

Model: BD280

Affordable ABPM and strictly guideline-based SBPM for accurate out-of-office blood pressure measurement.

Instruction Manual





The BIOS Diagnostics BD280 Ambulatory Blood Pressure Monitor is designed to provide reliable and unbiased ambulatory and self blood pressure measurement results, and strictly follows European Society of Hypertension (ESH), American Heart Association (AHA) and Hypertension Canada recommendations for out-of-office blood pressure measurement ¹.The BD280 device has been clinically validated according to the ESH protocol.

¹ O'Brien E, Asmar R, Beilin L, Imai Y, et al. European Society of Hypertension recommendations for conventional, ambulatory and home blood pressure measurement. European Society of Hypertension Working Group on Blood Pressure Monitoring. J Hypertens 2003;21:821-848.



Indications For Use

The BIOS Diagnostics Ambulatory Blood Pressure Monitor, Model BD280, is designed to measure the systolic, diastolic and pulse rate of an adult individual by using a non-invasive oscillometric technique with an inflatable cuff wrapped around the upper arm. This device can provide ambulatory and self blood pressure measurements results. It offers a programmable 24-hour patient out-of-office blood pressure measurement on the ambulatory mode. This device can be used in both home and professional environments. The BD280 can be used in connection with a computer running the BIOS Diagnostics BD280 Analyzer software. The memory data can be transferred to the computer by connecting the monitor via a USB cable.

Clinical Information and Benefits

For adults with arm cuff circumference sizes ranging from 14 - 52 cm.

Additional Cuffs (Sold Separately):

BD087: Small (14 – 22 cm) BD090: Extra Large (32 – 52 cm)

The clinical indications for ambulatory blood pressure monitoring include the assessments of hypertension, abnormal 24-hour blood pressure patterns, and the treatment of the patients by healthcare professionals.

Contraindications

- The measuring arm suffers from injuries (e.g. open wounds) or conditions (e.g. intravenous drip and blood vessel stent implant) making it unsuitable for surface contact or pressurization of the arm.
- The application of the cuff would apply undue pressure on a limb where intravascular access/therapy, or an arteriovenous shunt is present. Temporary interference with blood flow could result in injury to the patient.
- · Avoid taking measurements on the arm on the side of a mastectomy or lymph node removal.
- Avoid taking measurements of patients with diseases or environmental conditions that lead to uncontrollable motions (e.g. trembling or shivering).

Precautions

Follow the instructions for use. This document provides important product operation and safety information regarding this Blood Pressure Monitor. Please read this document thoroughly before using the device and keep it for future reference.

Follow the instructions for use for cleaning and disinfecting the device and cuff.

Check with your personal physician that operation of our device does not result in prolonged impairment of blood circulation before using.



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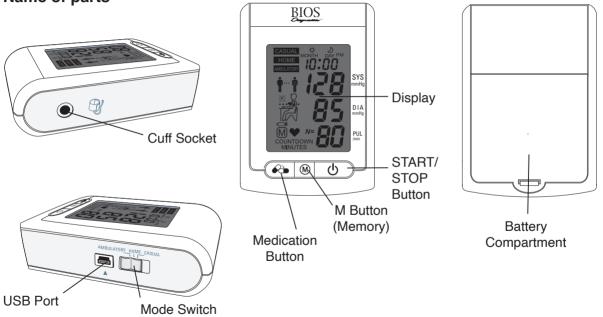
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Product description

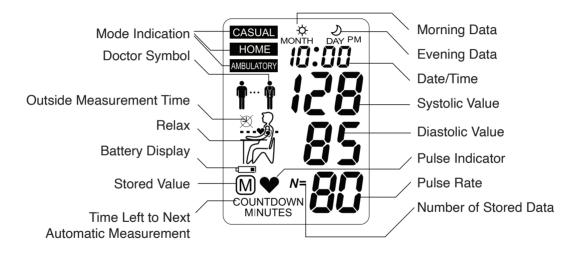
Name of parts





Product description

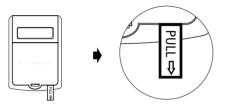
Display



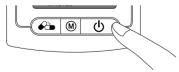
Before using BD280 for the first time

Activating the Device

Pull out the protective strip from the battery compartment.



 Set the year – Upon removing the protective strip or installing new batteries, the Year number flashes in the display. Use the M Button to select the Year. Press the START/STOP Button to confirm your selection.



M Button equals *select*. START/STOP Button equals *confirm*.

