NEAUVIA™
DEVICES

PLASMA IQ

USER MANUAL

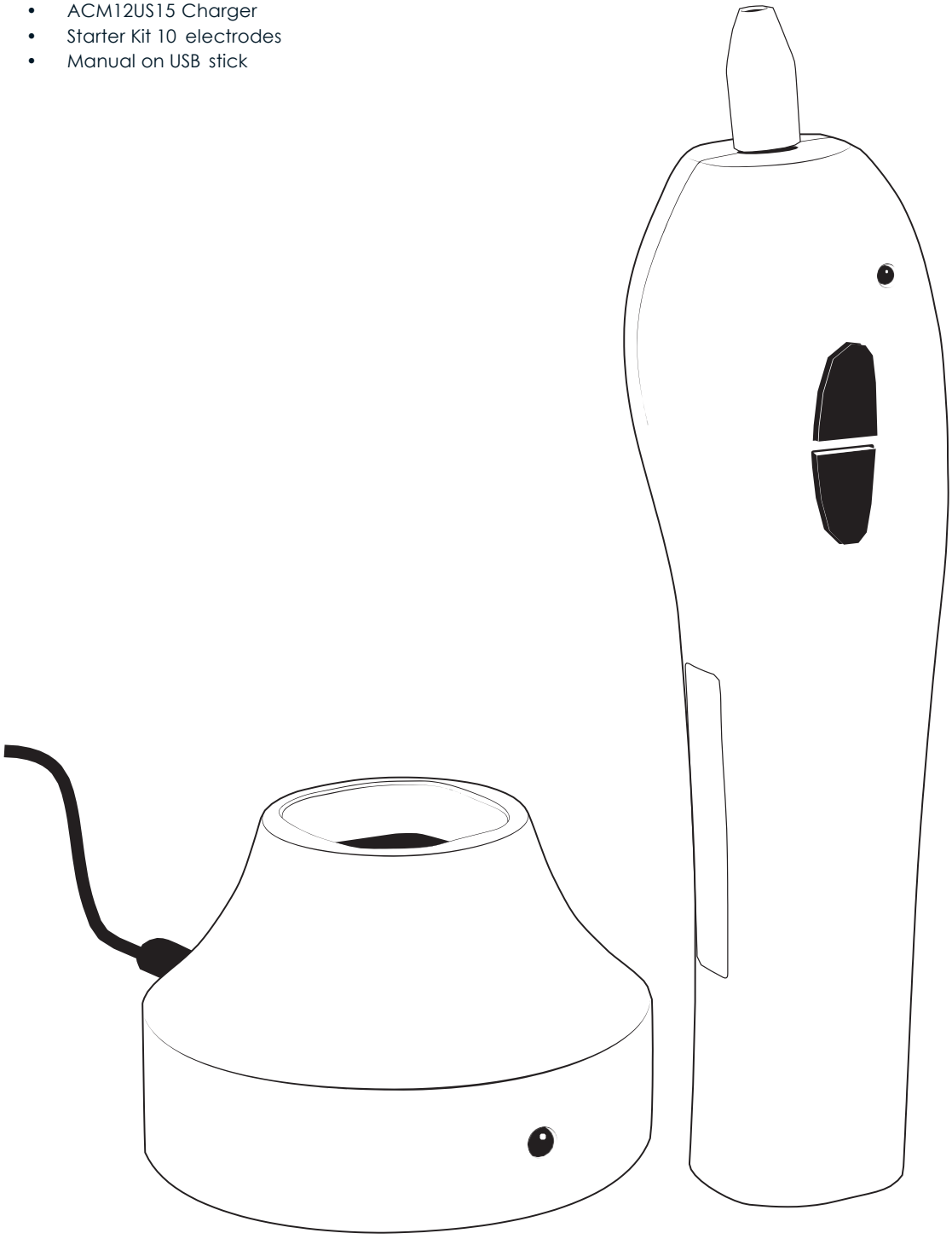
Neauvia North America Customer Service: 1-866-836-3113.

