getemed

Operating Manual

PhysioMem® PM 100 2G

Tele ECG Event Recorder

+++ DRAFT for type approval of wireless charging transmitter pad +++

Cardiac Diagnostics,
Vital Signs Monitoring
Telemonitoring

Content

1 Intended Use, Indications and Operation 5
1.1 Intended Use 5
1.2 Indications 5
1.3 Mode of Operation 6
2 Regulatory Compliance and Labeling 7
2.1 Regulatory Compliance 7
2.2 Information on the Device Labels 9
2.3 Symbols on the Packaging Label 11
3 Safety and Reliability 12
3.1 Definitions 12
3.2 General Warnings 13
3.3 General Cautions 14
3.4 Safety and Reliability Only with Proper Maintenance 16
3.5 Cleaning the Recorder and Accessories 17
3.6 Disposing of the Device, Batteries, and Accessories 18
3.7 Established Medical Practices 18
3.8 Manufacturer Responsibility 18
4 Control Elements, Putting into Operation 19
4.1 Control Elements 19
4.2 Putting into Operation, Fully Charging the Battery 20
5 Recording and sending an ECG 25
5.1 How and where you apply the device 25
5.2 Recording an ECG 26
5.3 Sending an ECG Recording 28
5.4 Switching off the Device 30
6 The System of PhysioMem and ReSTA 31
6.1 Overview 31
6.2 ECG Report 32
7 Meaning of Display Symbols and Audible Notifications 35
7.1 Display Symbols 35
7.2 Audible Notifications 37

8 Troubleshooting 38
8.1 Symptom, Cause, and Recommendation 38
8.2 Error Codes Displayed 39
9 Accessories, Ordering Information 40
10 Specifications 41
10.1 Classification 41
10.2 General 41
10.3 ECG and Heart Rate 41
10.4 Data Transfer 42
10.5 Operation Conditions 42
10.6 Storage and Transport Conditions 42
10.7 Charging Pad 42
10.8 Scope of Delivery 43
10.9 EMC Specifications 43
10.9.1 General Specifications 43
10.9.2 Electromagnetic immunity (line-bound disturbances) 44
10.9.3 Electromagnetic immunity (conducted and radiated RF disturbances) 45

Revision History

Revision	Publication Date	Description
A	2014-12-03	1st Publication
B	2015-01-20	Symbols and Labeling updated
C	2016-04-13	Symbols and Labeling updated
D	2016-08-11	Symbols and Labeling updated
E	2017-06-07	Update for RED compliance
DRAFT	2018-09-07	Update for RED and FCC compliance

1 Intended Use, Indications and Operation

These operating instructions are intended for medical professionals.

1.1 Intended Use

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

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 pe- diatric (over 10 kg body weight) patients with asymptomatic and symptomatic disturbances of the cardiac rhythm and for the evalua- tion of recurrent unexplained episodes of racing heart, syncope, pal- pitations or dizziness.

Patients with an age of less than 14 years need support from adults.

The device is not indicated for patients whose clinical condition re- quires continuous monitoring of vital physiological parameters, where the nature of variations is such that it could result in immedi- ate danger to the patient.

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

1.3 Mode of 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.

A wireless charging transmitter pad is used to recharge the battery of the PhysioMem PM 100.

2 Regulatory Compliance and Labeling

2.1 Regulatory Compliance

CE 0197

The CE Mark and Notified Body Registration Number signifies the device including accessories meets all essential requirements of the Medical Device Directive 93/42/EEC.

CE

The CE Mark signifies the device including accessories meets all essential requirements of the Radio Equipment Directive 2014/53/EU.

This device including accessories complies with Part 18 of the FCC Rules.

CAUTION: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the product.

NOTE: This equipment has been tested and found to comply with the limits for a wireless power transfer, pursuant to Part 18 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.

- Increase the separation between the equipment and receiver.

- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

- Consult the dealer or an experienced radio/TV technician for help.

RF Exposure Compliance

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

2.2 Information on the Device Labels

The symbols and content of the device labels is described below.

