boso TM-2430 PC2

EN Instruction manual

boso
BOSCH + SOHN
GERMANY

Table of contents

Contents of package

24-hour blood pressure
measuring device
TM-2430 PC2

Case

Battery
charger

Two sets of batteries, with three batteries
per set
(one set is already inserted in the device)

Cuff for adults
(standard CA11/washable)

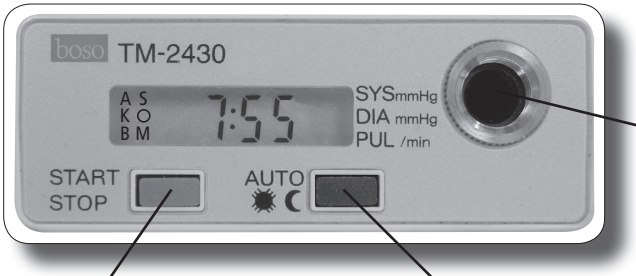
Hip bag with
detachable straps
and belt

Instruction manual for:
TM-2430 PC2
battery charger
profile manager

One boso profile manager
CD-ROM

USB cable
(serial interface types are also available)

Overview of the device



Symbols on the blood pressure monitor

START STOP 	START/STOP button
AUTO 	AUTO button (DAY/NIGHT button)
A	Automatic mode active
S	Sleep mode active
K	Irrelevant
O	Irrelevant
B	Battery flat (no more readings can be taken and no more data can be transferred)
M	Memory full, 350 readings (no more readings can be taken)
SN	Serial number
	Year of manufacture
	Protect against liquids
CE 0124	Device complies with the European Medical Devices Directive.
	Device must not be discarded with household waste.
	Defibrillation-protected BF device
	Manufacturer
	Read instructions for use

Display screen

Systolic blood pressure

Time

Diastolic blood pressure

Error message

Pulse

Introduction

Dear customer,
Thank you for purchasing this boso blood pressure measuring device. The boso brand offers optimum quality and accuracy. 96% of all German general practitioners, physicians and internists work in practice with blood pressure instruments from boso (API survey conducted by GfK 01/2016). This device has undergone our strict quality control procedures and will be a reliable partner in monitoring your patients' blood pressure.

⚠ Please read this manual carefully before using the device for the first time, because blood pressure readings can only be taken properly if the device is used correctly.
The " " symbol in this manual indicates action to be taken by the user.

Please contact your specialist supplier or the manufacturer for help in preparing for first use, using the device or maintenance (contact details are given on the inside back cover of this manual).

If you sell the device, please include this manual.

This blood pressure measuring device complies with European requirements that are set out in the German Medical Device Act (mark: CE 0124) and with the International Standard IEC 80601-2-30 : "Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers".

Metrology tests (see page 28) must be conducted at regular intervals when the device is used in a medical context.

Purpose

Non-invasive recording of systolic and diastolic blood pressure and pulse frequency in humans over a period of typically 24 hours.

Area of use and safety instructions

The boso TM-2430 PC2 blood pressure measuring device operates according to the oscillometric principle of measurement. The device is used to take readings over a 24-hour period. It is suitable for use both in hospitals and in community medicine. It is not suitable for use on young children, infants or on unconscious patients without supervision.

N.B.

⚠ Do not allow the air tube to be compressed or its diameter to be reduced.

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

⚠ The cuff must not be placed on top of wounds, as this could lead to further injuries.

⚠ Ensure that the cuff is not placed on an arm 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, do not place the cuff on the arm on the side on which the operation took place.

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

⚠ The device is not protected against the possible effects of high-frequency (HF) surgical devices.

Safety instructions

⚠ If any liquid has been spilt on the device, immediately remove the batteries and send the device to the customer service department (see page 25 for the address) for inspection.

⚠ Only use the batteries contained in the pack which you received.

⚠ Check the batteries for damage. Never use damaged batteries.

- There is no known risk due to defibrillator discharge.
- Medical electrical devices are subject to particular precautions in relation to electromagnetic compatibility, and must be installed and used in accordance with the EMC information given on pages 30 and 31.

⚠ Notify the manufacturer immediately of any unexpected operational status or any event which has or could have caused damage to health.

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

- Assembly, extension, resetting, alterations or repairs have been carried out by individuals approved by the manufacturer.
- The device is used in accordance with the manual.

⚠ This device must be maintained by trained and approved staff.

⚠ 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.

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

Before first use

You should charge the batteries supplied with the device before starting to use the boso TM-2430 PC2. Follow the instructions given on pages 18 and 19 (replacing and charging batteries). Then install the boso profile manager. This software will allow you to programme the blood pressure measuring device and assess stored data.

