getemed

Instructions for Use

CardioMem® CM 100 XT

ECG Loop Recorder

Revision 04 EN

Cardiac Diagnostics

Vital Signs Monitoring

Telemonitoring

Contents

1 Information about this Manual

This Manual was published by

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

The information provided in this Manual applies to CardioMem CM 100 XT, version 1.1.x, and CM 100 Configurator, version 1.3.x. It does not apply to earlier versions.

Revision history

Revision	Publication date	Description
01	2017-11-10	1st edition
02	2018-03-06	2nd edition
03	2019-09-09	3rd edition: Contents for Tele ECG and modified housing added
04	2020-02-01	4th edition: Symbol RCM and accessories added

2 Intended use

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 on patients whose symptoms occur infrequently;
- Document the impact of an initiating drug therapy for arrhythmias;
- Document the recurrence of arrhythmias after discontinuation of a drug therapy;
- Document the results after an ablation procedure for arrhythmias;
- Evaluate syncopes on patients whose symptoms occur infrequently.

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

- Tachycardia
- Bradycardia
- Atrial fibrillation
- Pause

The device is intended for use in home and clinical environments. Home environments include rural, urban and suburban residential areas, as well as schools, offices and retails environments. The device may also be used during transport. The device is not intended for use near active RF surgical equipment or in shielded rooms of magnetic resonance imaging (MRI) system. The device is battery-powered and uses a non-volatile memory to store the ECG data. The device is not intended for use as a critical care monitoring system and must not be used in emergency situations.

3 Indications and contraindications

3.1 Indications

CardioMem CM 100 XT is intended for adult and pediatric patients (weight >10 kg) who require monitoring of the following cardiac arrhythmias: Tachycardia, bradycardia, atrial fibrillation, and pause.

3.2 Contraindications

Contraindications include the use on patients

- With known allergies or hypersensibilities to adhesives or hydrogels;
- With potentially life-threatening arrhythmias, or
- Who require inpatient / hospital monitoring.

4 Regulatory information

4.1 MDD compliance

The CE mark and the notified body registration number indicate that the recorder complies with the basic requirements of the EU Directive 93/42/EEC (MDD).

CE 0197

4.2 Radio frequency compliance

The CE mark indicates that the recorder complies with the fundamental requirements of the EU Directive 2014/53/EU (RED).

4.3 Classifications

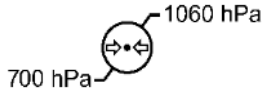
MDD 93/42/EEC classification	Class IIa
Protection against electric shock	Type BF, non-defibrillation-proof applied part
Mode of operation	Continuous
Method(s) of sterilisation recommended by the manufacturer	Not applicable

5 Labelling

The following symbols are used on the recorder and / or on the packaging:

CardioMem CM 100 XT	Device type (CardioMem CM 100), model (XT)
2017-03-22	The name and address of the manufacturer are specified to the right of this symbol. The date of manufacture is specified below the manufacturer symbol.
(01) 04250903200212 (11) 170227 (21) 8521712345 SN (241)78220001 REF	UDI marking comprising the matrix code with GTIN (01), date of manufacture (11), device serial number [SN] (21) and the order number [REF] (241)
REF 78120001	Barcode with kit order number [REF]
CE 0197	CE mark followed by the registration number notified body of the manufacturer
	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.
IP64	This symbol indicates that the device is protected in accordance with IP64 against the ingress of fluids and foreign matters; 6 = dust-protected, 4 = protection against splash water.
	This symbol indicates that the recorder is powered by a replaceable, non-rechargeable battery.

	This symbol refers to the obligation to dispose of the recorder in accordance with the relevant environmental regulations. For further information, refer to the “Disposal of device, batteries and accessories” section on page 62.
	Observe the Instructions for Use. Before starting work with the recorder, make sure that you have read and understood the Instructions for Use.
	General warning sign Observe the information in the Instructions for Use for proper use of the device.
SN	Serial number
REF	REF (catalogue) number for identification and ordering of the product
	Pushbutton
60 °C -20 °C	Temperature range –20 °C ... 60 °C Specifies the upper and lower limits for the permissible temperature during storage and transport
93 % 0 %	Humidity range 0% ... 93% Specifies the upper and lower limits for the permissible humidity during storage and transport

	Atmospheric pressure range 700 hPa ... 1,060 hPa Specifies the upper and lower limits for the permissible atmospheric pressure during storage and transport
	Keep away from heat Indicates that the recorder must be kept away from heat sources
	Keep dry Indicates that the recorder must be kept away from rain and other sources of moisture
	Fragile Indicates that the contents are fragile and should be handled with care
	Maximum stacking height: 10 boxes
	The packaging is recyclable.
	RCM (Regulatory Compliance Mark – Australia & New Zealand)

6 Safety information

6.1 Definitions

The terms “Warning” and “Caution” are used in these Instructions for Use to indicate hazards and the degree of severity. A 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 risk or unsafe practice which, if not avoided, could result in minor personal injury or damage to the product or property.

NOTICE indicates application notes or other useful information to ensure that you get the most from the product.

6.2 General warning notes

WARNING NO MONITORING DEVICE

The recorder is not intended for monitoring of the clinical condition of a person.

Do not use CardioMem CM 100 XT as a monitoring device.

WARNING MIXING UP RECORDINGS

The patient's life or health can be put at risk if the patient is assigned an examination of a different patient, resulting in an incorrectly assigned diagnosis.

Make sure that no recordings are saved in the device before the recorder is used for the next patient.

WARNING ELECTROSURGERY

There is the risk of burns and injury hazards for the patient.

Always disconnect the recorder form the patient before using an electrosurgical device.

WARNING EXPLOSION HAZARD

Electrical sparks can cause explosions in the presence of certain gases.

Do not use the recorder in an oxygen-enriched environment or in the vicinity of flammable or explosive gases.

First check whether the patient is liable to be in such an environment, e.g. for job-related reasons.

WARNING ELECTRIC SHOCK

An electric shock or malfunction can occur if the electrodes come into contact with electrically conductive materials.

Always keep the contacts of the electrodes away from other conductive parts, including earth.

Make sure that no contact to other conductive parts is possible if the electrodes loosen during recording.

WARNING GENERAL HAZARDS FOR THE PATIENT

The instructions provided in these Instructions for Use do not supersede the notes regarding recognised medical practices of medical care.

Always observe the recognised medical practices for medical care.

WARNING RISK OF CONTAMINATION OR INFECTION

The recorder or its accessories could be contaminated with bacteria or viruses after use.

If so, observe the following standard procedures for handling contaminated objects and the following safety notes:

- Always use protective gloves when touching the equipment.
- Isolate the material by using appropriate packaging and labelling.
- Contact the addressee and label the packaging accordingly before shipping the equipment.

Clean and disinfect device and accessories after each use.

WARNING HAZARD OF SUFFOCATION

Small parts and packaging material represent a suffocation hazard.

Make sure that small parts are always out of the reach of children.

WARNING ELECTRIC SHOCK

Before starting cleaning or maintenance work, first disconnect the recorder from the patient.

WARNING EXTREME TEMPERATURES

The performance of the device can be impaired in case of extreme temperatures.

If the recorder has been stored at a temperature close to the upper or lower limit, wait at least 4 hours to allow the recorder to reach ambient temperature.

WARNING PETS AND VERMIN

Pets and vermin may entail a risk for the safety of the patient.

For example, pets can cause damage from biting or exude fluids over the recorder and its accessories. Vermin can also cause damage impairing the functioning of the device.

Make sure that no pets or vermin come into contact with the device or its accessories.

6.3 General precautions

CAUTION CONDUCTIVITY

Do not use the recorder if mechanically damaged.

Send the recorder to an authorised workshop for repair.

CAUTION CONDUCTIVITY

Do not use the recorder if the cover of the battery compartment is missing.

Fit the cover before using the recorder.

CAUTION RISK OF INFECTION AND CONTAMINATION

Reusing consumables that came into contact with the patient entails the risk of infecting further patients.

Do not use consumables (e.g. electrodes) if they have already been used for a patient.

CAUTION RISK OF INFECTION AND CONTAMINATION

Returned parts and products that have not been disinfected entail the risk of infection for our service personnel.

Especially for protection of our service personnel, always disinfect both the recorder and the USB cable before you send it to us for inspection or maintenance.

CAUTION DAMAGE TO THE DEVICE ARISING FROM LEAKING BATTERIES

Batteries may leak if not used for longer.

Always remove the battery from the recorder if you intended not to use the recorder for longer than a week.

CAUTION INSUFFICIENT RECORDING QUALITY

Damaged recorders or accessories can lead to insufficient ECG quality.

Check the recorder each time before you connect recorder and electrodes to the patient.

CAUTION MALFUNCTION OR DAMAGE OF THE RECORDER

Any changes in temperature or humidity can cause formation of condensate inside the recorder.

Allow the recorder to become dry and wait another two hours before starting work.

CAUTION DAMAGE TO THE RECORDER

Only the battery compartment of the recorder may be opened, not the recorder itself!

Do not apply force when handling the recorder.

CAUTION SAFETY ONLY WITH APPROVED ACCESSORIES

Safe and reliable operation of the recorder is only possible when using the supplied and approved accessories.

Observe the information provided in these Instructions for Use and in the instructions delivered with the accessories.

