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JETT PLASMA VETERINARY II

Instruction for Use

℞ Only

CE 1023

Distributed **PetNetwork** Manufactured in the Czech Republic by COMPEX

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1. General information

Prior to using the JETT PLASMA VETERINARY device, you must read, understand and follow all the safety and security precautions described in this Instruction for Use. Observe all safety instructions during the treatment. Be all the time advised about appropriate indications and contraindications, when using the JETT PLASMA VET device.

The JETT PLASMA VETERINARY device may be operated only by the veterinarian staff trained by the manufacturer or the authorized distributor or by the person who may work with the medical devices in conformity with the national legislation and treat the indications shown in sec. 3.5.1, within the scope of the Instruction for Use, who has been familiarized well with the commonly known risks and with the benefits and contributions of stimulating the treated area by a plasma discharge. This trained person may further train other veterinarians or medical staff within his/her workplace in accordance with the local and national laws. Disinfection and sterilization of the device and its accessories may also be performed by a tech trained by a veterinarian. A written record must be kept about each passed training. Treatment in natural body cavities and ophthalmic indications may be performed by a veterinarian only.

JETT PLASMA VETERINARY is a portable DC electrosurgery. It is a medical device designed for dermatological and ophthalmic interventions, which works on the physical principle of sequence of the spark discharges with the generation of plasma.

Prior to first putting the device into operation the TAPE calibration has to be performed (see sec. 5.2)!

The device JETT PLASMA VETERINARY is allowed to use only with supplied XP Power ACM18US05 adapter.

Prior to putting the JETT PLASMA VETERINARY device into operation, be so kind and read these instructions carefully and thoroughly. Observe all cautions and warnings contained herein.

2. Pack contents

2.1 Standard content of a pack

The device JETT PLASMA VET with Plasma Pen III/M holder	
Instruction for Use	
Plasma Pen III/M	
Rechargeable battery NR18650-30Q, napětí 3,6 V, 24 000 mAh	
Network adapter cable with relevant end piece XP Power ACM18US05	

Extension cable for network adapter	
Curly connection cable for disposable elctrode	
20 pcs of disposable CE electrodes 4 pcs of electrodes in a pack HRTR59BP 50x94 mm	
Connection cable for cylinder electrode	
Cylinder electrode	

Golden applicator 14.4 mm	
Golden applicator 24.4 mm	
Cone applicator	
Flat applicator, diameter 3 mm	
Flat applicator, diameter 5 mm	
Flat applicator, diameter 10 mm	
Flat applicator, diameter 20 mm	

2.2 Optional accessories

ophthalmology applicator gold	
ophthalmology applicator steel	
isolated applicator L44	
isolated applicator L64	

THE DEVICE MAY BE USED WITH ORIGINAL ACCESSORIES ONLY PROVIDED BY THE MANUFACTURER!!!

3. Intended use

JETT PLASMA VETERINARY is the medical device intended, based on the physical principle of a sequence of spark discharges generated by DC, to treat skin and mucous membranes. The device can also be used to eliminate scars, smaller warts, fibromas, hemangiomas and unwanted skin formations, angiectases, keratoses, etc. Some of the indications (verruce vulgaris, condylomata accuminata, molluscum contagiosum) can be treated, using isolated applicators themselves even inside natural body cavities. The product is intended for surgical interventions.

The medical device is also intended for treatment in the field of cosmetics (it is not included in the conformity assessment process). In the field of cosmetics is used mainly to rejuvenate the skin but also for acne, dilated veins, spider nevi, pigment spots, age spots and shallow and deep wrinkles treatment and non-surgical blepharoplasty.

3.1 Patient population

Patients of all age groups can be treated, after excluding the below stated contraindications, Patients of all age groups can be treated, after excluding the below-stated contraindications, using JETT PLASMA VETERINARY.

3.2 Ablative treatment

For ablative treatment the OPHTHALMOLOGY and DERMATOLOGY GOLD APPLICATORS modes are used and where the phenomena of electrofulguration, electrodessication and electrocoagulation do occur. In these modes, skin cells are already destroyed and these modes are used successfully to remove veins and benign tumors, for example. The spark discharge is also a carrier of thermal energy, and when the tip of the device is brought to approximately 0.5-4 mm to the skin, the tip of the applicator can generate a temperature of up to 80 °C on the applicator tip. These phenomena are specifically used in the following ablative treatments:

- stop minor capillary bleeding,
- elimination of scars and minor warts,
- elimination of hemangiomas (benign mesenchymal blood vessel tumours) and small venectases,
- elimination of undesirable skin formations - fibromas,
- deep wrinkles and non-surgical blepharoplasty.

The list of all indications can be found in sec. 3.5.1 Indications. The treating veterinarian always determines the number of treatments.

The plasma channel generated by the DC excitation voltage is very narrow (ca 1 mm^2), and, thanks to it, skin treatment and eventual targeted skin cell destruction is very accurate. The device can be used to treat surface of the body as well as the skin and mucous membranes inside the oral, nasal, genito-anal areas and the zone round the eyes.

Example of treatment (desiccation, fulguration, coagulation)

In the course of ablative treatment, golden applicators are used and intensity of the spark discharge is set within 1-5. In this case, the veterinarian applies (if necessary) a suitable anaesthetic on the patient's skin, disinfected with a suitable disinfectant, and then initiates the treatment itself, where the sequence of spark discharges performs treatment of one of the indications shown in the Instruction for Use. During the skin treatment, the bar graph shows the efficiency of the spark discharge.

3.3 Non ablative treatment

For the indication blepharitis is used non ablative treatment. The treatment is made with Flat applicator, diameter 3mm for Plasma Pen. Using this applicator there is the rejuvenation of mucosa of the eye.

3.4 Description of function

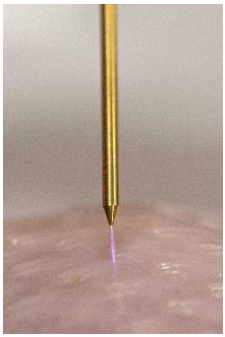
The effects shown above are achieved by the sequence of spark discharges generated by DC voltage. The spark discharges generate heat that warms the skin. The DC fulguration (from Latin fulgur = lightning) was used for the first time in 1982 to ablate the AV node. The AC fulguration has been applied for many years already in high-frequency electrocautery for elimination of various skin artifacts or warts. The generated AC fulguration spark shower covers a large area of ca 1 cm^2. The JETT PLASMA VETERINARY device uses the DC generated spark discharge, which has many advantages compared with AC fulguration:

- the discharge is very narrow (ca 1 mm^2);
- skin treatment and targeted destruction of skin cells is very accurate;
- there is no damage to the surrounding tissue.

3.4.1 Principle of discharge generation

The device creates the spark discharge with plasma generation by applying the DC voltage of ca 5 kV with the maximum current of 2 mA. At a breakdown voltage of 5 kV between the tip of the device and the conductively connected patient's skin (to the device), the air containing the free electrons receives enough energy for breakdown. The air is ionized, becoming plasma and ceasing to be an insulator.

Plasma is the ionized gas consisting of ions and electrons, generated by electron disruption from the electron package of the gas atoms or by molecule rupture (ionization). The plasma can also be defined as the fourth state of matter.



In our case, it is a quasi-neutral, low-temperature plasma with approximate equality of positively charged ions and negatively charged electrons. Plasma formation is an accompanying phenomenon of all electrical discharges in the ionized gas, including air.

Plasma is generated in all discharges of all existing electrocautery devices in the fulguration mode. This mode is also uses by the JETT PLASMA Medical II device. It generates the plasma flow which, when acting on the biological tissues, triggers a specific response mechanism. This action of the plasma flux on the tissue allows to reach a very effective peeling, tissue renewal, strengthening, higher elasticity, and also to enhance tissue resistance and its defence.

3.4.2 Action on the skin during ablative treatment

1. Significant increase in concentration of type I collagen.
2. Reduction in the number of keloid fibroblasts in the area of the scars.
3. Increase in extracellular Na^+ concentration.
4. Increase in intracellular K^+ concentration.
5. Increase in chemotaxis.
6. Increase in growth factor level and increase in NO (nitric oxide) concentration.
7. Proved increase in migration of fibroblasts and their proteosynthesis.
8. Increase in skin permeability and reduction of the skin barrier function for penetration of the positively charged ions or water-soluble compounds.
9. New orientation of the newly generated or formed collagen fibres in the direction of the DC current.
10. Reduction in pain in the point of application, for example after injury, and accelerated healing.

Treatment of the skin by applying spark discharge is a completely natural phenomenon, where the desired effect occurs physiologically. No foreign chemicals are introduced into the skin.

Electrofulguration is application of an electric discharge, generated between the tip of the device and the skin of a patient at the distance of 2 mm. In our case, electrofulguration affects only a small area of the patient's skin thanks to generation of the spark discharge by the DC voltage.

