



## USER MANUAL

Blue laser 450 nm

Permanent removal of fibromas, soft tissues and skin benign lesions

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# 1 PRELIMINARIES

## 1.1 General Definition

Milesman Blauman is conceived and designed for the definitive removal of fibromas, soft tissues, and benign lesions from the skin through the emission of a 450 nm blue beam in impulses mode.

This advanced system is based in the technology of the diode laser of the latest generation and offers a number of advantages. The main characteristic and one of its multiple qualities is an optimum combination of a favorable wavelength and some excellent characteristics of impulse, with a compact and easy design that permits carrying out with confidence and comfort all the treatments for those that are designed and controlled the whole process through a tactile screen, in a way that the foreseen results are guaranteed.

Milesman Blauman (see figure 1) is configured by a central unit, a pedal, a power cable and a hand piece connected to the central unit through a cable.

Generally and in a standardized use, the handpiece is placed on the users skin and emits a light impulse once the pedal is pressed down. The screen, which is placed in the front part of the central unit, permits controlling the functions of the laser exit and other characteristics in the system. Milesman Blauman connects without difficulty taking an external AC power.

The fundamental method of the Blauman diode laser is based on the selective photothermolysis. Through this procedure, it is possible to eliminate the vascularized tissues and benign lesions by way of a laser light of 450 nanometers that penetrates very little into the dermis. The oxyhemoglobin of the lesion absorbs the energy emitted by the light, which produces a rapid heating of the lesion and consequently, its degeneration.

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 Blauman.



CAUTION

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



Figure 1

## 1.2 User Training

Milesman Blauman can only be used by adequately trained professionals in the handling and secure use of the system

Besides a 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 European 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

Blauman is a blue diode laser intended to remove benign lesions, soft tissues and little fibromas.

Fibromas are benign tumors that are composed of fibrous or connective tissue. They can grow in all organs.

In the oral medicine and dermatology it's usual small surgeries, including the excisional biopsy of benign lesions.

The blue laser does not work through water absorption but rather on the absorption of melanin and hemoglobin chromophores.

This specific feature allows obtaining specific advantages in the surgical field: absence of bleeding during surgery, with optimum visibility of the operating field.

## **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.

Treatment should not be attempted in patients with active infections (herpex) or open wounds in the treatment site.

## **1.5 Warnings**

Observe all safety precautions described in this manual.

## **1.6 Precautions**

Respect all safety precautions which are described in 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.

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 power 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 the efficacy of removing fibromas, soft tissues and benign lesions in just one session.

## **1.8 Possible complications and side effects**

The most common side effects are redness and swelling that usually appear immediately after the laser session and that usually go away in 24 to 48 hours.

As the treatment consists in a controlled removal of the lesion, after the treatment there will be a healing process and a crust will appear 48h after the treatment. The size of the crust will be exactly the same as the treated lesion.

The crust will last between 2 and 6 weeks and immediately after, when it comes off, the new skin will be slightly lighter, and will be pigmented in contact with the sunlight.

It might be a temporary alteration in the repigmentation process of the skin, becoming lighter or darker. This alteration might last 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 Milesman Blauman:

- 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.



**DANGER**

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.



**CAUTION**

Signals a potentially dangerous situation that could produce damage in the equipment.



**USE PROTECTIVE EYEWEAR**

Signals that everyone in the room must use protective eyewear.



# 2 SAFETY INDICATIONS AND RULES

## 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 Milesman Blauman.

Also, all the users of Milesman Blauman 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 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 Milesman Blauman.

Consult chapter 1.2 of this manual to expand on the information or contact the Attention to the client service.

The user of Milesman Blauman 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



Milesman Blauman 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 Milesman method of 430 to 470 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 Milesman equipment a remote interlock deposit 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 Attention to the client 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 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.

### **2.2.1 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 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 Milesman, of 430 to 470 nanometers. Except for the USA users, the correct standard can be the EN 207, in which case 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**

Only the authorized technicians and those trained for the Milesman 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 equipments 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 Milesman equipment.



If the external casing were to open, a damaging exposition to the optical radiation and electrical voltages could be triggered off, even after unplugging the laser. Only the authorized technicians and those trained for the Milesman 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 Milesman Blauman 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.



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

## **2.5 Safety components**

Milesman Blauman has been conceived with a design that results in 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, Milesman Blauman 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:

#### **2.5.1.1 Energy control**

Checks that the laser emission is found in the specific energy ratios for every laser impulse. 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.

#### **2.5.1.2 Remote interlock**

It's intended to avoid damage of 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.

### **2.5.2 Pedal**

The energy of the laser only flows out if the pedal is pressed which prevents the possibility of involuntary emissions.

### **2.5.3 Resounding emission signal**

Each laser impulse has a resounding signal with the purpose of indicating the operator the emission of the laser and increases the safety. For this, do not try to decrease the volume or deactivate the emission signal. 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 re-establish to its correct functioning.