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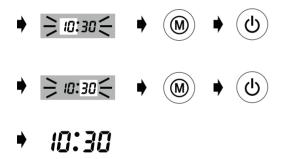
2) Set the month – Use M Button to set the Month. Press the START/STOP Button to confirm.



3) **Set the day** – Press M Button to set the Day. Press the START/STOP Button to confirm.



4) Set the time – Once the Hour and Minutes have been set and the START/STOP Button pressed, the date and time are set, and the current time is displayed.



5) To change the date and time, briefly take out and put back one battery from the battery compartment. The Year number will flash. Complete the process as described above.

Confirm cuff size

A variety of different cuff sizes are available for use with the BD280 device. (S, XL sizes are also available, but not included.)

* Do not use a cuff other than the original cuff contained in this kit!



M (Medium size)

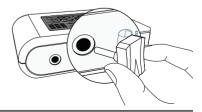
22 - 32 cm (8.7 - 12.6 inches)

M is the correct size for most people.



L (Large size)

32 - 42 cm (12.6 - 16.5 inches)



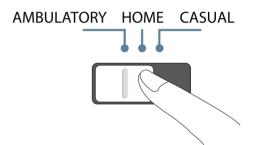
Selecting the operation mode

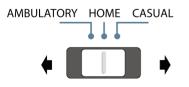
Prior to each measurement, use the Mode Switch on the side of the device to select the proper measurement mode. The BD280 offers three measurement modes: "AMBULATORY", "HOME" or "CASUAL" mode.

"AMBULATORY" Mode

Select "**AMBULATORY**" mode for fully programmable 24-hour patient out-of-office blood pressure measurement.









Selecting the operation mode

Programmable measurement intervals

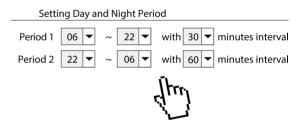
The device automatically takes measurements at fixed intervals of 15, 20, 30, or 60 minutes, as programmed by the physician.

Set measurement periods

To better suit each patient's lifestyle, awake (day) and asleep (night) hours can be programmed using the provided BD280 software. Intervals for each measurement period can also be programmed independently.

15 30 20 60

* The default measurement interval is 30 minutes.



Selecting the operation mode (cont.)

Two measurement periods

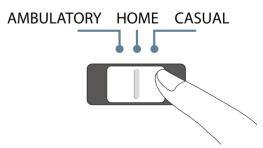
Each measurement period can be programmed to start at anytime, between 4AM and 10AM, and the asleep measurement period can be set to anytime between 9PM and 2AM. Measurement intervals can be set to 15, 20, 30, or 60 minutes.

"HOME" Mode

Protocol Emboddo

Select "**HOME**" mode for patient home blood pressure measurement in accordance with the guidelines of the European Society of Hypertension (ESH), American Heart Association (AHA) and Hypertension Canada.







No measurements on non-work days

The patient should carry out readings on 7 consecutive working days (or normal week days), **No readings should be taken on "non-working" days** (or particularly relaxing days) in this mode!

Two sets of measurements per day

ESH guidelines recommend one double measurement be taken in the morning between 06:00 and 09:00 and one double measurement taken in the evening between 18:00 and 21:00.





Selecting the operation mode (cont.)

Extended measurement period

The BD280 device offers an extended measurement period and allows morning measurements between 04:00 and 12:00 and evening measurements between 18:00 and 24:00.

Evaluation

After measurements have been carried out for a total of 7 working days, patients return to the office with the BD280 device for an evaluation of their home blood pressure measurement data.





Outside these times, measurements cannot be taken and the symbol on the left will be displayed on the screen.



When measurements have been carried out for the full 7 days, the doctor symbol will flash on the screen.



Selecting the operation mode (cont.)

"CASUAL" Mode

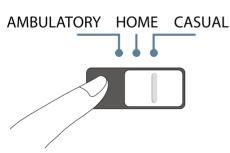
In "CASUAL" mode, the device functions like a regular blood pressure monitor – single measurements are automatically stored and can be reviewed by the physician at a later date.

250 measurements safely stored

The BD280 device can store up to 250 single measurements in "CASUAL" mode.

* When memory is full, each new measurement will automatically overwrite the earliest measurement.



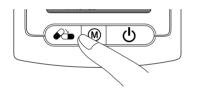




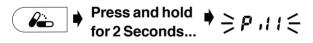
Recording the taking of medication

Medication record

The patient can record the time medication is taken by pressing the Medication Button.



