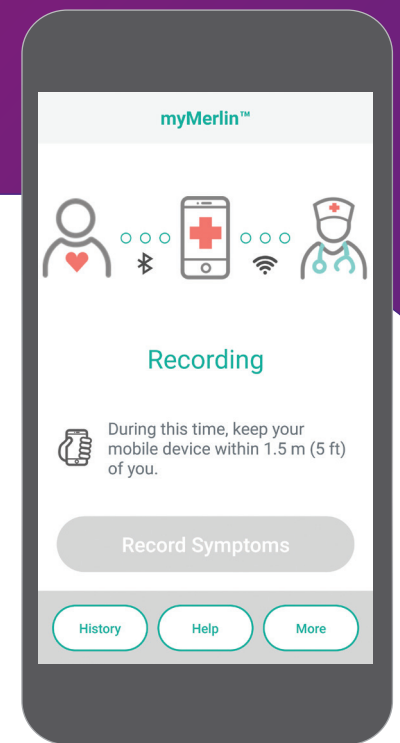ANDROID‡ AND APPLE‡

OPERATING SYSTEM UPDATES

Impact to myMerlin™ for Confirm Rx™ ICM Mobile App

New operating system updates for Android‡ 10 and Apple‡ iOS‡ 13 could impact remote monitoring by the myMerlin™ for Confirm Rx™ ICM mobile application (myMerlin app). The app uses Bluetooth® technology to communicate with your heart monitor. A secure internet connection (either cellular data or Wi-Fi‡) is how information is delivered to your doctor's clinic. The appropriate Bluetooth® and internet settings on your smartphone are important to ensure the app works properly.
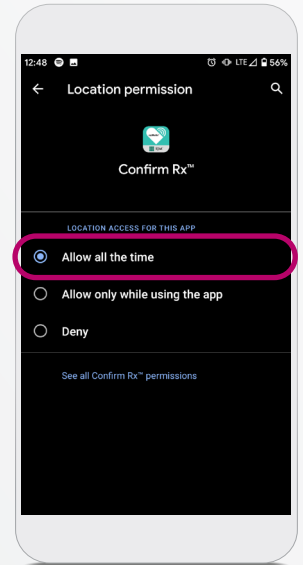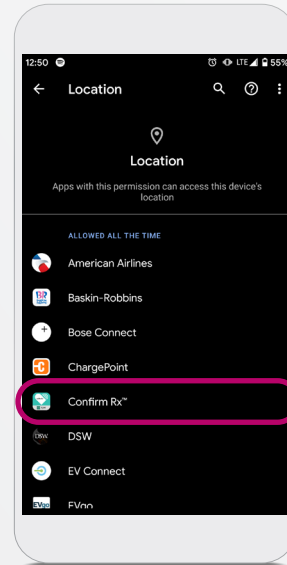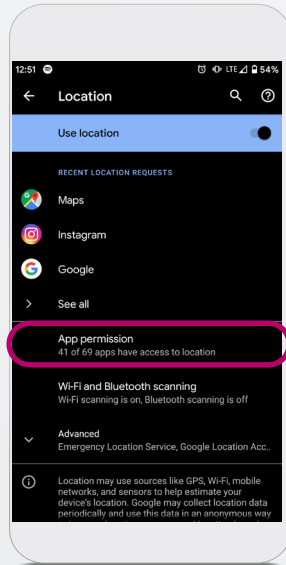
ANDROID‡ 10

BLUETOOTH® SETTING

Location Services must be **ON** for the myMerlin™ app to work correctly. The Android 10 OS update requires app-specific permission to use Location Services in the background. Since the myMerlin app regularly performs background Bluetooth® communication with your Confirm Rx™ ICM, Bluetooth® technology must be allowed to run all the time.

Here's how to check your Bluetooth® setting:

1. From your Home screen, tap **Settings.** Then tap **Location**.

2. Tap **App permission**.

3. Select Confirm Rx app and then **Allow all the time**.

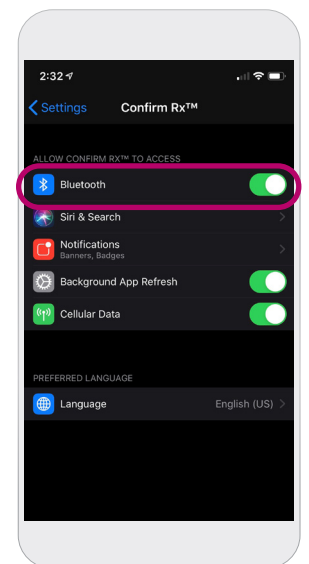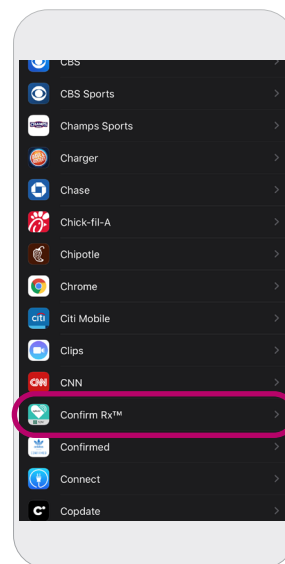NOTE: **IF YOU HAVE AN ABBOTT-ISSUED MOBILE DEVICE, THERE IS NO NEED TO ADJUST YOUR SETTINGS.**

APPLE‡ iOS‡ 13

BLUETOOTH® SETTING

Bluetooth® technology, with iOS 13, must now be turned **ON** for individual apps. Since the myMerlin app regularly uses Bluetooth® technology to communicate with your Confirm Rx ICM, the app-specific Bluetooth® settings must be specifically turned **ON** for the app to work properly.

