

BTL-08 ABPM

USER'S MANUAL



BEFORE YOU START

This manual has been written for the owners and operators of the BTL-08 ABPM products. It contains general instructions on operation, precautionary practices and maintenance. While we would like you to start using your equipment right away, we encourage a thorough reading of this manual in order to fully understand the operational features of your product.

All of us at BTL wish you every success with your BTL-08 system. We pride ourselves on being as responsive as possible to our customer's needs. Your suggestions and comments are always welcome since we believe an ongoing relationship with our customers is critically important to our future product line. Please call us or email us your suggestions.

Please remember to complete the warranty registration form printed in this manual. The warranty form should be returned to us no later than 30 days following installation of your equipment to initiate warranty protection.

Again, thanks for being a BTL customer. In the event of a problem, or if you require service, please make an initial call to your local distributor, who will decide whether to refer the problem to our office.

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1 GENERAL CHARACTERISTICS OF THE DEVICE

The BTL-08 ABPM ambulatory blood pressure recorder is manufactured by BTL Industries Ltd. The BTL-08 ABPM SW has been developed by **BTL Industries Ltd.**

All title and copyrights in and to the BTL-08 ABPM SW, the accompanying electronic and printed materials, and any copies of the BTL-08 ABPM SW are owned by **BTL Industries Ltd.** The BTL-08 ABPM SW is protected by copyright laws and international treaty provisions. For details please read the software license agreement.

BTL recorders working with the BTL-08 ABPM SW described in this manual, including ambulatory blood pressure (ABP) recorders **BTL-08 ABPM** and **BTL-08 ABPM Plus** . Both are manufactured by **BTL Industries Ltd.**

Indications for ambulatory blood pressure monitoring

The following indications are listed in the European Society of Hypertension recommendations for ambulatory blood pressure measurement, 2003.

- Suspected white-coat hypertension
- Suspected nocturnal hypertension
- To establish dipper status
- Resistant hypertension
- Elderly patient
- As a guide to antihypertensive drug treatment
- Type 1 diabetes
- Hypertension of pregnancy
- Evaluation of hypotension
- Autonomic failure

Contraindications

- Non-cooperative patients, unconscious or otherwise incapable patients
- Patients requiring urgency / emergency cardiac care
- Patients with coagulation disturbances (for ABP monitoring)
- Patients with serious mobility or other impairments without supervision
- Children without supervision; children younger than 8 years

2 IMPORTANT INFORMATION – PRECAUTIONS FOR USE – READ CAREFULLY



● **BTL-08 ABPM recorders should not be used if any of the following cases apply:**

- patients without an indication for ambulatory blood pressure monitoring
- non-cooperative patients
- patients in any way unable to operate a recorder as intended
- patients requiring urgency / emergency cardiac care
- unconscious or otherwise incapable patients
- patients with serious mobility impairments without supervision
- patients with coagulation disturbances
- children without supervision
- children under the age of 8 years
- No user serviceable parts inside. BTL recorders contain high complexity electronic and fine mechanical components. If you have any problems, please refer your recorder to qualified service personnel.
- Take care to avoid blocking the air flow in the tube of the cuff and twisting the tube. Make sure the cuff and its tubing or the lead wires do not cause strangulation or a circulation problem. Should the patient experience arm numbness or pain remaining after any blood pressure reading is completed, the cuff should be removed to avoid permanent vascular or neural injury.
- Though the blood pressure measurement algorithm used in BTL-08 ABPM recorders has been tested and found to function properly on patients with atrial fibrillation or other common arrhythmias, the oscillometric blood pressure measurement method is generally recommended for use only with special caution in patients with arrhythmias, Parkinson's disease, or other diseases with tremor.
- Always consult a physician for the interpretation of the blood pressure measurements. Note that any blood pressure recording may be affected by the body position, the physiological condition of the patient, and other factors.



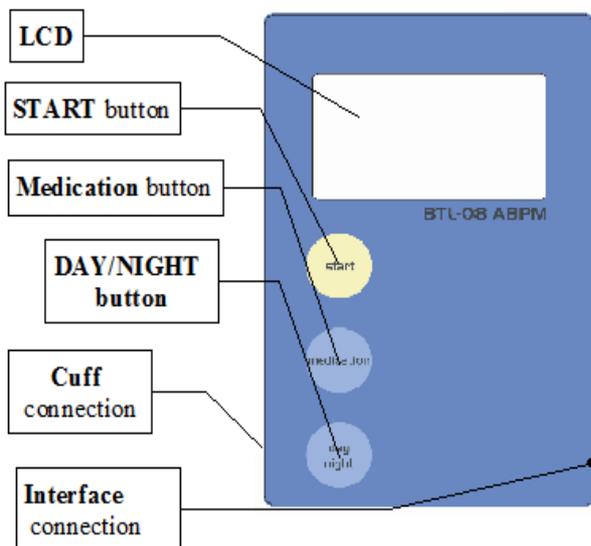
- BTL-08 ABPM is an internally powered type CF device. Protection vs. ingress of water: none. Mode of operation: continuous. The device is not protected against defibrillators or other high frequency surgical equipments.



- Blood pressure measurements determined with the algorithm of the BTL-08 ABPM recorder on adults are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method Korotkoff phase V, within the limits prescribed by the American National Standard for Electronic or Automated Sphygmomanometers. The algorithm used in the BTL-08 ABPM fulfills the requirements of the British Hypertension Society Validation Protocol for Automated Blood Pressure Measuring Devices.

3 RECOMMENDED USE OF AMBULATORY BLOOD PRESSURE RECORDS

The BTL-08 ABPM device is a compact, lightweight monitoring unit typically worn by the patient for 24 hours. BTL-08



ABPM is a compact, lightweight device, which operates with two AA size accumulators or batteries. The memory is capable of storing 600 measurements. Stepwise pressure deflation ensures quality measurements, even if disturbing environmental factors occur. You may find the battery compartment and the rating label on the backside housing. The serial number is placed on the rating label; however it is also stored electronically in the solid state memory of the device. On the front side of the housing, there is the LCD, the buttons of the device and a sticker displaying the name of the device. The device can be connected to the serial or USB port of an IBM compatible PC with an optoelectronic interface which has its socket positioned on the opposite side from the cuff connector. Patients can start extra blood pressure readings or mark symptomatic events.

