

User manual

ABPM-05, ABPM-04 and BlueBP-05
ambulatory blood pressure monitors with
CardioVisions software
(from version 1.18)



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Important information on ABPM-05, ABPM-04 and BlueBP-05 systems. Read carefully, please.

	<p>This symbol on a Meditech recorder is a warning that you should read the accompanying documentation (this manual).</p>
	<p>ABPM-05, ABPM-04 and BlueBP-05 ambulatory blood pressure monitors and CardioVisions software are manufactured and developed by Meditech Ltd. All title and copyrights in and to the CardioVisions software, the accompanying electronic and printed materials and any copies of the CardioVisions software are owned by Meditech Ltd. The CardioVisions software is protected by copyright laws and international treaty provisions. For details please read the software license agreement.</p> <p>Contact details: 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</p> <p>Contact us for further product and service information. Meditech Ltd. maintains a quality assurance system certified according to MSZ EN ISO 9001:2008 and MSZ EN ISO 13485:2003.</p> <p>Notified body: SGS Yarsley Unit 202b, Worle Parkway, Weston-super-Mare, BS22 0WA Fax: +44 1934 522 137 Web: www.sgs.com</p>
	<p>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.</p>
<p>model BP5, BP4 or BB5</p>	<p>Device type. (BP5= ABPM-05, BP4= ABPM-04, BB5= BlueBP-05)</p>
	<p>Each device complies with the requirements of the EU Medical Devices Directive. 0120 is the identifier of Notified Body (SGS Yarsley).</p>
<p>MDD IIa</p>	<p>MDD classification IIa. EMC class B. EMC group 1.</p>
<p>MDR II</p>	<p>According to Canadian regulations the device classification is MDR II. (Medical Device Regulation of Canada, Rule 10.1 of MDR (SOR/98-282:13Mar2007)).</p>
	<p>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 equipments.</p>
<p>YYYY/nnnnnn</p>	<p>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</p>
	<p>This symbol shows that according to regulations the monitors should be handled as electronic waste during rollout.</p>
	<p>The device communicates via Bluetooth connection. (Bluetooth V2.0+EDR, class2)</p>

	<p>Blood pressure measurements determined with the algorithm of an ABPM-05, ABPM-04 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 the ABPM-05, ABPM-04 and BlueBP-05 also fulfills the requirements of the British Hypertension Society Validation Protocol for Automated Blood Pressure Measuring Devices.</p>
	<p>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.</p>

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1. Recommended use of ambulatory blood pressure monitors

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

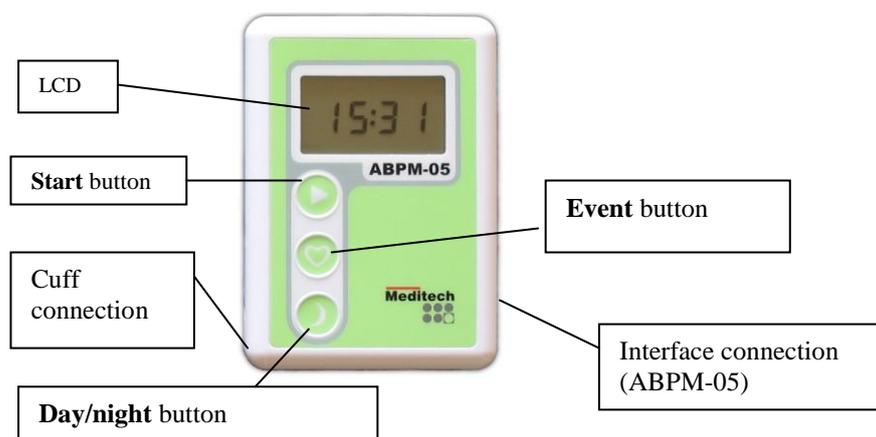
Contraindications

- Non-cooperative patients, unconscious or otherwise incapable patients
- Patients requiring urgency/emergency cardiac care
- Patients with coagulation disturbances
- 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.

2. Devices

ABPM-05 and BlueBP-05

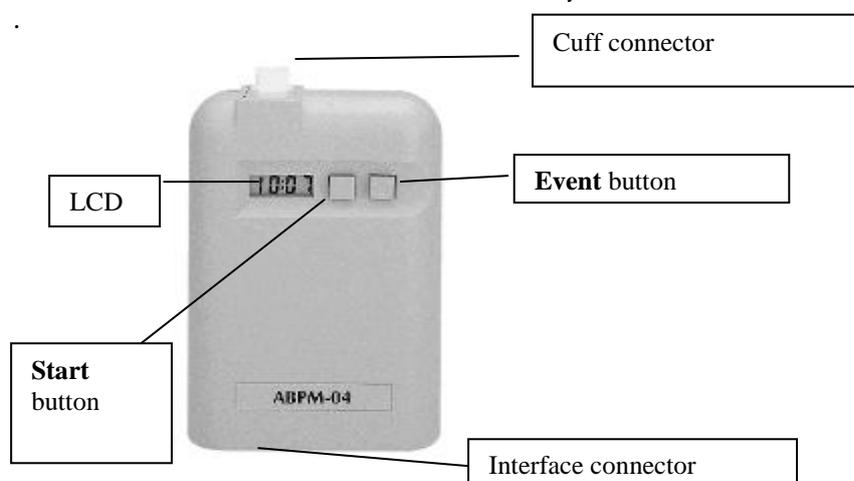
ABPM-05 and its Bluetooth-capable version, BlueBP-05 is a programmable, oscillometric ambulatory blood pressure monitor, which is typically worn by the patient for 24 hours. ABPM-05 and BlueBP-05 are compact, lightweight devices, which operate with 2 AA size accumulators or batteries. More than 600 measurements can be stored in the device memory. Stepwise pressure deflation ensures quality measurements, even if disturbing environmental factors occur. The battery compartment and the rating label are on the backside of the housing. The serial number can be found on the rating label and 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 ABPM-05 device can be connected to the serial or USB port of a Windows compatible PC with an optoelectronic interface. The socket is positioned on the opposite side from the cuff connector. BlueBP-05 can be connected to a Windows based PC with a Bluetooth adapter. Patients can start extra blood pressure readings or mark events.

