Patient Enrollment
Reference Guide

Merlin.net™ Patient Care Network (PCN)
Patient Enrollment

- To enroll a patient in Merlin.net™ PCN, select the Enroll a new patient link. The enrollment link is present on either:
  - Recent Transmissions page
  - Patient List
Patient Enrollment – Enroll Patient by Device

- If patient information already exists in the St. Jude Medical device tracking system*
  - Enter the implanted device name (model), device serial number and patient date of birth
  - Select Enroll

*Currently the Merlin.net PCN only provides data for US and Canadian patients

*Required field
Patient Enrollment – Enroll Patient by Device

- The system automatically populates the demographic data on the Patient & Device Data screen as they were entered into the database.
- Confirm the information matches what the clinic has in their system for the patient, make updates as needed.
Enroll patients by using their Merlin.net™ PCN Number

- This option is only available if the patient is already enrolled in Merlin.net™ PCN and is being transferred to a new Merlin.net™ PCN account

- Select Enroll

Enroll a Patient

Enroll Patient by Device

Try this option first for auto enroll or transferring a patient

- Device name:
- Device Serial #:
- Date of birth: MM-DD-YYYY

Enroll

Enroll Patient by Merlin.net™ Number

*Merlin.net™ number:

Enroll

Enroll Manually

Use this option for manual enrollment.

Enroll

* Required field
Patient Enrollment - Enroll Patient Merlin.net™ PCN Number

- A patient’s Merlin.net™ PCN number is automatically assigned by the system upon first being enrolled
  - The Merlin.net™ PCN number is unique to each patient
- The clinic enrollment date is the date a patient was enrolled at the current clinic
  - Note: If a patient transfers from one clinic and is re-enrolled in another clinic, this date will change to reflect the current clinic enrollment date
Patient Enrollment- Enroll Manually

- If patient information does NOT already exist in the St. Jude Medical device tracking system:
  - Enroll patients using the Enroll Manually option
    - Note: If a patient is having their device replace, simply change the device in the existing patient profile
  - Select Enroll to begin
Patient Enrollment- Manual Enrollment Wizard

The Enrollment Wizard facilitates easy and complete patient enrollment starting with the Patient & Device Data

1. **Patient & Device Data**
2. Transmitter
3. Follow-up Schedule
4. DirectAlerts™ Notification
5. Baseline Clinical Data
6. Enrollment Complete
Patient Enrollment- Enroll Manually

- A blank patient profile form appears
- Input patient demographic information to complete the patient profile
Patient Enrollment- Patient & Device Data

- Required fields—initially, first name, last name AND patient ID are marked as required, denoted with *

- Once a name is entered, the patient ID is no longer required or if a clinic assigned patient ID is entered, the name fields are no longer required

- Remember: Merlin.net™ PCN ID is system assigned upon enrollment but the patient ID is clinic assigned and optional
Patient Enrollment- Patient & Device Data

- Required fields are accented in red, and a pop-up message appears if the Save and Close or Continue buttons are selected before required fields are completed
- Input required fields and select Continue
Patient Enrollment- Emergency Contact

- You may choose to notify an Emergency Contact with a DirectCall™ message when a Merlin.net™ PCN alert is sent to the patient's Merlin@home™ transmitter.
  - The Emergency contact will receive an automated phone call indicating the patient has a device related issue and to contact them as soon as possible.
- Fill in Emergency Contact information and select Close.
Patient Enrollment- DirectCall™ Message

- Decide if DirectCall messages will be used to remind a patient of a scheduled or missed transmission appointment.
- If DirectCall messages are not available in a patient's profile (as shown below Disabled), the Clinic Preference for DirectCall messages is turned off.
Patient Enrollment- DirectCall™ Message

- Select the method for DirectCall message
  - Ensure the patient phone number is entered correctly
    - Note the country code and area code must be entered in the correct format
- There are geographic limitations to the SMS text options
  - All OUS countries can choose to have SMS DirectCall messages sent to both clinicians and patients
  - All US clinics can receive SMS DirectCall messages but we do not support SMS DirectCall messages to patients
Patient Enrollment- DirectCall™ Message

- Send DirectCall™ messages and Call the clinic alerts from the Merlin@home™ transmitter
- Notify Patient times between which both the transmitter or the clinic can notify the patient
  - The clinic default setting is chosen by clinic administrator
  - Times between 09:00 (9:00 a.m.) and 16:00 (4:00 p.m.) are shown as an example, but it can be customized
Patient Enrollment- DirectCall™ Message

- Choose patient language preference for DirectCall messages
Patient Enrollment- Order Transmitter

- The transmitter section offers two options
  1. Order transmitter
     - Used when sending transmitter to the patient’s home
     - Currently not available in all geographies
     - Note: a warning to complete address appears if this option is selected and address information is incomplete
  2. Patient has transmitter
     - Used for generator replacements, upgrades or if the transmitter is issued in the office or at implant
Patient Enrollment- Manual Enrollment Wizard

The enrollment wizard will then guide you to the Transmitter page to setup transmitter operating preferences

1. Patient & Device Data
2. Transmitter
3. Follow-up Schedule
4. DirectAlerts™ Notification
5. Baseline Clinical Data
6. Enrollment Complete
Once order transmitter has been selected, the date on which it was ordered will be populated in the Ordered Date field.