Electrodessication is evaporation of cell liquids with subsequent destruction of cutaneous and subcutaneous cells. Evaporation is caused by the thermal energy generated by the oscillating spark discharge. A relatively low electric power is generated here, 3 W as a maximum which, by affecting a small area only, it is able to cause evaporation of the cell liquids.

Electrocoagulation is a process, where the thermal energy of the spark discharge causes evaporation of water in cells and disruption of their structure. High temperature results in coagulation of tissue and blood proteins, which is utilized for eliminating small bleeding, i.e. closing small veins of 2-3 mm diameter. The treated area is stimulated by a spark discharge with plasma generation; the application tip is 2 mm distant from the skin. The power acts only in a very narrow discharge beam and treats a small area, and a very solid coagulation effect is achieved locally.

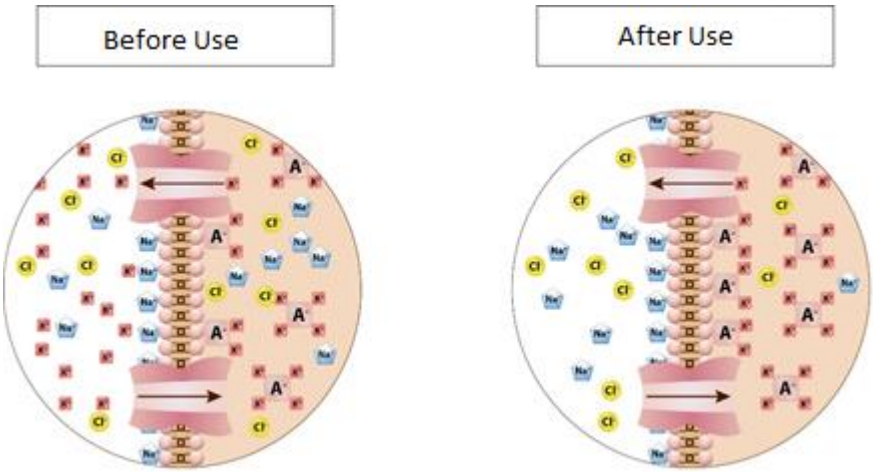
Electrodessication, electrofulguration or electrocoagulation can be used for a number of indications in various medical fields. A detailed summary of applications will be the very subject of training, together with the handover of the device. The device can be used in classical surgery or dermatology and in other medical disciplines.

3.4.3 Action on the skin during non ablative treatment

Each cell has a membrane potential on its membrane (difference of electrical potential between two membrane sides). There is a negative charge on the inside of the cell membrane and the positive charge on the outside. Ageing of the skin results in uneven distribution of the electrical charge (potential) across the cell membrane and, thus in change of the electrical voltage of the membrane.

The membrane potential is generated and further affected by potassium and sodium cations, the sodium cations pass through the cell membrane with great problems only, while the potassium cations penetrate very easily.

The DC current, passing through the cells, leads to change in the membrane potential (membrane depolarization). Depolarization results in change of positions of individual types of ions and/or their passage through the membrane. By correctly distributing the ions on the inner and outer sides of the membrane, the membrane potential will again be stabilized. Electrical voltage of the cell membrane is increased and the membrane is stretched. If this process occurs in the majority of skin cells in a particular area, then skin stretching can be visible to the naked eye.



The electrocautery devices utilizing alternating current are unable to depolarize the membrane, because effects of the alternating current on the cell are either irritating, trophic or analgesic (the effect depends on the used frequency and intensity) and not depolarizing, because the alternating current is unable to pass through the cell membranes.

3.5 Indications and contraindications

3.5.1 Indications

Benign vascular lesions

- angioma (hemangioma, naevus capillaris), teleangiectasia

Skin lesions

- keratosis (verruca seborrhoica, keratosis senilis, keratosis seborroica)
- keratoacanthoma
- fibroma
- xanthelasma

Infectious lesions

- verruca plana, verruca vulgaris
- condylomata accuminata
- molluscum contagiosum

Pigment changes (hyperpigmentation)

- melasma (chloasma)

Ophthalmology indications

- blepharitis;
- stenosis puncti lacrimalis;
- xanthelasma;
- trichiasis;
- distichiasis;
- ectropion;
- entropion.

If isolated applicators are used, the above indications can also be treated in natural body cavities (oral cavity, nasal cavity, rectum, vagina).

3.5.2 Contraindications

The trained operator is obliged to make sure provably that the patient to be treated does not suffer from any of the following contraindications, which fact is subject to recording (the Informed Consent is included as the integral part of this Instruction for Use):

- Peacemaker, Holter ECG monitoring system;
- Another implanted electrical device;
- Epilepsy;
- Pregnancy;
- Metal implants in the treated area;
- Skin diseases and skin inflammations in the treatment area;
- Acute inflammatory disease;
- Any untreated/badly treated disease in treatment area;
- Oncological disease in treatment area;

In case if oncological etiology of the lesion is suspected, the lesion must be examined by a dermatologist.

Before and after treatment, the patient should not take photosensitizers, it can increase the occurrence of pigmentation changes.

3.5.3 Possible side effects

During and immediately after treatment, varying degrees of pain, in rare cases, weak erythema, edema, scab and swelling itching as a result of healing can appear.

Like all treatments, this medical device can have side effects that may not happen to everyone.

When using the medical device JETT PLASMA Medical II, the following side effects may be experienced:

- Hyperpigmentation, which can be prevented by photoprotection after surgery. Skin is protected from sunlight by using SPF 50+ creams and by wearing sunglasses and headgear for at least 7-10 days after the procedure.
- Depigmentation that can be prevented by proper treatment after the intervention with healing creams to promote epithelization.
- Scars that can be prevented by proper treatment after the intervention with healing creams to promote epithelization, by photoprotection and silicone patches
- Rarely an allergic reaction to a disinfectant or a local anaesthetic may occur. Prior to treatment, the physician should check the information about the patient's allergies.
- Feeling of metal in the mouth
- Tingling, where electrode is placed.

3.5.4 Residual risks

Attention to residual risks which cannot be eliminated by construction of the device:

- Risk arising from the use of other than supplied or specified adapter.
- Risk of high-temperature burns in the patient in the site of application when the intensity of the spark discharge is set to the highest degree using gold applicators.
- Risk arising from the use of non-original accessories, eg connection cable, adapter, etc.
- Risk arising from the use of damaged accessories and equipment.
- Risk arising from the performing treatments out of the intended use.

4. Warnings and precautions

Safety instructions in this part of the Instruction for Use as well as in its other parts.

4.1 Introductory precautions

Protect the device from falls and shocks to avoid damage of the device.

DO NOT USE the accessories other than those delivered by the manufacturer.

All parts of the device must be connected in their designed precise positions.

DO NOT plug the device in greasy, smoky, humid or dusty environments and at the places where the device could get into the contact with water.

FOLLOW the recommended treatment time and treatment method.

If a patient reports any unusual feelings during the treatment, interrupt the treatment immediately and contact the manufacturer!

Bend neither the supply cable nor other accessories by force and do not place any heavy or sharp things on them (danger of fire or electric shock).

DO NOT plug more electric cables or more device into one power source/socket (danger of fire).

INSPECT device and cables for damage prior to each use, especially the insulation. This may be done visually under magnification or with a high voltage insulation testing device. Insulation failures may result in burns or other injuries to the patient or operator.

Check the designed power source prior to plugging the device. If the power source other than recommended one is used, network adapter can be damaged or fire ignited.

It is necessary to monitor effect of the plasma discharge continuously during the treatment. If any unexpected effect on the skin cells appears, the tip must be taken off the skin immediately and action of the plasma discharge on the skin cells must be interrupted at once.

Never leave the high voltage on unattended above the device applicator position, unwanted approach or touch could result in patient injury or the operator, fire or explosion of flammable vapours.

4.2 Error messages on device display

The device indicates the following warning messages.

The battery is running low
Rechargeable battery INR18650-30Q, voltage 3.6 V, 24 000 mAh is discharged, connect the device to the network for charging.

4.3 Error messages on the device display

Device internal error
The device cannot be used and have to be sent to the manufacturer.

Not connected or wrong accessory connection
Check you have accessories attached or if the connected accessories does not belong to the device JETT PLASMA Medical II. If the message still appears after connecting the correct accessories – send the device to the manufacturer.

Change the battery
Battery INR18650-30Q, voltage 3,6 V, 24 000 mAh is damaged or has reached the end of its service life. Order a new battery from the manufacturer (the battery is user replaceable)

4.4 Warnings following from use of the device

Original accessories
Only original accessories from the manufacturer may be used with the device. When using the accessories other than the original ones (adapter, applicators, connection components), there is a risk of injury and destruction of the device.

