

**kECG®**

Wireless ECG Holter Recording System

II 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 use of outpatient electrocardiographic systems (Holter/loop recorder).

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.

**Note**

Read these instructions carefully before use.

- Keep the instructions for use constantly at the **kECG** site.

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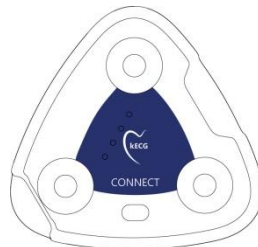
1. Scope of delivery

The delivery of the kECG Set includes the following parts:

1 pc. recorder module (kECG)



1 pc. Reader/ Charger module (kECG CONNECT)



1 pc. micro USB cable



1 pc. liveECG Init (USB Stick with liveECG Init Software installed, optional)



1 pc. liveECG Blue (Bluetooth dongle, optional)



1 pc. Instructions for use (kECG IFU)

To avoid subsequent complaints, check the scope of delivery as follows:

- Unpack the delivered components and carefully check the components for damage.
- Check the delivery for completeness.
- Please report missing or damaged products to your distributor immediately. Complaints made at a later date can no longer be taken into account.
- If you do not use the device for a long time, please refer to the instructions on storage and transport (-> **Chapter 8**).



Note

The parts/devices described in this chapter can also be purchased individually via the distributor. Please refer to the order information in **Chapter 9**.

2. Features

The **kECG** is a medical device for long-term Holter ECG data recording with the following features:

- No cables necessary/High wearing comfort for the patient/low effort for cleaning and re-processing.
- Easy application or removal of the adhesive electrode(s) via three pushbuttons.
- Continuous recording of three ECG signals **up to 7 days with the kECG-1** and **up to 18 days with the kECG-3** with a fully charged battery
- Recording of three ECG signals up to 60 days by changing batteries and ECG electrodes.
- Recording of usual 24h – 48h Holter ECGs.
- Support for event marking by the patient (e.g. in case of symptoms or medication).
- Secure and simple data download via the integrated USB interface in conjunction with the **kECG CONNECT**.
- Bluetooth® interface for patient-specific initialisation of the device
- Support of standardized ECG data formats such as MIT, ISHNE, EDF+..

Highlights / Advantages:

By using single-use electrodes in conjunction with state-of-the-art hardware and software technology, **kECG®** enables permanent recording of long-term ECGs well over 24h with very high signal quality and at the same time maximum patient comfort.

By eliminating previously common cables and due to the integrated intelligence, **kECG®** requires almost no operation steps and thus enables (especially for ambulant applications with elderly patients) ECG recordings without affecting patients in their usual living environment and quality of life.

For the first time, this enables practicable, efficient, and safe “round the clock” long-term ECG recordings.

By simply changing the single-use electrodes and recharging the battery, **kECG®** can be used as a long-term recorder for ECG recordings up to 60 days.

Clinical claims and benefits:

- **kECG®** enables continuous and correct ECG “round the clock” recording for up to 18 days to detect and monitor cardiac arrhythmias thanks to cable-free technology.
- By simply changing the single-use electrodes and the battery, **kECG®** can be used as a long-term recorder for ECG recordings up to 60 days.
- **kECG®** works completely cable-free and offers an increased level of comfort and quality of life for the patient. System advantage: Does not affect the sleep pattern of patients.
- Good signal quality by eliminating the cables and derivating the vectors on the smallest area (low-artefact, low-interference ECG recordings).
- For both the cardiologist and the patient, the device offers the advantage that it is very easy to configure, commission and use.
- **kECG®** enables secure and fast data download to an evaluation/analysis station via integrated USB interface.
- **kECG®** support a manual event marking by the patient (e.g. in case of symptoms or medication).

2.1 Intended use

kECG is a device for the continuous measurement and digital storage of ECG signals during the patient's daily activities as part of a long-term/Holter ECG. The recorded data are used to diagnose cardiac arrhythmias.

The recorded data is downloaded from **kECG** to a PC in a medical facility and evaluated with suitable Holter-ECG analysis software. A doctor evaluates the normal and abnormal ECG data for further therapeutic measures.

2.2 Contraindications

- **kECG** must not be used on the open heart.

2.3 Adverse reactions

- Although the electrodes defined for **kECG** are very skin-compatible and comply with normative requirements (EN ISO 10993-1), allergic skin reactions (e.g. redness, inflammation or itching) can be caused by the adhesive layer of the electrodes in patients.
- Clarify possible skin allergies with the patient. Contact the electrode manufacturer for more detailed information.
- Increased skin irritation is expected in patients treated with cortisone preparations.
- Be very careful when attaching and removing the electrodes from the skin surface.

2.4 Characterization of Patients

The following patient groups are intended for the **kECG**:

- Patients with symptoms/suspected heart rhythm disorders of supraventricular or ventricular origin (e.g. pauses, bradycardia, supraventricular tachycardia, supraventricular/ventricular extrasystoles, ventricular tachycardia, atrial fibrillation).
- Patients with difficult to detect heart rhythm disorders (e.g. paroxysmal atrial fibrillation).
- Patients after implantation of a pacemaker for pacemaker control.
- Patients after electrophysiological procedures, heart attacks, strokes, heart valve transplants.
- Patients with suspected or diagnosed and treated diseases such as heart failure, apnea, atrial fibrillation.
- The **kECG** is suitable for use in children with a body weight less than 10 kg (provided that electrodes are used which are suitable and approved for children < 10 kg)

3. General product description

3.1 Structure and components

Structure:

The **kECG** includes of the following components according to **Chapter 1 (Scope of Delivery)** and **9 (Accessories and Disposables)**:

Recorder module (**kECG**):

This module includes the electronics for measuring and storing the 3 ECG leads.

Apply the recorder module → **Annex 1**.

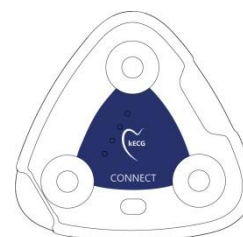


Reader/ Charger module (**kECG CONNECT**):

This module is used both to read out the ECG recordings stored on the recorder module and to charge the integrated LiPO battery on a PC (-> **Chapter 10.4**).

Read out an ECG recording -> **Annex 2**.

Charging the integrated battery -> **Annex 3**.



Initialisation software (**liveECG Init**):

With the help of the **liveECG Init Software**, an ECG recording can be initialised (patient information) and started. In addition, this software offers the possibility to check and optimize the signal quality of the ECG leads before starting the recording and cyclically afterwards.

Initialise and start an ECG recording → **Annex 2**.



liveECG Blue (Bluetooth Dongle):

The Bluetooth dongle is used to initialise an ECG recording via the Bluetooth interface using the **liveECG Init Software**.

Initializing and starting an ECG recording -> **Annex 2**.



3.2 Control and display elements

Control elements:

The kECG does not include any control elements.

Display elements:

The kECG includes 3 LEDs for displaying device/battery and error status as follows:

- Green LED: Display of the current device status.
- Yellow LED: Display of battery status.
- Red LED: Display the error status.

In addition, the LEDs are used for optically coded display of the 3 ECG signals → **Annex 2/Chapter 11**; status indicators on the device.

3.3 Variants

The kECG is available in the two versions **kECG-1** and **kECG-3**.

- The recording time with a fully charged battery is
 - **Up to 7 days** for the **kECG-1**.
 - **Up to 18 days** for the **kECG-3**.



Note

- Due to the aging of the battery, the recording time may decrease over time when the battery is fully charged. Please see the notes in → **Annex 3 / Chapter 5** for the battery life.
- Longer recordings can be achieved by charging the battery cyclically.
- The recorder has internal data storage, which is sufficient for a recording time of approx. 60 days.

4. Warnings/ safety notes

4.1 General precautionary notes



Attention

This chapter contains information to ensure safety and functionality in the application of **kECG**. To maintain safety and function, please read these chapters carefully and observe the information contained therein.



Note

- Read the instructions carefully before use.
 - Keep the instructions for use constantly at the **kECG**.
-
- The use of **kECG** 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 ambulant electrocardiographic systems (Holter/loop recorders).
 - For ambulant recordings, patients must be instructed to handle **kECG** beforehand. Patients who are unable to operate **kECG** after thorough training (change and application of electrodes, batteries, e.g. disabled or demented people) should be excluded from recording, unless they can rely on the support of third parties who can be assigned to the application in your usual living environment.
 - The **kECG** is not suitable for monitoring the clinical condition of patients, as it does not have a signal display and cannot trigger an alarm!
 - Observe the limit values for environmental conditions (temperature, air pressure, operating altitude and humidity) specified in the technical data for the storage, transport and operation of **kECG**. Operate the **kECG** only within these limits.
 - Store and transport the **kECG** only in the original packaging.
 - Avoid sudden changes in temperature or humidity.
 - Protect the device from penetration of liquids and dust.

**Attention**

- When operating, use only the accessories and disposables specified in **Chapter 9** (batteries, electrodes, etc.).
- Do not expose the device or batteries to direct solar radiation and avoid the direct proximity of heat sources (microwaves, heaters or ovens).
- The device should not be operated in a potentially explosive environment.
- The **kECG** must not be sterilised.
- Please refer to the instructions for cleaning and re-processing in **Chapter 8.1** as well as the instructions for disposal in **Chapter 8.5**.
- After attaching the electrodes and/or **kECG** to the patient, care must be taken that the electrodes or the electrode contacts of the recorder do not come into contact with other conductive parts, including grounding lines (POAG etc.).
- Reading out the ECG recordings may only happen if the device has no connection to the patient (via the ECG electrode contacts)
- In case of longer storage (more than 8h), remove the battery from the recorder to prevent damage caused by leakage.
- Do not open the **kECG** recorder module and do not use force.
- Please refer to the information on service and repair in **Chapter 8.3**, as well as the information on safety control in **Chapter 8.4**.
- Defects/damaged devices/components may no longer be operated and must be repaired. In these cases, please contact your dealer/distributor.
- The **kECG** can be operated without impairment with cardiac pacemakers or other stimulators if all the devices involved are used according to their intended purpose.

