Escuela de
Ingeniería y Arquitectura
Universidad Zaragoza

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Programa Oficial de Postgrado en Ingenierias
Transversales
Master de Ingenieria Biomedica

Merlin.net Patient Care Network

Cardiac Device Remote Care System

September 2010 – February 2011

Masters Final Project - Curso 2010-2011
September 2011

Author: Elie Elia Abou Jaoude
Director: Pablo Laguna Lasaosa

Acknowledgments

First of all, I would like to thank St. Jude Medical for the opportunity they offered me to be part of the company for six months and their warm welcome.

I would also like to thank my internship supervisor, Professor Pablo Laguna Lasaosa, for his kind attention, his advice and availability.

And last but not least, all my thankfulness to the St. Jude Medical CRM team, and all the back-up teams for their help in making this project a success.

Thank you all,

RESUMEN:

El crecimiento de la población vieja aumenta la presión sobre los sistemas de salud tradicionales que sufren de un aumento de los costos y la disminución de los recursos materiales y humanos.

La telemedicina aplicada a dispositivos cardíacos nos permite la monitorización remota del estado clínico de los pacientes con insuficiencia cardiaca, y allane el camino a un enfoque amplio y multidisciplinario de gestión de la enfermedad, que ofrece ventajas tanto en términos de resultados clínicos y de ahorro económico. A través de los últimos años, la telemedicina ha demostrado tener el potencial para mejorar la seguridad de los pacientes con respecto a los acontecimientos espontáneos clínicos y eventos relacionados con el dispositivo implantado.

El objetivo principal del proyecto es la implementación de la solución de Telecardiología en los hospitales franceses. Este objetivo envuelve una amplia serie de misiones y funciones a partir de la comprensión técnica del sistema y pasando por la tareas de soporte técnico de formación y de marketing.

La gestión de un proyecto de Telecardiología comienza con un conocimiento general pero esencial de las arritmias cardíacas, y los dispositivos proveídos por la empresa en términos de desfibriladores y marcapasos, lo que me permite entender los aspectos médicos del sistema que estamos presentando a los hospitales.

Una vez que la patología clínica y los aspectos de su tratamiento se aclararon, entré en los detalles del dispositivo de Telecardiología y sus parámetros; más concretamente, los datos transmitidos por internet, y el análisis y la comprensión de estas transmisiones. Esta parte fue seguida directamente por una auto-formación sobre los aspectos técnicos del sistema: la comunicación por radiofrecuencia, los circuitos, la transmisión por red celular, la base de datos y el servidor web.

Este período de formación técnica no se ha definido realmente en el tiempo, sabiendo que la parte de práctica se inició desde el primer día con el apoyo técnico y los casos reales. Mi misión consistió en el despliegue del sistema, con todos los aspectos complementares que incluyen la inauguración de nuevos centros, el apoyo técnico para los pacientes, médicos, profesionales de la salud y representantes de ventas. Otros aspectos de mi proyecto, como documentos de marketing, capacitación de personal y redacción de procedimientos también serán cotizados y detallados con otros aspectos complementarios, incluidos los aspectos reglamentarios y legales de la telemedicina.

SUMMARY:

The growth of the aging population increases the pressure on traditional healthcare systems that suffer from increased costs and diminishing resources. Remote care as it is today is revolutionizing the cardiac implantable devices' monitoring methods, by shifting from device-centered safety follow-up, to patient centered solutions and individualized patient care, in order to improve alert management, and patient heart condition monitoring. The cardiac prosthesis communicates with the transmitter installed at the patient's home. The transmitter uses the telecommunications network, to transmit cardiac, device data and parameters to the server.

The main objective of this project is the implementation of St. Jude medical's remote care solution in the French hospitals. This objective covers a wide series of missions and starting from the technical understanding of the system and going through the different marketing, regulatory and technical support tasks.

Once the clinical pathology and the treatment aspects are clarified, the project goes through the details of the device follow-up and parameters and more specifically, the data transmitted on the server and the analysis and comprehension of the technical aspects of the system: the RF communication, the circuits, the cellular transmission and the web server.

My mission consisted on the system's deployment, with all the aspects complementing this phase, including the opening of new centers, personnel training, technical support for patients, doctors, healthcare professionals and sales representatives. Other aspects of my project, like marketing documents, personnel training and procedures redaction will also be listed and detailed with other complementary facets, including regulatory and legal aspects.

Contents

Introduction

The growth of the aging population increases the pressure on traditional healthcare systems that suffer from increased costs and diminishing resources. Recent advances in biosensor and communications technologies enable the design of advanced and cost-effective Telehealth monitoring solutions that promise to improve the level of care and quality of life for patients, and to expedite the shift in healthcare delivery from hospitals to the community.

Although different definitions may be found for Telemedicine and Telehealth, and while the differences between them are a source of constant debate, the definition commonly accepted as I see it is that "Telemedicine is the delivery of healthcare services, where distance is a critical factor, using information and communication technologies for the exchange of information for diagnosis, treatment and prevention of disease".

Remote care as it is today is revolutionizing the implantable device monitoring methods, by shifting from device-centered safety follow-up, to perspectives centered on individualized patient care, in order to improve alert management, and patient heart condition monitoring.

This shift enabled the remote monitoring of the clinical condition for heart failure patients, and paved the way to a broad, multidisciplinary approach of disease management, offering advantages both in terms of clinical outcome and economic savings. Through the last years, remote monitoring has proved to have the potential to improve patients' safety regarding both spontaneous clinical events and device-related events.

This medical revolution is at the same time a technical and engineering challenge that goes from the elaboration and design of the system to the implementation of the remote care solution in the medical centers and the patients' home.

Chapter 1 : The Context

I - The Company

St. Jude Medical develops medical technology and services that focus on putting more control into the hands of those who treat cardiac, neurological and chronic pain patients worldwide. The company is dedicated to advancing the practice of medicine by reducing risk wherever possible, and contributing to successful outcomes for every patient. St. Jude Medical is headquartered in St. Paul, Minnesota and has four major focus areas that include: cardiac rhythm management, atrial fibrillation, cardiovascular and neuromodulation.

The St. Jude Medical product portfolio includes implantable cardioverter defibrillators (ICDs), cardiac resynchronization therapy (CRT) devices, pacemakers, electrophysiology catheters, mapping and visualization systems, vascular closure devices, heart valve replacement and repair products, spinal cord stimulation and deep brain stimulation devices.

St. Jude Medical develops and manufactures the following types of products:

- Cardiac resynchronization therapy devices for heart failure
- Artificial pacemakers and implantable cardioverter defibrillators (ICDs) for treating cardiac rhythm disorders
- Diagnostic and therapeutic electrophysiology catheters
- Introducers, catheters, and vascular closure devices for cardiology and vascular access
- Mechanical and tissue heart valves plus valve repair products
- Spinal cord stimulators for intractable pain

Company Facts

Headquarters	St. Paul, Minnesota, USA
Stock Exchange	New York Stock Exchange (NYSE) under STJ symbol
Founded	1976 in St. Paul, Minnesota
2009 Net Sales	$4.681 billion
Employees	More than 14,000 worldwide
Global Reach	Products sold in more than 100 countries

Highlights

St. Jude Medical is committed to continuous innovation and growth in its people, product portfolios and clinical research programs. The company sees growth opportunities in each of its technology platforms:

Atrial Fibrillation

St. Jude Medical is a pioneer and leader in the AF market, which is estimated to be about $2 billion. The company offers the industry's broadest product portfolio for the EP lab, aiding physicians in the diagnosis and treatment of cardiac arrhythmias. Their sponsorship of IRASE AF, which could lead to an AF indication for an ablation catheter, and CABANA are reflective of the company's commitment to advancing the management of AF through important clinical research.

Cardiac Rhythm Management

The worldwide CRM market was approximately $11 billion in 2010. The St. Jude Medical CRM business launched several new devices in 2010 including RF pacemakers, an ST segment monitoring ICD. The company will begin clinical trials on a number of new technologies in 2011, including a left atrial pressure monitor, an MRI-compatible pacemaker and a quadripolar pacing system.

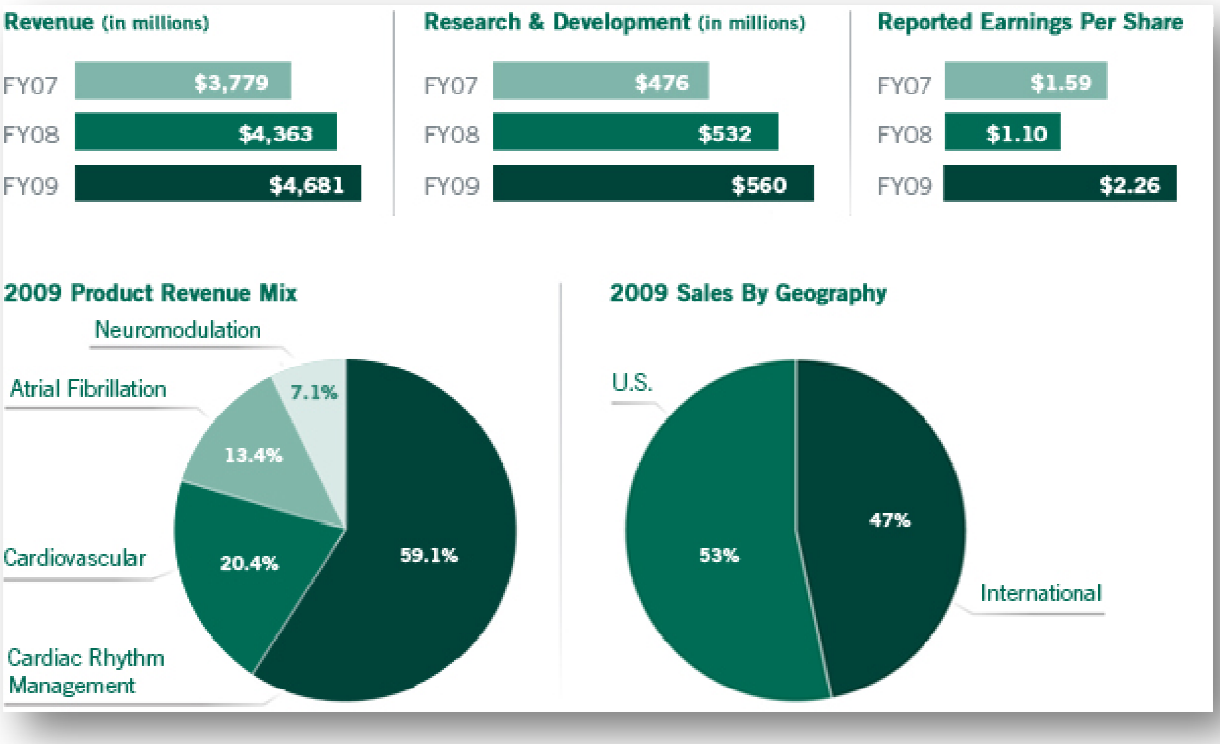
Neuromodulation

St. Jude Medical participates in the $1 billion spinal cord stimulator market and the $360 million deep brain stimulation (DBS) market. The company launched its first DBS system in Europe during 2009, and has the smallest, longest lasting spinal cord stimulator on the market. The company also has clinical research programs focused on potential indications for depression, Parkinson's disease and numerous other disease states.

Cardiovascular

St. Jude Medical participates in segments of the interventional cardiology and cardiac surgery markets totaling approximately $2.5 billion. We have strong franchises in FFR (Fractional Flow Reserve) measurement systems, vascular closure and heart valve repair, and with the launch of Trifecta™ and Roll-x™ they entered the markets for pericardial stented tissue valves and coronary guide wires during the second in 2010.

