

μCor™ Heart Failure and Arrhythmia Management System

Patient Instruction Manual

Rx Only

ZOLL®

20B0078 Rev N

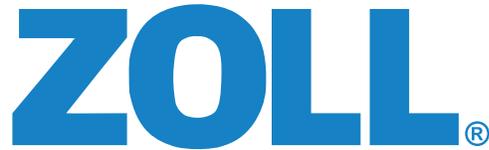
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If you have any questions, contact ZOLL
24 hours a day, 7 days a week:
Toll free (USA) 1.888.592.3798



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Patents: Patent: www.zoll.com/patents

Symbols Glossary: The symbols glossary is located in **Appendix B** of this manual.

Welcome to the ZOLL μ Cor™ Heart Failure and Arrhythmia Management System

The μ Cor™ 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.

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 μ Cor 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 μ Cor™ Heart Failure and Arrhythmia Management System is intended to periodically record, store, and transmit Thoracic Fluid Index. The μ Cor 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 μ Cor 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 μ Cor™ 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 μ Cor 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 μ Cor 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 μ Cor 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)

- 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 μ Cor 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 μ Cor System. This may cause the μ Cor System to not perform as intended. The system contains no user-serviceable components. Any changes, modification, or servicing of the μ Cor 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 μ Cor System on top of, below, or in close proximity to other electronic devices because it could result in improper operation.
- The μ Cor 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 μ Cor 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 μ Cor System shows signs of damage or is not working properly.
- Keep the μ Cor System out of reach of children.

The μ Cor™ System Components



Patch



Sensor



Charger



Gateway



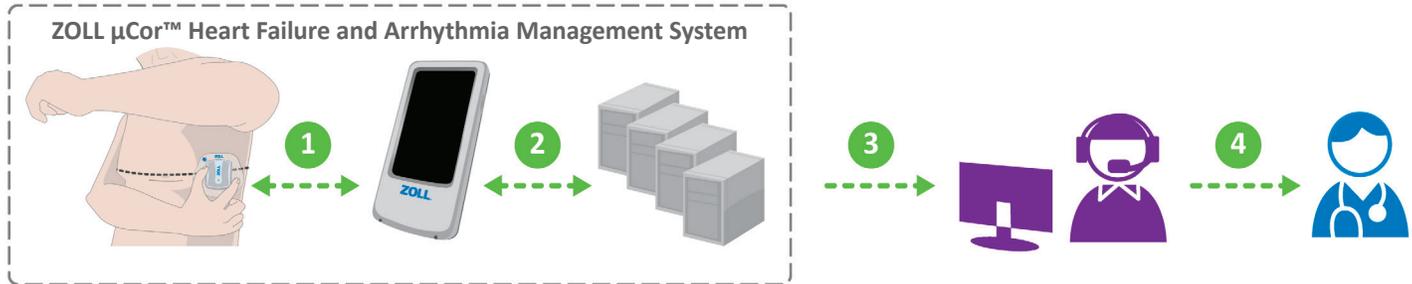
Power Cord

- **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 μ Cor™ 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 μ Cor™ System

Before You Begin

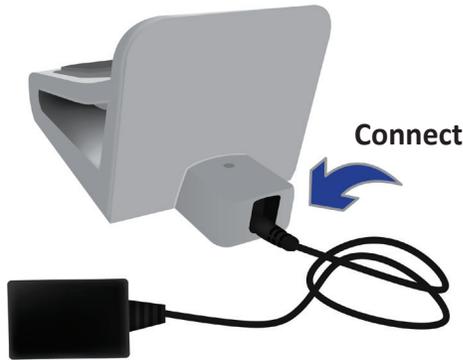
This section helps you set up and start wearing the μ Cor™ Heart Failure and Arrhythmia Management System.

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

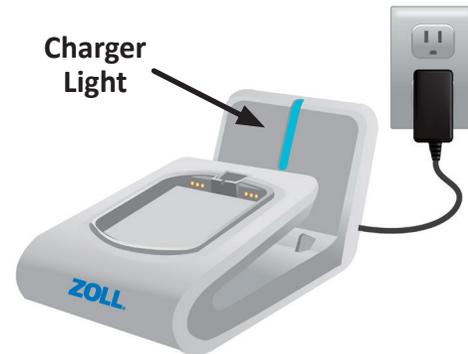
1 Charge the Sensor: **First Use and Every 5 Days**

IMPORTANT

Set up Charger in your bedroom or where you sleep.



