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Remote Monitoring of Implantable Pacemaker, Cardioverter Defibrillator, and Cardiac Resynchronizer

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1. Introduction

Implantable pacemakers (P), cardioverter defibrillators (CD), cardiac resynchronization systems (CRS), closed-loop recorders, and hemodynamic monitoring implantable products offer multiple programmable options, which allow storage of large quantities of diagnostic information related to the device's function. Traditionally, these mechanisms require direct interrogation to allow seeing the scheduled parameters and stored data to identify and correct possible malfunctioning and improve rescheduling therapy. Implantation of these devices (P, CD, and CRS) has been increasing day by day, thus considerably increasing patients' handling and healthcare system work load. To reduce the time that outpatient services impose and to optimize patient care, manufacturers of these devices offer increasingly more refined remote questioning instruments. Recent technological progresses and a better administration of economical resources may probably allow widening of the use of remote monitoring in the upcoming years.

2. Remote monitoring systems

Currently, there are different monitoring devices and almost all manufacturers have introduced their own version of remote monitoring systems (Figure 1); for example, Biotronik has introduced the Biotronik Home Monitoring® system; Medtronic® has introduced the CareLink® Network; Latitude® Patient Management system has been introduced by Boston Scientific®, and St. Jude Medical's Merlin.net® Patient Care Network (PCN). All these equipments can be compared according to their main characteristics (Table I), and to be implemented, they need to be equipped with an antenna that communicates to a small external device known as transmitter that is able to question the diagnosis parameters of the data stored in most of the devices, either with patient's active participation or at pre-scheduled intervals.

Parameters	Biotronik Home Monitoring®	Medtronic Carelink® Network	Boston Scientific Latitude®	Merlin.net® Patient Care Network (PCN)
FDA's date of approval	2001	2005	2006	2007
Device name	CardioMessenger®	PatientLook SentryCheck (OptiVol)	Latitude Communicator	Merlin@home
Characteristics	Portable	Stationary	Stationary, interactive	Stationary, voice-interactive
Telemetry at home USA	MICS	MICS, antenna	Antenna and wireless	MICS
Telemetry - rest of the world	MICS	Antenna	Not available	Antenna
Wireless products	All products	DAI and DAI + ResBiv	All products	DAI and DAI + ResBiv
Reminders / Manual transmission	Automatic	No	Yes	Yes
Patient takes actions in case of event	CardioMessenger® / Recall	Audio	Audio	Vibration
Telemetry range	4-GSM band, GPRS, mobile, <i>analog</i> line	<i>Analog</i> line	<i>Analog</i> line	<i>Analog</i> line
Interaction during transmission	No	No (wireless) Yes (Analog line)	No (wireless) Yes (Analog line)	No (wireless) Yes (Analog line)
Transmission	Daily, follow-up, event messages (automatic)	Scheduled follow-up, event message (started by the patient)	Scheduled follow-up, event message (started by the patient)	Started by the patient (manual)
Event transmission route	Fax, Internet, e-mail, text message	e-mail, text message	Fax, phone	Fax, Internet, EMR
Early detection	<24 hours (all events)	<24 hours (certain kind of events)	<24 hours (certain kind of events)	Not available
Data storage	Long term	Long term	Long term	Long term
EMR interface	HL7	HL7, EMR	HL7	HL7, EMR
Data presentation	Event- and signaling-based	Event-based	Orientation in signaling	Event-based
Real-time EGM	Event-generated	Holter and pacemaker	Holter and pacemaker	Not available
Holter transmission	>45 sec.	10 sec.	10 sec.	30 sec.

Parameters	Biotronik Home Monitoring®	Medtronic Carelink® Network	Boston Scientific Latitude®	Merlin.net® Patient Care Network (PCN)
Sensor	IC monitor	OptiVol®, Cardiac Compass	Weight, BP, symptoms, pacemaker statistics	Statistics and surface ECG
Repercussion on long-lasting battery	Low	High	High	Not available

Abbreviations: MICS = Medical implant and Communications bandwidth (402-405 MHz), GSM = Global System for Mobile Communication, GPRS = General Packet Radio Service, HL7 = Interface standard, EMR = Electronic medical records, EGM = intracavitary electrocardiogram, IC = Heart failure, DAI = Implantable automatic defibrillator, DAI + ResBiv = Implantable automatic defibrillator plus biventricular resynchronizer

Table 1. Remote monitoring systems



Fig. 1. The four remote monitoring systems currently in use.