4 USING THE BUTTONS

On the front side of the housing, below the LCD, you may find three buttons: the **START** button, the **MEDICATION** button and the **DAY/NIGHT** button. If the device is turned on, then every button press is accompanied by a short beeping sound.

Cancel a blood pressure measurement

The patient can interrupt a blood pressure measurement by pressing a button at any time while the cuff is inflated. This will result in immediate fast cuff deflation. Such interruption is limited to the measurement in progress only and has no effect on further operation. **This function is available with all three buttons.**

Manual blood pressure measurement

If it seems necessary, the patient can start an additional, manual blood pressure measurement by pressing the START button shortly. The result with a manual measurement marker will be stored in the memory of the device. Typical causes for this use: dizziness, pain (angina pectoris or headache), palpitation.

Switching the device off

Press and hold the START button for more than 10 seconds then release it when two horizontal segments appear on the LCD, this way BTL-08 ABPM will be switched off. If you do not release the button in 2 seconds after the two horizontal segments appeared, the recorder will return to normal operation. This feature helps to avoid unintended power-off. **The device can only be switched on manually. While the recorder is switched off normal functions are not available, even prescheduled measurements will not be triggered. Therefore switching off the device is only necessary in case of valid reasons.**

Switching the device on

BTL-08 ABPM is switched on to normal operation if the **START** button is pressed and held for more than 3 seconds. If the device is switched off, no other functions are available.

LCD check

Press and hold the **START** button to light up all segments of the LCD to check if they all work correctly.

Battery voltage check

Press and hold the **START** button for more than 5 seconds to display battery voltage on the LCD (e.g. 2_64, equal to 2.64 V). After checking the voltage, please release the button, because after additional 5 seconds, the device may turn off. The unit will then return to displaying time. The voltage for fully charged accumulators should be over 2.5 V, and for fresh alkaline batteries over 3 V.

Set a patient event marker

The patient can mark any event without starting a manual blood pressure measurement by pressing the **MEDICATION** button briefly. Typical causes for this use are taking medicine. The patient should be instructed to record the reason for setting an event marker in a diary.

Mark time of going to bed and rising from bed

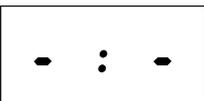
If this function is disabled during programming, the patient can press the **DAY/NIGHT** button to mark the times of going to bed (in the evening) and rising from bed (in the morning).

Manual DAY/NIGHT shift

If this function is enabled during the programming, then the patient can manually shift the measurement frequency period (day or night) by pressing the **DAY/NIGHT** button. The shift is available in the two hour period before the prescheduled shift.

4.1 DISPLAY

BTL-08 ABPM will show important status information as well as the process and result of individual readings on its LCD. The most important displays are listed here. In addition to these most important displays, a lot of extraordinary situations and errors have their own code displayed on the LCD. These codes are stored together with recorded data and they are listed in the BTL-08 ABPM program. This helps service personnel to identify causes of an unexpected behaviour, result or error.

	Normal status: time is displayed.		Night mode: time is displayed, moon sign is lit.
	Blood pressure measurement initiated.		Pumping for measurement current pressure [mmHg].
	Deflation during blood pressure measurement, the current pressure is displayed [mmHg].		Heart symbol blinking in tune with pulse: measurement in progress.
	Systolic value of just completed measurement [mmHg].		Diastolic value of just completed measurement [mmHg].
	Pulse rate value of just completed measurement [beats per minute].		Blood pressure measurement cancelled by pressing a button.
	Event marker set due to button push.		The crossed battery symbol warns about low battery.
	Communication with personal computer.		
	Error code display.		LCD check: all segments are displayed.
	The recorder is switched off.		Battery voltage display (2.37 V).

Please note that the BTL-08 ABPM might not meet its performance specifications if stored or used outside the specified environmental conditions.

5 WORKING WITH BTL-08 ABPM

The recorder must be programmed with the BTL-08 ABPM software installed on the computer. Once the pre-programmed time is reached, the recorder will commence operating automatically and perform blood pressure measurements based on the monitoring plan. To obtain reliable BP readings, certain rules must be observed.

5.1 RULES OF MONITORING

1. Inform the patient about the goal and expected results of the monitoring. Provide an event diary and rules to observe.
2. Patients can fit the recorder comfortably with the adjustable straps.
3. It is advisable to wear a thin shirt under the ABP cuffs. This does not influence the accuracy of blood pressure measurement, but it prevents problems caused by long-time wear of the cuff (sweat, itching, soreness, etc.).
4. The cuff should be properly placed and connected.
5. Patients should avoid excess movement during blood pressure measurements. They should hold their arm loose, slightly away from their chest.
6. Should the blood pressure measurements cause bloodshots, torpidity or pain in the hand, the cuff should be removed from the arm immediately and disconnected from the recorder. Such occurrence should be reported to the physician latest after the monitoring session.
7. Patients should not remove the recorder even at night. By loosening the straps, they can avoid problems when turning in their sleep. The recorder does not disturb most patients at night.
8. Patients may start extra blood pressure measurements with the **START** button of the BTL-08 ABPM recorder. They should mark events such as taking medication with the **MEDICATION** button. They should also mark the time of going to bed and rising from bed, with the **DAY/NIGHT** button. They may interrupt any single blood pressure measurement if necessary by pressing any button.
9. Should the batteries run down during a monitoring session, they can be simply replaced. Monitoring will continue, and data will not be lost.
10. Patients should never measure anybody else's blood pressure with an ABP recorder during an ambulatory blood pressure monitoring session.

5.2 CONNECTING THE BTL-08 ABPM RECORDER TO THE PC

Please connect the optical interface, which was delivered with the device, to the USB port of the PC. The other side of the interface cable which is a two-point plastic connection should be connected to the socket of the BTL-08 ABPM, in a way that the red plastic ring is directed to the lower side of the device. Start the BTL-08 ABPM software and open the **Options** menu, then click on the **Communication** tab on the left side of the screen. On the appearing window, select BTL-08 ABPM on the right side and then click on the **USB icon**. In case of a serial port, please provide the ID of the serial port (COM port) to which you connected the device. If you are unable to do so, then tick the **Auto search com port** option. In order to check the communication please connect the device to the PC (charged batteries, device switched on) in the above mentioned way and then click on the **Test** button. If the communication was successful then the software will display the serial number and the firmware version of the device.

