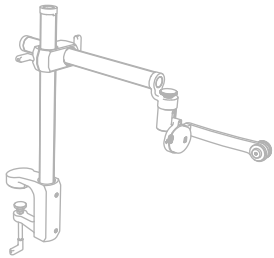
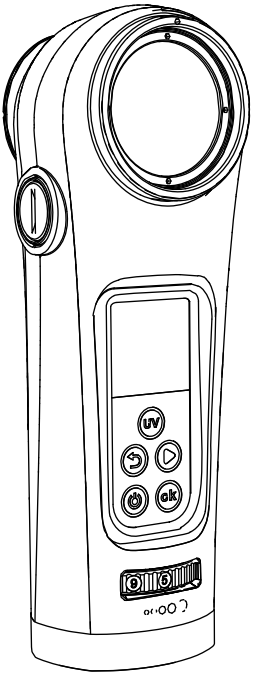
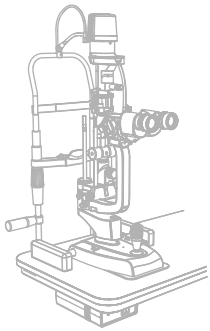
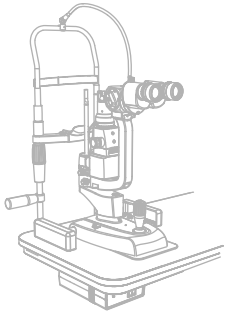
CSO® COSTRUZIONE STRUMENTI OFTALMICI









UV-A EMITTER FOR TREATING THE CORNEAL COLLAGEN CROSS-LINKING

INSTRUCTIONS FOR USE

C-eye

CSO®
COSTRUZIONE STRUMENTI OFTALMICI

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C-EYEIFUENGCSO0207012025

CE 0051

ENG

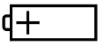
1 INTRODUCTION

The device is the result of extensive research, conducted with experts to ensure the product's technical innovation, quality and design.

1.1 SYMBOLS

The following symbols may be displayed in the instructions for use, on the package or on the device:

Symbol	Meaning
	Caution
	Danger of electric shock
	Read the instructions for use
	General obligation
	Instructions for use
	Note. Useful information for the user
	General prohibition sign
	Manufacturer
CE 0051	CE Marking (Directive 93/42/EEC) Identification number of the notified body (IMQ)

	Medical device
	Waste disposal in compliance with Directives 2012/19/EU (WEEE) and 2011/65/EU (RoHS II)
	Fragile, handle with care
	Keep dry
	Transport temperature limits: -40 °C and +70 °C
	Transport humidity limits: 10% and 95%
	Transport pressure limits: 500 hPa and 1060 hPa
	Internal rechargeable batteries
	Battery position

1.1.1 DEVICE SYMBOLS

Symbol	Meaning
	Type B applied part

1.2 GENERAL WARNINGS

These instructions for use refer to the C-eye device (hereinafter "device").

THE ORIGINAL TEXT IS IN ITALIAN.

Before using the device or after a long period of non-use, carefully read these instructions for use. Follow the directions provided in the instructions for use and on the device.

Always keep these instructions for use in an accessible and nearby place. If you decide to sell this device to a new user, remember to include these instructions for use, complete and readable.

Keep the original box and packaging, as the free-of-charge support service does not cover damage resulting from inadequate packaging of the device when sent back to an authorised Service Centre.

Before using the device, check that there is no sign of damage due to transport or incorrect storage, which could compromise the correct operation of the device.

It is forbidden to reproduce, in full or in part, texts or images contained in these instructions for use without the written authorization of the Manufacturer.

The Manufacturer reserves the right to modify the contents of the instructions for use without prior notice.

1.3 REFERENCE REGULATIONS

1.3.1 EU DIRECTIVES

- Directive 93/42/EEC and subsequent modifications and additions concerning medical devices
- Regulation (EU) 2017/745 of the European Parliament and Council of 5 April 2017 on medical devices (to the extent applicable)
- Directive 2012/19/EU on waste of electric and electronic equipment (WEEE)

1.3.2 TECHNICAL STANDARDS

- IEC 60601-1 - "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance"
- CEI IEC 60601-1-2 - "Medical Electrical Equipment – Collateral Standard: Electromagnetic Compatibility"
- IEC 62471 - Photobiological safety of lamps and lamp systems
- UNI CEI EN ISO 14971 - Medical devices. Application of risk management to medical devices
- Commission Regulation (EU) No. 207/2012 of 9 March 2012 on electronic instructions for the use of medical devices
- Directive 2014/53/EU RED on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC
- ETSI EN 301 489-3 - Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 40 GHz
- ETSI EN 300 330 - Short Range Devices (SRD); Radio equipment in the frequency range 3 kHz to 25 MHz; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU

1.3.3 QUALITY MANAGEMENT SYSTEM STANDARDS

- UNI CEI EN ISO 13485 - Medical devices. Quality management systems - Requirements for regulatory purposes

1.4 WARRANTY

The Manufacturer is responsible for the compliance of the device with EU Directive 93/42/EEC as amended by 2007/47/EC for:

- performance
- safety and reliability
- CE marking

The Manufacturer rejects all responsibility for:

- installation and start-up that is not carried out in compliance with the directions and precautions reported in the instructions for use
- use of the device that fails to comply with the instructions for use or precautions reported in the instructions for use
- use of non-original accessories or spare parts
- repairs and safety checks not carried out by expert, qualified and trained personnel authorised by the Manufacturer
- failure of the electrical system of the premises where the device is installed to comply with the technical standards, laws and regulations in force in the country where the device is installed
- direct or indirect consequences or damage to objects or persons caused by the misuse of the device or erroneous clinical analysis obtained from its use

The Manufacturer guarantees the device for 24 months after the invoice date. The warranty covers the replacement by the Manufacturer or an authorised Service Centre of components and materials and the corresponding labour. Shipping and transport costs are to be paid by the customer.

The warranty does not cover:

- repairs of malfunctions caused by natural disasters, mechanical shocks (falls, collisions, etc.), electrical system defects, negligence, misuse, maintenance or repairs carried out with non-original materials
- any other misuse or use not intended by the Manufacturer
- damage caused by service failings or inefficiencies due to causes or circumstances out of the Manufacturer's control
- wear and/or deterioration of parts caused by normal use of the device and failures caused by misuse of the device or by maintenance carried out by personnel not authorized by the Manufacturer

To request maintenance interventions or obtain technical information about the device, contact an authorised Service Centre or the device Manufacturer directly.

The customer will not be refunded for damage caused by device downtime.

1.5 MANUFACTURER IDENTIFICATION

C.S.O. SRL
Costruzione Strumenti Oftalmici
Via degli Stagnacci, 12/E
50018 - Scandicci (FI) - ITALY
phone: +39-055-722191 - fax +39-055-721557
cso@csoitalia.it
www.csoitalia.it

2 SAFETY

2.1 SAFETY WARNINGS

DANGER
Danger of electric shock. Do not let water fall on the device. Do not immerse the device in water or other liquids.

DANGER
Danger of electric shock. If the power cables are damaged, request their substitution at an authorised Service Centre to prevent any risk.

DANGER
Danger of electric shock. Unplug the USB power supply cable and the mains power supply unit and always switch off the device before disinfecting or cleaning the device and before any maintenance operation.

DANGER
Danger of electric shock. Do not leave the USB power supply cable in contact with sharp edges or cutting parts. Always fix the power supply cables in place with ties.

CAUTION
Do not use the device if visibly damaged. Periodically inspect the device and connection cables to check for signs of damage.

CAUTION
Always keep the device out of the reach of children.

CAUTION
Danger of falling device. The device and accessories must be correctly positioned and locked into place.

CAUTION
Danger of tripping and falling. Do not leave loose cables, as they might be of obstacle or danger for the patient or operator.

CAUTION
Danger of falling device. Do not leave loose cables in places where people may walk.

CAUTION
If you notice a strange odour or smoke coming out of the device or if it becomes hot, turn it off immediately. Do not continue to use a damaged device or damaged component. Danger of injuries.

CAUTION
When the device is connected to the network adapter, ensure the power source is easily accessible.

CAUTION
Danger of falling device. The device and accessories must be correctly positioned and locked into place.
Pay attention during the device installation operations. In case of accidental fall of the device, carry out the CHECK-UV procedure and, if necessary, contact the Manufacturer.

CAUTION
Prior to any treatment, check that the device and lenses have not been damaged. In case of anomalies, contact the Manufacturer.

The device is to be used only for the purposes of the treatment prescribed for the patient.

It is forbidden to carry out any maintenance operation on the device not indicated in the instructions for use.

It is forbidden to place the device in humid, dusty places or environments subject to sudden variations in temperature and humidity.

It is forbidden to use any extension cables not authorised by the device Manufacturer.

