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Product features



Contents of package

1 **boso-medicus vital**
blood pressure monitor



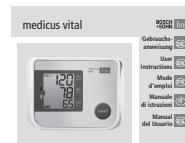
4 LR 6 (AA) batteries



1 CA 04 universal cuff



1 User
instructions



1 Bag









WHO
classification
sticker



1 Blood pressure
record card













Symbols on the blood pressure monitor

Symbol	Function/meaning
	START/STOP button
	Direct current
	Serial number
	Year of manufacture
	Type BF: The device, cuff and tubing have been designed to protect the patient against electric shock.
	Reading in progress. Flashes as soon as a heartbeat was detected.





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Symbols on the blood pressure monitor

Symbol	Function/meaning
	Cardiac rhythm disorder or movement during reading.
	Movement during measurement.
	Rate of recurrence of cardiac arrhythmias.
	Stored value
	Display average value
	Battery fully charged.
	Battery partly discharged.
	Replace battery as soon as possible.
	Flashing! No further reading possible. Replace battery.
	Protect against liquids








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Symbols on the blood pressure monitor

Symbol	Function/meaning
<i>SYS</i>	Systolic blood pressure in mmHg
<i>DIA</i>	Diastolic blood pressure in mmHg
<i>PUL</i>	Pulse per minute
CE 0124	Device complies with the European Medical Devices Directive.
	Device must not be discarded with household waste.
	Manufacturer
	Read instructions for use
	Polarity of power supply port

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Symbols on the power supply unit

Symbol	Function/meaning
	Only for use in enclosed spaces.
 	Protection class II device
	Thermal fuse
	Fuse
	Device complies with the European Medical Devices Directive
	Polarity of the mains adapter plug


Quick guide

- ➔ Insert batteries, ensure correct positioning (P. 54)
- ➔ Connect cuff to monitor (P. 58)
- ➔ Attach cuff (P. 59)
- ➔ Start (and stop) a measurement by pressing the start button (P. 62)

Measured systolic, diastolic and pulse values are displayed after the measurement is completed (P. 64)

- ➔ Retrieving values from memory (P. 66): Press the START-button for about 3 seconds with the monitor switched off. The first value displayed is the average

value of all stored measurements together with the WHO classification. The individual measurement values are then displayed in sequence.

 This quick guide does not replace the detailed information on the use and safety of the blood pressure monitor featured in the user instructions.




Please be sure therefore to read the user instructions!

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Introduction

Dear Customer,
We are delighted that you have decided to purchase a bosco blood pressure monitor. The bosco brand is synonymous with optimal quality and precision and is also number 1 among professionals: 96% of all German general practitioners, physicians and internists work in practice with blood pressure instruments from bosco (API survey conducted by GfK 01/2016). The experience gained from decades of use by professionals has also been incorporated into all the patient monitors for home measurement. This instrument has also passed our strict quality control procedures and is your reliable partner for monitoring your blood pressure values.

 Please read these user instructions before using the instrument for the first

time, as correct blood pressure readings can only be obtained if the instrument is operated correctly.

In these user instructions, „➡“ means an action by the user.

To get help concerning usage or maintenance please contact your dealer or the manufacturer (contact details can be found on the back cover of this manual).

An unexpected operating condition or an incidence which has worsened the health condition or could have worsened the health condition should be reported to the manufacturer immediately.

If the instrument is to be sold, ensure that these user instructions are enclosed.

Introduction

The bosomedicus vital blood pressure monitor is suitable for patients with an upper arm circumference of between 22 and 48 cm.

The use of accessories not referred to in these instructions for use can undermine safety.

Wireless communication devices, such as home networking devices, mobile phones, cordless phones and their base stations, walkie-talkies can affect this blood pressure monitor. Therefore, a minimum distance of 11 feet should be kept from such devices.

Purpose

Non-invasive recording of systolic and diastolic blood pressure and pulse rate in adults. Not suitable for use on newborn babies and infants. The device is suitable for self-measurement at home. The patient is regarded as the operator.

The instrument can be used with any arm circumference as shown on the corresponding cuff.

The logo consists of the letters 'EN' in a bold, sans-serif font, enclosed within a white circle. This circle is set against a dark grey rectangular background.

Blood pressure values

To determine the blood pressure, **two values** need to be measured:

- **Systolic (upper) blood pressure:**

This is produced when the heart muscle contracts and blood is forced into the blood vessels.

