Meditech

User Guide

ABPM-05 & BlueBP-05

Ambulatory Blood Pressure Monitors

BHS protocol applied

AAMI protocol applied

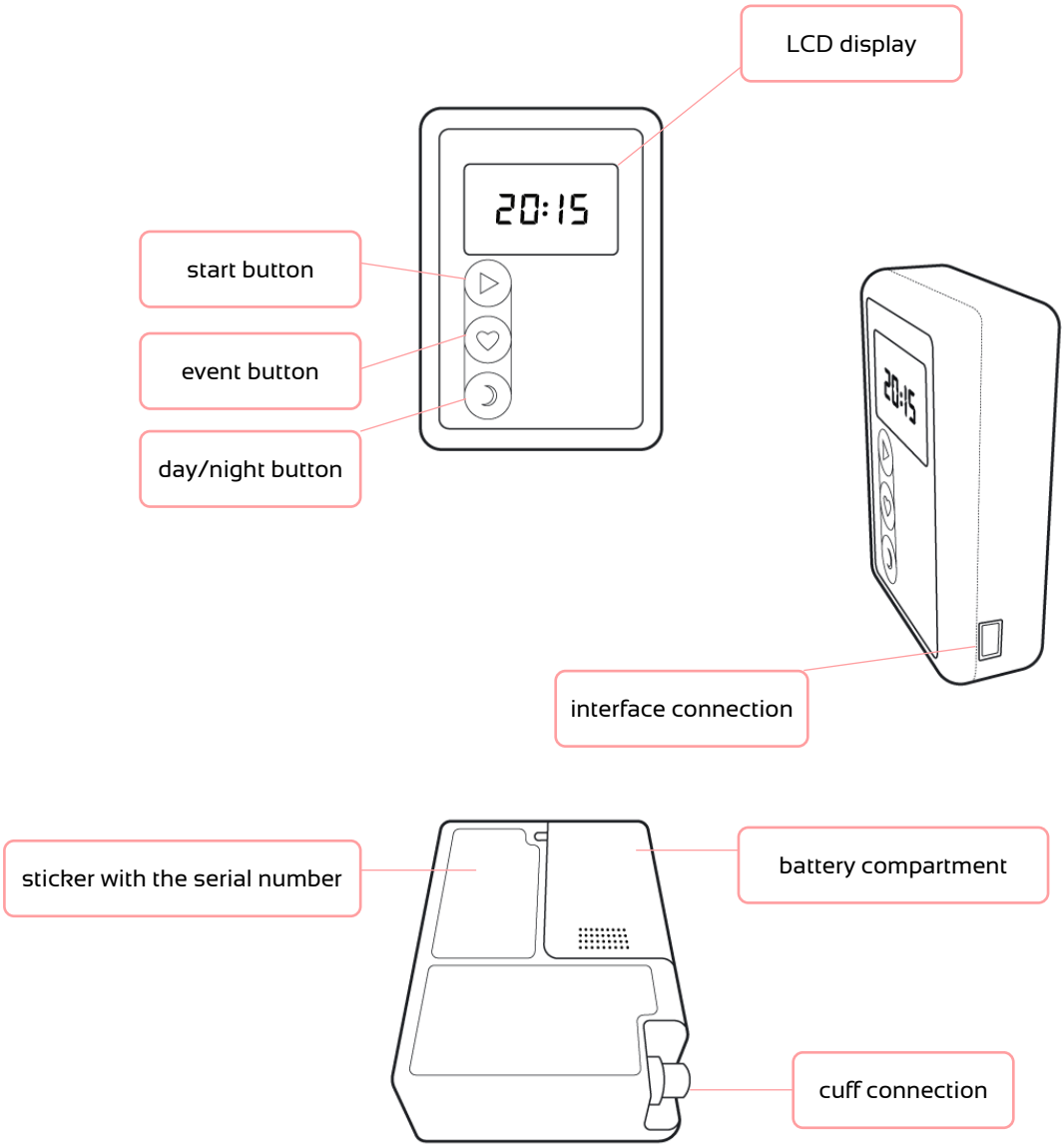
Table of Content

Product Description

Meditech ABPM-05, and its Bluetooth-capable version BlueBP-05, provides accurate information on blood pressure variability, overnight dipping and morning surge for reliable hypertension management and control.

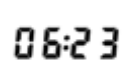
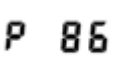
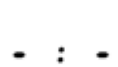
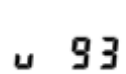
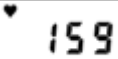
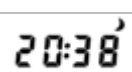
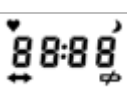
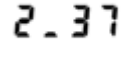
Both ambulatory blood pressure monitors incorporate an algorithm validated to BHS (British Hypertension Society) and AAMI (Association for the Advancement of Medical Instrumentation) protocols.

Name of parts

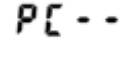


LCD display

Information displayed on both ABPM-05 and BlueBP-05.

	Normal status: time is displayed.		Pulse rate value of just completed measurements (beats/minute)
	Blood pressure measurement initiated (mmHg)		Event marker set during a button push
	Pumping for measurement, current pressure is displayed (mmHg)		Error code display
	Deflation during measurement, current pressure is displayed (mmHg)		The device is switched off.
	Systolic value of just completed measurement (mmHg)		The blood pressure measurement is cancelled by pressing a button.
	Diastolic value of just completed measurement (mmHg)		Heart symbol blinking: measurement in progress (mmHg)
	Night mode: time is displayed, moon sign is lit.		LCD check: all segments are displayed
	Battery voltage display (2,37V)		The crossed battery symbol warns of low battery

