NEAUVIA™
DEVICES

IQ

PLASMA IQ

TRAINING MANUAL

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

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1.0 Introduction

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Introduction

PLASMA IQ utilizes a treatment method called plasma fulguration, which causes controlled skin damage. It offers a low-risk procedure, with minimal side effects. The device works through the generation of an electrical arc, which causes epidermal fulguration, with minimal effect on surrounding tissue. The PLASMA IQ works by creating an arc between the device tip and the skin, by ionizing the gas particles in the air. The resultant production of plasma causes fulguration of the epidermis of the skin, turning a solid straight into gas. It creates 1mm^2 or small treatment spots that show as tiny brown carbon crusts or scabs. These will remain for approximately a week before dropping off.

This Training Manual is only a means of support in the correct operation of the device. The PLASMA IQ device should only be used by medically licensed and certified practitioners who have undergone training conducted by authorized Neauvia trainers or distributors. The manufacturer shall not be liable for any potential damage resulting from improper operation of the device or treatments performed by untrained personnel who are not fully certified.

PLASMA IQ is used in the removal and destruction of skin lesions and the coagulation of tissue.

PLASMA IQ is Rx only.

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.

2.0 Patient Consultation

1

Communicating with your patient and establishing an environment where they feel cared for and comfortable is a crucial step to set the tone of the treatment experience.

PLASMA IQ is used in the removal and destruction of skin lesions and the coagulation of tissue.

Take a moment to talk with your patient to understand:

- Why is the patient interested in a PLASMA IQ treatment?
- What indication does the patient want to address?
- What level of change is the patient looking for? Discuss the number of treatments that would most likely support this level of change.

Share before and after imagery to help set expectations for results.

WARNING:
NOT FOR USE IN THE GENITAL AND EYE AREAS.
USE CAUTION AROUND SENSITIVE SKIN AREAS SUCH AS THE LIPS.

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.

2

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)
- 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

2.0 Patient Consultation

RISKS OF PLASMA IQ TREATMENT:

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

Treatment Side Effects

The use of this device could result in side effects. The table below lists the known skin reactions that may occur following treatment with the device.

Possible Side Effects	How to assess and react
Mild pain / discomfort in the area being treated	This is expected and is normal for all Plasma treatments.
Itchiness in the treatment area	This is quite common for Plasma treatments and should subside after a short period. Do not scratch the area as this could remove the scabs and potentially result in mild scarring.
Skin redness after treatment	This is expected and is normal for all Plasma treatments. You can keep on using the device as instructed once skin redness has disappeared.
Hyperpigmentation	Hyperpigmentation is higher risk with Fitzpatrick skin types V and VI but can occur in all skin types. Patch tests before treatment and rigid adherence to aftercare guidelines will reduce this risk to a minimum. Hyperpigmentation will disappear over time and there are Hyperpigmentation cream available OTC to assist.

Importance of a test spot

Plasma treatment can cause hyperpigmentation in some individuals. Based upon currently available data, the highest risk groups for this response are those with skin type V and VI. Always administer a test spot by firing 4-5 plasma pulses into an area that is not visible (for example, behind the ear or the back of the knee). Allow two to four weeks before administering a full treatment to observe patient's healing. This is recommended to see how the patient's skin reacts to the treatment and to then explain to the patient the importance of the aftercare instructions and SPF 50 protection.

3.0 Preparing the device

1

To make sure your patient feels at ease and informed, be sure to help set expectations about what the treatment entails.

Describe the process and prepare them for:

- What are the stages of the treatments?
- What types of sensations can they expect throughout the treatment?
- What should they expect immediately after the treatment?
- What kind of after care they should follow to promote the best results?

2

At the end of the treatment:

- Review the post-treatment recommendations and treatment plan and schedule for your patient to achieve desired results.

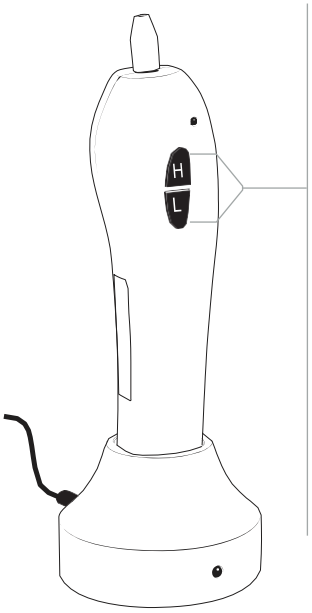
3.0 Preparing the Device

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



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

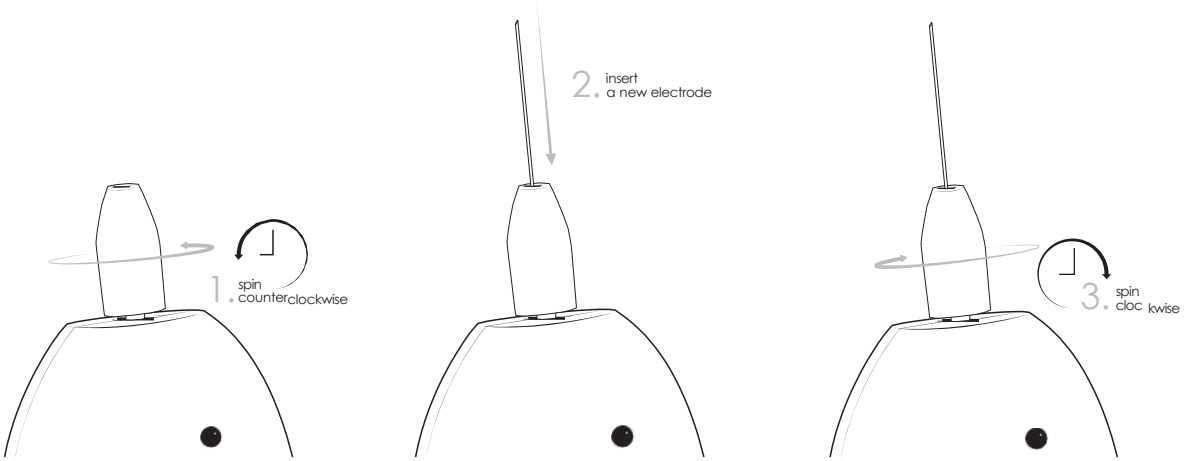
Figure 1: Device PLASMA IQ

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.

