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# USER MANUAL

# Description - introduction

This Guide contains references to important information for system operation as well as recommendations for best practices concerning selection, treatment, counselling, and care of patients being treated with the AgeJet system, and hence must be read by all operators prior to use of the AgeJet System.

It is intended to be a guide for use of the AgeJet system and is not a substitution for appropriate clinical training in aesthetic procedures and the pre- and post-treatment care of patients undergoing such procedures. The information presented in this Guide is derived from clinical studies and experience as well as 'best practice' from experienced users of Agejet and nitrogen plasma devices.

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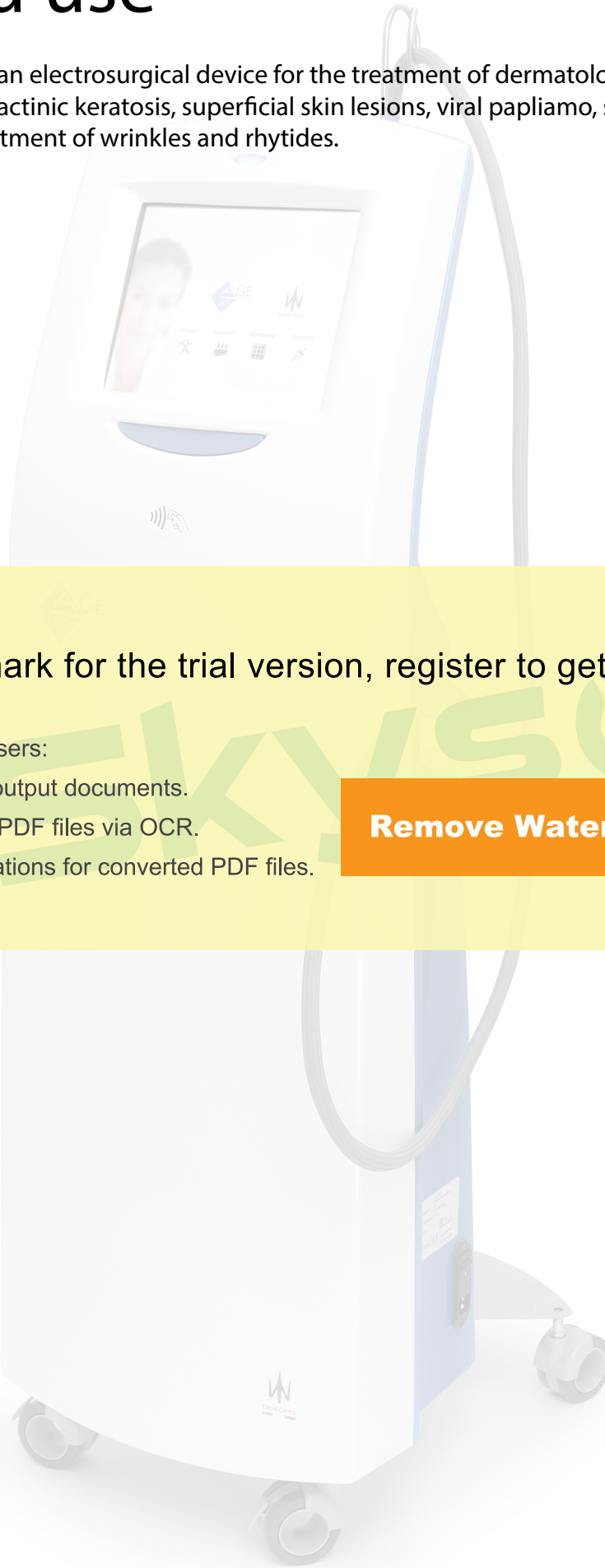
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# Intended use

The AgeJet system is an electrosurgical device for the treatment of dermatologic conditions including acne scars, actinic keratosis, superficial skin lesions, viral papilloma, seborrheic keratosis and the treatment of wrinkles and rhytides.



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# Device Description

The AgeJet system is an electrosurgical device intended for use in dermatological applications by qualified medical practitioners.

The AgeJet unit comprises of the following basic components.

1. Main body/Plasma generator
2. Handpiece/Cable assembly
3. Footswitch (pneumatic pedal)
4. Nitrogen gas cylinder

The Main body/Plasma generator (1) contains the power supply, the devices touch screen control panel, ON/OFF switch, attachment ports and handpiece. The main body also provides a secure storage area for the nitrogen gas cylinder. The device is powered via a standard 110/120VAC power cable which is connected to a suitable mains outlet. The main body allows the operator to control the device via a touchscreen and generates the power to create the plasma via the handpiece.

The handpiece (2) is comprised of a main body, interchangeable plasma output tip, stainless steel spacers and forced air outlet to cool the treatment area. The purpose of the handpiece

is to convert Radiofrequency (RF) energy from the device into plasma and function as an applicator and guide, delivering the energy to the skin. The plasma output tip is not held

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The pneumatic pedal (3) (250W A) Air switch serves for the activation of the plasma output allow the user to turn ON or turn OFF the output by pressing the switch.

The operating principle of the AgeJet device is based on the ionization of nitrogen gas. The ionization of a gas is a process for which a gas, initially neutral, is ionized by applying a strong electric field at high voltage inside it. The phenomenon of the electric discharge in the nitrogen gas leads to the dielectric breaking of the bonds of nitrogen isolation. The generator produces high-voltage pulses through a high-frequency sinusoidal oscillator that overcomes normal electrical isolation of nitrogen. The energy that flows from it, visible in the form of a strong glow, is called Plasma. The operator controls the energy via the devices touch screen keypad in increments of 0.25 joules. The treatment is achieved through controlled heating of the outer layers of the skin so that part or all the epidermis becomes non-viable and there is controlled thermal modification to the underlying dermis.

# Contraindications

Physicians should be trained in the techniques of non-surgical cosmetic treatments and the risks and complications associated with that treatment particularly in groups that might be considered to have concomitant diseases or taking medications that may affect the healing or outcome of treatment.

The use of the AgeJet System is contraindicated when, in the judgment of the physician, (or other medically qualified user), the procedure would be contrary to the best interest of the patient. Contraindications include:

Patients with keloid scars

Patient with pacemakers (internal or external) and other implanted medical devices

Patients affected by carcinomas or different types of neoplasm/neoplasia regarding every tissue, organ, apparatus, or body system.

Patients with compromised immune systems

Patients with active skin infections

Patients with skin inflammatory conditions, lesions, diseases, or disorders

Patients who have recently undergone a treatment of skin resurfacing

Pregnant women

Use of self-tanning products within 1 week of treatment.

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# Warnings



Risk of fire. Do not feed the AgeJet System with flammable gases. Only Nitrogen N2 medical grade gas (purity>99.99%) is allowed.



Combustible material. Keep away combustible materials, such as flammable gas, from the area of treatment.



Do not use in the presence of flammable anaesthetic or oxidizing gases (such as nitrous oxide (N2O) and oxygen) or near volatile solvents (such as ether or alcohol), as an explosion may occur.



Dangerous voltage. Do not insert fingers or other objects into the tip or in the handpiece, risk of burns from high RF power.

The device must only be used under the continuous supervision of qualified persons such as doctors.

The equipment should be only used in licensed practices and in compliance with all regulations in force.

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To avoid ineffective treatments DO NOT use the plasma generator nozzle or parts thereof after the advised use period. Use of the nozzle after the advised use period will increase the risk of ineffective treatment or injury to the patient may occur.

To prevent excessive treatments Do NOT repeatedly treat a single confined area of skin. Repeated plasma pulses confined to a small area of skin may cause hyperpigmentation where scarring may appear and healing time prolonged.

An erythema may be present for some weeks after treatment. Like for laser treatments, some side effects are normal.

Do NOT use the AgeJet system with an unsuitable power supply. Use the AgeJet system only with the power leads supplied and ensure they are correctly connected to a suitable grounded outlet. Failure to adhere to this may risk damage to the AgeJet system and has the potential for electrical fire.

Do NOT use the AgeJet system close to sources of water or where liquids may ingress into the system.



# Warnings

Do NOT attempt to use any other connectors other than those supplied with the system. Do NOT insert any other objects into any connection ports.

Do not leave the device closed in a hot or cold environment where temperatures could exceed the recommended storage temperatures and cause damage to the device.

Do not expose AGE JET to direct sunlight, the device can operate in the following environmental conditions: humidity 30-75% atmospheric pressure 700-106 hPa temperature 10 to 35° C.

It is an electro-medical device and requires special precautions regarding the EMC and must be installed and operated in accordance with the information contained in this manual . Please refer to section 5 Summary table of EMC test

Please note that portable and mobile radio equipment can affect the operation of the electro-medical device.

The device should not be used in proximity of other equipment or positioned on such devices. Please refer to section 5 Summary table of EMC test.

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TRIWORKS GROUP declares that all the parts and components that meet biological tissues are bio compatible and that the equipment is designed and manufactured in such a way as not to cause harmful effects for the health and hygiene of the user in terms of intended use.

It is absolutely forbidden to modify any of the parts, accessories, or spare parts of this device.

Periodic maintenance with regular intervals is recommended on handpieces to detect cracks and check the integrity of the cables and conductors.

Handpieces should not be used in combination with massages using pressurised water.

Handpieces should be handled with care so as not to have side effects from the treatment.

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# Symbols

The following symbols are present on the device:



Warning, see user manual.



Warning, presence of electromagnetic field.



Warning, dangerous voltage.



Electro-medical equipment (BF type) with floating part.



Alternating current (AC) symbol.



Grounding symbol.

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Product marketed in the European Community.



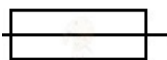
High.



Fragile, load and unload with care.



Store in a dry place.



Date of manufacture



Serial Number



Prescription only: caution: Federal law restricts this device to sale by or on the order of a physician.

# Symbols



Conformity to RAEE Directive



Refer to instruction's manual.



