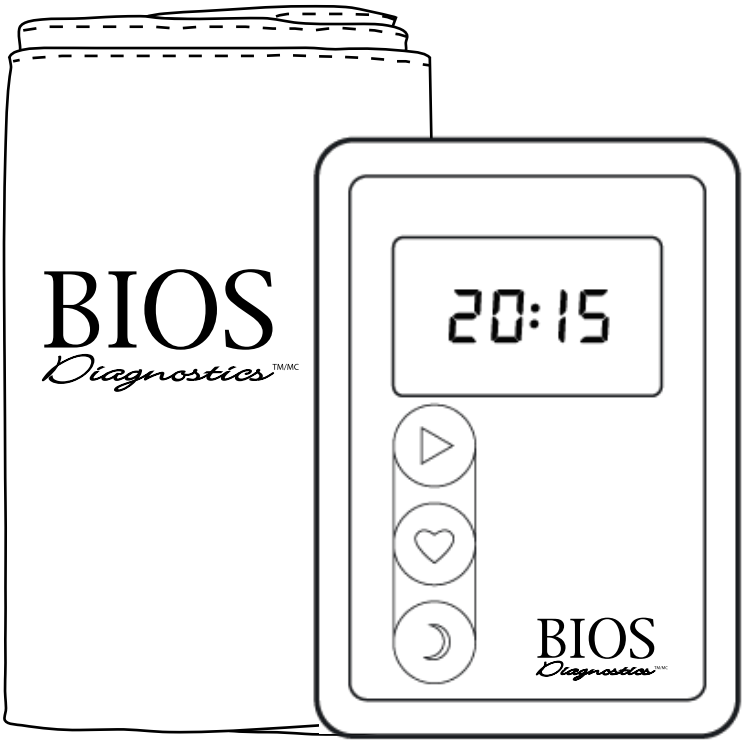
BIOS
Diagnostics™/MC

Ambulatory Blood Pressure Monitor

For 24 or 48 hour continuous monitoring



ABP-01

Instruction Manual

09.24.18

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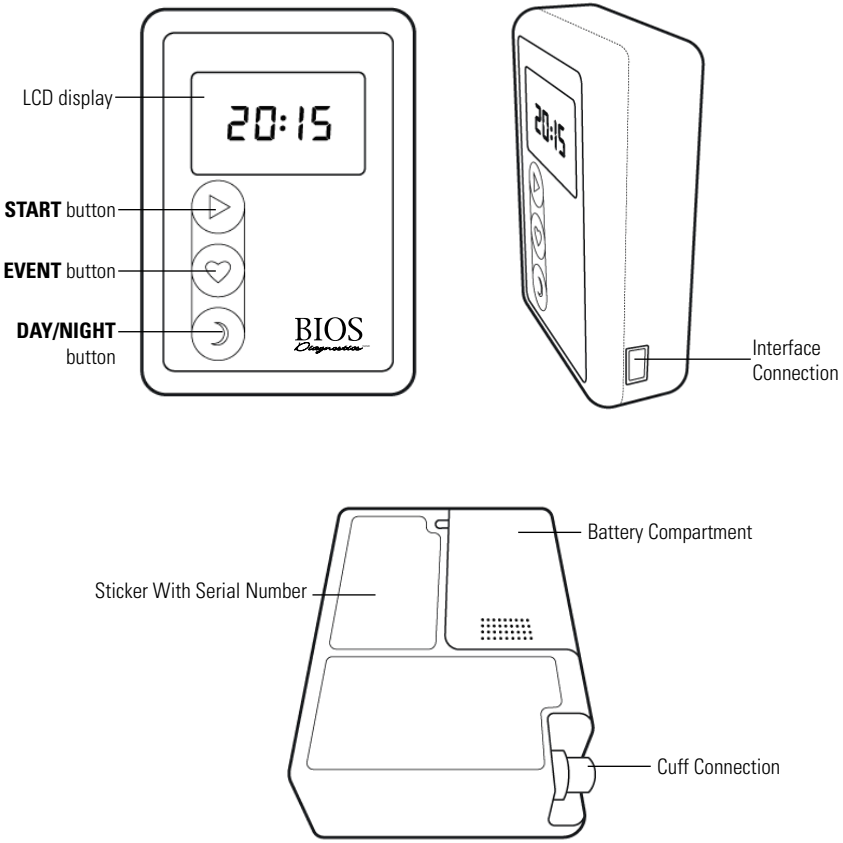
1. Product Description

