Merlin.net[™] Patient Care Network (PCN) Version 5.0

Product Highlights

- Merlin.net PCN version 5.0 from St. Jude Medical allows more efficient remote management of patients with implanted cardiac devices, including pacemakers, implantable cardioverter defibrillators and cardiac resynchronization therapy devices.
- One-screen Follow-up allows clinicians to view, print, schedule, export and archive from the Recent Transmissions page. This feature also saves time and simplifies follow-ups by allowing clinicians to take action on up to 50 patient files at once.
- DirectAlerts[™] Notification is a physician notification system that provides physician-designated patient alerts between follow-ups.
- Mobile DirectAlerts[™] Notification allows alert-triggered EGMs and reports to be viewed directly on a smartphone; notifications are sent with a doctor's individualised security stamp.
- Patients now have a new way to connect from home for remote follow-ups and monitoring with Merlin.net PCN Wi-Fi Connectivity.
- Alerts generated from the device-based CorVue™ Congestion Monitoring feature, which measures intrathoracic impedance in multiple vectors for improved accuracy, are displayed; options for both patient and physician alerts are provided.
- EHRDirect™ Export allows automatic export of transmission data from Merlin.net PCN to a clinic's EHR system. This allows seamless integration of data so care teams can make informed clinical decisions more quickly, without the need for expensive intermediary systems. This feature meets the Integrating the Healthcare Enterprise (IHE™) guidelines, supporting Health Level-7 (HL7) standards.
- Inductive Merlin@home™ transmitters† can now be used with newer Epic™ family devices and Atlas™ family devices as well as other newer devices. Going forward, inductive Merlin@home transmitters† will be issued to patients with newer Epic ICD or Atlas ICD implants. However, Housecall™ Plus transmitters will still be available† for patients with older Epic ICDs and Atlas ICDs.
- Merlin.net PCN now features device support for the Unify Quadra™ CRT-D and the Accent™ MRI RF Pacemaker.
- SmartSchedule™ is an 18-month, rotating perpetual calendar that creates an automatic follow-up transmission schedule. Clinicians can specify length of time, including 91-day and 182-day periods, between transmissions to coordinate follow-ups with the clinic's reimbursement calendar.
- DirectCall™ Message is an integrated and automated patient communication system designed to save clinic time by reducing routine calls otherwise performed by medical office staff.
- DirectTrend™ Viewer provides dynamic views of device and clinical trends for comprehensive patient management.
- Merlin.net PCN was the first medical device network to be awarded ISO 27001 certification, a stringent worldwide information security standard.





Customer Support: 46-8-474-4756

IS 541672

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of Biret Jummary: Prior to using these devices, please review the instructions for use for a complete listing or indications, contraindications, contraindications, contraindications, contraindications, contraindications, contraindications, 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, Mindicates that the name is a trademark of, or licensed to, St. Jude Medical or noe 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.

