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POSITION PAPER

EHRA consensus on prevention and management of interference due to medical procedures in patients with cardiac implantable electronic devices

For the European Heart Rhythm Association (EHRA), Heart Rhythm Society (HRS), Latin America Heart Rhythm Society (LAHRS), Asian Pacific Heart Rhythm Society (APHRS)

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Background

Definitions and scope of the problem

Interference is defined as disturbance generated by an external source that potentially affects the functioning of cardiac implantable electronic devices (CIEDs)—i.e. cardiac pacemakers (PMs), implantable cardioverter defibrillators (ICDs), cardiac resynchronization therapy (CRT) devices, and implantable loop recorders (ILRs).[1] Energy forms such as radiation, magnetic or electromagnetic fields (EMFs), as well as acoustic signals potentially cause interference due to oversensing (i.e. signals that are sensed by the device that do not reflect myocardial depolarization) and subsequently temporary suppression or inappropriate delivery of device therapy, programming errors (device reset), or even permanent CIED malfunction (Table 2).

The majority of interference sources are non-biological in origin and occur in the hospital environment,[2] and most inappropriate CIED responses are potentially avoidable. Electromagnetic interference (EMI) can be detected by device interrogation and analysis of intracardiac electrocardiograms (*Figure 1B*) and is not a rare finding in CIED patients: in single-centre studies, the incidence of EMI in CIED was determined as 1.87% per patient-year, while episodes with clinical impact were present in 0.27%.[3,4]

Thus, information about sources, mechanisms, device effects, and EMI prevention is important for CIED patients as well as caregivers.

Methodology

A panel of 20 CIED experts was set up by EHRA to write an international consensus statement. Members of associated societies, i.e. the US (HRS), the Latin American (LAHRS), and the Asian Pacific Heart Rhythm Society (APHRS), also designated two authors each to complete the collaborative group.

Sections of the consensus were divided according to the type of medical intervention and special foci were defined for surgical procedures (electrocautery), therapeutic radiation, and magnetic resonance imaging (MRI). The authors were asked to perform a detailed

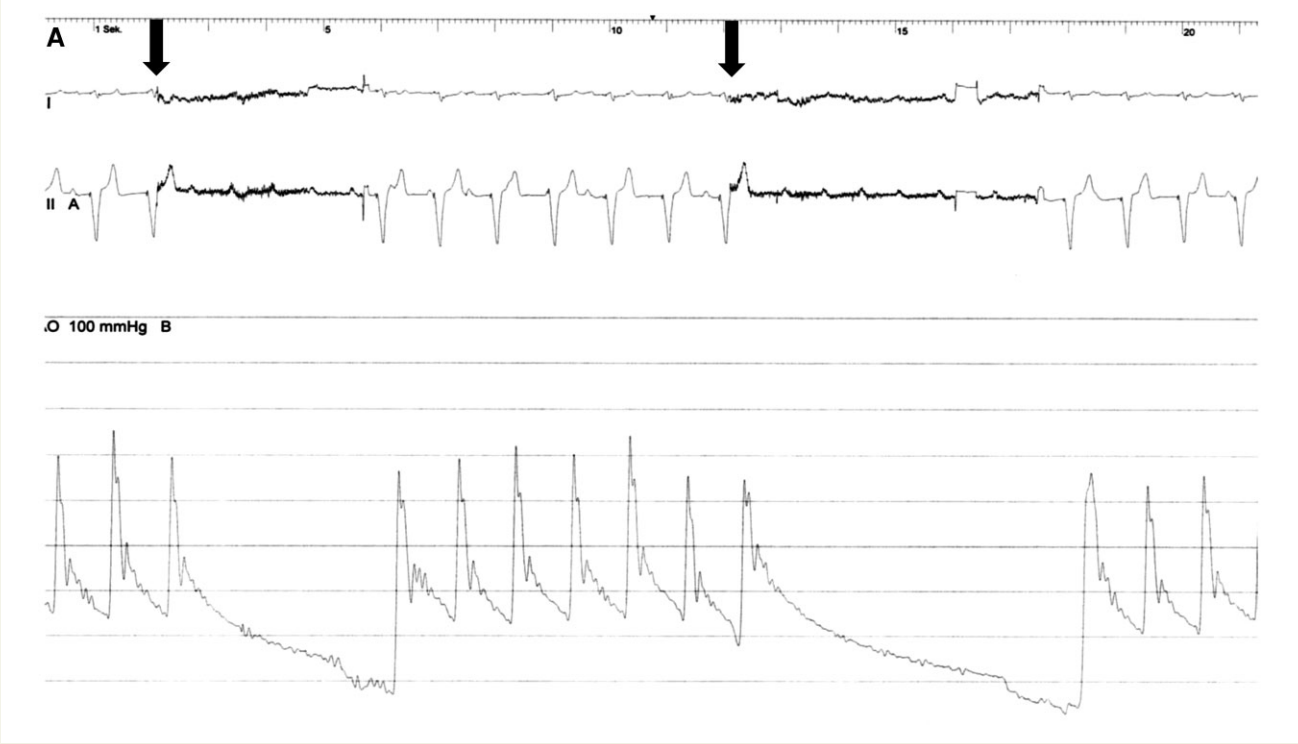

Figure 1 (*A*) Inhibition of right-ventricular pacing by unipolar electrocautery during revision of the atrial lead in a 64-year-old PM-dependent patient: ECG Leads I and II and invasive blood pressure measurements are shown; arrows indicate the initiation of cautery bursts (arrow), leading to pacing inhibition and subsequent drops in blood pressure.

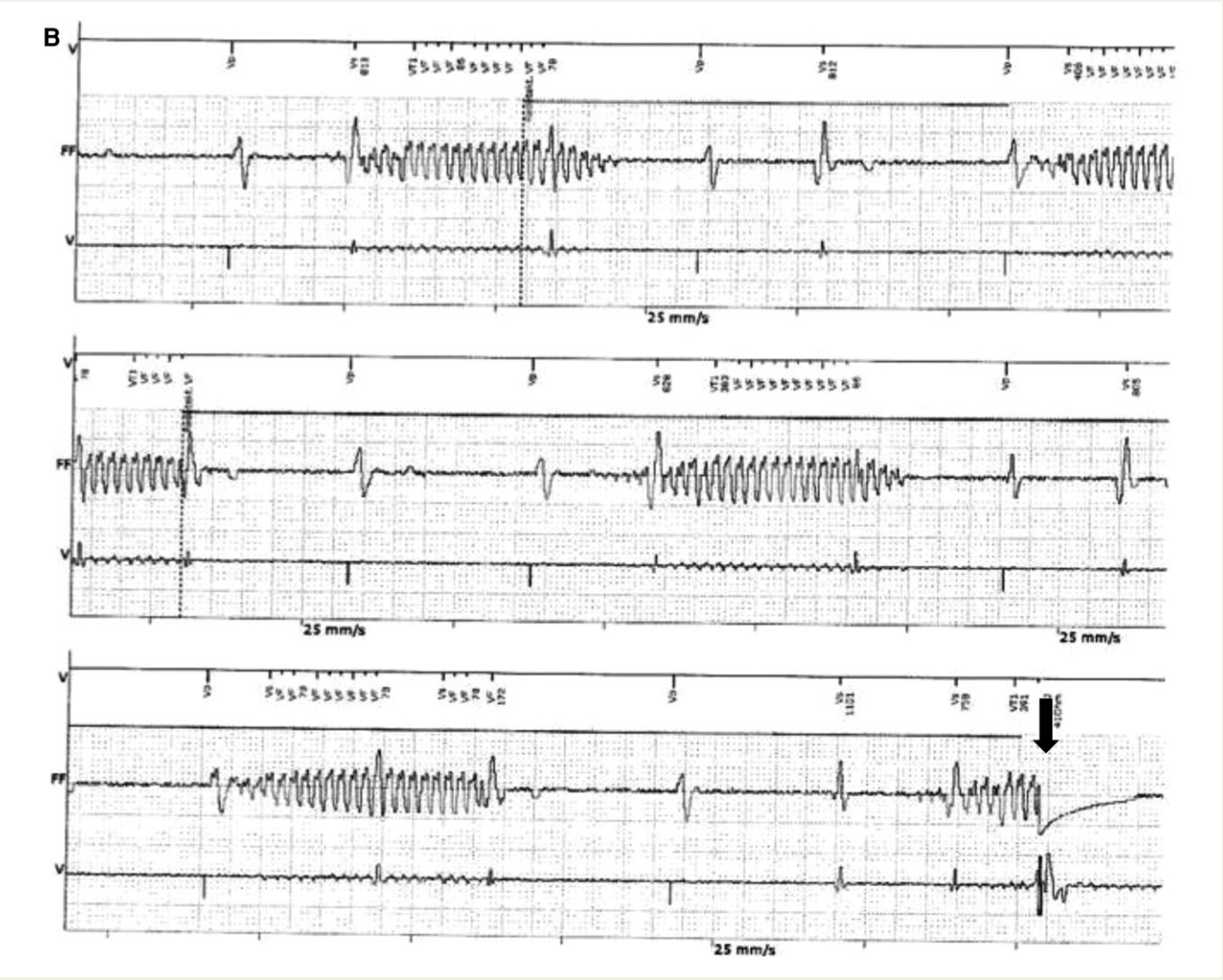

Figure 1 (*B*) Ventricular oversensing in a 69-year-old VVI-ICD patient with ischaemic cardiomyopathy during TENS: electrical bursts result in the inhibition of ventricular pacing and detection of VF leading to shock therapy (arrow).

literature review including case reports, observational studies, and randomized trials published until 30 June 2021 and to weigh the strength of evidence for or against a particular procedure based on these published trials and/or on expert opinion. In controversial areas, a consensus was achieved by agreement of the expert panel after detailed discussions. Technical features from manufacturers published in the literature or operating manuals were also taken into account.

Categories of the consensus document were used according to the Colour Heart (*Table 1*).

Overview of signals causing electrical interference

Multiple sources of interference exist in the hospital environment. Potential-associated risks depend on patients' characteristics, the intervention, and the CIED used. Both EMFs and radiation can affect CIED function.[5] Details on possible effects and incidence are listed in *Table 2*.

Cardiac implantable electronic device responses to interference

Oversensing by EMI can result in a variety of CIED behaviours: in pacing systems, oversensing of noise on the atrial channel will result in triggered ventricular pacing or inappropriate detection of atrial high-rate events and mode switching. Oversensing in the ventricular channel will be interpreted as intrinsic R-waves and typically result in the inhibition of ventricular pacing, which may cause asystole and syncope in PM-dependent patients (*Figure 1A*). In an ICD, oversensing on the ventricular channel will not only cause ventricular pacing inhibition but is also likely to result in shock therapy for ventricular fibrillation (VF), if it lasts long enough (*Figure 1B*).

Whereas transient EMI can temporarily modify CIED function, longer and repeated episodes are able to change the setting of the device to a programming that does not resolve spontaneously after EMI discontinuation. This behaviour may result in a 'backup mode', 'reset mode', or 'power on reset', which can make reprogramming the device necessary.

Table 1 Categories used in the document according to the color heart table.

Consensus statement	Definition	Symbol
Indicated or 'should do this'	Scientific evidence that a treatment or procedure is beneficial and effective, or is strongly supported by authors' consensus	
May be used	General agreement and/or scientific evidence favour the usefulness/efficacy of a treatment or procedure	
Should not be used	Scientific evidence or general agreement not to use or recommend a treatment or procedure	

The categorization for our consensus document should not be considered directly similar to the one used for official society guideline recommendations which apply a classification (I–III) and level of evidence (A, B, and C) to recommendations.

In ILR, electrocautery, radiation, and MRI do not change programmed parameters, sensing fidelity, or battery parameters but may cause artefacts in stored electrocardiograms (*Table 3*).[6]

Evaluation of cardiac implantable electronic device patients

Pre-procedural evaluation

Proper planning of the procedure is essential to ensure CIED patient safety and that the procedure runs smoothly. The following points need to be addressed (*Table 4*).

Details about device type, manufacturer, battery status, and CIED settings need to be determined prior to the intervention. If medical records or a device card are not available, a chest X-ray is very helpful and can determine the type of device (appendix; Figures 7 and 8) and whether there are any abandoned leads. Alternatively, an algorithm[11] and two systems based on artificial intelligence, available as an App ('Pacemaker-ID')[12,13] or as a web-based platform,[13] have been shown to yield accuracies of 85, 89, and 71%, respectively, to identify the device manufacturer, based upon chest X-ray.[14]

Table 2 Signals causing interference with CIED: possible effects and considerations

Signal type	Common sources	Possible effects	Incidence	Specific considerations
Electromagnetic fields	Electrocautery	D, O, R, I	H	Effect depends on field strength as well as distance to the generator and leads
	Radiofrequency catheter ablation for cardiac arrhythmias	D, O, I	H	
	Non-cardiac radiofrequency ablation	O, I	M	
	Radiofrequency identification devices	O, I	L	
	Electrical stimulation therapy (TENS, EMS, SCS)	O, I	H	
	Therapeutic diathermy	O, I	L	
Therapeutic ionizing radiation	Gamma rays	D, O, R, I, sudden battery depletion	L	Effect depends on accumulated radiation dose on the generator and specifically neutron contamination
	Photon beam		M	
	Proton beam		H	
	Carbon ion		L	
Acoustic waves	Lithotripsy	D, O, I	L	Shockwave may cause mechanical derangement
Miscellanea	Electrical cardioversion or defibrillation	R, D	M	
	Electroconvulsive therapy	I	M	
	Tissue expanders employing magnets	I	L	Effect depends on location with respect to CIED
	Electromyograms	O	L	Effect depends on location with respect to CIED
Multiple signals	Magnetic resonance imaging (MRI)	D, O, R, I, sudden battery depletion	H	Effect depends on MRI conditionality and programming of device

D, direct damage to the device/leads; O, oversensing; R, reset of pulse generator; I, inappropriate pacing or anti-tachycardia ICD therapy; H, high incidence (>1/10); M, moderate incidence (around 1/100); L, low incidence (<1/1000); EMS, electrical muscle stimulation; MRI, magnetic resonance imaging; SCS, spinal cord stimulation; TENS, transcutaneous electrical nerve stimulation.

