Instructions for Use

CMCT Monitoring System

Rx Only

ZOLL

CMCT Monitoring System Instructions for Use

PLEASE READ THIS ENTIRE INSTRUCTIONS FOR USE BEFORE OPERATING THE CMCT SYSTEM

For assistance with the µCor 3.0 System, please contact **ZOLL** at:

121 Gamma Drive
Pittsburgh, PA 15238 USA
Phone toll free (USA) 1.888.592.3798

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

Symbols Glossary
The symbols glossary is located in Section 9 of this Instructions for Use

User Guide RA-72-002-034-ENG

Version 1 · March 2017

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Part I: General Information

1 INTRODUCTION

The CMCT System is a wearable, wireless system that is used to aid clinicians in the diagnosis and identification of various clinical conditions, events and/or trends. It consists of the CMCT wearable Sensor and Patch, a portable data transmission device (Gateway), and a Charger. The Sensor unit continuously records and transmits ECG data to the data transmission device, and from there to the ZOLL monitoring center. Other physiological parameters such as thoracic impedance, heart rate, respiration rate, activity and posture are recorded periodically and are also transmitted, via the data transmission device to the monitoring center. Certified technicians at the ZOLL Monitoring Center review received data and prepare clinical reports to the prescribing physician. The CMCT System is designed for use in outpatient clinic and home settings for up to 30 days.

2 INDICATIONS FOR USE

The CMCT System is intended to continuously record, store, and transmit ECG, Heart Rate, Activity, and Posture to medical professionals. The CMCT System also periodically records, stores, and transmits Respiration Rate and Thoracic Impedance to medical professionals.

The CMCT System 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, supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, paroxysmal SVTs), ventricular ectopy, bradyarrhythmias and conduction disorders

ii. with fluid-management problems;

iii. taking diuretic medication;

iv. living with heart failure;

v. living with end-stage renal disease;

vi. recovering from a coronary artery disease-related event; and/or suffering from recurrent dehydration.

3 WARNINGS AND PRECATIONS

- Do not use the CMCT System if you:
  - Have allergies or skin sensitivities to electrode hydrogel and/or acrylic based adhesives.
  - Are pregnant (the CMCT System has not been tested on pregnant women).
  - Have skin breakdown in areas where device (Patch + Sensor) placement is required.
- The CMCT 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 CMCT System is not intended to replace direct communication with healthcare providers.
- Data provided by the system should be used by physicians along with all other clinical findings and exams to come to a diagnosis.
- Patients should talk to their healthcare provider immediately if there are any concerns or if their condition changes.
- Remove the device (Patch + Sensor) from your body prior to an MRI scan, or any emergency medical procedure. The CMCT System is not compatible for use with MRI machines.
- If you have an implanted pacemaker or defibrillator, do not place the Sensor directly on top of the implanted device. Consult with your physician about the correct placement of the device for you.
- Sensor and Data Transmission Device must be turned OFF prior to boarding an airplane. Remove Sensor from Patch and call ZOLL for further instructions.
- Do not wear the Patch for more than 5 days. Replace the Patch every 3 days, or more frequently when needed. The Patch is designed for a maximum of 5 days use only.
- No creams of lotions should be applied to the skin immediately prior to the application of the Patch.
- Do not re-use the Patch. Once the Patch is peeled off or removed, discard immediately. The Patch is designed for single use. Re-using the Patch may result in poor adhesion to the body and may affect measurements.
- 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, a topical,

anti-inflammatory cream may be applied (in consultation with your health care provider).

- Do not submerge the Sensor in water by swimming or sitting in a tub. The Sensor is water-resistant, but not waterproof. Wearing the Sensor while showering is okay.
- Keep the Charger and Data Transmission Device away from water.
- The power adapter connector should not be touched or manipulated when the Power Adapter is connected to the supply mains.
- Do not change, modify, or disassemble any parts or components of the CMCT System. The system contains no user-serviceable components. Any changes, modification, or servicing of the CMCT System will only be performed by ZOLL.
- Connect the Charger to the AC adapter that is provided with the system in the original packaging. Using any other AC adapter may damage the Charger and may have electric hazards.
- Place the Sensor in the Charger when not in use.
- When using the µCor 3.0 System, use only cables and accessories provided by ZOLL. Using non-approved cables and accessories may affect the EMC performance
- Do not stack the µCor 3.0 system with other devices or equipment.
- Discontinue use and contact ZOLL if the CMCT System shows signs of damage or is not working correctly.
- Keep the CMCT System out of reach of children.

