

HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs): Description of Techniques, Indications, Personnel, Frequency and Ethical Considerations

Developed in partnership with the Heart Rhythm Society (HRS) and the European Heart Rhythm Association (EHRA); and in collaboration with the American College of Cardiology (ACC), the American Heart Association (AHA), the European Society of Cardiology (ESC), the Heart Failure Association of ESC (HFA), and the Heart Failure Society of America (HFSA). Endorsed by the Heart Rhythm Society, the European Heart Rhythm Association (a registered branch of the ESC), the American College of Cardiology, the American Heart Association

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Preamble

This document represents expert consensus concerning the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs). The views expressed are of the international writing group consisting of seven cardiac electrophysiologists representing the Heart Rhythm Society (HRS), six from the European Heart Rhythm Association (EHRA) as well as one heart failure specialist representing the Heart

Failure Society of America and another from the Heart Failure Association of the European Society of Cardiology. Members from our writing group also represented the American College of Cardiology (Kenneth A. Ellenbogen, MD), the European Society of Cardiology (Silvia G. Priori, MD, PhD), and the American Heart Association (David L. Hayes, MD). The topic covered by this document includes the monitoring of CIEDs with a description of the technology, indications for use, personnel involved in monitoring and the frequency and types of monitoring events. Also covered are issues in regard to data management, regulatory environments, reimbursement and ethical considerations in respect to device

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inactivation. This statement summarizes the opinion of the writing group members based on their own experience in treating patients, as well as a review of the literature, and is directed to all health care professionals, health care institutions, CIED manufacturers and governmental, reimbursement and regulatory bodies who are involved in the care of patients with CIEDs. When using or considering the guidance given in this document, it is important to remember that the ultimate judgment regarding care of a particular patient must be made by the health care provider and patient in light of all the circumstances presented by that patient.

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Introduction

Cardiovascular implantable electronic devices (CIEDs) have expanded in number and complexity since their introduction in 1958 and now include cardiac pacemakers, implantable cardioverter-defibrillators (ICD), implantable cardiovascular monitors and implantable loop recorders. Distinctions are not always complete; bradycardia support, ventricular tachyarrhythmia therapy, biventricular stimulation, arrhythmia monitoring, and heart failure data are often combined into a single device. Many aspects of CIED monitoring are discussed in this document, including, monitoring technology; indications, frequency and content of device follow-up; data management; personnel roles and responsibilities; CIED management in dying patients; and reimbursement issues. However, beyond listing the required elements, it is beyond the scope of this document to describe the technical details used during each type of CIED follow-up visit.

It is estimated that in 2006, approximately 280,000 pacemakers and 160,000 ICDs were implanted in North America, while the corresponding numbers for the countries of western and central Europe were 250,000 and 50,000, respectively. This expanding population of patients with implantable cardiac devices requires special care within a framework of principles that optimizes their management. The incidence of CIED implantation is increasing with the estimated implanted prevalence of these devices in 2007 throughout North America and Europe as listed.

	Pacemakers	ICDs	CRTs
North America	564,074	234,780	148,092
Europe	683,472	87,747	61,010

The logistics of monitoring these devices have already placed a substantial and increasing burden on the cardiovascular community.¹

Number of follow-up encounters/year	Pacemaker therapies	ICD therapies
North America	1,610,000	2,065,000
Europe	1,680,000	500,000
Total numbers	3,290,000	2,565,000

Based on one encounter/year for Pacing in North America and Western Europe. 2.5 encounters/year for ICDs in Western Europe, and 3.5 in North America. Pacemaker therapies are pacemakers with and without CRT and ICD therapies are ICDs with and without CRT.

Implantable cardiovascular devices are indicated for the treatment, diagnosis and monitoring of bradycardia, tachycardia and heart failure. As the indications for implantation broaden and the frequency of device utilization increases, the management of these patients and their devices has become a distinct and at times complex medical service. This service diversity spans the entire spectrum of subjects, including those who are healthy or ill, sedentary or active, youth or seniors. In addition, since these are implantable devices, there is an ongoing opportunity and responsibility to manage both the patient and device. However it is the purpose of this guidance document to focus on outlining the management of just the *CIED* from the time just after implantation until explantation or the patient's death. Although important, the evaluation and management of *the patient* and the use of external diagnostic tools not intrinsic to the implanted device are not the focus of this document and will be discussed only as adjunctive issues.

The topic of device follow-up has been long neglected, and although widely practiced there is little in the way of guidance for practicing physicians, hospitals, regulatory agencies and private and public insurance agencies to provide these services. In addition, there have been important and substantial advances in the diagnostic and therapeutic tools provided by these devices and in the strategies and instruments used for their management. This document is written to describe the medical aspects of these activities, in other words what is needed to provide the *medically appropriate level of care*. Despite the relative paucity of previous publications on this topic, there is substantial experience, skill and consensus. It is the consensus of the writing committee, representing primary care in North America and Europe that is presented in this document. However, in order for patients to receive this level of care there is a need to develop and implement the technical, logistical and financial systems related to CIED follow-up. The implementation details will vary in differing geographic locations with diverse medical and governmental structures, but it is the intent to provide guidance for universally applicable and clinically appropriate monitoring of CIEDs throughout North America and Europe.

Definitions

Cardiovascular implantable electronic device (CIED):

Cardiovascular implantable electronic devices include the pacemaker (PM), implantable cardioverter-defibrillator

(ICD), cardiac resynchronization device (CRT), implantable loop recorder (ILR) and implantable cardiovascular monitor (ICM). Pacemakers, ICD and CRT devices have been described in detail and all of these devices collectively have been termed cardiovascular implantable electronic devices (CIEDs).^{2,3}

Clinically employed allied professional (CEAP):

The diverse group of nurses, physician assistants, technologists, technicians, and engineers who are dedicated to promoting excellence in the care of patients with CIEDs, who have cardiac rhythm or heart failure disorders. The CEAP works in collaboration with and/or under the direct supervision of a CIED physician and is not employed by a CIED manufacturer.

Heart failure (HF) care:

For patients with CRT devices or for those who have an ICM in place, some CIED follow-up clinics will also be responsible for HF management. In the case of clinicians providing care in an HF Clinic, the HF physician may be responsible for acting on device output, such as hemodynamic data (either in person or remote and in "real time" or not). In these cases, there must be an explicit understanding and an agreement of responsibilities and scope of care between the CIED Clinic physician and the HF physician.

Device interrogation:

Uses telemetry to retrieve information on the CIED programmed parameters and data stored in the CIED memory. These data may be retrieved and stored directly in a CIED programmer, on a dedicated personal computer or retrieved and stored remotely on a server to be viewed on an Internet website.

Device programming:

Is a non-invasive, stable, reversible change in some of the operating parameters of the CIED that enables the physician/CEAP to select CIED settings to assess and optimize the CIED system performance and longevity and to tailor these parameters to meet the individual patient's condition.

Home monitor/communicator:

A device designed to receive telemetry from a specific CIED and transmit the encrypted data using telephone technology to a remote-secure monitoring center or file server. Often the home monitor/communicator is stationary and connected to the Internet through an analog telephone line in a patient's home, but it can also be mobile/portable unit and connected via cellular technology.

Implantable loop recorder (ILR):

ILRs are CIEDs that store in device memory recordings of the heart rhythm and data derived from the cardiac rhythm.

Implantable cardiovascular monitor (ICM):

ICMs are CIEDs that store cardiovascular physiologic data such as intracardiac pressure waveforms and other data in the device memory, but instead of focusing only on heart

rhythm, the hemodynamic and cardiovascular physiologic information stored in these devices is used as an aid in managing patients with chronic cardiac diseases such as heart failure.

Industry employed allied professional (IEAP):

The IEAP has expertise with CIED technology and is employed by the CIED manufacturer. Although the IEAP may have formal credentials of a CIED nurse or EP lab technician and may be certified by the International Board of Heart Rhythm Examiners as a certified cardiac device specialist, there are limits on the roles and activities that these people can engage. The details are listed in Section 4 and quoted from the 2001 NASPE guidelines for the "Industry Employed Allied Professional."⁴

Programmer:

A device designed to receive telemetry from a family of CIEDs from a specific manufacturer; will display and print the information to the operator and temporarily or permanently adjust (program) the behavior of the CIED. Generally the programmer technology includes a specifically modified microcomputer and a programming wand or antenna to communicate with the CIED. The programmer can be equipped with a printer, storage devices such as hard drives and communication connections such as Ethernet, USB, WiFi, infrared and parallel and serial port connections.

