ePatch
ECG Sensor

Instructions For Use

Product Catalog Numbers:
REF ePatch 2.0
REF 02-01997
REF 02-02045
REF 02-02251

04/2026
02-02034 Rev. F

Braemar
a BioTelemetry company

ENGLISH-US ONLY
Instruction Manual

Notices

℞ only

Prescription use only (U.S. Federal Law)

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Read the Instructions for Use before use of the product and keep these instructions for future reference. Failure to follow the instructions in this document may result in injuries to the user or the patient and damage to the ECG Sensor and/or the accessories.

Use of the ePatch ECG Sensor and compatible ECG Electrode accessories for purposes other than those intended and expressly stated by the manufacturer, as well as incorrect use, incorrect operations, or modifications made to the ePatch ECG Sensor and compatible ECG electrode accessories may relieve the manufacturer (or his agent) from all or some of the responsibilities for resultant noncompliance, damage, injury.

IMPORTANT: The ECG Sensor is not provided with physiological-type alarms and the ECG Sensor does not maintain, nor does it help to maintain the life of the patient. The ECG Sensor is intended to be used under the direction of a healthcare professional for diagnostic purposes only. The patient must therefore be instructed by the healthcare professional to act on any health symptoms that may arise, as he would do if he was not wearing the ECG Sensor.

The ECG Sensor is MR Unsafe. Do not enter an MRI scanner room or an MR system while wearing the ECG Sensor. Doing so may result in image artifacts within the MR scan and/or injury.

Table of Contents

1 Description, indications for use, contraindications, warnings, and precautions

Please read these instructions carefully before using the ePatch ECG Sensor (later termed ECG Sensor) or any of the accessories. Contact the healthcare professional or Braemar Manufacturing LLC. with any questions.

1.1 Description

The ePatch ECG Sensor (later termed ECG Sensor or ePatch) is intended for continuous recording of heart action potentials (ECG). While in use, the ECG Sensor is connected to a compatible ECG Electrode accessory (later termed ECG Electrode), such as an ECG Electrode Patch (later termed Patch or Patch ECG Electrode) and placed on the patient.

The ECG Sensor interfaces with a compatible Charge Adapter. The ECG Sensor is rechargeable and reusable. The ECG Sensor contains internal non-volatile storage that stores the ECG data until the file with the ECG data is deleted. The ECG Sensor contains embedded software for recording ECG, storing ECG, and charging. When the ECG Sensor is connected to a PC through the Charge Adapter, the recorded ECG files are accessible as a USB mass storage device.

There are four (4) models of the ePatch ECG Sensor used in the US:

- REF ePatch 2.0
- REF 02-01997
- REF 02-02045
- REF 02-02251

1.2 Indications for use

ePatch ECG Sensor is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety.

The ECG Sensor is intended for use by adolescents 18-21 and adults.

1.3 Intended Users/Intended Use Environment

Intended Users: Healthcare professionals (e.g., Physicians, nurses) and lay-users (patients and their respective care givers).

Intended Use Environment: The ECG Sensor is intended for use in hospital/health care facilities and in a home setting.

1.4 Intended Population

The ePatch ECG Sensor is intended for use by adolescents 18-21 and adults.

1.5 Contraindications

Please refer to the Instructions for Use associated with the compatible accessories for their specific Contraindications.

1.6 Warnings

 This ECG Sensor has not been evaluated to support its use on infants, or on pregnant and/or breastfeeding women.
 The ECG Sensor is not intended for use on patients with an implanted pacemaker or an Implantable Cardioverter-Defibrillator (ICD).
 Do not use the ECG Sensor in an X-ray, computed tomography (CT), or magnetic resonance imaging (MRI) environment. This may affect the scanning results, may lead to malfunction of the ECG Sensor, and it may injure the patient.
 Remove ECG Sensor prior to defibrillation.
 Do not tamper with, disassemble or modify ECG Sensor or accessories, as this may affect functionality or performance. A slight electrical sensation may be experienced.
 Use the ECG Sensor with compatible accessories supplied by the manufacturer. Otherwise, electrical shock or damage to the ECG Sensor may occur. In addition, the ECG signal quality could be affected.
 Use of other equipment or accessories not specified in this Instructions For Use document might lead to skin irritations, allergy, electrical shock, and malfunction of the ECG Sensor. Use of other chargers may damage the device and/or accessories.
 Keep products out of reach of unsupervised infants, children, and pets, as this could potentially cause a choking hazard or cause suffocation if placed over face or mouth. There is a danger of strangulation if the provided USB Cable and/or lead wires are misused.
 Please refer to the Instructions for Use associated with the compatible accessory for their specific Warnings.

1.7 Precautions

Do not use a broken ECG Sensor. This can cause electric discharge or decrease the quality of the acquired ECG signals.

Do not touch the terminals at the backside of the ECG Sensor or let them touch other conductive parts or earth. This may damage the ECG Sensor.
If the ECG Sensor is not firmly connected to the ECG Electrode Patch, it is not splash proof (Protection level IP24). To avoid malfunction, make sure both parts are firmly connected with no gaps and do not expose to direct jet of water or liquid.
Do not expose the internal parts of the ECG Sensor, the Charge Adapter, or the AC Adapter to any liquids. Do not submerge the ECG Sensor, the Charge Adapter, or the AC Adapter in any liquid. This may cause electric short circuiting or electrical discharge.
Minimize the number of devices connected to the patient. Otherwise, there is a risk of accumulation of leakage current.
Store and use the ECG Sensor within temperature, pressure, and humidity ranges specified in Section 10.1.4.
Avoid exposing any part of the ECG Sensor to heat sources, heat radiators and fireplaces, direct exposure to sunlight, nebulizers, or electrical steam kettles. Temperature changes cause condensation and moisture that can lead to malfunction of the ECG Sensor.
Before using the ECG Sensor, allow it to acclimate to ambient temperature. For reference, if the temperature difference between the ECG Sensor and the environment is above 10ºC, a 20-minutes wait time in an intermediate temperature is recommended.
Mobile phones, transmitters, and similar equipment generating radio frequency (RF) emissions should not be placed next to the ECG Sensor during use. This can affect the ECG Sensor. Follow the recommendations regarding the separation distance specified in the manufacturer's declaration for EMC in this Instructions for Use document, see Annex 1.
Do not lie directly on the ECG Sensor.
Do not connect the ECG Sensor to external electrical equipment.
Please refer to the Instructions for Use associated with the compatible accessory for their specific Precautions.

2 The ECG Sensor interfaces and markings

The ECG Sensor interfaces with the Charge Adapter and is compatible with ECG Electrode Patch, Flex Adapter, or Lead Wire Adapter (LWA) accessories. The front side of the ECG Sensor has a charging indicator and a status indicator.

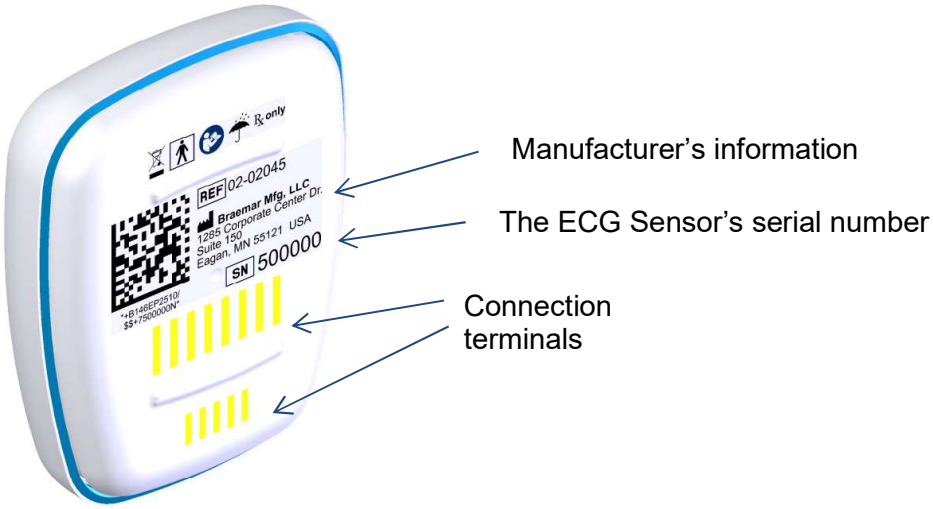
The front side of the ECG Sensor:

1. There are three (3) different LED lights that can appear:
   - Charging indicator (one white light)
   - Status indicator (one red or green light)

2. If a constant or flashing red light appears, consult the Troubleshooting Guide in chapter 8

3. When charging, the white LED will flash. When fully charged, the white LED will stop flashing and remain solid (see above)

The back side of the ECG Sensor:



Representative example of the back of ePatch ECG Sensor

3 ePatch ECG Sensor Accessories

The following accessories are compatible with the ePatch ECG Sensor. Refer to the information provided with the accessory for further information.

