Medtronic

SEEQ™
Mobile Cardiac Telemetry (MCT) System

_____

Draft for Radio Regulatory submission to FCC
Created March 12, 2015

_____

Instructions for use

Caution: Federal law (USA) restricts this device
to sale by or on the order of a physician.

Table of Contents

Instructions for use

FOLLOW THESE INSTRUCTIONS CAREFULLY AND WATCH YOUR INSTRUCTIONAL VIDEO BEFORE USING THE SEEQ MCT SYSTEM.

Medtronic Customer Support USA: 1-877-247-7449

The SEEQ Mobile Cardiac Telemetry (MCT) System is a wearable, wireless arrhythmia detection system that is used to aid clinicians in diagnosing suspected cardiac arrhythmias. It consists primarily of the Wearable Sensor monitoring device and the Transmitter (portable data transmission device). The SEEQ MCT System, in combination with interpretation services provided by the Medtronic Monitoring Center, as well as secure online review of data (for prescribing physicians only), enables patient- and physician-friendly arrhythmia detection for up to 30 days at a time.

How the SEEQ MCT System works

Once activated, the Wearable Sensor continuously monitors the heart and automatically collects ECGs. When rhythm abnormalities are detected, data is automatically transmitted from the Wearable Sensor to the Transmitter, which then automatically transmits the data to the Medtronic Monitoring Center. Patients can also trigger transmission of ECGs when they experience cardiac symptoms by using the Patient Trigger Button. Certified cardiographic technicians at the Medtronic Monitoring Center review received data and document symptoms reported to the Medtronic Monitoring Center by patients. Reports prepared by the Medtronic Monitoring Center are delivered to the prescribing physician and made available to them at www.medtronic.com to provide them with data for their diagnosis and identification of various clinical conditions, events and/or trends. Prescribing physicians may also be contacted by the Medtronic Monitoring Center directly when arrhythmias that meet pre-defined criteria are detected.

IMPORTANT:

- **The SEEQ MCT 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.**
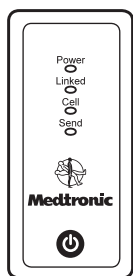
- **The SEEQ MCT System is not intended to replace direct communication with healthcare providers. Medtronic does not provide medical advice to patients. Patients should communicate with their prescribing physician to obtain medical advice.**
- **Data provided by the system should be used by physicians 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.**
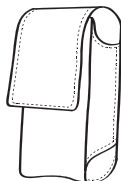
Getting started

Step 1: Locate the components of the SEEQ MCT System
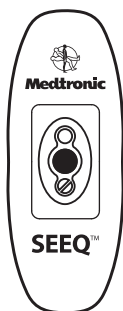
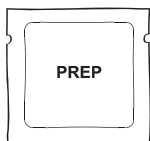|	
	The **Wearable Sensor** is a wearable device that collects and transmits physiological data. One or more Wearable Sensors may be included in the package (inside a foil pouch), depending on the length of the prescription.
	The **Transmitter** is a device that receives data from the Wearable Sensor and transmits it to Medtronic.
	The **Transmitter Case** is used to carry the Transmitter.
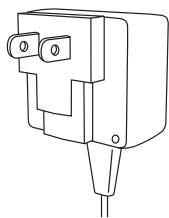
|	
	The **Transmitter Charger** is used to charge the Transmitter.
\n\nPREP	The **Prep Wipes** are used for cleaning skin before applying the Wearable Sensor.
Product Literature	Literature includes these instructions and other information for patients.

Step 2: Charge the Transmitter

- Connect the Transmitter Charger connector to the Transmitter and plug it into a standard electrical outlet.

- If the lights on the Transmitter do not turn on, briefly press the Power Button for less than 1 second to power-up the Transmitter.

- If LED indicators turn ON, the Transmitter has powered up.

- To fully charge the battery, it is important to keep the Transmitter connected to wall power for at least 6 hours.

Connector

Medtronic

Power Button
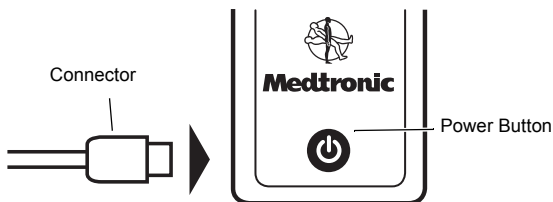
Step 3: Prepare for Wearable Sensor application

- **Trim as much hair as possible** from the intended location (for men) on the upper left chest, as seen in the diagram (for example, using an electric razor or hair trimmer). Trim an area slightly larger than the Wearable Sensor.