Section 1: description of CIED technology

CIEDs have numerous programmable features and can also store substantial amounts of diagnostic information related to device function, arrhythmia frequency, cardiovascular hemodynamic parameters including transthoracic impedance and patient activity. Bidirectional telemetry using encoded and encrypted radiofrequency signals allows transmission of information to the CIED from the programmer and from the programmer to the CIED. This process permits review of the programmed parameters and stored diagnostic data and reprogramming of CIED parameters to correct identified malfunctions and/or to optimize CIED function.⁵ The evolution of CIED technology has led to the development of specialized CIED follow-up clinics that are staffed by trained physicians and CEAPs.⁶⁻⁸

In addition to programmer based interrogations, CIED follow-up has been expanded with a system of remote interrogation tools. These home monitors/communicators employ telephone based links to extend the bidirectional telemetry links into the patient's home or with cellular technology unrestricted by land lines.⁹⁻¹³ In addition to information stored within the CIED, other medical information may be transmitted from linked measurement devices such as sphygmomanometers or weight scales. Remote transmissions may be completed by connecting the transmitter to any form of telecommunication network (e.g., both wired and wireless). While the technology presently exists to enable remote programming as well as remote interrogation of CIEDs, as of 2008, the programming feature is not yet clinically implemented. The availability of remote monitoring and, in the future, remote programming of CIEDs requires a change in CIED follow-up paradigms and protocols. Remote monitoring technology reduces the need for

some face-to-face clinic visits and may facilitate, when needed, visits triggered by a clinical event. In addition, remote monitoring and the warehousing of monitoring data may facilitate the detection of CIED system performance issues and clinical conditions that may lead to the need for increased frequency of in person or remote surveillance.

Wearable defibrillators, Holter monitors, and cardiac event monitors are similar to CIEDs but are not included in this discussion further other than to acknowledge that the technologies and systems used to manage these tools overlap substantially with the CIEDs discussed in this document.

Technology available for CIED monitoring

During face-to-face evaluations of the CIED, several functional parameters of the implanted device are checked using a specifically designed instrument (programmer) produced by the manufacturer of the CIED. The information retrieved during the interrogation of the CIED is used to evaluate 1) the function of the device including the programmed settings and when present 2) physiologic parameters concerning the cardiovascular status of the patient. Whenever appropriate, it is possible to modify CIED settings and functions to optimize the device operation and to customize the CIED parameters to patient specific and clinically appropriate values.

During remote interrogation, the measured CIED and recorded clinical patient data as well as the programmed parameters of the device can be retrieved from the CIED. Although technically feasible and almost certainly reliable, implementation of temporary or permanent remote programming has not yet been permitted. Protecting patient safety is the primary concern and the reason that remote programming is not currently used. This concern is related to the limited ability to respond to potential changes in the patient's condition as a result of the altered CIED parameters. As greater experience with remote monitoring is gained and as a secure support system for remote management of patients is developed, this is likely to be implemented.

The programmer is a computer with specific software and associated hardware modifications that provide for the highly reliable exchange of the encrypted information and precise communication with the CIED. The programmer uses bidirectional telemetry to receive the stored information from the CIED and to modify (program), as appropriate, the settings of the CIED. Traditionally a "wand," attached by a wire to the programmer, is positioned on the body's surface over the CIED implantation site to receive the telemetry signal. However the distance for radiofrequency communication has increased from several cm (2–5 inches) to several meters (10–20 feet) and some devices communicate without a wand. The longer distance telemetry is device specific but employs either the Industrial, Scientific and Medical (ISM) band from 902–928 MHz or a subsection of the Medical Implant and Communications (MICS) band from 402–405 MHz. Use of telemetry in these frequency spectra allows the telemetric signal to be reliably and securely sent directly to and from the programmer and the CIED, which is more than 10 feet (3 meters) distant. This is useful during CIED implantation, in the device clinic (using a programmer) and also in the patient's home as a part of

remote monitoring (remote telemetry device). When the encrypted data need to be transmitted very long distances (miles-km) from remote cities (e.g., home), the communication is done via telephone lines or cellular phone technology, typically from the home monitor/communicator to the CIED clinic or data repository.

Programmers have integrated printers to document the CIED settings, but home monitor/communicators and programmers can also communicate the interrogated data to a remote printer for a hard copy presentation or be transferred to a CIED database or Electronic Medical Record (EMR). To connect to the database or EMR, the data are saved and transferred via disc, CD ROM, USB drive, directly by a network cable, Bluetooth or WiFi communication to an Internet or intranet network connection. The ISM and MICS radiofrequency communication is used only for connecting the CIED to the programmer or remote telemetry device and not for connecting the programmer to printers, saved files, the database, EMR or registries.

Remote monitoring systems enable patients with CIEDs to transmit the stored programmed and measured data stored within the CIED using a remote telemetry device home monitor/communicator, as mentioned above. These bedside or handheld communication devices employ either a wand with short distance radiofrequency communication employed by programmers or by the long distance ISM or MICS band radiofrequency telemetry described above. This home monitor/communicator is then linked by telephone to a central (Internet based) data repository where the data are stored and analyzed and disseminated electronically.^{14,15}

Remote monitoring of pacemakers to a limited degree has occurred for decades using transtelephonic monitors using modem technology. These older style monitors transmit the patient's heart rhythm recording by converting the electrocardiographic information into sound and send it over the telephone lines to a decoding machine, which changes the sound back into the "rhythm strip" on the other side. This technique permits the physician to monitor heart rate, rhythm and battery status. To a limited degree it also permits an assessment of sensing and capture function. It is important to consider that the remote interrogation monitoring systems, which are progressively being introduced by all of the CIED manufacturers, are not to be used in patients implanted with some older CIED models.

Section 2: indications, paradigms, frequency and content of CIED follow-up

A variety of follow-up paradigms exist, although the previously published guidelines are no longer accurate and primarily refer to pacemaker follow-up based on earlier generations of implantable devices. The ideal follow-up paradigm will be determined for the individual patient by the follow-up clinic physician(s) and CEAPs. Factors that will influence the follow-up paradigm might include patient preferences, the patient's underlying medical condition, CIED-related issues, geographic isolation from direct follow-up, cost-effectiveness of follow-up paradigms and the follow-up clinic resources. In addition, some physicians and patients for technical, personal and medical reasons may prefer face-to-face evaluations. The role of the

Industry Employed Allied Professional (IEAP) in CIED follow-up is discussed in Section 4.

Goals of follow-up

The major goals of CIED monitoring programs can be divided into four groups: patient-related, device-related, disease-related and communication-related objectives. These include providing patient and family education and reassurance, maintaining patient records and institutional databases, assessing and optimizing CIED system performance and safety, in addition to identifying and correcting, if possible, any device system abnormalities, anticipating the need for and planning elective CIED replacement, when feasible monitoring cardiac arrhythmias and physiologic parameters, and communicating information related to CIED monitoring to involved physicians and other health care providers where appropriate. The specific goals of CIED follow-up are summarized in *Table 1*.

Paradigms for CIED follow-up

In person monitoring (physician and/or CEAP physically present):

Traditionally, monitoring of CIEDs has been performed by a trained physician or CEAP in a designated CIED follow-up clinic, medical institution or physician's office. The completeness of this in person CIED monitoring session may vary depending on the indication for the encounter.

Table 1 Goals of monitoring CIEDs

Patient related

- Optimize the patient's quality of life
- Optimize pacemaker/ICD system function to meet the patient's clinical requirements
- Identify patients at risk and initiate appropriate follow-up with field safety corrective action/safety alerts
- Triage non-CIED-related health problems and make appropriate referrals

CIED related

- Document appropriate CIED function
- Identify and correct abnormal CIED behavior
- Maximize pulse generator longevity while maintaining patient safety
- Identify CIEDs approaching end of battery life, to identify leads at risk of failure, and to organize CIED replacements in a non-emergent manner

Disease related

- Document the nature and frequency of arrhythmias over time and correlate with patient symptoms and determine the appropriateness of CIED response to these arrhythmias
- Document (where feasible) hemodynamic status, transthoracic impedance, patient activity and other physiologic parameters over time as part of chronic disease monitoring in heart failure
- Monitor response to therapy

Communication

- Maintain a patient database
- Timely communication to the patient and relevant health care providers of CIED- and disease-related information
- Provide technical expertise and education to colleagues, patients, and community

Complete CIED evaluation:

Includes interrogation of the device, review of device data and device programming parameters and temporary programming for assessment of system function such as capture thresholds and sensing thresholds. Permanent programming changes may or may not be made on completion of the follow-up visit. This evaluation may be performed by a physician or by the CEAP trained in CIED follow-up under CIED or HF physician supervision (*Tables 2 and 3*).

