

Plasma Plora

User manual



Table of contents

1. Introduction – General information..... 3

 1.1. Package contents..... 4

2. Intended use..... 5

3. Indications and contraindications 5

 3.1. Indications 5

 3.2 Contraindications..... 5

4. Function Description 6

5. Description of Symbols 7

 5.1 Symbol on the cover of the device, on the device and its equipment..... 7

 5.2 Symbols from the Manual 9

6. Warnings and precautions 9

7. Operation of the device 12

8. Definition of plasma 15

 8.1 The nature of discharge generating..... 16

9. Effect on cells 16

10. Use 17

11. Types of treatment 17

12. Working protocols for the treatments 18

13. Technical information, warranty, service, periodical safety checks in the given period 19

 13.1 Basic technical information 19

 13.2 Warranty 20

 13.3 Storage, maintenance and safety technical checks..... 20

1. Introduction – General Information

Plasma Plora is a low-power portable DC (Direct Current) device (electrocautery). This medical device is used for the treatment of skin, elimination of tiny capillary bleeding, removal of small warts and elimination of couperosis, red veins, acne and pigment spots. It also helps with to remove scars and stretchmarks.

The effects are achieved with a help of “a spark” discharge generated by DC (Direct Current) voltage. This kind of discharge generates a heat that warms the skin and desirable indications are treated. It is the DC fulguration (from Latin “fulgur” that means lightning) that was first used in 1982 at the ablation of AV knot. For many years, AC fulguration has been used in high-frequency electrocauters to destroy various skin protuberances or warts. Generated sparks in AC fulguration operate on a relatively big area of 1 cm². Unlike this, Plasma Plora uses DC fulguration with the spark flow area of 1mm², which is a great advantage because of its accuracy in removal of undesirable skin protuberances or warts without damaging of the surrounding tissues.

Using a high breakdown voltage of about 5kV, which is between the tip of the device and conductively connected (to the device) skin of a patient and maintaining the distance of 2mm between the tip and skin (this constant distance is provided by a specific applicator), a spark discharge is generated with a corona at its side. To be able to generate the spark discharge, the air (containing free electrons) must absorb a great amount of energy leading to the breakdown of the air - it ceases to be an insulant and starts to conduct the electric current – the discharge is generated. The air is ionized and it becomes Plasma.

Only a properly trained doctor who has read and understood all the instructions given in this manual and who is acquainted with generally known dangers and benefits of the stimulation of the treated place with Plasma discharge can operate Plasma Plora. Before using Plasma Plora, it is necessary to read and understand all instructions and safety precautions in this Manual and you are obliged to follow them. During the treatment, make sure that you follow all safety instructions. You should also always be acquainted with indications and contraindications of the Flora Plasma Medical use.

1.1 Package Contents

THE DEVICE SHOULD BE USED ONLY WITH THE ORIGINAL AUTHORIZED EQUIPEMENT SUPPLIED BY THE MANUFACTURER.

<p>Plasma Flora Handpiece and body</p>	
<p>Grounding pad (50*90) *2</p>	
<p>Golden needle tip</p>	
<p>Golden cone tip</p>	
<p>silver tips</p>	
<p>Power cord</p>	
<p>Manual</p>	

2. Intended use

PLASMA FLORA MEDICAL is a medical device that uses the physical principle of the succession of sparkle discharge generated by DC. It is used to treat skin, stop small bleeding, removal of small warts, hemangiomas mesenchyme tumors of veins and undesirable skin structures, venectasia, melisma, fibroma and keratosis.

3. Indications and contraindications

3.1. Indications

- angioma senilis
- verrucae seborrhoicae
- verrucae plane
- angiokeratoma
- teleangiectasie
- lentigo (검버섯)
- fibroma molle
- keratoacanthoma
- conydomata acuminate
- moluscum contagiosum
- verrucae vulgaris
- verrucae filiformes
- naevus capillaris
- naevus araneus
- keratosis actinica
- keratosis senilis
- keratosis seborrhoica
- melasma

3.2. Contraindications

- Pacemaker, Holter blood pressure monitoring system or ECG
- Other implanted electrical device
- Epilepsy
- Pregnancy
- Metal implants in the treatment area

Trained operation personnel of the device must be provably ensured that the treated patient does not suffer from any contraindications and this must be proven by signed informed consent.

