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Mobile Cardiac Complex Analyzer

clue^{medical}



Operating Instructions
clue medical and clue medical BASIC*

* not available in every country

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As a **clue medical** or **clue medical BASIC** user, you have decided on a state of the art telemedicine system. Thanks to their complex evaluation options, in addition to the one-channel ECG, **clue medical** and **clue medical BASIC** also allow measurement and display of autonomic nervous system activities.

Indications for Use

clue medical and **clue medical BASIC** are handheld battery operated single channel electrocardiographs intended for recording and transmitting ECG data by patients who are concerned about their heart rhythm. **clue medical** and **clue medical BASIC** allow the patient to record their ECG data into the device memory and transmit it for display by healthcare professionals.

Specifically, **clue medical** and **clue medical BASIC** are intended for patients that are concerned about their heart rhythm or have experienced the following symptoms that are suggestive of abnormal heart rhythm:

- Skipped beats
- Pounding heart (palpitations)
- History of arrhythmia

clue medical and **clue medical BASIC** ECG data is intended to be used by a licensed health care practitioner. These measurements are not intended for any specific clinical diagnosis. The clinical significance must be determined by the physician.

1. Intended use

clue medical and **clue medical BASIC** are systems for one-channel recording of application-specific ECG sections for the purpose of determining heart rhythm disturbances, heart rate variability (HRV) as well as the activity of the autonomic nervous system (sympathetic, parasympathetic regulation) as indicators of cardiovascular stress, recovery and balance. The data can be sent either telemetrically using a computer or a mobile phone network to a defined recipient.

clue medical BASIC

With **clue medical BASIC** recorded data are sent directly to a computer (PC/Notebook) via an USB IrDA adapter or Bluetooth interface. Transmission and display depend on the technical parameters of your computer (see Chapter 10).

clue medical

In addition to the **BASIC**-functions, recorded data can be sent telemetrically to the **clue medical Server** using a mobile phone as modem or a computer (PC/Notebook) with Internet connection (by using the enclosed USB IrDA stick). Please pay attention to the technical requirements (see Chapter 10).

Description

A recording time of 2 minutes and a sampling rate of 1 KHz enable **clue medical** and **clue medical BASIC** to provide diagnostic quality information on heart rate variability (HRV) and the effect of the autonomic nervous system on heart activity and the cardiovascular system. This is accomplished by intelligent signal processing, namely through

highprecision determination and evaluation of RR intervals (beat to beat), taking into account stationarity requirements.

The following information is provided by the 2 minute recording:

1. a complete one-channel ECG over a period of 2 minutes
2. a signal-averaged ECG with the characteristic time values
3. average cardiac cycle and heart frequency, absolute (SDNN) and relative (CV) heart rate variability
4. a tachogram of cardiac cycle durations including cardiovascular divisions
5. a spectral analysis (FFT) including surface area measurements derived from such for sympathetic and parasympathetic activity as well as their balance.

To get more information about the scientific background of the measurement of **clue medical** and **clue medical BASIC** please visit our website on www.cluemedical.com.

2. Safety information

Please pay careful attention to all safety instructions and warning symbols contained in these operating instructions. Read these instructions thoroughly prior to use of the product, they contain important information for users of **clue medical** and **clue medical BASIC**. Keep these instructions in a safe and accessible place.

The operating personnel must be thoroughly acquainted with the following symbols for precautions and warnings:

CONTRA-INDICATIONS

clue medical and **clue medical BASIC** are contra-indicated for use:

- during treatment with electrosurgery devices or electrocoagulation,
- during simultaneous defibrillation,
- in the presence of overly strong electromagnetic interference fields (antennas, high voltage transformers, generators, MRI's),
- in combination with an external pacemaker,
- for recording an intracardiac ECG,
- by infants weighing less than 10 kg (22 lbs).

WARNINGS

WARNING!

Warnings describe potential serious adverse reactions and safety hazards.

PRECAUTIONS

CAUTION!

Precautions are statements of a hazard that warn you of a potentially hazardous situation or unsafe practice, which, if not avoided, may result in minor or moderate injury or damage to **clue medical** and **clue medical BASIC**.

To ensure safe use of the device you should be able to read, speak and understand English. You must be able to operate the device on your own after reading this manual and receiving detailed instructions from your physician. If you are not comfortable with the instructions for use and instructions from your physician, you should not take **clue medical** and **clue medical BASIC** home with you. If you are hearing impaired, please consult your physician on whether it is possible for you to use the device.

WARNINGS

WARNING!

Interference

1. **clue medical** and **clue medical BASIC** should not be used in intensive care areas in order to rule out confusion with alarms.
2. The fixed electrodes are made of surgical stainless steel and also contain nickel portions. If irritation occurs upon skin contact, we recommend using the adhesive electrodes.

PRECAUTIONS

CAUTION!

3. The device including associated parts should be inspected at regular intervals to ensure that it is intact. This is done by visual inspection of the appropriate parts.
4. In-service inspections pursuant to the ordinance on the operation of medical devices (MPBV) are not necessary.

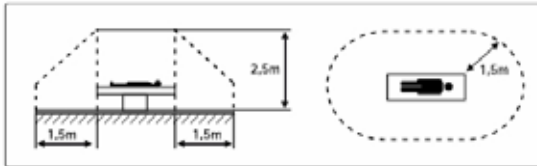
5. Due to the signal quality and the frequency response (0.05 -40Hz) on the adhesive electrodes, **clue medical** and **clue medical BASIC** is suitable for evaluating ST segments. An automatic analysis is not provided for.

6. When printing the pdf-analysis, please ensure that automatic scaling is off and that zoom is set to 100 %. The representation is correct if the total length of a 10 second ECG section is exactly 25 cm. Due to display problems with some printers, correct resolution cannot be guaranteed.

7. **clue medical** and **clue medical BASIC** are battery-operated devices. The included standard AAA battery is replaceable and may only be disposed of in refuse containers provided for that purpose. Batteries do not belong in household garbage! As a consumer, you are legally obligated to return used batteries. You can discard your old batteries at public collection points or anywhere where batteries of the same type are sold.

8. In case of prolonged periods of disuse, the battery should be removed from the device.

9. No devices which have not been inspected pursuant to EN 60601-1 may be located in the patient's surroundings. The standard for general requirements for safety, including the essential performance characteristics of medical devices, must be followed.



