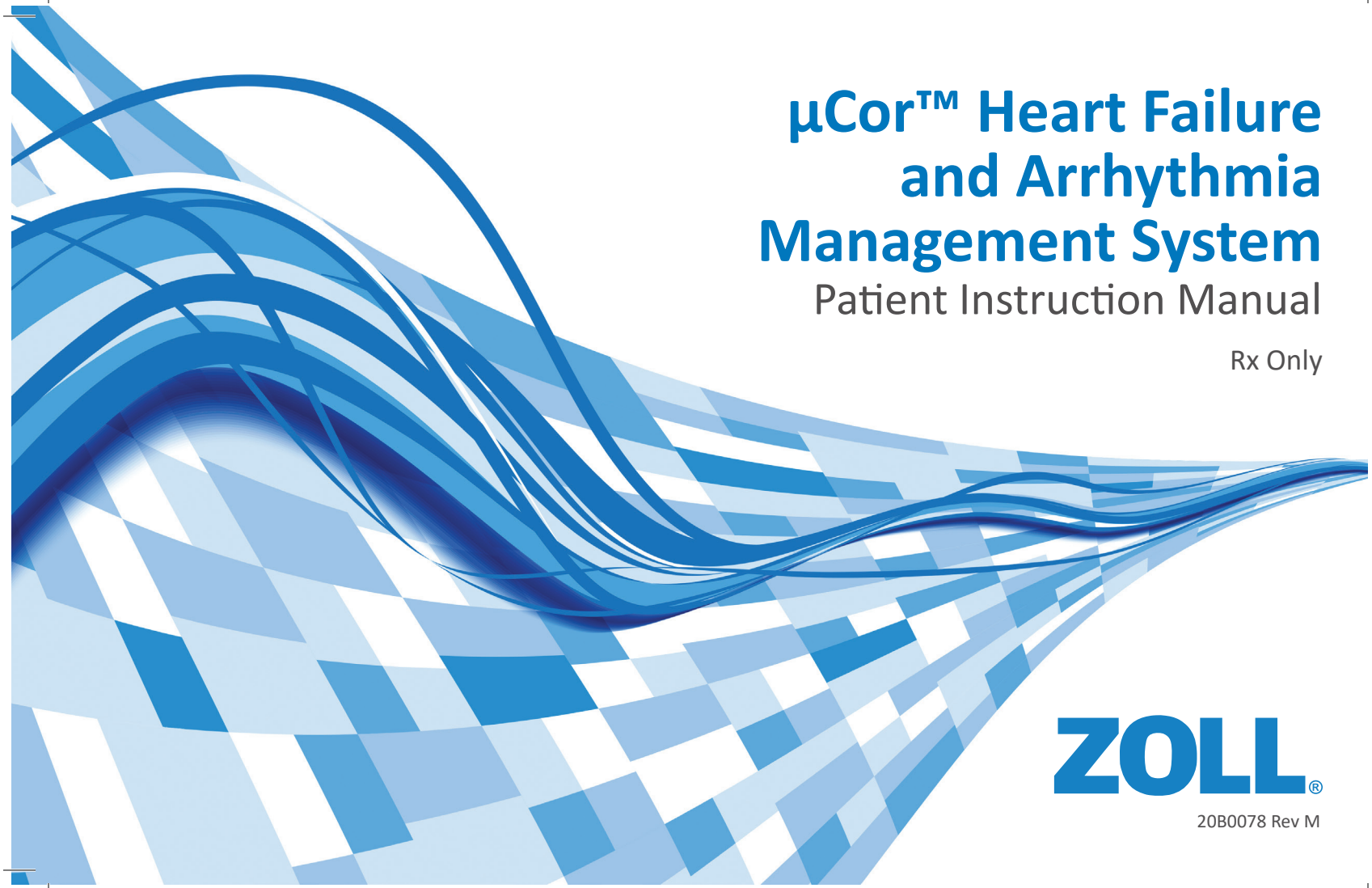
µCor™ Heart Failure and Arrhythmia Management System

Patient Instruction Manual

Rx Only



ZOLL®

20B0078 Rev M

This page intentionally left blank.

Table of Contents

This page intentionally left blank.

If you have any questions, contact ZOLL

24 hours a day, 7 days a week:

Toll free (USA) 1.888.592.3798

121 Gamma Drive ● Pittsburgh, PA 15238 USA

Disclaimer: Information, operation, specifications, and product appearance may change without notice.

Patents: Patent: www.zoll.com/patents

Symbols Glossary: The symbols glossary is located in **Part 6** of this manual.

Welcome to the ZOLL µCor™ Heart Failure and Arrhythmia Management System

The µCor™ System is a wearable medical device that is intended to continuously record, store, and transmit your medical data to healthcare professionals.

Once placed on your body and activated, the wearable Sensor automatically collects your body's heart rhythm (ECG), Thoracic Fluid Index, Heart Rate, Respiration Rate, Activity, and Posture measurements. You can also activate a patient trigger when experiencing symptoms by double tapping the Sensor when it is on your body.

Your data are automatically transmitted from the Sensor to the Gateway, and from there to ZOLL for analysis by certified technicians. The certified technicians also prepare reports according to the defined criteria as requested by your prescribing physician. Data provided in the report aids your prescribing physician in the diagnosis and identification of various clinical conditions, events and/or trends.