2.2 DEVICE IDENTIFICATION

2.2.1 REGISTRATION DATA IN THE LIST OF MEDICAL DEVICES

The device registration data can be verified on this page of the website of the Ministry of Health:
[Ministero della Salute - Ricerca dispositivi]

2.2.2 DEVICE DATA PLATE

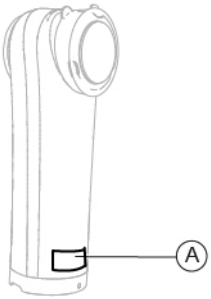


Fig. 1 - Data plate position

Fig. 2 - Device data plate

Pos	Description
A	Device data plate

2.2.3 C-BASE ACCESSORY DATA PLATE

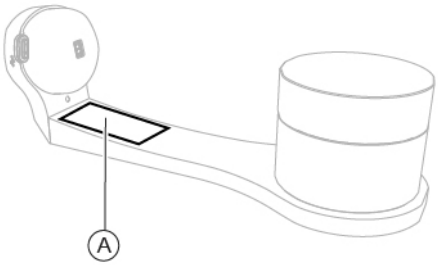


Fig. 3 - Data plate position

Fig. 4 - C-BASE accessory data plate

Pos	Description
A	Data plate

2.2.4 C-SL1 ACCESSORY DATA PLATE

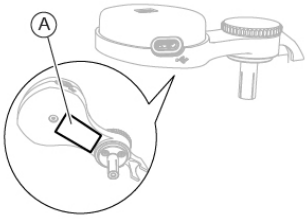


Fig. 5 - Data plate position

Fig. 6 - C-SL1 accessory data plate

Pos	Description
A	Data plate

2.2.5 C-SL2 ACCESSORY DATA PLATE

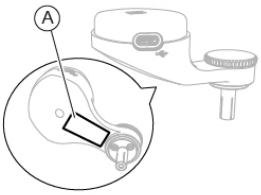


Fig. 7 - Data plate position

Fig. 8 - C-SL2 accessory data plate

Pos	Description
A	Data plate

2.2.6 C-ST ACCESSORY DATA PLATE

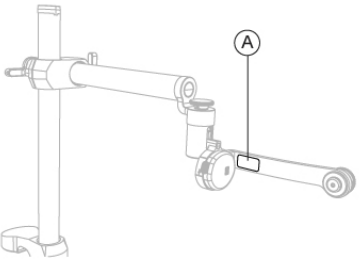


Fig. 9 - Data plate position

Fig. 10 - C-ST accessory data plate

Pos	Description
A	Data plate

2.2.7 C-VIEW ACCESSORY DATA PLATE

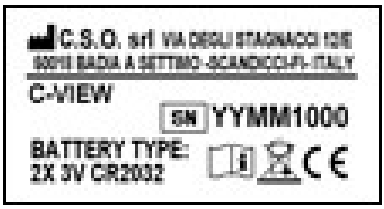


Fig. 11 - C-View accessory data plate

Pos	Description
A	Data plate

2.2.8 MAINS POWER SUPPLY DATA PLATE

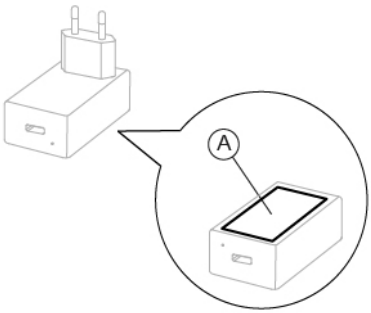


Fig. 12 - Data plate position

Fig. 13 - Mains power supply data plate

Pos	Description
A	Data plate

2.3 INTENDED USE

C-eye is a medical device used exclusively for the treatment of corneal pathologies in the context of the ophthalmological clinical activity.
The device has been designed to carry out treatment with the practice known as corneal cross-linking.
Specifically, it was designed to treat the following pathologies:

- Keratoconus
- Corneal ectasia (post refractive or iatrogenic surgery)
- PMD (Pellucid Marginal Degeneration)
- Infectious keratitis
- Sterile Corneal Welding
- Bullous keratopathy

The cross-linking technique consists in the photopolymerisation of the stromal fibres through the combined action of a photosensitising substance (Riboflavin – vitamin B2) and the UV radiation generated by the device.
The device has been designed to be placed:

- in a vertical position with the device installed on the slit lamp
- in a horizontal position with the device installed on the C-ST accessory.

The user interface consists of a membrane keypad with 5 keys and an OLED display. The set treatment details and the battery charge status are shown on the display.
The device is powered by rechargeable batteries inside the device.

The device can also be powered via the 5V mains power supply included in the supply. Alternatively, it is possible to use a mains power supply with equivalent technical characteristics that complies with the IEC 60601-1 standard and is identified as belonging to class II.

The device has no known contraindications.
The main features of the device are listed below.

Protocols

Through the interface, the device enables to carry out one of the following treatments:

- Keratoconus 1: 3 mW/cm^2 for 30 minutes with continuous light (fluency 5.4 J/cm^2)
- Keratoconus 2: 9 mW/cm^2 for 10 minutes with continuous light (fluency 5.4 J/cm^2)
- Keratoconus 3: 18 mW/cm^2 for 5 minutes with continuous light (fluency 5.4 J/cm^2)
- Keratoconus 4: 9 mW/cm^2 for 13 minutes and 12 seconds with continuous light (fluency 7.2 J/cm^2)
- Keratoconus 5: 15 mW/cm^2 for 12 minutes with pulsed light (1" ON, 1"OFF) (fluency 5.4 J/cm^2)
- Keratoconus 6: 18 mW/cm^2 for 12 minutes and 58 seconds with pulsed light (1" ON, 1"OFF) (fluency 7.0 J/cm^2)
- Keratoconus 7: 30 mW/cm^2 for 8 minutes with pulsed light (1" ON, 1"OFF) (fluency 7.2 J/cm^2)
- Keratoconus 8: SUB 400 Micron.
- Keratitis 1: 30 mW/cm^2 for 4 minutes with continuous light (fluency 7.2 J/cm^2)
- Keratitis 2: 30 mW/cm^2 for 5 minutes and 33 seconds with continuous light (fluency 10 J/cm^2)
- Refractive 1: 30 mW/cm^2 for 1 minute and 30 seconds with continuous light (fluency 2.7 J/cm^2)

The device must only be used by specialist practitioners within the limits of the law and the regulations for the exercise of the profession.

The device is classified in accordance with technical standard IEC 60601-1 as an electro-medical device, and is therefore suitable for installation in the patient area.

CAUTION

The C-BASE accessory for checking the UV source calibration and the recharging of the device battery must be placed outside the patient area.

Patient area: any volume in which a patient with applied parts may intentionally or unintentionally come into contact with other electromedical devices or electromedical systems, masses or foreign masses, or other people in contact with these elements.

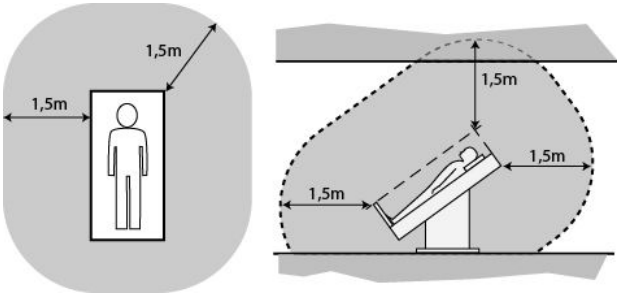


Fig. 14 - Patient area

2.4 MEDICAL DEVICE CLASSIFICATION

Technical data	Value
Classification based on annexe IX of Directive 93/42/EEC and subsequent modifications	Class IIb

2.5 ELECTROMEDICAL DEVICE CLASSIFICATION

Classification in compliance with technical specification IEC 60601-1

Technical data	Value
Type of protection against direct and indirect contacts	Class II
Applied parts	Type B
Protection degree against humidity	IPX0
Sterilisation or disinfection method	This device can be disinfected
Degree of protection in the presence of anaesthetics or flammable detergents	No protection
Degree of electrical connection between device and patient	Devices with part applied to the patient
Use conditions	Continuous operation

2.6 ENVIRONMENTAL CONDITIONS

Phase	Technical data	Min	Max
Transport	Temperature	-40°C	+70°C
	Atmospheric pressure	500 hPa	1060 hPa
	Relative humidity	10%	95%
Storage	Temperature	-10°C	+55°C
	Atmospheric pressure	700 hPa	1060 hPa
	Relative humidity	10%	95%
Use	Temperature	+10°C	+35°C
	Atmospheric pressure	800 hPa	1060 hPa
	Relative humidity	30%	90%

CAUTION
Danger of damage to the device. During transport and storage, the device may be exposed to the environmental conditions described, only if kept in the original package.