Manufacturer



## Product label

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**TRIWORKS GROUP srl**  
Via Don G. Mucciardi, 5  
86020 Campochiaro (CB)

**SN**

  
0011836000006



# Unpacking

1. Take the equipment out of the box.
2. Make sure no damage has occurred during shipping.
3. Make sure that the equipment is complete (please check the list below)

Power cable (length 2.5 m)



Handpiece

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Tip



# Unpacking

Handpiece holder with thermal sensor



Cylinder holder plate kit

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User Manual

If an accessory is missing or damaged, please contact your dealer. Do NOT attempt to repair any damaged component or accessory. Attempting to repair any damaged component or accessory will void the manufacturer's warranty and may lead to a risk of injury,

# Positioning

1. Do not expose AGE JET to direct sunlight; the device can operate in the following environmental conditions: humidity 30-75% atmospheric pressure 700-106 hPa temperature -40-75° C.
2. Maintain a safe distance from heating appliances.
3. Do not cover the ventilation grill.
4. Use a flat and stable base.
5. Do not place objects on the unit.
6. Do not spill liquids on or near the unit. If this happens, DO NOT turn on the unit, or if already on, turn it off immediately and consult one of the authorised TRIWORKS GROUP service centres.
7. It is advisable to keep AGE JET in a cool and dry place, to not overloading the heat exchanger

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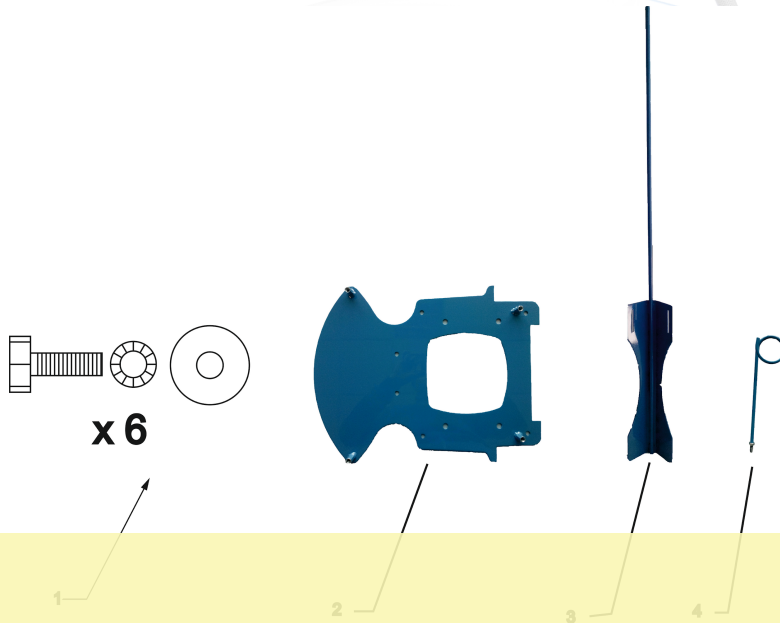
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# Installing cylinder holder

The cylinder holder kit is made up of the components in picture 1:



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Picture 1

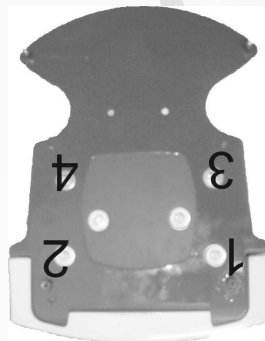
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Let the main body of the AgeJet system down on a table or flat surface with the front cover facing downward. Use a cloth between the surface/table and the device to avoid damaging the cover.

Attach the base plate (2) the plate to the bottom of the device and verify the correct position by following the profile and alignment of the four holes, while the access protrudes from the rear of the system., Use the 4-screw supplied, as shown in picture 2:

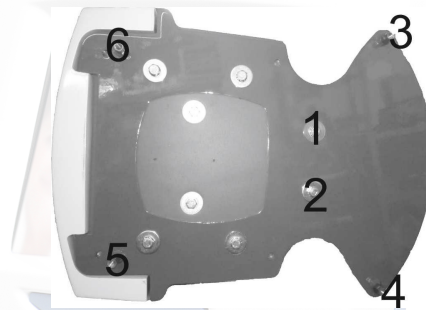


Picture 2



# Installing cylinder holder

Turn the device on one side and secure the cable holder shaft in points (1) and (2) and the castors in points (3), (4), (5) and (6) as reported in picture 3:



Picture 3

Put the device in an upright position. on the castors and screw the cable tray at the end of the cable holder shaft.

Before you tighten the cable tray, turn it so that the hole which houses the cable is directed towards the front of the unit and then tighten by hand the nut (1) as in

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Picture 4

# Important

1. Check that the network voltage and frequency of your electrical wiring is compatible with the voltage and frequency of your version of AGE JET (see plate on the back of the device).
2. Connect the power cable supplied in the cup on the right side of the unit.
3. Connect the handpiece and the pedal (see chapter Connections).
4. Mount the handpiece holder and connect the sensor on the rear panel.
5. To turn on the device, turn the switch to I.

The use of accessories, transducers, and cables other than those specified, except those sold by TRIWORKS GROUP as spare parts, may cause an increase in emissions and a malfunction of the unit.

Handpieces and tips for the treatment, such as spare parts, or replacements, can be provided only by TRIWORKS GROUP.

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# Device Description



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1. LED indicator unit (shown turned on/off)
2. Touch Screen display
3. RFID reader sensitive area
4. Pneumatic pedal
5. Cylinder holder holder plate
6. Handpiece
7. Handpiece holder
8. Nitrogen Gas Cylinder
9. Fairlead

Picture 5 shows all the AGE JET parts.

It is essential to follow the instructions and receive an adequate training program on the appropriate use of the device before starting to use the machine. It should be easy for the user to become familiar with the functions and protocols of the device. The following pages contain the instructions for the correct use of the menus and the control keys/buttons of the device. All the button icons have been designed to be simple and intuitive to facilitate the work of the end-user.

# Rear panel and cup connector



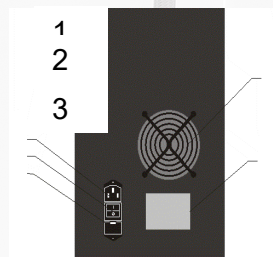
Picture 5a

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Picture 5b

1. Socket for power cable
2. Main switch
3. Fuse box

# Cylinder connection



Picture 6

1. Knob for opening and/or closing high pressure gas.

2. Cylinder pressure indicator

3. Cylinder pressure indicator, second stage/ two stage pressure regulator

4. Low cylinder pressure adjustment knob

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Cylinder and pressure regulator are the basic operating components.

The pressure regulator reduces and stabilizes the pressure of the gas in the cylinder.

The optimal operating pressure of AGE JET is 1.4 bar. The supplied regulator is set by the factory at that specific pressure.

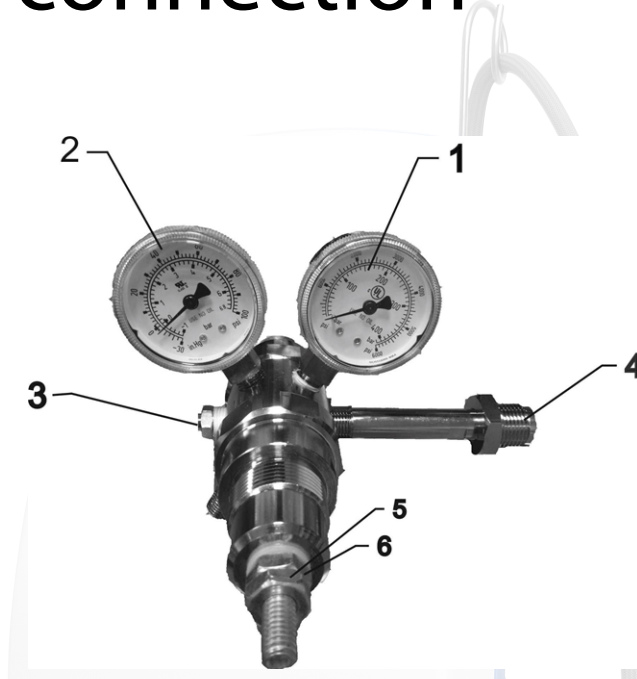
The output of the pressure regulator is connected to the rear panel of the AGE JET through a hose with quick coupling/connections.

**Warning:**

- Use only medical gas.
- The gas cylinder is at high pressure.
- Refer to the manufacturer and/or the distributor of the cylinder with regards to transportation and storage
- The cylinder is heavy, handle with care during transport, removal, and installation.
- Always close the cylinder valve before any operation of removal and/or replacement



# Cylinder connection



Picture 6a

Picture 6a shows the two-stage pressure regulator of the cylinder. This is a watermark for the trial version, register to get the full one!

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Indicator (1) shows the value of the gas pressure. The cylinder has a pressure of 200 bar. The indicator decreases as the gas is released, until it reaches the value of about 0 bar when the cylinder is empty. Therefore, during the functioning, it shows how much gas is still available in the cylinder. Indicator (2) shows the output pressure (1.4 bar). The connection is based on a quick coupling: to lock it, just insert the tube into the connector; to unhook the pipe, just push the edge of the connector downwards and pull the tube upwards at the same time. The regulator must be connected to the cylinder through the connector 4 interposing the supplied gasket.



Picture 6b

Picture 6b shows how to interpose the gasket (1) and connect the attachment to the cylinder. In the last phase, a key is used to tighten the connector. A tightening made with insufficient force could cause the gas leakage from the connection.



# Rear panel connections



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AGENT connections are shown in Picture 7.

The low-pressure nitrogen hose is connected to the gas inlet connector through quick release couplings. The hose is supplied with the unit.

The handpiece has three connections: gas, air, and the RF power connector.

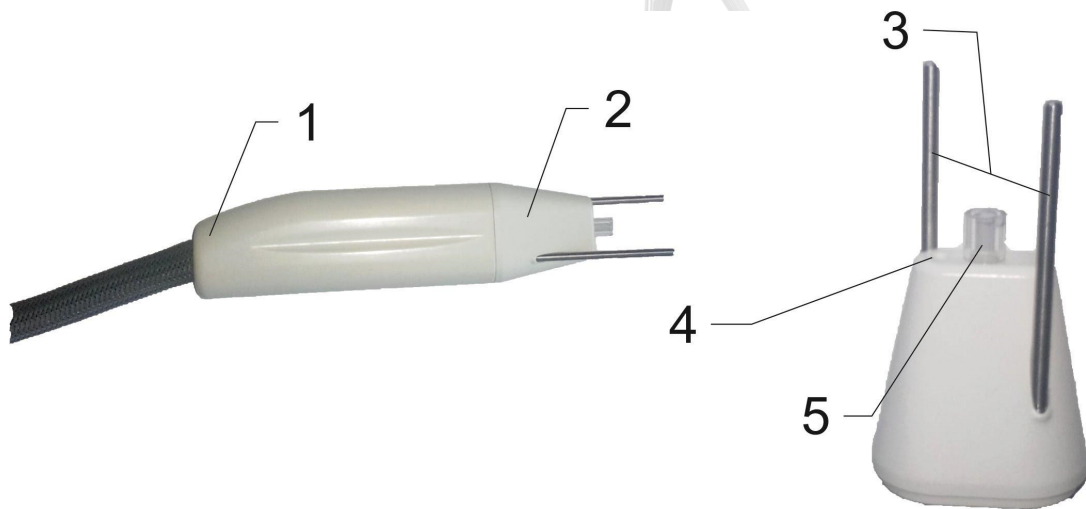
The pedal is of a pneumatic type, connected with the device through a plastic tube.

The handpiece holder, equipped with an internal thermal sensor, must also be connected in the rear panel.



**WARNING** – Make the connections when the device is completely switched off.

# Handpiece Description



Picture 8

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The ASE JET handpiece is composed of the main body and the interchangeable tip, as shown in Picture 8.

The device includes a forced air skin cooling system. From the hole in (4) comes out a jet of air to cool the treated part during treatment.

The energy delivered from the device is converted into plasma within the handpiece when the tip is properly inserted. The tip on the top of the handpiece is an integral part in the plasma generation. The tip has a lifetime of 15000 shots at 1 Joule. The fibre inside the tip will deteriorates with each shot of plasma generated. The remaining available shot are clearly displayed in the main treatment interface.

# Handpiece Description

The Tip is supplied with 3 sets of distance guides (3)

The Guide length is specific to different energy settings.