4. Function Description

The device generates spark discharge and Plasma using DC 5kV with a maximal current of 1 mA which has also an AC part due to an oscillation (instability) of spark discharge. Plasma Plora Medical should be operated only by a provably trained doctor because the energy absorbed by body can be, in cases of some applications, used for targeted destruction of skin cells.

At the highest levels (6, 7 and 8), this device is used for electro fulguration, electrodesiccation and electrocoagulation.

The highest intensities can destroy skin cells. The tip of the device can reach temperatures up to 80°C, when the tip gets as close to skin as 0,5 – 1 mm.

Electrocoagulation: This can be prevented by using a distance glass tube overreaching the tip by 2 mm.

Electrofulguration affects only a small area of skin, as the generated spark discharge with the creation of Plasma is not emitted in a wide beam as it is in case of application of AC electric current rather in a narrow region (1mm²). During the application, a doctor can target the treatment area relatively accurately, for example in case of warts removal and other undesirable skin perturbations.

Electrodesiccation is evaporation of cell liquids with a subsequent destruction of subcutaneous cells. Evaporation is caused by thermal energy generated by oscillating spark discharge. A relatively low electric power, at maximum 1.8 W is applied and as it affects only a small area, it can cause the evaporation of cell liquids.

Electrocoagulation is a process in which thermal energy of the spark discharge causes evaporation of water in cells and it disrupts their structure. High temperature causes coagulation of tissue and blood proteins, which is used for stopping a small bleeding – to closure of small veins with a diameter of 2-3 mm. The treated area is stimulated by spark discharge with a creation of plasma at the distance of 2mm from the skin. The discharge is applied with a smaller power (1.8 W), compared to common electrocauters. Concerning the fact, that this power works in a very thin discharge beam and treats only a small area, there appears a considerably good local coagulation effect without a need to sterilize the application tip.

Electrodesiccation, electrofulguration or electrocoagulation can be used for the treatment of various indications in various medical fields. A detailed summary of application possibilities will be a subject of training together with the handover of the device. The device can be used in classical surgery, dermatology, gynecology or dental medicine.

At medium intensities (5-6) when there is no considerable destruction of skin cells, the device is used for the treatment of small veins, couperosis, scars and stretchmarks or pigment spots. Here,






the thermal energy of the spark discharge is used for the removal of skin cells with accumulated melanin. These intensities can be satisfactorily used for the veins removal.

The spark discharge also opens Na/K channels of cell membranes in skin cells. Together with this, being generated by AC voltage with a minus pole on the tip, it can help with the absorption of various serums of negative ions character into the skin. Unlike other technologies, it works with a higher energy and a doctor can apply an optimal amount of serum very effectively.

The desired effect is supported by the simultaneous opening of Na/K channels and the heat generated by the spark discharge. At the lowest intensities (1-4), the spark discharge is used solely for aesthetic treatments that can be a supplement to a medical treatment or an extension of the offering of medical clinics or ambulances. The spark discharge generates a flow of negative electrons and positive ions. The discharge is generated by the DC current and there is a negative pole at the tip of the device. Most of cosmetic preparations contains negative ions that are very well processed thanks to the polarization. These intensities are used for lifting, treatment of wrinkles and rejuvenation.

5. Description of Symbols

5.1. Symbols on the cover of the device, on the device and its equipment

Symbol	Title	Content
	Prohibition	Indicates prohibitions on use of the product other than the use of the clinician and prohibitions on misuse
	Emphasis	Describe important tips for use and explain how to avoid errors that can cause problems with the device.
	Caution	Describes the possibility of personal injury or damage to the product due to negligence in the use of the device.
	Warning	Indicates the cases that it may cause injury to the clinician, the patient, and staff personnel, or that the device may have a severe impact.
	Danger	Describes a hazardous condition that could result in an electric shock or fire, which could cause serious injury to the clinician or patient and staff personnel.

5.2. Symbols of the Manual



=PRECAUTION! The text with the label "Precaution" covers possible dangers that could cause minor or medium injuries or a damage of the device.












=WARNING! The text with the label "WARNING" covers possible dangers that could cause serious injuries or a destruction of the device.
















=Danger! The text with the label "WARNING" covers possible dangers that could cause direct dangerous situations and serious injuries.

6. Warning and precautions

Get familiar with these symbols and their explanations before you start to operate the device.

