Meditech ABPM-05

ambulatory blood pressure monitor

User manual

UK Distributor
P.M.S (Instruments) Ltd Tel 01628 773233 www.pmsinstruments.co.uk

Important information – precautions for use – read carefully!

This symbol on a Meditech recorder is a warning that you should read the accompanying documentation (this manual).

The **ABPM-05** ambulatory blood pressure recorder is manufactured by

Meditech Ltd.

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Contact us for further product and service information.

Meditech Ltd. maintains a quality assurance system certified according to MSZ EN ISO 9001:2000 and MSZ EN ISO 13485:2003.

Notified Body
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Meditech ABPM-05 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

Though the blood pressure measurement algorithm used in Meditech ABP 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 blood pressure measurements. Note that any blood pressure recording may be affected by body position, the physiological condition of the patient, and other factors.

CE 0120

Meditech ABPM-05 described in this manual complies with the requirements of the EU Medical Devices Directive (93/42 EEC).
0120 is the identifier of Notified Body (SGS Yarsley)

MDD IIa MDD classification IIa. EMC class A. EMC group not applicable.

Meditech ABPM-05 is an internally powered type CF device.
Protection vs. ingress of water: ordinary.
Mode of operation: continuous.

2006/5nnnnn The first four digits of the serial number of a recorder show the year of production. The number "5" following the slash serves as device type identifier. The rest is the actual serial number.

This symbol shows that according to regulations ABPM-05 should be handled as electronic waste during rollout.

Blood pressure measurements determined with the algorithm of a Meditech ABP 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 also fulfils the requirements of the British Hypertension Society Validation Protocol for Automated Blood Pressure Measuring Devices (algorithm used in all Meditech ABP recorders is identical to that used in the Meditech ABPM-04 device, which received grade B for both systolic and diastolic accuracy; validation study published in Blood Pressure Monitoring 1998; 3(6):363-8 by I Barna & al).

! For information on cuffs and their application, see page 11.

! Take care to avoid blocking the air flow in the tube of the cuff. 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.

! 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.

File ID: BP5B2210

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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
- Though the blood pressure measurement algorithm used in ABPM-05 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

Care and maintenance

Protection and cleaning

ABPM-05 ambulatory blood pressure recorders are not specially protected against spills or ingression 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 including a shower, bath, or swimming pool. 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. Meditech recorders are covered by a two-year warranty under general warranty conditions of Meditech Ltd, see relevant section. This warranty does not cover any malfunction or defects arising from improper use, 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. Contact Meditech or your distributor for service information.

Roll-out
Meditech recorders may include an internal NiCd coin cell which may fall under the category of hazardous waste and should be disposed of properly. All other parts of should be handled at roll-out as normal electronic waste.

Safety concerns

Electric shock hazard protection
Meditech recorders meet relevant shock hazard protection standards. ABPM-05 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 Meditech recorders, keep at least a 2 meter distance between patient and computer. Meditech 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 may qualify as hazardous waste and should be disposed of properly. Meditech recorders do not contain any materials qualified as pharmaceutical substance or tissue of animal origin. They emit no material or energy 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 behaviour, proper handling of the recorder used, and expected results of monitoring in advance. ABPM-05 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.

The recorder must be programmed from the CardioVisions 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.

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 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 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 ABPM-05 recorder, marked with a triangle. They should mark events such as taking medication, waking up or going to sleep with the EVENT button, marked with a heart. They should mark the time of going to bed and rising from bed with the DAY/NIGHT button, marked with a crescent moon. 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.

Before you begin, you must have the CardioVisions program properly installed and configured on your computer, and the recorder correctly connected. To program your recorder, you will need a Meditech optical interface cable properly connected to your computer's serial port (or to a USB port using a standard USB-to-serial converter) and the communication port correctly selected in the CardioVisions software.

A successful monitoring session consists of the following steps:

1. Inform your patient about monitoring rules well in advance.
2. Insert two fully charged, AA size batteries into the battery compartment and check their voltage.
3. Start the CardioVisions program, select the ABPM-05 recorder type for use.
4. Enter new patient data or select patient from the database.
5. Apply the cuff to the patient.
6. Connect the recorder to the computer.
7. Create a monitoring plan.
8. Send the monitoring plan from the computer to the recorder unit.
9. Give detailed instructions to the patient who has to wear the recorder.

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

10. Check if the plan is completed.
11. Remove the unit and cuff from the returned patient.
12. Ask for the patient diary, and ask the patient for any events, symptoms, observations or complaints.
13. Start the CardioVisions program and select the ABPM-05 recorder type for use.
14. Transfer collected data from the recorder to your database.
15. Analyze blood pressure profile.
16. Create and print a report.

Batteries

ABPM-05 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, for they may contain acidic electrolytes which may leak and corrode electronic components. Never use batteries damaged in any way. Should the batteries still 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 is 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 ABPM-05 recorders, it is advised to check their voltage before programming the recorder. 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.

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 main batteries in the recorder for at least one day; this will recharge the backup cell. It is possible to use the recorder normally in the meantime. 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 ABPM-05 recorder to perform 250-300 blood pressure measurements during a 24-48 hour long monitoring session. 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 rechargeables or two new, long-life AA alkaline batteries into the compartment as shown in the polarity drawing. Close the compartment. 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.

