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## Telemonitoring of the Pacemaker

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### 1. Introduction

With increasing knowledge about the cardiovascular diseases and with more advanced technology, indications for implantation of pacemakers are expanding. By the end of 2007, about 560,000 pacemakers were implanted in North America and 680,000 in Europe. With the increasing prevalence of pacemakers, management and follow up of these complex patients is becoming an ongoing issue. Close monitoring and interrogation of their pacemakers remains a main part of the complete evaluation of these patients. It is estimated that in North America and in Europe, there are 3.2 million pacemaker encounters per year. Due to huge number of patients, following all the patients in the outpatient clinic/hospital on the regular basis may not be feasible. Hence, it has been suggested that telemonitoring system could provide a practical substitute to the time-consuming and expensive in-office visits. In this chapter, we will be describing the current technologies and also provide an update on this rapidly evolving topics, by incorporating the latest data and on-going trials.

*Telemonitoring* is defined as the use of audiovisual and other information technologies to monitor patient status at a distance; it can be used in monitoring the cardiac and respiratory status of patients. In 1905, Einthoven transmitted Electro Cardio Gram (EKG) from a hospital to his home using a telephone line. In 1920s, Winters transmitted the heart sounds using a radio link. Later on in the 1960s, with increasing technological advances, the United States navy used the telemonitoring system to transmit their soldiers' physiologic data from the ships to their shore hospital at Florida, USA (Institute of Medicine). In the past few decades, telemonitoring attained a robust development. Recent Heart Rhythm Society / European Heart Rhythm Association expert consensus on monitoring the cardiac devices (Wilkoff et al., 2008) recommended that patients with pacemakers/defibrillators should be monitored at regular intervals based on the time elapsed after the device implantation. (Table 1)

Telemonitoring may be subdivided into:

1. Remote follow-up:

Device data will be transferred from the patient to the physician's office or to the central data processing center in a *predetermined scheduled time* using the wand / transmitter.

2. Remote monitoring:

In addition to the transmission of the data from the device on a *daily basis, unscheduled transmission of the predefined alerts* (e.g. battery depletion, improper sensing / capture), will

also happen. The data from the device will be transmitted and the physician will be notified, according to the predefined settings by the physician (e.g. information given to the physician/health care provider through SMS, emails, contacting the office through phone).

Minimum frequency of monitoring of pacemakers either in person or remotely		
	Remote monitor	In person follow - up
Within 3 days of Implantation	-	X
2-12 weeks post implantation	-	X
Every 3-12 months after implantation	X	X
Every 1-3 months at signs of battery depletion	X	X
Annually until depletion of battery	-	X

Table 1. Timeline for follow up of the Pacemakers

X – Recommended; - Not recommended

### 3. Bidirectional telemetry:

In addition to the remote monitoring of the pacemakers, *remote interrogation and remote programming* of the pacemakers can be done with newer revolutionary technologies.

## 2. Importance of monitoring the pacemaker:

Monitoring of pacemakers is necessary for both patient- and device-related factors. Wilkoff et al. (2008) described the various important reasons and goals of monitoring pacemakers. By closely monitoring the pacemakers, the clinician would achieve the goals outlined below. (Table 2)

Patient Centered Factors
Optimize the patient's quality of life
Identify the patients at risk (based on the alerts) and appropriate follow up
Identify any abnormal brady / tachy arrhythmias
Identify non device related problems and appropriate referrals
Patient safety
Peace of mind for the patient

Device Related Factors
Optimize the pacemaker function to meet patients' need
Identify and correct abnormal device function
Identify the end of life of the battery, monitor lead dysfunction
Monitor the various alerts by the device and triage accordingly
Maintain a database for future research purpose.

Table 2. Factors effecting pacemaker placement

### 3. Description of the telemonitoring technology:

Implanted pacemakers are pre-equipped with a micro-antenna, which communicates with a small external device, commonly known as transmitter. A receiver or “wand,” is attached by a wire to the programmer and positioned on the body’s surface over the pacemaker implantation site to receive the telemetry signal from the pacemaker. The wand will be *talking* to the device as radiofrequency signals (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). The distance for radiofrequency signal communication has increased from several cm to several meters and some devices can even communicate without a wand. The transmitters are able to interrogate programmed parameters and diagnostic data stored in the device memory with active participation of patient (via a wand), or automatically (wandless), at preset time intervals. The data downloaded from the device by the transmitter is then uploaded as an encrypted data, to a secured clinical database either by a standard analog phone line or through wireless GSM (Global System for Mobile) connection. The programmer is a computer with specific software and associated hardware modifications that provide highly reliable exchange of the encrypted information and precise communication with the cardiac device. The transmission of these data may be initiated by patient (as a scheduled transmission or event triggered (symptom / alert by device)).

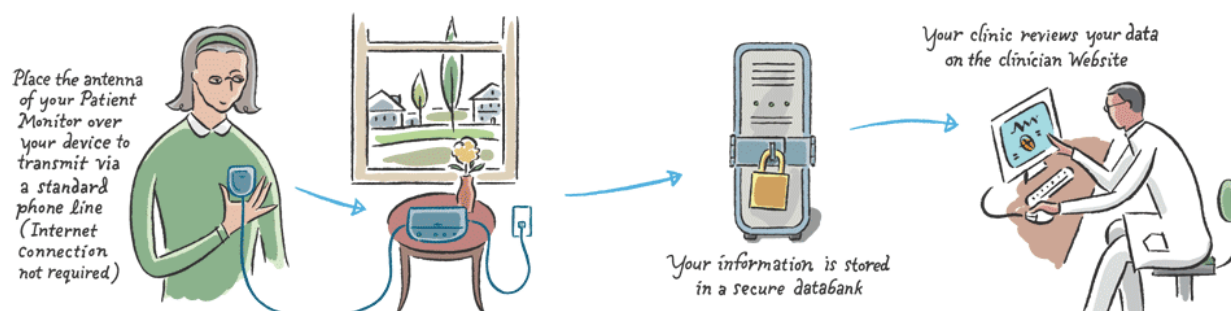


Fig. 1. Telemonitoring technology.