Once captured, the data from that device are uploaded using a transmitter that has a standard analogical telephone line or wireless telephones, to a safe central where the data are processed. The patient receives messages or event alerts through an acoustic signal (*beep*) and/or vibrations, and in certain systems, such alerts are used to indicate that the patient should start the data manual transfer from the transmitter to a central base. During transmission, the level of participation varies depending on the manufacturers’ and the patient’s clinical condition, and the urgency of the processed data may trigger a rapid alert

to the physician through an email, text messages, fax, or a phone call, in which a detailed report is simultaneously published in a secure website for the visualization of the physician or another authorized reviewer.

Most of the remote monitoring systems transmit patients' data through standard telephone lines, either on a weekly or fortnightly basis. Yet, we should not forget that there are other equipments, such as Biotronik Home Monitoring®, in which the transmission is based on a wireless telephone that could be carried in the belt or handbag, which is capable of capturing the stored information daily. Still, with either system, the patient's information can be continuously controlled and the variables that are included more frequently are battery status, battery impedance, electrode impedance, post-shock impedance, arrhythmia detection, therapies administered, and average heart rate. Furthermore, it is possible to record an electrogram (EGM) of the event that triggered the alert or, failing this, a change in the electrode impedance, caused by a fracture or the device elective replacement, as well as inefficiency to deliver a stimulus, onset of atrial fibrillation (AF) events, and heart failure (HF) deterioration.

Typically, transmission parameters differ among equipments; nevertheless, they are adjustable to each patient. The physician can set specific alert conditions according to the patient's base disease. Remote monitoring reports are generated and sent with different alert levels, so that the individual may answer according to their urgency. For instance, the physician could be notified within an hour (if so scheduled) in case of ventricular tachycardia or increase in ventricular extrasistolia: two events that trigger an alert of different levels. The main differences among the remote monitoring procedures relate to the data transmission frequency and reporting, the necessary level of patient participation for the transmission success, and the movement capability that they offer. No system allows the programming remote control a functionality that probably will not be available soon because of ruling issues and the legal medical rate.

3. Types of remote monitoring systems

The **Biotronik Home Monitoring®** system transmits data on a daily basis, at fixed intervals and soon after a clinically relevant event has occurred. Home Monitoring® has introduced the first equipment of this kind in 2001 and it is currently available in over 50 countries. The equipment can be programmed per event line and individual surveillance parameters. The usual events included in these devices are atrial monitoring for AF detection, HF monitoring, and high-definition intracavitary EGM (Figure 2), similar to the therapies being administered.

This system bases its functioning in three steps: The first step is the communication between the implanted generator and the patient device, named CardioMessenger (CM) (Figure 3). The generator emits a message at a medical implant-reserved frequency (402–405 MHz) to the CM, activating a radiofrequency (RF) circuit integrated to the head of the implanted equipment. On the scheduled time, the patient must be from 20 cm to 2 m far from the CM to ensure successful transmission.

The second step relates to the CM message delivery to the service central in Germany, via GSM/GPRS cellular. The CM zips and codes the information using the standard known as Digital Encryption Standard (DES), owing to which the patient can be elsewhere in the world with access to a cellular network, and the system will function normally (Figure 4).

