



# MILESMAN COMPACT USER MANUAL



V 1.0

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# 1. PRELIMINARIES

## 1.1. General definitions

The equipment is designed to be used for reduction of unwanted hair and to permanently remove hair in hirsutism treatments.

Some of the Compact's multiple beneficial qualities are an optimum combination of efficacious wavelengths, characteristics of the laser pulse tailored for optimal hair removal and an original and exclusive technology of integrated cooling. All of this technology fits in a lightweight machine with a compact design that permits transport with confidence and comfortable treatments. designed and controlled the whole process through a tactile screen, in a way that the foreseen results are guaranteed.

The equipment is configured by a central unit, a pedal, a power cable and a hand piece connected to the central unit through an umbilical cord.

Generally and in a standardized use, the handpiece presses on the user's skin and emits a light pulse once the pedal or the trigger are pressed down.

The screen, which is placed in the upper part of the central unit, permits controlling the functions of the laser exit and other characteristics in the system.

This equipment connects without difficulty taking AC power.

The fundamental method of the diode laser is based on selective photo thermolysis. Through this procedure, it is possible to eliminate the hair by way of a laser light of 810 nanometers that deeply penetrates into the dermis. The melanin of the hair absorbs the energy emitted by the light, which produces a rapid heating of the hair and the follicle and consequently, its degeneration.

To avoid as much as possible the feeling of overheating, this equipment has introduced a cooling mechanism conductive to the skin that is applied by the handpiece cooling tip, which permits limiting the accumulation of heat in the epidermis, rich in melanin, and increases the tolerance of the application.

Like in all types of lasers, it is necessary to take a series of previous care, or precautions to guarantee good use and safety in the application. Study in detail the whole user manual before putting the machine to use. Besides it is very recommendable that the user receives a training course before using Milesman Compact.

The use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

## **1.2. Users Training**

The COMPACT diode laser equipment can only be used by adequately trained professionals in the handling and secure use of the system

Besides safety training of the laser applicable to all the personal, it is very recommendable that the user and the business implant a training and safety program. To expand on this information, you can consult the latest version of regulations ANSI Z136.3 or the Europe standard EN 60825-1 section 3:

The users should assist one unit of training, a practical unit of training supervised by a qualified user and specific courses of the speciality that can be taught during academic seminars or universities.

## **1.3. Indications for use**

The Pulsed Diode Array Laser System Milesman Compact is intended to permanently remove hair in the hirsutism treatments in all skin types (Fitzpatrick I-VI), including tanned skin.

## **1.4. Contraindications**

Patients who have had prior problems with laser therapy, should be carefully screened before treatment. Additionally, persons known to form skin keloids may be more prone to scarring after any skin trauma, including laser treatment.

Laser hair removal should not be attempted in patients with active infections in the treatment site. Caution is advised in treating patients with any of the following relative contraindications:

- A history of keloid scarring
- Active infection or a history of herpes simplex in the treatment area
- Use of depilatories or other hair removal treatments, such as waxing, plucking or electrolysis, within the preceding 6 weeks
- Hypersensitivity to hydroquinone or other bleaching agents, if applicable
- Use of oral Accutane (Isotretinoin) within the preceding 6 months

## **1.5. Warnings**

Darker skin types and individuals with a suntan are at a higher risk for pigmentary changes in the treatment area.

These patients should be treated with lower fluences and/or longer pulse than similar skin types that are untanned.

Sun exposure to the treatment area immediately after treatment and for one month following may also increase the risk of pigmentary changes in the treatment area.

Observe all safety precautions described in this manual.

## **1.6. Precautions**

The darkest and bronzed types of skin have a larger probability of experimenting alterations of pigmentations in the treated area.

The applications that are carried out in these people should have greater or smaller fluency during the pulse than those who have similar skin types but are not bronzed. The alterations of pigmentation in the treated area can also rise with cause to being inadequately exposed to immediate sun after the session and during the following month.

Respect all safety precautions which are described in Chapter 2 just as in the rest of this manual.

Only the operator can start laser treatment after adequate and rigorous training and once accustomed with the safety of the laser and with the device.

The laser can cause thermal damages in the skin. The risk can be larger depending on the rise of the intensity of the laser and the type of skin pigmentation.

Generally, as with the effectiveness of the session like the response of swelling before possible damages of the skin are linked with the fluency.

With higher fluency levels, a major effectiveness and a major inflammatory response exist, which increases the probability of producing damages in the epidermis. For this, it is recommended to start the session with one degree of prudent exposure to go progressively enlarging the fluency until achieving the desired effects.

## **1.7. Previous studies**

The previous studies have demonstrated that it is each concrete zone of the body which determines the necessary time to know if the treated area offers a reduction of stable hair, for a long term or permanent. If the treated area of the body offers a reduction of hair during a greater period than the complete growth cycle of this area, it could be considered that the reduction of hair will be stable, constant for a long period or permanent results.

The table 1 reflects the duration of the phases of hair growth in the treated parts of the body in previous studies.

Area	Telógen (Months)	Anagen (Months)	Global (Total Months)
Back	3-6	3-6	6-12
Upper leg half	3-6	3-6	6-12
Forearm	3-5	1-2	4-7
Lower leg half	3-4	4-5	7-9

Table 1: Duration of the phases of growth

## 1.8. Possible complications and side effects

The most common side effects are the redness and the swelling that usually appear immediately after the laser session and that usually go away in 24 to 48 hours. Other possible side effects that depend on the fluency and type of skin can be the darkening or lightening of the skin.

Around 20% of the people treated presented temporary alterations in the pigmentation of the skin, which were healed in a period of 1 to 3 months; however, in some cases they lasted 12 months. It has not been observed nor described the appearance of scars or permanent pigmentation in any person.

Following, it is reproduced some minor complications observed in some users, reflected in the empirical studies of the diode equipment:

- Possibility that can arise, after the session, superficial erosions of the treated area.
- Possibility with mild discomfort during the session that can be solved with the application of external calming creams. The use of local anaesthesia is not very frequent.
- Possibility that one to three days after the session mild bruises can appear in the exposed area.

## 1.9. Meaning of used symbols

	Signals the possibility of danger to being exposed to a radiation laser which can cause serious wounds for the operator, the user or the surrounding personal.
	Signals the possibility of different dangers besides radiation, as an electric discharge or a fire, which can cause serious injuries for the operator, the user or the surrounding personal.
	Signals a potential dangerous situation that could produce damage in the equipment.



UTILIZAR  
GAFAS  
PROTECTORAS

Signals that everyone in the room must use protective eyewear.

## 2. SAFETY INDICATIONS

### 2.1. General definition

The care and precautions that have been taken for the correct use of the laser are pretty extensive. In this chapter, we signal the most important and recommend that the users of the laser complete these precautions with other types of extra information about the latest technology advances which have been developed and applied in different products.

There is special information available for the users of the laser equipment and is recommended to follow the advice of the latest standard edition. Between these recommendations, it is essential, for everyone that can be exposed to the laser, the use of protective eyewear against the laser, which has an adequate nominal optic density for the wavelength of the MILESMAN COMPACT

Also, all the users of the diode laser equipment or people that work near should have knowledge of the potential risks. Therefore, it is necessary to make sure that all the personal studies in detail have the following safety indications. Only those with actual training and adequate knowledge for using the laser are authorized to carry out the treatment, help in carrying out or providing assistance for the MILESMAN COMPACT.

Consult chapter 1.2 of this manual to expand on the information or contact the Customer Service”.

The user of the equipment is not authorized to carry out the technical service of the machine. Only the manufacturer or the authorized technical service specialists can carry out the checks, technical service and possible repairs.

### 2.2. Ocular hazards



The laser equipment emits a light that can cause eye damage of distinct seriousness.



It is essential that everyone that can be exposed to the laser light use protective eyewear or any other type of eye protection that fulfill the national and international safety rules. The ocular protection should have an optical density (OD) greater or equal to 5 with a wavelength of the method of 750 to 830 nanometers. Except for the USA users, the adequate standard can be the EN 207 in which case, the ocular protection should be the L5. Only the laser can be used in a closed room in which everyone should have their eyes protected. In the room, the direct exposure to the eyes is not secure from any distance.

Therefore, cover all the windows in the laser room with an opaque material and should take all the necessary precautions so that nobody has access without authorization to the room.

Besides, to guarantee the fulfilment of the ANSI Z136.3 and EN 60825-1 rules they should place laser safety signs in all the accesses while they are using the laser.

To increase the safety, with the equipment a remote interlock device is delivered that can connect itself to the entrance door to the treatment room with the purpose of deactivating the emission of the laser if the door were to open accidentally during a treatment. It also supplies a certified approved signal, besides an ocular protection. In the case of needing protective eyewear or additional safety signs, get in contact with the Customer Service.



It is mandatory that all people that can be exposed to the laser use adequate ocular protection while the main power and keyswitch are on.