The data will be processed in central processing center, which is usually maintained by the device manufacturers. The data will be uploaded in a secure website and a health care provider can login and look into the events (Figure 1). In addition to the uploading of the data to website, depending on clinical urgency, the concerned health care provider will be notified via email, SMS, fax or telephone call as predefined by the physicians. Moreover, some manufacturers follows a traffic light like system, in which the alerts will be sent to the clinician in varying colors like red, yellow and green, depending on the magnitude of the problem. Otherwise, after initiating manual transmission, patient also can call the physician, who can login to the password protected secure website and look into the events.

Typically, the following informations are transmitted to database: heart rate, battery status, lead integrity, pacing lead impedance, episodes of arrhythmias, delivered antitachycardia pacing, percent pacing, histogram, real-time and magnet Electrograms (EGM), stored EGMs

and arrhythmia summary with mode switch duration. These data will help the clinician to diagnose any active problems. In addition, monitoring of the silent events like asymptomatic atrial fibrillation is *very important* as these arrhythmias are proven to be an independent risk factor for increased mortality in patients with heart failure. In addition to these data, patient can also enter his blood pressure measurements, body weights and other symptoms related to heart failure (in patients with Cardiac Resynchronization Therapy {CRT}). Based on these data, physicians would be able to make changes in the management of the patient's condition.

Programmers can also communicate the interrogated data to a remote printer for a hard copy presentation or be transferred to a database or Electronic Medical Record (EMR). To connect to the database or to EMR, the data are saved and then transferred via disc, CD ROM, USB drive, directly by a network cable, Bluetooth or Wi-Fi communication to an internet or intranet network connection. The ISM and MICS radiofrequency communication is used only for connecting the pacemaker to the programmer or remote telemetry device and not for connecting the programmer to printers, saved files, the database, EMR or registries.

#### **4. Types of remote transmission:**

##### **4.1 Patient initiated remote transmission:**

In this mode of transmission, the initiation of data transfer from the pacemaker is done by the patient himself / herself. This may be a regular, scheduled transmission or an unscheduled transmission, triggered either by the patient symptoms (like shortness of breath, lightheadedness, syncope, palpitations) or in response to an alert given by the pacemaker (usually an audible sound or vibration).

##### **4.2 Device initiated remote transmission:**

In this mode of transmission, initiation of data transfer from the pacemaker is done by the pacemaker itself. Data will be transferred on a regular scheduled basis, at fixed time intervals (often at night, when the patient is lying in bed). Usually, the patient need not place the wand over the pacemaker. The pacemaker itself will "talk" to the home monitor/communicator and initiate transfer. If there is any change in patient's physiologic data or any new alerts by the pacemakers, there will be an unscheduled initiation of the data transfer from the pacemaker, even without the knowledge of patient.

##### **4.3 Transtelephonic monitoring without interrogation:**

This is one of the older techniques. This technology is solely limited to pacemaker follow-up. In this method of transmission, patient must initiate data transmission through a telephone. Each transmission usually includes an initial rhythm strip and then a rhythm strip demonstrating magnet rate of pacing system. Telephone transmissions provide only a brief snapshot of cardiac rhythm and thus intermittent problems may not be detected. It still has some value in monitoring the pacemakers approaching end of life and in need of elective replacement of the battery.

#### **5. Types of various tele monitors by 4 major companies:**



The following four types of remote monitors are produced by the various pacemaker manufacturers:


### 5.1 Biotronik


In 2001, Biotronik introduced wireless remote monitoring of cardiac devices. Biotronik Home Monitoring uses three simple colours to quickly and automatically convey a wealth of vital information to physicians who need on-the-spot patient data anywhere, any time. When activated, Home Monitoring<sup>®</sup> (Biotronik & Co. KG, Berlin, Germany) transmits data systematically on a daily basis, at a fixed time of day (usually in the night times), via a special cell phone-like instrument (CardioMessenger<sup>®</sup>, Biotronik Figure 2)) kept within 2 m from the implanted device. The transmission utilizes state-of-the-art encrypted SMS technology to transfer worldwide data to a dedicated center.



Fig. 2. CardioMessenger<sup>®</sup> from Biotronik

Event notifications are assigned by the physician with a red or yellow colour-code to ensure that only serious  or important  patient status changes are alerted to the physician. The "red-dot" principle serves as a simple navigator that lets physicians quickly assess the patient's status at a glance while allowing them to focus only on those cases with clinically relevant events. In addition to color-coded messages on the internet, the physician receives a notification via email, fax, or text message in case of serious changes in the patient's status.

Red  indicates a severe deviation from a defined threshold with high priority.

Yellow  indicates an important deviation from a defined threshold with priority.

White indicates the absence of any severe or important change.

When a clinically relevant status change occurs, Biotronik Home Monitoring<sup>®</sup> generates an event alert via email, SMS, or fax to the physician while simultaneously displaying the severity of the patients' status on the secure Biotronik Home Monitoring<sup>®</sup> website. It also offers information that might allow the detection of adverse events on average of 2 and 5

months earlier than feasible by standard care in patients followed quarterly and biannually, respectively (Ellery et al., 2006). The majority of the alerts are disease-related, prompted by atrial fibrillation, ventricular arrhythmias, and ICD or CRT therapy, in particular.

