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POSITION STATEMENT

Cardiac Society of Australia and New Zealand (CSANZ) Position Statement on the Follow-Up of Cardiovascular Implantable Electronic Devices 2022

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Recognising the need for a national approach for the recommended best practice for the follow-up of implanted cardiac rhythm devices to ensure patient safety, this document has been produced by the Cardiac Society of Australia and New Zealand (CSANZ). It draws on accepted practice standards and guidelines of international electrophysiology bodies. It lays out methodology, frequency, and content of follow-up, including remote monitoring; personnel, including physician, allied health, nursing and industry; paediatric and adult congenital heart patients; and special considerations including magnetic resonance imaging scanning, perioperative management, and hazard alerts.

Keywords Pacemaker • AICD • Follow-up • MRI

Introduction

Cardiovascular implanted electronic device (CIED) follow-up is a complex task requiring periodic assessment of device function, retrieval of stored health and technical data, and adjustment of the device's programmed settings. The health of the patient and the performance of their device are intimately related, and follow-up requires a coordinated team-based approach to management of clinical and CIED care. Until recently, most follow-up care was through in-person CIED interrogations that require the patient to attend a device follow-up clinic. Improvements in technology now allow CIED interrogations to occur from a location remote to the device clinic, usually the patient's home. The majority of patient's follow-up of their CIED involves an amalgam of in-person and remote follow-up, involving input from physicians and allied professionals trained in CIED follow-up and, in many cases, from the device manufacturer.

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Box 1. Summary and Key Recommendations.

Follow-up of implanted cardiac rhythm devices should be performed by a team including physicians, nurses and cardiac device physiologists trained in device management working in cooperation with the medical team responsible for providing clinical care.
The safety of cardiovascular implanted electronic device (CIED) patients relies on competent support by a cardiac device physiologist. The writing committee recommends a co-ordinated national approach to training and credentialling of cardiac device physiologists in Australia, similar to that available in New Zealand.
Remote monitoring of CIEDs is the standard of care and should be offered to all patients when possible.
We recommend a hybrid of in-person checks and remote monitoring of CIEDS individualised according to patient and device circumstances. We do not stipulate a minimal period for in person checks for adult patients but recommend that in person review be undertaken periodically as required by clinical and device circumstances.
CIED management in paediatric patients should be supervised by a large paediatric cardiology centre. Paediatric patients require annual in person CIED review.
Magnetic resonance imaging, perioperative management and hazard alerts are an increasing burden on the workforce that manage CIEDS and need to be factored into the resourcing of a CIED service. Management of patients with CIEDs undergoing procedures which could affect the device should follow a protocol-based approach.

The purpose of this report is to set out the standards expected for follow-up of CIEDs by the CSANZ.

This report draws heavily from accepted practice standards and guidelines of the international electrophysiology bodies [1–18]. International recommendations for CIED follow-up are largely based on a consensus that has been developed in tandem with the evolution of CIEDs from simple non-programmable pacemakers (PPMs) to complex devices with a multiplicity of functions and extensive health and technical data storage. The consensus recommendations for in-person follow-up have not been subject to rigorous trial examination. Where trial evidence exists (mostly for remote follow-up) it is used to inform this document [19–31].

This report discusses follow-up of the various categories of permanent pacemakers (PPMs), implantable cardioverter-defibrillators (ICDs), cardiac resynchronisation therapy (CRT) devices and implantable loop recorders (ILRs). The general aspects of CIED follow-up are discussed, however detailed review of the requirements for individual devices is beyond the scope of this document. A summary and key recommendations are available in Box 1.

Methodology, Frequency, and Content of Follow-Up

Methodology

Historically, follow-up of CIEDs has required in-person attendance for evaluation of device function. Over recent years, remote monitoring has become a sizeable part of CIED follow-up with robust evidence demonstrating its safety and feasibility [19–31]. Traditional in-person CIED checks remain fundamental to patient and device management and are necessary when remotely transmitted data is incomplete and when programming changes are required.

Remote monitoring of CIEDs consists of two incoming information pathways: (1) scheduled transmissions; and (2) alert transmissions. Both send information to a dedicated website where the information is reviewed by a cardiac device physiologist or physician. Patient consent is obtained to allow their personal data to be collected and saved.

Scheduled Transmissions are planned transmissions containing a complete device interrogation report, conducted at predetermined (3–12 monthly) intervals. These require a special device (communication monitor) that uses radio-frequency (RF) to conduct the transmission. The patient may have a personal device or attend a facility that has one of these for use with other patients. These facilities may include a cardiologist office or hospital setting e.g., emergency department, and more recently in pharmacies [32]. Newer CIEDs have Bluetooth capability, and some can use a smart phone application to send a scheduled transmission to the website [33,34].

