

# Remote Management of Cardiac Patients

## THE FOREFRONT OF A NEW STANDARD

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*“There are not many strategies that yield patient, physician and financial benefit. Remote Patient Management of cardiac patients does, however, and is an all around win. It actualizes the promise of integrating health care and information technology.”*

— **David Donnelly, CEO**  
CardioVascular Group, P.C.  
Lawrenceville, Georgia



The prevalence and cost of heart disease is staggering. The American Heart Association (AHA) approximates that every 39 seconds an American will die from cardiovascular disease.<sup>i</sup> A leading cause of death for Americans, sudden cardiac arrest claims 325,000 lives each year.<sup>ii</sup> Atrial fibrillation (Afib), an irregular heartbeat, is the most common heart rhythm disorder affecting an estimated 2.2 million Americans, and has been independently associated with a 50%-90% increase in risk of death.<sup>iii</sup> Today's cost of treating cardiovascular disease is prohibitive as it consumes 17% (\$445 billion) of U.S. health expenditures. Even more eye opening, however, is the prevalence and cost of cardiovascular disease as the population ages. The AHA projects that by 2030, 40.5% of the U.S. population will have some form of cardiovascular disease. The direct and indirect costs of medical care and lost productivity will rise to approximately \$1.1 trillion, a two-and-a-half fold increase from today.<sup>1</sup>

The incidence of cardiovascular disease compels clinicians, health systems and administrators to innovate a new model of

care to manage the burgeoning cardiac population, ensure quality care, and optimize limited human and capital resources. New paradigms will require an approach that departs from the “usual and customary” mindset to an approach that challenges traditional business models and long standing “standards-of-care.” Remote Patient Management (RPM) of individuals with implantable cardiac devices, defibrillators and pacemakers provides the solution for innovating “business as usual” approaches for cardiac devices. Broadly defined, RPM allows clinical data that is stored in a patient's implanted cardiac device to be monitored, evaluated and managed through a remote interface that transmits data through a network to health care providers for clinical review. Remote patient management enables the daily oversight of patients with heart arrhythmias, alerting providers to clinical abnormalities or device malfunctions. The capability and efficacy afforded by cardiac devices with RPM, specifically devices with wireless technology, has propelled the management of cardiac device patients to the next level and is redefining the standard of care for patients with implanted devices.

Cardiac Rhythm Management companies, such as St. Jude Medical, Boston Scientific, Medtronic, and Biotronik, have developed cutting-edge devices with remote capability. For nearly a decade, health care teams have employed devices with remote capability to provide demonstrable benefits to patients to prevent sudden cardiac death and address arrhythmias, both symptomatic and asymptomatic. Intuitively, affording care teams the ability to closely monitor clinical status both within an office setting and remotely, especially for conditions like atrial fibrillation which are often asymptomatic, provides a win-win for the patient and provider. Intuition and evidence have converged to substantiate remote patient management's clinical and administrative benefits. For example, the ALTITUDE study, which aimed to measure the long-term impact and outcome of patients with implantable cardioverter defibrillators and cardiac resynchronization therapy devices, reported that survival was significantly better if patients were transmitting device

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information to remote networks. Specifically, ALTITUDE found that “follow-up on the network was associated with a 50% relative reduction in the risk of death.<sup>IV</sup>” David Lee Scher, M.D., an RPM pioneer and former cardiac electrophysiologist, now of DLS Healthcare Consulting, LLC states, “It is hard to argue with both practical experience and clinical studies demonstrating that RPM results in improved health care efficiency, decreased costs, and improved patient outcomes. If you really want to manage the health status of this patient population, you can’t do it without remote patient management.”

### MODELS FOR FOLLOWING DEVICE PATIENTS

	Office Based Follow-up Only	Office + Remote Follow-up
Access to physicians for scheduled visits	X	X
Access to physicians for urgent visits	X	X
Quarterly device interrogation i.e., device data (battery life) diagnostic data, lead integrity	X	X
Ability to conduct quarterly device interrogations remotely		X
Daily transmission of device diagnostic data for the care team		X
“On demand” visibility of device status and diagnostic data for the care team		X
Transmission of diagnostic alerts to the care team in “real time”		X

## Remote Patient Management: Defining a New Standard

Longstanding practice for managing patients with implanted devices remains rooted in the traditional care model: one centered upon office visits. In this model, patients routinely require an in-clinic wound check shortly following device implant, followed by scheduled quarterly or semi-annual follow-ups. During these clinic visits, the device is “interrogated” (i.e., telemetry established between device and programmer for device integrity checks), which is then downloaded to each vendor’s proprietary medical device programmer. Because information is only downloaded during office visits, valuable and potentially

