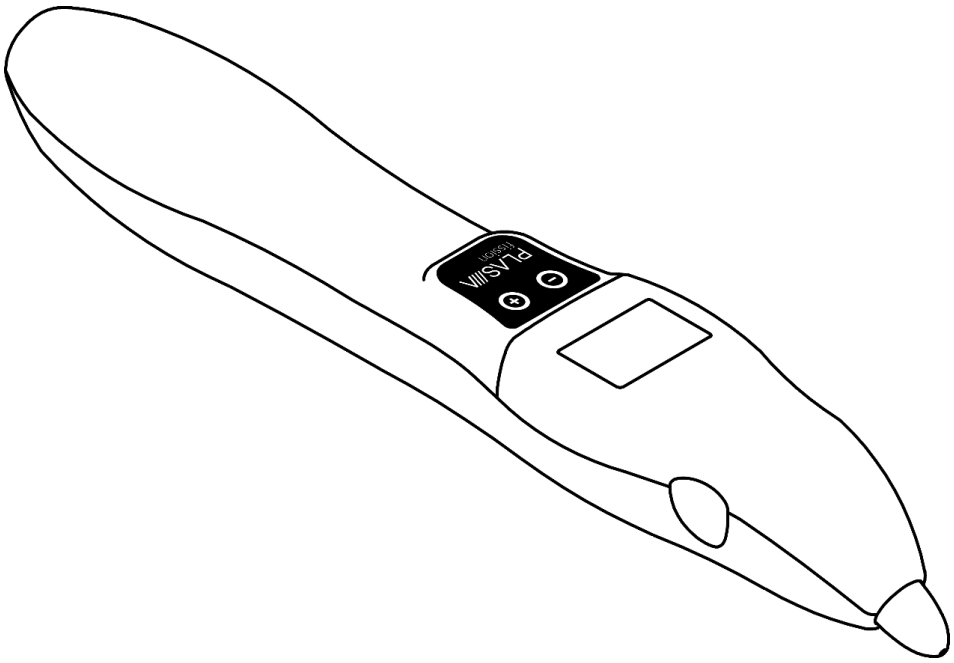
MIKROVOLT



PLASMA fission

Medical Device User Manual

CE 2274

Manufacturer Contact Details:

MIKROVOLT sp. z o.o.

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The Manual Version: 1.6 dated February 15, 2024

Table of Contents

Introduction

Thank you for purchasing Plasma Fission medical device and welcome to the users of Mikrovolt sp. z o.o. products. We have put great care and attention into making sure that the device works reliably in accordance with the technical and operational conditions specified in the User Manual. It is our hope that the product will meet your expectations. For this to happen - prior using Plasma Fission - please thoroughly read the device guidelines included in the User Manual, see its features as well as its operating and controlling principles.

Definition of Terms Used in the User Manual

Warning

WARNING ----------

This symbol warns the operator not to take possible action which may pose a threat and cause serious adverse reaction, injury or death. This symbol also indicates that the operator needs to carry out a specific activity to avoid potential threats and risks mentioned above.

---------- WARNING

Caution

CAUTION ----------

The symbol indicates important information and when underestimated may result in patient injuries or cause material damage e.g. damage to the product.

---------- CAUTION

Information

INFORMATION ----------

The symbol draws the users's attention to the relevant issues related to device and its operating and controlling principles.

---------- INFORMATION

General Precautions Before Using the Device

Visual Examination

Only authorized medical staff should be allowed access to the Plasma Fission device.

Prior using the Plasma Fission, the operator should visually check the technical condition of the device in order to detect any visible mechanical damage, defects, cracks, etc. In addition, it needs to be checked whether all the additional accessories stated on the page 15 of the following User Manual are complete. In the event of non-compliance, please contact the distributor.

Follow the recommendations contained herein to avoid personal injury, damage to the product or it accessories.

WARNING ----------

Not conducting periodic inspections of the Plasma Fission medical device and any modification of the equipment, changes or repairs carried out by unauthorized personnel may cause the product to malfunction or to other serious consequences for the safety of its users.

---------- WARNING

CAUTION ----------

Present User Manual contains the guidelines necessary for the proper operating of the Plasma Fission medical device. It is not intended to be a guide to carry out treatment using plasma beam generated by this device.

The Plasma Fission device functions as intended only when used in accordance with the User Manual of the Mikrovolt sp. z o.o. company. Warranty terms defined by the Mikrovolt sp. z o.o. for the Plasma Fission product do not apply if the device is not used as instructed in the User Manual provided. The Mikrovolt sp. z o.o. company does not assume any responsibility for any damage or injuries caused by the incorrect use of Plasma Fission or by any repairs carried out by an unauthorized staff.

Periodic inspections of the Plasma Fission device need to be conducted at least once every 2 years.

---------- CAUTION

Certification Mark

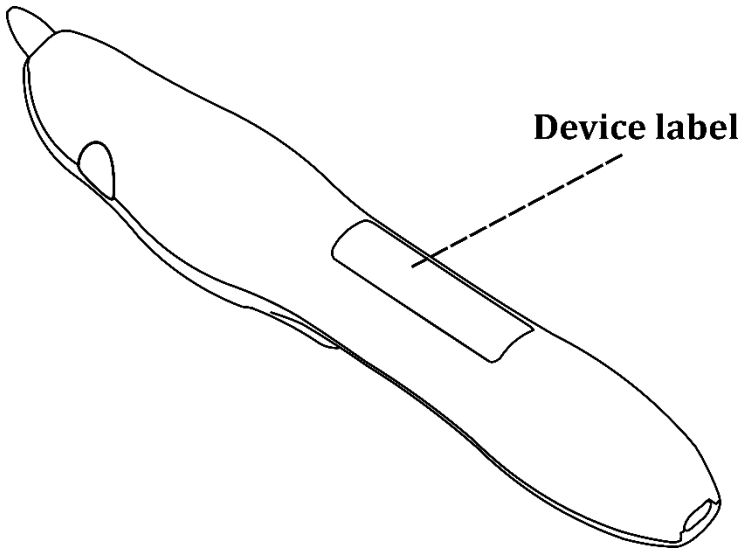
CE Mark

The CE Conformity Mark represents that the Plasma Fission medical device complies with the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. It also reflects that the Mikrovolt sp. z o.o. company implemented and maintain a Quality Management System in accordance with the requirements of the PN-EN ISO 13485:2016 standard under the supervision of TÜV NORD Polska sp. z o.o. CE_{2274} Conformity Mark is valid only with regard to Plasma Fission medical device. Disposable accessories and any other additional equipment recommended for use with the Plasma Fission device have the CE Conformity Marks issued by their manufacturers.

