

Medtronic

MyCareLink Heart™ Mobile Application

Product Information for Clinicians

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1 Warnings and precautions

Warning: The patient should not rely on the app during a medical emergency. If the patient experiences a medical emergency, instruct him or her to seek medical attention immediately.

2 About MyCareLink Heart

2.1 About the MyCareLink Heart App

The MyCareLink Heart application (called the “app” from now on) runs on a smart phone (called the “phone” from now on) or tablet. It uses Bluetooth®¹ wireless technology in the patient’s phone or tablet and a connection to the Internet to automatically transfer data between the patient’s heart device and the Medtronic CareLink Network. The data is used to monitor the patient’s heart device.

2.2 Overview of the App

These instructions explain how to install, set up, and use the app. Instruct the patient to first follow the instructions in the app for questions about using the app or problems with the app. If the patient requires further assistance, instruct him or her to contact Medtronic.

This app does not replace the patient’s Medical Device Identification card or the patient’s medical records. Instruct the patient to always carry his or her Medical Device Identification card or temporary patient ID card. The Medical Device Identification card or temporary patient ID card identifies the patient as having a heart device.

2.3 Intended use

The app is intended for patients who have a phone or tablet and a heart device.

The app uses a phone or tablet and the Internet to automatically transfer data between the patient’s heart device and the Medtronic CareLink™ Network. The clinic retrieves the patient’s heart device data from the Medtronic CareLink™ Network for clinical review. The patient can use the app to view a summary of information and record symptoms to discuss with his or her doctor at a later visit.

2.4 Contraindications

There are no known contraindications.

2.5 Conditions for Use


The app can be used anywhere that allows the patient to connect to a Wi-Fi™* or cellular network (called the “Internet” from now on). Instruct the patient to keep his or her phone or tablet close to his or her heart device (within 6 in or 15 cm and 3 feet or 1 m) to ensure that the app can transmit the patient’s heart device data to the Medtronic CareLink Network.



2.6 Identifying Warnings and Precautions

Inform the patient that warnings and precautions for the app are identified in the patient manual by the following methods:

- The warnings and precautions symbol
- Use of yellow text and a larger font size

2.7 Symbols

<div>EC</div> <div>REP</div>	Authorized representative in the European Community
	Manufacturer

	Warnings and precautions
	Profile icon

2.8 Model Number

MSW003

MSW004

2.9 App Version

To view version information for the app, instruct the patient to tap  > **About** from the **Dashboard** tab. The **About** screen opens.

The **MyCareLink Heart™** section on the **About** screen displays the following information about the app:

- **Model No.:** This is the model number of the patient's app.
- **Version:** This lists the version number and unique identifying number of the patient's app.

2.10 How to Contact Medtronic

Patients can contact Medtronic if they have questions about the app that are not covered in the patient manual, or if they find errors in this patient manual or with the app.

Patients in the United States

Patients can call 1-800-929-4043 to speak with a Patient Services Specialist. Staff is available Monday through Friday from 7:00 AM to 7:00 PM (Central Time).

Website information is available 24 hours a day: www.medtronic.com

Patients can submit questions, suggestions, or requests by using the online form provided at www.medtronic.com/contact-us/.

Patients in Canada

Patients can call 1-888-660-4616 to speak with a Patient Services Specialist. Staff is available Monday through Friday from 9:00 AM to 5:00 PM (Eastern Standard Time).

Patients in Japan

Patients can call 0120-360-553 to contact the Medtronic CareLink Call Center. Staff is available Monday through Friday from 09:00 to 17:00 (except holidays).

Patients in Australia and New Zealand

Patients can call 1800-668-670 in Australia, and 0800-377-807 in New Zealand, to speak with a Medtronic representative.

Patients Outside the United States, Canada, Japan, Australia, and New Zealand

Patients can contact Medtronic using the information found in the "Addresses" section of the patient manual.

3 Phone and Tablet Information

3.1 App Security

Medtronic recommends that patients follow security measures when using the app on their phones or tablets.

Medtronic uses industry accepted technical security controls to protect the app and information in the app. Instruct the patient to take the following actions to ensure the security of the app:

- Install the app and all app updates from the Apple™ App Store™ or the Google Play™ store. Medtronic apps are free of known security vulnerabilities when they are downloaded from an official app store.
- Install app updates when they are released.
- Use a passcode or PIN to protect his or her phone or tablet. The password or passcode protects the information if the patient's phone or tablet is lost or stolen.

When the app detects a security issue, the app may close itself. The app may also block information from being exchanged with the Medtronic CareLink Network if it detects a security issue. If the patient thinks there is a security concern with the app, instruct the patient to contact Medtronic. You can also check to see if the patient's heart device data is being transmitted to the Medtronic CareLink Network.

3.2 Network Security

Instruct the patient to follow good security measures when he or she connects a phone or tablet to a network. A network is either the patient's home wireless network (called the "home network" from now on) or a public Wi-Fi™* network.

When the patient connects his or her phone or tablet to a network, instruct him or her to follow these security measures:

- Only connect to trusted and secured networks.
- Check the home network for security risks before the patient uses it to run the app. Secure his or her home network with anti-virus software and a password.

Check the security of the home network if the patient makes changes to it. Changes to the patient's home network could introduce security risks. Changes to the patient's home network include configuration changes or changes to his or her home network components, hardware, software, or firmware.

3.3 Installation Instructions

Information for installing and setting up the app is located at the following website: www.mclheart.com

Instruct the patient to follow these instructions when he or she installs and sets up the app.

3.4 Supported Phones and Tablets

The MyCareLink Heart app has requirements for the patient's phone or tablet and operating system (called the "OS" from now on) version. The app cannot transfer data between the patient's heart device and the Medtronic CareLink Network if the requirements are not met.

The requirements for the patient's phone or tablet and OS version will change over time. The patient may need to update, or replace, his or her phone or tablet and OS to use the app to transfer data between his or her heart device and the Medtronic CareLink Network.

The patient may need to consider additional monitoring options if he or she is unable to meet these requirements.

Refer to the following website for information on supported phones or tablets and OSs for the app: www.mclheart.com

3.5 OS Support for the App

The patient's phone or tablet's OS will need to be updated periodically to support the app.

The app is checked when it opens to ensure compatibility with the patient's OS.

The patient may need to update the OS to a newer version if his or her phone or tablet is using an older version of the OS.

If the patient has upgraded to a newer version of the OS that does not yet support the app, the patient will not be able to install a previous version of the OS.

Instruct the patient to consult with his or her doctor or contact Medtronic if the patient has questions about updating the phone or tablet's OS.

Refer to the following website for information on supported phones or tablets and OSs for the app: www.mclheart.com

3.6 Updating the App

Medtronic will periodically push updates to the app to the patient's phone or tablet.

Depending on the patient's phone or tablet settings, updates to the app may happen automatically, or the patient may need to manually approve updates.

If an update to the app is available and has not been installed automatically, the patient will be prompted to update the app when the app is launched. The patient will not be able to use the app until the update is installed.

If the patient is unable to update the app from the app store, his or her phone or tablet may no longer be supported.

Instruct the patient to check the list of supported phones or tablets at the following website: www.mclheart.com

The app has minimum phone and tablet requirements for the app to monitor the patient's heart device. The minimum requirements for the patient's phone or tablet will change over time. The patient may need to update, or replace, his or her phone or tablet to use the app to monitor his or her heart device. The patient may need to consider additional monitoring options if he or she is unable to meet these requirements.

3.7 Uninstalling the App

Instruct the patient that he or she should talk with his or her doctor before uninstalling the app. If you have chosen a different remote monitoring option for the patient, then let the patient know if he or she should uninstall the app.

To uninstall the app, the patient should use the standard method for uninstalling apps on his or her phone or tablet. Refer the patient to the instructions for his or her phone or tablet to find out how to uninstall an app.

3.8 Deleting the MyCareLink Heart Account

Talk to the patient about other remote monitoring options before he or she deletes his or her MyCareLink Heart account.

If the patient deletes his or her MyCareLink Heart account, the app will no longer do the following:

- Send heart device data to his or her clinic
- Display notifications about that patient's heart device

To delete the account, instruct the patient to tap  > **Profile** > **Delete MyCareLink Heart Account** and then follow the steps on the app screens to complete the account deletion.

4 Setting Up the App

4.1 Profile

The patient can edit his or her contact information and set notification preferences for the app.

The **Profile** screen displays the patient's name, email address, and phone number. The patient can edit his or her email address or phone number and confirm preferences for how he or she wants to receive notifications from the Medtronic CareLink Network to the app.


4.2 Setting Profile Preferences

The patient can edit his or her email address and phone number settings in the app. The patient's email or phone number is used to send the patient notifications from the Medtronic CareLink Network to the app.