### **2.5.4 Electronic lock.**

With the aim being to carry out the international safety regulations, Milesman Blauman is equipped with an electronic lock that does not permit the laser to function in an accidental way. This mechanism is a kind of electronic switch situated in the central unit that can be found joined or independent to the normal energy circuit for laser impulses.

### **2.5.5 Emergency stop button. Main Button**

The laser emission immediately stops when the pressure is taken off the pedal. In the case of an emergency, the possibility exists of stopping by way of the emergency button which is situated on the front side of the central unit.

### **2.5.6 Power supply design**

The power supply is external and is CE marked what allow a wide range of safety and more isolation of the general supply system for the patient and for the user too.

## **2.6 Central unit indicators**

The Milesman Blauman unit has informative labels and advertising in various places, completing as with all the requirements of the national and international regulation organizations.

Following the mentioned labels are reproduced and specified in Figures 2 and 3.

Laser opening label close to the handpiece tip:



Figure 2

The first screen that is shown immediately after switching on the laser warns about the laser type.

# WARNING

This device emits blue light that could be harmful to the naked eye.  
Please wear blue spectrum protective glasses when operating the device.

LASER RADIATION  
AVOID EYE OR SKIN EXPOSURE  
TO DIRECT OR SCATTERED RADIATION  
CLASS 4 LASER PRODUCT 450nm +/-10nm 50w

**Accept**

Figure 3

The legal description of the laser is contained on the rear side of the unit

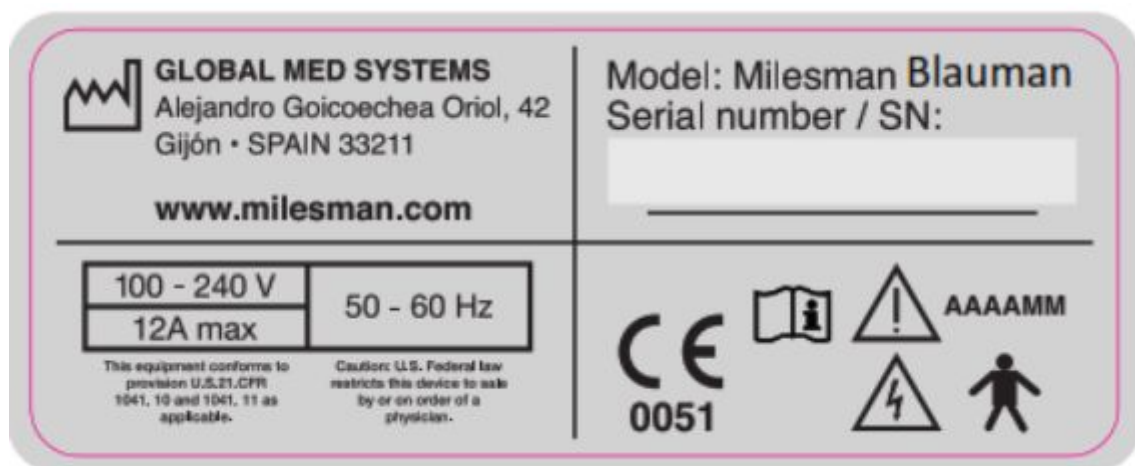


Figure 4

# 3 DESCRIPTION OF THE EQUIPMENT

## 3.1 Generalities

The Milesman Blauman is based in the laser technology of diode and produces blue light impulses used to remove benign lesions from the skin. The components of the system are: a central unit, a pedal, a power cable and a hand piece connected to the central unit with a cable.

The laser light emerges from the diode laser array through a sapphire handpiece. 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 front side of the central unit.

Like in all impulse laser systems, the Milesman Blauman laser device generates a constant and monochromatic light impulse that respects some parameters determined by wavelength. The wavelength is approximately 450 nanometers in the blue spectrum area.

The characteristics of the most represented pulse for the previous applications are:

- Pulse length, in this manual are measured in milliseconds
- Power, measured in watts, which means, the quantity of optical energy per second applied in a concrete area in the skin. The power 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 impulses 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 main unit (see Figure 5) is made up by a circular casing with the following parts:

#### 3.2.1.1 Main power button

This button works as a button for turning the system on and off. It acts as well as an emergency button.

