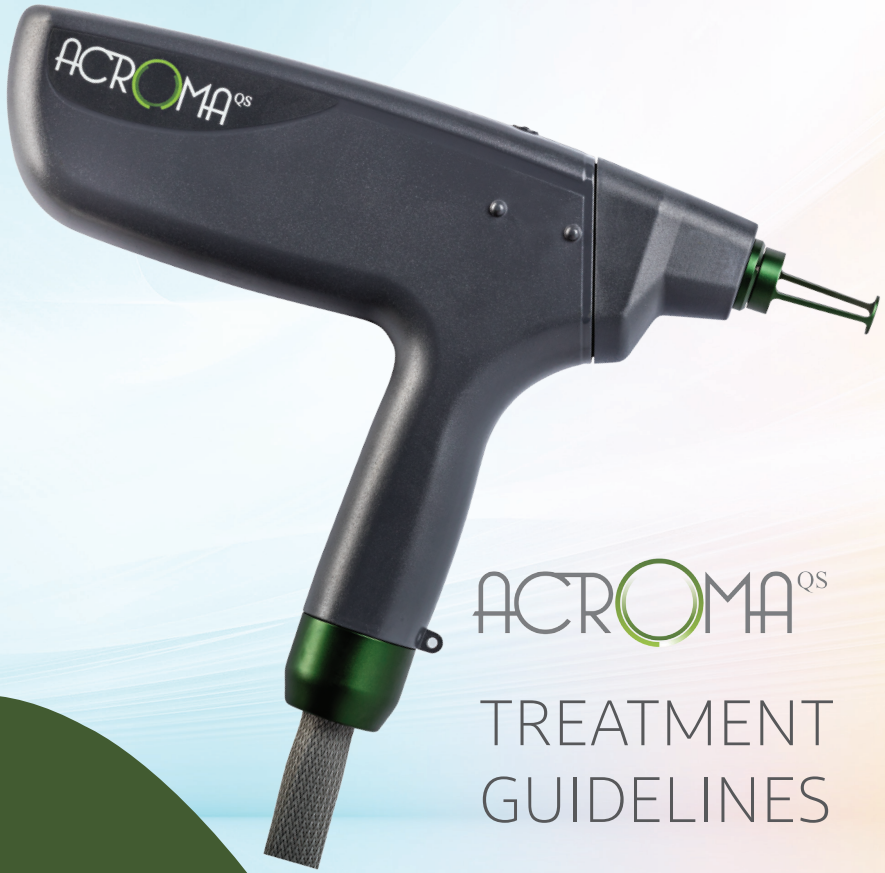

ACROMA QS

TREATMENT GUIDELINES

etherea MX

ETHEREA-MX®
ACROMA-QS®

VERSION 1.2 - NOVEMBER 2017

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IMPORTANT WARNINGS

- Practical training offered by the company is critical for understanding the device and the technique. However, this does not supercede any other medical qualification required for its correct use.

- Before handling and/or operating the device, reading the relevant Instruction Manual is required.

- The ETHEREA® device and its respective ACROMA-QS® handpiece should only be operated by qualified professionals. User qualifications, as well as installation and support requirements to carry out procedures, vary from country to country, so professionals should refer to the relevant local regulating agencies for information.

- This document is not intended to be a complete and absolute guide for using the equipment and is offered as a response to the referenced indications. It is implied that the operator of the device in question has all training and the necessary qualifications to properly perform the procedures proposed herein.

- The parameters suggested here are not absolute in clinical practice. Operators should understand how the treatment interacts with the target tissue and be guided by their own clinical experience and professional judgment.

- It is advisable to have a pre-treatment questionnaire prepared, with instructions for patients, explaining the anticipated effects pre- and post-treatment, medical history, patient consent, and any other documents that may be considered critical and compliant with local laws and regulations. Purely for illustration and exemplification purposes, VYDENCE® provides templates of these forms along with this manual.

- Always proceed with photographic documentation of all treatment stages. Talk to your patient and explain all risks that the procedure involves, as well as the potential results and their limitations.

