getemed

User Manual

CardioMem® CM 100 XT

ECG-Recorder

Revision 01

Cardiac Diagnostics

Vital Signs Monitoring

Telemonitoring

Contents

1 Information about this Manual

This manual is owned by

GETEMED Medizin- und Informationstechnik AG
Oderstr. 77, 14513 Teltow, Germany.

Revision History

Revision	Publication Date	Description
01	2017-11-10	1st Publication

2 Intended Operator

The device is intended to be used by trained operators under the direct supervision of a medical professional in a medical facility or by the patient after instruction by a medical professional in the patient's home.

The patient is an intended operator.

3 Intended Use

The CardioMem CM 100 XT is intended to continuously analyse and periodically record ECG data for later evaluation by a medical professional in order:

- to document arrhythmias in individuals whose symptoms occur infrequently
- to document the impact of initiating drug therapy for an arrhythmia
- to document the recurrence of an arrhythmia after discontinuation of drug therapy
- to document the results after an ablation procedure for arrhythmia
- to evaluate syncope in individuals whose symptoms occur infrequently.

The ECG recording is triggered manually by the patient or automatically by a programmable timer or by an algorithm that can detect the following arrhythmias:

- Tachycardia
- Bradycardia
- Atrial Fibrillation
- Pause

The device is intended to be used in both home environments and clinical environments. Home environments include urban/suburban/rural, school/office/retail environments, and vehicles like trains, airplanes and cars. The device is not intended to be used near active HF surgical equipment and in RF shielded rooms of systems for magnetic resonance imaging (MRI). The device is battery driven and utilizes non-volatile memory to store ECG data. The device is not intended to be used as a critical care monitoring system and should not be used in emergency situations.

4 Indications

The CardioMem CM 100 XT is indicated for those adult and pediatric (weight > 10kg) patients who require monitoring for the detection of the following non-lethal cardiac arrhythmias: tachycardia, bradycardia, atrial fibrillation, and pause.

Contraindications:

- Patients with known allergies or hypersensitivities to adhesives or hydrogel.
- Patients with potentially life-threatening arrhythmias, or who require inpatient / hospital monitoring.

5 Definitions

The terms “warning” and “caution” are used throughout this manual to point out hazards and to designate a degree or level of seriousness. Familiarize yourself with their definitions and significance. Hazard is defined as a source of potential injury to a person.

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 minor personal injury or damage to the product or property.

NOTE provides application tips or other useful information to assure that you get the most from your equipment.

6 Regulatory Information

6.1 Medical Device Compliance

The CE Mark and Notified Body registration number signifies that this equipment is in compliance with the essential requirements of the EU Regulation 93/42/EEC (MDD) by declaration of the manufacturer.

CE 0197

6.2 Radio Frequency Compliance

The CE Mark signifies that this equipment is in compliance with the essential requirements and other relevant provisions of the EU Regulation 2014/53/EU (RED) by declaration of the manufacturer.

CE

6.3 Medical Device Classification

MDD: Class IIa.

Protection against electric shock: Type BF, non-defibrillation-proof applied part.

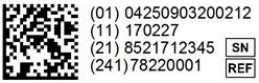
Mode of operation: Continuous operation.

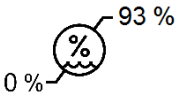
Method(s) of sterilization recommended by the manufacturer: Not applicable.

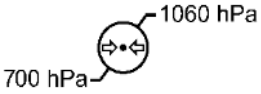
7 Labeling

7.1 Symbols

The following symbols appear on the device and / or on the packaging:

CardioMem CM 100 XT	Device Type (CardioMem CM 100) and model (XT),
 2017-03-22	Name and address of the manufacturer. Below the solid factory symbol is the date on which the device was manufactured. Next to the solid factory symbol is the name of the manufacturer.
 (01) 04250903200212 (11) 170227 (21) 8521712345 SN (241)78220001 REF	UDI Label; matrix code with GTIN (1), date of manufacturing (02), device identifier [SN] (21) and device catalogue number [REF] (241)
 REF 78120001	Barcode with Kit catalogue number [REF]
 CE 0197	CE marking, followed by the certification number of the notified body of the manufacturer.
	The symbol informs medical professionals that the device is classified as “body floating” (BF) and that it is NOT protected against defibrillation.
IP64	The ingress protection classification of the device is IP64, whereby 6 = dust proof, 4 = protected against splashing water.

	The symbol indicates that the device is powered by a replaceable, non-rechargeable battery.
	This symbol indicates that you must dispose of the device properly. Further information is provided in the section “Disposing of the Device, Batteries or Accessories“.
	Follow the Instructions for Use. Read and understand the operator's manual before using the device or product.
	General warning sign. Observe the information in the operating manual for proper use of the device.
	Serial number.
	REF (reference) number to identify and order the product.
	Push-button
	Temperature Limits -20°C ... 60°C. Indicates the upper and lower temperature limits allowed for the device’s storage and shipping.
	Humidity Limits 0% ... 93%. Indicates the upper and lower humidity limits allowed for the device’s storage and shipping.

	Atmospheric pressure Limits 700hPa ... 1060hPa. Indicates the upper and lower atmospheric pressure limits allowed for the device's storage and shipping.
	Keep away from heat Indicates that you need to keep the container away from sources of heat.
	Keep dry Indicates that you need to keep the container away from rain and other sources of moisture.
	Fragile Indicates the contents are fragile and should be handled with care.
	Maximum stack size: 10 packages.
	The packaging is capable of being recycled.

7.2 Type Label

The type label is located on the back of the device (Figure 1).

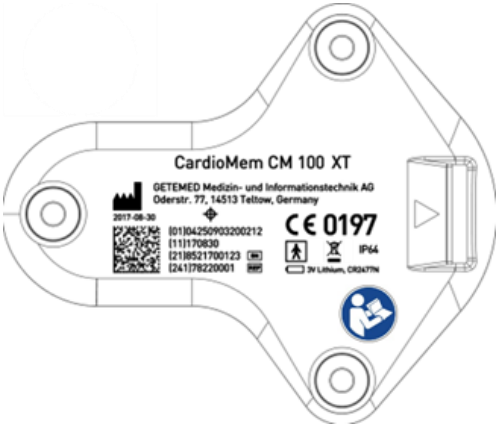


Figure 1 – Type label

7.3 Packaging Label

The packaging label is located on the side of the cardbox (Figure 2).

