

Lead Wire Adapter Accessory for ECG Recorders

Instructions For Use

Product Catalog Numbers:
REF Lead Wire Adapter 02-00139



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ENGLISH
Instruction Manual

Notices

R_x only

Prescription use only (U.S. Federal Law)



Legal Manufacturer:

Braemar Manufacturing LLC.

1285 Corporate Center Drive

Suite 150

Eagan, MN 55121 USA

Phone: 800.328.2719

Fax: 651.286.8630

E-Mail: sales-braemar@gobio.com



Philips.com/IFU

Electronic Instructions for Use can be found at: www.philips.com/ifu



Read the Instructions for Use before use of the product and keep these instructions for future reference. The Lead Wire Adapter is an accessory to compatible ECG diagnostic devices such as the ePatch or BTPS-1000 (Mobile Cardiac Outpatient Telemetry) ECG Recorders. Failure to follow the instructions in this document may result in injuries to the user or the patient and damage to the ECG Recorder and/or the Lead Wire Adapter. For more information regarding the compatible ECG Recorders, refer to the device specific Instructions for Use.

Use of the Lead Wire Adapter (LWA) for purposes other than those intended and expressly stated by the manufacturer, as well as incorrect use, incorrect operations, or modifications made to the Lead Wire Adapter may relieve the manufacturer (or his agent) from all or some of the responsibilities for resultant noncompliance, damage, injury.

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

Please read these instructions carefully before using the lead wire adapter (LWA) accessory with a compatible ECG Recorder. Contact the healthcare professional or product customer service with any questions.

1.1 Description

The Lead Wire Adapter (LWA) is reusable and uses off-the-shelf surface electrodes that are for single use only. The surface electrodes must be disposed of and replaced in accordance with the information provided with the surface electrodes. The LWA includes a lanyard/cradle, 3 electrode lead wires with snaps and off-the-shelf surface electrodes. The lanyard/cradle is placed around the patient's neck. The electrode lead wires snap onto the off-the-shelf surface electrodes and the surface electrodes are placed on the patient as directed in section 3.3 of this document.

1.2 Indications for use

The lead wire adapter (LWA) is indicated for use in conjunction with a compatible ECG Recorder. Refer to Table 1 below for a list of compatible ECG Recorders.

Table 1: Device Compatibility

Trade or Proprietary Name	Device Description	Catalog Number (REF)	Compatible ECG Recorder
Lead Wire Adapter	Lead wire adapter electrode	02-00139	ePatch ECG Recorder*, Catalog Numbers 02-01650, 02-00105, 02-01997, 02-02045, 02-02046
			Braemar Telemetry Patch System (BTPS-1000)*, also known as MCOT; Catalog Numbers 02-01561, 02-01606, 02-01846, 02-01889, 02-01897

* Please note that not all product configurations described in this document are available for sale in every geography. Please contact the healthcare provider or product customer service in your country with any questions.

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 Lead Wire Adapter is intended for use in hospital/health care facilities and in a home setting.

1.4 Intended Population




The Lead Wire Adapter is intended for use by adolescents 18-21 and adults.

1.5 Contraindications

The compatible Lead Wire Adapter is not intended for use in the following cases:

- Patients with severe allergies to adhesive materials or hydrogel.
- Do not place the Lead Wire Adapter on broken, damaged, or irritated skin. Apply the Lead Wire Adapter ONLY on clean intact skin and NEVER on open wounds, lesions, infected, or inflamed areas.

1.6 Warnings

	Keep away from infants and small children. Potential choke hazard due to small parts There is a danger of strangulation if the cords are misused.
	The Lead Wire Adapter is not intended for use on infants, or on pregnant and/or breastfeeding women.
	Remove the Lead Wire Adapter, and if connected, the compatible ECG recorder, prior to entering in an X-ray computed tomography (CT), or magnetic resonance imaging (MRI) environment.

1.7 Precautions

Use only Manufacturer Approved Accessories <ul style="list-style-type: none">- Always use the Lead Wire Adapter together with a compatible ECG Recorder (Refer to Table 1) that is supplied by the manufacturer.- Do not use accessories other than the ones provided or replaced by the manufacturer.- Use of accessories other than the ones provided may result in increased Radio Frequency (RF) emissions or decreased immunity to electromagnetic interference of the system.- Use of ECG Recorders other than the compatible devices in Table 1 might also lead to skin irritations, allergy, electrical shock and malfunction of the ECG Recorder.
Connection to Components <ul style="list-style-type: none">- Only connect the components as described in this Instructions for Use. Never connect the accessory to any external electrical item other than the compatible ECG Recorder.
Do not Tamper with Device <ul style="list-style-type: none">- Do not use accessory if package is tampered or defective.- There are no serviceable parts in the accessory.
Single Use/Multiple Uses <ul style="list-style-type: none">- The surface electrodes are a single use item; do not reuse the surface electrodes. The Lead Wire Adapter is reusable.
Device Storage Temperature and Shelf Life <ul style="list-style-type: none">- Refer to the instructions for use provided with the surface electrodes for further information.- The Lead Wire Adapter can be reused for an expected service life of 1 year.

2 Lead Wire Adapter Configuration

2.1 LWA Formation

The Lead Wire Adapter utilizes three (3) surface electrodes (Figure A below). Refer to Table 1 for the list of compatible ECG Recorders.



Figure A: Lead Wire Adapter (LWA) with lanyard

2.2 Electrodes

The electrodes (Figure B) are for single use only (these electrodes are also referred to as off-the-shelf surface electrodes, off-the-shelf electrodes, or surface electrodes). Refer to the information provided with the surface electrodes for further information.