5.3 MONITORING STEP BY STEP

Before you begin, you must have the BTL-08 ABPM software properly installed and configured on your computer, and the recorder correctly connected. To program your recorder, you will need a BTL optical interface cable properly connected to your USB port and the communication port correctly selected in the BTL-08 ABPM software.

A successful monitoring session consists of the following steps:

1. Inform your patient about monitoring rules well in advance.
2. Start the BTL-08 ABPM program, select the BTL-08 ABPM recorder type.
3. Enter new patient data or select patient from the database.
4. Create a monitoring plan with respect to the patient's lifestyle.
5. Insert two fully charged, AA size batteries into the battery compartment and check their voltage.
6. Connect the recorder to the computer.
7. Send the monitoring plan from the computer to the recorder unit.
8. Apply the cuff to the patient with the device placed in the pouch.
9. Give the patient diary to the patient along with detailed instructions about the rules and the usage of the device.

--- Monitoring session (typically 24 hours) ---

10. Remove the unit and cuff from the returned patient.
11. Ask for the patient diary, and ask the patient for any events, symptoms, observations or complaints.
12. Start the BTL-08 ABPM program and select the BTL-08 ABPM recorder type.
13. Connect the device to the PC and then transfer collected data from the recorder to your database.
14. Analyze the blood pressure profile.
15. Create and print a report.

5.4 USING THE BTL-08 ABPM SW

The BTL-08 ABPM SW package provides means to handle BTL ambulatory blood pressure recorders as well as the data collected by such recorders. From BTL-08 ABPM SW it is possible to initialize (program) a recorder and transfer (read) collected data from a recorder to your computer. BTL-08 ABPM SW stores data transferred to the computer in its database for easy future access. The database offers user access control, organizing patient data in folders similar in appearance to those used for normal document storage, but with a high degree of safety for sensitive medical data. It also offers a comfortable archive-and-restore feature for a safe backup of large size recordings. BTL-08 ABPM SW provides detailed graphical and tabular displays of recorded data, a comprehensive set of editing features and full statistical analysis, all in a highly customizable user interface. Its efficient report generator and editor can create standard reports automatically, but also allows for free editing of any report component like a word processor. More about BTL-08 ABPM SW is in 6th chapter.

In summary, BTL-08 ABPM SW lets you:

- manage (select, initialize and read data from) recorders
- browse patients and the results of monitoring sessions in a database
- view, edit and analyze data in a recording
- create, save and print a freely editable report.

5.5 CUFFS AND THEIR APPLICATION

It is advisable to wear a thin shirt or blouse under the cuff. This does not influence the accuracy of blood pressure measurements but it prevents possible problems caused by long-time wear (sweating, itching, etc.). Place the cuff on the upper arm so that the rubber tube points towards the patient's shoulder and the bladder is placed above the brachial artery, if possible. Contrary to the usual placement with the tube pointing downwards, the advantage is that the patient can wear a loose jacket over the cuff. Connect the rubber tube of the cuff into the air plug connector, which you can find on the long edge closer to the buttons of the BTL-08 ABPM recorder. Connect the cuff turning it clockwise with slight pressure.

Note: It is recommended that the cuff be applied as tightly as acceptable for the patient. A too loose cuff will cause much longer blood pressure measurement times and possibly aborted measurements. With an overly loose cuff, the recorder must pump to tighten the cuff on the arm and then it must reach the pressure necessary for measurement. This causes considerable inconvenience for the patient and results in less data for evaluation. If the patient removes the cuff for a period during the monitoring session, it should be re-applied with appropriate tightness, with help from another person, if necessary. Should blood pressure measurements cause bloodshots, torpidity or pain in the hand, the cuff should be removed from the arm and disconnected from the recorder. Such occurrence should be reported to the physician at once but latest after the monitoring session.

BTL-08 ABPM recognizes and functions with three different cuff sizes. Please set the appropriate cuff size to be used during the programming of the device. **Attention**, inappropriate setting of the cuff size may lead to device malfunctioning, which is inconvenient for the patient and may lead to an unsuccessful measurement.

Name	Bladder dimensions	Sleeve dimensions	Arm circumference *range
Normal adult	12.5 x 22.5 cm	16 x 52 cm	24-32 cm
Small adult (child)	6 x 28.5 cm	9 x 41 cm	under 24 cm
Large adult	14.5 x 32 cm	16 x 70 cm	32-42 cm

* When properly applied, the end of the sleeve (the one closer to the tube) should fall in the indicated range.

The cuff is the component which, by definition of the relevant standard, is protected against a defibrillator discharge.

Caution!

Substitution of a cuff different from that supplied might result in measurement error and/or in certain cases cause damage to the main recorder unit.

5.6 ACCESSORIES

- **set**

one (1) plastic case

one (1) BTL-08 ABPM recorder unit

one (1) serial or USB interface unit with twin optical cable

one (1) pouch for recorder, with shoulder and waist straps

one (1) normal adult size cuff

four (4) AA rechargeable batteries

one (1) battery charger

one (1) CD with BTL-08 ABPM SW and with user manual

- **recorder package**

one (1) BTL-08 ABPM recorder unit

one (1) pouch for recorder, with shoulder and waist straps

one (1) normal adult size cuff

Accessories may vary from place to place.

6 BTL-08 ABPM SW EDITIONS AND SYSTEM REQUIREMENTS

6.1 PERSONAL EDITION DEFINITION

BTL-08 ABPM SW Personal Edition can be installed on a single computer and used only by one user at a time. The use of ABPM devices is possible with an unlimited number of recorders.

6.2 COMPUTER REQUIREMENTS

BTL-08 ABPM SW can be installed on most Windows-based personal computers, but please check before installation whether your computer meets the following requirements.