Device Information

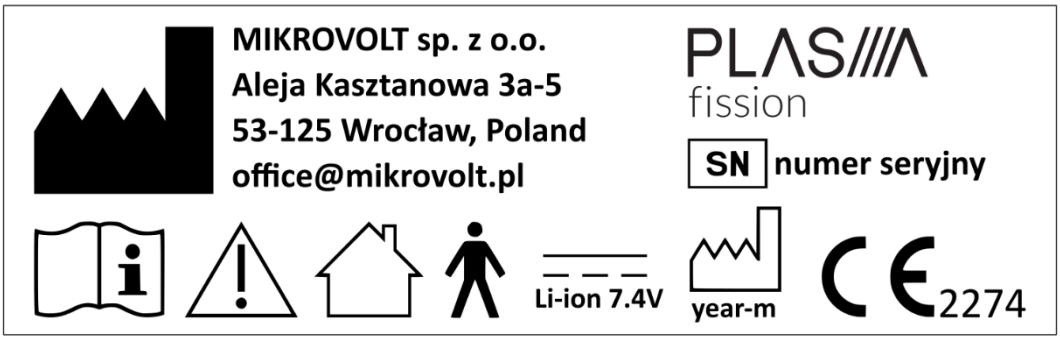
Medical Device Label

Medical Device Label is placed on the bottom of the device, in accordance with the figure below.



Design of the Medical Device Label

In accordance with the appropriate standards Plasma Fission device is marked with the label of the following design:

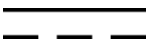


Medical Device Label Content Description

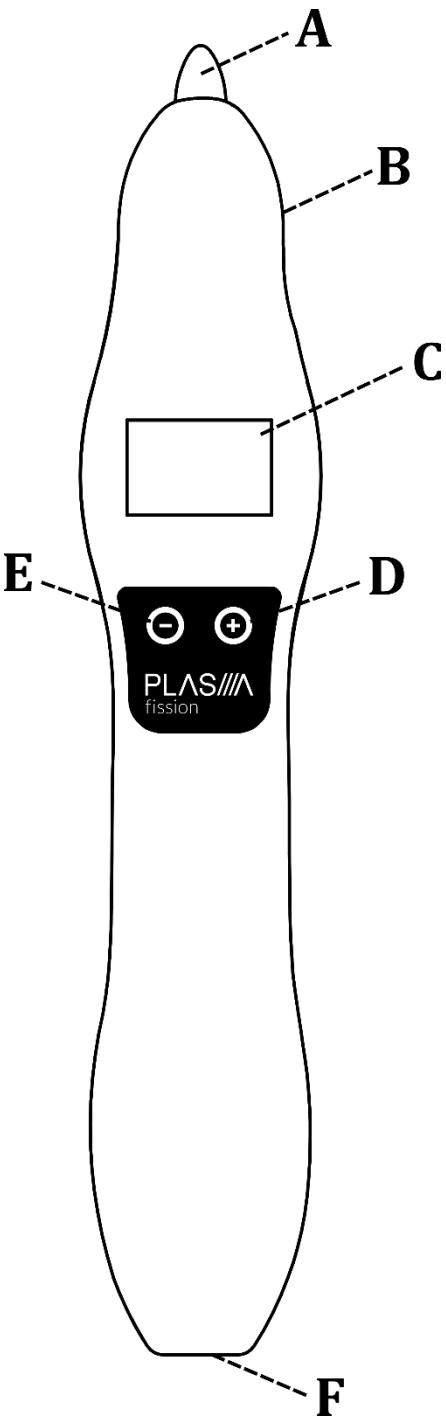
Each medical device must be accompanied by its label which, apart from the serial numbers, also bears markings connected with the rules of use and with the power supply method of the product.

Markings are applicable to PN-EN ISO 15223-1:2022-01 and PN-EN 62744:2015-02 standards.

Used Symbol	Title and Designation Number of Standard	Description of Symbol
	PN-EN ISO 15223-1:2022-01 (medical devices) Symbols to be used with medical device labels General requirements	Indicates the medical device manufacturer as defined in EU Regulations 2017/745 of 5 April 2017
	PN-EN ISO 15223-1:2022-01 (medical devices) Symbols to be used with medical device labels General requirements	Indicates the need for the user to consult the instruction for use of the medical device prior the first use
	PN-EN ISO 15223-1:2022-01 (medical devices) Symbols to be used with medical device labels General requirements	Indicates the need for the user to consult the instructions for use of the medical device for important cautionary information such as warnings, precautions or cautions that cannot, for a variety of reasons, be presented on the medical device itself
	PN-EN 62744:2015-02 Representation of states of objects by graphical symbols	Indicates that the device is designed for indoor use

CE 2274	Directive 93/42/EEC	CE marking on the product indicates manufacturer's declaration confirming that the product comply with the applicable EU health, safety and environmental protection essential requirements along with the number of supervising unit
	PN-EN ISO 15223-1:2022-01 (medical devices) Symbols to be used with medical device labels General requirements	Indicates the date of manufacture of the medical device
	PN-EN 62744:2015-02 Representation of states of objects by graphical symbols	Indicates that the device is powered by the bult-in DC power supply
	PN-EN 62744:2015-02 (medical devices) Representation of states of objects by graphical symbols	Indicates the type B applied part that directly contacts a patient
SN	PN-EN ISO 15223-1:2022-01 (medical devices) Symbols to be used with medical device labels General requirements	Indicates the manufacturer's serial number of the product so that a specific medical device can be identified

Names of Parts



A	Head with magnetic mounting of treatment electrode
B	Plasma generator power button (RUN)
C	Screen
D	"+" button to turn on the device; increasing the set power of plasma generator
E	"-" button to turn off the device; reducing the set power of plasma generator
F	Charging port

Device Description

Plasma Fission generates a precise plasma beam of up to 1 mm in length and with a diameter of 0,15 mm by means of which patient's tissue sublimation is carried out. The main product is an indivisible whole and belongs to the hand-held devices. All the components are enclosed in a single housing. The user is not able to open the housing and access the components. The product is equipped with control software. The physician has access to the user interface and the device is operated by it. The apparatus also includes treatment electrodes along with an AC adapter.