4.2 Precautions



Note

- The **kECG** is suitable for use in children with a body weight less than 10 kg.
- When choosing the electrodes, pay attention to the suitability of the electrodes for Holter and long-term ECG recordings, especially with regard to skin compatibility
- For children use electrodes that are suitable for Holter/Long-Time ECG recordings on children.



Attention

- The **kECG** is shower-resistant.
- Nevertheless, it is recommended to remove **kECG** from the electrode (from the body) before showering. Do not spill liquids over the device.
- Protect the device from moisture, dust or dirt, especially when the battery compartment is open.
- Make sure that if multiple **kECG** is used in parallel to different patients, the recorded data is correctly assigned to the respective patients.
- Use only the electrodes or electrodes specified in **Chapter 9** (Disposables) which are suitable for long periods of use (**Annex 1**).

4.3 Electromagnetic influence



Attention

- Magnetic and electric fields or ionizing radiation can influence the function of the device. Therefore, do not operate **kECG** near devices that produce large electromagnetic fields or ionizing radiation, such as RF chirurgic, X-ray, magnetic resonance (MR) environment or diathermy devices.
- Wireless power transfer (WPT), 5G cellular networks, Security systems (e.g., electromagnetic anti-theft systems (EAS), and metal detectors) can influence the function of the device. Therefore, do not operate **kECG** near to such RF emitters.
- Special precautions with regard to electromagnetic compatibility (EMC) in **Chapter 11** should be taken into account.

4.4 MR Compatibility



Attention

Warning: **MR-unsafe!**

Do not expose the **kECG** to a magnetic resonance (MR) environment.

- The **kECG** may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core.
- Thermal injury and burns may occur due to the metal components of the **kECG** that can heat during MR scanning.
- The **kECG** may generate artifacts in the MR image.

The **kECG** may not function properly due to the strong magnetic and radiofrequency fields generated by the MR scanner.

4.5 Cybersecurity



Note

Since the **kECG** does not have any network connections or remote maintenance functions and because of its hardware and software architecture, the **kECG** is very secure against cyber attacks and intentional data manipulation by unauthorized third persons.

Nevertheless, please note the following information to protect against manipulation by unauthorized persons.



Attention

- Never store or keep the device unsupervised, especially when unauthorized or even unknown persons are present.
- Ensure that the device is only used by authorized, known persons.
- To evaluate the ECG data, only use analysis software that has medical product approval respectively evaluation systems that contain cyber security measures themselves.
- Delete data that is on the device immediately after downloading it to the evaluation system.

- Never use the device in application environments that do not have any cybersecurity protection measures themselves. This is especially important when the evaluation system is integrated in an unsecured network.
- For outpatient applications: Inform the patient about the dangers and cybersecurity measures mentioned here.

4.6 Obligation to Report



Note

Please note that serious incidents that occur during operation of the device must be reported immediately to the manufacturer and the relevant authorities in the country in which the device is being operated.

4.7 Analysis Systems



Attention

- Note that the computers used in the compatible analysis systems or for charging the integrated battery (-> **Chapter 10.4**) must meet the normative requirements of EN 60601-1, or at least the normative requirements for information technology equipment, in order to ensure the readout of the recorded ECG data via the USB cable.



Note

- The **kECG** includes:
 - no integrated analysis or diagnostic functions
 - no monitoring, detection, signalling or display of life-threatening arrhythmias or changes in morphology
- It is therefore not suitable for applications that require at least one of these functionalities.
- All analysis functions can only be performed via appropriate compatible analysis system.
- The recorded ECG data of the **kECG** are not suitable for the analysis of amplitude changes (e.g. change of amplitude in the ST segment).

-
- The recorded ECG data must not be used for morphological ECG interpretation to derive diagnoses for amplitude-specific heart disease (e.g. ischemic heart disease, repolarization anomalies).

4.8 Product liability



Note

The manufacturer of **kECG** assumes product liability only under the following conditions:

- If **kECG** was operated exclusively with original accessories according to **Chapter 9**.
- Where repairs to **kECG** and accessories have been carried out exclusively by the manufacturer or by the manufacturer authorised and trained.
- If the present instruction manual has been observed during the application.
- If the safety checks have been carried out in accordance with **Chapter 8.4**.

4.9 Warranty

The warranty periods for all reusable components (recorder module) of the **kECG** are 12 months.



Note

Excluded from warranty claims are:

- Damage due to normal wear.
 - Damages due to misuse and/or use of wrong accessories.
 - Damage due to unauthorized/unauthorized modification or repair of the components or if the components have not been used or maintained in accordance with the instructions in this manual.
 - Damages due to force exposure including fall/case damage.
 - Damage caused by penetrating liquids, dust and dirt.
-
- After-sales service or repair work under warranty does not lead to an extension of the warranty.

5. ECG - recording/operation/analysis

5.1 Applying the recorder

For details on how to apply kECG to the patient, see **Annex 1** to these instructions for use. Read this annex carefully and observe the relevant descriptions and instructions, in particular on the patient's preparation and the selection and placement of the electrodes.

In particular, **Annex 1** contains information on the following topics:

- Suitable electrode types.
- Positioning of the electrodes.
- Preparation of the skin surface.
- Configuration of the kECG.
- Applying the kECG recorder.

5.2 Initialisation and application of the kECG

Details and recommendations for initialisation, execution of ECG recordings and ECG analysis with compatible ECG analysis software can be found in **Annex 2** to this instructions for use. Read this annex carefully and observe the relevant descriptions and instructions.

In particular, **Annex 2** contains information on the following topics:

- Installation of the kECG initialisation software.
- Charging of the integrated battery.
- Initialisation and start of ECG recordings.
- Information on the execution of long-term recordings.
- Cyclic function- and signal controls.
- Readout and ECG analysis with compatible analysis software.

5.3 Usage recommendations for users and patients

Usage recommendations for users (doctors, specialists, assistants) and patients can be found in **Annex 3** to these instructions for use.

In particular, this annex contains instructions for users and patients on the use and maintenance of functionality in long-term ECG recordings.

In particular, **Annex 3** contains information on the following topics:

- General recommendations for putting into service and maintaining the operation.
- Recommendations for patient training.
- Instructions for body care.
- Change of electrodes.
- Charging of the integrated battery.

5.4 Definition of manual event markers

The **kECG** offers the possibility that the patient can define manual event markers at any time, for example if he feels “uncomfortable” or if he suspects arrhythmias (with appropriate symptoms). Event markers can be defined by the patient as follows:

- Double click/double stroke on the housing of the **kECG**.
- After the definition of a manual event marker, the **kECG** switches to the status “**Signal control/ECG display**”.
- In this state amplitude modulated (and therefore brightness modulated) display of the 3 ECG signals via the LEDs of the **kECG** takes place. Please refer to **Annex 2, Chapter 11** to these instructions for use.



Note

- To make sure that a manual event marker has been detected by **kECG**, double-click on the case until the state “Signal Control/ECG Display” is displayed.
- In the installed ECG analysis software (e.g. PADSYS Holter, Cardiolight), defined manual event markers can be found very quickly and the correlated ECG sections can be displayed.

5.5 Compatible analysis systems

According to the purpose, the kECG only serves the recording of long-term ECGs. An evaluation of the recorded signals must be carried out via compatible analysis systems available on the market.



Note

Hint to compatible analysis systems are listed in **Chapter 10.4 (technical data)**.

6 Self-testing internal monitoring and protection measures

kECG

6. Self-testing, internal surveillance and protection measures

6.1 Self-testing

The kECG has the following internal monitoring and protection measures:

Self-test after switching on:

After switching on (after charging the battery and removing the recorder module from the kECG CONNECT), the kECG independently carries out an extensive functional test, during which all functions of the device necessary for operation are tested. During this test, the following functions of kECG will be tested:

- Test of the internal microcontroller (RAM, Flash, Timer and Function).
- Test of internal supply voltages.
- ECG amplifier test (configuration and function test).
- ECG memory test (read/write test, size and free memory).
- Test of integrated rechargeable battery (capacity check).
- Test of the USB and Bluetooth interface (write/read test).

Self-test during operation:

During operation, kECG additionally checks the following functions cyclically:

- Test of internal supply voltages.
- ECG memory test (read/write test, size and free memory).
- Test of the integrated rechargeable battery (capacity check).



Note

If a result of a self-test is negative, the ECG recording is not started and the kECG goes into the "error" state. This condition is displayed via the permanently activated red LED for a duration of approx. 1h (→ Annex 2/Chapter 11). Then the kECG switches itself "OFF".

6.2 Internal monitoring and safeguard measures

The kECG includes the following internal protective measures:

- Defibrillation resistance according to EN 60601-1 (recovery time ≤ 5 s).
- Stress resistance/test voltages Application part according to EN 60601-1.
- Leak currents application part according to EN 60601-1.

6.3 Electrode monitoring

The kECG checks the electrode/skin contact cyclically during the ECG recording as follows:

- If an electrode impedance limit is exceeded, a zero line or a pseudo QRS complex with a frequency of 60 bpm shall be recorded for the duration of exceeding this limit (state pause, → **Annex 2, Chapter 11**).
- If the limit value is lower, the ECG recording will be continued again.

6.4 Cyclical function control by the user

kECG supports functional control by the user (doctor or patient). The function control can be performed by the user in the following ways:

- By checking the status indications in accordance with **Annex 2, Chapter 7**.
- By activating the signal control in accordance with **Annex 2, Chapter 8**.

7. Troubleshooting

Although **kECG** has extensive self-testing and monitoring functions, dysfunctions can occur occasionally. Please note the following information:

Problem description	Possible cause	Troubleshooting
No LED lights up after booting the device (after removing the recorder from the kECG CONNECT).	➤ Battery failure (empty battery). ➤ Error recorder module.	➤ Charge the battery again. ➤ Contact service.
Red error LED lights up after booting the device (after removing the recorder from the kECG CONNECT).	➤ Self-testing mistakes. ➤ Battery failure. ➤ Signal memory defective or insufficient free space.	➤ Charge the battery again. ➤ Empty signal memory. ➤ Contact service.
kECG cannot be initialised after application to the patient.	➤ No patient contact. ➤ Error recorder module. ➤ Bluetooth module not available on PC/tablet, not activated or defective.	➤ Read user manual. ➤ Check patient contact, reactivate signal control. ➤ Check Bluetooth interface on PC/tablet. ➤ Contact service.
No status display during recording (Green LED permanent OFF).	➤ Battery empty. ➤ Error recorder module.	➤ Read ECG. ➤ Charge the integrated battery and start a new recording. ➤ Contact service.

