Merlin.net[™] Patient Care Network

Arrhythmia and Device Management Application

Help Manual



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Introduction

This manual contains information and instructions for interacting with the Merlin.net[™] Patient Care Network (PCN). Refer to the appropriate device user's manual for a complete listing of device-specific indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

Intended Purpose

The Merlin.net[™] PCN is intended to allow clinicians to view and remotely monitor a patient's implanted heart device data and condition via the web portal by receiving the data from a transmitter, programmer or mobile application and displaying it for review on Merlin.net PCN by authorized clinic personnel.

Intended Users

The Merlin.net[™] PCN should be used by or under the supervision of physicians or allied health professional trained in the management of implantable heart devices.

Indications

The Merlin.net[™] PCN is indicated for remotely monitoring patients with bradyarrhythmias, tachyarrhythmias, sinus pauses, and/or heart failure who have compatible implantable heart devices.

Intended Patient Population

The Merlin.net[™] PCN is intended for healthcare professional who are managing patients with a compatible implanted heart device who require remote monitoring and follow-up. Please see the compatible implanted heart device IFUs for specific intended population.

Intended Clinical Benefits

The intended clinical benefits of telemonitoring system transmitters may include the following:

- Secured transmission of patient data
- · Frequent remote monitoring of patients implanted with cardiovascular implantable electronic devices (CIEDs)
- Reduction in hospitalizations

Log In

Access the Merlin.net[™] Patient Care Network (PCN) at europe.merlin.net.

See System Requirements (page 11) to ensure you have the correct applications to log in to europe.merlin.net.

To log in to the Merlin.net PCN:

1. Enter the user ID and password and select the Sign in option.

- If this is your first time logging in:
- 1. Enter the user ID and the temporary password given to you by your clinic administrator and select the Sign in option.
- 2. Enter and confirm the new permanent password.
- Merlin.net PCN prompts you for an authentication code.
- 3. Select email to receive an authentication code.
- 4. Check your email to receive your authentication code
- 5. Enter your authentication code.
- 6. Select the Verify code option.
- 7. Read the Terms and Conditions and select the Accept option.

Password Requirements

Use the instructions displayed on the Merlin.net[™] PCN screen to set your password.

If you forget your password, in the Log In window, select the Forgot my User ID and/or Password option, type your user ID and email address. A new temporary password will be emailed to you. You are prompted to type your password the next time you log in to the Merlin.net PCN. You can also change your password in the My Account window by selecting your Signed in as user name.

If you are a clinic administrator and you forget your user ID, contact Technical Support (page 11).

Merlin.net Applications

The Merlin.net[™] PCN contains the following application:

- The Arrhythmia and Device Management Application. Provides information about and enables management of the patient's device.
- The Merlin.net PCN can interface with the following Merlin@home™ transmitter models: EX1100 and EX1150.

Log Out

To log out, select the Sign out option in the upper right-hand corner of the screen. Before closing your browser, sign out or terminate your session.

NOTE: The Merlin.net[™] PCN will time out after 60 minutes of inactivity.

Arrhythmia and Device Management Application

Clinic Types

The referring clinic:

- Enrolls new patients, receives transmissions and alerts.
- Has access to all of the patient management functions of the implanting clinic.

Recent Transmissions

The Recent Transmissions tab displays transmissions that have not been archived. If it is archived it will show up in the list of All Transmissions (page 6). Each transmission is the result of a remote follow-up session. See Follow-up Sessions (page 12). The following table shows information displayed on the Recent Transmissions tab (depending on your clinic's configuration). See the More Actions dropdown menu (page 4) to add or remove columns.