Performance and Progress

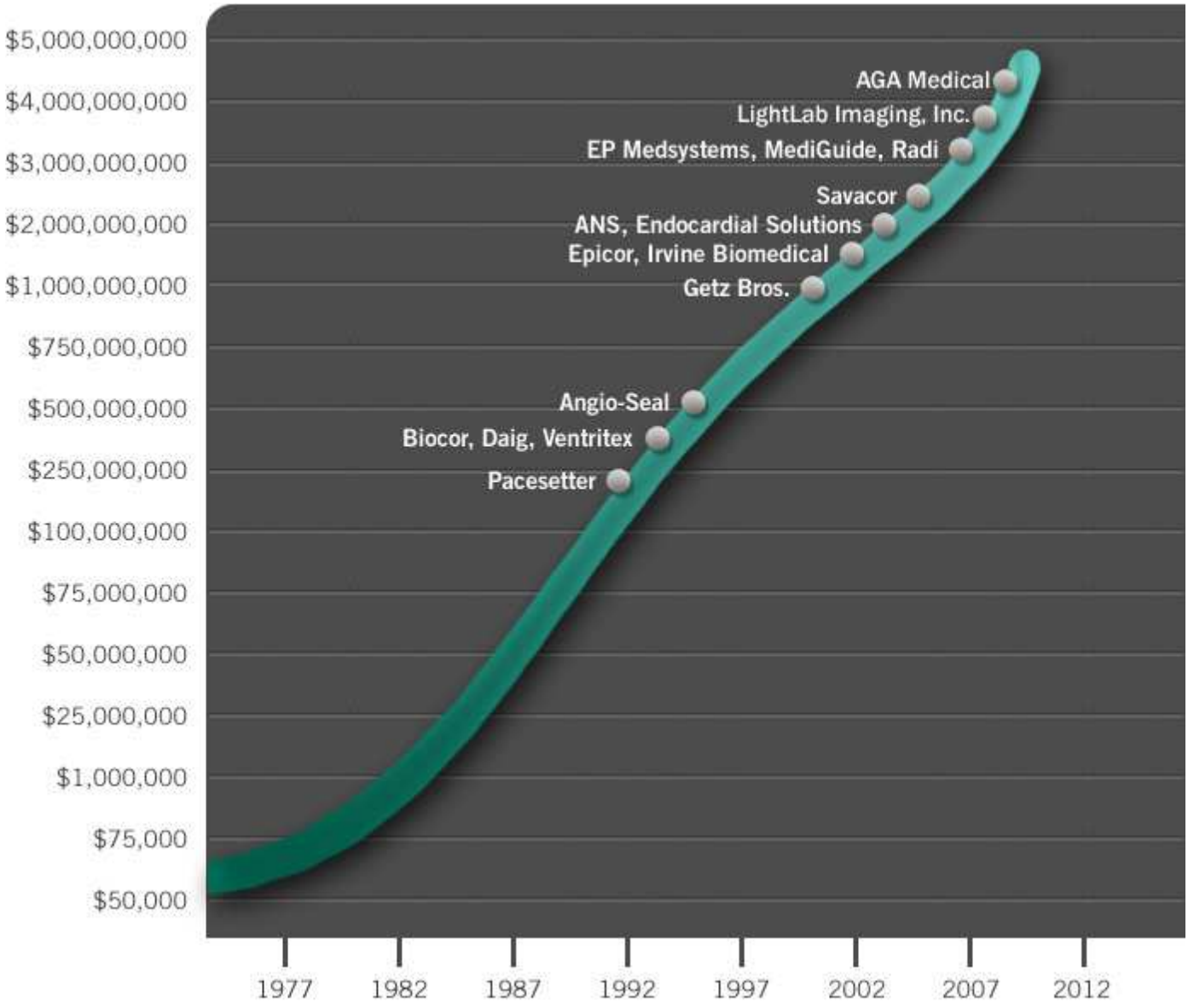


History of St. Jude Medical

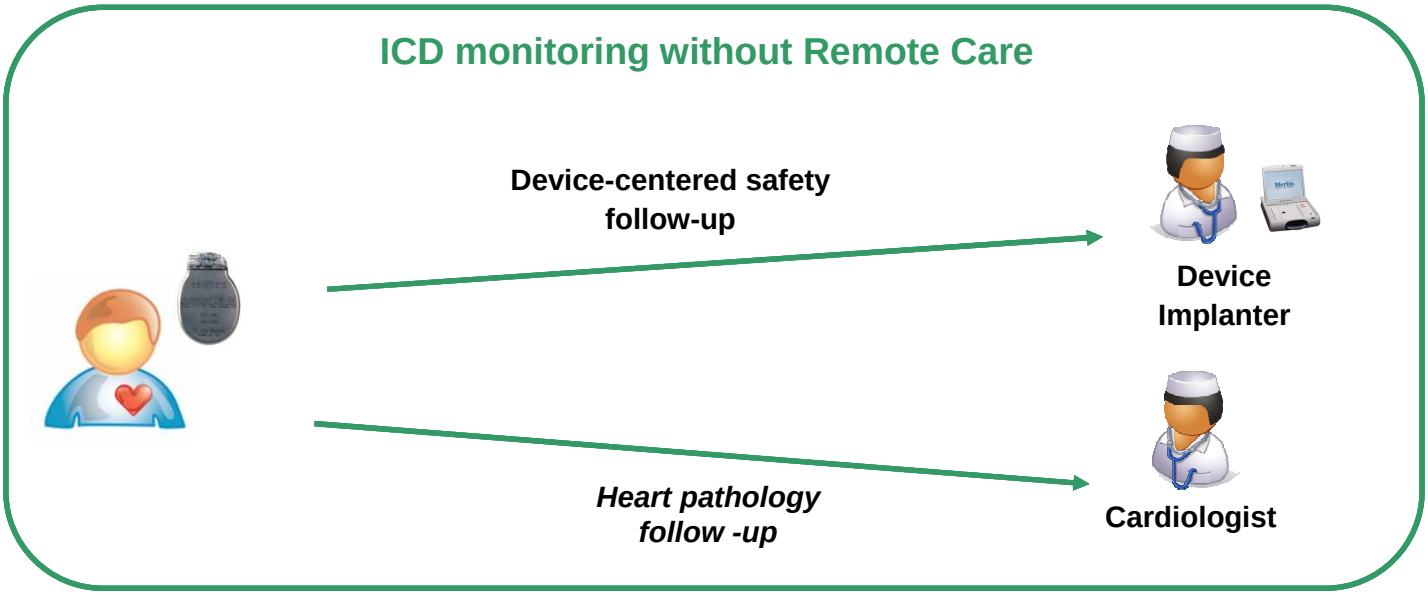
St. Jude Medical was founded in 1976 in St. Paul, Minnesota, as a pioneering manufacturer of bi-leaflet implantable mechanical heart valves. The company's innovative heart valve design soon became the "gold standard" for mechanical heart valves.

The company's founder, Manuel Villefana, named the company St. Jude Medical after the patron saint of hopeless causes, as a gesture of gratitude after praying to the saint to help his son (also named Jude) survive a life-threatening heart condition.

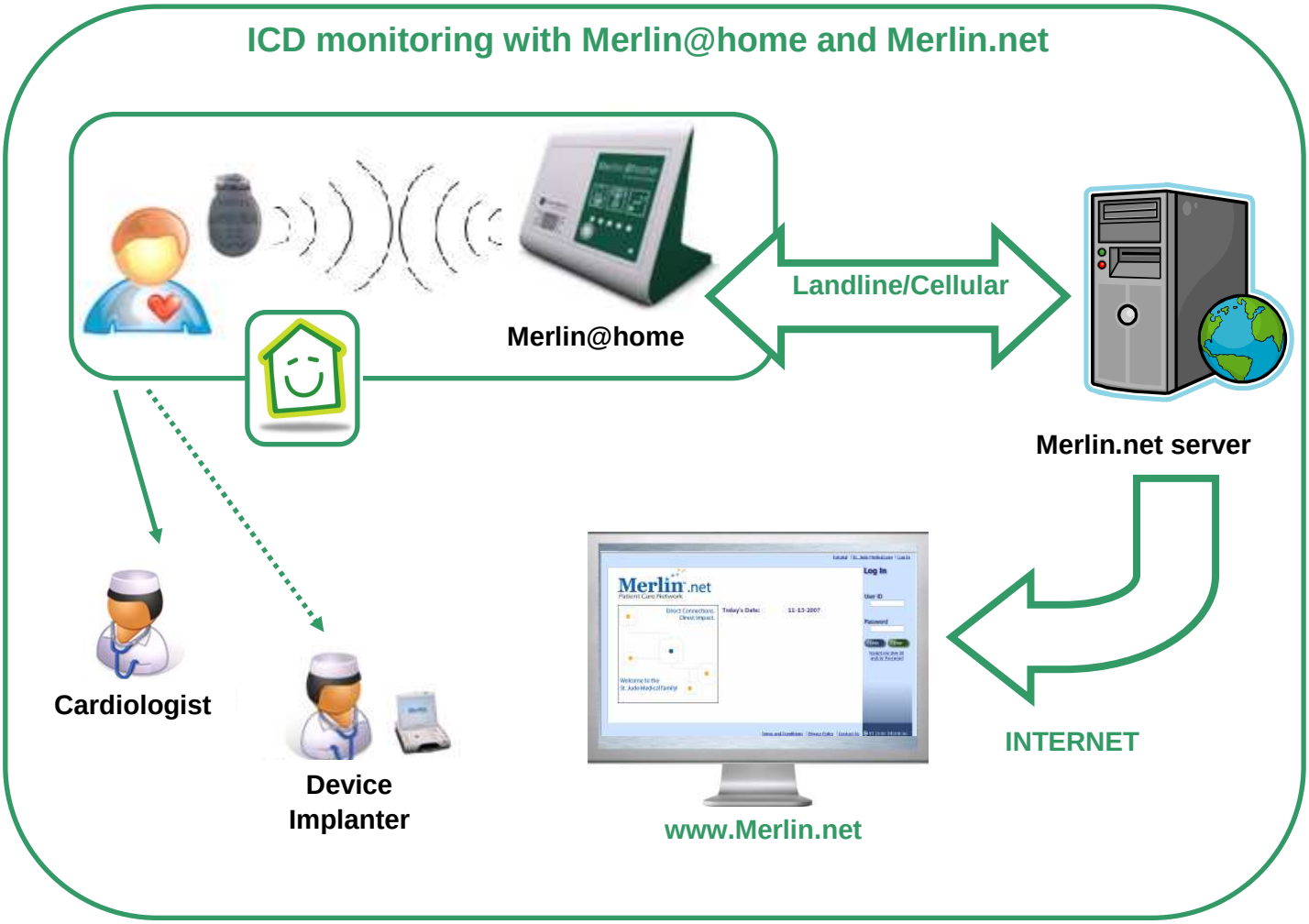
Since the company's first major acquisition of Pacesetter in 1994, St. Jude Medical has continued to grow into a global leader in cardiac and neurological device technology, broadening its product portfolio through internal development and strategic acquisitions.



II - What is Remote Care?



The conventional approach to cardiac implantable device follow-up involves patients attending regularly scheduled in-clinic visits to verify the functionality and safety of the implanted devices: During these visits the device is checked using a "programmer" that can communicate with the device and allows a health care professional to evaluate the system's integrity, cardiac parameters and determine the device settings. At the same time the patient is still followed-up by his cardiologist for his pathology's monitoring. Device follow-up visits vary from every three months to every year according to the facility, the physician's preferences and the resources' availability. Usually, no examination occurs between follow-up visits.



With Merlin.net system, the cardiac prosthesis communicates with the Merlin@home transmitter installed at the patient's home. The transmitter uses the telecommunications network (landline or cellular), to transmit both cardiac and device data and parameters to the Merlin.net server. The clinicians can schedule follow-ups on Merlin.net to monitor their patients, and for these patients they also receive the different kinds of alerts generated by the implantable device. This system allows continuous monitoring of implanted patients and minimizes their periodic monitoring visits.

The patient continues to visit both the device implanter and the cardiologist for follow-ups but meanwhile his heart condition and his device are monitored on a daily basis using the alert notifications, and the conventional follow-ups can be replaced by remote follow-ups which are proven to be as effective and accurate.

III - Mission and Objectives:

The main objective of this project is the **implementation** of the remote care solution in new hospitals. This objective covers a wide series of missions and duties starting from the technical understanding of the system and going through the different marketing, regulatory and technical support tasks.

Being able to manage a project in cardiac remote care starts with a general yet essential knowledge of the cardiac arrhythmias, and the products offered by the company in terms of defibrillation and pacing, allowing me to better understand the medical aspects of the system that we are proposing to the hospitals.

Once the clinical pathology and the treatment aspects were clarified, I went into the details of the device follow-up and parameters and more specifically, the data transmitted on Merlin.net and the analysis and comprehension of these transmissions. This part was directly followed by an auto-training on the technical aspects of the system: the RF communication, the circuits, the cellular transmission and the web server.

This technical training period wasn't really defined in time, knowing that the practical part started since the first day with basic technical support and real cases. My mission consisted on the system's deployment, with all the aspects complementing this deployment including the opening of new centers, technical support for patients, doctors, healthcare professionals and sales representatives. Other aspects of my project, like marketing documents, personnel training and procedures redaction will also be listed and detailed with other complementary facets, including regulatory and legal aspects.

For my project to succeed I had to synchronize between these different factors and prioritize the fundamental and vital objectives. In my mission, I always had to keep in mind that the main priority of this entire field and offstage work was to fulfill one goal:

The patient's well-being and the medical team's satisfaction.

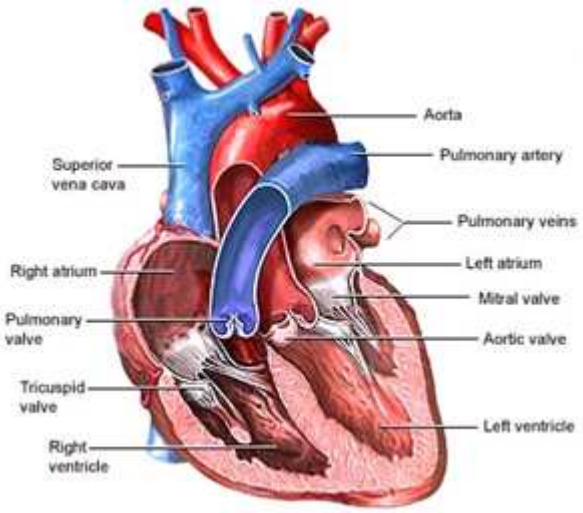
Chapter 2 : Cardiac Rhythm Management

In order to explain the remote care environment, a basic understanding of the heart functioning, pathologies and cardiac solutions, is necessary. In this chapter I will briefly explain all about the arrhythmias we monitor through our system.

I - The Heart: Briefly

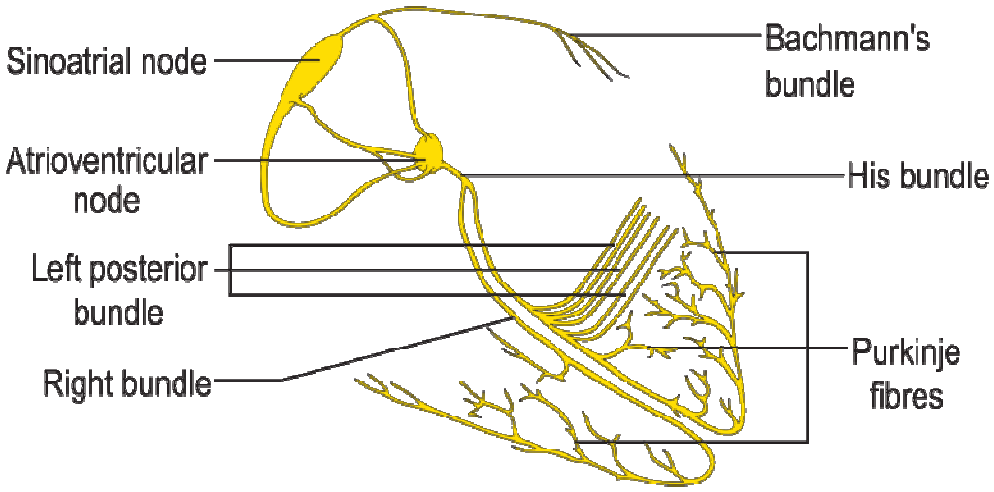
The heart is a myogenic muscular organ that is responsible for pumping blood throughout the blood vessels by repeated, rhythmic contractions.

Starting in the right atrium, the blood flows through the tricuspid valve to the right ventricle. Here, it is pumped through the pulmonary semi lunar valve and travels through the pulmonary artery to the lungs. From there, oxygenated blood flows back through the pulmonary vein to the left atrium. It then travels through the mitral valve to the left ventricle, from where it is pumped through the aortic semi lunar valve to the aorta. The aorta forks and the blood are divided between major arteries which supply the upper and lower body. The blood travels in the arteries to the smaller arterioles and then, finally, to the tiny capillaries which feed each cell. The (relatively) deoxygenated blood then travels to the venules, which coalesce into veins, then to the inferior and superior vena cava and finally back to the right atrium where the process began.



2.1 The Heart's anatomy

The heart is effectively a syncytium, a meshwork of cardiac muscle cells interconnected by contiguous cytoplasmic bridges. This relates to electrical stimulation of one cell spreading to neighboring cells.



2.1 The Heart's conduction system

Signals arising in the SA node (and propagating to the left atrium via Bachmann's bundle) stimulates the atria to contract. In parallel, action potentials travel to the AV node via internodal pathways. After a delay, the stimulus is conducted through the bundle of His to the bundle branches and then to the Purkinje fibers and the endocardium at the apex of the heart, then finally to the ventricular myocardium.

Microscopically, the wave of depolarization propagates to adjacent cells via gap junctions located on the intercalated disk. In a functional syncytium, electrical impulses propagate freely between cells in every direction, so that the myocardium functions as a single contractile unit. This property allows rapid, synchronous depolarization of the myocardium.

While normally advantageous, this property can be detrimental as it potentially allows the propagation of incorrect electrical signals. These gap junctions can close to isolate damaged or dying tissue, as in a myocardial infarction.

II - Arrhythmias and Solutions

Arrhythmia is a term for any of a large and heterogeneous group of conditions in which there is abnormal electrical activity in the heart. The heart beat may be too fast or too slow, and may be regular or irregular.