ABPM-04

ABPM-04 is a silent, PC-based ambulatory blood pressure monitor, which can be programmed for even 51 hours. The operation is ensured by 4 AA rechargeable batteries. 300 measurements can be made by a battery set, while the device itself can store 600 measurements. The patient can start extra measurement, indicate events or set special day/night indication by pressing a device button. ABPM-04 operates with Meditech normal, small and large cuffs. The state of the batteries can be checked by the voltage display function. The device can be connected to any standard PC with its optical interface cable.



3. Accessories

Set (delivery either in plastic case or carton box)

- 1* ABPM device
- 1* serial (ABPM-04) or USB (ABPM-05) interface cable or Bluetooth dongle (BlueBP-05)
- 1* pouch for the recorder with shoulder and waist straps
- 1* normal size cuff
- 1* battery charger with two sets of rechargeable batteries
- 1* CD with the latest software and manual
- 1* user documentation (quality certificate and event diary)

Recorder package (delivery in a carton box)

- 1* ABPM device
- 1* pouch for the recorder with shoulder and waist straps
- 1* normal size cuff
- 1* quality certificate

Accessories may vary from place to place.

4. Using the buttons

On the front side of **ABPM-05** and **BlueBP-05**, below the LCD, you can find three buttons: START button is marked by a triangle, EVENT button is marked by a heart and DAY/NIGHT button, which is marked by a crescent moon. If the device operates, each button press is accompanied by a short beeping sound.

On the front side of **ABPM-04** there is the unmarked START and the EVENT button, which is marked by a circle. Each button press is accompanied by a short beeping sound. The following functions relate to all devices – otherwise it is clearly indicated.

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.

Manual blood pressure measurement

If it seems necessary, the patient can start an additional, manual blood pressure measurement by pressing the START button shortly (less than 5 seconds). Results 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. If the device is switched off, it can be switched on again 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 justified in case of valid reasons.

Switching the device on

The device can be switched on by pressing and holding the START button 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, but less than 10 seconds to display voltage on the LCD (e.g. 2_64 is equal to 2,64V). After checking the voltage, release the button. The unit will then return to display time. The voltage for fully charged accumulators should be over 2,5V in case of ABPM-05 and BlueBP-05 and 5,37V in case of ABPM-04.

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 cause for this use is taking medicine. The patient should be instructed to record the reason for setting an event marker in a diary.

Marking the time of going to bed and rising from bed – ABPM-05 and BlueBP-05 only

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

Manual DAY/NIGHT shift – ABPM-05 and BlueBP-05 only

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. The switch is available in the two hour period before the prescheduled shift.

Bluetooth functions

You can initiate the Bluetooth mode by pressing the START and the EVENT buttons simultaneously.

Switching to Bluetooth discoverable mode

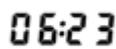
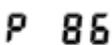
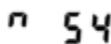
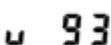
The device switches to discoverable mode, making it connectable to all Bluetooth devices, by pressing the two buttons simultaneously for longer than three seconds and then releasing them. In this state the PC will connect to the device and you can read out the recorder data of the last measurement or you can also programme the device for the next monitoring session. After reading out or programming the Bluetooth connection is automatically ceased.

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 if the connection fails to be established in one minute.

5. Display

ABPM shows important status information, the processes and the results of individual readings on its LCD. The most important displays are listed here, in addition to these, a lot of extraordinary situations and errors have their own code displayed on the LCD. These codes, stored together with recorded data, will be listed in the device memory and can be displayed by the software. Information displayed on each device:

	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.

145	Systolic value of just completed measurement (mmHg)	OFF	The blood pressure measurement is cancelled by pressing a button.
92	Diastolic value of just completed measurement (mmHg)		

Information displayed on ABPM-05 LCD screen only:

PC	Communication with a personal computer	0-	Blood pressure measurement initiated (kPa)
7-	Pumping for measurement, current pressure is displayed (kPa)	12-	Deflation during measurement, current pressure displayed (kPa)
88:88	LCD check: all segments are displayed	21-	Heart symbol blinking: measurement in progress (kPa)
19.2	Systolic value of a just completed measurement (19,2 kPa)	12.3	Diastolic value of a just completed measurement (kPa)

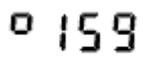
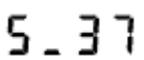
Information displayed on both ABPM-05 and BlueBP-05

159	Heart symbol blinking: measurement in progress (mmHg)	2.37	Battery voltage display (2,37V)
20:38	Night mode: time is displayed, moon sign is lit.	16:23	The crossed battery symbol warns of low battery

Information displayed on BlueBP-05 only:

PC--	The device is in Bluetooth discoverable mode
------	--

Information displayed on ABPM-04 LCD screen only:

	Rectangle blinking: measurement is progress (mmHg)		Battery voltage display (5,37V)
	Communication with a personal computer		LCD check: all segments are displayed
	Low battery voltage (three dots below)		

6. Technical parameters

Technical parameters		
ABPM-05	BlueBP-05	ABPM-04
Power supply		
2 AA rechargeable NiCd or NiMH batteries or 2 AA alkaline batteries		4 AA rechargeable NiCd or NiMH batteries or 4 AA alkaline batteries
Display		
liquid-crystal		
Data storage		
internal solid state memory		
Data transmission		
serial or USB cable	serial Bluetooth transfer	serial or USB cable
Operating environment		
temperature		
10-45 °C		
humidity (non condensing)		
10-95%	10-80%	10-95%
atmospheric pressure		
70-106 kPa		83-103 kPa
Storage conditions		
temperature		
-20 - 50 °C		
humidity (non condensing)		
10-95%	10-80%	10-95%
Size		
70*99*30 mm		82*124*33,5 mm
Weight (batteries included)		
240g		330g
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 and AAMI protocol		
Pressure sensor		
stepwise deflation		
Inflation		
automatically controlled pump		
Safety		
maximum inflation 300 mmHg (40 kPa), independent safety release valve		
Deflation and rapid air release		
automatic pressure release valve		

Please note that the device may not meet its performance specifications if stored or used outside the specified environmental conditions. Both measuring and LCD display in kPa is available in ABPM-05 device only. This is an option which can be selected in the software. The unit of measurement can be changed later in the database.