- Carefully follow the recommendations provided under PRECAUTIONS, CONTRAINDICATIONS and SIDE EFFECTS.

- ETHEREA® ACROMA-QS® is electro-medical equipment that can pose a safety hazard to the operator and/or the patient under certain circumstances, especially in cases of improper installation, use, operation and maintenance.

- Goggles should be worn by everyone present in the procedure room during operation. Never wear goggles that do not meet the requirements specified by the manufacturer.

1. USAGE INDICATIONS

ACROMA-QS® is a procedure indicated for a population of healthy patients. The ACROMA-QS® handpiece is indicated for 1. LASER at 1064 nm: tattoo removal (dark blue, black and/or darker pigments), several pigmentary lesions (including, but not limited to, lentigines, eye bags, Nevus of Ota, nevi, café-au-lait spots, hyperchromia) and non-ablative rejuvenation (LASER toning); and 2. LASER at 532 nm: tattoo removal (red, orange, yellow or green pigments), pigmentary lesions (including, but not limited to, café-au-lait spots, solar melanosis, senile lentigines, Becker's nevus, ephelides, seborrheic keratosis). ACROMA-QS® is also indicated for melasma treatments.

2. CONTRAINDICATIONS

General contraindications for LASER procedures are:

pregnancy or breastfeeding;

age group, at the discretion of the medical professional, according to the procedure indication;

systemic and immunodeficiency disorders;

a history of acute infections and/or active infectious processes;

a history of heart problems (pacemaker, arrhythmia, etc.);

a history of intolerance to anesthesia or related conditions;

a history of coagulopathic bleeding;

a history of poor scar formation;

a tendency of keloid formation;

uncontrolled hormonal disorders;

localized disease in the treatment area (malignant lesions);

an area with filling of phagocyted or non-reabsorbed substances;

tanned skin;

photosensitivity and/or allergic to sunlight;

epilepsy or derived/related disorders;

use of ASPIRIN® or anticoagulants within two weeks prior to the procedure;

use of ibuprofen or alcohol within two weeks prior to the procedure;

use of photosensitizing medications, such as tretinoin and estrogen;

diabetes, except if controlled.

3. SIDE EFFECTS AND ADVERSE EFFECTS

SIDE EFFECTS

Among the side effects and adverse effects reported in literature, pain and ecchymosis are commonly evidenced. Aside from these, others should also be considered, such as:

swelling, edema or erythema;

irritation or hypersensitivity;

hot/burning sensation;

hyper- or hypopigmentation;

superficial thrombophlebitis;

purpura ;

ulcers or burns;

hypertrophic scars and keloids;

We also stress the risk of eye damage due to accidental therapeutic light exposure. For this reason, both the patient and the operator must wear goggles during the entire treatment.

After treatment, most patients will experience a slight sunburn sensation, which typically disappears without treatment within 2-3 hours. In some patients, hyperpigmentation occurs even where there is sun protection, which usually disappears within a certain period of time (transient effect). In rare cases, however, especially when treating absent or reduced pigmentation (hypopigmentation), the coloration change in the area may be permanent.

Incorrect parameterization and/or improper use of the device and handpieces may lead to burns, ulcerations and scarring, which can be permanent.

ADVERSE EFFECTS

As with most LASER procedures, there is an intrinsic risk of mild to severe side effects, especially:

- infections;
- scars or healing difficulties;
- keloid formation;
- tissue ulceration and/or burns;
- tissue necrosis;
- complications related to anesthetic administration;

4. PRECAUTIONS

Analyze the treatment area, checking whether there is any obvious damage to the tissue. Assess the skin type and tanning. If unhealed wounds or recent intense tanning are found, postpone the treatment.

Direct exposure to sunlight should be avoided for at least 4 weeks before the application and throughout the entire treatment. Even with clothing, care and attention should be used before exposure to the sun in order to prevent any resulting complications.

Always remove any traces of makeup, impurities, cream or perfume in the area to be treated.

