

ECG Electrode Patches for use with Compatible Ambulatory Electrocardiogram (ECG) Recorder



Product Catalog Numbers and Descriptions:

REF 02-01507 ePatch ECG Electrode (40 count box)

REF 02-01640 Patch ECG Electrode (40 count box)

REF 02-01615 Patch ECG Electrode (US only, 40 count box)

Instructions for Use

ENGLISH

Subject to modification

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Notices:

R_x only

Prescription use only (U.S. Federal Law)

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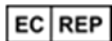
Philips.com/IFU

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

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



EU MDR information - The ECG electrodes patches are Class I devices and comply with the requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.



Philips Medical Systems Nederland B.V.
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The Netherlands

Incident Reporting – Any serious incident that has occurred in relation to the ECG Electrode Patch accessories should be reported to Braemar and the competent authority of the Member State in which the user and/or patient is established.

Throughout this document, the ECG Electrode Patch accessory will be referred to as 'ECG Electrode Patch', 'electrode patch' or 'patch', and the compatible ambulatory electrocardiogram (ECG) Diagnostic Device will be referred to as the 'ECG Recorder'.

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1 Device Description, Indications for Use, Contraindications, Warnings, and Precautions

Please read these instructions carefully before using the ECG Electrode Patch (later termed electrode patch or patch) with a compatible ECG Recorder. Contact the health care professional or product customer service in your country with any questions.

1.1 Device Description

The electrode patches are intended to be used with a compatible ECG Recorder (reference Table 1 below) to record surface ECG measurements of a patient. The electrode patches are patient-worn non-sterile disposable medical device accessories for application on uninjured skin, and provide the connection to the compatible ECG Recorder.

There are two models of the electrode patches, as shown in Table 1 below:

Trade or Proprietary Name	Device Descriptor	Catalog Number (REF)	Intended Compatible ECG Recorder
ePatch®	ECG Electrode	02-01507 (box of 40)	ePatch® ECG Recorder* (Model 1.0)
Patch	ECG Electrode	02-01640 (box of 40) 02-01615 (US only, box of 40)*	ePatch® ECG Recorder, Catalog Numbers 02-01650, 02-00105*, 02-01997*, 02-02045*, 02-02046 Braemar Telemetry Patch System (BTPS-1000)*, Catalog Numbers 02-01561, 02-01606, 02-01846, 02-01889, 02-01897

Table 1

* 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.

The ePatch and Patch ECG electrodes are identical in materials used and similar in design. The differences between the two electrode patches are due to the intended compatible ECG Recorder (reference Table 1 above); the Patch electrode has four integrated electrode circuits to record surface ECG of a patient and the ePatch electrode has three integrated electrode circuits.

NOTE: An electrode patch is not a diagnostic device on its own and when connected to a compatible ECG Recorder, aids the ECG Recorder in recording of ECG. Consult the applicable ECG Recorder's Instructions for Use for further information.

1.2 Intended Purpose/Indications for Use/Target Population

The ECG Electrode Patch accessory is indicated for use with a compatible ambulatory electrocardiogram (ECG) diagnostic device for recording of ECG from adolescents 18 - 21 years and adults. The Patch electrode accessory is intended for use by health care providers and lay-users whenever there is a need for ambulatory ECG monitoring. The Patch electrode accessory is intended for use in hospital/health care facilities and in a home setting.

1.3 Intended Users/Intended Use Environment





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

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

1.4 Contraindications

- Do not use the electrode Patch on patients with severe allergies to adhesive materials or hydrogels.
- Do not place the electrode Patch on broken, damaged, or irritated skin. Apply the electrode Patch ONLY on clean intact skin and NEVER on open wounds, lesions, infected, or inflamed areas.

1.5 Warnings

	Never apply the electrode Patch to face or mouth as this can lead to a suffocation hazard.
	The electrode Patch has not been evaluated to support its use on infants, or on pregnant and/or breastfeeding women.
	Keep electrode Patch away from infants and children. Potential choke hazard due to small parts.
	Remove the electrode Patch, and if connected, the compatible ECG Recorder, prior to entering an X-ray, computed tomography (CT), or magnetic resonance imaging (MRI) environment.

1.6 Precautions

Do not tamper with, disassemble, or modify the electrode Patch. Doing so may affect functionality or performance.
The electrode Patch is single use only and can be worn for up to 5 days. The electrode Patch cannot be re-used after being separated from the ECG Recorder – a new electrode Patch must be used.
The electrode Patch has an 18-month shelf life when stored in its sealed package at temperatures between 5°C and +27°C (41°F to 80.6°F). The electrode Patch should be protected against environmental limitations during storage and shelf life.
Do not use the electrode patch if the package is tampered with, defective, opened or past its expiration date.
The electrode Patch should never be exposed to direct jets of water or any other liquid material. Doing so may cause condensation and affect quality of ECG recording.
Careless removal of the electrode Patch may cause damage to the skin.
Use or repeated use of the electrode Patch may cause or increase skin irritation, discomfort, or redness.

1.7 Potential Undesirable Side Effects

Skin irritation, discomfort, redness from use or from repeated use of skin contacting electrode Patch.