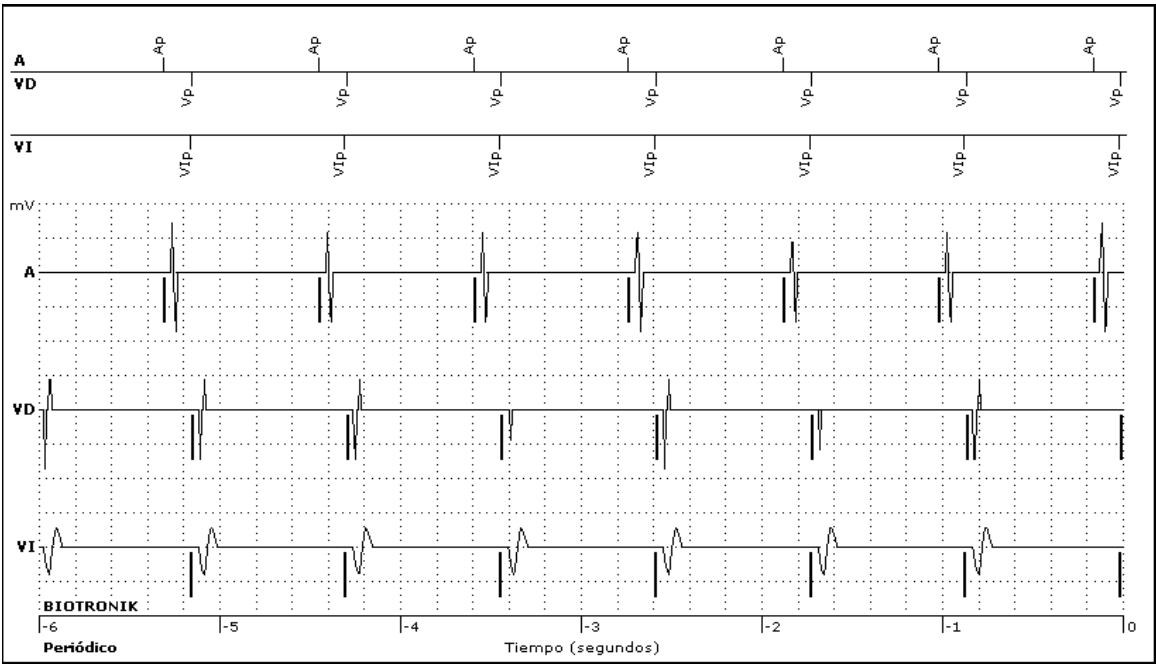


Fig. 2. An intracavitary ECG of a resynchronizer with implantable automatic defibrillator, which was sent as a device periodical report of the Biotronik Home Monitoring® system, available in the Internet. The mark channel can be observed at the top and the electrocardiograms can be found at the bottom. Abbreviations: Ap = Stimulation of the right atrium. Vp = Stimulus of the right ventricle. VIp = Stimulus of the left ventricle. A = EGM of the right atrium. VD = EGM of the right ventricle. VI = EGM of the left ventricle.



Fig. 3. Three types of CardioMessenger® of Biotronik Home Monitoring® system.