#### 3.2.1.3 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 on it.

To guarantee correct functioning of the screen it is necessary to routinely clean, such as indicated in chapter 7. 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 user interface and consequently that the power 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





Figure 5: Front view

### 3.2.2 Rear part

The rear part of the main unit has the following elements (see Figure 6):

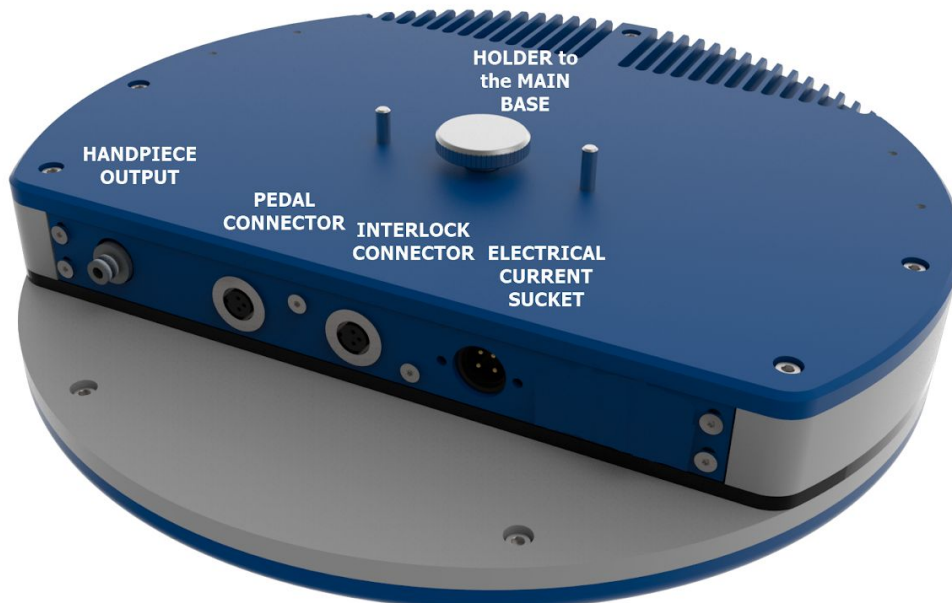


Figure 6: rear view of the unit

### **3.2.2.1 Ventilation grills**

The main 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.

### **3.2.2.2 Fastening Pin**

The fastening Pin lets the laser to be fastened on a wall or a base

### **3.2.2.3 Socket for the electrical current cable**

The laser 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.

### **3.2.2.4 Remote interlock**

The interlock allows detecting if a door of the room is open.

It is a safety measure that protects against accidental access of someone not related to the laser treatment without 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.

### **3.2.2.5 Plug in for the pedal**

This plug in, in the front part permits inserting the pedal cable. To turn it on, firmly press the pedal cable in the socket and to disconnect, hold the pedal cable close to the main unit and extract the socket tube. To avoid any danger, the pedal is electric

## **3.3 The pedal**

The pedal connects to the rear part of the main unit such as described. When the system is working, the pedal is the element controlling the laser shooting to enable the laser to emit. The pedal is also responsible for controlling the electronic lock, so that it is only open if the pedal is pressed. To avoid any danger the pedal is neumatic.

## **3.4 Handpiece**

The handpiece has a size of 0.3 mm x 0.1mm

Figure 7. Hand piece





# 4 INSTALLATION PROCESS

## 4.1 Installation

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

## 4.2 Previous exam

When receiving the Milesman Blauman, the first step is to observe the package and verify if any imperfection or damage has occurred. If it has any remarkable imperfections, communicate it to the transport company and contact Milesman Customer Care Service. It is advisable to let the machine at room temperature before carrying on installing it.

## 4.3 Unpacking

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

The box should contain the following items:

- 1 laser with a handpiece connected to the main unit
- 1 pedal
- 1 power supply
- 2 operator goggles
- 1 magnifying goggles
- Protecting foams that have to be stored for future shippings

## 4.4 Considerations in the installation to assure a right functioning of the device

Milesman Blauman has been tested to work without electromagnetic compatibility problems

Milesman Blauman needs special cautions regarding electromagnetic fields so that it has to be installed and put in motion according to the requirements supplied in this user manual.

### Warnings

- In case of one of the supplied accessories (pedal, cables, handpiece) need to be replaced always do it with original parts from Milesman.
- Using the device with other accessories different from the ones supplied by Milesman, might affect both emission and electromagnetic immunity causing an anomalous functioning of the laser and for other nearby devices.

The device functioning might be affected by the use of RF portable communication equipments and nearby cell phones.

Milesman Blauman is NOT waterproof

## ***4.5 Setting up and connection to the electrical network***

Follow these instructions for setting up:

1. Unpack the device as indicated in the previous chapter.
2. Place the Milesman Blauman on a table.
3. Find the connection to the pedal in the rear side of the main unit and connect the pedal enough so as to introduce it into the connector.
4. Find the power inlet in the rear part of the main unit.
5. Insert the AC power cable in the power inlet of the main unit. Pay attention to hear a “click” to assure that is properly connected. Connect the other side of the power cable to an electrical connection with an earth wire.
6. Press the main button located at the front part of the central unit. In this moment, you should be able to see the light of the touch screen.
7. From that point it's possible to work with the laser

If in doubt, please contact your local area representative or contact the milesman 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, it has to ensure that the protective eyewear are available to work with this device (see technical specifications) and all electrical connections are correct.

