

# **Remote monitoring and follow-up of cardiovascular implantable electronic devices in the Netherlands**

**An expert consensus report of the Netherlands Society of Cardiology**

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## **Abstract**

Remote monitoring of cardiac implanted electronic devices (CIED: pacemaker, cardiac resynchronization therapy device and implantable cardioverter defibrillator) has been developed for technical controls and follow-up using transtelephonic data transmission. In addition, automatic or patient triggered alerts to the cardiologist or allied professional can respond if necessary with various interventions. The advantage of remote monitoring appears obvious in impending CIED failures and suspected symptoms but is less likely in routine follow-up of CIED. For this follow-up the indications, quality of care, costs and cost-effectiveness and patient satisfaction have to be determined before remote CIED monitoring can be applied in daily practice. Nevertheless remote CIED monitoring expands rapidly in the Netherlands without professional agreements about methodology, responsibilities of all parties involved and that of the device patient, and reimbursement.

The purpose of this consensus document on remote CIED monitoring and follow-up is to lay the base for a nationwide, uniform implementation in the Netherlands. This report describes the technical communication, current indications, benefits and limitations of remote CIED monitoring and follow-up, the role of the patient and device manufacturer and costs and reimbursement. The view of cardiology experts and of other disciplines in conjunction with literature was incorporated in a preliminary series of recommendations. In addition, an overview of questions related to remote CIED monitoring to be answered is given. This consensus document can be used for future guidelines for the Dutch profession.

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## Chapter 1: Introduction.

Cardiovascular implantable electronic devices (CIED) are categorized as implantable pacemakers (PM), implantable cardioverter-defibrillators (ICD), cardiac resynchronization therapy devices with or without cardiac defibrillator and cardiac arrhythmia monitor devices. After CIED implantation regular technical checks of the CIEDs are mandatory to examine the performance, safety and remaining longevity of the implanted device. In addition an in-hospital examination of the device recipient (device patient) is sometimes needed to evaluate his/her physical and mental condition and if required, to adjust the function of the CIED to changing needs of the device recipient. Guidelines recommend the frequency and intensity of these medical and technical follow-up visits.<sup>1, 2</sup>

Recently remote CIED interrogation from a patient's residence has been introduced as a novel method of care in cardiology.<sup>3-18</sup> With transtelephonic methods technical information is collected about the attributes, settings and status of CIED and where applicable delivery of electrical therapy by CIED and the resulting outcome. Some physiological parameters of the device patient can also be monitored. This remote interrogation can be used for scheduled and unscheduled technical and patient monitoring and follow-up. This information can result into alerts that may require a response of the cardiologist or allied professional.

How remote monitoring contributes to patient care has been reported in several recent studies.<sup>9, 15, 17, 18</sup> However the indications, clinical relevance, cost effectiveness, management and organization of remote monitoring are hardly established by prospective randomised trials.<sup>16, 19-21</sup> In addition many organizational and legal aspects as well as reimbursement are until today matter of dispute. Consequently remote monitoring of CIED is now carried out in very variable and fragmented way in daily practice and lacks a uniform methodology thus creating uncertainty for all parties involved.<sup>22</sup>

To overcome this uncertainty it is crucial to make an inventory of all components of remote monitoring in order to promote a uniform methodology in clinical practice. This consensus report intends to elucidate these components and explores the pitfalls hampering a standard care of device patients in terms of quality, technical and legal issues, safety, costs and reimbursement. In absence of high level of evidence (class 1), cardiology experts and those from various disciplines contributed to the advisories and conclusions of this consensus report. These efforts resulted in a preliminary series of recommendations for remote monitoring. This consensus report aims to become the founding base for future guidelines for remote monitoring of CIED to develop in the Netherlands.<sup>23</sup>

Footnote 1. Although the acronym AIMD (Active Implantable Medical Device) is used in the Medical Device Directive 93/42/EEC, in this document the term *CIED* (Cardiovascular Implantable Electronic Device) is used, as this term limits the AIMD's as those used only for cardiovascular application.

Footnote 2. Remote CIED monitoring potentially enables to reprogram operational device algorithms e.g. to adapt pacing features. Although this approach reflects true "remote cardiac rhythm management" its application appears not advisable at this moment due to unknown safety issues and legal uncertainties and needs to be investigated.

## Chapter 2: Technical description of remote monitoring

### *The communication chain.*

Remote monitoring is capable to send information from a CIED about programmable features, information on device function, arrhythmias, cardiovascular hemodynamic information, patient clinical status and registrations of stored electrograms to an external device, the *transmitter*. This transmitter has to be in the proximity of the patient to be able to communicate with the CIED. When the transmitter has received the data stream from the CIED, it sends this data encrypted to a central server of the manufacturer of the CIED.

The manufacturer's device provides these data in a protected environment for the cardiologist or allied professional; these data is suitable for incorporation in the hospital information system (HIS). In contrast to in-hospital continuous cardiac rhythm monitoring, in remote monitoring the CIED communicates with the transmitter only at scheduled times e.g. once a day.

