

myLUX™ Patient App

for Insertable Cardiac Monitor

REF 2925

Patient Handbook

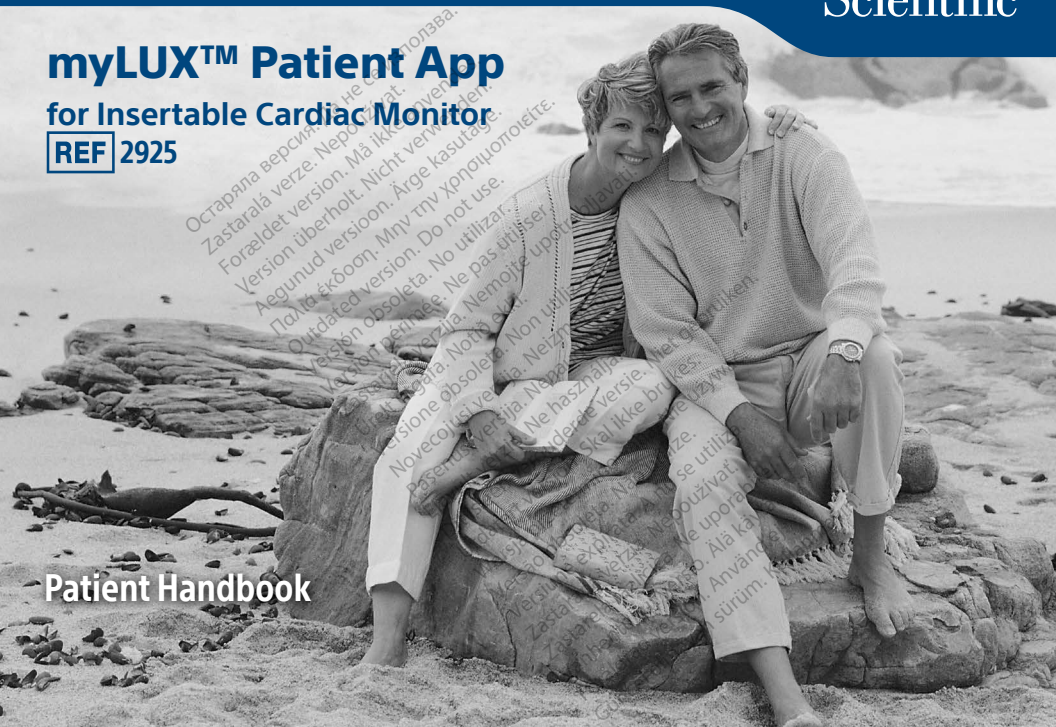


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Introduction

Your doctor has recommended a Boston Scientific Insertable Cardiac Monitor (ICM) system. This system is designed to monitor and record your heart rhythm for clinical evaluation.

Your doctor may have recommended this system for one of the following reasons:

- You have experienced symptoms such as fainting, heart racing or fluttering, shortness of breath, or light-headedness that may suggest a heart condition.
- You are at risk of developing an abnormal heart rhythm.

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- You have a known heart condition that your doctor wants to monitor.

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 in evaluating your symptoms.

This handbook describes the ICM system and explains how to use the myLUX patient app. Your health care provider will discuss any potential risks or side effects that may be associated with your ICM system. However, be sure to carefully read and understand all warnings and safety precautions discussed in this guide.

A glossary is located at the back of the handbook. It defines many of the words you will see in the upcoming pages, as well as those you may hear from your health care providers.

The figures used in this manual are intended as examples only and may not match what you see when using the ICM system. Figures and instructions that describe the mobile device are representative. Your actual mobile device may vary slightly in appearance.

If you have questions about what you read in this handbook, ask your health care provider. They are your best resource for information.

Summary of Safety and Clinical Performance

For customers in the European Union, use the device name found in the labeling to search for the device's Summary of Safety and Clinical Performance, which is available on the European database on medical devices (Eudamed) website:
<https://ec.europa.eu/tools/eudamed>.

Your ICM system

The ICM system consists of the following:

- Insertable Cardiac Monitor (“ICM device”)
- Magnet
- myLUX patient app (“app”)

CAUTION: The 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.

How your ICM system works

Your ICM device automatically records and stores irregular heart rhythms or “arrhythmias”, whether you are near the mobile device with your app or not.

