

# Flex Electrode Accessory for ECG Diagnostic Devices



ENGLISH  
Instruction Manual



*Read this manual before use. Keep it for future reference.*

Thank you for purchasing the Flex Electrode Accessory for Arrhythmia Diagnostic Devices.

## **Rx only**

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

The Flex Electrode is an accessory to compatible ECG diagnostic devices such as the ePatch® 2.0 or BTPS-1000 (Mobile Cardiac Outpatient Telemetry). Table 1 provides the Flex Electrode covered by this manual. For more information regarding the compatible ECG diagnostic device, refer to the device specific IFU.

## **Manufacturer**



Braemar Manufacturing LLC.  
1285 Corporate Center Drive  
Suite 150  
Eagan, MN 55121  
USA

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## Disclaimer

Braemar is only responsible for the security, reliability, and performance of this accessory if:

- The place where the accessory is used meets the requirements for electrical installations IEC and other applicable regulations
- All repairs, revisions, or modifications, both in and out of the warranty period, are made by technical staff of Braemar
- The accessory is used in accordance with the recommendations stated in this Instruction Manual

Product layout and information in this Instruction Manual may change without notice. The manufacturer assumes no responsibilities for errors that may appear in this manual.

**IMPORTANT:** This accessory has been designed for maximum safety. All of the operating instructions should be read before using the accessory with the appropriate device. Failure to do so may result in injuries to the user or the patient and damage to the device and/or the accessory.

**IMPORTANT:** The choice to accept and use the accessory with the appropriate device is the responsibility of the medical professional. The medical professional should consider the symptoms presented by the patient before using the accessory.

**IMPORTANT:** The accessory is not provided with physiological-type alarms, do not maintain and do not help to maintain the life of the patient. The patient must therefore be instructed by the medical professional to react on any health symptoms that may arise, as he would do if he was not using the accessory.

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# 1 Indications for use, contraindications, warnings, and precautions

Please read this chapter carefully before you use the Flex Electrode with a compatible ECG diagnostic device. In case of doubts, unexpected events, or complaints, please contact your distributor.

## 1.1 Indications for use

The Flex Electrode is indicated for use in conjunction with a compatible ECG diagnostic device. Refer to Table 1 below for a list of compatible ECG diagnostic devices.

**Table 1: Device Compatibility**

Product Name	Part Number	Compatible ECG Diagnostic Device
Flex Electrode	02-01576	ePatch® 2.0
		Braemar Telemetry Patch System (BTPS-1000)

## 1.2 Limitations in Use and Contraindications


The Flex Electrode is not intended for use in the following cases:

- Patients with known allergies to adhesive materials or hydrogel.
- Flex Electrode should not be placed on broken, damaged, or irritated skin.

### R<sub>x</sub> only

**Caution:** U.S. Federal law restricts this device to sale by or on the order of a physician.

## 1.3 Warnings

	<p>The accessory should be kept away from infants and small children due to the following potential hazards:</p> <ul style="list-style-type: none"> <li>- Cords can be a strangulation hazard to infants and children, keep cords away from infants and children.</li> <li>- Small components which may fit in the mouth may be a choking hazard.</li> </ul>
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## 1.4 Precautions

<p><b>Use only Manufacturer Approved Accessories</b></p> <ul style="list-style-type: none"> <li>- Always use the Flex Electrode together with a compatible ECG diagnostic device (Refer to Table 1) that is supplied by the manufacturer.</li> <li>- Do not use accessories other than the ones provided or replaced from the manufacturer.</li> <li>- Usage of accessories other than the ones provided may result in increased Radio Frequency (RF) emissions or decreased immunity to electromagnetic interference of the system.</li> </ul>
<p><b>Connection to Components</b></p> <ul style="list-style-type: none"> <li>- Only connect the components as described in this manual. Never connect the accessory to any external electrical item other than the compatible ECG diagnostic device.</li> </ul>
<p><b>Do not Tamper with Device</b></p> <ul style="list-style-type: none"> <li>- Do not use accessory if package is tampered or defective.</li> <li>- There are no serviceable parts in the accessory.</li> <li>- Disassembling the accessory described in this instruction will void warranty and may alter performance.</li> </ul>
<p><b>Single Use/Multiple Uses</b></p> <ul style="list-style-type: none"> <li>- The off-the-shelf surface electrodes (electrodes) are a single use item; do not reuse the electrodes. The Flex Electrode is reusable and should be returned to the provider at the end of your monitoring period.</li> </ul>
<p><b>Patch Storage Temperature and Shelf Life</b></p> <ul style="list-style-type: none"> <li>- For off-the-shelf electrodes, refer to the instructions provided by the original manufacturer.</li> </ul>

