

REMOTE MONITORING TECHNICAL MONOGRAPH

SCIENTIFIC EVIDENCE REGARDING THE INCREASING NEED FOR MONITORING, PATIENT SAFETY, CLINICIAN EFFICIENCY, AND COSTS

■ Overview

Regular monitoring is required for patients with implanted cardiac devices. Historically, this has been done via scheduled clinic appointments. Current technology allows for remote monitoring (RM), which has several benefits.

Evidence supports RM as a safe and effective tool for evaluating patient status. Research has demonstrated that patient and clinician satisfaction with RM is very high. The technology is easy to use, and it saves time and money when compared with traditional clinic visits.

This summary highlights the scientific evidence pertaining to:

- Patient Safety
 - The Increasing Need for Monitoring
 - The Impact of RM on Event Detection and Patient Treatment
- Clinic Efficiency and Costs
 - The Impact of RM on Clinician and Staff Time
 - The Impact of RM on Healthcare Costs
- Satisfaction
 - Clinician Satisfaction with RM
 - Patient Satisfaction and Quality of Life with RM

According to Nielsen et al. (2008):

“If all patients eligible for ICD implantation actually receive them, the cardiology workforce performing ICD controls will face massive additional workload with insufficient resources.”¹ (p. 729)

■ Patient Safety

Increasing Need for Monitoring

There has been a significant increase in the number of patients receiving implanted cardiac devices, and cardiology clinics are struggling with the burden of routine follow-ups.²

- Researchers estimate that the number of patients receiving implanted cardiac devices such as implantable cardioverter defibrillators (ICDs), cardiac resynchronization devices (CRTs), and pacemakers will double, thus increasing the need for monitoring.²
- Current standards recommend clinic visits every 3 to 6 months, with increased frequency as the implanted device ages.³

- Patient monitoring must be done by clinicians with specialized electrophysiological training, and there are not enough specialized physicians to handle the increasing number of patients requiring surveillance.^{2,3}
- Some clinicians hoped to reduce the frequency of patient follow-up visits. However, recent situations with device malfunctions have led to a need for more monitoring.³
- Scheduled visits are insufficient and often unproductive. Actionable problems that occur are rarely found during routine follow-up visits.^{1,3} **(See Case Study 1)**

According to Schoenfeld et al. (2004):

“The growing demands for implantable device follow-up is pushing clinics to their maximum capacity. Any solution that reduces the bottleneck will significantly impact how care is delivered. Remote follow-up offers an alternative for overcrowded and overwhelmed clinics, and considerable convenience for patients.”² (p. 757)

Case Study 1:

Heidbüchel et al. (2008: University of Leuven in Belgium) selected 169 ICD patients and analyzed their 1,739 follow-up visits.³

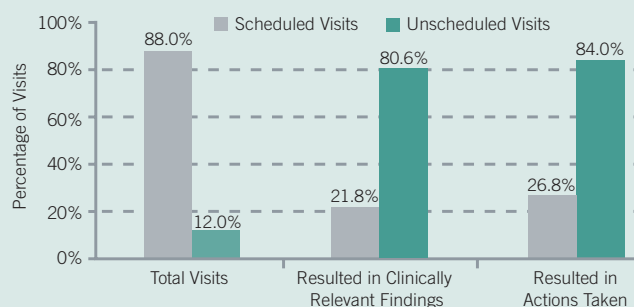
1,530 of the 1,739 visits were previously scheduled. **(See Figure 1)** Standard scheduled visits accounted for 88% of all visits, but only resulted in relevant findings during 21.8% of these visits, and in actions during only 26.8%. However, no treatment or device changes were made for 90% of patients.

209 of the 1,739 visits were unscheduled. Although unscheduled visits only accounted for 12% of all visits, 80.6% of them resulted in clinically relevant findings and 84% resulted in actions taken.

