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Rev.E

R-Evo Smart E
R-Evo Smart S
R-Evo Smart CR

MEDICAL DEVICE FOR OCULAR SURGERY

MANUAL FOR INSTALLATION AND USE

Optikon 2000 S.p.A is the manufacturer of the R-Evo Smart, a medical device for phacoemulsification and vitrectomy.

The product complies with the requirements of the Medical Device Directive 93/42/EEC.

INDEX

1. EXCLUSION OF LIABILITY

The user of this Medical Device must carefully read the specific warnings provided in this manual. It is the responsibility of the operator to ensure that the personnel in charge acquire a thorough knowledge of the operation of the instrument before use. In no case the Manufacturer is responsible for accidental or indirect damages caused to the purchaser, operators or patients following the use of the product.

Use of the Medical Device is subject to professional medical evaluation. The Manufacturer is not responsible for any clinical problem resulting from improper use of the appliance and does not provide any medical recommendation.

The Manufacturer declares to be responsible for safety, reliability and performance only in the following cases:

- updates, calibrations and repairs carried out by personnel authorised by the Manufacturer;
- the instrument is used in accordance with the instructions for the user;
- the electrical system to which the appliance is connected is in compliance with the IEC safety standards.

IMPORTANT NOTE:

At the time of printing this manual, every effort has been made to ensure that all illustrations and information accurately represent the product and its operation. It is however possible that, during the duration of this manual, changes are made to the product in order to continue to effectively meet the needs of users. Such changes may be made without notice.

Manufacturer:
OPTIKON 2000 S.p.A.

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2. LIMITED WARRANTY CONDITIONS

All equipment and accessories sold and installed in the European Union are guaranteed by the Manufacturer against manufacturing and material defects, for ONE YEAR from the date of invoice. The warranty of consumables is limited to the first use of the appliance.

For warranty conditions applicable outside the European Union, contact your authorised distributor.

All parts covered by the warranty will be repaired or replaced free of charge.

The warranty includes the search for the cause of the defect, the repair of the fault and the final inspection of the unit or components.

The warranty does not cover problems resulting from misuse, accidents, misuse, tampering or modifications by persons not belonging to the manufacturer's authorised technical service.

The Manufacturer reserves the right to check, in case of failure, if the instrument and/or its accessories have been modified or tampered with in any way, or if they have been damaged due to improper use.

Similarly, the Manufacturer reserves the right to modify the instrument and/or its accessories if operating techniques require such changes.

The warranty is void if the serial number of the included instrument and/or accessories has been lost or has been tampered with and found to be illegible.

The warranty does not include the cost of sending the instrument and accessories: all shipping costs, packaging, etc. will be borne by the customer.

In the event of an explicit request for intervention by the Manufacturer's technicians, all travel and accommodation costs shall be borne by the customer.

OPTIKON 2000 S.p.A. is not liable for any damage incurred during transport. If this situation should arise, the customer must immediately inform the carrier who carried out the delivery.

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3. GENERAL INFORMATION

3.1 LEGEND OF SYMBOLS

All information about the safety aspects of using this Medical Device is provided. This section contains a summary of the most important safety information.

Hazard symbols

The following safety information has been included in the user manual. Take note of this information and take special care in the cases indicated.

⚠	**WARNING**	Indicates a hazard that can cause damage resulting in **fatal** or **serious injury**.
⚠	**CAUTION**	Indicates a hazard that can cause **accidents for which medical care is required**.
	INFORMATION	Indicates a hazard that can cause **injuries for which medical care is not required**.

3.2 TABLE OF SYMBOLS

The table below shows some I.E.C. approved symbols and their meanings. These symbols are often used on medical instruments to enable quick and simple communication of information and warnings. At times two or more symbols are combined together in order to obtain special meanings.

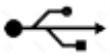
These symbols are placed on the label of the R-Evo Smart. Before using the appliance, familiarize yourself with the symbols and the definitions shown in the table.

SYMBOLS PUBLISHED BY THE IEC

SYMBOL	DESCRIPTION
	MANUFACTURER
	DATE OF MANUFACTURE
	ALTERNATING CURRENT
	RF EMISSIONS
	OFF (DISCONNECTED FROM THE MAINS)
	ON (CONNECTED TO MAINS)
	TYPE B APPLIED PART
	TYPE BF APPLIED PART
	SEPARATED WASTE COLLECTION FOR ELECTRICAL/ELECTRONIC EQUIPMENT
	EQUIPOTENTIALITY
	CONSULT THE OPERATING INSTRUCTIONS

	FUSE RATING
	COMPRESSED AIR INLET
	AIR INJECTION SOCKET
	ILLUMINATION SOURCE SOCKET
	SOCKET FOR DIATHERMY
	PEDAL SWITCH SOCKET

OTHER SYMBOLS ON THE DEVICE

	SILICONE OIL INJECTION SOCKET
	PHACO SOCKET
	VITRECTOMY SOCKET
	KNOB FOR UNLOCKING CASSETTE
	USB SOCKET
	Irrigation solution
	CONTROLLED IRRIGATION

3.3 TARGET GROUP

This user manual is intended for physicians, nurses and other medical and technical personnel involved in preparing, operating or maintaining the device after appropriate training. It is the duty of the customer or institution to instruct and train all personnel who must use the Medical Device.

Additional service activities are not part of this user manual. These activities will be carried out by staff specially trained in this regard by OPTIKON 2000 S.p.A.

Scope of application

Purpose

The R-Evo Smart Surgical Medical Device has been designed to be used in operating theatres by qualified medical personnel (eye surgeon) for surgical procedures for the treatment of the anterior ocular segment. The equipment was designed for irrigation, irrigation/aspiration, crystalline phacoemulsification, anterior vitrectomy, bipolar diathermy coagulation techniques. The R-Evo Smart CR also features the functions of posterior vitrectomy, air and silicone oil tamponade, endo-ocular illumination. The Medical Device is intended for use in clinics, hospitals and other institutions dealing with human medicine.

3.4 INTENDED USE

The R-Evo Smart is intended for use in surgical treatments such as extracapsular extraction, phacoemulsification or glaucoma of the anterior segment of the human eye, the R-Evo Smart CR model also for surgical treatment of retinal detachment and other pathologies of the vitreous body and the posterior segment of the human eye. Any malfunctions occurring during use are indicated by a message displayed on the display and by alarm signals.

Any use other than the one stated above, is excluded as it may cause unforeseeable risks. In particular, the use of this system in brain or heart surgery is excluded.

⚠ **WARNING**

Risk of injury to the patient!

- The diathermy section of the R-Evo Smart surgical systems should not be used with patients with pacemakers or other cardiac stimulators without having previously consulted a cardiologist.

3.5 NOTES FOR THE OPERATOR

- Use the Medical Device only for the intended purpose, as described.
- Comply with the legal regulations regarding market surveillance and obligatory reporting applicable in the respective country, as well as any further regulations and standards.

User qualification

- Please familiarize yourself with the contents of the user manual before starting the device. Please note the instructions for use of the other equipment as well.
- Before using the device, all medical staff must have read and understood all the instructions in this user manual.
- Keep the user manual in a place that is easy to access at any time by the staff using the Medical Device.
- The Medical Device must be used only by qualified medical personnel, aware of the possible risks due to the use of this device and who have received complete and adequate training for the prevention and management of any clinical complications.
- The Medical Device should only be used by a staff who has received adequate training and instructions. It is the duty of the customer or institution to instruct and train all personnel who will use it.
- It is essential to have adequate training to install and use R-Evo Smart devices correctly, this training is offered by OPTIKON 2000 S.p.A. Contact the OPTIKON 2000 S.p.A. local service centre for more information.

Transport

⚠ **CAUTION** **Risk of injury to the patient's eye!**

The Medical Device has been packaged in such a way as to minimize the risk of damage during transport.

- In case you should observe any damage due to

transport, inform the carrier and do not use the device.

- For long-distance transport (eg dismantling, return for repair, etc.), the device must be placed in its original packaging or in special packaging. For further information, contact your dealer or the OPTIKON 2000 S.p.A. technical service.

Assembly and installation

INFORMATION

Risk of damaging the Medical Device!

- Make sure that the installation and use conditions of the device comply with the surgical requirements:
  - Low vibration
  - Clean environment
  - Assess of excessive mechanical loads

INFORMATION

Risk of interferences and malfunctions!

- This Medical Device requires special precautions regarding EMC (Electomagnetic Compatibility), it must be installed and commissioned according to the EMC information and indications given in the accompanying documents.

INFORMATION

Risk of interferences and malfunctions!

- This Medical Device should not be used in proximity of other devices. If it must be used close to other equipment, it must be carefully observed to verify normal operation in the actual configuration in which it is used.

INFORMATION

Risk of damaging the Medical Device!

The maximum height of the IV pole is 225 cm from the ground.

- Do not install the R-EVO SMART systems in rooms with a low ceiling.

INFORMATION

Risk of damaging the Medical Device!

If the ventilation openings are closed and blocked, the device may overheat.

- Install the R-EVO SMART so that the ventilation openings are neither closed nor obstructed.

⚠ **WARNING**

Risk of explosion or fire hazard!

The Medical Device is not suitable for use in hazardous areas.

- R-Evo Smart systems must not be used:
  - in areas at risk of explosion.
  - if inflammable anesthetics or volatile solvents, such as alcohol, benzene or similar chemicals, are present at a distance of less than 25 cm.

- Do not use or store the system in damp rooms. Do not expose the system to water splashes, dripping water or sprayed water.

- To ensure safe operation, do not install the Medical Device in a location that may be exposed to heaters or radiators, direct sunlight, or any other heat source at excessive temperatures.

Operation

⚠ **CAUTION**

Risk of injury to the patient or the user!

- Observe the maximum loads indicated for the following components:
  - Maximum load on the instrument tray, 1 kg.
  - Maximum load of the bottle and irrigation solution, 0.5 kg.

⚠ **CAUTION**

Risk of injury to the patient or the user!
Danger of overturning when crossing doorsteps.

- Push the medical device slowly and carefully using its handles when crossing doorsteps up to 3 cm. If the doorstep is higher than 3cm it must be moved by two people.

INFORMATION

Risk of minor injury to the patient!

A moving white dot logo at the bottom right of the screen indicates that the device is working properly.

- If the dots around the logo stop moving, the device is stopped, and you must stop using it.
- Before any use, carry out the installation, the surgical configuration and the operating procedures described here. If a malfunction occurs that is not corrected using the "Correction of malfunctions" chapter, please put the

"non-working" label on the device and contact the OPTIKON 2000 S.p.A. technical service.

- Carefully follow the instructions when installing and using the unit in order to prevent harmful interference by with other devices.
  This Medical Device has been tested and found compliant to the emission and immunity limits established by the IEC60601-1-2:2014 standard for electro-medical devices. These limits are conceived to ensure proper protection from interferences in a typical medical environment. However, interferences may still exist in a specific installation. If the system causes harmful interference with the function of other devices (can be detected by turning the unit off and on again), the user is encouraged to try to remedy the interference by one or more of the following measures:
    - Reorient or relocate other devices.
    - Increase the distance between the devices.
    - Connect the unit to a power outlet other than the one to which the other devices are connected.
    - Contact your dealer or the technical service of OPTIKON 2000 S.p.A.
- The sound emission capacity of the device is tested at startup.
  Verify that a beep sounds is emitted when initializing the system.
- Any malfunctions occurring during use of the medical device are indicated by a message on the display and by alarm signals. Resolve the malfunction and confirm the message by pressing the corresponding key in the display. If the malfunction can not be eliminated, or if the error occurs again, do not continue to use the device, but put up signs indicating that it is "out of order" and contact your dealer or the OPTIKON 2000 S.p.A. technical service.
- Do not pull on the power cables or other connecting cables.
- When moving the Medical Device make sure that no tubes are crushed or pulled out.
- Portable and mobile radio communication devices can affect operation of the Medical Device

- Never leave the Medical Device unattended when the light source is switched on, to avoid causing damage to the patient's retina due to excessive irradiation time.

Maintenance

- The Medical Device is a sophisticated high-tech product. To ensure optimal performance and safe operating conditions, we recommend, as part of a normal maintenance program, to have an annual inspection performed by technical staff authorized by OPTIKON 2000 S.p.A.
- To avoid a decrease in the safety of the Medical Device, due to ageing, wear, etc. the institution operating the device must ensure, in compliance with the applicable national regulations, that regular safety checks have been carried out on the prescribed schedule and on the stipulated exent. The technical safety checks must be carried out exclusively by the manufacturer or by qualified personnel. The scope of the security engineering controls should include at least the following items:
  - Availability of the user manual
  - Visual inspection of the device and its accessories to verify the absence of damage and the readability of the symbols and labels.
  - Protective earthing impedance test
  - Current leakage test
  - Functional test of all switches, buttons, outlets, and indicator lamps of the Medical Device.

Modifications

⚠ **WARNING**

Risk of injury to the patient's eye!
Modified products may break during application and cause device malfunctions.

- Do not change the shape of the handpiece for vitrectomy or the tip used with the R-EVO SMART systems (e.g. do not bend, cut or scratch).

⚠ **WARNING**

Risk of injury to the patient's eye!
Changes due to the application of manual force on the upper part of the infusion pole could result in an incorrect level of the bottle and injury to the patient.

- The height level of the infusion pole must not be changed by applying manual force.
- Modification and repair of the Medical Device or any other system used together with it must only be performed by the OPTIKON 2000 S.p.A. or other appropriately authorized personnel.

Disposal

CAUTION

Environmental pollution!
Environmental pollution may occur if the waste is disposed of incorrectly!

- Do not dispose of the Medical Device along with normal domestic waste.
  Separate disposal according to the local laws/regulations governing the disposal of electrical and electronic equipment is required.
- Infected items may contaminate the user or the environment. Dispose of waste collection fluids in accordance with local or government regulations and laws on the disposal of organic material.

Approved accessories

WARNING

Risk of injury to the patient's eye!

- Use only items approved and recommended by OPTIKON 2000 S.p.A.

CAUTION

Risk of injury to the patient's eye!

- Use only original accessories and consumables manufactured by OPTIKON 2000 S.p.A. for use with R-EVO SMART systems. Consult the Instructions for Use of the accessories to check their compatibility with the R-EVO SMART.

- The use of accessories and cables not included in the packaging of the Medical Device could lead to an increase in electromagnetic interference or reduce the immunity of the device to such interference. For these systems use only spare parts approved by OPTIKON 2000 S.p.A.
- Additional equipment connected to electrical medical devices must comply with IEC or ISO standards (e.g. IEC 60950 for data processing equipment). In addition, all configurations must comply with the requirements for medical electrical systems (see IEC 60601-1-1 or Clause 16 of the 3rd edition of IEC 60601-1). Any person who connects additional equipment to a medical electrical appliance is configuring a medical system and is therefore responsible for compliance with the regulations relating to medical electrical systems. Note that local laws have priority over the aforementioned regulations. If in doubt, consult your dealer or the OPTIKON 2000 S.p.A. technical service.

Electric system

INFORMATION

Risk of equipment malfunction!

- Never connect a USB device to the medical device while it is in use.
- Use only USB pendrives that are free from viruses.

