IEM®

HeartX

Recorder

Instructions for Use

Table of Contents

1 Information on the Manual

1.1 Publication Information

The information in this manual applies only to the HeartX Recorder and related Accessories. Due to continuing product innovation, specifications in this manual are subject to change without notice.

This manual is developed and owned by GETEMED Medizin- und Informationstechnik AG (GETEMED), Oderstr. 77, 14513 Teltow, Germany.

CardioDay is a trademark owned by GETEMED.

Microsoft and Windows are either registered trademarks or trademarks of Microsoft Corporation in the United States and/or other countries.

The CE mark indicates that the product complies with medical device regulations of the European Union and other jurisdictions recognizing this mark:

Revision History

Revision	Publication Date	Description
01	26.03.2025	Initial release

Contact your local representative for related product manuals.

2 Regulatory and Safety Information

2.1 Introduction

This document provides comprehensive guidelines for the operation and handling of the HeartX Recorders and associated applications, collectively referred to as the "systems," "devices," or "products." It is specifically designed for operators of these devices.

In addition, optional software such as CardioDay is available for use during the patient setup phase. This standalone software allows operators to configure the recorder with patient demographic data, visually monitor ECG waveforms, adjust recorder settings, and initiate the recording process.

The HeartX Recorder is intended for use with both adult and pediatric patients, including those weighing less than 10 kg.

This section provides information about the safe use and regulatory compliance of this system. Familiarize yourself with this information, and read and understand all instructions before attempting to use this system. Both the HeartX Recorder and the Stand-alone-application are medical devices. As such, they were designed and manufactured to the appropriate medical regulations and controls.

Disregarding the safety information provided in this manual is considered abnormal use of this system and could result in injury, data loss, or a voided warranty.

2.2 Intended Purpose

The device is intended to continuously record up to 3-channel ECG data. The recorded data is downloaded for analysis and subsequent evaluation by a trained physician or healthcare professional. Patients include pediatrics weighing less than 10 kg, children and adults in home environments, hospitals or hospital-like facilities. The device is suitable for patients who may benefit from long-term continuous electrocardiographic recording, including, but not limited to, patients with conditions such as palpitations, syncope, chest pain, shortness of breath, or patients who need to be monitored to assess current cardiac function. The device is not intended for use as a critical care monitoring system and must not be used in emergency situations.

2.3 Indications and Contraindications

2.3.1 Indications for Use

The device is suitable for patients who may benefit from long-term continuous electrocardiographic recording, including, but not limited to, patients with conditions such as palpitations, syncope, chest pain, shortness of breath, or patients who need to be monitored to assess current cardiac function.

2.3.2 Contraindications

There are no known contraindications for the use of these devices.

2.4 Labels and Symbols

2.4.1 Medical Device Compliance

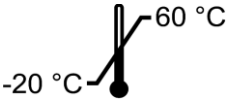
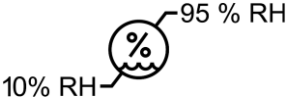
The CE mark and the notified body's registration number confirm that this medical device complies with the essential requirements of Regulation (EU) 2017/745 (MDR).

2.4.2 Used Symbols

The following symbols may appear on the device or its packaging. Familiarity with these symbols assists in the safe use and disposal of the equipment.

Symbols are used to convey warnings, cautions, prohibitions, mandatory actions, or information. Any hazard symbol on your device or packaging with markings in color indicates there is certain danger and is a warning. Any hazard symbol on your device or packaging that is in black and white indicates a potential hazard and is a caution.

Symbol	Description
SN	Serial number
REF	REF (catalogue) number
	UDI marking comprising the matrix code with GTIN (01), date of manufacture (11), device serial number [SN] (21) and the order number [REF] (241)
DE yyyy-mm	Name and address of the manufacturer (including country) and also, if applicable, the date of manufacture in year and month
CE 0197	CE mark followed by the notified body registration number of the manufacturer
	Observe the Instructions for Use
IP21	This symbol indicates that the device is protected in accordance with IP21 against the ingress of fluids and foreign matters; 2 = protected against solid objects larger than 12.5 mm, 1 = protected against vertically falling drops of water or condensation