2.7 DISPOSAL AT THE END OF THE USEFUL LIFE

Instructions for the correct disposal of the device pursuant to European Directives 2012/19/EU and 2011/65/EU regarding the reduction of the use of dangerous substances in electrical and electronic equipment, as well as waste disposal.
At the end of its useful life, the device must not be disposed of with urban waste. The device may be delivered to designated separate collection centres set up by the municipal administration or to dealers that offer this service. Separately disposing of an electrical device prevents potential negative consequences for the environment and health caused by improper disposal and allows the materials it is made of to be recycled so as to attain significant savings in energy and resources. The data plate of the device displays the symbol of the crossed-out wheeled bin. The crossed-out wheeled bin symbol indicates the obligation to collect and dispose of electrical and electronic equipment separately at the end of their useful life.

The user must consider the potentially dangerous effects for the environment and human health arising from the improper disposal of the whole device or its parts.

Should the user wish to dispose of the device at the end of its useful life, the Manufacturer facilitates its potential reuse and recovery and the recycling of the materials contained therein. This prevents the release of hazardous substances into the environment and promotes the conservation of natural resources. Before disposing of the device, it is crucial to take into consideration European and national regulations, which prescribe the following:

- not to dispose of it as urban waste, but separate its parts, seeking advice from a firm specialised in the disposal of electrical/electronic equipment or the local administration in charge of waste collection
- in the event that a new device is purchased from the same Manufacturer to replace an old one placed on the market before 13 August 2005, equivalent and with the same functions as the new device, the Distributor or Manufacturer is legally required to collect the old device

- if the user decides to dispose of a used device placed on the market after 13 August 2005, the Distributor or Manufacturer is legally required to collect it
- the Manufacturer takes care, by joining the appropriate technological waste disposal consortium, of the treatment and recycling of the used device collected, bearing any costs.

The Manufacturer is available to provide the user with information regarding the dangerous substances contained in the device, the recycling of these substances and the potential reuse of the used device.
Strict administrative sanctions for those failing to comply are provided for by law.
For specific information about disposal in countries other than Italy, contact your local Dealer.

2.8 MANUFACTURER DECLARATIONS

2.8.1 ELECTROMAGNETIC COMPATIBILITY

The device is subject to specific requirements regarding electromagnetic compatibility (EMC). The following factors may cause electromagnetic interference:

- Portable and mobile radio frequency (RF) communication devices located in the vicinity of the device.
- Other products installed near or connected to the device.
- Accessories, cables and spare parts not specified in the instructions for use and not sold by CSO as spare parts.

When using the device, certain precautions must be taken to respect EMC, including:

- Observe the instructions for use.
- Follow the restrictions and instructions in this section.

Restrictions on essential performance

The device provides the following essential performance: UV emission accuracy. If the UV emission is damaged due to electromagnetic interference, the device will warn the user with a message.

Danger from electromagnetic radiation

CAUTION

Using the device in the vicinity of other devices or connected to other devices not described in the instructions for use (e.g. in combination with an ophthalmic table) may cause interference with the functioning of the device.

Should it be necessary to use the device with other devices not described in the instructions for use, all devices must be monitored to ensure correct functioning.

CAUTION

Do not use portable high-frequency (HF) communication equipment (such as antenna cable and external antennas) and do not place equipment cables within a 30 cm (12 inches) radius around the device. Otherwise, a deterioration in the performance of the device can be expected.

CAUTION

The use of accessories, transducers and cables other than those specified or supplied by the manufacturer of this equipment could lead to increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

CAUTION

Portable radio frequency (RF) communication equipment (including peripherals such as antenna cables and external antennas) must be used at a distance of no less than 30 cm (12 inches) from any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment may occur.

Environmental conditions for intended use

The device is intended for use in professional healthcare facilities as regards electromagnetic compatibility. These are in particular hospitals and doctors' surgeries, including those connected to the public electricity network (e.g. in residential areas), and opticians' and optometrists' premises.
The device is not intended for operation in the following environments:

- Home healthcare (e.g. residential accommodation, nursing homes)
- Outdoor environments
- In vehicles (for example, cars, trains, ships, planes)
- Other special environments (for example military facilities, heavy industry, medical treatment or diagnostic facilities with high-powered devices. These include in particular high-frequency surgical devices, short-wave therapy equipment and magnetic resonance devices)

The device is designed to be used in a room with the following electromagnetic characteristics:

Emission test	Compliance	Electromagnetic environment
Radio frequency emission. CISPR 11	Assembly 1	The device uses radio frequency energy only for its internal functioning. The device's electromagnetic emissions are very low and should not cause interference with nearby electronic devices.
Radio frequency emission. CISPR 11	Class B	The device may be used in all environments, including domestic ones. The device can be connected directly to a low-voltage electric network like that of residential buildings.

Emission test	Compliance	Electromagnetic environment
Harmonic emissions. IEC 61000-3-2	Class A	The device may be used in all environments, including domestic ones. The device can be connected directly to a low-voltage electric network like that of residential buildings.
Limitation of voltage changes, voltage fluctuations and flicker. IEC 61000-3-3	Compliant	The device may be used in all environments, including domestic ones. The device can be connected directly to a low-voltage electric network like that of residential buildings.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment
Electrostatic discharge. IEC 61000-4-2	±6 kV in contact. ±8 kV in air	±6 kV in contact. ±8 kV in air	The floors must be made of wood, concrete or ceramic tile. If the floors are covered with synthetic material, the relative humidity must be at least 30%.
Temporary/rapid sequences of electrical pulses. IEC 61000-4-4	±2 kV for power supply lines. ±1 kV for input/output lines	±2 kV for power supply lines. Not applicable	The mains power supply must be that of a typical commercial or hospital environment.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment
Impulse. IEC 61000-4-5	±1 kV differential mode. ±2 kV common mode	±1 kV differential mode. ±2 kV common mode	The mains power supply must be that of a typical commercial or hospital environment.
Voltage dips. Brief disruptions and variations in voltage on power supply input lines. IEC 61000-4-11	<5% Un for 0.5 cycles. 40% Un for 5 cycles. 70% Un for 25 cycles. <5% Un for 5 s	<5% Un for 0.5 cycles. 40% Un for 5 cycles. 70% Un for 25 cycles. <5% Un for 5 s	The mains power supply must be that of a typical commercial or hospital environment. If the device user requires continued operation during power outages and voltage dips, the device must be powered by an uninterrupted power supply or battery.
Magnetic field at mains frequency (50/60Hz). IEC 61000-4-8	3 A/m	3 A/m	The magnetic fields at mains frequency must have the same levels as a typical commercial or hospital environment.
RF conducted IEC 61000-4-6 RF radiated IEC 61000-4-3	3 Vrms from 150kHz to 80 MHz 3 V/m From 80 MHz to 2.5 GHz	3 Vrms 3 V/m	(1)

(1) Portable and mobile RF communication equipment must be used no closer to any part of the device, including cables, than the recommended separation distance (d) calculated from the equation applicable to the frequency of the transmitter.

d=1.167*sqrt (P)

d=1.167*sqrt (P) 80 MHz to 800 MHz

d=2.333*sqrt (P) 800 MHz to 2.5 GHz

P: maximum output power rating of the transmitter in watts (W), according to the transmitter Manufacturer.

d: recommended distance in metres (m) at which portable radio frequency (RF) devices can be used.

The field strength emitted by fixed RF transmitters, as determined by an electromagnetic site survey, must be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

(Un) is the AC mains voltage prior to application of the test level.

At 80 MHz and 800 MHz, the higher frequency range applies. The exposed electromagnetic environment may not apply in all situations.

Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

3 DESCRIPTION

3.1 SUPPLY DESCRIPTION

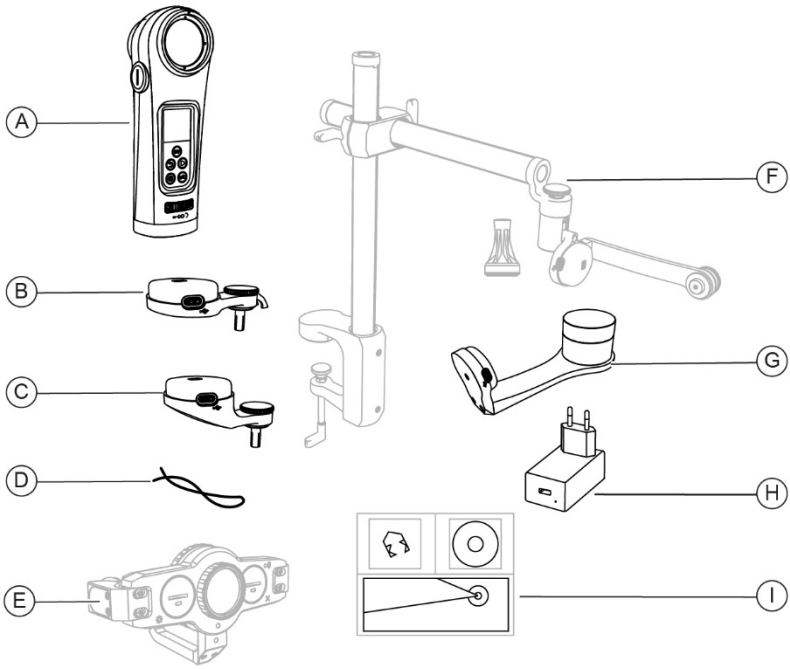


Fig. 15 - Supply composition

Optional: accessory not provided with the basic supply.

