

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™; Pacerart™; 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., Pacerart 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



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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 Tachy Therapy Disabled
Device Alert Triggers*	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, Catalanian Spanish, UK English

Patient

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

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Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use. Devices depicted may not be available in all countries. Check with your St. Jude Medical representative for product availability in your country. Unless otherwise noted, ™ indicates a registered or unregistered trademark or service mark owned by, or licensed to, St. Jude Medical, Inc. or one of its subsidiaries. ST. JUDE MEDICAL, the nine-squares symbol and MORE CONTROL. LESS RISK. are registered and unregistered trademarks and service marks of St. Jude Medical, Inc. and its related companies. ©2009 St. Jude Medical, Inc. All Rights Reserved. Paceaart is a trademark of Medtronic USA, Inc. Cardiostation is a trademark of Universal Medical Inc., a mednet company. NextGen is a trademark of NextGen Healthcare Information Systems, Inc. GEMMS is a trademark of Gateway Electronic Medical Management Systems, LLC. Lumedx is a trademark of Lumedx Corporation. GE Centricity is a trademark of GE Healthcare. Allscripts is a trademark of Allscripts, LLC. IHE is a trademark of Healthcare Information and Management Systems Society Corporation. Misyis is a trademark of Misyis PLC. Printed in Belgium. Order No: GMC607EN



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