10. **clue medical** and **clue medical BASIC** work in a temperature range of 10°C to 45°C. To ensure safe operation, it must be free of condensation. Any large change in the surrounding temperature should therefore be avoided.

11. The device should be protected from mechanical strains such as blows, shocks and scratches.

12. **clue medical** and **clue medical BASIC** are not designed for emergency situations. In acute emergencies, please contact an emergency medical service immediately.

13. **clue medical** and **clue medical BASIC** are not waterproof and must therefore remain protected from water. They may not be operated in water or in the rain. If the device has become wet inside, it can no longer be used and must be replaced.

14. When transmitting with a mobile phone, a safety distance of at least 30 cm (12") should be kept between the user's/patient's sternum (heart) and the mobile phone (electromagnetic radiation).

15. **clue medical** and **clue medical BASIC** may only be repaired by the manufacturer or authorized repair persons.

16. Before giving the **clue medical** or **clue medical BASIC** to a second user, delete the memory of the device before passing it on (see Chapter 6).

17. Do not use any accessories that have not been provided other than adhesive electrodes bearing the CE label or batteries meeting the technical specs indicated (see Chapter 9. technical data).

18. All conductive parts of the electrodes and attached plug connections including neutral electrodes must not come in contact with any other conductive parts, including the ground.

19. If more than one device is used on a patient at one time, the sum of the leakage currents should be monitored.

3. Declaration of compliance

This product complies with directive 93/42/EEC on medical devices. **clue medical** and **clue medical BASIC** are approved pursuant to directive 93/42/EEC for medical devices as class IIa products. Class IIa products have to be labeled with the identification number of the inspection authority.

This device fulfils the requirements of the following standards:

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-2-25
- IEC 60601-2-47



4. Packaging and accessories

clue medical and **clue medical BASIC**

- 1 device
- 1 instruction manual (2 copies for US market)
- 1 neck strap
- 1 AAA battery
- 1 IrDA USB adapter

The packaging consists of one carton

Optional accessory

- electrode cable
- package of adhesive electrodes (AMBU K041026)
- carrier belt

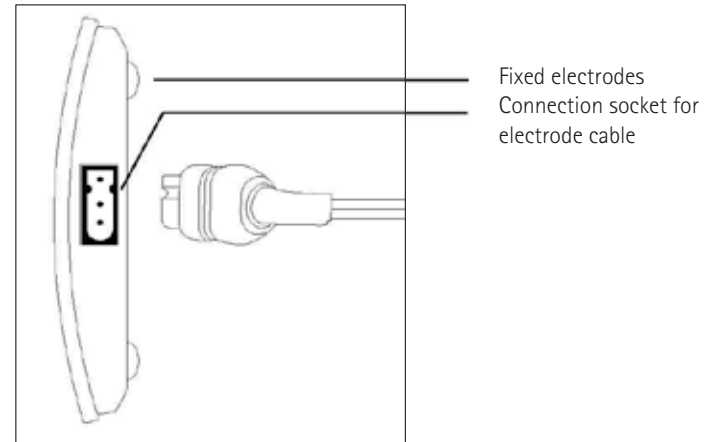
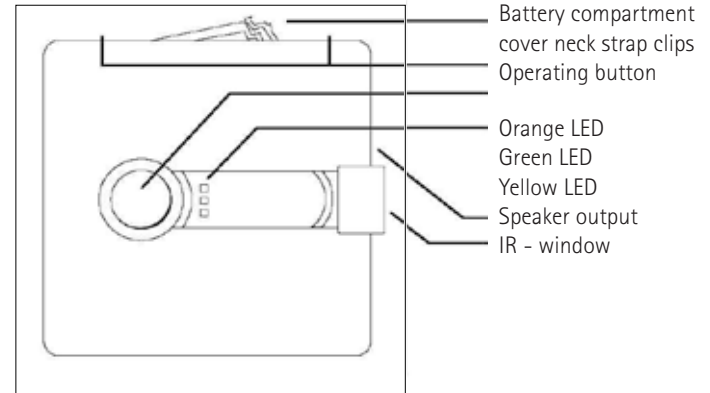
If one of the components listed is missing, please contact your distributor immediately.

All device components and accessories can be reordered directly from an approved supplier.

Name	Order Number
clue medical BASIC (Product group 102)	102 0 06 04 01
clue medical (Product group 102)	102 0 06 04 02
Neck strap	100 0 06 07 01
Three pole electrode cable	100 1 06 03 01
"Blue Sensor" adhesive electrodes	100 0 06 01 01
Carrying belt	102 0 06 06 01
USB-IrDa stick	100 0 06 02 01

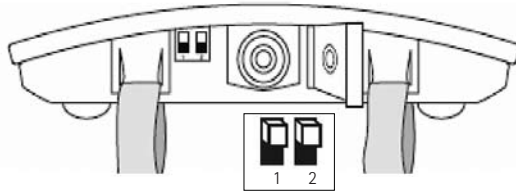
For ordering replacement parts or technical questions please contact your distributor

5. Device overview / controls



Changing modes of transmission

corresponding DIP switches are located inside the battery compartment.



example: transmission to server using Bluetooth
(i.e. with a mobile phone)

Pos.	Switch 1	Switch 2
up ↑	Transmission to clue medical Server (only clue medical)	Bluetooth
down ↓	Direct Transmission	Infrared

6. Instructions for Use

Power on

Before you start for the first time the protection foil for the battery has to be removed. After pressing the operating button once, **clue medical** and **clue medical BASIC** are immediately ready for use. You will know the device is ready for use when the green LED flashes up and you hear one ascending tone.

The yellow LED flashes when the device-memory is full. **clue medical** and **clue medical BASIC** can store a maximum of 30 recordings. If the memory is full, you will have to transmit the data before you can record again.

Changing the battery

The orange LED flashes up, when the battery-power is insufficient. To change the battery, the battery compartment must be opened. Any commercially available AAA battery is permitted. In addition, rechargeable 1.2 V NiMH batteries may also be used.