## DID YOU KNOW?

17	percent of U.S. health expenditures spent treating cardiovascular disease
39	average number of seconds between American deaths from cardiovascular disease
40.5	percent of U.S. population projected to have a form of cardiovascular disease by 2030
16,000	estimated shortage of cardiologists in the U.S. by 2050
325,000	Americans that die from sudden cardiac arrest each year
800,000	number of cardiac devices implanted in the U.S. each year
2,200,000	Americans with atrial fibrillation
3,600,000	number of office visits required to check implanted cardiac devices each year

life-saving information (both clinical and device function related) remains dormant in the device, invisible to the watchful eyes of an expert care team for upwards of ninety-one days. Colin Movsowitz, M.D. of the Cardiology Consultants of Philadelphia, P.C., highlights the inadequacy of the traditional model, one that provides only a static snapshot in time view of the patient’s health status. He notes that “actionable data is just sitting there [in the device], and there is little value in stored information that I cannot access.”

Contrary to the traditional, office-based model, devices with remote capability ensure consistent visibility as the device is capturing and transmitting data daily. If significant clinical abnormalities or any device system function concerns are detected, the care team will be notified. In the majority of cases where there are no urgent alerts, the devices are still interrogated quarterly, yet these interrogations occur remotely, reducing the need for patients to visit the office. While remote patient management does not eliminate the option of an in-office visit, reliance on in-person office visits is reduced. The remote capability delivers a strong value proposition for both the clinician and the patient. David Sandler, M.D., Director of Electrophysiology at Oklahoma Heart Institute notes that his remotely monitored patients “typically only come to the office once a year, yet I am watching them more closely, and providing personalized care constantly. The patient does not need to travel to the office to be hooked up to a machine to download information that my team could have viewed remotely. I feel that we are using staff time more efficiently, and patients are happier knowing that they can eliminate the inconvenience of office visits while increasing our ability to proactively monitor their clinical status.”

## The Differentiating Power of Wireless Technology for Cardiac Rhythm Management

Implantable cardiac devices with remote functionality provide unparalleled capability to provide daily oversight of patients. Many practitioners like Suneet Mittal, M.D., Director of the Electrophysiology Laboratory at The Valley Hospital Health System of New York and New Jersey, predominantly implant devices that are remote capable. He believes that “if a patient is going to get a device, there is no reason not to accept remote monitoring. Why wouldn’t a patient want their doctor to know what is going on?”

As Dr. Mittal notes, the patient’s best interest is advanced when their physician is fully informed. While remote management greatly improves upon the legacy standard of care, not all systems are created equal. Devices with remote capability can transmit data to a monitored network through either a patient-initiated data

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transmission or an automated, wireless process. In the patient-initiated model (referred to as inductive monitoring), each time the patient desires to remotely transmit data the patient must place a wand over the region of their chest where the device is located and then engage a monitor, typically placed in their bedroom, to transmit the data. In the automated model, devices with radio frequency wireless capability transmit the data to the monitor and ultimately the interrogated device network, usually while the patient is asleep. The benefit of wireless connectivity cannot be underestimated as it obviates the need for the patient to actively engage in the workflow of the transmission process. RPM systems requiring a higher threshold of patient adherence (i.e., inductive monitoring) still provide benefits, but patient compliance can be a substantial barrier in care provision and is a well-documented challenge for clinicians and patients alike. Poor patient compliance with medications, for example, is estimated to cause 89,000 premature deaths and \$100 billion in excess hospitalizations as more than half of Americans fail to comply with medication regimens. Remote patient management with wireless capability can help to avoid the type of compliance pitfalls witnessed with medication regimens by automating the data transmission process, thus minimizing the dependence and need for repetitive, patient activated transmissions.

### MAKING REMOTE PATIENT MANAGEMENT WORK FOR PATIENTS

	Patient Initiated (Inductive)	Wireless, Automated
Patient required to be within 15 feet of monitor to transmit data	X	X
Patient can be asleep while data is transmitted		X
Data can be transmitted wirelessly		X
Patient required to engage an external device (i.e., wand) each time they wish to capture data	X	
Patient required to engage a monitor each time they wish to transmit data	X	