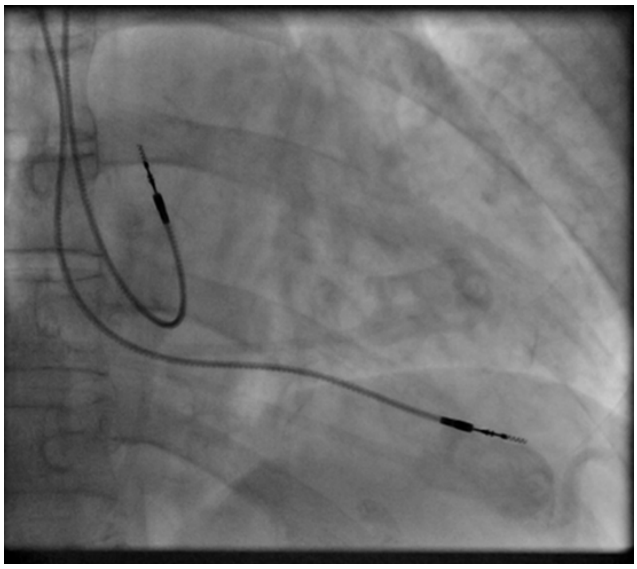
Some arrhythmias are life-threatening medical emergencies that can result in cardiac arrest and sudden death. Other arrhytmias cause symptoms such as an abnormal awareness of heart beat (palpitations), and may be merely annoying. These palpitations have also been known to be caused by atrial/ventricular fibrillation, wire faults, and other technical or mechanical issues in cardiac pacemakers/defibrillators. Still others may not be associated with any symptoms at all, but may predispose the patient to potentially life threatening stroke or embolism.

a) Bradycardias and Pacemakers

Bradycardia is a slow cardiac rhythm, (less than 60 beats/min). This may be caused by a slowed signal from the sinus node (termed sinus bradycardia), a pause in the normal activity of the sinus node (termed sinus arrest), or by blocking of the electrical impulse on its way from the atria to the ventricles (termed AV block or heart block). Heart block comes in varying degrees and severity. It may be caused by reversible poisoning of the AV node (with drugs that impair conduction) or by irreversible damage to the node. Bradycardias may also be present in the normally functioning heart of endurance athletes or other well conditioned persons.

A **Pacemaker** is a medical device which uses electrical impulses, delivered by electrodes contacting the heart muscles, to regulate the beating of the heart. The primary purpose of a pacemaker is to maintain an adequate heart rate, either because the heart's native pacemaker is not fast enough, or there is a block in the heart's electrical conduction system. Modern pacemakers are externally programmable and allow the cardiologist to select the optimum pacing modes for individual patients.

Permanent pacing with an implantable pacemaker involves transvenous placement of one or more pacing electrodes within a chamber, or chambers, of the heart. The procedure is performed by incision of a suitable vein into which the electrode lead is inserted and passed along the vein, through the valve of the heart, until positioned in the chamber. The procedure is facilitated by fluoroscopy which enables the physician or cardiologist to view the passage of the electrode lead. After satisfactory lodgment of the electrode is confirmed the distal end of the electrode lead is connected to the pacemaker generator.

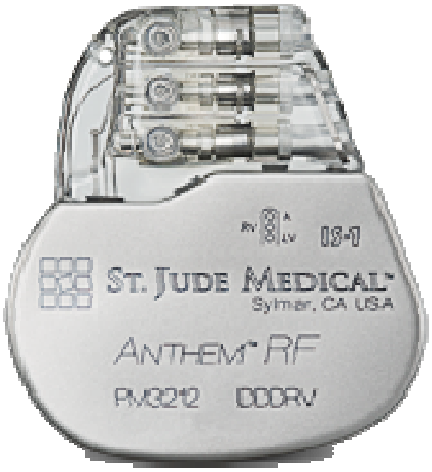


2.3 Right atrial and right ventricular leads as visualized under x-ray during a pacemaker implant procedure. The atrial lead is the curved one making a U shape in the upper left part of the figure.

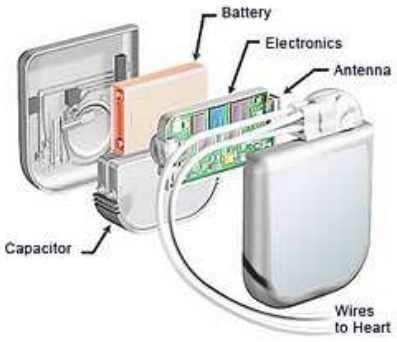
There are three basic types of permanent pacemakers, classified according to the number of chambers involved and their basic operating mechanism

Single-chamber pacemaker: In this type, only one pacing lead is placed into a chamber of the heart, either the atrium or the ventricle.

Dual-chamber pacemaker: Here, wires are placed in two chambers of the heart. One lead paces the atrium while the other paces the ventricle. This type is more similar to the natural pacing of the heart. It assists the heart in coordinating the function between the atria and the ventricles.



Rate-responsive pacemaker: This pacemaker has sensors that detect changes in the patient's physical activity and automatically adjust the pacing rate to fulfill the body's metabolic needs.



The pacemaker generator is a hermetically sealed device containing a power source, usually a lithium battery, a sensing amplifier which processes the electrical manifestation of naturally occurring heart beats as sensed by the heart electrodes, the computer logic for the pacemaker and the output circuitry which delivers the pacing impulse to the electrodes.

Most commonly, the pacemaker is placed below the subcutaneous fat of the chest wall, above the muscles and bones of the chest. However, the placement may vary on a case by case basis.

b) Tachycardia, Fibrillation and Defibrillators

Tachycardia, in adults and children over 15, is a resting heart rate faster than 100 beats/minute. It usually results from the addition of abnormal impulses to the normal cardiac cycle. Abnormal impulses can begin by one of three mechanisms: automaticity, reentry or triggered activity. A specialized form of re-entry problem is termed fibrillation.

Fibrillation is when an entire chamber of the heart is involved in a multiple micro-reentry circuits, and therefore quivering with chaotic electrical impulses. It can affect the atrium (atrial fibrillation) or the ventricle (ventricular fibrillation); ventricular fibrillation is imminently life-threatening.

Atrial fibrillation affects the upper chambers of the heart, known as the atria. Atrial fibrillation may be due to serious underlying medical conditions, and should be evaluated by a physician. It is not typically a medical emergency.

Ventricular fibrillation occurs in the ventricles (lower chambers) of the heart; it is always a medical emergency. If left untreated, ventricular fibrillation (VF, or V-fib) can lead to death within minutes. When a heart goes into V-fib, effective pumping of the blood stops. V-fib is considered a form of cardiac arrest, and an individual suffering from it will not survive unless cardiopulmonary resuscitation (CPR) and defibrillation are provided immediately.

Defibrillation is performed by applying an electric shock to the heart, which resets the cells, permitting a normal beat to re-establish itself. For patients that are considered at risk of sudden cardiac death due to ventricular fibrillation and ventricular tachycardia, an implantable cardioverter-defibrillator (ICD) is advised.

Implantable cardioverter-defibrillator (**ICD**) is a small battery-powered electrical impulse generator which is implanted in patients who are at risk of sudden cardiac death due to ventricular fibrillation and ventricular tachycardia. The device is programmed to detect cardiac arrhythmia and correct it by delivering a jolt of electricity. In current variants, the ability to revert ventricular fibrillation has been extended to include both atrial and ventricular arrhythmias as well as the ability to perform biventricular pacing in patients with congestive heart failure or bradycardia.

ICDs constantly monitor the rate and rhythm of the heart and can deliver High Voltage therapies, by way of an electrical shock, when the electrical manifestation of the heart activity exceeds the preset number. More modern ICDs at St-Jude Medical can distinguish between ventricular fibrillation and ventricular tachycardia (VT), and may try to pace the heart faster than its intrinsic rate in the case of VT, to try to break the tachycardia before it progresses to ventricular fibrillation. This is known as fast-pacing, overdrive pacing, or anti-tachycardia pacing (ATP). ATP is only effective if the underlying rhythm is ventricular tachycardia, and is never effective if the rhythm is ventricular fibrillation.

2.4 The Unify™ CRT-D and Fortify™ ICD can deliver 40J, the highest energy of any ICD available today

Chapter 3 : Check-up and Remote Monitoring

Once the device is implanted, it is periodically checked to ensure the device is operational and performing appropriately. Depending on the frequency set by the following physician, the device can be checked as often as necessary. Routine device checks are typically done in-office every six months, though will vary depending upon patient/device status.

Historically, this has been done via scheduled clinic appointments. Current technology allows doing it by remote monitoring (RM). 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.

I will try to explain the use and advantages of remote monitoring through facts and examples and then develop the technical aspects of our technology.

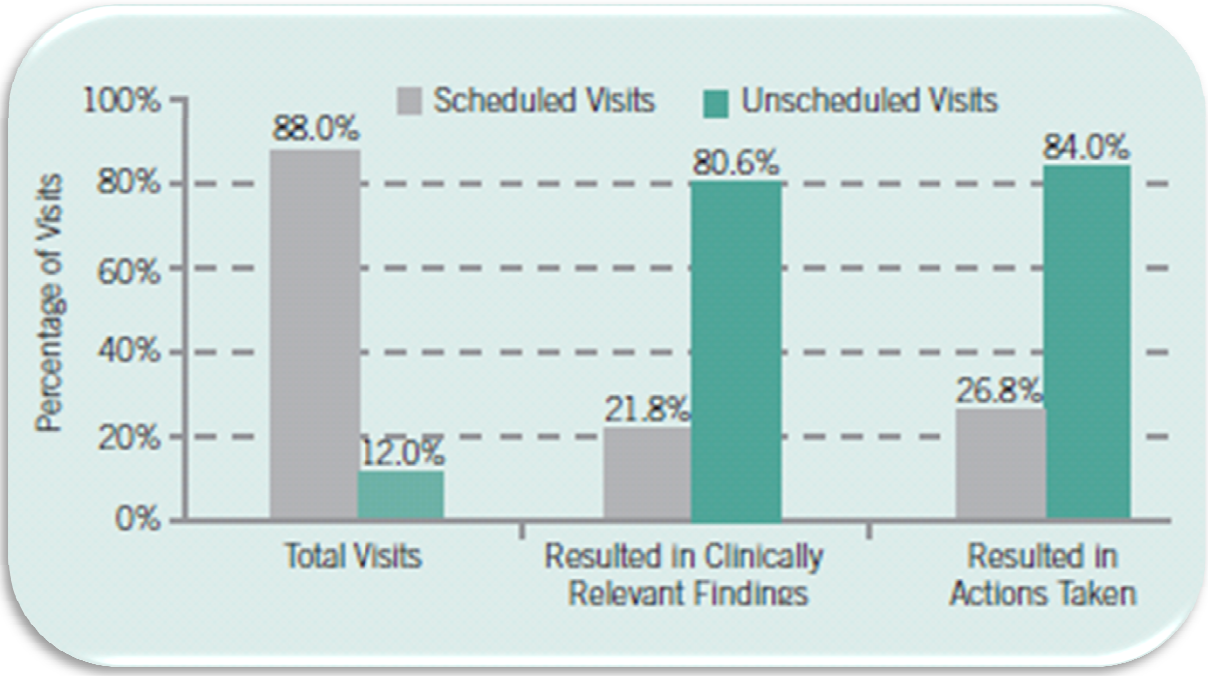
I - Remote Monitoring Advantages

a) Patient Safety

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: 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.

Current standards recommend clinic visits every 3 to 6 months, with increased frequency as the implanted device ages: this 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. 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.

Scheduled visits are insufficient and often unproductive. Actionable problems that occur are rarely found during routine follow-up.



3.1 Value of Scheduled Visits versus Unscheduled Visits
[Source: Heidbüchel et al. (2008) N=1,739]

b) Event Detection and Patient Treatment

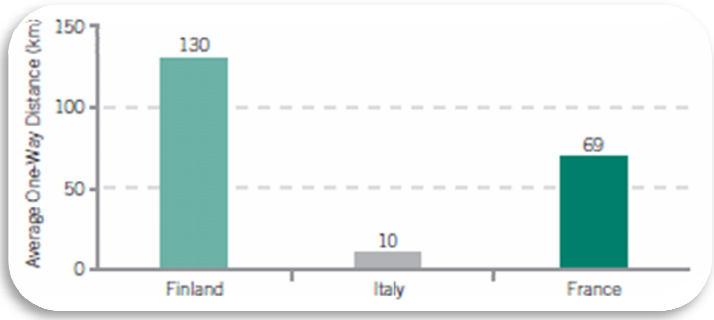
Remote monitoring is an effective tool for evaluating patient status: It enhances patient safety by allowing medical staff to identify and treat problems early and provide individualized optimal care. RM results in the earlier detection of many conditions; it specially allows asymptomatic and minimally symptomatic conditions to be detected significantly earlier. In several recent studies, medical staffs were able to catch device issues earlier with RM than with routine visits and physicians were able to design more individualized therapy.

Researchers have established that most of the problems caught during clinic visits would have been found by RM and a research team found that RM would have been just as effective as a clinic visit in 94% of 1,739 evaluated cases

c) Efficiency and Costs

RM allows physicians to evaluate patient data in less time than conducting in-person clinic visits. It takes less time to evaluate data from remote transmissions than it does during standard visits. Alternate organizational systems allow qualified nurses or software systems to sift through data and bring only important information to the attention of the doctors. In addition to reducing clinician and staff time, RM can also decrease expenses to patients and healthcare providers in terms of clinic face to face visits, and transportation.

There is 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. Remote monitoring resulted in considerable cost savings for patients, by eliminating the costs associated with traveling to the clinic, lost work time, and visit co-pays.

