



The myMerlin™ mobile app is used with the Confirm Rx™ Insertable Cardiac Monitor to continuously monitor your heart's rhythm and share that information with your doctor.

**In an emergency, do not use the app, and call your doctor.**

For simplicity, these questions use the term myMerlin™ mobile app instead of myMerlin™ for Confirm Rx™ ICM mobile app. The terms cardiac monitor and heart monitor both refer to the Confirm Rx™ Insertable Cardiac Monitor.

Some features or mobile platforms described below may not apply based on the app version and the country the app is in use.

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## **About the myMerlin™ mobile app**

### **What does the myMerlin™ mobile app do?**

myMerlin™ mobile app connects your smartphone to your Confirm Rx™ ICM (also known as a heart monitor or cardiac monitor) and automatically sends your heart monitor information to your doctor. The app does this using Daily Device Checks and Automatic Scheduled Transmissions. It also allows you to manually record your symptoms as they happen.

### **How does the myMerlin™ mobile app communicate with my heart monitor?**

The app uses Bluetooth® wireless technology to communicate with your heart monitor.

### **How does the myMerlin™ mobile app communicate with my clinic?**

The app uses the internet, either Wi-Fi<sup>†</sup> or cellular data, to send data to your clinic. For timely transmissions, please make sure your smartphone stays connected to the internet.

### **How do I select the language of the myMerlin™ mobile app?**

The app uses the same language as your smartphone. If the language of your smartphone is not supported by the app, it will default to English.

### **How do I stay connected to my doctor?**

Make sure your Bluetooth® and Notifications settings are ON and your smartphone has a strong connection to the internet using Wi-Fi<sup>†</sup> or cellular data.

### **How do I turn Bluetooth® ON?**

This can be done in your smartphone Settings menu. For help with this, check your smartphone manual.

**Do I need to hold my smartphone over my heart monitor to connect using Bluetooth® technology?**

No. If Bluetooth<sup>®</sup> is ON and you keep your smartphone within 5 feet (1.5 meters) of you, the app will be able to communicate with your heart monitor. For best results, keep your smartphone nearby as you sleep.

### **Do I always need to keep Bluetooth<sup>®</sup> technology ON and be connected to the internet?**

The app uses Bluetooth<sup>®</sup> technology to communicate with your heart monitor and Wi-Fi<sup>‡</sup> or cellular data to send information to your clinic. Keep these settings ON to make sure the app can work properly.

### **How do I know if I am connected to the internet?**

If you are connected to the internet using cellular data, the top corner of your smartphone screen should display an icon and letters or numbers, such as LTE or 4G.

From the Settings menu of your smartphone, you can turn Wi-Fi<sup>‡</sup> ON and check to see if your smartphone is connected to a network.

Check your smartphone manual for details on both.

### **What is a Daily Device Check?**

During a Daily Device Check, myMerlin<sup>™</sup> mobile app checks the status of your heart monitor and reports new data back to your clinic. “Device” refers to your heart monitor. NOTE: Daily Device Checks are not displayed in the History tab.

### **What type of information is sent to the clinic in a Daily Device Check?**

The myMerlin<sup>™</sup> mobile app retrieves the information that your doctor needs to monitor your condition. This includes arrhythmias detected by the heart monitor.

### **What is an Automatic Scheduled Transmission?**

It is a special transmission scheduled by your doctor. It is like a Daily Device Check but includes all the information since your last scheduled transmission. Past Automatic Scheduled Transmissions are displayed in the History tab.

### **How often does the app check my heart monitor?**

Typically, the app connects to your heart monitor once each day to collect information and send it to your clinic. However, this depends on the settings and schedule determined by your doctor.

#### **What time of day does the app check my heart monitor?**

These checks usually happen during the night while you are sleeping. Keep your smartphone near you (within 1.5 meters or 5 feet) when you sleep. If you are not near your smartphone at that time, the app will occasionally try again and will notify you if there is a problem connecting with your heart monitor.