- The Medical Device is set to be used with a line voltage of 100 - 240 V (± 10%), 50-60Hz. Check that the local line voltage matches this voltage.
- Always replace the fuse with one of the same type.
- To reduce the risk of electric shock, do not remove the protective cover. To replace the fuses, contact an authorized technical service.
- Connect the R-EVO SMART to a mains power supply with the features shown on the rear panel of the console. To ensure safe operation, the medical device must have adequate grounding.
- To avoid the risk of electric shock, the device must only be connected to a power supply with adequate grounding.
- Before connecting or disconnecting the unit to the mains, ensure that the main switch is turned off.
- The main switch must be turned off when the device is not in use.
- Before replacing the fuses, switch the device off and let it cool down for a few minutes.
- If required by law and guidelines of the country in which you are using, the Medical Device must be connected to a UPS.
- Do not place containers containing liquids on the Medical Device. Make sure that no cleaning products are allowed into the device.
- Never try to connect electrical connectors by forcing them (plugs, sockets). If a connector does not fit easily into a socket, make sure it is not intended for another socket. If a connector is damaged, contact your local OPTIKON 2000 S.p.A. technical service.
- Do not use electric extension cords or multiple plugs.
- The systems must be grounded correctly to ensure safe

operation.

- Equalization of additional potential: The Medical Device must be provided with connectors with earth protection.

Diathermy application

WARNING

Risk of injury in patients with pacemakers!
There is a potential danger to patients with cardiac pacemakers or stimulation electrodes due to the possibility that the generator for diathermy causes RF interference. The pacemaker may fail.

- If you have concerns in this regard, please contact a knowledgeable physician for advice.

WARNING

Risk of injury to the patient's eye!

- When the bipolar diathermy handpiece and a monitoring system are used simultaneously, all monitoring system electrodes that are not protected by resistors or high frequency inductors should be located as far away from the diathermy electrodes as possible.
- Risk of burns or fire; do not use diathermy near conductive materials such as metal bed parts, inner-spring mattresses, and the like. Replace the electrode cables as soon as there is any evidence of wear.
- Use only OPTIKON 2000 S.p.A. original diathermy cables.
- Serious burns from RF (radio frequencies) may occur if the output current of the diathermy system is diverted to the operator due to careless use.
- The bipolar diathermy cable must not touch the patient or other cables.
- Always use the lowest output diathermy power level which is compatible to the surgical application.
- Evidence of low output level or faulty operation of the bipolar diathermy handpiece, even though the equipment has been set for normal use, may indicate a bad contact in the electrodes connections.
- Using the bipolar diathermy handpiece, do not use flammable anesthetics, nitrogen monoxide or oxygen, if sufficient ventilation by a suitable aspiration system is not guaranteed.
- Flammable materials, such as disinfectants and cleaning products must be allowed to evaporate before using the bipolar diathermy handpiece. Some materials such as wool, cotton or gauze, if impregnated with oxygen, can ignite due to sparks

coming out of the appliance during normal use.

- Interference may occur with other medical devices due to use of the bipolar diathermy handpiece.

Irrigation/aspiration applications

WARNING

Risk of injury to the patient's eye!
If the irrigating solution is placed too low, the pressure in the patient's eye may be too low.

- Make sure that the irrigation solution is always positioned at a higher level than the patient's eye.
- Observe the instructions described in the chapter " Set-up of the irrigation/aspiration tubing " in this manual. If the indications specified therein are not followed, serious consequences may occur.

- Correct set-up of irrigation and aspiration lines is critical to ensure proper operation of the R-EVO SMART systems.
- Switching from peristaltic to Venturi mode can cause a anterior chamber to collapse if a low-impedance phaco tip is used (e.g. a large-diameter phaco tip) and if the vacuum is set to a high level. To ensure patient safety, before restarting the aspiration after switching from one type of pump to another, always check that the vacuum setting is correct for the type of pump used.
- Use only original OPTIKON 2000 S.p.A. tubing sets.
- Do not initialise the handpiece (Priming) when it is in use on the patient's eye, as this could result in patient injury.
- Before any intervention, make sure that sufficient saline solution is available. Check the amount of balanced salt solution during the entire duration of the operation.
- During operation, continue to check the level of balanced salt solution in the infusion bottle. If the amount of balanced salt solution is considered insufficient to complete the operation, immediately notify the surgeon and replace the bottle or the infusion bag by following the procedures below:

IRRIGATION BY GRAVITY

- Stop the surgical procedure and remove the handpiece from the incision.
- Close the infusion tube clamp.
- Unhook the bottle from the infusion pole when it is almost empty.

- Remove the spike of the infusion set from the bottle, taking care not to touch it with your hands or any other unsterile material.
- Insert the spike of the infusion set into the cap of the new bottle and hook it onto the IV pole.
- If the drip chamber becomes completely empty, squeeze it to fill it with balanced salt solution until it is approximately 50% full.
- Re-open the infusion clamp.

- If air bubbles are observed in the irrigation tubings, ask the surgeon to activate irrigation until the bubbles are expelled, before reinserting the handpiece into the patient's eye.

CONTROLLED INFUSION

- Stop the surgical procedure and remove the handpiece from the incision.
- Close the infusion tube clamp.
- Disconnect the air tube from the "CONTROLLED" outlet located on the R-Evo Smart pump plate.
- Turn off the near-empty infusion liquid container from its support.
- Remove the spike of the infusion set, taking care not to touch the needle with your hands or any other unsterile material.
- Insert the spike of the infusion set into the cap of a new container and hang it from the outflow nozzle holder.
- Connect the air tube from the "CONTROLLED" output of the R-Evo Smart medical device.
- Re-open the irrigation clamp.

- If air bubbles are observed in the irrigation tubings, ask the surgeon to activate irrigation until the bubbles are expelled, before reinserting the handpiece into the patient's eye.

Ultrasound application

WARNING

Risk of injury to the patient's eye!
Do not check the operation or the vibration of the phaco tip by touching it with the fingers: Prolonged exposure or direct contact with the vibrating tip may cause tissue damage.

- Never place your hand or finger on the phaco tip or the silicone sleeve of the phaco handpiece while testing the phaco handpiece (Priming).

CAUTION

Risk of injury to the patient's eye!
Burns caused by excessive ultrasonic energy!

- The noise of the vibrations should increase by setting the power of the ultrasounds to higher values, a constant high noise at all power levels indicates a malfunction of the device.

CAUTION

Risk of injury to the patient's eye!
Improper movement of the phaco tip or silicone sleeve in the incision could cause damage to the patient's cornea.

- Do not twist against or apply pressure to the incision.

CAUTION

Risk of injury to the patient's eye!
Corneal burns caused by excessive ultrasound energy.

- Use the lowest ultrasonic output power intensity, compatible with the surgical application.
- To check the operation of the handpiece, do not activate the ultrasounds with the phaco tip in the air. The ultrasound power should be applied to the handpiece with the tip inserted into a sterile test chamber filled with balanced salt solution or into a container with sterile liquid at room temperature. If these instructions are not followed, it is possible to damage the phaco tip and/or the phaco handpiece.
- Make sure that the handpiece is properly connected to the R-Evo Smart appliance's irrigation/aspiration system and is used only with the latter.
- High buzzing from the handpiece with minimal power adjustment may indicate a malfunction of the power adjustment circuit and result in corneal burns or

endothelial damage. Contact your dealer or the technical service of OPTIKON 2000 S.p.A.

- Never press the tip or silicone sleeve against the wound to prevent the phaco tip from overheating.
- Unwanted increases in output power may indicate a malfunction of the R-Evo Smart Surgical Medical Device. Contact your dealer or the technical service of OPTIKON 2000 S.p.A.

Vitrectomy applications

- Never activate the vitrectomy handpiece with the blade in the air. The vitrectome must always be tested with the blade in a sterile solution container. The test carried out in the air will cause irreparable damage to the cutting system.

Illumination (R-Evo Smart CR only)

WARNING **Risk of injury to the patient's eye!**

- Adjust the intensity of the light irradiation and the corresponding exposure duration by selecting appropriate irradiation settings.

WARNING **Risk of injury to the patient's eye!**

Damage to the retina due to excessive power.

- Although the fibre optic endo-ocular illumination system is designed not to emit infrared and ultraviolet radiation except in a small quantity, to avoid possible damage to the retina, always use the minimum intensity compatible with the surgical applications.

INFORMATION **Risk of minor injury to the patient!**

The light output connectors are hot when the light is on.

- Switch off the light and wait several minutes before touching the light output connectors!
- To reduce the risk of damage to the retina, the tip of the fibre optic light probe should not be located in the immediate vicinity of the retina.

Air-Silicone oil tamponade (only R-Evo Smart CR)

WARNING **Risk of injury due to excessive air pressure!**

- An audible air leakage at start-up may indicate a malfunction of the silicone section. Consult the OPTIKON 2000 S.p.A. Technical Service.

- To avoid possible eye infections, only use original OPTIKON 2000 S.p.A. air tamponade tubes with an air sterilisation filter.
- The use of a non-standard air-tamponade tubing kit could compromise the accuracy of intraocular pressure and alter the sterility of the injected air.
- During the injection of silicone oil, the intraocular pressure is not controlled by the R-Evo Smart CR, therefore the surgeon must take care of the intraocular pressure control (IOP). It is important to check the flow of silicone at the injection pressure set before inserting the cannula into the eye.
- Release the pedal to stop the silicone oil injection. In an emergency, the silicone oil infusion tubing can be removed from the silicone supply unit.

3.6 GENERAL SPECIFICATIONS

PARAMETERS	SPECIFICATION
Manufacturer:	OPTIKON 2000 S.p.A. via del Casale di Settebagni, 13 00138 Rome - Italy
Model:.....	R-Evo Smart E/R-Evo Smart S/R-Evo Smart CR
Compliance with regulations: ...	93/42/EEC Medical Device Directive (MDD)
Technical standards:	EN60601-1; EN60601-1-2; EN60601-2-2 EN80601-2-58
ENVIRONMENTAL SPECIFICATIONS	
Storage and transport:	temperature from -10°C to +70°C, humidity 10-100% (non-condensing), atmospheric pressure 500 - 1060 hPa
Operation:.....	temperature range from + 10 ° C to + 35 ° C, humidity 30-75%, atmospheric pressure 900 - 1060 hPa (for maximum vacuum); 810 - 1060 hPa (for vacuum up to 500mmHg)
ELECTRICAL SPECIFICATIONS	
Input Voltage:	100-240 Vac.
Frequency:	50/60 Hz
Required power:	200 VA
Fuses:	100-240 Volt: T3.15AH 250V
COMPRESSED AIR SPECIFICATIONS (Reco Smart S and CR models only)	
Inlet air pressure:.....	from 500 and 800 kPa (from 72 and 116 PSI)
Air consumption:.....	32 Normal litres/minute
IRRIGATION	
Fluid delivery:.....	by gravity; eye pressure determined by the height of the irrigation source, or Controlled
Valves:	solenoid driven pinch valve
Control:.....	System pedal
ASPIRATION	
Aspiration pump types:	R-Evo Smart E: Peristaltic R-Evo Smart S and CR: Peristaltic and Venturi
Actuating medium:	(Venturi pump) pressurized air coming from an external source at 500 ÷ 800 KPa (72 ÷ 116 PSI)
Default vacuum level:.....	user programmable
Available vacuum range:.....	from 5 to 650 mmHg
Default flow rate:.....	user programmable

PARAMETERS	SPECIFICATION
Available flow range:.....	from 2 to 65cc/min (peristaltic only)
Vacuum rise time:	adjustable on 25 levels (0.5s - 12s)
Linear aspiration mode:	linear aspiration control, through system pedal, (for vacuum and/or flow) from zero to maximum user programmable
Safety device:	vacuum sensor, measures the vacuum in the aspiration line
Control:.....	system pedal

POSTERIOR VITRECTOMY (R-Evo Smart CR only)

Handpiece type:.....	pneumatically powered guillotine cutter (VIT)
Cutting method:.....	reciprocating motion
Default cut rate:	user programmable
Available cut rate:.....	from 60 to 5000 cuts per minute (OptiVit) from 120 to 10.000 cuts per minute (Twedge)
Port size:	0.5mm
Actuating medium:	pressurized air from an external source
Operating pressure:	2,6 bar approx
Linear cutting mode:	linear control of the cut rate, controlled via system footswitch.
Control:.....	system pedal

ANTERIOR VITRECTOMY

Handpiece type:.....	pneumatically powered guillotine cutter
Cutting methods:	reciprocating motion
Default cut rate:	user programmable
Available cutting rate:	from 60 to 1000 cuts per minute (Revo Smart E) from 60 to 5000 cuts per minute (Revo Smart CR and S)
Port size:	0.5mm
Operating Modes:	pressurized air from an external source (R-Evo Smart S and CR) or integrated dry compressor (R-Evo Smart E)
Operating pressure:	from 2.6 bar
Linear cutting mode:	linear cut rate from 0 to preset controlled via system pedal
Control:.....	system pedal

DIATH (DIATHERMIA)

Type:.....	bipolar generator, the generator stops when the RF power supply is not needed

PARAMETERS	SPECIFICATION
Operating frequency:	2 MHz
Rated power:	9W (200 Ohm LOAD)
Maximum voltage without load: .	100 V
Default power:	user programmable
Available power:	from 5 to 100% (percent)
Linear mode:	allows the linear control of the DIATHERMY power by means of system pedal
Handpiece type:.....	bipolar microforceps, slim stat pencil eraser, handpieces for intraocular diathermy
Diathermy cable:.....	two conductors, 26 Gauge, 75 Ohm, 200V max, steam autoclavable; use only the original diathermy cable.
Control:.....	system pedal
ILLUMINATION (R-Evo Smart CR only)	
Source type:	Two independent LED lamps
Luminous flux:	400+400lm
Intensity adjustment:	20 levels + 4 filters for protection and improvement of visualization of epiretinal membranes
AIR INJECTION SECTION (R-Evo Smart CR only)	
Nominal pressure:.....	from 5 to 120 mmHg
Actual IOP:	Nominal pressure ± 3 mmHg
Safety devices:	Air activation sound
SILICONE INJECTION SECTION (R-Evo Smart CR only)	
Nominal pressure:	from 0.4 to 5 bar
Signals:	Silicone injection activation sound, Alarm for Low pressure at air inlet
PHACOEMULSIFIER	
Handpiece type:.....	piezoelectric available with four or six crystals
Frequency:	approx. 40KHz
Tip stroke:	from 0 to 100µm
Power control:.....	panel or linear control of U/S power by means of system pedal.
U/S mode:.....	Linear or panel; continuous, Autolimit, short pulse, HD pulse, single burst, multiple burst, continuous burst
Timer U/S:	from 0.00 minutes to 9.59 minutes - Equivalent Phaco Time display

PARAMETERS	SPECIFICATION	
CLASSIFICATION OF THE EQUIPMENT ACCORDING TO THE IEC 60601-1 STANDARD		
Type of protection against electric shock:.....	Class I	
Degree of protection against electric shock:		
Diathermy:	Type BF, floating at high and low frequencies	
U/S:	Type B	
Vitrectomy	Type BF	
Lighting:	Type BF	
Air:	Type BF	
Silicone:	Type BF	
Degree of protection against water inlet (unit):	IPX0	
Degree of protection against harmful ingress of water (pedal):	IPX8	
Degree of safety of application in the presence of a flammable anaesthetic mixture:	not suitable	
DIMENSIONS		
Height:.....	35 cm	(152cm with trolley)
Width:.....	43 cm	(57 cm with trolley)
Depth:.....	50 cm	(74 cm with trolley)
Weight:	17 Kg	(60 kg with trolley and pedal)

NOTE:
1) The weight and dimensions shown are approximate.
2) Specifications are subject to change without notice.

3.7 EMC TABLES

ELECTROMAGNETIC EMISSIONS

	The emissions of this device make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If used in a residential environment (for which CISPR 11 Class B is normally required) this device may not provide adequate protection for radio-frequency communication services. The user may need to have means for mitigation, such as repositioning or redirecting the device.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSION

The **R-Evo Smart** systems are intended for use in the electromagnetic environments specified below. The customer or the user of the **R-Evo Smart** must ensure that it is used in such an environment.

