



FREQUENTLY ASKED QUESTIONS (FAQ)

The myMerlinPulse™ mobile application is used with your Abbott implantable cardiac defibrillator (ICD) or a cardiac resynchronization therapy defibrillator (CRT-D) to collect and share important information about your heart with your healthcare provider. This is known as remote monitoring. For simplicity, we use “myMerlinPulse app” and “app” instead of “myMerlinPulse mobile application”.

In an emergency, do not use the app. Seek immediate medical care. The myMerlinPulse app is not intended for emergency use.

Some features or settings described below may not apply based on the app version used or the country where the app is used.

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ABOUT THE myMERLINPULSE™ APP

What does the app do?

Based on how your healthcare provider has set up your app, the app can automatically collect relevant data from your implanted heart device and send it to your clinic. You can also send a transmission from the app, at your clinic's request.

APP SETTINGS FOR YOUR MOBILE DEVICE

What app settings do I need for an Android[®] device?

Keep:

- Your mobile device charged
- The app running in the background (do not force quit or close)

Turn ON:

- Bluetooth[®] wireless technology
- Internet connectivity (cellular data or Wi-Fi[®])
- Location setting, and allow Location permission for the app. Note: For devices with Android[®] 10 and above, you will need to set the app's permission to "Allow all the time"
- App Background Data (allow)
- App Notifications and Continuous Monitoring

Accept:

- App updates (or enable App Auto Updates)

Turn OFF:

- App Digital Wellbeing features
- App Battery Optimization or Power Monitor (do NOT optimize the battery for the app)
- App Data Saver mode
- Power Saving /Battery Saver (name varies by phone)

For further details, refer to your mobile device manual or your myMerlinPulse app patient manual.

What app settings do I need for an iPhone[‡]?

Keep:

- Your mobile device charged
- The app running in the background (do NOT force quit or close)

Turn ON:

- Bluetooth[®] wireless technology (for iOS[‡] 13 and above, you may also need to turn on Bluetooth[®] technology permission for the app)
- Internet connectivity (cellular data or Wi-Fi[‡])
- App Notifications

Accept:

- App updates (or enable App Auto Updates)

Turn OFF:

- Screen Time Downtime and App Limits features
- Offload Unused Apps feature
- Low Power Mode

For further details, refer to your mobile device manual or your myMerlinPulse™ app patient manual.

APP NOTIFICATIONS YOU MAY RECEIVE

If you see “App Background Data is Off”:

Go to your Android[‡] device’s settings and enable use of the app in the background.

If you see “Battery Optimization is On”:

Go to your Battery Settings on your Android[‡] mobile device to turn OFF Battery Saver.

If you see “Bluetooth^{®‡} is Off”:

Under Settings, turn Bluetooth[®] wireless technology ON.

If you see “Communicating with your Heart Device”:

Keep the app open and within 1.5 meters or 5 feet of you during this process so your app can connect with your heart device.

If you see “Compatibility Message”:

Update your app and/or your mobile device so the app can function as intended.

If you see “Connection Problem”:

Open the app for instructions to allow the app to communicate with your heart device.

If you see “Connection to Clinic Lost”:

Your app had difficulty connecting to your clinic. Follow any troubleshooting instructions available in the notification. You may need to open the app to check for any further steps to resolve the issue. See the FAQ section for “If you see a notification that your app had a problem sending data to your clinic”.

If you see “Service Unavailable”, it means:

The app is unable to communicate with your clinic at this time. Do nothing and it should resolve itself if you stay connected to the internet.

If you see “Heart Device Needs Attention”:

Open the app to view a message about your heart device.

If you see “Adjust Location Settings”:

On your Android® mobile device’s settings panel, turn Location ON. In addition, you may need to check your Location permission setting for the myMerlinPulse™ app:

- If you have an Android® Operating System (OS) version 10 or above: Navigate to the Android® app permission settings menu and set the myMerlinPulse app Location permission to “Allow all the time”
- If you have Android® OS version 8 or 9: Navigate to the Android® app permission settings menu and set the myMerlinPulse app Location permission to “Allow”

In order for Bluetooth® wireless technology monitoring to work, the Android® OS requires the app to have Location permission turned ON. Abbott does not collect information about your location.

