001

CORNEAL ESTHESIOMETER BRILL

EN

INSTRUCTIONS FOR USE

Please read these instructions for use before using the product

MD

CE 0051

Brill engines

Corneal Esthesiometer Brill
001

Instructions for use v02

Made in Spain

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BRILL ENGINES products are designed and manufactured under quality processes certified by the UNE-ISO 13485 standard.

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1. WARNINGS AND PRECAUTIONS

Please read these instructions carefully before using the Corneal Esthesiometer Brill. They contain important information on its use and maintenance. Keep these instructions for future reference.

⚠ WARNINGS:

- The esthesiometer must only be used by qualified healthcare personnel and it will be used especially by the professional in the field of eye health.
- Use the esthesiometer only for assessing corneal sensitivity. Any other use is considered inappropriate and the manufacturer accepts no liability for any damage caused by inappropriate use or its consequences.
- The esthesiometer should be used in an upright position with the nozzle facing forward, never tilted upwards or downwards. Preferably, place it on the slit lamp. If you trigger the air pulse with the nozzle tilted upwards, you run the risk that the device will temporarily stop working, and an error message will appear on the display. In this case, technical service assistance will be required to unlock it.
- The esthesiometer must not come into contact with the patient's eyes.
- The esthesiometer must only be repaired by qualified technical service personnel. Do not attempt to repair this device or have it repaired without the authorization of the manufacturer. The device does not need calibration or any other kind of maintenance. If it malfunctions, please contact the qualified technical service or the distributor listed in these instructions.
- The esthesiometer does not need to be calibrated because the sensor that measures pressure levels is a pressure sensor that is digitally compensated and calibrated during production, and a final test ensures conformity with the latest revision of the manufacturer datasheet. The entire process is a highly automated procedure validated during internal audits according to ISO9001:2015 certification. Standard industrial practices apply regarding reference equipment and tolerances (including safety margins).
- The mechanical operating system of the equipment is a fixed system that cannot give rise to variations as it is designed. Therefore, there is no possibility that the equipment discharge air at a pressure different from any of the five established ranges in case of malfunction.
- The esthesiometer must be used according to these instructions. The safety of the operator and the performance of the device cannot be guaranteed if the equipment is used in a way not specified by the manufacturer.
- Modifications to this device are prohibited, including replacing, removing or altering any of its components. Any modification must be authorized by the manufacturer.
- This product must not be used if it is damaged, and before each use, it must be checked for possible signs of damage or deterioration.
- The esthesiometer does not come into contact with the patient at any time, and the pressure exerted on the eye by the released air is almost undetectable. Therefore, no warning about using the esthesiometer with the patient is necessary.
- It must not be used near inflammable substances.
- Keep it out of the sight and reach of children.

⚠ PRECAUTIONS:

- After opening the case, check for external damage or breakage, and that all components are present. If you suspect there may be a problem with the esthesiometer, please contact the qualified technical service or the distributor listed in these instructions.

- Do not immerse, spray or pour liquids onto the esthesiometer or its accessories. Dry any liquid on the surface of the esthesiometer immediately.
- Do not knock, shake, or drop the device, as this may damage the electronic components.
- Do not use solvents or strong cleaning solutions on any part of this device, as this could damage it. See the Maintenance section for detailed cleaning instructions.
- Do not use anesthesia on the eye, it is not necessary for the examination and can alter the results.
- Never use the esthesiometer if it is wet or if ambient humidity is over 90%.
- The esthesiometer meets the applicable electromagnetic compatibility requirements (IEC 60601-1-2); however, there may be interference if it is used close (<1 m) to a device generating high-intensity electromagnetic emissions (for example, a mobile phone).
- Avoid resting the instrument on the nozzle. The nozzle is made of an elastomer material and may be permanently deformed if subjected to external conditions it was not designed for.
- If you are not going to use the device for the next 15 days, switch it off and unplug the adaptor. Keep the esthesiometer in its case.

2. INTENDED USE. USAGE INDICATIONS. CONTRAINDICATIONS

Corneal esthesiometry is the scanning technique used in ophthalmology to measure the cornea's sensitivity. The instrument used in this technique is the esthesiometer.

Corneal Esthesiometer Brill is a non-invasive device designed to assess the corneal sensitivity of the human eye by healthcare professionals (ophthalmologists and eye health staff) for aid in diagnosis of impairment of corneal sensation.

