USER'S MANUAL

EN 2019-01; 05.02.2019

- TESLA Former
- TESLA Former prestige
  - FMS – Functional Magnetic Stimulation

CE 2265

CONTENTS

These instructions are written for the following Iskra Medical devices:

TESLA Former (Code: 1800586)
TESLA Former prestige (Code: 1800587)

Read this manual thoroughly in order to avoid any problem that may occur during installation, use, and/or maintenance of the device, and could result in damage to the device, operator or patient!

1 INTRODUCTION

TESLA Former is device which is used for muscle strengthening on areas of glutes, hamstring area, arms and pelvic floor using the new technology of FMS (Functional Magnetic Stimulation).

The pulsed magnetic field has the effect on motoric nerves which causes muscle contraction. Even through clothes. During treatment, the patient lies on therapeutic table or sits on a comfortable chair, fully dressed. Each individual treatment lasts approximately 30 minutes and is generally performed every second day. Improvements can be expected after eight treatment sessions. Functional magnetic stimulation results in increased strength in muscle mass. The patient feels muscle contracting during the treatment. The treatment is painless and has no known side effects.

The device incorporates medical and non-medical functionality. For further information please see the Indications and Contraindications chapter.

2 SAFETY

2.1 WARNINGS

It is allowed to connect only original accessories on the device. For connecting any other accessories or for using in any other purposes as prescribed, manufacturer will not be responsible.

WARNING!
Do not expose to humidity or touch with wet hands.

WARNING!
Do not put under direct sun light.

WARNING!
Avoid strong impacts or vibrations.

WARNING!
It is prohibited to use liquids during the therapy (water, oil, cream…). The therapy should be performed through thin clothing (no direct contact between skin and applicator).

WEAR EAR PROTECTION!
The device produces high levels of noise which, under long exposure, can cause noise-induced hearing loss. Operators should wear appropriate hearing protection accessories.

2.2 SAFETY MEASURES

- Leave the device in the operating environment for at least an hour if it has been brought from an environment where the temperature is lower (higher) than the lowest (highest) permitted operating environment temperature (see Environmental conditions section).
- No electrical devices with high power consumption should be connected to the mains voltage at the same time as the device.
- The device should be kept at least 2 m away from other devices that emit electromagnetic radiation while in operation (UKW, microwaves, magnetotherapy devices...).
- The device should not be installed or used in the following conditions:
  - moist rooms or rooms near sources of water,
  - rooms near chemicals,
  - near heat sources (ovens, air conditioning...),
  - exposed to direct sunlight,
  - in dusty rooms.
- Turn the device off during storms.
- Dispose of a used device, its accessories or packaging in accordance with local or national regulations.

- **Electrical and mechanical safety:**
  - Do not open the cover. Opening the device may lead to safety risks!
  - Check if the electrical voltage required by the device (see the product's descriptive sticker) matches the mains voltage.
  - The device contains surge protection (protection against lightning strikes, mains voltage fluctuations etc.), radiofrequency disturbance filters and an additional protective grounding connector.
  - The device is grounded using the grounding connector in the main power cable. Make sure that the power source is properly grounded.
  - Never cover the fan on the back of the device.

- **Fire safety:**
  - Do not install or use the device in areas with an increased risk of fire (gasses in the room) or areas with high humidity.
  - Do not use flammable fluids to clean or disinfect any part of the device!

If the device does not work as listed in these instructions turn it off and disconnect it from the mains voltage. Call an authorized service provider!

2.3 INTENDED OPERATOR

a) Education:
- secondary school finished, graduated; or
- lower degree graduation, course for device usage carried by manufacturer authorized performers

b) Knowledge
- understanding User manual (all information in User manual should be understood)
- recognizing indications/contraindications

c) Language understanding
- English, or
- at least: language used in User manual

d) Experience
- 6 months of practice in the cosmetics or medicine field (6 months), or
- course for device usage carried by manufacturer authorized performers

3 DEVICE PRESENTATION

3.1 BASIC EQUIPMENT

Item	*pcs*
Mains cable (230V,EURO plug)	*1*
User's Manual	*1*

Table 1: Basic set

3.2 OPTIONAL EQUIPMENT

Item/Code
Applicator FMS large (Code: 1511306)
Applicator FMS medium (Code: 1511305)
Fixing rubber strap 3,2 x 100 cm (Code: 1504111)
Arm for applicator FMS (Code: 1600631)
Trolley*

Table 2: Optional equipment

*For current selection of trolleys please contact the manufacturer or distributor.

