getemed

Operating Manual

PhysioMem® PM 100

Tele ECG Event Recorder

Cardiac Diagnostics
Vital Signs Monitoring
Telemonitoring

Content

1 Intended Use, Indications and Operation

These operating instructions are intended for medical doctors and medical personnel.

The "GETEMED Medizin- und Informationstechnik AG" is hereafter referred to as "GETEMED AG".

1.1 Intended Use

The PM 100 device is a two-channel cardiac event recorder for transmitting multiple event recordings via cellular telephony networks to a compatible receiving system, such as ReSTA from the GETEMED AG.

The device is intended for patient activated recordings.

The PM 100 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 and cars. Airplanes are excluded as long as the use of cellular radio equipment is not allowed during flight. The device is battery-driven and utilizes a FLASH memory to store ECG data. The PM 100 is not intended to be used as a critical care monitoring system and should not be used in emergency situations.

1.2 Indications

The PM 100 is indicated for the diagnostic evaluation of adult and pediatric (over 10 kg body weight) patients with asymptomatic and symptomatic disturbances of the cardiac rhythm and for the evaluation of recurrent unexplained episodes of racing heart, syncope, palpitations or dizziness.

The device is not indicated for patients whose clinical condition requires continuous monitoring of vital physiological parameters,

where the nature of variations is such that it could result in immediate danger to the patient.

The device is not indicated for patients with an implanted cardiac pacemaker or ICD.

1.3 Operation

The patient places the device on his chest and activates the recording by pressing the button. The device records short ECG strips and transfers them to a central receiving system.

The transmission takes place wirelessly via the integrated GSM module. The PhysioMem PM 100 is not intended for recording and transferring of real-time data. Depending on the availability of the GSM or other networks (e.g., the Internet), the transmission of the data can be delayed.

The device runs on a rechargeable battery and stores ECG data in a non-volatile FLASH memory.

2 CE Compliance, Device Labels and Packaging Label

The following section explains the symbols used with the recorder.

2.1 CE Compliance

With the CE marking and the certification number, GETEMED AG confirms that the device complies with all relevant standards and the essential requirements listed in Annex I of the Medical Device Directive 93/42/EEC.

CE 0197

The device also features a radio module that is approved in accordance with Article III of the Radio & Telecommunications Terminal Equipment Directive 1999/5/EC.

2.2 Information on the Device Labels

The labels show the name and address of the manufacturer along with the product and model identification.

Fig. 1 Device label of the recorder

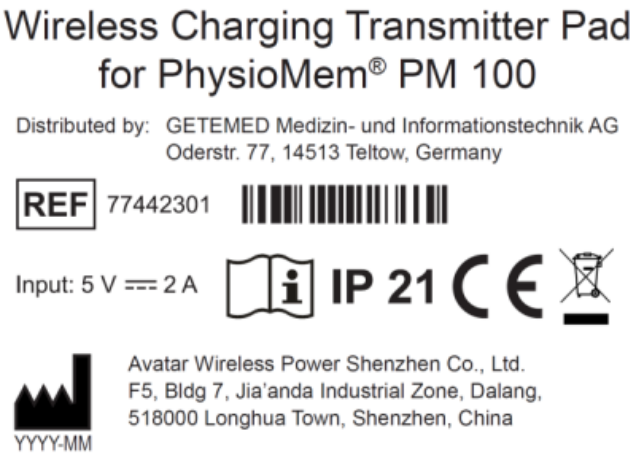


Fig. 2 Device label of the charging pad

The following symbols appear on the device label:

Observe the information in the operating manual for proper use of the device.

REF (reference) number to identify and order the product.

Serial number

The heart symbol informs clinicians that the device is classified as "cardiac floating" (CF) and that it is NOT protected against defibrillation.

IP64

The ingress protection classification of the PhysioMem is IP64, whereby
6 = dustproof
4 = protected against splashing water

IP21

The ingress protection classification of the charging pad is IP21, whereby
2 = protected against objects > 12.5 mm
1 = protected against dripping water

The symbol indicates that the device has an integrated lithium polymer LiPo rechargeable battery.

This symbol indicates that you must dispose of the device properly. Further information is provided in the section "Cleaning the Recorder and Accessories" on page 15.

Below the solid factory symbol is the year in which the device was manufactured.
Next to the solid factory symbol is the name of the manufacturer.

Non-ionizing electromagnetic radiation

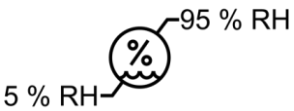
The symbol indicates that the equipment emits elevated, potentially hazardous levels of non-ionizing radiation (electro-magnetic energy) for diagnosis or treatment.