4 DETAILED DESCRIPTON OF THE CMCT SYSTEM

4.1 SYSTEM COMPONENTS

The CMCT System consists of the following components:

- Patch
- Sensor
- Charger
- Data transmission device (Gateway)
- Server

Each component will be further described within this Section.

4.2 HOW CMCT SYSTEM WORKS

Once activated, the wearable Sensor automatically acquires ECG, thoracic impedance, Heart Rate, Respiration Rate, Activity, and Posture measurements. Patients can also activate a patient trigger when they experience symptoms by double tapping the Sensor when it is on the body. Data are automatically transmitted from the Sensor to the Data transmission device, and from there to the Server for analysis. Certified technicians at the Monitoring Center review the data generated by the Server and prepare reports according to the pre-defined criteria as requested by the prescribing physician. Data provided in the report will aid the prescribing physicians in the diagnosis and identification of various clinical conditions, events and/or trends. The CMCT System is designed for use in outpatient clinic and home settings.

4.3 PRESCRIPTION DURATION AND MEASUREMENT SCHEDULING

The CMCT System is intended for up to 30 days of monitoring.

During the prescription period, the Sensor will automatically acquire your clinical measurements. As described previously, data acquired by the body-worn Sensor will be transmitted wirelessly to the data transmission device, which will then be forwarded to the remote Server for data analysis, and subsequently to the Monitoring Center for review and report generation. See **Figure 1** for a graphical illustration of the data transmission.

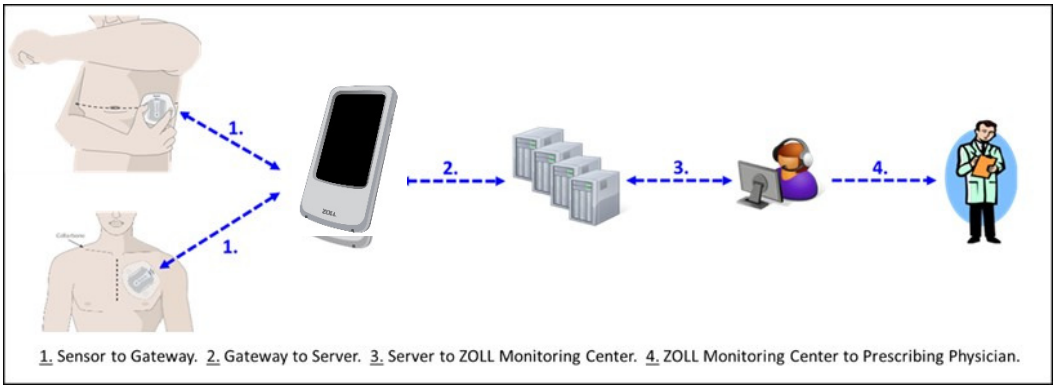


Figure 1: Data transmission of the CMCT System

4.4 PATCH

The Patch (as shown in **Figure 2**) consists of a plastic frame intended for housing the Sensor, and two ECG electrodes on each side of the frame. It is applied to your body.

The Patch is a single-use disposable item. As described in the General Warnings and Precaution Section, it should not be worn for more than 3 days. At the end of 3 days, it should be replaced with a new Patch.

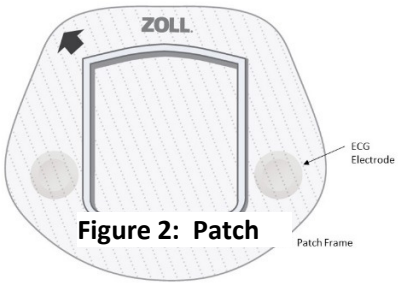


Figure 2: Patch

4.5 SENSOR

The Sensor (as shown in **Figure 3**) is a battery powered unit that acquires your measurements. The Sensor connects to the Patch via the snap-in clip and positioning tabs. Through the adhesive backing on the Patch, the device becomes wearable.

The Sensor is not disposable and needs to be returned to ZOLL upon the completion of the prescription.

As shown in **Figure 3**, a light indicator is located close to the center and serves to communicate the Sensor's status at different points of use. Note that the light indicator is visible only when lit.