Table 3 Possible effects of EMI on PM, ICD, and ILR

Pacemakers (PM)	Effect (T/P)
Pacing inhibition in the ipsilateral chamber (e.g. ventricular pacing inhibition due to oversensing on the ventricular channel)	T
Cross-chamber pacing in the contralateral chamber (e.g. ventricular pacing due to oversensing on the atrial channel)	T
Alteration of rate responsive behaviours (e.g. activation of CIED sensor by monitoring equipment)[7,8]	T
Asynchronous pacing, loss of AV (atrioventricular) synchrony in dual-chamber devices, e.g. due to noise reversion mode	T
Inappropriate automatic mode switching or atrial anti-tachycardia pacing due to oversensing in the atrial channel	T
Modification of measured pacing/sensing thresholds	T
Run-away PM (PM-induced tachycardia as a result of EMI)	P
Power on reset and backup mode	P
Implantable defibrillators (ICD)	**Effect (T/P)**
Modified anti-bradycardia function (as in PM above)	T
Inappropriate shocks or anti-tachycardia pacing, if oversensing in the ventricular channel occurs due to EMI	T
Long–short–long sequence pacing or inappropriate pacing related pro-arrhythmia	T
Truncation of pacing output when EMI is sensed on the defibrillation circuits[9]	P
Sudden battery depletion	P
Implantable loop recorders (ILR)	**Effect (T/P)**
Artefacts mimicking tachyarrhythmias[10]	T

P, permanent effect on CIED; T, transient effect on CIED.

Table 4 Checklist before the procedure

Understanding of the planned procedure (e.g. target zone of radiotherapy, indication, and anatomic location of surgical procedure, prone patient position during intervention, etc.)	✓
Identification of device (CIED type, manufacturer, battery status, settings, etc.)	✓
Evaluation of PM-dependency	✓
Risk stratification for periprocedural (ventricular) arrhythmias	✓
Estimation of likelihood of electromagnetic (or other) interference	✓
Determination of needs and means of CIED function (i.e. magnet application vs. reprogramming)	✓

For ILR, no specific measures are needed, except for retrieval of stored electrograms, as these might be overwritten by artefacts during the procedure.

Pacing dependency

Pacing dependency is defined as the absence of intrinsic escape rhythm or a low heart rate (usually <50 bpm) causing symptoms related to bradycardia that may result from sinus arrest or atrioventricular (AV) block.[15,16] While this can be deduced from the patient's medical history such as previous AV junction ablation procedure and near 100% pacing burden from previous CIED interrogation reports, it can only be confirmed with a careful CIED follow-up. Indeed, high pacing burden may simply reflect device programming such as high base rate pacing or short AV delay in a dual-chamber or CRT system. Conversely, patients who show a consistent intrinsic AV rhythm >50 bpm on an ECG are not pacing-dependent. However, the presence of intrinsic rhythm during testing does not provide any guarantee that this is a stable phenomenon, especially during anaesthesia.

Taken together, even in an apparent non-pacing-dependent patient undergoing a medical procedure at high risk of EMI, continuous rhythm monitoring must be provided.

Risk stratification for perioperative ventricular arrhythmias

Evaluation of risk for ventricular arrhythmia depends on the patient's history and underlying cardiac disease, indication for CIED implantation, and history of recent (last 6 months) sustained ventricular arrhythmias or ICD therapies. Surgery stimulates stress responses with the autonomic imbalance and may result in electrolyte disorders, fluid shifts, and increased myocardial oxygen demand. These factors increase ventricular arrhythmia risk in patients affected by structural heart disease and channelopathies. In contrast, anaesthetic neuraxial techniques, adequate antiarrhythmic therapy, and post-operative pain management may reduce arrhythmic burden.[17,18]

Post-procedural evaluation

At the end of the procedure, a report needs to be generated including relevant CIED or arrhythmic events [e.g. evidence of device dysfunction, presence of arrhythmias, electrical cardioversion (ECV), etc.]. In procedures that carry a risk of EMI or device damage, or if device dysfunction was observed, a full CIED follow-up needs to be performed immediately after the procedure, including testing of leads and battery, detection of arrhythmias/interferences, delivery of ICD therapy, and evaluation of the programmed parameters. Electrical reset of the device is possible (although very rare) and needs to be ruled out as well.[19–21]

Patients with peri-procedurally inactivated ICD therapy should be monitored until device check and reprogramming. Further follow-ups should be evaluated on a case-to-case basis. Remote monitoring is useful to provide timely alerts of device dysfunction (Tables 5).[21,22]

Table 5 Post-procedural checklist for CIED patients undergoing procedures at high risk of EMI or device damage

Check if there was a change in programming prior to or during the surgical or diagnostic procedure	✓
Evaluate symptoms attributable to device malfunction after a surgical or diagnostic procedure (mainly when surgery was performed with unipolar surgery close to the device or if electrical cardioversion was performed)	✓
Check device (programming, telemetry, thresholds, battery status, alerts, EGMs)	✓
Reprogramme to pre-procedural settings, if necessary	✓
Reactivate ICD tachyarrhythmia detection and therapy as soon as possible.	✓
In patients with devices undergoing remote monitoring parameters, device status and EGMs can be checked by telemonitoring	✓

Pre-procedural evaluation of CIED patients

A full understanding of the planned procedure is required, the device should be identified, battery status and CIED settings documented, PM-dependency and risk for periprocedural ventricular arrhythmias evaluated, the likelihood of electromagnetic (or other) interference estimated, and the needs and means (i.e. magnet application vs. reprogramming) of CIED function determined

Post-procedural evaluation of CIED patients

In procedures that carry a risk of EMI or device damage, or if signs for device dysfunction were observed intraoperatively, a CIED follow-up needs to be performed as soon as possible after the procedure

Procedures

Surgery

Practical advice and personnel

Reliable ECG monitoring is mandatory in any CIED patient undergoing a surgical procedure using electrocautery. Members of the involved personnel should be aware that there may be difficulties in identifying paced complexes on the monitoring equipment due to bipolar pacing or low-amplitude signals of the selected ECG lead. Digital monitors may remove high-frequency signals which include PM spikes unless options that display pacing spikes are enabled in the setup. This accentuation scheme occasionally marks artefacts as pacing spikes. Electrocautery may further render the ECG uninterpretable when it is applied. Thus, ECG monitors should be optimized for CIED patients (i.e. settings to visualize pacing spikes and paced as well as intrinsic beats) before surgery. It is furthermore vital to monitor the peripheral pulse, whether by contour display pulse oximetry or arterial waveforms, and prevent confusion with ECG artefacts.[23]

Defibrillation pads should be applied >15 cm away from the pulse generator for backup pacing/defibrillation (ideally in an anteroposterior position) to avoid damage of the CIED.[24] Also, electrosurgery grounding pads should be placed >15 cm away for CIED. A magnet (≥10 G) should be readily available at all times for all CIED patients. A second or stronger magnet may be required to close the reed switch in obese individuals or deeper implants.

Ideally, CIED-trained personnel and programmer should be available onsite, as changes in a patient's condition during a procedure may require reprogramming (e.g. requirement to accelerate pacing rate in an ICD patient in whom magnet application only results in inactivation of anti-tachycardia therapy).

Electromagnetic interference with electrocautery

The principal risk of CIED patients undergoing surgery is EMI due to electrocautery, which may result in the inhibition of pacing, noise reversion mode (with asynchronous pacing), and inappropriate ICD therapy due to oversensing. The incidence of adverse events occurring during surgery is most likely under-reported, and may even go unnoticed (e.g. inappropriate shocks in a patient under myorelaxants). The intraoperative risk of inference increases with closer proximity to the CIED, specifically to the leads, and with the mode of electrocautery (uni- or bipolar, coagulation/high voltage vs. cutting/low voltage).

Previous recommendations of the American Society of Anesthesiologists state that inactivation of ICD therapy is not necessary, if surgery is conducted with unipolar electrocautery below the umbilicus.[23,25] However, this may not be the case if the return electrode is placed close to the device,[19,26] or if a full-body return electrode pad is used (e.g. Megadyne™ pads), as inappropriate ICD shocks have been described in these instances.[26–28] In a prospective multicentre observational study including 331 CIED patients undergoing surgery, reprogramming was only performed in ICD patients and in PM-dependent patients, if surgery was performed <15 cm from the generator.[19] Magnet application was used in ICD patients with procedures above the iliac crest, while no reprogramming or magnet application was applied in PM patients (including those who were pacing-dependent) or in ICD patients with interventions below the iliac crest. Indeed, EMI was detected in 18 of 40 (45%) patients with thoracic procedures, but in none of the 143 patients with procedures below the iliac crest and none of the patients experienced an electrical reset of their CIED. Therefore, surgery below the iliac crest with a return electrode placed on the thigh may be performed safely without magnet application or reprogramming.

Intermittent application of electrocautery may also lower the risk of EMI. Nevertheless, inappropriate ICD shocks despite burst application of unipolar electrocautery have been reported due to insufficient clearing of the tachycardia counters between applications.[29] Thus, bipolar electrocautery[30] or ultrasonic scalpels should be preferred, if possible, to reduce the risk of EMI.

Finally, systematic device follow-ups after surgery are only mandatory if CIED malfunction is suspected, if significant exposure to EMI

Table 6 Magnet response with PM (modified from Jacob et al.[11])

Manufacturer	Default response[a]	Remarks
Abbott	DOO/VOO/AOO 100 bpm	Can be programmed to 'OFF'; if AutoCapture is enabled the device will go to high output mode for the duration of magnet placement
Biotronik	'AUTO' mode: DOO/VOO/AOO 90 bpm for 10 beats, then back to programmed mode	Can also be programmed to 'ASYNC' with continued DOO/VOO pacing at 90 bpm (also during standard device interrogation), or to 'SYNC' (with continued programmed pacing at lower rate limit) mode
Boston Scientific	DOO/VOO/AOO 100 bpm	Can be programmed 'OFF' and 'store EGM' with storage of electrograms and no change in pacing
Medtronic	DOO/VOO/AOO 85 bpm	No magnet response for Micra© leadless PM; for older devices (e.g. Adapta©, Sensia©); magnet application is ignored within 1 h of device interrogation, unless data are manually erased at the end of the session
Microport/Sorin	DOO/VOO/AOO 96 bpm	Can be programmed 'OFF'

[a]Magnet rate is lower than the indicated values in case of battery depletion.

occurred, or to reprogramme device settings that had been changed for the procedure.

Intraoperative use of magnets

Magnet application with ≥10 G field strength will result in a magnet response, when aligned with the reed switch/Hall sensor (*Tables 6* and *7*). Of note, magnets provided by CIED manufacturers are usually of >80 G field strength. The site of magnet placement is important[11] and some devices may require a more eccentric application of the magnet regarding the generator casing in order to optimize field alignment. Magnet response in PM and ICD is summarized in *Tables 6* and *7*.

In PM, the application of a magnet leads to asynchronous pacing (AOO, VOO, or DOO mode) at the magnet rate (*Tables 6* and *7*). Of note, in Biotronik PM models, magnet response is only active for 10 beats, and the device reverts to normal synchronous pacing immediately afterwards (Auto-Mode). This requires repeated perioperative application of the magnet to avoid interference. Alternatively, the magnet response can also be programmed asynchronously (Async). However, with this programming, the magnet mode will also be continuously active during routine device interrogation, which is not optimal for follow-up. Older Medtronic devices (pre Advisa®/Astra®/Azure® series) suspend magnet detection for 60 min after removal of the programming head, rendering the application of a magnet shortly after programming useless (unless data are manually erased at the end of the session). Finally, Medtronic Micra® leadless PMs do not have any magnet response.

Asynchronous pacing might cause stimulation in the vulnerable phase and result in ventricular pro-arrhythmia. Therefore, patients need to be monitored during magnet application or operation in an asynchronous mode and emergency equipment including an external defibrillator with transcutaneous pacing capabilities needs to be readily available.

In ICD, magnet application will only disable detection of tachyarrhythmias (and thereby antitachycardia therapy) without affecting pacing mode (except for some Microport/Sorin ICD; *Tables 6* and *7*). Therefore, device reprogramming is necessary for PM-dependent ICD patients. It is important to be aware of the response (i.e. transient audible tone) which results from effective magnet application. Some devices (Biotronik, Abbott, and recent Microport/Sorin ICD) do not emit any indication of a magnet response, and it may be preferable to reprogramme the device in these instances.

Application of magnets on the ICD for procedures using electrocautery more than 15 cm from the device simplifies workflow and has been shown to be safe with a significantly shorter duration of inactivated ICD therapy compared with device reprogramming in a single randomized study.[31] However, magnet placement may not be adequate in some procedures, specifically if prone or lateral positioning is needed for surgery. Thus, CIED reprogramming should be performed before the procedure starts and remain effective during the entire procedure if the device is located close to the operative field (<15 cm) or if a magnet cannot be securely affixed in a satisfactory position.

