

A QUANTUM MOLECULAR RESONANCE DEVICE

REXONEYE

USER'S MANUAL

REXON-EYE Patented product

Product Code: 4001007



REXONEYE

This Manual is an essential part of the **REXON-EYE** medical device, as it describes its operation and how it is used. It must therefore be read carefully before using the device. All safety instructions or warning notes must be respected.

The **REXON-EYE** Medical Device must be used by qualified medical personnel only.

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1. WARNINGS AND SAFETY

1.1. DEFINITIONS

For the purposes of this manual, the following terminology will be used:

WARNING: indicates a potentially dangerous situation which, if not avoided, may result in serious injury to the patient or operator.

CAUTION: indicates a potentially dangerous situation which, if not avoided, may result in minor injury to the patient or operator.

PRECAUTION: indicates a potentially dangerous situation which, if not avoided, may result in property damage. **NOTE**: refers to an indication provided by the manufacturer deemed important or useful for the use of REXON-EYE. This information is not related to any hazard or dangerous situation.

1.2. INTENDED USE

REXON-EYE therapeutic device uses a particular low intensity, high frequency electrical stimulation called Quantum Molecular Resonance (QMR®). REXON-EYE is applied for the treatment of ocular surface disorders, described as a series of pathological conditions - determined or worsened by a variety of events (e.g. traumas, inflammation, deficiency, infections, etc.) - that cause anomalies of the eyelid and ocular surface epithelia (corneal and conjunctival epithelia) and the composition of the tear film, with important visual impairment effects. REXON-EYE acts by stimulating the natural physiological cellular metabolism and promoting regenerative capacity of cells and tissues.

In the specific case of Dysfunctional Tear Syndrome (DTS), it can be assumed that the specific frequencies of QMR results in functional benefits to the ocular annexes, reactivating the tear system by stimulating the activity of the glandular tissue and the physiological lacrimal secretion.

1.3. WARNINGS

1.3.1. General warnings

- The output power level should be as low as possible for the intended purpose and in any case not such as to cause any discomfort to the patient.
- The patient should not come in contact with metal parts that are grounded or have an appreciable coupling capacity to the ground.
- **CAUTION**: The patient must remain still and relaxed during treatment, with his/her eyes closed.
- WARNING: To avoid the risk of electric shock, the device must only be connected to grounded power supply networks.
- If REXON-EYE has not been in use for some time, it is advisable to initially set a low intensity and then, if necessary, increase it gradually until it reaches a value that causes the patient to feel a perceivable but pleasing heat sensation.
- **CAUTION**: a failure of REXON-EYE could result in an unexpected and undesired increase in the power delivered.
- There is a potential risk for patients with cardiac stimulators or other stimulating electrodes due to possible interference that could compromise the correct functionality of those implanted device. It is recommended that you read the information in section 1.4.
- There is a potential risk for cancer patients undergoing chemotherapy and / or radiotherapy. It is recommended to read the information in paragraph 1.4.
- It is recommended not to use any other electro-medical equipment on the patient at the same time as REXON-EYE, in order to avoid any interference.
- It is recommended not to use the REXON-EYE device in patients who underwent surgery less than a month before, just as a precautionary measure against potential risks of infection.
- Connect REXON-EYE directly to the wall socket, preferably without using extensions. Failure to observe this warning may affect the operation of the device. If extensions are used, check the presence and integrity of the ground conductor.

- If using a shared extension between REXON-EYE and other devices, ensure that the total power consumption of the connected devices does not exceed the maximum current allowed for that extension type.
- The use of this device near or on other devices should be avoided, as this may lead to incorrect operation. In these cases, it is necessary that the device and the other equipment are kept under observation to verify their normal functioning.
- The use of accessories, transducers and cables other than those specified or supplied by the manufacturer of this equipment could lead to higher electromagnetic emissions or a decrease in the level of electromagnetic immunity of this device, resulting in incorrect operation. For more information about the accessories, see chapter 4.5.
- Transportable RF communication equipment (including peripherals such as antenna cables and external antennas) should be used at a distance of not less than 30 cm (12 inches) from any part of the REXON-EYE generator, including its own cables. Otherwise, the performance of the device may be degraded.
- It is recommended to use the REXON-EYE generator only in the presence of EM EQUIPMENT and EM SYSTEMS that declare the compatibility of the provisions of paragraph 5.2.2.6 of the technical standard IEC EN 60601-1-2 (4th edition).
- CAUTION: Do not rotate the dial (knob) while it is pressed. REXON-EYE correctly interprets the command only at the release of the dial.

1.3.2. Explosion and fire hazards

- REXON-EYE should not be used in the presence of flammable, explosive, liquid or gaseous substances. Do not use the device in places where it may become wet.
- Flammable materials used for cleaning, such as solvents, must be allowed to evaporate completely before using the device.
- Before operating the device, make sure that the connections are in accordance with the instructions provided.

1.3.3. Mask (active) electrode hazards

- Check the integrity of this accessory (mask and its cable) before use and connect it to the equipment only when the latter is not turned on. Do not use damaged accessories or in case of cracks and signs of excessive wear.
- The connecting cable must be positioned in such a way as to minimize physical contact with the patient or other cables.
- Avoid placing unnecessary accessories on or near the patient and placing them in a place isolated from the patient.
- Use only original accessories. Otherwise, the manufacturer declines any responsibility.
- Before replacing the accessories, check that the device is turned off.
- Verify the correct positioning of the mask electrode on the patient's eyelids. It must adhere to the eyelids without applying an excessive and therefore annoying pressure and must be positioned in order to cover similar areas in the two eyes. A misalignment of the mask could lead to the perception of greater warmth on one eye compared to the other. No gel or other substances are required between the mask and the patient's eyelids.
- For hygienic reasons, the mask must be used always interposing the appropriate disposable cloth between it and the patient's eyelids.
- At the end of the treatment, the patient may report a slightly blurred vision. This occurrence is transitory and resolves within a few minutes. It is not due to any electrical events, but simply to the mechanical pressure exerted by the mask on the eyeball, e.g., when the elastic band holding the mask in place is too tight. Therefore, be sure to place the mask in contact with the eye without exerting too much pressure.