- **Diastolic (lower) blood pressure:**

This is present when the heart muscle expands and fills with blood again.

Blood pressure measurement values are expressed in mmHg (mm of mercury).

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The World Health Organization (WHO) has defined the following cut-off values for assessing blood pressure:

	systolic	diastolic
High blood pressure (hypertension)	over 140 mmHg	over 90 mmHg
Borderline normal blood pressure	130 to 139 mmHg	85 to 89 mmHg
Normal blood pressure	120 to 129 mmHg	80 to 84 mmHg
Optimum blood pressure	up to 119 mmHg	up to 79 mmHg

Blood pressure values

Whether medical treatment is necessary depends not only on the blood pressure, but also on the patient's risk profile. Please contact your GP if one of the values (systole, diastole) consistently exceeds the cut-off point for high blood pressure.

Self-measurement of blood pressure often produces somewhat lower values at home

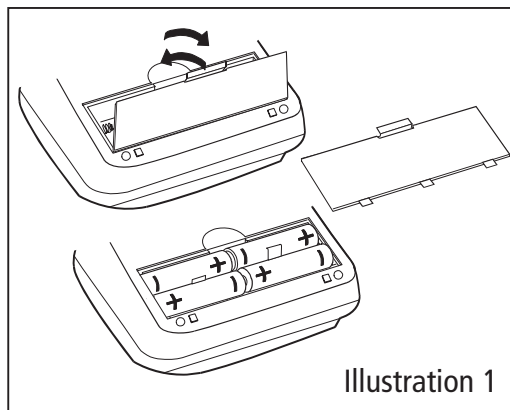
than at the doctor's. The German Hypertension League has therefore defined lower cut-off values for home measurements:

Home measurement:	135/85 mmHg
Measurement in the doctor's surgery:	140/90 mmHg



Starting up

The device must be installed and put into operation in accordance with the instructions in this manual.



- ➔ Use only high quality leak-proof batteries of the correct specifications (see "Technical data" P. 75).

⚠ **Never** mix old and new batteries or different makes.

⚠ If the batteries are not inserted correctly, the monitor will not work and this may cause the batteries to heat up and leak, damaging the monitor.

➔ Inserting the batteries





The battery compartment is located on the underside of the monitor. Insert batteries in the battery compartment as shown in illustration 1.

- ➔ Remove the batteries if the monitor is not to be used for any length of time.

⚠ Batteries that are short-circuited can become hot and cause burning.

Starting up

The monitor has a battery status display (see P. 46)

-  Battery fully charged.
-  Battery partially charged.
-  Replace battery soon.
-  Flashing! No further measurements possible.
Replace battery.


Care for the environment

Do not dispose of used batteries and charger units in domestic waste. You can take these to collection sites for used batteries or special waste. Contact your local authority for information.

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General instructions for self-measurement

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1. Fluctuations in blood pressure are quite normal. Even when measurements are repeated, there can be marked differences. Single or irregular measurements do not provide reliable information about the actual blood pressure. A reliable evaluation is only possible if regular measurements are taken under comparable conditions and the measurement values entered in the blood pressure record card.
2.  Self-testing does not mean self-treatment. Do not on **any** account change the dose of medicine prescribed by your doctor of your own accord.
3. Irregular heartbeats can affect the accuracy of the monitor or result in incorrect measurements (see page 71).
4. Incorrect measurements can also occur in patients with a weak pulse (possibly in patients wearing a pacemaker, for example). The blood pressure monitor itself has no effect on the pacemaker.
5. The device has not been validated for use on pregnant women.
6. Always take the measurement in a calm and relaxed state.
You are recommended to check your blood pressure twice a day – in the morning on getting up and in the evening once you have relaxed after work.
7. Always measure your blood pressure from the arm with the higher blood pressure values (where not required otherwise (see page 60)).

General instructions for self-measurement

To do this, measure the blood pressure first in both arms and thereafter always from the arm with the higher blood pressure.

Preparing to measure your blood pressure

Note on cuff sizes:

 The monitor may only be used with the following cuff types. These should be chosen according to the upper arm circumference printed on them.

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Type	Arm circumference	Order number
CA01	22 – 32 cm	143-4-764
CA02	32 – 48 cm	143-4-757
CA04	22 – 42 cm	143-4-765*

* included in the standard.