Minimum Requirements Suggested Configuration

CPU 350 MHz Pentium II 2 GHz P4 or equivalent

RAM 64 MB - 512 MB

VGA 800x600 @ 16 bit color 1024x768 @ 16 bit color

HDD about 40 MB for the software + disk space for database *

OS Windows 98 SE / Me / 2000 / XP

* The disk space necessary for the database depends on recorder type, number of patients and number of examinations. Typically, it takes 75 MB to store 1000 ABPM recordings without reports. ABPM recordings are small.

7 INSTALLATION AND FIRST START

As with any software installation, you need a proper access level to the computer on which you want to install BTL-08 ABPM SW. Do not install more than one BTL-08 ABPM SW on the same computer. The edition is available on the installation CD accompanying a BTL monitoring system.

7.1 INSTALLING BTL-08 ABPM SW PERSONAL EDITION

Insert your installation CD into your CD drive and (provided the auto-run feature is not disabled) you will see a start screen. If the auto-run feature is disabled, open the CD folder and run (double-click) the setup.exe program. A typical installation wizard will start.

Before you install BTL-08 ABPM SW, you need to go through the typical steps, as follows:

- Choose language to install
- Accept license agreement
- Choose target folder of installation
- Choose Start menu folder for start-up icon placement

The default installation language of BTL-08 ABPM SW will be that of your Windows system (if such a language version of BTL-08 ABPM SW is available), but setup offers you to choose another language from a list. To install this SW, you must first carefully read and accept the license agreement, which you can also read at the end of this manual. Then you can select the options you wish to install; necessary components include the BTL-08 ABPM SW itself. Then you will be asked to select the target folder of the installation. BTL-08 ABPM SW will by default be installed in your Program Files folder, in a BTL subfolder, and finally a subfolder with the appropriate BTL-08 ABPM SW release version information. If you have a previously installed earlier version of BTL-08 ABPM SW, the setup wizard will locate it for you and will offer to install the new version to overwrite the old one. This will not influence your database, or any program settings – they will be preserved from your previous installation. This happens only if you install the new BTL-08 ABPM SW to the same folder where the old installation is located. If you select another target folder, you will have two different BTL-08 ABPM SW installations with independent databases, which may cause confusion and should therefore be avoided. Before you perform an upgrade, as with all software, it is advisable to create a safety backup of your existing installation. In the next screen of the setup wizard, you can choose a Start menu folder where setup will place the usual shortcuts for the SW: a startup icon, a help icon and an uninstallation icon. By default this is the BTL folder of your Start menu. After finishing the setup the installation will proceed. Wait until you see a screen prompting you to finish the installation. BTL-08 ABPM SW setup will place a startup icon on your desktop as well.

7.2 INSTALLATION RESULTS: FOLDERS, SHORTCUTS AND PROGRAMS

After a successful installation, BTL-08 ABPM SW Personal Edition setup places a startup icon (a shortcut) with the proper name and version number on your desktop. The necessary files will by default be installed in a BTL folder under your Program Files folder. Setup places a folder with a similar name in your Start menu, by default under the BTL folder there. In this Start menu folder, you will find a startup icon (shortcut) for BTL-08 ABPM SW, another shortcut for BTL-08 ABPM SW Help, and a third shortcut for the removal (uninstallation) of BTL-08 ABPM SW. You can start BTL-08 ABPM SW either with the desktop startup icon, or with the one in your Start menu.

7.3 FIRST START

After a successful installation, you can start BTL-08 ABPM SW with the proper startup icon (shortcut). When you first start BTL-08 ABPM SW, you will be logged in as a BTL-08 ABPM SW system administrator, and a first start wizard will guide you through the following steps to personalize your installation:

- Welcome screen
- Change BTL-08 ABPM SW system administrator settings
- Add a BTL-08 ABPM SW user
- Modify default report header

Please note that these settings can be modified later during the regular use of BTL-08 ABPM SW, but are necessary to start with from the beginning, so some steps above are a must before you start.

7.3.1 BTL-08 ABPM SW SYSTEM ADMINISTRATOR SETTINGS

After a welcome screen on first start-up, BTL-08 ABPM SW will ask for the BTL-08 ABPM SW system administrator's login name and password. Please note that these can (and maybe should) differ from your general Windows administrator properties. The input boxes for both the login name and the password will be admin by default. Please change this to your preferred admin login name and password to prevent system security problems. Write your preferred admin login and password down on a piece of paper, and lock it away in a safe place. Do not lose the system administrator's login and password, or you will be unable to access indispensable functions, such as adding new users, changing data access levels. The system administrator cannot view medical measurement data nor edit reports. If you use BTL-08 ABPM SW Personal Edition on your computer which only you have access to in a well protected environment, it may seem overly cautious and therefore be annoying to have to use a password protection in BTL-08 ABPM SW. Therefore it is possible to allow zero-length password for users in the admin settings screen, by removing the tickmark from the password required box. This does not mean that users cannot use a password if they like; it just means they may choose to leave the password empty.

7.3.2 ADDING A BTL-08 ABPM SW USER

Because his tasks are mainly administrative and technical, the BTL-08 ABPM SW system administrator by definition cannot open and view medical measurement data. Therefore it is necessary to create at least one "normal" user in BTL-08 ABPM SW, sometimes this is called a user account. More users can be added by the system administrator later; the first startup procedure lets you – that is, requires you to – create only one. The bold labels in this screen show that the last name, login name and password fields are necessary to proceed, others are optional. If the password required checkbox has been unchecked in the previous screen, it is possible to leave the password box here empty – technically this is known as a zero length password. In this case the label of the password box will not be bold. With the create icon on desktop checkbox it is possible to create a personalized BTL-08 ABPM SW start-up icon on the Windows desktop with the name of the user just added here. The properties of such an icon will include the user's login name so if BTL-08 ABPM SW is started with such a personalized shortcut icon, the user will only have to type a password, or, if the password is empty, a shortcut so personalized will log the user in directly to BTL-08 ABPM SW. Please note that this can mean a serious data security risk if anyone else other than the intended user has access to the computer, so use this possibility of comfort with extra caution only.