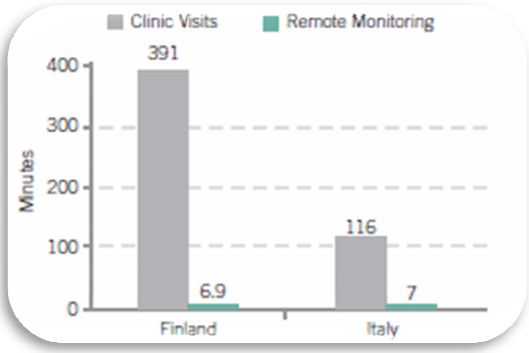


3.2 Average Travel Distance Required per Clinic Visit for Study Participants

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

3.3 Average Time Required, Including Travel, per Follow-up for Study Participants

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



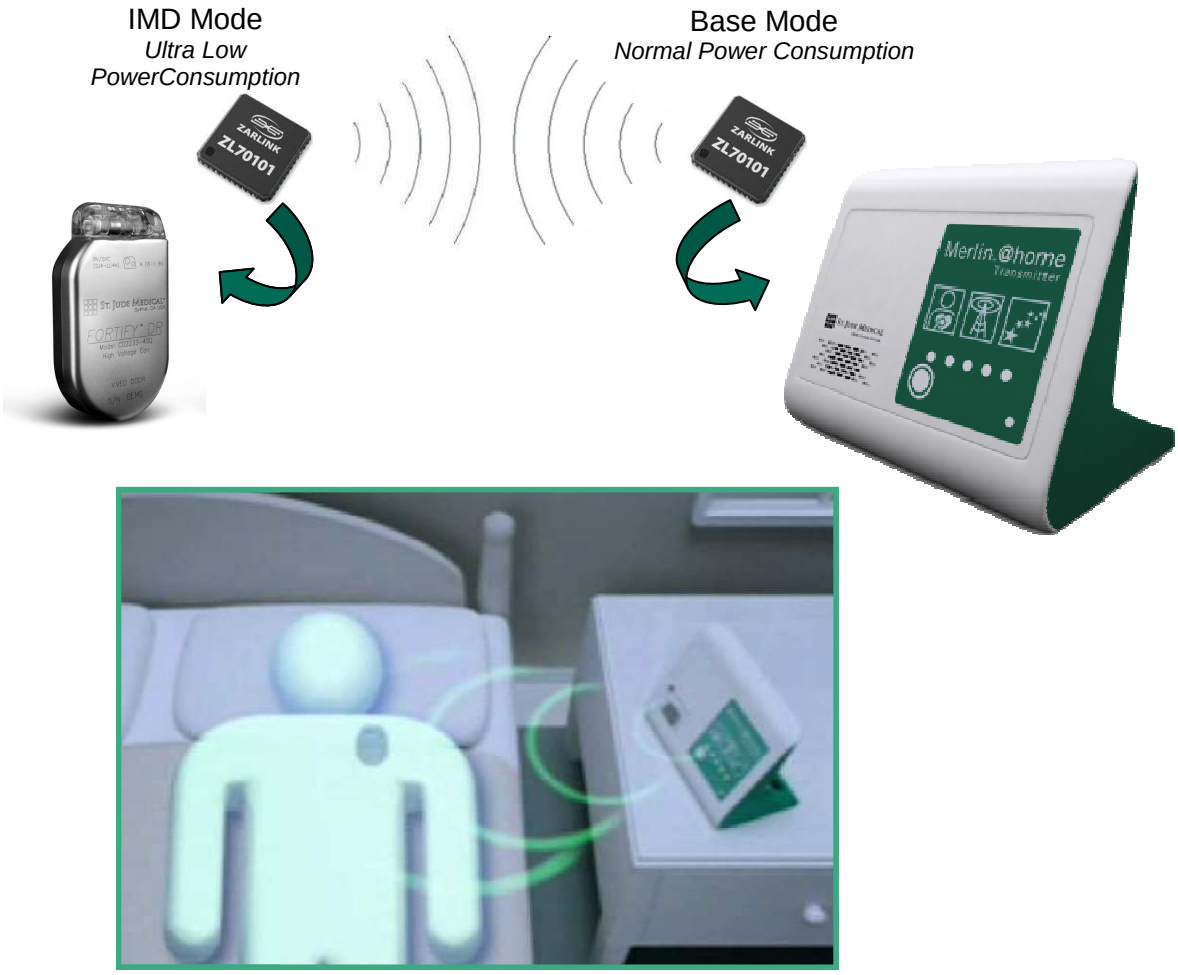
II - The transmitter: Merlin@home

The Merlin@home transmitter system allows remote patient monitoring and follow-ups. The transmitter is typically set-up by the bedside for communication while the patient sleeps (2AM to 4AM). It collects nightly diagnostic readings from the ICD and securely transmits the data to the physician's office via the Merlin.net server. The transmitter is also updated with the follow-up schedules, entered on Merlin.net by the clinician, each time it connects. A weekly maintenance check and software updates are also operated by the server on the patient's transmitter.

a) Reading: Transmitter - Device Communication

The Merlin@home transmitter communicates with the St-Jude Medical devices equipped with RF antennas. Two separate circuits are used during this communication:

The St. Jude Medical devices already support a 2.45 GHz band based asynchronized wakeup and 400 MHz (MICS: Medical Implantable Communication Service) band based synchronized wakeup. The 2.45 GHz band base asynchronized wakeup uses 2.45 GHz band to wake up the RF transceiver in the ICD and then switches to 400 MHz band for communication. This scheme is asynchronized so the ICD is always listening for base station's request for wakeup and communication can be established anytime. The MICS band based synchronized wake up uses 400 MHz band to wake up the RF transceiver as well as for communication. This scheme is synchronized so the ICD listens to the base station's request for wakeup periodically. The base station can wake up the ICD and establish communication only at a predefined time (typically every 2 hours when the ICD is listening for wakeup request from the base station). However, there are drawbacks for both these wakeup schemes. Once the communication is established the transmitter (base) recuperates the data from the device and sends it to Merlin.net server using landline or cellular connection.



3.4 The Merlin@home – Device communication

b) Transmission: Transmitter - Server Communication

Once all the information has been gathered the transmitter sends this information to the server via an integrated modem that is compatible with non-unbundled landlines and a cellular adapter.

In France, the strategy used is to provide transmitters with cellular adapter, knowing that it does not require any additional hardware and operates on the power supply of the Merlin@home transmitter. The USB Cellular Adapter can be plugged into any Merlin@home transmitter to allow the data transmission on the 3G and GSM bands of the cellular network. The adapter automatically searches and connects to the network when within the coverage

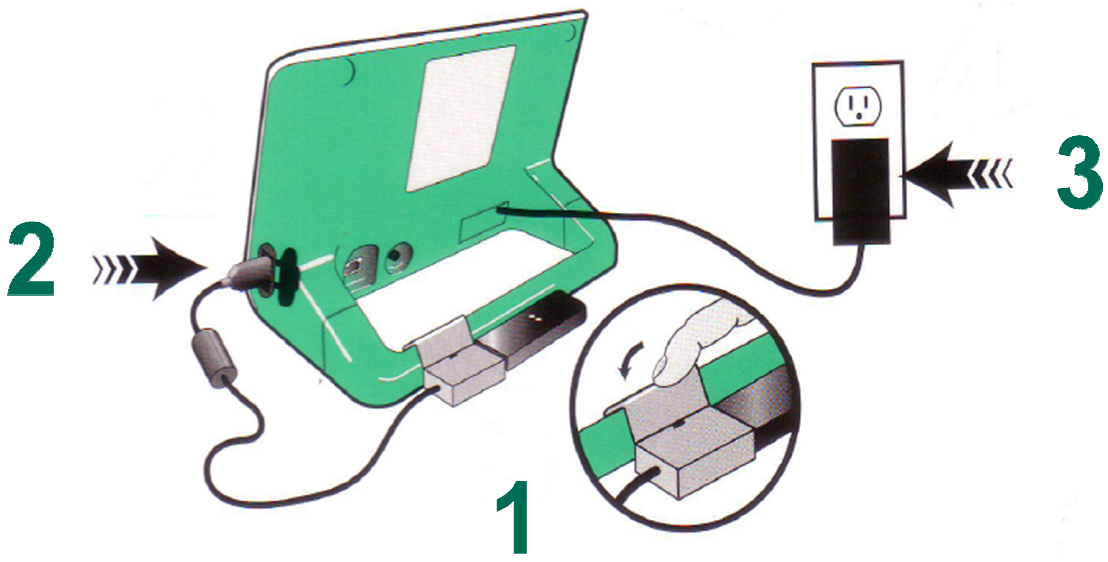
area, providing patients with an improved capacity to transmit data remotely and to leverage the full potential of the Merlin.net Patient Care Network.

In France we have found that the number of patients with compatible landlines is diminishing. The cellular connection is also a big advantage for patients who travel. It offers both accessibility and convenience. It is an important portable accessory that physicians can consider when selecting the right device system for a given patient knowing that it provides a reliable transmission option.

Patients, for whom we experience problems with cellular transmissions, are equipped with a landline connection if eligible.

A communication between a transmitter and the server can be initiated for four main reasons:

- Manual Patient initiated transmission
- Scheduled transmission set-up by the center
- Alert initiated transmission
- Weekly maintenance check and software update



3.5 Cellular Merlin@home transmitter set-up

III - Merlin.net: The Patient Care Network

The encoded data is sent via a secure connection to the Merlin.net server. The first time a transmitter connects to the server, it holds the device serial number and gets paired to the matching patient's profile. Once the "device-transmitter-profile" pairing is done, the transmitter then directly downloads and uploads the data from/to the corresponding profile.

The best way to explain the functioning and utility of Merlin.net is to redraw the circuit of a patient's monitoring starting from the site's configuration and through patients enrollment, follow ups and alert management. My role in this circuit will be developed in Chapter 4.

a) Merlin.net General Configuration

After enrolling a new clinic in Merlin.net, the profile should be configured to match the centers' expectations and work environment. The flexibility of the different features allows the clinicians to optimize as well the monitoring of each patient according to his needs.

The Users are defined according to their status: Clinicians, Healthcare Professionals and Assistants. This allows the user to have different levels of access according to his status. Each user will also have access to different patients disregarding his status which allows the staff to only see the patients they are monitoring when they log in to merlin.net

The Transmission Reports parameters can also be changed from a user to another and the default parameters can also be chosen by the clinic administrator.

The EHR exportation, which transfers the patient's data from Merlin.net to the hospital's database, allows integrating the follow up transmissions into the patient's medical history.

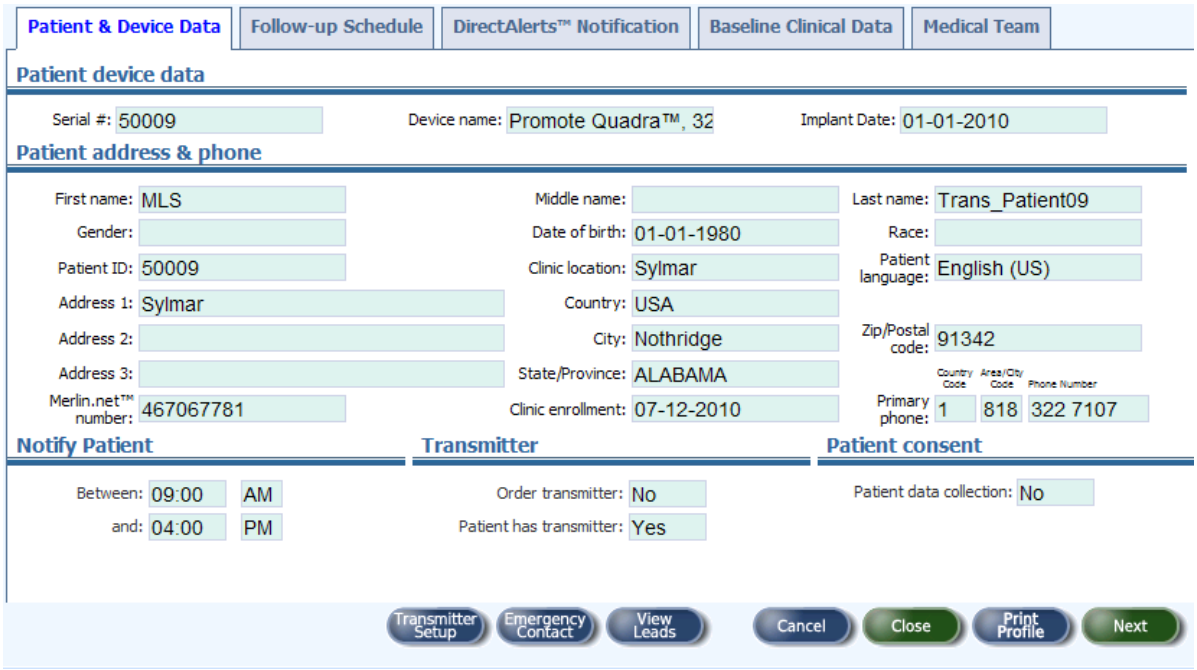
The clinic's schedule, as in opening hours, days and holidays so the website can manage the notifications sent to the center.

b) Patient Enrollment

Once the configuration of Merlin.net is done, the clinic can now enroll its first patient. To be a candidate for remote monitoring, a patient should have a St-Jude Medical RF device, and should also match to the following criteria:

- Patient with SFR network coverage at home. (Network used by our cellular adapter provider)
- If it is not the case, the patient should have a non-unbundled phone line. (France Telecom)
- Matching schedules for the patient's follow-ups
- Patient consent for Remote Monitoring

If these conditions are fulfilled the patient can be enrolled on Merlin.net:



3.7 Patient enrollment page on Merlin.net

The first step is to enter the patient and device information to create the profile. The device's serial number and model should be always double checked, knowing that they participate to the pairing process and would make it fail if ever a wrong entry was detected.

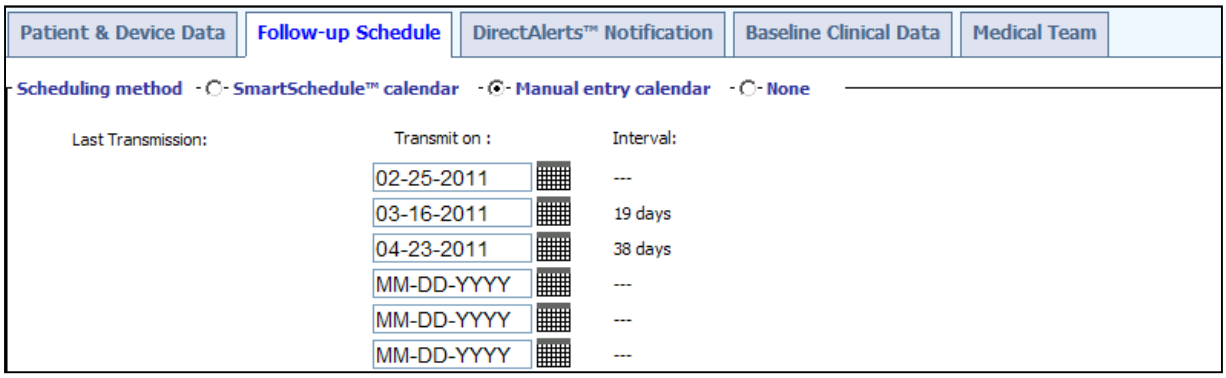
Once this first step has been confirmed, the patient can receive his Merlin@home transmitter and proceed to the pairing. A designated person from the center, previously trained by our team takes a new Merlin@home transmitter and pairs it with the patient's device. Once the pairing has been confirmed, the patient is trained on the basic use of his transmitter, and on how to perform a manual transmission. After he signs the patient's consent form, the patient and the clinic agree on the follow-up schedules. After that, the patient can go home with his transmitter and plug it back next to his bed.

c) Scheduled Transmissions

Depending on the remote follow-up schedule discussed with the clinic, Merlin.net offers different types of schedules to match each patient's and clinic's expectations. The clinic can program scheduled transmissions for a single patient, a group of patients or the entire clinic's patients at a time. Two scheduling methods are available on Merlin.net:

Manual entry calendar:

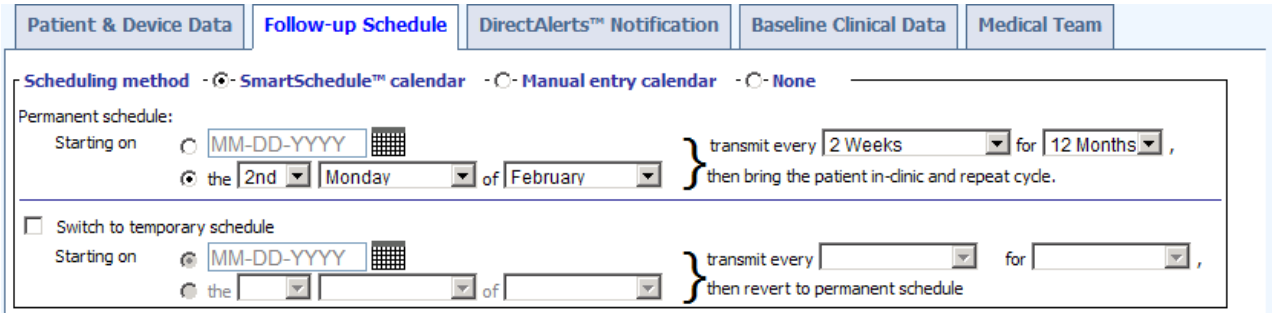
The exact dates (up to 6 follow-ups) are chosen and set by the clinician matching the patient's agenda and needs:



3.8 Manual entry transmission calendar on Merlin.net

SmartSchedule Calendar:

The transmissions can be scheduled on time base (days, weeks, months) starting from a certain day of the month and for a definite time before repeating the cycle. As shown in the example below, this patient will start transmitting on the second Monday of February, every two weeks for a whole year. In case this schedule should be interrupted for any reason, a temporarily schedule option allows to switch to another transmission rate and time base for a certain period in order to match the patient's condition.



