BTL-08 HOLTER

USER'S MANUAL

CONTENTS

1 GENERAL CHARACTERISTICS OF THE DEVICE

BTL-08 Holter is an advanced ECG electrocardiogram recorder. It is primarily intended for patients with symptoms that may be related to cardiac arrhythmia, such as heart palpitation, fainting or temporary loss of consciousness. Clinical indications also include the assessment of efficacy of anti-arrhythmia therapy, recording and detection of myocardium ischemia, verification of the pacemaker operation and others.

BTL-08 Holter records the electric activity of the human heart using electrodes attached to a patient's chest for a relatively long period of time – usually from 24 to 48 hours. The data are then compared with the patient's activities throughout the period. The comparison and the analysis facilitate a more precise diagnosis.

A timely examination with **BTL-08 Holter** may detect serious cardiac irregularities that would be undetectable by standard ECG examination methods (cardiac arrhythmia, shape of ECG curve). The device has been designed for long-term recording of the patient's normal activities, has no known contraindications, and facilitates ambulatory recording and recording of patients, whose condition does not allow for ECG stress examination.

BTL-08 Holter consists of a digital recorder (a Holter monitor), patient cables, self-adhesive electrodes and PC assessment workstation equipped with software for subsequent analysis and session archiving.

BTL-08 Holter, together with BTL CardioPoint-Holter software, enables a detailed analysis, diagnostics and printing of ECG curves. Although equipped with a very wide range of functions, it nevertheless features a very user-friendly interface.

The BTL-08 Holter can be used for recording of infants weighting less than 10 kg because it complies with IEC 60601-2-47:2012 standard defining the frequency spectrum characteristics (§201.12.4.4.108).

The BTL-08 Holter can be used for measurement of ST segment shifts because it complies with IEC 60601-2-47:2012 standard defining the frequency spectrum characteristics (§201.12.4.4.108).

1.1 INTENDED PURPOSE

BTL-08 Holter is a portable device intended for a continuous non-invasive recording of the cardiovascular electrical activity and the related data such as audio data and patient's movements.

1.2 USER PROFILE

The BTL-08 Holter shall be used by medically educated personnel as well as by patients during their common activities. The medically educated user (professional user) shall be familiar with all safety precautions, operating procedures and maintenance instructions given in this User's Manual.

1.3 OPERATING ENVIRONMENT

The BTL-08 Holter is intended to be used primarily in hospitals, but it can also be used in clinics, medical centers or wherever the Holter ECG monitoring is performed. The BTL-08 Holter can be used during patients' usual activities in common life.

1.4 PATIENT PROFILE

The BTL-08 Holter can be used on all adult or paediatric patients without limitation of age, gender, height and weight, including paediatric patients with less than 10 kg of weight.

1.5 FUNCTION RELATED TO PATIENT

In specific cases the patient can operate the device. The role of the patient is to record the daily activities by patient push button. For this purpose is essential to be familiar with information descried in the chapter 4.3.2 Comments. Other related chapters: 2.5 Check of disconnected leads, 6.2 Device safety and 7.1 Technical parameters are advised to be familiar with. Other chapter are intended for medically educated persons.

1.6 INDICATIONS

The indications for Holter ECG monitoring include, among others, assessment of presence, absence and intermittent or transient condition changes of:

- Arrhythmias
- Conduction defects
- Myocardial ischemia
- Heart rate variability
- Neurohumoral influence
- Structural myocardial changes
- Myocardial necrosis
- Previous invasive cardiovascular treatment

1.7 CONTRAINDICATIONS

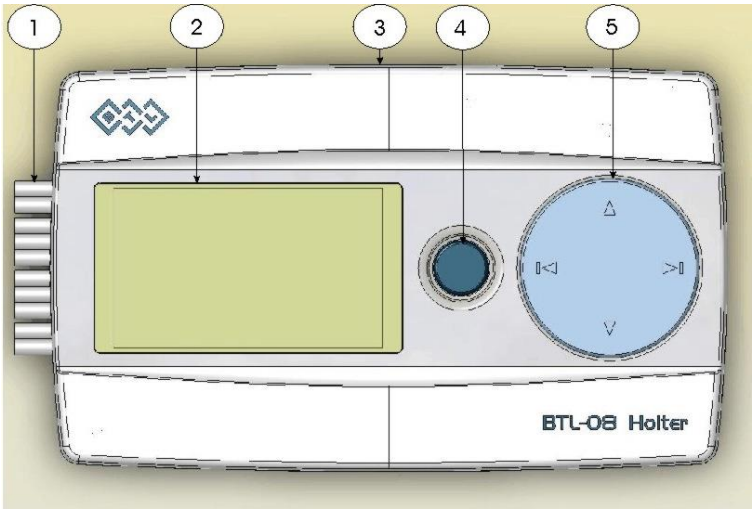
There are no known contraindications for Holter ECG monitoring examinations.

1.8 POSSIBLE SIDE EFFECTS

There are no known possible side-effects for Holter ECG monitoring examinations.

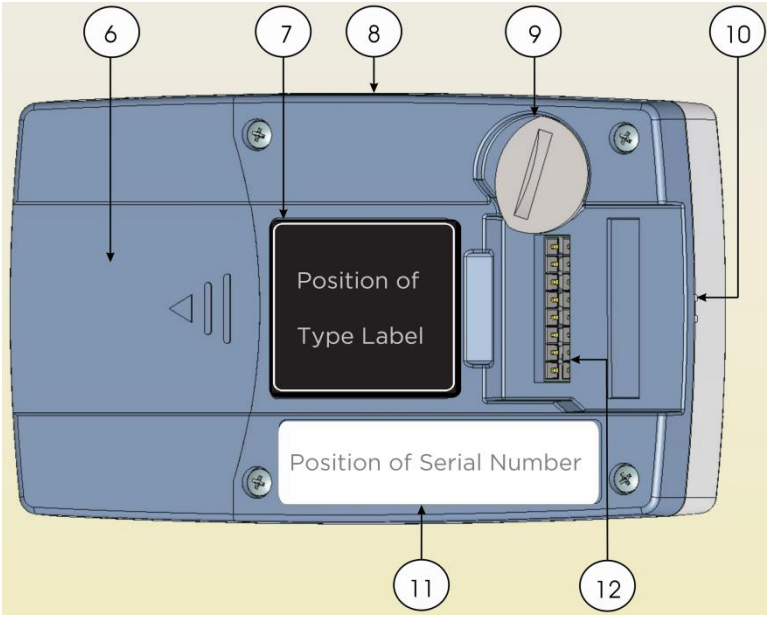
2 INSTRUCTIONS FOR USE

2.1 TOP PANEL OF THE BTL-08 HOLTER



1. patient cables
2. display
3. USB connector
4. patient push-button
5. four-way controller