Intended user

The *Corneal Esthesiometer Brill* is designed to assess the corneal sensitivity of the human eye. It will be mainly used by ophthalmologists and eye care staff (optometrists, nurses).

Physicians from other medical specialties may use the device at their discretion and under their responsibility.

Intended patient population

The pressures exerted on the eye by the *Corneal Esthesiometer Brill* are based on those exerted by the Cochet-Bonnet esthesiometer. The patient feels the slight jet of air injected into the eye and must communicate it to the ophthalmologists and/or to the eye care staff.

For that reason, the only restriction when using the *Corneal Esthesiometer Brill* is that the device must be used on patients who are able to communicate whether they feel the puff of air emitted by the esthesiometer or not.

The device is not contraindicated in other special populations such as pregnant or lactating women and the elderly.

Operator qualification

The *Corneal Esthesiometer Brill* does not require any special preparation. The Instructions for Use detail how to proceed with its use.

Contraindications

There are no contraindications related to the Brill Corneal Esthesiometer when used as intended by the manufacturer.

In post-surgery scenarios, the possible use of the device must be determined by the ophthalmologist criteria.

3. INTRODUCTION

The *Corneal Esthesiometer Brill* is designed to produce pulses of air at different intensities, suitable for assessing the tactile sensitivity of a patient's cornea. This patented design uses pulses of air in different ranges of pressure, directed at different areas of the surface of the patient's cornea. The patient's verbal responses indicate at what pressure range they feel the pulse of air.

The *Corneal Esthesiometer Brill* is indicated for detecting a deterioration in corneal sensitivity that can be triggered by multiple factors such as diabetes, ocular herpes, wearing of contact lenses, some types of dry eye and keratoconus or Keratopathy.

Loss of sensitivity in the cornea can lead to dysfunction of the blinking and tearing reflex and eventually damage to the corneal epithelium. For this reason, the assessment of corneal sensitivity has high diagnostic value when evaluating the health of a patient's ocular surface.

4. CONTENTS OF THE CASE

The case contains:

- Esthesiometer.
- Charging dock.
- Power adaptor.
- Instructions for use.
- External button with extra connector.

5. DESCRIPTION AND FEATURES

The *Corneal Esthesiometer Brill* is a device designed to evaluate corneal sensitivity non-invasively and comfortably and is quick and easy to use. The stimulus used is pulses of air emitted at a set pressure.

The device features are as follows:

- Five stimulation levels with a pressure range of approximately 1-2 mbar - 8-9 mbar. The device works with low pressure ranges which are safe for eyes. Each pressure range is defined as the average estimated pressure over a Ø 0.4 mm surface which is a 4 mm distance from the outlet nozzle.
- It can be used hand-held or placed on a slit lamp, according to the preference of the healthcare professional.
- Reproducibility of the air pulses.
- Includes battery and charging dock.
- Electronic positioning system comprising a camera and two IR LEDs.

The clinical benefit of the esthesiometer is the aid in the diagnosis of loss of corneal sensitivity. Therefore, it helps diagnose pathologies, mainly ocular, that occur with loss of corneal sensitivity.

6. PARTS OF THE ESTHESIOMETER

Front of the device (figure 1):

- Nozzle (1): made of an elastomer material (TPE) to avoid damaging the cornea if it should accidentally come into contact with the surface of the patient's eye.
- Electronic positioning system: comprising a camera (2) and two IR LED indicators (3). Indicates the correct distance between the output nozzle and the corneal surface.

Back of the device (figure 2):

- Shoot button with indicator light (1): to switch the device on/off and to deliver the air pulse during evaluation. When the indicator light on the shoot button lights up green, the equipment is ready to deliver a pulse of air within the established pressure range.
- Wheel (2): for selecting the pressure level (2).
- Screen (3).
- Pressure display (4): indicates the pressure of the output channel in millibars.
- Stimulus level display (5): indicates the selected pressure level.

Underside of the device (figure 3):

- Slit lamp adapter (1): enables the esthesiometer to be coupled to a slit lamp for ease of use.

See section 12, "PROCEDURE", which explains how to couple the esthesiometer to the slit lamp.

Figure 1. Front of the device
1: Nozzle. Made of elastomer material.
2: Camera lens.
3: Indicator LEDs.

Figure 2. Back of the device
1: Shoot button.
2: Level selector wheel.
3: Screen.
4: Pressure display.
5: Stimulus level display.

Figure 3. Slit lamps adapter
1: Integrated slit lamp adapter.