- **Using the Prep Wipe provided**, clean the skin where the Wearable Sensor will be applied and **allow time to dry** (clean an area slightly larger than the Wearable Sensor).

- Do not use any creams or lotions on your skin before application as this will impact monitoring.
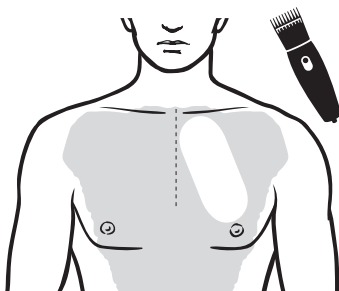
IMPORTANT: Monitoring will be affected if hair is not trimmed or if skin is not cleaned with the Prep Wipe. If this happens, you may be required to use another Wearable Sensor.

- Remove the Wearable Sensor from the foil pouch by tearing at the notch. If you see any illuminated lights on the Wearable Sensor before application, contact Medtronic Customer Support at 1-877-247-7449.

- Grasp the top side of the Wearable Sensor as seen in the diagram and turn it over to view the underside.

- Carefully remove each tab from the underside of the Wearable Sensor to expose the adhesive gel.

IMPORTANT: Take care not to touch the adhesive gel while you handle the Wearable Sensor.

Step 4: Apply the Wearable Sensor to your chest

- Bring the Wearable Sensor close to your upper left chest, taking care to hold it only as described in Step 3.
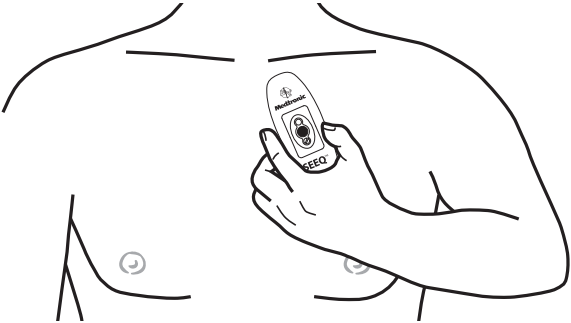
- As seen in the diagrams below, position the end of the Wearable Sensor with the Medtronic logo pointing upwards just below the **collarbone** and angle the device towards the **nipple**. To minimize skin irritation, do not place the Wearable Sensor over broken or damaged skin.

Male

Collarbone

Sternum

Female

Collarbone

Sternum
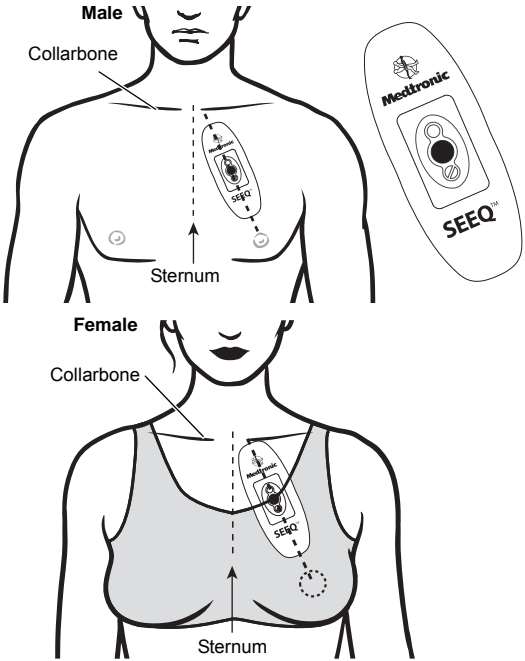
- Petite patients can angle the Wearable Sensor slightly away from the nipple and towards the left arm for a comfortable fit, as seen below.

Collarbone

Sternum
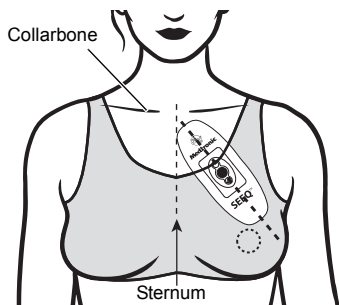
- Once applied, use the palm of your hand to firmly apply pressure across the surface of the Wearable Sensor. Then, use your fingers to press the edges of the Wearable Sensor onto your skin.
- Avoid strenuous motion, activity, or showering for 30 minutes after Wearable Sensor application.

