

1. Preface

This instruction is intended for doctors (specialists in cardiology, electrophysiology and cardiac surgery as well as emergency doctors) as well as to other doctors and authorized personnel who are familiar with the handling and application of ECG electrodes in combination with ambulatory ECG systems (Holter/loop recorders).

Specialists must be able to cope with the risks and complications associated with the use of outpatient electrocardiographic systems by means of appropriate precautions and measures.

Read this guide carefully before use of the livePatch Single-Patch ECG Electrode. Careful attention to the instructions for use is a prerequisite for correct use and safety for patients and users.

2. Medical purpose

The livePatch Single-Patch ECG Electrode is an accessory to the 3 channel EKG Holter-/Longterm Recorders from livetec Ingenieurbüro GmbH and is used with this devices in order to create a 3-channel electrocardiogram.

3. Contraindications and exclusions

The livePatch Single-Patch ECG electrode is intended for single use only and must only be used on intact (uninjured) skin.

4. Users

The use of livePatch Single-Patch ECG Electrode may only be performed under the supervision of physicians (specialists in cardiology, electrophysiology and cardiac surgery, as well as emergency doctors) or trained professionals who are familiar with the handling and use of ECG electrodes in combination ambulant electrocardiographic systems (Holter/loop recorders).

For ambulant recordings, patients must be instructed to handle the livePatch Single-Patch ECG Electrode beforehand. Patients who are unable to operate the livePatch Single-Patch ECG Electrode after thorough training (applying, detaching), e.g. disabled patients should be excluded from usage, unless they can rely on the support of third parties who are able to support the patient in completing a successful test. Patients which are treated with cortisone preparations should be excluded for ambulant recordings.

5. Application instructions

- Note that the livePatch electrode can only be used with a livetec ECG recorder
- Do not use solvent-containing liquids to cleanse the skin, as such agents can lead to skin reactions when enclosed under the electrode.
- The livePatch is suitable for single use only. When used again, the adhesive force and electrical properties may be insufficient. There is also a risk of cross-infection from one patient to another.
- After removing the livePatch from the protective film, the film should be disposed of in a dedicated waste container.
- The livePatch should only be used by medical personnel or under the supervision of medical personnel who are familiar with proper positioning and application.
- Do not soak, rinse or sterilise as this can leave harmful residue or cause a malfunction of the electrodes.
- Electrodes in open packs (pouches) can dry out. Open the package only if necessary. Note the expiry date on the label of the packaging. The shelf life is 2 years.
- Electrodes should be used within 5 days after opening the package (pouch).

6. Safety warnings

- The livePatch must only be applied to healthy, uninjured and dry skin (for example, not to open wounds, lesions or in infected or inflamed areas).
- Protective films of the livePatch may have sharp edges, so caution should be exercised when removing the electrodes from the bag.
- The livePatch must be removed from the patient during XRAY and MRI scans, otherwise there may be burns.
- In electrosurgical procedures, position the livePatch as far away as possible from the operating area. This minimises unwanted RF flow, which could lead to skin burns.
- The livePatch should only be used by medical personnel or under the supervision of medical personnel who are familiar with proper positioning and application.

- **Removing the electrode:** The livePatch can damage the skin if they are not carefully removed. Pay particular attention if the skin is excessively sensitive, especially in children, but also in elderly or diabetics patients or patients who have taken specific drugs for a long time that can cause drug-induced side effects on the skin.
- Especially by patients which are treated with cortisone preparations.
- The livePatch is not suitable for use on children < 10 kg.
- The livePatch must be replaced if it no longer sticks firmly to the skin, but no later than after 7 days or if skin reactions occur. To minimise the risk of skin irritation when replacing the electrodes, the new electrode should be relocated.

If a serious incident occurred during or as a result of the use of the livePatch, report it to the manufacturer and the relevant regulatory authority.

7. Possible adverse events

Although the materials used for the livePatch electrode are very skin-friendly and meet the normative requirements (EN ISO 10993-1), allergic skin reactions (e.g. reddening of the skin, itching, small blisters, inflammation) can be caused in patients. In these cases, stop the ECG recording or place a new electrode on another location.

Increased skin reactions/ irritation can be expected in patients treated with cortisone preparations.

Clarify possible skin allergies with the patient before application.