Warning and precautions	
	<p>All parts of the device must be connected in their places in the designed positions.</p> <p>Use of a power adaptor other than the supplied one or the one that fits all specifications is strictly prohibited.</p> <p>Do not plug the device in greasy, smoky, humid or dusty environment and at the places where it could get into the contact with water.</p>
	<p>Follow the recommended treatment time and treatment method. Do not use any equipment other than the equipment supplied by the manufacturer.</p>
	<p>If a patient feels and unusual feelings during the treatment, pause the treatment immediately and contact the manufacturer.</p>
	<p>Do not bend the supply cable or any other equipment with force and do not place any heavy or sharp objects on them (danger of fire or electric shock).</p>
	<p>Do not plug more than one device into one power source (danger of fire).</p>
	<p>Check the parameters of power source before plugging the device in.</p>
	<p>It is necessary to monitor the effect of plasma discharge on skin cells during the treatment. If any unexpected effect appears, the tip must be taken off the skin immediately and treatment must be stopped immediately.</p>
	<p>Written consent, training of the staff: Only trained doctors can use the device. DANGER: The trained staff must make sure that the patient does not suffer from any of the contraindications before the treatment. Training of the operators is provided either by the manufacturer or authorized distributor. The trained staff has a certificate entitling to work with Plasma Plora Medical. The trained staff must make sure that his workplace untrained people cannot work with the device.</p>
	<p>Preparatory heating of skin – Caution: The temperature of skin cannot exceed 41°C, which is done by the trained staff by controlling the skin with touch thermometer.</p>

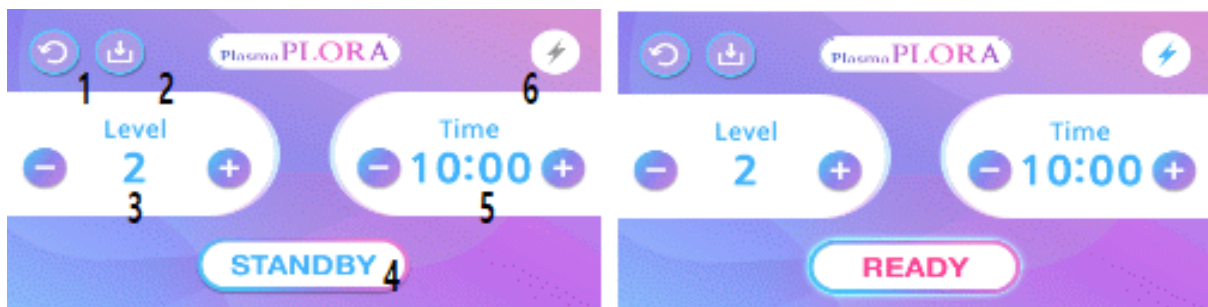
	<p>Protection of skin from electric discharge - Caution: In case of skin irritation. Application tip must be lead closely to the application gel. The optimal distance during application is 1-2 mm. After thorough consideration, a doctor can use a conductive serum instead of conductive indifferent gel.</p>
	<p>Treatment close to the area of the eyes - operation with sharp tip. Caution: It is necessary to carry the treatment in a safe distance from the eyes of the patient. The trained staff must make all possible precautions to protect your patient. Application must be done in an absolute stillness and any other people should not let the closeness of the treatment, as they could distract the operator. The trained staff takes all the responsibilities for the training.</p>
	<p>Grounding - Caution: Before the treatment begins, the patient must be grounded by a grounding disposable electrode which is stuck on the right shoulder blade.</p>
	<p>Do not touch the tip - Caution: Neither operator nor the patient can touch the tip during the treatment.</p>
	<p>Do not touch the patient - Warning: The trained staff is not allowed to touch the patient conductively. If there is a need to touch patient, it is necessary to use rubber protective gloves.</p>
	<p>Changing of application tip - Danger: When the application type is being used, the Flora Plasma Device MUST BE unplugged from the power source. The device has 6 tips – (needle, cone, flat silver tip, and 3 other silver tips).</p>
	<p>The trained staff can only use the manual for the qualification training. Danger: The trained person can use only the equipment supplied by the manufacture. It is forbidden to open the device, because there is a risk of electric shock.</p>
	<p>After every use, the tip must be cleaned and disinfected.</p>
	<p>Protect the device from hits and shocks.</p>
	<p>Danger: Do not pull the electric cable by force and do not touch it with wet or moist hand.</p>
	<p>Danger of explosion or fire. Do not use the device in places where there are explosives or flammable substances such as anesthetics, alcohol, gas or detergents. If it is possible, we recommend using non-volatile substances.</p>

