BOSCH +SOHN boso

Instructions for use

boso TM-Serie
24-hour blood pressure monitor

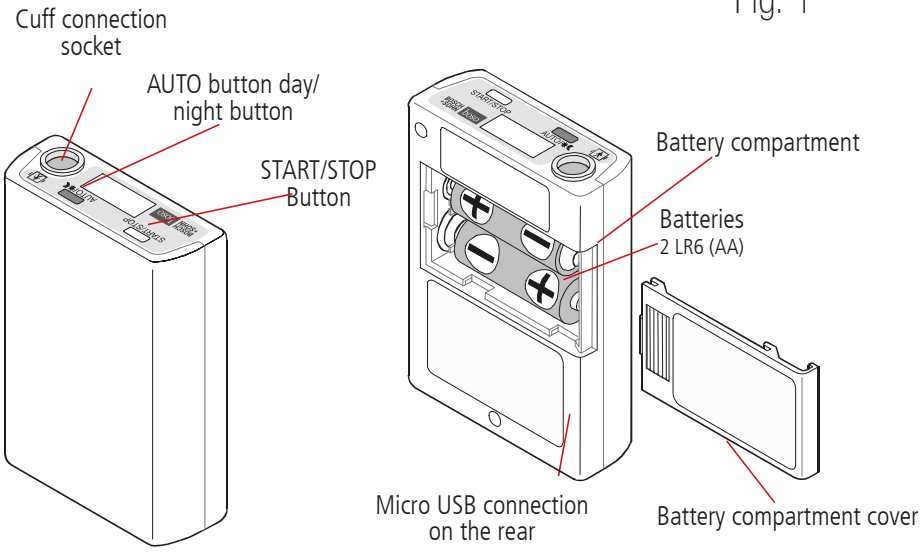
EN

CE 0124

Contents

Device overview

Fig. 1



Scope of supply with complete accessories*

- 24-hr blood pressure monitor
- Transport case
- battery charger
- 2x battery sets with two batteries each (one set already inserted in the unit)
- Cuffs for adults
  - Size M CA91 washable
  - Size L CA92 washable
- Waist bag with removeable carrying belt and strap
- Instruction manual for:
  - boso TM-Serie
  - XD profile manager
- Important notes
- Medical Devices Book
- CD-ROM
  - boso XD profile manager
- USB connection cable

*Scope of delivery varies depending on the version of the unit.

Icon explanation

Observe the electronic instructions for use

Important notes/warnings

Order number

CE marking

Unique Device Identifier

Switzerland - Authorisation

Medical device

Store in a dry place

Fragile, handle with care

Temperature limits

Humidity limit

Action note for the user

Symbols on the measurement device

START/STOP button

AUTO button (DAY/NIGHT BUTTON)

Automatic mode active

Sleep mode active

Battery charged

Battery partially charged

Battery empty no further measurement
or data transfer possible

Storage full, 600 measurements,
no further measurements possible

Serial number

IP22

Protection against foreign bodies and water:
The IP classification is the degree of protection provided by enclosures according to IEC 60529. This unit is protected against solid foreign objects with a diameter of 12 mm and larger, such as fingers.
This unit is protected against falling dripping water when the housing is tilted up to 15°.

Symbols on the measurement device

Do not dispose of the appliance
in the household waste .

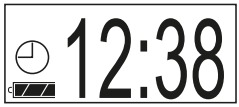
Defibrillation protected device type BF

Manufacturer

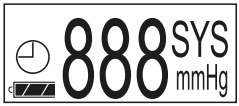
Date of manufacture

Read instruction manual

OLED display



Clock display,
if no measurement is taking place



Display of the measurement values:

SYS	- Systolic blood pressure
DIA	- Diastolic blood pressure
PUL	- Pulse
mmHg	- Unit for blood pressure
/min	- Unit for pulse

Fault display

Introduction

Dear customer, we are very pleased that you have decided to purchase a boso long-term blood pressure monitor. The boso brand stands for the highest quality and precision. Currently, 96 % of all German general practitioners, practitioners and internists work with boso blood pressure monitors in their practice (API study by GfK 01/2016). This device has passed our strict quality control and is your safe partner for checking your patients' blood pressure values.

⚠ Please read these instructions for use carefully before using the device for the first time, as correct blood pressure measurement is only possible if the device is handled correctly.