Red error LED glows while recording.	➤ Error recorder module. ➤ Signal memory defective or insufficient free space. ➤ Battery empty. ➤ Other error Self-testing.	➤ Read ECG. ➤ Charge the integrated battery and start a new recording. ➤ Contact service
No Bluetooth connection to kECG .	➤ Bluetooth module on PC, tablet not available, not activated or broken. ➤ Error recorder module.	➤ Read ECG. ➤ Charge the integrated battery and start a new recording. ➤ Check Bluetooth interface on PC/tablet. ➤ Contact service.
ECG recording cannot be read.	➤ kECG CONNECT not connected to the analysis system. ➤ Error recorder module. ➤ Recorder settings in analysis system not configured correctly (drive/recorder settings).	➤ USB connector; check kECG CONNECT (USB cable, recorder placement in the kECG CONNECT). ➤ Recorder settings check of the analysis system. ➤ Contact service.
Green LED does not light up during charging.	➤ kECG CONNECT not connected to the analysis system. ➤ Error recorder module. ➤ No contact between recorder module and kECG CONNECT.	➤ USB connector; check kECG CONNECT (USB cable, recorder placement in the kECG CONNECT). ➤ Check contact pins for dirt or damage. ➤ Contact service.

8. Maintenance

Please refer to the following instructions on the maintenance of the kECG.

8.1 Cleaning/ Re-Processing of the device

Clean and re-process kECG after each application to a patient. **Ensure sufficient ventilation.**

Cleaning:

- Moisten a soft cloth with soap solution or aqueous alcohol solution (70 % ethanol/30 % water).
- Clean the kECG.

Re-Processing:

- Moisten a soft cloth with an aqueous alcohol solution (70 % ethanol, 30 % water) or a plastic-suitable cleaning solution, better cleaning cloths or tissues, for sensitive medical devices according to MDR (e.g. HARTMANN Bacillol 30 Tissues (Art. No. 981312/please ask your distributor)).
- Wipe the kECG.



Note

- Do not use abrasive cleaning agents to clean the device.
- kECG must not be cleaned with organic solvents such as petrol, alcohols or ethers in order to avoid material fatigue, discoloration or breakage.



Attention

- Do not immerse the kECG in water and other liquids. Under no circumstances should liquid enter the recorder.
- You cannot sterilize kECG. Do not sterilize the device with steam, ethylene oxide, ultrasound or gamma rays.
- Note the safety data sheet of the disinfectant. Flammable gases are released. The cleaning/disinfectant can cause serious eye damage.

8.2 Storage and transportation

Store and transport **kECG** as well as all accessories and disposables according to **Chapter 9** only according to the specifications in the technical data (→**Chapter 10.3**).

Use the original packaging of the device for storage and transport. Please note the instructions on the transport packaging for the environmental conditions.

8.3 Service and repairs



Note

Unlawful opening leads to loss of the guarantee. In case of service or repair, please contact your distributor.



Attention

Unauthorized repairs or modifications to **kECG** or accessories may lead to impairments of the function or hazards for users or patients and are not permitted. Repairs may therefore be performed only by the manufacturer or by persons authorized by him. Unlawful opening the device or changing the integrated rechargeable battery leads to loss of the guarantee. In case of service or repair, contact your distributor.

8.4 Safety control



Attention

In accordance with EN 62353 and in order to ensure the good maintenance and the safety of the device, the manufacturer recommends the following tests for the operator, which he can also carry out by himself as long as he has suitable tools and skills. If further support is needed for testing, please contact the **kECG** sales.

Visual inspection: Housing damage.

Functional tests:

- No error indicator by red LED after booting.
- Signal control according to instructions for use **Annex 2, Chapters 7 and 8.**
- Recording of test signals, reading out data and checking signal quality for interference.

The check interval should be < 36 months.

8.5 Disposal



The **kECG** and all components including electrodes and batteries must be disposed of in accordance with national regulations (e.g. WEEE Directive 2012/19/EU for Europe). We offer you to return the device for disposal to your specialist dealer, distributor or the manufacturer

9. Ordering information, accessories and disposables

9.1 Ordering information

Please note the following ordering information to purchase the **kECG**, accessories or disposables.

Contact your distributor to purchase the items.

Basic equipment:

- **kECG set**: Holter Recorder set according to **chapter 1**
- **kECG recorder** : Holter Recorder
- **kECG CONNECT** : Reader/ Charger module

Accessories:

- **liveECG Init**: USB Stick with **liveECG Init** Initialization Software for MS-Windows
- Compatible ECG- Analysis Software according to Chapter 10.4
- **liveECG Blue** (Bluetooth dongle for initialization software, optional)
- **liveECG Tab / liveECG Viewer**: Android-App for mobile devices (for example tablet) with pre-installed initialization software (third party, optional)
- Adapter cable micro USB to USB

Disposables:

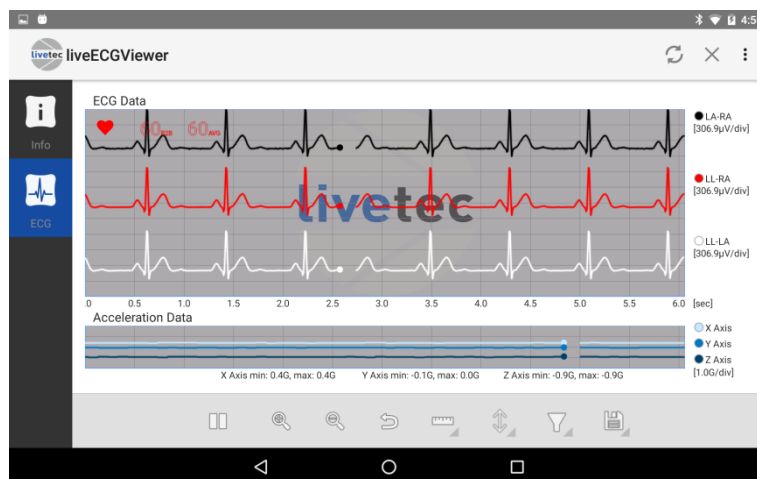
The following disposables are available either from the specialist dealer/distributor or from the relevant suppliers on the market:

- Market-standard, decentralised ECG electrodes for Holter/long-term recordings, e.g. AMBU BlueSensor L/ VLC/ P or SKINTACT FS-VB01/ T-V001.

Only use high quality disposables! Please contact your distributor for recommendations.

9.2 Optional accessory **liveECG Viewer**

For the graphical online display of the ECG leads, the manufacturer provides an optional, free Android APP (**liveECG Viewer**), which can be obtained on request from the distributors of the **kECG**.



If you are interested and for further information, please contact your distributor.



Note

- The **liveECG Viewer** is not a medical device within the meaning of the MDR (EU) 2017/745.
- Note that the **liveECG Viewer** is only for signal display and not for signal and/or function control of **kECG**.
- The **liveECG Viewer** is not intended for patient diagnosis and does not contain diagnostic functions.

10. Technical data

10.1 Symbols and inscriptions

	CE marking. The device complies with the requirements of the European Medical Device Regulation MDR (EU) 2017/745.
	Medical Device
	Manufacturer information.
	Date of manufacture
IP54	IP degree of protection.
	Classification of the application part according to IEC 60601-1. Defibrillation-protected application part of type BF.
	Refer to instruction manual/booklet.
	Refer to instruction manual/booklet (for reader/charger module).
	Serial number (if available).
 < 10 kg	Suitable for ECG recordings in children with a body weight of less than 10 kg.
4 Digit Number	Number of used Bluetooth module (last 4 digits of Bluetooth MAC-Address)

	Temperature range Storage and transport.
	Area relative humidity storage and transport.
	Ambient air pressure Storage and transport.
	Keep it dry.
	Fragile Goods
	Avoid direct sunlight.
	Top.
	Recycling.
	UN 3481 Package contains lithium-ion batteries

GS1 Application Identifier (AI)	(01) Global Trade Item Number (GTIN, UDI-DI) (11) Production date (YYMMDD) (21) Serial number
--	---

10.2 Condition indicators on the device

	The kECG includes 3 LEDs for displaying device/battery and error status. For details see Annex 2, Chapter 11 to these instructions for use.
--	---

10.3 Technical Data

Classification and standards	
Classification:	➤ Application part type BF according to EN 60601-1 ➤ Portable device with internal power supply ➤ Moisture protection degree: IP54 (complete protection against contact, protection against dust deposits inside and protected against water spray) ➤ Defibrillation resistance according to EN 60601-1
Directives and standards	➤ Medical Device Regulation MDR (EU) 2017/745 ➤ EN 60601-1: Medical electrical equipment ➤ EN 60601-1-2: Electromagnetic compatibility ➤ EN 60601-1-11: Medical equipment in home environment ➤ EN 60601-2-47: Outpatient electrocardiographic systems ➤ EN 62336-1: Medical devices Suitability for use
Operating time	➤ Up to 7 days (kECG-1) /Up to 18 days (kECG-3) / 24 hours per day with fully charged battery. ➤ If the battery is charged cyclically, permanent measurements up to max. 60 days are also possible.
Product life cycle	➤ 5 years
Data on the recorder module	
Number of ECG channels	➤ 3
Sampling rate	➤ ≥ 200 S/s (depending on the evaluation system)
Resolution ADC	➤ 16 bits (depending on the evaluation system)
Amplitude resolution	➤ $\leq 1\mu\text{V}$ related to input
Measuring range	➤ 100 mV
Frequency response	➤ 0,1 (0.05) – 70 Hz
Electrode monitoring	➤ Yes, about impedance measurement
Accuracy of parameters	➤ According to EN 60601-2-47:Outpatient electrocardiographic systems
Supply	➤ Over integrated LiPo-battery, 440 mAh, 3.8V
Data format	➤ depending on the evaluation system used
Dimensions	➤ approx. 50 x 50 x 13,5 mm