1.3.4. Neutral plate hazards

• The neutral plate is subject to wear and in principle it should be replaced annually, depending on its usage. It is anyway recommended to periodically check for its good condition. If some wear signs appear, e.g., scratches or cuts on the surface, breaks on the edge of the plate or on the connection

cable, immediate replacement is recommended. To preserve the neutral plate over time, we recommend positioning it during treatment on a horizontal surface, large enough to prevent it from bending at the sides and not too soft so as to limit the formation of creases.

- The neutral plate must be replaced when it begins modifying its electrical properties (reduced conductivity). This condition may occur because of breakages and / or scratches on the surface or edge of the electrode, which may lead to an alteration in the power setting with respect to the usual values.
- Before each use, check the integrity of the QMR neutral plate, in particular as regards the connection of the blue plastic connector.
- The neutral plate must be positioned in such a way that the contact surface with the patient is as wide as possible. A marked drop in the output power from the device may be due to poor positioning of the neutral plate.
- For hygienic reasons, a disposable tissue must be always placed between the neutral plate and the patient body.
- It is important that the surface between the patient and the neutral plate is perfectly dry and remains so during the treatment. If it becomes damp, for example due to patient's sweat, an altered transmission of the electric current may be established, generating an intense sensation of heat perceived by the patient in the area in direct contact with the neutral plate. In this case, stop treatment immediately and dry the surface of the plate.
- Do not use the neutral plate on paediatric patients or in patients weighing less than 15 kg.
- The use of gels or other substances is not required nor advisable in the application of the neutral plate to the patient.

1.3.5. Disposable cloth hazards

- The use of the disposable cloth is essential for patient hygiene and to avoid transmission of viruses and bacteria. It is waterproof on one side, therefore liquids (e.g. tears and / or sweat) cannot cross the strip. This also prevents to compromise the normal functioning of the mask.
- Only the disposable cloth supplied by Resono Ophthalmic must be used. The manufacturer declines any responsibility from the use of any different materials, as they may significantly affect the correct delivery of therapy.

1.4. PRECAUTIONS FOR USE

Read and follow the following instructions carefully.

- REXON-EYE can only be used by properly trained medical personnel. The physician is the only person authorized to set the value of all treatment parameters.
- The level of power delivered must be as low as possible to achieve the desired therapeutic effect and in any case not to cause any discomfort to the patient.
- In case of any problems, immediately turn off REXON-EYE using the main power switch, disconnect the power cord from the power outlet and contact the manufacturer Resono Ophthalmic.

It is advised not to use REXON-EYE on the following patient categories, as the device has not been tested yet on them:

- a) pregnant women,
- b) patients carrying active implantable devices (e.g., pacemakers and hearing aids),
- c) neonatal or paediatric patients,
- d) oncologic patients under treatment,
- e) patients who underwent ocular surgery in the last month.

In the event of a major illness, do not proceed to treatment without consulting the specialist physician caring for the patient.

There is a possibility of interferences with other medical equipment, if these are obsolete and / or do not comply with current regulations concerning the safety of electro-medical equipment.

1.5. ESSENTIAL PERFORMANCE

The minimum level of performance of the Rexon-Eye device guaranteed by the manufacturer is as follows:

- Stable power emission in relation to the setting select by the operator.
- Display shows the actual status of the device in terms of function.
- Power regulation even during energy supply.
- In case of any type of disturbance (mechanical, electromagnetic, etc.) that can affect the performance of the device, it must put itself in a condition of non-danger for the patient and user.

Therefore, in the event that any electromagnetic disturbances degrade the essential performances, the device could show error messages or unexpected behaviours that however do not involve unacceptable risks for the patient or the user.

2. PRESENTATION

2.1. DEVICE MODEL

The present manual refers to model REXON-EYE:

CODE	DESCRIPTION
4001007	REXON-EYE

2.2. PRODUCT DESCRIPTION

REXON-EYE is an innovative device that, through the use of low-power high-frequency currents, promotes the stimulation and regeneration of cells and tissues.

The basis for this therapeutic effect lies in the specific spectrum of frequencies used. This is based on the principle of Quantum Molecular Resonance, i.e., the ability to transfer energy to biological tissues in the form of oscillating electric fields, developed and patented by Telea Electronic Engineering and by Resono Ophthalmic for the specific applications in ophthalmology.

REXON-EYE therapy is totally non-invasive, does not cause any pain or excessive heating and thus does not require any analgesic product or external skin cooling systems. During treatment, the patient only experiences a slight heat sensation in the skin area underneath the mask electrode. Treatment duration typically ranges from 10 to 30 minutes per session, depending on the physician-defined therapy parameters.

promotes cellular stimulation and tissue regeneration in a peculiar way, keeping the tissue temperature low and

avoiding therefore any risks and side effects that any excessive temperature rise may result.

REXON-EYE is applied for the treatment of ocular surface disorders, described as a series of pathological conditions - determined or worsened by a variety of events (e.g. traumas, inflammation, deficiency, infections, etc.) - that cause anomalies of the eyelid and ocular surface epithelia (corneal and conjunctival epithelia) and the composition of the tear film, with important visual impairment effects. REXON-EYE acts by stimulating the natural physiological cellular metabolism and promoting regenerative capacity of cells and tissues. In the specific case of Dysfunctional Tear Syndrome (DTS), the specific frequencies of QMR determine important clinical benefits, stimulating the lacrimal system by reactivating the activity of the glandular tissue and the physiological tear secretion.