The next step is to **press the start button**, and the initial screen with milesman logo will show up.



Figure 9: start button

Immediately afterwards a laser warning, there is a screen to check the functioning of the pedal, and immediately after it will be shown a protection screen that needs a password. The password by defect is **1234**.

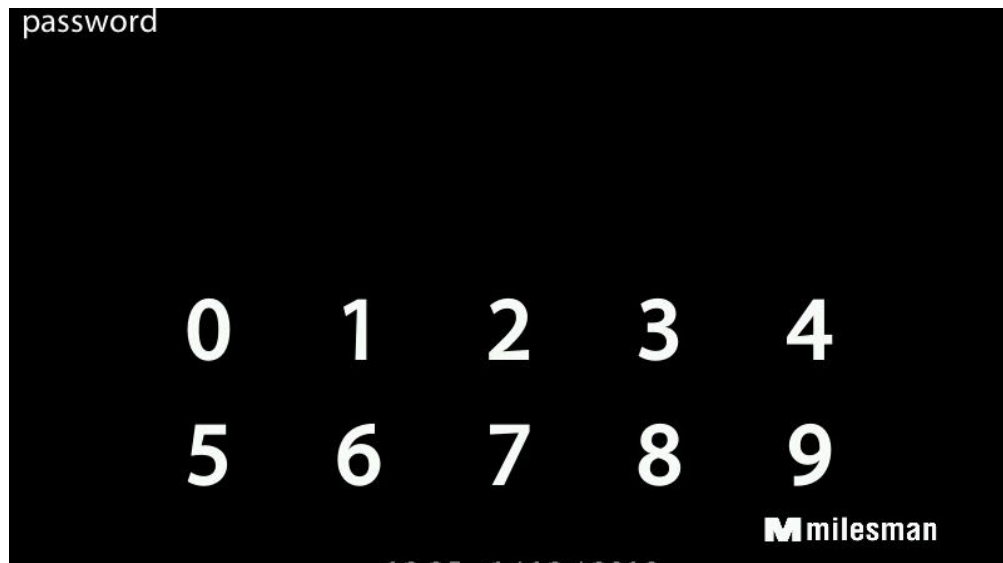


Figure 10

Once the password has been submitted the next screen is the home screen from where the main unit can be controlled (figure 11).



Figure 11

## 5.2 Actions on the setting screen

Once the device has been initialized the screen on figure 11 will be showed. From that moment the user can carry out the following actions:

- Start Working
- **Settings**, from where the user will be able to
  - Choose language
  - Access to the device info
  - Set the auto lock timing
- Lock, to return to the password screen.

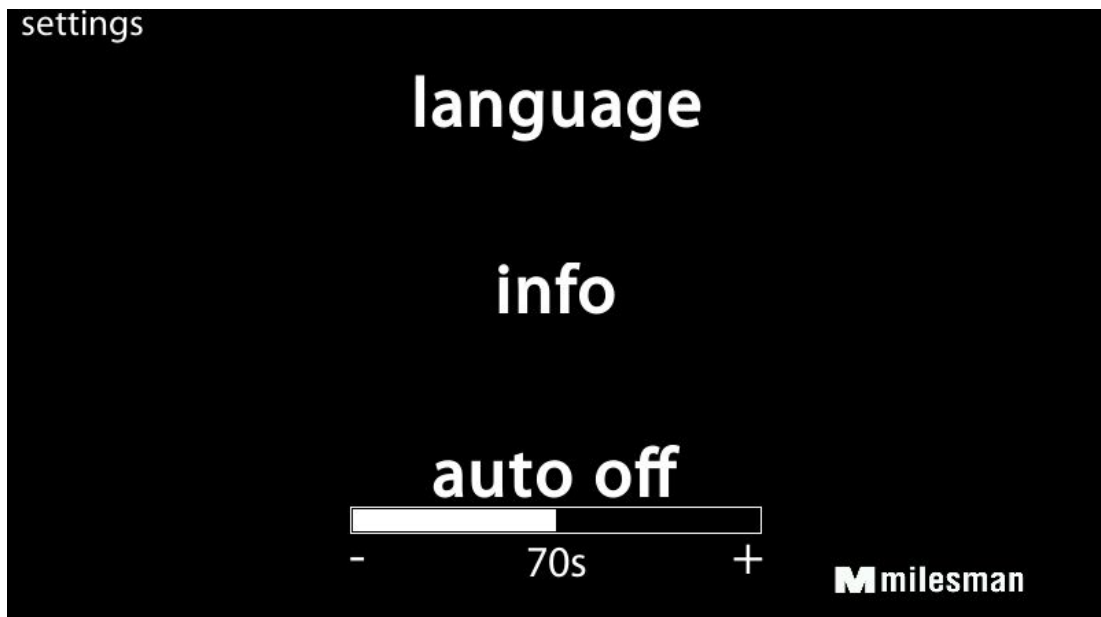


Figure 12

### 5.2.1 Language selection

Pressing “language” the user can change the language. There are 3 different languages Spanish, English and German.