These instructions for use for the devices of the boso TM-Serie familiarise you with the use of the ambulatory blood pressure monitor and the associated accessories. To be able to use all device settings, measurement protocols as well as all evaluation options of the recorded blood pressure measurements, you also need the medical software boso XD profile manager. For instructions on how to use the software, please refer to the separate software instructions for use.

Please familiarise yourself with both instructions for use before first use. The manufacturer reserves the right to change the information in these instructions for use without notice. The current version can be downloaded from the website: https://www.boso.de/downloads

The instruction manual must be kept with the product to have it available at all times.

In these instructions for use  is used for an action of the user.

For help with commissioning, use or maintenance, please contact your specialist dealer or the manufacturer (contact details on the back cover of this instruction manual).

These instructions for use must be enclosed with the unit when it is sold. This blood pressure monitor complies with the current European regulations and the international standard IEC 80601-2-30: "Particular requirements for the safety, including essential performance, of automated non-invasive blood pressure measurement devices".

The use of the device in pregnant women or in pre-eclampsia is not intended.

If the device is used for medical purposes (in accordance with the Medical Devices Operator Ordinance), metrological checks must be carried out at regular intervals (see section Test Instructions).

Intended purpose

Non-invasive recording of systolic and diastolic blood pressure values and pulse rate of individuals over a period of usually 24 hours.

Side-effects of the blood pressure measurement over 24 hours

Petechiae, bleeding or subcutaneous haematomas on the measuring arm can occur with any blood pressure measurement, even if the cuff fits correctly.
Patient-dependent risk as a result of treatment with anticoagulants or patients with coagulation disorders occurs regardless of the type of meter. Always check if the patient has coagulation disorders or is being treated with anticoagulants.

Scope of application

The blood pressure monitors of the boso TM-Serie work according to the oscillometric measuring principle. The device is intended for 24h measurement in the patient's usual environment and is to be used only under medical supervision and after precise instruction by doctors or medical professionals. The device is not suitable for infants, newborns, or for unsupervised use with unconscious patients or patients with impaired cognitive abilities.

Notes/safety instructions


Compression or a reduction in the cross-section of the air hose must be avoided.


Excessively frequent measurements can lead to injuries by impairing the blood flow.


The cuff must not be applied over wounds as this may cause further injury.


Make sure that the cuff is not applied to an arm whose arteries or veins are or have been under medical treatment (e.g. shunt).


For women with a mastectomy, do not apply the cuff to the arm on the amputated side of the body.


During the measurement, malfunctions may occur in medical devices that are used simultaneously on the same arm.


The unit has no protection against possible influences from high frequency (HF) surgical equipment.

Safety information


If liquid has been spilled on the unit, remove the batteries immediately and send the unit to the customer service address (section Warranty Conditions/Customer Service) for inspection.


Watch out for damage to the rechargeable batteries or batteries. Never use damaged batteries.

Safety information

There is a risk of strangulation with the shoulder strap and cuff tube.

A patient with impaired cognitive abilities may only use the device under supervision.

Do not place the shoulder strap and cuff tubing around the patient's neck.

The cuff hose is always laid under the clothing (also at night).

If the appliance is used with children, this must be done with special care and under constant supervision.

Instruct the patient to turn off the device, remove the cuff and notify the doctor if they experience pain, swelling, redness or numbness in the arm around which the cuff is placed. (It is likely that the patient may experience mild to moderate discomfort when having their blood pressure measured.)

The measuring process can be interrupted at any time by pressing one of the buttons. This deflates the cuff and the device can be removed.

Instruct the patient to protect the unit from liquid penetration. In particular, the patient must be advised not to wear the device while showering.

If the unit has been exposed to moisture or if liquid has entered during cleaning/use, it must no longer be fitted to patients.

Safety information

Medical electrical equipment is subject to special precautions regarding electromagnetic compatibility and must be installed and commissioned in accordance with the EMC instructions section.

Maintenance work on this unit must be carried out by trained and authorised personnel.

Due to the risk of strangulation by the tube and cuff, the device must not be within the reach of unsupervised children or used on unsupervised patients with impaired cognitive abilities or on patients under anaesthesia.

The device must not be used by children without supervision.

Do not use the device near babies. This can lead to accidents or damage.

The manufacturer is only responsible for the impact on the safety, reliability and performance of the device if:

Assembly, extensions, new settings, changes or repairs have been carried out by persons authorised by him.

The appliance is used in accordance with the instructions for use.