8. Outpatient applications

- In outpatient applications, patients must be trained by medical personnel in handling the livePatch (applying and detaching)
- **In particular, patients must be made aware of the risks as described in the previous chapter (safety warnings)**
- **Patients which are treated with cortisone preparations should be excluded from ambulant/ outpatient recordings**

9. Symbols used

	CE marking		Store Dry		Batch number
	Silver-silver chloride electrode		Ambient temperature		Reference/Order number
	Latex-free		PVC-free		Usable until/ Expiry date
	Follow instructions for use		Avoid direct sunlight		Adults
	Manufacturer information		Date of manufacture		Children ≥ 10 kg
	Do not reuse		Prescription		Children < 10 kg
	Medical device		GTIN number		Composite/ Low-Density Polyethylen

10. Manufacturer information and order information

Manufacturer:	livetec Ingenieurbüro GmbH, Marie-Curie-Str. 8, 79539 Lörrach, Germany www.livetec.de/ Email: info@livetec.de
Order number:	105898 (purchased via your distributor or manufacturer)

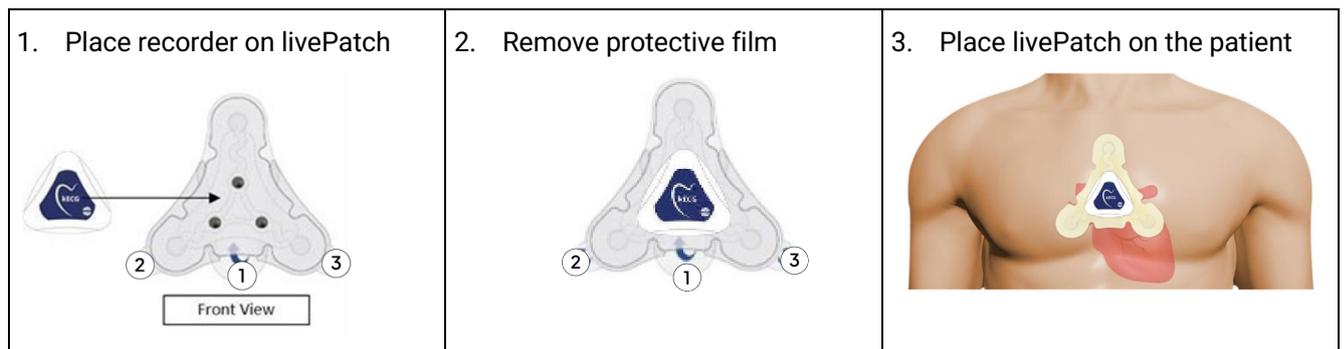
11. Application

Prepare the skin:

- If necessary, the area on which the electrodes are to be positioned should be cleaned with a mild soap and water and then thoroughly dried.
- Shave hairy areas if necessary. If the skin impedance is too high, lightly cleanse or abrade the surface.

Apply the livePatch to the patient skin:

- First, attach the livePatch to the recorder using the push buttons.
- Then remove the protective film, in the order 1, 2, 3 as shown in the diagram below.
- Attach the ECG recorder to the patient according to the placement hints below.

**Placement:**

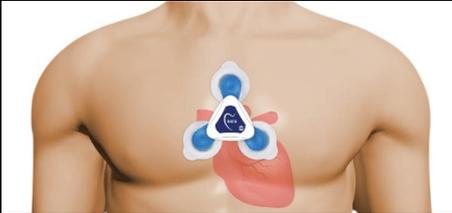
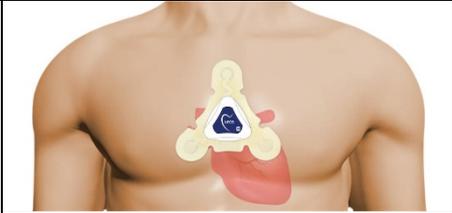
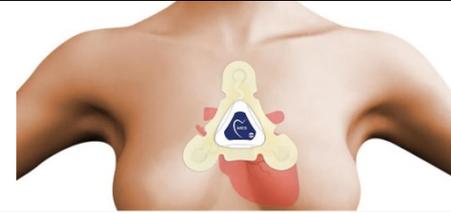
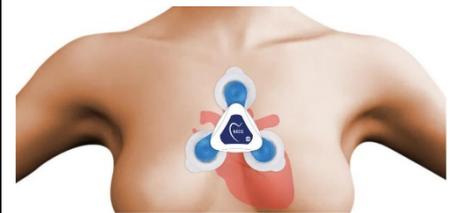
- When placing the livePatch on the patient, refer to the diagrams in chapter 12 (but the correct positioning of the electrodes is usually determined by the hospital/doctor).
- Also note the additional application and positioning information in the ECG recorder manual.
- Avoid mechanical stress on the livePatch when placing on the patient
- Try to place the livePatch in such a way, that both the patch and attached Holter device sit on the least curved areas of the patient's chest
- Place the electrode on the skin by gently, circular, even pressing along the adhesive edge.