For the list of available accessories and models, contact the authorised Service Centre.

Pos	Name		Description
A	Device		UV emitter for corneal collagen cross-linking treatment. The device contains internal batteries.
B	C-SL1 accessory		The accessory allows the device placement on slit lamp models equipped with illumination from above. The accessory is equipped with a connector for the USB power supply cable.
C	C-SL2 accessory		The accessory allows the device placement on slit lamp models equipped with illumination from below. The accessory is equipped with a connector for the USB power supply cable.
D	USB power supply cable		The (5V) USB power supply cable enables connection between the accessories and a power source (USB port of the PC, external USB power supply, power bank).
E	C-View accessory	Optional	The accessory allows to verify the correct working distance between the device and the patient's eye by projecting light beams.
F	C-ST accessory	Optional	The accessory consists of a stand fitting with adapter and the C-FOCUS accessory. The stand fitting allows to position the device and treat the patient in a horizontal position. The C-FOCUS accessory (included with the C-ST accessory) allows to verify the correct working distance between the device and the patient's eye.
G	C-BASE accessory		The accessory allows the CHECK-UV procedure to be carried out and the device's internal batteries to be charged.
H	Mains power supply		The mains power supply allows connection between the device or one of the accessories and a power socket.
I	C-eye Procedure Kit	First supply only	**The C-eye Procedure Kit is not produced by C.S.O. SRL.**

3.1.1 DEVICE

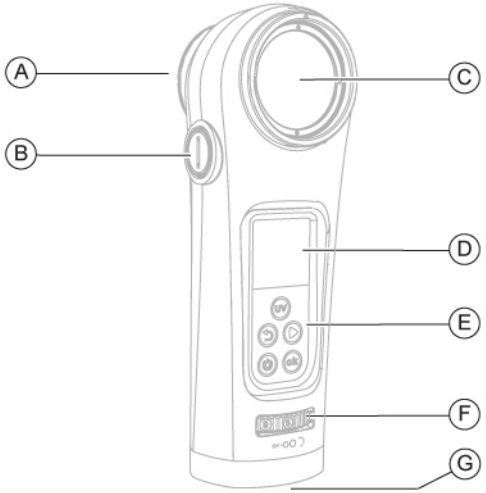


Fig. 16 - Device

Pos	Description
A	UV emitter
B	Connector for C-ST accessory
C	Observation lens
D	Display
E	Keypad
F	Dial for choosing the aperture of the diaphragm (from 5 to 12 mm)
G	Base

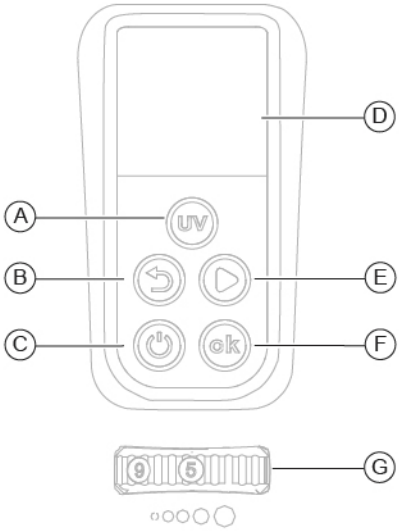


Fig. 17 - Keypad

Pos	Name
A	UV button (yellow - activation; green - ready for use)
B	Back button
C	ON/OFF button
D	Display
E	Next button
F	OK button
G	Dial for adjusting the aperture of the diaphragm (from 5 to 12 mm)

3.1.2 C-BASE ACCESSORY

The accessory allows the measurement of ultraviolet emissions (CHECK-UV) and the device's internal batteries to be charged. The CHECK-UV procedure validates the functioning of the device.

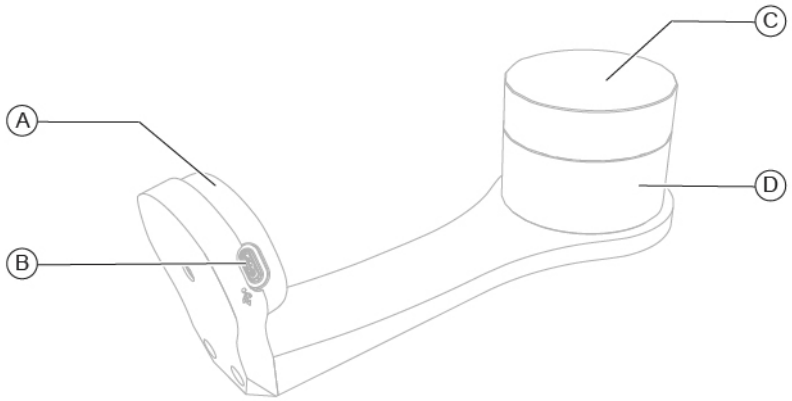


Fig. 18 - C-BASE

Pos	Description
A	Magnetic adapter and battery charger
B	USB power supply cable connector
C	Protective cap
D	Ultraviolet emission measuring head of the device

3.1.3 C-SL1 AND C-SL2 ACCESSORY

The accessory enables the device placement on the slit lamps.

Accessory	Slit lamp model
C-SL1	With illumination from above
C-SL2	With illumination from below

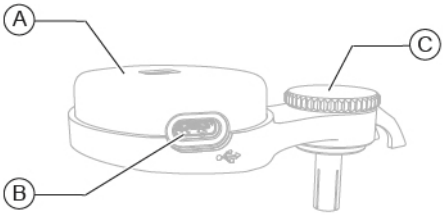


Fig. 19 - C-SL1 accessory

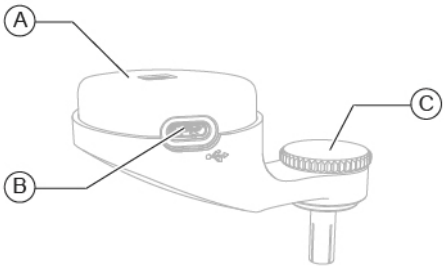


Fig. 20 - C-SL2 accessory

Pos	Description
A	Magnetic adapter
B	USB power supply cable connector
C	Locking dial

3.1.4 MAINS POWER SUPPLY

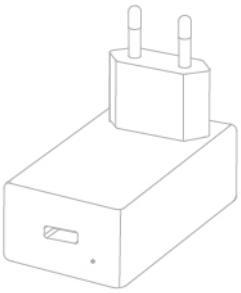


Fig. 21 - Mains power supply

If it is necessary to use a mains power supply unit other than the one supplied by the Manufacturer, ensure that the technical characteristics are equivalent, that it complies with the IEC 60601-1 standard and that is identified in class II.

Technical data	Value
Power input	100-240V - 50-60 Hz - 160-80 mA
Power output	Max 7 W
Rated output current	1.4 A
Rated output voltage	+5V
Connector	USB
Operating temperature range	0°C/+45°C
Humidity	≤90% without condensation

3.1.5 C-ST ACCESSORY

The accessory consists of a stand fitting with adapter and the C-FOCUS accessory.
The stand fitting allows to position the device and treat the patient in a horizontal position. The C-FOCUS accessory (included with the C-ST accessory) allows to verify the correct working distance between the device and the patient's eye.

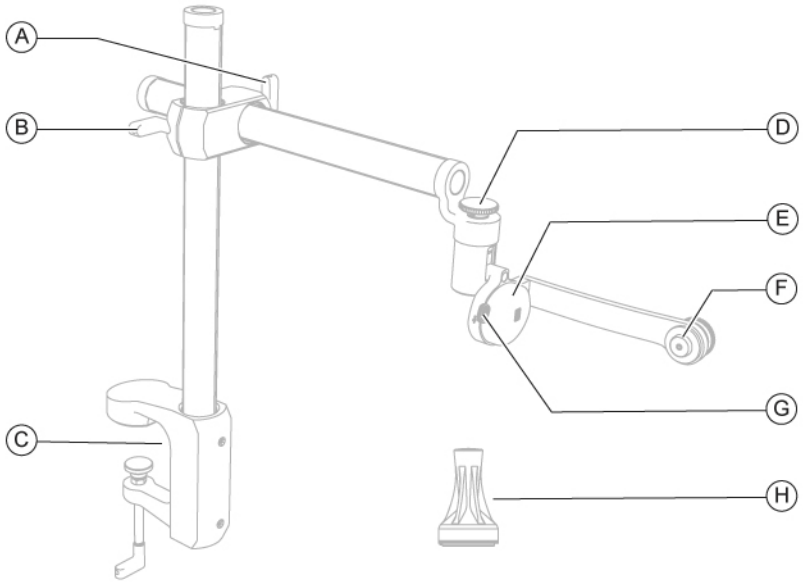


Fig. 22 - C-ST accessory

Pos	Description
A	Lever for adjusting the depth position
B	Lever for adjusting the height position
C	Locking vise
D	Adjustment knob
E	Magnetic adapter
F	Side locking dial
G	USB power supply cable connector
H	C-FOCUS accessory

3.1.6 C-VIEW ACCESSORY

The accessory allows to verify the correct working distance between the device and the patient's eye by projecting light beams.