Leading the way in this field has been St. Jude Medical, which is creating both product and process innovation to facilitate patient compliance for remote patient management. From a technology perspective, St. Jude Medical provides radio frequency wireless capability across its current portfolio of pacemaker, implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy (CRT) technologies from implant to follow-up. Additionally, St. Jude Medical technology allows the device and the home monitor to be paired at the point of care prior to discharge from the hospital. Pairing at the point of care – whether at implant, post-op, pre-discharge or in the clinic – allows the patient to immediately begin transmitting to the network. Without this capability, other device companies must mail transmitters to the patient, which creates a potential three to four week delay in initiation of monitoring. This delay reduces the likelihood that patients will comply with remote monitoring for a number of reasons, chief among them that they often “feel better” weeks later. St. Jude Medical’s innovative pairing process has improved patient compliance as physicians monitoring patients with St. Jude Medical devices are seeing high patient utilization with its remote monitoring network, the Merlin.net® Patient Care Network (PCN). St. Jude Medical’s effort to facilitate patient compliance is part of a complete care approach: a strategy seamlessly synchronizing data collection and data visibility through its cutting edge wireless devices, patient monitor transmitters, the Merlin.net PCN portal, and direct electronic health record (EHR) integration.

### REMOTE PATIENT MANAGEMENT TECHNOLOGY COMPARISON

<small>PM = PACEMAKER ICD = IMPLANTABLE CARDIOVERTER DEFIBRILLATOR</small>	Biotronik		Boston Scientific		Medtronic		St. Jude Medical	
	PM	ICD	PM	ICD	PM	ICD	PM	ICD
Diagnostic device follow-up	x	x	x	x	x	x	x	x
Wireless (RF) diagnostic device follow-up	x	x		x		x	x	x
Wireless (RF) at device implant				x		x	x	x
Pairing at point of care of device: home monitor							x	x
Alert notification for AT/AF burden threshold exceeded	x	x		x		x	x	x
Alert notification for V Rate during AT/AF threshold exceeded						x	x	x
Alert notification for AT/AF Episode threshold exceeded	x	x					x	x
Complete wireless device diagnostics with stored episodes		x		x		x	x	x

## Industry Implications

The clinical, administrative and patient-centric benefits of the remote technology are many. While a number of early adopters, both clinicians and patients, have enjoyed clinical and safety benefits afforded by RPM, it wasn’t until the 2007 recall of Medtronic’s Sprint Fidelis lead for its ICD that many realized the capabilities and value of remote patient monitoring, especially related to capturing device failures proactively. Recent studies have confirmed other benefits including the recognition that RPM is a safe alternative to traditional in-office models and that remotely monitored patients require fewer annual in-clinic and hospital visits compared to home monitoring with automatic daily surveillance (3.8 vs 2.1 respectively).<sup>V,VI</sup> Remote patient management of cardiac devices offers a safe, outcomes-based and scalable platform for the management of cardiac patients with implantable devices.

Clinicians and administrators alike can assess the implications of remote patient management for their organizations through the following lenses:

### The Intersection of Clinical Data and Timing

An important differentiator for devices with remote capability, specifically ones with radio frequency wireless technology, is the ability to deliver exacting data to clinicians and their team. This ability allows physicians to inform and diagnose with greater precision. Studies have documented that diagnostic errors occur in 17% of adverse events, often because of the potential number of unknowns attributed to a patient’s clinical status.<sup>VII</sup> Several trials and studies evaluating the impact of remote patient management, including CONNECT and TRUST<sup>VI,VIII</sup>, have demonstrated the power of remote patient management to inform timely, meaningful decisions. The CONNECT trial concluded that when compared to standard in-office follow-up, wireless remote monitoring with automatic clinician alerts reduced the time to a clinical decision from 22 days in the traditional in-office check to 4.6 days for remote monitoring. The TRUST study noted that physician alerts from devices consistently provide actionable data, classifying 62% of alerts as “meaningful” and 84% of alerts as “timed appropriately.” Conversely, for a routine in-office device check (the traditional standard of care), clinicians reported that “new and meaningful information” was only obtained for 24% of visits. Afib, the most widespread heart arrhythmia, can be particularly challenging to treat during infrequent office visits as 21% of newly diagnosed patients are asymptomatic.

### Managing Volume and Positioning for Growth

With over 800,000 pacemakers and implantable cardioverter defibrillators placed in the U.S. annually, in-clinic volume for device interrogations and patient follow-up requires over 3.6 million office visits, many of which could be managed remotely.<sup>IX</sup> RPM can help to manage existing volume while



also generating capacity to deal with the growing demand for treating cardiovascular disease.

Sanjay Deshpande, M.D., Medical Director of Electrophysiology at Columbia St. Mary's Hospital, Milwaukee, WI, adopted remote patient management in its infancy in 2002. He noticed that practice patterns began to change, volumes were increasing, and as he looked to the not-so-distant future, he could see the "crowd building outside his door." His outreach clinic was growing in leaps and bounds, and the traditional in-office model would not provide the scalability to manage the growing need for his services. He states that "the math was pretty obvious that there were a growing number of patients and implants, and we were not going to have room in our clinics from an efficiency perspective." He believes that the "longer people resist the movement to remote monitoring, they risk the same fate as dinosaurs because there is no way traditional delivery models will support an efficient device clinic today." This is compounded by estimates that the current number of cardiologists would need to double by 2050 to erase the expected shortage of 16,000 cardiologists.<sup>x</sup> Practices and payers alike need strategies to achieve efficiency while remaining vigilant to health status improvements. Local Medicare contractors and many private payers provide coverage for remote device monitoring.