The housing was contoured in such a way to assure that when the doctor holds it in hand, they can freely carry out the procedure. The device is powered by the built-in battery. The device starts charging automatically when connected to the AC adapter included in the set. It is only used to charge the battery. Carrying out treatments with the AC adapter connected is not possible.

INFORMATION ----------

The device is non-intrusive and surgically non-invasive.

The device is IPX0 waterproof class rated, which means that it not protected against water.

The device is designed for continuous operation.

---------- INFORMATION

Intended Use of the Device

Plasma Fission, according to the classification, is an active therapeutic product designed to remove small skin lesions. It is used for dermatological treatment through the sublimation of the epidermis or of diseases that the doctor deems necessary (possible) to be removed without the histopathological examination. The physician shall assesses skin lesions using available techniques, relying on the medical knowledge, and on this basis qualifies the lesion for removal with the Plasma Fission device.

The process of sublimation of the epidermis proceeds as follows:

1. the operator brings the electrode of the turned on device closer to the patient's skin;
2. then the electrode is brought to a distance of less than 1 mm, the plasma arc ignites;
3. coagulation of skin area is performed just below the treatment electrode.

The product is intended in particular for the removal and alleviation of the following diseases:

- seborrhoeic keratosis
- lymphoblastoma
- fibroid
- xanthomatosis
- wartlike
- molluscum contagiosum
- telangiectasia
- naevus pigmentosus
- naevus (e.g. of Miescher)
- hyperkeratosis
- dermatochalasis (blepharoplasty).

The target group are patients with indications for the removal of skin lesions without the need for histopathological examination.

Authorized Medical Staff

Plasma Fission medical device shall only be used by the qualified medical staff in medical facilities.

Physicians of the following specializations are entitled to use Plasma Fission:

- dermatologist
- plastic surgeon
- general surgeon
- doctor of aesthetic medicine.

Each user is required to read the User Manual carefully before the first use of Plasma Fission.

The User Manual should be kept in a dry, safe and easily accessible place, known to all users of the device.

Additional Equipment and Disposable Accessories

Together with the Plasma Fission device, the manufacturer shall provide the following additional equipment and disposable accessories:

- dedicated 10ZSI 12/1 AC power adapter
- transport case

and

- disposable sterile Ballet Technologies treatment electrodes, model F6 or F12, which can be purchased directly from Mikrovolt sp. z o.o.

CAUTION ----------

The Plasma Fission device has been tested and approved for use with additional equipment and disposable accessories mentioned above.

The Mikrovolt sp. z o.o. company shall not be liable for the use of additional equipment or disposable accessories other than those provided with the Plasma Fission product. The use of additional equipment and disposable materials other than those mentioned before may limit the warranty granted by the Mikrovolt sp. z o.o. company on the Plasma Fission device.

Follow the recommendations contained in the User Manual on single use of the treatment electrodes.

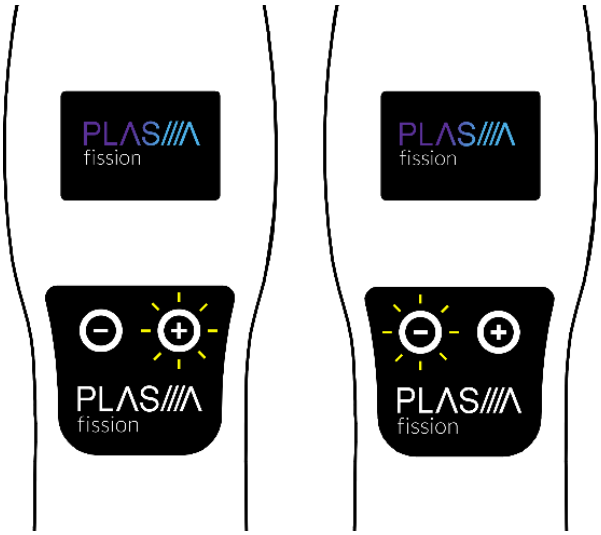
---------- CAUTION

Device Operating Information

Turning the Device On and Off

To turn on the Plasma Fission, press and hold the "**+**" button for 3 seconds. Boot Plasma Fission logo appears on the screen and is then followed by the main menu screen.

To turn off the device, press and hold the "**-**" button for 3 seconds. Plasma Fission logo appears on the screen and the device switches off right after.



CAUTION ----------

Do not press down hard on the protective glass of the screen and do not use sharp objects to operate the buttons.

---------- CAUTION

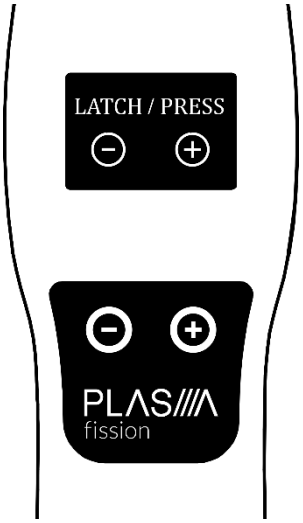
CAUTION ----------

The device shall not be used contrary to its intended purpose. It must not be thrown or shaken.

---------- CAUTION

Operating Mode Selection

In the main menu you can select one of the two operating modes - **LATCH** operating mode (by pressing the "**-**" button) or **PRESS** operating mode (by pressing the "**+**" button). In the **LATCH** operating mode, pressing the **RUN** button once starts the plasma generator. To switch off the generator, press the **RUN** button again. In the **PRESS** operating mode, you must keep pressing the **RUN** button continuously for the plasma generator to run.

