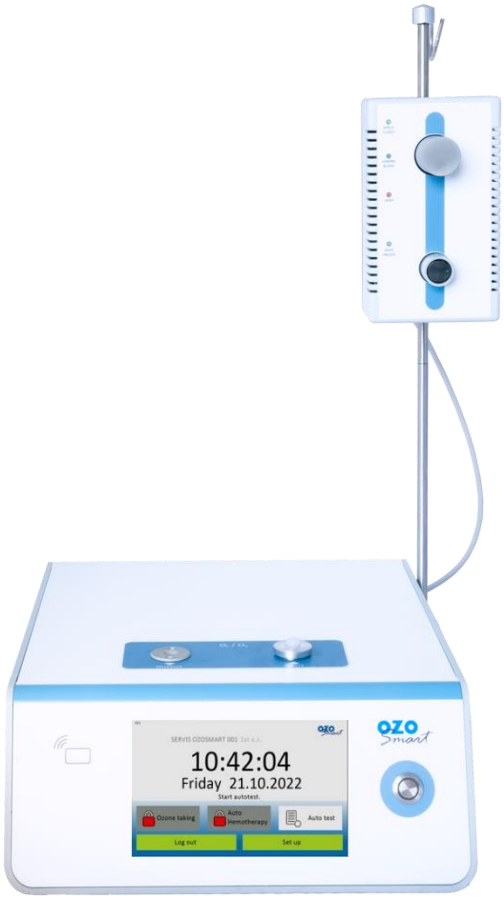
Instructions for use

Ozosmart

device for ozone therapy



Keep the document for further use!

Reg.no.: LPME21002AR02
Date of issue of last version: 29th May 2023

ZAT a.s., K Podlesí 541, 261 01 Příbram VI, CZ
e-mail: zat@zat.cz; tel.: +420 318 652 111

This Instructions for use mention basic information necessary for safe use, control, and maintenance of the device for ozone therapy.

For the operation of the device, both medical and technical training is necessary.

Before the device for ozone therapy is used, there is an obligation to study these Instructions for use. The instructions for use are to be carefully kept for further use!

Ozosmart

Device for ozone therapy

Warning on safety and damage of the device for ozone therapy

In these instructions, you can find warnings on safety as well as the possibility of damage to the device for ozone therapy. The mentioned instructions are to be observed to avoid injury to users or patients or to avoid damage to the device for ozone therapy.

Warning – it is a warning against something that can cause injury in case this warning is ignored. You have been informed on what you must or can not do to avoid or reduce the danger that threatens you or other persons.

Notification – it is a warning against something that can cause damage to the device for ozone therapy or its accessories in case this warning is ignored. You have been informed on what you must or can not do to avoid or reduce the danger of damage to the device of its accessories.

Issued by/ Manufacturer: ZAT a.s., K Podlesí 541, 261 01 Příbram VI, Czech Republic

Contacts:
Tel.: +420 318 652 111;
E-mail: zat@zat.cz
web: http://www.zat.cz

CE 2265

Content:

ZAT a.s., K Podlesí 541, 261 01 Příbram VI, CZ
e-mail: zat@zat.cz; tel.: +420 318 652 111

Important notifications

1. A device for ozone therapy can only be used for the purpose that it is intended for – users who have provably learned its properties, functions, and way of application.
2. Instructions for use are accompanying documentation of the device for ozone therapy.
3. Instructions for use are to be carefully kept. Any manipulation with this device is conditioned by full comprehension and observing these instructions. Pay high attention to WARNINGS AND NOTIFICATIONS mentioned in these Instructions for use and placed on the device itself.
4. The device for ozone therapy is supplied in set individual components of that are selected concerning the required properties necessary for safe function. It is not permitted to replace these components or to connect other devices or electrical appliances to the device for ozone therapy.
5. It is not permitted to dismantle parts of the device for ozone therapy except for the selected parts mentioned in these Instructions.
6. The instructions of this document must be observed, otherwise, there can occur damage or incorrect function of the device for ozone therapy.
7. The device for ozone therapy can be only connected to the electrical wiring that meets technical requirements.
8. This device must be connected to the power supply power with earthing protection to avoid the risk of injury through electric current.
9. The device is to be connected to the backed-up distribution of el. power to reduce the risk of emergency disconnection.
10. The device has no measuring function and uses recommended sterile consumables.
11. In case of biological staining, it is necessary to perform immediate disinfection and decontamination of the parts of the device for ozone therapy.
12. All repairs to this device can only be performed by a trained service technician. To keep the correct function of the device, we recommend to use ZAT technicians to solve repairs of the device.
13. **Warning!** Due to the danger of injury caused by electric current, do not remove the protective cover of the device, if the device is being used or connected to the power supply.
14. Should some of the following situations happen, have the device checked by a service technician:
    a. There occurred damage to the power supply cable or plug.
    b. Water or other liquid has got into the device.
    c. The device has been exposed to moisture.
    d. The device does not work following the Instruction for use.
    e. There occurred damage to the device due to a fall.
    f. The device shows clear signs of damage.
15. Before cleaning, the device is to be disconnected from the socket. The cleaning itself is to be performed using a wet cloth. For cleaning, do not use spray or liquids spread directly on the device.
16. **Warning!** You can avoid short-circuiting the device and subsequent damage to it by avoiding its contact with liquids. In case the liquid is poured on the device, the operation of the device is to be immediately finished and a service technician is to be contacted.
17. The device for ozone therapy can only be used in a room with the possibility of intensive ventilation. In case the device is placed in a room without the possibility of ventilation, the room must be equipped with an ozone detector and protective mask for breathing ways with a carbon filter for all persons inside the room.
18. The device is to be placed on a suitable surface. Fall, both the fall of the device itself or the fall of some other object on it, could cause damage to the device.
19. For safe disconnection of the device from the power supply, get the socket from the plug. The socket to which Ozosmart will be connected in must be easily accessible for easy and safe disconnection of the device.
20. **Warning!** This device is not suitable for use in the presence of flammable anesthetics or systems of life support.
21. For assembly and cleaning, only the agents approved by the manufacturer are to be applied.
22. Cleaning, maintenance, and disinfection of the parts of the device mentioned in chapters 10.1.1 - 3 cannot be performed when the device is being applied to a patient.
23. **Warning!** Do not modify/repair the device without the consent of the manufacturer.

1. IDENTIFICATION OF MEDICAL DEVICE

The medical device Ozosmart is a therapeutic device intended for ozone therapy.

The device for ozone therapy Ozosmart:

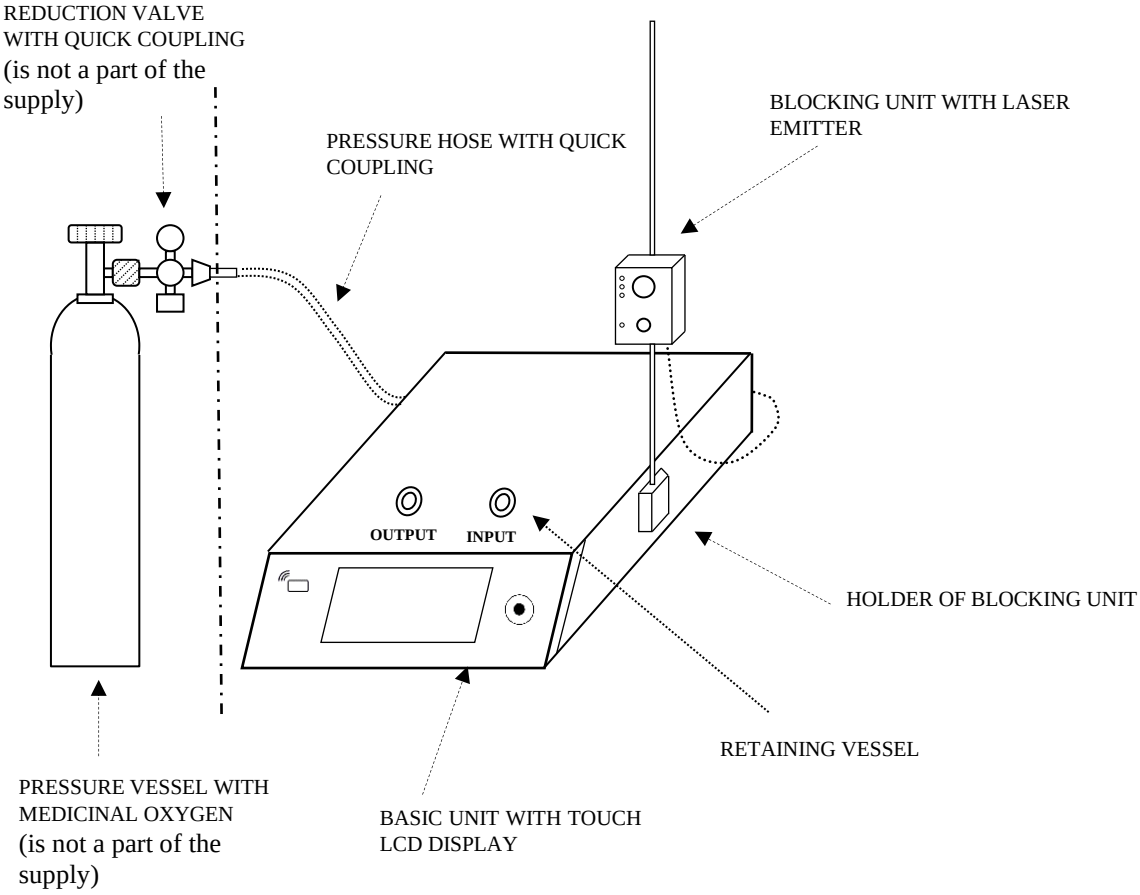
• Active therapeutic medical device class IIb according to 2017/745 (MDR)

• Dependent on the source of electric power supply

• Electric medical system according to ČSN EN 60601-1

• Contains software equipment

• The device has no measuring function and sterile parts



CE 2265

Users´ software equipment:

Program of the device for ozone therapy: version 1.0

Manufacturer: ZAT a.s., K Podlesí 541, 261 01 Příbram VI, Czech Republic

2. INTENDED PURPOSE OF USE OF MD

Ozosmart, the device for ozone therapy, is an active therapeutic medical device that is intended as a supplementary therapy in clinical and outpatient practice for rectal/vaginal administration of ozone, filling of bags, saturation of liquids, minor and major autohemotherapy with anti-inflammatory, anti-bacterial, anti-viral, anti-fungal and immune-restoration effects, supporting blood supply of tissues.

3. ADVERSE EFFECTS

Side effects of medical device Ozosmart have not been detected.

Side (unwanted) effects of ozone therapy are monitored and described in Madrid Declaration on Ozone Therapy (3rd edition, 2020):

Most of the side effects reported could be related to *mala praxis*: administration technique, administration route, the concentration of ozone administered, etc.

Grade of reported adverse effects (AE) according to NIH (2010) criterion:

Grade 1 Mild
(Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated).

- Some patients reported a brief and transient feeling of local heat and slight pain during the ozone injection.
- Hematoma at the ozone infiltration site in one patient.
- Four patients reported the sensation of itching on lips and tongue at the end of the session, three patients described nausea and a bad taste in the mouth during re-infusion of ozonated blood and one patient suffered dyspnea during the administration of therapy.
- Onset of euphoria after the application of ozone using the oxygenation and extracorporeal ozonation of blood in 15 patients treated for skin lesions secondary to arterial ischemia.

Grade 2 Moderate
(Minimal, local, or noninvasive intervention indicated, limiting age-appropriate instrumental activities of daily living (ADL).

- Onset of reduction of sensitivity in the legs of two patients in the group treated with ozone and corticoids that remitted in two hours.
- Five patients reported lumbar and leg pain after the ozone injection that resolved spontaneously, and eight patients showed mild corneal irritation and reversible dyspnea after the administration of ozone.
- When ozone was administered by rectal insufflation, cases of bloating and constipation were reported.

Grade 3 Severe
(medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care).

- Vertebrobasilar stroke.
- One acute bilateral vitreoretinal hemorrhage.
- One case of meningeal irritation.
- Three cases of viral hepatitis.
- A series of cases of severe infection complications during treatment of spinal degenerative pathologies

- Acute prevertebral abscess secondary to intradiscal chemonucleolysis through ozone therapy
- Vasoconstriction during fast re-infusions at the application of major autohemotherapy.
- Secondary suppurative complications regarding ozone therapy in the treatment of lumbar spine pain.
- Case report of spondylodiscitis after ozone therapy in the treatment of cervical disc.
- Case report of strong headache following after the ozone therapy: pneumocephalus after epidural method of treatment of lumbar hernia.
- Case report of explosive headache caused by non-intended epidural puncture during ozone therapy at a patient with cervical hernia of disc
- Hard accretion of soft tissues and bone structure of patients who have got ozone injections in an intraformational way.

Grade 4
(life-threatening consequences; urgent intervention indicated).

- One case of gas embolism was reported in the peri-ganglionic venous plexus involving the vertebrobasilar artery which was manifested clinically as local pain for several minutes and cleared in a few days.
- One case of an embolism at posterior spinal artery syndrome and heart attack following the ozone therapy.
- One case of loss of consciousness. After its re-gaining, there were detected ataxia, aphasia, hemiparesis, and paralysis of the sixth left nerve after paravertebral ozone injection.
- One case of cardiopulmonary arrest and pneumocephalus after epidural ozone therapy
- Myocardial heart attack after ozone therapy (major autohemotherapy).
- Ischemic stroke after ozone therapy (Anton´s syndrome).
- Case report when the ozone therapy caused sinus arrest of a hypersensitive patient with chronic kidney malfunction (treated by major autohemotherapy).
- Case report of transient corticoid blindness after intradiscal ozone therapy.

Grade 5
(Death related to adverse effects)

- Four cases of death caused by gas embolism after the administration of ozone by direct intravenous injection.
- One case of death following ozone application by autohemotherapy to treat psoriasis.
- One case of death by fulminating septicemia following ozone therapy for lumbar disc herniation.

4. SYMBOLS REPLACING SIGNS ON THE DEVICE

ZAT	Manufacturer´s logo		Read Instructions for use
	Manufacturer		**Attention!**
OZO Smart	Designation of the device – marketing logo		External part type B
CE 2265	CE designation with number of notified bodies		Warning; Laser beam
	Equipotential termina		Instruction for disposal of product
	Attention, high voltage in the device	MD	Medical device
RoHS	Restricted use of hazardous substances	UDI	Unique identifier of medical device
70 GL	Type of waste: Clear glass		Intended for repeated use
KŘEHKÉ FRAGILE	Attention, fragile		

5. SAFETY INSTRUCTIONS

a. Ozone cannot be inhaled during therapy! There could occur damage to breathing ways. In the course of the open administration of ozone (bags, ocular, vaginal application, etc.) we recommend working with the protection of breathing ways with a carbon filter as personal protection.

b. In the workplace, there cannot be exceeded ozone concentrations mentioned in hygienic regulations according to currently valid legislation. In case of leakage of any amount of ozone, ventilate the room and leave it.

c. Any serious adverse incident that occurred about the device, must be reported to the manufacturer and related body of the member state in which the user and/or the patient is located.

d. A medical device (MD) is intended for patients older than 18 years.

e. Only trained users that have been instructed can work with the device.

f. A user can not be the patient at the same time.

g. The mentioned contraindications are to be strictly observed.

h. The recommended dose is not to be exceeded.

i. Only the consumable material recommended by the manufacturer to be used.

j. Before the administration, the instructions of the patient are to be performed and we recommend signing the Patient´s informed consent.

k. Safety regulations for work with medicinal oxygen and pressure vessels are to be observed.
(ČSN 07 8304 and related standards).

l. Only the reduction valve for the stipulated output pressure is to be used.

m. Only the pressure vessels with medicinal oxygen (meeting the standards of locally approved medicals) by an authorized supplier are to be used.

n. Replacement of empty pressure vessel to be performed with a closed valve on the pressure vessel and switched off device.

o. When you do not use the device, the valve on the pressure vessel is to be closed and the device to be switched off or to be put in sleep mode.

6. USERS ´ QUALIFICATION

The device for ozone therapy can only be operated by a qualified person (trained person).

According to the manufacturer, doctors and authorized therapists that have undergone a training ensured by the manufacturer are only permitted to operate the device. The trainer must have provable long-term experience in the field of ozone therapy.

The training must include:

- familiarization with hygienic and safety principles and regulations
- familiarization with properties of ozone
- familiarization with operation and working of the device Ozosmart
- practical verification of the ways of ozone administration
- procedures in case of detecting a failure

7. OZONE – BASIC PROPERTIES AND NOTIONS

7.1. BASIC PROPERTIES

Ozone is a colorless gas with a characteristic bad odor.
Its molecule is created by three atoms of oxygen. The chemical symbol is O_3.