TABLE OF CONTENTS

1. KIT CONTENTS

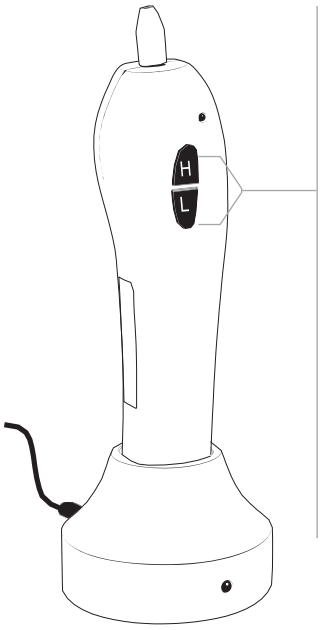
The basic set includes:

- PLASMA IQ device
- The docking station
- ACM12US15 Charger
- Starter Kit 10 electrodes
- Manual on USB stick



2. PRODUCT DESCRIPTION

PLASMA IQ is an electrosurgical device used in non-invasive surgery in the field of aesthetic medicine. The electrosurgical unit (ESU) consists of a plastic housing containing a radio frequency generator. The ergonomically designed housing allows for easy and comfortable one-handed operation. Activation of the current generation takes place only when one of the control buttons is pressed. There are two control buttons on the housing, High "H" and Low "L". The handheld device is cordless and is charged in a docking station prior to use.



On the device, there are two buttons used to provide two different output voltages, marked with inscriptions "H" high and "L" low.

Figure 1: Device PLASMA IQ

Microcurrent radio frequency flows through a given point on the patient's body, resulting in temperature increase, which in turn allows for controlled tissue destruction. The microcurrent flow through the body can only take place at one selected point. Energy is automatically fed through the tip of the electrode to the skin when within the appropriate proximity.

The device is battery powered (11.1 VDC), and the inverter is formed by a high voltage (1400 Vp with an open circuit) at a frequency of 40 kHz, output current with a value of 5 AMPS.

Manufacturer's data and service data:
Neauvia North America, 8480 Honeycutt Road, Raleigh NC 27615.

WARNING: PLASMA IQ DEVICE CAN CAUSE HARM TO THE USER AND/OR PATIENT IF NOT USED AS INSTRUCTED, USED FOR OTHER PURPOSES, OR CONTRADICTORY TO THE INTENDED METHOD OF OPERATION DEFINED IN THIS USER MANUAL. THE USER MUST FOLLOW TREATMENT PROCEDURES AND ABIDE BY THE GUIDELINES DEFINED IN THE USER MANUAL, AT ALL TIMES. THE PLASMA IQ DEVICE MAY ONLY BE USED WITH NEAUVIA PROVIDED ACTIVE ELECTRODES.

3. PRODUCT SPECIFICATIONS

Power charger	230VAC 50 / 60Hz 15W
Output voltage of the charger	1A 12,6V
Maximum power output	5W
Output frequency	40 kHz
Maximum output voltage	1400 Vp
Maximum output current	12.7 mA
Maximum HEATING FACTOR	0,002A^2S
Dimensions of the product	30 x 36 x 190 mm
Weight	250 g
Battery	11,1 VDC, 3 Cell Lithium
Dimensions charger	fi 80 mm / h 60 mm
Weight charger	500 g
Environmental conditions of use	Temperature:50 ÷ 77 °F Pressure: 980 ÷ 1060 hPa Humidity: 93% max
Environmental conditions Storage	Temperature:32 ÷ 122 °F Pressure: 980 ÷ 1060 hPa Humidity 10% - 90%
Electrical Safety Class	Class II
Classification	By. IEC 60601-1-2 Group 2, Class B
Applied part type	Active electrode applied part BF
Protection class	IP21
Mode of operation:	Continuous mode of operation

Technical specifications active electrodes for the device PLASMA IQ:

Length:	30 mm
Diameter:	0.6 mm
Maximum output voltage:	1.4 kVAC
Material:	Stainless Steel 316 L

Use only with PLASMA IQ device

Patient does not have contact with the device.

4. DESCRIPTION OF INCLUDED SYMBOLS

WARNING!

Read the manual

Applied part type F

AC Power Unit

Electrical Safety Class II

Caution High Voltage

Do not dispose with normal trash.
Check manual for proper disposal.

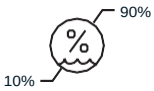
Single Use Only

Handle with care.
Do not drop.

Keep dry

Handle with care, keep dry

Temperature storage
and transport conditions



Humidity storage and
transport conditions

For prescription use only

5. INDICATIONS FOR USE

PLASMA IQ is used in the removal and destruction of skin lesions and coagulation of tissue. Target population: women and men aged 22 to 90.