#### Event-Driven Care

Remote patient management provides the capability to deliver an event-driven care model rather than a one-size-fits-all approach. Dr. Movsowitz believes that the business-as-usual value proposition driven by in-office, quarterly device checks is outmoded. As the TRUST study reported, 90% of scheduled remote monitoring checks required no action or in-person visit. Since a minority of monitored patients need to be seen in the office, "the device should tell you when to come for a visit... remote patient monitoring ends the 'well baby visit,' a notion

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gaining importance in a changing payment marketplace." What Dr. Movsowitz references as the "well baby visit" is the needless requirement that asymptomatic patients, who are being actively monitored, visit the office. In this way, RPM accomplishes two objectives: it ensures that monitored patients are evaluated daily for their health status, while simultaneously allowing physicians to focus on patients in the office who need hands-on care.

#### Practice Impact

Managing patients with remote devices and responding to clinical alerts raises concerns about the impact that a constant stream of data may have on a practice. Concerns about disrupted workflow, and 3 AM emergency calls arise. However, as experienced electrophysiologists note, physicians can create algorithms to manage the alerts, defining which events require immediate action and which can be addressed on a less acute timetable. Scott Adelman, M.D., an invasive cardiologist with Kaiser Permanente who oversees Kaiser's Northern California technology integration, quells concerns about what some may consider the "invasive" nature of RPM on practices. He notes that the devices are "completely configurable, and in some ways make practices easier. If patients with implantable devices are not managed remotely, I would have to see them all in the office. With remote monitoring, I can look at a dashboard in the morning and receive immediate feedback based on who meets alert guidelines."

Additionally, concerns about daily 3AM calls are overblown. He states that "the 3AM alerts are the exception, not the rule. Many of the arguments [against RPM] are fear arguments, and people are not trying to make technology work for them."



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### EHR Integration

Follow the money. More than \$30 billion in EHR incentives have been put forth by the federal government to drive EHR adoption. These incentives are indicative of what administrators of integrated networks already know, policy makers want, and physicians desire at the point of care: a truly connected digital health care ecosystem. The power of embedded clinical information through EHR integration will enable improved decision making and diagnoses. As Dr. Movsowitz notes, “I need information about remote monitoring in context of the chart: when was the last visit, what medications were prescribed, what is the patient’s history?” Organizations like St. Jude Medical provide direct integration of RPM data with market leading EHR vendors such as GE, Epic, Allscripts, NextGen, ScottCare and GEMMS.

### The Business Imperative

The prevalence of cardiovascular disease presents both challenges and opportunities. The constant pressure to enhance throughput, drive efficiency, improve operating margins, and deliver better outcomes is a daunting task. Dave Donnelly, CEO at CardioVascular Group, PC, a sixteen-physician practice based in the Greater Atlanta region (with four physicians that implant devices, two of which are electrophysiologists), has first-hand knowledge of the challenges in managing growth. His group implanted over 1,500 devices in a recent two-year period, and during that time, migrated many of the patients to remote monitoring via the St. Jude Medical Merlin.net PCN and subsequently integrated that data into their EHR. Efficiency is critical in Mr. Donnelly’s mind. He notes, “Anything we can do to open and relax the rate limiters and improve throughput is key. Even if we don’t view volume and throughput as a crisis today, it will be a crisis in the near future.” The CardioVascular Group

views remote patient management as a strategic differentiator for the practice because the remote connection helps them enhance the patient experience, providing the security of constant clinical oversight. While implementing remote patient management is not simply plug and play, Mr. Donnelly notes that it is “one of the rare opportunities for relatively low effort/expense and high returns, especially in a health care economy challenged by costs, but poised for growth.”

## Final Thoughts

Remote patient management is a proven strategy that enables the management of implantable cardiac devices by providing a solution that is patient-centric, consumption-sensitive, and one that contributes to health status improvement. As patients become more “connected” and as care becomes increasingly less centralized, remote management of patients with cardiac devices delivers today on the promise of a true health information ecosystem: one that promotes continuity of care and population health management.

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**Brief Summary:** Prior to using these devices, please review the instructions for use for a complete listing of indications, contradictions, warnings, precautions, potential adverse events and directions for use.

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