Selecting the cuff and connecting it to the TM-2430 PC2

Selecting the cuff

Only use genuine CA11, CA12 and CA13 cuffs.

Select the correct cuff for the arm circumference printed on it.

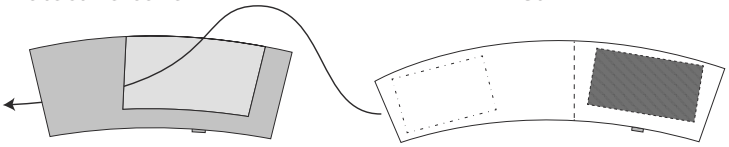
Connecting the cuff

Screw the air connection plug of the cuff tube directly into the air connection socket of the blood pressure measuring device (see figure 1).

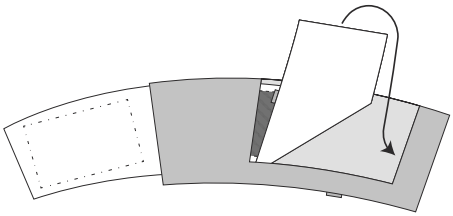
Fitting protective covers (optional)

If necessary you can also use protective covers to prevent soiling (see accessories on page 26). Apply the protective covers as described below:

Protective cover *Cuff*



Pull the cuff through the loop in the protective cover



Attach the protective cover to the cuff by means of the Velcro fasteners.

Care instructions for protective covers: machine wash, maximum temperature 60°C

Fitting the cuff

Place the cuff on the bare upper arm so that the yellow marking is lying over the Arteria brachialis. Most people have higher blood pressure in the left arm, which is why blood pressure is measured in the left arm. However, in individuals who have higher blood pressure in the right arm, readings should be taken on the right arm.
The cuff should be placed about 2-3 cm above the elbow. It must not be too tight; you should still be able to fit a couple of fingers between the arm and the cuff.

⚠ It is important that the cuff does not interfere with circulation once the reading has been taken. Place the cuff tube over the shoulder (see figure 1) and tape it to the shoulder. The blood pressure measuring device is carried in the bag, which is supported either by a belt which the patient is wearing or by the straps supplied.

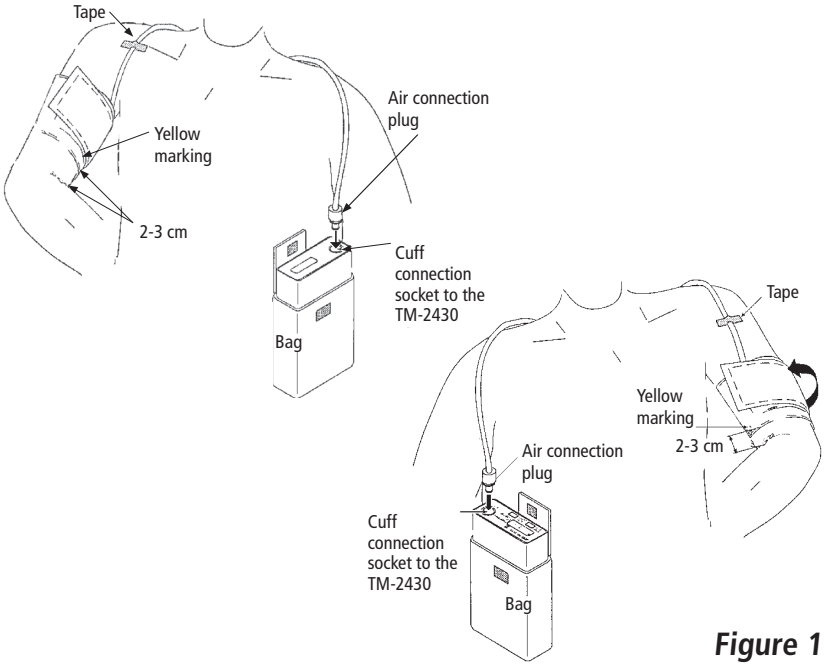


Figure 1

Once the cuff has been correctly fitted, a test reading can be taken with the boso TM-2430 PC2 using the START/STOP button (the result will only be displayed if the device has been programmed accordingly). If this reading is successful, automatic interval control (see below) can be started. The test reading will be assessed along with the other readings.

⚠ **Please note** that the oscillometric method of measuring blood pressure can give inaccurate results in some types of patients. Individuals with cardiac dysrhythmia, arteriosclerosis, circulation disorders or diabetes, or who have a pacemaker, should undergo a comparative reading with an auscultatory device before you start to take readings. The same applies to pregnant women.