2.2 REAR PANEL OF THE BTL-08 HOLTER



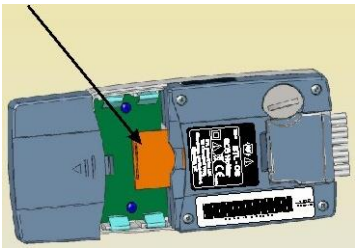
6. battery compartment
7. ID label
8. USB connector
9. patient cable lock
10. microphone and loudspeaker apertures
11. serial number plate
12. connector for patient cables

2.3 INITIAL SETUP

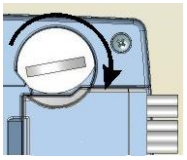
Remove the device from the protective wrapping. The device should be kept out of the direct sunlight. Do not place any hot objects or objects filled with water or any other liquid onto the device. Do not place the device near any equipment which produces strong electromagnetic, electric or magnetic field (diathermic or X-Ray devices etc.), as this could have a negative effect on the device function.

For further questions, please contact an authorized BTL service centre.

To switch the device on:



- Charge the battery in the included charger (basic accessories).
- Open the battery compartment (6) and insert an SD memory card in the slot with label facing up (see picture).
- The memory card clicks when inserted properly. To eject, press the card softly and the card will slide out.
- Connect the 5 or 10-lead patient cables (10).
- When the patient cable is connected to the device, lock it by the lock (9) depicted on the picture.



Note: To turn the lock use a coin or a similar object inserted in the central groove.

Insert a set of fully charged batteries into the battery compartment (6) and close it. The device will beep and the LCD display will turn on and show the **Main Menu**.

The BTL-08 Holter's factory time was set in the GMT +3 hours time zone. If the device is used in a different time zone, correct the preset time before using it. Proceed according to Chapter 4.3.3 to change the time manually or according to Chapter 3.2.1 to change it automatically (in this case the device is connected to a PC via USB cable and synchronizes its clock with Windows system).

2.3.1 INSTALLATION OF USB ACCESSORIES TO PC

Plug the cable of the USB hub to the PC. This will give you 4 additional USB ports for connection of the following holter accessories:

- USB cable for connection of the holter unit.
- Connect the SD card reader with the attached cable.
- Plug in the USB key of the BTL CardioPoint-Holter program and install the program according to the attached manual.

2.3.2 INSTALLATION OF THE BTL CARDIOPOINT-HOLTER SOFTWARE

Please insert the installation USB with **BTL CardioPoint-Holter** software into a USB port on your computer. Follow the instructions of the installation wizard and the information in the user manual of BTL CardioPoint-Holter application.

Minimum PC configuration:

Please see **BTL CardioPoint-Holter** user manual.

For more information on the **BTL CardioPoint-Holter** software, please contact your local BTL branch or distributor.

2.4 DEVICE RESET

If the device stops responding (due to an electromagnetic interference or for any other reason), you can reset it to its initial settings by replacing and reinserting the batteries (**9**). The device will restart and switch on immediately and you will be able to use it as usual.

2.5 CHECK OF DISCONNECTED LEADS

The device will indicate any unconnected or wrongly attached electrodes or cables by an acoustic signal and by a warning message on its display.

Before the start of the ECG signal recording, you can also check the quality of the signal on the device display (**Main Menu – Test**). You can view either the signal monitor or the lead quality monitor. The level of noise is depicted by the height of the vertical line, where the lower the line the better the signal quality. Disconnected electrode is shown as a dashed line.

If the device shows a disconnected electrode, check the attachment of the electrodes to the patient. It is prudent to start recording only when the device ceases to show an error in electrode connection.

If you start recording the signal even though the device shows a misconnected electrode, the recording might misrepresent the patient's actual condition.

2.6 BATTERIES

The exact type of batteries required for the device is specified in Chapter **Technical Specifications**. In order to guarantee the minimum operating time, we recommend using exclusively batteries supplied by BTL.

We also recommend using a set of freshly charged batteries for each recording session. Do not use charged batteries which were stored for more than 3 weeks, as charged but unused batteries gradually self-discharge. The self-discharging effect is an inherent restriction of the technology used and cannot be eliminated.

After inserting batteries the device will automatically check their condition. If it detects that the batteries are partially or completely flat, it will indicate the fact by an acoustic signal and by the "Low Battery" warning on the display. The warning message will remain on the display for a period of 15 minutes at the least.

If the batteries become flat during a recording session, it is necessary to replace them with fully charged batteries within 1 hour. If the batteries are replaced in time, the device will resume the recording session. However, the device will not continue in the examination, if the batteries are not replaced in time.

Note: The data recorded before the battery runs flat are stored in the memory card and can be freely accessed and analyzed.

Please charge the batteries using only the charger included in the basic accessories supplied with BTL-08 Holter.

The full charging takes from 3 to 4 hours. The charger will indicate that the batteries have been fully charged by a green LED light.

If you want to avoid gradual self-discharging, leave the batteries in the charger even after they have been fully charged. The trickle charger will supply the batteries with a small amount of current, which will prevent them from self-discharging and keep them fully charged.

If the battery starts losing its capacity and begins to discharge more rapidly, replace it with a new one.

Protect the batteries against short-circuits. If a battery starts leaking, stop using it immediately.

3 EXAMINATION

3.1 PLACEMENT OF ELECTRODES

The BTL-08 Holter can only be used with self-adhesive electrodes that are disposable and single-use only. The electrodes should be discarded according to hospital or physician guidelines.

The quality of the ECG signal recording is primarily affected by the contact between the patient's skin and the electrode. To ensure that the electrode is properly attached, please observe the following recommendations:

- The skin should be warm, the patient should be relaxed.
- Use an alcohol pad to clean the sites. If the patient has noticeable hair on electrode sites, shave the hair with a safety razor.
- Abrade tough and roughened skin on electrode areas (with a pumice stone, for example).
- Electrodes in an opened pouch may dry out, therefore do not open pouch until necessary. Dry electrodes may decrease the ECG signal quality.

Patient's clothing – please inform the patient that the following clothing limitations apply during the recording session:

- natural fabrics only (cotton, silk, linen, hemp) Artificial fabrics may induce static discharges, which create similar artefacts as a pacemaker discharge.
- no underwired underwear

Electrode attachment: attach the electrode with a hypoallergenic adhesive tape. Adjust the electrode cable into the shape of a loop around the electrode. The movement of an unfixed cable may cause an artificial shift in isoline and distort the subsequent ST analysis.