Table 1. Information displayed on the Recent Transmissions tab

Information Type	Description
Patient	Patient name and patient ID number (assigned by your clinic). Select the patient's name or patient ID to view the Patient Profile (page 6).
	 Open envelope icon. Indicates the Physician or Allied Professional User Types (page 9) have viewed or printed the transmission report.
	 Closed envelope icon. Indicates the Physician or Allied Professional User Types (page 9) have not viewed or printed the transmission report.
Transmission	Indicates the date; time; and if there is a patient-initiated transmission, an alert-initiated transmission, or a scheduled transmission. Select the transmission date and time to view the Transmission Details (page 4).
	 Patient initiated. The patient initiates an unscheduled transmission.
	 Alert initiated. A transmission occurs because the daily device check detects an alert.
	 Scheduled. The transmission arrives within 24 hours of scheduled date. For patients monitoring their device using mobile patient applications, the transmission is marked as scheduled when it results from a scheduled follow-up on the mobile patient applications.
Schedule	Select the date of the next scheduled transmission, or None if there is no scheduled transmission, to view or change the patient's follow-up schedule (page 6). The number of days between the current transmission and the next transmission is also shown.
Location	Location of the patient's clinic.
Device	Shows the model name and serial number of the device that is implanted in the patient at the time of the transmission. The model name and serial number can be different from a past transmission if the patient's device has changed.
DirectAlerts™ Notification feature	Shows a red flag or yellow flag for new alerts detected in the transmission. If a DirectAlerts notification contains both a red and yellow flag, only the red flag will show. Select the flag to navigate to the DirectAlerts notification feature for the patient to customize the DirectAlerts settings.
Alerts List	Shows a list of alerts. If the transmission alerts list contains a link related to episodes, then you can navigate to the episodes and electrograms (EGMs) for that transmission. See Transmission Details (page 4).
Latest Comments	Shows the latest comment for the patient. Select the pencil icon to add comments.
Checkbox	Select the checkbox to perform an action on one or more transmissions, then select the More Actions dropdown menu (page 4).

To filter the Recent Transmissions tab, do either of the following:

Select one or more options from the Search dropdown menu.

• Type information such as the patient name, ID, or device in the search field.

To sort a column in the Recent Transmissions tab

• Select the column header.

NOTE: For information on transmission issues or incomplete reports, contact Technical Support (page 11).

Archive a Transmission

Your clinic determines the steps required to complete a follow-up session. All transmissions can be archived.

NOTE: If your clinic is a service provider account, your administrator must grant you privileges to archive a transmission. See Clinic Profile (page 7).

To archive a transmission:

1. Select the checkbox for one or more transmissions.

- 2. Select the Archive button.
- The transmission is removed from Recent Transmissions, but you can still access it from the Patient List (page 5):
- 1. In the Patient List tab (page 5), select the Patient Name.
- 2. Select the All Transmissions link.

Print a Transmission

- 1. Select the checkbox for one or more transmissions.
- 2. Select the Print button.
- 3. Select the reports you want to print. You can also print all reports for the transmissions that you selected.
- 4. Select the Print button.

NOTE: Your Merlin.net[™] PCN administrator sets the default printing preferences for your clinic, but you can choose your own preferences each time you print.

More Actions Dropdown Menu

Select the checkbox for one or more transmissions to:

- Mark as unviewed
- Export Transmission (page 4)
- Copy transmission to disk (page 4)

From the More Actions Dropdown menu you can also:

- Print List
- Download Spreadsheet
- Add or Remove Columns

Export Transmission

NOTE: For Merlin.net[™] PCN administrators: To export a transmission, you must enter clinic export options. See Change Clinic Settings (page 9).

To export the PDF reports associated with a transmission to a PC database or your computer (transmission data):

- 1. In the Recent Transmissions tab, select the checkbox for the transmission(s) you want to export.
- 2. Select the More Actions dropdown menu.
- 3. Select Export Transmission.
- 4. Select the Export Type.
- 5. Select the Export button.

Copy Transmission to Disk

You can copy transmissions from the Merlin.net[™] PCN to a PC hard drive, network drive, or USB drive.

- 1. Select the checkbox for one or more transmissions you want to copy.
- 2. Select the More Actions dropdown menu.
- 3. Select Copy transmission to disk.
- 4. Navigate to the location where the transmission is to be saved.
- 5. Select the Save button.

Transmission Details

To view the Transmission Details:

Select the Transmission Date and Time link.

Transmission Details may include the following links or reports (depending on the patient's device, the type of transmission, and your clinic's configuration): **Summary.**

- The FastPath[™] Summary link shows information on the overall status of the device.
- The Episode Summary link shows information about any episodes reported in the transmission.
- The Diagnostics Summary link shows a summary of paced and sensed events. More details are in the Extended Diagnostics tab.
- Percent Pacing link displays the Percent Pacing graph. The percentage of atrial and/or ventricular pacing is shown over time. Percent Pacing alerts are
 marked with a triangle.
- MRI Summary link shows any MRI information reported in the transmission.
- Patient Info and Leads link.¹ The Patient name, implant date, and lead information appear only if they were entered in Patient Information on the
 programmer.

Alerts and Episodes.

• The Alert Summary link shows the alerts for a transmission.

The Episodes and EGMs link shows all the episodes for a transmission. To view or print the episode or EGM report, if available, select the Date/Time link or the EGM button. If there is an EGM available, clicking on the EGM icon will open the episode PDF.