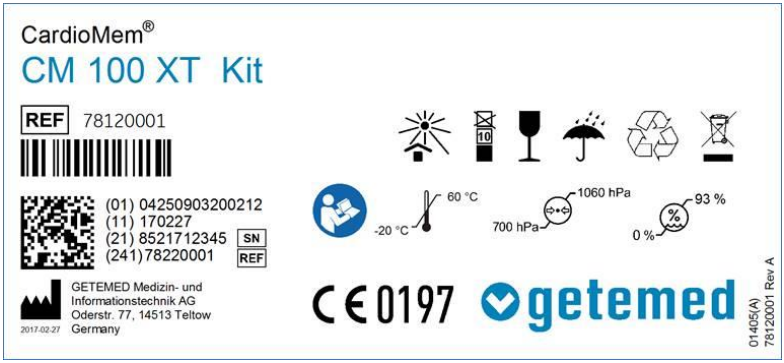


Figure 2 – Packaging label

8 Safety Information

8.1 General Warnings

1. RISK OF CONTAMINATION OR INFECTION - Device and accessories may be contaminated with bacteria or viruses after use. If any contamination of the device or accessories has occurred, observe the standard procedures for handling contaminated objects and the following precautions:

- Use protective gloves to handle the equipment.
- Isolate the material by using suitable packaging and labelling.
- Contact the addressee before sending the equipment.
- Clean and disinfect the device and accessories after every use.

2. MIXING UP RECORDINGS - The patient's life or health may be put at risk if the Patient is assigned a different patient's examination, thus resulting in an incorrectly assigned diagnosis. To ensure that a recording is not assigned to the wrong patient, always make sure that the device memory has been deleted before the device is used in the next patient.

3. NO MONITORING DEVICE - The device is not intended for monitoring the clinical condition of a person.

4. ELECTRIC SHOCK or device malfunction may occur if electrodes contact conductive materials. Keep the conductive parts of lead electrodes and associated parts away from other conductive parts, including earth. Also make sure that no contact to other conductive parts is possible if the electrodes loosen during recording.

5. ELECTROMAGNETC EMISSIONS - Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

6. ELECTROMAGNETC EMISSIONS - Electrical medical equipment should be used no closer than 30 cm (12 inches).

Otherwise, degradation of the performance of this equipment could result.

7. ELECTROMAGNETIC RADIATION - Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches). Otherwise, degradation of the performance of the device could result.

8. ELECTROMAGNETC COMPATIBILITY - Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

9. SERVICE AND REPAIR - The device must not be serviced or repaired while in use.

8.2 General Cautions

1. General hazard - The device must not be used if mechanically damaged.

2. General hazard - The device must not be used if the battery compartment door is lost. Replace the battery compartment door before the device will be used.

3. General hazard - Before starting a recording, make sure that the battery compartment door is closed and latched.

4. Risk of choking – Small parts can pose a choking hazard. Keep such parts out of children's reach.

5. Infection risk – Reuse of disposable parts that come into contact with patients pose a risk of infecting patients. Do not reuse disposable parts that have had direct contact with the patient, such as ECG electrodes.

6. Infection risk – Returning parts and products that have not been disinfected exposes our service personnel to a risk of infection.

7. Protect the device against mechanical damage by shocks, pressure and scratches. Otherwise, the correct functioning of the device can no longer be guaranteed.

8. Malfunction or damage of the device – Changes in temperature and humidity can cause condensation inside the device. Wait at least two hours after the externally visible dampness of the device has disappeared before reusing it.

9. Malfunction or damage of the device – Remove the battery when the device is not used for a longer period of time.

10. Risk of skin irritation - ECG electrodes may cause skin irritation if used for a very long time.

11. Electrosurgery – There is a risk of burns and injury to the patient. If an electrosurgery device is used, disconnect the ECG electrodes from the device.

12. Replacement of battery - Use only batteries of the type Renata CR2477N. The use of a different type of battery can cause damage or malfunction. Replacement by inadequately trained personnel could result in a hazard (such as excessive temperatures, fire or explosion).

13. Wet environments - The device is protected against splashing water. Nonetheless it should not be worn under the shower. You must not wear the device when swimming or bathing. The ingress of water can cause damage or malfunction.

14. The device and accessories must not be sterilized.

15. Cleaning and disinfection - Do not use solvents such as ether, acetone, or petroleum ether; such substances can damage the plastic of the device's housing.

16. Disposal of batteries - Do not dispose batteries together with the normal waste. You are required to dispose of any batteries in accordance with local and national regulations.

17. Safe and reliable operation of the device is only possible when using the supplied and approved accessories.Repair and Maintenance - Repairs must be carried out only by persons authorized by the manufacturer.

18. Repair by inadequately trained personnel could result in a hazard, e. g. excessive temperatures or high voltages. Replacement of the electrodes and of the battery can be done by the patient.

19. Malicious software –Software delivered is scanned for viruses but can, nevertheless, be intruded by malicious software. We recommend the following: Install a good quality virus scanning program and regularly up-date it. Establish procedures to avoid infected software reaching your computer in the first place, e.g., check the source of any software you use and use only original software packages.

20. Downloading data via USB - The download of data should be performed by a medical professional after the patient has returned the device. This operation should not be performed by the Patient.

9 Warranty and Service Information

Only authorized service personnel should repair the device. Any unauthorized attempt to repair equipment under warranty voids that warranty.

The device does not require any special service to maintain its safety and performance during the expected service life.

It is the operator’s responsibility to report the need for repair to the manufacturer or to one of his authorized agents. If you find or even suspect a malfunction, send the device for testing to the address shown below. Please add a detailed description of the observed malfunction.

In case of an unexpected operation or event or if you need technical support contact the manufacturer at the address shown below.

GETEMED Medizin- und Informationstechnik AG
Oderstr. 77, 14513 Teltow, Germany
www.getemed.de

10 Cleaning and Desinfection

CAUTION: Do not use solvents such as ether, acetone or petroleum ether; such substances can damage the plastic of the device's housing.
CAUTION: Remove the battery and close the battery compartment door before cleaning or disinfecting the device.

Clean the device before performing surface disinfection. Use a lint-free cloth slightly moistened with water or a mild soap solution to wipe the device.
Disinfect the device at regular intervals, prior to first use, and before passing it on to another person. GETEMED recommends disinfecting the device with a 70 % alcohol solution.

11 Operating Elements

The device features a push-button (1), a LED (2) and a speaker (Figure 3).
The push-button is marked with the following symbol: ⊙

Figure 3 – Operating elements

11.1 Event Button

The push-button is used to perform the following functions:

Function	User Action
Switch on the device	Press and hold for more than a second until a beep sounds. NOTE: The device cannot be turned off unless the battery is removed.
Start a recording	Press and release. A double beep will sound to confirm the recording has started.
Mark an event during recording	Mark an event during recording.

11.2 LED

This multi-color LED indicates the device status:

Device status	Status indicator
Ready for recording	Shining green
Recording in progress	Flashing green
Open lead	Flashing yellow
Contains recording	Shining yellow
Low battery	Flashing red
USB connected	Shining cyan
Error	Flashing green, red, blue and flashing red afterwards

For a detailed description of all notifications refer to section "Notifications (LED and Speaker)".