7. SWITCHING ON AND OFF

To start the esthesiometer, press the shoot button (see the section "Parts of the *Corneal Esthesiometer Brill*"). The screen will automatically switch on and show the Brill Engines logo, as shown in figure 4. Next, the camera will switch on and the infra-red positioning LEDs will appear.

To switch off the esthesiometer, again, press the shoot button for 3 seconds. When it is switched off, place the esthesiometer on the charging dock to protect the outlet from dust and other particles and to avoid possible falls.

The esthesiometer will switch off automatically when it has been idle for 5 minutes.

Figure 4. Switching on the esthesiometer

8. CHARGING

The esthesiometer comes with a charging dock. Connect the power adaptor included in the case to the charging dock and plug it in.

To charge the device, place it on the charging dock, as shown in figure 5. While charging, the indicator light on the charging dock will light up orange. When the esthesiometer is fully charged, the indicator light will change from orange to green.

If the equipment is not charging correctly, the indicator light on the charging dock will change to red. In this case, remove the esthesiometer and place it on the charging dock again.

Figure 5. Esthesiometer + charging dock

9. EXTERNAL BUTTON

The esthesiometer comes with an external button for delivering air pulses remotely (figure 6).

To connect the external button to the esthesiometer, plug the magnetic USB-C connector provided at the end of the wire, as shown in figure 7.

Open the silicone USB port cover protector from the base cover, and connect the external button, as shown in figure 8.

Press the external button to deliver an air pulse remotely.

Figure 6. External button

Figure 7. USB-C connector + wire

Figure 8. Connecting the external button

Figure 9. External button connected

10. PATIENT PREPARATION

Before using the *Corneal Esthesiometer Brill*, make sure the patient is in an optimal position for the test, preferably with their head upright.

If using the device coupled to a slit lamp, the patient must be positioned with their chin and forehead leaning on the support, in a relaxed position. Ask them to take off their glasses, if applicable, and to blink and breathe normally.

If the patient wears contact lenses, at least 24 hours must have passed since the last time they were wearing them for the results to be reliable.

To help calm the patient, you can show how the procedure works by applying an air pulse to the back of their hand.

Steps to take before performing the esthesiometry:

1. Ask the patient to blink to ensure the entire corneal surface is covered by the tear film.
2. During the esthesiometry, allow the patient to blink regularly to spread the tear film over the cornea, as eye dryness is a factor which alters sensitivity.

11. PROCEDURE

The esthesiometer can be used handheld or attached to a slit lamp, based on the preference of the healthcare professional.

To attach it to a slit lamp, follow these steps:

1. Turn the esthesiometer upside down. Unscrew the adaptor in opening 1 in the bottom of the esthesiometer (figure 10).
2. Screw the adaptor into opening 2 by its widest end.
3. Finally, slot the esthesiometer into the axle of the slit lamp (figure 11).

Figure 10. Underside of the esthesiometer

Figure 11. Placing the esthesiometer on a slit lamp

How to use the esthesiometer:

Hold the esthesiometer in one hand, leaving your thumb free to work the controls. This leaves the other hand free to open the patient's eyelids, if necessary. Remember to position the back of the device, with the screen, towards you, and the nozzle towards the patient.

The esthesiometer should be placed 5 mm away from the cornea (with a margin of ± 1 millimeters). The device must be held in a vertical position.

Once the patient is suitably positioned, as explained in Section 10, "PATIENT PREPARATION", proceed with the following steps:

1. Switch on the esthesiometer. As explained in Section 7, "SWITCHING ON AND OFF", when the esthesiometer is switched on, one of the stimulus levels (1-5) appears by default.
2. Next, turn the wheel to select the desired stimulus level. Level 1 is the minimum stimulus, and Level 5 is the maximum stimulus. The selected level will be shown on the display screen. For example, in image (1) of figure 12, Level 5 has been selected.
3. To ensure the evaluation takes place at the right distance (4 mm from the cornea, with a margin of ± 1 millimeters), the esthesiometer has an electronic positioning system. The image of the eye appears on the screen with two LEDs. Bring the device closer or further away until the two LEDs converge and form a single LED on the corneal surface, as shown in image (2) of figure 12.
4. Next, if the shoot button is green, press it. If it is red, wait for it to turn green before pressing. After pressing the button, the pressure display will light up indicating the millibars of pressure recorded from the air pulse, and and the shoot button will turn red, as shown in image (3) of figure 12.