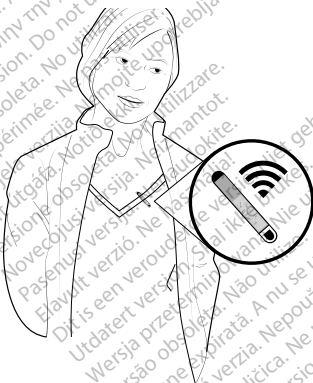


Figure 1. ICM device records heart rhythm

The app on your mobile device collects irregular heart rhythms stored on your ICM device and automatically sends that data to your clinic to review.



Figure 2. App sends data

Your clinic will contact you if there is a need for further review.



Figure 3. Health care provider accesses data

Insertable Cardiac Monitor

This small electronic device runs on a battery that is safely sealed within its case. The ICM device is the only part of the ICM system inserted in your body. It is typically placed just under the skin in the left chest area (“Figure 4. An ICM device inserted” on page 10). Depending on your physical anatomy and lifestyle considerations, your health care provider will determine the best placement for your ICM device.

Your health care provider can program the settings on your ICM device to meet your specific needs.

As you go about your daily activities, your ICM device monitors your heart rhythm. When an irregular heart rhythm is detected, the ICM device, as programmed by your health care

provider, records and stores the information. The recorded data is transmitted and reviewed by your health care provider periodically on a schedule they determine. Talk to your health care provider if you have questions about how you are being monitored.

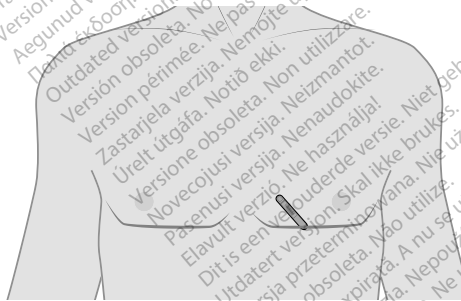


Figure 4. An ICM device inserted

Boston Scientific Corporation does not monitor the data that is transmitted by your ICM system. Only an authorized health care provider monitors your personal health information.

Materials

The ICM device materials that come in contact with the body have been tested for bio-compatibility. The ICM device is made up of titanium and other materials ("Table 1. Patient-contacting Materials for ICM Model M301" on page 12). Allergic reactions are uncommon, but you should discuss any known allergies to materials with your health care providers.

Table 1. Patient-contacting Materials for ICM Model M301

Material	% of Total Exposed Surface Area
Cured epoxy	13%
Titanium (with titanium nitride coating)	10%
Parylene coating	77%

Magnet

Magnet model 6386 is required to set up your app. Your health care provider will inform you as to if and how they want you to use the magnet beyond the initial app setup. For information on care and handling of the magnet, refer to the Instructions for Use provided with the magnet.

myLUX patient app

myLUX is a software application (app) for patients who have an ICM device. The app communicates with your ICM device using **Bluetooth**¹ Low Energy technology.

Transmissions are sent periodically on a schedule determined by your health care provider. These transmissions typically occur overnight and the process is silent and automatic.

Your app allows you to send data stored on your ICM device, view messages from your clinic, and more. For information on app features, see “Using your app” on page 28.

1 The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Boston Scientific Corporation is under license. Other trademarks and trade names are those of their respective owners.

Once setup is complete, your app will only connect to your ICM device. Use only as directed by your health care provider. Unauthorized use could interrupt the prescribed operation of your ICM device.

If your health care provider gave you a Boston Scientific mobile device, the app will be pre-installed. The mobile device allows your app to communicate with your ICM device as well as transmit data; however, it will not have the capability to make phone calls. If you need immediate medical attention, call your health care provider or seek emergency medical services using something other than the mobile device provided with your ICM system.

When software updates are needed, they will be sent to your mobile device automatically. If the updates include a mobile

device system update, a Wi-Fi connection may be needed in order to complete the update.

Clinical Benefits of Your ICM System

The primary benefit of your ICM system is to record your heart rhythm during a prolonged period of time. Prolonged monitoring is particularly helpful if your symptoms or abnormal rhythms are sporadic and might be missed by other forms of monitoring. Recording heart rhythms assists your health care provider when making a decision related to your heart condition and your risk of developing abnormal heart rhythms, or symptoms that could be related to a cardiac arrhythmia such as fainting, heart racing or fluttering, chest pain, shortness of breath, or light-headedness.

The ICM system automatically detects and records abnormal heart rhythms based on how your health care provider programs the system according to your medical situation. Additionally, if you are given a myLUX patient app, you may be able to record your symptoms. When your health care provider activates this option, your ICM device records your rhythm and shares that information with your health care provider which allows them to correlate how you are feeling with what the ICM device records. The ICM system also offers your health care provider the option to monitor your heart rhythm and program your ICM device remotely (when you are not in the clinic or hospital), reducing your number of visits to the clinic.