It is prohibited to fix your eyes on an open laser, in the handpiece tip, even though wearing the protective eyewear against the laser, since the contrary runs the risk of suffering distinct serious injuries.



Avoid as much as possible the positioning of the laser light to whatever place that is not the calibration port or the prevented treatment area. The emission and reflection of the laser always carries a risk and can cause injuries of diverse considerations.



The eyelids, eyelashes and other delicate zones which are found in the osseous area that surrounds the eye socket should not be exposed to the laser light since it can cause ocular damage. To maximise the safety, the user should use permanent metallic protective eyewear during the facial sessions.

#### **Ocular safety observations:**

- Determine the exact treatment room and place the approved safety laser signs in visible places.
- Cover all windows to make impossible that the laser beam can escape from the treatment room.
- Limit the entry of people into the treatment room while the session is being carried out. Only the essential people should have access to the session, people who know the safety fundamentals and are properly trained.
- Never position the laser beam towards another element that is not the calibration port or the treated area.
- Verify that the laser pedal is clean, and that it works correctly. Place the pedal in an adequate position, in a way that it is neither used by accident nor can be confused with any other component.
- Do not look directly at the opening of the laser of the handpiece tip.
- Use authorized protective laser eyewear, with an optical density of greater or equal to 5 with a wavelength of the , of 790 to 830 nanometers. Except for the USA users, the correct standard can be the EN 207, in which case it should use ocular protection L5.

Protect oneself as much as the operator as the client and any other person that is in the room.

- Do not try to take off the covered protectors of the hand piece since it could cause being exposed to the high intensified laser light.

### **2.3. Electrical hazards**

The diode laser equipment has internal pieces of high voltage that can produce injuries or electrical discharges. As can happen on occasions with high voltage components, it is possible that they maintain the load during some time, even after the laser is unplugged.

Only the authorized technicians and those trained for the equipment can handle or remove a part of the exterior casing or the insert of the calibration port.

Do not wet nor spray the laser center, the handpiece or the tactile screen with liquids since they can deteriorate the electrical equipment and possibility of electrical discharge. If the power cable is frayed or deteriorated you should not use the unit. To clean the tactile screen it is necessary to previously turn off the equipment.



If the external casing were to open, a damaging exposition to the optical radiation and electrical voltages could be triggered, even after unplugging the laser. Only the authorized technicians and those trained for the equipment can operate or remove a part of the external casing.

### **2.4. Fire hazards**

The probability exists that a fire hazard can be produced since the laser absorbs energy that can increase the temperature of any material. As this foundation is the root of many applications of great utility, it obligates taking precautions to avoid a possible fire of the easier combustible materials. In the case of the diode laser equipment you should apply the following cautions:

- Before any treatment it is necessary to wait until the inflamed products evaporate completely. Normally they are liquids that are used to clean the skin or the handpiece tip, for example, alcohol.
- The calming products that are applied onto the skin or by inhalation should have the classification of “non inflammable”.
- Take special precaution in the use of oxygen, since it is an accelerant of the combustion of any inflammable element.
- We recommend not using combustible elements like gauzes and wraps in treated areas. If it was necessary, the fire hazard is reduced by maintaining them damp or in water. Equally, the textile materials should be moved from the treated area.
- Do not use the laser with any type of cover.



Prohibited using the laser in the presence of liquids and flammable gases, like alcohol, acetone and the ether.

## **2.5. Safety Components**

The diode laser equipment has been conceived with a design that results comfortable, practical and safe, so much for the operator as the client.

Next, we detail the most important safety components and in the 3rd and 4th chapters you can find more information about the definitions and the recommendations of the use of these and other safety components.

### **2.5.1. Safety interlocks**

To guarantee the maximum safety, the equipment is equipped with a complete control mechanism which indicates if the system is fulfilling all the safety indicators. If a failure were to happen, it would be necessary to solve the problem and re-establish the system before returning to activate the laser. The control mechanism contains the following:

- **Energy control:** Checks that the laser emission is found in the specific energy ratios for every laser pulse. If it manifests a current higher or lower than normal in the laser, it shoots a system failure and causes an advisory to the user.
- **Temperature control:** Prevents functioning of the system if the temperature of the diode or the temperature sensor of the tip jumps out of the valid ratios of operativity.
- **Remote interlock,** is intended to avoid damage to people who could come in on the treatment room without goggles. This interlock is connected to the external door and the device is stopped when somebody opens it.
- **Flow control** is intended to warn of the absence of coolant's flow through the refrigeration pipes. When this absence is detected, an error message appears on the screen and the device is stopped. In this way it avoids a patient's burn and the damage of the diode array.

### **2.5.2. Pedal and handpiece shooting**

The energy of the laser only flows out if the pedal or handpiece trigger are pressed which prevents the possibility of involuntary emissions. With the pedal pressed the laser can shoot several times

With the trigger pressed the laser can shoot (1) either pressing firm and letting up on the hand piece trigger for each pulse (2) or maintaining the trigger pressed without interrupting.

### **2.5.3. Resounding emission signal**

Each laser pulse has a resounding signal with the purpose of indicating the operator the emission of the laser and increases the safety.

In rare occasions failures can occur in the signal; in case there was not a resounding tone accompanied to the emission you should suspend the use of the system until the problem is solved and reestablish to its correct functioning.

### **2.5.4. Emergency Stop Button**

The laser emission immediately paralyzes when the pressure is taken off the pedal and the hand piece triggers. In the case of an emergency, the possibility exists of stopping by way of the emergency button which is situated on the side of the keyswitch of the central unit.

To restart the system, you only have to turn the button to the right until it is lifted again.

Later follow the conventional starting instructions. Since the emergency stop button is for exceptional situations, follow the proceeding of Section 5.4 to know how to turn off the system in a conventional way.

### **2.5.5. Handpiece design**

The diode laser equipment contains various particulars in the hand piece design that increase your safety.

**First**, there is no need for an articulated arm nor any other form of emission beam since the laser emission comes out of the hand piece and not in the central unit as occurs in conventional laser systems. In its place the 's handpiece has a condensed light incorporated in only one piece which combines the spreading of thousands of transmitters to generate a uniform light beam with a square shape. Besides, the fact the laser emission originates in the handpiece prevents the production of damaging optical radiations, neither in the central unit, nor in the umbilical cord.

**Second**, the sapphire tip supports the clients during the use of the system, which limits the diffusion of the light and at the same time increases the effectiveness.

### **2.5.6. Power supply design**

This design, that gives it the medical certificate, allows a wide range of safety and more isolation of the general supply system for the patient and for the user too.

### **2.5.7. Calibration**

Once turned on the equipment will have to perform the calibration process. If the machine detects that energy emitted does not fit the parameters displayed, it shows a calibration error.

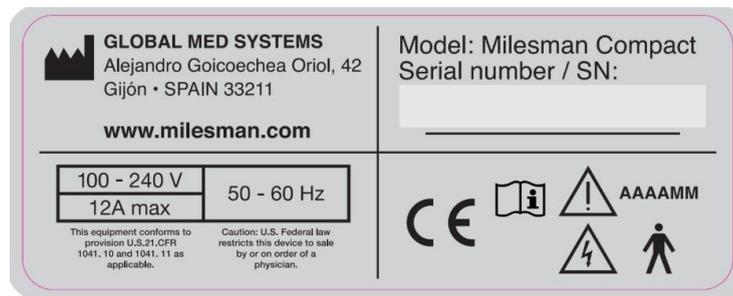
## **2.6. Main unit indicators**

The main unit has informative labels and advertising in various places, completing as with all the demands of the national and international regulation organizations. Following the mentioned labels are reproduced and specified

Laser opening label close to the handpiece tip:



Manufacturer information and identification labels placed on the side of the main unit



## Symbols

Indicates  the medical device manufacturer, as defined in EU Directives 93/42/EEC

Indicates  the need for the user to consult the instructions for use.

Indicates  the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

Indicates  Warn of electricity.

Indicates  Identify a type B applied part complying with IEC 60601-1.

Laser emission labels placed on the side of the central unit:





## **3. DESCRIPTION of the EQUIPMENT**

### **3.1. Generalities**

The diode laser equipment is based on the laser technology of diode and produces infrared light impulses used for the elimination of hair. The components of the system are: a central unit, a pedal, a power cable and a hand piece connected to the central unit with an umbilical cord.

The laser light emerges from the hand piece through the diode laser array and it is projected to the exterior by means of a sapphire tip that also serves to cool the skin.

Besides, this equipment provides a controller based in the microprocessor (the microcontroller) that carries out the functions of the control system, tracking of failures and control of the functionality of the laser.

The operator interacts with the controller through a tactile screen which is found in the upper part of the central unit. Like in all pulse laser systems, the COMPACT laser equipment generates a constant and monochromatic light pulse that respects some parameters determined by wavelength. The wavelength is approximately 810 nanometers in the spectrum area near the infrareds and out of visible range.