When using a **5-lead patient cable** connect the electrodes in the following order:

- Connect the electrode C first.
- Then connect other limb electrodes R, L, F, N.

When using a **10-lead patient cable** connect the electrodes in the following order:

- Connect the electrode N (in AHA marking electrode RL) first.
- Then connect other limb electrodes R, L, F (in AHA marking electrodes RA, LA, LL).
- Finally connect the chest electrodes in the following order: C4 – C2 – C1 – C3 – C6 – C5 (in AHA marking electrodes V4 - V2 - V1 - V3 - V6 - V5).

The following chapters describe the precise location of electrodes for the selected lead system.

3.1.1 3 CHANNELS

This attachment method is suitable for all standard Holter examination methods. This connection provides higher amplitudes of the ECG curve than the resting ECG connection. Use a 5-lead patient cable to connect the electrodes as follows:

IEC MARKING

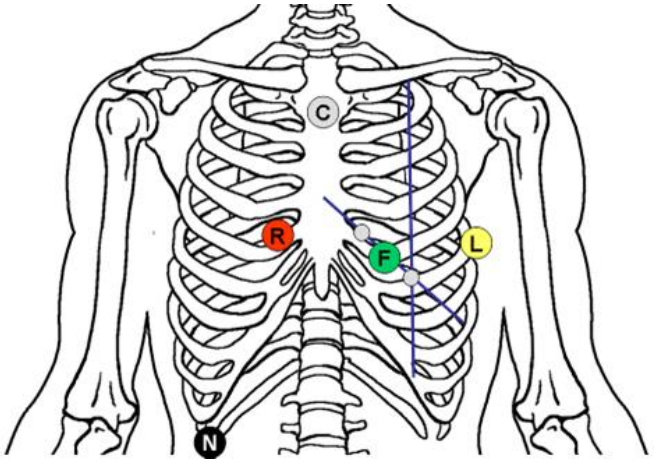
C – white - cranial end of the sternum (manubrium connection)

R – red - right border of the sternum, fifth rib

L – yellow - left anterior axillary line, fifth intercostal space along the MDCL line

F – green - forth rib, halfway between the left sternum and MDCL line

N – black - right anterior axillary line, costal edge



3.1.2 7 CHANNELS

This type of connection is known as the simplified Mason-Likar lead system and it is particularly suitable for the examination of arrhythmia or in case of possible defibrillation. The shapes of QRS complexes at this connection correspond to the resting ECG for the specific position of the patient.

Use a 5-lead patient cable for connection.

IEC MARKING

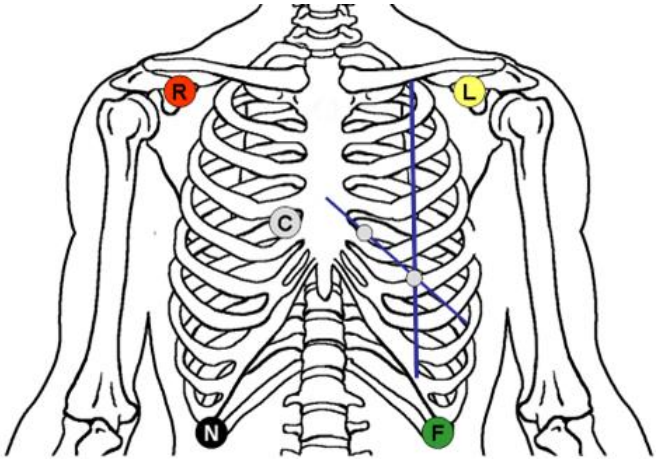
C – white - right border of the sternum, fourth intercostal space

R – red - right lateral clavicle

L – yellow - left lateral clavicle

F – green - left anterior axillary line, costal edge

N – black - right anterior axillary line, costal edge

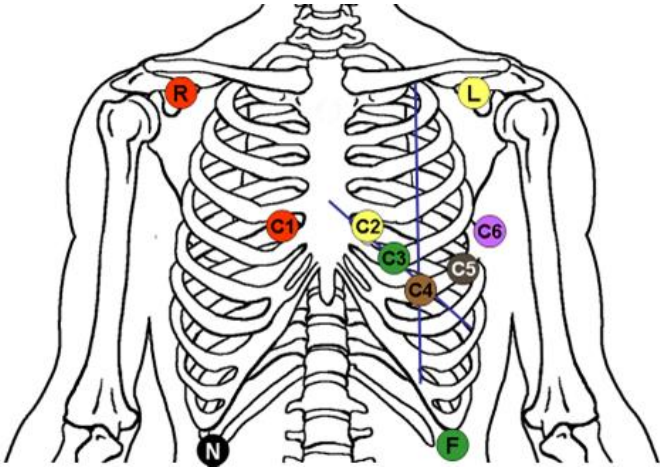


3.1.3 12 CHANNELS

This type of connection is known as the Mason-Likar lead system. It is suitable for the examination of arrhythmia and ischemia. The shapes of QRS complexes at this connection correspond to the resting ECG for the specific position of the patient.

Use a 10-lead patient cable for connection.

IEC MARKING



N – black - right anterior axillary line, under the costal edge

R – red - right lateral clavicle

L – yellow - left lateral clavicle

F – green - left anterior axillary line, costal edge

C4 – brown - fifth intercostal space along the MDCL line

C2 – yellow - fourth intercostal space, left border of the sternum

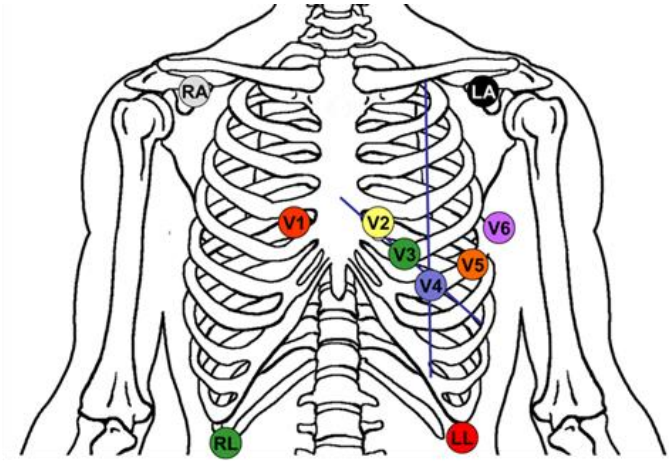
C1 – red - fourth intercostal space, right border of the sternum