	<p>Danger of skin damage! Plasma Plora Medical device set on the intensity of 6, 7 and 8 can irreparably damage skin. You should know the device can destroy skin cells at the intensity of 7 and 8, as well as level 6.</p>
	<p>Danger of electromagnetic interference. Do not use the device close to other electronic or electric devices, as the electromagnetic interference could appear.</p>

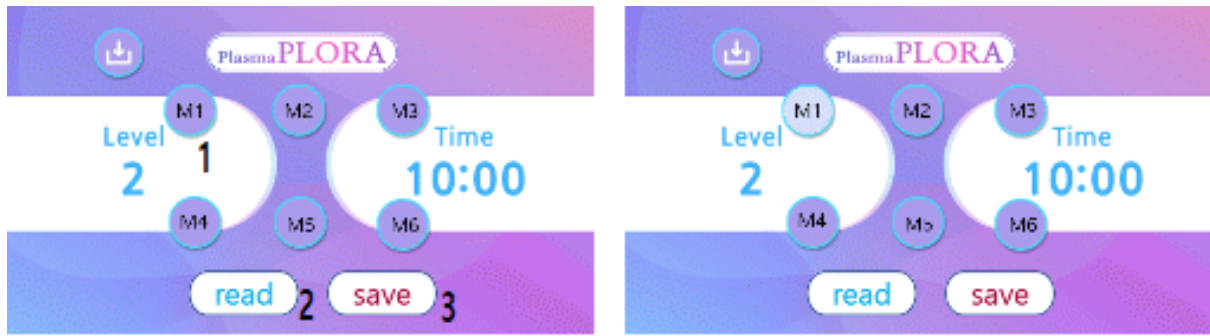
7. Operation of the device



Silver tip screen

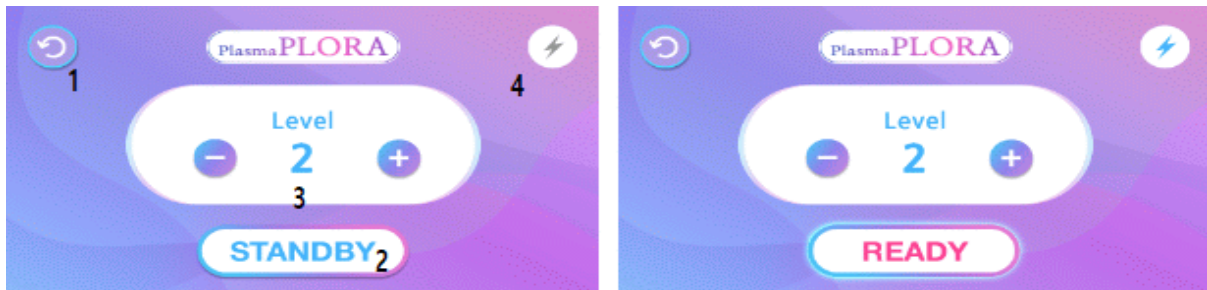


1.	Back button
2.	Memory Save / Load Button
3.	Level control button
4.	STANDBY / READY button
5.	Button to adjust the time (1 minute increments) Press + or - button continuously to adjust quickly
6.	OFF when STANDBY / ON when READY



1.	M1~M6 button	Button to select memory space
2.	Read button	Button to select memory parameter (level, time).
3.	Save button	Button for parameter (level, time) saved in selected memory.

Gold tip screen



1.	Back button
2.	STANDBY / READY button
3.	Level control button
4.	OFF when STANDBY / ON when READY



1.	Tip holder	A space used to hold the tip of the handpiece
2.	Handpiece holder	A space used to hold the handpiece
3.	Monitor	Monitor the touch screen to operate the device
4.	Ground leakage circuit breaker	It will automatically turn off the power when overload (15A).
5.	Handpiece connector	It is used to connect the handpiece cable.
6.	Pad line connector	It is used to connect the pad line connector
7.	PowerInet	It is used to connect the power cord wire to supply 220V power. (Power supply fuse 250V 15A)
8.	Power Switch	ON/OFF button

Before every start of the device, carefully check the power cable, connecting cables, disposable grounding electrode with its connecting cable and device including its tip. If you encounter any damages, do not switch the device on and call the authorized service!

a) Plug the adapter the power source (230V, 50Hz)

b) When the patient is ready for the treatment, stick a disposable grounding electrode on the patient's shoulder.