3.9 SmartSchedule calendar on Merlin.net

d) DirectAlert

One of the most important features of Merlin.net is the capacity to communicate the device's alerts directly to the concerned staff. As discussed before, during the daily communication between the device and the transmitter the alerts are communicated and they directly initiate a transmission on Merlin.net. Depending on the alert's nature and the alert configuration on Merlin.net, it will be transmitted to the appropriate person by phone, SMS or fax. The staff can then go on Merlin.net in order to check the transmission.

Configuration:

Each device supports different kinds of alerts. The management of these alerts depends on each patient, pathology and device. Merlin.net allows the clinicians to choose the alerts they want to receive personally, the alerts they want to transfer to the health care professionals and the alerts they don't need and that should be turned off.

The alerts will then be split into three types:

- **Urgent:** These alerts are commonly sent to the clinician and the medical team. The urgent alerts are commonly the device/patient life threatening ones.
- **Standard:** The standard alerts are generally sent to the healthcare professionals and assistants so they can be taken into account and treated with a lower emergency level.
- **Off:** Some alerts are turned off due to the patient's condition, to avoid receiving them frequently, knowing that they will be triggered very often, and that they don't represent any significant diagnosis.

3.10 ICD Alert configuration example

		Send to Clinic via:					
Distributed Alerts:	**Highlighted in Recent Transmissions List**	**Fax**	**Email**	**Text Msg.**	**Phone**	**Do Not Notify**	**Send to Medical Team**
Urgent Alerts							
During office hours	☑	○	○	◉	○	○	
After office hours	☑	○	○	◉	○	○	☑
Standard Alerts							
During office hours	☐	○	◉	○	○	○	
After office hours	☐	○	◉	○	○	○	☐

3.11 Alert distribution example

The optimization of the alert management allows a more efficient monitoring of each patient and a very high safety standard. For example, an alert marked as **urgent** for an **out of range high voltage lead's impedance** allows the clinician to convene the patient to check his lead's integrity and connectivity. That would eventually avoid inappropriate shock delivery, increasing with that the treatment efficiency, as well as the patient's safety and well-being.

Remote monitoring is revolutionizing the implantable device care system: The risk factor is lowered for the patient and the clinician has a better view on the disease and the emergency alerts. Yet, deploying a new process in the traditional medical care habits is always a challenge, especially when high-tech machines and software are involved. On the other hand, remote monitoring is an efficient yet time-consuming process: The patient needs to be informed on how the system works and the clinician needs to take the time to read the transmissions, monitor the alerts and schedule the follow-ups.

The engineering role in the remote monitoring deployment goes beyond the ability to understand the system's functioning and to troubleshoot: We are introducing a new healthcare method, and our challenge is to train and follow the clinician and the patients through all the steps, to insure that their usage of the system remains efficient and easy.

Chapter 4 : The Project

In this chapter I will go through the detailed missions of my project with the difficulties and challenges of each task. Deploying remote monitoring includes the opening of new centers, technical support for patients, doctors, healthcare professionals and sales representatives. Other aspects of my project, like marketing documents, personnel training and procedures redaction will also be listed and detailed with other complementary facets, including regulatory and clinical aspects.

I - New centers and system deployment

Merlin.net has been deployed for the first time in 2008. Until now, the number of centers equipped was limited and the patient enrollment has been slow. The deployment has been slackened by the French healthcare system, and by the costs that are covered by St-Jude Medical. Another aspect, that remains undeniable, is the change of the physician's conventional methods by introducing a new way to monitor the implantable devices.

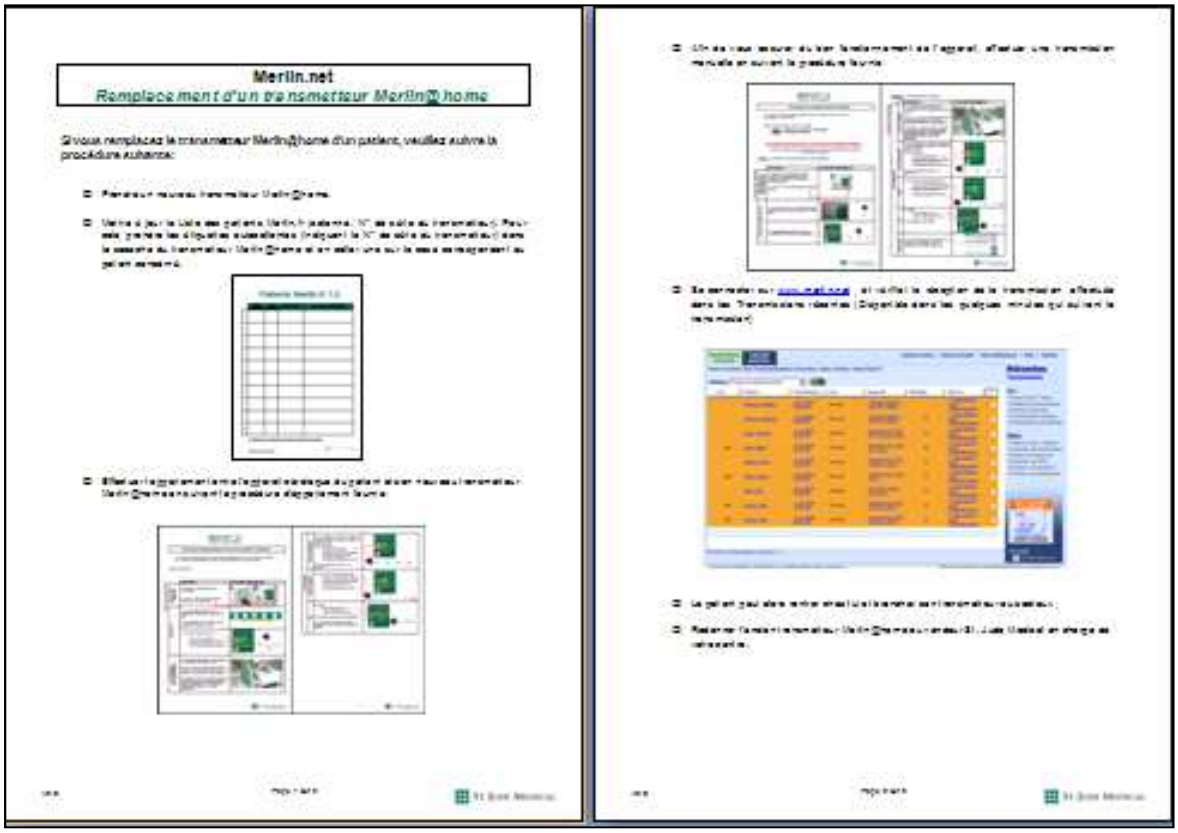
Starting September 2010, the company's strategy has changed due to the increasing need for remote care that was sensed on the field. The results of the forecast I have made in December with our sales representatives, expected to multiply by three in 2011 the number of actual enrolled patients. To be able to ensure the same service quality with this fast increasing centers number, we had to "industrialize" our methods and procedures.

a) Procedures

The best way to gain time and efficiency, was to create procedures to make the centers autonomous on the system's management as fast as possible. We decided to create a "Merlin.net Reference Guide" that would include the different procedures, check-lists and all the information the center would need to enroll and monitor its patients using our system.

This reference guide is structured and indexed to help the clinician/CRA (Clinical Research Associate) find the detailed procedure for every task.

To replace a patient's transmitter for example, the center can find the accurate step by step procedure:



4.1 Transmitter replacement procedure

Challenge: How would a clinician/patient think?

When writing a procedure, I had to put my system's knowledge aside and think how to make this information understandable by any person who will have to operate the system. I always began by drawing the procedure's step by step plan and try to develop each step, by referring either to other procedures or to simple tasks the operator could easily accomplish.

Before validating a procedure with my superior, I always used to give it to any employee in the company, who wasn't familiar with the system, and ask him to complete the procedure with our system to see if the steps were clear and explicit. This test phase was necessary to confirm that the information was accessible by any operator and that the "language" used was simplified, yet precise.

b) Physician's expectations and Merlin.net configuration

After the decision has been taken to open a new center, discussions are initiated with the concerned physicians to present the system and listen to the physicians' expectations and needs, in term of follow-ups, alert distribution and center configuration. The questions and outlook are different from a physician to another depending on their work methods and task distribution in their teams.

At this stage, we define the different accounts that should be created on Merlin.net (Physician, Healthcare Professionals and Assistants) gathering all the medical staff of the center depending on their role and responsibilities. The doctors will then have to define the DirectAlert distribution (urgent and standard alerts) as discussed in Chapter 3: Usually the device related alerts are marked as urgent and the rest are commonly marked as standard.

Merlin.net Accounts:

- *Healthcare Professional:*
  By default, He can see all the center's patients.
  He can perform all the "daily" tasks in Merlin.net, including the transmissions archiving.
- *Physician (administrator or not)*:
  By default, He can only see his patients.
  Can be given access to all the center's patients.
- *Assistant*:
  Can only consult the transmissions and schedule the patient's follow-up dates.
- When a "Healthcare Professional» or "Physician" reads a Transmission, it is marked as "Viewed" and Merlin.net remembers the last account and date of visit.

Challenge: Who is responsible for what?

Our main concern is to define the responsibilities to ensure that the alerts will be read and the transmissions will be consulted and analyzed:

Usually this task is assigned to a healthcare professional, typically a CRA that will receive a special training and will have the following responsibilities:

- Enroll the patients on Merlin.net and deliver their transmitters at the hospital (training, pairing, patient consent form…)
- Consult their mailbox daily to check for eventual alerts.
- Consult regularly (at least weekly) Merlin.net for patients' monitoring:
  - Reading/archiving transmissions
  - Reading eventual messages
  - Follow-up schedules

My mission is to ensure that these tasks are assigned to the right staff. For example, if the alerts and transmissions are not read by the medical staff, the purpose of remote monitoring is lost: This is why responsibilities are the main objective of our discussion with the physician, and always remind them that remote monitoring helps them monitor their patients in a more efficient way, but will never do the monitoring alone.

All these discussions then allow us to configure the center's Merlin.net profile and accounts. The "default" parameters discussed in Chapter 3, are then configured with the healthcare professional according to the physician's expectations and the center is now ready to enroll its first patient.

c) Staff Training and First Enrollment

We always try to have the staff trained and the first patients enrolled the same day, so we can cover all the training aspects, especially the ones related to the transmitter's pairing and handling. The first part of the training consists on presenting all the aspects of Merlin.net and ensuring that the staff understands how to configure the different parameters like alerts, schedules, transmissions, archiving and others.

Next, we start by enrolling the first patient on merlin.net as explained in Chapter 3 and then we assist the staff on their first transmitter delivery/pairing while explaining every single step along with the issues that can eventually be encountered and the basic trouble-shooting actions.

If we have the opportunity, we try to enroll more than one patient, so different cases can be covered, and we get the opportunity to show the staff how to explain (training) to the patient everything he should know about our system and about the way it should be handled.

Challenge: Trouble-shoot simple cases and always give an explanation

On the training day, we try to be exhaustive and cover all the possible cases. We also use the "Reference Guide" to show all the different situations and the easy way to solve/manage them.

Example: Reading issues upon transmitter's pairing:

Upon pairing the transmitter goes on **"Read Error"** after trying to read the device:

Read Icon and five Leds Blinking:

4.2 Read Error

This behavior means that the transmitter can not find the device or can not finish reading the information. The typical solution for such an issue would be to get the transmitter closer to the device (patient's chest) and re-launch the pairing.

The proposed solution would eventually solve the problem: The given reason is simply the distance between the device and the transmitter.

This is how we simplify the real reason why this is happening: The wake-up circuit (2.45GHz) has a short (low power) range causing the transmitter not to be able to call the device and establish a communication if the device is far (>2m) as explained in Chapter 3.II.a.

II - Technical Support and Trouble-shooting

Like every complex system, our remote monitoring network encounters slight or more complicated issues either on the transmitters, on Merlin.net or on our servers. Other issues can also be encountered with the usual procedures or simple wrong entries. For the remote monitoring technical support, I had the responsibility of all the French centers assistance and trouble-shooting. I was also responsible for the field and quality reporting, as well as the investigations with the European remote monitoring technical support.

a) Remote Monitoring – Technical support

The European technical support for St-Jude Medical's Remote Monitoring is centralized in Veddesta – Sweden. Three correspondents are responsible for the investigations on the different cases we submit. In France, the law prohibits us to have any access to the center's profiles and data, in order to protect the patients' privacy: Our technical support can help us with this restriction and even give us detailed information about the connection parameters and the profiles configuration that allows us to better understand and solve the issues.

We usually turn to them when the basic trouble-shooting fails. Their level of access allows them to have a global view on the different parameters that may be causing the problem and give us their advice.

Challenge: How to prevent an issue to occur again?

I usually used to submit the issue to them as fast as possible to gather more information about the problem's possible reasons. This information would then allow me to intervene in a more efficient and targeted way. Remote Monitoring's support also helped me give a more precise answer to the centers in many situations: For me, it was never about solving the problem but always about three basics that allowed me to succeed in this trouble-shooting task:

- Find the precise reasons of the issue
- Define the steps that will lead to an eventual solution
- Go back to the reasons and see how we can prevent this issue to occur again

b) Issues at the center

Two main parts of the remote monitoring circuit take place at the hospital:

The Merlin.net entries and the Transmitter pairing.

Merlin.net as described above is an interactive website that coordinates the follow-ups and alerts of each patient with the entries of the clinic. This coordination job depends on many human factors, especially on the transmitter's side (unplugged, unable to connect), but also on the clinic's side where the patient's information, preferences and schedules are entered.