Alert Transmissions occur when pre-specified criteria are met, e.g., abnormal lead parameters, arrhythmias, battery depletion. Alerts require the patient to possess a home transmitter specifically paired to their CIED, or (as above) an application on the patient's phone.

Advantages of remote monitoring centre around timely detection of actionable events such as device dysfunction and cardiac arrhythmias with mortality benefit demonstrated in some studies [19–23]. Convenience and improved efficiency are further potential benefits. Remote monitoring reduces the number of in-person checks and is especially pertinent in rural and regional communities, reducing travel for both patients and treating teams (physicians, cardiac device physiologists, and administrative staff). Remote monitoring may also be particularly beneficial in elderly patients with mobility issues requiring high level care, and in poorly compliant patients who frequently do not attend in-person appointments [35,36].

Limitations of remote monitoring include the inability to perform programming changes to resolve problems or optimise device performance. Remote monitoring information may be deficient in older devices which do not perform automatic lead measurements such as threshold testing. Performance of provocative manoeuvres to test lead integrity, optimisation of exercise sensors and physical examination of the implant site are also not possible. Further disadvantages include the inability to address psycho-social issues and manage clinical concerns such as heart failure.

Establishing a remote monitoring service is a significant challenge. It is time consuming and requires substantial administrative and technical support from cardiac device physiologists. The expectations and responsibilities of all involved parties must be clearly defined, and patient education is paramount [5–8]. Both patient and clinic responsibilities should be clearly documented. Providing feedback to the patient regarding the satisfactory function of their remote communication and the results of remote interrogations is important, as this is frequently a patient concern specific to this mode of device assessment. There are practical challenges to providing services to geographically remote communities which may have limited access to specialised medical services and poor telecommunications infrastructure. As a result, methods of achieving the following recommendations will necessarily differ from clinic to clinic. Regional clinics may partner with a tertiary institution in a "buddy arrangement" to achieve best practice follow-up for their patients. Nevertheless, despite these challenges, remote monitoring is the standard of care and when feasible, should be offered to all patients.

We advocate a hybrid approach to device follow-up and have formulated a recommendation encompassing both in-office review and remote monitoring. These recommendations acknowledge that not all patients have access to remote monitors, or remote monitoring services, and in these cases, continuation of solely in-person CIED follow-up is appropriate [1–7].

Frequency

A suggested frequency of device follow-up is shown in Figure 1. Initial reviews and in-person follow-up can be performed by either the treating cardiologist or the cardiac device physiologist. The three parallel arms of CIED review (Remote Monitoring for Alerts, Scheduled Checks and Clinical Care) continually interact and influence each other causing deviations in the frequency, as well as the mode (in-person or remote), of device checks. This guideline does not stipulate a mandatory minimal interval for in person device check. In some instances, all required information is obtained from a remote scheduled transmission, device programming is not indicated and an additional in person device check would be low value care, adding little or nothing to device management. Nonetheless, periodic, in person review is an essential aspect of follow-up care for all patients to manage the underlying cardiac condition as well as for device management. The frequency of clinical review is beyond the scope of this guideline, but it is incumbent on the care team to ensure appropriate clinical care is received by the patient and this will invariably require direct patient contact.

Examples of deviations to follow up scheduling and mode (in-person or remote) include:

Postponed in-person CIED appointments:

- For logistical reasons e.g., patients who are at end-of-life where more frequent device interrogation may be inappropriate/undesirable
- For deferment of routine checks due to public health concerns e.g., COVID-19 infection risk.

Additional clinically indicated CIED checks:

- CIED check performed in the emergency department or hospital admission for other medical reasons
- Interrogations and programming performed pre- and post magnetic resonance imaging (MRI) scanning (see below)
- Device surveillance over the period of radiation therapy
- Perioperative check prior to surgical procedure
- When device information is used for clinical management e.g., investigation of syncope, and optimisation of heart failure management
- In other specific circumstances e.g., patients with complex congenital heart disease and CIEDs, or patients with a complex device history, the physician may choose to monitor predominantly in person.

Additional interrogations based on device indication:

- Triggered by home monitoring alert e.g., treated ventricular arrhythmias, newly detected atrial fibrillation (AF), lead, or battery alert
- Increased device surveillance e.g., devices subject to hazard alert, battery monitoring, and known device/lead integrity issue under surveillance.

Content of CIED Follow-Up

Detailed itemisation of the content of CIED follow-up is beyond the scope of this guideline. The general requirements are shown in Table 1 below. An example of the detail required from a complete in office check is shown in Appendix 1.