Emissions testing	Compliance Level	Electromagnetic environment
RF emissions CISPR 11	Group 1	The **R-Evo Smart** Medical Device uses RF energy only for its internal function. Hence the RF emissions are very low and are not likely to cause any interference with electronic devices located nearby.
RF emissions CISPR 11	Class A	The **R-Evo Smart** Medical Device is suitable for use in all the establishments other than domestic and directly connected to the public low-voltage power supply network that supplies buildings used for residential purposes.
Harmonic Emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / oscillating emissions IEC 61000-3-3	Not applicable	

ELECTROMAGNETIC IMMUNITY

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY The **R-Evo Smart** systems are intended for use in the electromagnetic environments specified below. The customer or the user of the **R-Evo Smart** must ensure that it is used in such an environment.			
Test of immunity	**IEC 60601-1-2 Level of test**	**Compliance level**	**Electromagnetic environment**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ± 2; 4; 8; 15 kV air	±8 kV contact ± 2; 4; 8; 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines 100kHz	±2 kV for power supply lines ±1 kV for input/output lines 100kHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0.5 cycles 0 % U_T for 1 cycle 70 % U_T for 25 cycles 0 % U_T for 250 cycles	0% U_T for 0.5 cycles 0 % U_T for 1 cycle 70 % U_T for 25 cycles 0 % U_T for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **R-Evol Smart** requires continued operation during power mains interruptions, it is recommended that the **R-Evo Smart** be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: UT is the a.c. mains voltage before the application of the test level

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The **R-Evo Smart** systems are intended for use in the electromagnetic environment specified below. The customer or the user of the **R-Evo Smart** should assure that it is used in such an environment.
Portable and mobile RF communications equipment should be used no closer to any part of the **R-Evo Smart**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter

Immunity Test	**IEC 60601-1-2 Test level**		**Compliance level**	**Recommended separation distance**
Conducted RF EN 61000-4-6	3 Veff 150kHz to 80MHz		3 Veff	**d**= 30cm
Radiated RF EN 61000-4-3	3 V/m 80MHz to 2.7GHz		3 V/m	**d**= 30cm
Immunity to proximity fields from wireless RF communication devices IEC 61000-4-3	TETRA 400 380 – 390 MHz	27 V/m	27 V/m	**d**= 30cm
	GMRS 460 FRS 460 430 – 170 MHz	28 V/m	28 V/m	
	LTE Band 13, 17 704 – 787 MHz	9 V/m	9 V/m	
	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 800 960 MHz	28 V/m	28 V/m	
	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 5 1700 – 1990 MHz	28 V/m	28 V/m	
	Bluetooth, WLAN, 802.11 b/g/n, RIFD 2450, LTE Band 70 2400 – 2570 MHz	28 V/m	28 V/m	
	WLAN 802.11 a/n 5100 – 5800 MHz	9 V/m	9 V/m	
				Interference may occur in the vicinity of equipment marked with the following symbol: 

The **R-Evo Smart** intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **R-Evo Smart** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitter) and the **R-Evo Smart** as recommended below, according to the maximum output power of the communications equipment.

Maximum output power of the transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150KHz to 80MHz $d = 1.2 \times \sqrt{P}$	**80MHz to 800MHz** $d = 1.2 \times \sqrt{P}$	**800MHz to 2.7GHz** $d = 2.3 \times \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters with maximum output power not listed in the table above, the recommended separation distance *d* in meters (m) can be estimated with the equation applicable to the transmitter frequency, where *P* is the maximum output power of the transmitter in watts (W) in accordance with what is indicated by the transmitter manufacturer.

Note:

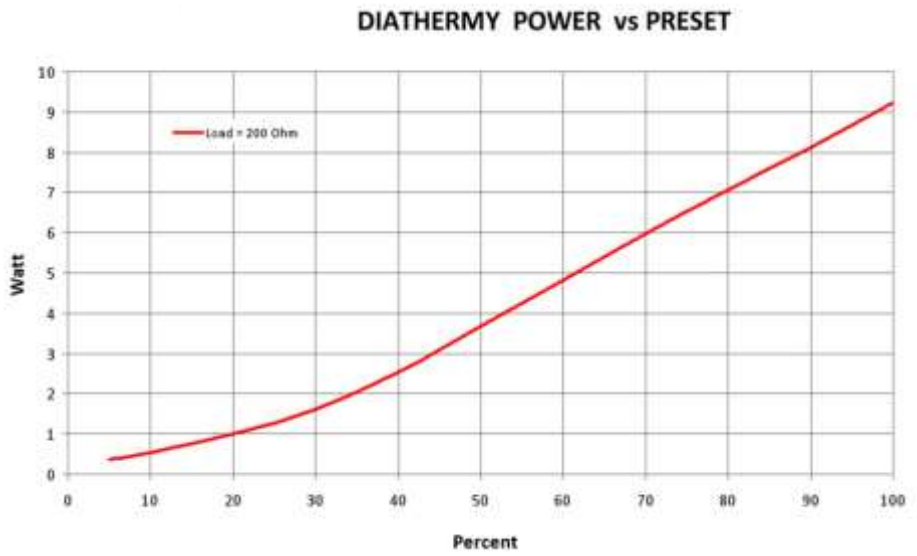
(1) at 80MHz and at 800MHz, the separation distance for the higher frequency range applies.

(2) These guidelines should not be applied in all situations. Electromagnetic propagation is influenced by absorption and reflection of structures, objects and people.

The field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and television broadcasts can not be predicted theoretically with precision. To access an electromagnetic environment generated by fixed RF transmitters, an investigation of the electromagnetic site must be considered. If the measured field strength in the place where the R-Evo Smart is used exceeds the applied RF compliance level indicated above, the R-Evo Smart must be observed to verify normal operation. If abnormal performance is observed, additional measures will need to be taken, such as re-orienting or relocating the unit.

Other than the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

3.8 POWER CHARACTERISTICS IN DIATHERMY APPLICATIONS



3.9 CIRCUIT DIAGRAMS

On request, OPTIKON 2000 S.p.A. provides wiring diagrams, parts lists, descriptions, calibration instructions or other information to help the operator's trained technical personnel repair the repairable parts of the equipment.

4. INSTALLATION AND OPERATION

Before the first start

CAUTION

Risk of injury to the patient's eye!
The Medical Device must be installed by the technical service of OPTIKON 2000 S.p.A. or by an expert authorized by it. Ensure that the following requirements are met for the entire duration of operation:

- The connection parts are inserted correctly. The connection screws are tightened.
- All cables and plugs are in perfect condition, e.g. show no signs of wear, kinks or other damage.
- The rated voltage of the instrument corresponds to the voltage of the network line at the place of installation.
- The plug can only be connected to an outlet equipped with a earth protection conductor in perfect condition.
- The device is connected to the power cord supplied by OPTIKON 2000 S.p.A.

Before each use

CAUTION

Risk of injury to the patient's eye!

- Ensure that all specified "Operation Requirements" are observed.
- Reconnect the covers or plugs removed on the front. Close all existing openings with their plugs.
- Make a note of all the symbols and signs posted on the Medical Device.
- The ventilation openings must not be closed or covered.
- Check that the R-EVO SMART is located in a place where there is sufficient space for manoeuvring in order to avoid damaging the cables, to guarantee total freedom of movement of the Medical Device and that it has easy access to the power switch to disconnect the appliance from the mains.
- Connect the equipotential connector on the back of

the instrument to the equipotential connector of the operating room using an equipotential bonding cable. If necessary, have a second ground reference in the event of a malfunction of the main earth plug.

- The power plug is used as a means to electrically isolate all poles simultaneously from the MAINS SUPPLY. Do not place the appliance in such a way that it is difficult to disconnect the power plug from the wall socket
- Check the parameter settings of the selected user profile to prevent unwanted behaviour of the Medical Device.

After each use

- At the end of the operating session, disconnect all the surgical accessories. Reinsert the instrument tray into the appropriate compartment on the console.
- Use the main power switch to turn off the Medical Device.
- The main switch must be turned off when not in use. The power cord plug must be removed from the mains supply.
- (CR only) Disconnect the compressed air supply tube from the operating room system.

Responsibility and guarantee

The warranty and the liability depend on the applicable contractual stipulations.

INFORMATION

Loss of warranty rights

No changes must be made to the Medical Device. The manufacturer is not responsible for damage caused by tampering with the device by unauthorized persons. Furthermore, this will cause loss of any right to request warranty claims.

4.1 DESCRIPTION OF THE DEVICE

R-Evo Smart systems offer the modules and surgical functions described below:

Irrigation system

R-EVO SMART surgical systems have both gravity irrigation and controlled irrigation.

Irrigation by gravity

When irrigation is fed by gravity, the flow rate of the liquid and the irrigation pressure are determined by the level of height at which the infusion source is located. The R-EVO SMART controls an automatic motorised infusion pole that can be located to accommodate the height of the irrigation container.

⚠ **CAUTION**

Risk of injury to the patient's eye!

Use the higher hook to suspend balanced salt solution bottle for anterior segment surgery.

Use the lower hook for posterior segment surgery.

Use the lower hook when performing Controlled irrigation.

CONTROLLED IRRIGATION

If the "Controlled Irrigation" function is used, the irrigation pressure is automatically set by the R-EVO SMART. This system offers several advantages for controlling irrigation pressure compared to the gravity irrigation system, such as dynamic intraocular pressure control with compensation for fluctuations due to aspiration flow, both in cataract and retinal surgery. To use controlled irrigation, you must have the controlled irrigation bag or drip chamber for controlled irrigation. These optional accessories are provided by OPTIKON 2000 S.p.A. A valve is used for sterile control of the On/Off status of irrigation by means of the foot switch or by means of a soft key in the graphical user interface.
Always use the lower IVP hook when performing Controlled irrigation.

Aspiration system

The R-EVO SMART S and R-Evo Smart CR surgical systems have an aspiration function created by a two-pump system.

Depending on the surgical needs or preferences, the surgeon can select a flow pump (peristaltic) or a vacuum pump (Venturi).

The R-Evo Smart E has only a peristaltic pump.

The I/A cassette is housed on the pump plate on the side of the machine.

The fluids and particulate materials are aspirated with the distal end of the tip and deposited in the collection tank of the I/A cassette.

A vacuum safety sensor monitors the vacuum level in the aspiration line and adjusts the pump action as required. This vacuum reading is performed with a "closed system": A sterile membrane in the I/A Cassette completely separates the vacuum sensor from the sterile fluids.

⚠ **CAUTION** **Risk of infection for the patient's eye!**

Do not reuse the single-use material!

The pumps of the R-EVO SMART are controlled by a microprocessor. The vacuum level can be preset from the touch screen or controlled by the surgeon with the foot switch (linear mode).

Vitrectomy

The vitrectomy handpiece connects to the vitrectomy socket. Essentially it is made up of two parts:

- TIP OF THE CUTTER (blade) and
- BODY (containing the compressed air drive mechanism).

The vitrectomy handpiece uses the single-acting actuator principle: the pressure causes the blade to move forward (closing the cutting port). When the pressure is no longer applied, the return movement is achieved by a built-in spring.

The tip contains the cutting element formed by an external part (fixed) and an inner tube, which moves forward/backward in a longitudinal direction, the two tubes are matched to each other.

The inner tube is used for aspiration, it and has a blade at the front end with a sharp outer edge. At the front end, the outer tube has a side opening for cutting and aspiration.

The tissues are cut and aspirated simultaneously, thanks to the reciprocal longitudinal action of the inner tube, generated by pneumatic impulses coming from the surgical system.

The extremely close distance between the outer and inner tubes creates a slight constant tension that provides a self-sharpening effect. It is evident that this precision combines with the guillotine design to offer ideal cutting properties. The cutting speed (60 to 5000 cuts/min Vit, and 120 to 10.000 cuts/min Twedge for the R-Evo Smart CR) and vacuum level (5 to 650 mmHg) can be adjusted using the graphical control elements on the touch screen.

Bipolar diathermy

Bipolar diathermy uses radiofrequency (RF) currents to produce heat on the body's tissues and then cause coagulation. The energy of an RF oscillator (inside the device) is led to a pair of electrodes (diathermy pliers or diathermic pencil) that touch the biological tissues to be treated. The application of high-frequency bipolar (RF) contributes to the reduction of unwanted neuromuscular stimulation.

Both surgical systems generate an output power adjustable from 0.1 to about 9 Watt @ 200 Ω.

Illumination (R-Evo Smart CR only)

The R-Evo Smart CR has two high intensity LED lamps (source for fibre optic lighting), provided with filters for protection of the retina from the blue component of the light and to obtain optimal viewing conditions during the retinal surgical procedures.

Each of the two independent lighting systems is powered by an LED lamp focused on the head of the optical fibre. LED lamps emit no radiation outside the visible spectrum, for this reason, no UV or IR protection filters are required and maximum safety for the patient is guaranteed. An electronic system allows adjustment of lighti intensity on 20 levels, without affecting the colour of the light. Three yellow filters (435nm, 475nm and 515nm) are available to emphasize the presence of membranes when dyes are used and to protect the patient's eye from unnecessary exposure to blue light radiation, allowing for long-lasting treatments. A green filter improves the contrast, even in the absence of

dyes, darkening the red structures with respect to the membranes (white) and other eye tissues.

Air tamponade (only R-Evo Smart CR)

The air- tamponade system uses sophisticated technology for automatic control of ocular pressure. This allows the surgeon to introduce sterile air at a pre-set pressure (in mmHg), while the system automatically balances the variations due to possible leaks coming from the surgical incisions.

The air delivery module of the R-Evo Smart CR Medical Device is designed to provide sterile, low-pressure air adjustable over the entire 5-120 mmHg range.
An encapsulated disposable membrane filter is mounted to the external air supply tube, connected to the front panel air socket, so that virtually all types of particles are removed when air passes through the filter. An automatic system, controlled by touch screen or pedal, allows you to switch from irrigation with BSS to air tamponade and vice versa, without having to operate any manual tap.

Silicone oil tamponade (only R-Evo Smart CR)

The silicone oil injection device is a unit formed by a syringe, previously filled with silicone oil, connected by high pressure tubing to the front panel of the Medical Device.

The syringe is activated by compressed air which is controlled linearly by the foot switch.

Phacoemulsification

The piezoelectric handpiece made by OPTIKON 2000 S.p.A. can be connected to the phaco socket. The handpiece contains a piezo transducer that oscillates at a frequency of 40 KHz (+4.5 kHz/-1 kHz) with an amplitude of about 100µm. The piezo transducer of the handpiece includes three different components:

- **The PIEZOELECTRICAL CERAMIC ELEMENT** that converts the electrical energy supplied by the control console directly into mechanical oscillating movements at about 40,000 cycles per second (40 kHz).
- The **BODY** that amplifies and mechanically transmits the movement of the ceramic piezoelectric element to the tip.

- The **PHACO TIP** that vibrates longitudinally and therefore facilitates the fragmentation of the tissue in a circumscribed area about the contact surface between the tip and the cataract. The maximum number of re-uses of the tips are described in the Instructions for Use enclosed with the tips.

The internal energy loss processes of the ceramic piezoelectric element cause the transducer piezo to overheat when vibrating at high frequencies, the fluid drawn in by the eye is also used to dissipate the heat produced.

R-EVO SMART systems features the patented **Minimal Stress** system, which facilitates the measurement of the movement (stroke) of the tip in real time. This information is used by the microprocessor to stabilize the stroke of the tip.