2 Clinical Benefits

The clinical benefit of having a small wearable device for the electrode patch is related to the high level of patient compliance when wearing the device and lay user or healthcare persons ease of applying and instructing the use of the device. Traditional Holter monitors typically required 3-5 leads to be placed, whereas the electrode patch is a single placement (user friendly/ simpler).

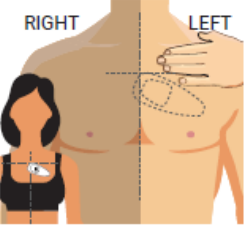
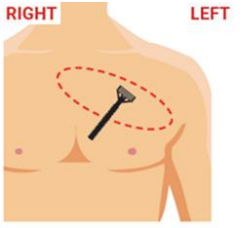
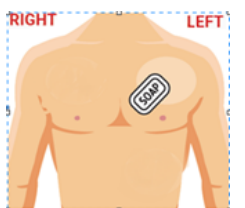



3 Set-Up

3.1 Skin Preparation

It is important to properly prepare the skin, according to the instructions below, before applying the electrode Patch to the body.

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

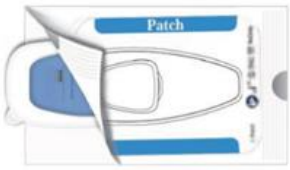

NOTE: Instructions that follow pertain to the slanted position. For sternum positioning please refer to the compatible ECG Recorder Instructions For Use, (reference Table 1 in Section 1.1).

	<p>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.</p>
	<p>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.</p>
	<p>3. Clean the area with soap and water.</p>
	<p>4. Dry skin thoroughly using a towel.</p>
	<p>5. Gently rub the skin using the exfoliation pad (if provided) in a circular motion for 1 minute. This step may help in providing a better ECG signal.</p>
<p>2-3 min</p> 	<p>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.</p>

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

3.2 Connect the ECG Recorder and the Electrode Patch

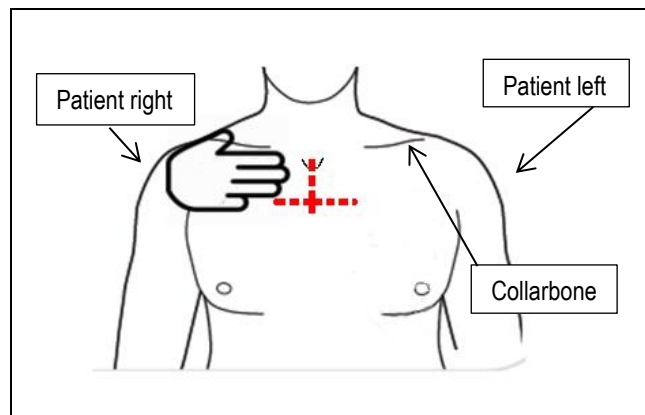
NOTE: Do not connect the ECG Recorder and the electrode Patch until after skin preparation.

	<p>1. Peel open the packaging and remove the electrode patch.</p> <p>Always check the use by date on the packaging of the Patch before use.</p> <p>Do not open the Patch packaging until the Patch is to be used. Otherwise, the adhesive material might dry.</p>
	<p>2. Consult the applicable ECG Recorder's Instructions for Use (reference Table 1 in Section 1.1) for information on how to connect the ECG Recorder to the Patch.</p> <p>Once the Patch and the ECG Recorder are connected (e.g., the combined assembly), the ECG Recorder powers on and starts the recording depending on the type of ECG Recorder being used.</p>

3.3 Apply the Electrode Patch to the Skin


NOTE: Once the ECG Recorder 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.

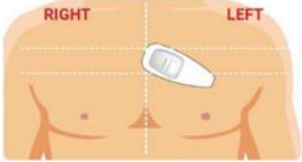

The ECG Recorder can be placed in two (2) different positions on the chest; a sternum position or a slanted position. The following diagrams illustrate the areas of the chest where it can be applied.



NOTE: Instructions that follow pertain to the slanted position. For sternum positioning please refer to the compatible ECG Recorder Instructions For Use, (reference Table 1 in Section 1.1).

Follow the steps below to apply the ECG Recorder on the chest:

	<p>1. Hold the ECG Recorder 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.</p> <p>NOTE: Do not touch the adhesive part of the Patch; doing so may reduce the Patch's ability to adhere to skin.</p>
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	<p>Apply the ECG Recorder to chest on a slight angle as shown in the illustration, by following these steps:</p> <ol style="list-style-type: none"> 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 Recorder) should be closest to the center of the chest. 4. Press all sides of the Patch so it will adhere to the skin. <p>NOTE: Wait one (1) minute before proceeding to the next step. This is important to ensure firm adhesion to the skin.</p>
	<ol style="list-style-type: none"> 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 Recorder so that the Patch will firmly adhere to the skin. 7. Smooth any wrinkles by pressing around the entire Patch 8. The combined assembly 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 Recorder is removed from the Patch.

For additional illustrations of how to apply the Patch to the chest, refer to the applicable ECG Recorder's Instructions for Use (reference Table 1 in Section 1.1).

