16
Device Therapy for Remote Patient Management

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Abstract

Remote device (CIED) monitoring has become a mainstay of clinical practice involving implanted devices such as pacemakers, defibrillators, and implantable loop recorders. The aims of remote monitoring are to provide accurate, timely, and economical information about both device functions and disease status. Remote monitoring is an integral component of comprehensive CIED management and, as an extension, serves as an additional important tool in device performance surveillance.

While this chapter is unrevised from the 1st edition, and some of the statistics are out of date and some of the company systems have changed, the concepts and directions remain intact.

Keywords

Remote Monitoring • Device follow-up • Device interrogation • Device surveillance • Implantable monitors

Introduction

It is important that new medical technologies, including that of the present topic, remote monitoring and management of devices and diseases using implantable devices, provide answers to questions and help solve problems and not simply provide new and expensive "toys". We live in a world in which geographic proximity to advanced medical care is of major importance for those afflicted with many types of illness. And yet, there are vast areas of our world which do not have such proximity, so-called underserved areas. Additionally, even our most advanced medical facilities struggle with volumes of patients and the ability to provide timely care to all who need this care. We are also substantially challenged by the need to collect information about implantable device performance in a meaningful and comprehensive way. Finally, the cost, both in monetary terms and in human aggravation, of traditional in-hospital and in-clinic care using conventional approaches continues to escalate. Remote monitoring and management of chronic and even acute conditions using implanted devices offer substantial answers to each of the major

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medical issues alluded to above. This chapter will describe what is surely only the beginning foray into this emerging technology and evolving concept.

Remote monitoring of intracardiac devices is a concept which has been reviewed in literature [1], but continues to evolve, and, at the time of this writing, appears to be gaining rather rapid momentum. While technology has allowed remote monitoring of implantable devices, especially pacemakers and more recently ICDs, for decades, the ability to acquire more extensive device and patient data using remote monitoring is a phenomenon that began in only the last few years. Twenty years ago we were able, using telephone line communications, to obtain information about heart rates, pacemaker output amplitude and duration, and ECGs. Today we can, using sophisticated but easily available computer linkages, obtain remotely virtually all information stored in the most sophisticated devices. This includes electrograms and information about remote and recent cardiac arrhythmic and even hemodynamic events. In the not too distant future, it is virtually certain that we will be remotely programming devices as the technology advances and professionals and patients (and regulators) become more comfortable in doing so. While much of the focus in this area has been on device monitoring, it is clear that, with the evolution of implantable physiological and now chemical sensors, monitoring of chronic and even acute illnesses will be possible. While there is an inevitable concern about the expense of developing and implementing these exciting technologies, it is likely that remote monitoring of implanted devices and diseases will actually reduce the cost of healthcare as fewer hospitalizations and both scheduled and unscheduled outpatient visits occur. There appears to be a substantial opportunity to use remotely acquired device information, logged into computer-based databases as an adjunct to other device performance surveillance systems.

In this chapter a summary of currently available remote monitoring by several different companies will be discussed. The reader is reminded, again, that because this area is changing rapidly, information here may soon need to be updated.

Current Uses and Goals for the Future

Rationale for Remote Monitoring

Patient Safety

Patient safety will inevitably drive much of the impetus toward closer monitoring and prompt notifications. Remote monitoring would allow more frequent device checks, with the potential for more timely trouble-shooting. The Heart Rhythm Society recommends that manufacturers of devices develop and utilize wireless and remote monitoring technologies, for the identification of abnormal device behavior as early as possible. This group has also recently stressed the importance of reducing the underreporting of device malfunction [2]. The ACC/AHA/NASPE Guidelines for Implantation of Cardiac Pacemakers and Arrhythmia Devices recommend close monitoring of devices (specifically ICDs), with frequency of follow-up dictated by the patient's condition. Intervals specified are 1–4 months, with in office visits supplementing transtelephonic evaluations no less than every 3 months [3]. Current practices have extended the times between follow-up visits.

Benefits Achieved Through Remote Monitoring

There is evidence for the benefit of some types of remote monitoring, in chronically ill patients such as those with advanced heart failure, thereby achieving morbidity and mortality benefits. Although not yet fully evaluated in randomized trials, it is anticipated that the same benefit may be obtained by remote monitoring of parameters measurable by implanted devices [4]. Interventions such as education and nurse telephone calls may reduce hospitalization by increasing disease awareness and compliance, along with therapy changes [5]. A mortality benefit was shown in the randomized, controlled WHARF trial, using a scale and symptom response system, with information transmitted via telephone. There was a 56 % reduction in mortality ($p < 0.003$) in the monitored group, speculated to be due to facilitated communication of important events to physicians [6]. These benefits have also been seen with a single home visit prior to discharge from the hospital [7] and with a more comprehensive

disease management program managed telephonically [8]. A recent European study compared automated telemonitoring (weight, blood pressure, heart rate, and rhythm) with nurse phone calls and usual care, finding reduced admission days and mortality in the telemonitored group [9]. Over the course of the 240-day follow-up period, hospital stays were reduced by 6 days, and mortality rates were 45 % in the usual care group, which was compared to 27 % in the nurse care group and 29 % in the telemonitored group, a significant reduction ($p = 0.032$).

Integration of Care

The centralized storage of remotely obtained data will permit improvements in integration of care. Information is available for both the heart rhythm specialist, as well as the heart failure physician or any other physician participating in the patient's care. If the observations of remote monitoring trials are correct, it should be possible to improve patient care by accessing this information. This may also facilitate communication regarding important patient care issues between subspecialists that often practice significant distances apart. Remotely obtained data may facilitate a multidisciplinary approach to patient care. It will also allow access of this data by physician extenders, such as physician assistants and nurse practitioners, who can aid in acting promptly on critical data.

Resource Conservation

Resource conservation may be one of the most compelling reasons to pursue remote monitoring. It is estimated that evaluation of remotely obtained data may take as little as 8 min [10] compared to 30 min for a traditional, in-office follow-up. Travel costs may be minimized. By reducing the interaction time required, more patients may be served. Time management and cost of follow-up care will be important considerations as the population ages and device indications grow.

Future Uses

As we move to more comprehensive, actually complete, device data availability remotely and as the implanted devices gather increasingly useful physiological information, new goals for remote care will likely emerge, changing the paradigm to one coupling modification of therapy with remote monitoring. It is easy to envision substantially improved clinical algorithms and modifications based on data obtained by this monitoring. Investigationally, using implanted devices, medical modifications have been made based on remote observations, including changes in agents such as beta-blockers, ACE inhibitors, and diuretics [4]. Future standards will almost certainly include remote programming of device settings. Programming to accomplish faster or slower pacing rates and AV interval modifications to minimize ventricular pacing could occur. In more technically challenging situations, changes could be made to more complex anti-tachycardia algorithms such as we do now in-clinic. In the future, home-based care might be possible that would otherwise necessitate hospitalization, with remotely available information such as hemodynamic parameters analogous to those obtained in the setting of a critical care unit.

Novel technologies will incorporate and likely improve on the remote monitoring, making a spectrum of routine to advanced care not only reliable, but possible financially advantageous for society. This may offer not only benefits with regard to resource conservation, but palliation of end-stage disease.