(Remove watches and metal accessories attached to your body.)

c) By pushing the "+" button, you can increase the intensity. Numbers "2, 3, 4, 5, 6, 7, 8" appear one by one. These are safe intensities that do not cause the destruction of skin cells.

Decrease of safe intensities can be done by pushing the "-" button.

d) If the intensity of the spark discharge is set already, it is possible to set a higher voltage (6kV) at the tip of the device by pushing the button STANDBY /READY.

As soon as the tip approaches the patient's grounded skin to a distance below 2 mm, the spark discharge ignites.

e) If you want to turn the high voltage at the tip of the device off, you must push the button STANDBY / READY. The change of the intensity of the discharge can be made only when the device is switched off, because there isn't 6-kV voltage at the tip.

f) The level can be increased by 1 by pressing the + button once. The time in the silver tip screen can be adjusted by pressing the button once.

g) Usage and format of the tip

1) Silver flat and conic applicator

Flat and conic applicators are used only for cosmetic treatments (intensities 1-5) of stretchmark, wrinkles and rejuvenation. The flat applicator is designed for the treatment of bigger areas. it causes electrical stimulation of cells by DC current – Na/K channels are opened and cell membranes are depolarized. The tip of the silver flat and conic is in contact with the skin. (make sure to apply gel on the skin).

2) Golden applicator with precise tip

It is designed for face treatments and precise removals of skin.

h) Caution

작동을 했을 때, 화면에 표시(4)된 표시에 불빛이 나오지 않으면 케이블 연결을 확인 후에도
않으면 파워가 공급되지 않은 것으로 사용을 금지합니다.

If display (4) on the screen does not appear when it is switched on, or after checking the cable connection., that means the power is not supplied and you should not use the device.

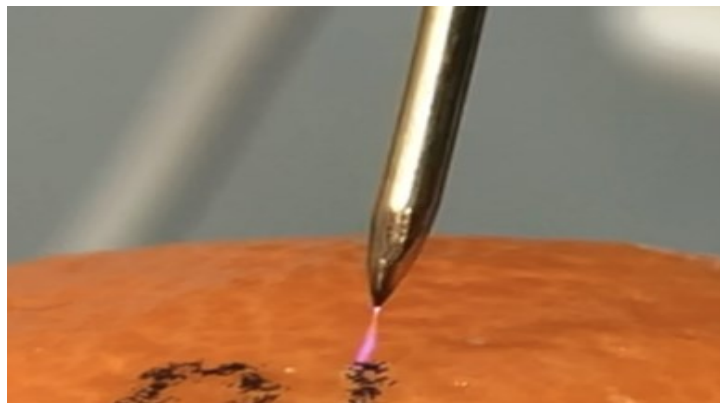
i) Cosmetic treatment (Strength 1-5)

If approach the tip of the device to a treated place covered by conductive serum (for example hyaluronic acid) as near as 2mm above the gel, it causes a dielectric breakdown of the air between the tip of the device and it generates a spark discharge. These sparks treat patient's skin. The time of treatment should not exceed 30 minutes.

j) Medical treatment (desiccation, fulguration, coagulation) at the maximum intensity level of 6 – 8. In this case, if it is necessary, the doctor applies only suitable anesthetics on patient's skin and then the treatment begins.

k) Ending the treatment

The procedure can be ended any time by pushing the ""STANDBY / READY"" button. In this case, the device pauses automatically and the treatment can be resumed by pushing the button ""STANDBY / READY"" again.



Spark discharge between the tip

8. Definition of plasma

Plasma is an ionized gas consisting of ions and electrons created by the separation of electrons from the electron shell of gases or by ionization. Plasma can be also defined as the fourth form of matter.

In this case plasma is quasineutral and low-temperature, in which there is an approximately the same number of positive ions and negative electrons. The creation of plasma is a concomitant

phenomenon of all electric discharges in an ionized gas including air. This means that plasma is created in all current electrocauteries in the fulguration mode.