The µCor System is intended for use in an outpatient clinic and home settings.

Contact ZOLL at 1.888.592.3798 if you have any questions.

Indications for Use

The µCor™ Heart Failure and Arrhythmia Management System is intended to periodically record, store, and transmit Thoracic Fluid Index. The µCor System is also intended to continuously record and store, and periodically transmit ECG, Heart Rate, Respiration Rate, Activity, and Posture. The data provided can aid medical professionals as they diagnose and identify various clinical conditions, events, and/or trends.

The µCor System is intended for use in clinic and home settings and is indicated for patients who are 21 years of age or older:

i. Who require monitoring for the detection of non-lethal cardiac arrhythmias, such as, but not limited to, atrial fibrillation, atrial flutter, ventricular ectopy, and bradyarrhythmias; or
ii. who require fluid management.

Warnings

- Do not use the µCor™ Heart Failure and Arrhythmia Management System if you have allergies or skin sensitivities to electrode hydrogel and/or acrylic based adhesives. Irritation such as redness or itching may develop.
- Do not use the µCor System if you have skin breakdown in areas where device (Patch + Sensor) placement is required, as this can cause further injury to your skin.
- Do not use the µCor System if you have significant swelling on the left side of your chest where the device is applied. Significant swelling may adversely affect device function.

Precautions

- If you are pregnant, consult with your prescribing physician before using the device.
- Remove the device (Patch + Sensor) from your body prior to a magnetic resonance imaging (MRI) scan. The µCor System is MRI unsafe.
- Remove the device (Patch + Sensor) if any pain or discomfort occurs. If skin irritation, discomfort, redness, itching, or rash persists after the device is removed, contact your physician.

... Precautions continued on next page

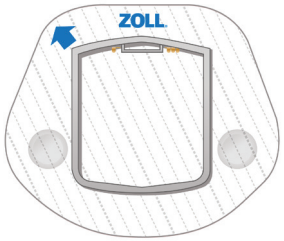
Precautions (continued)

- If you have an implanted pacemaker or defibrillator, do not place the Sensor directly on top of the implanted device. This may cause the Sensor to not perform as intended.
- Do not submerge the Sensor in water by swimming or bathing in a tub. The Sensor is water-resistant, but not waterproof.
- It is okay to wear the Sensor while showering. If wet, dry the Sensor before placing it into the Charger.
- Keep the Charger and Gateway away from water. Water entering the Charger or Gateway may damage the device and/or cause the Charger or Gateway to not perform as intended.
- Connect the Charger to the Power Cord that is provided with the system. Using any other power cord may damage the Charger or result in electrical hazard.
- When using the µCor System, use only cables and accessories provided by ZOLL. Using non-approved cables or accessories may affect device performance.
- Do not change, modify, or disassemble any parts or components of the µCor System. This may cause the µCor System to not perform as intended. The system contains no user-serviceable components. Any changes, modification, or servicing of the µCor System will only be performed by ZOLL.
- The ability of the device to predict fluid balance in patients is variable and should be considered on an individual basis and in conjunction with other available clinical data.

Important Information

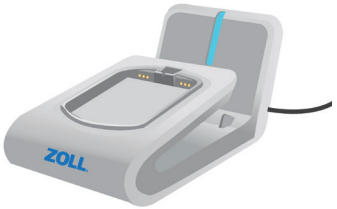
- When traveling by aircraft, patients should remove the Sensor from the Patch and turn off the Gateway while on the plane to prevent interference with aircraft systems.
- Do not place the µCor System on top of, below, or in close proximity to other electronic devices because it could result in improper operation.
- The µCor System is not intended to be an alarm or to alert patients or physicians, and will not summon emergency response in the event help is needed.
- The µCor System is not intended to replace direct communication with healthcare professionals.
- Data provided by the system may be used by healthcare professionals along with all other clinical findings and exams to come to a diagnosis.
- Patients should talk to their prescribing physician immediately if there are any concerns or if their condition changes.
- Do not apply creams or lotions to the skin immediately prior to the application of the Patch. This may result in poor adhesion to the body or may affect measurements.
- Place the Sensor in the Charger when not in use. Doing so will ensure the Sensor is fully charged upon next use.
- Discontinue use and contact ZOLL if the µCor System shows signs of damage or is not working properly.
- Keep the µCor System out of reach of children.