Accessory	Part Number
Patch ECG Electrode (box of 40)	02-01615
Lead Wire Adapter	02-00139
Flex Adapter	02-00143

3.1 ECG Electrode Patch

ECG Electrode Patch

ECG Electrode Patch with connected ECG Sensor

The ePatch ECG Sensor can be used with the ECG Electrode Patch accessory. See Annex 3 for channels and configurations.

3.2 Lead Wire Adapter (LWA)

Lead Wire Adapter

The ePatch ECG Sensor can be used with the Lead Wire Adapter (LWA) accessory. See Annex 3 for channels and configurations.

3.3 Flex Adapter

Flex Adapter

The ePatch ECG Sensor can be used with the Flex Adapter accessory. See Annex 3 for channels and configurations.

4 How to get started?

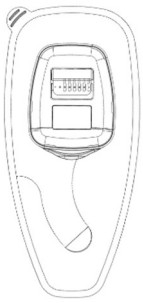
This chapter describes how to start a recording. The steps must be followed point by point.

4.1 Step 1: Understanding the ePatch ECG Sensor system

ePatch ECG Sensor

The ePatch ECG Sensor, also referred to as ECG Sensor**,** acquires the patient's ECG signals and stores them internally. The ECG Sensor is rechargeable and reusable. The ECG Sensor must only be used in combination with one of the compatible accessories as detailed below.

ECG Electrode Patch accessory



ECG Electrode Patch

The ECG Electrode Patch, also referred to as Patch, is for single use only and must be disposed of and replaced after 5 days of wear.

LWA accessory

Surface Electrodes Example

LWA

The Lead Wire Adapter (LWA) is for optional use with the ePatch ECG Sensor. The surface electrodes are for single use only. Refer to the information provided with the surface electrodes for further information.

Flex Adapter accessory

Surface Electrodes Example

Flex Adapter

The Flex Adapter is for optional use with the ePatch ECG Sensor. The surface electrodes are for single use only. Refer to the information provided with the surface electrodes for further information.

4.2 Step 2: Clean and Disinfect the ECG Sensor if used prior on a patient

NOTE: The information in this section is for use by healthcare professionals processing Sensors for use on the next patient.

Ensure that the Sensor is cleaned and disinfected prior to use and prior to application of the Sensor on a new patient. Follow the instructions in Chapter **Error! Reference source not found.**.

4.3 Step 3: Prepare and charge the ECG Sensor

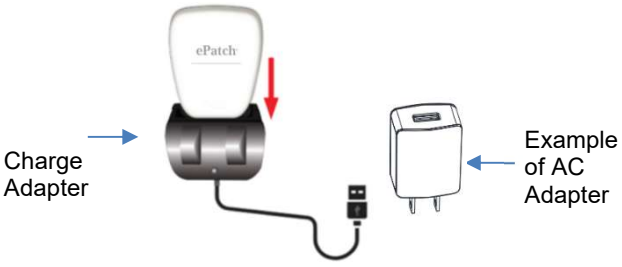
NOTE: The information in this section is for use by healthcare professionals.

Before each recording, prepare and charge the ECG Sensor as described below.

Charging components

The ECG Sensor can be charged using the Charge Adapter in two (2) ways (if supplied):

- Using the AC Adapter (fast charging. Recommended)
- Using a computer's USB port (will charge slowly. Not recommended)



Charging components	Part Number
Charge Adapter	02-00109
Power Supply AC/DC USB 5V 0.55A US (AC Adapter)	01-02038

NOTE: Use the ECG Sensor with compatible accessories and components supplied by the manufacturer. Otherwise, electrical shock or damage to the ECG Sensor may occur. In addition, the ECG signal quality could be affected.

1

NOTE: Always use an ECG Sensor that is fully charged and ready to use. Otherwise, the recording time might be affected.

Use the provided Charge Adapter to connect the ECG Sensor to a powered-on computer (slow charging), or to an AC Adapter plugged into an electrical socket (fast charging).

2

While charging the ECG Sensor, a flashing white light will appear. When fully charged, a constant white light will appear indicating it is ready to use. Allow recharge of the ECG Sensor until the charging indicator shows a constant white light.

If a red light appears, refer to the Troubleshooting Section, chapter 8.

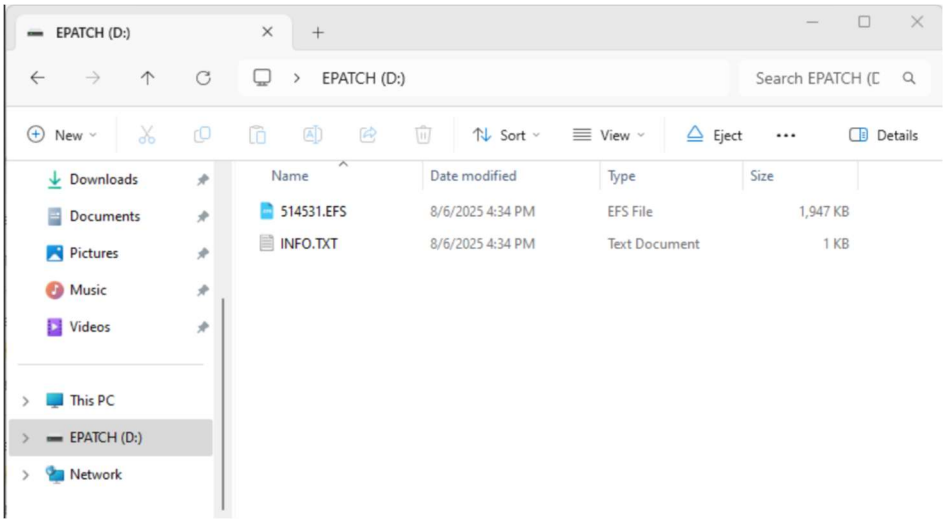
3

Ensure that any previously recorded data (with the file extension.EFS) is copied to a computer and deleted from the ECG Sensor before the ECG Sensor is re-used for a new recording, please see chapter 5 for further instructions.

View Sensor Configuration Settings

Access the INFO.txt file to view the Sensor's configuration settings, including the maximum recording duration and ECG channels settings.

To view the INFO.txt file, connect the Sensor to a powered-on computer using the Charge Adapter. Once connected, open the INFO.txt file to view the configuration details, located in the ePatch drive on the computer (see screenshot below).



Example of INFO.txt file location

An example for the Sensor's configuration settings is provided in the following screenshot.

Example of INFO.txt file for 7 Days 2 Channels

Recording Length:	The maximum number of recording hours set for the Sensor For example, 168 hours = 7 days, 120 hours = 5 days
ECG Storage:	The sample frequency
Number of ECG Channels:	The number of ECG Channels
ECG Bit Resolution:	ECG ADC Resolution
Accel Storage:	The accelerometer storage
Event Trigger:	Event Trigger functionality

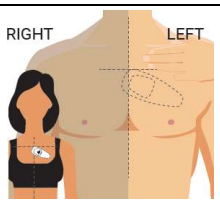
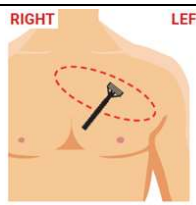
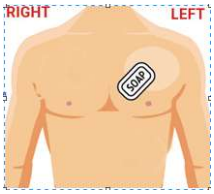
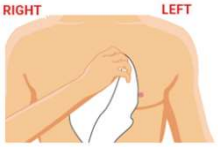
File Mode:	ECG file handling
Startup Delay:	Startup timer delay
Sensor Serial Number:	The serial number of the Sensor
Sensor Model:	The Sensor model part number
Sensor Type:	The Sensor model name
Configuration ID:	The configuration settings file part number
Software Version:	The firmware version of the Sensor
ePatch-2.0 ECG Buffer:	Data buffer setting

NOTE: The INFO.txt file is for information only on the ePatch Sensor settings. You cannot change the Sensor settings from the INFO.txt file.