Paediatric and Congenital Heart Disease Patients

There are no CIEDs designed specifically for the paediatric and congenital heart disease (CHD) patient group. Patient age and size, baseline cardiac anatomy, prior surgery and interventions, existing tachyarrhythmias and the requirement of future interventions all play an important role in selecting the appropriate device, implantation method and device programming [37]. Innovative approaches are often required in small children and complex CHD to adapt the use of CIEDs that have been designed for the structurally normal adult heart. Children also require special

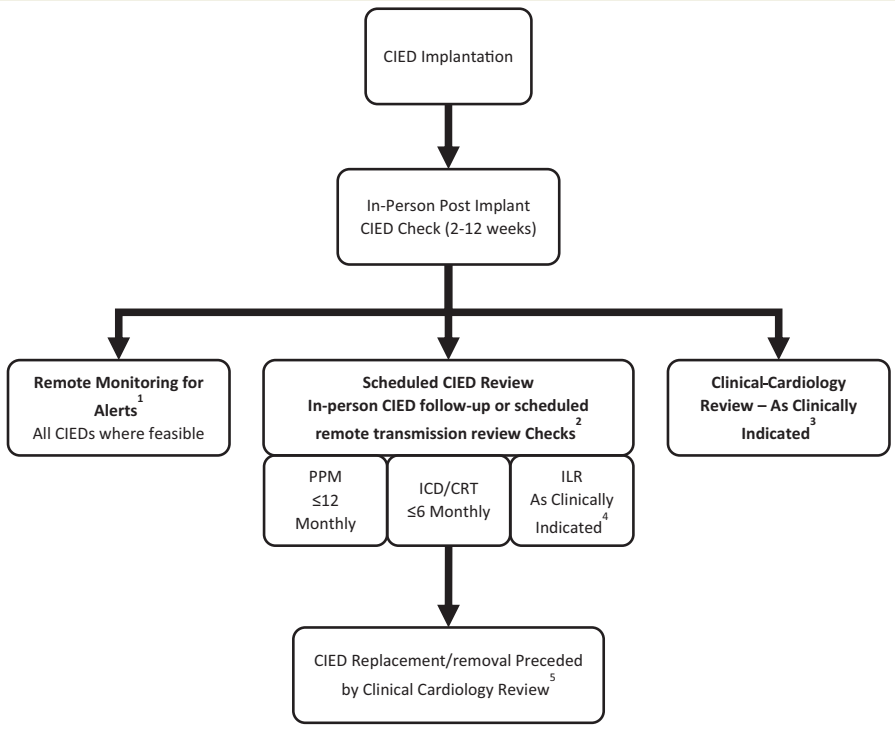

Figure 1 Schema for CIED follow-up.
1. Remote monitoring for alerts is only possible for devices with wireless capability. Some of the older generation CIEDs do not have wireless capability, and in these devices remote monitoring includes only patient initiated 'remote transmissions' using a manual handset.
2. Scheduled CIED checks include:

a. An in-person check.
b. A remote interrogation from a shared communicator (e.g., CareLink Express Medtronic, Minneapolis, MN, USA and MerlinOnDemand Abbott, Abbott Park, IL, USA) placed at a hospital, pharmacy, or office.
c. A scheduled remote transmission from a remote communicator.
d. Paediatric patients require annual in person check.

3. Clinical Cardiology Review is recommended periodically for all patients with CIEDs. This may occur simultaneously with a scheduled CIED check by the one cardiologist. Alternatively, clinical review may involve a non-CIED cardiologist. This emphasises the need for regular and timely communication between all involved parties.
4. Frequency of ILR follow-up is dictated by clinical need. **Scheduled CIED review** may not be necessary if the patient has been provided with **Remote Monitoring.**
5. A **Clinical Cardiology Review** is strongly advised prior to CIED replacement. Clinical circumstances may have changed since the previous procedure and the recommendations for CIED implantation may need revision.
Abbreviations: CIED, cardiovascular implanted electronic device; ICD, implantable cardioverter-defribillator; CRT, cardiac resynchronisation therapy; PPM, permanent pacemaker; ILR, implantable loop recorders.

considerations in relation to growth and the potential change to requirement of pacing. Almost all CIED implantations and long-term treatment plans require tailoring to each individual patient due to the heterogeneity of the patient group. As such, it is crucial that CIED management, including follow-up, is performed at a large paediatric cardiology centre where multidisciplinary discussions and input from paediatric cardiac surgeons, interventionalists, electrophysiologists and imaging specialists can be obtained [37]. Additional input from allied health including paediatric-trained cardiac device physiologists, nursing and psychologists is also important in the long-term management of these patients.

