

# **>>** | The LUX-Dx™ ICM System



If you've been experiencing symptoms like fainting, palpitations, or shortness of breath, your health care team may recommend the LUX-Dx™ insertable cardiac monitor (ICM), a small device that monitors and records your heart rhythms.

The LUX-Dx ICM System\* is used to check for arrhythmias. That's when the heart is beating too fast, too slow, or in an irregular pattern. It's a diagnostic tool, which means it's used to identify a potential issue, not treat it.

### The LUX-Dx ICM System has three parts:

The insertable cardiac monitor (ICM)



The myLUX™ Patient App,\*\* downloadable on your smartphone or pre-installed on a mobile device provided by Boston Scientific

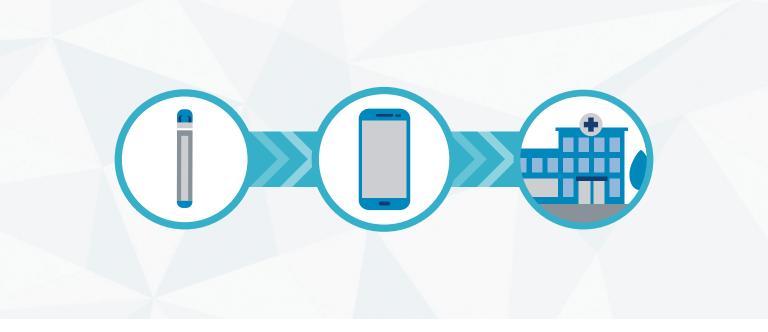


3 A magnet



\*LUX-Dx™ ICM System refers to LUX-Dx™, LUX-Dx II™, or LUX-Dx II+™ System, depending on what the patient is prescribed.

\*\*The downloadable myLUX Patient App is only available for LUX-Dx II ICM and LUX-Dx II+ ICM. It is not available for the LUX-Dx ICM.



#### **How it works**

Your LUX-Dx™ ICM device automatically records and stores irregular heart rhythms, or arrhythmias, whether you are near your smartphone or not. The app will then send the data from your ICM device to your clinic for review. This generally happens overnight and is silent. The clinic will look at the data and contact you if there's a need for further review.

### **Heart monitoring**

Several types of devices can be used to monitor your health data and heart rhythms, including smartwatches, Holter monitors, and ICMs. The LUX-Dx ICM device is inserted just under your skin to provide long-term, continuous monitoring over multiple years.

**CAUTION:** The LUX-Dx ICM System is not meant to assist with health emergencies. If you need immediate medical attention, call your health care provider or seek emergency medical services.

# Reasons your health care provider may have recommended an ICM

The following are some common reasons health care providers might want to monitor your heart rhythm with an ICM. Talk to your health care team about your specific condition.

**Atrial fibrillation:** An abnormal heart rhythm that occurs when the atria (upper chambers of the heart) beat irregularly, which means they move quickly and in an irregular pattern. Your health care team may refer to this as AF, AFib, suspected AF, postablation AF monitoring, or AF management.

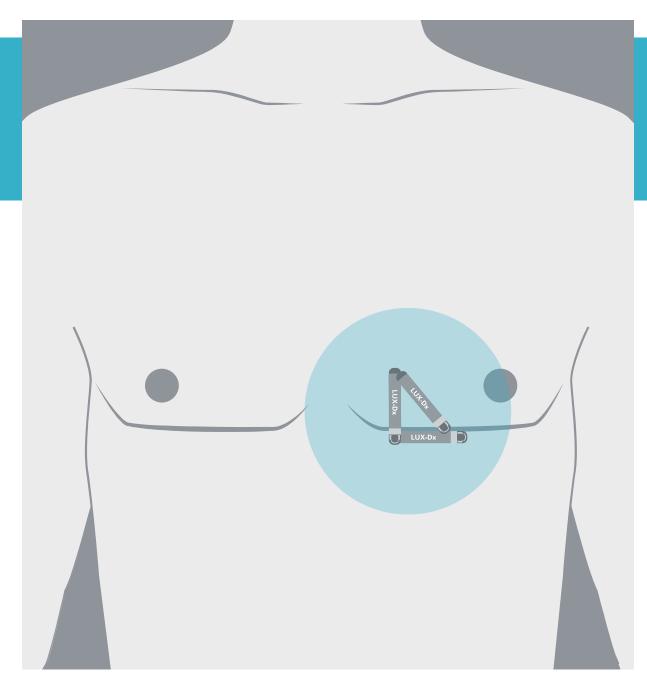
**Cryptogenic stroke:** A stroke with an unknown cause. Monitoring the heart may help your health care team find the cause.

