Merlin™ 2 Remote Support

Help Manual



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[‡] Indicates a third-party trademark, which is property of its respective owner.

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System Description

The Merlin™ 2 Remote Support feature is intended to provide cardiac healthcare professionals and authorized Abbott Medical personnel with remote programmer session capability, enabled by network connectivity on the Merlin™ 2 Patient Care System (PCS) programmer. The Merlin 2 Remote Support feature comprises the following components:

- Merlin 2 PCS (programmer Model MER3700, programmer software Model MER3400) with the Merlin 2 Remote Support feature
- Merlin[™] Live Connect (Model MLC1000) and web application

Remote access is enabled through the Merlin 2 PCS programmer and allows a remote user to remotely view and control the Merlin 2 PCS programmer interface via the Merlin Live Connect web app. The remote access allows a remote user authorized by Abbott Medical to provide direct programmer support to a local user (a patient care provider) who is with the patient and a Merlin 2 PCS programmer. Throughout a remote session, the remote user and local user are in contact through a phone call, which occurs outside the Merlin 2 Remote Support feature. The following figure shows a summary of interactions with the Merlin 2 Remote Support feature.

Figure 1. Merlin 2 Remote Support description



- 1. Merlin 2 PCS programmer connected to Merlin 2 Remote Support
- 2. Local user (patient care provider with patient present)
- 3. Remote user (authorized Abbott Medical representative)
- 4. Merlin Live Connect (MLC1000) and web app

This manual contains information and instructions for interacting with the Merlin 2 Remote Support feature of the Merlin 2 PCS programmer. For a complete listing of device-specific indications, contraindications, warnings, precautions, potential adverse events, and directions for use related to the programmer, refer to the Merlin 2 PCS Model MER3700 User's Manual.

NOTE:

- The Merlin 2 Remote Support feature is only available with the Merlin 2 PCS programmer.
- A qualified local user initiates a remote session with an authorized remote user, and both the local user and remote user are present and in contact over the phone during the entire session.
- The local user must get consent from the patient before starting a remote session, and the local user must remain with the patient throughout the remote session.
- In this document the Merlin 2 Remote Support feature is referred to as "remote support" and the Merlin 2 PCS programmer is referred to as "programmer."

Getting Started With Remote Support

Contents

- System considerations (page 2)
- Safety considerations (page 2)
- Remote support button and states (page 2)
- Remote support borders and states (page 2)
- Passwords and keys (page 3)

System Considerations

- Merlin™ 2 PCS (Merlin 2 PCS Programmer [Model MER3700] Merlin 2 PCS Programmer Software [Model MER3400]) containing the software update of version 1.9.X or higher
- Reliable high-speed Internet connection (Wi-Fi‡ or Ethernet) to allow for uninterrupted, fully synchronized support during a remote session
- Reliable telephone connection to allow for real-time audio communication between the local user and remote user

Safety Precautions

- CAUTION: During a remote session, the remote user must not use the following programmer features:
 - Cardioversion
 - Arrhythmia inductions and electrophysiology (EP) studies, such as Burst, Shock-on-T, DC Fibber, and NIPS
 - Intrinsic rhythm sensing and manual capture tests (with pacer-dependent patients)
 - Pacing system analyzer (PSA) usage

Note that the local user can still use these features if desired and per standard clinical practice.

- Local user and remote user must remain in audio contact via a reliable telephone connection throughout the remote session to communicate instructions and any changes in patient status, connection status, and user and patient needs.
- Local user must remain with the patient throughout the remote support session, continually monitor the patient, and communicate any changes in the patient's status to the remote user.
- Local user must have the training and ability to perceive patient conditions and react accordingly. Additionally, the local user must be qualified
 to recognize and respond to emergencies that might occur during use of the programmer.
- Emergency equipment must be available at all times.
- The role of the remote user is to provide technical support for programming. All medical and therapeutic decisions are the responsibility of the local user or other authorized medical professional present at the local user site and must be made per standard clinical practice.

Remote Support Button and States

The following table describes the button for initiating a remote session. This button is accessible only from the programmer's Start-Up screen.

Table 1. Remote support button states and their meanings

Button	Description of Button		
2	Enabled state. Connectivity to the remote support feature is enabled and available.		
2	Disabled state (dimmed). Connectivity to the remote support feature is disabled and unavailable. A local user needs to retrieve and input a connectivity key (CK) to enable remote support.		

Remote Support Borders and States

The following table describes the color borders that appear around the programmer screen to indicate different states during a remote support session. No border means a remote session is not active.