Table 2 Factors determining the type and frequency of CIED follow-up

Patient related

- Stability of rhythm and cardiovascular symptoms
- Specific issues requested by the patient, family or local physician to the CIED clinic
- Change in anti-arrhythmic or heart failure therapy
- High or unstable pacing thresholds
- Frequency of ICD therapies
- Patient's inability to accurately report symptoms
- Planned surgeries/medical interventions
- Patient distance from follow-up clinic
- Other medical/social factors

CIED related

- Historical reliability of the CIED system (consider lead and pulse generator independently, defibrillation thresholds)
- Age of CIED
- Programmed parameters (factors that influence battery longevity, pacing thresholds, pacing frequency, frequency of shock therapy)
- Complexity of CIED
- Arrhythmia/heart failure diagnostics (including physiologic monitoring, transthoracic impedance, patient activity)
- Medications that may influence pacing or defibrillation threshold, arrhythmia detection

Disease related

- Frequency and severity of symptoms
- Changes in cardiovascular therapy

Table 3 Minimum frequency of CIED in person or remote monitoring*

Pacemakers/ICDs/CRT

- Within 72 hours of CIED implantation (**In Person**)
- 2–12 weeks post implantation (**In Person**)
- Every 3–12 months pacemaker/CRT-P (**In Person or Remote**)
- Every 3–6 months ICD/CRT-D (**In Person or Remote**)
- Annually until battery depletion (**In Person**)
- Every 1–3 months at signs of battery depletion (**In Person or Remote**)

Implantable loop recorder

- Every 1–6 months depending on patient symptoms and indication (**In Person or Remote**)

Implantable hemodynamic monitor

- Every 1–6 months depending on indication (**In Person or Remote**)
- More frequent assessment as clinically indicated (**In Person or Remote**)

*More frequent in person or remote monitoring may be required for all above devices as clinically indicated.

Results of programming made by the CEAP should be approved by a CIED physician specialist or by a physician with expertise in CIED management. Complete CIED evaluation should be undertaken at routine scheduled device follow-up visits per the recommended schedule for that particular device. Complete CIED evaluation may also be required if the patient develops significant cardiac or arrhythmic symptoms (e.g., shock therapy, worsening congestive heart failure or sustained palpitations) or if a CIED alert is detected (e.g., patient hears an audible alert, or a remote transmission is triggered by a CIED programmed alert).

Interrogation evaluation:

Involves the in person or remote (e.g., from patient's home) interrogation and review of CIED data without additional device testing or programming changes. This evaluation may be performed by a physician or by the CEAP at a designated follow-up site. CIED interrogation without programming may be indicated for a number of conditions. Some examples include monitoring response to antiarrhythmic drug or heart failure therapy, monitoring battery voltage/impedance for indicators of battery depletion or monitoring device function if the device is subject to a field safety corrective action or safety alert.

Periprocedural CIED evaluation/reevaluation:

Involves interrogation and review of specific device data and function and possibly temporary reprogramming of a CIED parameter prior to and/or following a scheduled surgery, procedure or test. The programming is designed to avoid causing morbidity during the procedure and to prevent damage to the CIED. An example is temporarily programming off tachycardia detection or ICD therapies in a patient undergoing surgery where electrocautery may be applied in close proximity to an ICD and reprogramming the original parameters on completion of the procedure.

Remote monitoring:

Some implantable cardiac CIEDs have the capacity to have interrogation evaluations done outside of a medical facility, usually the patient's home. Remote monitoring has the potential to provide timelier and nearly identical information on CIED performance as a traditional in person interrogation. Some method for communication of information between the patient and the physician and/or CEAP responsible for CIED follow-up is an important component of remote monitoring.

Patient initiated remote transmission:

Includes interrogation and transmission of CIED and patient data. This interrogation and data transmission must be initiated by the patient. This encounter may be a scheduled CIED interrogation planned by the follow-up clinic or an unscheduled CIED interrogation activated by a patient symptom (dyspnea, ICD shock or palpitations) or detection of a CIED alert (audible tone or vibration).

CIED initiated remote transmission:

Includes interrogation and transmission of device and patient data. Depending on the CIED, the patient may *not* have to apply a wand in proximity of the device but the

home monitor/communicator must be within a certain distance of the patient/device for a successful link and interrogation. The trigger for the transmission is either time (scheduled date and time) or programmed CIED alerts, e.g., significant change in lead impedance, development of persistent atrial fibrillation (AF), frequent episodes of nonsustained ventricular tachycardia, delivery of frequent shocks, or changes in hemodynamic status.

Transtelephonic monitoring without interrogation:

Allows for frequent monitoring of the pacing rate, determination of the underlying rhythm and timely detection of battery depletion. This technology is solely limited to pacemaker follow-up. Each transmission usually includes an initial rhythm strip and then a rhythm strip demonstrating the magnet rate of the pacing system. Telephone transmissions provide only a brief snapshot of the cardiac rhythm and thus intermittent problems may not be detected. Given the limitations of telephone transmissions to detect device system problems, this approach should not be the sole means of pacemaker follow-up.⁶ Telephone transmissions have value in monitoring pacemakers approaching battery depletion and need for planned replacement.

Type and frequency of CIED follow-up:

The factors determining CIED follow-up type and frequency are summarized in *Table 2*. In person device monitoring with the presence of a physician or a CEAP is indicated currently when CIED programming is required or anticipated. The patient's medical condition will also determine whether CIED monitoring is performed in person or remotely. If the patient's cardiovascular status is unstable or frequently changing, in person follow-up may be required to address the management of the underlying medical problems. Since remote device monitoring is not accompanied by a direct cardiovascular assessment and may not be accompanied by a cardiovascular history, it is recommended that any patient with a CIED be assessed in person at least once a year. Remote monitoring of CIEDs is indicated when the patient's medical condition is stable and no anticipated device programming is required. Remote monitoring has value during the maintenance phase of CIED follow-up (stable device function), during accelerated follow-up to plan elective device replacement and in the case of a field safety corrective action/safety alert where accelerated monitoring may detect a CIED malfunction.

At present, there are wide variations in device follow-up frequency worldwide. Recognizing that the frequency and type of device monitoring must be individualized based on device- and patient-related factors, the minimal recommended schedule of device follow-up is summarized in *Table 3*. In person monitoring should be performed for each patient following implantation but before hospital discharge. Many complications, such as lead dislocation and perforation, can be seen within 24 hours after implantation. This assessment should document normal CIED function, establish patient specific programming, document initial telemetry values, ensure the absence of operative complications, educate and emotionally support the patient and the family and provide a CIED identification card to the patient. Review of an initial chest x-ray to document

electrode position in the heart is essential. The first post-discharge visit may take place in the first 4 weeks after implantation. A second in person follow-up should be performed during the early surveillance period (4 to 12 weeks post implant). At the first or second visit, sutures may be removed and at both visits the wound is carefully assessed for appropriate healing. At the second visit, interrogation of the CIED is mandatory to document appropriate device function and review diagnostics. Careful analysis of pacing and sensing thresholds should be done and device programming should be performed to optimize the CIED function for the patient and to optimize device longevity. For some patients with cardiac resynchronization therapy, procedures for optimization of CRT therapy may be undertaken at this visit. At this visit, clinical or CIED-related warnings that might trigger a consultation should be carefully explained to the patient. If remote CIED monitoring is available and desired, this should be carefully explained to the patient and family. When a patient cannot visit the electrophysiologist or implanting physician because of geographic location, physical or emotional reasons, or there is concern about CIED performance or a medical problem he or she should visit a local physician with CIED expertise.

Either in person or remote follow-up should be planned every 3–12 months thereafter depending on the patient's clinical condition and the type of CIED. ICD follow-up should usually occur at no longer than 6 month intervals. Since not all devices with pacing therapies have automatic features to measure pacing or sensing thresholds, an in person assessment of these parameters is recommended every 6–12 months, with the frequency varying based on the variables described in *Table 2*.

Intensified (monthly) in person or remote monitoring should be considered when the CIED nears its elective replacement indicator (ERI). Specific indicators of battery depletion should be used to initiate a change in surveillance frequency. Intensified in person or remote monitoring (interval tailored to the situation) may also be implemented in the event of a suspected lead or CIED dysfunction or in the event of a field safety corrective action or safety alert.

CIED assessment

The content of a CIED follow-up assessment depends on clinical and technical factors and upon the type of CIED. A large number of parameters can be monitored. The content and frequency of device encounters are determined by the factors listed in *Table 2* and should be considered the patient's prescription. Suggested guidelines for content of follow-up are provided in *Table 4*.

Although remote CIED follow-up has the potential to increase patient safety and convenience, prospective randomized or observational studies of the benefit, content and frequency of remote follow-up have not yet been performed in large numbers of patients. More clinical information is needed to document the magnitude of the clinical benefit of this new technology, the optimal frequency and intensity of its use as well as its economic impact on the health care system and the patient.^{16–19} A wide range of follow-up frequencies and intensities are recommended in *Tables 3* and *4*. The CIED follow-up prescription must be individualized to the patient's clinical status.

