

Instructions for use boso TM-2430 PC2



THE MODERN, RELIABLE HEALTH CHECK

boso
BOSCH + SOHN
GERMANY

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Preliminary information

You have selected the bosco TM-2430 PC2 sphygmomanometer, a 24-hour computer controlled blood pressure recorder using state-of-the-art technology. The unit has been specially developed for round-the-clock monitoring and operates on the oscillographic principle. The pressure variations (oscillations) resulting from the pulse waves and transmitted by the cuff are stored and evaluated by a microprocessor. The major advantage of this method is that no microphone is required. Normally, the reliability of a blood pressure measurement is strongly dependent on the accuracy with which the microphone is positioned when the cuff is put into place.

This sphygmomanometer complies with the European directives underlying the guidelines for medical products (CE symbol), as well as the European Standard EN 1060 Part 1: 'Non-invasive Sphygmomanometers - General Requirements' and Part 3: 'Supplementary Requirements governing electronic blood pressure measurement systems'.

The technical testing procedures - to be carried out at least every 2 years - can be performed either by the manufacturer or by an authorized service agent in accordance with the directives regulating the manufacturers of medical products.

The technical testing procedures are detailed on page 18 of these instructions.

Area of application

The bosco TM-2430 PC2 sphygmomanometer works on the oscillometric principle and is used in 24-hour monitoring of blood pressure. It is suitable for use in both hospitals and in private practices. The unit is not suitable for use on infants and newborns.

Important information

- Compression, pinching or a reduction in the cross-section of the air tube must be avoided.
- The unit is not equipped with protection against high frequency (HF) surgical equipment.
- Risks arising from defibrillator discharge according to the European standard EN 60 601-2-30 are not known.
- If liquid is spilled on the unit, the storage batteries must be removed immediately and the unit sent to the customer service for inspection (see p. 11 for address).

The manufacturer is only then responsible for faults relating to the safety, reliability and performance of the unit if:

- assembly, expansion, resetting, alterations or repairs have been carried out by persons authorized by him, and
- the unit has been operated in accordance with the instructions for use.

Equipment and documentation supplied

- 24-hour sphygmomanometer TM-2430 PC2
- Carrying case
- Battery charger unit
- Two sets of storage batteries of three batteries per set
- Adult-sized cuff (standard)
- Hip pocket with removable carrying strap
- Operating instructions for:
 - TM-2430 PC2
 - Battery charger unit
 - profile manager
- A CD-ROM bosso profile manager
- PC connection cable

Setting up the bosso TM-2430 PC2

Before you begin working with the bosso TM-2430 PC2, you should install the bosso profile manager. This software enables the unit to be programmed and the data recorded to be evaluated.

Important notes:

Please use only storage batteries with 2100mAh, 1.2V, NiMH in order to make sure that the TM-2430 PC2 is working properly for 24 hours.

In addition to the three storage batteries which ensure the power supply, the TM-2430 PC2 has an internal battery for the storage of measurements and settings.

For a smooth handling, please proceed as follows:

In order to avoid error code E00 (see page 14 of the instruction manual), which appears as soon as the internal battery is empty, please

1. insert charged storage batteries even if the unit is not used.
2. keep the ON/OFF switch in ON position while charged storage batteries are inserted. This ensures that the internal battery is kept fully loaded.

If the switch is in OFF position, the power supply of the internal battery is interrupted and the settings will be lost after approx. 10 days.

3. before applying the unit, please use a set of recently charged storage batteries.

If the unit is not used for a longer period of 4 weeks or more, the switch in the battery compartment has to be in OFF position. Remove the storage batteries in order to avoid damages caused by leakage.

Before applying the unit again, please recharge the internal battery as follows:

1. insert recently charged storage batteries.
2. the switch in the battery compartment has to be in ON position. Leave the TM-2430 PC2 switched on for approx. 12 hours. The internal battery will be recharged.
3. before applying the unit, please use a set of recently charged storage batteries.