11.3 Signaltöne

The device provides the following audible feedback:

Device status	Notification
Button pressed	Single beep
Open lead	Three beeps
User interaction required / check device state	Three beeps

12 Preparing the Recording

12.1 Inserting a Battery

Push the latch with the thumb nail to unlock the battery compartment door (Figure 4).

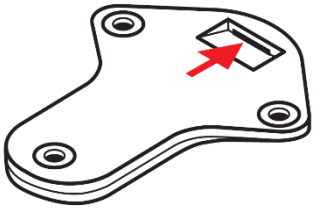


Figure 4 – Unlock the battery compartment

Remove the battery compartment door. Take a new 3V Lithium CR2477N battery and place it in the battery compartment. Mind the correct polarity. Push the battery in the battery holder until it snaps into place (Figure 5).

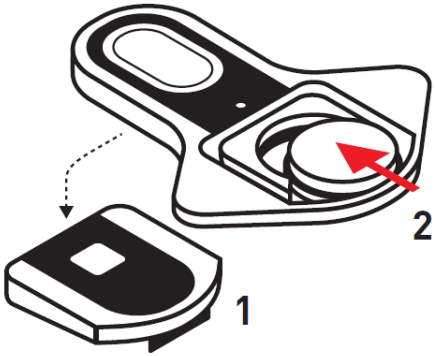


Figure 5 – Insert a battery

Insert the battery compartment door and push down until the latch snaps into place (Figure 6).

Figure 6 – Close the battery compartment door

12.2 Instructing the Patient

It is the responsibility of the medical professional to provide the patient with the following information required for a safe use of the device.

CAUTION: Notify the doctor if skin problems develop. In rare cases allergic reactions may occur.
CAUTION: Do not expose the device to water by taking a bath or a shower.
CAUTION: Do not expose the device to extreme temperatures. The operating temperature of the recorder must not go below 5°C or above 45°C. In hot climates, stay in temperature-controlled environments as much as possible.
CAUTION: Do not expose the device to sudden temperature or humidity changes. Quick changes in temperature or humidity can cause condensation. Do not bring the device into the proximity of heat sources, such as heaters and ovens, and do not expose it to direct sunlight.
CAUTION: Keep a distance from electrical equipment. Do not use an electric blanket when you are wearing the recorder.
CAUTION: Keep the device away from children and pets.
CAUTION: Replace electrodes which are loosened during recording.

Marking an event

Instruct the patient to press the Event Button briefly during a recording to mark an event. A short beep informs the patient that the event has been marked.

Recording Diary

We also recommend having the patient maintain a diary to record activities, symptoms and the corresponding times during the ECG recording. The header of this diary should include patient demographic data, recorder identification and medication taken.

12.3 Preparing the Patient's Skin

Careful skin preparation is the key to an interference-free recording.

- Select the electrode placement sites. Refer to "Placing the Device" for descriptions of electrode placement.
- Ensure that each site is dry, clean and free of hair.

NOTE: Use a lint free cloth to dry the skin

12.4 Connecting the Electrodes

Place the device face down on a sturdy level surface (desk). Take three new single use ECG electrodes. Do not yet remove the protective film from the contact side of the electrodes!
Snap the studs of the electrodes into the adapters on the rear side of the device (Figure 7).

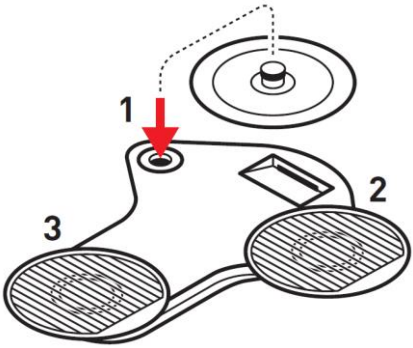


Figure 7 – Connecting the electrodes

CAUTION: Only use disposable electrodes that are clearly marked as ECG electrodes. Otherwise allergic skin reactions could occur.
CAUTION: Do not reuse disposable ECG electrodes that have been used in an other patient. Infections could be the consequence.
CAUTION: Observe the expiry date of the ECG electrodes. Do not use expired ECG electrodes. Bad signal acquisition could be the consequence.

12.5 Placing the Device

Remove the protective film from the electrodes (Figure 8).

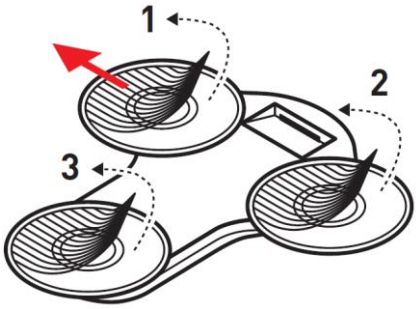


Figure 8 – Remove the protective film

Place the device on (a) the sternum or (b) the upper left chest and press gentle (Figure 9).

a) b)

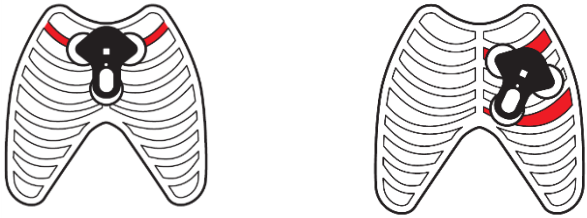


Figure 9 – Placing the device

Make sure that all electrodes adhere properly on the skin.

12.6 Switching on the Device

Press the push-button until a beep sounds. The LED shows a color sequence when the device starts.

12.7 Check the Lead Quality

If the lead quality is good and the device is not in open lead condition the LED is shining green.
If the lead quality is poor or the device is in open lead condition the LED is blinking yellow.

13 Starting the Recording

Press the push-button to start the recording (Figure 10).
The recording only starts if no low battery and no open lead are detected.

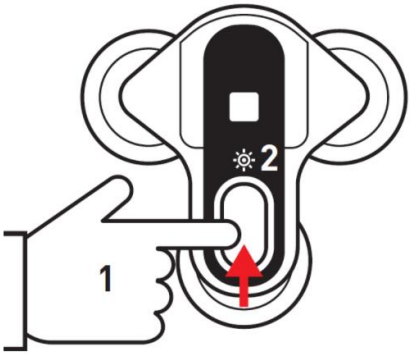


Figure 10 – Starting the recording

NOTE: If a previous recording is still stored on the device, the LED will shine yellow and the recording will not start. You will need to download or erase the recording before continuing.

14 Recording an Event

14.1 Recording Modes

The device features two recording modes:

- Manual recording of an event, activated by pressing the push-button.
- Automatic recording of an event, activated by algorithms for automatic arrhythmia detection (Auto-Trigger) or activated by a timer.