The µCor™ System Components



Patch

Sensor



Charger

Gateway

Power Cord

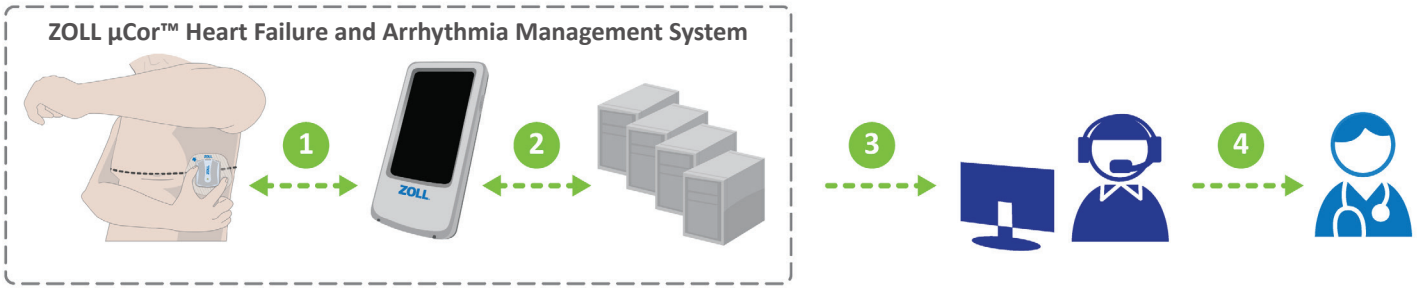
- **Patch** – Disposable, adhesive patch that is applied to your body. It contains a plastic frame that houses the Sensor, and two ECG electrodes on each side of the frame. Patch should not be worn for more than 7 days.
- **Sensor** – Battery powered device that collects your clinical measurements. Sensor connects to Patch via the snap-in clip and positioning tabs.
- **Charger** – Recharges the Sensor and the Gateway.
- **Gateway** – Sends your data from the Sensor to the server for data analysis.
- **Power Cord** – Plugs into a standard power outlet to provide power to the Charger.

How the µCor™ System Works

During your prescription period, the Sensor automatically collects your clinical measurements.

1. Your data, collected by the wearable Sensor, are transmitted via *Bluetooth*® to the Gateway.
2. From the Gateway, your data are then forwarded to the remote server for analysis where your data are viewed by ZOLL. You do not need to configure the system for *Bluetooth*® or cellular connection. ZOLL does this for you.

3-4 ZOLL provides your data report to your prescribing physician.



Data Transmission of the µCor™ System

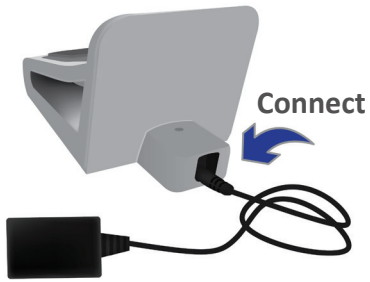
Before You Begin

This section helps you set up and start wearing the µCor™ Heart Failure and Arrhythmia Management System.

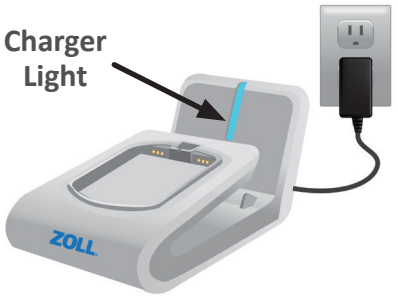
1. Gather all of the µCor™ System components.
2. Make sure none of the components have been damaged during shipping. If a component is damaged, call ZOLL.
3. Follow *Part 2: Getting Started* steps 1 – 6 in this guide.

1 Charge the Sensor: First Use and Every 5 Days

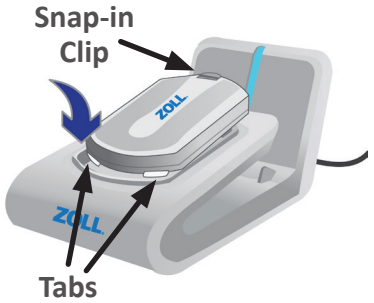
IMPORTANT: Set up Charger in your bedroom or where you sleep.



1. Connect Power Cord to Charger.



2. Connect Charger to a power outlet in your bedroom. A blue light shows when Charger has power.



3. Tilt lower part of Sensor with the tabs on the bottom into Charger. Snap the Sensor clip into place. Sensor light is orange while it charges.

... step **4.** continued on next page →

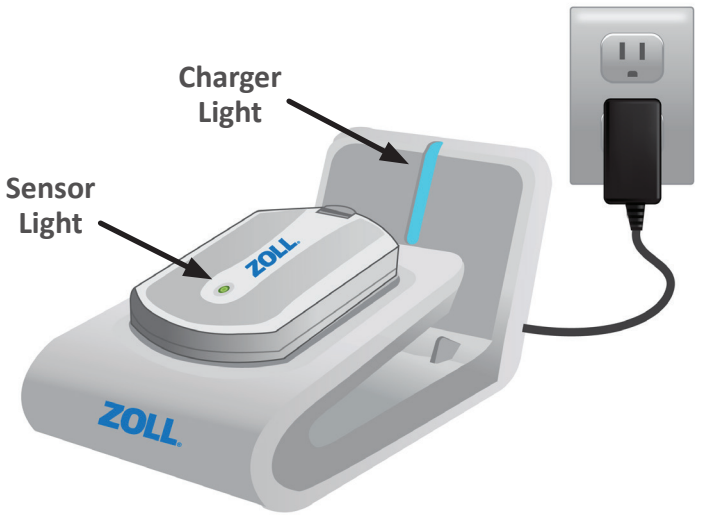
1 Charge the Sensor: First Use and Every 5 Days (continued)

-1h- Sensor charges in about one hour.