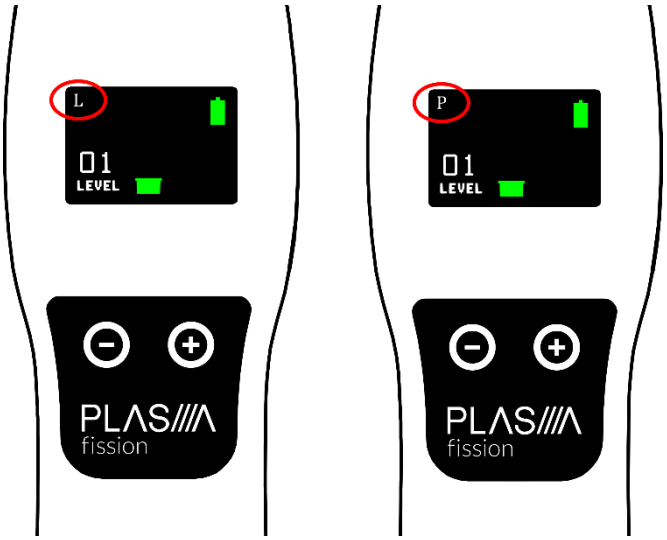


CAUTION ----------

In the event of high electrostatic discharge (ESD) between the user and the device, the operation of the device may be disrupted, and as a result of which Plasma Fission restarts automatically and returns to screen with the LATCH and PRESS operating modes selection.

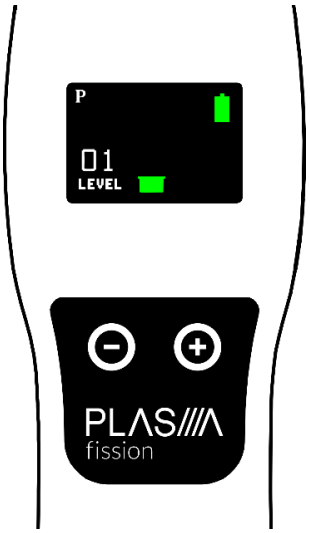
---------- CAUTION

After selecting the operating mode, in the upper left corner of the display screen the "**L**" letter (if the **LATCH** operating system is selected) or the "**P**" letter (if the **PRESS** operating system is selected) appears.



Device Operating Information

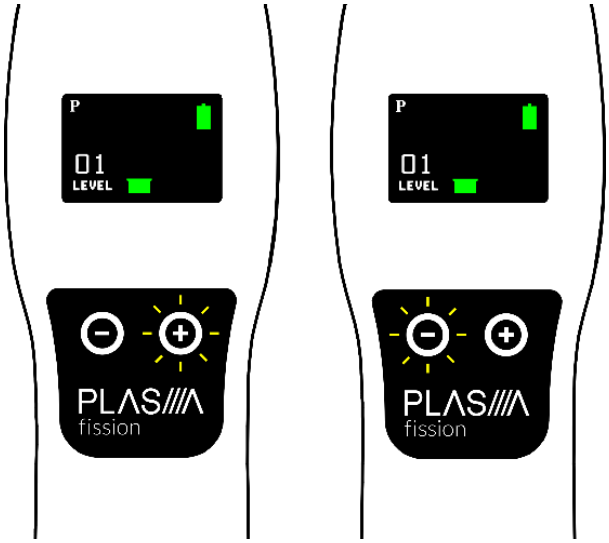
The main screen displays - through a bar graph format - plasma beam power indicator. It corresponds to the power level showed as a numerical value on the left part of the screen.



After turning the device on, its power level is set to level **01.**

While operating the device, the information about the battery charging status is displayed in the upper right corner of the screen.

During operation, you can increase and reduce the set power of the plasma beam by using the "+" or "-" buttons. The device distinguishes ten power levels – from level **01** to level **10**, where level **01** being the lowest power of the plasma beam and level **10** being the highest.

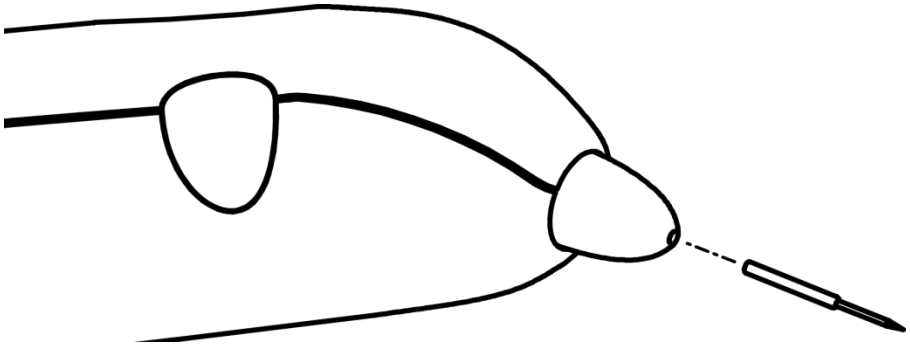


Treatment Electrode Mounting and Removing

Prior the procedure, treatment electrode shall be mounted. For that purpose, insert its thicker part into the opening in the device head. With the MagClick® system, the electrode is placed within the head without the use of any tools.

To remove the electrode after the treatment ended, grasp it by its protruding part and pull. MagClick® system releases the electrode making it possible to take it out.

It is recommended to use sterile disposable treatment electrodes approved by the manufacturer and listed on page 15. Used electrodes must be discarded in a medical waste container, and then sent for disposal.



CAUTION ----------

During mounting, the treatment electrode should connect with the head on its own. Do not use force when performing these activities.

The electrode should be mounted through a foil-paper blister. From then on until the procedure is ended, the operator should not pull the electrode out or touch it.

