

3dPiL

Comfort

Capactuel
MEDICAL
Preventive and Restorative Aesthetic



CE 0197

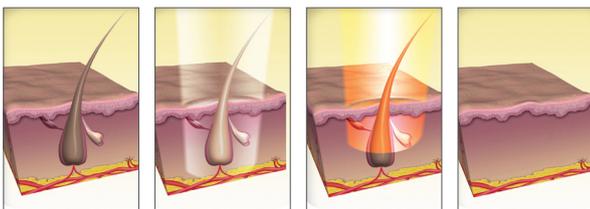
FDA
K152898

The power and precision of a 808, 755, 1064nm laser for a secure permanent hair removal.

3DPiL uses a technology based on selective photo-thermolysis (light and heat). The laser light is absorbed by the melanin of the hair follicles and converted into heat. The increase in temperature on the hair follicle will be large enough to irreversibly damage its structure. The hairs will disappear after a natural physiological process until a permanent hair removal is achieved. The laser energy is selectively absorbed by the hair follicles, so that the surrounding tissues will not overheat and suffer no lasting damage. This laser is suitable for all types of skin and hair. It allows the removal of unwanted hair on all parts of the body: Face, underarms, bikini areas, lower or upper limbs ... The treatment is very fast and convenient thanks to an easily manipulable handpiece that allows access to safely to the targeted areas. As a class 4 laser product, the 3DPiL laser therapy system produces a beam of high density and power. The equipment must be used by a trained professional to avoid any danger or injury. Equipped with a high-performance cooling system and an ultra-precise control interface, 3DPiL allows up to 300 million secure shots to be taken and the device to be highly profitable over time.

> Mechanism of treatment by selective photo-thermolysis.

The main chromophore for laser hair removal is melanin residing in the hair shaft. Melanin remaining in the inner and outer epithelial sheath can also serve as a secondary chromophore. In theory, the laser energy delivered to the capillary stem serves as a heat sink, which transfers energy to the hair follicle and perifollicular tissue. The conduction of heat from the stem is what ultimately damages the follicle. Follicular damage is sufficient to achieve a permanent reduction of the hair system. Although multiple factors play a role in the response of the follicle following the procedure, it appears that the wavelength, flow, pulse duration and dot size are the main factors determining the success of the treatment. The purpose of laser hair removal is to achieve follicular destruction but destruction of the hair shaft without sufficient energy transfer will result in temporary hair removal. This is most often seen with low power lasers.



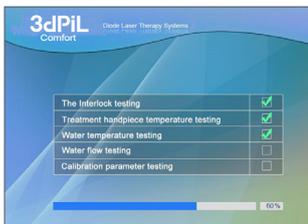
Different stages of selective photothermolysis treatment



Use of the laser on leg or torso in the frame of the permanent hair removal.

> Fields of application and contraindications.

By acting on melanin, the 3DPiL diode laser is mainly intended for hair removal and permanent reduction of hair in a progressive and painless way through heat emission. On average, permanent hair removal can be expected after 8 to 10 sessions. In parallel, the device can be used to treat leg veins and small vascular lesions by absorbing photons emitted by the hemoglobin contained in the red blood cells. Treatment is prohibited in case of: Recent treatment by other means (waxing with honey or electrolytic wax); Active infectious lesions or open wounds in the treatment area; Photosensitivity or taking photosensitizers during the last 3 months; Exposure to the sun during the last 4 weeks; Tattoos or scars in the treatment area; Hypertension or serious heart disease; Diabetes, AIDS, SLE, epilepsy, mental disorders, breastfeeding ...



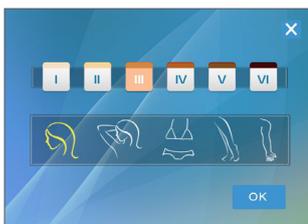
Self-test screen



Device setting screen



Laser setting



Skin types and areas selection

> Secure start and reserved to authorized personnel.