Removal of electrodes:

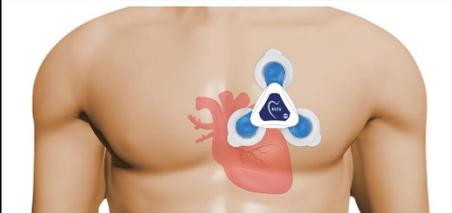
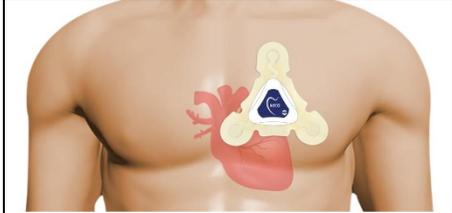
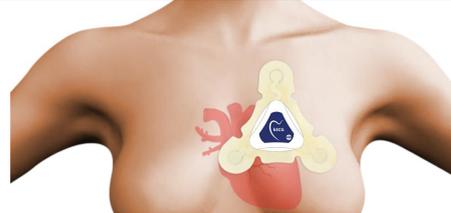
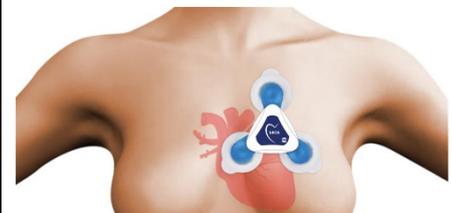
- After use, carefully remove the electrode with one hand and support the underlying skin with the other. Torsion or quick removal can lead to skin injuries. Pay particular attention if the skin is excessively sensitive, especially in children, but also in elderly or diabetics patients or patients who have taken specific drugs for a long time that can cause drug-induced side effects on the skin.
- Especially in patients being treated with cortisone, the electrode should be removed very carefully and gently.
- Gel left on the skin can be removed with paper towels or washed off with water.
- Dispose of the product in accordance with local regulations or the requirements of the hospital or health institution.

12. Placing/ Positioning

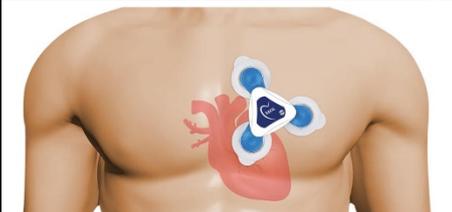
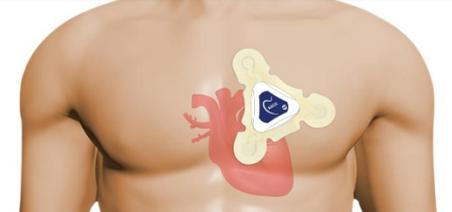
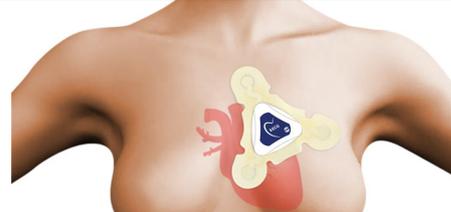
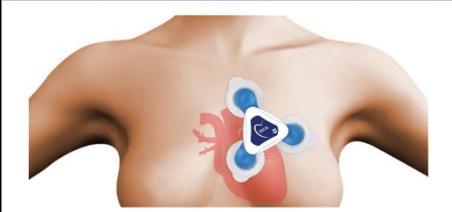
Middle rib cage

Reference to recorder user manual	Man	Woman
		
	<p>Notes:</p> <ul style="list-style-type: none"> • Make sure that the electrodes are not positioned too high, the lower electrodes should be positioned as close as possible to the horizontal heart axis. • Female patients: Positioning is the same for all breast sizes. 	

Left Chest, option 1

		
	<p>Notes:</p> <ul style="list-style-type: none"> • Make sure that the electrodes are not positioned too high, the lower electrodes should be positioned as close as possible to the horizontal heart axis. • When placed on the left chest: Make sure that the electrodes are not positioned too far to the left, the right electrode poles should be placed as close as possible to the sternum. • Female patients: Positioning is the same for all breast sizes. 	

Left Chest, option 2

		
	<p>Notes:</p> <ul style="list-style-type: none"> • Make sure that the electrodes are not positioned too high, the lower electrodes should be positioned as close as possible to the horizontal heart axis. • When placed on the left chest: Make sure that the electrodes are not positioned too far to the left, the right electrode poles should be placed as close as possible to the sternum. • Female patients: Positioning is the same for all breast sizes. 	