In areas where access to such tertiary care is not readily available, it is acceptable for the CIED follow-up to be performed at qualified centres by non-paediatric specialists, or non-electrophysiology paediatric cardiologists with a shared care arrangement with a tertiary centre as described above. Many adults with CHD have similar complex issues and require ongoing multidisciplinary input at a tertiary centre, and a transition to such centres from a paediatric centre is essential.

Table 1 General requirements for cardiac device interrogation programming and testing.

Cardiac Device	Interrogation, Programming and Testing
ILR	• Evaluation of wound site for in-person checks • Battery status • Evaluation of recorded episodes, data and trends in context of reported symptoms and clinical presentation • Evaluation and optimisation of all programmed parameters (including assessment of criteria used for automatic events e.g., bradycardia/tachycardia intervals and pauses, AF) • Creation of a detailed report to be sent to managing physician. • Storage of all relevant data
PPM	• As per ILR above with the following additional checks • Assessment of presenting and underlying rhythms • Evaluation of lead integrity, including pacing and sensing thresholds and lead impedances • Assessment and optimisation of chronotropic "rate" response
ICD/S-ICD	• As per ILR and PPM above with the following additional checks • Morphology template if applicable • Review tachycardia therapy settings and events
Conduction System Pacing and CRT	• As per ILR, PPM and ICD above • Additionally, these devices usually require greater input with more complex programming. Reviews often involve extended clinical evaluation, utilising additional resources e.g., 12-lead ECG

Abbreviations: ILR, implantable loop recorders; PPM, permanent pacemaker; ICD, implantable cardioverter-defibrillators; S-ICD, subcutaneous implantable cardioverter-defibrillators; ECG, electrocardiogram; AF, atrial fibrillation; CRT, cardiac resynchronisation therapy.

In addition to monitoring the CIED itself, it is crucial to evaluate CIED-related consequences frequently with ancillary testing, such as 12-lead ECG, Holter monitoring, exercise stress test and chest X-ray [17]. Given rapid physiologic changes in young children and disease related changes in patients with congenital heart disease, ancillary testing may need to be repeated periodically.

At least one annual in-person CIED check and cardiology review is recommended in paediatric patients. Remote transmission in the interim is recommended every 3-12 months for pacemakers and 3-6 months for ICDs [17]. The frequency of both remote transmission and in-person check should be individualised to optimise safety, particularly in the high-risk patient population such as small children, children with inherited arrhythmia disease, complex CHD, and epicardial systems.

Recommendations for programming and testing in paediatric patients, in addition to the requirements in adult patients, are outlined in Table 2 below:

Personnel

Physician

The training requirements for physicians engaged in CIED follow-up are detailed in the CSANZ guidelines 'Guidelines for advanced sub-specialty training in Cardiac Implantable Electronic Devices (CIEDs): selection, implantation and follow-up' (https://www.csanz.edu.au/wp-content/uploads/2014/12/Sub_spec_Training_CIED.pdf). Like the present document, the training guidelines are based on consensus opinion and contemporaneous international guidelines [10,11]. The CSANZ track 1 requirements, which do not include the need for competency in device implantation, include:

- Completion of advanced training in cardiology or cardiothoracic surgery at centre which includes at least two physicians that are experts in device implantation, at least one cardiac electrophysiologist and at least one allied professional trained and working regularly in CIED follow-up. The training centre should implant at least 100 devices annually and be engaged in all aspects of device follow-up including remote monitoring;
- Demonstration of competency in the technical aspects of pacing principles as described in this position statement;
- Participation in 150 follow-up visits with exposure to remote monitoring.

Maintenance of competency requirements require following a minimum of 50 devices annually. The CSANZ training guidelines state "this guideline makes recommendations on minimum numbers both for training and maintenance of competency. It should be stressed that these are minimum numbers and do not necessarily reflect best practice" (https://www.csanz.edu.au/wp-content/uploads/2014/12/Sub_spec_Training_CIED.pdf).

In this writing committee's opinion, practical maintenance of competency in CIED follow-up entails more than annual follow-up of a limited number of devices. Devices evolve at a rapid rate and to remain competent, physicians need to be actively engaged in continuing education in this subspeciality. How this is achieved will vary according to individual circumstance, but the principles are the same as for maintenance of competency in other medical fields. In some

Table 2 Recommendations for programming and testing in paediatric patients, in addition to the requirements in adult patients.