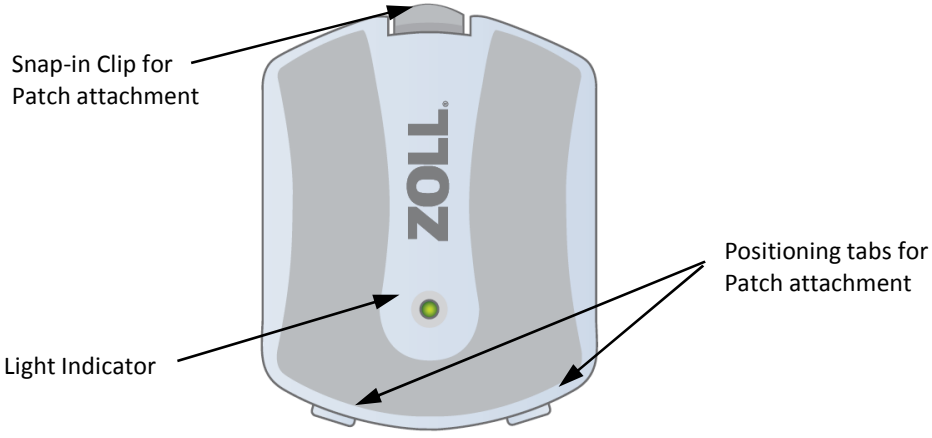


Figure 3: Sensor

4.6 CHARGER

A dedicated Charger (as shown in **Figure 4**) is supplied with the CMCT System for recharging the Sensor and the Data Transmission Device. A blue light appears when the Charger is connected to an AC outlet.

Figure 4: Charger

4.7 DATA TRANSMISSION DEVICE (GATEWAY)

A Data Transmission Device or Gateway is responsible for sending data from the Sensor to the Server for data analysis. When the screen display is on, the gateway battery status is visible on the screen. Once the battery status is under a certain level, a short beeping sound will be made every few minutes until the battery is depleted or the Gateway is placed in the Charger. Make sure you charge the gateway daily.

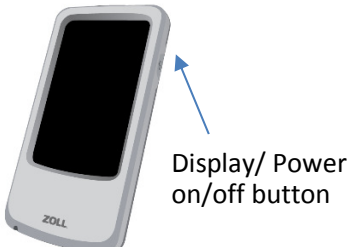


Figure 5: Gateway

4.8 SERVER

The Server refers to the hardware and the processing software and resides in a remote cyber-secure location. The software analyzes the data recevied from the Sensor via the Gateway and processes the data into clinical values for presentation to your healthcare provider after review by certified technicians at the Monitoring Center.

4.9 DEVICE (SENSOR + PATCH) PLACEMENT LOCATION

There are two locations for device (Sensor + Patch) placement: (1) below left armpit (side location); and (2) upper left chest (front location). See **Figure 6**.

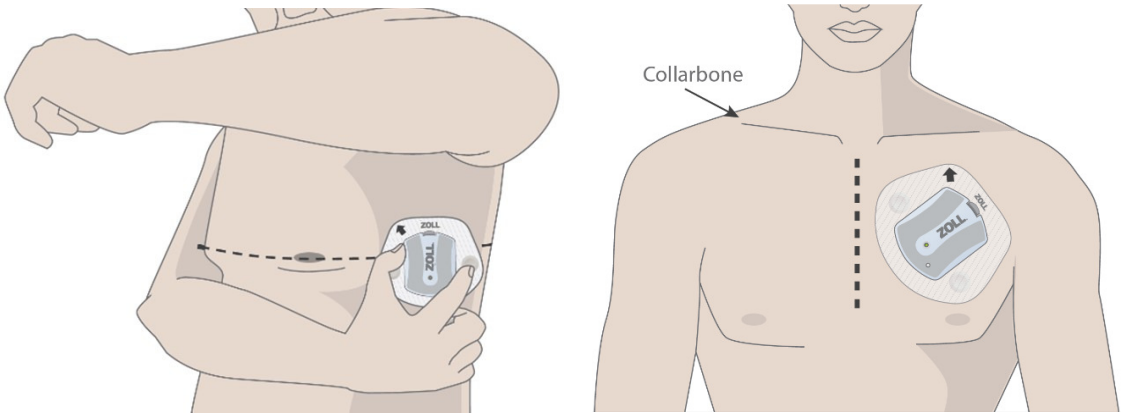


Figure 6: Device (Sensor + Patch) placement location

5 DIRECTIONS FOR USE

5.1 GETTING STARTED

5.1.1 LOCATE THE COMPONENTS OF THE CMCT SYSTEM:

1. Patch in Envelope
2. Sensor
3. Charger
4. Gateway
5. Power Cord (or AC Adapter)
6. Preparation Wipes

See **Figure 7**.

5.1.2 CHARGING THE SENSOR – FIRST USE AND EVERY 3 DAYS

IMPORTANT: Set up Charger in bedroom or room where you sleep. This allows device to send data to ZOLL at least once a day.