Fig. 1. Device label of the recorder

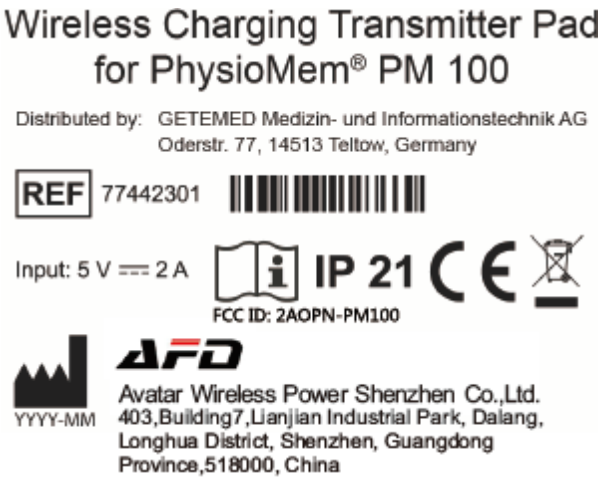
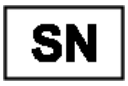


Fig. 2. Device label of the charging pad

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

Observe instructions for use

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 and 4 = protected against splashing water

IP21

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

CE mark and registration number of the notified body

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 “Disposing of the Device, Batteries, and Accessories”

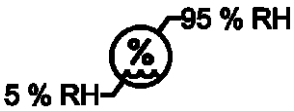
Below the solid factory symbol is the date at which the device was manufactured. Next to the solid factory symbol is the name of the manufacturer.

Non-ionizing electromagnetic radiation

FCC ID 2AOPN-PM100	Federal Communications Commission Identification
	Observe instructions for use

2.3 Symbols on the Packaging Label

The symbols and content of the packaging label is described below.

	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
	Maximum stack size: 10 packages
	Fragile, handle with care
	Recycling

3 Safety and Reliability

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

STRANGULATION BY THE 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 accesso- ries 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 section 3.5, page 17.

WARNING

NOT A MONITORING DEVICE – The PhysioMem PM 100 recorder is not a monitoring device and is not intended for monitoring the clini- cal 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 – 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) can cause malfunctioning of these devices.

3.3 General Cautions

CAUTION

While acquiring data do not use mobile phones or other electrical devices close to PM 100 that may cause interference, such as computers or electrical tools.

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 guaran- teed.

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 pre- vent 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. If you find or even suspect a malfunction, send the device for testing to GETEMED or a facility authorized by GETEMED. 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 sur- face 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 manufacturers instructions. E 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.

If you have questions concerning the disposal of this product, con- tact GETEMED 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.
- 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

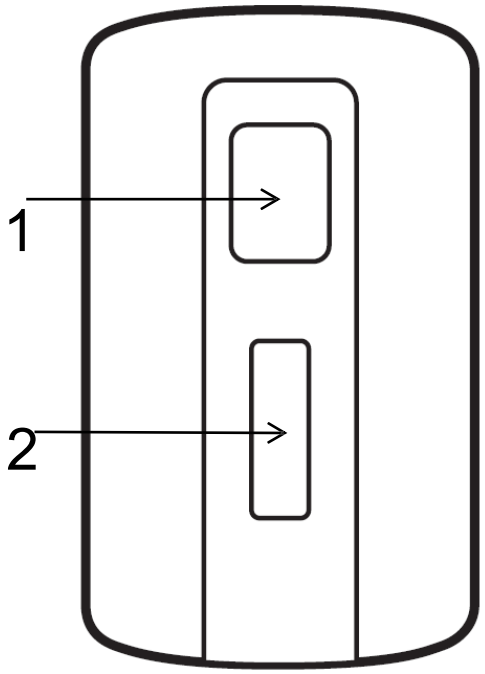


Fig. 3. Button and display

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.

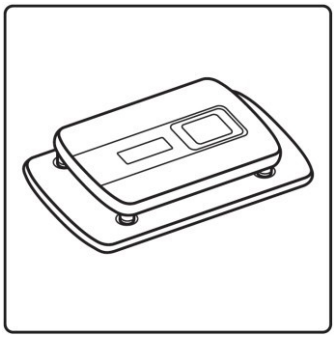


Fig. 5. PhysioMem on the charging pad

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

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 35)

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

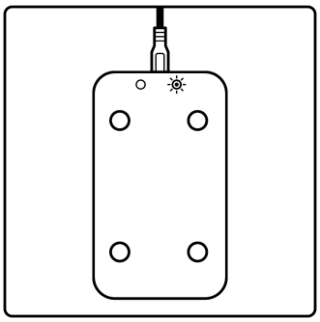


Fig. 6. Charging pad connected to power supply

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.