⚠ Do not start the machine without putting the cuff on.

⚠ The appliance contains small parts; these can cause a choking hazard if accidentally swallowed by babies.

⚠ The performance of the unit may be affected by excessive temperature, humidity or altitude.

Commissioning

Before you start working with boso TM-Serie devices, you should charge the batteries supplied. To do this, proceed as described in section ''Changing and charging the batteries''. Then install the boso XD profile manager. This software enables the programming of the blood pressure monitor and the evaluation of the stored data.

Selection and connection of the cuff
on boso TM-Serie devices

Cuff selection

⚠ Only original cuffs CA91, CA91R, CA92, CA93 and CA94 must be used.

The cuff must be selected according to the printed arm circumference.

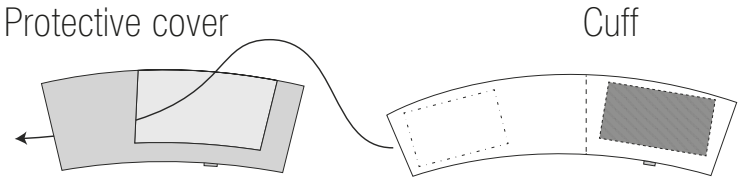
Connecting the cuff

The air connection plug of the cuff tubing is screwed directly into the air connection socket of the blood pressure monitor (see Fig. 4).

Attachment of the protective covers (optional)

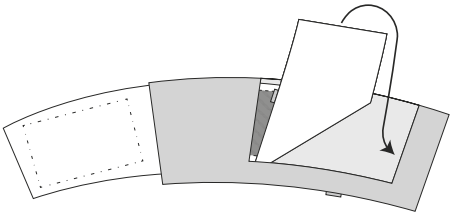
If necessary, you can also use protective covers (see section Accessories) to protect against soiling.
Put on the protective covers as shown below:

Fig. 2



Pull the cuff through the tab of the protective cover.

Fig. 3



Attach the protective cover to the cuff with the Velcro fasteners on the inside.

Care instructions for protective covers:

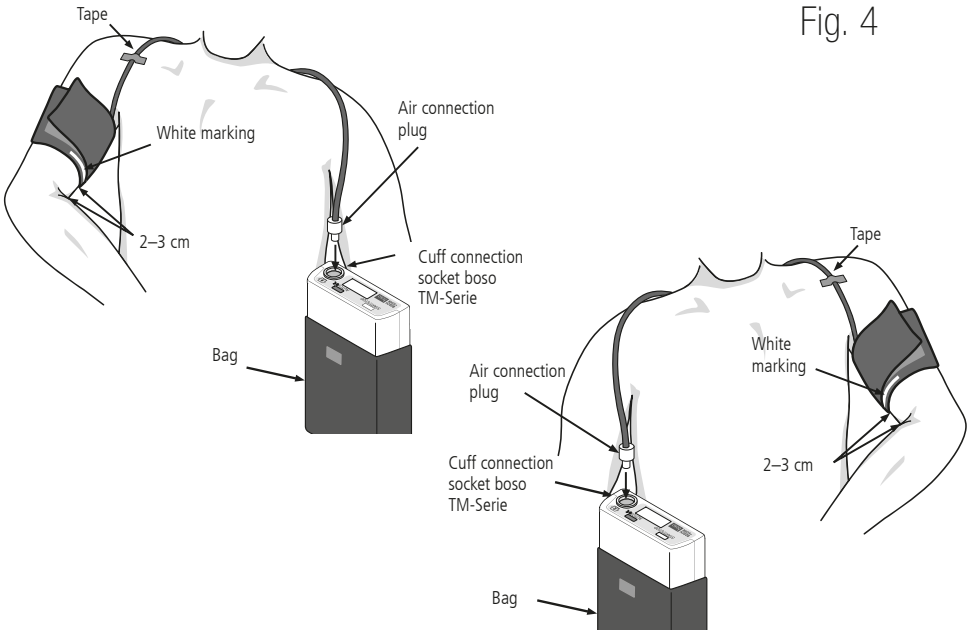
machine wash at max. 60 °C

Attaching the cuff

Place the cuff on the unclothed upper arm so that the white marking lies on the arteria brachialis. For most people, blood pressure is higher on the left arm, so blood pressure is measured on the left arm. If the blood pressure is higher on the right arm, it should be measured on the right arm.
The cuff should be approx. 2-3 cm above the crook of the elbow. The cuff should not be too tight, about two fingers should still fit between the arm and the cuff.