Information displayed on BlueBP-05 only

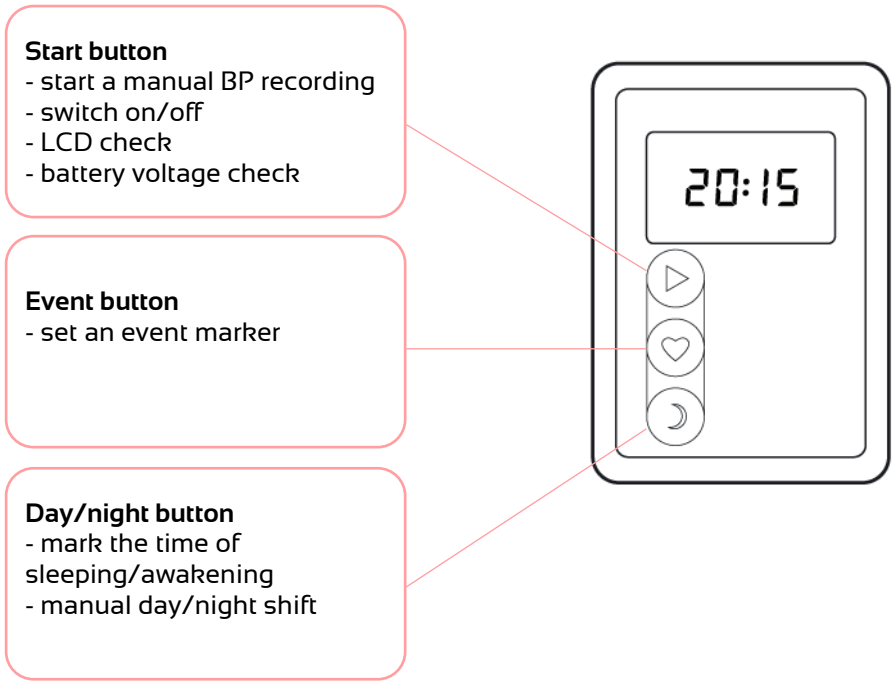
	The device is in Bluetooth discoverable mode

Information displayed on ABPM-05 only

PC	Communication with a personal computer	u 0-	Blood pressure measurement initiated (kPa)
n 7-	Pumping for measurement, current pressure is displayed (kPa)	u 12-	Deflation during measurement, current pressure displayed (kPa)
19:2	Systolic value of a just completed measurement (19,2 kPa)	♥ 21-	Heart symbol blinking: measurement in progress (kPa)
12:3	Diastolic value of a just completed measurement (kPa)		

Buttons

The monitor has 3 buttons: start, event and day/night. Any blood pressure measurement can be interrupted by pressing any button at any time while the cuff is inflated. This will result in immediate fast cuff deflation.



Start button functions

- to start a manual blood pressure measurement (press shortly)
  Typical causes for this use: dizziness, pain (angina pectoris or headache), palpitation.
- to switch the device off (press and hold for more than 10 seconds)
  Press and hold the Start button until 2 horizontal segments appear on the LCD (- -).
- to switch the device on (press and hold for more than 3 seconds)
- to check the LCD
  Press and hold the start button to light up all segments of the LCD to check if they all work correctly.
- to check battery voltage (press and hold for more than 5 seconds but less than 10 seconds)
  The voltage for fully charged accumulators should be over 2,5V (2_50 on the LCD).

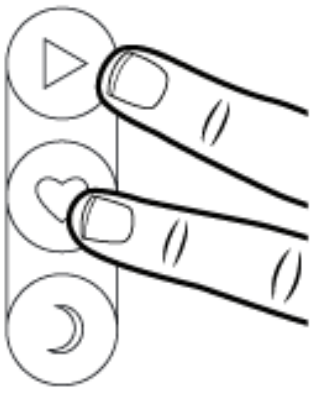
Event button functions

- to set a patient event marker (press shortly)
  Typical cause for this use is taking medicine. The patient should be instructed to record the reason for setting an event marker in a diary.

Day/night button functions

- Marking the time of sleeping and awakening
  If the day/night shift function is disabled during programming, the patient can press the day/night button to mark the time of sleeping (in the evening) and awakening (in the morning).
- Manual day/night shift (only in the 2 hour period before the prescheduled shift)
  If this function is enabled during the programming, the patient can manually shift the measurement frequency period (day or night) by pressing the day/night button.

Bluetooth functions – BlueBP-05 only

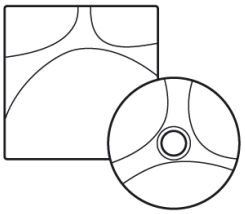


- Switching to Bluetooth discoverable mode to start communication
You can initiate the Bluetooth mode by pressing the Start and the Event buttons simultaneously for longer than 3 seconds then release them, until you can see this on the LCD screen: PC --.

- Switching off Bluetooth discoverable mode
You can switch off the Bluetooth mode by pressing the Start and the Event buttons simultaneously. The discoverable mode is automatically ceased after reading out or programming or if the connection fails to be established in one minute.

How to Use the Monitor

1. Install the software



Install either CardioVisions or EasyABPM software to your PC from the installation CD. If the CD does not automatically start, run the start.exe program.

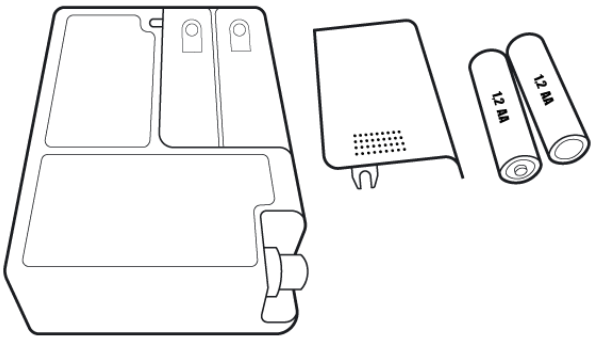
CardioVisions: for ABPM-05 and/or BlueBP-05 (also for research purposes).

EasyABPM: for ABPM-05 (for quick and basic solutions).