The History of Monitoring

Transtelephonic Monitoring

The early history of device monitoring began with trans-telephonic monitoring (TTM) of early pacemakers in the 1970s [11]. In the early era of pacemaker systems, battery longevity and lead performance were unpredictable. Early telemetry helped ensure patient safety, and provided a level of convenience for patients who were too ill to travel or lived substantial distances from clinics. Transtelephonic transmission was accomplished by connecting electrodes to the patient (wrists, ankles, etc., depending on system design) and to a transmitter, which was then coupled with the mouthpiece of the

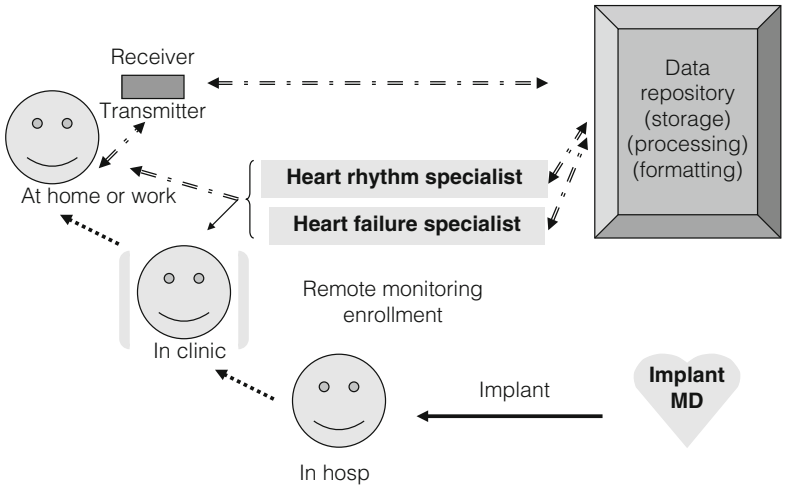


Figure 16–1. A schematic representation of a generic remote monitoring program. Other clinicians could be involved either directly or indirectly by receiving the remote monitoring report from the "data repository" or from one of the other clinicians

telephone. The only information available initially was rate determination with a reasonable evaluation of capture and sensing with the device as programmed. Interference artifacts often compromised the recordings obtained. Poor patient understanding of equipment use was also challenging [12]. ECG tracings were obtained in regular and magnet modes, and were required to be of 30 s duration, and a significant part of the medical record [13]. As technology progressed, threshold testing became available, via magnet induced reduction in pacemaker output.

Early Studies Using Transtelephonic Monitoring

Use of these systems became more sophisticated over time. A case report in 1984 described the use of TTM to monitor the use of an early device with anti-tachycardia therapy [14]. A trial published in 1992 confirmed symptoms of AF and SVT correlated with data obtained from transtelephonic ECG monitoring. There was significant correlation between symptoms and documented arrhythmia, with 70 % of calls related to symptoms showing PSVT or PAF attacks [15]. Use of TTM in following ICD patients was described in a report in 1995, in 18 patients, allowing identification of spontaneous arrhythmias, and assessment of the success of therapies delivered [16]. The feasibility of this type of monitoring had been well established. Expansion of device features and better internet technology lead to a greater sophistication for remote monitoring as well.

Current Examples of Remote Monitoring

Over the past several years, with improvement in device telemetry, remote communication and computer technology, major device manufacturers have developed and implemented increasingly sophisticated remote monitoring systems. While each device manufacturer's monitoring systems are restricted to their devices, and there are substantial differences among the systems, all are evolving and are aimed at greater patient safety and satisfaction as well as greater follow-up efficiency. This section explores examples of currently available technology. A general schematic of how most remote monitoring systems work is shown in Fig. 16.1. A synopsis of comparative features among the four systems discussed below is contained in Table 16.1.

Biotronik

The Biotronik remote monitoring system Home Monitoring™, uses wireless phone technology to transmit patient information, called to a centralized server, via a patient transceiver. Biotronik initially received a license to

Table 16–1. Historic manufacturer's monitoring systems

	Biotronik	Boston Scientific/Guidant	Medtronic	St Jude Medical
Name	Home Monitoring™	Latitude™	CareLink™	Housecall Plus™
Remote monitoring connection	Cellular or standard analog telephone line (not digital compatible)	Standard analog telephone line (not digital compatible)	Standard analog telephone line (not digital compatible)	Standard analog telephone line (not digital compatible)
Frequency/channel bandwidths of wireless components	Medical implant communications system (403 MHz); channel bandwidth 100 kHz	FCC license category used by any industrial, consumer, scientific or medical products (914 MHz)	Medical implant communication service band (402–405 MHz); multiple channel bandwidth 300 kHz	
Access	Secure internet network, internet access for multiple clinicians	Secure internet network; internet access for multiple clinicians; limited patient access	Secure internet network, internet access for multiple clinicians	Maintained in office or by service providers; no internet access
Data available	Battery voltage, pace and shock impedances, EGMs, arrhythmia and therapy data	Complete device data, EGMs, blood pressure and weight	Complete device data, EGMs, hemodynamic data	Complete device data, EGMs, surface ECG
Alerts	Internet, email, pager, cell phone or fax	Critical – call to physician and page to local representative; urgent – fax to office and information sent to internet website	Pager or voicemail notification, with patient information to be accessed on internet	Service center call to clinician
Manufacturer charges	At implant (hospital)	At implant (hospital)	At follow-up (clinic billed quarterly)	Clinic or third party (equipment purchase)

use the frequency in 2001 for wireless monitoring of pacemakers. ICD monitoring followed in 2002, with CRT-D monitoring initiated in 2006. Biotronik remote monitoring is, as of October 2006, in use by approximately 52,000 worldwide patients, with 12,000 of these in the United States.

Home Data Acquisition

Stored data is obtained wirelessly, automatically on a pre-determined schedule. A radio frequency transmitter is integrated into the implanted device circuitry, which communicates with the patient transceiver. Data can be acquired by the transceiver at a distance of 2 m from the implanted device. The transmitter is small, and can be worn or carried by the patient. The data is transmitted via GSM cellular telephone technology, and can also be used with a standard telephone land-line. Data is transmitted daily at programmed times. Patient triggered reports can be obtained as well. Transmission (unidirectional) occurs over the Medical Implant Communications System at 403 MHz with a channel bandwidth of 100 kHz. Data is transmitted to the Biotronik Service Center.

Data Obtained

Device related information obtained at interrogation includes such data as battery voltage, and pace and shock impedances. Routine remote device data acquisition using this system has the potential to identify significant events such as lead malfunction with sudden increase in pacing threshold (Fig. 16.2). For example, lead fracture which, in this case, was a result of patient manipulation (twiddler's syndrome) [17] was identified remotely (Fig. 16.3).

Patient related parameters reported, using this system, include atrial and ventricular arrhythmias, and therapies delivered for ventricular tachycardia and ventricular fibrillation. Intracardiac electrograms (IEGMs) are available for scrutiny of events, to determine whether therapy was appropriate. Other parameters can be remotely tracked, including mean heart rate, paced and intrinsic percentages, percent CRT pacing, ventricular ectopy and mode switching. Resting heart rate and patient activity level are also available.