Notifications provide the patient with information about his or her transmissions and clinic status. Notifications also give the patient information to start troubleshooting problems with the following items:

- Network connection issues
- Problems with the phone or tablet connecting to the patient's heart device

To set profile preferences, instruct the patient to complete the following steps:

1. Tap  > **Profile**.
2. Tap **Edit**.
3. To edit the email address, tap the field in the Email Address section and enter a new email address.
4. To edit the mobile phone number, tap the fields in the Mobile Phone Number section:
 - To edit the phone number country code, tap the field that lists the phone number country code. If a phone number was not previously entered, the field lists a Select Country prompt. A drop-down menu expands. Tap the country code to select it.
 - To edit the phone number, tap the field that lists the current mobile phone number. If a phone number was not previously entered, the field is labeled with a Mobile Phone Number prompt. Enter a phone number to use with the app.

If a phone number is not entered, some **Message Preferences** settings may not be available.

5. Tap **SAVE**.

5 Messages

5.1 Messages - Receiving Notifications from the App

The app sends the patient notifications. Notifications provide information about successful or missed transmissions. Notifications also help the patient start troubleshooting problems with a network connection or problems with connecting the patient's phone or tablet to the heart device. Message preference options may vary by the patient's geography. All message preference options may not be available in the patient's geography.

Notification methods can be set up in the **Message Preferences** section of the app. To receive email or text message notifications, the patient needs to enter an **Email Address** or **Mobile Phone Number** in the **Edit Profile** section of the app.

Email – The patient can receive notifications via email.

Email notifications may not be available in all geographies.

Text Message – The patient can receive notifications via text message.

App Notifications – These notifications are sent from the Medtronic CareLink Network to the app and appear on the patient's phone or tablet.

Table 1. Notification of App Problems

Notification	What the notification means	Applicable device type
Open MyCareLink Heart so the app can reconnect your heart device and clinic.	<p>The patient will receive this message if the app has been unable to communicate with the patient's heart device for 4 days. Instruct the patient to check the following items to reconnect the app to his or her heart device and keep the app Active:</p> <ul style="list-style-type: none"> • Reopen the app from the phone or tablet's home screen. • Keep the app open and running in the background. • Keep the phone or tablet nearby throughout the day. The phone or tablet needs to be nearby for the app to communicate with the heart device. <p>Check that the app is Active on the Home tab or address any messages on the Home tab.</p>	Therapeutic and diagnostic devices
Your scheduled transmission was not received on DD-MM-YYYY. Open the app to send a transmission.	<p>The patient will receive this notification if he or she missed a scheduled automatic transmission by more than 5 days. When a transmission is missed, that patient's clinic may request that he or she send a manual transmission.</p> <p>Missed automatic transmissions can be caused by one or more of the following issues:</p> <ul style="list-style-type: none"> • The app is not Active. • The patient's phone or tablet is not connected to the Internet. • There is no Internet connection available. • The app is not open and running in the background. • The patient's phone or tablet is not near the patient when transmissions are scheduled to occur. <p>The app will provide information to help the patient troubleshoot the cause of the missed automatic transmission and keep the app Active.</p> <p>Note: The date format for this notification may vary by the country where the patient lives.</p>	Therapeutic devices
Your transmission was successful. It was received by your clinic on the following date: DD-MM-YYYY	<p>The patient receives this notification when the clinic receives his or her heart device data transmission.</p> <p>Note: The date format for this notification may vary by the country where the patient lives.</p>	Therapeutic devices
You are now enrolled and connected to your clinic.	The patient's clinic has completed the enrollment. The clinic can receive the patient's heart device data through the app.	Diagnostic devices

5.2 Message Preferences


Messages provide patients with information about the app. Patients can select how they want to receive messages from the app. Messages can be sent by email, text message, and by notifications to the patient's phone or tablet.

When patients select the email or text notification method, they need to confirm that they can receive email or text messages. Patients need to respond to a confirmation message before they can begin receiving notifications from the app.

Message Preferences options may vary by the patient's geography. All message preference options may not be available in the patient's geography.

5.3 Setting Initial Message Preferences

To set **Message Preferences**, instruct the patient to complete the following steps:


1. Tap  > **Settings**.
2. Tap **Message Preferences**.
3. Slide the switch next to each message type to enable or disable that message type.
If a mobile phone number is not entered on the **Edit Profile** screen, the **Text Message** option is not available as a message option. Tap the **EDIT PHONE NUMBER OR EMAIL** link to enter or change the phone number or email.
4. Tap **VERIFY EMAIL** or **VERIFY TEXT/SMS**.
A message displays to verify the email address or phone number change. Follow the instructions in the email or text message sent from Medtronic to confirm the email address or phone number change.
5. Tap **OK**.
6. Tap **SAVE**.

When the patient completes the steps for setting **Message Preferences** and the notification method is confirmed, messages can be received from the app.

Note: A confirmation email is also sent to the patient if the email address or phone number is changed.

5.4 Changing Message Preferences

To change **Message Preferences**, instruct the patient to complete the following steps:

1. Tap  > **Profile**.
2. Tap **Message Preferences**.
3. Slide the switch next to each message type to enable or disable that message type.
Tap **EDIT PHONE NUMBER OR EMAIL** to change or edit the phone number.
4. Tap **SAVE**.

Note: The patient will receive a confirmation email if the email address or telephone number was changed.

6 Keeping the Patient's Heart Device Connected to the App

6.1 How MyCareLink Heart works with the patient's heart device and clinic

The patient's heart device and the app communicate throughout the day. The heart device sends out a secure signal several times an hour that only the app can read. Most of the time this signal is simply telling the app that there is nothing to report.

If the heart device has data to send to the clinic, it sends out a signal telling the app it has data that needs to be sent. The app communicates with the heart device using Bluetooth® Low Energy to get the data. Then the app sends the data to the Medtronic CareLink Network using the Internet. The app can send data through Wi-Fi™* or the cellular network for the patient's phone or tablet.

When the app's **Home** tab says **Active**, that means the app is ready to communicate with the heart device and the Medtronic CareLink Network.

The timestamp on the **Home** tab of the app lists the last time the app detected one of those secure signals.

6.2 About Remote Monitoring

When the app is **Active**, it can connect to the patient's heart device. The app collects data from the patient's heart device and transfers it to the Medtronic CareLink Network. Remote monitoring occurs when the patient's heart device data is transferred to the Medtronic CareLink Network and reviewed by the patient's clinician.

Remote monitoring transfers data and information in the following way:

- The app transmits the patient's heart device data to the Medtronic CareLink Network.
- A doctor or clinician reviews the patient's transmitted heart device data and CareAlerts from the Medtronic CareLink Network.
- The patient receives important notifications about his or her remote monitoring status.

6.3 Keeping the App Active

To help make sure that remote monitoring is successful, certain settings must be selected on the patient's phone or tablet. The app automatically checks the status of the settings on the patient's phone or tablet and the permissions for the app. If all of the settings are configured correctly, the **Home** tab shows the app is **Active**.

Instruct the patient to check the following requirements for remote monitoring to be successful:

- Keep the phone or tablet turned on and adequately charged for normal use.
If the patient's phone or tablet powers down, the app will not be able to communicate with his or her heart device or send the heart device data to the Medtronic CareLink Network.
- Keep the phone or tablet connected to the Internet with a Wi-Fi™* or cellular connection to transfer the heart device data to the Medtronic CareLink Network.
- Keep the app open and running in the background.
- Keep the phone or tablet nearby throughout the day.
- The **Home** tab shows that the app is **Active**.

When the app is **Active**, the app can connect to the patient's heart device and send data to the Medtronic CareLink Network. If the requirements for the app to remain **Active** are not all met, a message about that requirement is shown on the **Home** tab.

6.4 Configuring Phone and Tablet Settings

To ensure that the app can connect to the patient's heart device, certain settings must be selected in the patient's phone or tablet.

The app automatically checks the status of the settings on the patient's phone or tablet and the permissions settings for the app. If all of the settings are configured correctly, the **Home** tab shows the app is **Active**.

When the app is **Active**, the app can connect to the patient's heart device and send data to the Medtronic CareLink Network.

Tell the patient to check following settings on his or her phone or tablet to ensure that the app is **Active**:

- Enable Bluetooth® on the phone or tablet.
- Turn on notifications in the phone or tablet's **Settings**. When notifications are turned on, the app can display important messages about updating the app or the OS on the phone or tablet.
- For the Apple™* iOS™*
 - Confirm that the **Background App Refresh** setting is enabled. The app cannot transfer data between the heart device and the Medtronic CareLink Network if the **Background App Refresh** setting is disabled.
 - Limit the use of **Low Power Mode**. The **Low Power Mode** setting for the phone needs to be turned off for the app to transfer data between the heart device and the Medtronic CareLink Network. If **Low Power Mode** is used to extend the phone's battery life for a limited time, turn it off when possible. Turning off **Low Power Mode** helps to ensure that the app is able to transfer data between the heart device and the Medtronic CareLink Network. Do not leave **Low Power Mode** on at all times.
 - Bluetooth® must be turned on for the app in the phone or tablet app permissions settings.
- For the Android™* OS
 - Turn on the **Location** setting in the phone or tablet's **Settings**.
 - For Android™* 9 and previous versions, turn on the **Location** setting in the app's **Permissions**.
 - For Android™* 10 and later versions, set the app **Location** setting permission to **Allow all the time**.
 - The battery optimization setting must be turned off for the app to transfer data between the heart device and the Medtronic CareLink Network. When battery optimization is turned on for the app, the app cannot transfer data between the heart device and the Medtronic CareLink Network.
 - Turn off the battery saver or power saver mode. The battery saver or power saver mode on the phone or tablet must be turned off for the app to transfer data between the heart device and the Medtronic CareLink Network. If battery saver mode is used to extend the phone or tablet battery life for a limited time, turn it off when possible. Turning off the battery saver mode helps to ensure that the app is able to transfer data between the heart device and the Medtronic CareLink Network. Do not leave the battery saver mode on at all times.