Always talk to the patient before the procedure and explain the type of treatment to be performed in detail. Try to find out the reason for seeking this kind of procedure. Make an effort to understand the expectations and communicate the real result possibilities, side effects and adverse effects, as well as the treatment duration and number of sessions.

When in doubt about the parameter to be used, treat a small test area for subsequent evaluation. Choose the least exposed area. For SKINTYPES I-III, wait 30-60 minutes to evaluate. For SKINTYPES III-VI, it is advisable to wait at least 24 hours. Always start with the minimum recommended parameters.

Always fire shots perpendicular to the application area. Always fire with the patient's skin touching the delimiters. Never shoot the LASER away from the skin.

Make sure all items related to the procedure's SAFETY and equipment used are understood and considered, especially those regarding the use of goggles.

BE EXTREMELY CAREFUL when using the LASER to treat areas around the eyes. Avoid radiation emitted by the LASER. Proper eye protection should be worn by the patient being treated. The LASER light beam should always be directed at the skin and outside of the orbital area (use intraocular protection).

Only use the equipment after reading and fully understanding this APPLICATION PROTOCOL, taking into consideration all warnings indicated previously under IMPORTANT WARNINGS.

5. APPLICATION PROTOCOL

The parameters proposed here are not an absolute guide for clinical practice. The operator should use his/her own clinical experience and professional judgment to perform any treatment proposed herein.

GENERAL ORIENTATION

TOPICAL ANESTHETICS AND FORMULATION

The use of anesthetics can be prescribed to increase the patient's comfort during the procedure. However, it warrants emphasis that, due to the procedure's inherent nature, there is insufficient data to confirm the real efficacy of analgesia.

Clinical experience shows that combining micro-focused ultra-sound technology with a topical anesthetic may cause an allergic reaction and lead to the formation of papules on some treated areas.

Using a topical anesthetic prior to the treatment is a choice that depends on the physician's clinical criteria. There are several alternatives and formulations available on the market. They include:

a. 7% lidocaine and 7% tetracaine anesthetic gel (i.e.: PLIAGLIS®);
b. 4% lidocaine anesthetic gel (i.e.: DERMOMAX®);

References to formulations herein are indicative of clinical practice and should not be interpreted, under any circumstances, as an absolute guideline for clinical reference. The physician's judgment will determine the suitability of use. Prior evaluation of the formulation's toxicity, including its usage history, must ALWAYS be considered, especially regarding its use on the patient.

It is critical to ALWAYS FOLLOW THE DRUG SUPPLIER'S DIRECTIONS regarding handling and required safety precautions (before, during and after treatment) and the efficacy of desired effects. More importantly, make sure to understand the risks of adverse effects and how to proceed if they occur. The size of the area, application time and duration of anesthesia varies by manufacturer and/or supplier;

Be careful when using the anesthetic on mucosa (lips, nostrils and especially the eyes);

NEVER PROVIDE OR PRESCRIBE ANESTHETICS FOR HOME USE.

ANALGESICS AND ANTI-INFLAMMATORY DRUGS

Administration of oral or sublingual analgesic or anti-inflammatory drugs is a clinical consensus commonly associated with the procedure above. This may increase comfort during the procedure, although there is a certain variability due to the patient's physiology.

TATTOO REMOVAL

Tattoo removal using a ACROMA-QS® LASER is an increasingly popular procedure and one of the few treatments able to remove tattoo pigments Treatment results depend on the tattoo colors, how long ago it was applied, pigment penetration depth and type of ink used.

Tips measuring 3 and 5 mm are FOCUSED, so the nominal distance indicated by the tip spacer should be strictly respected.

For LASER at 1064 nm, a 5 mm tip is recommended for tattoos with high pigment concentration, and 3 mm is recommended for lower pigment concentration.

Because this is a relatively painful procedure, using a topical anesthetic may be necessary for patient comfort during the LASER treatment.

Using cold air systems (SIBERIAN®) during the procedure helps to mitigate the pain.