2.3 Symbols on the Packaging Label

REF (reference) number to identify and order the product

Serial number

The upper and lower temperature limits allowed for the device's storage and shipping



The upper and lower humidity limits allowed for the device's storage and shipping

Keep dry.

Handle with care.

Maximum stack size: 10 packages

3 Safety and Reliability

Carefully read this manual. It contains important information.

3.1 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.

With this symbol, the physician finds special information or notes.

3.2 General Warnings

WARNING
MIXING UP RECORDINGS –The patient's life or health may be put at risk if the patient is assigned a different patient's ECG recording, thus resulting in an incorrectly assigned diagnosis.

Take special care to always select the correct examination and the correct patient.

Before the device is given to another patient, check that there are no more recordings stored on the device.

WARNING
NECK LANYARD – Neck lanyards present a possible strangulation risk.

Do not wear the device with the neck lanyard around your neck while you are sleeping.

WARNING
RISK OF CONTAMINATION OR INFECTION – Recorder and accessories may be contaminated with bacteria or viruses after use.

If any contamination of the recorder 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 labeling.
- Contact the addressee before sending the equipment.
- Clean the recorder and accessories after every use. For information, refer to the chapter "Cleaning the Recorder and Accessories" on page 15.

WARNING
NOT A MONITORING DEVICE – The PhysioMem PM 100 recorder is not a monitoring device and is not intended for monitoring the clinical condition of a patient.

Do NOT use the PhysioMem as a monitoring device.

WARNING
EXPLOSION HAZARD – Electrical sparks can cause explosions in the presence of certain gases.

Do not use device in an oxygen-enriched environment or around other flammable or explosive gases.

Establish whether the patient is liable to be in such an environment, possibly for job-related reasons.

WARNING
MALFUNCTION OF PACEMAKERS AND ICD's – The PhysioMem PM 100 recorder has an integrated mobile transmission module. Active mobile transmission devices in the close vicinity of pacemakers and implantable cardioverters/defibrillators (ICD's) can cause malfunctioning of these devices.

3.3 General Cautions

CAUTION
While sending data, do not use mobile phones next to the device.

CAUTION

Switch off the device in locations where the use of mobile network devices is totally or at times forbidden (e.g., intensive care unit, plane).

CAUTION

The temperature of the recorder must not go below 5 °C or above 45 °C. Do not expose the device to sudden temperature or humidity changes.

Quick changes in temperature or humidity can cause condensation. Then, the correct functioning of the device can no longer be guaranteed.

CAUTION

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

CAUTION

Do not use the device if it has been damaged or has malfunctions.

CAUTION

In order to avoid a wrong assigning of ECG data, keep the device protected against unauthorized access by third persons.

3.4 Safety and Reliability Only with Proper Maintenance

CAUTION
Proper maintenance is vital for long-term safety and reliability of the recorder. Each time before giving the recorder to a patient, visually check the recorder for damage.

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

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

For hygienic reasons and especially to help protect our service personnel, please disinfect the recorders before returning them to us for inspection or maintenance.

CAUTION
If the device is not in use, switch it off and store it with care to prevent accidental activation. This could result in incorrect ECG interpretation. Also, switch off the device before shipping to prevent inadvertent data transmission.

CAUTION
Repairs must be carried out only by persons authorized by GETEMED AG. If you find or even suspect a malfunction, send the device for testing to GETEMED AG or a facility authorized by GETEMED AG. Please add a detailed description of the observed malfunction.

3.5 Cleaning the Recorder and Accessories

Observe the following guidelines when cleaning the recorder and accessories:

- Switch off the device before cleaning/disinfection.
- Disinfect the recorder and the charging pad at regular intervals, prior to first use, and before passing it on to another person.
- Clean the recorder and the charging pad before performing surface disinfection.
- Use a lint-free cloth slightly moistened with water or a mild soap solution to externally clean the recorder and carrying pouch.

CAUTION
Do not submerge the recorder or allow fluid to enter the recorder under any circumstances.

- Wash the storage pouch by hand at 30 °C (86 °F). Do not machine wash or dry the carrying pouch.
- Use cleaning and disinfection agents only in accordance with the manufacturer's instructions, for example, be sure to use the correct dilution factor.

GETEMED recommends disinfecting the device with a 70% alcohol solution.

CAUTION
Do not use solvents such as ether, acetone, or petroleum ether; such substances can damage the plastic of the device's housing.