EXAMPLES OF INCORRECT WEARABLE SENSOR APPLICATION
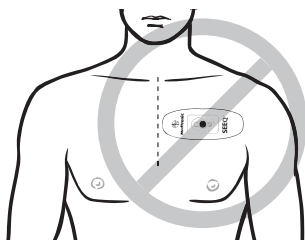
Horizontal
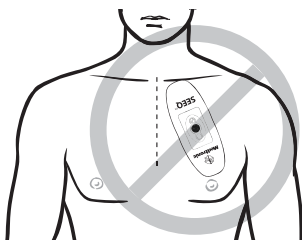
Upside down

Applied over the nipple

Applied under the arm

IMPORTANT: Monitoring will be affected if the Wearable Sensor is not applied correctly. If this happens, you may be required to use another Wearable Sensor.

Step 5: Confirm the Wearable Sensor has activated

- If you see a single blinking green light within the circle symbol, it means the Wearable Sensor is working properly.

- If you DO NOT see this light within 15 minutes of application, please call Medtronic Customer Support at 1-877-247-7449.
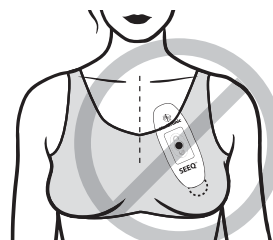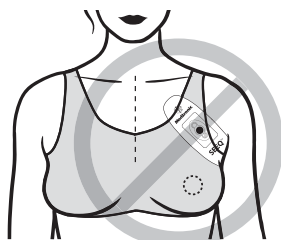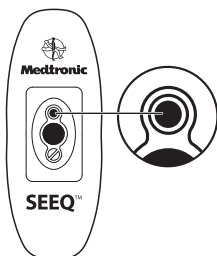

Key things to remember

- Do not dispose of the SEEQ MCT System box or the postal return label. They will be used to ship the components back to Medtronic at the end of monitoring.

- Wear the Wearable Sensor continuously until you see the following two symbols (⊙ and ⊗) appear on the Wearable Sensor display. (Refer to the section "When to remove or replace the Wearable Sensor" on page 11.)

- You can wear the Wearable Sensor while you shower (it is water resistant), but do NOT submerge the Wearable Sensor in water (for example, by swimming or sitting in a hot tub). Avoid excessive rubbing of the Wearable Sensor while showering.

- Once applied, do not remove and then reapply or reposition the Wearable Sensor. If this happens, you may be required to use another Wearable Sensor (that is, it is meant for one-time use).

- Keep the Transmitter close to you at all times (within 30 feet [9 meters]) and charge it daily (for example, each night while you sleep).

- Whenever you feel symptoms, push the blue Patient Trigger Button in the middle of the Wearable Sensor device until you hear a beep.

Using the SEEQ MCT System during the monitoring period

What to do when you feel cardiac symptoms

Whenever you feel cardiac symptoms, push the blue Patient Trigger Button in the middle of the Wearable Sensor device until you hear a beep.

This will direct the Wearable Sensor to transmit a record of your heart rhythm (that is, ECG) to your Transmitter, which will then automatically transmit the information to the Medtronic Monitoring Center for review by Medtronic technicians.

This information will then be provided to your physician.
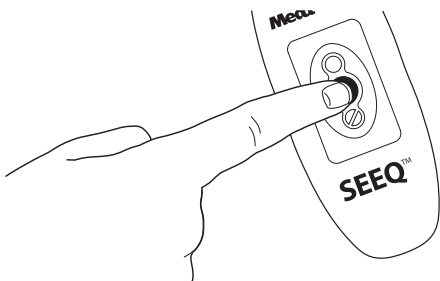
IMPORTANT: You may be contacted by a technician from the Medtronic Monitoring Center to discuss symptoms when the Patient Trigger Button is used. When you experience any symptoms, please make note of the following to discuss with a technician:

- **type of symptoms**
- **time of symptoms**
- **duration of symptoms**
- **what you were doing**

How to use the Transmitter

The Transmitter should be kept within 30 feet (9 meters) of you at all times to allow transmission of data from the Wearable Sensor to the Transmitter:

- During the day, carry the Transmitter with you using the Transmitter Case. The Transmitter must be placed in the case with the LED lights and switch buttons visible through the clear plastic cover of the case. If the case is to be carried in close contact with the body, it must be placed so that the back side is next to the body and the controls are visible through the clear plastic cover.
- At night, keep the Transmitter close to you while you sleep (for example, on a nightstand).

