INSTRUCTION MANUAL

Non-invasive electromagnetic therapy device TOR according to BEMP.941523.001TY

OPERATION MANUAL BEMP.941523.001P3







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TOR non-invasive electromagnetic therapy device users do not require special medical training.

There are no contraindications for using TOR device. No possible side effects have been identified.

Read this Instruction manual and operation manual carefully before use.

INSTRUCTION MANUAL

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1 DEVICE TOR



Figure 1 – Appearance of the device TOR:

- 1. electronic unit;
- 2. power cable;
- 3. grounding cable.



Figure 2 – Appearance of face panel of device TOR:

Indicator "OPERATION"*;
 Indicator "VENTILATION"

* **Note:** When indicator is on, the device creates electromagnetic effect in accordance with established parameters.







Figure 3 – Appearance of rear panel of device TOR :

- 1. USB-port*;
- 2. display
- 3. control buttons: cancel «ESC», up button «▲», down button «▼», button «ENTER»;
- 4. power cable connector;
- 5. fuse;
- 6. ON/OFF button
- 7. ground terminal.

* **Note:** USB connector is a technological connector, designed to configure TOR device at the factory.

2 | BEFORE INSTALLATION

- 1. Make sure that device body is free of dents and other defects
- 2. Make sure that power and grounding wires are free of damages or breaks
- 3. For installation of TOR device for operation in open space, it is necessary to ensure protection of device from atmospheric precipitations

3 | INSTALLATION

Install TOR device on horizontal solid surface so that its impact area would be maximum.



Figure 4 – Installation of TOR device on the surface.





If necessary, attach the device to hanger/bracket or install it on tripod.



Figure 5 – Installation of TOR device:

1. bracket;

2. tripod

To ensure maximum effect, it is recommended to ensure minimum space of 50 cm between a human and the device. Radiation angle of the device is 90°.

4 | CONNECTION



Figure 6 – Connection of cable.

Insert power cable into respective port on the device and connect plug to the socket. "ON/OFF" button will become green. Press it and wait until the device will be downloaded. (see Figure 7).

IMPORTANT:

To ensure safe operation of the device it is necessary to ground it. Mains sockets should be fitted with grounding. If grounding is absent, use grounding wire (included into scope of supply).







Figure 7 – Loading of the parameters when the device is switching on.

After downloading, main menu screen will appear. Option 1 in this menu may be "SWITCH ON" or "SWITCH OFF».

If "SWITCH OFF" appear on the screen, the device will work in coronavirus prevention mode. If "SWITCH ON" is selected, press "ENTER" button. The prevention mode procedure includes cyclical operation of the device: exposure for 15 minutes and pause for 15 minutes at 100% power exposure.

Basic setting of TOR device is completed.

To switch the device to therapy mode, change power or operation schedule (time and days of the week) – one should make additional adjustments (page 13).

5 SHUTDOWN

To interrupt the effect: select "SWITCH OFF" by means of up button « \blacktriangle », down button « \blacktriangledown » and press "ENTER" in main menu. For complete shutdown of the device, press "ON/OFF" button.



Figure 8- Main menu.

Figure 9 – ON/OFF button.

6 ADDITIONAL SETTINGS

1. Using buttons « \blacktriangle » and « \blacktriangledown » select option "SETTING" and press "ENTER" button.



Figure 10 - Main menu.

2. Setting of TOR device operation.



Figure 11 – Setting menu.

A) Setting of TOR device (CYCLES)

Using buttons «▲» and «▼» select option "CYCLE" and press "ENTER" button.



Figure 12- Setting of cycle "WORK/PAUSE".





Depending on the purpose of impact (prevention or treatment), set the duration of operation of device and pause in minutes. For this purpose, select necessary option using buttons « \blacktriangle » and « \blacktriangledown » and press "ENTER" button. The cursor will move right. Set necessary time using buttons « \bigstar » and « \blacktriangledown » and eress "ENTER".

Treatment (COVID-19):

Set recommended WORK time to 5 minutes and PAUSE time to 1 minute.

Prevention (COVID-19):

Set recommended WORK time to 15 minutes and PAUSE time to 15 minutes.

After setting operation cycle, select option "APPLY" and press Enter button.

By default, TOR device is set to operate in prevention mode. If user changes parameter, the device will save all settings, as well as after turning off.

B) Setting of impact power



Figure 13 – Power setting menu

To ensure optimal operation of TOR device, select power value (%) depending on exposed area:

- Area up to 40 m2 50% power;
- Area from 41 to 100 m2 -70% power;
- Area above 101 m2 -100% power

For this purpose, press "ENTER" button. Then cursor will move right. Select necessary power using buttons «▲» and «▼» and press "ENTER" button again.