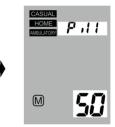
1) Press and hold the Medication Button for 2 seconds and the Pill icon will appear.



* A Medication record can be recorded in any of the three modes.

2) Release the Medication Button. The Pill icon and the recorded time will alternate on the display.





♦ ⇒ ₽ ,1 1 € ⇒ 10:00 €

3) Medication record is saved after the beep sound.

BEEP **€** ♦ Saved

* The beeper can be disabled via software setting.



50 records safely stored

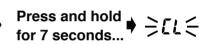
The BD280 device can store up to 50 medication records.

* When the memory is full, the device will display Full.

Delete stored medication records

To clear the memory of all medication records, press and hold the Medication Button for 7 seconds. The "CL" symbol will flash. Press M to delete the memory or START/STOP to cancel the deletion.







* Pressing the M Button to delete data will erase all medication record data in the selected mode.



Measurement interval programming

Installing the software program

Installation

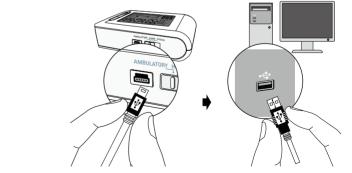
- The BIOS Diagnostic BD280 Analyzer Software is available from the BIOS Medical Website: https:// biosmedical.com/pages/software-downloads
- 2) Simply follow the instructions provided in the installation window on the computer screen.
- When installation is finished, be sure to restart the computer before working with the program for the first time.

Restart vour

computer

Connecting the device to a computer

- Connect the device to a computer via a USB cable. A successful connection is displayed by "PC" on the device.
- 2) Start the software program.
- 3) Enter name, identity number, and date of birth to create a new record (if required).



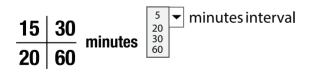


Measurement interval programming

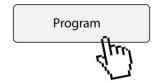
Programming the interval schedule

 Use the drop-down menu on the lower left of the screen to choose the begin and end time for each measurement period.

 Assign the measurement intervals for each period by using the drop-down menu to choose from 15, 20, 30, or 60 minutes as the measurement interval.



 Once you have completed the settings, press "Program to BP device" to program the schedule into the device.



Taking blood pressure measurements

In "AMBULATORY" mode

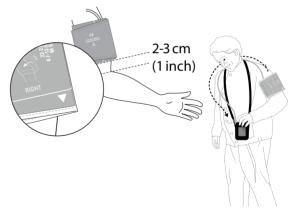
Be sure the device is set to "AMBULATORY" Mode.



1) Preparing measurement arm – Remove all clothing covering or constricting the measurement arm.



* Avoid rolling up long sleeves, as this may lead to constriction of blood flow to the measurement arm. 2) Positioning the cuff and device – Fit the cuff closely, but not too tight. Make sure that the cuff is 2 - 3 cm (1 inch) above the elbow with the tube on the inside of the arm. The measurement tube should point upward and be mounted over the patient's shoulder.





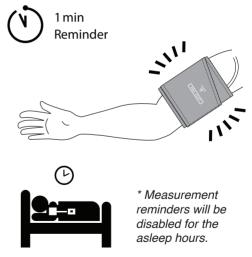
Taking blood pressure measurements

 Next measurement indicator – The device will display the next measurement time, indicated by a countdown in minutes on the display.



* The screen will display X countdown minutes to indicate the time to the next automatic measurement.

4) Measurement reminder – One minute before the next scheduled measurement, the device will partially inflate and immediately deflate the cuff to remind the patient of the next measurement.



5) **Measurement reminder** – Five seconds before the next measurement, the device will emit a short series of beeps to notify the patient of the coming measurement.



* The beeper of Ambulatory Mode can be disabled via software setting.



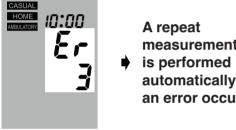
* The device will not beep prior to asleep measurement in "AMBULATORY" mode. 6) During measurements – the patient should be reminded to remain still, refrain from talking, and to breath normally during the measurement. If driving or operating equipment when a measurement begins, the patient should, when safe, relax the measurement arm.



* The patient can stop any single measurement at anytime by pressing the START/STOP Button.



7) Repeat measurements in the case of an error - The device will automatically repeat the measurement after a two minute countdown should an error occur during measurement.



measurement automatically if an error occurs.

* If the repeat measurement encounters an error again, the device will take an extra measurement after a four minutes countdown. If the extra measurement is not successfully, the device will record an error message.