## 5.2 CareLink®

CareLink® is produced by Medtronic, Minneapolis, MN, USA. The monitor produced by CareLink® is very small, about a pound in weight and easy to carry in a brief case. On the scheduled day, patients have to simply connect their monitor to a regular phone line, push the start button, and hold the antenna over heart device. The monitor sends the device information and turns itself off when the transmission is done. Data will be transferred to the secure central data collecting system; from there, the information will be passed on to the health care personnel as guided by the urgency of the information.

If patients have a Medtronic heart device with Conexus Automatic Monitoring, the device data may be sent automatically, usually while the patient is sleeping. These transmissions are scheduled by the clinical team. On the scheduled night, the device “wakes up” and communicates with the monitor. The monitor silently sends the device data, without assistance from the patient.

Heart devices with automatic monitoring are able to send a CareAlert® notification to the database, when certain conditions are met, such as low battery or an irregular heartbeat. This information will be appropriately transmitted to medical team (Figure 3).

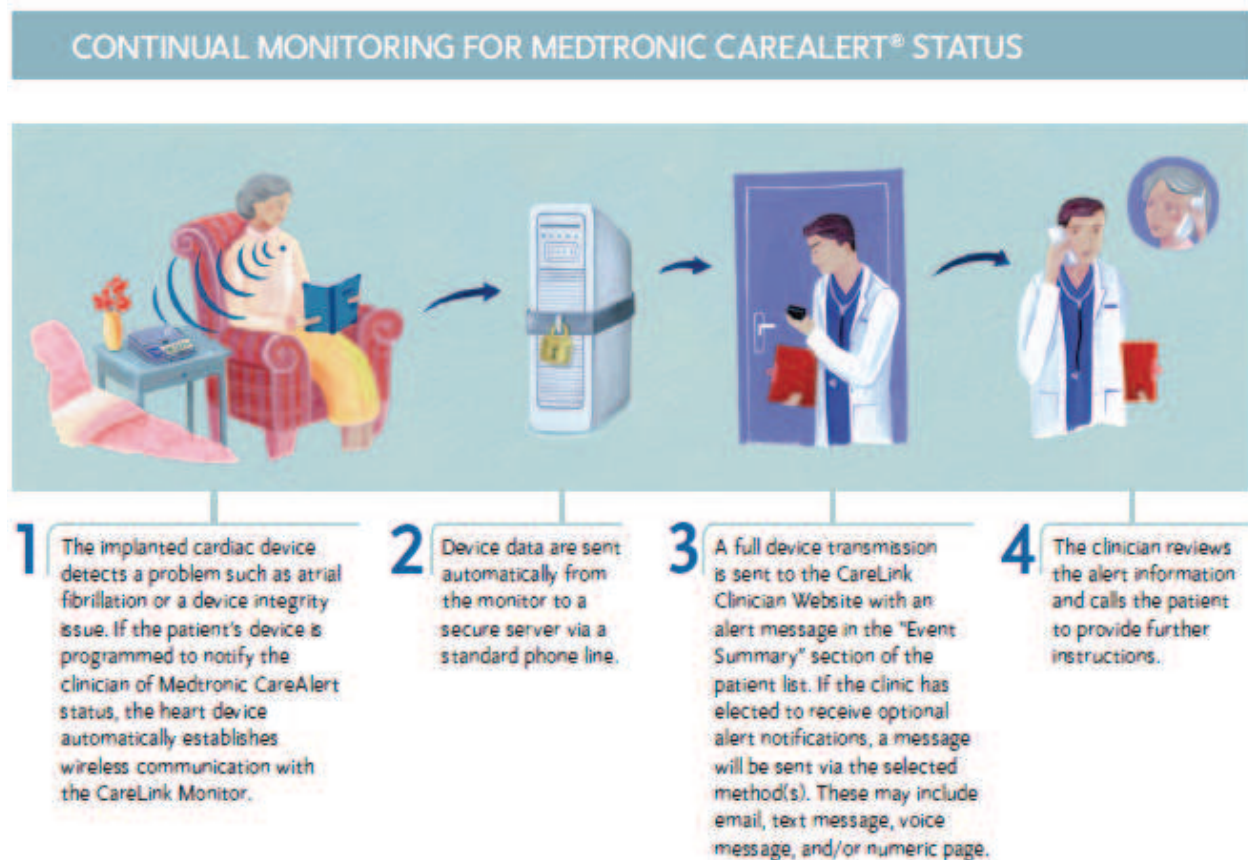


Fig. 3. CareAlert®

### 5.3 Latitude

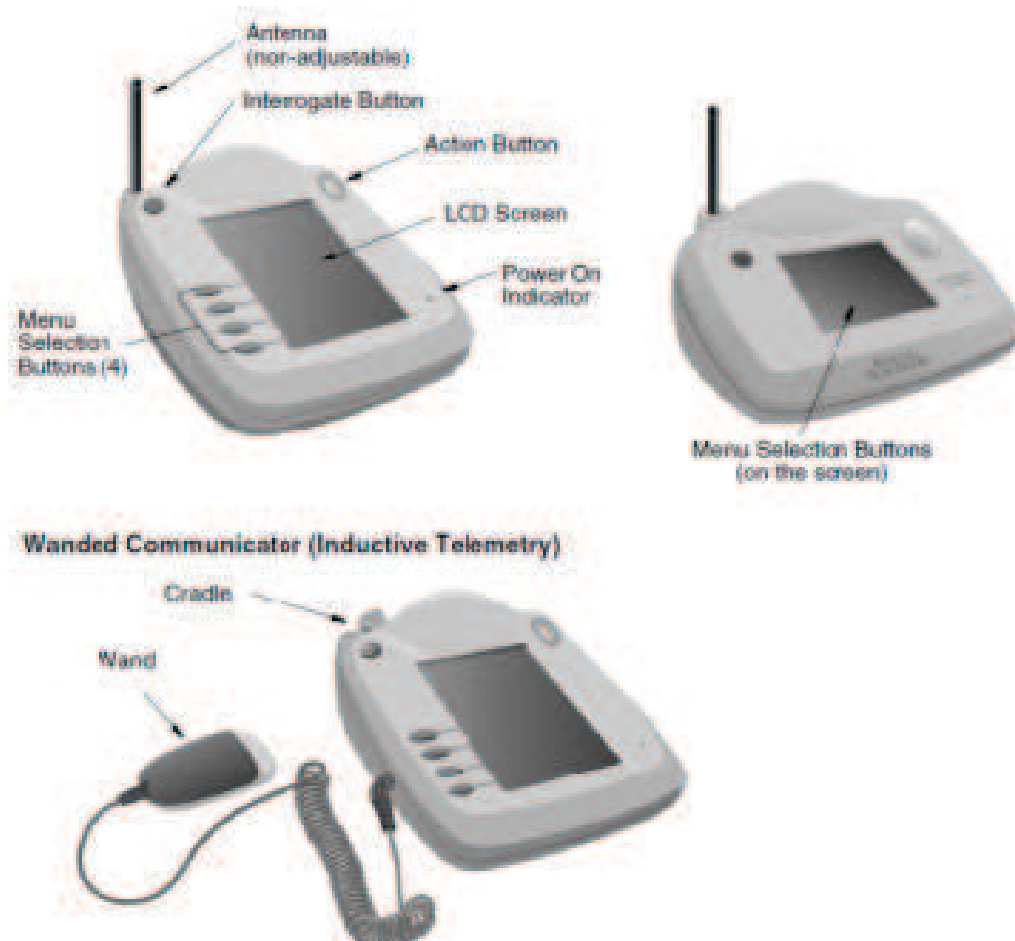


Fig. 4. Latitude Home Monitoring System

Latitude system uses a wireless (e.g. radio frequency or Bluetooth®) feature that offers daily and/or weekly status checks with physician notification. This feature can be activated for patients who have a device that uses ZIP Wandless Telemetry, and/or for patients who use the weight scale from the Latitude Heart Failure Management system.

There are two levels of alert conditions: red alerts and yellow alerts. The alerts are designed to provide the physician advance notification of a potential health or device problem. Conditions that could potentially leave the patient without available device therapy result in declaration of a red alert (Table 3). Notification of red alerts is not configurable, as the device-following physician will always be notified if a red alert is detected on the Latitude secure server. By default, notification is sent by telephone, but there are several notification options for red alerts as described in “Red Alert Notification Preferences.”



<b>Daily Measurement Red Alerts</b>
<ul style="list-style-type: none"> <li>• High or low shock lead impedance</li> <li>• High or low right ventricular pacing lead impedance</li> </ul>