It has very strong oxidation properties. It is very unstable, and it is quite quickly decomposed to oxygen O_2.
Half-life (the time during which the concentration drops to a half) with pressure 101,3 kPa is as follows depending on the temperature:

30 °C - 26 minutes	5 °C - 110 minutes
25 °C - 35 minutes	0 °C - 139 minutes
20 °C - 44 minutes	-5 °C - 184 minutes
15 °C - 58 minutes	-10 °C - 256 minutes
10 °C - 76 minutes	-15 °C - 361 minutes

Ozone concentration in the gas mixture is given by amount of O_3 in a unit of mixture volume mg / m^3, μg / ml, 1 g / m^3 = 1 mg/ l = 1 μg / ml
or a proportionate part of O_3 to the total amount of mixture
ppm - parts per million (the millionth part) 1 ppm = 0,0001 %

For a mixture of ozone (O_3) and air there applies 1 mg / m^3 = 0,509 ppm.
For a mixture of ozone (O_3) and oxygen (O_2) there applies 1 mg / m^3 = 0,455 ppm, 1 μg / ml = 455 ppm .

Hygienic requirements for working environment enable ozone concentration average 0,1 mg/m^3 (0,05 ppm) and the limit one 0,2 mg/m^3 (0,1 ppm).
By smelling, we percept the concentration 10x lower 0,02 mg / m^3 (0,00002 μg /ml - 0,01 ppm).

7.2. USABLE PROPERTIES OF OZONE

Through oxidation, ozone disposes of high-molecular complex compounds, chlorinated biphenyls, organic compounds, poisonous aromatic substances, cyanide, phenols, sulfur, iron, and manganese. It performs deactivation of carcinogens. Strong deodorizing effects distort bad odor substances and thus reduction of bad odor.

High solubility in liquids and a short half-life enable high saturation with oxygen. Bactericidal, virucidal, and antimycotic properties are used for disinfection in water treatment, and in the food and pharmaceutical industry.

In medical practice, there are used all these properties for the treatment of blood perfusion disorders, viruses, bacterial and mycotic diseases, and for activation of the immune system.

8. TECHNICAL DESCRIPTION

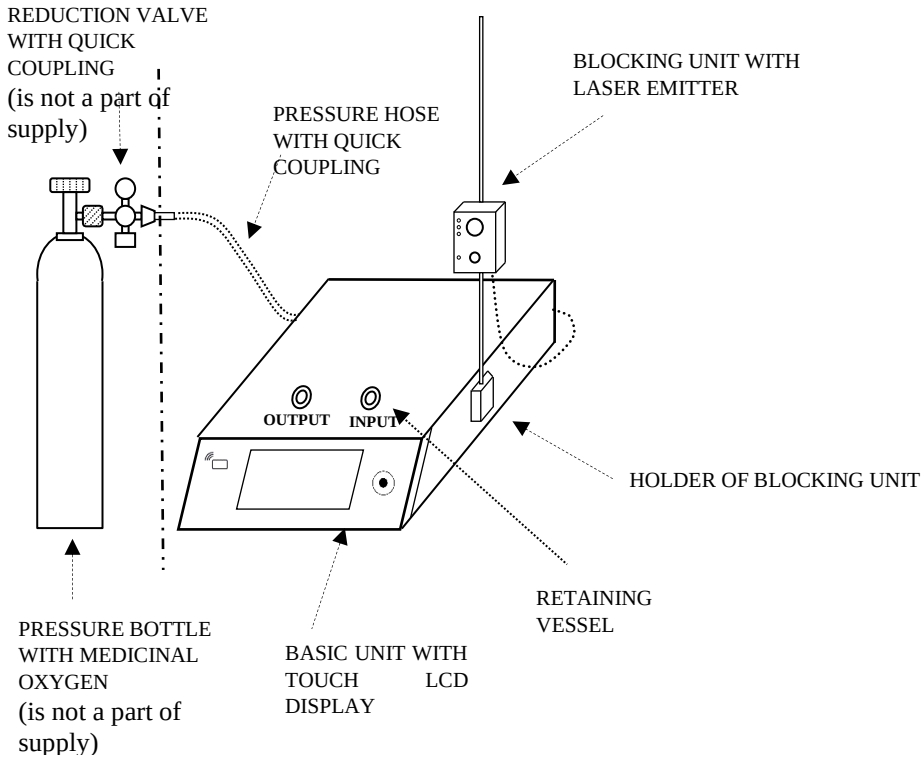
8.1. DESCRIPTION OF DEVICE FOR OZONE THERAPY

The device Ozosmart consists of:

- basic unit with network power supply
- checking and blocking unit
- holder of blocking unit
- pressure hose with quick coupling.

A pressure vessel with medicinal oxygen and a reduction valve is not a part of the supply.

8.2. DESCRIPTION OF PARTS OF THE DEVICE



- Sampling flange (OUTPUT) is used for sliding of syringe or end of the hose for taking ozone. Checking contact monitors completeness of connection.

- Retaining vessel (INPUT) with a content check is used for connecting transfusion set or entrance in ozone disposal device. The retaining vessel prevents the suction of impurities into the device. An insert in the vessel is possible to be removed in the switched-off state after unscrewing the flange, to be cleaned and put back. The flange is sealed up with a seal ring. In case of leakage of the flange intactness of the seal ring is to be checked. The damaged ring is to be possibly replaced with the new one.

8.2.1.FRONT PANEL

Front panel with touch display, card reader, authorization card, and button

TOUCH DISPLAY

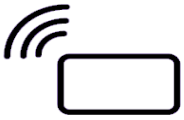
- provides information on the current operation of the device and set up parameters of individual modes and at the same time, it is used for the setup of parameters of device operation itself.
  - **The number of the current display is shown in the left upper corner.**

CARD READER WITH AUTHORIZATION CARD

- is used for log-in of the operation staff by putting on the authorization card.

BUTTON

- with backlight, it has a concrete function in individual modes (mentioned on the display)


Card reader

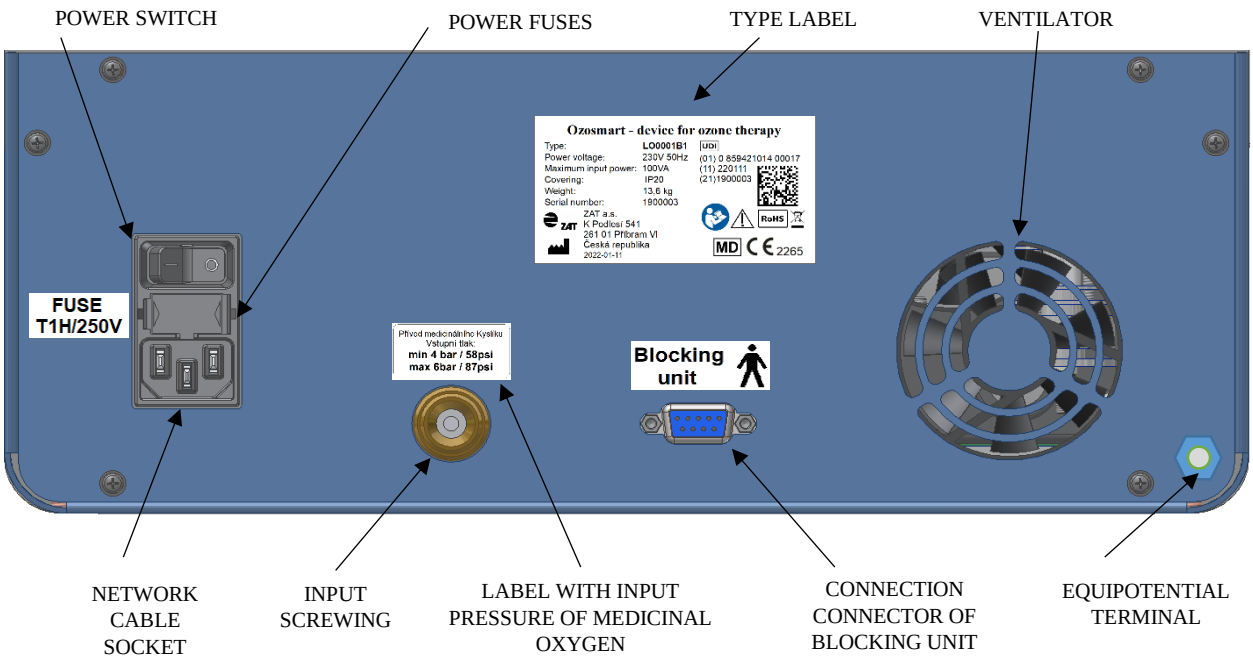

Authorization card

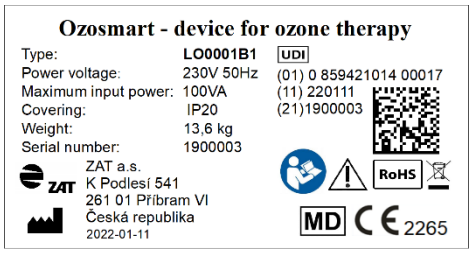

Button

8.2.2.REAR PANEL

POWER FUSES
- protect network circuits of the device in case of current failure

POWER SWITCH
- is used for switching on or switching off the device





Example of label contains important information

POWER CABLE SOCKET
- is used for connecting power input

TYPE LABEL
- contains the serial number and basic data on the device

VENTILATOR
- cools inner space of the device by air circulation

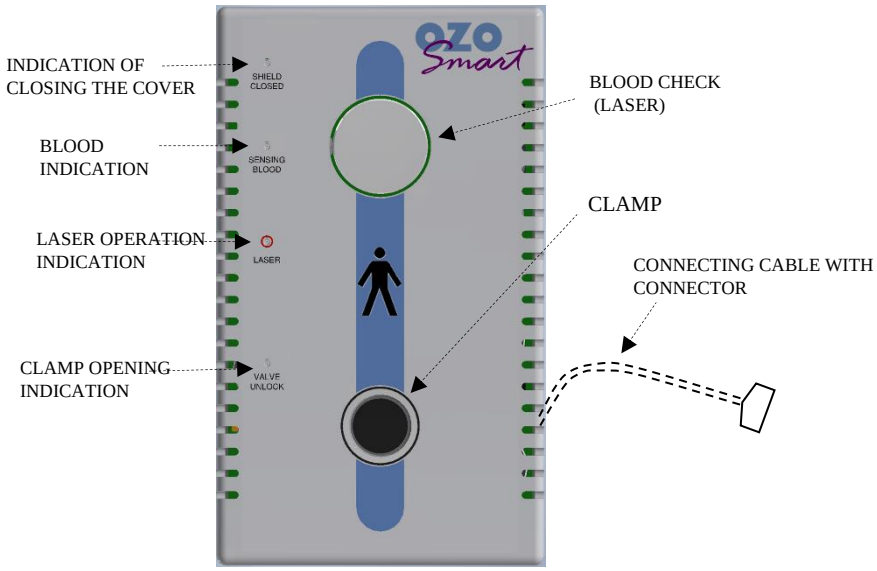
LABEL WITH INPUT PRESSURE OF MEDICINAL OXYGEN
- 4bar, maximum 6bar

INPUT SCREWING
- is used for connecting input hose of medicinal oxygen from reduction valve of pressure-on-pressure vessel with medicinal oxygen (mounting wrench no. 19)

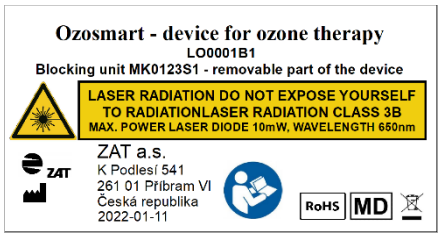
CONNECTING CONNECTOR OF BLOCKING UNIT
- is used for connecting removable blocking unit

EQUIPOTENTIAL TERMINAL
- is used for the connection of the earthing system

8.2.3.BLOCKING UNIT WITH LASER EMITTER



On the top part of the blocking unit for blood treatment, there is placed a laser label in case of taking autohemotherapy.
The blocking unit is an attaching part type B



On the lable, there is mentioned maximum optical output of laser and wave length of radiation.

BLOOD CHECK (LASER)

- sensor chamber of blood presence and laser emitter check for blood treatment

CLAMP

- pressure-grip valve of taking the hose

CONNECTING CABLE WITH CONNECTOR

- is used for connection to the basic unit

COVER CLOSING INDICATION

- by lighting up, it gives a signal on closing the sensor chamber of blood presence check and laser emitter

BLOOD INDICATION –lighting, gives a signal on blood presence in the taking hose going through the checking chamber

LASER OPERATION INDICATION

- by blinking and acoustic signalization indicates the function of radiation laser.
- **The volume of the acoustic indication is possible to be set up at the rear side of the blocking unit.**
- **The operation of the laser is blocked during the opening of the laser cover.**

CLAMP OPENING INDICATION

- opening of the pressure valve of the taking hose is signalized by lighting up.
- **in case of exceeding temperature of the clamp, there occurs closing of pressure valve and blinking of the signalization (VALVE UNLOCK).**
- **Repeated switching on – opening of the valve occurs after its cooling.**

8.3. SAFETY OF APPLICATION IN THE PRESENCE ANAESTHETIC FLAMMABLE MIXTURES

The device is not suitable to be used in the presence of a flammable mixture of anesthetics and air or oxygen or nitrous oxide.

Operation mode:
The device is intended for permanent operation.

Electromagnetic compatibility according to ČSN EN 60601-1-2 ed.3: 2016+A1:2021 determines the environment in which the device can work, see tab. EMC.

Neither this medical device nor the consumables related to it contain derivatives from human blood or animal tissues.

Protection of the environment see the instructions for product disposal see chapter 13.

The device has multiple application use (more in chap. 9.5.). Biochemical effect of ozone in organism ensures support of blood protrusion of all tissues including CNS, it has bactericidal, fungicidal, and virucidal properties, it has an immune-restoration effect, energetic contribution, supports regeneration of tissues.

It is intended to be used in the environment defined by the below-mentioned operating conditions.

It is not intended for any other use than the one mentioned in the instruction for use.

It is not intended for the generation of ozone in the spaces in which there are people and animals because there can occur damage to breathing ways when inhaling ozone with concentrations higher than safe.

Ozone causes very fast degradation of all common materials depending on concentration and length of effect.

The device is following the requirements of harmonized standards ČSN EN 60601-1 ed.2: 2007 + A1:2014, ČSN EN ISO 13485: 2016, ČSN EN ISO 14971:2020. The device meets the requirements of GD no. 481/2012 and directive no. 2011/65/EU on the restriction of uses of some dangerous substances in electric and electronic devices (RoHS).

Type of protection against injury from electric current:
- Device class I
- To lower the risk of an injury through electric current, this device has to be connected to a power supply network with protective earthing.

Protection against water effect:
- Covering IP 20 according to ČSN EN 60 529

8.4. TECHNICAL DATA

8.4.1.OPERATING CONDITIONS

Application environment – outpatient care provided in hospitals or other health care institution under a medical supervision when medical devices are provided to the ill, injured or handicapped patients for therapeutic purposes. The medical device is intended to be used in accordance with the purpose of use.

Limit climate conditions for keeping operability:

surrounding air temperature	+10 °C - +40 °C
relative air humidity	30% - 75%
atmospheric pressure	700 hPa - 1060 hPa

Climate conditions for which there is guaranteed required reliability:

surrounding air temperature	+18 °C - +25 °C
relative air humidity	30% - 65%
atmospheric pressure	840 hPa - 1060 hPa

The working environment must be without aggressive vapors.