Other interferences and risks with surgery

Unipolar electrocautery in the vicinity of the generator may rarely cause damage to the circuitry or result in an electrical reset. External monitoring of respiratory rate may furthermore interfere with CIED and cause rapid pacing in devices with a minute-ventilation sensor.[7,32] Likewise, closed-loop stimulation rate response sensors in Biotronik PM and ICD react to ventricular contractility (and indirectly to mental stress). Therefore, inadequate pacing rates may be observed during interventions,[33] although there are no reports to date of issues with this feature in the perioperative period. Mobilization of the patient may also cause rapid pacing in devices with accelerometers and rapid pacing may be interpreted as ventricular tachycardia. It may therefore be advisable to inactivate rate response during or after surgery, if an inappropriate rate response is observed.

Table 7 Magnet response with implantable cardioverters (ICD) (modified from Jacob *et al.*[11])

Manufacturer	Signal	Default brady mode	Default tachy mode[a]	Remarks
Abbott	None	No change	Detection and therapy off	Can be programmed to 'OFF'
Biotronik	None	No change	Detection off	Since Lumax series: effect lasts for 8 h only even if magnet is still in place
Boston Scientific (including S-ICD)	Acoustic signal	No change	Therapy off	Can be programmed to 'OFF'
Medtronic	Acoustic signal	No change	Detection and therapy off	
Microport/Sorin	None	DOO/VOO/AOO 96 bpm without rate response or mode switch; max. pacing output	Detection off	For Platinium© devices, the magnet rate is not enabled

[a]Inactivation of detection will automatically result in no therapies being delivered

Intraoperative monitoring of somatosensory-evoked potentials (SSEPs) emits signals, which may be sensed by the PM/ICD and cause interference. This specific effect may be remedied by reducing the frequency and power of the signals.[33] Radiofrequency scanning to check for retained surgical sponges may also emit EMI, but this has only been reported to cause interference with temporary PM.[34,35]

Guidewires or catheters in close contact with CIED leads may rarely cause mechanical interference resulting in pacing inhibition, inappropriate shocks[36], or lead dislodgement. Lead dislodgement may also result from cannulation for cardiac surgery or mobilization of the heart during cardiac or thoracic surgery. Sternotomy may cause damage to subcutaneous ICD (S-ICD) leads. Finally, defibrillation thresholds may increase in thoracic surgery procedures in case of a pneumothorax.

Suggested protocols for perioperative cardiac implantable electronic device management

The incidence of EMI during electrocautery depends on strength, polarity, and distance of EMI to the device, as well as CIED type (ICD, PM, or ILR) and configuration (e.g. unipolar or bipolar leads, sensing thresholds, and filters). In large prospective registries, no cases of permanent device damage, inappropriate device therapies, or clinical emergencies were observed if specific management protocols were established and followed.[19,30] Specifically, bipolar electrocautery rarely leads to EMI and should be preferred. If unipolar cautery is chosen, grounding needs to be installed contralaterally and as distant as possible from the CIED to keep the EMF away from the device.[31] Full-body return electrodes (e.g. Megadyne™ pads) should be imperatively avoided.

In ICD patients and PM-dependent patients with surgery within 15 cm of the generator, CIED should be reprogrammed as magnet application may be difficult due to proximity to the operating field.[19,31] Reliable ECG monitoring should be continued after reprogramming until adequate CIED function is confirmed by CIED-trained personnel. There seems to be very limited risk of EMI with surgery performed at or below the iliac crest.[19] However, in the interest of simplicity and patient safety, the panel advises routinely applying a magnet in ICD patients and in PM-dependent patients. Since the magnet does not influence antibradycardia function in ICD, reprogramming of the device is the only option in these patients, if they are PM-dependent. A magnet should be secured on the device in all other ICD patients and in case of asystole or haemodynamically relevant bradycardia during surgery in non-pacing-dependent PM patients.

Perioperative CIED management algorithms are shown in *Figure 2*.

Magnetic resonance imaging

Risks and consequences of magnetic resonance imaging

Magnetic resonance imaging has its precise indications for the diagnosis and follow-up of different pathologies. It is estimated that 50–75% of patients with CIED will need to undergo MRI during the lifetime of their device.[37] The possible consequences of interference created during MRI on CIED are described in *Table 8*. The most frequently observed transient device malfunction is oversensing (see the Overview of signals causing electrical interference section).

Most observational studies report no or only rare, but significant changes in electrical parameters. The most common notable changes

Table 8 Possible consequences of the magnetic fields of MRI in CIED

Change of stimulation mode producing asynchronous stimulation (rarely results in haemodynamic consequences)
Triggering of atrial or ventricular arrhythmias by delivery of stimuli in the vulnerable phase of the atrium or ventricle
Torque inside the pocket of the device; sensation of vibration (rare)
Heating of cardiac tissue adjacent to lead electrodes and modification of pacing/sensing thresholds
PM reprogramming, reset, or (transient) signs of battery depletion
Over- and undersensing
Reactivation of anti-tachycardia therapy due to electrical reset

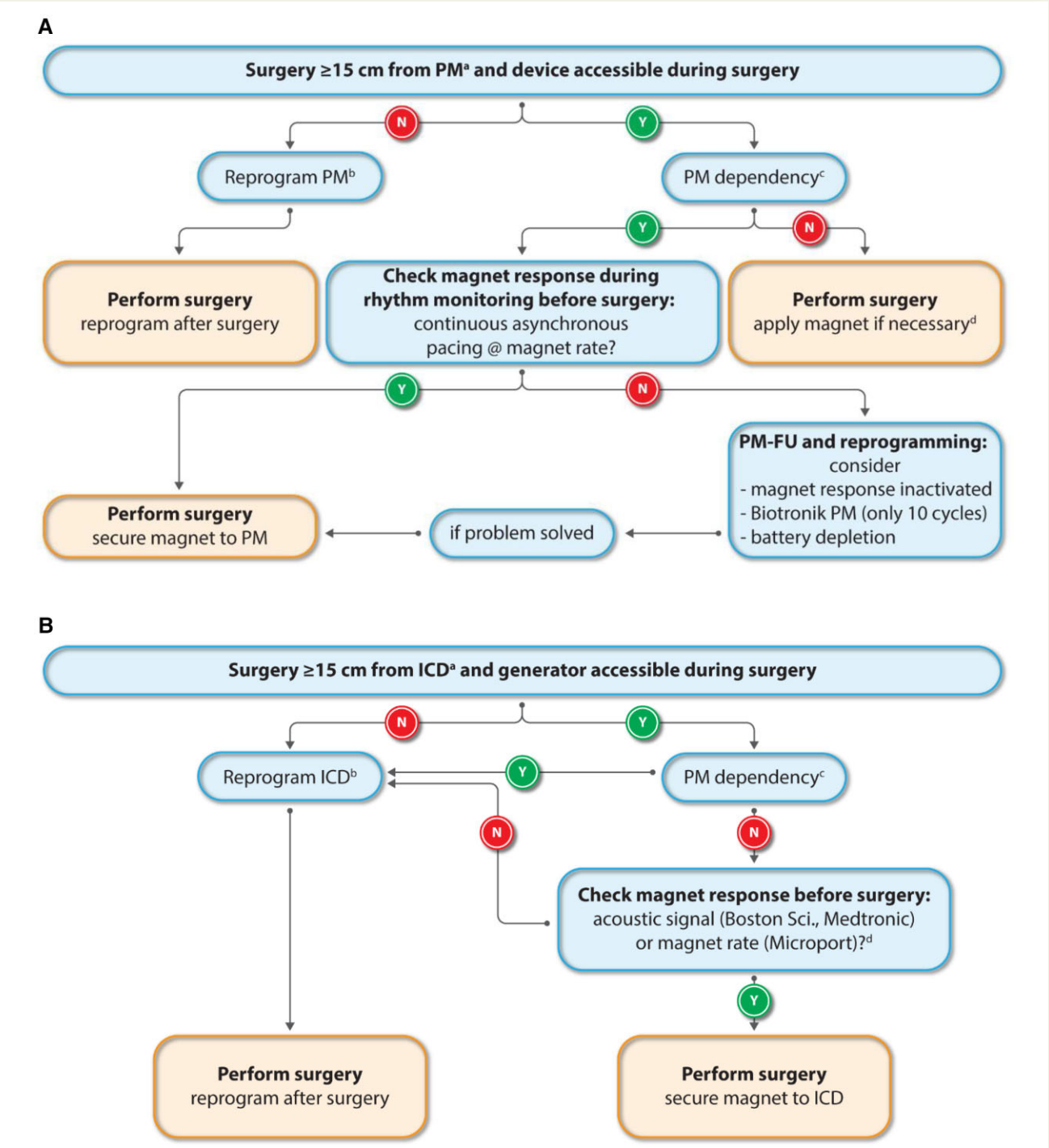

Figure 2 (*A*) Algorithm for perioperative management of PM (including CRT-P) during surgery: [a]reprogramming/magnet application is optional, if surgery is performed below the iliac crest and no full-body return electrodes are used; [b]asynchronous mode (D00/V00/A00); rate response may be inactivated to avoid rapid pacing with patient mobilization or respiratory monitoring (if the PM has a minute-ventilation sensor); [c]absence of intrinsic escape rhythm or heart rate <50 bpm causing symptoms; [d]asystole or haemodynamically relevant bradycardia during electrocautery. (*B*) Algorithm for perioperative management of ICD including CRT-D during surgery: [a]reprogramming/magnet application is optional, if surgery is performed below the iliac crest and no full-body return electrodes are used; [b]asynchronous mode and inactivation of tachycardia detection and/or therapy; rate response may be inactivated to avoid rapid pacing with patient mobilization or respiratory monitoring (if the PM has a minute-ventilation sensor); [c]absence of intrinsic escape rhythm or heart rate <50 bpm causing symptoms; [d]Boston Sci, Medtronic: acoustic signal; Abbott: acoustic from Galant series (none for older ICD); Microport/Sorin: pacing at 96 bpm in programmed mode; Biotronik: no magnet response.

from baseline are decreases in P-wave amplitude (4% of patients), as well as increases in atrial (4%), right ventricular (4%), and ventricular capture thresholds (3%).[20,38–42]

Intraoperative management of PM and ICD

Reliable ECG monitoring is mandatory in any CIED patient undergoing a surgical procedure including electrocautery	
Monitoring of peripheral pulse by pulse oximetry or arterial waveforms should be performed additionally to ECG monitoring in any CIED patient undergoing a surgical procedure including electrocautery	
Bipolar rather than unipolar electrocautery[30] or ultrasonic scalpels should be used, if possible, the return pad positioned as far as possible from the CIED and cautery should be applied as short bursts to reduce the risk of EMI	
Intraoperative use of magnets for PM should be favoured if possible (device accessible during the procedure, adequate magnet response during rhythm monitoring before surgery) and when required to avoid EMI, to simplify workflow, and shorten the duration of asynchronous pacing	
ICD reprogramming is required in PM-dependent patients, if the operative field is <15 cm from the device, or if the device is not accessible during the procedure	
It is advisable to secure a magnet over all ICD which are not reprogrammed, during electrocautery, if EMI is likely	
CIED-trained personnel and programmers are encouraged to be available on the hospital/clinic premises to reprogram ICD if a magnet is used, as changes in a patient's condition during a procedure may require reprogramming of pacing parameters	
It is advisable to reprogramme all ICD in PM-dependent patients and systems, which do not emit an indication of magnet response	
Full-body return electrodes should be avoided for surgery in CIED patients (unless the device is programmed appropriately before the procedure)	

Between the late 1980s and 2001, few deaths were reported in CIED patients undergoing MRI. However, these fatalities were poorly characterized and no electrocardiographic data are available.[43,44] Worldwide, no deaths have been reported in CIED patients during physician-supervised MRI procedures in the last 2 decades.[20] Importantly, most of the above-mentioned evidence comes from reports involving legacy PM, most likely not in use anymore. Reports including more recent devices found no functional issues in most PM or ICD exposed to prolonged MRI scans.[44] Most of the available evidence does not include patients with abandoned leads, devices implanted in non-thoracic areas, and those approaching battery depletion, and in most of the studies, 1.5 T MRI scans were used.

According to the recently published ESC guidelines on cardiac pacing and CRT,[45] indications for MRI should be strongly reconsidered in the presence of surgical epicardial or connected fractured leads or in the case of lead adapters or extenders. There is a potential threat that abandoned leads may act as 'antennas' with significant tissue heating.[46] However, recent studies have shown no adverse events [47–49] and therefore MRI (1.5 T; SAR 1.5 W/kg) may be performed in this setting, if the benefits of the exam outweigh its risks.

Requirements for equipment and staff performing magnetic resonance imaging in cardiac implantable electronic device patients

Magnetic resonance imaging in patients with CIED should only be performed in centres with appropriate teams, protocols, and equipment. Collaborative relationships between radiologists, physicists, cardiologists, and allied health staff members are essential for safe outcomes. Protocols primarily depend on the indication of the scan and MRI conditionality of the CIED.

Personnel

Cardiac implantable electronic device–trained personnel (i.e. cardiologists and allied health professionals) are necessary to provide appropriate care for CIED patients before and after MRI scans. The panel advises to complete the checklist confirming indication, check PM-dependency, MRI conditionality of the device, presence of abandoned leads, and obtain consent. Cardiac implantable electronic device–trained personnel are responsible for interrogating device function and to programme appropriately for the scan. Magnetic resonance imaging technologists are responsible for performing the scan (number and the length of scan sequences) with additional input from MRI physicists. It is imperative that personnel are trained in basic life support and in addition able to provide transcutaneous pacing in case of MRI scans in non-conditional CIED in PM-dependent patients. Additionally, an MRI radiologist should be available to address the need for additional image sequences. In the event of cardiac resuscitation, the teams should have access to cardiologists and emergency teams for further management (see the Emergency section).

