RFNC-VNIIEF
ROSATOM

FEDERAL STATE UNITARY ENTERPRISE "RUSSIAN FEDERAL NUCLEAR CENTER – ALL-RUSSIAN RESEARCH INSTITUTE OF EXPERIMENTAL PHYSICS"

UNIT FOR NITRIC OXIDE THERAPY AIT-NO-01
TU 32.50.21 -001 -07623615-2017 (trade name "TIANOX")

OPERATING MANUAL

ИАМФ.941589.001 РЭ

Registration certificate:
No. RZN 2020/10977 dated 06/22/2020

Declaration of conformity:
РОСС RU Д-RU.АД37.В.31931/20
dated 07/09/2020

Sarov

Contents

This operating manual is intended to familiarize consumers with technical information about the product - Unit for nitric oxide therapy AIT-NO-01 (trade name "TIANOX"), hereinafter referred to as the Unit. The document contains information about its design, principle of operation, technical characteristics and instructions necessary to ensure correct and safe operation, installation, maintenance, storage and transportation.

The Unit complies with the requirements of TU 32.50.21-001-07623615-2017, GOST R 50444 and documentation set ИАМФ.941589.001.

Registration certificate: No. RZN 2020/10977 dated 06/22/2020.

During installation, operation, maintenance of the Unit, in addition to this manual it is necessary to be guided by the requirements of the applicable "Regulations for Operation of Consumer Electrical Installations", "Rules for Technical Safety during Operation of Electrical Installations by Consumer" and other regulatory documents specified in this operating manual.

The Unit does not pose a danger to life, health, property of consumers and the environment during operation, provided that the requirements of the current operational documentation are observed.

ATTENTION! The reliability and safety of the Unit operation, as well as its service life, depend on proper use, so please read this manual carefully.

Unit manufacturer: FSUE RFNC-VNIIEF

Manufacturer's address:

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1 Unit description and operation principle

1.1 Purpose

1.1.1 The Unit is designed to produce and deliver a gas mixture containing nitric oxide (NO) to a patient's respiratory circuit and to monitor the concentration of NO in the respiratory mixture supplied to a patient.

1.1.2 The main field of application of the Unit is inhalation therapy with nitric oxide (NO-therapy).

1.1.3 The Unit is intended for use in stationary conditions of clinics, hospitals and other medical institutions.

1.1.4 Depending on possible consequences of failures during its use, the Unit belongs to Class “B” as per GOST R 50444.

1.1.5 Depending on the perceived mechanical effects, the Unit belongs to group 2 as per GOST R 50444 (mobile Unit, not intended for operation during mobility within the boundaries of a medical institution).

1.1.6 Depending on the type of protection against electric shock, it is a class I product as per GOST R IEC 60601-1.

1.1.7 Depending on the degree of protection against electric shock, it is a product with a working part of type B as per GOST R IEC 60601-1

1.1.8 Depending on the degree of protection against dangerous penetration of water or solid particles - IP20 as per GOST R IEC 60601-1.

1.1.9 Class of potential risk of the Unit - 2b as per GOST 31508.

1.1.10 Depending on the mode of operation, it is a product with a continuous mode of operation as per GOST R IEC 60601-1.

1.1.11 According to the permissible sound level, the Unit belongs to the 1st group as per Sanitary Norms No. 3057 (sound level A ≤ 50 dB).

1.1.12 Climatic version of the Unit - MCC 4.2 ("moderately cold climate", operation at a temperature from +15 to +35°C) as per GOST 15150.

1.1.13 Type of the product according to the nomenclature classification: Code 180790, Nitrogen monoxide delivery Unit, systemic.

1.2 Technical specifications

1.2.1 The Unit produces NO-containing gas mixture from ambient air.

1.2.2 The Unit provides regulation of NO concentration in NO-containing gas mixture. Permissible deviation from the set values of NO concentrations is ±20%;

1.2.3 Volume flow rate of NO-containing gas mixture at the Unit outlet is 0.45±0.2 l/min.

1.2.4 The Unit monitors NO, NO_2 concentration in the gas mixture supplied to a patient.

Component	UoM	Range	Range area	Absolute permissible error	Relative permissible error	Least significant digit value of indication
NO	ppm	0-100	0-10	±1ppm	-	0.1ppm
			10-100	-	±10%	
NO_2	ppm	0-50	0-10	±1ppm	-	0.1 ppm
			10-50	-	±10%	

Concentration readings are shown on the monitoring unit display. Display resolution 240x128 pixels, display height 53±5 mm, display width 92±5 mm.

1.2.5 The least significant digit value of NO and NO_2 indication is 0.1 ppm.

1.2.6 Volumetric flow rate of the gas mixture taken for monitoring is 0.45 ±0.2 l/min.

1.2.7 The Unit provides for the possibility of setting alarm thresholds according to the

following parameters:

- maximum concentration of NO (NO_{max}) in the breathing circuit;
- minimum concentration of NO (NO_{min}) in the breathing circuit;
- maximum concentration of NO_2 (NO_2max) in the breathing circuit;

When the NOmax and NO_2max thresholds are triggered, NO generation is automatically stopped and an audible alarm is activated.

Acoustic characteristics of audible alarm:

Sound level 85 ± 5 dB at a distance of 10 cm. Period 1±0.3s.

Permissible deviations of the concentration of NO and NO_2 from the established maximum and minimum thresholds, at which an alarm is triggered, should be ± 20%;

1.2.8 Maximum allowable time for establishing the operating mode is 10 minutes.

1.2.9 Power consumption 100 VA.

1.2.10 Power supply: 220V / 50Hz.

1.2.11 The Unit weight is not more than 30 kg.

1.2.12 Unit overall dimensions: height - 1400 mm, base diameter - 700 mm.

1.2.13 Overall dimensions and weight of the units of the Unit:

No.	Unit name	Weight, kg	Dimensions, mm (W × H × D),
1	NO and NO_2 monitoring unit	1.75	228×202×116
2	Generator	6.4	362×322×160
3	Neutralizer	3.0	115×300×105
4	Purification unit	1.9	115×300×105
5	Electric unit	complete 12	160×90×240
6	Air supply unit		
7	Stand with base		660×1325×660
8	Monitoring unit bag	0.62	360×240×122
9	Handle for removing purification unit flask	0.05	26×26×122

1.2.14 Monitoring unit software version: Periodic change is allowed with the release of new updates.

The software safety class according to the degree of severity is class A. The software is installed on the monitoring unit and it cannot change the concentration of nitric oxide synthesized in the generator. The generator has no microprocessor and software. The change in the concentration of nitric oxide is carried out in manual mode using mechanical regulators. To reduce the risk of accidental maladjustment, the design provides two-level regulation: a mode selection switch and fine adjustment knobs within each mode.

1.2.15 Tubes for connecting the Unit to the breathing circuit are available upon request (RU No. FSZ 2009/03551).

1.2.16 Length of the power supply cable of the Unit should be 1700 (+300) mm.

Length of the monitoring unit power cable from the rack outlet should be 150 (±50) mm.

Length of the generator power cable from the rack outlet should be 400 (±100) mm.

Length of the cable with RS-232 connectors from the rack outlet should be 200 (±50) mm.

1.2.17 Concentration of NO and NO_2 in the gas mixture at the outlet of the neutralizer does not exceed the MAC as per GOST 12.1.005. MAC of NO_2=2 mg/m^3 (1.05 ppm). MAC NO=5 mg/m^3(4.01 ppm).

1.2.18 The Unit includes an air supply unit. The volume flow rate of the supplied air is 5±2 l/min.

1.2.19 The list of materials from which the gas path of the Unit is made:

Tubes: polyvinyl chloride of PME-80 grade, TU 6-01-1208-79 (manufactured by Federal State Unitary Enterprise "Research Institute of Polymers", Dzerzhinsk, Nizhny Novgorod region).

Discharge chamber body: Block polyamide PA 6 of A grade, TU 2224-036-00203803-2012.

Discharge chamber parts: Aluminum alloy D16, GOST 4784-97.

The head of the discharge chamber, the body of the purification unit, nozzles: stainless steel 12X18H10T, GOST 5632-72.

Fittings of the Purification unit: Suspension polyvinyl chloride PVC-S-7059-M, GOST 14332-78.

Pump parts (in the air supply unit and generator) that come into contact with gas:

head - crystalline polyphenylene sulfide of Fortron PPS 1140L4 grade, produced by the international company Celanese;

pistons and valves - rubber SKEPT-40 TU2294-087-05766563 and fluoroplast-4, grade "O", GOST 10007-80.

Dyes are not used.

1.2.20 Service life of the Unit is at least 5 years.

1.3 Composition of the Unit

General view of the Unit is given in Figure 1.1.

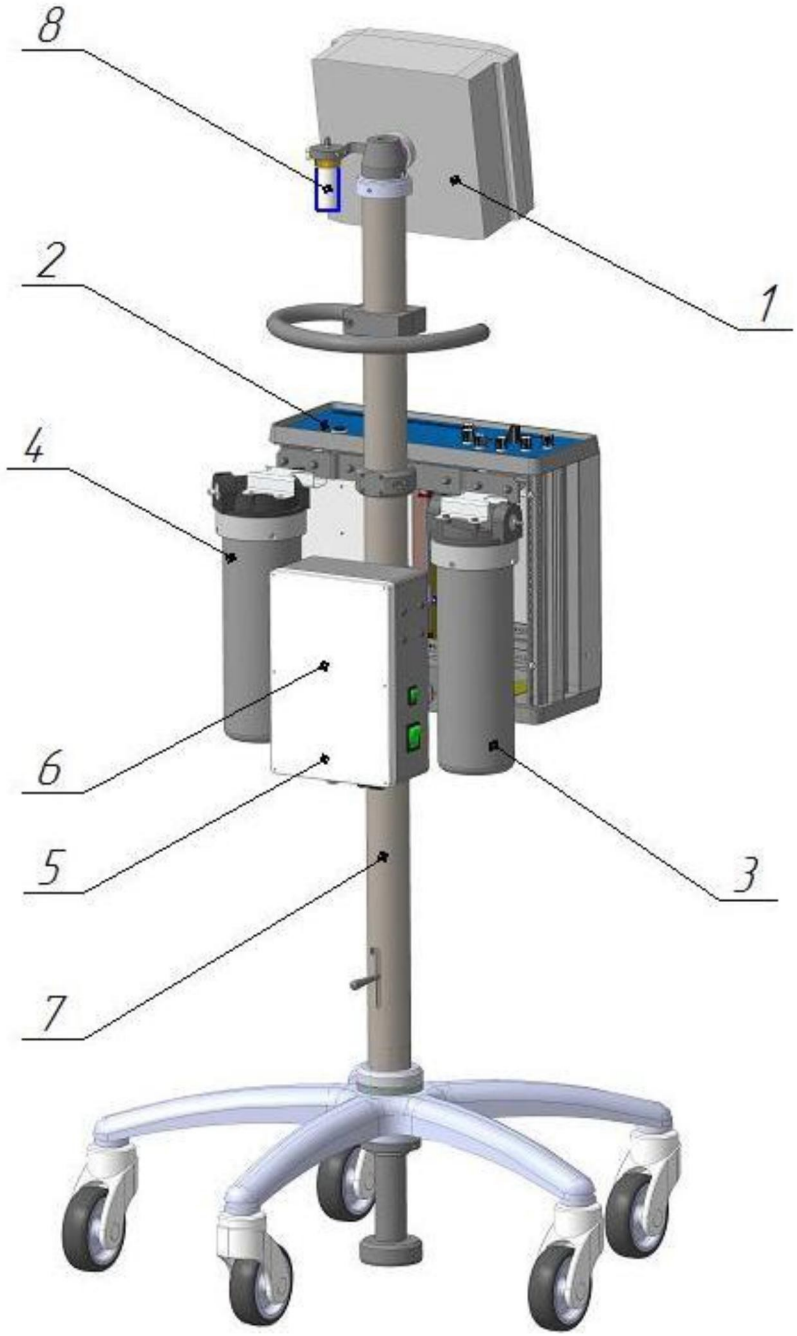


Figure 1.1 - General view of the Unit for nitric oxide therapy
1 - NO and NO_2 monitoring unit; 2 - generator; 3 - neutralizer;
4 - Purification unit; 5 - electric unit; 6 - air supply unit;
7 - rack with base; 8 - moisture separator;

1.3.1 NO generator

The NO generator is intended for the synthesis of nitric oxide.
The generator includes the following structural components:

- control unit (CU);
- power source (PS1);
- power source (PS2);
- power source (PS3);
- discharge chamber (DCh);
- high-voltage generator (HVG);
- gas path;

- fan;
- piston pump.