If you see “Mobile Device Memory Low”:

Clear storage space on your mobile device because the available memory is running low. When the mobile device memory runs too low, the app will not be able to perform its functions. Refer to your mobile device’s manual for help with freeing up storage space.

If you see “No Internet Connection”:

Go to your mobile device’s settings to turn Wi-Fi® or cellular data ON so your app can transmit data to your clinic.

If you see “App Not Paired”:

Go to the app and follow the on-screen prompts to complete setup again.

When you complete Setup again, you will need to receive an activation code by email or by text. Then, you will need to enter that activation code in the app before you can proceed to the Pairing step. For more information on the Pairing step, refer to the Setup section in the myMerlinPulse mobile application patient manual.

If you see “Your heart device needs attention” and may have heard a sound from your heart device:

Call your clinic to let them know. If you need to know when the notification occurred, you can find that information in the History section.

If you see a notification that your app has an issue but everything looks normal:

That means the app sent you a notification before it was able to automatically resolve the issue. The app is working correctly.

If you see a notification that your app had a problem sending data to your clinic:

Make sure you have an internet connection and that Wi-Fi* or cellular data is ON in your mobile device settings. You may need to move to another location for a better cellular signal or connect to a different Wi-Fi* network. Once you have internet connectivity or a strong cellular signal, the app will automatically retry sending the data.

If you see a notification that your app can’t connect to your heart device:

Tap on the notification to launch the app. On the home screen, the issue may be displayed at the top of the screen. Follow steps to resolve the issue displayed. Once the issue is fixed, you can manually press the “Connect Now?” button or let the app automatically connect to your implanted heart device.

If you see a notification that your app or operating system (OS) needs to be updated:

Update them to ensure the app is fully functional. We suggest leaving app auto-updates enabled so the app can update itself as new updates become available.

- If the app or operating system are out of date but still functioning, you may close the notification and keep using the app. However, be aware that the app may not have full functionality.
- If the app or OS are out of date and no longer functioning, you will not be able to close the notification. In this case, update the app, your OS, or both, before using the app.

HOW TO STAY CONNECTED

How close should I keep my mobile device to my implanted heart device?

Keep your mobile device within 5 feet or 1.5 meters of you. When you go to bed, keep your mobile device on your bedside table next to you.

Do I always need to keep Bluetooth® technology ON and be connected to the Internet?

The app uses Bluetooth® wireless technology to communicate with your implanted heart device, and Wi-Fi* or cellular data to send data to your clinic. Keep these settings ON to keep the app functioning properly. For more information, see ***What to Know for When You Travel*** within this FAQ.

PAIRING THE APP WITH YOUR HEART DEVICE

Can I pair my heart device with more than one mobile device?

No. For security reasons, you can pair your heart device with only one mobile device. If you pair your heart device with a second mobile device, the first mobile device's app will be deactivated. Please choose the device that you will most likely keep turned ON, charged and with you.

What and where is the heart device serial number?

A serial number is a unique number assigned to your heart device. It's located on your heart device patient ID card provided to you by your clinic.

Can the app become unpaired with my heart device?

Yes. If this happens, go through the pairing process again.

If I get a new mobile device, will I have go through the set-up process again?

Yes. To pair your heart device with your new mobile device, you will need to go through the set-up process again. You will need an activation code, which can be received through email or text message. Note that the app on your previous mobile device will no longer work once you complete set-up on your new mobile device.

Why do I need an activation code?

The activation code is a security measure used if you need to go through the set-up process again. The app will be locked after multiple unsuccessful activation code entries. Contact Technical Support to unlock your account. Go to the Help & Support page for contact information.