3.3 TECHNICAL DATA

Device name:	**TESLA Former**	**TESLA Former prestige**
Code:	1800586	1800587
Magnetic field strength:	max 2,5 Tesla up to 50 Hz (above 50Hz strength decreasing)	
Therapy frequency:	1 to 160 Hz	
Number of channels.	2	
Modulation:	amplitude or frequency modulation	
Amplitude modulation options:	10% - 50% (sine, full-wave rectification)	

Frequency modulation options:	1 to 160 Hz from the set frequency	
The modulation period is adjustable relative to active time:	active time divided by an integer	
Active time:	1 s to 20 s	
Pause time:	0 s to 240 s	
Max no. of steps per program:	30	
Max duration of each step:	1 s to 20 min	
Therapy duration:	1 - 60 min	
Manual programs:	yes	
Pre-set programs:	yes	
Pre-set protocols:	yes	
Body part programs:	yes	
Pre-set programs:	119	
Manual programs:	100	
Fuse:	2 x T8A	
Input voltage:	240V AC, 50~60Hz	
Power:	1500 VA	
IP protection:	IPX0	
Size (W x L x H):	40 x 51 x 26 cm	47 x 60 x 27
Weight:	9,6 kg	10,5 kg
IEC 60601/1 classification:	Class I, Type BF	
MDD 93/42/EEC classification:	Class IIa	

Table 3: Technical data

3.4 DEVICE PRESENTATION

3.4.1 FRONT SIDE

Figure 1: TESLA Former

Figure 2: TESLA Former prestige

1. Touchscreen LCD
2. Applicator tray

3.4.2 REAR SIDE

Slika 1: Zadnja stran – TESLA Former prestige

1. Applicator connector Ch B
2. Applicator connector Ch D
3. Applicator connector Ch A
4. Applicator connector Ch C
5. Ventilation opening
6. Descreptive label
7. Service port (only for service purpose)
8. Connector for external grounding system
9. Fuse compartment
10. Mains cable socket
11. Main switch (ON/OFF).

WARNING!

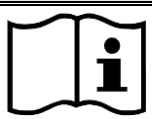
Never cover the ventilation opening while the device is in use.

3.4.3 APPLICATORS

Chair for Pelvic and Back

Applicator FMS medium (Diameter Ø12 cm)
Applicator FMS large (Diameter Ø16 cm)

3.5 MARKINGS AND GRAPHICAL SYMBOLS

SYMBOL	DESCRIPTION	LOCATION ON THE SYSTEM
	**Consult instructions for use** Indicates the need for the user to consult the instructions for use.	Descriptive label

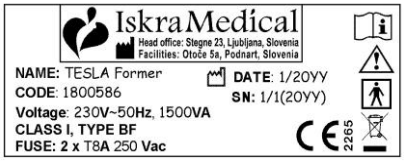
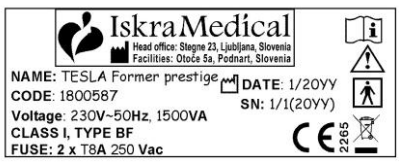
SYMBOL	DESCRIPTION	LOCATION ON THE SYSTEM
	**CAUTION** Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	Front panel
	**DISPOSAL** The device must NOT be disposed of together with other waste. The used device, its accessories or packaging should be disposed of in accordance with national and local laws or returned to the manufacturer.	On the descriptive label
Symbol for a type BF applied part 	The instrument is designed to ensure a special level of electrical protection against electric shocks, particularly at allowed leakage current, and reliability of protective grounding. Applicators are isolated from all other parts of the equipment to such a degree that the patient leakage current allowable in a single-fault condition is not exceeded when a voltage equal to 1.1 times the highest rated mains voltage is applied between the applicators and ground.	On the front side, below the screen.
Potential equalization point 	The device has a built-in potential equalization point that is connected to its conductive parts for safety reason. The point is designed to be connected to an external protective grounding system using a grounding lead.	On the back of the device.
Descriptive label:   	**DATE** - Production date (month/year). **SN** - Serial number.	On the back of the device.