6.5 Keeping the App Open

Instruct the patient to keep the app open and running on his or her phone or tablet so that the patient's heart device stays connected to the app. The app can either be open in the foreground or running in the background of the patient's phone or tablet. The app does not need to be visible in the foreground on the screen of the patient's phone or tablet to stay connected to the patient's heart device. The app can be open and running in the background and stay connected to the patient's heart device while the patient uses other apps on the phone or tablet. If the patient closes the app, instruct the him or her to reopen it and check that the app is **Active** so that the app can connect to the patient's heart device again.

Instruct the patient to keep the phone or tablet charged. The app will not send transmissions if the phone or tablet is turned off or is off because the battery is not adequately charged.

6.6 Keep the app running in the background

The patient may see messages to keep the app open and running in the background when he or she is using the app.

Mobile devices allow many apps to run at the same time. When the app the patient is using is in the foreground, the other apps that are open are considered in the background.

When the app is running in the background, it is still working to communicate with the patient's heart device and the Medtronic CareLink Network. The app regularly checks the heart device and sends information to the Medtronic CareLink Network if necessary.

If the patient forces the app to close, it is not running in the background and it will not be able to check the heart device or send information to the Medtronic CareLink Network. The patient can switch to another app as long as the app is running in the background.

If the patient closes the app, a notification may be sent to open the app. Instruct the patient to reopen the app and let it run in the background. When the app is open and running in the background, it can continue to communicate with the patient's heart device and the Medtronic CareLink Network. The patient's clinic can then review the heart device data.

6.7 Patient Proximity to the Phone or Tablet

Instruct the patient to keep the phone or tablet near him or her throughout the day to make sure that the app stays connected to his or her heart device. Medtronic recommends that the patient keep the phone or tablet near him or her (within 6 in or 15 cm and 3 feet or 1 m) for a minimum of 3 continuous hours throughout the day.

When the patient keeps the phone or tablet near him or her throughout the day, the app can communicate with the patient's heart device and send the heart device data to the Medtronic CareLink™ Network.

- Communicating with the patient's heart device can take 5 to 15 minutes. Communication between the app and the heart device can be interrupted if the phone or tablet is not near the patient (within 6 in or 15 cm and 3 feet or 1 m).
- Sending heart device data to the Medtronic CareLink™ Network can take between 3 to 24 hours. The heart device data may not be successfully sent to the Medtronic CareLink™ Network if the patient's phone or tablet is not near him or her (within 6 in or 15 cm and 3 feet or 1 m) for a minimum of 3 continuous hours throughout the day. If the app supports therapeutic heart devices, it displays a notification when the patient's clinic receives his or her transmission.

7 Using the App with Therapeutic Heart Devices

7.1 Using the App on Multiple Phones or Tablets

The app can be installed on multiple phones or tablets, but it is recommended that the patient install it on his or her primary phone or tablet.

The patient's heart device and patient information are connected to his or her email address. To use the app on a secondary phone or tablet, the patient will need to log in with the same email address as his or her primary phone or tablet. The patient must set up his or her primary phone or tablet before adding a secondary phone or tablet.

If the patient upgrades to a new phone or tablet, the patient should remove the app from his or her old phone or tablet. Instruct the patient to remove the app from his or her old phone or tablet after the patient installs the app on a new phone or tablet.

The information in **Symptom Journal** and **Vitals Tracking** is not shared across multiple phones or tablets. If the patient has more than one phone or tablet, he or she will need to track this information separately in each phone or tablet. If the patient replaces his or her phone or tablet, the information cannot be transferred to a replacement phone or tablet.

7.2 Home Tab

The **Home** tab provides the patient access to the following information about the app:

- Connection status to show if the app is **Active**
When the app is **Active**, the patient's heart device data can be sent to the clinic.
- Messages for app permissions or phone or tablet settings
- Information on the heart device's estimated battery life and the next automatic transmission date

When the **Home** tab displays a red dot, there are new messages for the patient to review.

7.3 Dashboard Tab

The following features of the app are accessible from the **Dashboard** tab:

- Messages
- The patient's heart device information

- Vitals tracking for weight, blood pressure, and heart rate
- A journal to record symptoms
- Physical activity tracking
- Education information
- Information on the patient's heart device's estimated battery life and the next automation transmission date

When the **Dashboard** tab displays a red dot, there are new messages for the patient to review.

If the patient's phone or tablet is not connected to the Internet, only **Symptom Journal** and **Vitals Tracking** are available.

7.4 Heart Device

The patient can view information about his or her heart device on the **Heart Device** screen.

From the **Dashboard** tab, instruct the patient to tap **Heart Device**.

The **Heart Device** screen shows the following information about the patient's heart device:

- **Average Battery Longevity** – the estimated remaining battery life for the patient's heart device
- **Device Type** - the type of heart device the patient has implanted
- **Implanted** – the date the patient's heart device was implanted
- **Model Number** – the model number of the patient's heart device
- **Serial Number** – the serial number of the patient's heart device
- **Device Name** – the product name of the patient's heart device

7.5 Transmissions

7.5.1 Sending Heart Device Data to the Patient's Clinic

The app must be **Active** to send transmissions to the Medtronic CareLink Network. The app uses Bluetooth® wireless technology to communicate with the patient's heart device to receive data and then uses the patient's phone or tablet and the Internet to send the patient's heart device data to his or her clinic. The clinic uses that data to monitor the patient's heart device.

There are two types of transmissions: automatic and manual.

Automatic Transmissions – Automatic transmissions are scheduled by the patient's clinic. Instruct the patient to keep his or her phone or tablet near his or her body during the scheduled transmission time. The patient does not need to interact with the app to send automatic transmissions.

Manual Transmissions – The patient can send a manual transmission when the following situations occur:

- When the clinic asks the patient to send a transmission.
- If the patient receives a notification from the app that a scheduled automatic transmission was missed.

The patient's transmissions happen automatically. At times, the patient's clinic may request that the patient send a transmission manually.

To send a transmission, instruct the patient to check the following phone or tablet and app settings:

- The phone or tablet battery must be charged to use the app. The app will not send transmissions if the phone or tablet is turned off or is off because the battery is not adequately charged.
- The phone or tablet must have the Bluetooth® wireless connection turned on. The app will not be able to receive data from the patient's heart device without a Bluetooth® wireless connection.
- The phone or tablet must be connected to the Internet. The patient's phone or tablet must be connected to the Internet to transfer his or her heart device data to the Medtronic CareLink Network.
- The patient must stay within 6 in (15 cm) and 3 feet (1 m) of his or her phone or tablet until the transmission is complete. The communication between the patient's heart device and the app could be interrupted if the patient does not stay close to his or her phone or tablet. The app displays a notification when the patient's clinic receives the transmission.
- The app must be open on that patient's phone or tablet and running in the background.

Phone or tablet settings for Apple™* iOS™*:

- The **Background App Refresh** setting must be enabled. The app cannot send automatic transmissions to the Medtronic CareLink Network if the **Background App Refresh** setting is disabled.
- Limit the use of **Low Power Mode**. If **Low Power Mode** is on then the app cannot send an automatic transmission to the Medtronic CareLink Network.
- Bluetooth® must be turned on for the app in the phone or tablet's app permissions settings.

Phone or tablet settings for the Android™* OS:

- For Android™* 9 and older OS versions, turn on the **Location** setting in the phone or tablet's **Settings**. Also, turn on the **Location** setting in the app's **Permissions**.
- For Android™* 10 or later OS versions, turn on the phone or tablet's **Location** setting. Also, set the app **Location** setting permission to **Allow all the time**.
- The battery optimization setting must be turned off for the app. The app cannot send automatic transmissions to the Medtronic CareLink Network if the battery optimization setting is on for the app.
- Turn off battery saver mode.

Troubleshooting windows may appear after the patient taps **Send Transmission**. Instruct the patient to close the help window and then tap **Send Transmission** to reattempt the transmission.