After the end of the measurement, the blood circulation must not be impaired by the cuff. Place the cuff tube over the shoulder (see fig. 4). Fix the cuff tube to the shoulder with tape. The blood pressure monitor is carried in the pouch either on an existing belt or with the included carrying strap.

Fig. 4



Carrying out measurements
with boso TM-Serie devices

After the cuff has been properly put on, a test measurement can be triggered on the boso TM series device by means of the START/STOP button (measurement is only displayed if the device has been programmed accordingly). If the display is off, activate it by pressing any button. If this measurement is successful, the automatic interval function (see below) can be started. The sample measurement is included in the evaluation.

Please note that the oscillometric measurement method can lead to measurement inaccuracies in some types of patients. Persons with cardiac arrhythmia, arteriosclerosis, circulatory disorders, diabetes or pacemaker wearers should have a comparative measurement taken with an auscultatory device before starting the measurement. This also applies to women during pregnancy.

External disturbing influences, such as movements of the measuring arm, disturbing vibrations, e.g. due to driving or the use of public transport during the measurement, can lead to incorrect measurements. For this reason, the record kept by the patient must be viewed and included in the evaluation of the measurement results.

Starting the automatic interval

To start the automatic interval, press and hold the black AUTO button until "◴" appears in the blood pressure monitor display and is acknowledged by a short signal tone (after approx. 5 seconds).

If the device is operated in "Sleep button" mode, the patient must press the black AUTO button before going to sleep. The display shows "⏲" for automatic and "☾" for sleep mode. After getting up, the black AUTO button must be pressed again. The "☾" in the display disappears.

Automatic adjustment of the pump-up level
(only in automatic interval mode)

The boso TM-Serie device automatically pumps up to the required pressure level. If this inflation height is not sufficient, the unit automatically inflates again approx. 60 mmHg above the original inflation level.

Limiting the maximum pumping level

The device of the boso TM-Serie has the option of limiting the inflation height. For the corresponding procedure, please refer to the boso XD profile manager instructions for use.

Performing a manual measurement

A manual measurement can be started by the patient at any time in addition to the automatic measurements. This can be sensible following physical or emotional stress. To do this, activate the display, then press the white START/STOP button.

Aborting measurements

To cancel the measurement, the white START/STOP button on the boso TM-Serie must be pressed.
If the measurement is to be taken at a later time, a manual measurement can be started at any time using the white START/STOP button.

As soon as the device is removed from the patient after the 24-hour

Ending the measurement and transferring the measurement data

measurement has been completed, the automatic function must be switched off. To do this, press and hold the black AUTO button until the "🕘" disappears from the blood pressure monitor display (approx. 5 seconds).

Then connect the boso TM-Serie device to the computer using the USB connection cable. Transfer the data according to the instructions for use boso XD profile manager.
After transferring the measured data, it his highly suggested to delete the data memory.