Symbol	Description
IP67	This symbol indicates that the device is protected in accordance with IP67 against the ingress of fluids and foreign matters; 6 = dust-protected; 7 = protected against temporary immersion in water up to 1 meter for 30 minutes
	This symbol informs medical experts that the recorder is protected against electric shock in accordance with the class of protection "Body floating" (BF) and NOT protected against defibrillation.
	This symbol refers to the obligation to dispose of the device in accordance with the relevant environmental regulations.
	Temperature range –20 °C ... 60 °C during storage and transport
	Humidity range 10% ... 95% during storage and transport
	Atmospheric pressure range 70 kPa ... 106 kPa during storage and transport
	Fragile
	Keep away from heat
	Keep dry
	The packaging is recyclable

Symbol	Description
MD	Medical device
LiPo 3,7 V/550 mAh	Lithium Polymere rechargeable battery inside
FC	FCC approval symbol for US and Canada
eIFU Indicator www.iem.de/user-manuals	eIFU indicator - web based instructions reference

2.5 Warnings, Cautions and Notices

A Hazard is a source of potential injury to a person or damage to property or the system.
This manual uses the terms DANGER, WARNING, CAUTION, and NOTICE to point out hazards and to designate a degree or level of seriousness. Familiarize yourself with the following definitions and their significance.

Definition of Safety Conventions

Convention	Definition
DANGER	Indicates an imminent hazard, which, if not avoided, will result in death or serious injury.
WARNING	Indicates a potential hazard or unsafe practice, which, if not avoided, could result in death or serious injury.
CAUTION	Indicates a potential hazard or unsafe practice, which, if not avoided, could result in moderate or minor injury.
NOTICE	Indicates a potential hazard or unsafe practice, which, if not avoided, could result in the loss or destruction of property or data.

2.5.1 Safety Hazards

The following message refers to the system as a whole.

CAUTION
Only connect the docking station to USB power sources that meet the EN IEC 60950 or EN IEC 62368 standards to avoid potential safety hazards and to ensure compliance with regulatory requirements. Using non-compliant power sources may damage the device or lead to unsafe operation.

2.5.2 Incident Reporting

A serious incident is a device malfunction that results in death or serious injury, or may lead to death or serious deterioration of health.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

2.6 Cleaning and Disinfecting

To maintain the HeartX Recorder, it is important to follow the steps below for cleaning and disinfection. These steps must be performed at regular intervals, prior to first use, and before passing the device on to another person.

Preparation:

- Let the device switch off before cleaning and disinfection.

Cleaning:

- Use a lint-free cloth slightly moistened with a mild soap solution to wipe the surface of the device.
- Ensure all visible dirt and debris are removed from the device and especially on the gold-plated contacts before proceeding to disinfection.

Disinfection:

- Disinfect the device using a 70% alcohol solution.
- Ensure to follow the recommended application time for the disinfectant, which is 10 minutes for a 70% alcohol solution.
- After the application time, use a lint-free cloth slightly moistened to remove any residue from the disinfectant.

Limitations:

- The device is capable of withstanding up to 800 cleaning/disinfection cycles (equivalent to 5 years of normal use).
- Machine reprocessing is excluded for this product, and the device is not intended for sterilization.
- Solutions containing the following compounds are known to damage the product:
    - Dimethyl Benzyl Ammonium Chloride
    - Quaternary Ammonium Chloride solutions
    - Abrasive cleaners or solvents of any kind
    - Acetone
    - Ether / petroleum ether
    - Ketone
    - Betadine
    - Sodium salts

Validation and Responsibility:

- The instructions listed above have been validated by the medical device manufacturer as suitable for preparing the device for reuse.
- It is the responsibility of the user to ensure that the cleaning and disinfection process carried out with the available equipment, materials, and personnel achieves the desired results.
- This requires verification, validation, and routine monitoring of the process to ensure it is effective.

2.7 Disposal Information

The HeartX Recorder and its accessories contain materials such as metals and plastics that must be disposed of in an environmentally friendly manner after their service lifetime has expired. Please return the device and accessories to your authorized dealer or the manufacturer for proper disposal.