It is advised to use tools such as a checklist (*Table 9*) as a standard to ensure proper management and that CIED parameters are reprogrammed after the scan.

Equipment

Essential equipment for safe procedures in the imaging room includes MRI-compatible ECG systems and photoplethysmography transducers. The information from the ECG monitors and photoplethysmographs must be displayed so that these are visible to all team members. Zone 3, which is outside the MRI scanning room, should be equipped with an automatic external defibrillator capable of providing transcutaneous pacing, and resuscitation equipment. A code cart should be available on the hospital/clinic premises in the case of MRI scans in non-conditional CIED. In the event of an emergency, the patient should be transferred to Zone 3, where magnet application, cardiopulmonary resuscitation, external pacing, and defibrillation can be performed. In addition, communication systems

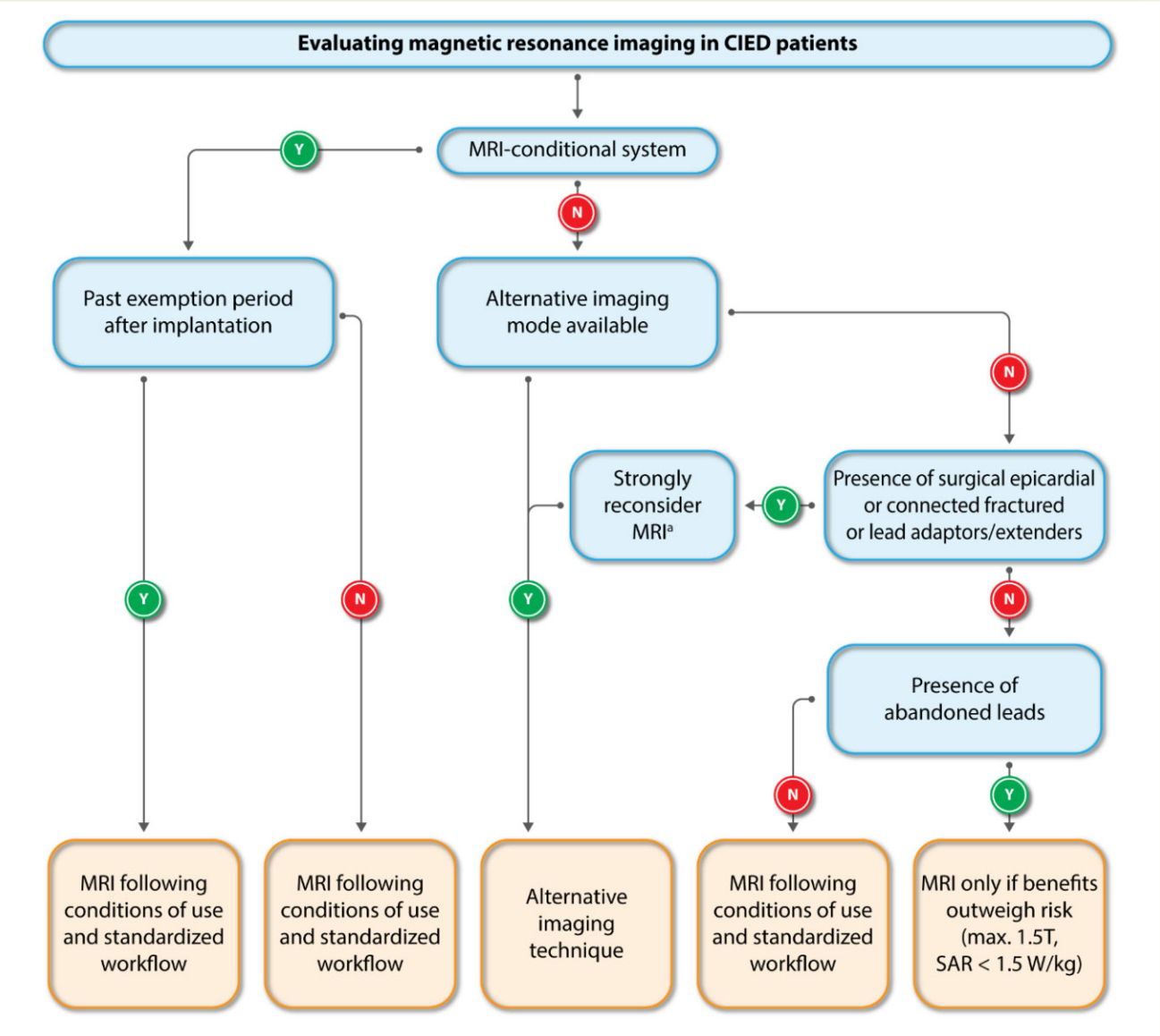

Figure 3 Flowchart for evaluating magnetic resonance imaging in CIED patients. MRI, magnetic resonance imaging; SAR, specific absorption rate. [a]Consider only if there is no imaging alternative and the result of the test is crucial for applying life-saving therapies for the patient. Adapted from the 2021 ESC guidelines on cardiac pacing and CRT.[45]

with the patient should be available to enable to convey any concerning symptoms.

Management in magnetic resonance imaging–conditional devices

Magnetic resonance imaging–conditional CIED have modifications intended to minimize the content of ferromagnetic material in the system and to reduce the potential for EMI, current induction, and heating.[50]

No device has been labelled completely MRI-safe by American or European regulation authorities. Conditions have been defined according to their use in the MRI environment. When used in a specific MRI environment in accordance with the imposed conditions, these MRI-conditional devices do not pose any specific risk to the patient.[51,52] For every patient, it must be determined whether the CIED system meets MRI conditionality. In general, these are systems consisting of the device and leads from the same manufacturer and labelled MRI-conditional. The CIED's approved magnetic field strengths and SARs for scanning should be identified (most of the MRI-conditional systems are approved for 1.5 T scans, most recent systems are approved for 3 T scanning). All device models and leads should be checked for MRI compatibility before scanning is performed. These can be identified by model name, number, and manufacturer at http://www.MRIsafety.com or https://mri.merlin.net/ (Abbott/St Jude Medical), https://www.promricheck.com (Biotronik), https://www.bostonscientific.com/imageready (Boston Scientific), http://www.MRIsurescan.com (Medtronic), https://www.crm.microport.com/automri/ (Microport/Sorin).

Table 9 Checklist for institutional workflow

Pre-scan check	
>6 weeks post-implant?	✓
MRI-conditional PM or ICD system?	✓
Are there other active non-conditional leads *in situ*?	✓
Are there abandoned leads, lead connectors/extenders, or surgical epicardial leads *in situ*?	✓
Is the patient undergoing MRI PM-dependent?	✓
Are there personnel able to perform CPR and a code cart present during the MRI exam?	✓
Is there an external defibrillator with transcutaneous pacing capabilities in the MRI suite?	✓
Are there CIED-trained personnel available to perform a full device interrogation prior and immediately after MR scan?	✓
Document pre-scan programme states and values	✓
Document battery status, pacing threshold, sensing, and lead impedance	✓
Is the device programmed to 'MRI mode'?	✓
- Asynchronous mode (D00/V00/A00)	✓
- Inhibited mode (DDI/VVI/AAI)	✓
- Inactive mode (0D0/0V0/0A0/000)	✓
- Bipolar pacing and sensing	✓
- Magnet response inactivated	✓
- Anti-tachycardia therapy inactivated	✓
- Advanced features inactivated (e.g. CRT ventricular sense response)	✓
During the scan	
ECG, blood pressure, pulse oximetry monitoring	✓
After scan check	
Re-interrogate device and check lead parameters	✓
Is the 'MRI mode' deactivated?	✓
Are original settings reprogrammed?	✓
Remote monitoring (RM) should be encouraged especially in non-MRI-conditional systems and in case of high-risk features	✓

Finally, all MRI-conditional generators contain a dedicated MRI programming mode which can be activated before and inactivated after a scan. 'MRI-mode' activation results in system integrity checks, asynchronous pacing for pacing-dependent patients or non-sensing or inhibited modes for non-pacing-dependent patients, disabling of tachycardia detection, inactivation of magnet mode and of advanced features (e.g. ventricular sensed response of CRT devices), increased pacing output, and restoration of pre-scan parameters.

So far, although 'mixed' CIED systems combining MRI-conditional components of different manufacturers have been used without adverse effects,[51] they are not labelled as being MRI-conditional. An MRI mode should be programmed and CIED-trained personnel on-site is not obligatory, but otherwise, these systems should be managed in the same manner as non-MRI-conditional ones.

The MRI mode needs to be activated as closely as possible to the MRI facility and adequate monitoring should be ensured during 'MRI mode', especially in ICD patients. Recent devices from several manufacturers can be programmed to an automatic activation of the MRI mode (AutoMRI©; Microport/Sorin, MRI AutoDetect©; Biotronik). After CIED interrogation and programming, an MRI mode is activated during the MRI scan and automatically reverts to usual settings after the scan. This feature significantly facilitates workflow and makes the second follow-up after the scan unnecessary.

Magnetic resonance imaging may be performed without the presence on the premises of a cardiologist or CIED-trained personnel, in a patient with an MRI-conditional system with adhesion to product labelling, if this is in accordance with institutional policy (which should stipulate that a cardiologist with proficiency in device programming is at least on call) and if appropriate programming is performed before and after the MRI scan.

Management in non-magnetic resonance imaging–conditional devices

Definition

Common examples of non-conditional CIED systems are legacy systems or MRI-conditional generators combined with MRI-conditional leads from other manufacturers or non-MRI-conditional leads, and the presence of abandoned, fractured, or surgical epicardial leads, as well as lead adapters/extenders.

General considerations

In a large registry including non-MRI-conditional PM and ICD patients undergoing 1.5 T scans, lead or device failures were not observed if patients had been appropriately screened and programmed before the procedure.[41] Considering the absence of randomized trials, the recently published ESC guidelines on cardiac pacing and CRT, therefore, state that MRI should be performed in non-MRI-conditional devices, if no alternative imaging mode is available and if no epicardial leads, abandoned or damaged leads, or lead adaptors/extenders are present.[45] There is evidence from small series that MRI can even be safely performed in patients with surgical epicardial, abandoned or damaged leads, or lead adaptors/extenders.[47,49] Evidence of safety of >1.5 T MRI scans in non-MRI-conditional CIED is reported in only 107 patients from 4 studies, so MRI scans should be limited if possible to 1.5 T.[20] Thus, taking certain precautions, most patients with MRI non-conditional CIED implants may undergo well-indicated MRI. The presence of an ICD generator or PM-dependency places these patients at increased risk that should also be taken into account and be discussed with the patient. Conversely, the panel does not advise to remove abandoned leads solely to be able to perform an MRI scan as the risk of extraction outweighs that of the scan based on current evidence.[48,53]

Historically, patients who underwent implantation within the last 6 weeks were not included in the studies assessing the safety of MRI. However, no relation between lead failure and time from implantation was discovered early after implantation in a small observational study[54] and the MagnaSafe registry.[41] Accordingly, the 2021 ESC guidelines on cardiac pacing and CRT state that MRI should be considered despite the exemption period.[45]

In patients with non-MRI-conditional CIED, who undergo MRI scan, pulse oximetry ± ECG should be monitored and personnel

with the ability to perform cardiopulmonary resuscitation and transcutaneous pacing should be available onsite during the scan. Cardiac implantable electronic device–trained personnel should be readily available on the hospital/clinic premises and should be present onsite during the MRI examination with the appropriate device programmer in higher-risk situations (e.g. PM-dependency, surgical epicardial leads, abandoned leads, lead extenders/adaptors).

Very few cases of MRI in patients with temporary external PM have been reported.[55,56] Magnetic resonance imaging scans should be avoided in this setting but may be performed in the absence of an alternative imaging technique, if the benefit largely outweighs the risks.

Interrogation and programming of the device

Patients with non-MRI-conditional devices should have a device interrogation before and after the MRI. The device evaluation should include battery voltage, lead(s) impedance(s), detection, and pacing threshold. In general, tachycardia detection and/or anti-tachycardia treatment should be deactivated in ICD (as well as in PM with atrial ATP) and advanced features (e.g. VVT mode of CRT devices) should be disabled. In pacing-dependent patients, the device programming mode should be asynchronous (AOO, VOO, or DOO), and the programmed lower rate should be sufficiently high to avoid competing pacing ($\geq$20 bpm above intrinsic rate). In non-pacing-dependent patients, who are unlikely to require pacing for intermittent severe bradycardia (e.g. with paroxysmal AV block), the device programming should be in an inhibited (DDI, VVI, or AAI) or preferably a non-pacing-mode (OAO, OVO, or ODO). The latter modes do not require inactivation of advanced features or magnet response (*Figure 4*).

Magnetic resonance imaging scanning recommendations for non-magnetic resonance imaging–conditional devices

- Favour 1.5 T rather than 3 T.
- SAR $\leq$ 2 W/kg.
- Gradient magnetic field slew rate $\leq$ 200 T/m/s.
- Minimize the number and length of sequences (B1 + RMS$\leq$ 2.8 μT).

Follow-up after magnetic resonance imaging scanning

Remote monitoring should be encouraged to regularly check CIED parameters. If remote monitoring is unavailable, an additional in-person follow-up ~1 week after the MRI scan should be scheduled in case of significant changes in lead impedances, detection amplitudes, or increases in pacing thresholds are detected after the scan.