The characteristics of the most represented pulse for the previous applications are: in first place, its duration, in this manual are measured in milliseconds; and second, the density or fluence, measured in joules per square centimeter, which means, the quantity of optical energy applied in a concrete area in the skin. The density or the fluence is the most important characteristic to have in mind the hour of application.

Other important laser parameters exist like the frequency of repetition, measured in pulses by seconds (Hz).

In this chapter we will list and describe the characteristics and general functions of the components in this equipment. The use of the laser and the correct use of these components are described in Chapter 5

### **3.2. Main Unit**

#### **3.2.1. Front part**

The front part of the central unit is made up by an ergonomic casing with the following parts:



### **3.2.1.1. Screen**

This screen constitutes the interface joined with the system controller that is based in the microprocessor. Its functioning is very easy, just by selecting the functions of the screen pulsing with one finger.

To guarantee correct functioning of the screen it is necessary to routinely clean, such as indicated in Section VII. Be careful with the use of grease, treatment gel or any other contaminating product on the screen because it can produce pressure on the buttons and in the interface of the user and consequently that the density continues increasing even though the operator does not continue pressing the tactile screen. For this, it is not recommendable using contaminating products on the screen.

### **3.2.1.2. Plug in for the pedal**

This plug in, in the rear part permits inserting the pedal tube. To turn it on, insert the pedal cable in the socket and to disconnect, pull out the pedal cable close to the central unit and extract the socket tube.

### **3.2.1.3. Emergency stop button**

In case of an emergency, the laser can be turned off immediately through the emergency stop button which is located on the front part of the central unit. To put the system in function again, just turn the button towards the right until it lifts again.

### **3.2.1.4. Plug in for the Remote interlock**

This device is designed to connect a remote device that allows detecting if a door of the room is open.

It is a safety measure that protects against the accidental access of someone not related to the laser treatment without the adequate eye protection. If this happens, the equipment stops automatically.

If the user wants to install this interlock device, he should contact our Customer Care Service. The connector must be always in the equipment to allow its operation.

### **3.2.2. Rear part**

The rear part of the central unit is integrated by the following elements:

#### **3.2.2.1. Socket for the electrical current cable**

The operative is put in motion with a power cable. The female end of the power cable adjusts in this socket and the male end connects to an electrical plug with the adequate voltage.

#### **3.2.2.2. Main power button**

This button has two functions, as an automatic switch for protecting the system of possible current alterations and also works as a button for turning the system on and off.

During the day, you may leave this button on to activate and deactivate the system with the keyswitch (night time or weekends) or if the equipment is going to be moved, it is required to turn off the main power switch.

#### **3.2.2.3. Ventilation grills**

The central unit is designed with grills in the rear part as in the front part which serve to cool with air the internal components. To avoid overheating, do not cover or block these grills.

### **3.2.3. Pedal**

The pedal connects to the front part of the central unit such as described.

When the system is working, the pedal or the trigger are the elements controlling the laser shooting to enable the laser to emit.

It is necessary to press one of both, or the pedal or the trigger of the handpiece in order to let the laser generate a pulse.

### **3.2.4. Handpiece**

The handpiece has the following elements incorporated: the diode laser battery, which generates the laser light; the prism that condenses the light to generate an uniform square beam; and a sapphire tip, which is responsible for cooling the area to be treated through direct contact with the skin

By means of an umbilical cord, the power, the control signals and the cooling liquid are interconnected to the central unit.

## 4. INITIAL INSTALLATION

### **4.1. Installation**

The rules for installing the COMPACT diode laser equipment are very simple and can be followed by any user without difficulty. If any problem or difficulty might arise, contact the Customer Care Service.

### **4.2. Previous exam of the outer packaging**

When receiving the COMPACT diode laser equipment, the first step is to observe the package and verify if any imperfection or damage has occurred.

If it had any remarkable imperfection, communicate it to the transport company and contact the Customer Care Service.

It is advisable to let the machine at room temperature before carrying on installing it.

### **4.3. Unpacking and checking material**

Once everything is ready to install the COMPACT equipment, the next step is to open the container and verify that all the components are there and that there is no imperfection.

1. Open the carton and remove the protections.
2. Remove the equipment
3. Remove the protective plastic bag.

We recommend that you save the packaging in a safe place and in good condition, as if it was necessary to transport equipment such packages ensure maximum protection.

### **4.4. Installation considerations to ensure proper operation of the equipment**

The COMPACT equipment has been tested to work seamlessly with EMC

The COMPACT equipment needs special precautions regarding electromagnetic fields and must be installed and put into service according to the documentation provided in this manual.

List of all supplied accessories (cable and pedal):

- CABLE IEC-60320 7,5 M (C13 / SCHUKO-M) REF: FA84 Cable based on the connector IEC-60320. At one end has Schuko (male) connector and the other IEC-60320-C (female) connector. Tri-pole cable 7.5 m that meets EU regulations regarding diameter (6.5-6.8mm).
- PEDAL.

*! The operating of the COMPACT equipment may be affected by the use of RF communication equipment portable and mobile nearby*

*! The Class A devices are equipment suitable for use in all establishments other than domestic premises and which are directly connected to a distribution network of low voltage electricity supplies buildings for domestic use.*

## **4.5. Setting up and connection**

Follow these instructions for setting up:

1. Unpack the main unit as indicated in the previous chapter. Remove the packing and verify that the system is correctly placed.
2. Find the connection to the pedal in the front part of the central unit and insert the cable of the pedal enough into the connector.
3. Find the power inlet in the rear part of the central unit.
4. Insert the power cable of the AC in the power inlet of the central unit. Connect the other side of the power cable to an electrical connection with an earth wire. It might be necessary to use a special type of plug together with the COMPACT equipment power cable, due to the electrical outlets not following any international standardized criteria.
5. Connect the main button located at the rear part of the central unit. At this moment, you should be able to see the light of the touch screen. (in case this doesn't happen check the emergency button is not activated)

If in doubt, please contact your local area representative or contact the Customer Care Service to receive the necessary assistance

## 5. INSTRUCTION of USE

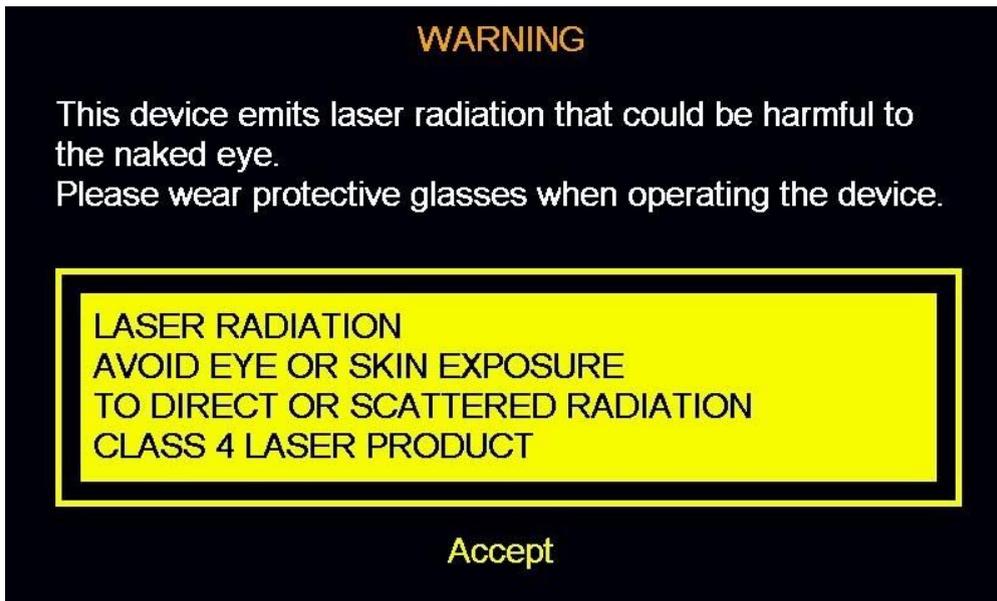
### 5.1. First connection

As a previous step, the user must check if the room conditions are adequate. Likewise, he has to ensure that the protective eyewear is available to work with this equipment (see technical specifications) and all electrical are correct. After this checking, the laser equipment can be turned on, activating the switch placed on the rear part.

*! In case that the laser doesn't switch on, check out that the power cable of the AC is properly inserted in the power inlet of the central unit and that the emergency button is NOT pressed. To put the system in function again, just turn the button towards the right until it lifts again.*

The touch screen will turn one in white, black or several colours while the interface is initialized to control the system. Once initialized, the startup screen with a Milesman Compact logo will appear for a few seconds, after that another screen warning about the laser type and safety measures





Once the warning screen is accepted, a screen will show up to enter a password to avoid unauthorized persons can access the system.



The default password is **1234**

## **5.2. Initial screen**

Once the password has been correctly entered, the initial screen is shown either the working mode or the settings menu can be chosen.

