

Abbott DM3500 Insertable Cardiac Monitor System User Manual

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Abbott DM3500 Insertable Cardiac Monitor System



Introduction

Your clinician has determined that it is beneficial for you to have a monitoring system to help identify the cause of symptoms you experience. Your monitoring system consists of the Abbott Medical Confirm Rx™ insertable cardiac monitor or the Jot Dx[™] insertable cardiac monitor and the myMerlin[™] mobile application (app). This

manual answers some common questions about your monitoring system and explains how to use the app. Read all of the instructions in this manual before using the app.

What is the myMerlin™ Mobile Application?

The myMerlin™ mobile application is a software application for your smart phone or other mobile device (with the exception of tablets). The app uses Bluetooth® Low Energy (BLE) technology to communicate with your cardiac monitor. The app can be used to initiate recording of the heart's electrical activity by your cardiac monitor, read the information about your heart's activity from your cardiac monitor, and send this information to a clinician for remote monitoring.

How does my monitoring system work?

Your monitoring system works in two ways:

- Automatically. Your clinician will set your cardiac monitor to monitor and record your heart's electrical activity.
 The recorded heart activity will be automatically sent to your clinic during the night while you sleep, as required by your clinician.
- On Command. When you experience symptoms, you can use the app to tell your cardiac monitor to record
 your heart's electrical activity. The app will send your symptoms and recorded heart activity to your clinician.

NOTE: Your clinician will identify the symptoms for which you should record your heart's electrical activity. Space is provided at the front of this book for you to write down any special instructions given to you by your clinician.

What is the insertion procedure like?

The insertion typically involves a simple surgical procedure. The doctor numbs the area with local anaesthesia, makes a small incision, and places the cardiac monitor just under the skin in the chest through the small incision.

What is recovery like?

Your clinician may ask you to limit some of your activities because of your symptoms. In general, people who have a cardiac monitor can perform almost all their normal activities. Your clinician will also give you information about caring for your incision and bathing.

What is a follow-up visit like?

You may go to your clinician's office or clinic for follow-up visits. During a follow-up visit, your clinician uses a programmer, a specialized computer, to review information stored in your cardiac monitor. Your clinician can also use the programmer, without surgery, to change how your cardiac monitor is set up. Your clinician uses the information from your cardiac monitor to help identify the cause of your symptoms or asymptomatic cardiac rhythms. An office visit usually lasts about 30 minutes or less. Your clinician will determine your follow-up visit schedule. Your clinician may also remotely review the information sent from your cardiac monitor without you having to visit the clinic.

What special precautions do I need to follow?

Your cardiac monitor is not magnetic and has no moving parts. However, you should avoid devices which generate a strong electric or magnetic interference (EMI). EMI could cause inappropriate data storage or prevent data storage. Moving away from the source of EMI or turning it off will usually allow the cardiac monitor to return to its normal mode of operation.

You should always use caution with the following:

- Medical procedures. Although your cardiac monitor should be unaffected by most medical procedures, you should notify your doctor, dentist, physical therapist, chiropractor, or any other health care provider that you have a cardiac monitor.
- Communication equipment. Communication equipment such as microwave transmitters or high-power amateur transmitters may generate enough EMI to interfere with the performance of your cardiac monitor if you are too close to the source of EMI.
- Wireless communication devices. Wireless communication devices such as computers that operate on a
 wireless network, cellular phones, smart phones, tablets, and even cordless telephones may generate enough
 EMI to interfere with the performance of your cardiac monitor if you are too close to the source of EMI.
- Household appliances. Household appliances such as microwave ovens, electric blankets, and power tools should not damage your cardiac monitor. However, they may interfere with the performance of your cardiac monitor.
- Industrial equipment. A variety of industrial equipment may generate enough EMI to interfere with the performance of your cardiac monitor. These include, but are not limited to: arc welders; induction furnaces; very large or defective electric motors; and internal combustion engines with poorly shielded ignition systems.
- Metal detectors and security systems. Metal detectors found in airports and government buildings, and electronic article surveillance/anti-theft (EAS) systems such as those at the point of sale and entrances/exits of stores, libraries, banks, etc., emit signals that may interfere with the performance of your cardiac monitor. To minimize the possibility of interference, simply walk through these areas at a normal pace and avoid lingering near or leaning on these systems. If your cardiac monitor triggers an alarm, show your identification card to security personnel.
- Mobile devices. Your cardiac monitor has been tested for use with smart phones and other mobile devices (excluding tablets). Based on the results of the tests, the cardiac monitor should not be affected by the normal operation of smart phones and mobile devices when used more than 6 in from the cardiac monitor.
- To minimize the possibility of interference, do not carry your smart phone or mobile device in a breast pocket or on a belt within 6 in of the cardiac monitor.
- Use your smart phone or mobile device on the side of your body opposite from the cardiac monitor.
- Do not place your smart phone or mobile device directly over your cardiac monitor.