**Syncope:** Also called fainting or passing out; usually happens when blood pressure is too low and the heart doesn't pump enough oxygen to the brain.

**Palpitations:** Feeling like your heart is beating very quickly, fluttering, or beating irregularly.

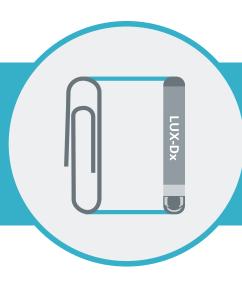
**Ventricular tachycardia:** When the ventricles (lower chambers of the heart) beat faster than normal and/or in an irregular pattern.

Other:		



**POSSIBLE INSERTION LOCATIONS** 

The LUX-Dx™ ICM device is small – about the length of a paper clip. It runs on a battery that's safely sealed within the device.



### The insertion procedure

At the beginning of your procedure, your health care team will usually numb the area where the device will be inserted. The provider will make a small incision. Typically the incision is on the left side of the chest. But, the provider will determine the best place to insert it.

After making the incision, the provider will insert the ICM device under your skin. Then the incision will be closed. Your health care team will let you know how to care for your incision.

Recovery from your insertion procedure should not prevent you from returning to an active lifestyle. But, be sure to ask your health care team what's recommended for you.

# The myLUX™ Patient App and RhythmCARE™ Assist service make remote monitoring easy

#### myLUX Patient App

After your procedure, it's time to set up your myLUX app so you can be remotely monitored.

The myLUX app will collect information about irregular heart rhythms stored on your LUX- $Dx^{TM}$  ICM device and automatically send that information to your health care team.

Your health care provider may have given you two choices for the myLUX app:

- 1 Download the app on your own smartphone
- Use a mobile device **provided by Boston Scientific**, with the app pre-installed

The steps are slightly different for these two options, so be sure to review the  $myLUX^{TM}$  Patient App Step-by-Step Setup Guide that was included in your myLUX TM Patient Education Packet.

Your health care team may help set up the app or you may be asked to do it at home.

If you are using the myLUX app on a mobile device provided by Boston Scientific, remember that this mobile device is intended just for using the app and transmitting your data to your health care team. It's not a phone that you can use to make calls, text, or browse the internet, even in an emergency. In case of an emergency, be sure to call emergency medical services on your regular phone.

#### **RhythmCARE** Assist service

If you are using your own smartphone for the app, you will be offered a supplemental service, RhythmCARE Assist, at no extra cost to you or your clinic. This service will help you set up your app and, should it become disconnected, will help you resume your connection so your clinic can keep monitoring your heart remotely and give you peace of mind about your care.

Ask your health care provider about RhythmCARE Assist so you can sign up for this free service on the day of your procedure.

# Best practices and troubleshooting tips to stay connected

Your myLUX<sup>™</sup> app on your smartphone or the Boston Scientific provided mobile device transmits your heart rhythm data stored on your LUX-Dx<sup>™</sup> ICM to your myLUX app. It is very important to keep your app connected so your health care provider can continue monitoring your heart rhythm remotely. Keep these best practices in mind.



Plug in and charge your smartphone or mobile device each night.



Place your smartphone or mobile device within 6 feet of where you sleep at night.



Keep your smartphone or mobile device powered on at all times. If you use a mobile device provided by Boston Scientific, press and hold the power key until the screen lights up to turn on your device.

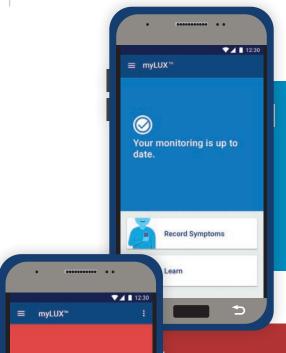


Connect your smartphone or mobile device to the internet via a WiFi or cellular connection.

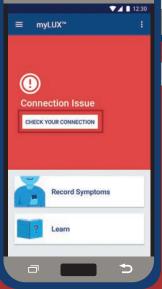


Keep Bluetooth® on so your app can connect to your ICM device.