Programming the measuring mode, duration and interval



Start the evaluation software. On the start screen, select *TM-2430 PC*. Connect the sphygmomanometer via the PC connection cable to the computer. For programming use 'Initialize Unit' or 'Programming TM-2430 PC'. The programming window now appears. There are three modes available:

- Standard periods / intervals
- Sleep button
- Programmable periods / intervals

1. Standard periods / intervals

In this mode, the unit records in the period from 07:00 until 22:00 hours every fifteen minutes and from 22:00 until 07:00 every thirty minutes (in accordance with the recommendations of the German League for Combating High Blood Pressure).

2. Sleep button

By pushing the button [ ] on the TM-2430 PC2 in this mode, the patient has the possibility of deciding for himself just when the night and daytime periods should begin. The advantage of this programming mode is that the measurement intervals can be adjusted to suit the needs of the individual patient. The measurement interval is fifteen minutes during the day period and thirty minutes during the night period.

3. Programmable periods / intervals

In this mode two freely programmable intervals and periods can be set.

The clock time and the date can be taken directly from the PC. When the automatic interval control is deactivated, the measurement readings are displayed after each measurement.

When the automatic interval control is active, it is, however possible to suppress the display of the readings on the unit. To do this, remove the marker in the corresponding button.

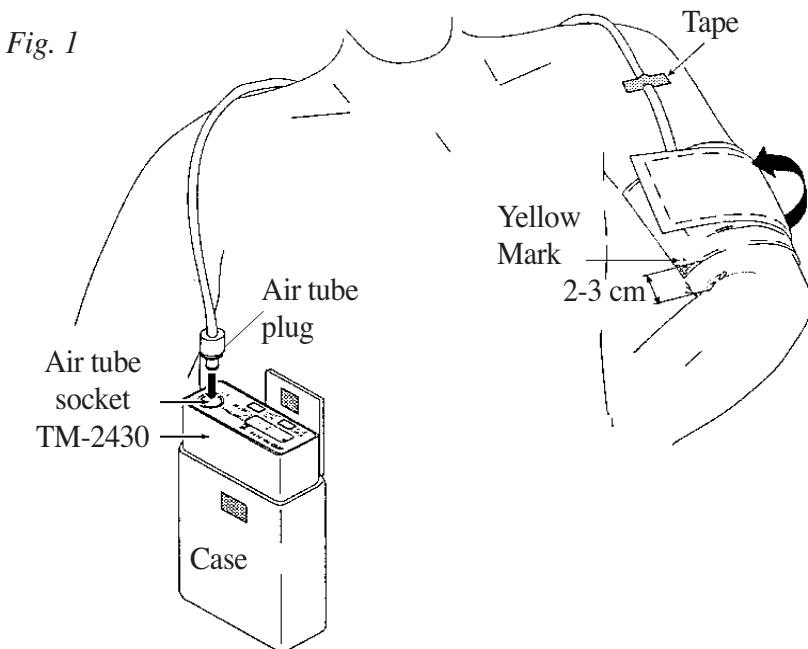
Once programming is complete, separate the boso TM-2430 PC2 from the PC connection cable.

Connecting the cuff

The air connection plug of the cuff's air tube is screwed directly onto the air connection socket (see Fig. 1).

How to wear the cuff

Place the cuff onto your bare upper arm so that the yellow mark lies over the brachial artery. Most persons have a higher blood pressure on their left arm. Therefore the measurement should be taken on the left arm. If the blood pressure is higher on the right arm, the measurement should be taken on the right arm. The cuff should be positioned about 2-3 cm above the elbow. The cuff must not sit too tightly, two fingers should still be able to pass between the cuff and the arm. Blood circulation must not be impeded by the cuff. Pass the cuff's air tube over the shoulder, behind the neck and then fasten the tube to the shoulder with a piece of tape (see Fig. 1). The sphygmomanometer can be worn suspended from a belt in its case or carried by the strap provided.






Measuring with the boso TM-2430 PC2


Once the cuff has been correctly positioned a trial measurement with the TM-2430 PC2 can be performed by pressing the START/STOP button. If this measurement is successful, the automatic interval control (see below) can be activated. The trial measurement is included in the data evaluation.

