

INVIKTA



Table of Contents

Theory	page 3
What is Light ?	page 3
What is EMR ?	page 3
Electromagnetic Spectrum	page 4
Intense Pulsed Light Therapy	page 4
Targeted Chromophores	page 5
Laser Filter Overview	page 5
Introduction to The 808 Diode Handpiece	page 6
Pre- treatment Guidelines	page 7
Treatment Area Exclusion Criteria	page 7
Contraindications	page 7
Guidelines and Operation Procedures	page 8
Safety	page 8
Operator Tips and Helpful Hints	page 9
Treatment Plan	page 9, 10
Hair Removal Guidelines and Clinic Treatment Instruction	page 10
Treatment Parameters for Hair Removal	page 11
Formation of Hair and Melanin	page 11
Hair Growth Cycle	page 12
Hair Removal End-point and Treatment Schedule	page 12
SHR Clinical Parameter Settings	page 13

Theory

Light, heat, destruction.

As this light energy is converted into thermal energy and targeted it destroys the follicles, which destroys the regeneration capacity and permanent hair removal can be achieved.

The Diode Laser Hair Removal Device's 808 nm treatment is a single wavelength. It successfully achieves laser hair removal by delivering high energy into the skin through selectively absorbing the energy surrounding the hair follicles. Through this hair removal process the laser destroys the hair follicle while protecting the surrounding skin. This diode laser can deliver various settings to be safely and comfortably used on all skin types.

Having an 808nm diode laser allows the practitioner/clinician to safely and effectively treat all skin types and hair colors. This particular instrument makes treatment on all skin types possible (Fitzpatrick I-VI), it comes equipped with pre-programmed settings and protocols for patient comfort, safety and efficacious treatments.

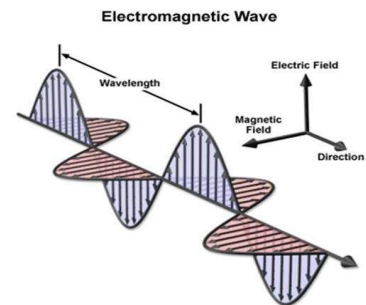
Primarily, the wavelength of 808nm diode is targeting the chromophore melanin in the hair shaft with a high concentration of energy. This means light energy passes the shaft into the follicle and papilla with little to no energy absorbed by the surrounding skin tissue, this makes it safer for skin containing more melanin. The distribution of heat throughout the follicles is also achieved through a customized and programmed pulse format, allowing mostly all of the energy to be absorbed into the hair follicles resulting in destruction of the hair follicles.

What is **Light**?

- Light is electromagnetic radiation (**EMR**) of any wavelength.

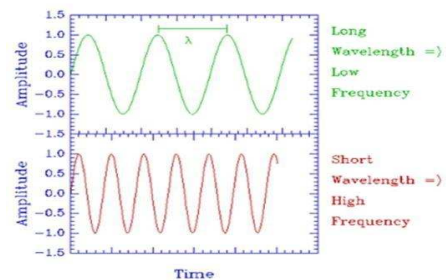
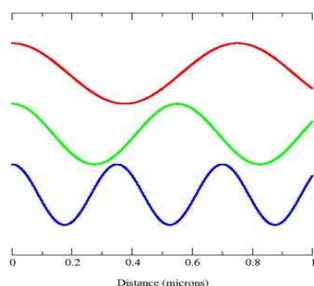
What is **EMR** Electromagnetic Radiation?

- EMR is when energy presents itself in a form of wave like motions.
- There are two factors in EMR:
 - It has both electric and magnetic field components.
 - They work perpendicular to each other and their direction of energy transmission (see above).



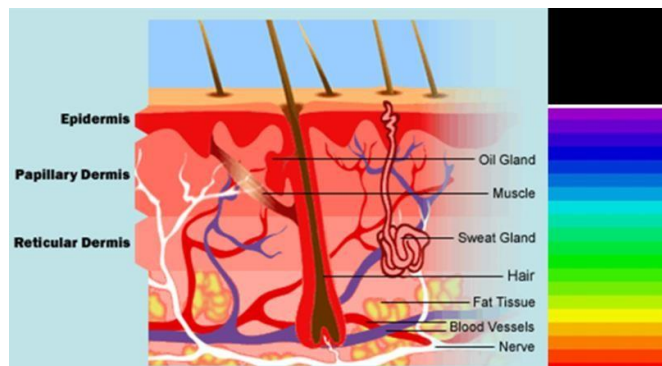
Theory tells us that **light** consists of **tiny particles** which have wavelike properties associated with them.

Light is composed of particles called photons.