Plasma is created in all discharges in all current electrocauteries in fulguration mode. Plasma Medical uses this phenomenon by its ability to generate the flow of Plasma. This flow affects biological tissues and it triggers a specific reaction mechanism. This effect of plasma flows on tissues enables you to reach a very effective peeling, tissue recovery, its tightening, improvement of flexibility and it also stimulates immunity and resistance of tissues.

8.1 Characteristics of discharged electricity

The spark discharge itself is generated by a high voltage of 5kV at a very low current < 1 mA. Between it and the tip of the device place 2 mm above the skin, the discharge is generated. The electric circuit is closed by a disposable grounding electrode placed on the right shoulder blade of the patient.

9. Effect on cells

Every cell has a membrane potential on its membrane (the difference of electric potential between the two sides of the membrane). Inner side of the membrane has a negative charge, the inner side has a positive charge. As the skin is ageing, the electric charge is distributed unevenly along the membrane, and the electric voltage of the membrane is changed

The Membrane potential is created and influenced by potassium and sodium cations. It is difficult for sodium cations to pass through the cell membrane, whereas potassium cations can pass through it very easily

When DC electric current flows through cells, the membrane potential is change, the membrane is depolarized and this means that it can make various ions (Na⁺, K⁺) to change the position and pass the membrane as well. The correct distribution of cations on the inner and outer side of the membranes makes the membrane potential balanced. Electric voltage of skin membrane is increased and the membrane tightens. If this process appears in most cells in one area, the skin tightening is observable by naked eye.

Other electrocauteries using AC current are not able to depolarize the membrane, because the effects of AC current either irritate cells or its effect of cells is trophic or analgetic (depending on the used frequency and intensity). The depolarization does not occur because AC current is not able to pass through cell membranes.

Plasma Plora was designed to for controlled destruction of skin cells and other cells at the higher intensities of adjustable spark discharge. This is achieved thanks to the fact that at the highest intensities, the spark discharge carries a thermal energy as well and this thermal energy can

evaporate small warts and close small vessels, which can be used for the treatment of red vessels, couperosis and to stop small capillary bleeding during small surgeries. It works with a continual sparks flow carrying thermal energy. As soon as this flow reaches the skin, the skin is heated. The spark channel generated by DC voltage is very slim (approx. 1mm²), and therefore the treatment and the targeted destruction of cells is very precise.

The treatment of skin by spark discharge is a completely natural process and the desired effect is achieved thanks to physiological processes. No chemical substances are injected into the skin.

10. Use

The device can be used for the treatment of:

- Face
- Neck
- Breasts
- Arms
- Abdomen
- Legs

11. Types of treatment

The treatment by Plasma Plora is suitable for patients with:

- Shallow and deep wrinkles
- Acne – suitable after the acute phase is over, for better healing and prevention from scars
- Couperosis (dilated vessels) – for closing vessels
- Pigment spots
- Scars and stretch marks
- Removal of Small warts
- Bleeding/ capillary bleeding/ after a minor surgery/ stops bleeding

The number of treatments is set by a doctor. For evaporation of warts and stopping of capillary bleeding, only one treatment is necessary.

In case of cosmetic treatments, when the patient desires a long-lasting effect, 6 – 8 sessions are necessary. Between the 1st and the 2nd treatment, there should be 3 free days, after every other treatment, a longer free period of 1 week is recommended. One treatment including preparation time and aftercare takes 1 hour. After this sequence, the effect of the treatment lasts up to half a

year. Then it is necessary to repeat the sequence based on the individual results. We recommend repeating the treatment once a month for lasting effect.

12. Process protocols for the treatments

1. Skin must be cleaned well. Deep and surface cleaning is necessary to prepare the skin for the absorption of plasma discharges

2. The skin must be heated thoroughly, which causes dilatation of collagen tissues. It is possible to use heating mask, heating by CryoJett device or by means of an intensive manual massage together with the use of a suitable cosmetic product (for example a serum based on the skin type). Cosmetic product is absorbed more easily due to the heat. However, it is necessary to check the temperature and reactions of patient's skin.

!! BEWARE: Step 2 (heating) must be skipped when the treatment of couperosis is done, the heat would dilate the vessels!!

3. In case of cosmetic treatments, apply a 1 – 2 mm thick layer of ultrasound gel on the treated area with a help of brush or cosmetic spatula. Be especially careful around eyes and lips, where the skin is very thin. If the patient feels an unpleasant tingling, add more gel.