7. Care and maintenance

Protection and cleaning

The Meditech ambulatory blood pressure monitors 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 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! 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. To wash the cuff please do the following:

1. Remove the bladder.
2. Wash by hand the sleeve with lukewarm water and regular washing liquid suitable for black material. Rinse well.
3. If required, wipe the bladder with a mild cleaning tissue.
4. Allow both bladder and sleeve to air dry.
5. Replace bladder in the sleeve.

Regular checks, warranty, service

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.

Roll-out

Each ABPM recorder include 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.

8. Safety concerns

Electric shock hazard protection

Each ABPM recorder meets the relevant shock hazard protection standards. ABPM-05 and BlueBP-05 operates with two 1.5V AA batteries or two 1.2V AA rechargeable batteries, while ABPM-04 uses four 1.5V AA batteries or four 1.2V rechargeable batteries. This 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 and ABPM-04 communicate using a plastic optical cable, whose 4 m standard 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. 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.

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 behaviour, 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.

9. The use of the monitors

The recorders can be programmed by CardioVisions software installed on a personal computer. Once the preprogrammed time is reached, the recorder starts operating automatically by taking blood pressure measurements according to the monitoring plan.

Connecting the recorders to the PC

You can connect Meditech recorders depending on the recorder type to your computer in several ways. ABPM-05 and ABPM-04 are equipped with a connector slot for a special optoelectronic communication cable – with these recorders, the computer-end of the interface cable has to be properly plugged into a corresponding socket on the computer before inserting its small recorder-end plug into the socket on the recorder for communication between the CardioVisions software and the recorder.

BlueBP-05 is capable of wireless communication with the computer using Bluetooth technology. For successful communication, you need a properly connected and installed Bluetooth adapter.

ABPM-05, ABPM-04: communication with an optical interface cable

Steps to follow for the first connection:

- Locate a free 9-pin serial port (also called RS232) or USB port (often labelled ) on your computer.
- Take the optoelectronic interface unit with the optical cable out of package.
- Connect the interface unit to the port.

If you have a serial RS232 port on your computer, just plug in the 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. If you have a USB port on your computer then connect the USB-type optoelectronic interface from Meditech.

- 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 the red mark on the cable to the red mark on the 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 CardioVisions software.

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 CardioVisions software, click the **Tools** menu, then 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 **Meditech USB** or the **Serial port** 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 or enable the **Auto search com port** checkbox, and click the **Test** button.

BlueBP-05: wireless Bluetooth communication

BlueBP-05 is an ambulatory blood pressure monitor with wireless communication. 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, contain detailed information how wireless devices can be used, and this is described in detail in CardioVisions 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 CardioVisions.

If you wish 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.

- a) Open the **Tools - Options** dialog of CardioVisions 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.
- b) In the appearing dialog you can see Meditech recorders which have already been added to your computer. Place fresh batteries into the new BlueBP-05 recorder and make it Bluetooth discoverable.

For this, in case of BlueBP-05, press the START and the EVENT button simultaneously for longer than 3 seconds, 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 stand by mode. If a recorder switches back to standby mode, make it discoverable again. After you have made a recorder discoverable, click on the **Add** button.

- c) If there is a moving torch on the screen, the PC searches for Bluetooth devices. Should a recorder switch back to stand by 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, please click on it.

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

Monitoring step by step

Before you begin, you should have the CardioVisions software properly installed and configured on your computer, and the recorder correctly connected. To program your ABPM-05 or ABPM-04 recorder, you will need a Meditech optical interface cable properly connected to your computer's serial or USB port and the communication port correctly selected in the CardioVisions software. To program BlueBP-05, you will need a properly installed and connected Bluetooth dongle, and the communication correctly set in the CardioVisions software.

Programming by using a PC

1. Inform your patient about the monitoring rules well in advance.
2. Programming:
Start the CardioVisions programme and select either ABPM-05, ABPM-04 or BlueBP-05 from the device types. Click on Device/Programming device.
3. Enter new patient data or select patient from the database.
4. Create monitoring plan adjusted to the patient's daily routine.
5. Insert two (in case of ABPM-05 and BlueBP-05) or four (in case of ABPM-04) 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 use of the device.

Manual programming (ABPM-05 only)

ABPM-05 can be programmed without a PC by using the device buttons.

Programming options

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:

- First plan: measurements every 15 minutes at day and every 30 minutes at night.
- Second plan: periods with 20 minutes at day and 40 minutes at night.
- Third plan: 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.

Measurement timing

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.

Manual programming step by step

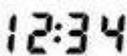
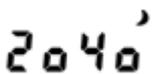
- Press and hold START and DAY/NIGHT button at the same time continuously. Measurement frequency of the measurement plans will be displayed after 10 seconds for 3-3 seconds.
- In order to choose the measurement plan, you should release the buttons while the specific plan is displayed. You will hear two 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 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 happens 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.

Software

The devices programmed manually can be used by CardioVisions software version 1.13 or later versions.