- If a window indicates that the patient's phone or tablet's **Location** setting is off, instruct the patient to tap **SETTINGS** in the window. Tapping **SETTINGS** takes the patient to a screen that allows the patient to turn on the **Location** setting for the phone or tablet.
- If a window indicates that the patient's app **Location** setting is off, instruct the patient to tap the option to turn on the **Location** setting if the option is available. Otherwise, instruct the patient to tap **SETTINGS** in the window. Tapping **SETTINGS** redirects the patient to a screen where he or she can turn on the **Location** setting for the app.
- If a window prompts the patient to allow the app to run in the background, instruct the patient to close the window and then tap **ALLOW** or **YES** to stop optimizing battery usage for the app.

7.5.2 Sending a Manual Transmission

The patient should only send a transmission manually when his or her clinic requests that he or she send a transmission manually.

To send a transmission manually, instruct the patient to complete the following steps:

1. From the **Dashboard** tab, tap **Messages**.
2. Tap **Send Transmission**.
A message appears to confirm that the clinic knows that a transmission is being sent manually.
3. Tap **YES**.

The app will begin sending the transmission. The app will provide instructions during the transmission process.

Sending a transmission will take up to three hours. Instruct the patient to keep the app open and running in the background until the transmission is sent. The app displays a notification when the patient's clinic receives the transmission.

7.6 Checking the Status of the Patient's Transmissions

The patient can check to see whether transmissions were sent to the Medtronic CareLink Network.

Instruct the patient to complete the following steps to check whether transmissions were sent to the Medtronic CareLink Network:

1. From the **Dashboard** tab, tap **Messages**.
The **Messages** screen displays.
2. Locate the transmission to check.
 - **Sending Transmission....**: A transmission that is still being sent to the Medtronic CareLink Network is listed as **Sending Transmission....**
 - **Transmission received**: Transmissions that were successfully sent to the Medtronic CareLink Network are listed as **Transmission received**.
3. Tap the message to open it and see additional information about the transmission.

7.7 What to Tell the Patient to Do If a Transmission Is Not Sent

Transmissions must be successfully sent to the Medtronic CareLink Network so that the patient's clinic can review his or her heart device data.

If the patient sent a transmission and it was not successful, instruct him or her to try one or more of the following actions:

- Check all the phone or tablet and app requirements listed in *Section 7.8, What the Patient Should Check if a Transmission is Not Sent, page 11*.
- Confirm that the **Home** tab shows the app is **Active**.
- Try to resend the manual transmission in a few minutes.

Instruct the patient to contact his or her doctor or Medtronic Patient Services if the following items have occurred:

- He or she has checked the phone or tablet and app settings, and the app is still unable to send a scheduled automatic transmission or manual transmission.
- If the patient has no scheduled automatic transmissions listed at the top of the **Home** or **Dashboard** tabs.
- If a scheduled automatic transmission or manual transmission is not listed as a **Transmission received** on the **Messages** screen.

7.8 What the Patient Should Check if a Transmission is Not Sent

If an automatic transmission did not occur, or if a manual transmission was not sent successfully, instruct the patient to check the following requirements:

- Is the patient's phone or tablet battery adequately charged? The patient's phone or tablet must have sufficient power to be turned on. The app cannot send a transmission if the patient's phone or tablet is turned off because the battery is not adequately charged.
- Does the **Home** tab show that the app is **Active**? The app must be **Active** to send a transmission. For more information, see *Section 6.4, Configuring Phone and Tablet Settings, page 7*.
- Is the patient's phone or tablet within 6 in (15 cm) and 3 feet (1 m) of him or her for a 3-hour duration? The patient's phone or tablet must be within 6 in (15 cm) and 3 feet (1 m) of his or her body for at least 3 hours to communicate with his or her heart device and to send data transmissions to the Medtronic CareLink Network. The app displays a notification when the patient's clinic receives the transmission.
- Is the app open and running in the background? The app must be open and running in the background to communicate with the patient's heart device and to send data transmissions to the Medtronic CareLink Network.

7.9 Vitals Tracking

7.9.1 About Vitals Tracking

The patient can use **Vitals Tracking** to manually record measurements for weight, blood pressure, and heart rate and to track those measurements over time. Tracking measurements in **Vitals Tracking** is optional. The data the patient collects is not used to treat the patient's medical condition. The patient can use the data to help maintain a healthy lifestyle.

The **Vitals Tracking** screen displays the patient's measurements summary. The patient can also view weekly or monthly charts to see trends in his or her measurements over time. When the patient records vitals measurements, the measurements are stored in the app only and are not sent to the patient's clinic.

The information the patient tracks in **Vitals Tracking** is only saved to one phone or tablet. It cannot be shared across multiple phones or tablets. If the patient has more than one phone or tablet, the information needs to be tracked separately in each phone or tablet. If the patient replaces the phone or tablet, the information cannot be transferred to a replacement phone or tablet.


7.9.2 Vitals Settings

The patient can set weight values to track his or her weight changes over time on the **Vitals Settings** screen. The settings on the **Vitals Settings** screen are used to display weight values in imperial or metric units and to set daily or weekly weight change values.

Changes to the patient's **Vitals Settings** are displayed on the **Vitals Tracking** screen in the **Weight** section.

7.9.3 Selecting Vitals Settings

To select **Vitals Settings**, have the patient complete the following steps:

1. Tap  > **Settings**.
2. Tap **Vitals Weight**.
3. Select a weight **Unit**:
 - **lbs** (pounds)
 - **kgs** (kilograms)
4. Select a **PER DAY** and a **PER WEEK** weight value in the **I do not want my weight to change more than:** section.
5. Tap **SAVE**.

7.9.4 Viewing Vitals Tracking Data and Graphs

The patient can view and compare daily, weekly, and monthly data for vitals categories the patient has chosen to track.

To view **Vitals Tracking** data, the patient must have vitals tracking enabled for the category he or she wants to view, and the patient must have recorded vitals measurements for that category.

Vitals Tracking allows the patient to view trends over time in his or her recorded vitals measurements. The patient can view daily values for any day on which data was recorded, or view weekly or monthly graphs.

Recorded vitals measurements are stored only in the app, and are not sent to the patient's clinic. To view **Vitals Tracking**, instruct the patient to complete the following steps:

1. From the app's **Dashboard** tab, tap **Vitals Tracking** to view today's recorded measurements. If no vitals are recorded today, no data is shown.
 - Tap < or > to view recorded measurements for previous or next days.
 - If the patient is tracking weight measurement, and has set daily or weekly baseline values, daily values that meet or exceed baselines will be displayed in red.
2. Tap **WEEK** or **MONTH** to view tracking graphs for the patient's recorded vitals measurements. If the patient is tracking multiple categories, he or she can scroll to see additional graphs.

Option	Description
Display Values	Tap this switch to turn display of recorded values on the WEEK graph on or off.
< and >	Tap to view graphs for the previous or next time period.
< Back	Tap to return to the Vitals Tracking screen.

7.9.5 Entering Weight Measurements

The patient can enter weight measurements manually to track his or her weight trends over time.

When the patient records his or her weight manually, the most recent recorded weight is displayed on the screen. The **Vitals Tracking** screen displays the patient's weight gain or loss since yesterday and since last week.

Instruct the patient to complete the following steps to track weight manually:

1. From the **Dashboard** tab, tap **Vitals Tracking > Weight**.
2. Use the scrolling number pickers to select the weight measurement.
3. Tap **SAVE** to record the weight measurement for today. The data is added to the **Vitals Tracking** screen.
A pop-up confirmation message appears.
4. Tap **OK**.

7.9.6 Entering Blood Pressure and Heart Rate

The patient can manually enter his or her blood pressure and heart rate.

When the patient records his or her heart rate and blood pressure, the most recent entries are displayed on the screen.

Instruct the patient to complete the following steps to track his or her blood pressure or heart rate:

1. From the **Dashboard** tab, tap **Vitals Tracking**.
2. Select the blood pressure or heart rate vital:
 - **Systolic**
 - **Diastolic**
 - **Heart Rate**
3. Enter the **SYSTOLIC** and **DIASTOLIC** values for blood pressure using the scrolling number picker.
When recording blood pressure measurements, Systolic pressure is the higher number, and Diastolic pressure is the lower number. Blood pressure values are recorded in millimeters of mercury (mmHg), which is a unit of pressure commonly used to describe blood pressure.
4. Enter a **HEART RATE** measurement using the scrolling number picker.
5. Tap **SAVE** to record the values for today. The data is added to the **Vitals Tracking** screen.
A pop-up confirmation message is displayed.
6. Tap **OK**.

7.10 Symptom Journal

7.10.1 Using Symptom Journal

The patient can use the **Symptom Journal** to log any symptoms he or she experiences between in-office visits. The patient can record the symptoms he or she experienced, the time when he or she experienced the symptoms, and add comments to the journal entry. The patient can share the logged symptoms with his or her doctor at the patient's next in-office visit. The symptoms the patient logs in the journal are not sent to the patient's clinic. They are only stored in the app on the patient's phone or tablet. The patient can also view previously logged symptoms.