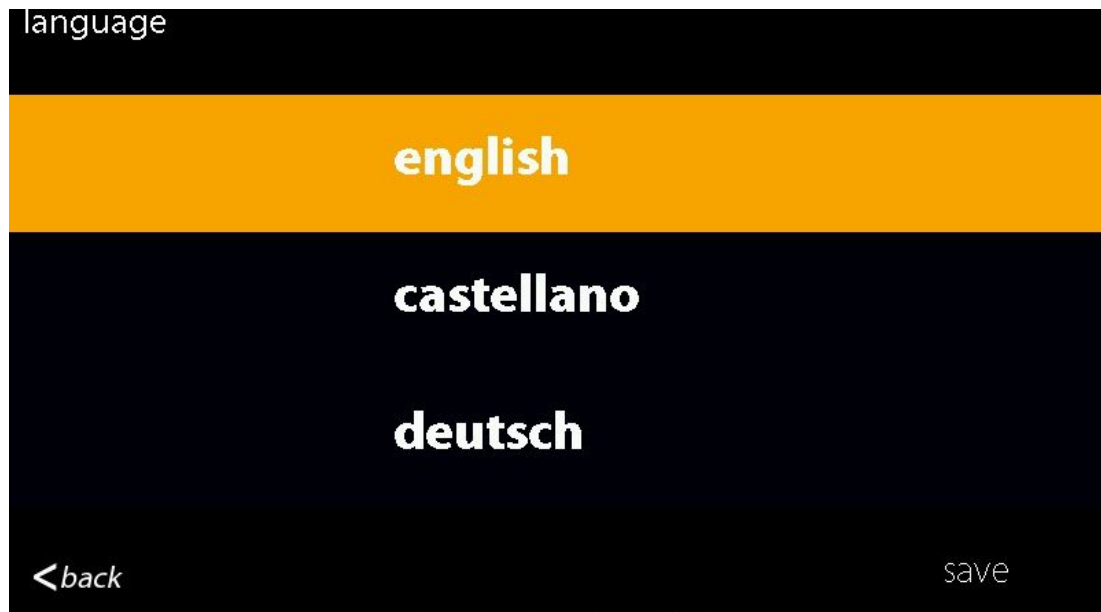


Figure 13

Once a language has been selected proceed to save and automatically the settings screen will be shown. Since that moment that language will be used every time the laser is switched on .

## 5.2.2 Device INFO

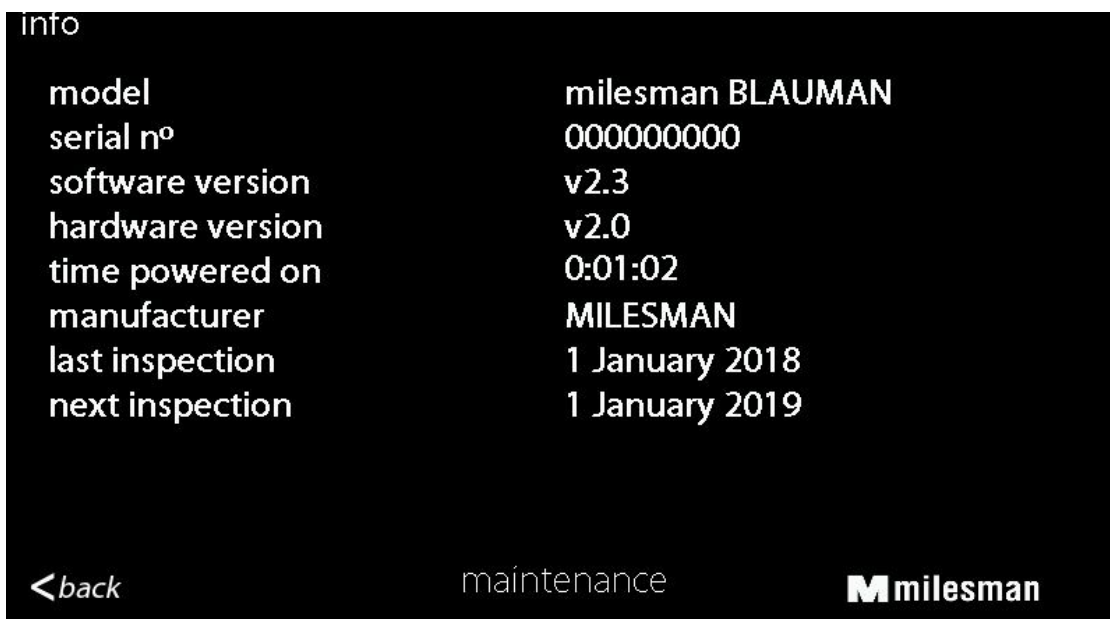


figure 14

## 5.2.3 Auto OFF

After a time without firing on “ready” mode the laser automatically switch to “standby” mode to avoid unwanted shots. Press buttons + or - to increase or reduce this time.

