Scope of delivery

1 Blood pressure monitor	1 Instruction manual
1 Blood pressure cuff*	1 Case*

*may not be included in special order

Symbols

CE 0124	CE mark
	Date of manufacture
	Manufacturer
mmHg	Measurement unit for determining blood pressure
	Proper functionality of the unit is tested up to a drop height of 1 metre
	Relative humidity limit
	Temperature range in degrees Celsius
REF	Order number
	Important notes
	Comply with instruction manual
MD	Medical device
UDI	Unique product ID
SN	Serial number
CH REP	Switzerland - Authorisation

Before using please read these instructions for use carefully and keep them in a safe place.

The metrological check - at least every 2 years - can be carried out either by the manufacturer or by authorised service providers in accordance with the Medical Devices Operator Ordinance.

Preliminary remarks

This blood pressure monitor complies with the international standard ISO 81060-1.

The device can be used with any arm circumference as indicated on the associated cuff.

Modification of the device and/or accessories is not permitted. This can result in measurement errors.
The device can be used by any user who has knowledge of auscultatory blood pressure measurement.

Intended purpose

Non-invasive measurement of systolic and diastolic blood pressure in humans.

Indication

Checking blood pressure in humans. Diagnosis, monitoring or suspicion of hypotension or hypertension.

Contraindication

Blood pressure should not be measured in the following cases:
- Venous or arterial access
- Lymphoedema (e.g. mastectomy)
- Fresh surgical wounds

Intended users

The boso aneroid devices are used by doctors or healthcare professionals trained in auscultatory blood pressure measurement.

Target patient group

The boso aneroid devices are suitable for measuring blood pressure in adults, children, infants and newborns.

Important notes

⚠ Keep the unit away from strong vibrations (do not bump or drop it) and protect it from dirt and moisture. Make sure that the cuff is not damaged by sharp objects (needle, scissors, etc.).

⚠ The device must no longer be used if there is visible damage, leakage or misalignment of the pressure pointer (e.g. zero point shifted).

⚠ Do not inflate above 300 mmHg!

⚠ The measuring time should not exceed 2 min. There must be a break of at least 2 minutes between 2 measurements.

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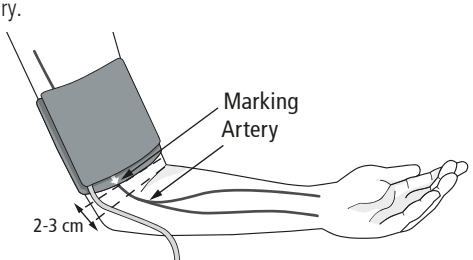
The patient must observe the following when measuring blood pressure:

⚠ Sit comfortably
⚠ Do not cross the legs
⚠ Lean on or otherwise support the back and arms
⚠ Remain as relaxed as possible during the measurement and do not speak
⚠ Rest for 5 minutes before the first measurement

Attaching the cuff

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



⚠ Important: The stethoscope membranes for listening to the Korotkoff sounds must be placed on the artery inside the upper arm.

Put the cuff on so that the lower edge of the cuff ends approx. 2-3 cm above the crook of the elbow and the centre of the rubber bag (marking on the cuff) is above the artery. The cuff should not be too tight, about two fingers should still fit between the arm and the cuff.

Make sure that rolled up clothes do not put pressure on the arm, which would affect the blood circulation. It is better to take off tight-fitting items of clothing before measuring.

Performing a measurement

⚠ Blood pressure must always be measured on the arm with the higher pressure values. To do this, first measure the blood pressure on both arms and then always on the arm whose blood pressure value is higher.

Close the valve completely by turning the air release screw clockwise or by pumping it hard on devices with a push-button valve. Inflate the cuff beyond systolic pressure. By turning the air release screw (anticlockwise) or operating the push button, the release speed can be adjusted. The WHO (World Health Organisation) recommends a release rate of 2 to 3 mmHg/sec.

⚠ To avoid a reading error, read the pressure values perpendicular to the scale.

⚠ It is recommended that during auscultatory measurement

- of adults the phase V (K5)
- of children aged 3 to 12 years the phase IV (K4)
- of pregnant women phase V (K5) is used, except for those where sounds are audible when the cuff is deflated, in which case phase IV (K4) of the Korotkoff sounds should be used.

K5 is the point at which the sounds heard with the stethoscope are no longer audible. K4 is the point at which the sounds heard with the stethoscope change from a clear beating sound to a muffled beating sound. After the measurement is finished, open the release valve completely for rapid cuff deflation.pressure in adults, children, infants and newborns.

Cuffs

Only use boso cuffs that are suitable for your device (1-tube, 2-tube or 2-in-1 tube cuffs). The cuff must be chosen to fit the arm circumference. To obtain reliable measurement results, please measure the arm circumference with a measuring tape and compare it with the information on the cuff. If you need a different or a range of cuff size(s), please contact your dealer.

Supplementary instructions for fitting the boso nova S

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Wall model:
Mount the wall screws in the wall according to the enclosed drilling template. Hook the unit into the mounted wall screws from above.

Additional accessories:
Spiral tube, 2 screws 4x35, 2 wall anchors 6x30, drilling template.

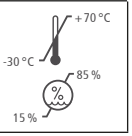
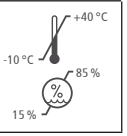
Rail model:
The unit can be fixed with the rail clamp for standard rails in the hospital area. To do this, tighten the screw clockwise.

Additional accessories:
Spiral tube, rail clamp with screw.

Stand model:
Assemble the stand according to the enclosed instructions. Attach the device to the stand.

Additional accessories:
Spiral tube.

Technical specifications

Measuring range	Pressure display accuracy	Storage conditions	Operating conditions
0 – 300 mmHg	± 3 mmHg or 2% of the reading values (larger value applies)		

Cleaning device and cuff

⚠ To clean the device, please use only a soft, dry cloth.

⚠ To clean the cuff, please remove the rubber bag. The cuff sleeve can be washed by hand at max. 30 °C.

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Disinfection

For disinfection of the device by wiping (minimum exposure time 5 min.) and for spray disinfection of the cuff we recommend the disinfectant Microzid Sensitive Liquid (Schülke & Mayr).

⚠ Disinfect the device and cuff after each measurement on a patient.

⚠ The boso aneroid devices described in these instructions for use are intended for reuse on multiple patients.

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:

1. the death of a patient, user or other person,
2. the temporary or permanent serious deterioration of the state of health of a patient, user or other person,
3. a serious risk to public health.

Please send reports of serious incidents to:

E-Mail: vigilanz@boso.de
Fax: +49 (0) 7477 9275 56

Warranty/Customer Service

This product comes with a 2-year quality guarantee 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 (disinfected) must be sent together with the original proof of purchase to:

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

Disposal

Please ensure disposal of the unit in accordance with all regional and national environmental regulations.