Electrical block diagram of the generator is given in Figure 1.2.

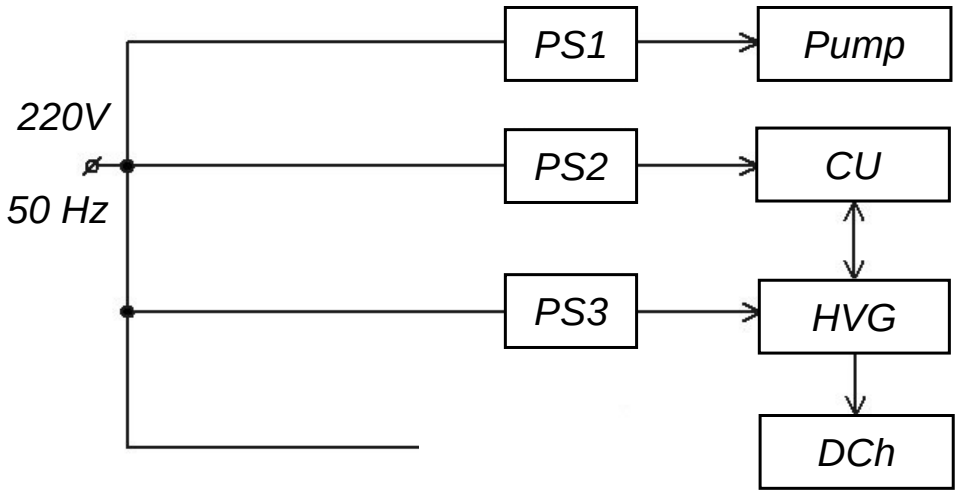


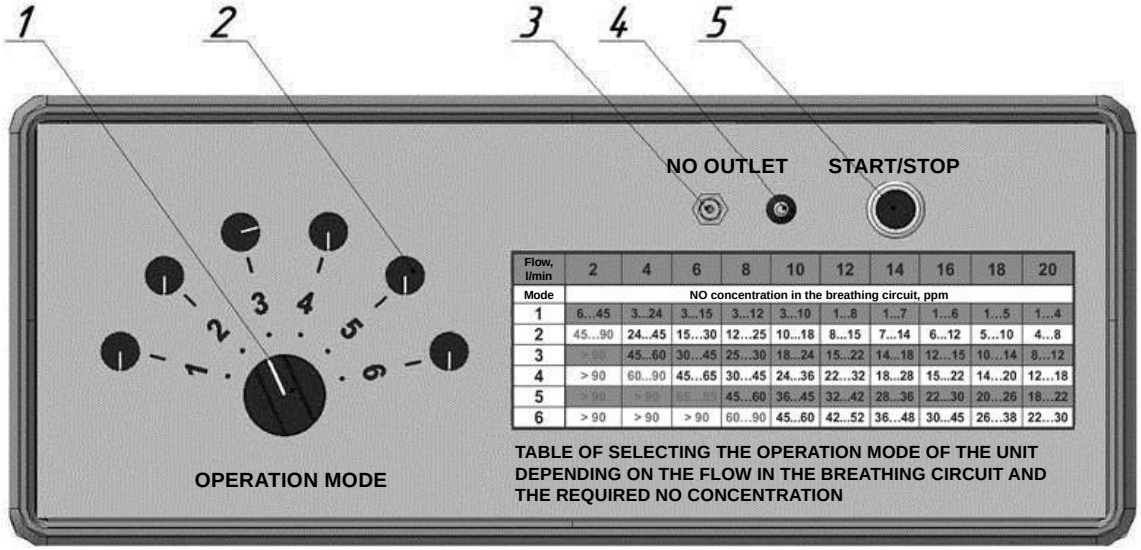
Figure 1.2 - Electrical block diagram of the NO generator

Synthesis of NO is carried out in the discharge chamber in a repetitively-pulsed diffuse discharge from the ambient air.

Air is supplied to the discharge chamber by means of a piston pump at a flow rate of 0.45±0.2 l/min. Voltage pulses of alternating polarity with highly stable electrical and temporal parameters are applied to the electrode system of the discharge chamber with PS3. This determines the accuracy and stability of the energy input in each pulse and, as a consequence, the stability of NO concentration in the output mixture. Adjustment of the concentration of nitric oxide is carried out by changing the pulse repetition rate. The design of the chamber ensures the preliminary ionization of the gap for a reliable start of generation. The commands to control the Unit are generated by the control unit CU. The electrical power supply of the units and assemblies of the Unit is carried out by power sources PS1 and PS2. The HVG is intended for the formation of a repetitively-pulsed diffuse discharge in the DCh of the Unit.

The generator is made in a frame type case. On the sides, the frame is closed with metal removable U-shaped covers (with a corrosion-resistant decorative coating) that are attached to the side braces. The NO generator control panel is attached to the load-bearing frame. The control panel has a film coating.

The appearance of the control panel is shown in Figure 1.3.



Flow, l/min	2	4	6	8	10	12	14	16	18	20
Mode	NO concentration in the breathing circuit, ppm									
1	6…45	3…24	3…15	3…12	3…10	1…8	1…7	1…6	1…5	1…4
2	45…90	24…45	15…30	12…25	10…18	8…15	7…14	6…12	5…10	4…8
3	> 90	45…60	30…45	25…30	18…24	15…22	14…18	12…15	10…14	8…12
4	> 90	60…90	45…65	30…45	24…36	22…32	18…28	15…22	14…20	12…18
5	> 90	> 90	65…90	45…60	36…45	32…42	28…36	22…30	20…26	18…22
6	> 90	> 90	> 90	60…90	45…60	42…52	36…48	30…45	26…38	22…30

Figure 1.3 – NO generator control panel

1 - rotary switch of operation modes; 2 - knobs for fine adjustment of NO concentration; 3 - NO outlet nozzle;
4 - LED indicator of NO synthesis activation;
5 - NO synthesis on/off button.

On the bottom panel of the generator there is a connector for the power cable, a power switch, a fuse and an RS-232 connector for communication with the monitoring unit. The Unit automatically stops NO generation when an emergency relay signal is received from the monitoring unit about exceeding the set NOmax and NO_2max concentration thresholds.

1.3.2 Monitoring unit

The Unit is designed to monitor the concentration of NO, NO_2 in the patient's breathing circuit. The principle of operation is based on the use of electrochemical measuring sensors. The sensors are mounted on a sensor chamber, into which a gas sample is supplied by a piston pump. Signals coming from the sensors are fed to the conditioning amplifiers, after which they are converted into digital form on an analog-to-digital converter and fed to the microprocessor controller for processing. The microprocessor converts the signal into a measured value, taking into account the units of measurement (ppm) and displays the measurement result on the display located on the front panel of the Unit (see Fig. 1.4). The device uses a liquid crystal graphic display. On the front panel of the Unit there is a membrane keypad for managing monitoring, obtaining additional information and setting alarm thresholds. The purpose of the keys is given in Table 1.1. The membrane keyboard is abrasion resistant, but can be damaged by a sharp object.

The monitoring block is fixed and has no degrees of freedom.

Figure 1.4 - Monitoring unit front panel

Table 1.1 - Assignment of keys on the monitoring unit keyboard

	Entering the menu for setting NOmax, NOmin and NO_2max thresholds.
	Entering the "BASIC SETTINGS" menu in the measurement mode.
	Exiting the current mode or menu, refusal from editing without saving changes.
	Confirmation of the entered value.
DIGITS	Selecting a menu item, entering a numerical value when editing, key 5 - "up" and key 0 - "down".
	Checking the background concentration of NO_2 and NO in the air.
	Measurement stop and start (pause).
	Turning the device on and off during service maintenance and calibration.

The monitoring unit has an emergency mode relay, which is activated in case of exceeding NO and (or) NO_2 concentration levels in relation to the set NOmax and NO_2max thresholds. The signal through the RS-232 port is fed to the NO generator.

On the lower surface of the unit body there is a panel of pneumatic and electrical connectors (see Fig. 1.5).

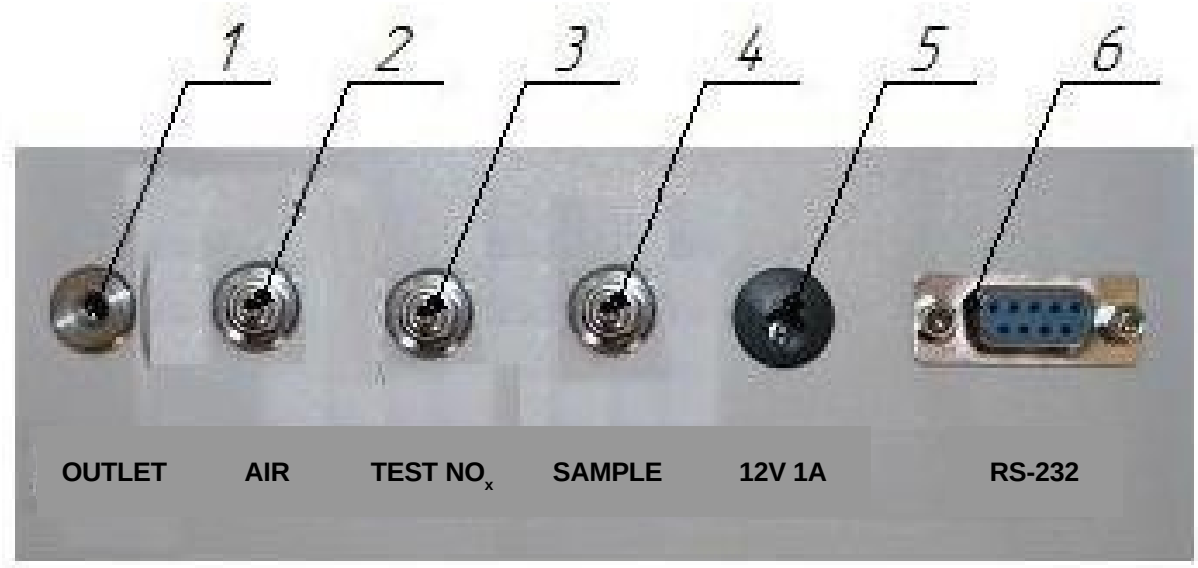


Figure 1.5 - Connector panel

1 - gas sample OUTLET after analysis; 2 - air intake for purging sensors; 3 - air intake for the NO_X test; 4 - input of the analyzed gas mixture; 5 - connector for power supply; 6 - RS-232 port

1.3.3 Purification unit

The unit is designed to treat the synthesized NO-containing gas mixture from NO_2. The NO_2 concentration after the purification unit should be not more than 5% of the NO concentration. The principle of the unit operation is based on the process of chemical adsorption of NO_2. A granulated medical absorbent based on calcium hydroxide is used as an adsorbent.

The medication has a registration certificate of Roszdravnadzor No. FSZ 2009/03551.

Material of a unit flask - stainless steel.

The purification unit has a dismountable structure with replaceable cartridges (Fig. 1.6). Cartridge case material - polyvinylchloride. The frequency of replacement of the purification unit cartridge is regulated by the Unit maintenance procedure (see paragraph 3.3.3).