To comply with applicable regulations, the following components will be separated and disposed of properly:

- lithium-ion battery,
- casing,
- printed circuit boards,
- accessories (USB-cable, docking station, etc.).

Disposable ECG electrodes must not be disposed of with household waste. They should be collected in a sealed container or plastic bag and taken to a local recycling center. Reusable accessories must be returned with the recorder.

Before returning the device, all parts must be cleaned and disinfected as described in section 2.6.

If you have any questions about disposal, please contact your authorized dealer or the manufacturer.

3 Product Overview

This chapter describes the main features of the recorder. You will be presented more specific information and graphics in the following sections.

3.1 Recorder, Docking Station and Application

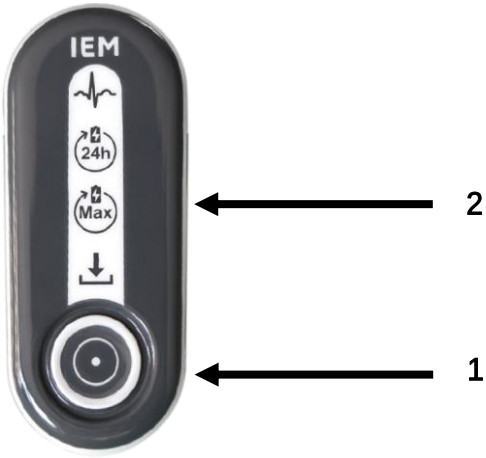
The HeartX Recorder is a compact device designed for long-term, 3-channel Holter ECG recordings. One of the key features of the HeartX Recorder is its automatic pacemaker pulse detection, which operates as a standard feature without requiring any user configuration. Pacemaker pulses are visualized using dedicated analysis software. The recorder is worn directly on the chest for comfortable, discreet use over extended periods.

The HeartX Recorder docking station is used to charge the device and transfer recorded ECG data. Equipped with gold-plated contacts, it ensures a stable connection for reliable data transfers via USB, while simultaneously charging the device to keep it ready for use.

An optional external application (App) can be used for patient setup and data management. These applications allow operators to configure the recorder with patient demographics, inspect real-time ECG waveforms, adjust settings, and start recordings. One such example is CardioDay, a software that runs on a standard PC with a Microsoft Windows operating system. After data transfer via the docking station, these applications facilitate detailed ECG analysis and reporting.

3.2 Operating Elements of the Recorder

The recorder has a Button (1) that allows to switch on the recorder and start a recording, and Status LEDs (2) that provide visual indicators for lead-off detection, battery life, memory status, and device operation.



3.2.1 Button

The **Button** is marked with the symbol  and is used to perform the following function:

Action	Function	Feedback
Press and hold until a beep sounds	Switch on the recorder	A single beep confirms the recorder is powered on.
Press and release	Start a recording without the app	A double beep confirms that recording has started.

Recording can only be started if the ECG electrodes are in contact with the skin and the lead-off detection does not prevent the start.

3.2.2 LEDs and Symbols

The front of the recorder displays four key symbols: ECG, 24h, Max, and Download, each with an LED indicator. The colour and flashing frequency of these LEDs represent the current status of the recorder, providing important information about lead-off, battery levels, and data availability.

During the startup process, the LEDs light up in the following order, alternating between green and orange:

1. ECG-LED: Orange, then green
2. 24h-LED: Green
3. Max-LED: Green
4. Download-LED: Orange, then green

This sequence confirms that the recorder is powering on correctly and preparing for use. In case of an error, both the ECG-LED and Download-LED will fast flash orange, indicating an issue that requires immediate attention to resolve the malfunction or connectivity problem. If an error occurs during the startup process, the device is switched off after thirty seconds.

3.2.3 Device States and LED Configuration

The table below provides an overview of the LED symbols on the front of the recorder, detailing their behaviours and the corresponding statuses they indicate.