CAUTION
Do not sterilize the recorder or accessories.

3.6 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 GETEMED AG or its representatives.

CAUTION
The symbol with the waste bin reminds you not to dispose of devices that contain batteries together with normal waste. As the end user, you are required to dispose of any batteries in accordance with local and national regulations.

3.7 Established Medical Practices

Instructions listed in this manual IN NO WAY supersede established medical practices concerning patient care.

Under all circumstances, proceed according to established medical practices.

3.8 Manufacturer Responsibility

The manufacturer is responsible for safety, reliability, and performance only if the following conditions are met:

- Assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by GETEMED AG.
- PhysioMem 100 is used and stored in accordance with the information given in this manual.

4 Control Elements, Putting into Operation

4.1 Control Elements

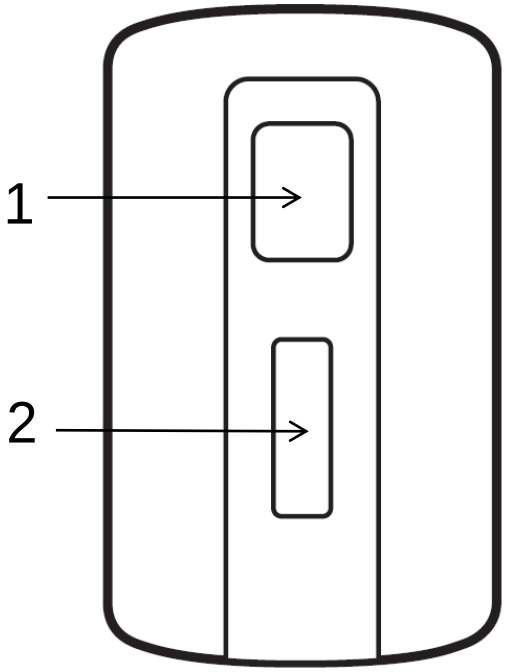


Fig. 3 Button and display

1 Button for switching on and off and for starting a recording

2 Display for the indication of operating modes and error codes

The four electrodes for the ECG lead are positioned on the back (Fig. 4) of the recorder.

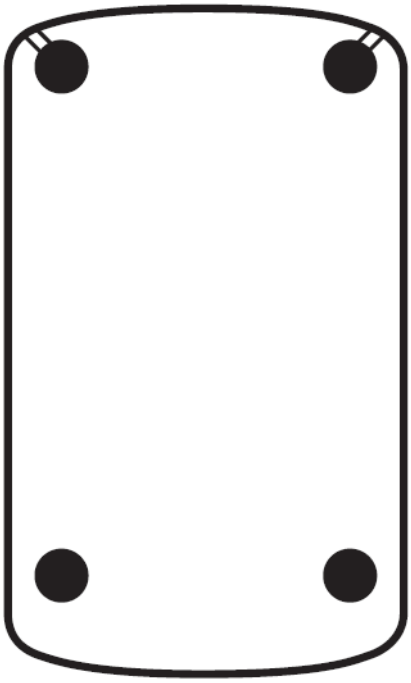


Fig. 4 Back of the recorder with electrodes

4.2 Putting into Operation, Fully Charging the Battery

NOTE
If the ambient temperature is lower than 0 °C, the device should not be charged.

The device has a built-in rechargeable battery, which is charged by inductive coupling with the charging pad.

Before first use of the device, the battery has to be fully charged.

Use the USB cable to connect the included charging pad (Fig. 5) to the power supply plug and connect this to the mains supply. Then place the PhysioMem on the charging pad.

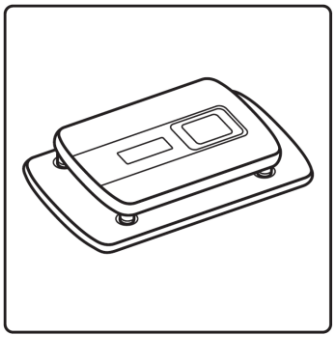


Fig. 5 PhysioMem on the charging pad

To position the PhysioMem properly, use the indentations on the charging pad and place the recorder's electrodes into these indentations.

After the PhysioMem has been switched on, the display of the PhysioMem and an LED on the charging pad show that the battery is being charged (see the table in section 7.1, page 34).

The green LED is lit as soon as the charging pad is connected to the power supply system.