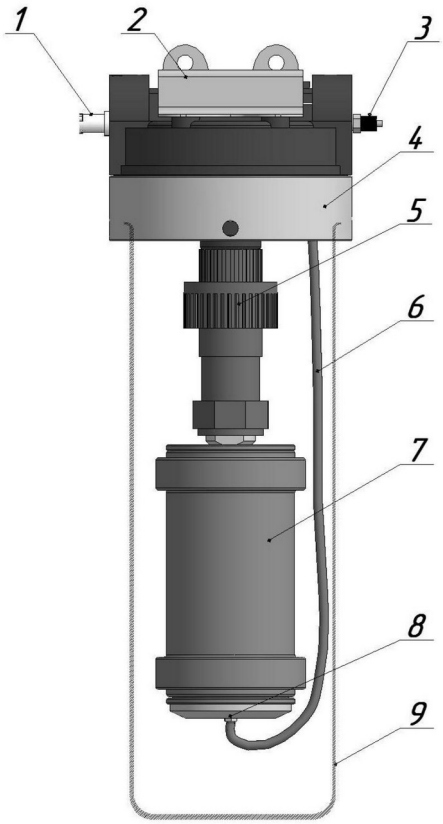


Figure 1.6 - Purification unit structure

1 - gas outlet;
2 - mounting bracket;
3 - gas inlet;
4 - cover;
5 - detachable coupling;
6 - connecting pipe;
7 - replaceable cartridge;
8 - cartridge nozzle;
9 - flask.
10 - handle for removing the flask.

Figure 1.6 - Purification unit

1.3.4 Neutralizer

Neutralizer *1* (see Fig. 1.7.) is designed to treat the gas sample from NO and NO_2 after monitoring. A pipe from the “SAMPLE OUTLET” fitting of the monitoring unit is connected to the inlet nozzle 2.

The neutralizer is a two-component adsorption catalytic destructor. For NO_2 adsorption, a calcium hydroxide absorbent is used. To neutralize NO, a catalytic decomposition method is used. The concentration of NO and NO_2 in the gas mixture at the outlet of the neutralizer (nozzle 3, Fig. 1.7) should not exceed MAC as per GOST 12.1.005. MAC of NO_2=2 mg/m^3 (1.05 ppm).

MAC of NO = 5 mg/m^3(4.01 ppm). Material of a neutralizer flask - stainless steel.

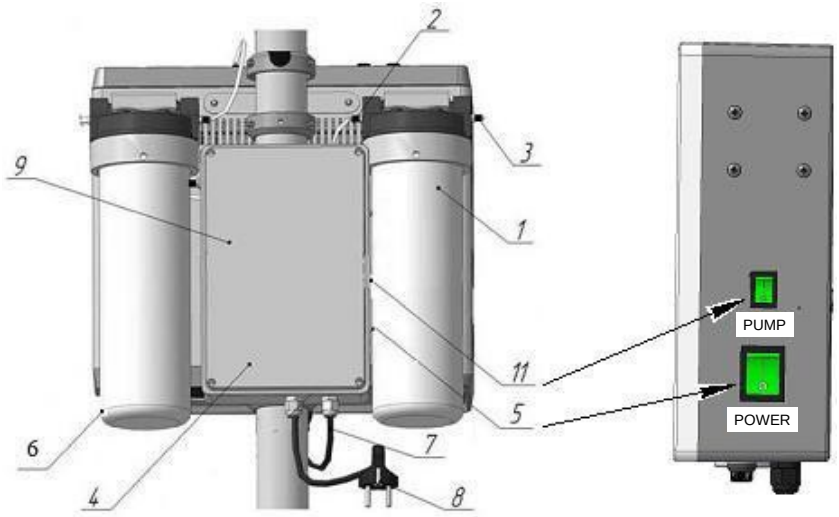
1.3.5 Electric unit

Electric unit *4* (see Fig. 1.7) is arranged in a plastic box together with the air supply unit. The power source of the monitoring unit and the distribution terminal block are arranged in the electric unit. On the outer panel there is a button "POWER" *5* with a light indicator of the Unit

operation. In the lower part of the unit, a mains power cable *8* with a plug and a power cable *7* of the NO generator with a mains connector are brought out through the cable glands.

1.3.6 Air supply unit

Block *9* (see Fig. 1.7) is arranged in the plastic box of the electric unit and provides air supply to the patient's therapeutic circuit. The volume flow rate of the supplied air is 5±2 l/min. The presence of an air supply unit provides the possibility of autonomous operation of the Unit in the absence of external air stimulators. Turning on the air supply is carried out using the "PUMP" button *11*, located on the side wall of the unit.



1 - neutralizer;
2 - neutralizer inlet nozzle;
3 - neutralizer outlet nozzle;
4 - electric unit;
5 - "POWER" button;
6 - purification unit;
7 - NO generator power cable;
8 - mains cable;
9 - air supply unit;
11 - "PUMP" button;

Figure 1.7 - Neutralizer, electric unit and air supply unit

1.3.7 Complete scope of supply

The scope of supply includes:

1. " Unit for nitric oxide therapy AIT-NO-01, TU 32.50.21001-07623615-2017".

Unit composition:

- NO, NO_2 monitoring unit;
- generator;
- electric unit;
- purification unit;
- neutralizer;
- air supply unit;
- stand with the base;
- handle for removing purification unit flask;
- tubing for connection to breathing circuit: "Devices and respiratory systems for anesthesia and respiratory units, aerosol and oxygen therapy", RU No. FSZ 2009/03551 (if necessary).

2. Accessories:

- monitoring unit bag;
- fuse.

3. Documentation:

- operating manual;
- logbook.

1.4 Unit design and operation

All units and parts of the Unit are arranged on a mobile rack with a five-prong base. The central pipe of a rack is made of steel with the chrome plating. In the central part of the rack

there is a retractable device for movement retention.

The block diagram of the Unit operation is shown in Figure 1.8.

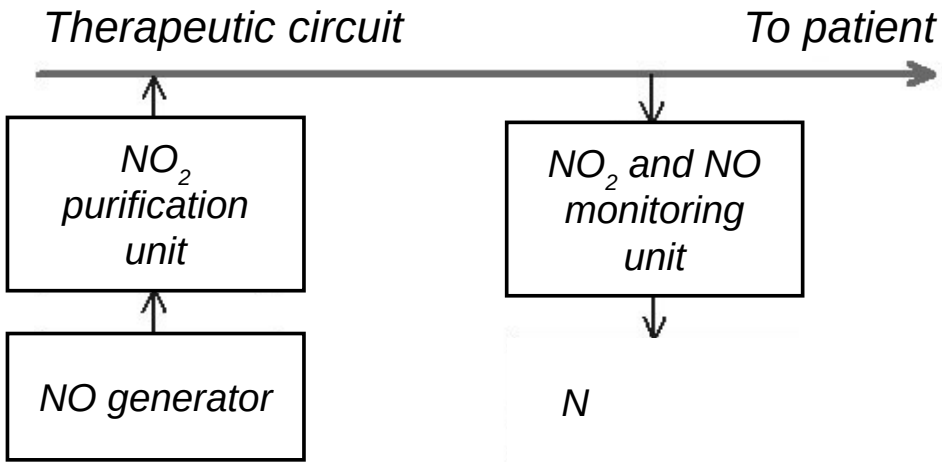


Figure 1.8 - Block diagram of the Unit operation

The NO-containing gas mixture synthesized in the generator enters the purification unit at a space velocity of 0.45±0.2 l/min and is then fed into the patient's therapeutic circuit. In the circuit, NO is mixed with the main respiratory flow, which is supplied from an external stimulator (ALV apparatus, compressor, oxygen concentrator, etc.) or from the air supply unit of the Unit. Immediately before delivery to the patient, a gas sample is taken from the breathing circuit for analysis in the monitoring unit. The volumetric velocity of gas sent to monitoring is 0.45±0.2 l/min. Concentration of NO and NO_2 in the breathing mixture supplied to the patient is displayed in ppm. In order to maintain measurement accuracy, the mode of purging electrochemical sensors with “clean air” is periodically switched on. The purge turns on automatically and does not require operator intervention. The purge interval is determined by the internal diagnostic system. After monitoring, the gas mixture is treated to separate from nitrous gases in the neutralizer.

1.5 Instrumentation

The following measuring instruments are used to monitor the operability of the Unit and to carry out maintenance:

- Gas analyzer AGM-510

NO from 0 to 100 ppm, error ±10% NO_2 from 0 to 50 ppm, error ±10%

- Gas rotameter with a measurement range of up to 1.5 l/min and with an allowable basic error of not more than ±10%;

1.6 Marking

1.6.1 Marking is made in accordance with GOST 12969.

1.6.2 The Unit has a data plate according to the requirements of GOST 12971, which contains the following:

- trademark of the manufacturing plant;
- Unit designation;
- number of the Unit according to the numbering system of the manufacturing plant;
- year of manufacture of the Unit;
- rated voltage and frequency of alternating current of the supply mains;
- rated power consumption;
- symbol indicating the degree of protection against electric shock - a product with a working part of type B. The working part complies with the requirements of GOST R IEC 60601-1 for ensuring protection against electric shock, in particular the requirements for the

allowable leakage current to a patient and additional current in the patient's circuit (sign No.19, Table D.1, GOST R IEC 60601-1);

- ⚠ "Warning" symbol - Caution! Refer to the operating manual (sign No.10, table D.1, GOST R IEC 60601-1).
- designation of technical conditions for the Unit;
- number and date of registration certificate;
- classification depending on the degree of protection against dangerous ingress of water or solid particles - IP20.

1.6.3 Sealing of the Unit is carried out at the manufacturing enterprise in the places where the removable covers of the NO generator are fastened with screws to the side braces.

1.6.4 Removal of seals from the Unit is carried out by the company providing maintenance (scheduled and repair work). After carrying out the relevant works, the Unit is sealed with the company's seal press.

1.6.5 Transport marking is made in accordance with GOST 14192.

Handling signs are applied to the transport container with the following meanings:

“Fragile. Handle with care!”, “This side up!”, “Protect from moisture!”.

1.7 Packing

1.7.1 The Unit packing corresponds to requirements of GOST 2789 and GOST 9378.

1.7.2 Materials and substances used for packing the Unit are safe for human health and the environment.

1.7.3 All components of the unit, except for the monitoring unit, are supplied fixed on the rack. The monitoring unit is placed in a transport bag.

1.7.4 The NO generator, electric unit, monitoring unit, air supply unit, neutralizer and purification unit are additionally packed in a polyethylene case with temporary anti-corrosion protection using static air drying with silica gel as per GOST 9.014.

1.7.5 The Unit and accessories are placed in a plywood box.

1.7.6 Overall dimensions of the shipping container are not more than 740x740x1500 mm.

1.7.7 The packing contains a set of accompanying documentation in a sealed bag.

1.7.8 The category of packing according to requirements for the protection of products from climatic factors of the external environment corresponds to KU-1 as per GOST 23170.

1.7.9 A packing list is included in each shipping container with the following data:

- name of the manufacturing enterprise;
- designation of the Unit type and its name;
- date of packing;
- signature of the person responsible for packing.

2 Intended use

2.1 Operational restrictions

2.1.1 Unit operating conditions:

- heated enclosed space, absence of oil vapors, explosive and chemically active substances, smoke, drip moisture;
- ambient air temperature from 15 to 35°C;
- relative humidity up to 80% at 25°C;
- availability of supply and exhaust ventilation as per GOST 12.4.021;

2.1.2 Power quality requirements as per GOST R 54149;

2.1.3 The Unit is intended for operation in explosion-proof rooms.

2.1.4 Indications for the use of the Unit:

1. Precapillary pulmonary hypertension in adults.
2. Precapillary pulmonary hypertension in children, including newborns.

2.1.5 Contraindications to the use of the Unit:

Absolute:

1. methemoglobinemia (congenital and acquired).

Relative:

1. hemorrhagic diathesis;
2. intracranial hemorrhage;
3. severe left ventricular failure (NYHA classes III and IV).

2.1.6 Possible side effects

1. Methemoglobinemia is a rare complication of inhaled NO therapy: according to one large study, the concentration of methemoglobin > 5% was observed in 2.3% of patients and in no case exceeded 7%. Methemoglobinemia is observed only in patients receiving doses of NO more than 40 ppm; children with methemoglobin reductase deficiency have an increased risk of developing this complication.