Changing the batteries

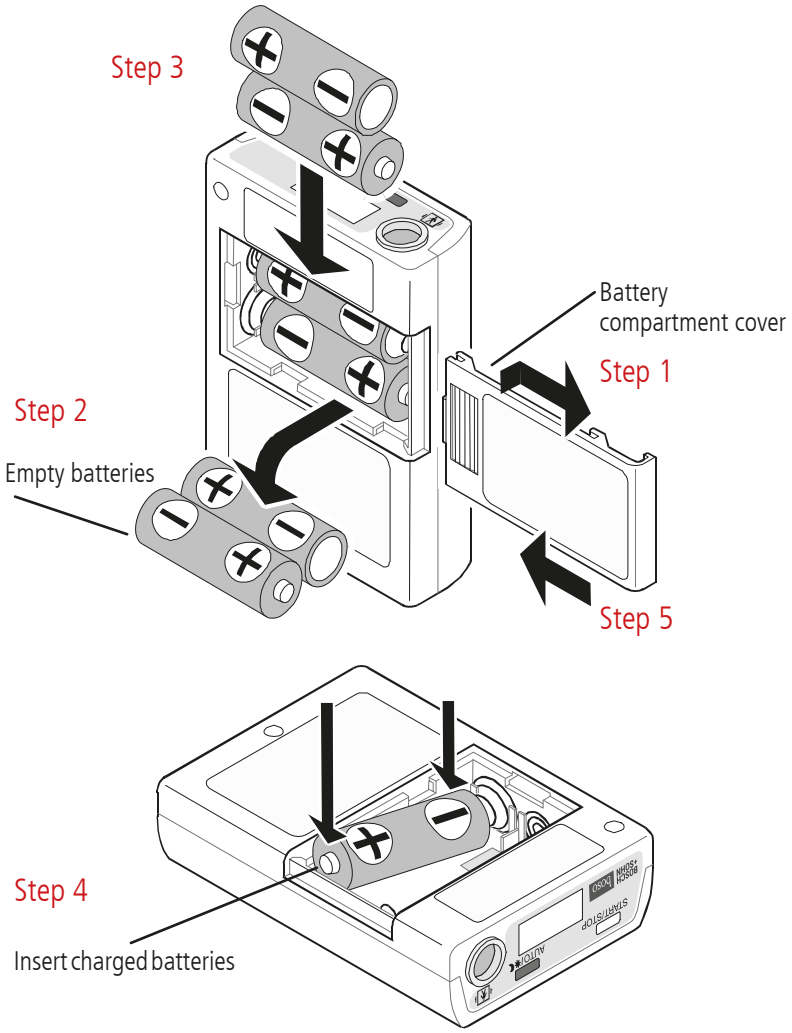
We recommend changing the used battery pack after each 24-hour measurement and replacing it with the freshly charged battery pack.
To prevent data loss, the data stored in the boso TM-Serie device is buffered by an internal battery. This battery is automatically charged via the battery pack. With a fully charged battery pack, the data remain stored for approx. 10 days. To fully charge the battery when using the unit for the first time, switch on the unit with fully charged batteries for approx. 24 hours.

To change the batteries, proceed as follows (see fig. 5):

- Open the battery compartment cover (step 1)
- Remove the empty batteries (step 2) and reinsert the charged batteries (step 3) (note polarity!) (Step 4))
- Close the battery compartment cover (Step 5)

Changing the batteries

Fig. 5



Charging the batteries

Insert the rechargeable batteries into the charger and plug it into a power socket. If the blue LED lights up, the battery packs are being charged. The charging process takes roughly 11 hours for a fully charged battery pack. After 13 hours, the charger automatically switches off the charging process.

⚠ Important note regarding battery charging

To ensure proper functioning of the boso TM-Serie device for more than 24 hours, use only rechargeable batteries with the following ratings: min. 1900 mAh; 1.2 V; NiMH or batteries (Type AA 1.5 V).
In addition to the two rechargeable batteries required for the power supply, the device of the boso TM series also contains an internal battery to save the programme setting in the device.

To avoid loss of programming and stored readings when the internal battery is discharged, please observe the following procedure:

- Insert charged batteries into the unit even when it is not in use.
- The state of charge of the internal battery is thus constantly kept at a high level. If the power supply to the internal battery is interrupted, the settings of the boso TM-Serie device will be lost after approx. 10 days.
- Before placing the unit on a patient, please replace the batteries in the unit with a set of freshly charged batteries.

If the batteries are short-circuited, they may become hot and cause burns and scorching damage to the unit.
Do not touch the batteries and the patient at the same time.

Longer storage of the device

If the unit will not be used for a long time (4 weeks or more), remove the batteries to prevent possible damage due to leakage.
Before the device is then attached to a patient again, the internal battery must be charged and the device reprogrammed.

- Insert freshly charged batteries.
- Please leave the battery packs in the device for two hours.
  The internal battery is recharged during this time.
- Reprogram the device.
- Before attaching the device to a patient, replace the batteries with a set of freshly charged ones.

Error messages

Error code	Cause	Remedy
0:00	Time sets to 0:00 when battery is replaced	Device must be reprogrammed.
E03 E90	Zero point adjustment not possible	Deflate cuff completely.
E04	Empty battery	Charge or replace batteries.
E05	Leakage	Disconnect the cuff from the device and reconnect. If the error occurs repeatedly, contact your sales partner.
E06	Pressure above 299 mmHg	The arm must be kept still during measurement.
E07	User abort via START/STOP button	
E08 E10	No or non-interpretable oscillations	The arm must be kept still during measurement.
E09	Error of the activity sensor	Remove and re-insert the battery packs.