2. Setup the monitor

2.1 Install 2 AA batteries into the monitor

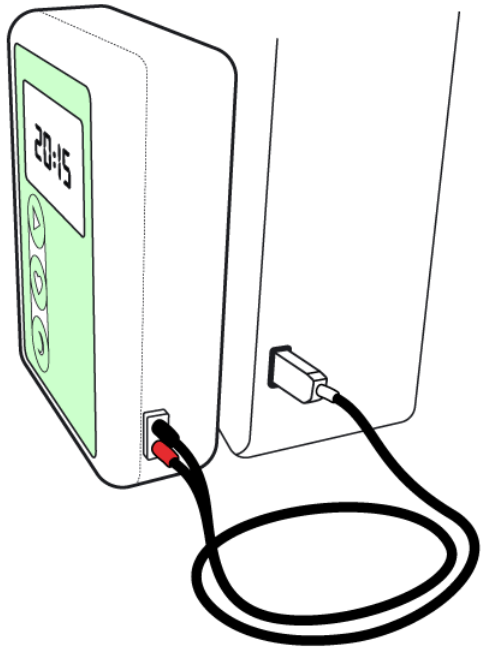
Accumulator voltage should be over 2.5V. To check: press the Start button for at least 5 seconds.



2.2 Setup communication between the monitor and the PC

ABPM-05

ABPM-05 works with a special USB optical cable, which connects the monitor to your PC. Always install the software before connecting the USB optical cable to the PC! (The USB driver is installed together with the software, in the absence of which the PC will not recognize the interface.)



Locate a USB port (often labelled) or free 9-pin serial port (also called RS232) on your computer.
If you have a USB port on your computer, connect the USB-type optoelectronic interface from Meditech. If you have a serial RS232 port on your computer, just plug in the OI3 or any newest serial optoelectronic interface. If you have a USB port on your computer but you have a serial optoelectronic interface, use a USB-to-serial converter.

Take the optoelectronic interface unit with the optical cable out of package.

Connect the interface unit to the port.

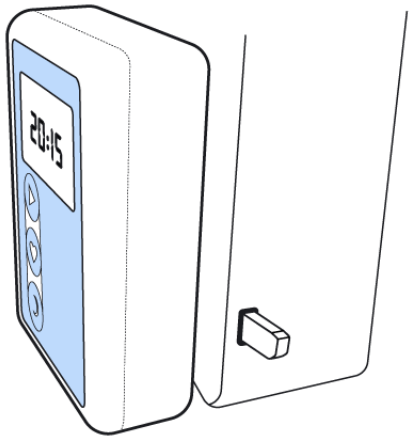
Connect the recorder to the optical cable.

If a Meditech USB optical interface cable has been supplied to your monitor, always install the USB driver before connecting the USB cable to the computer! The USB driver can be installed with CardioVisions software installation!

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.

BlueBP-05

BlueBP-05 is capable of wireless communication with the PC using Bluetooth technology. For successful communication, you need a properly connected and installed Bluetooth adapter. Most up-to-date computers today come with in-built Bluetooth capability, or are easily extendible using a small USB Bluetooth dongle (supplied by Meditech as well).

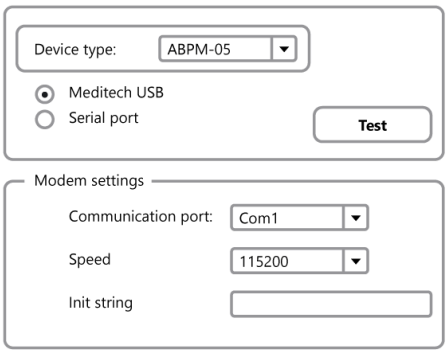


Make your monitor Bluetooth discoverable by pressing the Start and the Event buttons together for longer than 3 seconds.

Bluetooth functionality works seamlessly in Windows XP Service Pack 2 or newer releases, but it can be usually handled 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 our software Help as well.

3. Test communication

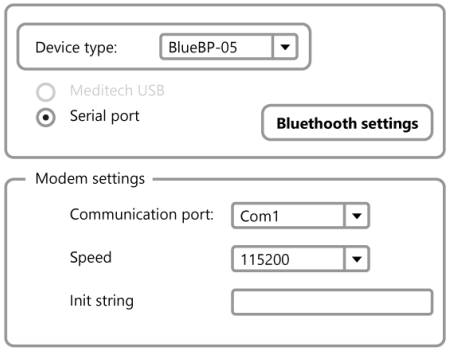


ABPM-05

CardioVisions:
Tools/Options/Communication.
Select ABPM-05, select the type of your interface unit, select the required port or simply click on Test.

EasyABPM: Device/Read data.

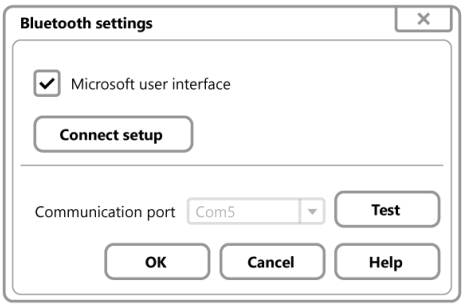
BlueBP-05



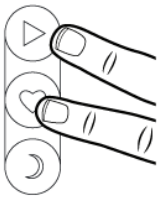
If you want to use a BlueBP-05 with Bluetooth under Windows XP SP 2, follow the steps below. With other Windows versions, please refer to the documentation of the Bluetooth device used in your computer.

Start CardioVisions and click *Tools/Options/Communication*, select BlueBP-05 and click on *Bluetooth settings*.

In the appearing dialog, click on the *Connect setup* button to go to the next step.

