

MILESMAN COMPACT DESCRIPTION OF MEDICAL DEVICE



INDICATION

The equipment is designed to be used to permanently remove hair in the hirsutism treatments.

As hirsutism is a disease that consists of an uncontrolled production of hair all over the body and the face, the treatment has to permanently remove hair

FUNCTIONAL DESCRIPTION

Laser hair removal is a medical procedure that uses a concentrated beam of light (laser) to remove unwanted hair.

During laser hair removal, a laser emits a light that is absorbed by the pigment (melanin) in the hair. The light energy is converted to heat, which damages the tube-shaped sacs within the skin (hair follicles) that produce hairs. This damage inhibits or delays future hair growth.

Although laser hair removal effectively delays hair growth for long periods, it usually doesn't result in permanent hair removal. Multiple laser hair removal treatments are needed for initial hair removal, and maintenance treatments might be needed as well. Laser hair removal is most effective for people who have light skin and dark hair.

HOW IT WORKS

Hair color and skin type influence the success of laser hair removal. The basic principle is that the pigment of the hair, but not the pigment of the skin, should absorb the light. The laser should damage only the hair follicle while avoiding damage to the skin. Therefore, a contrast between hair and skin color — dark hair and light skin — results in the best outcomes.

The risk of damage to skin is greater when there is little contrast between hair and skin color, but advances in laser technology have made laser hair removal an option for people who have darker skin. Laser hair removal is less effective for hair colors that don't absorb light well: gray, red, blond and white. However, laser treatment options for light-colored hair continue to be developed.

The device combines a specific wavelength with pulse unique characteristics that makes it suitable for the intended purpose.

One of the main innovations that the device introduces is its unique regulated cooling system at the tip (from 0°C to -3°C) that enables an efficient application of energy with the best results.

The device has a touch screen that allows extensive control (energy density, firing frequency, pulse duration, etc.) and provides the user with valuable information (number of shots, Jules counter, etc.)

The COMPACT is a TRANSIENT devices as the tip of the handpiece is in intermittent contact the maximum duration of a session is 60 minutes

COMPONENTS

The device consists of

- A main console where electronic components, external connections, and safety components are located,
- An umbilical cord, through which the handpiece is connected with the main console, containing cooling tubes and signal cables,
- A handpiece where the trigger is located as well as a refrigerated tip and laser diode bars.

MAINTENANCE

The devices needs to be checked every year to inspect all the components and the correct functioning. Only authorized personnel from the company or from the official representative is permitted to carry out this inspection.

The lifetime of the laser is 10-12 years

ACCESSORIES

There is no accessory with the laser

WARNINGS

The energy produced by the Milesman Compact Diode Laser System classified it as a Class IV laser. Class IV represents the highest power lasers; for this reason, the user must take precautions to prevent unintended exposure of laser energy to the eye and skin from either direct or diffusely reflected laser beams. The wavelength of light emitted by the Milesman Compact Diode Laser is approximately 800 nm, in the near-infrared portion of the electromagnetic spectrum. It is highly absorbed by melanin in the skin and hair follicles, but less so by skin cells without melanin. This laser light is not readily absorbed by water or

glass and may pass through windows. It can also be reflected off of smooth metallic surfaces.

The users of this product are basically aesthetic doctors, dermatologist and plastic surgeons, although there are other possible doctors or medical personnel that might use it.

The environment where it is used is medical environment (clinics, private practices, etc)

Ocular Protection

Milesman Compact Diode Laser produces a high-intensity beam of energy, it has the potential to cause ocular injury to the operator, treatment room personnel and the patient. Consequently, no one should look directly into the laser light source or at scattered laser light from reflective surfaces. In addition, special protective eyewear must be worn by all persons potentially subject to exposure.

Minimizing the Risk of Skin Burns

To ensure that all of the people entering the treatment room know which laser is being used, appropriate warning signs indicating the type of laser and its wavelength must be prominently displayed on the outside of the operating room door. During treatment, the door of the room should be kept closed. Because the laser light can pass through glass, all of the windows in the treatment room must be covered with opaque covers. Smooth objects can reflect the laser beam. Reflection hazards can exist several feet beyond the laser beam aperture. The operator should avoid directing the laser beam at unintended objects. Regardless of the colour of a surface, reflection is a potential hazard when the laser strikes a non-absorbing surface such as a metallic surgical instrument. Whenever possible, low or non-reflecting instruments should be used.

The Milesman Compact Diode Laser System uses a cold sapphire lens that is held in direct contact with skin during laser treatment to focus the light and protect the epidermis from thermal damage. When used properly, this type of delivery system also helps minimize the potential risk of reflected laser light, and the laser should only be fired when the delivery system is placed against the patient's skin.

Minimizing the Risk of Electrical Hazards

The covers enclosing the active components of the laser should not be removed except by certified service engineers. The area around the laser should be kept dry. The laser should not be operated if the power cable is faulty or frayed. Finally, the laser should be inspected regularly and serviced, and a written record of both service and maintenance should be kept.

Minimizing the Risk of Fire Hazards

The 800 nm laser energy produced by Milesman Compact Diode Laser System has a relatively low risk of drapes, gowns or other potentially flammable materials in the operating room. However, to minimize the risk of fire hazards, the following precautions should be observed:

- Flammable skin preparation agents (e.g., alcohol) should either not be used in the treatment room or should be allowed to dry completely before beginning the procedure.
- Anesthetics administered topically or by inhalation must be approved as non-flammable.
- Particular care must be taken when oxygen is used in the room. Oxygen can accelerate the combustion of any flammable material.
- Use of combustible materials, such as gauze and drapes, should be avoided in the treatment area. Clothing should be kept well away from the area of treatment.
- The laser should not be operated with any cover or drape over the laser.
- An appropriate fire extinguisher should always be available inside the room or just outside the door.

SPECIFICATIONS

Laser	Milesman Compact
Type	AlGaAs laser diode matrix
Diode optical power	2,000 W
Nominal wavelength	810 nm
Pulse width	5 – 150 ms
Pulse repetition rate	≤ 8 Hz
Optical window	0.39 x 0.39 in - 10 x 10 mm
Recommended power supply	
Voltage, frequency, current	100 – 240V. 50 – 60 Hz, 12 A
Connection to public main	Single phase grounded outlet
Classification	
Eye risk nominal distance	164 ft - 50 m
Protective glasses	Optical density at 790 – 830 nm ≥ 5
Physical parameters	
Central unit weight	9 kg
Central unit size (W x D x H)	350mm X 420mm X 230mm
Operating radius of umbilical cord	59 in - 1.5 m
Environmental conditions	
Temperature, humidity, pressure	60 – 80°F, 0 - 70%, 13 – 16 psi 15 – 30°C, 0 – 70%, 90 – 110 kPa
Classifications	
FDA Classification	Class II Laser
CDRH Classification	Class IV Laser
MDD Classification	II B
Classification according EN 60825-1 norm	4
Operation Classification	INTERMITTENT