Notifications

With the Biotronik System, as with others discussed later, critical patient and device data can be transmitted to physicians. Notification is made

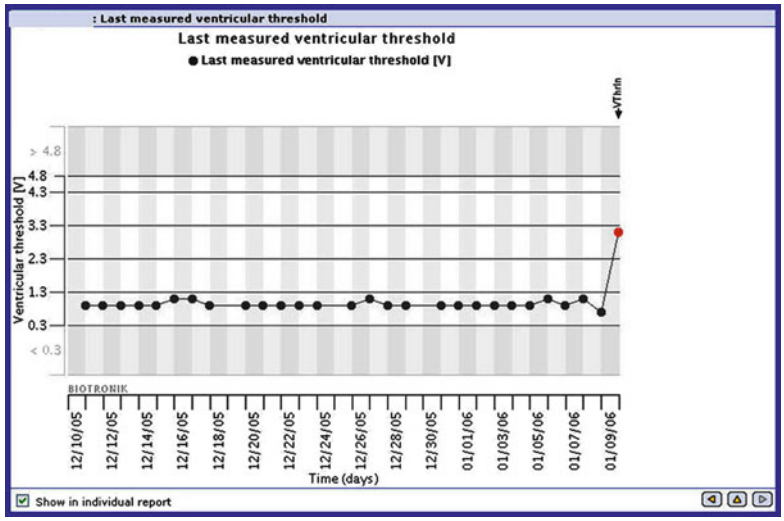


Figure 16–2. This data is an example of a remotely acquired report using the Biotronik Home Monitoring™ system. This report shows a sudden increase in pacing threshold (Courtesy of Biotronik)

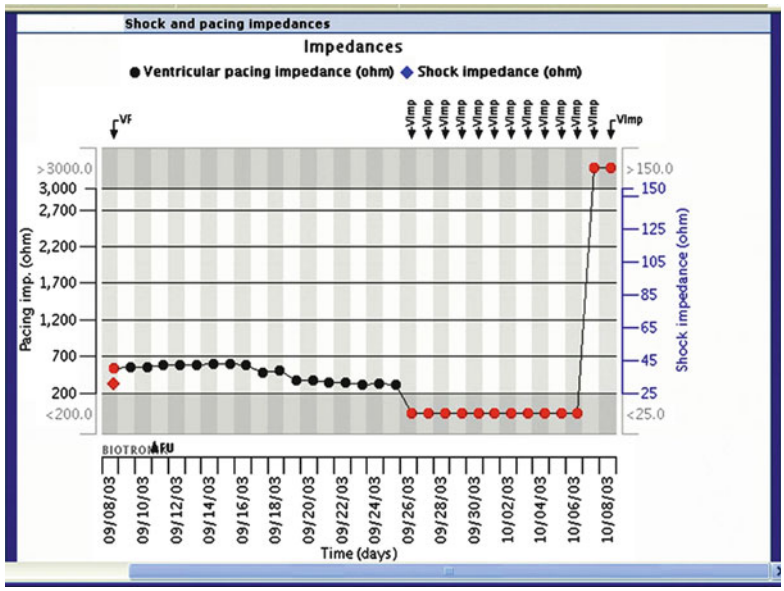


Figure 16–3. This is another example of a remotely acquired report of the Biotronik Home Monitoring™ system. This report shows an initial drop in impedance on a pacing lead over a several week period, indicating an insulation breach, followed by a dramatic increase in lead impedance indicating a fracture. This clinically was a result of "twiddler's syndrome" (Courtesy of Biotronik)

according to physician preference, including options of internet, email, pager, cell phone or fax. Notifications can be patient initiated in the case of symptoms. In such cases a patient can wave a magnet over the device, resulting in immediate transmission of data. If a patient receives therapy for certain events (ventricular tachycardia, ventricular fibrillation, supraventricular tachycardia, etc.) the medical team can be notified immediately. If the physician so chooses, he/she can be notified of these events within 1 min of the event, by one of the methods mentioned above.

Cost

The manufacturer's charge for use of these added features, including the cellular service, is included at the time of device implantation. There are no additional charges for use for the life of the implanted device. The remote

monitoring charges by physicians to patients using this and other manufacturers' systems are currently under review and revision.

Boston Scientific/Guidant

The remote monitoring system offered by Boston Scientific, called Latitude™, was introduced to the market in 2006. It is, as of this writing, in use by approximately 6,500 patients. With the newest implantable devices, this technology permits not only remote monitoring but also "wireless" implant and "wireless" in-office follow up. This is accomplished by a new telemetry system in which the distance between the implanted device and the data acquisition device is substantially increased over earlier versions. There is also optional hardware, a Bluetooth enabled blood pressure cuff and scale, which can be used with the system.

Home Data Acquisition

Remote interrogations can be performed automatically on as much as a daily basis. Frequency and day of the week can be specified and modified. Interim follow-ups can be arranged, even on prespecified dates. Patient initiated interrogations are also possible (clinician enabled). Scheduling options exist for active monitoring notifications and can be changed according to physician and patient preference (daily or weekly). Data is transmitted from the patient's device to a wireless "communicator", a transceiver, kept in the home. This system currently requires a standard telephone line. Communication occurs via the Industrial, Scientific, Medical band at a frequency of 914 MHz.

Data Obtained

Downloaded information appears on an internet website, maintained on encrypted servers that comply with privacy rules. System information can be followed by multiple physicians. Although the physician viewed information is the same, schedules, alerts and notifications can be individualized for different physicians. At the time of data acquisition, critical information is deemed to fall into certain predetermined alert categories ("red" or "yellow"), in addition to standard patient care information.

A report is generated with features designed to assist with heart failure management (Fig. 16.4). Arrhythmias including atrial fibrillation and ventricular fibrillation and ventricular tachycardia are recorded. Weight, blood pressure (if scales and blood pressure cuffs are also included), activity, heart rate maximum, minimum and means are available. Autonomic parameters such as heart rate variability (HRV) determinations are incorporated in the report. Weight monitoring, as noted an optional feature, can highlight changes of 5 lbs in 1 week or 2 lbs pounds in a 1 or 2-day period.

The Boston Scientific system offers access to some non-traditional data via remote reporting. Patient quality of life issues can be addressed via self report questions that may be answered with the home monitor, a function programmable to either "on" or "off". Questions are asked weekly. Symptom queries include fatigue, dizziness, edema, orthopnea and PND (Fig. 16.5). The system also includes the ability to give patient access to limited information, via internet access. Patient-available data include dates of recent and scheduled interrogations, weight, blood pressure, battery status, and contact information.