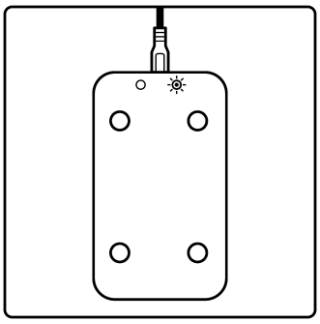


Fig. 6 Charging pad connected to power supply

On the left of the green LED, also the orange LED is lit if the PhysioMem is placed on the charging pad. The orange LED indicates that the battery is being charged.

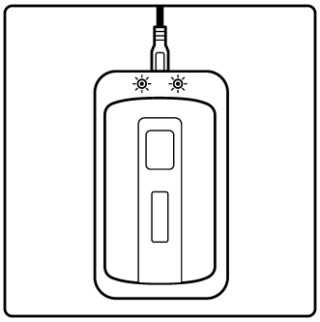


Fig. 7 Indication of the charging process

In addition, a short double beep will sound if the PhysioMem is placed on the charging pad. The short double beep will also sound if the PhysioMem is switched on while it is on the charging pad.

If the battery of the PhysioMem has been fully charged, the orange LED goes out and only the green LED is lit (Fig. 8).

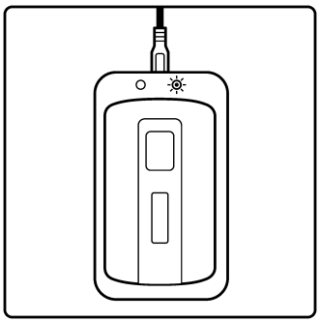


Fig. 8 Charging process completed

NOTE
If the orange LED flashes after the PhysioMem has been placed on the charging pad, an error with the charging process has occurred. In this case, disconnect the charging pad from the power supply and reconnect it.

If the orange LED continues to flash, inform the service of GETEMED AG.

NOTE
Even during charging, you can take the device from the charging pad and use it for a recording.

NOTE
If you put the PhysioMem on the charging pad while the battery has already been fully charged to 100 %, the double beep does not sound and the orange LED is not lit.

Charging the battery after complete discharge takes approx. 3 hours.

A fully charged battery lasts approx. 5 days in typical use (3 ECG recordings per day).

Press the button (1) to switch on the PhysioMem. The progress indicator in the display shows that the device is being powered up. (Fig. 9)

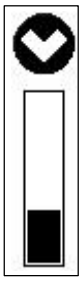
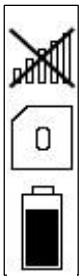


Fig. 9 Progress indicator showing that the device is being powered up

Once the device is ready for use, the display changes to the main display (Fig. 10).



← Mobile transmission active / inactive

← Number of ECG recordings stored

← Charging state of the battery

Fig. 10 Main display

NOTE
If the battery power is too low for using the device, this is indicated in the display (Fig. 11) when a recording is started.

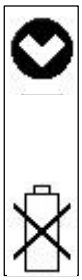


Fig. 11 Indication of insufficient battery power

5 Recording and sending an ECG

5.1 How and where you apply the device

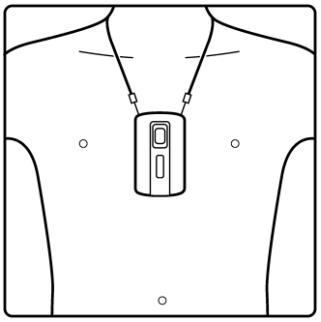


Fig. 12 *Recorder on the patient's chest*

The ECG electrodes are integrated like little feet in the back of the PhysioMem.

To record an ECG, put the device directly on your chest. The correct position of the device is mid sternum (Fig. 12).

Make sure that all four electrodes have skin contact and that there are no pieces of clothing or other items between electrode and skin.

The manufacturer recommends always wearing the device by means of the included neck lanyard. In this way, no time is lost when an ECG is to be recorded.

Attach each of the two end loops of the neck lanyard to the attachment holes (1) of the recorder and connect the neck lanyard to the adjustment clips (2) supplied. Finally adjust the length of the neck lanyard (Fig. 13) to suit your needs.

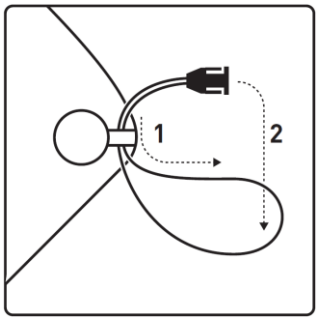


Fig. 13 How to adjust the neck lanyard

5.2 Recording an ECG

During recording, hold the device steady and press the four electrodes firmly on the chest (Fig. 12).

Then press the button (1) to start the recording.