Electromagnetic Spectrum

- The depth of the penetration in the skin is completely determined by the size of the wavelength.
- In general the longer the wavelength, the deeper the depth of light penetration.
- Light red in color penetrates the deepest, it is the longest wavelength.
- More superficial penetration takes place with light that has shorter wavelengths, such as violet and blues.

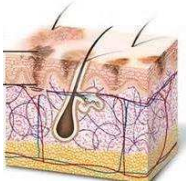


Intense Pulsed Light Therapy

- **Intense Pulsed Light (Laser)** is a broadband of multiple light wavelengths.
- Laser Technology is based on the principle of Selective Photothermolysis, it is a broadband of multiple wavelengths.
 - Photo = Light
 - Thermo = Heat
 - Lysis = Destruction
- When Laser is administered the light is absorbed by chromophores, which are light sensitive molecules in the skin to induce a change.
- Photothermal is light energy converted to thermal energy, also known as heat. Whereas photochemical is a chemical reaction initiated by the absorption of light energy. Both photothermal and photochemical energy can induce said change in skin.

TIP: Selective photothermolysis is the destruction of ONLY a selected tissue without harm to the surrounding tissue.

Target Chromophores



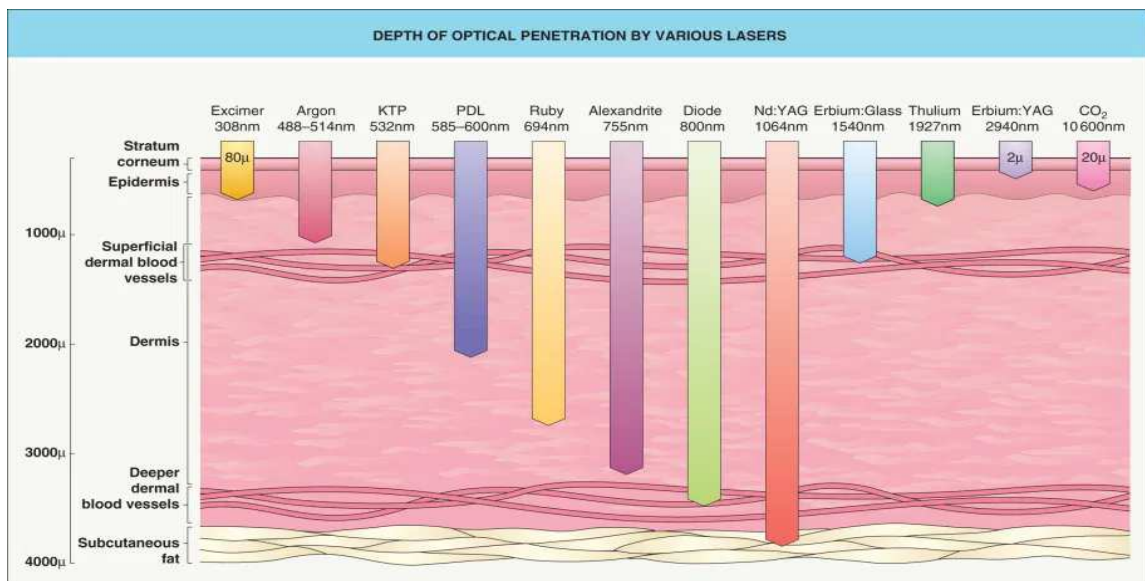
- Thermal relaxation time, also known as TRT, is the time it takes for heat to leave the tissue that is targeted by the laser.

TIP: TRT = time it takes for treated tissue to cool down.

- TRT in the skin (epidermis) for melanin is 3 to 7 ms.
- TRT for melanin in hair (follicles) is 40 to 100 ms.

TIP: It takes longer for hair to cool because hair follicles are found deeper beneath the skin. Whereas hyperpigmentation takes less time to cool as it is superficially formed in the skin top layers, the surface.

Laser Filter Overview



Pre-treatment Guidelines

- To provide the most effective and safest treatments the following steps are to be followed:
 - Review Medical History of patient
 - Why patient is seeking this treatment
 - Set realistic expectations
 - Never over promise
 - Report on any change in medical condition
 - Review treatment procedure, parameters, number of treatments, intervals, maintenance, and post treatment guidelines.
- Treatment Considerations:
 - Treatment of patients with skin type I-VI
 - See list of contraindications/ other considerations
- Inform Patient of:
 - Response to treatment varies from patient to patient
 - Transient erythema/ edema usually appears during or immediately post treatment and typically resolves within 48 hours.
 - All procedures will require a patient commitment to a schedule of treatments.

TIP: Patient must sign consent forms, take before and after photos.