CAUTION SAFETY AND RELIABILITY ONLY WITH PROPER MAINTENANCE

Proper maintenance is vital for long-term safety and reliability.

Observe the information provided in this Manual to ensure proper maintenance.

CAUTION DAMAGE TO DEVICE AND ACCESSORIES

Unauthorised personnel do not have the proper training required to repair the recorder. Repairs performed by unauthorised personnel can lead to damage on the device or its accessories.

If you determine or suppose any malfunctions or defects, send the recorder to an authorised workshop for checking. Please enclose a detailed description of the noticed malfunction.

CAUTION ADVERSE ENVIRONMENTAL IMPACTS

Electrical devices and accessories contain metal and plastic parts which must be disposed of properly.

Dispose of the recorder and its accessories in accordance with the applicable local and national waste regulations after expiry of the product lifetime.

CAUTION POSSIBLE LOSS OF ECG RECORDING OR POOR SIGNAL QUALITY

The recorder might be used with insufficient results if the patient does not have all relevant information.

It is the responsibility of the doctor to provide the patient with the information required for the ECG recording. For further information, see Section “Instructing the patient”.

CAUTION ELECTROMAGNETIC EMISSIONS

The use of accessories other than those specified or provided by the manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity of the recorder, resulting in improper operation.

Only use the accessories specified and provided by the manufacturer.

CAUTION ELECTROMAGNETIC EMISSIONS

Any other electromedical equipment in the vicinity of the recorder can impair the performance of the recorder.

Make sure that there is always is distance of at least 30 cm (12 in) between the recorder and any other electromedical equipment. The doctor must inform the patient correspondingly where necessary.

CAUTION MOIST ENVIRONMENTS

The ingress of water into the recorder can cause damage or malfunctions. (The recorder is protected against splash water.)

The doctor is obliged to inform the patient that the recorder must not be worn during swimming, bathing or showering.

CAUTION REPAIR AND MAINTENANCE

Repair by inadequately trained personnel could result in hazards, e.g. due to excessive temperatures or high voltages. Only the electrodes and battery may be replaced by the patient.

Repairs must only be performed by persons who are authorised by the manufacturer to do so.

CAUTION MALICIOUS SOFTWARE

The delivered software is scanned for viruses, but can, nevertheless, be intruded by malicious software.

We recommend installation of an advanced anti-virus software and regularly updating it.

Install appropriate procedures to prevent infected software from reaching your computer. For example, check the source of any software you use and use only genuine software packages.

CAUTION DOWNLOADING DATA VIA USB

Data should only be downloaded by medical professionals, not by the patient!

7 Warranty and service information

Only authorised personnel are allowed to repair the recorder. Any unauthorised attempts to repair the device will make any warranty claims null and void.

The recorder does not require any special maintenance to maintain its safety and performance features during the expected lifetime.

It is the operator's responsibility to report the need for repair to the manufacturer or one of his authorised representatives. If you determine or suppose any malfunction, send the recorder 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

8 Cleaning and disinfection

CAUTION

Do not use solvents, such as ether, acetone or paraffin oil; such substances can damage the material of the housing.

CAUTION

Before cleaning or disinfecting the device, remove the battery and close the battery compartment.

Before performing surface disinfection, clean the recorder.

Use a lint-free cloth slightly moistened with a mild soap solution to wipe the recorder.

Disinfect the recorder at regular intervals, prior to first use and before passing it on to another person.

GETEMED recommends to use a 70% alcohol solution for disinfection.

9 Operating elements

The recorder possesses a pushbutton (1), a LED status indicator (2) and a buzzer (Fig. 1).

The following symbol can be found on the pushbutton: ⊙

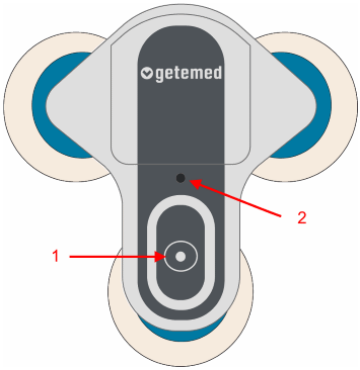


Fig. 1 – Operating elements

9.1 Pushbutton

The pushbutton is used to perform the following functions:

Function	Operator action
Switching on the device	Press and hold down for more than a second until a beep sounds. **NOTICE** The recorder can only be turned off by removing the battery.
Saving an event during recording	Press and release; a beep signals that the event has been saved.

9.2 Visual and acoustic signals

The recorder states are indicated by way of a multi-colour LED status indicator and acoustic signals:

Recorder status	LED status indicator	Buzzer
Device is starting	Flashing green, red and blue	Single beep
Pushbutton pressed	-	Single beep
Recording in progress	Flashing green	-
Open lead	Flashing orange	Three beeps
Memory occupied	Is lit orange	-
Bluetooth pairing activated	Flashing blue	Tune
Bluetooth pairing completed	-	Tune
Bluetooth communication in progress	Flashing blue	-
Low battery	Flashing red	Three beeps
USB connected	Shining in cyan	-
Error	Flashing green, red, blue, and then red	Three beeps

9.3 Lead scheme

The device can record acquire two channels (Fig. 2):

A = Channel 1

B = Channel 2

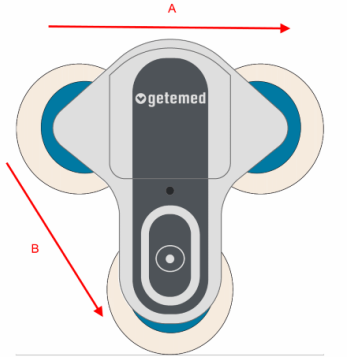


Fig. 2 – Lead scheme

10 Preparing the recording

You may set the limit values of automatic heart rate detection for each patient individually, as explained in the “The “Setup” window” section on page 43.
To prepare the recording, in addition, perform the following steps:

- Inserting the battery
- Instructing the patient
- Preparing the skin of the patient
- Connecting the electrodes to the recorder
- Attaching the device to the patient
- Turning on the recorder
- Checking the signal quality

10.1 Inserting the battery

Use a ballpoint pen to unlock the battery compartment. Hold the recorder securely in one hand with the rear to the top and gently push the tip of the ballpoint pen into the hole (1) until the latch is released. The battery compartment opens downward (2) and can be removed now (Fig. 3).

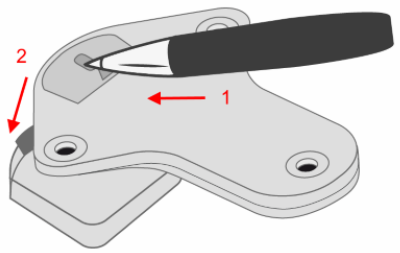


Fig. 3 – Opening the battery compartment

CAUTION

Do not apply too much force. The recorder could be damaged.

CAUTION

Always use a ballpoint pen. Do not use sharp or pointed objects. They could cause injuries.

Remove the cover of the battery compartment.

Insert a new CR2477N 3V lithium battery. Observe the polarity. Push the battery under the battery clip until it snaps into place (Fig. 4).

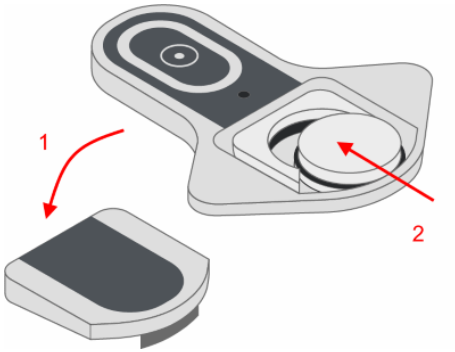


Fig. 4 – Inserting the battery

Fit the cover of the battery compartment. Push down until the latch snaps into place (Fig. 5).

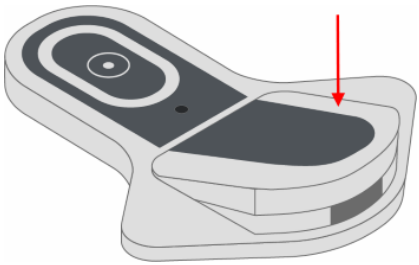


Fig. 5 – Closing the battery compartment

10.2 Instructing the patient

It is the responsibility of the doctor to provide the patient with the following information required for safe use of the recorder.

CAUTION

If you have any skin problems, inform the doctor. In rare cases, allergic reactions can also occur with biocompatible electrodes.

CAUTION

Do not expose the recorder to water! Do not shower or bath when wearing the recorder.

CAUTION

Do not expose the recorder to extreme temperatures. The operating temperature of the recorder must always be in the range between 5 °C and 45 °C.

CAUTION

Do not expose the recorder to sudden temperature or humidity changes. Do not bring the recorder in the vicinity of heat sources, such as furnaces or cookers, and do not expose the device to direct sunlight.

CAUTION

Keep sufficient distance from electrical equipment. Do not use an electric blanket when wearing the recorder.

CAUTION

Keep the recorder away from children and pets.

CAUTION

Electrodes that are loosened during recording must be replaced.

10.2.1 Saving an event manually

Instruct the patient to press the pushbutton briefly during the recording to mark an event. A short beep informs the patient that the event has been saved.

10.2.2 Recording diary

We recommend having the patient maintain a diary to record activities, symptoms and the corresponding times during the ECG recording.

The header of the diary should include data required to identify the patient and recording and for the medication taken during the recording.

