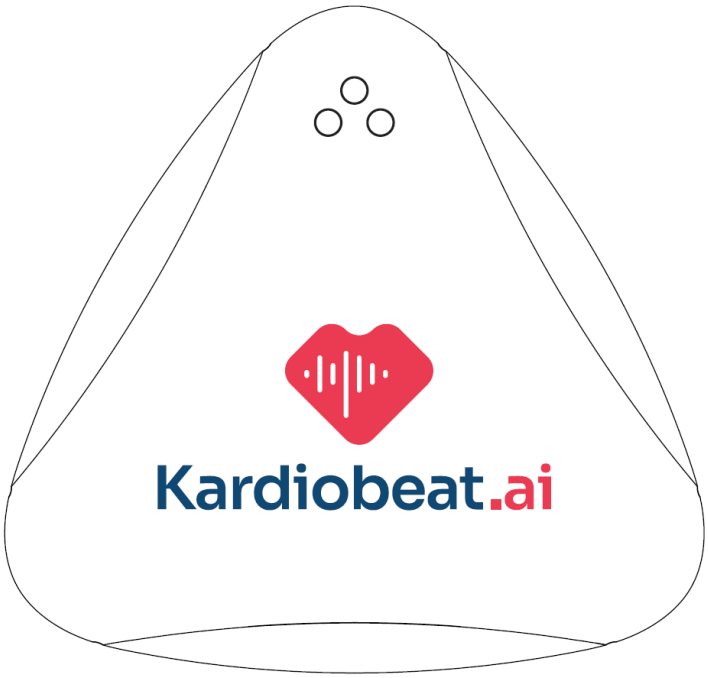

Kardiobeat.ai

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) 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 **Kardiobeat.ai**.

Copyrights

Manufacturer

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Distributor

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technical@medicalgorithmics.com
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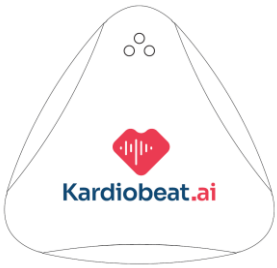
Your Local Contact

III Table of contents

1. Scope of delivery

The delivery of the **Kardiobeat.ai** Set includes the following parts:

1 pc. recorder module (**Kardiobeat.ai**)	
1 pc. Reader/ Charger module (**Kardiobeat.ai CONNECT**)	
1 pc. micro USB cable	
1 pc. initialisation software (**Kardiobeat.ai Init**), consisting of USB stick with software and Bluetooth dongle (small)	 
1 pc. Instructions for use (**Kardiobeat.ai IFU**)	

1 packaging unit decentralised ECG electrodes	

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 **Kardiobeat.ai** 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 disinfection.
- Easy application or removal of the adhesive electrode(s) via three pushbuttons.
- Continuous recording of three ECG signals **up to 12 days with the Kardiobeat.ai** with a fully charged battery.
- Recording of three ECG signals up to 60 days by changing batteries and ECG electrodes.
- Recording of usual 24 h – 48 h 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 **Kardiobeat.ai 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 decentralised single-use electrodes in conjunction with state-of-the-art hardware and software technology, **Kardiobeat.ai** enables permanent recording of long-term ECGs well over 24 h with very high signal quality and at the same time maximum patient comfort.

By eliminating previously common cables and due to the integrated intelligence, **Kardiobeat.ai** 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, **Kardiobeat.ai** can be used as a long-term recorder for ECG recordings up to 60 days.

Advantages for the cardiologist:

- Simplest configuration, commissioning and application.
- Secure recordings by **cable-free technology**; also over long periods of time (no loose cables, no loose adhesive electrodes, and no bad electrode contacts).
- Modular concept enables ECG recordings over theoretically unlimited periods of time.
- High signal quality by eliminating the cables and derivation of the vectors on the smallest area (low-artefact, low-interference ECG recordings).
- Low patient instruction effort for ambulant recordings.

Benefits for the patient:

- No impairment of quality of life and habits. After a short wearing period, you don't notice the **Kardiobeat.ai** anymore.
- Simplest operation/handling by patients even during longer recording periods (only necessary to change the electrodes and the battery).

2.1 Intended use

Kardiobeat.ai 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 **Kardiobeat.ai** 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

- **Kardiobeat.ai** must not be used on the open heart.

2.3 Adverse reactions

- Although the electrodes defined for **Kardiobeat.ai** 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.