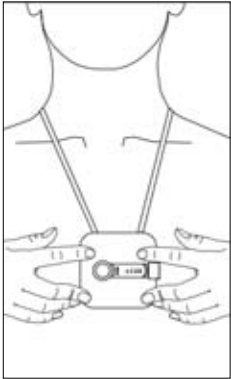
Deleting device memory

To clear the device memory the DIP switch 2 has to be in "Infrared-position" (switch 2 "down ↓")
Turn on **clue medical** or **clue medical BASIC** and press the operating button again for at least 10 seconds. Successful deletion will be confirmed with an ascending tone. The yellow LED lights for a few seconds. Normally deletion is not necessary because after a successful transmission the recordings will be deleted automatically.

Recording with fixed electrodes

Place **clue medical** or **clue medical BASIC** on the sternum as shown in the picture. When using without the neck strap, the clips for the neck strap should be pointing upwards in order to ensure proper recording of the signal.

Turn on **clue medical** or **clue medical BASIC** and press the device against the chest. After being switched on, the device automatically determines if there is a signal coming from proper skin contact or the adhesive electrodes.



If **clue medical** or **clue medical BASIC** detects a signal, the recording starts automatically and the green LED flashes. If skin contact is interrupted or if contact pressure is too low, then this will be indicated by a continuous warning signal. The end of the recording is acoustically confirmed with an ascending tone and the yellow LED flashes up.

CAUTION!

Be sure that all four fixed electrodes are placed on the skin and that there is no clothing between the electrodes and the skin. If you have a lot of chest hair, move **clue medical** or **clue medical BASIC** back and forth gently and then increase the contact pressure in order to make contact with the skin. The device will indicate insufficient skin contact with a beep sound.

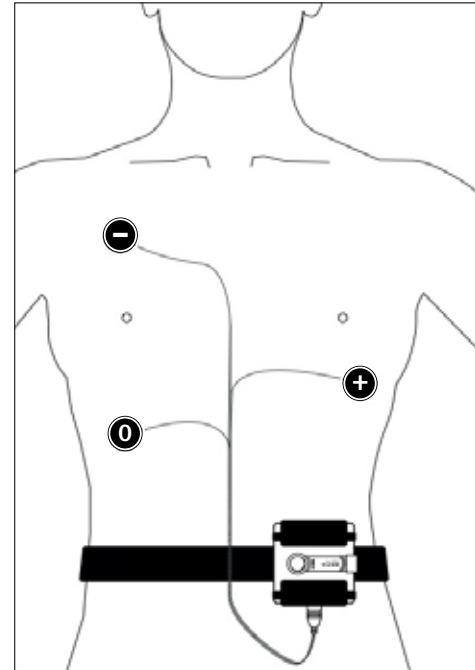
WARNING!

clue medical and **clue medical BASIC** should only be used on healthy, intact skin (not on wounds, scars, etc).

Recording using adhesive electrodes

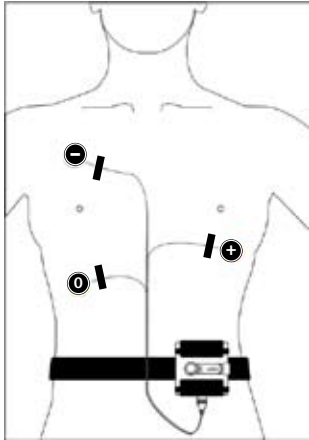
Connect the electrode cable to **clue medical** or **clue medical BASIC** as shown in the picture. The adhesive electrodes are connected to the electrode cable with the snap fastener. Remove the protective film from the electrodes.

Place the adhesive electrodes with the correct polarity as shown.



CAUTION!

In order to prevent tensile stress on the cables, particularly during movements, attach the electrode cable to the skin with medical bandages a few cm away from each of the connection points of the adhesive electrodes as shown.



clue medical or **clue medical BASIC** can also be worn in a carrier belt (optionally available) over your clothing. After being switched on, **clue medical** or **clue medical BASIC** will automatically detect a proper signal. If **clue medical** or **clue medical BASIC** does detect a signal, then the recording is started automatically. The green LED flashes during measurement. If skin contact is interrupted during recording, **clue medical** or **clue medical BASIC** will emit a continuous warning signal. The end of a successful measurement is confirmed with an ascending tone.

Transmitting data

If you have a **clue medical BASIC** you can transmit the recorded and visualized data **only as a pdf-file directly to a computer** (usually to desktop on PC/notebook) via an IrDA or Bluetooth compatible interface. Transmission to the **clue medical Server** via computer or mobile phone is not possible. Transmission and display depend on the technical parameters of your computer (see Chapter 10).

If you have a **clue medical**, recorded data can be sent telemetrically directly to a computer in form of a pdf-visualization (see **clue medical BASIC**), or via computer or mobile phone with Internet connection to the **clue medical Server** for protected global access. The recordings can be viewed and managed 24 hours a day, using a defined user-ID and password chosen by you via **www.cluemedical.com** under "365/24 :: clue central login". Transmitting via mobile phone is – besides Infrared or Bluetooth capability – only bound to the network requirements of the particular location and if applicable of the technical standards of different mobile phone network providers.

Note: The recording has to be completed first, before the transmission can be started.

Transmitting via computer or mobile phone (clue medical)

The recorded data can be transmitted via computer or mobile phone with Internet connection to the **clue medical Server**. In this case the computer or mobile phone act as a modem and allows an automatic connection to the **clue medical Server** to transmit the recorded data from your **clue medical** device for visualization and storage. You do not need to dial any numbers for the transmission to occur.

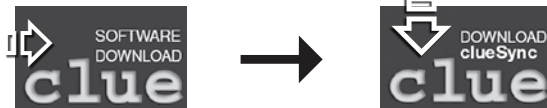
Before transmitting via computer or mobile phone, you need to activate the **clue medical** device once on **www.cluemedical.com** under "365/24 :: clue central login" (see also Chapter 7).

You will also need to ensure that in case of using your mobile phone it is set up with an Internet gateway¹.

In case of **using a computer with Internet connection** to transmit the recorded data to the **clue medical Server**, it is essential that a small program (clueSync) is running which can be downloaded and installed prior to transmitting data.



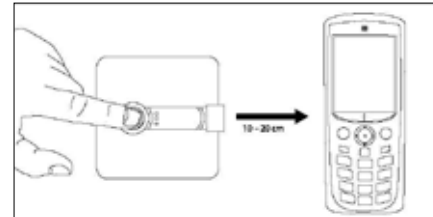
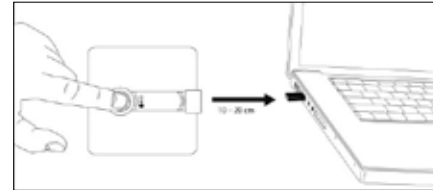
If running you can see the clueSync-symbol at the task bar of your PC. You'll find the download sign below on our homepage (**www.cluemedical.com**).