---------- CAUTION

WARNING ----------

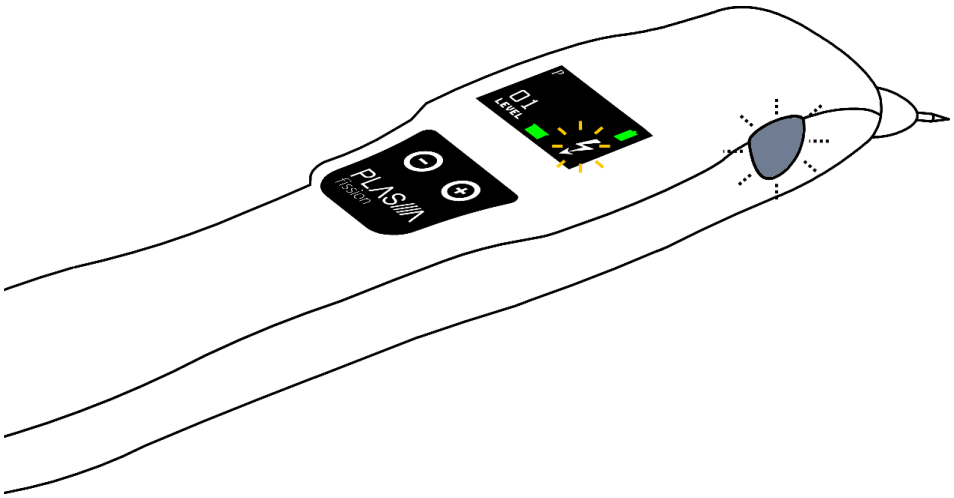
During operation, the head or the electrode must not come into contact with metal objects.

It is forbidden to remove the treatment electrode when the plasma generator is running. Switch off the generator to remove the electrode.

---------- WARNING

Procedure Performance

Having selected the specific plasma beam power, proceed to the treatment. To make a plasma arc, press the **RUN** button located on the right side of the apparatus. In effect, a lighting symbol will be displayed on the screen, notifying the operator of the high voltage which occurred in the device head.



CAUTION ----------

During procedure, hold the device firmly and steady in the hand.

---------- CAUTION

INFORMATION ----------

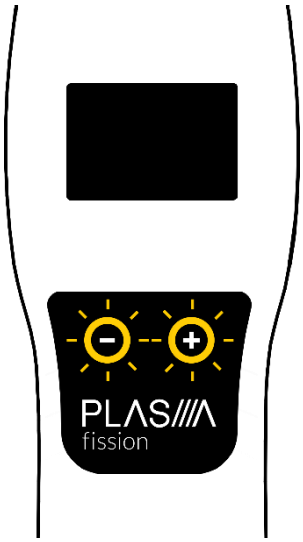
For the time of the procedure, it is recommended to wear protective gloves.

Plasma Fission device is constructed in such a way that when the generator is running, it does not cause the patient to get electric shock as a result of the direct skin contact with the electrode or the head.

---------- INFORMATION

Power-saving Mode

When unused for at least 3 minutes, the device automatically enters standby mode. The main screen turns off, and the "**+**" and "**-**" buttons illuminate in orange flashing light. After another 3 minutes of inactivity, the device turns off.

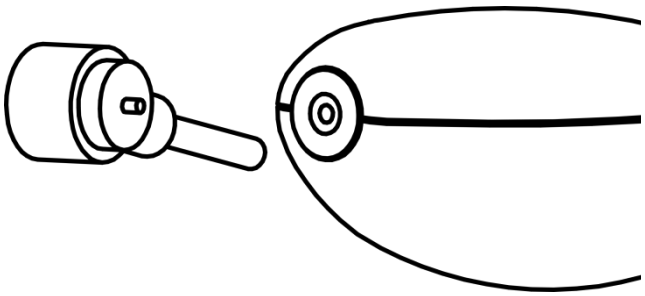


Battery Charging

To charge the battery, please proceed as follows:

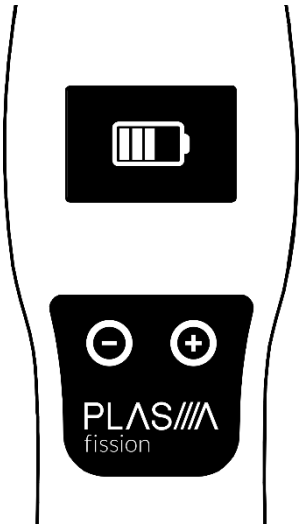
- connect the AC adapter to the single-phase 230 V power socket;
- connect the AC adapter to the Plasma Fission device with a magnetic tip cable.

Use only the AC adapter provided with the Plasma Fission product.



The magnetic plug of the charging socket prevents the improper connection of the AC adapter.

Once connected, the battery charging symbol appears on the screen.



When the battery is fully charged, a symbol of full battery confirming that displays on the screen. Consequently, unplug the AC adapter from the single-phase 230 V power socket.

When charging is complete the device turns off, which is indicated by the orange flashing light around the buttons.

CAUTION ----------

Using accessories and cables other than those provided by the manufacturer, may result in the increased electromagnetic emissions or reduced electromagnetic immunity of the device and consequently - equipment malfunction.

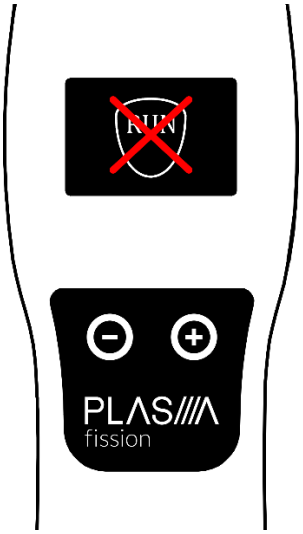
Do not attempt to perform the procedure while the machine is charging.

---------- CAUTION

Security and Control System of Device Operating

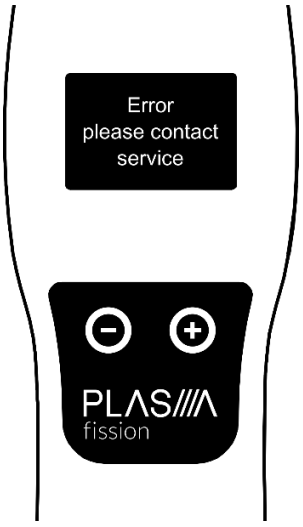
Control of Locked Button for Creating a Plasma Arc

If the **RUN** button is pressed, locked or damaged when switching on the device, the symbol of the **RUN** button crossed out displays on the screen and after a while, the device turns off. In such case, release the button and restart Plasma Fission. In the event of recurring notification on the screen, contact the distributor.