- For 0.5J the longest distance guides should be used. This is 50mm long.
- For 0.75J the medium Distance guides should be used. This is 43mm long.
- For 1-4J the shortest distance guides should be used. This is 36mm long.



The correct distance piece for the selected energy is displayed on the interface.

The use of the incorrect Distance Guides will either increase or decrease the delivered energy.



To avoid the use of plasma tip past its lifetime an internal and automatic counter detect the number of performed shot. When the tip has used up its useful life a clear message will be displayed, and the user should replace the old tip with a new one. Please refer to Replacing Tip section of this Manual

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Like the tip also the handpiece has a lifetime of 480000 shots. The rf aerial inside the handpiece will deteriorates with each shot of plasma generated. The remaining available shot for the handpiece is clearly displayed in the main treatment interface.



To avoid the use of plasma handpiece past its lifetime an internal and automatic counter detect the number of performed shot. When the handpiece has used up its useful life a clear message will be displayed, and the user should replace the old handpiece with a new one. Please refer to Replacing Handpiece section of this Manual



automatic blocking of the AgeJet system occurs to prevent the use of the Handpiece past its lifetime. Please refer to Replacing Handpiece section of this Manual to avoid the interruption of the service Installation.

# Getting Started

## Start-up of the equipment



Before switching on the device, it is important to verify.

1. That all connections are secure, and that the system is connected to a suitable grounded main outlet.
2. The nitrogen cylinder is connected and turned on.
3. The handpiece with tip is inserted into the handpiece holder.

Switch on the device turning on 1 the switch placed near the socket for the power supply wire.

After a few seconds, the device displays:

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Picture 9a



Before Press “Confirm” the handpiece with the tip must be into the holder



After pressing “Confirm” the equipment performs 5 shots of plasma to measure and test the delivered energy



# Start-up of the equipment.



Do not hold the handpiece by hand near the skin or near clothes! Possibility of burn or flame

If the measured energy is correct, the device shows the following message:



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# Menu Description

## Main Menu



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1. Settings menu
2. Database menu
3. Treatment's menu
4. Program's menu

When the equipment is switched on, the main menu will be displayed.

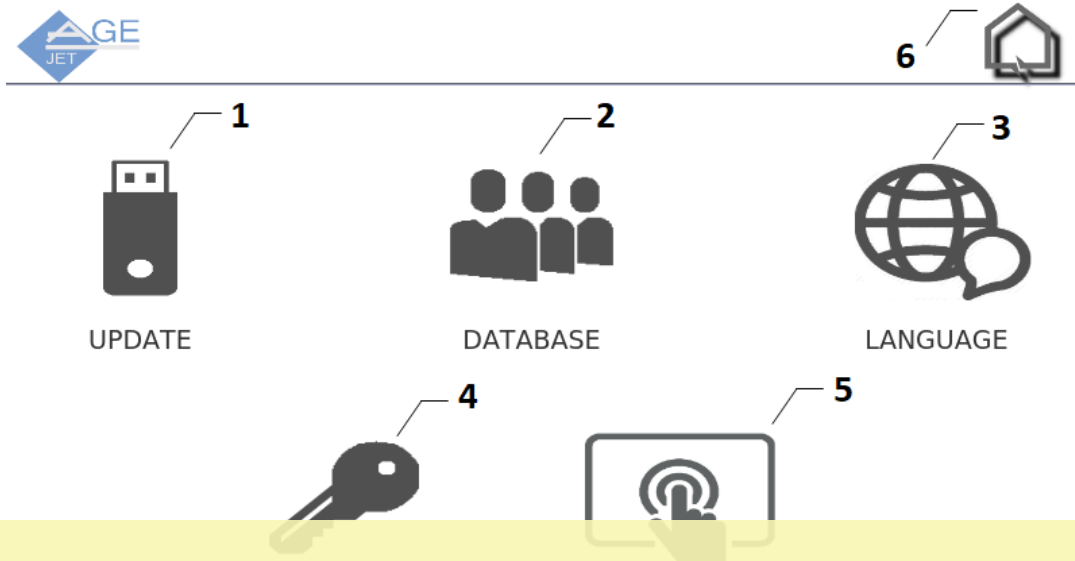
In the Settings menu, it is possible to adjust settings such as language, and manage updates, backups, and display calibration.

By selecting the Database menu, it is possible to access the device database whose save personal data and treatments of each single patient. The Treatments Menu permits to access to the appropriate treatment quickly, directly choosing the proper handpiece. The programs Menu allows to access to the programs area where it is possible to store new programs or choose one of the presents to start the treatment.



# Menu Description

## Settings Menu

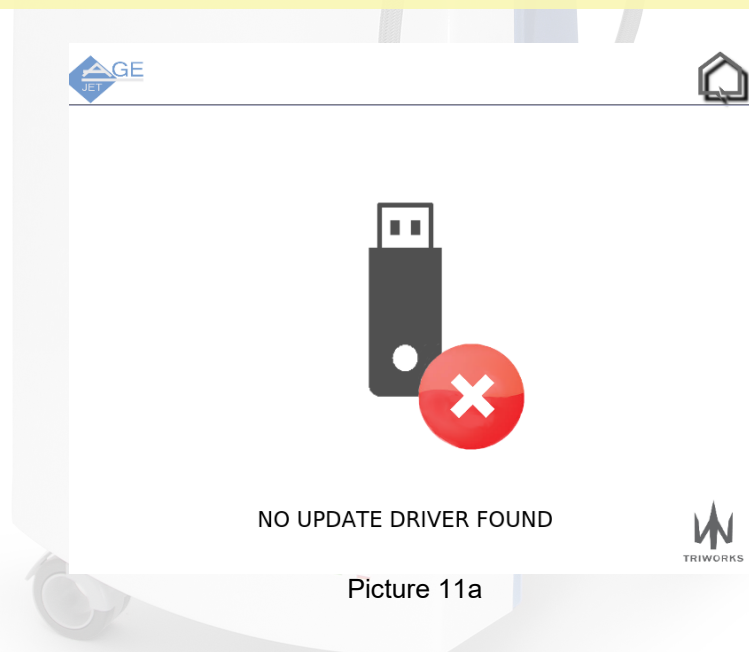


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# Menu Description

## Settings Menu cont.

2. Database settings: allows to access the DATABASE settings (Picture 11b).



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The EXPORT DATABASE icon allows to export the database and save as a csv file. The BACKUP DATABASE icon allows to back up the database information. The user may do a maximum of 3 backups. If 3 backups already exist, the last back up will replace the oldest one.

The RESTORE icon allows to select a backup file and restore the patients' data. If no backup is found, the screen in Picture 11c will be displayed.

The EMPTY DATABASE icon allows to delete all patient's data (Picture 11d).

# Menu Description

Settings Menu cont.

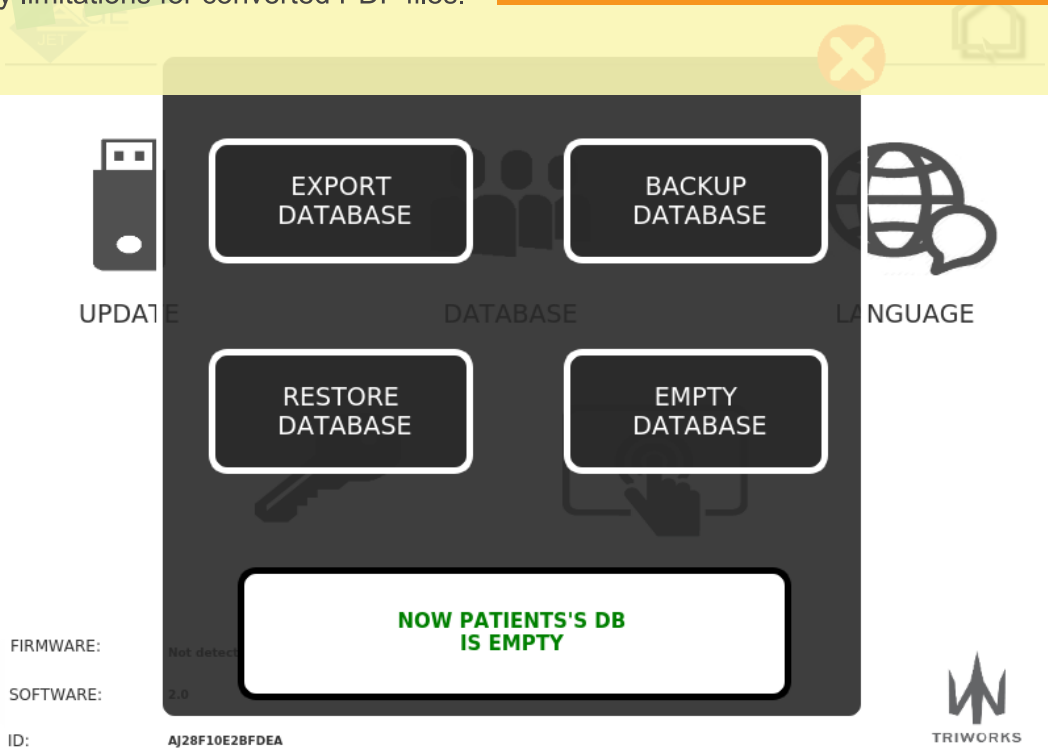


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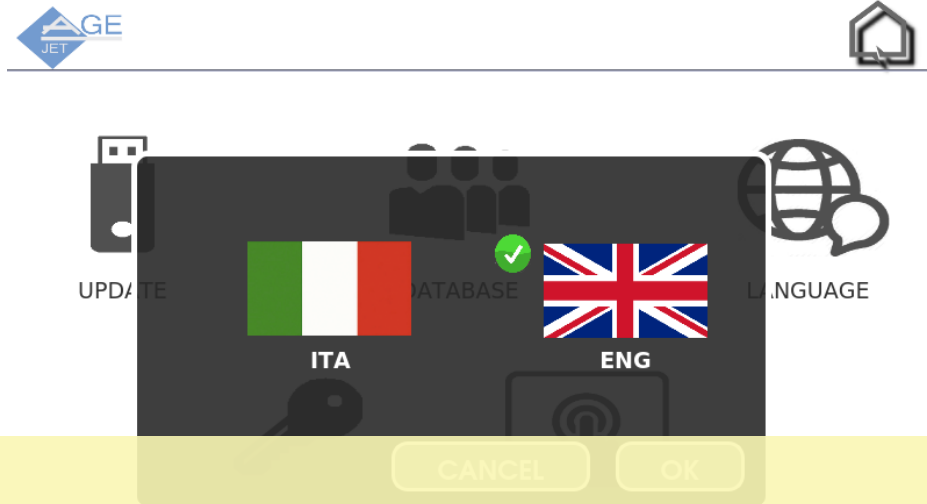