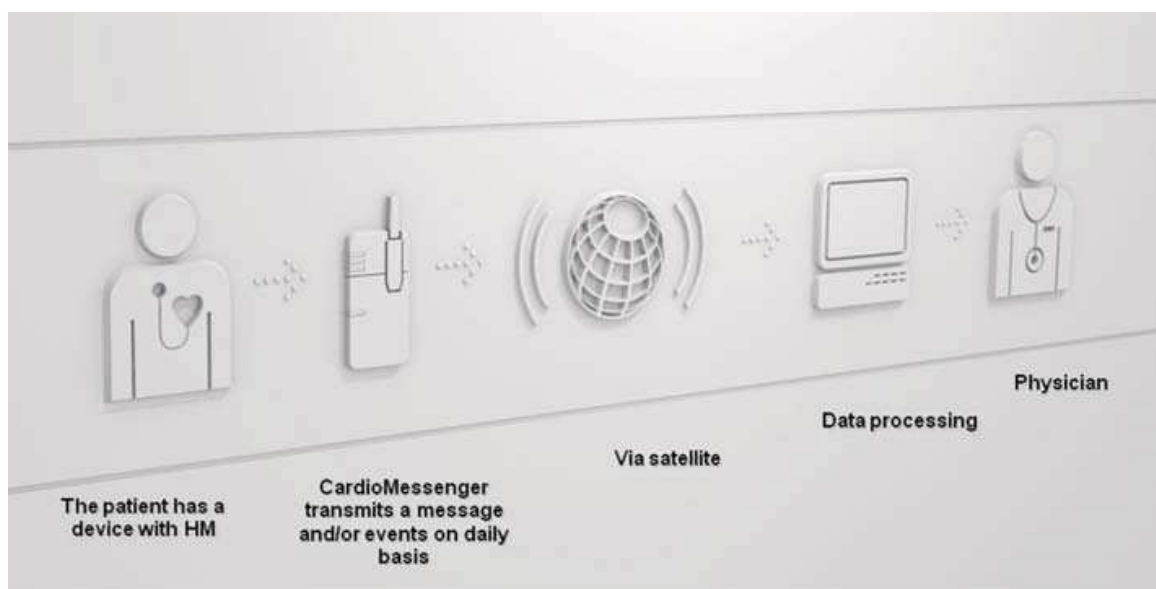


Fig. 4. Chart showing for whom the Biotronik Home Monitoring® system works. The approximate transmission time is of about 5 minutes.

This is an automatic system performing the following types of transmissions and messages:

1. Every 24 hours, at a physician-preset time, the device sends a transmission containing the data gathered along the last 24 hours and the CM issues a message to the service center.
2. When any major cardiac event or change occurs in the device's or electrodes' technical parameters, a message is immediately sent.

In the third step, the physician receives a report issued from the service center based in Germany, named CardioReport, to which he/she will have access through an internet-based secure webpage (Figure 5). He/she may also receive a text message (SMS), fax, or e-mail informing him/her that the patient must be monitored in case of an adverse event. In the internet, the physician will have access, from any computer, to whole information related to the event and/or report, and to the device and its electrodes, which will have the following characteristics:

- Home page: Intuitive platform that allows the physician to rapidly visualize patients who need more attention.
- Consolidated report (CardioReport) per patient, continuously updated.
- Control and recognition of changed events and the possibility to recognize alert changes.
- Fields to add comments and remarks, which relate to both the patient and his/her clinical history.
- Time line: history of detailed events on a time line.

The system rapidly transmits symptomatic or asymptomatic events, regardless of the patient's location, in that it is automatic, silent, and does not require his/her participation. The follow-up can be either monthly, quarterly, or half-yearly, and the physician may also access the accumulated files published in an internet-secure site for rapid review and evaluation of its evolution.

The **CareLink®Network (Medtronic®)** system is designed to perform remote monitoring of the status of the implanted device and includes a monitor and an antenna, through which the patient and/or the medical personnel may interact.

Pacientes para revisión				
Pacientes 1 - 6 de 6				
Buscar <input type="text"/>		Mostrar 10 20 50		1 - 6 de 6
ID de paciente	Hallazgo	Implante/NS	Implantación	Comentario
1	Cable S-imp. ...	Kronos LV-T 79693186		
2	Implante ERI ...	Lumax 300 HF-T 60414607		
3	Implante DetOff. ...	Kronos LV-T 79690709		
4	Monitor de IC BajTRC. ...	Kronos LV-T 79693214		
5	Arritmia aur. A-Mon. ...	Lumax 340 HF-T 60450148	08-oct-2009	Cardiomiopatía dilatada FEvi 25% , F...
6	Monitor de IC V-HR. ...	Lumax 340 HF-T 60443704	28-sep-2009	Cardiomiopatía dilatada isquémica FEV...
Ver Pacientes para revisión Todos los grupos de pacientes Todos los tipos de implante Monitorización activada Vista extendida Guardar / Imprimir (PDF)				

Fig. 5. Page available at the Biotronik Home Monitoring® website portal in which the patients’ conditions can be observed. Red and yellow colors, characteristics of the signaling, according to the level of attention that should be addressed; in this case, yellow color indicates review and red signifies urgent review.

The monitor is small and has an antenna that connects to an analogical telephone line. The user (who may be the patient him/herself) has to press a button to switch it on and place the antenna onto the implanted device. The monitor questions and transmits the patient’s technical and physiologic data stored in it and 10 seconds, in real time, of the EGM.

The monitor will automatically call a toll-free telephone number and send the information to the servers of the CareLink® system using a safe connection. To inform the patient that the transmission has successfully occurred, the monitor uses audible tones and visual indicators.

There are two types of monitors, manuals and automatics, which work in a similar way, even with some small differences. CareLink® monitors operate with a single specific implantable device, i.e. each monitor is linked to the serial number of the implanted equipment and will not work in another patient, because the server will not accept transmissions made from a CareLink® monitor associated with another device. There is a webpage where it is possible to visualize the condition of the discharged patients using a PC with Internet through a web browser (Figure 6), and only registered personnel will have access to the data of the patients followed up in that center.