The main advantages of this system are the following:

- The preset power U/S indicates the effective stroke of the tip and corresponds to the amplitude in microns of the oscillating movement of the tip.
- Different phaco handpieces are equalized and compensated for the typical loss of efficiency due to the effects of time.
- The tip vibration is no longer influenced by differences in the hardness of the cataract or by the fluctuations in the temperature of the handpiece.
- The average energy required and peak energy are lower than in the standard phacoemulsification.
- Reduction of bouncing of cataract fragments.
- The phaco handpieces can be tested by the device to verify efficiency, thus avoiding device operations below acceptable limits.

The power of the ultrasound can be generated in Continuous or Pulse mode.

- In **Continuous Mode**, the phaco energy is supplied to the handpiece continuously and without interruption if the foot switch is pressed past the point of mechanical feedback 2 (zone C, see description "System Pedal").

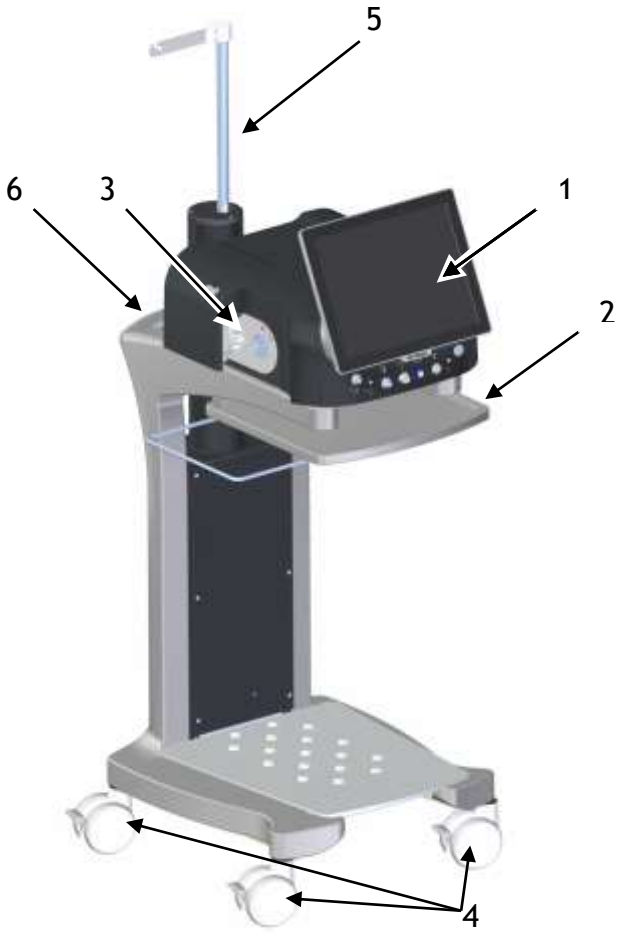
- In **Pulse Mode**, the power is output as pulses at preset intervals, if the footswitch is located in zone C after

passing position 2. The surgeon can select the following settings in pulse mode:

- "Pulsed" mode: ultrasound is available both in panel mode and in linear mode. Ultrasonic pulses are generated, the pulse repetition rate can be adjusted between 1 and 100Hz. For any frequency, it is possible to adjust the duration of the active cycle (duty cycle) on one of three levels (called "Standard", "Cold", "Ice cold" and corresponding approximately to an active cycle of 50%, 25% and 10 % respectively), in order to limit the ultrasound energy used to the minimum necessary.
- The 'HD pulse' mode automatically adapts the pulsed duty cycle to the occlusion state of the tip, so as to emulsify the 'captured' cataract fragments more quickly from the tip without introducing unnecessary energy when the tip is clear of occlusions.
- The **Single burst mode** provides single ultrasonic bursts with a duration of 120 ms. The surgeon must return the footswitch to zone C, pause for about ½ second, then press it into zone C to obtain another single burst.
- The **Multi burst mode** generates ultrasounds with a duration of 80 ms, with additional bursts generated (about 1 burst per second) when the footswitch switches from tactile position 2 and reaches zone C. When the footswitch is pressed over the stop limit, the pulse frequency increases up to the maximum speed of 4 bursts per second.
- The **Cont burst mode** yields a pulse duration of 80 ms. Once the foot switch has passed tactile position 2 and reaches area C, the pulse are generated consecutively at an increasing rate. At maximal depression of the foot switch, the bursts blend together and the units delivers continuous ultrasound power..

4.2 MEDICAL DEVICE COMPONENTS

4.2.1 Overall view (optional trolley with tray and electric IV pole)



1 15" monitor with touch screen
The monitor with touch screen allows the operator to set the parameters and read their current value. The touch screen can be covered with a suitable fabric to be used in a sterile environment.

2 Instrument tray
The instrument tray allows the surgeon or nurse to prepare the surgical set and the necessary accessories. The tray is connected to an articulated arm. For a sterile use, OPTIKON 2000 S.p.A. provides a disposable cover sheet. If the instrument tray is not used, it can be stored in its housing.

3 Case I/A and pump plate
The I/A cassette must be installed in this position.

4 Wheels with locking system
R-Evo Smart systems have four pivoting wheels that allow easy positioning of the instrument in the operating room. The locking tabs are used to prevent the Medical Device from moving.

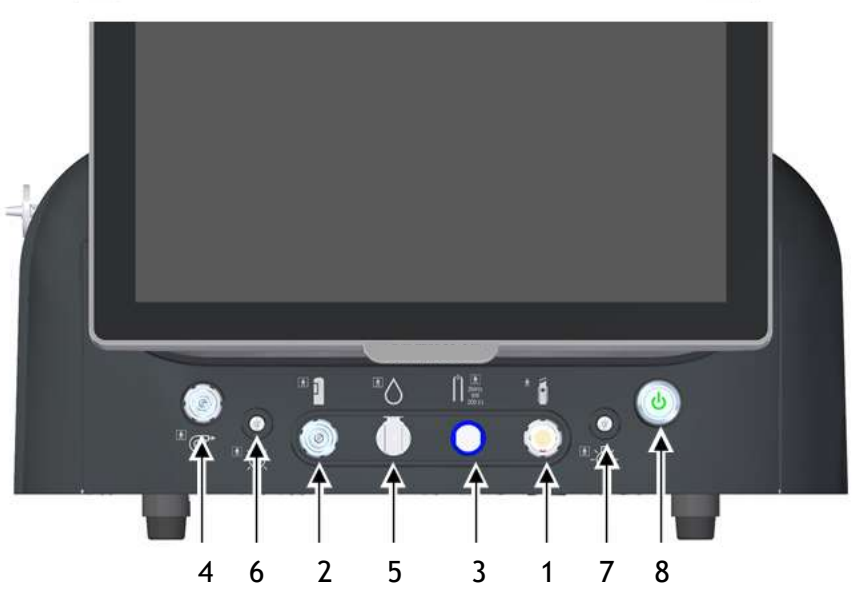
To position the device, at least two locking tabs must be pressed downwards.

- Press the locking tab down to lock the wheel.
- Turn the locking tab upward to unlock the wheel.

5 Irrigation pole with bottle holder
The computer controlled electric pole allows moving to the memorized height the balanced salt solution container during procedures involving gravity irrigation. The higher hook is only used for anterior segment surgery performed with gravity feed irrigation. The lower hook is for posterior segment surgery and also to suspend the irrigation BSS container during any surgical procedure involving "controlled irrigation".

6 Handle
This is used to move and place the Medical Device in the operating room.

4.2.2 **Front panel connectors and control elements (CR)**



1 US socket (Phaco)
The connector of the phaco handpiece connects to this socket

2 Vitrectomy socket
The connector of the vitrectomy handpiece connects to this socket.

3 Diathermy socket
The connector of the bipolar diathermy handpiece connects to this socket.

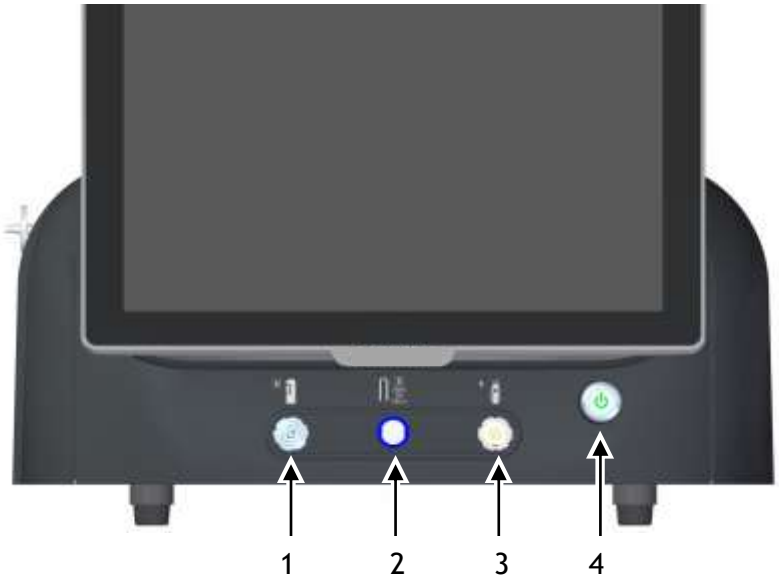
4 Air Intake
The air hose connector with the filter connects to this socket.

5 Silicone oil injection socket
The connector of the silicone oil tamponade system connects to this socket.

6-7 LED light sources with filters sockets
The fibre optic connector connects to this socket.

8 Power button
This key with indicator light allows the instrument to be switched on and out of stand-by mode. The mains switch on the rear panel must be in the (I) on position. The device must be switched off using the software button on the touchscreen.

4.2.3 **Front panel connectors and control elements (E and S)**



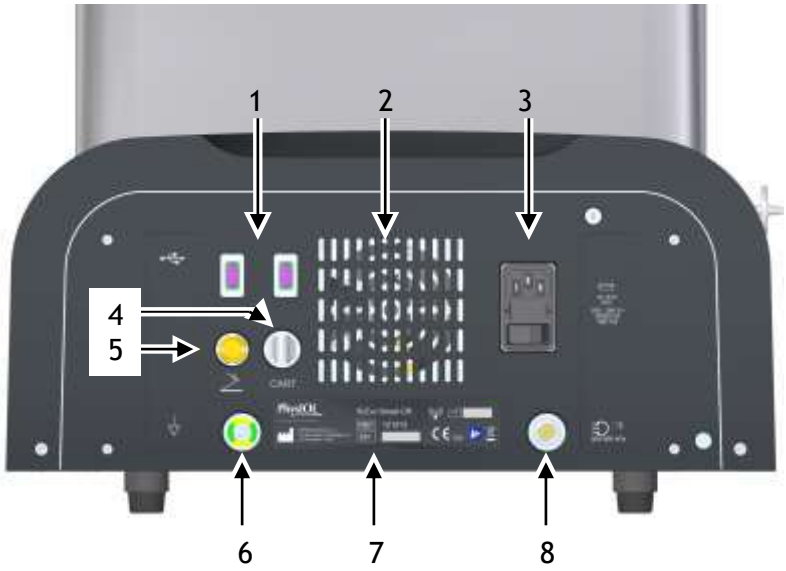
1 US socket (Phaco)
The connector of the phaco handpiece connects to this socket

2 Vitrectomy socket
The connector of the vitrectomy handpiece connects to this socket.

3 Diathermy socket
The connector of the bipolar diathermy handpiece connects to this socket.

4 Power button
This key with indicator light allows the instrument to be switched on and out of stand-by mode. The mains switch on the rear panel must be in the (I) on position. The device must be switched off using the software button on the touchscreen.

4.2.4 **Back panel connectors and control elements**



1 USB connectors
A USB pendrive for updating software or for importing/exporting user programs can be connected to these sockets.

2 Ventilation grid
Air inlet of the internal ventilation system of the instrument. When placing the instrument in the operating room, be careful not to obstruct the ventilation grid.

3 Power switch, fuse holder and power plug
The power switch is used to turn the Medical Device on and off.
Once turned on by this switch, the device goes into stand-by status, to put it into operational status, press the "Power on" key on the front panel.
Connect the Medical Device only to an outlet provided with a protective earth conductor.

4 Cart connector
Connect the optional equipment cart to this socket. The connection allows the electric irrigation bottle pole, integrated in the trolley, to be operated.

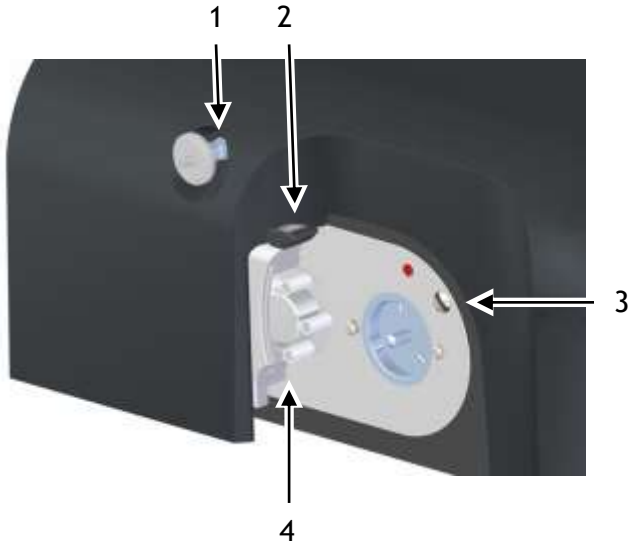
5 Pedal connector
The pedal connector is connected to this socket.

6 Connector of the earthing system
This connector can be used to connect the R-EVO SMART CR to the system earth connection.

7 Identification and marking Label
Contains data such as manufacturer, serial number of the instrument, year of manufacturing of the Medical Device, etc.

8 Air inlet socket
Input for the external compressed air for the Venturi pump, the vitrectomy handpiece and the silicone oil injection (only R-Evo Smart).
The air pressure must be 500 to 800kPa. The available flow must be at least 32Nl/min.

4.2.5 Side view



1 Controlled Irrigation Outlet
The connector for the pressurization of the balanced salt solution bottle or the pressurization of the controlled infusion bag must be connected to this socket.

2 I/A cassette release button
By briefly pressing this button, the peristaltic pump rotor moves backwards, allowing the I/A cassette to rotate anti-clockwise and to remove it from the pump plate.

3 Fluid level sensor
This sensor detects the presence of the I/A cassette and the level reached by the fluids drawn into the collecting tank. Stops aspiration when the tank is full.

4 Rotor of the peristaltic pump
Allows aspiration with peristaltic pump, also has the function of valve in the case of aspiration with Venturi pump (R-Evo Smart S and CR).

4.2.6 System pedal

The pedal for surgical equipment allows the surgeon to activate the selected function on the device he is using. The "On/Off" functions are activated with the side buttons, while the linear functions are activated with the central paddle.

The pedal has the following functions:

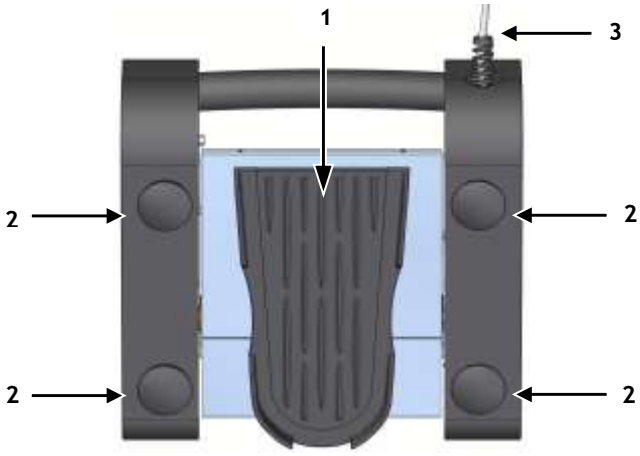
- Nine "On/Off" commands based on the settings of the device to which it is connected.
- Simultaneous linear control of two functions, by pressing and/or rotating the pedal sideways. For example: The U/S power and the degree of aspiration or cutoff frequency of the vitrectomy and the degree of aspiration.