In the specific case of Dysfunctional Tear Syndrome (DTS), it can be assumed that the high frequency of the electric field results in functional benefits to the ocular annexes, reactivating the tear system by stimulating the activity of the glandular tissue and the physiological lacrimal secretion.

REXON-EYE has a dual channel output for the mask electrode and an input for the neutral plate. Since the current transmitted by the device is monopolar, the neutral plate must always be in contact with the patient. The power is transmitted to the patient through the entire contact surface of the mask.

The mask electrode actually embeds two distinct electrodes, one for each eye and having an area suitable to cover the whole surface of the eyeball; each electrode is connected to the generator via its own electrical connection. The two distinct electrodes are separately activated, so that at any one time only electrode is active. The time interval for the switching between electrodes is one of the treatment parameters set by the physician.

The spectrum of the alternating current transmitted by the device consists of multiple frequencies, with a fundamental frequency of 4 MHz and its harmonic (multiple) frequencies up to 64MHz.

2.3. OPERATION DESCRIPTION

REXON-EYE can only be used in the presence of medical personnel specifically trained in the use of this device. The physician is the only person authorized to set the value of all treatment parameters.

Resono Ophthalmic offers the opportunity to take part in training courses to provide the user with the knowledge and skills necessary for the correct use of the device. The duration and frequency of these courses is tailored to the needs of the customer.

REXON-EYE has no trapping area according to the definition provided by EN 60601-1. During use, it is recommended to place the device in such a way that it is not burdensome and is placed steadily on a solid surface.

Treatment is performed with the patient sitting or lying down (for example on a chair or armchair) and with his/her eyes closed (lowered eyelids) throughout the treatment period while the mask electrode is activated. The neutral plate must be placed on the chair or armchair seat, under the patient thigh, so that to maximize the contact area with the patient's body. The operator must be in-between the patient and REXON-EYE, so as to always have visibility of the patient as well as of REXON-EYE display.

2.3.1. Operational environment

REXON-EYE can be used in any ophthalmology medical clinic fully compliant with the regulations regarding electrical wiring and with environmental conditions (temperature and humidity) as described in 5.1.

Do not use other electro-medical equipment on the patient at the same time as REXON-EYE, in order to avoid any interference between them.

Do not use REXON-EYE in a surgical environment or in the vicinity of critical care or life support devices.

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3. DEVICE DESCRIPTION



3.1. SYMBOLS

This paragraph explains the meaning of the symbols and labels used on the device, in accordance with the applicable international standards

	Type CF Applied part	紊	Keep away from sunlight
\wedge	Warning	\sim	Alternating current
F	HF isolated patient circuit (floating)	X	Refer to WEEE directive
CE	CE marking	REF	Catalogue number
\checkmark	Equipotential node	LOT	Lot code
Ĵ	Keep dry	SN	Serial number
	Expiration date	8	Do not re-use
(((•)))	Non-ionizing radiations	NON	Non-sterile
	Fuse	LANEX	Does not contain latex
	Manufacturer		Obligation to followuser's instructions
\bigcirc	Stop button		Neutral plate
	Manufacturing date	0051	Notified Body Code

3.2. LABEL AND SERIGRAPH DESCRIPTIONS

Images of nameplate and serigraphs on the device panels are shown below. In order to facilitate the identification of the position of various parts, please refer also to the pictures shown below.

3.2.1. Nameplate



3.2.2. Front side panel



- A. AMPHENOL 5pinconnector to connect the mask (active) electrode.
- B. Dial (knob equipped with a rotary encoder) for menu navigation and therapy parameters setting.
- C. ODU 2 pin connector to connect the neutral plate.

3.2.3. Rear sidepanel



- D. Equipotential node connector.
- E. Power switch.
- F. Power socket
- G. ODU connector (4-pole) for connecting the stop button

3.3. STANDARD EQUIPMENT OF THE DEVICE

REXON-EYE is equipped with the following standard accessory kit:

Code	Description	
-	Power cable L=2.5m with country specific plug type	1
2509170R	REXON-EYE English manual	1
4002028MR	REXON-EYE mask (active) electrode size M with cable	1
4002018R	Stop button	1
4002031R	Disposable cloth	100
2503019CR	QMR neutral plate with cable	1

3.4. OPTIONAL EQUIPMENT OF THE DEVICE

The following accessories are optional, supplied according to customer requirements:

Code	Description
4002028LR	REXON-EYE mask (active) electrode size L with cable
4002029R	Cable for REXON-EYE mask electrode, 5 pins, L=2 m

3.5. ACCESSORY DESCRIPTION

As mentioned, REXON-EYE acts by stimulating the physiological cellular metabolism and promoting the regenerative capabilities of cells and tissues. The stimulation energy is delivered in the form of an electrical current applied via an active electrode in contact with the surface of the patient body through a cloth. This current is then collected by the neutral plate, also in contact with the patient, which closes the electrical circuit.

3.5.1. REXON-EYE mask (active) electrode

The mask electrode is the way through which the electrical energy produced by REXON-EYE is transmitted to the biological tissue. The mask is available in two sizes: L and M, see figure below for actual dimensions.

The mask electrode actually contains two distinct electrodes, one for each eye and having an area suitable to cover the whole surface of the eyeball; each electrode is connected to the generator via its own electrical connection. The two electrodes are separately activated, so that at any one time only electrode is active.

The mask is a multi-use accessory; to avoid the risk of infection, a disposable cloth is applied over the mask at the internal side (towards the patient), so as to prevent direct contact with the skin of the patient.

Always check the integrity of the mask before each use, making sure that it does not show signs of deterioration and, if necessary, replace it with a new one.



It is recommended to keep the mask inside the supplied package after use; it must then be stored in a dry place in order to preserve its physical and electrical characteristics.

It is advisable not to disconnect the cable from the mask, in order to avoid damaging the contacts of the mask and of the cable itself.