Error messages

Error code	Cause	Remedy
E20	Pulse < 30 or > 200	Check the position and fit of the cuff.
E21 E22	No interpretable oscillations in the area of diastole (E21) or systole (E22)	
E23	Systole-diastole < 10 or > 150 mmHg	
E30	Measuring time longer than 180 seconds	Contact your sales partner.
E31	Deflation longer than 90 seconds	Contact your sales partner.
E48	Pulse cannot be measured	The arm must be kept still during measurement.
E52	Storage error	Contact your sales partner.
E91	Pressure inside the cuff too high / maximum pressure set too low	Set a higher maximum pressure. The arm must be kept still during measurement.

After use

Cleaning and disinfection

To clean the boso TM-Serie device and the cuff, please use a soft cloth that may be moistened with soapy water.
For the protective covers: machine wash at max. 60 °C.

Never use solvents, benzine, spirits or abrasive cleaners for cleaning!

Disinfection:
For disinfection by wiping (exposure time at least 5 minutes) the device, we recommend the disinfectant Antifect Liquid (Schülke & Mayr). We recommend using spray disinfection for disinfecting the cuff. Especially if the device is used by several patients, make sure that the cuff is cleaned and disinfected regularly.

Disposal information

Used batteries and rechargeable batteries must not be disposed of in household waste. You can take them to a collection point for used batteries or to hazardous waste. Please contact your municipality for more information.

Customer information on the recycling of commercial waste electrical equipment

1) Purpose

Based on the EU Directive 2012/19/EU, the German implementation of the ElektroG was revised in 2021. The amended ElektroG3 came into force on 01.01.2022. The background to this is to steadily improve the collection rates of e-waste and to achieve a rate of > 65 %. In this document we inform you about the return option we have created for your waste electrical equipment (WEEE) from the commercial sector.

2) Manufacturer's declaration on the return option

For commercially used appliances, a collection can take place at the end of the life cycle via our recycling partner (see point 3). For this purpose, a notification must be sent to our return partner or to "Bosch+ Sohn GmbH u. CO. KG", stating the articles and their number. The customer then receives an offer from our recycling partner for coordinated collection at the point of generation. The customer is free to opt for this collection or to take the WEEE to his own disposal system and to comply with the corresponding obligations.

3) Authorised recycling partner

The authorised recycling company for the company "Bosch+Sohn GmbH u. CO. KG" is:

WEEE Return GmbH
Lahnstraße 31
12055 Berlin

4) Contact details for the return option

A return can be registered by telephone or by e-mail. The following options are available to the waste owner:

Phone: +49 (0) 74 77 92 75-0
E-Mail: zentrale@boso.de

Obligation to report incidents

A serious incident shall be reported to the manufacturer and to the responsible authority of the Member State in which the user and/or patient is established.

A "serious incident" means an incident that directly or indirectly had, could have had, or may have had any of the following consequences:

the death of a patient, user, or other person; the temporary or permanent serious deterioration of the health of a patient, user, or other person; a serious public health hazard. Please send reports of serious incidents to:

E-Mail: vigilanz@boso.de
Fax: +49 (0) 74 77 10 21

Warranty conditions / customer service

This product is covered by a 2-year factory warranty from the date of purchase.
The date of purchase must be proven by invoice. Within the warranty period, defects resulting from material or manufacturing faults will be repaired free of charge. Guarantee services do not extend the guarantee period for the entire appliance, but only for the replaced components.

The warranty does not cover wear and tear (e.g. cuff), transport damage or any damage caused by improper handling (e.g. failure to follow the instructions for use) or by tampering by unauthorised persons. The guarantee does not give rise to any claims for damages against us. The buyer's statutory claims for defects pursuant to Art. 437 of the German Civil Code (BGB) shall not be restricted.

In the event of a claim under the warranty, the unit must be sent together with the original proof of purchase to:

BOSCH + SOHN GmbH u. Co. KG
Bahnhofstr. 64, 72417 Jungingen, Germany


Maintenance work on this unit must be carried out by trained and authorised personnel.

The unit must not be modified without the permission of the manufacturer.

Accessories

Please use only the accessories recommended by the manufacturer.