<b>Red Alerts Indicating Potential Loss of Therapy</b>
<ul style="list-style-type: none"> <li>• Device battery has reached end of life (EOL)</li> <li>• Remote monitoring disabled due to limited battery capacity</li> <li>• High or low shock lead impedance detected when attempting to deliver a shock</li> <li>• High voltage detected on shock lead during charge</li> <li>• Ventricular tachycardia mode change due to magnet</li> <li>• Ventricular tachycardia mode set to value other than monitor + therapy</li> <li>• Possible malfunction</li> <li>• Device parameter error</li> </ul>

Table 3. Red alert notifications occur for the above conditions, depending on device model

<b>Device battery has reached Elective Replacement Indicator (ERI)</b>
<b>Explant indicator reached</b>
<b>Voltage was too low for projected remaining capacity</b>
<b>Ventricular pacing leads</b>
<ul style="list-style-type: none"> <li>• Low right ventricular intrinsic amplitude</li> <li>• High right ventricular intrinsic amplitude</li> <li>• Low left ventricular intrinsic amplitude</li> <li>• High left ventricular intrinsic amplitude</li> <li>• Low left ventricular pacing lead impedance</li> <li>• High left ventricular pacing lead impedance</li> </ul>
<b>Atrial pacing leads</b>
<ul style="list-style-type: none"> <li>• Low atrial intrinsic amplitude</li> <li>• High atrial intrinsic amplitude</li> <li>• Low atrial pacing lead impedance</li> <li>• High atrial pacing lead impedance</li> </ul>
<b>Arrhythmias</b>
<ul style="list-style-type: none"> <li>• Shock therapy delivered to convert arrhythmia (ventricular)</li> <li>• Accelerated arrhythmia episode (ventricular)</li> <li>• Atrial arrhythmia burden within a 24-hour period</li> </ul>
<b>Patient triggered event stored</b>
<b>Pacing</b>
<ul style="list-style-type: none"> <li>• Cardiac resynchronization therapy pacing percentage</li> <li>• Right ventricular pacing percentage</li> </ul>
<b>An average daily weight change of 2 pounds or more over multiple days</b>
<b>Change of 5 pounds or more any time within a week</b>

Table 4. Yellow alert notifications occur for the above conditions, depending on device model and on the physicians' preference

Notification of yellow alerts is optional by the physicians. Notification for yellow alerts is provided through the Latitude website and, optionally by other methods such as fax. A physician may choose to receive some, all, or none of the yellow alerts. Yellow alert notifications can be configured for the above conditions, depending on device model (Table 4).

