DUALMODE

TREATMENT GUIDELINES

etherea MX

ETHEREA-MX®
DUALMODE®

VERSION 1.2 - NOVEMBER 2017

vydence medical | An Adavium Medical company

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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 Instructions Manual is required.

- The ETHEREA® device and its respective DUALMODE® 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 is 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® DUALMODE® 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.

- Always check the integrity and cleanliness of the nozzle lenses before each procedure. Never use the nozzle if the lens has any visible damage. If cleaning is required, perform the procedure according to the product's Instruction Manual.

- 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. Also, even when wearing proper goggles, never look directly at the emitted light beam.

- The DUALMODE® LASER should be handled with extreme care regarding accidental eye exposure. There is a high potential risk of permanent eye damage. EVERYONE IN THE PROCEDURE ROOM IS REQUIRED TO WEAR SUITABLE GOGGLES.

IMPORTANT WARNINGS

- Considering the risk of accidental eye exposure to the beam, never use the LASER in places with reflective surfaces.

- The DUALMODE®Er:YAG LASER at 2940 nm is an ablative treatment mode that promotes vaporization of the target tissue. Thus, considering the tissue particles suspended in air, using a protective facial mask with activated carbon filter, as well as an appropriate vapor vacuum cleaner, is indispensable. Lenses and spacers must be kept clean. Spacers may be removed and autoclaved.

WHENEVER THE LASER IS IN USE, it is extremely important to properly protect the beam's outlet either by using the respective nozzle or the protective cover. This procedure prevents the ingress of solid particles into the LASER cavity, which could lead to permanent damage to the product.

1. USAGE INDICATIONS

DUALMODE® is a procedure indicated for a population of healthy patients. The DUALMODE® handpiece is intended for ablative LASER treatments with or without beam fractioning, fractional resurfacing and photo rejuvenation, collagen stimulation to treat fine lines and moderate to severe wrinkles, scars (atrophic, hypertrophic, acne, traumatic and surgical), keratosis, benign pigmentary skin lesions, warts and superficial tissue vaporization, coagulation and ablation.

The DUALMODE® handpiece is also indicated for intra-oral collagen stimulation, intimate rejuvenation and urinary incontinence treatments.

2. CONTRAINDICATIONS

General contraindications for the DUALMODE® LASER and/or light 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;
- ongoing use of vitamins A and K;
- 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

It is critical to correctly assess the skin type. SKINTYPES IV-V present a higher risk of hyperpigmentation after treatment. The use of external cooling units and parameterizing the procedure at longer pulse width, can minimize the occurrence of this kind of effect;

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.

The use of external cooling units before, during and after treatment is highly advisable. An example of these units is the SIBERIAN® device.

LASER light should be applied at a perpendicular angle in relation to the treatment area (approx. 90°);

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.

After the first sequence of shots, wait a few minutes. This step is important for increasing the procedure's safety index. Observing the result takes time, especially in darker skin;

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

BE EXTREMELY CAREFUL when using light to treat areas around the eyes. Avoid radiation emitted by the light at any of the available wavelengths. Proper eye protection should be worn by the patient being treated. The light beam should always be directed at the skin as far as possible from 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.

For patients with more pain sensitive skin, topical anesthetic can be used.

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.

FRACTIONAL RESURFACING

The resurfacing procedure acts by ablating surface tissue to stimulate its regeneration and resulting replacement, while also promoting collagen stimulation in the dermis. The effect is an improvement in the appearance of wrinkles and scars, as well as tissue lightening in pigmentary lesions resulting from photo-aging. It's a safe and effective procedure, although relatively aggressive to the tissue, considering the resulting destruction and re-epithelization.

Make sure the DUALMODE® handpiece is properly coupled to the ETHEREA® platform.

Clean the treatment area again using a suitable makeup remover or neutral soap to remove any traces of loose hair or even perfume, deodorant, sunscreen, etc.; The area needs to be completely dry before the treatment begins;

Using external cooling before the treatment session begins, including ice bags, is ALWAYS recommended, considering the need to protect the skin and improve the patient's comfort, as well as the therapeutic efficiency of the procedure;

Make it clear to the patient that each session will require average social downtime of 4-7 days, depending on the treatment aggressiveness and the desired results;

Treatment success may come with some adverse effects on the epidermis - usually moderate to intense edema and erythema. Should these occur, reduce the fluence used.

