![Abbott logo]

Next Generation ICD and CRT-D Solutions

REMOTE MONITORING

CLINICIAN GUIDE

for myMerlinPulse™ App

HIGH-VOLTAGE HUGE IMPACT

POWERFULLY CONNECTED

Abbott's next generation ICD and CRT-D solutions use smartphone connectivity to streamline remote monitoring and encourage greater patient engagement.

PIONEERING DYNAMIC TECHNOLOGY

Deliver accurate, optimized care with features you can intuitively program to meet your patients' changing needs.
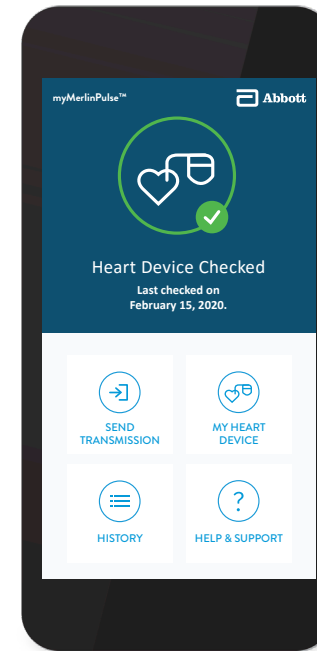
PATIENT-CENTRIC OUTCOMES

Achieve clinically meaningful outcomes with technology designed to fit seamlessly into your patients' day-to-day lives.

MR

1.5T AND 3T MRI READY SOLUTIONS*

Gallant™ HF
Smartphone Connectivity

Gallant™ DR
Smartphone Connectivity

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myMERLINPULSE™ APP

The app can be paired with Abbott's ICD and CRT-D solutions to remotely monitor your patients. With this app, patients can:

myMerlinPulse™ — Abbott

Heart Device Checked
Last checked on
February 15, 2020.

SEND TRANSMISSION

MY HEART DEVICE

HISTORY

HELP & SUPPORT

CHECK CONNECTIVITY STATUS
to ensure their device is being properly monitored

SEND DATA MANUALLY
as instructed by a clinician

ACCESS DEVICE STATUS
to check battery status and model number

VIEW HISTORY
of scheduled data transmissions, connection issues and patient notifications

FIND SUPPORT
resources, such as clinic info, technical support numbers and FAQs

*For additional information about specific MR Conditional ICDs,CRT-Ds and leads, including scan parameters, warnings, precautions, adverse conditions to MRI scanning and potential adverse events, please refer to the Abbott MRI Ready Systems Manual at medical.abbott/manuals.

RECOMMENDED REMOTE MONITORING **WORKFLOW**

1

DOWNLOAD APP

The myMerlinPulse™ app is available for compatible iPhone‡ and Android‡ smartphones.

Download on the App Store

GET IT ON Google Play

Encourage patients to download the app onto their personal smartphone prior to their procedure. As per your clinic's protocol, remind patients to bring their smartphone the day of their procedure and for all in-clinic follow up visits.

For patients using an Abbott mobile transmitter, the app is preinstalled.

2

ENROLL PATIENT

Before pairing, you must enroll the patient in the Merlin.net™ Patient Care Network (PCN).

Remember to enter the patient's email address or mobile number in order to receive an activation code (when required). If a patient is already enrolled in Merlin.net PCN, the patient's profile can be updated for the new device.

3

PAIR DEVICE

Make sure to have a strong Wi-Fi‡ or cellular data connection and Bluetooth® wireless technology turned ON before you pair.

Remote monitoring cannot start until pairing is completed. We recommend promptly pairing the device post implant with the patient's smartphone or as per your clinic's protocol.

Patients can learn more about their device and app at **MyHeartHealth.com.** Resources include tutorial videos, digital brochures and more.

APP **DOWNLOAD**

The myMerlinPulse™ app is available for download on the Apple‡ App Store‡ or Google Play.‡ It is best to have your patients download the app prior to their procedure.

Download on the App Store

GET IT ON Google Play

Compatible Smartphone and Operating Systems (OS) Combinations

The app is compatible with smartphones that meet the following minimum requirements:

ANDROID‡ PHONES	**iPHONE‡**	**BLUETOOTH® TECHNOLOGY**
version 8.0 or later	iOS‡ version 12.0 or later	4.2 or higher

LET US KNOW

Always report smartphone and OS issues to our Remote Care Technical Support at:

International: **46-8-474-4756**
US: **1-877-756-4873**

TIPS FOR YOUR PATIENTS

The following tips can help your patients keep their app connected, so that you can ensure continuous remote monitoring of their device.

