

**BOSCH
+SOHN**

boso



User manual

boso ABI-Serie

Ankle-brachial index measurement system



CE 0124

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Contents of package

- System for determining the ankle-brachial index (ABI)
- Carrying case
- Power pack
- Upper arm cuffs | 2 cuffs (arm circumference 22 – 42 cm), incl. tube
- Ankle cuffs | 2 cuffs (leg circumference 18 – 38 cm), incl. tube
- User manuals for:
 - boso ABI-Serie
 - profil-manager XD
- Medical device book
- Guarantee certificate
- CD-ROM
 - boso profil-manager XD
- USB cable 3.0 m
- Brochures + poster

Explanation of symbols



eIFU Indicator

Read the electronic user manual



Temperature limits



Air humidity limit



Store dry



Fragile, handle with care



Date of manufacture



Action note for the user



Switzerland – authorisation



Medical device



Important information/warnings



Order number

Symbols on the measuring device



Unique device identification



Serial number



Manufacturer



Read user manual



Protection class II device



Equipotential bonding



The device may not be discarded via household waste



USB connection

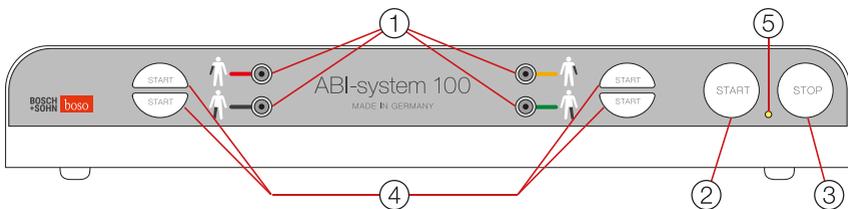


Degree of electrical shock protection: Type BF

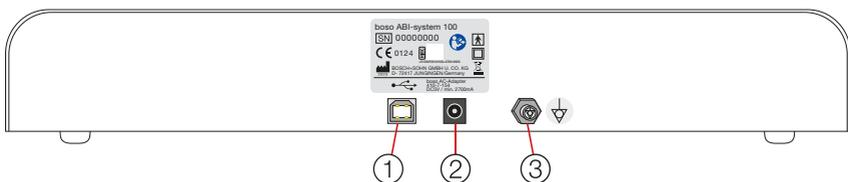
CE0124 CE mark

Device overview

Front of the device



Back of the device



Device overview - Front of the device (Fig.1)

① Cuff connections

-  Cuff connection, right arm (colour code: red)
-  Cuff connection, right leg (colour code: black)
-  Cuff connection, left arm (colour code: yellow)
-  Cuff connection, left leg (colour code: green)

② START button

A measurement can be started manually using this button.
All 4 cuffs will be inflated.

③ STOP button

The measurement can be manually discontinued using this button.
All cuffs will be deflated and the display switched off.

④ Buttons to start an individual measurement

Individual measurements on the limbs can be started using these buttons.

⑤ Operating display

The display is lit and green as soon as the device is supplied with operating voltage.



To completely disconnect the device from the mains voltage, pull the power pack out of the socket.

Device overview - Back of the device (Fig.2)

① USB connection for type B plug

② Mains connection

③ Equipotential bonding

Legend - Software + ABI

mmHg Pressure unit (millimetre mercury column)

Sys Systolic blood pressure in mmHg

Dia Diastolic blood pressure in mmHg

PP Pulse pressure in mmHg
Pulse pressure = Difference between systole - diastole

Pul Pulse value in 1/min

Arr Arrhythmia
Indication of whether a pulse irregularity of over 25% was observed during the measurement

ABI Ankle-brachial index
ABI = Ratio of systolic pressure of the leg measurement and higher systolic pressure of the arm measurements

baPWV Pulse wave velocity at the upper arm-ankle

cfPWV Pulse wave velocity between carotid aorta and femoral aorta

Δ Arm Sys Diff Arm Sys in mmHg
Difference between the systolic values of the left and right upper arm

Δ Arm Dia Diff Arm Dia in mmHg
Difference between the diastolic values of the left and right upper arm

Preliminary remark



Please read this user manual carefully before initial use.