* If the device stops taking measurements, the patient should return the device to the physician to determine the cause of error.

8) Storing measurement data – The BD280 automatically stores each measurement result, along with the measurement date and time. A total of 250 measurements can be stored at once.



* The display of BP reading and memory of Ambulatory Mode can be disabled via software setting.

In "HOME" mode

Be sure the device is set to "HOME" Mode.



 Before the measurement – Patients should be informed to avoid physical activity, eating or smoking before each measurement. The patient should sit down for at least 5 minutes before the measurement and relax.



2) Applying the cuff – Patients should be trained on how to properly fit the cuff to their own arm. The cuff should fit closely around the arm, but not too tight, and be placed 2-3cm above the elbow with the tube on the inside of the arm. The patient should support the arm at the same height as the heart during measurement, sit comfortably, uncross the legs, put feet flat on the floor and the back should be supported.



* Additional instructions on taking proper blood pressure measurement can be found on the https://biosmedical.com/pages/how-to-take-your-blood-pressure website.

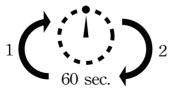
* Any blood pressure reading can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic condition.



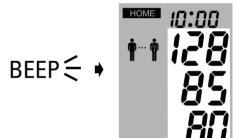
3) **Start the measurement** – Press the START/STOP Button to start measurement.



4) During the measurement –The cuff will inflate automatically. One measurement cycle includes two measurements. Once the first measurement is complete, the second measurement will begin after 60 seconds.



5) Finishing the measurement – Once the two measurements are complete, measurement data is automatically stored for later reference by the physician. If an error displays after the measurements, the process should be repeated once again.



* The patient should relax as much as possible and not talk during the measurement procedure as this may influence the readings.

In "CASUAL" mode

Be sure the device is set to "CASUAL" Mode.



 Before each measurement – Patients should be informed to avoid physical activity, eating or smoking before each measurement. The patient should sit down for at least 5 minutes before the measurement and relax.



2) Applying the cuff – Patients should be trained on how to properly fit the cuff to their own arm. The cuff should fit closely around the arm, but not too tight, and be placed 2 - 3cm above the elbow with the tube on the inside of the arm. The patient should support the arm at the same height as the heart during measurement.



* Additional instructions on taking proper blood pressure measurement can be found at https://biosmedical.com/pages/how-to-take-your-blood-pressure



3) **Start the measurement** – Press the START/STOP Button to start measurement.



 During the measurement – The cuff will inflate automatically. A single measurement will be completed for each push of the START/STOP Button.



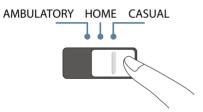
- 5) Finishing the measurement Once the measurement is complete, measurement data is automatically stored for later reference by the physician. If an error displays after the measurements, the process should be repeated once again.
- 6) Storing measurement data The BD280 automatically stores each measurement result, along with the measurement date and time. A total of 250 measurements can be stored at once.



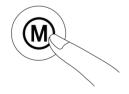
Viewing, deleting and transferring measurements

Viewing measurements

1) Use the Mode switch to first select the type of measurements wished to be viewed.

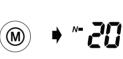


2) Then press the M Button.



In "AMBULATORY" mode

 When the M Button is pressed, it briefly displays the total number of measurements stored, e.g. N=20.





* "A" is displayed when the number shown is the average of all data.

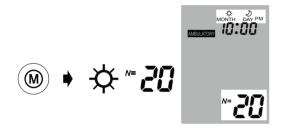
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* "- -" will display when the number of measurements is less than 12.



Viewing, deleting and transferring measurements (cont.)

2) Pressing the M Button again displays the average of all morning data.



3) Pressing M Button once again shows the average of all evening data.



* All individual readings can be viewed by repeatedly pressing the M Button.

* The display of BP reading and memory of Ambulatory Mode can be disabled via software setting.

* "A" is displayed when the number shown is the average of all data.

* "- -" will display when the number of measurements is less than 12.

In "HOME" mode

 When the M Button is pressed, it briefly displays the total number of measurements stored, e.g. N=20.



Viewing, deleting and transferring measurements (cont.)

2) Pressing the M Button again displays the average of all morning data.

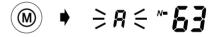


3) Pressing M Button once again shows the average of all evening data.

* All individual readings can be viewed by repeatedly pressing the M Button.