- These visits were due to:
 - ICD intervention (47%)
 - Symptoms or patient request (33%)
 - Surgery (11%)
 - Product advisories (7%)
 - Study related reasons (2%)

Figure 1.
Value of Scheduled Visits Versus Unscheduled Visits

[Source: Heidbüchel et al. (2008) N=1,739]



Lazarus (2007) stated:

“The exponential growth rate of cardiac devices implantation calls for new methods of long-term surveillance with a view to optimize patient safety and care, alleviate the burden of caregivers, lower health care cost, and address regulatory and legal issues.”⁴ (p. 1)

The Impact of Remote Monitoring on Event Detection and Patient Treatment

Remote monitoring (RM) is an effective tool for evaluating patient status.³ It enhances patient safety by allowing medical staff to identify and treat problems early and provide individualized optimal care.^{1, 4, 5}

- RM results in the earlier detection of many conditions. Specifically, RM allows asymptomatic and minimally symptomatic conditions to be detected significantly earlier.^{1, 3, 4, 6, 7} **(See Case Studies 2, 3, and 4)**
- In several recent studies, medical staff were able to catch device issues earlier with RM than with routine visits.^{1, 3, 4, 6, 8}

- RM enables physicians to design more individualized therapy.^{1, 8}
- Researchers have established that most of the problems caught during clinic visits would have been found by RM.³
- One research team found that RM would have been just as effective as a clinic visit in 94% of 1,739 evaluated cases.³
- Another research team suggested that RM may result in increased resource savings during long-term follow up.⁷

Raatikainen et al. (2008) concluded:

“Since all unscheduled data transmissions were resolved using the remote-monitoring system, our data suggest that remote monitoring can be safely used to evaluate symptoms of the patients and to detect potential problems with the device (e.g. depletion of the battery). This eliminates the need for unwarranted trips to the emergency room and device clinic, which is like [sic] to alleviate the anxiety of the patients as remote monitoring provides a prompt response to their concerns.”⁵ (p. 1149)

Case Study 2:

Ricci et al. (2008: San Filippo Neri Hospital in Italy) monitored 117 patients with defibrillators or pacemakers for an average of seven months.⁷

- A nurse identified 133 events among 56 RM patients
- A physician diagnosed numerous conditions and identified problems with ICD programming and intervention using RM data **(See Table 1)**
- Follow-up and treatment changes included the following:
 - Phone calls with the clinician (18 cases)
 - In-hospital visits (48 cases)
 - Prescription therapy changes (29 cases)
 - Device reprogramming (12 cases)
 - Further diagnostic tests (6 cases)
 - Hospitalization for impending heart failure (1 case)
- The discovery of atrial fibrillation (AF) after implant was considered particularly important, as AF is a risk factor for stroke and death.
 - AF occurred in 28% of patients, and 55% of the cases had not been diagnosed prior to RM.
 - Clinicians made the following treatment changes for patients with AF discovered during RM:
 - Anticoagulation initiated
 - Antiarrhythmic medications modified
 - Electrical cardioversion required (3 cases)

Table 1.
Clinical Findings During Remote Monitoring
(n=56; 133 events analyzed)

[Source: Ricci et al. (2008)]

	Pacemakers (number of events)	ICDs (number of events)
Atrial Fibrillation 64 events among 33 patients 18 patients were previously undiagnosed	58	6
Impending Heart Failure	1	12
Unsustained Ventricular Tachycardia	8	1
Sustained Ventricular Tachycardia or Fibrillation	0	12
Inappropriate ICD Intervention	0	5
Suboptimal Programming	30	1

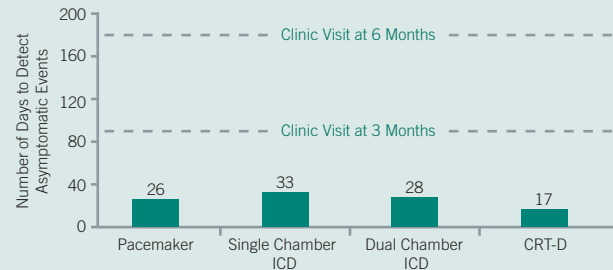
Case Study 3:

Lazarus (2007: InParys Clinical Research Group in France) analyzed a worldwide database of 11,624 patients spanning 23 countries.⁴

- Remote monitoring (RM) allowed problems to be caught significantly earlier than expected with standard clinic visits. (See Figure 2)
- Events among asymptomatic patients were caught an average of two months earlier for three month follow-up visits, and five months earlier for six month follow-up visits.
- When patients with ICDs and CRT-Ds were tracked with RM, asymptomatic events were caught in one-third of the time it would have taken with standard clinic visits alone.
- Similarly, events of this type were identified a full month earlier if patients with single chamber ICDs used RM.

Figure 2.
Time Elapsed Before Detection of Asymptomatic Events:
Remote Monitoring Versus Standard Visits

[Source: Lazarus (2007) N=11,624]



Case Study 4:

Joseph et al. (2004: Cleveland Clinic in the United States) evaluated the impact of a remote ICD monitoring device (St. Jude Medical Housecall II™) by tracking 124 patients over a six month period.⁶ During that time, patients transmitted data a total of 570 times at an average of 5 times per patient. Each transmission was analyzed by a certified technician, who sent results to an electrophysiologist (EP) for review. Whenever there was an abnormal finding, the technician contacted an EP directly.