6. GUIDELINES FOR USE

PLASMA IQ device is intended for use during non-invasive surgery. The PLASMA IQ device is intended for use only in professional health care settings. PLASMA IQ is Rx only.

7. WARNINGS FOR USE AND ADVERSE EVENTS

Discuss contraindications with your patient and ensure that he/she doesn't have any pre-existing conditions that would make a treatment ineffective or unsafe. PLASMA IQ is Rx Only.

CONTRAINDICATIONS:

- Birthmarks and Port-wine Stains
- Warts
- Tattoos
- Blood Coagulation (Hemophilia)
- Auto-immune disorders (Lupus)
- Fitzpatrick Scale 4-6
- Patients with an implanted pacemaker
- Patients with metal or electrically conductive implants
- Cancer
- Pregnancy and breastfeeding
- Cardiac Disorders
- Cardiovascular Diseases
- Uncontrolled Diabetes
- Circulatory Disorders
- Active Herpes or Shingles
- Skin Disorders including psoriasis, eczema, dermatitis, Vitiligo
- Scars including hypertrophic, keloid scars or previous occurrences of keloid scars

PRECAUTIONS: Consult with the patient on the following

- Hyper-pigmentation
- Uncontrolled Epilepsy
- Anemia
- Medications or herbal supplements
- Eye conditions or prior surgeries/treatments
- Toxins, chemical peels, retinols, and/or dermal fillers in the treatment area
- Topical Anesthetic Intolerance
- Recent surgical procedures

NOTE: Contact lens use during and after procedure is not recommended

RISKS OF PLASMA IQ TREATMENT:

- Swelling & bruising
- Scabbing & crusting
- Skin discoloration
- Scarring
- Redness & tenderness

This device has not been studied in combination with any other treatment.

8. DEVICE SAFETY MEASURES

- Under no circumstances should you use the device with a damaged power cord. To replace a damaged cable or plug, please contact Neauvia North America customer service at 1-866-836-3113.
- Never pull the plug with wet hands or pull on the electric cable.
- In the event of malfunctions in the device, damage or any suspected damage, immediately switch it off and disconnect the plug from the socket.
- Under no circumstances should you start the damaged device. All repairs and maintenance should be carried out exclusively by the manufacturer. In the case of independent repairs, the manufacturer excludes all liability for any damage. Visual inspection alone may not be sufficient to ensure that electrical insulation is intact.
- Do not use this device in oxygen-rich environment. Using this device in oxygen-rich environment can result in hazard of fire or explosion.
- Protective eye-wear, filtration masks, and effective smoke evacuation equipment should be used.
- AC/DC power adapter connected to the docking station is a mains isolation element according to IEC 60601-1. To disconnect device from mains, remove this power adapter from mains connection.
- AC/DC power adapter is for disconnecting device from mains. Do not place it in a way that could block possibility of disconnecting it from mains.
- Do not activate the instrument when not in contact with target tissue, this may cause injuries due to capacitive coupling with other surgical equipment.
- Do not use with hybrid trocar systems when using monopolar active components. This may result in alternate site burns. Use only all-metal or all-plastic trocar systems.

Warning: Do not make any modifications to the device.

Warning: Servicing must be performed only by persons authorized to do so in writing by the manufacturer.

Warning: Do not directly touch the output electrode of the product with sensitive parts such as the user's eye or the patient's eye. In addition, treatments should not be performed within the orbital rim, which includes the upper and lower eyelids.

9. DEVICE PRECAUTIONS

- Active electrodes, which are temporally unused should be stored in a location isolated from the patient.
- The output power of the device should be as low as necessary to achieve the intended result of the operation.
- The use of flammable gases (e.g. N2O nitrous oxide) or oxygen should be avoided if surgery is carried out within the torso or head, unless the gases are vented. Wherever possible, use non-flammable agents for disinfection and cleaning. In the case of the use of flammable substances, disinfection or cleaning, wait for them to evaporate and only then start generator use. If there is a risk that flammable solutions can come in contact with the patient during use then all liquids should be removed before starting the treatment using the generator. Particular attention should be paid to the safety when using flammable gases. Some materials (e.g. cotton or gauze) in the case of oxygen saturation may ignite from sparks generated during normal use of the HF generator.
- PLASMA IQ is equipped with the ability to control power output aspects by buttons installed on the side of the ESU. For this reason, the electrode active mode can be changed during operation without additional steps to change device parameters.
- The Plasma IQ device is an RF high frequency generator, and therefore electromagnetic waves emitted by the device can affect the operation of other electronic equipment in the ambient space. HF generator frequency can cause unintended increase in power output devices.