3. General product description

3.1 Structure and components

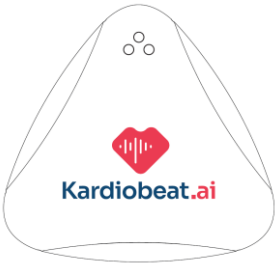
Structure:

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

Recorder module (Kardiobeat.ai):

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

Apply the recorder module **—> Annex 1.**



Reader/ Charger module (Kardiobeat.ai 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.**

Decentralised disposable electrodes:

Using three decentralised single-use ECG adhesive electrodes, the recorder module measures and calculates the leads. The electrodes are also a disposable part.

Applying and changing the electrodes —> **Annexes 1 and 3.**

Initialisation software (Kardiobeat.ai Init):

The **Kardiobeat.ai Init** software is delivered together with BluetoothStick (**Kardiobeat.ai Blue)** and used to initialise an ECG recording via the Bluetooth interface

and to start the recording. In addition, the signal quality of the ECG leads can be checked and optimised during initialisation before starting the recording and then cyclically.

3.2 Control and display elements

Control elements:

The **Kardiobeat.ai** does not include any control elements.

Display elements:

The **Kardiobeat.ai** 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 **Kardiobeat.ai** is available in one version:

- The recording time with a fully charged battery is
  - **Up to 12 days** for the **Kardiobeat.ai**

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 **Kardiobeat.ai** 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 **Kardiobeat.ai**.

- The use of **Kardiobeat.ai** 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 **Kardiobeat.ai** beforehand. Patients who are unable to operate **Kardiobeat.ai** 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 **Kardiobeat.ai** 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 **Kardiobeat.ai.** Operate the **Kardiobeat.ai** only within these limits.

- Store and transport the **Kardiobeat.ai** 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 **Kardiobeat.ai** must not be sterilised.

- Please refer to the instructions for cleaning and disinfection in **Chapter 8.1** as well as the instructions for disposal in **Chapter 8.5**.

- After attaching the electrodes and/or **Kardiobeat.ai** 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.).

- In case of longer storage (more than 8 h), remove the battery from the recorder to prevent damage caused by leakage.

- Do not open the **Kardiobeat.ai** 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 **Kardiobeat.ai** 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 **Kardiobeat.ai** 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 **Kardiobeat.ai** is shower-resistant.
- Nevertheless, it is recommended to remove **Kardiobeat.ai** 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 **Kardiobeat.ai** 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 **Kardiobeat.ai** near devices that produce large electromagnetic fields or ionizing radiation, such as RF chirurgic, X-ray, magnetic resonance therapy or diathermy devices.
- Special precautions with regard to electromagnetic compatibility (EMC) in **Chapter 11** should be taken into account.

4.4 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 **Kardiobeat.ai** 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 **Kardiobeat.ai** 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).

4.5 Product liability

Note

The manufacturer of **Kardiobeat.ai** assumes product liability only under the following conditions:

- If **Kardiobeat.ai** was operated exclusively with original accessories according to **Chapter 9**.
- Where repairs to **Kardiobeat.ai** 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.**

4.6 Warranty

The warranty periods for all reusable components (recorder module) of the **Kardiobeat.ai** 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 **Kardiobeat.ai** 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 **Kardiobeat.ai.**
- Applying the **Kardiobeat.ai** recorder.

5.2 Initialisation and application of the Kardiobeat.ai

Details and recommendations for initialisation, execution of ECG recordings and ECG analysis with the **PocketECG PC Client software (hereinafter PC Client)** can be found in **Annex 2** to this instructions for use and in the user manual of the **PC Client software**. Read this annex carefully and observe the relevant descriptions and instructions.

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

- Installation of the **Kardiobeat.ai** 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 **PC Client 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 Initialisation and start of ECG recording using Kardiobeat.ai Init

For details on how to initialize and start of ECG recording, see Annex 4 to these instructions for use. Read this annex carefully before using **Kardiobeat.ai Init.**

In particular, **Annex 4** contains information on the following topics:

- Installation of the software
- Initialisation and start of ECG recording
- Cyclical control of ECG leads.

5.5 Definition of manual event markers

The **Kardiobeat.ai** 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 **Kardiobeat.ai.**
- After the definition of a manual event marker, the **Kardiobeat.ai** switches to the status **"Signal control/ECG display"**.
- In this state amplitude modulated (and therefore brightness modulated) display of the 3 ECG cables via the LEDs of the **Kardiobeat.ai** 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 **Kardiobeat.ai**, double-click on the case until the state "Signal Control/ECG Display" is displayed.
- In the **PocketECG PC Client**, defined manual event markers can be found very quickly and the correlated ECG sections can be displayed.
- See instructions for use (IFU) for the module **PocketECG PC Client** ECG analysis software.