## 2 Flex Electrode Configuration

### 2.1 Flex Electrode

The Flex Electrode has 2 electrodes which connect to the off-the-shelf surface electrodes. Refer to Table I for the list of compatible ECG diagnostic devices. See Annex 1 for channels and configurations.



### 2.2 Electrodes (later termed off-the-shelf surface electrodes, off-the-shelf electrodes or surface electrodes)

The surface electrodes are for single use only and must be disposed of and replaced, generally recommended after 2 days of wear.



Example of surface electrodes.

### 3 Flex Electrode Set-up

#### 3.1 Proper Placement and Preparing the Skin:

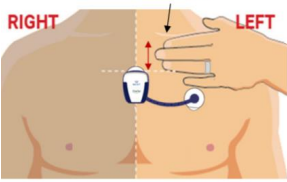
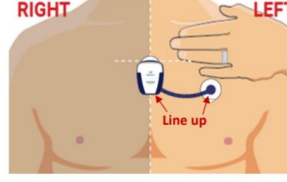
Wash/Shave:	
	<p>It is important to prepare your skin before getting started. If needed, shave the area where the Flex Electrode will be placed using the razor supplied in the Skin Prep Pack.</p>
	<p>Wash the area with soap and water and dry thoroughly with a towel. Do not apply lotions or oils.</p>
	<p>Dry skin thoroughly using a towel.</p>

#### 3.2 Connecting the sensor and the Flex Electrode:

Follow the compatible device instructions (See Table 1) for connecting the sensor to the Flex Electrode.

#### 3.3 Attaching the Electrodes/Flex Electrode:

	<p>Remove the surface electrode strip from the pouch and use the perforations to separate two surface electrodes from the strip. Leave the plastic backing on the surface electrodes.</p>
	<p>While the surface electrodes are still on the plastic backing, snap the surface electrodes into the connector on the back of the Flex Electrode and lead.</p>
	<p>When you remove the plastic backing, be careful not to touch the adhesive.</p> <p>NOTE: The surface electrodes should be changed out every other day.</p>

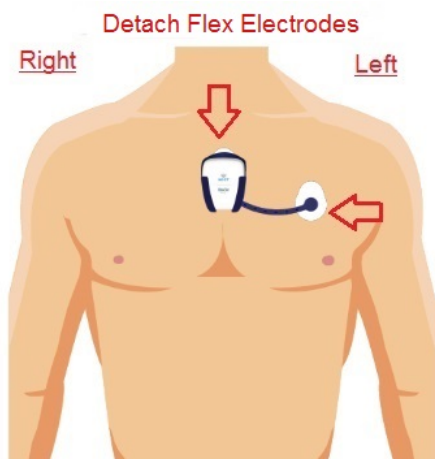
	<p>Place your left hand on the left side of your chest so that your index finger is just below the collarbone.</p> <p>Position the Flex Electrode so that it is lined up with your chin and three finger widths below your collarbone.</p> <p>Press the Flex Electrode firmly against your chest.</p>
	<p>Line up the second electrode so that the arm lays flat against your chest and the button snap is lined up with the bottom of the Flex Electrode. Be careful not to straighten the arm. Keep a bend so it looks like a smile.</p> <p>Press the second electrode firmly against your chest.</p> <p>After the electrodes are on your body wait 10-15 minutes to allow the electrodes to fully adhere to your skin before proceeding to the next step.</p>

**NOTE:** Each disposable electrode can only be worn for up to 2 days and is then recommended to be replaced.

## 4 What to remember during use?

### 4.1 Showering

The Flex Electrode is **NOT** water-resistant; therefore, swimming or bathing should be avoided. Remove the Flex Electrode (and the sensor) before showering by unsnapping the leads from the Flex Electrode, remove the Flex Electrode from the body and set aside. You can shower with the surface electrodes on as they are water-resistant. Shower normally.