CAUTION: Do not bring your mobile device into the scanner magnet room. Mobile devices are considered MR Unsafe.

What items will I receive?

You will receive product documentation regarding your monitoring system. In addition, you will need to download the myMerlin[™] mobile application onto your smart phone or mobile device. Abbott Medical recommends using your own smart phone or mobile device, if it meets the system requirements of the app. Refer to the Download the myMerlin[™] Mobile Application section (page 10) for information. Abbott Medical may provide you with a mobile device, if necessary. This mobile device allows you to communicate with your cardiac monitor as well as transmit data. The app will be pre-downloaded onto the mobile device for you.

Your Patient Identification Card

A patient identification card will be given to you. This card does the following things:

· Identifies you as having an inserted medical device

- Identifies the cardiac monitor and serial number and location of your cardiac monitor to help determine if you can safely receive an MRI scan
- · Helps you pass through security systems like those in airports
- · Provides information that allows your physician to be contacted in an emergency

For additional information about your card, contact Technical Support. Your patient identification card includes several symbols. The table below provides an explanation of those symbols.

When can I begin using the myMerlin™ Mobile Application?

In most cases, you can begin using the app immediately after your cardiac monitor is inserted. Your clinician will give you instructions on when to use the app.

When do I record my heart's electrical activity with the myMerlin™ Mobile Application?

Your clinician will give you specific instructions on when to record your heart's electrical activity with the app.

Using the myMerlin™ Mobile Application

The app has two main functions:

- Record Symptoms. Begin data recording in your cardiac monitor when you experience symptoms.
- Automatic Remote Monitoring. Your clinician can remotely review the data stored in your cardiac monitor.

NOTE: You can record important telephone numbers and special instructions at the beginning of this book.

To ensure that your app communicates and transmits data properly:

- Do not close or quit the myMerlin[™] mobile application. If the app is closed, it is not transmitting. The app needs
 to be running in the background to be able to perform automatic remote monitoring.
- Remember to re-launch the myMerlin mobile application after restarting your smart phone or mobile device.
- Make sure your Bluetooth® wireless technology and Notifications settings are ON and your smart phone or mobile device has a strong connection to the internet using Wi-Fi‡ or cellular data.
- The time it takes for the myMerlin mobile application to transmit data depends on the strength of the cellular or Wi-Fi signal.
- Keep your smart phone or mobile device charged and at your bedside within 5 ft (1.5 m) of you during your scheduled nightly checks.

App Settings

What app settings do I need for Android‡ devices?

Turn ON 1 for Android‡ devices

- Location Services
- · Background Data (allow)

Turn OFF for Android devices

- · App Digital Wellbeing features
- myMerlin[™] mobile application Battery Optimization or Power
- Monitor (do NOT optimize the battery for the myMerlin mobile application)
- App Data Saver mode
- Power Saving /Battery Saver (name varies by smart phone or mobile device)

Allow

- myMerlin mobile application updates (or enable App Auto Updates)
- Location permission at all times for the myMerlin mobile app.
- (The app does not collect data about your location.)

What app settings do I need for iPhone‡?

Turn ON 2 for iPhone‡ devices

· App Background App Refresh

Turn OFF for iPhone devices

- Screen Time Downtime and App Limits features
- · Offload Unused Apps feature
- · Low Power Mode
- Allow app updates (or enable App Auto Updates)

Precautions

- Do not use the app if your smart phone or mobile device is damaged.
- Keep your smart phone or mobile device charged or have a power supply nearby. Familiarize yourself with your smart phone or mobile device's battery life so you can anticipate its recharging needs.
- For regulatory statements regarding your smart phone or mobile device, refer to the manufacturer's website.

Download the myMerlin™ Mobile Application

Your clinician will let you know when you can start using the app. Smart phones and mobile devices are regularly tested for compatibility. For a list of recommended smart phone and mobile device models, please visit the cardiovascular abbott website, or contact Technical Support.

Your smart phone or mobile device must meet the following system requirements:

- Android‡ OS version 9.0 or greater
- iOS‡ version 13.0 or greater

To download the app:

- Make sure your smart phone or mobile device is connected to a cellular or Wi-Fi network.
- Go to a public mobile application store such as the iOS‡ App Store or Google Play‡ store and locate the myMerlin™ mobile app.
- Tap the myMerlin icon.
- Follow the onscreen prompts to install the app.