The information that the patient tracks in **Symptom Journal** is only saved to one phone or tablet. It cannot be shared across multiple phones or tablets. If the patient has more than one phone or tablet, the patient will need to track this information separately in each phone or tablet. If the patient replaces his or her phone or tablet, the information cannot be transferred to a replacement phone or tablet.

7.10.2 Recording New Symptoms

The patient can add new symptoms to his or her **Symptom Journal** log and share them with his or her doctor at the next in-office visit. Any symptoms the patient logs are stored in the app only and are not sent to the patient's clinic.

Instruct the patient to complete the following steps to add symptoms to his or her **Symptom Journal** log:

1. From the **Dashboard** tab, tap **Symptom Journal**.
The **Symptom Journal** screen displays.
2. Tap **RECORD NEW SYMPTOMS**.
A pop-up confirmation appears.
3. Tap **OK**.
4. Tap one or more of the following symptoms to add to the **RECORDED SYMPTOMS** log:
 - Dizzy
 - Shortness of Breath
 - Palpitations
 - Fainted
 - Swelling
 - Heart Fluttering
 - Fatigue
 - Tap **Add Other Symptom** to add a symptom that does not appear in the list.
5. Tap **NEXT**.
6. Select an option from the **When did they occur?** list.
7. Enter any additional information about the symptom in the text field.
Note: The patient can use a maximum of 250 characters to describe the activity.
8. Tap **SAVE**.
A pop-up confirmation screen appears.
9. Tap **OK**.

The symptoms are added to the patient's **RECORDED SYMPTOMS** log.

7.10.3 Deleting Recorded Symptoms

The patient can delete symptoms that he or she added to the **Symptom Journal**.

The patient can perform the following steps to delete a symptom from the **Symptom Journal**:

1. From the **Dashboard** tab, tap **Symptom Journal**.
The **Symptom Journal** screen appears.
2. From the **RECORDED SYMPTOMS** section, tap the symptom the patient wants to delete.
The **Symptom Journal** screen appears.
3. Tap **DELETE**.
4. Select one of the following options:
 - Tap **DISCARD** to delete the symptom.
 - Tap **RETURN TO SUMMARY** to return to the **Symptom Journal** screen. Tapping **RETURN TO SUMMARY** keeps the symptoms in the **RECORDED SYMPTOMS** list.

7.11 Physical Activity

7.11.1 Physical Activity Information

The **Physical Activity** screen tracks the amount of time that the patient has spent doing physical activity. The app uses data from the patient's heart device and creates views of the patient's physical activity. The patient can view his or her daily activity level and compare it to the previous day. The patient can also view averages of his or her physical activity for the past week or month.

7.11.2 Viewing Physical Activity Information

Instruct the patient to complete the following steps to track **Physical Activity**:

1. From the **Dashboard** tab, tap **Physical Activity**.
2. Tap **DAY**, **WEEK**, or **MONTH**.
Tap **DAY** to see the type and number of minutes of physical activity for that day. Tap **WEEK** or **MONTH** to see the amount of time of physical activity for the last week or month in a graph.

7.12 Education

The patient can access educational material about his or her heart device and find answers to common questions about heart devices and living with an implanted medical device.

To access the education information, the patient's phone or tablet must be connected to the Internet.

The patient can tap **Education** from the **Dashboard** tab to view information about how heart devices work, the conditions heart devices are used to treat, how remote monitoring works, and answers to common questions about living with a heart device.

7.13 Travel Considerations

Most app features are unavailable unless the phone or tablet is connected to the Internet.

If the phone or tablet is not connected to the Internet, the patient's transmissions can be delayed and **Education** information cannot be viewed. To access all of the features of the app and send transmissions, instruct the patient to connect the phone or tablet to the Internet.

Internet access is subject to local capabilities and may not be available while traveling. To avoid data or roaming charges, the patient can turn off cellular data on his or her phone or tablet completely. The patient can connect his or her phone or tablet to the Internet using a Wi-Fi™* connection where available. Wi-Fi™* is available in many airports, hotels, and restaurants. The patient may need to accept terms of use or conditions to connect a phone or tablet to a Wi-Fi™* network. If the patient does not accept the terms of use or conditions, the phone or tablet may not be able to transfer heart device data from the app to the Medtronic CareLink Network.

The patient can access the features of the app when the phone or tablet is in **Airplane Mode** by connecting to a Wi-Fi™* and Bluetooth® after the phone or tablet enters **Airplane Mode**.

Instruct the patient to check the **Home** tab to confirm the app is **Active**.

8 Using the App with Diagnostic Devices

8.1 Using the App on Multiple Phones or Tablets


The patient can install the app on multiple phones or tablets.

The heart device and patient information are connected to the patient's email address. To use the app on another phone or tablet, the patient needs to log in with the same email address as his or her primary phone or tablet. The patient's primary phone or tablet must be set up before he or she adds another phone or tablet.

If the patient is using the app on more than one phone or tablet, he or she needs to set one phone or tablet as the primary phone or tablet. The patient can only record symptoms on his or her primary phone or tablet if **Symptom Recording** is enabled for the app.


8.1.1 Setting a Primary Phone or Tablet

To record symptoms on the patient's phone or tablet, he or she will need to set the phone or tablet as the primary phone or tablet. The patient can only record symptoms on the primary phone or tablet if **Symptom Recording** is enabled for the app. To set the phone or tablet as the primary phone or tablet, instruct the patient to perform the following steps:

1. Tap  > **Settings**.
2. Tap **Symptom Recording**.
3. Tap **YES**.
4. Tap **OK** in the confirmation pop-up.

8.1.2 Changing the Primary Phone or Tablet

The patient can record symptoms on a different phone or tablet by setting a secondary phone or tablet as the primary mobile device. The secondary phone or tablet must also have the app installed. The patient can only record symptoms on the primary phone or tablet if **Symptom Recording** is enabled for the app. Instruct the patient to perform the following steps to set a secondary phone or tablet as the primary phone or tablet:

1. Open the app on the secondary phone or tablet.
2. Tap  > **Settings**.
3. Tap **Symptom Recording**.
4. Tap **YES**.
5. Tap **OK** in the confirmation pop-up.

8.2 Home Tab

The **Home** tab provides access to the following information about the app:

- Connection status to show if the app is **Active**

When the app is **Active**, the patient's heart device data can be sent to the clinic.

- Messages for app permissions or phone or tablet settings

When the **Home** tab displays a red dot, there are new messages for the patient to review.

8.3 Dashboard Tab

The following features of the app are accessible from the **Dashboard** tab:

- Messages
- The patient's heart device information
- A journal to record symptoms
- Education information

When the **Dashboard** tab displays a red dot, there are new messages for the patient to review.

Symptom History and recording new symptoms are available if **Symptom Recording** is enabled for the patient's app.

If the patient's phone or tablet is not connected to the Internet, the patient can record new symptoms if **Symptom Recording** is enabled for his or her app. The other features of the **Dashboard** tab are not available until his or her phone or tablet is connected to the Internet.

8.4 Heart Device

The patient can view information about his or her heart device on the **Heart Device** screen.

From the **Dashboard** tab, instruct the patient to tap **Heart Device**.

The **Heart Device** screen shows the following information about the patient's heart device:

- **Device Type** - the type of heart device the patient has implanted.
- **Implanted** – the date the patient's heart device was implanted
- **Model Number** – the model number of the patient's heart device
- **Serial Number** – the serial number of the patient's heart device
- **Device Name** – the product name of the patient's heart device

8.5 Symptom History Log

8.5.1 Using Symptom History

The **Symptom History** log lists the symptoms the patient records. **Symptom History** is available if **Symptom Recording** is enabled for the patient's app. The patient can record information about the symptoms he or she experienced and add comments to a journal entry. The patient can also view previously logged symptoms.

Symptoms that the patient records in the app **Symptom History** log are not displayed to the clinician unless the heart device also records a corresponding symptom episode. The **Symptom History** log saves all information that the patient records about symptoms. The patient can bring the phone or tablet to the next in-office visit to show his or her doctor the symptoms recorded in the app. Patients should talk to their heart doctors about how best to share symptom information.

Refer to the device manual for the diagnostic device for information about how the device records symptom episodes.

If the patient is using the app on more than one phone or tablet, the patient needs to set one phone or tablet as the primary phone or tablet. The patient can only use the primary phone or tablet to record symptoms. The patient can change the primary phone or tablet that he or she uses to record symptoms.

8.5.2 Viewing the Symptom History Log

Instruct the patient to complete the following steps to view his or her symptom history log:

1. From the **Dashboard** tab, tap **Symptom History**.

The **Symptom History** screen displays. Any symptoms that were recorded are displayed in the **RECORDED SYMPTOMS** list.

Tap **LOAD MORE** to display additional recorded symptoms that are not displayed in the **RECORDED SYMPTOMS** list.