After setting power level, select option "APPLY" and press Enter button.

C) Setting correct time and day of the week.



Figure 14 – Menu for setting time and selecting day of the week

Setting exact time and day of the week is necessary for correct compliance with the operation schedule of TOR device.

Time setting:

Select option "TIME" by means of «▲» and «▼» buttons and press "ENTER" button. The cursor will move right. Using buttons «▲» and «▼», set hours and press "ENTER" button. Then cursor will move right for setting minutes. Set correct hours and minutes and press "ENTER" button.

Setting day of the week:

Using buttons « \blacktriangle » and « \blacktriangledown » buttons and press "ENTER" button. The cursor will move right. Using buttons « \blacktriangle » and « \blacktriangledown », select day of the week and press "ENTER" button.

After setting select option "APPLY" and press "ENTER" button.





D) Device operation schedule

The operation of TOR device can be set to definite days and hours. It is possible to create up to 12 operation schedules.



Figure 15 – Menu for setting device operation schedule

The display will show operation schedule setting menu. Select setting option by means of « \blacktriangle » and « \blacktriangledown » buttons .



Figure 16 – Menu for setting days and hours

ON setting:

Selection option "ON" by means of «▲» and «▼» buttons and press "ENTER" button. Cursor will move right. Set hours by means of «▲» and «▼» buttons and press "ENTER" button. Then cursor will move right for setting minutes. After setting correct hours and minutes, press "ENTER" button.

OFF setting:

Select option "OFF" by means of «▲» and «▼» buttons and press "ENTER" button. Cursor will move right. Set hours by means of «▲» and «▼» buttons and press "ENTER" button. Then cursor will move right for setting minutes. After setting correct hours and minutes, press "ENTER" button.

Setting working days:

Using buttons «▲» and «▼», select option "DAY" and press "ENTER" button. Place cursor against necessary days by pressing alternatively «▲» and «▼» buttons. Place cursor against necessary days and confirm selection by pressing ENTER button. If it is necessary to select all days choose «ALL», press "ENTER" button.

Schedu	le days	- 1
All.	Wed.#	Sat.‡
Mon. #	Thu.#	Sun.‡
Tue. *	Fri.#	Back

Figure 17 – Schedule day setting menu

After setting, select option "APPLY" and press "ENTER" button.



OPERATION MANUAL

BEMP.941523.001PЭ





This operating manual (hereinafter referred to as OM) shall be applied to «Noninvasive electromagnetic therapy device TOR according to BEMP941523.001 TV» (hereinafter - referred to as TOR).

Information on initial release, last revision and list of changes for OM:

Initial version 1.0, 01.08.2020.

Current version 2.0, 09.09.2021.

TOR meets the requirements of the following national standards: GOST R 50444-92, GOST R IEC 60601-1-2010, GOST R IEC 60601-1-2-2014, GOST R IEC 60601-1-6-2014, GOST R IEC 62304-2013, GOST R ISO 15223-1-2014. Software hazard class (hereinafter referred to as the «Software»): class A («No injuries or damage to health possible») according to GOST R IEC 62304.

Software version: 001.001.

Software version numbering system: XXX.XXX

XXX. - three digits before dot change when the software functionality changes.

 $\ensuremath{\mathsf{.XXX}}$ - the three digits after the dot change for software correction that does not affect functionality.

Registration certificate No. P3H 2021/15459 from 23.09.2021.

Operation Manual for TOR is intended for operators.

The procedures set out in this OM should be strictly observed during the operation and maintenance of TOR.

Training and commissioning of TOR is not required since TOR is supplied with all the necessary settings and full OM, which is enough for a qualified employee to learn the principles of TOR.

Contact information about the developer, manufacturer of maintenance and service center:

GRANIT Concern JSC.

Address: 119019, Moscow city, Gogolevsky Boulevard Street, building 31, block 2.

Phone number: +7 (495) 642-97-42.

E-mail address: info@granit-concern.ru.

This OM should always be available to all personnel operating TOR. This OM should be kept in a safe place to avoid damage and to preserve its usability.

1 | DESCRIPTION AND OPERATION OF MEDICAL DEVICE

1.1. DESCRIPTION OF OPERATION PRINCIPLE OF TOR 1.1.1. Purpose

TTOR is intended to be used as supporting equipment in combination with standard methods for COVID-19 treatments to accelerate the elimination (elimination) of SARS-CoV-2 virus from the nasopharynx.