BIOS Diagnostics™ ABP-01 provides accurate information on blood pressure variability, overnight dipping and morning surge for reliable hypertension management and control.

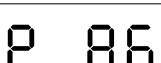
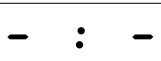
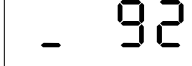
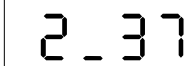
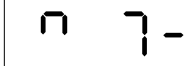
The ambulatory blood pressure monitor incorporates an algorithm validated to BHS (British Hypertension Society) and AAMI (Association for the Advancement of Medical Instrumentation) protocols.

About the Ambulatory Blood Pressure Monitor



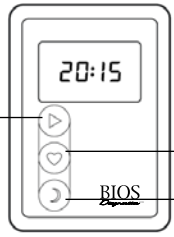
1.1 LCD Display

Information displayed on ABP-01.

	Normal status: time is displayed		Pulse rate value of just completed measurements (beats/minute)
	Blood pressure measurement initiated (mmHg)		Event marker set during a button push
	Pumping for measurement, current pressure is displayed (mmHg)		Error code display
	Deflation during measurement, current pressure is displayed (mmHg)		The device is switched off
	Systolic value of just completed measurement (mmHg)		The blood pressure measurement is cancelled by pressing a button
	Diastolic value of just completed measurement (mmHg)		Heart symbol blinking: measurement in progress (mmHg)
	Night mode: time is displayed, moon sign is lit		LCD check: all segments are displayed
	Battery voltage display (2,37V)		The crossed battery symbol warns of low battery
	Communication with a personal computer		Blood pressure measurement initiated (kPa)
	Pumping for measurement, current pressure is displayed (kPa)		Deflation during measurement, current pressure displayed (kPa)
	Systolic value of a just completed measurement (19,2 kPa)		Heart symbol blinking: measurement in progress (kPa)
	Diastolic value of a just completed measurement (kPa)		

1.2 Buttons

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



Start Button
- Start a manual BP recording
- Switch on/off
- LCD check
- Battery voltage check

Event Button
- Set an event marker

Day / Night Button
- Mark the time of sleeping/awakening
- Manual day/night shift

1.2A Start Button Functions

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

1.2B Event Button Functions

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

12.C Day/Night Button Functions

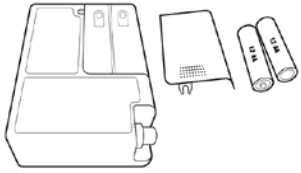
1. Marking the time of sleeping and awakening.
   If the day/night shift function is disabled during programming, the patient can press the day/night button to mark the time of sleeping (in the evening) and awakening (in the morning).
2. Manual day/night shift (only in the 2 hour period before the prescheduled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

2. How to Use the Monitor

2.1 Install the software

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

Hardware & Software requirements



Minimum: CPU: 800MHz, RAM: 256 MB, VGA: 1024*768, free disk space: 10MB + 30MB for 1000 studies, USB connection port

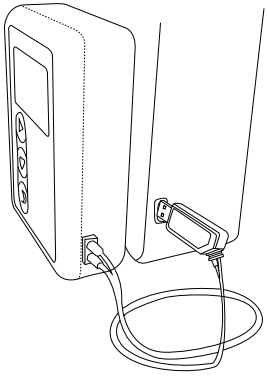
Operating system: Windows XP SP2.