1.1 Connect Power Cord to Charger.

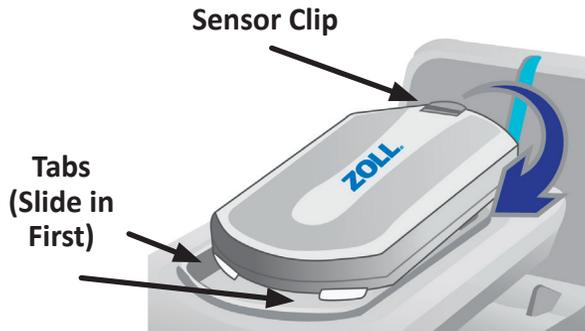


1.2 Connect Charger to a power outlet in your bedroom. A blue light █ shows when Charger has power.

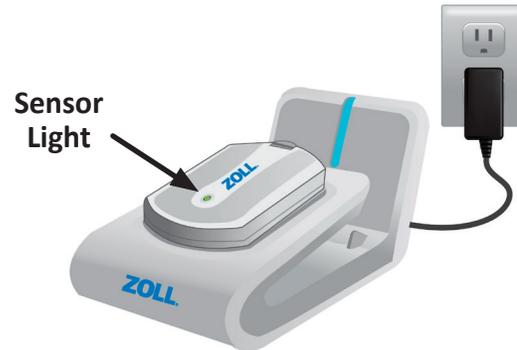
1 Charge the Sensor: **First Use and Every 5 Days** (continued)

IMPORTANT

Sensor charges in about one hour.



1.3 Insert tabs on the bottom part of the Sensor into the Charger. Snap the Sensor clip into place. Sensor light is solid orange ● while it charges.



1.4 Sensor is fully charged when the orange light ● changes to solid green ● .

See "Appendix A: Understanding the System Indicators and User Interface" on page 27 for more information about the Sensor light.

2 Charge the Gateway: **First Use and Every Day**

IMPORTANT



The Gateway takes about three hours to fully charge.

2.1 Place Gateway on Charger.



2.2 The Gateway screen should light up. A charging symbol (lightning bolt) will display over the battery status icon along with the percent charge.

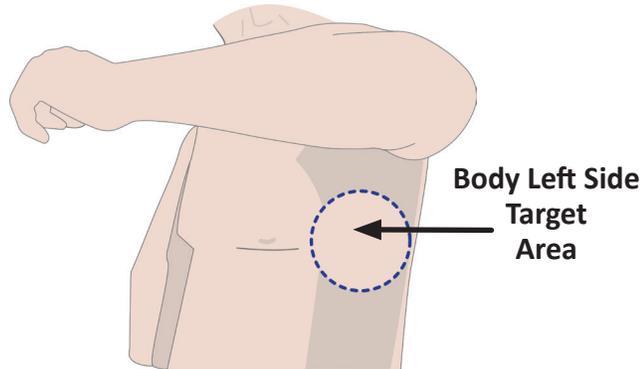
Gateway
Battery
Status Icon



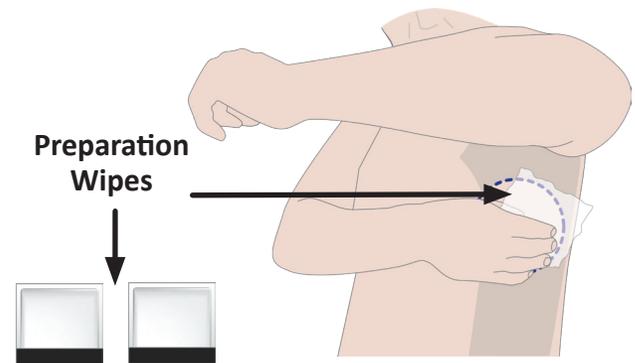
3 Prepare Your Skin: **Every Time You Apply a Patch**

IMPORTANT

This step ensures good adhesion to your skin.

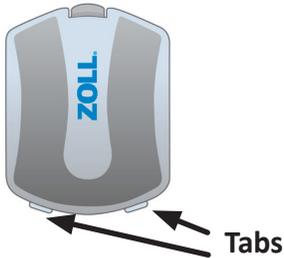


- 3.1** Remove all clothing and undergarments from your upper body.
- 3.2** Trim hair (if any) on your left side in the Target Area.

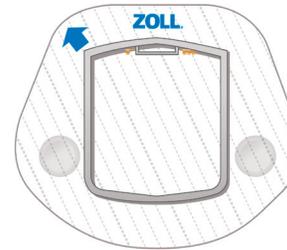


- 3.3** Use provided Preparation Wipe to scrub the left side Target Area.
- 3.4** Repeat step **3.3** with a second Preparation Wipe. Allow your skin to dry.