Picture 11d

# Menu Description

## Settings Menu cont.

3. Language settings: it is possible to access the screen of LANGUAGE settings (Picture 11e).

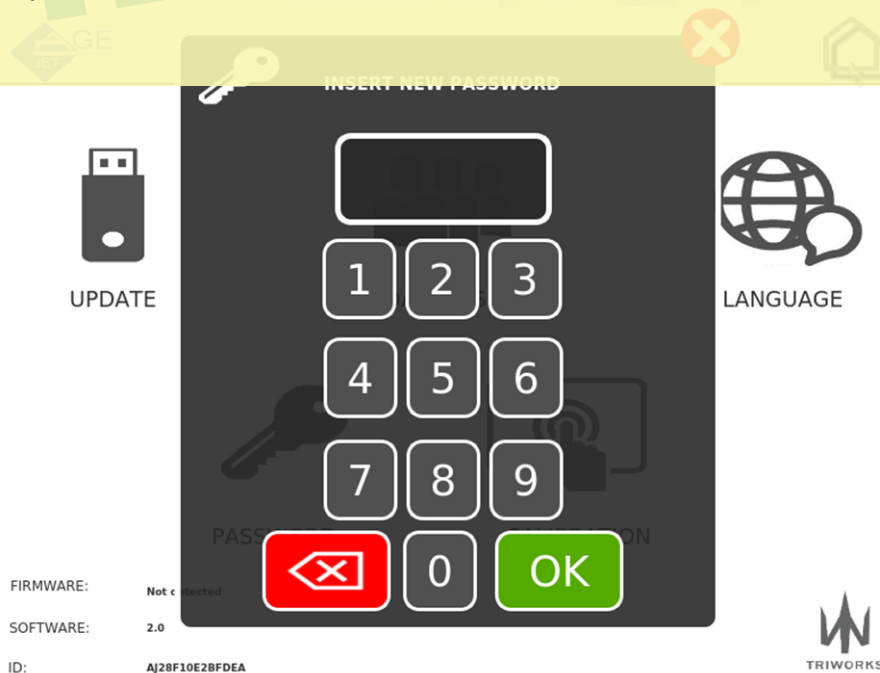


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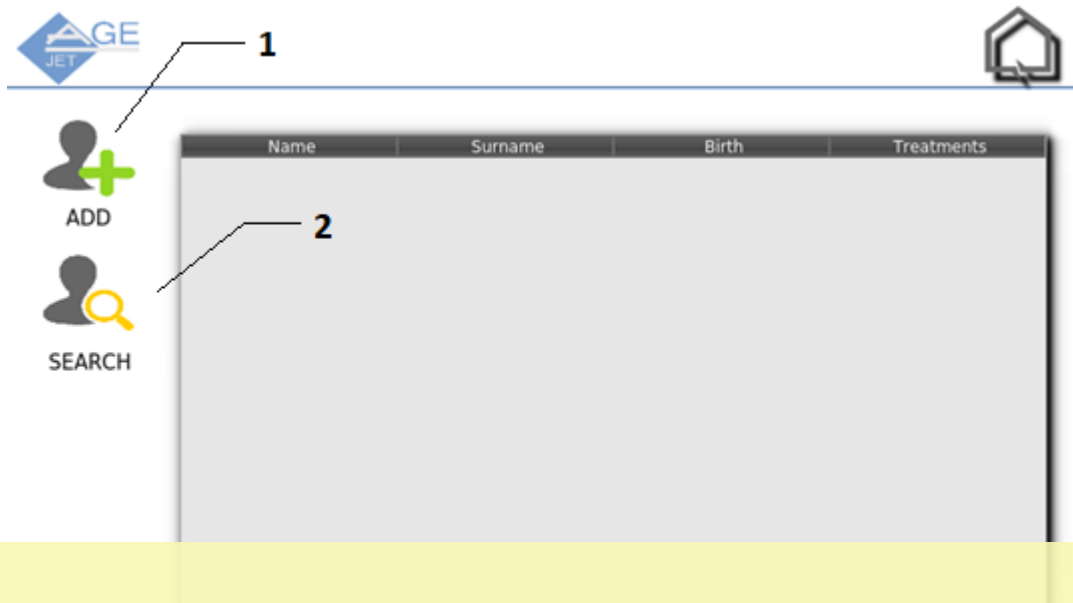


Picture 12

5. Calibration procedure: access the display calibration procedure.
6. Home: returns to the main menu.

# Menu Description

## Database Menu



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To search for patients in the database, tap on the SEARCH icon (Picture 13), enter the name or surname or part of them and then press OK.

To add a new patient, tap ADD, insert the patient data in the proper fields (Pictures 14, 15, 16) and press OK.

To save the new data press SAVE (Picture 17).



# Menu Description

Database Menu cont.

AGE

Please, insert patient's name

NAME: ALICE

SURNAME: -----

BIRTHDATE: --/--

OK

Q W E R T Y U I O P

A S D F G H J K L

↑ Z X C V B N M ↵

Picture 14

Please, insert patient's surname

NAME: ALICE

SURNAME: COOPER

BIRTHDATE: --/--

BACK OK

Q W E R T Y U I O P

A S D F G H J K L

↑ Z X C V B N M ↵

TRIWORKS

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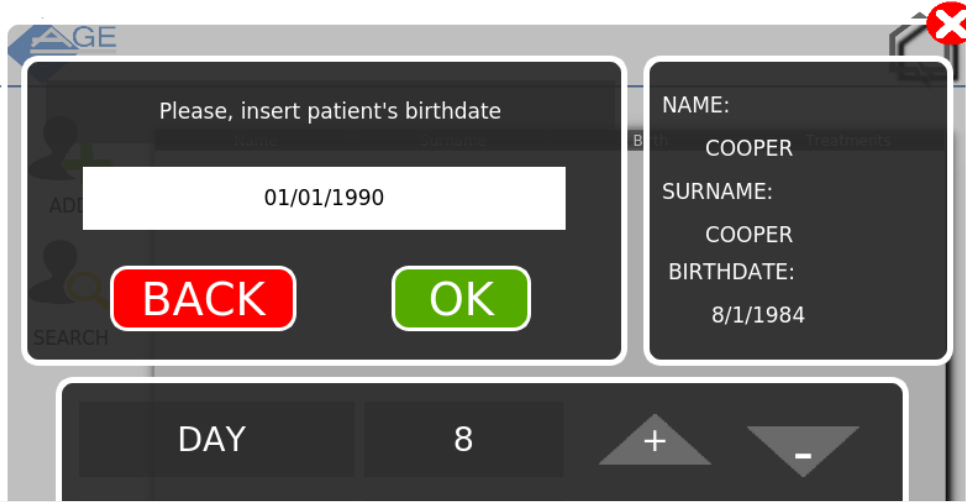
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Picture 15

# Menu Description

Database Menu cont.

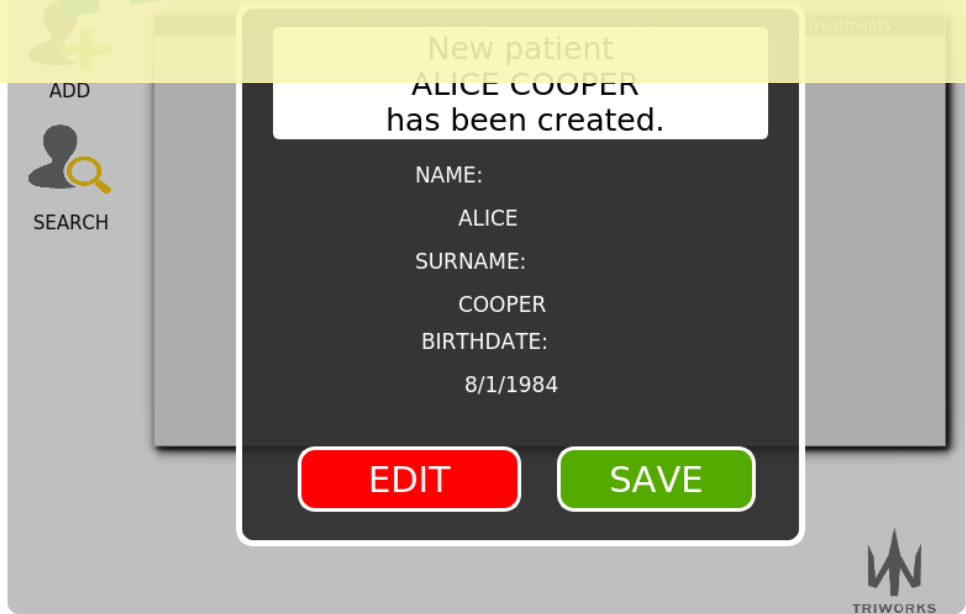


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Picture 17

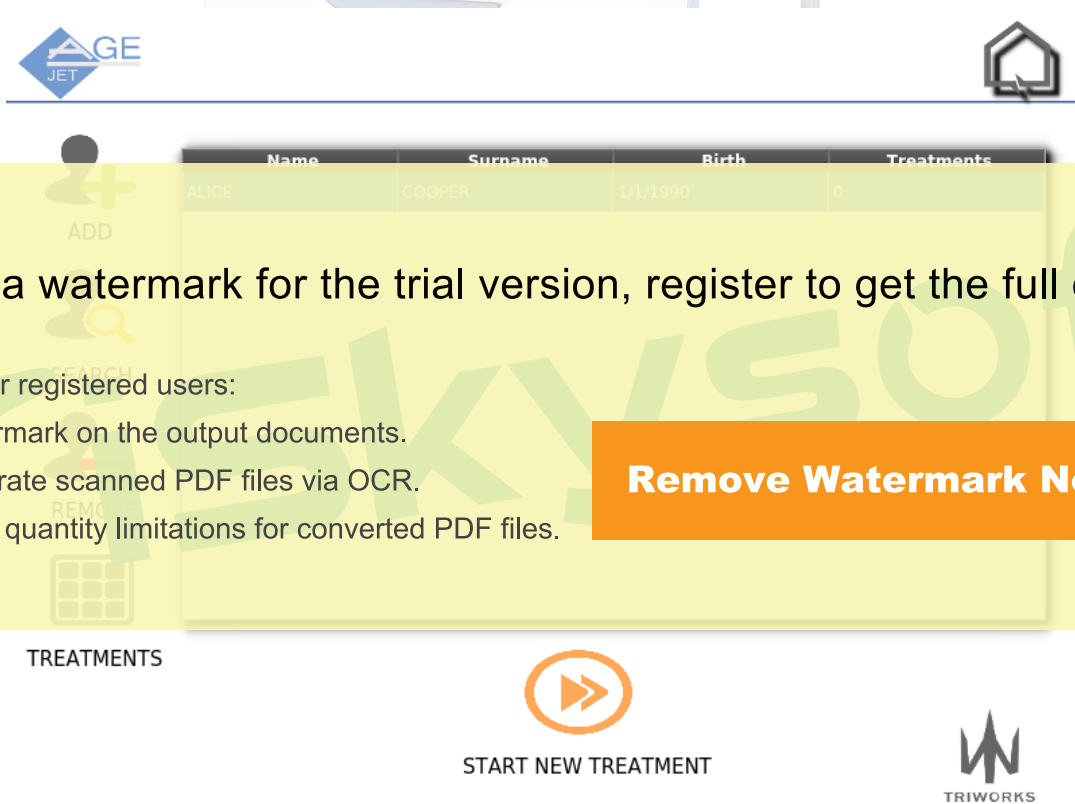
# Menu Description

## Database Menu cont.

To delete a patient from the list, select the patient and press the REMOVE icon (Picture 18).

To see the treatments history of the selected patient, press the TREATMENTS icon (Picture 18).