Correct treatment
The trained operator may treat the permitted areas only (see the indications). It is permitted to use the device only within the scope of the Instruction for Use and training. Otherwise there is the risk of tissue damage and injury.

Replacement of the applicator tip
When replacing the applicator tip, the JETT PLASMA Medical II device must be disconnected demonstrably. Risk of burns by spark discharge to operator.

Plasma Pen III/M
If any damage anywhere on the connection cable (white can be seen) is revealed, it must be sent to the manufacturer.

Work with network adapter
DO NOT pull cable of the adapter by force and do not touch it with a wet hand. There is the risk of electric shock.

General risks
If there is a thunder, lightning or earthquake, unplug the network adapter (risk of fire).

Risk of explosion or fire
DO NOT USE the device in locations where flammable substances such as anaesthetics, flammable disinfectants, alcohol, gas or solvents can be present. We recommend to use non-volatile compounds, if possible. If any volatile, flammable substance is used on the patient, then it is necessary to wait until possible flammable vapours are vented away. Energy of the spark discharge is so high that it can ignite even other combustibles such as paper, textiles as well as oils or flammable creams (e.g. paraffin wax), etc., both on the patient and anywhere in the neighbourhood, if safe handling is not observed.

Danger of electromagnetic interference
DO NOT USE the device in close proximity to other electronic and electrical devices as there is the risk of mutual electromagnetic interference.

Danger of damage to skin
The JETT PLASMA Medical II in OPHTHALMOLOGY (intensity 2-5) and DERMATOLOGY (intensity 1-5) is irreversibly damaging the skin cells. Use these intensities only when you want to specifically destroy skin cells (e.g., wart evaporation). Always be aware that the device is capable of destroying skin cells at these intensities and double-check that you have set the correct intensity value before each application. This means that if you are doing a non-ablative treatment without deliberately destroying the skin cells, always choose DERMATOLOGY-SILVER APPLICATORS.

Written approval, staff training
The device may be used only by demonstrably trained doctors or by the staff as permitted by the national legislation! Neither operator nor patient can have a pacemaker, Holter ECG meter or other implanted electrical device!
Before each treatment, the trained staff must make sure that the patient does not suffer from any contraindication, and the informed consent must be filled in by the patient. Training of the operators is provided either by the manufacturer or by the authorized distributor. The trained staff receives a certificate authorizing its holder to work with JETT PLASMA Medical II device. The trained staff must make sure that no untrained person will work with the device in the workplace. The person trained by the manufacturer or by the distributor may train other persons on the relevant workplace.
The trained staff must permanently follow the working procedures set by the manufacturer and must avoid the following safety risks:

Plasma Pen III/M connector
Never use a device with an unlocked or damaged connector. There is a risk of further damage or fire!

Connecting of connection cable
Always connect the patient connection cable to the device before connecting the patient or giving him cylinder electrode. On the contrary, always disconnect the patient before disconnecting the cable from the device. Otherwise, if the connection connector falls into a liquid or humid environment, the patient may be injured by electric shock!

Use of a high-frequency surgical device
Simultaneous use of a high-frequency surgical device with a JETT PLASMA Medical II device on a patient may cause burns and damage the device.

4.5 Precautions following from use of the device

Skin protection from electric discharge
In the case of non-ablative treatments, ie. In the DERMATOLOGY-SILVER APPLICATORS mode, a sufficient layer of indifferent conductive gel must be applied to the skin at the application site. The trained operator is obliged to keep the application tip in the application gel. Physicians may use conductive sera instead of an indifferent conductive gel.

Treatment close to the eyes and treatment using a sharp tip
A sharp tip treatment (14.4 / 24.4 mm gold applicator, conical applicator, ophthalmic applicator, isolated L44 / L64 applicator) from a safe distance from the eyes should be performed.
The trained staff must make all possible precautions to protect eyes of the patient. Application must be performed at maximum peace, and all the other people that could distract the doctor during a complex procedure must be excluded. The trained operator takes all responsibility for not using the sharp tip close to the eyes contrary to the instructions acquired during the training.

Patient-device connection
Before starting treatment, the patient must be connected by a disposable CE electrode. This electrode is sticked by the operator as close as possible to the treatment area – it is forbidden to stick it on the back, chest, head, eyes and front of the neck or by using a cylinder electrode (if the disposable electrode is uncomfortable for patient). Wrong electrode application may increase the risk of cardiac fibrillation! Alternatively using a cylinder electrode (if disposable electrode is uncomfortable to patient) which patient have to hold firmly throughout the treatment. The patient is moistened with a cloth for better conductivity before inserting the cylinder electrode into the hand. During treatment, the patient must not be in conductive contact with metal parts connected to the ground or with a large capacity against the ground (metal parts of a chair or bed, etc.)

Do not touch the tip
Neither the operator nor the patient should touch the application tip during application.

Do not touch the patient
The trained staff may not touch the patient conductively. If there is a need to touch the patient's skin, a non-conductive rubber glove has to be used.

Before the first use and after each use, the device with its accessories and the Plasma Pen III/M have to be cleaned and disinfected properly. Do not use flammable disinfectants. For applicators and cylinder electrode, which come into contact with the patient skin, sterilization is required! Otherwise, there is a risk of infection!

Ophthalmology applicator Gold/Steel
If the ophthalmology applicator is bent, it cannot be straightened any more.

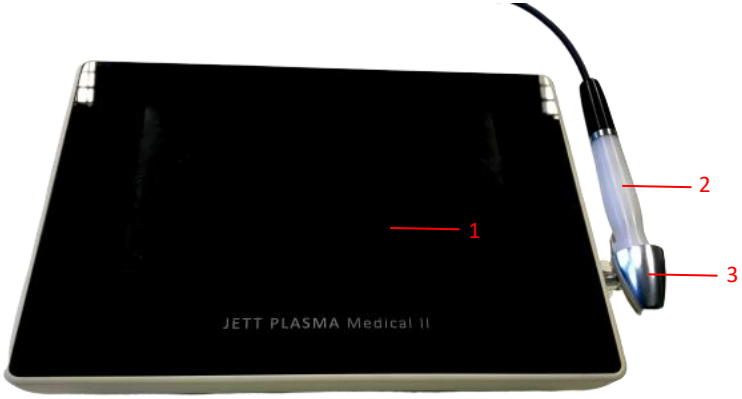
Side effects
If treatment is performed on the faces of the patient having an amalgam seal, slight tingling in this area may occur. When treating the neck zone, there may be twitching movements due to a large number of nerve endings.

Cleaning the device and the Plasma Pen III/M
Neither the device nor the Plasma Pen III/M is waterproof. It may not be exposed to excessive moisture or liquid flow.

5. Device control

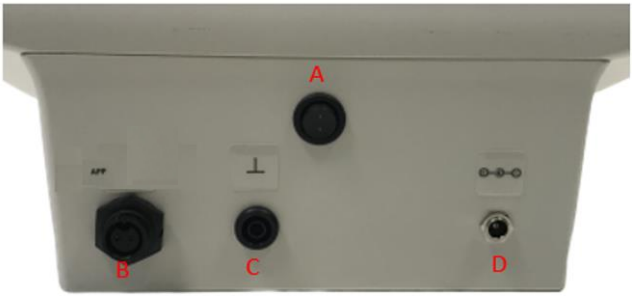
5.1 The device description

Carefully check the condition of the disposable electrode and the curly connection cable (cylinder electrode and connection cable) and the condition of device including the applicators before each start-up. If you reveal any damage, do not switch the device on and contact the manufacturer!



1) Touch screen

2) Plasma Pen III/M
3) Plasma Pen III/M holder



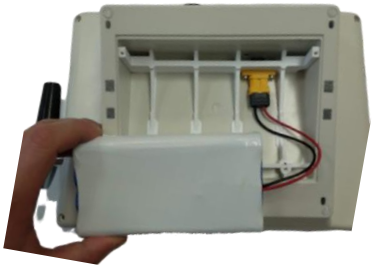
A) On/OFF switch
B) Socket for Plasma Pen III/M
C) Socket for connection cable
D) Socket for network adapter

5.2 Commissioning and operation

JETT PLASMA Medical II is powered by a rechargeable battery or included network adapter to charge the battery. To charge the battery, plug the adapter to the network 100-240 V, 47/63 Hz and the other end into the JETT PLASMA Medical II socket. ⊖—C—⊕ The JETT PLASMA Medical II device can also be used while the battery is charging. Before using of device connect all accessories to each connector on the back panel of the device. The Plasma Pen III/M connector must be locked by turning union nut clockwise. To disconnect the Plasma Pen III/M connector is necessary to disconnect the connector by turning the union nut counter-clockwise and then pull out the connector. Connect the adapter as mentioned above and charge the battery.