Items You Should Receive

You may receive some or all of the following items with your ICM system as determined by your health care provider:

- myLUX patient app pre-installed on a mobile device in a case
- Mobile device power adapter(s) with USB cable
- Mobile device stand
- Magnet in shielded box with extra adhesive strips
- Magnet Instructions For Use
- myLUX Patient App for Insertable Cardiac Monitor Patient Handbook (this book)
- myLUX Patient App for Insertable Cardiac Monitor Quick Start Guide
- Implant Card

Your Insertion Procedure

Your ICM device is inserted using local anesthesia to numb the area. During the procedure, your health care provider will make an incision, insert the ICM device under the skin, and close the incision.

Insertion risks

As with any medical procedure, it is important to understand that, while complications do not happen very often, there are risks associated with the insertion of an ICM device. You should talk with your health care provider about these risks, including those listed below.

Contact your health care provider if you notice any swelling, warmth, or drainage around your incision or if you develop a fever while your incision is healing.

Some of the risks encountered during the insertion procedure include, but are not limited to, the following:

- Infection
- Breakdown of the tissue near the device
- Device migration from the original insertion site
- Bleeding or fluid accumulation under the skin
- Pain and discomfort
- Local tissue reaction
- Tissue damage

Temporary procedural adverse events are expected in some patients. These include, but are not limited to, discomfort, pain, and other body symptoms that might be related to medications used or procedures performed during implant.

Talk with your health care provider so that you thoroughly understand all of the risks and benefits associated with the insertion of this system.

Recovery

Recovery from your insertion procedure should not prevent you from returning to an active lifestyle. Your health care provider will help you decide what level of activity is best for you and answer any questions you have about living with your ICM device. Follow your health care provider's post-operative instructions.

Have your health care provider complete the "Your ICM system information" and "When to call your health care provider" forms on "Forms" on page 74.

Your Implant Card

When you receive your ICM device you will be given an Implant Card.

Whether you are going away for the weekend or running a quick errand, carry your Implant Card with you. In an emergency, the card will alert medical and security personnel that you have an inserted device.

Your Implant Card contains your name, your health care provider's name and phone number, and the model number of your ICM device.

Attaching the magnet

If you were instructed to use the magnet as part of your ICM system, you may choose to attach it to the back of the mobile device case. This will help ensure that the magnet is readily available if your app instructs you to use it.

To attach the magnet to your mobile device case:

1. Remove the blue magnet from the silver box labeled "Magnet in shielded box."
2. Locate the adhesive circle pre-applied to the back of the mobile device case.

3. Use the tab to peel off the adhesive backing (“Figure 5. Remove adhesive backing” on page 24).
4. Place the back side of the magnet (the side with the Boston Scientific logo) on the adhesive and press firmly (“Figure 6. Magnet attached to mobile device case” on page 24).



Figure 5. Remove adhesive backing



Figure 6. Magnet attached to mobile device case

Setting up your app

Before you can use your app, it must be set up.

The following are required to complete the setup:

- The magnet provided for use with your app
- A Wi-Fi or cellular connection

To set up your app:

1. Power on your mobile device.
2. Tap the **myLUX** icon to open the app. A screen will display indicating that the language is set to English.

Touchscreen Tip: Gently and quickly tap the screen with your fingertip. Do not use your fingernail.

3. To continue with English as your setting, tap **NEXT** and proceed to the next step. To change the language setting, tap **CHANGE LANGUAGE** and complete the following:

- Select your preferred language by dragging the up/down arrows (↕) to move it to the top of the list and then tap **DONE**.

A screen will display in the selected language indicating the language you selected.

- Tap **NEXT**.
4. Tap **START SETUP** on the Welcome to myLUX screen.
5. Follow the instructions on the screen.

NOTE: If the app is not able to connect to a cellular network, you will be prompted to connect to Wi-Fi to complete the setup.

A message will confirm when the setup is complete. Tap **DONE**.

Using your app

Your app is set up for automatic remote monitoring. This section describes tasks you can perform related to using your app and additional features.

Opening your app

Keep your mobile device powered on at all times to allow your app to continue monitoring. To open your app, tap the **myLUX** icon.

Monitoring Status

Connected (✔)

When you see this icon, you know that everything is working fine -- no action is needed.