The in-line format allows a detailed report, in which it counts on a Cardiac Compass® visualization system that allows visualization of up to 14 months of accumulated parameters, namely, atrial and ventricular stimulation, heart rate, atrial fibrillation events, and the response of the heart rate to the patient’s activity. The CareLink®Network (Medtronic®) system includes in its follow-up those devices available in OptiVol®, a single sensor for the increase in the pulmonary fluid used for the early detection of deterioration of HF. This sensor indicates the ratio between the liquid status and the intrathoracic impedance, and the system is driven through a device-issued audible tone, which asks the patient to start a period of communication sessions in response to the events that the implanted device has detected, as well as relevant clinical changes in the system: arrhythmias, administered therapies, etc. The description customization for each patient requires the use of a programmer during the outpatient visit. Manual programming also needs to define the transmission.

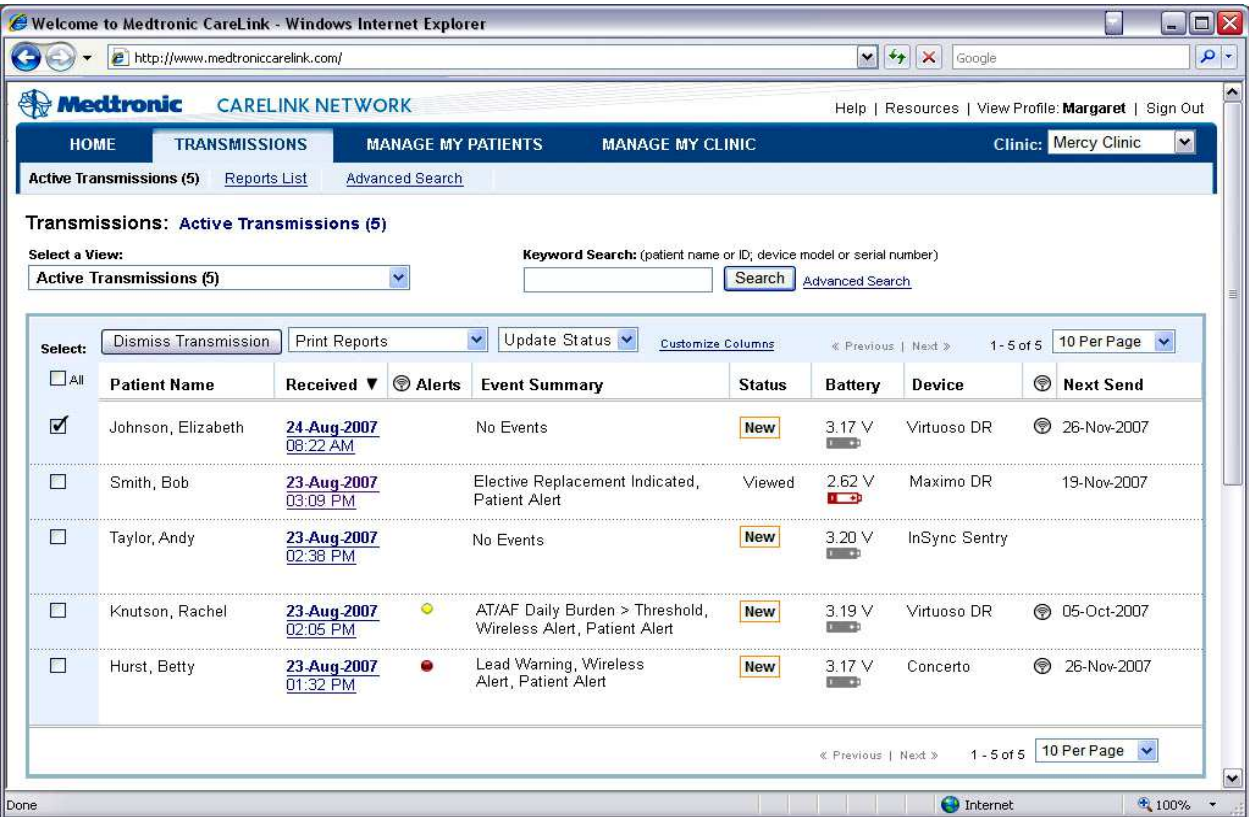


Fig. 6. Webpage of the CareLink® Network (Medtronic®) system in which a list of patients, type of alert under the signaling scheme, and type of event, battery voltage, and type of device can be observed.