Magnetic resonance imaging

A standardized protocol and checklist to treat CIED patients during MRI scans should be outlined	♥
Situations at risk, such as the presence of abandoned or fractured leads, surgical epicardial leads, lead adapter or extenders, ICD or patients being PM-dependent, should be identified	♥
Patients should be monitored with pulse oximetry ± ECG during the entire MRI scan	♥
An asynchronous pacing mode (D00/V00/A00) should be programmed in PM-dependent patients	♥
An inhibited pacing mode (VVI/DDI/AAI) with inactivation of magnet mode and advanced features (noise reversion, ventricular sense response, anti-tachycardia pacing) should be programmed in patients, who are not PM-dependent but are at risk for severe bradycardia/asystole; otherwise, a non-pacing mode should be programmed (and does not require inactivation of magnet response or advanced features)	♥
Other pacing functions (magnet, rate response, noise reversion, ventricular sense response, AF response) should be deactivated in asynchronous and inhibited pacing to ensure that sensing of electromagnetic interference does not lead to unwarranted pacing	♥
Tachyarrhythmia detection and/or therapies (ATP/shock) should be deactivated in ICD patients to avoid delivery of unwarranted therapies	♥
In patients with non-MRI-conditional CIED systems, MRI may be performed in special settings (ICD generator, PM-dependent patients, recently implanted CIED, epicardial leads)	♥
CIED-trained personnel do not need to be present onsite during MRI scans in patients with MRI-conditional systems, if the appropriate MRI mode is activated	♥
CIED-trained personnel need to be available onsite with the appropriate device programmer during the MRI scan in higher-risk situations (PM-dependent and ICD patients, devices including surgical epicardial leads, abandoned leads, lead extenders/adaptors) in non-MRI-conditional systems	♥
It is advisable to perform CIED programming as closely as possible to the MRI facility and adequate monitoring should be ensured during MRI mode, especially in ICD patients	♥
Remote monitoring is encouraged after MRI scans, especially for non-MRI-conditional CIED systems and in patients at risk (ICD generator, PM-dependent patients, epicardial LV leads)	♥
Emergency management of CIED patients undergoing MRI should be performed in Zone 3 (outside the MRI scanning room)	♥
Abandoned leads should not be extracted with the purpose of performing MRI	♥

Cardiac interventions

Several cardiac interventions can cause EMI in CIED. However, published literature to guide evidence-based recommendations is sparse.

Cardioversion or defibrillation

A significant proportion of patients presenting for ECV or undergoing defibrillation carry PM or ICD. The high-voltage shock used may lead to serious complications such as reversion to a backup mode, loss of capture secondary to an increase in pacing thresholds, and direct electrical and/or thermal damage to the pulse generator or myocardium at the lead tip.[57] However, no CIED-related complications or adverse events were documented following ECV in a recent retrospective study.[58] Likewise, complications associated with ECV of CIED

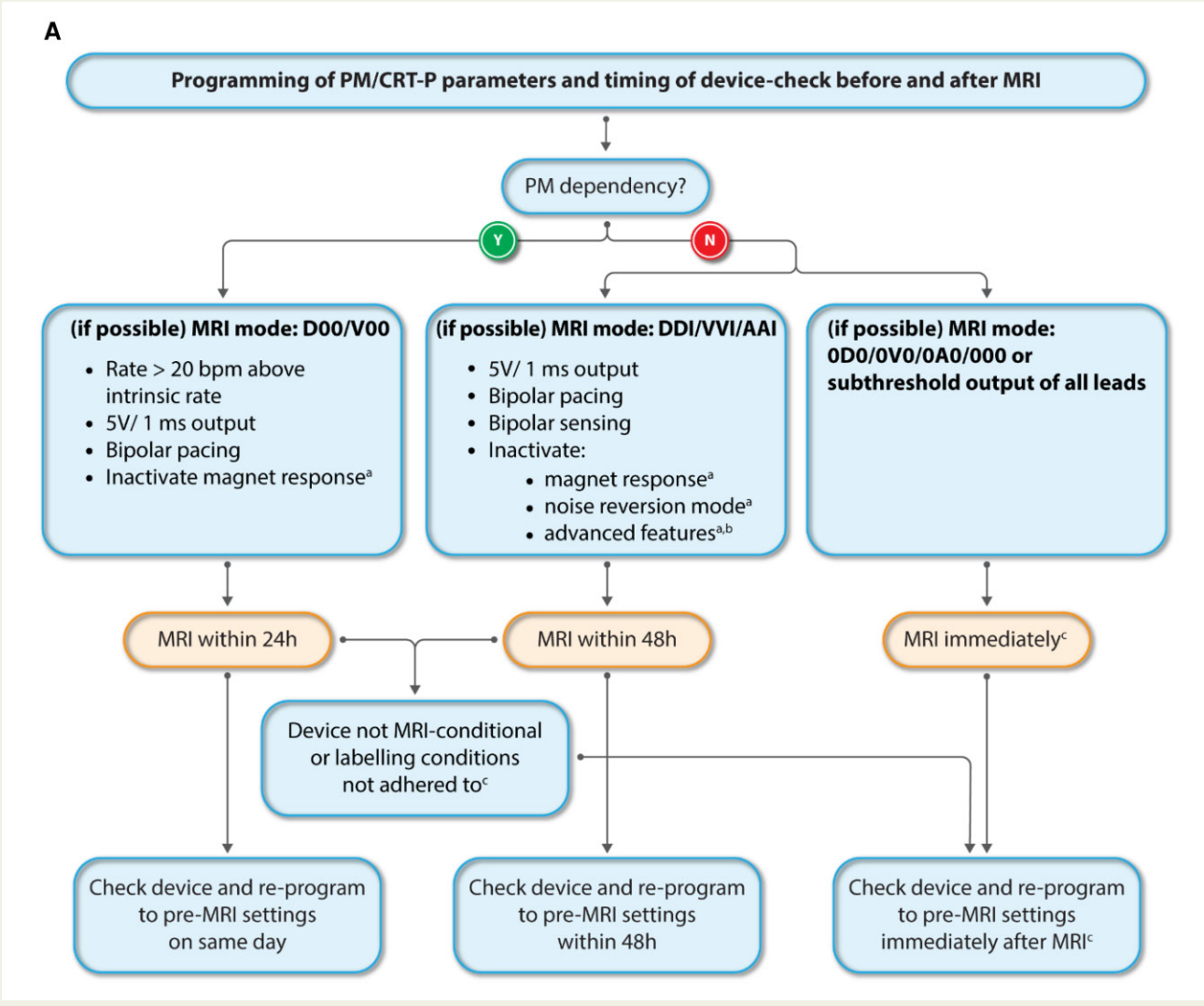

Figure 4 Programming of device parameters and timing of device check before and after MRI: (*A*) PM and CRT-P patients. (*B*) ICD and CRT-D patients; AF, atrial fibrillation; CRT, cardiac resynchronization therapy; MRI, magnetic resonance imaging. [a]If available. [b]Rate hysteresis; atrial anti-tachycardia pacing; CRT-triggered ventricular pacing; premature ventricular complex and premature atrial contraction triggered pacing; atrial fibrillation therapies—rate smoothing; overdrive pacing; conducted AF response. [c]In CIED with automatic MRI mode activation, the scan may be performed electively after the pre-scan follow-up and reprogramming after the intervention may not be necessary; adapted from ESC guidelines for cardiac pacing and CRT 2021.[45]

patients were reported in only 11 of 1809 patients (0.6%, range 0–4%) in a recent survey among German centres. Risk factors for complications included legacy CIED, short distance between ECV pads and the device, and non-anteroposterior pads positioning.[59] Although not commonly performed, internal cardioversion of atrial fibrillation has also been found to be safe and effective in ICD patients.[60]

Transcutaneous pads should ideally be placed in the anterior–posterior position with the anterior pad as far away from the generator as possible (at least 15 cm) in CIED patients undergoing ECV or external defibrillation.[24] Devices should be interrogated following any ECV and/or prior to patient discharge from the hospital based on the risk factors described above,[59] or if a CIED malfunction is suspected on telemetry or ECG.

Catheter ablation of cardiac arrhythmias

In patients with CIED undergoing radiofrequency catheter ablation, considerations must be given for the possibility of oversensing with inappropriate inhibition of pacing, mode-switch or noise reversion, inappropriate tachyarrhythmia therapy, damage to lead–tissue interface, and electrical reset of the device.[61,62] Modern pulse generators and leads are less sensitive to EMI due to the development of improved shielding and adequate programming.[63] Nonetheless, the panel advises to avoid direct contact between ablation catheters and the CIED systems. Specifically, ablation near the lead should be performed with caution and depending on the indication.[64] Furthermore, it is advisable that elective ablation procedures are delayed as long as possible after implantation to reduce the risk of dislodgement.[65]

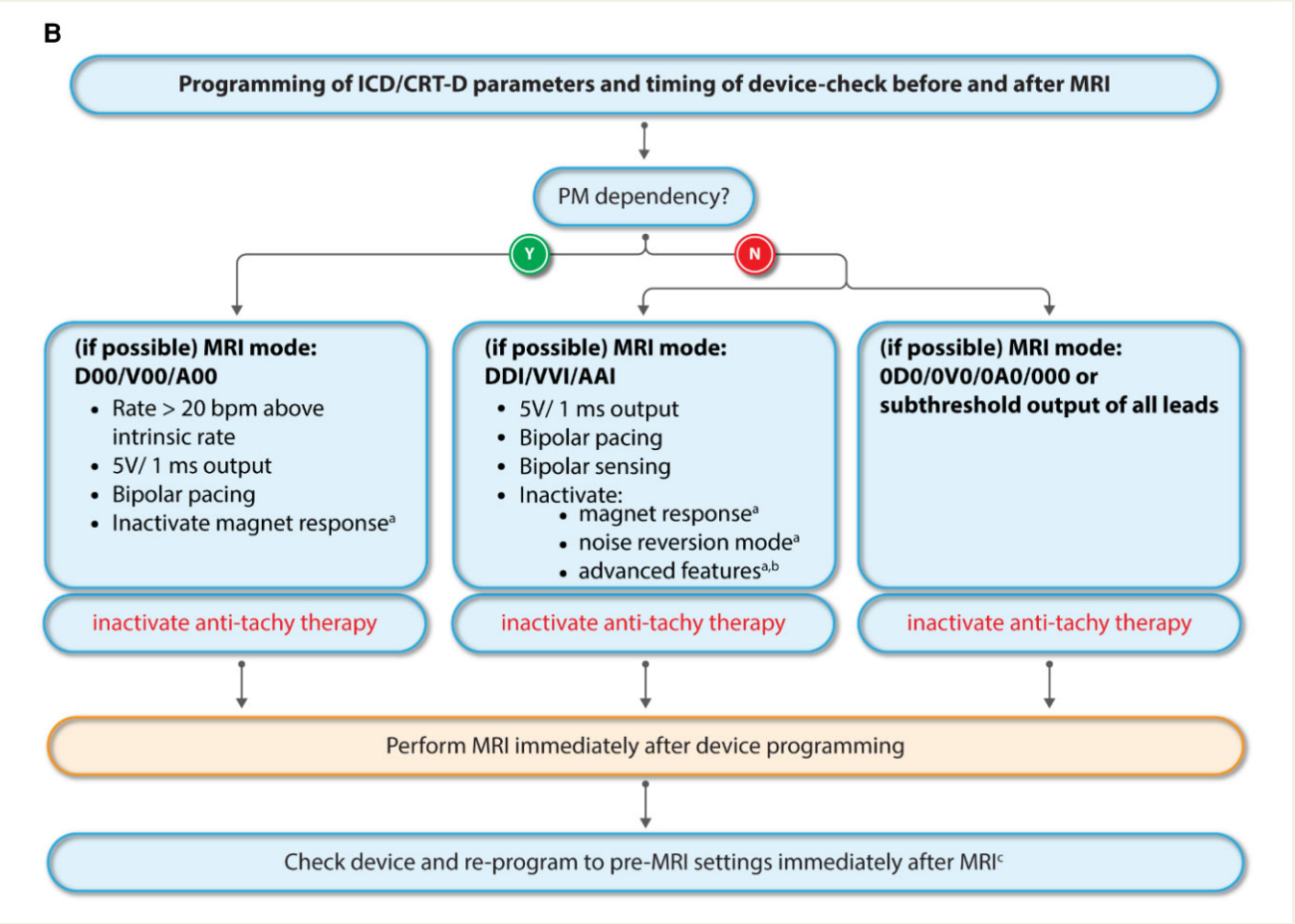

Figure 4 Continued

Due to the proximity of RF ablations and CIED components, the risk of interference during catheter ablations of cardiac arrhythmias and clinical sequelae is high. Therefore, the panel advises specific programming of the CIED before RF catheter ablation procedures including inactivation of anti-tachycardia therapies in ICD patients. At the conclusion of the RF ablation procedure, CIED should be interrogated and reprogrammed prior to the patient leaving the procedural room.