LCD displays for manual programming

	<p>Normal status: time is displayed.</p>		<p>2. measurement plan: 20/40 minute day/night intervals</p>
---	--	---	--

1234	10 second delay state	3030'	3. measurement plan: 30/30 minute day/night intervals
.530'	1. measurement plan: 15/30 minute day/night intervals	0000	Programming is in progress: blinking signal

Rules of monitoring

- Inform the patient about the goal and expected results of the monitoring. Provide an event diary and inform him about the rules to observe.
- Put the device into the pouch. The patient should fit the adjustable straps of the pouch.
- 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.
- 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.
- The patient 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 patient at night.
- The patient can initiate extra blood pressure measurements with the START button of the recorder (marked by a triangle in case of ABPM-05 and BlueBP-05 and unmarked in case of ABPM-04). By pressing the EVENT button the patient can mark events, e.g. taking medication etc. In case of ABPM-05 and BlueBP-05 only, the time of going to bed and rising from bed can be marked by the DAY/NIGHT button (moon symbol). If necessary, any blood pressure measurement can be interrupted by pressing any of the device buttons.
- Should the batteries run down during a monitoring session, they can be simply replaced. Monitoring will continue and data will not be lost.
- The patient should never measure anybody else's blood pressure with the recorder during an ambulatory blood pressure monitoring session.

Monitoring session (typically 24 hours)

10. Remove the unit and the 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 software and select the proper recorder type.
13. Connect the device to the PC and transfer the collected data from the recorder to your database.
In CardioVisions software select ABPM-05, ABPM-04 or BlueBP-05 from the device types and click on Device/Read data from xxx, where xxx indicates the name of the selected device.
If you have selected manual programming or the device was programmed from another database, record patient information into the database after reading in data.
14. Analyze the blood pressure profile.
15. Create and print the report.

10. Batteries

The Meditech ambulatory blood pressure monitors operate either with normal batteries or with AA rechargeable batteries. (ABPM-05/BlueBP-05: two 1.5V AA batteries or two 1.2V AA rechargeable batteries, ABPM-04: four 1.5V AA batteries or four 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 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. Do not start a new monitoring session with low batteries. The typical voltage for fully charged rechargeable batteries should be over 2,5 V (ABPM-05/BlueBP-05) or 5,2V (ABPM-04), and for fresh alkaline batteries, over 3 V (ABPM-05/BlueBP-05) or 6V (ABPM-04). It is possible to check battery voltage with the START button. (Please check the *Using the buttons* topic 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. 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/four properly charged, high capacity AA rechargeable or two/four new, long-life AA alkaline batteries into the compartment as, then close the compartment.

11. Cuffs and their application

It is advisable to wear a thin shirt or blouse under the cuff. This does not influence the accuracy of the 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 air connector of the cuff into the air connector socket of the device, which you can find on the long edge closer to the buttons of the ABPM-05/BlueBP-05 recorder or on the top of the ABPM-04 recorder. Connect the cuff turning it clockwise with slight pressure.

Note: 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.

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.

The monitors recognize three different cuff sizes. The size to be used should be set during 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 ¹
Normal adult	12 x 25 cm	15 x 56 cm	29-38 cm
Small adult	9 x 18 cm	11 x 32 cm	max 32 cm
Large adult	15 x 33 cm	17 x 77 cm	35-46 cm

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 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.

¹ When properly applied, the end of the sleeve (the one closer to the tube) should fall in the indicated range.

12. Using CardioVisions software

The CardioVisions software package provides means to handle Meditech ambulatory blood pressure and ECG recorders. With CardioVisions it is possible to initialize (programme) a recorder, check ECG signal quality of an ECG recorder applied to a patient in real time mode, and transfer (read) collected data from a recorder to your computer. CardioVisions 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. Please create safety backups of your files and folders regularly, because this is the only way to restore data with this feature. CardioVisions 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. In summary, CardioVisions lets you:

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

Caution! Certain antivirus software programs can severely slow down CardioVisions. This can be avoided by adding the CardioVisions file formats as exceptions in the antivirus software. E.g: *.ff2 and *.sm0 files.

CardioVisions editions and system requirements

Personal and Network Edition

CardioVisions comes in two different editions.

CardioVisions **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 without registration with an unlimited number of recorders from CardioVisions 1.10.

Multiple users can work with one database in a computer network at the same time using CardioVisions **Network Edition**. This edition has to be installed on a server computer in a network, where users have access to CardioVisions over the network from the workstations. The use of the Network Edition requires registration.

Using Personal Edition for personal purposes

Demo data in CardioVisions Personal Edition are specifically included so that all features which would otherwise require registration will still work in an unregistered installation. There is no demo feature of CardioVisions Network Edition.

Computer requirements

CardioVisions can be installed on most Windows-based personal computers, but check before installation whether your computer meets the following requirements.

Minimum

CPU: 350 MHz Pentium II

RAM: 64 MB

VGA: 800*600 @ 16 bit color

LAN: 10Mbit/s

Suggested

CPU: 2 GHz P4 or equivalent

RAM: 512 MB

VGA: 1024x768 @ 16 bit color

LAN: 100 Mbit/s

HDD: about 40 MB for the software + disk space for database²

Operating system: Windows 98 SE / Me / 2000 / XP / Windows 7

Please note that certain features of CardioVisions require a lot of calculations, so the faster your computer is, the shorter time you will need to get a 24-hour ECG recording analyzed.

ABPM installation and first start

There are two very common errors that occur installing CardioVisions software.

- The default user is admin and this account is created with the installation. In order to use the device you must create a 'user' account. The Admin cannot access the recorder or patient data.
- Registration does not apply to ABP monitors. This process is for other products only.

Installing CardioVisions Personal Edition

CardioVisions Personal Edition should be installed if you want to use the software on one PC or if you need demo data only. You need to go through the following steps:

- Select your preferred language
- Read and accept the License Agreement
- Choose components to install
Here the installation of the USB driver is strongly advised.
- Choose recorder types you want to use
- Select the target folder of the installation
- Choose a Start menu folder for usual shortcuts.