Principle of operation: based on the use of weak electromagnetic radiation, continuously induced by high voltage pulses on the electrodes of electromagnetic field exciter (hereinafter referred to as «exciter») to affect humans.

TOR is wearable, portable and mobile, not intended for operation during transport and movement within the medical institution.

Scope of use: the device can be used in medical and treatment-andprophylactic institutions, for carrying out anti-epidemiological actions.

Potential consumers are persons (users) who are part of the medical staff of the organization operating TOR who have studied the Operation Manual.

Operating values of air temperature at operation are from minus 20 °C to plus 40 ° C and humidity no more than 80% at a temperature plus 40 °C.

Class depending on the potential risk of use: 2a according to GOST 31508, the order of the Ministry of Health of the Russian Federation No. 4μ dated 06.06.2012.

Depending on the possible consequences of failure in the process of using TOR belongs to class B according to GOST R 50444.

Depending on the perceived mechanical effects of TOR refers to group 2 according to GOST R 50444.

Type of clinical design of TOR is Y1.1 according to GOST R 50444, but with temperature limit from -20 ° C to + 40 ° C and humidity of not more than 80% at temperature of + 40 ° C.

TOR is an electrical device of class I without a working part according to GOST R IEC 60601-1.

Degree of protection of TOR against dangerous penetration of water or solid particles in accordance with GOST 14254-IP20B.





1.1.2. Risks of use of TOR, contraindications, expected and predictable side effects associated with intended use of TOR.

<u>Indications for use</u>: auxiliary equipment in combination with standard treatments for COVID-19, designed to accelerate the elimination of SARS-CoV-2 virus from nasal pharynx.

There are no contraindications to the use of TOR.

Possible side effects are not detected during using of TOR.

Precautions:

- when transporting device at low temperatures, it is necessary to keep TOR at room temperature for 2 hours before switching on.
- it is forbidden to use TOR with a damaged power cord, ground cable. It is forbidden to connect the TOR to the mains if the insulation of the power cable and the plug housing are damaged or there are other defects that may result in content of personnel with live parts.
- TOR should be earthed to protect against electric shock
- it is forbidden to include TOR in the network with an alternating current voltage other than 220 V \pm 10% and a frequency other than 50 Hz \pm 0.5 Hz.
- · do not leave the TOR switched on unattended.
- it is forbidden to allow unauthorized persons to operate TOR.

Unauthorized persons are persons who are not a part of the medical staff of the organization operating the TOR, as well as persons who have not read Operation Manual.

1.1.3. • Unauthorized persons are persons who are not a part of the medical staff of the organization operating the TOR, as well as persons who have not read Operation Manual. TOR does not contain medical drugs, materials of animal and (or) human origin.

1.1.4. Composition of TOR

TOR composition should corresponds to content specified in table 1.

TABLE 1			
NAME	DESIGNATION	QNTY OF PCS	REMARK
Electric unit	BEMP.941523.002	1	
Power cable	Trademark KEMA KEUR, manufacturer DEKRA, Germany	1	Purchased item
Grounding cable	ВЕМР.685614.024СБ	1	
Operational manual	ВЕМР.941523.001 РЭ	1	On paper and electric medium
Data sheet	ВЕМР.941523.001 ПС	1	On paper medium
ACCESSORIES			
Thermal Fuse 2 A 250	Siba, Germany	1	Purchased item





Figure 1 – Appearance of the device TOR:

1. electronic unit;

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power cable;
 grounding cable.



Figure 2 – Appearance of face panel of device TOR:

1. Indicator "OPERATION"*;

2. Indicator "VENTILATION"

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Figure 3 – Appearance of rear panel of device TOR :

- 1. USB-port*;
- 2. display
- 3. control buttons: cancel «ESC», up button «▲», down button «▼», button «ENTER»;
- 4. power cable connector;
- 5. fuse;
- 6. ON button
- 7. ground terminal.

* **Note:** USB connector is a technological connector, designed to configure the TOR device at the factory.

1.1.5. Technical characteristics of TOR

Characteristics of TOR in accordance with those specified in table 2.