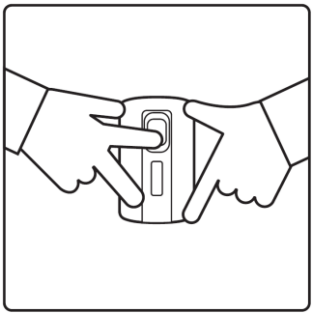


Fig. 14 How to press the start button

The recording duration is 40 seconds. During this time, breathe steadily, refrain from jerky body movements, and avoid changing the device's position on the chest.

During recording, every heart beat (R-R') is accompanied acoustically by a short beep.

The device also detects if an electrode has no skin contact. As soon as an electrode loses skin contact during recording, the heart beat will not be detected anymore. The beep does not sound until all four electrodes have skin contact and the heart rhythm is detected again.

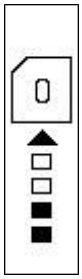
NOTE
An irregular beep during recording does not necessarily indicate a cardiac arrhythmia. In most cases, a technical error has occurred during the recording (artefacts).

NOTE
When the beep fails during recording correct the position of the device and press it more firmly on the chest.

With strong chest hair, shortly move the device back and forth so that no hair obstructs the contact between electrodes and skin.

NOTE
Skin contact of the electrodes can be impaired when the skin is too dry.

Moisten the electrodes with a little water when the skin is dry and there is no beep.



← Number of recordings stored

← Progress indication of the recording (see the "Meaning of Display Symbols and Audible Notifications" section on page 34.)

Fig. 15 Display during recording

During recording, the mobile transmission module of the device stays switched off.

5.3 Sending an ECG Recording

NOTE
The device uses public telecommunication networks to transmit data. Interruptions are possible depending on the network coverage, availability of the services and line quality. Therefore, it cannot be guaranteed that the transmission is always successful.

After recording, the device automatically switches to sending mode and in the display, the number of recordings not yet sent is shown together with a progress indication:

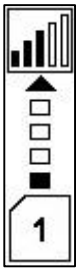
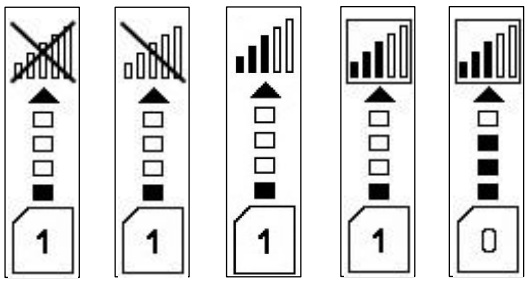


Fig. 16 Sending a recording, progress indication

The device independently establishes a connection to a mobile network and then sends the recorded data.

It is not possible to establish a connection to a mobile network manually.



Progress indication during sending (see Section 7)

A B C D E

Fig. 17 Sending a recording, progress indication steps

Step sequence of the display during transmission:

A ECG in storage – mobile transmission switched off

B ECG in storage – no mobile network

C ECG in storage – connection to mobile network established

D ECG in storage – connection to ReSTA established

E ECG in storage – connection to ReSTA / status message

After sending, the main display is shown again.

Each ECG recording successfully sent is then deleted from the storage.

The mobile transmission module is switched off automatically.

If the transmission of one or several ECG fails immediately after recording, the transmission process is repeated automatically.
PhysioMem repeats the transmission at the following time intervals:

- first repetition immediately after failure of the first transmission process
- three further repetitions each after 15 minutes
- next repetition after 5 hours and after every 24 hours

NOTE
If the ECG data cannot be transmitted, e.g., because of a poor mobile network connection, changing the location of the device is recommended (e.g., go outdoors, change the side of the street, etc.).
Observe the times set by the repetition intervals described above.
If the mobile network connectivity is always insufficient in your area, send the ECG from another area.

NOTE
The transmission process cannot be repeated manually.

NOTE
You can start a new recording anytime during transmission. In this case, the transmission is interrupted. The ECG recording stays stored until the next transmission.

5.4 Switching off the Device

To switch off the device, press the button (1) for longer than 10 seconds and hold it until the device switches off and the display goes blank.

NOTE
Ensure that the device is always ready for use and only switch it off if you will not use it for a longer time, e.g. on a plane or if a reset becomes necessary.

6 The System of PhysioMem and ReSTA

6.1 Overview

ReSTA is a server-based software for receiving and transmitting vital signs data (ECG).