Weight	➤ approx. 23 g
Data on the kECG CONNECT	
Dimensions	➤ approx. 56 x 56 x 13 mm
Weight	➤ approx. 25g
Environmental conditions Operation	➤ Temperature: + 5 °C – + 40 °C ➤ Relative humidity: 15 % to 90 % (non-condensing) ➤ Air pressure: 700-1060 hPa
Environmental conditions Storage/transport (without battery)	➤ Temperature: – 25 °C – + 70 °C ➤ Relative humidity: 15 % to 90 % (non-condensing) ➤ Air pressure: 700-1060 hPa
Housings	➤ Plastic/ABS
Interfaces to the readout device	➤ USB interface (USB – 2.0) ➤ Read data rates: approx. 15 MBytes/s ➤ Write data rates: approx. 10 MBytes/s ➤ Charging: +5 V_{DC}, max. 0.5 A
Bluetooth interface	➤ Bluetooth 5.1 ➤ Frequency band: 2402 – 2480 MHz ➤ Type of modulation: GFSK (PI/4DQPSK, 8DPSK) ➤ Maximum radiated power: 8 dBm (BT Class 2)
Data of the kECG CONNECT	
Dimensions	➤ approx. 56 x 56 x 13 mm
Weight	➤ approx. 20 g
Manufacturer information	
Manufacturer	➤ livetec Ingenieurbuero GmbH, Marie-Curie-Str. 8, 79539 Loerrach, Germany

¹ For long-term storage of the device, a storage temperature of 20-30°C is recommended. To maintain the capacity of the integrated battery under these storage conditions, the device must be charged at least every six months. If the device does not show any function after removal from storage, three complete charging cycles to reactivate the full battery capacity are recommended by the battery manufacturer.

10.4 Compatible analysis systems



Note

- Since the kECG supports standardised ECG data formats such as MIT, ISHNE, EDF+ etc., the kECG can be operated with multiple analysis systems that support these data formats.
- Please contact the kECG sales department if you have questions regarding suitable compatibility analysis systems.



Attention

- Please note that the computers used in the compatible analysis systems used must at least meet as far as possible the normative requirements of EN 60601-1 or at least the normative requirements for information technology equipment in order to ensure the readout of the recorded ECG data via the USB interface and that the integrated battery can be charged .

11. Information on electromagnetic compatibility

The **kECG** is intended for operation in the electromagnetic environment of medical care facilities (Professional Healthcare) and in domestic environments. The customer or the user of **kECG** should ensure that the operation takes place in an electromagnetic environment that complies with the following requirements.



Attention

- The manufacturer shall guarantee compliance of the device with the EMC requirements only when the specified accessories are used. The use of other accessories may result in increased emission of electromagnetic interference or reduced strength against electromagnetic interference.
- Portable and mobile RF communication devices (including their accessories such as antenna cables and external antennas) should be at least 30 cm (12 inches) distance from all parts of the **kECG** including connected electrodes. Non-compliance can lead to a reduction in the performance characteristics of the device.
- The **kECG** shall not be wear in a magnetic resonance (MR)-, diathermie- or electrocautery environment.
Under the influence of these environments, data recording can be temporarily disturbed or interrupted, although basic safety and essential performance is not affected.
- When the **kECG** is used in an environment with wireless power transfer (WPT), 5G cellular networks, security systems (e.g., electromagnetic anti-theft systems (EAS), and metal detectors), data recording can be temporarily disturbed or interrupted, although basic safety and essential performance is not affected.
- The apparatus shall not be placed directly next to or stacked with other equipment. If such an arrangement is nevertheless necessary, the apparatus must be observed in order to verify its intended operation in this arrangement.



Note

- Further EMC instructions can be found in the safety instructions in **chapter 4.3**.
- Under the influence of increased electromagnetic interference, data recording can be temporarily disturbed or interrupted. This has no influence on the validity of the existing recorded data and its

subsequent analysis.

- In compliance with the EMC and electromagnetic environment guidelines listed in this user manual, no restriction of performance characteristics over the entire life of the medical device is to be expected.

Essential Performance

The kECG contains essential performance functions according the following table:

List of essential performance functions
Distorted/ falsified recorded ECG data/ signals (e.g. because of EMI, ESD, device malfunction) must not result in "wrong positive diagnosed Arrhythmic Events"

Manufacturer's declaration of electromagnetic interference

Interference measurement	Compliance	Electromagnetic environment - Guide
HF emissions (CISPR 11)	Group 1	The kECG uses RF energy exclusively for its internal function. Therefore, its RF emission is very low and it is unlikely that adjacent electronic devices will be disturbed.
HF emissions (CISPR 11)	Class B	kECG is suitable for use in all facilities, including those in the residential area and those directly connected to the public utility network, which also supplies buildings used for residential purposes.
Transmissions of harmonics (IEC 61000-3-2)	<u>Not applicable</u> (< 75 W)	
Transmissions of voltage fluctuations/flicker to IEC 61000-3-3	<u>Not applicable</u> (< 75 W)	

11 Information on electromagnetic compatibility (EMC)

Manufacturer's declaration on electromagnetic immunity

Immunity tests	Test level IEC 60601-1-2:2014/AMD1:2020	Conformity level	Electromagnetic environment - Guidelines
Electrostatic discharge (ESD) (IEC 61000-4-2)	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ±15 kV air discharge	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ±15 kV air discharge	Floors should be made of wood or concrete or with ceramic tiles. If the floor is fitted with synthetic material, the relative humidity shall be at least 30 %.
Magnetic field at frequencies of 50/60 Hz (IEC 61000-4-8) 150 Hz (EN 60601-2-47)	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Magnetic fields at the mains frequency should correspond to the typical values found in a business or hospital environment. kECG does not contain magnetically sensitive components or circuit elements.
Conducted RF disturbances (IEC 61000-4-6)	3 Veff 0,15 - 80 MHz 6Veff in ISM bands between 0,15 and 80 MHz 80% AM at 1 kHz	<u>Not applicable</u>	Portable and mobile radios should be used at no distance from kECG , including lines, than the recommended protection distance of 30 cm: Support for the management of the EM environment and management of medical devices for EMC, including evaluation of the EM environment, investigation and reporting of EMI problems and location selection, is provided by the AAMI TIR 18 guideline.
Irradiated RF disturbances (IEC 61000-4-3)	3 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz	 Disturbances are possible in the environment of devices carrying this image sign.
Near field of wireless RF communication devices	385MHz – 5,7GHz 9-28V/m	385MHz – 5,7GHz 9-28V/m	
Note 1: At 80 MHz and 800 MHz the higher frequency range applies.			
Note 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic quantities is influenced by absorptions and reflections of buildings, objects and humans.			
Note 3: Table 9 of IEC 6100-2-1:2014 gives all test frequencies and immunity levels for wireless RF communication devices. Information is also provided to calculate the minimum protection distances depending on the power, frequency band and immunity level.			

Immunity in the near field of wireless RF communication devices

(IEC 60601-1-2:2014/AMD1:2020, Table 9):

Test Frequency	Band ¹⁾	Service ¹⁾	Modulation ²⁾	Maximum power	Distance	Immunity test level	Conformity level
MHz	MHz			W	meter	(V/m)	(V/m)
385	380-390	TETRA 400	Puls modulation ²⁾ 18 Hz	1,8	0,3	27	27
450	430-470	GMRS460, FRS 460	FM ³⁾ ± 5 kHz deviation 1 kHz sinus	2	0,3	28	28
710 745 780	704-787	LTE Band 13, 17	Puls modulation ²⁾ 217 Hz	0,2	0,3	9	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Puls modulation ²⁾ 18 Hz	2	0,3	28	28
1720 1845 1970	1700-1900	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Puls modulation ²⁾ 217 Hz	2	0,3	28	28
2450	2400-2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Puls modulation ²⁾ 217 Hz	2	0,3	28	28
5240 5500 5785	5100-5800	WLAN 802.11a/n	Puls modulation ²⁾ 217 Hz	0,2	0,3	9	9

Note: In order to achieve the immunity test level, the distance between the transmitting antenna and the **kECG** can be shortened to 1 m if necessary. The test distance of 1 m is permitted in accordance with IEC 61000-4-3.

¹⁾ For some services only the uplink frequencies are included.

²⁾ The carrier is modulated with a rectangular signal with a touch ratio of 50 %.

³⁾ Alternatively to frequency modulation, a 50 % pulse modulation at 18 Hz can be used. Since this does not correspond to the current modulation; this would be the worst case.

11 Information on electromagnetic compatibility (EMC)

Immunity to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz

(IEC60601-1-2:2014:AMD1:2020, Table 11)

Test frequency	Modulation	Immunity test level (A/m)
30 kHz ^{a)}	CW ^{a)}	8 ^{a)}
134,2 kHz	Pulse modulation ^{b)} 2,1 kHz	65 ^{c)}
13,56 MHz	Pulse modulation ^{b)} 50 kHz	7,5 ^{c)}

a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) r.m.s., before modulation is applied.

Distributor - Hotline - Contact:



livetec Ingenieurbüro GmbH
Marie-Curie-Str. 8
79539 Lörrach
GERMANY

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For local contact:
Please visit the website
of your distributor



Subject to modifications due to technical development
GA-0059-1010, Rev. 2026-04-01

**kECG®**

Applying the recorder

Suitable electrode types

Selection and positioning of electrodes

Preparation of the skin surface

Configuration of the **kECG**

Applying the recorder

II Preface

This guide contains instructions for applying the **kECG** Holter recorder system to the patient.

Read the instructions and recommendations carefully before using **kECG**.

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1. Suitable electrode types

For the use of the **kECG Holter recorder systems** it is recommended to use the following types of electrode:

- **SKINTACT** decentralised electrodes, type FS-VB01/ T-V001, available through the distributor of the **kECG**.
- **AMBU** decentralized electrodes, type „**Blue Sensor L**“ or „**Blue Sensor VLC**“ (for sensitive skin), for children „**Blue Sensor P**“, available from the distributor of the **kECG Holter recorder systems** or from specialist retailers.