## 5.3 Working Screen

### 5.3.1 Access to work screen

To access the work screen press start

### 5.3.2 Treatment Screen Setting parameters

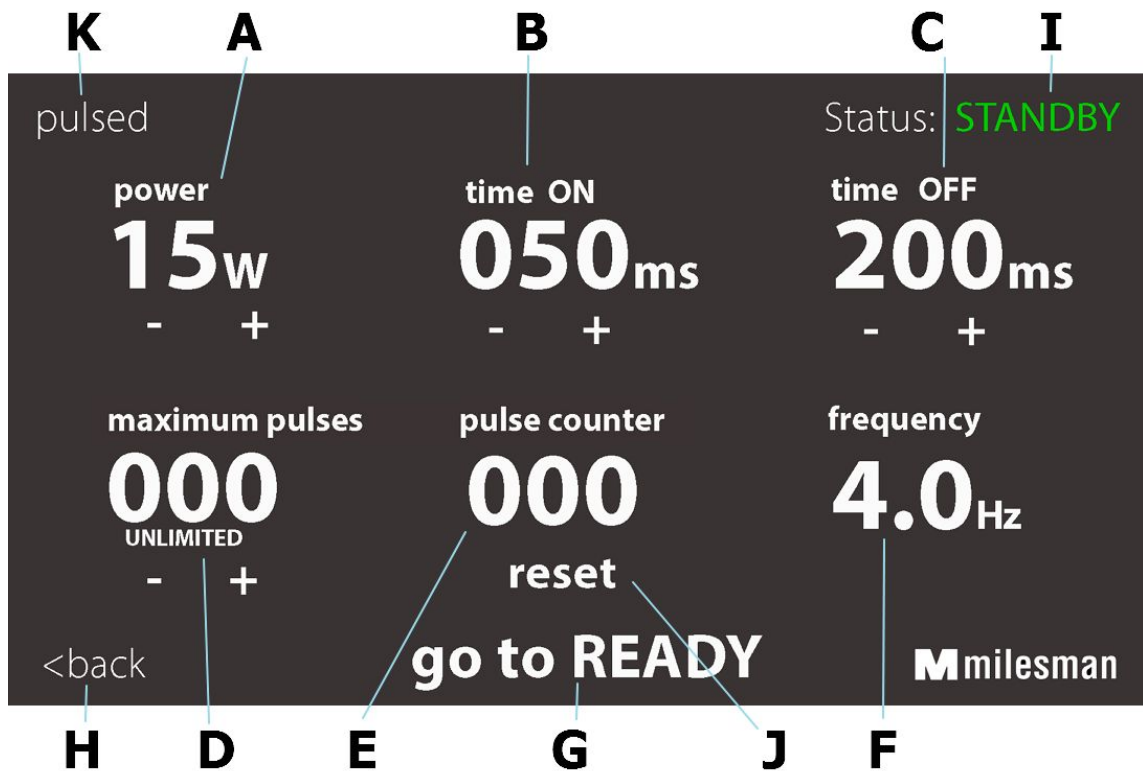


Figure 15.

#### 5.3.2.1 Buttons to increase or decrease the power of the treatment. (A)

Indicates delivered Watts. Watts can be varied at any moment except when the laser status is Ready.

#### 5.3.2.2 TIME ON Button (B)

Indicates the desired firing length in millisecond.

It can be varied at any moment except when the laser status is Ready.

Every time that the pulse length is varied the frequency (F) is automatically calculated.

#### 5.3.2.3 TIME OFF Button (C)

Indicates the desired resting length between shots in milliseconds .

It can be varied at any moment except when the laser status is Ready.

Every time that the pulse length is varied the frequency (F) is automatically calculated.

#### 5.3.2.4 Button to limit the maximum number of shots every time the pedal is stepped. (D)

It is possible to set the maximum number of shots every time that the pedal is stepped without releasing. The values ranges from 1 and 999.

It is also available the "000 UNLIMITED" option to deactivate the shot-limit.

It will be shown the "000 UNLIMITED" option by defect .

If the pedal kept stepped the device will release shots until the set limit is reached. When the pedal is released the counter comes back to zero.

#### 5.3.2.5 Partial shot counter (E)

Inform about the number of shots since the last time the reset button was pressed. (J)

#### 5.3.2.6 Shots per second information Hz. (F)

Calculate the frequency or number of shots per second considering the firing time (B) and the resting time between shots (C).