10.3 Preparing the skin of the patient

Careful skin preparation is the key to error-free recording.

- Select the points where you wish to fit the electrodes. For further information, refer to the “Attaching the device to the patient” section on page 30.
- Make sure that the skin where you wish to mount the electrodes is dry, clean and free of hair.

NOTICE

Use a lint-free cloth to dry the skin.

10.4 Connecting the electrodes to the recorder

Place the recorder with the front side down to a level surface (table).

Take three new disposable ECG electrodes. Do not yet remove the protective film from the contact sides of the electrodes.

Snap the studs of the electrodes into the adapters on the rear of the recorder (Fig. 6).

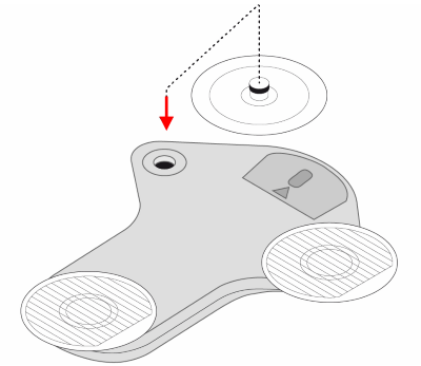


Fig. 6 – Connecting the electrodes

CAUTION

Only use ECG electrodes that are clearly marked as such for single use. Otherwise, allergic skin reactions can occur.

CAUTION

To avoid infections, do not use electrodes that have already been used by another patient.

CAUTION

Observe the expiration date of the ECG electrodes. Do not use ECG electrodes after their expiration date because this could impair the signal quality.

10.5 Attaching the device to the patient

Carefully remove the protective film from the electrodes (Fig. 7).

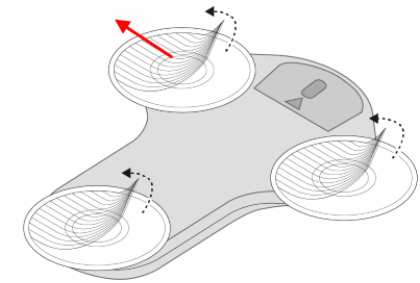


Fig. 7 – Removing the protective film

Place the recorder on the sternum (a), the upper left chest (b) or, turned by 180°, on the sternum (c) and gently press (Fig. 8).

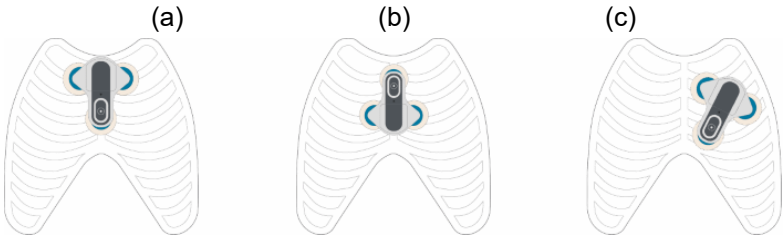


Fig. 8 – Attaching the device

Check that all electrodes are in good contact with the skin.

Excessive sweating can cause the electrodes to slide, become loose or fall off. Physical activities which may cause excessive sweating should be avoided.

10.6 Turning on the recorder

Press the pushbutton until a beep sounds. A colour sequence is displayed on the LED to indicate that the recorder is starting (Fig. 9).

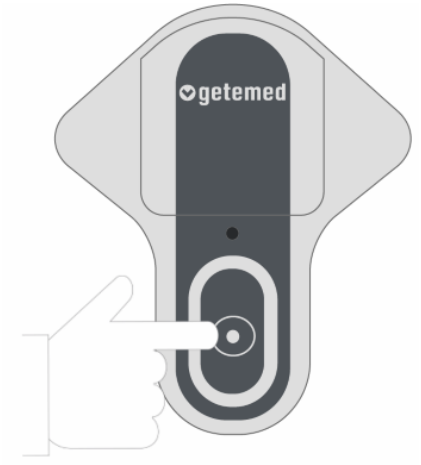


Fig. 9 – Turning on the recorder

10.7 Checking the signal quality

If the signal quality is good and the recorder is not in an open lead condition, the LED flashes green to indicate that the recorder is ready to operate.

If the signal quality is poor or the recorder is in an open lead condition, the LED flashes orange, indicating that the recorder is not ready to operate.

Check the conditions between the device and the electrodes.

Replace one or more electrodes where necessary.

11 Recording an event

The device records events either when the patient presses the pushbutton, automatically when settable limit values are exceeded or specified target values are not reached, or at settable time intervals.

You can set the **pre- and post-event times** as explained in the “The “Setup” window” section on page 43.

11.1 Manual recording by pressing the pushbutton

Manual recording is always available even if automatic recording is activated.

The patient must press the appropriate pushbutton to start manual recording either whenever any symptoms occur or at regular intervals specified by the doctor.

An acoustic signal (beep) sounds to indicate that the recording was started.

11.2 Automatic recording

Automatic recording is always started either when the recorder has detected an event or at specified time intervals.

11.2.1 Automatic detection of arrhythmias

The recorder uses built-in algorithms for automatic detection of certain arrhythmias (bradycardia, tachycardia, atrial fibrillation, pause).

These algorithms are based on the continuous detection of the R waves and the calculated heart rate values. The automatic arrhythmia detection is automatically turned off if the ECG signal is noisy or very weak.

You may specify the limit values and other parameters for automatic arrhythmia detection by way of the software CM 100 Configurator.

For more information, refer to the “The “Setup” window” section on page 43 and the “Description of automatic rhythm detection” section on page 60.

NOTICE

Even though the algorithms have been clinically validated, 100% detection and classification of arrhythmias cannot be guaranteed.

Automatic arrhythmia detection does not function properly on patients with cardiac pacemakers.

11.2.2 Time-triggered recording

If you intend to control the recording by time, you can set the ECG recording intervals as explained in the Section “Setup”. Time intervals between 1 and 24 hours can be selected.

12 End of recording

Carefully disconnect the recorder form the electrodes and remove the battery to stop recording. The recording automatically stops in the following situations:

- Full memory
- Low battery

12.1 Removing the electrodes

Slowly peel off the electrodes, starting at their outer edges. Dispose of the used electrodes in the household waste.

CAUTION

To avoid infections, do not use electrodes that have already been used by another patient.

13 Using the CM 100 Configurator software

The CM 100 Configurator software is an accessory for CardioMem CM 100 XT. It is intended for use by trained medical professionals (users) in medical institutions. The software runs on PCs on which the Microsoft Windows operating system is installed. The software has no direct diagnostic or therapeutic purpose.

The software enables the user to download data from the device via USB and store locally on a PC.

Furthermore, the software can be used to adapt the setting parameters of the recorder to the requirements of the appropriate patient.

13.1 Required hardware and software

To be able to run the CM 100 Configurator software, the following hardware and software are required:

CPU	Core i3 2 GHz processor or equivalent
Memory	Min. 4 GB RAM
Hard drive	200 MB for installation of the application and required components; at least 1 GB recommended for data backup
Interfaces	1 x USB 2.0 port or higher
Graphic resolution	Minimum: 1,024 x 768 Recommended: 1,920 x 1,080
PC operating system	Windows 7 / 8.1 / 10
Framework	Microsoft.NET, version 4.7.2 or higher
Report Generator	Adobe Reader, version 10 or higher

NOTICE

The software is not intended for use in virtual environments or installation on terminal servers.

13.2 Installation

The installer is an executable file that can be downloaded from

https://www.getemed.net/downloads/CM100/CM100Configurator_Setup.exe.

It installs all program files and the USB driver required for communication with the device CardioMem CM 100 XT.

Copy the installation file to a local folder on your PC.

Double-click on the installation file to start the installation process. You will be prompted to specify a valid installation path (Fig. 10) and a path for the ECG data storage folder (Fig. 11).

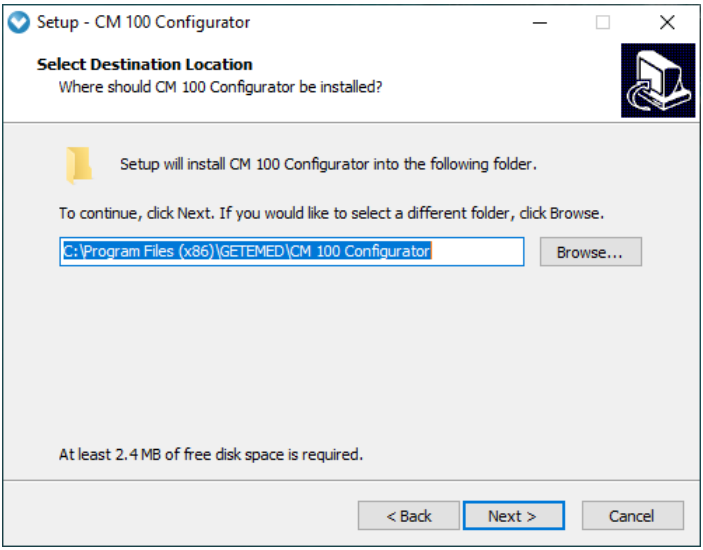


Fig. 10 – Installation path

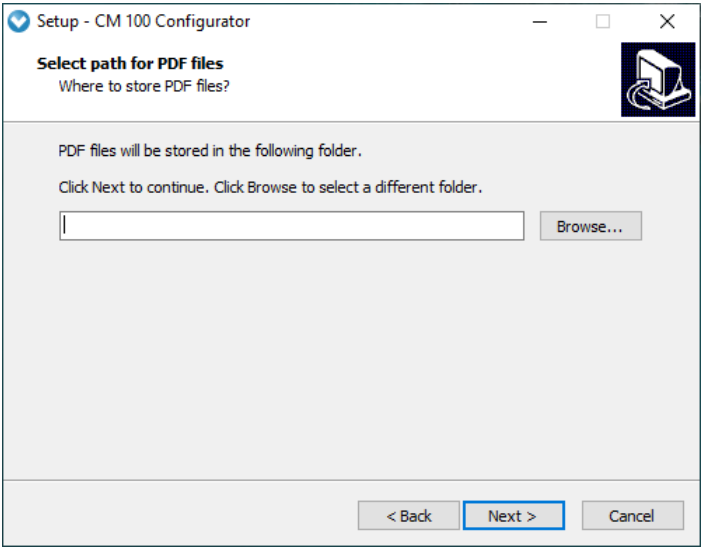


Fig. 11 – Download path

You will be asked whether you wish to create a program icon on your desktop. Then you can start the installation with the specified settings.