Latitude® Patient Management System (Boston Scientific®) admits almost all Boston Scientific® devices, namely CD and RCS, depending on the implanted device and on the fact that it is operated through telemetry or a wireless transmitter to question the device at home, usually on a weekly basis. The transmitter also uses a ground analogical system to transmit data that can be configured to be used in several countries. A unique characteristic of this product is the possibility to wirelessly connect weight and blood pressure scales for the remote monitoring of the HF condition; also in addition, the patient may obtain an automatic weekly report of his/her condition (fatigue, ankle edema, orthopnea, etc.). Notices of events may be individually configured based on the “red” and “yellow” alerts. Furthermore, the customized data transmission system allows different physicians (general physician, cardiologist, and electrophysiologist) to improve the follow-up in HF clinics.

St. Jude Medical’s Merlin.net® Patient Care Network (PCN) is an implant procedure and implantable device clinical follow-up remote transmission system that stores data for up to 7 years. The implant system is provided through InvisiLink® Wireless telemetry and the follow-up is provided through the RF Merlin@home® transmitter, which receives the DirectCall® messages; furthermore, it offers an online agenda. A useful characteristic is the possibility offered to the physician to indicate warnings and regular remainders for medical appointments in the patient’s transmitter and to make automatic calls to patients with the results. The monitoring system sends daily notices known as DirectAlerts® and can export a database by integrating the Healthcare Enterprise (IHE) system. The Merlin@home® system is a small box, similar to a phone operating in the medical device band in the 402–405 MHz

range. It has a start button that allows the interrogation to be started by the patient, and has status lights for both the transmitter and the transmission in one icon and connects to an analogical telephone line. On a daily basis, it checks the status of the implanted device and notification is sent to the physician through e-mail, fax, text message, phone call, or Internet (Figure 7). The device may be used in emergency rooms. In addition, there is a version that is not wireless. The system has both manual and automatic programming; pool programming is possible and it also offers DirectCall® message feature; notifications (DirectAlert®) that allow the patient’s condition to be monitored may be configured either as urgent or report. It has a DirectTrend™ visualization that graphically shows the stimulation percentage trend.