In "CASUAL" mode

 When the M Button is pressed, it briefly displays the total number of measurements stored, e.g. N=63, followed immediately by the average of all measurements stored in memory.



 All individual readings can be viewed by repeatedly pressing the M Button.





Deleting measurements

Data from "AMBULATORY", "HOME" and "CASUAL" mode measurements can be deleted independent of each other.

1) Use the Mode switch to first select the type of measurements you wish to delete.

AMBULATORY HOME CASUAL



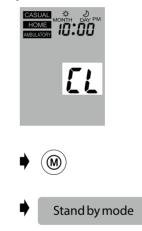
2) Press the M Button and hold it until the CL symbol flashes.



Press and hold



3) Release the M Button and press it once more while the delete symbol flashes.

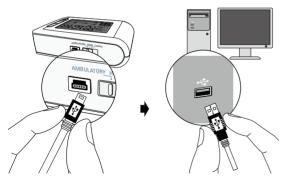


* Each deletion will erase entire records of each mode.

Viewing, deleting and transferring measurements (cont.)

Transferring measurements

- 1) Connect the device to a computer. A successful connection is displayed by "**PC**" on the device.
- 2) Start the software program.
- To transfer the data in all three modes and the medication compliance record, click "Download BP data to PC".



Software commands		
Store data	Click "Save Excel report" or "Save PDF report", the file name is formed automatically from the patients identity number and the suffix "BD280_ (date). xls". or "BD280_ (date).pdf"	
View the data	Click "Open file"	
Delete the memories	Click "Clear Memory"	
Close the program	Click "Exit"	

* Please unplug and re-plug the USB cable to the PC if the software instructs you to do so.

* The program will prompt to synchronize the date/ time of the device to that of the PC.

* Store your data before using "Clear Memory" or "Exit".

* System Requirements: 1GHz CPU. 512MB Memory, 4.5GB free hard disk space, Microsoft Windows 7 SP1 / 8 / 10.



Appendix

Ensure using new batteries

New batteries should be used for each patient monitoring session. "AAA" alkaline batteries are the main power source of BD280.

How to Replace batteries

- 1) Open the battery compartment at the back of the device.
- Put in the batteries Be sure to have correct polarity as shown by the symbols in the compartment.





Battery indicator

When the device is connected to a computer, the pump runs for 1 second instantaneously. Then "Pc --" is displayed. The voltage of the batteries is displayed on the PC screen. If the voltage is low, the buzzer of the device beeps. The battery icon and number indicating voltage are displayed on the screen of device. It is a reminder to replace the batteries. The buzzer keeps beeping until the batteries are replaced.



- * Caution: do not use rechargeable batteries.
- * Use 4 new, long-life 1.5V, size AAA alkaline batteries.
- * Do not use batteries out of expiration date.
- Remove batteries if the device will not be used for a prolonged period.

Safety, care, accuracy test and disposal

Safety and protection

This device should only be used for the purposes described in this booklet. The device is comprised of sensitive components and must be treated with caution. The manufacturer cannot be held liable for damage caused by incorrect application.



- Avoid kinking, compression, and moving of the cuff tube during device operation to ensure the safety of the patient and reliability of the device performance. If the connected tube is kinking, it may cause continuously elevation of the cuff pressure and interference of the blood flow, then might result in harmful injury to the patient.
- Overly frequent measurement within a short time (e.g. 5 10 minutes) may reduce peripheral perfusion and cause injury. After a measurement is completed, loosen the cuff and rest the arm for a few minutes to restore limb perfusion, before taking another measurement.
- Interruption of blood flow during measurement may temporarily affect the operations of other medical equipment used on the same limb (e.g. pulse oximeter).
- · Beware the risk of strangulation by the supplied cable and tubes of the device.
- Do not use accessories which were not provided by Thermor Ltd., or it may cause unpredictable risks.
- Ensure that children do not use the device unsupervised; some parts are small enough to be swallowed.
- · Only activate the pump when cuff is installed.
- · Do not use the device if you think it is damaged or if anything appears unusual.
- Read the further safety instructions in the individual sections of the instruction manual.
- Do not connect the device to a computer until prompted to do so by the computer software.

Observe the storage and operating conditions described in the "Technical specifications" section of this manual.



Protect the device from water and moisture



Protect the device from direct sunlight



Avoid proximity to electromagnetic fields, such as those produced by mobile phones



Never open device



Protect device from impact and drops



Do not immerse or spray the device



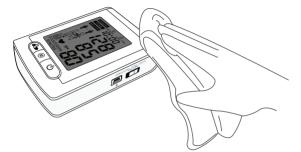
IP20: Protected against solid foreign particles with a diameter of more than 12.5 mm, no protection against water.