External disturbances, e.g. movements of the measuring arm, disturbing vibrations e.g. driving by car or the use of public transport during the measurement can lead to incorrect measurements.

For this reason, the protocol recorded by the patient has to be examined and included in the assessment.

Starting automatic interval control

To start automatic interval control, hold the black button down until the letter "A" appears on the display screen of the blood pressure measuring device and a brief audible signal is emitted (after about 5 seconds) to indicate that the button has been held down for long enough.

When the device is being used in sleep mode, the patient must press the black button before going to sleep. An "S" for sleep appears on the display screen next to "A" for automatic. The patient must press the black button again after getting up, and the "S" on the display screen then disappears.

Automatic inflation pressure adjustment
(only in automatic interval control mode)

For the first five readings in automatic interval control mode, the boso TM-2430 PC2 inflates to approximately 185 mmHg. From the 6th reading onwards, the inflation pressure is adjusted according to the last systolic results. From the 6th reading onwards in automatic interval control mode, the inflation pressure is approximately 40 mmHg above the weighted average of the most recently measured systoles (the most recent systole has a higher weighting).
If this inflation pressure is not sufficient, the device automatically reinflates to approximately 60 mmHg above the original inflation pressure.

Maximum inflation pressure restriction

The boso TM-2430 PC2 has the ability to restrict the inflation pressure. See the boso profile manager manual for details of how to do this.

Taking a manual reading

Patients can start a manual reading in addition to the automatic readings at any time. This can be useful if a patient has been exposed to physical or mental strain, for example. This is done by pressing the START/STOP button.

⚠ Interrupting readings

To interrupt a reading, press the START/STOP button on the TM-2430 PC2. If you wish to restart the reading subsequently, press the START/ STOP button at any time to start a manual reading.

Finishing a reading and transferring results

You must switch off automatic interval control as soon as the patient has handed in the device after a 24-hour reading has been taken. Hold the black button down until the "A" on the display screen of the blood pressure measuring device has disappeared (about 5 seconds).

Then connect the TM-2430 PC2 to the computer via the PC connection cable. Transfer the data according to the instructions in the boso profile manager. You are strongly advised to empty the results memory once the results have been transferred.

Replacing batteries

We recommend that the set of batteries in the device should be replaced by a freshly charged set once a 24-hour reading has been completed.
To avoid data loss, the data stored in the boso TM-2430 PC2 is buffered by means of an internal battery, which is automatically charged by the external batteries. A fully-charged internal battery stores data for approximately 10 days. To charge the internal battery fully before using the device for the first time, keep the device switched on for approximately 24 hours with fully charged external batteries.
Replace the batteries as follows (see figure 2):

Open the internal battery compartment cover
Switch off the device
Remove the flat batteries and insert charged batteries, taking care to respect polarity
Switch on the device
Close the internal battery compartment cover

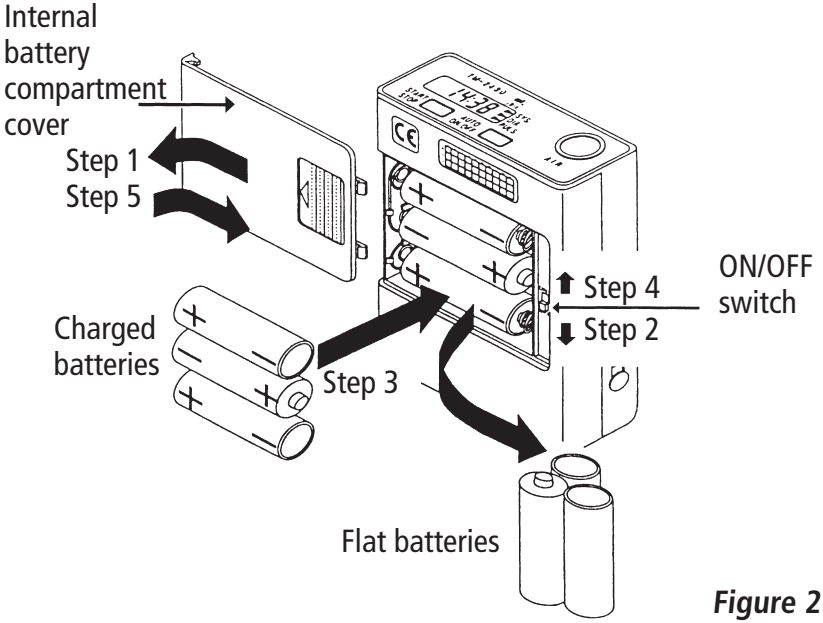


Figure 2

Charging batteries

Place the batteries in the charger and then plug it in. Once the green LED lights up, the batteries are being charged. Completely flat batteries take around 42 hours to charge. According to the battery charger manual, it will normally take only around 10 hours to charge batteries that have been used to perform a 24-hour reading.