4.4 Step 4: Prepare the skin (when using the ECG Electrode Patch)

Do not place the Patch on broken, damaged, or irritated skin. Apply the Patch ONLY on clean intact skin and NEVER on open wounds, lesions, infected or inflamed areas.

Expose the chest and prepare the skin according to the steps below (example illustrations for slanted position):

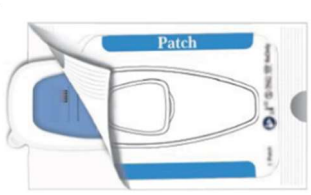
	1. Determine the chest area needing to be prepared by referring to the diagram. Locate the collarbone on the left side of the body and measure three (3) finger widths down (when using a slanted position) or three (3) finger widths below the upper rim of the sternum (when using a sternum position).
	2. If hair is on the chest, wash and shave the area where the Patch will be placed. Start at the center of the chest and shave the entire area marked in the red circle of the diagram.
	3. Clean the area with soap and water.
	4. Dry skin thoroughly using a towel.

	5. Gently rub the skin using the scrub pad (if provided) in a circular motion for 1 minute. This step may help in providing a better ECG signal.
	6. It is important to wait for a minimum of 2-3 minutes until the skin is completely dry before applying the Patch. While waiting, continue to the next steps.

NOTE: Do not apply oils or lotions in the cleaned area before attaching the Patch to the skin. The quality of the signals might be decreased if the skin is not properly prepared.

4.5 Step 5: Connect the ECG Sensor and the ECG Electrode Patch (when using the ECG Electrode Patch)

NOTE: Do not connect the ECG Sensor and the Patch until after skin preparation. The ECG Sensor powers on and starts the recording within five (5) minutes after it has been connected to the Patch. Premature connection may therefore shorten the length of the recording time.

	1. Peel open the packaging and remove the Patch. 2. Always check the use by date on the packaging of the Patch before use. 3. Do not open the Patch packaging until the Patch is to be used. Otherwise, the adhesive material might dry.
	4. Place the ECG Sensor onto the blue plastic cradle of the Patch.
	5. Press down firmly as shown to snap the ECG Sensor in place. Ensure no gaps are visible between parts. You will hear several clicks.
	6. Once connected, a constant green light will appear followed by a flashing green light (for about 30 seconds) indicating the ECG Sensor is working. The recording will automatically start when the flashing green light stops.

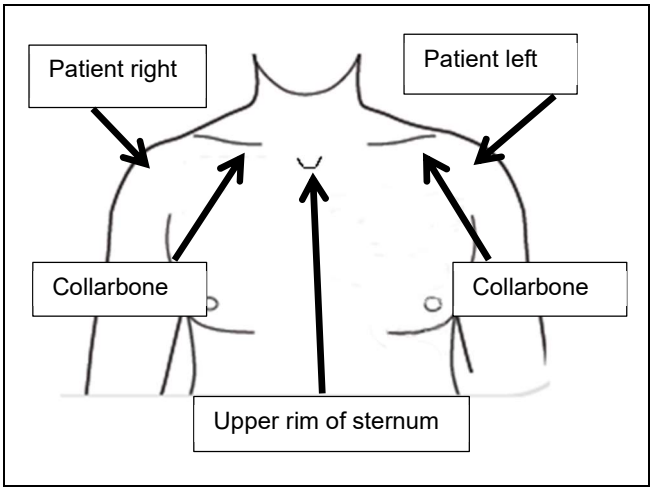
Correct- No Gap 	7. To avoid malfunction, visually inspect and make sure both parts are firmly connected with no gaps. **CAUTION:** If the ECG Sensor is not firmly connected to the Patch, it is not splash proof. This may cause ingress of liquids to the internal parts of the ECG Sensor which may result in electrical short circuiting and malfunction of the ECG Sensor.
Incorrect- Gap 	8. If gaps are visible between the ECG Sensor and the Patch, press the two items firmly together to close the gaps.

4.6 Step 6: Apply the ePatch ECG Sensor with ECG Electrode Patch (when using the ECG Electrode Patch)

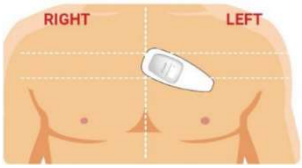
NOTE: Once the ECG Sensor is connected to the Patch, place on the chest as instructed. Avoid repositioning the Patch after the first skin contact. Repositioning may result in poor contact between the Patch and the skin. A poor contact could decrease the quality of the recorded ECG signals and a new recording might be required. If the Patch is not placed correctly, please start over with a new Patch.

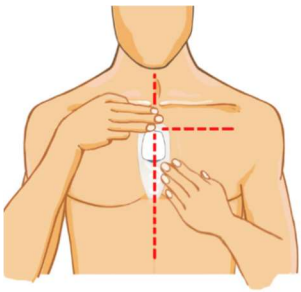
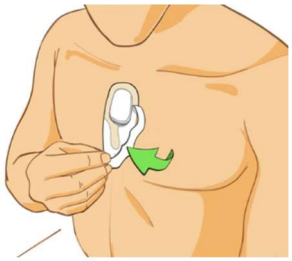
NOTE: Use the *Holter Symptom Event Diary* to record the Start Date and Start Time of the Sensor placement on the chest.

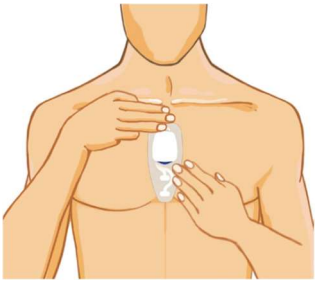
The ECG Sensor can be placed in two (2) different positions on the chest; a sternum position or a slanted position. The following diagrams illustrate the areas of the chest where it can be applied.



Follow the steps below to apply the ECG Sensor on the chest in either position:

	1. Hold the ECG Sensor with one hand. Peel off the transparent plastic back liner from the Patch with the other hand. This exposes the adhesive part of the Patch. **NOTE:** Do not touch the adhesive part of the Patch; doing so may reduce the Patch's ability to adhere to skin.
	**Option 1: ePatch ECG Sensor in slanted position** Apply the ECG Sensor to chest on a slight angle as shown in the illustration, by following these steps: 2. The top edge of the Patch should be three (3) finger widths down from the collarbone in the center of the chest. 3. The widest part of the Patch (near the ECG Sensor) should be closest to the center of the chest. 4. Press all sides of the Patch so it will adhere to the skin. **NOTE:** Wait one (1) minute before proceeding to the next step. This is important to ensure firm adhesion to the skin.

	**Option 2: ePatch ECG Sensor in sternum position** Apply the ECG Sensor to the chest in a vertical position as shown in the illustration, by following these steps (stretching the chest may assist): 2. The top edge of the Patch (near the ECG Sensor) should be three (3) finger widths down from the collarbone in the center of the chest. 3. The widest part of the Patch (near the ECG Sensor) should be closest to the center of the chest. 4. Press all sides of the Patch so it will adhere to the skin. **NOTE:** Wait one (1) minute before proceeding to the next step. This is important to ensure firm adhesion to the skin.
	5. Gently peel off the top white liner paper of the Patch by starting with the raised tab. 6. After the top liner is removed, press firmly around all of the edges of the Patch and on the ECG Sensor so that the Patch will firmly adhere to the skin.

	7. Smooth any wrinkles by pressing around the entire Patch. 8. The ECG Sensor is now correctly placed. The recording will automatically start when the flashing green light stops. The recording will stop after the predefined recording time has elapsed or when the ECG Sensor is removed from the Patch (please see Chapter 7).