#### 5.4 Merlin@Home®:

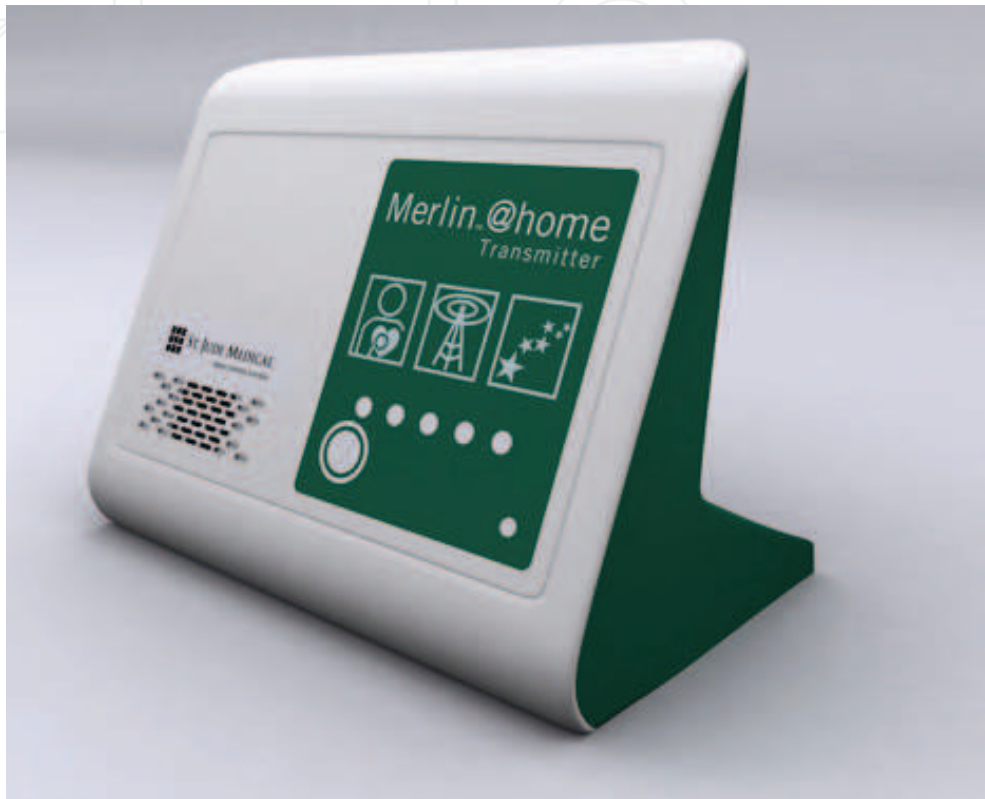


Fig. 5. Merlin@ home Transmitter®

In 2008, St Jude got FDA approval for Merlin@ home transmitter® (Figure 5), a radio frequency wireless technology that remotely monitors patients' implanted cardiac devices. The Merlin@ home transmitter's ®wireless technology gives patients the additional comfort of having devices automatically checked. Since the transmitter initiates scheduled follow-up and uses radio frequency wireless telemetry to download data from device, entire follow-up procedure is conducted without any direct patient involvement. The only requirement is that each patient remains within range of the transmitter while it reads his or her device. Patients also may initiate data transmissions as instructed by their physicians. Data downloaded by the Merlin@home transmitter® is sent to Merlin.net, a secure, internet-based data management system, where it is stored for review by the patient's physician. The data can also be linked in to the Electronic Health Record / Electronic Medical Record directly and can be stored there for future references.

#### Table comparing the 4 types of available remote monitors:

Major differences among the available systems include degree of patient involvement in data transmission, transmission modality, transmission scheduling, and patient alerts as detailed in Table 5.

	Biotronik	Medtronic	Boston Scientific	St Jude
System Name	Home Monitoring™	CareLink™	Latitude™	Merlin.net™
System Activation	Automatic	Automatic / Manual	Automatic / Manual	Automatic / Manual
Approved in	America and Europe	America and Europe	America and Europe	America and Europe
Device to Programmer	Wireless	Wand / Wireless	Wand / Wireless	Wand / Wireless
Programmer to Server	4 - band GSM network (Cellular network)	Analogue phone line	Analogue phone line	Analogue phone line
Patient involvement	No	Yes	Yes	No
Patient device characteristics	Portable	Stationary	Stationary	Stationary
Frequency of transmissions	Daily FU; Alert events	Scheduled FU; Alert events	Scheduled FU; Alert events	Scheduled FU; Alert events
Remote follow up	Yes	Yes	Yes	Yes
Remote Monitor	Yes	Yes	Yes	Yes
Data storage	Website long term	Website long term	Website long term	Website long term
Data presentation	Processed as graphs and tables	Standard as in Programmer	Standard as in Programmer	Standard as in Programmer
Real - time /stored EGM (duration)	45 seconds	10 seconds	10 seconds	30 seconds
Transmission time	<0.5 minute	<3 minutes	5 minutes	< 3 minutes
Feedback to the patient via transmitter	LED indicating the status	LED indicating the status	Automatic text and audio messages	LED indicating the status
Special Features	Wireless PMs	Configurable red and yellow alerts	Configurable red and yellow alerts	Automated phone calls to patients

Table 5. Comparison of the four different available remote monitors

## 6. Benefits of telemonitor

According to the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines (Wilkoff et al., 2008), the primary goal of these remote, automated, wireless, or

internet-based cardiac rhythm device monitoring systems is to identify the abnormal device behavior in a more timely fashion, automatically and accurately determining the status of certain implanted device functions, thereby decreasing the reliance on reporting by the patients and physicians. However, in addition to the primary goal of earlier diagnosis, it does have other various advantages as described below.