With its commissioning device based on the use of a key switch, the device can only be started by an authorized person with training. Before starting, first make sure that the emergency stop button is released. Activate the key switch, water cooling and screen start to operate, the system is started. After 5 seconds, a colored screen appears. In order to enable you to benefit in the best conditions of the ignition self-test phase, to have quick and easy access to the parametric functions necessary for precise and safe care, 3DPiL has been equipped with a 10.4-inch touch screen and a clear and ergonomic interface. The setting system options, equipment status control, device management can be achieved and optimized via this display device with high added value.

> Self-test phase to ensure the proper operation of the device.

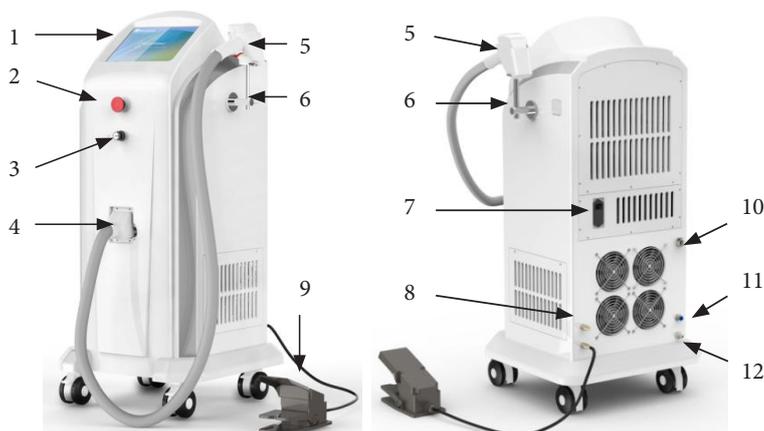
The device, once launched, displays the management interface and then goes into self-test within 5 seconds. The self-test phase verifies: the connection status, the temperature calibration parameters, the water flow and the handpiece. If one of the tests fails, a warning message appears with an indicative error code inviting the user to consult the user manual or those listed. The system remains shut down until the problem has been resolved. If all the tests are succeed, the device gives access to the setting screens of the application.

> Parameterization, emission modes and laser power.

Fluence, pulse duration, frequency, wavelength 808nm, 755nm, 1064nm, skin type, body part, the device can be quickly configured thanks to easily identifiable and configurable functions. Decisive choices for the personalization of the laser, the skin type (6 levels : «I, II, III, IV, V, VI») and targeted body area (5 zones : Face, Underarms, Bikini area, Lower limbs , Upper Members) can be selected with a single click. Before the formal treatment, the practitioner can then adjust the parameters, such as «Fluence», «Frequency» and «Pulse duration» on a test area, taking into account the skin profile and type of treatment, in order to avoid any discomfort or skin damage. 3 shoot triggering modes are available through the handpiece button and the footswitch : triggering by pressing the handpiece button, triggering by pressing the pedal, triggering by pressing both the button handpiece and operating the pedal. Once triggered, the shot is made by a window located on the handpiece and mainly composed of sapphire glass for effective cooling effect on epidermis by contact. Faced with the density and power of emission of the laser, a patented cooling system based on air, water and semiconductors is installed to guarantee stability and performance of the device over time.

> Technical parameters.

Laser Source / Laser Category	Diode stack / Class 4
Laser wavelength	808, 755, 1064nm
Electrical safety classification	Type B Class I
Pulse duration / Frequency / Fluence	5ms-400ms / 1Hz-10Hz / 0-120J/cm2
Laser aperture / Spot size	14 x12mm / 12 x 14, 14x16, 12 x 20 mm
Cooling methods	Air cooling, water cooling and semi-conductor cooling
Input power / power source	1300VA / 110-240VAC,50-60Hz
Fuse protector	T12AH250V
Dimensions (Length Width Height) / Net Weight	480 x 470 x1045 mm / 40Kg



Device description. **3dPiL**

- 1 - 10.4 inch touch screen.
- 2 - Emergency switch.
- 3 - Key switch.
- 4 - Connector of treatment handpiece.
- 5 - Treatment handpiece.
- 6 - Holder of treatment handpiece.
- 7 - Power cordInlet.
- 8 - Inter lock connector.
- 9 - Foot Switch.
- 10 - WaterInlet.
- 11 - Vent.
- 12 - Drain.



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