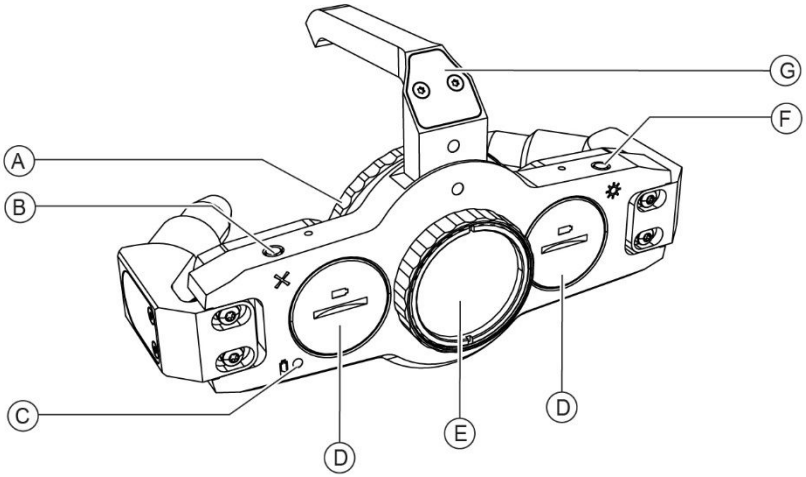


Fig. 23 - C-View accessory

Pos	Description
A	Locking dial
B	Projection button
C	Battery charge indicator
D	Battery compartment
E	Observation lens
F	Auxiliary lighting button
G	Auxiliary lighting accessory

3.1.7 C-EYE PROCEDURE KIT

The C-eye Procedure Kit is not produced by C.S.O. SRL.
The C-eye Procedure Kit is supplied with the device for the first delivery only.
The C-eye Procedure Kit can be ordered separately.

The C-eye Procedure Kit contains the following medical devices, to be used during the treatment:

- Riboflavin RIBO-KER.
- 1 Blepharostat.
- 1 C-eye CAP protection to be placed on the UV emitter. The CAP C-eye protection is disposable and is made from biocompatible material, in compliance with the ISO 10993 standard.

3.2 TECHNICAL DATA

Technical data	Value
Power supply	4 rechargeable BK8AAAB Nikel Metal Hydrade batteries. With power supply cable and 5V power supply unit only if the device is mounted on the accessories.
Diaphragm opening	From 5 to 12 mm
Light source	UV-A 365 nm
Dimensions (Height x Length x Depth)	182 x 55 x 62 mm
Device weight	450 g
Weight of the C-SL1 accessory (lamps with illumination from above)	110 g
Weight of the C-SL2 accessory (lamps with illumination from below)	170 g
Weight of the C-ST accessory, stand fitting (optional)	1900 g
Weight of the mains power supply	550 g
Weight of the USB power supply cable	140 g
Working distance between device and patient	36 mm ± 5 mm (*)

(*) The value indicated refers to the optimal distance between the device's UV emitter and the patient's eye (C-eye CAP excluded).

4 INSTALLATION

4.1 SAFETY WARNINGS

CAUTION
Danger of falling device. The device and accessories must be correctly positioned and locked into place.

4.2 HOW TO INSTALL THE DEVICE ON THE SLIT LAMP

CAUTION
Danger of falling device. The device must be correctly installed on the slit lamp.

The installation of the device on the slit lamp requires the use of the C-SL1 or C-SL2 accessory.
Choose the C-SL1 or C-SL2 accessory based on the lamp model selected. Use the C-SL1 accessory for slit lamps with illumination from above. Use the C-SL2 accessory for slit lamps with illumination from below.

In this section, the C-SL1 and C-SL2 accessories are referred to as "accessory". The installation procedure for the C-SL1 and C-SL2 accessories is identical.

1 Turn the slit lamp lighting assembly 90° to the left or right.
2 Remove the cap (A).

Fig. 24 - Turn the lighting assembly

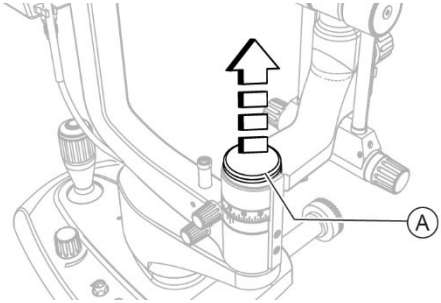


Fig. 25 - Remove the cap

3 Insert the accessory pin (B) in its position (C).
4 Turn the locking dial (D) to lock the accessory on the slit lamp.

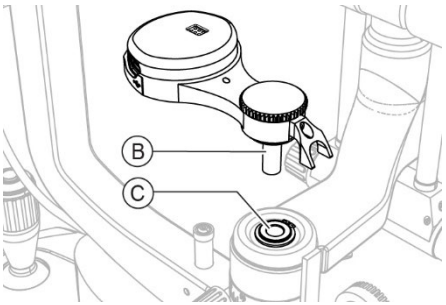


Fig. 26 – Placement of the accessory

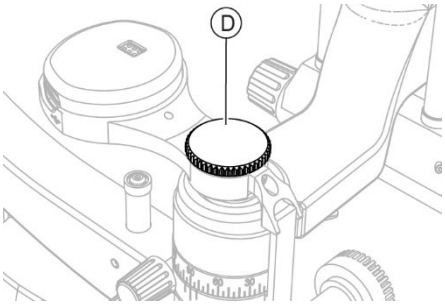


Fig. 27 - Turn the dial

5 Place the device base (E) on the magnetic adapter (F).

The UV emitter of the device must be turned facing the patient's eye. The observation lens of the device must be aligned with the shooting channel of the slit lamp microscope.

6 Unscrew and remove the protective cap (G) of the observation lens.

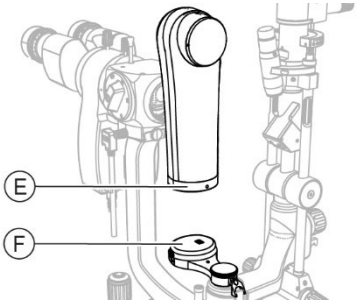


Fig. 28 - Device positioning

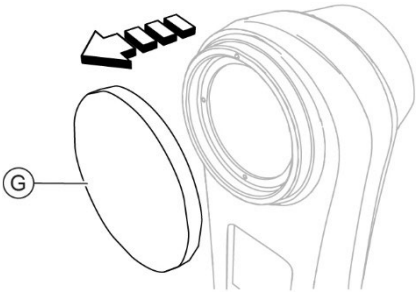


Fig. 29 - Remove the protective cap

7 Remove the protective cap (H) of the UV emitter.

8 Check that the device lenses are undamaged.

9 Install the C-eye CAP protection on the UV emitter.

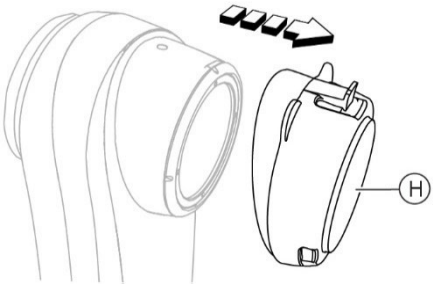


Fig. 30 - Remove the protective cap

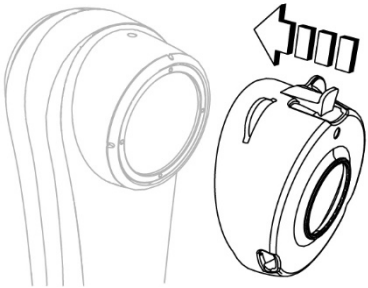


Fig. 31 - Position the C-eye CAP protection

The C-eye CAP protection is supplied with the C-eye Procedure Kit. The CAP C-eye protection is disposable and is made from biocompatible material, in compliance with the ISO 10993 standard.

4.3 HOW TO INSTALL THE DEVICE ON THE C-ST ACCESSORY

CAUTION

Danger of falling device. The C-ST accessory must be installed on a stable and horizontal surface. The device must be correctly installed on the C-ST accessory.