Speak to your patient and provide realistic expectations related to the LASER tattoo removal treatment, also making clear the risks involved, such as partial tattoo removal, scars, burns and others (see ADVERSE EFFECTS).

Transient effects of whitening (hypochromia), erythema, edema and cutaneous elevation usually appear after treatment. In some cases, bleeding and/or fluid drainage may occur.

More recent tattoos and a higher pigment concentration will require a higher number of treatment sessions. Recent tattoos (less than 6 months) are more difficult to treat.

Usually, professional tattoos insert pigments deeper into the skin, which are more difficult to treat than amateur tattoos. The same applies to outlines and traces.

Pigmented tattoos using inks made with high concentrations of iron or titanium oxide may become darker instead of lighter.

SKINTYPES above IV deserve special attention, because they are predisposed to hypertrophic scars and keloids.

Before the procedure, always shoot the LASER at the least exposed test areas to select and set the best parameter to use. Wait at least 24 hours.

We recommend using the 532 nm tip only for SKINTYPES I-III. During application, allow ~1 mm interval between shots.

The ideal treatment parameter is reached when intense lightening of the pigmented area is noted immediately after the shot, without forming either blisters or vesicles.

The number of sessions will depend on the type of tattoo pigment, the depth of penetration and the intensity tolerated by the patient, among other factors. Thus, the complete treatment may range from 4-20 sessions. The interval between sessions should be 45 days for the first sessions and 30 days for the subsequent ones.

After the procedure, we recommend using a soothing cream or topical corticosteroid and a gauze dressing. Keep the treated area dressed for at least 24 hours.

Some medical professionals agree that using silicone-based patches might help prevent the formation of hypertrophic scars or keloids in predisposed individuals. Using this patch for 22 hours a day is recommended for at least 10 days after each session.

After the lesion is lightened, the LASER can no longer penetrate the tissue, so subsequent passes will have no effect. Pulse stacking is not recommended, especially at high power.

INK COLORS- BLACK, DARK BLUE AND DARK GREEN			
SPOT SIZE	λ	REPETITION RATE	ENERGY
3 mm	1064 nm	1-5 Hz	600-900 mJ
5 mm	1064 nm	1-5 Hz	600-1500 mJ

INK COLORS- RED AND ORANGE			
SPOT SIZE	λ	REPETITION RATE	ENERGY
5 mm	532 nm	1-3 Hz	600-1200 mJ
3 mm	532 nm	1-3 Hz	600-900 mJ

*Note: 532-nm spots can also be used for black pigments, as long as they are lighter and/or have been previously treated with 1064 nm.

PIGMENTARY LESIONS

Vascular and pigmentary lesions, of the body and face, are a frequent aesthetic problem. Skin aging, hormonal imbalances, the use of certain drugs and especially exposure to the sun are the most common causes for the appearance of melanosis and spots. Red patches with an intrinsic vascular component are lesions derived from excessive blood vessels irrigating the target area.

The ACROMA-QS® LASER is designed to remove dermal and epidermal pigmented lesions, and is considered a safe and effective system for selective pigment treatment without affecting the surrounding skin or adjacent tissues.

We recommend using the 532 nm tip (KTP) only for PHOTOTYPES I-III. During the procedure, always leave ~1 mm spacing between shots.

The 532-nm (KTP) tip is a treatment option for light melanosis or flat keratosis only when the treatment using the 1064-nm tip has little or no clinical efficacy. The procedure's clinical efficacy is assessed through an immediate frost effect right after the shot at the lesion.

The number of sessions usually ranges from 2 to 4. The interval is usually around 30 days, depending on the aggressiveness of the treatment. For Nevus of Ota indications, sessions range from 6-10, with a regular interval of 45-60 days.