If you encounter problems downloading the app, contact Technical Support.

NOTE:

To keep your personal information secure:

- Only download and install the official Abbott Medical registered application.
- Use your smart phone or mobile device's locking capability so that a PIN is required to unlock the mobile device.
- Inform the clinic or Abbott Medical in the event that your smart phone or mobile device is lost or stolen.

Connectivity Services

Call center agents may contact you after your implant to provide services including the following:

- education on the myMerlin[™] mobile app and smart phone/ mobile device technology
- pairing of the app to the smart phone/mobile device
- troubleshooting of the app and smart phone/mobile device

Set up the myMerlin™ Mobile Application

After you download the app, set up the app on your smart phone or mobile device. You will need the serial number located on your patient identification card.

NOTE: During setup, the app may ask you for permissions, such as location services and notifications. The permissions are necessary for the app to function as intended. However, battery optimization should be disallowed for the myMerlin™ mobile app.

To set up the app:

- Open the myMerlin Mobile app.
- Review and accept the Terms and Conditions and Privacy Policy.

NOTE: Before you continue with the setup, make sure that Bluetooth® wireless technology is on and that you are connected to a cellular or Wi-Fi network. Keep your smart phone within 5 ft (1.5 m) of you during the setup process.

- Tap the Set Up Now button to proceed.
- Enter your date of birth and the serial number of your cardiac monitor and then tap the Next button.
- Tap the Pair Now button to pair your cardiac monitor with your smart phone or mobile device.

NOTE: Pairing with Bluetooth® wireless technology may take several minutes.

- If prompted, enter the code that is shown on the screen.
- Tap the Done button to complete the setup.

There may be times when you need to set up the app after the initial setup. The setup steps are the same as those in this section except that an additional activation code is required. Follow the instructions on the screen of your smart phone or mobile device to complete the activation code process.

Keep your Smart Phone or Mobile Device at your Bedside

The app automatically reads the information about your heart's electrical activity from your cardiac monitor and sends it to a database where your clinician can review it. The communication occurs during the night while you sleep. Make sure your smart phone or mobile device is sufficiently charged and keep it at your bedside every night. Do not close or quit the myMerlin™ mobile application. If the app is closed, it is not transmitting. The app needs to be running in the background to perform automatic remote monitoring. Make sure your Bluetooth® wireless technology and Notifications settings are ON and your smart phone or mobile device has a strong connection to the internet using Wi-Fi‡ or cellular data.

Record your Symptoms

When you experience symptoms, you can use the app to wirelessly record your heart's electrical activity.

NOTE: Your clinician will tell you whether or not you need to record symptoms. Your app will not have the Record Symptoms button if you do not need to record symptoms.

To record your symptoms:

- Tap the Record Symptoms button on the bottom of the Home screen.
- Select the symptoms you are experiencing and then tap the Done button. You may also tap Done without
 selecting any symptoms. The app starts connecting to your cardiac monitor in order to begin recording your
 heart's electrical activity, and will indicate its progress (for example, connecting, recording or reading data from
 your cardiac monitor).

NOTE: Connecting to your cardiac monitor may take several minutes. Make sure that you keep your smart phone or mobile device with you during this time.

- A Success message displays after recording is complete. The app will automatically send the recorded heart activity information to your clinician.
- Tap the DONE button.

Additional Features

You can use the buttons at the bottom of the Home screen to access information about your monitoring system. Refer to the table below for details.

Table 1. Additional features

Button name	Description
Home	Tap this button to return to the Home screen.
History	Tap this button to view a history of events.
Help	Tap this button to access learning resources and frequently asked questions (FAQs), as well as information about the myMerlin™ app and contact information.
My Device	Tap this button to view information about your cardiac monitor.

Troubleshooting

An error message appears on the screen of your smart phone or mobile device when there is an issue with your app. Follow the prompts on the screen to resolve the issue. If you are unable to resolve the issue, contact Technical Support.

Technical Support

If you have trouble using the app or have any questions regarding its use, contact Technical Support. Monday through Friday (8AM to 8PM Eastern Standard Time)

- 1 877 756 4873 (toll-free within North America)
- 1818 493 4258

HELP

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Documents / Resources



Abbott DM3500 Insertable Cardiac Monitor System [pdf] User Manual DM3500 Insertable Cardiac Monitor System, DM3500, Insertable Cardiac Monitor System, Cardiac Monitor System, Monitor System

References

- **□** Home | Abbott U.S.
- **□** Patents | Abbott Products | Abbott U.S.