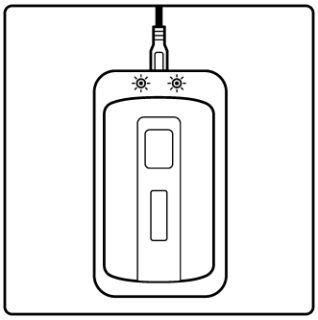


Fig. 7. Indication of the charging process

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).

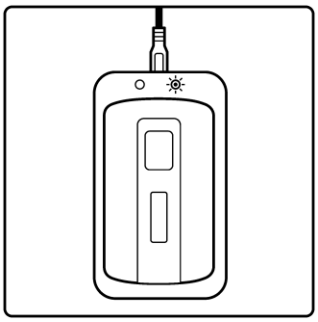


Fig. 8. Charging process completed

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.

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.

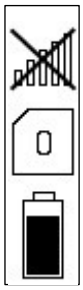
Charging the battery after complete discharge takes approx. 3 hours.

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.

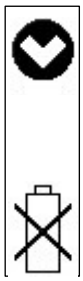


Fig. 11. Indication of insufficient battery power

5 Recording and sending an ECG

5.1 How and where you apply the device

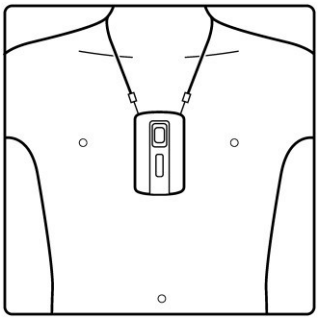


Fig. 12. Recorder on the patient's chest

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 attach- ment 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.

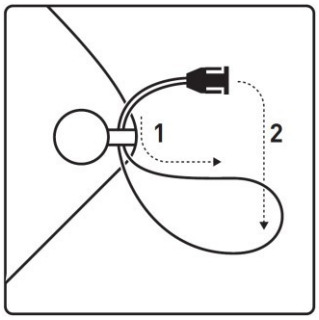


Fig. 13. How to adjust the neck lanyard

5.2 Recording an ECG

During recording, hold the device steady and press the four elec- trodes firmly on the chest (Fig. 14).

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

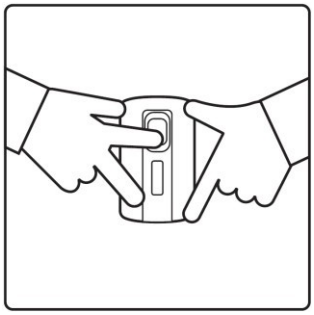


Fig. 14. How to press the start button

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 re-cording (artefacts).

NOTE

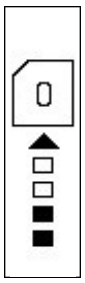
When the beep fails during recording correct the position of the de- vice and press it more firmly on the chest.

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 35)

Fig. 15. Display during recording

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

5.3 Sending an ECG Recording

NOTE

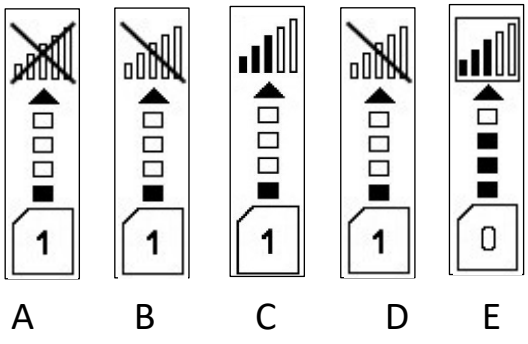
The device uses public telecommunication networks to transmit data. Interruptions are possible depending on the network coverage, availability of the services and line quality. Therefore, it cannot be guaranteed that the transmission is always successful.

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 (Fig. 17).

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



← Progress indication during sending (see section 7)

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 sent – connection to ReSTA / status message

After sending, the main display is shown again.

Each ECG recording successfully sent is then deleted from the stor- age.

The mobile transmission module is switched off automatically.

If the transmission of one or several ECG fails immediately after re- cording, the transmission process is repeated automatically.

PhysioMem repeats the transmission at the following time intervals:

- first repetition immediately after failure of the first transmission pro- cess
- 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 recom- mended (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 sec- onds 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 be- comes 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).