Before each use we recommend to:

- check the integrity of the accessories and connect them to the equipment only when it is not turned on;
- do not use if breaks, cracks, or creases are visible on the mask.do not reuse the disposable cloth but discard it after use.

3.5.2. QMR neutral plate

The neutral plate is essential to close the electrical path and therefore allow the therapeutic energy to be delivered. It consists of a conductive metal plate covered by a specific insulating layer; the transfer of energy between plate and patient is due to the capacitive coupling between the plate and the body of the patient.



The neutral plate must be placed on the couch or armchair seat so as to maximize the contact surface with the patient. Particular attention should be paid to positioning elderly people or lean subjects.

There is no direct contact between the plate and the patient, since the latter is usually dressed and for hygiene purposes a paper sheet is nevertheless interposed. The plate can be easily cleaned by manual cleaning with a damp cloth without any cleaning solutions. Dry thoroughly before reuse.

The plate is already supplied with the appropriate cable and adapter. Do not attempt to separate them from the plate.

Before each use we recommend to:

- check the integrity of the accessories and connect them to the device only when it is off,
- do not use if breakages, cracks, or folds are visible on the plate, the blue connector, or the cable.

4. TECHNICAL CHARACTERISTICS

4.1. INPUT TECHNICAL DATA

Input voltage and frequency	100-230V~50/60Hz
Max absorbed power	300VA

4.1.1. Fuses

Fuses are internal and not directly accessible from outside. Technical data for fuse are: 10A 250Vand low breaking capacity.

4.2. OUTPUT TECHNICAL DATA

All specifications are nominal and subject to change without prior notice. Each specification must be considered with a tolerance of \pm 20% from the stated value, considering an ambient temperature of 25 °C and a nominal input voltage of the line equal to the value given on the label above the power outlet.

Output frequency	frequency spectrum between4MHz and 64MHz (patented spectrum)	
Max output power	40W/200 Ωdouble channel (mask electrode)	

4.2.1. Output current

The maximum output current during use, for each operating mode is as follows:



4.2.2. Output Values

The output values reported here correspond to the nominal current or power output values in case of nominal load and correspond to those listed on the label containing the nameplate data in the rear panel of the device.

Particular attention should be paid when measuring the high frequency current / power emitted by REXON-EYE. To reproduce the values reported here, it is necessary to set up a test environment as described in the regulations and to utilise the appropriate tools.

The first two diagrams in the next page report the values of the output current and power when considering a load variable in the $10 \Omega - 1000 \Omega$ range. The upper panel reports the plots for the output current (red line) and power (blues line) at maximum (Full setting) power setting. The lower panel reports the same plots for halved (Half setting) power setting.

The bottom panel shows the values of the output power at different settings of the dial, with the load set at the nominal value of 200 Ω .

These plots are only indicative; please refer to the test report for the quantitative plots for the specific device (see serial number).



Output curves with variable load (full setting)



Output curves with variable load (half setting)



Output power with variable setting and load fixed at nominal value (200 $\Omega).$

4.3. TECHNICAL CHARACTERISTICS

4.3.1. Dimensions and weigh

Width	40 cm
Height	18 cm
Depth	35 cm
Weigh	8 Kg 11 Kg (with standard packaging)

4.3.2. Classification

REXON-EYE is classified as:

- Class I portable equipment with type "CF" applied parts, according to EN 60601-1;
- device with enclosure, not protected against water penetration (IPX0);
- device not suitable for use in the presence of flammable anaesthetic mixtures (i.e., a flammable anaesthetic blend with air, oxygen or nitrous oxide);
- device not intended for use in an oxygen-rich environment;
- device for continuous operation; the maximum activation time is equal to 30 minutes.

4.3.3. Reference standard

REXON-EYE complies with applicable standards for basic safety and essential performance for electro-medical devices, such as EN 60601-1 and EN 60601-1-2.

REXON-EYE complies with the European Directive 93/42/EEC and its subsequent amendments and additions (2007/47/EC), therefore it has CE mark 0051. According to such directive, REXON-EYE is a Class Iia Medical Device.

4.4. REXON-EYE FEATURES

The main features of REXON-EYE are:

- Quantum Molecular Resonance device with patented technology
- Quartz-controlled frequency generation
- Self-Monitoring Technology (SMT): internal self-test at power-up and monitoring of the correct flowing from the device
- Button for immediate shutdown of the device
- High isolation floating patient circuit
- Acoustic and visual signal indicating power activation
- Double channel output
- Super Quiet Technology (SQT): high-frequency energy emission with low noise
- Cooling Boost Technology (CBT): increased cooling in case of high performance
- Simple and easy to use control panel
- Digital rotary encoder to select functions.

For a complete list of accessories, please refer to the updated catalogue. Each code corresponds to a different accessory; please refer to the article number on the package of the individual accessories.

WARNING. Given the peculiarity of the technology and the frequencies used, the materials used in the manufacturing of accessories play a decisive role in generating the Quantum Molecular Resonance phenomenon and in achieving the desired performance, even in terms of patient safety.

The mechanical fall tests prescribed by EN 60601-1 have been carried out at a height of 1.5 meters, worsening the normal use condition specified in the regulatory requirement.

WARNING. The maximum nominal voltage of all accessories is 250 V. It is recommended to use accessories with a setting that does not exceed 80% of the available maximum output power. The use of the maximum output power involves high-frequency output voltage higher than the maximum nominal voltage of the accessories, resulting in a possible damage.

CAUTION. Only the use of original accessories ensures the functional performance of quantum molecular resonance (QMR).

Resono Ophthalmic guarantees the performance of the device if and only if the original accessories, designed and manufactured for the exclusive use with REXON-EYE, are used.