NOTICE

It is recommended to uninstall an existing installation of the CM 100 Configurator software and to make a backup of all stored ECG data before installing a new version of the software.

13.3 Checking the system time

CAUTION

It is imperative to check the system time of the PC. An incorrect system time can cause incorrect assignment of the ECG reports between the patients.

13.4 Connecting the USB download cable to recorder and PC

WARNING

RISK OF ELECTRIC SHOCK – Only use the USB download cable supplied by GETEMED to connect the recorder to a PC.

CAUTION

Make sure that the PC complies with the latest version of the IEC 60950 standard for safety of IT equipment.

NOTICE

Connecting the recorder to a PC incorporated in an IT network together with other equipment could result in previously unidentified risks to patients, users and third parties. The responsible organisation must identify, analyse, evaluate and control these risks.

Changes to the IT network, such as:

- Changes in the configuration of the network/data coupling configuration
- Connection of additional components for network/data coupling
- Disconnection of components from network/data coupling
- Update of components connected to the network/data coupling
- Update of components connected to the network/data coupling

could cause new risks that require additional analysis. Refer to the standard EN 80001.

The download cable has two different connections - for the recorder and for the PC.

Insert the USB-A connector of the download cable into a free USB port of your PC.

Open the battery compartment of the recorder (1) and remove the battery (2). Insert the device connector of the download cable into the socket (see illustration) of the recorder (3) as shown in (Fig. 12).

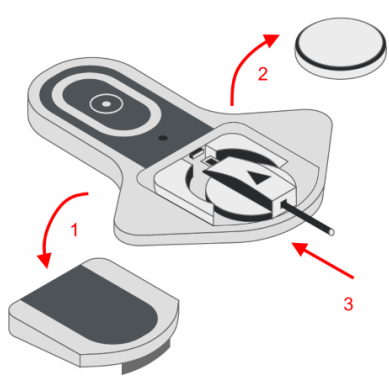


Fig. 12 – Connecting the device connector of the download cable to the recorder

13.5 Turning on the recorder

Press the pushbutton to turn on the recorder (Fig. 13). A beep sounds; after the start-up sequence, the LED lights up cyan.

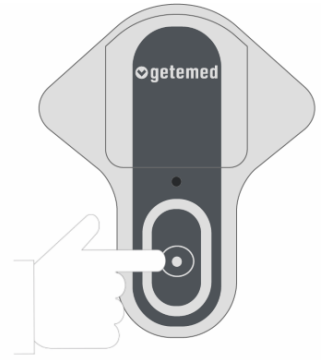


Fig. 13 – Turning on the recorder

13.6 Starting the CM 100 Configurator software

Double-click on the appropriate icon on the desktop to start the application. The starting window that then appears displays the software version and manufacturer information.

Click on the button “Connect to recorder” to establish the communication (Fig. 14).

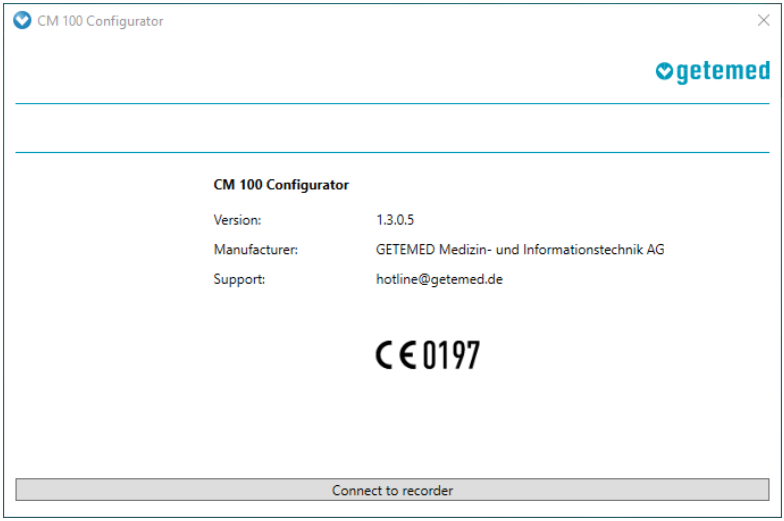


Fig. 14 – Starting the CM 100 Configurator software

13.7 The “Information” screen

The “Information” screen is displayed after the communication has been established between the recorder and the “Configurator” software.

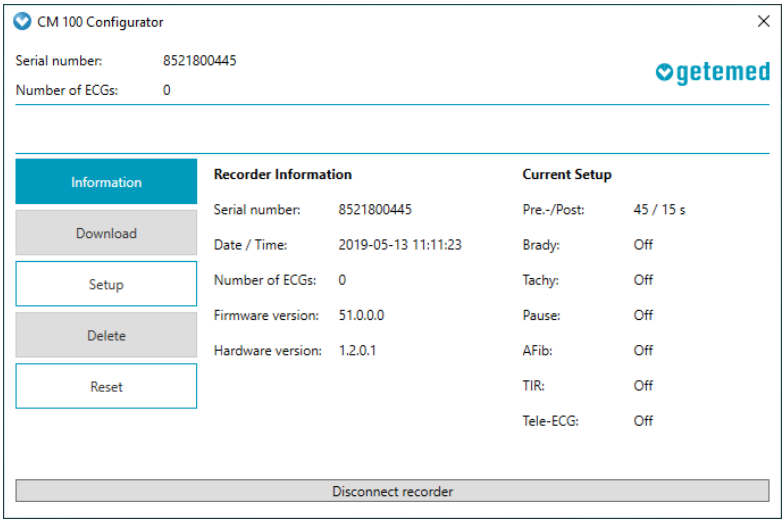


Fig. 15 – The “Information” screen

Buttons for opening further windows are displayed on the left-hand side of the “Information” screen.

Furthermore, the serial number of the connected recorder, the number of the ECG data stored on the device and further information for unambiguous identification of the appropriate recorder and of the recording are displayed in the centre of the “Information” window.

The current settings of the event limit values and other recording parameters are displayed on the right-hand side of the “Information” window.

13.8 The “Download” window; downloading a recording

WARNING

The patient's life or health can be put at risk if the patient is assigned an examination of a different patient, resulting in an incorrectly assigned diagnosis.

Click on the “Download” button in the “Information” window. The “Download” window is opened (Fig. 16).

If no data are stored in the device, the download function has been deactivated.

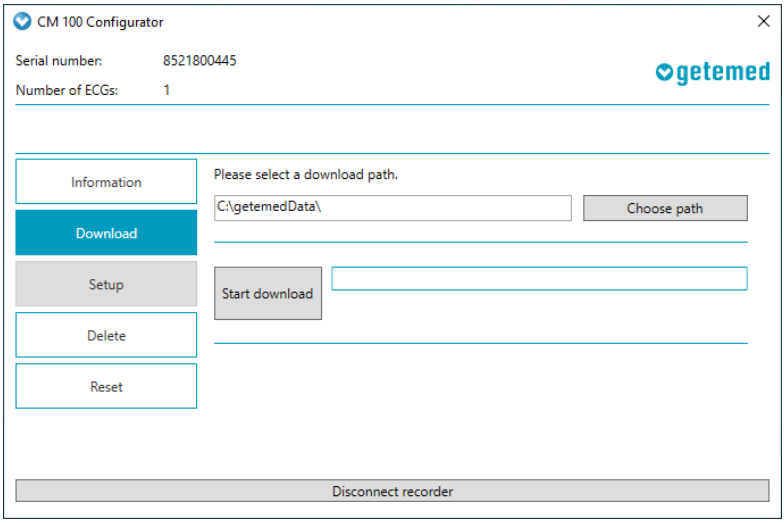


Fig. 16 – Downloading recordings, selecting the path

13.8.1 Selecting a folder and starting the download

The storage path for the ECG data has already been preselected during the installation. You can change the path before starting the download.

Click on the “Start download” button to copy the ECG data to the selected folder (Fig. 16).

13.8.2 Deleting data on the recorder

Click first on the “Delete” button and then on “Delete recordings” to delete all data in the memory of the recorder (Fig. 17).

The number of stored ECG files is displayed in the upper left corner of the “Download” screen. “0” is displayed when the process is completed.