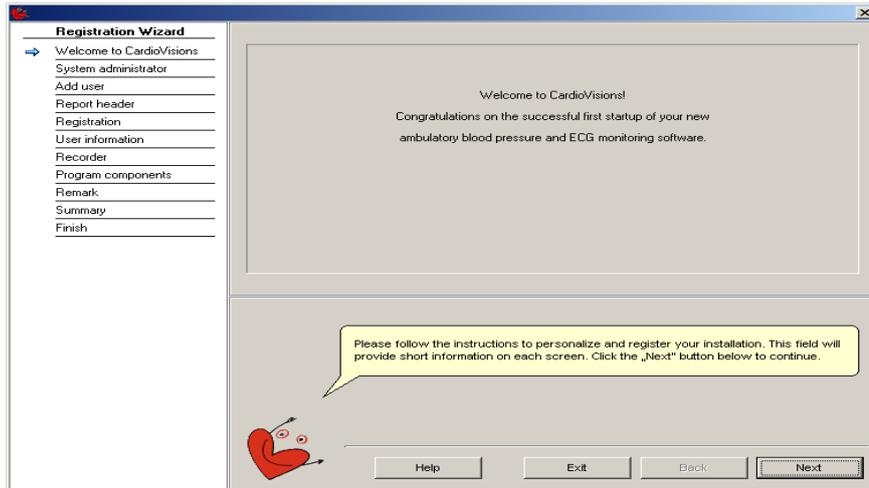
After finishing the installation, CardioVisions setup creates a startup icon on your desktop.

First start

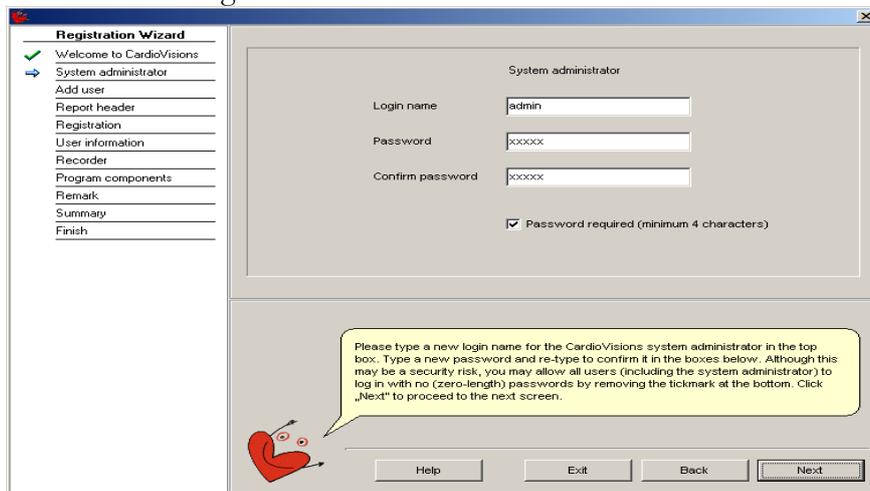
You can start CardioVisions with the created shortcut on your desktop. At first you will be logged in as a system administrator (admin) who can start a registration, add new users or change data access levels. After the first start you will see the following screens:

² 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. The installation of demo data requires about 200 MB, too.

- Welcome screen

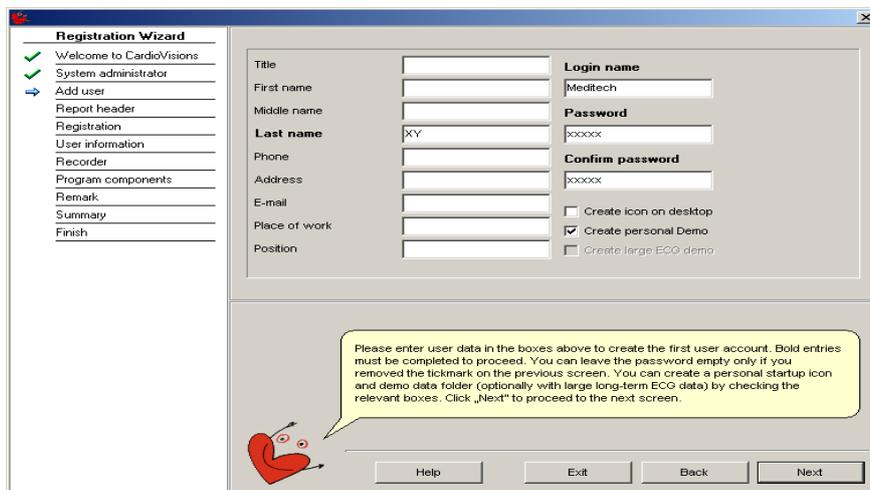


- System Administrator settings



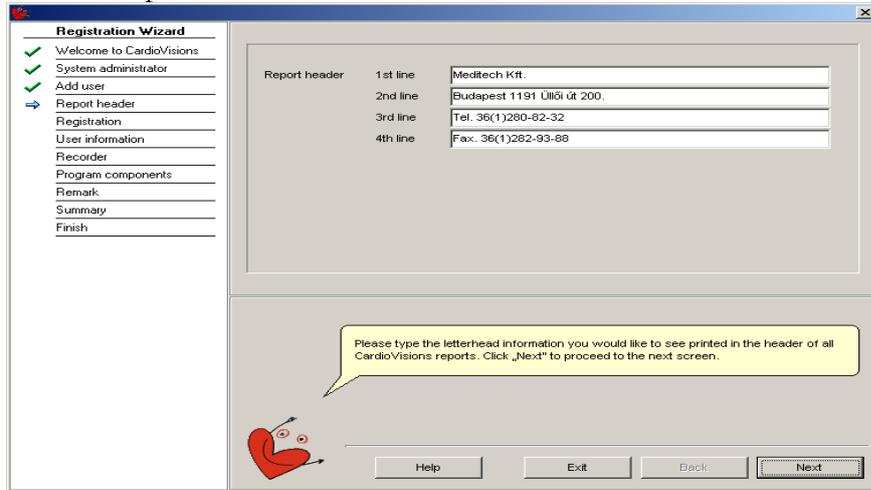
Your default login name and password is **admin/admin**. Default settings can be modified here. Reminder: the system administrator cannot see medical data, as it is only the user who has access to measurements.