8.4.2.POWER SUPPLY

Power distribution voltage 230 V +10% -10% with frequency 50 Hz

8.4.3.INPUT POWER

maximum input power	100 VA
input power in standby state	up to 20 VA

8.4.4.INPUT MEDIUM

- medicinal oxygen (complying with the quality standards of local medical legislation) from pressure vessel or fixed oxygen distribution of health care facilities 4bar, maximum 6bar

8.4.5.BASIC COMPOSITION OF SUPPLY

- basic unit with a card
- blocking unit with a laser emitter
- holder of blocking unit
- oxygen pressure hose with quick coupling and screwing
- POWER supply
- reserve insert of the inner retaining vessel with seal
- set for Autotest (connecting hose of outputs for Autotest and disinfection, pin for blood simulation)
- instructions for use

8.4.6.STORAGE CONDITIONS

- surrounding air temperature +5 °C - +45 °C
- relative air humidity 30% - 75%
- atmospheric pressure 700 hPa - 1060 hPa

8.4.7.TECHNICAL AND OPERATING CHARACTERISTICS

- dimensions of basic unit (length x width x height) 380x340x140 mm
- dimensions with connected blocking unit (length x width x height) 380x410x660 mm
- dimensions of blocking unit itself (length x width x height) 150x110x190 mm
- total weight 13,6 kg
- selection of operation mode and application parameters
- selection of ozone concentration in mixture of $O_3 + O_2$ 1 ÷ 80 μg / ml O_3
- selection of the amount of taken mixture $O_3 + O_2$ 100 ml ÷ 3000ml
- supplied amount of mixture $O_3 + O_2$ 0,2 or 0,8 l/min acc. to mode
- laser emitter with output up to 10mW, 630 - 690 nm class 3B
- optic and acoustic indication of laser operation
- an optical indication of the device operation
- an acoustic and optical indication of failure and error
- in the course of the application, there is performed a current check of the required parameters of the application

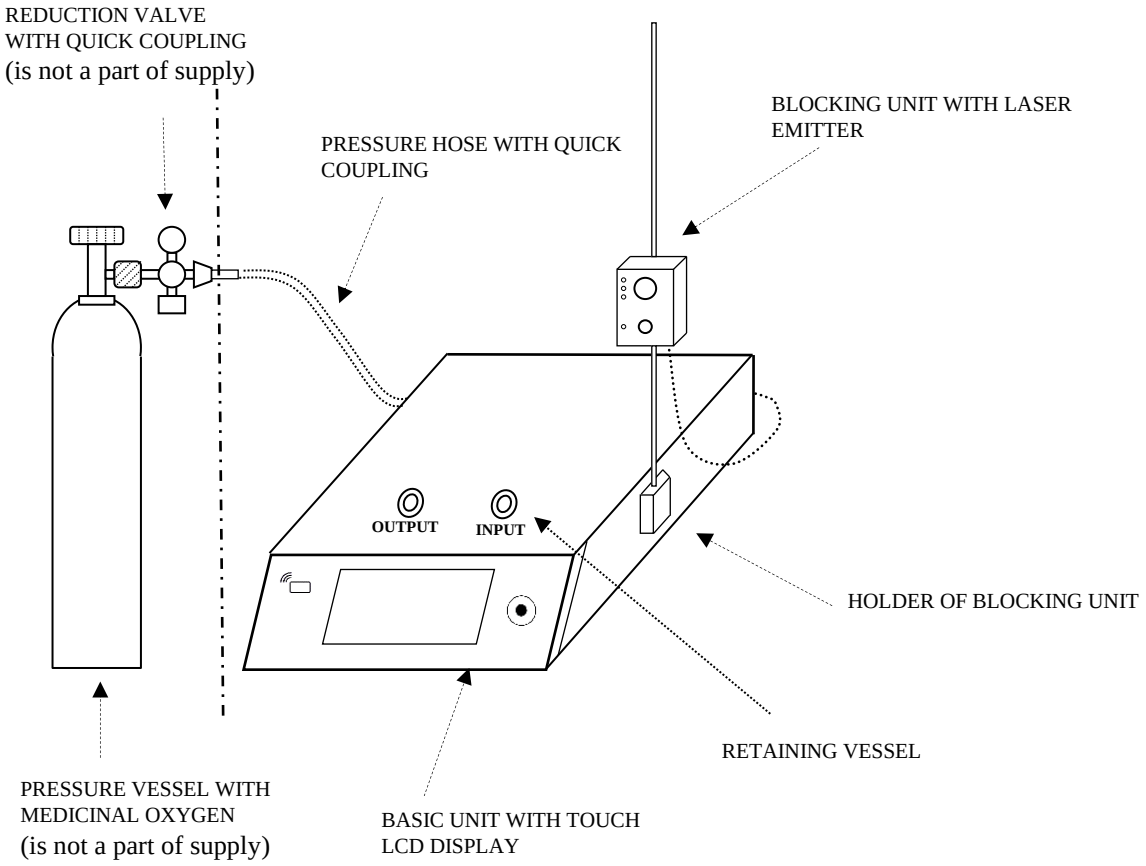
8.4.8.LIFETIME OF EQUIPMENT

The assumed lifetime of the equipment is more than 10 years, provided that there are performed periodic safety technical inspections (STI).

9. PUTTING INTO OPERATION

We recommend the following procedure for the first putting into operation or longer putting out of the operation of the device:

- A guide rod is to be fixed in the holder of the blocking unit. The blocking unit with laser emitter is put on the rod.
- A cable of the blocking unit to be connected to the basic unit.
- Pressure hose with screwing to be fixed to the basic unit (mounting wrench no. 19), using quick coupling on the hose, it gets connected to a source of oxygen either in the fixed oxygen distribution or to a reduction valve screwed on the pressure vessel with medicinal oxygen.
- Basic unit to be connected using supply cable to the network power supply.
- The device is to be disinfected according to chapter 10.



9.1. SWITCH ON OF THE DEVICE

We recommend the following procedure when putting it into operation:

Before putting it into operation, check the intactness of the insulation of the input power cable and the intactness of the cover of the power connector.

In case some part is damaged, the cable can not be used!

The device is to be connected to the power (by inserting the power input of the device in the socket).

Input pressure of oxygen is mentioned on the label next to connecting screwing.
Quick coupling of oxygen hose to be inserted either in the quick coupling of reduction valve on the bottle with oxygen or in the fixed oxygen distribution.

The valve of the pressure vessel with medicinal oxygen is to be opened (slowly) and check the tightness of the connection.

Switch on the basic unit with a power supply switch on the rear side.
The switching is indicated by the lighting of the display with the Home display.

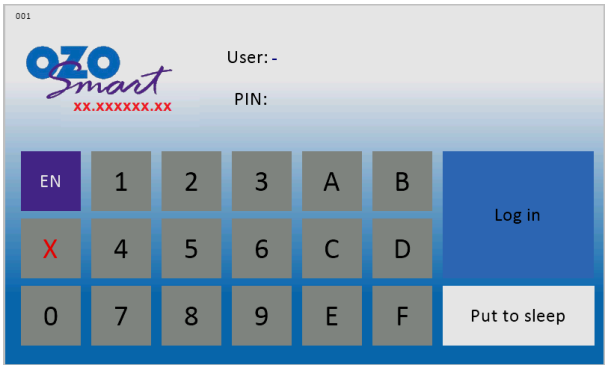
9.1.1.HOME DISPLAY

Home display no. 000 at start of the device

Notification:

The minimum time for repeated connection of the device to the power after its disconnection (switch off) is 5 minutes.

9.1.2.LOG IN



Log in screen no. 001

Log in procedure:

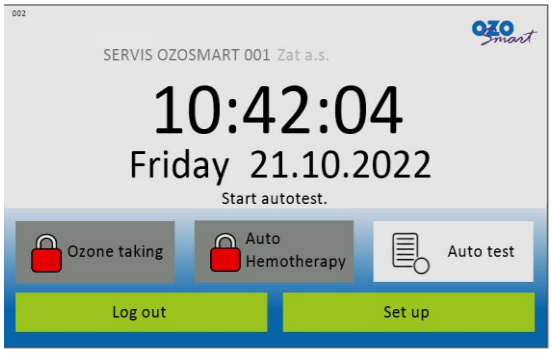
- Attach authorization card
- Enter PIN
- Select “LOG IN“

NOTE: Number **xx.xxxxxx.xx** sets a program version and a hardware version

Log in screen is in the initial state in English and using the button EN it is possible to change a language.

MAIN SCREEN

NOTE: In case it has been preset, the "AUTO TEST" mode is automatically selected and started.



Main screen no. 002
Displays:
- Information on a loged-in user
- Time / Day of week / Date
- Possibility of selecting individual modes:

Ozone taking - Auto Hemotherapy – Auto test

- Button Log out
- Button Set up

Press the button 

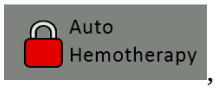
, you get back on ***log in screen*** no.001

Press the button 

, you get on the screen ***Setting*** no.006

Press the button 

, you get on the screen ***Taking of ozone*** no. 004

Press the button 

, you get on the screen ***Auto Hemotherapy*** no.005

NOTE:

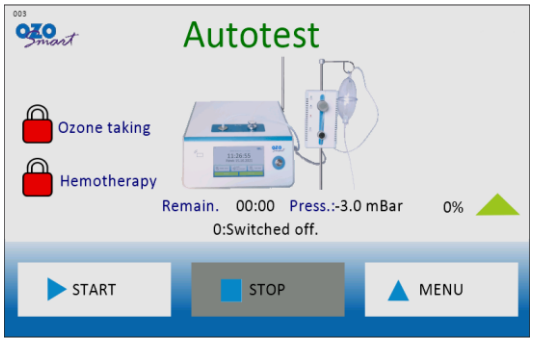
Buttons *Taking of ozone* and *Auto Hemotherapy* are only accessible after successful performing the Auto test

Press the button 

, you get to the screen ***Autotest*** no. 003

9.2. "AUTOTEST" MODE

Performs a check of the entire device. The check must be started after each switch on of the device. Before switching on of ***Autotest***, all cables from the INPUT and OUTPUT flanges are to be disconnected.



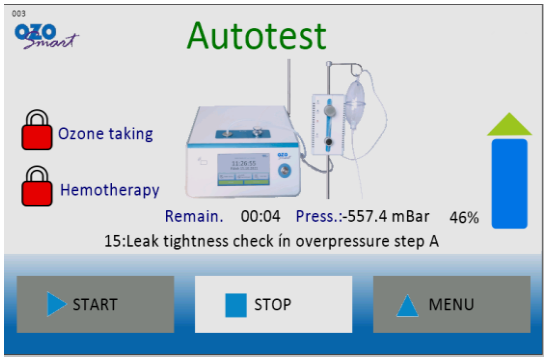
Autotest screen no. 003

START Press the button START,
you start ***Autotest*** of the device

MENU Press the button MENU,
you get back on the Main screen no.002

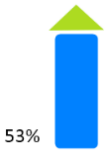
Start ***Autotest*** by pressing the button START

Watch statement of the going on ***Autotest*** in the lower part of the screen above button STOP



Going on ***Autotest***

- Preess the button STOP, you can finish ***Autotest*** of the device early



Total indicator of the already completed part of ***Autotestu*** in the scope 0 - 100%

<u>Inspection of individual parts of the device is divided into 30 checking points:</u>

Check 1: Clearing of pressure gauge
- Rinsing of the device and calibration of pressure measurement

Check 2: Test of input pressure
- Check of input pressure of medicinal oxygen

Check 3 - 7: Total rinsing steps A - E
- Check of passability of individual gas ways

Check 8 and 9: Check input pressure (> 500 mBar) and (>1000 mBar)

- Check of pressure of medicinal oxygen for 500 mBar and 1 000 mBar

Check 10 - 12: Check for passability with pressure steps A - C

- Check of passability of individual gas ways with pressure

Check 13 and 14: Leakage check-in under pressure steps A and B

- Leakage and under pressure check of parts of the system under pressure

Check 15 - 17: Rinsing and leakage check in overpressure steps A and B

- Rinsing of the device and check of pressure and leakage check of individual parts of the system in overpressure

Check 18 and 19: Input leakage check steps A and B

- Leakage check of input valves of the system and ozone generator

Check 20 and 21: Test of generator and ozone disposal device steps A and B

- Check of generator and ozone disposal device.

NOTE:
The test continues in the case if the connected Blocking unit is in cooperation with operation staff.

Check 22: Check the blood simulation cotter pin

- Check of blood sensor

Check 23: Rinsing of the device

- Rinsing of the device

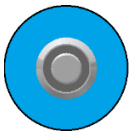
Check 24 - 26: Cyclic connecting of laser and clamp

- Check for a switch on / switch off of the clamp (pressure valve of bleeder cable)
- Check of switch on / switch off of radiation laser

NOTE:
The switch on of the clamp is changed with the switch on of the radiation laser.

Check 27 -29: Connect the hoses

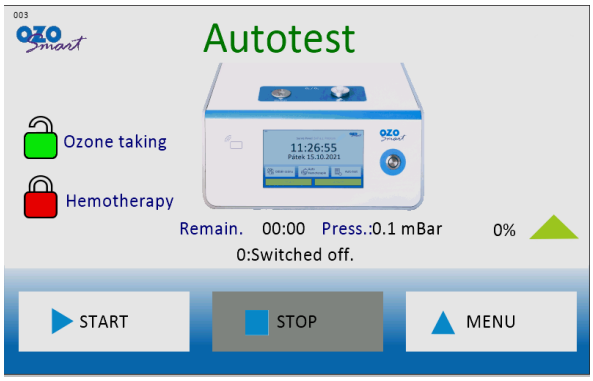
- After the acoustic signaling and prompt on the display - "Connect the hoses", there must be within 60 sec. the ***OUTPUT*** and ***INPUT*** sampling outputs connected by a tube with compatible terminals. The countdown can be ended by pressing the button.



- There will be performed leakage check of the outputs for taking of ozone.

Check 30: Simulate presence of blood with cotter pin

- After acoustic signalization and command on the screen – „Simulate presence of blood with cotter pin“, there must be within 20 sec. performed a simulation of the presence of blood on the blocking unit.
- In the chamber of blood check, a pin for the simulation of blood from basic consumables is to be inserted.



Example of screen

- Completed ***Autotest***

Without connected Blocking unit (or with evaluation of error of Blocking unit)

NOTE.

- In case the Blocking unit has not been connected before the start of ***Autotest***, the ***Auto Hemotherapy*** mode is not accessible.

- In case during ***Autotest*** there has been detected a defect of some block, ***Autotest*** is terminated, and the detected error is shown or additional specification in the lower part of the display.

A list of possible errors in the course of ***Autotest*** of the device:
To be checked in case of occurrence.

Defect no.	Description of defect	Possible cause - elimination
9	Loss of communication with LCD!	Failure of communication with LCD – contact service
10	Ventilator failure!	Blocked ventilator - contact service
1001	Pressure is lower than 500 mBar!	Main oxygen closure is closed – check whether there is sufficient pressure in the main supply.
1002	Pressure is lower than 500 mBar!	
1003	The ozone disposal device has not been switched on!	Ozone disposal device does not work - contact service
1004	Pressure has not been set up in time!	The impassibility of ways – disconnect hoses from flanges INPUT and OUTPUT
1005	Pressure is higher than 200 mBar!	
1006	The ozone disposal device has not been switched on!	Ozone disposal device does not work - contact service
1007	Pressure is higher than 200 mBar!	The impassibility of ways – disconnect hoses from flanges INPUT and OUTPUT
1008	The ozone disposal device has not been switched on!	Ozone disposal device does not work - contact service
1009	Pressure is higher than 200 mBar	The impassibility of ways – disconnect hoses from flanges INPUT and OUTPUT

1010	The ozone disposal device has not been switched on!	Ozone disposal device does not work - contact service
1011	Pressure is higher than -650 mBar!	Vacuum pump does to work or works in sufficiently - contact service
1012	Pressure is higher than -300 mBar!	
1013	Pressure is higher than 1100 mBar!	Incorrect input pressure - check whether there are pressure 5 bars in the main intake (beyond the reduction oxygen valve)
1014	Pressure is lower than 1000 mBar!	Incorrect input pressure - check whether there are pressure 5 bars in the main intake (beyond the reduction oxygen valve)
1015	Pressure is higher than 70 mBar!	The impassibility of ways – disconnect hoses from flanges INPUT and OUTPUT
1016	The ozone generator has not been switched on!	Ozone generator does not work - contact service
1017	Pressure is higher than 20 mBar!	The impassibility of ways – disconnect hoses from flanges INPUT and OUTPUT
1018	The ozone generator has not been switched on!	Ozone generator does not work - contact service
1019	The ozone generator has not been switched on!	Ozone generator does not work - contact service
1020	Pressure is higher than 20 mBar!	The impassibility of ways – disconnect hoses from flanges INPUT and OUTPUT
1022	The ozone generator has not been switched on!	Ozone generator does not work - contact service
1022	The ozone generator has not been switched on!	Ozone generator does not work - contact service
1023	Pressure is higher than 20 mBar!	The impassibility of ways – disconnect hoses from flanges INPUT and OUTPUT
1024	Forgotten cotter pin of blood simulation!	In the blocking unit, there is inserted a cotter pin of blood simulation – the cotter pin of blood simulation to be removed
1025	Forgotten cotter pin of blood simulation!	Cotter pin of blood simulation has not been inserted – cotter pin of blood simulation to be inserted in the next test
1026	Hoses have not been pressed up in time!	Flanges INPUT and OUTPUT have not been interconnected - INPUT and OUTPUT to be interconnected in the next test
1027	The ozone disposal device has not been switched on!	Ozone disposal device does not work - contact service
1028	Pressure is higher than 100 mBar!	The impassibility of ways – disconnect hoses from flanges INPUT and OUTPUT
1029	The ozone disposal device has not been switched on!	Ozone disposal device does not work - contact service
1030	The ozone generator has not been switched on!	Ozone generator does not work - contact service
1031	The clamp has overheated!	There has occurred overheating of clamp – wait till the clamp has got cooled
1032	Forgotten cotter pin of blood simulation!	In the blocking unit, there is inserted a cotter pin of blood simulation – the cotter pin of blood simulation to be removed

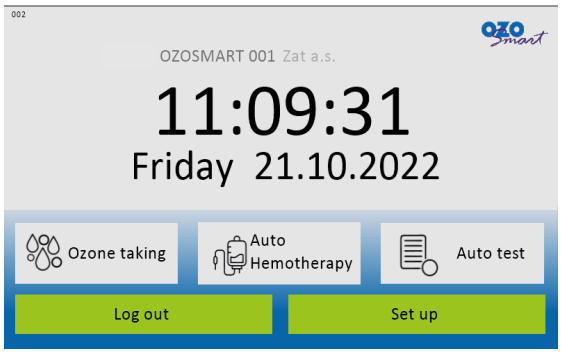
1033	Blood has not been simulated in time!	Blood simulation has not been inserted – cotter pin of blood simulation to be inserted in the next test
1034	The ozone disposal device has not been switched on!	Ozone disposal device does not work - contact service
1035	The ozone generator has not been switched on!	Ozone generator does not work - contact service
1036	The clamp has overheated!	There has occurred overheating of clamp – wait till the clamp has got cooled
1037	Pressure is lower than 650 mBar!	Flange INPUT and OUTPUT are leaking

9.3. SWITCH OFF OF THE DEVICE – END OF WORK

After completion of work, it is necessary to disconnect the pressure hose from the source of oxygen. If you use medicinal oxygen in a pressure vessel, ***close the valve of the pressure vessel***. Loosen pressure in reduction valve by disconnecting a repeated connecting of attaching quick coupling on pressure hose. When connecting to fixed oxygen distribution, loosen - disconnect the oxygen hose of the device by a quick coupling. Switch off the basic unit by supply switch on the rear side of the device.
Authorization card to be kept against unauthorized use of the device.