Not Connected (❗)

When you see this icon, you know that your app is not able to connect to your ICM device or the Internet.

If your app cannot connect to your ICM device or to a cellular or Wi-Fi network, a message will appear on the screen instructing you to check your connection. Follow the instructions on the screen. A message will confirm when your app is connected.

Record Symptoms

Use your app to record information about symptoms you are experiencing. Your ICM device records your heart rhythm along with the symptom information and stores it to be sent at the next transmission.

Your health care provider will tell you if you need to record symptoms. Your app will not have the Record Symptoms button if you do not need to use this feature.

To record your symptoms:

1. Tap **Record Symptoms** on your app's main screen.
2. Follow the instructions on the screen.

NOTE: Connecting to your ICM device may take several

minutes.

A message will confirm when the transaction is complete.

3. Tap **DONE**.

Manual Transmissions

Your ICM system is set up to automatically collect data stored on your ICM device and send it to your clinic to review. Manual transmissions are in addition to automatic transmissions and are intended for limited use. Send manual transmissions only as directed by your health care provider.

To send a manual transmission:

1. Tap the Menu icon () in the upper left corner of your app screen.

2. Select **Manual Transmission**.
3. Follow the instructions on the screen.

NOTE: Connecting to your ICM device may take several minutes.

A message will confirm when the data was sent.


4. Tap **DONE**.

Connect to Wi-Fi

You can connect to Wi-Fi at any time by completing the following steps.

To connect to Wi-Fi:


1. Press the Home button on your mobile device.

2. Tap the down arrow in the upper right corner of your screen.
3. Tap the Settings () icon.
4. Tap **Wi-Fi**.
5. If a list of available Wi-Fi networks displays, tap to select a network from the list.
6. Follow the instructions on the screen. You may be prompted to enter a network password to connect.
7. The screen will indicate when you are connected.
8. Press the Home button on your mobile device.
9. Tap the **myLUX** icon to return to the app.

Securing your mobile device screen

If your health care provider gave you a Boston Scientific mobile device, you have the option to lock your mobile device screen to prevent others from accessing your app.

To secure your mobile device screen:


1. Press the Home button on your mobile device.
2. Tap the down arrow in the upper right corner of your screen.
3. Press the Settings () icon.
4. Tap **Screen Lock**.
5. Tap to select the method you want to use (e.g. PIN, Password) and follow the instructions on the screen.

6. Press the Home button on your mobile device.
7. Tap the **myLUX** icon to return to the app.

Change your language setting

If your health care provider provided you with a Boston Scientific mobile device, the language setting was selected during app setup. You can change the language setting at any time.

To change the language setting:

1. Press the Home button on your mobile device.
2. Tap the down arrow in the upper right corner of your screen.
3. Tap the Settings () icon.
4. Tap **Language** on this screen and on the next screen.

- Select your preferred language by dragging the up/down arrows (↕) to move it to the top of the list and then tap **DONE**.
- Press the Home button on your mobile device.
- Tap the **myLUX** icon to return to the app.

Additional Features

Table 2. Additional Features

Feature	Allows you to...
Connection Check	check that your app is able to send data to your clinic. Select this option from the Menu (☰) icon.

Feature	Allows you to...
Learn	access education and training content related to use of your ICM device and the types of cardiac conditions it monitors. Select this option from the main app screen.
Message	view a new message from your clinic. This option is available on the main app screen only when you have a message to view. You cannot respond to messages through the app. Contact your clinic if you have questions.

Monitoring Ended Due to Inactivity

Boston Scientific reserves the right to turn off monitoring if a mobile device provided by Boston Scientific has been inactive for a substantial period of time. Any of your personal data stored on the mobile device will be deleted when monitoring is turned off.

Living with your ICM system

The ICM device's monitoring of your heart will not cause any noticeable sensations. However, your health care provider may want you to record symptoms.

Discuss with your health care provider what these symptoms are and how to record them.

Patient responsibilities

It is important to follow your health care provider's instructions as well as these recommendations:

- Your health care provider will arrange a follow-up plan with you to check your ICM device. For more information, see “Patient follow-up options” on page 42.
- Use your app and magnet only as directed by your health care provider. Report any serious incidents related to the app and magnet (i.e., an event requiring medical attention) to your health care provider, to Boston Scientific, and to the relevant local regulatory authority for medical devices in your country.
- Follow the instructions in the warnings and precautions provided in this handbook. See “Important safety information” on page 48.
- Keep your mobile device powered on at all times.