1. Connect the Charger to a power outlet in your **bedroom**. A Blue light on the Charger means the Charger has power.
1. Place the Sensor on the Charger. Wait for a solid green light ● to appear on the Sensor, this means it is fully charged and ready for use. Once removed from the Charger, the green light will disappear.
2. The Sensor, typically, takes about one hour to charge.

See **Figure 8**.

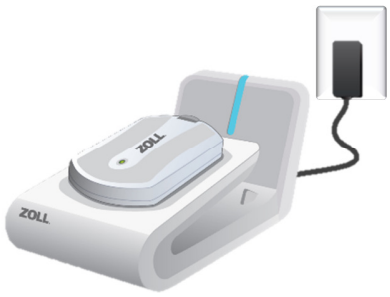


Figure 8: Charging the Sensor

5.1.3 CHARGING THE GATEWAY – FIRST USE AND EVERY DAY

1. Place the Gateway on the Charger in its designated area.
2. The Gateway screen should light up and display it is being charged. Once removed from the Charger, the Gateway screen will display battery status in percent.
3. The Gateway, typically, takes about three hours to charge.

See Figure **9**.

Figure 9: Charging the Gateway

5.2 PREPARING THE SKIN

IMPORTANT: This step ensures good adhesion to skin.

1. Remove your bra/ undershirt.
2. If hair is present, trim hair at the Patch location indicated by your physician. See images below.
3. Use provided Prep Wipes to clean area where Patch will be applied and allow skin to dry.

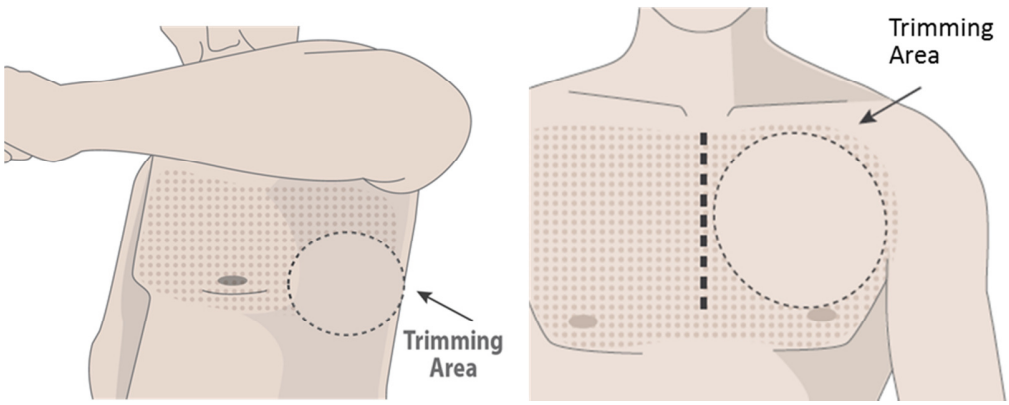


Figure 10: Trimming area

5.3 CONNECTING THE SENSOR TO THE PATCH

1. Remove the Sensor from the Charger.
2. Hold the Patch so that the word “ZOLL” on the Patch is right-side up.
3. Place the lower tabs of the Sensor on the lower part of the Patch frame.
4. Press the rest of the Sensor onto the Patch until you hear a snap. The Sensor should be firmly attached to the Patch.

See **Figure 11**.

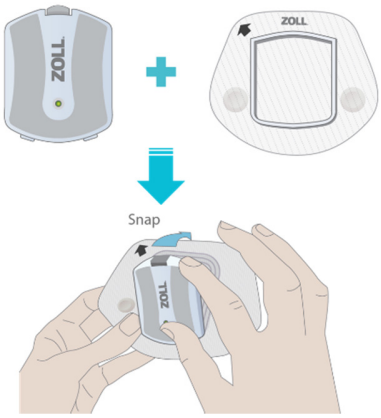


Figure 11: Sensor Patch attachment

5.4 APPLYING THE DEVICE

The device can be applied to either of the two locations detailed below. Once you wear the device in one location, you will continue to wear the device at the same location for the entire duration of your prescription.

5.4.1 LEFT-SIDE LOCATION

1. Stand in front of a mirror.
2. Remove both parts of the Patch liner.
3. Turn the Patch so that the word “ZOLL” on the Patch is at the top.
4. Raise the left arm to shoulder height.
5. If needed, slightly move the breast aside when applying the Patch.
6. Place the Patch below the left arm pit with the nipple aligned anywhere between the top and middle of the Sensor. See **Figure 12**.
7. Ensure the Patch is completely adhered to the skin.