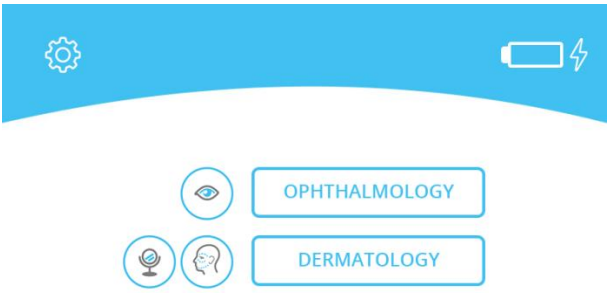
a) Connection and replacement of the battery

Connect the battery before the first use of the device. Using a PH1 screwdriver, unscrew the battery cover and connect the battery using the connector. Insert the battery into the device and put back and screw the battery cover.



b) Turn on the device and setting the treatment parameters

Turn on the device is done by using the switch on the back of the device. After switching on the required ophthalmology or dermatology treatment is selected. In dermatology is necessary to choose from silver or gold applicators.

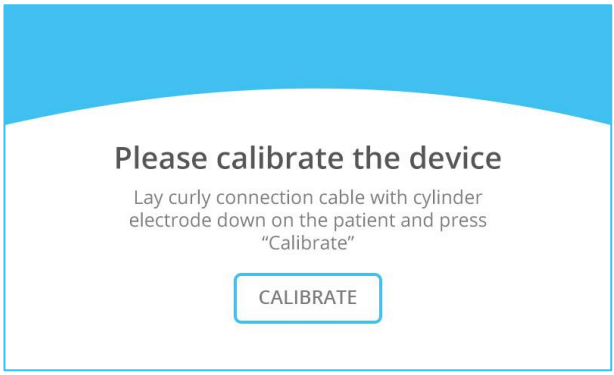


It is possible to switch to another language variant using the gear wheel.

c) TAPE calibration

TAPE calibration is required to correct patient and device connection (if the device is powered by a battery without charging, calibration should be performed before each treatment).

Connection cable lay on the patient in a way that the terminal of connection cable should not touch the patient conductively. Now calibrate the device with calibrate button.



After TAPE calibration, on the screen you will see a notification for setting of intensity and duration of treatment. If it is necessary the patient connection calibration can be repeated by clicking on the symbol

d) Patient device connection

Once the patient is ready for treatment, the patient must be galvanically connected to the JETT PLASMA Medical II using the connection accessories:

- **disposable electrode** - it is necessary to clean the site before application; its use is recommended for one treatment only; store the unused electrodes in the original sealed packaging. The disposable electrode must be sticked as close as possible to the area to be treated, it is forbidden to stick to the back or chest.
- **cylinder electrode** – has to be held firmly in the hand. Cylinder electrode is used only in the case when the disposable electrode is unpleasant to the patient.

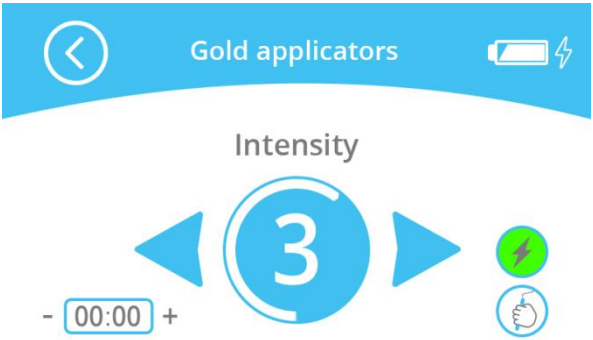
Plug the connection cable connector into the socket of device ⊥ and the other end to electrode. The correct patient device connection is indicated by symbol . If the symbol flashes on ,check that disposable electrode does not peel off or rest on the patient's skin. Or that the cable has not been disconnected or the patient has not released the cylinder electrode or has dry palm.

If it is necessary the patient connection calibration can be repeated by clicking on the symbol

e) Intensity settings

Now it is possible to set the intensity of the treatment. Intensity selection is made on the touch screen. The intensity is set using the arrows. To select an intensity is made by touch the intensity on the circle on the screen (the circle will turn blue). After setting the intensity it is no possible to change the intensity. This function can be unlocked by touch the circle again with the selected intensity. The confirmed intensity is unlocked and the treatment is stopped by interrupting the patient's conductive connection with the device.

The treatment time can be set by touching the + and - symbols on the screen. Touch these symbols will change the time by 1 minute after a while holding by 10 min. The maximum set time is 40 min. The time is counted when the high voltage generator is switched on. When the patient is receiving current a green flash appears on the screen.



f) Switching on the high voltage source
If the intensity of the instrument is already set (Plasma Pen III / M illuminates green), pressing the button on the Plasma Pen III/M activates the high voltage connection to the device tip (Plasma Pen III/M illuminates green and orange).

g) Ignition of spark discharge
As soon as the tip of the instrument or the Plasma Pen III/M approaches approx. 2 mm to the treatment area, the spark discharge is ignited.

h) Extinguish the spark discharge
To turn off the spark discharge, press the Plasma Pen III/M button or remove the applicator.

i) Types of applicators and their use
Applicator replacement can be done by pushing the head towards the Plasma Pen III / M body and then pulling out the existing applicator. You only need to push the selected applicator into the Plasma Pen III/M head. Replace only when the machine is switched off.

1) <u>flat applicators</u>
Flat applicator, diameter 3 mm is used for blepharitis non-ablative treatment
Flat applicators are used only for non-ablative treatments (COSMETICS settings) for wrinkles and rejuvenation. Flat applicators are designed for treatment on larger surfaces. These applicators move over the skin covered with conductive indifferent gel or serum and electrically stimulate the cells by direct current, i.e., opening the potassium potassium channels and then depolarizing the membranes.

2) <u>cone applicator</u>
The conical applicator is designed for accurate non-ablative treatment. The use is the same as for flat applicators with the difference that we use a

conical applicator for precise treatment of small areas of the skin (eg deep wrinkles).

3) gold applicators 14.4 and 24.4 mm
They are intended to treat the skin to precisely remove skin artifacts or to perform fulgurizing micro-burns of the skin near the wrinkles to turn the skin off after treatment.

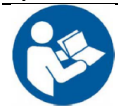
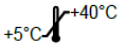
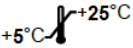
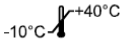
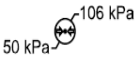
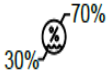
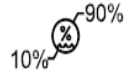
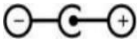
4) ophthalmology applicator gold and steel
The applicator can be used for treatment in the area of the anterior, posterior eyelid and mucous membranes, where the thermal effect of the spark discharge achieves eg increased elasticity of connective fibers around the glands and their ducts, stimulation of impassable tear ducts and a follicle of algae that interfere with the eye and irritate it unpleasantly, or to restore shape and dissolve fat cells. If the ophthalmology applicator is bent, it cannot be straightened any more.

5) insulated applicators L44 and L64
Applicators can be used to treat indications (see Indications) in natural body cavities without damaging the environment during treatment.

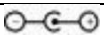
j) Termination of the procedure
The procedure is terminated by releasing the Plasma Pen III/M button and deselecting the instrument intensity setting.

k) Switching off the device
After completing the procedure, turn the instrument off by pressing the ON/OFF switch. You can then plug it in to charge the battery.

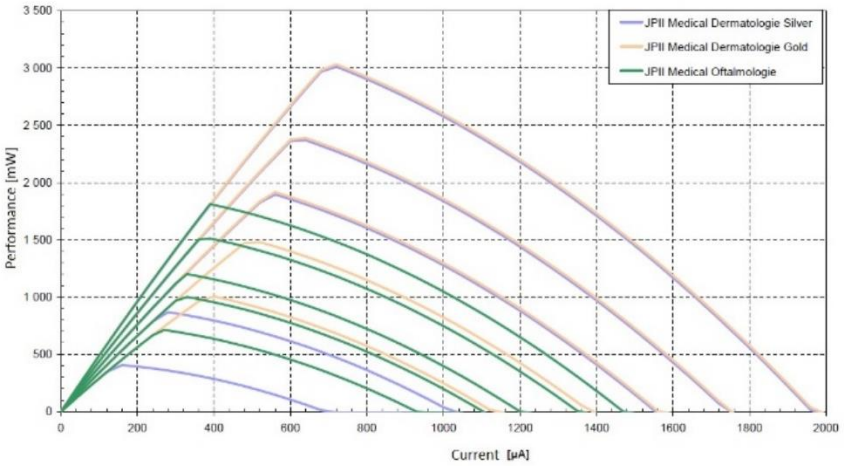
5.3 Symbols on the cover of the device, on the device itself and on accessories