- Add a CardioVisions user



Here you are required to create a user account by filling in the empty spaces, but at least the bold entries. Creating a user is necessary to see medical data.

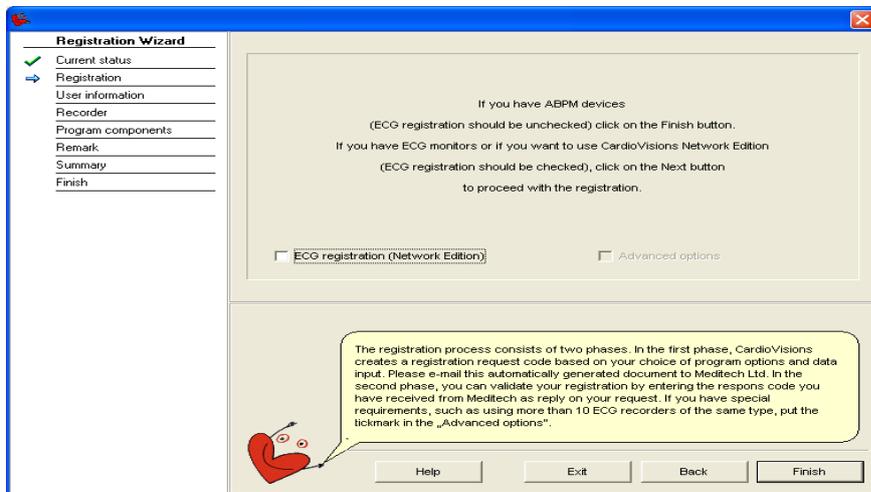
- Modify the default report header



In this screen you can change the report header data, which can be seen on the top of all printed report pages.

- Registration

Registration is not necessary for ABP monitors. This function is for other devices only. You can quit by '*Finish*' button.



If you want to make recordings, login as a User into the software.

Installing CardioVisions Network Edition

If you wish to access CardioVisions functions from several workstations in a computer network, you have to install CardioVisions Network Edition. The installation procedure looks quite similar to that of the Personal Edition (see above), but the result is quite different. While Personal Edition setup installs a typical program where you have a single executable file to start and then you can access all functions, the Network Edition setup will install two separate applications, two executable files: one for the networked CardioVisions database engine application (also called the database server), and another for the so-called CardioVisions client application, i.e., the user-end of the program to ask for data over the network from the database engine on any workstation. Therefore, the Network Edition has to be installed on a properly configured server computer. After the installation, the CardioVisions database engine will be automatically started by default whenever the server computer is started. The Network Edition has to be installed on the server computer, on the individual workstations only a shortcut has to be created. Then, as a result, the database engine will run on the server computer continuously, and the CardioVisions client can be started on any workstation with a proper shortcut (startup icon). For all normal user purposes, the CardioVisions client of the Network Edition is indistinguishable from the program used in the Personal Edition. There is one important difference in behaviour, however: if you use the Network Edition and the server computer is shut down, it will not be possible to start CardioVisions from the workstations. Similarly, even if the server computer is switched on, but the CardioVisions database engine is not running (it is stopped, shut down or not started at all), it will be impossible to use CardioVisions.

Compared to the installation of CardioVisions Personal Edition, there is one additional step to take during the installation of the Network Edition. After you have chosen the recorder type(s) to use, you are asked to select an IP-address (a network property) through which the database engine can communicate with the client(s) running on any workstation. This is a question only if the server has multiple network adaptors, either for intra- or extranet purposes, or because of different physical subnets.

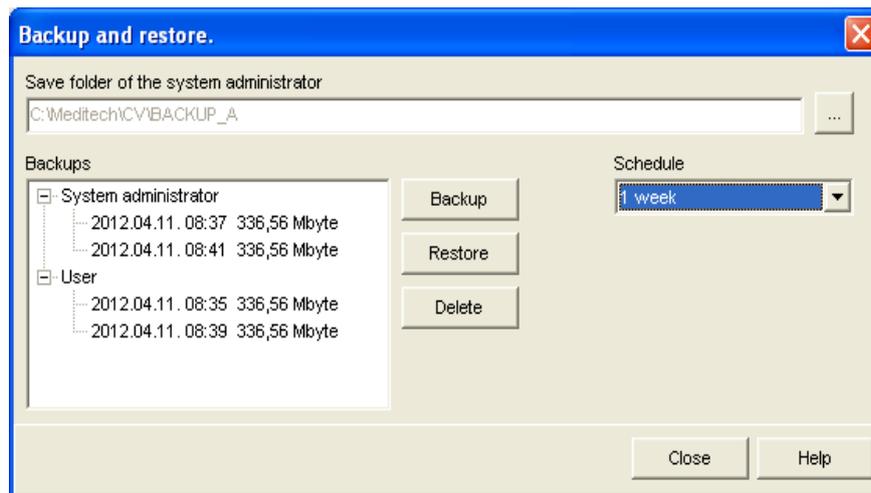
To complete your CardioVisions Network Edition installation, you have to manually share the “CLIENT” folder of your installation with read-only access from all workstations and you have to create a shortcut on each workstation pointing to the CardioVisions client application executable file in this folder (its name is CV001.EXE). This is best done manually as automatic sharing is either impossible or can have serious security risks, and once the shortcut is created, you can simply “copy-paste” it to all workstations where you want to use CardioVisions. If you have any doubt, consult your computer network administrator.

It is possible to configure your own CardioVisions database engine application to use different options in the unlikely case of networking problems. Since database engine is an auto-configuring application, change a working configuration only if it is absolutely necessary and always with the close assistance of an experienced network specialist. To change database engine configuration, first request all users to log out from CardioVisions and close all CardioVisions clients on all workstations, then bring up the database engine application from the system tray on the server computer by double-clicking its icon, then choose Server – Stop, then select the required command of the Config menu. After your changes, choose Server – Start to make the CardioVisions database engine services available to users again.