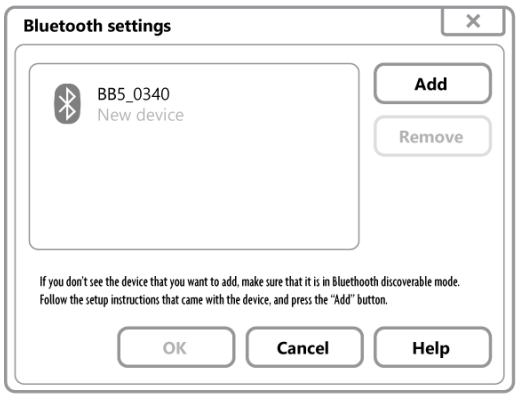


Make your device Bluetooth-discoverable by pressing the Start and the Event button simultaneously for longer than 3 seconds, and then release them. The LCD displays the PC-- marking, indicating the recorder is discoverable. The recorders remain discoverable for a minute then switches back to standby mode. If a recorder switches back to standby mode, make it discoverable again.



If there is a moving torch on the screen, the PC searches for Bluetooth devices. Should a recorder switch back to standby mode due to a timeout, make it discoverable again then click on the *Add* button.

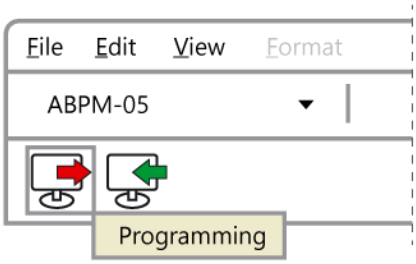
After the search the found devices are listed. The name of the recorder in case of BlueBP-05 is BB5_*xxxx,* where *xxxx* is the last four digits of the serial number found on the back of the recorder. After selecting the appropriate recorder, the *OK* button becomes active, click on it.



As authentication key (PIN) enter the last four digits of the serial number. After entering the PIN, click on the *Finish* button. 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.

4. Program the monitor

4.1 Start programming

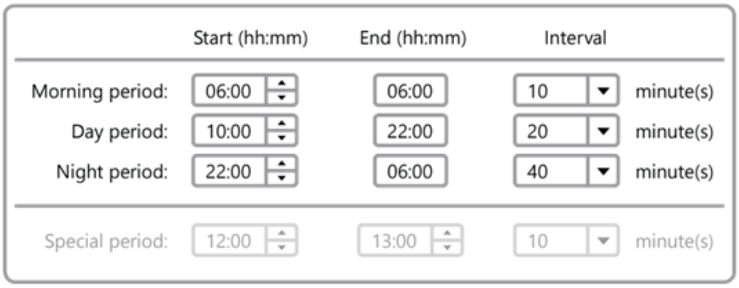


CardioVisions (Home screen): select your device type and click programming.

EasyABPM: Device/New examination

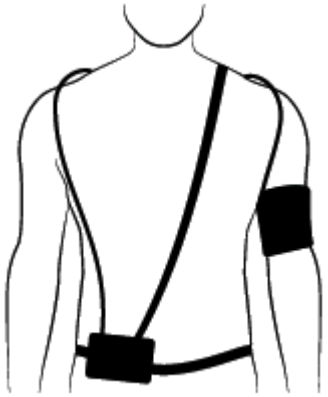
4.2 Enter new patient data or select patient from the database.

4.3 Create a monitoring plan adjusted to the patient's daily routine by filling out the parameters for the new study.



4.4 Send the monitoring plan from the computer to the recorder unit.

5. Fit the patient with the monitor



5.1 Apply a proper-size cuff to the patient's non-dominant arm and be sure that the artery indicator is over the brachial artery.

5.2 Connect the hose to the monitor.

5.3 Place the monitor in the pouch and affix the patient with the belt.

5.4 Start a manual BP reading to verify if the monitor is working properly.

5.5 Provide a diary for the patient (a sample is available on the installation CD) and inform the patient about the goal and the expected results of the monitoring and about the use of the monitor.

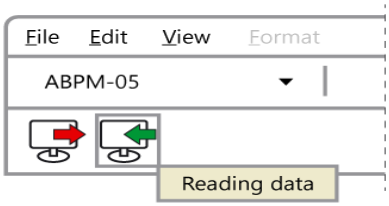
6. Retrieve data

6.1 Remove the unit and the cuff from the returned patient and ask for the patient diary for any events/symptoms/observations or complaints.

6.2 Start the software.

6.3 Establish communication between the monitor and the PC and retrieve data.

CardioVisions (Home screen): select your device from the dropdown list and click on Reading data. If you have selected manual programming or the device was programmed from another database, record patient information into the database after reading in data.



EasyABPM: Device/Read data

7. Customize, review & print data

7.1 Customize your standard report

CardioVisions: Tools/Options/Standard reports/ABPM report

EasyABPM: Tools/Settings/Report

7.2 Review the study and edit data if necessary.

7.3 Create and save or print the report

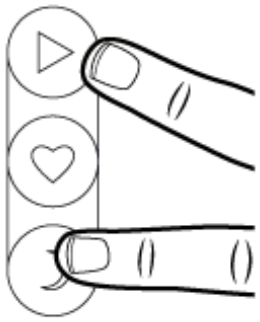
ABPM-05 Manual Programming

ABPM-05 if programmed manually can be used by CardioVisions software 1.13 or later versions. Plans are stored in the inbuilt memory of the device and they cannot be changed. The following three measurement plans can be selected during the programming of the device:

PLAN A): measurements every 15 minutes at day and every 30 minutes at night.
PLAN B): periods with 20 minutes at day and 40 minutes at night.
PLAN C):30-minute periods independent of day or night time.

Other settings are the same in all the three plans: undecided cuff size, 300 mmHg pressure limit, LCD display enabled, manual day/night shift disabled. Daytime starts at 6:00, while nighttime starts at 22:00, special session is disabled. Patient data can be selected or created later in CardioVisions database.

How to program manually



Press and hold the Start and the Day/night buttons simultaneously. Measurement frequency of the measurement plans will be displayed after 10 seconds for 3-3 seconds.

