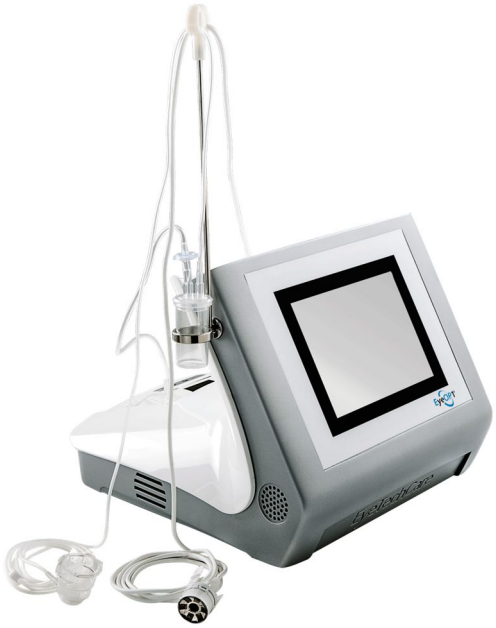
EyeOP1 & associated EYEOP-PACK

USER MANUAL

Version J of **2022/12/13**

English



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The original version of this manual was written in French.

This device is CE-marked, in compliance with the directives 93/42/CEE and 2007/47/CE on medical devices.

1. SECTION 1: INTRODUCTION

1.1 Use of the manual

The present manual contains the instructions for use of the EyeOP1 electro-medical device (Control Unit) and the associated EYEOP-PACK consumable (sterile single-use device) composed of a therapy probe and a coupling cone equipped with a liquid trap. The system is indicated for clinical ophthalmologic use enabling cyclocoagulation of the ciliary body with focused ultrasound for the non-invasive treatment of glaucoma.

The manual provides the duly trained users with complete and detailed instructions for use. Use of the medical device described in this manual must always be prescribed by a qualified physician.

The manual is divided into several parts covering all aspects of the use of the medical device and also safety aspects of focused ultrasound. Read the manual thoroughly before using the device and keep it for further use.

The term '*Medical device*' used in this manual refers to the combination of the *EyeOP1 control unit* and associated *EYEOP-PACK consumables*.

1.2 Icons and symbols

In order to make reading and understanding of the manual easier, the following symbols will be used:

	**= Warning**	This symbol is used to indicate an important warning regarding safety of the device.
	**= Prohibition**	This symbol mainly informs the reader of a prohibited action linked to the safety.
	**= Important information or mandatory action**	This symbol is used when a mandatory action must be done or if specific or additional information is added by the writer.

1.3 Abbreviations

Abbreviations	Complete name	Abbreviations	Complete name
IOP	Intraocular pressure	MHz	Megahertz
M	Meter	GHz	Gigahertz
mm	Millimeter	W	Watt
mm Hg	Millimeter of mercury	V	Volt
°C	Degree Celsius	VA	Voltampere
°F	Degree Fahrenheit	kg	Kilogram
Hz	Hertz	g/L	Gram per liter
hPa	HectoPascal	atm	Atmosphere

2. SECTION 2: GENERAL INFORMATION

2.1 Intended use and indications

This medical device (EyeOP1 control unit and associated EYEOP-PACK consumables) is intended to treat glaucoma. This device allows for non-invasive treatment of glaucoma via coagulation of part of the ciliary body by using focused ultrasound in order to reduce the production of aqueous humor and thereby to decrease the intraocular pressure (IOP*). This treatment is called a UCP Procedure ("Ultrasound Cyclo Plasty").

This type of treatment is indicated for adult patients (over the age of 18) who have glaucoma (open-angle or angle-closure glaucoma) characterized by ocular hypertension greater than or equal to 21 mmHg (for 6-sectors protocol) and greater than or equal to 30 mmHg (for 8-sectors protocol).

**Intraocular pressure measurement is considered with normal central corneal thickness values (Standard pachymetry).*

Expected clinical benefits:

- Reduction of intraocular pressure by more than 20% (by reducing the production/secretion of aqueous humor) to slow down and/or stop the progression of glaucomatous neuropathy.
- Reduced risk of infectious and hemorrhagic complications (non-invasive technique) compared to conventional surgical techniques (filtering surgeries).

2.2 Contra-indications

Contra-indications are as follows:

- Normal tension glaucoma,
- Scleral thinning or ectasia,
- Eye tumour,
- Eye infection,
- Anatomy of the eye non-compatible with the positioning of the device,
- Thyroid orbitopathy,
- Choroidal hematoma,
- Aphakia,
- Valve or any other element on the ocular surface preventing proper positioning of the device on the ocular surface,
- Patient's history of retinal detachment, macular edema, choroidal hematoma, and/or uveitis.

Practitioner is asked to not treat under these conditions.

Precautions:

- A second treatment can be proposed.
- There are no contraindications to conducting a second ultrasound treatment procedure. No increased occurrence of side effects related to retreatment has been reported. The interval between two treatments is left to the judgment of the qualified practitioner.

2.3 Poor indications

Pathologies or patient's history for which the treatment with the medical device may have a limited efficacy and/or may induce higher risk of complications are as follow:

- Diabetic patient with or without diabetic-retinopathy,
- Retinal vein occlusion,
- Vitrectomy,
- Multiple intra vitreous injections,
- Age-related Macular Degeneration (AMD), especially the exudative form,
- High myopia.

Note:

Knowing the results of the clinical studies on secondary glaucoma (neovascular, pigmentary, pseudo-exfoliative, etc), the patient's response rate is lower than for primary open angle and angle closure glaucoma.

The responsibility to treat patients with these poor indications with the medical device is left to the judgement of the qualified practitioner.

2.4 Adverse effects

Possible adverse effects or complications during treatment and/or clinical follow-up (expected adverse effects) are:

- **Anterior chamber**:
  - Mild / moderate intraocular inflammation of the anterior chamber of the treated eye (tyndall effect …).
  - Severe intraocular inflammation (uveitis, etc.).
  - Hyphema.
- **Crystalline lens:**
  - Induced cataract (clouding of the lens).
  - Progression of existing cataract.
  - Phacodonesis (tremulousness or vibration of the lens with eye movement, often due to lens subluxation).
  - Subluxation of the lens.
- **Intraocular pressure:**
  - Hypertonia: > 10 mmHg compared to the initial IOP (transient /chronic: less/more than 3 months).
  - Hypotony: intraocular pressure less than 6 mmHg (transient /chronic: less/more than 3 months).
  - Phthisis of the eyeball.
- **Eyelid:**
  - Blepharitis.
  - Bleeding of the internal lining.
- **Cornea:**
  - Superficial corneal complications (superficial punctate keratitis, ulcers).
  - Deep corneal complications (edema, opacity, decompensation, corneal dystrophy).
- **Sclera and conjunctiva:**
  - Scleral thinning and/or spots on sclera.
  - Conjunctival ulceration/erosion.
  - Scleral ulceration.
  - Limbal-scleral perforation.
  - Conjunctival hyperemia, chemosis, conjunctival bleeding.
  - Subconjunctival haemorrhage, conjunctivitis.

- **Visual acuity – Refraction:**
  - Change in refraction (induced astigmatism, etc.).
  - Transient (< 3 months) or permanent (> 3 months) decrease in visual acuity.
  - Transient monocular diplopia.
- **Retina – Choroid – Vitreous humor:**
  - Retinal complications (retinal tear, retinal detachment).
  - Choroidal, vitreous hemorrhage.
  - Choroidal detachment.
  - Macular edema.
- **Pain:**
  - Transient acute ocular pain.
  - Chronic ocular pain.
  - Headaches.
- **Eyeball:**
  - Infection of the eyeball.
- **Iris:**
  - Burning of the iris.
  - Iris and lens synechiae.
  - Iris and corneal synechiae.
  - Goniosynechiae.
  - Paresis.
  - Mydriasis.
  - Corectopia.

2.5 User profile

This medical device (EyeOP1 Control Unit and associated EYEOP-PACK consumables) is not intended to be used by a layperson to perform a treatment.

It is intended for use by public or private sector ophthalmologists who specialize in the treatment of glaucoma or cataract (for combined cataract/glaucoma treatment). The ophthalmologist is trained for the use of the appropriate protocols.

In addition, the present User Manual supplied the EyeOP1 Control Unit is available to the user, detailing the treatment procedure.

The trained ophthalmologist may be assisted by a nurse or intern in performing the treatment preparation and monitoring during the treatment procedure.

2.6 Treatment session

A treatment session corresponds to the treatment of one eye, the therapy probe being set up with appropriate parameter configuration. The treatment must be prescribed by a qualified physician.

2.7 Anesthesia

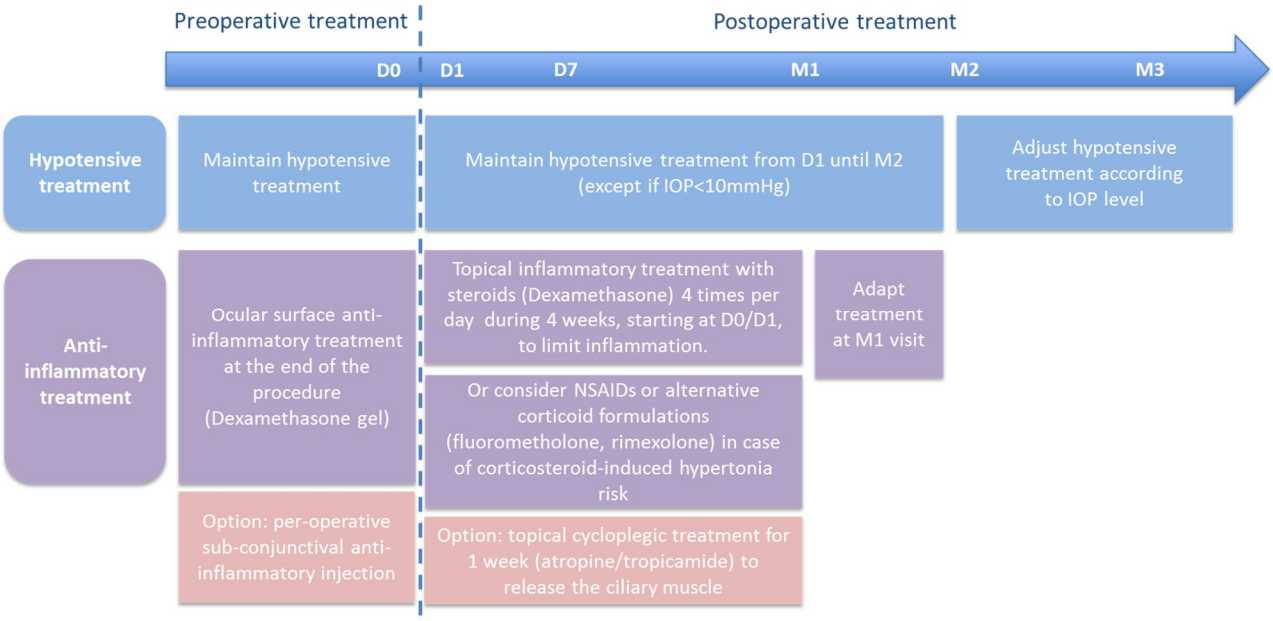
Anesthesia (general, local or topical) must be performed on the patient before the treatment session.

The patient must lie on his back (supine position) and remain still throughout the treatment so as not to shift the coupling cone and therapy probe out of position.

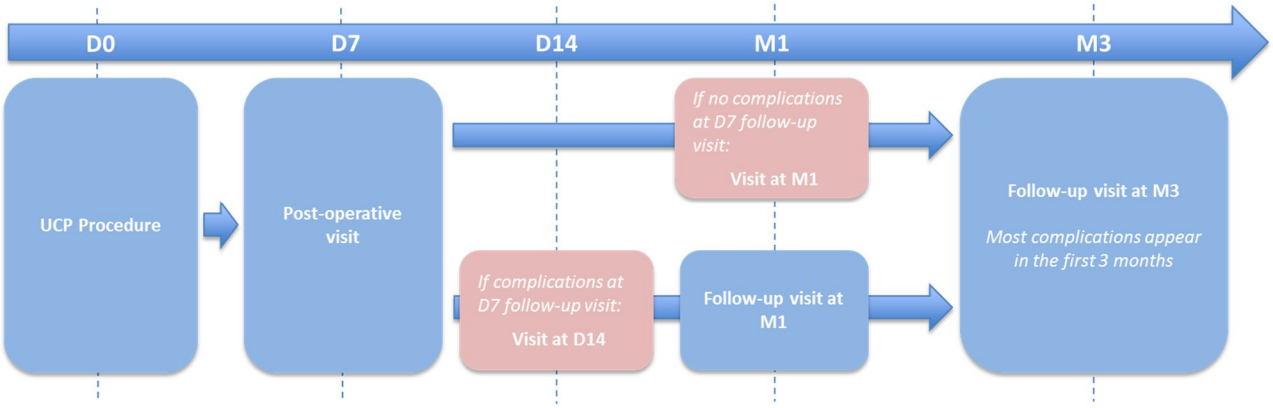
The physician or operator using the medical device must be present throughout the treatment and carefully supervise the patient.