✓ **KEEP myMERLINPULSE™ APP OPEN**

Do not quit the app. Remind patients to relaunch the app anytime the smartphone is restarted, or if they purchase a new smartphone.

Their Abbott implantable device is continuously monitoring their heart. When patients are near their smartphone, it will retrieve any new data from their device and send it to their clinic.

✓ **STAY CONNECTED TO INTERNET**

Keep the smartphone connected to Wi-Fi‡ or cellular data with a STRONG signal.

✓ **KEEP BLUETOOTH® TECHNOLOGY ON**

The implantable device cannot communicate with the app when Bluetooth® wireless technology is turned OFF.

✓ **STAY CLOSE**

Recommend patients keep their smartphone close (within 5 feet or 1.5 meters), even while sleeping , and always plug in their smartphone before going to bed. If the app doesn't seem to be working at night, turn OFF devices with Bluetooth® wireless technology, like speakers or clocks.

✓ **TURN OFF POWER SAVE**

In the smartphone's settings, turn OFF battery saver/optimization/low power features for the app.

✓ **TURN NOTIFICATIONS ON**

Allow notifications from the app and turn ON the app setting for Background Data Usage.†

†The Background Data Usage setting is for an Android‡ smartphone and is not a required setting for iPhone.‡

ENROLL
NEW ABBOTT PATIENTS
IN MERLIN.NET™ PCN

Patients must be enrolled in the Merlin.net PCN before you can pair their device to the myMerlinPulse™ app. If a patient is already enrolled in Merlin.net PCN, refer to instructions for UPDATING CURRENT PATIENT PROFILES.

1

Navigate to **MERLIN.NET** and login using your credentials.
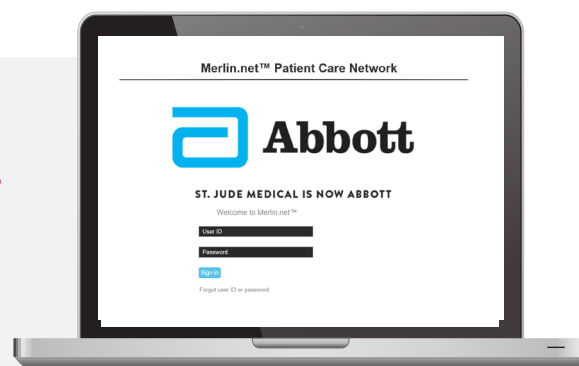
2

Click on **ENROLL A NEW PATIENT** (in Quick Links).

3

Click on **ENROLL** under **ENROLL MANUALLY**.

4

Input the required patient and device data. Patient mobile number or email is required and may be used when pairing your patient's device.

5

You may continue through **PATIENT PROFILE PAGES** to review default monitoring preferences, create a schedule and modify any Direct Alerts for the patient.

6

Continue through enrollment steps and click **FINISH**.

NEED REMOTE CARE TECHNICAL SUPPORT?

Your local Abbott representative can assist with any questions. Abbott also maintains a line for technical questions and support:

International: **46-8-474-4756**
US: **1-877-756-4873**

UPDATE CURRENT PATIENT PROFILES
IN MERLIN.NET™ PCN

If a patient already has an Abbott device and was enrolled in Merlin.net PCN, you can update the patient's profile with the new device data.
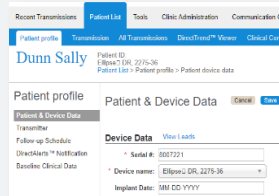
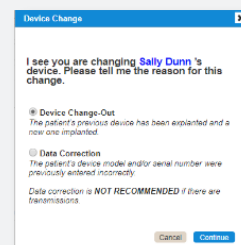**1** Navigate to **MERLIN.NET** and login using your credentials.

2 Click on **PATIENT LIST** tab and locate the patient who received a new device.

3 Update the **DEVICE DATA** with the new serial number, device name and implant date. Click **SAVE**.

4 Select **DEVICE CHANGE-OUT** on the pop-up screen. Click **CONTINUE**.

Continue through and click **FINISH**. The patient's Merlin.net PCN record is now updated. Data about the new device will be available along with the patient's historical data.

MANAGE SETTINGS

Monitoring your patients through our mobile app can help you manage the information your patients send to you.