Table 4: Oznake in grafični simboli

3.6 ENVIRONMENTAL CONDITIONS

	NORMAL OPERATION	TRANSPORTATION AND STORAGE
Environmental temperature:	**+10 °C to +40 °C**	**-20 °C to +60 °C**
Relative humidity:	**30 % to 75 %**	**20 % to 90 %**
Atmospheric pressure:	**500 hPa to 1060 hPa**	**500 hPa to 1060 hPa**

Table 5: Environmental conditions

4 INSTALLATION INSTRUCTIONS

Installing the device is simple and user-friendly. No special procedure that the user could not perform alone is required. Just follow these steps:

- Remove the device packaging.
- Check the contents of the case. **If some of the ordered equipment is missing, inform the manufacturer or seller!**
- Place the device onto the workspace.
- Plug the applicator into the socket on the rear of the device *(**Napaka! Vira sklicevanja ni bilo mogoče najti.**Napaka! Vira sklicevanja ni bilo mogoče najti.– no. 5).*
- Plug the mains cable into a power source (on the rear of device)
- Turn the device ON using the main ON/OFF switch *(**Napaka! Vira sklicevanja ni bilo mogoče najti.**–no. 7)*
- The device is ready for use. Follow the instructions for **using the device**.

5 WORKING WITH THE DEVICE

5.1 MAIN MENU

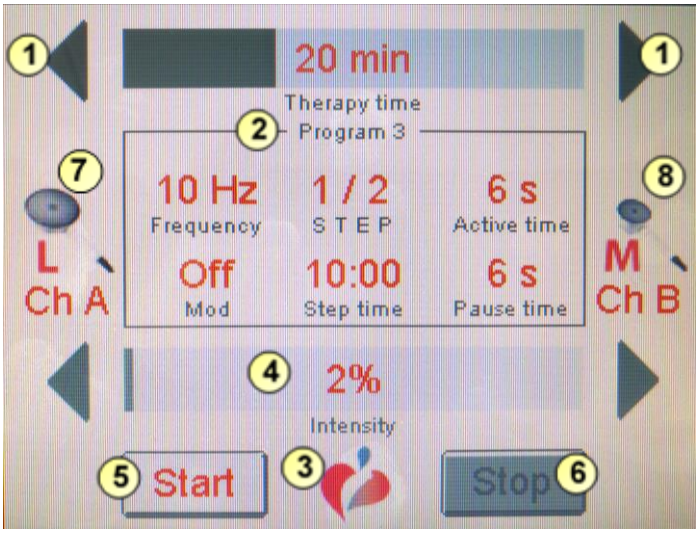


Figure 3: Main menu

1. Set the therapy duration - To increase or decrease, press the left or right arrow. To quickly set the value, slide your finger along the rectangle.
2. Shows the selected program
3. Press logo to enter the info menu
4. Set applicator intensity (20 – 100%)
5. START button – starts therapy
6. STOP button – stops therapy
7. Select the applicator on the channel A
8. Select the applicator on the channel B

5.1.1 MAIN MENU - DETAILED DESCRIPTION

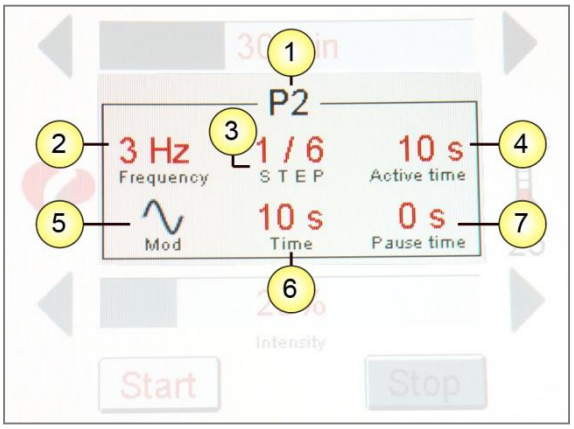


Figure 4: Main menu - description

1. Selected program
2. Selected frequency
3. Step display
4. Active time in individual step
5. Selected modulation
6. Duration of an individual step
7. Pause time in individual step

5.2 USER DEFINED PROGRAM

To add user defined program you need to define the program yourself by adding new group.