It is at this time that the user can perform through the icons, the actions of:

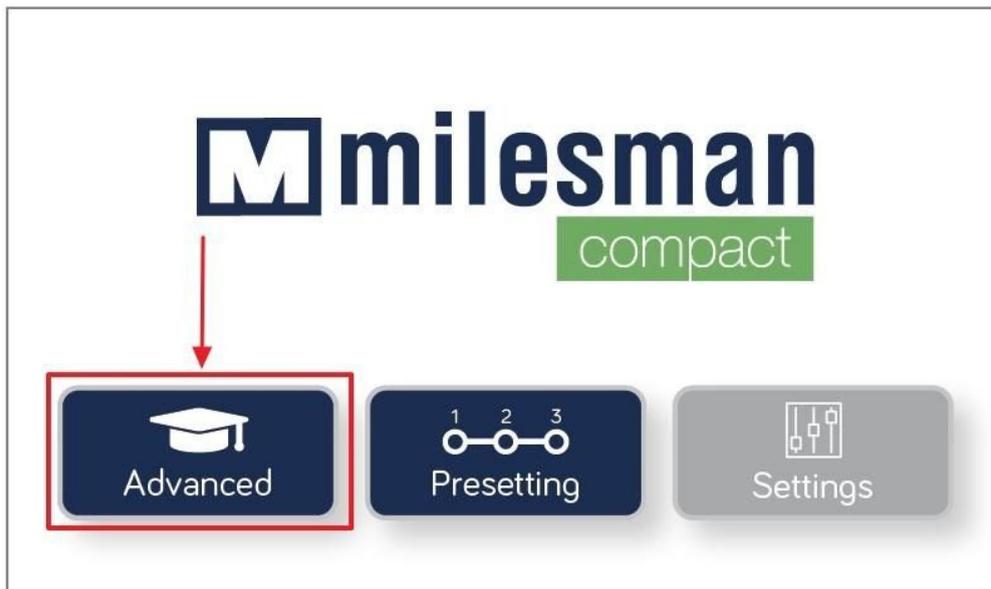
- Access to the advance working mode (parameters are set by the operator)
- Access to the preset working mode (user is walked through different options)
- Access to the setting mode where screen, maintenance, volume or autolock can be set



*Main Menu*

### **5.2.1. Advanced Mode**

The Advanced Mode is recommended for those users that have experience working with diode lasers for hair removal



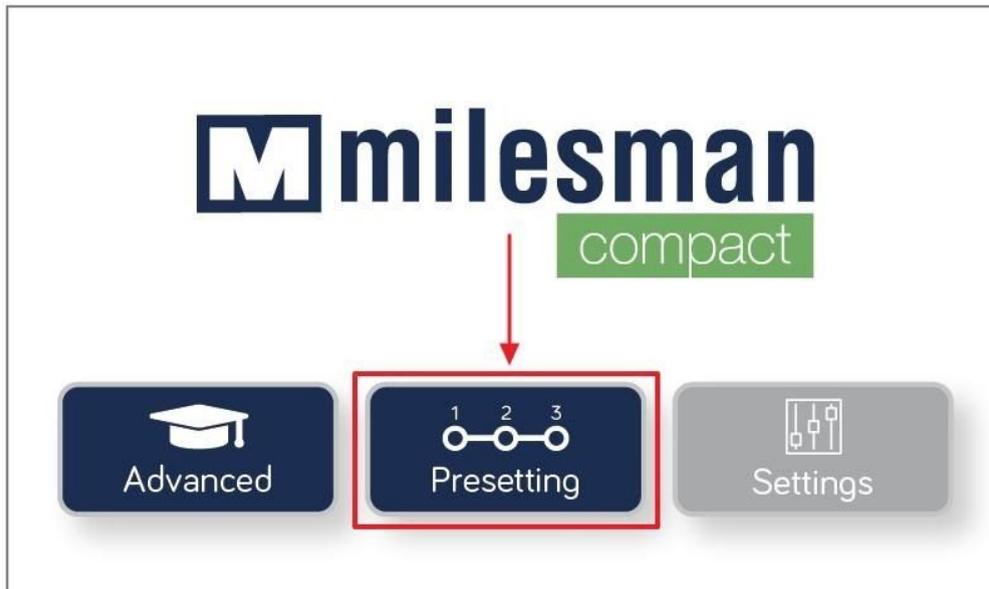
*Advanced Selection*

The access to this mode takes the user to the “working screen” and the differentiating feature of this mode in relation to the “presetting mode” is that on the “Advanced” mode there is a total freedom to fix any of the existing parameters (Fluence, Pulse Length and Repetition rate)

The only limitation that exists is fixed by the system. There is a maximum fluence depending on the pulse length setting or the repetition rate setting.

### 5.2.2. Presetting Mode

The Presetting mode is recommended for all users without experience on working with diode laser and that wants to have a guide that recommends the parameters to use.



*presetting screen*

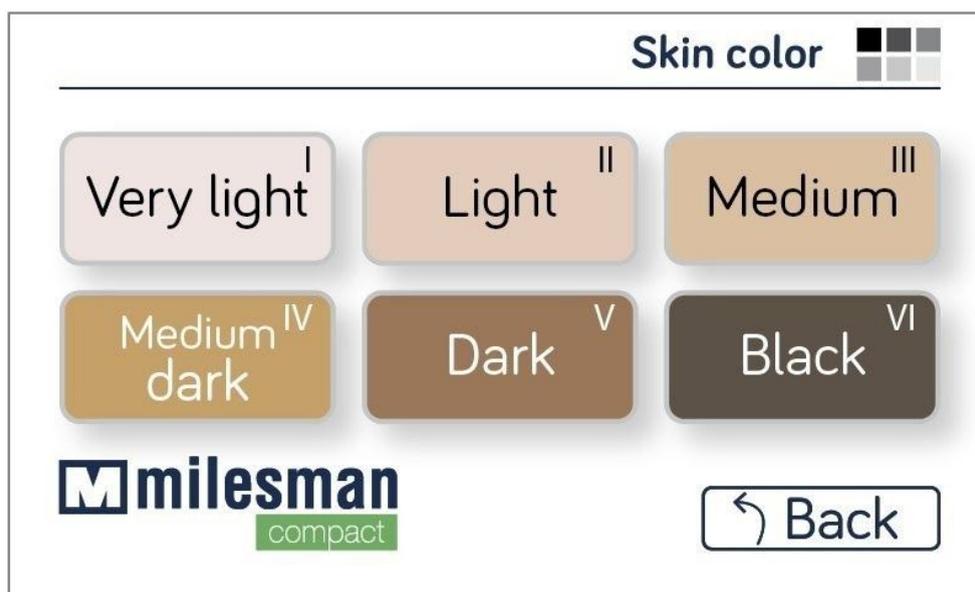
Before accessing to the working screen, in the presetting mode is required the following information that will let to suggest the parameters to work:

- **Skin Color.** There can be 6 types of skin colors that coincide with the 6 Fidpatrick phototypes. Very Light (i), Light (I), Medium (III), Medium-Dark (IV), Dark (V) and Black (VI). To select the skin color, select the button that contains the color.



*Skin Color Selection*

- **Hair Color.** There can be 4 types of hair colors: Black, Brown, Light brown or Blonde.



*Hair color selection*

- **Hair Diameter.** There can be 3 hair sizes: Fine, Medium, Coarse.



*Hair diameter Selection*

Once all the parameters have been selected, the “working screen” will be shown, and once there the shown parameters will be able to increase or decrease only two units. (Fluence, Pulse width, Frequency).

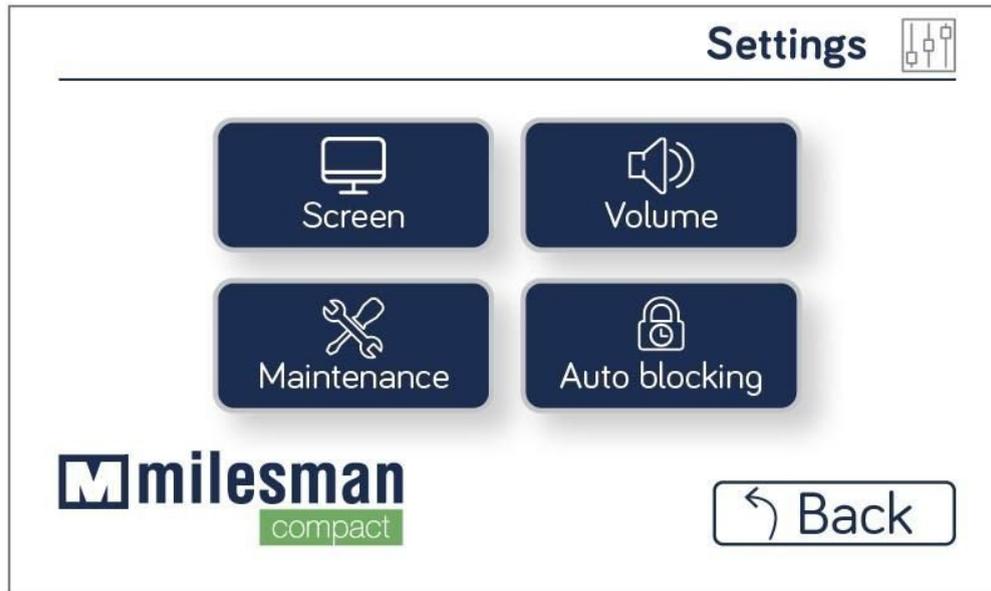
*! The presetting mode is a SUGGESTED parameter and in NO CASE means that these are the 100% right parameters. The Operator is fully responsible for the results of the treatment. In the event of the parameters suggested are too high or too low, it's recommended to access to the advanced mode and set the new parameters that the operator considers necessary.*