Table 2. Remote support border states and their meanings

Border Color	Description of Border		
Yellow	Connection partially established. The connection between the programmer and the web app is partially established. It appears during remote session initiation and after the remote session has been ended. Attached to the border is a yellow X icon, which the local user can select to end remote session initiation.		
Green	Connection established. Remote session is connected, and the remote user is now able to remotely control the programmer. Attached to the border is a green X icon, which the local user can select at any time to end the remote session.		

Table 2. Remote support border states and their meanings

Border Color	Description of Border		
Red	Connection disrupted. Remote session was disrupted (disconnected) from the local user's side, and the session has ended. Attached to the border is a red X icon, which the local user can select to clear the red border. This allows the local user to restart the session, if desired. Before restarting the session, the local user should confirm the strength of their current network or change to a more reliable network.		

Passwords and Keys

The following table describes the passwords and keys you will need to use the remote support feature.

Table 3. Descriptions of remote support passwords and keys

Key or Password Type	Description		
Connectivity key (CK)	Key that enables remote support feature connectivity in the programmer. The programmer generates the CK automatically. If the remote support feature ever becomes disabled on the programmer, the CK is required to re-enable it.		
Wi-Fi‡ password	Password that connects the programmer to a local private Wi-Fi network.		
Session PIN	Unique identification number that is specific to a remote session. It is generated randomly by the programmer each time the local user initiates a remote session. The local user shares the session PIN with the remote user to help complete the remote connection.		

Setting Up Connectivity With Remote Support

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- Enable connectivity (page 4)
- Connect to a network (page 4)
- Disable connectivity (page 5)
- Troubleshooting for connectivity and set-up (page 5)

Enable Connectivity

Before you can begin using the remote support feature, ensure that the programmer connectivity features are enabled, which allows you to connect to the Internet and begin a remote session. If the connectivity features are disabled, the remote support icon will appear dimmed (**) on the Start-Up screen and will require a connectivity key (CK) to enable them.

Retrieve the Connectivity Key

- 1. From the Start-Up screen, select Tools > Maintenance > Special Functions. The Special Functions window opens.
- 2. Under Restricted Functions, select Retrieve Connectivity Key.
- 3. Call Technical Support according to the on-screen instructions, and share the information that is displayed with the Technical Support representative. Technical Support will guide you through the steps to retrieve the CK.

NOTE: The CK will not change unless you choose to regenerate it. You can regenerate the CK by selecting Regenerate Key from the Connectivity Key window, and a new CK appears on screen.

4. After you have retrieved the CK from the Connectivity Key window, select Done to return to the Start-Up screen.

Enable Connectivity Features

- 1. From the Start-Up screen, select Tools > Networks > Enable/Disable Connectivity. The Enable/Disable Connectivity window opens.
- 2. Select Enable, and select the Key box to open the on-screen keyboard.
- 3. Enter the CK, and select Done. See Retrieve the Connectivity Key (page 4) for details on determining the CK.
- 4. Select Done. The Connectivity Features are enabled as noted by the enabled remote support icon (🖭) on the Start-Up screen.

Connect to a Network

Remote support requires that the programmer is connected to a network. At least, you will need to be aware of your network SSID (network name) and network password if connecting to Wi-Fi‡. Other useful network credentials include your network's MAC address, security type, encryption type, and security key. Contact the facility's Internet Technology (IT) department if you are unsure about the necessary network details.

NOTE: Remote support requires an Ethernet (802.3u/ab) or a secure Wi-Fi network (802.11n/ac) connection. The only supported Wi-Fi connections are those that support WPA2-PSK or WPA2-Enterprise security. Connections cannot be established with captive or unsecured Wi-Fi networks.

Connect With Wi-Fi

- 1. From the Start-Up screen, select Tools > Networks > Configure Networks. The Network Setup window opens and shows a list of available networks.
- 2. If needed, select Refresh Network List to refresh the list of available networks.
- 3. Select the desired secure wireless (Wi-Fi‡) network from the list.
- 4. In the network window that opens, enter the network password and other network details that may be required for the selected network using the on-screen keyboard. Select Done.
- 5. Select Connect.

NOTE: You can also select to enter a Wi-Fi network manually or by selecting a network from the saved network list. A saved network is one to which the programmer has previously connected and is automatically saved to the list. This type of network can be selected without requiring you to re-enter network details (e.g., network password).

Connect With Ethernet

- 1. Make sure Ethernet cable is connected to the active Ethernet port on the programmer (which is marked as the active port on the programmer).
- 2. From the Start-Up screen, select Tools > Networks > Configure Networks. The Network Setup window opens and shows a list of available networks.
- 3. If needed, select Refresh Network List to refresh the list of available networks.
- 4. Select the desired secure Ethernet network from the list, configure the network settings as requested, and select Connect.