5.6 Compatible analysis systems

According to the purpose, the **Kardiobeat.ai** 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

The currently available, **Kardiobeat.ai** compatible analysis systems are listed in **Chapter 10.4 (technical data).**

6. Self-testing, internal surveillance and protection measures

6.1 Self-testing

The **Kardiobeat.ai** 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 **Kardiobeat.ai CONNECT**), the **Kardiobeat.ai** 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 **Kardiobeat.ai** 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, **Kardiobeat.ai** 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 **Kardiobeat.ai** goes into the “error” state. This condition is displayed via the permanently activated red LED for a duration of approx. 1 h **(—> Annex 2/Chapter 11).** Then the **Kardiobeat.ai** switches itself **“OFF”.**

6.2 Internal monitoring and safeguard measures

The **Kardiobeat.ai** 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 **Kardiobeat.ai** 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

Kardiobeat.ai 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 **Kardiobeat.ai** 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 **Kardiobeat.ai 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 **Kardiobeat.ai CONNECT**).	➢ Self-testing mistakes. ➢ Battery failure. ➢ Signal memory defective or insufficient free space.	➢ Charge the battery again. ➢ Empty signal memory. ➢ Contact service.
Kardiobeat.ai 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 **Kardiobeat.ai.**	➢ 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.	➢ **Kardiobeat.ai CONNECT** not connected to **PocketECG PC Client**. ➢ Error recorder module. ➢ Recorder settings **PocketECG PC Client** not configured correctly (drive/recorder settings).	➢ USB connector; check **Kardiobeat.ai CONNECT** (USB cable, recorder placement in the **Kardiobeat.ai CONNECT**). ➢ Recorder settings Check **PocketECG PC Client.** ➢ Contact service.
Green LED does not light up during charging.	➢ **Kardiobeat.ai CONNECT** not connected to **PocketECG PC Client.** ➢ Error recorder module. ➢ No contact between recorder module and **Kardiobeat.ai CONNECT.**	➢ USB connector; check **Kardiobeat.ai CONNECT** (USB cable, recorder placement in the **Kardiobeat.ai CONNECT**). ➢ Check contact pins for dirt or damage. ➢ Contact service.

8. Maintenance

Please refer to the following instructions on the maintenance of the **Kardiobeat.ai**.

8.1 Cleaning/ Disinfection of the device

Clean and disinfect **Kardiobeat.ai** 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 **Kardiobeat.ai**.

Desinfect:

- 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 MDD and MDR
  (e.g. HARTMANN Bacillol 30 Tissues, please ask your distributor).
- Wipe the **Kardiobeat.ai.**

Note

- Do not use abrasive cleaning agents to clean the device.
- **Kardiobeat.ai** 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 **Kardiobeat.ai** in water and other liquids. Under no circumstances should liquid enter the recorder.
- You cannot sterilize **Kardiobeat.ai**. 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 **Kardiobeat.ai** 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 **Kardiobeat.ai** 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 **Kardiobeat.ai** 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 **Kardiobeat.ai** 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 **Kardiobeat.ai**, accessories or disposables.

Contact your distributor to purchase the items.

Basic equipment:

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

Accessories:

- **PocketECG PC Client** ECG analysis software (PC Client Software)
- **Kardiobeat.ai Init** (initialization software)
- **Kardiobeat.ai Blue** (Bluetooth dongle for initialization software)
- **Kardiobeat.ai Viewer**: Android Tablet with pre-installed initialization software (third party)
- Adapter cable micro USB to USB

Disposables:

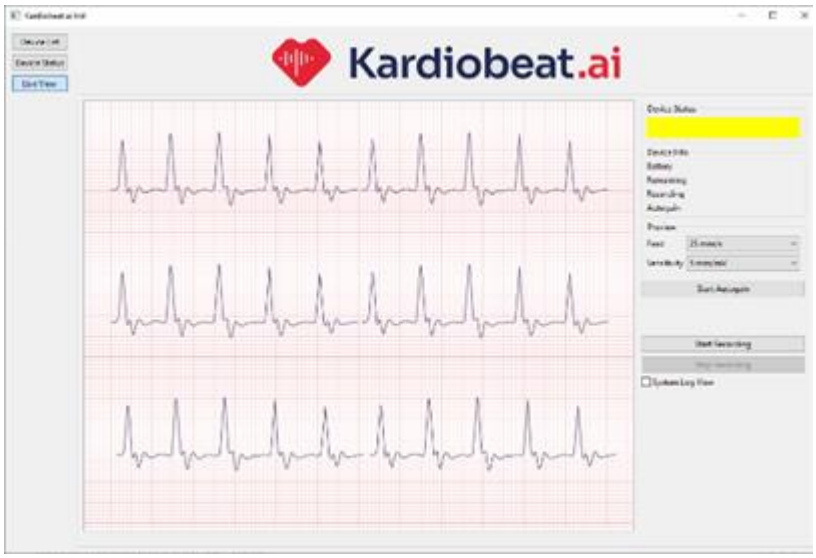
The following disposables are available either from the specialist dealer/distributor or from the relevant suppliers on the market:

- 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 Kardiobeat.ai Viewer

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



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

Note

- The **Kardiobeat.ai Viewer** is not a medical device within the meaning of the Medical Device Directive 93/42 EEC.
- Note that the **Kardiobeat.ai Viewer** is only for signal display and not for signal and/or function control of **Kardiobeat.ai**.
- The **Kardiobeat.ai Viewer** is not intended for patient diagnosis and does not contain diagnostic functions.

10. Technical data

10.1 Symbols and inscriptions

CE 0633	CE marking. The device complies with the requirements of the European Council Directive 93/42/EEC for medical equipment.
 YYYY	Manufacturer information and date of the year of production
IP54	IP degree of protection.
	Classification of the application part according to IEC 60601-1. Defibrillation-protected application part of type BF.
	Follow Instructions for use.
SN	Serial number.
 **< 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.

	Avoid direct sunlight.
	Top.
	Recycling.

10.2 Condition indicators on the device

	The **Kardiobeat.ai** 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 Devices Directive 93/42/EEC ➢ 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: Medical devices Suitability for use
Operating time	➢ Up to 12 days / 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	➢ <= 1µV 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, 330 mAh, 3.7 V
Data format	➢ depending on the evaluation system used
Dimensions	➢ approx. 50 x 50 x 13,5 mm
Weight	➢ approx. 23 g

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 Kardiobeat.ai 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

The **PocketECG PC Client** software can be used for ECG data analysis, see Instructions for use **PocketECG PC Client** interoperable with medical devices.

Note

- Since the **Kardiobeat.ai** supports standardised ECG data formats such as MIT, ISHNE, EDF+, the **Kardiobeat.ai** can be operated with analysis systems that support these data formats.
- Please contact the **Kardiobeat.ai** sales department if you have questions regarding the compatibility and application of the **Kardiobeat.ai** with certain analysis systems.

Attention

- Please note that the computers used in the compatible analysis systems 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.

11. Information on electromagnetic compatibility

The **Kardiobeat.ai** is intended for operation in the electromagnetic environment of medical care facilities (Professional Healthcare) and in domestic environments. The customer or the user of **Kardiobeat.ai** 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 **Kardiobeat.ai** including connected electrodes. Non-compliance can lead to a reduction in the performance characteristics of the device.
- 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.

11 Information on electromagnetic compatibility (EMC)

Manufacturer's declaration of electromagnetic interference

Interference measurement	Compliance	Electromagnetic environment - Guide
HF emissions (CISPR 11)	Group 1	The **Kardiobeat.ai** 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	**Kardiobeat.ai** 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)	**Not applicable** (< 75 W)	
Transmissions of voltage fluctuations/flicker to IEC 61000-3-3	**Not applicable** (< 75 W)	

Information on electromagnetic compatibility (EMC)

Manufacturer's declaration on electromagnetic immunity

Immunity tests	Test level IEC 60601-1-2:2014	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. **Kardiobeat.ai** does not contain magnetically sensitive components or circuit elements.
Conducted RF disturbances (IEC 61000-4-6) Irradiated RF disturbances (IEC 61000-4-3)	3 Veff 0,15 - 80 MHz 6 Veff in ISM bands between 0,15 and 80 MHz 80% AM at 1 kHz 3 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz	**Not applicable** 3 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz	Portable and mobile radios should be used at no distance from **Kardiobeat.ai**, 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.  Disturbances are possible in the environment of devices carrying this image sign.
Near field of wireless RF communication devices	385 MHz – 5,7 GHz 9 – 28 V/m	385 MHz – 5,7 GHz 9 – 28 V/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.

11 Information on electromagnetic compatibility (EMC)

Immunity in the near field of wireless RF communication devices (IEC 60601-1-2:2014, 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 **Kardiobeat.ai** 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.

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