### 5.2.3. Settings



*Setting Screen*

Hereafter the following screen is shown:



*Settings Screen*

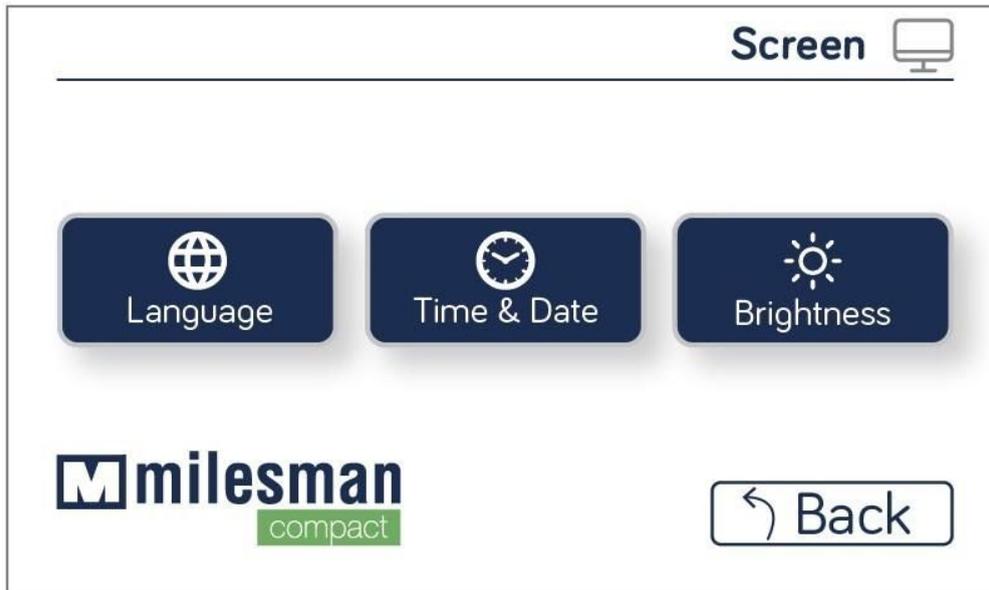
From that setting screen it's possible to access to the control of:

- **Screen** (languages, time and brightness)
- **Maintenance** Where it's possible to access the technical information of the laser such as the serial number, the factory counter of the fired shots, the amount of hours that the lasers have been firing, the amount of delivered Joules and the temperature of the cooling liquid.
- **Auto locked**, where it's set the number of seconds that has to pass from the last shot to the device gets automatically blocked.
- **Volume**, (disabled)

#### **5.2.3.1. Screen**

On the screen menu we can set the parameters related to the user interface.

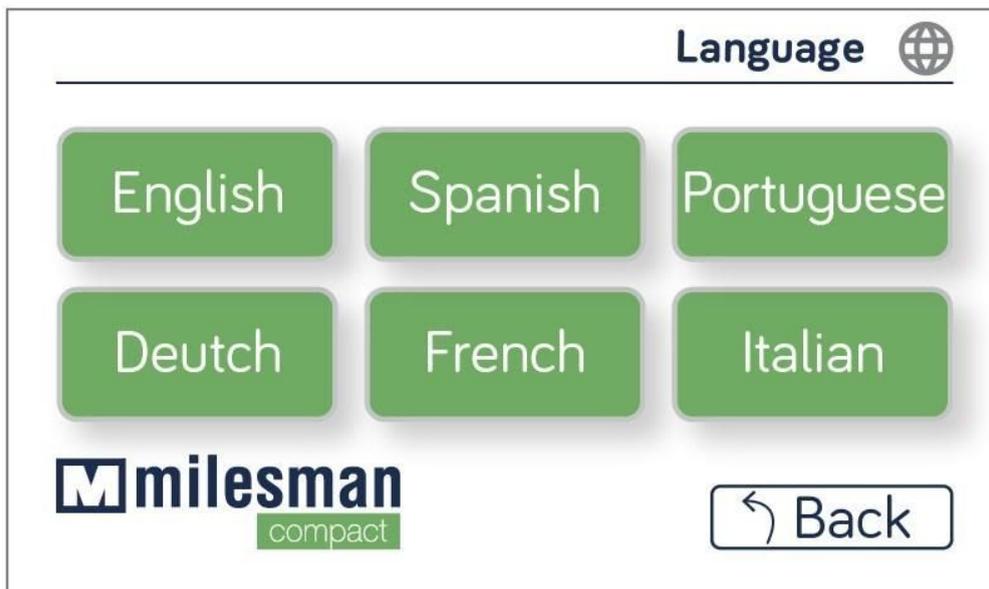
- **Language:** In this section it's possible to select among the languages that we want to see the parameters and the messages.
- **Time:** This screen is disabled since the time is preset internally
- **Brightness:** It's set the brightness of the screen



*Screen Settings*

#### **5.2.3.1.1. Language**

On the “language” icon the user can change the interface language. There are 6 different options: English, Spanish, Portuguese, Deutch, French and Italian.



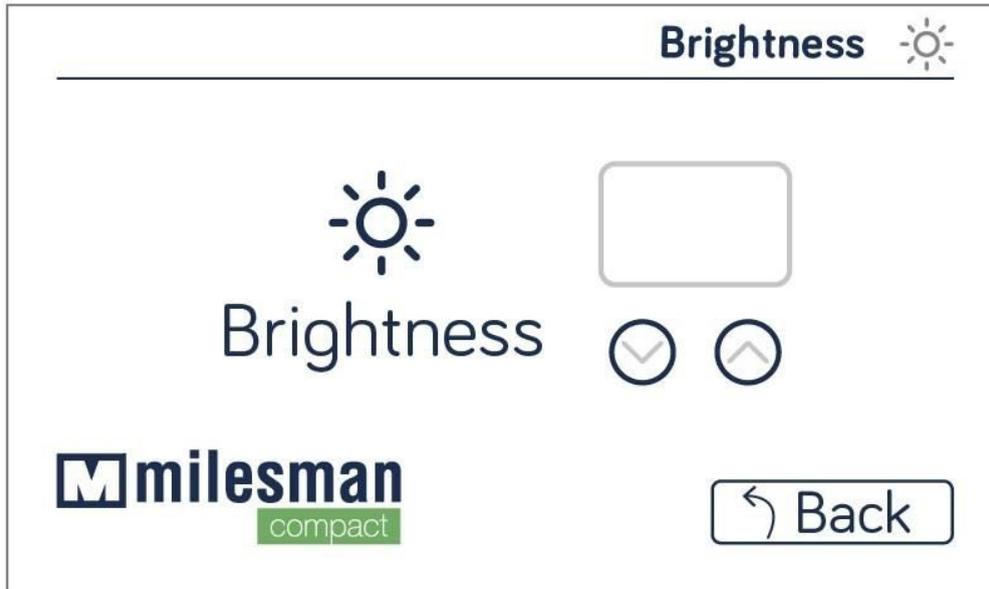
*Language Selection*

Once the button is pressed, you will be forwarded to the setting screen. From that moment every time the laser is switched on, it will be done with the selected language.

#### **5.2.3.1.2. Date and Time**

This screen is disabled since the time is preset internally.