2.8 Pre- and post-treatment

2.8.1 Recommendations concerning hypotensive and anti-inflammatory medications



2.8.2 Recommendations concerning post-treatment follow-up



3. SECTION 3: SAFETY AND PRECAUTIONS FOR USE

This section concerns the safety and precautions for use of the medical device (EyeOP1 control module, its accessories and associated EYEOP-PACK consumables). These precautions must be taken in order to ensure optimal product performance, treatment efficacy, as well as patient and operator safety.

3.1 General safety

The EyeOP1 control module and associated EYEOP-PACK consumables form a medical device that generates focused ultrasound via the therapy probe. Consequently, several precautions and general safety measures must be taken:

It is essential to thoroughly read and understand the contents of the present manual before using the EyeOP1 control unit, its associated accessories and EYEOP-PACK consumables.

The medical device is not intended for use other than that described in the present manual and for which it was designed.

The EyeOP1 control unit and EYEOP-PACK consumables presented herein have been developed and tested for a specific use within the frame of glaucoma treatment by coagulation of the patient's ciliary body, upon prescription of a qualified physician, and upon selection of parameters specific to each therapy probe. No other use shall be made of this device.

Installation of the medical device must be carried out by a physician approved by EYE TECH CARE.

Only accessories and options authorized by EYE TECH CARE shall be used with the medical device described in the present manual. The mains supply cable must not be replaced by the user. Use of any other equipment shall be subject to authorization upon request to EYE TECH CARE.

The various elements of the EYEOP-PACK consumable are intended for single-use. Consequently, they must not be reused. They must be discarded in appropriate containers after use (contaminated waste).

The medical device shall never be left unattended when in operation. The operator shall be present throughout the treatment.

All technical software supplied with the medical device are exclusively intended for usage and indications initially defined by the manufacturer. Any other use must be excluded.

No other software shall be installed on the device without written authorization from EYE TECH CARE. Doing so could induce a risk of failure of the equipment, or even a risk for the patient safety or environment.

Do not expose the medical device to a material that could affect its operation, such as magnetic fields, external electrical influences, electrostatic effects, etc.

Do not use the medical device in the presence of flammable or explosive gases.

The users shall comply with the maintenance guidelines provided by EYE TECH CARE in order to preserve the safety and performance of the medical device. That is why a periodic

maintenance (annual) must be done by EYE TECH CARE or person qualified by EYE TECH CARE in order to do the necessary maintenance and calibration operations.

3.2 General warnings

3.2.1 Warnings on the medical device

It is essential to read and understand these warnings before going further into the manual:

Only a properly trained and qualified users shall use the EyeOP1 control unit, its associated accessories, EYEOP-PACK consumables and mains supply cables described in the present manual.

The EyeOP1 control unit is only compatible with the associated EYEOP-PACK consumables. Consequently, only EYEOP-PACK sterile consumables can be used with the EyeOP1 control unit. Likewise, EYEOP-PACK sterile consumables should not be used with a device other than the EyeOP1 control unit.

Use of the medical device, or any part thereof, other than as described in this manual will, under no circumstances, be construed as the responsibility or liability of EYE TECH CARE.

Use of the medical device described herein must always be prescribed by a qualified physician and shall consequently never occur under other conditions.

EYE TECH CARE shall not be held responsible if the user does not comply with all procedures or recommendations described in the present manual and/or if he uses the device to other aims than the claimed intended use.

The room where the device is installed shall meet the requirements on electric equipment. EYE TECH CARE cannot be held responsible if these requirements are not met.

Any technical interventions on the medical device other than those authorized by EYE TECH CARE can induce partial or total suspension of the warranty.

The maintenance operations shall be done by technicians trained and qualified by EYE TECH CARE. EYE TECH CARE shall not be held responsible if the user refuses maintenance operations by a trained and qualified technician, or if he does it by himself.

Switch off the electrical mains and disconnect the system from the mains supply before cleaning or inspection.

CE 0459 identification is placed on the medical device to indicate that the medical device was produced in compliance with the current European Directives on medical devices

The EyeOP1 medical device is not intended for domestic use. If it is not installed in compliance with the instructions for use, it can cause interference that could damage other more sensitive equipment or be disrupted by their possible excessive radio-electric emissions. It may be necessary to take mitigation measures, such as reorientation or installation of the EyeOP1 control unit in another room, or shielding of the location.

Moreover, cellular phones and other mobile communication equipment must not be used close to the medical device, since they could affect it. Any other device used close to the EyeOP1 device must comply with the IEC 60601-1-2 standard.

When an error message appears, it is recommended to read and understand the message, to write it down in order to make the technical diagnostic easier, to discontinue treatment if the procedure is not described in the present manual, and to rapidly inform EYE TECH CARE (or the local distributor).

If unusual events persist or if unidentified problems occur, do not try to dismantle the medical device. Take note of the problem and contact the technical department of EYE TECH CARE at **support@eyetechcare.com**, or the local representative

The procedure to be followed for collecting, discarding, destroying or recycling the equipment, its sub-assemblies, associated accessories and single-use devices, shall comply with the regulation in force in the country and/or hospital where it is being used (if necessary, contact the local agent or distributor).

The EYEOP-PACK single-use consumable must be discarded immediately after use in the appropriate container (contaminated waste).

The end-of-life EyeOP1 Control Unit being considered as an electric/electronic waste (WEEE), EYE TECH CARE will recover and dispose of it according to the WEEE waste collection and recycling procedure. To this end, contact the local representative. By doing so, the user acts positively for the environment, preservation of natural resources and health protection.

3.2.2 Main warnings on treatment

Only a properly trained and qualified users shall use the EyeOP1 control unit, its associated accessories and EYEOP-PACK consumables described in the present manual.

The EYEOP-PACK consumable, containing the therapy probe and coupling cone, is intended for single-use. Consequently, it must not, under any circumstance, be reused.

The EYEOP-PACK elements are ethylene-oxide sterilized. Before use, check the sterility of the product by making sure the packaging is undamaged.

Do not resterilize the EYEOP-PACK elements, before or after use. In case of sterility problems due to damaged packaging, do not use the product.

Check for leakage of the coupling cone tubing, this could prevent sufficient suction.

An inappropriate re-sterilization by the user, not authorized by EYE TECH CARE, could damage the elements of the EYEOP-PACK consumable, such as the probe's transducers, and could lead to under-treatment and/or undesired treatment on surrounding tissues.

The parameters of the therapy probe are specific to each probe and determine the ultrasound energy delivered to the patient. They are automatically detected by the Control Unit once the therapy probe is connected to it.

Proper positioning of the coupling cone and therapy probe is essential, so the patient must remain still in order not to displace them. If these recommendations are not complied with, this may cause improper treatment to be delivered, or even patient injury.

The operator must be present at all times during the treatment and carefully supervise the medical device and the patient.

3.3 Protection against electric shocks

In order to protect the persons against electric shocks, the following recommendations must be followed:

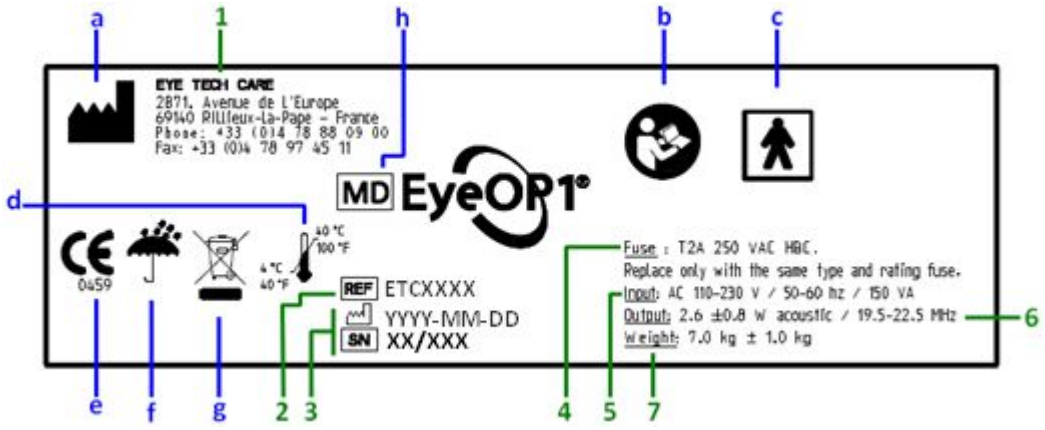
- To avoid any risk of electric shock, this device must be connected to an earthed mains network.
- Always comply with the rules and specifications on electrical installations.
- Never open the EyeOP1 Control Unit. Only qualified personnel are authorized to undertake such an operation.
- Keep the Control Unit away from liquids and never spray water or other liquids on it.
- In case of breakdown or prolonged disuse, it is recommended to disconnect the device.
- If the EyeOP1 control unit is moved, check that the electric plug is suitable for the equipment.
- In case of fire and risk for a device, disconnect the EyeOP1 control unit from the mains network and contact the relevant staff.

3.4 Labelling

Before going further into this manual, read and understand the information appearing on the EyeOP1 Control Unit and EYEOP-PACK labels.

For better traceability, the Unique Device Identifiers (UDI) appears on the labelling of the different levels of packaging of the device and on the device itself when possible and appropriate. The UDI code is preceded by the **UDI** symbol

3.4.1 Signage plate of the EyeOP1 Control Unit



The signage plate of the EyeOP1 device is located on the rear side. It bears the following information:

1. Address and telephone number of manufacturer (EYE TECH CARE).
2. Commercial code of the product.

3. Date of manufacture (year and month) and serial number of the unit.
4. Type and characteristics of changeable fuses.
5. Supply voltage (V), frequency (Hz), and maximum absorbed power (VA).
6. Nominal power (acoustic W) and nominal output frequency (MHz) of the therapy probe.
7. Weight of the Control Unit.

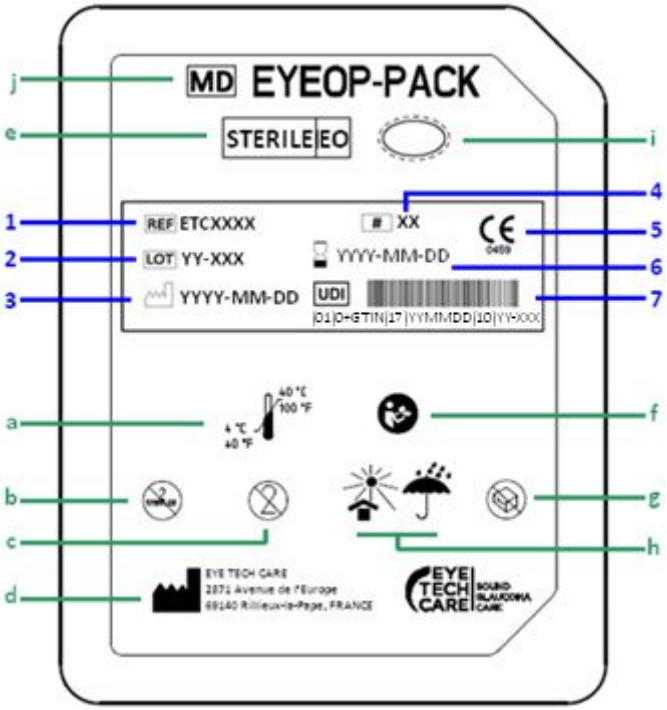
a. "Manufacturer" symbol accompanied by manufacturer's address on label (1.)
b. Warning: Essential to refer to instructions for use.
c. Applied part of the type BF medical device
d. Temperature of storage
e. CE marking
f. Storage in a dry place
g. The control unit to be discarded is WEEE (waste electrical and electronic equipment). Return it to an appropriate collection point for processing, recovery, and recycling of this type of waste or to a distributor.
h. "MD" for "Medical Device".

3.4.2 EYEOP-PACK labels

The EYEOP-PACK contains several labels affixed in various locations on the primary and secondary packaging.

3.4.2.1 Tyvek covering and label of the PET primary packaging

The various elements of the EYEOP-PACK are packaged in a PETg (polyethylene terephthalate glycol) blister, a recyclable plastic material closed with a Tyvek covering, the content of which has been ethylene-oxide sterilized. This primary package is contained in an individual carton box. The printed tyvek covering contains important information. Moreover, an adhesive label is affixed to it.