C3 – green - halfway between C2 and C4

C6 – purple at C4/C5 height in the central axillary line

C5 – black - at C4 height in the anterior axillary line, halfway between C4 and C6

AHA MARKING



RL – green - right anterior axillary line, under the costal edge

RA – white - right lateral clavicle

LA – black - left lateral clavicle

LL – red - left anterior axillary line, costal edge

V4 – blue - fifth intercostal space along the MDCL line

V2 – yellow - fourth intercostal space, left border of the sternum

V1 – red - fourth intercostal space, right border of the sternum

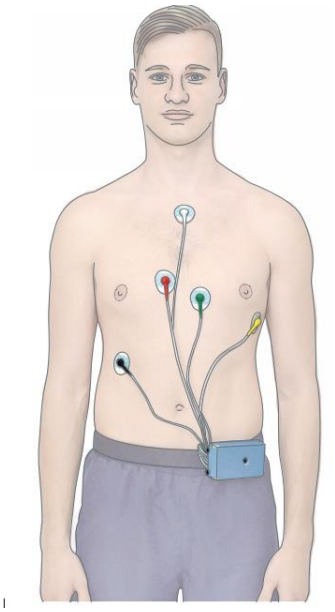
V3 – green - halfway between V2 and V4

V6 – violet - at V4/V5 height in the central axillary line

V5 – orange - at V4 height in the anterior axillary line, halfway between V4 and V6

3.1.4 WEARING OF THE HOLTER

When the electrodes are attached on the patient´s body and patients cable are inserted to the holter connector the device is intended for wearing in the pouch, which could be attached by belt around the waist.



3.2 START OF EXAMINATION

There are several methods how to insert the examination parameters and start recording. The following chapters describe the methods in more detail.

3.2.1 START EXAMINATION VIA USB CABLE

- Connect the **BTL-08 Holter** device to your PC via the USB cable (8).
- Run the **BTL CardioPoint-Holter** software.
- Proceed according to the User's Manual for the **BTL CardioPoint-Holter** software.

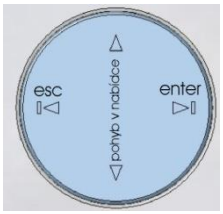
3.2.2 START EXAMINATION VIA PRE-SET SD CARD

This way of activation enables to start examination without connection to a computer by means of a pre-prepared SD card. If the examination is started this way, the BTL CardioPoint-Holter keeps the automatic assignment of examination to the patient.

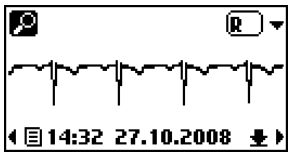
It is particularly useful for preparation of cards for individual patients in advance and enables the holter to be installed at the patient by a nurse, without the PC and the BTL CardioPoint-Holter software.

- Connect the memory card reader into USB socket.
- Insert an empty SD card into the reader.
- Run the **BTL CardioPoint-Holter** application.
- Proceed according to the User's Manual of the **BTL CardioPoint-Holter** software.
- Insert the memory card into the device. When you turn the device on, it will display the "Setting Saved" message and the "Continue" option 
- When you confirm the "Continue" option, you will move to the Examination option, where you can check the pre-set data.
- If everything appears in good order, press the enter button  on the controller (5) for a couple of seconds to start examination.

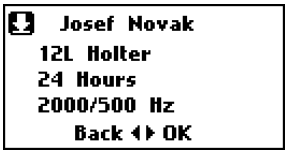
3.2.3 START EXAMINATION FROM THE DEVICE



- Insert batteries and switch the device on (6).
- The LCD will display the Main Menu. You can move between the items of the menu using a four-way controller (5).
- Enter the required information (date and time of recording session, type of lead system used, date, time, etc.) via the Main Menu – Exam Settings.
- Enter **Main Menu – Examination** and check the quality of attachment of electrodes on the patient‘s body. You will see a screen showing a signal from a selected electrode. Use up or down buttons to select an electrode for which you wish to display the signal.



- Press the **enter** button on the controller (5) to pass to the next screen and check the entered data.



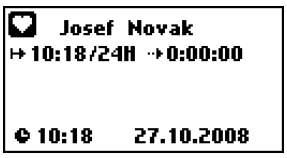
- If everything is correct, start recording by long pressing of the **enter** button ▷▯ on the controller (5).

3.2.4 AUTOMATIC START OF THE EXAMINATION USING THE DEVICE

- The device containing batteries (6), which is not connected with PC (BTL CardioPoint-Holter program) and is left for 20 minutes without pressing a key, will start examination automatically.
- This feature of the device shall eliminate the risk that the operator forgets to start the patient's examination.

3.3 PROCESS AND END OF EXAMINATION

After the start of examination the display shows information about the recording in progress:



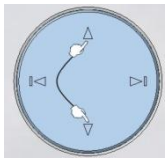
- patient's name
- start time of the recording (on the bottom line)
- recording time
- recording time elapsed (hours: minutes: seconds)

During the recording the display goes out. After short pressing of any button the display lights up for 15 seconds.

When the examination is running, the user is alerted by a sound signal and a display message that an electrode is wrongly connected (Chapter 2.5) or that the batteries are low (Chapter 2.6). Always follow the instructions in this Manual.

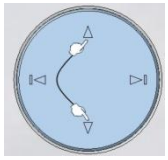
The device also alerts the user if the batteries are out.

The signal recording will stop at the end of the pre-set examination session. The device will indicate the end of the examination by an acoustic signal and by a message on the display.



If you start recording by mistake, remove and replace the batteries. The device will show the message "Record found. Searching…". If you do not want to save the completed record, press both the up and down arrow of the four-way controller (5). The device will offer an option to erase the old record and prepare the device for a new record on the same memory card.

After finding the interrupted examination the device offers the user to follow up with it and waits for 2 minutes for the rejection. If the user does not reject the query within the 2 minutes, the device follows up with the examination automatically.



If you want to interrupt the running examination at any time, press the up and down arrow of the controller (5) simultaneously. Then take the batteries out from the device.

If you do not erase a completed record, the device will not allow you to start a new recording session with the same memory card and you will have to replace the memory card with an empty one. If the card contains an old examination record, which you want to keep, do not use the device.

The device will also automatically stop the examination after the time period set by the operator before the start and announces it by a sound signal and the "Recording finished!" message on the display.