Note: if this field is blank, this indicates the order was not saved.

Transmitters usually take about 10-14 business days for delivery.
Patient Enrollment-Transmitter

- Configure settings for the transmitter to interact with the device:
  - RF daily DirectAlerts™ notification checks are applicable to RF transmitters only, reading will only come through if an alert is detected
  - Lockout unscheduled transmissions or DirectAlerts™ notification checks: prevents the patient from performing manual transmissions and manual device checks respectively

![Image of a Patient Enrollment form]

- **Transmitter Setup Preference**
  - Fill in the transmitter model and serial if you would like a transmitter to directly pair to this patient's Merlin.net profile without first attempting to read the patient's device.

- **Last Connection**
  - This information populates once a patient's transmitter has had a successful connection to Merlin.net. The data updates at least once every 7 days if the transmitter is plugged in and not experiencing connection issues.

- **Setting**
  - **Perform RF daily DirectAlerts™ checks**
  - **Lockout unscheduled transmissions**
  - **Lockout unscheduled DirectAlerts™ checks**

- **Volume**: Low

- **Recent shipment information**
  - **Transmitter Serial No.**: 123
  - **Transmitter Model**: 456
  - **Ordered Date**: 04-05-2016
Patient Enrollment-Transmitter

- Finally, select if you would like to collect DirectTrend™ viewer diagnostics
  - Collect DirectTrend™ Viewer Diagnostics allows automatic weekly collection of diagnostic data into the DirectTrend™ Viewer of the Merlin.net PCN
  - When selected, trended data is sent to Merlin.net PCN each week

```
Enroll a Patient

Transmitter
Transmitter Setup Preference

Fill in a transmitter model and serial if you would like a transmitter to directly pair to this patient's Merlin.net profile without first attempting to read the patient's device.

Transmitter Serial:
Transmitter Model:

Note: If the patient's Merlin.net enrollment information is incorrect and a transmitter's model and serial is put into those fields, the transmitter will pair to the device which the patient does not have. If this happens, the patient will not be followed remotely.

Last Connection

This information populates once a patient's transmitter has had a successful connection to Merlin.net. The data updates at least once every 7 days if the transmitter is plugged in and not experiencing connection issues.

Transmitter Serial:
Transmitter Model:
Transmitter last updated on:

Settings

- [ ] Perform RF daily DirectHears™ checks
- [ ] Lockout unscheduled transmissions
- [ ] Unschedule Unscheduled DirectHears™ checks
- [ ] Collected DirectTrend™ Viewer Diagnostics

Volume: Low

Recent shipment information

Transmitter Serial:
Transmitter Model:
Ordered Date: 9/4/2014

Shipped Date:
```
Patient Enrollment-Transmitter

- Adjust the volume on the transmitter if needed
  - Default setting is Low
  - The Off option enables visual status indicators, instead of audible signals, for the patient, so that the transmitter flashes lights instead of beeping

Transmitter Setup Preference

<table>
<thead>
<tr>
<th>Transmitter Serial #:</th>
<th>Transmitter Model:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: If the patient’s Merlin.net enrollment information is incorrect and a transmitter’s model and serial is put into these fields, the transmitter will pair to the device which the patient does not have. If this happens, the patient will not be followed remotely.

Last Connection

<table>
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</tr>
</thead>
<tbody>
<tr>
<td>Na</td>
<td>Na</td>
</tr>
</tbody>
</table>

This information populates once a patient’s transmitter has had a successful connection to Merlin.net. The date updates at least once every 7 days if the transmitter is plugged in and not experiencing connection issues.

Settings

- Perform RF daily DirectedAlerts™ checks
- Lockout unscheduled transmissions
- Lockout unscheduled DirectedAlerts™ checks
- Collect DirectedTrend™ Viewer Diagnostics

Volume:

- Low
- High
- Off

Recent shipment information
Patient Enrollment-Transmitter

- When a transmitter is successfully paired with a patient’s device, the current transmitter setup information is automatically populated
- Select Continue
Patient Enrollment-Transmitter

- This information populates once the patient’s transmitter has had a successful connection to Merlin.net™ PCN.
- The data updates at least every 7 days if the transmitter is plugged in and not experiencing connection issues.
- The last connection date will update anytime the Merlin@home™ transmitter connects, for pairing, transmissions, or weekly updates.
Patient Enrollment- Manual Enrollment Wizard

The enrollment wizard guides you to the Follow-up Schedule page to setup patient specific scheduling parameters

1. Patient & Device Data
2. Transmitter
3. **Follow-up Schedule**
4. DirectAlerts™ Notification
5. Baseline Clinical Data
6. Enrollment Complete
Patient Enrollment- Follow-up Schedule

- The preferred scheduling method selected in the clinic profile is the scheduling default for patients upon enrollment but can be adjusted as needed.
- Input desired scheduling parameters for routine remote transmissions to occur.
- Note: if "none" or manual entry calendar is selected and there are no dates, or the dates have expired, you may not receive any remote transmissions for the patient.