9.4. ACTIVITY MODES

The activity modes are divided into three groups according to the character of the operation.



Selection of group will be performed from ***Main screen no. :002***

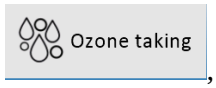
With button
- ***Ozone taking***
- ***Auto Hemotherapy***

- ***Auto test*** (check of the device)

9.4.1.ADMINISTRATION OF OZONE

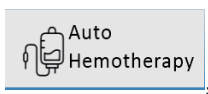
Medical ozone can be administered locally or in total. To achieve the coactive effect, there can be applied various ways of administration in a combined way or separately.

Detailed ways of administration have been taken from Madrid Declaration on Ozone Therapy (3rd edition, 2020).

Press the button 

, you select the mode ***Ozone taking***

To this group, there belong the following modes:
1. taking for IM (**I**ntra**M**uscular administration)
2. taking for R/V Ins. (**R**ectal /**V**aginal **Ins**uflation)
3. preparation of bag
4. bag filling
5. disposal of the bag
6. saturation of liquids

Press the button 

, you select the mode ***Auto Hemotherapy***

To this group, there belong the following modes:
1. taking of blood
2. blood saturation
3. blood reinfusion

9.5. OZONE ADMINISTRATION MODES

9.5.1. TAKING FOR IM (INTRAMUSCULAR ADMINISTRATION) / INTRADISC TREATMENT

1) Intramuscular administration

Required consumables:
- Set for i.m. administration

It is used for filling of injection syringe with a mixture of $O_3 + O_2$.

Intramuscular administration (Minor autohemotherapy) is an immune stimulant therapy, comparable to “auto-vaccination”.

Method: 5 mL of blood is removed intravenously and collected into a 20 mL disposable syringe prefilled with the same amount of ozone-oxygen mixture (5 mL). Intensively shake for 30 s and slowly inject intramuscularly along with the gas.

Cycles: 5-10 treatments once a week.

2) Intradiscal Treatment

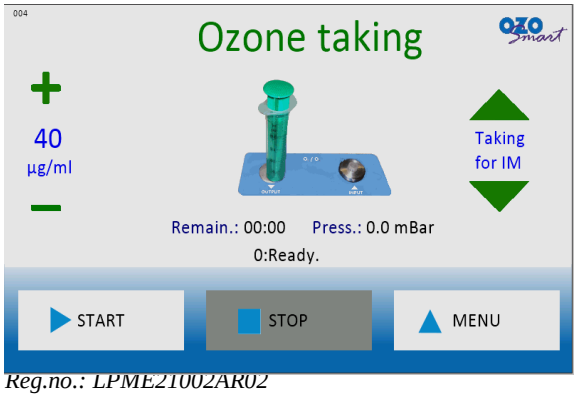
Required consumables:
- Set for intradiscal administration

In general, only one intradiscal infiltration should be performed under the mobile radiologic arch or fluoroscopic control or CT. The patient has to be under sedation (not general anesthesia) and with an antibiotic prophylactic therapy on the same day of the procedure. In some cases, the intradiscal infiltration can be repeated within (2-4) weeks.

For lumbar discolysis, a (5-10) mL mixture of oxygen-ozone at a concentration of (25-35) µg/mL is used. All animal models have shown annulus disruption secondary to concentrations of 50 µg/mL or greater, so it is advisable not to use concentrations over 40 µg/mL. The needle used is Chiba 25G x 3 1/2 (0.5 x 90) or 22G (0.7 x 203) mm.

For cervical discolysis, (2-3) mL with ozone at a concentration of (25-35) µg/mL is used. The needle used is Chiba 25G x 11/2” (0.5 X 40 mm).

The discolysis with ozone, although effective after only one treatment, requires specific infrastructure (for radiological control), an anesthetist and experienced personnel in the execution of the technique. Even though the paravertebral technique requires more sessions, it is equally effective and has a minimum level of risk.



The ozone taking mode ***screens no.:004***

Mode **Taking for IM** will be selected by repeated click on the button ▲ or ▼

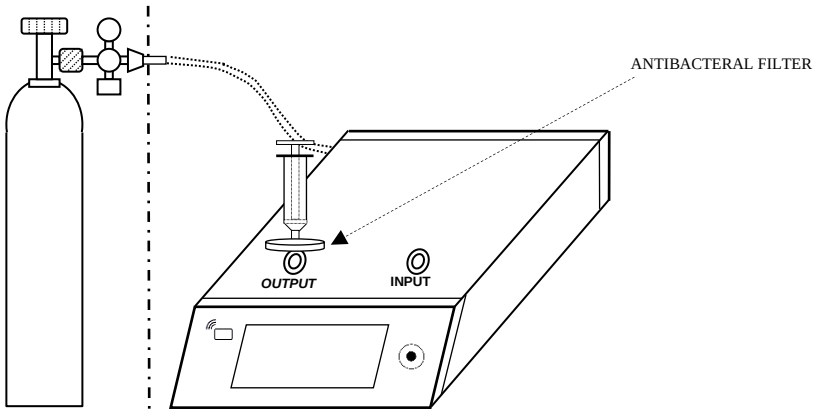
ZAT a.s., K Podlesí 541, 261 01 Příbram VI, CZ
e-mail: zat@zat.cz; tel.: +420 318 652 111

Press the buttons + and −, you set up the required ozone concentration in the taken mixture Ozone concentration can be selected in the scope 1 ÷ 80 µg O_3 / ml $O_3 + O_2$ in pre-set steps.

Pres the buttons ▲ and ▼, you select the further mode of ozone taking.

Press the button STOP, and you select ***standstill***.

The syringe with the piston in the lower position with a bacteriologic filter is to be inserted with a slight press with simultaneous rotating into the taking flange ***OUTPUT*** on the upper surface of the basic unit.



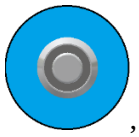
Start the mode to be opened by pressing the button START
The activity is indicated by a record of events in the lower part of the display above the button STOP

- Input pressure of oxygen inlet is checked
- The device is rinsed with ozone and ozone concentration in the mixture is stabilized

Filling of syringe with ozone

Beeping and blinking button (for 15 sec) gives signal that during this time it is possible to start filling of syringe with ozone **by pressing and permanent holding** of the button

- From the syringe, there is sucked remaining air and then it is filled in with ozone of the setup concentration (for max. 2 min). Pressure in the syringe is shown with the description „*Pressure:*“

– By loosening the button  , the filling of the syringe is terminated and there is started equalizing of pressure in the mixture in the syringe with its measurement.

– The equalizing of pressure is indicated in the record of events: "*Equalizing of pressure*"

– Termination of the equalizing is indicated in the record of events: "*Switched off*"

Filled in a syringe is possible to be removed from taking flange by a slight pulling with simultaneous rotation.
Subsequently, the syringe is to be held with a hole (needle) upwards before administration.

The mode can be terminated with the 

button

Or with a statement of **some error states:**

Defect no.	**Statement of error states**	**Possible cause – elimination**
2001	Pressure is lower than 500mBar!	The main oxygen valve is closed – check whether there is sufficient pressure in the main inlet.
2002	The ozone generator has not started!	Ozone generator does not work – contact service
2003	The ozone generator has not started!	Ozone generator does not work – contact service
2004	The ozone generator has not started!	Ozone generator does not work – contact service
2005	The ozone disposal device has not started!	Ozone disposal device does not work - contact service
2006	The ozone generator has started!	The ozone generator does not work correctly – contact service
2007	The ozone disposal device has not started!	Ozone disposal device does not work - contact service
2008	It has not succeeded to suck out!	OUTPUT flange is leaking – syringe with a filter to be inserted
2009	The ozone generator has not started!	Ozone generator does not work – contact service
2010	It has not succeeded to fill in!	Time of taking (filling of the syringe) lasts longer than 120 seconds

9.5.2.TAKING R/V INS. (RECTAL /VAGINAL INSUFFLATION)

It is used for rectal and vaginal administration of mixtures $O_2 + O_3$.

1) Rectal Insufflation

Required consumable material:

– Set for rectal insufflation

The Rectal insufflation of ozone is a systemic route. The gas is quickly dissolved in the luminal contents of the bowel, where mucoproteins and other secretory products with antioxidant activity readily react with ozone to produce reactive oxygen species (ROS) and lipid peroxidation products. These compounds penetrate the muscular mucosa and enter the circulation of venous and lymphatic capillaries. This non-invasive technique can be used without risk in pediatric and elderly patients, and in patients with difficult access to veins for MAH. Generally, this is well tolerated and allows scaling doses similar to those used by MAH.

In chronic illnesses, the proper dosage of medical ozone produces temporary oxidative stress tolerance, so patients require repeated cycles of ozone therapy (20 sessions one/daily, constituting one cycle). It is recommended to increase the dose in each consecutive cycle, repeated at a 3 to the 4-month interval in the first year. If there are more than six months between each cycle, doses must be the same as in the first cycle. Beneficial results are reported following rectal dosing (low, middle, and upper middle doses). High doses will only be used after two cycles of ozone therapy with an interval of three months each.

The range of concentration is 10–35 µg/ml.

The range of volume is 100–200 ml.

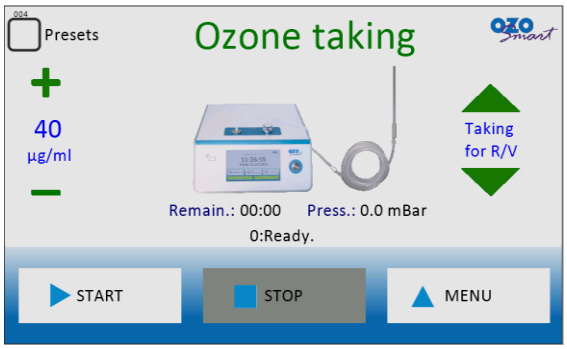
Concentrations higher than 40 µg/ml can hurt the enterocyte.

2) Vaginal Insufflation

Required consumable material:

– Set for vaginal insufflation

Ozone concentrations of (10-30) µg/ml and a volume between (1-2) L at a continuous flow rate of 0.1 L/min to 0.2 L/min for 10 min are used. A vaginal wash with ozonized water must be carried out previously. After application, the use of a lubricating gel is recommended due to the drying effect of ozone in the mucous membrane.

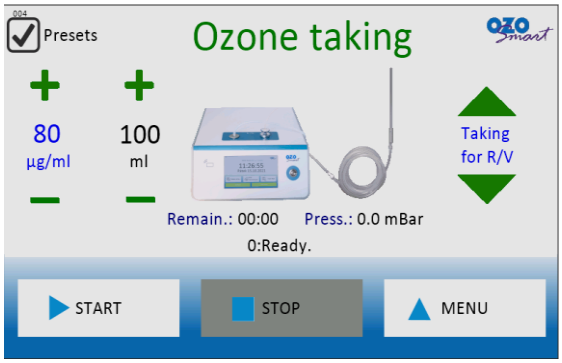


Mode for taking of ozone ***screen no.:004***

Select the mode **Taking for R/V** by repeatedly pressing the button, ▲ or ▼

Press the buttons + and − **µg / ml,** you set up the required ozone concentration in the taken mixture.

Ozone concentration can be selected in the scope of 1 ÷ 80 µg O_3 / ml O_3 + O_2 in the pre-set steps.



Press the button ☑ ***Presets,*** you choose or eliminate the possibility to measure the taken amount

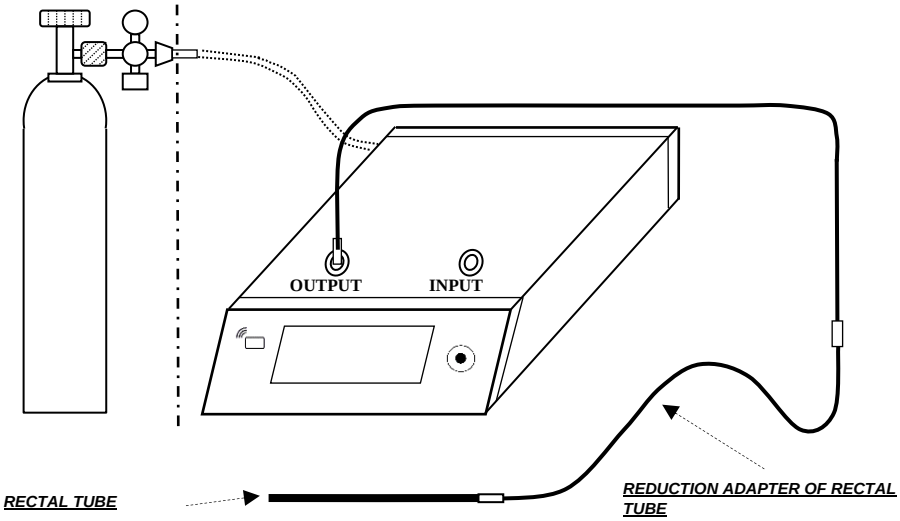
Press the buttons + and − **ml,** set up the required amount of taken mixture. The amount can be chosen in the scope of 100 ÷ 3000 ml in the pre-set steps.

In case there is no selected amount of the taken mixture, you can determine the taken amount by the time taking duration.
The flow rate is constant at 200 ml/min.

Press the button ▲ or ▼ , you select further from ozone-taking modes.

Button STOP selects ***standstill***.

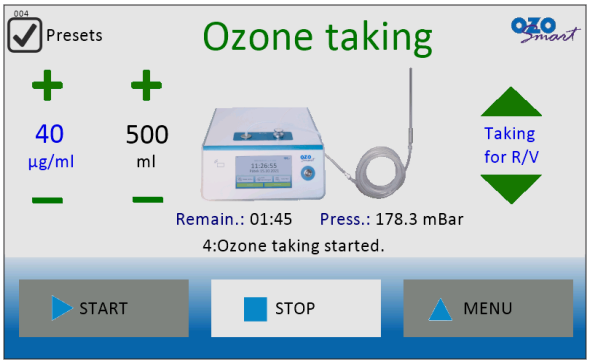
End of the tube to be inserted with slight pressure with simultaneous rotating into the taking flange **OUTPUT.**
End of the tube of reduction adapter to be connected to the rectal tube. Application end of the rectal tube to be inserted in rectum or vagina according to a requirement for administration.



You start the mode by pressing the button 

The activity is indicated by a record of events in the lower part of the display above the button STOP

- There is checked input pressure of oxygen inlet
- The device is rinsed with ozone and ozone concentration in the mixture is stabilized



Start and course of administration is signalized in an acoustic way.

There is 1 minute and 45 seconds remaning till end of taking

Pressure at taking is + 178.3 mBar (overpressure)

Note.
In case the value of time is getting lower, there is a measured required amount of taken mixture (indicated period till the end of taking).
In case the value of time is getting higher, there is not required the taking the pre-set amount of mixture (indicated total time of taking).

Taking can be ended with the button 

or with a notification:

Completed – there was taken the required amount of mixture or taking lasts longer than 30 minutes
STOP! temperature - working temperature of device exceeded

Or with some of the error states:

Defect no.	Description of defect	Possible cause - elimination
3001	Pressure is lower than 500 mBar!	The main oxygen valve is closed – check whether there is sufficient pressure in the main inlet.
3002	Pressure is higher than 250 mBar!	Pressure at the taking of mixture is higher than + 250 mBar
3003	The ozone generator has not started!	The ozone generator does not work well - contact service
3004	The ozone disposal device has not started!	Ozone disposal device does not work - contact service
3005	Pressure is higher than 250 mBar!	
3006	The ozone disposal device has not started!	Ozone disposal device does not work - contact service

9.5.3.PREPARATION OF BAG

It is used for emptying the bag before administration of mixture $O_2 + O_3$.