To choose the measurement plan, release the buttons when the specific plan is displayed. You will hear two beeps and the LCD will display four blinking „o" letters, which indicates that programming the device is in progress. After a successful programming you can hear 5 beeps, and the selected plan can be seen again. If programming fails for some reason, the E90 error code will be displayed on the LCD.

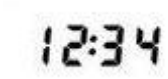
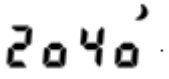
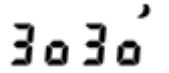
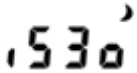
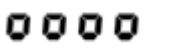
In case of manual programming there is no time setting. If the time setting is

如果是手动编程，则没有时间设置。如果时间设置不精确，则测量时间可能是错误的。如果要使用手动编程功能，请不要让设备长时间没有电池。如果可能发生这种情况，请将电池重新插入设备，通过PC对设备进行编程来设置内部时钟，并将电池留在设备中（建议的周期为24小时）。第一次测量具有控制目的，在编程后的第二分钟开始，然后在接下来的五分钟内不能开始其他测量。其余的测量以特定的15/20/30/40分钟间隔进行，在6:00和22:00小时轮班进行测量。最后一次测量正好是第二次测量后24小时。

imprecise, the time of measurements may be false. If you want to use the manual programming function, do not leave the device without batteries for a longer period. If it could happened so, insert batteries again into the device, set the inner clock by programming the device by a PC and leave the batteries in the device (the suggested period is 24 hours).

The first measurement has a controlling purpose and it starts in the second minute after programming, then other measurements cannot be started in the next five minutes. The rest of the measurements are taken at specific 15/20/30/40 minute intervals and there are measurements at the 6:00 and 22:00 hour shifts. The last measurement is exactly 24 hours after the second measurement.

LCD displays

	Normal status: time is displayed.		2. measurement plan: 20/40 minute day/night intervals
	10 second delay state		3. measurement plan: 30/30 minute day/night intervals
	1. measurement plan: 15/30 minute day/night intervals		Programming is in progress: blinking signal

Patient Information

Wearing a thin shirt under the cuff is recommended.
It does not influence the accuracy of the blood pressure measurement, but it prevents problems caused by long-time wear of the cuff (sweat, itching, soreness, etc.)

The cuff should be properly placed on and connected.
The cuff tube should be pointed towards the patient's shoulder and the white tissue-sign (textile cuff) or the 'artery' indicator (PU fabric leather cuff) on the cuff should be placed above the brachial artery.

Hold your arm slightly away from your chest during a measurement.
Patients should avoid excess movement during blood pressure measurements. They should hold their arm loose, slightly away from their chest.

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.

Press any button to stop a blood pressure measurement.
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.

Don't remove the recorder even at night.
By loosening the straps, patients can avoid problems when turning in their sleep. The recorder does not disturb most patients at night.

Use the buttons, if necessary.
The patient can initiate extra blood pressure measurements by pressing the Start button. By pressing the Event button the patient can mark events, e.g. taking medication etc. The time of going to and rising from bed can be marked by the Day/night button.

Should the batteries run down during a monitoring session, they can simply be replaced.
Monitoring will continue and data will not be lost.

Don't block the air flow in the cuff tube.
Take care to avoid blocking the air flow in the tube of the cuff and twisting the tube.

Never measure anybody else's blood pressure with the recorder during an ambulatory blood pressure monitoring session.

Cuffs

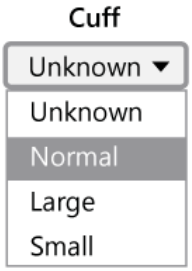
Dimensions

Name	Bladder dimensions	Arm circumference range
large	15*33 cm	33-42 cm
normal	12*25 cm	25-32 cm
small	9*18 cm	18-24 cm

If the patient's arm circumference range is out of the ranges indicated above, use the cuff which best fits for the patient and make a so-called undercuffing or overcuffing calculation.

Application

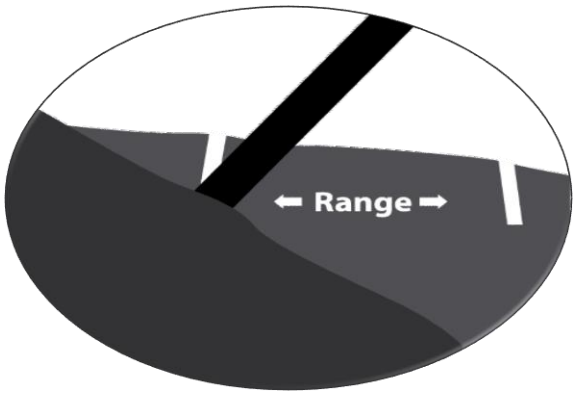
Set the cuff size during programming the monitor
The monitors recognize three different cuff sizes. The size to be used should be set during programming of the device. Inappropriate setting of the cuff size may lead to device malfunctioning, which is inconvenient for the patient and may lead to an unsuccessful measurement.



Wear a thin shirt or blouse under the cuff
It is advisable to wear a thin shirt or blouse under the cuff, because it prevents possible problems caused by long-time wear (sweating, itching, etc.).

Apply the cuff and be sure the artery indicator is over the brachial artery
Place the cuff on the upper arm so that the rubber tube points towards the patient's shoulder and the white tissue-sign and the 'artery' indication of the cuff 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.

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



Connect the hose to the monitor
Connect the air connector of the cuff into the air connector socket of the device by turning it clockwise with a slight pressure.