Symbol	Status Category	LED Behavior	Meaning
ECG-LED	Lead-Off Status	Constant green	ECG quality is good
	Lead-Off Status	Flashing orange	Lead-off resulting in poor ECG signal
	Recording Status	Slowly flashing green	Recording in progress
24h-LED	Battery Status	Flashing green	Charging for 24 hours of use
	Battery Status	Constant green	Battery sufficient for 24 hours
Max-LED	Battery Status	Flashing green	Charging for the pre-set usage duration
	Battery Status	Constant green	Battery sufficient for the set number of days
Download-LED	Download Status	Constant orange	Recording available
	Download Status	Flashing orange	Downloading in progress

3.2.4 Audible Notifications

The HeartX Recorder provides the following audible feedback:

Status	Buzzer Notification
Recorder is turned on	Single beep
Recording has started	Double beep
Recording cannot start (e.g. due to weak battery)	Three low beeps
USB detection (docking station)	Short double beep
Recorder is switched off	Single beep
Bluetooth pairing confirmation	Short double beep
Bluetooth pairing successful	Rising tone sequence
Bluetooth pairing failed	Three beeps (low frequency)
Error (during startup)*	Repeating beeps

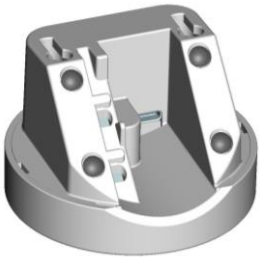
*If an error occurs during the startup process, the device is switched off after thirty seconds.

3.3 Performing a Device Reset

If the recorder becomes unresponsive and can no longer be operated, it can be reset by placing it on the connected docking station and holding the Button for more than 10 seconds. After switching on, the recorder performs a series of internal tests. If the ECG- and Download-LED are fast flashing orange, the recorder has encountered a fault and requires service.

3.4 Charging the Battery

The device is equipped with a built-in rechargeable lithium-polymer battery, which is charged via the provided docking station. To install the docking station, start by connecting the USB cable to the port located at the bottom of the docking station. Ensure that the cable is properly placed in the provided cable guide to prevent strain on the connection. This helps reduce the risk of cable damage over time.



Once the cable is secured in the guide, connect the other end to a compatible USB power source, such as a computer or USB wall adapter, to provide power and enable data transfer between the recorder and the connected device.

CAUTION

Only connect the docking station to USB power sources that meet the EN IEC 60950 or EN IEC 62368 standards to avoid potential safety hazards and to ensure compliance with regulatory requirements. Using non-compliant power sources may damage the device or lead to unsafe operation.

Place the device on the docking station, ensuring that the USB contacts on the back of the device align with the spring-loaded pins of the docking station to establish a secure connection. The magnets on the docking station will assist in properly positioning the device. The charging process will start automatically once the device is correctly placed. The device can be charged even when it is switched off.

The device's LEDs provide clear indications of the charging process. While the battery charge is insufficient for a 24-hour recording, the 24h-LED will blink, and the Max-LED will remain off. Once the charge reaches a sufficient level for a 24-hour recording, the 24h-LED will stay constantly on, and the Max-LED will begin blinking, indicating that the battery is continuing to charge.

When the battery is fully charged, both the 24h-LED and Max-LED will be constantly on, and the charging process will automatically stop. You can interrupt the charging process at any time by simply removing the device from the docking station.

When the battery is completely discharged, the charging process will take approximately 1 hour. Once fully charged, the battery provides power for up to 7 days under typical operating conditions. In situations where a 24-hour recording is required, the device only needs about 20 minutes of charging time to ensure sufficient power for that period.

3.5 Preparing the Recording

This chapter provides instructions on how to properly guide the patient, prepare their skin, place the electrodes, and start the recording.

It is the responsibility of the operator to provide the patient with the necessary information required for a safe and effective ECG recording.

Before assigning the recorder to another patient, ensure that the data from the previous recording has been transferred and erased. The recorder will not start a new recording if previous data remains stored.

We recommend the following steps to prepare for the recording, with each step explained in detail in the subsequent sections:

1. Instruct the patient.
2. Prepare the patient's skin.
3. Attach the electrodes to the HeartX Recorder.
4. Place the electrodes, along with the HeartX Recorder, on the prepared patient's skin.