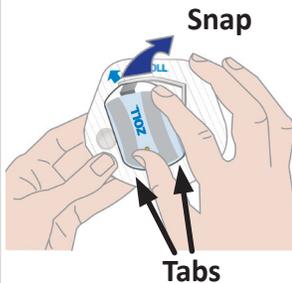
4 Connect Sensor to Patch



4.1 Hold Sensor so the tabs are on the bottom.

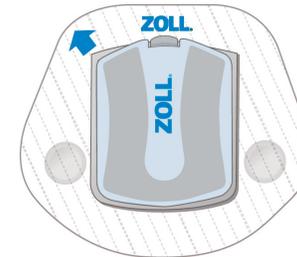


4.2 Hold Patch so that the ZOLL logo is at the top.



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

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

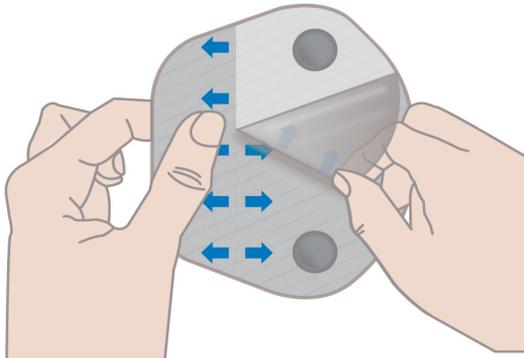


4.5 Sensor should be firmly attached to Patch.

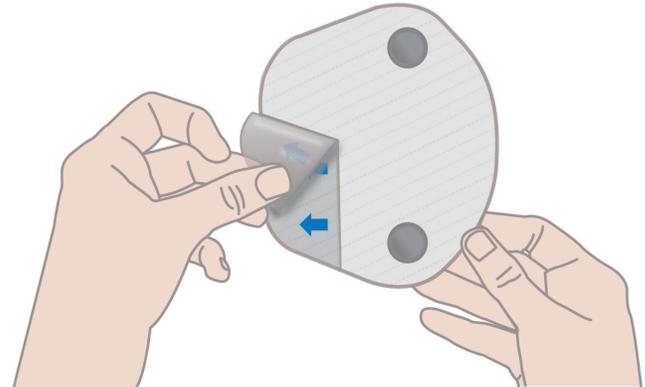
5 Peel Off Patch Liner — 2 Pieces

IMPORTANT

The back liner of the Patch is cut between the rows of blue arrows. Try not to touch the sticky adhesive.



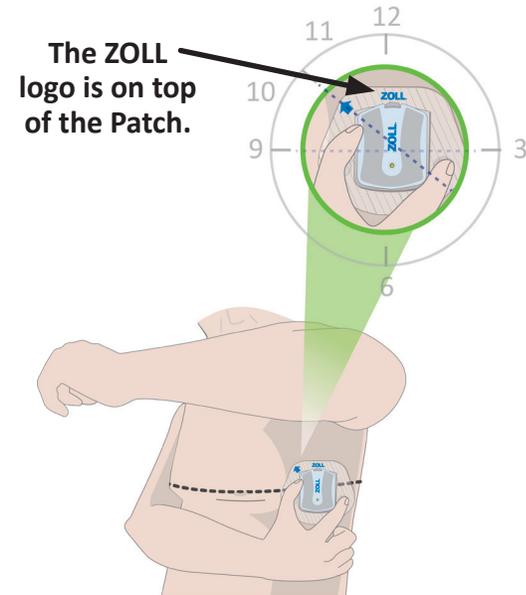
5.1 Peel off the larger liner piece first.



5.2 Peel off the smaller liner piece.

6 Sensor + Patch Body Placement

- 6.1 Stand in front of a mirror.
- 6.2 Raise your left arm to shoulder height.
- 6.3 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.
- 6.4 Make sure Patch is smooth and flat on your skin.
- 6.5 Is the arrow  pointing between 10 and 11 o'clock?
- 6.6 If Yes, REMAIN STILL. Within 30 - 60 seconds, the Sensor light temporarily turns green , indicating that the Sensor is ready to monitor.

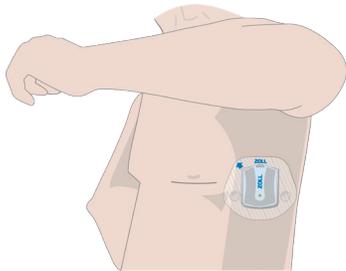


If NO Green Light  Call ZOLL at 1.888.592.3798.