Notifications

The relative importance of information may trigger physician contact, varying from a fax sent to the physician office to physician and local industry representative calls. If this feature is not enabled, the patient is notified. "Red" events are those that are considered critical to the continuing appropriate operation of the implanted system. Such events include battery end of life, impedance aberrancies, low right ventricular intrinsic (R wave) amplitudes, and high voltage detected on the shock lead during charge. When these criteria are met, the company calls the physician and contacts the local representative. "Yellow" alerts are noted on weekly checks. Alert events include such

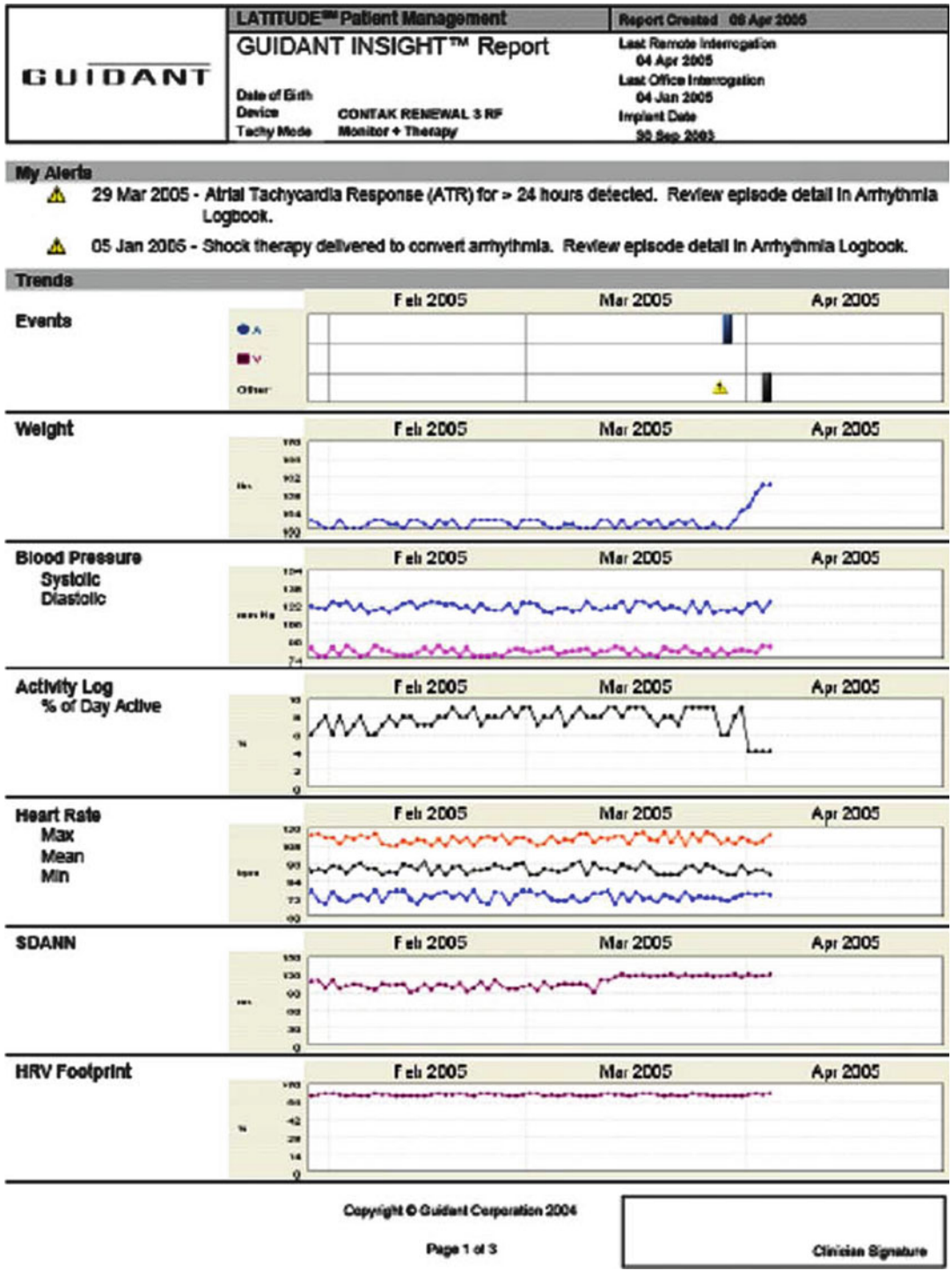
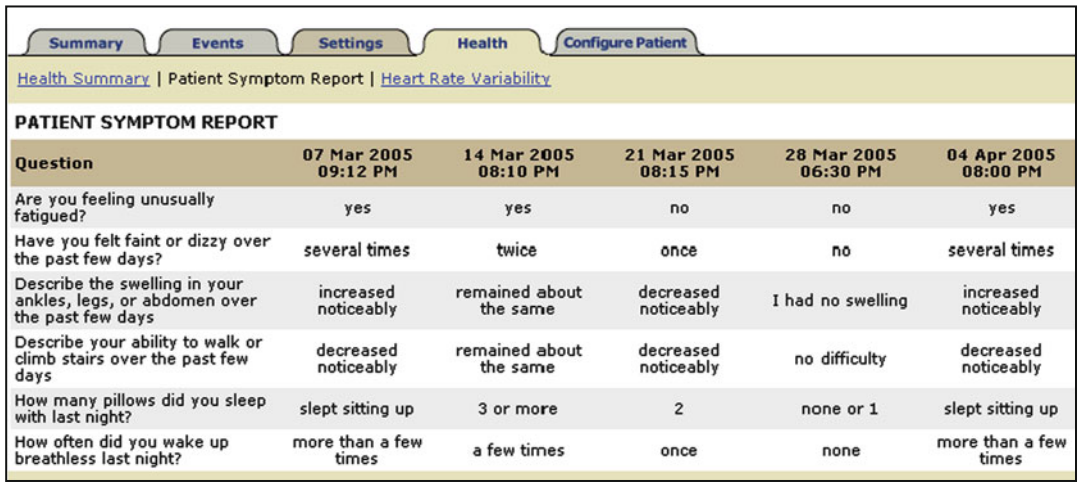


Figure 16–4. An example of a heart failure report generated on Boston Scientific's Latitude™ system. Note the inclusion of both blood pressure and weight data (Courtesy of Boston Scientific)



Summary | Events | Settings | Health | Configure Patient

Health Summary | Patient Symptom Report | Heart Rate Variability

PATIENT SYMPTOM REPORT

Question	07 Mar 2005 09:12 PM	14 Mar 2005 08:10 PM	21 Mar 2005 08:15 PM	28 Mar 2005 06:30 PM	04 Apr 2005 08:00 PM
Are you feeling unusually fatigued?	yes	yes	no	no	yes
Have you felt faint or dizzy over the past few days?	several times	twice	once	no	several times
Describe the swelling in your ankles, legs, or abdomen over the past few days	increased noticeably	remained about the same	decreased noticeably	I had no swelling	increased noticeably
Describe your ability to walk or climb stairs over the past few days	decreased noticeably	remained about the same	decreased noticeably	no difficulty	decreased noticeably
How many pillows did you sleep with last night?	slept sitting up	3 or more	2	none or 1	slept sitting up
How often did you wake up breathless last night?	more than a few times	a few times	once	none	more than a few times

Figure 16–5. An example of a patient symptoms report generated by the Boston Scientific Latitude™ system (Courtesy of Boston Scientific)

arrhythmic events such as shock delivery, type and timing of tachyarrhythmias, and patient triggered events. Significant weight changes are noted. Device specific parameters are noted, including battery status, and lead parameters including intrinsic amplitude and pacing lead impedance. These less critical "yellow" events are noted on the clinician accessible website, and a fax is sent to the physician office.