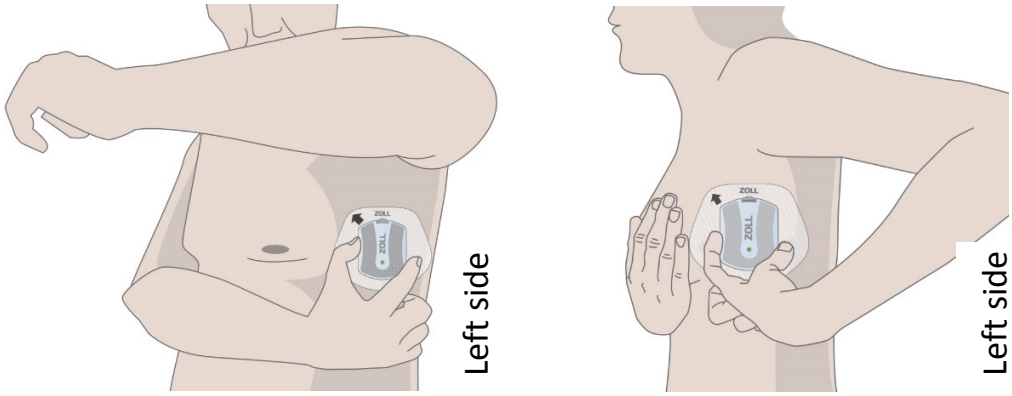


Figure 52: Device (Sensor + Patch) applied to left-side location

8. Stay still and wait for a green light to appear on the Sensor, which signals it is ready to monitor (refer to **Section 6** Trouble Shooting if a blinking amber light appears instead). Note that the green light will last for several seconds, after which the light indicator will remain off. **Figure 13** illustrates examples of incorrect device placements for the side locations.

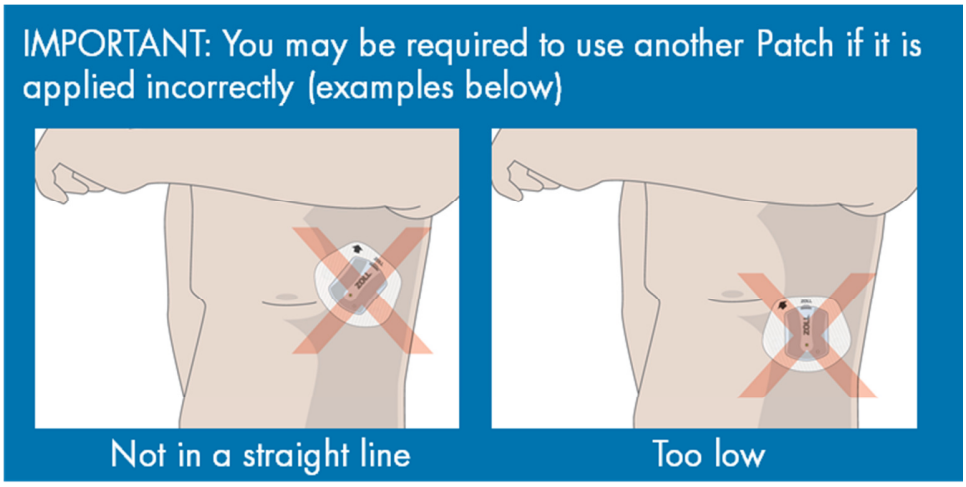


Figure 63: Side location incorrect placement

5.4.2 CHEST LOCATION

1. Stand in front of a mirror.
2. Remove both parts of the Patch liner.
3. Position the Patch on the upper left chest, just below the collarbone, and angle the device towards the nipple. The arrow on the Patch should point up (↑). See **Figure 14**.

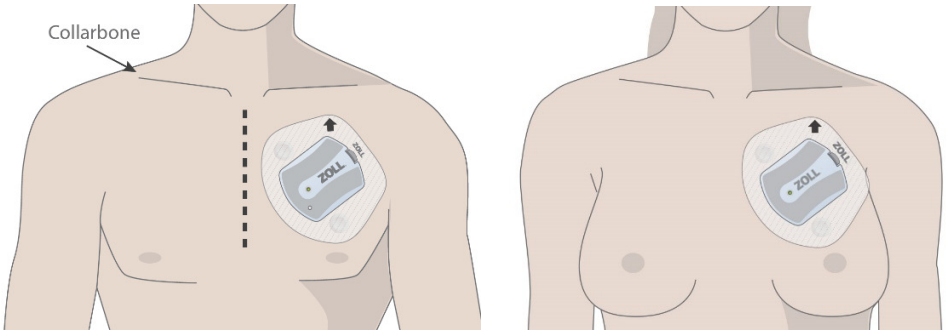


Figure 74: Device (Sensor + Patch) applied to front

4. Ensure the Patch is completely adhered to the skin.
5. Stay still and wait for a green light to appear on the Sensor, which signals it is ready to monitor (refer to **Section 6** Troubleshooting if a blinking amber light appears instead). Note that the green light will last for several seconds, after which the light indicator will remain off.
6. **Figure 15** illustrates examples of incorrect device placements for the front location.