### **6.1 Reduction in clinic visits**

In a study by Brugada (2006), 271 patients with a Biotronik ICD and Home monitoring systems were routinely followed every three months over the course of a year. Retrospective analysis of the Biotronik Home Monitoring data showed that as many as half of the regular scheduled visits may have been skipped, without impairing patient safety. In addition to reducing the scheduled clinic visits, remote follow-up may avoid unscheduled visits following an ICD shock. After a shock / alert, the patient may perform manual transmission of the data to the physician for determining the appropriateness of the shock, and it may be then decided whether the patient should be seen for device reprogramming or modification of drug therapy.

### **6.2 Early diagnosis of worsening clinical scenarios:**

Implantable cardiac devices can play a key role in the early detection and treatment of atrial fibrillation (AF) / atrial tachyarrhythmia (AT), which is an important marker of cardiac mortality. The possibility of early detection of AT/AF remains poor when relying on patient symptoms alone. Furthermore, reliance on patient symptoms alone may result in inappropriate medical therapy such as early discontinuation of anticoagulation. Intermittent monitoring via long-term event recorders or Holter monitors can be inadequate in documenting paroxysmal atrial tachyarrhythmias. Given the morbidity and mortality associated with AT/AF and the fact that AT/AF is often asymptomatic, early treatment and close monitoring may be helpful in reducing the risk of stroke and in monitoring treatment efficacy.

These devices can accurately detect and continuously monitor for atrial tachyarrhythmias. The devices also have extensive reporting capabilities and can provide an objective picture of the cumulative length of time that a patient experiences atrial tachyarrhythmias. Hoppe et al. (2006) did a retrospective analysis of the Cardiac Resynchronization in Heart Failure (CARE-HF) study involving 409 patients with CRT devices. They found that AF was documented without the aid of the device in 16.1% of the patients, while the device-based diagnostics detected AT/AF in an incremental 22% (93/409) of the patients during a mean follow-up of 29.4 months. In a study of patients with AT/AF who also had an AT500R pacemaker (Medtronic, Inc., Minneapolis, MN) or a GEMR III ICD (Medtronic, Inc., Minneapolis, MN), Purerfellner et al. (2004) found that the devices had AT/AF episode detection accuracy of 95.3% and 95.7%, respectively, and an AT/AF burden sensitivity of 95.3%.

High ventricular rates in a patient with atrial arrhythmias are indicative of poor rate control. Poor rate control in itself can lead to the development of HF and can exacerbate existing HF. Additionally, poor rate control has been linked to earlier time to first hospitalization, HF exacerbation, and inappropriate ICD shocks, as noted by Hoppe et al (2006). In people with CRT devices, a fast ventricular response to AF can lead to a loss of biventricular pacing as the device mode switches to asynchronous pacing. Given that patients with HF can derive benefits from even small changes in hemodynamic status, the amount of biventricular pacing should be as close to 100% as possible in order to maximize patient benefit from the therapy.

Therefore, early identification of poor ventricular rate control allows for more rapid clinical interventions including changes in drug regimen or other treatment modalities (e.g., ablation) to optimize rate control with the goal of reducing hospitalizations and unnecessary shocks as well as helping to maximize the delivery of biventricular pacing in people with a CRT device.

### **6.3 Improved patient satisfaction**

Most patients readily accept remote monitoring, and feel secured by the use of this technology to improve their healthcare. Studies have shown a high patient satisfaction rate, ease of use, and compliance with the use of remote monitoring systems (Joseph et al 2004). Patients feel reassured being consistently in contact with hospital. In an Italian multi center trial by Marzegalli et al (2008), with the CareLink® system, 99% of patients rated the monitor setup as very or somewhat easy since their first transmission. About 98% of the patients found the antenna very easy or somewhat easy to position since the first transmission, and the time required for the procedure rated as brief or very brief in all after a short practice. Personal knowledge of the nurse who actually calls the patient in case of problems tremendously increases patient assurance and compliance.

### **6.4 Cost saving**

The economic aspects have not been evaluated extensively. A study from France examined the potential cost savings for long-term care of ICD recipients assisted by Home Monitoring ([www.theheart.org](http://www.theheart.org)). A multicenter database for this study included 502 patients from six university hospitals. Costs of conventional ICD follow-up examinations were compared with the expected costs of follow-up coupled with telemonitoring. Assuming that telemonitoring may obviate up to 2 visits per year, the expected decrease in costs for follow-up visits was estimated at \$2,149 per patient during the 5 years of expected service life of the device. Transportation expenses were the main component of the overall costs, and the savings due to telemonitoring were particularly significant when the distance between the patient home and the medical facility is longer. However, these results must be viewed with caution as this is looking only at expected, not actual costs and there is no robust data available at this time.

### **6.5 Time saving**

As all the data gathered during a normal in-office device interrogation can be sent remotely to the device clinic for evaluation, the patients and accompanying persons save time by using the remote monitoring network. In a study conducted by Raatikainen et al. (2008), the average time saved was about 3 hours per patient per visit and it was directly related to the travelling distance to the device clinic. Also, the physicians on average save 20 minutes and other office staff saved 45 minutes for each visit, delivering the same care through the remote network.