Cardiac Device	Interrogation, Programming and Testing
Paediatric PPM	• Evaluation of the presenting and intrinsic cardiac rhythm is recommended [17] • Appropriate heart rate setting require adjustment according to the patient age, as well as complexity of the patient's cardiac anatomy and haemodynamic status • Rate response requires individualised adjustment by age and activity level as there can be significant lifestyle changing throughout childhood. • Rate response typically not useful in infants and should be considered only when the patient is older and becomes more mobile • Guidelines on pacing in CHD generally recommend minimisation of ventricular pacing [18]
Paediatric ICD	• Inappropriate shock rates are higher than in the adult population, owing to sinus tachycardia, supraventricular arrhythmias, T-wave oversensing and increased rate of lead fracture requiring specific paediatric programming of detection zones [38].
Ancillary Testing [17]	• 12-lead ECG on an annual basis • Two view chest X-ray at the first post-implant follow-up and every 1–3 years based on patient-specific considerations. • Imaging important for patients with epicardial leads to monitor for any risk of cardiac strangulation. • Echocardiogram for patients who are ventricular paced >40% of the time every 1–3 years. • Lead-related valve regurgitation needs monitoring in patients with transvenous leads, particularly as the lead configuration may change with patient growth • Holter and exercise stress test are recommended to assess: o New arrhythmia concerns o Symptoms related to activity o To assist with device optimisation, particularly rate response

Abbreviations: ECG, electrocardiograph; ICD, implantable cardioverter-defibrillators; CHD, congenital heart disease; PPM, permanent pacemaker.

cases, where there are practical limitations to on-going training, linking with a mentor may be required. The over-arching requirements are for the physician signing off on a device report to be satisfied they can independently perform all aspects of the device check as shown in Table 1 and to be engaged in a process of continuing medical education involving CIEDs.

Allied Health Workforce

Employees in the cardiac device physiologist role provide support to physicians and other health care professionals during the implant and ongoing management of CIEDs. Cardiac device physiologists may be employed by a clinician, government health service or by device manufacturers and resellers. The supervising cardiologist bears ultimate responsibility for the decisions of the cardiac physiologist, irrespective of their employer.

Cardiac device physiologists may perform CIED follow-up and make programming changes without direct medical supervision. In many cases the cardiac device physiologist is the only point of clinical contact for routine device follow-up. Consequently, they provide a central role in the follow-up of cardiac devices and patient care.

The education and training pathway for cardiac device physiologists involves a Bachelor of Science (BSc) degree and employment as a cardiac physiologist. In Australia, workplace training and industry provided education form the basis of training in CIED follow-up. Postgraduate qualifications are strongly encouraged but often not mandatory.

In Australia, there is no government requirement for cardiac device physiologists to have a recognised, field-specific qualification, or to be registered as health practitioners. By contrast, cardiac sonographers require registration to practice. New Zealand cardiac physiologists are 'self-regulated' by their own Clinical Physiologist Registration Board (CPRB) and require proof of continuing professional development (CPD) and an annual practicing certificate. Work is underway to have this recognised by the Ministry of Health New Zealand.

New Zealand's Society of Cardiopulmonary Technology (SCT) mandates a 2-year postgraduate diploma for new cardiac physiologists with a further 2-year CIED certification in managing CIEDS which includes practical assessments and a logbook. This is now a prerequisite for those who wish to sit the Allied Professionals Certified Cardiac Device Specialist (CCDS) Exam, completed through the International Board of Heart Rhythm Examiners (IBHRE). New Zealand recognises the British Heart Rhythm Society Exam in Cardiac Devices for those recruited from overseas as equivalent to IBHRE.

Australia currently lacks an affordable, locally accessible, and nationally recognised postgraduate training program for cardiac device physiologists. The de facto qualification

currently most accepted in Australia is successful completion of the Allied Professionals Certified Cardiac Device Specialist (CCDS) Exam through the International Board of Heart Rhythm Examiners (IBHRE). There are some limitations to the IBHRE, most notably the lack of on-site assessment, or logbook requirements.

The safety of CIED patients relies on competent support by a cardiac physiologist who specialises in cardiac devices. The writing committee believes that a coordinated national approach to skills requirements, training, and qualifications of cardiac device physiologists in Australia would be beneficial to patients, staff and employers.

Nurses

In Australia and New Zealand, Registered Nurses are governed by national boards (Australian Health Practitioner Regulation Agency [AHPRA], Nursing and Midwifery Board of Australia, and the Nursing Council of New Zealand) and they operate within defined scopes of practice.

Nurses are a valuable part of the device management team. Their responsibilities frequently include pre CIED implant patient education, preadmission workup, scheduling of surgical procedures, and wound management.