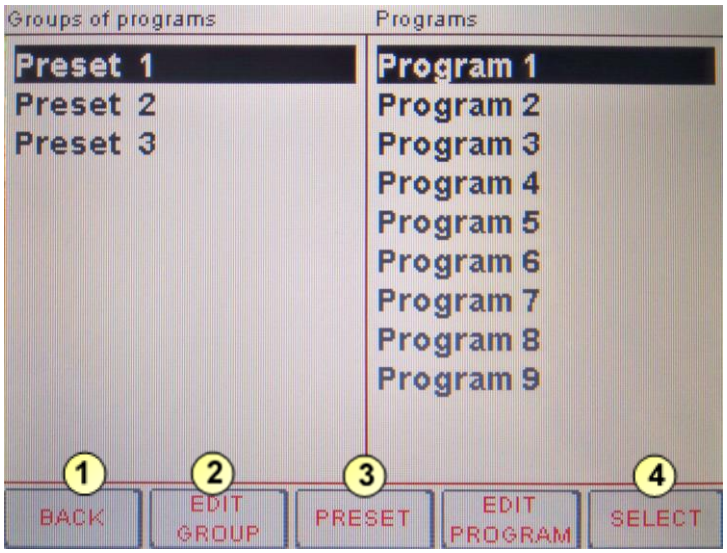


Figure 5: Creating user defined program

1. BACK – Return to previous menu
2. EDIT GROUP – go to the menu shown on the Figure 10.
3. PRESET – go back to the preset programs.
4. SELECT - Select program

5.2.1 EDIT GROUP, EDIT PROGRAM

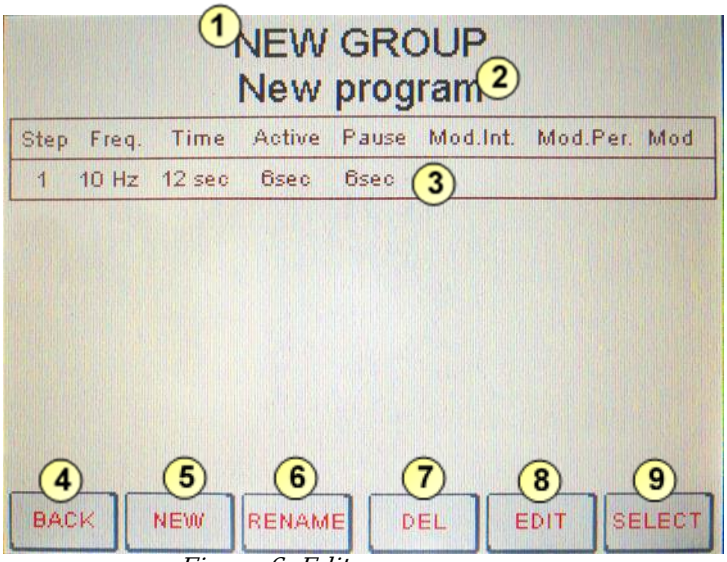
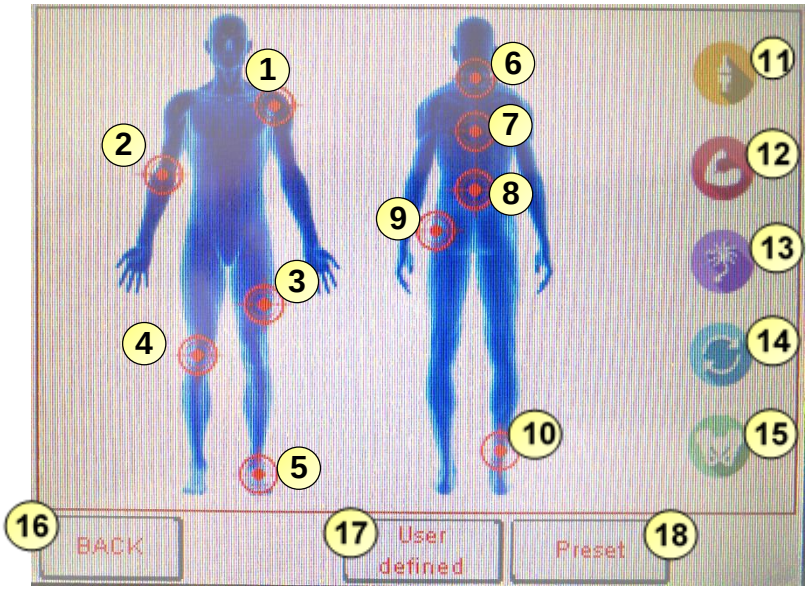