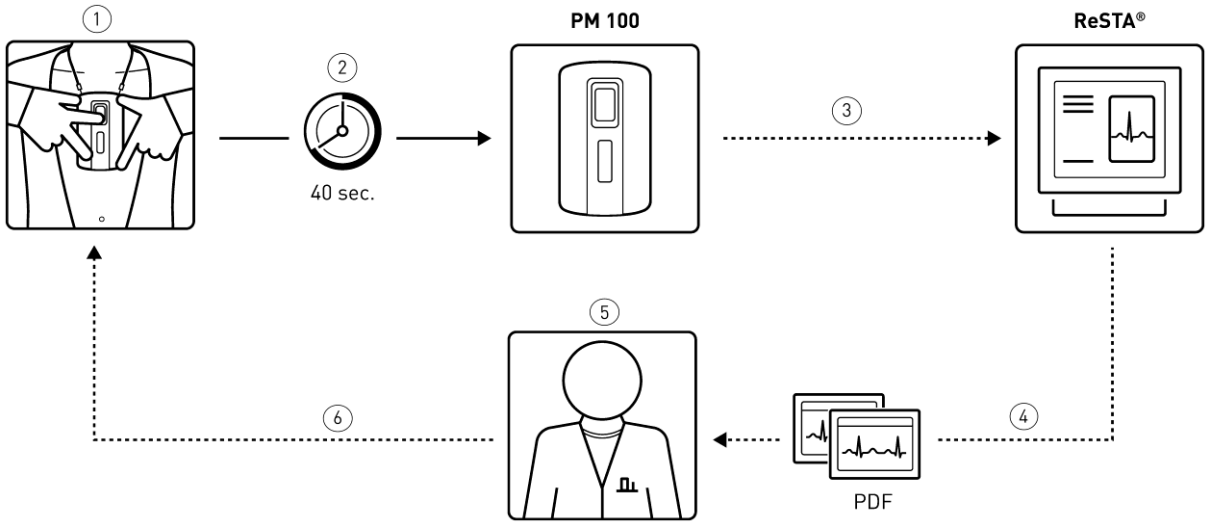


Fig. 18 Path of data transfer

(1) Patient (2) Measurement (3) Transmission
(4) Email (5) Physician/Hospital (6) Analysis

ReSTA receives the data sent by PhysioMem via a mobile network, converts these data to a defined data format and redirects them via a mobile network to a defined target address.

In ReSTA, the device number of the respective PhysioMem is assigned to the defined target address (e-mail). This connection remains established until the physician requires any changes. Thus, all ECG recordings incoming in ReSTA will be assigned to the target address automatically.

An incorrect matching of ECG and target address is precluded.

CAUTION

The attending physician as receiver of an ECG has to ensure that these ECG data are assigned correctly to a patient.

During the entire transmission process, no patient-related data are used. It is in a medical facility that the ECG recording is assigned to a patient by healthcare professionals. And only there, the identity of the sender of the ECG recording is known.

If the transmission of an ECG recording is completed, ReSTA sends a confirmation signal to the respective PhysioMem and the ECG sent is deleted from the storage of the device.

6.2 ECG Report

The ECG report consists of two A4 pages in landscape format and includes all relevant ECG and device information (Fig. 19).

On the two pages, four lines are shown with two ECG channels of 10 seconds duration each at a scale of the time axis of 25 mm/s.

The head of the report includes information on the PhysioMem used, on the recording and transmission times, on the ECG lead, and a field for comments.

At the bottom of every ECG stripe, the heart rate in beats per minute, and the RR‘ interval in milliseconds is shown.