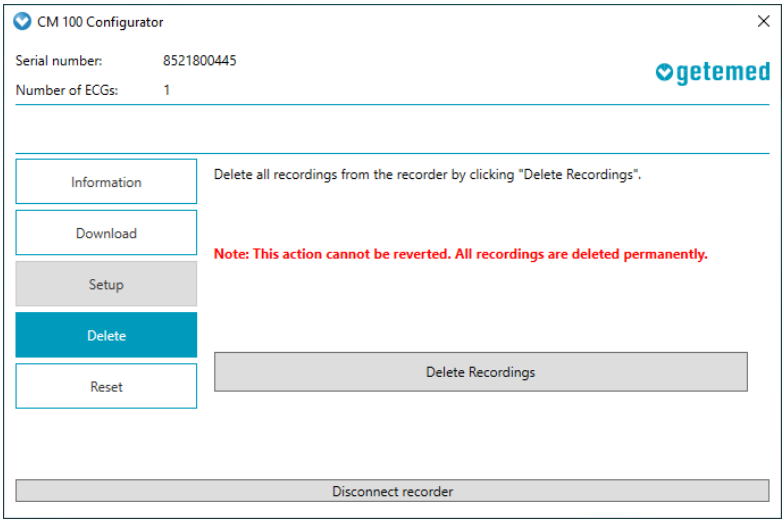


Fig. 17 – The “Delete” window

13.9 The “Setup” window

To change the recorder settings for a patient, click on the “Setup” button in the “Information” window. The “Setup” window is opened.

If no ECG data are stored in your device, “Setup” is deactivated. Before you change any settings in “Setup”, first download the ECG data and delete the memory of the recorder.

You can make the following settings in the “Setup” window:

- “Pre-/post-event time”
  The time recorded prior to and after detection of an event, specified in seconds.

- The individual trigger limits
  The heart rate limit values for automatic recording of tachycardia or bradycardia and the limit value in seconds from which a “pause” is detected and recorded.
- ON/OFF of automatic atrial fibrillation detection (AFib)
- TIR trigger (time interval recording)
  The time interval for automatic time-triggered ECG recording
- ON/OFF of “Tele-ECG mode” for automatic transmission of recordings to a Bluetooth-enabled device (Fig. 18).

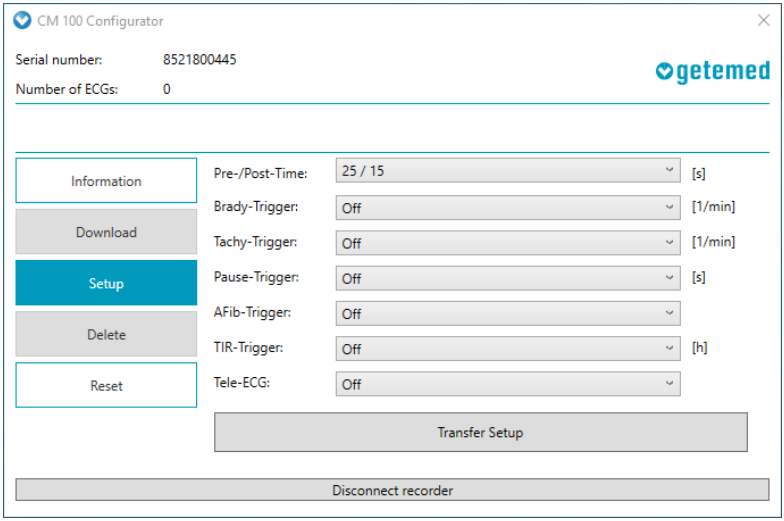


Fig. 18 – Setup

Click the “Transfer setup” button to transfer the new settings to the recorder.

13.9.1 Pre- and post-event times

The following settings are possible:

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

(*) = default setting

The “Length of ECG recording” results from the settings for pre- and post-event times.

13.9.2 Settings for automatic detection of events

The following limit values and parameters can be set:

Parameter	**Settable values**	**Default**
Brady trigger (bpm)	OFF, 30, 40, 50, 60	OFF
Tachy trigger (bpm)	OFF, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 210, 220, 230, 240	OFF
Pause trigger (seconds)	OFF; 2; 2.5; 3; 3.5; 4	OFF
AFib	OFF, ON	OFF
TIR (time interval recording)	OFF, 1 h ... 24 h (1h interval)	OFF
Tele ECG	OFF, ON	OFF

13.10 The “Default settings” window

To restore the factory settings, click the “Default settings” button in the “Information” window. The “Default settings” window is opened (Fig. 19).

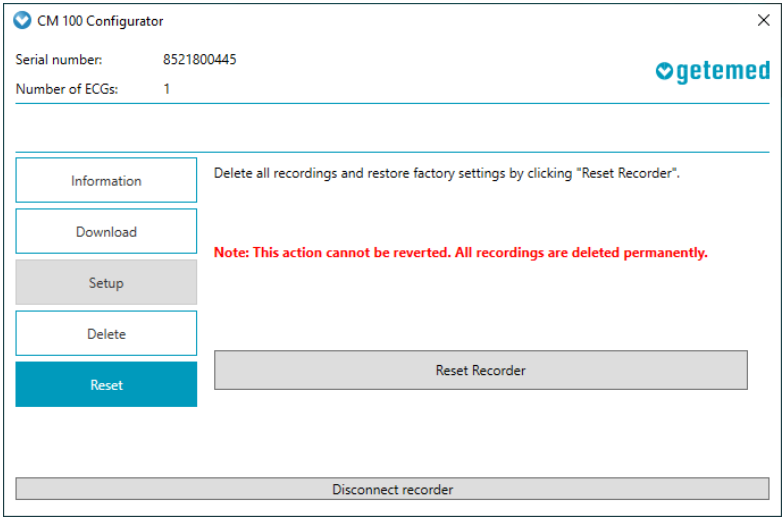


Fig. 19 – Default settings

NOTICE

This action cannot be undone! All saved data and settings are deleted, and the setup of the recorder is reset to the factory settings.

To restore the factory settings of the recorder, click on “Reset recorder”. The factory settings are displayed in the “Information” window as the current settings (Fig. 20).

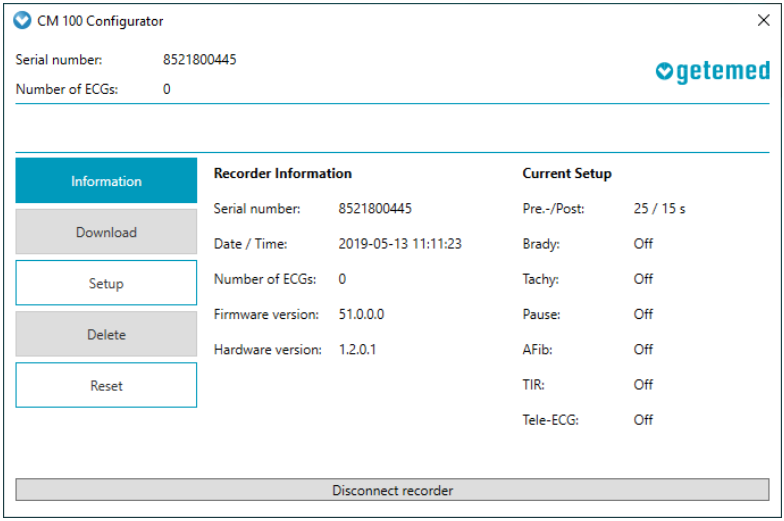


Fig. 20 – Factory settings restored

13.11 Disconnecting the recorder

Click on the “Disconnect recorder” button to disconnect the USB connection. Remove the device connector of the download cable from the device.

13.12 Licence information

The CM 100 Configurator software uses software components that have been published under an Open Source license. The license information can be found in the installation folder in the file “LicenseInformation.txt”.

13.13 Importing recordings with CardioDay®

The software CardioDay can also be used to import recorded events. For further information, refer to the CardioDay User Manual.

14 Displaying the ECG report

WARNING

To evaluate ECG reports, use the software “Adobe Reader”, version 10 or higher. If you use a different PDF viewer software, accurate display cannot be guaranteed.

The ECG reports can be found in the selected download directory. Double-clicking on a file opens the ECG report in Adobe Reader (Fig. 21).

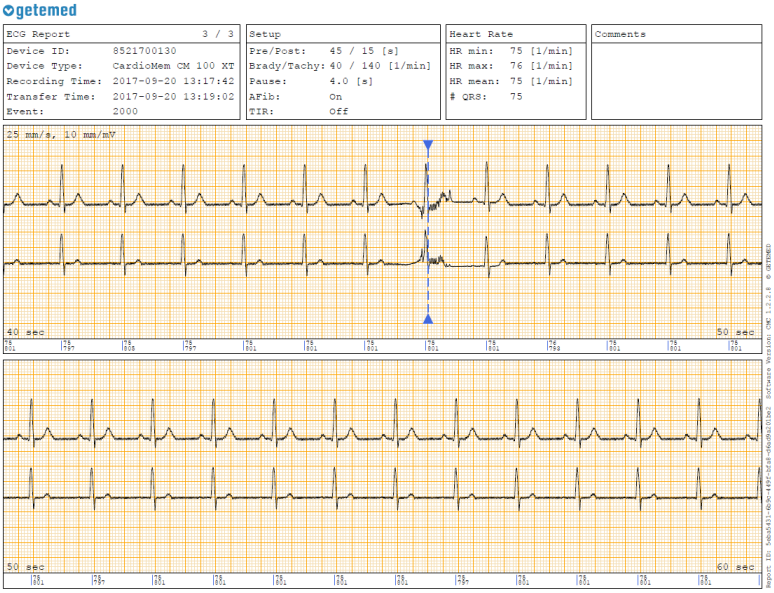


Fig. 21 – ECG report

14.1 Information contained in the ECG report

The ECG report comprises a header area and a data area. It is possible to enter comments on the right of the header area.