Cost

Weight scales and blood pressure cuff are available as optional components to the Latitude™ system. Manufacturer charges for use of the rest of the system are billed at the time of implant. As previously discussed, physician charges for remote follow-up are currently being reviewed and revised.

Medtronic

The remote monitoring system used by Medtronic called CareLink™ was launched in 2002. Approximately 85,000 patients (involving approximately 1,000 clinics) are using the network as of October 2006. Transmission captures device parameters, including diagnostics, and stored episodes of arrhythmia events. A prospective evaluation of the system was completed prior to market release, and demonstrated a high level of physician satisfaction with the system [18], with 96.5 % of physicians reporting that it was either somewhat easy or very easy to use. Patients also found the device easy to use, with 98.1 % reporting that the monitor was either somewhat easy or very easy to use. In addition to remote monitoring, Medtronic has recently introduced a new generation of devices that permit "wireless" implant, in-office follow-up, and automated remote follow-up, similar in function to that described with Boston Scientific's Latitude system. These systems which eliminate a "programming head" from the sterile field at the time of implant may have the additional advantage of reducing implant time by allowing activities such as pocket closure while doing final programming and interrogation. They also make clinic follow-up more streamlined, potentially. The most important advantage of the "long-distance" telemetry linkages, however, is that it allows automatic remote monitoring to occur, without the need for patients to take specific action to initiate a transmission.

Home Data Acquisition

Just as with the other systems, the monitors (transceivers) used in patient homes are FDA approved. These transceivers are portable and can be used outside of the home including internationally, and are patient specific. Downloaded information is stored on a secure internet system

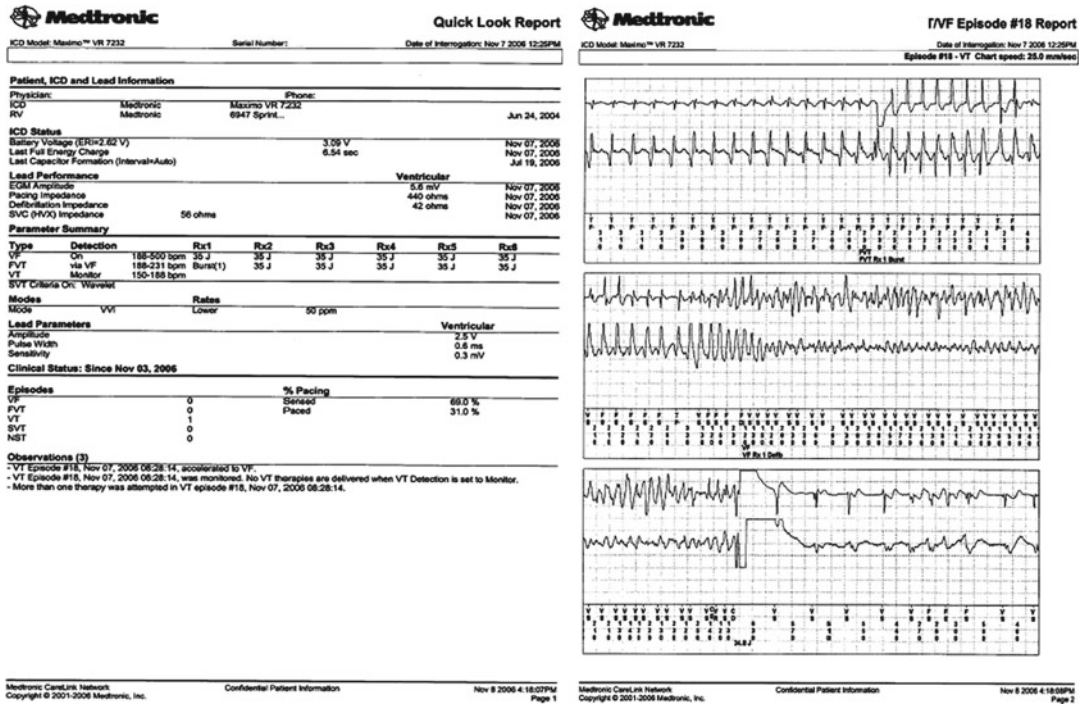


Figure 16–6. A Medtronic CareLink™ remote monitoring report on a patient with ventricular tachycardia that was accelerated by anti-tachycardia pacing resulting in ventricular fibrillation successfully defibrillated with a single internal shock

that is password protected. Telemetry is transmitted (bidirectionally) on the Medical Implant Communication Service Band, 402–405 MHz. Use of this band may have advantages in prevention of interference caused by other wireless devices such as cell phones that operate at other frequencies. With CareLink™, telemetry can occur on a variable, "clearest" MICS channel of up to 300 kHz (within the 402–405 MHz band), which helps ensure a strong signal. Telemetry range between implanted device and home receiver-transmitter is dependant on conditions including the model of the implanted device, but may be achieved at a minimum of 2–5 m with the most recently developed implantables. As above, "wireless" technology now allows automated interrogations, in addition to patient initiated downloads with older devices that do not possess the "long-distance" telemetry of newer implanted devices. Automated relay of information may allow for earlier monitoring of arrhythmias or device related issues. This automation may also simplify compliance issues for patients and physicians.

Data Obtained

A complete set of stored and real-time device information, just like that obtainable in-clinic, can be obtained at the time of remote interrogation, including both device and patient specific information including arrhythmia events data, with EGMs on therapy delivery (Fig. 16.6), and specialized heart failure management reports (Fig. 16.7). Even hemodynamic information now available from some implanted devices is available remotely. This remote monitoring system has been used with FDA approved systems [19] and still investigational implantable hemodynamic monitors [20–22] as well. The ability to monitor chronic conditions remotely such as heart failure promises to further hasten the development, implementation, and acceptance of this technology.

Notifications

Clinician alerts are initiated by device recognition of preset conditions. The system automatically