Users can – in fact, they are strongly advised to – change their password when they log in to BTL-08 ABPM SW for the first time, with the password originally selected by the system administrator during user account creation. If they choose to use no password protection, that is, an empty (zero length) password. Users can change their password any time using the **New password** command of the **Tools** menu in BTL-08 ABPM SW.

7.3.3 REPORT HEADER

In this screen of the first start wizard it is possible to change the default report header data to show data you would like to see on top of all printed report pages.

When you click the **Next** button after entering your report header details, BTL-08 ABPM SW will create the user settings, the demo data and personalized icons. Therefore, it is not possible to use the **Back** button after you click **Next** here.

7.4 OPTOELECTRONIC INTERFACE CABLE

To register a recorder as a key device, check electrode placement, send a monitoring plan to the recorder, or transfer collected medical data to the computer, the recorder has to be connected to the computer. Steps to follow for the first connection:

1. Locate a USB port (often labeled ) on your computer.
2. Take the optoelectronic interface unit with the optical cable out of the package. In case of the serial interface cable, the interface unit is integrated in the serial plug with the optical cable. The USB interface unit has a small USB plug (similar to a USB pen drive) with an oblique socket for the independent optical cable.
3. Connect the interface unit to the port.

If you have a USB port on your computer, and you have a serial optoelectronic interface, use a USB-to-serial converter. If you have a USB port on your computer and a USB-type optoelectronic interface from BTL, insert one end of the optical cable into the miniature oblique optical socket on the USB interface dongle, matching the red marks on the cable and on the interface label, then insert the USB plug into the USB socket on the computer. It is advisable not to disconnect the optoelectronic interface unit from the computer if it is used on that computer regularly.

4. Connect the recorder to the optical cable.

Connect the small optical plug at the free end of the optical cable into the socket on the the device matching red mark on cable to red mark on recorder labels. Insert and push it gently until it clicks in place. Simply pull to remove. Do not pull the cable itself, always handle the plug.

A recorder so connected is ready for communication with the BTL-08 ABPM SW.

If you do not use the USB port for other purposes, it is advisable to connect the interface unit as described above only once, during first installation. Then the interface unit with the optical cable is constantly connected to the computer, and only the free end of the optical cable has to be inserted in the socket on the recorders to establish the connection. The interface unit converts optical signals to electric ones and vice versa. The twin optical cable transfers optical signals between the interface unit and the recorder. The cable is flexible, but it is sensitive to overfolding and to cutting forces. If you fold the optical cable in too small radius, or if a strong cutting force (e.g. by the edge of a drawer) is applied to it, the optical cable may become optically distorted, which might result in communication errors.

In the BTL-08 ABPM SW, click the **Tools** menu, click the **Options** command, and in the appearing **Options** dialog, select **Communication** on the left. On the right panel, select the required recorder type, then select the **BTL USB** option as appropriate for the interface unit you have connected to the computer. To check communication, connect the recorder (with batteries in it and switched on) to the recorder-end of the optical cable, select the required port number or enable the **Auto search com port** checkbox, and then click the **Test** button.

7.5 WIRELESS BLUETOOTH CONNECTION

BTL-08 ABPM Plus is a recorder with wireless communication. It operates with Bluetooth(R) technology. Most up-to-date computers today come with in-built Bluetooth capability, or are easily extendible using a small USB Bluetooth dongle. Bluetooth functionality works seamlessly in Windows XP Service Pack 2 or newer releases, but it can be usually added to older Windows versions as well. Windows XP Help, as well as the documentation of Bluetooth dongles, contains detailed information how wireless devices can be used, and this is described in detail in BTL-08 ABPM SW Help as well. However, if you use the above mentioned devices, you may need the following information during the first startup procedure after the installation of BTL-08 ABPM SW.

1. If you wish to use a wireless, Bluetooth-capable BTL recorder, open the **Tools - Options** dialog of BTL-08 ABPM SW and select the **Communication** category. Select the type of the recorder, then click on the appearing **Bluetooth settings** button. In the appearing dialog, click on the **Connect setup** button to go to the next step.
2. In the appearing dialog you can see BTL recorders which have already been added to your computer. Place fresh batteries into the new BTL-08 ABPM Plus recorder and make it Bluetooth discoverable.

Press the START and the MEDICATION button simultaneously for longer than 3 seconds, then release them.

The recorder remains discoverable for a minute then switch back to stand by mode. If the recorder switches back to standby mode, make it discoverable again.

After this you have made the recorder discoverable, click on the **Add** button.

3. If there is a moving torch, the PC searches for Bluetooth devices. Should the recorder switch back to stand by mode due to a timeout, make it discoverable again then click on the **Add** button.
4. After the search the found devices are listed. The name of the recorder is BTL-08ABPM, where this is the last four digits of the serial number found on the back of the recorder. Selecting the appropriate recorder, the **OK** button becomes active, please click on it.
5. As authentication key (PIN), please enter the last four digits of the serial number. After entering the PIN, click on the **Finish** button.
6. Wait until the system installs and configures the new Bluetooth device.

By clicking on the **Test** button you can check the communication. Make the recorder discoverable before the test as described above.

8 BTL-08 ABPM SW LICENSE AGREEMENT

IMPORTANT - READ CAREFULLY: This License Agreement is a legal agreement between you (either an individual or a single legal entity) and BTL Industries Ltd.. for the BTL-08 ABPM SW, which includes computer software (SOFTWARE) and may contain accompanying data carrier, printed material and 'on-line' or electronic documentation. By installing, copying, or otherwise using the SOFTWARE, you agree to be bound by the terms and all the information and conditions described in this Agreement. If you do not agree to the terms of this Agreement, promptly return the unused SOFTWARE to the place from which you obtained it.

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Separation of Components: The SOFTWARE is licensed as a single product. Its component parts may not be separated for any purposes.

Rental: You may not rent or lease the SOFTWARE from anyone except from BTL or an authorized representative of BTL.

Demonstration: You may only demonstrate SOFTWARE if all the information described in this Agreement is disclosed to third parties.

Software Transfer: You may not transfer any of your rights under this Agreement, to any other party, without the prior written consent of BTL Industries Ltd.