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 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. The application of the cuff over a wound can cause further injury! The application of the cuff and its pressurization could result in injury to the patient because of

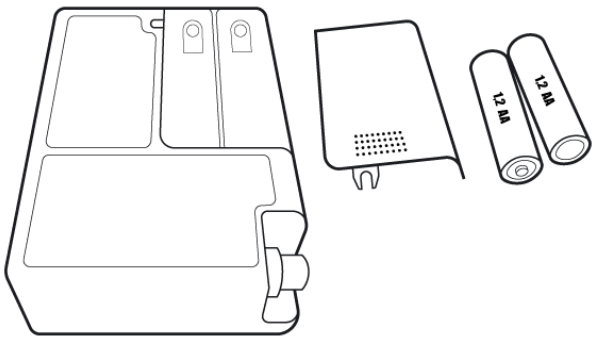
temporary interference to blood flow on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present. The pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring medical equipment on the same limb.
No relevance can be shown in the application of the cuff and its pressurization on the arm of the side of a mastectomy.

The cuff should be applied as tightly as comfortable for the patient.
A too loose application may result in longer or aborted measurements, because the device has to pump even to reach the proper tightness. Longer measurements may cause inconvenience for the patient, and aborted measurements result in less data for evaluation. If the patient removes the cuff for a period during the monitoring session, it should be reapplied with appropriate tightness, with help from another person, if necessary.

The cuff is the component which, by definition of the relevant standard, is protected against a defibrillator discharge. The substitution of a cuff different from that supplied by Meditech might result in measurement error and/or in certain cases it causes damage to the main recorder unit.

Batteries

Meditech ABPM-05 and BlueBP-05 operate either with two 1.5V AA normal batteries or with two 1.2V AA rechargeable batteries.



A set of properly charged, high capacity batteries will enable both recorders to perform 250 blood pressure measurements during a 24-48 hour long monitoring session. If you use alkaline batteries, choose high capacity, long-life products to enable reliable operation.

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 then close it.

Use standard alkaline or NiCd/NiMH 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.

Do not start a new monitoring session with low batteries.
It is strongly recommended to use freshly charged accumulators or new batteries with each 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 Meditech ambulatory blood pressure monitors, it is advised to check their voltage before programming them. The typical voltage for fully charged rechargeable batteries should be over 2,5V and for fresh alkaline batteries, over 3V. Battery voltage check: Press the Start button for at least 5 seconds.

If measurements do not start in due time keep fresh batteries in the recorder
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. If the recharging of the cell is not successful, the backup cell must be changed by the service personnel. This is an out of warranty act.

If the batteries run down, replace them even during a monitoring session
Should the batteries run down during a monitoring session, they can be replaced. Monitoring will continue and data will not be lost.

Remove the batteries if the recorder is out of use
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.

Safety Concerns

Electric shock hazard protection
Both ABPM-05 and BlueBP-05 recorder meet the relevant shock hazard protection standards. The devices operate with two 1.5V AA batteries or two 1.2V AA rechargeable batteries, which excludes all electric shock hazards, even in the unlikely case of multiple device errors.

Many personal computers do not meet shock hazard protection standards or strict safety regulations applicable to medical devices. Therefore, during the computer-based use of Meditech recorders, keep at least a 2 meter distance between the patient and the computer. This is the required minimum safety distance. ABPM-05 communicates via a plastic optical cable, the 3 m standard length of which 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. BlueBP-05 recorders communicate via radiofrequency transmission (Bluetooth). This ensures the perfect electronic separation from the PC.

Biocompatibility
To avoid infection risks, and for general hygienic reasons, the device, cuff and tubing should never contact the patient's skin directly. Cuff materials meet the related biocompatibility requirements.

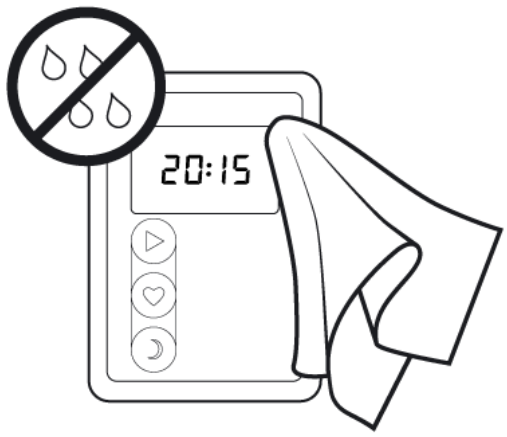
Hazardous materials
Used batteries qualify as hazardous waste and should be disposed with care. Meditech recorders do not contain any materials qualified as pharmaceutical substance or tissue of animal origin. They emit no material hazardous to humans.

Risk of incorrect diagnosis

The basic intended use of Meditech recorders is to record blood pressure and pulse rate values. Patients should be informed about rules of cooperative behavior; proper handling of the recorder used, and expected results of monitoring in advance. The 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.

See chapter Cuffs for more information!

Cleaning & Protection



Meditech ambulatory blood pressure monitors are not specially protected against spills or ingression of water or other liquids.

Cleaning the monitor
A recommended means of cleaning is to wipe the recorder with a disinfectant cleaning tissue. 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.

Cleaning the cuffs
To clean the textile cuff please do the following:
- Remove the bladder.
- Wash by hand the sleeve with lukewarm water and regular washing liquid suitable for black material. Rinse well.
- If required, wipe the bladder with a mild cleaning tissue.
- Allow both bladder and sleeve to air dry.
- Replace bladder in the sleeve: place the sleeve with its pocket-side up and put the integrated bladder into the pocket pulling the rubber tube through the hole designated for it. Place the opposite end of the rubber below the inner ply of the sleeve. Adjust the bladder to the linings of the sleeve.

To clean the PU leather fabric cuff, please do the following:
Wipe the sleeve with a damped cloth or detergent/disinfectant tissue (e.g.: ethanol 70%, isopropyl-alcohol 70%, microzid). The bladder cannot be removed!

Avoid any leakage into the tube while cleaning the cuff. (Plug the end of the tube.)
Don't take the unit into a sterilizing machine!
Don't use bleach!

Protection
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 wet environment e.g.: shower, bath or swimming pool. In case of minor effects of 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!

Maintenance

Verification of the pressure measurement accuracy is recommended biannually.