⚠ Important information on battery charging

In order to ensure that the TM-2430 PC2 functions properly over a 24-hour period, only use batteries with the following rated properties: min. 1500 mAh; 1.2 V; NiMH.
In addition to the three external batteries required for power supply, the TM-2430 PC2 also has an internal battery to protect the results and programme settings within the device.

Follow the instructions given below to prevent the error code E00 appearing (see page 20). This code appears on the display screen of the TM-2430 PC2 when the internal battery is flat:

- Insert charged batteries in the device even when it is not in use. Leave the ON/OFF switch in the ON position whenever charged batteries are in the device. This keeps the internal battery charged at all times. If the switch is set to the OFF position, the power supply to the internal battery is interrupted and the settings of the TM-2430 PC2 will be lost after approximately 10 days.
- Please replace the batteries in the device with a set of freshly charged batteries before fitting the device to a patient.

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

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

Charging batteries

If the device is not used for an extended period (4 weeks or more), set the switch in the internal battery compartment to OFF and remove the external batteries in order to prevent any damage that may be caused by leakage.
The internal battery will need to be recharged and the device will need to be reprogrammed before the device can be used on a patient.

Insert freshly charged batteries.
Set the switch in the internal battery compartment to ON and leave the TM-2430 PC2 switched on for at least 2 hours. The internal battery will recharge during this time.
Reprogramme the device.
Replace the batteries with a set of freshly charged batteries before fitting the device to a patient.

Error messages

Error code	Cause	Solution
E00	Device not programmed	Reprogramme device
E03 E90	Zero point cannot be aligned	Deflate cuff completely
E04	Batteries flat	Charge or replace batteries
E05	Leak	Remove cuff from device and reconnect. Contact your distributor if the error occurs repeatedly.
E06	Pressure above 320 mmHg	The arm must be kept still while the reading is being taken.
E07	Operator has interrupted the reading using the START/STOP button	
E08 E10	No oscillations, or no measurable oscillations. Maximum pressure has been set too low.	The arm must be kept still while the reading is being taken. Select higher maximum pressure.

Error messages

E20	Pulse < 30 or >200	Check position and fit of cuff
E21 E22	No measurable oscillations in the diastolic (E21) or systolic (E22) range	
E23	Difference between systolic and diastolic readings < 10 or > 150 mmHg	
E30	Reading takes longer than 120 seconds to perform	Contact your distributor.
E31	Deflation takes more than 60 seconds	Contact your distributor.
E32	Programme error	Switch off device and restart.
E50	Offset error	Contact your distributor.
E52	Memory error	Contact your distributor.

Error messages

Error code	Cause	Solution
E53	No contact with batteries	Remove batteries, check contacts and clean if necessary, replace batteries. Contact your distributor if the error occurs again.
E55 E56 E57	Deflation error	Contact your distributor.
E70 E71 E72 E73	Data transfer error	Check the connection to the PC. Contact your distributor if the error occurs repeatedly.

Cleaning and disinfection

Please use a soft cloth, moistened in soapy water if necessary, to clean the boso TM-2430 PC2 and the cuff. Protective covers should be machine-washed at up to 60° C.

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

Disinfection:
For disinfectant wipes (at least 5 minutes exposure time) of the device and the cuff, we recommend the disinfectant liquid Antifect Liquid disinfectant (Schülke&Mayr). To disinfect the the cuff, we recommend spray disinfection. Ensure that the cuff is regularly cleaned and disinfected, especially if the device is being used by several patients.

Disposal instructions

Used internal and external batteries must not be discarded in household waste. You can take them to a collection point for used batteries or dispose of them in specialist waste disposal facilities. Please contact your local council for more information.
This device is covered by the scope of EC Directive 2002/96/ EG (WEEE). It cannot be disposed of via local authority waste disposal facilities for used electrical equipment. boso has approved a company which will dispose of this device in accordance with the law. See the back cover of this manual for the address to contact for more information.
Do not throw the packaging material away, send it for recycling.

Warranty Conditions / customer service

We give 2 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.

⚠ This device must be maintained by trained and approved staff. Do not modify this equipment without authorization of the manufacturer.

Accessories

⚠ Please only use the accessories recommended by the manufacturer.