Figure 6: Edit programs menu

1. Name of program group
2. Name of program
3. Preview settings of selected program
4. BACK – Return to previous menu
5. NEW – Add new program
6. RENAME – Rename selected program
7. DEL – Remove selected program
8. EDIT – Edit selected program
9. SELECT – Select program

5.3 SUGGESTIONS



1. Shoulder area
2. Elbow
3. Hamstring area
4. Knee
5. Ankle and foot
6. Cervical spine disorder
7. Thoracic spine disorder
8. Lumbar spine disorder
9. Hip areas
10. Achilles tendonitis
11. Bones
12. Muscles
13. Neurology
14. Circulation
15. Incontinence
16. Back button
17. User defined programs
18. Switches programs menu to preset programs

Figure 7: Programs menu (suggestions)

Symbol descriptions

Applicators					
Sym.	**Desc.**	**Sym.**	**Desc.**	**Sym.**	**Desc.**
	Large applicator		Medium applicator		
Preset programs					
Sym.	**Desc.**	**Sym.**	**Desc.**	**Sym.**	**Desc.**
	Bones		Muscles		Neurology
	Circulation				
Waveforms					
Sym.	**Desc.**	**Sym.**	**Desc.**	**Sym.**	**Desc.**
	Amplitude modulation, sine		Amplitude modulation, rectified sine		Frequency modulation
	Soft start - Amplitude ramp (from zero to max in 1 sec.)		Reduce intensity	-(Off)	Modulation disabled
FM	Frequency modulation	AM	Amplitude modulation	Inten.	Intensity
Freq.	Frequency				