4. Sensor is fully charged when the orange light 🟠 changes to green 🟢.

Note:

- Make sure the Sensor is dry before placing into the Charger.
- Place the Sensor in Charger when not on your body. This ensures the Sensor is fully charged upon next use.



Charging the Sensor

Sensor While in Charger: Understanding the Lights

Solid Orange

Sensor is charging and is not full.

Sensor takes about 1 hour to fully charge.

Solid Green

Sensor is fully charged and ready for use.

No Light

When Sensor is out of the Charger, the light turns off.

See **Part 4: Troubleshooting** if there is no light when placed in the Charger.

2 Charge the Gateway: First Use and Every Day

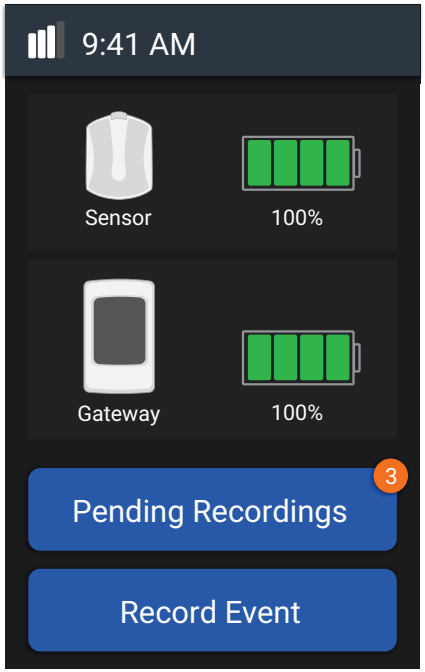
- Charge the Gateway nightly in the Charger. Leave the Gateway on the Charger every night when you sleep. Gateway power can last up to 18 hours before needing to be recharged.
- Once the battery charge is under 20%, a short beeping sound is made every 20 minutes until the battery is depleted or the Gateway is placed in the Charger.
- The Gateway takes about three hours to fully charge.

1. Place Gateway on Charger.

2. The Gateway screen should light up and display a battery status icon with the percent charge.

3. When the Gateway is fully charged, remove it from the Charger.

Understanding the Gateway Interface



Pending Recordings Button

This button only appears if there are patient activated recordings that have not been sent to ZOLL.
See page 25.

Sensor Battery Status
See page 22.

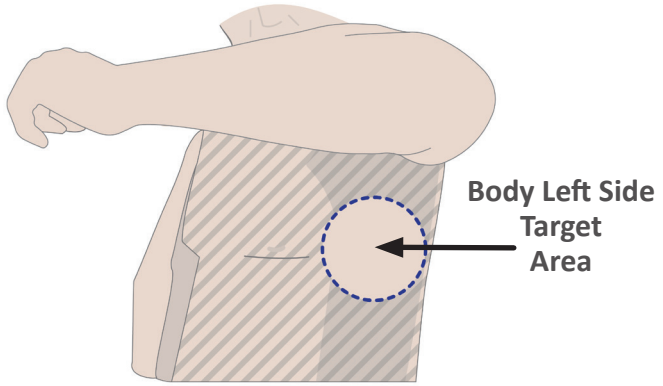
Gateway Battery Status
See page 22.

Number of Pending Recordings
See page 25.

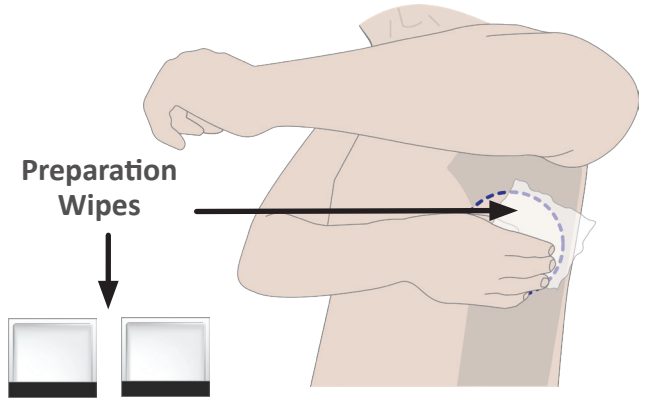
Record Event Button
See page 23.

3 Prepare Your Skin: Every Time You Apply a Patch

IMPORTANT: This step ensures good adhesion to your skin.

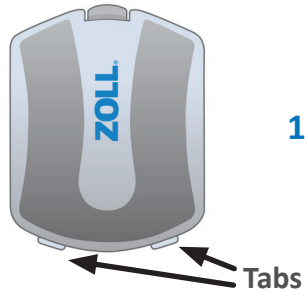


1. Remove all clothing and undergarments from your upper body.
2. Trim hair (if any) on your left side in the Target Area.

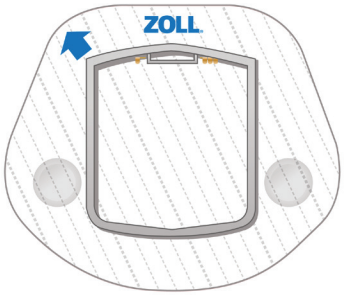


3. Use provided Preparation Wipe to scrub area where Patch is to be applied.
4. Repeat step 3 with a second Preparation Wipe. Allow your skin to dry.