2. Tap on a recorded symptom.

The **Symptom Summary** screen displays. Information that was recorded about the symptom is listed.

3. Tap **PREVIOUS** or **NEXT** to view the other recorded symptoms in the **RECORDED SYMPTOMS** list.

8.6 Recording New Symptoms

The patient can record information about symptoms he or she experiences if **Symptom Recording** is enabled for his or her app. The information about the patient's symptoms can be shared with his or her doctor during clinic appointments.

To record symptoms, the patient will need to set his or her phone or tablet as his or her primary mobile device.

If the patient is using the app on more than one phone or tablet, he or she will need to set one phone or tablet as the primary phone or tablet. The patient can only use his or her primary phone or tablet to record symptoms. The patient can change his or her primary phone or tablet that he or she uses to record symptoms. To record new symptoms, instruct the patient to complete the following steps:

1. From the **Dashboard** tab, tap **RECORD NEW SYMPTOMS**.
A pop-up confirmation displays.
2. Tap **OK**.
3. Tap one or more of the following symptoms to add to the **Symptom History** log:
 - **Dizzy / Lightheaded**
 - **Short of breath**
 - **Heart pounding**
 - **Faint**
 - **Heart fluttering**
 - **Other**
4. Tap **NEXT**.
5. Tap one of the options in the **What was your activity level?** list:
 - **Not at all active**
 - **A little active**
 - **Active**
 - **Very active**
6. Tap **NEXT**.
A pop-up confirmation screen displays.
7. Enter any additional information about the activity in the **What were you doing?** field.
Note: The patient can use a maximum of 250 characters to describe his or her activity.
8. Tap **SUBMIT**.

The symptoms are added to the patient's **Symptom History** log.

8.7 Education

The patient can access educational material about his or her heart device and find answers to common questions about heart devices and living with an implanted medical device.

To access the education information, the patient's phone or tablet must be connected to the Internet.

The patient can tap **Education** from the **Dashboard** tab to view information about how heart devices work, the conditions heart devices are used to treat, how remote monitoring works, and answers to common questions about living with a heart device.

8.8 Travel Considerations

Most app features are unavailable unless the phone or tablet is connected to the Internet.

If the phone or tablet is not connected to the Internet, only **RECORD NEW SYMPTOMS** is available if **Symptom Recording** is enabled for the patient's app. Transmissions are delayed until the phone or tablet is connected to the Internet. To access all of the features of the app and send transmissions, instruct the patient to connect the phone or tablet to the Internet.

Internet access is subject to local capabilities and may not be available while traveling. To avoid data or roaming charges, the patient can turn off cellular data on his or her phone or tablet completely. The patient can connect his or her phone or tablet to the Internet using a Wi-Fi™* connection where available. Wi-Fi™* can be found in many airports, hotels, and restaurants. The patient may need to accept terms of use or conditions to connect his or her phone or tablet to a Wi-Fi™* network. If the patient does not accept the terms of use or conditions, his or her phone or tablet may not be able to transfer heart device data from the app to the Medtronic CareLink Network.

The patient can access the features of the app when the phone or tablet is in **Airplane Mode** by connecting to a Wi-Fi™* network. The patient may need to enable Wi-Fi™* and Bluetooth® after the phone or tablet enters **Airplane Mode**.

Instruct the patient to check the **Home** tab to confirm the app is **Active**.

9 App Message Explanations for Therapeutic and Diagnostic Devices

9.1 About App Help Messages

The following sections describe help messages that patients could see within the app.

9.2 Bluetooth is off

The app uses Bluetooth®, as needed, to receive data from the patient's heart device. The Bluetooth® wireless connection on the patient's phone or tablet must be turned on for the app to communicate with the patient's heart device.

When the Bluetooth® wireless connection is turned on, the app connects automatically to the patient's heart device.

Tell the patient to navigate to the phone or tablet **Settings** to turn on Bluetooth®.

Note: For iPhone™* and iPad™* users, Bluetooth® permission must be turned on for the app.

The app uses Bluetooth® to receive data from the patient's heart device. The patient needs to grant the app permission to use Bluetooth® to allow the app to communicate with the heart device.

To allow the app to use Bluetooth®, instruct the patient to complete the following steps:

1. Navigate to the phone or tablet **Settings**.
2. Tap **MCL Heart** to access settings for the app.
3. Turn on the Bluetooth® setting for the app.

9.3 Grant MyCareLink Heart Permission to Use Bluetooth

Note: Information in this section applies only to Apple™* phones and tablets.

The app uses Bluetooth® to receive data from the patient's heart device. Instruct the patient to grant the app permission to use Bluetooth® to allow the app to communicate with his or her heart device.

To allow the app to use Bluetooth®, instruct the patient to complete the following steps:

1. Navigate to the phone or tablet's **Settings**.
2. Tap **MCL Heart** to access settings for the app.
3. Turn on the Bluetooth® setting for the app.

9.4 Check Wi-Fi/Cellular connections

The app cannot establish a connection to the Internet on the patient's phone or tablet. The patient must connect the phone or tablet to a Wi-Fi™* or cellular network to send a transmission.

If the patient uses a cellular network to connect the phone or tablet to the Internet, instruct the patient to try one or more of the following options:

- Tap **Settings** and verify that cellular or mobile data is turned on.
- Check that the phone or tablet has cellular service.
- Check that the phone or tablet is in an area with strong cellular reception.
- Check that the data plan for the current billing cycle is not used up.

If the patient uses Wi-Fi™* to connect the phone or tablet to the Internet, instruct the patient to try one or more of the following options:

- For Apple™* phones and tablets, tap **Settings > Wi-Fi** and select a Wi-Fi™* network.
- For Android™* phones and tablets, tap **Settings**, navigate to **Wi-Fi** and select a Wi-Fi™* network.
- Select another Wi-Fi™* network if the current selection is still not working.
- Some Wi-Fi™* networks require accepting terms and conditions before connecting the phone or tablet to the Internet.

9.5 Cannot connect to the Internet

The app cannot establish a connection to the Internet on the patient's phone or tablet. The patient must connect the phone or tablet to a Wi-Fi™* or cellular network to send a transmission.

If the patient uses a cellular network to connect the phone or tablet to the Internet, instruct the patient to try one or more of the following options:

- Tap **Settings** and verify that cellular or mobile data is turned on.
- Check that the phone or tablet has cellular service.
- Check that the phone or tablet is in an area with strong cellular reception.
- Check that the data plan for the current billing cycle is not used up.

If the patient uses Wi-Fi™* to connect the phone or tablet to the Internet, instruct the patient to try one or more of the following options:

- For Apple™* phones and tablets, tap **Settings > Wi-Fi** and select a Wi-Fi™* network.
- For Android™* phones and tablets, tap **Settings**, navigate to **Wi-Fi** and select a Wi-Fi™* network.

- Select another Wi-Fi™* network if the current selection is still not working.
- Some Wi-Fi™* networks require accepting terms and conditions before connecting the phone or tablet to the Internet.

9.6 App setup was not completed

If the patient receives this message, the initial app setup process was not completed. Instruct the patient to log into the app and check the following information to complete the setup process:

- The patient's heart device serial number was entered incorrectly.
- The patient was not close to the phone or tablet during the setup process.

Instruct the patient to check the following items if he or she is having connection issues during the app setup process:

- Stay within 6 in (15 cm) and 3 feet (1 m) of the phone or tablet during the setup of the app.
- The app uses the phone or tablet's Bluetooth® wireless technology to connect to the heart device.
Check that Bluetooth® is enabled on the phone or tablet.
Bluetooth® must be turned on for the app in the phone or tablet's app permissions settings.
- Keep the app open and running in the background until the setup is complete.

9.7 System is temporarily unavailable

When the patient receives this message, certain areas of the app are not available right now because of a Medtronic network issue. Instruct the patient to keep the app open and keep his or her phone or tablet connected to the internet. The app will try to connect to the Medtronic network when it is available again. Also, the patient can try to connect again later.

9.8 MyCareLink Heart™ server is down for maintenance

If the MyCareLink Heart server is down for maintenance, app functionality will be limited until maintenance is complete.

Information the app receives from the server will not be shown in the app.

The patient's phone or tablet will also not be able to send transmissions until maintenance is complete.

9.9 Please allow notifications

Instruct patients to allow notifications on their phones or tablets so that they can receive messages about the use of the app.

If notifications for the app have been turned off, the patient will not receive messages.

Instruct the patient to turn on notifications in his or her phone or tablet app settings per the following steps.

1. Tap **OK**.
2. Tap **ALLOW** to allow notifications.

To turn on the **Notifications** settings permission from the patient's phone or tablet, instruct the patient to complete the following steps:

For Apple™* phones and tablets:

1. Navigate to **Settings** on the patient's phone or tablet.
2. Tap **Notifications > MCL Heart**.
3. Ensure that **Allow Notifications** is enabled.