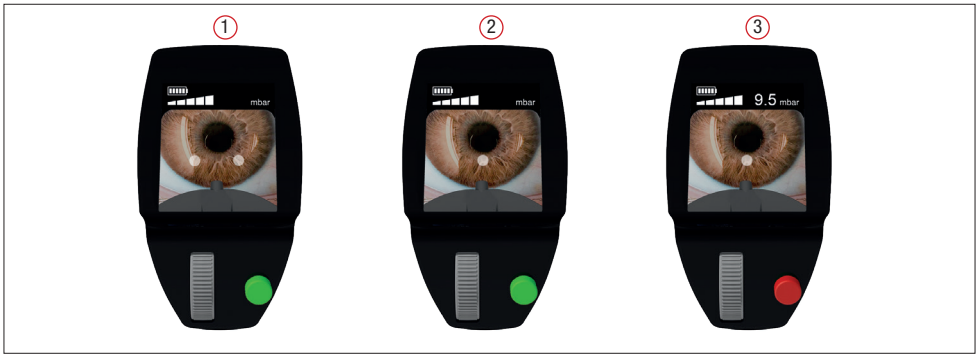

Figure 12. The esthesiometry procedure

After the first air pulse has been fired, the patient response will be evaluated - in other words, whether they have perceived the stimulus.

To fire the next air pulse, turn the wheel to select another stimulus level, and repeat the same operation.

We recommend beginning with the lowest stimulus and increasing the levels until the patient perceives the stimulus. Once this level has been determined, repeat the operation in the opposite direction, beginning with the highest stimulus level and reducing it until the patient no longer perceives the air pulse on their cornea.

12. INFORMATION AND ERROR MESSAGES

MESSAGE	DESCRIPTION	ACTIONS
When the esthesiometer is switched on and after an air pulse has been fired, the shoot button will show a steady red light.	This means the esthesiometer's mechanism is preparing to deliver an air pulse.	Wait for the light on the shoot button to turn green before pressing it.
Empty battery symbol.	The battery has run out of power.	Recharge the device on its charging dock.
After firing an air pulse, the button shows a flashing red light.	The internal pressure in the output circuit is not within the expected range for the stimulus range.	Repeat the esthesiometry procedure, and if it does not resolve the problem, contact the technical service.
When the equipment is switched on, the screen shows an incident or the image freezes.	Internal error found.	Restart the equipment.
When the esthesiometer is placed on its charging dock, the indicator light on the charging dock is orange.	The esthesiometer is recharging correctly.	Continue charging until the indicator light on the charging dock turns green.
When the esthesiometer is placed on its charging dock, the indicator light on the charging dock is green.	The esthesiometer battery is fully charged.	The esthesiometer is ready for use.
When the esthesiometer is placed on its charging dock, the indicator light on the charging dock is red.	Charging error. Most likely, the esthesiometer is not correctly positioned.	Remove it and place it back on the charging dock.

13. TECHNICAL INFORMATION

Model: 001.

Dimensions:
- Esthesiometer: 56 mm (W) * 203 mm (H) * 135 mm (L).
- Charging dock: 70 mm (W) * 114 mm (H) * 123 mm (L).

Weight:
- Esthesiometer: 600 g.
- Charging dock: 560 g.

Software: v25.

Battery: Fullwat model LIR18650-26I. 2 cells connected in series, each one 3.7 V.

Power adaptor: Unifive model UMVUE3012-050020SA (EU) / UMVUU3012-050020SA (USA).

Pressure range: 1-2 mbar - 8-9 mbar.

Display unit: millibars (mbar).

The serial number is on the underside of the device.

Operating conditions:
- Temperature: +10 ºC to +35 ºC.
- Relative humidity: 30% to 90%.

Atmospheric pressure: 800 hPa to 1060 hPa.

Storage and transport conditions:
- Temperature: -10 ºC to +55 ºC.
- Relative humidity: 10% to 95%.

Atmospheric pressure: 700 hPa to 1060 hPa.

Accessory software modules provided: the device consists of hardware (HW) and software (SW). SW is installed in a MCU STM32 family which is programmed using IAR. The available ports to modify or access that SW are the programming port and the CAN port. Using the programming port, the whole software can be changed. Using the CAN port, in specific conditions and messages, certain behavior is forced into the machine.

Operative platform: the device is programmed using IAR. No operating system is required to run this embedded system so it is a bare metal implementation.