- Do not carry your mobile device in a breast pocket or on a belt if that places the magnet within 15 cm (6 inches) of your ICM device.
- To ensure successful automatic transmissions of data from your ICM device to your clinic, keep the mobile device with your app charged and within 2 meters (6 feet) from where you sleep. If this is not possible, keep the mobile device where you spend a considerable amount of time each day. The mobile device should also be kept in a location that receives an adequate cellular or Wi-Fi signal.
- To avoid interference from electronic equipment, when using your app, maintain a separation distance of 2 meters (6 feet) from 2.4 GHz wireless devices such as Wi-Fi enabled devices and wireless baby monitors. The mobile device should be

kept in a location with similar separation from electronic equipment.

- Carry your Implant Card with you at all times.
- Tell your family doctor, dentist, and emergency personnel that you have an inserted device, and show them your Implant Card so that they can take any necessary precautions.

Patient follow-up options

Your health care provider will schedule follow-up sessions with you, as needed.

During follow-ups, your health care provider can review information collected by your ICM device since the last follow-

up, check battery status, and adjust any programmed settings, if needed.

There are two follow-up options: clinic visits and remote follow-up sessions. Your health care provider will decide how often to schedule your appointments.

It is important that you attend clinic visits, even if you are feeling well.

If your health care provider wants to monitor you remotely, you will receive an app. The app is used to gather data from your ICM device on a regular schedule that is set by your health care provider. The data gathered by your app is sent from your mobile device to your clinic using a cellular or Wi-Fi connection. See

“Patient responsibilities” on page 39 for information on where to store your mobile device to ensure successful transmissions.

The app cannot be used to directly reprogram or change any functions of your ICM device. Only your health care provider can do this by sending the changes to your ICM device using the secure clinician website.

Traveling

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. For information on transmitting data during travel, see “Precautions” on page 53.

If you have any concerns about traveling, including how you will be monitored or other follow-up support, check with your health care provider or Boston Scientific before, during, or after your trip.

For information on passing through airport security systems, see “Airport security” on page 61.

What you should know about your ICM device's battery and the lifetime of your ICM device

The lifetime of your ICM device is based on the battery. The battery will last up to three years. There are factors that could affect battery life including programmed settings. Your ICM device will regularly check its own battery. At every follow-up visit, the health care provider will also check the battery status.

Returning, replacing, or disposing of your ICM system

Talk with your health care provider to understand if and when your ICM device needs to be replaced.

If you need to replace the mobile device containing your app or any accessories of the ICM system (e.g., magnet, USB cable) because of damage or malfunction, contact Boston Scientific to learn how to return and replace them.

If you no longer need to use your app or any electronic accessories, contact your local authorities to learn how to dispose of electronic items. Dispose of it only as directed as it may contain encrypted health data.

There are no special requirements for disposal of the magnet or the Patient Kit packaging.

Остаряла версия. Да не се използва.
Zastaralá verze. Nepoužívat.
Forældet version. Må ikke anvendes.
Version überholt. Nicht verwenden.
Aegunud versioón. Árgu kasutage.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Outdated version. Do not use.
Version obsolete. Ne použít.
Version périmée. Nemojte upotrebljavati.
Zastarjela verzija. Ne uporabite.
Úreált útgáfa. Notið ekki.
Versione obsoleta. Ne pas utiliser.
Novecojusi versija. Nenaudokite.
Pasenusi versija. Neizmantoj.
Elavult verzió. Ne használja.
Dit is een verouderde versie. Niet gebruiken.
Utdatert versjon. Skal ikke brukes.
Wersja przeterminowana. Nie używać.
Versão obsoleta. Não utilize.
Zastarana verzija. Nepoužívat.
Zastarela verzija. Ne uporabite.
Vanhentunut versio. Älä käytä.
Föråldrad version. Använd ej.
Güncel olmayan sürüm. Kullanmayın.

Important safety information

Electromagnetic interference

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 rate. They could also delay or prolong communication between your ICM device and your app. This type of interference is called Electromagnetic Interference (EMI). EMI includes radio-frequency (RF) interference from wireless electronic products.

Typically, the ICM system will resume normal function when you turn off or move away from the electronic device causing the EMI.

Your ICM system is designed to minimize the potential for encountering EMI. This means that normal operation of your ICM system will not be affected by the electromagnetic fields generated by most electronic devices that you encounter in your daily life.

However, it is important for you to be aware of some electronic devices which may have the potential to interfere with your ICM system's normal function. "Environmental safety precautions" on page 54 will help you understand known risks and the safety of particular appliances, tools, and activities.