#### **What does it mean when I see “Daily device check in progress...” when I open the app?**

The app is performing your Daily Device Check or sending an Automatic Scheduled Transmission to your clinic. The process may take several minutes (in some cases it may take more than 15 minutes, and the countdown timer will restart). During this time, keep the app open. You may record symptoms at any time if you need to.

#### **Do I need to confirm that my clinic received my heart monitor information?**

No. Your app will tell you if there is a problem sending the information to your clinic.

#### **Can I use other apps on my smartphone while using myMerlin™ mobile app?**

Yes, but never close or quit the myMerlin™ mobile app on your smartphone. The app needs to be running in the background to work. If the app is closed, it is not working as intended. If you are using the app to Record Symptoms be sure to keep the app open until the app has completed sending information.

#### **Can I close the myMerlin™ mobile app after it has finished its task to save the battery on my smartphone?**

No. The app should be continuously open in the background.

#### **Will the app drain my smartphone battery?**

No. The app only uses battery when it needs to perform a task, like sending a transmission to your clinic. Even when the app does perform a task, it uses very little battery.

#### **How does myMerlin™ mobile app use Notifications?**

The myMerlin™ mobile app uses Notifications to let you know if there was an issue connecting to your heart monitor or sending information to your clinic. If you see a Notification, open the app either by tapping on the Notification or using the app icon to see if any action is needed by you.

**If my Notifications are turned OFF, will that impact the app's ability to remotely monitor my device?**

The app will still be able to monitor your device if there are no connection issues. If your Notifications are OFF, you will not be alerted if the myMerlin™ mobile app needs your attention.

**How do I turn Notifications ON if I originally turned them OFF when setting up the app?**

You can turn Notifications ON from your smartphone Settings menu.

**Does using Location Services impact the battery level of my smartphone?**

It may but some Android‡ versions require the Location Services to be ON for Bluetooth® communication to work. Some Android versions do not require the use of Location Services for the use of Bluetooth® technology. It depends on the operating system version of your Android phone.

**Does the app collect my location information? Does the app track me?**

No. Android‡ version 6.0.0 and later requires Location Services be ON for Bluetooth® communication to work properly between your app and your heart monitor.

**What security measures are taken to keep my information safe between my heart device and the mobile app on my smartphone?**

The Confirm Rx™ ICM encrypts its wireless communication using AES 128-bit encryption and can be paired to only one, authenticated smartphone at a time. The device verifies the 128-bit key at the beginning of every communication. The device also uses Bluetooth® wireless technology low-energy protocols, and proprietary pairing protocols as an added security measure.

**What security measures are taken to keep my information safe when data is sent to my clinic?**

The myMerlin™ mobile app encrypts wireless communication to the database receiving your information, Merlin.net™ Patient Care Network, through a secure TLS connection using SHA 256 cryptographic protection. The Merlin.net PCN is

housed in a secure data center that is ISO27001:2013 certified. All data is restricted to authorized users only, as set by your clinic. Merlin.net PCN is certified through the EU-US Privacy Shield program to transfer patient information from the EU to the U.S.

## Pairing the myMerlin™ mobile app with your heart monitor

### Why do I need to pair the app with my heart monitor?

This is how your doctor can collect information from your heart monitor. Your heart monitor sends your heart rhythm information to the myMerlin™ mobile app, and the app sends that information to your doctor.

### Can I pair my heart monitor with more than one smartphone?

No. For security reasons, you can only pair your heart monitor to one smartphone at a time. To pair your heart monitor to a different smartphone than the one you originally paired with, you need to download and install the app on the new smartphone and perform the pairing process. You will need an activation code to complete pairing. The original smartphone will no longer be paired with your heart monitor.

### What is the Confirm Rx™ ICM serial number and where can I find it?

A serial number is a unique number assigned to your heart monitor for identification purposes. It's located on the heart monitor patient identification (ID) card given to you by your doctor.