See "Troubleshooting" on page 23-25 for more information.

Every Day

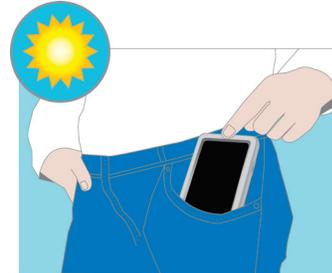
Wear the Sensor



Wear the Patch with the Sensor at all times, even in the shower and when sleeping.

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

Carry the Gateway



Carry the Gateway, keeping it within 30 feet of the Sensor.

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

Every Night

Charge Gateway



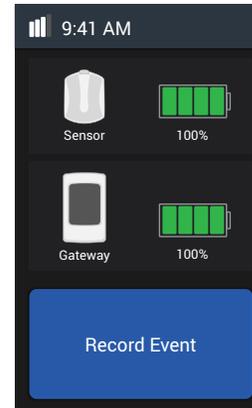
At night, keep the Gateway in the Charger on a table close to you while you sleep. *See “Charge the Gateway” on page 12.*

Gateway power can last up to 18 hours.

Once 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.

As Needed

Record a Symptom



If you feel a symptom, use the Record Event button on your Gateway to send information from your Sensor for review. *See “How to Record a Symptom & Activity Level: From Gateway” on page 20.*

Every 5 Days

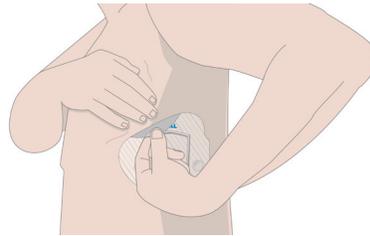
Charge the Sensor



Charge the Sensor every 5 days. See *“Charge the Sensor”* on page 10-11.

Every 7 Days

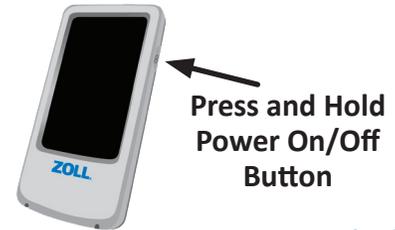
Replace the Patch



Replace the Patch on your body every 7 days. See *“Replace Patch on Your Body”* on pages 21-22.

If You Travel

Turn Off & Store System



Press and Hold
Power On/Off
Button

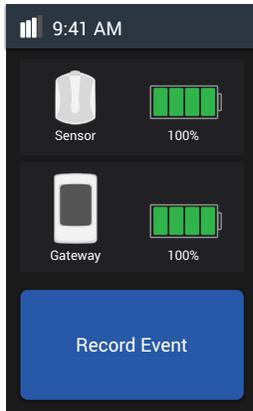
When boarding an airplane:



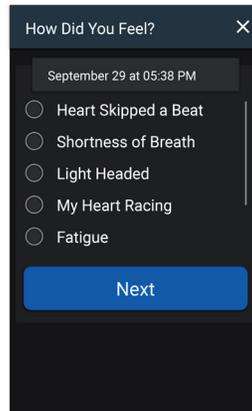
1. Remove Sensor from the Patch.
2. Turn the Gateway OFF to prevent interference with aircraft systems. Press and hold the Power button until the power menu appears. Then press .

How to Record a Symptom & Activity Level: From Gateway

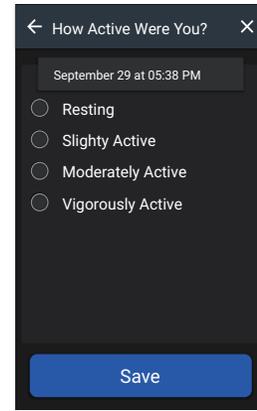
When you experience a symptom, you can use the Gateway as follows to send information to your prescriber for review.