Here's how to check your Bluetooth® setting:

1. From your Home screen, tap **Settings.** Then tap **Confirm Rx**™.

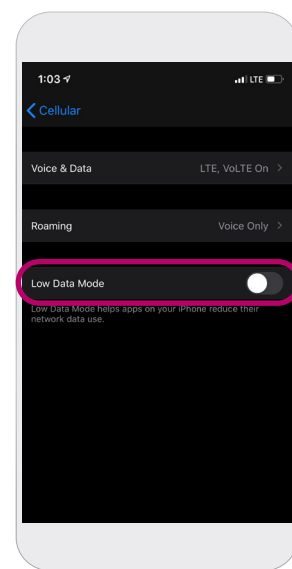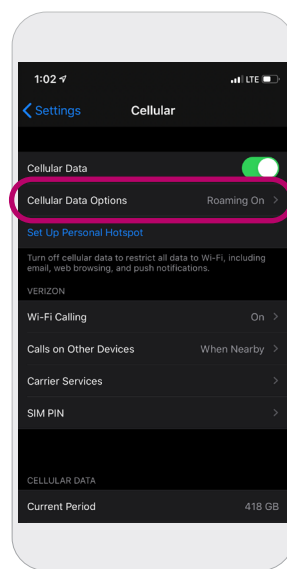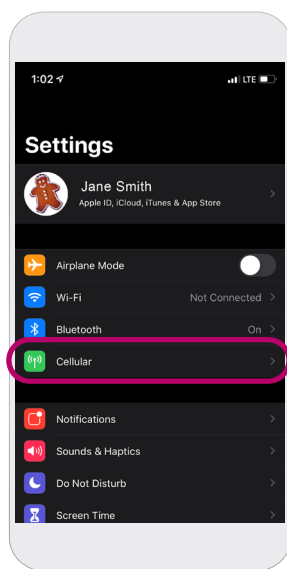2. Tap the slider next to Bluetooth into the **ON/green** position.

APPLE‡ iOS‡ 13 (continued)

LOW DATA MODE SETTING

Your Apple smartphone needs access to the internet to securely connect with your doctor's office. If the iOS‡ 13 Low Data Mode settings are **ON**, apps running in the background cannot access the internet using cellular data or Wi-Fi‡. The myMerlin app requires the "Low Data Mode" setting to be **OFF** for cellular data and Wi-Fi‡.

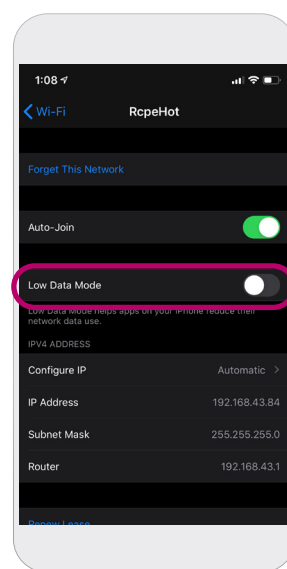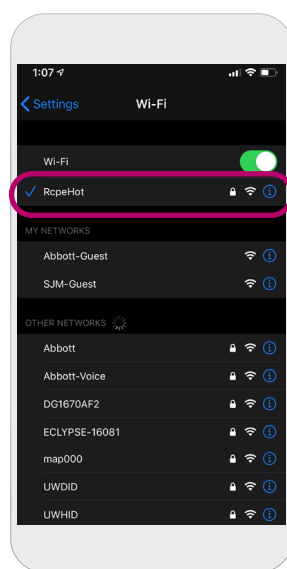Here's how to check your cellular setting:

1. From your Home screen, tap **Settings.** Then tap **Cellular**.

2. Tap **Cellular Data Options**.

3. Ensure the Low Data Mode is in the **OFF/Gray** position.

Here's how to check your Wi-Fi‡ setting:

1. From your Home screen, tap **Settings.** Then tap the Wi-Fi network you are using.

2. Ensure the Low Data Mode is in the **OFF/Gray** position.

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 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 inserted 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 schedules and enable or disable features on a patient's myMerlin™ for Confirm Rx™ ICM 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™ mobile app provides periodic patient monitoring based on clinician configured settings. Data is resent if the transmission was 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.

Abbott