Cuffs

Adults (normal)	CA11	22 - 32 cm	257-4-400
Adults (large arms)	CA12	32 - 45 cm	257-4-410
Children	CA13	16 - 22 cm	257-4-420

Protective covers (10)

Normal	256-7-400
Large arms	256-7-410
Children	256-7-420
5 normal and 5 large arms	256-7-405

Other accessories

Charger	535-7-120
NiMh batteries (3, AA)	535-7-125
Hip bag with straps	515-7-110

Technical data

Product:	Blood pressure measuring device for 24-hour readings
Type designation:	boso-TM-2430 PC2
Rated voltage:	3 x 1,2 V DC
Power supply:	3x NiMh batteries (AA)
Measurement range:	40 – 280 mmHg 30 – 200 Puls/min
Maximum deviation of cuff pressure measurement:	± 3 mmHg or 2% of the reading (whichever is greater)
Maximum deviation of pulse rate display:	± 5%
Results storage:	350 results
Operating conditions:	+10°C to +40°C <85% relative humidity (non condensing)
Storage conditions:	–20°C to +55°C 10-95% relative humidity
Weight:	155 grams without batteries
Dimensions (W x H x D):	72 mm x 27 mm x 100 mm

Technical data

Typical battery life:	1,000 charging cycles (depending on inflation pressure and frequency of use)
Anticipated life of the device:	10 years
Anticipated life of cuffs:	10.000 readings
Protection against foreign bodies and water:	IP 20 / IP 22 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. Without hip bag this device is not protected against water (IP 20). This device is protected in the hip bag against falling dripping water when the housing is tilted up to 15° (IP 22).
Clinical test:	Accuracy complies with the requirements of ISO 81060-2

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

Switch off the boso TM-2430 PC2 using the ON/OFF switch. Then set up the test as shown in figure 3. Hold the START/STOP button down and switch the device on again. The START/STOP button must be held down until a flashing "0" appears in the display screen of the TM-2430 PC2. Wait until the «0» in the display screen has stopped flashing. Then 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. To return to measurement mode on completion of the test, the START/STOP button must be held down for about 3 to 4 seconds (an audible signal will indicate when the button has been held down for long enough). The device then counts down from 10 to 0 and is then in measuring mode (time is displayed).

C) Correct orientation

The upper and lower halves of the casing are connected by an orientation mark to make sure that they are correctly oriented.

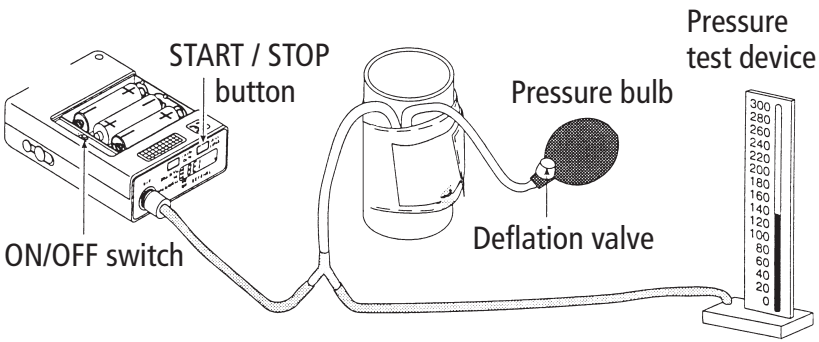


Figure 3

boso EMC notes

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according the EMC information provided in the following.

Portable and mobile RF communication equipment (e.g. cell phones) can affect Medical Electrical Equipment.

The use of accessories and cables other than those specified (other than boso original parts) may result in increased emissions or decreased immunity of the unit.

Guidance and manufacturer's declaration – electromagnetic emissions		
The boso unit is intended for use in the electromagnetic environment specified below. The customer of the user of the boso unit should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The boso unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The boso unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	n.a.	
Voltage fluctuations/flicker emissions IEC 61000-3-3		

Guidance and manufacturer's declaration – electromagnetic immunity			
The boso unit is intended for use in the electromagnetic environment specified below. The customer or the user of the boso unit should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	n.a.	
Surge IEC 61000-4-5	± 1 kV differential mode ±2 kV common mode	n.a.	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 s	n.a.	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	
NOTE : U_T is the a.c. mains voltage prior to application of the test level.			

EMC notes

Guidance and manufacturer's declaration – electromagnetic immunity			
The boso unit is intended for use in the electromagnetic environment specified below. The customer or the user of the boso unit should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any party of the boso unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	$d = 1,2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the boso unit is used exceeds the applicable RF compliance level above, the boso unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such als re-orienting or relocating the boso unit.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the boso unit			
The boso unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the boso unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the boso unit as recommended below, according the the maximum output power of the communications equipment.			
Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter 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
0,1	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 transmitter rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according the the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

CE 0124

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