In case of special events detected by the CIED or triggered by the patient, the transmitter will send a non-scheduled transmission to the server which will be delivered to the cardiologist or allied professional by e-mail and/or short message service (SMS). When no abnormalities are detected, a transmission occurs as a scheduled agenda-based virtual follow up. Although the CIED continuously collects data, the transmitter will only send the data according to scheduled time intervals e.g. once every day. Thus in a technical sense, *no* continuous 24 hours/day, 7days/week monitoring of the device and/or of the CIED patient is until now possible. Device companies cannot be held responsible for delays or lack of alerts and follow-up due to failing landline or global system for mobile communications (GSM) technology.

### 2.1.1 *Communication between CIED and transmitter (Fig1).*

To remotely monitor a patient, the data from the CIED is transferred to the hardware installed at the patient's residency. The initial method to communicate with the CIED is the classic induction coil, the so called programming wand. The coil has to be placed within centimeters over the implanted device. This communication depends on patient compliance. Today's CIEDs are equipped with bidirectional radio frequent (RF) communication, operating in the frequency range between 403 MHz and 406 MHz. With the use of this radio technique, data is automatically send from the CIED to a local transmitter in the direct proximity of the patient.

### 2.1.2. *Communication between the transmitter and the manufacturer's remote monitoring data centre.*

The data is forwarded to the manufacturer's remote monitoring data centre. A transmitter is used to receive, amplify and transmit the signals. The data can be send to the manufacturer's remote monitoring data centre by the conventional telephone cable network often called "landline" or by a digital cellular phone technology such as general packet radio service (GPRS) or satellite. All communication between the transmitter and the manufacturer's data centre should be encrypted to guarantee patient privacy and safety.<sup>24</sup>

### 2.1.3 *Communication between the manufacturer's data centre and the cardiologist.*

The raw data are received in the manufacturer's remote monitoring data centre where the data are automatically transformed to a format that is readable for the cardiologist and allied professional using the internet.

Footnote 3: In this report this device is designated as *transmitter* rather than the more appropriate but unfamiliar, generic term *transponder*

The manufacturer's graphical user interface (GUI) permits scrolling through the stored data to allow analysis by the cardiologist or allied professional. The presented data have the identical format as compared to the programmer based interrogation during an in-hospital visit. In addition the manufacturer's system analyses and compares the data with programmed values to produce alerts. Alarm messages are sent by e-mail or by digital cellular phone short message service (SMS).

#### *2.1.4. Interoperability.*

To promote an integral follow-up of the device patient, all information including remote monitoring data should be instantaneously and centralized be available to the cardiologist or allied professional. Interoperability in remote CIED monitoring is therefore imperative. To ensure this approach, the technology and contents of the information must be exchangeable by applying standards on various levels of processing, communication and semantics.

The ultimate target is the avoidance of any handwritten file but direct automated reading and filling out of data from the patient at home to the electronic patient document (EPD) of HIS saving time and preventing flaws.

##### *2.1.4. a. Communication between the manufacturer's data centre and the hospital information systems:*

Patient data should be regarded as part of the patient file and should be stored in HIS. Nowadays differences exist between the format and screen displays of the device manufacturers and the local HIS. This difference inhibits a uniform approach to store and display remote monitoring data. Efforts should be made to implement nationwide the Integrating the Healthcare Enterprise (IHE) specification of Implantable Device – Cardiac – Observation (IDCO) for data from CIED. This specification, together with the IEEE 11073 - 10103 - MDC-IDC Nomenclature constitutes the foundation for exchange.

##### *2.14. b. Communication between the manufacturer's data centre and the national health information technology infrastructure:*

The concept of the national health IT infrastructure aims to connect all well-maintained health information systems to this infrastructure. The main component is the switch point where an index of the location of record fragments of the patient is maintained. Any accredited health care professional is able to query the switch point for certain types of information. The system will retrieve the requested information from the sources that are linked to the switch board. This infrastructure could potentially also be used to make CIED data available for authorized cardiologists and allied professionals and hospitals. The National Cardiac Devices Registry (NCDR) founded by the Netherlands Society of Cardiology, can contribute to this objective.