The Transmitter should be kept ON at all times to allow transmission of data from the Wearable Sensor to the Transmitter. The Transmitter may be manually turned OFF by pressing and holding the Power Button for more than 6 seconds. When a Transmitter is in an OFF state (no lights are on), it can be turned ON by briefly pressing the Power Button for less than 1 second. However, please keep the Transmitter turned ON at all times to allow data transmission.

IMPORTANT: If you are out of range of the Transmitter or required to turn it off (for example, when on an airplane or if asked by Medtronic Customer Support), you can continue to wear the Wearable Sensor and use the Patient Trigger Button to document symptoms. All of your data will be stored on the Wearable Sensor and sent to the Transmitter when you are again within range or when the Transmitter is turned back on.

How to charge the Transmitter

- Charge the Transmitter daily (for example, every night while you sleep).

- The Transmitter may take up to 6 hours to fully charge.

- With an adequate charge, the Transmitter can be used for up to 12 hours before needing to be recharged.

- The Linked, Cell, and Send lights on the Transmitter are utilized by Medtronic Customer Support for troubleshooting. Refer to these lights only if asked by a Medtronic Customer Support representative.

Power light:
Green on: Adequate charge
Yellow on: Low charge
Flashing: Charging required
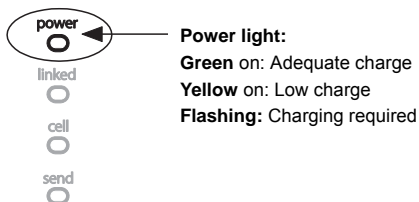
IMPORTANT: If the battery on the Transmitter runs out, you can continue to wear the Wearable Sensor and use the Patient Trigger Button to document symptoms. All of your data will be stored on the Wearable Sensor and transmitted once the Transmitter is charged.

When to remove or replace the Wearable Sensor

Each Wearable Sensor is designed to operate with normal wear and tear over the course of use for up to 7.5 days. The Wearable Sensor is also water resistant. You can keep wearing the Wearable Sensor while you shower, but do not submerge it in water (for example, in a bath or hot tub).

Depending on the length of your prescription, you may need to wear more than one Wearable Sensor. As seen in the diagram below, the Wearable Sensor display will let you know when it should be removed.

- If you see a single blinking green light within the filled circle symbol ⊙, this means the Wearable Sensor is working properly. You should continue to wear the device.

- If you also see two red lights within the circle with a crossed line symbol ⊘, you should remove and replace the device with a new Wearable Sensor (unless your monitoring period is over).
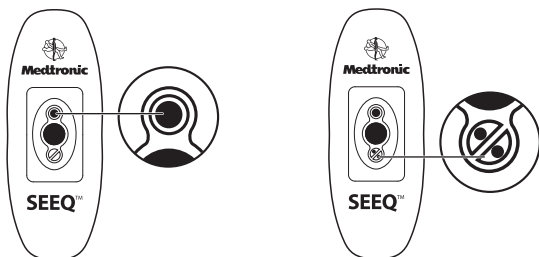
IMPORTANT: Each Wearable Sensor should be worn continuously until the two red lights behind the circle with the crossed line are seen. This may take up to 7.5 days, but could be less. Once it has been removed, do not reapply the removed Wearable Sensor as this will affect monitoring (that is, it is meant for one-time use only). Please call Medtronic Customer Support at 1-877-247-7449 if you have any questions about when to remove the Wearable Sensor.

How to remove the Wearable Sensor

- Grasp an edge of the Wearable Sensor with one hand and begin to peel it away from your skin.
- Using the other hand, slowly and gently push the skin away from the Wearable Sensor as it is removed.

IMPORTANT: Rapid removal can cause skin irritation. If irritation persists after Wearable Sensor removal, consult your healthcare provider for topical treatment options.

What to do with a used Wearable Sensor

- Do not dispose of used Wearable Sensors. See the following section for instructions.
- The Wearable Sensor has a Lithium battery and must not be disposed of in a fire.