Table 4 Content for CIED in person or remote monitoring

Pacemaker or ICD required parameters: in person or remote monitoring: 3–6 months suggested

- Battery voltage and battery impedance
- Magnet rate (for pacemakers)
- Charge time (for ICDs)
- Update current rhythm diagnosis and pacemaker dependency

Pacemaker/CRT-P in person follow-up: 6–12 months suggested

- Battery voltage (and impedance)
- Magnet rate
- Pacing and sensing threshold(s) for atrium, right and left ventricles (all leads)
- Pacing lead impedance(s) for all leads
- Arrhythmias detected by device (e.g., mode switches, high ventricular rate episodes, etc.)
- % of pacing/sensing in each chamber
- Review of programmed parameters
- Review of any "safety" or automatic device alerts
- Review of hemodynamic measurements or recordings of any other programmed parameters (e.g., heart rate variability, activity level, etc.) when available

ICD/CRT-D in person follow-up: 3–6 months suggested

- Battery voltage (and impedance)
- Capacitor charge time
- Pacing and sensing threshold(s) for atrium, right and left ventricles (all leads)
- Pacing lead impedance(s) for all leads
- Shocking impedances for defibrillation leads
- Arrhythmias detected by device
- % of pacing/sensing in each chamber
- Therapies required for termination of SVT/VT/VF
- Review of main programmed parameters
- Review of any device triggered alerts
- Review of hemodynamic measurements when available

Implantable loop recorder in person or remote monitoring: 1–6 months suggested

- Integrity of sensing system
- Arrhythmias (symptomatic) recorded
- Arrhythmias (asymptomatic) stored

Implantable hemodynamic monitor in person or remote monitoring: 1 week–3 months suggested

- Battery function
- Integrity of lead
- Hemodynamic measurements of variable(s) being monitored
- Arrhythmias detected

Section 3: data management considerations

In the era of electronic data storage and Internet-based data transmission, data safety and confidentiality issues have become paramount concerns. There are no uniform worldwide regulations governing manufacturer tracking or record-keeping requirements. In the United States, there is a legal requirement for registration and tracking of clinical devices, including CIEDs (Safe Medical Devices Act of 1990²⁰; amended by the FDA Modernization Act of 1997). In Europe there is only a requirement for the manufacturer to keep manufacturing and distribution records of CIEDs (Active Implantable Medical Device Directive of June 1990).²¹ In both North America and Europe, manufacturers are required to monitor the performance of their device (post-marketing surveillance), to submit reports on adverse events to the

regulatory authority, and to take appropriate corrective and preventive actions. However it is a basic global clinical necessity for follow-up physicians, clinics and hospitals to maintain CIED registration and to facilitate timely and effective communication with patients.

Data registration and maintenance (secure and permanent) is the joint responsibility of the CIED manufacturer, distributor (where involved), implanting center and physician. The registration must comprehensively document all system elements, patient data and relevant clinical information. The system elements include the model and serial numbers of the CIED, leads, adapters, and any other implanted items. In addition to device data, patient data must be included with the system registration. The patient data should include accurate patient demographics, date of device implant, communication details such as address and telephone number and all rhythm diagnoses at the time of CIED implantation or replacement.²² Relevant clinical information about device removal or abandonment of a CIED should be reported and tracked so that devices no longer in service can be eliminated from the tracking processes in the event of future field safety corrective actions or safety alerts. This permits accurate manufacturer assessment and reporting of device reliability and survivability under actual use conditions. Standardization of implant, removal, deactivation and abandonment diagnoses facilitates the ability to understand the causes of CIED failure and other reasons contributing to intervention as recently emphasized by statements by HRS and EHRA.^{23,24}

Device implant registry

Our “global society” in which patients travel internationally would benefit from having a centralized registry to manage mobile patients and such a data source would allow accurate information on device use, removal and abandonment. As it currently stands, companies, governments and/or health care providers independently store device-related data and there is no method to consolidate these data in case of need such as quality monitoring and safety alert/field safety corrective actions. The optimal solution is a single, centralized, international device registry collating and reconciling all information on every patient but it is the fact that today such an ideal is unachievable as the barriers are numerous.

Currently, each country is required to maintain its-own registration and tracking data. However laws governing the need for submission and storage of the data required to care for patients and to allow for notification in case of a field safety corrective action or safety alert are incomplete and often incompatible between nation states. Governments, health care systems, manufacturers and professional associations must commence a process that can lead to international agreement on the optimal level of data storage and access (for clinical use, research and health care-planning). This must particularly address the prohibition of data provision with patient identifiers to repositories outside of one’s own national borders as this greatly limits the data fluidity necessary in the global health care environment.

In order to be most effective, the registry data must be as complete as possible.²² It should be mandatory by law that registration data be submitted at the time of implant,

Table 5 CIED registry options

1) Option 1: Manufacturer stores own data
a) Advantages
i) Implant data obtained at time of surgery
ii) No additional cost to the health care system (they already have databases to manage these data)
b) Disadvantages
i) Lack of coordination with other manufacturers’ databases
ii) Incomplete and inaccurate data due to abandonment and change-out with other manufacturer’s device
iii) Lack of a universal system to access data
(1) Need to call multiple manufacturers to obtain required data
2) Option 2: Government run database
a) Advantages
i) Consolidation of data into one site
ii) Allows data comparison and conflict resolution
b) Disadvantages
i) Each government would have to run a database
(1) More expense
(2) Lack of coordination between databases
ii) Redundancy of effort with increased overall expense and duplication
3) Option 3: Health care providers store data
a) Advantages
i) Protection of patient data at the source
ii) Potentially most compliant with restrictive privacy laws
b) Disadvantages
i) Widely dispersed data without ability to search or notify
ii) Completely unworkable in case of a field safety corrective action or safety alert
iii) Data gathering for reliability nearly impossible
iv) Patient mobility makes finding implant and follow-up information extremely difficult

explant or abandonment of any device. To further complete the integrity and completeness of such a registry, it would be possible to leverage other data sources, such as the National Death Index from Medicare (USA), and other European and North American data sources. Linking to the National Death Index would provide an opportunity to bring “closure” to a patient file. It may even be possible to query the physician of record as to the cause of death to be stored as an additional data element. Other registry options with attendant advantages and disadvantages are noted in *Table 5*.

It should be noted that a number of device registries and databases currently exist. Many of these collect similar data, but are based in different countries or are run by people with proprietary interests. A listing of these entities is provided in Appendix I.

State of the art security is mandatory to maintain confidentiality for patients and protect proprietary interests of device manufacturers with facilitated access for health care providers to expedite patient care. Often data sets without patient identifiers are useful to create benchmarks analyzing demographics and temporal trends to improve care without compromising privacy. Having access to the registration data allows the best management of patients

who may not be able to provide device information when presenting emergently.

Follow-up data management

The responsibility for follow-up data should be delegated to the implanting/follow-up physician or institution. However, patients should be able to access their own implant and follow-up data to verify and request an update if appropriate. By participating in the maintenance of their own data, keeping accurate records of demographics would be made easier and more accurate.

It is recognized that different device models may provide various types and degrees of data. The follow-up is best managed using longitudinal stored and measured CIED data. Both single data point information, graphs and trended data facilitate CIED and patient disease and comorbidity management. Both registration data and follow-up clinical data are best managed in a database. The basic elements that should be collected have been discussed in Section 2 (summarized in *Table 4*).

Key to the usefulness of a database is the accuracy of the data being placed into it. Manual data entry should be discouraged as it creates the opportunity for error. Universally accepted data output and exchange formats need to be defined by the manufacturers to facilitate accurate and efficient data transfer from the programmers to the database. A database that directly communicates with the registration system would automatically update patient demographics and contact information, as well as correctly identify the CIED follow-up physician.

The recent advent of highly sophisticated technologies that facilitate “remote” data acquisition and transmission is revolutionizing the processes of device data collection. Linking of CIED data acquisition to patient disease and comorbidity management data may be best achieved by remote CIED data retrieval. Thus a “remote management” strategy will become the standard of care in the immediate future and perhaps by the end of this decade. It is in the area of disease management that this development has created a new set of opportunities and problems. The opportunities include the ability to collect huge amounts of data over time via remote monitoring services. The ability to interrogate, transmit and store these data provides access to a large number of patients and their devices. Significant concerns have been raised regarding where remotely collected data are stored relative to the country where the device is registered. Again, the “globalization” of follow-up and of patient mobility makes it virtually impossible to keep the data within the borders of a single country. Patients currently transport their data across national boundaries within the CIED. Remote interrogations make the data available and stored securely on the Internet, thus available across national boundaries. These issues must be addressed by governments in order to provide the legal framework for effective and efficient patient and device management.

Safety alert and field safety corrective actions

It must be reiterated that access to patient registration data becomes most critical when a field safety corrective action, safety alert or “recall” is issued.²³ A central registry point greatly simplifies notification of the follow-up physician and the patient. Until a global device registry becomes a

reality, national and regional registries must develop information technology solutions that can serve as a centralized resource and act as the conduit for manufacturers and regulatory agencies.

Section 4: responsibilities and roles of personnel

It is important to realize that all parties involved in CIED monitoring must be responsible for specific aspects of the process in order to achieve optimal success from monitoring. Parties that have specific responsibilities include the patient, caregivers (which includes the referring physician and the physician and authorized CEAP that do the actual monitoring), the device manufacturer and regulatory agencies.