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 shirt or blouse. 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 ABPM-05 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 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 latest after the monitoring session.

Meditech ABPM-05 recognizes and functions with three different cuff sizes.

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 ABPM-05 device is a compact, lightweight monitoring unit typically worn by the patient for 24 hours. It has a battery compartment and a rating label on its back housing. The serial number is placed on the rating label. It is also stored electronically in the solid state memory of the device. On the front housing, there is the LCD, the buttons of the device and a sticker displaying the name of the device. The cuff connector is located on the side. ABPM-05 operates with two AA size accumulators or batteries. The device can be connected to the serial port of an IBM compatible PC with an optoelectronic interface whose socket is positioned on the opposite side from the cuff connector. The recorder is easily initialized connected to a personal computer using an optical cable link. Patients can start extra blood pressure readings or mark symptomatic events.

Accessories

■ set

one	(1)	alucase or carton packaging (depending on order)
one	(1)	recorder unit
one	(1)	serial 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)	CardioVisions software CD
one	(1)	user guide

■ recorder package

one	(1)	carton packaging
one	(1)	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.

The **START** button is marked with a triangle, closest to the LCD. Its functions:

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. ABPM-05 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. While the recorder is switched off, normal functions are not available. The recorder can only be switched on manually.

Switching the device on
ABPM-05 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). The voltage display lasts until you release the button, but not more than 5 seconds. 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.

Cancel a blood pressure measurement
The patient can interrupt a blood pressure measurement by pressing either button at any time while the cuff is pressurized. 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.**

The **EVENT** button is in the middle, marked with a heart. Its function:

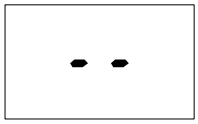
Set a patient event marker
The patient can mark any event without starting a manual blood pressure measurement by pressing the EVENT button briefly. Typical causes for this use: waking up, going to sleep, taking medicine. The patient should be instructed to record the reason for setting an event marker in a diary.

The **DAY/NIGHT** button is farthest from the LCD, marked with a moon. Its function:

Mark time of going to bed and rising from bed
If this function is enabled 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).

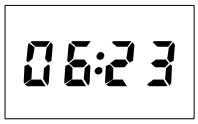
Displays

ABPM-05 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 CardioVisions program. This helps service personnel to identify causes of an unexpected behavior, result or error.

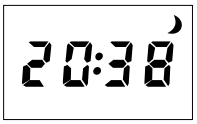


Two dashes:
recorder switched off

LCD check:
all segments
are displayed

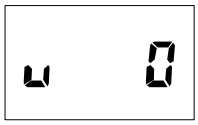


Normal status:
time is displayed

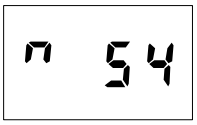


Night mode:
time is displayed,
moon sign is lit

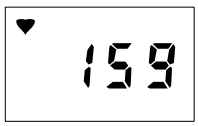
Communication with
personal computer



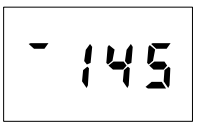
Setting zero pressure
level for blood pressure
measurement



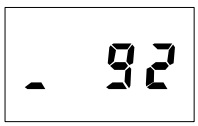
Pumping for
measurement
current pressure [mmHg]



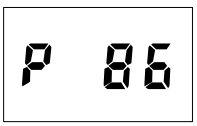
Heart symbol blinking
in tune with pulse:
measurement in progress



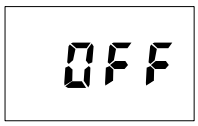
Systolic value of just
completed measurement
[mmHg]



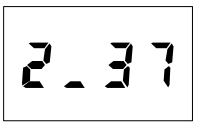
Diastolic value of just
completed measurement
[mmHg]



Pulse rate value of just
completed measurement
[beats per minute]

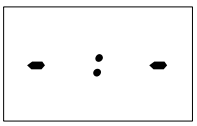


Blood pressure
measurement cancelled
by pressing a button



Battery voltage display
(2.37 V)

Error code display



Event marker set with
buton

Technical parameters

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:
on serial optical cable, 115200Baud

PC interface:
special optoelectronic serial interface with 9 pin Canon RS232 connector

Operating environment:
+10 to +45 °C of temperature
10 to 95 % humidity, non condensing
70 to 106 kPa atmospheric pressure

Storage conditions:
-20 to +50 °C of temperature
10 to 95 % humidity, non condensing

Size:
70 x 99 x 30 mm

Weight:
app. 240 g (batteries included)

Blood pressure measurement method:
oscillometric

Blood pressure maximum storage:
over 600 measurements

Pressure measurement range:
0-300 mmHg

Static accuracy:
± 3 mmHg or ± 2% of measured value (stability: 2 years)

Blood pressure measurement range:
30-260 mmHg

Blood pressure measurement accuracy:
the BP measuring algorithm has been BHS-validated in Meditech ABPM-04 device

Pressure sensor:
piezo-resistive

Inflation:
automatically controlled pump

Safety:
maximum inflation 300 mmHg; independent safety release valve

Deflation and rapid air release:
automatic pressure release valve

(a) 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.
(b) 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.
(c) 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.
(d) 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, 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. 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 CardioVisions 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.