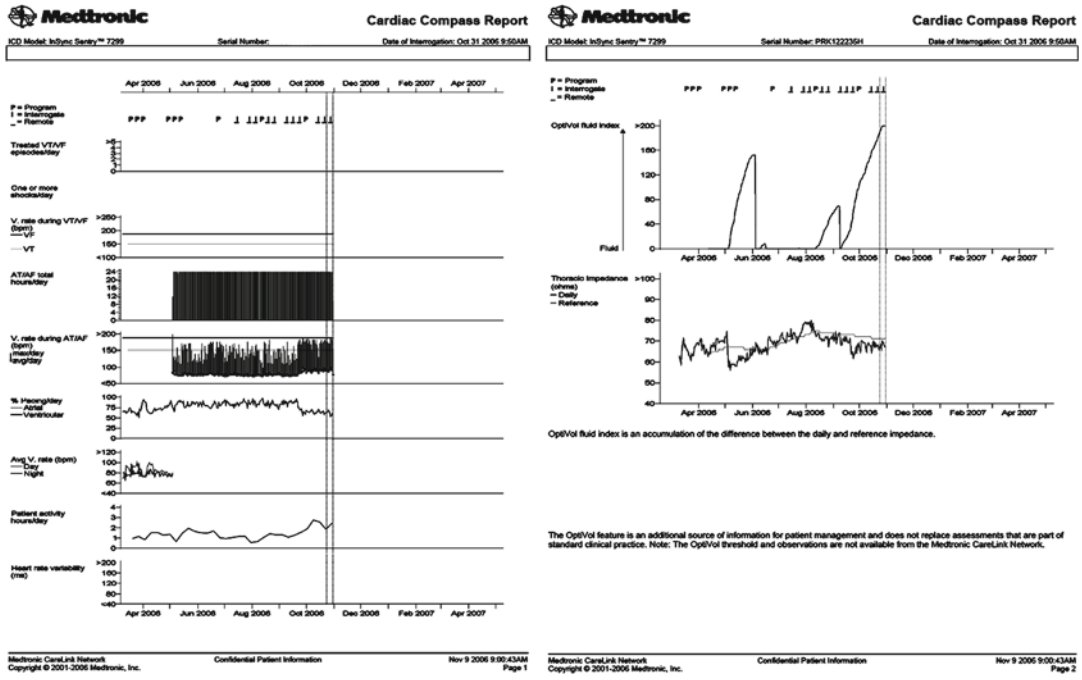


Figure 16–7. A Medtronic CareLink™ remote monitoring heart failure report on a patient using OptiVol, a measurement of transthoracic impedance as an indicator of heart failure status

sends a transmission when an alert is initiated. Alerts may be sent to the clinic or physician, to either voicemail or a pager. Information in the alert includes patient name and date of birth, type of alert, and a phone number to reach the patient.

Data obtained via alerts can be tailored according to physician preference. This allows for ongoing interaction with the system by different types of physicians. Device performance reports including all the standard information from interrogation, or heart failure management reports, may be sent to the heart rhythm specialist, or the heart failure physician, or both.

Cost

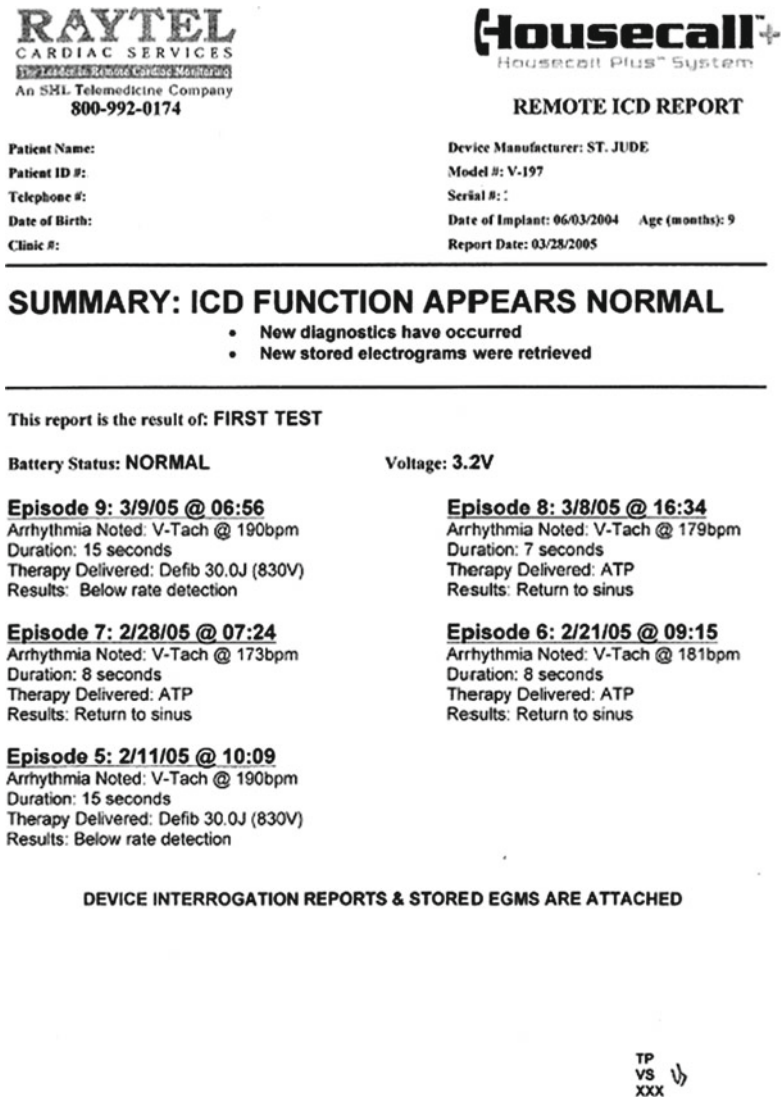
Manufacturer charges for the remote monitoring system are recurring, and are billed to the clinics where the monitoring takes place. Physician billing for these services is being reviewed and revised and there is significant variability, geographically, in third-party reimbursement for these, currently.

St. Jude Medical

The remote monitoring system marketed by St Jude Medical, Housecall Plus™, was introduced in October 2005, and has 7,000 patient enrollments as of October 2006. The system, different than the previous three discussed, utilizes live medical professionals (either in the patient's physician office or in service centers) to interface with patients during the transmission process. An early iteration of the system was evaluated in 124 patients, and found to have a high level of patient satisfaction, along with "safe and successful" monitoring [23].

Home Data Acquisition

Like the other systems described, data is obtained via a multi-part system. The device itself is the first part, the home transceiver in the patient's home a second part and the receiver is the final part, which may be owned and operated by service centers or by physicians. The home transceiver is equipped with



RAYTEL
CARDIAC SERVICES
The Leader in Remote Cardiac Monitoring
An SRL Telemedicine Company
800-992-0174

Housecall+
Housecall Plus™ System

REMOTE ICD REPORT

Patient Name:
Patient ID #:
Telephone #:
Date of Birth:
Clinic #:

Device Manufacturer: ST. JUDE
Model #: V-197
Serial #:
Date of Implant: 06/03/2004 Age (months): 9
Report Date: 03/28/2005

SUMMARY: ICD FUNCTION APPEARS NORMAL

- New diagnostics have occurred
- New stored electrograms were retrieved

This report is the result of: FIRST TEST

Battery Status: NORMAL Voltage: 3.2V

Episode 9: 3/9/05 @ 06:56
Arrhythmia Noted: V-Tach @ 190bpm
Duration: 15 seconds
Therapy Delivered: Defib 30.0J (830V)
Results: Below rate detection

Episode 8: 3/8/05 @ 16:34
Arrhythmia Noted: V-Tach @ 179bpm
Duration: 7 seconds
Therapy Delivered: ATP
Results: Return to sinus

Episode 7: 2/28/05 @ 07:24
Arrhythmia Noted: V-Tach @ 173bpm
Duration: 8 seconds
Therapy Delivered: ATP
Results: Return to sinus

Episode 6: 2/21/05 @ 09:15
Arrhythmia Noted: V-Tach @ 181bpm
Duration: 8 seconds
Therapy Delivered: ATP
Results: Return to sinus

Episode 5: 2/11/05 @ 10:09
Arrhythmia Noted: V-Tach @ 190bpm
Duration: 15 seconds
Therapy Delivered: Defib 30.0J (830V)
Results: Below rate detection

DEVICE INTERROGATION REPORTS & STORED EGMS ARE ATTACHED

TP
VS
XXX

Figure 16–8. A remote monitoring report from St. Jude Medical's Housecall Plus™ coupled with Raytel service center (Courtesy of St. Jude Medical)

two ECG wristbands, a telemetry wand to place right over the device and a built-in speakerphone, so patients can speak with the technician assisting with the download process. A standard telephone jack (with land-line) and power outlet are required. After the data is received and formatted, there is PDF export capability, to capture information for email, in office use such as in an electronic medical record, or other uses. Data can be maintained locally if a physician so chooses (and purchases the necessary equipment), or on servers controlled by service providers, currently the more commonly used approach.