Termination: Without prejudice to any other rights, BTL may terminate this Agreement if you fail to comply with the terms and conditions of this Agreement. If such event occurs, you must destroy all copies of the SOFTWARE and all of its components.

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MISCELLANEOUS

This Agreement is governed by the laws of Hungary. Should you have any questions concerning this Agreement, please contact BTL Industries Ltd.

LIMITED WARRANTY

BTL Industries Ltd. guarantees, that (a) the SOFTWARE under normal use will perform substantially in accordance with the accompanying written/electronic documents for a period of ninety (90) days, and all supplementary hardware will be free from defects in materials and workmanship under normal use for one (1) year from the date of receipt.

NO OTHER WARRANTIES. BTL DISCLAIMS ALL OTHER WARRANTIES, EITHER EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, WITH REGARD TO THE RECORDER UNIT, ANY ACCESSORY OR OTHER ACCOMPANYING HARDWARE, AND THE BTL-08 ABPM SW. NO LIABILITY FOR CONSEQUENTIAL DAMAGES. IN NO EVENT SHALL BTL BE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT, OR CONSEQUENTIAL DAMAGES WHATSOEVER (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF BUSINESS PROFITS, BUSINESS INTERRUPTION, LOSS OF BUSINESS INFORMATION, LOSS OF DATA, OR ANY OTHER PECUNIARY LOSS) ARISING OUT OF THE USE, OR INABILITY TO USE THIS PRODUCT, EVEN IF BTL HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

9 CARE AND MAINTENANCE

Protection and cleaning

BTL-08 ABPM ambulatory blood pressure recorders are not specially protected against spills or ingress of water or other liquids. Do not immerse the recorder in water or any cleaning fluid, and protect it from spills and splashes. Do not expose it to heavy rain or steam, and do not wear it in a wet environment e.g: shower, bath, or swimming pool. In case of minor effects of a wet environment, wipe off water drops with a dry cloth. Keep the recorder in a normal dry room for at least one hour before use if condensation is suspected. In case of ingress of water in the recorder, remove batteries from the unit, and refer the unit to authorized service. Never place a recorder unit in a disinfecting or sterilizing machine! A recommended means of cleaning is to wipe the recorder with a disinfectant cleaning tissue, e.g., Henkel Ecolab Incides, or a similar product. Alternatively, wipe with a slightly damp cloth then dry it with an antistatic tissue. Do not expose recorders to extreme heat or radiation, including long exposure to direct strong sunlight.

Regular checks, warranty, service

Verification of pressure measurement accuracy is recommended biannually. BTL-08 ABPM recorders are covered by a two-year warranty under general warranty conditions of BTL Industries Ltd., see relevant section. This warranty does not cover any malfunction or defects arising from improper use, the use of inadequate accessories, accident, theft, or use of the device outside operating environmental specifications or intended measurement range. Removing the closing label from the back side of the device voids this warranty. There are no user serviceable parts inside BTL recorders; they contain high complexity electronic and fine mechanical components. If you have any problems, please refer the recorder to qualified service personnel. Contact BTL or your distributor for service information.

Roll-out

BTL-08 ABPM recorders include an internal NiCd coin cell which may fall under the category of hazardous waste and should be disposed of properly. The device should be handled at roll-out as normal electronic waste.

Bateries

BTL-08 ABPM ambulatory blood pressure recorders operate with two 1.5V AA batteries or two 1.2V AA rechargeable batteries. Use only standard long-life (alkaline) batteries, or standard NiCd or NiMH rechargeable batteries of the proper size. Do not use lithium batteries. Do not mix different battery types, do not mix new and old batteries. Never use batteries of low or unknown quality or pre-used batteries, as they may not cover the power needs of the recorder, and they may damage the recorder, or they may contain acidic electrolytes which may leak and corrode electronic components. Never use batteries damaged in any way. Should the batteries run down during a monitoring session, they can be replaced. Monitoring will continue and data will not be lost. If you do not use the recorder, it is advisable to remove batteries since they may run down due to the constant small power consumption of the integrated circuits of the device. Data in the recorder are not lost even if batteries run down or are removed. Used batteries may fall under the category of hazardous waste and should be disposed of properly.

Important! It is strongly recommended to use freshly charged accumulators or new batteries with every patient so that batteries do not run down during monitoring, even in case of very high blood pressure values and/or a long monitoring session. After inserting batteries in BTL-08 ABPM recorders, it is advised to check their voltage before programming the recorders. Do not start a new monitoring session with low batteries. The typical voltage for two fully charged rechargeable batteries should be over 2,5 V, and for fresh alkaline batteries, over 3 V. It is possible to check battery voltage with the START button. (Please check the *Using the buttons* section for more details.)

Important! If a recorder is not used for a long period, the in-built backup cell ensuring the operation of the internal clock may get discharged. In this case keep freshly charged batteries in the recorder for at least one day; this will recharge the backup cell. It is possible to use the recorder afterwards. If the backup cell is not properly charged, the internal clock may work incorrectly, and the recorder may not start measurements in due time.

Two sets of rechargeable batteries and a charger are by default included in the complete set. Please refer to the relevant product descriptions when charging batteries. A set of properly charged, high capacity batteries will enable an BTL-08 ABPM recorder to perform 250 blood pressure measurements during a 24-48 hours long monitoring session. If you opt to use alkaline batteries, choose high capacity, long-life products to enable reliable operation. A small crossed battery sign on the LCD shows low battery voltage.

In order to change batteries, take the recorder out of the holder pouch and remove the battery compartment cover on the back-side. Place two properly charged, high capacity AA rechargeable or two new, long-life AA alkaline batteries into the compartment as shown in the polarity drawing. Close the compartment.

10 SAFETY OF THE DEVICE

ATTENTION!