Cuffs

Size M	CA91	20 - 31 cm	259-4-400
Size M (right)	CA91R	20 - 31 cm	259-4-440
Size L	CA92	28 - 38 cm	259-4-410
Size XL	CA94	36 - 50 cm	259-4-430
Size S	CA93	15 - 22 cm	259-4-420

Protective covers (10 pieces)

Size M left and right	259-7-400
Size L	259-7-410
Size XL	259-7-430
Size S	259-7-420
5x size M and 5x size L	259-7-405

Other accessories

Charger	535-7-130
NiMh batteries (2 pieces, Mignon)	535-7-131
Waist bag with carrying strap	515-7-116

Technical specifications

Product:	Blood pressure measuring device for 24-hour measurement
Type designation:	See equipment labelling
Rated voltage:	2x 1.5 V DC or 2x 1.2 V DC
Power supply:	2x NiMh batteries (Mignon)
Measuring range:	Systole: 60 - 280 mmHg Diastole: 30 - 160 mmHg Pulse: 30 - 200 pulse/min
Maximum deviation of the cuff pressure:	±3 mmHg or 2 % of reading (whichever is greater)
Maximum deviation of the pulse reading:	±5 %
Measurement storage:	600 measurements
Operating conditions:	+10 °C to +40 °C rel. humidity 30 - 85 % (non-condensing) Air pressure 700 - 1060 hPa
Storage conditions:	+20 °C to +60 °C 10 - 95 % rel. humidity Air pressure 700 - 1060 hPa
Weight:	135 grammes without batteries

Technical specifications

Dimensions (W x H x D):	66 mm x 25 mm x 95 mm
Typical battery life:	1000 charging cycles (depending on pump-up level + frequency of use)
Expected service life of the unit:	10 years
Expected service life of the cuff:	10,000 measuring cycles
Clinical test:	The measurement accuracy meets the requirements of ISO 81060-2

Test instruction for metrological checks

A) Functional check

A functional check of the unit can only be carried out on humans or with a suitable simulator.

B) Checking for tightness of the pressure circuit and deviation of the pressure indication

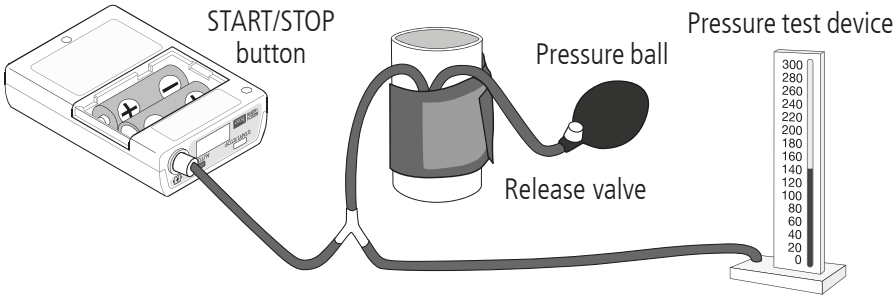
Remove the batteries. Then create a test setup as shown in Fig. 6. Immediately after reinserting the batteries, press and hold the white START/STOP button. The white START/STOP button must be held down until a "0" appears in the display of the boso TM-Serie device.

Then carry out the test for deviation of the pressure indication and tightness of the pressure circuit (observe the setting time of the cuff - at least 30 seconds) in the usual way. To return to the measuring mode after the test has been completed, the batteries must be removed again and reinserted.

C) Securing

For securing, the housing halves (upper and lower part) are connected with a securing tag.

Fig. 6



EMC information

Medical electrical equipment is subject to special precautions regarding EMC and must be installed and commissioned in accordance with the guidelines given below.
Portable and mobile HF devices (e.g. mobile phones) can affect medical electrical equipment.
The use of third-party accessories (not original boso parts) may result in increased emissions or reduced immunity of the device.

Guidelines and manufacturer's declaration - Electromagnetic emissions

The boso blood pressure monitor is intended for operation in the electromagnetic environment specified below. The customer or the user of the boso blood pressure monitor should ensure that it is used in such an environment.

Emission measurements	Compliance	Electromagnetic Environment Guidelines
HF emissions according to CISPR 11	Group 1	The boso blood pressure monitor uses HF energy exclusively for its internal function. Therefore, its HF emission is very low and it is unlikely to interfere with nearby electronic equipment.
HF emissions according to CISPR 11	Class B	The boso blood pressure monitor is intended for use in all establishments, including domestic establishments and those directly connected to a public supply network which also supplies buildings used for domestic purposes.
Harmonics according to IEC 61000-3-2	not applicable	
Voltage fluctuations/ flicker according to IEC 61000-3-3		

Guidelines and manufacturer's declaration - Electromagnetic interference immunity

The boso blood pressure monitor is intended for operation in the electromagnetic environment specified below. The customer or the user of the boso blood pressure monitor should ensure that it is used in such an environment.