NOTE: The initial position of the EGM will be at the Trigger position (when available), and the initial gain will fit the displayed EGM.

The full episode list can be downloaded to a CSV file.

• The Extended Episodes tab provides detail on the episodes reported in the transmission.

Diagnostics.

- Extended Diagnostics link
- Heart In Focus[™] link shows a report on the patient's status that the clinician can send to the referring physician.
- ST Monitoring link
- AT/AF link
- DirectTrend Report link
- Tachy Diagnostics link ²
- Brady Diagnostics link ³

Tests.

- Test Results
- RTM Trend link. Shows the Real-Time Measurement Trend report.
- Capture Threshold link
- CRT Toolkit ⁴

Parameters.

Other.

View Merged Report

² Available for Atlas and Epic device families only.

¹ Available for Atlas and Epic device families only.

 ³ Available for Atlas and Epic device families only.
 ⁴ Available for CRT devices only.

Available for CRT devices only.

Quick Links

Use the links provided to access clinic messages and information for transmissions or patients with similar status.

Patient List

The Patient List tab shows information for each patient in your clinic's Merlin.net[™] PCN.

The Patient List tab contains the following information (depending on your clinic's configuration). See the More Actions dropdown menu (page 5) to add or remove columns.

Patient. Patient name and patient ID number (assigned by your clinic).

 Select the patient's name to view the Patient Profile (page 6). The number 2 appears next to the patient's name if the patient is enrolled in both Merlin.net Applications (page 2). When you move your mouse over the number 2, the name of the patient's clinic for the other application appears.
 Patient Status. Specifies if the patient is Active or Expired, his or her device has been Explanted, he or she has been Removed from the Merlin.net PCN.

Device. Shows the model name and serial number of the device that is implanted in the patient at the time of the transmission. The model name and serial number can be different from a past transmission if the patient's device has changed.

Implant Date. Shows the implant date for the patient's currently implanted device.

All Transmissions. Shows the number of remote and in-clinic transmissions. Select the link to view the patient's past transmissions.

Latest Transmission. Shows the date of the most recent transmission. Select the link to view Transmission Details (page 4).

Next Transmission. Shows the date of the next scheduled transmission or None if there is no scheduled transmission. Select the date or None to view or change the patient's follow up schedule (page 6).

Connectivity. Shows the transmitter connection status to the Merlin.net PCN and the patient's implanted device.

Last Transmitter Communication. Shows the date the last time the patient's transmitter connected to Merlin.net PCN.

Connection Type. Indicates the method the patient's transmitter used to connect to the Merlin.net PCN. This is only available when the Patient List page is filtered for patients with Disconnected Transmitters or patients with Snoozed Disconnected Transmitter Monitoring.

Connectivity Note. A clinic-entered note about the patient connectivity status. This is only available when the Patient List page is filtered for patients with Disconnected Transmitters or patients with Snoozed Disconnected Transmitter Monitoring.

Latest Comments. Shows the latest comment about the patient's device. Select the pencil icon to add comments.

Checkbox. Select the checkbox to perform an action on a patient, then select the More Actions dropdown menu (page 5).

To filter the Patient list tab, do either of the following:

- Select one or more options from the Search dropdown menu.
- Type information such as the patient name, ID, or device in the search field.
- To sort a column in the Patient list tab:
 - Select the column header

Enroll a Patient

NOTE:

- The patient's medical team member should be enrolled before you enroll a new patient, so the medical team can appear in the patient's profile. See Add a User (page 9).
- If your clinic is a service provider account, you must enroll a patient to ensure his or her profile is associated with his or her transmissions. See Clinic Profile (page 7).
- A patient must be enrolled in the Arrhythmia and Device Management Application to view his or her information.

To enroll a new patient:

- 1. Select the Enroll New Patient button.
- 2. Choose one of the following:
 - Enroll a new patient (manually).
 - Enroll a patient by given name at birth, surname at birth, and date of birth.⁵
 - Enroll via INS (national individual registration number / French national eHealth ID number).⁶
- 3. Select the Enroll button.
- 4. For enrolling a new patient (manually), enter the information in each field for Patient & Device Data (fields marked by an asterisk (*) are required fields).
- 5. Select the Continue button.
- 6. Enter the information for each of the following:
 - Transmitter, Follow-up Schedule, DirectAlerts™ Notification, and Baseline Clinical Data
- 7. Select the Save and Close button.
- 8. Select the Finish button.