The myMerlinPulse™ app allows patients to send transmissions to the Merlin.net PCN when instructed by their clinic. You can choose to disable this feature.
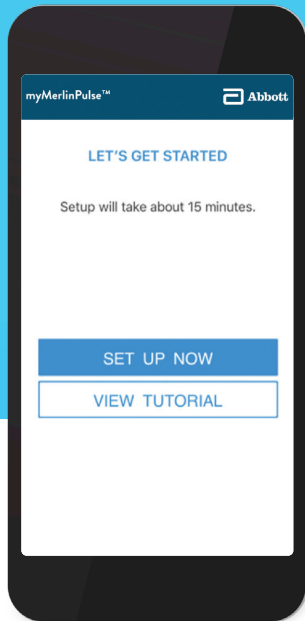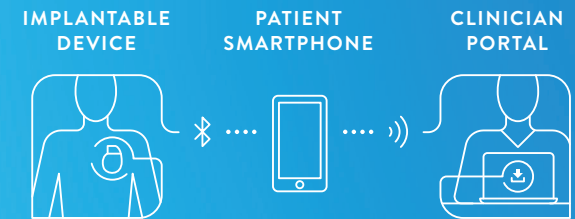
HOW TO LOCK PATIENT-INITIATED TRANSMISSIONS

In the **TRANSMITTER** section of the patient enrollment in the Merlin.net PCN, you may manage when patients send you transmissions.

"Lockout unscheduled transmissions" disables the **SEND TRANSMISSION** button on the patient app. You may enable or disable this feature at any time.
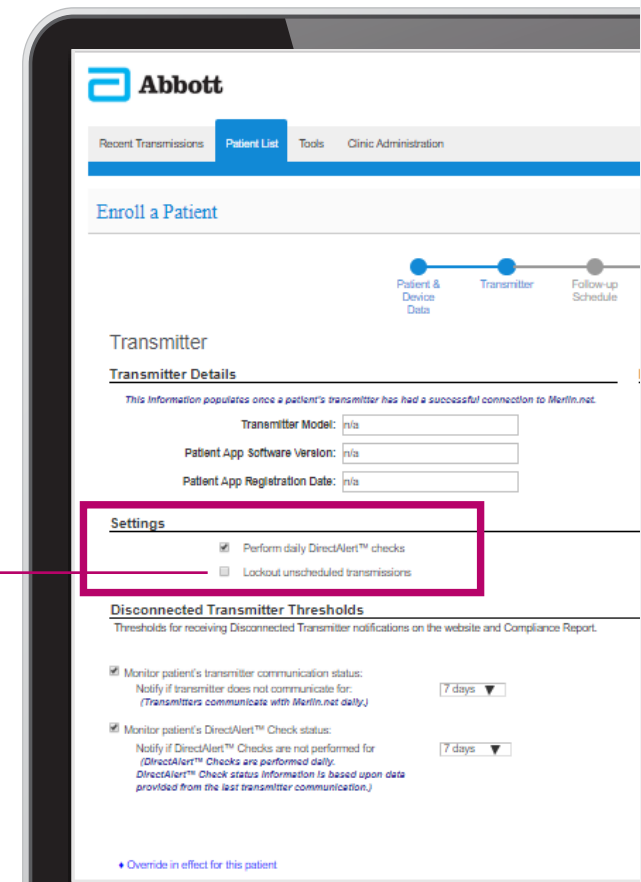
STEP 1
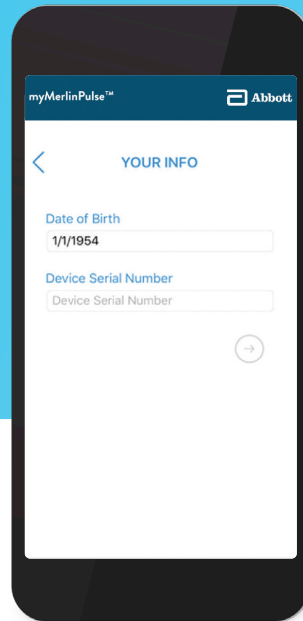OPEN myMERLINPULSE™ APP
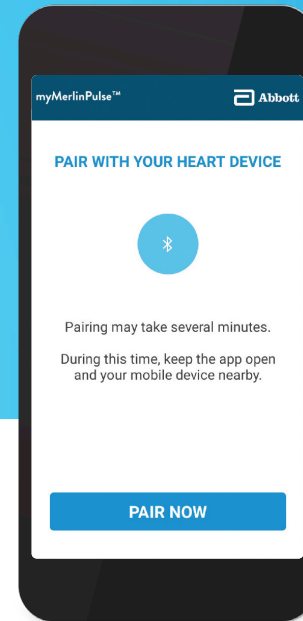
Tap **SET UP NOW** and then continue with setup.

STEP 2
ENTER PATIENT INFORMATION

Enter patient's date of birth and device serial number.

Tap the **ARROW**.

STEP 3
PAIR DEVICE

Tap **PAIR NOW.**

For iOS‡ devices, a pairing request for "CM" message will appear; enter the code shown at the top of the screen and tap the **PAIR** button.

