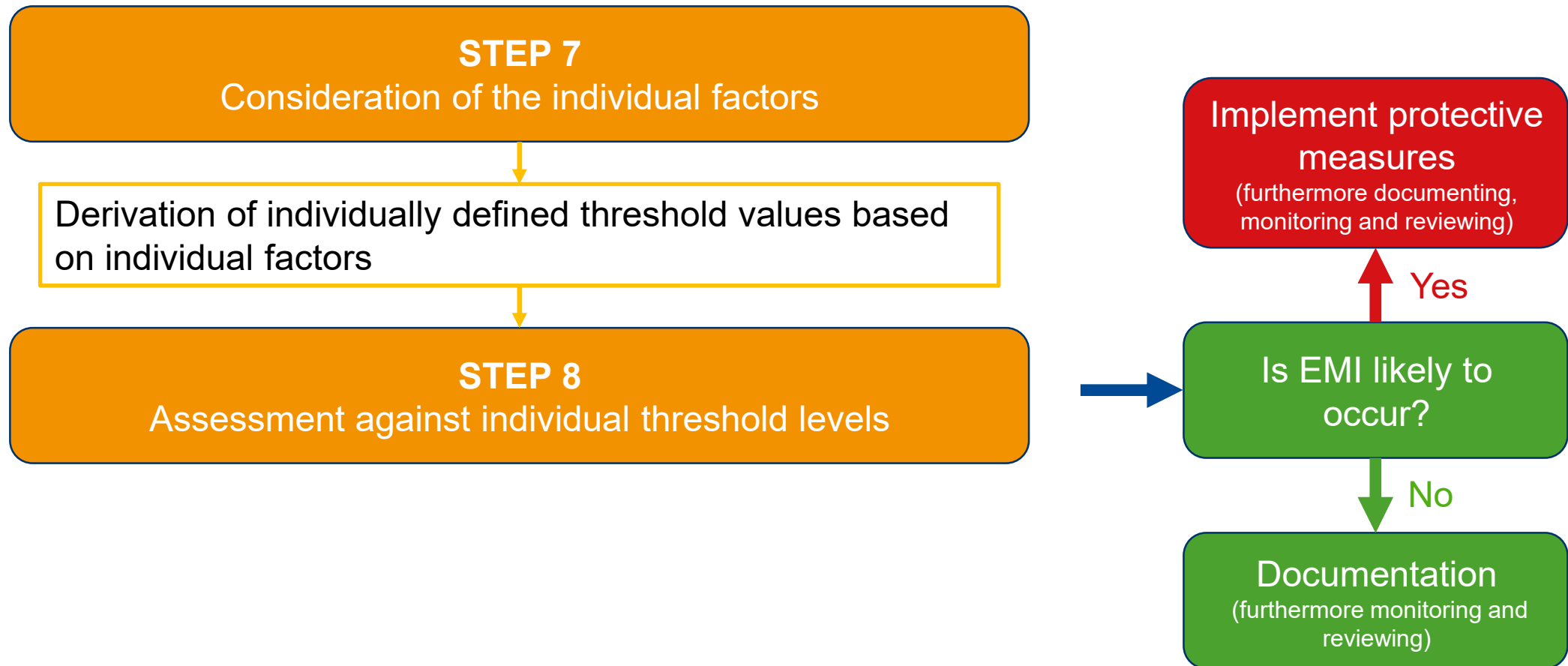
- type of CIED (Pacemaker, ICD)
- device model
- operation mode
- lead type for sensing (unipolar, bipolar)
- sensing threshold
- implant location
- patient indication(s)

implant card

	Vorher	Aktuell
Modus		VVIR
Grundfr. Tag/Nacht...		60/60 bpm
Frequenzhysterese...		AUS bpm
Repetitiv		----
Such		----
Nachtprogramm		AUS bpm
Nachtbeginn		----
Nachtende		----
Sensor		
Max. Aktiv.-Freq.		120
Sensorverstärkung		4
Autom. Verstärkung		EIN
Sensorschwelle		Mittel
Frequenzanstieg		2 bpm/cyc
Frequenzabfall		0.5 bpm/cyc
Obere Grenzfrequenz...		---- bpm
Impulsamplitude		3.5 V
Impulsdauer		0.40 ms
Amplitudensteuerung		AUS
Empfindlichkeit		2.5 mV
Refraktärzeit		300 ms
Polarität Pace		BIPL
Polarität Sense		BIPL
Elektroden-Check		AUS



Risk assessment for workers with CIEDs (according to EMFV)