Prophylactic prescriptions for patients with a history of herpes is a common report in clinical literature. Due to the unprotected tissue exposure in the environment, there is a great risk of fungi and/or bacterial infections.

Post-treatment clinical recommendations must be properly prescribed in detail, and strictly followed, considering their importance of proper recovery and prevention of undesirable effects, such as contact dermatitis;

Shoot the LASER at an area of little or no visible exposure. Wait a few minutes and check the effects on the tissue. For SKINTYPES I-III, wait at least 15 minutes. For SKINTYPES IV-VI, 24 hours. Reactions considered normal, immediately after the treatment, may be noted as mild erythema and edema.

If there is no noticeable change in the appearance of tissue, increase the fluence value at regular increments. Note the correlation of the resulting adverse effects;

In case of intense edema, apply a soothing lotion.

If this is the patient's first treatment session or if there are any questions about using the device, choose to set more conservative parameters. Observe the patient's reaction to the shots to set the best parameter for the specified treatment.

Wear intraocular protection when treating the periorbital area. Using the LASER on the palpebral area without proper protection may result in irreversible vision damage.

Do not apply the LASER on tattoos or permanent makeup. Be very careful when performing the procedure on the hair and eyebrow areas – if necessary, protect the area to ensure a safer procedure;

Conduct the treatment with little or no overlap between shots. After the first treatment pass, retouch the areas that have not yet been treated;

Observe the immediate tissue reaction as the treatment progresses. Be extremely cautious regarding undesirable effects;

It is important to note that the face has areas with less skin thickness. On these areas, take caution when using more aggressive parameters is critical.

Punctiform bleeding is a common adverse effect of the treatment due to the epidermal vaporization. This is easily controlled with manual pressure. You can use sterile gauze to clean these areas;

The ablative treatment follows a specific logic, as shown on the table below. Physical application logic and LASER interaction with the tissue are critical for knowing the treatment limitations and possible improvement opportunities, including the clinical efficacy and safety;

FRACTIONAL RESURFACING	
POWER (mJ/mtz); FLUENCE (mJ/cm²)	The higher it is, the more aggressive the treatment
NUMBER OF PASSES	The higher it is, the more aggressive the treatment
mtz/cm²	The higher it is, the more aggressive the treatment
PULSE WIDTH < 500 µs	Purely ablative effect
PULSE WIDTH > 1 ms	Purely coagulative effect, according to the time
DUALMODE	Ablative shot immediately followed by coagulative shot

PIGMENTARY LESIONS

The number of sessions can range from 2 to 4. The interval is usually around 20 to 30 days, depending on the aggressiveness of the treatment.

PIGMENTARY LESIONS				
POWER	PULSE WIDTH	SPOT SIZE	PASSES	FITZPATRICK
10 - 12.5 mJ/mtz	300 µs	8/100 mtz	1-3	I-IV
2,5-3,5 mJ/mtz	300 µs	8/400 mtz	1-3	I-IV
13-19 J/cm^2	300 µs	6 mm	2-4	I-IV
13-16 J/cm^2	300 µs	2.5 mm	1-4	I-IV

MILD WRINKLES AND FINE LINES

The number of sessions can range from 3 to 5. The average interval is around 30 days, depending on the aggressiveness of the treatment.

MILD WRINKLES AND FINE LINES				
POWER	PULSE WIDTH	SPOT SIZE	PASSES	FITZPATRICK
12,5-25 mJ/mtz	1 ms	8/100 mtz/cm^2	1-4	I-IV
20-45 mJ/mtz	2 ms	8/100 mtz/cm^2	1-3	I-IV
3-7,5 mJ/mtz	2 ms	8/400 mtz/cm^2	1-2	I-IV

MODERATE TO SEVERE WRINKLES

During the first year of treatment, the number of sessions initially prescribed may range from 3 to 5, with an ideal average interval of 60 days. This period may be changed according to the aggressiveness of each application. Maintenance sessions should be performed once or twice a year.

MODERATE TO SEVERE WRINKLES				
POWER	PULSE WIDTH	SPOT SIZE	PASSES	FITZPATRICK
12,5-15, 20-50 mJ/mtz	300 µs, 3 ms	8/100 mtz/cm^2	1-2	I-IV
12,5-15, 30-60 mJ/mtz	300 µs, 5 ms	8/100 mtz/cm^2	1-2	I-IV
2-3, 3-9 mJ/mtz*	300 µs, 3 ms*	8/400 mtz/cm^2*	1*	I-III*

*For severe wrinkles, a 8/100 mtz/cm2 tip can be used as a support method for areas with intense grooves. However, discretion is advised when using it due to the possibility of adverse effects.