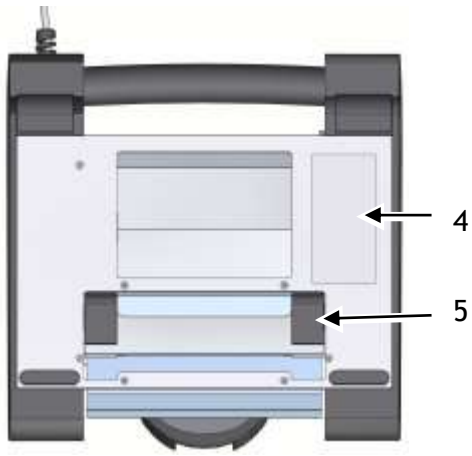
⚠ **CAUTION**

Risk of infection!
The pedal can not be autoclaved.

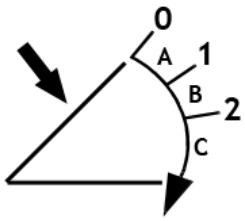
- For information on cleaning and/or disinfection of the pedal, refer to the "Care and Maintenance" section of this manual.

The system pedal consists of the following elements:





1 Central paddle
It can be moved horizontally and vertically to activate given functions. The vertical direction is divided into three zones with two tactile positions. Some functions are assigned to each zone and can be activated by pressing the pedal (see image on the side).



Rest position
Zone A is located between the rest position 0 and the first tactile position 1.

Tactile position 1
Zone B is located between the first tactile position and the second tactile position.
Tactile position 2
Zone C is located between the second tactile position and the stop limit.

2 Lateral buttons

3 Connection cable
To connect the pedal to the socket on the rear panel of the R-EVO SMART.

4 Nameplate data label
Contains data such as manufacturer, serial number of the instrument, year of manufacture of the Medical Device, etc.

5 Adjustable feet
These feet can be folded down, allowing you to adjust the height of the back of the pedal to two positions.

The multi-function pedal can be programmed via the R-EVO SMART monitor-touch screen. For more details, see chapter "5.6.8 Programming the pedal"

4.2.7 TACTILE SCREEN AND USER INTERFACE

R-Evo Smart systems are equipped with an interactive touch screen and LCD (liquid crystal display). The user interface consist of a graphic software that works on the Linux platform and simulates the various keys and displays.

The user can select the device function and adjust the related parameters by touching the screen in the appropriate areas. The current values and the preset values for each parameter are displayed. If a sterile transparent drape is placed on the monitor, the device can be activated with sterile gloves.

In order to make the interface screen as much readable as possible, the R-Evo Smart user interface has been designed so that function keys, preset and actual parameters values are always visible on the screen, while setup keys for less frequently used settings are hidden during equipment operation. Parameters are logically grouped in parameter windows.

In the example on the left, the maximum preset limit for the U/S power (35µm) is shown both in the centre of the dial and in the radial indicator.

Ultrasound is emitted in pulsed mode (33Hz) with low duty cycle (Cold).

The current U/S power (20 µm) is indicated by the green coloured zone from 0 to 20.

To adjust the parameter value, the user touches the area of the quadrant near the new desired preset limit.

Accurate adjustment can be achieved by touching the - and + keys located under the dial.

To set the status or value of parameters that are changed less frequently, such as linear or panel control (fixed) or emission mode, the user touches the "Ultrasound" button located at the top of the window.

This opens a new window that allows the control of all additional parameters.

Tap a key to change the desired parameter, then "OK" to close the opened window.

Some settings, e.g. Pulsed, may require to present to the user a dial, buttons or other additional controls.

A bar at the top of the touchscreen contains a variety of buttons and indicators:

1. "Back" key
   Pressing this button returns to the previous screen, from which you can select a new user program.
2. Indicator of the user's program.
   Shows the name of the user program currently in use.
3. Foot switch program button/indicator.
   The footswitch can be configured to work according to the surgeon's preference. To access the list of programs available for the footswitch, press this button.
4. Cancel button.
   It allows to cancel any modification made by the user to the active program. The button is not active (grey writing) when no changes have been made yet.
5. Save button.
   It allows updating the current user program with all the changes made by the user (current configuration). The predefined (Default) programs can not be modified and saved with the same name.

6. Save as button...
   It allows to save the current configuration as a new user program.
7. Alarm button/indicator.
   Pressing this button displays a list of currently active alarms on the screen. The frame around the button varies in colour based on the most serious error that may be active:

   grey: no error, blue: information, yellow: partial malfunction, red: malfunction and dangerous situation.

A status bar, located at the bottom of the screen, indicates the current status of the device by expanding the indicator related to the active surgical function (in the example shown above, Sculpt or "sculpture").

Touch the button indicator of any other surgical function to switch the device to the desired operating mode.

A logo, surrounded by flashing white dots, indicates that the Medical Device software is working normally.

INFORMATION **Risk of minor injury to the patient!**

- If the dots around the logo stop moving, the Medical Device is stopped and you must stop using it.
  The user must periodically look at the logo to check the status of the device.

The error messages of the device are divided into three severity levels:

-  Warnings have higher priority. Errors of this level are numbered 1xx and indicated by a red symbol. An error of this priority requires to interrupt the use of the equipment.
-  Caution signs have a lower priority than previous ones. The errors that belong to this level are numbered with 2xx and indicated by a yellow symbol. An error with this priority only prevents the use of a specific function.
-  Information has the lowest priority. The errors that belong to this level are numbered with 3xx and indicated by a blue symbol. An error with this priority requires attention from the user to carry out a specific action.

Refer to the "System alarm messages" chapter of this manual for a detailed description of all error messages, their causes and possible corrective actions.

Equipment warnings and error messages are displayed on the screen in pop-up windows. When the user acknowledges the warning or error message, the pop-up window disappears, the error is stored in the table of warnings/error messages.

As a reminder of the alarm condition still active, the alarm symbol (the bell located at the top right of the screen) will appear surrounded by the colour of the highest active alarm priority.

Tap on the alarm symbol to display a list of all active alarms.

Press the OK button to close the alarm list and return to normal operation.

All 1xx and 2xx errors are automatically inserted into the system memory and are accessible via the Service mode by OPTIKON 2000 S.p.A. technical service personnel.

For more information on using the graphical user interface, refer to the description of the use of individual device functions.

4.3 INSTALLATION PROCEDURE

4.3.1 Installation of the equipment

The unit has been packaged in such a way as to minimize the risk of damage during transport.

- Open the packaging and examine the components for damage. When cutting the packaging material, be careful not to damage the contents.

The R-Evo Smart E REF 111009 (S 111010) (CR 121012) consists of the following parts:

Code	DESCRIPTION
111009 111010 121012	Console R-Evo Smart E; or R-Evo Smart S Console; or Console R-Evo Smart CR
	Protective cover
1X10XXU0	Instructions for multilingual use.
	IEC60601 safety test report (attached to the manual)
	2 3.1AHT fuses
554138	Network cable
374578	Compressed air supply hose (CR and S only)
112105	Multi-function pedal

Optional cart:

REF	DESCRIPTION
181006	CART
181006U	Operation manual Bottle lifter trolley

⚠ **CAUTION**

Risk of injury caused by damage during transport

- If the packaging or contents are damaged, immediately notify the carrier (post office, railway or shipping agent) and the OPTIKON 2000 S.p.A. technical service.
- Check that the contents correspond to what is indicated in the enclosed shipping documents. Immediately notify the OPTIKON 2000 S.p.A. technical service of any discrepancy.

To install the Medical Device, proceed as follows:

It is essential to receive appropriate training for the correct installation and operation of the R-EVO SMART

systems. Training is provided by OPTIKON 2000 S.p.A. Consult your OPTIKON 2000 S.p.A. technical service for more detailed information.

It is the user's responsibility to clean and sterilize the handpieces, tips and any other reusable microsurgical accessory.

- Open the packaging of the medical device and its accessories.
- Pull out the R-EVO SMART from its shipping packaging.
- Check the Instructions for Use when removing sterile and resterilisable microsurgical accessories from the packaging.
- For R-Evo Smart S and CR, check that the pressure supply complies with the value indicated on the rear panel (from 500 to 800 kPa - from 72.5 to 116 psi).
- For the R-Evo Smart S and CR, connect the compressed air supply hose to the rear panel "GAS INLET" port and to the wall compressed air supply line.
- Connect the pedal cord to the socket on the rear panel of the R-Evo Smart.
- If you use the optional equipment cart with instrument tray, connect the electric pole control cable to the rear panel of the R-Evo Smart.
- Connect the AC power cord to the R-Evo Smart power outlet.
- Connect the other end of the AC power cord to the wall outlet.

Moving Your Device

If the optional tool trolley is used, it is equipped with a handle which can be used to easily and safely transport the Medical Device to a different installation location. Use the handle for the purpose indicated.

⚠ **CAUTION**

Risk of injury due to damage during movement

- If the tool is moved using the optional cart, if you have to overcome a small step (max 3cm), push very slowly using the handle.

Four locking tabs on the wheels make it easy to find the installation position.

- If one of the locking tabs is pressed:
  The trolley can be placed easily and effortlessly, in any orientation, in the surgical room near the operating table.

All- Locking tabs have been pressed in:
The tool carrier is secured in place and avoids any movement. After placing the Medical Device in the desired place in the operating area, press down on the locking tabs.

Installation of the Medical Device in the operating room

To install the device in the operating room using the optional cart, proceed as follows:

- Release all the locking tabs of the wheels.
- Grab the tool carriage from the handle and gently push it towards the desired position.
- The trolley must be placed on a levelled floor.
- Press at least two of the locking tabs on the wheels and make sure that the carriage can not move by itself.
- The power plug is used as a means of electrically isolating all poles simultaneously from the MAINS SUPPLY. Do not place the appliance in such a way that it is difficult to disconnect the power plug from the wall socket

Preparation for sterile operations

CAUTION

Risk of infection!
The patient or user may become infected if the accessories lose their sterility.

- Place sterile accessories on the instrument tray covered by the sterile drape supplied or, however, on a secure surface to prevent accidental drops.
- For sterile use of the touch screen, use the supplied sterile drape.
- The Medical Device may only be used by properly trained personnel.

Sterile single-use drapes are designed to use the tray and touch screen in sterile conditions. The following accessories are available for the R-EVO SMART:

- SCREEN COVER DRAPE FOR R-EVO SMART
- R-EVO SMART TRAY COVER

Please comply with the Instructions for Use of each article when using the drapes.

Powering the device on

Before turning on the device, check the following:

- The compressed air line has been connected (R-Evo Smart S and CR only).
- The power cord has been connected.
- The pedal has been connected.

⚠ **WARNING**

Risk of injury to the patient's eye!

- An audible air leak at start-up may indicate a malfunction of the silicone section.

  Contact your dealer or the technical service of OPTIKON 2000 S.p.A.

⚠ **CAUTION**

Functional test

- The software checks the validity of the calibration at power on. If there is any discrepancy, the default safe calibration is stored and you are prompted to calibrate the device (5 beeps).

  Contact your dealer or the technical service of OPTIKON 2000 S.p.A.

To use the Medical Device, proceed as follows:

- Set the power switch on the rear panel to the on position (I).
- Press the power button on the front panel until the indicator lamp lights up.
- The electric irrigation pole rises and lowers by a few centimetres.
- The device performs a self-test, during which a start splash screen shows the R-EVO Smart logo.
- When the device is on, the first menu appears on the screen. User can choose among “Surgery”, “System settings” and “Service”.
- At the first start-up, the R-evo Smart operating interface is set in English, the “Surgery” page shows the standard user profiles, "Default", the user can choose a different language in the “System settings” page.

During subsequent accesses, the system also shows any new user and program added, the interface will be in the chosen language.

4.3.2 Installation of the I/A cassette

For a correct installation of the cassette, proceed as follows:

- Connect the male Luer lock connector of the administration set into the corresponding connector on the short tube at the top of the I/A Cassette.
- Insert the I/A cassette in the side panel by aligning the reference line on the I/A cassette with the corresponding point on the side panel.
- Turn the I/A cassette clockwise until it stops.

⚠ **CAUTION**

Risk of infection!

When replacing the infusion bottle, pathogens may enter the bottle and contaminate the balanced saline solution.

- Never touch the drip chamber spike when connecting, replacing or removing the infusion bottle.
- Insert the drip chamber spike into the rubber stopper of the infusion bottle or the controlled irrigation infusion bag.
- Connect the end of the irrigation and aspiration lines to the corresponding connectors of the handpieces.

⚠ **CAUTION**

Risk of injury to the patient!

- Before using the handpiece, always perform the "Priming" procedure for the preparation and testing of the irrigation/aspiration tubes. During this procedure, the operation and proper installation of the I/A Cassette and Irrigation/Aspiration Tubes is verified and the I/A System is also filled with sterile saline. This way, possible malfunctions and injuries to the patient are avoided.

To remove the I/A cassette, proceed as follows:

Press the "PUSH" button to remove the I/A cassette after the surgery has been completed.

Wait until the peristaltic pump is completely retracted.

- Rotate the I/A cassette counter-clockwise until its reference line and the corresponding point on the pump panel are aligned.
- Remove the I/A cassette.

4.3.3 Installation of phaco accessories

CAUTION

Risk of injury to the patient's eye!
If the "priming" is done while the tip is used on the patient, this could cause serious damage to the patient's ocular structure.

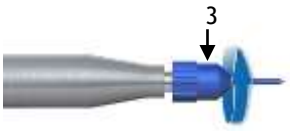
- Never perform the "Priming" preparation and test procedure while you are using the device on a patient.

Connection of the tip to the handpiece

- Tighten the desired tip (2) on the end of a handpiece (1), making sure the threads are correctly engaged. Tighten the tip only with your fingers.

- Carefully position the wrench opening (on the side of the flange) on the tip (2) without damaging the tip, so that the key engages the slots at the base of the tip.
- Carefully tighten the tip with the appropriate wrench clockwise.
- Remove the key from the tip.

Connection of the silicone sleeve (sleeve) to the tip



Carefully slide the silicone threaded sleeve (3) onto the tip until the threads are engaged.

- Slowly tighten the silicone sleeve on the phaco handpiece until the silicone sleeve end leaves exposed the amount of phaco tip desired by the surgeon.
- The phaco handpiece (1) is now ready to receive the irrigation/aspiration tubes of the surgical systems.

Connection of irrigation/aspiration tubings

- To connect the aspiration tube of the irrigation/aspiration tube assembly, insert the end of the female connector into the corresponding male connector of the phaco handpiece and tighten while pressing and turning slightly.
- To connect the irrigation hose of the irrigation/aspiration tubing assembly, insert the end of the male Luer into the corresponding female connector of the handpiece and tighten while pressing and turning slightly.

Preparation procedure and "Priming" test

- Fill the test chamber (9) of balanced saline solution and slide it over the silicone sleeve.
- Position the test chamber at the level of the patient's eye.
- Connect the I/A cassette to the console if you have not already done so, and connect it to the irrigation bottle.
- Plug the power supply plug of the handpiece into the U/S socket (1) on the front of the unit.
- Press the button <Prime> (preparation) in the lower left corner of the screen.
- After completing the preparation procedure, the display will show the message "Ultrasound Ready".

4.4 USER'S PROGRAMS

Configuring programs for users

All predefined parameters of the R-EVO SMART can be adapted to the user's individual needs. The parameters thus set are saved to be reused later in programs and assigned to users.

The R-EVO SMART can store up to 30 different users and up to 40 programs per user.

⚠ **CAUTION**

Risk of injury to the patient!

- Improper changes made to the settings during application may result in patient injury.