What to do at the end of monitoring

When your prescription is complete, you must return all of your **Wearable Sensors**, the **Transmitter**, the **Transmitter Charger**, and the **Transmitter Case**, to avoid being billed for the value of the system. Follow the steps below to return the components to Medtronic:

- Remove the postal return label provided in the original box.

- Place the Wearable Sensors, the Transmitter, the Transmitter Charger, and the Transmitter Case in the original box.
- Attach the postal return label to the outside of the package.
- Place the package in the mail. No additional postage is required.

IMPORTANT: Please return the components only when your prescription is complete. Call Medtronic Customer Support at 1-877-247-7449 if you need information about the status of your prescription.

Indications for use, contraindications, and precautions

Indications for use

The SEEQ Mobile Cardiac Telemetry (MCT) System is intended to continuously measure, record, and periodically transmit physiological data. The System is indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias such as, but not limited to, supraventricular tachycardias (for example, atrial fibrillation, atrial flutter, paroxysmal SVTs), ventricular ectopy, bradyarrhythmias, and conduction disorders. The SEEQ MCT System monitors, derives, and displays the following: ECG, and Heart Rate.

Description of the system

The SEEQ MCT System consists primarily of the Wearable Sensor monitoring device and the Transmitter data transmission device. Once activated, the Wearable Sensor continuously monitors the heart and automatically collects ECGs. When rhythm abnormalities are detected, data is automatically transmitted from the Wearable Sensor to the Transmitter, which then automatically transmits the data to the Medtronic Monitoring Center. Patients can also trigger transmission of ECGs when they experience cardiac symptoms by using the Patient Trigger Button. Certified cardiographic technicians at the Medtronic Monitoring Center review received data and document symptoms reported to the Medtronic Monitoring Center by patients. Reports prepared by the Medtronic Monitoring Center are delivered to the prescribing physician and made available to them at www.medtronic.com to provide them with data for their diagnosis and identification of various clinical conditions, events and/or trends.

Based on the indications, the SEEQ MCT System may be used for the following:

- ▪ patients who require monitoring for suspected or known, non-life threatening arrhythmias

- ▪ patients with symptoms such as chest pain, syncope, light-headedness or near syncope, vertigo, dizziness, fall, palpitations, transient ischemic episodes, and dyspnea (shortness of breath) that might be due to cardiac arrhythmias

- ▪ patients with cardiac arrhythmias associated with co-morbid conditions

- ▪ obtaining correlation of rhythm with symptoms when symptoms have unknown etiology

- ▪ evaluating possible arrhythmias in a) patients recovering from cardiovascular or thoracic surgery; b) survivors of myocardial infarction; c) patients with diagnosed sleep disorder breathing

- ▪ evaluating benefits after initiating or discontinuing pharmacological therapy (for example, anti-arrhythmic, beta-blocker, anti-coagulation therapies).

- ▪ assessing the results of an ablation procedure for an arrhythmia

- providing data to guide treatment decisions (for example, pharmacological or procedural/device-based treatments) and assessing treatment results in patients with non-life threatening arrhythmias

Contraindications

- patients with known allergies or hypersensitivities to adhesives or hydrogel
- patients with potentially life-threatening arrhythmias, or who require inpatient / hospital monitoring

Precautions

- Minute ventilation sensing on implantable devices should be disabled for the duration of Wearable Sensor usage.
- The Wearable Sensor should be removed prior to external defibrillation or an MRI scan.
- The Wearable Sensor may cause mild discomfort, skin irritation, redness, itching, rash, or contact dermatitis in some individuals. The device should be removed if any pain or discomfort occurs. If skin irritation or redness persists after the device has been removed, a topical anti-inflammatory cream may be applied to the area (in consultation with your health care provider).
- The Wearable Sensor is intended for single patient use and should not be reapplied it if peels off or is removed (that is, it is meant for one-time use).
- The Wearable Sensor should not be applied to broken, damaged, or irritated skin.
- The Wearable Sensor is water resistant but not waterproof. It should not be submerged in water (showering is acceptable, but swimming and submersion bathing are prohibited).
- The Wearable Sensor should not be disassembled.
- Do not apply the Wearable Sensor if it appears damaged upon receipt.
- No creams or lotions should be applied to the skin immediately prior to the application of the Wearable Sensor.
- Store the Wearable Sensor in a cool, dry location. The device is designed to withstand environmental temperature fluctuations between -4 °F to 149 °F (-20 °C to 65 °C).
- The system has not been fully evaluated for use with infants weighing less than 22 pounds (9.9 kilograms).
- The system is not designed to detect pacemaker spikes.