¹ For support contact your mobile phone service provider

To send data via computer or mobile phone, plug in and activate the enclosed IrDA stick or pair clue medical with the receiving Bluetooth device².

In case of using IrDA (Infrared-connection) position the interfaces in a direct line of sight 10 to 20 cm apart as shown in the picture below.



In case of using Bluetooth, a successful pairing between your device and the receiving mobile phone is needed before transmitting data. For details of how to pair see page 22 to 26.

² For more information read the instruction manual of your mobile phone/computer respectively contact your vendor.

Press the button twice. **clue medical** or **clue medical BASIC** will acknowledge successful transmission with flashing of the yellow LED and confirming successful data transfer to the **clue medical Server** with an ascending tone.

Three tones in a row (two short, one long) signify that transmission was unsuccessful and the orange LED flashes up. In this case, transmit the data again.

With each transmission, all new recordings are transferred, approx. 25 Kbytes of data are transmitted per recording.

The memory is only deleted automatically if the transmission was successful.

IF THE YELLOW LED FLASHES

Data transmission is in progress. After a successful transmission, a positive confirmation tone sounds for each recording to confirm successful transmission.

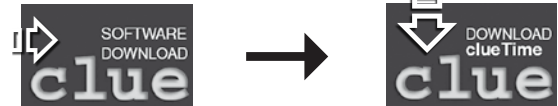
IF THE ORANGE LED FLASHES

If the transmission was not successful, then a negative confirmation tone sounds and the orange LED flashes. The data are still stored in the device and the transmission can be reattempted at any time again.

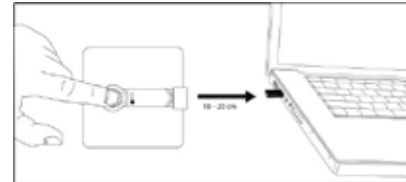
Transmitting via USB IrDA-stick (Infrared) directly to a computer (**clue medical** and **clue medical BASIC**)

Before data can be directly transmitted to a computer, the specific settings for the USB IrDA adapter must be configured as indicated by the manufacturer and the **clueTime**-program, (which can be downloaded from www.cluemedical.com) has to be installed and started. **clueTime** is needed for date and time synchronisation between **clue medical** or **clue medical BASIC** and the

computer. The actual synchronisation will happen during transmission.



The enclosed IrDA-stick will be connected to the computer using an USB slot. Optionally, an existing IrDA interface on your computer can be used too. To transmit the data, position **clue medical** or **clue medical BASIC** 10 to 20 cm from the IrDA stick, facing it with the Infrared window, as shown in the picture.



Press the operating button twice. A window opens up on the computer display which asks to permit data to be received with a mouse-click. Successful transmission to the computer's desktop is then acknowledged on the screen. After this you'll find a pdf file on the desktop with the device name, its serial number (S/N) and recording number. This file can then be opened with the free Acrobat Reader from Adobe and then individually managed. This information can be communicated to your physician. Only your physician can make a medical interpretation of these results. The manufacturer is not responsible for the interpretation of the recordings performed with **clue medical** or **clue medical BASIC**. **clue medical** and **clue medical BASIC** will confirm successful transmission to the PC with flashing of the yellow LED and with an ascending tone.

If you are using **clue medical** and try to contact the **clue medical Server** and store the measurement there successful data transfer to the Service Center will also be confirmed with an ascending tone.

Three tones in a row (two short, one long) signify that transmission was unsuccessful; the orange LED flashes up. In this case, transmit the data again.

With each transmission, all recordings are transferred (approx. 25 Kbytes of data are transmitted per recording). The memory is only deleted automatically if the transmission is successful.

IF THE YELLOW LED FLASHES

Data transmission is in progress. After successful transmission, a positive confirmation tone sounds for each recording to confirm successful transmission.

IF THE ORANGE LED FLASHES

If the transmission is not successful, then a negative confirmation tone sounds and the orange LED flashes. The data are automatically stored in the device and the transmission can be repeated.

CAUTION!

When transmitting, make sure that there are no computing devices (i.e. Laptops, printers etc.) nearby with their infrared or Bluetooth interfaces activated.

Transmitting via Bluetooth directly to a computer (clue medical and clue medical BASIC) or via a computer / mobile Phone to the clue medical Server (clue medical)

Note: Pairing is not possible during measurement.

Note: During pairing don't wear your **clue medical** or **clue medical BASIC** on your body, because you would start a new recording and will therefore not be able to initiate pairing. If you use adhesive electrodes please disconnect the electrode cable from your **clue medical** or **clue medical BASIC**.

#	Step	Preferences		Signal
		clue medical or clue medical BASIC	receiving device	
1	Preparation for pairing		Activate the Bluetooth-module and be sure that it can be found by other Bluetooth-devices. How to make this please read the user manual of the receiving device. Note: after successful pairing you can change the Bluetooth settings back to invisible. Note: if you need additional information please read the user manual of your receiving device or ask your vendor.	
2	Position your device and attempt to deactivate other Bluetooth-receivers close-by	There should not be any RF active device within 1m of the clue medical or clue medical BASIC to avoid physical interferences and distortion effects to the RF signal. If possible, please de-activate other Bluetooth-compatible devices within a radius of 7m to minimize unsuccessful first attempts to pair clue medical or clue medical BASIC with the intended receiver. If there are other active BT devices in range during pairing mode, you may need more than one try to pair to the intended receiver device.		