If your personal or professional lifestyle requires you to spend a significant portion of your day around sources that generate strong electromagnetic fields, talk with your health care provider about those specific sources.

Household appliances and common tools

It is safe to operate most household appliances, office equipment, and common tools that are properly grounded and in good working order. See “Environmental safety precautions” on page 54 for a list of items that need to be kept a safe distance from your ICM device.

Electronic equipment

Electronic equipment could interfere with wireless communication between your app and your ICM device. See “Patient responsibilities” on page 39 for instructions on avoiding such interference.

Warnings and precautions

Read and follow all warnings and precautions discussed in this section. Failure to heed the warnings and precautions may result in failure to monitor or record an arrhythmia. Talk to your health care provider if you have any questions or concerns regarding this information.

Warnings

The magnet 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. Keep the magnet at least 15 cm (6 inches) away from items sensitive to magnetic fields (such as hearing aids, pacemakers, or other implanted devices), including your ICM device when the magnet is not being used to initiate communication between your ICM device and your app.

Precautions

Contact your health care provider if you notice any swelling, warmth, or drainage around your incision or if you develop a fever while your incision is healing.

Use of the magnet to initiate communication has been accounted for in the projected battery life of the ICM device. Using this feature more often than instructed by your health care provider may lead to a decrease in the battery life of the ICM device.

Your app can only connect to your ICM device. Use as directed by your health care provider. Unauthorized use could interrupt the prescribed operation of the ICM device.

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 Wi-Fi, the mobile device containing your app will transmit the data once a connection can be established.

When the mobile device containing your app is not in use, make sure the location where you store it is secure and take appropriate measures to prevent theft or unauthorized access. See “Securing your mobile device screen” on page 34.

Environmental safety precautions

This section presents the environmental safety precautions for which you must be aware. Be sure to carefully read and understand each of these precautions. If you still have questions or concerns regarding these precautions, please contact your health care provider or Boston Scientific.

If you use any of the following items, it is important that you keep them the recommended distance away from your ICM device to avoid EMI.

Items that should not be placed directly over your ICM device, but are otherwise safe to use:

- Cordless (household) telephones
- Electric razors
- Hand-held massagers
- Portable computer laptops or tablets
- Headphones or earbuds

NOTE: The headphones or earbuds used with portable electronic devices often contain permanent magnets. Avoid placing them over your ICM device or draping them around

your neck. Store them at least 15 cm (6 inches) away from your ICM device.

Items that should remain at least 15 cm (6 inches) away from your ICM device, but are otherwise safe to use:

- Cellular phones, including PDAs and portable electronics with integrated cellular phone functionality

NOTE: For more information about cellular phones, see “Cellular phones” on page 62.

- Devices transmitting Bluetooth or Wi-Fi signals (cellular phones, laptops, tablets, wireless Internet routers, etc.)

NOTE: The mobile device provided for use with your ICM system is safe to use, as instructed.

WARNING: Keep the magnet, which may be attached to the back of your mobile device case, at least 15 cm (6 inches) away from your ICM device, when it is not being used to initiate communication between your ICM device and the app.

Items that should remain at least 30 cm (12 inches) away from your ICM device, but are otherwise safe to use:

- Electric yard and handheld power tools (plug-in and battery-powered), such as saws, drills, lawn mowers, leaf blowers, and snow blowers
- Chain saws
- Home power generators
- Remote controls with antennas
- Slot machines

- Stereo speakers

Items that should remain at least 60 cm (24 inches) away from your ICM device, but are otherwise safe to use:

- Arc and resistance welders
- Police radio antennas and antennas used to operate a CB, ham radio, or other radio transmitter
- Running motors and alternators, especially those found in vehicles

NOTE: Avoid leaning over running motors and alternators of a running vehicle. Alternators create large magnetic fields that could affect your ICM device. However, the distance required to drive or ride in a vehicle is safe.

Items that should not be used:

- Body-fat measuring scales
- Jackhammers
- Magnetic mattresses and chairs

Avoid environments that contain strong electric or magnetic fields such as the following:

- Strong magnets such as those used in auto wrecking yards and other industrial environments
- Industrial power generators
- Large TV/Radio transmitting towers
- Power plants and high voltage power lines

If you have questions about EMI and safety concerning a particular appliance, tool, or activity, please call Boston Scientific at 1.866.484.3268.