Warning

- No modification of this equipment is allowed.

Services for physicians

Prescription duration:

After registering with Medtronic, physicians can prescribe the SEEQ MCT System for up to 30 days at a time. As each Wearable Sensor is designed to last for up to 7.5 days, prescription lengths greater than one week will be enabled through the use of more than one Wearable Sensor.

Clinical reports:

Clinicians can receive clinical reports, including Episode, Daily, and End of Use Reports, directly from the Medtronic Monitoring Center by fax and/or email. Clinical data can also be securely reviewed online at www.medtronic.com. Clinicians may download and/or print clinical reports, review collected ECGs, and also establish service preferences. For any questions about online use, please contact Medtronic Customer Support at 1-877-247-7449.

Notifications:

The Medtronic Monitoring Center may send Episode Reports and contact prescribing physicians directly when arrhythmias that meet pre-defined criteria are identified. Contact information and notification preferences will be established upon registration and can be updated.

IMPORTANT: Patient data available for transmission during the monitoring period are updated for physician display upon detection of a clinical event OR every two hours when no events are detected, assuming a) the Wearable Sensor is within 30 feet (9 meters) of Transmitter, b) the Transmitter has been appropriately installed as specified in "How to use the Transmitter" and has sufficient power and c) sufficient cellular coverage for data transmission exists. Analysis of ECGs by the Medtronic Monitoring Center may also affect the timing of ECG display. Additional patient data may be available after the end of monitoring.

Specifications, compliance, and symbols

Specifications

The following performance specifications are at 68 °F (20 °C) unless otherwise stated.

	Wearable Sensor	**Transmitter**
Shelf life	Refer to Wearable Sensor pouch label	N/A
Battery Charger power requirement	N/A	100-240 VAC, 50/60 Hz
Battery life	7.5 days (180 hours), non-rechargeable	Provides 12 hours of function before recharging
Operating temperature	32 °F to 113 °F (0 °C to 45 °C)	32 °F to 113 °F (0 °C to 45 °C)
Maximum temperature of the applied part	111.2 °F (44 °C)	N/A
Storage temperature (power off)	-4 °F to 149 °F (-20 °C to 65 °C)	-4 °F to 149 °F (-20 °C to 65 °C)
Operating humidity	10% to 95%	10% to 95%
Storage humidity	5% to 95%	5% to 95%
Operating atmospheric pressure	700 hPa to 1060 hPa	700 hPa to 1060 hPa
ECG Sampling rate Digital resolution Input dynamic range Input offset dynamic range	200 Hz (+/-5%) 16bits +/-5 mV +/-300 mV	N/A
Impedance measurements Peak current injection RMS current injection	40 uA 29 uA	N/A
Measurement ranges Heart Rate	25 to 250 bpm	N/A
Data storage Capacity	7.5 days	N/A
Weight	1.8 oz / 50 g max	5.3 oz / 150 g max
Communication means	Bluetooth between Wearable Sensor and Transmitter	Cellular Phone between Transmitter and Server

Arrhythmia Detection Algorithms and Automatic ECG Collection

In addition to patient-triggered collection of ECGs using the Patient Trigger Button, the SEEQ MCT System also uses proprietary algorithms based on rate, rhythm, and morphology to continuously analyze rhythm abnormalities and to initiate automatic ECG transmission. ECGs are automatically transmitted upon detection of the following conditions:

- Heart Rate >= 130 bpm
- Heart Rate <= 40 bpm
- Pause >= 3 seconds
- Atrial Fibrillation
- Ventricular Tachycardia/Ventricular Fibrillation

For example, the detection algorithm of the SEEQ MCT System detects the peak of each R-wave and calculates the interval between successive R-waves. The RR intervals are then used to calculate beat-to-beat heart rate values. RR intervals are also aggregated into 5-minute and 24-hour averages to summarize patient heart rate over the monitoring period. For Pause detection, the algorithm monitors the time between successive R-wave peaks. A pause trigger is activated if an internal timer advances to 3 seconds without R-wave detection.