The information shown on these labels is described and explained in the table below and must be fully understood by the user:

Adhesive label affixed to the EYEOP-PACK lid:

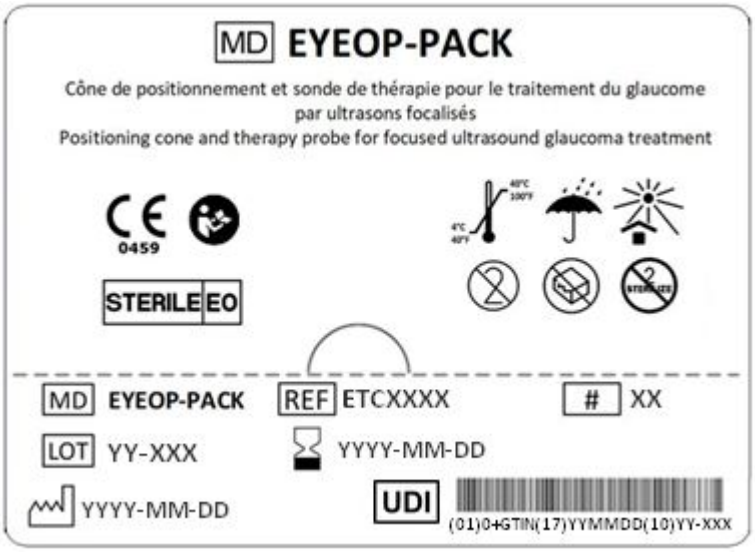
1. Commercial code of the product.
2. Lot number.
3. Date of manufacture.
4. Size of the therapy probe and coupling cone (= Model).
5. CE marking.
6. Expiration date
7. Unique Device Identifier (UDI)

EYEOP-PACK printed lid:

a. Upper and lower temperature limits for use and storage
b. Do not re-sterilize.
c. Do not reuse/single use.
d. 'Manufacturer' symbol accompanied by manufacturer's address on the label.
e. Sterilization by ethylene-oxide.
f. Warning: Imperatively refer to instructions for use.
g. Do not use if the packaging (especially the sterile barrier system) is damaged.
h. Storage conditions: store in a dry place, protected from heat (in accordance with the storage condition described on the labelling and in this user manual §9.2).
i. Symbol which identifies the sterile barrier system (covered blister).
j. "MD" for "Medical Device".

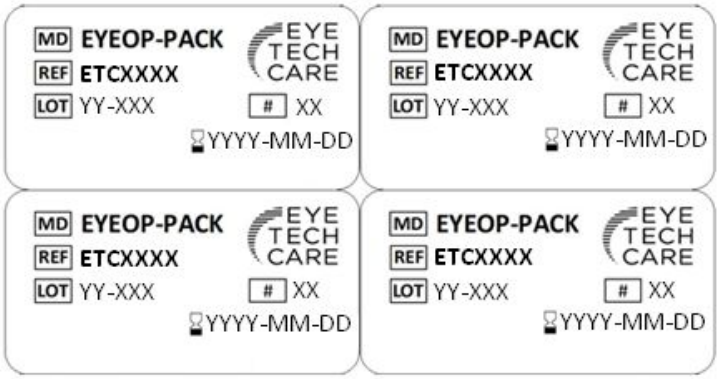
3.4.2.2 Adhesive label of the individual carton box

A label is affixed on the carton box containing the PETG blister. Part of this label is folded over the lid of the box thereby enabling to check that the equipment has not been opened. It contains detailed information about the contents of the EYEOP-PACK *(see § 4.2.1)*.



3.4.2.3 Sheet of detachable labels

The individual box contains a sheet of 4 identical labels to be used by the operator/user in order to ensure traceability of the product according to the procedures in force in the establishment. The information contained is similar to that present on the adhesive label affixed on the box lid.



3.4.3 Electromagnetic compatibility tables (EMC)

The medical device (EyeOP1 control unit and associated EYEOP-PACK consumables) requires specific precautions to be taken with respect to the EMC and must be installed and operated according to the EMC information provided in the tables below.

Cellular phones and other mobile communication devices must not be used close to the medical device, since they could affect its operation. Any other device used close to the medical device must comply with the IEC 60601-1-2 standard. Any incident related with electromagnetic compatibility must be reported to the manufacturer.

Exposure of patients equipped with active implantable medical devices (pacemaker…) to the EyeOP1 control unit and associated EYEOP-PACK consumables must be supervised by a cardiologist.

This symbol means that any equipment emitting radio waves must be OFF when close to the device.

This symbol means that the equipment features a RF transmitter.

Directives and manufacturer's claim – electromagnetic emissions		
The medical device is intended for use in the electromagnetic environment described below. The customer or medical device user must ensure that it is used in such an environment.		
Emission trials	**Compliance**	**Electromagnetic environment - directives**
RF emissions CISPR 11	Group 1	The medical device uses RF energy only for internal functions. Consequently, its RF emissions are very low and not liable to provoke interferences in any neighbouring electronic devices.
RF emissions CISPR 11	Class A	The medical device is suitable for use in all premises other than domestic and those directly linked to the public low voltage supply system feeding domestic use premises.
Harmonic emissions IEC 61000-3-2	Class A	

Voltage fluctuations/ Flicker IEC 61000-3-3	Complies	

Directives and manufacturer's claim – electromagnetic immunity

The medical device is intended for use in the electromagnetic environment described below. The customer or medical device user must ensure that it is used in such an environment.

Immunity testing	Test level IEC 60601	Compliance level	Electromagnetic environment - directives
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV in contact ± 8 kV in the air	Complies Complies	The floor must be made of wood, concrete or thin set tile. If the ground is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient burst IEC 61000-4-4	± 2 kV for electrical feed lines ± 1 kV for input/output lines	Complies Complies	The quality of the mains supply system must be that of a typical commercial or hospital environment.
Transient voltage surges IEC 61000-4-5	± 1 kV between phases ± 2 kV between phase and ground	Complies Complies	The quality of the mains supply system must be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on input electrical feed lines IEC 61000-4-11	<5 % U_T (>95 % dips of U_T) during 0.5 cycle 40 % U_T (60 % dips of U_T) during 5 cycles 70 % U_T (30 % dips of U_T) during 25 cycles <5 % U_T (>95 % dips of U_T) during 5 s	Complies Complies Complies Complies	The quality of the mains supply system must be that of a typical commercial or hospital environment. If the medical device user demands continuous operation during the mains supply failure, it is recommended to feed the EyeOP1 control unit from a failure-free energy supply or from a battery.
Magnetic field at the mains supply frequency (50/60 Hz) IEC 61000-4-8	3 A/m	Complies	The magnetic fields at the mains supply frequency must feature the specific levels of a representative location in a typical commercial or hospital environment.

Note: U_T is the voltage of the AC power supply before application of the test level.

Directives and manufacturer's claim – electromagnetic immunity

The medical device is intended for use in the electromagnetic environment described below. The customer or medical device user must ensure that it is used in such an environment.

Immunity testing	Test level as per IEC 60601	Compliance level	Electromagnetic environment - directives
Conducted RF emissions IEC 61000-4-6 Radiated RF emissions IEC 61000-4-3	3 Veff from 150 kHz to 80 MHz 3 V/m from 80 MHz to 2.5 GHz	3 V 3 V/m	The RF communication mobile devices should not be used closer to any part of the medical device (including cables) than the recommended separation distance, calculated from the equation applicable to the transmitter frequency. **Recommended separation distance:** $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ *80 MHz to 800 MHz* $d = 2.34\sqrt{P}$ *from 800 MHz to 2.5 GHz* where *P* is the transmitter maximal power output in watts (W), according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). It is important that fixed RF transmitter field intensity, determined by an electromagnetic investigation on site[a], be less than the compliance levels, for each frequency range[b] Interferences may occur close to the device marked with the following symbol: 

Note 1: at 80 MHz and at 800 MHz, the highest frequency range applies.

Note 2: These directives may not apply in all cases. Electromagnetic propagation is affected by absorption and reflection of structures, objects and persons.

[a] The field intensities of fixed transmitters, such as base stations for radiotelephones (cellular) and terrestrial mobile radios, amateur radio, MA and MF radio, and TV diffusion, cannot be theoretically predicted with accuracy. To assess the electromagnetic environment produced by the fixed RF transmitters, an electromagnetic investigation must be conducted on site. If the field intensity, measured at the location where the medical device is being used, exceeds the above applicable RF compliance level, the medical device must be checked for normal operation. If abnormal performances are observed, it may be necessary to take additional measures, such as reorienting or repositioning the medical device.

[b] As pertains to the frequency range from 150 kHz to 80 MHz, the field intensities must be less than 3 V/m.

Recommended separation distances between RF communication mobile devices and medical device

The medical device is intended for use in an electromagnetic environment in which RF radiated emissions are controlled. The customer or medical device user can contribute to preventing electromagnetic interferences by maintaining a minimal distance between the mobile device/RF mobile communication device and medical device, as recommended below, in function of the maximal emission power of the mobile communication device.

Maximum rated output power of the transmitter (in W)	Separation distance depending on the transmitter frequency (in m)		
	from 150 kHz to 80 MHz $d = [3.5/3]\sqrt{P}$	from 80 MHz to 800 MHz $d = [3.5/3]\sqrt{P}$	from 800 MHz to 2.5 GHz $d = [3.5/3]\sqrt{P}$
0.01	0.12	0 .12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.7	3.7	7.4
100	11.7	11.7	23.4

For transmitters whose maximum rated output power is not indicated in the above table, the recommended separation distance *d* in meters (m) can be assessed by using the equation applicable to the transmitter frequency, where *P* is the transmitter maximal output power in watts (W), according to the transmitter's manufacturer.

Note 1: at 80 MHz and at 800 MHz, the separation distance for the highest frequency range applies.

Note 2: These directives may not apply in all cases. Electromagnetic propagation is affected by absorption and reflection of structures, objects and persons.

3.5 Safety system and precautions

3.5.1 Characteristics and roles of the general system safeties

Safety checks are constantly being performed by the medical device software throughout the various phases of its use. The following table lists the checks and describe their role and consequences in case of occurrence of the problem they are meant to solve:

Definition	Description	Activated by	Action on	When
ON/OFF button	*Starts/Stops the device*	User (equipment)	Controls general power supply and consequently all sub-assemblies	Continuously
Fuses	*Switches off the mains supply*	Electrical overcurrent (equipment)	Turns off the device and protects the sub-assemblies	Continuously
Firing pedal	*Starts the firing, and immediately stops it in case of pedal release*	User (equipment)	Turns off power supply to the RF electronic board of the generator	Continuously
Watchdog communication	*Displays a message when communication between MMI and RF generator is lost*	Device (equipment + software)	Displays a user message	Start screen
Suction release	*Displays a message when suction is lost (vacuum decay)*	Device (equipment + software)	Displays a user message	During treatment
Adaptation failure	*Detects an adaptation failure on the line of transducers*	Device (equipment + software)	Turns off power supply to the RF electronic board (RF generator)	During treatment

Definition	Description	Activated by	Action on	When
Power failure	*Stops firing*	Device (equipment + software)	Turns off power supply to the RF electronic board (RF generator)	During treatment
Control of power output	*Control of emitted RF power by Wattmeter*	Device (equipment + software)	Turns off power supply to the RF electronic board (RF generator).	During treatment
RF shooting indication/ Ultrasound	*Visualization of the ultrasound/RF shooting power (user information)*	Device (equipment + software)	Activates the ultrasound beam on the sector being shot	During treatment
Off-time	*Imposes a time interval between two shots*	Device (software)	Sets a time interval between two shots and displays remaining time before next shot. Sound signal during waiting period.	During treatment
Probe detection	*Checks integrity of the probe data and compatibility of the probe model.*	Device (software)	Displays an error message asking the user to change probe	At probe connection & before start of treatment phase

3.5.2 Dysfunction

When the software detects an error or abnormality, the user is informed by an error message displayed on the Control Unit screen.

When an error message appears, it is highly recommended that the user:

- Read and understand the message,
- Write down the message in order to make technical diagnostic easier, if necessary,
- Discontinue treatment if, necessary,
- Rapidly inform the EYE TECH CARE technical department at **support@eyetechcare.com** or the local representative.

3.5.3 Emergency stop device

Should the treatment need to be discontinued in an emergency, the operator must release pressure from the firing pedal (otherwise depressed during treatment), which will automatically stop the treatment procedure. If needed, stop aspiration by pressing on the suction button (on top of the firing pedal). Remove the therapy probe and the coupling cone from the patient's eye.

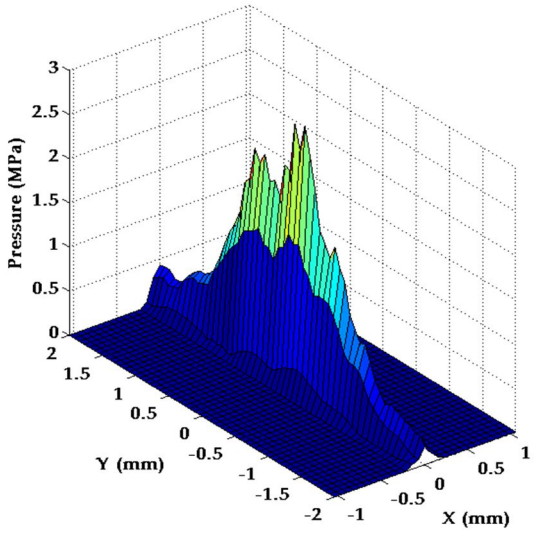
To start treatment again, if needed and appropriate, follow the procedure described in part **2. Management of interruptions in the treatment sequence** of **Section 7**.

4. SECTION 4: DESCRIPTION OF THE EyeOP1 DEVICE AND EYEOP-PACK CONSUMABLE

4.1 General presentation and focused ultrasound principle

The EyeOP1 control unit, combined with the sterile single-use EYEOP-PACK consumable, is intended for clinical use in ophthalmology, enabling to treat glaucoma by cyclo-coagulation of the ciliary body with focused ultrasound delivered by the therapy probe, thereby allowing for a reduction of the intraocular pressure (IOP).