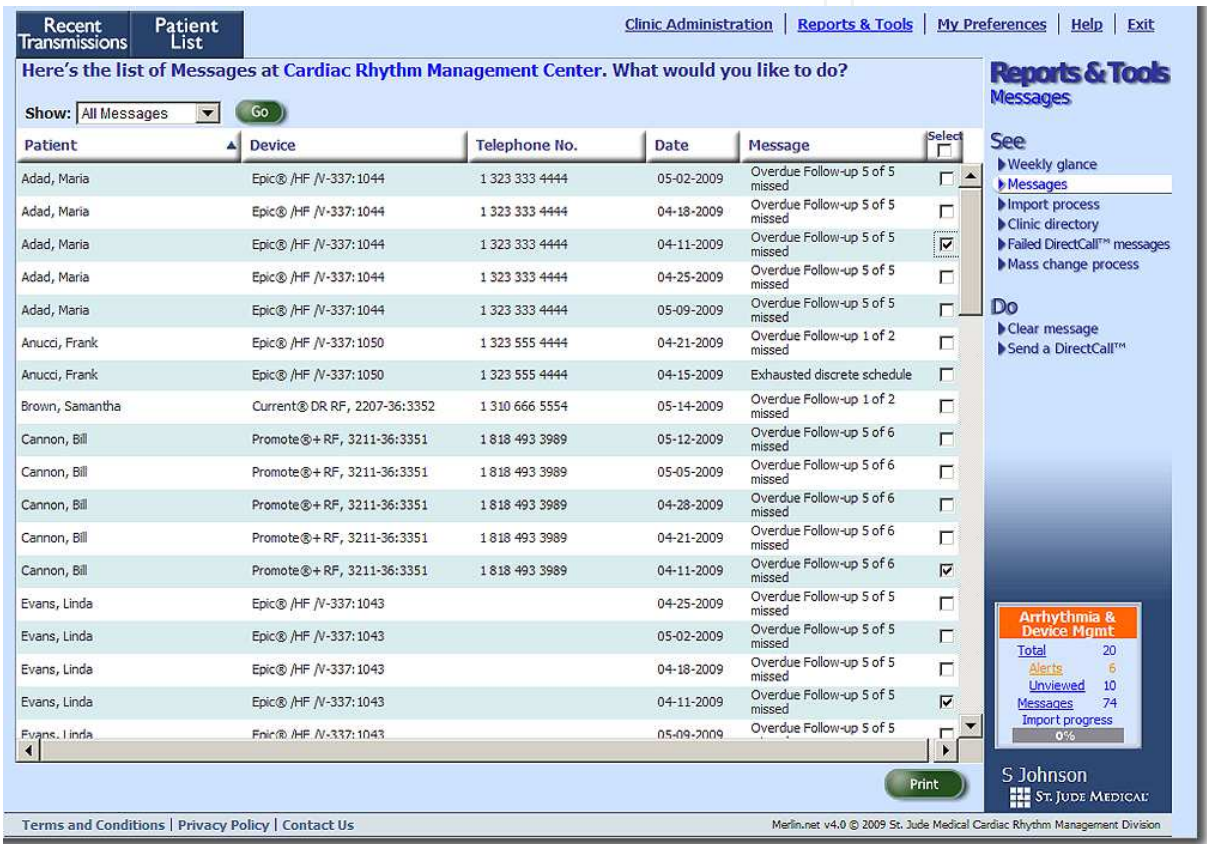


Fig. 7. Webpage of the Merlin.net® Patient Care Network (PCN) system in which the list of patients, type of devices, and other characteristics can be observed.

4. Benefits of remote monitoring

The Heart Rhythm Society (HRS) and the European Heart Rhythm Association (EHRA) have defined that the main purpose of remote monitoring is to identify the device’s abnormal behavior as soon as possible to limit the sub-registration of its malfunctioning. This is how they have also established the determining factors to set the device follow-up frequency; something of utmost importance was to establish the minimum interval required to provide follow-up, either on-site or remotely (Table II). Currently, the Biotronik Home Monitoring® seems to be the best system for the early detection of the abnormal behavior of the device. This may be particularly pertinent in the

Conditions	Type of monitoring
Within the first 72 hours after having implanted a P,CD, CRS	Personally
Two to twelve weeks after having implanted a P,CD, CRS	Personally
Three to twelve months after having implanted a P, CRS	Personally or remotely
Three to twelve months after having implanted a CRS + defibrillator and CD	Personally or remotely
Annually, until the battery voltage reduction	Personally
Monthly, until three months, with data related to the battery voltage reduction	Personally or remotely

Abbreviations: P = Pacemaker, CD = Cardioverter defibrillator, CRS = Cardiac resynchronization system

Table 2. Minimum follow-up time required for remote monitoring or onsite visit of P, CD, and CRS

case of warning-programmed equipment; the daily control of the device may allow the expecting behavior without needing to shorten the follow-up intervals, which reduces the patient’s anxiety. The reported adverse events include, among others, the imminent dysfunction caused by battery worn-out, electrode defects, and inefficient shocks. Some similar remarks with other remote monitoring systems suggest a potential of similar output, even if with lower risk of early detection.

Another important target of remote monitoring is the reduction in the number of followed-up patients attending the hospital. Remote monitoring could become a tool that, maybe, could replace visits to the hospital, which may be unnecessary when remote monitoring has not detected any issues. It has to be mentioned that nowadays the remote monitoring systems have improved the data capture format as well as alert-reporting, which is partially user-defined, and simplification of their interpretation, what has enhanced the time scheduled for its analysis.

Remote monitoring can also has a positive impact on the quality of the medical service and the patient’s quality of life, because:

- It allows the early detection of arrhythmias, changes in the device functioning, or changes in the patient condition during follow-up.
- It helps in providing individual programming time aimed to optimize the handling of patients having frequent arrhythmias or technical complications, cost reduction, and workloads imposed by the patients having no complications or having stable clinical conditions.
- The acceptance of patients to the state-of-the-art reliability that the implanted device operates properly, along with the advantage of reduced number of hospital visits.