1 Place the locking vise (A) of the C-ST accessory on the edge of a table top.

2 Tighten the locking pin (B) to lock the C-ST accessory to the table top.

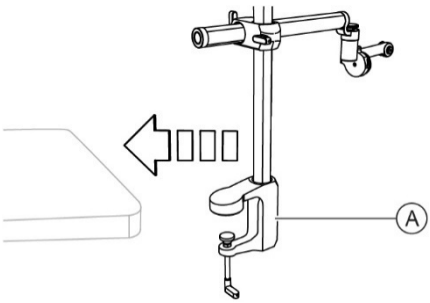


Fig. 32 - Position the locking vise

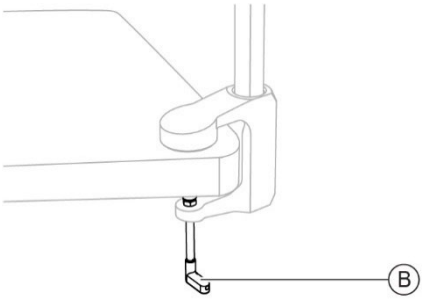


Fig. 33 - Tighten the locking pin

Adjust the depth of the C-ST accessory.

3 Operate the adjusting lever (C) until the desired position is reached.

Adjust the height of the C-ST accessory.

4 Operate the adjusting lever (D) until the desired position is reached.

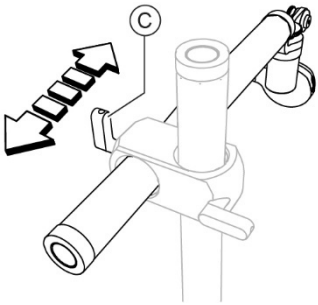


Fig. 34 - Adjust the depth

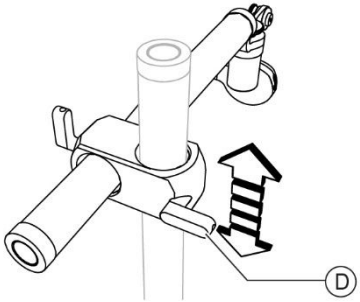


Fig. 35 - Adjust the height

5 Remove the side protection (E) on the device.

6 Place the device base (F) on the magnetic adapter (G). The keypad must face upwards.

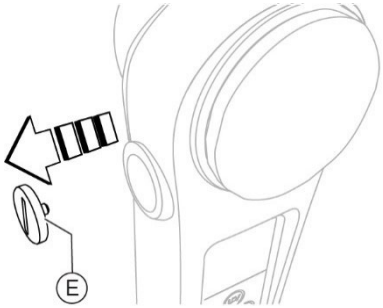


Fig. 36 - Remove the side protection

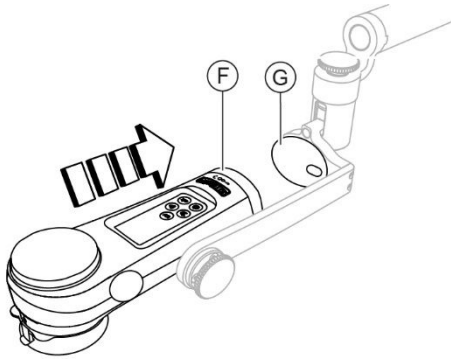


Fig. 37 - Device positioning

7 Use the side locking dial (H) to lock the device to the C-ST accessory.

8 Unscrew and remove the protective cap (I) of the observation lens.

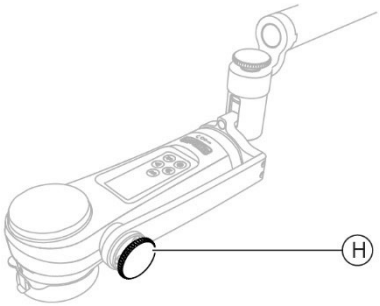


Fig. 38 - Operate the locking dial

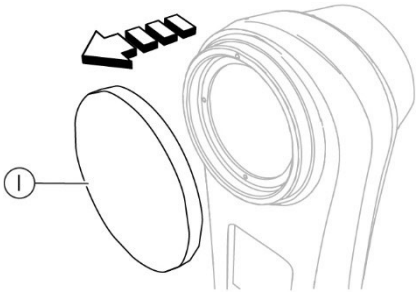


Fig. 39 - Remove the protective cap

9 Remove the protective cap (J) of the UV emitter.

10 Check that the device lenses are undamaged.

11 Install the C-eye CAP protection on the UV emitter.

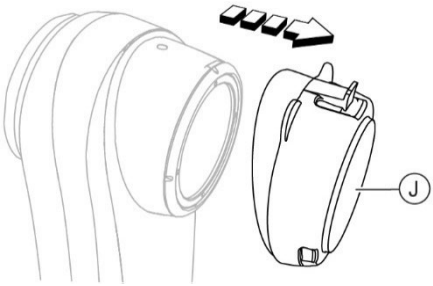


Fig. 40 - Remove the protective cap

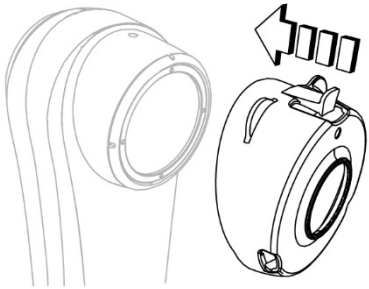


Fig. 41 - Position the C-eye CAP protection

The C-eye CAP protection is supplied with the C-eye Procedure Kit. The CAP C-eye protection is disposable and is made from biocompatible material, in compliance with the ISO 10993 standard.

5 USE

5.1 SAFETY WARNINGS

CAUTION
When the device is connected to the network adapter, ensure the power source is easily accessible.

When using the device away from power sources, always ensure that there is enough battery power to perform the scheduled treatments.

5.2 HOW TO CHARGE THE DEVICE BATTERIES

CAUTION
Do not leave the USB power supply cable in contact with sharp edges or cutting parts. Always fix the power supply cables in place with ties.

To charge the batteries, the device must be switched on. If the device is turned off, the batteries will not charge. Always ensure that the device is switched on when charging the batteries.

If it is necessary to use a mains power supply other than the one supplied by the Manufacturer, read paragraph **"Mains power supply" on page 34.**

It is forbidden to use cables or extension cables not authorised by the device Manufacturer.

1 Connect the USB power supply cable to the mains power supply provided.
2 Connect the USB power supply cable to the C-BASE accessory.

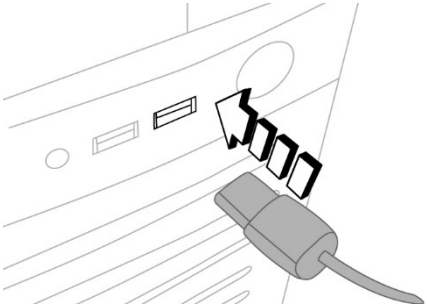


Fig. 42 - Connect the USB-A power supply cable

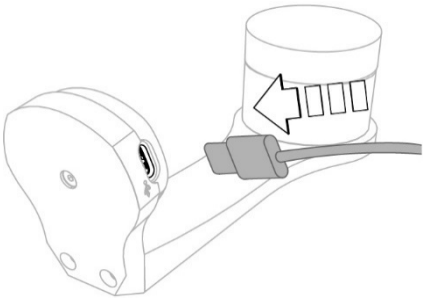


Fig. 43 - Connect the USB-C power supply cable

3 Remove the protective cap (A) of the measuring head of the C-BASE accessory.
4 Place the device base (B) on the magnetic adapter (C) of the C-BASE accessory.

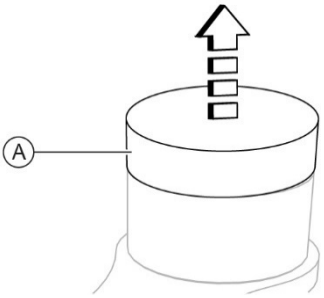


Fig. 44 - Remove the protective cap

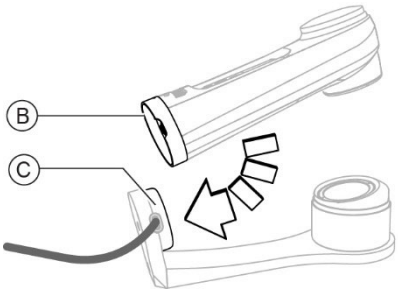


Fig. 45 - Device positioning

5 Gently place the UV emitter (D) on the measuring head (E) of the C-BASE accessory.
The device will start automatically.

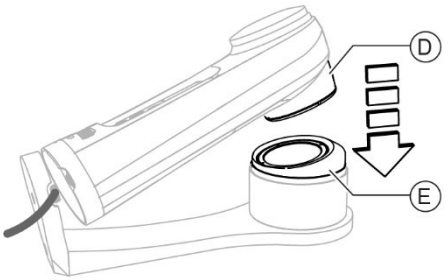


Fig. 46 - Place the UV emitter on the measuring head

6 Check the battery charge level.
The magnetic adapter of the C-BASE accessory automatically charges the device batteries.