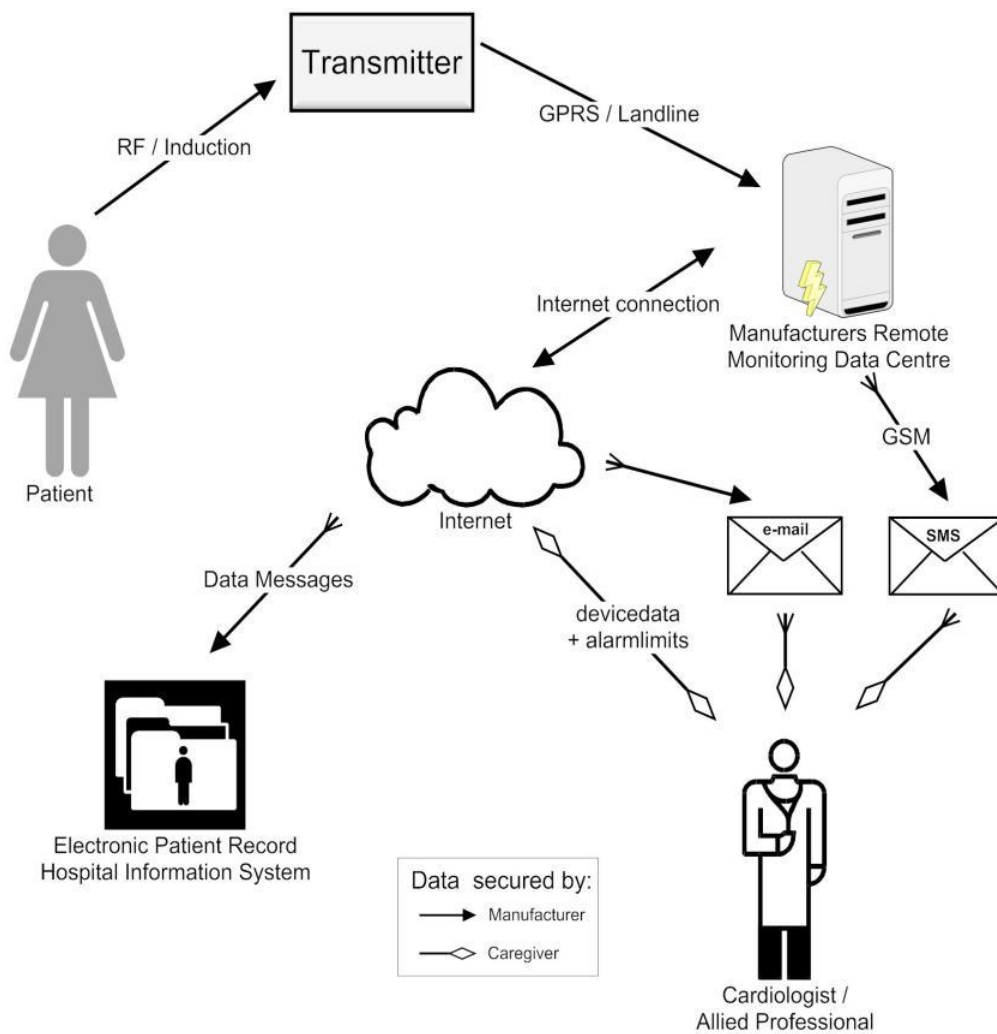


Figure1. Global overview of remote monitoring and remote follow-up dataflow

## Chapter 3: Indications, benefits and limitations of remote CIED monitoring 285

### 3.1. Types of remote monitoring:

Scheduled transmission of programmed alerts of either device related e.g. abnormal lead resistance or patient related events e.g. onset of atrial fibrillation (AF) from the manufacturer's remote monitoring system to the cardiologist is until now most frequently applied. This type of remote monitoring includes detection and mailing of events that had been initially programmed by the cardiologist or allied professional. The second type is transmission of a patient activated alert that indicates the occurrence of specific symptoms. The third type is "remote follow-up" defined as remote device interrogation at scheduled intervals. This method can partly replace the in-hospital technical CIED control.

### 3.2. Indications for remote monitoring of implanted devices:

Literature shows a wide spectrum of reasons to perform remote CIED monitoring.<sup>7, 8, 10-15, 17, 18, 25, 26</sup> The reason of CIED implantation, the severity of illness of the device patient, and the opportunity to follow high risk CIED or field actions/safety alerts of devices appear beneficial indications.<sup>27</sup> For devices and/or leads with high risk of technical malfunction or large technical complexity (e.g. ICD) remote monitoring appears favorable.<sup>28</sup> Remote monitoring can also be applied to document the underlying cause of symptoms of the device patient comparable to Holter monitoring. Because of lack of evidence for efficiency or cost/effectiveness, the indications for remote CIED monitoring are currently hardly established and therefore *routine* remote monitoring of patients with PM, CRT or ICD should be evaluated in further studies.<sup>2, 4, 6, 16</sup> If remote monitoring is applied, the cardiologist's decision is based on assumed better patient care and /or quality of life and tailored for the individual patient.

### 3.3. Timing of response to alerts:

As stated in the technical description (see chapter 2) routine remote CIED monitoring cannot offer a continuous surveillance of the device patient. Consequently a 24 hours/day, 7 days/ week alert response from the cardiologists to the device patient is not technically feasible. Furthermore evidence of cost/effectiveness of continuous remote monitoring in terms of an immediate response of the cardiologist or allied professional to the alerts is hardly documented.<sup>3, 6, 16, 21</sup>

### 3.4. In-hospital visits additional to remote CIED monitoring:

Current guidelines for CIED follow-up advise on methods and frequency of technical controls. For conventional follow up at least one visit per year for the simplest single-chamber PM and 6 monthly follow up for the more complex dual-chamber PM is advised whereas for the ICD patient after the 1<sup>st</sup> implantation or replacement a more frequent follow up is recommended.<sup>1</sup> In congestive heart failure and CRT the course of the failing heart or incidence of arrhythmia determine the intervals of in-hospital visits.<sup>1</sup> Regarding remote CIED monitoring it is recommended that any patient with a CIED be assessed in person at least once a year.<sup>2</sup> However the frequency of the in-hospital visits has to be left to the cardiologist's discretion.