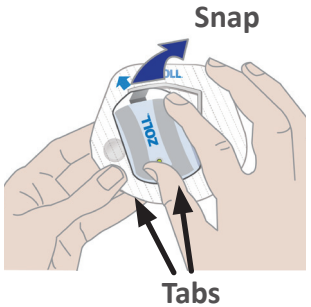
4 Connect Sensor to Patch



1. Hold Sensor so the tabs are on the bottom.

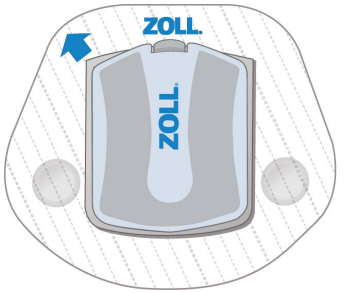


2. Hold Patch so that the ZOLL logo is at the top.



3. Tilt and insert the lower part of Sensor with the tabs into the bottom of Patch frame.

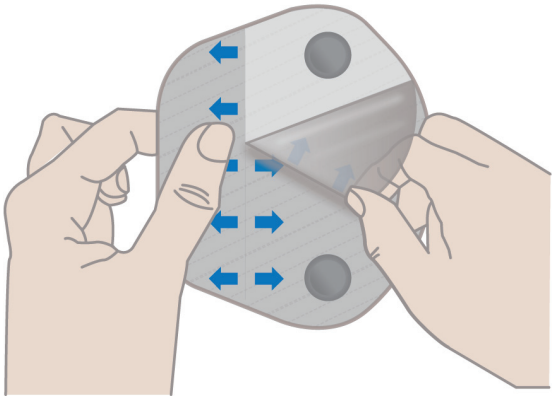
4. Press Sensor onto Patch until you hear/ feel it snap in place.



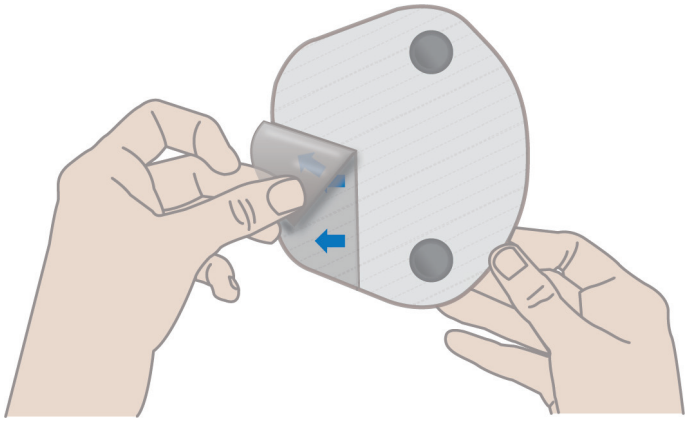
5. Sensor should be firmly attached to Patch.

5 Peel Off Patch Liner — 2 Pieces

The liner on the back of the Patch is cut to create two separate pieces. Be careful to not touch the sticky adhesive.



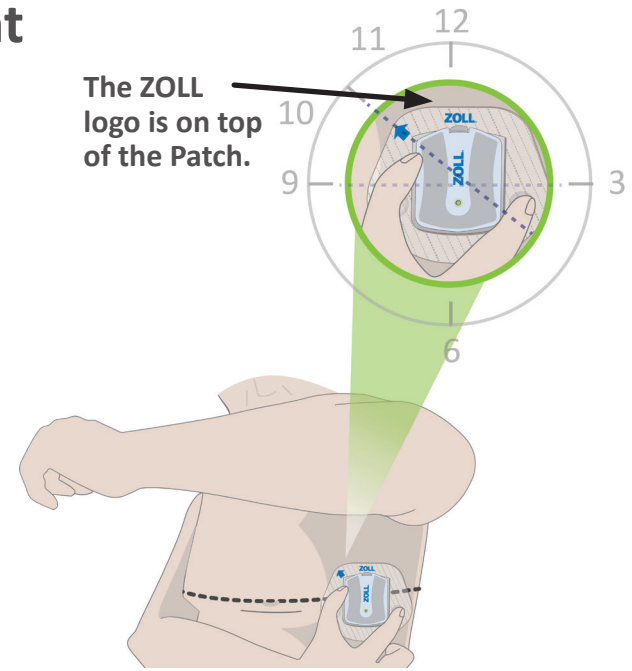
1. Peel off the larger liner piece first.



2. Peel off the smaller liner piece.

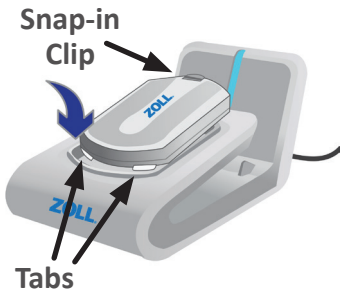
6 Sensor + Patch Body Placement

1. Stand in front of a mirror.
2. Raise your left arm to shoulder height.
3. Place Patch about 2-3 fingers wide below your underarm, so that ZOLL is horizontal on the top of Patch. The arrow ↖ should point between 10 and 11 o'clock. If needed, slightly move the breast aside when applying Patch.
4. Make sure Patch is smooth and flat on your skin.
5. Is the arrow ↖ pointing between 10 and 11 o'clock?
6. If Yes, REMAIN STILL. A green light ● will appear on the Sensor within 30 - 60 seconds, indicating the Sensor is ready to monitor.