2. An increase in the level of toxic metabolites (NO_2) is possible with the use of high doses of inhaled NO (>100 ppm). NO_2 concentrations above 3 ppm can lead to lung damage, pulmonary edema, pulmonary hemorrhages, and disruption of surfactant production.

2.2 Preparation of Unit for use

2.2.1 Safety measures for preparing the Unit

When preparing the Unit for use and during its operation, it is necessary to comply with safety requirements in accordance with the applicable "Rules for the technical operation of electrical installations by the consumer" and "Rules for technical safety during the operation of electrical installations by the consumer"

CAUTION! To avoid the risk of electric shock, this equipment should only be connected to supply mains with protective earthing**.**

ATTENTION! All cable connections may only be made when the power supply is switched off.

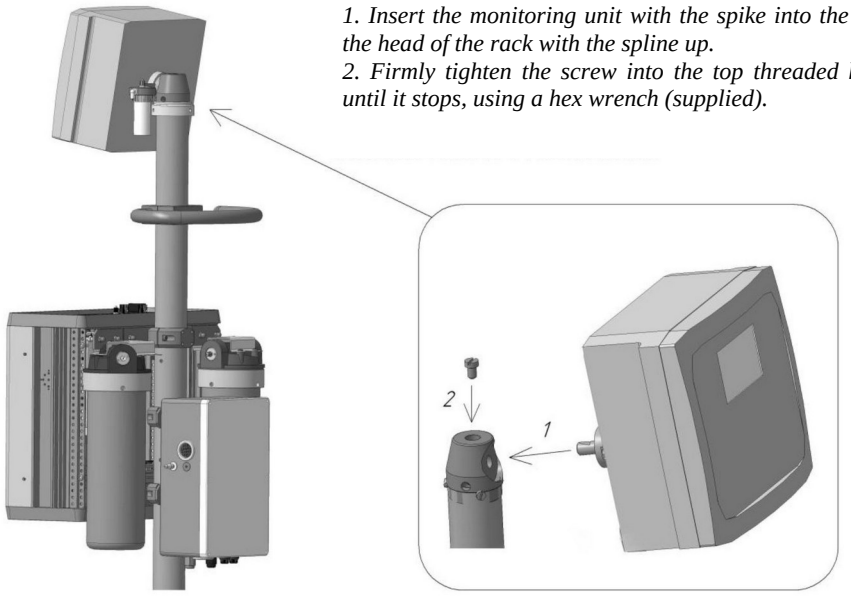
2.2.2 Unit installation

ATTENTION! If the Unit has been at a temperature below 0°C (after transportation) then before turning it on it is necessary to keep the Unit at normal temperature in the packing for at least 12 hours.

2.2.2.1 Take the Unit out of the transport packing, remove plastic covers.

2.2.2.2 Carry out external inspection and make sure that there are no mechanical damages to the elements of the Unit, and tubes, nozzles and wires are intact.

2.2.2.3 Install the monitoring unit to the mounting seat at the top of the rack, as shown in Figure 2.1. The unit is attached to the rack using a detachable connection, in the sequence shown in Figure 2.1.



1. Insert the monitoring unit with the spike into the docking hole on the head of the rack with the spline up.
2. Firmly tighten the screw into the top threaded hole of the head until it stops, using a hex wrench (supplied).

Figure 2.1 - Location and fixing of the monitoring unit

2.2.2.4 Connect the plug of the power cable to connector 5 of the monitoring unit (see Fig. 1.5).

2.2.2.5 Connect the tube coming from the neutralizer (pos.3 Fig.1.1) to the nozzle of the monitoring unit with the inscription "OUTLET" (pos.1 Fig.1.5).

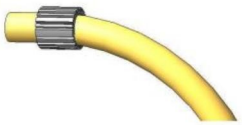
The tube on the nozzle is fixed with a captive nut.

The method of connecting the tube with the nozzle is shown in Fig. 2.2.

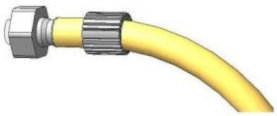
ATTENTION! Detachable connections should ensure air-tightness of the gas path.

1. Unscrew the captive nut of the nozzle

2. Pass the connecting tube into the opening of the captive nut



3. Push the tube onto the cone of the nozzle until it stops in the thread



4. Tighten the captive nut of the nozzle

Figure 2.2 - Sequence of connecting the tube with the nozzle

2.2.2.6 Connect the cable from the NO generator with the RS-232 connector to the "RS-232" port (pos.*6* Fig.1.5) of the monitoring unit. Tighten the nuts until they stop.

2.2.2.7 Put a transparent plastic flask on the cover of the moisture separator.

2.2.3. Procedure for checking the Unit readiness

After carrying out the installation operations, it is necessary to check the Unit readiness for its intended use. Checking the Unit readiness consists in an external inspection and checking the connection of the Unit units.

2.2.3.1 Scope and sequence of external inspection

Check the correct installation of the Unit in accordance with paragraph 2.2.2 of this OM.

Check the external surface of the Unit elements for the absence of dents, cracks and mechanical damage affecting the performance of the Unit functions.

Check the external surface of the Unit elements for the absence of sharp corners, cutting edges and burrs capable of causing cuts to the personnel during operation.

Check connecting pipes for external damage and kinks.

Check the external surface of the Unit elements for visible contamination.

2.2.3.2 Checking connection of Unit units

Connections of the Unit units are shown in Figure 2.3.

The monitoring unit should be fixed in the required position.

Power cable *1* should be connected to the connector of the monitoring unit "= 12V 1A" (para 2.2.2.4).

Pipe *2* should connect the neutralizer inlet nozzle (pos. *2* Fig. 1.7) with the “OUTPUT” nozzle of the monitoring unit (pos. *1* Fig. 1.5). The pipe is routed inside the vertical pipe of the rack.

The pipe *3* should connect the "SAMPLE" nozzle on the monitoring unit (pos. *4* Fig. 1.5) with the filter 13 located on the corner connector 9 on the top cover of the moisture separator *8.*

Pipe 4 should connect the “NO OUT” nozzle on the NO generator control panel (pos. *3* Fig. 1.3) with the “GAS IN” nozzle on the purification unit (pos. *3* Fig. 1.6).

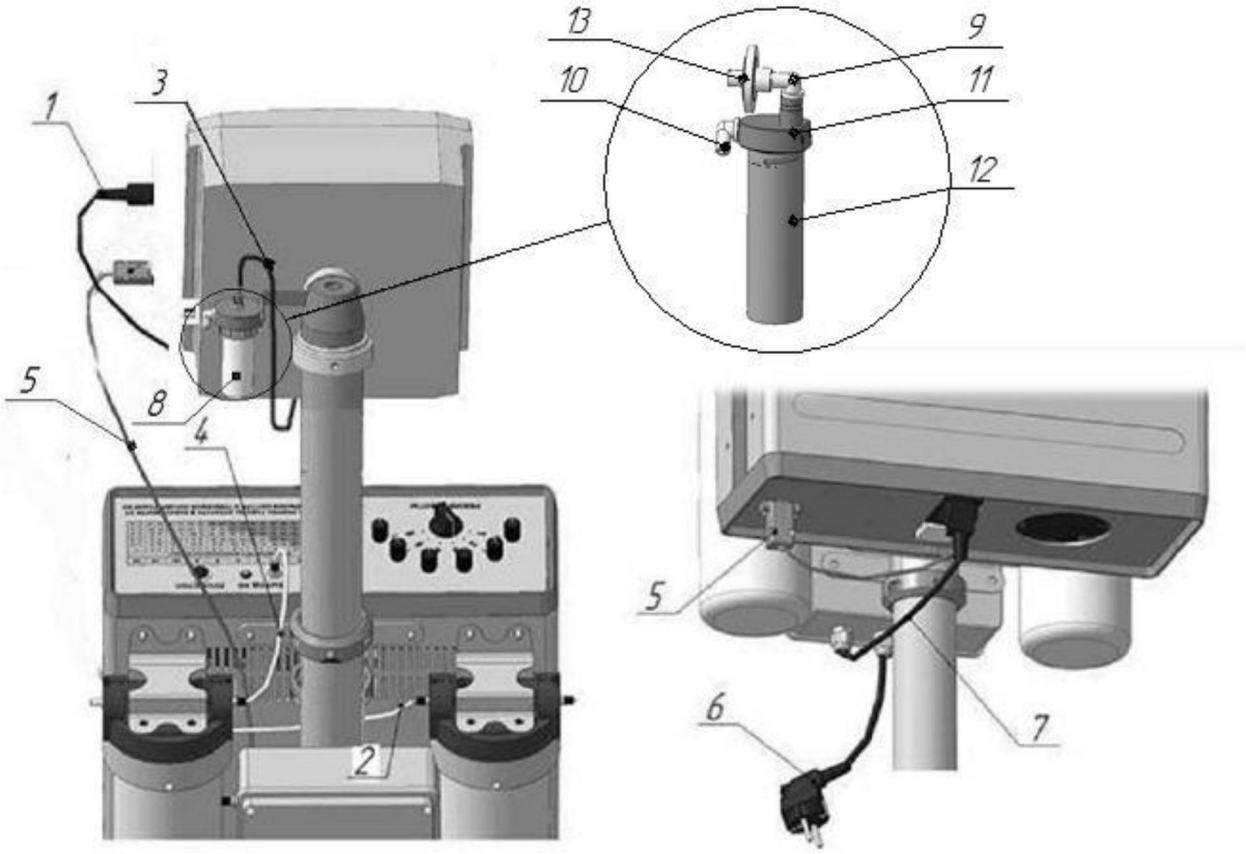


Figure 2.3 - Connecting the Unit units

Mains power cable *7* of the NO generator coming out of the electric unit (para 1.3.5) should be connected to the mains socket on the rear panel of the NO generator. The power switch should be in ON position.

The monitoring unit and the NO generator should be connected by cable *5* with RS-232 connectors. The cable is routed inside the rack pipe.

Power wire *6* should be connected to a mains socket.

A transparent plastic flask *12* should be tightly put on the cover of the moisture separator *11* until it stops (Fig. 2.3).

The Unit is considered ready for its intended use and for connection to the breathing circuit if the results of the external inspection and checking the connection of the units are positive.

2.2.4 Connecting the Unit to the breathing circuit

The Unit is connected to the breathing circuit by means of connecting the NO supply line and the NO and NO_2 monitoring line to the patient's inspiratory line *6* (see Fig. 2.4). On the NO supply line, tube *2* is connected to fitting *1 of the purification unit.* Detachable connection of the Luer-Lock type. The second end of the tube *2* is connected to the patient's inhalation line *6* through the virus-bacterial hydrophobic filter 5.

On the monitoring line, a tube *4* is connected to the moisture separator 7 through the Luer-Lock connector (Fig. 2.4). The second end of the tube *4* is connected to the patient's inhalation line *6.* The virus-bacterial hydrophobic filter 5 is connected to the upper nozzle of the moisture separator and then the gas enters the monitoring unit without droplet moisture.

ATTENTION! The connection of the monitoring unit to the respiratory tract should be carried out **only** through a moisture separator; the virus-bacterial hydrophobic filter should be connected downstream the moisture separator to the angled connector located on the top of the cover. Otherwise, the Unit will go into inoperable state and require the intervention of qualified

personnel to eliminate the consequences.

Tubes *2* and *4* for connecting the Unit to the breathing circuit should be not more than 2 meters long (prefer a shorter one) and have inner diameter of 1.2...2 mm. Using tubes with other specifications may cause the Unit to malfunction. Type of connection with the Unit - Luer-Lock.

ATTENTION! During therapy the monitoring of NO and NO_2 concentration in the breathing circuit should be carried out continuously.

ATTENTION! Virus-bacterial hydrophobic filters should be installed on the NO supply line and the NO and NO_2 monitoring line to prevent the risk of cross-contamination.

Filters are specially designed to protect against contamination of equipment on monitoring lines.

Virus-bacterial filters should have a registration certificate and should be approved for use on the territory of the Russian Federation.