4 What to remember during use

4.1 Showering

NOTE: If the ECG Recorder is not firmly connected to the Patch, it is not splash proof. When the ECG Recorder 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 Recorder by shielding it away from the direct spray of the shower with a hand or a cloth.



CAUTION: Do not swim or submerge the ECG Recorder in water or any form of liquid. The ECG Recorder is water resistant when combined with the Patch, but it is not waterproof. Fully immersing may render the ECG Recorder inoperable, may cause recorded ECG data to be unreadable, or may affect proper functionality.

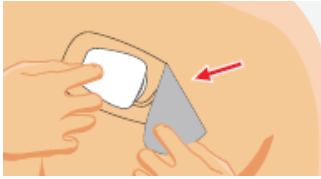
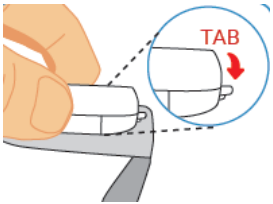
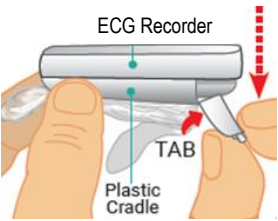
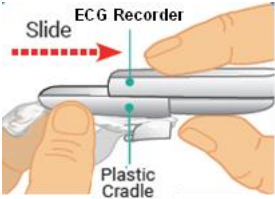

4.2 After a shower

After taking a shower, always inspect the ECG Recorder to Patch connection, and adhesion of the Patch to the skin. If needed, replace Patch. Continued use of a damaged Patch may affect quality of ECG measurements.

4.3 Activities

Activities that result in excessive sweating might loosen the Patch, or cause gel to leak out. If this occurs, remove the combined assembly by following the instructions in Section 5 of this document and separate the ECG Recorder from the Patch per the instructions in the applicable ECG Recorder's Instructions for Use. Apply a new Patch per the instructions in Section 3.2 and Section 3.3 of this document.

5 How to remove the Patch from the body













Remove the Patch	
	<p>CAUTION: Careless removal of the Patch may cause damage to the skin.</p> <ol style="list-style-type: none"> 1. Firmly press the ECG Recorder with your fingers against the chest as shown with the red 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 Recorder. 3. Adhesive residue can be removed by washing the area with soap and water. <p>NOTE: This motion will reduce stress to the skin during the removal of the Patch.</p>
Separate the ECG Recorder from the Patch	
	<ol style="list-style-type: none"> 1. Hold Patch as shown. Fold the clear adhesive out of the way to locate the tab on the plastic cradle of the Patch. <p>Note: Do not use a tool to separate the ECG Recorder from the Patch. This might damage the ECG Recorder.</p> <p>Note: Do not separate the ECG Recorder from the Patch while worn. This may cause damage to the skin.</p>
	<ol style="list-style-type: none"> 2. Apply downward pressure on the tab to snap it open. This will require some force.
	<ol style="list-style-type: none"> 3. Hold down the blue plastic cradle and then gently push the ECG Recorder to slide off as shown. The ECG Recorder should slide off easily. 4. The ECG Recorder will now stop the recording automatically (unless recording has already stopped due to the predefined recording time having elapsed).
	<ol style="list-style-type: none"> 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. <p>Note: The ECG Recorder is reusable and should not be discarded.</p>







6 Troubleshooting

If this section does not help to solve the issue experienced, the Patch may have a malfunction that prevents normal operations. Do not use a Patch that may have a malfunction. Instead, use a new Patch or please contact Customer Service or the distributor and specify the problem.






Issue	Solution
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 the healthcare professional.
Patch comes loose from skin	Stick the Patch back on the skin by pressing down the adhesive edges. If that does not work, contact the healthcare professional. You may need to replace the Patch.
Gel leaking out of Patch	<ul style="list-style-type: none"> - Remove the Patch by following instructions in chapter 5. - Apply new Patch by following instructions in chapter 3.

7 Glossary of Symbols

Symbol	Description
	Manufacturer
	Quantity in package
	Do not use if package is damaged
	Caution
 <small>Philips.com/IFU</small>	Electronic instructions for use
	Temperature limit
	Do not re-use
 	Does Not Contain PVC
	Does Not Contain Natural Rubber Latex
	CE mark Indicates that the product conforms with standards for products sold within the European Union.
	Medical Device

Symbol	Description
	Use By Date
	Batch Code
	Catalogue number
	Country of Manufacture
	European Authorized Representative
	Prescription use only (U.S. Federal Law)

8 Authorized Representative and Importer Information

 European Authorized Representative	Philips Medical Systems Nederland B.V. Veenpluis 6 5684PC Best The Netherlands
 European Union Importer	Philips Medical Systems Nederland B.V. High Tech Campus 52 5656 AG Eindhoven The Netherlands
 UK Responsible Person UK Importer	Philips Electronics UK Limited Ascent 1, Aerospace Boulevard Farnborough, GU14 6XW United Kingdom
 Swiss Authorized Representative	Philips AG Seestrasse 87 CH-8810 Horgen
 Swiss Importer	