#	Step	Preferences		Signal
		clue medical or clue medical BASIC	receiving device	
3	Check DIP-Switch settings	Please make sure, that the DIP-Switches settings of your device is correct (switch 2 "up ↑") Note: If switch 2 remains in the "down" ↓ position you may accidentally delete memory.		
4	Switch on your clue medical	Press the button once – then release.		Short flash of orange-green-yellow LED – then the green LED lights up
5	Start pairing	Press the button once again and hold it for approx. 8 seconds. A signal should occur and a Bluetooth compatible device is sought.		Descending tone – yellow LED flashes
6	Receiving device found	Once a Bluetooth-receiving device is found, the green LED flashes along with the yellow.		Green+yellow LED flashes. When no device is found: orange lights and three successive tones (twice short, once long)

#	Step	Preferences		Signal
				On your receiving device a password is required. Please enter 1111 and confirm. Note: if you don't have a password call on your receiving device, make sure, that the device is visible. Note: If both LEDs flash (yellow and green), it could be possible that another, still activated Bluetooth-device near you has received the password call of your clue medical or clue medical BASIC . In this case wait for the failure tone and start the procedure again.
7	Confirm the successful pairing			Mostly you get from your device a success-report which you have to confirm. Note: you get also a positive signal from your clue medical or clue medical BASIC . Successful: green LED lights and ascending tone Failure: orange LED lights and three successive tones (twice short, once long)
8	Pairing successful			
9	Start transmission	To start the transmission press the button twice		Yellow LED flashes

#	Step	Preferences	Signal
10		<p>On your receiving device you will get a message which you have to confirm (If you have authorized clue medical or clue medical BASIC you will not get this message)</p> <p>note: you can find your clue medical or clue medical BASIC in a list of coupled/ authorized devices on your receiving device. You can change these settings so that you don't have to confirm a message for each transmission.</p>	<p>Yellow LED flashes, the green LED lights, if the transmission was successful.</p> <p>Failure: orange lights and three successive tones (twice short, once long)</p>
11	Transmission successful	After transmission clue medical or clue medical BASIC switch off automatically	

clue medical or **clue medical BASIC** are now ready to start a measurement again. If no signal is detected **clue medical** or **clue medical BASIC** switch off automatically.

Note:

clue medical or **clue medical BASIC** use RF-energy below the internationally recommended level during Bluetooth transmission. If you want to reduce such a RF-exposure keep your head and body about 50 cm away from the devices during transmission.

Note:

After successful pairing it is possible to set your receiving device back to "invisible". This means that no third Bluetooth device can find your device to try pairing. For further information please read the operating manual of your receiving device or contact your vendor.

Note:

After transmission **clue medical** or **clue medical BASIC** switches off automatically. This ensures that no further transmission may occur.

The pairing information is stored in the memory of both **clue medical** or **clue medical BASIC** and the receiving device.

With the next transmission attempt, **clue medical** or **clue medical BASIC** contacts the most recent Bluetooth partner. If you intend to connect a new receiving device you can press the button for more than 8 seconds at the next Bluetooth transmission session and initiate a new pairing session.

The table below provides a summary of the indicator lights and acoustic signals:

Spec No.	Purpose	Usage	Acoustic signal	Optical signal
A5.1	Start ECG recording	Press button 1x short	Increasing tone	All LEDs flash – green LED lights up
A5.2	Recording finished		Recording finished	Yellow LED lights up for appr. 10sec.
A5.12	Recording not possible (memory full)			Yellow LED lights up for appr. 10sec.
A5.13	ECG transmission IrDa	Press button 2 x short		Yellow LED flashes
A5.14	Transmission successful		Increasing tone Beepbeepbeepbeepbeep for each ECG (min1 – max10)	Green LED lights up for appr. 10sec.
A5.15	Reset (erase all ECG)	Press button for 10 sec.		Yellow LED lights up
A5.16	Confirmation of reset, all ECG data erased		Descending tone	All LEDs flash
A5.17	Incomplete transmission		Descending tone Beepbeep-beep – beepbeep-beep	Orange LED lights up
A5.18	Start transmission with no ECG in memory		Descending tone Beepbeep-beep – beepbeep-beep	Orange LED light up

7. Activating an account on the clue medical Server

In order to transmit data from the **clue medical** device to the **clue medical Server** you will need to set up an account on www.cluemedical.com. (note: this feature is not available for **clue medical BASIC**)

Procedure:

1. Visit the **clue medical** website (www.cluemedical.com)
2. Go to "365/24 :: clue central login"
3. Go to "create a new account"
4. Enter a personal user name
5. Enter a personal password that contains at least 8 characters (at least one capital letter and one number have to be contained e.g. "Testpass1")
6. Re-enter the password to confirm
7. Go to "create account"

After this procedure a personal account exists and you can activate your **clue medical**.

1. Login on **www.cluemedical.com** on our **clue medical Server**
2. Under "my devices" you will find a button "add device"
3. Here you have to enter the serial number and the activation code of the **clue medical** (You can find the serial number and activation code on the backside of your user manual)
4. Once your **clue medical** has been activated you can find it under "my devices" and you can see all following transmitted measurements.

8. Cleaning and care of your clue medical or clue medical BASIC

- The device and the electrode cable should be cleaned as needed with a damp, soft, lint-free cloth. Warm water, mild soap (pH neutral) or a commercial cleaning product suitable for plastic can also be used.
- The device should be disinfected according to the following instructions at regular monthly intervals and each time the device is given to a patient:
 - o The device and the cable should be cleaned with a damp, soft, lint-free cloth. Warm water, mild soap (pH neutral) or a commercial cleaning product suitable for plastic can also be used.
 - o Commercially available, aldehyde-free surface disinfectants must be used for this purpose (e.g. Gigasept, Dentalrapid AF).
 - o No liquid may get inside of the device while disinfecting it.
 - o Ether, benzene and acetone may not be used.

WARNING!

When cleaning, please be sure that no liquid gets inside the device as this could place the user/patient in danger and destroy the device. If this nonetheless does happen, please contact the **clue medical** hotline under +43 (0)1 7007 32551.

In case of damage the device may no longer be used and must be replaced.

In order to protect the environment, we ask that you dispose of and use all materials and cleaning products properly. The device does not cause any environmental pollution either in or out of operation. The adhesive electrodes should be properly disposed of according to the indications of the electrode manufacturer and may not be reused.