Suggested: CPU: 2 GHz, RAM: 512 MB, VGA: 1280*1024, free disk space: 10MB + 30MB for 1000 studies, USB connection port

Operating system: Windows7

2.2. Setup the monitor

Install 2 x AA batteries into the monitor.



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

Setup communication between the monitor and the PC

ABP-01 works with a special USB optical cable, which connects the monitor to your PC. Always install the software before connecting the USB optical cable to the PC! (The USB driver is installed together with the software, in the absence of which the PC will not recognize the interface.)

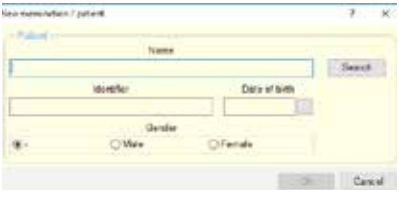
Locate a USB port on your computer and connect the USB driver. Then connect the USB optical cable into the USB driver.

IMPORTANT: It is very important to always plug the USB driver into the computer first, and then plug the USB optical cable into the USB driver otherwise a malfunction can occur.

The twin optical cable transfers optical signals between the interface unit and the monitor. The cable is flexible, but it is sensitive to overfolding and to cutting forces. If you fold the optical cable in too small of a 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.

3. Programming the Monitor

1. Open the EasyABPM software.
2. Start a new examination/patient profile by clicking on Device ⟶ New Examination or by clicking on the "New Examination" icon .



Note: You can also select a patient from the database.

3. Enter the patients name, date of birth and gender. Assign a patient identifier number. Press OK to confirm.

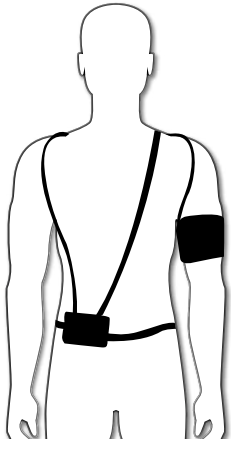
4. Create a monitoring plan based on the requisition form filled out by the patient's physician.
    a. Ensure to select the correct sized cuff the patient will wear.
    b. The start time of the examination can be adjusted.
    c. Set the length of time to 24 hours or 48 hours.

To edit the interval program, click on the < > button.

a. Adjust the active, passive, morning and special (if applicable) period and interval times.

b. Press OK to confirm.

5. Click on the RELEASE button, the software will speak to the monitor and set up all the parameters from the software to the ambulatory monitor.
6. Exit out of the software and unplug the monitor from the computer.



4. Fit the Patient with the Monitor

1. Apply a proper size cuff to the patient's non-dominant arm and be sure that the artery indicator is over the brachial artery.
2. Connect the hose to the monitor.
3. Place the monitor in the pouch and affix the patient with the belt and straps.
4. Start a manual BP reading to verify if the monitor is working properly and

to ensure proper fit and comfort for the patient.

5. Inform the patient about the goal and the expected results of the monitoring and about the use of the monitor.

5. Retrieve Data

1. Remove the monitor and the cuff from the returned patient.
2. Plug the monitor to the computer using the USB optical cable.
3. Highlight the correct patient's name from the database.
4. Click on Device ⟶ Read Data or click on the "Read Data" icon.
5. Once the data is downloaded the software will open the examination file.

6. Customize, Review & Print Data

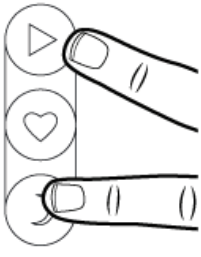
1 Customize your standard report
EasyABPM: Tools ⟶ Settings ⟶ Report
2. Create and save or print the report, by clicking on File ⟶ Print Review
3. Patient should follow up with their physician to discuss the results

7. Manual Programming

ABP-01 if programmed manually can be used by EasyABPM Software. Plans are stored in the inbuilt memory of the device and they cannot be changed. The following three measurement plans can be selected during the programming of the device:

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

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



How To Program Manually

Press and hold the START and the DAY/NIGHT buttons simultaneously. Measurement frequency of the measurement plans will be displayed after 10 seconds for 3-3 seconds.

