



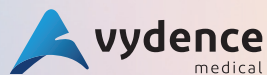
INTENSE IR

# TREATMENT GUIDELINES



ETHHEREA-MX®  
INTENSE-IR®

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 Intense-IR®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 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 is 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® Intense-IR®is an electro-medical device that can pose a safety hazard to the operator and/or the patient under certain circumstances, especially in the event 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. Also, even when wearing proper goggles, never look directly at the emitted light beam.

# 1. USAGE INDICATIONS

The Intense-IR® handpiece is indicated for subdermal heating to stimulate collagen to treat skin laxity and provide skin tightening.

## 2. CONTRAINDICATIONS

General contraindications for the Intense-IR® and/or light procedures are:

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pregnancy or breastfeeding ;

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

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systemic and immunodeficiency disorders;

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

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

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a history of intolerance to anesthesia or related conditions;

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a history of coagulopathic bleeding;

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a history of poor scar formation;

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a tendency of keloid formation;

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uncontrolled hormonal disorders;

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localized disease in the treatment area (malignant lesions);

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

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tanned skin;

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ongoing use of vitamins A and K;

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photosensitivity and/or allergic to sunlight;

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epilepsy or derived/related disorders;

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

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

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use of photosensitizing medications, such as tretinoin and estrogen;

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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:

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swelling, edema or erythema;

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irritation or hypersensitivity;

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hot/burning sensation;

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hyper- or hypopigmentation;

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superficial thrombophlebitis;

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purpura;

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ulcers or burns;

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hypertrophic scars and keloids;

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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.

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## ADVERSE EFFECTS

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

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infections;

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scars or healing difficulties;

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keloid formation;

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tissue ulceration and/or burns;

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tissue necrosis;

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complications related to anesthetic administration;

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## 4. PRECAUTIONS

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It is inadvisable to use wax (hot or cold), shaving creams, tweezers, tanning creams, lotions or spray within 2 weeks before the start of treatment or between sessions.

---

Before every procedure, ALWAYS clean the sapphire coupler with gauze. Traces of impurities on the coupling interface may result in HOTSPOTS, compromising the treatment. This can also lead to unwanted adverse effects for the proposed therapeutic indication (hyper or hypochromia).

---

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.

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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 PHOTOTYPES I-III, wait 30-60 minutes to evaluate. For PHOTOTYPES 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 trigger the light with the sapphire away from the skin.

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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 the 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 outside the orbital area (use intraocular protection).

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

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## 5. CLINICAL REFERENCE GUIDE



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.

### MODE OF APPLICATION: STATIC OR STAMPING

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In the static or stamping technique, fluence, shot time, pre-shot cooling time (pre-cooling), post-shot cooling time (post-cooling) and tip cooling degree (cooling) must be programmed;

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In this mode, shots will be divided into two (minimum) or three stages:

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pre-shot cooling time (or pre-cooling): the handpiece LED turns blue and a beep will sound intermittently;

---

shot time: The handpiece LED turns yellow and a beep will sound intermittently at a higher frequency;

---

post-shot cooling time (or post-cooling): the handpiece LED turns blue and a beep will sound intermittently;

---

Shots are triggered side by side, without overlapping. Shot stacking is not recommended;

---

IN THE STATIC OR STAMPING APPLICATION MODE, IT IS CRITICAL THAT THE WHOLE SAPPHIRE IS IN CONTACT WITH THE TREATMENT AREA DURING THE ENTIRE SHOT. ANY POORLY COUPLED AREA MAY CAUSE SEVERE DISCOMFORT AND POSSIBLE BURNS.

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When firing shots on outlines or protruding bone areas, such as the jaw, decrease the parameters by about 30%. MAINTAIN COUPLING WITH THE SAPPHIRE. In these areas, the dynamic technique may be preferred.

---

The optimum dose threshold in the static technique is when the patient reports a slight "sting" at the end of the shot. This threshold varies from person to person and from area to area. To use the single pass technique, the patient needs to be more tolerant of this feeling in order to achieve good results.

For a good result in multiple pass application, a total of 3 passes should be performed, unless the skin is extremely sensitized. For the neck area, one general pass and two upward passes on diagonal lines should be applied.

Before applying the shot to the spot, it is advisable to fire at the patient's palm or application area with lower output so that the patient is aware of the power level that will be applied. Talk to the patient and explain that it is extremely important not to move during the shot so that sapphire doesn't come uncoupled from the skin.