TABLE 2							
NAME	CHARACTERISTICS						
Electronic unit	 Overall dimensions: (LxWxH) (205,4x180,0x432) mm Acceptable tolerance ± 10 mm Weight: 8,840 kg Acceptable tolerance ± 10% 						
Power cable	 Length 1.8 m ± 10% Weight: 200 g (± 10 g) Connector type: IEC C13 						
Grounding cable (BEMP.685614.024CБ)	 Length: 5000 mm ± 50 mm •Weight: 150 g (± 10 g) 						

- The electronic unit is equipped with tripod sockets with a thread 1/4" -20 in the bottom panel for installation on a support and on the side panels of the device so that it would be possible to fix it on suspended brackets.
- The electronic unit is equipped with display that has the following characteristics:
 - Resolution (20 x 4) of the symbol;
 - Display size (70 x 25.2) mm. Tolerance ± 10%.
- A protective seal is installed at the bottom of junction of the TOP cover with the bottom panel, on the right and on the left, to prevent uncontrolled opening.
- Rated supply voltage of 220 V AC 50 Hz. Acceptable deviation of supply voltage ± 10% from the nominal value. Frequency tolerance ± 0.5 Hz.
- The rated power consumption of TOR should not exceed 150 VA.
- Peak voltage between the electrodes of the exciter at full power in the range (5-6.5) kV.
- The frequency of high-voltage pulses applied to the electrodes of the exciter is within the range (100-150) Hz.





- High-voltage pulses applied to the electrodes of the exciter with the following characteristics:
 - peak voltage value within (5-6.5) kV;
 - the magnitude of the pulse voltage change should be within the range (300-2000) V;
 - pulse frequency within the range (100-150) Hz;
 - pulse steepness is not normalized.
- Electromagnetic radiation generated during normal operation of the TOR should not exceed the norms of industrial radio interference (IRP), established for industrial, scientific, medical and household (ISMH) high-frequency devices of group 1 class A in accordance with GOST 51318.11 (SISPR 11), when tested at the measuring site, the measuring distance is 3m:
 - in the frequency band 30-230 MHz: 50 dB (μ V / m);
 - in the frequency band 230-1000 MHz: 57 dB (μV / m).
- TOR effective range:

The range of TOR is determined according to table 3.

TABLE 3. Dimensionless coefficient of radiation exposure of TOR device W, depending on the exposure time and distance, with an accuracy of 10%.

t-min R-m	5	10	15	20	25	30	40	50	100	150	200	230
2	1,5	1,44	1,38	1,34	1,29	1,25	1,18	-	-	-	-	-
5	1,58	1,52	1,47	1,42	1,37	1,32	1,25	1,18	-	-	-	-
10	1,75	1,69	1,63	1,57	1,52	1,47	1,38	1,3	-	-	-	-
15	2,35	2,21	2,14	2,07	2	1,89	1,83	1,68	1,36	-	-	-
20	3,65	3,5	3,38	3,26	3,16	3,05	2,87	2,71	2,1	1,67	1,34	-
30	4,26	4,1	3,95	3,81	3,69	3,57	3,33	3,17	2,45	1,95	1,56	1,36

- Software (hereinafter referred to as software) is stored in the internal permanent memory of TOR microprocessor and ensures the following:
 - Establishment of an operating mode of 1sec.;
 - Radiation control is intended for technological purposes in the manufacture of TOR. During operation, the voltage between the Umax electrodes (5-6.5) kV is used. Radiation control is ensured with fixed voltage values at the electrodes:

- peak voltage between electrodes Umax (5-6.5) kV;
- voltage between electrodes, Umax equal (Umax /1,4) ± 20%;
- voltage between the electrodes, Umax, equal (Umax /2) \pm 20%.
- Control of the exposure period, with setting the values of the cycles OPERATION and PAUSE in minutes, from 0 to 30 minutes, with increment of 1 minute. OPERATION or PAUSE period that is equal to 0 should ensure long-operation mode.

Recommended values for treatment: OPERATION period: 5 minutes, PAUSE period: 1 minute, 3 cycles, 2 times per day, 5 days

Recommended values for prevention: OPERATION period: 3 minutes, PAUSE period: 10 minutes, the number of cycles is not limited.

- Setting operation schedule for TOR by user, up to 12 programs, with the indication for each schedule program:
 - start time: the day of the week is set (Monday, Tuesday, Wednesday, Thursday, Friday, Saturday, Sunday), hour (values 0-23, with increment of 1 hour) and minutes (values 0-59, with increment of 1 minute);
 - end time: set the day of the week (Monday, Tuesday, Wednesday, Thursday, Friday, Saturday, Sunday), hour (values 0-23, with increment of 1 hour) and minute (values 0-59, with increment of 1 minute);
 - the value of the voltage between the electrodes set above.

If no schedule program is set, TOR will operate without a schedule. If schedule programs (one or more) are set, TOR only operates within the time (from start time to end time) set by each schedule program.