Ultrasound beams, generated by the concave piezoelectric transducers present in the therapy probe, propagate easily through the non-transparent biological tissues without damaging them and can reach the focal zone, i.e. the targeted ciliary body. The radiation penetrates the eye with an effective intensity (IE_{eff}) of 60 ± 11 W/cm^2. At the focal zone, the delivered energy allows for quasi-instantaneous thermal build-up which will destroy the targeted cells through coagulation necrosis.



Pressure at the focal zone generated by the focused ultrasound shot by a transducer of the therapy probe

The medical device is composed of several functional elements:

- The EyeOP1 Control Unit which enables to set up the parameters and control the procedure throughout the treatment.
- The therapy probe, the active element which is connected to the EyeOP1 Control Unit and delivers the focused ultrasound via the six transducers.
- The coupling cone, a non-active part in contact with the eye, which ensures proper positioning of the therapy probe on the eye.

4.2 Description of the device elements

The system is composed of the following elements:

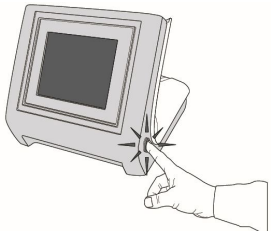
- The EyeOP1 Control Unit
- The sterile single-use EYEOP-PACK consumable, containing a therapy probe and a coupling cone (equipped with a suction circuit and a liquid trap).

4.2.1 The EyeOP1 Control Unit

The EyeOP1 Control Unit enables to set parameters and to control the treatment procedure. In contrary of the sterile single use EYEOP-PACK consumable, the EyeOP1 Control Unit can be used for several patients (with an use in adequation with the conditions described in this User Manual).

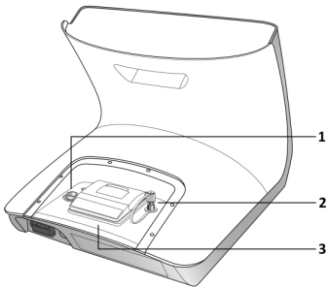
The EyeOP1 Control Unit comprises the following elements:

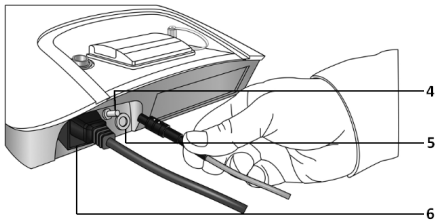
- ✓ Touch screen,
- ✓ ON/OFF button,
- ✓ Mains supply feeding cable,
- ✓ Connections located at the rear (connections for the therapy probe cable and for the suction tubing of the coupling cone, etc.),
- ✓ Cable and liquid trap holder,
- ✓ Printer,
- ✓ Dual function foot pedal (IPX8 classification) with a 3-m cable: large square pedal = firing pedal (treatment) and small round pedal = suction pedal.



Front view of the Control Unit:

- The touch screen is in the middle
- The ON/OFF button is on the side.



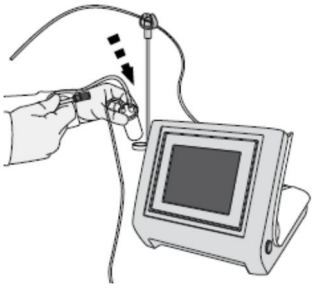


Rear views of the Control Unit:

- The printer containing a paper roll (3) is in the middle,
- Connection for the therapy probe (1) cable is on the left side,
- Connection for the suction circuit (2) is on the right side.
- Connection for the pedal (5) cables is on its right.
- The mains supply connection (6) is on the left,

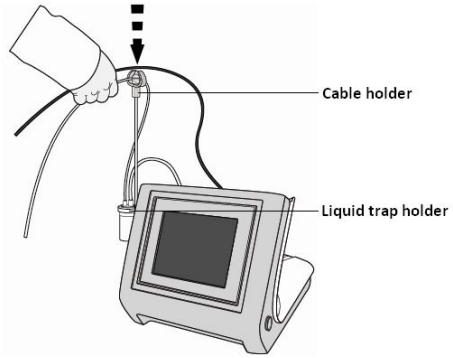
- Potential equalization terminal (4), marked with  . This is provided only to have a reachable earth potential during electrical test (leakage current). It is not necessary to plug it during treatment.

This conductor is not intended for protecting grounding



Front view of the Control Unit with attached cable holder:

- The liquid trap holder is on the side,
- Arrange the cables as shown below.



4.2.2 The single-use EYEOP-PACK consumable

The EYEOP-PACK is a sterile single-use consumable, necessary for operating the medical device via connection to the EyeOP1 Control Unit. It is prescribed by an ophthalmologist for a given patient, and contains the therapy probe, as well as the coupling cone linked to a liquid trap (see figure 1). The EYEOP-PACK comes in three diameters, i.e. 11, 12 and 13 mm. All elements are described hereafter.

The EYEOP-PACK elements are ethylene-oxide sterilized and are packaged in a PETg blister closed with a tyvek covering, and inserted in an individual carton box with a sheet of traceability labels. The EYEOP-PACK must be stored in a dry place at normal pressure, protected from light.

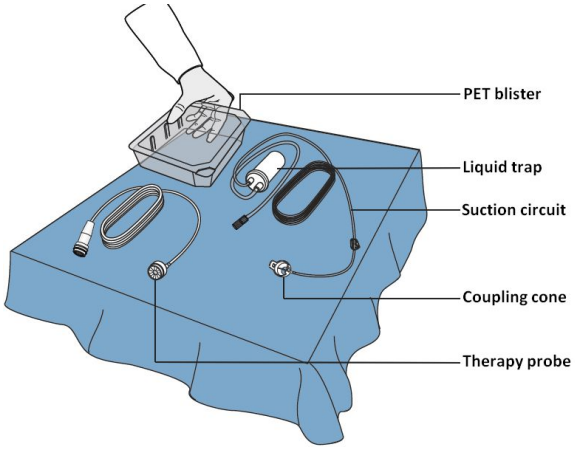


Figure 1: Contents of the EYEOP-PACK

The EYEOP-PACK is a sterile single-use consumable. Contamination of the patient could occur in case of re-use. An inappropriate re-sterilization by the user, not authorized by EYE TECH CARE, could damage the elements of the EYEOP-PACK consumable, such as the probe's transducers, and could lead to under-treatment and/or undesired treatment on surrounding tissues.

The EYEOP-PACK elements are ethylene-oxide sterilized. Make sure that the plastic packaging and tyvek covering are not damaged before use, in order to ensure that the sterility has been preserved. Make sure that the sterility indicator placed on the carton box is green, meaning that the sterilization process has been successfully processed on the consumable.

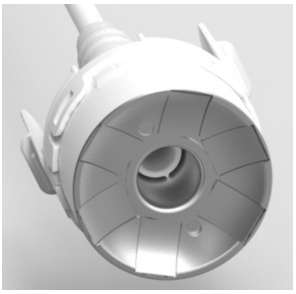
Do not re-sterilize the EYEOP-PACK elements, before or after use. In case of sterility problem due to damaged packaging, do not use the product.

The expiry date is printed on the various labels of the EYEOP-PACK device. Do not use the EYEOP-PACK after this date. Use the EYEOP-PACK elements only with the EyeOP1 device.

The EYEOP-PACK also contains a short illustrated 'Instructions for use' leaflet which does not exempt the user from reading the present User Manual.

4.2.2.1 The therapy probe

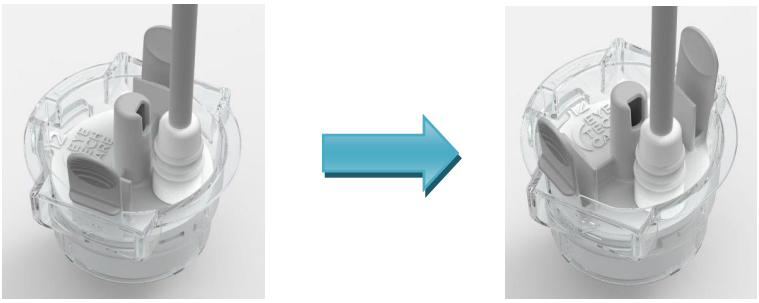
The therapy probe is composed of six piezoelectric transducers, distributed over a section of the circumference, which will deliver ultrasound. During treatment, the probe, a BF type applied part, is placed on the eye by means of the coupling cone and is connected to the Control Unit via a cable which transfers the electric signal enabling the generation of ultrasound beams. There are three different sizes, i.e. 11, 12 and 13 mm, adapted to the ocular anatomy of the patient to be treated.



4.2.2.2 The coupling cone and its liquid trap

The coupling cone is equipped with a liquid trap. In direct contact with the eye, the coupling cone is required to secure the therapy probe on the eye to be treated since the probe is inserted in the cone. The cone also comprises a suction ring, enabling the surgeon to fasten the cone on the eye once the vacuum system is activated on the control unit, and keep it centred on the eye and prevent it from moving, thereby allowing for optimal treatment to be safely achieved.

The coupling cone allows the treatment of 8-sectors, thanks to the 6 transducers of the therapy probe. In order to do that, the therapy probe can be rotated by the user after the treatment of the six first sectors to treat the additional sectors in the second position obtained.



Therapy probe in the coupling cone:
- Left: in its first position for the treatment of the first six sectors
– Right: in its second position for the treatment of the following sectors (for 8-sectors protocol).

4.2.2.3 EYEOP-PACK model selection

Three EYEOP-PACK models are available (11 mm, 12 mm and 13 mm model).

Before any treatment with the medical device, the user must determine the appropriate model/size of EYEOP-PACK consumable to use with the eye to treat. The appropriate size is chosen by the user using a nomogram and its instructions for use (provided by EYE TECH CARE and included in the EyeOP1 Control Unit transport case).

Read the instructions joined with the nomogram carefully before use.

The determination is made by rotating the nomogram disk so that the measured axial length and the white-to-white distance of the eye to be treated correspond, thus showing the EYEOP-PACK model to be used.

Measures of the axial length and of the white-to-white distance by the user:

The devices for measuring the axial length and the white-to-white distance approved for appropriate and safe use of the nomogram are listed in the instructions for use accompanying the nomogram.

If the user does not have one of these approved devices or if the biometric measurements cannot be performed, **the only way** to determine the probe size is to send ultrasound scans (UBM/OCT) to the EYE TECH CARE Technical Service at the following e-mail address: **support@eyetechcare.com**.

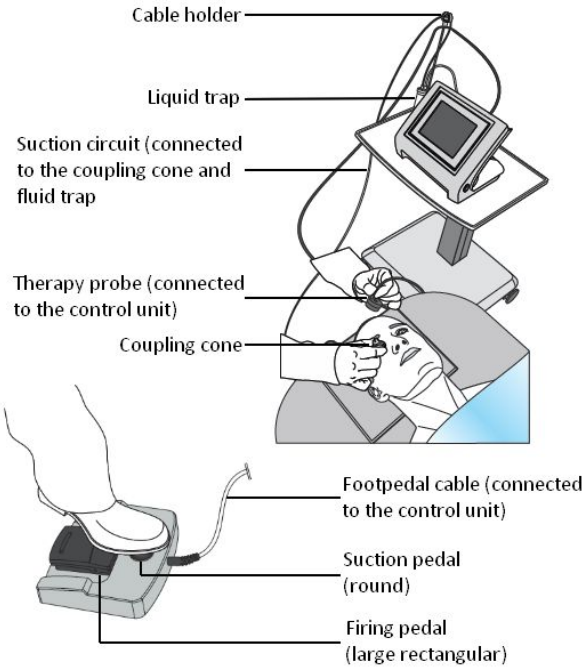
If the nomogram shows that the eye to be treated is outside specifications ("*UCP Treatment not applicable*"), the eye should not be treated with the medical device.

Do not use the nomogram without its user instructions, or if the state of the nomogram and/or its user instructions no longer allow it to be used safely.

In the event of loss, or if the nomogram and/or its user instructions no longer allow the device to be used safely, contact the Technical Service for a replacement tool at the following e-mail address: **support@eyetechcare.com**.

Ensure that only the latest version of the nomogram that has been sent to you by EYE TECH CARE is used. In case of doubt, contact EYE TECH CARE at the following email address: **support@eyetechcare.com**.

4.3 Description of the system installation and treatment configuration



The EyeOP1 Control Unit must be used in a hospital environment, in an operating theatre or ambulatory (depending on anaesthesia conditions), and connected to an adequate electrical plug (230 V) on a mains supply withholding at least 10A.

To fully stop mains supply, press on the ON/OFF button or disconnect the mains supply plug. As both elements are used as sectioning devices, they must remain easily accessible.

The EyeOP1 Control Unit must be installed in a stable horizontal position in a cleared area, next to the patient's head.

Check that the cables are not too tight, tangled, or knotted.

4.4 Summary of the technical performances of the device

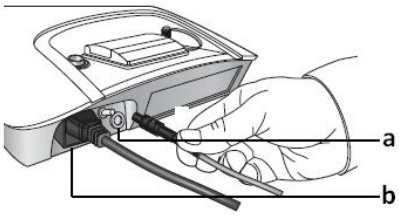
Whatever the treatment protocol selected by the user in accordance with the indications (see SECTION 2 §2.1), **the firing time is 8 seconds per sector and 20 seconds of pause time between each sector**.