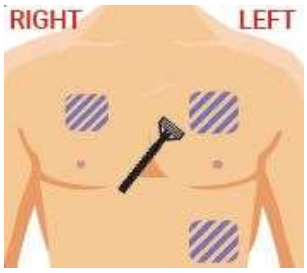
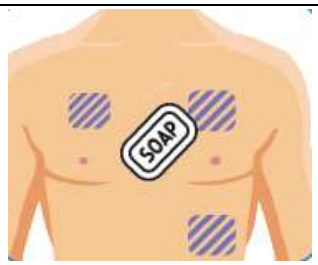
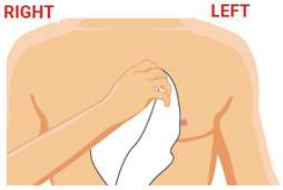
4.7 Step 7: ePatch ECG Sensor with Lead Wire Adapter Set-up (when using the Lead Wire Adapter)

NOTE: Do not connect the ECG Sensor and the LWA until after skin preparation. The ECG Sensor powers on and starts the recording within five (5) minutes after it has been connected to the LWA. Premature connection may therefore shorten the length of the recording time.

NOTE: Use the *Holter Symptom Event Diary* to record the Start Date and Start Time of the Sensor placement on the chest.

Prepare the skin

Expose the chest and prepare the skin according to the steps below:

	1. Determine the chest area needing to be prepared by referring to the diagram. If hair is on the chest, wash and shave the area where the electrodes will be placed.
	2. Clean the shaded areas with soap and water.
	3. Dry skin thoroughly using a towel.

	4. It is important to wait for a minimum of 2-3 minutes until the skin is completely dry before proceeding to the next step.

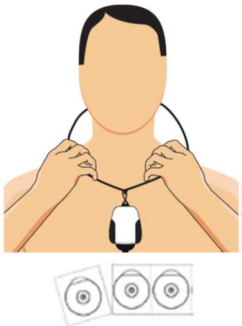
NOTE: Do not apply oils or lotions in the cleaned areas before attaching the electrodes to the skin. The quality of the ECG signals may be decreased if the skin is not properly prepared.

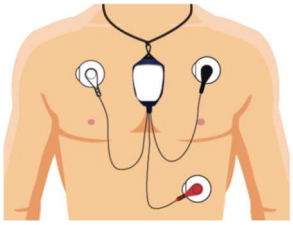
4.8 Step 8: Connect the ePatch ECG Sensor and the LWA (when using the Lead Wire Adapter)

	1. Push the ECG Sensor through the top of the LWA until it is firmly in place.
	2. After the ECG Sensor has been properly inserted into the LWA, a constant green light will appear followed by a flashing green light (for up to about 30 seconds) indicating the ECG Sensor is working. The recording will automatically start when the flashing green light stops.

4.9 Step 9: Attaching the LWA (when using the Lead Wire Adapter)

NOTE: Use the *Holter Symptom Event Diary* to record the Start Date and Start Time of the Sensor placement on the chest.

	1. Connect the lanyard to the LWA (if needed). 2. Place the lanyard over the head and around the neck. 3. Remove a packet of surface electrodes from the pack. 4. Peel open the packet and remove three (3) surface electrodes. 5. Snap each of the three (3) wires into the electrodes. 6. Leave the adhesive liner on the electrodes. **NOTE:** Refer to the information provided with the surface electrodes for replacement instructions.

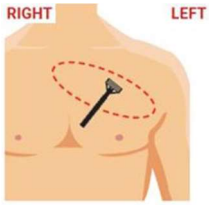
	7. Start with the **black lead**. Peel the adhesive liner off the back of the surface electrode and place the black electrode approximately three (3) fingers below the collarbone on the **left side** of the chest. 8. Next, attach the **white lead**. Peel the adhesive liner off the back of the surface electrode and place the white electrode approximately three (3) finger widths **below the collarbone on the right** side of the chest. 9. Lastly, place the **red lead**. Peel the adhesive liner off the back of the surface electrode and place the red electrode on the **lower rib on the left side** of the body. **NOTE:** When removing the adhesive liner, be careful not to touch the adhesive.
	10. The LWA is now correctly placed. The recording will automatically start when the flashing green light stops. The recording will stop after the predefined recording time or when the ECG Sensor is removed from the LWA.

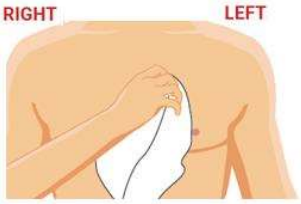
4.10 Step 10: ePatch ECG Sensor with Flex Adapter Set-up (when using the Flex Adapter)

NOTE: Do not connect the ECG Sensor and the Flex Adapter until after skin preparation. The ECG Sensor powers on and starts the recording within five (5) minutes after it has been connected to the Flex Adapter. Premature connection may therefore shorten the length of the recording time.

Prepare the skin

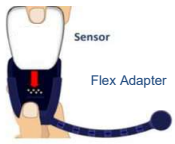
Expose the chest and prepare the skin according to the steps below

	1. Determine the chest area needing to be prepared by referring to the diagram. 2. If hair is on the chest, wash and shave the area where the electrodes will be placed.
	3. Clean the area with soap and water

	4. Dry skin thoroughly using a towel
	5. It is important to wait for a minimum of 2-3 minutes until the skin is completely dry before proceeding to the next step.

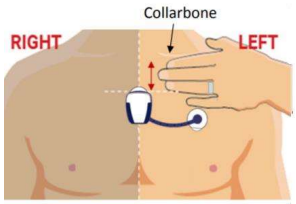
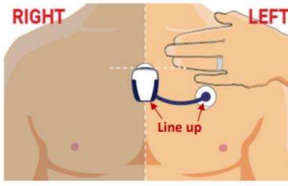
NOTE: Do not apply oils or lotions in the cleaned areas before attaching the electrodes to the skin. The quality of the ECG signals may be decreased if the skin is not properly prepared.

4.11 Step 11: Connect the ECG Sensor and the Flex Adapter (when using the Flex Adapter)

	1. Slide the ECG Sensor into the Flex Adapter. A green light on the ECG Sensor will flash briefly when the ECG Sensor is completely inserted.
	2. Once connected, a constant green light will appear followed by a flashing green light (for about 30 seconds) indicating the ECG Sensor is working.

4.12 Step 12: Attaching the Flex Adapter (when using the Flex Adapter)

	**Attaching the Surface Electrodes:** 1. Remove the surface electrode strip from the pouch and use the perforations to separate two (2) electrodes from the strip. Leave the adhesive backing on the electrodes. 2. While the electrodes are still on the adhesive backing, snap one (1) electrode into the connector on the back of the Flex Adapter and snap the other electrode on the connector on the back of the Flex Adapter lead. 3. Peel the adhesive backing off the back of the surface electrodes. When removing the adhesive backing, be careful not to touch the adhesive. **NOTE:** Refer to the information provided with the surface electrodes for replacement instructions.

	**Attach Flex Adapter and Flex Adapter Lead:** 4. Place the left hand on the left side of the chest so that the index finger is just below the collarbone. 5. Position the Flex Adapter so that it is lined up below the chin and three (3) finger widths below the collarbone. 6. Press the Flex Adapter firmly against the chest.
	7. Line up the second electrode so that the arm of the Flex Adapter lays flat against the chest and the button snap is lined up with the bottom of the Flex Adapter. Be careful not to straighten the arm. Keep a bend so it looks like a smile. 8. Press the second electrode firmly against the chest. 9. After the electrodes are on the body wait 10-15 minutes to allow the electrodes to fully adhere to the skin before proceeding to the next step.

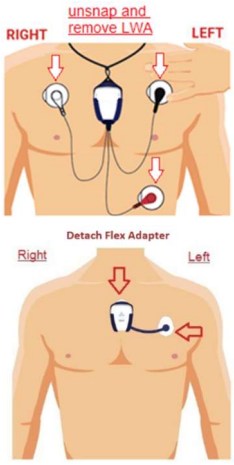
NOTE: Depending on configuration, the ECG Sensor in an LWA or Flex Adapter set-up can record for up to 14 continuous days on a full charge (1-channel at 256 Hz. See Annex 2). However, each surface electrode should be changed out in accordance with the information provided with the surface electrodes.

5 What to remember during recording and use

5.1 Showering

If the ePatch ECG Sensor is not firmly connected to the Patch, it is not splash proof. When the ECG Sensor is properly inserted into the Patch, water splashing against the enclosure from any direction will have no harmful effect. While showering, it is recommended to face away from the shower head and deflect any direct showering water from impinging on the ECG Sensor by shielding it away from the direct spray of the shower with a hand or a cloth.