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

Fig. 22 – ECG report, header area

The following information is displayed in the header of the ECG report (Fig. 22):

(1) – Device ID / serial number, device type, recording and transmission time, event code (see table below).

The event code is displayed as a four-digit number:

Event	**Value**
Bradycardia, recorded automatically	0010
Tachycardia, recorded automatically	0020
Pause / asystole, recorded automatically	0040
Atrial fibrillation (AFib) – start, recorded automatically	0080
Atrial fibrillation – end, recorded automatically	0081
Bradycardia, recorded automatically during ongoing AFib	0090
Tachycardia, recorded automatically during ongoing AFib	00A0
Pause / asystole, recorded automatically during ongoing AFib	00C0
Time-triggered recording	1000
Time-triggered recording during ongoing AFib	1080
Manually recorded event	2000
Manually recorded event during ongoing AFib	2080

(2) – Recorder setup, pre- and post-event times, event detection limit values, detection of AFib and TIR ON/OFF

(3) – Heart rate information, minimum, maximum and mean heart rates, number of detected QRS complexes

The data area of the ECG report displays the ECG characteristic with a recording speed of 25 mm/s and an amplitude of 10 mm/mV.

The number of pages depends on the length of the ECG recording. The time of detection of an event is highlighted by way of a vertical line in the ECG report.

NOTICE

The accuracy of the heart rate readings depends on the ECG signal quality. The heart rate readings can be inaccurate if the ECG signal is noisy.

15 Description of the “Tele ECG” mode

This Chapter provides the information required to use the tele ECG function:

- General information
- Starting the PhysioGate App
- Operating the PhysioGate App
- Bluetooth pairing
- Checking the transmission
- Licence information
- Data privacy information

15.1 General information

The ECG recordings can be sent from the recorder automatically via Bluetooth short-range communication to a compatible smartphone with Android operating system. The recordings can then be forwarded via the Internet from the smartphone to a receiving system (e.g. GETEMED ReSTA) for further processing (Fig. 23).

To this end, the PhysioGate App must be installed on the smartphone.

Upon the customer's request, CardioMem CM 100 XT is delivered with a smartphone with the PhysioGate App preinstalled. It is not possible to use smartphones not provided by GETEMED.

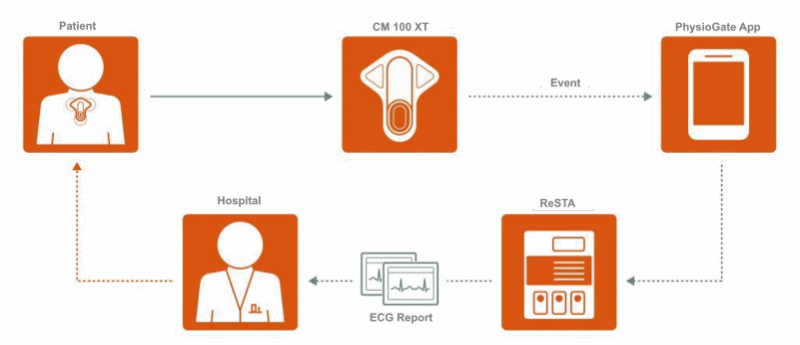


Fig. 23 – Tele ECG

ECG recordings that have been successfully transmitted via Bluetooth are deleted in the memory of the recorder. Failed transmissions are repeated automatically after 15 minutes, 1 hour and 24 hours. New ECG recordings will reset the timer.

If the Bluetooth transmission fails permanently, it is also possible to download the ECG recordings via the USB connection by way of the CM 100 Configurator software.

The operation of the smartphone is described in the corresponding manual.

CAUTION

Do not use the smartphone with the PhysioGate App other than as described in these Instructions. Otherwise, the receipt and forwarding of ECG data could be delayed or blocked.

NOTES

- The memory capacity of the recorder in the “Tele ECG” mode is limited to 50 recordings.
- The battery lifetime of the device is strongly dependent on the number of recordings and transmissions. Premature exhaustion of the battery is possible if the recorder records and transmits very often.
- The smartphone on which the PhysioGate App has been installed should be charged daily at least one hour.

- The Bluetooth transmission works within a range of approx. 5 metres. The patient should always carry the smartphone with the PhysioGate App with him.

15.2 Starting the PhysioGate App

The PhysioGate App starts automatically when the smartphone is turned on. It runs as a background service. To open the PhysioGate App, tap on the app icon (Fig. 24).

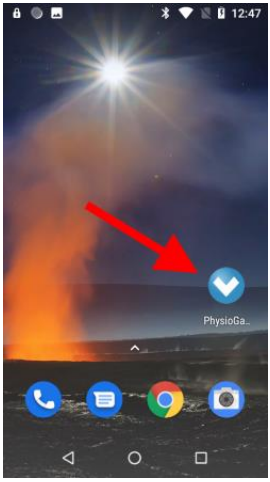


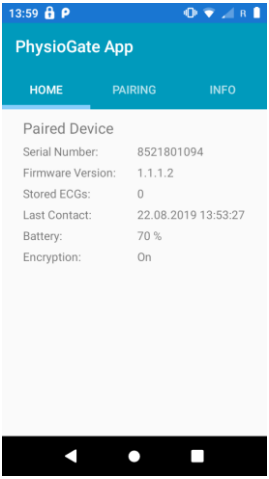
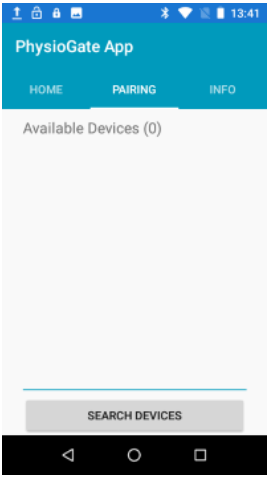
Fig. 24 – Starting the PhysioGate App

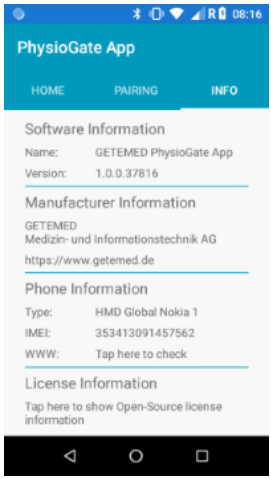
NOTES

- Always switch off the smartphone or activate the airplane mode whenever required by the situation. Any data not yet sent will remain in the memory and transmitted later.
- Do not switch off the smartphone without any reason and do not quit the PhysioGate App manually. Data transmission is only possible as long as the PhysioGate App is running.

15.3 Operating the PhysioGate App

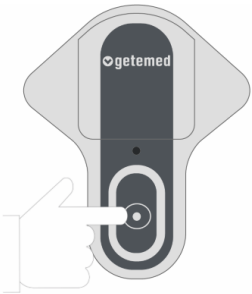
The PhysioGate App provides three screens which are called by tapping on the appropriate title in the menu bar.

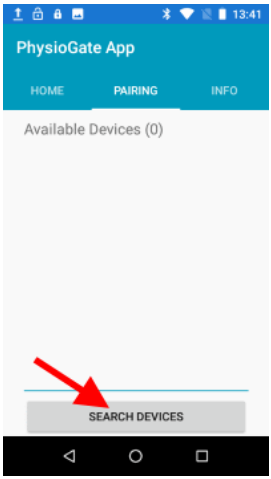
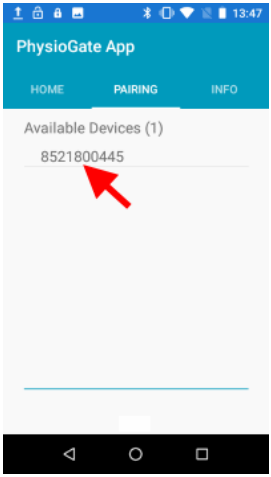
The HOME screen (Fig. 25) is displayed when the app is opened. It displays the data of the paired device: • Serial number • Firmware version • Number of unsent ECG recordings stored in the device • Last contact between the recorder and the PhysioGate App • Last battery status of the device • Encryption status of the Bluetooth communication	 Fig. 25 – HOME screen
Use the PAIRING screen (Fig. 26) to start pairing (see description below).	 Fig. 26 – PAIRING screen

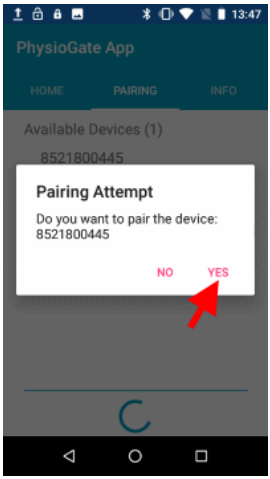
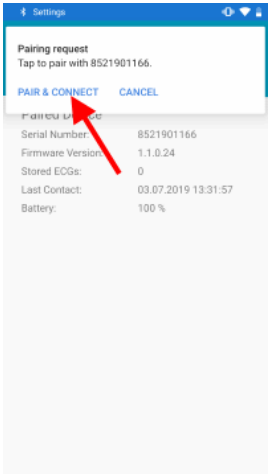
The INFO screen (Fig. 27) displays the following information about the PhysioGate App: • Name • Version • Manufacturer the smartphone: • Type • IMEI • Connectivity status (WWW) and license information.	 Fig. 27 – INFO screen