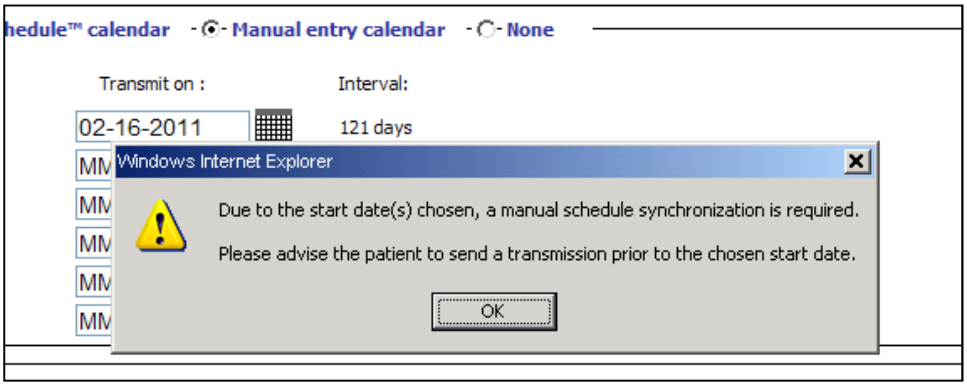
This can lead to multiple misunderstandings related to the system, leading to a total confusion of the medical staff. They spontaneously call us for trouble-shooting:

Challenge: Master all the Merlin.net possible behaviors and messages

When the clinic staff called, they explained the issue they were having on Merlin.net as clearly as they could, and then, it was up to me to define exactly in which section their issue was situated and how to guide them through it and explain the situation:

As a simple example, let's take a follow-up schedule:

The nurse goes to the Data Entry Schedule of one of the patient's center and schedules a transmission in the next couple of days; when saving she gets the following message:



4.3 – "Send a transmission" message on Merlin.net

Before calling the patient, the nurse calls me and explains approximately the situation. It is up to me then to determine the exact situation from the cases I have already seen, and explain the origin and reasons of this message:

- When a follow-up is scheduled for a date that is **closer than one week** from today this message will automatically appear. As a matter of fact, for the transmitter to download the next follow-up date it should connect to the server.

- As discussed in Chapter 3 II – b, a communication between a transmitter and the server can be initiated for four main reasons:

    - Manual Patient initiated transmission
    - Scheduled transmission set-up by the center
    - Alert initiated transmission
    - Weekly maintenance check and software update

- Knowing that the weekly maintenance check can take a whole week to happen, Merlin.net asks the operator to perform a manual transmission which is the only other choice that guaranties the connection to the server and the new schedule download.

Solution:

If the nurse absolutely needs this transmission at this precise date, she should indeed ask the patient to perform a manual transmission after she has entered the new follow-up date. If not, we advise the centers to schedule the next transmission more than one week before the due date to be sure to have it downloaded and performed by the transmitter.

This solution is a typical example on how I had to communicate my knowledge of merlin.net to the centers, case by case, and how I had to analyze the different issues to be able to always give a pleasant solution.

The transmitter pairing is also a multifactor procedure, knowing that it implies a matching between the data on Merlin.net and the information that is retrieved on the implanted device. This procedure is typically operated by the staff at the hospital upon the transmitter's delivery to the patient: At the training stage, this procedure is explained and demonstrated on first enrollments, yet many issues can result on a pairing failure and the need for assistance:

After enrolling the patient on Merlin.net, the pairing procedure consists of:

- Taking a new transmitter
- Setting-up the transmitter as described in fig 3.5
- Placing the transmitter in front of the patient and pressing the “Start Button”

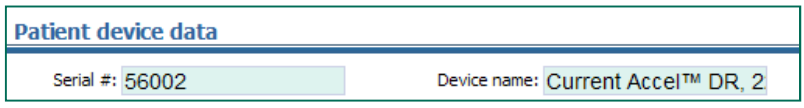
4.4 Launching the pairing procedure

The transmitter will then communicate with the closest St-Jude implantable device and gather the device information, and then try to match this data with an existing Merlin.net profile. If the operation succeeds the “Stars Icon” will light-up and the patient can then leave the center with his transmitter.

Challenge: Ensure that all the steps are completed adequately

One of the issues that the center usually calls us for is the pairing failure that is represented by a “Read Error” at the end of the pairing procedure: The transmitter can not find the corresponding device on any Merlin.net profile.

This problem usually results from a wrong entry on the patient’s profile: The matching process between the device name and serial number and the profile’s entries failed.



4.5 Device information entry on Merlin.net

Solution:

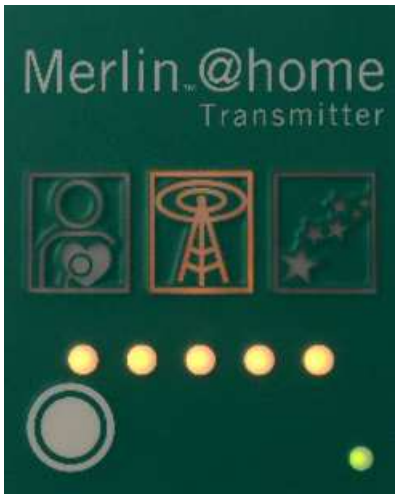
After verifying and correcting the device's name and serial number on Merlin.net, the pairing attempt can be initiated and it will normally succeed to pair the transmitter to the adequate profile.

In this kind of issue for example, we can help the center detect the mismatch directly by consulting the technical support and checking the connection data of this transmitter that resulted on the pairing failure.

c) Issues at patient's house

The patient is the final user of our system and the least trained to understand the functioning of the transmitter. As discussed in Chapter 3, nearly all of our transmitters are connected to the server by wireless cellular connection, meaning that their connection depends on many unstable factors in terms of data transfer and network coverage. The main problems encountered with our transmitters, at the patient's house are related to what we call "Send Error", which is a persistent transmission attempt failure. The "Send Error" can occur for many reasons, and most of the time these reasons remain undetermined. It can be a:

- Low signal strength
- Momentarily overcharged server
- Unsuccessful weekly maintenance check
- Bug on the transmitter's software



4.6 Send Error

The transmitter is, by default, on standby mode. Upon "Send Error" the "Send Icon" lights up with the five Leds blinking and beeping. Directly after that the center calls me for assistance and usually asks me to call the patient for troubleshooting:

We try to avoid the patient contact as much as possible for legal reasons, but sometimes the medical staff cannot troubleshoot the problem and we are forced to get in contact with the patient. When trouble-shooting with the patient, we take a lot of factors into account, like the patient's age, physical and mental condition and we always try to give him easy operations.

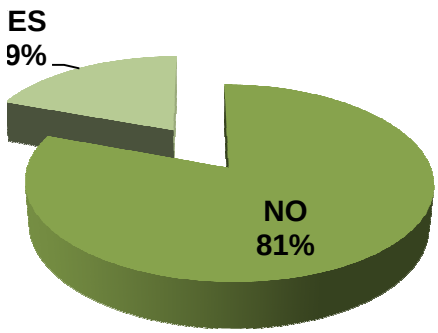
Challenge: To understand and to be understood

In most of the cases, we are able to deduce the transmitter's behavior by listening to the "beeps" coming out of it. The engineers created a "beep" code for each step of a manual transmission allowing us to monitor the behavior by phone. On the other hand, sometimes the trouble-shooting gets more complicated, and we need the patient to describe the transmitter's and cellular adapter's behavior, and to operate simple tasks.

Depending on the patient's comprehension level and ability to help us troubleshoot, we formulate our queries, instructions and questions to make sure that **we understand** the transmitter's behavior, and that **we are understood** for the simple tasks that the patient should accomplish.

For some issues, we cannot solve the case by phone and we need to run some tests at the patients' house. I made a couple of interventions of this kind for persisting problems.

After we have tried all troubleshooting means, the last option remaining is the replacement of the patient's transmitter. For most of the patients, we can send the transmitter and assist them for the set-up by phone. For others, we can intervene at the patients' house or ask them to visit their center for replacement. The centers have the replacement procedure in their "Reference Guide" to facilitate the task.



4.7 Transmitters replaced for troubleshooting

d) Field and quality reporting

All the incidents we trouble-shoot are reported internally using an FER (Field Event Report). For remote monitoring, we reported all the incidents that were directly related to our system and not to the patient's or medical staff usage. Nearly all of my reports were about transmitter related issues, and most of all about transmission issues.

Once an incident or issue is reported, we have the obligation to submit an FER in the next 48 hours. This report is then validated by the French vigilance team and submitted to the appropriate investigation team. If the concerned transmitter has been replaced, it is returned and sent for investigation too. This circuit guarantees a close quality follow-up on our system and the detection of any eventual major problem at a preliminary stage to avoid greater issues.

4.8 Field Event Report Summary

Challenge: Software updates Field Action

When delivered, the Merlin@home transmitter runs the latest software available. Once installed at the patient's house, the transmitter upgrades his software version by connecting to the server and downloading the updates. The transmitters are upgraded by batches to avoid having issues on all the transmitters if it fails for a certain reason.

Two days after the beginning of my project, a batch of French transmitters was upgraded to the latest software version. Unfortunately, the upgrade contained an entry error that made the connection between the transmitter and the server impossible. Correcting this error was impossible and the decision was taken to replace the whole batch:

The legal and quality departments gave us the Field Action Plan including:

- The physician notification
- The objectives and procedures
- The reporting forms

I was responsible for the implementation of this field action and the coordination with the centers for the transmitters' replacement. Knowing that this action began a few days after the beginning of my project, the challenge was all about accomplishing an intensive personal training to be able to troubleshoot any possible incident and explain the different approaches.

After this field action, we realized that we were not ready for such an intervention rush and decided to implement new methods and procedures:

I proposed to start thinking about a trouble-shooting database that would help us organize this task and avoid any loss of information.

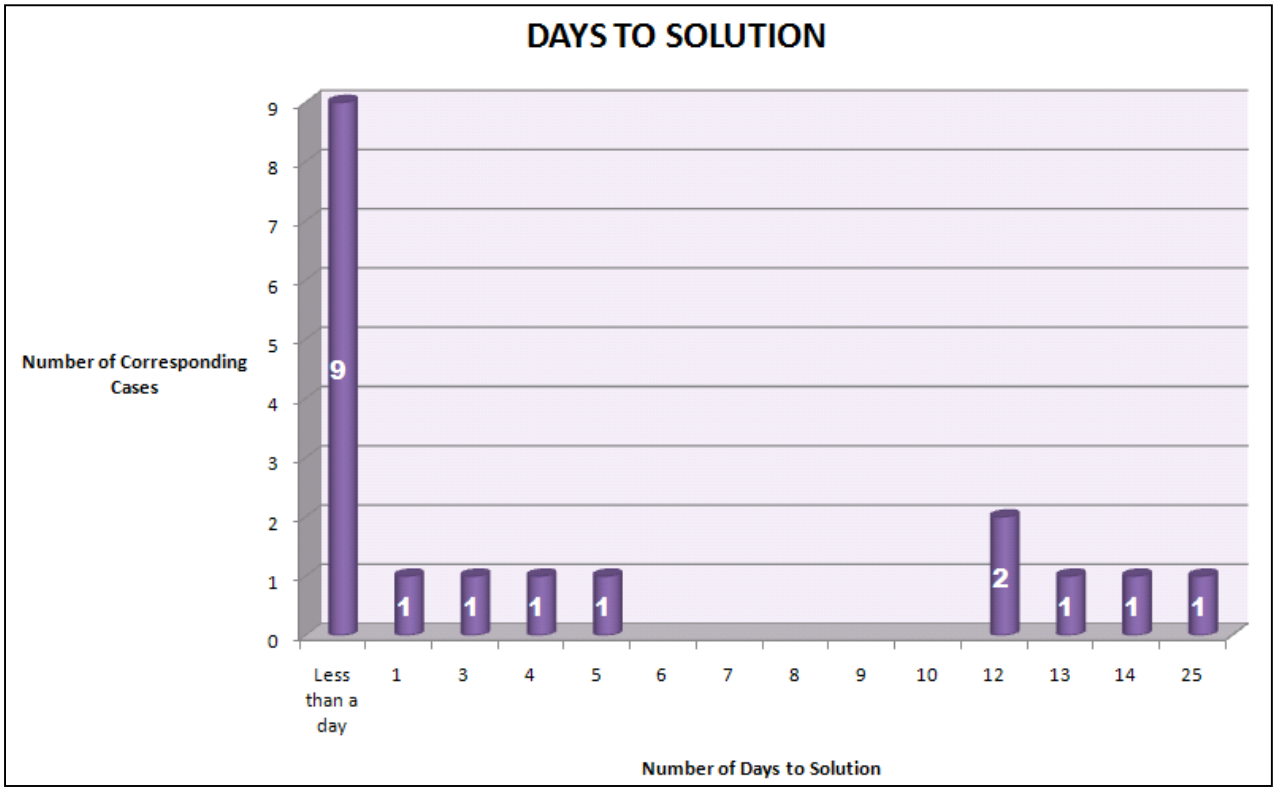
e) Trouble-shooting Database

A plan was then established for this database, and we chose a data organization that would allow us to extract statistical data such as the number of days it takes us to troubleshoot each problem, characteristic reasons and solutions of the submitted cases and regional

statistics. It took me about two weeks to finalize the data entry fields and the statistical extraction graphs.

Later on, the database kept evolving during a tests period to fit our expectations and needs:

For example, to know if our troubleshooting speed was evolving in time, I designed a “Days to Solution” graph in which shows us the number of days it took us to solve each issue:



4.9 Number of days to solution for December 2010

All the graphs are automatically generated and updated from the data entry; these graphs allowed us to establish interesting statistics on our activity, and they also gave us an overview on the issues and solutions we were giving. The more this database ages the strongest the statistics will be and much more information will be extractable for analysis.

III - Marketing, clinic and legal

I decided to talk about the marketing, clinic and legal aspects in the same section because in remote care these domains are still mutually dependent. In France, Telemedicine is just starting to be recognized by the healthcare system as a medical care method, but it still is not legally equivalent to a classic follow-up visit. The legal aspects have evolved in the last few years after the first clinical trials have shown the benefits of remote care. Our role as manufacturer is to help the medical society discover and adopt remote monitoring, by offering the service and leading clinical trials in order to fasten the identification of remote care.

a) Marketing and competition

Marketing is a total system of business activities designed to plan, price, promote and distribute want-satisfying goods and services to present and potential customers. To be able to price Remote Monitoring as a service, St-Jude Medical and its competitors are still promoting the service by offering it to their French centers. This marketing strategy encourages the medical society to discover RM and to integrate it in their classical follow-up procedures. Once it is integrated, the service should become indispensable allowing us to distribute it.

My role in this strategy is to valorize the benefits of our system and to make it seem easy to use by helping the centers with technical support, and providing them with the easy and understandable procedures. In this role, communication skills are a must to gain our clients' confidence.

On the other hand, competitive intelligence is also necessary to be able to emphasize the qualities of our system. During my project, I did a lot of research about our remote monitoring competitors and their systems and analyzed the following points:

- System features and advantages
- Clients satisfaction and complaints about the competitors systems
- Press releases and marketing strategies
- Market study and competitors expansion

Biotronik Cardiomessenger™ mobile transmitter of the Home Monitoring system

St-Jude Medical Merlin@home™ wireless transmitter

Boston Scientific wireless transmitter, weight scale, and blood pressure monitor of the Latitude Patient Management™ system

Medtronic transmitter (Home Monitor) of the CareLink™ network

4.10 Remote Monitoring competition

All four systems have their pros and cons in terms of connectivity, reliability and size. Most importantly, Remote Monitoring, as it is today, remains sales argument for the implantable devices of each of the companies:

For the centers that have adopted remote monitoring as a classical procedure, the surgeons will implant the devices with the best remote care system. This is the only financial factor of remote care systems today in France, while waiting for the systems to be priced.

b) Clinical and legal approach

In France, Telemedicine has been a debate subject for the last few years with the publication of the first positive clinical results. The first French decree concerning Telemedicine has been released during my internship on October the 26th as a first step towards the full integration of remote care in the French healthcare system.