10. OPERATING CONDITIONS & TRANSPORT

This product may not be

- Used in rooms with flammable gases
- Exposed to atmospheric conditions
- Exposed to moisture and liquid substances
- Exposed to fire and high temperatures
- Used immediately after transport between environments of slightly different temperatures (in this case, wait until the condensed water evaporates)
- Keep the device at least 1 m away from other devices while the device is in operation
- The device is intended for use only in professional medical facilities. PLASMA IQ is Rx only.

11. DISPOSAL OF EQUIPMENT

The product contains electronic parts. It should be disposed of in accordance with applicable law. The product contains lithium batteries - you must follow the regulations regarding the disposal of this type of batteries.

12. MEDICAL PRODUCT WARRANTY

The manufacturer is not responsible for the malfunction of the product if it is used in a manner inconsistent with this manual.

For PLASMA IQ devices that are under warranty, Neauvia North America will arrange to supply our customer a means to ship the defective device to our service department for necessary repairs and will ensure that the customer is supplied a temporary device for use during the repair process in a timely manner.

See section 19 for additional warranty details.

13. CLEANING AND DISINFECTION

- Plasma IQ device does not directly contact the patient. The Operator of the Plasma IQ device is advised to use proper protective equipment including gloves. The Plasma IQ device should be cleaned before and after each use. The active electrode is for single use only and must be discarded after the treatment.
- Do not use abrasives and free chlorine and oxygen - they may damage the case.
- Clean the device with a cleaning product such as 70:30 IPA or facility approved cleaning agent for 3-5 minutes and disinfect with a disinfecting product such as with Caviwipes or facility approved disinfectant for 3-5 minutes. Ensure that the device remains wet per the specifications of the chosen disinfectant. Refer to the cleaning and disinfection label for specific time frames. Allow to air dry until no longer visibly wet (approximately 3-5 minutes).

Maintenance

If you experience technical difficulty with your device, contact Neauvia North America at 1-866-836-3113 email service@neauvia-us.com PLASMA IQ devices in the United States and Canada should not be serviced by third party technicians. The warranty is void if the medical device has been opened, tampered with or repaired by an unauthorized technician. Neauvia North America will arrange to supply our customer a means to ship the defective device to our service department for necessary repairs and will ensure that the customer is supplied a temporary device for use during the repair process in a timely manner.

The device is not equipped with any fuses that can be replaced by third party operators or service personnel. There are no serviceable parts inside the device. Service Personnel must hold a valid certificate issued by manufacturer to perform any repairs of this equipment.

No parts of the equipment should be serviced or maintained while in use with a patient.

14. ELECTROMAGNETIC COMPATIBILITY

Declaration regarding electromagnetic compatibility in accordance with EN ISO 60601-1-2 is available on request at the manufacturer's premises.

The PLASMA IQ device has been tested for compliance with EN ISO 60601-1-2.

The PLASMA IQ device has been classified by EN ISO 60601-1-2 as Group 2, Class B.
The Plasma IQ has an essential performance which is that there shall be no change in operating mode or false alarm , the delivered power shall not be higher than +20% of the set power.

The PLASMA IQ device is intended for use only in professional healthcare facilities.
The PLASMA IQ device is intended for use in the electromagnetic environment described below. The user is responsible for ensuring that the environment in which the device is used has met the following requirements.
The PLASAM IQ device is only used with the active electrode.

Description	**Comments**
Emission of radiated disturbances in accordance with PN-EN 55011: 2012	Range 30 -1000MHz
Conducted disturbance emission - disturbance voltage according to PN-EN 55011:2012	Range 0.15 - 30 MHz
Resistance to electrostatic discharge ESD according to PN-EN 61000-4-2:2011	Air discharge voltage: 2,4,8,15; polarity +/- Contact -8kV, + 8kV
Resistance to electromagnetic fields with radio frequencies in accordance with PN-EN 61000-4-3: 2007 + A1; 2008 + A2: 2011	Range 80-2700 mHz 3V/m Proximity field: 385, 450, 710, 745, 780, 810, 870, 930, 1720, 1845, 1970, 2450, 5240, 5500, 5785 mHz
Resistance to rapid transient (BURST) in accordance with PN-EN 61000-4-4:2013-05	+/- 2kV, 100Hz
Resistance strokes (SURGE) in accordance with PN-EN 61000-4-5:2014-10	Line to line: 0.5 and 1.0kV Line to earth: 0.5, 1.0 and 2.0kV
Resistance to conducted disturbances induced by a radio frequency field in accordance with PN-EN 61000-4-6: 2014-04	0,15 – 80 MHz 3V r.m.s.
Resistance to sags, short breaks and voltage changes according to PN-EN 61000-4-11:2007	