Required consumable material:

– Set for vacuum therapy

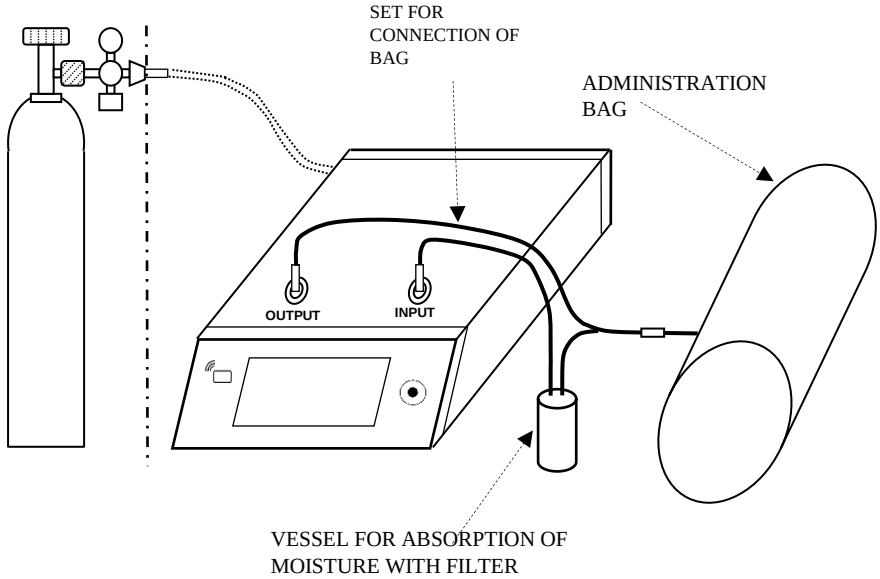
Concentrations range of 5 – 40 µg/ml are used for periods of 20, 10, and 5 min, depending on the stage and evolution of the wound. Once the infection is controlled and the healthy granulation tissue appears, the frequency and concentration of the procedure have to be reduced to accelerate and induce the healing process.

Note: It is necessary to moisten the area and to remove all the air from the bag by vacuum before insufflating the gas into the bag. At the end of the procedure, the remaining ozone gas must be suctioned before removing the bag.

Ozone taking mode ***screen no. :004***

Mode ***Prepare bag*** to be selected by repeated clicking on the button or

In the administration bag, insert a limb that you will apply the ozone mixture on, and close the bag using the cuff. Connect the administration bag using connecting set and a vessel for absorption of moisture.



Preparation of bag to be started by pressing the button START

The activity is indicated by a record of events in the lower part of the display above the button STOP.

Preparation of bag has started

Bag is being emptied with pressure **–121.3 mBar** (underpressure)

There is 3 minutes 49 seconds remaining till automated termination

The mode can be ended with a STOP button if the bag is empty or with some of these error states:

The ozone disposal device has not started! – ozone disposal device does not work

STOP ! ***temperature –*** working temperature of device exceeded

Has not succeeded to suck out! – preparation of bag lasts longer than 4 minutes

Pressure is higher than -500 mBar!- pressure in the bag is lower than -500 mBar (under pressure)

Impurities in retaining vessel – retaining vessel at the ***INPUT*** is contaminated (must be cleaned, there could occur contamination of the device)

9.5.4.FILLING OF BAG

It is used for the application of a mixture of O_2 + O_3 in the bag. It immediately follows the mode „ ***prepare bag*** “.

Select the mode by repeated click on the button or

Press the buttons and **µg / ml** and set up required ozone concentration in the taken mixture.

Ozone concentration can be selected in the scope of 5 ÷ 40 µg O_3 / ml O_3 + O_2 in pre-set steps.

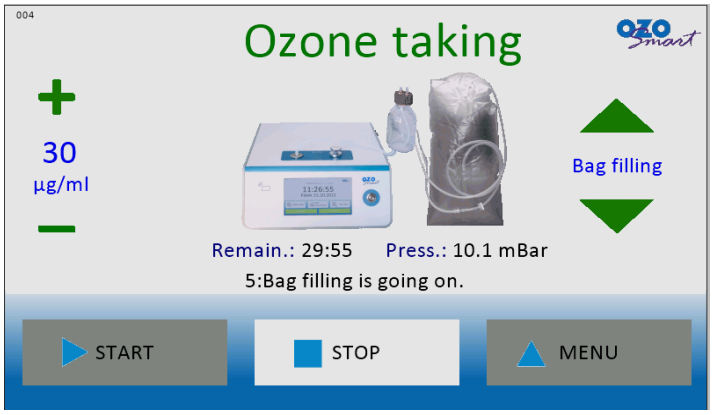
Press the buttons and , you select further from the ozone-taking modes.

Button STOP selects ***standstill***.

The filling of the bag with the mixture O_3 + O_2 is started by pressing the button START

The activity is indicated by a record of events in the lower part of the display above the button STOP

There is checked input pressure of oxygen inlet
The flow rate is constant at 800 ml/min.
The device is rinsed with ozone, and ozone concentration in the mixture is stabilized



Signalization of start of bag filling

There are 29 minutes and 55 seconds remaining till completion

Pressure during filling is + 10.1 mBar (overpressure)

The mode can be terminated by clicking on the button 

or by some of the error states:

Pressure is lower than 500mBar! – medicinal oxygen from the pressure vessel has not had sufficient pressure

Pressure is higher than 250 mBar! – pressure at the taking of mixture is higher than + 250 mBar
The ozone generator has not started! – ozone generator does not work

The ozone disposal device has not started! – ozone disposal device does not work

STOP ! temperature – working temperature of the device exceeded

Completed – during the taking of a dose, there has been taken required amount of mixture

Not succeeded to fill – taking lasts longer than 30 minutes

9.5.5.DISPOSAL OF BAG

It is used for the disposal of mixture O_2 + O_3 in the bag after administration.
It immediately follows the mode "***bag filling***".

The mode ***Disposal of the bag*** to be selected by repeated click on the button ▲ or ▼

The button STOP selects ***standstill***.

Disposal of the content of the bag is started by clicking on the button START

The activity is indicated by a record of events in the lower part of the display above the button STOP

Bag is emptied with the pressure – 121.4 mBar (underpressure)

There are 3 minutes and 56 seconds till completion of suction

The mode can also be terminated by the button STOP, in case the bag is empty, or by some of the error states:

The ozone disposal device has not started! – the ozone disposal device does not work, observe safety instructions see p. 10

STOP ! ***temperature*** **–** working temperature of the device exceeded

Not succeeded to suck out! – disposal of bag lasts longer than 4 minutes

Pressure is higher than -500 mBar!- pressure in bag is lower than -500 mBar (under pressure)

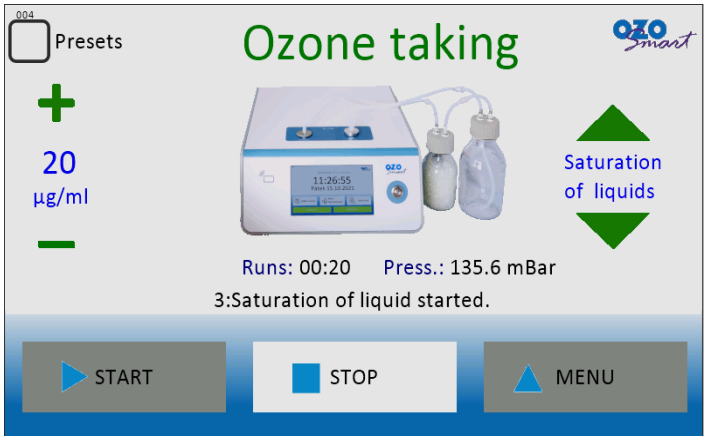
Impurities in retaining vessel ⚠ – retaining vessel in ***INPUT*** is contaminated (must be cleaned – see chapter 10.1.1., there could occur contamination of the device)

9.5.6.SATURATION OF LIQUIDS – WATER SATURATION

Required consumable material:

– Set for ozonation of liquids

The preparation of ozone in water is carried out by using a glass cylinder, filled about ¾ with bi-distilled water through which the gas mixture has to be bubbled continuously for at least (5–10) min to achieve saturation. The unused ozone flows out via silicone tubing into a destructor and is converted to oxygen.



Signalization of start of application

Water saturation just run for 20 seconds

Pressure during saturation is + 135.6 mBar (overpressure)

Buttons + and − **µg / ml** set up a required ozone concentration in the taken mixture.
Ozone concentration can be selected in the scope of 1 ÷ 80 µg O_3 / ml $O_3 + O_2$ in the preset steps.

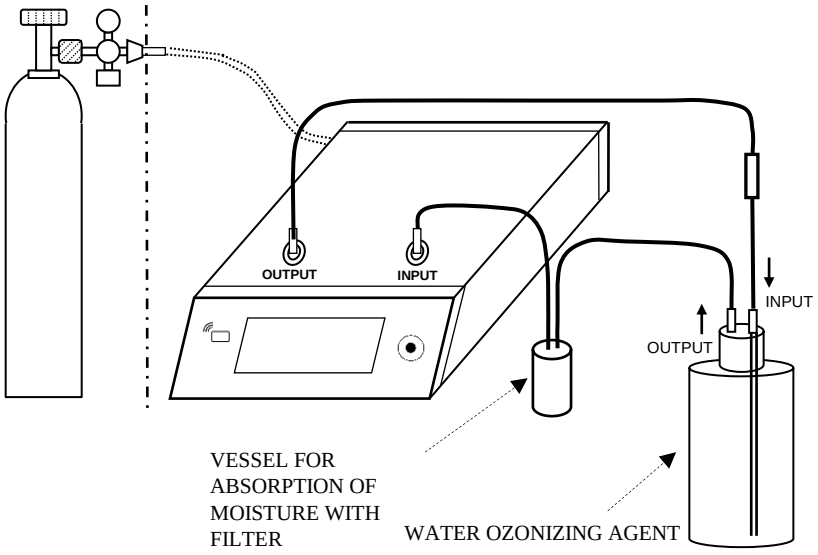
Buttons + and − **ml** set up a required amount of taken mixture. The amount can be selected in the scope of 100 ÷ 3000 ml in preset steps.

In case there is not selected an amount of taken mixture, you determine a taken amount from the duration time of the taking.
The flow rate is constant at 200 ml/min.

Buttons ▲ and ▼ select further from the modes of ozone taking.

Button STOP selects ***standstill.***

Connect a set for water ozonation and vessels for absorption of moisture according to the picture. End of the hose to be inserted with slight pressure in the taking flange ***OUTPUT*** with simultaneous rotation.



Ozonizing agent to be filled with distilled water max. 0,9 l.

Attention!

Inspection before the beginning of administration:

In the retaining vessel for absorption of moisture, there cannot be any liquid!

Start the ozonation of water by clicking on the button 

The activity is indicated by a record of events in the lower part of the display above the button STOP

The device is rinsed with ozone, and ozone concentration in the mixture is stabilized

Note.
In case the value of time is lowered, the required amount of taken mixture is measured – there is indicated a period till completion of the taking.
In case the value of time is increasing, there is no required taking of a pre-set amount of mixture – there is indicated a total time of taking.

Saturation can be terminated by clicking on the button 

by the completion of taking a selected dose or some of the error states:

Pressure is lower than 500mBar! – medicinal oxygen from the pressure vessel has not had sufficient pressure

Pressure is higher than 250 mBar! – pressure at the taking of mixture is higher than + 250 mBar

The ozone generator has not started! – ozone generator does not work

The ozone disposal device has not started! – ozone disposal device does not work

STOP ! temperature – working temperature of the device exceeded

Completed – there has been taken the required amount of mixture at dose taking

Not succeeded to fill – taking lasts more than 30 minutes of the selected amount of mixture or the taking lasts longer than 30 minutes

Impurities in retaining vessel  – retaining vessel at ***INPUT*** is contaminated (must be cleaned, there could occur contamination of the device)

Attention!

Saturation of the solutions different from the ones recommended in the instructions for use can lead to damage to the device or injury to maintenance staff.

9.5.7.SATURATION OF LIQUIDS – SATURATION OF SPECIAL SOLUTIONS

It is used for the production of saturated special solutions.

Required consumable material:

- Set for ozonation of special solutions

The solution is saturated for 10 minutes and requires fast transfusion because of a drop in concentration in the time course.

The recommended dose of ozone:
The ozonized saline solution is carried out with very low ozone concentrations which are calculated according to the weight of the patient.
Low ozone dose: 1 µg/kg.
Medium ozone dose: 2 µg/kg.
High ozone dose: 5 µg/kg.

Dose Formula:
Dose (µg) = dissolved ozone concentration (µg/mL) · Volume (mL) saline solution.
Example: Patient's weight = 80 kg; Saline solution volume = 200 mL.

Low ozone dose:
1 µg/kg * 80 kg= 80 µg.
80 = ozone gas concentration * 25% * 200
Dissolved ozone concentration in saline solution=0.4 µg/L.
Ozone concentration to mark from the generator = 1.6 µg/L.

Medium ozone dose 2 µg/kg:
2 µg/kg * 80 kg= 160 µg.
160 = ozone gas concentration * 25% * 200
Dissolved ozone concentration in saline solution=0.8 µg/L.
Ozone concentration to mark from the generator = 3.2 µg/L.

High ozone dose 5 µg/kg:
5 µg/kg * 80 kg= 400 µg.
400 = ozone gas concentration * 25% * 200
Dissolved ozone concentration in saline solution=2 µg/L.
Ozone concentration to mark from the generator = 8 µg/L.

The upper limit of the concentration of ozone in the ozonized saline solution is 2 µg/L; exceeding this limit is dangerous and can cause phlebitis. The exceptional cases are severe sepsis and severe viral infections. In such cases, the concentrations may be increased up to 5µg/L to 8 µg/L

Note: The volume of saline solution used for one procedure is (200-400) mL. The number of procedures for one cycle of treatment is 6 to 10. Procedures are conducted daily or every other day.

Mode ***Saturation of liquids*** to be selected by repeated click on the button ▲ or ▼

With the button ☑ ***Presets,*** you select or cancel the possibility to measure the taken amount

With the buttons + and − **µg / ml,** you set up the required ozone concentration in the taken mixture.
Ozone concentration can be selected within 1 ÷ 80 µg O_3 / ml $O_3 + O_2$ in pre-set steps.

With the buttons + and − **ml,** you set up the required amount of taken mixture. The amount can be selected within 100 ÷ 3000 ml in pre-set steps.

In case there is no selected amount of taken mixture, the taken amount is to be determined from the time of duration of taking.
The flow rate is constant at 200 ml/min.

With the buttons ▲ and ▼, you select further from the modes of ozone taking.

With the button ■ STOP, you select ***standstill.***

We connect a set of hoses for the ozonation of special solutions to the vessel for absorption of moisture according to the picture.

Attention! Pay attention to the correct connection of injection needles **0,9x25mm** (yellow) and **0,8x120mm** (green) to identically marked hoses. The needles are to be inserted into a bottle of infusion solution.

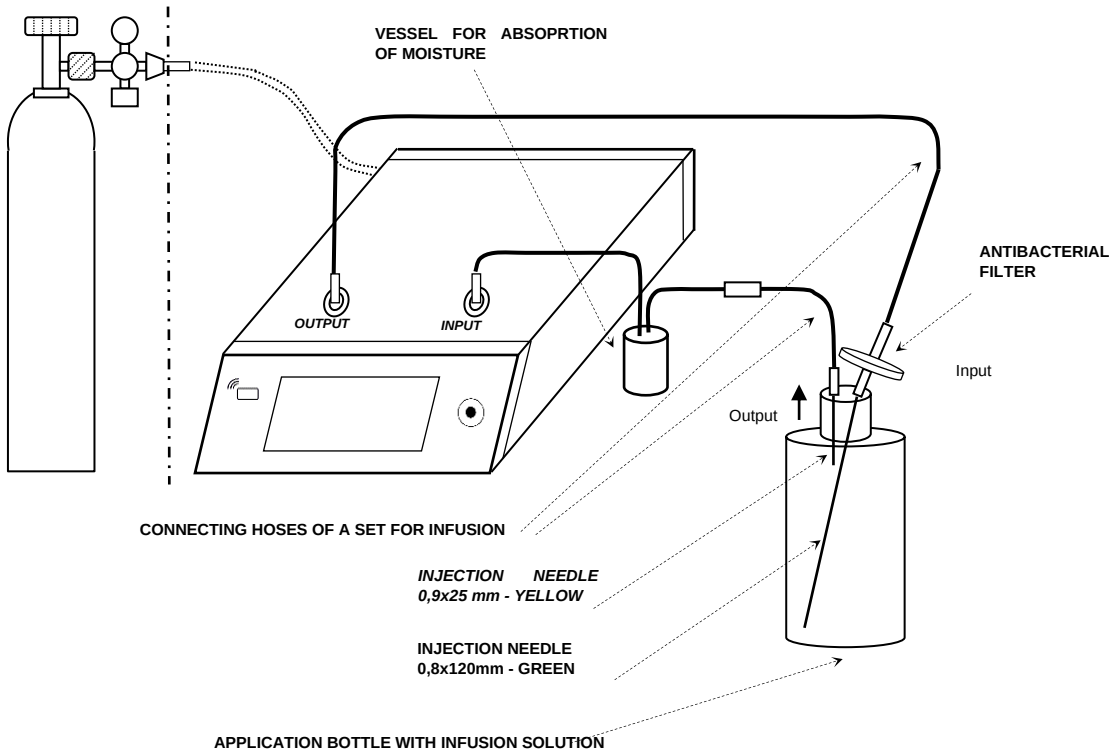
NOTE.