### 5.3.2.7 “go to READY” ó “go to STANDBY” (G)

It permits to change the laser status from “READY” to “STANDBY”:

- “READY”: indicates that all controls and temperatures are right and that the laser is ready to fire by only stepping on the pedal. In this status the screen colour is red.
- “STANDBY”: indicates that the laser is blocked and in a standby status therefore it is not possible to fire.

### 5.3.2.8 “BACK” BUTTON (H)

It lets to go back to the home screen

### 5.3.2.9 Current Device Status (I)

Indicates the current device status. It can be READY or STANDBY

### 5.3.2.10 Working mode (K)

Indicates that the device is in pulsed mode.

Once all the desired parameters are selected it is possible to change to “READY” mode by pressing “go to READY”. Immediately after pressing this button the back-screen changes to red.

## 5.3.3 Treatment Screen Working Mode

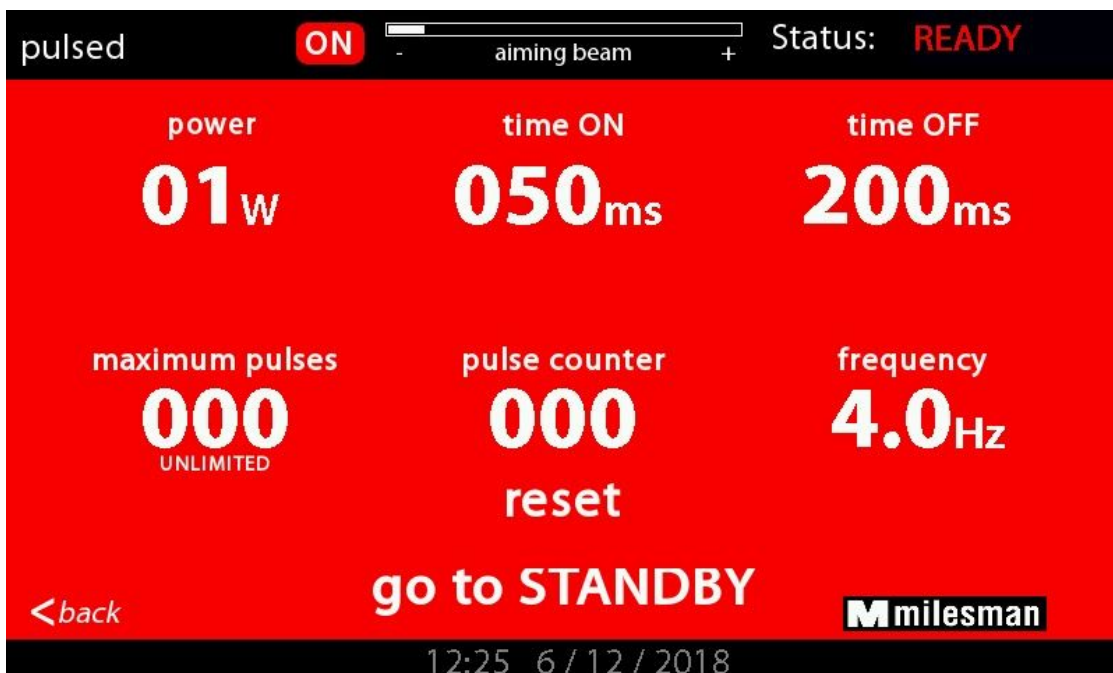


Figure 16

### 5.3.3.1 “go to READY” or “go to STANDBY”

It permits to switch the laser status from “READY” to “STANDBY”:

- “READY”: indicates that all controls and temperatures are right and that the laser is ready to fire by only stepping on the pedal. In this status the screen colour is red.
- “STANDBY”: indicates that the laser is blocked and in a standby status therefore it is not possible to fire.



### 5.3.3.2 Current Device Status (I)

Indicates the current device status. It can be READY or STANDBY

### 5.3.3.3 Working mode (E)

Indicates that the device is in pulsed mode.

Once all the desired parameters are selected it is possible to change to “READY” mode by pressing “go to READY”. Immediately after pressing this button the back-screen changes to red.

## 5.4 Device Switch off

To switch off the device press the ON/OFF button.



Figure 17

This button is also used as a “emergency stop” when laser is working.

# 6 USERS TREATMENT

## 6.1 Instructions for use

Blauman is a blue diode laser intended to remove benign lesions, soft tissues and little fibromas.

Fibromas are benign tumors that are composed of fibrous or connective tissue. They can grow in all organs.

In the oral medicine and dermatology it's usual small surgeries, including the excisional biopsy of benign lesions.

The blue laser does not work through water absorption but rather on the absorption of melanin and hemoglobin chromophores.

This specific feature allows obtaining specific advantages in the surgical field: absence of bleeding during surgery, with optimum visibility of the operating field.