The recording duration depends on the preset parameters (refer to section "Setup").

14.2 Manual Recording

Manual recording is always available, even if automatic recording is activated. A manual recording should be started when symptoms occur or at regular intervals on advise of the physician.

The recording is triggered by pressing the button. An acoustic signal indicates that the recording has started.

14.3 Automatic Recording

The device has built-in algorithms for automatic detection of certain arrhythmias (bradycardia, tachycardia, atrial fibrillation, pause). Those algorithms are based on the continuous detection of the QRS complexes and the subsequently determined heart rate values.
The automatic rhythm detection is automatically switched off when the ECG signal is heavily disturbed or very weak. The triggers for the automatic arrhythmia detection will be adjusted by means of the software *CM 100 Configurator*.
Refer to section 16 of this manual for more information.

NOTE: Even though the algorithms implemented are highly developed and thoroughly tested, 100% detection and classification of arrhythmias cannot be guaranteed. Automatic

rhythm detection is not functioning properly in patients with cardiac pacemakers.

Time triggered Recording

The device can start the ECG recording automatically based on a preset timer. The possible timer interval is 1h ... 24h.

15 End of Recording

Disconnect the device carefully from the electrodes and remove the battery to stop the recording.
The recording stops automatically in the following situations:

- The memory is completely occupied
- The battery is exhausted

15.1 Removing the Electrodes

Slowly peel off the electrodes starting at their outer edge. Dispose the used electrodes in the household waste.

CAUTION: Used electrodes must not be used again. Infections could be the consequence.

16 Use of the CM 100 Configurator Software

The software CM 100 Configurator is intended to be used as an accessory for the device CardioMem CM 100 XT .The software is intended to be used by trained medical professionals (user) in medical facilities.The software is running on a personal computer equipped with the Microsoft Windows operating system.

The software enables the user to download data from the the device via an USB connection and to store them locally on the personal computer.

Furthermore the software enables the user to adjust setup parameter of the device in order to customize device settings for the needs of the individual patient.

The software has no direct diagnostic or therapeutic purpose.

16.1 Required Hardware and Software

Hardware having the following minimum specifications is required:

CPU:	Core i3 2 GHz Processor or performance equivalents
Memory:	4 GB RAM or more
Hard drive:	200 MB for installation of the application and required components, recommended at least 1 GB for data storage
Interfaces:	1 x USB 2.0 port or higher
Graphic resolution:	minimum: 1024 x 768, recommended: 1920 x 1080

The following operating systems are supported:

- Windows 7
- Windows 8.1
- Windows 10

To run the application the Microsoft .NET Framework 4.5.2 or above is required. The .NET Framework can be downloaded from Microsoft.

NOTE: The application is not intended to be used in virtual environments and for installation on terminal servers.

16.2 Installation

The installer is an executable file that can be downloaded from

```
http://www.getemed.net/downloads/CM100/CM1
00Configurator_Setup.exe
```

It installs all program files and the USB driver that is necessary for the communication with the CardioMem CM 100 device.

Copy the installation file to a local folder on your PC. Double-click the file to start the installation process. You will be prompted to enter a valid installation path and a path for the ECG data storage folder (Figure 11).

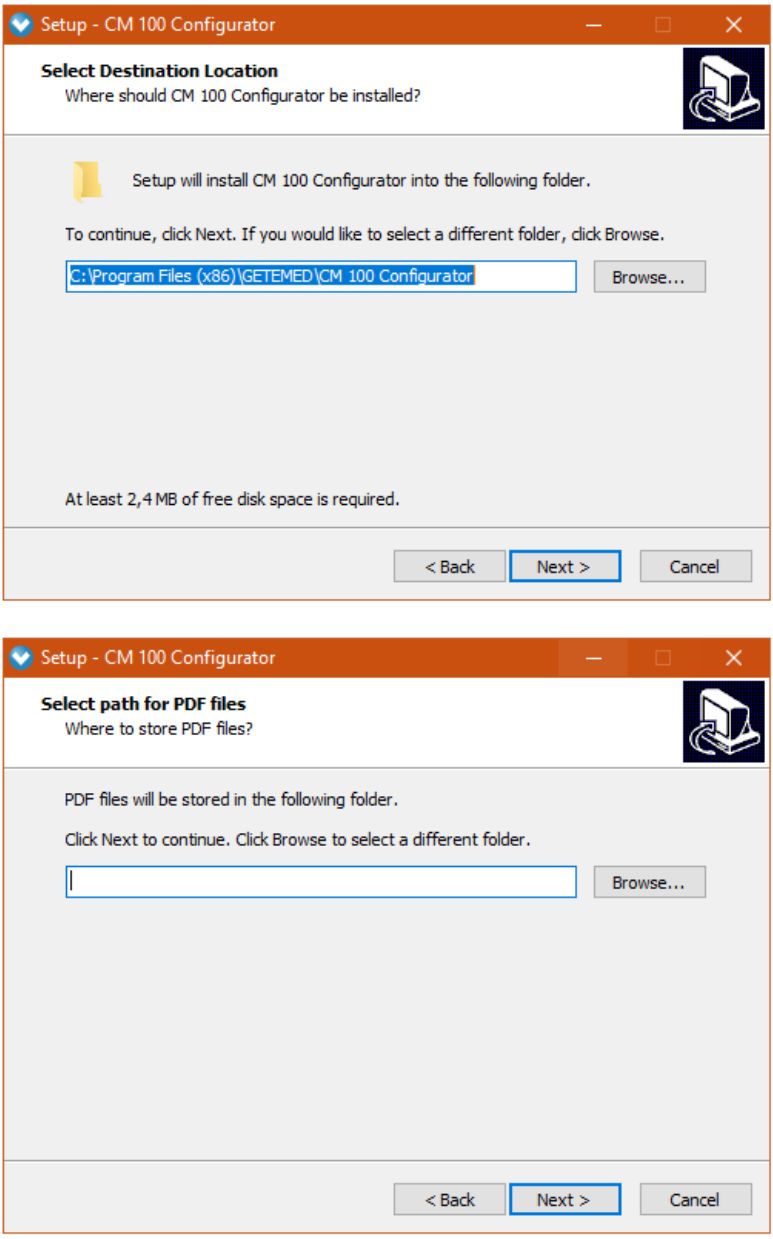


Figure 11 - Installation

You will be asked if a program symbol should be created on your Desktop. Afterwards you can start the installation with the specified settings.

NOTE: It is recommended to remove an existing installation and make a backup of all stored ECG data before installing a new version of the software.

16.3 Check the System Time

CAUTION: Check the system time of the PC - a wrong system time can cause confusion of ECG reports between patients.