As a result of the remote monitoring:

- 6 patients were hospitalized or sent to the emergency room for evaluation
- 18 patients had unscheduled appointments in the clinic

In addition, clinicians were able to:

- Confirm that therapy was delivered for 54 incidents of ventricular tachyarrhythmia (VT)
- Confirm that therapy was aborted for 22 cases of nonsustained ventricular arrhythmias
- Identify 30 incidents of VT that were not sustained
- Diagnose 5 patients with AF
- Detect problems with ICD generators or leads in 32 cases
- Triage patients faster in the emergency room, due to faxing the device interrogations prior to patient arrival

According to Joseph et al. (2004):

“The straightforward conclusion from these results suggests that remote interrogation of ICDs significantly reduces the number of face-to-face patient to physician encounters. This is accomplished while shortening the time to document asymptomatic or minimally symptomatic dysrhythmias and increasing the likelihood that electrical dysfunction is detected before a serious and potentially lethal malfunction is manifest.”⁶ (p. 164)

Clinic Efficiency and Costs

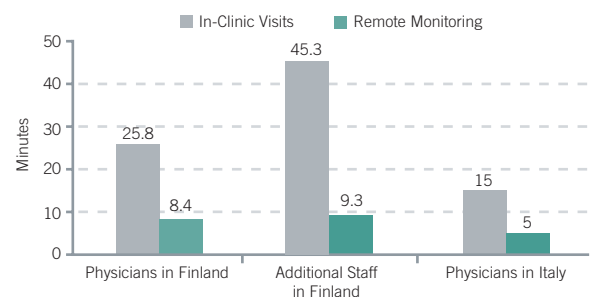
Impact of Remote Monitoring on Clinician and Staff Time

Remote monitoring (RM) allows physicians to evaluate patient data in less time than conducting in-person clinic visits.⁴

- Research teams have reported that it takes less time to evaluate data from remote transmissions than it does during standard visits.^{5,9}
- Alternate organizational systems allow qualified nurses or software systems to sift through data and bring only important information to the attention of the doctors.⁷
- Raatikainen et al. (2008) found significant reductions in physician and staff time required to evaluate patients when RM was used.⁵ Marzegalli et al. (2008) confirmed that physicians saved time with RM.⁹ (See Figure 3)

Figure 3.
Physician Time Required to Evaluate Patient Status

[Sources: Raatikainen et al. (2008: Finland), Marzegalli et al. (2008: Italy)]



The Impact of Remote Monitoring on Healthcare Costs

In addition to reducing clinician and staff time,^{4, 6, 7} remote monitoring (RM) can also decrease expenses to patients and healthcare providers.⁵

Researchers in Italy, Finland, and France have found that RM can reduce the need for scheduled and unscheduled clinic visits.^{5, 9, 10}

Routine Scheduled Visits

- Marzegalli et al. (2008: Italy) estimated that at least half of the scheduled visits could be replaced by RM.
- The cost of a scheduled clinic visit depends on the transportation costs and regional price of follow-up visits.^{5, 9, 10} (See Table 2)
- Eliminating unnecessary visits substantially reduces costs to both patients and clinics.⁴
- Raatikainen et al. (2008: Finland) decreased the direct cost to healthcare providers by 155 € for every standard office visit that was replaced by a RM transmission.⁵

Unscheduled Visits

- Marzegalli et al. (2008) demonstrated that RM may eliminate the need for one additional unscheduled visit per patient per year.⁹
- Raatikainen et al. (2008) also indicated that RM could reduce the need for unscheduled visits.⁵ During the nine-month study period:
 - 18 clinical issues were identified via RM.
 - All of the issues were addressed by physicians without requiring face-to-face visits with patients.
 - The estimated cost savings of handling these events remotely rather than bringing these patients to the hospital was substantial. (See Table 3)

Table 2.
Cost for a Routine Scheduled Visit, by Country

[Sources: Marzegalli et al. (2008), Raatikainen et al. (2008), Fauchier et al. (2005)]

	Italy	Finland	France
Transportation costs	18.41 €	74.36 €	121 USD
Routine ICD follow-up	47.77 €	210 €	94 USD