Data Obtained

The data obtained, much like with the other systems discussed, is essentially the same as in-office reports obtained from a standard programmer. There are real time surface EGMs obtained from wristbands, along with stored electrograms from episodes where therapy was indicated and may have been delivered. Device specific information is assessed, including battery status, thresholds, and impedance measurements, along with other more specific programmed algorithms. Summaries of clinically relevant events may be obtained (Fig. 16.8), along with episode specific EGMs

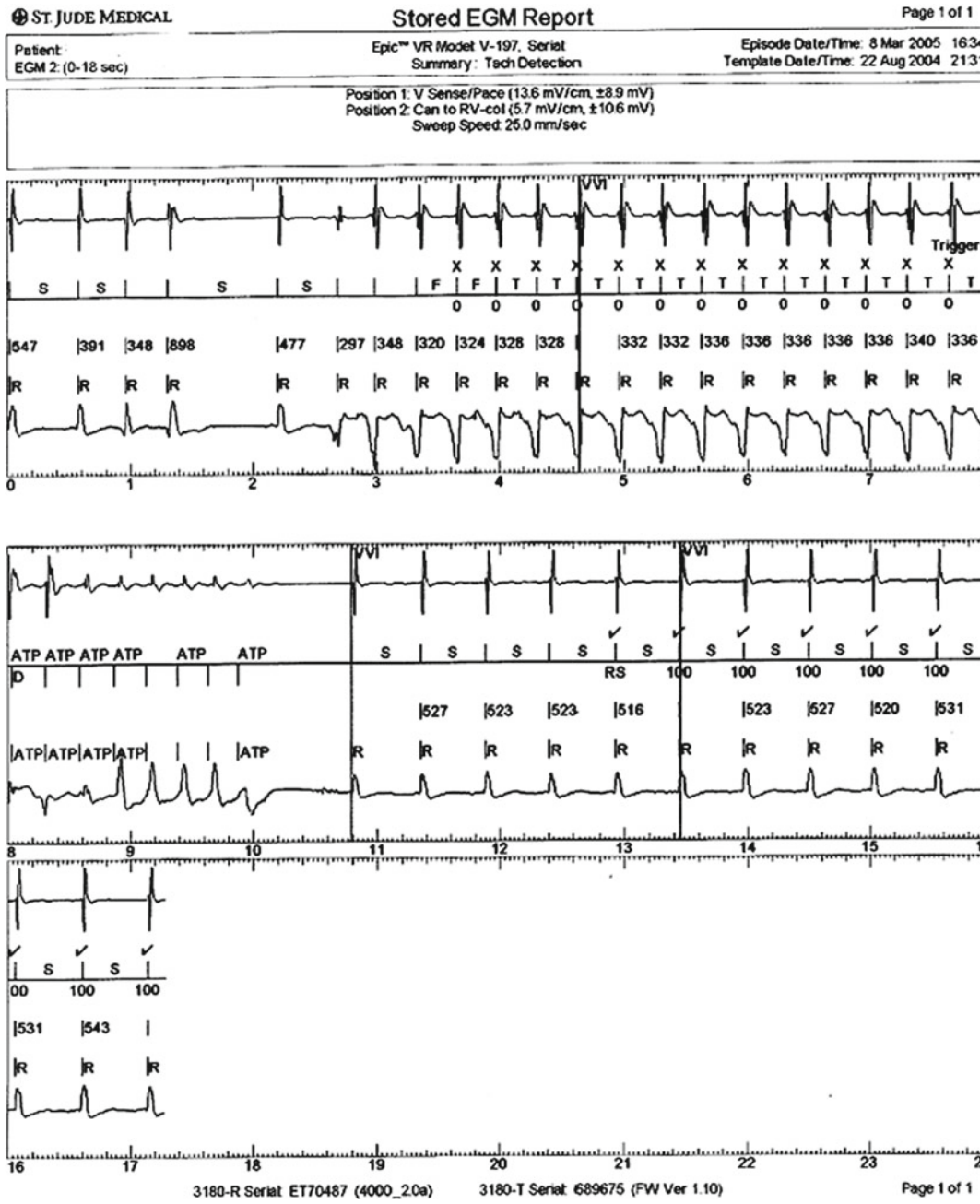


Figure 16–9. A St. Jude Housecall Plus™ remote monitoring report showing details of an arrhythmia event (ventricular tachycardia) successfully treated with anti-tachycardia pacing (Courtesy of St. Jude Medical)

(Fig. 16.9). In the service centers, data is evaluated by technicians who have become testamurs of NASPExAM (now referred to as IBHRE, International Board of Heart Rhythm Examiners).

Notifications

Critical issues are dealt with initially via the service center (if utilized). The physician may be notified in the case of pre-selected and customized notification criteria, such as therapy

delivery, battery compromise, or impedance changes. Under the physician maintained system, information is received by persons designated by the physician practice.

Cost

There are manufacturer charges for the receiver and the transmitter. Payment structures vary according to whether equipment is owned or leased, or how service centers are utilized. There are two service centers which can be used with the system, according to practice choice. There are no service fees associated with ongoing use of the system.

Billing for the services provided varies according to the model used, physician-maintained or by service providers, and involves variable billing of technical and professional fees associated with interrogation.

Challenges

Privacy

One of the challenges for remote monitoring is privacy protection. Technology has and will no doubt attempt to keep up with federal and international standards for protection of personal information, such as HIPAA, which dictates standards of protection of the privacy of personal health information. While technical challenges such as encryption of data and human challenges such as adequate training of personnel about privacy issues require careful attention, all involved, to date, appear committed to privacy protection.

Data Management

Management (and formatting for use) of great volumes of data involved in remote monitoring will be problematic. Large volume practices could potentially be challenged with the day to day data management of patients with more advanced illness and implanted devices being remotely monitored, such as those typically seen in tertiary care centers. While such data is likely to lead to improved patient care, it is also likely that care pathways will need to be developed in offices specifically to deal with remotely monitored devices and patients. It is probable that large practices will have implanted device remote monitoring "centers" where data will be maintained, formatted and parceled out to clinicians who can use the information for patient management. Smaller practices may rely solely on manufacturer or other "third-party" entities for data acquisitions, formatting, and management. It is important to point out that centralized data banks may be most important in improved device surveillance and reporting efforts.

Costs and Reimbursement

The direct and indirect costs of this technology will be significant. As has been discussed, direct costs are billed at the time of implant, or are recurring. There will be further expenses, both direct and indirect, in managing the data (physician time, added staff, etc.). At the time of this writing, reimbursement may be obtained in many states, by a variety of insurers for these services. The Centers for Medicare and Medicaid Services (CMS) issued a transmittal (Transmittal 979) in June 2006 authorizing reimbursement for remote monitoring of pacemakers and ICDs using in-office electronic analysis codes. While the initial forays into more sophisticated remote follow-up have targeted ICDs and CRT devices because of reimbursement issues, it is anticipated that over time, virtually all devices including pacemakers will be included.