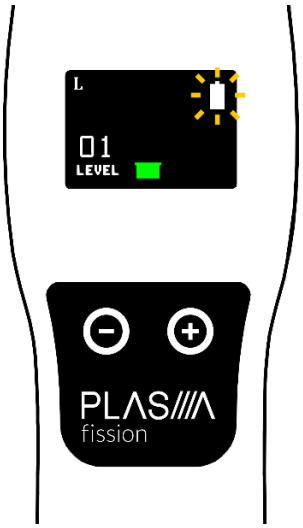
Incorrect Operation of the Device

If any device parameter format is incorrect and it may not be possible to use to product safely, the following message appears on the display: *Error, please contact service*. Then Plasma Fission turns off after 15 seconds. In such a situation, you should not attempt to perform the procedure using other generator parameters or with a different operating mode, but the device must be sent to the distributor.

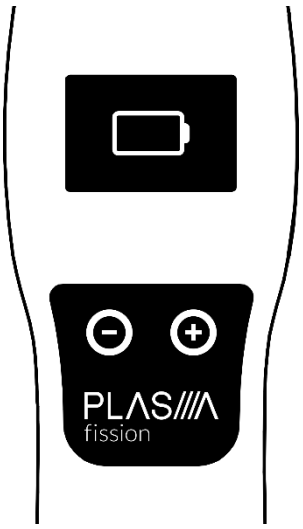


Control of the Discharged Battery

If the battery symbol flashes in the upper-right corner of the screen once you switched on the device, it indicates the battery is discharged. The device is then locked and is not possible to perform procedures. After 30 seconds, Plasma Fission turns off automatically so as not to lead to further battery discharge. In such case, the device should be connected to the AC adapter.

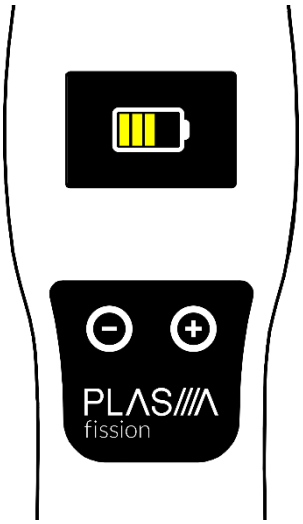


If the empty battery symbol flashes on the screen once you switched on the device, it indicates the battery is discharged. The device is then locked. After 15 seconds, Plasma Fission turns off automatically so as not to lead to further battery discharge. In such case, the device should be connected to the AC adapter.



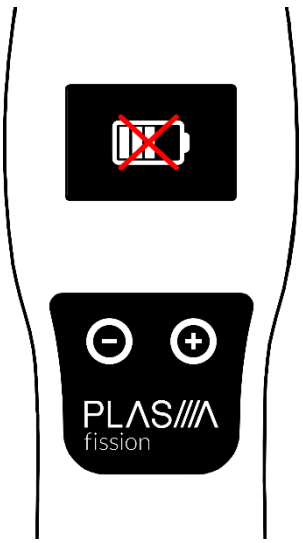
Battery Cell Overcharging Control

If a flashing battery with a yellow filling is displayed on the screen while charging the battery, this indicates that the voltage level of the battery cell has been exceeded. Charging is stopped and the device must be disconnected from the AC adapter. The flashing battery symbol with a yellow filling notifies the operator that the battery needs to be replaced due to its significant consumption.



Damage Control of the Battery

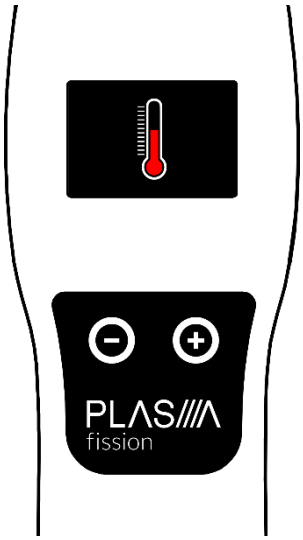
If the battery is damaged or fully consumed, the voltage control system responds and the symbol of the crossed out battery is displayed. The device must be sent to the distributor to replace the battery.



Battery Charging Over-temperature Control

If the battery temperature exceeds 55°C while charging, the screen displays the flashing thermometer symbol and the charging is stopped.

When the battery temperature drops below 50°C, charging is resumed automatically.



CAUTION ----------

Avoid charging the Plasma Fission device at the ambient temperature of above 40°C.

---------- CAUTION

Technical Specification

Maximum output power of the plasma generator:	1.6 W
Dimensions of the device:	L210 × W36 × H31 mm
Weight of the device:	135 g
Dimensions of the suitcase:	L282 × W197 × H72 mm
Treatment electrode:	disposable, sterile (medical device)
Diameter of the treatment electrode:	6 mils (0.15 mm), 12 mils (0.3 mm)
Method of the treatment electrode mounting:	magnetic (MagClick® system)
Battery operating time:	up to 8 hours – depending of the selected plasma beam power level
10ZSI 12/1 AC adapter:	12 VDC 0.8 A
Battery charging time:	3 hours
Battery power:	8.14 Wh
Battery type:	lithium-ion
AC adapter connector:	magnetic
Length of the AC adapter cable:	90 cm

Contraindications

The procedure with Plasma Fission device should not be performed in pregnant and lactating women.

For people with cardiac pacemakers, it is recommended to arrange the cardiac consultation before the procedure.

The Plasma Fission device cannot be used in patients who after consulting a dermatologist or a surgeon require a histopathological examination of the skin lesion to be removed.

Precautions

If needed, the doctor may, in order to protect the device from contamination, cover it with a medical sheath (condom) - so only the treatment electrode is visible.

When the user notices that the plasma arc is too large for the size of the treatment site, the power of the device shall be reduced.

Be careful not to puncture the skin uncontrollably with the treatment electrode during the procedure.

Before the procedure, disinfect the treatment site.

It is recommended to remove unwanted hair in the treatment area.

It is recommended to remove any jewellery near the treatment area.

If, as a result of a standard use, the operator notices that the device becomes inordinately hot, they should stop the treatment immediately.

If any message appears on the screen during the procedure, follow the appropriate recommendations of the following User Manual.

If the damage of packaging containing the treatment electrode is noticed, this might mean that the treatment electrode is non-sterile. It is recommended to use a new treatment electrode.

This device does not contain any parts that are suitable for replacement by the user. Do not change or adapt the device.

It is forbidden to repair the device on their own. If a fault occurs, contact the distributor.

Twisted or bent cord may cause problems with the proper charging of the device.