3.5.1 Handling Instruction for the Patient

- Notify the HEALTHCARE PROFESSIONAL if skin problems develop.
- In rare cases, even when using biocompatible electrodes, allergic reactions may occur.
- Do not expose the recorder to permanent submersion, high pressure and high jet water temperature.
- Do not expose the device to extreme temperatures.
- The temperature of the recorder must not go below 5°C (41°F) or above 45°C (113°F). In hot climates, stay in temperature-controlled environments as much as possible. In cold climates, wear the recorder under outer garments.
- Do not expose the device to sudden temperature or humidity changes.
- Quick changes in temperature or humidity can cause condensation. Do not bring the recorder into the proximity of heat sources, such as heaters and ovens, and do not expose it to direct sunlight.
- Keep a distance from electrical equipment, such as an electric toothbrush.
- Do not use an electric blanket when you are wearing the recorder.

3.5.2 Preparing the Patient's Skin

To ensure proper electrode adhesion and high-quality ECG signal recording, it is important to adequately prepare the patient's skin before attaching the electrodes. Follow these steps for optimal skin preparation:

1. Clean the skin: Gently clean the designated electrode areas using an alcohol wipe or a mild soap and water solution to remove any oils, lotions, or dirt. Ensure the skin is completely dry before proceeding.
2. Shave excessive hair: If the patient has significant hair in the areas where the electrodes will be placed, carefully shave the skin to create a smooth surface for better electrode contact.
3. Exfoliate the skin: Using a medical abrasive pad or gauze, gently rub the skin to remove dead skin cells and further improve electrode adhesion. This also helps reduce skin impedance for a clearer ECG signal.
4. Check for skin integrity: Examine the skin for any signs of irritation, injury, or sensitivity. Avoid placing electrodes on damaged or compromised skin.

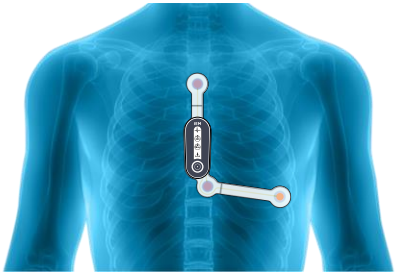
By following these steps, you can ensure effective electrode placement and a reliable ECG recording.

3.5.3 Placing Standard Electrodes

To ensure accurate ECG recording, follow these steps for electrode placement and setup:

1. Refer to the provided illustrations for the two recommended placement options.
2. Place the electrodes according to the images, either near the collarbone or on the chest near the sternum, depending on the selected placement strategy.
3. Peel the backing from each electrode and press them firmly onto the skin in the designated areas, either near the collarbone or sternum.
4. Ensure the electrodes adhere securely to maintain a stable connection. Gently press them to confirm proper contact with the skin.

*1



*2

*3

3.5.4 Patient ID Management Functionality

The recorder has the capability to receive a Patient ID and other demographic information from connected apps (i.e. CardioDay), ensuring that all recorded data is correctly and uniquely assigned to the patient.

If the Patient ID and demographic information are not transferred before starting a recording, the recorder will automatically generate an Auto-ID. This Auto-ID is composed of:

- Recorder Serial Number: A unique manufacturer-specific code that identifies each recorder.
- Sequential Number: A running number that ensures each new recording is uniquely marked.

By combining these two elements, each recording is uniquely identifiable, even when no specific Patient ID or demographic information has been provided.

3.6 Switching on the Recorder

If no LEDs are visible, the recorder is switched off. In this case, press and hold the Button until you hear a single beep, confirming that the device has been switched on.

As the recorder performs a series of internal tests after being switched on, you will need to wait for the following indications:

- The ECG-LED will flash orange if no electrodes are connected.
- The ECG-LED will light up permanently green if the electrodes are properly connected.
- The Download-LED will be off if no previous measurement is stored. If a recording is stored, the Download-LED will light up permanently orange.
- The 24h-LED or Max-LED will indicate the battery status. If neither is lit, the battery may be too low, and the device will need to be charged before proceeding.

3.7 Starting the Recording

Before starting the recording, ensure that the device and electrodes are properly set up for a successful ECG recording:

- No Stored Recordings: Verify that no previous recordings are stored on the device. If needed, delete them using the app or Holter analysis software.
- Battery Status: Confirm that the device is fully charged and not in a low power condition.
- Proper Electrode Attachment: Ensure that the electrodes are securely attached to the patient's skin and making good contact.
- Lead-Off Detection: The system monitors impedance changes to detect whether the electrodes are correctly attached. The ECG-LED should light up green, indicating proper contact.