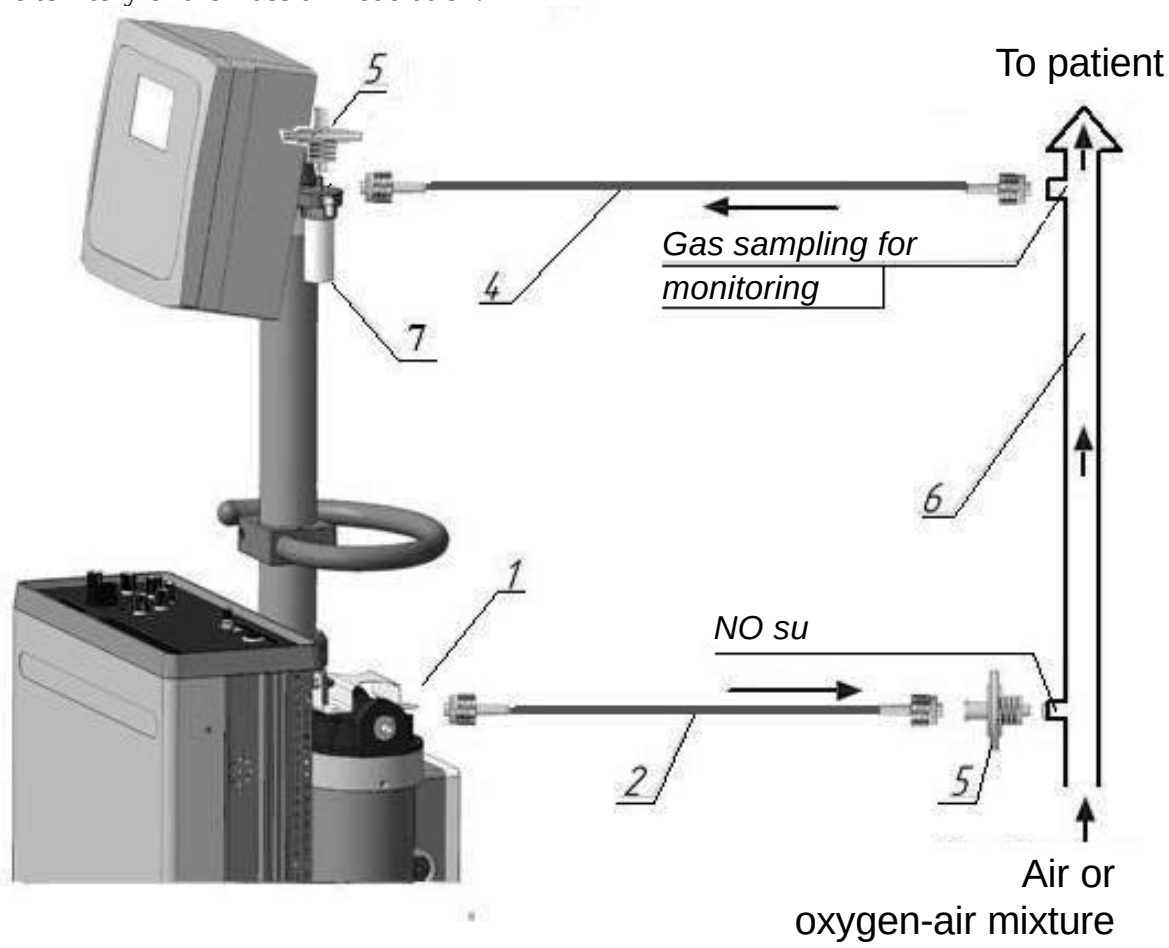


Figure 2.4 - Connecting the Unit to the breathing circuit

ATTENTION! Sampling of gas mixture for monitoring should be carried out as close as possible to the patient.

The Unit can work with various types of breathing circuits, the specific design of which depends on the method of carrying out NO-therapy. The requirements given in paragraph 2.2.3 of this OM should be met regardless of the type of breathing circuits used.

2.3 Using the Unit

The Unit in the working position is fixed with the help of a device for movement retention (Fig. 2.5)

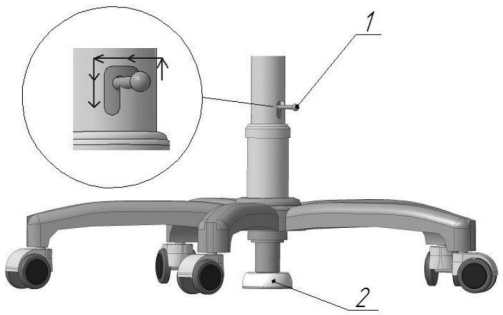


Figure 2.5 - Device for movement retention

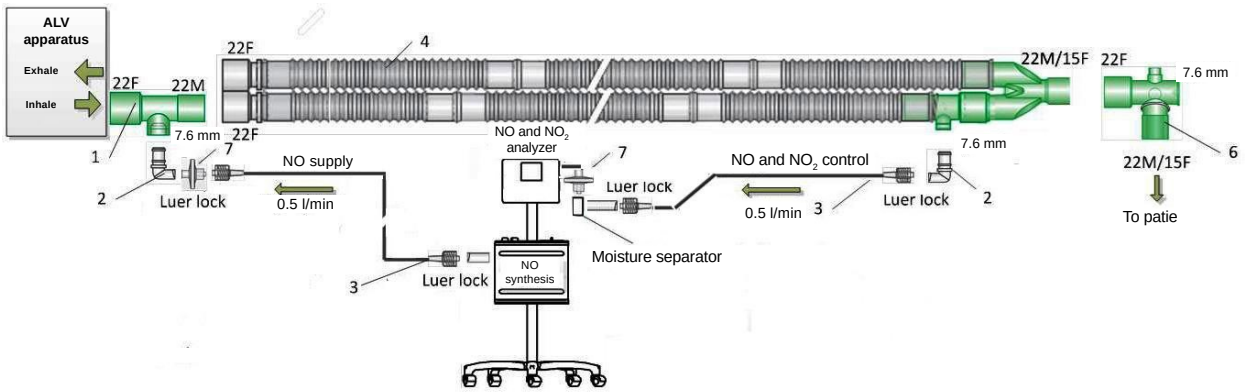
To fix the Unit in working position, move the lever *1* along the path shown in Fig. 2.5 and lower the locking support *2* until it hits the floor. To move the Unit, raise the locking support by moving the lever in the reverse direction. The Unit should be moved by the handle (Fig. 1.1) located on the vertical pipe of the rack.

ATTENTION! During operation, the Unit should be fixed in working position by a device for movement retention.

When using the Unit, it is necessary to periodically clean its external surfaces from dirt. Cleaning is carried out by wiping the Unit with a swab moistened with a disinfectant. Penetration of disinfectant into the Unit is not allowed. Otherwise, it is necessary to keep the Unit under normal conditions for at least eight hours until the liquid is completely dried out. Disinfection is carried out according to OST 42-21-2 with a 3% hydrogen peroxide solution (GOST 177) with the addition of 0.5% detergents.

ATTENTION! During the Unit operation, it is necessary to visually monitor the liquid level in the moisture separator (pos.*8* fig.2.3). The liquid level in the flask (pos.*12* Fig.2.3) should not exceed 10 ml (mark 10 ml on the flask). If the level is exceeded, the liquid should be drained. To do this, carefully pull the flask off the cover of the moisture separator (pos.*11* in Fig.2.3). Then put the empty flask on the cover of the moisture separator until it stops.

Given below for example is one of the possible diagrams for connecting the Tianox Unit to the ALV breathing circuit using Intersurgical components.



All parts of the circuit are disposable, hydrophobic filters *7* and tubes of the monitoring line *3* should be changed for each patient.

Pos.	Description of components*	Quantity in the diagram	Code in the catalog
1	Straight connector 22F - 22M with 7.6 mm outlet.	1 pcs.	1964000
2	7.6mm Luer angle detachable connector.	2 pcs.	2711000
3	Respiratory gas monitoring line.	2 pcs.	2725000

	Inner diameter 1.2 mm. M Luer lock / M Luer lock.		
4	Breathing circuit for nitric oxide treatment. Length 1.6 m	1 set	2000058
6	Angular connector 22F - 22M/15F with 7.6mm outlet.	1 pcs.	1893000
7	Hydrophobic filter for monitoring line with Luer port.	2 pcs.	2715000

*The diagram shows products from the INTERSURGICAL catalog.

2.3.1 Selecting the operating mode of the Unit

The Unit has 6 modes of operation, which provide NO-therapy with different flow rates in the respiratory circuit. The choice of mode is made depending on the flow rate in the breathing circuit and the required concentration of NO. The choice is made according to Table 2.1. For ease of use, the table is placed on the control panel of the NO generator.

ATTENTION! The mode selection table shows guide values for concentrations. The actual concentration of NO and NO_2 in the breathing circuit is displayed on the screen of the monitoring unit.

The modes are set by turning the switch (pos.*3* in Fig.2.6) to one of six positions. The position number corresponds to the mode number. Fine tuning knobs are installed opposite each position. By turning the fine-tuning knobs (pos. *7* in Fig. 2.6), the NO concentration is finely adjusted within the range of the corresponding mode. In order to increase the NO concentration, turn the fine adjustment knob clockwise, to decrease the concentration, turn it counterclockwise. After each mode change or concentration adjustment, the Unit needs time to reach a steady state. After the Unit reaches the steady state, the readings of the NO concentration on the screen of the monitoring unit should stabilize. The adjustment is made until the desired NO concentration in the breathing circuit is reached.

Flow, l/min	**2**	**4**	**6**	**8**	**10**	**12**	**14**	**16**	**18**	**20**
Mode	**NO concentration in the breathing circuit, ppm**									
1	**6...45**	**3...24**	**3...15**	**3...12**	**3...10**	**1...8**	**1...7**	**1...6**	**1...5**	**1...4**
2	**45...90**	**24...45**	**15...30**	**12...25**	**10...18**	**8...15**	**7...14**	**6...12**	**5...10**	**4...8**
3		**45...60**	**30...45**	**25...30**	**18...24**	**15...22**	**14...18**	**12...15**	**10...14**	**8...12**
4	**>90**	**60...90**	**45...65**	**30...45**	**24...36**	**22...32**	**18...28**	**15...22**	**14...20**	**12...18**
5	**>90**	**>90**	**65...85**	**45...60**	**36...45**	**32...42**	**28...36**	**22...30**	**20...26**	**18...22**
6	**>90**	**>90**	**>90**	**60...90**	**45...60**	**42...52**	**36...48**	**30...45**	**26...38**	**22...30**

Table 2.1 - Selection of operating mode of the Unit depending on the flow rate in the breathing circuit and the required NO concentration

2.3.2 Unit switching on

Before switching on, the Unit should be prepared for use and connected to the breathing circuit in accordance with paragraph 2.2.

The Unit is turned on in the following sequence (see Fig. 2.6):

2.3.2.1 Fix the Unit in working position using the movement retention device (Fig. 2.5).

2.3.2.2 Connect the Unit to the mains.

2.3.2.3 Set "POWER" switch (pos.*1* in Fig.2.6) on the electric unit to On position: «**I**». The indicator light on the button should light up.

The monitoring unit turns on automatically. After checking the monitoring conditions, the gas sensors of the monitoring unit are zeroed, which lasts 60 seconds. If during this time the required stability of the output signals of the sensors is not achieved, then the setup time will be automatically added. Upon completion zero setting, the monitoring unit will automatically

switch to the measurement mode.

2.3.2.4 Turn on the air supply unit (if therapy will be carried out with the use of such unit) by the “PUMP” switch (pos.2 in Fig.2.6) on the side wall of the unit.