Backup

Creating a backup from CardioVisions database is strongly recommended to prevent data loss. It is advised to create a backup often, monthly, weekly or even daily depending on the frequency of the software usage.

The function is available both for the User (Tools/Backup) and for the System Administrator (Tools/System administrator tools/Backup and restore). While the former can create backups only manually, the latter has the possibility to create backups both manually and automatically according to preset intervals.



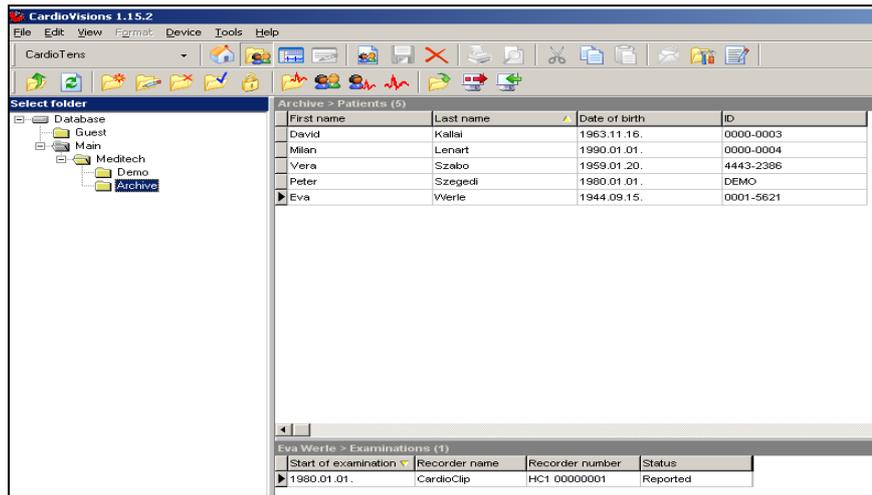
The User's backups, from which only the last two can be stored, are saved into C:\Meditech\CV\Backup_U, while the System Administrator's backups, the number of which is unlimited, are saved into C:\Meditech\CV\Backup_A.

Automatic backup can be made weekly, fortnightly or monthly. If the function is selected the backup will automatically be done compared to the last backup in the preset schedule.

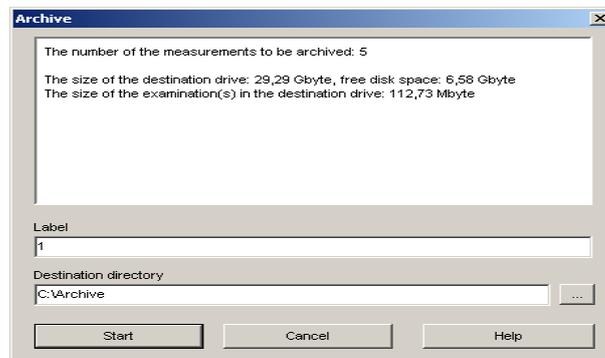
Archiving

CardioVisions data archiving refers to the long-term storage of the large-size recordings in order to free up space in the database. Archiving can be done either by the User or the system administrator. The process is the following:

- 1.) Enter the software and go to the Database screen.
- 2.) Create a new folder into which you can collect the selected examinations which have to be archived.

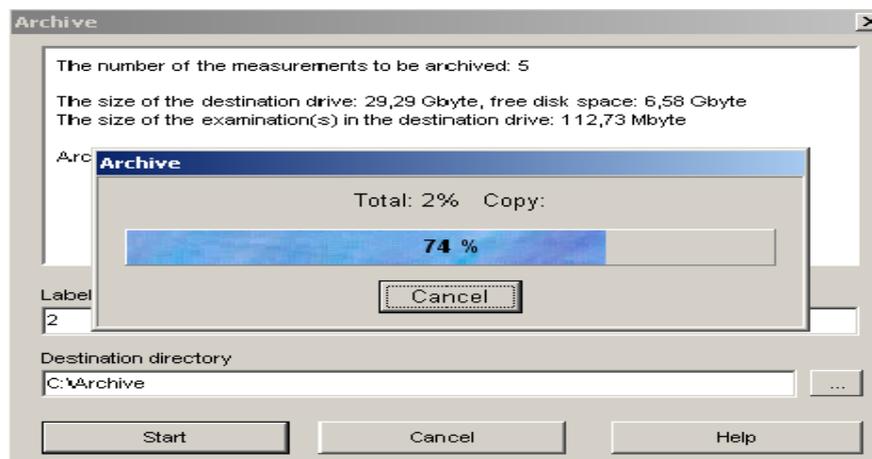


3.) After clicking 'Tools/Archive examinations from the selected folder', a new panel will appear on your screen, which will inform you about the number and the size of the measurements in the folder and the size of your destination drive.



Select the folder in the destination directory in which you want the examinations to be saved. You should type in or select the name of the destination directory to archive to the hard disc.

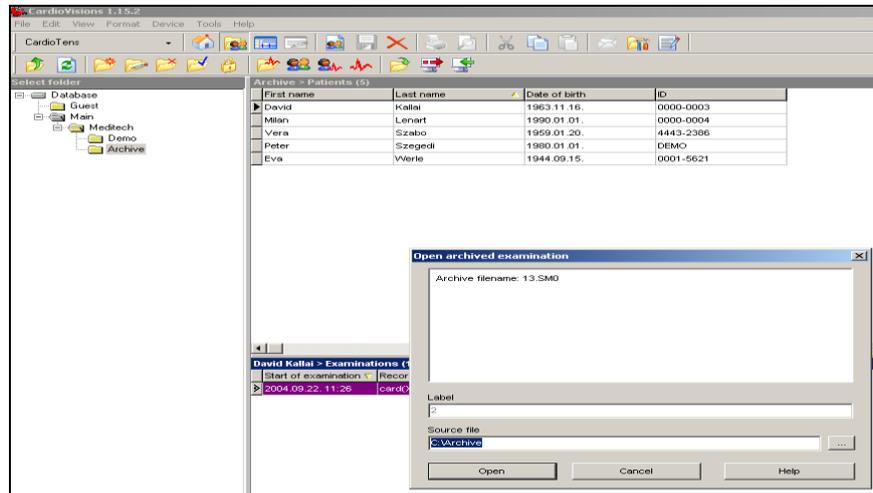
4.) If you have made sure that the size of the data to be archived does not exceed the size of the free space on the destination drive you can start the process. The speed and the duration of the process depends on the size of the recordings.