For Android™* phones and tablets:

1. Navigate to **Settings** on the patient's phone or tablet.
2. Tap **Notifications**.
3. Navigate to **MCL Heart**.
4. Turn on the **Notifications** setting.

9.10 Notifications are off

Instruct patients to allow notifications on their phones or tablets so that they can receive messages about the use of the app.

If notifications for the app have been turned off, the patient's phone or tablet will not receive messages.

Instruct the patient to turn on notifications in his or her phone or tablet app settings per the following steps.

For Apple™* phones and tablets:

1. Navigate to **Settings** on the patient's phone or tablet.
2. Locate the app settings for MCL Heart.

3. Tap **Notifications**.
4. Enable the setting to allow notifications.

For Android™* phones and tablets, instruct the patient to turn on notifications in the patient's phone or tablet settings per the following steps depending on where the patient is located in the app:

While using the app

1. Tap **Resolve**.
2. Tap **Allow** to allow notifications.

While using the app after the patient declined notifications

1. Tap **Settings**.
2. Tap **Notifications**.
3. Enable the setting to allow notifications.

To turn on the **Notifications** settings permission from the patient's phone or tablet, instruct the patient to complete the following steps:

1. Navigate to **Settings** on the patient's phone or tablet.
2. Tap **Notifications**.
3. Navigate to **MCL Heart**.
4. Turn on the **Notifications** setting.

9.11 App update required

Medtronic will periodically push updates to the app to the patient's phone or tablet.

Depending on the patient's phone or tablet settings, updates to the app may happen automatically, or the patient may need to manually approve updates.

If an update to the app is available and has not been installed automatically, the patient will be prompted to update the app when the app is launched. The patient will not be able to use the app until the update is installed.

If the patient is unable to update the app from the app store, the patient's phone or tablet may no longer be supported.

Instruct the patient to check the list of supported phones or tablets at the following website: www.mclheart.com

The app has minimum phone and tablet requirements for the app to monitor the patient's heart device. The minimum requirements for the patient's phone or tablet will change over time. The patient may need to update, or replace, his or her phone or tablet to use the app to transfer data between his or her heart device and the Medtronic CareLink Network. Discuss additional monitoring options with the patient.

9.12 App is not supported by the operating system

The app is not supported by the OS on the phone or tablet.

The app may be in the process of being evaluated to ensure compatibility with the phone or tablet's OS.

If the patient is using a newer version of the OS that does not yet support the app, he or she will not be able to go back to a previous version of the OS.

Instruct the patient to check the list of supported phones or tablets at the following website: www.mclheart.com

Discuss additional monitoring options with the patient.

9.13 Initial setup is in progress with another phone or tablet

The patient needs to wait for his or her primary phone or tablet to be set up before adding a secondary phone or tablet.

The patient will see this message if the initial setup is in progress on his or her primary phone or tablet and the patient tries to log into the app on a secondary phone or tablet. Instruct the patient to wait to tap the link in the invitation email until after he or she has completed setting up primary phone or tablet.

9.14 Allow the app to run in the background

Note: Information in this section applies only to Android™* phones and tablets.

When battery optimization is turned on, the app cannot transfer data between the patient's heart device and the Medtronic CareLink Network.

The patient can tap one of the following buttons:

- Tap **ALLOW** or **YES** to let the app transfer data between the patient's heart device and the Medtronic CareLink Network. The patient's heart device data is retrieved from the Medtronic CareLink Network.
- Tap **DENY** or **NO** to not let the app transfer data between the patient's heart device and the Medtronic CareLink Network.

Medtronic recommends that patients tap **ALLOW** or **YES** to let the app transfer data between the patient's heart device and the Medtronic CareLink Network.

9.15 App Location setting is off

Note: Information in this section applies only to Android™* 9 and previous versions.

The **Location** setting for the app needs to be turned on for the app to receive data from the patient's heart device. The patient's phone or tablet uses Bluetooth® to communicate with the patient's heart device. Android™* phones and tablets must have the **Location** setting turned on for Bluetooth® to work.

To turn on the **Location** setting from the app, instruct the patient to perform the following steps:

1. Tap **Settings** from the **App Location setting is off** window.
2. Tap **Permissions**.
3. Turn on the **Location** setting.

To turn on the **Location** setting from the patient's phone or tablet, instruct the patient to perform the following steps:

1. Navigate to the phone or tablet **Settings**.
2. Locate the phone or tablet application settings, and tap **MCL Heart > Permissions**.
3. Turn on the **Location** setting.

9.16 Phone or tablet Location setting is off

Note: Information in this section applies only to Android™* phones and tablets.

The **Location** setting for the patient's phone or tablet needs to be turned on for the app to receive data from his or her heart device. The patient's phone or tablet uses Bluetooth® to communicate with the patient's heart device. Android™* phones and tablets must have the **Location** setting turned on for Bluetooth® to work.

To turn on the **Location** setting from the app, instruct the patient to perform the following steps:

1. Tap **Settings** from the **Phone or tablet Location setting is off** window.
2. Turn on the **Location** setting.

To turn on the **Location** setting from the patient's phone or tablet, instruct the patient to perform the following steps:

1. Navigate to the phone or tablet **Settings**.
2. Locate the **Location** setting for the phone or tablet.
3. Turn on the **Location** setting.

9.17 Set App Location Permission to "Allow all the time"

Note: Information in this section applies only to phones and tablets on Android™* 10 or later.

The app uses Bluetooth® Low Energy to communicate with the patient's heart device. The app **Location** setting must be set to Allow all the time due to how the Android™* OS uses Bluetooth® Low Energy. The app cannot communicate with the patient's heart device as frequently if he or she selects a different app **Location** setting.

The app does not collect or use any location information when the app **Location** permission is set to **Allow all the time**.

To set the **Location** setting permission to **Allow all the time**, instruct the patient to complete the following steps depending on where he or she is located in the app:

During initial setup of the app

1. Tap **CLOSE** from the **Set App Location Permission to Allow all the time** window.
2. Tap **Allow all the time** on the Android™* location window.

During initial setup of the app if the Android™* location window is bypassed

1. Tap **SETTINGS** from the **Set App Location Permission to Allow all the time** window.
2. Tap **Permissions**.
3. Tap **Location**.
4. Tap **Allow all the time**.

While using the app

1. Tap **SETTINGS** from the **Set App Location Permission to Allow all the time** window.
2. Tap **Allow all the time** on the Android™* location window.

While using the app if the Android™* location window is bypassed

1. Tap **SETTINGS** from the **Set App Location Permission to Allow all the time** window.
2. Tap **Permissions**.
3. Tap **Location**.
4. Tap **Allow all the time**.

To turn on the **Location** setting permission from the phone or tablet, complete the following steps:

1. Navigate to **Settings** on the phone or tablet.
2. Locate app settings.
3. Tap **MCL Heart > Permissions**.
4. Tap **Location**.
5. Tap **Allow all the time**.

9.18 Allow MyCareLink Heart to Connect to Your Heart Device

Note: Information in this section applies only to phones and tablets on Android™* 12 or later.

The app uses the **Nearby devices** setting to communicate with the patient's heart device. Instruct the patient to allow the app permission to use the **Nearby devices** so that the app can communicate with his or her heart device.

To allow the app to use the **Nearby devices** permission, have the patient complete the following steps:

1. Tap **GO TO SETTINGS** in this message.
2. Tap **Apps** to access the apps installed on your phone or tablet.
3. Tap **MCL Heart**.
4. Tap **Permissions**, then tap **Nearby devices**.
5. Tap **Allow**.

9.19 Turn off Low Power Mode

Note: Information in this section applies only to Apple™* phones.

The **Low Power Mode** setting for the patient's phone needs to be turned off for the app to send automatic transmissions to the Medtronic CareLink Network.

If the patient uses Low Power Mode to extend the phone battery life for a limited time, tell the patient to turn off Low Power Mode when possible. Turning off Low Power Mode helps to ensure that the app is able to send automatic transmissions. Instruct the patient not to leave Low Power Mode on at all times.

Tell the patient to complete the following steps to turn off Low Power Mode:

1. Navigate to the phone **Settings > Battery**.
2. Turn off the **Low Power Mode** setting.

9.20 Turn off Low Data Mode

Note: Information in this section applies only to Apple™* phones and tablets.

The **Low Data Mode** setting for the patient's phone or tablet needs to be turned off for the app to send automatic transmissions to the Medtronic CareLink Network.

If the patient uses **Low Data Mode** to reduce cellular data or Internet use for a limited time, inform him or her to turn off **Low Data Mode** when possible. Turning off **Low Data Mode** helps to ensure that the app is able to send automatic transmissions. Inform the patient to not leave **Low Data Mode** on at all times.

Inform the patient to check that **Low Data Mode** is off both for cellular and Wi-Fi™* networks.

To turn off **Low Data Mode** for a cellular network, inform the patient to complete the following steps:

1. Navigate to the phone or tablet's **Settings**.
2. Tap **Cellular > Cellular Data Options**.
3. Turn off **Low Data Mode**.