Graphic symbol	Meaning	Graphic symbol	Meaning
	Follow the Instruction for Use.		Galvanic connection with the device
	Manufacturer		Temperature range for use of the device, min. temperature +5°C, max temperature +40°C
	Serial number		Temperature range for storage of the device, min. temperature +5°C, max. temperature +25°C
	Lot (batch)		Temperature range for storage and transportation of the device, min. temperature −10°C, max. temperature +40°C
	Applicator of the BF type		Pressure range, min. 50 kPa, max. 106 kPa
	Electric waste (after expiry of the service life of the device) may not be disposed of together with the municipal waste.		Restriction of humidity for use of the storage device, min. 30 %, max. 70 %.
	Device of the class of protections II.		Restriction of humidity for transportation of the device, min. 10%, max. 90 %.
	Use indoors.		Protect from rain.
	Protection from a lightning.		Designation of the socket for connection of the network adapter
APP	Identification of the Plasma Pen III / M connection socket		Designation of the galvanic connection socket
	Federal law restricts this device to sale by or on the order of a physician or of a person who may work with the MD in conformity with the national legislation.		Catalogue number

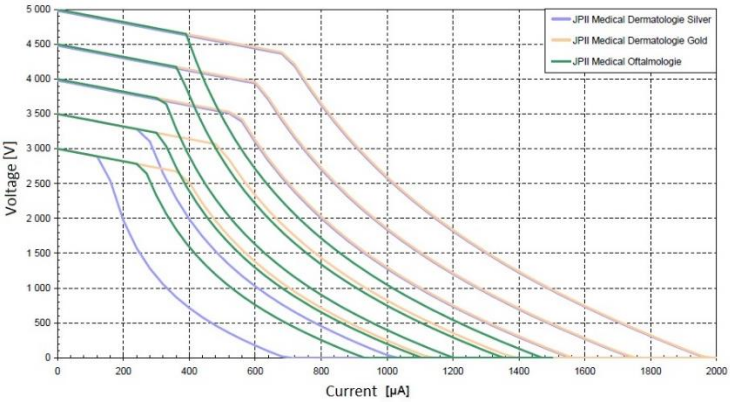
6. Basic characteristics

Class of protection against electric shock	II
Class of protection	IP20
Device type model	with the applied part of BF type
Power supply – external source (adapter) – built-in accumulator	5 V (DC), max. 2,5 A 3,6 V, 24 000 mAh (Li-Ion battery)
Automatic battery charging	after connecting an external power supply
Battery charge status indication	bargraph on display
External power supply type (supplied accessories)	XP Power ACM18US05
Power supply input voltage	100-240 VAC
Power supply input frequency	47-63 Hz
Power supply input current	Max. 0,5 A
Power supply output	5 VDC, max. 2,5 A, 
No-load HV generator voltage	(3 – 5) kV (DC), (without detecting patient connection, the output voltage is zero - the HV generator cannot be turned on)
Output impedance of generator	900 kΩ (+5 %)
Maximum power on applicator (plasma)	(0,2 – 3) W
Maximum output current (at output short circuit - applicator and indifferent electrode)	(0,7 - 2) mA (DC)
Time for safe tip voltage after shutdown	max. 7 s
Detection of patient connection	yes
Dimensions	275 x 125 x 185 mm
Weight	cca 1,7 kg
Relative air humidity range:	30–70 %
Ambient temperature range	+5°C to +40°C
Atmospheric pressure range	70–106 kPa
Working environment	with respect to the basic function of the device - to generate the spark discharge, the device may not be used in an environment where any combustible gases may be present, either in the primary form of gas or as fumes of flammable substances
Storage conditions	Store in the original packaging in a dry and dry place at +5 ° C to +25 ° C and 30-70% humidity
Transportation	transport in the original packaging in a covered transport area, at a temperature of −10 ° C to +40 ° C and a relative humidity of 15–90% without condensation, atmospheric pressure range 70–106 kPa

Performance characteristics of JETT PLASMA Medical II



Voltampere characteristics of JETT PLASMA Medical II



7. Service life

Device	5 years
Network adapter	10 years
Extension cable for network adapter	2 years
Plasma Pen III / M	2 years
Cone applicator	30 sterilization
Flat applicator diameter 3 mm	30 sterilization
Flat applicator diameter 5 mm	30 sterilization
Flat applicator diameter 10 mm	30 sterilization
Flat applicator diameter 20 mm	30 sterilization
Golden applicator 14.4 mm	30 sterilization
Golden applicator 24.4 mm	30 sterilization
Ophthalmology applicator Gold	30 sterilization *
Ophthalmology applicator Steel	30 sterilization *
Isolated applicator L44	30 sterilization
Isolated applicator L64	30 sterilization
Cylinder electrode	30 sterilization
Connection cable for cylinder electrode	1 year
Curly connection cable for disposable electrode	1 year
Disposable electrode	set by the manufacturer

* Ophthalmology applicator Gold and Steel has a shelf life of 3 months and a maximum of 30 sterilization cycles.

The service life of the device and accessories is calculated from the beginning of their use.

Any modification of the medical device JETT PLASMA Medical II is strictly forbidden!!!

8. Storage, maintenance and safety technical inspections

8.1 Storage

- Ideal storage temperature: +5 °C to +25 °C;
- Store the device indoors, in a well-ventilated room, protected from direct sunlight and humidity;
- store the device unplugged from the el. power source.

8.2 Regular maintenance and cleaning

- Maintenance - the operator is obliged to observe all provisions of the Instruction for Use. It is not permitted to interfere with the device, all maintenance operations have to be performed by the manufacturer within the scope of the annual inspections.
- The applicators and cylinder electrode have to be sterilized before the first use and after each application (see sec. 8.2.2)! The device, Plasma Pen III/M, network adapter, extension cable and connection cables have to be disinfected before the first use and after each application, using tissues (see sec. 8.2.1)!

8.2.1 Cleaning and disinfection

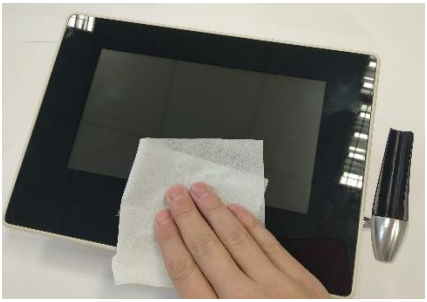
Firstly, the precleaning procedure is done. Removal of visible surface contaminations with Bacillol® 30 Tissues.

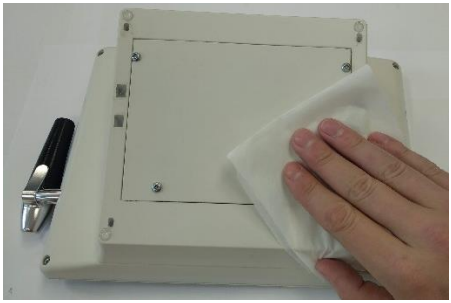
Before the first use and after each treatment, thorough disinfection of the device, Plasma Pen III/M, curly connection cable for disposable electrode, curly connection cable for cylinder electrode, network adapter, extension cable, must be performed, using Bacillol® 30 Tissues.

The device body and the Plasma Pen III / M, the adapter and the connection cables and adapter extension cable are not waterproof. It is sufficient to disinfect their surface by wiping with a tissues so that the disinfected surface is moist for min. 1 minute or using appropriate cleaning tools (e.g. cleaning brushes diameter 5 mm and 11-16 mm) which are soaked in Bacillol® AF surface disinfectant. Parts of the medical device that could not be directly reached by Bacillol® 30 Tissues (e.g. deepening, connections, etc.) should be thoroughly cleaned and disinfected by cleaning brushes soaked in Bacillol® AF surface disinfectant.

The device must be completely disinfected, including the battery and the Plasma Pen III/M holder separately. Removing the battery is shown in section 5.2, the Plasma Pen III/M holder must be removed by mechanical force. Each component must be disinfected separately.

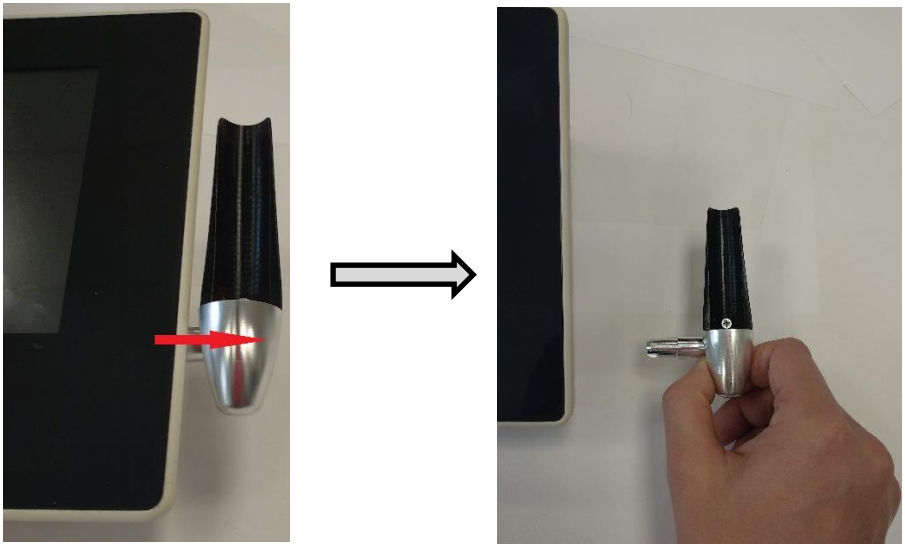
1. Thoroughly clean and disinfect the device body from the front and back by wiping with Bacillol® 30 Tissues.