Attention

- Always note the “durability date” of the electrodes according to the technical data and the information on the packaging of the electrodes.
- In case of open packs: Use the single-use electrodes within a maximum of 5 days (please pay attention to the manufacturer’s information).
- When choosing the electrodes, pay attention to the suitability of the electrodes for Holter and long-term ECG recordings, especially with regard to skin compatibility or suitability for use in children under 10 kg.

2. Positioning of the electrodes



Note

Position of the electrode:

Although the **kECG** includes a variety of measures for high-quality, stable signal dissipation, the following recommendations should be taken into account when attaching the electrode:

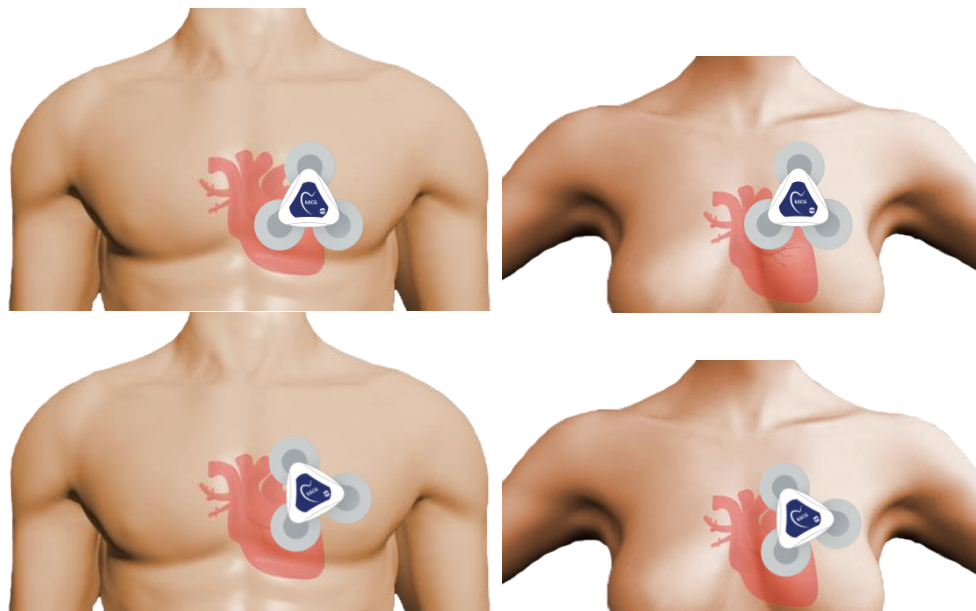
- Place the electrodes according to the following recommendations.
- If possible, avoid placing the electrodes directly on muscle tissue.
- Try to place the electrode(s) in such a way that as little curved skin surface as possible must be balanced.
- The use of **decentralized electrodes** reduces artefacts (e.g. for more corpulent patients) and can be better placed on complex skin surfaces.

The electrodes used can be positioned as follows:

Recommended position: Middle rib cage



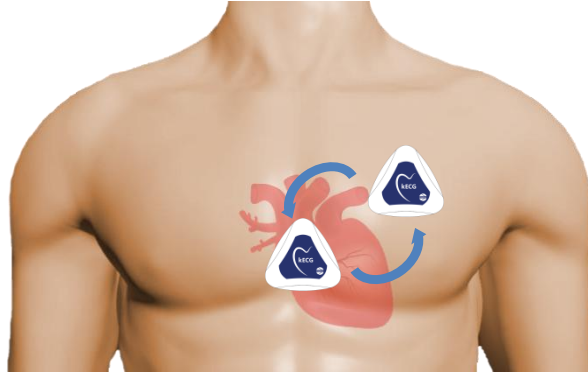
Alternative position: Left chest



Notes on positioning:

- Position the electrodes according to the pictures.
- Make sure that the electrodes are not positioned too high; the lower electrode(s) 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 sternum.

Prepositioning without adhesive electrode(s)



Recommendation:

- Find the optimal location with the help of the **liveECG Init** or **liveECG Viewer** visualisation.
- The positioning closer to the atrium increases the P-wave.



Note

Hints for attaching the electrodes:

- Avoid mechanical voltage on the electrodes.
- A good positioning should also prevent a “raising” of the electrodes during movements.
- Try to place the electrode(s) in such a way that as little curved skin surface as possible must be balanced.

3. Preparation of the skin surface

Carefully prepare the patient to whom you want to apply the electrodes as follows:

- Carefully shave the area of the patient in which the electrodes should be placed (if necessary).
- Clean the body with soap and water or available cleaning and contact agents for ECG recordings.
- Then dry the area carefully.



Note

- In patients who use Body Lotion, the skin must be cleaned or degreased particularly carefully.

4. Configuration of the kECG

Prepare the kECG for use in the following steps:

- Charge the battery of the kECG according to **Annex 3, Chapter 5**.
- Ensure that the battery is fully charged.
- Remove the recorder from the **kECG CONNECT**.



Note

- After removing the recorder from the charger, the recorder performs a self-test. All 3 LEDs of the kECG must light up cyclically (state “**self-test**”).
- Following the self-test, the kECG switches to a power-saving idle state in which it waits for contact with the patient.
- After applying the recorder to the patient and recognizing contact to the patient, the kECG switches to „**Initialization**“ and awaits initialization of the ECG recording -> **Annex 2, Chapter 4**.
- Status indicator -> **Annex 2, Chapter 11**.

5. Applying the kECG

Apply the kECG recorder to the patient as follows:

- Attach 3 individual **electrodes to the kECG** recorder according to the following image.



- Remove the protective foils on the undersides of the electrodes.
- Apply the kECG recorder to the patient by sticking the electrodes and recorders to the patient's skin in accordance with the recommendations of **Chapter 2**.
- Press with medium force on the recorder and on the outer contours of the electrodes.

**Note**

- After applying the **kECG** to the patient, it is essential to perform signal control and optimization of the signal amplitude with suitable software. Note the instructions in **Annex 2** of the instructions for use („Initialisation and Application with analysis systems“)

**Note**

- Note the usage recommendations for the correct electrode positions -> **Chapter 2**.
- After attaching the **kECG** to the patient, the **kECG** switches to „**Ready for Initialisation**“. This state is indicated by a cyclic double flashing of the green LED at the top of the **kECG** recorders. In this state, **kECG** waits for initialisation by suitable software.
- If no initialisation takes place within 10 minutes, the **kECG** recorder **starts** independently with the ECG recording.
- During the initialisation of the **kECG**, the **kECG** switches to the state „**Initialisation**“. This state is indicated by a cyclic flashing of the green LED every 2s.

**Attention**

- Make sure that all 3 contacts of the electrode and the recorder module are connected. Check this by slightly lifting the recorder module at each electrode contact.

**kECG®**

Initialisation and application with compatible ECG analysis systems

Installation of the software

Initialisation and start of ECG recording

Change of electrodes, Charge the battery

Cyclic function and signal control

Body care for long-term shots

Readout and ECG analysis

II Preface

This guide includes a guide to how to use the **kECG Holter recorder system** with compatible analysis software.

Read this guide carefully before using the **kECG recorder** with compatible analysis software. Please also note the instructions in the manual of the used analysis software.

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1. Scope of delivery

Scope of delivery of the **kECG Holter recorder system** see instructions for use of the **kECG**, Chapter 1.

Scopes of delivery of the **used analysis software** see instructions for use of the respective analysis software.

2. Installation of the software

2.1 Installation of **kECG** initialisation software (**liveECG Init**)

Variants:

The **liveECG Init** initialisation software is available in the following variants:

- For Microsoft Windows
- For Android tablets (only for recommended tablets)

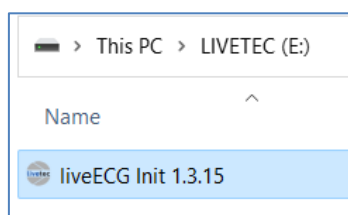
Installation Windows version:

To install **liveECG Init** initialisation software on Windows computers, proceed as follows:

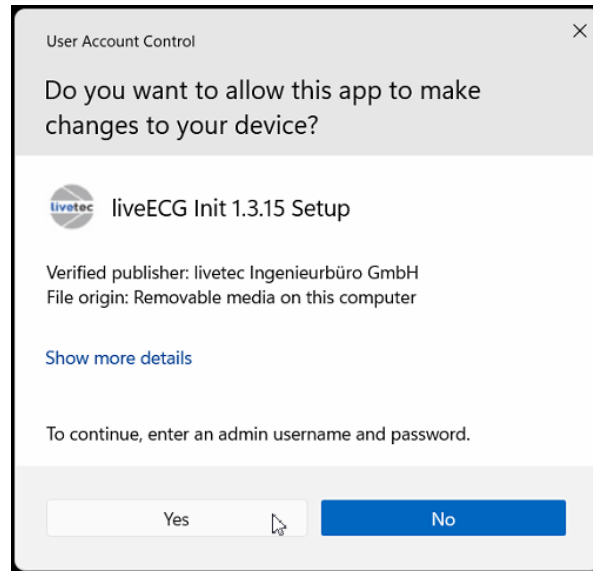
- Insert the USB stick with the initialisation software into a USB slot of your computer.
- Start the installation as follows:

Windows:

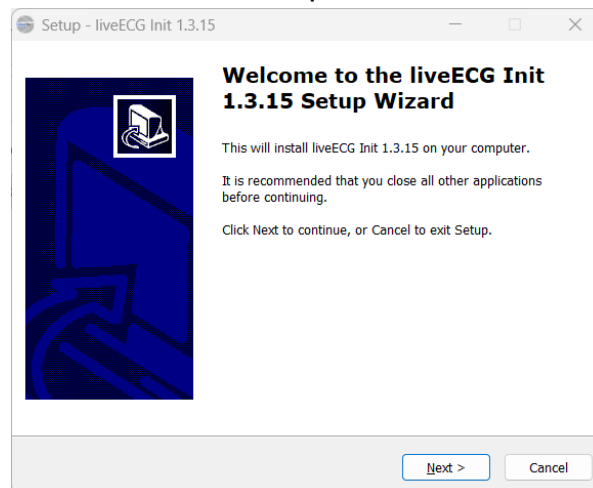
Start the installation software on the USB stick (file "**liveECG Init.exe**") by double-clicking on the corresponding executable file.