Some centres may employ cardiac nurse specialists or nurse practitioners who access and utilise device reports (diagnostics and alerts) to aid in medication management and overall clinical care. Nurses may also have roles in administration and team coordination.

Independent device interrogation, programming, and interpretation of CIEDs is not within the usual nursing scope of practice. If nurses are performing these duties, they must have training in electrogram interpretation and device function (e.g., completion of IBHRE or equivalent plus ongoing CPD and appropriate registration). The responsibilities and scope of practice for each member of the team should be clearly defined and understood.

Industry

In Australia and New Zealand, device manufacturers are the principal purveyors of CIEDs. Wholesalers and independent distributor arrangements are uncommon. The device companies (Industry) are frequently involved in providing technical support and advice both at the time of implant and during the follow-up period.

With increasing complexity of CIEDs it has become difficult for physicians to remain familiar with extensive programmable features and software algorithms across the range of CIED devices. Industry holds an important role in facilitating the optimal device programming for each patient and in troubleshooting device-related issues. Industry provide and maintain the device programmers that are a prerequisite for CIED follow-up.

Industry is also integrally involved in the provision of remote monitoring (RM) services. The company that supplies the CIED maintains the RM servers and supply the equipment and software required for the CIED to transmit information to these servers.

The patient data from remote monitoring is almost entirely stored outside of Australia and New Zealand on each companies' servers. The security and availability of the data is managed individually by the device companies according to international guidelines. It is important that the consent process of enrolment of a patient into a RM service acknowledges that the patient's data will be stored and secured by the device company outside of Australia and New Zealand [7]. Some providers may elect to download and store the information locally, but the primary source material remains with the device company.

In Australia some physicians choose to have industry or third-party providers assess and analyse the RM data, including interpretation of any transmitted alerts. This is essentially a private arrangement between the responsible physician caring for the patient and the company or third-party providing the RM assessments. Ultimately the physician takes responsibility that the RM data is assessed and acted upon in a timely fashion.

Historically in Australia, industry has, at the request of some treating physicians, assisted with routine CIED follow-up both in the public hospital sector and in private clinics. In many instances there is public funding provided to the physician for undertaking device follow-up. If the physician chooses to have industry assist in this process it is a private agreement between the physician and the industry personnel providing the service. In New Zealand, industry support private implants and sometimes attend complex public implants. However, many centres in New Zealand do not require industry support. In New Zealand all follow-up is performed in the public system by cardiac device physiologists. When industry provides assistance at implantation and follow-up it remains the physician's responsibility to supervise this process and to take responsibility for the outcomes.

Special Considerations

Radiotherapy, Perioperative Management, MRI, Hazard Alerts

Many medical procedures produce electromagnetic interference (EMI) which can affect CIED function. The most commonly encountered source of EMI in the hospital setting is unipolar electrocautery. Other sources of EMI include MRI, electroconvulsive therapy, lithotripsy, therapeutic radiation, transcutaneous electrical nerve stimulation (TENS) units and transthoracic defibrillation/cardioversion. Ventilation can also affect some CIEDs [14].

Adverse events that can occur from EMI include:

- Inappropriate ICD therapy (including shocks)
- Pace inhibition leading to asystole/significant bradycardia
- Inappropriate pacing
- Higher rate pacing due to exercise sensor interaction

- Device malfunction or "reset"
- Discharge from hospital with incorrect programming
- Complete device failure

The principles of management of CIEDs during medical procedures are:

1. Diligent and timely communication between the specialists performing the procedure and the specialists/cardiac physiologists who follow the patient's CIED;
2. The availability and use of a local and or state/province based pathway for management of patients with CIEDs undergoing procedures which have the potential for adverse interaction with CIEDs. The use of a standardised workflow substantially reduces the risk of adverse events compared to an ad hoc approach;
3. The complexity of devices and the nuances of each procedure mean that a simple prescription for all patients is not possible.

Operative Diathermy

In most cases, the CIED follow-up team should be consulted before surgery and advice given by either the follow-up CIED physician or a suitably accredited cardiac device physiologist. Detailed advice can be obtained from the HRS and BHRS guidelines and institutions are recommended to develop or adopt a protocol to minimise the risk of adverse events [14,15].

Radiation Therapy

Radiation therapy can affect devices directly with transient oversensing during therapy and from degradation of circuit components from the cumulative dose received. Unpredictable effects from neutron contamination may also occur. The literature and management considerations are discussed in detail in the HRS guidelines [12] and an example of a locally developed protocol is shown in Appendix 2 of this document.