All the devices are covered by a two-year warranty under general warranty conditions of Meditech Ltd, see relevant topic. 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 Meditech recorders; they contain high complexity electronic and fine mechanical components. If you have any problems, please refer the recorder to qualified service personnel. All consequences of improper servicing are the sole responsibility of the user. Contact Meditech or your distributor for more service information. Documentation and service know-how are available at Meditech and the distributor entities as well.

Disposal

Each ABPM recorder includes an internal NiCd coin cell which falls under the category of hazardous waste and should be disposed with proper care. The other parts of the device should be handled as normal electronic waste at roll-out. Used batteries may also fall under the category of hazardous waste and should be disposed with proper care.

Indications & Contraindications

Indications

- 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, including pre-eclamptic patients
- Evaluation of hypotension
- Autonomic failure

Contraindications

- Non-cooperative patients, unconscious or otherwise incapable patients
- Patients requiring urgency/emergency cardiac care
- Patients with coagulation disturbances
- Patients with serious mobility or other impairments without supervision
- Children without supervision, or children younger than 8 years
- Though the blood pressure measurement algorithm used in the monitors has been 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.

Possible Accessories list

- USB interface cable (ABPM-05); Bluetooth USB dongle (BlueBP-05)
- pouch for the recorder with shoulder and waist straps
- normal size cuff
- 2 sets of AA long-life battery (recommended capacity: min. 1600 mAh)
- CD containing the latest software, user manual and patient diary
- user documentation (patient information and declaration of conformity)

Device accessories may vary from order to order.

Technical Specifications

Technical Parameters	ABPM-05	BlueBP-05
power supply	2 AA rechargeable NiCd or NiMH batteries or 2 AA alkaline batteries	
display	liquid-crystal	
data storage	internal solid state memory	
data transmission	USB optical cable	serial Bluetooth transfer
operating environment		
device temperature	10-45 °C	
cuff temperature	10-40 °C	
humidity (non condensing)	10-95%	
atmospheric pressure	70-106 kPa	
storage & transportation		
temperature	-20 - 50 °C	
humidity (non condensing)	10-95%	
size	70*99*30 mm	
weight (batteries incl.)	240 g	
blood pressure measurement method	oscillometric	
blood pressure maximum storage	over 600 measurements	
measurement range	blood pressure: 30 - 260 mmHg (4-35 kPa); pulse: 40-200 beat/minute	
passive accuracy	+/- 3mmHg (0,4 kPa) or +/- 2% of measured value (stability: 2 years)	
blood pressure measurement accuracy	measuring algorithm validated to BHS & AAMI protocol	
pressure sensor	piezo resistive	
inflation	automatically controlled pump	
safety	maximum inflation 300 mmHg (40 kPa), independent safety release valve	
deflation & rapid air release	automatic pressure release valve	

Troubleshooting

If you need support, please check out:
www.meditech.hu/q&a.html

If you cannot find the answer to your question or if you require service(s), please submit the following form as completely as possible:
www.meditech.hu/troubleshooting.html

Error codes

Error code	Explanation
measurement error	
E1: aborted measurement	The measurement timeout is over, the measurement had to be aborted (the patient was moving)
E2: manually interrupted	The measurement was stopped by pressing a button. The display differs from others: "OFF" on the LCD.
E3: battery rundown	The batteries exhausted during measurement.
E4: batteries replaced	The batteries were replaced during measurement.
E8: pressure limit exceeded	The pressure in the pneumatic system exceeded the preset pressure limit
E9: temporary disturbance	External electric signal - static discharge - disturbed the operation of the device.
cuff error	
E31: cuff missing or loose	There was no cuff connected to the device or the cuff was too loose on the patient's arm.
E32: cuff tubing clogged	The cuff is clogged or the rubber tube is broken.
E33: cuff leaking or loose	There is a hole in the cuff or it is rather loose on the patient's arm.
E34: cuff not on arm	The patient did not wear the cuff.
device error	
E90: device error	The device could not measure due to a hardware error.
E99: device error	The device does not start automatic measurement until the next programming.

Meditech product warranty information

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.

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.

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.

SERVICE WARRANTY. Meditech Ltd. undertakes half year warranty on the servicing carried out.

SOFTWARE WARRANTY. The CardioVisions 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 representative address of Meditech Ltd. unless otherwise displayed upon a commercial invoice or any other valid business document duly signed by the supplier and the recipient of the Meditech product. If such business document displaying a certain site for warranty validity cannot be presented, this warranty is valid at Meditech HQ office in Budapest, Hungary. 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. Warranty conditions do not apply to putative defects that are considered to be defects by the Partner due to inadequate knowledge or improper use of the products. Products returned with such putative defects are subject to service checkup charge. 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. Meditech 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. Meditech 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 software.

No liability for consequential damages. In no event shall Meditech 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 CardioVisions software, even if Meditech has been advised of the possibility of such damages.

Conventions

ABPM-05/BlueBP-05 ambulatory blood pressure monitors and CardioVisions/EasyABPM software are manufactured and developed by Meditech Ltd. All title and copyrights in and to the CardioVisions/EasyABPM software, the accompanying electronic and printed materials and any copies of the CardioVisions/EasyABPM software are owned by Meditech Ltd. CardioVisions/EasyABPM software is protected by copyright laws and

international treaty provisions. For details please read the software license agreement.

Meditech Ltd.
1184 Budapest, Mikszáth Kálmán utca 24., Hungary
Tel.: (1) 280 8232, (1) 280 8233
Fax: (1) 282 9388
Mail: meditech@meditech.eu
Web: www.meditech.eu
Contact us for further product and service information. Meditech Ltd. maintains a quality assurance system certified according to ISO 9001:2008 and ISO 13485:2003.