16.4 Connect the USB Download Cable

WARNING: Risk of electric shock - Only use the USB Download Cable that is provided by GETEMED to connect the device to a personal computer (PC).

CAUTION: The PC used must comply with the most recent version of the international standard IEC 60950 for safety of IT equipment.

NOTE: Connecting the device to a PC that is incorporated into an IT network together with other equipment could result in previously unidentified risks to patients, operators or third parties. The responsible organization should identify, analyse, evaluate and control these risks.
Changes to the IT network such as:

- network / data coupling configuration change
- connection of additional items to network/data coupling
- disconnecting items from network/data coupling
- update of equipment connected to network/data coupling
- upgrade of equipment connected to network/data coupling

could introduce new risks that require additional analysis. Observe the standard EN 80001.

Connect the two parts of the download cable.

Connect the download cable to a free USB port of the PC. Open the battery compartment door of the recorder (1) and remove the battery (2).
Connect the device plug of the download cable to the socket (Figure 12) of the device (3).

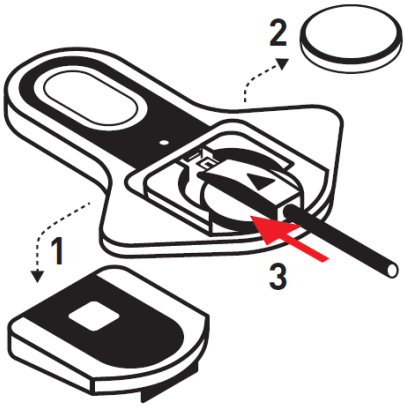


Figure 12 – Connect the download cable

16.5 Switch on the Device

Press the push button to switch on the device (Figure 13). A beep sounds and after the startup sequence the LED is shining cyan.

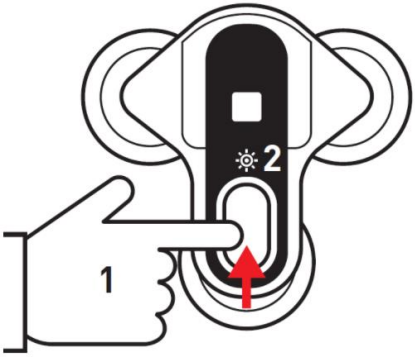


Figure 13 – Switch on the device

16.6 Start the CM 100 Configurator Software

The application can be started by double-clicking the desktop icon.
The startup screen shows version and manufacturer information. Click the button "Connect to recorder" to establish the communication link (Figure 14).

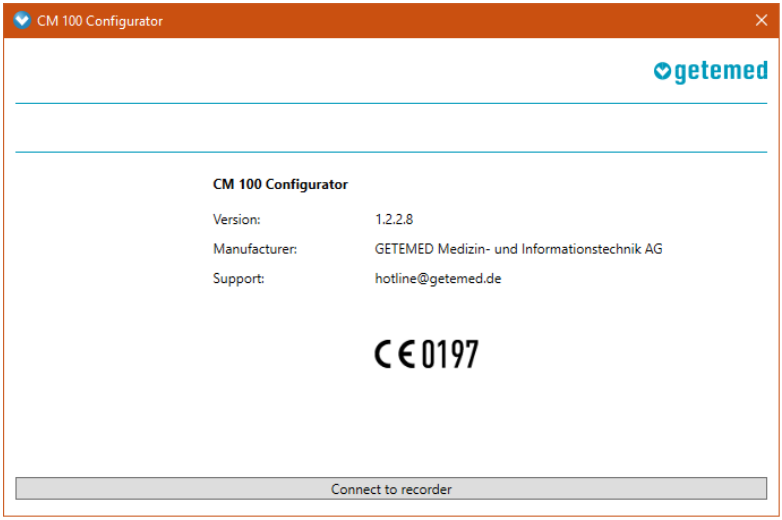


Figure 14 – Start the CM 100 Configurator software

16.7 Downloading Recordings

The download feature is available in the information screen which is displayed once a connection to the recorder has been established. The Download feature is not active if there are no data on the recorder.

In the upper left corner the information screen shows the serial number of the connected recorder and the number of ECG files stored in the memory of the recorder.

Click the button "Download" to go to the download screen (Figure 15).

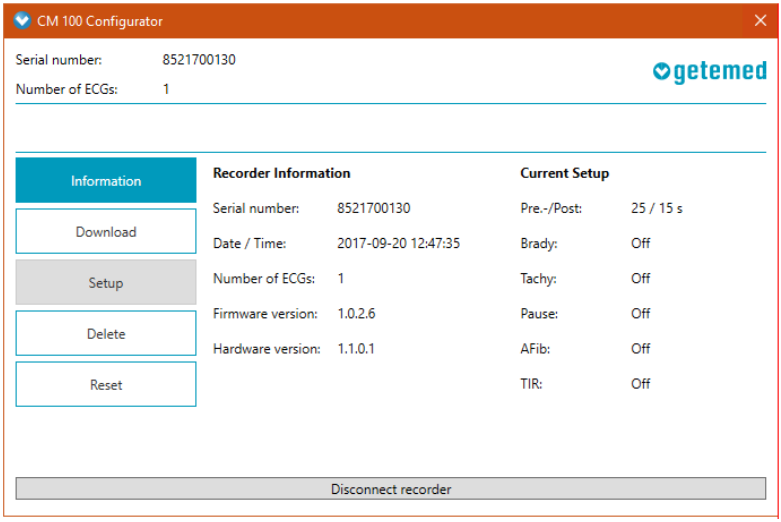


Figure 15 – Downloading recordings

Select Folder

The storage path for the ECG data has been pre-selected during the installation. You can change the path before starting the download.

Click the button "Start Download" to copy the ECG data to the selected folder (Figure 16).

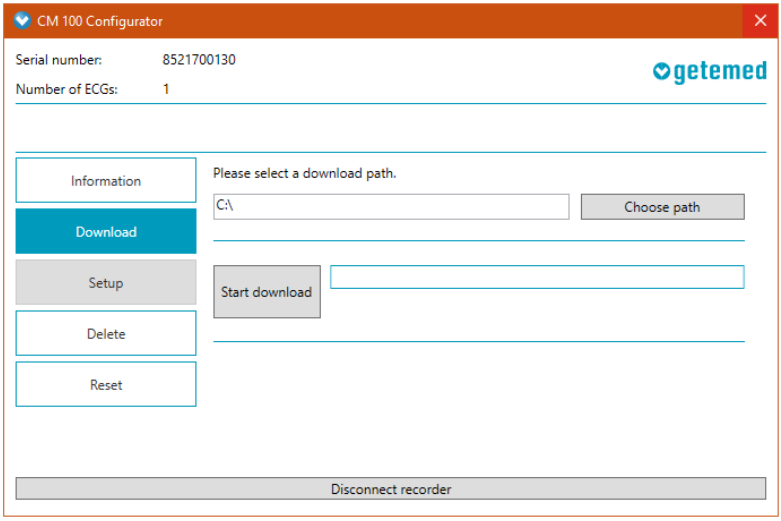


Figure 16 – Select folder

Delete Data on Device

WARNING: To ensure that a recording is not assigned to the wrong patient, always make sure that the device memory has been deleted before the device is used in the next patient.