MRI

CIEDs currently available for implantation are now almost universally 'MRI conditional' – meaning that patients with these devices can undergo relatively safe MRI scanning under specific conditions [12]. All PPMs and ICDs require mandatory programming adjustments for MRI scanning. ILRs do not require programming adjustments, however retrieval of ILR event data should be performed prior to MRI if the ILR is not remotely monitored. The Royal Australian and NZ College of Radiologists (RANZCR) has a guideline on MRI Safety standards which contains a section on CIEDs [39] and there are detailed guidelines available from HRS [12]. The technical requirements for safely scanning CIEDs are complex, require precise identification of CIEDs and in many cases prolong scan times (http://www.mrisafety.com/).

Protocols for scanning patients with MRI conditional devices require identification of the device and programming recommendations by the CIED team followed by attendance of a cardiac physiologist to provide programming support [12,40]. This latter requirement precludes MRI in facilities where cardiac physiologists are lacking and involves substantial additional costs when cardiac physiologists are available to attend. The practical effect is to limit access to MRI for patients with CIEDs especially in regional areas. Some CIEDs are able to recognise an MRI field and switch to an appropriate program automatically [41]. Others have a "time out" facility so in theory, only programming pre scan is required. These developments may in time improve access to MRI.

Older "legacy" CIEDs are not MRI conditional, and many patients have abandoned leads which are not considered MRI conditional. There is good evidence that the risks of MRI in these patients are mostly very small and where there is a strong clinical indication, MRI can usually be performed with appropriate precautions which may include attendance of the patient's physician [12,39,42]. It is important that access is not denied to essential MRI investigation simply from an unwillingness to accept even a very low level of risk.

Medical Device Hazard Alerts/Recalls and Reporting of Adverse Events

Safety monitoring in clinical practice relies heavily on voluntary reporting of adverse safety events by the providers that follow up CIEDs. In Australia, these adverse events are reported to the Australian government through the Therapeutic Goods Administration (TGA) Medical Device Incident Reporting and Investigation Scheme (IRIS). The device manufacturer should also be informed. In New Zealand the mechanism for reporting is through the New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE) (https://www.medsafe.govt.nz).

Each manufacturer catalogues reported adverse events or deficiencies in relation to safety, quality, efficacy (performance) or presentation, and is required to publish regular product performance reports. When a manufacturer learns that there is a problem with a CIED component, it is legally required to notify the TGA and propose management recommendations. This may result in a formal medical device "hazard alert" possibly accompanied by a voluntary recall and distribution suspension.

Recommendations vary depending on the nature of the hazard alert, and may include suggestions for enhanced follow-up, such as increased device surveillance, software upgrades where possible, or hardware replacement [1,2,5,16]. Remote monitoring of devices known to be subject to hazard alert is often highly desirable to facilitate the early identification of adverse events in individual patients [43,44].

Conflict of Interest

James Leitch receives support for device follow-up from Abbott, Biotronik, Boston Scientific, Medtronic and LivaNova. Caroline Medi receives support for device follow-up

from Abbott, Biotronik, Boston Scientific, Medtronic and LivaNova. Irene Stevenson receives support for device follow-up from Abbott, Biotronik, Boston Scientific and Medtronic and has received speaking fees and travel assistance from Medtronic. Edward Toal has received educational and travel support from Abbott, Boston Scientific, Biotronik and Medtronic. All other authors have no conflicts of interest to declare.

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Appendices. Supplementary Data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.hlc.2022.01.008.

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Appendix 1.

In person CIED follow-up: elements to document in device clinic records and to include in reports and correspondence as required

[1,2] **Patient details:**	ID number, name, date of birth
[1,2]**Date of follow-up:**	
[1,2]**CIED category:**	PPM, ICD, CRT-P, CRT-D, ILR
[1]**Manufacturer and Model:**	
[1]**Implant date** (of CIED):	
Subsequent device surgery:	Date and brief details [1]Are any of the leads <3 months old
[2]**Remotely monitored:**	**Y/N/pending**
[1,2]**Indication** for CIED:	**PPM**: sick sinus syndrome, AV block, syncope, etc.
	ICD: primary or secondary prevention.
	CRT: LBBB, HF, QRS width, ejection fraction
	Additional relevant history: e.g., other heart pathology such as cardiomyopathy, IHD, valve surgery, EP intervention history, ejection fraction etc.
[1,2]**FDA/TGA Safety alerts** on CIED generator or lead(s) if applicable:	Comment as required
Abandoned (capped) leads in situ?	**Y/N**
[2]**MRI conditional** hardware?	**Y/N**
[1,2]**Battery status:**	e.g., time remaining till ERI, battery voltage, battery impedance
[,2]**Presenting rhythm**:	e.g., *"A sense V pace at ~65 bpm"* • Store IEGM trace • Measure and document surface ECG QRS width when required
[1]**Underlying rhythm** (if present):	e.g., *"complete heart block, V rate ~ 38 bpm"* • store IEGM trace
[1,2]**Pace Dependant:**	**Y/N** • Store IEGM trace (if manually demonstrated)