To choose the measurement plan, release the buttons when the specific plan is displayed. You will hear two beeps and the LCD will display four blinking "o" letters, which indicates that programming the device is in progress. After 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.

Imprecise, when programing manually, 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 long period.This happens, insert batteries again into the device, set the inner clock by programming the device by a PC and leave the batteries in the device (the suggested period is 24 hours).

The first measurement has a controlling purpose and it starts in the second minute after programming, then other measurements cannot be started in the next five minutes. The rest of the measurements are taken at specific

15/20/30/40 minute intervals and there are measurements at the 6:00 and 22:00 hour shifts. The last measurement is exactly 24 hours after the second measurement.

LCD Displays

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

8. Patient Information

a. **The cuff should be worn on the patient's bare arm.**

b. **The cuff should be properly placed on and connected.**
The cuff tube should be pointed towards the patient's shoulder and the 'artery' indicator on the cuff should be placed above the brachial artery.

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

d. **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 monitor.**
Such occurrence should be reported to the physician later after the monitoring session.

e. **Press any button to stop a blood pressure measurement.**
Should the blood pressure measurements cause bloodshots, torpidity or pain in the hand, the cuff should be removed from the arm immediately and disconnected from the monitor. Such occurrence should be reported to the physician after the monitoring session.

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

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

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

i. **Do not block the air flow in the cuff tube.**
Take care to avoid blocking the air flow in the tube of the cuff and twisting the tube.

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

9. Cuffs

Dimensions

Name	Arm Circumference Range
Small	18 - 24 cm / 7" - 9.4"
Normal	25 - 32 cm / 9.8" - 12.5"
Large	33 - 42 cm / 13" - 16.5"

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

9.1 Application

Set the cuff size when programming the monitor.

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

9.2 Apply the cuff and be sure the artery indicator is over the brachial artery

Place the cuff on the upper arm so that the rubber tube points towards the patient's shoulder and the 'artery' indication of the cuff is placed above the brachial artery, if possible. Contrary to the usual placement with the tube pointing downwards, the advantage is that the patient can wear a loose jacket over the cuff.

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

9.3 Connect the hose to the monitor

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

NOTE: *Take care to avoid blocking the air flow in the tube of the cuff and twisting the tube. Make sure the cuff and its tubing do not cause strangulation or a circulation problem. Should the patient experience arm numbness or pain remaining after any blood pressure reading is completed, the cuff should be removed to avoid permanent vascular or neural injury. The application of the cuff over a wound can cause further injury! The application of the cuff and its pressurization could result in injury to the patient because of temporary interference to blood flow on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present. The pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring medical equipment on the same limb.*

No relevance can be shown in the application of the cuff and its pressurization on the arm of the side of a

mastectomy.

The cuff should be applied as tightly as comfortable for the patient.

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

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

10. Batteries

The ABP-01 operates either with two 1.5V AA normal batteries or with two 1.2V AA rechargeable batteries.

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

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

a. Use standard alkaline or NiCd/NiMH rechargeable batteries

Use only standard long-life (alkaline) batteries, or standard NiCd or NiMH rechargeable batteries of the proper size. Do not use lithium batteries. Do not mix different battery types; do not mix new and old batteries. Never use batteries of low or unknown quality or pre-used batteries, as they may not cover the power needs of the monitor, and they may damage the monitor, or they may contain acidic electrolytes which may leak and corrode electronic components. Never use batteries damaged in any way.

b. Do not start a new monitoring session with low batteries.

It is strongly recommended to use freshly charged 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 the ambulatory blood pressure monitor, it is advised to check their voltage before programming them. The typical voltage for fully charged rechargeable batteries should be over 2,5V and for fresh alkaline batteries, over 3V.