Theft detection and security systems

Electronic antitheft systems (including tag deactivation) and security gates or tag readers that include radio frequency identification (RFID) equipment (often found in store and library doorways, at checkout counters, and in point-of-entry access control systems) should not impact your ICM device's ability to detect and monitor your heart rate if you follow these guidelines:

- Walk through theft detection and security systems at a normal pace.
- Do not lean against or linger near these systems.
- Do not lean against checkout counter-mounted or handheld tag deactivation systems.

- Avoid lingering near entrance and exit doorways, as some theft detection systems may be hidden in the walls or the floor in these areas.
- Most home security systems are unlikely to affect the proper function of your ICM device.

Your ICM device is unlikely to set off the alarm from an electronic antitheft or security system.

Airport security

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 Implant Card.

Airport security wands could temporarily affect your ICM device's ability to detect and monitor your heart rate if the wand is held over it for a period of time. If possible, ask to be hand-searched instead of being searched with a handheld wand. If a wand must be used, inform the security personnel that you have an implanted device. Tell security personnel not to hold the wand over your ICM device and to perform the search quickly.

If you have questions about airport security, call your health care provider or Boston Scientific at 1.866.484.3268.

Cellular phones

Keep your cellular phone at least 15 cm (6 inches) away from your ICM device. Your cellular phone may be a potential source of EMI and could affect your ICM device's operation. This interaction

is temporary, and moving the phone away from your ICM device will return it to proper function. To reduce the chance of interaction, follow these precautions:

- Maintain a distance of at least 15 cm (6 inches) between the cellular phone and your ICM device. If the phone transmits more than 2 watts, increase the distance to 30 cm (12 inches). If the phone relies on external antennas and power amplifiers/boosters, increase the distance to 60 cm (24 inches).
- Hold the cellular phone to your ear on the opposite side of your body from your ICM device.
- Do not carry a cellular phone in a breast pocket or on a belt if that places the phone within 15 cm (6 inches) of your ICM device.

These precautions apply only to cellular phones, not to household cordless phones. However, you should avoid placing your household cordless phone receiver directly over your ICM device.

NOTE: The mobile device provided by Boston Scientific for use with the ICM system is safe to use, as instructed.

Dental and medical procedures

Before undergoing any medical procedure, tell the doctor or technician that you have an implanted device. Your doctor or technician may need to speak with the health care provider who monitors your ICM device before performing the procedure.

- Some medical procedures may require precautionary measures to prevent or minimize data interference.
- Some medical procedures could damage your ICM device or affect its ability to detect and monitor your heart rate.
- Some medical procedures may cause electrical reset.

Be especially careful with the following procedures:

- **Magnetic Resonance Imaging (MRI):** This is a diagnostic test that uses a strong electromagnetic field. The ICM is MR Conditional. This means that it has been demonstrated to be safe for patients with an ICM to undergo an MRI scan under certain conditions if those conditions are met. However, there may be other reasons you may not be able to have an MRI scan. Talk to your doctor before receiving an MRI scan to

confirm that you meet the eligibility criteria.

The mobile device and magnet contain materials that, if brought into an MRI environment, could pose harm to patients and MRI equipment. Do not bring the mobile device with your app or your magnet into the MRI scanner room (typically called MRI safety zone IV).

- **Diathermy:** This uses an electrical field to apply heat to tissues in the body and could damage your ICM device or injure you. Diathermy should not be performed.
- **Electrocautery:** This is sometimes used during surgical procedures to stop vessels from bleeding. Electrocautery can affect your ICM device, but can still be performed if

necessary. Contact your health care provider after the procedure to verify that your ICM device functions properly.

- **External defibrillation:** This is a procedure, typically used in medical emergencies, that uses external equipment to deliver an electrical shock to your heart to restore a rapid and irregular heart rate to a normal rhythm. External defibrillation can affect your ICM device, but can still be performed if necessary. If you receive external defibrillation, be sure to contact your health care provider as soon as possible following the emergency to verify that your ICM device is functioning properly.
- **Lithotripsy:** This is a medical procedure that is used to break up stones in the urinary tract (e.g., kidney stones). Lithotripsy can damage your ICM device if certain precautions are not

taken. Talk to your health care provider as well as the doctor performing the procedure about what can be done to protect your ICM device.

- **Other implanted medical devices:** Devices co-implanted with the ICM system (including but not limited to, implantable neurostimulation systems, ventricular assist device, or implantable drug pumps) can result in interactions that could compromise the function of the ICM, the co-implanted device, or both. If you have further questions, talk to your health care provider.
- **Therapeutic radiation treatment for cancer:** This procedure can affect your ICM device and will require special precautions. If you should need radiation treatment, talk to

your health care provider as well as the doctor performing the medical procedure.