9. Device Specifications

Measurements L/D/W	76 mm x 72 mm x 15 mm
Weight with battery	56 g
Weight without battery	49 g
Operating temperature range	10°C to 45°C
Storage temperature range	-20°C to 60°C
Transport temperature range	-20°C to 60°C
Relative humidity	10% to 95% non-condensed
Operating time w/o change of battery	>400 measurements
Risk class	II a
Degree of protection	BF / IP 20
ECG lead	2 x 1 channel
ECG recording	bipolar and neutral electrodes
Input voltage	10 mV p-p
DC offset correction	< 300 mV
Frequency range: adhesive electrodes ³	0.05 – 40 Hz (-3dB)
Frequency range: fixed electrodes	0.1 - 40Hz (-3dB)
Scanning rate	1000 Hz
Resolution of AD conversion	12 Bit
Memory	30 recordings max.
Battery type	AAA alkaline (1,5V)
	Rechargeable types allowed (NiMH 1.2V)
Battery display	Optical
Electrode monitoring	Yes
IrDA Transmission	Modem (IrComm) to central server over Internet connection
IrDA Transmission	Obex push (PDF file) directly to recipient
Method of heart rate measurement	Average ECG over 2 minutes
Bluetooth module	LMX9838

10. Technical requirements for transmission

With **clue medical** or **clue medical BASIC** you have purchased a high-quality medical device. Because the device is designed to be used with other devices you may experience technical issues unrelated to the **clue medical** or **clue medical BASIC**. We are happy to assist you in configuring your computer systems but you may need to contact the manufacturer of your other devices if the problem persists.

Mobile telephone requirements

Your mobile telephone must have an IrDA or Bluetooth interface and be Internet-capable in order to carry out a data-transmission. Read your mobile phone instruction manual carefully and/or seek advice from your mobile phone provider.


Computer or notebook system requirements

- Computer or notebook with Adobe Reader Version 6.0.1 or higher installed. Download Adobe Reader free of charge at www.adobe.com
- Available USB port
- Operating system: Windows XP - Service Pack 2 or Windows VISTA

Read your computer or notebook instruction manual carefully. For USB IrDA/Bluetooth adapters which are not part of **clue medical** or **clue medical BASIC** accessories, please follow their installation instructions.

Troubleshooting

Problem	Solution
Orange LED flashes when device is turned on	Replace the AAA battery (Item 7 CHANGING THE BATTERY).
Yellow LED glows when device is turned on	Device memory is full. Transmit the data in order to delete the memory (Item 7 TRANSMITTING).
A continuous tone sounds during recording	Device has lost skin contact and indicates this until it regains skin contact. Press the device more firmly against the skin during recordings. If the patient has a lot of chest hair, move the device gently back and forth in order to ensure that there is sufficient skin contact during the recording. When recording with adhesive electrodes, attach the electrode cable to the skin with common bandages a few cm below each of the connection points of the adhesive electrodes.
Data printout is not to scale	On the printer, turn off automatic scaling and set zoom to 100 %. The display is correct if the total length of a 10 second ECG is exactly 25 cm.

Problem	Solution
Transmission via mobile phone is not possible, orange LED flashes with acoustic signaling	The IrDA- or Bluetooth interface on your mobile phone may not be activated – Follow the instructions for your mobile phone. The distance between the interfaces may be too large or too small or the interfaces are not parallel to each other. Reposition the devices.
Transmission via IrDA stick is not possible, orange LED flashes with acoustic signaling	Check the system requirements of the Computer. Make sure the USB IrDA stick is properly installed. Check the distance and position of the IrDA interfaces.
You've forgotten your login data	Call your vendor
IrDA transmission ok, PDF is not on the desktop	Under "settings", go to your computer's "control panel" and make sure that under "wireless connections", the desktop is set as the standard folder for data received.
Symbol  on my PDF printout next to date and time	It is a note that time and date of your clue medical or clue medical BASIC should be updated with a special program (clueTime). Please follow the instructions on the homepage www.cluemedical.com .

11. Explanation of terms

Heart rate variability (HRV)

Heart rate variability (HRV) refers to variations in the heart rate over a shorter or longer measurement period in a heart beat to heart beat analysis. Accordingly, the heart beat is not normally uniform, but varies in a characteristic fashion. HRV is a parameter of the autonomic function of the heart as well as a measure of the heart's ability to regulate itself.

Autonomic nervous system

The autonomic nervous system, consisting of the sympathetic, parasympathetic and enteric nervous system, innervates the smooth musculature of all organs as well as the heart and glands. It regulates the vital functions of breathing, circulation, digestion, metabolism, gland secretion, body temperature and reproduction. It is not arbitrarily controllable; it is autonomous. In addition to the hormone system, it represents one of the two information systems between the individual organs.

Sympathetic nervous system

A component of the autonomic nervous system. It regulates the cardiovascular system including organ activity and causes an increase in performance, increases, among other things, heart rate (pulse) and blood pressure and is also an indicator or measure for stress. The organs controlled by the sympathetic nervous system are the smooth muscle tissues of all organs (arteries, bowels, excretory and sexual organs, hair, pupils), cardiac muscle fibers and some glands (sweat, salivary, digestive glands). Moreover, adipose cells, lipocytes, hepatocytes, renal tubules, lymphatic tissues (e.g. thymus, spleen, lymph nodes) and parts of the immune system are sympathetically innervated.

Parasympathetic nervous system

Another component of the autonomic nervous system. It is also described as vagus nerve since it serves the metabolism, regeneration and build up of the body's own reserves. The parasympathetic nervous system takes care of rest, recovery and protection and automatically controls most internal organs and circulation. It reduces heart rate (pulse) and blood pressure and is significantly affected by respiration. The parasympathetic nervous system controls the smooth muscles and glands of the gastrointestinal tract, the excretory organs, sexual organs and lungs. It also innervates the atria of the heart, the lacrimal and salivary glands in the head area and the inner eye muscles. In contrast, it has no direct impact on the preparatory glands and the entire vascular systems (with few exceptions, such as the genital organs). This is the critical difference between the parasympathetic and sympathetic nervous system, the latter of which innervates all vessels.

Normal range resting heart rate

Range: 60 - 80 beats per minute

Heart rate bradycardia

Slow resting heart rate compared to the normal range, fewer than 60 beats a minute.

Borderline resting heart rate

Range: 80 - 100 beats per minute.

Heart rate tachycardia

With (sinus) tachycardia, the resting heart rate originating in the sinus node is over 100 beats per minute.

Tachogram of cardiac cycle durations

If you determine, for each heart action μ , within a given measurement time (e.g. 2 minutes with a medical device) the associated cardiac cycle duration TH (μ) (e.g. the applicable RR interval) and plot it as a function of the corresponding heart action, you get the "tachogram of cardiac cycle durations" as a characteristic cardiovascular function.

Consequently, the beat to beat variations and thus the heart rate variability are illustrated in such a representation.