5.4 INFO Menu, Entering the code for timed device lockup

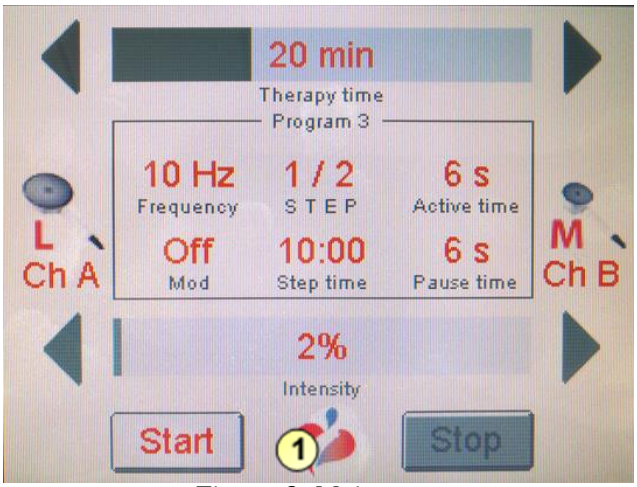


Figure 8: Main menu

1. Press logo to enter the info menu

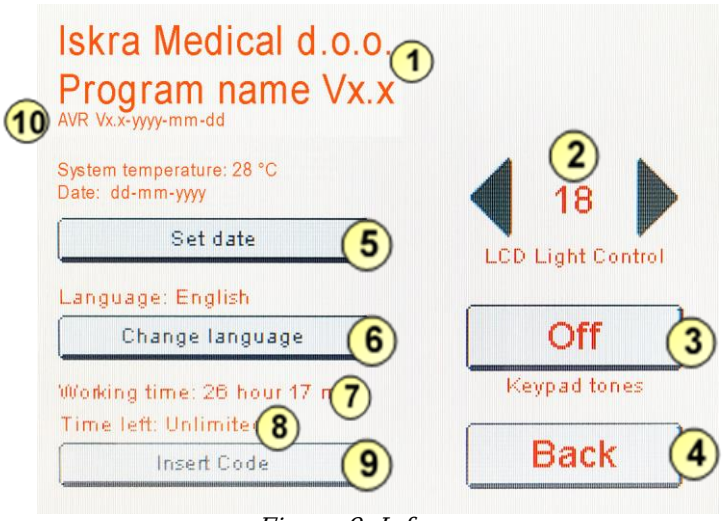


Figure 9: Info menu

1. Program version
2. LCD screen brightness (To change, use the left arrow (◄) to decrease and the right arrow (►) to increase)
3. Turn keypad tones ON / OFF
4. BACK - Return to main menu
5. SET DATE – customise the date
6. CHANGE LANGUAGE – chose the language
7. Working time
8. TIME LEFT:
   a. Unlimited – Can be used as long as desired
   b. Locked – Device cannot currently be used
   c. Time until device is locked
9. INSERT CODE – Insert new code
10. Current version of the avr software (low level control of the device

6 INDICATIONS AND CONTRAINDICATIONS

6.1 INDICATIONS

- Acute pain of the musculoskeletal system
- Degenerative rheumatism
- Neuropathies: Motor, Sensory, Sensory-motor, Mononeuropathies, Polyneuropathies
- Posttraumatic states
- Rehabilitation after immobilization
- Sports injuries
- Postoperative states
- Bone fracture healing
- Wound healing
- Chronic prostatitis
- Erectile dysfunction

6.1 NON-MEDICAL APPLICATIONS

- Body reshaping
- Cellulite reduction
- Fat burning
- Improvement of microcirculation
- Acceleration of lymph flow
- Increase in muscle tone
- Skin toning
- Increasing metabolism that leads to better muscle and adipose tissue condition
- Muscle strengthening
- Relief of pain of the musculoskeletal system
- Muscle relaxation

6.2 CONTRAINDICATIONS

- Pregnancy

- Cancer
- Epilepsy
- Complete muscle tear at or near the site of stimulation
- Cardiac pacemakers
- Severe active pulmonary conditions
- Medication pumps
- Implants made of ferromagnetic metal at or near the site of stimulation
- Endometriosis
- Open wounds at or near the site of stimulation
- Cardiac arrhythmia
- Recent surgery
- Hearing aid

7 THERAPY GUIDELINES

7.1 GENERAL

CAUTION:
These instructions contain information that can help you determine thet herapy parameters. User must remain aware that therapy parameters must be adapted to the patient's skin type and the type of therapy conducted.

During the patient's first visit, the therapist should:

- Explain the therapy procedure to the patient.
- Get a detailed patient history, including previous types of therapy, and determine whether the patient is suitable for the therapy.
- Determine the patient's expectations, explain the limitations and point out that several therapy sessions will be required.
- Tell the patient that therapy may be slightly unpleasant and that the skin may be reddish briefly (for a few hours) after therapy.
- Place the patient in a comfortable position and ask them to remove all the jewelry.

WARNING!
The applicator should not come into contact with ferromagnetic metal. Please check each patient.

7.2 THERAPY

- For acute conditions, use frequencies up to 20 Hz. Smaller pauses can also be used.
- For chronic conditions, use frequencies above 20 Hz.
- During therapy, make sure to achieve at least minimal muscle contraction. Muscles can be treated selectively. For optimal outcome, the patient should participate with voluntary muscle activity during therapy.
- If the patient has a larger muscle mass, use higher power settings than for a patient with a smaller muscle mass.
- If the therapy is being performed due to back pain (lumbalgia, lumboischialgia), we also recommend abdominal stimulation.
- Shoulder pain therapy (arthralgia, tendinitis, calcification) should be performed on both the front and rear sides of the shoulder.

- During therapy, the patient may feel a slight heat below the applicator. If the patient finds the feeling unpleasant, the heat can be prevented by placing a thin towel over the therapy area of the patient's body.

Recommended therapy duration:

- For acute pain: 10 – 15 min
- For chronic pain: 30 – 45 min

WARNING:
The therapeutic head should be cleaned with alcohol after each therapy in order to avoid skin infections.

8 MAINTENANCE

The maintenance activities described in this section should be performed by the user. All other repair and maintenance should only be performed by an authorized service provider:

- Turn the device off and disconnect it from the power supply. Wait a few minutes before proceeding with cleaning!
- Performing maintenance while the device is on can be dangerous to the user and/or the device!