If the ECG-LED flashes orange, reattach the electrodes to improve the connection.

Once all prerequisites and lead-off detection are confirmed, you can begin the ECG recording:

- Press the Button to start the recording.
- The recording will start if the device is charged, electrodes are properly attached, no previous recordings are stored, and no faults are detected.
- The ECG-LED will slowly flash green, indicating that the recording is in progress.

3.7.1 Auto-Start

If the start sequence is completed, the recorder detects a signal from all three channels, and the ECG-LED lights up permanently green, the recorder will automatically start the recording after eight minutes.

While the auto-start function ensures the Holter study begins even if the user forgets to press the Button, it is recommended to manually start each recording. The automatic start function should be considered a backup feature only.

Once the recording has started automatically, it is not possible to access the recorder's demographic and ECG data using an app until the recording has been stopped, and the data has been deleted via an ECG analysis and evaluation software (i.e. CardioDay).

3.7.2 Auto-Switch-off

If the recording has not been started, the recorder will automatically switch off after eight minutes if no ECG signal is detected and the ECG-LED continues to flash orange, or if no communication via USB occurs.

If a recording is stored and the device is switched on, the recorder will automatically switch off after 30 seconds if no communication via USB occurs.

3.8 Completing the Recording

The recorder automatically switches off once the set recording duration has been reached. If the recorder is on the docking station at the time of completion, it will not switch off. Instead, the Download LED will light up orange, and the ECG data can be downloaded immediately using the ECG analysis and evaluation software. The recorder retains the recorded data for at least one month after the recording has finished.

The only way to end a recording prematurely is to use the ECG analysis and evaluation software or to perform a device reset. Instructions for performing a device reset can be found in the section "Performing a device reset." If the recording is ended prematurely before the set recording duration is reached, the recording will stop at that point but will still be stored correctly for later analysis.

3.9 Transferring the ECG Data to a PC

Place the recorder in the HeartX recorder docking station, which is connected to a PC equipped with transmission software (e.g., HeartX Lift) or ECG analysis and evaluation software (e.g., CardioDay). After the recorder switches on automatically, it will perform a series of internal tests. You must wait until the Download-LED lights up orange before initiating the data transfer. This process may take up to 10 seconds.

The transfer of recorded data can be manually initiated by the user through the transfer or ECG analysis and evaluation software. Once the data transfer is complete and the recording has been deleted, the Download-LED will turn off. For more details on transferring ECG data, refer to the instructions for the analysis and evaluation software.

3.9.1 Compatible Software

The data stored by the recorder is fully compatible with the HeartX Lift transmission software. Other software may also be compatible; for specific inquiries regarding additional software solutions, please contact GETEMED for further information and support.

3.9.2 Software Functionality

Various software applications, including CardioDay evaluation software, HeartX Lift transfer software, and other validated software products, provide essential functionality for managing and communicating with the HeartX Recorder. These applications support both Bluetooth and USB connections, allowing for secure communication and efficient data management.

The applications provide the following functionality:

- Initiate a secure connection to the recorder via Bluetooth or USB.
- Transfer a patient ID and demographic data to the recorder.
- View and adjust the recorder's settings, including recording configuration and device status.
- Set the duration of a recording on the recorder.

- Display the rechargeable battery status to ensure the device is sufficiently charged.
- View patient demographic information stored in the recorder.
- View and set the date and time of the recorder's internal clock.
- Notify the technician if the battery is too weak to start a new recording.
- Alert the technician if the previous recording has not been deleted.
- Delete a recording and demographic data from the recorder.
- Reset the HeartX Recorder if necessary.

Not all software products offer the full range of functionalities or support both Bluetooth and USB connections. Always check the specific capabilities of the software to ensure it meets your needs.

4 Supplies and Accessories

This chapter identifies supplies and accessories that are approved for use with your system.