Do not swim or submerge the ECG Sensor in water or liquids. The ECG Sensor is water resistant when combined with the Patch, but it is not waterproof.



For the LWA Set-up: The ECG Sensor is NOT water resistant when worn with the LWA; therefore, do not shower, bathe or swim while wearing the ECG Sensor in the LWA Set-up.

Before showering/bathing/swimming, unsnap the leads from the surface electrodes, remove the surface electrodes from the skin, remove LWA with ECG Sensor and set aside.

For the Flex Adapter Set-up: The ECG Sensor is NOT water resistant when worn with the Flex Adapter; therefore, do not bathe or swim while wearing the ECG Sensor in the Flex Adapter Set-up.

Before showering, unsnap the surface electrodes from the Flex Adapter, remove the surface electrodes from skin, and set aside the ECG Sensor and Flex Adapter.

CAUTION: *Do not swim while wearing the ePatch ECG Sensor device and ECG Electrode Patch/LWA/Flex Adapter. Do not submerge ePatch ECG Sensor in any form of liquid. Fully immersing may render the ECG Sensor inoperable, may cause recorded ECG data to be unreadable, or may affect proper functionality.*

5.2 After a shower

Patch Set-up: After taking a shower, always inspect the ECG Sensor to Patch connection, and adhesion of the Patch to the skin. If needed, replace Patch. Continued use of a damaged ECG Electrode Patch may affect quality of ECG measurements. Please follow the instructions in chapter 4, steps 3-5.

LWA Set-up: Reapply new surface electrodes and re-attach the lead wire. Please follow the instructions in Chapter 4, steps 6-8.

Flex Adapter Set-up: Reapply new surface electrodes and re-attach the Flex Adapter. Please follow the instructions in Chapter 4, steps 9-11.

5.3 Activities

Activities that result in excessive sweating might loosen the Patch, or cause gel to leak out. If this occurs, remove and replace the Patch by following instructions in Chapter 7 for removal, and in Chapter 4 for applying a new Patch.

5.4 Skin irritation

Minor discomfort, skin irritation, reddening, itching, or rash can occur by use of the ePatch ECG Sensor system. Any sign of severe skin irritation or allergy should be reported to the healthcare professional and closely monitored to avoid development of more serious reactions.

6 Perform an Event Marker

The healthcare professional may ask you to perform a digital event marker in the recorded ECG data file (if enabled). The digital event marker is an optional functionality that provides a means to mark an event with a timestamp if a health-related symptom is felt. The use of this functionality will not result in loss of data and will have no impact on the data monitoring function of the ePatch ECG Sensor.

6.1 How to perform an Event Marker

Double tap the middle of the ECG Sensor rapidly (two taps within one (1) second) and the status indicator on the ECG Sensor will show a constant green light for one (1) second.

6.2 When to perform an Event Marker

Examples of when an Event Marker can be performed:

- When feeling shortness of breath
- When feeling chest pain
- When feeling dizziness
- When feeling palpitations

Holter Symptom Event Diary

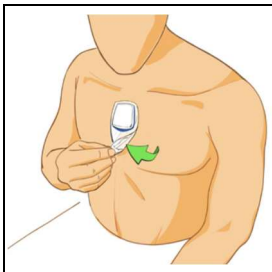
You may be asked to fill in a symptom event diary to record your activities and symptoms. Be sure to include the day and time that your monitoring period had started on the front page.

Whenever you experience a symptom, be sure to write the day and time of its occurrence in the Holter Symptom Event Diary.

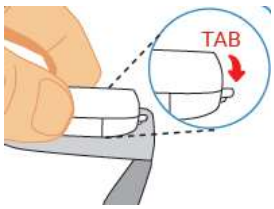
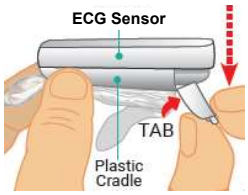
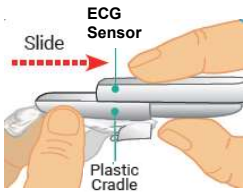
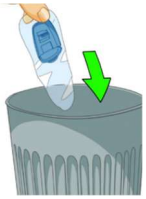
7 How to end the recording and transfer the data

The recording can be stopped at any time by separating the ECG Sensor from the Patch as described below (refer to Step 3 if using the LWA or Flex Adapter set-up). If the recording is not manually stopped, it will automatically stop after the predefined recording time has elapsed (the recording time depends on the configuration of the ECG Sensor, please see Annex 2).

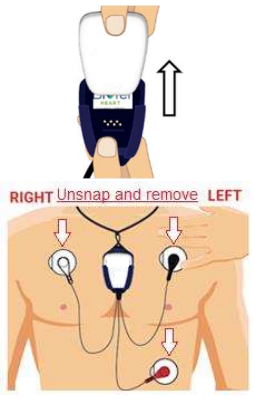
7.1 Step 1: Remove the ePatch ECG Sensor from the body

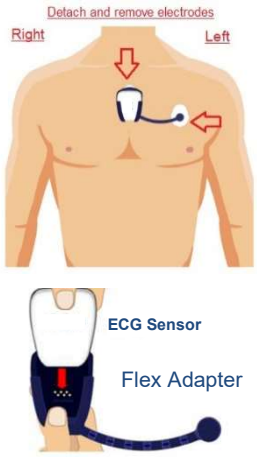
	**CAUTION:** Careless removal of the Patch may cause damage to the skin. 1. Firmly press the ECG Sensor with your fingers against the chest as shown with the green arrow. 2. With the other hand gently pull the clear adhesive material downwards and then outwards in a direction away from the body and the ECG Sensor. 3. Adhesive residue can be removed by washing the area with soap and water. **NOTE**: This motion will reduce the stress to the skin during the removal of the Patch.

7.2 Step 2: Separate the ECG Sensor from the Patch

	1. Hold Patch as shown. Fold the clear adhesive out of the way to locate the tab on the blue plastic cradle of the Patch. **NOTE**: Do not use a tool to separate the ECG Sensor from the Patch. This might damage the ECG Sensor. **NOTE**: Do not separate the ECG Sensor from the Patch while worn. This may cause damage to the skin.
	2. Apply downward pressure on the tab to snap it open. This will require some force.
	3. Hold down the blue plastic cradle and then gently push the ECG Sensor to slide off as shown. The ECG Sensor should slide off easily. 4. The ECG Sensor will now stop the recording automatically (unless recording has already stopped due to the predefined recording time having elapsed).
	5. The Patch is for single use only and is disposable. It should be handled as normal waste and disposed of in accordance with the instructions provided by the healthcare professional. **Note:** The ECG Sensor is reusable and should not be discarded.

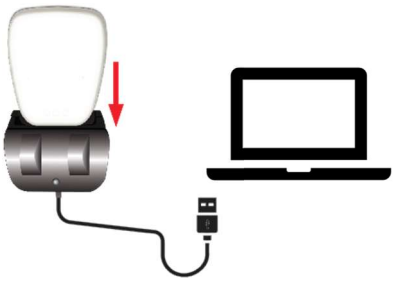
7.3 Step 3: Remove the Lead Wire Adapter (LWA) or Flex Adapter

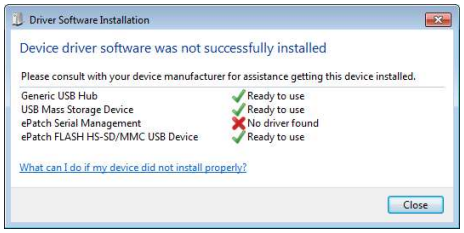
	**LWA (If used)** 1. Gently push the ECG Sensor out from the Lead Wire Adapter and gently remove leads and electrodes from the body.

	**Flex Adapter (If used)** 1. Unsnap both the Flex Adapter and the Flex Adapter lead from the surface electrodes and gently remove the electrodes from the body. 2. Slide out the ECG Sensor from the Flex Adapter.

7.4 Step 4: Transfer the ECG recording to a computer

NOTE: The information in this section is for use by healthcare professionals.