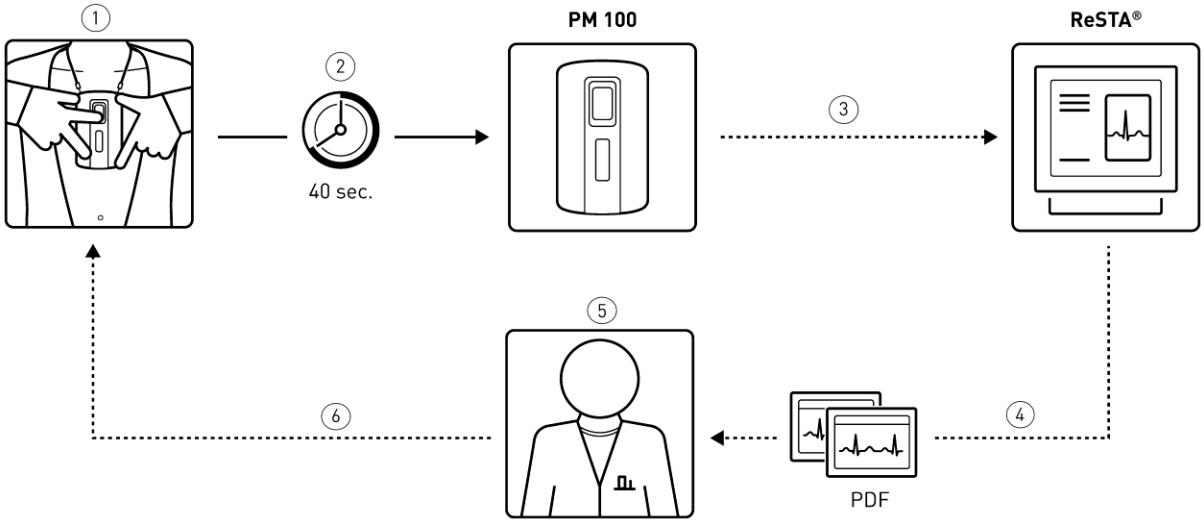


Fig. 18. Weg der Datenübertragung

(1) Patient (2) Measurement (3) Transmission

(4) Email (5) Physician/Hospital (6) Analysis

ReSTA receives the data sent by PhysioMem via a mobile network, con- verts 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 as- signed to the defined target address (e-mail). This connection re- mains established until the physician requires any changes. Thus, all ECG recordings incom- ing in ReSTA will be assigned to the target ad- dress 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 as shown.

The heart rate in beats per minute [bpm] is continuously calculated from the time that elapses between two consecutive beats. Averaging is not used for the calculation.The device is not indicated to detect Pauses automatically.