Characteristics of the interface: the device has a common STM32 programming JTAG connector, and a USB type C routed as a CAN bus.

IT security measures, including protection against unauthorized access: There are no security measures inside the device because normal users do not know how to operate with CAN and the actions that can be performed using that bus have low impact in the device (e.g. the air pulse cannot be manipulated in any way).

Peculiarities of mobile computing platforms or other devices or equipment required to operate the software as intended: No special requirements are necessary to operate the *Corneal Esthesiometer Brill*.

14. PREVENTIVE MAINTENANCE

After using the *Corneal Esthesiometer Brill*, switch off the device and place it on the charging dock to protect the nozzle from dust and other particles, and to protect it from possible falls. If you are not going to use the esthesiometer in the next 15 days, disconnect it from the power adaptor and store it with the charging dock in the case.

This device does not require regular maintenance. If you have any questions about the appropriate functioning of the product, please contact the technical assistance service.

Battery: The esthesiometer contains a battery which needs replacing approximately every 2 years, depending on usage time.

The equipment lifespan is established as 10 years.

15. CLEANING AND DISINFECTION

The *Corneal Esthesiometer Brill* must only be cleaned by hand without immersion in liquid, as described below. Do not place the device in an autoclave or submerge it in cleaning liquids. Always disconnect from the power source before cleaning.

Gently wipe the exterior surface with a clean, lint-free cloth dampened with a suitable cleaning and disinfecting solution bearing the CE mark.

Make sure that excess solution does not enter the device. Be careful not to overload the cloth with solution.

Dry the surface with a clean, dry, lint-free cloth.

16. RETURNS OR REPAIRS

Contact the manufacturer's technical service or the distributor for shipping instructions. Unless the manufacturer or distributor indicates otherwise, the accessories do not have to be sent with the *Corneal Esthesiometer Brill*. Use a suitable box and packaging material to protect the device in transit. Return the equipment using a delivery method that includes confirmation of delivery.

Technical service contact information:
BRILL ENGINES SL
Carrer Munner, 8
Barcelona (Spain)
Tel. +34 93 417 09 11
info@brillengines.com

17. REGULAR SAFETY CHECKS

We recommend users carry out the following checks every 24 months:

- Check the equipment for mechanical and/or functional damage.

- Check that the safety labels are legible.

NOTE: this equipment does not require calibration or maintenance.

18. SYMBOLS

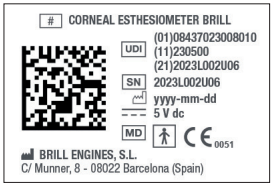

Figure 13. Esthesiometer label

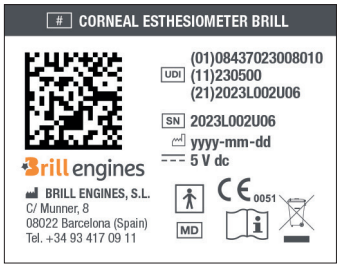

Figure 14. Charging dock label

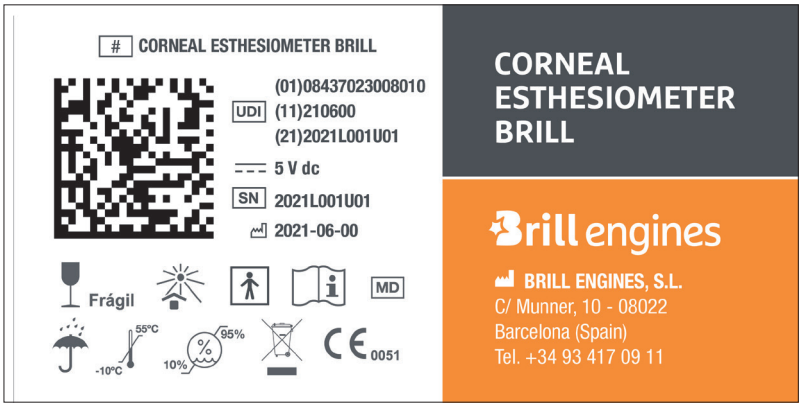

Figure 15. Outer packaging label

MD Medical Device	CE 0051
Warnings	Precautions
Manufacturer	Date of manufacture
REF Catalogue number	SN Serial number
Consult instructions for use	5 VDC direct current
An electrical safety classification Class II appliance	Electrical safety type BF
Keep dry	Fragile, handle with care
-10°C 55°C Temperature limits	10% 95% Humidity limits
Keep out of direct sunlight	Disposal of electronic waste. (Applicable in the European Union and other European countries with separate waste collection systems). To reduce the environmental impact of WEEE (waste electrical and electronic equipment) and minimize the volume of WEEE waste disposal, we recommend recycling and reusing this equipment at the end of its lifespan

19. MANUFACTURER'S INDICATIONS AND STATEMENT

The *Corneal Esthesiometer Brill* contains an internal power source (battery) and an external power source (charging dock). As such, it meets the requirements for Class II electrical medical equipment when connected to mains electricity and the requirements for internally powered electrical medical equipment when not connected.