More Actions Dropdown Menu

Select the checkbox for a patient and select the More Actions dropdown menu to:

- Mass Change Process (page 5)
- Clear overdue status (available when the Patients with overdue follow-up filter is applied)
- Snooze notifications (available when the Patient List page is filtered for patients with Disconnected Transmitters or patients with Snoozed Disconnected Transmitter Monitoring)

From the More Actions Dropdown menu you can also:

- Print List
- Download Spreadsheet
- Add or Remove Columns

Mass Change Process

The mass change process enables you to make Scheduling and Messaging (page 7) changes for several patients at one time. To make a Mass change:

- 1. Select the checkbox for one or more patients.
- 2. Select the More Actions dropdown menu.
- 3. Select the mass change process link.

⁵ This enrollment option is available only in France.

⁶ This enrollment option is available only in France.

- 4. Select the field(s) to update.
- 5. Select the Save button.

Patient Information

Patient Profile

Select the patient's name from either the Recent Transmissions tab or the Patient List tab to go to the Patient Profile page. The Patient Profile includes the following links:

Patient and Device Data. Includes the patient's contact and emergency contact information. You can also View Leads (page 6) for the patient.

 Medical Team lists the physicians and clinicians assigned to review the patient's transmissions and receive alerts. See DirectAlerts[™] Settings (page 8). Service Providers (page 10) accounts restrict the physicians who can view patient records.

Transmitter. Includes information about the patient's Merlin@home transmitter.

- Perform daily DirectAlerts notification checks. Checks the patient's device daily for alerts that trigger a DirectAlerts notification.
- Lock out patients from sending unscheduled transmissions or DirectAlerts notification checks.
- Disconnected Transmitter Thresholds allow you to set thresholds for receiving notifications if the patient's transmitter is not connecting to the Merlin.net[™] PCN or if the patient's transmitter is not connecting to the patient's device to perform Device Alert checks.

Follow-up Schedule. Includes settings for the patient schedule and diagnostic clearing.

NOTE:

- Changes made to the follow-up schedule in the patient's profile override the clinic's default settings.
- To view the patient's follow-up schedule, select the View schedule button.
- If you select the Clear Diagnostics, Clear Episodes, or Clear Stored EGMs options, the items selected for clearing are only cleared during scheduled follow-ups. For patients using Merlin@home transmitters, clearing also occurs after patient-initiated follow-ups. Trended diagnostics cannot be cleared.

Clearing options depend on the transmitter used:

Merlin@home™ transmitter. Clear each individually (three checkboxes)

DirectAlerts™ Notification. Includes settings to select and classify the alert type notification. You can set the Merlin.net PCN to notify the clinic or the patient's medical team during or after office hours, or the patient's Merlin@home transmitter.

NOTE:

Changes made to DirectAlerts Notification settings in the patient's profile override the clinic's default DirectAlerts settings.

Baseline Clinical Data. You can record the patient's HF information and history when he or she was first admitted to the clinic.

View Lead Information

The patient's lead information appears in the Patient Lead Data window only if it was entered in Patient Information on the programmer. The patient must have at least one successful transmission before this information appears in the Merlin.net[™] PCN.

To View Lead Information from either the Recent Transmissions tab or the Patient List tab:

- 1. Select the Patient Name.
- 2. Select the View Leads link.

Edit a Patient

To edit a Patient Profile (page 6):

1. Select the patient name from the Patient List tab.

- 2. Select the Edit button.
- 3. Edit the information in the necessary fields.
- 4. Select the Save button.

NOTE: If you change the serial number or device name in the Patient and Device Data page and select the Save button, a screen appears asking if you want a device change out or data correction. Device change out option should only be selected after an explant of a valid device (patient gets a replacement device). Data corrections should only be selected if the previously entered model or serial numbers were entered incorrectly on the Merlin.net™ PCN. Data correction means that the patient's device is the same, but the serial number or device name entered in the Merlin.net PCN is being corrected. The serial number and device name must match the patient's device for the patient to successfully set up his or her transmitter and send transmissions.

Transmission

See Transmission Details (page 4).

All Transmissions

View All Transmissions for a patient:

- 1. Select the Patient's Name.
- 2. Select the All Transmissions Link.

Tools

Weekly Glance

The Weekly Glance shows the schedule for upcoming transmissions. Only the next scheduled follow-up for each patient is shown.