Notified body: SGS United Kingdom Ltd.; 202B Worle Parkway, Weston-super Mare, BS22 WA, UK; Fax: +44 151 350 6600

!	**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.**
	No user serviceable parts inside. Meditech recorders contain high complexity electronic and fine mechanical components. If you have any problems, please refer your recorder to qualified service personnel. The device cannot be modified by the user!
	This symbol is a warning that you should read the accompanying documentation.
REF BP5 or BB5	Device type (BP5 = ABPM-05, BB5 = BlueBP-05)
	Certification mark of the Russian Federation.
	Direct current
	Consult the User Manual. This symbol warns that you should read the accompanying documentation.
	This signal directs attention to the description of that part.
	Manufacturer
	Date of production
UoO	Identification of USB optical interface

	Device corresponds to the standards of USB (Universal Serial Bus)
CE 0120	Each device complies with the requirements of the EU Medical Devices Directive 0120 is the identifier of Notified Body (SGS UK)
MDD IIa	MDD classification IIa. EMC class B. EMC group 1.
MDR II	According to Canadian regulations the device classification is MDR II. (Medical Device Regulations of Canada, Rule 10.1 of MDR SOR/98-282:13Mar2007.)
	The monitors are internally powered type CF devices. Protection vs. ingress of water: none. Mode of operation: continuous. The devices are not protected against defibrillators or other high frequency surgical equipment.
IP22	Protection against environmental impact: First digit "2": Protected against mid-sized solid objects (>12 mm). Second digit "2": Protected against splash (vertically in a max. of 15 degrees). This protection refers only to BP5 and BB5.
SN YYYY/nnnnn	Serial number. The first four digits of the serial number of a recorder show the year of production. The rest is the serial number. For example: 2007/123456
	This symbol shows that according to regulations the monitors should be handled as electronic waste during rollout.
	The device communicates via Bluetooth connection. (Bluetooth V2.0+EDR, class2)
	Blood pressure measurements determined with the algorithm of an ABPM-05, or a BlueBP-05 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 ABPM-05 and BlueBP-05 also fulfills the requirements of the British Hypertension Society Validation Protocol for Automated Blood Pressure Measuring Devices.

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.

Electromagnetic emission

Meditech ambulatory blood pressure monitors are suitable for use in the specified electromagnetic environment. The purchaser or user of the device should assure that they are used in an electromagnetic environment as described below.

Emission test	Compliance	Electromagnetic environment
Radiated and conducted RF emission CISPR 11	Group 1	ABPM-05/BlueBP-05 uses RF energy only for their internal function. Therefore, the emission is very low and it is not likely to cause any interference in nearby electronic equipment. Except for Bluetooth communication usage. (The Bluetooth radiofrequency communication is carried out at the 2.4GHz frequency; class2, Bluetooth 2.0+EDR)
Radiated and conducted RF emission CISPR 11	Class B	ABPM-05/BlueBP-05 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 use.
Harmonic emission IEC61000-3-2	Not applicable	---
Voltage fluctuations/ Flickers IEC61000-3-3	Not applicable	---

Electromagnetic immunity

Meditech ambulatory blood pressure monitors are suitable for use in the specified electromagnetic environment. The purchaser or user of Meditech products should assure that they are used in an electromagnetic environment as described below.

Monitor	Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment
ABPM-05	Electrostatic discharge (ESD) IEC 61000-4-2	± 6KV contact ± 8 KV air	± 8 KV air	Floors are wood, concrete or ceramic tile, or floors are covered with synthetic material and the relative humidity is at least 30 percent.
BlueBP-05			± 6KV contact ± 8 KV air	
ABPM-05 & BlueBP-05	Electrical fast transient/burst IEC 61000-4-4	± 2KV for power supply ± 1KV input/output lines	Not applicable	Mains power quality is that of a typical commercial and/or hospital environment.
ABPM-05 & BlueBP-05	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.

Monitor	Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment
ABPM-05 & BlueBP-05	Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip) for 0.5 cycle; 40% UT (60% dip) for 5 cycles; 70% UT (30% dip) for 25 cycles; <5% UT (>95% dip) for 5 sec. Note: U_T is the nominal voltage of mains.	Not applicable	Mains power quality is that of a typical commercial and/or hospital environment.
ABPM-05 & BlueBP-05	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.
ABPM-05 & BlueBP-05	Conducted RF IEC 6100-4-6	3V eff 150KHz-80MHz	Not applicable	Mains power quality is that of a typical commercial and/or hospital environment
ABPM-05 BlueBP-05	Radiated RF IEC 61000-4-3	3V/m 80MHz-2,5GHz	3V/m	Recommended Separation distance: d=[3,5/V1]√P d=[3,5/3V/m]√P (80MHz – 800MHz) d=[7/3V/m]√P (800MHz – 2,5GHz) where: P is the highest radiated power disclosed by the manufacturer of transmitter [W] and d is the recommended separation distance [m]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[1] a should be less than the compliance level in each frequency range [2] You may observe disturbance nearby any of those equipment which has the following indication: 

Note: in case of frequency 80MHz or 800 MHz, the formula for the higher range is applicable.
Note: these are guidelines. Actual conditions may vary.

[1] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.
2 Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance

Meditech ambulatory blood pressure monitors are intended to be used in electromagnetic environment with controlled RF disturbances. The purchaser or user of the devices may help to reduce electromagnetic disturbances by defining the separation distance between the transportable or mobile RF telecommunication equipment (transmitters) and the device, depending on the highest output power of the telecommunication equipment.

Separation distance in function of the frequency of the transmitter (m)			
The highest output power of the transmitter (W)	150KHz-80MHz d=(3,5/V1)√P	80MHz-800MHz d=(3,5/E1)√P	800MHz-2,5GHz d=(7/E1)√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].

Note: in case of frequency 80MHz or 800 MHz, the formula for the higher range is applicable.
Note: These are guidelines. Actual conditions may vary.

The information in this document is subject to change without notice. Please also read the related electronic user manuals available on the accompanying CD!