4.6. EM COMPATIBILITY

Manufacturer's Guide and Declaration – Electromagnetic Emissions The REXON-EYE device is expected to work in the electromagnetic environment as specified below. The customer or user of the REXON-EYE device must ensure that it is used in such an environment. **Emission tests** Compliance Electromagnetic environment – Guide **RF** emissions Group This REXON-EYE, during stand-by mode, uses RF energy only for its internal function. Therefore, the RF emission is very low and not (CISPR 11) 1* likely to cause any interference in nearby electronic equipment. This REXON-EYE is suitable for use in all establishments, including **RF** emissions Class B domestic establishments and those directly connected to the (CISPR 11) public low-voltage power supply network that supplies buildings Harmonics emissions Class A used for domestic purposes. (IEC 61000-3-2) Voltage / flicker fluctuations Complies (IEC 61000-3-3)

* According to IEC 60601-1-2_2007 Annex D, high frequency surgical EM equipment, when active, should be classified as group 2 equipment, because they apply RF energy to the patient. In this case the REXON-EYE device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.

Phenomenon	Basic EMC standard or test method	Immunity test levels required for Professional healthcare facility environment	Compliance test levels
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF electromagnetic fields	IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See last table of this paragraph	See last table of this paragraph
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz

Manufacturer's declaration - Electromagnetic immunity - Enclosure port

Manufacturer's declaration – Electromagnetic immunity – Input a.c. power port

Phenomenon	Basic EMC standard or test method	Immunity test levels required for Professional healthcare facility environment	Compliance test levels
Electrical fast transients / bursts	IEC 61000-4-4	±2 kV 100 kHz repetition frequency	±2 kV 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV	± 0,5 kV, ± 1 kV
Surges Line to ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	±0,5 kV, ±1 kV, ±2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips	IEC 61000-4-11	0 % UT; 0,5 cycle	0 % UT; 0,5 cycle

		At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0 % UT; 250/300 cycle	0 % UT; 250/300 cycle

Manufacturer's declaration – Electromagnetic immunity – Patient coupling port

Phenomenon	Basic EMC standard or test method	Immunity test levels required for Professional healthcare facility environment	
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz

Test specifications for enclosure port immunity to RF wireless communications equipment

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	lmmunity Test level (V/m)
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0,3	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
810	800 – 960	GSM 800/900,	Pulso			
870		iDEN 820,	modulation	2	0,3	28
930		LTE Band 5	18 Hz			
1720		GSM 1800; CDMA 1900:				
1845	1700 – 1990	GSM 1900; DECT;	Pulse modulation	2	0,3	28
1970		LTE Band 1, 3, 4, 25; UMTS	217 Hz			
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
5240 5500 5785	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9

5. INSTALLATION, USE AND WARNINGS

5.1. CONDITIONS OF USE, TRANSPORT AND STORAGE

The conditions of use and storage of the accessories may vary from those shown below, which affect the device. Therefore, please refer to the instructions in the accessories package.

	Ambient temperature	Relative humidity	Atmospheric pressure
CONDITION OF USE	+10°C (50°F) ÷ +40°C (104°F)	30% ÷ 75% non-condensed	700hPa ÷ 1060hPa
TRANSPORT ANDSTORAGE	0°C (32°F) ÷ +50°C (122°F)	20% ÷ 80% non-condensed	500hPa ÷ 1060hPa

It is recommended to keep the accessories in the original package. Accessories must be stored in a sufficiently dry place to preserve their physical and electrical characteristics.

5.2. DEVICE INSTALLATION

Installing REXON-EYE is simple and straightforward and does not require any special attention. However, it is recommended that:

- 1. during installation, in order to avoid crushing or falling, the device must be placed on a solid surface, away from the patient and areas subject to accidental bumps;
- 2. for proper ventilation, the device must be far enough from walls that hinder air recirculation. It must be free from any objects or bullets placed at the bottom or laterally that may increase the heating of the internal circuitry. It is absolutely forbidden to cover the ventilation slots; such an action may not allow the device to work in safety conditions;
- **3.** place REXON-EYE so that it is easy to unplug the power cord from the network, in case of urgent need for isolation from the network.

Before connecting the power cord to the mains socket, check that REXON-EYE suffered no damage during transport and make sure that the characteristics of the power supply on the available outlet match the rating data on the main label of the device.

5.3. PREPARATION TO USE

5.3.1. Starting procedure

Switching on REXON-EYE is performed by connecting the power cord to the mains socket and turning the main switch to ON.

WARNING. To avoid the risk of electric shock, the device must only be connected to grounded power supply networks.

5.3.2. Indications on treatment parameters

In this paragraph, as a <u>reference</u>, we provide indications about the operating parameters to be used with the mask electrode placed on the eye area (placed over the eyelids with closed eyes), in which the treatment is performed.

Treatment is done with the patient sitting or lying down (e.g., on a reclining chair), free from bulky clothing (jackets, etc ...), in contact with the neutral plate positioned on the seat of the chair. Place the disposable cloth on the back of the mask to cover the electrodes, checking that it completely covers the contact surface between the mask and the patient (as in the picture), then apply the mask on the eye area by having the patient wearing it as a pair of goggles.



The nominal therapy protocol provides for a treatment session duration of 20 minutes, to be

repeated once a week for 4 weeks, and an initial power of 4 (arbitrary units). This power value must be increased or decreased, if necessary, according to the sensation of heat felt by the patient in the area of application of the mask.

As guiding principle in choosing values for the therapeutic parameters, the patient's sensation of heat must be taken into account. In particular, it is important in order to optimize the treatment that the patient declares to feel a moderate, pleasant and never unpleasant heat during the treatment.

The QMR treatment sends a signal to activate the therapeutic effect, i.e., the natural regeneration of cells. If the power is too high, it will only generate unpleasant or painful heat without providing any benefit. If it is too low, the electrical signal may not reach a level high enough to overcome the electrical resistance of the skin and stimulate natural cell regeneration.

It is also very important to keep in mind that the sensitivity to heat and / or pain can be very different from patient to patient. Therefore, with the same therapy parameters, several patients may report that they experience significantly different feelings among themselves.