In order to provide relevant, exception-based arrhythmia reporting, the SEEQ MCT System proprietary ECG analysis algorithms proactively manage redundant reporting of ECGs for a select set of arrhythmias when persistently detected:

- Tachycardias with heart rate >= 130 bpm and < 165 bpm
- Bradycardias with heart rate >= 30 bpm and < 40 bpm
- Atrial Fibrillation
- Ventricular Tachycardia < 165 bpm

For these arrhythmias, the Wearable Sensor algorithm detection sensitivity and positive predictive value results, which are obtained from the respective databases in strict accordance with EC-57[a] and with 0% downtime, are as follows:

Test Rhythm Name	Sensitivity (%)[a]	Positive Predictive Value (%)[a]
QRS Detection (average) Including all Tachycardias with heart rate >= 130 bpm and < 165 bpm, Bradycardias with heart rate >=30 bpm and <40 bpm	AHA: 98.95 MIT-BIH: 99.83	AHA: 99.34 MIT-BIH: 99.84
AF Duration (gross)	MIT-BIH: 90	MIT-BIH: 85

[a] as measured by EC-57 standards testing on 12NOV2013

Redundant reporting of ECGs for this select set of arrhythmias is managed as follows:

- ▪ The Wearable Sensor will report no more than two (2) ECGs for each of these arrhythmias each hour.
- ▪ The Wearable Sensor will wait ten (10) minutes before allowing a subsequent ECG to be reported for each of these arrhythmias.

Note: a) ECGs are reported for all Tachycardias with heart rate >= 165 bpm, all Bradycardias with heart rate < 30 bpm, and all Pauses >= 3 seconds; b) the Wearable Sensor keeps a complete count of all arrhythmias that are detected; c) supplemental ECGs are also reported i) every six (6) hours for prolonged Atrial Fibrillation episodes and ii) every twenty-four (24) hours, irrespective of the presence of an arrhythmia.

Transmitter maintenance

Please attempt to keep the Transmitter dust free. If necessary, gently wipe the Transmitter with a soft dry cloth to clean the surface. The Transmitter is not waterproof and should be kept dry. This device does not have user serviceable components inside. Do not disassemble, crush, puncture, short external contacts or circuits, dispose of in fire or water, or expose the battery pack to temperatures higher than 149 ˚F (65 ˚C).

Electromagnetic interference

This equipment complies with International Standard IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipment. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information provided upon request by calling Medtronic Customer Support at 1-877-247-7449. Portable and mobile RF communication equipment can affect nearby medical electrical equipment.

FCC Compliance Information

Wearable Sensor and Transmitter devices comply with Part 15 of the Federal Communications Commission (FCC) Rules – Radio Frequency Devices: Operation is subject to the condition that (1) this device does not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by Medtronic could void the user's authority to operate the equipment. Note: 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 when the equipment is operated in a residential environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications.

Exposure to radio frequency signals

To maintain compliance with FCC RF exposure guidelines when you carry the Transmitter on your body, use only the Transmitter Case supplied by Medtronic. Be sure to insert the Transmitter in the case as instructed in "How to use the Transmitter". Use of accessories that are not expressly approved by Medtronic are not approved and might cause violation of the FCC RF emissions and RF exposure guidelines.

Specific absorption rate data

The Transmitter meets the U.S. Government requirements for exposure to radio waves when used as directed in this document.

The Transmitter is a radio transmitter and receiver. It is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission (FCC) of the U.S. Government when used as directed in previous sections of this document. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The exposure standard for wireless devices employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6W/kg. Tests for SAR are conducted using standard operating positions as specified in this document. Before a wireless device model is available for sale to the public, it must be tested and certified by the FCC that it does not exceed the limit established by the government-adopted requirement for safe radio frequency exposure under the recommendations of the International Commission on Non-Ionizing Radiation Protection (ICNIRP).

The FCC has granted an Equipment Authorization for this wireless device model with all reported SAR levels evaluated and is in compliance with the FCC RF emission guidelines when the Transmitter is used as directed in this document.

Symbol definitions

📖	Consult instructions for use	⊘	Do not reuse
📖	Follow instructions for use	⧖	Use-by (year-month) or (year-month-date)
⚠	Caution: consult accompanying documents	LATEX	Latex free
LOT	Batch number	SN	Serial number
�	Date of manufacture	REF	Catalogue number

NON STERILE	Non-sterile		Manufacturer's name and address
	Temperature limitations		Collection of electrical and electronic equipment
	The entire Wearable Sensor is a type BF applied part; Denotes device is not in direct contact with cardiac muscle		Wireless transmission symbol
IP35	Ingress Protection 3 means protection against objects >=2.5 mm in diameter (tools) 5 means protection against water jets (shower)	R only	Federal (USA) law restricts this product to sale by or on the order of a physician.
	Class II equipment		Keep dry
$C\epsilon$	Conformité Européenne (European Conformity). This symbol means that the device fully complies with European Union Acts.		