If this is an Android‡ device, the pairing will proceed on its own.

Keep the smartphone within 5 ft/1.5 m of the patient.

> If this is not the first time pairing, you will need an activation code. You can select to receive the activation code via email or text.
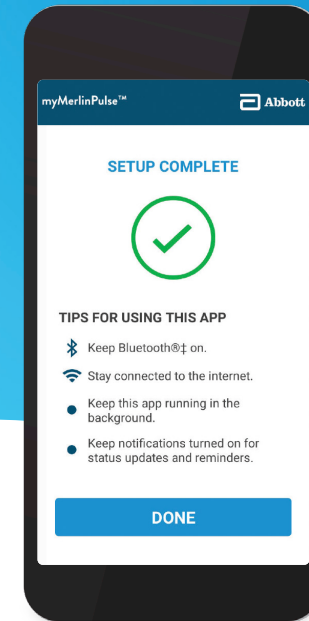
STEP 4
YOU'RE CONNECTED!

Your patient's device is now paired with the smartphone.

From the app's home screen, patients can send transmissions, view history or access help and tutorials.

PAIRING DEVICE

BEFORE YOU BEGIN

Once the myMerlinPulse™ app is downloaded, setup will take you up to 15 minutes. Before trying to pair, make sure the smartphone has a strong internet connection and Bluetooth® wireless technology turned ON.

FREQUENTLY ASKED
QUESTIONS

CAN MULTIPLE SMARTPHONES CONNECT TO THE SAME DEVICE?

No, for security reasons the device can only pair with one smartphone. If the device is paired with another smartphone it will be unpaired from the previous smartphone.

CAN MY PATIENT CHOOSE A DIFFERENT LANGUAGE FOR THE APP?

Yes, this app is currently available in 38 languages. The app will automatically show in the language set as default within the smartphone. If the smartphone is configured in a language that is not part of these 38 languages, English will be the default language.

WILL THE USE OF THE APP AFFECT THE IMPLANTED DEVICE'S BATTERY LONGEVITY?

No, the use of the patient app communicating through encrypted Bluetooth® wireless technology with Abbott's next generation of ICDs does not adversely impact longevity more than the RF monitoring available on our current platform. The longevity estimates indicated in our manuals integrate the use of remote monitoring and result in a device longevity that is superior to existing Abbott high-voltage devices of the same size.

WILL THE APP DRAIN THE SMARTPHONE'S BATTERY?

The app will have a minimal impact on a smartphone's battery. It is important to remind patients that device checks happen at night. Patients should be advised to plug in their smartphone near them before going to bed.

HOW IS PATIENT DATA PROTECTED?

Securing patient data is our number one priority for remote monitoring.

- Communication is limited to a single authenticated, paired app
- Each device creates a unique 256-bit key for the paired app that is verified at the start of every communication. Monitor access is denied if the unique key is not verified
- The myMerlinPulse™ app transmits to the Merlin.net™ Patient Care Network through a secure, encrypted connection. Access to patient data is restricted to clinic authorized users

WILL A PHONE OPERATING SYSTEM (OS) UPGRADE AFFECT THE OPERATION OF THE APP?

Phone manufacturers issue OS updates regularly. Not all OS updates will require an update of the paired app. Some things to consider:

- Patients may experience a delay between the release of a manufacturer's phone update and a version of our app that is compatible with it
- Patient may need to manually update the app if their smartphone settings are not setup to enable automatic updates

HOW MUCH CELLULAR DATA DOES THE APP USE?

Transmissions are scheduled at night. If the smartphone is connected to Wi-Fi‡ with good signal strength, then the OS will use the faster transmission path (Wi-Fi‡ and not cellular data).

If the smartphone does not have Wi-Fi‡ connection, all the transmissions are done using cellular data. Approximately 200MB/month will be used, which is about 10% of a 2GB monthly plan.

HOW MUCH DATA WILL BE USED WHEN THE APP IS UPGRADED TO NEWER VERSION?

Although this will depend on the size of the newer app version, we approximate about 70MB of additional data usage during the upgrade process. Patients can set up preferences within their smartphone to upgrade the app only when Wi-Fi‡ is available to avoid using cellular data.

EMPOWERING YOU.
EMPOWERING YOUR PATIENTS.
POWERED BY ABBOTT.

CUSTOMER SUPPORT

Device Technical Services

International: **46-8-474-4147**
US: **1-800-722-3774**

CRMTechnicalServices@abbott.com

Remote Care Technical Services

International: **46-8-474-4756**
US: **1-877-756-4873**

Remote.Monitoring@abbott.com

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.

Abbott