HOW TO USE THE APP

Can I use other apps while using the myMerlinPulse™ app?

Yes, but do not close or force quit the myMerlinPulse app on your mobile device; it must run in the background to work properly.

Will the app drain my mobile device battery?

The app wakes up only when it needs to connect to your heart device for device checks and automatic clinic transmissions, which only take a few minutes to complete. For more information about battery settings, see ***App Settings for Your Mobile Device*** within this FAQ.

WHAT TO KNOW FOR WHEN YOU TRAVEL

Should my mobile device travel with me?

Yes, you need your mobile device with you, and your app running, to continue to monitor your heart device. Keep your mobile device turned ON, charged, and near you, including when you go to bed. Stay connected to the internet (Wi-Fi[®] or cellular data) as often as possible. Depending on where you travel and your mobile device plan, additional charges may apply.

How should I plan ahead for lack of internet access?

Inform your clinic of your travel arrangements. Your heart device constantly monitors your heart activity and records cardiac events. If the app detects anything your doctor wants to be aware of, it will send the information to your clinic when you are connected to the internet. Stay connected to the internet (Wi-Fi[®] or cellular data) as often as possible.

FEATURES OF THE APP

What is a daily device check?

If device checks are enabled by your clinic, the app automatically checks your heart device for information that your clinic is monitoring. If the app sees information on your heart device that your clinic has chosen to monitor, the app sends a report to your clinic. Keep your app near your heart device (within 5 feet or 1.5 meters) for daily checks to occur.

For more information about what your clinic is monitoring with your daily device checks, contact your clinic.

When does the app perform daily device checks?

Device checks typically occur around 2 a.m. every day. Keep your mobile device near you (within 5 feet or 1.5 meters) when you sleep. If you are not close to your mobile device at that time, the app will retry automatically when you are nearby. Device checks occur automatically. If you open the app and happen to see a “Connect Now” button, you may tap the button to manually complete the check.

What is an automatic scheduled transmission?

In addition to any reports related to daily device checks, the app can automatically send information from your implanted heart device to your healthcare provider on a schedule set by your clinic. Under the History section, you can see when your automatic scheduled transmissions were sent to your clinic.

For more information about your scheduled transmissions, contact your clinic.

I'm not feeling well. What should I do?

If it's an emergency, seek immediate medical care. The app is not intended for emergency use. If it's not an emergency, contact your clinic for further instructions. If your clinic requests you to send a transmission, tap "Send Transmission".

How do I send a manual transmission?

If your healthcare provider requests a transmission, tap "Send Transmission" to send information from your heart device to your clinic. Stay close to your mobile device (within 5 feet or 1.5 meters) while information is being collected and sent.

Transmissions may take a few minutes. Under the History section, you can see when manual transmissions occurred.

Will sleeping far away from my mobile device affect remote monitoring?

Yes. Keep your mobile device near you (within 5 feet or 1.5 meters) while you sleep. This allows the app to perform daily checks and transmissions as scheduled. If the mobile device is not nearby while you sleep, the app will automatically keep trying. The next time you are near your mobile device, the app will connect with your heart device. The app will notify you if there was a problem connecting to your heart device.

Do I need to confirm my clinic received my heart device data?

No. You can confirm that your daily device check has been performed when you open the app. You also can confirm automatic scheduled transmissions were sent under the History section.

Are all transmissions that my app sent to my clinic shown in the History section?

Only manual and automatic scheduled transmissions are shown in the History section. The completion status of your latest device check is displayed on the app home screen.

We do not recommend uninstalling or deleting the app. If you are unable to resolve an issue, please contact Technical Support.