This device meets standard UNE-EN 60601-1-2 on electromagnetic compatibility (EMC) and will not cause problems for other equipment or be affected by other devices. As a precaution, avoid using this device close to other high-intensity equipment.

MANUFACTURER'S GUIDE AND STATEMENT - ELECTROMAGNETIC EMISSIONS		
This equipment is designed for use in an electromagnetic environment specified below. The equipment user must ensure it is used in this environment.		
RF emissions CISPR 11	Group 1	The environment uses RF energy only for its internal function. Because of this, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The equipment is suitable for use in all establishments, including domestic (non-industrial) establishments and those connected directly to low voltage mains electricity supplying buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations / flickers IEC61000-3-3	Compliant	

MANUFACTURER'S GUIDE AND STATEMENT - ELECTROMAGNETIC IMMUNITY			
This equipment is designed for use in an electromagnetic environment specified below. The equipment user must ensure it is used in this environment.			
Electrostatic discharge (DES) IEC61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors must be conductive (wood, concrete, or ceramic tile). If floors are covered with synthetic material, the relative humidity must be over 30%.
Transient / fast bursts IEC 61000-4-4	±2kV network supply lines ±1KV input/output lines	±2kV network supply lines	The quality of the supply network must be that of a typical commercial setting or a hospital.
Network frequency magnetic field (50/60Hz) IEC 61000-4-8	3 A/m	3 A/m	Network frequency magnetic fields must be at the characteristic levels of a typical commercial setting or a hospital.

Compliant with:

UNE-EN ISO 15004-1	Ophthalmic instruments. Fundamental requirements and test methods. Part 1: General requirements applicable to all ophthalmic instruments.
UNE-EN 60601-1	Electrical medical equipment. Part 1: General requirements for basic safety and essential performance.
UNE-EN 60601-1-2	Electrical medical equipment. Part 1-2: General requirements for basic safety and essential performance. Collateral standard: Electromagnetic compatibility. Requirements and tests.
UNE-EN ISO 62366	Medical devices. Application of usability engineering to medical devices.
UNE-EN 62304	Medical device software. Software life-cycle processes.

20. REFERENCES

1. Benitez-delCastillo JM , et col. Decrease in tear secretion and corneal sensitivity after laser in situ keratomileusis. Cornea. 2001; 20(1:30-32).

2. Shoja MR; Besharati MR. Dry eye after Lasik for myopia: incidence and risk factors. European Journal of Ophthalmology. 2007; p. 17: 1-6.

3. Taehoon Oh et col. Changes in the tear film and ocular surface after cataract surgery. Japanese Journal of Ophthalmology. 2012; (56: 113-118).

21. GUARANTEE

This product is guaranteed by the manufacturer against all manufacturing defect or failure of materials, under appropriate usage conditions, for 2 years from the invoice date of the original purchaser. Under this guarantee, the sole obligation of the manufacturer is to repair or replace defective parts or products.

This guarantee applies to products that have not undergone manipulation or alteration of any kind, used according to their intended use, installed and operated according to the manufacturer's instructions, without having suffered any damage due to accident or negligence, and without the serial number having been erased or altered. This guarantee will not apply to products that have been sold, repaired, or installed beyond the control of the manufacturer, the technical service center, or the distributor authorized by the manufacturer.

All claims based on this guarantee must be made in writing and addressed to the manufacturer, the technical service center, or distributor authorized by the manufacturer who made the original sale, attaching a copy of the invoice.

NOTICE REGARDING SERIOUS INCIDENTS:

Any serious incident that has occurred in relation with the device must be reported to the manufacturer of the device and the competent authority in the member state in which the user and / or patient is established.

The contact information for the manufacturer of this device to report a serious incident is as follows: (info@brillengines.com)

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These instructions for use can also be found on the company's web address: www.brillengines.com

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brillengines.com