Click the button "Delete Recordings" to delete all data in the memory of the device (Figure 17). The number of stored ECG files displayed in the upper left corner of the screen will change to "0" once the operation is completed.

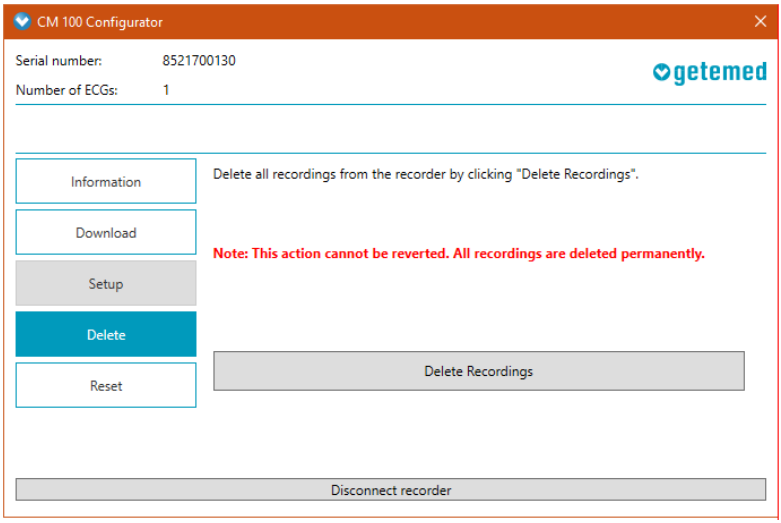


Figure 17 – Delete data

ECG Report

WARNING: For the review of ECG reports the software Adobe Reader Version 10 or above must be used.If a different PDF viewer software is used the accuracy of the presentation cannot be guaranteed.

The ECG reports are located in the selected download folder. Double-click on a PDF file to open it in the Adobe Reader for review (Figure 18).

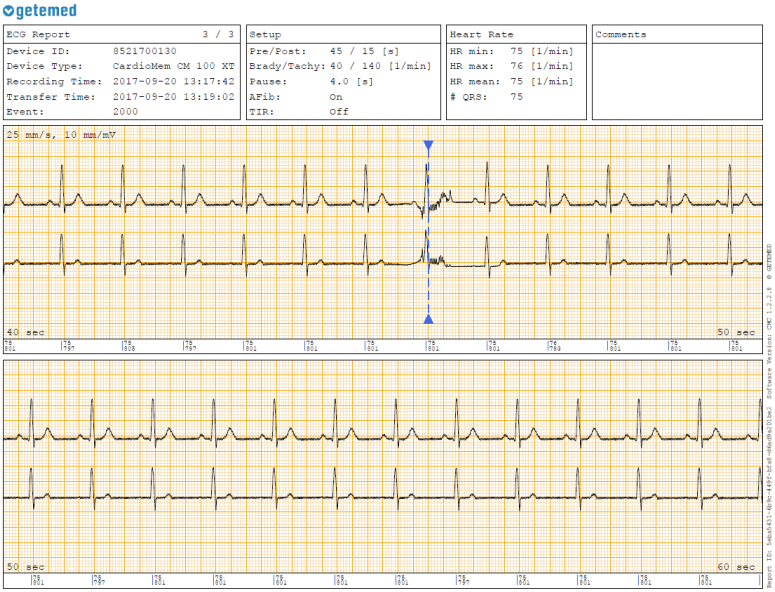


Figure 18 - ECG report

Information in the ECG Report

The ECG report comprises a header part and a data part. The header of the ECG report () shows the following information:(1) - Device ID / serial number, device type, recording and transmission time, event code (see the table below).

ECG Report (1)		1 / 2
Device ID:	8521600110	
Device Type:	CardioMem CM 100 XT	
Recording Time:	19.01.2017 21:14:06	
Transfer Time:	20.01.2017 08:27:35	
Event:	0080	

Setup (2)	
Pre/Post:	25 / 15 [s]
Brady/Tachy:	40 / 140 [1/min]
Pause:	4.0 [s]
AFib:	On
TIR:	Off

Heart Rate (3)	
HR min:	50 [1/min]
HR max:	86 [1/min]
HR mean:	70 [1/min]
# QRS:	45

Figure 19 - ECG report, header

The event code is displayed as 4-character value:

Event	Value
Auto-triggered Bradycardia	0010
Auto-triggered Tachycardia	0020

Event	Value
Auto-triggered Pause / Asystole	0040
Auto-triggered Atrial fibrillation (AFib) start	0080
Auto-triggered Atrial fibrillation (AFib) end	0081
Auto-triggered Bradycardia during ongoing AFib	0090
Auto-triggered Tachycardia during ongoing AFib	00A0
Auto-triggered Pause / Asystole during ongoing AFib	00C0
Time interval record	1000
Time interval record during ongoing AFib	1080
Manually triggered event	2000
Manually triggered event during ongoing AFib	2080

(2) - Device setup, pre- and post-time, auto trigger

(3) - Heart rate information, minimum, maximum and mean heart rate, number of recognized QRS complexes

In the data part of the ECG report the ECG trace is presented at a speed of 25 mm/s and a gain of 10 mm/mV.
The number of pages depends on the ECG length. The time of the event triggering is indicated in the ECG report by a vertical line.

NOTE: The accuracy of heart rate readings depends on the ECG signal quality. Heart rate readings can be inaccurate in case of a strongly disturbed ECG signal.

16.8 Setup

The setup feature is available in the information screen which is displayed once a connection to the recorder has been established. The setup feature is not active if there are ECG data stored on the device. Download the ECG data first and delete the device memory before changing the setup.

Click "Setup" to go to the setup screen. In the setup screen you can adjust the settings for pre- and post-time (this is the time in seconds before and after an event is triggered), the thresholds and the timer for the automatic triggering of ECG recording based on the heart rate and rhythm and the timer for the time controlled automatic ECG recording (Figure 20).