### 5.2.3.1.3. Brightness

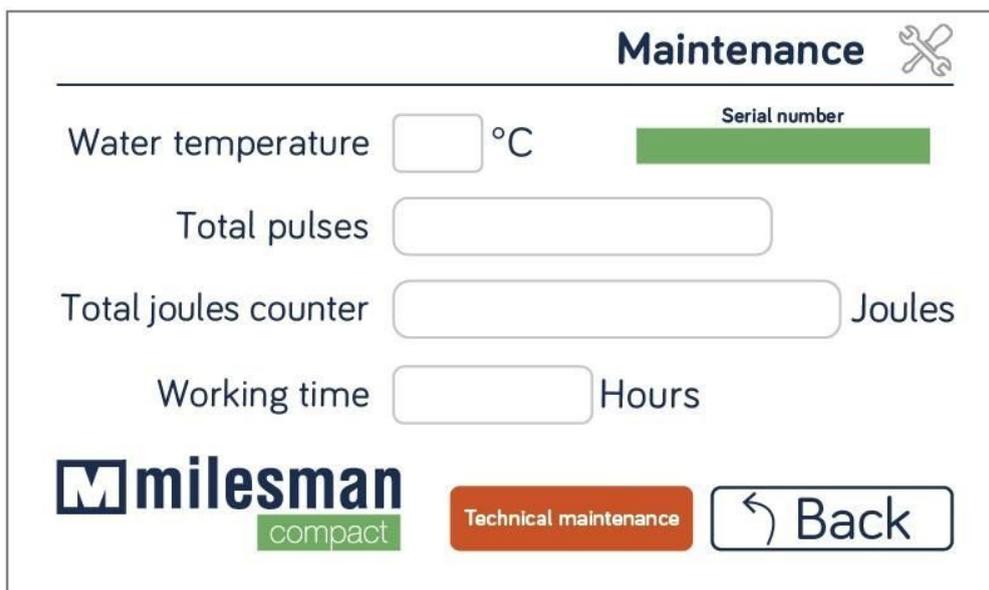


*Brightness Setting*

From this screen it's possible to set the brightness of the screen. Set the buttons + and – to increase or decrease the brightness. At the same moment you will see how the brightness changes on the screen.

### 5.2.3.2. Maintenance.

The maintenance screen shows very important information about the laser:



*Maintenance Screen*

- **Temperature of the water.** It's the temperature of the cooling circuit, it is usually between 20 and 30°C. In case it's higher the laser will automatically stop.
- **Total pulses.** It's the number of laser shots since the laser was manufactured. It's a factory counter that can't be reset.
- **Joule Counter.** In each shot an amount of joules per cm<sup>2</sup> are applied, this counter keeps the total amount of applied joules since the laser was manufactured.
- **Working time.** Every time a shot is fired, this has a duration (milliseconds). This counter counts the number of hours that the diode bars have been ON. As an example, in 1,000,000 shots at 20 milliseconds is equivalent to 20,000 seconds ON that is 5.5 hours.
- **Serial Number of the laser.**
- **Button to Access to the Maintenance Menu** for technicians, it requires an special password only permitted to the official technical service and it's to access to the advanced setting of the laser.

### 5.2.3.2.1. Default mode setting

The default mode offers suggestion on how to work the different combinations of skin color, hair color and hair thickness

It could happen that the factory suggested parameters are not the desired ones because they are too powerful or too light, that is why it is allowed to access a suggested parameter setting mode.

To access this screen, press the "technical maintenance" button and enter the code (request this code from the factory or the nearest distributor).

	Fine	Medium	Coarse
Blonde	100 calculated: 24J	99 calculated: 24J	98 calculated: 23J
Light	98 calculated: 24J	97 calculated: 24J	96 calculated: 23J
Brown	96 calculated: 23J	95 calculated: 23J	94 calculated: 22J
Black	94 calculated: 22J	93 calculated: 22J	92 calculated: 22J

Fluence: 24 J/cm²    Minimum power: 60%    Maximum power: 100%

Buttons: I, II, III, IV, V, VI, SAVE

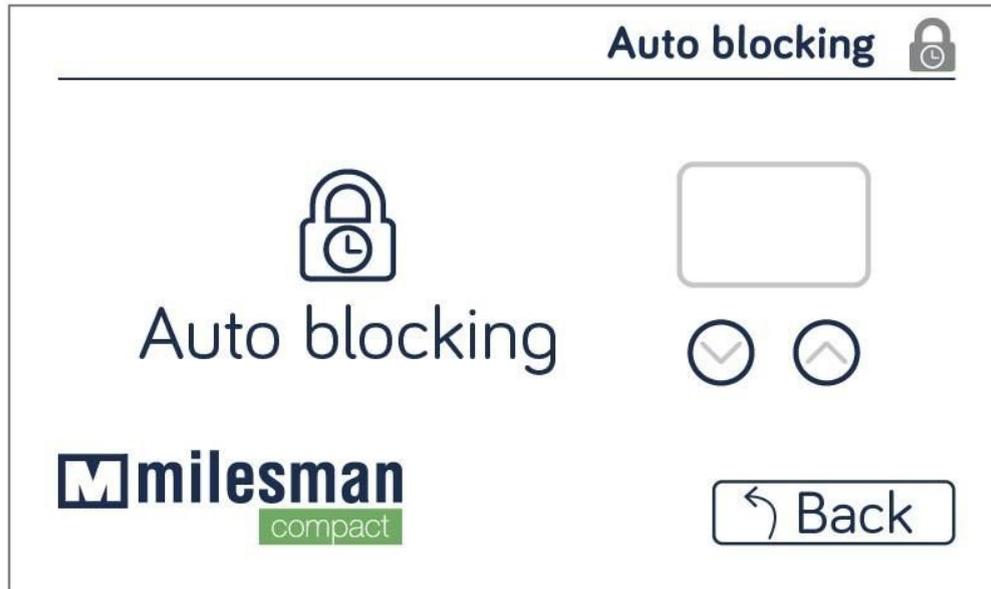
First it has to be decided the skin phototype in which you want to set the parameters

Energy density: It is the base energy density on which the rest of parameter are calculated:

- Minimum power

- Maximum power
- All combinations

### 5.2.3.3. Auto-block

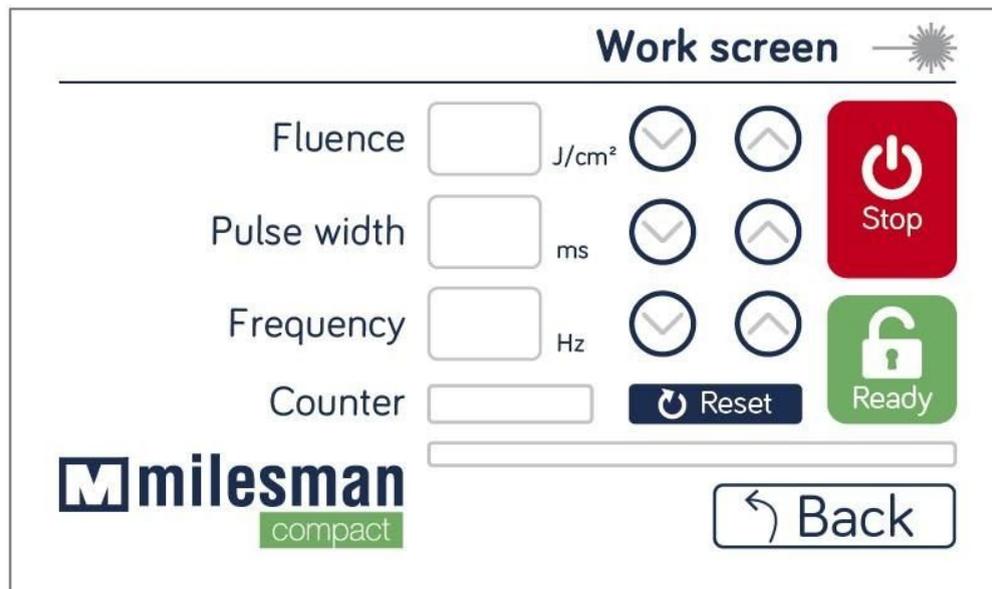


*Auto Blocking Setting*

With the aim of not unintentionally shooting when the laser is on “READY” mode, there is an option to automatically block the laser after a number of seconds or minutes since the last shot, changing to “BLOCKED” mode.

On this screen it's possible to set the number of seconds to pass since the last shot was fired, to automatically block the laser.

### 5.3. Work Screen



*Work Screen*

On the work screen the following parameters can be set:

- Fluence measured in  $J/cm^2$
- Pulswidth, measured in milliseconds (ms)
- Frequency or number of shots per second, measured in Hertz Hz.

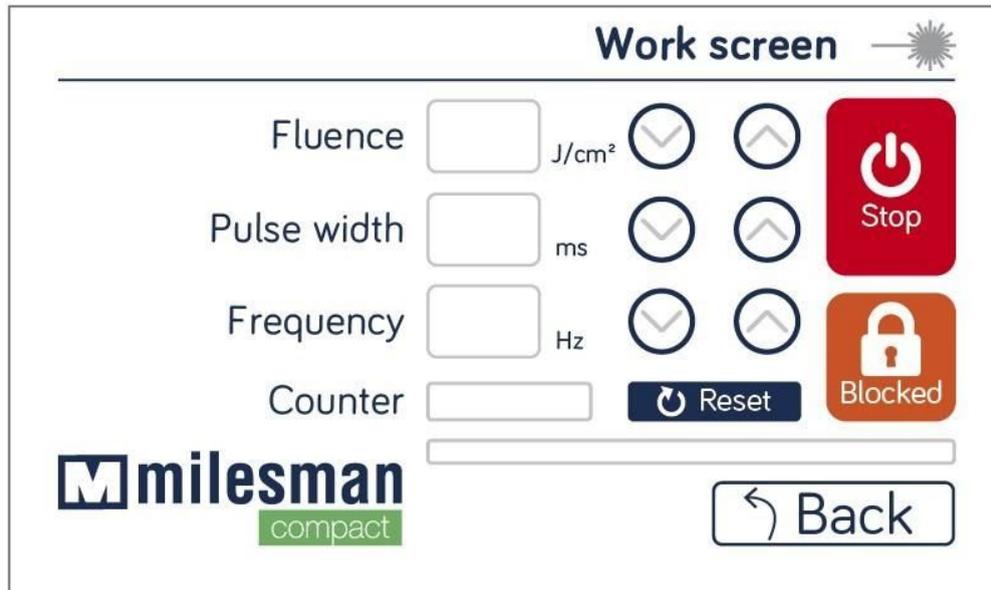
For those three parameters there are arrows to increase or decrease the values of these parameters.