Battery voltage check: Press the START button for at least 5 seconds.

c. If measurements do not start in due time keep fresh batteries in the recorder

If the monitor is not used for a long period (4-6 months), the built-in backup cell, ensuring the operation of the internal clock, may get discharged. In this case keep freshly charged batteries in the monitor for at least one day; this will recharge the backup cell. It is possible to use the monitor afterwards. If the backup cell is not properly charged, the internal clock may work incorrectly, and the monitor may not start measurements in due time. If the recharging of the cell is not successful, the backup cell must be replaced. This is an out of warranty act.

d. If the batteries run down, replace them even during a monitoring session

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

e. Remove the batteries if the monitor is out of use

If you do not use the monitor, 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.

11. Safety Concerns

a. Electric shock hazard protection

The ABP-01 monitor meets the relevant shock hazard protection standards. The device operates with two 1.5V AA batteries or two 1.2V AA rechargeable batteries, which excludes all electric shock hazards, even in the unlikely case of multiple device errors.

Many personal computers do not meet shock hazard protection standards or strict safety regulations applicable to medical devices. Therefore, during the computer-based use of the recorder, keep at least a 2 meter distance between the patient and the computer. This is the required minimum safety distance. ABP-01 communicates via a plastic optical cable, the 3 m standard length of which allows for the required safety distance. The plastic optical cable ensures perfect electric separation and reduces the effects of external electric noise. It does not conduct electricity.

b. Hazardous materials

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

c. Risk of incorrect diagnosis

The basic intended use of the monitor is to record blood pressure and pulse rate values. Patients should be informed about rules of cooperative behavior; proper handling of the monitor, and expected results of monitoring in advance. The monitors only provide data to support diagnostic decisions of a qualified physician; they do not automatically provide a diagnosis of any kind. During the evaluation of recorded blood pressure values, possible artefacts due to external disturbances, motion artefacts, and electrical noise should be observed and handled with caution.

See chapter Cuffs for more information!

12. Cleaning & Protection

The ambulatory blood pressure monitor is not specially protected against spills or ingression of water or other liquids.

Cleaning the monitor

A recommended means of cleaning is to wipe the recorder with a disinfectant cleaning tissue. Alternatively, wipe with a slightly damp cloth then dry it with an antistatic tissue. Do not expose monitors to extreme heat or radiation, including long exposure to direct strong sunlight.

To clean the PU leather fabric cuff, please do the following:

Wipe the cuff with a damped cloth or detergent/disinfectant tissue (e.g.: ethanol 70%, isopropyl-alcohol 70%, microzid). The bladder cannot be removed!

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

Protection

Do not immerse the monitor in water or any cleaning fluid and protect it from spills and splashes. Do not expose it to heavy rain or steam and do not wear it in a wet environment e.g.: shower, bath or swimming pool. In case of minor effects of wet environment, wipe off water drops with a dry cloth. Keep the monitor in a normal dry room for at least one hour before use if condensation is suspected.

In case of ingress of water in the monitor, remove batteries from the unit, and refer the unit to authorized service.

Never place the monitor in a disinfecting or sterilizing machine!

13. Maintenance

Verification of the pressure measurement accuracy is recommended biannually.

All the devices are covered by a two-year warranty under general warranty conditions of BIOS Medical, 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 the recorder; they contain high complexity electronic and fine mechanical components. If you have any problems, please call the BIOS Blood Pressure Hotline . All consequences of improper servicing are the sole responsibility of the user. Contact BIOS Medical for more information.

14. Disposal

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

15. Indication & Contraindications

Indications

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

Contraindications

- Non-cooperative patients, unconscious or otherwise incapable patients
- Patients requiring urgency/emergency cardiac care
- Patients with coagulation disturbances
- Patients with serious mobility or other impairments without supervision
- Children without supervision, or children younger than 8 years
- Though the blood pressure measurement algorithm used in the monitors has been found to function properly on patients with atrial fibrillation or other common arrhythmias, the oscillometric blood pressure measurement method is generally recommended for use only with special caution in patients with arrhythmias, Parkinson's disease or other diseases involving tremors.