Prior to implantation of any CIED that must be monitored and/or is capable of providing monitoring a “care agreement” should be in place that sets expectations for patient follow-up. This agreement may be formal or informal. For example, it could exist in the form of a letter of understanding or an existing policy that is in force and relates to the following areas: a) identification of the clinician who is responsible for receipt (including timelines for acknowledgment of data) of remote monitoring data; b) identification of who will initiate the response (and to whom, patient or other clinicians such as a HF Clinic clinician) regarding the monitored data received; c) the clinician identified in (b) will update the other members of the care team—especially the primary care provider—and will state by which manner (verbal or preferably written).

It should be stated from the outset that there is a great deal of heterogeneity in the management of many aspects of monitoring when comparing individual caregivers, hospitals and countries. The heterogeneity is particularly striking when legal issues are considered. Even though what becomes practically allowable or expected in specific environments will be important “locally,” the discussion of the responsibilities of all parties involved in remote monitoring will focus on what is medically appropriate.

Patient responsibilities

When the CIED is implanted, pre- and/or post-implant, the patient must be educated regarding the need for the device, the device function, any restrictions that apply post-implant, post-implant follow-up methods, and schedules. Assuming all appropriate components of CIED education are offered to the patient, it is the responsibility of the patient and/or the patient’s family to carefully study the information and have a thorough understanding of all components. That is not to say that patients are responsible for their own education about the device. However, it is the patient and/or the patient’s family’s responsibility to review the information, ask more questions if there is confusion, and be clear about the follow-up schedule and adherence to the follow-up schedule.

The patient receives an identification card either at the time of implant or following implant. It is the patient’s responsibility to carry the identification card with him/her to facilitate care when he/she see a caregiver (especially a new caregiver or one associated with a new medical

Table 6 Necessary patient information

GENERAL INFORMATION	Patient contact information CIED physician contact information
	Recurrence of symptoms that existed prior to CIED implantation Change in cardiac medications, specifically antiarrhythmics Encounter with another follow-up center, specifically if any programming was performed Major medical issues that could in any way impact CIED management. For example:
CLINICAL INFORMATION	<ul style="list-style-type: none"> • Trauma at or near the site of the implanted device • Need for therapeutic radiation at or near the implanted device • Diagnosis of a terminal illness • Significant change in mental status • Development of a new clinical condition or planned invasive medical procedure • Exposure to a “shock” from an electrical source

condition) that may not have medical information related to CIED implantation.

If the patient has a change in contact information, e.g., change of address or telephone number, it is his/her responsibility to convey that information to the follow-up personnel. In addition to the need to contact the patient for regular follow-up, there may be other situations when the surveillance clinic will need to contact the patient more urgently, e.g., in the event of an advisory notice. It is critical that the caregivers be able to easily locate and contact the patient or the individual responsible for the patient.

Anything related to the patient’s medical condition that could potentially have an impact on CIED management should be conveyed to the center conducting device follow-up. Even though there may be other situations/issues that are not commonly encountered, *Table 6* includes those things that the patient should be instructed to report to the follow-up center.

Responsibilities of referring/follow-up physician

The referring physician usually provides follow-up clinical cardiovascular care for the patient. In the event the referring and follow-up physicians are not the same person, the latter would be expected to subsume the responsibilities noted here. The referring physician plays an important role in the process of CIED monitoring. There is an important interdependent relationship between the referring or primary care physician, the implanting center, the implanting physician and the CIED follow-up clinic. Discharge reports and implant information and reports from device follow-up should be sent to the referring and/or primary care physician.

The implanting physician has the responsibility to inform the CIED clinic and also the referring physician about any significant changes in the patient’s status that might impact device care or the patient’s care in general. This may include definite or suspected potential complications of

implantation, frequent therapies from the device, specific programmed features that could affect symptoms, etc. Likewise, the referring or primary care physician shall similarly inform the CIED clinic or clinician of significant changes in the patient care that might affect interpretation of symptoms or device performance. This would, of course, also include informing the device clinic of the patient’s death and the circumstances of death. The expected form of communication should be written and each clinician should document this in his/her clinical notes. If there are ambiguities of responsibility for care (medication changes, etc.) or perceived conflicts, direct communication between/among health care providers is required.

Personnel roles and responsibilities

CIED physician:

In the CIED follow-up clinic, responsibilities may be assigned to a physician or an authorized CEAP with expertise in device management. However, it must be remembered that the physician in the CIED follow-up clinic whose name is used to sign off on any orders is ultimately responsible for all aspects of that encounter of the patient’s CIED management.

The CIED follow-up caregivers are responsible for an appropriately timed follow-up schedule as dictated by the type of device and type of follow-up. In the case of CRT or hemodynamic monitoring devices, follow-up processes may involve specialists in HF (*Table 3*). Device follow-up caregivers are responsible for maintaining records of the patient’s follow-up. Components of the stored information should include:

- Original device indication and access to patient history
- Original implant operative record and implant values
- Access to prior transmissions, remote downloads and in-clinic assessments

There must be a systematic assessment and process for response to downloaded information from patients with remote access monitoring. At this time remote data may be delivered in a variety of ways to the physician responsible for the patient’s device follow-up. A well defined after-hours process (preferably written) must exist that will reliably provide a physician to respond to “urgent” alerts generated from remote monitoring.

If a CIED field safety corrective action or safety alert occurs, the follow-up physician is responsible for having a system in place that will assure identification of the patients with the affected pulse generator or lead and facilitate a plan of action for managing the advisory. The manufacturer of the product which is on advisory or recall status may provide a suggested action plan but it is the physician and his/her local institution that must ultimately decide how to manage the patients that they are following.

The CIED follow-up caregivers need to provide direction for patients with any device-related questions. Questions may arise related to sources of electromagnetic interference, travel, battery depletion, participation in competitive sporting activities, intimacy and many other issues that are difficult to predict. Although patient care responsibilities may be delegated to others with significant device experience the CIED physician should be available to handle

queries if needed by the caregivers to whom clinic duties have been delegated.

For the HF patients with CRT devices or those who have hemodynamic monitoring in place, some CIED follow-up clinics will also be responsible for HF management. These responsibilities include download and interpretation of in person or remote hemodynamic data, enacting change in heart failure treatment plan or device programming, and scheduling of future clinical and/or device assessments. Regardless of the place of care, monitoring information would normally be provided to all caregivers involved. Therapeutic heart failure-related decisions should be made by the caregivers responsible for HF management. All therapeutic decisions related to both device management and HF management should be documented and communicated in a timely fashion to others involved in the patient's care. In particular, in person or remote monitoring data should usually be made available to the HF Clinic in time for the next clinical visit.

The responsibilities of the IEAP have long been debated. For many years, in many practices, private and academic, industry personnel would take responsibility for a great deal of patient follow-up. In some situations they were expected to staff the patient follow-up sessions, and at times do independent programming, i.e., program the patient without the physician being immediately available. In 2001 the Heart Rhythm Society (formerly the North American Society of Pacing and Electrophysiology [NASPE]) formed a working group that published a statement on the "Industry Employed Allied Professional"⁴; an update/revision is expected to be posted on the Heart Rhythm Society's website in 2008. However, it should be repeated that what is in this document refers to the guidelines published in 2001 and that there is continued debate regarding some of the guidance summarized in the list below.

Role of industry employed allied professional⁴

The IEAP's role is to provide technical expertise on the implant, use and operation of their companies' equipment with the following stipulation:

1. The IEAP's activities shall be only at the request of the responsible physician;
2. IEAP's can participate in the implantation procedure but as a rule should not enter the sterile field unless they have been granted clinical privileges at the institution
3. IEAP's should perform technical support with the physician in close proximity (that is, in the same room or close enough to respond within minutes);
4. IEAP's may provide technical support to allied professionals employed by the institution that practice "incident to" the responsible physician. The presence of the IEAP does not change the required level of physician supervision of the clinically employed allied professional (CEAP)
5. IEAPs shall not provide technical assistance in a clinical environment when they are alone and unsupervised
6. IEAPs should not provide assistance in a patient's home in the absence of a responsible physician or CEAP. Under rare or emergent circumstances, an IEAP might assist a patient remote from supervision if under direct written

order from the responsible physician and only to the extent allowed by the specific order;

7. Except in an emergency, an IEAP shall not provide technical assistance related to a competitive manufacturer's device;
8. Patients may not be billed for services provided solely by an IEAP. A physician or CEAP is not, however, prohibited from billing for services they themselves deliver with the assistance of an IEAP.

IEAPs shall abide by any and all hospital policies that pertain to their presence and clinical activity. If such policies conflict with applicable state, provincial, or federal law or regulation such as the Health Insurance and Portability and Accountability Act (HIPAA), such law or regulation shall take precedence at all times.

Because remote monitoring was not available in 2001, the Society's Guideline did not reference the industry applied professional's role for the interaction with this technology. Some of the principles, however, apply. IEAPs should not be asked to routinely go the patient's home, hospital or health care facility to perform care based on perceived need that arises as a result of a remote monitoring transmission other than as permitted in the list above.