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Rx Only

Brief Summary: This product is intended for use by or under the direction of a Physician. Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Intended Use: The Implantable Cardioverter Defibrillator (ICD) and Cardiac Resynchronization Therapy Defibrillator (CRT-D) devices are intended to provide ventricular antitachycardia pacing and ventricular cardioversion/defibrillation. The CRT-D devices are also intended to resynchronize the right and left ventricles. The myMerlinPulse™ mobile application is intended for use by people who have an Abbott Medical implanted heart device and access to a mobile device. The app provides remote monitoring capability of the implanted heart device by transmitting information from the patient's implanted heart device to the patient's healthcare provider.

Indications: The ICD and CRT-D devices are indicated for automated treatment of life-threatening ventricular arrhythmias. CRT-D devices are also indicated to treat symptoms in patients who have congestive heart failure with ventricular dyssynchrony. In addition, dual chamber ICD and CRT-D devices with the AT/AF detection algorithm are indicated in patients with atrial tachyarrhythmias or those patients who are at significant risk of developing atrial tachyarrhythmias. MR Conditional ICDs and CRT-Ds are conditionally safe for use in the MRI environment when used in a complete MR Conditional system and according to instructions in the MRI-Ready Systems manual. Scanning under different conditions may result in severe patient injury, death or device malfunction. The myMerlinPulse™ mobile application is indicated for use by patients with supported Abbott Medical implanted heart devices.

Contraindications: Contraindications for use of the pulse generator system include ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction. The myMerlinPulse™ mobile application is contraindicated for use with any implanted medical device other than supported Abbott Medical implanted heart devices.

Adverse Events: Possible adverse events associated with the implantation of the pulse generator system include the following: Arrhythmia (for example, accelerated or induced), Bradycardia, Cardiac or venous perforation, Cardiac tamponade, Cardiogenic shock, Death, Discomfort, Embolism, Endocarditis, Erosion, Exacerbation of heart failure, Excessive fibrotic tissue growth, Extracardiac stimulation (phrenic nerve, diaphragm, pectoral muscle), Extrusion, Fluid accumulation within the device pocket, Formation of hematomas, cysts, or seromas, Heart block, Hemorrhage, Hemothorax, Hypersensitivity, including local tissue reaction or allergic reaction, Infection, Keloid formation, Myocardial damage, Nerve damage, Occlusion/Thrombus, Pericardial effusion, Pericarditis, Pneumothorax, Pulmonary edema, Syncope, Thrombosis, Valve damage. Complications reported with direct subclavian venipuncture include pneumothorax, hemothorax, laceration of the subclavian artery, arteriovenous fistula, neural damage, thoracic duct injury, cannulation of other vessels, massive hemorrhage and rarely, death. Among the psychological effects of device implantation are imagined pulsing, depression, dependency, fear of premature battery depletion, device malfunction, inappropriate pulsing, shocking while conscious, or losing pulse capability. Possible adverse device effects include complications due to the following: Abnormal battery depletion, Conductor fracture, Device-programmer communication failure, Elevated or rise in defibrillation/cardioversion threshold, Inability to defibrillate or pace, Inability to interrogate or program due to programmer or device malfunction, Incomplete lead connection with pulse generator, Inhibited therapy including defibrillation and pacing, Inappropriate therapy (for example, shocks and antitachycardia pacing [ATP] where applicable, pacing), Interruption of function due to electrical or magnetic interference, Intolerance to high rate pacing (for example dyspnea or discomfort), Lead abrasion, Lead fracture, Lead insulation damage, Lead migration or lead dislodgement, Loss of device functionality due to component failure, Pulse generator migration, Rise in DFT threshold, Rise in pacing threshold and exit block, Shunting of energy from defibrillation paddles, System failure due to ionizing radiation. Additionally, potential adverse events associated with the implantation of a coronary venous lead system include the following: Allergic reaction to contrast media, Breakage or failure of implant instruments, Prolonged exposure to fluoroscopic radiation, Renal failure from contrast media used to visualize coronary veins. Refer to the User's Manual for detailed intended use, indications, contraindications, warnings, precautions and potential adverse events.

No potential adverse events have been identified with use of the myMerlinPulse™ mobile application.

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