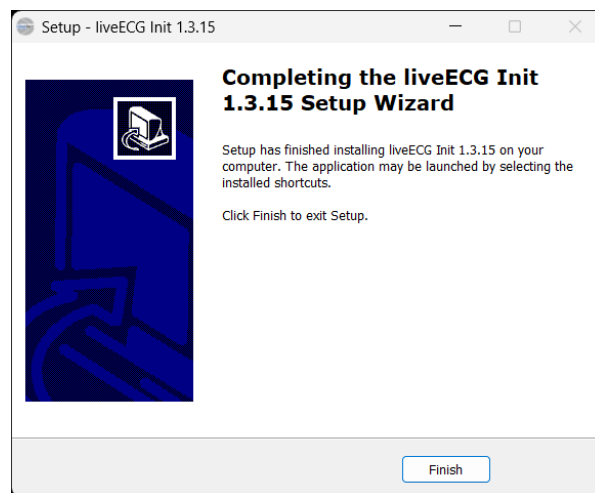
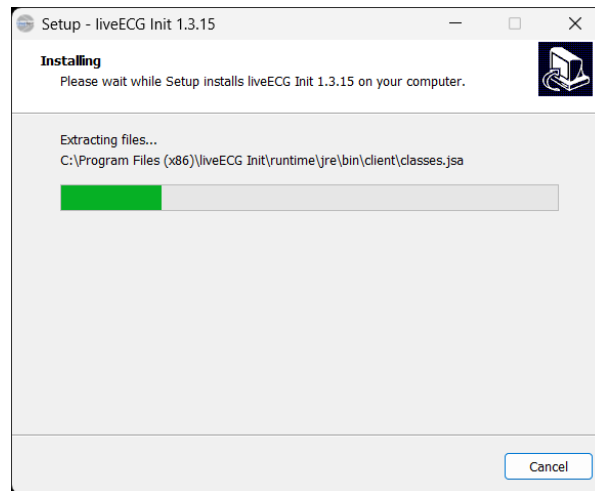


- If a user with restricted rights is logged in, the administrator access data is prompted:

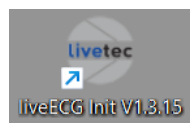


- Then the installation process starts.





- After that, the application can be started on the desktop using the created icon.



System requirements:

- Operating system: From Windows 11 (32bit or 64bit) and higher.
- Minimum hardware requirements: Intel or AMD dual-core processor 1.8GHz or higher.
- Recommendation: Intel Core i3, i5 or i7 from 2.0GHz.

Android version (for tablets):

You will receive the **liveECG Init** initialisation software for Android tablets pre-installed on an appropriate Android tablet. The product name is **liveECG Viewer**.

System requirements:

- The android version of the **liveECG Init (liveECG Viewer)** initialisation software comes only pre-installed on recommended tablets.

2.2 Installation of the used Holter analysis software

Refer to the User Manual of the used analysis software/ system

3. Charging the integrated battery

Charge the battery according to the instructions in **Annex 3, Chapter 5** to the **kECG** instructions for use (**user recommendations and patient training**).

4. Preparing the patient and applying the kECG to the patient

To prepare the patient for ECG recording and to apply **kECG** to the patient, precede according to the instructions in **Annex 1** of the **kECG** Instructions for Use (**Applying the Recorder**).

5. Initialisation and start of ECG recording

After the **kECG** has been attached to the patient's body, the ECG recording should be initialised and started as follows:



Note

- In order for the ECG recording to be initialised, **kECG** must be in the state "**Ready for initialisation**" or state "**Signal control/ECG display**".
- You can see the state "**Ready for initialisation**" by the fact that the green LED on **kECG** flashes 2 times in a row every 2 seconds. This condition is activated automatically after the **kECG** has been applied to the patient.
- They recognise the state of "**signal control/ECG display**" by the fact that all 3 LEDs on the **kECG** flash at the rhythm of the heart rate. This state can be activated at any time by double-clicking on the housing of the **kECG** recorder.
- See **Chapter 11** of this **Annex**.

You can initialise the **kECG** and start ECG recording as follows:

- Initialisation via **liveECG Init Initialisation software** => **Chapter 5.1**.
- Initialisation via **liveECG Viewer** => **Chapter 5.2**.
- Initialisation via installed ECG analysis software => **Chapter 5.3**.

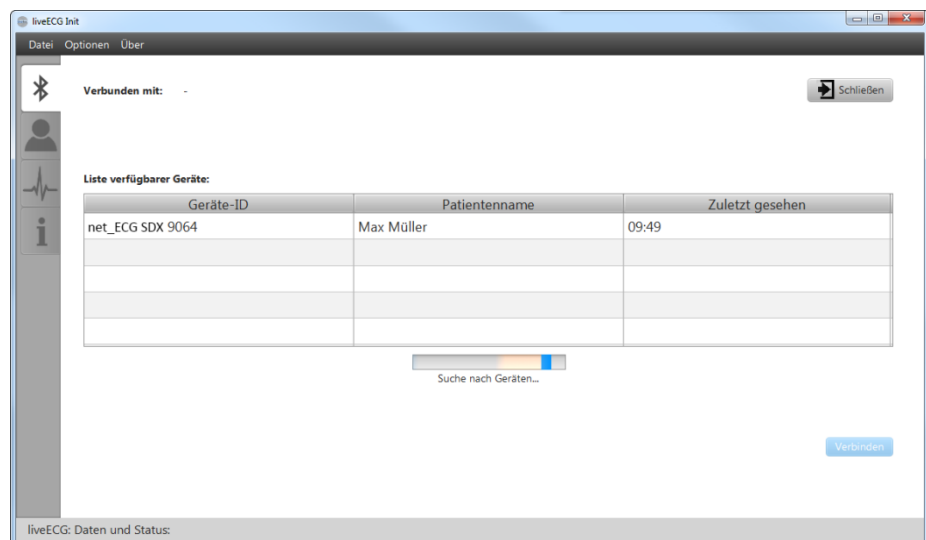
5.1 Initialisation with the **liveECG Init** software

Proceed as follows to initialise the **kECG** using the **liveECG Init initialisation software**:

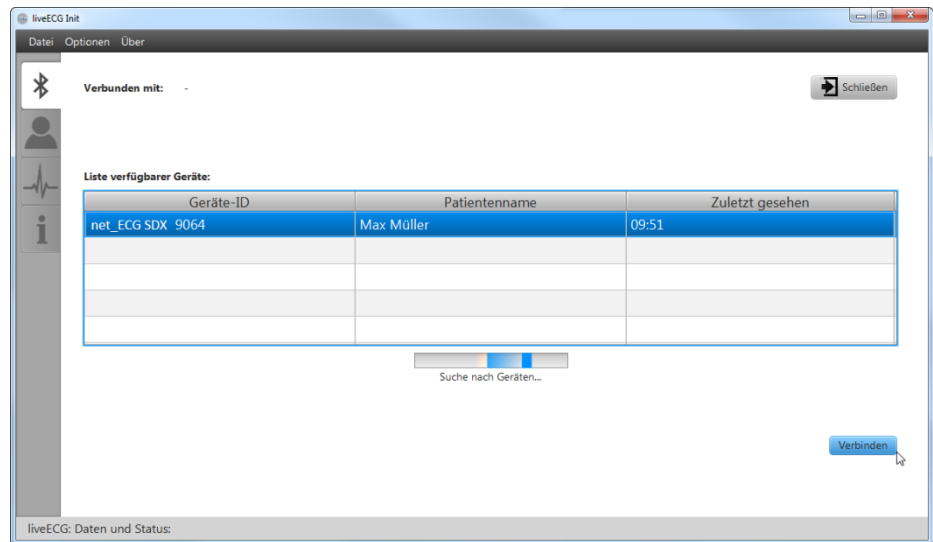
- Start the **liveECG Init initialisation software** by double-clicking with the left mouse button on the following icon on your desktop:



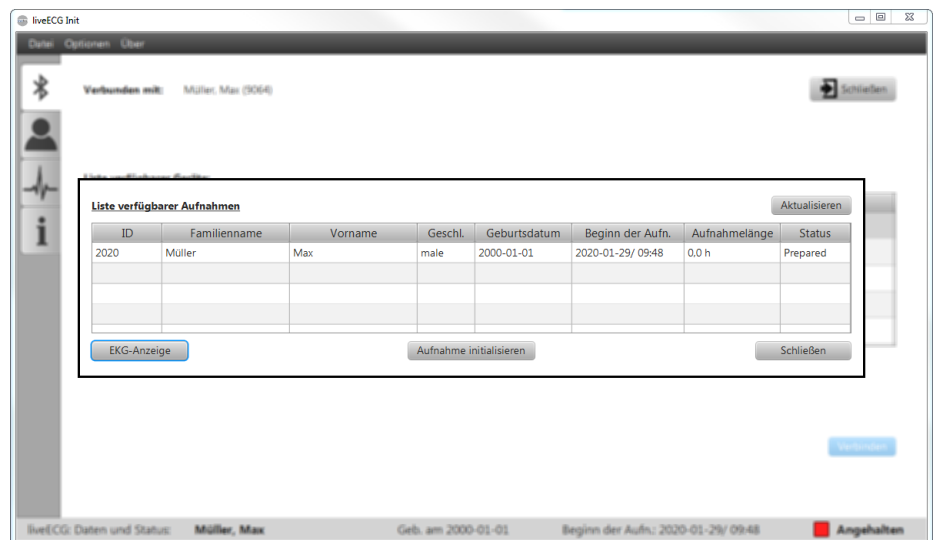
- After a few seconds the screen appears according to the following image.
- In this view, the initialisation software searches for available **kECG** devices and displays them in the list.



- Select the patient's **kECG** device for which a recording is to be initialised and performed, with the left mouse button and then click the **"Connect"** button.