Responsibilities of manufacturer

There are significant differences in the way in which the CIEDs are regulated in the European Union (EU) and the United States.²⁵ In the EU, implantable medical devices are regulated by one EU Directive that has been transposed into the national laws of each member state.²⁶ The key aspect of medical device regulation in the EU is that the manufacturer is responsible for ensuring that devices meet all of the essential requirements (i.e., list of requirements regarding safety and performance, and/or specific technical requirements). For medium-to-high risk devices (class IIa, IIb, III) the manufacturers call on a third party to assess conformity and then apply for "CE mark" certification. The CE marking process relies on the individual nations to implement regulatory control over the devices. In the United States medical devices are regulated by a single agency, the Food and Drug Administration within the U.S. Department of Health and Human Services. The current normative that deals also with implantable devices is the Food and Drug Administration Modernization Act (FDAMA).²⁷ In the United States, different than within the European Union, the FDA requires class III medical devices to demonstrate *efficacy* in addition to safety.

CIED Tracking

Both European and North American regulatory agencies require manufacturers to perform post-market surveillance and tracking of implantable devices.^{28,29} Tracking is intended to facilitate patient notification and device recall in the event there is risk to patient health and requires attention.

Tracking methods must provide certain clinical information about the location of a tracked device within a specified period of time. Although most manufacturers use similar approaches, the method of tracking is left at the discretion of individual manufacturers. Manufacturers are responsible

for providing a permanent identification card for each patient.

In addition to tracking the location and status of the device, a medical device manufacturer is required to know specific information about the patient and the device such as: device identification (model and serial number), date of shipment, patient identification, date of implant, prescribing and implanting physician, and (when applicable) date and reason for returned product.

Manufacturers must make sure that the tracking method meets all requirements legislated by the competent authorities within individual European countries and/or by federal regulatory bodies in the U.S.

Personal health information must be protected at all times during the tracking process. Patients may refuse to have their device tracked. In that case, the refusal should be documented by the caregiver and the information provided to the manufacturer.

Safety alerts and field safety corrective actions

Both in Europe and in North America manufacturers are required to institute and keep up-to-date systematic procedures to review experience gained from implantable devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions.^{26,27}

Manufacturers are obliged to report to competent authorities all incidents (i.e., events which have led to a death or serious deterioration in the state of health of a patient, user, or other person) or near incidents (i.e., events which might lead to a death or a serious deterioration in health). The manufacturer has to report on these events within a specified time period.

In assessing the link between the device and the incident or near incident, the manufacturer should take into account the opinion of health care professionals, the results of its own preliminary assessment of the incident, evidence of previous similar incidents, and other evidence held by the manufacturer. Safety alerts (recalls) or field safety corrective action notices are issued by the manufacturer directly to implantable device purchasers and/or users, usually following consultation with the local competent authority in Europe or with the FDA in the U.S. Regulatory bodies may also issue their own advisory notices.

It is important to emphasize that the term “recall” has no universal meaning worldwide. In the United States, the FDA uses the term recall to encompass many different actions.²³ In Europe, terms such as “advisory notice” or “field safety corrective action or FSCA” are used.²⁸ The word recall may also miscommunicate the need or urgency to remove the pacemaker, ICD or lead. This implication comes from borrowed connotations derived from recalled cars or children’s toys. It is unusual that an implantable device subjected to a recall requires a surgical intervention. For this reason the Device Performance Task Force of the Heart Rhythm Society urged the U.S. Food and Drug Administration to alter the language to describe these events as safety alerts instead of recalls.²³

Technical assistance

The manufacturer provides both the implanting physician and follow-up clinic with technical assistance regarding

implantable devices. In order to facilitate the follow-up process and improve efficacy, when requested, the manufacturer or distributor also provides technical and educational assistance for interpretation of stored data, elective replacement indicator (ERI), questions regarding longevity, etc.

Government

The government’s responsibility is to ensure that appropriate legislation and regulations are in place to permit the timely, efficient and effective collection and sharing of data in patients with CIEDs. Effective oversight mechanisms are required in order to ensure the above legislation and policies are followed and that personal health information is protected.

- **Regulatory agencies**—Regulatory agencies for a specific country or region are responsible for monitoring device performance with information submitted by manufacturers and keeping abreast of other information gathering centers such as www.pacerandicregistry.com and the NCDR (National Cardiovascular Device Registry)³⁰: http://www.hrsonline.org/Policy/ICDRegistry/icd_registry.cfm.

Regulatory agencies are also responsible for activating appropriate advisory warnings when there is sufficient evidence that patient safety may be a concern. This includes dictating the required action by a manufacturer when safety concerns exist and overseeing the investigation as well as the approval of new devices.^{23,24}

Professional societies

Professional societies have the primary obligation to develop guidelines in an attempt to provide optimal care for all patients with a CIED.³¹ In addition they should provide educational venues that allow caregivers to have the most recent information regarding CIED management.

Hospital and/or outpatient facility

Responsibilities exist for the inpatient and/or outpatient facilities in which the patients receive their care. These components have been addressed in prior guidelines and readers are referred to these citations.^{32,33}

Section 5: ethical considerations

CIED management in dying patients

Medical decisions near the end of life, the autonomy of dying patients under medical care, and the withholding or withdrawal of life-prolonging medical treatments^{34–36} are widely discussed in both the medical and nonmedical communities. There is limited literature that focuses specifically on CIEDs and associated issues arising in terminally ill patients. There is not an established set of guidelines.^{37–42}

This section was written to aid practitioners in making decisions regarding end of life care of persons with CIEDs. It should not be construed as legal or medical advice, nor dictating an exclusive course of treatment or procedure. Variations in practice are clearly warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

Termination of CIED therapy: the rationale, the goals and the consequences

For a terminally ill patient the nature and function of CIEDs should be reviewed and revised in the specific context of the patient's underlying condition and prognosis. Pacemakers and defibrillators are medical treatments and are subject to the same ethical and clinical considerations as any other treatment. The decision to deactivate these devices, even in particularly extreme cases and after clear instructions from patients who are competent to decide, is a potentially problematic event for care providers. The primary aim behind the rationale for deactivation must always be to respect the patient's right to live, or at least to die with dignity, while limiting any therapeutic action that increases the patient's level of stress, pain, or anxiety.

It is worth re-emphasizing that the nature of pacemaker therapy, and thus the rationale behind any decision to discontinue it, is quite different from the equivalent decision in the case of defibrillator therapy. Pacing, as an on-going treatment, is not perceptible to the patient and therefore does not likely contribute to a patient's suffering. It is not likely to unnecessarily prolong life in a patient with terminal physiology as pacing will eventually be ineffective in this patient. Discontinuation of pacing in a pacemaker dependent patient may hasten death which one could argue is inconsistent with generally accepted principles of palliative pre-terminal care; on the other hand, discontinuation of pacing therapy should be kept distinct from that of euthanasia or physician-assisted suicide. ICD shocks can be considered equivalent to applying resuscitative efforts and can contribute to suffering that may violate the patient's or designated official's wishes. The deactivation of ICD anti-tachycardia therapies should be seen as similar to having "do not attempt resuscitation" orders invoked, but in some circumstances deactivation of ICD antitachycardia pacing therapies may be considered independently from deactivation of ICD shock therapy.

Clinical considerations

More specifically, the main circumstances that may prompt the patient, his/her family, and/or health care providers to evaluate the possibility of terminating device therapy, could be summarized as follows:

First: the patient's quality of life, as modulated by the function of the device

Quality of life is inevitably a subjective matter and must be assessed mainly by the patient rather than by the treating physician. Patients can usually, on the basis of their individual preferences and personal philosophy, determine the combination of elements that define a valued quality of life and can specify which medical intrusions would encroach upon that quality of life.⁴³

Frequent or repetitive electrical shocks from defibrillator therapy are acknowledged to have a negative impact on a patient's quality of life. If the situation becomes intolerable legitimate consideration may be given to deactivation of the device under the following conditions:

- A deterioration of the patient's cardiac condition which can lead to multiple episodes of ventricular

tachyarrhythmias that are not reversible with pacing algorithms and require multiple shocks. Of course, leaving the device programmed off should be a last resort: after all the possibilities for limiting or eliminating the arrhythmia have been exhausted—drugs, catheter ablation, and surgical ablation. To date, the number of defibrillator therapies that significantly alters quality of life has not been determined, nor can such an evaluation be made, depending as it does on the tolerance level of the individual.

- Worsening of the patient's overall clinical condition as a result of coexistent diseases (such as cancer, stroke, or dementia). A non-negligible proportion of patients with ICDs progressively develop diseases that contribute to the occurrence of ventricular tachyarrhythmias and frequent therapeutic interventions by their device. Such patients are usually in the final stages of non cardiac system failure, with disturbances of oxygenation, and/or significant anemia, etc. Whether or not the arrhythmia is due to the patient's cardiac condition or to a coexisting disease, patients in an advanced stage of suffering, with a short expectancy of survival and a low quality of life, may consider even one defibrillator shock as significantly harmful.