WARNING!
Maintenance inside the device should only be
Performed by an authorized service provider!
Warranty is void if the device is opened by an unauthorized person!

- If the device will not be in use for a while, store it in a box or at least cover it with a cotton sheet.
- If the device does not work as described in these instructions, we recommend an inspection by an authorized service provider.
- Do not use any optional equipment or accessories that are not listed in this manual.

8.1 CLEANING THE DEVICE

- **Cleaning the exterior of the device:**

Clean the exterior of the device weekly. Wipe all plastic parts with a soft rag moistened with soapy detergent or with soap suitable for external cleaning of electrical equipment. Dry all surfaces with a clean rag.

WARNING!
Do not use solvents to clean the device. Never spray the device with any cleaning fluids, as they may cause a short-circuit in the wiring!

- **Cleaning the applicators**

Clean the applicators after each therapy session. Use disinfectants or diluted alcohol.

- No sterilization required.

8.2 MAINTENANCE TABLE

MAINTENANCE	MAINTENANCE DESCRIPTION	PERFORMED BY	FREQUENCY
Regular	Cleaning the external surfaces of the device.	User	Weekly
Regular	Cleaning/disinfection of applicators	User	After each session (patient)
Regular	Testing the device before the beginning of a working day.	User	Daily
Preventive	Inspection of applicators and cables (in case of damage, call an authorized service provider!).	User	Weekly
Periodic inspection	Cleaning the interior of the device, tests of proper operation, audit.	Authorized service provider	Every 18 months
Periodic inspection	Tests of output values and electrical safety.	Authorized service provider	Every 18 months

Table 6: Maintenance table

TO ENSURE OPTIMAL PERFORMANCE, WE RECOMMEND THAT THE DEVICE IS CHECKED EVERY 18 MONTHS BY THE MANUFACTURER OR AUTHORIZED REPRESENTATIVE.

LIFETIME OF THE DEVICE IS A 5 YEARS.

GUARANTEE FOR SERVICING AND SPARE PARTS IS A 5 YEARS.

9 MEASURES IN CASE OF MALFUNCTION

Symptoms	Possible cause	Damaged part	Solution
Device does not turn on when main ON/OFF switch is flipped.	The power cable is not properly connected or the power socket is not connected to the mains voltage.	/	Check the main cable as well as the connection between the device and socket.
	Problems with mains voltage.	/	Check if the power cable and mains voltage are as required.
	Destroyed fuses.	Fuse	Replace fuses with new fuses that have the same technical properties.

Table 7: Measures in case of malfunction

9.1 FUSE REPLACEMANT

If the device does not turn on when the main switch is flipped, it is likely that the fuses have been destroyed. Follow these steps to replace them with new ones:

1) Turn off the device.

2) Disconnect it from the power source.

3) Wait one minute.

4) Open the fuse compartment (see figure: rear side of the device)

5) Change the fuse and close the fuse compartment.

6) Connect the device to the power source and turn it on.

CAUTION!

If the device does not work as described in these instructions, we recommend an inspection by an authorized service provider.

Manufacturer *(Proizvajalec)*: **Iskra Medical d.o.o.**
Head office *(Sedež podjetja)*: Stegne 23, 1000 Ljubljana, Slovenia
Manufacturing *(Proizvodnja)*: Otoče 5a, 4244 Podnart, Slovenia
✆ +386 4 53 25 760 | ✉ info@iskramedical.eu | www.iskramedical.eu

10 APPENDIX – Electromagnetic environment

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

Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±2 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%. (!) In case of malfunction due to electrostatic discharge, reset the apparatus by switching power ON/OFF.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines (!) ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment. Temporary loss of function or performance may occur which is self-recoverable.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40% U_T (60 % dip in U_T) for 0,5 cycle 40% U_T (60 % dip in U_T) for 0,5 cycle 40% U_T (60 % dip in U_T) for 0,5 cycle	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40% U_T (60 % dip in U_T) for 0,5 cycle 40% U_T (60 % dip in U_T) for 0,5 cycle 40% U_T (60 % dip in U_T) for 0,5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	[V1] 3 V	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=[\frac{3,5}{V_1}]\sqrt{P}$ $d=[\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d=[\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	[E1] 3 V/m	