### If I get a new smartphone, will I need to set the app up again?

Yes. You will need to download and install the app on your new smartphone and pair it with your heart monitor.

### Why do I need an activation code when pairing my app again?

The activation code is for security purposes.

### Can the app become unpaired?

Yes, if you delete "DM" in your Bluetooth® Settings menu you will need to pair your heart monitor and app again. If the app becomes unpaired for other reasons, you will need to delete "DM" from your Bluetooth® Settings menu before repairing your heart monitor and app.

# Recording a Symptom

The myMerlin™ mobile app is not intended for emergency use. In case of emergency, call emergency services or contact your doctor. If you're experiencing symptoms that are not an emergency and you've discussed sending transmissions with your doctor, use the app to record and send them.

## How do I record a symptom?

Open the app on your smartphone and press the 'Record Symptoms' button. You should keep your smartphone nearby and the app open until the 'Success' message displays. This process can take about 15 minutes to complete.

## When will my doctor see the symptoms I recorded?

Depending on your doctor's preference, the symptoms may be sent immediately or during routine transmissions.

## Should I call my clinic when I record symptoms?

Your doctor will have provided instructions about what to do when you experience symptoms.

## Can I check to see what symptoms were recorded?

Yes. You can view the app's History tab to see the symptoms you've recorded. Your clinic will let you know if you should come in for a check-up.

## What do I do if I don't see a Record Symptoms button?

If you don't see a big, blue Record Symptoms button on the app home screen, it may be because there is a message that you need to respond to first, symptom recording may not be relevant to your condition or because your clinic does not support this functionality.

# Travel

## Should I take my smartphone with me when I travel?

Yes. Keep your smartphone charged and turned ON. Make sure Bluetooth® is ON and your phone is near you at night. Stay connected to the internet (Wi-Fi† or cellular data) as often as possible. Depending on where you travel and your smartphone plan, additional charges may apply.

### How should I plan for lack of internet access?

As soon as you have a good connection again, the app will send your information to your clinic. However, try to stay connected to the internet (Wi-Fi<sup>‡</sup> or cellular data) as often as possible.

### Will time zone changes affect my remote monitoring?

No. The app will automatically use the time zone your phone is using to ensure you don't miss your Daily Device Checks and Automatic Scheduled Transmissions.

### Will sleeping far away from my smartphone affect monitoring?

Yes. Keep your smartphone near you (within 5 feet or 1.5 meters) while you sleep. If the smartphone is not nearby while you sleep, the app will try to connect with your heart monitor again later. The app also will notify you if there was a problem connecting to your heart monitor.

## Troubleshooting myMerlin™ mobile app

### What are the smartphone settings that allow the myMerlin™ mobile app to perform optimally?

- Make sure the smartphone is ON and charged
- Keep the app open (do not force quit the app; make sure it is running in the background); relaunch the app after turning the smartphone ON
- Keep Bluetooth® ON
- Stay connected to the internet (Wi-Fi<sup>‡</sup> or cellular data)
- Keep your smartphone near you (within 5 ft./1.5 m.), especially at night
- Shut OFF Battery Low Power Mode/Battery Saver and Battery Optimization for the myMerlin™ for Confirm Rx™ ICM mobile app (specifics depend on your type of smartphone)
- Allow automatic app updates

### iOS<sup>‡</sup> Specific:

- Turn OFF screen time downtime and app limits
- Turn ON 'Background App Refresh'
- Shut OFF 'Offload Unused Apps'
- Turn OFF "Low Data Mode" for Cellular and Wi-Fi (iOS 13 and later)
- Allow myMerlin App to use Bluetooth® technology (iOS 13 and later)

### **Android<sup>‡</sup> Specific:**

- Turn ON “Location Services” (Android 10 and later: Select the option “Allow all the time”)
- Turn ON “Background Data”
- Shut OFF “App Digital Wellbeing”
- Shut OFF “App Data Saver”
- Shut OFF “Background Bluetooth Scanning”