All the sectors of the selected protocol are mandatory (the user cannot modify the number and disposition of the treated sectors of the selected protocol). Treatment parameters (off-time, firing time per sector, allowed protocols) cannot be set by the user.

Acoustic power	2,6 Wac $^{\pm 0,8\ Wac}$ during 8 seconds per sector
Operation frequency of the RF generator of the EyeOP1 Control Unit	19,5 – 22,5 MHz $^{\pm 0,05\ MHz}$

5. SECTION 5: SWITCHING ON THE EyeOP1 CONTROL UNIT

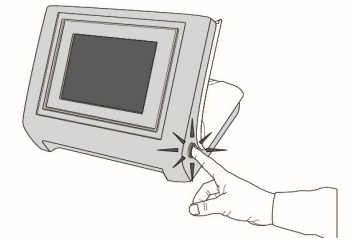
1. Connect (with normal force) the control pedal to the dedicated connector (a) at the rear of the Control Unit.



It is not necessary to use force to connect the pedal. If the connection to the Control Unit is impossible, it is probably due to the asymmetric connector avoiding an inappropriate connection. In that case, rotate the connector until to be able to insert it without using force.

2. Connect the power supply cable to the rear of the Control Unit (**b**) and plug it to 230V mains supply.

3. Depress the ON/OFF button located on the side of the Control Unit and wait 30 seconds to access the Main Menu.



*If the Control Unit is equipped with a rechargeable battery, if the "**RAAA051 Low Battery**" message is displayed on-screen during control unit start-up (this may occur if the control unit is left unused for several months), please leave the latter powered on for 24 hours after the treatment session, in order to recharge the battery, thus preventing complete discharge that would require servicing by EYE TECH CARE before the device could be reused.*

As long as the battery is not completely flat however, knowing that it is not used to back up the control module data internally, and knowing it recharges whenever the module is powered on, there is no risk of the control module powering off and a treatment can be safely performed.

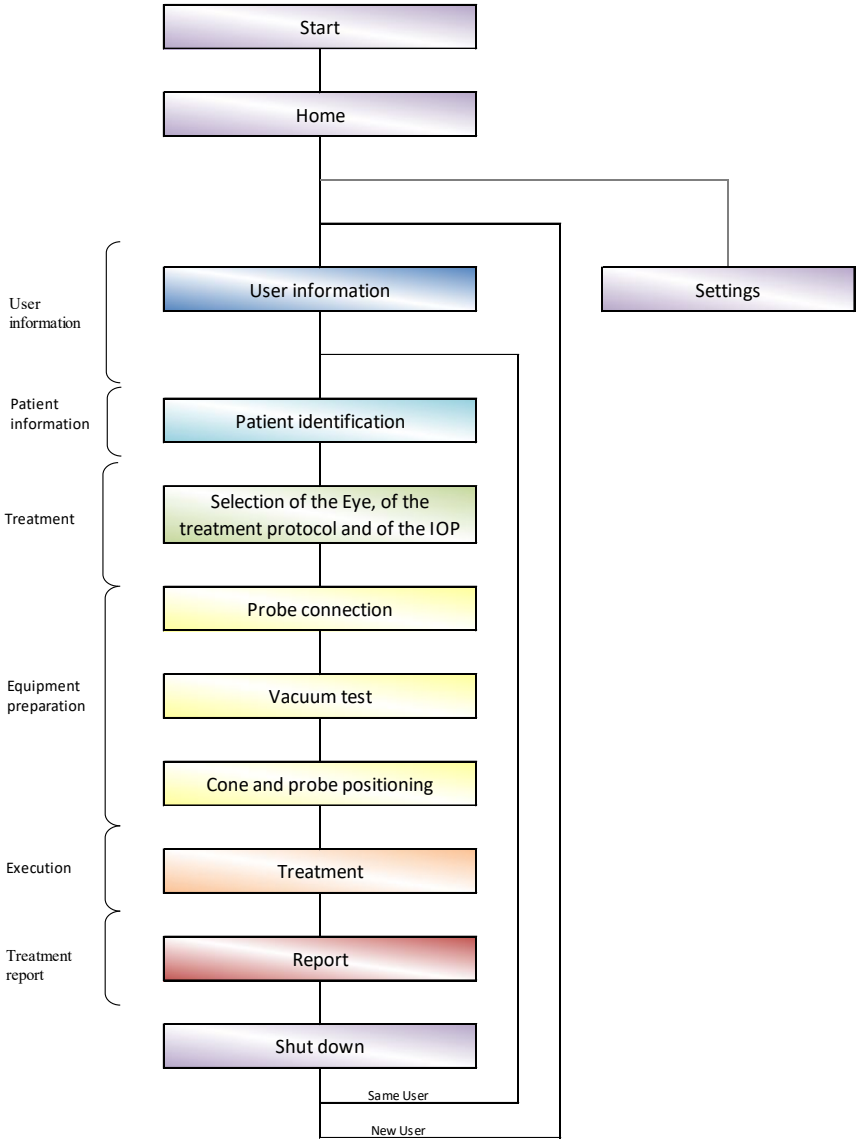
If the Control Unit is equipped with a non-rechargeable battery, if an error message is displayed on-screen asking to replace the battery (meaning that the battery will be flat soon), please contact the EYE TECH CARE Technical Department according the procedure described in Section 7 §3 "Breakdowns and errors".

As long as the battery is not completely flat however, knowing it is not used to back up the data internally, there is no risk of the control unit powering off and the started treatment procedure can be safely performed.

6. SECTION 6: DESCRIPTION OF THE TREATMENT PROCEDURE

6.1 General operation

The device operation follows the standard treatment procedure described in the following synopsis. Each step will be detailed in part **3. Detailed operation** of this section.



6.2 General rules and conventions

6.2.1 Screens and navigation bar

To almost each step of the synopsis (***see previous part***) there is a corresponding screen on the Control Unit. Navigation between screens can be achieved using the bar present at the bottom of the screen (**figure 2**):

- Pressing the right-hand side arrow enables to go to the next screen,
- Pressing the left-hand side arrow enables to return to the previous screen.

Figure 2: navigation bar

In some cases, when the conditions required to go to previous or next screen are not met (incomplete process, data not entered or incorrect, etc.), the corresponding arrows are blackened (**figure 3**), and pressing on them will have no effect.

Figure 3: switch to the next screen is not possible

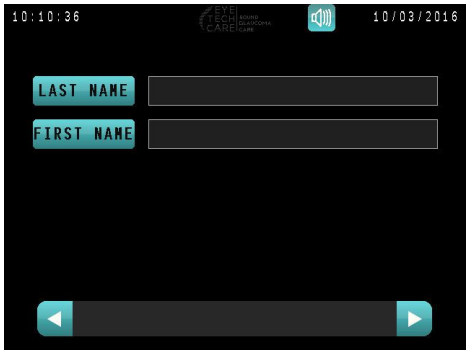
In some cases, this navigation bar is implicit and therefore is not displayed. It is replaced by the selection of an action (e.g. on the Main Menu).

6.2.2 Data entry

To enter data (names, figures …), the user must:

1. Press on the data entry field or on **LAST NAME** or **FIRST NAME**. A virtual keyboard is then displayed.
2. Enter the characters using the virtual keyboard.
3. Validate the entry by pressing on ✓.

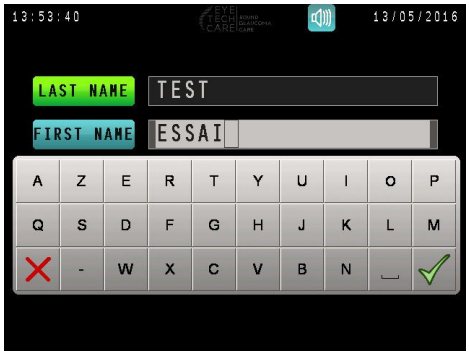
After each entry, validate by clicking on ✓ in order to move to the next step.



If no data has been entered, the field color is blue. If the entry is not valid, the field color is red.

When entered data are correct, the field color becomes green and the move to the next step is authorized and automatic.

In case of error or incorrect data entry, or if the first character is a spacing « ␣ », the field color is red and prevents moving to the next step. The value entered must then be corrected.



6.3 Detailed operation

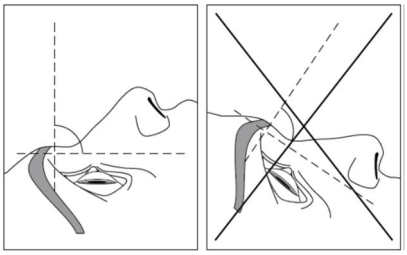
The following parts describe in chronological order the steps to be followed in order to ensure proper operation of the medical device.

Before starting the procedure, make sure you have read and understood the 'safety and precautions for use' part of **Section 3**.

The anesthesia (general, local or topical) must be performed on the patient only after the medical device has been switched ON and after checking its proper operation.

Leave enough time for the anesthesia to be effective. The treatment should not be painful if the anesthesia is administered properly.

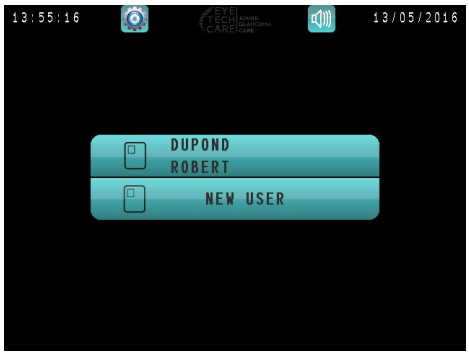
The patient must be immobile and lying flat on his/her back, so as to have a vertical optical axis (*see below*) for the entire duration of the treatment and preparation.



Before each treatment, make sure that the printer is fed with enough paper in order to print the treatment report: see '**§4.3. Checking, replacing and repositioning the printer paper'** of **Section 7.**

6.3.1 Step 1. Information for the physician-ophthalmologist-user

After turning on the machine, the user must identify himself in the Main Menu:



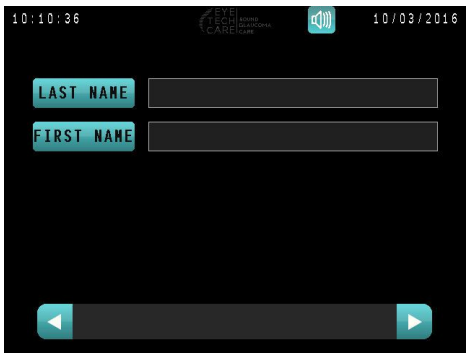
1. Select **USER**

   If the previous treatment procedure was performed by the same user, you can select the key with the latter's last and first names, and thus go directly to step 2.

2. Enter the user's last name and validate.
3. Enter the user's first name and validate.

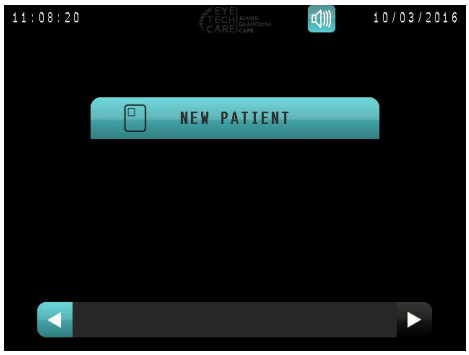
   The physician's first name and last name can include between 1 and 20 characters each, and must not begin with a space "␣".

4. Once the two fields have been correctly filled in, the system automatically moves to the next step.



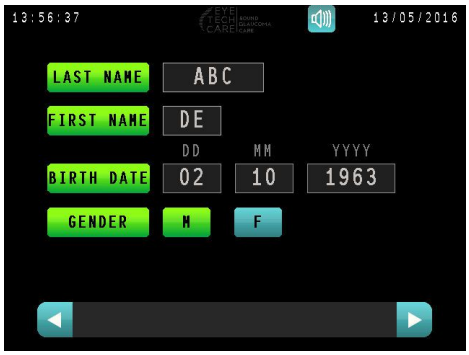
6.3.2 Step 2. Patient information

1. Select **NEW PATIENT** in order to enter information on the patient to be treated.



This option must be ticked regardless of the patient to be treated and no matter if he/she has already undergone a previous treatment in the past.

2. Enter the patient's last name (the 3 first letters at a maximum) and validate.
3. Enter the patient's first name (the first two letters at a maximum) and validate.
4. Enter the date of birth and validate.
5. Enter the patient's gender by clicking on the corresponding key.
6. Go to next step by pressing on the arrow at the bottom right corner of the screen.

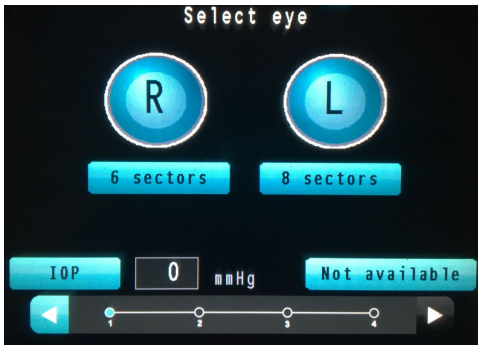


6.3.3 Step 3. Selection of the eye and of the number of sectors to treat

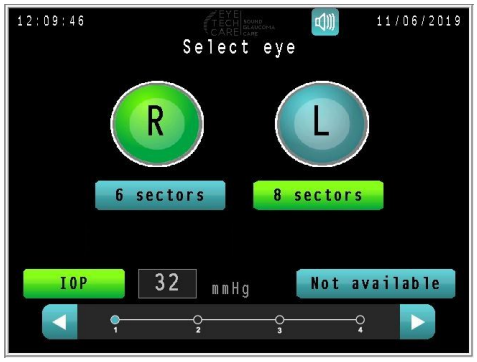
1. Select the **patient's eye** to be treated by pressing on the desired eye. The selected eye then lights up in green.