To start a new treatment on a patient stored in the database, select the patient, and press the icon START A NEW TREATMENT (Picture 18); the Treatments Menu will appear (Picture 19).



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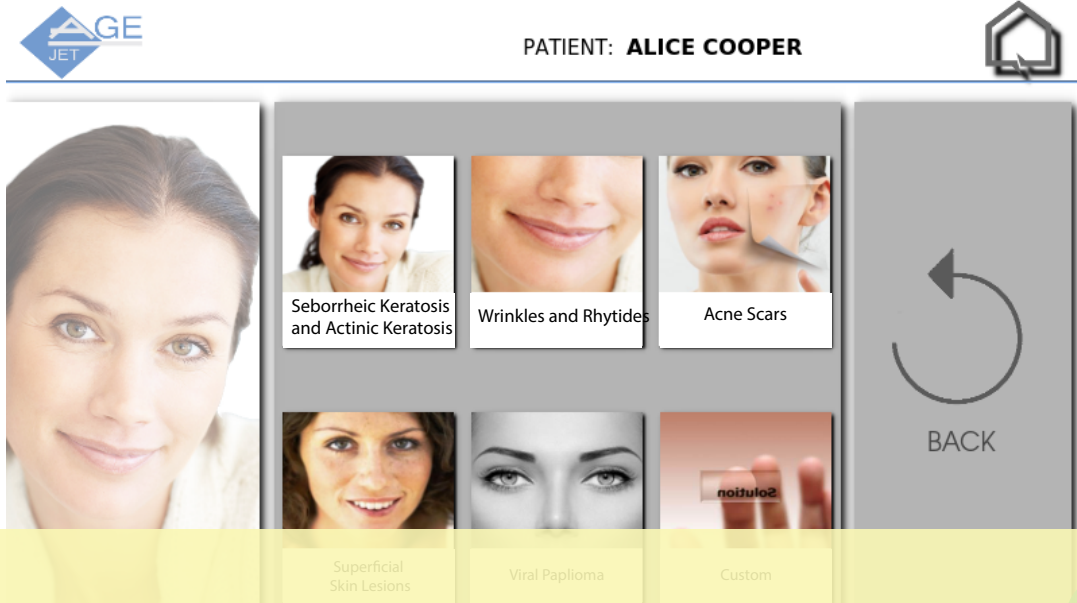
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Picture 18

# Menu Description

Database Menu cont.



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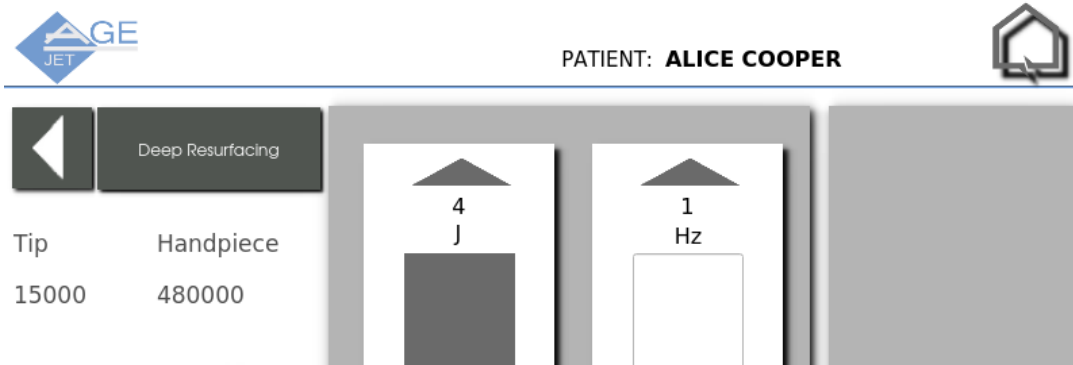
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# Menu Description

## Database Menu cont.

Once selected the specific treatment to perform, the PLAY MENU will appear (Picture 20). Press START to start the treatment (For further details see the Start Menu section).



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Picture 20





# Menu Description

## Treatment Menu

Each patient may react differently to treatment by Nitrogen plasma. Spot tests are suggested during initial consultation 3 to 4 weeks prior to actual treatment to ensure an effective treatment is administered.

The physician should monitor the healing profile of the patient post treatment and then decide on the frequency of any further treatments. As a guide,

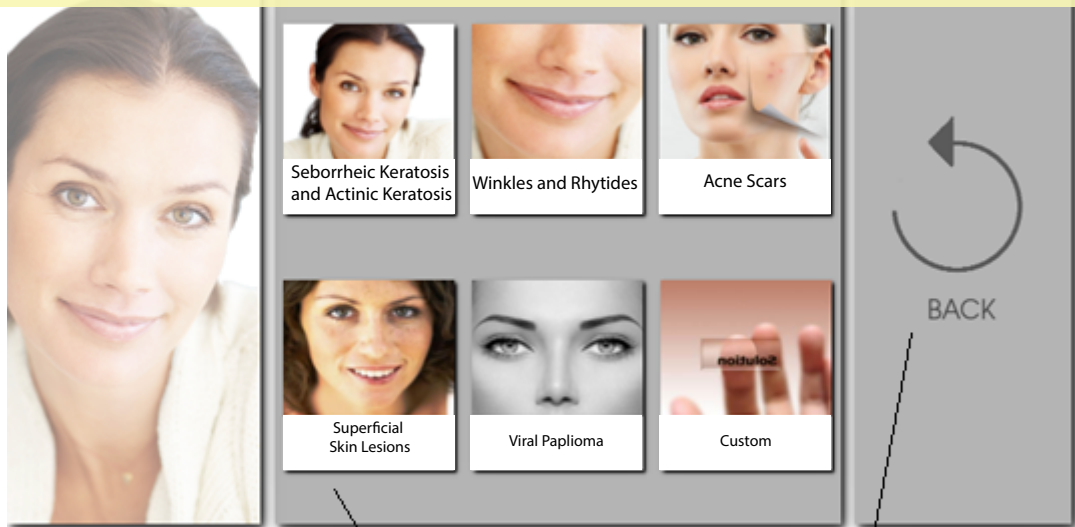
- maximum number of treatments per patient at energy >3J is one per 3 months.
- maximum number of treatments per patient at energy >1J is one per month.
- <1J is 2 treatments per month.

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1

2



Picture 21

# Menu Description

## Treatment Menu cont.

1. Area treatment selection
2. Button to go back/Back button.

In this screen you can make the choice of the type of pathology that you want to treat. The various choices have different protocols of treatment, by pressing the corresponding icon on the pathology that you want to treat.

The custom treatment can be used for other cleared indications and allows the physician to select the treatment parameters to suit the indication and desired treatment outcome.

In this section/screen it is possible to choose the indication the user intends to treat.

The different choices refer to different treatment protocols, by pressing/pressing on the icon related to the specific indication to be treated.

The Custom treatment does not include recommended protocols: it simply permits the treatments guidelines selection as needed by the user, although default settings can be selected from the table in Agejet protocols.

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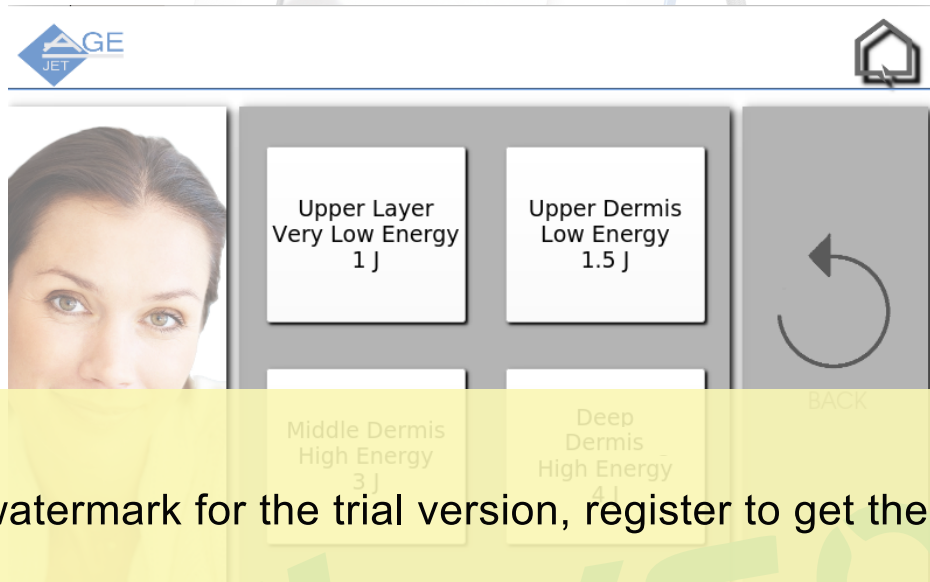
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# Menu Description

## Treatment protocol selection

After selecting the treatment to perform from the Treatment menu, the Protocols window will open. Each treatment is associated with one or more protocols, as show in Picture 22.



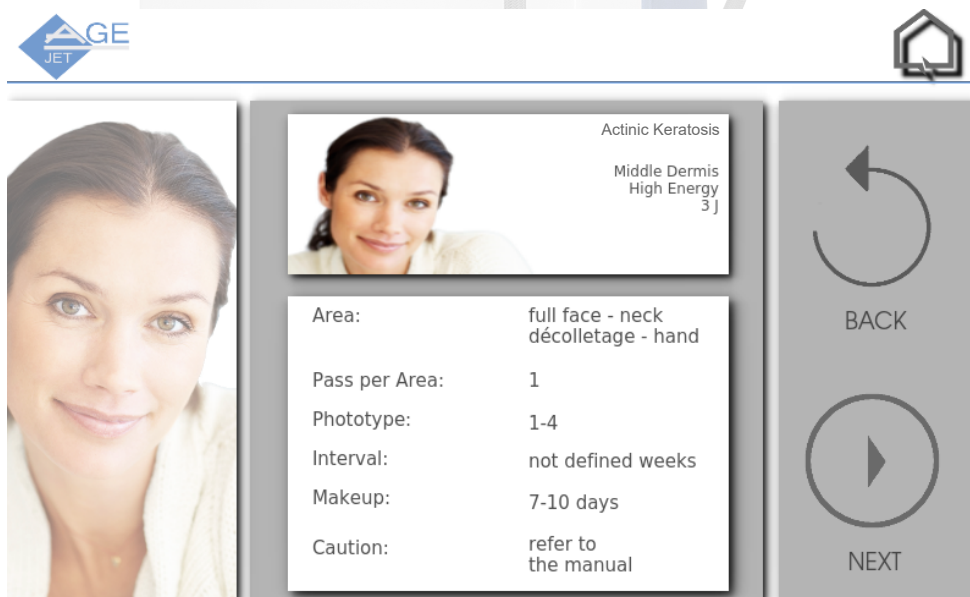
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to perform a specific protocol, tap the corresponding icon. Each protocol has its own set of pre-set parameters and indications (Picture 23).



Picture 23

# Menu Description

## Treatment protocol selection

To proceed with the treatment phase, press the NEXT button.  
Tap the BACK icon to exit and go back to the previous screen (protocol selection of Picture 18).