This user manual is a part of a modular system comprising two parts:

- User manual for boso ABI-Serie
- User manual for boso profil-manager XD

To be able to use all of the device functions of the boso ABI-Serie, please use both of the available user manuals.

Please familiarise yourself with both user manuals before initial use. The manufacturer reserves the right to modify the information in this user manual without notice. The current version can be downloaded from the website: <https://www.boso.de/downloads>

Introduction

Dear Customer,

We are pleased that you have decided to purchase a system to measure the ankle-brachial index.

Your boso ABI-Serie device is an innovation on the market of blood pressure measurement technology for medical professionals. It easily measures the ankle-brachial index (ABI). The system works according to the oscillometric measurement principle. The pressure fluctuations (oscillations) caused by the pulse waves and transferred from the cuffs are stored and evaluated by the microprocessors. The major advantage of this measurement method is that it does not require any microphone or Doppler which need precise positioning in order to ensure the reliability of the readings.

This blood pressure monitor complies with the current European regulations as well as international standard IEC 80601-2-30:

“Particular requirements for basic safety and essential performance of automated type non-invasive sphygmomanometers.”

The metrology test – every 2 years at the latest – can be performed by the manufacturer, the authority responsible for metrology, or persons who meet the requirements of the German Medical Device Operator Ordinance (MP-BetreibV), section 6. The instructions for the metrology test can be found in the chapter “Metrology test instructions” of this manual.

Medical electrical devices are subject to particular precautions in relation to electromagnetic compatibility and must be installed and put into operation in accordance with the EMC information given.



The operating instructions must be kept together with the product so that they are available at all times.



The icon in this manual indicates an action to be taken by the user.

Intended use

Non-invasive recording of the systolic and diastolic blood pressure value at the limbs: left upper arm, right upper arm, left ankle, right ankle. The ankle-brachial index (ABI) that can be determined as a result is used to indicate the presence of peripheral arterial occlusive disease.

Contraindications



The same exclusion criteria apply to the oscillometric ABI measurement as to a Doppler measurement.



The device is not suitable for infants and toddlers.



Do not use the device on patients with severe heart failure.

Important information



Cardiac arrhythmia can impair the measurement accuracy of the device and lead to faulty measurements.



Adverse effects may occur in persons with cardiac pacemakers if they have a weak pulse.



The device is suitable for patients of any age whose upper arm circumference is between 22 and 48 cm and whose ankle circumference is between 18 and 38 cm.



The device was not validated for use in pregnant women.



Do not use the device unattended on unconscious, helpless, or unresponsive persons.



Do not place the cuffs over open wounds, implanted stents, and lymphoedema.



When performing consecutive measurements, wait at least 2 minutes between each measurement.



Make sure that the air tube is not kinked during the reading. The resultant blood congestion could cause injury.



The process of taking blood pressure must not stop the circulation for an unnecessarily long time (more than 2 minutes). In the event of device malfunction, press the Stop button and remove the cuffs from the limbs.



In the case of a patient with limited cognitive ability, the measurement should be performed only under supervision by medical staff.



The long 2 m and 3.5 m cuff tubes present a risk of strangulation.



Excessively frequent readings can impair circulation and consequently lead to injury.

 The cuff must not be fitted over wounds as this could lead to further injury.

 Ensure that the cuffs are not placed on an arm or leg of which the arteries or veins are undergoing or have undergone medical treatment, e.g. a shunt.

 In the case of women who have had a mastectomy, the cuffs should not be placed on the arm on the side from which the breast has been removed.

 Medical devices being used on the same arm at the same time may malfunction.

 Operation in the vicinity of strong electromagnetic fields (e.g. due to radiation devices, mobile phone(s)) can cause malfunction (see EMC information).

 The computer used for the evaluation must meet the requirements according to EN 60601-1.

 If you sell the device, the following must be included:
- User manual for boso ABI-Serie
- User manual for boso profil-manager XD, incl. software

 The device must be set up such that the plug of the power pack is easily accessible.

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

 If the device was exposed to moisture or if liquid got into the device during cleaning/use, no measurements should be performed on the patient.

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

 assembly, extensions, reinstallation, alterations or repairs have been carried out by individuals approved by the manufacturer.

 the device is used in accordance with the manual.