L for patient's left eye.
R for patient's right eye.

Only one eye can be selected at a time. To change the selection, click on the other eye.



2. Select the number of sector to treat (6 or 8 sectors) by touching the appropriate button.
3. Entering the IOP value (Intra-Ocular Pressure):
   a. Press on the IOP entry field or on IOP to enter the value in mmHg.
   b. Validate the entry.
   c. Go to next step by pressing on the arrow in the bottom right corner of the screen.



It is impossible to return to previous steps once passed to the next screen.

It is not possible to enter an IOP value greater than 99 mmHg.

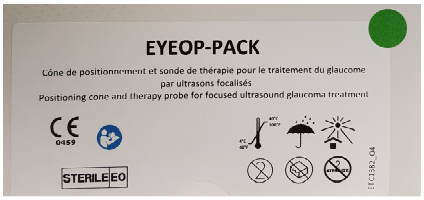
If no IOP value is displayed, click on Not available.
To deselect this option, press again on the same key.

6.3.4 Step 4. Equipment preparation

1. Opening the EYEOP-PACK consumable:

The carton box and the covered blister are not sterile, whereas the content of the covered blister is sterile. So, in order to avoid any contamination of the therapy probe and the coupling cone during the unpacking of the consumable, this step should not be done by the surgeon who will position and maintain the device on the patient's eye, but by a nurse. The therapy probe and the coupling cone which will be placed on the patient must be handle in order to avoid the contamination of the patient (with sterile gloves).

Before unpacking the EYEOP-PACK consumable, make sure the sterility indicator placed on the carton box is green, meaning the device has been successfully sterilized. If the indicator is red or missing, do not use the product.



a. Remove the covered blister from the carton box.

Before unpacking the EYEOP-PACK consumable, make sure the packaging is not damaged and sterility has not been altered. The covered blister is the sterile barrier system: if its visual examination (blister, lid, sealing) reveals the loss of the sterility of the content (damaged or unintentionally opened), do not use the product.

b. Remove the lid of the EYEOP-PACK blister packaging by pulling the tab of the inferior right corner of the lid.

c. Gently spill the content (therapy probe and equipped coupling cone), without touching it, on a sterile field.

Make sure to handle the therapy probe only via its cable outlet and/or by its wings and the coupling cone with sterile gloves in order to avoid contaminating the part indirectly in contact with the patient's eye.

Check that the various elements of the EYEOP-PACK are undamaged (therapy probe, coupling cone, suction circuit).

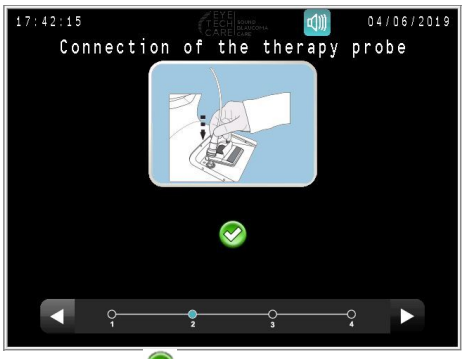
Handle the therapy probe with care. A shock applied to the transducers could damage them and affect the treatment safety. In case of doubt, use a new EYEOP-PACK.

2. Connecting the therapy probe to the EyeOP1 Control Unit:

a. Connect the therapy probe to the rear of the Control Unit (as shown on the screen):

1. Grip the probe connector by the upper part of the connector,

2. Orientate the engraved visual cue of the probe connector (a vertical line) with the one of the Control Unit (a red dot),
3. Then, push the probe connector to the maximum.



b. Attach the cable to the cable holder of the Control Unit.

c. Once the therapy probe is correctly connected and detected as "Valid", ✔ is displayed; moving to the next step is automatic.

Once the probe is correctly connected, do not disconnect it before the end of the treatment.

During this step of connection of a therapy probe, the EyeOP1 Control Unit will check the validity of the probe (never been used, integrity of the chip containing the probe parameters, transmission of the specific parameters of power and frequency of each transducer). ***If the therapy probe is detected as valid, the Control Unit will mark the probe as "used" since this step, and it will be possible to use this therapy probe to treat the patient's eye only during this treatment procedure.***

Once marked as "used", the therapy probe cannot be used in another treatment procedure for the same patient, even if the user has aborted the treatment procedure before the treatment step with this probe.

If the probe is not connected quickly enough, the detection result may be unsuccessful. Restart detection by pressing ***Probe > Try again <.***

Invalid or missing probe:

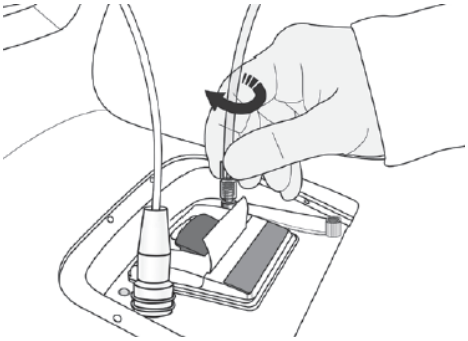
The probe detection is unsuccessful if:

- *No probe is connected (as shown opposite)*
- *The probe is defective,*
- *The probe has previously been used,*
- *The probe is incompatible.*

In this case, connect a new appropriate probe, check its connection, and select ***Probe > Try again <.***

3. Connecting the coupling cone tubing to the Control Unit:

a. Connect the coupling cone tubing to the Control Unit, as shown on the screen and opposite illustration, by inserting it in the connector. Then, screw to lock.

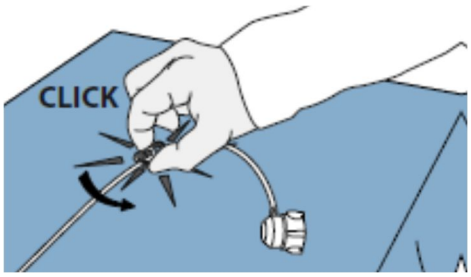


b. Position the liquid trap in its holder on the left side of the Control Unit.

c. Attach the tubing to the cable holder of the Control Unit.

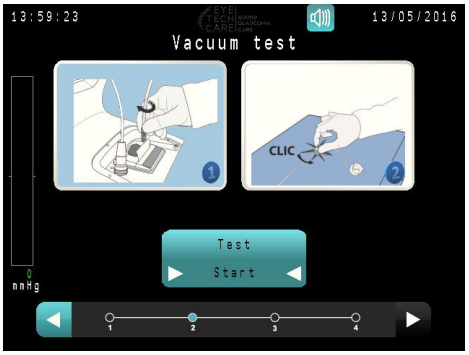
4. Vacuum test:

This test allows you to validate proper operation of the suction system once the tubing is connected to the Control Unit.



a. Clamp the tubing using the clamp provided, as shown on the screen, and leave it clamped until test completion.

b. Start the vacuum test by pressing on **Test >Start<** and wait a few seconds for the test results.



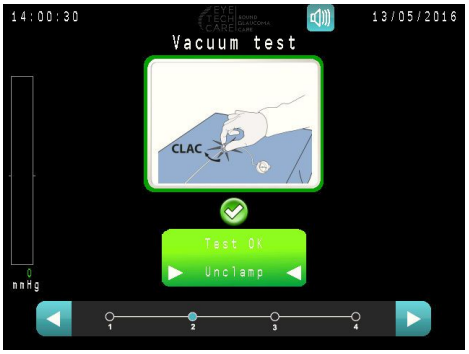
During the test, a "Testing" message is displayed until a sufficient and stable vacuum level is achieved

.

c. Results of vacuum test:

If the test complies:

1. Unclamp the tubing and validate by pressing on the **Test >Unclamp<** icon.
2. Move to the next step by pressing on the arrow (now blue) in the bottom right corner of the screen.



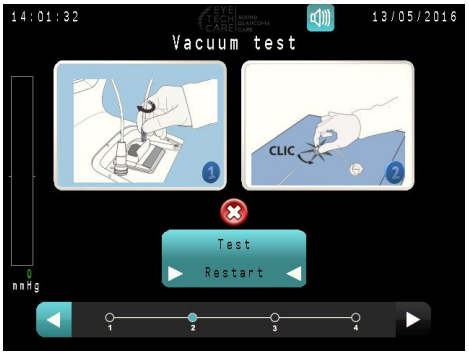
It is impossible to return to previous steps once the vacuum test has been carried out.

If the test does not comply:

1. Check proper connection and integrity of the tubing and make sure it is clamped.

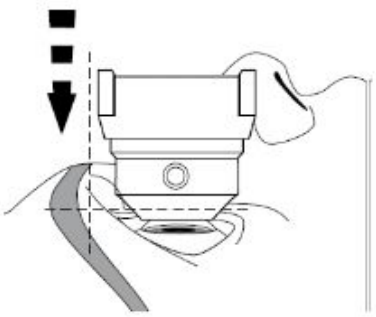
If a leak is detected, replace the device.

2. Repeat the test by pressing on **Test >Restart<** while making sure the tubing is correctly clamped.



It is impossible to move to the next step as long as the vacuum test is unsuccessful.

5. Positioning the coupling cone on the patient's eye:

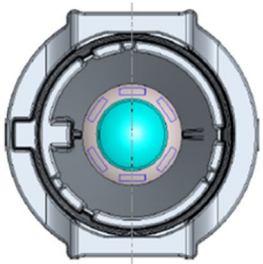


a. Wet the ocular surface with a few drops of standard saline solution.

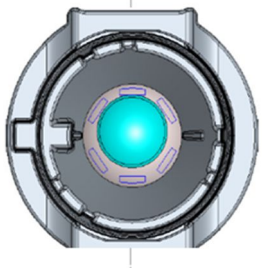
b. Position the coupling cone on the eye, respecting the orientation of the meridians (tubing must be placed on the temporal side), **according to a horizontal plane (no tilt of the cone) and keeping vertical the patient's optical axis.**

c. **Center the coupling cone in order to visualize a uniform peripheral white ring** (visible inside the cone) **and keeping vertical the patient's optical axis.** Make sure not to rub the conjunctiva too much.

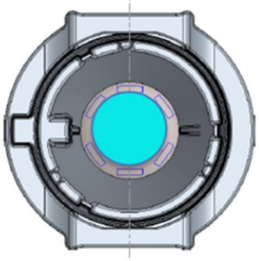
A minimal uniform scleral ring ≥ 2mm is needed



Good centering

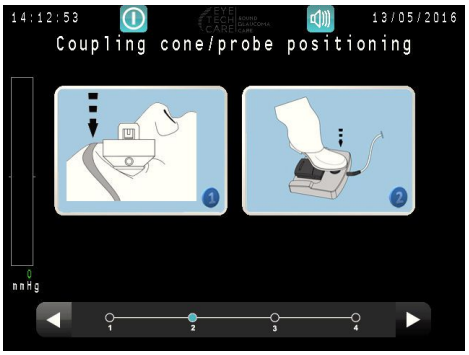


Bad centering: reposition the coupling cone before the treatment.



Insufficient sclera ring (<2mm): do not treat.

d. Activate the vacuum pump by pressing on the suction button, in order **to maintain the coupling cone well-centered and to secure it on the eye**.



Always be sure to keep the coupling cone correctly centered throughout the treatment procedure.

Should centering of the coupling cone be unsatisfactory, stop suction by pressing again on the suction button, then start over again from step 1.

Moving to the next step is possible only if the coupling cone is properly secured on the eye, via sufficient and stable vacuum level, in which case the bar on the left side goes green.

e. If the vacuum test complies, the move to the next step is automatic.

6. Positioning the probe in the coupling cone:

a. Grasp the therapy probe by its tabs (**without squeezing**), in superior-inferior position, and insert in the coupling cone **until the lower ridge on each tab rests on the rim of the cone (do not push)**. The cable of the probe must be in nasal position.

b. Then, squeeze the tabs gently to let the probe drop into place at the bottom of the coupling cone.

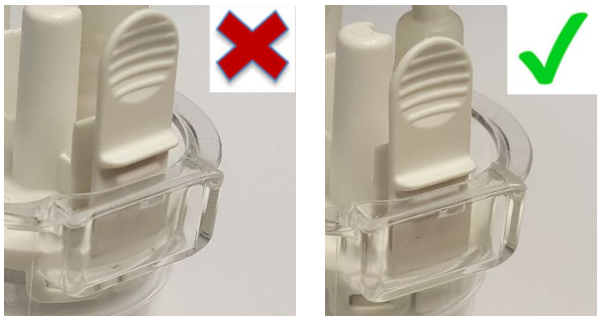
A distinct "*click*" noise will be heard and "felt", which indicates the probe is correctly locked in place.

Release the tabs of the probe.

Do not try to rotate the probe in the coupling cone.