**WARNING:** Please note that the parameters can be modified according to the physician/user discretion, based on the age of patients, pain perception threshold and skin phototype. The physician/user can also change other parameters in compliance with the security standards.

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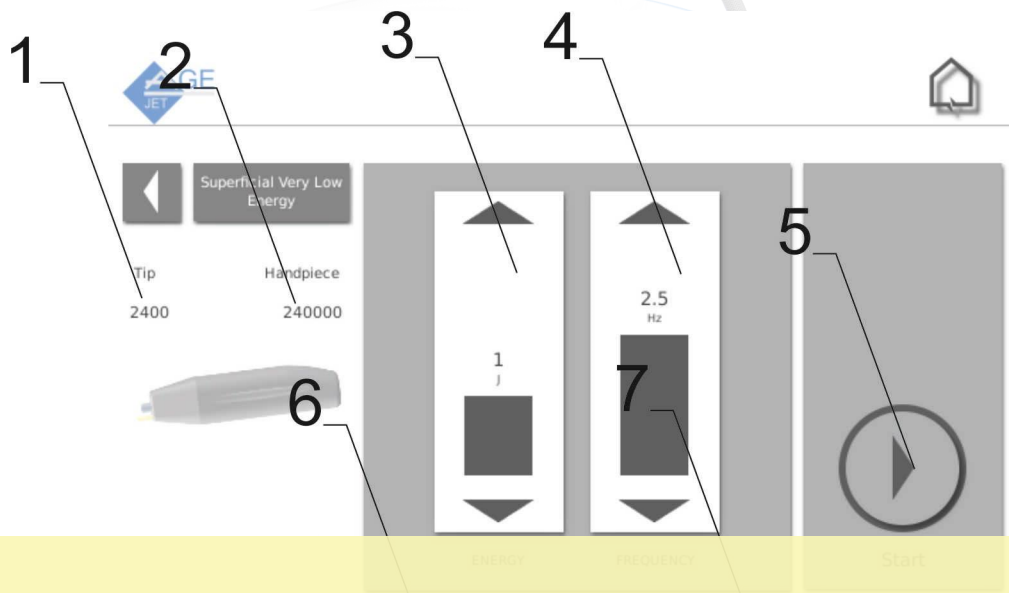
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# Menu Description

## Start Menu



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# Menu Description

## Start Menu cont.

1. Available shots in the Tip
2. Available shots in the handpiece
3. Energy indicator bar
4. Pulse repetition frequency indicator bar
5. Start button.

Picture 24 shows the device status before starting the treatment; any pressure on the pneumatic pedal (object 4 in Picture 5) in such a state does not produce the activation of the plasma.

With reference to Figure 24:

In (3) the energy of each pulse is adjusted: tap the Up/Down Arrows to increase/decrease the energy value.

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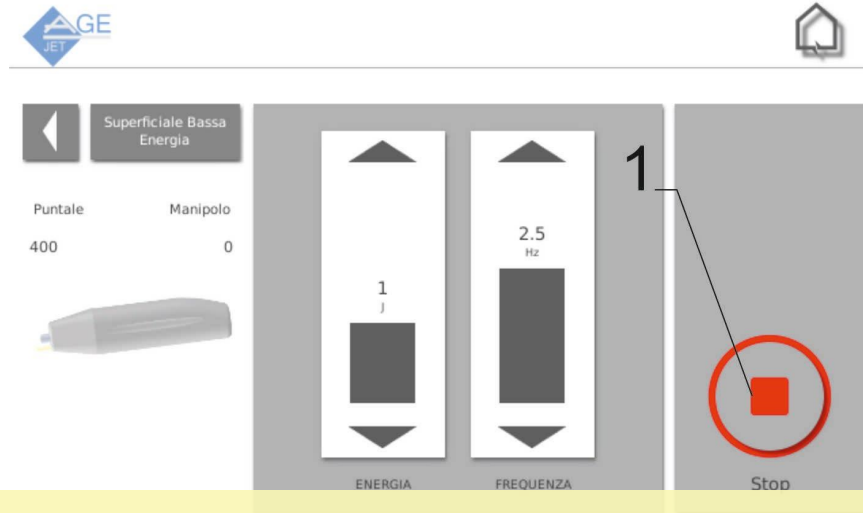
Button (7) turns on and off the forced air outlet on the handpiece during treatment, to relieve the area under treatment.

(6) shows the count of shots emitted during the current treatment.

(1) and (2) show the shots that can still be carried out respectively by the tip and handpiece. Please refer to the Tip and Handpiece Counter section if this manual for more information

# Menu Description

Start Menu cont.



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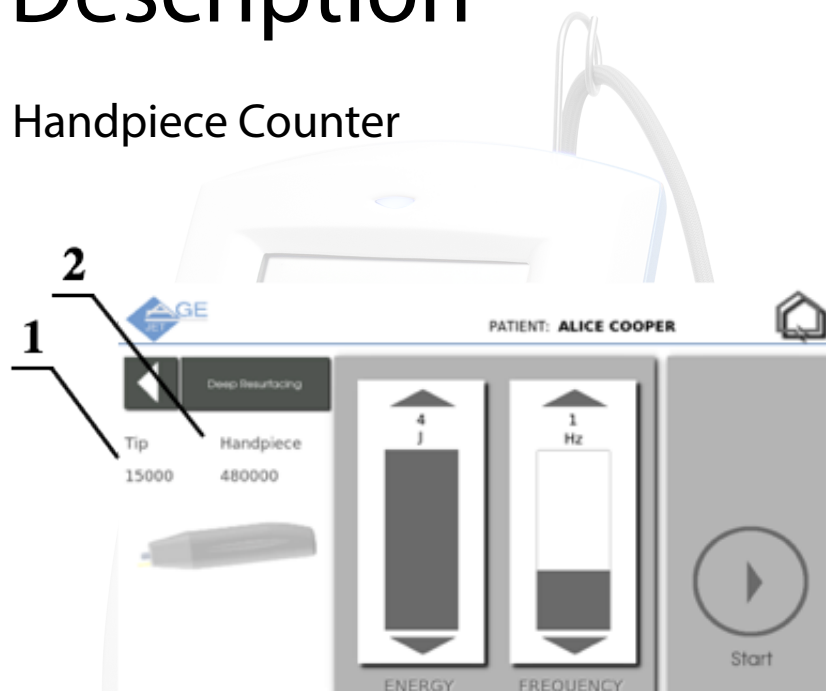
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# Menu Description

## Tip and Handpiece Counter



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The tip has a lifetime of 15000 shots at 1 Joule. The fibre inside the tip will deteriorates with each shot of plasma generated. The device automatically calculates the increased tip deterioration when a higher level of energy >1.5J has been selected by the user increasing the tip counts per single shot.

- Below 1,5 Joule ☒ 1 tip shot.
- From 1,75 Joule to 3,5 J ☒ 4 tip shots
- From 3,75 Joule to 4,0 J ☒ 8 tips shots

The remaining available shot are clearly displayed (1) in the main treatment windows below the HANDPIECE label (Picture XX).

The handpiece has a lifetime of 480000 shots. The pin inside the tip will deteriorates with each shot of plasma generated but it is less effected by the level energy set by the user. For all level of energy available each shot accounts for 1 handpiece shot counts.

The remaining available shot are clearly displayed (2) in the main treatment windows below the TIP label (Picture XX).

# Operation sequence and methods of use

After running the start-up procedure, the device displays the main menu as in Picture 10. Press on "Treatments" icon to access the operation of the device. From here you can choose from the following beauty treatments:

- Acne Scars
- Wrinkles and Rhytides
- Superficial skin lesions
- Actinic Keratosis
- Viral Papilloma
- Seborrheic Keratosis

After choosing the indication, it is possible to specify varieties for the pulse's energy intensity and for the recommended interval of days between each treatment.

After choosing the treatment the device shows a summary of the treatment parameters and indications.

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In the next screen, START MENU, bars appear already set with the parameters stored in the treatment selected.

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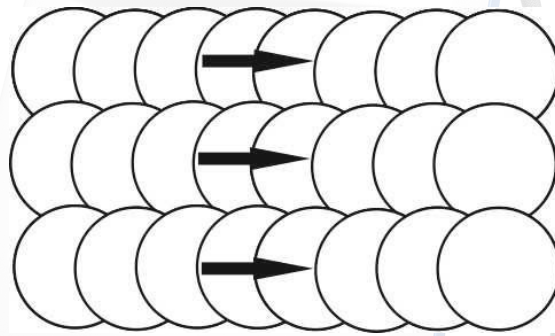
To get the expected clinical results...:

- The handpiece should be kept as perpendicular as possible to the area to be treated.
- The spacers should always lightly touch the treatment area to obtain the same constant effect on all the different parts of the treated area.

Different protocols require different distance between each shot. The most uniform result, and especially when using energy levels above 1j the distance between the centres of each plasma pulse should be about of 6mm. increasing the distance for energy levels below 1 j where multiple treatments will be used to achieve a uniform result is acceptable.

To treat an area, it is necessary to apply pulses of plasma in a series of organised lines as shown in Picture 27. At the end of each line, it is necessary to go back and start over again,

# Operation sequence and methods of use



Picture 27

The pulse repetition frequency must be chosen to create the imprint/trace described properly. In case of the selection of faster repetitions, the user must move from one point to another more quickly to ensure the same imprint/trace.

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# Age Jet treatment protocols

The following Table summarises the protocols available for Age Jet:

Treatment	Area-mode	Settings
ACNE SCARS	Acne scars <i>High energy</i> 4 J	Power: 4 J Area: Scars Pass per area: 1 Phototype: 1 - 4 Interval: not defined weeks Makeup: 7-10 days Cautions: refer to the manual
	Low Energy 1.5 J	Power: 1.5 J Area: skin patches Pass per area: 1 Phototype: 1 - 4 Interval: 3 weeks Makeup: 4-5 days Cautions: refer to the manual
		Power: 3 J Area: skin patches Pass per area: 1 Phototype: 1 - 4 Interval: 3 weeks Makeup: 5-7 days Cautions: refer to the manual
WRINKLES AND RHYTIDES	Skin laxity 2 J	Power: 2 J Area: skin patches Pass per area: 1 Phototype: 1 - 4 Interval: 3 weeks Makeup: 5-7 days Cautions: refer to the manual

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# Age Jet treatment protocols

Treatment	Area-mode	Settings
ACTINIC KERATOSIS	High energy	Power 1.5 to 3.5j Treat area affected. Single pass Phototype 1-3 Interval 6 to 12 weeks Make up 10 to 14 <u>days</u> <u>Cautions:dermatologists only</u>
SEBORRHEIC KERATOSIS	High energy	Power: 3 to 4j Treat only keratosis. Double pass Phototype: 1-3 Single treatment only <u>Cautions: Dermatologists only</u> Treat individual papilloma only <u>Cautions: dermatologists only</u>

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# Maintenance

## Cylinder replacement

When the gas pressure is insufficient, the device will show the message as in Picture 28:



Gas flow too low. Increase the pressure gas  
or change the gas cylinder.

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Picture 28

If the valve on the cylinder is opened and the high-pressure indicator of the regulator shows a pressure close to 0, it means that the cylinder is empty and should be replaced.