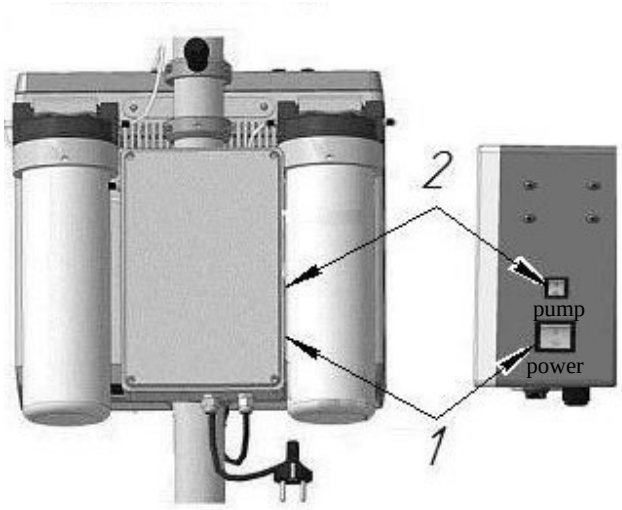
2.3.2.5 Set the operating mode of the Unit using switch *3*. The mode is selected depending on the flow in the respiratory circuit and the required therapeutic dose of NO in accordance with paragraph 2.3.1.

2.3.2.6 Turn on NO generation by pressing button *5* "START/STOP". The light indicator *6* should light up. The time for the Unit to reach the steady state of operation is not more than 10 minutes.

The screen of the monitoring unit displays the concentration of NO, NO_2 in the patient's breathing circuit.

2.3.2.7 According to the readings of the monitoring unit, set the required NO concentration in the breathing circuit using the fine adjustment knobs *7*.

1. Set switch *1* "POWER" to "I"

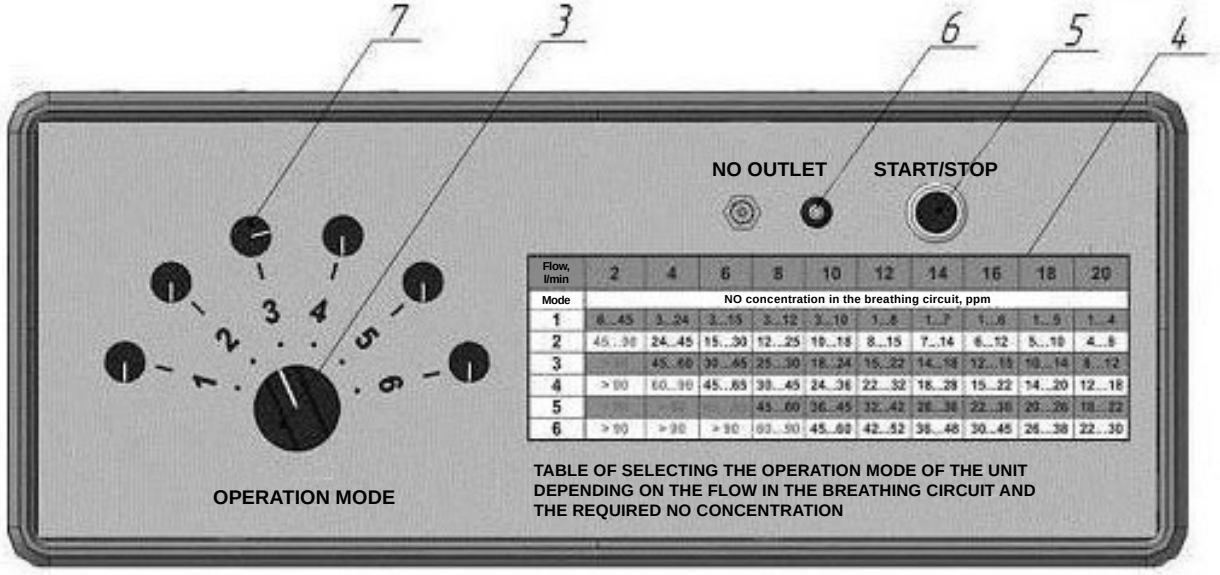


2. Select the operating mode of the Unit according to Table *4*.

Flow, l/min	2	4	6	8
Mode	Concentration			
1	6…45	3…24	3…15	3…12
2	45…90	24…45	15…30	12…
3			30…45	25…
4	> 90	60…90	45…65	30…4
5	> 90	> 90	65…85	45…6
6	> 90	> 90	> 90	60…

Example: Flow 6 l/min, NO = 40 ppm
Choose mode 3

3. Set the operating mode of the Unit with switch *3*.
4. Turn on NO generation by pressing the START/STOP button *5*.
Wait one minute for the monitoring unit readings to stabilize
5. Set the NO concentration with the fine adjustment knob *7*.



Flow, l/min	2	4	6	8	10	12	14	16	18	20
Mode	NO concentration in the breathing circuit, ppm									
1	6…45	3…24	3…15	3…12	3…10	1…8	1…7	1…6	1…5	1…4
2	45…90	24…45	15…30	12…25	10…18	8…15	7…14	6…12	5…10	4…8
3		45…60	30…65	25…30	18…24	15…22	14…18	12…15	10…14	8…12
4	> 90	60…90	45…65	30…45	24…36	22…32	18…28	15…22	14…20	12…18
5				45…60	36…45	32…42	28…38	22…30	20…26	18…22
6	> 90	> 90	> 90	60…90	45…60	42…52	38…48	30…45	26…38	22…30

TABLE OF SELECTING THE OPERATION MODE OF THE UNIT DEPENDING ON THE FLOW IN THE BREATHING CIRCUIT AND THE REQUIRED NO CONCENTRATION

Figure 2.6 - Procedure for Unit turning on

ATTENTION! After each adjustment of the concentration or change of the operating mode of the Unit, it takes time (1-3 minutes) to stabilize the readings of the monitoring unit.

ATTENTION! Connecting the patient to the breathing circuit is allowed only when the Unit is in steady state with stabilized readings of NO and NO_2 concentrations on the screen of the monitoring unit.

ATTENTION! It is necessary to periodically drain the liquid from the flask of the moisture separator. Liquid level control is carried out visually. The frequency depends on the level of humidity in the respiratory tract.

2.3.3 Unit switching off

2.3.3.1 Turn off NO generation by pressing the "START/STOP" button (pos. *5* in Fig. 2.6). The light Indicator *6* should go out.

2.3.3.2 Wait for the time necessary to purge the gas path of the Unit and the breathing circuit. The purge time depends on the breathing circuit type and volume flow. The purge is considered complete if the NO concentration in the breathing circuit is less than 2 ppm according to the monitoring unit.

2.3.3.3 Set the switch (pos.*1* in Fig.2.6) on the electric unit to Off position: "**O**".

The monitoring unit will switch to the sensor purge mode and, after it is completed, will automatically turn off.

2.3.3.4 Disconnect the Unit from the mains.

ATTENTION! It is forbidden to turn off the Unit without purging. The NO remaining in the gas paths will turn into a NO_2-resistant toxic metabolite as a result of the reaction of interaction between NO and O_2.

2.3.4 Setting threshold concentrations

High and Low NO and High NO_2 concentration thresholds can be set in the Unit. When the threshold value of concentration is reached, an audible alarm is triggered. The parameter triggered by the alarm flashes on the screen of the monitoring unit. Thresholds are set using the monitoring unit keyboard. The monitoring unit should be turned on in the measurement mode.

To set thresholds, press the key  . In the "THRESHOLD SETTING" menu, use the keys 1, 2, 3 to select the required item:

1: NO max 80 ppm
2: NO min 00 ppm
3: NO_2 max 03 ppm

Values are entered using the numeric keypad. Values are entered in ppm units. After setting all the necessary values of threshold concentrations, press the  key, the monitoring unit will return to the measurement mode. The set threshold concentrations are stored in the permanent memory of the monitoring unit and will remain there after the Unit is turned off. Threshold values are changed in the same way. The following threshold concentrations are set at the factory by default: NOmax=80 ppm, NOmin=0 ppm, NO_2max=3 ppm.

ATTENTION! When the concentration of NO or NO_2 reaches the threshold value, an intermittent sound signal is heard, and the value that triggered the alarm flashes on the screen of the monitoring unit. The alarm is not removed until the cause of its activation is eliminated. NO generation stops. To restart the generation, it is necessary to completely turn off the Unit in accordance with paragraph 2.3.3, and then turn on the Unit in accordance with paragraph 2.3.2, while eliminating the cause of the alarm.

2.3.5 Unit normal operation mode

During normal operation of the Unit, the indicator (pos.*2* Fig.2.6) on the electric unit and

the NO generation indicator (pos.*6* Fig.2.6) should be on. In the flask (pos.*12* Fig. 2.3) of the moisture separator, the liquid level should not exceed 10 ml (below the 10 ml mark on the flask). If the level is exceeded, the liquid should be drained.

The monitoring unit should be turned on in the monitoring mode. During normal operation of the Unit, the screen of the monitoring block displays the concentration of NO and NO_2, the set concentration thresholds and additional information. To maintain measurement accuracy, the "zero" setting mode is periodically switched on.

Zeroing interval, min:

1st zeroing - 15, 2nd zeroing - 20, 3rd zeroing - 30, 4th zeroing - 45, 5th zeroing - 60, any further - 90. Deviations maximum 30 seconds.

The screen view of the monitoring unit during normal operation of the Unit is shown in Figure 2.7.

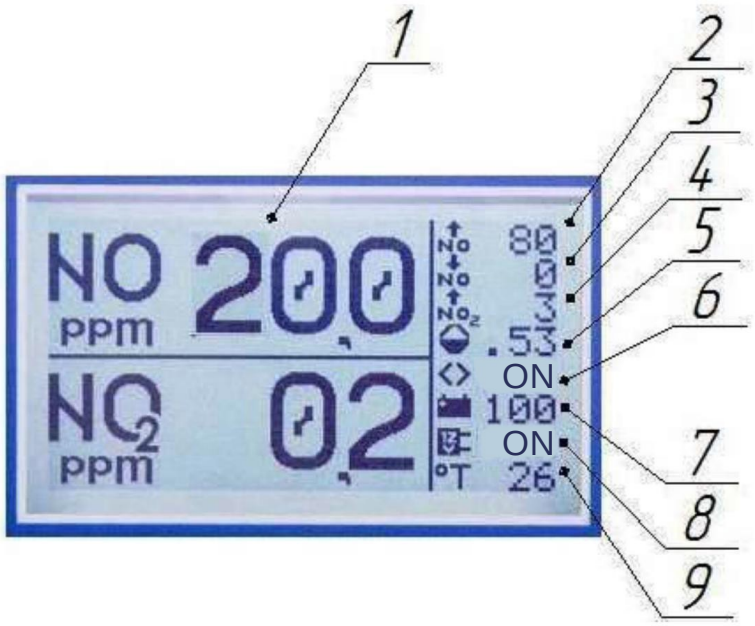


Figure 2.7 - Screen view of the monitoring unit in the measurement mode during normal operation of the Unit

1 - Field with indication of monitoring results.
2 - Threshold value of maximum NO concentration, ppm.
3 - Threshold value of minimum NO concentration, ppm.
4 - Threshold value of maximum NO_2 concentration, ppm.
5 - Consumption of the selected gas sample, l/min.
6 - Indication of enabled averaging.
7 - Charging indicator of the built-in battery, %.
8 - Indication of external power on.
9 - Temperature of the monitoring unit, °C.

2.3.6 Unit troubleshooting

Table 2.3 should be used to identify and troubleshoot the Unit. The table shows malfunctions that can be eliminated by the service personnel without the involvement of service specialists.

Table 2.3 - List of possible failures of the Unit

Failure, external manifestations	Possible cause	Remedy
NO generation is not enabled by the start/stop button on the	1. The generator is not connected to the mains supply.	1. Connect the mains cable to the NO generator.