NOTE: You can also select to enter an Ethernet network manually.

Change Networks

If you find that your selected network is unreliable and has become prone to connectivity disruptions during a remote session, you should consider changing networks.

To change networks, select Tools > Networks > Configure Networks from the Start-Up screen. The Network Setup window that opens shows a list of available networks, both Ethernet and Wi-Fi‡. Note that an Ethernet connection is less prone to signal degradation or interruption; it is identifiable in the network list as a wired connection. If selecting a Wi-Fi network, select a secured network with a strong signal.

Disable Connectivity

You can disable connectivity features anytime by following these steps. When connectivity features are disabled, the programmer will not be able to connect to a network or start a remote session.

- 1. From the Start-Up screen, select Tools > Networks > Enable/Disable Connectivity. The Enable/Disable Connectivity window opens.
- 2. Select Disable. The Connectivity Features are disabled as noted by the disabled remote support icon (🔤) on the Start-Up screen.

Troubleshooting for Connectivity and Set-Up

Table 4. Troubleshooting for connectivity and set-up

Issue	Potential Cause	Potential Solution	
Cannot find a Wi-Fi‡ network	The Wi-Fi network is hidden (undetectable).	Connect to the Wi-Fi network manually.	
Cannot find an Ethernet network listed in available networks	The Ethernet cable is not connected to the active port on the programmer	Confirm that the Ethernet cable is connected to the active port on the programmer. Check the programmer hardware instructions for use for more information.	
	The Ethernet cable is not connected to an active Ethernet connection in the facility.	Confirm that the Ethernet connection in the facility is active.	
	The network is hidden.	Connect to the Ethernet network manually.	
Cannot connect to a network	The network is unsecured, which is prevented by the programmer's security protocols	Connect to a different, secured network from the network list.	
	The network is not configured for MAC-based access, which is prevented by the programmer's security protocols	Connect to another network from the network list	

Instructions for Local Users

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- Before beginning a session (page 6)
- Starting a session (page 6)
- During a session (page 6)
- Ending a session from the programmer (page 6)
- Troubleshooting for local users (page 6)

Before Beginning a Session

- Make sure you have the contact phone number for the remote user. If possible, schedule a time for the remote session with the remote user. If you are unsure who to call or do not have a direct number for the remote user, call 1 800 PACE ICD.
- Get permission from the patient to conduct the remote session. The patient must be with you at all times during a session, and you must be on a call with the remote user throughout this session. During a session, the patient should be comfortably seated or lying down.

Starting a Session

NOTE:

- From the moment you start a remote session, you have about 10 minutes to contact the remote user, deliver the PIN, and accept the terms of use before the session times out. Therefore, you should contact the remote user by phone before initializing the remote session as recommended in the following steps. If the session times out, restart these steps for starting a session.
- If you experience any issues while trying to start a remote session, make sure to communicate what you are experiencing with the remote user over the phone, who may be able to help you troubleshoot the issue. See Troubleshooting for Local Users (page 6) for additional details.

Make sure you have gathered all the required information for a remote session, have the connectivity features enabled, and are connected to a network with a reliable Internet connection.

- 1. Contact the remote user (Abbott Medical representative) by phone.
- 2. From the Start-Up screen, select the enabled remote support icon (2). The Initializing Remote Session window opens and runs a checklist to start a remote session. Make sure to tell the remote user if any part of the initialization checklist fails and troubleshoot with them as needed.
- 3. When the Remote Session Pin window opens, share the remote session PIN with the remote user to help complete the remote session connection. You will also need to share the programmer's serial number with the remote user to help them confirm they are connecting to the correct programmer.
- 4. When the Remote Session Terms of Use window opens, read the terms of use carefully. If you consent, select the Accept Terms of use box and select Start Session. The border around the programmer screen turns yellow to indicate that the remote user is still completing the remote session connection.
- 5. After the remote session connection is completed, the border around the programmer screen turns green to indicate an active remote session.

During a Session

- During a session with a remote user, you still have the ability to select screen features and control the programmer. To avoid interacting with screen features at the same time as the remote user, make sure to actively communicate with the remote user when you intend to touch the programmer screen.
- The programmer also has physical buttons on the console, which you may need to press during a remote session as per clinical practice.Communicate these actions to the remote user over the phone to help ensure only one user is implementing programming actions at a time.
- Ensure that you remain with the patient throughout the Remote Support session, continually monitor the patient, and communicate any changes in the patient's status to the remote user.