Messages

Messages include information about:

- Invalid transmitter pairing attempt. The patient failed to set up the transmitter for the first time.
- Transmitter not set up. The patient's transmitter is ordered or recorded in the Merlin.net[™] PCN but the transmitter is not yet set up within a defined period of time.
- DirectAlerts[™] notification could not be delivered because of incomplete contact information.

Select the check box for one or more transmissions to:

• Clear Message. Select the check box, select the Clear Message button.

Print. Select the checkbox, select the More Actions dropdown menu, select Print.

Import Process

Import Process allows you to transfer a patient's records (archive data) to your clinic's Merlin.net[™] PCN using a USB drive from either of the following systems:

- Merlin[™] PCS
- Merlin 2[™] PCS

NOTE: Any records that you import to the Merlin.net PCN must belong to a patient that is in your clinic's Merlin.net PCN database. The Patient List tab lists all patients in your clinic's Merlin.net PCN database.

Importing session records from Merlin and Merlin 2 PCS programmers allows selected reports from the programmer to be uploaded to the Merlin.net PCN. DirectAlerts[™] notifications will not be distributed for alerts that were present on the programmer when uploaded to the Merlin.net PCN. Reports will be uploaded in the archived state and viewable only using All Transmissions, not on the Recent Transmissions Page.

- To import a patient record:
- 1. Select the Tools tab.
- 2. Select the Import Process link.
- 3. Select the Browse button.
- 4. Navigate to the location of the patient record.
- 5. Select the Open button. Depending on its size, the record takes 5 to 20 minutes to appear in the Import Records screen.
- 6. On the Import Records screen, select the checkbox next to the patient record.
- 7. Select the Import selected records link.

To view the record:

- 1. Select the Patient List tab.
- 2. Select the link in the All Transmissions column.
- 3. Select the Transmission Time, Date link for the record.

Your User Profile and Preferences

To access your User Profile and Preferences, select your name next to Signed in as, at the top of the screen.

Change your User Profile and User Preferences

In your user profile, you can change your contact information (address, phone and fax numbers, email address) and Security Stamp, but you cannot change your profile data. Any changes you make to your user profile are saved globally.

NOTE: Ensure your phone number and email address are correct to receive communications from the Merlin.net[™] PCN. Communications include password resets, DirectAlerts[™] notifications, and authentication codes.

Your Merlin.net PCN administrator sets your clinic's Merlin.net PCN default preferences, but you can change the preferences for your account. Your account preferences apply to your Merlin.net PCN account only.

- To change your user profile and preferences:
- 1. Select your name next to Signed in as at the top of the screen.
- 2. Select the Edit button.
- 3. Select the field or fields to update.
- 4. Select the Save button.

Your Password

To change your password:

- 1. Select your name next to Signed in as, at the top of the screen.
- 2. Select the Change Password link.
- **3.** Type your current and new passwords.
- 4. Select the Save button.

For more information, see Password Requirements (page 2).

Clinic Administration

To manage user and clinic accounts, you must have administrator privileges. Any changes made to a user or clinic profile or to preferences are saved globally.

NOTE: To ensure Abbott Medical emails are not sent to your spam folder, add MNotification@abbott.com and noreply@abbott.com to your contact list. For more information, contact Technical Support (page 11).

Clinic Profile

- The Clinic's Profile shows:
 - Clinic Details
 - Address and Contact information
 - Regional settings

Edit a Clinic's Profile

To edit a Clinic Profile (page 7):

- 1. Select the Edit button.
- 2. Change the information.
- 3. Select the Save button.

Scheduling and Messaging

Follow-up schedule options include:

- Preferred scheduling method.
- SmartSchedule[™] calendar enables you to determine patients' automatic follow-up schedules.

- Manual entry calendar enables you to enter a date for each follow-up for each patient. Expired Day-at-a-Time schedules appear in the Messages (page 6) window.
- None means there are no follow-ups scheduled. You must remind the patient to send transmissions.

To determine the actual schedule:

- For each patient, see Patient Profile (page 6).
 - NOTE: Changes made to the follow-up schedule method in the patient's profile override the clinic's default settings.

For several patients at one time, see Mass Change Process (page 5).

Transmitter Settings.

- Perform daily DirectAlerts[™] checks ⁷. Checks the patient's device daily for alerts that trigger a DirectAlerts notification.
- Lock out patients from sending unscheduled transmissions or DirectAlerts checks. If the lock out option is checked, patients are not allowed to conduct
 unscheduled sessions or DirectAlerts checks.
- Collect DirectTrend[™] Viewer Diagnostics ⁸
- Automatically Clear. Clears selected diagnostics, Episodes, and Stored EGMs at the end of each follow-up.