Interference immunity tests	IEC 60601-test level	Compliance level	Electromagnetic Environment - Guidelines
Static electricity discharge (ESD) according to IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should be wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30 %.
Fast transient electrical disturbance/bursts according to IEC 61000-4-4	±2 kV mains cables ±1 kV for input and output lines	Not applicable	
Surges according to IEC 61000-4-5	±1 kV push-pull voltage ±2 kV common-mode voltage	Not applicable	
Voltage dips, short-time interruptions and fluctuations of the supply voltage according to IEC 61000-4-11	< 5 % U_T for 1/2 period (> 95 % dip) 40 % U_T for 5 periods (65 % dip) 70 % U_T for 25 periods (30 % dip) < 5 % U_T for 5 s (> 95 % dip)	Not applicable	
Magnetic field at the supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	

NOTE: U_T is the AC mains voltage before the test level is applied.

EMC information

Guidelines and manufacturer's declaration - Electromagnetic emissions

The boso blood pressure monitor is intended for operation in the electromagnetic environment specified below. The customer or the user of the boso blood pressure monitor should ensure that it is used in such an environment.

Interference immunity tests	IEC 60601-test level	Compliance level	el-magn. Environment - Guidelines recommended safe distance
			Portable and mobile radios are used at no closer distance from the boso blood pressure monitor, including the leads, than the recommended protective distance calculated using the equation appropriate to the transmitting frequency:
Conducted HF disturbances according to IEC 61000-4-6	3 V_{eff} 150 kHz - 80 MHz	3 V_{ef}	$d = 1.2\sqrt{P}$
radiated HF disturbances according to IEC 61000-4-3	3 V/m 80 kHz - 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ for 80 MHz - 800 MHz $d = 2.3\sqrt{P}$ for 800 MHz - 2.5 GHz
			With P as the nominal power of the transmitter in watts (W) according to the transmitter manufacturer's specifications and d as the recommended protective distance in metres (m). The field strength of stationary radio transmitters is lower than the compliance level[b] at all frequencies according to an on-site investigation[a]. Interference is possible in the vicinity of units with this symbol.

NOTE 1: For 80 MHz and 800 MHz, the higher value applies.

NOTE 2: These guidelines may not apply in all situations. The propagation of electromagnetic waves is influenced by absorption and reflection from buildings, objects and people.

[a] The field strength of stationary transmitters, such as base stations of radio telephones and land mobile services, amateur stations, AM and FM radio and television transmitters, cannot theoretically be predicted exactly. To determine the electromagnetic environment due to stationary HF transmitters, a site survey is recommended. If the determined field strength at the location of the boso blood pressure monitor exceeds the compliance level specified above, the boso blood pressure monitor must be observed with regard to its normal operation at any application location. If unusual performance characteristics are observed, it may be necessary to take additional measures, such as reorienting or relocating the boso blood pressure monitor. [b] Over the frequency range from 150 kHz to 80 MHz, the field strength is less than 3 V/m.

Recommended safe distances

between portable and mobile HF communication devices and the boso blood pressure monitor. The boso blood pressure monitor is intended for operation in an electromagnetic environment in which radiated HF disturbances are controlled. The customer or the user of the boso blood pressure measuring device can help prevent electromagnetic interference by maintaining minimum distances between portable and mobile HF communications equipment (transmitters) and the boso blood pressure measuring device as recommended below according to the maximum output power of the communications equipment.

Rated power of the transmitter	Protective distance according to transmission frequency m		
W	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.01	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters whose rated power is not specified in the above table, the distance can be determined using the equation associated with the respective column, where P is the rated power of the transmitter in watts (W) as specified by the transmitter manufacturer.

NOTE 1: An additional factor of 10/3 was used to calculate the recommended separation distance of transmitters in the frequency range from 80 MHz to 2.5 GHz to reduce the likelihood that a mobile/portable communication device inadvertently introduced into the patient area would cause interference.

NOTE 2: These guidelines may not apply in all situations. The propagation of electromagnetic waves is influenced by absorption and reflection from buildings, objects and people.

BOSCH +SOHN boso

BOSCH + SOHN GmbH u. Co. KG
Bahnhofstraße 64 | 72417 Jungingen, Germany
T +49 (0) 74 77 92 75 - 0 | E zentrale@boso.de | www.boso.de