15.4 Bluetooth pairing

Recorder and smartphone must be paired before data transfer via Bluetooth is possible. Pairing is usually performed by the manufacturer or an authorised service partner of the manufacturer. If the pairing must be repeated (e.g. in case of replacement of the smartphone), perform the following steps:

Press the pushbutton to turn on the recorder. Press and hold down the pushbutton (>5 s) to activate Bluetooth on CardioMem CM 100 XT until a tune sounds and the LED flashes blue (Fig. 28).	 Fig. 28 – Activating Bluetooth

Open the PhysioGate App on your smartphone. Open the PAIRING screen. Tap on SEARCH DEVICES (Fig. 29).	 Fig. 29 – Searching for devices
Available devices are displayed in a list. Tap on the entry of a device in the list you wish to pair with the recorder (Fig. 30).	 Fig. 30 – List of devices

Click on YES to confirm the attempt of pairing (Fig. 31).	 Fig. 31 – Confirmation of the pairing attempt
Confirm the pairing request (Fig. 32). A tune indicates that the pairing was successful.	 Fig. 32 – Request confirmation

15.5 Checking the transmission

Prepare the recorder, switch on and attach to the patient as described above.

Switch on the smartphone on which the PhysioGate App is installed. Open the PhysioGate App, select the INFO screen and check that the connectivity status (WWW) is “OK” (Fig. 33 and Fig. 34).

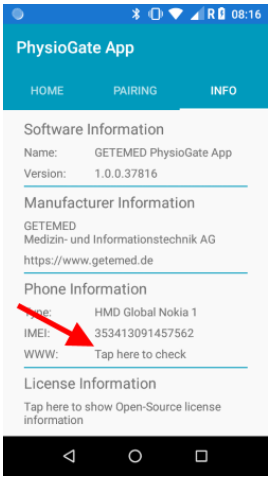


Fig. 33 – Tap to check

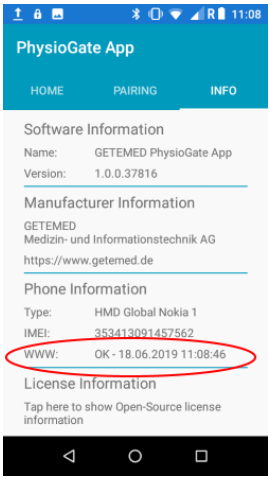


Fig. 34 – WWW status

15.6 Licence information

The PhysioGate App uses software components that have been published under an open source license. The license information can be displayed by way of the INFO screen (Fig. 35 and Fig. 36).

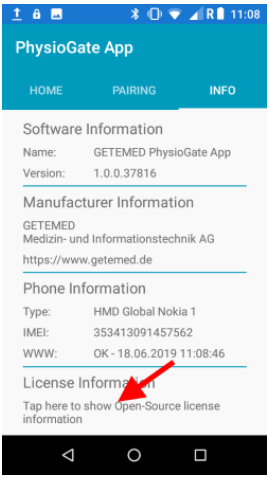


Fig. 35 – Tap to display

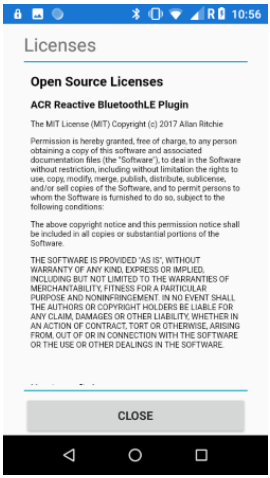


Fig. 36 – Licence information

15.7 Data privacy information

The PhysioGate App does not collect, store or transmit information allowing identifications or tracking of persons. The assignment of ECG recordings to a certain patient lies in the responsibility of the doctor.

NOTICE

Inform GETEMED immediately if your smartphone on which the PhysioGate App has been installed is lost or was stolen.

16 Description of automatic rhythm detection

16.1 Heart rate detection

The heart rate in beats per minute [bpm] is continuously calculated from the interval of two consecutive R waves. Heart rate detection is an essential feature of the recorder. Heart rates in the range between 30 bpm and 240 bpm are detected with a tolerance of max. 10%.

In case of electromagnetic interference, the heart rate detection can produce false results or temporarily fail.

The effectiveness of the heart rate detection was not proven for patients doing any kind of pacemaker therapy. Pacemaker rhythms could be detected not precisely.

16.2 Detection of bradycardia and tachycardia

A bradycardia event is recorded once the specified pre-event time has elapsed and the heart rate has fallen below the specified limit value 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 be able to determine the end of a bradycardia, the heart rate must not fall below the pre-set limit value for at least 90 beats.

A tachycardia event is triggered once the specified pre-event time has elapsed and the heart rate has exceeded the specified limit value for more than four consecutive beats.

The next tachycardia event will not be triggered until the end of the previous tachycardia event has been detected. To be able to determine the end of a tachycardia, the heart rate must not exceed the specified limit value for at least 90 beats.

The automatic recording of events is suppressed if

- Open leads are detected by the recorder;
- Signal noise is detected or
- The calculated heart rate is not valid.

16.3 Detection of atrial fibrillation (AFib)

The onset of AFib is detected once three arrhythmic changes of two consecutive RR' intervals have been determined within the last 16 QRS complexes.

AFib will continue if an onset of AFib has been previously determined and at least one arrhythmic change of two consecutive RR' intervals was determined during the last 16 QRS complexes.

AFib ends if no arrhythmic change of two consecutive RR' intervals have been found in the last 16 QRS complexes for a period of more than 20 seconds. Otherwise, AFib will continue.

The automatic triggering is suppressed if

- Open leads are detected by the recorder;
- Signal noise is detected or
- The calculated heart rate is not valid.

16.4 Pause detection

A pause is detected if the interval between two consecutive R waves is greater than the specified limit value for pause or if an asystole is determined for a period longer than the limit value specified for pause.

17 Disposal of device, batteries and accessories

Electrical devices contain metal and plastic parts. To avoid environmental damage, the recorder and its accessories must only be disposed of in accordance with the relevant disposal directives at the end of their service life.

If you have any questions regarding the disposal of the product, do not hesitate to contact the manufacturer or its representatives.

18 Troubleshooting

Symptom	Cause	Remedy
CM100 XT: Device cannot be turned on (LED is not lit).	Low battery or no battery inserted	Insert new battery.
CM 100 XT: Recording cannot be started (LED is lit orange).	Memory full	Connect the recorder to the PC and the CM 100 Configurator software and switch it on. Start CM 100 Configurator and check the recorder status. Download the ECG data and delete the memory of the recorder.
CM 100 XT: Recording cannot be started (LED is flashing orange, 3x beeps when the pushbutton is pressed).	Open lead	Check the contacts of the electrodes. If an electrode became detached, clean the skin and replace the electrode.
CM 100 XT: LED is flashing red.	Low battery	Replace the battery of the CM 100 XT.
CM 100 XT: Incomplete recording	Low battery	Replace the battery of the CM 100 XT.

Symptom	Cause	Remedy
CM 100 XT: Device does not switch to normal mode (LED is flashing alternately red, green and blue).	General device error	Remove and reinsert the battery. If the problem persists, contact your dealer or the service representative of the manufacturer.
Incorrect time stamp on the ECG report	Internal backup battery exhausted	Use the download cable to connect the CM 100 XT to a PC at least 12 hours to charge the backup battery.
CM 100 XT, PhysioGate App: Bluetooth pairing not possible – Device not found.	Bluetooth on CM 100 XT is deactivated	Press and hold down the pushbutton on the CM 100 XT until a tune sounds and the LED flashes blue. Repeat the Bluetooth pairing.
CM 100 XT, PhysioGate App: ECG transmission (Bluetooth) does not function.	CardioMem CM 100 XT and smartphone not coupled	Check the INFO screen in the PhysioGate App for the serial number of the coupled device. If no or an incorrect serial number is displayed, start pairing.
	The PhysioGate App does not run on the smartphone	Unlock the screen and start the PhysioGate App.
	The smartphone is not connected to the Internet.	Check the WWW status in the INFO screen in the PhysioGate App. If the status is not OK, change your location and try again.

Symptom	Cause	Remedy
	Bluetooth is disabled on your smartphone.	Enable Bluetooth, see manual of your smartphone.
	“Mobile Data” or “Data Roaming” is turned off on your smartphone.	Turn on “Mobile Data” and “Data Roaming”. See manual of your smartphone.
	Airplane mode is turned on on your smartphone.	Deactivate the airplane mode. See manual of your smartphone.
	The smartphone is turned off or the battery is low.	Turn on your smartphone and recharge the battery if necessary.
	CardioMem CM 100 XT is not configured for the “Tele ECG” mode.	Connect the recorder to the PC and the CM 100 Configurator software and switch it on. Start CM 100 Configurator and check the recorder status. Download saved ECG data and delete the memory of the recorder. Then enable the “Tele ECG” mode.
CM 100 XT, PhysioGate App: Encryption: Off	The pairing on the smartphone was deleted.	Press and hold down the pushbutton on the CM 100 XT until a tune sounds and the LED flashes blue. Repeat the Bluetooth pairing.