[Diagram of patient enrollment and follow-up schedule]

[Form for scheduling options: SmartSchedule calendar, Manual entry calendar, None]

- Permanent schedule: Starting on [DD-MM-YYYY], transmit every [3 Months] for life.
- Switch to temporary schedule: Starting on [DD-MM-YYYY], transmit every [ ] for [ ]

[Form for reverting to permanent schedule:]

transmit every [ ] for [ ]

then revert to permanent schedule:
Patient Enrollment- Follow-up Schedule

- The clear function allows the user to clear data from the patient’s implanted device after the transmitter has completed a Read action for a patient-initiated or scheduled transmission, but not for alert initiated transmissions
  - **Diagnostics:** Clears diagnostics but not trended data
  - **Episodes:** Clears episode directories
  - **Stored EGMs:** Clears stored EGMS

Select Continue
Patient Enrollment- Manual Enrollment Wizard

The enrollment wizard guides you to the DirectAlerts™ notification page to set individualized alert selections for your patient.

1. Patient & Device Data
2. Transmitter
3. Follow-up Schedule
4. DirectAlerts™ Notification
5. Baseline Clinical Data
6. Enrollment Complete
Patient Enrollment-DirectAlerts™ Notification

- Initially, clinic preferences determine DirectAlerts notification settings; the user can subsequently customize settings for each patient
- Both Red and Yellow flags will trigger an alert initiated transmission, the distinction between the two is how you wish to be notified of the alert
  - The red flag indicates urgent delivery
  - Yellow flag indicates standard delivery
- The Inform Patient feature enables the transmitter to display a Call Clinic indication when the alert for which it is selected is enabled. This indicates to the patient to call their clinic as there is information you would like to discuss with them
Patient Enrollment-DirectAlerts™ Notification

- A diamond next to a box indicates the selection differs from the clinic’s preferences

- Selecting Off does not turn off the alert in the device nor indicate the alert is turned off; Off does indicate the Merlin@home™ transmitter will not look nor detect these alerts on the device, therefore they cannot trigger a transmission
Patient Enrollment-Medical Team

- The Medical Team is applicable to: Patient filtering on the Recent Transmissions and Patient List pages
- DirectAlerts™ notifications when Send to Medical Team is selected as a method of after-hours notifications
- A patient’s alert-initiated transmissions are sent to the medical team member listed first

- The On-Call Physician is the default medical team member and cannot be removed from the list, but position on the list can be adjusted using the "move up" and "move down" arrows
Patient Enrollment- Medical Team

- To add a Clinician to the patient’s Medical Team list:
  1. Highlight the name of the clinician to be added
  2. Select the Add button
  3. The clinician’s name will be added to the medical team list
Patient Enrollment- Medical Team

- To highlight the implanting physician's name in beige, select the physician from the list and then select Mark Implanting.
Patient Enrollment- Manual Enrollment Wizard

The enrollment wizard guides you to the Baseline Clinical Data page to include information regarding your patients condition at the time you starting following them remotely.

1. Patient & Device Data
2. Transmitter
3. Follow-up Schedule
4. DirectAlerts™ Notification
5. Baseline Clinical Data
6. Enrollment Complete
Patient Enrollment- Baseline Clinical Data

- Baseline Clinical Data is an optional screen; however, once data is entered, the Date baseline was taken field becomes mandatory.
- Select Continue.

This area can be used to record baseline measurements taken when your patient was first admitted into clinic records.
Patient Enrollment- Manual Enrollment Wizard

The enrollment wizard guides you to complete the enrollment process.

1. Patient & Device Data
2. Transmitter
3. Follow-up Schedule
4. DirectAlerts™ Notification
5. Baseline Clinical Data
6. Enrollment Complete
Patient Enrollment- Enrollment Complete

- Once all steps are completed, the Enrollment Complete screen appears, giving the option of finishing the process or viewing the patient's schedule.
Patient Enrollment- Enrollment Complete

- View Schedule option

- Selecting Finish returns you to the Patient List
Patient Enrollment - Manual Enrollment

- A warning message is displayed if you try to navigate away from the enrollment wizard prior to completing a patient’s enrollment process.

![Warning message dialog box](image)
Remote Care

Device Monitoring

For:
- Transmitter setup questions
- Fax/email delivery questions or modifications
- Transmission or connectivity difficulties

Phone:
US: 1-877- My Merlin
ID: please contact the local rep or call (+46) 8 474-4756

Email:
mymerlin@sjm.com US
Remote.monitoring@sjm.com ID
Rx Only

Brief Summary: Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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