Another main legal concern in the French system is the data privacy for which the CNIL is responsible:

The *"Commission nationale de l'informatique et des libertés"* or CNIL is an independent French administrative authority whose mission is to ensure that data privacy law is applied to the collection, storage, and use of personal data. The main principles for regulation of personal data processing are as follows:

- All illegal means of data collection are forbidden
- The aim of the data files must be explicitly stated
- People registered in files must be informed of their rights, for example, for rectification and deletion of data on demand
- Finally, no decision about an individual can be decided by a computer.

Our system is in line with all these regulations and yet many debates are still opened on the data privacy subject, data storage and encryption. During my project, I had to make sure that these regulations were respected and that all our documents and profiles remained anonymous. The patients were always represented by their device serial number and only the medical staff has access to the patient data and information.

Clinical studies:

All the patients monitored in Merlin.net are systematically enrolled in French St-Jude clinical survey **Merlin.fr**:

In Merlin.fr, we collect all the data concerning the Remote Monitoring system Merlin.net and the Merlin@home transmitter with defibrillators and implantable pacemakers to demonstrate:

- **Feasibility and Reliability:** Remote Monitoring integration in the healthcare facilities
- **Comparability:** between the medical decisions taken by Remote Monitoring and classic follow-ups performed in the center

The survey results will soon be subject to publication with very promising results.

Chapter 5 : Prospective analysis & conclusion

I - Challenges and prospective analysis

a) Professional Contribution

The project was for me, one more opportunity towards my future employment goals. After my first internship in a medical device company, this internship was a positive evolution in terms of responsibilities and project management. In fact, I had to develop “Merlin.net” under all its aspects like a product manager. The project enclosed engineering facets, for the technical and implementation parts, as well as marketing and human contact. My position allowed me to work with many internal divisions of St-Jude Medical around the world and discover the company’s work ethics and values. On the client’s side, I have deepened my knowledge in medical practice and environment and I got to meet some of the most talented cardiologists in France.

One of the biggest challenges on the professional side was our team size. The only people in charge of the St-Jude medical RM system were my boss and I. We have always managed to overcome this team volume difficulty by prioritizing and splitting the tasks to optimize our work time. Another challenge that helped me develop my communication skills was the patient’s contact in which our speech is always adapted to each case and situation.

The project and the company offered me an ideal environment, to strengthen my professional experience, and focalize on my future employment objectives.

b) Personal Contribution

If I had to change this section’s title, I would put “strictness and communication”: I managed to develop, during these 6 months, an efficient work method to organize my work. I learned to prioritize in task management to always give rigorous and satisfying results. I also succeeded to develop my communication skills and manners in order to adapt them to the each interlocutor and satisfy his needs.

I also developed a weak point I had, which is the ability to learn from others by listening, and founding my answers on their expectations and discourse. This helped me improve my persuasion skills and assert myself on different conflict points.

During this second experience in the company environment, I focused on each of my colleagues' missions and work environment to make my career choice easier according to my personality and potential. I think that the medical device environment suits these expectations and I will carry on in this same sphere for my job.

II - Conclusion

To conclude about Remote Monitoring, I would like to quote Dr Kenneth A Ellenbogen (Medical College of Virginia, Richmond): “ICD remote monitoring is an incredibly powerful microscope". In fact, the medical device remote care provides frequent, convenient, safe and comprehensive monitoring of the prosthesis and the patient’s condition. Device and patient related problems can be reliably detected and reduce the frequency of outpatient visits. Patients are highly satisfied with the convenience and ease of use of the systems. The surveillance of device performance is a potentially important future capability. In the future an exponential growth in implementation of remote monitoring is likely to occur in the field of implanted devices including ICDs, pacemakers, and implantable disease monitors.

As the positive clinical surveys publications keep on falling, the legal context of telemedicine should be adjusted and allow the growth of remote monitoring. On the other hand, the medical society’s interest in remote care is rising and remote follow-up systems are becoming a must in many centers, making the service’s evolution easier and faster.

I enjoyed working in an evolving sphere, where engineering and science are implementing new solutions and contributing to the advance of healthcare and the well-being of patients. Through my experience, I realized that everything is still to be done in this domain, and more remote monitoring applications will rise in the next few years to help clinicians and patients in their daily life.

This project just confirmed my will to carry on in the medical device environment as a product manager. My personality and objectives perfectly fit the companies’ expectations for such a position and my job research will be focalized on this domain and activity.

References

Books and Publications

- Cardiac Rhythm Management – SJM CRM Team
- Livre Blanc de la Télécardiologie (2008) – Pr. Salem Kacet & Denise Silber
- Telehealth World Magazine – (Spring 2008)
- St. Jude Medical: Enhanced MICS - Devanshi Shah – Thesis CPSU 2010
- Journal of General Internal Medicine – 2007

Websites

- SJM Online Courses: http://corporate.sjm.com
- Tic Santé: www.ticsante.com
- SJM PROFESSIONALS:
    - http://www.sjmprofessional.com/Products/US/CRT-Systems/Merlin-net-Patient-Care-Network.aspx
    - http://www.sjmprofessional.com/unitedkingdom/cardiac-rhythm-management/product-highlights/remote-monitoring-and-patient-management.aspx

Appendix

Appendix 1: Personal activity statistics

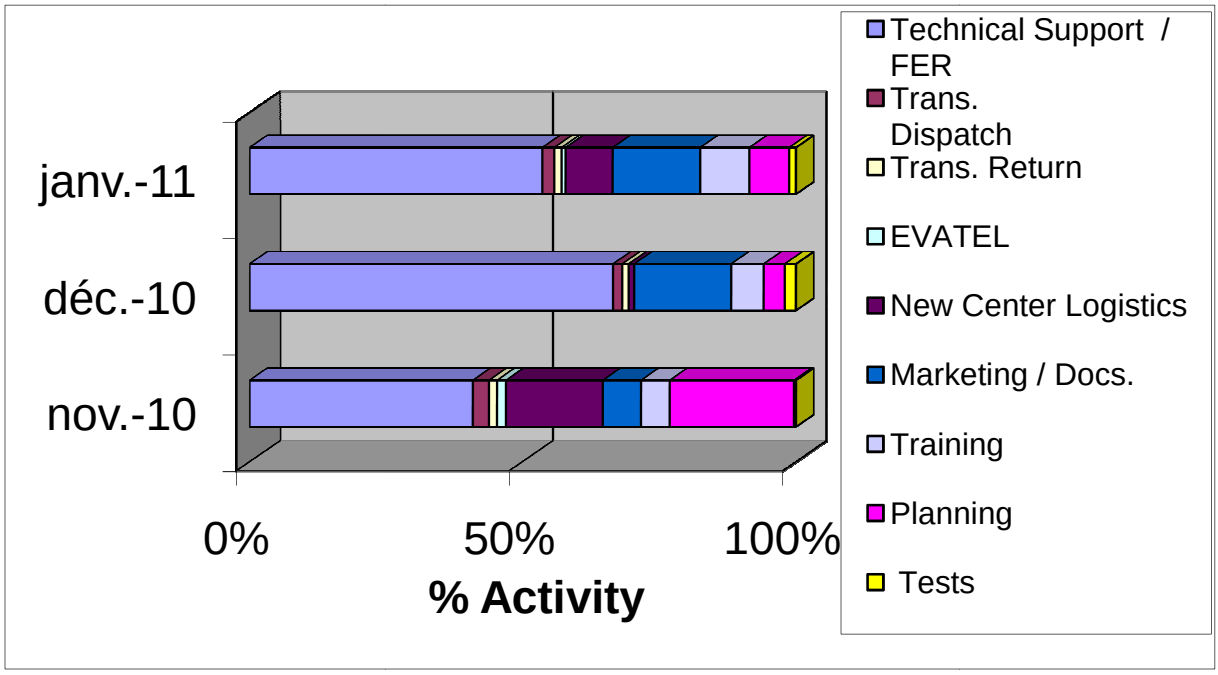
Appendix 2: Merlin.net Spec Sheet

Appendix 3: Transmission Summary: Fastpath

Appendix 4: Merlin.net Connectivity Fact Sheet

Appendix 1: Personal activity statistics

Starting November, I began to monitor my activity on a daily basis and you will find below my activity's statistics for November, December and January:



Technical Support / FER	Trans. Dispatch	Trans. Return	EVATEL	New Center Logistics
Technical support by phone to centers, patients and SJM representatives + FER reporting	Transmitter shipping to individuals/hospitals + warehouse checking	Transmitter returns/ Vigilance Department	All EVATEL study documents, communications and invoices	New centers documents, opening and support

Marketing / Docs.	Training	Planning	Tests
All procedures and marketing documents preparation	All trainings	Discussions and time taken on planning activities + Meetings	Tests operated on the remote care system

Appendix 2: Merlin.net Spec Sheet

Merlin.net™ Patient Care Network

Version 4.0

SPECIFICATIONS

Merlin.net Patient Care Network (PCN) represents a major advancement in remote monitoring and device management. It provides a complete follow-up and its features include:

- DirectCall™ Message, an integrated and automated patient communication system designed to reduce routine calls usually performed by medical office staff
- A direct connection to electronic health record (EHR) systems without the need for expensive intermediary systems with EHRDirect™ Export. This feature meets the Integrating the Healthcare Enterprise (IHE™) guidelines, supporting Health Level-7 (HL7) standards.
- DirectTrend™ Viewer provides dynamic views of device and clinical trends
- DirectAlerts™ Notification, a physician notification system for critical device alerts
- Online scheduling tool for automated follow-ups
- Standard database export format for external data processing
- Ability to view, print, archive and export up to 50 patient records at a time
- Archive storage capabilities for a minimum of seven years
- Compact, automatic bedside transmitter with wireless RF
- Collaboration feature allows physicians to exchange reports via built-in system

Storage For All Of Your Patient Device Data

Merlin.net PCN is an Internet-based central repository for patient device data that allows physicians to connect directly to their patients' stored device data any time from anywhere Internet access is available. Device data can be collected from implant procedures, in-clinic follow-ups and remote transmissions. Programmer data can be uploaded to Merlin.net PCN. Data is stored and easily accessed on Merlin.net PCN for a minimum of seven years.

Connections to Your EHR

Merlin.net PCN is the first cardiac rhythm management system to pass EHR standard guidelines set forth by IHE, utilizing HL7 standards. EHRDirect Export allows data and all reports to be exported directly from Merlin.net PCN to your EHR or to a third party device management system.

Direct Impact on Your Productivity

Merlin.net PCN features DirectCall Message, a unique patient communication system designed to reduce clinic workload associated with routine follow-up compliance efforts. It can be used to make reminder calls for missed appointments or to notify patients that their device data has been reviewed and all is normal or that the patient should call the clinic for additional information. When used with the online scheduling feature, it provides a complete, interactive tool to minimize routine work and provide more control over patient management.

Merlin.net PCN features an easy-to-use interface and produces easy-to-read reports in the same format as Merlin™ PCS programmer reports. Clinicians can save time by selecting up to 50 patient records at a time to view, print, export and archive.

Remote Monitoring with the Merlin@home™ Transmitter

Data can be transmitted from the patient's compatible ICD, CRT-D or pacemaker directly to Merlin.net PCN from the comfort of their own home using the Merlin@ home radio frequency (RF) transmitter. Compatible devices include Current™/ Promote™ and Accent™/Anthem™ RF family devices. Complete diagnostics, including stored electrograms, are transmitted to provide all of the patient data required for a full evaluation of the patient's device performance.

Remote monitoring is designed to provide greater convenience and flexibility to your patients, and provide assurance of device and health status to both you and your patients.

The platform uses MICS (Medical Implantable Communications Standard) and provides scheduled follow-ups and daily alert checks with no patient action – even while the patient sleeps.

Merlin.net PCN Specifications	
Connectivity	
Direct data export to EHR	EHRDirect Export enables direct export to EHR via IHE or HL7 (2.x and 3.0) format without the need of an intermediary system.
Compatible EHR/Data Management Systems	All HL7 compliant EHR systems are compatible. Systems currently interface with (US experience): NextGen™ (via eMedApps); GEMMS™; Paceart™; Cardiostation™; Medical Micrographics; others available soon (Epic™, Allscripts™, Misys™). Ongoing work to integrate with Lumedx™; GE Centricity™ non-US based EHR systems
IHE Compatible	YES
Supports HL7	YES
Direct data export to PC database (i.e. Paceart System and Cardiostation Patient Management System)	YES
Scheduling	
Online Scheduling	Authorized users may schedule patient follow-ups. Automated scheduling (SmartSchedule™ Calendar) and manual scheduling options available
Unscheduled transmissions/Patient-initiated transmissions	Able to transmit outside of fixed appointment time as needed with physician approval. Able to lock out patients from sending unscheduled transmissions

ST. JUDE MEDICAL

MORE CONTROL. LESS RISK.

Merlin.net™ Patient Care Network (PCN) Version 4.0

Merlin.net PCN Specifications

Alerts & Notifications

Daily Alert Surveillance	DirectAlerts™ Notification available with Merlin@home™ transmitter for Promote™ RF, Current™ RF, Accent™ RF, Anthem™ RF and AnalyST™ RF devices. Event based or full disclosure uploads as needed
Programmable Alerts	Physician/clinician option to select only the alerts they want to receive
Diagnostic Alert Triggers*	ST Episode Detected **AT/AF Episode Duration > Threshold **AT/AF Burden > Threshold **Avg. V Rate During AT/AF > Threshold Percent RV Pacing > Threshold Percent BiV Pacing < Threshold High Ventricular Rate Episodes Recorded
Therapy Alert Triggers*	High Voltage Therapy Delivered Successful ATP Pacing Delivered Therapy Accelerated Rhythm
Device Alert Triggers*	Tachy Therapy Disabled Charge Time Limit Reached Possible HV Circuit Damage Device Reset Device at ERI HV Lead Impedance Out of Range Atrial Pacing Lead Impedance Out of Range (Dual Chamber and CRT Devices) RV Pacing Lead Impedance Out of Range LV Pacing Lead Impedance Out of Range (CRT Devices) Device Programmed to Emergency Pacing Values Back Up VVI Possible High Voltage Lead Issue LV Pacing Lead Impedance Out of Range RV Pacing Lead Impedance Out of Range (CRT Devices) High Voltage Lead Impedance < Lower Limit High Voltage Lead Impedance > Upper Limit Device Parameter Reset
Alert Notification Options	E-mail, fax, SMS, website or voice message. Method of notification can be configured based on urgency: Standard Alert and Urgent Alert
Alert Reports	Alert Summary Report AT/AF alert report accompanies AT/AF alert that the physician chooses to be notified of.

Transmitters

Merlin@home RF (radio frequency)	For use with compatible RF devices
Ability to link/re-link transmitter to a patient's device remotely	Transmitter stays with the patient when changing clinics or when patient receives new device from the same family.