Symptom	Cause	Remedy
CM 100 Configurator: Error in the USB connection (Error! USB device not connected!).	Either the USB download cable is not connected to the PC or the CM 100 XT is turned off.	Connect the USB download cable to the PC. Turn on the recorder (the LED is lit orange after the starting sequence) and click on the button “Connect to recorder” to establish the connection for communication.
CM 100 Configurator: The data download to a PC does not function. (Error! No data download!).	The ECG recordings could not be downloaded.	Click on “Disconnect recorder” and then on “Connect to recorder” to reset the USB connection. If this does not function: • Exit the CM 100 Configurator software. • Remove the USB download cable (the device is turned off). • Reconnect the USB download cable and restart the recorder. • Start the CM 100 Configurator software. • Click on “Connect to recorder” and repeat the download. • Check that ECG reports are in the pre-set download folder.
CM 100 Configurator: The data download to a PC does not function. (Error! Data download incomplete!).	One or several ECG recordings contain errors.	
CM 100 Configurator: The ECG data could not be stored on the PC.	Either missing write access to download folder, download folder no longer exists or hard disk full.	Check the download folder and create a new download folder if necessary. Repeat the download.

Symptom	Cause	Remedy
(Error! No data saved!).		
CM 100 Configurator: The ECG report could not be created. (Error! No PDF file created!).	Program installation defective or damaged.	Install the CM 100 Configurator anew. Repeat the download.
CM 100 Configurator: The ECG data stored on the device cannot be deleted. (Error! Data not deleted!).	Communication error	Click on “Disconnect recorder” and then on “Connect to recorder” to reset the USB connection. If this does not function: • Exit the CM 100 Configurator software. • Remove the USB download cable (the device is turned off). • Reconnect the USB download cable and restart the recorder. • Start the CM 100 Configurator software. • Click on “Connect to recorder” and repeat deleting.
CM 100 Configurator: The setup cannot be transferred to the device.	Communication error	Click on “Disconnect recorder” and then on “Connect to recorder” to reset the USB connection. If this does not function: • Exit the CM 100 Configurator software.

Symptom	Cause	Remedy
(Error! Setup not transferred!).		• Remove the USB download cable (the device is turned off). • Reconnect the USB download cable and restart the recorder. • Start the CM 100 Configurator software. • Click on “Connect to recorder” and make the settings anew.
CM 100 Configurator: The “Tele ECG” mode cannot be set.	The device comprises personal data.	To continue, reset the device to the factory settings or do not use the “Tele ECG” mode.

19 Information regarding consumables and accessories

Designation	REF / order number
Protective bag	78451002
Instructions for Use	78812021
Brief Guide	78821021
Battery Renata CR2477N	Q001 12477
Disposable ECG electrodes *	90131
Download cable *	78412001
CM 100 Download Cable Kit for the use with CardioDay * (Download cable, Bluetooth dongle and Short instructions)	78412001-1
CM 100 Configurator software *	78313011
PhysioGate App and compatible smartphone *	78460001

*) Not included in the standard scope of supply – please order separately.

20 Specifications

20.1 General

Classification:	IIa acc. to 93/42/EEC (MDD)
Type of applied part:	BF (body floating), non-defibrillation-proof applied part
Application time (typical):	7 ... 14 days
Dimensions (W x L x H):	76 mm x 89 mm x 14 mm
Weight:	Approx. 39 g (incl. battery)
Battery type:	3 V lithium, Renata CR2477N
Operating mode:	Continuous mode for 14 days
Battery life (typical):	14 days
Material:	PC+PET plastic housing
Degree of protection:	IP64
Service life of the recorder:	7 years
ECG lead:	2 channels, 3 electrodes
Heart rate:	30/min ... 240/min, tolerance +/- 10%
Digital signal processing:	512 Hz / 16-bit
Lower limit frequency:	0.05 Hz
Upper limit frequency:	70 Hz
Dynamic input voltage:	+/- 6 mV
Input voltage:	+/- 300 mV
Open lead detection:	Yes

Operating conditions

Temperature range:	5 °C ... 45 °C
Relative humidity:	0% ... 93%, non-condensing
Ambient pressure:	1,060 hPa ... 700 hPa (-380 m ... 3,000 m)

Transport and storage conditions

Temperature range:	-20 °C ... 60 °C
Relative humidity:	0% ... 93%, non-condensing
Ambient pressure:	1,060 hPa ... 700 hPa (-380 m ... 3,000 m)

Wireless capabilities

The recorder receives and sends electromagnetic energy so as to meet its intended purpose.
The characteristics of sender and receiver are specified below.

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

20.2 Electromagnetic compatibility

Medical electric devices require special precautions with regard to electromagnetic compatibility (EMC) and are to be installed and commissioned in accordance with the information provided in this document.

Guidelines and manufacturer's declaration - Electromagnetic emissions

The recorder is intended for operation in electromagnetic environments as specified below. It is to be guaranteed by the customer or user of the device that it is only operated in such environments.

Emission tests	Compliance	Electromagnetic environment - standards
RF emissions acc. to CISPR 11	Group 1	The device uses RF energy exclusively to perform its internal functions. Its RF emissions are very low, and it is unlikely to impair adjacent electronic devices.
RF emissions acc. to CISPR 11	Class B	The device is intended for use in all institutions, including residential areas, and such institutions that are connected immediately to a public supply network that also supplies buildings used for human habitation.
Emission of harmonic current emissions acc. to IEC61000-3-2	Not applicable - the device is battery-operated	-
Emission of voltage changes, voltage fluctuations and flicker acc. to IEC 61000-3-3	Not applicable - the device is battery-operated	-

Guidelines and manufacturer's declaration - Electromagnetic interference immunity (conducted disturbances)

The recorder is intended for operation in electromagnetic environments as specified below. It is to be guaranteed by the customer or user of the device that it is only operated in such environments.

Noise immunity tests	IEC60601-1-2 test level*	Compliance level*	Electromagnetic environment - standards
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	Floors should be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Fast electrical transients / bursts acc. to IEC 61000-4-4	Not applicable - the device is battery-operated and does not have patient or supply cables.	-	-
Surges acc. to IEC 61000-4-5	Not applicable – the device is battery-operated and does not have patient or supply cables.	-	-
Voltage dips, short interruptions, and voltage variations of the supply voltage acc. to IEC 61000-4-11	Not applicable - the device is battery-operated	-	-
Power frequency magnetic field (50/60 Hz) acc. to IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should comply with the typical values as to be found in industrial and hospital environments.

Standards and manufacturer's declaration - Electromagnetic interference immunity (conducted and radiated RF disturbances)

The recorder is intended for operation in electromagnetic environments as specified below. It is to be guaranteed by the customer or user of the device that it is only operated in such environments.

Interference immunity tests	**IEC60601-1-2 test level***	**Compliance level***	**Electromagnetic environment - standards**
Conducted RF disturbances acc. to IEC 61000-4-6	3V RMS; 150 kHz ... 80 MHz	3V RMS	The distance to other portable or mobile RF devices is not less than 30 cm to the recorder and the leads.
-	6V RMS in ISM bands in the range between 0.15 MHz and 80 MHz	6V RMS in bands as per Table 5, Note N)	Tests on the site have shown that the field strength of stationary radio transmitters is less than the compliance level in all frequency ranges.
Radiated RF disturbances acc. to IEC 61000-4-3	10V/m 80 MHz ... 2.7 GHz Interference immunity to wireless communication devices	10V/m acc. to Table 9**	Interference can occur in the vicinity of devices bearing the label shown below: 

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

NOTE: The standards mentioned above might not apply in all situations. The propagation of electromagnetic waves is affected by absorption and reflection produced by buildings, 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 sine	2	0.3	28
710 745 780	704 ... 787	LTE bands 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 bands 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	-

NOTICE To achieve the required immunity test level, the distance between the transmitting antenna and the ME device or ME system can be reduced to 1 m where necessary. The test distance of 1 m is permitted in accordance with IEC 61000-4-3.
a) For a few services, only the uplink frequencies are provided. b) The carrier must be modulated by way of a 50% duty cycle square wave signal. c) 50% pulse modulation at 18 Hz can be used as an alternative to the RF modulation. That would be the worst case since it is actually not a modulation.

WARNING

Do not use the device in the vicinity of or stacked with other devices since this could lead to improper operation. If such a use is inevitable, check this and the other devices for normal functioning.

WARNING

The use of accessories, transducers and cables other than those specified by the manufacturer of the device can lead to increased electromagnetic emissions or reduced electromagnetic interference immunity of the device and to improper functioning.

WARNING

Always keep a distance of at least 30 cm between portable RF communication equipment (including peripherals, such as antenna cables and external antennas) and each part of the recorder, including the cables specified by the manufacturer. Otherwise, the performance of the recorder could be impaired.

21 List of figures

CE 0197

REF 78812021

GETEMED

Medizin- und Informationstechnik AG

Oderstr. 77 / 14513 Teltow / Deutschland

Telephone: 03328 / 3942- 0

Telefax: 03328 / 3942-99

info@getemed.de / www.getemed.de

Revision 04 EN / 2020-02-01