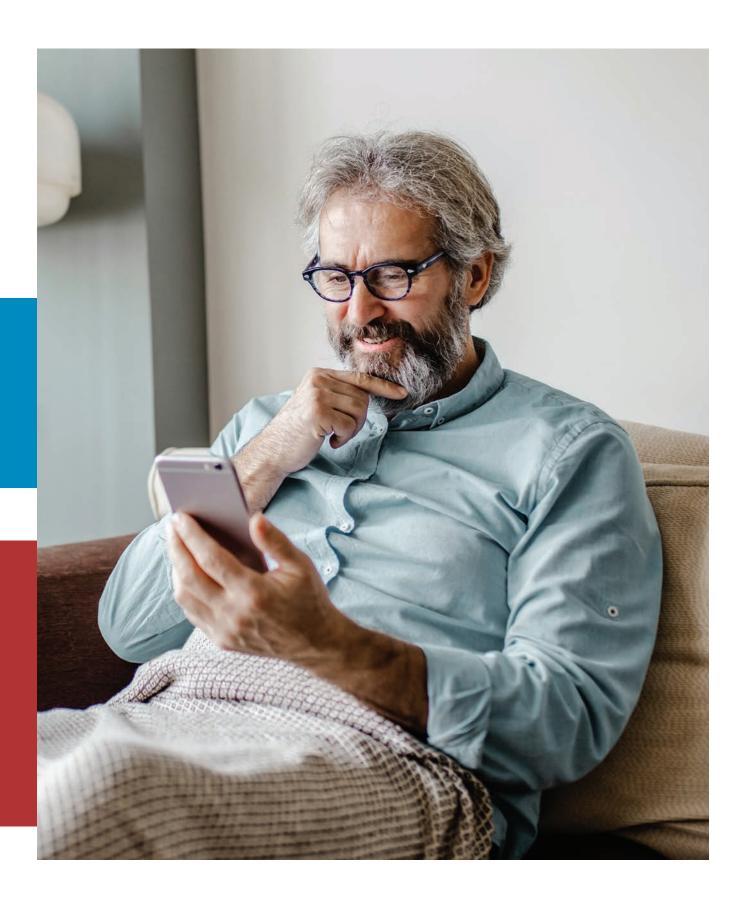
Check your myLUX™ app connection every few days by tapping into the app and looking for a blue screen:



If you see a blue screen with the check mark icon noting your monitoring is up to date, no action is needed.



If you see a red screen and the exclamation point icon, your app is not able to connect to your ICM device or the internet. An option to check your connection will appear on the red screen. Tap the button to check your connection and follow the on-screen instructions. A message will confirm when your app is connected.



# If you are using your own smartphone, remember the following:

- Do not quit (i.e., do not swipe up to close the app) or uninstall the app
- If you restart your smartphone, be sure to tap the app icon to reopen it
- Keep notifications turned on for your myLUX™ app
- Keep background refresh and background data usage on
- Do not activate any settings on your smartphone that may hinder the app's ability to conduct device checks in the background. This includes power save, low power, or battery optimization features
- If you've signed up for RhythmCARE™ Assist, be sure to read any emails or text messages you receive. They will guide you through reconnecting the app with videos and instructions

# If you are using a mobile device provided by Boston Scientific:

Restart your myLUX mobile device every once in a while to ensure its optimal performance. Hold down the power button for a few seconds until the "Restart" prompt appears on the screen. Tap **Restart**.

**NOTE:** This is just an example of where the power button could be located. It is usually a single button located along the top or right edge of the mobile device. It may be in a different place based on specific mobile device models.



## Need help?

For additional help or questions, please call Boston Scientific at **1-866-484-3268**, Monday–Friday during business hours, and select the option for LUX-Dx™ ICM.

### Frequently asked questions

Is the myLUX™ Patient App free?

Yes.

#### Is the RhythmCARE™ Assist service free?

Yes. It is free at no extra cost to you or your clinic. It is exclusively offered to patients who choose to download the myLUX app on their personal smartphones and sign up for the service. The RhythmCARE Assist service is different from remote monitoring services provided by your clinic. Read the *RhythmCARE Assist System Service Guide* for more details.

Talk to your health care provider about the potential charges related to the remote monitoring of your heart.

#### How much data usage will the myLUX app need?

Your myLUX app's monthly data consumption is equivalent to a few minutes of web browsing or less than a minute of video streaming each day.

#### Can I have an MRI scan with a LUX-Dx™ ICM?

Your LUX-Dx ICM device is MRI Conditional. This means that it has been demonstrated to be safe for patients with an ICM to undergo an MRI scan under certain conditions. However, there may be other reasons you may not be able to have an MRI scan. Talk to your health care provider before receiving an MRI scan to confirm that you meet the eligibility criteria.