4.0 Pre-Treatment Care

Pre-Treatment Recommendations:

1

Avoid sun exposure or tanning beds for 2-4 weeks before treatment. Ideally, begin applying SPF 50 to prep skin for 2-4 weeks prior to treatment.

5.0 Technique

Recommended Voltage Parameters

LOW voltage should always be used as an initial measure before increasing voltage for more intensive fulguration. It is recommended to use the LOW setting whenever possible for patient safety and comfort.

* button LOW - 650 V (Controlled fulguration, delicate areas of face, lip area)

* button HIGH - 950 V (Controlled fulguration)

5.1 Technique: Zig-Zag Pattern Technique

Zig-zag pattern technique protocol

1. Apply short energy pulses in non-linear pattern working in a zig-zag motion to ensure distribution of energy pulses for patient comfort.
2. Pulses should be at least 1mm apart.

Zig-zag pattern technique step-by-step

1. Apply numbing cream to treatment area as prescribed by physician and allow 10-20 min to take effect.
2. Carefully remove numbing cream.
3. Cleanse the skin using gauze and a non-alcohol antiseptic.
4. Dry area completely with gauze.
5. Attach single use, disposable electrode to the PLASMA IQ device as instructed on page 6.
6. Press the L button to set voltage parameters to low.
7. Apply short energy pulses in non-linear pattern working in a zig-zag motion to ensure distribution of energy pulses for patient comfort.
8. Pulses should be at least 1mm apart.
9. Continue until the full treatment area is covered.
10. When the area is complete, move to the next area and repeat steps 2-9.
11. Cleanse treated area with gauze and non-alcohol antiseptic.
12. Apply moisturizer such as petroleum jelly as directed by physician.

6.0 Skin Lesion

Skin lesion treatment protocol

Treatment Parameters:	Begin at Low (L) and move to High (H) if needed
Treatment Time:	About 1-2 min.
Treatment Frequency:	1 treatment

Skin lesion treatment technique step-by-step

1. Apply numbing cream to treatment area as prescribed by physician and allow 10-20 min to take effect.
2. Carefully remove numbing cream.
3. Cleanse the skin using gauze and a non-alcohol antiseptic.
4. Dry area completely with gauze.
5. Attach single use, disposable electrode to the PLASMA IQ device as instructed on page 6.
6. Ensure power setting is correct for treatment area/type.
7. Use arc in random pattern to cover the skin lesion.
8. Cleanse treated area with gauze and non-alcohol antiseptic.
9. Apply moisturizer such as petroleum jelly as directed by physician.
10. Protection of the treatment site is recommended.

7.0 Post-Treatment Recommendations

Post-Treatment Recommendations:

1. Apply moisturizer such as petroleum jelly as directed by physician. Avoid touching or cleansing the area for at least 12 hours post procedure and ensure that hands are clean when applying moisturizer. In case of infection, consult with a physician.
2. You may experience some stinging in the treated area immediately following treatment. This is normal and typically only lasts for about an hour, though some variation in time may occur.
3. Continue to apply moisturizer such as petroleum jelly twice a day after gentle cleansing. Additional moisturizer can be applied as needed if dryness occurs.
4. Do NOT pick at or scratch at scabs as this may delay healing or affect outcomes.
5. Avoid sunlight, exercise, heat, steam or sweat for 48 hours post treatment.
6. After 2 days, begin applying at least SPF 50 to the treated area daily.
7. Do NOT use makeup, mascara, or creams other than sunblock on treated area until scabs have healed, approximately 1 week.

8.0 Device Maintenance

1 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.

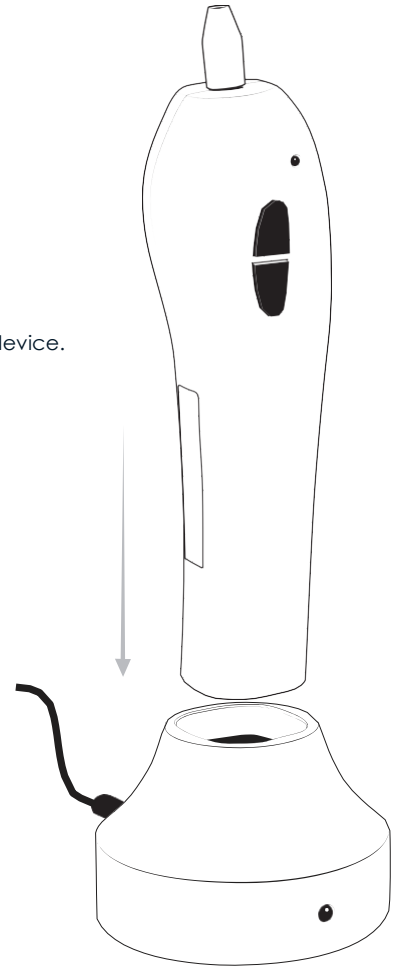
2 Charging the device

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.



8.0 Device Maintenance

3

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).

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Maintenance

If you experience technical difficulty with your device, contact Neauvia North America at 1-866-836-3113 or 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 the customer a means to ship the defective device to the Neauvia North America 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 the manufacturer to perform any repairs to this equipment.

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

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