 The Sensor's serial number	1. Make note of the serial number of the ECG Sensor, which is found on the back of the ECG Sensor The recording is stored on the ECG Sensor in an EFS-format (ePatch File System). The EFS file name holds the ECG Sensor serial number.
	2. Clean and disinfect the Sensor. Follow the instructions in Chapter**Error! Reference source not found.**. 3. Slide the ECG Sensor into the Charge Adapter 4. Connect the USB side of the Charge Adapter to a USB port of a computer. 5. The charging indicator on the ECG Sensor will now indicate the battery status with constant or flashing white light (please see Chapter 2). **Note:** If a red status indicator on the ECG Sensor is lit, follow instructions in Troubleshooting, Chapter 8.



6. When initially connected, the computer's operating system may need to install drivers to access the ECG Sensor as a USB Mass Storage Device. Please allow up to 5 minutes for the installation of the drivers.

   If after waiting 5 minutes the ECG Sensor remains inaccessible as a USB Mass Storage Device, follow instructions in Troubleshooting section, Chapter 8.

   In certain occasions, an error message may pop up, like the one shown, which you can close. You will still have access to the data even if not all drivers are installed.

NOTE: Please note that as long as the USB Mass Storage Device is accessible, it should be possible to transfer the recording to a computer.

7. Open Windows Explorer or similar.

8. Open the ECG Sensor drive.

9. Check the file's Date Modified. If it does not match the year of the patient hookup, do not use this Sensor for the next patient. The ECG data file created can be used to generate a patient report. However, do not assign or reuse this Sensor for another patient, as it must be reset to ensure accurate time and date capture.

NOTE: Make sure that the patient's diary has the start date and start time of sensor placement on the chest.

10. Copy or move the recorded ECG data file (.EFS) to the desired location on the computer.

    Note: Ensure that all data is copied and deleted from the ECG Sensor before the ECG Sensor is re-used for a new recording.

7.5 Data Privacy & Security

The data stored on the ePatch ECG Sensor are pseudo-anonymized measurements that are used to generate an ECG waveform for the purpose of retrospective diagnosis of ECG arrhythmias.

Additional data protection measures, up to and including encryption, may be enabled as required by local privacy laws.

For any questions, please contact Braemar Manufacturing, LLC.

7.6 Returning the Sensor and Holter Symptom Event Diary

NOTE: The information in this section is to be used by patients/caregivers

Return the Sensor and Holter Symptom Event Diary to your healthcare professional or mail back items in the box and return bag as provided in your kit.

8 Troubleshooting

If this section does not help to resolve the issue experienced, the ECG Sensor or the accessories may have a malfunction that prevents normal operations. Do not use an ECG Sensor or any accessories that may have a malfunction. Instead, please contact Braemar Manufacturing LLC. and specify the problem. Note that it may be difficult to see the charging indicator and the status indicator LEDs if the ECG Sensor is placed in direct sunlight.

Issue	Solution
The ECG Sensor shows a constant red light when it is connected to an electrode or a power source	If you are a patient experiencing this issue, call your healthcare professional or Braemar Manufacturing LLC. If you are a healthcare professional, follow these steps: - If connected to a Charge Adapter, then disconnect and reconnect. If it continues to fail, change the Charge Adapter - If connected to an ECG Electrode Patch, then replace the electrode (see Chapter 2). - If connected to either a Flex Adapter or LWA accessory, then remove the ECG Sensor and reconnect to the electrode (see Chapter 2). - If red light persists, contact Braemar Manufacturing LLC. for Customer Support.

Issue	Solution
The ECG Sensor shows a flashing red light when it is connected to an electrode	If you are a patient experiencing this issue, call your healthcare professional or Braemar Manufacturing LLC. If you are a healthcare professional, follow these steps: - Connect the ECG Sensor to a computer using a Charge Adapter and ensure that all .EFS files are deleted from the ECG Sensor (see Chapter 7).
The charging indicator (white light) is not turned on when the ECG Sensor is connected to a power source	- Ensure that the Charge Adapter is firmly connected to both the ECG Sensor and the power source (see Chapter 2). - If the ECG Sensor is fully discharged, it may take several minutes before the charging indicator turns on. Allow the ECG Sensor to recharge for 5 – 10 minutes at least before checking.
The ECG Sensor drive is not visible on the computer	- Disconnect the ECG Sensor in Charge Adapter from the computer. - Re-connect the ECG Sensor in Charge Adapter to the computer. Make sure that the Charge Adapter USB cable is firmly connected to both the ECG Sensor on one end and the USB port of the computer on the other. - If the ECG Sensor has fully discharged, it may take several minutes before the ECG Sensor drive appears on the computer. Allow the ECG Sensor to recharge for 5 – 10 minutes at least before checking.
The ECG Sensor does not show a green light when it is connected to an ECG Electrode Patch or Lead Wire Adapter	If you are a patient experiencing this issue: - Ensure that the ECG Sensor is correctly connected to a compatible ECG Electrode Patch or LWA (See Chapter 4). - If persists, contact your healthcare professional or Braemar Manufacturing LLC. If you are a healthcare professional, follow these steps: - Ensure that the ECG Sensor is correctly connected to a compatible ECG Electrode Patch or LWA (See Chapter 4). - Ensure that the ECG Sensor is fully charged (see Chapter 4). **NOTE:** Remember that the flashing green light stops automatically once the recording starts (up to five (5) minutes after the ECG Sensor and the ECG Electrode Patch or LWA were connected).

Issue	Solution
The ECG Sensor does not show a green light to acknowledge the marking of an event	- The green light turns on briefly for one (1) second when receiving an event marking. When marking an event, look closely at the ECG Sensor (preferably in front of a mirror) to ensure that the green light is seen. - Try double-tapping again with a higher tapping frequency. You should tap it twice within one (1) second. - Try double-tapping again with increased firmness. - If using a Patch, ensure that the ECG Sensor is firmly connected to the Patch with no gaps. - If using a LWA, ensure that the ECG Sensor is firmly in place. - If using a Flex Adapter, ensure that the ECG Sensor is completely inserted. - If it is still not possible to mark an event, the ECG Sensor may have stopped recording due to the predefined recording time having elapsed, or the event marker function may have been disabled in the ECG Sensor.
Irritated or reddened skin	- You may be experiencing an allergic reaction to the adhesive of the Patch. If you experience irritation worse than minor itching, contact your healthcare professional.
Patch comes loose from skin	- Stick the Patch back on your skin by pressing down the adhesive edges. - If that does not work, contact your healthcare professional, you may need to replace the Patch.
Gel leaking out of Patch	- Remove the Patch by following instructions in Chapter 7 for removal. - Place new Patch by following instructions in Chapter 4 for applying a new Patch.

9 Cleaning, Disinfection, Maintenance, and Disposal

NOTE: The information in this section is to be used by healthcare professionals processing Sensors for use on the next patient.

Do not reuse single use accessories.

9.1 Cleaning & Disinfection Before/After Patient Use

NOTE: Follow the instructions described in this section to clean and disinfect the ECG Sensor in the following situations, in order to prevent cross contamination:

- After use of the Sensor on a patient.
- Prior to placing the Sensor in a Charge Adapter (make sure Sensor is visibly dry before placement in a Charge Adapter).
- Prior to use of the Sensor on the next patient to prevent cross contamination.

NOTE: Wear protective gloves when handling Sensors returned from patients, during cleaning and disinfection.

Step 1: Prepare Sensor

Separate the Sensor from any ECG Electrode accessory (Patch blue cradle, Lead Wire Adapter or Flex Adapter), or remove the Sensor from the Charge Adapter.

Step 2: Remove Debris and Clean

1. Examine the Sensor enclosure looking for any visible residue, debris, stains, discoloration or marks on the Sensor. Pay close attention to the crevices at the edges of electrical contact, inside corners of the back case ribs, and any areas of the Sensor where debris may accumulate such as the blue seal area (refer to images a, b and c below in Step 3).

2. If you notice any visible residue, debris, stains, discoloration or marks on the Sensor, remove those with an acetone-free cleaning agent such as Medline Adhesive Remover Pads (not supplied with the Sensor). If still present, use a combination of an acetone-free cleaning agent, a latex free erase, and/or a plastic razor blade (not supplied with the Sensor).

3. Rub the entire Sensor enclosure with a prepared 70% Isopropyl Alcohol (IPA) solution (not supplied with the Sensor). Pay close attention to the Sensor's blue seal (refer to image c below) and wipe it entirely. You may use any of these application forms:
    a. A wipe saturated in 70% IPA but not dripping
    b. A dampened soft cloth saturated in 70% IPA but not dripping
    c. Directly spray the Sensor with 70% IPA mist and use a clean, soft cloth to wipe

4. Visually inspect the Sensor for residue, debris, stains, discoloration or marks. If any are visible, repeat the steps in this section as necessary.