### 4.2 Activities

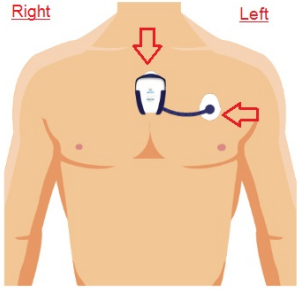
Activities that result in excessive sweating might decrease the adhesive property of the surface electrodes. If surface electrodes become loose, replace by following instructions in chapter 5 for removal and chapter 3, for applying new surface electrodes.

### 4.3 Skin Irritation

Minor discomfort is expected when the Flex Electrode is attached to the skin. The materials selected for the Flex Electrode are biocompatible and are purposed for this use. However, if skin irritation does occur and becomes uncomfortable for continued use then remove the Flex Electrode and contact your medical practitioner or Customer Service department.



## 5 How to remove the accessory

<p>Detach and remove electrodes</p> <p>Right Left</p> 	<p>Unsnap both the Flex Electrode device and the lead and gently remove the electrodes from the body.</p> <p>To remove the sensor from the Flex Electrode, refer to the instructions provided with the compatible ECG diagnostic device.</p>
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## 6 Troubleshooting

**CAUTION:** If this guide does not help to solve your problem, the accessory might have a malfunction that prevents normal operation. Do not use any accessory that might have a malfunction. Instead, please contact your distributor and specify the problem.

What's wrong?	How to fix it?
Irritated or reddened skin	You may be experiencing an allergic reaction to the electrodes of the Flex Electrode. If you experience irritation worse than minor itching, call your prescribing physician.
Electrode comes loose from skin	Replace electrode(s) with new ones and place on the body in a slightly different location.

## 7 Cleaning, maintenance, and disposal

### 7.1 Cleaning

Clean the Flex Electrode using disinfectant towelettes listed below, prior to use on a new patient to prevent cross contamination. Do not use other chemical products or detergents for cleaning not listed below. Wear proper protective equipment when cleaning.

Compatible cleaning materials (not supplied with the product):

1. CaviWipes (Isopropanol based) disinfectant towelette or equivalent
2. Sani Professional Disinfecting (Ammonium Chloride based) disinfectant towelette or equivalent

### 7.2 Maintenance

Cleaning is the only recommended maintenance of the Flex Electrode. There are no serviceable parts of the Flex Electrode. It is recommended that electrodes used from the Flex Electrode be changed out every other day.

### 7.3 Disposal

The Flex Electrode is reusable and should be returned to the provider at the end of your monitoring period.

The off-the-shelf surface electrodes are single use. Dispose of the electrodes properly in accordance with your local ordinances or the instructions of your prescribing physician. The electrodes may need to be recycled in accordance with local laws. Refer to the instructions provided by the original manufacturer.

## 8 Specifications and symbols




### 8.1 Flex Electrode Environment Specifications


Enclosure protection degree:	IP21 (when the sensor is connected to a compatible Flex Electrode)
Operating conditions:	
Temperature:	+5°C to +40°C
Pressure:	700 – 1060 hPa
Relative humidity:	15% - 93% (non-condensation)
Storage conditions (including between uses):	
Temperature:	+5°C to +27°C
Relative humidity:	Up to 93% (non-condensation)
Transportation conditions:	
Temperature:	0°C to +40°C
Relative humidity:	Up to 93% (non-condensation)

Exceeding the recommended operating, storage, and transportation conditions may result in reduction of the performance of the accessory.

### 8.2 Symbols

#### Symbols for Flex Electrode

Symbol	Description
	Manufacturer
	Catalogue number
	Protect from moisture

Symbol	Description
	Refer to instruction manual
<b>R<sub>x</sub> only</b>	Prescription use

## Annex 1 Channels and Configurations



The Flex Electrode 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.