- **Transcutaneous Electrical Nerve Stimulation (TENS)**

unit: This is a device prescribed by doctors or chiropractors for control of chronic pain. A TENS unit can affect your ICM device and will require special precautions. If you must use a TENS unit, talk to your health care provider.

Most medical and dental procedures will not affect your ICM device. Some examples include:

- Dental drills and cleaning equipment
- Diagnostic X-rays
- Diagnostic ultrasound procedures

- EKG machines
- CT scans
- Mammograms




NOTE: Mammograms will not interfere with your ICM device. However, your ICM device could be damaged if it gets compressed in the mammogram machine. Make sure the doctor or technician knows that you have an implanted device. Allow sufficient time for your incision to heal before performing a mammography procedure.









If you have questions about a specific appliance, tool, medical procedure, or piece of equipment, please talk to your health care provider or call Boston Scientific at 1.866.484.3268.








Symbols in Labeling

The following symbols may be used on packaging and labeling:

Table 3. Symbols in Labeling

Symbol	Definition
	Serial Number
	Bluetooth®
	Discard with electronic waste

	Temperature limitation
	Consult instructions for use
	Recyclable Package
	Authorized Representative in the European Community
	Australian Sponsor Address
	Medical Device under EU Legislation
	Reference Number
	Manufacturer

	Date of manufacture
	myLUX patient app icon
	Person identification
	Date
	Health care center or doctor
	MR Unsafe
	MR Conditional

Forms

Have your health care provider complete the following:

Your ICM system information

ICM Model Number: _____

ICM Serial Number: _____

Date device was inserted: _____

When to call your health care provider

- If you notice any swelling, redness, or drainage from your incision.
- Before traveling for an extended period of time or relocating.
- _____
- _____

CAUTION: The 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.

Your medical contact information

Health Care Provider Names/Phone Numbers:

Clinic or Hospital Name/Address/Phone Number:

Medications (list):

Contact us

By Mail:

Boston Scientific Corporation
4100 Hamline Avenue North
St. Paul, Minnesota 55112-5798 USA

By Telephone:

Worldwide: 1.651.582.4000

Visit us on the Internet

Boston Scientific's website, www.bostonscientific.com, offers a variety of information of interest to people with cardiac devices, including frequently asked questions about living with your ICM device, health tips, patient stories, and links to additional resources.

Glossary

App (application)

Software that runs on a mobile device. See also, **myLUX**.

Arrhythmia

An abnormal heartbeat that is too fast, too slow, or irregular.

Cardiac monitor

See **Insertable Cardiac Monitor**.

Electromagnetic field

Invisible lines of force that result from electrical fields (produced by voltage) and magnetic fields (produced by current flow).

Electromagnetic fields decrease in strength the farther they are from their source.

Electromagnetic interference (EMI)

Interference that occurs when your ICM device interacts with an electromagnetic field. See also **electromagnetic field**.

Health care provider

The person that you see at your clinic. This may be your doctor, a nurse, a technician, or someone else that works for your doctor.

Heart rhythm

A series of heartbeats. You may hear your health care provider refer to your rhythm as being normal or irregular. A normal heart rate typically ranges from 60 to 100 beats per minute at rest.

ICM device

See **Insertable Cardiac Monitor**.

Insertable Cardiac Monitor (ICM)

Also called an ICM device or a cardiac monitor. The ICM is a small electronic device inserted under the skin in your chest area used to monitor and record your heart rhythms.

Insertable Cardiac Monitor system

See **LUX-Dx Insertable Cardiac Monitor system**.

LUX-Dx Insertable Cardiac Monitor system

A set of products designed to be used together to record your heart rhythms and send them to your health care provider. For patients, the system includes the ICM device, magnet, and an app.

Mobile device

Hardware on which your app is installed. The mobile device enables your app to transmit data between your ICM device and your clinic; however, it will not have the capability to make phone calls.

myLUX

Also called the app or patient app. A software application used to transmit data from your ICM device to your health care provider.

Patient app

See **myLUX**.

Secure clinician website

A secure computer location that stores patient and clinic data. Only authorized medical personnel can access your medical data using a password-protected website.

Transmission

The process of gathering heart data from your ICM device and sending it to your clinic to review.

Wi-Fi

Wireless networking technology that allows a mobile device to connect to the Internet without a wired cable connection.





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