### **What should I do when I get a Notification that myMerlin™ mobile app couldn't send information to my clinic (“Data Not Sent to Clinic”)?**

Tap the Notification to open the myMerlin™ mobile app (or use the app icon to open it directly). If a ‘Send Data Now’ button is displayed, make sure Wi-Fi<sup>‡</sup> is ON and/or you are connected to cellular data with a strong signal (if your signal is not strong, you may need to move to another location to get a better signal). You may tap the ‘Send Data Now’ button or allow the app to automatically try again later.

### **What do I do if I received a Notification that information couldn't be sent to my clinic and when I open the app, everything looks normal?**

This means that the app sent you a Notification, and then was able to connect to the internet and send the information to your clinic. No action is needed by you.

### **What should I do if I get a Notification that my app couldn't connect to my heart monitor (“Device Check Incomplete”)?**

This notification means that the app was not able to connect to your heart monitor using Bluetooth® technology. Tap the Notification to open the myMerlin™ mobile app (or use the app icon to open it directly). You may see a screen with a countdown timer and “Device check in progress”. If you see this screen, let the process complete. If a ‘Try Now’ or ‘Connect Now’ button is displayed, check to ensure your Bluetooth® is ON. After you've confirmed your Bluetooth® is ON, you may tap the “Try Now” or “Connect Now” button to connect to your heart monitor or allow the app to automatically try again later.

To help the app connect properly overnight, please ensure that the app is open and Bluetooth® technology is ON. See the app settings earlier in this document to help you.

### **What do I do when I get a Notification that the app couldn't connect to my heart monitor, but the app says it was checked today?**

This means that the app sent you a Notification, and then was able to connect and check your heart monitor. No action is needed by you.

## Who should I contact if I need help?

You may contact your clinic or Abbott Remote Care Technical Support. To view contact information for your clinic or Abbott Remote Care Technical Support, please select the More button on the bottom right of the app and go to the Contact tab.

Abbott One St. Jude Medical Dr., St. Paul, MN 55117 USA, Tel: 1-651-756-2000

### Rx Only

**Indications:** The Confirm Rx™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for other cardiac arrhythmias. It is also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation. The Confirm Rx™ ICM has not been specifically tested for pediatric use.

**Contraindications:** There are no known contraindications for the insertion of the Confirm Rx™ ICM. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically insertion device can be tolerated.

**Adverse Events:** Possible adverse events (in alphabetical order) associated with the device, include the following: Allergic reaction, Bleeding, Chronic nerve damage, Erosion, Excessive fibrotic tissue growth, Extrusion, Formation of hematomas or cysts, Infection, Keloid formation and Migration. Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

**Additional Information:** Clinicians must log onto Merlin.net™ Patient Care Network to view transmissions from patients' Confirm Rx™ ICM. On Merlin.net™ PCN they can configure transmission schedule and enable or disable features on patient's myMerlin™ for Confirm Rx™ mobile app. Review of transmissions is dependent on the clinician and may not happen immediately following delivery of such transmissions.

**Limitations:** Patients may use their own Apple‡ or Android‡ mobile device to transmit information from their Confirm Rx™ ICM using the myMerlin™ for Confirm Rx™ mobile app. To do so the device must be powered on, app must be installed, Bluetooth® wireless technology enabled and data coverage (cellular or WiFi‡) available. The myMerlin™ for Confirm Rx™ app provides periodic patient monitoring based on clinician configured settings. Transmission data is resent if not sent successfully. However, there are many internal and external factors that can hinder, delay, or prevent acquisition and delivery of ICM and patient information as intended by the clinician. These factors include: patient environment, data services, mobile device operating system and settings, ICM memory capacity, clinic environment, schedule/configuration changes, or data processing.

An Abbott mobile transmitter is available for patients without their own compatible mobile device.

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