### 3.5. Benefits of remote CIED monitoring

The major advantage of remote CIED monitoring is the timely detection of CIED failures or deviations of the programmed device values. A fast response to mailed alerts by the cardiologist or allied professional can prevent potential harm to the device patient.<sup>8, 10, 12, 13, 15, 17, 18, 25</sup> Secondly, time and efforts of the cardiologist and allied professional, and of the device patient and the accompanying family can be saved by scheduled remote CIED follow-up by avoidance of in-hospital visits for technical CIED follow-up visits. Thirdly, remote CIED monitoring can be used for temporary purposes as rapid detection of technical failures related to field action/safety alert or avoidance of frequent controls at time of anticipated battery depletion of the implanted device. Fourthly, it is expected that remote monitoring can counteract the pending imbalance between the annually increasing load of care in more, older and more complex CIED patients.<sup>29-31</sup>

### 3.6. *Limitations of remote monitoring*

Remote CIED monitoring delivers a substantial amount of data to be handled by the cardiologist and allied professional. This overflow is intrinsically related to continuous monitoring and storage of CIED measurements as well as of stored cardiac and biological signals of the device patient that are transmitted to the manufacturer's remote monitoring centre at scheduled intervals. Their clinical relevance is often unknown in terms of risk and prognosis. This information may falsely initiate the prescription of drugs or force to unnecessary CIED reprogramming and hospital referral leading to over-treatment.

Apart from the clinical consequences, the overflow of data generated by remote monitoring may increase the daily workload of the cardiology staff requesting more personnel and budget. Remote monitoring might unfavorably affect the attitude of the device patient because this approach can be falsely appreciated as an alternative way for unrestricted and immediate access to care. Furthermore, alerts and other information resulting from remote monitoring may bring about imbalance of mental condition and health perception of the device recipient.<sup>32-34</sup> These potential disadvantages require further specific studies. Anticipating the results of these studies, one should accept that alerts and responses to alerts are reserved to specific conditions as technical failures or abnormalities of CIED function specified in the monitoring protocol of the individual device recipient

### 3.7. *Measurements of quality of care of remote monitoring:*

Because of the novelty of this type of patient care, that elicits uncertainty about benefit, adverse effects and costs, measures to determine the quality of care are urgently needed. Clinical and technical characteristics that predict potential benefit of remote monitoring have to be developed. The set of recommendations delivered in this document by experts can serve as a standard (see chapter 7). Current technology of transmission, storage, alerts and communication between manufacturer's remote monitoring centre, cardiologist and allied professional and HIS will further develop and these products should also be incorporated in the predictors of benefit.

### 3.8. *Conclusions:*

1. Remote CIED monitoring can be applied but its indications are hardly scientifically established. Therefore remote monitoring cannot be considered an obligatory patient care and is in daily practice left to the cardiologist's decision.
2. From the technical point of view remote CIED monitoring does not imply continuous monitoring but scheduled or unscheduled information to the cardiologist or allied professional. Until now evidence lacks to justify 24 hours/7 days week based remote monitoring. Waiting for clear evidence, handling of remote monitoring should be restricted to hospital office hours.
3. Considering benefits and limitations of remote monitoring, prospective comparative studies are needed to assess the contribution of remote CIED monitoring to the care of the device patient. The cost-effectiveness of the indications for various CIED categories and predictors of benefit should be assessed.
4. Technical developments of remote monitoring require interaction with manufacturers to facilitate uniform methods of care and guarantee clinical relevance of remote monitoring.

## **Chapter 4: The role of the patient in remote monitoring**

### 4.1. *Patient participation:*

Remote CIED monitoring relies on regular contact between the device recipient and transmitter at scheduled intervals (e.g. at home during the night). Therefore the device recipient must be in the proximity of the transmitter. Patient compliance includes matching of mental functioning as well as visual and acoustic capacities of the device patient to proper handling of the communication system. Remote monitoring also relies on patient accessibility for alerts from the hospital and counseling by the cardiologist and allied professional.

4.2. *Continuous surveillance.* The device patient might perceive that remote CIED monitoring brings out a continuous surveillance of the implanted device and cardiac rhythm. However, as stated in chapter 2, transmitting of surveillance data occurs at regular intervals and not continuously. The same holds for delivery of alerts to the hospital. A delay in receiving a transmission can occur which rules out continuous monitoring.



The internet communication can be falsely perceived as an alternative way for immediate or easy access to patient care in the hospital or emergency department. However, alerts and response to alerts have to be reserved to specific conditions, technical failures and particular appointments with the patient. A commitment of the patient to the appropriate use of remote CIED monitoring is therefore indispensable (see Written information 7b).

*4.3. Responsibilities:* Patients receiving remote CIED monitoring should accept responsibilities for proper handling and care for the transmitter, prevention of damage and measures for proper communication with the device centre. These aspects are already formalized by current legal rules of ownership, in terms of “good clinical practice”.<sup>35</sup> Information to the device patient should point to these responsibilities regarding all parts of remote monitoring and follow-up. In case of serious acute events the patient should ask for care in the conventional way.