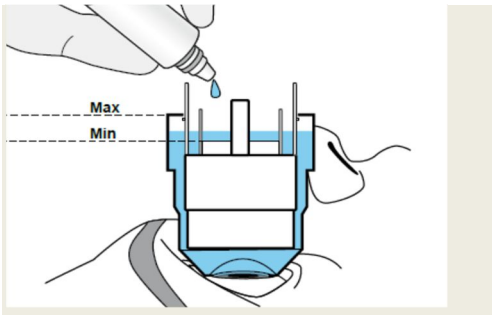
If the "click" noise is not heard, or if the user is uncertain that the probe is properly locked in, remove the probe from the coupling cone, and restart the insertion procedure at step **a**.

Visually ensure that the tabs of the probe are securely locked into place on the rim of the coupling cone.



Always be sure to not move the coupling cone and the therapy probe in its position on the eye throughout the treatment procedure (maintain it centred).

c. Fill the therapy probe and the coupling cone with standard sterile saline, **at room temperature**, to a level between Min. and Max. as shown on the image below, then validate by pressing on Cone filled with BSS.



Wait a few seconds after filling to ensure that there is no leak before the treatment starts.

Throughout the treatment procedure, make sure the device remains filled but not overfilled with saline solution (see proper levels at right).

d. Go to the next step by pressing on the blue arrow in the bottom right corner of the screen.

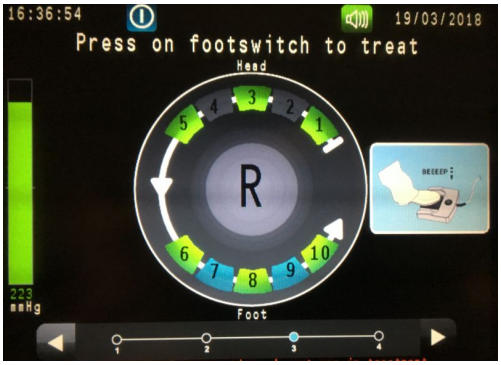
Moving to the next step is possible only if the coupling cone is securely positioned on the eye, indirectly indicated by the 'green' vacuum level bar.

In case of suction problems (vacuum level in red), an error message is displayed. Stop suction by pressing on the suction button, and start over again from the 'Positioning the coupling cone on the patient's eye' step.

6.3.5 Step 5. Treatment

Once the therapy probe is correctly positioned on the eye, treatment can start. The treatment consists of one (6-sectors protocol) or two (8-sectors protocol) sessions of treatment (example below for 8-sectors protocol).

1. **<u>Start the treatment session by pressing - and maintaining pressure - on the firing pedal.</u>**



The firing on the first sector of the sequence starts after a short countdown.

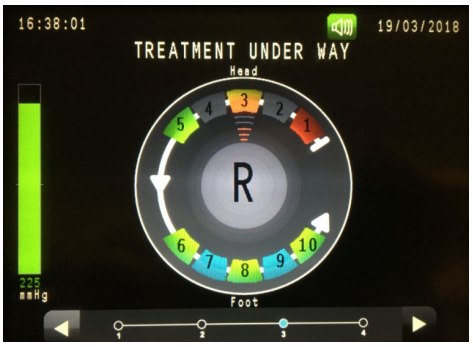
*The firing time on each sector lasts **8 seconds**, and there is a 20-second interval between two consecutive shots.*

Maintain the coupling cone and the therapy probe in its position on the eye throughout the treatment procedure in order to keep it correctly centered.

***Pressure must be maintained on the pedal throughout the treatment, including off-time between two sectors, as shown on the screen by a countdown**. Releasing this pedal results in immediate stoppage of the treatment.*

*Management of interruptions in the treatment session is described in **point 2 of Section 8 Errors and Warranty**. During the treatment phase, check that the saline level has not gone down. If necessary, top up again. The saline level must never drop below the minimum level.*

2. Treatment under way (as indicated by the change in colour of sectors being treated).

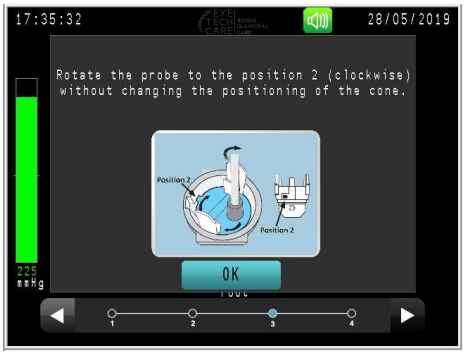


The green colour denotes the sector has not been treated yet.
The orange colour under which the waves are depicted is being treated.
The red colour denotes the sector has been successfully treated.
The orange colour denotes the sector has only been partially treated.
The blue colour denotes the sector which will be treated in the second session of treatment.
The gray colour denotes the sector which will not be treated (for 6-sectors protocol, the sector 7 and 9 are also filled with gray).

3. Once the first session of treatment done, release the firing pedal

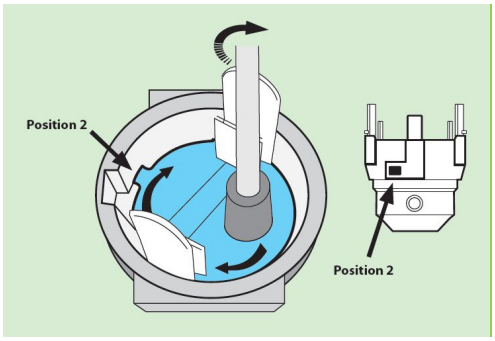
For 6-sectors protocol, refers to **Step 6** "Treatment completion".

For 8-sectors protocol: after a loading period, a message is displayed, asking the user to rotate the therapy probe in the coupling.



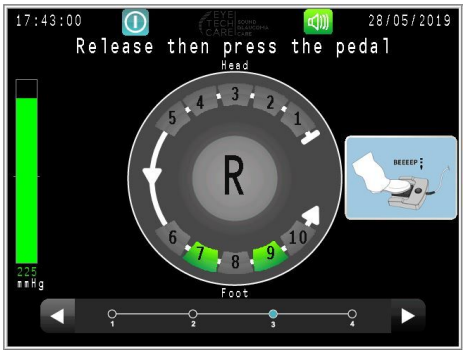
4. Rotation of the therapy probe in the coupling cone *(only for 8-sectors protocol):*

Rotate the therapy probe in the coupling cone in the clockwise direction up to the stop, without forcing, by using the wings of the probe. Once done, release the wings in order to maintain the probe in its second position. Then, push the **OK** button.



Do not move the coupling cone, and keep it centered on the eye during the rotation of the therapy probe.

5. **<u>Start the second treatment session by releasing</u>** (if not already done) then by pressing - and maintaining pressure - on the firing pedal.



The shoot on the first sector of the sequence starts after a short countdown.

*The firing time on each sector lasts **8 seconds**, and there is a 20-second interval between two consecutive shots.*

6.3.6 Step 6. Treatment completion

1. When treatment is completed, suction automatically stops. Release the firing pedal.

2. The Control Unit automatically displays the Treatment Report screen describing operations carried out for each sector, and a first automatic print (default print) is delivered by the printer located at the rear of the Control Unit.

Additional prints of the treatment report can be obtained by pressing on **PRINT**.

Even if the automatic printing is disabled in the Settings Menu (§4.2), if one or more interruptions occurred during the treatment, an automatic print is systematically delivered.

Accuracy of values displayed is as follows:

- *Negative pressure : ± 5%*
- *Firing time : ± 0.1 sec*
- *Frequency : ± 10 Hz*
- *Power : ± 10%*

3. Remove the coupling cone and therapy probe from the patient's eye, while carefully sponging up the liquid contained in the center of the device, and discard everything appropriately (contaminated waste).

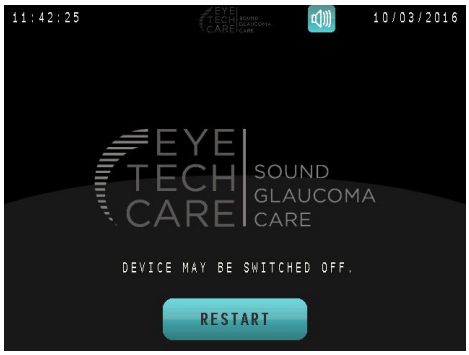
4. Disconnect the therapy probe by grabbing it by the lower side of the connector, then raise the "locking-ring" allowing an easy disconnection (see picture aside).

5. Move to the next step by pressing on the blue arrow in the bottom right corner of the screen.

6. Shut down the Control Unit by pressing the ON/OFF button on the side of the device.

OR

Select the RESTART icon to start a new treatment - with the same user or not- without shutting down the Control Unit.



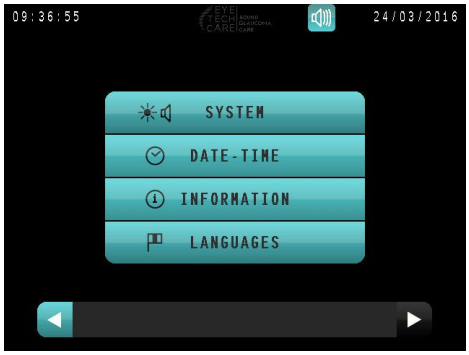
6.4 Other settings

In the Main Menu screen, it is possible to access the Settings Menu to adjust different parameters by selecting the  icon at the top of the screen.

6.4.1 Adjusting the screen brightness and sound volume

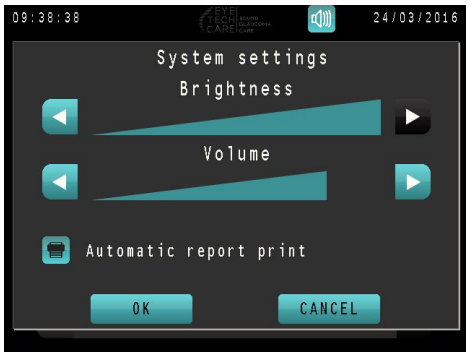
1. When in the Settings Menu, press on SYSTEM.

To return to the main menu, press on the blue arrow on the bottom left corner of the screen.



2. Press on the left and right arrows on each side of the bargraphs to adjust the screen brightness and volume.

With some Control Units, the sound volume is not adjustable.

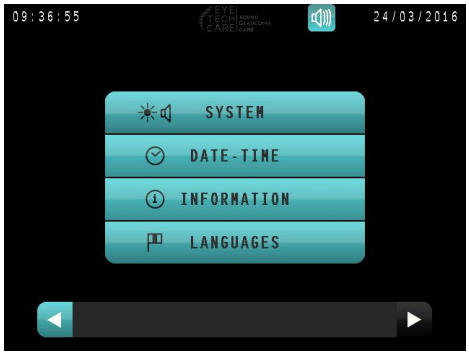


3. Press on OK to validate the changes and return to the Settings Menu, or press on Cancel to return to the Settings Menu without modifying these parameters.

It is possible to adjust the volume during the treatment by selecting the icon *at the top of the screen and by pressing on the* + *and* - *icons. With some Control Units, these buttons are not available.*

6.4.2 Adjusting automatic treatment report printing

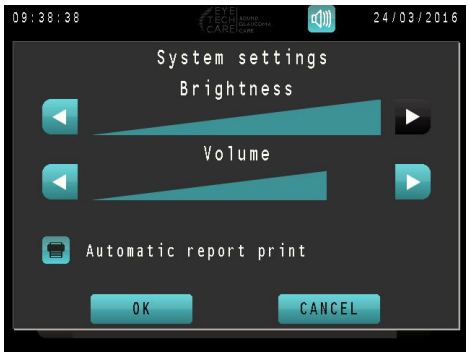
1. Press the **SYSTEM** icon on the Settings Menu screen.



To return to the Main Menu, press the blue arrow in the bottom left-hand corner of the screen.

2. Press the Icon. When it turns green, this means that automatic printing is enabled and that a paper printout will automatically be produced upon completion of each treatment.

3. Press **OK** to validate your changes and return to the Settings Menu, or press **Cancel** to return to the Settings menu without changing these settings.



6.4.3 System information

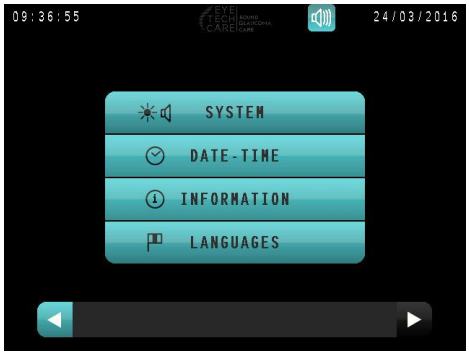
This screen summarizes information on the Control Unit (software, serial number, etc.).

Select **INFORMATION** in the Setting Menu to reach this screen.

No information can be modified.