The heat itself is not the therapeutic effect but is only used to assess whether the QMR current enters effectively in tissues with sufficient amplitude to activate tissue regeneration. Since it is not possible to directly measure this current inside the eye, the perceived heat is used as an indirect measure.

Based on the experience acquired in the use of the device, however, discretion is left to the physician, on a case by case basis, in choosing the most appropriate parameters to be adopted.

In order to ensure the correct delivery of the treatment to both eyes, the mask should be positioned symmetrically on patient's face (over the disposable cloth) and using the hook placed on the elastic band (see picture below) to support the connecting cable. This hook has been specifically designed to support the cable during treatment, preventing that its weight increases the pressure applied by the mask to one eye.

Adjust the elastic band according to the patient feeling. The mask must adhere to the eyelids without exerting an excessive, and therefore annoying, pressure and must be positioned so as to cover identical areas in the two eyes.

If the patient warns that she/he feels a heat sensation of different intensity in the two eyes, pause the treatment and carefully reposition the electrode, as described above. Only then resume therapy by pressing START.

It should be noted, however, that this perception may vary slightly between the two eyes also because of a different sensitivity to heat, and that this is to be considered normal. It is therefore possible to set different power values in each eye, to ensure a better uniformity in the delivery of therapy (e.g., right eye at power 4 and left eye at power 5). The different power settings on the two electrodes do not interfere with the effectiveness of the treatment. The possibility of separately choosing the power to be delivered to the two eyes has been adopted just to take into account the fact that the physiology and sensitivity of the patient may be slightly different in the two eyes.



5.3.3. Treatment setting

When powered on, the device displays the **self-test** screen for a few seconds.



Once the self-test phase has ended, the display automatically switches to the MAIN MENU screen. Turning the dial on the front panel moves the cursor and, by pressing it, the screen for the selected item opens.



Pressing the virtual **START** button by pressing the dial switches to the THERAPY SETUP screen, where you can set the therapy parameters. Turning the dial moves the highlighting cursor sequentially to the slots dedicated to set the duration and the delivered power, for the left and the right electrode (eye), whose values can be set separately. Once the cursor is positioned above the slot of the parameter you want to set, press the dial to select the item and then, by turning the dial, you can set the desired value. Finally, pressing the dial again confirms the value and deselects the slot.



After setting the duration and power parameters for both electrodes, selecting **START THERAPY** and pressing the dial starts the therapy (current emission); pressing the dial once again will stop the therapy.

Selecting **<BACK** and pressing the dial returns to the main screen.

Once the therapy is started, the device automatically shows the THERAPY EXECUTION screen, which displays the elapsed time inside the centre circle at the centre of the display and other information such as "SWAP TIME" (the remaining time to switch from right to the left or left to right eye) and the power output "POWER".



Selecting **<THERAPY SETUP** and pressing the dial interrupts the therapy and returns to the THERAPY SETUP screen while selecting **■STOP THERAPY** and pressing the dial immediately terminates the therapy.

CAUTION. Do not rotate the dial while holding it down. REXON-EYE correctly interprets the command only when the dial is released.

5.3.4. Acoustic signals

The device emits an acoustic signal (double beep) when the STOP button is pressed or when the therapy ends. The acoustic signal indicates the stop of the power output by the generator.

5.4. TURNING OFF PROCEDURE

Turning off the device is performed by turning the main switch to OFF.

If REXON-EYE is used for multiple consecutive therapies or short distances, it is recommended not to turn off the device. In fact, leaving the device in standby mode, the cooling fans remain in operation, ensuring faster cooling of the components electronic.

5.5. EMERGENCY AND PROTECTION MEASURES

At any time, the operator can intervene by switching to the ■STOP THERAPY command on the display, stopping the power output. Selecting later ►START THERAPY will resume exactly from the point where it was suspended.

The patient can also stop the current emission by using a special remote control (Stop Button), which has been previously delivered to him. This functionality has been designed to ensure both maximum patient safety and psychological support, enabling the patient to stop the treatment if deemed necessary.

"Stop Button"		Wire: L=2m
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If the patient suspended the current emission by pressing the Stop Button, the therapy can only be resumed by the operator by selecting the ►START THERAPY command on REXON-EYE display.

It should be emphasized that this therapy does not include the use of analgesic creams or external cooling media; the degree of patient sensitivity is not therefore altered in any way.

5.5.1. Device temperature control

The device adopts thermal probes for internal temperature control. Intensive use of the device could lead to a sizable increase in the internal temperature. The operation of the temperature control module disables the current emission and the display shows 'THERMAL FAULT' (see picture below).



It is necessary to wait for the device to cool down before using it again. It is also recommended to leave the device on to speed up the lowering of the internal temperature.

5.6. POSSIBLESIDE EFFECTS

The patient must always feel a moderate and never unpleasant heat. The patient must be duly informed of this before the therapy begins. If the heat is or becomes excessive and therefore annoying during the therapy, the patient must immediately inform the operator, who will immediately stop the emission of energy and then adjust the intensity to lower values.

At the end of therapy, the skin of the treated area may be slightly reddened. Redness usually disappears within 30 minutes without leaving any permanent effect.

CAUTION. In the case of subjects with dermatological problems, particular attention should be paid to the evaluation of the "redness" of the eyelids skin, which, if present, should be mild and transient. If this is not the case, the treatment must be immediately suspended.

CAUTION. The intended use, which is "treatment of ocular surface disorders", whether or not associated with qualitative and quantitative problems of the tear film, may be appropriately limited to situations where no irreversible alteration of the eye surface structures or infections are present.

At the end of the treatment, the patient may report a slightly blurred vision. This occurrence is transitory and resolves within a few minutes. It is not due to any electrical events, but simply to the mechanical pressure exerted by the mask on the eyeball, e.g., when the elastic band holding the mask in place is too tight. Therefore, be sure to place the mask in contact with the eye without exerting too much pressure.