Before removing the regulator, close the cylinder valve.

Remove the regulator and install it on the new cylinder, tighten it firmly.

Open the cylinder valve and make sure there is no leakage of gas.

At this point, press CONFIRM on the device display, and the pressure control will immediately execute.

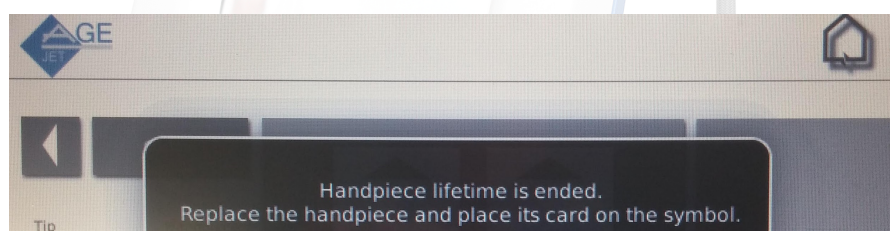
# Maintenance

## Replacing the tip

The tip contains material which progressively deteriorates due to the plasma emission. The number of pulses that the tip can emit is 15000 shots.

The tip is supplied together with a RFID (radio frequency identification) enabling key.

The tip consumes when the pulse count of the tip reaches zero. At that point, the device will require the insertion of a new tip and the use of the RFID key provided with the tip. The screen will be as follows:



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Figure 29

The procedure consists of:

- Removing the exhausted tip by pulling it out from the handpiece and inserting the new one in the same way
- Placing the card on the front of the device, in correspondence with the symbol:
- Pressing confirm and waiting for the reading is performed with the updating of the counter of the tip shots.



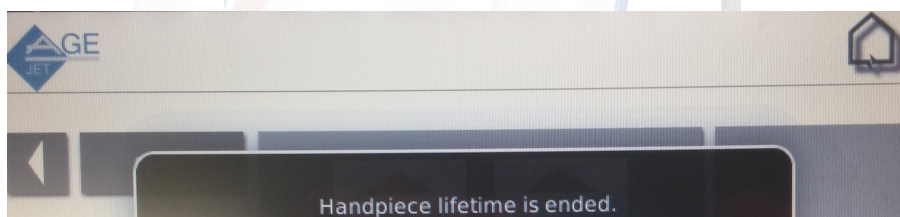
### WARNING!

You must avoid to reusing exhaust tips, in addition to compromising the effectiveness of the treatment, there are risks due to possible leakage of degraded material from the tip.

# Maintenance

## Handpiece replacement

The handpiece, as the tip, has material inside that deteriorates on each pulse of plasma emitted. For this reason, the number of pulses that the handpiece can emit is 480000. The handpiece is supplied with a RFID (radio frequency identification) enabling key. When the pulse count of the handpiece reaches zero, the device continues to operate until the pulse count of the tip also reaches zero. At that point, the device requires the insertion of a new handpiece. The screen below shows:



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Picture 30

The procedure consists of:

- Disconnecting the air connector, gas connector and power connector of the hand piece and then, connect the new handpiece.
- Placing the card on the front of the device, in correspondence with the symbol:



- Press confirm and wait for the reading is performed by updating the counter of the handpiece shots.

### WARNING!

Do not reuse for any reason exhaust handpieces; in addition to compromising the effectiveness of the treatment, they will rapidly increase the consumption of new tips.



# Maintenance

## Device Cleaning

**WARNING:** all cleaning and maintenance operations should be carried out with the device disconnected from the network supply.

You can clean the AGE JET device with a soft damp cloth. Be careful not to use any solvents, or abrasive or alcohol-based products. It is advisable to moisten the cloth with distilled or demineralised water before using it to clean the equipment.

## Handpiece Cleaning

To clean the handpiece after a treatment the users should remove any visible residual with a tissue to prevent the drying of soil/contamination and to facilitate the subsequent cleaning step.

The second step of the handpiece cleaning procedure is to moisten a cloth with any FDA approved FDA cleaning and the user must apply enough gentle friction on handpiece for 2 minutes.

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## Fuse replacement

The operation of extra maintenance which can be carried out by the user consists of replacing the fuses on the power line.

This operation must be carried out with the device disconnected from the network supply.

1. With the aid of a tool open the fuse holder drawer (3, Pic. 1b) of the power outlet.
1. Remove the blown fuse and replace it with the spare or a new one of the same type.
2. Close the fuse drawer.

**WARNING:** If the new fuse blows when AGE JET is switched on, you must contact a qualified service centre.

# Maintenance

## Out of service

If the machine must be taken out of service for a period longer than 15 days, it is necessary to clean the machine and check if it has been effectively disconnected from electricity sources. It is recommended to disconnect the handpieces and roll up the cables into large spirals.

## Disposal

Improper disposal of Waste Electrical and Electronic Equipment (WEEE) may result in severe damage to the environment and human health due to the hazardous substances that may be contained in the equipment or its components.

To protect the environment, do not throw the equipment or accessories and/or spare parts into domestic waste at the end of its useful life, but take it to the collection point for medical equipment required by law. TRIWORKS GROUP is available to help the user dispose of the product correctly.

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# Troubleshooting

Your supplier is your first point of contact for all service issues.

Please read the chapters on installation and operation and consult the following list of common problems. The user will find that some issues can be easily solved. Were the problem persist your supplier will provide engineering service at your premise as required, though at their discretion they may remove the system to the Service Centre for repairs



The user must not try to open the unit and repair it by himself.

Problem	Cause	Solution
The device does not turn on	Power cable not connected properly.	Tighten the connector, pushing it well down.
	Power switch in position 0.	Put the switch in position 1.
	Faulty circuit	Repair the fuse service centre
The device displays the following error message: <i>Gas flow too low, increase gas pressure gas or change cylinder</i>	The cylinder is empty. The cylinder is closed. The regulator is closed. Gas circuit internal fault	See chapter "Cylinder replacement"  Correctly open the knob on the cylinder at high pressure  Use the pressure regulator bringing the pressure to 1.4 bar on the second stage.  Contact the service centre

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# Troubleshooting

Problem	Cause	Solution
The device displays the following error message: <i>Check the pressure of the gas</i>	Gas pressure too high	Check the secondary pressure on the regulator indicator.
The device does not emit plasma, only gas is detected on output	Handpiece not connected correctly.  Faulty tip	Restore connections.  Try another tip.

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For any other problem

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# EMC TABLES

## Protection circuits test

Port	Testing Current (A)	Application Time (s)	Acceptable value ( $\Omega$ )	Measured value. (m $\Omega$ )	Standard
Grounded parts	25	60	0.1	57	EN 60601-1 EN 60601-2-2

## Voltage test applied

Port	Testing Voltage kVac	Application Time (s)	Standard	Note
Protection of the operator against live parts	1.5	60	EN 60601-1 EN 60601-2-2	1-2
Protection of the operator against secondary circuits	1.5	60	EN 60601-1 EN 60601-2-2	1-2
Protection of the parts	1.5	60	EN 60601-1 EN 60601-2-2	1-2
Protection of the secondary circuit	1.5	60	EN 60601-1 EN 60601-2-2	1-2

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# EMC TABLES

## Measurement of leakage current during operation

Port	Limit ( $\mu\text{A}$ )	Measured value. ( $\mu\text{A}$ )	Standard	Note
Earth leakage current (normal conditions)	5000	164	EN 60601-1 EN 60601-2-2	1-2-3
Earth leakage current (failure mode)	10000	268	EN 60601-1 EN 60601-2-2	1-2-3
Touch current (normal conditions)	100		EN 60601-1 EN 60601-2-2	1-2-3
Touch current (failure mode)	500	160	EN 60601-1 EN 60601-2-2	1-2-3
Patient leakage current from the Applied Part via the patient to Earth (normal conditions)	100	-----	EN 60601-1 EN 60601-2-2	4

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# EMC TABLES

## Measurement of leakage current during operation

Port	Frequency field (MHz)	Test level	Test type	Standard	Outcome
Casing	30-1000	Class A	Radiated emissions	EN 60601-1-2	P
AC supply	0.15-30	Class A	Conducted emissions	EN 60601-1-2	P
AC supply	-----	-----	Harmonic current emissions	EN 60601-1-2	P
AC supply	-----	-----	Voltage & flicker fluctuations	EN 60601-1-2	P
Casing	-----	±15 kV (air) ±8 kV (contact)	Electrostatic discharge immunity	EN 60601-1-2	P
AC supply	-----	±2 KV	Immunity to fast transients (Burst)	EN 60601-1-2	P
Casing	80-2700	3 V/m (Modulation AM 80% 1kHz)	Immunity to radiated electromagnetic fields	EN 60601-1-2	P
AC supply	0.15-80	(Modulation AM 80% 1kHz)	Immunity to conducted electromagnetic fields	EN 60601-1-2	P
AC supply	-----	±1 KV	Immunity against electrostatic discharges	EN 60601-1-2	P
AC supply	-----	30% 25 cycles > 95% 5 cycles	Power supply interruption	EN 60601-1-2	P
Casing	0.00005	30 A/m	Immunity testing to power frequency magnetic fields	EN 60601-1-2	P

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# EMC TABLES

## Electromagnetic compatibility

Electronic medical devices are subject to precautions in respect of electromagnetic compatibility (EMC).

This device may ONLY be used for the purposes described in this Instruction for Use and must be set up and put into operation taking account of the EMC information.

### Environmental conditions:

The device has been tested according to electromagnetic compatibility (EMC) and is suitable for the use in a healthcare environment (CISPR 11 Class B).

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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# EMC TABLES

Guide and Declaration of the Manufacturer – electromagnetic emissions			
AGE JET is designed to work in the electromagnetic environment, as specified below. The client or the user should use the electro-medical device in this specific environment.			
Emission tests	Compliance	Electromagnetic environment – guide	
RF Emissions CISPR 11	Group 1	The system of <i>AGE JET</i> uses the RF energy only for the internal functioning of the device. Therefore, the RF emissions are very low and realistically these emissions do not cause any type of interference with nearby electrical equipment.	
RF Emissions CISPR 11			The system of <i>AGE JET</i> can be used in all types of environments: except in the domestic environment and those in direct contact with a public low-voltage power network destined for various domestic uses. The following warning must be provided.
Harmonic emissions IEC 61000-3-2	Class A, B, C, D, or NA	Class A	The system of <i>AGE JET</i> can be used in all types of environments: except in the domestic environment and those in direct contact with a public low-voltage power network destined for various domestic uses. The following warning must be provided.
Voltage fluctuations / flicker emissions IEC 61000-3-3	Conformity or NA	Compliant	The system of <i>AGE JET</i> can be used in all types of environments: except in the domestic environment and those in direct contact with a public low-voltage power network destined for various domestic uses. The following warning must be provided.