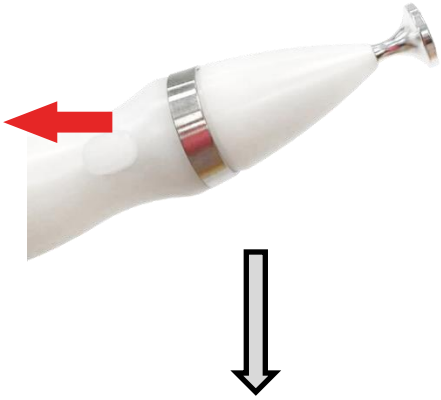
Clean and disinfect the connectors with a cleaning brush and Bacillol® AF.

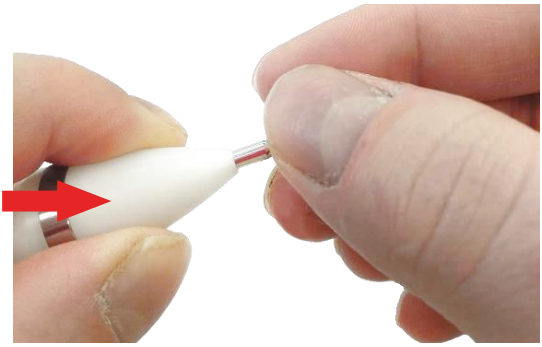
2. Remove the Plasma Pen III/M Holder by pulling.



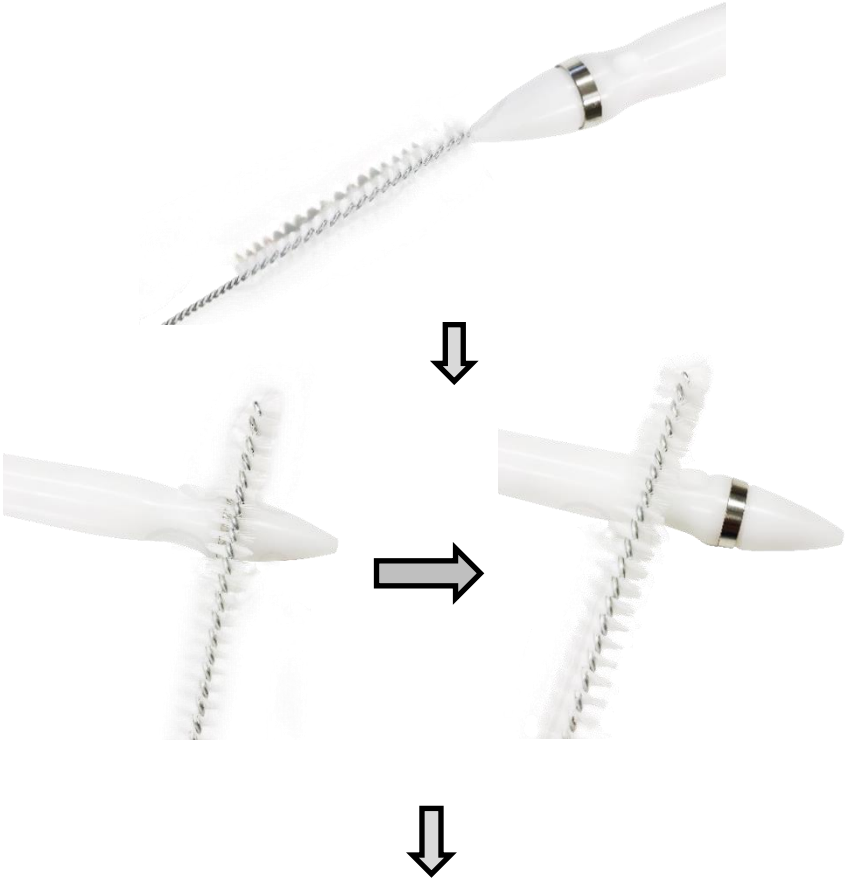
Thoroughly clean and disinfect the disassembled holder by wiping with a Bacillol® 30 Tissues, including the socket connection for holder - clean and disinfect the socket with a Bacillol® AF and the cleaning brush.

3. Disconnect the Flat Applicator 10 mm by squeezing the Plasma Pen III / G head and then pulling it out.





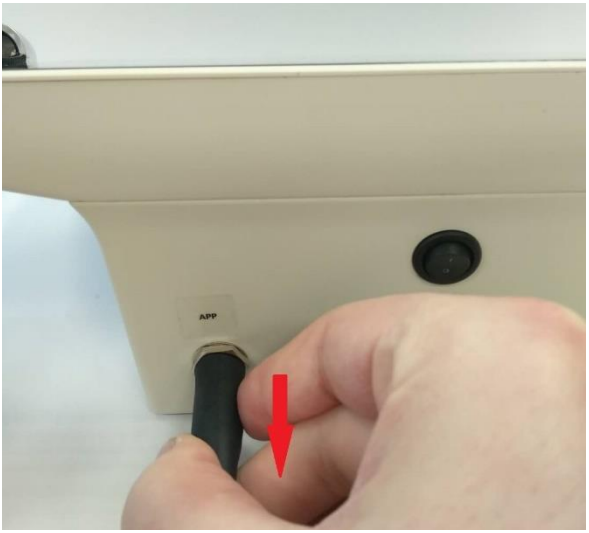
Clean and disinfect the Plasma Pen III/G along its perimeter, including the cable and applicator connection head.

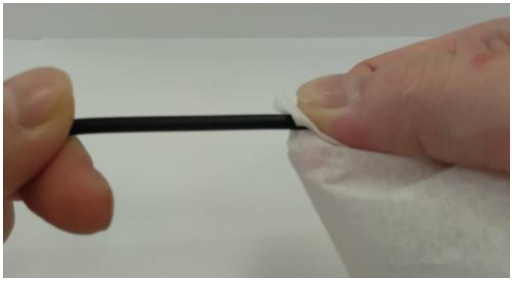


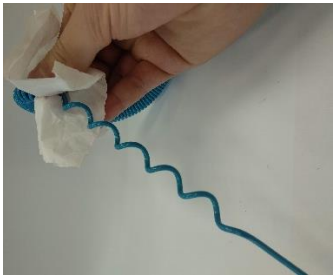
4. Disconnect the adapter and adapter extension cables from the device and disconnect the relevant adapter end piece. Disconnect the end piece by pressing the push button and then pulling on the end piece.

Clean and disinfect the disassembled adapter and adapter extension cable by wiping with Bacillol® 30 Tissues.

5. Disconnect the connection cable from the device for the cylinder / disposable and thoroughly clean and disinfect the cable by wiping with a Bacillol® 30 Tissues.







8.2.2 Sterilization

The isolated applicator is intended to perform treatments in natural body cavities and have to be sterilized by following procedure:

1. Bomix® Plus - cleaning and disinfection - dipping the electrode in 0.5% solution for 15 minutes or 2% solution for 5 minutes. If the applicator becomes dirty, the applicator is wiped with a brush during immersion.

2. Rinse with distilled and dry
3. Packed in a steam sterilization bag
4. Steam sterilization at 134 ° C for at 3 minutes or in conformity with the national legislation. Isolated applicators themselves have the character of a hollow tool. This is a standard complexity of a cavity - it is necessary to use the sterilizers with the standard complexity of a cavity.
5. Storage for further use - bulk can be used 6 days after sterilization with intact sterile packaging.

The rest of applicators and cylinder electrode is intended for body surface treatment, golden applicators may come into contact with damaged skin during treatment and flat applicator, diameter 3 mm, ophthalmology applicators may come into contact with the mucous membrane of the eye and have to be sterilized by following procedure:

1. Bomix® Plus - cleaning and disinfection - dipping the electrode in 0.5% solution for 15 minutes or 2% solution for 5 minutes. If the applicator or cylinder electrode becomes dirty, the applicator or cylinder electrode is wiped with a brush during immersion.


2. Rinse with distilled and dry
3. Packed in a steam sterilization bag
4. Steam sterilization at 134 ° C for at 3 minutes or in conformity with the national legislation.
5. Storage for further use - bulk can be used 6 days after sterilization with intact sterile packaging.