The ankle-brachial index

To determine the ABI value, the systolic blood pressure values of the arms and legs must be measured. Blood pressure readings are expressed in mmHg (mm mercury column).

The ABI value is calculated as the ratio of the systolic pressure of the leg measurement (the averaged pressure of the posterior tibial artery and anterior tibial artery) and the higher systolic pressure of the arm measurements.

Using the device for the first time



Before you start working with boso ABI-Serie devices, install the boso profil-manager XD using the enclosed installation CD-ROM. Please observe the information in the manual of the boso profil-manager XD. The software enables the measured data to be evaluated and managed.

At the back of the device is the connection port for the power pack (Fig. 2 back of the device, connection 2), for the USB connection (Fig. 2 back of the device, connection 1) and the connection plug for the equipotential bonding conductor (Fig. 2 back of the device, connection 3).

If the ABI-Serie device is supplied with operating voltage via the power pack and connected via the USB cable to the computer (on which the boso profil-manager XD software was installed beforehand), the cuffs can be connected according to their colour coding (Fig. 1 front of the device, cuff connections 1) to the front of the device. The tubes of the 4 cuffs as well as the 4 cuff connections on the front of the device are identified with the colours Red (right arm cuff), Yellow (left arm cuff), Black (right ankle cuff) and Green (left ankle cuff).

Use only the bosso power pack (art. no. 410-7-154).

This power pack has been stabilised with regard to output, accurately set, and correctly polarised.

Conventional power packs can damage the electronics and result in loss of the manufacturer's warranty.



To establish equipotential bonding, connect a suitable conductor to the intended equipotential bonding on the device. The requirements of EN 60601-1 on equipotential bonding additionally apply. The equipotential bonding conductor may not be used as a protective conductor connection. A corresponding equipotential bonding conductor is not included in the contents of the package.

Preparation of the ABI measurement



The measurement must take place on a supine patient in order to obtain comparable pressure ratios at the arms and legs. The legs should not be crossed.

Prior to the measurement, the patient must lie quietly for approx. 5 minutes.

Placing the cuffs



The device may be used only with original bosco cuffs CA04, CL04, CA02 or CA03.

Type description		Circumference	Order no.
Upper arm cuff	CA04	22 - 42 cm	143 - 4 - 768
Ankle cuff	CL04	18 - 38 cm	143 - 4 - 769
Upper arm cuff	CA02	32 - 48 cm	143 - 4 - 771
Upper arm cuff	CA03	16 - 22 cm	143 - 4 - 773

Select the correct cuffs according to the arm circumference printed on them. The cuffs are colour-coded. Place the individual cuffs according to their colour coding (analogous to the symbols next to the air connection sockets on the device) on both upper arms and both ankles.

Place the upper arm cuffs such that the lower edge of the cuff is approx. 2-3 cm above the elbow. The cuff must be positioned so that the marking lies on the brachial artery (Fig. 3 / 4).



Never position metal brackets over arteries
→ Risk of incorrect readings

Left arm

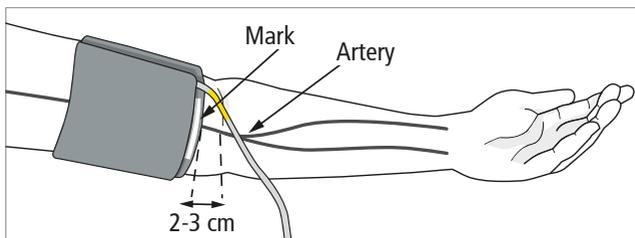
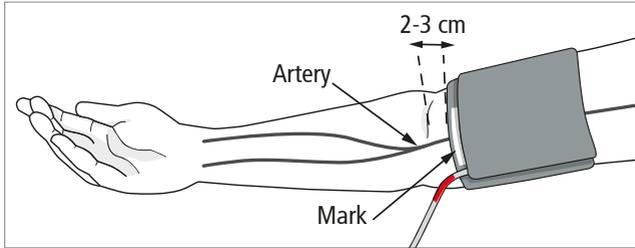


Fig. 3

Right arm

Fig. 4



Place the ankle cuffs such that the lower edge of the cuff is approx. 1-2 cm above the ankle. Position the cuff such that the white mark is on the posterior tibial artery. Ensure that the cuff is fitted tightly on the ankle.