6. CLEANING, DISINFECTION AND STERILIZATION

6.1. CLEANING OF THE DEVICE

Proper cleaning and maintenance, as well as compliance with the requirements outlined below, ensure REXON-EYE is working properly, as well as prolonging the good state of the device over time.

- Before cleaning, unplug the power cord from the power supply.
- Do not use flammable, explosive, plastic or abrasive solvents.
- You can clean with a damp cloth (e.g., benzalkonium chloride) and then with a dry cloth.
- Do not spray nor pour liquids directly on the device nor on the ventilation slots, do not put in autoclave or sterilize with gas.
- Do not immerse the device in water.
- After any external cleaning of the device, dry all parts thoroughly before putting the device back into operation.

Cleaning the device should be done with a soft cloth dampened with water. The use of neutral pH detergent solutions is permitted. Do not spraying substances against the casing. **During cleaning, do not use excessive amounts of liquid and absolutely avoid penetrating the device**.

Do not use diluents, detergents, acid solutions, aggressive solutions or flammable liquids for the external cleaning of the device and accessories. The use of such substances, together with improper use of the accessories, as well as damaging the device, will invalidate the warranty.

6.2. CLEANING OF THE ACCESSORIES

The above about the device also applies to cleaning the accessories. Check the integrity of the accessories before using them. It is recommended not to use damaged accessories and do not attempt to repair them.

6.2.1. Cleaning

We recommend cleaning the accessories that could be in contact with the patient, such as the stop button.

In addition to the mandatory disposable cloth usage, we strongly recommend for mask electrode headset to be properly sanitized between each patients' sessions, for increasing bacteria and virus protection. Please make sure to use sanitizing solutions / wipes not containing any oil, as oily substances can damage the headset itself and make it unsuitable and possibly unsafe for the QMR therapy with REXON-EYE.

For the same reason, the rubber inner surface of the mask should be only gently wiped with a soft cloth, avoiding pouring or even spraying the sanitizing liquid directly onto it.

The use of gauze soaked with alcohol-based (> 60%) disinfectant is recommended. It is recommended not to use any acid or corrosive substance and to check the device integrity before each use.

No sterilization and reconditioning operations are required for REXON-EYE accessories.

7. MAINTENANCE

REXON-EYE does not need any special maintenance and the common directions for electronic devices must be observed.

- Periodically inspect the device power cord, casing, and front panel functionality. Regularly inspect all accessories, such as mask electrode and connection cables. If they show signs of deterioration or wear they must be replaced.
- It is recommended not to disconnect the cable from the mask after having connected it the first, in order to avoid damaging the contacts of the mask and of the cable itself.
- It is recommended to periodically check the perfect state of the plate neutral plate and replace it if there is any wear, exposed metallic parts, or broken insulating layer. It is recommended to replace the neutral plate at least once a year.
- For no reason REXON-EYE must be opened, e.g., for cleaning or control purposes. There is no need to clean the device internally, and in any case this operation must be done exclusively by qualified technical personnel and authorized by the manufacturer Resono Ophthalmic.
- Have the device checked at least every two years. In particular, it is advisable to check the low-frequency dispersion currents and power curves. For optimal use of the device and to ensure its maximum performance, it is also recommended to perform maintenance properly in the recommended times and ways.
- The manufacturer Resono Ophthalmic provides authorized service centres with instructions for controlling, repairing, and calibrating the device as well as instructions and assistance when replacing any electronic component. It is specified that the lithium battery contained in the device is not replaceable by the user or unauthorized personnel.
- At the end of the useful life of the device, refer to the procedures for disposal of Electrical and Electronic Equipment (WEEE).
- It is recommended that you keep the original packaging for any shipments to the manufacturer or authorized service points. The liability for damage resulting from improper packaging is with the customer.

For all maintenance, calibration, and control operations refer to the service centres authorized by the manufacturer Resono Ophthalmic.

8. TROUBLESHOOTING

ANOMALY	POSSIBLE CAUSE	WHAT TO DO	
The device does not turn on.	The power cord is incorrectly plugged in or the mains voltage is missing.	Check that the power cord is correctly plugged in on both sides and verify the presence of th mains voltage.	
	Power button	Verify that the power button is in the ON position.	
After power-up and self-test, the FAULT LED lights up	Malfunctioning of control systems	Press the dial to resume the test. If the problem persists, switch off the instrument and turn it on again after at least 10 seconds. If the problem persists, contact the authorized service centres, the manufacturer Resono Ophthalmic.	

9. WARRANTY

The warranty is valid for 24 months from the date of sale of the device by Resono Ophthalmic and covers any defects in manufacture. However, the 2-year warranty does not include electrodes and accessories, as these components wear faster. Defective electrodes and accessories are covered by Resono Ophthalmic. However, this warranty does not extend to electrodes and accessories that may deteriorate or wear over time.

The warranty also does not cover:

- damages resulting from improper use or neglect and normal wear;
- faults due to natural disasters or fire;
- damages due to improper repairs or repairs unauthorized by Resono Ophthalmic.

The specified warranty terms may not be applied to products or parts repaired or modified by third parties outside the manufacturer's Resono Ophthalmic factory or to products subject to misuse, neglect or accident. The cost of transport for the repair of the device, electrodes and accessories is always borne by the Customer.

NOTICE. Resono Ophthalmic shall not be liable for any direct or indirect damage to persons or property resulting from improper use of the device or during the period of inefficiency of the device.

NOTICE. Resono Ophthalmic does not respond to any damage or malfunction of the device due to the use of nonoriginal accessories.