Second: expected survival and status of the patient's life. The futility of therapy

The World Health Organization's definition of palliative care⁴⁴ states that the control of physical, psychological, social, and spiritual suffering is essential in order to achieve the best possible quality of life for patients with incurable illnesses and their families. This definition regards dying as a "normal process" that should be watched over with care and sensitivity so that it may occur without pain, discomfort, or stress, but with dignity.⁴⁵ Any characterization of a treatment as futile presupposes that the patient's condition is terminal, irreversible, and that death is imminent. Such futility assessments must be approached with extreme caution, since subjective judgments of quality of life vary greatly and depend to a large extent on a physician's personal values.⁴⁶⁻⁴⁹

In judging the question of futility in the case of patients with ICDs we must distinguish two broad categories of terminally ill conditions. The first refers to terminal conditions of non-cardiac origin, such as severe, hopeless infections in cancer victims, or vegetative states (strokes, posttraumatic, etc.). The second concerns the final stages of cardiac diseases, such as advanced heart failure, which can be complicated by repeated persistent ventricular tachyarrhythmias. The concept of futility, especially in the latter category, could be assigned when the ICD is no longer able to restore a stable cardiac rhythm. Any decision about the deactivation of an ICD must clearly aim primarily at relieving the patient's pain and discomfort.

Methods of CIED therapy termination

Current CIEDs provide extensive programming capabilities, although not necessarily recommended, pacemakers can be programmed into an OOO, ODO, or OSO mode. If these modes are not intrinsically available, the rate can be lowered and output voltage and pulse width adjusted

down to a sub-threshold level, so as to make the device non-functional. A more active approach is the surgical removal of the device. Such an approach, however, is likely to cause discomfort and inconvenience to the already suffering patient and is not recommended.

In the case of ICDs, the antitachycardia pacing and shock defibrillator function of the device may be noninvasively deactivated with appropriate programming or, for most devices, with continuous application of a magnet over the generator. It is important to remember that the caregiver, together with the patient or surrogates, should decide whether the antitachycardia pacing algorithms should be deactivated, or just the shock therapy. Whether the pacing function of an ICD should also be inactivated is a decision that should be governed by principles already stated in the case of the pacemaker patient. It should also be noted that a decision not to replace a pacemaker or ICD device that has reached its elective replacement indicator or end of life is a passive approach available for terminating device therapy.

The termination of device therapy, whether a pacemaker or an ICD, must be distinguished from the deactivation of the diagnostic or remote-monitoring capabilities of the device. Under rare circumstances, the patient may not wish to know (or for others to know) the status of his device or, alternatively, if any arrhythmias have occurred. Alert features may trigger an alarm under a variety of situations, such as lead or device malfunction, declining battery, or arrhythmia detection. The decision to disable detection and remote monitoring and/or deactivate alarms requires additional discussion between the patient and the health care provider.

Ethical and legal considerations

As already stated, there is a medical, bioethical, and legal consensus that even a patient who is *not* terminally ill has the right to refuse any or all treatment provided the patient is cognitively competent and aware of the consequences.⁵⁰ This right is based on the concept of autonomy, a value accorded major weight in western societies. Withholding or withdrawing treatment on the patient's instruction is not equivalent to aided suicide or euthanasia, because the latter will cause death irrespective of disease, whereas non-treatment merely allows the progression of a disease from which the patient already suffers. Apart from ethical and legal considerations, cultural and religious differences may influence a patient's decision. This factor must be taken into account by caregivers and the patient's beliefs should be given precedence over their own.

The patient may refuse implantation, and may also request deactivation or removal of his/her device. Any such request will potentially create dilemmas for patients and caregivers, especially if the patient is pacemaker dependent, where the interruption of treatment will have an immediate and dramatic result. Physicians should not impose their moral values on their patients. Some patients with malignant tumors may, for example, be resolute in wanting to keep their ICD activated.⁵¹ The decision to inactivate an ICD cannot be made unilaterally by the patient's medical provider.⁵² On the other hand, caregivers who personally object to disabling an ICD should not be compelled

to do so and the patient should be offered an alternative caregiver.⁴⁵

Before any alteration or deactivation of an implanted device function is considered, a thorough discussion should be sought with the patient (if able) and his/her family or official designee. In this discussion, the physician must communicate the details of the patient's medical condition and the predicted consequences of any decisions that involve the patient's implanted device. If the patient chooses an option that involves device deactivation, then the following must be reflected in the process and the record (a more detailed description is given in *Table 7*):

- The documentation of the caregiver's perception of the patient's cognitive and psychological state, including the confirmation of the patient's decision-making competence
- Documentation of communication with the patient's family
- A written, signed and witnessed consent by patient or legal representative

It is widely accepted that family members may act as surrogate decision makers for a patient who is cognitively incapacitated. Such surrogates should usually advocate for the patient's expressed wishes, if known, or otherwise should use their best judgment in determining the patient's most probable choice.

Finally, there is the special category of patients who have given a clear prior directive in the form of a "do not resuscitate (DNR)" or "do not attempt resuscitation (DNAR)".⁵³ Such a directive prohibits the use of efforts to reverse a cardiac or pulmonary arrest.⁵⁰ When there is a DNAR order in force, the withholding of CPR or external defibrillation may be extended to other life prolonging, non-palliative treatments, like an ICD. In such cases deactivation of the device should be seriously considered. Nonetheless, patients with an ICD who have a DNR directive may still benefit from ongoing ICD therapy if:

- The arrhythmias being treated reflect the primary cardiac condition and not an irreversible secondary medical illness;
- Prompt ICD therapy confers the likelihood of added survival with meaningful quality of life and without post-arrest disabilities (e.g., cognitive); and the patient concurs with this approach.⁴⁵

If the patient's decision making capacity is judged to be compromised or doubtful, or when relatives or other surrogates believe the patient to be incompetent, then the correct decision making requires the participation of an experienced arbitrator who is acceptable to all parties. Such a person could be someone with a legal background, or a member of the hospital's ethics committee.

From the point of view of both patient psychology and health care practice, the timing of the discussion about device deactivation is of great importance when the patient is capable of decision making. It has been demonstrated that anticipating earlier deactivation of an ICD device as part of a comfort care strategy may result in fewer shocks during the final days of a patient's illness.⁵⁴ It must be stated categorically here that, regardless of any

Table 7 CIED deactivation: stepwise protocol

Level of intervention	Communication and documentation	Details
I. Initial approach	Preliminary discussion	<ul style="list-style-type: none"> Well in advance of need. <ul style="list-style-type: none"> Patient, family members, caregivers.
II. Indications of declining condition <ul style="list-style-type: none"> Progressive cardiac dysfunction Malignancy Dementia 	More detailed and continuing discussion	<ul style="list-style-type: none"> Benefits/risks of deactivation. Medical, ethical, legal, religious, cultural aspects. Discuss disabling of: <ul style="list-style-type: none"> pacemaker function. ICD therapies. diagnostic capabilities. alert and/or remote monitoring capabilities.
III. Patient or legal representative desires CIED deactivation	May require legal consultation	<ul style="list-style-type: none"> Written documentation of: <ul style="list-style-type: none"> caregiver's perception of the patient's cognitive and psychological state, including confirmation of patient's decision-making competence. signed and witnessed consent. communication with the patient's family.
IV(a). Deactivation—Unlikely to be associated with immediate 3death	Details of re-programming must always be reviewed and documented by the physician	<ul style="list-style-type: none"> Deactivation may be performed by a suitably trained person upon the express, written orders of the physician (e.g., appropriately trained nurse, physician assistant, or manufacturer's field representative). Encourage supportive individuals to be present, including family members and clergy.
IV(b). Deactivation—That will result in immediate death	Must be performed by a physician	<ul style="list-style-type: none"> Whenever possible, supportive individuals must be present, including family members and clergy.

advance directives signed by the patient, device deactivation must be preceded by a new discussion with the patient and the obtaining of written, signed and witnessed consent.

Section 6: reimbursement considerations

The implication of this document describing the purpose, process, personnel, equipment and techniques required for device follow-up is that the human and financial resources are available to accomplish the task. Unfortunately the implantation of the device has been the focal point of reimbursement and the ongoing application of the therapy has received much less attention. In North America there is a system that provides some reimbursement for the time, equipment and personnel involved in device follow-up, but this is less consistent in other parts of the world including most of the nation states of Europe.

As the technology advances, including the application of remote interrogation and advanced diagnostics, new models for reimbursement are required. It is easier to value face-to-face time than remote interrogations done over a longer period of time, collecting information for 3 or more months. This transformation of event based follow-up to life monitored follow-up for intervals of time requires new economic models and safeguards against abuse. The importance of remote monitoring as compared to office visits extends beyond the organizational aspects (e.g., patients do not miss working days for going to hospital, physicians and technicians save time reviewing data on the computer). A most important aspect of remote

monitoring is that it leaves the frequency of system check up to individual situations. Some patients require or may individually request more frequent system checkups for a variety of reasons (e.g., recurrence of arrhythmic events or recently modified parameters for sensing, pacing or therapy, or advisory devices or leads) and such a need may be temporary. In such instances the availability of a remote system for device follow-up becomes a way of delivering much better care to patients and may prove life saving. In Europe the implant rate is lower than in North America; however, there is an expected increase in the near future in relationship to the release of evidence based guidelines.^{55,56} As cardiovascular implantation prevalence increases, the value of remote monitoring increases substantially. The availability of remote monitoring seems to be a fundamental requirement to facilitate patients' access to therapy.