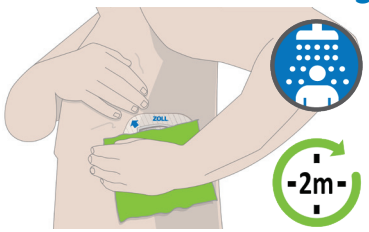


If NO Green Light ● Call ZOLL at 1.888.592.3798.

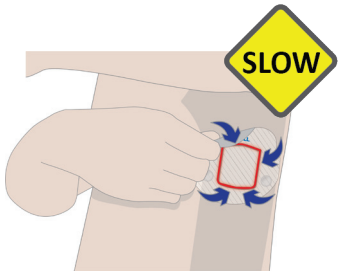
Replace Patch on Your Body: Every 7 Days



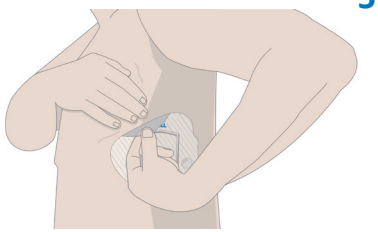
1. Press Sensor snap-in clip and remove Sensor from Patch.
2. Place Sensor in Charger.



3. Hold a warm wet washcloth against the Patch to get it wet for approximately 2 minutes. This may be done in the shower.



4. **Slowly** peel each corner of Patch toward the center until only the area under frame (area outlined in red) remains attached to your body.

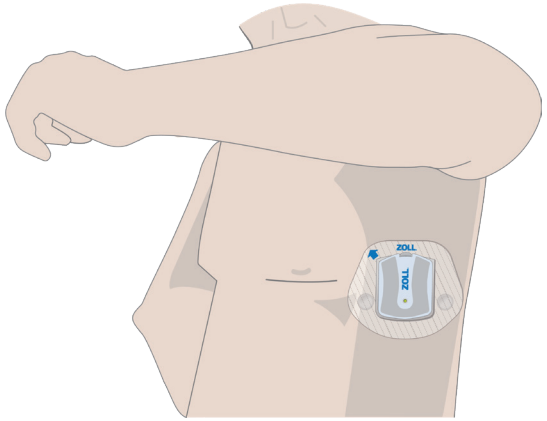


5. **Slowly** peel the remaining Patch while holding the skin against your body as tightly as possible.

... step 6. continued on next page →

Replace Patch on Your Body: Every 7 Days (continued)

6. Discard Patch immediately. Do not reuse.

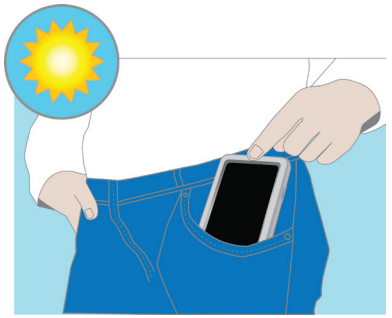


7. Once Sensor is fully charged, repeat steps 3 through 6 starting on page 15 using a *new* Patch. Be sure to apply the *new* Patch as close to location of the previous Patch as possible.

How to Use Gateway

To allow for proper communication and data transfer keep Gateway:

- Turned ON*
- Within 30 feet of the Sensor
- In an area with cellular phone coverage



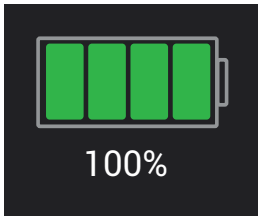
During the day, carry the Gateway with you.

At night, keep the Gateway in the Charger on a table close to you while you sleep.

The Gateway may be turned ON and OFF manually by pressing and holding the Power button for several seconds.

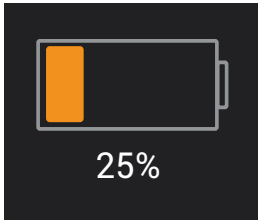
* When boarding an airplane, turn the Gateway OFF to prevent interference with aircraft systems.

Gateway Interface: Understanding the Battery Status for Sensor and Gateway



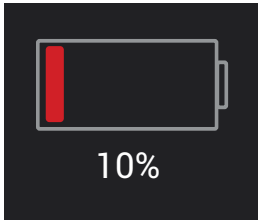
Green

Battery is charged. The number of green bars represents the percent of battery power capacity from 26% to 100%.



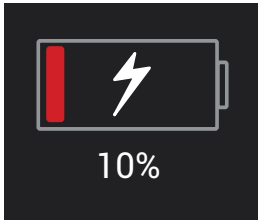
Orange

Battery is at 11% to 25% percent of battery power capacity.



Red

Battery is at 1% to 10% percent of battery power capacity. Place Sensor or Gateway immediately in Charger.