Step 3: Disinfect the Sensor

1. Apply 70% IPA on the Sensor by using:
   - A new wipe saturated in 70% IPA but not dripping
   - A new dampened soft cloth saturated in 70% IPA but not dripping
   - Directly spray the Sensor with 70% IPA mist
2. Wipe down the entire Sensor enclosure. Pay close attention to the Sensor's blue seal (refer to image c below) and wipe it entirely.
3. Ensure the entire Sensor enclosure remains visibly wet with 70% IPA for **4 minutes** by applying additional prepared wipes, dampened cloths or applying a liquid spray mist of 70% IPA.
4. The Sensor must be dry before further processing.

		
a. Crevices at the edges of electrical contacts example	b. Inside corners of the Back Case ribs example	c. Blue seal example

Step 4: Inspect the Sensor

1. If the Sensor has damage, it cannot be reused. Sensor damage may include the following:
   - Labeling that is not clear or legible
   - Visible contamination on the Sensor enclosure
   - Cracked or chipped Sensor enclosure
   - Damaged blue seal
   - Corroded or damaged electrical contacts.
2. If the above damage is observed, contact Braemar Manufacturing, LLC. or Customer Support.

9.2 Maintenance

There are no serviceable parts on the ECG Sensor or on its compatible accessories and components.

9.2.1 Preventative Maintenance

Check periodically that the ECG Sensor and its compatible accessories and components are not broken, have no external damage, and that the performance is acceptable (i.e., length of recording has not diminished from a fully charged battery).

If issues are detected that cannot be resolved, please contact Braemar Manufacturing LLC. or Customer Support.

During transportation, storage, and between uses, it is recommended to store the ECG Sensor, the Charge Adapter, and the AC Adapter in the provided packaging.

Only use the ECG Sensor with compatible accessories supplied by the manufacturer.

9.2.2 Corrective Maintenance

If the ECG Sensor presents an issue that prevents normal operation and that cannot be solved after consulting the Troubleshooting section (Chapter 8), please contact Braemar Manufacturing LLC. or Customer Support, and specify the type of problem.

9.3 Calibration

The ECG Sensor and its compatible accessories and components do not require calibration.

9.4 Disposal

The ECG Sensor is reusable and should be returned by the patient at the conclusion of the predefined recording time to the prescribing physician, or by mailing back the Sensor in its box and return bag as provided in the kit.

For disposal instructions for a specific accessory, refer to the accessory IFU (see Chapter 3 for list of accessories).

9.5 Disposal of Electrical and Electronic Devices

Never dispose of the ECG Sensor, the Charge Adapter or the AC Adapter in the household trash. It must be disposed of properly and may need to be recycled in accordance with the statutory requirements in your area.

10 Specifications, compliance, and symbols

10.1 Specifications

10.1.1 ePatch ECG Sensor

Device classification (EN 60601-1) Class:	Internally Powered, Type BF applied parts, not protected against defibrillator, no functional earth terminal
Data acquisition:	1, 2, or 3 channels ECG, Event Marker [a]
Recording time:	Up to 14 days [b] (the recording time is configurable by manufacturer)
Sampling rate:	128, 256, 512, or 1024 Hz [a]
Resolution:	12 bit or 16 bit, depending on customer preference
Frequency response:	0.05 to 55Hz
Input range ECG Channels:	180 mV (Peak-to-Valley) CMRR (common mode rejection ratio): >60 dB @ 50/60 Hz
Input impedance:	10 MΩ
Connections:	1 ePatch Specific 8-Terminals Connector for connection to a compatible accessory
Storage medium:	2 GB internal storage
Maximum data file size:	2 GB EFS-file (ePatch File System)
Expected service life:	Minimum 300 uses or two years whichever one comes first

[a] The number of recorded ECG channels and the sampling frequency depends on the configuration of the ECG Sensor. Note that not all combinations of channels and sampling frequencies are possible.

[b] The maximum recording time for a configuration with one ECG channel and a sampling frequency of 256Hz is 14 days but other configurations are possible, if configured, see Annex 2.

The maximum possible recording time is increased when the number of recorded ECG channels and/or the sampling frequency is decreased. Likewise, the maximum possible recording time is decreased when the number of recorded ECG channels and/or the sampling frequency is increased. See Annex 2 for recording times for various configurations. Note that the recording time of the ECG Sensor may be configured to be less than the maximum possible recording time.

10.1.2 Battery (ECG Sensor)

The ECG Sensor is powered by an integrated battery with the following specifications. The battery is not replaceable.

Type:	Rechargeable lithium-ion battery
Battery capacity:	500 mAh (Nominal)
Battery life:	300 charge cycles
Maximum charge current:	500 mA

Charging the ECG Sensor should only be performed using the Charge Adapter and AC Adapter, or via a computer using the Charge Adapter connected to a USB port. Use of other charging devices may damage the ECG Sensor and/or the accessories.

NOTE: During periods of extended storage, fully charge the ECG Sensor once every 12 months.

10.1.3 Dimensions and weight (ECG Sensor)

Dimensions (W x H x D):	40 x 49 x 12 mm
Weight:	20 g

10.1.4 Environmental Conditions and Device Life (ECG Sensor)

Enclosure protection degree:	IP24 (when the ECG Sensor is firmly connected to a compatible Patch/ electrode)

Operating conditions:

Temperature:	+5°C to +40°C
Pressure:	700 – 1060 hPa
Relative Humidity:	15% - 90% (non-condensation)

Transport and Storage conditions (including between uses):

Temperature:	-25°C to +50°C
Relative Humidity:	15% - 93% (non-condensation)
Device Life:	Non-perishable, battery charge level to be maintained.

CAUTION: Exceeding the recommended operating, storage, and transportation conditions may result in reduction of the performance of the ECG Sensor and/or accessories.

NOTE: For environmental conditions for the compatible accessories, refer to the instructions for use specific to the accessory:

Accessory	**Part Number**
Patch ECG Electrode (40 count box)	02-01615
Lead Wire Adapter	02-00139
Flex Adapter	02-00143

10.1.5 System requirements

The ECG Sensor requires a standard computer with the following minimum specifications to read out the recorded data:

- Microsoft® Windows 10 or Mac OS X 10.7 by Apple Inc.
- 1.5 GHz processor
- 512 MB RAM
- USB 2.0 port for connection of the ECG Sensor to a computer using the Charge Adapter
- 1 GB of free hard-drive space

10.2 Compatible accessories and components

The ECG Sensor is used in combination with the following accessories and components:

- Accessories
    - ECG Electrode Patch
    - Lead Wire Adapter
    - Flex Adapter
- Components
    - Charge Adapter
    - AC Adapter (USB 5.0 VDC, minimum 500 mA)

10.3 Glossary of Symbols

Symbol	Description
 ISO 60417-5333	Type BF Applied Part
 ISO 7000-3500	Electronic instructions for use
 ISO 7010-M002	Refer to instruction manual
 ISO 7000-0626	Protect from moisture
℞ only 21 CFR 801.109	Prescription use only (U.S. Federal Law)
REF ISO 7000-2493	Catalogue number
 ISO 7000-3082	Manufacturer
 ISO 60417-6414	WEEE (Waste Electrical and Electronic Equipment) Directive (2002/96/EC)
SN ISO 7000-2498	Serial number
 IEC 62570	MR Unsafe

Annex 1 Electromagnetic compatibility

Table 1 – Guidance and Manufacturer's declaration – electromagnetic emissions – for all Medical Electrical equipment and Medical Electrical systems.

Guidance and manufacturer's declaration - electromagnetic emissions		
The ECG Sensor is intended for use in the electromagnetic environment specified below. The customer or the user of the ECG Sensor should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The ECG Sensor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ECG Sensor is suitable for use in all establishments. Including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	ECG Sensor with charger was tested and is compliant.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	ECG Sensor with charger was tested and is compliant.

Table 2 – Guidance and manufacturer's declaration – electromagnetic immunity – for all Medical Electrical equipment and Medical Electrical systems.