Creation of users and programs

Creating a new user or a new program

- Before creating a new user or program, set the desired parameters in the cataract (Anterior Segment) or retina (Posterior Segment) mode.
- The "Cancel" button becomes active when a parameter is changed. If you press the button <Cancel>, the settings prior to the changes are recalled.
- Press the "Save as" button
- A virtual keyboard with the current user name is displayed.
- If the new program belongs to the current user, enter the name of the new program and press the "Save" key. If you want to save a new program, your name must include at least three characters and one letter.
- To create a new user, press "New User". The cursor is then moved to the "User" field where a name can be entered for the new user.
- Confirm the name of the new user by pressing the "Save" button, then move the cursor to the "Program" field.

Save the program for an existing user

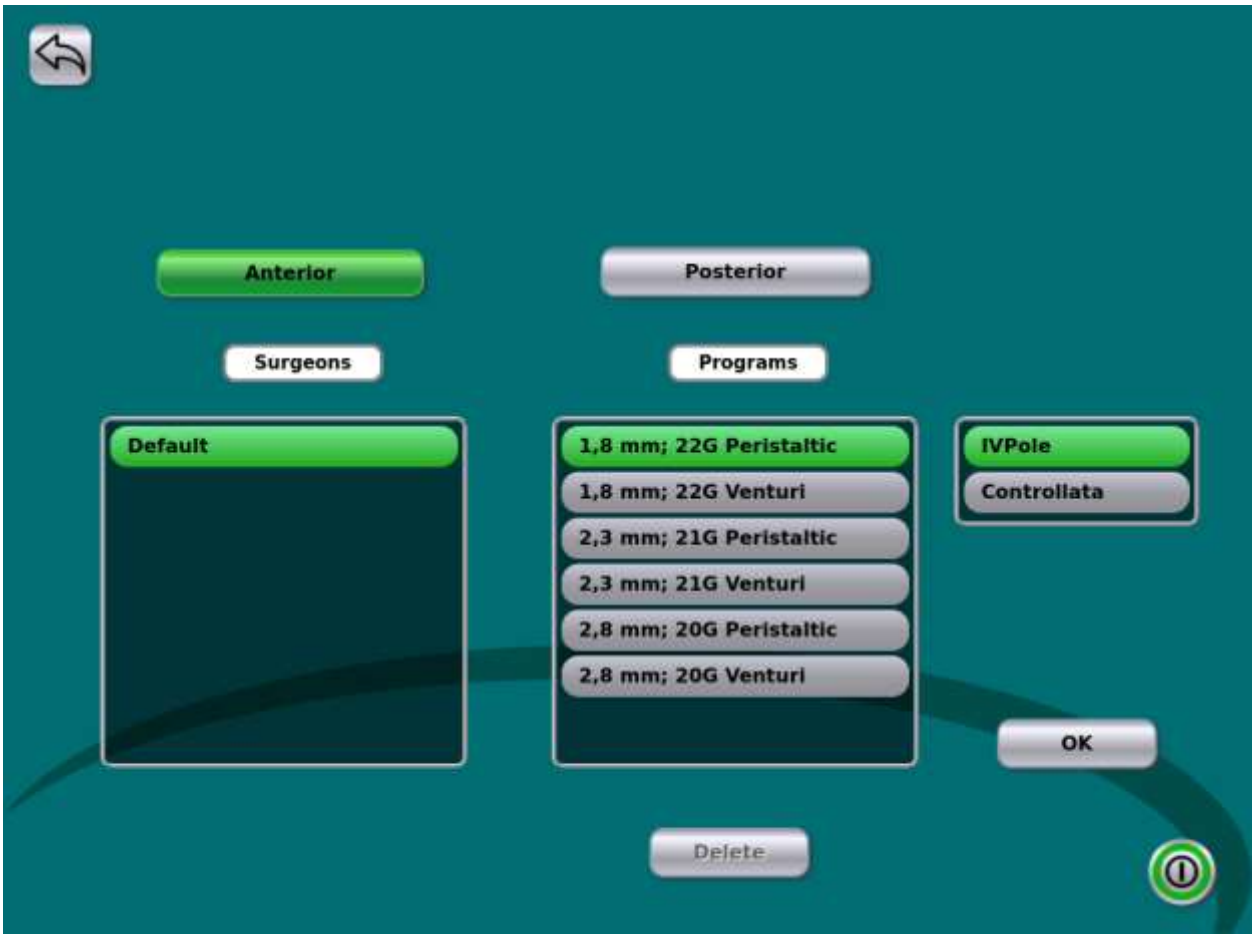
- Press the "Select user" button. Existing users are displayed in a call pop-up window.
- Select one of these users and press the "OK" button.
- The pop-up window closes and the cursor moves to the "Program" field, where the name for the new program can be entered.

Program editing

- Adjust the different parameters of the medical device in cataract or retina mode.
- The "Cancel" button is activated to indicate that a program has been changed. If you press the "Cancel" button, the previous settings are restored.
- To save the changes made in the same program permanently, press the "Save" button.

  Program changes Default (Defaults) can not be saved. To save changes in a new program, you need to create a new program (Save as...).

Cancellation of a program



- Select the program you want to delete.
- The button with the name of the active program is in green. Press the "Delete" button to delete the active program (after confirmation).
- The previous program of the same user will be loaded, if it exists.

If all the active user's programs have been deleted, the user is removed, and the device loads the DEFAULT program (DEFAULT). DEFAULT programs can not be deleted.

4.5 OPERATION

4.5.1 Irrigation/Aspiration

Installation of irrigation and aspiration tubings and I/A cassette

- For information on installing the irrigation and aspiration tubings and the I/A cassette, refer to the relevant chapter.

Connection of tubings and handpiece

- Select the required I/A cannula and insert it carefully into the coaxial I/A handpiece.
- Rotate the silicone sleeve on the I/A cannula cap.

The silicone cap should be pressed gently until the silicone sleeve passes the aspiration connector located on the I/A cannula.

- Connect the irrigation/aspiration lines of the irrigation/aspiration lines installed by sliding the ends connectors into the corresponding irrigation and aspiration connectors of the handpiece tube.

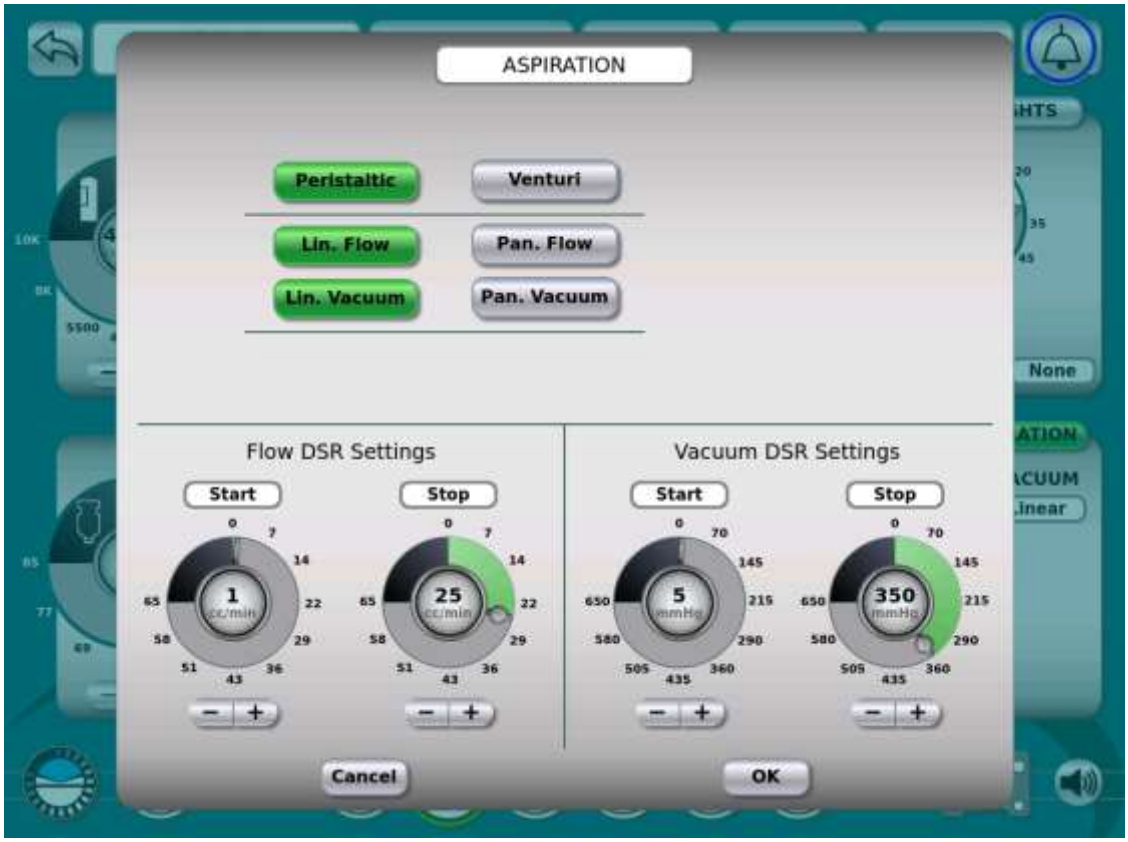
For information on the installation and application of bimanual handpieces, refer to the Instructions for Use of the respective handpiece.

Function selection

- Touch the button <Cortex> (Cortical).

Settings for aspiration

- The R-EVO SMART systems are equipped with an I/A cassette, so both the peristaltic pump and the Venturi pump (R-Evo Smart S and CR only) are available at the same time. To switch the two aspiration modes, press the "Peristaltic" or "Venturi" button in the "Aspiration" panel.



CAUTION

Risk of injury to the patient's eye!

- When switching from the peristaltic pump to the Venturi or rotary pump during surgery without changing settings, there is a Risk of injury to the patient.

INFORMATION: the flow rate and the vacuum limit can be set independently for the peristaltic pump, for Venturi pump only vacuum can be set. When using the Venturi pump, the current flow rate increases with vacuum settings and aspiration cannula dimensions.

WARNING

Risk of injury to the patient's eye!

By changing the height of the IV pole by forcing it manually, it is possible to obtain an incorrect indication of the height of the bottle and injure the patient.

- Do not force the IV pole to change its height.

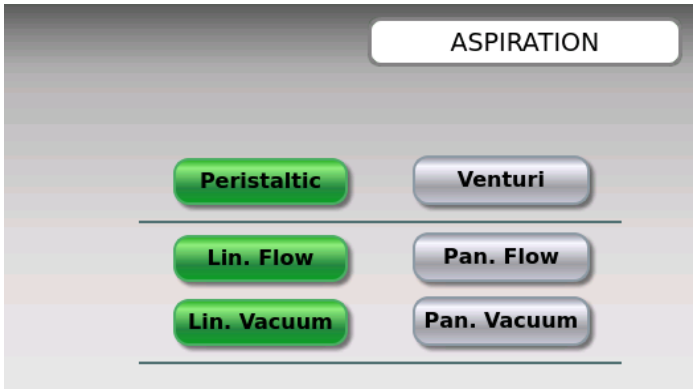
CAUTION

Risk of injury to the patient's eye!

It is possible to cause anterior chamber instability if the height of the IV pole or the vacuum settings is not correct!

- Start with low vacuum safety settings and gradually increase them to determine the correct vacuum and height settings for the IV pole, making sure the anterior chamber is stable.

The set flow values (only for the peristaltic pump) and the vacuum level can be adjusted using the + - keys or the cursor.



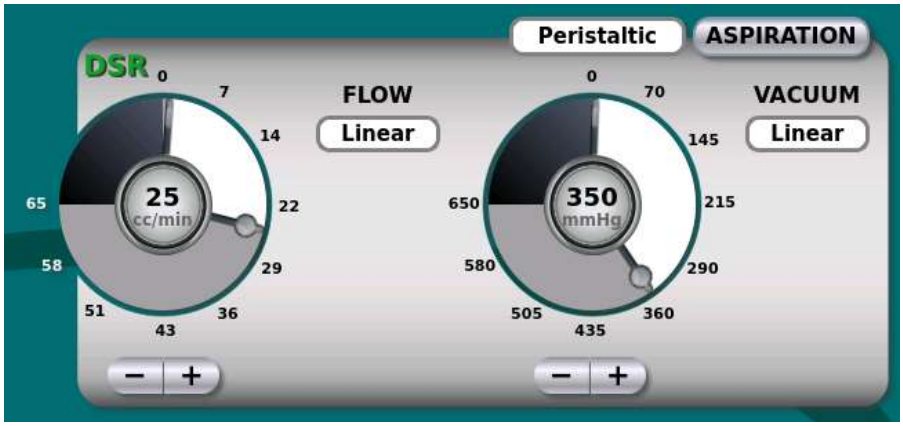
The vacuum and flow can be controlled either in "panel" (that is, fixed) or "linear" control mode.

To switch to "linear" mode; press the Lin Flow button and/or Blank Lin, and to switch to "panel" (fixed) mode, press the Pan Flow button and/or Vacuum Pan.

In "panel" mode, a function, when activated by the pedal, automatically reaches the value set in the user program.
In "linear" mode, the surgeon can, by pressing or turning the pedal, linearly control the value of the function from zero to the set limit.

When in “linear” mode, the Surgeon, by footswitch depression or rotation, can linearly control the function value from a start value to a final “stop” value previously set in “DSR Settings” (Dynamic Setting Regulation).

Values set in “DSR Settings” are shown in the working screen by two finger indexes delimitating the linear regulation range.



Irrigation settings

- Set the height of the IV pole according to the vacuum settings and the connected tip, in order to maintain an adequate balance of the liquids.
- Activate irrigation by pressing the foot switch beyond its standby position.

Continuous irrigation (irrigation flows even after releasing the footswitch) can be activated by pressing the "On" button on the touch screen, or by pressing the corresponding side button on the footswitch, depending on the programming of this 'last.

- To stop continuous irrigation, press the touch screen's "Off" button, or press the foot switch again.

⚠ **WARNING**

Risk of injury to the patient's eye!
The intraocular pressure is reduced if the amount of balanced salt solution is insufficient.

- Check the level of balanced salt solution in the infusion bottle during surgery. If the level is too low, the surgeon will replace the bottle or the infusion bag.

4.5.2 Phacoemulsification

If the message "Connect handpiece" is displayed on the screen, this means that the handpiece is not connected or is not recognized by the machine.

Preparation and test ("Priming")

The message "Please, prime" indicates that the "Priming" preparation and test procedure must be carried out. Press the "Prime" button (prepare) to start the procedure; the connection and correct operation of the irrigation/aspiration tubings are checked and these are completely filled with balanced saline solution. Irrigation/aspiration preparation and testing can be skipped under certain conditions, e.g. when the handpiece or the tip is to be replaced after successfully passing the priming. To skip the irrigation/aspiration preparation and test procedure, press the footswitch past zone C: A pop-up window opens and you are asked if you really want to skip the preparation procedure.

Ultrasound Test (Ultrasound adjustment and verification)

Every time a handpiece is connected or replaced, it is necessary to perform a simple preliminary ultrasound test. The purpose of this procedure is to tune the phacoemulsifier unit on the connected handpiece, verifying, at the same time, the correct functioning of the system. At the end of the "Priming" procedure, or if it has been skipped, the unit automatically starts the Ultrasound Test procedure. If the adjustment and verification are not successful, the message "Please check tip" is displayed, for four seconds, and the user must repeat the preparation procedure.

INFORMATION

Phaco tip damage!

- Do not activate the handpiece with the phaco tip in the air. The ultrasounds must be activated with the phaco tip inserted into a test chamber filled with infusion solution or into a container with sterile liquid at room temperature. If these instructions are not followed, it is possible to damage the phaco tip and/or the phaco handpiece.