Limitations

Limitations potentially imposed by this type of care will need to be addressed. Patient care teams will need to ensure that patients feel their care is being enhanced, rather than being compromised, by new technologies. These paradigm changes will likely require time to gain acceptance by the general medical community. Future trials will be designed to validate this approach to patient care and information, and also to investigate the potential economic aspects of remote care. As with any change in care paradigm, concerns will, no doubt, exist about not

only the feasibility of the new care style, but also patient acceptance.

Conclusions

It appears that we are on the brink of a new era in healthcare of patients with or at high risk of chronic, and even acute, diseases. Remote monitoring of both implanted devices and chronic illnesses using implanted devices has been developed, technologically, to a point of broad-based utility and availability. Most companies now marketing implantable electronic devices such as pacemakers and defibrillators have developed manufacturer-specific remote monitoring systems. While there are substantial differences in the technology and formatting of the different systems, there are common goals for all of the systems.

Rapid access by patients, even in geographies significantly remote from device and disease expertise, is facilitated by using remote monitoring systems. Patients in need can be more closely monitored using such systems and both the hassles and time for device and disease follow-up can be minimized, potentially at significant financial savings and certainly with improvement in patients and patients' families peace of mind and sense of wellbeing. From physicians' perspectives, with what will certainly be dramatic increases in patient volumes as our population ages as well as increases in absolute numbers, the improved efficiencies of remote monitoring will allow better human resource usage by minimizing unnecessary routine (and other) face to face visits with patients. It is likely that even hospitalizations can be reduced by remote monitoring systems as more consistent follow-up is done even for patients who otherwise would have difficulty achieving such follow-up because of geographic, physical, or economic restrictions. Remote monitoring and associated data-basing of device performance is an as yet untapped opportunity for dramatic improvement in device-performance surveillance.

While the future appears bright for this emerging discipline of remote monitoring, much work needs to be done to further expand what can be monitored remotely, especially in monitoring diseases, as well as other activities that can be accomplished such as remote programming of device function. Additionally, making certain that implementation of these new concepts, technology, and systems is accomplished in economically viable ways is a challenge of utmost importance.

References

1. Schoenfeld MH, Reynolds DW. Sophisticated remote implantable cardioverter-defibrillator follow-up: a status report. Pacing Clin Electrophysiol. 2005;28(3):235–40.
2. Carlson MD. Recommendations from the Heart Rhythm Society Task Force on Device Performance and Guidelines. Heart Rhythm. 2006; 3(10):1250–73.
3. ACC/AHA Guidelines for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices. A report of the American College of Cardiology/ American Heart Association Task Force on Practice (Committee on Pacemaker Implantation). J Am Coll Card. 1998;31(5):1175–209.
4. Adamson PB, Magalski A, Braunschweig F, et al. Ongoing right ventricular hemodynamics in heart failure: clinical value of measurements derived from an implantable hemodynamic monitor. J Am Coll Cardiol. 2003;41(4):565–71.
5. Shah NB, Der E, Ruggerio C, et al. Prevention of hospitalizations for heart failure with an interactive home monitoring program. Am Heart J. 1998; 135(3):373–8.
6. Goldberg LR, Piette JD, Walsh MN, et al. Randomized trial of a daily electronic home monitoring system in patients with advanced heart failure: the Weight Monitoring in Heart Failure (WHARF) trial. Am Heart J. 2003;146(4):705–12.
7. Stewart S, Vandenbroeck AJ, Pearson S, et al. Prolonged beneficial effects of a home-based intervention on unplanned readmissions and mortality among patients with congestive heart failure. Arch Intern Med. 1999;159(3):257–61.
8. Galbreath AD, Krasuski RA, Smith B, et al. Long-term healthcare and cost outcomes of disease management in a large, randomized, community-based population with heart failure. Circulation. 2004;110:3518–26.
9. Cleland JG, Louis AA, Rigby AS, Janssens U, et al. Noninvasive home telemonitoring for patients with heart failure at high risk of recurrent admission and death: the Trans-European Network-Home-Care Management System

(TEN-HMS) study. J Am Coll Cardiol. 2005;45(10): 1654–64.
10. Falk D, Straub K. Practice efficiency improvements resulting from the use of Medtronic CareLink Network remote monitoring system. Fairfield: Human Factors International; 2004.
11. Furman S, Escher DJ. Transtelephone pacemaker monitoring. In: Schaldach M, Furman S, editors. Advances in pacemaker technology. Berlin: Springer; 1975. p. 177–94.
12. Ellenbogen KA, Kay GN, Wilkoff BL. Clinical cardiac pacing. Philadelphia: W.B. Saunders; 1995. p. 796–8.
13. Furman S, Hayes DL, Holmes DR. A practice of cardiac pacing. 3rd ed. Mount Kisco: Futura; 1993. p. 580–2.
14. Lyons C, Schroeder P, Shankar K, et al. Transtelephonic monitoring of a tachycardia-terminating pacemaker. Pacing Clin Electrophysiol. 1984;7(1):34–6.
15. Bhandari AK, Anderson JL, Gilbert EM, et al. Correlation of symptoms with occurrence of paroxysmal supraventricular tachycardia or atrial fibrillation: a transtelephonic monitoring study. Am Heart J. 1992;124(2):381–6.
16. Fetter JG, Stanton MS, Benditt DG, et al. Transtelephonic monitoring and transmission of stored arrhythmia detection and therapy data from an implantable cardioverter defibrillator. Pacing Clin Electrophysiol. 1995;18(8):1531–9.
17. Scholten MF, Thorton AS, Theuns DA, Res J, Jordaens LJ. Twiddlers syndrome detected by home monitoring device. Pacing Clin Electrophysiol. 2004;5 Suppl 1:30S–1.
18. Schoenfeld MH, Comptom SJ, Mead RH, et al. Remote monitoring of implantable cardioverter defibrillators: a prospective analysis. Pacing Clin Electrophysiol. 2004;27(Pt 1):757–63.
19. Yu CM, Wang L, Chau E, et al. Intrathoracic impedance monitoring in patients with heart failure. Circulation. 2005;112:841–8.
20. Steinhaus D, Reynolds DW, Gadler F, et al. Implant experience with an implantable hemodynamic monitor for the management of symptomatic heart failure. Pacing Clin Electrophysiol. 2005;28: 747–53.
21. Magalski A, Adamson P, Gadler F, et al. Continuous ambulatory right heart pressure measurements with an implantable hemodynamic monitor: a multicenter, 12-month follow-up study of patients with chronic heart failure. J Card Fail. 2002;8(2): 63–70.
22. Kjellstrom B, Igel D, Abraham J, et al. Transtelephonic monitoring of continuous haemodynamic measurements in heart failure patients. J Telemed Telecare. 2005;11(5):240–4.
23. Joseph GK, Wilkoff BL, Dresing T, et al. Remote interrogation and monitoring of implantable cardioverter defibrillators. J Interv Card Electrophysiol. 2004;11:161–6.