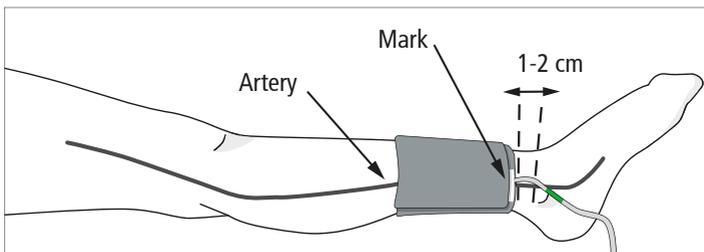


Allocation of cuffs → limbs

The correct allocation of the cuffs to the individual limbs can be checked using an individual measurement on the left or right arm and on the left or right leg.

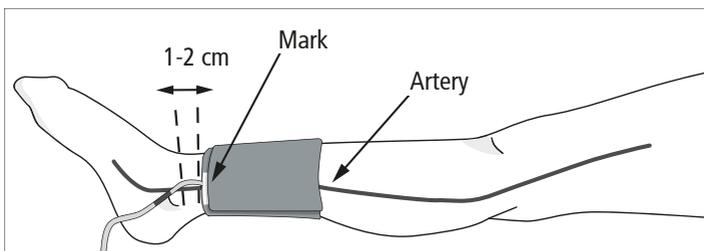
Left foot

Fig. 5



Right foot

Fig. 6



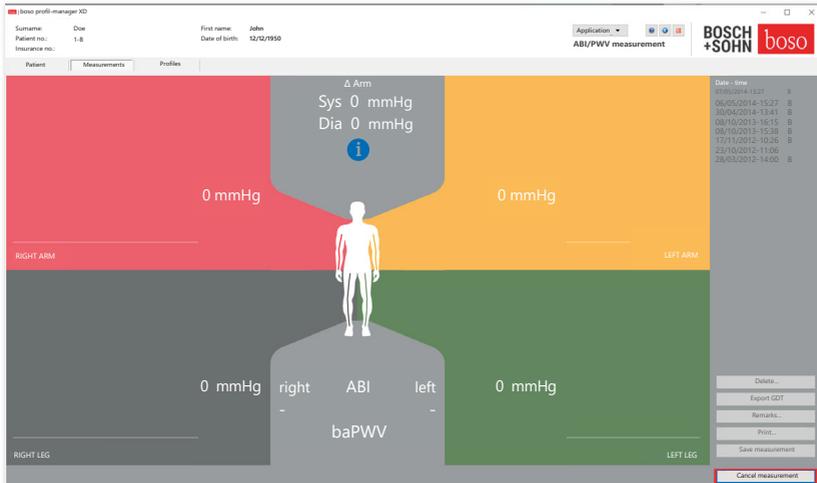
Performing the ABI measurement



A measurement can be discontinued at any time by pressing the “Cancel measurement” button in the software or the STOP button on the device; upon doing so, all cuffs will be automatically deflated. Alternatively, the cuffs can be removed from the limbs at any time.

Screenshot | boso profil-manager XD

Fig. 7



Select “ABI measurement” in the “Measurements” registry. After a brief calibration process (approx. 3 seconds), the ABI system starts the ABI measurement. The device has intelligent automatic inflation for gentle inflation at the right cuff pressure. When the correct inflation pressure has been reached, the pumps switch off and the air in the cuffs is automatically released.



At this point, if not before, the patient must keep all four limbs completely still and may not talk.