Procedures with the Plasma Fission device should not be performed when the patient is connected to the vital signs monitoring devices, e.g. a cardiac monitor, or is undergoing an ABPM examination (ambulatory blood pressure monitoring).

CAUTION ----------

The growing number of electrical equipment used in offices – such as computers or mobile phones – makes the medical devices vulnerable to electromagnetic interferences that can cause them to malfunction, and this in turn can lead to the danger. Medical devices must not interfere with the operation of the other devices. The PN-EN 60601-1-2:2015 standard clarifies the requirements for electromagnetic compatibility and the level of electromagnetic interferences immunity of the medical devices. Its observance prevents the development of dangerous situations during the operation of an active medical device

Plasma Fission complies with the PN-EN 60601-1-2:2015 standard in terms of immunity to electromagnetic interferences and electromagnetic emissions. Nevertheless, when operating the Plasma Fission, do not use mobile phones and similar devices that generate a strong magnetic field nearby (see page 39: Electromagnetic Environment, table).

---------- CAUTION

Possible Side Effects

As a consequence of a skin contact with the generated plasma beam, a thermal burn not exceeding 1% of the total body surface area may occur.

Additional Steps

Battery Maintenance

In order to use the Plasma Fission device powered by the built-in battery properly, charge it regularly. It is recommended to perform full charge cycles. A single full battery charge enables a day of continuous operation of the device.

To avoid damage to fully discharged battery, it is suggested to charge it at the latest within 2 days from the moment of the battery discharge. If after a certain period of intensified exploitation battery capacity drops significantly, this implies that the battery is worn out and needs to be replaced. To replace the battery, contact the distributor.

Cleaning and Disinfection

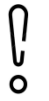
1. It is recommended to regularly clean the entire device and the head with a soft, damp cloth soaked in medical spirit (e.g. *Lysoformin, Aniosyme, Oxivir, Viruton*). The manufacturer does not assume responsibility for the use of any other type of cleaning and disinfecting product.
2. Clean the device only when it is switched off. During the mentioned activity, the treatment electrode must not be mounted in the device head and the charging of battery is not allowed.

CAUTION ----------

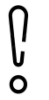
Disinfectants containing active surfactants or iodine should not be used. These solutions may crack or discolour the housing.

---------- CAUTION

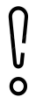
CAUTION ----------



Do not use sharp objects to clean Plasma Fission device. To avoid damaging the surface, do not clean the product with abrasive, corrosive or flammable cleaning agents.

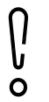


Do not wash the device directly under running water.

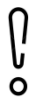


Do not sterilize the device.

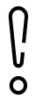
Do not use a damp or wet device. After wiping the Plasma Fission device with a damp cloth soaked in medical spirit, wait for the preparation to evaporate completely. Use the device only when dry.



Keep the device dry, protect it against extreme high or low temperatures as well as mechanical stress. Plasma Fission device should not be exposed to direct sunlight as this may interfere with its proper functioning.



The user of the device should not perform any maintenance work that is not described in this chapter. The device may only be serviced by an authorized technician.



Periodic inspections should be performed in accordance with the recommendations of this User Manual, as described in the chapter General Precautions Before Using the Device on page 6.

---------- CAUTION

Cleaning and Maintenance Schedule

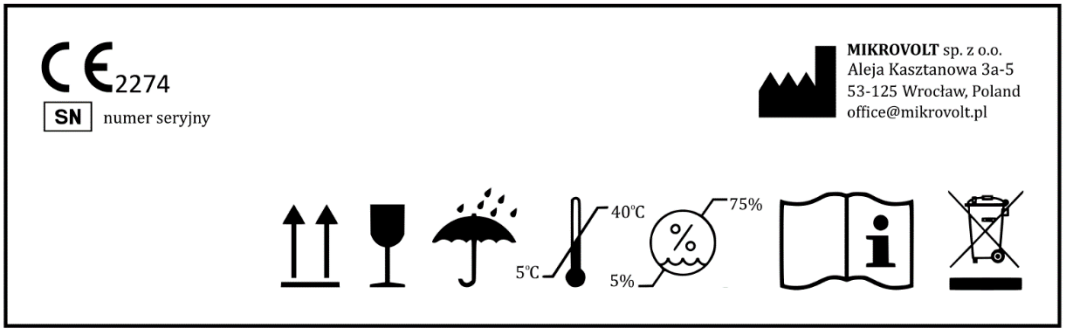
Below is the schedule recommended for Plasma Fission device users to follow in order to ensure the maintenance of high standards of device operation. These guidelines also make it possible to maintain hygiene of the outer parts of the device, which contributes to the patient safety.

Frequency	Activities
Before and after each treatment	✓ Disinfection – wiping the outer parts of the device with medical spirit (e.g. *Lysoformin, Aniosyme, Oxivir* or *Viruton*).
Once a month	✓ A thorough visual inspection of the device, e.g. checking if the buttons function smoothly.
Once every three months	✓ Charging the battery if the device is not in use. ✓ Checking the accessories condition, e.g. ensuring that the charging cable or AC adapter are not damaged.
If necessary	✓ Cleaning the power connector of the device with medical spirit (e.g. *Lysoformin, Aniosyme, Oxivir* or *Viruton*). ✓ Cleaning the accessories, e.g. cable, if dirty.

Transport and Storage

Transport and Storage

Figure below shows the design of the transport label which is placed on the shipping cardboard box.



Transport Label Content Description

Each medical device must be accompanied by its transport label, which - apart from the serial numbers of the medical device in the cardboard box - also contains specific information on the storage conditions: the range of permitted temperature and humidity, as well as markings related to the transport rules: D*o not throw; Protect from humidity; Do not throw into the garbage (recycle)*. Markings are applicable to the Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment.

CAUTION ----------

The device and its accessories should only be carried in the suitcase provided by the manufacturer.