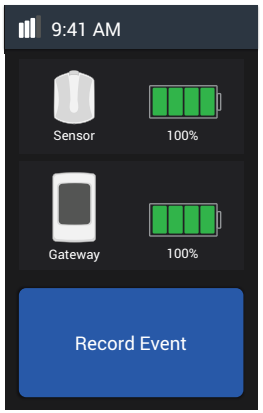


Charging Icon

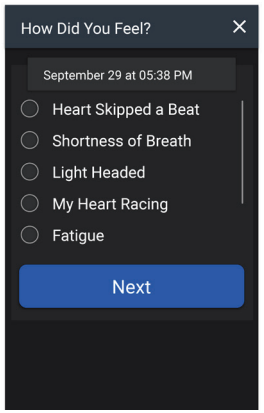
The Gateway or Sensor battery is charging in the Charger.

How to Record a Symptom & Activity Level: From Gateway

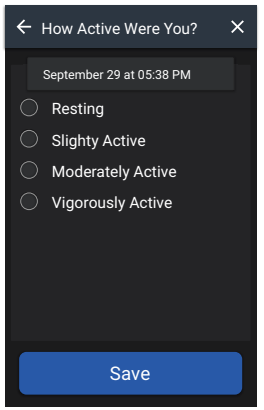
When you experience a symptom, you can use the Gateway as follows to send information to your prescriber for review. Gateway is the **preferred** method for recording a symptomatic event.



1. Select Record Event.



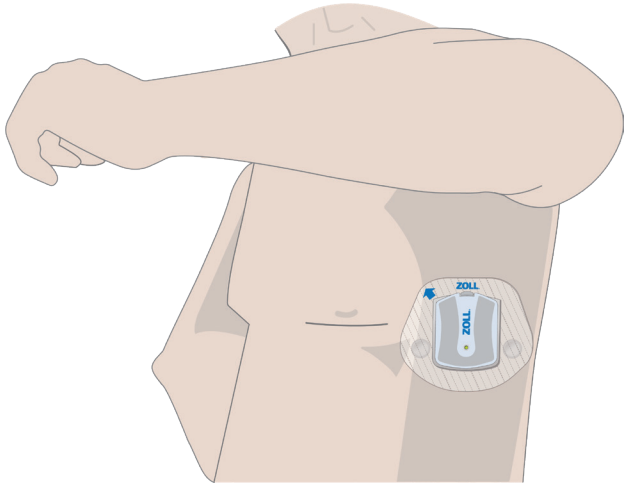
2. Select a symptom that describes how you feel.
3. Select Next.



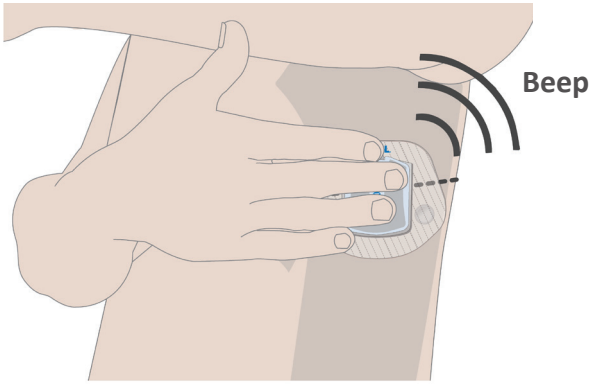
4. Select your activity level.
5. Select Save.

How to Record a Symptom & Activity Level: From Sensor

Using the Gateway is the **preferred** method for recording a symptomatic event. However, you can also activate a recording by double tapping on Sensor when you experience a symptom.



1. Remain still.

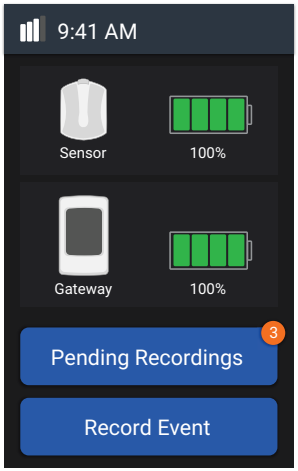


2. Double tap Sensor with the palm of your hand.
3. You will hear a beeping sound indicating that the trigger has been activated.

... step **4.** continued on next page →

How to Record a Symptom & Activity Level: From Sensor (continued)

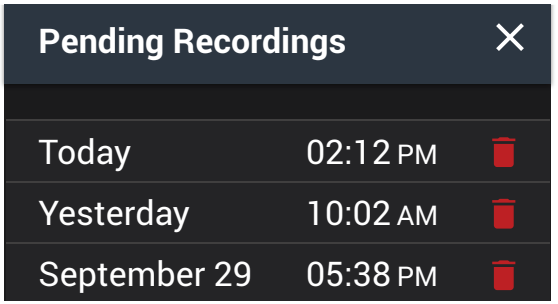
When you initiate a recording by double tapping the Sensor, you can use the Gateway to assign a symptom and activity level for your prescriber to review.



4. Gateway shows the number of your Pending Recordings in the orange circle ●.

Press the Pending Recordings button.

If you are near the Gateway and you do not record a symptom and activity level, your Pending Recordings are automatically sent to ZOLL within one hour. Your recordings will no longer be visible on the Pending Recordings list.



5. Select the Date and Time to record a Symptom and Activity Level.

Note: To delete a Pending Recording select the red trash can 🗑.