## **7. Drawbacks:**

### **7.1 Non compliance**

Some elderly people have difficulty when using transmission systems for which manual transmission is requested and need assistance from their relatives. A minority of patients do not accept remote monitoring. Reasons for that include concern about privacy, fear of technology, and concern about the risk of losing human contact with the nurses and

physicians. Some patients showed lower compliance post implantation, perhaps by forgetting to send transmissions or by switching off the transmitter. These are usually patients who did not accept their disease and device implantation. For them, psychological support and counseling are recommended.

### **7.2 Patient safety due to technical problems:**

Transmission failures due to technical issues are rare. Infrequent transmission failures (2%) were observed due to mobile phone network defects or patients' absence from home. Technical problems related to the mobile phone, e.g., battery depletion or a deactivated monitor were rarely reported. In a study of 93 patients, Wallbrück et al. (2002) assessed the feasibility of an automatic long-distance monitoring system for pacemaker patients, and the clinical relevance of transmitted data. Automatic daily transmission (mostly during the night) and patient triggered transmission were enabled. The number of received and sent messages was compared. To check data integrity, the transmitted data were compared with those collected by the pacemaker programmer. Three patients (3.2%) were excluded due to insufficient mobile net coverage at their living site. The authors showed that 89.7% of the messages automatically generated by the implanted devices and 64.8% of patient-triggered messages were received at the Home Monitoring Service Center. Various reasons could explain message failure: patient away from home at the time of transmission, monitor was switched off, device not correctly loaded, device too far away from the patient bed, or GSM network coverage unreliable. The interruption in the sequence of messages ranged from 1 to more than 4 days. In another study, Toselli et al. (2004) reported the data obtained from 894 scheduled reports, of which 876 (98%) were successful. When the investigators compared the Home Monitoring data with those retrieved during conventional ICD interrogation at the time of in-clinic follow-ups, they did not observe any difference.

### **7.3 Patient confidentiality**

Data confidentiality is an issue of particular importance for the device company and for the physician. Since the data are now transmitted via internet in the vast majority of cases, the system is secured at each step of transmission – from the patient to the home monitoring service centre and from there to the physician. As with any advanced transmission technology, hacking is a potential issue. Hackers could transmit the same radio signals – causing a defibrillator to shock or shut down, or divulge a patient's medical information – without needing a programmer. It is widely believed that the risk of unauthorized access to an ICD is unlikely, given the considerable technical expertise required. (Wireless ICD programming vulnerable to hackers, report claims. <http://www.theheart.org/article/847781.do>).

### **7.4 Patient-physician relationship**

Joseph et al (2004) have shown a high patient satisfaction rate, ease of use, and compliance with the use of remote monitor. However, some patients may find difficulty in using the technology and they may feel that they lost the human contact with a health care provider. Proper explanation and psychological support to them holds the key.

### **7.5 Legal issues**

As with any technology, patients should be informed about the advantages and disadvantages. Home Monitoring was developed to allow earlier detection of technical or

arrhythmic events, but it does not protect the patient against such events nor does it allow any remote intervention by a physician. In case of an event, in addition to the use of the monitor, the patient must activate the Emergency Medical Services (EMS) as appropriate. Home monitoring devices are not a replacement for EMS. A written informed consent form should be used to ensure that the patient has been properly informed about the system and that the patient agreed to use of it.

### 8. Reimbursement:

In the USA, on June 9, 2006, Centers for Medicare & Medicaid Services (CMS) published a transmittal stating that physicians should use (and carriers should pay for) existing Current Procedural Terminology codes 93731, 93734, 93741 and 93743 (the in-office pacemaker and ICD interrogation codes) for remote monitoring of cardiac devices. Reimbursement rates vary from state to state, and in some instances are the same as an in-office visit without device programming. In Germany, the procedural reimbursement for remote monitoring is nearly the same as that offered for standard follow-up visits. Furthermore, there is currently no limit to the number of remote interrogations by physicians, who can either monitor the patient status at regular intervals (e.g., every 3 months), or in response to selected special events, or both. United Kingdom offers no reimbursement for remote monitoring. In France, the fees are fixed, and clinics and hospitals are reimbursed according to levels of activities. In Italy, the Italian Association on Arrhythmias and Cardiac Pacing is working with the National Public Health Service to develop reimbursement codes for remote monitoring.

### 9. Ongoing trials in telemonitoring of the Cardiac devices

Remote monitoring may be particularly useful in patients with cardiac resynchronization therapy, as they are most likely to have transmissions of medically related events. As detailed in table 6, a number of different randomized trials are currently underway to assess the utility of telemonitoring of pacemakers and defibrillators specifically looking for signs of volume overload, heart failure, shocks etc

Study Title	Condition	Device	Status
CareLink® Evaluation	Heart Failure	Medtronic CareLink®	Not yet recruiting
Clinical Evaluation Of Remote Monitoring With Direct Alerts To Reduce Time From Event To Clinical Decision	ICD / CRT	Merlin.NET®	Recruiting
A Randomized Trial of Remote Monitoring of Implantable Cardioverter Defibrillators Versus Quarterly Device Interrogations in Clinic	VT / VF	CareLink® monitoring system	Active, not recruiting
Telemedical Interventional Monitoring in Heart Failure	Heart Failure		Active, not recruiting