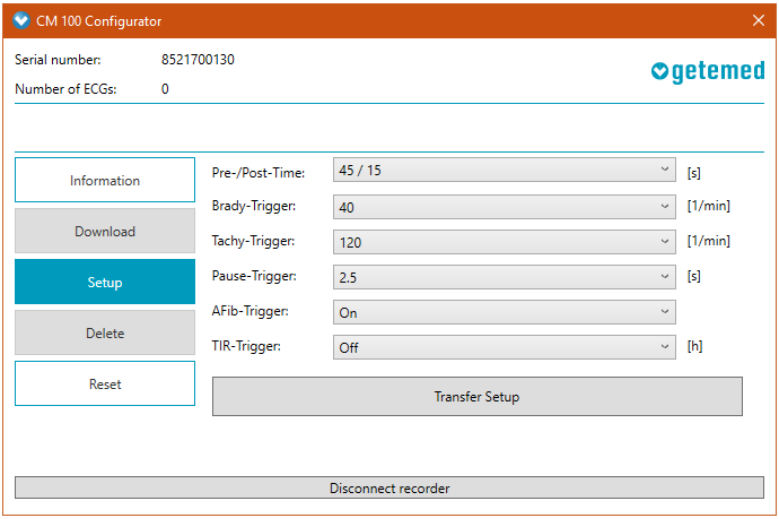


Figure 20 - Setup

Click the button "Transfer Setup" to transfer the new settings to the device.

Auto-Trigger

The following trigger parameters can be adjusted:

Trigger	Possible values	Default
Bradycardia	OFF, 30 bpm, 40 bpm, 50 bpm, 60 bpm	OFF
Tachycardia	OFF, 100 bpm, 110 bpm, 120 bpm, 130 bpm, 140 bpm, 150 bpm, 160 bpm, 170 bpm, 180 bpm, 190 bpm, 200 bpm, 210 bpm, 220 bpm, 230 bpm, 240 bpm	OFF
Pause	OFF, 2 s, 2,5 s, 3 s, 3,5 s, 4 s	OFF
Atrial fibrillation	OFF, ON	OFF
Timer	OFF, 1 h ... 24 h (increment 1h)	OFF

Pre- and Post-Time

The following settings are possible:

Settings (s)	25 / 15	45 / 15 *	30 / 30	60 / 30	60 / 60
Length of ECG recording (s)	40	60	60	90	120

(*) = default setting

Restore Default Settings

The feature restore factory / default settings is available in the information screen which is displayed once a connection to the device has been established.

Click "Reset" to proceed (Figure 21).

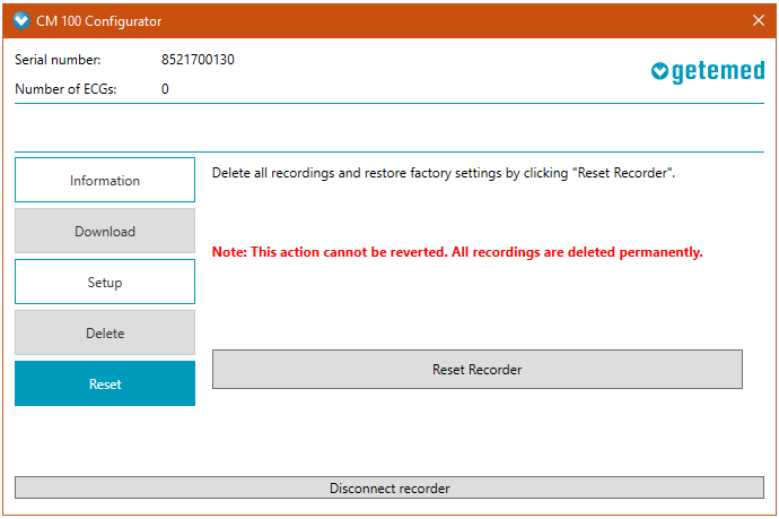


Figure 21 - Restore default settings

NOTE: This action cannot be reverted. All data on the device will be deleted and the setup will be changed to factory settings.

Click "Reset Recorder" to restore factory settings. You will be redirected to the information screen and the factory settings are displayed as current setup (Figure 22).

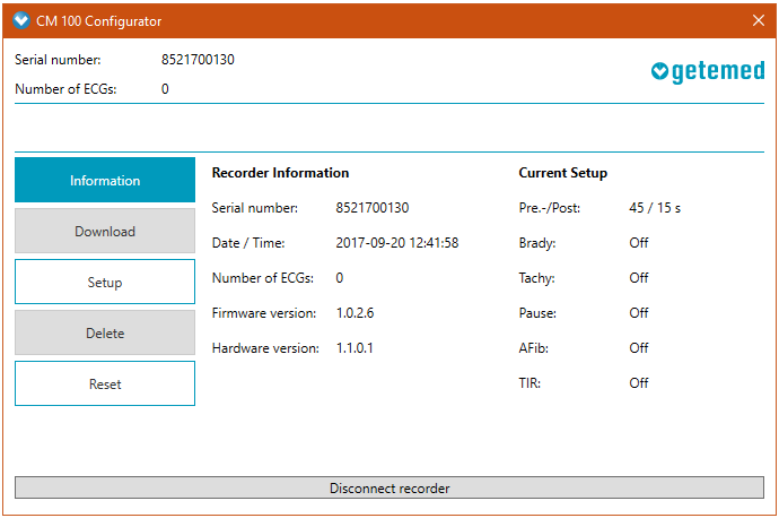


Figure 22 – Default settings restored

16.9 Disconnect the Device

Click the button "Disconnect recorder" to unlink the USB connection. Disconnect the device plug of the Download Cable from the device.

17 Description of automatic Rhythm Detection

17.1 Heart Rate Detection

The heart rate is continuously calculated in beats per minute [bpm] from the time that elapses between two consecutive beats. The heart rate detection is an essential performance characteristic of the device. It works from 30 bpm to 240 bpm with a tolerance of max. 10%.

The heart rate detection may produce false results or temporarily stop working in case of electromagnetic disturbances.

17.2 Detection of Bradycardia and Tachycardia

A bradycardia event will be triggered once the preset pre-event time has elapsed and the heart rate falls below the preset trigger limit for more than three consecutive beats.
The next bradycardia event will not be triggered until the end of the previous bradycardia event has been detected. To determine the end of a bradycardia, the heart rate must not fall below the preset trigger limit for at least 90 beats.

A tachycardia event will be triggered once the preset pre-event time has elapsed and the heart rate rises above the preset trigger limit for more than 4 consecutive beats.
The next tachycardia event will not be triggered until the end of the previous tachycardia event has been detected. To determine the end of a tachycardia, the heart rate must not exceed the preset trigger limit for at least 90 beats.

The automatic triggering is supressed when

- the device is in open lead condition;
- signal noise has been detected or
- the calculated heart rate is invalid.