Failure, external manifestations	Possible cause	Remedy
NO generator panel	2. Faulty fuse. 3. The internal protection has tripped due to a spontaneous power failure. 4. Power switch on the bottom panel of the NO generator is in OFF position.	2. Replace the fuse. 3. Check the availability of voltage in the mains, correct connection of the Unit, integrity of the mains cables. After that, turn the Unit off and on again with the "POWER" switch on the electric unit 4. Set the NO generator mains switch to ON position
When the Unit is on, the monitoring unit does not switch on	1. The power cable is not connected to the monitoring unit	1. Connect the power cable to the monitoring unit.
In the measurement mode of the monitoring unit, the screen reads “LOW FLOW”	1. Use of an inappropriate monitoring line (tube and filter), clogged filter or kink (clamping) of the tube.	1. Bring the monitoring line in accordance with the requirements of paragraph 2.2.3, replace the bacterial filter, eliminate the kink in the tube.
The Unit does not turn on with the on / off button on the electric unit.	1. No voltage in the mains.	1. Restore the voltage in the mains.
The monitoring unit shows zero (or too low) NO concentration when generation is on, or question marks are on the screen of the monitoring unit instead of indications.	1. The tightness of the NO supply line is broken. 2. The tightness of the monitoring line is broken. Moisture separator cover is loose. 3. Incorrect connection of assembly units and improper connection of the Unit to the breathing circuit. 4. Liquid has entered the monitoring unit, such as condensation from the respiratory tract.	1.2. Check the integrity of the connecting pipes and nozzles on the NO monitoring and supply lines. Captive nuts of nozzles and Luer connectors should be screwed in as far as they will go. Make sure that the flask of the moisture separator is put on the cover until it stops. 3. Make sure that the Unit units are connected, and the Unit is connected to the breathing circuit in accordance with paragraph 2.2.3. 4. Make sure that the gas for monitoring is supplied through the moisture separator and the liquid level in the moisture separator flask does not exceed 10 ml. To dry the monitoring unit, turn on the Unit without switching on the NO generation for at least 5 hours. If the problem persists, contact the service department.

2.3.7 Safety precautions during the Unit operation

During operation of the device, all pipes of the gas path should be securely fastened to the corresponding fittings using union nuts (Fig. 2.2), and the Luer Lock connectors should be screwed up to the stop.

The maximum allowable concentration (MAC) of NO and NO_2 during operation of the Unit in the air of the working area according to GOST 12.1.005 should not exceed for MAC of NO_2 = 2 mg/m^3 (1.05 ppm). MAC of NO=5 mg/m^3 (4.01 ppm), hazard class 3 according to GOST 12.1.007.

ATTENTION! Control of NO and NO_2 content in the air of the working area should be carried out constantly. The control should be carried out by the verified measuring means of the consumer. If MAC is exceeded, works cannot be carried out!

ATTENTION! The operation of the Unit is allowed only in a room equipped with a working system of supply and exhaust ventilation as per GOST 12.4.021. During the therapy, ventilation should be continuous.

ATTENTION! Personnel not younger than 18 years of age, physically qualified and certified to perform these works, are allowed to independently operate the Unit.

Connecting a patient to a breathing circuit with an NO-containing gas mixture is allowed only when the Unit is in steady operation with stabilized NO and NO_2 readings on the screen of the monitoring unit.

ATTENTION! When the Unit is operated in combination with external stimulators of the respiratory mixture (oxygen concentrator, compressor, artificial lung ventilation Unit, etc.), the generation of nitric oxide should be switched on only after turning on the external stimulator. Nitric oxide should be supplied to the steady flow of gas mixture.

ATTENTION! When the Unit is operated in combination with external stimulators of the respiratory mixture (oxygen concentrator, compressor, artificial lung ventilation Unit, etc.), the generation of nitric oxide should be switched off before turning off the external stimulator. Before turning off the external stimulator, you should wait for the time necessary to purge the gas path of the Unit and the breathing circuit. The purge time depends on the breathing circuit type and volume flow. The purge is considered complete if NO concentration in the breathing circuit is less than 0.5 ppm according to the monitoring unit.

ATTENTION! In the event of a leak in the NO supply line, the NO generation should be switched off.

ATTENTION! When the inscription “LOW FLOW” appears on the screen of the monitoring unit in the measurement mode, it is necessary to turn off NO generation.

ATTENTION! In case of accidental ingress of liquid into the Unit, it is necessary to stop work and call a specialist.

ATTENTION! If the monitoring unit does not turn on when the Unit is switched on, it is forbidden to start NO generation.

ATTENTION! The use of cables other than those supplied by the manufacturer of the Unit may lead to increase in the electromagnetic emission or decrease in the Unit noise immunity.

ATTENTION! During therapy, the monitoring unit should be in the monitoring mode. Threshold concentrations of NOmax, NOmin and NO_2max should be set in accordance with the NO-therapy methodology.

ATTENTION! Modification of this product without the permission of the manufacturer is forbidden!

CAUTION! To avoid the risk of electric shock, this equipment should only be connected to a supply mains with protective earthing.

When using the Unit as intended, it is necessary to comply with safety requirements in accordance with the applicable "Rules for the technical operation of electrical installations by the consumer" and "Rules for technical safety during the operation of electrical installations by the

consumer".

When using the device, it is necessary to comply with the requirements of the Fire Safety Rules for Healthcare Institutions PPBO 07-91.

2.3.8 Electromagnetic compatibility

The device complies with requirements of GOST R IEC 60601-1-2 (for devices of group 1, class B as per GOST R 51318.11, not related to life support systems).

In order to ensure electromagnetic compatibility, the Unit should be installed and put into operation in accordance with the information given in Tables 2.3.1 - 2.3.3.

Table 2.3.1

<table>
<tr><td colspan="3">Manufacturer's manual and declaration - electromagnetic emission</td></tr>
<tr><td colspan="3">The Unit is intended for use in the electromagnetic environment specified below. The purchaser or user of the Unit should ensure that it is used in the specified electromagnetic environment.</td></tr>
<tr><td>Emission test</td><td>Compliance</td><td>Electromagnetic environment - instructions</td></tr>
<tr><td>Industrial radio interference as per GOST R 51318.11</td><td>Group 1</td><td rowspan="4">The device uses radio frequency energy only for internal functions. The level of radio frequency emission is low and is not likely to cause malfunction of nearby electronic equipment.
The Unit is suitable for use in any location, including residential buildings and buildings directly connected to the distribution mains supplying residential buildings.</td></tr>
<tr><td>Industrial radio interference as per GOST R 51318.11</td><td>Class B</td></tr>
<tr><td>Harmonic components of the consumed current as per GOST 30804.3.2</td><td>A</td></tr>
<tr><td>Voltage fluctuations and flicker as per GOST 30804.3.3</td><td>Complies</td></tr>
</table>

Table 2.3.2

Manufacturer's manual and declaration - noise immunity			
The Unit is intended for use in the electromagnetic environment specified below. The purchaser or user of the Unit should ensure that it is used in the specified electromagnetic environment.			
Electromagnetic compatibility testing	Test level as per IEC 60601	Noise immunity compliance level	Electromagnetic environment - instructions
Electrostatic discharges (ESD) as per **GOST 30804.4.2**	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	The floor in the room is made of wood, concrete or ceramic tiles. With floors covered with synthetic material, the relative humidity of the air is at least 30%.
Nanosecond impulse noise as per **GOST 30804.4.4**	±2 kV for power supply circuits	±2 kV for power supply circuits	Power quality in the building electrical mains should be that of a typical commercial or hospital environment
High-energy microsecond impulse noise as per **GOST R 51317.4.5**	±1 kV when interference is applied according to “wire-wire” scheme; ±2 kV when interference is applied according to “wire-ground” scheme	±1 kV when interference is applied according to “wire-wire” scheme; ±2 kV when interference is applied according to “wire-ground” scheme	Power quality in the building electrical mains should be that of a typical commercial or hospital environment

Table 2.3.2 (continued)

Voltage dips, short interruptions and voltage changes in the input power lines as per GOST 30804.4.11	<5% U_n (voltage interruption > 95% U_n) for 0.5 and 1 period 40% U_n (voltage dip 60% U_n) for 5 periods 70% U_n(voltage dip 30% U_n) for 25 periods; <5%U_n(voltage interruption >95% U_n) for 5000ms	<5% U_n (voltage interruption > 95% U_n) for 0.5 and 1 period 40% U_n (voltage dip 60% U_n) for 5 periods 70% U_n(voltage dip 30% U_n) for 25 periods; <5%U_n(voltage interruption >95% U_n) for 5000ms	The quality of electrical energy in the building electrical mains should correspond to the typical conditions of a commercial or hospital environment. If the user of the Unit requires continuous operation during mains power interruptions, it is recommended that the Unit be powered by a battery or an uninterruptible power supply.
Commercial power frequency magnetic field as per **GOST R 50648**	3 A/m	3 A/m	The levels of power frequency magnetic field should correspond to the typical conditions of a commercial or hospital environment
Note - U_n is the level of the mains voltage before the test exposure			

Table 2.3.3

Manufacturer's manual and declaration - noise immunity			
The Unit is intended for use in the electromagnetic environment specified below. The purchaser or user of the Unit should ensure its use in the specified environment.			
Noise immunity test	Test level as per IEC 60601	Noise immunity compliance level	Electromagnetic environment - instructions
Conducted interference induced by radio frequency electromagnetic fields as per **GOST R 51317.4.6**	3V (rms value) in the band from 150 kHz to 80 MHz, outside the frequencies allocated to HF ISMH devices[1])	V**1** = 3 V (rms value)	The distance between the mobile radiotelephone communication system used and any element of the Unit, including cables, should not be less than the recommended separation distance, calculated as per the equation below for the transmitter frequency. The recommended separation distance is: $d=\left[\frac{3,5}{V_2}\right]\sqrt{P}$ where d - separation distance, m, P - transmitter output power, W $d=\left[\frac{3,5}{E_1}\right]\sqrt{P}$ (from 80 to 800 MHz);
Radiated radio-frequency electromagnetic field as per **GOST R 30804.4.3**	3 V/m in the band from 80 MHz to 2.5 GHz	E**1** = 3 V/m	$d=\left[\frac{7}{E_1}\right]\sqrt{P}$ (from 800MHz to 2.5GHz);

			According to the observational results of the electromagnetic situation[1)] the field intensity in the propagation of radio waves from stationary radio transmitters should not exceed the level of correspondence in each frequency band[2)]**).** Interference may occur in the vicinity of equipment marked with the symbol 

[1)] The field intensity in the propagation of radio waves from stationary radio transmitters, such as base stations of radiotelephone mains (cellular/wireless) and terrestrial mobile radios, amateur radio stations, AM and FM broadcast transmitters, and television transmitters can not be determined by calculation with sufficient accuracy. To this end, the practical measurements of field intensity should be carried out. If the measured values at the location of the Unit exceed the applicable levels of compliance, it is necessary to observe the operation of the Unit in order to check its normal functioning. If a deviation from normal functioning is detected during the observation, additional measures such as reorientation or relocation of the Unit should be taken.

[2)] Outside the frequency band from 150 kHz to 80 MHz, the field intensity should be less than V1 = 3 V/m.

Notes

1 A higher field intensity is used at frequencies of 80 MHz and 800 MHz.

2 The above expressions are applicable not in all cases. The propagation of electromagnetic waves is affected by absorption or reflection from structures, objects and people.

Table 2.3.4

Recommended values for separation distance "d" between portable and mobile radio frequency communications equipment and the Unit.			
The Unit is intended for use in an electromagnetic environment in which the levels of radiated interference are monitored. The purchaser or user of the Unit may avoid the effects of electromagnetic interference, providing a minimum separation distance "d" between portable and mobile radio frequency communications equipment (transmitters) and the Unit, as recommended below, taking into account the maximum output power P of communications equipment.			
Nominal maximum transmitter output power P, W	Separation distance, m, depending on the transmitter frequency		
	$d=1{,}2\sqrt{P}$ in the band from 150 kHz to 80 MHz	$d=1{,}2\sqrt{P}$ in the band from 80 MHz to 800 MHz	$d=2{,}3\sqrt{P}$ in the band from 800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
Notes 1 A higher field intensity is used at frequencies of 80 and 800 MHz. 2 The above expressions are applicable not in all cases. The propagation of electromagnetic waves is affected by absorption or reflection from structures, objects and people. 3 When determining the recommended separation distance "d" for transmitters with a nominal maximum output power not specified in the table, the nominal maximum output power "P" in watts specified in the Unit manufacturer's documentation is substituted into the above expressions.			