#### *4.4. Ownership of the transmission system:*

Until now the payment for the transmitter and additional tools vary widely markedly. The total cost is until now compensated by the health insurance company. Hospital variations occur in the payment of transmitter hardware. Sometimes the cost of the transmitter is included in the device costs but in other circumstances the transmitter is charged separately. Therefore a uniform format for reimbursement of all facilities of remote monitoring, namely incorporation in the reimbursement structure is strongly advocated.

Transmitters are paired to a unique CIED and therefore they are not exchangeable between patients. This inhibits the transfer or loaning of the transmitter to other device patients e.g. after death. Technical facilities for exchange of the transmission systems can promote flexibility of remote monitoring. When the patient ownership would be abandoned, the hospital can become the owner of the transmission systems. It is however unclear whether this transition would reduce investments and maintenance time.

#### *4.4. Conclusions:*

- a. The implementation of remote CIED monitoring in hospitals also involves patient information about the expectations and restrictions of this method, and the contribution and responsibilities of the device patient.
- b. The ownership of the transmitting systems by the hospital can promote the flexibility of remote monitoring for reusing but it is unclear whether this approach will reduce the overall costs.
- c. Organizations of CIED patients should be asked to participate in patient information about these subjects in order to facilitate proper perception of the advantages and disadvantages of remote CIED monitoring.
- d. It is advised to compose a written consent between the hospital or cardiologist and the patient regarding the respective responsibilities, duties and limits of remote CIED monitoring. Several subjects should be addressed as the responsibility for the analysis of the transmitted data, timing of analysis of transmitted data and feedback to the patient, regulations about unscheduled transmissions.

## **Chapter 5: The contribution of the device manufacturer to remote monitoring**

### *5.1 Introduction:*

The development of remote CIED monitoring was started many years ago initially to employ technical follow-up by telephone<sup>25, 26, 36, 37</sup> For the device manufacturer remote monitoring constituted also a tool to follow devices that were assigned as field action/ safety alert or high risk for sudden failure. Furthermore data of remote monitoring can be used after informed patient consent for assessment of long-term CIED performance contributing to improved post-market CIED surveillance.

The market competition of the device branch has resulted in a large variety of tools due to differences in design, presentation of collected data, programming facilities and communication features. Such a variety may have a negative impact on patient safety as clinicians may get confused when they deal with different manufactures that handle critical issues in a different ways. In the past the responsibilities of the CIED manufacturers with regard to security and confidentiality resulted into a series of USA and European regulations. However, implementation of remote CIED monitoring enlarges clearly the manufacturer’s responsibilities and these should be clarified. These aspects and the manufacture’s interaction with the cardiologist, allied professional and hospital have also to be

formalized.

#### *5.2. Privacy:*

Transmitted data and alerts may be communicated by the device provider through e-mail or by telephone or SMS and received in the hospital. These messages must be encrypted to guarantee patient privacy. Access to manufacturers' websites to assess CIED data of specific patients should also take place in a secure way (https).

#### *5.3 Safety:*

The accuracy of data receipt in the manufacturer's remote monitoring center, data transmission to the hospital and priorities with respect to alerts belong to the manufacturer's responsibility. The manufacturer is responsible for the 24hrs/day 7 day/week availability of service but can make agreements about a temporary gap in monitoring for specific reasons. Access to the manufacturer's remote monitoring center should be secured by a (changing) robust password. However the manufacturer cannot be held responsible for failures due to insufficient patient instruction delivered by the cardiologist or allied professional or the misinterpretation of those instructions by the patient. This also applies for failed transmission, temporary delay or missing alerts due to disorders of landline or GSM technology; in principle telecom service providers are responsible for this part of the communication link, though the manufacturer has the responsibility to select a reliable provider.

Because remote monitoring is susceptible for computer security breaches of various origin, performance, safety and privacy are at stake, requiring specific security controls. A minimum format for secure data transport is mandatory for both manufacturer and hospital environment. <sup>25</sup>

#### *5.4. Storage of technical and patient data:*

The manufacturer is not the owner of the patient data. Patient data should be regarded as part of the patient file and therefore should be stored for a limited time in the manufacturer's remote monitoring system; appropriate back-up of all data is needed. Patient data should be treated according standard rules (NEN 7510)

Storage of patient data ends after final transmission of data to the hospital where storage is obliged over a 15 year interval. <sup>38</sup> If the manufacturer wants to elaborate or store patient data longer, non reversible transformation into an unidentifiable format is necessary.

#### *5.5: Technical developments:*

The current technology of remote monitoring will further develop by data reduction, communication with electronic patient records and personal health records and by adding more features. These developments require interaction between CIED manufacturers and health care providers to promote uniform methodology and to evaluate the clinical relevance of technical progress. To avoid clinically irrelevant applications of remote CIED monitoring, interaction between cardiology professionals and CIED manufacturers should be intensified.