Treatment Area Exclusion Criteria

- Inflammation at the treatment area
- Tattoos
- History or current permanent makeup
- Moles

Contraindications

- Always review with patient before every session for the following:
 - Cancer, in particular skin cancer
 - Epilepsy
 - Hormonal disorders, unless under control
 - Undiagnosed lesions
 - Disease which may be stimulated by light
 - Diabetes, unless under control
 - Vitiligo (hypo pigmentation)
 - Treatment area exclusion criteria
 - Inflammation at the treatment area
 - History or current permanent makeup
 - Pregnancy, expectation of pregnancy, postpartum or nursing
 - Active infection or herpes simplex in the treatment area
 - Fragile and dry skin
 - Use of anticoagulants
 - Tattoos
 - Moles
 - History of keloid scarring

Guidelines and Operation Procedures

- The cutoff filter in nanometers is made for darker skin tones, it targets the chromophore of melanin in the hair follicles.
- It is important that the correct treatment settings and filters are selected for the patient according to their hair and skin type.
- The Laser operator is to follow standard procedure before a patient is accepted for treatment.
- The patient is required to schedule a consultation and test spot prior to a laser treatment session.
- The objective is to treat at the highest tolerated energy fluence (joules/ cm²), according to the patient's comfort and the reaction / appearance of the skin following a laser pulse.
- The energy levels then can be turned up to the recommended maximum energy settings. Laser operator should continuously monitor the skin's reaction during treatment.

TIP: A test procedure must ALWAYS be performed even if treating the same patient, in a new area.

Safety

- **Precautions to Avoid Side Effects**
 - Ask the patient if their skin's appearance is their natural one.
 - Teach the patient post treatment skin care guidelines.
- **Typical Side Effects Post Laser**
 - Localized herpes virus infection, if treated without medication.
 - Micro-crusting.
- **Type of Treatment Error**
 - Inappropriate energy fluence treatment setting.
 - Ignoring contraindications.
 - Inadequate cooling.
- **Specific Guidelines to Minimize Side Effects**
 - Professional training.
 - Limit treatment settings according to Fitzpatrick Skin Type.
 - Patients must sign informed consent forms.
 - Laser operator must perform test procedure
 - Avoid areas of skin that should not be treated (melanoma, ect.)
 - Avoid treating tanned patients.
 - Patients with Fitzpatrick skin types III-VI should only be treated with appropriate filter and safety settings.

Operator Tips and Helpful Hints

- A patient informed consent form must be signed prior to a laser treatment, as it explains any possible side effects and ensures the patient has been given an explanation of the procedure and expected outcome.
 - Patients are required to read and understand the consent form, signing each clause as which is required for insurance purposes.
- The area to be treated should be documented with the patient during the consultation to ensure proper treatment preparation of the area.
- Requirements for any and all laser treatments are as follows: skin type and hair color should be assessed and documented and pre-determined with the recommended safety settings prior to the treatment being given.
- Fitzpatrick skin classification and typing should be measured by a visual assessment, this can only be done in a visible physical range in person.
- Photo documentation of the patient's treatment area is required before and after each procedure for the patient's chart during the entire treatment course.
- For hair removal treatment patients are not to shave, wax, or do any epilation over the entire treatment course.
- Always review contraindications before each treatment.

Treatment Plan

Hair Removal

- Clean the treatment area, ensuring the skin is completely dry.
 - Cover any beauty spots, moles, and avoid all tattoos.
 - Patients must shave the area prior to hair removal treatment.
 - Apply a layer of ultrasound gel to ensure proper conduction of the energy throughout the entire treatment.
 - Both the operator and the patient **MUST** wear eye protection for the entire duration of the treatment.
1. Choose safety settings according to hair type and Fitzpatrick skin type.
 2. Select patients Fitzpatrick skin on the display screen.
 3. Choose the energy fluence and pulse duration according to the hair type and Fitzpatrick skin type of the patient.
 4. Continue adjusting energy fluence and pulse duration on treatment screen until a positive end point of perifollicular edema and or erythema with no epidermal reaction has occurred.

TIP: Darker Hair – Lower energy fluence, Longer pulse duration
 Lower = Longer

Lighter Hair – Higher energy fluence, Shorter pulse duration
 Higher = Shorter

A. Untreated Skin



B. Edema/Erythema
 Epidermal

5. Cover the area with 10% overlapping.
6. Treatment Schedule:
 - 6 - 10 sessions required
 - 3 - 4 weeks intervals, because the hair has its own growth period and dormant period, so it's only effective to remove the hair in the growth period.
 - Maintenance: 1 treatment every 3 – 6 months or as required.