- Control of the internal components of TOR subject to heating, with actuation of fans for forced cooling of TOR upon achievement of temperature above + 40 °C.
- TOR has a light indication: green: operation indicator; yellow: ventilation, actuation of forced cooling fans. Yellow color means normal functioning of TOR, with actuation of forced cooling fans for TOR. Power button is equipped with voltage indicator, located on TOR rear panel.





1.1.6. Marking

1.1.6.1. TOR should be marked on name plate and contain the following information:

- product name;
- name of the manufacturer;
- trademark of the manufacturer;
- address of the manufacturer;
- designation of device;
- month and year of TOR issue;
- number and date of registration certificate;
- serial number No.___;
- maximum power consumption;
- type of current;
- frequency of the supply network;
- IP20B;
- the inscription: «Made in Russia».
- 1.1.6.2. Face panel of TOR device should contain the following marking:
 - designation of indicators:
 - green: «OPERATION»
 - yellow: «VENTILATION».
- 1.1.6.3. The rear panel of the TOR should contain the following information:
 - name plate that contain information specified in clause 1.4.2;
 - indication of the type of power supply (alternating current);
 - grounding indication (symbol according to GOST R IEC 60601-1);
 - Inscriptions on controls: «ESC», « \blacktriangle » and « \blacktriangledown » «ENTER»;
 - power button: «O» (OFF), «I» (ON);
 - voltage, current for the fuse at the installation site.
- 1.1.6.4. The marking of the earthing cable should contain the following:
 - inscription: grounding cable.

1.1.6.5. Consumer (transportation) marking should meet requirements of GOST 14192 and contain the following:

- name of manufacturer and/or its trademark
- product name
- factory number
- packing year and month

- designation of specifications;
- designation of storage and transportation conditions.

Handling marks "Protect from moisture", "Do not turn over", "Up"

1.1.6.6. Marking contains marks, specified in table

SYMBOL	DESCRIPTION
\sim	Alternate current
Ť	Protect from moisture
<u></u>	Up
為	Do not turn over
Inscriptions on controls: «Esc», «▲», «▼», «Enter»	Cancel "ESCAPE", up button «▲», and down button «▼», "ENTER" button
-	ON button
	Grounding sign

1.1.7. Packing

TOR is packed in consumer (transport) packing. Consumer (transport) packaging is made of corrugated cardboard according to GOST 9142. Operation manual, data sheet must be enclosed in an envelope or plastic bag according to GOST 10354. Each transport container should be packed according to GOST R 50444.





INTENDED USE OF MEDICAL DEVICE

1.2. OPERATION LIMITS

- Use TOR at a temperature from 20 $^\circ$ C to + 40 $^\circ$ C and humidity of more than 80% at a temperature +40 $^\circ$ C;
- · Work only in gloves.

1.3. PREPARATION OF MEDICAL DEVICE FOR USE

If it is necessary to use a tripod and / or suspension bracket (not included in the maintenance kit), the tripod and / or suspension bracket should have the following characteristics:

- threaded bracket with thread 1/4" -20 for connection to the corresponding tripod socket (s) of TOR;
- · keep the device in a fixed position;
- value of the maximum suspended mass exceeding the mass of the TOR by 20%.
- 1.3.1. Medical Device connection procedure

1.3.1.1. Place TOR on a solid surface or install on a tripod / suspension brackets (a tripod and / or a suspension bracket are not included into scope of supply of TOR).

1.3.1.2. Connect the ground cable to the connector on the rear panel of TOR.

1.3.1.3. Connect the power cable to TOR and 220 V AC mains 50 Hz. Switch on / off button to ON position.

1.3.2. Use procedure

1.3.2.1. Once TOR is actuated, parameter downloading process will appear on display as shown on Figure 2.



Figure 2 – Parameter downloading process upon actuation 1.3.2.2. Upon completion of parameter downloading process, main menu will appear on display as shown on figure 3.



Figure 3 – Main menu

For further use of «▲», «▼» buttons (figure 1.2), select necessary menu option and press "ENTER" button. Upon selection of command in menu "SWITCH OFF", the device will off. If menu command "SETTING" is selected, device setting will open. To return back to previous menu option, press cancel button "ESC".

Remark: If operator doesn't take any actions within 10 seconds, the software will return display to main menu.

1.3.2.3. Device setting (figure 4).



Figure 4 – Device setting menu "SETTING"

This menu item allows you to configure the parameters:

- · product life cycle;
- product power;
- · product schedule;
- · operating time of device;
- product information.

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1.3.2.4. Operation cycle.

Select menu option "CYCLE" to access cycle setting menu as shown on figure 5.