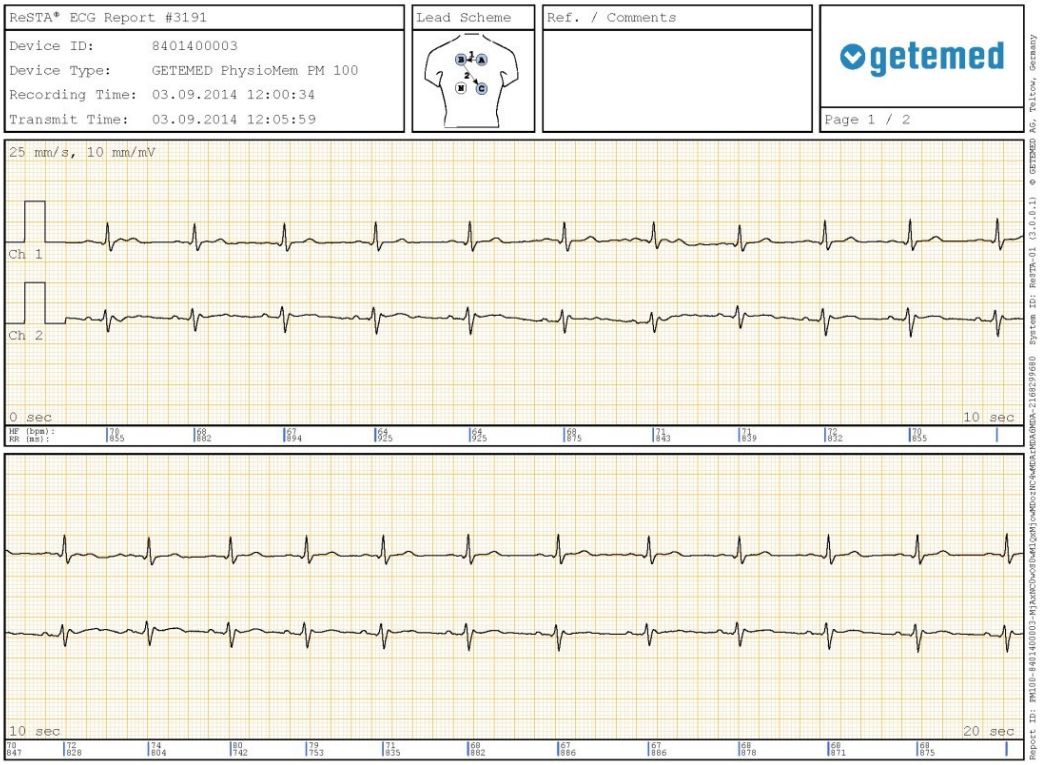


Fig. 19. ECG report

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 the Device” section on page 30.

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 20).

NOTE

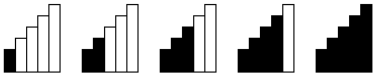
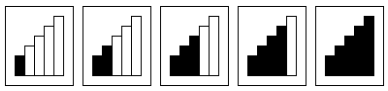
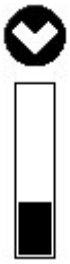
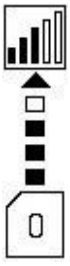
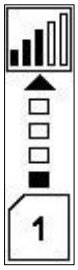
Always switch off the device prior to any shipping and only ship it in the storage pouch and in the packaging supplied.

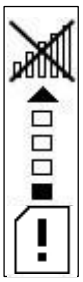
NOTE

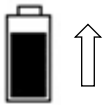
Disconnect the power plug from the network connector if the charg- ing pad is not used. Make sure that you always have access to the power network connector.

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 to100 %), connected	
Powering up	
Recording in progress (25, 50, 75, 100 %)	
Transmission in progress (25, 50, 75, 100 %) continuous	

Condition	Symbol
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.	 En continu
Charging of the battery required	Charging capacity is not sufficient for sending an ECG. A recording can be performed.	

7.2 Audible Notifications

Condition	State	Comment	Signal
Success	REC	Process has been finished success-fully.	Rising sequence of 4 short beeps
Confirmation	REC, BOOT	Process has been started success-fully.	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 charg-ing in progress	IDLE	Device is on charg-ing 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 20).
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 man- ufacturer.	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 re- peated automatically. If nec- essary, change your location.

8.2 Error Codes Displayed

E01-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 manu- facturer.

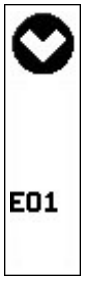


Fig. 20. Example of error code display

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). 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.

9 Accessories, Ordering Information

	Product	REF Number
1	PhysioMem PM 100 2G 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	Bag	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..... ... 20 to +60 °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

Input voltage ..... Switched mode power supply,
100-240 VAC, 50/60 Hz

Output voltage ..... 5 VDC

Ingress protection IP21

Operation Frequency ..... 109.39kHz - 174.3kHz

Max. RF power transmitted … -8.12dBµA/m @10m

10.8 Scope of Delivery

PhysioMem® PM 100 2G, charging pad, power supply and USB cable, neck lanyard, operating manual, patients's guide, storage pouch.

10.9 EMC Specifications

10.9.1 General Specifications

Guidance and manufacturer's declaration – electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctua-tions / Flicker emissions IEC 61000-3-3	Not applicable	

10.9.2 Electromagnetic immunity (line-bound disturbances)

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact (electrode snaps only, direct dis-charge on device not possible due to pouch) ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are cov-ered with synthetic material, the relative humidity should be at least 30%.
Electric fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	Not applicable	Not applicable
Surges IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	5% UT (>95% dip in UT) for 1/2 period < 5% UT (>95% dip in UT) for 1 period 70% UT (30% dip in UT) for 25 periods <5% UT (>95% dip in UT) for 5 s	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Not applicable	Not applicable

NOTE: UT is the AC mains voltage prior to application of the test level.

10.9.3 Electromagnetic immunity (conducted and radiated RF disturbances)

Guidance and manufacturer's declaration – electromagnetic immunity

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

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

Distributor:

Manufacturer:

CE 0197

REF 77811011

GETEMED
Medizin- und Informationstechnik AG
Oderstr. 77 / 14513 Teltow
Phone: +49 3328 3942-0
Fax: +49 3328 3942-99
info@getemed.de / www.getemed.de

Revision DRAFT / 2018-09-07