Subcutaneous ICD detect RF signals subcutaneously and therefore carry a particularly high risk for inappropriate shocks caused by EMI. Thus, ICD therapy should be disabled during radiofrequency ablation.[66]

In the setting of cryoablation, EMI has not been reported among CIED patients. Indeed, AVN ablation using cryo-energy has been safely performed without EMI in case reports.[67] An *in vitro* study suggests that cryoablation and radiofrequency ablation may be safely performed without effects on lead integrity. In contrast, there is a paucity of data on newer energy sources.[68] However, complications may result from direct lead contact and micro- and macro-dislodgements.[65,67]

Irreversible electroporation utilizing high-voltage pulses is an emerging strategy for catheter-based cardiac ablation.[69] Although preliminary data of electroporation pulses delivered close to CIED do not indicate adverse consequences for either the function of the device or treatment outcome, no available data are strictly related to cardiac ablation safety in CIED patients. Furthermore, the risk of harmful interference can be minimized by synchronization of the delivery of electroporation pulses with the electrocardiogram.[70]

Percutaneous coronary interventions

Although rare, contact-related noise during percutaneous coronary intervention (PCI) coronary guidewire advancement is reported, and this may lead to inappropriate shocks and potential pacing inhibition due to the proximity of the lead tip to the coronary lumen. Accurate evaluation of distance between CIED leads and guidewire together with device interrogation after the intervention may prevent complications.[36,71] Therefore, a 12-lead ECG should be recorded, especially after high-risk coronary interventions (e. g. shock wave, rotablation) close to CIED lead and CIED follow-up should be performed in case of documented arrhythmias or patients' symptoms.

Cardiothoracic surgery and cardiac implantable electronic device generator replacement

As with any surgical intervention involving electrocautery near the CIED, cardiac surgery and generator replacements may result in

EMI and affect patient safety. Pacemakers malfunction including lead damage, output failure, inappropriately low pacing rate, and reversion to backup pacing mode have been reported following unipolar electrosurgery during cardiothoracic surgery, generator replacement, or upgrade procedures despite programming to asynchronous pacing mode in certain pacemaker models.[72] Thus, bipolar electrocautery should be preferred in cardiac surgery and careful attention must be paid to the positioning of the electrocautery return electrode far away from the CIED and utilization of lower cautery power setting.[73] Anti-tachycardia function of ICD needs to be inactivated prior to generator changes and open-heart surgery. Guidewires or catheters in the vicinity of CIED leads may furthermore cause mechanical interference resulting in pacing inhibition or inappropriate shocks. Thus, a CIED follow-up and appropriate programming need to be performed as soon as possible after cardiac surgery.

Left ventricular assist devices

Cardiac implantable electronic devices electromagnetic interference has been described between CIED and left ventricular assist device (LVAD).[74] These issues include interference with telemetry resulting in the inability to interrogate the CIED, disruption of HeartMate 3 function,[75] oversensing of the implanted LVAD leading to pacing inhibition or inappropriate shocks, decreased R-wave sensing, lead dysfunction, and altered DFT threshold.[76,77] Therefore, careful and regular CIED interrogation, programming (e.g. inactivation of high-frequency amplification[74] or even inactivation of ICD therapy) and management are warranted in these circumstances and remote monitoring is encouraged throughout LVAD operation.

Electrical cardioversion or defibrillation

In patients with CIED undergoing external direct-current cardioversion or defibrillation, transcutaneous pads should ideally be placed in the anterior–posterior position with the anterior pad as far away from the CIED as possible

CIED interrogation should be performed following cardioversion and prior to patient discharge from hospital in high-risk patients (legacy CIED, short distance of pads to device, or non-antero-posterior position of pads) after external cardioversion

Catheter ablation

For radiofrequency catheter ablation of cardiac arrhythmias in a CIED carrier, specific programming of the CIED is indicated to avoid oversensing due to EMI and to ensure appropriate pacing and avoid inappropriate ICD shocks during the procedure

Catheter ablation within 1 cm of the CIED lead should be undertaken with great caution and only in specific indications

Percutaneous coronary intervention

A 12-lead ECG is advisable after PCI, and CIED follow-up is encouraged in case of symptoms or signs suggestive of device malfunction

Cardiac surgery and CIED generator replacement

Bipolar electrocautery using low power settings should be preferred, and CIED should be reprogrammed to reduce the risk of EMI

In LVAD patients remote monitoring of CIED is useful

Therapeutic radiation

Incidence, risk factors, and consequences

An increasing number of CIED patients need radiotherapy (RT) for the treatment of cancer. The annual rate of RT in patients with a CIED was estimated as 4.33 therapies per 100 000 persons in 2012 according to a survey in Western Denmark.[78] The rate of CIED malfunction varies between 2 and 7%, and depends on treatment plans, location, and cumulative dose of radiation (although the correlation is poor) as well as type and shielding of the devices. Accordingly, opinions on risk stratification and protective measures for therapeutic radiation in CIED patients were heterogenous in a recent EHRA survey.[79]

Radiotherapy may induce CIED dysfunction primarily via directly damaging the memories of the generator (78–80% of all malfunctions) and less likely due to EMI caused by the linear accelerator.[80] Malfunctions of the CIED either occur transiently during RT ('soft error') or induce reversion of the device software into 'reset' or 'back-up' modes ('hard error').[81] Transient malfunctions are rare and mainly related to EMI during RT and may lead to asystole by pacing inhibition in PM-dependent patients, but RT may also induce inappropriate ICD therapies. In contrast, an electrical reset reverts the software to factory settings with rudimentary CIED programming and may thus suppress necessary ICD therapies. In most cases, the problem can be solved by reprogramming the device; however, generator replacement due to permanent hardware damage is necessary in rare cases.[82] Fortunately, most electrical resets caused by RT did not result in emergency situations, but only transient bradycardia, hypotension, or heart failure in retrospective studies.[78,83–85]

Factors determining the risk of CIED malfunction are:

- PM-dependency of patients undergoing RT.
- Type of CIED: ICD and CRT defibrillator (CRT-D) devices are considered higher risk for malfunction.
- Type of RT energy: (neutron contamination due to) photon beam energy >10 MV, electron energy of >20 MeV or proton therapy are considered as high risk for CIED malfunction.[86]
- Cumulative absorbed dose the generator is directly exposed to:
  - Dose >5 Gy: high risk of CIED damage (thorax, neck upper extremity),
  - Dose 2–5 Gy: intermediate risk of CIED damage,
  - Dose <2 Gy: low risk of CIED damage (usually ≥5 cm distance from the device).

Practical advice and personnel

Modern CIED very rarely need to be preventively relocated to a contralateral pectoral position or even replaced by a leadless pacemaker. These measures only need to be initiated if the CIED interferes with adequate RT delivery.[80] If this is not the case, each CIED should be evaluated (type and manufacturer, PM-dependency, adequate function, battery voltage) and a device-specific treatment plan (including dose estimation and risk

Table 10 Risk stratification for CIED malfunction

Cumulative radiation dose the generator is directly exposed to	<2 Gy	2–5 Gy	>5 Gy
Photon beam energy	<10 MV		>10 MV
Non-pacing-dependent	Low risk	Intermediate risk	High risk
Pacing-dependent	Intermediate risk	Intermediate risk	High risk
ICD generator	High risk	High risk	High risk

stratification) should be outlined by CIED specialists and radiation oncologists prior to the initiation of RT. In general, radiation exposure directly to the device should be minimized to prevent CIED malfunctions.

Risk stratification for all CIED patients should be performed similar to that described earlier (*Table 10*)[84,87]

The impact of shielding on pulse generators to inhibit scatter radiation and potential CIED malfunction is minimal and usually not necessary. However, audiovisual monitoring needs to be provided in all and ECG monitoring can be discussed on an individual basis (e.g. in case of neutron contamination or after device reset has been observed) in ICD and high-risk PM patients. Availability of a defibrillator with transcutaneous pacing capabilities, personnel trained in CPR, a code cart, and a magnet (>10 G field strength) in the therapy room also needs to be ensured for all CIED patients.

The following additional measures are recommended for PM patients during the entire course of RT.

Low-risk group:

- Pacemakers interrogation before the first and after the last fraction of RT.
- Cardiac implantable electronic device–trained personnel should be available on call.

Intermediate risk groups:

- Pacemakers interrogations before, at mid-term, and after radiation or remote monitoring.
- ECG monitoring in case of symptoms; magnet application if CIED dysfunction is observed or suspected.
- Cardiac implantable electronic device–trained personnel should be available on call.

High-risk groups:

- Remote monitoring should be initiated; if not available at least weekly CIED interrogations should be performed.
- ECG monitoring can be discussed on an individual basis; ECG monitoring in case of symptoms, magnet application if CIED dysfunction is observed or suspected.
- Cardiac implantable electronic device–trained personnel should be available on call.

Implantable cardioverter defibrillator and CRT-D patients have a high risk for tachyarrhythmias and anti-tachycardia devices may be more susceptible to malfunctions due to RT. Furthermore, EMI caused by linear accelerators may cause inappropriate shock therapies in rare instances.[88] As these events occur infrequently, inactivation of atrial and ventricular anti-tachycardia therapy by magnet application or re-programming of the ICD should not be performed routinely, but may be discussed in high-risk cases. Remote monitoring should be initiated, especially if the cumulative radiation dose to the generator exceeds 2 Gy. If the latter is not available, at least weekly CIED interrogations should be performed (*Figure 5*).

Therapeutic radiation

CIED should be evaluated prior to radiation and a patient-specific treatment plan (including radiation dose estimation or measurement) should be outlined by CIED specialists and radiation oncologists prior to initiation of treatment

CIED interrogation and ECG monitoring should be performed according to risk stratification during radiation therapy and after completion of the last fraction of treatment

CIED-trained personnel readily available or on call is encouraged during radiation fractions for all CIED patients

Relocation of a CIED for radiotherapy is not indicated, unless the device interferes with adequate tumour treatment

Transcutaneous electrical nerve stimulation, electrical muscle stimulation, spinal cord stimulation

Incidence and risk factors

Electrical stimulation therapy (EST) such as transcutaneous electrical nerve stimulation (TENS), electrical muscle stimulation (EMS), or spinal cord stimulation (SCS) have been used for decades for the treatment of various pain conditions and other neuromuscular disorders including stroke, spinal cord injury, and refractory angina pectoris.[89–94] In TENS and EMS, different modalities of electrical current are applied using temporarily attached stimulation patches, whereas SCS requires surgical implantation of stimulation electrodes. In general, asymmetric biphasic impulses are delivered continuously with a frequency of 2–80 Hz. These interventions have been shown to interfere with PM[95] as well as ICD[96] therapy. Data available on the incidence of clinically relevant interference between EST and CIED [95,97–105] are sparse, but cases are likely under-reported.

There is limited information on specific risk factors of clinically significant interference between EST and CIED. However, numerous case reports and retrospective studies demonstrate that all kinds of CIED might theoretically be affected by the application of EST.[104] Whereas mode of EST stimulation and the respective current applied (mono- or biphasic) appear to be of minor relevance, the location of current application seems to be the most critical parameter. Bilateral application of energy (i.e. device within the flow of current) close to the CIED appears to be associated with the highest likelihood for interference with CIED.[106]

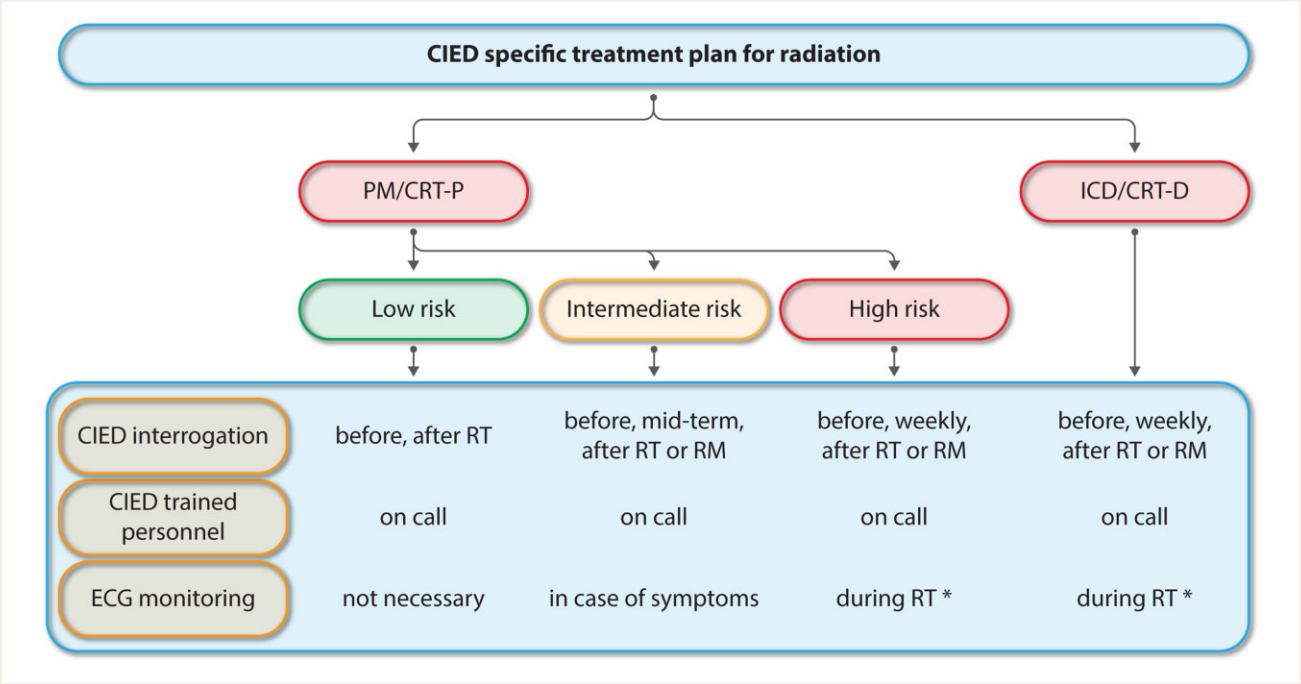

Figure 5 Algorithm for the management of CIED patients during RT: RT, radiotherapy; RM, remote monitoring; *can be discussed on an individual basis or in case of symptoms

Depending on the implanted CIED, the mode of EMI detection as well as the modality of applied current, various effects might be observed in patients with CIED undergoing EST or SCS with similar effects to those observed during electrocautery. Thus, EST may cause oversensing and clinically relevant bradycardia, or asynchronous pacing. Furthermore, patients with ICD and CRT-D devices might be compromised by delivery of inappropriate shocks or even inhibition of treatment due to VT/VF detection failure.[106]

Monitoring, equipment and staff

Since most of these EST modalities are used in an outpatient setting or as continuous long-term therapy (SCS), specific measures should be taken before initiating therapy to ensure optimal safety and efficacy in CIED patients. Specifically, the treating device centre should be consulted and an individual treatment plan should be designed by physiotherapists and CIED specialists for each patient. If the team reaches a decision for a particular EST, an in-office CIED follow-up with real-time analysis of the device EGM and marker channels should be performed during initiation of EST, especially if the patient is PM-dependent. In the absence of CIED interference, subsequent EST applications can be applied safely, provided locations of therapy, energy application settings, and CIED programming remain unaltered. In case of changes in the EST protocol, above-mentioned measures should be repeated.[107]

Telemonitoring is encouraged and the EST session should be immediately interrupted in case of cardiac symptoms. Thereafter, the CIED, EST indication, and the specific treatment plan should be re-evaluated together with a CIED specialist.