Ending a Session From the Programmer

You can end a remote session from the programmer at any time by following these steps:

- 1. Select the green "X" in the upper right corner of the screen.
- 2. In the window that opens, select Stop Sharing to end the session. When the remote session has ended, the green border around the programmer screen is no longer visible.

Troubleshooting for Local Users

Table 5. Troubleshooting for local users

Issue	Potential Cause	Potential Solution
Cannot complete remote connection with remote user (session initialization time-out)	Connected to a Wi-Fi‡ network with poor connectivity (weak signal) that is causing the session initialization process to be delayed and to time out.	 Reposition or relocate the programmer for better Wi-Fi signal strength, if possible. Select an Ethernet network or a different secured Wi-Fi network with a better signal strength from the list of available networks or by connecting manually.

Table 5. Troubleshooting for local users

Issue	Potential Cause	Potential Solution
	Part of the session initialization checklist is failing, which is indicated by an "X" beside the item instead of a checkmark.	 Tell the remote user over the phone which initialization checklist item is failing. Follow the instructions of the remote user to troubleshoot the exact issue.
During the remote session, the actions of the remote user are out of sync with what you see on the programmer screen	Remote user fails to enter the correct remote session PIN before the session initialization period times out. Local user fails to accept the terms of use before the session initialization period times out. Local user's network connection is weak.	1. Confirm that you have given the correct PIN to the remote user over the phone. 2. Confirm that the remote user is trying to connect to the correct programmer based on your programmer's serial number. You can locate the programmer serial number in the bottom right of any session initialization window during the connection process. 3. Restart the session initialization process and generate a new session PIN. Make sure you are connected to a reliable high-speed network with good signal strength to avoid delays in the session initialization process. 1. Check the programmer's network connection to confirm the signal strength is sufficient for the remote session, and change to a network with a stronger
	Remote user's network connection is weak.	connection strength if needed. 2. When you change networks, you may need to reinitiate a remote session from the Start-Up screen. After confirming your programmer's network connection is sufficient, ask the remote user over the phone to confirm the same about
During the remote session, the green border	Local user's network connection was lost.	Confirm with the remote user over the
around the screen turns red (e.g., session was interrupted)		 phone that the connection was lost. 2. Check your network connection with the programmer. 3. Change networks if the signal is too weak to support a remote session or if the network is disconnected.
	Remote user's network connection was lost.	1. Confirm with the remote user over the phone that the connection was lost. 2. After confirming that the programmer is still connected to the network, confirm with the remote user that their network is still connected.
Phone call is disconnected unexpectedly during a remote session	Remote user or local user phone accidentally lost signal or otherwise was disconnected.	Wait for the remote user to contact you using the call-back number you provided at the beginning of the remote session.
Programmer loses power during a remote session	The power to the programmer became disconnected	 Alert the remote user that the programmer lost power. Reconnect the programmer to power, and reinitiate a remote session from the Start-Up screen.
An undesired programming action or misprogramming action is performed	Both the local user and remote user are interacting with the programmer screen at the same time.	Communicate clearly to the remote user over the phone that an emergency or other issue requires you to interact with the screen or programmer console and you need the remote user to stop controlling the screen.

Instructions for Remote Users

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- Starting a remote session (page 8)
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- Completing a remote connection (page 8)
- Navigating a remote session (page 8)
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- Troubleshooting for remote users (page 9)

Starting a Remote Session

A remote user is a trained, qualified Abbott Medical representative with authorization and credentials to operate the remote support application (Merlin™ Live Connect web app) and provide support to local users.

Before starting a remote session, the remote user should be contacted by the local user by phone to allow for continuous audio communication. Additionally, the remote user should check with the local user to ensure that the programmer is connected to a network with a strong reliable connection. The remote user should also make sure they are operating the web app from a reliable network to prevent session disruptions.

NOTE: The Merlin Live Connect web app must be operated on a computer that meets the following requirements:

- Operating system (OS): Microsoft‡ Windows 10X‡
- Supported Internet browsers: Microsoft Edge‡ and Google Chrome‡
- Minimum display resolution: 1024 x 768 pixels

Logging In to the Web App

- 1. Go to the Merlin™ Live Connect web app page on a supported Internet browser, and log in using your remote user credentials.
- 2. Instruct the local user to select the remote session icon on their Start-Up screen, if they haven't already done so.
- 3. Ask the local user for the remote session PIN, enter the PIN on the web app screen, and select Next.
- 4. Follow the on-screen prompts to gather the local user's information, confirm the programmer serial number with the local user, and accept the terms of use.