The manufacturer Resono Ophthalmic is responsible for the fundamental safety, reliability and performance of the device only if:

- REXON-EYE has not been modified, tampered with, nor without seal;
- the installation and preparation procedures described in this manual are observed;
- assembly, calibration, modification or repair operations are carried out by suitably trained personnel of Resono Ophthalmic or authorized by written mandate;
- the electrical installation of the premises complies with local regulations and regulatory requirements, and
- REXON-EYE is used in accordance with its intended use and in accordance with the operating instructions.

Please note that the breaking of the seal or the opening of the device by personnel NOT AUTHORIZED by Resono Ophthalmic involves the cancellation of the warranty rights and the responsibility for the CE certification by Resono Ophthalmic.

WARNING. It is recommended to use ORIGINAL electrodes and accessories, which have been specially designed for the required conductive and mechanical properties.

NOTICE. Due to possible frequent updates, Resono Ophthalmic reserves the right to make changes to what is described in this document without prior notice, considering as valid only the latest revision of the document.

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Waste Electrical and Electronic Equipment

Directives 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment and 2002/96/EC on waste electrical and electronic equipment are designed to tackle the fast-increasing waste stream of electrical and electronic equipment and complements European Union measures on landfill and incineration of waste. Increased recycling of electrical and electronic equipment will limit the total quantity of waste going to final disposal. Producers will be responsible for taking back and recycling electrical and electronic equipment. This will provide incentives to design electrical and electronic equipment in an environmentally more efficient way, which takes waste management aspects fully into account. Consumers will be able to return their equipment free of charge. In order to prevent the generation of hazardous waste, Directive 2002/95/EC requires the substitution of various heavy metals (lead, mercury, cadmium, and hexavalent chromium) and brominated flame retardants (polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE)) in new electrical and electronic equipment put on the market from 1 July 2006.

Italiano	
	Smaltimento dei rifiuti elettrici ed elettronici (applicabile nell'Unione Europea e negli altri paesi europei con servizio dl raccolta differenziata) II simbolo presente sul prodotto o sulla sua confezione indica che il prodotto non verrà trattato come rifiuto domestico. Sarà invece consegnato al centro di raccolta autorizzato per il riciclo dei rifiuti elettrici ed elettronici. Assicurandovi che il prodotto venga smaltito in modo adeguato, eviterete un potenziale impatto negativo sull'ambiente e la salute umana, che potrebbe essere causato da una gestione non conforme dello smaltimento del prodotto. Il riciclaggio dei materiali contribuirà alla conservazione delle risorse naturali. Per ricevere ulteriori informazioni più dettagliate Vi invitiamo a contattare l'ufficio preposto nella Vostra città, il servizio per lo smaltimento dei rifiuti domestici o il negozio in cui avete acquistato il prodotto.
English	
	Disposal of old Electrical &Electronic Equipment (Applicable throughout the European Union and other European countries with separate collection programs) This symbol, found on your product or on its packaging, indicates that this product should not be treated as household waste when you wish to dispose of it. Instead, it should be handed over to an applicable collection point for the recycling of electrical and electronic equipment. By ensuring this product is disposed of correctly, you will help prevent potential negative consequences to the environment and human health, which could otherwise be caused by inappropriate disposal of this product. The recycling of materials will help to conserve natural resources. For more detailed information about the recycling of this product, please contact your local city office, household waste disposal service or the retail store where you purchased this product.
Français	
	Disposition concernant les anciens équipements électriques et électroniques (applicable dans l'Union Européenne et dans d'autres pays européens avec des systèmes de collecte séparés) Ce symbole sur le produit ou sur son emballage indique que ce produit ne sera pas traité comme perte ménagère. Au lieu de cela il sera remis au point de collecte dédié pour le recyclage de l'équipement électrique et électronique. En s'assurant que ce produit est trié et jeté correctement, vous contribuerez à empêcher de potentielles conséquences négatives pour l'environnement et la santé humaine, qui pourraient autrement être provoquées par la manutention de rebut inadéquate de ce produit. La réutilisation des matériaux aidera à conserver les ressources naturelles. Pour des informations plus détaillées sur la réutilisation de ce produit, vous pouvez contacter votre mairie, la société de collecte et tri des rebuts ménagers ou le magasin où vous avez acheté le produit.
Deutsch	
	Entsorgung von alten Elektro- und Elektronikgeräten (gültig in der Europäischen Union und anderen europäischen Ländern mit separatem Sammelsystem) Dieses Symbol auf dem Produkt oder auf der Verpackung bedeutet, dass dieses Produkt nicht wie Hausmüll behandelt werden darf. Stattdessen soll dieses Produkt zu dem geeigneten Entsorgungspunkt zum Recyceln von Elektro- und Elektronikgeräten gebracht werden. Wird das Produkt korrekt entsorgt, helfen Sie mit, negativen Umwelteinflüssen und Gesundheitsschäden vorzubeugen, die durch unsachgemäße Entsorgung verursacht werden könnten. Das Recycling von Material wird unsere Naturressourcen erhalten. Für nähere Informationen über das Recyceln dieses Produktes kontaktieren Sie bitte Ihr lokales Bürgerbüro, Ihren Hausmüll Abholservice oder das Geschäft, in dem Sie dieses Produkt gekauft haben.
Espanol	
	Disposición sobre los equipos eléctricos y electrónicos antiguos (Aplicable en la Unión Europea y en otros países europeos con sistemas de recogida selectiva) Este símbolo, en un producto o en un paquete, indica que el producto no puede ser tratado como un residuo doméstico. Por el contrario, debe depositarse en un punto de recogida especializado en el reciclaje de equipos eléctricos y electrónicos. Al hacer esto, usted ayuda a prevenir las potenciales consecuencias negativas que pueda sufrir el entorno y la salud humana, que podrían producirse si este producto fuera desechado de forma incorrecta. El reciclaje de materiales ayuda a conservar los recursos naturales. Si desea más información acerca del reciclaje de este producto, contacte con la delegación de su ciudad, con el servicio de recogida de residuos o con la tienda en la que adquirió este producto.

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