Disconnected Transmitter thresholds. You can set thresholds to be notified when:

DirectAlerts checks are not received by the Merlin.net PCN.

Clinic Hours and Holidays

Clinic hours and holidays specify:

- Your clinic's normal office hours
- Holidays that your clinic is closed
 - NOTE:
 - If a follow-up is scheduled on a holiday, the follow-up occurs as scheduled.
 - On holidays, DirectAlerts[™] notifications are sent according to the after office hours schedule.
 - Each clinic is responsible for monitoring its own holiday schedule.

Change Clinic Hours/Holidays

To change Clinic Hours/Holidays:

- 1. Select the Edit button.
- 2. Change the information.
- **3.** Select the Save button.

DirectAlerts[™] Settings

DirectAlerts[™] Settings notifies the clinic or patient when the patient's device triggers an alert.

- Alert types are categorized by device type. You can choose:
 - Alert types that cause notification. Set alerts as Red, Yellow, or OFF (does not trigger notification).
 - Merlin@home™ transmitter only. Inform Patient feature notifies the patient via their Merlin@home transmitter. Some alerts, such as % Pacing, do not support the Inform Patient feature. When the patient is informed of an alert, their emergency contact is also notified (if specified).
 - To view supported device model numbers, select the Show devices button. NOTE:
 - For DirectAlerts™ settings notification of some alert types, you must enable the alert in the device using the Merlin™ PCS or Merlin 2™ PCS.
 - Merlin@home transmitter only. The Backup VVI alert, even if enabled, is sent to the Merlin.net[™] PCN only if the patient's Merlin@home transmitter with RF capability and device are within arm's length.
 - The % Pacing alert is triggered by the weekly enhanced diagnostics data collection.
 - Not all alerts for each device model are available in the Merlin.net PCN for distribution. For information about alerts for a patient's device, see the DirectAlerts Notification tab in the patient's profile.
 - Changes made in the Patient Profile override the clinical default settings.
 - For existing patients in the clinic, only those DirectAlerts settings without overrides will be updated. Review alert settings for existing patients after changing the clinic level settings.
 - The DirectAlerts Notification settings for the clinic will be used when enrolling new patients.⁹

Notify the clinic about:

- Red or yellow alerts during or after office hours. The clinic's hours are specified in Clinic Hours and Holidays (page 8).
- Where DirectAlerts notifications are sent during office hours and after hours. You can specify notification via email, text message, or phone, and whether
 notification is sent to the patient's medical team.

Abbott provides default DirectAlerts settings by device and monitoring method. To change the clinic's DirectAlerts settings:

- 1. Select the device type and monitoring method link.
- 2. Select the Edit button.
- 3. Change the clinic's DirectAlerts settings.
- 4. Select the Save button.

Clinic Settings

Clinic settings are the default setting for all Merlin.net[™] PCN users in the clinic. Clinic settings include:

Report settings. Select the reports that are printed by default. Select the time range of clinical comments that are printed. Select clinic preferences for options listed under Other Features, as applicable.

Clinical Comments. Free form text enables clinicians to write their own clinical comments. Pre-set comments enables clinicians to choose from a list of predefined comments.

NOTE: A user can change some of the clinic's default settings for their account.

⁹ For existing patients in the clinic, only those DirectAlerts settings without overrides will be updated. Review alert settings for existing patients after changing the clinic level settings.

⁷ Merlin@home transmitter Models EX1150 and EX1150W only.

³ Automatic collection is not supported when using Merlin@home Transmitter Model EX1100.

Change Clinic Settings

- 1. Select either Report Settings, Export Options or the Clinical Comments link.
- 2. Select the Edit button.
- 3. Change the information.
- 4. Select the Save button.

Clinic Users

The Clinic User list shows all current Merlin.net[™] PCN users in your clinic. To filter the User list, select an option from the All User Types dropdown menu. To sort the User list, select a column header.

User Types

All users can view all transmissions in the Recent Transmissions tab. User types include:

- Physician:
 - Views only his or her patients' transmissions by default
 - Can archive transmissions
- Allied Professional
- Can archive transmissions
- Assistant
- Views a transmission. The "viewed" status does not change
- Cannot archive transmissions

Add a User

When adding a user (page 9), you can choose whether to give a user administrator privileges.