17.3 Detection of Atrial Fibrillation (AFib)

The onset of AFib will be detected once three arrhythmic changes of two consecutive RR' distances have been found within the last 16 QRS complexes.
AFib continues if AFib onset has been previously detected and at least one arrhythmic change of two consecutive RR' distances was found within the last 16 QRS complexes.
AFib ends if no arrhythmic change of two consecutive RR' distances was found within the last 16 QRS complexes for a period longer than 20 seconds; otherwise it continues.

The automatic triggering is supressed when

- the device is in open lead condition;
- signal noise has been detected or
- the calculated heart rate is invalid.

17.4 Pause Detection

A pause will be detected if the time between two consecutive beats exceeds the preset value for the pause trigger or asystole is determined for a longer period then the preset pause trigger value.

18 Disposing of the Device, Batteries and Accessories

Electrical devices and accessories contain metal and plastic parts. To avoid any adverse environmental impact, dispose of the device and its accessories in accordance with applicable waste regulations after the product's lifetime has expired.

If you have questions concerning the disposal of this product, contact the manufacturer or its representatives.

19 Troubleshooting

Symptom	Cause	Recommendation
Device cannot be switched on (LED is not shining)	Battery exhausted or no battery inserted	Insert a new battery
Recording cannot be started (LED is shining yellow)	Memory occupied	Connect the device to a PC with the software CM 100 Configurator and switch it on. Start the software CM 100 Configurator and check the device status. Download data and erase the memory of the device.
Recording cannot be started (LED is flashing yellow. 3x beep when button is pressed)	Open lead	Check leads
Incomplete recording	Battery exhausted	Insert a new battery
Device does not go into normal operation mode after start (LED is repeatedly flashing red, green, blue)	General device failure	Remove and reinsert the battery. Contact your distributor or the service of the manufacturer if the problem remains.
Wrong timestamp on ECG report	Internal backup battery exhausted	Connect the device to a PC with the download cable for at least 12 hours to recharge the internal battery

20 Notifications (LED and Speaker)

Device Condition / Error	**LED**					**Buzzer**
	Red	**Green**	**Blue**	**Yellow**	**Cyan**	**Beep**
Device switched on	1x 0,25s	1x 0,25s	1x 0,25s			1 x
Recording in progress		flashing, pause 5s				
Open lead				flashing, pause 1s		3 x 3, pause 15s (repeated after 15min, 60min, 24h)
Battery exhausted	flashing, pause 1s					
Batt. exhausted + Button pressed	flashing, pause 1s					3x
Event, manual recording		flashing 1 x 1s				
Event, manual recording not possible						3x
Bluetooth ON automatic			flashing, pause 1s			
Error (general)	flashing	flashing	flashing			
- POST fail	flashing, pause 1s					
Batt. exhausted at start	shining 3s					
USB detected					shining	
Memory occupied				shining		

21 Accessories, Ordering Information

Product	REF Number
Protective Bag	78451002
Instructions for Use / Operator Manual	78812011
Battery Renata CR2477N	Q001 12477
Single use ECG electrodes *	90131
Download Cable *	78412001
USB Cable *	78412002
CM 100 Configurator Software *	78313011

*) Not included in the delivery - order separately.

22 Specifications

22.1 General

Classification:	IIa according to 93/42/EEC (MDD)
Applied part type:	BF (Body Floating), non-defibrillation-proof applied part.
Operating time (typical):	7 ... 14 days
Dimensions (W x L x H):	76 mm x 89 mm x 14 mm
Weight:	approx. 39 g (including battery)
Battery type:	3 V Lithium, Renata CR2477N
Mode of operation:	Continuous operation for at least 14 days
Battery life (typical):	14 days
Material:	PC+PET plastic casing
Ingress protection:	IP64
Life time (device and accessories excluding battery and ECG electrodes):	7 years
ECG leads:	2 channels, 3 electrodes
Heart rate:	30 /min ... 240 /min, tolerance +/- 10%
Digital signal processing:	512 Hz / 16 Bit
Lower frequency threshold:	0.05 Hz
Upper frequency threshold:	70 Hz
Input voltage:	+/- 6 mV
Open lead detection:	yes

22.2 Operating Conditions

Temperature:	5 °C to 45 °C
Relative humidity:	0 % to 93 %, non-condensing
Ambient pressure:	1060 hPa ... 700 hPa (-380 m ... 3000 m)

22.3 Transport and Storage Conditions

Temperature:	5 °C to 45 °C
Relative humidity:	0 % to 93 %, non-condensing
Ambient pressure:	1060 hPa ... 700 hPa (-380 m ... 3000 m)

22.4 Wireless Capabilities

The device intentionally receives and transmits RF electromagnetic energy for the purpose of its operation.
The characteristics of receiver and transmitter are described below.

Wireless technology:	Bluetooth Low Energy Frequency: 2 402 MHz ... 2 480 MHz (2.4GHz ISM band)
Modulation:	Gaussian frequency shift keying (GFSK)
Radiated power:	0 dBm = 1 mW

22.5 Electromagnetic Compatibility

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to EMC information provided in this document.

Guidance and manufacturer's declaration - electromagnetic emissions

This device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure 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 - device is battery driven	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Not applicable - device is battery driven	

Guidance and manufacturer's declaration - electromagnetic immunity (line-bound disturbances)

This device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that the device is used in such an environment.

Immunity test	IEC60601-1-2 test level*	Compliance level*	Electromagnetic environment— guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 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%.
Electrical fast transient / burst IEC 610004-4	Not applicable - device is battery driven and has no patient leads or power supply lines		
Surge IEC 61000-4-5	Not applicable - device is battery driven and has no patient leads or power supply lines		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable - device is battery driven		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity (Conducted and radiated RF disturbances)
This device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that the device is used in such an environment.

Immunity test	IEC60601-1-2 test level*	Compliance level*	Electromagnetic environment— guidance
Conducted RF IEC 61000-4-6	3 V effective value 150 kHz to 80 MHz	3 V effective value	Portable and mobile RF devices are not used at closer than 30 cm to the device including leads
	6 V effective value in the ISM bands between 0,15 MHz and 80 MHz	6 V effective value in the ISM bands according to table 5, Note N	The field strength of stationary radio transmitters is, as determined by an electromagnetic site survey, at all frequencies smaller than the compliance level.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz Immunity against wireless RF communication devices	10 V/m according to table 9**	Interference may occur in the vicinity of equipment marked with the following symbol: 

*) = Specifications according to EN 60601-1-2: 2015

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

**) EN 60601-1-2: 2015, table 9:

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz Sinus	2	0,3	28
710 745 780	704 - 787	LTE Band 13,17	Pulse modulation b) 217 Hz	0,2	0,3	9
9	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28
1720 1845 1970	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28
5240 5500 5785	5100 – 5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment, could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

23 List of Figures

Distributor:

CE 0197

REF 78812021

Manufacturer:

getemed

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