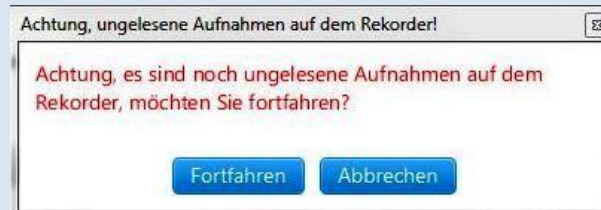


- The following screen appears.
- In this view, the ECG recordings present on the **kECG** are shown in tabular form.



Note

- If there is still a valid ECG recording on the **kECG**, which has not yet been read out and evaluated, the following message appears:



- Click the **“Continue”** button if you still want to initialise and start a new recording (or want to append to the existing recording).
- Click on **“Cancel”** if you want to first read out and analyse the still existing recording.
- To start a new ECG recording, select the existing recording with the left mouse button and then click the **“Initiate recording”** button.
- The following screen appears:

- Enter the patient's data (with mouse and keyboard) and then click the **“Apply”** button. The entered patient data is transferred to the **kECG recorder**.
- After performing an automatic gain adjustment (AutoGain). After successful AutoGain, all three ECG leads should have a similar amplitude in the range of approximately 1.5 mV. The following screen will appear:



- This screen is used for online display of the ECG signals of the patient and for optimising signal quality and signal amplitude.
- Optimise the signal quality and amplitude of ECG signals as follows:

Signal optimization for signals with high noise, artifacts or strong zero line fluctuations:

- Check whether the **kECG** is correctly connected to the electrodes.
- Remove the **kECG** and the electrode from the patient, clean the skin surface of the patient and reapply a new electrode/ **kECG**.
- Position the electrode/the **kECG** in a place as close to the heart as possible (see also **Annex 1/Chapter 2**).



Note

Good signal quality is given if all 3 signals have the following characteristics:

- No signal disturbances (noise).
- Few artefacts and little zero-line fluctuations.
- The amplitude of all signals should be between 1 and 2 mV.

Optimising the signal amplitude:

- Optimise the signal amplitude over the switching surfaces **"AutoGain"** and **"Amplification"** until the amplitude of each

channel is in the range between 1 and 2 mV.

- At these amplitudes, the best analysis results are achieved.

Start the ECG recording:

- Then start the ECG recording via the button **"Start the recording"**. Then confirm the start.
- The following screen appears:



Note

- You can recognise a successful start of the ECG recording via the State line at the bottom (start of recording is displayed via a green dot and the text "Recording").
- You will also recognise a successful start of ECG recording at **k**ECG itself. After a start of the ECG recording, the LEDs flash in the heart rhythm of the patient. See also **Chapter 11** of this document (state displays).
- Then quit the program using the **"Close"** button.

5.2 Initialisation with the **liveECG Viewer APP**

The initialisation of the **kECG** and the start of ECG recording with the help of the **liveECG Viewer APP** are identical to the initialisation with the **liveECG Init** initialisation software.

Only the appearance of the **liveECG Viewer APP** is slightly different from the **liveECG Init** initialisation software.

For information on the **liveECG Viewer APP**, refer to the operating manual, chapter 9.1/ 9.2.

5.3 Initialisation with installed analysis software

Some analysis software systems like **PADSY Holter** or **Cardioline Cubeholter Software** already include the **liveECG Init** software. Refer to the instructions in the corresponding user manual when using software with integrated **liveECG Init** software.

6. Change of electrodes

Switch electrodes according to the instructions in **Annex 3, Chapter 4** to the **kECG** instructions for use (**user recommendations and patient training**).

7. Cyclical function control

A cyclical functional control should be performed during an ECG intake. Note the following hints:



- A cyclic flashing of the green LED in a rhythm of 1 or 2 seconds indicates a correct function of the **kECG**.



- The light of the red LED indicates an error.
- In this case, charge the integrated battery and reapply the **kECG**.
- Stop the ECG recording and notify the service if the red LED still lights up afterwards.



- The yellow LED indicates the discharge state of the integrated battery.
- Charge the integrated battery at the latest when the yellow LED flashes at 1s rhythm (1 Hz).



Note

- Note the description of the state displays in **Chapter 11** of this document.



Note

- If the **kECG** is temporarily removed from the electrode (e.g. during body cleansing or when changing the electrode), this is recognised by the **kECG** and the device changes to the State "Pause".
- In this state, instead of an ECG's, we recorded a zero line or a pseudo QRS complex at 60 bpm.
- After the re-attachment of the **kECG** on the electrode (after detection of the patient contact), the device proceeds independently with the ECG signal recording and storage (state "ECG recording").
- The states "ECG recording" and "Pause" are displayed by **kECG** via the green State – LED (-> Chapter 11).

8. Cyclical control of ECG leads

Especially for ECG recordings over long periods of time, it may make sense to occasionally check and optimise the quality of ECG signals, e.g. after changing the electrodes or the battery.



Note

You can perform the cyclic signal control using the **liveECG Init initialisation software**, the **liveECG Viewer APP** or the installed analysis software as follows:

- Activate the **"Signal Control/ECG Display"** state.
- This state can be activated at any time by double-clicking on the housing of the **kECG** recorder (see also **Chapter 11**).
- Start the **liveECG Init** initialisation software and connect to the **kECG** of the patient whose signals you want to control/optimize as described in **Chapter 5**.
- Activate the ECG signal display.
- Optimise the signal amplitude and signal quality as described in **Chapter 5** of this document.

9. Body care

Please refer to the instructions in **Annex 3/Chapter 3** of the instructions for use on the patient's personal care, especially in the case of long-term recordings (**user recommendations and patient training**).

10. Stop ECG recording and analysis of ECG recording

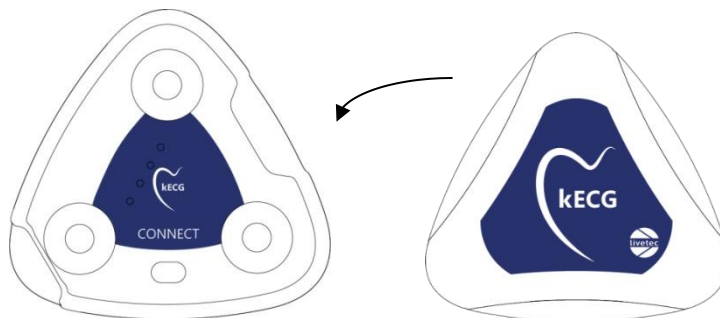
Proceed as follows to finish an ECG recording and then evaluate the recording with the used analysis software system:

Stop ECG recording:

- To finish the ECG recording, simply remove the **kECG** from the electrodes.

Read out the ECG recording/import into the used analysis software:

- Connect the **kECG CONNECT** to the computer on which the used analysis software is installed, via the supplied USB cable.
- Place the **kECG** in the **kECG CONNECT**.



- Then import the ECG recording from the **kECG** into the analysis system used and analyse the ECG recording according to the instructions in the respective user manual of the analysis system used.



Attention

- Make sure that the software of the analysis system is configured correctly so that the **kECG** recorder is recognised by the system and they can work properly together.
- Follow the instructions in the user manual of the analysis system used.
- ECG recordings may only be read out if the device has no connection to the patient (via the ECG electrode contacts).

11. State display of the kECG

Display elements of the kECG:



	The kECG includes 3 LEDs for displaying device/battery and error State as follows:
	➤ Green LED: Display of the current device state and additional signal control channel 3.
	➤ Yellow LED: Display of battery state and additional signal control channel 2.
	➤ Red LED: Display of error state and additional signal control channel 1.

State "Charge"

	In this state the integrated battery of the kECG is charged. The following states are displayed during charging:
	➤ Green LED: Blinks in 2s rhythm when charging. ➤ Green LED: Permanently "ON" when battery is fully charged. ➤ Yellow LED: Indicates the battery status (see below)
 Note	This state is started automatically as soon as the device is placed in the kECG CONNECT .

State „Self-test“:

	In this state, kECG performs an internal self-test, during which all
--	---

	important functions of the device are tested.
	➤ All 3 LED's flash every 2s for the duration of 1s.
 Note	This state is automatically activated after the kECG is removed from the kECG CONNECT. This state is equivalent to "Device ON".
	➤ State "Error ": The red LED lights up continuously for 15 s if the self-test detects a device error and thus no ECG recording is possible. ➤ In this case contact the service team.

State „Ready for initialisation“:

	In this state, kECG is ready for initialisation by the liveECG initialisation software . This state is displayed as follows:
	➤ Green LED flashes every 2s twice for the duration of 200ms.
 Note	This condition is automatically activated after self-testing has been carried out.

State „Initialisation“

	In this state an initialisation by the liveECG Init initialisation software takes place. This state is displayed as follows:
	➤ Green LED flashes every 2s for the duration of 1s.
 Note	This state is achieved as soon as the initialisation software liveECG Init is connected to the kECG and an initialisation takes place.

Note	
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State „Signal Control/ECG display“:

 Note	In this state an amplitude modulated (with brightness modulated) display of the 3 ECGs via the 3 LEDs of the kECG takes place as follows:
	➤ Display channel 1 (derivation I), amplitude/ brightness modulated
	➤ Display channel 2 (derivation II), amplitude/ brightness modulated
	➤ Display channel 3 (derivative III), amplitude/ brightness modulated
 Note	In this modulated display, the R-spike as well as the T-wave of the ECG is visible.
 Note	This state is automatically activated after initialisation and start of ECG recording. However, this state can be activated as desired during the ECG recording by a “double click” with medium force on the kECG. This state is active for approx. 120s after activation. Then the kECG switches to the state “ECG recording”.

State „ECG recording“:

	In this state an ECG measurement and recording takes place. Patient contact is available.
	➤ Green LED flashes every 2s for the duration of 200ms.

State „Pause“:

	In this state the ECG measurement and recording is interrupted
--	--

	because there is no patient contact:
	➤ Green LED flashes every second for the duration of 200ms.