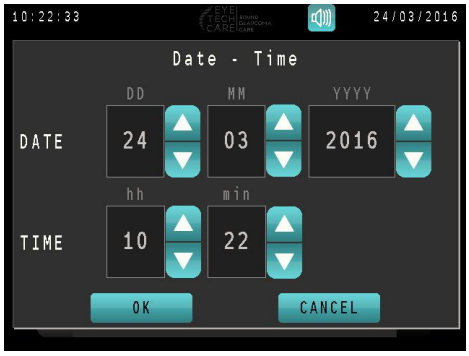
6.4.4 Setting the date and time

1. Press on **DATE - TIME**.



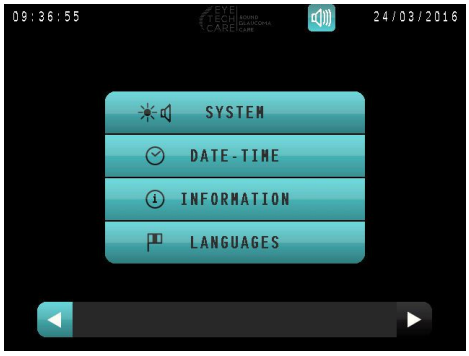
2. Set the date and time by screening the values using the and arrows.

3. Press on **OK** to validate the changes and return to the Settings Menu, or press on **CANCEL** to return to the Settings menu without modifying these parameters



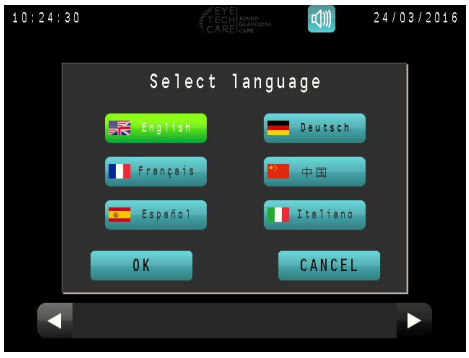
6.4.5 Language selection

1. Press on **LANGUAGES**.

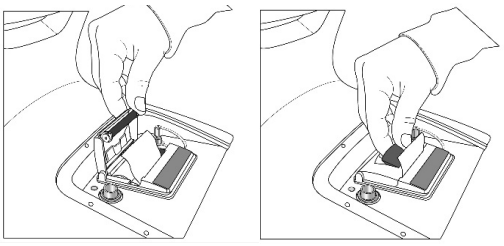


2. Select the language by pressing on the corresponding key.

3. Press on **OK** to validate the changes and return to the Settings Menu, or on **CANCEL** to return to the Settings Menu without modifying these parameters.



6.4.6 Checking, replacing and repositioning the printer paper



To check, change or reposition the printer paper, lift the black lever at the rear of the Control Unit, as shown here, in order to open the printer cover. Replace the paper and/or reposition, if necessary.

The two buttons under the printer have the following functions:

- >>: scrolling the paper (keep button depressed).
- II: pausing the printer. Press a second time to cancel the pause.

A paper roll is already in the printer of the delivered the EyeOP1 Control Unit. An additional spare paper roll is also supplied in its transport case. In case of need of additional printer paper, contact the EYE TECH CARE technical department at **support@eyetechcare.com**, or the local representative.

7. SECTION 7: ERRORS AND WARRANTY

7.1 Warranty

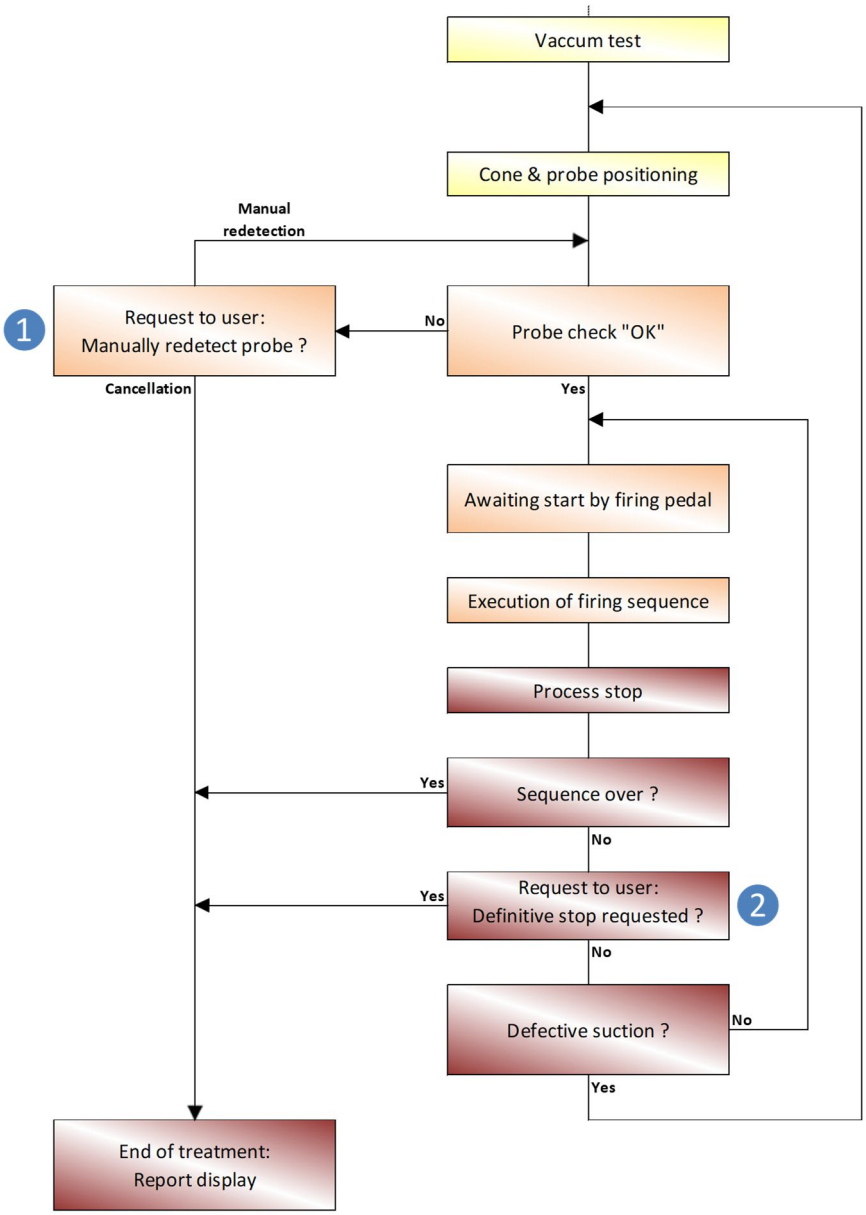
The EyeOP1 Control Unit must be checked and revised once a year by qualified personnel appointed by the manufacturer.

EYE TECH CARE cannot be held responsible for safety, reliability and incorrect operations under the following conditions:

1. When installation, improvements, adjustments, modifications, preventive or corrective maintenance actions have not been carried out by authorized and qualified personnel appointed by EYE TECH CARE.
2. If the room where the device is installed does not comply with electrical specifications and recommendations.
3. When the medical device is not being used in compliance with instructions and recommendations described in the present manual, or given by qualified personnel.
4. When parts or accessories have been replaced with parts or accessories non-qualified or non-authorized by EYE TECH CARE.

7.2 Management of interruptions in the treatment sequence

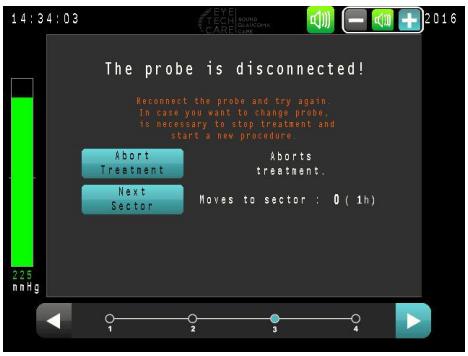
The firing sequence automatically stops at treatment completion. However, in some cases, the sequence can be prematurely discontinued either on purpose (in case of emergency) or inadvertently (firing pedal release), or due to an error (e.g. suction problem). In any event, a completely or partially treated sector must not be retreated. The following diagram illustrates the management of sequence interruptions. The user only has to follow this procedure on the screen of the Control Unit.



1 **<u>The therapy probe is no longer detected on reaching the treatment initialization step</u>**:

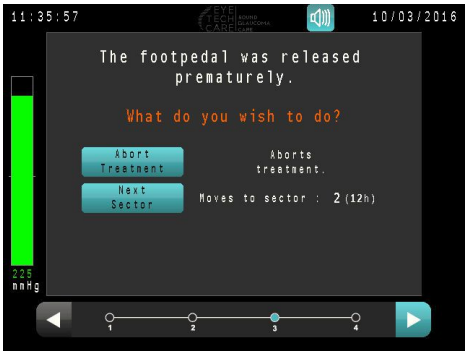
A message informs the user that he may:

- Either **permanently cancel the treatment**. He will be redirected to the Treatment Report screen,
- Or **restart manual detection of the probe** after rechecking its correct connection to the control unit.



2 **<u>If an interruption (intentional or otherwise) of the treatment occurs before the complete treatment of all sectors</u>:**

The user has the option to **permanently discontinue the treatment** or **resume the next sector** (example to the right when firing pedal is released).



If the user opts to continue the treatment, he will resume with the next untreated sector that would have been treated before the interruption occurred (the clock and sequence number of the next sector is shown).

If the interruption occurs while firing in a sector, it will be partially treated and may not be completed.

If the interruption occurs during a pause, or before firing in the first sector, the treatment will resume in the sector that would have been treated after that pause.

If the treatment interruption is due to a suction problem (intentional break or otherwise, etc.), and the user opts to continue treatment, he will be redirected to the cone coupling step on the patient's eye. Position the coupling cone as described in §.5 of the Step 4.

Concerning the 8-sectors protocol, after a treatment interruption from the 7th, the user has to check that the probe is still rotated, particularly after a loss of suction for which the user will be redirected to the cone positioning step.

7.3 Breakdowns and errors

When the software detects an error or abnormality (see for instance the table in **part 5.1** of **Section 3,** or else the synopsis of the previous page, system error), an error message displayed on the Control Unit screen informs the user.

When an error message appears, it is highly recommended to:

- Read and understand the message
- Write the message down in order to make the technical diagnostic easier,
- Discontinue treatment, if needed,
- Rapidly inform EYE TECH CARE at **support@eyetechcare.com**, or the local representative.

If the medical device does not function or if a problem occurs for unknown reasons, contact the EYE TECH CARE technical department at **support@eyetechcare.com**, or the local representative.

Furthermore, if the medical device is damaged due to use other than described in the present manual, immediately inform the technician.

The user and/or patient should report to EYE TECH CARE and the competent authority of the country in which the user and/or patient is established any serious incident that has occurred in relation to the EyeOP1/EYEOP-PACK medical device.

In case of any occurrence of incident (breakdown, errors, side effects, etc), if any data concerning the treatment needs to be transmitted to EYE TECH CARE, the user must ensure that the patient's data are anonymized, in order to not reveal his identity (first name, last name, birthday …); it is recommended to use the same codification as the one proposed by EyeOP1 (for example, for 'Jean Dupont": JE DUP).

8. SECTION 8: MAINTENANCE AND CLEANING

- Use a cloth moist with soapy or bleach water (2 teaspoons per litre of water) to clean the Control Unit.
- The medical device must be clean and dry before each use.
- Between each use, place the Control Unit in its container, or cover it between two close-range sessions.
- The system must be clean and dry before being stored after usage.

Switch off the mains power supply and disconnect the system from the mains before any cleaning or inspection.

Never spray any liquids on the Control Unit. No liquid or cleaning agent must penetrate inside the system. This would create serious problems and damage the system.

Due to incompatibility with the Control Unit materials, do not use scouring powders, organic solvents, alcohol, benzene or other incompatible agents.

The device must not be opened, for any reason.

9. SECTION 9: TRANSPORTING, MOVING AND STORING THE MEDICAL DEVICE

9.1 Transportation

For transportation, the weight (7 kg) and dimensions (L x W x H = 365 x 320 x 265 mm) of the Control Unit must be taken into account.

When transporting the EyeOP1 Control Unit over short distances, carry using the handle located at the rear. Avoid shocks and carry using both hands.

To transport the device over long distances, place the Control Unit in its storage case and avoid shocks.

9.2 Storage and use conditions of the Control Unit and EYEOP-PACK

Storage	
Storage temperature	*4 to 40 °C*
Relative humidity	*20 to 80 %*
Pressure	*750 hPa to 1013 hPa (1 atm)*
Transport	
Storage temperature	*4 to 40 °C*
Relative humidity	*20 to 80 %*
Pressure	*750 hPa to 1013 hPa (1 atm)*

Use	
Operating temperature	*15 to 25°C*
Relative humidity	*20 to 80 %*
Pressure	*At atmospheric pressure close to normal pressure (1 atm)*

When the medical device is stored after use, disconnect the firing pedal and the power cable from the control unit.

9.3 Lifetime

The lifetime of the EyeOP1 control unit is 7 years.
The validity period of the EYEOP-PACK consumable is 36 months.

10. INFORMATION ON USER MANUAL

- The latest version of the User Manual can be obtained by downloading it through the EYE TECH CARE's website on the bottom of the "Healthcare professionals" page:
  https://eyetechcare.com/en/healthcare-professionals/focused-ultrasound

- Compared to the previous version of the User Manual on the market, the different updates are as follow:

SECTION	COMMENTS
SECTION 3 §3.4	Addition of a Unique Device Identifier (UDI) mention.
SECTION 3 §3.4	Update of the dates format of the labelling.
SECTION 3 §3.4.2.1 & 2	Update of the labeling mentioning the UDI.