16. Accessories List

- Ambulatory blood pressure monitor
- USB optical with USB driver cable

- Pouch for the recorder with shoulder and waist straps
- Small, normal and large cuffs
- 2 x AA long-life battery (recommended capacity: min. 1600 mAh)
- CD containing the latest software, user manual and patient diary
- Storage case

17. Technical Specifications

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	USB optical cable
Operating Environment	
Device Temperature	10-45°C / 50-113°F
Cuff Temperature	10-40°C / 50-104°F
Humidity (Non Condensing)	10-95%
Atmospheric Pressure	70-106 KPa
Storage & Transportation	
Temperature	-20 to 50 °C / -4 to 122°F
Humidity (Non Condensing)	10-95%
Size	70 x 99 x 30 mm
Weight (Batteries Incl.)	240 g
Blood Pressure Measurement Method	Oscillometric
Blood Pressure Maximum Storage	Over 600 measurements
Measurement Range	Blood pressure: 30 - 260 mmHg (4-35 kPa); pulse: 40-200 beat/minute
Passive Accuracy	+/- 3mmHg (0,4 kPa) or +/- 2% of measured value (stability: 2 years)
Blood Pressure Measurement Accuracy	Measuring algorithm validated to BHS & AAMI protocol
Pressure Sensor	Piezo resistive
Inflation	Automatically controlled pump
Safety	Maximum inflation 300 mmHg (40 kPa), independent safety release valve
Deflation & Rapid Air Release	Automatic pressure release valve

18. Error Codes

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

19. Product Warranty Information

MONITOR WARRANTY. The main monitor 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 monitor only. This warranty does not cover any accessories that might come with the monitor.

ACCESSORIES WARRANTY. The non-disposable accessories delivered with the monitor unit will be free from defects in materials and workmanship under normal use and service for a period of one (1) year from the date of receipt. This warranty does not cover disposable accessories, packaging materials, accumulators and batteries, cuffs, or any of their components.

CUFF WARRANTY. The cuff - 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.

100% Satisfaction Guarantee

If at any time, you are not completely satisfied with the performance of this device, call our BIOS Medical Hotline and speak with a customer service representative, who will make arrangements to have the device repaired or replaced to your full satisfaction.

If you have questions regarding the operation of your monitor call the
BIOS Medical Hotline: 1-866-536-2289

Should repair be necessary, return the unit with all component pieces. Enclose proof of purchase and $5.00 for return shipping and insurance. Ship the unit **prepaid** and insured (at owners option) to:

BIOS | Medical
Repair Department
16975 Leslie Street
Newmarket, ON L3Y 9A1
www.biosmedical.com
Email: support@biosmedical.com

Please include your name, return address, phone number, and email address. BIOS Medical will repair or replace (at BIOS Medical option) free of charge any parts necessary to correct the defect in material or workmanship.

Please allow 10 days for repair and return shipping.

!	Always consult a physician for the interpretation of the blood pressure measurements. Note that any blood pressure recording may be affected by the body position, the physiological condition of the patient, and other factors. No user serviceable parts inside. BIOS Medical recorders contain high complexity electronic and fine mechanical components. If you have any problems, please refer your recorder to qualified service personnel. The device cannot be modified by the user!
	This symbol is a warning that you should read the accompanying documentation.
REF BP5	Device type (BP5 = ABP-01)
	Certification mark of the Russian Federation
	Direct current
	Consult the User Manual. This symbol warns that you should read the accompanying documentation.