 Note	➤ In this state, instead of an ECG's, a zero line or a pseudo QRS complex is recorded at 60 bpm (ppm). ➤ This state automatically changes to the state "ECG recording" as soon as the patient contact is detected again within approx. 24h. ➤ After 24h, the current recording is terminated and the device goes into to "Rest" state.
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State „End“:

	This state indicates the end of a recording. This condition is achieved e.g. after a serious error or after a detection of an empty battery.
	➤ All LED's off.

State „Battery State“:

	The battery State is displayed at kECG as follows:
	Condition EOS-1: Residual battery life ≥ 12 h ➤ Yellow LED flashes every 2s for a duration of 200ms.
	Condition EOS-2: Residual battery life ≥ 6 h ➤ Yellow LED flashes every second for the duration of 200ms.

State „Error State“:

	A serious error leading to the interruption of the recording is displayed at kECG as follows:
	➤ Red LED is permanent ON. ➤ Troubleshooting See kECG Instructions for use, Chapter 7.

**kECG®**

Application recommendations for users and for patient training

Putting into service and general instructions

Recommendations for patient training

Body care

Change of electrode

Charging the battery

Manual event markers

II Preface

This guide contains instructions and recommendations for users and patients for the use of the **kECG Holter recorder system**, especially for recordings over longer periods of time.

Read recommendations carefully before using the **kECG recorder**.

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Your
Distributor
Hotline /
Contact

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1. Start operation and general instructions



Note

When commissioning and operating the **kECG** Holter recorder system, please note the following information:

- Note the usage recommendations for applying the **kECG** recorder (**Annex 1 of the Instructions for Use**).
- Clean (save if necessary) and dry the area where the electrodes are placed carefully.
- Do not use electrodes whose packaging is open for more than 5 days (consider the manufacturer's recommendation).
- Make sure that the integrated battery is charged before starting an ECG recording.
- Pay attention to the correct connection of the recorder to the electrodes.
- Place the electrodes carefully.
- Check the adhesive resistance of the electrodes several times a day.
- Check the contact of the recorder to the electrodes several times a day (by raising the recorder at the corners).
- When using radio-based phones (e.g. mobile phone/mobile phone/smart phone/tablet PC/DECT phone/radio), a distance from the **kECG recorder** of at least 30 cm should be respected. The devices must not be stored on the **kECG recorder**. This applies in principle to other electrically operated devices (e.g. hair dryer, shaver, computer, WLAN, etc.).

2. Patient training



Note

Before using the **kECG** Holter recorder system, train patients carefully in the use of the system and, in particular, provide them with the following instructions:

- The adhesive resistance of the electrodes should be checked by the patients several times a day.
- The electrodes should be changed at least every 2 days, in hot weather or bad adhesive contact every 24 hours.
- The contact of the recorder to the electrodes should be checked regularly and several times a day (by carefully lifting the recorder at the contacts to the electrode).
- Direct contacts/impacts with/to the **kECG** should be avoided as far as possible.
- The patient should sleep as far as possible in supine position.
- The patient should avoid strong physical activity such as jogging or sports in general or strenuous physical work unless these activities are instructed by a doctor. This serves to improve the signal quality (e.g. avoiding shocks and shocks).
- If possible, no tight clothing should be worn in the chest area.
- Train the patients in carrying out personal care according to the following chapter.
- During an ECG recording (especially for long-term recordings), regularly observe the battery status display on the **kECG**. If the yellow LED flashes in a 1s rhythm, contact your doctor immediately.



Attention

- The **kECG** is shower-resistant. Nevertheless, it is recommended to remove **kECG** from the electrode (from the body) before showering.
- Do not spill liquids over the device.

2.1 Precautions for the patient, skin irritation



Note

- The kECG is suitable for use on children under 10 kg.



Attention

- Although the electrodes defined for kECG are very skin-compatible and comply with the normative requirements (ISO 10993-1/5/10), longer records may cause skin irritation (itching, redness).
- In these cases, stop the ECG record and contact your doctor immediately.
- Increased skin irritation is expected in patients treated with cortisone preparations. You should also do very carefully here when attaching and removing the electrodes from the skin surface.

3. Body care for long-term recordings

Especially for applications >24 hours, the following instructions should be taken into account for daily personal care (both inpatient and outpatient):

Cleaning without shower/bathroom:

- If possible, save the area around **kECG** from cleaning without a shower/bath if possible. For such cleaning, **kECG** does not need to be removed from the electrode.



Warning

Showers:

- The **kECG** is shower-resistant.
- Nevertheless, it is recommended to remove **kECG** from the electrode (from the body) before showering.



Note

- When showering, the electrodes can remain on the body.
- After showering, dry the electrode carefully and wait a few minutes until the electrode is completely dried before reconnecting the **kECG** to the electrode.



Warning

Bathing/swimming:

- Remove **kECG** from the electrode (from the body) before bathing or swimming. Also remove the electrode from the body.
- After the bath, apply the **kECG** to the body again according to the instructions in **Chapter 4**.
- Dry the skin carefully before sticking the new electrode onto the body.



Note

- Always glue a new electrode to the same place as the predecessor electrode.
- Instructions on removing/applying **kECG** from the electrode and changing the electrode can be found in the following chapter.

4. Change of electrode

The electrodes defined for the use of the **kECG** are suitable for ECG recordings over several days and have very good adhesive and contact properties. However, it is recommended to change the electrodes after 2 days at the latest, at warm and hot temperatures every 24 hours. Proceed as follows:

- Remove the **kECG** /electrode from the patient's body and separate the **kECG** from the electrodes.
- Clean the body surface according to the instructions in **Annex 1 to the instructions for use (apply the recorder)**.
- Also remove any adhesive residues of the predecessor electrode.
- Dry the skin before applying the new electrode.
- Use new electrodes and first apply the electrode(s) to the **kECG** recorder according to the following images:
- Remove the protective foils on the undersides of the electrodes.



- Then attach the **kECG** recorder with the electrodes to the patient's skin.
- Press with medium force on the recorder and on the outer contours of the electrode.
- Always glue a new electrode to the same place as the predecessor electrode.



Note

VI Application recommendations for users and patient training



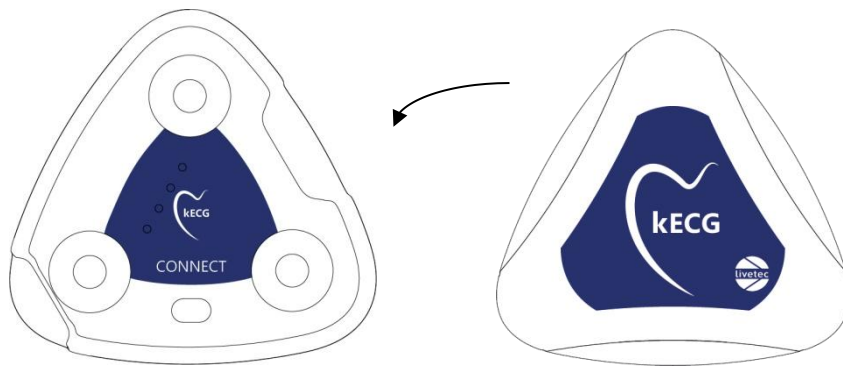
Attention

- Always note the “durability date” of the electrodes according to the technical data and the information on the packaging of the electrodes.
- In case of open packs: Use the electrodes within a maximum of 5 days (compliance with manufacturer’s recommendation).
- Please refer to the instructions for cortisone preparations in **Chapter 2.1**.

5. Charging the battery

Proceed as follows to charge the battery:

- Connect the **kECG CONNECT** to the USB interface of the computer on which the analysis software is installed using the micro-USB cable provided.
- Insert the **kECG** into the **kECG CONNECT** according to the illustration:



- The status of the integrated battery is indicated by the LED status display as follows:
 - Charging: Green LED blinks in a 2s rhythm.
 - Full charge: Green LED permanently ON.
 - -> **Annex 2/ Chapter 11.**
- Remove the **kECG** from the **kECG CONNECT**, after fully charging and reapply the recorder module to the electrodes or use new electrodes as described in **Chapter 4** (recommended).



Note

- After removing the **kECG** from the **kECG CONNECT**, the unit switches on automatically and all 3 LED's of the **kECG** must light up cyclically for a few seconds (**state "self-test"**).
- Recommended ambient temperature during charging: +15°C - +35°C.
- For long time recordings it may be necessary to recharge the battery. A fully charged battery allowed a recording time of up to 18 days.

VI Application recommendations for users and patient training

kECG

- The integrated battery has a limited life span, which depends on many factors. If the running time of the unit becomes considerably shorter than usual, the end of the battery life has been reached. In this case, send the device to the service department for battery replacement.



Attention

- During an ECG recording (especially for long-term recordings), regularly observe the battery status display on the kECG.
- Charge the battery as soon as the status display shows the status "EOS-2" (yellow LED flashes every second).
- Always fully charge the battery before starting a recording.
- Do not open the device under any circumstances, e.g. to replace the battery itself. This is strictly reserved for the service.

6. Cyclical function control

During an ECG intake, a cyclical functional check should be carried out as follows. Note the following hints:



- A cyclic flashing of the green LED in a rhythm of 1 or 2 seconds indicates a correct function of the kECG.



- The light of the red LED indicates an error.
- In this case, charge the battery and reapply the kECG.
- Stop the ECG recording and notify the service if the red LED still lights up afterwards.



- The yellow LED indicates the discharge state of the battery.
- Charge the battery at the latest when the yellow LED flashes in the 1s rhythm.

7. Definition of manual event markers

The kECG offers the possibility that the patient can define manual event markers at any time, for example if he feels “uncomfortable” or if he suspects arrhythmias (with appropriate symptoms). Event markers can be defined by the patient as follows:

- Double click/double stroke on the housing of the kECG.
- After the definition of a manual event marker, the kECG switches to the status **“signal control/ECG display”**.
- In this state an amplitude modulated (thus brightness modulated) display of the 3 ECG derivatives via the LEDs of the kECG takes place.



Note

- To make sure that a manual event marker has been detected by kECG, repeat the double click on the case until the state **“signal control/ECG display”** is displayed and all 3 LEDs (red, yellow green) on kECG flash at heart rhythm.