- If necessary, leave the device on the C-BASE accessory and wait for charging to complete.

Check the battery charge indicator	Battery charge indicator	Description
On. Green colour.	100% autonomy.	Fully charged. The device can be used for ten treatments.
On. Yellow colour.	75% autonomy.	Partially charged. The device can be used for eight treatments at most.
On. Red colour.	25% autonomy.	Partially charged. The device cannot be used. Recharge the device batteries as soon as possible.
Off.	0% autonomy.	Batteries drained. The device does not start. Recharge the device batteries as soon as possible.

5.3 HOW TO SET TIME AND DATE

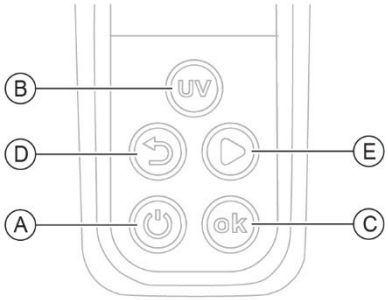


Fig. 47 - Keypad

1 Press the device ON/OFF button (A).
The device switches on.
2 Press and hold down the UV button (B) until a confirmation message appears on the display.
3 Press the OK button (C) to access the time and date editing screen.
4 Set time and date using the back (D) and forward (E) buttons.
5 Press the OK button (C) to confirm each new digit.

The date is displayed in the following format: *mm/dd/yyyy.*

5.4 HOW TO PERFORM THE CHECK-UV PROCEDURE

The measurement of ultraviolet emissions (CHECK-UV) is completed to make sure that the device is working correctly.

The CHECK-UV procedure must be carried out at the first start-up of the device or after the device has been left unused for a long period of time. During the CHECK-UV procedure, the batteries are recharged.

Check the device stability prior to starting the procedure.
The CHECK-UV procedure is essential in order to obtain precise measurements.

Ensure that the lenses of the device and C-BASE accessory are clean and undamaged. If necessary, clean the lenses using a soft cloth.

Do not use solvents or thinners to clean the lenses.

Do not turn off the device or remove it from the C-BASE accessory during the UV CHECK procedure. Otherwise, the UV CHECK procedure must be repeated.

Do not disconnect the USB power supply cable during the CHECK-UV phase. Otherwise, the UV CHECK procedure must be repeated.

1 Connect the USB power supply cable (A) to the C-BASE accessory.
2 Connect the USB power supply cable (B) to the mains power supply provided.

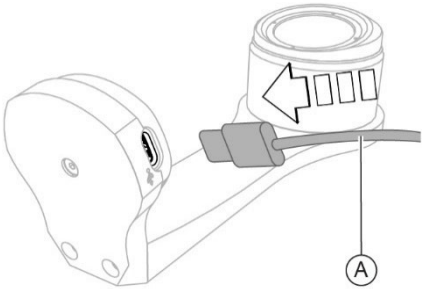


Fig. 48 - Connect the USB-C power supply cable

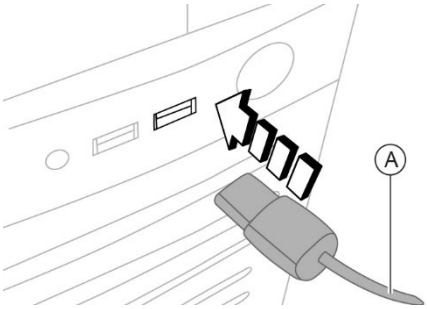


Fig. 49 - Connect the USB-A power supply cable

3 Remove the protective cap (B) of the measuring head from the C-BASE accessory.
4 Remove the protective cap (C) of the UV emitter.

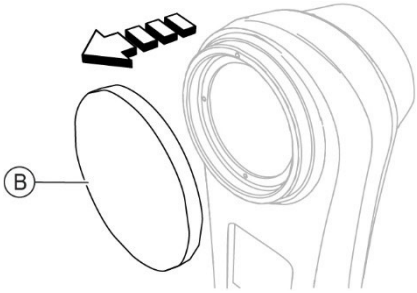


Fig. 50 - Remove the protective cap

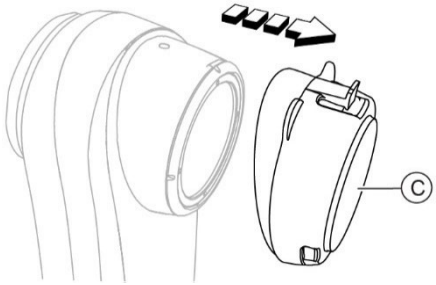


Fig. 51 - Remove the protective cap

5 Place the device base (D) on the magnetic adapter (E) of the C-BASE accessory.

6 Gently place the UV emitter (F) on the measuring head (G) of the C-BASE accessory.
The device will start automatically.

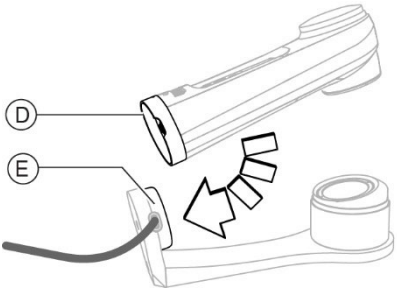


Fig. 52 - Device positioning

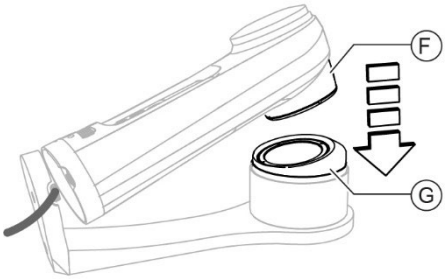


Fig. 53 - Place the UV emitter on the measuring head

7 Verify the correct start-up of the device and the CHECK-UV procedure on the display.
The UV-CHECK procedure will take a few minutes.
At the end of the CHECK-UV procedure, a confirmation message will appear on the display.
If not, repeat the procedure.
If the problem persists, contact an authorised Service Centre.

8 Remove the device from the C-BASE accessory.

9 Reposition the protective caps on the device and C-BASE accessory.

10 Disconnect the USB power supply cable from the C-BASE accessory.

5.5 HOW TO PREPARE THE PATIENT FOR THE TREATMENT

If the patient is wearing contact lenses, ensure they have been removed before applying Riboflavin.

For the correct application of Riboflavin, refer to the Riboflavin manufacturer instructions.

1 Ask the patient to sit down.
2 Follow the procedure in the clinical protocol of the treatment to be performed.

5.6 HOW TO POSITION THE PATIENT FOR THE SLIT LAMP TREATMENT

For information on how to position and adjust the slit lamp and chin rest, refer to the instructions for use of the slit lamp Manufacturer.

1 Ensure that the device is well aligned with the microscope.
2 Ask the patient to sit down.
3 Show the patient how to position their face against the chin cup and forehead rest.
4 Check that the eye is correctly positioned in relation to the shooting channel.
- If necessary, adjust the chin rest. Raise or lower the chin cup by rotating the knob.
5 Check that the eye to be treated is correctly positioned in relation to the UV emitter of the device.
Place the device at a working distance of 36 ± 5 mm.
6 Rotate the eyepieces to focus the image.
7 Move the slit lamp towards the patient's eye.
8 Focus on the corneal vertex.

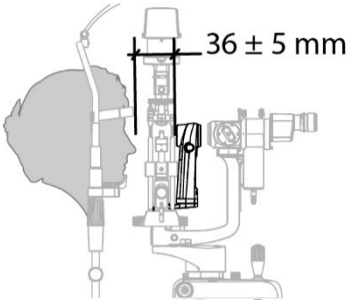


Fig. 54 - Working distance

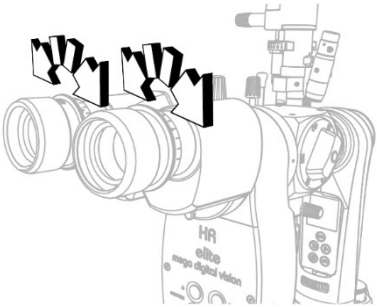


Fig. 55 - Turn the eyepieces

9 Ask the patient to look directly ahead and keep their eyes open during the treatment.

10 Use the buttons on the device to select the clinical protocol to be performed.
For further details about the procedure, read paragraph **"How to perform the treatment" on page 58.**
The time remaining until the end of the treatment appears on the display.

Throughout the treatment on the patient's eye, monitor the device to make sure that it is working correctly.