Part Number	Description
86100-IEM	HeartX Recorder
86151-IEM	HeartX Recorder Docking Station
86551-IEM	USB-C to C data and charging cable
86650-EN-IEM	HeartX Recorder Instructions for Use, EN
86660-UNI	HeartX Recorder Quick Start Guide, Multilingual
86501	Patch Typ „F“ (female) *1
86502	Patch Typ „M“ (male) *2
90131	Gel-Electrodes *3

5 Troubleshooting

This section explains error signs and troubleshooting recommendations.

5.1 Recorder Troubleshooting

Trouble Indicators	Cause	Recommendation
The **24h-LED** and/or the **Max-LED** don't light up green. An error tone sounds when you try to start the recording.	Battery power is low.	The battery is not fully charged. Recharge the rechargeable battery in the docking station.
The **ECG-LED** flashes orange once every second. An error tone sounds when you try to start the recording.	Electrode is not connected.	Connect all snaps from the device to the ECG electrodes.
The **Download-LED** is a solid orange.	Previous recording or patient entry has not been deleted.	To start a new recording, delete the recording and/or patient demographic data using the Holter analysis system software.
The **ECG-LED** stops flashing green during specified recording duration.	The recording has stopped before the specified recording duration has been reached.	The recording may have been started with a low rechargeable battery status. Download or delete the recording and recharge the rechargeable battery to start a new recording. Check the unit for physical damage. If the unit is damaged, contact service.
The **ECG-LED** and the **Download-LED** flashes orange with a frequency of 4 Hz	During charging, the defined operating temperature of 45 degrees Celsius is exceeded.	Wait until the recorder has cooled down. The charging process starts automatically.
	Self-test failed. Recorder cannot be started.	See section "Maintenance and Repair"

5.2 Bluetooth Troubleshooting

Trouble Indicators	Cause	Recommendation
Error while connecting recorder and app	Recorder and app device are either too close to or too far away from each other.	For best results, do not position the devices closer than 50 cm (approx. 20 inches) to each other or more than 10 m (approx. 11 yards) from each other.
	The app device's Bluetooth connectivity is not enabled.	Verify that your device's Bluetooth connectivity is enabled.
	Objects between recorder and application device affect the connection.	Remove any objects from the line of sight between recorder and application device.
	RF interfering devices affect the connection.	Remove any possible RF interfering devices from the vicinity of recorder and application device.
After starting a recording, no wireless connectivity active	The recorder's Bluetooth connectivity is not enabled because this is switched off after the start of a recording.	Stop the recording to be able to connect to the device via Bluetooth.

6 Maintenance and Repair

The device does not require any special maintenance to maintain its safety and performance features during the expected life-time.

Only authorized personnel are allowed to repair the device. Any unauthorized attempts to repair the device will make any warranty claims null and void.

It is the operator's responsibility to report the need for repair to the manufacturer or one of his authorized representatives. If you determine or suppose any malfunction, send the device for checking to the address specified below. Please add a detailed error description.

If you determine an unexpected operational condition or unexpected occurrences or if you need technical support, contact the manufacturer under the following address:

GETEMED Medizin- und Informationstechnik AG

Oderstr. 77, 14513 Teltow, Germany

www.getemed.de

7 Specifications

The following tables describe the product specifications, including tolerances for the product:

General

Component	Description
Recording channels	3 channels ECG Pacemaker pulses
Pacemaker pulse detection	1 channel
Recording time	7 days
Lead off detection	Yes
Defibrillator Proof	No
Degree of protection against electrical shocks	Type BF non-defibrillation-proof applied part.
Connectors	4 Pin connector for docking station, 3 electrode snaps
LEDs	ECG-LED, 24h-LED, Max-LED, Download-LED
Buttons	One Button for user interaction.
Time data backup	Within 6 month
Time accuracy	± 30 seconds per month (Device clock can synchronize with an external application)
Storage method	Digital memory, non-removable
Storage capacity	30 days
Data transfer method	USB 2.0 Hi-Speed, Bluetooth LE 5.2
Operating mode	Continuous recording