1. Select Record Event.

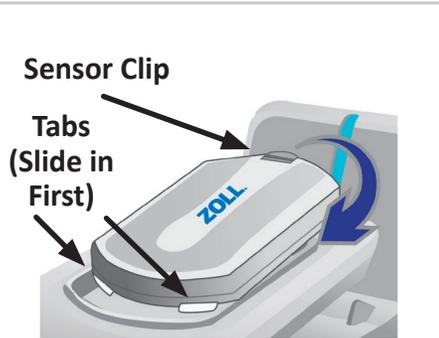


2. Select a symptom that describes how you feel.
3. Select Next.



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

Replace Patch on Your Body: **Every 7 Days**

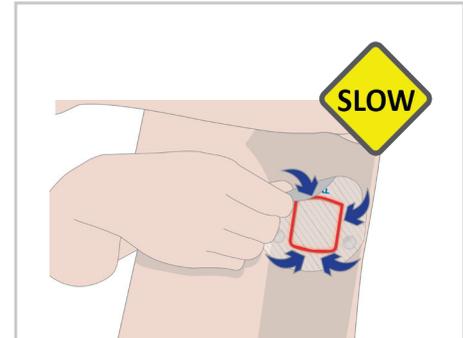


1. Press Sensor clip and remove Sensor from Patch on your body.

2. Insert tabs on the bottom part of the Sensor into the Charger. Snap the Sensor clip into place.



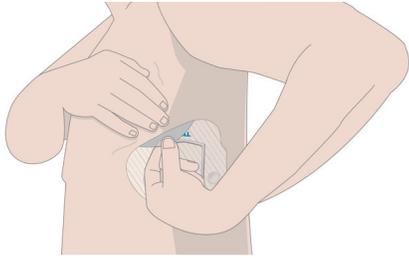
3. Hold a warm wet washcloth against the Patch to get it wet for approximately 2 minutes. This may be done in the shower.



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

... step **5.** continued on next page →

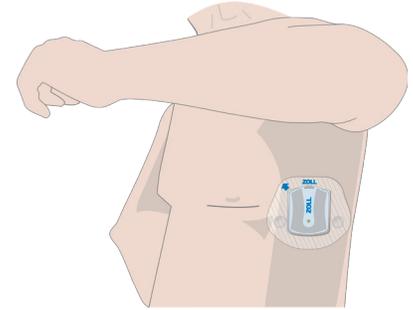
Replace Patch on Your Body: **Every 7 Days** (continued)



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



- 6.** Discard Patch immediately. Do not reuse.



- 7.** Once Sensor is fully charged, repeat steps **3** through **6** starting on page 13 using a **new** Patch. Be sure to apply the **new** Patch as close to the location of the previous Patch as possible.

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

Charging the Sensor

POTENTIAL ISSUES	POSSIBLE CAUSES	ACTIONS
Charger blue  light does not appear.	The supplied Power Cord is not properly inserted.	Make sure the Power Cord provided in the uCor System packaging is fully connected to the Charger. Make sure the Power Cord is connected to a known working standard power outlet.
	Charger is not connected to a standard power outlet.	Plug the Charger into a standard power outlet using the Power Cord provided in the uCor System packaging.
Sensor light does not turn on when Sensor is placed in the Charger.	Sensor is not properly connected to the Charger.	Remove Sensor from Charger. Reinsert the Sensor into the Charger, see Step 1.3 on page 11. The Sensor should charge within 1 hour. If Sensor does not charge call ZOLL at 1.888.592.3798.
	Charger is not connected to a standard power outlet.	Plug the Charger into a standard power outlet using the Power Cord provided in the uCor System packaging. When properly connected, the Charger light should be blue  . If the Charger light is not blue  call ZOLL at 1.888.592.3798.

Charging the Gateway

POTENTIAL ISSUES	POSSIBLE CAUSES	ACTIONS
Gateway does not seem to be charging when placed in the Charger. The Charging indicator (lightning bolt) does not appear when Gateway is placed in Charger.	Gateway is not properly sitting in the Charger.	Remove Gateway from Charger. Reinsert the Gateway in the Charger, see Step 2 on page 12. The Gateway should charge within 3 hours. If Gateway does not charge call ZOLL at 1.888.592.3798.
	Charger is not connected to a standard power outlet.	Plug the Charger into a standard power outlet using the Power Cord provided in the uCor System packaging. When properly connected, the Charger light should be blue  . If the Charger light is not blue  call ZOLL at 1.888.592.3798.

Placing the Sensor + Patch on your Body

POTENTIAL ISSUES	POSSIBLE CAUSES	ACTIONS
Sensor light is not temporarily green  after placing the Patch on your body.	Sensor is not charged.	Remove Sensor from Patch and insert into the Charger to charge, see Step 1.3 on page 11. The Sensor should charge within 1 hour. Connect Sensor in Patch. Look for the Sensor light to temporarily appear green  . If Sensor does not charge call ZOLL at 1.888.592.3798.