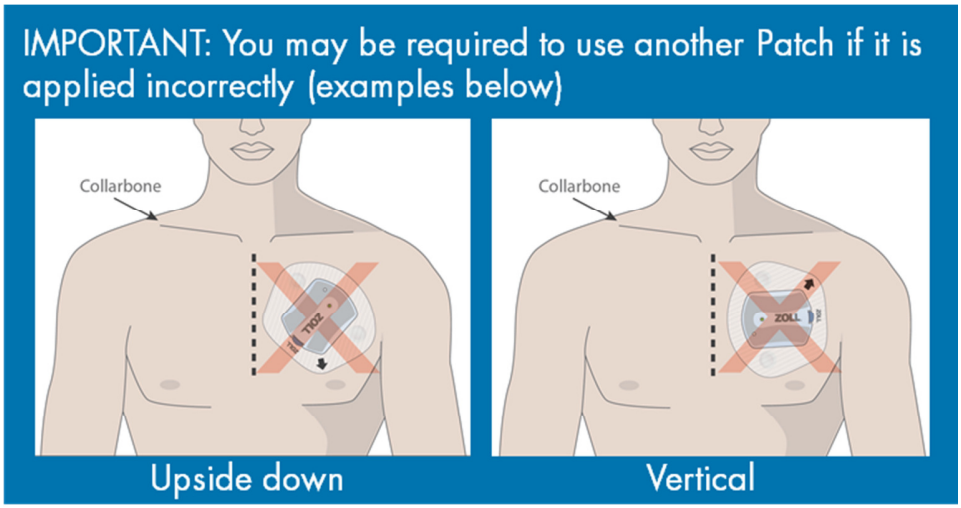


Figure 8: Chest location incorrect placement

5.5 HOW TO USE THE GATEWAY

1. Make sure to keep the Gateway not more that 10 meters away from the body at all times to allow proper communication with the Sensor.
    - During the day, carry the Gateway with you
2. At night, keep the Gateway on a nightstand close to you while you sleep
3. The Gateway may be turned ON and OFF manually by pressing and holding the Power button for several seconds.

Figure 96: Gateway Charging

    - When boarding an airplane, make sure to turn the Gateway OFF to prevent interference with aircraft systems.
    - Otherwise, please keep the Gateway ON at all times to allow proper communication with the Sensor.
4. Charge the Gateway daily, (for example, every night while you sleep)
    - The Gateway takes about 3 hours to fully charge
    - With an adequate charge, the Gateway can be used for up to 18 hours before needing to be recharged.

    See **Figure 16**.

5.6 REPLACING THE PATCH

5.6.1 REMOVE THE SENSOR FROM THE PATCH

1. Press the blue upper snap-in clip.
2. Tilt and remove the Sensor from the Patch while pressing the clip.
3. Place the Sensor in the Charger. Whenever the Sensor is not on the body, it should be kept in the Charger.

5.6.2 REMOVE THE PATCH FROM THE BODY

1. Hold the skin with one hand while using the other to gently peel-off the Patch. You may use a wet cloth to assist you in the process

2. Discard the Patch immediately. Do not reuse.

If required, replace the Patch with a new one according to the instructions in **Sections 6.2 to 6.4**. The Patch should be replaced at least once every five days. Make sure to place the new Patch on the same spot (or as closely as possible to the location) of the previous Patch).

5.7 RECHARGING THE SENSOR

1. The Sensor should be charged every three days, or with every replacement of the Patch, the sooner of the two.
2. Place the Sensor in the Charger. See **Figure 17**. The color of the light indicator on the Sensor will be amber when being charged. It will turn green when the Sensor is fully charged and ready to go.

Figure 107: Sensor Charging

5.8 SENSOR AND LIGHT INDICATOR STATUSES

The following is a summary of the light indicator statuses of the Sensor:

Sensor Position	Light Color	Meaning
Sensor in Charger	Solid green	Battery is fully charged and is ready for use. The solid green light will continue until the Sensor is removed from the Charger.
	Solid amber	Battery is not full and is being charged. The light will change to green once battery is charged and Sensor is ready for use.
Sensor on the body	Solid green	Sensor is ready for monitoring. This solid green light will last for several seconds, after which it will disappear.
	Blinking amber	Sensor error. Call ZOLL customer service at 1.888.592.3798.