Figure 5 – Cycle setting menu

The product cycle setting menu allows you to adjust operation time of the device using the corresponding «WORK» and «PAUSE» commands. Time is calculated in minutes. As shown on Figure 5, operation time is 1 minute and the pause time is 2 minutes.

Attention! After completing the product setup process, click option «APPLY».

1.3.2.5. Power (Figure 6).

Adjustment of radiation power is intended for production purposes upon manufacture of TOR. During operation, a value of 100% (voltage between the electrodes U_{max} (5-6,5) kV) is used.



Figure 6 – Power setting menu

This menu option allows you to adjust the power of device: 50%, 75% or 100%:

- the value «100%» sets the peak voltage between the electrodes $\rm U_{max'}$ equal to (5-6.5) kV;

- the value «75%» sets the peak voltage between the electrodes equal to (U $_{\rm max}$ / 1.4) ± 20%;
- a value of «50%» sets the peak voltage between the electrodes equal to (U $_{\rm max}$ / 2) \pm 20%.

1.3.2.6. Product operation schedule (Figure 7).



Figure 7 – Menu for selection of device operation schedule

This menu option allows selection of one of twelve operation schedules.

1.3.2.6.1. Operation schedule setting.

Menu for setting of one of twelve operation schedules is shown on figure 8.



Figure 8 – Operation schedule setting menu

This menu option allows to adjust ON time, OFF time and sett the day of the week (all days).





1.3.2.7. System time (Figure 9).



Figure 9 – System setting menu

This menu option allows setting system time shown in main menu.

1.3.2.8. Information about device (figure 10).



Figure 10 – Information about device

This menu option shows information about device: item code, software version, product serial number.

2 | TECHNICAL MAINTENANCE

2.1. GENERAL INSTRUCTIONS

2.1.1. Maintenance combines activities that are performed to prepare the product for intended use and maintaining its operating condition.

2.1.2. Timely and complete performance of maintenance of device is one of the most significant conditions for its maintenance of its availability, maintaining the stability of the initial parameters and the established service life.

2.1.3. Technical maintenance includes daily technical maintenance.

2.2. SAFETY MEASURES

2.2.1. This device should be maintained by personnel who has necessary skills for its operation.

2.2.2. It is forbidden to carry out maintenance when the product is switched on.

2.2.3. Technical maintenance.

Notes on maintenance of TOR should be recorded in the log, using an example below in the Figure.

NECESSARY MAINTENANCE/ DISCLOSED DEFECTS	ACCEPTED MEASURES	PERSON WHO IS RESPONSIBLE FOR MAINTENANCE	DATE

Figure – Example of a maintenance log





2.2.3.1. External and detailed inspection

Check:

- · condition of body;
- availability of mechanical damage, dust and dirt on the product body, power cords and grounding..

2.2.3.2. Disinfection

The outer surfaces of TOR should be treated

(according to SanPin 2.1.2630-10) with disinfectants, registered within the Russian Federation in the established order, for example, by wiping every 2 hours with use of alcohol-containing disinfectants with at least 70% content of ethyl alcohol or 60% content isopropyl.

2.2.4. List of software failures and errors

Software failures and errors during testing of the stable industrial version 001.000 are not revealed. In case of SW failure or errors, switch off device, wait for 1 minute and switch it on again. All cases of detection of failures or errors in software should be reported to the developer by e-mail office@granit-concern.ru.

SIGNS OF FAILURES AND ERRORS:

- · abnormal display of information on the display;
- · abnormal MD response to control button signals;
- violation of set cyclicity;
- violation of set schedule;
- refusal to turn on the display;
- · refusal to turn on the green indicator «WORK» when turning on the function;
- · failure to turn on the yellow «VENTILATION» indicator when the fans are on.

3 | REPAIR

3.1. TOR should be repaired only at manufacturer's site.

3.2. Fuse can be replaced by maintenance personnel who has practical skills in its operation and maintenance.

TO REPLACE FUSE, TAKE THE FOLLOWING ACTIONS:

3.2.1. Disconnect power cable from power socket.



Figure 11 – Location of fuse holder

3.2.2. Engage holder latch with screwdriver or any other tool and remove it from housing socket (figure 12).



Figure 12- Fuse holder latch





3.2.3. Remove fuse holder (figure 13).





3.2.4. Remove fuse from holder (figure 14).



- Figure 14 Removal of fuse from holder
- 3.2.5. Take fuse 2 A 250 V (hereinafter referred to as fuse) from the kit.
- 3.2.6. Install fuse on holder by pressing it so that it comes into holder (figure 15).





3.2.7. Insert the fuse holder with the fuse installed into the connector, orienting the latch of the holder toward the connector receptacle (figure 16).