Reimbursement of specialist physicians and hospital/clinics for in-person scheduled CIED follow-up has been adequate in some regions. However there are many clinical situations including perioperative programming that are not reimbursed. Specific reimbursement has not been generally available for remote CIED follow-up. Discussions are underway in various geographic locations to seek similar in person reimbursement for remote CIED evaluations. Currently, since in many countries there is no reimbursement for remote CIED follow-up there is a disincentive for adoption of this technology. This negative incentive may delay the benefits, improved quality of care and eventually the efficiency gains for health care providers. Without adequate value placed on these activities the promise of device therapy is hollow.

Conclusions

Intrinsic to the implantation of a CIED is the care of the patient and device after implantation. The purpose of the device is not implantation but ongoing therapy. However the therapy requires monitoring and adjustments, which implies the availability of resources, including space, equipment and personnel. With the goal of increasing the length and quality of the patient's life, appropriate monitoring of device therapy has the ability to enhance the likelihood that the patient can pursue his/her life with fewer interruptions by hospital admissions and operative interventions. Without follow-up the therapy is incomplete and without resources to achieve appropriate follow-up the desired outcome is unlikely.

Over the last decades there has been an exponential growth in the number of implantable devices, their electronic and software complexity, and widening of their function and application. This has led to a distinct and at the same time complex medical service as represented by monitoring of CIEDs. Until now, the complexity and importance of follow-up care and monitoring of CIEDs have been given too little attention by scientists, competent authorities and third-part payers. This is the first attempt to provide an expert consensus document on monitoring of CIEDs.

As outlined in this document, a few paradigm shifts have already occurred but many more are likely to come over the ensuing years. The large number of implanted devices has already put significant pressure on physicians, allied professionals, institutions and competent authorities for maintaining the high quality, quantity, efficiency and reliability that this group of patients deserves. Globalization and new Internet-based technologies for monitoring CIEDs are imposing new rules for patient data management and data-sharing. Competent authorities, national ministries of health, and patient organizations need to find practical and easy solutions for physicians to have rapid and complete access to device relevant data for delivering the most appropriate therapy. Moreover during CIED follow-up, new approaches to the ethical complexities may arise.

Appropriate follow-up monitoring of patients with CIEDs is critical to the achievement of maximal clinical benefit from their implantation and is essential for the prevention and management of potential adverse outcomes related to the device. The monitoring should be done by professionals who are specially trained and dedicated to this special patient population. With the increasing complexity of devices and the widening array of technologies involved in monitoring, the device industry, health care institutions and physician practices must provide the necessary infrastructure and personnel in order for this care to be effective and safe. Payers and regulators need to improve their recognition of the importance of CIED follow-up and develop adequate reimbursement strategies. There is no point investing in the device without comparable investment in the long-term follow-up and therapy!

Appendix I

Current standards for implanted device traceability for devices used in (A) clinical trials and (B) standard commercial transactions in the European Union (EU) with reference to North America.

A) For clinical trials, standard ISO 14155:2003⁵⁷ deals with traceability, both for the sponsor as well as the investigator.

Responsibility of the sponsor (chapter 8.2)

The sponsor shall 8.2.f) supply fully characterized devices which are the subject of the clinical investigation 8.2.o) ensure accurate device accountability and traceability systems

Note: it is not specified how the sponsor should achieve accountability and traceability, no reference to any specific systems is made. It is the manufacturer's responsibility to develop and maintain a system that ensures traceability.

Responsibility of the investigator (chapter 10.3)

The investigator shall (10.3.y) ensure that all devices that are the subject of the clinical investigation are accounted for. The quantity of the devices received should be reconciled with the quantities of devices used, discarded or returned.

B) For commercial products, medical device companies have to comply with the Medical Devices Directive 93/42/EEC,⁵⁸ which dictates (under Annex V) that the manufacturer must lodge an application for assessment of his Quality System with a notified body.

The application must include, amongst several other items, the documentation on the quality system:

- an undertaking to fulfill the obligations imposed by the quality system is approved;
- an undertaking to maintain the practicability and effectiveness of the approved quality system;
- where appropriate, the technical documentation on the types approved—a copy of the EC type-examination certificates;
- an undertaking by the manufacturer to institute and keep up to date—a systematic procedure to review experience gained from devices in—the post-production phase and to implement appropriate means to apply any necessary corrective action.

The ISO 9001⁵⁹ 13485^{60,61} standard fulfils essential requirements with respect to the Quality System, as dictated in the EU directive (EC directive 93/42). Notified Bodies will audit medical device companies for compliance with this Quality Standard, ISO 13485: 2003.

The United States has based its revised Quality System Regulation (21 CFR 820, Oct. 7, 1996) on the ISO 9001 and ISO 13485 quality system standards.

Certification by a Notified Body of medical device companies is based on the verification of many parameters throughout the production and management chain. The compliance of the quality management system implies traditional requirements for quality management such as design, development, manufacturing, installation and maintenance of medical devices but also more specific ones for example design controls, process controls (including environmental controls), special processes, traceability, record retention, and regulatory actions, which are critical for the medical device industry. Such certification is valid for 3 years while each year surveillance audits are conducted by the Notified Body.

Under chapter 7 of ISO 13485:2003, traceability is included as a requirement.

Note: In the EU, contrary to North America where device registration exists, medical device companies do not obtain any records of the patients who receive a commercially supplied device. This is due to EU and national privacy regulations. Traceability therefore means that companies need to keep track of all components, raw materials, etc., used for the manufacturing of finished products, and to keep track of the

customer (name, ship-to address) that receives the device (serial number/lot number) from the company. Responsibility of tracking devices to the patient rests with the purchaser of the device (clinician, hospital or health care system). During clinical trials the patient information is coded and not known to the sponsor. However, in case of need, the investigator can decode this information and identify the patient.

Appendix II. Author relationships with industry

Author	Consulting fees/ honoraria	Speaker's bureau	Ownership/ partnership/ principal	Research grants	Fellowship support and other benefit
Dr. Angelo Auricchio	Biotronik Boston Scientific Medtronic St. Jude Medical Sorin/ELA	None	None	None	Fellowship support: Boston Scientific*; Medtronic*
Dr. Josep Brugada	Biotronik Boston Scientific St. Jude Medical	None	None	Boston Scientific Medtronic	None
Dr. Martin Cowie	Medtronic* ResMed* Sanofi-Aventis* Sterling Medical Takeda*	None	None	None	Fellowship support Medtronic*; ResMed*, Takeda*
Dr. Kenneth Ellenbogen	Ablation Frontiers Atricure Biosense Webster Biotronik Boston Scientific Medtronic St. Jude Sorin/ELA	Reliant Pharmaceuticals Sanofi-Aventis	None	Biosense Webster Boston Scientific Impulse Dynamics Cameron Medical Medtronic St. Jude	None
Dr. Anne Gillis	Aryx Medtronic- Canada Medtronic*	None	None	Medtronic*	Fellowship support: Medtronic-Canada*; St. Jude-Canada* Other: Medtronic Registry*
Dr. David Hayes	AI Semi Blackwell/Futura* Boston Scientific* Medtronic* Sorin/ELA St. Jude	None	None	Boston Scientific* Medtronic* St. Jude	Fellowship support: Biotronik; Boston Scientific*; Medtronic*; Sorin/ ELA; St. Jude
Dr. Jonathan Howlett	None	None	None	None	None
Dr. Josef Kautzner	Biosense Webster Vitatron	St. Jude Medical	None	None	None
Dr. Charles Love	Medtronic	Medtronic St. Jude Medical	Medtronic St. Jude Medical	Biotronik Impulse Dynamics Medtronic* St. Jude Medical	None
Dr. John Morgan	Medtronic*	None	None	None	None
Dr. Silvia Priori	Medtronic Boston Scientific St. Jude Medical	None	None	Medtronic Boston Scientific	None
Dr. Dwight Reynolds	Boston Scientific Sorin/ELA		Medtronic*	Biotronik Medtronic*	Fellowship Support: Medtronic*
Dr. Mark Schoenfeld	None	None	None	None	None
Dr. Panos Vardas	Boston Scientific St. Jude Corp	None	None	None	None
Dr. Bruce Wilkoff	Boston Scientific Medtronic St. Jude Medical Sorin/ELA Medical	None	None	Boston Scientific* Medtronic* St. Jude Medical* Biotronik	None

* Indicates significant level relationship (more than \$10,000).

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- Source: EUCOMED (European Medical Technology Industry Association) unpublished data, website at: <http://www.eucomed.be/>.
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