MELANOSIS, OCHER DERMATITIS, HYPERCHROMIA			
SPOT SIZE	λ	REPETITION RATE	ENERGY
5 mm	1064 nm	1-3 Hz	600-1200 mJ
3 mm	1064 nm	1-3 Hz	600-1200 mJ

LIGHT MELANOSIS, FLAT KERATOSIS AND NEVUS OF OTA			
SPOT SIZE	λ	REPETITION RATE	ENERGY
3 mm	1064 nm	1-3 Hz	600-1200 mJ
5 mm	532 nm	1-3 Hz	600-1200 mJ
3 mm	532 nm	1-3 Hz	600-900 mJ

EYE BAGS, POST-INFLAMMATORY HYPERCHROMIA, EPHELIDES			
SPOT SIZE	λ	REPETITION RATE	ENERGY
7 mm	1064 nm	3-5 Hz	900-1500 mJ
5 mm	1064 nm	3-5 Hz	600-1200 mJ
9 mm, 100 mtz/cm^2	1064 nm	3-5 Hz	600-1500 mJ

PHOTO REJUVENATION

The ACROMA-QS® LASER has shown its versatility over a broad range of indications for many years. The use of a low-fluence Q-SWITCHED LASER as a non-ablative skin rejuvenation alternative to treat different skintypes with no restriction or absolute contraindication, provides an exclusive therapeutic option that is very popular in Asian countries. Non-ablative photo-rejuvenation mode using a Q-SWITCHED LASER is commonly known as LASER TONING.

Commercially known as LASER TONING, photo-rejuvenation with the ACROMA-QS®LASER is a completely painless treatment that aims for overall improvement of pigments, shrinking of dilated pores, and diminishing fine lines and wrinkles.

Usually 2-3 passes are made over the treatment area until mild erythema is achieved.

For better results, we recommend at least 8 treatment sessions at weekly or biweekly intervals.

PHOTO REJUVENATION AND EPIDERMAL LIGHTENING (LASER TONING)			
SPOT SIZE	λ	REPETITION RATE	ENERGY
7 mm	1064 nm	3-5 Hz	600-1200 mJ

MELASMA

Melasma is a very common dermatosis, distinguished by dark patches, especially on the face, causing a severe social impact in the people it afflicts. Several treatment methods and alternatives are currently available, with the ACROMA-QS® LASER representing a new, highly successful technique that is becoming a common option either alone or combined with other known therapies.

In 2011, the FDA approved a low-fluence q-switched LASER for the treatment of melasma. The ACROMA-QS® LASER acts by emitting ultra-short pulses (ns) specifically on melanocytes (creating photo-thermal and photo-acoustic effects), preventing the adjacent skin and tissues from being affected by generated heat.

Usually, 2-3 passes are made per treatment session, with 8 sessions at weekly intervals recommended.

Melasma is a recurring condition, and maintenance sessions should be performed as necessary. Worsening episodes after treatment are rare, but possible.

Using and/or combining conventional topical therapies to treat melasma may continue during the treatment with the ACROMA-QS® LASER.

Continuous use of a suitable sunscreen is key to the therapy's success, even after the treatment is complete.

MELASMA			
SPOT SIZE	λ	REPETITION RATE	ENERGY
7 mm	1064 nm	3-5 Hz	600-900 mJ

POST-TREATMENT

Using an SPF 60 sunscreen is recommended throughout the treatment and for at least 30 days before the first session. The patient should always use sunscreen on treated areas before and after the treatment.

Using waxes or shaving creams, tweezers or tanning creams is not recommended during the 2 weeks before and after the treatment.

Using a soothing lotion, applied in circular movements, as well as cool compresses, will help to minimize the burning feeling post-treatment. After the application and the procedure, the treated area should be washed gently for up to 3 days, avoiding intense rubbing.

Using LED, topical and/or oral corticosteroids is always recommended to soothe the skin immediately after each session.

Pre-/post-treatment clinical action is key to the therapy's success, and preventing unwanted and adverse effects.

Patients should also be instructed to immediately contact the doctor if any signs of infection (such as puss, pruritus, draining or fever), significant pain or complications and side effects emerge.

Patients should be advised to immediately seek professional healthcare for urgent care in the event of severe or abnormal side effects after the treatment.

Patients should return for medical follow-up as prescribed. The time to return is usually 24–72 hours after the procedure.

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