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Product Specifications

Merlin.net PCN Specifications			
Connectivity		Website Efficiency	
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	Batch operation	Automatic export to EHR is supported by version 5.0 through EHRDirect™ Export to increase clinic efficiency; print, archive, export to EHR, export
Compatible EHR/data management systems	All HL7-compliant EHR systems are compatible. Currently available with: GEMMS™ ONE EHR; Allscripts™ Professional EHR; NextGen™ Ambulatory EHR; EpicCare™ Ambulatory EHR; and	Consolidated data Data storage capabilities	to PC database up to 50 records at a time Remote transmissions and in-clinic data available online All patient transmissions and reports available for immediate access
	GE Centricity™ EHR. Plus compatible with device management solutions such as Paceart™ and ScottCare™ OneView. Ongoing	Data transfers	for a minimum of seven years Patient data follows patient when changing clinics or when patient
IHE compatible	work to integrate with other leading EHR systems. YES	Languages	receives new device English, Spanish, French, German, Italian, Japanese
Supports HL7 ISO 27001 certified	YES YES	User Interface	
Scheduling		Design principles	Similar to Merlin™ Patient Care System (PCS) programmer in colors and design; easy to learn for new users
Online scheduling	Authorized users may schedule patient follow-ups. Automated (SmartSchedule™ Calendar) and manual scheduling options available.	Report format Tracking of reviewed transmissions	Similar to Merlin PCS reports for easy orientation. Viewed field on recent transmissions allows quick indication of which reports have already been viewed; printing reports option to mark as
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.	Transmission status, reason for transmission displayed	viewed as well Scheduled, alert-initiated, patient-initiated
Alerts and Notifications		Next transmission column Number of days between transmissions	Date and intervals of next scheduled transmission Shown on recent transmissions, patient list, view schedule and
Daily alert surveillance	DirectAlerts [™] Notification available with Merlin@home [™] transmitter for all supported devices. Event-based or full disclosure uploads as needed.	ldentify previous user Rapid alert viewing	manual schedule pages Placing mouse over transmission time shows previous user Mouse-over alerts shows list of alert types and alert episodes
Programmable alerts Diagnostic alert triggers*	Physician/clinician option to select only the alerts they want to receive Congestion Duration Exceeded Programmed Threshold ST Episode Detected **AT/AF Episode Duration > Threshold	Clinical comments Arrhythmia and device management box Highlight transmissions with alerts Inbox/outbox Weekly glance	Free form, clinic defined or both Tally of recent transmissions by type Customisable by administration Recent transmissions/patient list segments files into new and old Convenient overview of upcoming transmissions
	**AT/AF Burden > Threshold **Avg. Y Rate During AT/AF > Threshold	Education	
Therapy alert triggers*	Percent RV Pacing > Threshold Percent BiV Pacing < Threshold High Ventricular Rate Episodes Recorded	Interactive practice site	Available
morapy diote triggero	High Voltage Therapy Delivered Successful ATP Pacing Delivered	Patient Communication	
Device alert triggers*	Therapy Accelerated Rhythm Longevity Analysis (requires Tech Services support) Tachy Therapy Disabled Charge Time Limit Reached Possible HV Circuit Damage Device Reset	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 Remote follow-up reminder call — sent automatically Remote follow-up missed call — sent automatically Emergency contact, if enabled — sent automatically
	Device in MRI Settings HV Lead Impedance Out of Range Atrial Pacing Lead Impedance Out of Range (Dual Chamber and CRT Devices) Device Programmed to Emergency Pacing Values Back Up VVI Possible High Voltage Lead Issue LV Pacing Lead Impedance Out of Range (CRT Devices) RV Pacing Lead Impedance Out of Range High Voltage Lead Impedance < Lower Limit High Voltage Lead Impedance > Upper Limit Device Parameter Reset	Multiple language support	DirectCall Message tool available in over 20 languages, including English, Spanish, French, Italian, Japanese, German, Dutch, Portuguese, Finnish, Swedish, Danish, Norwegian, Czech, Hungarian, Castilian Spanish, Polish, Turkish, Slovak, Catalonian Spanish, UK English
		Patient	
		Start-up guide	Transmitter Quick Start Guide (QSG) w/step-by-step setup options
		Support Materials for Patient and Clinic	
		Various support materials available. Please materials.	e meet with sales representative for full complement of training and support
Alert notification options	E-mail, fax, SMS, website, voice message or smartphone		
Alert reports	Alert Summary Report AT/AF alert report accompanies AT/AF alert	Merlin@home RF Transmitter Specification	18

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

Width: 9,18" Dimensions

Height: 6.33 Depth: 5,06" Wand cable length

Power cord length Minimum 1,5 meters V.92 (56K) - Custom Design Modem

Power source 100-240V Line voltage 50-60 Hz

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

RF models of the Unify™ Family of CRT-Ds, the Promote™ Family of CRT-Ds, the Current™ Family of ICDs, the AnalyST™ Family of ICDs, the Fortify™ Family of ICDs, the AnalyST™ Family of ICDs, the Fortify™ Family of ICDs, the AnalogsT™ Family of ICD

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

The Unify™ Family of CRT-Ds, the Promote™ Family of CRT-Ds, the Atlas™ Family of CRT-Ds, the Current™ Family of ICDs, the AnalyST™ Family of ICDs, the Epic™ Family of ICDs, the Convert™ Family of ICDs, the Anthem™ Family of CRT-Ps, the Accent™ Family of Pacemakers and the Nuance™ Family of Pacemakers (Japan)

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

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For use with compatible RF devices

Transmitter stays with the patient when changing clinics or when patient receives new device from the same family

Transmitter can be issued to patient and paired with his/her device

Ability to link/re-link transmitter to a patient's device remotely

before discharge for remote monitoring from day one





Transmitters

Merlin@home RF (radio frequency)

† Available in select markets only

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