3.4 EXPORTING DATA FROM BTL-08 HOLTER

Export the recorded data from the BTL-08 Holter into your PC by using a card reader.

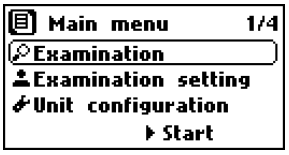
- connect the memory card reader into a USB slot
- insert the card into the card reader
- run the **BTL CardioPoint-Holter** software
- proceed according to the User's Manual of **BTL CardioPoint-Holter** software

3.5 MEASUREMENT AND DIAGNOSTICS RELIABILITY

The diagnostics can only be considered reliable if the reading has not been impaired by electromagnetic interference, myopotential noise and other artefacts or by any other interference, and provided that the device correctly determines the key points of the P-QRS-T complex.

4 MAIN MENU SETUP

This menu is displayed automatically when you switch the device on (i.e. as soon as you insert the batteries). The main menu contains the following submenus:



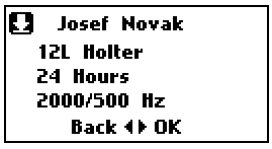
- Examination
- Examination setting
- Unit configuration
- Information

4.1 EXAMINATION

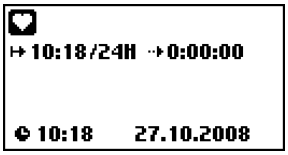
In this submenu press the enter button ▷▯ on the controller (5) to proceed to starting of examination.

First check the quality of attachment of electrodes on the patient‘s body. You will see a screen showing a signal from the selected electrode. Use up or down arrows to select an electrode for which you wish to display the signal.

Press the enter button on the controller (5) to pass to the next screen and check the entered data.



If everything is OK, start recording by long pressing of the enter button ▷▯ on the controller (5). The screen will display data about the recording in progress:



- start time of the recording (on the next line)
- recording time
- recording time elapsed (hours:minutes:seconds)

4.2 EXAMINATION SETTING

This submenu offers the following settings:

- duration of the recording session (**Duration**)
- lead system (**Lead System**)
- signal sampling frequency (**Frequency**)

4.2.1 DURATION

Select the total duration of the recording session. You can choose from the following options:

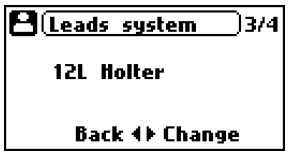
- 12h
- 24h
- 48h
- 7 days
- unlimited

4.2.2 LEAD SYSTEM

Select the lead system to be used in the test.

For the 5-wires cable you can choose from among:

- 7L Holter
- 3L Bipolar Holter

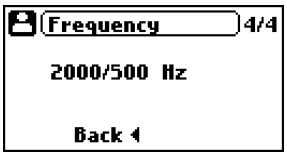


For the 10-wires cable you can choose from among:

- 12L Holter
- 12L Resting

4.2.3 FREQUENCY

This setting determines the signal sampling frequency, which affects the signal quality. The default value of 2000/500 Hz determines that the device samples 2000 samples per second.



Depending on the current signal quality saves the data in either of those frequencies. If the signal exhibits fast and notable changes (such as in a patient with a pacemaker), data are stored at 2000 samples/second, otherwise the lower sampling frequency is used instead (500 Hz).

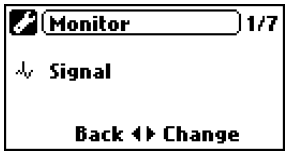
4.3 UNIT CONFIGURATION

This submenu allows you to:

- set up the signal visualization (Monitor)
- set up the patient push button (Notes)
- set up the time (Time)
- set up the date (Date)
- select the communication language (Language)
- switch on/off the keypad tones (Key tones)
- change the display contrast (Contrast)

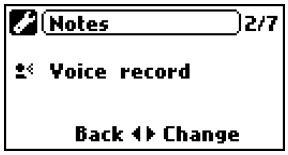
4.3.1 MONITOR

This option lets you select whether the display will show the quality of the **signal** or the signal **noise level** before the start of the ECG recording.



4.3.2 NOTES

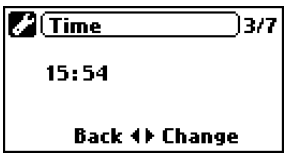
This option sets the function of the patient push button (4). During the recording, the patient push button may function as:

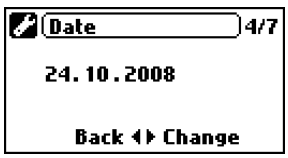


- Patient push button: when the patient presses the button the device will record any significant events (start and end of physical exertion, weakness, chest pain etc.)
- Voice record: in this setting the patient may press the patient push button to record a short voice recording (of up to 10 seconds). The patient does not have to remember the time or the cause of the event.

4.3.3 DATE AND TIME

This option sets the internal date and time in the device. The time and date are saved together with the recorded data. The device remembers the time and date even with flat batteries.

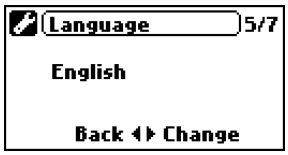




4.3.4 LANGUAGE

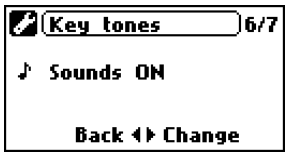
This option sets the language in which the device communicates.

The change will come into effect after the device restart.



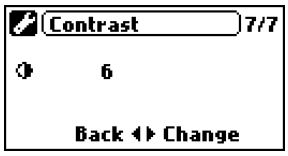
4.3.5 KEYPAD TONES

This option allows the user to switch on / off the keypad tones.



4.3.6 DISPLAY CONTRAST

This option allows the user to set the required display contrast. The contrast can be set by pressing the arrows on the four-way controller (5).



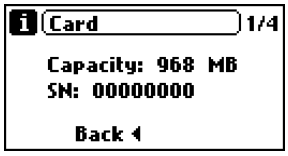
4.4 INFORMATION

This submenu displays:

- type and size of the inserted memory card (**Card**)
- information about the device owner (**Device Owner**)
- information about the device (**Unit info**)

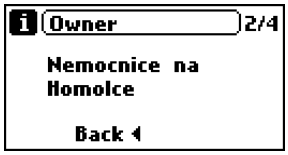
4.4.1 CARD

This option shows the size and serial number of the inserted memory card. The device will load the information automatically as soon as the memory card is inserted.



4.4.2 DEVICE OWNER

This option displays the name of the medical facility or the name of the doctor, who owns the device. The information is entered from the PC (via a USB cable or memory card reader).