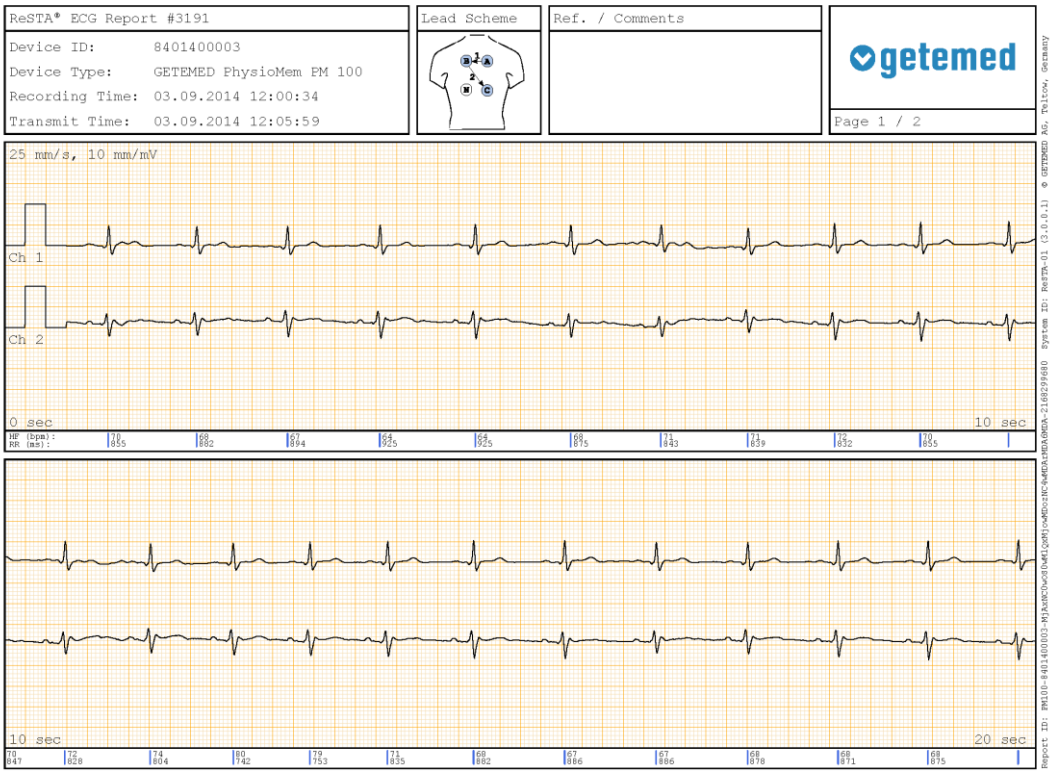


Fig. 19 ECG report

NOTE

The recording and transmission times refer to Central European Time or Central European Summer Time. (CET or CEST).

NOTE

Neither the PhysioMem nor the receiving system ReSTA store or transmit location data or personal information.

NOTE
In case of loss of the device immediately inform the technical service or contact the manufacturer.

NOTE
Use the storage pouch supplied for safe storing of the device when not in use.

NOTE
Switch off the device if this is not to be used for some time. Proceed as explained in the "Switching off" section on page 29.

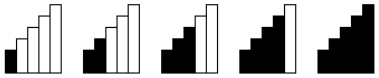
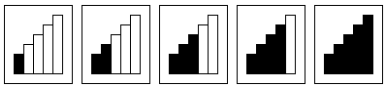
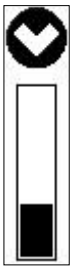
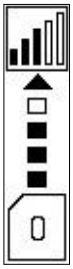
NOTE
Check the charging state of the device if it has not been used for some time and charge the device as explained in the "Putting into Operation, Fully Charging the Battery" section on page 19).

NOTE
Always switch off the device prior to any shipping and only ship it in the storage pouch and in the packaging supplied.

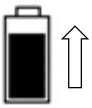
NOTE
Disconnect the power plug from the network connector if the charging pad is not used. Make sure that you always have access to the power network connector.

7 Meaning of Display Symbols and Audible Notifications

7.1 Display Symbols

Condition	Symbol
Mobile transmission switched off	
No mobile network connection	
Mobile network found (0 to100 %), not connected	
Mobile network found (0 to 100 %), connected	
Powering up	
Recording in progress (25, 50, 75, 100 %)	

Transmission in progress (25, 50, 75, 100 %) continuous	
Recording disturbed and deleted automatically. No data transmitted.	

Condition	Capacity	Symbol
Charging of the battery required	0 to 10 %	
Capacity display	20, 40, 60, 80 , 100 %	
Charging	Sequence in 20 % steps Capacity charged is shown as solid block.	 continuous
Charging of the battery required	Capacity charged is not sufficient for a recording.	

7.2 Audible Notifications

Condition	State	Comment	Signal
Success	REC	Process has been finished successfully.	Rising sequence of 4 short beeps
Confirmation	REC, BOOT	Process has been started successfully.	1 long beep
Error	REC	Storage full	3 short beeps (low frequency)
Recording in process	REC		1 short beep activated by every heart beat until recording has finished
Battery charging in progress	IDLE	Device is on charging pad.	Rising sequence of 2 very short beeps

8 Troubleshooting

This section gives troubleshooting recommendations and explains error codes.