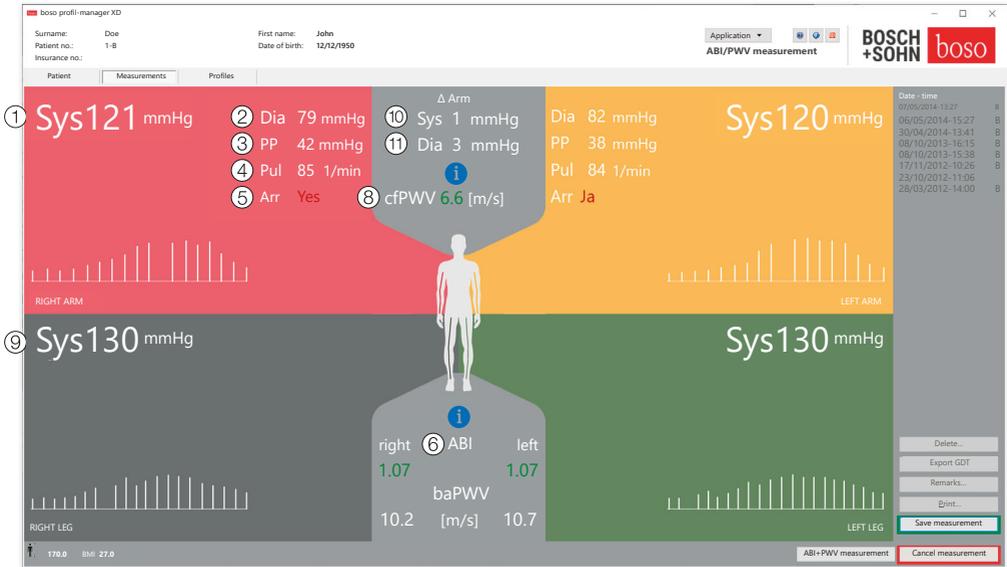
(optional)

Select “ABI+PWV measurement” in the “Measurements” registry or press the START button on the device. After the ABI measurement is completed (and an approx. 10-second pause), the ABI system 100 starts the PWV measurement.

The integrated valves automatically open to rapidly deflate the cuffs once the measurement is complete. The measured values are displayed in the bosco profil-manager XD. Individual remarks can be added for each measurement performed using the "Remarks" button. Remark templates can be defined and saved for later use.

Screenshot | bosco profil-manager XD

Fig. 8



Parameters in Fig. 7 are displayed each for the left and right half of the body.

- ① **Sys** Systolic blood pressure in the upper arm in mmHg
Display in red > 140 mmHg
- ② **Dia** Diastolic blood pressure in the upper arm in mmHg
Display in red > 90 mmHg
- ③ **PP** Pulse pressure in mmHg
Pulse pressure = systole - diastole
Display in red > 54 mmHg

- ④ **Pul** Pulse value in 1/min
- ⑤ **Arr** Arrhythmia:
Indication of whether a pulse irregularity of over 25% is observed during the measurement
Display in red indicates arrhythmia
- ⑥ **ABI** Ankle-brachial index ABI = Ratio of the systolic pressure measured in the leg and the higher systolic pressure measured in the arm. Display in red indicates an ABI < 0.9
- ⑦ **baPWV** Pulse wave velocity at the upper arm-ankle | optional
PWV measured at the upper arm-ankle.
Since there is no exact limit but only a grey area of 14 to 18 m/sec, the baPWV value is shown in neutral white only.
In some cases, the limit value is also determined individually depending on the sex, age and blood pressure of the patient.
- ⑧ **cfPWV** Pulse wave velocity between carotid aorta and femoral aorta | optional
cfPWC* calculated from the baPWV
Display in red ≥ 10 m/s (no display if both ABI values < 0.9)
The patient's height must be entered as this information is needed to calculate PWV.
- ⑨ **Sys** Systolic blood pressure at the ankle in mmHg
- ⑩ **Δ Arm Sys** Diff Arm Sys: Difference between the systolic values of the left and right upper arm in mmHg
Display in red > 10 mmHg
- ⑪ **Δ Arm Dia** Diff Arm Dia: Difference between the diastolic values of the left and right upper arm in mmHg
Display in red > 10 mmHg

* See also: Lortz J, Halfmann L, Burghardt A, Steinmetz M, Radecke T, Ja'nosí RA, et al. (2019): Rapid and automated risk stratification by determination of the aortic stiffness in healthy subjects and subjects with cardiovascular disease. PLoS ONE 14(5): e0216538. <https://doi.org/10.1371/journal.pone.0216538>

Storing the ABI measurement



To store a measurement, click on the “Save measurement” button.



The reading must be repeated if it is obviously incorrect!

Blood pressure is a dynamic parameter and can be influenced by various factors, such as:

- Movement before or during the measurement
- Physical state (stress, illness, etc.)