European Health Economic Trial on Home Monitoring in ICD Therapy (EuroEco)	VT / VF	Home Monitoring provided by Biotronik ICD devices	Recruiting
MONitoring RESynchronization deviCes and cARDiac patiEnts (MORE CARE)	Heart Failure	Medtronic CareLink®	Recruiting
Benefits of Implantable Cardioverter Defibrillator Follow-up Using Remote Monitoring	VT / VF / Heart Failure	Home Monitor®	Active, not recruiting
Home-Monitoring in Implantable Cardioverter Defibrillator (ICD) Patients	VT / VF	Home-monitoring provided by LUMAX ICD device and CardioMessenger II®	Recruiting
Effects of Remote Patient Monitoring on Heart Failure Management	Heart Failure	Heart failure remote patient monitoring system	Recruiting
Remote Follow-up of Patients Receiving Implantable Cardioverter Defibrillator for Prophylactic Therapy	VT / VF	ICD	Completed
TRIAGE-CRT Telemonitoring in Patients With CHF and Indication of CRT-D	Heart Failure/ CRT	Kronos™ LV-T, Lumax™ HF-T	Completed
Follow-up of Patients With Implantable Cardioverter Defibrillators by Home Monitoring (ANVITE)	VT / VF / Heart Failure	ICD / CRT / Home Monitor™	Recruiting
RAPID-RF: Remote Active Monitoring in Patients With Heart Failure	Heart Failure / Atrial Fibrillation	ICD / CRT	Completed
Supporting Care and Independence at Home	Heart Failure	Chronic heart failure monitoring system / Device: Lifestyle monitoring system	Recruiting
Home Monitoring in Cardiac Resynchronisation Therapy	Heart Failure	ICD / CRT	Completed
Psychosomatic Effects of Implantable Cardioverter Defibrillator With Home Monitoring Function (QUANTUM)	Arrhythmia/ Quality of Life	BIOTRONIK Lexos-T™ ICD with home monitoring/ Device: Lumos-T® ICD with home monitoring	Recruiting
Evolution of Management Strategies of Heart Failure Patients With Implantable Defibrillators	Heart Failure / SCD / ICD	Medtronic CareLink® system	Recruiting



Comparison Between Remote Patient Management and Standard Care in CRT-D and ICD-patients to Assess the Impact on Hospital Length of Stay Because of Heart Failure	Heart Failure / VT / VF	CareAlert® / ICD / CRT	Recruiting
Evaluation of the " Tele-follow-up " for the Follow-up of Implantable Defibrillators	Tele- follow-up of CHF	ICD / Telemedicine	Active, not recruiting
Actions elicited by In-hospital Follow-up of Cardiac Devices	In-hospital follow-up of cardiac device	ICD / Pacemaker	Recruiting

Table 6. Data from [www.clinicaltrials.gov](http://www.clinicaltrials.gov); accessed on July 22<sup>nd</sup> 2010

ICD: Implantable Cardioverter Defibrillator

VT: Ventricular Tachycardia

VF: Ventricular Fibrillation

SCD: Sudden Cardiac Death

CRT: Cardiac Resynchronization therapy

## 10. Remote programming

Bidirectional telemetry uses encoded and encrypted radiofrequency signals which allows transmission of information from the pacemaker to the programmer and from the programmer to the pacemaker. In this way, the clinician can "talk" to the pacemaker, interrogate and get the necessary data from it and if needed, he/she can reprogram the device by sending signals to the pacemaker to optimize pacemaker function. Despite sound technology to program the pacemakers remotely, it is not yet implemented due to concerns over patient safety and privacy. This concern is related to the limited ability to respond to potential changes in the patient's condition as a result of the altered device parameters. As greater experience with remote monitoring is gained and as a secure support system for remote management of patients is developed, this technology will likely be implemented. Moreover, patient safety is a concern as, if some one may hack in to the secure system and change the settings / deactivate the devices. There have been no reports to date of hacking of implantable devices.

## 11. Future directions

In the future, the use of telemonitoring might dramatically reduce hospitalization rates of patient after pacemaker or ICD implantation. As mentioned in the table 6, there are many ongoing trials researching the benefit of earlier detection of a patient's deterioration in clinical status (mainly heart failure) with the aid of Home monitoring. Clinical data such as trends in patients' daily activity, in the mean heart rate and in the occurrence of arrhythmia, along with technical parameters will be correlated with major cardiovascular events – death and hospitalization.

## 12. Conclusions

Rapidly evolving technological advances in wireless communication allow for the development of miniaturized devices and new techniques in telemonitoring. The safety of telemonitoring has been demonstrated in various trials. The clinical use of tele monitoring is very promising based on the ongoing trials. This novel feature seems to be very important and might impact costs and therapeutic decisions. The relationship between patients and their physicians who perform pacemaker and ICD follow-up with telemonitoring should be more clearly defined so that patient - physician relationship is maintained. Remote programming of the pacemakers is a possibility in future. However patient safety due to hacking is a real concern.

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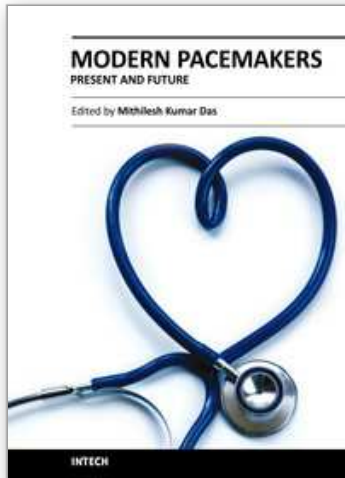
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Wireless ICD programming vulnerable to hackers, report claims.

<http://www.theheart.org/article/847781.do>.

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## **Modern Pacemakers - Present and Future**

Edited by Prof. Mithilesh R Das

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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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