Attach the cuff to the monitor by pressing the plug (click) into the socket on the left side of the unit. (See illustration 2).

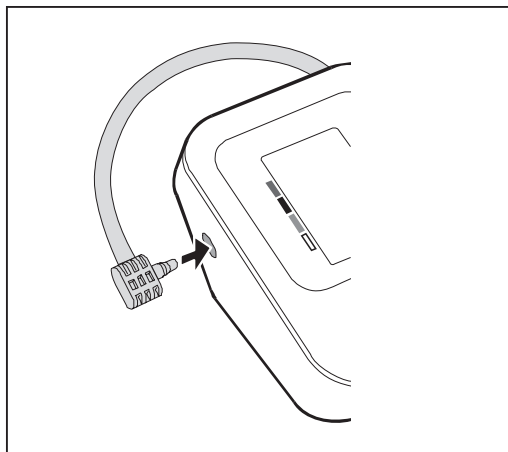


Illustration 2

Preparing to measure your blood pressure

Observe the following instructions when measuring your blood pressure:



Avoid smoking or drinking coffee for one hour before measuring your blood pressure.



Sit comfortably for the blood pressure measurement. Support your back and arms. Do not cross your legs. Place your feet flat on the floor.

Relax for 5 minutes before taking a measurement.

Do not move during the measurement.

Attaching the cuff

The measurement should be taken from the bare upper arm.



In the case of tightly fitting outer clothing, ensure that the blood supply to the arm is not cut off when the sleeve is rolled up (if necessary remove the article of clothing before taking the measurement).

➔ Open out the cuff into the shape of a ring and slide it over the upper arm until the bottom edge of the cuff is about 2-3 cm above the elbow. The cuff must be positioned so that the marking is over the artery (see illustration 3).

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Preparing to measure your blood pressure

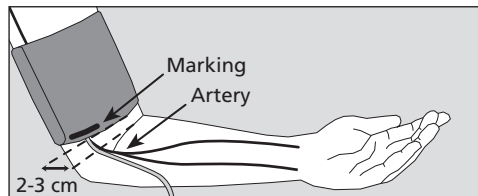


Illustration 3

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⚠ Do not attach the cuff over wounds as this can cause further injuries.

⚠ Ensure that the cuff is not attached to an arm where arteries or veins are undergoing or have undergone medical treatment (e.g. shunt).

⚠ For women who have had a breast amputated, do not attach the cuff to the arm on the amputated side of the body.

⚠ During the measurement, medical apparatus that are being used on the same arm at the same time, may malfunction.

⚠ The cuff must not be too tight. There should be enough space to fit roughly two fingers between arm and cuff.

⚠ The metal ring should **never** lie over the artery (see illustration 3) as this may produce a false reading.

➔ Grasp the end of the cuff that feeds through the metal ring and wrap it around the outside of your arm. Attach the Velcro fastener by applying gentle pressure.

Preparing to measure your blood pressure

- ➔ Place your arm with the cuff attached on the table, holding it relaxed and slightly bent so that the cuff is level with your heart.

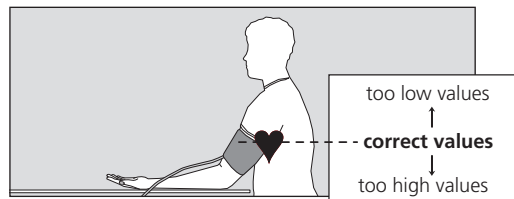


Illustration 4



Do not talk during the measurement.

- ⚠ Check that the air tube is not kinked during the measurement. This could cause congestion of the blood flow and subsequent injury.

- ⚠ The blood pressure measurement should not prevent the flow of blood for an unnecessary length of time (> 2 minutes). If the monitor fails to function correctly, remove the cuff from the arm.

- ⚠ Excessive frequent measurements can cause injury by restricting blood flow.

- ⚠ The device may not be used by unsupervised children.

- ⚠ Do not use the device near infants. This can lead to accidents or damage.

- ⚠ Do not start the device without putting on the cuff.

- ⚠ There are small parts that may cause a choking hazard if swallowed by mistake by infants.

Preparing to measure your blood pressure

⚠ If the ambient temperature changes significantly, leave the device about an hour to adapt to the new ambient temperature before using it.

⚠ The performance of the device can be affected by excessive temperature, humidity or altitude.