FFT spectrum

From the tachogram of cardiac cycle durations, a function in the time range, an equivalent representation in the frequency range can be derived using a mathematical operation: FFT spectrum, referred to in literature as the "(performance) spectrum of heart rate variability". This spectrum is made up of characteristic frequency ranges, in regards to the use of the clue medical family, the following ranges serve as a basis:

Low frequency range (LF) 0.04 to 0.15 Hz: Predominately, sympathetic cardiovascular activity can be attributed to this range and with it also physical and psychological stress.

High Frequency range (HF) 0.15 to 0.4 Hz: Typical for this range is parasympathetic (vagal) activity and with it breathing-synchronous heart rate fluctuations of respiratory sinus arrhythmia.

Very High Frequency range (VHF) 0.4 to 0.5 Hz: A cardiac risk marker can be attributed to this range which is beyond the activity of the resting components of the cardiovascular system.

Spectral measures

By determining applicable integral surface area measurements for the frequency ranges 0.04 - 0.15 Hz and 0.15 - 0.4 Hz for a absolute FFT spectrum and division with applicable normal values, absolute spectral measures M in percent can be introduced: M_{LF}^* [%]... weighted measure for sympathetic activity, stress and strain M_{HF}^* [%]... Measure for parasympathetic activity, relaxation and recovery M_{LF}^* represents the measure M_{LF} multiplied by the square of the average heart rate which the above standardized surface area measurement. It follows from the above that higher heart rates significantly raise this weighted measure M_{LF}^* whereas rates lower than the normal heart rate value of approx. $f_H = 70-1$

min considerably reduce it. This completely corresponds to physiological behavior since higher heart rates activate the sympathetic nervous system whereas heart rates below the normal value activate the parasympathetic nervous system.

Weighted balance

We know from physiology that in the LF range of the FFT spectrum, derived from the cardiac cycle duration tachogram, predominately the sympathetic nervous system is illustrated although vagal (parasympathetic) portions may also be included. Consequently, the balance determined from the straight LF and HF ratio can only be quantified to a limited extent. Applying the above spectral measures M_{LF}^* as a weighted measure and M_{HF} as a basis results in the weighted balance $B^* = M_{LF}^* / M_{HF}$.

Cardiovascular stress

Stress affects the nervous system by increasing sympathetic nervous system activity and inhibiting the vagus. As a result, the measure derived from the FFT spectrum M_{LF}^* represents a measure for sympathetic activity, stress and strain. In contrast, the measure M_{HF} is an indication of parasympathetic activity, relaxation and recovery. Since the weighted balance B^* is derived as a quotient from the two measures M_{LF}^* and M_{HF} , an increase in sympathetic activity, stress and strain can be inferred from a rise in B^* . If the weighted balance is reduced, however, a reduction of these sympathetic components, a rise in parasympathetic activity, of relaxation or recovery can be inferred. As such, M_{LF}^* and B^* represent quantitative measures for cardiovascular stress.

IrDA

Infrared Data Association - universal, wireless 2 way data transmission based on infrared light.

Sternum (breast bone)

Bone in the anterior centre of the thorax which connects to the ribs or their cartilaginous extensions.

12. Symbols and what they mean

CAUTION!

Precautions for safe use of the device.

WARNING!

Failure to heed this warning may result in serious injury to patients or damage to the device.



Attention, see accompanying documents



Date of manufacture



Manufacturer

SN

Serial Number



BF type applied part

WEEE symbol pursuant to DIRECTIVE 2002/96/EC



This symbol on the product or its packaging indicates that this product is not to be treated as normal household garbage, rather it must be disposed of at an acceptance point for recycling of electrical and electronic equipment. You can obtain more information from your local authority, the local disposal companies or the company where you purchased the product.



Lead-free pursuant to Directive 2002/95/EC
No lead is added to this product in any way.



The device contains components which are used to produce non-ionizing radiation

13. Warranty

All systems excluding sensors, cables and batteries are covered vis-à-vis the purchaser by a two year warranty. Telozo GmbH undertakes to repair any systems found to be defective under this warranty or to replace them with a new device at no charge provided that the defect was communicated to Telozo GmbH by the purchaser along with the serial number within the valid warranty period. This warranty is the sole and exclusive form of legal redress to which the purchaser is entitled for devices or accessories supplied which turn out to be defective in any way.

All repaired or replaced devices shall be delivered to the customer by Telozo GmbH free of charge. Costs for sending complaints to Telozo GmbH are excluded from this warranty.

These systems are sensitive devices and may only be repaired by experienced and specially trained personnel. The warranty shall become void if

- the device has been opened,
- maintenance work has been performed by personnel other than Telozo personnel,
- tampering or
- any forms of misuse or improper use of the device have occurred.

All work not covered by the provisions of the warranty shall be performed according to Telozo GmbH prices and charges applicable at the time the device is returned to Telozo GmbH.

WARRANTY EXCLUSION

THE WARRANTY STATEMENTS ESTABLISHED IN THIS MANUAL ARE EXCLUSIVE. NO OTHER WARRANTIES OF ANY NATURE, WHETHER LEGAL, WRITTEN, VERBAL OR TACIT, INCLUDING ANY GUARANTEE OF SUITABILITY FOR A PARTICULAR PURPOSE OR MARKETABILITY SHALL APPLY.

14. Manufacturer's Declaration of Compliance

The following table contains specific information on the conformity of this device with IEC Standard 60601-1-2.

clue medical uses RF energy for its functions.

Result of the EMC-tests according to IEC 60601-1-2: **clue medical** meets all the requirements

Fur further informations regarding EMC-testing please contact Telozo GmbH Telemedizin

Guidelines and Manufacturer's Statement –

ELECTROMAGNETIC EMISSIONS - For all DEVICES and SYSTEMS Guidelines and Manufacturer's Statement – ELECTROMAGNETIC INTERFERENCE EMISSIONS

clue medical is designed to operate in an electromagnetic environment as described below.

The **clue medical** customer or user should make sure that the device is operated in such an environment.