In patients with devices providing antitachycardia therapy (ICD and CRT-D), the first EST application should imperatively be performed under surveillance by CIED-trained personnel under continuous ECG monitoring and with a defibrillator nearby. If interference can be ruled out by analysing the real-time EGM and marker channels (after programming a high-sensitivity setting) in this test run, EST may be performed in this high-risk scenario.[108,109] Telemonitoring of the ICD system is similarly encouraged during the entire EST treatment period.

Electrical stimulation therapy (EST) in patients with CIED

TENS and other modalities of EST in CIED patients should only be applied after consultation of a CIED specialist	♥
EST should be performed as far away from the CIED as possible and unilateral current application should be preferred	♥
The first cycle of EST application in PM-dependent patients should be performed during monitoring of the EGM and marker channels by CIED-trained personnel to rule out interference	♥
The first cycle of EST application in ICD patients should be performed under surveillance by CIED-trained personnel using continuous ECG monitoring and with a defibrillator nearby	♥
In the absence of interactions after sufficient testing, EST may be performed in the absence of CIED-trained personnel	♥
Telemonitoring is encouraged during EST therapy in PM-dependent and ICD patients	♥

Other procedures: endoscopic gastrointestinal procedures, electroconvulsive therapy, urethral procedures, dental procedures, lithotripsy

Endoscopic gastrointestinal procedures

The frequency of EMI-related events during endoscopic procedures in patients with CIED remains exceptionally low. However, with the increase in complex endoscopic procedures that use RF energy (e.g. endoscopic submucosal dissection, endoscopic retrograde cholangiopancreatography with endoscopic sphincterotomy, and peroral endoscopic myotomy), there is an increase in the frequency of EMI-related events in CIED patients. Previous case series and retrospective reports, spanning both older and modern-day devices, documented multiple responses of implanted devices to periprocedural EMIs such as mode switching, failure to pace, inappropriate shocks, and even complete system malfunction. Data regarding risk factors for EMI during endoscopic procedures are sparse. The risk of EMI is highest if unipolar RF energy is used near the pulse generator or leads.[110–112]

- Diagnostic procedures: There is no risk related to interference in diagnostic procedures. Thus, neither CIED programming nor magnet application is needed.
- Endoscopic procedures using RF: RF energy used during endoscopy may generate CIED interference similar to electrocautery. Cardiac implantable electronic device leads are located in close proximity to the gastrointestinal (GI) tract, thus prolonged RF bursts may lead to inappropriate shocks, pacing inhibition with bradycardia or asystole, ventricular tachycardia, or CIED damage requiring replacement.[112] Thus, ECG monitoring should be applied in all CIED patients undergoing endoscopic interventions including RF energy. Additionally, a magnet may be secured to the generator of PM-dependent and ICD patients during unipolar electrocautery.[113] Alternatively, CIED need to be reprogrammed, if patient's position is unstable.
- Video endoscopic capsule: No significant interference related to CIED has been described.[114]

Electroconvulsive therapy

Electroconvulsive therapy uses a small electric current to produce a generalized cerebral seizure under general anaesthesia and is used mainly to treat severe mood and psychotic disorders. Electrodes are placed on the head and the duration of the electrical current application is typically brief (1–2 s). Most small series show that ECT can be safely and effectively administered in CIED patients.[115] However, ventricular oversensing[116] and inappropriate ICD shocks[117] have been described in case reports. Thus, reliable ECG monitoring should be provided and magnet application to transiently suspend antitachycardia therapy in ICD patients is recommended.

Extracorporeal shock wave lithotripsy

Shock wave lithotripsy (SWL) for renal stone removal employs high-energy shock waves produced by an electrical discharge. Lithotripsy has been shown to cause EMI in CIED patients based on older studies including legacy PMs. However, improvement in SWL (ECG gating of shock waves) and CIED technology have led to reduced incidence of EMI in bench experiments[118] and *in vivo* testing.[119] Clinical observations with modern devices show that SWL can generally be safely performed in PM and ICD patients.[120]

Thus, lithotripsy, as it is currently performed, does not lead to EMI with adverse consequences in CIED patients. Cardiac implantable electronic device reprogramming or magnet application is not deemed necessary during SWL. It is, however, reasonable to avoid placing the lithotripsy beam near the generator and to applyECG monitoring during the procedure.

Dental procedures

Common dental devices and equipment, except electrocautery, at a clinical application distance (20 cm) to the cardiac electronic devioce provoke only minimal interference in CIED.[121]Although interference can occasionally be detected, it usually does not lead to a significant alteration in CIED function and it does not translate into clinical events in treated patients. Therefore, the placement of a magnet over the device is advisable only in case of patient symptoms.

Monitoring, equipment, staff

The equipment required for monitoring and emergency situations is not different from other surgical procedures. Since most GI and urologic procedures are performed in a hospital environment, it is not difficult to obtain the necessary setup. In contrast, dental procedures are usually performed in office environments and adequate monitoring may be difficult to perform.

Endoscopy: Periprocedural ECG monitoring is advisable for endoscopic procedures, if the application of unipolar RF energy is planned

Endoscopy: A magnet may be secured to the generator of ICD patients during endoscopic interventions including unipolar RF energy

Lithotripsy: CIED patients may safely undergo lithotripsy without reprogramming the device or magnet application

Electroconvulsive therapy: Reliable ECG monitoring should be provided and a magnet should be applied in ICD patients to transiently suspend ICD therapies

Dental procedures: General CIED reprogramming or magnet application is not needed in dental procedures

Emergencies due to interference

Emergency protocol

A written emergency protocol, developed in accordance with the local CIED clinic, should be available and disseminated. Medical staff should be able to identify critical CIED situations (asystole, VF, cardiogenic shock), to immediately initiate basic life support and alert the emergency team. In the presence of clinically relevant events (sustained ventricular arrhythmias or arrhythmias, heart failure, chest pain, severe hypotension, appropriate or inappropriate ICD therapy, PM malfunctions), the session should be immediately interrupted,

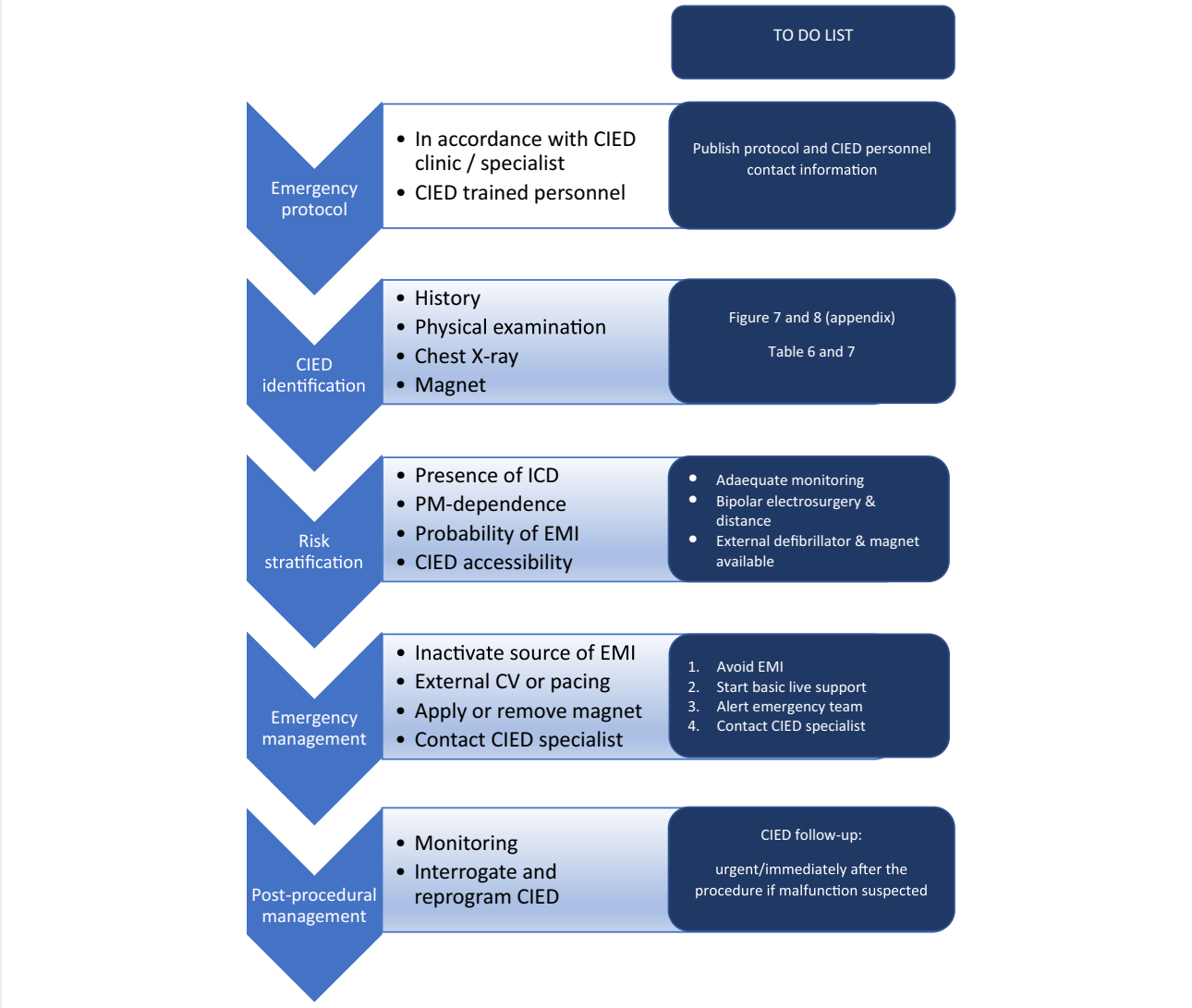

Figure 6 Checklist for the management of emergencies and complications due to interference.

the possible source of EMI identified, and the CIED clinic contacted (*Figure 6*).

Cardiac implantable electronic device identification and risk stratification

In an emergency, the CIED immediately needs to be identified by chart review and the CIED card. Particular attention should be given to gather information, if the patient carries an ICD, a CRT, or a PM, indications for implantation, CIED function, and current device settings.[122,123] Pacemaker dependency is of utmost importance and can be suggested by a history of prior AV node ablation, history of complete AV block, or if exclusively paced QRS complexes are present on telemetry. Finally, palpation of the generator identifies device location and frequently CIED type. Chest X-ray also helps to identify the type, location, and manufacturer of CIED, which makes it possible to consult the technical service of the manufacturer (appendix; *Figures 7* and *8*), if CIED-trained personnel is not available. Placing a magnet over the device during ECG recording may help to identify device type, if other methods fail.[124] An overview of CIED behaviour during magnet application is given in *Tables 6* and *7*.

Emergency management

A defibrillator with transcutaneous pacing capabilities should be connected to an unstable patient as soon as possible.

A magnet should be placed over the generator to reverse PM therapy into the asynchronous mode, if pacing inhibition, asystole/bradycardia, or a PM-mediated tachycardia is observed on telemetry. If inappropriate antitachycardia therapies are suspected in ICD patients, a magnet should be secured close to the device to inactivate ICD intervention. An external defibrillator needs to be connected

to the patient in these cases to ensure immediate emergency defibrillation.

Before emergency defibrillation or cardioversion of a patient with a CIED, all potential sources of EMI should be identified and inactivated, and the magnet should be removed to enable the ICD anti-tachycardia therapies. If the above measures fail to restore CIED function, emergency external defibrillation or cardioversion should be performed as needed together with advanced cardiac life support. Importantly, energy level and pad placement should be selected to minimize the current flowing through the generator and leads (Cardioversion or defibillation).

Post-procedural management

After an emergency during a procedure, a patient must remain fully monitored and a defibrillator needs to be readily available until CIED settings are restored (especially ICD therapy) and proper CIED function is confirmed. Intraoperative haemodynamic instability, arrhythmias, or any suspicion for inappropriate CIED function should prompt immediate follow-up by CIED-trained personnel.

Appendix

Noise-protection in cardiac implantable electronic device

Advances in lead manufacturing and improved generator design have significantly minimized the effects of EMI. Current devices incorporate non-ferromagnetic titanium casings for shielding. Similarly, pacing output circuitry and sensing amplifiers are protected from sudden and excessive voltage surges by the Zener diode that serves as a voltage regulator. The extent of interference can further be reduced by avoiding programming the leads with unnecessary high (numeric low value) sensitivity and using true bipolar sensing as opposed to unipolar or integrated bipolar sensing to avoid the 'antenna effect'.