Please note that the oscillometric method of blood pressure measurement can lead to measurement uncertainties in certain types of patient. For those suffering from cardiac dysrhythmia (heart rhythm disturbance), arteriosclerosis, circulatory disturbance, diabetes or for those with a cardiac pacemaker, a comparative measurement with an auscultatory device should be performed. This also applies to women during pregnancy.

Activating the automatic interval control

To begin recording automatically, the  button must be pressed. The button should remain depressed until an 'A' appears in the unit's display and the audible acknowledgement signal is heard (after about three seconds).

If the unit is being operated in the 'sleep' mode, the patient must push the  button before going to bed. In addition to the 'A' for automatic, the display now shows an 'S' for sleep mode. After getting up, the  button must be pushed again. The 'S' in the display disappears.

Once the unit is removed by the patient following a successful 24-hour measurement period, the automatic interval control must be deactivated. This is accomplished by keeping the  button pressed down long enough for the 'A' in the unit's display to extinguish (about three seconds).

Cancelling a measurement

To cancel measurements, the START/STOP button on the TM-2430 PC2 must be pushed. If the measurement is to be performed at a later time, a manual measurement can be initiated via the START/STOP button at any time.

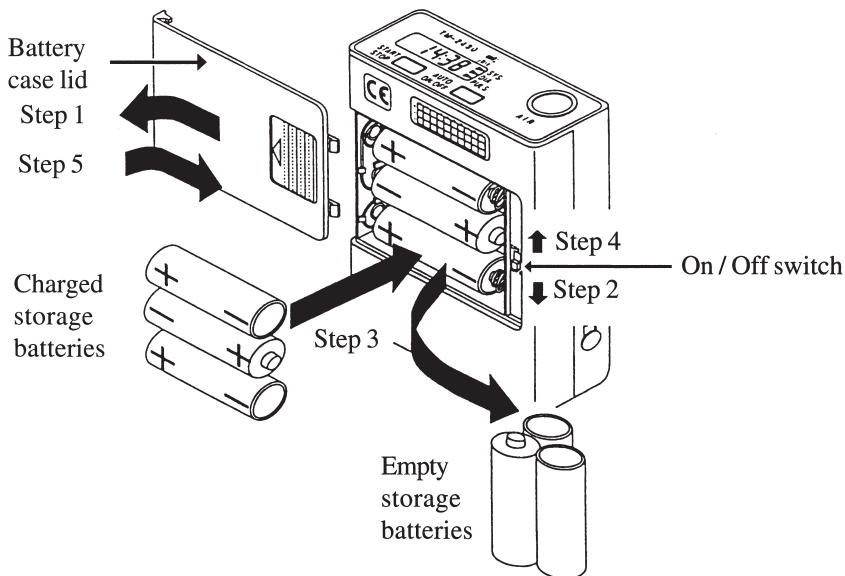
Replacing the storage batteries

To avoid loss of data, the storage locations in the TM-2430 PC2 are buffered.

To replace the storage batteries, proceed as follows (see Fig. 2):

1. Take off the battery case lid.
2. **Turn off the unit.**
3. Remove the empty storage batteries and replace with the new charged set (pay attention to the polarity!)
4. Switch on the unit.
5. Replace the battery case lid.

Fig. 2



Recharging the storage batteries

For information on how to recharge the storage batteries, please refer to the operating instructions of the charger unit supplied.

Use the two sets of storage batteries in alternation. Use each set of batteries for one series of measurements only.

Please help to keep the environment safe!

Empty batteries and storage batteries should not be thrown away with household waste. They can be handed in at a battery collection point or disposed of as special waste.

Please contact your local authority for details.

Guarantee and customer service information

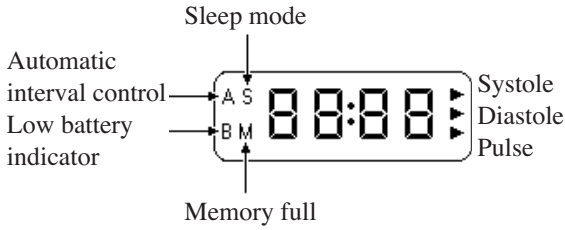
Under the terms of guarantee specified, we provide a two-year guarantee on this equipment. Accessories which are subject to normal wear and tear (e.g. cuffs), are excluded from the guarantee. For details of the conditions of guarantee, please refer to the guarantee card supplied.