Warning: Avoid using this device in close proximity to other devices or setting the device on or under another device because it can cause interference with proper device functions. If close proximity of devices can not be avoided, observe that both devices are work properly.

Warning: The use of accessories, cables or applicators other than those specified in this manual or supplied with the product may lead to an increase in electromagnetic radiation generated by the device or to reduce the electromagnetic immunity of the device and, as a result, to improper device operation. The device is to be used only with the active electrode.

Warning: Portable devices using wireless communication (including external antennas or antenna cables) should be used at a distance of not less than 30 cm from the PLASMA IQ.

15. OPERATING ACTIVITIES

The PLASMA IQ device does not have any user replaceable parts. It also has no user replaceable fuses. In case the device does not work, please follow the steps below:

1. Connect the charger adapter to the wall outlet.
2. Make sure that the charger LED lights up green. If the LED is not lit, check that the outlet to which the device is plugged in is getting sufficient power. If the LED is not lit, contact Neauvia North America customer service at 1-866-836-3113.
3. Place the device in the charger. After a while, the LED should turn red. If the LED does not change color and the device does not work, please contact Neauvia North America customer service at 1-866-836-3113.
4. Wait until the device is fully charged before using. The LED on the charger will turn green when the device is fully charged.
5. Remove the device from the charger. Press the H or L on the device. The LED on the device should light up indicating the device is ready to use.

Warning: The product is intended for use with treatment electrodes, which are disposable products. After each treatment it is necessary to remove the electrode from the device. A new one should be used for each treatment.

Warning: HF surgical accessories should be selected in a way to avoid incompability and unsafe operation.

Warning: The PLASMA IQ device may only be used with Neauvia provided active electrodes.

Warning: Operator should avoid HF output settings where maximum output voltage may exceed rated accessory voltage

Warning: Operator should regularly inspect the accessories. In particular, charger cables and HF energized devices should be checked for possible damage.

Warning: When using the PLASMA IQ device, the rated voltage should comply with specifications in this manual.

16. LIST OF INDICATORS

PLASMA IQ is not equipped with an alarm or warning systems.

Incorrect device operation may trigger the following indicators:

- No emission - in this case the LED on the device will not light up despite pressing the switch on the device
- Damaged battery - after placing the PLASMA IQ in the docking station, the LED on the device placed in the stand will not change its color to red
- The charger is not powered up - the docking station LED does not light up

Indicator Location	Indicator Color	Description
Device	Yellow	Active HF output
Docking station	Green	Docking station ready (not charging)
Docking station	Red	Charging of the battery in progress

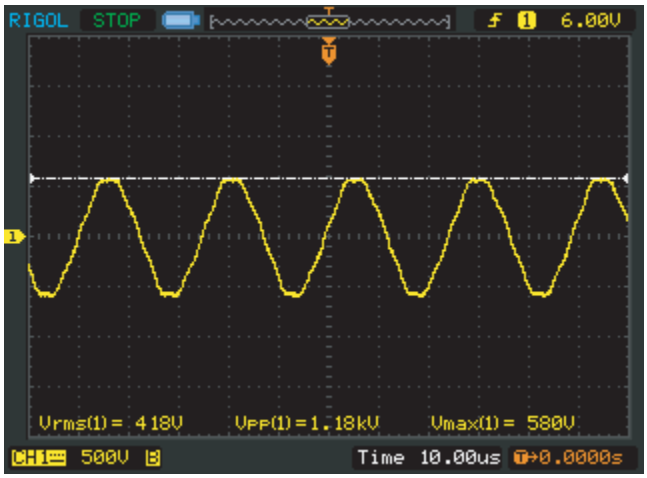
Warning: Avoid using this device in close proximity to other devices or setting the device on or under another device because it can cause it not to work properly. If this setting of devices is necessary, observe both devices work properly.