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Measuring your blood pressure

Your monitor has a memory with a capacity of 60 measurements.

➔ Start the measurement with the start button



⚠ Now hold the arm absolutely still and do not talk.

All the items on the LCD display appear briefly to indicate that the monitor is now ready for use (see illustration 5).

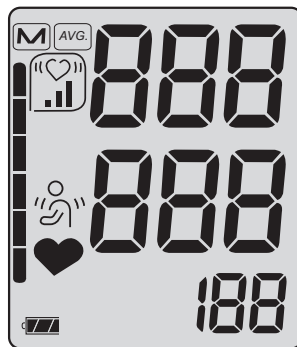


Illustration 5

Measuring your blood pressure

The pump starts to inflate the cuff.


The monitor has an intelligent automatic inflation system for gentle inflation to the correct cuff pressure.


The increasing cuff pressure is displayed.

When the **required pressure** is reached, the pump switches off and the air is released slowly from the cuff.

Interrupting a measurement:

A measurement can be interrupted at any stage by pressing the start button; the cuff deflates automatically.

During the measurement phase the descending cuff pressure and the flashing  symbol are displayed (see illustration 6).

Please keep your arm still if the symbol  appears while a measurement is being taken.

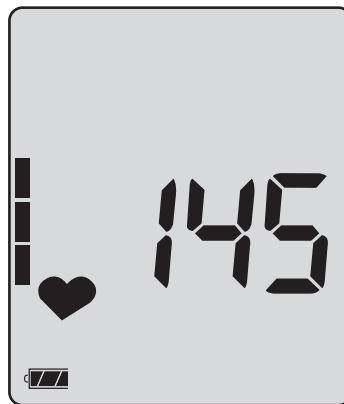


Illustration 6

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Measurement display

After the end of the measurement, the in-built valve opens automatically and the cuff deflates rapidly.

The measured blood pressure values (systole, diastole, pulse) are displayed (see illustration 7).

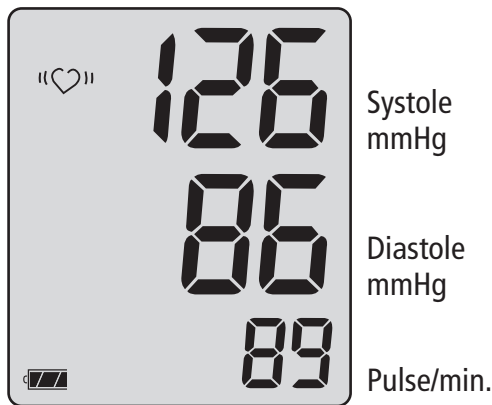



Illustration 7

The measurement is stored automatically. If the memory store is full (60 measurements), the **oldest** measurement is **deleted** and the current one stored.

Invalid measurements with an "Err" message (see page 70) are not stored.

If the symbol "♡" appears after the measurement, it is recommended that the measurement is repeated, holding the arm completely still. If the "♡" symbol appears again even with the arm held still, this may be an indication of an irregular heartbeat. Please discuss this with your doctor at your next visit.

Measurement display

The “” symbol indicates that the arm moved during measurement. You are advised to take another measurement.

Blood pressure is a dynamic parameter and can be affected by the patient’s position, e.g. sitting, standing, lying, moving, before or during the measurement, physical condition (stress, disease, etc.).

➔ If the measurement result is obviously wrong, repeat the measurement.

The unit switches itself off automatically after about 1 min. To repeat a measurement, press the start button again **briefly**.



Allow at least two minutes between measurements.

➔ If no further measurement is required, remove the cuff from the arm.

Completing the blood pressure record card

Retrieving the average value and WHO classification

- ➔ Enter each individual value in your record card.
- ➔ Retrieve your average value after 30 blood pressure measurements by pressing the START-button for about 3 seconds with the monitor switched off. The average values of all stored measurements (systolic, diastolic and pulse) are displayed.
- ➔ Enter the average value in the field specifically reserved for this in your record card.

If there is no measurement in the memory, "0" is displayed for systole, diastole and pulse.

If measurements were recorded with irregular heart beat, there is an additional symbol showing the prevalence of cardiac arrhythmias:



appears when up to 25% of the measurements have irregular heart beat.



appears when between 25% and 50% of the measurements have irregular heart beat.



appears when more than 50% of the measurements have irregular heart beat.