Performing a repeat ABI/PWV measurement



A gap of at least 2 minutes must be left between 2 consecutive readings.



To perform a repeat measurement, press the “ABI measurement” or “ABI+PWV measurement” button again.



To perform a measurement on only one limb, press the START button next to the corresponding symbol.

To determine the ABI, all measurements must be performed simultaneously.

Remove the cuffs from the patient's limbs if you do not want to perform another measurement.

After use

Cleaning and disinfection



Please use only a soft, dry cloth to clean the device. Small spots on the cuff can be removed using a damp cloth.



Never use solvents, petrol, alcohol or abrasives for cleaning.



Disinfection:

We recommend using Antifect Liquid disinfectant (Schülke & Mayr) to disinfect the device by wiping it, leaving the disinfectant on for at least 5 minutes. We recommend disinfecting the cuff with a spray. Ensure that the cuff is regularly cleaned and disinfected, especially if the device is being used by several patients.

Customer information for returning commercial waste electrical equipment

1) Purpose

Based on the EU directive 2012/19/EU, the German implementation for the Electrical and Electronic Equipment Act (ElektroG) was revised in 2021. The amended ElektroG3 took effect on 01/01/2022. The reason for this is to continuously improve the collection rates of electronic waste and achieve a rate of > 65%. In this document, we provide you with information about the return option we created for your commercial waste electrical equipment.

2) Manufacturer's declaration on the return option

Devices used commercially that are at the end of their service life can be picked up by our return partner (see point 3). To do this, a message should be sent to our return partner or to "BOSCH + SOHN GmbH u. Co. KG", indicating the article and number of items. Then the customer receives an offer from our return partner for the coordinated pick-up at the site where the devices are located. The customer is free to decide on this pick-up or to dispose of the electronic waste using their own disposal system and accordingly fulfil the associated obligations.

3) Commissioned return partner

Commissioned recycler for the company
"BOSCH + SOHN GmbH u. Co. KG" is:

WEEE Return GmbH
Lahnstraße 31
12055 Berlin

Incident reporting obligation

A serious incident is to be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is located.

A “serious incident” denotes an incident which had, could have had, or could have one of the following consequences, directly or indirectly:

Death of a patient, user, or another person; the temporary or permanent serious worsening of the state of health of a patient, user or other persons; a serious risk to public health.

Please send reports of serious incidents to:

Email: vigilanz@boso.de

Fax: +49 (0) 74 77 92 75-56

Warranty, guarantee, customer service

We provide a two-year manufacturer's warranty on this product from the date of purchase. The date of purchase must be shown by the invoice. Defects due to material or manufacturing errors are repaired free of charge within the warranty period. If parts are replaced under warranty, the warranty period is extended only for those parts, not for the entire device.

The warranty does not cover damage due to wear and tear (e.g. of the cuffs), transport damage or any damage caused by incorrect use (e.g. failure to comply with the instructions for use) or by intervention by unauthorised parties.

The warranty does not give you any claim for damages against us. This does not affect the purchaser's right to make a claim on the grounds of defects as set out in section 437 of the German Civil Code.

If you wish to make use of the warranty, you must send the device together with the original receipt to:

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



This device must be maintained by trained and approved staff. The device must not be altered without the manufacturer's consent.

Technical data

Principle of measurement:	Oscillometric
Type designation:	boso ABI-Serie
Measurement range (blood pressure, SYS):	60 to 240 mmHg
Measurement range (blood pressure, DIA):	40 to 140 mmHg
Cuff pressure:	0 to 300 mmHg
Maximum cuff pressure measurement deviation:	± 3 mmHg (max. difference right/ left ± 2 mmHg)
Measurement range (pulse):	30 to 190 pulses/min.
Maximum measurement deviation of the pulse display:	$\pm 5\%$
Maximum measurement deviation of the PWV display:	$\pm 5\%$
Operating conditions:	Ambient temperature +10 to +40°C Rel. air humidity 30 to 85%
Transport/storage conditions:	Ambient temperature -10°C to +60°C Rel. air humidity 15 to 85%
Power supply:	Power pack DC 5 V, 3.0 A, AC 100-240 V, 50-60 Hz, order no.: 410-7-154
Weight:	3.34 kg without power pack