---------- CAUTION

Used Symbol	Title and Designation Number Standard	Description of Symbol
	PN-EN 15223-1:2022-01 (medical devices) Symbols to be used with medical device labels General requirements	Indicates the range of storage humidity to which the medical device can be safely exposed
	PN-EN 15223-1:2022-01 (medical devices) Symbols to be used with medical device labels General requirements	Indicates the temperature limits to which the medical device can besafely exposed
	PN-EN ISO 780:2015 (medical devices) Symbols to be used with medical device labels General requirements	Transport marking: *This way up*
	PN-EN 15223-1:2022-01 (medical devices) Symbols to be used with medical device labels General requirements	Transport marking: *Fragile, handle with care*
	PN-EN 15223-1:2022-01 (medical devices) Symbols to be used with medical device labels General requirements	Transport marking: *Keep dry and away from rain*
	EU Directive 2012/19/EU: Marking of waste electrical and electronic equipment	Do not dispose of electronic products in the general waste stream

Product packaging

The assembled and tested device together with accessories are placed in a special transport suitcase with a custom-fit foam inside specifically designed for the device and accessories. Then, the suitcase is packed into the embellished packaging with an unique filler and later everything is packed into the shipping cardboard box made of five-layer cardboard. Packed cardboard box is consequently sealed with a tape.

Storage and Lifecycle of a Product

The device should be stored in a place where it is protected from:

- strong mechanical influences, such as: high temperatures, fall, pressure or impact;
- direct sunlight.

The device should be stored in a dry place, at room temperature.

Environment Conditions	**Operation and Storage**	**Transport Conditions**
Temperature	from +5°C to +40°C	from -20°C to +40°C
Relative humidity	from 5 to 75%, without condensation	

Based on the research, the manufacturer determined that the Plasma Fission device has a 10-year-lifecycle and the warranty period is 24 months from the date of purchase. However, the manufacturer obliges the purchaser to carry out - at least once every 2 years throughout the lifetime of the product - mandatory, paid, control procedures to check the functionality of the device, to measure the parameters and to replace the built-in battery with a new one. These activities shall be carried out to provide the patient and the operator with the highest level of safety during the use of the device.

Disposal

Pursuant to Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment, a product that is withdrawn from service must be handed over to appropriate facility dealing with the disposal of electrical equipment or returned back to the seller. Collecting, sorting and subsequent management of used equipment greatly facilitate the production of devices from the recycled materials and reduce the negative impact of waste on the environment and public health. Failure to satisfy the above requirements may result in the imposition of a statutory administrative penalty on the user.

Applicable Standards

The device meets the requirements of the following standards:

Standard	Title of the Standard
PN-EN ISO 14971:2020-05	Medical devices - Application of risk management to medical devices
PN-EN ISO 15223-1:2022-01	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
PN-EN 60601-1-2:2015-11	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Supplementary standard: Electromagnetic interference - Requirements and tests
PN-EN 62304:2010	Medical devices software - Software Life-cycle processes
PN-EN 60601-1:2011	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
PN-EN 62366-1:2015-07	Medical devices - Part 1: Application of usability engineering to medical devices
PN-EN ISO 13485:2016-04	Medical devices — Quality management systems — Regulatory requirements

Environmental Data

Electromagnetic Environment

Recommended Separation Distances Between Portable / Mobile RF Communications Equipment and the Plasma Fission Device			
The Plasma Fission is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Plasma Fission device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the Plasma Fission, as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power of the Transmitter [W]	**Separation Distances According to Frequency Transmitter [m]**		
	150 kHz–80 MHz $d = \left[\frac{3,5}{3}\right]\sqrt{P}$	**80 MHz–800 MHz** $d = \left[\frac{3,5}{3}\right]\sqrt{P}$	**800 MHz–2500 MHz** $d = \left[\frac{7}{3}\right]\sqrt{P}$
0.01	0.11	0.11	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23
Rated Maximum Output Power of the Mobile Phone	–	–	$d = \left[\frac{7}{30}\right]\sqrt{P}$
2W GSM/3G	–	–	0.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters [m] can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts [W], according to the transmitter manufacturer.			

Warranty Terms

1. The warranty period is 24 months from the date of purchase.
2. The warranty can be executed only upon the client's contact with the distributor of the Plasma Fission device. After providing the distributor with the necessary explanation, the Customer will be informed on the complaint procedure.
3. During the period of warranty, the repair shall only be carried out by the authorized service centre. The authorized service centre within the meaning of these warranty terms is the company indicated by the distributor.
4. The defects revealed during the warranty period shall be removed free of charge within 14 working days since the date of delivering device to the distributor's service centre. This period may be extended up to 28 days in individual cases.
5. The equipment to be repaired shall be delivered to the distributor's service centre in the original factory packaging. In case the original packing is not available, the damage to a product returned for service due to inadequate packaging shall be borne by the person submitting the complaint. The device is allowed to be sent in a substitutive package. Such packaging is considered to be a cardboard box made of at least three-layer cardboard, minimum 5 cm thick on each side, together with filling (e.g. foil, paper). The equipment itself must be wrapped in a bubble wrap at least twice.
6. Provided the implementation of warranty repair is to provide a valid sales/purchase receipt by the client.
7. The service centre reserves the right to refuse warranty service in the event of non-compliance of the document's data with the device, breach of the security seals or software changes by unauthorized persons.
8. The warranty coverage does not cover the devices that:
   a) are used contrary to the User Manual;
   b) are damaged caused by external factors (pollution, flood, atmospheric phenomena);
   c) are mechanical damaged: caused by a fall, scratch, etc.;
   d) are changed or used contrary to its intended use;
   e) are damaged due to improper use;
   f) are damaged due to the user's fault or ignorance;
   g) are damaged during transport to the service centre;
   h) have the manufacturer's seals broken.
9. The warranty does not cover activities specified in the User Manual and those which remain the sole responsibility of the Customer, e.g. battery charging.

10. In the event of an unjustified complaint, the customer is charged with costs associated with testing and shipping, both to the service centre and from it to the client.
11. After repairing, the item is sent to the address provided when reporting the defect.
12. Warranty Report will be prepared. The document will be submitted to the client together with the repaired device.
13. The property right of replaced or damaged parts and modules are transferred to service centre.
14. This warranty shall not exclude, limit or suspend the Customer rights when the provided product is inconsistent with the purchase agreement.
15. The relevant provisions of Polish law shall apply to all matters not covered by this warranty card.

In the event of a medical incident, please notify the manufacturer by writing to the following e-mail address:

office@mikrovolt.pl