Guidance and manufacturer's declaration - electromagnetic immunity			
The ECG Sensor is intended for use within the limits of the electromagnetic environment described below. The customer or the user of the ECG Sensor should ensure that it is used in such an environment			
IMMUNITY test	**EN/IEC 60601-1-2 4th Test Levels**	**Compliance Level**	**Electromagnetic environment- guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	**Test level:** ± 8 kV contact **Test level:** ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 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%.
Electrical fast transient/burst IEC 61000-4-4	**Test level:** ± 2 kV for power supply lines **Test level:** ±1 kV for input/output lines **Frequency:** 100 kHz	± 2 kV for power supply lines	Device is battery operated during normal use. While charging and connected to an AC/DC adapter, compliance is met by use of a UL marked AC/DC adapter.
Surge IEC 61000-4-5	**Test level:** ± 1 kV line(s) to line(s) **Test level:** ±2 kV line(s) to earth	± 1 kV line(s) to line(s)	Device is battery operated during normal use. While charging and connected to an AC/DC adapter, compliance is met by use of a UL marked AC/DC adapter.
IEC 61000-4-11 Voltage dips	**Test level:** 0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Device is battery operated during normal use. While charging and connected to an AC/DC adapter, compliance is met by use of a UL marked AC/DC adapter.
	Test level: 0 % *U*T; 1 cycle and 70 % *U*T; 25/30 cycles Single phase: at 0°	0 % *U*T; 1 cycle and 70 % *U*T; 25/30 cycles Single phase: at 0°	
IEC 61000-4-11 Voltage Interruptions	**Test level:** 0 % *U*T; 250/300 cycle	0 % *U*T; 250/300 cycle	

Power frequency magnetic field IEC 61000-4-8	**Frequency:** 50/60 Hz **Continuous Field:** 30 A/m	30 A/m 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home, commercial or hospital environment.
Proximity to Magnetic Fields IEC 61000-4-39	**Frequency:** 30kHz, continuous wave **Frequency:** 134.2kHz, pulse modulation 2.1kHz **Frequency:** 13.56MHz, pulse modulation 50kHz	8 A/m 65 A/m, 50% duty cycle square wave 7.5 A/m, 50% duty cycle square wave	Proximity to magnetic fields should be at levels characteristic of a typical location in a typical home, commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level			

Table 3 – Guidance and manufacturer's declaration – electromagnetic immunity – for all Medical Electrical equipment and Medical Electrical systems that are not life-supporting.

Guidance and manufacturer's declaration - electromagnetic immunity			
The ECG Sensor is intended for use within the limits of the electromagnetic environment described below. The customer or the user of the ECG Sensor should ensure that it is used in such an environment.			
IMMUNITY test	**EN/IEC 60601-1-2 TEST LEVEL**	**Compliance level**	**Electromagnetic environment-guidance**
Portable and mobile RF communications equipment should be used no closer to any part of the ECG Sensor including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Conducted RF IEC 61000-4-6	**Field Strength** 3 Vrms (outside ISM) & 6 Vrms (in ISM band [c]) **Frequency Range:** 150 kHz to 80 MHz **Modulation** AM 80%, Sinusoidal 2Hz	V1 = 3V V2 = 6 V	**Recommended separation distance** $d = [3.5 / V1]\sqrt{P}$ $d = [12/V2]\sqrt{P}$
Radiated RF IEC 61000-4-3	**Frequency Range:** 80 MHz-1000 MHz, 1 GHz-2.7 GHz **Field Strength:** 10 V/m **Modulation:** AM 80%, Sinusoidal 2Hz	E1 = 10 V/m	**Recommended separation distance** $d = [3.5 / E1]\sqrt{P}$ 80 MHz to 800 MHz $d = [7 / E1]\sqrt{P}$ 800 MHz to 2.7 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) [d]. 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 Hz 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 [ME EQUIPMENT or ME SYSTEM] is used exceeds the applicable RF compliance level above, the [ME EQUIPMENT or ME 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 [ME EQUIPMENT or ME SYSTEM] [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m. [c] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to			

13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

[d] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges

Table 4: Immunity to proximity fields from RF Wireless communications equipment

Clause 8.10 IEC 60601-1-2:2014				
Test Frequency (MHz)	**Band[i] (MHz)**	**Service[1]**	**Immunity Test Level (V/m)**	**Note**
385	380 to 390	TETRA 400	27	WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ECG Sensor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
450	430 to 470	GMRS 460, FRS 460	28	
710, 745, 780	704 to 787	LTE Band 13, 17	9	
810, 870, 930	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	28	
1720, 1845,1970	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	28	
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	28	
5240, 5500, 5785	5100 to 5800	WLAN 802.11 a/n	9	

[1] For some services, only the uplink frequencies are included.

Susceptibility to Common EM Emitters

Performance of the ECG Sensor may degrade if used in proximity to equipment where high intensity EM DISTURBANCES is expected like HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging where the intensity of EM disturbance is high.

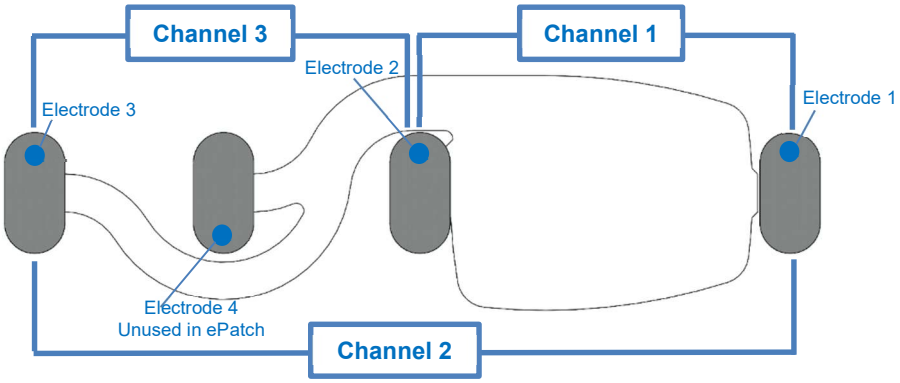
If the ECG Sensor is used in an environment with high EM DISTURBANCE there could be deterioration of measured or recorded ECG signal quality, device malfunction, or other unexpected behavior.

Annex 2 Recording time

Maximum possible recording time at different ECG Sensor configurations			
The maximum possible recording time is a function of battery life and storage capacity. Recording time is increased when the number of recorded ECG channels and/or the sampling frequency is decreased. Likewise, the maximum possible recording time is decreased when the number of recorded ECG channels and/or the sampling frequency is increased. Note that the recording time of the ECG Sensor might be configured to be less than the maximum possible recording time			
Sample frequency	**1 channel**	**2 channels**	**3 channels**
128 Hz	14 days	11 days	9 days
256 Hz	14 days	8 days	6 days
512 Hz	8 days	6 days	Configuration not available
1024 Hz	5 days	Configuration not available	Configuration not available

Annex 3 Electrode Configuration

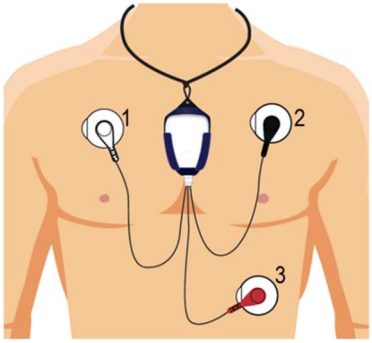
ECG Electrode Patch Configuration



Example configuration for a 3-channel recording

The Patch has three (3) active electrodes and channels can be created between electrodes 1, 2 or 3 in any combination.

Lead Wire Adapter Configuration



The Lead Wire Adapter utilizes three (3) electrodes. Channel 1 is formed by the white electrode (1 Right Arm) and black electrode (2 Left Arm), Channel 2 is formed by the white electrode (1 Right Arm) and the red electrode (3 Lower Left) and Channel 3 is formed by the black electrode (2 Left Arm) and the red electrode (3 Lower Left).

Electrode 1 is the common electrode to channel 1 and channel 2.

Flex Adapter Configuration

The Flex Adapter utilizes two electrodes. Channels 1 and 2 are formed by Electrodes 1 and 2. Channel 1 and channel 2 are connected in parallel.

Electrode 1 is the common electrode to channel 1 and channel 2.