6 TROUBLESHOOTING

The following table lists the recommended actions for potential issues with the CMCT System. Please call ZOLL at +972-9-9603900 if you need assistance with any of these instructions.

Signs	Possible Causes	Actions
Sensor light indicator is not on while sitting in the Charger for charging.	The Sensor does not sit properly in the Charger.	Remove the Sensor from the Charger and reinsert back to the Charger.
	The Charger is not connected to the power outlet.	Plug in the Charger to the power outlet using the power cable provided in the CMCT packaging. When properly connected, the light indicator on the Charger should be on and is green.
Sensor light turns blinking amber after being applied on the patient's body.	Sensor Error.	Contact ZOLL customer service at 1.888.592.3798.
Charger light indicator is not on.	The Charger is not connected to the power outlet.	Plug in the Charger to the power outlet using the power cable provided in the CMCT packaging. When properly connected, the light indicator on the Charger should be on and is green.
The Gateway screen does not indicate the Gateway is being charged while sitting in the Charger for charging.	The Gateway does not sit properly in the Charger.	Remove the Gateway from the Charger and reinsert back to the Charger.

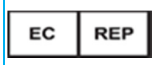
7 CLEANING AND RETURN OF SYSTEM

Users are not required to clean the CMCT System. When the monitoring period is over, use the box provided in the original packaging to return the CMCT System (Sensor, Charger, Gateway, power cable, and any unused Patches) to ZOLL.

8 MAINTENANCE

Users are not required to perform any maintenance for the CMCT System.

9 SYMBOLS GLOSSARY

Symbol	Title and designation # of the Standard	Title of Symbol	Symbol Ref #	Explanatory Text
	ANSI/AAMI/ISO 15223-1:2012, 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's manufacturer.
		Catalogue number	5.1.6	Product catalogue number.
		Date of manufacturer	5.1.3	Date when the device was made.
		Batch code	5.1.5	Batch or lot number for device traceabiltiy.
		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 safetly exposed.
		Do not re-use	5.4.2	The device is for single use only and not to be re-used.
		Non-sterile	5.2.7	The device is not sterile.
	ANSI/AAMI ES60601-	Refer to instruction manual/booklet	#10 (Table D.2)	See Instructions For Use.

	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	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 that Sensor is protected from light dust and against the effects of temporary immersion in water.
		Ingress protection	#2 (Table D.3)	Indicates that the Gateway is protected against solid foreign objects of 12.5mm or greater, and against vertically falling water drops.
		Direct current	#5 (Table D.1)	Direct current.
		No-ionizing radiation		Emits non-ionizing radiation
	ASTM F2503-13, Standard practice for marking medical devices and other items for safety in the magnetic resonance environment	MR Unsafe	Figure 9	Indicates that 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.

Part II: Technical Specifications

10 TECHNICAL SPECIFICATIONS

10.1 ACCURACIES

Parameter	Measurement Accuracy
TFC*	Error of less than 50cc fluid at a confidence level of 90%
HR	Accuracy higher than ±2 bpm or ±2%, the higher of the two
RR	Maximum error of ±2 bpm or 10% , the higher of the two
Activity	Active vs resting accuracy > 99% Walking time in hours per day. Error less than ±10% or ±5 minutes, the larger of the two.
Posture	Posture classification accuracy > 90%
Arrhythmias	• QRS Sensitivity >99% PPV> 99%** • VEB : Sensitivity > 94.9% PPV>93% ** • AF: Sensitivity > 93% PPV>86%***

* As measured in experiments conducted in the laboratory

** Based on algorithm testing preformed using the AHA Database for Evaluation of Ventricular Arrhythmia Detectors

*** Based on algorithm testing preformed using the MIT-BIH Arrhythmia Database

NOTE: Probability of acquiring p-waves signal is higher at the front location

Heart Rate Calculation

The CMCT system algorithm detects the peak of each R-wave and calculates the time interval between successive R peaks known as the RR interval. Heart Rate is calculated based on a 60 second moving average time window. For each window where valid ECG was detected, Heart Rate is computed in bpm as 60 divided by the average RR interval.

Pause Detection

The CMCT system algorithm is based on QRS detection. An RR interval longer than a configurable threshold is a potential pause. Verified intervals are declared as pause.