Website Efficiency

Batch operation	Print, archive, export to EHR, export to PC database up to 50 records at a time
Consolidated data	Remote transmissions and in-clinic data available online
Data storage capabilities	All patient transmissions and reports available for immediate access for a minimum of seven years
Data transfers	Patient data follows patient when changing clinics or when patient receives new device
Languages	English, Spanish, French, German, Italian

User Interface

Design Principles	Similar to Merlin™ PCS (programmer) in colors and design. Easy to learn for new users
Report Format	Similar to Merlin PCS reports for easy orientation
Tracking of Reviewed Transmissions	Viewed field on new transmissions allows quick indication of which reports have already been viewed
Identify previous user	Placing mouse over transmission time shows previous user.
Rapid alert viewing	Mouse-over alerts shows list of alert types
Clinical comments	Free form, clinic defined or both
Arrhythmia and Device Management Box	Tally of recent transmissions by type
Highlight transmissions with alerts	Customizable by administrator
Inbox/outbox	Recent transmissions and patient list segments files into new and old
Weekly Glance	Convenient overview of upcoming transmissions

Education

Online Tutorial	Simulates use of major features
Interactive Demo	Available

Patient Communication

Outbound automatic communication tool	Clinic-enabled DirectCall™ Message options: Missed appointment call – triggered by clinic Normal results call – triggered by clinic Call clinic message – triggered by clinic
Multiple Language Support	IVR tool available in over 20 languages, including English, Spanish, French, Italian, German, Dutch, Portuguese, Finnish, Swedish, Danish, Norwegian, Czech, Polish, Turkish, Hungarian, Slovak, Castilian Spanish, Catalonian Spanish, UK English

Patient

Start Up Guide	Transmitter Quick Start Guide (QSG) with step-by-step setup options

Support Materials for Patient and Clinic

	Various support materials available. Please meet with sales representative for full complement of training and support materials.

Merlin@home RF Transmitter Specifications

Transmitter Model Number	Ex 1150
Physical components	Single plastic enclosure with external transformer power supply
Weight (w/o power supply)	Less than 2.3 kilograms
Dimensions	Width: 9.18" Height: 6.33" Depth: 5.06"
Wand cable length	NA
Power cord length	Minimum 1.5 meters
Modem	V.92 (56K) – Custom Design
Power Source	AC
Line voltage	100-240V
Line frequency	50-60 Hz

Devices Supported by Merlin@home RF Transmitter & Merlin.net PCN

Current™ RF ICD, Promote™ RF CRT-D, Current Accel™ RF, Promote Accel™ RF, AnalyST RF, AnalyST Accel™ RF, Accent™ RF, Anthem™ RF

Devices Supported by Merlin.net PCN through USB Upload from Merlin PCS

Current, Current RF, Current Accel, Promote, Promote RF, Promote Accel, Atlas™ DR, VR, Atlas™ II DR, VR, HF, Atlas™II+ DR, HF, Atlas™ +DR, VR, HF, Epic™ DR, VR, HF, Epic™ II DR, VR, HF, Epic™ II+ DR, HF , Epic™ +DR, VR, HF, Convert™, Convert™ Plus, AnalyST™, AnalyST Accel™, Accent, Anthem

* Different devices support different alerts. Check "User's Manual" for full list of available alerts.

** If programmed 'On' in patient's device

ATRIAL FIBRILLATION CARDIAC RHYTHM MANAGEMENT CARDIOVASCULAR NEUROMODULATION

Global Headquarters
One St. Jude Medical Drive
St. Paul, MN 55117
USA
+1 651 756 2000
+1 651 756 3301 Fax

Cardiac Rhythm Management Division
15900 Valley View Court
Sylmar, California 91342
USA
+1 818 362 6822
+1 818 364 5814 Fax

St. Jude Medical Sweden AB
Veddestavägen 19
SE-175 84 Järfälla
Sweden
+46 8 474 40 00
+46 8 760 95 42 Fax

St. Jude Medical Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11
+32 2 772 83 84 Fax

St. Jude Medical Brasil Ltda.
Rua Frei Caneca, 1380
7º ao 9º andares
01307-002 - São Paulo (SP)
Brazil
+55 11 5080 5400
+55 11 5080 5423 Fax

St. Jude Medical (Hong Kong) Ltd.
Suite 1608, 16/F Exchange Tower
33 Wang Chiu Road
Kowloon Bay, Kowloon
Hong Kong SAR
+852 2996 7688
+852 2956 0622 Fax

St. Jude Medical Japan Co., Ltd.
3-1-30, Minami-Aoyama
Minato-ku
Tokyo 107 0062
Japan
+81 3 3423 6450
+81 3 3402 5586 Fax

SJMprofessional.com

Printed in Belgium. Order No: GMCRM607EN

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Appendix 3: Transmission Summary: Fastpath

(YTR2)
Accent™ SR 1110 (551013 prB.E.76)

FastPath® Summary

page 1 of 3
1 Mar 2009. 19:43 (GMT)

No Alerts

Note

Current Parameters

Mode	**VVI**
Base Rate	**60** bpm
V Pulse Amp	**5.0** V
V Pulse Width	**0.4** ms

Battery Information

Longevity estimate unavailable

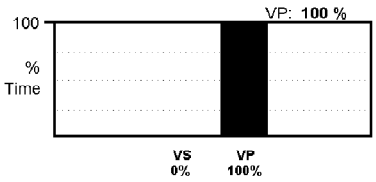
Voltage: ---

Magnet Rate	**100.0** ppm
Battery Current	---

Episodes

Episode Triggers are off

Events



Test Results (Last Session: 1 Mar 2009)

Automatic

	Ventricle
Capture	Today: **Not performed** No previous results
Sense	Today: **Not performed** No previous results
Lead Impedance	Today: **Not performed** No previous results

Patient

Patient Name	HENRY JAMES
Patient ID	YTR2
Patient Birth Date	28 Nov 1960
EF %	40%

Indications for Implant:

Device

Model	Accent™ SR 1110
Serial #	551013
Device Implant Date	23 Nov 2008

Implant Notes:

Lead Information

	V
Manufacturer	St. Jude Medical
Lead Family	Fixed Helix
Model #	1480K / 46 cm
Serial #	RH1
Implant Date	23 Nov 2008

All parameters reflect present values
Last Programmed: 1 Mar 2009 19:42
Parameters that are "n/a" are not printed

Bold values were changed this session (See Wrap-up™ Overview report for details)

- Manually-programmed
- Auto-programmed
- Automatic setting

Alert Triggers	Monitoring	Patient Notifier
V Lead Impedance Out of Range (200 - 2,000 Ω)	On	Off
Device at ERI	On	Off
Device Parameter Reset	On	On
Backup VVI	On	Off

Patient Notifier Delivery

Auditory Duration	6 sec
Number of Notifications	4
Time Between Notifications	10 hours

Episode Triggers	
High Ventricular Rate (5 @ 175 bpm)	Off
Noise Reversion	Off
Magnet Response	Off

Stored EGM Configuration

High V Rate EGM Max Duration	1 min
High V Rate Pre-Trigger Max Duration	14 sec
Channels (Storage)	2 (14 min)
Channel Configurations	Off / V Unipolar Tip

Accent™ SR 1110 (551013 prB.E.76)

FastPath® Summary

1 Mar 2009. 19:43 (GMT)

Basic Operation	
Mode	VVI
V. Triggering	Off
Magnet Response	Battery Test
V. Noise Reversion Mode	VOO
Sensor	Passive
Threshold (Measured Avg.)	Auto (+0.0) (2.0)
Slope (Measured Auto)	Auto (+2) (8)
Max Sensor Rate	130 bpm
Reaction Time	Fast
Recovery Time	Medium

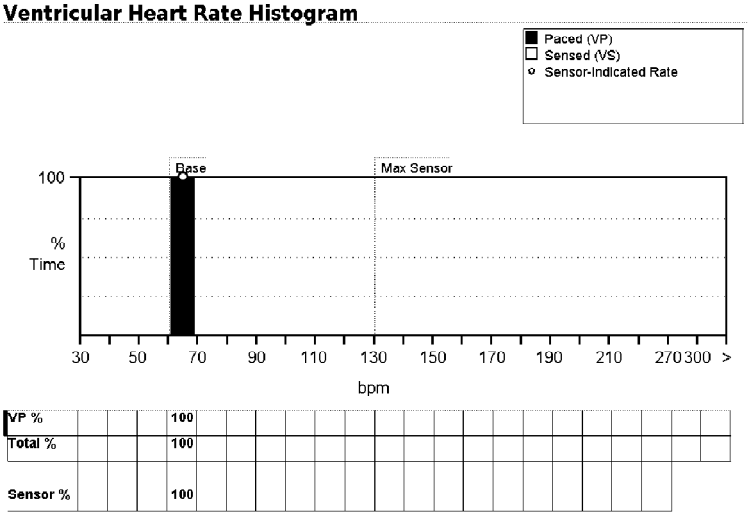
Rates	
Base Rate	60 bpm
Rest Rate	Off
Max Sensor Rate	130 bpm
Hysteresis Rate	Off

Capture & Sense	V
AutoCapture	Off
Pulse Amplitude (Safety Margin)	5.0 V (Unknown)
Pulse Width (Safety Margin)	0.4 ms (Unknown)
AutoSense	Off
Sensitivity (Safety Margin)	2.0 mV (Unknown)

Leads	V
Lead Type	Unipolar
Pulse Configuration	Unipolar
Sense Configuration	Unipolar Tip
Lead Monitoring	Monitor
Lower Limit	200 Ω
Upper Limit	2,000 Ω

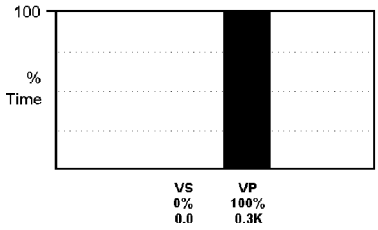
Refractories & Blanking	
Rate Responsive V Ref	Low
Shortest V Ref	175 ms
V Pace Refractory	250 ms
V Sense Refractory	250 ms

Ventricular Heart Rate Histogram



Events

	Sampled	Lifetime
VP	100 %	51 %
VSt	n/a	0 %



0m 0d 0h 4m Sampled since Last Cleared | Last Read: Today (19:43) | Last Cleared: Today (19:39)

Appendix 4: Merlin.net Connectivity Fact Sheet

Connectivity
Fact Sheet

WHAT IS CONNECTIVITY?

The intersection of the Internet and mobile technologies with innovative medical device therapies has created the ability to advance patient care through remote monitoring and EHR management.

There are many components involved in device connectivity: the programmer used in the physician's office to establish and optimize the device settings; the patient care network that stores device information, makes it accessible via the Internet or transfers the information to a electronic health record; the device itself, transmitting remotely using radiofrequency; and the unit that allows patients to transmit data at home from their device to their physician.

THE PROGRAMMER

The Merlin™ Patient Care System is a programmer for St. Jude Medical cardiac resynchronization therapy (CRT) devices, implantable cardioverter defibrillators (ICDs) and pacemakers. The system is designed to allow quick and efficient programming at the time of implant and at patients' follow-up visits.

The Merlin Patient Care System is a powerful, portable computer that is designed to help physicians efficiently conduct cardiac tests, analyze therapeutic and diagnostic data, and program implanted devices to meet patient needs.

Physicians can quickly make changes to device therapy through the system's LCD touch-screen, and the device settings can be downloaded in a .pdf format to be easily uploaded to electronic health record systems.

THE IMPLANTABLE DEVICE

Devices such as the Accent™ RF Pacemaker and Fortify™ ICD (implantable cardioverter defibrillator) feature radiofrequency (RF) telemetry for wireless communication with programmers used by physicians to interrogate and program devices.

RF telemetry enables secure, remote communication between the implanted device and the programmers in a clinician's office as well as in the EP lab. Wireless communication occurs while the device is being implanted and when patients see physicians for follow-up visits, allowing for efficient, more convenient care and device management.

REMOTE MONITORING

Until recently, patients with implanted cardiac devices were typically required to visit doctors' offices several times per year to have their device performance checked. With the advent of transmitters capable of downloading and transmitting full device data over telephone lines, the information can be acquired automatically and periodically sent from the patient's home to a secure website for review by an appropriate health care professional.

In addition to regular remote follow-up appointments, the Merlin@home transmitter also enables remote monitoring of devices. It conducts nightly diagnostic readings of the device, initiates unscheduled transmissions based on pre-defined alerts and securely transmits any vital device information to the patient's clinic.

The Merlin@home transmitter is transportable and can be set-up wherever a standard phone line is available, typically by the bedside for data transmission while the patient sleeps. Alternatively, using St. Jude Medical's Wireless USB Adaptor, a small device that plugs into Merlin@home transmitters, patients are able to transfer data to their physician over cellular networks. Data downloaded by the Merlin@home transmitter is sent to Merlin.net™ Patient Care Network (PCN), a secure, Internet-based data management system, where it is stored for review by the patient's clinic.

ELECTRONIC DEVICE RECORD MANAGEMENT

The Merlin.net PCN is an Internet-based central repository offered by St. Jude Medical for patient device data gathered at the time of implant procedures, during in-clinic follow-up visits and remote device interrogations. Data from every device interaction, whether it be remote, in-clinic or patient initiated, can be aggregated into the Merlin.net PCN to provide physicians with the ability to monitor and assess patient device data. Since the Merlin.net PCN was first launched in 2008, more than 100,000 patients have been enrolled worldwide. This enrollment milestone took similar competitive products more than five years to achieve.

Merlin.net PCN includes an automated interactive voice response feature, DirectCall™ Message, which clinics can use in substitution of routine patient telephone calls. The DirectCall Message automated communication system can call patients to remind them of upcoming remote follow-up appointments, notify them if they missed a remote follow-up appointment, inform patients that their remote transmissions have been reviewed by the clinic and the results look normal and inform patients to contact the clinic.

DirectCall Message does not replace necessary office visits or reduce contact with physicians. However, it is expected to reduce the number of routine calls usually made by clinic staff, while making sure that patients receive timely and important reminders and notifications.

St. Jude Medical is the only cardiac rhythm management company able to transfer information directly from the remote care system to a patient's electronic health record using the requirements established by the IHE (Integrating the Healthcare Enterprise), which promotes standards for securely sharing healthcare information across clinical settings. St. Jude Medical also fully supports HL-7, an important healthcare communication protocol. Meeting these standards helps make the transfer of patient data from Merlin.net PCN to the clinic's EHR system seamless and secure.

The data transferred using the Merlin@home transmitter are fully encrypted and meet or exceed all applicable national data privacy and security requirements in every country where the Merlin.net PCN is used. In addition, BSI Management Systems, an international standards testing, registration and certification organization, has awarded St. Jude Medical the information security certification ISO/IEC 27001:2005. This ISO certification, a stringent worldwide information security standard, recognizes that the St. Jude Medical Merlin.net PCN has established processes and standards that maintain the strictest levels of confidentiality, integrity and availability for its customers. The Merlin.net PCN is the first medical device data network to be recognized with this certification.

The Merlin.net PCN was also recognized as a silver winner of the 2009 Medical Design Excellence Awards, an award competition that is organized and presented by Canon Communications LLC and is the only awards program that exclusively recognizes contributions and advances in the design of medical products.