Even if more exact indicators of the patient’s clinical conditions have not been clearly defined, abnormal vitals, including inadequate increase in the heart rate at rest, minute ventilation, and a drop in intrathoracic impedance may be signals of HF deterioration. As adaptation to new technologies requires efforts to abandon what is already known, both hospital services and physicians are enthusiastically accepting this system.

5. Future perspectives

Remote monitoring may probably be included in the upcoming devices (P, CD, and CRS), and one can expect that new useful sensors will be made available soon. These progresses may introduce changes in the follow-up procedures and their goals, may allow the physicians to opportunely intervene to improve the clinical outcomes, and may cause reduction in medical expenses. New sensors may become necessary to prevent HF, as measure of intrathoracic impedance, intracardiac pressure, and minute ventilation. Other sensors that are potentially valuable for remote monitoring are function of the left ventricle, volume of the left ventricle and contractibility, oxygen venous saturation, muscular activity, and, finally, myocardium ischemia. The latter is related to recent publications in which one may obtain the reconstruction of a 12-derivation ECG through the implanted device (CRS, CD), obtaining a good correlation with the conventional surface ECG⁷. If we aggregate the possibility to obtain information through remote monitoring, its utility will be very helpful to discriminate myocardium ischemia, atrial and ventricle extrasistolia, and, most importantly, the possibility to distinguish between supraventricular tachycardia and ventricular tachycardia. Some of these sensors could be used in patients already implanted with P, CD, and CRS.

6. Conclusions

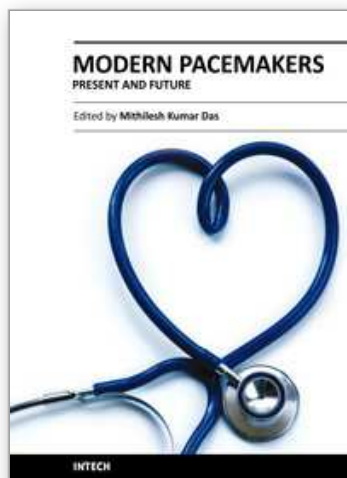
The remote monitoring system is a useful tool that can be used in health institutions to follow-up P, CD, and CRS, obtaining substantial benefits such as early diagnosis of arrhythmias, to adequately recommend a treatment. Reduction in the number of visits to device clinics allows the patient to freely perform his/her daily activities or travel, because he/she will be covered by continuous remote monitoring. Furthermore, there is the possibility that patients with any kind of limitation to attend the clinic, either because of any physical or transportation limitation, may find an alternative in this system. Finally, with remote monitoring, patients counting on any medical alert of *recall* could benefit from a stricter follow-up to detect possible system failures. With all these benefits, the satellite remote monitoring system offers an alternative to the on-site visit for the monitoring of the devices, though this may not replace medical visit.

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The book focuses upon clinical as well as engineering aspects of modern cardiac pacemakers. Modern pacemaker functions, implant techniques, various complications related to implant and complications during follow-up are covered. The issue of interaction between magnetic resonance imaging and pacemakers are well discussed. Chapters are also included discussing the role of pacemakers in congenital and acquired conduction disease. Apart from pacing for bradycardia, the role of pacemakers in cardiac resynchronization therapy has been an important aspect of management of advanced heart failure. The book provides an excellent overview of implantation techniques as well as benefits and limitations of cardiac resynchronization therapy. Pacemaker follow-up with remote monitoring is getting more and more acceptance in clinical practice; therefore, chapters related to various aspects of remote monitoring are also incorporated in the book. The current aspect of cardiac pacemaker physiology and role of cardiac ion channels, as well as the present and future of biopacemakers are included to glimpse into the future management of conduction system diseases. We have also included chapters regarding gut pacemakers as well as pacemaker mechanisms of neural networks. Therefore, the book covers the entire spectrum of modern pacemaker therapy including implant techniques, device related complications, interactions, limitations, and benefits (including the role of pacing role in heart failure), as well as future prospects of cardiac pacing.

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