Special solutions, the best 250ml in glass bottles to be applied.

Attention!

Inspection before the beginning of administration:

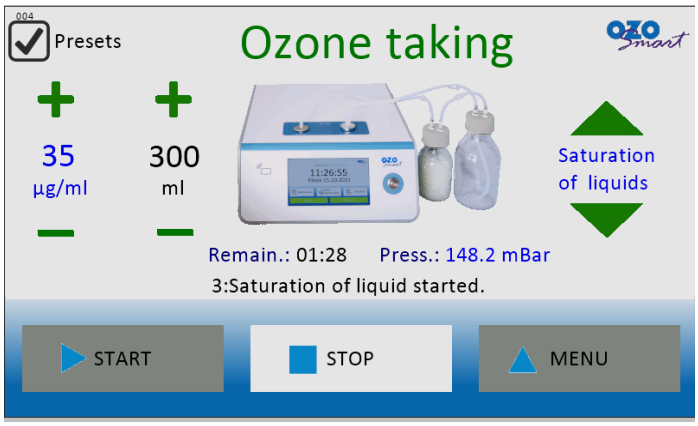
In the retaining vessel and vessel for absorption of moisture, there cannot be any liquid!



Start ozonation with a click on the button 

The activity is indicated by a record of events in the lower part of the display above the button STOP

The device is rinsed with ozone, and ozone concentration in the mixture is stabilized



Signalization of beginning of application ***Saturation of liquids***

There are 1 minute and 28 seconds remaining till completion of saturation

Pressure at taking is + 148.2 mBar (overpressure)

Note.
In case the value of time is lowered, there is a measured required amount of taken mixture – there is indicated time till termination of taking.
In case the value of time is increasing, there is no required the taking of pre-set amount of mixture – there is indicated total time of taking.

Saturation can be terminated by clicking on the button 

By the completion of taking of selected dose or some of the error states:

Pressure is lower than 500mBar! – medicinal oxygen from the pressure vessel has not had sufficient pressure

Pressure is higher than 250 mBar! – pressure at the taking of mixture is higher than + 250 mBar

The ozone generator has not started! – ozone generator does not work

The ozone disposal device has not started! – ozone disposal device does not work

STOP ! temperature – working temperature of the device exceeded

Completed – the required amount of mixture has been taken at taking of dose

Not succeeded to fill – the selected amount of mixture or taking lasts longer than 30 minutes

Impurities in retaining vessel  – retaining vessel at ***INPUT*** is contaminated (must be cleaned, there could occur contamination of the device)

NOTE.
After completion of saturation of liquids, there is performed ***Rinsing –*** rinsing of infusion solution and bottle of clear oxygen with measurement of pressure.
Rinsing is indicated by a record of events in the lower part of the display above the button STOP

Attention!

Saturation of the solutions different from the ones recommended in the instructions for use can lead to damage to the device or injury to maintenance staff.

9.6. AUTOHEMOTHERAPY MODES

THIS INSTRUCTION FOR USE TO BE CAREFULLY STUDIED BEFORE APPLICATION!

Required consumable material:

- Set for major autohemotherapy

The amount of blood to be used is between 50 ml and 100 ml. In case of an amount of blood higher than 200 ml, it is necessary to avoid any risk of hemodynamic disturbance, especially in cases of elderly and unbalanced patients.

The scale of taking safe blood is as follows: 1.2 ml/kg - 1.3 ml/kg. E.g.: a person with 85 kg; 1.2 • 85 = 102 ml of taken blood.

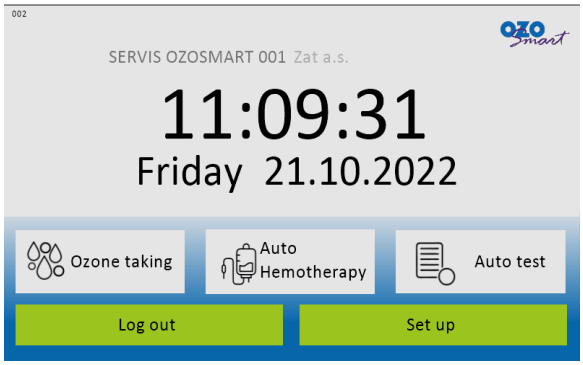
Perfusion set: Plastic equipment intended for retaining blood must observe ČSN EN ISO 15747 (856207) (European Union regulation). All vessels and equipment applied during ozone therapy must be resistant to ozone and cannot release phthalates as these particles are toxic to the organism. Due to this reason, it is more suitable to use glass for Major autohemotherapy. Plastic bags for Major autohemotherapy must be resistant to ozone and certified for blood collection from the side of the EU or FDA. There are not permissible any other modifications to perform transfusion of ozonized blood.

Ozone concentrations for a system application are between 10 μg/ml up to 40 μg/ml, the concentration of 70 μg/ ml and higher should not be applied due to increased risk of hemolysis, reduction of DPG and antioxidants, and subsequent inability of immune cells activation.

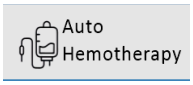
Anticoagulant: the most suitable to be applied is ACD-A Anticoagulant citrate dextrose Solution A, USP (2.13% free citrate ions) or Citrate sodium 3.8% 10 ml for every 100 ml of blood. Heparin is not suitable because it can evoke thrombocytopenia and aggregation of blood platelets, and Citrate sodium chelate calcium. The amount of ACD-A is between 7 ml and -10 ml for every 100 ml of blood.

Frequency of treatment: The number of treatment sessions and ozone dose applications will depend on the total state of a patient, his/her age, and the main disease. As a general rule there applies that ozone is increased every five sessions and this is administered in cycles the number of which between 15 and 20. From a medical point of view, the patient's improvement is shown between the fifth and tenth sessions, and there is assumed that after the twelfth session there has already been an activated antioxidation protective mechanism. Treatment is performed daily from Monday to Friday.

It also can be applied twice or three times a week. Cycles can repeat each 5-6 months.

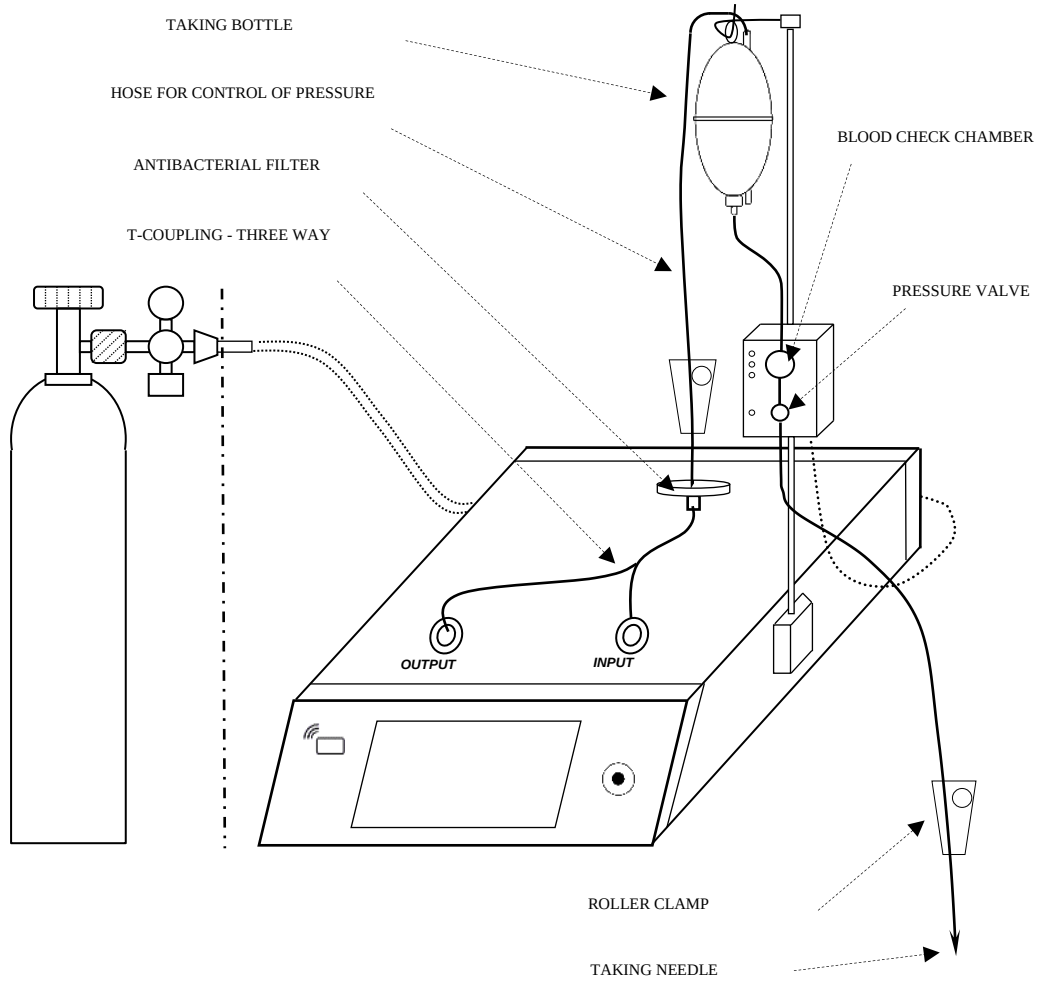


Selection of the Autohemotherapy mode is performed from ***Main screen no. :002***

with the button 

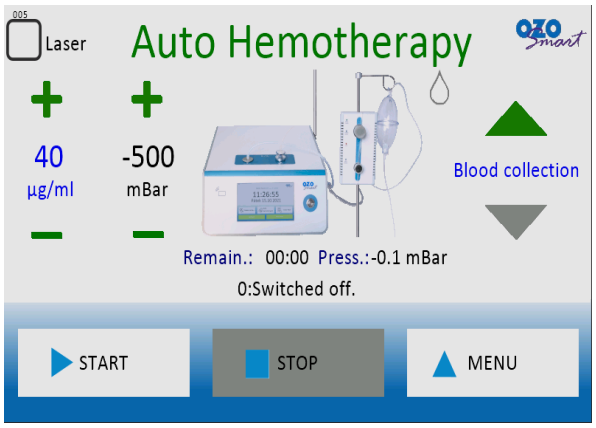
NOTE:

- In case the Blocking unit has not been connected before start of ***Autotest,*** the ***Auto Hemotherapy*** mode is not accessible.



Preparation:
An agent against blood coagulation is to be applied in a special taking bottle.
Connecting hose to be connected to flange **OUTPUT** and **INPUT**
End of the hose for control of pressure to be connected through an antibacterial filter to a connecting hose**,** its second end with the needle to be stuck in a hose of taking the bottle. The hose of transfusion set for blood taking is to be closed near the taking needle with a roller clamp. Taking bottle with transfusion set to be hung on a holder.
The hose of transfusion is set to be put in a blood check chamber (indication of cover closing check) and clamp (pressure valve) on a blocking unit.

9.6.1.BLOOD TAKING



Auto Hemotherapy mode screen no. :005

Mode ***Blood collection***

Is selected by click on the button or

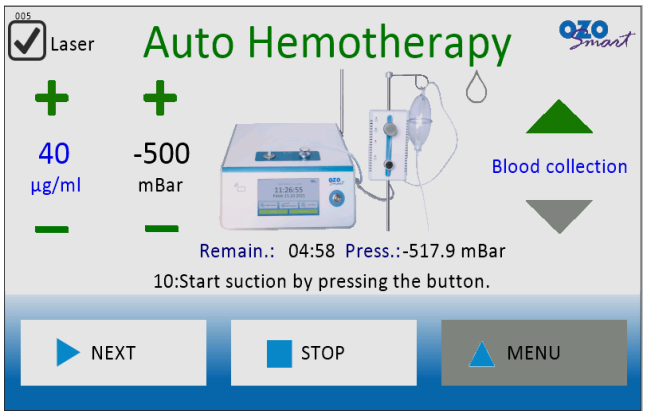
Pre-set concentration 40 µg / ml and underpressure -500 mBar

With the buttons + and − **µg / ml** you set up the required concentration of the mixture for blood saturation.
Ozone concentration can be selected within 1 ÷ 60 µg O_3 / ml $O_3 + O_2$ in pre-set steps.

With the buttons + and − **mBar** select required under pressure in taking the vessel
The under pressure can be selected within - 150 ÷ - 500 mBar.

With the button ☑ ***Laser*** you switch on / off the laser for blood radiation.

Button START starts taking of blood (creating under pressure)



Blood collection

☑ Laser radiation of blood at taking has started

Pre-set concentration 40 µg / ml

Current underpressure is -517.9 mBar

there has not been detected blood in the blood sensor chamber in hose

In case there has been selected ozone concentration for blood saturation, insert a needle for taking venous blood and start taking blood.

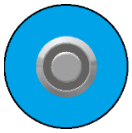
The activity is indicated by a record of events in the lower part of the display above the button STOP.

Operation of laser is indicated by whistling and blinking of an indication on blocking unit. There occurs ***opening of clamp*** on the blocking unit (indication is shining) and start of equalizing of required working under pressure.

There is pre-set under pressure -500 mBar at the first start of blood taking.

Release roller clamp on the taking hose.

There occur termination of pressure equalization at achieving required under pressure.

With the button  you start possible repeated suction that creates pre-set under pressure in the taking bottle. By the repeated click of the button during suction, it is possible to terminate pressure equalization.

With the button 

you select ***standstill***.

Other keys of mode selection are inefficient.

With the buttons  and you change required under pressure in taking bottle according to the immediate taking situation.

NOTE:
In case of pressure in the taking bottle is not equalized within 60 seconds up to the required value, suction is terminated.
There will not occur interruption or termination of blood taking.

In case of a defect of the radiation laser, the maintenance staff is notified by an error announcement.
Laser error
There will not occur interruption or termination of blood taking.

In case of an increase in the temperature of the device, the maintenance staff is notified by an error announcement.
Error Temperature
There will not occur interruption or termination of blood taking.

Termination of the mode of ***blood taking*** can be performed in two ways the motion of blood in transfusion set and in taking needle.

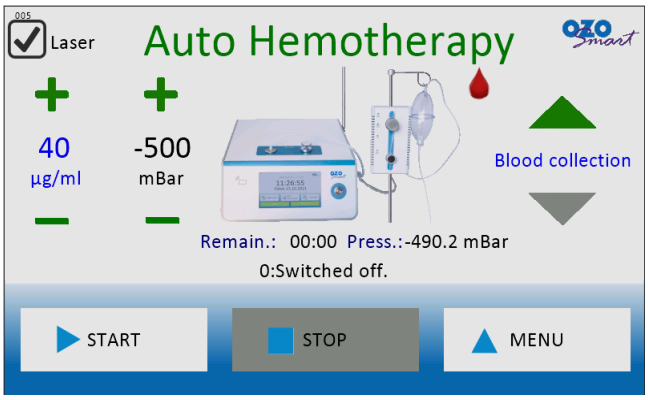
The first possibility of termination of the mode of ***Blood taking*** **without stopping of blood motion – *uninterrupted blood mode.***

With the button 

you get to the ongoing mode of blood saturation

The second possibility of termination of the mode of ***Blood taking*** **with the stopping of blood motion** – is ***interrupted blood mode.***

Taking of blood to be terminated by clicking on the button 



Taking of blood is interrupted

there has already been detected blood in the blood sensor chamber in the hose

There will occur closing of the clamp of the taking hose on the blocking unit and switching off the laser.

Taking of blood can be interrupted by an error state:

The ozone disposal device has not started! – ozone disposal device does not work

STOP! ***Temperature*** **–** working temperature of the device exceeded

Impurities in retaining vessel – retaining vessel at ***INPUT*** is contaminated
– (it must be cleaned, there could occur contamination of the device)

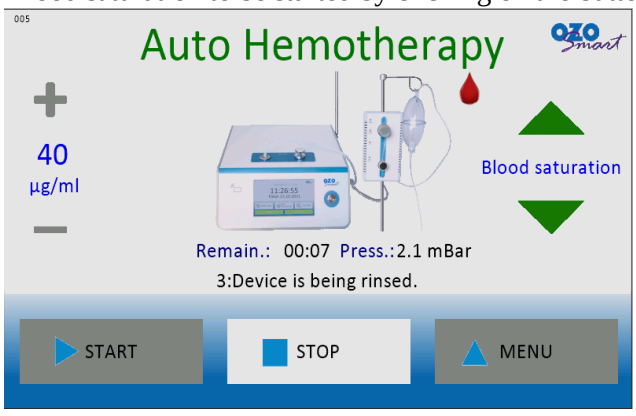
9.6.2.BLOOD SATURATION

The mode to be selected only from the mode of blood taking by clicking on the button
- in case the ***selection has been performed at ongoing blood taking*** (uninterrupted blood mode), there is selected, and started the mode of blood saturation is by clicking on the button NEXT

The clamp on the blocking unit remains open.