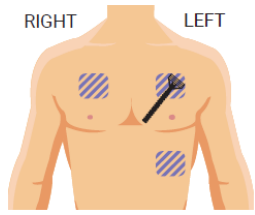
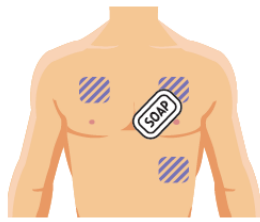
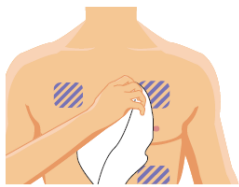



Figure B. Example of off-the-shelf surface electrodes.

3 LWA Set-up

3.1 Prepare the skin



NOTE: Do not connect the ECG Recorder and LWA until after skin preparation. Premature connection might shorten the length of the recording time.

Wash/Shave:	
	<ol style="list-style-type: none"> 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.
Clean Skin:	
	<ol style="list-style-type: none"> 3. Clean the shaded area with soap and water.
Dry Area:	
	<ol style="list-style-type: none"> 4. Dry skin thoroughly using a towel.
<p>2-3 min</p> 	<ol style="list-style-type: none"> 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.



Important Note: Do not apply lotion or oils 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.

3.2 Connect the ECG Recorder and the LWA

When connecting a compatible ECG Recorder (reference Table 1) with the LWA, follow these steps:

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

3.3 Attaching the LWA

Lanyard	
	<ol style="list-style-type: none"> 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. <p>NOTE: Refer to the information provided with the surface electrodes for replacement instructions.</p>
Electrodes	
	<ol style="list-style-type: none"> 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.

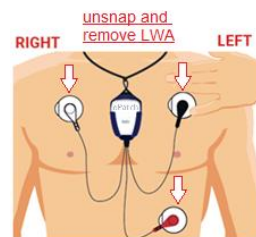
	<p>NOTE: When removing the adhesive liner, be careful not to touch the adhesive.</p> <p>10. The LWA is now correctly placed. The recording will automatically start when the flashing green light stops. The recording will stop after the predefined recording time or when the ECG recorder is removed from the LWA.</p>
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4 What to remember during use

4.1 Showering, bathing or swimming

The ECG Recorder is NOT water resistant when worn with the LWA; therefore, do not shower, bathe or swim while wearing the ECG Recorder 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 Recorder and set aside.



After showering/bathing/swimming, reapply new surface electrodes and re-attach the lead wire. Please following the instructions in chapter 3, steps 3.1-3.3

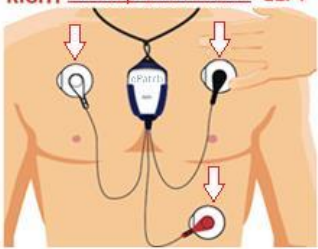
4.2 Activities

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

4.3 Skin irritation

Minor discomfort, skin irritation, reddening, itching, or rash can occur by use of the Lead Wire Adapter. 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.

5 How to remove the Lead Wire Adapter

	<ol style="list-style-type: none"> 1. Gently push the ECG Recorder out from the Lead Wire Adapter and gently remove leads and electrodes from the body.
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6 Troubleshooting

If this section does not help to resolve the issue experienced, the Lead Wire Adapter may have a malfunction that prevents normal operations. Do not use any accessory that may have a malfunction. Instead, please contact Customer Service or the distributor and specify the problem.

Issue	Solution
Irritated or reddened skin	You may be experiencing a reaction to the adhesive of the electrodes. If you experience irritation worse than minor itching, contact your healthcare professional.
Electrode(s) come loose from skin	Stick the electrode(s) back on your skin by pressing down the adhesive edges. If that does not work, replace electrode(s) by following instructions in chapter 3 while placing the electrodes on the body in a slightly different location.
The ECG Recorder does not show a green light when it is first connected to the Lead Wire Adapter	Ensure that the ECG Recorder is fully inserted into the LWA. Ensure that the ECG Recorder is fully charged. NOTE: Remember that the flashing green light stops automatically once the recording starts (up to five (5) minutes after the ECG Recorder and the LWA were connected).

7 Cleaning, maintenance, and disposal

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

7.1 Cleaning

NOTE: Follow the instructions described in this section after each use of the Lead Wire Adapter. Do not reuse single use accessories. Otherwise, there is a risk of infection to the patient.

Wipe down the LWA using only the compatible cleaning materials listed below, prior to use of the

LWA on a new patient. Do not use other chemical products or detergents. Wear proper protective equipment when wiping down the LWA.

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

There are no serviceable parts on the LWA.

7.3 Disposal

The LWA is reusable and should be returned at the conclusion of the predefined monitoring period.

The off-the-shelf 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

8.1 LWA Environment Specifications

Enclosure protection degree:	IP21 (when the ECG Recorder is connected to a compatible LWA)
Operating conditions: Temperature: Pressure: Relative humidity:	+5°C to +40°C 700 – 1060 hPa 15% - 93% (non-condensation)
Storage conditions (including between uses): Temperature: Relative humidity:	5°C to +27°C Up to 93% (non-condensation)
Transportation conditions: Temperature: Relative humidity:	0°C to +40°C Up to 93% (non-condensation)
Expected Service Life:	1 year

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

9. Glossary of Symbols

Symbol	Description
 ISO 7000-3082	Manufacturer
 ISO 7000-2493	Catalogue number
 ISO 7000-0626	Protect from moisture
 ISO 7010-M002	Refer to instruction manual
R_x only	Prescription Use
 Philips.com/IFU ISO 7000-3500	Electronic instructions for use