Frequently asked questions

What is a Wearable Sensor?

A Wearable Sensor is a patient-worn medical device designed to comfortably adhere to the skin. The device contains sensors that collect your ECG waveform (a tool for analyzing the activity of your heart).

How long will my Wearable Sensor last?

Each Wearable Sensor is designed to last up to 7.5 days. However, inappropriate Wearable Sensor application, or removal and reapplication of the Wearable Sensor during use, will affect monitoring. If this happens, you may be required to use another Wearable Sensor.

What information is transmitted to my physician?

Your heart activity is monitored 24 hours a day, 7 days a week by the Wearable Sensor. When unusual heart activity is detected or when you use the Patient Trigger Button, information is transmitted to the Medtronic Monitoring Center for review and delivery to your physician.

What do I do when I feel symptoms?

Whenever symptoms occur, trigger the Wearable Sensor to transmit a record of your heart activity by pushing the blue Patient Trigger Button located in the middle of the Wearable Sensor until you hear a beep. An ECG will be transmitted to the Transmitter and then transmitted to the Medtronic Monitoring Center for review and delivery to your physician.

How can I report my symptoms?

Technicians from Medtronic may call you to discuss your symptoms. Please make note of the type of symptoms, the duration of symptoms, when they happened, and what you were doing so it can be discussed with a technician. You should contact your physician if you need medical care.

Can I take a shower while wearing my Wearable Sensor?

Yes, the Wearable Sensor is water resistant so you can shower while wearing it. However, do NOT submerge the Wearable Sensor in water by swimming or sitting in a hot tub. In addition, avoid excessive rubbing of the Wearable Sensor during showering.

Will I need to change the battery in the Transmitter or the Wearable Sensor?

Battery replacement is not required for the Wearable Sensor and the Transmitter. However, we recommend that you charge the Transmitter every night.

How close must I be to the Transmitter to ensure that the data collected by my Wearable Sensor is transmitted?

Remain within 30 feet (9 meters) of the Transmitter for successful data transmission.

How often do I need to change the Wearable Sensor device?

When both of the following two symbols (⊙ and ⊗) appear on the Wearable Sensor display, you should remove the Wearable Sensor. Please apply a new Wearable Sensor if your monitoring period has not ended.

What if the Wearable Sensor causes my skin to itch?

If you experience skin irritation while wearing the Wearable Sensor, speak with your physician.

Should I carry the Transmitter with me when I travel?

Yes, take the Transmitter with you at all times. The Transmitter will remain charged for up to 12 hours. If you plan to be away for longer than 12 hours, take the Transmitter Charger with you.

Will I need to notify security screeners about my Wearable Sensor?

Carry the SEEQ MCT System patient travel card provided as part of your SEEQ MCT System when traveling or entering high security areas. Wearable Sensor and Transmitter devices may trigger security systems, but the devices will not be damaged. If your Wearable Sensor or Transmitter triggers a security system, simply show the security personnel this card and tell them you are wearing a medical device.

Can I wear a Wearable Sensor through an electronic antitheft system, such as in a store?

Yes, the Wearable Sensor will not set off antitheft systems and will not be damaged by them.

Can I use microwave ovens or TV remotes while wearing a Wearable Sensor?

Yes, it is safe to operate these devices as they will not affect performance of the Wearable Sensor.

Can I be close to wireless phones, WiFi, or other electromagnetic devices?

Yes, although some sources of Electromagnetic Interference (EMI) may temporarily disrupt data transmission.

Can I carry my cellphone while wearing the Wearable Sensor?

Yes, cellphones will not interfere with the Wearable Sensor device.

Will hot or cold environments affect the Wearable Sensor performance?

The Wearable Sensor provides accurate and reliable performance in a temperature range of 32 ˚F to 113 ˚F (0 ˚C to 45 ˚C).

Is my medical data protected during transmission?

Your data is transmitted securely to the Medtronic Monitoring Center and securely stored.

Medtronic

M958549A001