- in case the ***selection has been performed at not ongoing blood taking*** (interrupted blood mode), you select the mode of blood saturation.

Blood saturation to be started by clicking on the button START

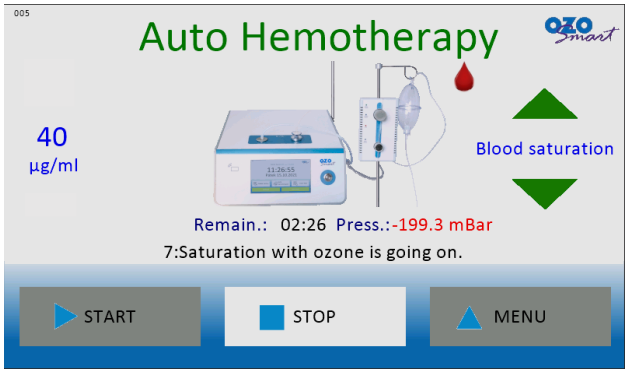


The device is rinsed with ozone.

Ozone mixtur eis stabilized.

Overpressure will be 200 mBar for filling with the mixture O3 + O2
(not possible to be selected)

The activity is indicated by a record of events in the lower part of the display above the button STOP



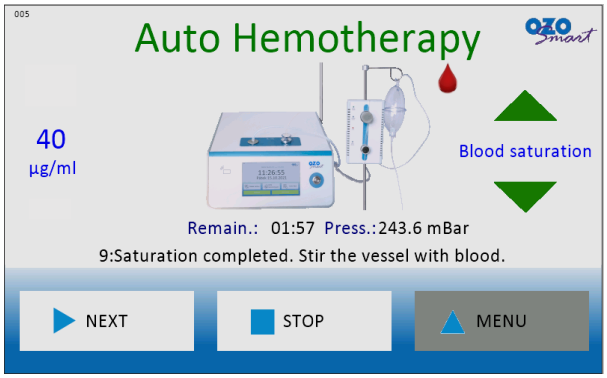
Current underpressure is -199.3 mBar

Ozone concentration at saturation is 40 g/ml (it has already been selected in the previous step of blood taking)

There is going on filling of taking bottle with the mixture O3 + O2 up to the overpressure of 200 mBar

In case there is achieved an initial state (overpressure 200 mBar) within 25 seconds, the operation staff is notified through an error state ***Not succeeded to pressurize!*** - ***There will occur interruption or termination of blood saturation.***

There is started filling of taking the bottle with the mixture $O_3 + O_2$.



There has been achieved overpressure of 200 mBar
Mix the vessel with blood for remaining time 1 minute and 57 seconds

In case of ozone, disposal does not work, the operation staff is notified through an error state: ***Ozone disposal device has not started!***
There will not occur interruption or termination of blood saturation.

In case there is not achieved overpressure of blood saturation (200 mBar) within 75 seconds, the operation staff is notified through an error state ***Not succeeded to pressurize!*** and there is shown the achieved overpressure.
There will not occur interruption or termination of blood saturation.

Note.
In case there is no achieved overpressure **Blood saturation** (200 mBar) within 150 seconds, the saturation is ***interrupted.***

Note.
Error states are not accumulated.

In case of an increase in the temperature of the device, the operation staff is notified through an error state **temperature**.
There will not occur interruption or termination of blood saturation.

The activity is indicated by a record of events in the lower part of the display above the button STOP.

Termination of the mode of ***blood saturation*** can be performed in two ways the motion of blood in transfusion set and taking a needle.

The first possibility is to terminate the mode of ***Blood saturation*** **without stopping the motion of blood** - not interrupting blood mode.

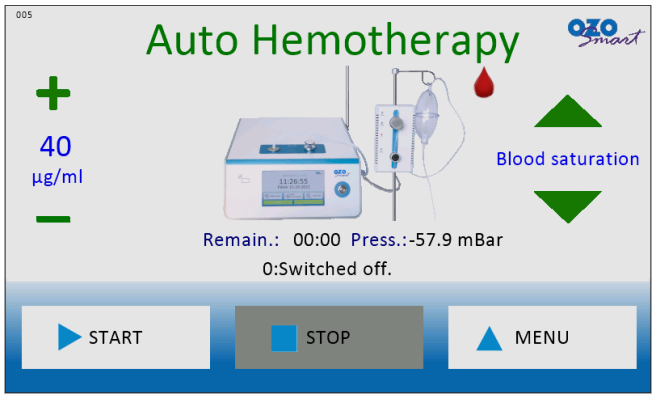
With the button 

, you go to the ongoing mode of blood reinfusion

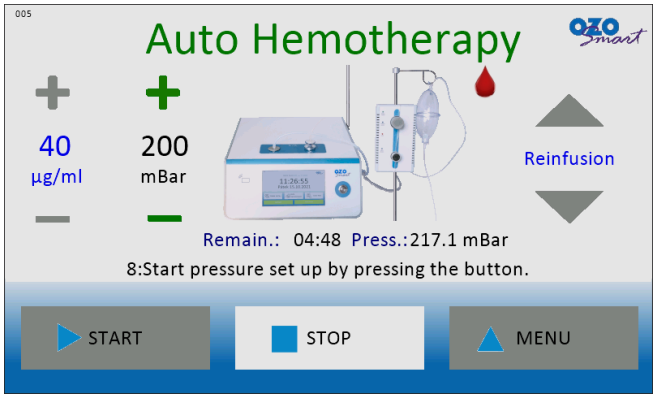
The second possibility is to terminate the mode of ***Blood saturation*** **with stopping motion of blood-** interrupted blood mode.

Blood saturation to be ***interrupted*** or ***terminated*** by clicking on the button 

There will occur closing of the taking clamp on the blocking unit in case it was open.



Blood saturation is ***interrupted*** with the possibility to repeat in case it was interrupted during setting of initial underpressure or filling of taking bottle with the mixture O_3 + O_2



Blood saturation is ***terminated with transfer to the mode Blood reinfusion*** in case it was interrupted during saturation (saturation time is subtracted)

Blood saturation can also be ***interrupted*** or ***terminated*** by an error state:

Pressure is lower than 500 mBar! - medicinal oxygen from the pressure bottle has not had sufficient pressure

Impurities in retaining vessel  **-** retaining vessel at ***INPUT*** is contaminated (must be cleaned, there could occur contamination of the device)

Not succeeded in pressurizing! - filling lasts longer than 150 seconds

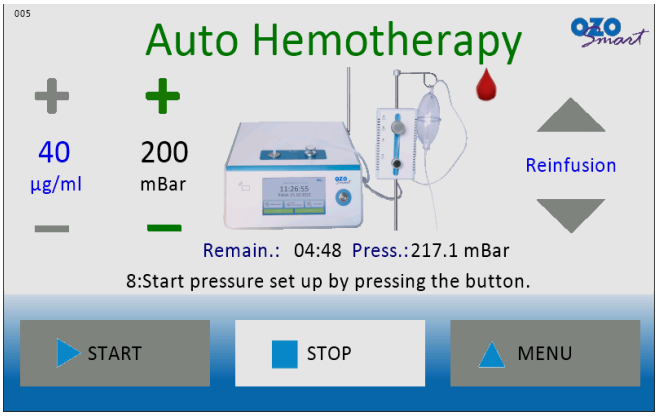
Not succeeded in pressurize in time! - blood saturation lasts longer than 120 seconds

Detected air in the hose! - in the taking hose of transfusion set, there is no blood

9.6.3 BLOOD REINFUSION

The mode to be selected only from the modes of blood saturation by clicking on the button 

- in case the ***selection has been made during ongoing blood saturation*** (uninterrupted blood mode), there is selected, and started the blood reinfusion mode.
  The clamp on the blocking unit remains open.



Required overpressure during reinfusion is set up at 200 mBar

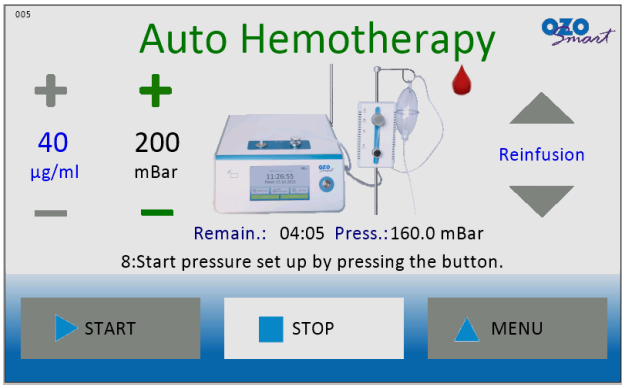
- in case the ***selection has been made during not-ongoing (interrupted) blood saturation*** (interrupted blood mode), there is selected the blood reinfusion mode.

Blood reinfusion, in case it was not started by a transfer from the blood saturation mode, to be started by clicking on the 

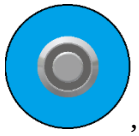
button

The activity is indicated by a record of events in the lower part of the display above the button STOP

There will occur an ***opening of the clamp*** on the blocking unit (indication shines) and equalization of required working overpressure.
At the first start of blood reinfusion, there is set up overpressure of 200 mBar.



- immediate pressure in taking bottle is 160.0 mBar
- required overpressure in taking bottle 200 mBar

With the button  , you start possible repeated equalization that creates a pre-set overpressure in taking a bottle. With a repeated click on the button, it is possible to terminate the pressure equalization.

With the buttons + and −, you change the required overpressure in taking the bottle according to the immediate situation of the ongoing reinfusion.
The overpressure can be selected within +50 ÷ + 500 mBar.

With the button , you only start pressure equalization.

In case the pressure in taking the bottle is balanced up to the required value within 45 seconds, the operating staff is notified through an error report: ***Not succeeded to pressurize in time!*** and the pressure equalization is terminated.
There will not occur interruption or termination of blood reinfusion.

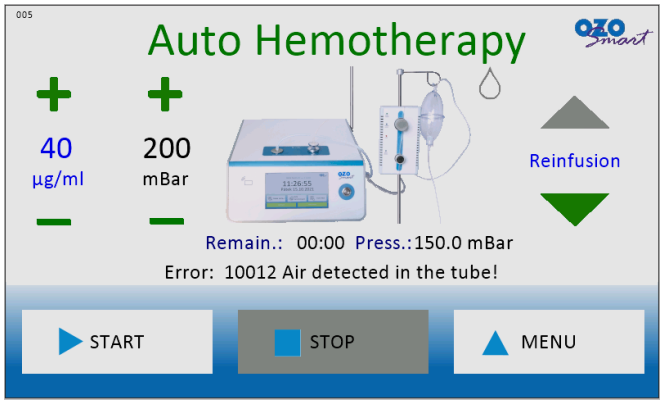
During an increase in temperature of the device, the operating staff is notified through an error report: **temperature**
There will not occur interruption or termination of blood reinfusion.

The activity is indicated by a record of events in the lower part of the display above the button STOP

You ***terminate*** blood reinfusion by a click on the button STOP

There will occur closing of the clamp – throttling of the taking hose on the blocking unit and cancellation of overpressure in the taking bottle.

NOTE
During the interruption of blood reinfusion, there is started equalization of overpressure in taking a bottle that is indicated by a record of events in the lower part of the display above the button STOP.



Reinfusion is terminated automatically by presence of air in the hose

Close the roller clamp on taking hose.
Remove the needle for blood taking and treat the patient after the needle mark.

Blood reinfusion can be interrupted by an error stat:

STOP! temperature – working temperature of the device exceeded

Impurities in  ***retaining vessel*** – retaining vessel at ***INPUT*** is contaminated (must be cleaned, there could occur contamination of the device)

Detected air in hose  - in the taking hose of transfusion set, there is no blood (taking bottle is empty), and reinfusion is terminated.

Note

From this mode, it is possible to select ***standstill*** by a click on the button 

.

Note
In case there is no communication with the mode for four minutes, there will occur an automated transfer to a ***standstill.***

9.7. DEFECT, FAILURE OF DEVICE, OR POWER SUPPLY VOLTAGE FAILURE

The below-described procedures are to be only applied in case there occurs a failure of the device or there occurs an outage of voltage or a defect of one-time application material.

9.7.1. PATIENT´S EMERGENCY DISCONNECTION PROCEDURE

Patient´s emergency disconnection procedure from the device:

1. Throttle carefully all connected hoses.
2. Disconnect the patient from the device.
3. Ensure maximum ventilation of the space, e.g. opening of all windows, switch on ventilation at full power.
4. Disconnect carefully a one-time material from the device.
5. Before final disposal of the applied material, leave it carefully closed for 4 hours so that there does not occur unwanted leakage of gases.

9.7.2. OZONE FILLING DISPOSAL PROCEDURE

The procedure of disposal of ozone filling and other vessels that cannot be hermetically closed:

1. Ensure maximum ventilation of the space, e.g. opening of all windows, switch on ventilation at full power.
   Note: do not ventilate the room into other parts of the building, there could occur contamination of the other rooms.
2. Remove carefully the bag from the patient Watch out carefully no direct inhaling of released gases!
3. The bag is to be slowly rinsed with air.

In case it is not possible to perform sufficient and intensive ventilation of the room, use a protective mask for breathing ways with a carbon filter for all present persons in the room. Enter the contaminated room just after 4 hours. There happens decomposition of ozone during this time.

10.DISINFECTION MAINTENANCE, PERIODIC CHECKS, AND PRODUCT DISPOSAL

10.1. CLEANING, MAINTENANCE, INSPECTION, DISINFECTION, PERIODIC CHECK

10.1.1. CLEANING

Cleaning is to be performed only in a switched-off state and with a closed valve of a pressure bottle with medicinal oxygen. The surface of the basic unit, blocking unit, reduction valve, pressure hose, and interconnecting cables are to be cleaned with wet soft textiles using common detergent agents (Jar, etc.).

10.1.2. MAINTENANCE

The device requires regular maintenance performed in the form of regular safety technical inspections (STI) see **10.1.5.**
Possible replacement of fuses is performed by a service technician with a disconnected power supply cable. The fuses are placed on the rear side of the basic unit in a separate case next to the network power supply socket.

Note
The vessel for absorption of moisture is suitable to be regularly checked depending on the amount of water saturation performance, infusions, and bag applications as by doing this, there occurs a gradual reduction of absorption abilities of the filling.
Therefore, it is necessary to replace the filling in the vessel for absorption of moisture in time.

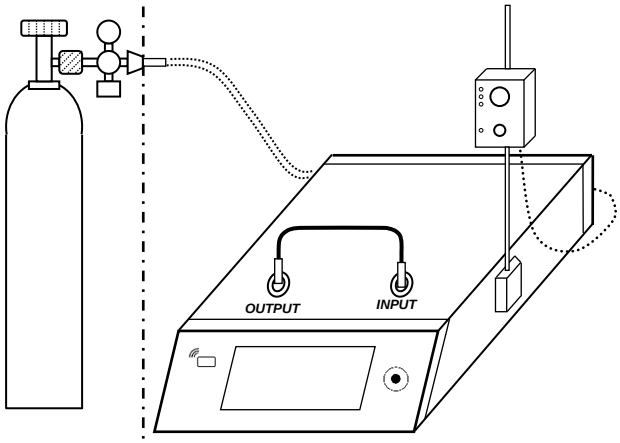
10.1.3. DISINFECTION

Disinfection of the surface of the device and the attachments is to be only performed in a switched-off state and with a closed valve of a pressure bottle with medicinal oxygen. The surface of the basic unit, blocking unit, reduction valve, pressure hose, and interconnecting cables are to be disinfected using common chemical procedures with approved agents MIKROZID, SAGROSEPT, GIGASEPT® INSTRU AF, GIGASEPT FF, etc.

Disinfection of the inner parts of the device is to be performed after installing the device in the mode of ***liquid saturation*** according to chapter 9.5.6. (without water ozonizing agent) with the following parameters:

- set up ozone concentration in the taken mixture up to 80 μg O_3 / ml O_3 + O_2
- set up an amount of the taken mixture to 2000 ml.

Taking flange ***OUTPUT*** to be connected using a connecting hose for ***Autotest*** and disinfection with connector ***INPUT***.



Disinfection of the device to be started by a click on the button 

The activity is indicated by a record of events in the lower part of the display above the button STOP

10.1.4. INSPECTION

Attention

Before each start of the device, it is necessary to perform a check of the connection of the pressure bottle with medicinal oxygen, reduction valve, connecting pressure hose, network power supply cable, and the blocking unit cable.

Before each use of the connecting hoses and attachments, it is necessary to perform a thorough check of the intact state.

A full check of the device is performed in the mode of ***Autotest*** after each switch on of the device or from the main display.