Table 3.
Estimated Cost Savings of Handling 18 Issues Remotely Rather than Patients Visiting the Hospital

[Source: Raatikainen et al. (2008)]

	Cumulative Cost
Cost to Patients	990.6 €
Cost to the City (18 events x 155 € for cost of visit)	2790 €
Cost to the KELA (Social Insurance Institution of Finland)	1060.1 €

Raatikainen et al. (2008) stated:

“In Western Europe, ~160 ICDs per million inhabitants are implanted annually. On the basis of our results, it can be calculated that if remote monitoring were to be applied to all the patients with new ICDs, the annual savings for the healthcare system would be 16-23 million euros. In addition, remote monitoring gives physicians extra time to counsel patients with critical conditions, ensuring medical efficiency, and better overall patient management, which is expected to reduce the cost of treatment even further.”⁵ (p. 1151)

Satisfaction

Clinician Satisfaction with Remote Monitoring

Research has demonstrated that clinician satisfaction with remote monitoring (RM) is very high. In several studies, clinicians reported that RM technology was easy to use.^{2, 5, 9} In addition, it saves time and money when compared to traditional clinic visits. (See Case Study 5)

Case Study 5:

Raatikainen et al. (2008: University of Oulu in Finland) conducted a nine month study which tracked 41 patients with ICDs using RM.⁵ During the study period, 82 scheduled RM transmissions and 82 clinic visits occurred.

- There were no adverse events related to the device and the researchers concluded that it was safe.
- All physicians reported that navigating the RM website was very easy.
- 97% of physicians said that it was easy or very easy to access the RM data.
- In most cases, physicians reported that the data was comparable to in-clinic device interrogation, and they were satisfied with the RM system performance.

Patient Satisfaction and Quality of Life with Remote Monitoring

Researchers in several countries have evaluated patient satisfaction and ease of use with remote monitoring (RM).^{2, 5, 6} Patients have been very satisfied with RM. They felt it was easy to learn how to use the technology, and that it was reliable.^{2, 5, 6} **(See Case Study 6)**

Several studies have demonstrated that:

- Patients thought RM was more convenient and saved time.^{5, 6}
- They considered it to have less negative impact on their social lives than clinic visits.⁶
- They reported feeling reassured that they were being monitored.^{1, 2}

Case Study 6:

Joseph et al. (2004: Cleveland Clinic in the United States) evaluated the impact of a remote ICD monitoring device (St. Jude Medical Housecall II™) on patient satisfaction and quality of life.⁶ They tracked 124 patients and found that patient quality of life after the implantation of a cardiac device was maintained for the entire six month study period.

Patient satisfaction with remote monitoring was very high with regard to:

- Data transmission
- Follow-up convenience
- Confidence in the system
- Ease of learning the technology
- Time required

According to Joseph et al. (2004):

“Patient satisfaction was extremely high throughout the study period ranging over the six month evaluation between 93% and 99%.”

“Almost uniformly the patients found follow-up with the system easy to learn and easy to accomplish. The system was convenient, saved time and was considered reliable.”⁶ (pp. 164-165)

Remote monitoring (RM) has been found to decrease patients’ need to rely on caregiver assistance.⁹ **(See Case Study 7)**

- Marzegalli et al. (2008) found that 57% of patients required help to attend a follow-up visit at a clinic.⁹
 - Only 39% of RM patients required assistance transmitting data at the beginning of the study.⁹
 - By follow-up three months later, this percentage dropped to 26%.⁹
- A study in Finland found patients were able to perform the transmissions without any assistance in 80% of the sessions.⁵

Case Study 7:

Researchers in Italy studied patient and clinician opinions about a remote monitoring (RM) system. Patients with cardiac resynchronization therapy defibrillators (CRT-Ds) were tracked for three months. They completed questionnaires about their satisfaction with the RM system, as well as the time and costs associated with follow-up.⁹

During the three month study, patients transmitted data 264 times. All of the participating patients reported that the RM system was easy or very easy to use. **(See Table 4)** Patient satisfaction was so high that 97% of patients would recommend the RM system to other patients.⁹ **(See Figure 4)**

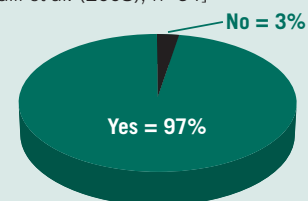
Table 4.
Ease of Use for Patients

[Source: Marzegalli et al. (2008), n=65]