General safety precautions:

- Carefully read the service instructions before the first activation of the device.
- The device should only be used under the control of a physician who determined the indication.
- All personnel, using this device must be knowledgeable in the servicing technique, maintenance and verification of the device and about the principles of safe work with the device.
- Place the device out of direct sunlight and out of reach of strong electromagnetic fields, to avoid undesirable interactions. In case of undesirable interactions place the device away from source of disturbance, or contact the authorised BTL service centre.
- Before every use, examine the device properly (loose cables, damaged cable insulation, functions of the display, etc.) and in case of any discrepancy stop using the device and contact the authorised BTL service centre. If the behaviour of the device shows any divergences from the function procedure described in the instruction manual, stop using the device and contact the authorised BTL service centre.
- If the device shows any signs of defects, or you are in doubt about its correct operation, stop the it immediately. If you cannot detect the source of doubts even after careful reading through the instruction manual, appeal to the authorised service department of the BTL device without delay. If the device is used contrary to this instruction manual, or it is used despite the device showing functional divergences from this instruction manual, then the user is responsible for any damage caused by the device!
- The device does not radiate or does not use any toxic materials during its operation, storage and transport under the given conditions.
- This device must be kept out of reach of the children.
- The device does not include any components to be reparable by the user, except the replacement kit. Do not remove any covers from the device. Repairs must always be provided by the authorised BTL service centre.
- Electric shock hazard protection - BTL-08 ABPM recorders meet relevant shock hazard protection standards. BTL-08 ABPM recorders operate with two 1.5V AA batteries or two 1.2V AA rechargeable batteries. This excludes all electric shock hazards, even in the unlikely case of multiple device errors. Use only standard long-life (alkaline) batteries, or standard NiCd or NiMH rechargeable batteries of the proper size. Do not use lithium batteries. Do not mix different battery types, do not mix new and old batteries, do not use damaged batteries.
- Many personal computers do not meet certain shock hazard protection standards or strict safety regulations applicable to medical devices. Therefore, during the computer-based use of BTL recorders, keep at least a 2 meter distance between patient and computer. This is the required minimum safety distance. BTL-08 ABPM recorders communicate using a plastic optical cable, whose 4 m standard (and up to 10 m optional) length allows for the required safety distance. The plastic optical cable ensures perfect electric separation and reduces the effects of external electric noise. It does not conduct electricity.
- Biocompatibility - To avoid infection risks, and for general hygienic reasons, the device, cuff and tubing should never contact the patient's skin directly.

- Hazardous materials - Used batteries qualify as hazardous waste and should be disposed of properly. BTL recorders do not contain any materials qualified as pharmaceutical substance or tissue of animal origin. They emit no material hazardous to humans.
- Risk of incorrect diagnosis - The basic intended use of BTL-08 ABPM recorders is to record blood pressure and pulse rate values. Patients should be informed about rules of cooperative behaviour, proper handling of the recorder used, and expected results of monitoring in advance. BTL-08 ABPM recorders only provide data to support diagnostic decisions of a qualified physician, they do not automatically provide a diagnosis of any kind. During the evaluation of recorded blood pressure values, possible artefacts due to external disturbances, motion artefacts, and electrical noise should be observed and handled with caution.

11 BTL PRODUCT WARRANTY INFORMATION

1. RECORDER WARRANTY. The main recorder unit will be free from defects in materials and workmanship under normal use and service for a period of two (2) years from the date of receipt. This warranty covers the recorder unit only. This warranty does not cover any accessories that might come with the recorder unit.
2. ACCESSORIES WARRANTY. The non-disposable accessories delivered with the recorder unit will be free from defects in materials and workmanship under normal use and service for a period of one (1) year from the date of receipt. This warranty does not cover disposable accessories, packaging materials, accumulators and batteries, cuffs, or any of their components.
3. CUFF WARRANTY. The cuff(s) - if delivered with a recorder unit - will be free from defects in materials and workmanship under normal use and service for a period of six (6) months from the date of receipt. This warranty covers the cuff(s) delivered with a recorder unit exclusively.
4. SOFTWARE WARRANTY. The BTL-08 ABPM software under normal use will perform substantially in accordance with the accompanying written/electronic documents for a period of ninety (90) days from the date of receipt.

This warranty is valid at the service address of BTL Industries Ltd., unless otherwise displayed upon a commercial invoice or any other valid business document duly signed by the supplier and the recipient of the BTL product. If such business document displaying a certain site for warranty validity cannot be presented, this warranty is valid at BTL HQ office in Plovdiv, Bulgaria. This warranty does not cover any malfunction or defects of the recorder unit or any of its accessories arising from improper use, the use of inadequate accessories, accident, theft, or use of the recorder unit outside its operating environmental specifications and intended measurement range. Removing the closing label from the back side of the recorder unit, or opening the unit any other way voids this warranty.

EXCLUSION OF BIOHAZARD. BTL will not accept for repair potentially infectious products or accessories, especially pouches and cuffs that might have been in direct contact with the patient, and could not be, or (potentially) were not, properly disinfected, even within the warranty period. If a problem occurs within the warranty period, such accessories will be replaced without any physical inspection, reserving the rights to hold an inspection when found necessary.

NO OTHER WARRANTIES. BTL disclaims all other warranties, expressed or implied, including, but not limited to, implied warranties of merchantability and fitness for a particular purpose, with regard to the recorder unit, any accessory or other accompanying hardware, and the BTL-08 ABPM software.

NO LIABILITY FOR CONSEQUENTIAL DAMAGES. In no event shall BTL be liable for any special, incidental, indirect, or consequential damages whatsoever (including, without limitation, damages for loss of business profits, business interruption, loss of business information, loss of data, or any other pecuniary loss) arising out of the use of or inability to use the recorder unit, its accessories and/or the BTL-08 ABPM software, even if BTL has been advised of the possibility of such damages.