Completing a Remote Connection

After confirming the terms of use on the web app, the session waits for the local user to accept the terms of use from the programmer. Once the local user has accepted the terms, the Web Rep Console opens.

- 1. Log in to the Web Rep Console.
- 2. On the account page that opens, the Web Rep Console automatically connects to the active programmer and the remote session begins signing on, showing the sign-on status at the top of the information panel on the right.
- 3. After successful sign on, a Screen Sharing window opens and screen sharing should begin automatically. When connection is successful, a window shows the local user's programmer screen with a green border around it, and a message appears in the chat that you can view and control the screen.

Navigating a Remote Session

- When making selections on the programmer screen during a remote session, actively communicate with the local user to confirm that the programming actions are being implemented.
- If during a remote session, you reach four minutes of web app inactivity, a warning will open on-screen informing you that the session will be disconnected after one minute. To continue working in the remote session, you must close the warning within a minute. Otherwise, the session will automatically disconnect.

Ending a Session From the Web App

As a remote user, you can end a session two ways: from the remote programmer screen or from the web app screen.

To end a remote session from the remote programmer screen, follow these steps:

- 1. Select the green "X" on the border in the upper right corner of the programmer screen.
- 2. In the window that opens, select Stop Sharing to end the session.
- 3. Confirm with the local user that they do not need to reconnect, and then close the web app.

To end remote session from the web app, follow these steps:

- 1. Select the X icon in the upper-right corner of the screen.
- 2. When the END OR HOLD window opens, select End Session to end the session.

NOTE: Remain in contact with the local user and work with them over the phone to confirm that the remote session has ended, and only then end the call.

Troubleshooting for Remote Users

Table 6. Troubleshooting for remote users

Issue	Potential Cause	Potential Solution
Failure to access the login page of the Merlin™ Live Connect web app	Remote user has entered the incorrect web address.	Confirm you have the correct web address, and retry.
	Remote user is not authorized to access the Merlin Live Connect web app.	Contact the system administrator to request access permissions.
You receive a "Please Enter Valid Pin" message	Time period to initiate the remote session has expired. The session PIN has expired.	Instruct the local user to reinitate a remote session from the programmer and generate a new session PIN.
Phone call disruption	Remote user or local user phone accidentally lost signal or otherwise was disconnected.	 Try calling the local user using the number you collected either at the start or during remote session initialization. If you cannot re-establish a phone connection with the local user, end the remote session.
Session disconnects unexpectedly and you receive a trying to reconnect screen	The network failed to maintain a connection.	 Communicate with the local user over the phone to help troubleshoot the cause. If the network issue can be resolved easily and before session time-out, then the session could be reconnected. Otherwise, ask local user to generate a new PIN and initiate a new remote connection.
	The session timed out.	 Communicate with the local user over the phone to confirm the session timed out. Ask local user to generate a new PIN and initiate a new remote connection.

Additional Information

Technical Support

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

- 1 818 362 6822
- 1800 722 3774 (toll-free within North America)
- + 46 8 474 4147 (Sweden)
- + 61 2 9936 1200 (Australia)
- medical.abbott/manuals

For additional assistance, call your local Abbott Medical representative.

To ensure that you have the latest software, please contact Technical Support or your local Abbott Medical representative.

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. The Merlin™ 2 PCS programmer is securely configured by default. Patients, clinical staff, and hospital IT staff do not need to configure the programmer or take any special action (for example, firewall use) to safeguard patient information and device data.

There are no infrastructure requirements, except for the presence of an Internet connection. The Merlin 2 PCS programmer communicates securely across Ethernet and Wi-Fi‡ connections. Connectivity is only active during user-initiated remote support activity. The Merlin 2 PCS programmer does not allow incoming connections. All data exchanged is protected through the use of authentication and encryption methods for secure communication. Insecure Wi-Fi connections are disallowed. The Merlin 2 PCS programmer will only connect to Abbott Medical resources.

The Merlin 2 PCS programmer logs security events, for example a failed installation of programmer software, and stores these log files on disk. These files can then be analyzed by Abbott Medical personnel during system forensics. They are not meant to be analyzed by the clinic's information technology personnel.

All safeguards for the devices will be provided throughout the stated warranty period or until a replacement product is available. In the rare event of a cybersecurity attack on the programmer that affects its ability to program the pulse generator, implanted device therapy will continue. Abbott Medical encourages the clinics to allow only authorized healthcare providers to use the Merlin 2 PCS, for example by requiring badged access to programmer locations. The cybersecurity bill of materials (CBOM) is available upon request.

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

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

Follow instructions for use on this website



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