8.1 Symptom, Cause, and Recommendation

Symptom	Cause	Recommendations
Battery cannot be charged.	Charging pad not connected to mains supply.	Connect USB cable to charging pad and mains supply.
	Device not positioned correctly on charging pad.	Correct the position of the recorder on the charging pad (s. section 4.2, page 19).
ECG data cannot be transmitted.	No mobile network connection.	Data transmission will be repeated automatically. If necessary, change location.
	Device has not been activated by the manufacturer.	Contact service or manufacturer.
	Data transmission failure.	Switch off the device and switch it on again.
No ECG recording possible.	Battery not charged.	Connect cable of charging pad to mains supply and place recorder on charging pad.
	Storage full.	Data transmission is repeated automatically. If necessary, change your location.

8.2 Error Codes Displayed

E01 to E05

If the display shows the GETEMED icon and one of the error codes E01 to E05, a system error has occurred in the recorder. In this case, contact the manufacturer's service or send the device to the manufacturer.

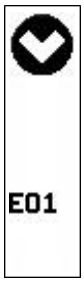


Fig. 20 Example of error code display

E06

If the E06 error code is displayed, contact the technical service.

E07

If the E07 error code is displayed, you have to restart the device. Press the button (1) for 10 seconds until the display goes blank. Then briefly press the button to restart the device.

If a restart does not solve the problem, contact the manufacturer's service or send the device to the manufacturer.

E10

If the E10 error code is displayed, the operating temperature of the device is too high or too low (see section 10.5, page 41). In this case, the device switches off automatically after 30 seconds. Only switch the device on again in an ambient where the temperature lays within the temperature limits given in section 10.5.

9 Accessories, Ordering Information

	Product	REF Number
1	PhysioMem® PM 100 Tele ECG Event Recorder	77212001
2	Charging pad	77442301
3	Power supply FW7713/EU for charging pad	77441101
4	USB cable for charging pad	77412001
5	Neck lanyard	77451001
6	Storage pouch	77451002
7	Operating Manual German/English	77811011
8	Patient's Guide German/English	77821011
9	Packaging	77900001

10 Specifications

10.1 Classification

Product class	IIa according to MDD 93 / 42 / EEC

10.2 General

Dimensions	114 mm x 68 mm x 15 mm
Weight	approx. 100 g
Battery type	integrated Lithium polymer rechargeable
Charging method	Inductive coupling with charging pad
Operating mode	40-second ECG recording followed by data transmission
User interfaces	Start button, LC-Display, acoustic buzzer
Material	ABS plastic casing, stainless steel electrodes
Ingress protection	IP64
Lifetime	7 years

10.3 ECG and Heart Rate

ECG leads	2 channels, 4 electrodes
Upper heart rate limit	240 / min
Digital resolution	256 Hz / 12 Bit
Lower freq. threshold	0,5 Hz
Upper freq. threshold	40 Hz

Analog resolution	3 µV
Open lead detection.....	Yes

10.4 Data Transfer

Transmission technology..	GSM Quad band module
RF frequency range.....	850/900/1800/1900 MHz
SAR value.....	1.95 W/kg

10.5 Operation Conditions

Temperature.....	5 to 45 °C
Relative humidity.....	10 to 95 %, non-condensing
Ambient pressure	106 to 50 kPa 106 to 80 kPa (power supply)

10.6 Storage and Transport Conditions

Temperature.....	–25 to +70 °C,
Relative humidity.....	5 to 95 %, non-condensing

10.7 Charging Pad

Dimensions.....	145 mm x 84 mm x 9 mm
Weight Charging Pad.....	approx. 50 g
Ingress protection	IP21
Power supply	Switched-mode power supply, input voltage 100-240 VAC, 50/60 Hz, output voltage 5 VDC

10.8 Scope of Delivery

PhysioMem® PM 100, charging pad, power supply and USB cable, neck lanyard, operating manual, patient's guide, storage pouch.

10.9 EMV-Spezifications According to IEC 60601-1-2

10.9.1 General Specifications, Table 201

Guidance and manufacturer's declaration – electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
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	Class A	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Complies	

10.9.2 General Specifications, Table 202

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electric fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines ± 1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for ½ cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (60 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	< 5 % U_T (> 95 % dip in U_T) for ½ cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (60 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8	3 A/m	3 A/m	If malfunctions occur, it may be necessary to position the device further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

10.9.3 Non Life-Sustaining Systems, Table 204

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 VRMS 150 kHz to 80 MHz	3 VRMS	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \cdot \sqrt{P}$ $d = 1.2 \cdot \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \cdot \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer and d is the recommended separation distance in meters [m]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

10.9.4 Recommended Separation Distances, Table 206

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power P of transmitter [W]	Separation distance d according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.67	11.67	23.34

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters [m] can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

For your notes.

Vertrieb / Sales:

Hersteller / Manufacturer:

CE 0197

REF 77811011

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