WARNING

Risk of injury to the patient's eye!

Although the R-EVO SMART systems are equipped with a sophisticated power control circuit to limit the power of the ultrasound supplied to the eye, care must be taken not to damage the endothelium of the eye (corneal damage).

- Use always the lowest ultrasound power, sufficient for cataract removal.
- The incision should not be made too tight with respect to the silicone sleeve and must allow a certain leakage of balanced salt solution.
- Do not stress the incision or twists the sleeve while trying to reach fragments of the nucleus in the eye.
- If the phaco tip is completely occluded by the nucleous, the aspiration flow stops and the tip is no longer cooled properly. Do not activate ultrasound for too long or high levels if the phaco tip is occluded.

In Ultrasound mode, in addition to the irrigation and aspiration parameters described in the previous section, it is possible to adjust the ultrasound mode and emission level.

Ultrasound can be emitted in Continuous, Pulsed modes (with three duty cycle levels, called "STD,"Cold"and "Ice cold "), Single Burst, Multiple Burst, Continuous Burst.

If, for aspiration, the peristaltic pump is used, it is possible to select the "Autolimit" mode that limits the power output to a maximum of 50 microns in case of occlusion, thus decreasing the probability of corneal damage.

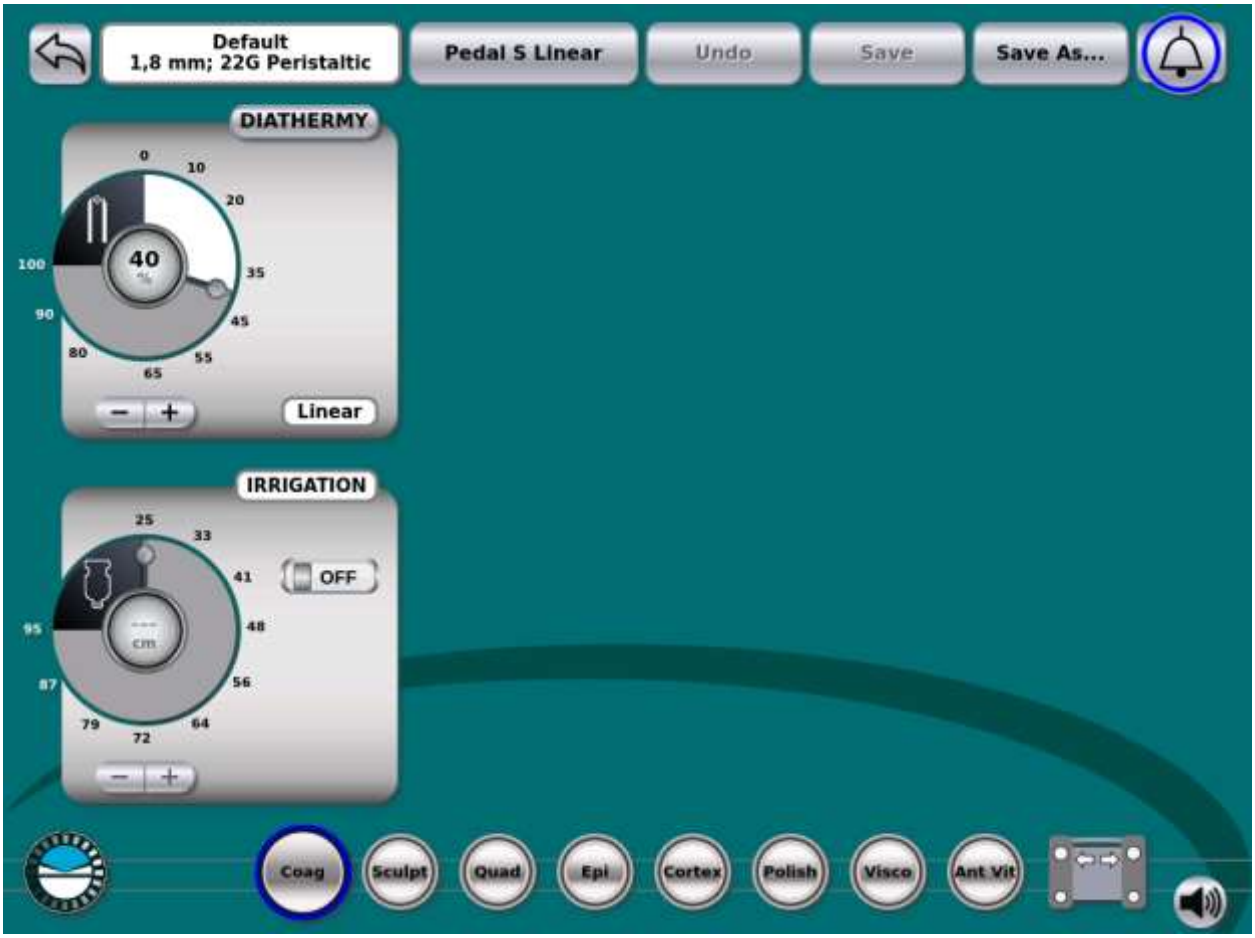
The "HD Pulse" mode, also available with peristaltic pump, automatically changes the duty cycle in pulsed mode according to the occlusion state of the tip, in order to minimize the time of emulsification of the cataract, while keeping low the ultrasound energy issued.

Basic settings for retina modes

4.5.3 Bipolar endothermy for retinal surgery

Connection of accessories

- Connect the desired endothermy handpiece, such as, for example, the diathermy pencil eraser, to the bipolar diathermy cord.
- Insert the bipolar diathermy cable connector into the diathermy socket on the console.



Settings for diathermy

- Adjust the preset power level in the "Coag" panel (diathermy) using the + - keys or the cursor. If you are not sure of the power level to use, it is best to start with low settings and eventually increase them gradually to achieve the desired surgical effect.

Bipolar diathermy can be activated in both "Panel" and "Linear" control modes. In the last case, the output power is linearly controlled from 5% to the preset limit, by pressing the pedal.

- To switch between "linear" and "panel" modes, touch the "Linear" and "Panel" buttons.

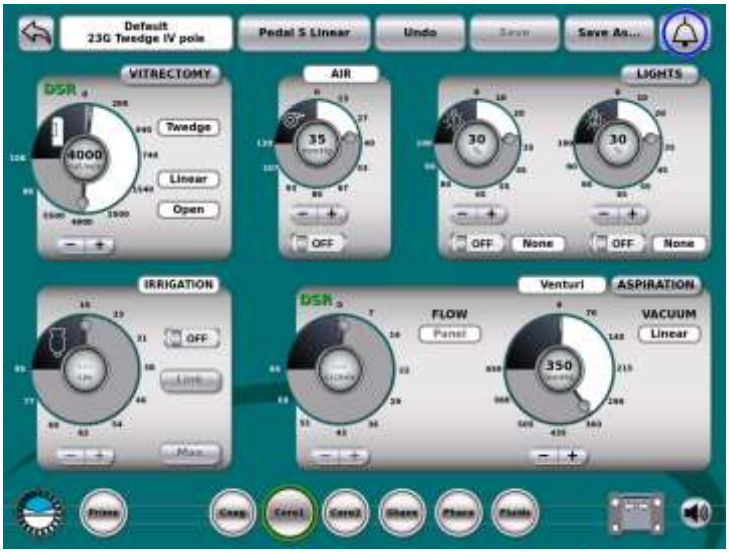
Adjusting a parameter does not change the default parameters. To return to the previous parameters press "Undo", to permanently save the new settings in the device memory refer to the chapter "Creating a User program".

4.5.4 **Vitrectomy**

WARNING

Risk of injury to the patient's eye!
If the vitrectomy handpiece is not connected properly, non-sterile air may enter the patient's eye.

- Before placing it in the patient's eye, the vitrectomy handpiece must always be tested for proper functioning in a sterile solution container.



In "Vitrectomy" mode, three sub-modes are available: “Core1”, “Core2” e “Shaving”.
These are three memory areas where optimal irrigation, aspiration and cut parameters can be saved for the different stages of vitrectomy.
It is possible to switch between the three phases either by touch screen or by using a multifunctional pedal.
A “Link” button in the irrigation frame allow linking irrigation pressure in all phases of the vitrectomy.
If the “Link” button is not active, the irrigation pressure can be independently set for the various phases
The "Max" button, in the irrigation box, raises the irrigation pressure above the arterial blood pressure, to temporarily arrest retinal bleedings.

WARNING

Risk of injury to the patient's eye!
Maintaining the irrigation pressure at values above the arterial pressure can cause permanent damage to the retinal function.

- The "Max" button must be activated for the shortest possible time. If the irrigation pressure is raised above 70mmHg, an alarm is triggered after approximately one minute.

Touching the "Vitrectomy" button accesses the vitrectome settings.
It is possible to choose the rest position (pedal not pressed) of the cutting port between "port open" and "port closed".
The duty cycle of the vitrectome can be set to one of three levels ("Low", "Medium", "High"). This affects the speed at which the vitreous is removed (at a higher duty cycle, this means greater removal capacity).
The cut rate can be controlled either in "Panel" or "Linear" mode. If “Linear” control mode is chosen, cutting frequency can be linearly controlled by system footswitch depression or rotation from a “Start” power to a final “Stop” power (DSR mode). Note that “Start” frequency can be set either smaller or greater than “Stop” frequency.

4.5.5 **Illumination**

The R-EVO SMART is equipped with an endo illumination system with LED lights with two independent light sources. The lamps are equipped with filters for reducing the blue component and a green filter.

- Connect the optical fibre for illumination to the desired fibre light socket on the front panel.

⚠ **WARNING**

Risk of injury to the patient's eye!

- Although the fibre optic endo-ocular illumination system does not emit infrared and ultraviolet rays, to avoid possible damage to the retina, always use the minimum intensity sufficient for the surgical application.

WARNING **Risk of injury to the patient's eye!**

- To reduce the risk of damage to the retina, the end of the fibre optic light probe must not be too close to the retina.

INFORMATION **Duration of Surgical Operation**

If the light is on and its connector is not engaged (optical fibre not connected) The R-EVO SMART automatically decreases the light output so as not to disturb the surgeon.

- Select the source you want to adjust and turn it on/off using the buttons <on/off>,
- Adjust the illumination intensity of the selected lamp using the <+ -> keys or the cursor.

The surgeon can choose one of four filters designed to emphasize the presence of membranes.

Moreover, the yellow filters protect the patient's eye from unnecessary exposure to blue radiation and therefore allow long-lasting treatments.

4.5.6 Tamponade

WARNING **Risk of injury to the patient's eye!**

- To avoid possible infection of the patient's eye, only use the original OPTIKON 2000 S.p.A. injection tube equipped with an air sterilisation filter for air tamponade.

CAUTION **Risk of injury to the patient!**

- Automatic monitoring of intraocular pressure is calibrated for the exclusive use of accessories manufactured and distributed by OPTIKON 2000 S.p.A. (membrane filters, tubings, scleral guides).

WARNING **Risk of injury to the patient's eye!**

- The silicone stop valve is checked during power on test. Make sure there is no hissing when turning the device on.

⚠ **CAUTION**

Risk of injury to the patient's eye!

- During the injection of silicone oil, the intraocular pressure (IOP) is not controlled by the R-Evo Smart CR, so it is the Surgeon who must take care of the same. It is important to check that the silicone oil flow is consistent with the injection pressure set before inserting the cannula into the eye.

⚠ **CAUTION**

Risk of injury to the patient's eye!

- Release the pedal to stop the silicone oil injection. In an emergency, close the injection stopcock or remove the silicone oil injection tube from the silicone supply unit.

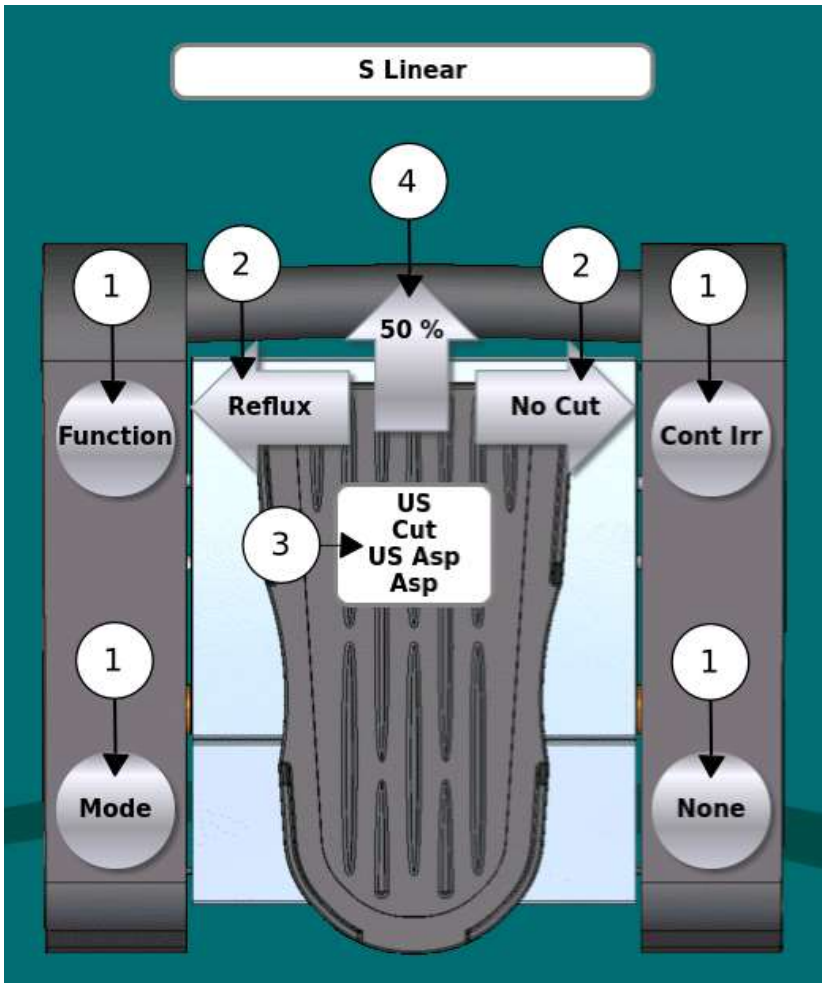
INFORMATION

Silicone oil loss

- To avoid leakage of silicone oil into the aspiration line of the I/A cassette, the silicone oil collection tank must be kept upright and replaced as soon as it is observed that it is filled with silicone oil.

- To speed up the removal of high density oil, you can use the included Y-connector to connect two removal groups and use them at the same time.
- For more information, refer to the documents attached to the silicone oil removal assembly.

4.5.7 **Pedal programming**



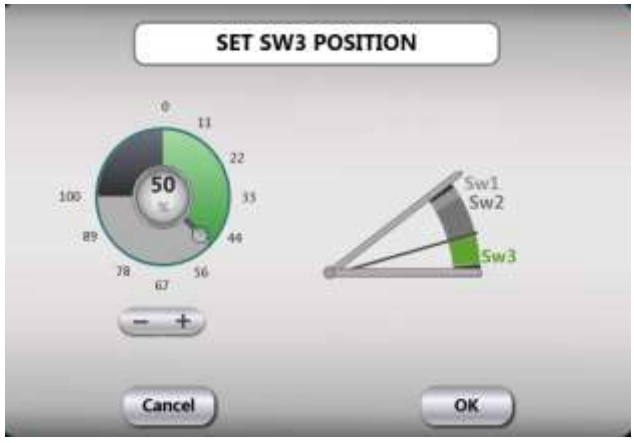
Press "Maintenance" to access the pedal programming graphical interface. Through this interface the user can customise the various pedal functions.

a. If the user presses one of the four side buttons (1) or one of the side arrow keys (2), a window appears where you can choose which function to associate with the single key or lateral movement of the main paddle.