To turn off **Low Data Mode** for a Wi-Fi™* network, inform the patient to complete the following steps:

1. Navigate to the phone or tablet's **Settings**.
2. Tap **Wi-Fi**.
3. Tap the name of the Wi-Fi™* network that the phone or tablet is connected to.
4. Turn off **Low Data Mode**.

9.21 Turn off battery saver mode

Note: Information in this section applies only to Android™* phones and tablets.

The battery saver or power saver mode for the patient's phone or tablet must be turned off for the app to send automatic transmissions to the Medtronic CareLink Network. If the patient uses the battery saver mode to extend the phone or tablet battery life for a limited time, instruct the patient to turn off the battery saver mode when possible. Turning off the battery saver mode helps to ensure that the app is able to send automatic transmissions. Instruct the patient not to leave the battery saver mode on at all times.

Tell the patient to complete the following steps to turn off battery saver mode:

1. Navigate to the phone or tablet **Settings**.
2. Locate the battery saver mode or power saver mode, and turn it off.

9.22 Turn on Background App Refresh

Note: Information in this section applies only to Apple™* phones and tablets.

The **Background App Refresh** setting must be turned on for the app to send automatic transmissions to the Medtronic CareLink Network.

Tell the patient to check the **Background App Refresh** setting for the phone or tablet and for the app:

1. Navigate to the phone or tablet **Settings**.
2. Tap **General > Background App Refresh**.
3. Turn on the **Background App Refresh** setting if it is not already turned on.
4. Turn on the **MCL Heart** app setting for **Background App Refresh** if it is not already turned on.

If the patient is using an iPhone™* and **Background App Refresh** is disabled, verify that **Low Power Mode** is off. To turn off **Low Power Mode** and enable **Background App Refresh**, tell the patient to access **Settings > Battery > Low Power Mode** and turn off **Low Power Mode**.

9.23 Please keep your app open and between 6 inches (15 cm) and 3 feet (1 m) of your heart device

The patient must stay within 6 in (15 cm) and 3 feet (1 m) of his or her phone or tablet to communicate with his or her heart device. The communication between the patient's heart device and the app could be interrupted if he or she does not stay close to his or her phone or tablet.

9.24 What does it mean to keep the app open and running in the background?

When the patient uses the app, he or she may see messages to keep the app open and running in the background.

Mobile devices allow many apps to run at the same time. The app the patient is looking at is in the foreground. All other apps that are open are running in the background.

When the app is running in the background, it is still working to communicate with the patient's heart device and the Medtronic CareLink Network. The app regularly checks the patient's heart device and sends information to the clinic if necessary.

If the patient forces the app to close, it is not running in the background and it will not be able to check the patient's heart device or send information to the Medtronic CareLink Network. The patient can use other apps as long as he or she has the app running in the background.

If the patient closes the app, he or she may receive a notification to open the app. Instruct the patient to reopen the app and let it run in the background so that the app can continue to communicate with his or her heart device and the Medtronic CareLink Network. The patient's clinic can then review his or her heart device data.

9.25 Read more details on how the app works with your heart device and clinic

The patient's heart device and the app communicate throughout the day. The heart device sends out a secure signal several times an hour that only the app can read. Most of the time this signal is simply telling the app that there is nothing to report.

The patient's heart device sends out a signal to the app when it needs to send data to his or her clinic. The app communicates with the heart device using Bluetooth® Low Energy to get the data, and then sends the data to the Medtronic CareLink Network using the Internet. The app can send data through Wi-Fi™* or the cellular network for the patient's phone or tablet.

When the app's **Home** tab says **Active**, that means the app is ready to communicate with the heart device and the Medtronic CareLink Network.

The timestamp displayed on the **Home** tab of the app is telling the patient the last time the app detected one of those secure signals.

10 App Message Explanations for Therapeutic Devices Only

10.1 Your clinic requests you send your scheduled heart device transmission.

If the app has been unable to send a scheduled transmission for more than 5 days, the patient will receive a notification from the app to send the transmission manually.

To have the patient send a manual transmission, tell the patient to tap **Messages** on the app **Dashboard** tab. Then tap **Send Transmission**.

The patient must stay within 6 in (15 cm) and 3 feet (1 m) of his or her phone or tablet until the transmission is complete. The communication between the patient's heart device and the app could be interrupted if the patient does not stay close to his or her phone or tablet. The patient must keep the app open and running in the background until the transmission is successfully sent.

If the patient has received a notification, instruct the patient to select the missed transmission notification, tap **Send Transmission** and then follow the on-screen instructions.

Sending a transmission will take up to 3 hours. The app displays a notification when the patient's clinic receives the transmission.

10.2 Transmission cannot be sent

The patient's phone or tablet cannot send a manual transmission while the app is performing another task in the background.

Instruct the patient to try to send the manual transmission again in a few minutes.

10.3 Your transmission was not sent

The app must be **Active** to send transmissions to the Medtronic CareLink Network. The app uses Bluetooth® wireless technology to communicate with the patient's heart device to receive data and then uses the patient's phone or tablet and the Internet to send the patient's heart device data to his or her clinic. The clinic uses that data to monitor the patient's heart device.

There are two types of transmissions: automatic and manual.

Automatic Transmissions – Automatic transmissions are scheduled by the patient's clinic. Instruct the patient to keep his or her phone or tablet near his or her body during the scheduled transmission time. The patient does not need to interact with the app to send automatic transmissions.

Manual Transmissions – The patient can send a manual transmission when the following situations occur:

- When the clinic asks the patient to send a transmission.
- If the patient receives a notification from the app that a scheduled automatic transmission was missed.

The patient's transmissions happen automatically. At times, the patient's clinic may request that the patient send a transmission manually.

To send a transmission, instruct the patient to check the following phone or tablet and app settings:

- The phone or tablet battery must be charged to use the app. The app will not send transmissions if the phone or tablet is turned off or is off because the battery is not adequately charged.
- The phone or tablet must have the Bluetooth® wireless connection turned on. The app will not be able to receive data from the patient's heart device without a Bluetooth® wireless connection.
- The phone or tablet must be connected to the Internet. The patient's phone or tablet must be connected to the Internet to transfer his or her heart device data to the Medtronic CareLink Network.
- The patient must stay within 6 in (15 cm) and 3 feet (1 m) of his or her phone or tablet until the transmission is complete. The communication between the patient's heart device and the app could be interrupted if the patient does not stay close to his or her phone or tablet. The app displays a notification when the patient's clinic receives the transmission.
- The app must be open on that patient's phone or tablet and running in the background.

Phone or tablet settings for Apple™ iOS™*:

- The **Background App Refresh** setting must be enabled. The app cannot send automatic transmissions to the Medtronic CareLink Network if the **Background App Refresh** setting is disabled.
- Limit the use of **Low Power Mode**. If **Low Power Mode** is on then the app cannot send an automatic transmission to the Medtronic CareLink Network.
- Bluetooth® must be turned on for the app in the phone or tablet's app permissions settings.

Phone or tablet settings for the Android™ OS:

- For Android™* 9 and older OS versions, turn on the **Location** setting in the phone or tablet's **Settings**. Also, turn on the **Location** setting in the app's **Permissions**.
- For Android™* 10 or later OS versions, turn on the phone or tablet's **Location** setting. Also, set the app **Location** setting permission to **Allow all the time**.
- The battery optimization setting must be turned off for the app. The app cannot send automatic transmissions to the Medtronic CareLink Network if the battery optimization setting is on for the app.
- Turn off battery saver mode.

Troubleshooting windows may appear after the patient taps **Send Transmission**. Instruct the patient to close the help window and then tap **Send Transmission** to reattempt the transmission.

- If a window indicates that the patient's phone or tablet's **Location** setting is off, instruct the patient to tap **SETTINGS** in the window. Tapping **SETTINGS** takes the patient to a screen that allows the patient to turn on the **Location** setting for the phone or tablet.
- If a window indicates that the patient's app **Location** setting is off, instruct the patient to tap the option to turn on the **Location** setting if the option is available. Otherwise, instruct the patient to tap **SETTINGS** in the window. Tapping **SETTINGS** redirects the patient to a screen where he or she can turn on the **Location** setting for the app.
- If a window prompts the patient to allow the app to run in the background, instruct the patient to close the window and then tap **ALLOW** or **YES** to stop optimizing battery usage for the app.

10.4 Transmission is in progress

The patient must stay within 6 in (15 cm) and 3 feet (1 m) of the phone or tablet while transmissions are in progress. If the patient does not stay close to the phone or tablet, the communication between the patient's heart device and the app could be interrupted.

10.5 Account Delete Acknowledgment

The patient should speak with their clinician before deleting their MyCareLink Heart account. Their clinician reviews the data sent from their heart device. If they delete their account and do not have a remote monitoring option, their heart device will not be remotely monitored. Their heart device will not be able to send data to their clinician.

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