#### *5.6. Conclusions:*

1. Regarding CIED remote monitoring, the responsibilities of the device manufacturer and the local cardiology professionals and hospital respectively should be formalized in a written agreement. This document covers technical, safety and privacy matters addressed in this chapter as well as agreements about data storage and mutual rights and agreements.
2. Uniformity of methods of remote CIED monitoring as well as standardized presentation of data ranks very high in the regulations to develop between device manufacturers and cardiology professionals.
3. Today's regulations for safety and privacy of CIED applicable to CIED manufactures have to be revisited with the employment of remote CIED monitoring particularly to prevent computer breaches of the device.

## Chapter 6: Costs and reimbursement of remote monitoring

### 6.1 Cost components for the hospital:

As shown in the scheme of remote monitoring (see chapter 2), the transmitter at the patient's residency, the manufacturer's information technology, terminals in the hospital and the HIS, constitute linking parts. The total cost of setting up the system, providing care and maintaining the system can be divided into different aspects:

#### Initial investments:

- Time and budget to connect the incoming data and alerts to the HIS and to maintain these connections and the database,
- The hospital and its cardiology department have to reserve technical and human facilities for remote monitoring and storage of the data,
- Organizational efforts,
- During the initial starting phase, the care providers have to familiarize themselves with the system and need to support the conventional follow-up

#### Resource use:

- Reading and interpretation of the alerts or scheduled remote follow-up,
- Patient instruction, telephonic and local checks of the chain of transmission often at the patient's residency,
- Response to and reassurance and counseling of the patient at his residency by information about the results,
- Administrative assistance for patient filing and storage of data,

#### Capital equipment:

- The transmitter at the patient's residence,

#### Maintenance:

- Maintenance of the web-application/ provider,
- Maintenance of the database,
- Maintenance of the physical system at the patient's residence,

Until today the purchase of the transmitter and belonging technical facilities as well as transmission of data and alerts are mostly free of charge for the patient.

### 6.2. Reimbursement of conventional CIED follow up:

Follow-up after CIED implantation and replacement carried out according to current guidelines <sup>1, 2</sup> is reimbursed by insurance companies applying standard reimbursement rules for this care. The follow-up includes at least one in-hospital medical consultation and a technical check of CIED of which the details are published at the website of *DBC Onderhoud* ([www.dbconderhoud.nl](http://www.dbconderhoud.nl)).

### 6.3. Reimbursement of remote CIED monitoring

Until now remote CIED monitoring is not reimbursed by health insurance companies. <sup>9, 29, 30</sup> In the absence of Dutch advisories or guidelines for remote CIED monitoring, health insurance companies can refuse reimbursement to the cardiologist, hospital and manufacturer and can ask for supplementary payment by the device patient. On the other hand with the purpose to improve quality of care, insurance companies and health authorities can propose the application of remote monitoring as the standard method. From the patient perspective, remote monitoring appears very attractive. The initial reports point to an important better health perception of the device patient with remote monitoring because of the perceived "short distance care" and easy access to the hospital. <sup>11, 13, 16, 30</sup> This additional gain of health perception therefore justifies additional costs. Furthermore, if remote monitoring becomes an evidenced based type of care for the CIED patient, payment by the device patient for remote monitoring is inappropriate and

should be covered by the health insurance company.

The costs for the cardiologists and hospital are at this moment fully unknown because implementation of remote CIED monitoring runs parallel to standard outpatient follow-up and requires in the initial years extra investments in information technology, more highly qualified personnel and other measures. In view of all these matters it is unclear whether the financial balance will end positively; this lack of knowledge requires prospective cost effectiveness studies in the Dutch healthcare setting <sup>19</sup>

It appears logical to incorporate remote CIED monitoring in the generic existing DBC structure. Pilot studies can already be started to examine the impact on time and costs of various technical and human components of remote CIED monitoring as well as the reasons and frequency of remote monitoring.

#### *6.4 Conclusions:*

1. Remote CIED monitoring is technically feasible and offers possibly beneficial care in specific indications. However, it has a major impact on time, technical facilities and personnel, and therefore appropriate reimbursement is needed.
2. Reimbursement is preferable applying the existing generic reimbursement structure.
3. Short term pilot studies are requested to evaluate the frequency and reasons of remote CIED monitoring currently done in the Netherlands to define without delay the degree and level of reimbursement.
4. Cost effectiveness studies of remote CIED monitoring should be initiated to evaluate the efficiency of various indications for remote monitoring in the Dutch health setting. The results should be used for fine-tuning of the current reimbursement structure.
5. Remote CIED monitoring can become a standard component of CIED patient care with indications based on evidence and guidelines.

## **Chapter 7: Preliminary recommendations for remote CIED monitoring**

### **a. Technical features:**

*1. Contents of alerts:* Initial experience with remote CIED monitoring delivered a series of preliminary recommendations for the content of default or optional programmed alerts (Table 1):

*2. Application of scheduled remote CIED monitoring:*

For all CIEDS default and optional alert features can be installed.

*PM:* Optional alert features include the detection of atrial and ventricular arrhythmia events, percentages of atrial and/or ventricular pacing, rate histograms and sensor driven pacing rhythms; this information can contribute to optimal individualized pacing.