Completing the blood pressure record card

Retrieving the average value and WHO classification

A dark rectangle appears on the left of the screen (see illustration 8), indicating the level of the average blood pressure value. Use the accompanying evaluation scale (see illustration 9) to identify the range within which your blood pressure falls under the WHO classification (see page 52). **The WHO display appears only with the average value display.**

➔ For your information, attach the sticker (WHO classification) supplied, to the back of your unit.

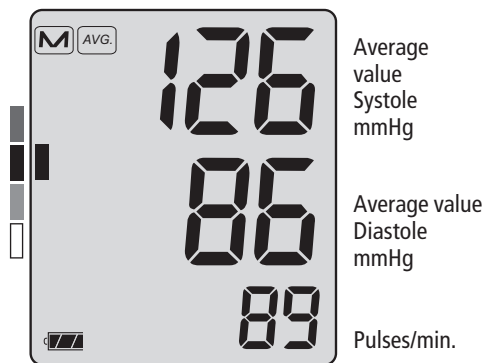


Illustration 8



WHO classification

- high blood pressure (hypertension)
- borderline normal blood pressure
- normal blood pressure
- optimum blood pressure

Illustration 9

Displaying individual stored values

After indication of the average values automatically all measured values are displayed in chronological order (starting with the most recent value). Before the values are shown, the number of the measurement is displayed (see illustration 10).

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The corresponding measurement value appears after 3 seconds (see illustration 11).



Illustration 10

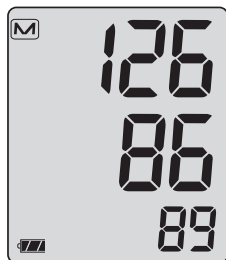


Illustration 11

Systole
mmHg

Diastole
mmHg

Pulses/min.

After the last value has been shown the device switches off automatically.


Erase the memory


Press and hold the START button for about 5 seconds with the monitor switched off. The display shows "CLR MEM". Release the START button. Then press the START button again. The display shows "CLR YES". Wait until the unit automatically shuts off.

Mains operation

The mains connection socket is located at the rear of the monitor.

Where required, use only the bosco power supply unit (**order number 410-7-150**). This power supply unit produces a rectified output of the correct polarity. Other commercially available power supply units can cause damage to the electronic components, which will invalidate the warranty. There is also a risk of fire with these other power supply units.

 Do not touch the batteries, the power supply unit socket and the patient at the same time.



 Remove the power supply unit plug from the blood pressure monitor when it is not in use.

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Error messages

If any problems occur during the measurement, the display will show an error message instead of a blood pressure reading.

Meaning of error messages:

	Cause of Err message:	Troubleshooting:
	Excessive variation in cuff pressure during measurement	Hold arm still.
	No valid pulse readings	Check position of cuff (see page 59) and repeat measurement.
	Systole – diastole difference too small: Systole – diastole ≤ 10 mmHg	Check position of cuff (see page 59) and repeat measurement.
	Incorrectly inflated	Cuff possibly too loose, attach cuff more firmly (see page 59)

Error messages

Cause of Err message:		Troubleshooting:
	The pulse value could not be determined correctly.	Check position of cuff and repeat measurement.
	Internal Error	Remove the batteries and briefly press START button. Put the batteries back into the monitor. If the error persists, return the instrument for repairs to the manufacturer.
		
	“♥” Display:	Troubleshooting: Repeat measurement recommended, holding the arm absolutely still. If the “♥” symbol appears again, even with the arm held still, this may be an indication of an irregular heartbeat. Please discuss this with your doctor at your next visit.

Cleaning and Disinfection

Cleaning Monitor:

Use a soft, dry cloth to clean your monitor.

Cleaning Cuff:

Small stains on the cuff can be removed carefully with a proprietary washing-up liquid.

Disinfection Cuff:

For disinfectant wipes (at least 5 minutes exposure time) of the device and the cuff, we recommend the disinfectant antiseptic liquid (Schülke & Mayr). To disinfect the cuff, we recommend spray disinfection. In particular, if the device is used on multiple users it is to pay attention to regular cleaning and disinfections of the cuff.

Warranty Conditions

We give 3 years warranty from the date of purchase. The purchase date has to be proven by the invoice. Within the warranty period defects are eliminated free of charge. After repairs the warranty period is not extended on the whole unit, but only to the replaced components.