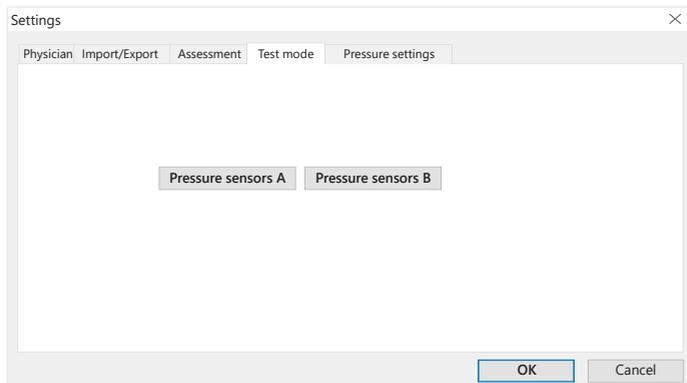
Dimensions (W x H x D):	460 mm x 83 mm x 290 mm
Classification:	Protective class II (symbol: ) Type BF (symbol: )
Clinical test (DIN 58130):	Accuracy of measurement complies with the requirements of EN 1060 part 3

Metrology test instructions

A) Function test

Function tests of the device can only be performed on a human subject or a suitable simulator.

B) Test of pressure circuit tightness and pressure display deviation:



- 1.) The test mode is activated using the "Pressure sensors A" or "Pressure sensors B" button in the "Test mode" sub-registry.

- 2.) After a brief calibration, the device is in test mode.
The current pressure is displayed in the corresponding fields of the bosso profil-manager XD.
- 3.) Carry out the pressure display deviation test and pressure circuit tightness test in the usual way, taking care to ensure that the cuff set-up time is at least 30 seconds.
Maximum difference of the pressure display right - left ± 2 mmHg.
- 4.) Perform test for all 4 extremities.
- 5.) End test by pressing the "Finish test" button.



"Pressure sensors B" can be activated only in the case of serial number 46620000 or higher or 47300000 or higher.

C) Safeguard

As a safeguard, the upper and lower parts of the housing were joined with a safety seal by the manufacturer. The unauthorised destruction of this safety seal renders the warranty invalid.

(optional) Special simulators are needed to perform functional tests of the device with the "PWV" option and these tests can only be carried out on the manufacturer's premises.

EMC information boso ABI-Serie

Medical electrical devices are subject to special precautions in relation to EMC and must be installed and put into operation in accordance with the guidelines listed below.

Portable and mobile HF equipment (e.g. mobile telephones) can affect medical electrical devices. The use of third-party accessories (not boso original parts) can lead to increased emission or reduced immunity of the device.

Guidelines and manufacturer's declaration - electromagnetic emission

The boso ABI-Serie devices are intended to be operated in the electromagnetic environment indicated below. The customer or user of a boso ABI-Serie device should ensure that it is used in such an environment.

Emission measurements	Compliance	Electromagnetic environment guidelines
HF emissions according to CISPR 11	Group 1	Devices of the boso ABI series use HF energy exclusively for their internal function. This means that the HF emissions are very low, and it is very unlikely that adjacent electronic devices would suffer interference.
HF emissions according to CISPR 11	Class B	Devices of the boso ABI series are intended for use in all facilities, including residential areas and areas which are connected directly to a public grid which also supplies buildings used for residential purposes.
Harmonic emissions according to IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker in accordance with IEC 61000-3-3	met	

Guidelines and manufacturer's declaration – electromagnetic immunity

The boso ABI-Serie devices are intended to be operated in the electromagnetic environment indicated below. The customer or user of a boso ABI-Serie device should ensure that it is used in such an environment.

Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment – Guidelines
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	Floors should have wood/concrete/ceramic tiles. If the flooring material is synthetic, the relative humidity must be at least 30%.
Electrical fast transient/ burst according to IEC 61000-4-4 (100 kHz)	± 2 kV power cables ± 1 kV for input and output cables	± 2 kV power cables ± 1 kV for input and output cables	Floors should have wood/concrete/ceramic tiles. If the flooring material is synthetic, the relative humidity must be at least 30%.
Surges according to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode voltage	
Voltage dips, brief interruptions and fluctuations in the supply voltage according to IEC 61000-4-11.	Test level - % Uref A/A 30 A/A 100 A/A 100 C/C 100	Duration s / phase ° 0.50 (0) 0.01 (0, 45, 90, 135, 180, 225, 270, 315) 0.02 (0) 5.00 (0)	The quality of the supply voltage should correspond to that of a typical business or hospital environment. If the user of a boso ABI-Serie device requires continued function even if interruptions in the power supply occur, it is recommended to power the boso ABI-Serie device from an uninterruptible power supply.
Magnetic field at the supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	30 A/m	30 A/m	

Guidelines and manufacturer's declaration - electromagnetic emission

The bosco ABI-Serie devices are intended to be operated in the electromagnetic environment indicated below. The customer or user of the bosco ABI-Serie device should ensure that it is used in such an environment.

Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment – Guidelines Recommended safety distance
Conducted HF interference radiation according to IEC 61000-4-6, ISM & amateur radio band ($6V_{\text{eff}}$)	$3 V_{\text{eff}}/m$ ISM: 0.15 MHz - 80 MHz Radio: 0.15 MHz - 80 MHz	$3 V_{\text{eff}}/m$ ISM: 0.15 MHz - 80 MHz Radio: 0.15 MHz - 80 MHz	Portable and mobile radio equipment is not used at a distance away from the bosco ABI-Serie device, including the cables, that is less than the recommended safety distance which is calculated according to the equation applicable to the transmission frequency: $d = 1.2 \sqrt{P^7}$
Spot frequencies: 380 MHz - 5800 MHz	$6 V_{\text{eff}}/m$	$6 V_{\text{eff}}/m$	
HF radiated interference in accordance with IEC 61000-4-3	$3 V_{\text{eff}}/m$ 150 kHz - 80 MHz	$3 V_{\text{eff}}/m$ 150 kHz - 80 MHz	$d = 1.2 \sqrt{P^7}$ for 80 MHz - 800 MHz where P is the nominal output of the transmitter in watts (W) according to information provided by the manufacturer of the transmitter and d is the recommended safety distance in metres (m). At all frequencies, the field strength of stationary radio transmitters is less than the compliance level ^b according to on-site testing ^c . Interference is possible in the vicinity of devices with this symbol. 

COMMENT 1: The higher value applies at 80 MHz and 800 MHz.

COMMENT 2: These guidelines may not be applicable in all situations. Electromagnetic waves are affected by absorption and reflection from buildings, objects and people.

^aThe field strength of stationary transmitters, such as base stations for radio telephones and land mobile services, amateur stations, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To determine the electromagnetic environment due to stationary HF transmitters, a site investigation is recommended. If the field strength determined at the site of the bosco ABI-Serie device exceeds the compliance level indicated above, the bosco ABI-Serie device must be observed at every place of use with regard to its normal operation. If abnormal performance is observed, additional measures may be necessary, such as the reorientation or implementation of the bosco ABI-Serie device. ^b Field strength <3 V/m at 150 kHz to 80 MHz.

Recommended safety distances between portable and mobile HF communication devices and the bosco ABI-Serie devices.

The bosco ABI-Serie is intended to be operated in an electromagnetic environment in which radiated HF disturbances are controlled. The customer or the user of a bosco ABI-Serie device can help prevent electromagnetic interferences by maintaining minimum distances between portable and mobile HF communication devices (transmitters) and the bosco ABI-Serie devices, as recommended below in accordance with the maximum output power of the communication device.

Rated output of the transmitter / W	Safety distance according to transmission frequency/m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P^7}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P^7}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P^7}$
0.01	0.12	0.12	0.23
0.1	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 nominal output is not stated in the table above, the distance can be determined by using the equation for the relevant column, where P is the nominal output of the transmitter in watts (W) according to the manufacturer of the transmitter.

COMMENT 1: To calculate the recommended safety distance of transmitters in the frequency range of 80 MHz to 2.5 GHz, an additional factor of 10/3 was used to reduce the likelihood of a mobile/portable communication device accidentally brought into the patient area leading to interference.

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