4.4.3 UNIT INFO

This option shows the key device information, its serial and firmware number.

The information might be necessary for the communication with the sales department

The device will load the data automatically when it is switched on.

5 LIST OF STANDARD ACCESSORIES

The device cannot be used with any accessories, medical aids and medical equipment other than those specifically listed below.

The list refers to accessories available for **BTL-08 Holter**.

Accessories for BTL-08 Holter*:

- Patient cable for Holter, 5-lead, IEC-EU
- Patient cable for Holter, 10-lead, IEC-EU
- Patient cable for Holter, 10-lead, AHA/AAMI
- Pouch with belt straps
- Rechargeable batteries, AA, 4 pcs
- SD card 2GB
- ECG electrodes, adult, universal self-adhesive

Accessories for BTL-08 Holter (set includes the BTL CardioPoint software)*:

- Patient cable for Holter, 5-lead, IEC-EU
- Patient cable for Holter, 10-lead, IEC-EU
- Patient cable for Holter, 10-lead, AHA/AAMI
- Pouch with belt straps
- Rechargeable batteries, AA, 4 pcs
- SD card 2GB
- ECG electrodes, adult, universal self-adhesive
- Portable case
- USB SD card reader
- Mini USB cable
- USB 2.0 HUB
- USB extension cable
- Battery charger
- User's manual
- BTL CardioPoint software USB

* Accessories are subject to alteration according to selected BTL-08 Holter model (see Chapter 7.2) and the conditions specific for the particular country.

6 MAINTENANCE AND SAFETY INSTRUCTIONS

The recommended intervals for inspection of the device are 24 months after installation, subsequently each 12 months. The intervals may differ according to the local regulations. The inspection shall be performed according to procedure authorized by BTL.

To keep the device clean, do not store or use it in extremely dusty environment for a long time. Do not immerse it in any liquid. Before each use, checks that the device and its accessories (especially cables) are not mechanically or otherwise damaged. Do not use the device if it is damaged!

Transport and storage

Keep the shipping container and all packaging materials. Transport the unit in original box to ensure maximum protection. Before transport, disconnect all cables. Take care to avoid shocks or jarring movements to the device during transport. This device should only be transported and stored under the conditions defined in the Chapter **Technical Parameters**.

Clean and disinfect after each client using approved cleaning agents. For example, Sekusept, Bacilol, and Incidur Spray can be used. For the cables of accessories, use Incidur Spray and the alike. DO NOT USE SOLVENTS!!

6.1 CLEANING

The device and its parts may only be cleaned with a damp, soft cloth. Dampen the cloth with water or a 2% detergent. Never use alcohol, ammonia, petrol, thinner etc. to clean the device.

Do not clean the device with abrasives, as this might damage its surface.

No part of the device is aseptic and needs to be sterilized.

6.1.1 DISPLAY CLEANING

You can clean the display with computer display cleaning agents or glass surface cleaning agents. The cleaning agents should only be applied by a spray. Lightly spray the centre of the glass display and wipe and polish the surface with a dry cloth. Use only a very slight pressure so that the display does not break.

Note: The cleaning agent must never get under the edge of the display, from where it could penetrate inside the device. The cleaning agent should never get in touch with any part of the device other than the glass panel.

6.1.2 CLEANING OF ACCESSORIES WHICH GET IN CONTACT WITH PATIENTS (E.G. ELECTRODES)

We recommend cleaning the said accessories after each patient, using disinfectants approved by as a relevant public health and hygiene authority. Recommended disinfectants include Sekusept or Bacilol and others, cables can be disinfected with Incidur spray etc.

 Never use GIGASEPT to disinfect the device and its accessories such as electrodes, cables etc.; otherwise irreparable damage to the device or accessories may occur!

6.2 DEVICE SAFETY

- Before first use, carefully read the user's manual.
- All professional staff that will use the device must be instructed as to the device operation, maintenance and checks, as well as on the safe handling of the device.
- The device should only be used in an environment specified in the Technical Specifications. It must not be used in any environment where there exists a risk of explosion. The device must also be protected against water. The device likewise should not be used in connection with flammable anaesthetics or oxidizing gas (O_2, N_2O etc.).
- Place the device out of direct sunlight and beyond the reach of strong electromagnetic fields to avoid mutual interference. If interference occurs, remove the device from the proximity of the source of interference or contact an authorized BTL service centre.
- Inspect the device carefully before each application (loose cables, damaged cable insulation, display or controllers malfunction, etc). Stop using the device if you discover any damage or malfunction and contact an authorized BTL service centre. Likewise stop using the device if it deviates from the behaviour described in this manual and contact an authorized BTL service centre.
- The internal lithium battery for the clock backup has limited service life (from 4 to 15 years, depending on the device version). When the battery is out, the device alerts after the switch-on by the message "Flat internal battery, contact service. Start recording thru BTL CardioPoint via USB". If the internal battery is out, the date and time are reset to "01.01.2005 00:00". For the correct function of the holter device it is necessary to set the correct date and time after each switch-on of the device. If you start recording from the BTL CardioPoint program through the USB cable, the time in the device is set according to the clock in the PC. In such case it is impossible to perform multi-day examinations, during which it is necessary to replace batteries, as described in Chapter 2.6. For the replacement of the internal lithium battery please send the holter to an authorized BTL service.
- If the device appears to be malfunctioning or if you have any misgivings about its proper functioning, switch the device off and disconnect it from the patient. If you fail to resolve the issue with the help of the user's manual, contact an authorized BTL service centre. Should the device be used contrary to the directions in this manual or despite the fact that it appears to be malfunctioning, the user will be held liable for any ensuing damage.
- Do not disassemble the device under any circumstances. The device does not contain any user replaceable parts. The internal lithium battery can be replaced only by an authorized BTL service centre.
- The connectors for accessories and other device connectors have been designed only for the parts and cables specified in the user's manual. The connection of any other components or cables might cause an injury by an electric discharge and seriously damage the device.
- Conductive parts of electrodes, including the N (RL) or C (V) electrode as well as any other conductive components of the device which get in direct contact with the patient's skin, must never touch any other conductors in the environment or the earth during ECG recording. Instruct the patient accordingly.
- During operation, storage and transport in the specified environment, the device does not use or radiate any toxic substances.
- If you bring the device from a cold environment into a warm room, do not switch it on before the temperature of the device stabilizes (for at least 1 hour).
- The device does not pose any hazard for patients with pacemakers.
- The device may also be used by children and infants who weigh less than 10 kg/22 pounds.