A guarantee claim can only be accepted if the card, which has been filled in and bears the stamp of the place of purchase, is sent in together with the unit.

For both guarantee and repair works, please send the equipment carefully packed and postage paid to you dealer or to:

BOSCH + SOHN GMBH U. CO. KG
Fabrik mediz. Apparate
Bahnhofstraße 64
72417 Jungingen
Germany

Display



Systolic blood pressure

128 ▶ Sys

Time

15:28

Diastolic blood pressure

87 ▶ Dia

Error indicator

E00

Pulse

68 ▶ Pulse

Key

Display	Designation	Description
A	Automatic interval control	Appears as soon as the automatic interval control is activated
S	Sleep mode	Appears as soon as the sleep mode is activated
B	Low battery	Appears as soon as the storage batteries are empty No more measurements are possible
M	Memory full	Appears as soon as 350 readings have been stored by the unit No more measurements are possible

Error code	Fault	corrective action
E00	No setting parameters present	Reprogram unit.
E03	Zero point adjustment not possible	Completely deflate cuff.
E04	Low battery	Recharge or replace storage batteries.
E05	Leak present	Remove the cuff from the unit and then reconnect. If the fault recurs, contact your supplier.
E06	Pressure exceeds 320 mmHg	Arm must be held still during measurement.
E07	Measurement cancelled by user via the START/STOP button	
E08 E10	No or non-analyzable oscillations. Maximum pressure defined to low.	Arm must be held still during measurement. Increase maximum pressure.
E20 E21 E22 E23	Pulse < 30 oder >200 no analyzable oscillations during the diastole or the systole Systole-diastole < 10 or > 150 mm Hg	Check the position and fit of the cuff
E30	Measurement time longer than 120 secs	Contact your supplier.
E31	Air release longer than 60 secs	Contact your supplier.
E50	Zero point adjustment faulty	Contact your supplier.
E52	Memory fault	Contact your supplier.
E53	Storage batteries without contact	Remove the batteries, check contacts and clean if necessary. Replace storage batteries. If the fault recurs, contact your supplier.

Error code	Fault	Corrective action
E55 E56 E57	Fault concerning speed of air release	Arm must be held still during measurement. If the fault recurs, contact your supplier.
E60	Intervals in error or incorrectly programmed	Check and correct the automatic interval settings.
E70 E71 E72 E73	Serial data transfer not possible	Reconnect the PC connection cable with the TM-2430 PC2. If the fault recurs, contact your supplier.
E74	Voltage breaks down during data transfer	Recharge or replace storage batteries.
E75	Data transfer error	Reconnect the PC connection cable with the TM-2430 PC2. If the fault recurs, contact your supplier.
E90	error pressure sensor	Contact your supplier.

Cleaning and care of the unit and the cuff

To clean the boso TM-2430 PC2 and the cuff, please use a soft cloth which may, if required, be moistened with a mild soap solution.

Never use solvents, petroleum or methylated spirits or scouring agents!

Accessories

Please use only accessories recommended by the manufacturer.

Available cuff sizes


	Identifier	Arm circumference	Order no.
Adult (standard)	CA 11	20 – 31 cm	257-4-400 (256-4-400)*
Adult (thicker arm)	CA 12	28 – 36 cm	257-4-410 (256-4-410)*
Children	CA 13	15 – 22 cm	257-4-420 (256-4-420)*

Further accessories

	Order no.
Charger unit	535-7-120
NiCd storage batteries (3 cells, mignon)	535-7-125
Hip case with carrying strap	535-7-110
USB-Adapter (from Windows 2000)	429-7-108