Please note that the smartphone or mobile device with the myLUX app and the magnet are unsafe in the MRI area and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Committee on MR Safety Guidelines.

#### What do I need to do when I travel?

Bring your app and accessories with you when you travel and continue to use them as instructed. Your ICM device will continue monitoring, even when you travel outside of your home country. When you are traveling, your app will continue to collect information from your ICM device. However, if you are unable to connect to a cellular network or WiFi, the smartphone or mobile device containing your app will transmit the data once a connection can be established.

Notify your health care provider before traveling for an extended period of time or relocating.

#### Can I go through airport security?

Yes, you can go through airport security, but your ICM device contains metal parts that may set off airport security metal detector alarms. The security archway will not harm your ICM device. Tell security personnel that you have an implanted device and show them your medical device identification card.

#### Do I need to have the phone with me all day?

You do not need to bring your phone or mobile device with you during the day unless instructed to do so by your health care team. However, make sure to place your phone or mobile device within 6 feet (2 meters) of where you sleep at night. If you can't place it near where you sleep, place it within 6 feet of a spot where you spend a considerable amount of time every day. Remember to bring it with you for your clinic appointments.

### Data privacy and security\*

Boston Scientific takes data privacy seriously and adopts measures to ensure the data is collected, stored, and sent to clinicians in a secure manner. This includes measures that involve encryption and secure and authenticated connections.

Boston Scientific recommends that patients follow these security measures when using the app on their smartphone or provided mobile device:



Keep your smartphone or mobile device with you or in a secure place



Secure your smartphone or mobile device with a lock screen to prevent others from accessing your app



When using a WiFi network, only connect to trusted networks with strong security that are protected with a password and firewall



Contact your clinic or Boston Scientific customer support if your smartphone or mobile device is lost or stolen

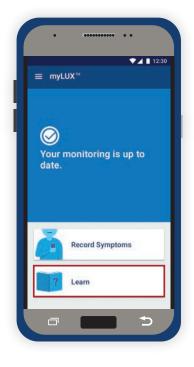


Only install and update the official Boston Scientific myLUX<sup>™</sup> Patient App from the App Store<sup>™</sup> or Google Play<sup>™</sup>

### Additional help/resources

To learn more about the LUX-Dx™ ICM System, tap the "Learn" button on the myLUX Patient App.

For additional questions, call your clinic or Boston Scientific at **1-866-484-3268**, Monday–Friday during business hours, and select the option for LUX-Dx ICM.



<sup>\*</sup>See patient manual for additional information.

# Discover more about the LUX-Dx™ ICM System.



Scan the QR code to visit the myLUX patient website.

#### myLUX™ Patient App and Insertable Cardiac Monitor System Important Information

The ICM system consists of the following: Insertable Cardiac Monitor ("ICM device"); Magnet; and myLUX patient app ("app"). The myLUX™ Patient App is for use with a BSC Insertable Cardiac Monitor (ICM) system which is a small device designed to monitor and record your heart rhythm once it has been placed under your skin. This information is shared via an automatic transmission to the clinic and your doctor for medical evaluation. The ICM and app are not intended to assist with medical emergencies; this means that it doesn't provide any treatment to the potential rhythms that could be recorded. Your myLUX™ Patient App is designed to work only with the ICM that your doctor has prescribed and implanted in you.

The ICM system does not treat cardiac arrhythmias (abnormal heartbeats that are too fast, too slow, or irregular), but rather it collects information for your health care provider to use to support their medical evaluation of your symptoms or condition. The ICM device's monitoring of your heart will not cause any noticeable sensations. Your ICM system is set up to automatically collect data stored on your ICM device and send it to your clinic to review according to the schedule your healthcare provider has set up. Your health care provider may also ask you to manually transmit data, however additional instruction will be provided if you need to do this as it should only be done on a limited basis.

Electromagnetic fields are created by devices which use electricity, including those which are plugged into a wall outlet or battery operated. Devices which emit strong electromagnetic fields may have the potential to temporarily interfere with your ICM device's ability to detect and monitor your heart rhythm. They could also delay or prolong communication between your ICM device and your myLUX<sup>™</sup> Patient app.

The magnet when provided with the ICM system may cause interference with devices sensitive to magnetic fields such as hearing aids, pacemakers, and other implanted devices. It can also permanently disable some magnetic strip cards.

Ask your health care provider if you have questions about any risks with using the myLUX™ App, the magnet or your ICM device.

Please refer to the Patient Handbook for the full warnings, precautions and important safety information. *Rx only* 

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