When it's reached the maximum limit of one of these parameters that affects the other two, the affected one accordingly decreases. For instance, from an specific amount of fluence, the number of shots per second Hz, decreases

There is also a counter and a "reset" button. This counter is reset every time the laser is switched on and off and let's check out the number of shots that have been done during one treatment or during one day or since the last reset.

The STOP button is to stop the laser and to go out from the work mode screen to the initial screen.

The "READY" button indicated that the laser is ready to shoot just pressing the trigger or pressing the pedal. If the "READY" button is hit, it changes to "BLOCKED" and the laser can't fire even pressing the trigger or stepping on the foot pedal. To go back again to the "READY" mode the "BLOCKED" button has to be hit again. This button is to avoid unintentional shots.



*Work Screen Blocked*

*! It's possible to set the time from the last shot to make the laser get automatically blocked. To do that go to Setting —> Auto block.*

Before starting to work check that the tip of the handpiece is cold.

#### **5.4. Switching off the laser**

Once the treatments have been finished, the laser has to be switched off. To do that, is that simple as switching off the main button on the rear of the device.

## **6. ABOUT the TREATMENT**

### **6.1. Instructions for use**

The purpose of the Milesman Compact diode laser equipment is permanent hair reduction, stable and long-term or permanent hair loss through selective application to melanin of hair follicles.

The permanent decrease of the hair means a constant reduction and a long term of the quantity of hair that continues to grow after a period of application. The volume of hair that regrows should stabilize during a greater time than the completed growth cycle of the follicles pilous, which wavers between 4 and 12 months, depending on the zone of the body.

The permanent decrease of hair does not necessarily apply to the elimination of all the hair in the applied area.

### **6.2. Contraindications**

Patients who have had prior problems with laser therapy, should be carefully screened before treatment.

Additionally, persons known to form skin keloids may be more prone to scarring after any skin trauma, including laser treatment.

Laser hair removal should not be attempted in patients with active infections in the treatment site.

For hair removal or treatment of pseudofolliculitis barbae, caution is advised in treating patients with any of the following relative contraindications:

- A history of keloid scarring
- Active infection or a history of herpes simplex in the treatment area
- Use of depilatories or other hair removal treatments, such as waxing, plucking or electrolysis, within the preceding 6 weeks
- Hypersensitivity to hydroquinone or other bleaching agents, if applicable
- Use of oral Accutane (Isotretinoin) within the preceding 6 months

### **6.3. Precautions**

The darkest types of skin and people with bronzed skin have a larger probability of experimenting alterations of pigmentations in the treated area. The applications that are carried out in these people should have greater or smaller fluency during the pulse than those who have similar skin types but are not bronzed.

The alterations of pigmentation in the treated area can rise also in cause of the inadequate exposition to immediate sun after the session and during the following month.

Respect all safety precautions which are described in Chapter II just as in the rest of this manual.

Only the operator can start laser treatment after adequate and rigorous training and once accustomed with the safety of the laser and with the device.



The laser can cause thermal damages in the skin. The risk can be larger depending on the rise of the intensity of the laser and the type of skin pigmentation. Generally, as with the effectiveness of the session like the response of swelling before possible damages of the skin are linked with the density. With higher density levels, a greater effectiveness and a greater inflammatory response exist, which increases the probability of producing damages in the epidermis. For this, it is recommended to start the session with one degree of prudent exposure to go progressively enlarging the density until achieving the desired effects

#### **6.4. Possible complications and side effects**

The most common side effects are the reddening and the swelling that usually appear immediately after the laser session and that usually go away in 24 to 48 hours. Other possible side effects that depend on the density and type of skin can be the darkening or lightening of the skin.

Around 20% of the people treated presented temporary alterations in the pigmentation of the skin, which were healed in a period of 1 to 3 months; however, in some cases they lasted 12 months. It has not been observed nor described the appearance of scars or permanent pigmentation in any person.

Following, it is reproduced some minor complications observed in some users, reflected in the empirical studies of the diode equipment:

- Possibility that arises, after the session, superficial erosions of the treated area.
- Possibility of mild discomfort during the session that can be solved with the application of external calming creams. The use of local anaesthesia is very infrequent.
- Possibility that one to three days after the session mild bruises can appear in the exposed area.

#### **6.5. Treatment**

The maximum density of energy permitted usually is inversely proportional to the degree of pigmentation of the skin which can achieve with a long duration of a defined pulse. If the treated skin has a dark degree of pigmentation, the emission of the density of energy with a more prolonged pulse can decrease the heating in the epidermis.

According to the increasing of the maximum density of energy permitted, the density of energy decreases so that the skin does not absorb as much energy of the laser and consequently, does not overheat. The cooling of the skin does not allow the epidermis to rise

in temperature and this way achieves limiting the risk of possible lesions, above all in clients with darker or bronzed skin.



The eyelids, eyelashes and other delicate zones which are found in the osseous area that surrounds the eye socket should not be exposed to the laser light since it can cause ocular damage. To maximise the safety, the user should use permanent metallic protective eyewear during the facial sessions.

The results of the empirical studies have shown that the elimination of hair can be achieved with pulse duration between 5 and 30ms ms and a density of energy between 15 and 30 J/cm<sup>2</sup>.

These ratios were used in the way of simple pulse and were effective in some people when the degree of reappearance of hair 3 months after the treatment was defined. See Section 1.7 to obtain more empirical test details.

## **6.6. Previous information for the user**

Before the session, the operator should consult with the user and offer him all classes of information about the characteristics of the problem. The different treatment options, the risks, the advantages, the inconveniences, the possible complications and the foreseen results.

Likewise the operator should warn the client, if necessary, of the conveniences to carrying out various sessions.

## **6.7. Previous steps for the treatment**



It is important to verify that the skin is conveniently shaved before starting the treatment, since the hair in the present area can reach high temperatures by shooting the laser, which can have negative consequences for the skin like thermal damage. Once shaved, carefully clean the surface of the user's skin to erase any left over hair.

In the results of the empirical tests carried out by the diode laser equipment, the treated area used to be shaved and cleaned before the starting of the laser session. Shaving the skin has the objective to reduce the discomfort, now that it prevents the superficial hair absorbs the energy. As said, it is necessary to shave and meticulously cleanse the surface of the skin, since the visible hair can reach high temperatures while the laser is shot, this can have negative consequences for the epidermis like thermal damages.

Equally as said that, in general, it is counter-indicated the use of depilatory products or other methods of hair elimination, like wax, tweezers or electrolysis, six weeks before treatment. In the empirical tests there was evidence that in general, bleaching agents are not necessary, like for example hydroquinone, before the treatment.

By carrying out these previous steps, we are decreasing at least the risk of epidermal lesions, discomfort, smell and possible dirt.

## **6.8. Amount of energy to apply**

The diode laser equipment operates by three magnitudes: the frequency of pulses, the pulse length and the density of energy. In the present chapter the general characteristics about amount and doses are presented. Once again, we advise the users to exchange information with experimented professionals and that they search for scientific publications to reach a level of optimal and actualized knowledge.

### **General considerations**

The selective photothermolysis consists in making that one pigmented element or chromophore absorbs the energy of the laser that is emitted in pulses. This pigmented element has a greater optical absorption than the fabric that surrounds it, to a wavelength of the laser.

In producing the pulse, the radiant energy converts in heat into the treated element thanks to the absorption producing an increase of temperature. Initially, the heat stays condensed in the treated element, however, later it expands the surrounding fabric that is cooler.

Its conduction is more or less slow and with brief pulses, the treated element is on top of its thermal threshold and the surrounding fabric is maintained under this threshold. Therefore, a greater density of energy usually causes a greater heating, since it frees more optical energy towards the chromophore than it absorbs.

### **Skin Pigmentation**

The maximum density of energy permitted usually is inversely proportional to the degree of pigmentation of the skin which is achieved with a long duration of a defined pulse. According to the increasing of the maximum density of energy permitted, the density of energy decreases so that the skin does not absorb as much energy as the laser and consequently, does not overheat.

If the treated skin has a dark degree of pigmentation, the emission of the density of energy with a more prolonged pulse can decrease the heating in the epidermis. The cooling of the skin does not allow the epidermis to rise in temperature and this way achieves limiting the risk of possible lesions, above all in users with darker or bronzed skin.