* Order number in () for units with serial numbers <= M0701400

Technical data

<i>Product:</i>	Sphygmomanometer for 24-hour measurement
<i>Model:</i>	boso TM-2430 PC2
<i>Nominal voltage:</i>	3 x 1.5 V DC
<i>Power source:</i>	3 x NiCd storage batteries (Mignon)
<i>Classification:</i>	Defibrillation-proof unit of type BF 
<i>Measurement range:</i>	40 – 280 mmHg 30 – 200 pulses/min
<i>Precision:</i>	Indicated pressure \pm 3 mmHg Pulse \pm 5%
<i>Operating conditions:</i>	+ 10 °C to + 40 °C 20 – 85% relative humidity
<i>Storage conditions:</i>	-20 °C to +70 °C 20 – 85% relative humidity
<i>Weight:</i>	220 grams
<i>Dimensions (W x H x D):</i>	72 mm x 27 mm x 100 mm
<i>Accessories:</i>	Storage battery charger unit

Interference between the boso TM-2430 PC2 and other pieces of equipment is not known.

Packaging material and units that are no longer used should be recycled and not simply discarded. Empty batteries and storage batteries should not be thrown away with household waste. They can be handed in at a battery collection point or disposed of as special waste. Please contact your local authority for details.



Clinical testing:

The clinical testing was performed in accordance with the recommendations of the AAMI (Association for the Advancement of Medical Instrumentation).

<i>Results:</i>	<i>Systematic measurement error</i>
	systolic blood pressure: - 0.33 mmHg diastolic blood pressure: - 0.14 mmHg
	<i>Empirical standard deviation</i>
	systolic blood pressure: \pm 3.95 mmHg diastolic blood pressure: \pm 4.39 mmHg

Technical testing procedures

A) Functional testing

Functional testing of the unit can only be performed on human subjects or using a suitable simulator.

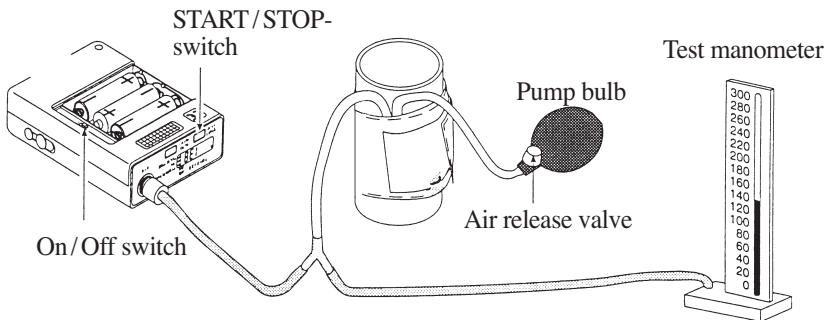
B) Leak testing of the pressure circuit and error testing of the display

Switch off the boso TM-2430 PC2 at the On/Off switch. Assemble the test apparatus as shown in Fig. 3. By keeping the START/STOP button pressed down, switch the unit on again. The START/STOP button must remain depressed until a '0' starts to blink in the display of the TM-2430 PC2. Wait until the '0' in the display is visible and has stopped blinking. Perform both the pressure reading variation tests and the leak testing of the pressure circuit in the usual manner (bearing in mind the settling time of the cuff of at least 30 seconds). To return to the measurement mode, the START/STOP button must be pressed down for about 3 – 4 seconds (audible acknowledge signal). The unit then counts down from ten to zero, after which it is in measurement mode (displays the time).

C) Security

For security purposes the two halves of the unit (upper and lower) are joined together with a security mark.

Fig. 3





EMC notes


Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to 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 bosco original parts) may result in increased emissions or decreased immunity of the unit.

Guidance and manufacturer's declaration – electromagnetic emissions		
The bosco unit is intended for use in the electromagnetic environment specified below. The customer of the user of the bosco unit should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The bosco 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 bosco 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 bosco unit is intended for use in the electromagnetic environment specified below. The customer or the user of the bosco 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.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The bosu unit is intended for use in the electromagnetic environment specified below. The customer or the user of the bosu 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 bosu 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 bosu unit is used exceeds the applicable RF compliance level above, the bosu unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the bosu 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 bosu unit			
The bosu unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the bosu unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the bosu unit as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	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 to 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.			

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