Electrical

Component	Description
Battery type	Rechargeable non-removable battery (3.7 V Li-Polymer rechargeable, 550 mAh)
Maximum power consumption (when charging via docking station)	550 mA
Average power consumption (when not charging)	Power Off: 70 µA Hookup: 16 mA Record: 2.1 mA
Operating time with freshly charged batteries	7 days
Recharging time	5 minutes for 24 hours
Frequency response	0.05 Hz to 55 Hz
Analog-to-digital converter	267 Hz, 24 bit
ECG data storage	256 Hz, 12 bit (2.93 µV)
Input voltage range ECG	± 6 mV
Common mode rejection	CMR > 80 dB per channel
Input impedance	> 10 MΩ

Mechanical

Component	Description
Dimensions	80.95 mm x 34 mm x 14.6 mm (3.19 in x 1.34 in x 0.57 in)
Weight	35 g (1.24 ounces), Housing including all parts required for function
Ingress protection	IP67
Vibration endurance	Non-operation: 0.1 G (10 Hz to 100 Hz)

Component	Description
	3 dB per octave (100 Hz to 200 Hz) 0.05 G (200 Hz to 2000 Hz)
Push endurance	250 N for 5 s against each side
Impact endurance	500 g steel ball from 1.3 m against each side
Shock endurance	Shock test with 15 G for 11 ms or 30 G for 6 ms
Drop endurance	Fall test from a height of 1.7 m onto a hard surface

Environmental

Component	Description
Operating temperature	5 °C to 45 °C (41 °F to 113 °F)
Operating humidity	10% to 95% relative humidity, non-condensing
Storage temperature	– 20 °C to 60 °C (– 4 °F to 140 °F)
Storage humidity	10 to 90% relative humidity, non-condensing
Ambient pressure	1060 hPa to 700 hPa (-380 m to 3000 m / -1,247 ft. to 9843 ft.)
Operating service life	5 years

Bluetooth Module

Component	Description
Approval	FCC, CE, IC/ISEDC, MIC/TELEC, KCC
Transmission technology	Bluetooth Low Energy (Bluetooth 5.2)
Range	Up to 10 m (10.93 yards) free field (Long Range)
HF Frequency range	2400 to 2483.5 MHz, ISM Band
Receiving signal	-98.6 dBm
Output transmission power	6 dBm

7.1 EMC Specifications according to IEC 60601-1-2

7.1.1 General Specifications

Guidance and manufacturer's declaration – **electromagnetic emissions**		
The device is intended for use in the electromagnetic environment specified below. The customer or the user should ensure that the device is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Not applicable	

7.1.2 Electromagnetic immunity (line-bound disturbances)

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user should ensure that the device is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact (electrode snaps only, direct discharge on device not possible due to pouch) ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electric fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	Not applicable	Not applicable (battery powered device)
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Not applicable	Not applicable (battery powered device)
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	5% UT (>95% dip in UT) for 1/2 period < 5% UT (>95% dip in UT) for 1 period 70% UT (30% dip in UT) for 25 periods <5% UT (>95% dip in UT) for 5 s	Not applicable	Not applicable (battery powered device)
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Not applicable	Not applicable
NOTE: U_T is the AC mains voltage prior to application of the test level.			

7.1.3 Electromagnetic immunity (conducted and radiated RF disturbances)

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user should ensure that the device is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V effective value 150 kHz to 80 MHz 6 V effective value in the ISM bands between 0,15 MHz and 80 MHz 10 V/m 80 MHz to 2,7 GHz Immunity against wireless RF communication devices	3 V effective value 6 V effective value in the ISM band according to table 5, Note N) 10 V/m According to Table 9	Portable and mobile RF devices are not used at closer than 30 cm to the device, including leads. The field strength of stationary radio transmitters is, as determined by an electromagnetic site survey, at all frequencies smaller than the compliance level. Interference may occur in the vicinity of equipment marked with the following symbol: 

7.1.4 Input Signal Reproduction Accuracy

The frequency response meets the following EN IEC 60601-2-47 requirements:

- The response of the recorder to a 5 mV 100 ms rectangular pulse does not show a baseline amplitude displacement of more than 0.1 mV referred to the baseline before the pulse. The slope outside the pulse is less than 0.3 mV/s. The leading edge overshoot is less than 10%.
- The responses to all pulses of a 1.5 mV, 40 ms triangular pulse train, which simulates a series of narrow R-waves, is within 80% to 110% of the response to a train of 1.5 mV, 200 ms triangular pulses.

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