- For more information about how to calculate heart frequency or detect/measure change of ST segment please consult the user's manual for BTL CardioPoint-Holder.
- To dispose of the device, it is necessary to remove both the batteries in the battery compartment and the internal lithium battery. The lithium battery does not belong to normal municipal waste and must be disposed of in accordance with applicable regulations. Without the batteries, the device can be disposed of normally, as it does not contain any toxic materials which could harm the environment.
- This type of electrocardiogram device has not been designed for on-line monitoring of the ECG signal concurrently with surgical VF equipment. The device must not be connected to a patient at the same time as surgical VF equipment.
- Do not use the electrical blanket when the holter examination is performed.
- Do not use the device in the presence of imaging equipment such as Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) devices, etc.
- Since a simultaneous connection of several devices might result in possible harmful consequences to the patient (mutual interference, multiplication of leaking currents) we do not recommend using the device together with other medical devices, unless described herein.
- The device and its accessories may only be used in accordance with the instructions described in this manual.
- This device must be kept out of the reach of children.
- This device must be kept out of the reach of pets.
- This device does not contain any user-serviceable parts or components. Do not remove any covers from the device. The device may only be repaired by an authorized BTL service centre.
- BTL-08 Holter can be used together with a defibrillator. The defibrillator must comply with the IEC 601-2-4 standard and its discharge must comply with discharge specified by standard IEC 601-2-25. The device is resistant against defibrillation only when an original BTL patient cable is used. No modification of this equipment is allowed.
- Children safety warning: pay attention to lead cables accomodation at children examinations to prevent possible strangulations (e.g. roll up and stick up patient cables' extra length)
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

6.3 USED SYMBOLS

	Warning
	Defibrillation-proof type CF applied part
	Class II equipment
	The device may also be used for children of a weight lower than 10 kg.
	Connect only an original BTL **USB cable to connectors marked** with the above label.
	Follow instructions for use (User's manual)
	Separate collection for electrical and electronic equipment
	Name and address of the manufacturer
	Date of manufacture
SN	Serial number of the device
	Caution
LOT	Batch code
REF	Catalogue number
CE	CE mark
IP22	IP classification is degrees of protection provided by enclosures in accordance with IEC 60529. This device is protected against solid foreign objects of diameter 12 mm such as a finger and greater, and against oblique falling water drops which gives trouble to normal operation.
MD	Medical device
EC REP	Authorized representative in the European Community

BTL-08 Holter may ONLY be connected to devices compliant with EN 60950-1 or EN 60601 standards.

7 TECHNICAL PARAMETERS

7.1 TECHNICAL PARAMETERS OF HOLTER

Type	**BTL-08 Holter**
Display:	LCD
Resolution:	5.2 cm / 2" display with 128 x 64 resolution
Cover:	made of ABS and PC
Keypad:	microswitches
Max. weight:	106 g (3.74 oz) ±2 g
Dimensions (l x w x h) in mm/inches:	102 x 62 x 24 mm / 4" x 2.44" x 0.94"
Service life of the device	5 years
Shelf life:	5 years
ECG recording	
Number of leads:	3/7/12 (according to the settings and placement of electrodes)
Number of electrodes:	5/10
Recorded leads:	3 leads: mV1, mV3, mV5
	7 leads: I, II, III, aVR, aVL, aVF, V1
	12 leads: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Record length:	200 – 900 MB at 24h (depends on signal and number of leads)
Check of disconnected leads:	yes, individual leads
Pacemaker detection:	100 µs / dedicated circuit with 40000 Hz detection function
Patient cables	
Cables length:	from 40 to 90 cm depend on leads
Service life:	6 months
Shelf life	5 years
Electrodes	
	Single use only
Shelf life:	1 month for opened pouches
	30 months for unopened pouches
Battery	
Type:	alkaline, lithium or NiMH
Size:	2x AA (IEC LR-03)
Recommended capacity:	2100 mAh
Charger:	external
Charging time:	5 hours
Service life of battery:	> 500 recharging cycles
Low capacity indicator:	acoustic signal and a sign on the device display
Internal power supply	
Lithium battery:	type CR1225, 3V, expected lifetime: 5 years
Memory medium	SD card (Secure-Digital)
Supported capacity:	256 MB – 2 GB
Operating conditions	
Temperature:	+1 °C (34 °F) to +55 °C (131 °F)
Relative humidity:	10 % to 95 %
Atmospheric pressure:	700 hPa to 1060 hPa
Operating position:	any
Type of operation:	permanent
Transport and storage conditions	
Temperature:	-10 °C (14 °F) to +55 °C (131 °F)
Relative humidity:	10 % to 95 %

Atmospheric pressure:	650 hPa to 1100 hPa
Operating position:	any
Other conditions:	transport only in the supplied package
Recording parameters	
Input impedance:	> 20 MΩ
CMR without digital filter (with digital filter):	> 100 dB (> 115 dB) – for 5 wires cable
Frequency range (digital filters off):	0.049 Hz – 220 Hz
Sampling frequency:	8x 2000 Hz
A/D converter resolution:	24 bits
Maximum electrode potential:	±393 mV DC
Dynamic Range:	66 mV_{PP}
Resolution:	1.52 µV
Signal compression:	lossless
Records of patient's voice messages	
Sampling frequency:	8 kHz
A/D converter resolution:	10 bits
Compression:	lossless
Recording quality:	phone call
Max. duration of one recording:	10 s
Movement sensor	
Sensor:	two-axis accelerometer
Acceleration range:	±5 g m/s^2 (0.176 oz m/s^2)
Sampling frequency:	100 Hz
A/D converter resolution:	10 bits
Compression:	lossless
Recording duration*	
Alkaline batteries:	around 75 hours
NiMH batteries 2500mAh:	around 51 hours
Lithium batteries:	around 116 hours
* The value depends on battery condition and in some cases might be different. If 10 wires ECG cable is used, the values may be slightly lower.	
Supported USB	
Standard:	USB specification 2.0, full-speed
Connector:	USB Mini-B
Attached segment:	CF-type
PC connection:	USB

7.2 MODELS

BTL-08 Holter is offered in 3 models:

Model	Number of channels	Number of leads	Recording Time
BTL-08 Holter H100	3	5	1-2 days
BTL-08 Holter H300	3/7	5	1-7 days
BTL-08 Holter H600	3/7/12	5/10	1-7 days

7.3 ESSENTIAL PERFORMANCE

Holter, together with the BTL CardioPoint software, complies essential performance requirements according standard IEC 60601-2-47:2012, section §201.4.101, which is listed below:

- heart rate
- supraventricular ectopy
- ventricular ectopy
- bradycardia data
- pauses
- ST segment shifts
- ECG hard copy

7.4 ELECTROMAGNETIC COMPATIBILITY (EMC)

Medical electrical equipment should be used with precautions according to the EMC directive and must be installed in compliance with the EMC notices disclosed in this manual; otherwise the equipment could be adversely affected by mobile RF transceivers.