- Administrator privileges enable a user to:
 - Add, change and remove other users' profiles
 - Assign a temporary password if a user forgets his or her password (page 2)
 - Modify clinic information and clinic preferences

Assign the user's email address and security stamp for the Mobile DirectAlerts[™] Application ¹⁰.

NOTE: Add a new user before adding his or her patient, so the user can appear in the patient's medical team. See Enroll a Patient (page 5).

For service provider accounts, administrators can give a user privileges to enroll a new patient, change or release patient profiles, and archive transmissions. Administrators can also determine which clinic locations are visible to a user. See Service Providers (page 10).

To add a user:

- 1. Select the Clinic Users link.
- 2. Select the Add a user button.
- 3. Enter the new user's profile information.
- 4. Select the Save button.

Delete a User

- 1. Select the Clinic Users link.
- 2. Select the User's Name.
- 3. Select the More Actions dropdown menu.
- 4. Select the Delete User link.

User Profile

- In the User List (page 9), select a user to view his or her profile, which contains:
 - User ID and password. You can reset the password when you change a user's profile. See Change a User Profile (page 9).
 - Profile data, including administrator privileges (page 9).
 - Contact information.
 - Application Preferences.
 - To change your default application preference: Select the Edit button, select the desired application default preference, and then select the Save button.

Change a User Profile

- 1. Select the Clinic Users link.
- 2. Select the User's Name.
- 3. Select the Edit button.
- 4. Change the information.
- 5. Select the Save button.

Clinic Locations

The Clinic Locations tab lists all your clinic locations in the Merlin.net™ PCN database. To sort the clinic location list, select the column header.

Add a Clinic Location

- 1. Select the Clinic Locations link.
- 2. Select the Add a location button.
- 3. Enter the new clinic's location information.
- 4. Select the Save button.

Delete a Clinic's Location

1. Select the Clinic Locations link.

- 2. Select the radio button of the Clinic Name.
- 3. Select the More Actions dropdown menu.
- 4. Select the Delete a Location link.

Service Providers

Service providers accounts include (depending on your clinic's configuration) the following attributes:

- Administrators control user privileges to enroll new patients, change patient profiles, or archive transmissions.
- Allied Professionals can view all patient records that belong to the clinic. However, a physician can view only patient records that have been assigned to:
 Physician's account. See Patient Profile (page 6).
 - Location at which his or her account has viewing privileges.

Patient Privacy Settings

This feature (depending on your clinic's configuration) securely sends DirectAlerts™ notification emails.

Additional Information

System Requirements

To operate the Merlin.net[™] PCN, the following must be installed on your computer.

NOTE: Performance issues may result with other configurations.

- Microsoft‡ Windows‡ 10 operating system. Android‡ and iOS‡ operating systems are also supported for most website functions.
- Modern browser, such as the Chrome‡ or Microsoft Edge‡ browser. Other browsers may work but could show reduced performance.

For optimal viewing of the Merlin.net PCN, your screen resolution must be 1440 x 900 pixels at a minimum.

Data Security

Abbott Medical takes a broad and deep approach to ensuring the safety, security and privacy of the patient information and data on our devices and systems connecting patients to healthcare providers and clinics. Patients, clinical staff, and hospital IT staff do not need to implement any cybersecurity controls for intended operation of the Merlin.net[™] PCN. All the cybersecurity controls are implemented by default. There are no configurable security configurations for external users, and there is no user action required if a cybersecurity vulnerability or incident is detected. Abbott Medical has processes to respond to cybersecurity vulnerabilities and incidents. Software updates are automatically installed whenever available.

The cybersecurity bill of materials (CBOM) for the MN5000 report generator is available upon request.

Visit the information page at abbott.com/cybersecurity to read more about the Abbott commitment to cybersecurity. Periodically, Abbott may update the website with important bulletins.

Summary of Safety and Clinical Performance

A summary of the safety and clinical performance for this device is available at https://ec.europa.eu/tools/eudamed. Search for your device in the UDI-DI Information section. This is the SSCP location after the launch of the European Database on Medical Devices/Eudamed.

UDI-DI Information

Please see the table below for the UDI-DI information for the Merlin.net[™] PCN.

Table 2. Basic UDI-DI Information

Basic UDI-DI	Model Number	Device Name	Device Type
5415067TEL0003K6	MN5000	MN5000 Report Generator	Web Based Software
Table 3. UDI-DI Information			
UDI-DI	Model Number	Device Name	Device Type
05414734509732	MN5000	MN5000 Report Generator	Web Based Software

Technical Support

In North America:

For Merlin.net[™] PCN patients, telephone Technical Support is available Monday through Friday (8 a.m. to 8 p.m. Eastern Standard Time). For clinicians, telephone Technical Support is available 24-hours a day.