5.) When the process is completed, a message window will notify you about it. Click the 'Close' button to exit the window. The archived examinations will be coloured purple in your

database. To open the examination like this, the program will ask the destination route of the archived data. If you have saved the data on the hard disc, just simply select the source file.

After archiving your files to a PC, you can copy data to a CD or DVD as well. If you choose this solution, write the name of the disc into the 'Label' field in order you can open the archived files easily later. If you want to have access to your archived files, place the disc in the drive with the appropriate label then select the source file.



6.) If you have started archiving to free up space in your database, enter the software as a system administrator and click 'Tools/ System administrator's tools/Maintenance'. Using this command will compress your database. Put a tickmark next to 'Integrity' to make sure that your database does not contain any injured data. Put a tickmark next to 'Packing' to create a smaller database. Note, please, that the process will require at least as much free space as the size of your database.



13. Meditech product warranty information

- (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, 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.

14. CardioVisions software license agreement

Important – read carefully: This License Agreement is a legal agreement between you (either an individual or a single legal entity) and Meditech Ltd. for the CardioVisions software, 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.

Software license: The SOFTWARE is protected by copyright laws and international copyright treaties, as well as other intellectual property laws and treaties. The SOFTWARE is licensed, not sold.

Grant of license: This Agreement grants you the following rights:

Software: You may install and use one copy of the SOFTWARE only on one computer.

Storage/Network Use: You may also store or install a copy of the SOFTWARE on a storage device, such as a network server, used only to install or run the SOFTWARE on your other computers over an internal network.

Description of other rights and limitations

Limitations on Reverse Engineering, Decompilation, and Disassembly: You may not reverse engineer, decompile, or disassemble the SOFTWARE.

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 Meditech or an authorized representative of Meditech.

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 Meditech Ltd.

Termination: Without prejudice to any other rights, Meditech 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.

Copyright

All title and copyrights in and to the SOFTWARE, the accompanying electronic and printed materials, and any copies of the SOFTWARE are owned by Meditech Ltd. The SOFTWARE is protected by copyright laws and international treaty provisions, therefore, you must treat the SOFTWARE like any other copyrighted material, except that you are allowed to make a copy of the software only for control and evaluation purposes. You may not copy the printed materials accompanying the SOFTWARE.

Miscellaneous

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

Limited warranty

Meditech 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. 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, or inability to use this product, even if Meditech has been advised of the possibility of such damages.

15. 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.

Monitor	Emission test	Compliance	Electromagnetic environment
ABPM-05	Radiated and conducted RF emission CISPR 11	Group 1	ABPM-05/ABPM-04/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. ³
ABPM-04			
BlueBP-05			
ABPM-05	Radiated and conducted RF emission CISPR 11	Class B	ABPM-05/ABPM-04/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.
ABPM-04			
BlueBP-05			
ABPM-05	Harmonic emission IEC61000-3-2	Not applicable	---
ABPM-04			
BlueBP-05			
ABPM-05	Voltage fluctuations/ Flickers IEC61000-3-3	Complies	ABPM-05/ABPM-04 is suitable for use in establishments directly connected to a public low voltage mains network.
ABPM-04		Not applicable	---
BlueBP-05			

³ The Bluetooth radiofrequency communication is carried out at the 2.4GHz frequency. (class2, Bluetooth 2.0+EDR)

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	± 6 KV 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.
ABPM-04			± 6 KV contact ± 8 KV air	
BlueBP-05				
ABPM-05	Electrical fast transient/burst IEC 61000-4-4	± 2 KV for power supply ± 1 KV input/output lines	Not applicable	Mains power quality is that of a typical commercial and/or hospital environment.
ABPM-04				
BlueBP-05				
ABPM-05	Surge IEC 61000-4-5	± 1 KV differential mode ± 2 KV common mode	Not applicable	Mains power quality is that of a typical commercial and/or hospital environment.
ABPM-04				
BlueBP-05				
ABPM-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.	Not applicable	Mains power quality is that of a typical commercial and/or hospital environment. If the user of Meditech ambulatory blood pressure monitors requires CLINICAL UTILITY during power mains interruptions, it is recommended that parts of the Meditech ABPM system where applicable be powered from an uninterruptible power supply.
ABPM-04				
BlueBP-05				

ABPM-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-04				
BlueBP-05				

Note: U_T is the nominal voltage of mains.

Monitors	Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment
ABPM-05	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 Meditech ABPM-05/ABPM-04, including cables, than the Recommended Separation Distance calculated the formula written below. Recommended Separation distance: $d=[3,5/\sqrt{P}]$
ABPM-04				
BlueBP-05			3V _{eff}	Portable and mobile RF communications equipment are used no closer to any part of Meditech BlueBP-05, including cables, than the Recommended Separation Distance calculated the formula written below.
ABPM-05	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].
ABPM-04				

BlueBP-05	Radiated RF IEC 61000-4-3	3V/m 80MHz-2,5GHz	3V/m	<p>Recommended Separation distance: $d=[3,5/\sqrt{V1}]\sqrt{P}$ $d=[3,5/3V/m]\sqrt{P}$ (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] and d is the recommended separation distance [m].</p> <p>You may observe disturbance nearby any of those equipment which has the following indication:</p> 
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- f) Note: in case of frequency 80MHz or 800 Mhz, the formula for the higher range is applicable.
- g) Note: these are guidelines. Actual conditions may vary.

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.

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