4. Apply the plasma flow treatment. Move the tip of the device firmly, slowly and carefully in wrinkles, 1 – 2 mm above the gel, as you have been taught at the training. If bigger areas are treated, use the flat applicator that touches the skin directly. Flat applicator should be moved on the skin on which the indifferent gel has been applied.

Example of forehead wrinkles treatment:

Move the applicator at the straight angle along the line back and forth and after that move the tip back and forth in the Zigzag way

Working protocol for the evaporation of warts -The skin must be sterilized, and it is recommended to use an anesthetic. In this case, the discharges of the highest intensity (7 and 8) are applied, and the spark flow desirably destroys skin cells. Because the area of the sparkle beam is exceedingly small, the wart is evaporated step by step and layer after layer, which enables a high precision of the destruction and a subsequent coagulation.

Coagulation working protocol – stopping the bleeding in minor surgeries. The intensity should be set at the level 7 or 8 and the doctor makes coagulation at the bleeding place, where the blood transforms into a solid matter.

13. Technical information, warranty, service, periodical safety technical checks in the given period

13.1 Basic information

Type of device: With an applied part of the BF type

Power supply: 100 ~ 240VAC / 50-60Hz

Consumption of power supply: max. 12VA

Voltage of plasma discharge generator: 0.8~5kV

Intensity of plasma discharge: 0.3~1.8W

Size: (Handpiece) 210 x 27 x 25 mm / (main body) 185 x 220 x 125 mm

Weight: 2.5kg

Humidity range: 30%~75%

Temperature range: +10 ~ +40°C

Working conditions - do not use the device in the presence of flammable anesthetics that the oxygen and nitrous oxide were mixed.

Protection class:

Storage: Store in the original package indoors, in a dry place with maximal temperature +5°C – 40°C and relative humidity of air up to 80%.

Transportation: transportation space with maximal temperature +5°C – 40°C and relative humidity of air up to 10- 100% without condensation.

Range of atmospheric pressure: 50kPa to 106 kPa.

Any kind of modification of Plora Plasma Medical is strictly forbidden!

13.2 Warranty

This product is covered by the warranty including the material imperfections and production faults for one year after the supply of the product. The manufacturer agrees to repair or change the product or its faulty parts in the time covered by the warranty, if these repairs are done by the manufacturer or its authorized agents.

The manufacturer takes responsibility for the security, reliability and effectivity of the

product only if all repairs, changes of parts or alterations of the product are made by the authorized staff, if the device was used in accordance with this manual, if the parameters of the electricity in the room where the device is plugged fit all the requirements set by law. If the product is sent to the manufacturer, the transport is paid by the user.

13.3 Storage, maintenance, and safety technical checks

How to store and maintain the product after use:

- Storage temperature: 5 - 40 °C
- Store indoors in well-aired places and protect from direct sunlight and humidity.
- Store unplugged from power supply

Regular maintenance, cleaning and periodical safety technical checks in given time.

- **Maintenance** – the operators are obliged to follow all the instructions in this manual.

The integrity of the device cannot be violated, maintenance can be done exclusively at the annual checks by the authorized service.

- The applicators must be disinfected after each use by common disinfectants stated below.
 - The body of the device can be disinfected by moist cloth only
 - Sterilization: a steam sterilization in an autoclave.
 - Sterilized: it is recommended to sterilize glass and metal material. Sterilize the electrode at 130°C.
- Ethylene oxide chemical sterilization.

Safety technical checks

If periodical safety technical checks (PSTC) are given by national laws or norms, they should be done annually. PSTC can be done only by a service worker or an authorized service. If the safety check has not been done by the manufacturer or an authorized service organization in a set period, the device must not be used until the check is done.

Service, maintenance or PSTC must not be done during the treatment of a patient.

Product warranty

Product warranty

Product name	Plasma Plora	customer's name	
Serial number		Phone number	
Address			
Distributor name		Phone number	
Address			
Purchase date		Product Warranty Period	1 year after purchase

1. This product is manufactured through strict management and inspection process.
2. If the product fails in normal condition within the warranty period, we will repair it for free.
3. Damage to the device caused by negligence or misuse, may be charged even if the warranty period remains.
4. If you have any questions or inquiries, please contact 'Healux' Customer Center.

Phone: (82) 2 2169-2880 Fax: (82) 2 2169 - 2888

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