[1,2]**Basic key parameters:**	• [1,2]Pacing **mode:**
	  ○ Using the generic/standardised letter coding system
	• [1,2]Pacing **rate** parameters:
	  ○ [1]**Lower rate**: base rate & below base rate settings such as rest rate/night rate/hysteresis rate
	  ○ **Exercise sensor rate** if applicable
	  ○ **Upper track rate** if applicable
	
	e.g. *"DDDR, 60-130 bpm, exercise sensor rate 120 bpm, hysteresis 50 bpm"*

	• **ICD therapy** settings:
	  ○ Monitoring zone if applicable
	  ○ [1,2]Lowest heart rate for **ATP** delivery
	  ○ [1,2]Lowest heart rate for **shock** delivery

[1]**Exercise "rate" response** sensor type if applicable	G sensor, Minute Ventilator, Closed Loop Sensor

[1]**Magnet response**	Specific to the CIED type, battery level and programming • [1]**PPM**: Mode, rate, rate response off, and any additional magnet related considerations *(such as pulse amplitude changes, or limited duration of asynchronous pacing)* • [1]**ICD**: Tachy therapy disabled, rate response off, and any additional magnet related considerations *[such as expected audible magnet alert tone (Medtronic, Boston), or shocks reactivated after 8 hrs (Biotronik), or changes to rate and pulse amplitude (e.g. MicroPort)]*
[2]**Clinical history:**	Determined by **patient interview** and **clinical observation** • Document any concerns about the wound, the device, and any other relevant symptoms
[1,2]Are the **lead test** results **satisfactory** and **stable?**	**Y/N/see comments**
CIED history since previous check:	Determined by evaluating CIED **stored events, numerical data and graphs** • Describe and store IEGM examples of diagnostically relevant rhythm events
• [2]**Percent pacing:**	Record percentage of pacing by each lead (RA, RV, LV, BiV)
• [2]**AF history:**	• Any previously reported history of AF (Y/N) • Overall burden: • Longest episode: • Most recent episode: • V rate during AF: (mean and peak)
• **SVT/NSVT/VT/VF** event history:	• Number and description of events (arrhythmia rate, duration and details of any therapy delivered) • Acceptable to write "no actionable rhythm events" if a detailed description is not warranted
• **Other relevant events:**	e.g., PMT/noise/magnet response/RNRVAS/oversensing/ undersensing/congestion/sleep apnoea
Compare all findings with previous reports	Comment as required
Programming optimisation (if required):	Document any adjustments performed (to ensure appropriate **safety**, **quality of life** and **battery life** outcomes)
[2]**Final rhythm** (if different to presenting rhythm):	Store IEGM trace and document surface ECG QRS width if required
[2]**Discussions with patient:**	Document **key conversation points** re patient education and support, e.g., *"Advised to speak to GP about sleep symptoms",* or *"instructions given re remote monitor troubleshooting".*
Correspondence with other health professionals:	Document correspondence made to other health professionals if additional (actionable) patient needs were identified during the CIED review.

[3]Programmer generated report including ALL advanced parameter settings:	The **programmer generated PDF**, will not be useful to non-CIED specialists, but must be generated and archived for expert reference during future CIED follow-up.
	• **Lead details** (including abandoned leads)**:** manufacturer, model number and date of implant
	• All **initial** programmed parameters
	• All **final** programmed parameters
	• Any **changed** parameters
	• **Lead test results** for each lead/coil as applicable:
	  ○ Sensed amplitude
	  ○ [1]Pace threshold
	  ○ Impedance
	  ○ **[1, 2]Adequate safety margins for the above**
	Ensure documentation of the actual tests for quality control (e.g. save test strip IEGMs, and/or daily test trends showing stability and standard deviation values if provided)
	• All **additional test results**, **device diagnostics,** and **relevant rhythm history,** Including performance graphs, battery data, numerical findings and relevant IEGMs.

[1] Items of special interest to anaesthesiologists

[2]Items most likely to be useful to a GP.

[3]The full programmer PDF is analogous to the image and data files generated by an Echo machine. It contains data that is essential for reporting, expert reference, and quality control, and should be archived by the CIED team (not left on the programmer or deleted).

Appendix 2.

An example of flow chart for management of patients with CIEDs undergoing radiotherapy (Personal communication Daniel Cehic and Phuong Tran, Geneiscare, October 2021).