ACNE SCARS

The number of sessions can range from 3 to 5. The average interval is around 30 to 60 days, depending on the aggressiveness of the treatment.

ACNE SCARS				
POWER	PULSE WIDTH	SPOT SIZE	PASSES	FITZPATRICK
12,5-15, 20-50 mJ/mtz	300 µs, 3 ms	8/100 mtz/cm^2	1-2	I-IV
12,5-15, 30-60 mJ/mtz	300 µs, 5 ms	8/100 mtz/cm^2	1-2	I-IV
2-3, 3-9 mJ/mtz*	300 µs, 3 ms*	8/400 mtz/cm^2*	1*	I-III*

HYPERTROPHIC SCARS

The number of sessions can range from 4 to 6. The average interval is around 45 to 60 days, depending on the aggressiveness of the treatment.

HYPERTROPHIC SCARS				
POWER	PULSE WIDTH	SPOT SIZE	PASSES	FITZPATRICK
12,5-15, 20-40 mJ/mtz	300 µs, 5 ms	8/100 mtz/cm^2	1-2	I-IV

STRETCH MARKS

The number of sessions can range from 4 to 8. The average interval is around 45 to 60 days, depending on the aggressiveness of the treatment.

STRETCH MARKS				
POWER	PULSE WIDTH	SPOT SIZE	PASSES	FITZPATRICK
12,5-15, 20-40 mJ/mtz	300 µs, 5 ms	8/100 mtz/cm^2	1-2	I-IV

DUALMODE INLIFT

INTRAORAL LASER LIFTING

The intraoral procedure for deep heating, collagen stimulation and deep face muscle contraction. A painless treatment, with no downtime and no phototype restriction. It can be performed at any time of the year, either as a single treatment modality or combined with other technologies. DualMode INLIFT technology operates with the exclusive microprocessed pulse trains, combining a longer total shot time with a single beam shot. The result is an even power delivery that promotes coagulation while reducing the total LASER ablation threshold.

Make sure the InLift applicator is properly coupled to the DUALMODE® handpiece with the platform already in operation.

During application, be careful not to apply or touch the tip on the teeth, because this could lead to mild discomfort.

The number of sessions usually ranges from 3 to 5. The interval is usually around 20 to 30 days, depending on the aggressiveness of the treatment.

Average of 50 to 100 shots on each side of the face, according to the patient's sensitivity. Using less output and a higher number of shots is ideal for inducing even heating.

The tip must be dismantled and properly cleaned between patients. It can be placed in an autoclave if necessary.

After the procedure, the patient may experience the formation of small lesions (cold sores) that disappear between 1 and 3 days.

INTRAORAL INLIFT LASER LIFTING			
MODE	POWER	NUMBER OF SHOTS	FITZPATRICK
FRACTIONAL INLIFT	30-40 mJ/mtz	50-100	I-VI

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.

It is recommended that patients raise their heads while sleeping during the first 2 days post-treatment. This reduces the edema appearance.

Edema and erythema are expected effects after treatment, which usually disappear completely within the 7 days following the procedure, depending on the aggressiveness of the treatment performed. In some cases, they may persist for up to 3 weeks;

Microlesions resulting from the fractional LASER beam application usually disappear within 24-48 hours after the treatment is complete. Initially, lesions have a diffuse erythema appearance; later, after the healing process begins, the appearance is similar to tanning. Post-treatment appearance of lesions, as well as the overall appearance of the area, vary according to the treatment intensity and aggressiveness. They may usually last from 3-30 days, extending to areas beyond the face.

Using a soothing lotion, applied in circular movements, as well as cool compresses, may 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.

During the immediate post-treatment, the use of occlusive water-based creams is extensively reported in literature. Dexpanthenol-based solutions (i.e. BEPANTOL®), may be used during the 4-day follow-up period. Applying other oil-based solution topical agents (Vaseline) may induce allergic reactions (i.e., contact dermatitis). Oral analgesics can also be prescribed to relieve the pain resulting from the procedure;

Pre-/post-treatment clinical action is key to the therapy's success, as well as for 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;

The total number of sessions varies depending on the case and treatment indication. Usually, 1-3 treatment sessions are required. The interval between sessions is 30 days and may be higher, depending on the application area and the aggressiveness of the treatment.

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