*ICD:* The detection of VF, VT and all VT types resulting in ICD discharge, aborted shocks and the number of appropriate and inappropriate shocks are indispensable to get insight in ICD functioning. Monitoring of the intrinsic ventricular signal for sensing has a high priority.

*CRT:* The percentage of biventricular ventricular pacing is a paramount feature of CRT functioning.

Condition	Device	Default	Optional	Scheduled	Unscheduled
Battery	PM/ICD/CRT	Battery Impedance		X	
	PM/ICD/CRT	Estimated Replacement time (ERT)		X	X
	ICD	Capacitor charge time		X	
Leads	ICD	Capacitor charge time > 18 seconds		X	X
		Lead Impedance		X	
	PM/CRT/ICD	20% deviation of normal values		X	X
Sensing	ICD	Shock impedance		X	
	ICD	Shock impedance out of range		X	X
	PM/ICD/CRT	Intrinsic atrial signals		X	
Threshold	PM/ICD/CRT	Intrinsic ventricular signals		X	
	PM/ICD/CRT	20% deviation of normal values	Detection of interference	X	X
	PM/ICD/CRT	Automatic atrial capture management		X	
Programming	PM/ICD/CRT	Automatic ventricular capture management		X	
	PM/ICD/CRT	20% deviation of normal values		X	X
	ICD	VT/VF therapy disabled		X	
Arrhythmias	PM/ICD/CRT	Device reset		X	X
	PM/ICD/CRT		Incidence	X	
	PM/ICD/CRT		Duration	X	
	PM/ICD/CRT		Supraventricular events	X	
	PM/ICD/CRT	Duration of AF exceeds consented time		X	X
	PM/ICD/CRT		Ventricular events	X	X
	ICD	VT Therapy		X	X
	ICD	VF therapy		X	X
	ICD	More than 3 therapies needed for termination		X	X
	ICD	Therapy not successful		X	X
Heart rate	PM/ICD/CRT		% Atrial and ventricular pacing	X	
			% Atrial and ventricular sensing	X	
			Rate histograms (intrinsic)	X	
			Sensor driven rate histograms	X	
Heart failure	PM/CRT/ICD		Heart failure monitoring parameters	X	X
	CRT	% biventricular pacing		X	X

3. *Triggered event monitoring:* For all CIEDs specific default and optional alert features can be installed as advised for scheduled monitoring.

4. *Comments on contents of remote monitoring:*

4a. Programming of the alert feature for the event VT requires a definition of this arrhythmia. According to the expert view VT is defined as rate > 180/m during 30 seconds because this pattern is associated with symptoms and risk.

4b. Programming of the alert feature for the impact of AF requires a definition of this arrhythmia. According to expert view mode switch of the pacing device after AF detection to VDIR or DDIR > 10% of day time and > 2 days monthly is classified as a serious AF incidence. Since inappropriate mode switch has been reported additional conformation is required.<sup>39</sup>

4c. It is advocated not only to rely on actual data of the alarm but also to get insight towards *trends* of the concerning alarms e.g. course of lead resistance.

4d. Not only the actual value of a measurement e.g. abnormal battery impedance but also facilities for comparing previous data permitting a trend evaluation, is strongly recommended.

### **7b. Patient management:**

Because written information is a crucial factor for a safe and accurate remote CIED monitoring and follow-up, it is advised to formulate an outline with minimal requirements of information for nation-wide use. The following elements should be addressed:

1. The device patient should become informed in such a way that he/she is aware that *regular* follow-up by remote monitoring is a safe and convenient way to replace some in-hospital visits. Remote CIED monitoring is not a continuous process but has to be limited to “office-hours” of the hospital. The information should include that alerts will be responded within a reasonable timeframe (e.g. in the day of receipt). The patient and provider should be familiar with this timing to avoid any misunderstanding.
2. The timing of response to an *alert* (patient and physician response time respectively) should be agreed between patient and cardiologist and allied professional. Regulations should be agreed how to reach the patient and the timing necessary to warn the device patient after a received alert. The impact of alerts resulting into any action (sometimes hospital referral) should be addressed. Since the stored data are a part of the medical file patient should be permitted to inspect own data.
3. Patients with remote CIED monitoring have to be informed about the results of the technical follow-up of the device and/or consequences of alerts. The frequency, intensity and timing of this information should be agreed the cardiologist and allied professional and device patient.
4. Consequences of the ownership of the equipment for remote CIED monitoring need to be clarified. The proper handling, consequences of damage and misuse of the transmission equipment need to be addressed.
5. The patient should be informed about the outcome of remote monitoring of his/her device. Furthermore, measures to prevent abuse of remote monitoring or unnecessary referral to the hospital can be given.
6. The patient should inform the cardiologist or allied professional in case of absence more than 20 days or any differently agreed interval to maintain the communication between provider and cardiologist and allied professional.
7. Electrical discharges, whether appropriate or not, will trigger alerts or evoke patient activated alerts. The ICD patient should be aware that these alerts can have major consequences, e.g. the temporarily withdrawal of the driving license.
8. The responsibility and contribution of the device manufacturer and internet provider for the execution of remote CIED monitoring should be clarified.
9. The information about remote monitoring of implanted devices is to be presented in easily understandable text and the cardiologist or allied professional and device patient has to sign that

the information is orally given and written information received. The oral information can be given per patient or in groups of device patients.