Interference emission measurements	Compliance	Electromagnetic environment – Guidelines
RF emissions according to CISPR 11	Group 1	clue medical uses RF energy for its functions. Its RF emission is very low and it is unlikely that electronic devices in close proximity will experience interference.
RF emissions according CISPR 11	Class B	clue medical is suitable for use in facilities other than residential ones which are directly connected to the PUBLIC POWER GRID which also provides power to buildings used for residential purposes.
Emission of harmonic current according to IEC 61000-3-2	not applicable	
Emission of voltage fluctuations/flicker according to IEC 61000-3-3	not applicable	

Guidelines and Manufacturer's Statement –

Electromagnetic INTERFERENCE IMMUNITY – for all DEVICES and SYSTEMS

clue medical is designed to operate in an electromagnetic environment as described below.

The **clue medical** customer or user should make sure that the device is operated in such an environment.


ELECTRO-MAGNETIC INTERFERENCE IMMUNITY tests	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTRO-MAGNETIC ENVIRONMENT guidelines
Discharge of static electricity (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be made of wood or concrete or feature ceramic tiles. If the floor consists of synthetic material, the relative humidity should be at least 30%
Electric fast transients/ bursts according to IEC 61000-4-4	± 2 kV for AC power lines ± 1 kV for input and output lines	not applicable clue medical ® has no lines longer than 3 meters.	
Surges according to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode voltage	not applicable clue medical ® is only battery-operated and has no AC supply lines.	
Blackouts, Brownouts and fluctuations of the power supply according to IEC 61000-4-11	< 5% UT (>95% crash of the UT) for ½ period 40% UT (60% crash of the UT) for 5 periods 70% UT (30% crash of the UT) for 25 periods < 5% UT (>95% crash of the UT) for 5s	not applicable clue medical ® is only battery-operated and has no AC supply lines.	
Supply frequency magnetic field (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields of the mains power frequency should comply with the typical values of business and hospital environments.

Note: UT is the mains alternating voltage before applying the test levels.

Guidelines and Manufacturer's Statement – ELECTROMAGNETIC INTERFERENCE IMMUNITY For DEVICES or SYSTEMS which are not LIFE-SUPPORTING

clue medical is designed to operate in an electromagnetic environment as described below.

The **clue medical** customer or user should make sure that the device is operated in such an environment.

ELECTROMAGNETIC INTERFERENCE IMMUNITY tests	IEC-60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTRO-MAGNETIC ENVIRONMENT guidelines
Conducted RF interference quantities according to IEC 61000-4-6	3 V _{eff} 150 kHz to 80 MHz	3 V _{eff}	Portable and mobile wireless devices should not be used in closer proximity to the clue medical® (including cables/lines) than the recommended safety distance calculated based on the transmitting frequency and the applicable formula. Recommended safety distance: $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ for 800 MHz to 2.5 GHz with P as the rated output of the transmitter in watts [W]
Radiated RF interference quantities according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	according to the information provided by the manufacturer of the transmitter and d as recommended safety distance in meters [m]. Field strengths from fixed RF transmitter as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Interference is possible in the proximity of devices featuring the following pictograph. 

- Note 1 The higher frequency range applies in case of 80 MHz and 800 MHz.
Note 2 These guidelines may not be applicable in all cases. The spread of electromagnetic quantities differs depending on the absorption and reflection of buildings, objects, and people.
Note a The field strength of stationary transmitters such as base stations of mobile phones and land mobile devices, ham radio stations, AM and FM radio, and TV broadcasters are theoretically not 100% predictable. A site study is recommended to determine the electromagnetic environment as it pertains to the stationary transmitters. If the measured field strength at the site where clue medical® is used site exceeds the concordance levels listed above, the clue medical® should be monitored to document proper functionality and operation as intended. Additional measures might become necessary, e.g., modifying orientation or a different location for the clue medical® if unusual performance characteristics are observed.
Note b The field strength should be less than 3 V/m for the frequency range of 150 kHz to 80 MHz.

Recommended Safety Distances between Portable and Mobile RF Telecommunications Devices – For DEVICES or SYSTEMS which are not LIFE-SUPPORTING

The **clue medical** is intended for use in an electromagnetic environment where RF interference quantities are controlled.

The customer/operator of the **clue medical**® can contribute to lowering electromagnetic emissions by complying with the minimum distance between portable and mobile RF telecommunications devices (transmitters) and the **clue medical**® – depending on the output power of the communication device listed below.

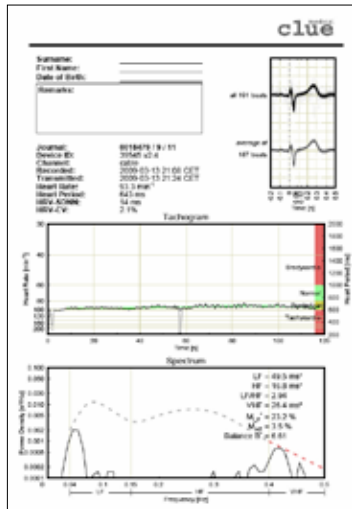
Rated output of the transmitter [W]	Safety distance based on the transmitting frequency [m]		
	150 kHz to 80 MHz $d = 1.17 \times \sqrt{P}$	80 MHz to 800 MHz $d = 1.17 \times \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33 \times \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.73
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11,70	11,70	23.30

The safety distance d in meters [m] for transmitters with a max. rated output not listed in the table above can be calculated by applying the corresponding formula in the respective column. P is the max. rated output of the transmitter in watts [W] as specified by the transmitter manufacturer.

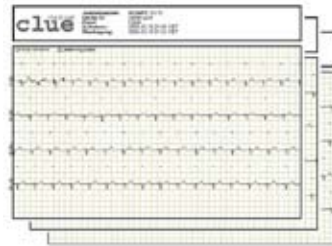
- Note 1 The higher frequency range applies in case of 80 MHz and 800 MHz.
Note 2 These guidelines might not be applicable in all cases. The distribution and spread of electromagnetic quantities differs depending on the absorption and reflection of buildings, objects, and people.

15. Analysis notes

1-page measurement values:



3-pages ECG:



- Journal: ID on the server/ count of all measurements/ count of memory erasure
- Device-ID: serial number and current Firmware-version
- Channel: indicates how recording was performed (adhesive or fixed electrodes)
- Recorded: time of recording
- Transmitted: time of transmission
- Heart Rate: measured over 2 minutes
- Heart Period: average Heart Rate Period
- HRV-SDNN: absolute Heart Rate Variability
- HRV-CV: relative Heart Rate Variability in %
- Tachogram: tachogram of cardiac cycle durations
- Spectrum: sympathetic and parasympathetic regulations
FFT analysis