	This signal directs attention to the description of that part.
	Manufacturer
	Date of production
Uo0	Identification of USB optical interface
	Device corresponds to the standards of USB (Universal Serial Bus)
CE 0120	Each device complies with the requirements of the EU Medical Devices Directive 0120 is the identifier of Notified Body (SGS UK)
MDD II a	MDD classification IIa. EMC class B. EMC group 1.
MDR II	According to Canadian regulations the device classification is MDR II. (Medical Device Regulations of Canada, Rule 10.1 of MDR SOR/98-282:13Mar2007.)
	The monitors are internally powered type CF devices. Protection vs. ingress of water: none. Mode of operation: continuous. The devices are not protected against defibrillators or other high frequency surgical equipment.
IP22	Protection against environmental impact: First digit "2": Protected against mid-sized solid objects (>12 mm). Second digit "2": Protected against splash (vertically in a max. of 15 degrees). This protection refers only to BP5.
SN YYYY/nnnnn	Serial number. The first four digits of the serial number of a recorder show the year of production. The rest is the serial number. For example: 2007/123456
	This symbol shows that according to regulations the monitors should be handled as electronic waste during rollout.
	Blood pressure measurements determined with the algorithm of an ABP-01 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 ABP-01 fulfills the requirements of the British Hypertension Society Validation Protocol for Automated Blood Pressure Measuring Devices.

20. 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

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

Emission test	Compliance	Electromagnetic environment
Radiated and conducted RF emission CISPR 11	Group 1	ABP-01 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.
Radiated and conducted RF emission CISPR 11	Class B	ABP-01 is suitable for use in domestic establishments and in establishments directly connected to the low voltage power supply network which supplies buildings used for domestic use.
Harmonic emission IEC61000-3-2	Not applicable	---
Voltage fluctuations/ Flickers IEC61000-3-3	Not applicable	---

Electromagnetic immunity

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

Monitor	Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment
ABP-01	Electrostatic discharge (ESD) IEC 61000-4-2	+ 6KV contact + 8 KV air	+ 8 KV air	Floors are wood, concrete or ceramic tile, or floors are covered with synthetic material and the relative humidity is at least 30 percent.
ABP-01	Electrical fast transient/burst IEC 61000-4-4	+ 2KV for power supply + 1KV input/output lines	Not applicable	Mains power quality is that of a typical commercial and/or hospital environment.
ABP-01	Surge IEC 61000-4-5	+ 1KV differential mode + 2KV common mode	Not applicable	Mains power quality is that of a typical commercial and/or hospital environment.

ABP-01	Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip) for 0.5 cycle; 40% UT (60% dip) for 5 cycles; 70% UT (30% dip) for 25 cycles; <5% UT (>95% dip) for 5 sec. Note: UT is the nominal voltage of mains.	Not applicable	Mains power quality is that of a typical commercial and/or hospital environment.
ABP-01	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.
ABP-01	Conducted RF IEC 6100-4-6	3V eff 150KHz-80MHz	Not applicable	Mains power quality is that of a typical commercial and/or hospital environment
ABP-01	Radiated RF IEC 61000-4-3	3V/m 80MHz-2,5GHz	3V/m	Recommended Separation distance: d=[3,5/V1]√P d=[3,5/3V/m]√P (80MHz – 800MHz) d=[7/3V/m]√P (800MHz – 2,5GHz) where: P is the highest radiated power disclosed by the manufacturer of transmitter [W] and d is the recommended separation distance [m]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey1 a should be less than the compliance level in each frequency range 2 You may observe disturbance nearby any of those equipment which has the following indication: 

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

Note: these are guidelines. Actual conditions may vary.

[1] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with

accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

[2] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance

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

Separation distance in function of the frequency of the transmitter (m)			
The highest output power of the transmitter (W)	150KHz-80MHz d=(3,5/V1)√P	80MHz-800MHz d=(3,5/E1)√P	800MHz-2,5GHz d=(7/E1)√P
0,01	Not applicable	0,12	0,23
0,1	Not applicable	0,38	0,73
1	Not applicable	1,2	2,3
10	Not applicable	3,8	7,3
100	Not applicable	12	23

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

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

Note: These are guidelines. Actual conditions may vary.

The information in this document is subject to change without notice.

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