6. Repeat steps 2 through 5 from page 23.

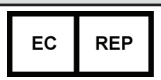
Actions for Potential Issues

The following table lists the recommended actions for potential issues with the µCor System. Call ZOLL if you need assistance with any of these instructions.

POTENTIAL ISSUES	POSSIBLE CAUSES	ACTIONS
Sensor light indicator is not on while sitting in Charger for charging.	Sensor is not sitting properly in Charger.	Remove Sensor from Charger and reinsert into Charger.
	Charger is not connected to a standard power outlet.	Plug Charger into a standard power outlet using the Power Cord provided in the µCor System packaging. When properly connected, the light indicator on the Charger should be blue.
Sensor light is blinking orange  after being applied on the body.	Sensor Error.	Call ZOLL at 1.888.592.3798.
Charger blue light  is not on.	Charger is not connected to a standard power outlet.	Plug Charger into a standard power outlet using the Power Cord provided in the µCor System packaging. When properly connected, the light indicator on the Charger should be blue.
Gateway screen does not indicate Gateway is being charged while sitting in Charger for charging.	Gateway is not sitting properly in Charger.	Remove Gateway from Charger and reinsert into Charger.

Maintenance and Cleaning

You are *not* required to perform any maintenance or clean the µCor System.

Symbol	Title and Designation # of the Standard	Title of Symbol	Symbol Ref #	Explanatory Text
	ANSI/AAMI/ISO 15223-1:2016, Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.	Manufacturer	5.1.1	Device manufacturer and date when the device was made (when relevant).
		Catalog number	5.1.6	Product catalog number.
		Date of manufacture	5.1.3	Date when the device was made.
		Batch code	5.1.5	Batch or lot number for device traceability.
		European representative	5.1.2	European representative.
		Serial number	5.1.7	Serial number for device traceability.
		Use-by date	5.1.4	Date after which the device is not to be used.
		Temperature limit	5.3.7	Storage temperature limits to which the device can be safely exposed.
		Do not re-use	5.4.2	The Patch is single-use only and not to be re-used.

Part 6: Symbols Glossary

Symbol	Title and Designation # of the Standard	Title of Symbol	Symbol Ref #	Explanatory Text
	ANSI/AAMI/ISO 15223-1:2016, Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.	Non-sterile	5.2.7	The device is not sterile.
		Humidity limitation	5.3.8	Humidity limitation.
	ANSI/AAMI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	Refer to instruction manual/booklet	#10 (Table D.2)	See Instructions For Use.
		Type BF applied part	#19 (Table D.1)	Device intended to deliver electrophysiological signal to or from the patient.
		Ingress protection	#2 (Table D.3)	Indicates the Sensor is protected from light dust and against the effects of temporary immersion in water.
IP21		Ingress protection	#2 (Table D.3)	Symbol for ingress protection rating for Charger.
IP22		Ingress protection	#2 (Table D.3)	Symbol for ingress protection rating for Gateway.

Symbol	Title and Designation # of the Standard	Title of Symbol	Symbol Ref #	Explanatory Text
	ANSI/AAMI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	Direct current	#5 (Table D.1)	Direct current.
		Non-ionizing radiation		Emits non-ionizing radiation.
		Wireless connection		Wireless connection.
	ASTM F2503-13, Standard practice for marking medical devices and other items for safety in the magnetic resonance environment.	Magnetic resonance (MR) unsafe	Figure 9	Indicates the device may cause unacceptable risks to the patients, medical staff, or other persons within the MR environment. The device should be removed prior to any MR scanning procedure.

FCC Compliance Statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

a) Reorient or relocate the receiving antenna.

b) Increase the separation between the equipment and receiver.

c) Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.

d) Consult the dealer or an experienced radio/TV technician.

Changes or modifications not expressly approved by the manufacturer could void the user authority to operate the equipment under FCC Rules.

THE MANUFACTURER IS NOT RESPONSIBLE FOR ANY RADIO OR TV INTERFERENCE CAUSED BY UNAUTHORIZED MODIFICATIONS TO THIS EQUIPMENT. SUCH MODIFICATIONS COULD VOID THE USER'S AUTHORITY TO OPERATE THE EQUIPMENT.

Cybersecurity

The µCor System uses the Sensor and Gateway for data transmission. Generally, data is transmitted from the Sensor to the Gateway once per minute via Bluetooth® and is then transmitted from the Gateway to the Server once per minute via cellular network. Communication modes that are not enabled in the µCor System are: Wi-Fi® and USB connection ports. Data is encrypted and firewalls are configured to only allow communication between authorized components of the system. The patient does not need to configure the system, ZOLL does this for the patient. Any installation, maintenance, or decommissioning of software or cybersecurity network environments will only be performed by ZOLL. In the unlikely event a cybersecurity event should occur with the µCor System, ZOLL will communicate the event to users with the appropriate action. If you experience an issue with the µCor System that you suspect is a cybersecurity event, call ZOLL at 1.888.592.3798.

This page intentionally left blank.

If you have any questions, contact ZOLL

24 hours a day, 7 days a week:

Toll free (USA) 1.888.592.3798

ZOLL®

121 Gamma Drive ● Pittsburgh, PA 15238 USA

Rx Only

Distributed by ZOLL Laboratory Services