Warning: The Unit for nitric oxide therapy AIT-NO-01 requires special measures to ensure ELECTROMAGNETIC COMPATIBILITY and should be installed and put into service in accordance with the EMC related information provided in the Operating Manual.

Warning: the use of mobile RF communication equipment may affect the Unit.

Warning: the use of accessories, transducers and cables not listed, with the exception of transducers and cables supplied by the manufacturer of the Unit as replacement parts for internal assemblies, may increase ELECTROMAGNETIC EMISSION or reduce the NOISE IMMUNITY of the Unit.

Warning: the Unit should not be used in close proximity to or in conjunction with other equipment and, if such use is necessary, verification of the normal functioning of the Unit in such configuration should be carried out.

3 Maintenance

3.1 General guidelines

Each time the Unit is turned on, the Unit's operability is checked in accordance with paragraph 2.2.3 of this OM.

Scheduled maintenance of the Unit is carried out once a year by a representative of the organization servicing the Unit. Replacing the cartridge of the purification unit and changing the fine filter of the monitoring unit can be done by service personnel. The manufacturer, upon request, will provide wiring diagrams, component specifications, instructions and other information necessary for service personnel to replace parts of the Unit that are determined to be replaceable.

3.2 Safety measures

When servicing the device, it is necessary to comply with safety requirements in accordance with the applicable "Rules for the technical operation of electrical installations by the consumer" and "Rules for technical safety during the operation of electrical installations by the

consumer".

During maintenance operations related toNO generation, the supply and exhaust ventilation system should operate as per GOST 12.4.021 and the concentration of NO and NO2 in the air of the working area should be constantly monitored by verified measuring instruments of the consumer.

When replacing the cartridge of the purification unit, changing the fine filter of the monitoring unit, it is necessary to turn off the Unit.

All connections or disconnections of cables may only be made when the power supply is switched off.

3.3 Unit maintenance procedure

3.3.1 Maintenance of the Unit should be carried out in accordance with Table 2.4.

Table 2.4 - Procedure of the Unit maintenance

Name of the maintenance object and work	Maintenance interval
NO generator. Fuse replacement.	As necessary (para 3.3.2 of OM)
Purification unit. Replacing the chemical absorbent cartridge.	Once a year (para 3.3.3 of OM)
NO generator, monitoring unit, purification unit, neutralizer. Checking the integrity of the gas paths and the serviceability of detachable connections.	Once a year
Neutralizer. Checking the degree of gas sample purification from NO and NO2.	Once a year
NO generator, purification unit. Checking NO and NO2 concentration at the Unit outlet.	Once a year
NO generator, monitoring unit. Checking the volumetric flow rate of the NO-containing gas mixture in the NO supply line and the monitoring line.	Once a year
Air supply unit. Checking the volumetric air flow rate.	Once a year

Table 2.4 (continued)

Name of the maintenance object and work	Maintenance interval
Rack. Checking the holding capacity of the movement retention device.	Once a year
Monitoring unit. Calibration. Maintenance.	Once a year
Monitoring unit. Checking the alarm activation when the threshold values of NO and NO_2 concentration in the breathing circuit are reached.	Once a year

* If necessary, these works can be carried out by service personnel.

3.3.2 The fuse is installed in the socket of the power switch located on the bottom panel of the NO generator.

Fuse type: fusible link VPB6-12,

rated current 4 A, voltage 250 V.

The fuse holder is not an accessible part of the medical device.

ATTENTION! The use of self-made fuses is prohibited.

3.3.3 Replacing the cartridge of the purification unit is carried out in the following sequence (Fig. 2.8):

3.3.3.1 Insert handle *2* into one of the holes on cover *1*. Unscrew the cover clockwise using the handle.

3.3.3.2 Remove cover *1* together with flask *3*.

3.3.3.3 Remove tube *4* from nozzle *5* by first unscrewing the captive nut. The way of connection and disconnection of the nozzle with a tube is shown in Fig. 2.2.

3.3.3.4 Unscrew the split sleeve *6* and remove the cartridge.

3.3.3.5 Install new cartridge *8* in reverse order. When assembling, make sure that the sealing ring *7* is in its mounting seat. Screw cover *1* using handle *2* until it stops.

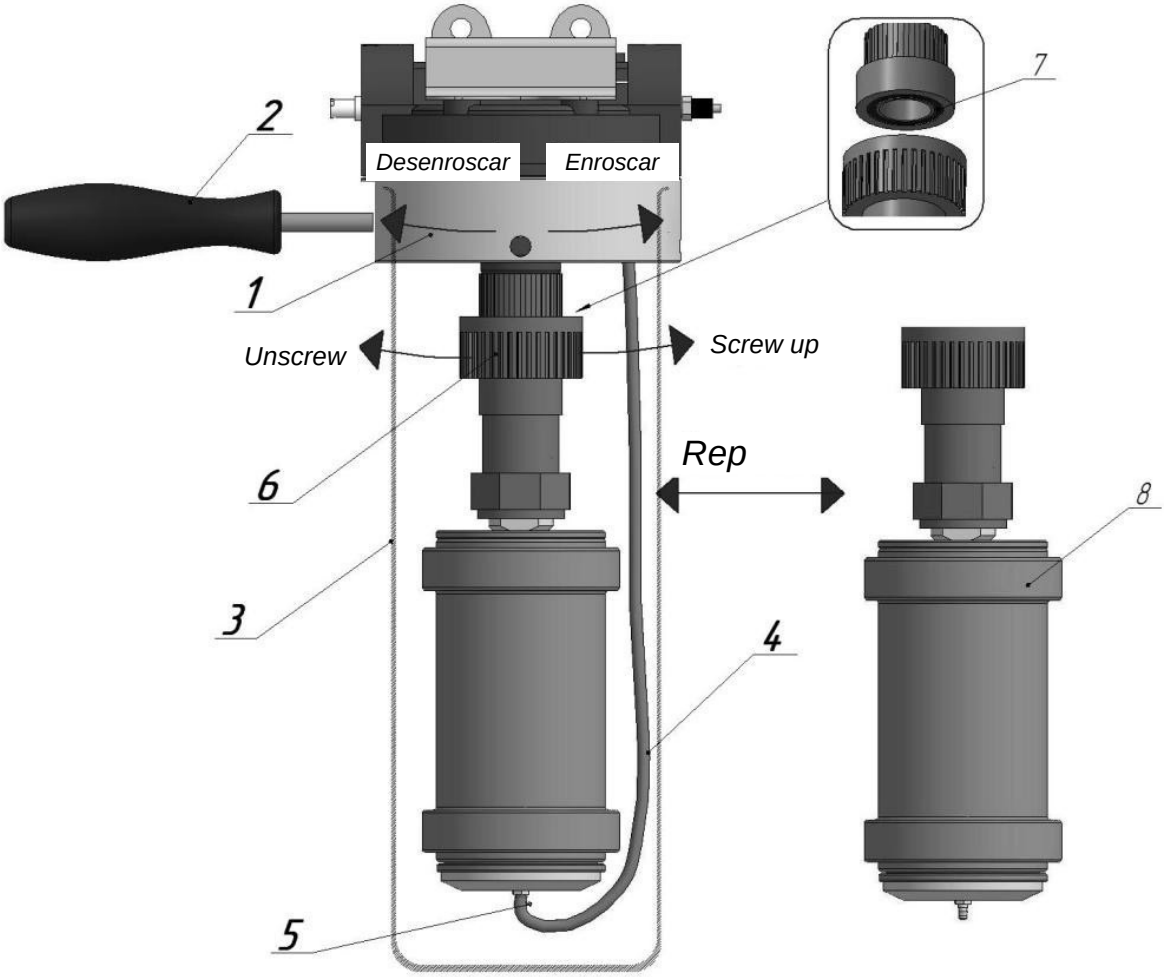


Figure 2.8 - Replacing the purification unit cartridge. Designation when ordering: "Unit purification cartridge AIT-NO-01"

3.3.4 Preventive inspection and preventive maintenance

Preventive inspection of the Unit should be carried out by the user daily. Checking the external surface of the Unit elements for the absence of mechanical damage, traces of corrosion, damage to cables, damage and kinks in the tubes is carried out by visual inspection. During the inspection, it is necessary to check the integrity of the connecting pipes and nozzles on the NO monitoring and supply lines. Captive nuts of nozzles and Luer connectors should be screwed in as far as they will go. Make sure that the Unit units are connected and the Unit is connected to the breathing circuit in accordance with the operating manual.

All works on connecting cables and tubes should be carried out with the Unit turned off.

Preventive maintenance performed by the user involves periodical cleaning the external surfaces of the Unit from contamination. Cleaning is carried out by wiping the Unit with a swab moistened with a disinfectant. Penetration of disinfectant into the Unit is not allowed. Otherwise, it is necessary to keep the Unit under normal conditions for at least eight hours until the liquid is completely dried out. Disinfection is carried out according to OST 42-21-2 with a 3% hydrogen peroxide solution (GOST 177) with the addition of 0.5% detergents. Cleaning should only be carried out with the Unit turned off.

ATTENTION! The power supply circuit of electrochemical sensors gradually discharges the battery of the monitoring unit, therefore, if the Unit is not in use, it is necessary to charge the battery at least once every six months to ensure the operability of the monitoring unit and the battery. To do this, it is necessary to turn on the mains supply of the Unit for at least 4 hours (Set the "POWER" switch on the electric unit to On position: "I". The light indicator located on the

button should light up).

4 Unit routine repair

The routine repair of the Unit is an unscheduled type of repair performed to ensure and restore the operability of the Unit and involves the replacement or restoration of its individual parts.

The routine repair of the Unit is carried out, depending on the complexity, at the place of use by the forces and means of the specialists of the manufacturer's organization or at the manufacturer's plant or its branches.

The Unit is a complex device, the operation of which is based on various physical principles. Repair, maintenance and adjustment of the Unit require specialized equipment and should be carried out by qualified personnel.

5 Transportation and storage

The Unit is transported by any type of transport in accordance with the technical conditions and rules for the carriage of goods in force on this type of transport.

The conditions of transportation and storage of the Unit in terms of the impact of climatic factors should comply with 1 (L) as per GOST 15150 (heated rooms with an air temperature of +5 to + 40°C).

The transportation conditions of the Unit with respect to the influence of climatic factors should comply with (M) as per GOST 23170. For transportation of the Unit in rigorous (R) conditions, additional measures should be provided to ensure a reliable and safe fastening.

Loading, transportation and storage of the Unit should be carried out observing the measures that exclude the possibility of damage to its components, as well as ensuring the safety of the protective coating.

Loading and unloading operations should be carried out in accordance with the general safety requirements as per GOST 12.3.009, as well as the safety rules and instructions in force at the work site.

Transportation of the product for repair should be carried out in the manufacturer's packing.

6 Disposal

The Unit does not contain toxic or hazardous materials.

The Unit that has worked out the specified time shall be disposed of in accordance with SanPiN 2.1.7.2790.

Waste hazard class - A (epidemiologically safe waste, close in composition to municipal solid waste according to SanPiN 2.1.7.2790).

7 Manufacturer's Warranty

7.1 The manufacturer ensures compliance of the Unit with requirements of this OM provided that conditions of operation, transportation and storage stipulated by the operating documents are observed.

7.2 Warranty operating life is 12 months. The warranty period is calculated from the date of signing the relevant Equipment Commissioning Certificate, provision of Services for training in operating rules and instructing specialists.

7.3 The warranty provides for free repair or replacement of the Unit components.

7.4 Warranty repair is carried out on the territory of the manufacturer or its branches. Delivery of a faulty Unit or its components is carried out at the expense and by the forces of the consumer, unless otherwise specified in the supply contract.

7.5 Replaced components of the Unit are the property of the manufacturer.

7.6 The warranty is valid provided that: the Unit is used strictly in accordance with the Operating manual, the factory seal is not broken, the defects are not related to external influences, the repair was carried out only by representatives of the manufacturer.

7.7 Warranty period of the Unit storage is 6 months.

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