10.2 ELECTRICAL (POWER) REQUIREMENTS

Sensor	
Max Power Consumption	0.85W
Nominal Power Consumption	0.02W
Max Rating	4.2V, 0.2A
Nominal Rating	3.7V, 0.01A
Battery Type	Li-Pol, 3.7V, 1050mAh

Charger	
Consumption during charging	14W
- **Input (plug)**	5VDC, 2.8A
Adapter	
- **Part Number**	UE24WCP1-050300SPA
- **Input**	100 to 240 VAC at 50/60Hz; 0.8A
- **Output**	5VDC; 3A

10.3 WIRELESS TRANSMISSION SPECIFICATIONS

Data Transmission	
Sensor to Gateway	Bluetooth (BT) 802.15, class 2
- **BT Transmission Range**	9 meters
Gateway to Server	Internet

BT Transmission	
Frequency range	2400-2483.5 MHz

Modulation	GFSK; PSK
PEAK OUTPUT POWER	9 dBm

RF Sensor	
Frequency range	0.5-2.5 GHz
Modulation	CW
PEAK OUTPUT POWER	-10dBm max. and below CISPR 11 levels

10.4 SENSOR DIMENSIONS

Sensor	
Height	69 mm (2.72”)
Width	53.44 mm (2.10”)
Depth	15.96 mm (0.63”)
Weight	66 gram (0.145 lb)

10.5 ENVIRONMENTAL & OTHER SPECIFICATIONS

Operating Conditions for the CMCT System	
Temperature	0°C and 40°C (or 32°F and 104°F)
Relative humidity	5%-93% non-condensing
Pressure	700hPa to 1060hPa

Storage Conditions for the CMCT System	
Temperature	10°C to 32°C (or 50°F to 89.6°F)
Relative Humidity	5%-93%, non-condensing

Shipping and Transport Conditions for the CMCT System	
Temperature	-30°C to 60°C (or -22°F to 140°F)
Relative Humidity [RH%]	5%-93%
Pressure	700hPa to 1060hPa

Patch Shelf Life	1 year
Sensor Battery Life	2 years or 300 charging cycles
Sensor Battery Operation Time	3 days average

11 COMPLIANCES

11.1 ELECTRICAL SAFETY

- The device complies with IEC/EN 60601-1, Edition 3.1 for general requirements of medical electrical equipment safety:
  - Mode of operation: spot measurement
  - Degree of mobility: portable
- The device complies with IEC 60601-1-11.
- The device complies with IEC 60601-2-47.
- The device complies with EC 57.

11.2 ELECTROMAGNETIC COMPATIBILITY (EMC)

- The device complies with IEC 60601-1-2, Edition 4, Class B.

Guidance and Manufacturer's Declaration – Electromagnetic Compatibility

Guidance and manufacturer's declaration- electromagnetic emissions		
The CMCT is intended for use in the electromagnetic environment specified below. The customer or the user of the CMCT should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR11	Class B	The CMCT isn't suitable for interconnection with other equipment. The CMCT is suitable for use in all establishments other than domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Conducted Emissions from AC main CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class B	

Guidance and manufacturer's declaration- electromagnetic immunity			
The CMCT is intended for use in the electromagnetic environment specified below. The customer or the user of the CMCT should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment-guidance**
Electrostatic discharge IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Immunity to Magnetic Field IEC 61000-4-8	30 A/m , 50Hz/60Hz	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Electrical fast transient/burst IEC 61000-4-4	±2 kV, 100 kHz Repetition frequency	±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Conductive Surges IEC 61000-4-5	±1 kV line to line	±0.5, ±1	Mains power quality should be that of a typical commercial or hospital environment.
Conducted Disturbances IEC 61000-4-6	3V frequency 0.15MHz-80MHz 6V in ISM and amateur radio bands between 0.15MHz and 80MHz	3V 6V	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips and Short Interruptions IEC 61000-4-11	0 % *U*T; 0,5 cycle At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° 0 % *U*T; 1 cycle and 70 % *U*T; 25/30 cycles Single phase: at 0°	0 % *U*T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°.0 % *U*T; 1 cycle and 70 % *U*T; 25/30 cycles Single phase: at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power source.

Guidance and manufacturer's declaration- electromagnetic immunity			
The CMCT is intended for use in the electromagnetic environment specified below. The customer or the user of the CMCT should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment- guidance**
Radiated Immunity IEC 61000-4-3	10 V/m, frequency 80MHz-2500 MHz 358-5800MHz PM 18Hz, 217Hz	10 V/m 9-28 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ZOLL CMCT including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. **Recommend separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF			

transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CMCT is used exceeds the applicable RF compliance level above, the CMCT System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CMCT.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

11.3 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.