Figure 16 - Installation of the fuse holder with installed fuse

3.2.8. Press fuse holder down into connector housing (figure 17).



Figure 17 – Completion of installation



3.2.9. Fuse is replaced (figure 18).

Figure 18 – View after replacement of fuse



4 | STORAGE

4.1. Manufacturer and user should store TOR in manufacture's shipping package at temperature from + 5 °C to + 40°C and air humidity of not more than 80% at temperature of + 25°C.

4.2. Devices should be stored in dry ventilated rooms at the distance of not more than 1 meters from heaters and should be protected from sunlight and atmospheric precipitations.

5 | TRANSPORTATION

5.1. Packed TOR should be transported by all types of closed vehicles in accordance with requirements of GOST R 50444 and shipping rules that are valid for certain type of vehicles.

5.2. TOR should be transported and stored in shipping package.

5.3. TOR should be transported in shipping package at temperature from + 5°C to + 40°C and air humidity of not more than 80% at temperature of + 25°C.

6 UTILIZATION

TOR should be utilized by manufacturer in accordance with procedure stipulated by SanPiN 2.1.7.2790 for medical wastes of A class in accordance with norms and rules that are valid within the Russian Federation as of the date of utilization.

7 | MANUFACTURER'S WARRANTIES

7.1. Manufacturer guarantees the compliance of TOR device with requirements of specifications BEMP. 941523.001 provided that user follows operation, storage and transportation conditions.

7.2. Guaranteed service life is 18 months since signing of shipping certificate.

7.3. Guaranteed service life: 12 months since its commissioning within guaranteed storage life.

7.4. Service life: 5 years.

7.5. The warranty doesn't apply to TOR that have defects due to mechanical damages caused due to careless or improper use and destruction of seals.

7.6. Within the warranty periods specified in p.7.2, manufacturer should remove consequences caused due to supply of TOR of improper quality or consequences of improper performance of work, remove defects of TOR, replace TOR for that which meets requirements of normative and technical documents and agreement terms, compensate customer losses for removal of TOR defects. Time, within which TOR can't be used due to failure, is not included into warranty period.

8 ELECTROMAGNETIC COMPATIBILITY DECLARATION AND MANUAL OF THE MANUFACTURER



Non-invasive electromagnetic therapy device TOR requires special measures for ensuring electromagnetic compatibility (EMC) in accordance with certification BEMP.941523.001TY. The device should be commissioned in accordance with EMC information specified in this operation manual and data sheet. High levels of emitted and conductive high-frequency electromagnetic interferences (EMI) from powerful or close high frequency sources or other equipment (personal and mobile RF communication equipment) may affect the operation of device.



Manufacturer's manual and declaration – electromagnetic emission

Non-invasive electromagnetic therapy device TOR is designed for use in electromagnetic environment specified below in accordance with specification BEMP.941523.001TY. Purchaser or user of the device should ensure operation of the device in electromagnetic environment.

TEST FOR ELECTROMAGNETIC EMISSION	CONFORMITY	ELECTROMAGNETIC ENVIRONMENT - INSTRUCTIONS					
Radio interference according to CISPR11	Group 1	Ioninvasive electromagnetic therapy device OR uses radio frequency energy only or internal functions in accordance with					
Radio interference according to CISPR11	Class A	specification BEMP 941523.001TY The emission level of radio frequency interference is low and is unlikely cause malfunctions of nearby electronic equipment.					
Harmonic components of current according to IEC 61000-3-2	Class A	Noninvasive electromagnetic therapy device TOR in accordance with specification BEMP 941523.001TY is suitable for use in any places, excluding residential houses and					
Voltage fluctuations and flicker according to IEC 61000-3-3	Confirms	buildings that are directly connected to electrical distribution network supplying residential buildings.					

Manufacturer's manual and declaration - interference immunity

Non-invasive electromagnetic therapy device TOR is intended for use in electromagnetic environment specified below in accordance with specification BEMP 941523.001TY. Device user and purchaser should ensure the use of the device in specified electromagnetic environment.