12 TECHNICAL PARAMETRES

<p>Power supply:</p> <p><i>2 AA rechargeable NiCd or NiMH batteries or 2 AA alkaline batteries</i></p> <p>Display:</p> <p><i>liquid-crystal</i></p> <p>Data storage:</p> <p><i>internal solid state memory</i></p> <p>Data transmission:</p> <p><i>on USB optical cable, 115200Baud</i></p> <p>PC interface:</p> <p><i>special optoelectronic serial or USB interface</i></p> <p>Operating environment:</p> <p><i>Temperature: 10 - 45 °C Humidity: 10 - 95 %, non condensing Atmospheric pressure: 70 - 106 kPa</i></p> <p>Storage conditions:</p> <p><i>Temperature: -20 - 50 °C Humidity: 10 - 95 %, non condensing</i></p> <p>Size:</p> <p><i>70 x 99 x 30 mm</i></p> <p>Weight:</p> <p><i>app. 240 g (batteries included)</i></p>	<p>Blood pressure measurement method:</p> <p><i>oscillometric</i></p> <p>Blood pressure maximum storage:</p> <p><i>over 600 measurements</i></p> <p>Pressure measurement range:</p> <p><i>0-300 mmHg</i></p> <p>Static accuracy:</p> <p><i>± 3 mmHg or ± 2% of measured value (stability: 2 years)</i></p> <p>Blood pressure measurement range:</p> <p><i>30-260 mmHg</i></p> <p>Pulse rate measurement range:</p> <p><i>40-200 beat per minute</i></p> <p>Blood pressure measurement accuracy:</p> <p><i>same measuring algorithm validated according to the BHS protocol</i></p> <p>Pressure sensor:</p> <p><i>piezo-resistive</i></p> <p>Inflation:</p> <p><i>automatically controlled pump</i></p> <p>Safety:</p> <p><i>maximum inflation 300 mmHg; independent safety release valve</i></p> <p>Deflation and rapid air release:</p> <p><i>automatic pressure release valve</i></p>
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13 EMC INFORMATION

Medical electrical equipment should be used with precautions according to EMC, and must be installed according to the EMC notices disclosed in this manual as mobile RF transceivers could adversely affect it.

Directive and declaration of manufacturer – Electromagnetic Emission		
BTL-08 ABPM is suitable for use in the specified electromagnetic environment. The purchaser or user of BTL-08 ABPM should assure that it is used in an electromagnetic environment as described below		
Emission test	Compliance	Electromagnetic Environment
Radiated and conducted RF emission CISPR 11	Group 1	BTL-08 ABPM 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.
Radiated and conducted RF emission CISPR 11	Class B	BTL-08 ABPM 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.
Harmonic emission IEC61000-3-2	Not applicable	---
Voltage fluctuations / Flickers IEC61000-3-3	Complies	BTL-08 ABPM is suitable for use in establishments directly connected to a public low voltage mains network.

Directive and declaration of manufacturer – Electromagnetic immunity			
BTL-08 ABPM is suitable for use in the specified electromagnetic environment. The purchaser or user of BTL-08 ABPM should assure that it is used in an electromagnetic environment as described below.			
Immunity test	IEC601-1-2 test level	Compliance level	Electromagnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	±6KV contact ±8KV air	±8KV air	Floors are wood, concrete or ceramic tile, or floors are covered with synthetic material and the relative humidity is at least 30 percent.
Electrical fast transient/burst IEC 61000-4-4	±2KV for power supply lines ±1KV for input/output lines	Not applicable	Mains power quality is that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	±1KV differential mode ±2KV common mode	Not applicable	Mains power quality is that of a typical commercial and/or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U _T (>95% dip) for 0.5 cycle; 40% U _T (60% dip) for 5 cycles; 70% U _T (30% dip) for 25 cycles; <5% U _T (>95% dip) for 5 sec.	Not applicable	Mains power quality is that of a typical commercial and/or hospital environment. If the user of BTL-08 ABPM requires CLINICAL UTILITY during power mains interruptions, it is recommended that parts of the BTL-08 ABPM system where applicable be powered from an uninterruptible power supply.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields are at levels characteristic of a typical location in a typical commercial and/or hospital environment.
Note: U _T is the nominal voltage of mains.			

Directive and declaration of manufacturer – Electromagnetic immunity

BTL-08 ABPM is suitable for use in the specified electromagnetic environment. The purchaser or user of BTL-08 ABPM should assure that it is used in an electromagnetic environment as described below.

Immunity test	IEC601-1-2 test level	Compliance level	Electromagnetic environment
Conducted RF IEC 6100-4-6	3V _{eff} 150KHz - 80MHz	Not applicable	Portable and mobile RF communications equipment are used no closer to any part of BTL-08 ABPM, including cables, than the Recommended Separation Distance calculated the formula written below. Recommended Separation distance: $d=[3,5/V_1]\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 80MHz – 2,5GHz	3V/m	$d=[3,5/3V/m]\sqrt{P}$; (80MHz – 800MHz) $d=[7/3V/m]\sqrt{P}$; (800MHz – 2,5GHz) where: P is the highest radiated power disclosed by the manufacturer of transmitter [W]; d is the recommended separation distance [m].

1. note: in case of frequency 80MHz or 800 MHz, the formula for the higher range is applicable.

2. note: These are guidelines. Actual conditions may vary.

Recommended separation distance

BTL-08 ABPM is intended to be used in electromagnetic environment with controlled RF disturbances. The purchaser or user of BTL-08 ABPM may help to reduce electromagnetic disturbances by defining the separation distance between the transportable or mobile RF telecommunication equipment (transmitters) and BTL-08 ABPM, depending on the highest output power of the telecommunication equipment.

The highest output power of the transmitter [W]	Separation distance in function of the frequency of the transmitter [m]		
	150KHz – 80MHz $d=[3,5/V_1] \sqrt{P}$	80MHz – 800MHz $d=[3,5/E_1] \sqrt{P}$	800MHz – 2,5GHz $d=[7/E_1] \sqrt{P}$
0,01	Not applicable	0,12	0,23
0,1	Not applicable	0,38	0,73
1	Not applicable	1,2	2,3
10	Not applicable	3,8	7,3
100	Not applicable	12	23

If this table does not contain the highest output power of the transmitter, the d separation distance [m] can be calculated by the formula, depending on the frequency of the transmitter, where P is the rated highest output power of the transmitter [W].

1. note: in case of frequency 80MHz or 800 MHz, the formula for the higher range is applicable.

2. note: These are guidelines. Actual conditions may vary.

14 MANUFACTURER

This product is manufactured in accordance with the EU Medical Devices Directive by:

BTL Industries Ltd.

161 Cleveland Way

Stevenage

Hertfordshire

SG1 6BU

United Kingdom

E-mail: sales@btlnet.com

<http://www.btlnet.com>

For service, please contact the service department at service@btlnet.com.



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