After use, the used applicators cylinder electrode is placed in a closable container where they are stored until the end of the working day, when cleaning and disinfection and subsequent sterilization are performed.

Sterilization is carried out before the first use and after each use.

The healthcare facility must validate the sterilization method.

8.3 Safety technical inspections

If safety technical inspections (STI) are requested by national regulations, they should be performed once a year. STI must be performed only by the service staff of the manufacturer or by an authorized service centre. If the safety inspection was not performed within the preset term by the manufacturer or an authorized service organization, the device may not be used until the STI is done.

Service, maintenance or the prescribed STI of the device may not be used during treatment of a patient.

8.4 Product retirement and disposal

The waste consisting of electrical or electronic devices can contain dangerous substances that may be harmful for the environment or human health. The JETT PLASMA Medical II and Plasma Pen III/M device are included in the group of electric waste and after expiry of its service life, it may not be disposed of with the municipal waste.

9. Servicing

Warranty and after-warranty servicing is performed by the manufacturer:

COMPEX, spol. s r.o.
Palackého třída 924/105
612 00 Brno
Czech Republic
e-mail: info@jett.eu

In the event of a fault or malfunction, send the device with the adapter and the connection cable to the manufacturer with a duly completed complaint report, which is part of this manual, to the address above. In case of not delivering the mentioned accessories you will be charged the used accessories. As soon as the complaint is settled, the manufacturer's statement will be mailed to you electronically, and the repaired device will be delivered to your billing address or to your delivery address.

10. Warranty

This product is covered by the warranty encompassing material imperfections and production faults for the time period of one year after delivery of the device and/or for further 12 months, if the STI has been performed by the manufacturer or the authorized service centre after the first year of use. The product has been sealed and the warranty ceases to exist if the seal/protection is damaged.

The manufacturer undertakes, depending on his possibilities, to repair the device or to replace its damaged parts for the whole term of the warranty, provided that these repairs or replacements are performed directly by the manufacturer or by his authorized representatives.

The manufacturer takes responsibility for safety, reliability and performance /effectiveness of the device only if all repairs, replacements or alterations of the product are performed by the authorized staff, if the device was used in accordance with this Instruction for Use, if the parameters of electric network (in the room where the device is plugged) satisfy all the requirements set by law.

If the product is sent back to the manufacturer, the user shall pay the transportation costs.

11. EMC

11.1 Essential performance

The JETT PLASMA Medical II has been tested and found to comply with the applicable limits for medical devices to EN 60601-1-2:2015 standard in relation to both immunity and emissions. However, special precautions should be observed, see chapter 4.

11.2 Electromagnetic interference

The JETT PLASMA Medical II device is intended for use in the environment of the home health care and is classified as Class B according to EN 55011:2016. It may not be used in the vicinity of active HF equipment and in the RF shielded room with the medical systems for magnetic resonance imaging, where intensity of EM disturbances is high.

Any loss or deterioration of the JETT PLASMA Medical II device function due to electromagnetic interference is not understood unacceptable risk to the patient or the operator. There is no need

to adopt any measures or actions to avoid adverse events for the patient or for the operator due to electromagnetic interference.

WARNING: Use of the JETT PLASMA Medical II device in the vicinity of or linked with other devices can result in incorrect operation. If such use is necessary, this device and other devices must be monitored to verify normal correct function.

WARNING: When using the JETT PLASMA Medical II, use only the supplied connection cables. The use of interconnection cables other than those supplied may result in non-compliance with the radiation requirements or the immunity of the device.

WARNING: Only the delivered network adapter source ACM18US05, manufactured by XP Power, may be used for charging the JETT PLASMA Medical II device.

WARNING: Do not use a portable radio-communication device (incl. the end devices such as antenna cables and external antennas) at the distance closer than 30 cm (12 inches) from any part of the JETT PLASMA Medical II device, incl. the connection cables. Otherwise, its functionality may be deteriorated.

11.3 Electromagnetic emissions

The JETT PLASMA Medical II device meets requirements of EN 55011:2016 for the lead-through emission limits, emitted for the Group 1, Class B.

Frequency band of 0.15–0.50 MHz:

- The quasi-peak value does not exceed 66 dB (µV), falls linearly with the frequency logarithm to 56 dB (µV);
- The mean value does not exceed 56 dB (µV), falls linearly with the frequency logarithm to 46 dB (µV).

Frequency band of 0.50–5 MHz:

- The quasi-peak value does not exceed 56 dB (µV);
- The mean value does not exceed 46 dB (µV).

Frequency band of 5–30 MHz:

- The quasi-peak value does not exceed 60 dB (µV);
- The mean value does not exceed 50 dB (µV).

Frequency band of 23–230 MHz:

- The quasi-peak value does not exceed 42 dB (µV/m), falls linearly with the frequency logarithm to 35 dB (µV/m)

Frequency band of 230–1000 MHz:

- The quasi-peak value does not exceed 42 dB (µV/m).

The JETT PLASMA Medical II device meets the requirements of EN 61000-3-2:2014 to limit harmonic currents injected into the public grid for Class A.

JETT PLASMA Medical II device meets the requirements of EN 61000-3-3:2013 to limit voltage changes, voltage fluctuations and flicker in the low-voltage distribution networks for the devices with a rated phase current ≤ 16 A not subject to conditional connection.

11.4 Electromagnetic immunity

The JETT PLASMA Medical II device meets the requirements for electromagnetic immunity in conformity with the standards shown below:

EN 61000-4-2:2009, test immunity level, electrostatic discharge (ESD):

- ±8kV for contact discharge;
- ±2, ±4, ±8kV, ±15kV for air discharge.

EN 61000-4-3:2006, test immunity level, irradiated high frequency:

- 10 V/m, 80 MHz up to 2.7 GHz;
- 80 % AM at 1 kHz.

EN 61000-4-4:2012, test immunity level, quick electrical transient phenomenon / pulse groups:

- ±2kV, repetition frequency of 100 kHz.

EN 61000-4-5:2014, test immunity level, shock coupled pulse:

- ±1kV between the lines;
- ±2kV between the line(s) and the ground.

EN 61000-4-6:2014, test immunity level, irradiated high frequency:

- 3 V, 150 kHz up to 80 MHz;
- 6 V, 150 kHz up to 80 MHz, 80 %AM at 1 kHz.

high-frequency line:

- 3 V/m 80 MHz up to 2.5 GHz.

EN 61000-4-8:2010, test level, network frequency magnetic field (50/60 Hz):

- 30 A/m 50 or 60 HZ.

EN 61000-4-11:2004, test level, short-term voltage drops,

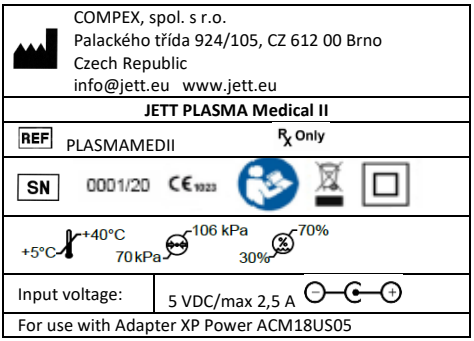
- 0 % U_T in 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°;
- 0 % U_T, 1 cycle;
- 70 % U_T, 25/30 cycles;
- Single phase: at 0°.

test level – voltage breaking:

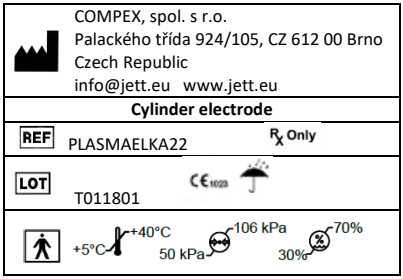
- 0 % U_T, 250/300 cycles.

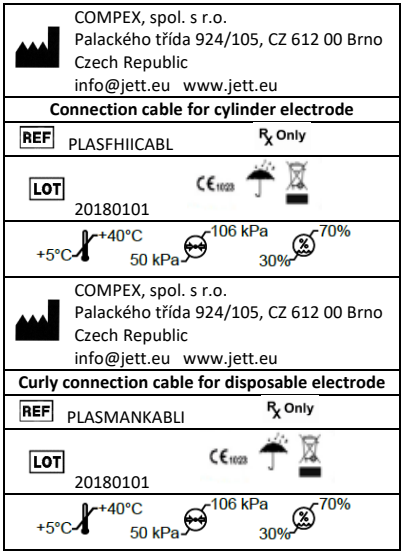
The standards have been used without any deviations.