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# EMC TABLES



Guide and Declaration of the Manufacturer – electromagnetic Immunity			
The system of <i>AGE JET</i> is designed to work in the electromagnetic environment, as specified below. The client or the user of this system must use the electro-medical device in this specific environment.			
IMMUNITY Test	Test level IEC 60601	Standard	Electromagnetic environment – guide
Electrostatic discharge (ESD) IEC 61000-4-2	in contact $\pm 8$ kV in the air $\pm 15$ kV	EN 60601-1-2	The floor must be built with wood, concrete, or ceramic tiles. If the floor is covered by synthetic materials, the relative humidity should be at least equal to 30%.
Transitions / sequence of rapid electrical pulses IEC 61000-4-4	$\pm 2$ kV for the supply lines	EN 60601-1-2	The quality of the line voltage should be the same of a business or hospital environment.
Overvoltage IEC 61000-4-11	$\pm 1$ kV between the phases to ground	EN 60601-1-2	The quality of the line voltage should be the same of a business or hospital environment.
Power supply interruption IEC 61000-4-11	$< 5\% U_t$ ( $> 95\%$ hole in $U_t$ ) for 5 s	EN 60601-1-2	The quality of the line voltage should be the same of a business or hospital environment. During the operation during the interruption in the voltage network, it is recommended the use of the EM device or EM system with an interrupted power supply or batteries.
Magnetic field in the network frequency (50/60 Hz) IEC 61000-4-8	3 A/m	EN 60601-1-2	The magnetic fields in the network frequency should have standard levels of a business or hospital environment.
NOTE $U_t$ is the mains voltage in c.a. before the application of the test level.			

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# EMC TABLES



Guide and Declaration of the Manufacturer –Electromagnetic Immunity			
The system of <i>AGE JET</i> is designed to work in the electromagnetic environment, as specified below. The client or the user of this system must use the electro-medical device in this specific environment.			
Immunity Test	Test Level IEC 60601	Standard	Electromagnetic environment – guide
Conducted RF. IEC 61000-4-6	3 V <sub>eff</sub> from 150 kHz up to 80 MHz.	EN 60601-1-2	<p>The RF communication device and the portable and mobile RF equipment should not be used nearby the AGE JET technology (included cables of recommended separation distances with the equation applicable to the frequency of the transmitter.)</p> <p><b>Recommended separation distances:</b></p> $d = 1,16\sqrt{P}$ $d = 1,16\sqrt{P} \text{ from 80 MHz up to 800 MHz}$
Radiated RF. IEC 61000-4-3	3 V/m from 80 MHz up to 2,7 GHz	EN 60601-1-2	$d = 2,33\sqrt{P} \text{ from 800 MHz up to 2,5 GHz}$
			<p>Interference can occur only when the device is placed near devices marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz the separation distance is applied to the highest frequency range.</p> <p>NOTE 2 These guidelines may not have an applicable value under all circumstances. The propagation of electromagnetic waves can be affected by the absorption and the reflection of buildings, physical persons, or objects.</p>			
<p><sup>a</sup> The field strength for fixed transmitters, as radio-telephone base stations (mobile phones /cordless), radio equipment, AM and FM radio transmitters, TV transmitters, theoretically cannot be calculated with precision. To assess an electromagnetic environment caused by fixed AGE JET is used overcomes the conformity level (see above), the device should be placed under inspection/examination. The correct operation and the safety standards of the device must be guaranteed under all circumstances. If certain anomalies occur, it is necessary to reposition/relocate the device and/or take some corrective and additional measures.</p> <p><sup>b</sup> The field strength in the frequency range from 150Hz to 80MHz shall not exceed a value of 2 V/m.</p>			

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# EMC TABLES

Recommended separation distance between portable and mobile radio communication devices and AGE JET			
AGE JET has been designed to work in electromagnetic environments in which radiated RF disturbances are kept under control. The client / user of this device can contribute to preventing the electromagnetic interferences, ensuring a minimum distance between the portable/ mobile radio communication devices (RF transmitters) and AGE JET, as recommended below. This in relation to the maximum power output of the radio-communication devices.			
The maximum rated engine power output power of the transmitter W	Separation distance according to frequency of transmitter M		
	from 150 kHz up to 80 MHz	from 80 MHz up to 800 MHz	from 800 MHz up to 2,5 GHz
	$d = 1,16\sqrt{P}$	$d = 1,16\sqrt{P}$	$d = 2,33\sqrt{P}$
0,01	0,11	0,11	0,23
0,1	0,36	0,36	0,73
1	1,16	1,16	2,33
10	3,66	3,66	7,33

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NOTE 1 At 80 MHz and 800 MHz the separation distance is applied to the highest frequency range.

NOTE 2 These guidelines may not be feasible under all circumstances. The electromagnetic propagation is affected by the absorption and by the reflection of structures, objects, and physical entities.



# Technical specifications\*

Power source	110/120 VAC 50-60 Hz
Absorption	620 VA
Device type	BF
Insulation class	I
Fuses	2 x T4A 250 V
RF output power for generating the plasma	1500 W - 50 Ohm
RF output frequency	2450 MHZ +/- 50 MHZ
Pulse duration	From 4 to 15 ms
Pulse power	From 0.5 to 4 J
Plasma spot size	About 6 mm diameter
Operating environmental conditions	Temperature 10 - 40°C Humidity 30 - 75% Pressure 700 - 1060 hPa
Environmental conditions for transport and storage	Temperature -40 - 75°C Humidity 30 - 75% Pressure 700 - 1060 hPa
Size l x h x w	1170 x 360 x 270 mm
Weight	25kg

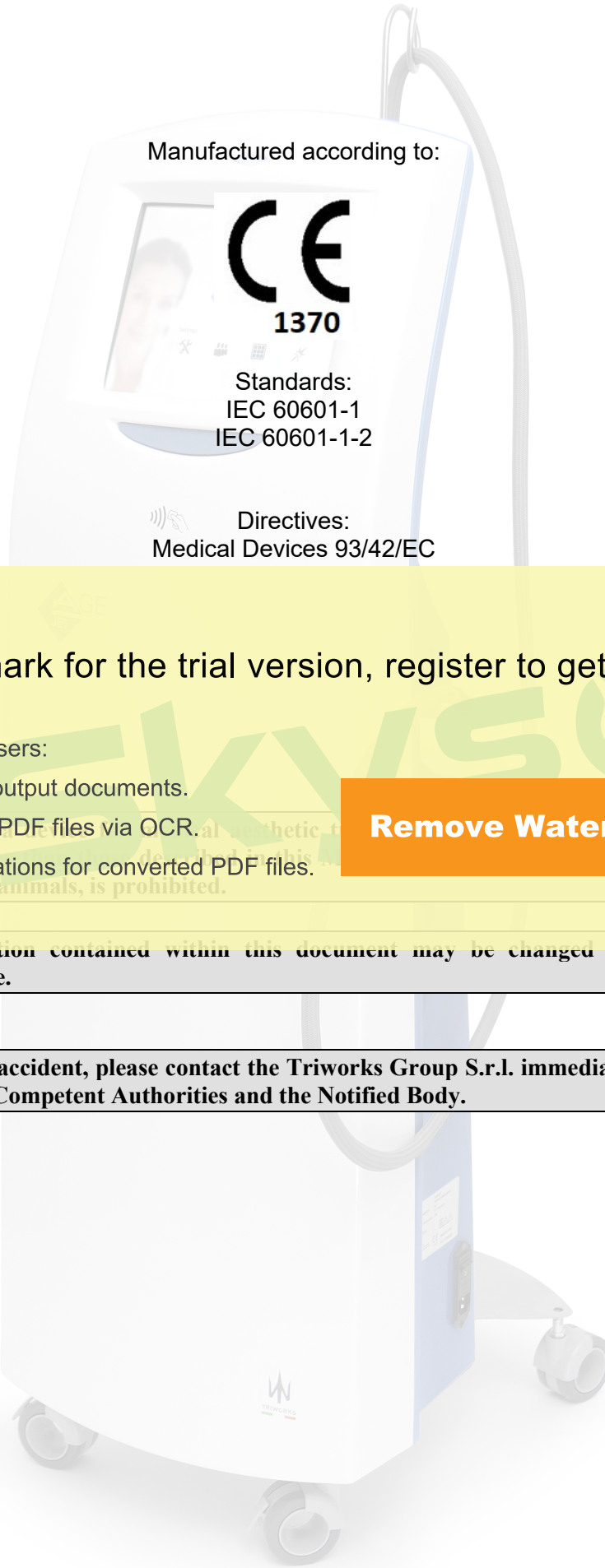
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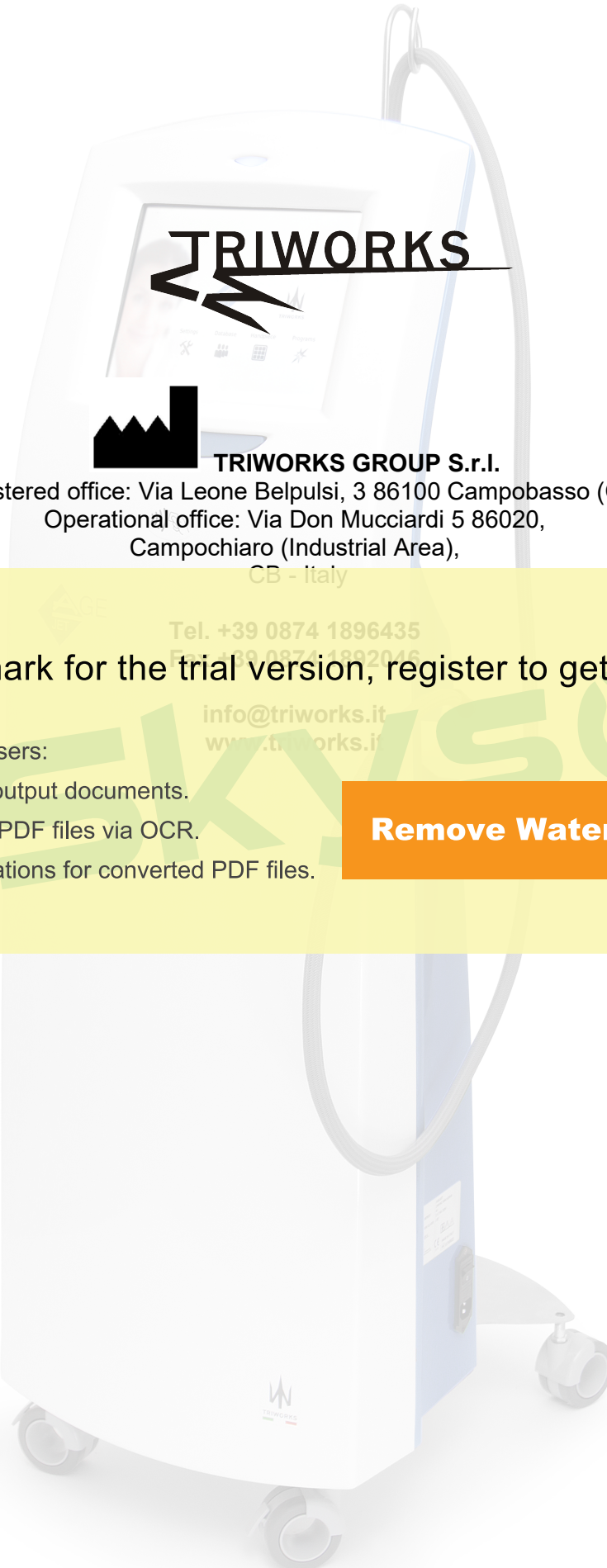
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