Placing the Sensor + Patch on your Body (continued)

POTENTIAL ISSUES	POSSIBLE CAUSES	ACTIONS
Sensor light is not temporarily green ● after placing the Patch on your body.	Sensor is not properly installed into the Patch.	Remove Sensor from Patch and place in Charger for at least two minutes, following Step 1.3 on page 11. Connect Sensor in Patch. Look for the Sensor light to temporarily appear green ●.
	Patch is not fully attached to your body.	Make sure all of the Patch on your body is smoothly attached to your skin. If large wrinkles or gaps exist under the Patch, remove the Patch from your skin and discard it. Place the Sensor back into the Charger. Then, follow Steps 4 through 6 pages 14-16 using a new Patch. Look for the Sensor light to temporarily appear green ●.
	Sensor has timed out. Note: When removed from Charger and placed in Patch, the Sensor turns off after about three minutes if you have not placed the Patch on your body.	Remove Sensor from Patch and place in Charger for at least two minutes, following Step 1.3 on page 11. Connect Sensor in Patch. Look for the Sensor light to temporarily appear green ●.
Sensor light is blinking orange ● after being applied on the body.	Sensor did not fully attach to transmit data.	Call ZOLL at 1.888.592.3798.

Maintenance and Cleaning

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

Appendix A: Understanding the System Indicators and User Interface



Solid Orange

While in Charger: Sensor is charging and is not full.

See "Troubleshooting" on page 25 if the light is blinking orange when placed on your body.



Sensor takes about 1 hour to fully charge.



Solid Green

While in Charger: Sensor is fully charged and ready for use.

When placed on body after charging: Sensor is ready to monitor.

See page 11 for more information.



No Light

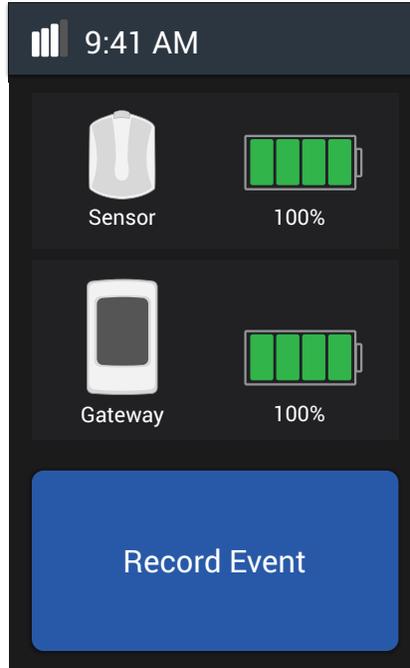
When Sensor is out of the Charger, the light turns off.

See "Troubleshooting" on page 23-25 if there is no light when placed in the Charger or on your body.

Gateway: Understanding the Interface

Cellular Signal

This icon shows the cellular signal strength.

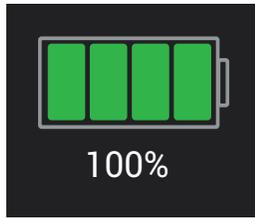


Sensor Battery Status
[See page 29.](#)

Gateway Battery Status
[See page 29.](#)

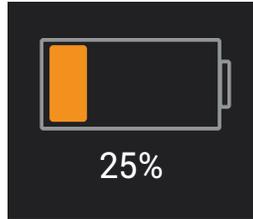
Record Event Button
[See page 20.](#)

Gateway Interface: Understanding the Battery Status for Sensor and Gateway



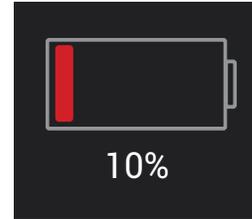
Green

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



Orange

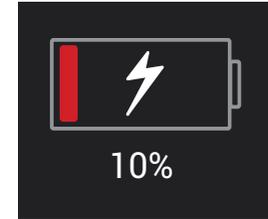
Battery is at 11% to 25% of battery power capacity.



Red

Battery is at 1% to 10% of battery power capacity.

Place Sensor or Gateway immediately in Charger.



Charging Icon

The lightning bolt displays over the battery symbol when the Gateway or Sensor is connected to the Charger.

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.

Appendix B: 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 μ Cor 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 μ Cor 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 μ Cor System, ZOLL will communicate the event to users with the appropriate action. If you experience an issue with the μ Cor System that you suspect is a cybersecurity event, call ZOLL at 1.888.592.3798.

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If you have any questions, contact ZOLL
24 hours a day, 7 days a week:
Toll free (USA) 1.888.592.3798

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