Beyond this first physical barrier, the next task is to recognize the non-physiological signals outside the normal cardiac signal frequency band of 10–60 Hz. Besides standard band filtering, manufacturers utilize feed-through capacitor filters that have been especially effective in rejecting EMI from cell phones.[125] Furthermore, high-frequency non-cyclic signals that replace isoelectric baseline can be categorized as noise by noise rejecting algorithms. These algorithms use the distinguishing feature, where short intervals (50–200 ms) of high frequency (>16 Hz) sensed events within refractory or right after blanking periods are likely to represent noise. Signals sensed during this noise sampling window result in resetting of this window and extension of the blanking period with repetitive sensing leading eventually to asynchronous pacing at the basic rate with short AV delays. Importantly, ICD therapies are usually not disabled by noise detection.

Reed switch and magnet mode

Placing a magnet ≥10 G field strength over the cardiac device results in a change of programming to a manufacturer-specific 'magnet mode' by closing the 'reed switch'.[11,126] Magnets provided by device manufacturers are usually of >80 G field strength. Of note, the magnets are best placed directly on the top of the device. But there are exceptions and the position of the magnet is recommended to be eccentric over the bottom or top end of the CIED.[11] Legacy PM and ICD contain a magnetic reed switch that is closed by a static magnetic field. Because of inadvertent activation or closure in most contemporary ICD, the magnetic reed switch and its function have been largely replaced by other technologies (integrated solid-state detection Boston Scientific; Hall effect sensor Medtronic; telemetry coil Sorin Group; GMR circuit St Jude Medical).

For PM, magnet application generally results in asynchronous pacing. In ICD, a magnet disables tachycardia detection without having an effect on pacing mode or rate. Using this simple manoeuvre pacing inhibition in PM as well as anti-tachycardia therapies can be actively avoided or treated, if interference due to procedures is anticipated. However, it is strongly recommended for the user to be thoroughly familiar with the specific 'magnet mode' for each individual CIED (*Tables 6* and 7).

Reprogramming of pacemakers and implantable cardioverter defibrillators

Device interrogation and programming avoids over- and undersensing of EMF and other signals causing interference in CIED and potential clinical consequences. Specifically, an asynchronous mode is programmed (i.e. A00, V00, or D00) before surgery in PM-dependent patients with a high risk of interference and during MRI to avoid oversensing. Moreover, tachycardia detection and/or anti-tachycardia therapy is inactivated in ICD and CRT-D devices, if a significant risk of EMI is anticipated. A basic rate increasing the intrinsic heart rate ≥20 bpm should be programmed to avoid pacing into the vulnerable phase of the cardiac cycle and rate response should be inactivated.

Asynchronous pacing might cause stimulation in the vulnerable phase and result in ventricular pro-arrhythmia. Moreover, ICD patients are at risk for sustained ventricular arrhythmia as long tachycardia detection and/or therapy is inactivated. Thus, patients should be monitored during magnet application and as long an asynchronous mode is programmed ICD therapy is inactivated.

Both magnet application and CIED reprogramming have their advantages and limitations. Magnets are easily available and there is no specific training needed, whereas device reprogramming needs specific training, but may be customized (*Table 11*). Thus, specific CIED management needs to be chosen on an individual basis.

Identification of cardiac implantable electronic device type on chest X-ray

See *Figure 7*.

Identification of cardiac implantable electronic device manufacturer based on X-ray markers

See *Figure 8*.

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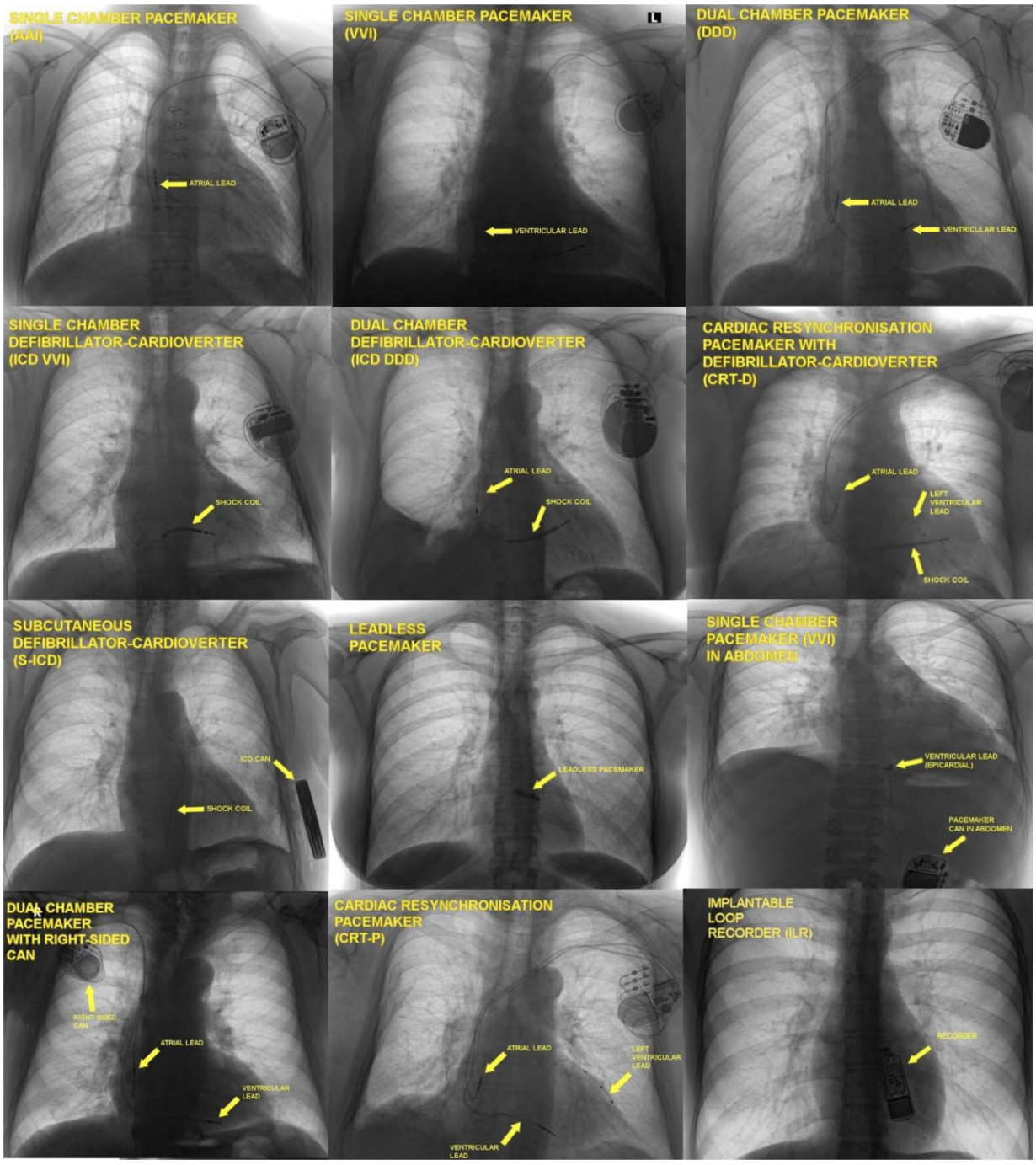

Figure 7 Chest X-ray to identify the type of CIED: typical X-ray pictures of the single-chamber PM (AAI, VVI), dual-chamber PM, single-chamber ICD, dual-chamber ICD, CRT device (PM and ICD), an S-ICD, a leadless PM, an epicardial PM and an implantable loob recorder (ILR) are shown; importantly, generators of transvenous devices can be implanted in a left and right pectoral pocket, a leadless PM is not equipped with a generator and the can of an S-ICD and an ILR are located on the left lateral thorax.

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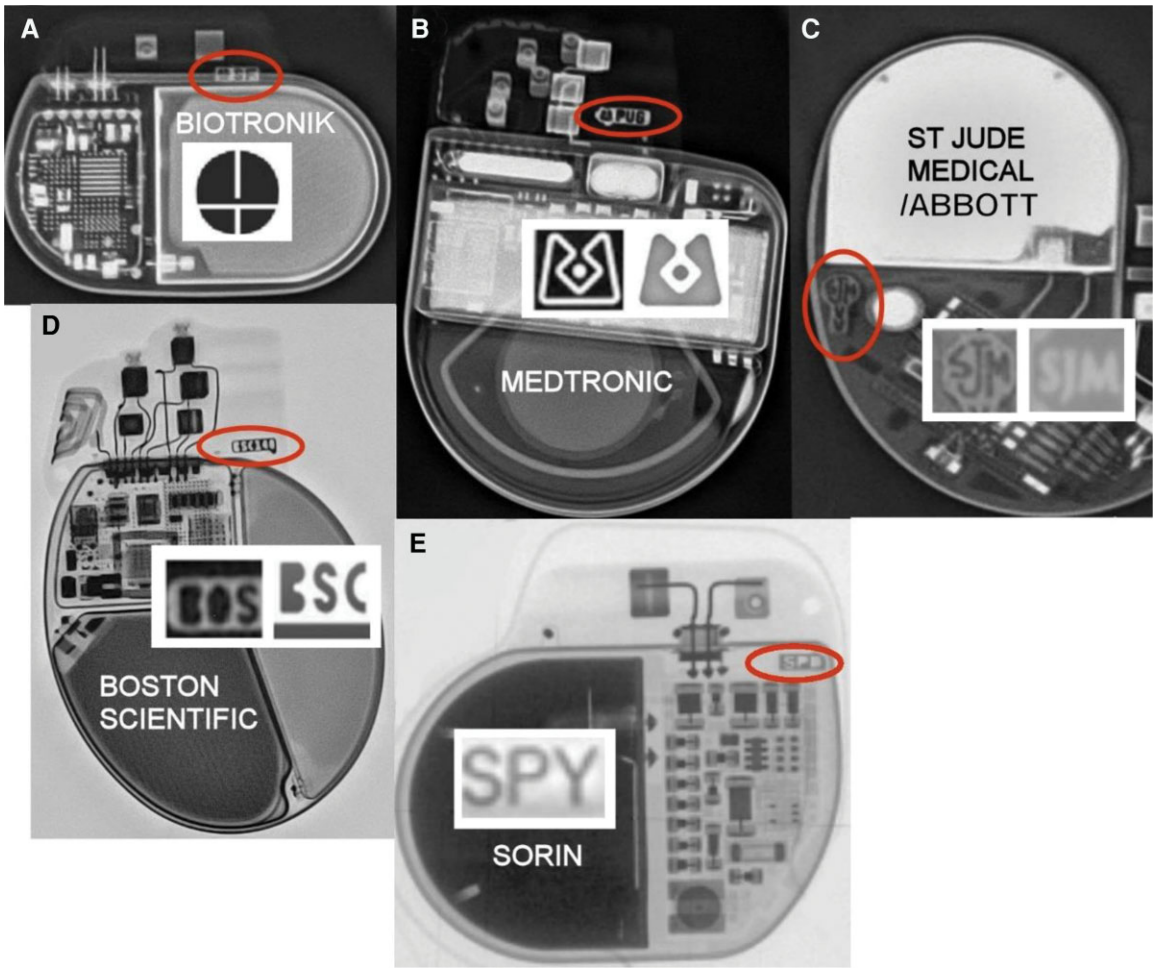

Figure 8 Identification of the CIED manufacturer based on X-ray markers: X-ray opaque symbols of individual manufacturers marked with a red ellipse and enlarged on the background of the CIED silhouette. (*A*) CIED manufactured by Biotronik, (*B*) by Medtronic, (*C*) by St Jude Medical/Abbott, (*D*) by Boston Scientific, and (*E*) by Ela/Sorin.

Table 11 Advantages and disadvantages of magnet application and reprogramming of CIED

	Availability	Effect	Disadvantages	Advantages
Magnet application	Ubiquitous No training needed Easily accessible	ICD: disabling only tachycardia detection and/or therapy PM: asynchronous pacing mode up to 100 bpm Sensor unaffected	Magnet dislodgement Obesity or deep position of CIED may hamper magnet effect 'Magnet mode' may be inactivated ICD: pacing inhibition still possible PM: asynchronous stimulation resulting in haemodynamic impairment	Immediately available Emergency setting to avoid shocks (ICD) or secure stimulation (PM) No reprogramming needed
CIED reprogramming	Limited Depending on trained personnel and programmer	Programming individual pacing mode (e.g. for CRT) Possible to enable tachy therapy Possible to enable rate response	Time-consuming Reprogramming needed Specially trained personnel necessary Individual management dependent on manufacturer Potential risk of programming errors (e.g. leaving ICD therapies inactivated at discharge)	'Customized' programming Stable setting during interventions Immediate device interrogation to reveal potential damage

(Medtronic, Pfizer, Bayer, Sandoz); M.S.: speaker honoraria (Biotronik, Boehringer-Ingelheim, Bristol Myers Squibb, Daiichi Sankyo, Medtronic); Ar.S.: consultant (Abbott, Medtronic), speaker honoraria (Bayer, Abbott, Medtronic, Biosense Webster), institutional research grants (Abbott); J.T.R.: speaker honoraria (Medtronic, Abbott, Boston Scientific), research grant (Medtronic), and institutional fellowship support (Abbott); K.V.: consultant for Medtronic, Boston, Abbott, Philips, Biosense Webster; research/educational grants from Medtronic, Biosense webster, Philips, Abbott; I.C., G.E., Av.S., M.S., and W.T.Y.: none declared.

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