Appendix

Device care

Clean the device with a soft, dry cloth.

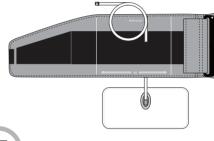


Accuracy test

We recommend the BD280 device be tested for accuracy every 2 years or after mechanical impact (e.g. being dropped). Please contact BIOS Medical to arrange for an accuracy test.

Cleaning the cuff

Take out the bladder. Fold and place the cuff cover inside a washing bag. Wash cuff cover with warm water and a mild detergent in washing machine. Air dry the cuff. DO NOT iron the cuff cover.





Do not iron the cuff!

🖌 Disposal

Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, and not as domestic waste.

Error messages

If an error occurs during measurement, the measurement is interrupted and an error message "Er" is displayed.

⇒Er €

• Please consult your doctor, if this or any other problem occurs repeatedly.

• If you think the results are unusual, please read through the information in this instruction manual carefully.



Error	Description	Potential cause and remedy
"Er 1"	Signal too weak	The pulse signals on the cuff are too weak. Re-position the cuff and repeat the measurement.
"Er 2"	Error signal	During the measurement, error signals were detected by the cuff, caused for instance by movement or muscle tension. Repeat the measurement, keeping your arm still.



Error	Description	Potential cause and remedy
"Er 3"	No pressure in the cuff	Adequate pressure cannot be generated in the cuff. A leak may have occurred. Replace the batteries if necessary. Repeat
"Er 5"	Abnormal result	the measurement. The measuring signals are inaccurate and no result can therefore be displayed. Read through the checklist for performing reliable measurements and then repeat the measurement.

Error	Description	Potential cause and remedy
"HI"	Pulse or cuff pressure too high	The pressure in the cuff is too high (over 300 mmHg) OR the pulse is too high (over 199 beats per minute). Relax for 5 minutes and repeat the measurement.
"LO"	Pulse too low	The pulse is too low (less than 40 beats per minute). Repeat the measurement.

Technical Specifications

Operating conditions:	 10 to 40 °C (50 to 104 °F) / 15 - 90 % relative maximum humidity / 80-105kPa
Storage conditions:	 -20 to +55 °C (-4 to +131 °F) / 15 - 90 % relative maximum humidity / 80-105kPa
Weight:	260g (including batteries)
Dimensions:	• 115 x 80 x 35 mm
Measuring procedure:	Oscillometric, corresponding to Korotkoff
Measurement range:	 Systolic blood pressure:60~255mmHg Diastolic blood pressure:40~200mmHg 40 - 199 beats per minute – pulse
Cuff pressure display:	 Range: 0 - 299 mmHg Resolution: 1 mmHg Static accuracy: pressure within ± 3mmHg Pulse accuracy: ± 5 % of the readout value
Expected service day:	 Device: 30,000 measurements Cuff: 30,000 measurements Battery: 800 measurements
Power source:	• 4x 1.5 V Batteries; size AAA

À	Kee Dr

^{eep} IP20: Protected against solid foreign particles with a diameter of ^{Jry} more than 12.5 mm, no protection against water.

Reference to Standards:	 Device corresponds to the requirements of the standard for non-invasive blood pressure monitor.
	EN 1060-1, EN 1060-3 EN 1060-4, IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 80601-2-30 ANSI /AAMI SP10
Electromagnetic compatibility:	Device fulfills the stipulations of the standard IEC 60601-1-2.

The stipulations of the EU Directive 93/42/EEC for Medical Devices Class II have been fulfilled.



Type BF applied part

* The USB port can only be connected to the device that complies with relevant safety standards (such as IEC 60601-1).

* The device will be ready within 24 hours from any temperature among storage condition back to the room temperature.

* BIOS Medical reserves the right to alter technical specifications without prior written notice.



Guarantee Card

This device is covered by a two-year limited guarantee from the date of purchase. This guarantee is valid only on presentation of the guarantee card completed by the owner confirming date of purchase or purchase receipt. Batteries, cuff and wearing parts are not covered by this guarantee.

Name:
Address:
Date:
Telephone:
Email:

Product: Ambulatory Blood Pressure Monitor Product Number: BD280 Serial Number: Date:



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Follow Instructions for Use. This document provides important product operation and safety information. Please read this document thoroughly before using the device and keep for future reference.