### **Pigmentation of the hair**

The color of the hair influences the minimum density of energy that needs to be available to achieve an effective elimination of itself. In the case of users with blonde hair, generally a longer density of energy is needed to reach the same results, since this type of light hair contains little melanin.

On the other side, the hair diameter influences the pulse duration and usually its correlation. With fine hair, a minor pulse duration is usually sufficient; on the contrary, with thick hair, greater pulse durations are required.

## **6.9. Cooling of the skin**

By way of conductive cooling in the skin, the cooling tip of the hand piece is capable of increasing the tolerated density, since it decreases the accumulated heat in the epidermis and produces a partial relief.

It is very recommendable cooling the skin for all types of users, above all for those that have dark or bronzed skin, since their epidermis absorbs more laser energy than other users with lighter skin.

## **6.10. Placement of the hand piece and proceeding of use**

In general, the hand piece is handled with a technique of “remove and place” or to “slide”. In the case of the hair elimination, the tip is placed in contact with the skin, applying a light pressure to fix good contact.

The next step is to shoot the laser. For the skin to adequately cool, the cooled sapphire tip should remain in contact with the skin during approximately from 1/10 to 1/4 of a second before the pulse.

- With the “remove and place” formula, the tip separates the skin after the pulse, to continue placing it in the following position and re-enter contact with the skin.
- With the “slide” formula, the tip is supported in the skin continually and it slides until the next treatment position once the laser pulse is generated. It is a convenient use of an active gel which facilitates the application of the laser.
- With the “sweeping” formula, the tip is supported in the skin continually and it slides back and forth several times (4-5) delivering many short shots at low fluence each one.

It is a convenient use of an active gel which facilitates the application of the laser.



Before the emission of the laser, it is important to support the instrument on the skin. The formula of repeated pulses only should be used by expert users, since it requires a handling technique of the hand piece to guarantee an adequate contact of the tip with the skin before producing the emission.



The eyelids, eyelashes and other delicate zones which are found in the osseous area that surrounds the eye socket should not be exposed to the laser light since it can cause ocular damage. To maximise the safety, the user should use permanent metallic protective eyewear during the facial sessions.

## **6.11. Post treatment cautions**

It's recommended a moisturizing cream following a laser treatment, and also the recommendation for the user was that they carefully clean the treated areas two times a day. Likewise, it was recommended to the user's that they apply a sun protector SPF 30 before going outside besides not exposing themselves to excess sun to prevent the risk of bronzing the skin.

This procedure will be continued during the days following the treatment until the skin is completely normalized.

# 7. MAINTENANCE AND DETECTION OF BREAKDOWNS

The user of the diode laser equipment only can carry out one unique maintenance operation which is the frequent and periodical cleaning of: the handpiece tip and the tactile screen.

It is recommendable that you revise and verify once a year the internal energy meter so that an optimal performance can be offered.

This task can be carried out by an authorized technician or could also be done at the factory, which necessarily implies the returning of the equipment. If the diode laser equipment were to give some problem or if it did not work adequately, consult the fast Guide of detection of breakdowns. In the case that the problem persists, go to the Customer Service. Remember that the user cannot carry out the technical service of any component; all the maintenance and repairing operations must be executed by the factory or by professional experts of the authorized technical service.



The external protection casings should be unchanging; the opening of some of them, except the insert of the calibration port, can produce some of these inconveniences and damages: exposition to optical radiations and dangerous electronic voltages, even once the laser is turned off, deteriorations in the machine, possibility of losing the guarantee.

The operations of the technical service and repairing only can be executed by experienced technicians and authorized people for the equipment.

## 7.1. *Cleaning of the handpiece tip*



During treatments it is important to regularly clean the handpiece. When the hair shaft gets carbonized, it leaves debris on the sapphire window. This build up can make it hot and can make it difficult for the laser light to penetrate and could cause damages in the epidermis and discomfort.

Cleaning the handpiece with alcohol prevents this barrier from forming. There is a small risk of infection because the handpiece is in direct contact with the skin. Therefore, between patients the handpiece should be disinfected with a liquid disinfectant such as Virex®.

Do not apply the disinfectant solution directly to the handpiece. Instead, apply a small amount of disinfectant to a clean cloth and use it to wipe the handpiece. Dry the handpiece with another clean cloth.



While the user's treatment is being carried out, the sapphire tip of the hand piece should maintain clean. If any strange substance or residue were to stay on the tip,

it could overheat by effect of the laser light and cause damages in the epidermis besides discomfort.

## **7.2. Cleaning of the screen**

Routinely clean the tactile screen to maintain it in a perfect state. Be careful with the use of grease, treatment gel or any other contaminating product on the screen because it can produce pressure on the buttons of the interface of the user and consequently that the density continues increasing even though the operator does not continue pressing the tactile screen. For this, it is not recommendable using contaminating products on the tactile screen.



Do not use abrasive cleaners or products for the cleaning of the screen because it can cause damage.



Also do not pulverize, spill or wet with any liquid or cleaning product the handpiece, central unit or tactile screen since it can cause imperfections or accidents in the equipment.



It is important to deactivate the equipment before proceeding to clean the tactile screen

## **7.3. Cleaning the central unit**

Routinely clean the exterior parts of the lasers central unit with a wet cloth and moist-ened with some cleaning substance like alcohol, distilled water, Cavicide® or Virex®. To continue, dry the surface with a clean cloth.



Also do not pulverize, spill or wet with any liquid or cleaning product the handpiece, central unit or tactile screen since it can cause imperfections or accidents in the equipment.

## **7.4. Calibration**

It is recommendable to revise and verify once a year the energy calibrator interior so that it offers an optimum performance. This job can be done either by an authorized professional of the technical service or by the factory, which can necessarily imply the returning of the equipment.

## **7.5. Breakdown detection guide**

Hereafter the most frequent faults:

### **7.5.1. If the laser does not turn on**

Carry out the following tests:

- That the AC power cable is completely and firmly inserted into the power outlet of the rear panel and in the power outlet of the wall.
- That the main power cable of the rear panel is “on”.
- That Emergency button is not pressed. To put the system in function again, just turn the button towards the right until it lifts again.

If the problem persists, go to the Customer Service.

### ***7.5.2. If the laser does not properly work***

Such as defined during the calibration, the laser cannot emit the maximum density of energy. Meticulously clean the handpiece tip.

If the density of energy is not sufficiently reached for the treatment, go to the Customer Service

### ***7.5.3. If the laser does not fire***

The laser can only be shot if it is in the “READY” function. If it shows the function “READY” and we press the handpiece trigger or the footswitch and the laser does not emit a shot, go to the Customer Service.

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## 9. TECHNICAL SPECIFICATIONS

### 9.1 Technical Sheet

<b>Laser</b>	<b>Milesman Compact</b>
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
<b>Recommended power supply</b>	
Voltage, frequency, current	100 – 240V. 50 – 60 Hz, 12 A
Connection to public main	Single phase grounded outlet
<b>Classification</b>	
Eye risk nominal distance	164 ft - 50 m
Protective glasses	Optical density at 790 – 830 nm ≥ 5
<b>Physical parameters</b>	
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
<b>Environmental conditions</b>	
Temperature, humidity, pressure	60 – 80°F, 0 - 70%, 13 – 16 psi 15 – 30°C, 0 – 70%, 90 – 110 kPa
<b>Classifications</b>	
FDA Classification	Class II Laser
CDRH Classification	Class IV Laser
MDD Classification	II B
Classification according EN 60825-1 norm	4
Operation Classification	INTERMITTENT

### 9.2 Norms

<b>Electrical tests</b>	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
<b>Safety</b>	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests except 8.2, 8.3, 8.4
<b>Safety of laser</b>	IEC 60825-1:2014 (EN60825-1:2014 / UNE-EN 60825-1:2015) Safety of laser products - Part 1: Equipment classification and requirements
<b>Safety of laser</b>	IEC 60601-2-22:2007 (EN 60601-2-22:2013 / UNE 60601-2-

	22:2014) Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
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## 10. MANUFACTURER



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## **WARRANTY**

This equipment is only repairable by the manufacturer.

This equipment is guaranteed for ONE year against any manufacturing defect from the date of purchase.

During this period the manufacturer will repair the equipment at no charge to the customer and in a reasonable time.

### **THIS WARRANTY DOES NOT COVER:**

- The expenses accrued for the transportation of the equipment, which will always be at the customer's expense.
- Accessories (except manufacturing defects) and consumables.
- Damage due to hits, falls, faults in the electrical installation, negligence, incorrect use and / or improper use of the device or improper use as detailed in General Warnings.
- Any other failure that does not result from a defect in manufacturing or workmanship.

### **THIS WARRANTY IS VOID BY:**

- Handling or removing guarantee seals.
- Manipulation of the equipment by anyone outside our technical service.
- Use of accessories that are not original.



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