Please note that not all functions can be associated with every button or movement of the paddle. The disabled functions are greyed out.

b. The label (3) shows the functions associated with the vertical movement of the main paddle (in the example, U/S, cutting and aspiration).

c. By pressing the up arrow (4) it is possible to adjust the starting point of the U/S, this allows to divide, according to the surgeon's preferences, the vertical stroke of the paddle between linear aspiration and linear regulation of the ultrasounds.



Once the pedal has been programmed and saved with its name, it can be recalled and used within the user programs.

5. System alarm messages

WARNING

Error messages on the touch screen

Error messages indicated by a red warning signal indicate a serious error in the device that can not be remedied by the user.

- In case of error messages indicated by a warning signal, contact the OPTIKON 2000 S.p.A. technical service.
- Take note of the explanations offered for each of the error messages on the following pages.

CAUTION

Error messages on the touch screen

The error messages indicated by a yellow warning signal indicate a moderate error that can be remedied by the user or by our technical service.

- Take note of the explanations offered for each of the error messages on the following pages.

INFORMATION

Error messages on the touch screen

Error messages indicated by a blue signal indicate a slight error, a warning or an instruction for the user.

- Take note of the explanations offered for each of the error messages on the following pages.

100 Error messages

Id	Message	Possible cause	Correction measurement
100	"Air pressure error"	visual + acoustic message Error in the air infusion system or controlled irrigation (the outlet pressure is much higher or lower than the preset pressure)	Contact the technical service of OPTIKON 2000 S.p.A.
101	"Pressure level error"	visual + acoustic message Incorrect pressure at the output of the proportional valve	Contact the technical service of OPTIKON 2000 S.p.A.

102	"Vacuum level error"	The vacuum exceeds the preset value in Venturi mode	Contact the technical service of OPTIKON 2000 S.p.A.
103	"Invalid diathermy power"	Fault in the diathermy system (the output power is much higher or lower than the preset power)	Contact the technical service of OPTIKON 2000 S.p.A.
104	"Ultrasound enabling error"	Error in the ultrasonic system (the output power is not activated even if the opposite is shown, due to an activation port error or a false contact of the cables)	Contact the technical service of OPTIKON 2000 S.p.A.

200 Error messages

Id	**Message**	**Possible cause**	**Correction measurement**
200	"Air enabling error"	Error in the air infusion system and controlled irrigation (the secondary transistor of the safety switch is checked at startup)	Contact the technical service of OPTIKON 2000 S.p.A.
201	"Watchdog error"	Error in the monitoring circuit (verified at startup)	Contact the technical service of OPTIKON 2000 S.p.A.
202	"Serial communication error"	Communication error between the graphical user interface and the control panel	Contact the technical service of OPTIKON 2000 S.p.A.
203	"Warning: active diathermy!"	Fault in the diathermy system (output power is activated due to an activation port error)	Contact the technical service of OPTIKON 2000 S.p.A.

Id	Message	Possible cause	Correction measurement
205	"Diathermy enabling error"	Fault in the diathermy system (the output power is not activated even though the opposite is shown, due to an error in the activation port or a false contact of the cables)	Contact the technical service of OPTIKON 2000 S.p.A.
206	"Reference voltage or power supply error"	Incorrect reference voltage in A/D transducer or +5V power value incorrect (verified at startup)	Contact the technical service of OPTIKON 2000 S.p.A.
208	"Warning: active ultrasound!"	Error in the ultrasound system (output power is activated due to an activation port error)	Contact the technical service of OPTIKON 2000 S.p.A.
209	"Vacuum offset error"	Error during preparation: excessive reading of the sensor in the absence of a vacuum	a) The preparation procedure was restarted after Err 210. Open the infusion clamp on the infusion unit, briefly open the continuous irrigation and restart the preparation procedure. b) The vacuum sensor must be calibrated. Contact the OPTIKON 2000 S.p.A. technical service to calibrate the unit.

Id	Message	Possible cause	Correction measurement
210	"No irrigation"	Error during preparation: The vacuum does not decrease after opening the venting valve.	Open the infusion clamp on the infusion unit, briefly open the continuous irrigation and restart the preparation procedure.
211	"Infusion pressure too high"	The IV pole is located at too high a level	Lower the IV pole as far as possible
212	"IV pole error"	IV pole error	Contact the technical service of OPTIKON 2000 S.p.A.
213 216	"LED 1 over-heating" "LED 2 over-heating"	The system for illumination 1 or 2 has reached an excessive temperature.	Make sure the ventilation grids on the rear panel are clear of obstructions. Turn off the superheated LED and use one of the other two light sources. If the problem persists, contact the OPTIKON 2000 S.p.A. technical service.

300 Error messages

Id	Message	Possible cause	Correction measurement
300	"Install the I/A cassette"	The I/A cassette is not connected	Connect the I/A cassette
301	"I/A cassette full, aspiration stopped"	The I/A cassette collection tank is full	Replace the I/A cassette
302	"Low input pressure"	The pressure of the external air supply is too low or equal to zero	a) The device is not connected to the compressed air supply or the stopcock is closed. Connect the device of the compressed air source or open the stopcock. b) The compressed air supply pressure of the device is less than 450 kPa (65 psi). Check the pressure in the compressed air circuit.
303	"Major leakage"	Error during preparation (Priming): the peristaltic pump can not establish a vacuum of 100 mmHg within 30 sec.	a) The test chamber is not installed on the sleeve. Ensure that the test chamber is properly installed on the sleeve. b) Irrigation/aspiration tubes are not connected to the handpiece. Connect the irrigation/aspiration tubings from the cassette to the handpiece. c) The I/A cassette is faulty. Replace the I/A cassette

Id	Message	Possible cause	Correction measurement
			d) The pump system must be recalibrated, contact the OPTIKON 2000 S.p.A. technical service.
304	"Aspiration line occluded"	Error during preparation (Priming): the vacuum level during preparation exceeds 300 mmHg	a) The handpiece and tip have not been properly cleaned before sterilisation. Replace the tip and/or handpiece. b) The I/A cassette is faulty. Replace the I/A cassette
305	"Minor leakage"	Error during preparation (Priming): the peristaltic pump can not establish a vacuum of 300mmHg	a) Irrigation/aspiration connectors are not fully inserted into the handpiece connectors. Connect the connectors correctly. b) The sleeve or test chamber is not mounted correctly. Verify that the test chamber is fully engaged with the sleeve and that the sleeve is correctly positioned on the handpiece.
306	"Check the US tip"	Error during Priming: the phaco handpiece can not be tuned	a) The phaco tip is loose. Tighten the phaco tip in the handpiece correctly using a phaco tip wrench. b) The phaco tip is damaged. Inspect the phaco tip and replace it as necessary.

Id	Message	Possible cause	Correction measurement
			c) the phaco handpiece is damaged. Replace the phaco handpiece
307	"Weak phaco handpiece"	The phaco handpiece can not oscillate to more than 50 micrometres.	a) Check to see if the phaco tip is loose, and if so, tighten it properly using a phaco tip wrench. b) It is normal for the piezo-ceramic element to deteriorate with use and after a number of sterilisation cycles. Send the handpiece to the OPTIKON 2000 S.p.A.technical service.
308	Install controlled irrigation	The controlled irrigation air line is not installed.	Install the controlled infusion system before continuing, or use the gravity system.
310	"Low power US"	The ultrasound handpiece can not oscillate with the amplitude set	a) Check to see if the phaco tip is loose, and if so, tighten it properly using a phaco tip wrench. b) It is normal for the piezo-ceramic element to deteriorate with use and after a number of sterilisation

Id	Message	Possible cause	Correction measurement
			cycles. Return the handpiece to the OPTIKON 2000 S.p.A. technical service.
311	Insert U/S handpiece	The U/S handpiece is not connected to the unit	Connect the U/S handpiece to the unit. If the problem persists even after, replace the handpiece.
312	Please, prime	The handpiece is connected but not initialized	See "5.4.3 Installing the phaco accessories".
313	Please, prime (of the vitrectomy cutter)	The vitrectomy handpiece is connected but not initialized.	Follow the instructions on the screen to initialize and verify the operation of the handpiece
314	Please, prime (of the I/A cassette)	The I/A cassette is connected but not initialized.	Follow the on-screen instructions to initialize and verify the operation of the I/A cassette
318	Select peristaltic to aspirate	In "Fluid" mode, while injecting silicone, the Venturi pump can not be used.	Select the peristaltic pump to aspirate while injecting silicone oil.

400 Other Messages

Id	Message	Possible cause	Correction measurement
400	"Do you want to skip the priming?"	One of the pedal switches has been pressed, the phaco handpiece is connected but not initialized.	a) The user inadvertently activates the foot switch. Remove the foot and press "NO" on the screen b) Faulty footswitch. Replace the pedal

Id	Message	Possible cause	Correction measurement
401	Stop priming	During the priming procedure the user presses the pedal	See "5.4.3 Installing the phaco accessories".

6. Care and maintenance

6.1 MAINTENANCE OF THE DEVICE

Replacing fuses

The fuses of the control unit are located in the mains socket on the back of the unit. To replace the fuse, proceed as follows:

⚠ **CAUTION**

Risk of injury to the user!
Hot fuses could cause burns.

- Before replacing the fuses, turn off the device and allow it to cool for a few minutes.

- Turn off the medical device with the power switch.

- Pull out the power cord.
- Press the lock lever (1) and remove the fuse holder.
- Remove the faulty fuses and install the new ones.

INFORMATION

Risk of damaging the Medical Device!
Incorrect fuses may damage the device.

- Use only specified fuses! Refer to the label on the rear panel for detailed information.

- Install the fuse holder again. Lock the lever (1) making it snap into place.
- Insert the power cord.
- Turn on the unit with the power switch.

Maintenance of the Medical Surgical Device

CAUTION

Risk of injury to the patient's eye!

A device malfunction could result in a risk of injury to the patient!

- Have the device checked by the authorized technical service in accordance with the provisions of IEC 62353 in the following cases:

- during the installation of the Medical Device,
- at regular intervals (every 12 months),
- during maintenance work,
- after repairs, upgrades, calibrations and updates of software and firmware.

INFORMATION

Risk of damaging the Medical Device!

- To keep the device safe, check the unit in accordance with the limits of electrical leakage, as established by the EN 60601-1 standard at least once a year. Contact the medtech division of your installation, your authorized distributor or the OPTIKON 2000 S.p.A. technical service.
- Store the R-EVO SMART in a dry and clean place.
- Remove the I/A cassette after each use.
- To avoid a decrease in the safety of the device, due to ageing, wear, etc. the user must ensure, in compliance with the applicable national regulations, that the normal safety technical checks have been carried out, prescribed for this Medical Device within the scheduled times and the stipulated measure. The technical safety checks must be carried out exclusively by the manufacturer or by qualified personnel. The scope of the security engineering controls should include at least the following items:

- Availability of the user manual
- Visual inspection of the Medical Device and its accessories to verify the absence of damage and the readability of the labels
- Grounding Tests
- Current leakage test
- Test operation of all device switches, buttons, sockets and tell-tales.

6.2 MAINTENANCE OF ACCESSORIES

CAUTION

Risk of injury to the patient or the user!
Wet surfaces may cause electric shocks, as they are conductive to RF currents.

- Make sure that the diathermy handpiece is completely dry before using it.
- Avoid dropping or using handpieces and accessories incorrectly.
- It is extremely important to handle these components with the utmost caution and to inspect them carefully for any damage or wear after each use.
- Periodically inspect the liquid hoses, fittings, O-rings and handpieces for damage and wear.
- Remove all parts before storage.
- Set the tip protection caps on the handpieces (where provided) before packing and storing.

6.3 CARE OF THE DEVICE

Cleaning

The medical staff is responsible for the maintenance of the medical device and all the equipment in optimal operating conditions. The simple steps described below are a practical guideline to define a suitable maintenance and care program.

⚠ **CAUTION**

Risk of infection!

- Clean the front panel with a soft cloth moistened with distilled water.

If necessary, use only a neutral detergent.

- It is not permitted to use media that could damage the device.
- For cleaning, refer to the indications given in the relevant instructions for use.

Sterilization

⚠ **WARNING**

Risk of injury to the patient's eye!

The console, pedal and IV pole can not be sterilized.

- For sterilisation of the surgical accessories, such as the tips, refer to the indications given in the corresponding instructions for use.

Disinfection

INFORMATION

Damage to the surface of the device!

- Use a disinfectant based on aldehyde and/or alcohol. The addition of quaternary compounds is allowed. To avoid damaging surfaces, disinfectants other than those listed below should not be used.

The maximum concentrations are:

- For alcohol (tested with 2 propanol): 60%
- For aldehyde (tested with glutaraldehyde): 2%
- For quaternary compounds (tested with DDAC): 0.2%

7. ACCESSORIES

This section lists accessories, spare parts and consumables for the R-Evo Smart provided by the OPTIKON 2000 S.p.A.
Consult the zone distribution and site www.optikon.com for detailed information on the individual products.

CAUTION

Risk of injury to the patient's eye!

- Use only original accessories and consumables manufactured by OPTIKON 2000 S.p.A. and intended for use with R-EVO SMART systems. Consult the Instructions for Use of the accessories to check their compatibility with the R-EVO SMART systems.

Accessories for general use

REF	Description
112105	Multi-function pedal

Accessories for the Posterior Segment (CR only)

Posterior vitrectomy
20, 23, 25G “Optivit” Vitrectomy probes
23, 25G "Twedge" Vitrectomy probes (double cut)
Endoillumination
20, 23, 25G "Standard" Endoillumination Probes
20, 23, 25G Wide Angle Endoillumination Probes
"Chandelier" Endoilluminators 20, 23, 25G
Irrigation and Aspiration
Administration set for controlled irrigation
"Easysys" I/A Cassette
20G infusion cannulae
Fluid removal cannulas 20, 23, 25G
Trocar with valves 23, 25G
Trocar without valve 23, 25G
Active and passive "Charles" aspiration handpieces
Fluid exchange
Air tube with filter and automatic valve
Silicone oil injection/removal kits

Diathermy
Handpieces for Endodiatermy 20, 23, 25G
Diathermy forceps
Diathermy Pencil eraser
Diathermy cable
Phacoemulsification
"Slim 4" handpiece for phacoemulsification (Anterior and Posterior)
"Six" phacoemulsification handpiece (Anterior and Posterior)
Phacoemulsification tips via Pars Plana "low friction".

Anterior Segment Accessories

Phacoemulsification
"Slim 4" handpiece for phacoemulsification (Anterior and Posterior)
"Six" phacoemulsification handpiece (Anterior and Posterior)
Tips for phacoemulsification for incisions from 1.8 to 3.2mm
"Flared" phacoemulsification tips for incisions from 1.8 to 2.9mm
Silicone sleeves for incisions from 1.8 to 3.2mm
Irrigation and Aspiration
Administration set for controlled irrigation
"Easysys" I/A Cassette
I/A handpiece for quick insertion tips
Straight I/A tips, with silicone sleeves for incisions from 1.8 to 3.2mm
Angled I/A tips, with silicone sleeves for incisions from 1.8 to 3.2mm
I/A tips with metallic sleeve
Diathermy
Diathermy Pencil eraser
Diathermy forceps
Diathermy cable
Anterior vitrectomy
20G Vitrectomy probe, with irrigation sleeve
20, 23, 25G Vitrectomy probes, without irrigation sleeve

Procedural packages for R-Evo Smart

OPTIKON 2000 S.p.A. provides customizable procedural packages for Vitrectomy and for Phacoemulsification.

The procedural packages consist of accessory assemblies that appear in the previous tables.

Consult the local distributor for detailed information.