Anatomic Site	Recommended Treatment Intervals
Face	2 - 4 weeks
Chin	4 - 6 weeks
Armpits/ Bikini	4 - 6 weeks
Back/ Legs/ Arms	4 - 6 weeks







Test Procedure

*Ask Clinical Trainer, will be taught during hands on portion of training

Hair Removal Guidelines and Clinic Treatment Instruction

Skin Typing (Fitzpatrick Skin Type):

Thomas B Fitzpatrick, a Harvard dermatologist, developed a skin typing scale to safely classify different amounts of melanin and pigments in the skin. It was developed in 1975 and is commonly used today. This scale functions by categorizing the skin 6 different classifications.

Skin Type	Reaction to Sun Exposure	Common Features
 Type I	- never tans - always burns	- pale skin - light eyes - light hair
 Type II	- occasionally tans - usually burns	- fair skin - light eyes
 Type III	- tans on average - sometimes burns	- fair to olive skin
 Type IV	- tans easily - rarely burns	- light brown skin
 Type V	- mostly tans darkly - almost never burns	- brown skin
 Type VI	- always tans darkly - never burns	- dark brown or black skin - dark eyes - dark hair

- Review skin typing questionnaire for practitioner to deliver to patient.

Treatment Parameters for Hair Removal

1. 808 nm diode- wavelength
2. Duration of Pulse
3. Configuration of Pulse
4. Energy Fluence = J/cm²
5. Hair Grow Cycle
6. Depth of Hair Follicle
7. Melanin Absorption Capability

*Device comes fully equipped with recommended safety settings, if the clinician prefers they can be tailored to each patient.

The principles of choosing - Pulse Duration (nm)		
Target size	Efficacy	Penetration (depth)
Longer – larger target	Longer – less aggressive	Longer – deeper
Shorter – small target	Shorter – more aggressive	Shorter – more superficial

Tip: A longer pulse induces a more gentle heating of the chromophore target.

Example: A large stock pot of water vs. foil

*Ask Clinical Trainer for explanation/ to be shown in clinical training.

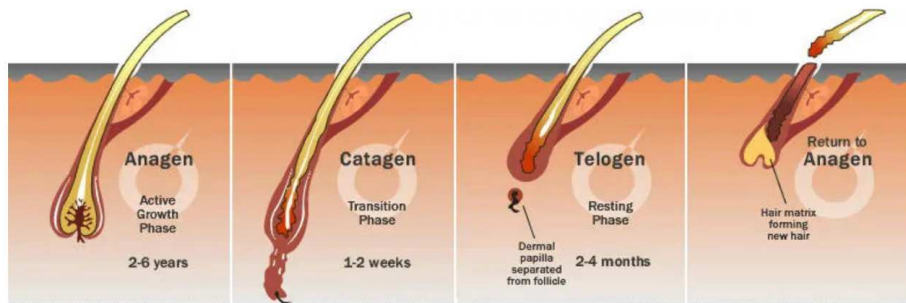
Formation of Hair and Melanin

- The dermis contains millions of hair follicles, they consist of:
 - Papilla- all hair follicle cells are generated in this tissue
 - Bulb – base of the follicle; this is the cavity, where the hair growth begins
- As hair cells are formed at the root, older hair cells are pushed upward causing hair growth.
- In this diode procedure the target chromophore is melanin.
- The hair follicle's melanin is sensitive to the absorption of all light.
- Coagulation of the follicle happens when light energy is transformed into heat energy and is absorbed by the hair follicle.

Notes:

Hair Growth Cycle

- Long term hair removal will only be achieved on hair that is in the antigen stage.



Tip: Follicle depth is influenced by thickness of hair.

Hair Removal (HR) Endpoint and Treatment Schedule

- **Treatment Guidelines:**
 - Hair **MUST** be shaved.
 - Do **NOT** wax or pluck during the entire treatment course.
 - Do **NOT** treat area where hair follicles have been removed by waxing or tweezing
 - Cover moles with white makeup pencil or white sticker.
 - Apply 1 mm – 2mm (for darker skin Types III – VI) of ultrasound gel to the treatment area.
 - Set machine according to patient’s individual treatment settings and skin type parameters according to test results and safety settings generated by the machine.
 - Pass over entire treatment area once
 - Raise the fluence slowly if need be to achieve a positive end point
- **Treatment Schedule:**
 - **Interval**, 1 treatment (txt) every 4 -10 weeks, according to table for anatomic site and recommended treatment interval.
 - **Treatment Course** of six to ten sessions per area for prime efficacy.
 - **Maintenance**, as needed or one session every six months.

Tip: Intervals may vary on patience’s individual results

- **End Point:**
 - S.O.S. the smell of success: the smell of burnt hair indicates you have reached a positive clinical endpoint for hair removal.
 - Positive end-point: Results in perifollicular edema and or erythema with no epidermal reaction in treatment area.
 - Erythema/ edema are the most common site reactions during and immediately after post treatment.
 - Tip: Do **NOT** treat hair that is lighter than the surrounding skin.