Patient Opinions about Remote Monitoring	Percent of Participants
Easy	60%
Very Easy	40%
Difficult	0
Very Difficult	0

Figure 4.
Patient Satisfaction: Percent Who Would Recommend Remote Monitoring to Other ICD Patients

[Source: Marzegalli et al. (2008), n=64]



Research found that there was a significant burden due to travel, time off from work, lodging expenses, and needing caregiver assistance when patients have to go to the clinic for follow-up.^{5,9} Raatikainen et al. (2008) found that remote monitoring resulted in significant cost savings for patients in Finland by eliminating the costs associated with traveling to the clinic, lost work time, and visit co-pays. In this study, patients who lived far away from the clinic benefited the most financially.⁵

Patients also spent significantly less time performing remote interrogations than attending clinic visits in both Italy and Finland.^{5,9} (See Figures 5 and 6)

Figure 5.
Average Travel Distance Required per Clinic Visit for Study Participants

[Sources: Raatikainen et al. (2008), Marzegalli et al. (2008), Fauchier et al. (2005)]

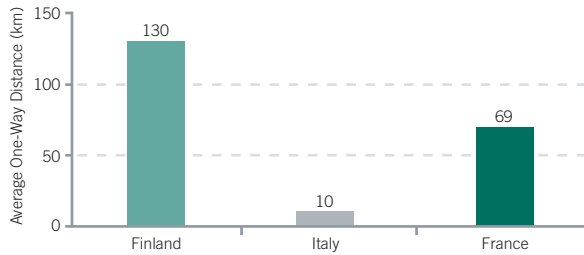
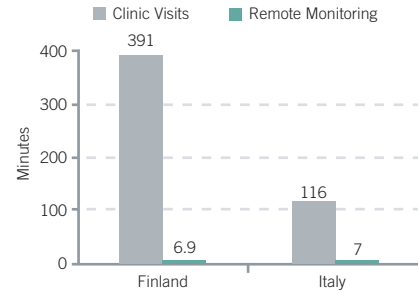


Figure 6.
Average Time Required, Including Travel, per Follow-up for Study Participants

[Sources: Raatikainen et al. (2008), Marzegalli et al. (2008)]



With regard to the RM system, Raatikainen et al. (2008) concluded:

“The system was easy to use and both the patients and hospital staff were satisfied with it. In addition, compared with the generally recommended ICD follow-up scheme, remote monitoring diminishes the annual cost of ICD follow-up by 524€ (41%) per patient in an area characterized by long travelling distances to the device clinic.”⁵ (p. 1149)

Conclusion

Several studies from multiple countries evaluated remote monitoring (RM) and established high satisfaction by both clinicians and patients.^{2, 5, 6, 9} RM allows physicians to detect asymptomatic events and device problems earlier than standard clinic visits.^{1, 3, 4, 6, 7} Remote monitoring decreases the burdens of regular in-clinic visits:

- RM takes less time for both patients and clinicians ^{6, 7}
- RM costs less for both patients and healthcare providers ^{4, 5, 7, 9, 10}
- RM requires less caregiver assistance than clinic visits ⁹

Evidence supports the implementation of RM as a convenient, cost effective, and well-liked method of evaluating patient status after the implantation of a cardiac device.^{4, 5, 7}

According to Nielsen et al. (2008):

“Home monitoring bears the potential to reduce the need for routine in-clinic ICD follow-up, in which the majority of cases reveal no need for interference, but cumulatively require significant personal and financial resources.”¹¹ (p. 732)

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ATRIAL FIBRILLATION CARDIAC RHYTHM MANAGEMENT CARDIAC SURGERY CARDIOLOGY NEUROMODULATION

St. Jude Medical, Inc.
Global Headquarters
St. Paul, MN 55117
USA
+651 483 2000
+651 766 3045 Fax

St. Jude Medical Europe, Inc.
The Corporate Village
Avenue Da Vinci laan, 11 - Box F1
B-1935 - Zaventem
Belgium
+32 2 774 68 11
+32 2 772 83 84 Fax

St. Jude Medical Brasil Ltda.
Rua Frei Caneca, 1380-9 A-CJ91/92
Sao Paulo - SP - Brasil
CEP 01307-002
+55 11 5080 5400
+55 11 5080 5423 Fax

St. Jude Medical (Hong Kong) Ltd.
Unit 2701-07, COSCO Tower,
Grand Millennium Plaza
183 Queen's Road
Central, Hong Kong
+852 2996 7688
+852 2956 0622 Fax

www.sjm.com



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