The use of accessories, transducers and cables other than those specified, with the exception of the transducers and cables sold by the manufacturer as the spare parts for the internal components, may increase the radiation or reduce the durability of the device.

Instruction and Declaration of Manufacturer – Electromagnetic Emission		
The BTL-08 Holter is intended for use in the electromagnetic environment as specified below. The user of the BTL-08 Holter device shall ensure that it is used in such environment.		
Emission test	***Compliance***	***Electromagnetic environment – instruction***
RF emissions CISPR 11	Group 1	BTL-08 Holter uses RF energy only for its internal function. Therefore, the emission is very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	BTL-08 Holter is suitable for use in domestic establishments and in establishments directly connected to the low voltage power supply network which supplies buildings used for domestic purposes.

Instruction and Declaration of Manufacturer – Electromagnetic Immunity			
The BTL-08 Holter is intended for use in the electromagnetic environment as specified below. The customer or user of the BTL-08 Holter device shall ensure that it is used in such environment.			
Immunity test	***Test level according to IEC601-1-2***	***Compliance level***	***Electromagnetic environment – instruction***
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV for contact ±15 kV for air	±8 kV for contact ±15 kV for air	The floors shall be wood, concrete or of ceramic tiles. If the floors are covered with synthetic material, the relative humidity shall be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields shall be at the levels characteristic for a typical location in a typical commercial and/or hospital environment.

<table>
<tr><th colspan="6">Instruction and Declaration of Manufacturer – Electromagnetic Immunity</th></tr>
<tr><td colspan="6">The BTL-08 Holter is intended for use in the electromagnetic environment as specified below. The user of the BTL-08 Holter device shall ensure that it is used in such environment.</td></tr>
<tr><th>Immunity test</th><th colspan="3">Test level according to IEC601-1-2</th><th>Compliance level</th><th>Electromagnetic environment – instruction</th></tr>
<tr><td>Conducted high frequency IEC 61000-4-6

Radiated high frequency IEC 61000-4-3</td><td colspan="3">3 V in 0,15 MHz – 80 MHz
6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz

10 V/m
80 MHz – 2,7 GHz</td><td>3 V in 0,15 MHz – 80 MHz
6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz

10 V/m
80 MHz – 2,7 GHz</td><td>Portable and mobile HF communications equipment shall not be used closer to any part of the BTL-08 Holter, including cables, than the recommended separation distance calculated from the formula suitable for the transmitter frequency.
Recommended separation distance
$d = [3,5/V_1]\sqrt{P}$
$d = [3,5/E_1]\sqrt{P}$ 80 MHz to 800 MHz
$d = [7/E_1]\sqrt{P}$ 800 MHz to 5.8 GHz
where P is the rated maximum output power in Watts (W) according to the manufacturer of the transmitter and d is the recommended separation distance in meters (m).
The intensities of the fields from fixed high-frequency transmitters, determined by the summary of the electromagnetic characteristics of the location[a], shall be lower than the compliance level[b] in every frequency band.
Interference may occur in the vicinity of a device identified with the following mark:  </td></tr>
<tr><td rowspan="12">Immunity to proximity fields from RF wireless communications equipment – Table 9. IEC 60601-1-2:2014

Performed according to IEC 61000-4-3</td><td>27 V/m</td><td>385 MHz</td><td>PM 18 Hz</td><td colspan="2" rowspan="12">Note: Compliance level is the same like test level.</td></tr>
<tr><td>28 V/m</td><td>450 MHz</td><td>FM 5 kHz</td></tr>
<tr><td rowspan="3">9 V/m</td><td>710 MHz</td><td rowspan="3">PM 217 Hz</td></tr>
<tr><td>745 MHz</td></tr>
<tr><td>780 MHz</td></tr>
<tr><td rowspan="3">28 V/m</td><td>810 MHz</td><td rowspan="3">PM18 Hz</td></tr>
<tr><td>870 MHz</td></tr>
<tr><td>930 MHz</td></tr>
<tr><td rowspan="3">28 V/m</td><td>1720 MHz</td><td rowspan="3">PM 217 Hz</td></tr>
<tr><td>1845 MHz</td></tr>
<tr><td>1970 MHz</td></tr>
<tr><td>28 V/m</td><td>2450M Hz</td><td>PM 217 Hz</td></tr>
<tr><td rowspan="3">9 V/m</td><td>5240 MHz</td><td rowspan="3">PM 217 Hz</td></tr>
<tr><td>5500 MHz</td></tr>
<tr><td>5785 MHz</td></tr>
<tr><td colspan="6">NOTE 1: In case of a frequency of 80 MHz or 800 MHz, the formula for higher frequency range is applicable.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
</table>

a)
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment for fixed HF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location, in which the BTL-08 Holter is used, exceeds the applicable HF compliance level as stated above, the BTL-08 Holter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BTL-08 Holter device.
b)
Over the entire frequency range from 150 kHz to 80 MHz the field strengths should be less than [V_1] V/m.

Recommended separation distances between portable and mobile HF communication devices and the BTL-08 Holter

The BTL-08 Holter device is intended for use in an electromagnetic environment in which radiated HF disturbance is controlled. The customer or the user of the BTL-08 Holter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF communication equipment (transmitters) and the BTL-08 Holter as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of the transmitter [W]	***Separation distance according to the frequency of the transmitter [m]***			
	150 kHz – 80 MHz		***80 MHz – 800 MHz***	***800 MHz – 2.7 GHz***
	$d = [3.5/V_1]\sqrt{P}$		***$d = [3.5/E_1]\sqrt{P}$***	***$d = [7/E_1]\sqrt{P}$***
	V_1=6V	***V_1=3V***		
0.01	0.06	0.12	0.035	0.07
0.1	0.18	0.37	0.11	0.22
1	0.58	1.17	0.35	0.7
10	1.85	3.7	1.11	2.21
100	5.8	11.7	3.5	7

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

NOTE 1: In case of a frequency of 80 MHz or 800 MHz, the formula for higher frequency range is applicable.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

8 MANUFACTURER

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CE 0197

Date of last revision: 05th October 2021

ID: 002-80MANEN02103