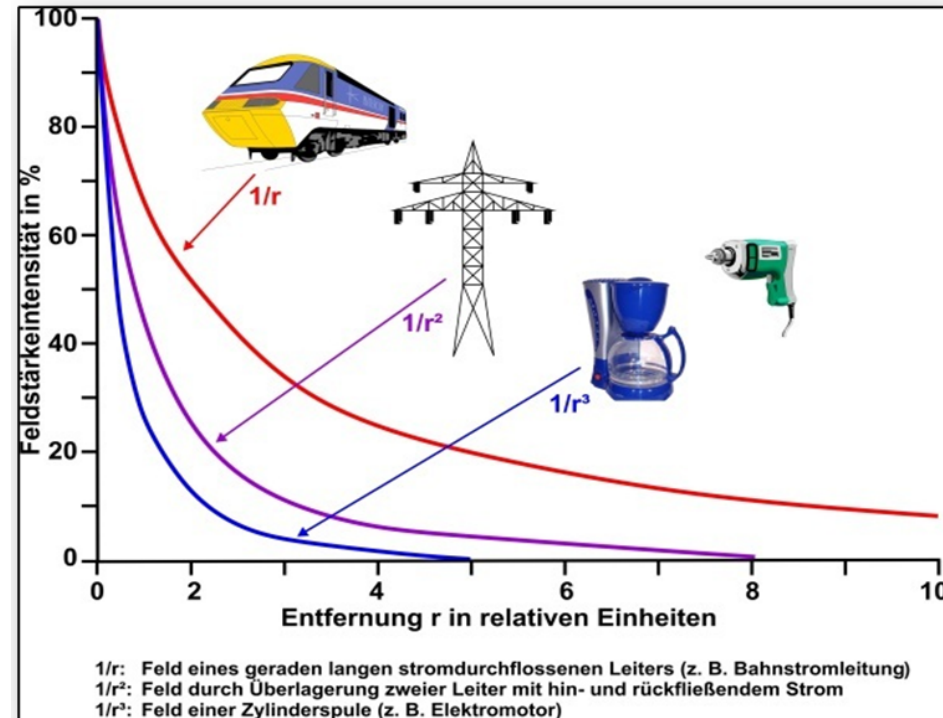


Protective Measures

Protective Measures

to reduce the risks arising from EMF exposure in the workplace

- Provision of information so that the workers understand the risks and how to minimise exposure
- Provision of specific information for workers with implants
- **Minimum compliance distance /safety distance**



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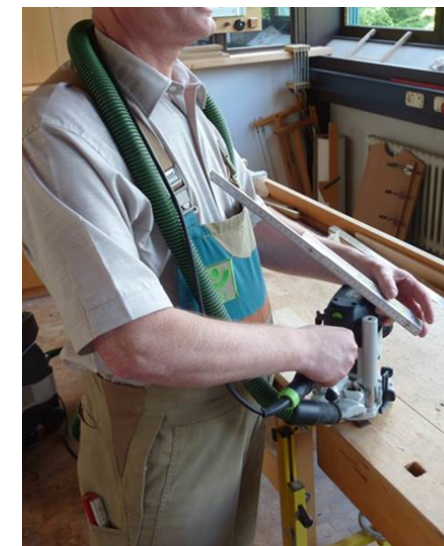
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- **Safety / Warning signs, floor markings**



Protective Measures

to reduce the risks arising from EMF exposure in the workplace

- Provision of information so that the workers understand the risks and how to minimise exposure
- Provision of specific information for workers with implants
- Minimum compliance distance /safety distance
- Safety / Warning signs, floor markings
- Written procedures / site safety information
- Adoption of good working practices
- Delimitation and restriction of access
- Fixed or moveable guarding, interlocks, shielding
- Substitution by less hazardous process or equipment
- Design and layout of workplaces and workstations
- **Very last option: ban from the workplace**



Practical experience

- Modern bipolar implants (PM or ICDs) are widely immune to EMF exposure in everyday life environment
- Simple protective measures (regarding to the occupational EMF exposure) are often sufficient to reintegrate workers with CIEDs back into their workplace



IFA

Institut für Arbeitsschutz der
Deutschen Gesetzlichen Unfallversicherung

IFA Technical Information on Electromagnetic Fields

<https://www.dguv.de/ifa/fachinfos/strahlung/elektromagnetische-felder/index-2.jsp>

Contact

[carsten.altekoester\(at\)dguv.de](mailto:carsten.altekoester(at)dguv.de)

Tel.: +49 30 13001-3581

Institut für Arbeitsschutz der Deutschen
Gesetzlichen Unfallversicherung (IFA)

Abteilung 5: Unfallprävention: Digitalisierung - Neue Technologien

Bereich 5.2: Maschinensicherheit, Industrial Security und Implantate

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Electromagnetic fields: key topics and projects



Zoom Image

Aluminium electrolysis furnace: a known source of high-strength static magnetic fields
Source: IFA

Electromagnetic fields are generated wherever a voltage is present or current flows. Employees working at electrical equipment and installations can therefore always be assumed to be exposed to electromagnetic fields. The exposure of office workers to fields generated by electrical office equipment, such as computers, monitors, etc., is negligible owing to the low field strengths of these devices. Other [field sources](#), for example on industrial installations for induction hardening and melting or on welding equipment, may however give rise to