11 DOPORUČENÝ SPOTŘEBNÍ MATERIÁL NEDODÁVANÝ VÝROBCEM

Set for rectal/vaginal insufflation

– fitting MTLS 230-J1A	1 pc
– one-way valve SCV67230	1 pc
– fitting 3060-J1A	1 pc
– silicon hose VENA®Bio Pure ISO 7	2 m
– catheter Nelaton female CH/FG 16	1 pc

Set for ozonization of liquids

– fitting MTLS 230-J1A	1 pc
– one-way valve SCV67230	1 pc
– one-way valve SCV67230/ML	1 pc
– silicon hose VENA®Bio Pure ISO 7	0,5 m
– reagent bottle 1000 ml with nozzle GL45	1 pc
– closure GL45 with two passable fittings	1 pc
– air stainless stone porosity 2 µm	1 pc
– disitilled water	max. 900 ml

Set for ozonization of special solutions

- fitting MTLS 230-J1A 1 pc
- silicon hose VENA®Bio Pure ISO 7 0,5 m
- one-way valve SCV67230/ML 2 pcs
- fitting MTLL 230-J1A 1 pc
- injection filter Sterifix® 0,2 μm (BBRAUN) 1 pc
- injection needle 0,8x120mm - GREEN 1 pc
- injection needle 0,9x25 mm – YELLOW 1 pc
- Physiological solution NaCl 0,9% 250 ml (in glass) 1 pc

Set for vacuum therapy

- fitting MTLS 230-J1A 1 pc
- fitting FTL 230-J1A 1 pc
- silicon hose VENA®Bio Pure ISO 7 0,1 m
- Self-Sealing Ozone Limb Bag SimplyO3 1 pc

Set for intramuscular application

- injection filter Sterifix® 0,2 μm (BBRAUN) 1 pc
- syringe 20 ml 1 pc
- syringe 10 ml 1 pc
- needle for i.m. application 1 pc
- connecting adaptor FTLLC-J2A 1 pc

Set for intradisc application

- injection filter Sterifix® 0,2 μm (BBRAUN) 1 pc
- syringe 10 ml 1 pc
- spinal needle 1 pc

Set for major autohemotherapy

- Y-connection – three-way Y230-J1A 1 pc
- reduction MTLS230-J1A 1 pc
- reduction MTLL230-J1A 1 pc
- reduction FTL230-J1A 1 pc
- silicon hose VENA®Bio Pure ISO 7 0,3 m
- Medozon i-Set, 300 ml 1 pc
- heparin; sodium oxalate or sodium citrate 1 pc

Small vessel for absorption of moisture

- fitting FTL 230-J1A 2 pcs
- silicon hose VENA®Bio Pure ISO 7 0,5 m
- reagent bottle 250 ml with nozzle GL45 1 pc
- closure GL45 with two passable fittings 1 pc
- air stainless stone porosity 5 μm 2 pcs
- drying preparation – silica gel clear; ø balls 2-5 mm 150 g

12 REGULAR SAFETY TECHNICAL INSPECTION (STI)

Following valid legislation, it is the obligation of a provider of health care to have a valid safety technical inspection. ZAT a.s. performs professional maintenance in the form of regular safety

technical checks of the product within intervals shorter than 12 calendar months, unless stipulated by current legal regulations otherwise.

Inspection of the device is performed based on the user´s order or provider of health care.
The inspection is necessary to be ordered a minimum of one month before the expiration of the prescribed period.
Guarantee repairs, post-guarantee repairs, and periodic safety technical inspections are to be only performed by the manufacturer or authorized service department.

Manufacturer: ZAT a.s., K Podlesí 541, 261 01 Příbram VI, Czech Republic

Contacts:
Tel.: +420 318 652 111
E-mail: zat@zat.cz
web: http://www.zat.cz

13 INSTRUCTIONS FOR PRODUCT DISPOSAL

Disposal of the device for ozone therapy is to be performed in specialized secondary waste collection points or to be sent back to the manufacturer to be disposed of.

Proceed according to valid legislation on waste when classifying the waste and its disposal.

The device for ozone therapy does not contain components apart from the battery.

14 GUARANTEE

The guarantee is provided for 24 months since the takeover of the product by the customer. The guarantee covers the quality, safety, and functionality of all supply components according to the handover protocol.

Guarantee is valid in case the following conditions are met:

1. Operation was performed according to the Instruction for use.
2. There has not happened a penetration of liquids due to incorrect operation.
3. There has not happened violent mechanical damage.
4. There have not been performed modifications and repairs.
5. The device was operated according to the conditions of chapters 8.4.1. and 8.4.2.
6. Defects did not result from common wearing of the device.

In case a client sends the device to be repaired, he/she takes over the risk of possible damage during transport due to imperfect packaging.

Guarantee and post-guarantee repairs, and periodic safety technical inspections are only performed by the manufacturer or an authorized service department.

Connection schemes, lists of parts, settings, and inspection regulations are only handed over to the authorized service departments after the successful completion of the service technicians training.

15 OXYGEN AND ITS FORMS

Oxygen atom exists in various forms in nature.

A. FREE PARTICLE O

Is highly reactive and unstable (is not radical).

B. OXYGEN O_2

This form is spread most, is stable, colorless as gas, and pale blue as the liquid. Oxygen in this form is vital but can be toxic for the organism at improper reactions. It plays important role in oxidation reactions that are performed in four steps of Felton´s reaction. Oxidation of nutrients CO_2 and H_2O is a final result in case of sufficient energy.
In case of a shortage of energy, this reaction is not performed fully and there are created a big amount of free radicals and acid metabolites. These substances cause **oxidation stress** in biological systems.
Oxidation stress is not a lack of oxygen but a shortage of free energy.

C. OXYGEN O_3 (OZONE) – ACTIVE OXYGEN

Is reactive and not stable (is not radical).
In its molecule, it has a surplus of energy.
It is commonly present in the air, namely in a ratio of 1 portion O_3 for 10 million parts of air i.e. cca 140 ug/m^3.
Through the reaction of water and oxygen in our body, there are created peroxides and ozone is released.
$H_2O + 2O_2 = H_2O_2 + O_3$
During compound of 2 mol. O_3, there are created 3 mol. O_2 and there is released energy that is used in oxidation reactions.
$O_3 + O_3 = 3O_2 + 286$ Kj
The organism can metabolize and use this form of oxygen. It is as vital as trace elements.

16 EFFECT OF OXYGEN ON HUMAN ORGANISM

A healthy human organism represents the correct activity of an entire complex of cell systems. The correct activity of these cell systems depends on the correct activity of individual cells. It is known that cells of our organism are damaged by stress, polluted environment, nutrition, diseases, and a lot of other factors. In damaged cells, there are going on changes in enzyme mechanisms responsible for energy systems and protective mechanisms against excessive oxidation and free radicals at the cell level. The most effective disposal of these problems is represented by stimulation and restoration of natural enzyme mechanisms at the cell level.

Disposal of these problems by a replacement with synthetic vitamins, antioxidants, enzymes, or coenzymes often leads to a worsening of the natural enzyme cell cycle.

Correct activity of cells of human organism is based on oxygen paradox:

Oxygen in various forms is essential for healthy life of a cell. Cells need oxygen to produce energy for vital cells functions.

Oxygen in various forms is harmful for life of cells. In case a cell cannot process oxygen effectively, there is established overprodcution of aggressive derivates that block and breach natural enzymatic mechanisms. There is created cell stress that represents a cause of most diseases.

17 INDICATION

- Inflammatory diseases (bacterial, viral, mycotic)
- Ischemic states
- Lowered immunity
- Chronic pain

18 CONTRAINDICATIONS

Administration of ozone is contraindicated in:

- acute and massive organ bleeding for possible worsening of bleeding
- glucose-6-phosphate dehydrogenase deficiency (favism, acute hemolytic anemia)
- thrombocytopenia less than 50 000 and serious coagulation disorders
- toxic hyperthyroidism states - Basedow Graves
- severe cardiovascular instability
- thyroid function disorders
- hypotension
- acute alcohol intoxication
- acute infarct of myocardium
- gravidity
- acute feverishness and septic states
- during convulsive states
- hemochromatosis
- hypoglycemia
- hypocalcemia
- allergy to ozone
- patients receiving treatment with copper or iron

For diabetics, especially with high doses of insulin, there is recommended to monitor their blood sugar level, there occurs a lowering of blood sugar level.
For the people heparinized on a long-term basis, in case they do not have bleeding manifestations, it is suitable to use lower dosing.
For oncology patients, it is suitable to undergo this therapy before, or after radiation or chemotherapy.
In using ozone therapy, there do not occur interactions with other medical procedures according to the literature.
Despite this, it is suitable to evaluate the possible interaction of oxygen (ozone) with medicine from the toxicity point of view.
Insulin, thyroidal hormones, adrenalin, noradrenalin, acetazolamide, aspirin, and apargauat can lead to increased toxicity of O_2 (O_3).
What is dangerous are fever, physical labor, and vitamin deficiency.
Toxicity is reduced by antioxidants, enzymatic as well as non-enzymatic (SOD, catalysis, vitamins E, C, A).
Oxygen reduces the effects of adrenalin, digitalis, lidocaine, reserpine, hypnotics, sedatives ethyl alcohol, and tetrachloride.
Oxygen increases the effects of betablockators, antiarrhythmics, antianginosing medicals, antiasthmatics, aminophylline, and insulin.

A. INTERACTION WITH OZONE

In the course of treatment with ozone, there can be applied antioxidation supplements (e.g. vitamin C and vitamin E). However, the presence of constituents in high concentrations in blood disturbs the activity of ozone as an oxidation agent and thus a good course of therapy. As a result of this, oral vitamins or antioxidants should not be administered in the course of treatment but only before or after the ozone therapy. The suppression period depends on the bioavailability of each specific antioxidant. It is recommended not to administer intravenous antioxidation therapy such as vitamin C or glutathione neither before nor during but only after the ozone therapy.

Ozone increases the effects of ACE inhibitors. Treatment using ozone for patients with anticoagulation therapy must be performed under the INK inspection. The patients receiving the treatment with copper or iron cannot receive treatment with ozone. There are supposed to be expected synergic effects of other oxidative therapies. About laser therapy, magnetic therapy, acupuncture, diathermy, or physiotherapy, there can be expected supplementary effects.

B. OZONE CONCENTRATION

We use a mixture of clear (medicinal) O_2 and O_3 in the ratio of **0,1 - 5% O_3 for 99,9 - 95% O_2** for application.

For determination of concentration, we use the ratio of a microgram (μg) of ozone in milliliter (ml) of a mixture of O_2 and O_3.

The therapeutic zone of ozone concentration is between 1 and 80 μg/ml.

There exist therapeutic, not effective, and toxic ozone concentrations. It was proved that concentrations of 10 μg/ml or 5 μg/ml or even lower have therapeutic effects with a wide safety range, i.e. it is accepted now that a therapeutic dose of ozone for **systematic use** (major autohemotherapy, rectal insufflation, intramuscular, etc.) within 500 μ*g* and maximum 4000 μg for each treatment concentrations from od 10 μg/ml up to 40 μg/ml are safe and effective.

It is necessary to define the amount of blood that is supposed to be taken. This is performed based on the weight of a treated patient. Hemodynamic/hypovolemic disorders with a loss of 15 % of the total amount of circulating blood (CBV) are not considered. In the case of major autohemotherapy, taking 2 % or more and 1.5 % is conservative. A person with 85 kg has CBV 65 ml / kg x 85kg = 5,525 ml. 2 % correspond with 110 ml of taken blood. The range of safe blood taking is as follows: 1.2 ml/kg for 1.3ml / kg with a limit of 102 ml for persons with 85 kg.

Example
A person with 85 kg; 1.2 • 85 = 102 ml of blood that is supposed to be taken. These doses turned out to be safe and effective. They activate cell metabolism and have immunomodulatory and antioxidation effects. It should be emphasized that each round of application has a minimum and maximum dosing, the same as concentration, and an amount that is supposed to be managed.

The total dose of ozone is equivalent to an amount of gas (ml) multiplied by ozone concentration (Dosing = Amount x Concentration). The dose is not given by kg of body weight but by response dependent on the dose and the concentration can be expressed even in μg/ml or as mg/l of ozone.

Studies covering the calculation of an ozone dose based on body weight are still going on. All

therapeutic dosing is divided into three types according to their action mechanism:

a) **Low doses:** These doses have an immunomodulatory effect and are applied for diseases where there exists a suspicion the immune system is under a big threat. For example, in the case of cancer in elderly and weakened patients.

b) **Middle doses:** They are immunomodulatory and stimulate the antioxidation enzyme of the protective system. They are most useful for chronic degenerative diseases such as diabetes, atherosclerosis, COPD, Parkinson´s syndrome, Alzheimer and senile dementia.

c) **High doses:** They have inhibitory effects on the mechanism that are shown in autoimmune diseases such as rheumatoid arthritis and lupus. They are especially involved for ulcers or infection injuries, and they are also applied for the preparation of ozonized oils etc.

19 CLINICAL BENEFIT

These are clinical benefits of medical device Ozosmart:

- significant reduction of pain, at least redcued pain intensity down to an acceptable level (VAS $\leq$ 3)
- healing/improvement of state of a chronic wound at least by one level at least at one of the assessed parameters (Wound, Ischemia, Infection) according to WIfI score in the PMCF protocol
- at least 80% success rate in avoiding amputation for patients indicated for high amputation and thus retaining his/her social status and mobility.

20 EMC TABLES

<table>
<tr><th colspan="3">Manufacturer´s declaration and instructions – electromagnetic radiations</th></tr>
<tr><td colspan="3">Ozosmart – the device for ozone therapy is intended to be applied in the electromagnetic environment specified below. A user of the device should ensure that it is used in such an environment.</td></tr>
<tr><th>Radiation test</th><th>Accordance</th><th>Electromagnetic environment - instructions</th></tr>
<tr><td>High-frequency radiation

CISPR 11</td><td>Group 1</td><td>Ozosmart device for ozone therapy uses high-frequency energy only for its internal function. Therefore, its high-frequency radiation is very low and it is not probable that it causes any interference of close electronic appliances.</td></tr>
<tr><td>High-frequency radiation

CISPR 11</td><td>Class B</td><td rowspan="3">Ozosmart device for ozone therapy is suitable to be applied in environments of professional health care facilities.</td></tr>
<tr><td>Harmonic radiation
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Variation of voltage / blinking radiation
IEC 61000-3-3</td><td>Satisfactory</td></tr>
</table>

Manufacturer´s declaration and instructions – electromagnetic resistance		
Ozosmart – the device for ozone therapy is intended to be applied in the electromagnetic environment specified below. A user of the device should ensure that it is used in such an environment.		
Resistance test	**Testing level according to IEC 60601 Satisfactory level**	**Electromagnetic environment – instructions**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	The floor should be wooden, concrete, or from ceramic tiles. In case the floor is covered with synthetic material, air humidity is supposed to be at least 30 %.
Fast electric transition phenomenon/group of impulses IEC 61000-4-4	± 2 kV for power supply ± 1 kV for input / output wire	The quality of the power supply power should be the one that is typical for the commercial or non-commercial hospital environment.
Surge impulse IEC 61000-4-5	± 1 kV between wires ± 2 kV between wires and earth	The quality of the power supply power should be the one that is typical for the commercial or hospital environment.
A short time drop of voltage, short interruptions, and slow changes of voltage on power supply input wires IEC 61000-4-11	< 5 % U_T (> 95 % short time drop in U_T) in 0,5 of cycles 40 % U_T (60 % short time drop in U_T) in 5 cycles 70 % U_T (30 % short time drop in U_T) in 25 cycles <5 % U_T (>95 % short time drop in U_T) in 5 s	The quality of the power supply power should be the one that is typical for the commercial or hospital environment. In case a user of Ozosmart has permanent operation during an outage of the power supply power, there is recommended that Ozosmart be powered from a power supply source with the permanent operation of from battery.
The magnetic field of power frequency (50/60 Hz) IEC 61000-4-8	30 A/m	Magnetic fields of power frequency are supposed to be at the levels of a characteristic typical place in a typical commercial or hospital environment.
Note: U_T is AC power voltage before application of testing level		
Wired high frequency IEC 61000-4-6	3 V 150 kHz - 80 Mhz	Removable and mobile high-frequency communication devices are not supposed to be used close to any part of Ozosmart including cables

Radiated high frequency IEC 61000-4-3

Test frequency (MHz)	Bandwidth [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Minimum separation distance (m)	IEC / EN60601 test level (V/m)	Compliance level (V/m)
385	380 - 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27	27
450	430 - 470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704 - 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9	9
745							
780							
810	800 - 960	GSM 800 / 900, TETRA 800, iDEN 820 CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28	28
870							
930							
1720	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28	28
1845							
1970							
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9	9
5500							
5785							

Note 1: these instructions do not have to apply in all situations. Electromagnetic spreading is affected by absorption and reflection from buildings, objects and people.
Note 2: Electromagnetic interferences are possible to minimized by connecting equipotential clamps of the device.