Warning: The use of accessories, cables or applicators other than those specified in this manual or supplied with the product may lead to an increase in electromagnetic radiation generated by the device or to reduce the electromagnetic immunity of the device and, as a result, to improper device operation.

Warning: Portable devices using wireless communication (including external antennas or antenna cables) should be used at a distance of not less than 30 cm from the PLASMA IQ.

17. DESCRIPTION OF WORKING MODES

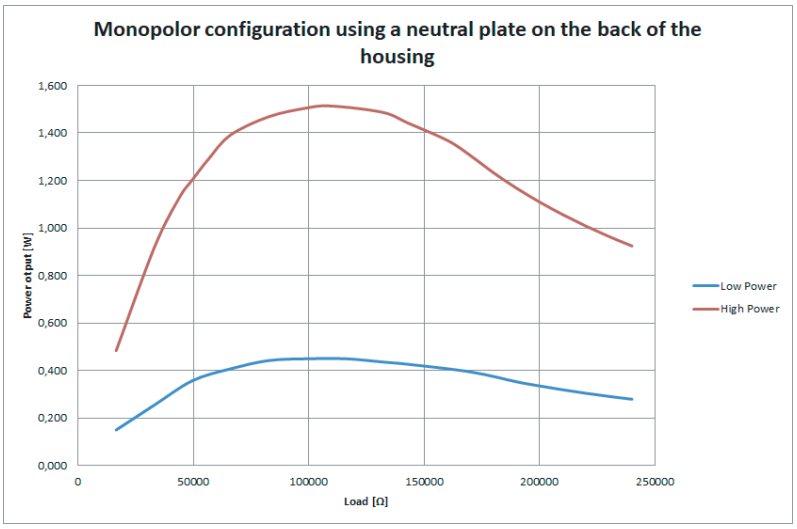
MAX. POWER	5 W
IMPEDANCE RATED	54 kΛ
FREQUENCY	40 kHz
MODULATION FREQUENCY	N/A



17. DESCRIPTION OF WORKING MODES

17.1 Output power graph

The following graphs shows dependency between device output power and load impedance.



The maximum output voltage levels:

- for High Power (the “H”) - 950 Vrms
- for Low Power (the “L”) - 650 Vrms

18. WORKING WITH THE DEVICE

18.1 Check component functionality

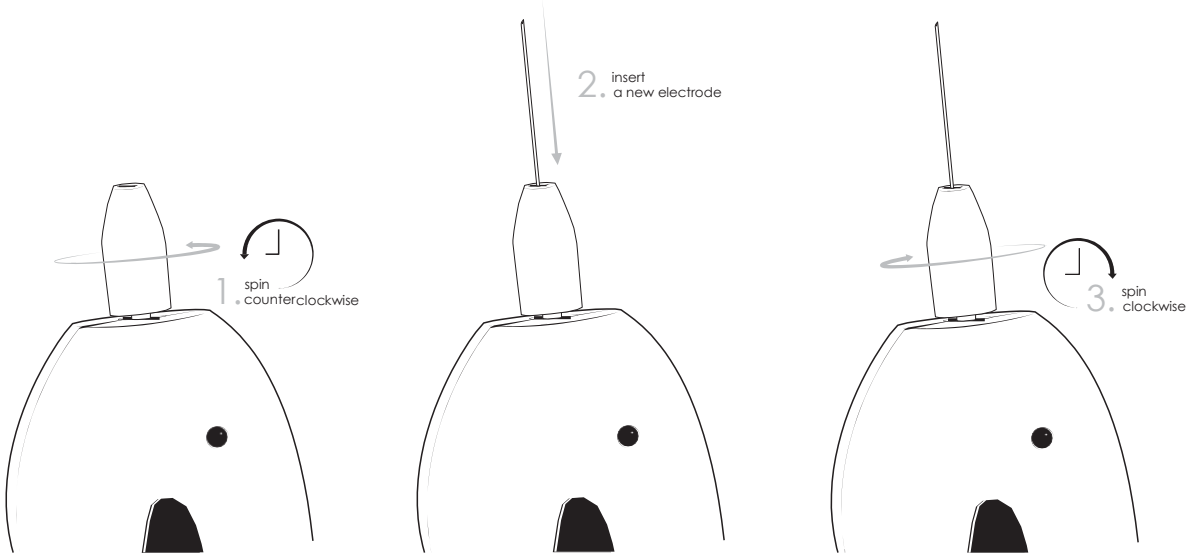
Before use, check that the device is working properly. To do this, the following procedure should be carried out:

- Connect the power supply and check that the green LED is on the docking station
- Take out the PLASMA IQ from the docking station, press the LOW button and check if the yellow LED turns on
- Take out the PLASMA IQ from the docking station, press the HIGH button and check that the yellow LED lights up

18.2 Preparing the device and equipment for work

Before starting work with the device, an active electrode should be inserted. In order to install the active electrode, ensure that the device is off and follow the steps below and the drawing:

1. Turn the spindle to the left;
2. Insert the treatment electrode;
3. Turn the spindle clockwise until it stops.



Warning: Do not apply excessive force when tightening the spindle. Do not use any tools to unscrew or screw the spindle.

18. WORKING WITH THE DEVICE

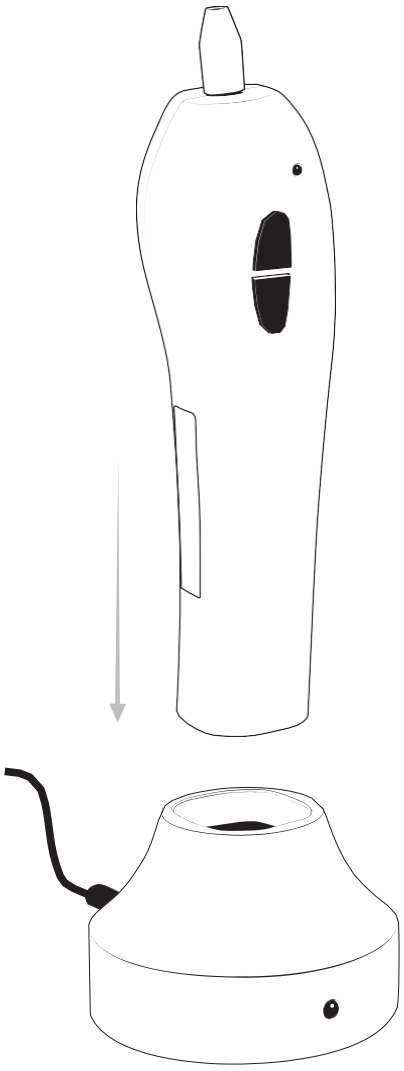
18.3 Charging the device

If the yellow LED does not turn on or a significant power drop is noticeable, it means that the PLASMA IQ needs to be recharged.

Warning: Do not leave the device uncharged or use the device before it is completely charged, because it may damage or shorten the life of the battery inside the device.

Before charging the device, do the following:

1. Remove the electrode used during the procedure;
2. Clean the device as it is described in the user manual;
3. Put the device on the docking station;



18. WORKING WITH THE DEVICE

18.4 Shutting down the device

To stop working with the device and shut it down, release all buttons, remove active electrode and place device on docking station.

Warning: To avoid personal and/or material damage, remove the electrode from the device after completing the procedure and when placing the device in the docking station.

Warning: The active electrode is a part that does not have electrical insulation, therefore, when installing or removing the active electrode, avoid touching the buttons that activate the device.

Warning: Place the active electrode in the correct position as described in the manual. If the electrode is mounted incorrectly it may affect the performance of the device.

Warning: Tighten the active electrode holder securely. Improper tightening of the handle can lead to the electrode slipping out of the handle during the surgery.

19. TERMS OF WARRANTY

- The PLASMA IQ device is covered by a warranty lasting 12 months from the date of purchase on the fiscal document delivery (accompanying document confirming the date of purchase) and / or invoice.
- Warranty is limited to replacement or repair of individual components or pieces with manufacturing defects.
- Warranty does not cover defects or damage resulting from improper maintenance, inadequate power supply, negligence or incompetence, as well as faults or damage to parts subject to standard wear.
- The warranty is void if the medical device has been opened, tampered with or repaired by unauthorized personnel. In the United States and Canada, defective devices must be reported and returned to Neauvia North America to be repaired by an authorized service technician.
- Technical repair service for the device is only available during the warranty period, 12 months from the date of purchase, unless an extended warranty is purchased.

NEAUVIA™
NORTH AMERICA

Neauvia North America Customer Service: 1-866-836-3113.