#### INFRARED TREATMENT INITIAL PARAMETERS - STATIC TECHNIQUE IR HANDLE - BODY

FLUENCE	SHOT TIME	PRE-COOLING TIME	POST-COOLING TIME	COOLING LEVEL
Multiple Passes				
45,5–65 J/cm <sup>2</sup>	5 s	3 s	0 s	V
58,5–78 J/cm <sup>2</sup>	6 s	3 s	0 s	V
65–104 J/cm <sup>2</sup>	10 s	3 s	0 s	V
Single Pass				
78–104 J/cm <sup>2</sup>	8 s	5 s	0 s	V
78–130 J/cm <sup>2</sup>	10 s	5 s	0 s	V

#### INFRARED TREATMENT INITIAL PARAMETERS - STATIC TECHNIQUE IR HANDLE - FACE

FLUENCE	SHOT TIME	PRE-COOLING TIME	POST-COOLING TIME	COOLING LEVEL
Multiple Passes				
39–58,5 J/cm <sup>2</sup>	5 s	3 s	0 s	V
50,5–70 J/cm <sup>2</sup>	6 s	3 s	0 s	V
65–78 J/cm <sup>2</sup>	10 s	3 s	0 s	V
Single Pass				
67,5–93,5 J/cm <sup>2</sup>	8 s	5 s	0 s	V
65–91 J/cm <sup>2</sup>	10 s	5 s	0 s	V

## MODE OF APPLICATION: DYNAMIC OR IN-MOTION

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In dynamic or in-motion technique, shot time should be set to 5–10 sec, the pre-shot cooling time (pre-cooling) to 0 sec, the post-shot cooling time (post-cooling) to 0 sec, and fluence and tip cooling temperature also need to be programmed;

---

In this treatment mode, there will be a single shot, with the time set respectively. At each shot, the LED will turn yellow and an intermittent beep at higher frequency will be heard during the whole shot.

---

The application must be dynamic, in continuous and repetitive movements;

---

IN THIS TECHNIQUE, IT IS CRITICAL FOR THE HANDPIECE TO BE IN CONSTANT MOVEMENT DURING APPLICATION, STOPPING ONLY WHEN THE SHOT IS INTERRUPTED;

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The scan technique should be applied to the whole area;

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This application mode is indicated for sensitive patients and areas of protruding bone, such as the forehead. Either way, the best sapphire coupling depends on the operator, resulting in greater comfort for the patient;

---

While using this technique, the sapphire will certainly come uncoupled at some point, so be careful with the fluence. This uncoupling will be minimized by the handpiece movement and, as a result, by the inconstancy of light application at a single spot. Either way, try to keep the sapphire coupled as much as possible, minimizing patient discomfort and preventing any complications;

---

For the neck area, only upward movements (application from the lower to the upper point, with no return) or back and forth movements (upward and downward movements until the shot ends) can be used. The technique should be chosen on a case-by-case basis. Apply for 5 minutes per area or until moderate to intense erythema and edema are obtained.

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**INFRARED TREATMENT INITIAL PARAMETERS - DYNAMIC TECHNIQUE**  
**IR HANDLE - BODY**

FLUENCE	SHOT TIME	PRE-COOLING TIME	POST-COOLING TIME	COOLING LEVEL
78-130 J/cm <sup>2</sup>	10 s	0 s	0 s	V

**INFRARED TREATMENT INITIAL PARAMETERS - DYNAMIC TECHNIQUE**  
**IR HANDLE - FACE**

FLUENCE (J/cm <sup>2</sup> )	SHOT TIME	PRE-COOLING TIME	POST-COOLING TIME	COOLING LEVEL
32,5-52 J/cm <sup>2</sup>	5 s	0 s	0 s	V
65-91 J/cm <sup>2</sup>	10 s	0 s	0 s	V

If there are no unwanted effects and the skin's reaction is not satisfactory, gradually increase the frequency.

If in addition to a good response there is severe edema or a burning sensation, immediately apply a soothing lotion or corticosteroid and reassess the parameters or technique.

# POST-TREATMENT

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The immediate reaction to the treatment is mild erythema, which usually disappears within 3 hours. Literature reports that such erythema may persist for up to 48 hours. If this is the case, revise the fluence parameters in a future application.

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The number of sessions usually ranges from 3 to 4, but studies show that the results can develop for up to 6 months. Some articles also indicate using the equipment for lifting effects. This effect can usually be noticed on the day of treatment.

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Twenty-eight (28) days is the most commonly used interval between sessions.

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Once the treatment is finished, apply a soothing lotion and a sunscreen.

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The treatment goal is subdermal heating. We therefore do not recommend cooling the area after treatment, unless there is significant erythema and edema and/or the patient reports a sensation of excessive heat.

---

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 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.

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

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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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