Excluded from the warranty are parts subject to normal wear and tear (e.g. cuff), transport damages and any damage caused by improper handling (e.g. non-compliance with the instructions for use). Damages due to disassembly by unauthorized persons are also excluded from warranty.

No claims for damages against us are substantiated by the warranty.

In the case of justified warranty claims the device has to be sent along with the original invoice to:

BOSCH + SOHN GMBH U. CO. KG,
Bahnhofstr. 64,
72417 Jungingen,
GERMANY.
www.boso.de



Customer service

Customer service:

Warranty and repair work must be undertaken by trained and authorised personnel. Do not modify this equipment without authorization of the manufacturer.

Send the monitor, carefully packaged and with sufficient postage, to your authorised dealer or directly to:

BOSCH + SOHN GmbH u. Co. KG
Serviceabteilung
Bahnhofstraße 64,
72417 Jungingen,
GERMANY
T: +49 (0) 74 77 / 92 75-0
www.boso.de

Disposal



Do not dispose of monitors and batteries in the domestic waste.

At the end of its lifespan, the monitor must be taken to a collection site for obsolete electronic items.

Please note that batteries and rechargeable batteries must be disposed of separately (local authority collection site).


Expected operational lifetime of the equipment: 5 years (using the unit 6 times a day).
Expected operational lifetime of the cuff: 2 years (using the unit 6 times a day).

Technical data

Measurement principle:	oscillometric
Measurement range:	Systolic: 60 to 279 mmHg Diastolic: 40 to 200 mmHg Pulse: 40 to 180 per minute
Cuff pressure:	0 to 299 mmHg
Memory store:	60 measurements
Display:	LCD
Operating conditions:	environmental temperature +10°C to +40°C Relative humidity 15 to 85% Air pressure 800 hPa to 1060 hPa
Transport/ Storage conditions:	environmental temperature -20°C to +60°C Relative humidity 10 to 95% Air pressure 700 hPa to 1060 hPa



Technical data

Power supply:	DC 6 V (4 x 1.5 V Mignon IEC LR 6 alkaline manganese batteries) Alternative special option: DC 6 V power supply unit, Order No. 410-7-150
 Typical battery life:	700 measurement cycles (depending on inflation pressure and frequency of use).
Battery check:	symbol display in LCD window
Weight:	282 g without batteries
Dimensions (WxHxD):	140 mm x 60 mm x 106 mm
Classification:	Medical device with internal energy source (in battery operation) / class II (in power supply unit operation), continuous operation mode
Applied part:	Type BF (☞)

Technical data

Protection against solid objects:

IP20

IP classification is the degree of protection provided by enclosures in accordance with IEC 60529. This device is protected against solid foreign objects of 12mm diameter and greater such as fingers. This device is not protected against water.

Clinical test:

Accuracy complies with the requirements of ISO 81060 Part 2

Maximum deviation of cuff pressure measurement:

± 3 mmHg or 2% of the reading (whichever is the higher)

Maximum deviation of pulse rate display:

± 5 %

Applicable standard:

IEC 80601-2-30 : "Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers"



Calibration checks - Testing instructions

(for trained specialist staff only)

Calibration checks – every 2 years at the latest – must be performed by the following institutions or persons:

- Manufacturer
- Trade measurements authorities
- Persons who fulfil the requirements of the legislation governing the operation of medical devices.

A) Function testing

Function testing of the monitor can only be carried out on a person or with a suitable simulator.

B) Testing of pressure circuit integrity and deviation of pressure display

Note:

- a) When the pressure in measurement mode increases above 299 mmHg, the quick release valve is triggered and the pressure circuit opens. When the pressure in test mode increases above 320 mmHg, the measured value display flashes.
- b) For the calibration checks a special test plug must be used. The test plug is available for a fee from the manufacturer.
A pump ball must also be introduced into the pressure circuit.

Calibration checks - Testing instructions (for trained specialist staff only)

Testing

- 1.) Remove batteries.
 - 2.) Hold start button pressed down and insert batteries.
 - 3.) Release start button.
The monitor is now ready for testing; the current pressure is displayed in the SYS and DIA fields.
 - 4.) Perform test for deviation of pressure display and pressure circuit integrity (observe setting time for cuff – at least 30 seconds) in the usual manner.
- 5.) Switch off monitor by pressing the START button again.



The device must not undergo service or maintenance while it is in use.

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