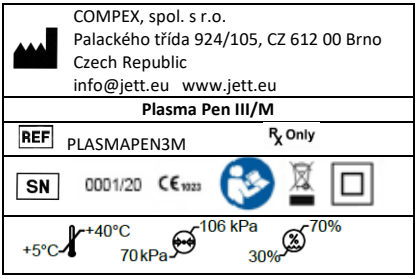
12. Rating plate of the device

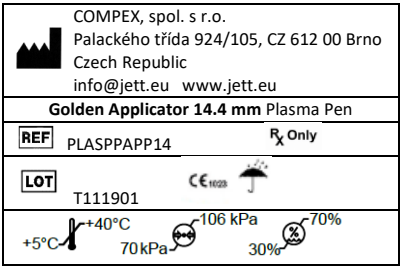


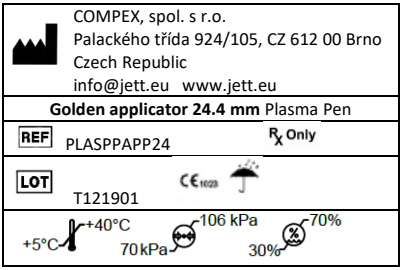
13. Rating plate of accessories

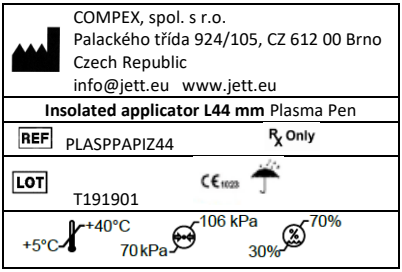


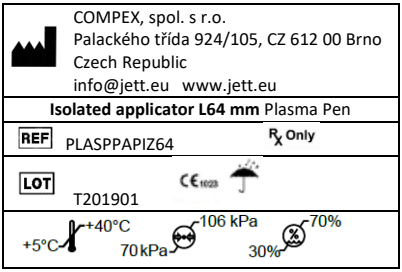












COMPEX, spol. s r.o.
Palackého třída 924/105, CZ 612 00 Brno
Czech Republic
info@jett.eu www.jett.eu

Ophthalmology applicator gold Plasma Pen

REF PLASPOFTASAD Rx Only

SN 0001/19 CE 1023

+5°C +40°C 70 kPa 106 kPa 30% 70%

COMPEX, spol. s r.o.
Palackého třída 924/105, CZ 612 00 Brno
Czech Republic
info@jett.eu www.jett.eu

Ophthalmology applicator steel Plasma Pen

REF PLASPPAPOFTS Rx Only

SN 0001/19 CE 1023

+5°C +40°C 70 kPa 106 kPa 30% 70%

COMPEX, spol. s r.o.
Palackého třída 924/105, CZ 612 00 Brno
Czech Republic
info@jett.eu www.jett.eu

Cone applicator Plasma Pen

REF PLASPPAPPSHA Rx Only

LOT T131901 CE 1023

+5°C +40°C 70 kPa 106 kPa 30% 70%

COMPEX, spol. s r.o.
Palackého třída 924/105, CZ 612 00 Brno
Czech Republic
info@jett.eu www.jett.eu

Flat applicator diameter, 3 mm Plasma Pen

REF PLASPPAPP3 Rx Only

LOT T171901 CE 1023

+5°C +40°C 70 kPa 106 kPa 30% 70%

COMPEX, spol. s r.o.
Palackého třída 924/105, CZ 612 00 Brno
Czech Republic
info@jett.eu www.jett.eu

Flat applicator diameter, 5 mm Plasma Pen

REF PLASPPAPP5 Rx Only

LOT T161901 CE 1023

+5°C +40°C 70 kPa 106 kPa 30% 70%

COMPEX, spol. s r.o.
Palackého třída 924/105, CZ 612 00 Brno
Czech Republic
info@jett.eu www.jett.eu

Flat applicator diameter, 10 mm Plasma Pen

REF PLASPPAPP10 Rx Only

LOT T151901 CE 1023

+5°C +40°C 70 kPa 106 kPa 30% 70%

COMPEX, spol. s r.o.
Palackého třída 924/105, CZ 612 00 Brno
Czech Republic
info@jett.eu www.jett.eu

Flat applicator diameter, 20 mm Plasma Pen

REF PLASPPAPP20 Rx Only

LOT T151901 CE 1023

+5°C +40°C 70 kPa 106 kPa 30% 70%

COMPEX, spol. s r.o.
Palackého třída 924/105, CZ 612 00 Brno
Czech Republic
info@jett.eu www.jett.eu

Extension cable for network adapter

REF PLASMAPRODLU Rx Only

LOT 20190101 CE 1023

+5°C +40°C 70 kPa 106 kPa 30% 70%

14. List of Annexes

Complaint Protocol
Informed consent
Sterilization card of applicator and cylinder electrode

Complaint protocol JETT PLASMA Medical II

Filled in by the claimant

Manufacturer	**COMPEX, spol. s r.o.**	
	Address	Palackého třída 924/105, 612 00 Brno Česká republika/Czech Republic
	E-mail:	info@jett.eu
****Claimant (company, contact person, phone, e-mail)**		
	**Invoice address	
	**Delivery address, if it is different than invoice address	
****No. and date of invoice issuance**		
****Date of detection**		
****Serial number**		
****Detailed description of the defect**		
****Package contents upon delivery***		
****Date of the claim**		

****Claimant's signature and stamp**	

* Always hand over the goods to the complaint with an adapter and connecting cable, to avoid prolonged complaint and increase costs.

****Obligatory field**

Informed Consent of the Patient with Treatment using JETT PLASMA Medical II

Name and surname: _____

Address: _____

Planned treatment: _____

Information about treatment

JETT PLASMA Medical II is the medical device intended, based on the physical principle of a sequence of spark discharges generated by DC, to treat skin and mucous membranes. The device can also be used to eliminate scars, smaller warts, fibromas, hemangiomas and unwanted skin formations, angiectases, keratoses, etc. Some of the indications (verruce vulgaris, condylomata accuminata, molluscum contagiosum) can be treated, using isolated applicators themselves even inside natural body cavities. The product is intended for surgical interventions.

The device may be used by a physician only, to treat the following diseases:

Benign vascular lesions

- angioma (hemangioma, naevus capillaris), teleangiectasia

Skin lesions

- keratosis (verruca seborrhoica, keratosis senilis, keratosis seborroica)
- keratoacanthoma
- fibroma
- xanthelasma

Infectious lesions

- verruca plana, verruca vulgaris
- condylomata accuminata
- molluscum contagiosum

Pigment changes (hyperpigmentation)

- melasma (chloasma)

Ophthalmology indications

- blepharitis;
- stenosis puncti lacrimalis;
- xanthelasma;
- trichiasis;
- distichiasis;

- ectropion;
- entropion.

The doctor is obliged to inform the patient about the postoperative treatment and familiarize the patient with the process of healing.

The Client hereby confirms that does not suffer from any of the following contraindications:

- Peacemaker, Holter ECG monitoring system;
- Another implanted electrical device;
- Epilepsy;
- Pregnancy;
- Metal implants in the treated area;
- Skin diseases and skin inflammations in the treatment area;
- Acute inflammatory disease;
- Any untreated/badly treated disease in treatment area;
- Oncological disease in treatment area;

In case if oncological etiology of the lesion is suspected, the lesion must be examined by a dermatologist.
Before and after treatment, the patient should not take photosensitizers, it can increase the occurrence of pigmentation changes.

WARNING: The person to be treated may not wear any metal things (watches, bracelets …)!

During and immediately after treatment, varying degrees of pain, in rare cases, weak erythema, edema, scab and swelling itching as a result of healing can appear.

Like all treatments, this medical device can have side effects that may not happen to everyone.

When using the medical device JETT PLASMA Medical II, the following side effects may be experienced:

- Hyperpigmentation, which can be prevented by photoprotection after surgery. Skin is protected from sunlight by using SPF 50+ creams and by wearing sunglasses and headgear for at least 7-10 days after the procedure.
- Depigmentation that can be prevented by proper treatment after the intervention with healing creams to promote epithelization.
- Scars that can be prevented by proper treatment after the intervention with healing creams to promote epithelization, by photoprotection and silicone patches

- Rarely an allergic reaction to a disinfectant or a local anaesthetic may occur. Prior to treatment, the physician should check the information about the patient's allergies.
- Feeling of metal in the mouth
- Tingling, where electrode is placed.

Additional client's questions and answers:

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Client Declaration:

I, the undersigned, hereby certify by my signature that I have been informed thoroughly about treatment with the JETT PLASMA Medical II device during the consultation which took place in/on .....

I understand the information concerning the treatment. I also confirm by my signature **that I do not have any of the contraindications as above, and I am aware fully that release of false information may result in the risk of my possible health problems.**

On the basis of the submitted information, considered complete and sufficient for my decision and upon a thorough and careful consideration, I agree fully and unreservedly with realization of the treatment.

In ……., on ……

……

Signature of the client

……

Signature of the informing person

Sterilization card of applicator and cylinder electrode

Accessory name:			
LOT:			
Information about sterilization:			
Sterilization cycle:	Date:	Name:	Signature:
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