For Merlin.net PCN support:

1 877 696 3754 (1 877 MY MERLIN) (toll-free within North America)

In Europe:

Telephone Technical Support is available Monday through Friday (08:00 to 17:00 Central European Time).

+46 8 474 4756 (Sweden) (Support in English and Swedish. For additional assistance, contact your clinic.)

Abbott Medical maintains 24-hour phone lines for technical questions and support:

- 1 818 362 6822
- 1 800 722 3774 (toll-free within North America)
- + 46 8 474 4147 (Sweden)

For additional assistance, call your local Abbott Medical representative.

If, in the course of use of this device, you have reason to believe that a serious incident occurred, please report it to the manufacturer. For customers in the European Union, report the serious incident to your national authority as well as to the manufacturer.

Patient Selection

To use the Merlin.net[™] PCN effectively, patients must:

 Have phone lines that use standard (RJ-11 modular) plugs, Wi-Fi‡, cellular, or compatible phone lines. Older plugs can only be used with an adapter. (Contact your phone company for additional information on adapters.). The Merlin@home™ transmitters cannot be used with phone systems in which the phone is wired directly into the wall.

NOTE: For more information see the Merlin@home Transmitter Model EX1100 User's Manual or the Merlin@home Transmitter Model EX1150, EX1150W User's Manual.

Supported Devices

The Abbott Medical device families that the Merlin.net[™] PCN supports are: ¹¹

NOTE: Some devices may not be available in your region.

- Accent[™] and Accent MRI[™] pacemakers
- Allure™, Allure™ RF, Allure Quadra™, Allure Quadra™ RF cardiac resynchronization therapy pacemakers (CRT-Ps)
- AnalyST[™] and AnalyST Accel[™] ICDs
- Anthem[™] pacemakers and Anthem[™] RF CRT-Ps
- Assurity[™], Assurity[™]+, Assurity MRI[™] pacemakers

¹¹ Devices must be programmed out of factory settings using a Merlin PCS or Merlin 2 PCS programmer before use with the Merlin.net PCN.

- Convert[™] ICDs
- Current[™], Current[™]+, Current Accel[™] ICDs
- Ellipse[™] ICDs
- Endurity[™], Endurity[™] Core, Endurity MRI[™] pacemakers
- Fortify[™], Fortify Assura[™] ICDs
- Merlin@home[™] transmitters
- Promote[™], Promote[™] RF, Promote[™]+, Promote Quadra[™], Promote Accel[™] CRT-Ds
- Quadra Allure[™], Quadra Allure MP[™], Quadra Allure MP[™] RF CRT-Ps
- Quadra Assura[™], Quadra Assura MP[™]CRT-Ds
- Unify™, Unify Assura™, Unify Quadra™, Unify Quadra MP™ CRT-Ds
- Zenex[™], Zenex[™] MRI, Zenus[™], Zenus[™] MRI pulse generators

For descriptions of specific Abbott Medical devices, warnings, cautions, and implantation instructions, refer to the user's manual for the applicable device.

Follow-up Sessions

There are two types of follow-up sessions:

- Remote follow-up sessions. In remote follow-up sessions, the transmitter retrieves data from the patient's device and sends it to the Merlin.net[™] PCN. For more information, see the appropriate transmitter manual.
- In-clinic follow-up sessions. You can import data from an in-clinic follow-up session into the Merlin.net PCN with a Merlin[™] PCS or Merlin 2[™] PCS programmer. See Import Process (page 7). For more information, see the manual for the Merlin PCS or the Merlin 2 PCS.

It is the physician's discretion to prescribe an in-clinic follow-up session to supplement the data from a remote follow-up session.

Troubleshooting

Some common situations can prevent a patient's transmitter from sending transmissions. They include:

- Software upgrade needed
- Hardware upgrade needed
- Issues with phone or wireless service providers

The patient's transmitter might require routine service to address these common situations. For more information, contact Technical Support (page 11).

Symbol Definitions

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

Symbol	Description
medical.abbott/manuals	Follow instructions for use on this website
	Importer
CH REP /CH-Importer	Swiss Representative/Swiss Importer
CE 0123	Affixed in accordance with European Union Medical Device Regulation 2017/745. Hereby, Abbott Medical declares that this device is in compliance with the essential requirements and other relevant provisions of this Regulation.



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CH REP /CH-Importer

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