### **7c. The in-hospital protocol of remote CIED monitoring:**

It is advised to compose an in-hospital protocol for remote CIED monitoring to describe the tasks and responsibilities of the cardiologist, allied professional and hospital management.<sup>40</sup> This protocol contains the indications of remote monitoring, programming of alerts and technical, organizational and administrative components of remote monitoring. It is advised to formulate an outline with minimal requirements for nationwide use, containing the following elements:

1. To perform remote monitoring specific cardiac knowledge, skills and experience of cardiac arrhythmias and CIEDs are necessary for the cardiologist and allied professional. Hospitals with a license to perform ICD implantations and hospitals without this license but with agreement of a licensed hospital can perform remote ICD monitoring and follow-up, provided clear written rules on responsibilities are made. Hospitals without a license to perform ICD implantations have to meet the same rules and regulations concerning ICD follow-up according to the Dutch Guidelines for ICD implanting centers.<sup>41</sup> All hospitals are free to execute remote monitoring of PM and CRT.
2. The cardiologist decides on the indication, the programming of alerts, frequency and duration of remote CIED monitoring. The cardiologist can transfer these activities to allied professionals according to the standing in-hospital protocol. Mutual interaction between cardiologist and allied professional is necessary to promote safety and relevance of programming and of responses to alerts.
3. The protocol also addresses the written information to the patient, and the priorities and logistic routes to cope with alerts and responses to alerts. The protocol should also underscore that alerts and other remote monitoring data will be responded within a reasonable time.
4. To avoid loss of patient information the communication between the remote monitoring chain and the hospital EPD should be encouraged. The cardiology department and the board of the hospital should supervise the contents, quality and implementation of this in-hospital protocol and the written information to the patient.
5. The protocol requests regular upgrading and can serve as a measure to assess the quality of care of device patients in the hospital.

## Addendum

### Technical standards for remote CIED monitoring

#### 1. Technical standards:

The Netherlands Standardization Institute (NEN) has drafted a *Nederlandse Technische Afspraak* (NTA) which, besides defining Telemedicine, covers the quality aspects of Telemedicine<sup>2</sup>. This NTA is now being revised and will become a Dutch national standard. It will contain requirements for telemedicine providers to develop a quality system that will monitor the risks associated with the service. As soon as this standard becomes available it is advisable to apply this standard for the remote monitoring and remote follow-up of CIEDs.

#### 2. Quality of the data communication:

Transmitted data are labeled to the unique serial number of the implanted device to prevent patient data being mixed between patients. Data integrity and communication between device, transmitter and manufacturer's remote monitoring data centre, are the responsibility of the manufacturer. Data encryption is thought to be energy. Encryption is done by the transmitter. The frequent interrogation of the device is battery consuming (estimated 3 months of a lifetime).

Regarding to the access of data stored at the manufacturer's remote monitoring data centre, mails and SMS messages should all comply with the Code of Practice for Information Security Management.

#### 3. Currents standards for connectivity can be assigned in three levels:

The *functional* specifications of interconnectivity can be found in documents published by *Integrating the Healthcare Enterprise* (IHE). IHE is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical need in support of optimal patient care. Furthermore IHE defines and publishes technical frameworks for developers and users.

By defining the syntax of message formats and communication rules DICOM and HL7 defines *technical* specifications. HL7, which is an abbreviation of *Health Level Seven*, is a standard for exchanging information between medical applications. This standard defines a format for the transmission of health-related information. "Level Seven" refers to the seventh level of the International Organization for Standardization (ISO) seven-layer communications model for Open Systems Interconnection (OSI) - the application level. *Digital Imaging and Communications in Medicine* (DICOM) is a standard for handling, storing, printing, and transmitting information in medical imaging.

For interoperability it is important that, after sending an observation taken by the implanted device, the *semantics* of the observation is clearly defined. IEEE 11073-10103 characterizes clinical terms by defining correct descriptions and definitions. It provides the nomenclature for the clinical observations taken by CIED's.

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**Abbreviations**

AF: Atrial Fibrillation

CIED: Cardiovascular Implantable Electronic Device

CRT: Cardiac Resynchronization Therapy

DDDR: Mode of atrial-ventricular cardiac pacing

DICOM: Digital Imaging and Communications in Medicine

EPR: Electronic Patient Record

EHR: Electronic Health Record

ERI: elective replacement indicator

GPRS: General Packet Radio Service

GSM: Global System for Mobile Communications

GUI: Graphical user interface

HL7: Health Level Seven, international healthcare standard

https: secure internet connection

ICD: Implantable Cardioverter Defibrillator

IDCO: Implantable Device – Cardiac – Observation

IHE: Integrating the Healthcare Enterprise

NEN: Nederlands Normalisatie-instituut

NTA: Nederlandse Technische Afspraak

PM: Pacemaker

SMS: Short message service

VVIR: mode of ventricular cardiac pacing

VT: ventricular tachycardia

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