## 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.

Treatment of leg veins, or treatment of benign pigmented lesions should not be attempted in patients with active infections in the treatment site.

For benign pigmented lesions, caution is advised in treating patients with any of the following relative contraindications:

- History of poor wound healing, keloid formation or bleeding disorders
- Active infection or a history of herpes simplex in the treatment area
- Hypersensitivity to hydroquinone or other bleaching agents, if applicable
- Use of oral Accutane (Isotretinoin) within the preceding 6 months
- Personal or family history of melanoma
- Dysplastic nevi
- Inability or unwillingness to follow the treatment schedule

## 6.3 Precautions

The alterations of pigmentation in the treated area can rise also in the 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 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 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:

- 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.
- the reddening and swelling that usually appear immediately after the laser session and that usually go away in 24 to 48 hours. Around 20% of the people treated presented
- temporary alterations in the pigmentation of the skin, after the healing process 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.

## **6.5 General Considerations about the treatment**



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.

## **6.6 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 inconvenience, 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 Power to apply**

Milesman Blauman operates by three magnitudes: the power, the pulse length, and the interval between shots

In the present chapter the general characteristics about amount and doses are presented. Once again, we advise the users to interchange information with experienced professionals and that they search for scientific publications to reach a level of optimal and actualized knowledge.

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 tissue 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 tissue 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 tissue is maintaining 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.

## **6.8 Placement of the hand piece and proceeding of use**

In general, the hand piece is handled placing it on the skin and using the red aiming beam to know where the blue beam will be fired. It is not necessary to use of an active gel to facilitate the application

of the laser.



PRECAUCIÓN

Before the emission of the laser, it is important to support the instrument on the 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.

## **6.9 Post treatment cautions**

Once the treatment has been performed it's advised to apply a moisturizing cream and not exposing the skin to sun unless a sun protection over SPF 50 is applied until the skin gets totally normalized.

# 7 MAINTENANCE AND DETECTION OF BREAKDOWNS

The user of Milesman Blauman only can carry out one unique maintenance operation which is the frequent and periodical cleaning of: the handpiece tip and the touch screen.

It is recommendable that you revise and verify once a year the complete system so that an optimal performance can be offered. This task can be occupied by an authorized professional technical service or could be also be done by the factory, which necessarily implies the return of the equipment. If Milesman Blauman 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 Attention to the client service. Remember that the user of the system cannot carry out the technical service of any component; all the maintenance and repairing operations must be executed by the factory or by the professional experts of the authorized technical service.



The external protection casings should be unchanging: the opening of some of them can produce some of these inconveniences and damages: exposition to optical radiations and dangerous electronic voltages, even once the laser is turned off, deterioration in the machine, the 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 Milesman equipment.

## 7.1 Cleaning of the handpiece tip

Once the treatment is finished, it is important to regularly clean the handpiece.

Cleaning the handpiece with alcohol prevents the laser does not correctly go out. There is a small risk of infection because the laser spacer 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.

## 7.2 Cleaning of the screen

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 power 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.



PRECAUCIÓN

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



PELIGRO

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.



**PELIGRO** It is important to deactivate the Milesman device before proceeding to clean the tactile screen.

## ***7.3 Cleaning the main unit***

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



**PELIGRO** 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 Breakdown detection guide***

### ***7.4.1 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 button is “on”. If the problem persists, go to the Attention to the client service.

### ***7.4.2 If the laser does not properly work***

Meticulously clean the handpiece tip. If the density of energy is not sufficiently reached for the treatment, go to the Attention to the client service.

### ***7.4.3 The laser does not shoot***

Check the footswitch is properly plugged. if even though it doesn't work go to Customer service.

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## 9 TECHNICAL SPECIFICATIONS

<b>Model</b>	<b>Milesman Blauman</b>
Type	Diode
Maximum power (average pulse power)	20 W
Nominal wavelength	450 nm
Pulse length	50 ms to 300 ms
Optical Window	focused between 0.50 and 30 mm
Beam divergence	20°C x 20°C nominal
<b>Recommended power supply</b>	
Voltage, frequency, current	100 – 240 V, 50 – 60 Hz, 12 A
Connection to public main	Single phase grounded outlet
<b>Classification</b>	
Eye risk nominal distance	50 m - 164 ft
<b>Protective glasses</b>	
Optical density at 430 – 470 nm	≥ 5
<b>Physical parameters</b>	
Central unit weight	2.2 Kg - 4.85 Lbs
Central unit size (Diameter)	25 cm - 9.8 in
Operating radius of cable	2 m - 78 in
<b>Environmental conditions</b>	
Temperature, humidity, pressure	15 – 30°C, 0 – 70%, 90 – 110 kPa 60 – 80°F, 0 - 70%, 13 – 16 psi
<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