

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 an 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.

On scheduled follow-up dates, the St. Jude Medical Merlin@home™ transmitter uses RF wireless telemetry to download data from a patient's device. The entire follow-up procedure is conducted without any direct patient involvement. The only requirement is that the patient remains within range of the transmitter while it reads data from his or her device.

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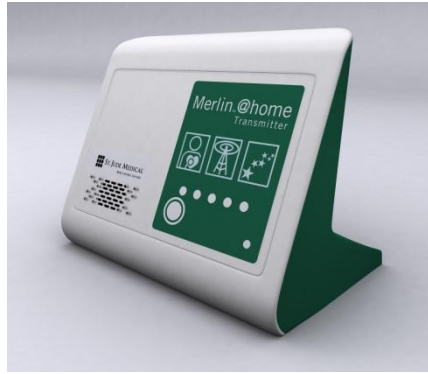
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In addition to regular remote follow-up appointments, the Merlin@home transmitter also enables remote monitoring of devices. It conducts nightly diagnostic readings of the device, initiates unscheduled transmissions based on pre-defined alerts and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

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