IMMUNITY TEST	IEC 60601 TEST	COMPLIANCE	ELECTROMAGNETIC
	LEVEL	LEVEL	SITUATION-GUIDANCE
Electrostatic discharges (ESD) according to IEC 61000-4-2	± 6 kV – contact ± 8 kV– air	± 6 kV - contact ± 8 kV- air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Продолжение таблицы

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC SITUATION-GUIDANCE
Nanosecond pulse interference according to IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/ output	±2 кВ – для линий электропитания ±1 кВ – для линий ввода/ вывода	Mains power quality should be that of a typical commercial or hospital environment.
High energy microsecond pulse interference according to IEC 61000-4-5	igh energy icrosecond± 1 kV for wire-to-wire interferenceJse interference ccording to IEC 1000-4-5± 2 kV for wire-to- ground interference		Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short	<5% Uн (voltage dip> 95% Uн) for 0.5 period 40% Uн (voltage dip 60% Uн) for 5 periods 70% Uн (voltage dip 30% Uн) for 25 periods <5% Uн (voltage dip> 95% Uн) for 5 sec.	<5% UH (voltage dip> 95% UH) for 0.5 period 40% UH (voltage dip 60% UH) for 5 periods 70% UH (voltage dip 30% UH) for 25 periods <5% UH (voltage dip> 95% UH) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If user of the device needs to provide continuous operation under possible mains voltage interruption, it is recommended to ensure power supply of the device from an uninterruptible power supply or the battery.
Magnetic field of industrial frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Industrial frequency magnetic field levels should be provided in accordance with typical commercial or hospital conditions

Note: U_{μ} – voltage level of the electrical network before the test impact



Manufacturer's manual and declaration – electromagnetic emission

Non-invasive electromagnetic therapy device TOR is designed for use in electromagnetic environment specified below in accordance with specification BEMP.941523.001TY. Purchaser or user of the device should ensure operation of the device in electromagnetic environment.

IMMUNITY TEST	IEC 60601 TEST	COMPLIANCE	ELECTROMAGNETIC SITUATION-
	LEVEL	LEVEL	GUIDANCE
Conductive interference induced by radio frequency electromagnetic fields according to IEC 61000-4-6 Radio frequency electromagnetic field according to IEC 61000-4-3	3 V (rms) within the band from 150 kHz to 80 MHz 3 V/m within the band from 80 MHz to 2.5 GHz	3 V 3 V/m	The distance between used portable radiotelephonic communication systems and any elements of the device, including cables, should be at least equal to recommended space distance that is calculated in accordance with terms applied to transmitter frequency. Recommended separation distance: $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$, $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$, (from 80 to 800 MHz); $d = \left[\frac{7}{E_1}\right]\sqrt{P}$, (from 800 MHz to 2,5 GHz), where <i>d</i> is the recommended separation distance in meters b); <i>p</i> is the rated maximum output power of the transmitter, W, set by the manufacturer

Продолжение таблицы

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC SITUATION- GUIDANCE		
			Field strength during propagation of radio waves from stationary radio transmitters, based on the results of observations of the electromagnetic environment a), must be lower than conformity level in each band. The effect of interferences may take place near equipment marked with		

- a. Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.





NOTE 1 At 80 MHz and 800 MHz apply a higher field strength value

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distances between portable and mobile RF communications equipment and device

Non-invasive electromagnetic therapy device TOR according to specification BEMP.941523.001TY is intended for use in an electromagnetic environment where radiated interference levels are monitored. The customer or user of the equipment can help to prevent electromagnetic interference by maintaining a minimum separation distance between portable and mobile RF communications equipment (transmitters) and apparatus as recommended below, taking into account the maximum output power of the communications equipment.

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER,	SPATIAL DISTANCE, D, M, DEPENDING ON TRANSMITTER FREQUENCY				
W	d=1.2 √P within the band from 150 kHz to 80 MHz	d=1.2 √P within the band from 80 to 800 MHz	d=2.3√P within the band from 800 MHz to 2,5 GHz		
0,01	0.12	0.12	0.23		
0,1	0.38	0.37	0.73		
1	1.2	1.2	2.3		
10	3.7	3.7	7.4		
100	11.5	11.5	23		

When determining the recommended values for the separation distance *d* for transmitters with a rated maximum output power not listed in the table, the rated maximum output power *P* in watts specified in the transmitter manufacturer's documentation is substituted into the above expressions.

Notes:

- 1. Under 80 and 800 MHz, the higher field strength applies.
- 2. The above expressions are not applicable in all cases. The propagation of electromagnetic waves is affected by absorption or reflection from structures, facilities and people
- 3. When determining the recommended separation distances d for transmitters with a rated maximum output power not listed in the table, the rated maximum output power P in watts specified in the transmitter manufacturer's documentation is substituted into the above expressions.



. REVISION LIST

Rev.	Number of	nber of sheet (sheets)			Total sheets (pages)	Doc. No.	Ref. No. supporting	Signature	Date
	Rev.	Repl.	New	Cancelled	in the document.		document and date		

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№ 01/2022



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