5.7 HOW TO POSITION THE PATIENT FOR TREATMENT WITH THE C-ST ACCESSORY

1 Seat the patient in a horizontal position.

2 Check that the eye to be treated is correctly positioned in relation to the UV emitter of the device.
Place the device at a working distance of 36 ± 5 mm.
To correct the working distance, use either the C-FOCUS accessory supplied with the C-ST accessory or the C-View accessory.

- To use the C-FOCUS accessory, follow the procedure described in paragraph **"How to use the C-FOCUS accessory" on page 54.**
- To use the C-View accessory, follow the procedure described in paragraph **"How to use the C-View accessory" on page 55.**

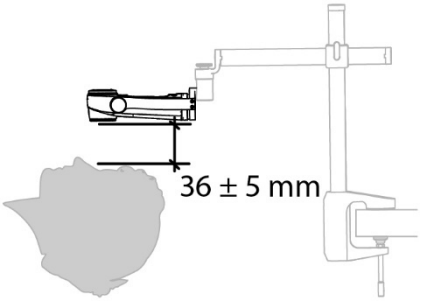


Fig. 56 - Working distance

3 Ask the patient to look directly ahead and keep their eyes open during the treatment.

4 Use the buttons on the device to select the clinical protocol to be performed.
For further details about the procedure, read paragraph **"How to perform the treatment" on page 58.**
The time remaining until the end of the treatment appears on the display.

Throughout the treatment on the patient's eye, monitor the device to make sure that it is working correctly.

5.7.1 HOW TO USE THE C-FOCUS ACCESSORY

Use the C-FOCUS accessory only when the device is installed and locked in place on the C-ST accessory.

1 Place the C-FOCUS accessory (A) on the observation lens (B) of the device.
2 Look through the C-FOCUS accessory and observe the corneal limbus: you will see two semicircles.
3 Turn the dial (C) on the C-ST accessory to adjust the height of the device.

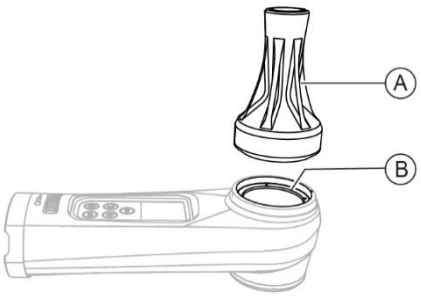


Fig. 57 - Position the C-FOCUS accessory

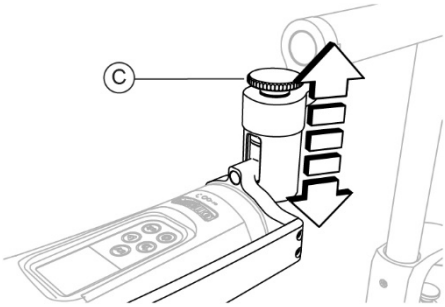


Fig. 58 - Adjust the height

The correct working distance is obtained when the corneal limbus appears sharp, forming a continuous circle.

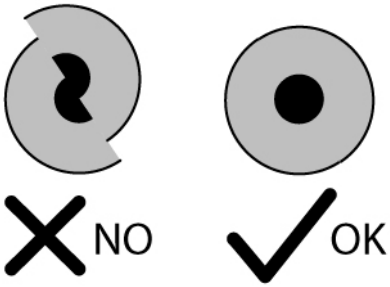


Fig. 59 - Corneal limbus: correct working distance

4 Remove the C-FOCUS accessory from the device.
5 Perform the treatment. Follow the procedure described in paragraph **"How to perform the treatment" on page 58.**

5.7.2 HOW TO USE THE C-VIEW ACCESSORY

Use the C-View accessory only when the device is installed and locked in place on the C-ST accessory.

1 Position the ring (A) on the back of the C-View accessory near the observation lens (B).
2 Turn the dial (C) clockwise to lock the C-View accessory to the device.

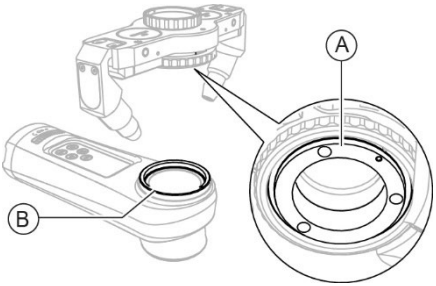


Fig. 60 - Position the ring

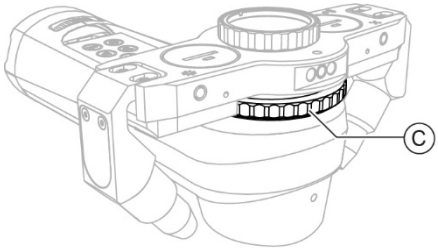


Fig. 61 - Turn the dial

3 Press the projection button (D) on the C-View accessory. The C-View accessory generates the projection of two light beams.

4 Turn the dial (E) on the C-ST accessory to adjust the height of the device.

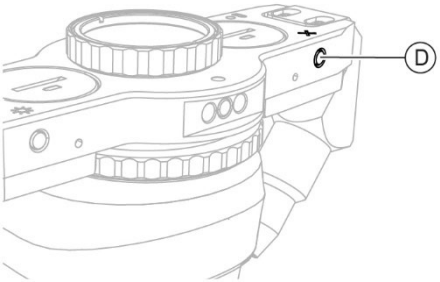


Fig. 62 - Press the projection button

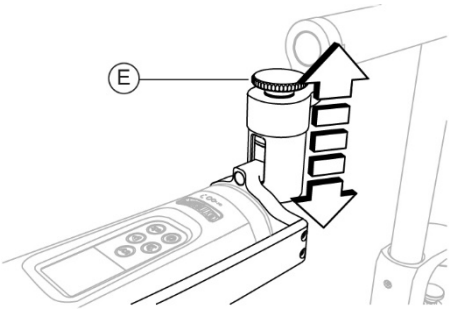


Fig. 63 - Adjust the height

The correct working distance is obtained when the two light beams intersect and form a cross.

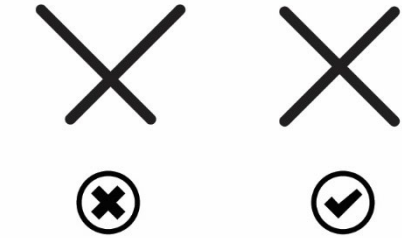


Fig. 64 - Light beams: correct working distance

The C-View accessory is also equipped with auxiliary lighting. If the working environment is too dark, switch on the auxiliary lighting.

- Insert the auxiliary lighting accessory (F) in position on the C-View accessory.
- Press the auxiliary lighting button (G) on the C-View accessory.

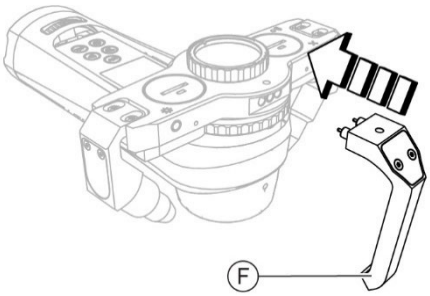


Fig. 65 - Insert the auxiliary lighting accessory

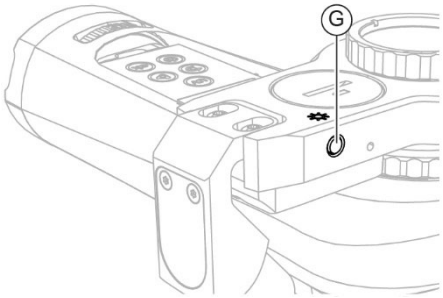


Fig. 66 - Press the auxiliary lighting button

The C-View accessory activates the auxiliary lighting.

5 Perform the treatment. Follow the procedure described in paragraph **"How to perform the treatment" on page 58.**

5.8 HOW TO PERFORM THE TREATMENT

Throughout the treatment on the patient's eye, monitor the device to make sure that it is working correctly.

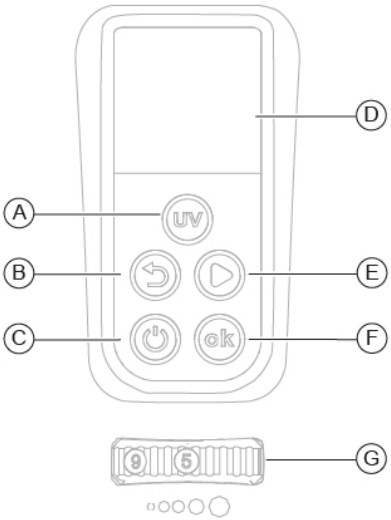


Fig. 67 - Keypad

1 Press the ON/OFF button (C) of the device.
The device switches on.
The background light of the buttons lights up white.
The logo appears on the display for a few seconds.
A screen requesting the scan of the Riboflavin solution package will appear.

2 Press the OK button (F) and bring the device closer to the package label.

The Riboflavin UDI code appears on the display.

3 Keep the package close to the device and press OK (F) to confirm.

If the UDI code is valid, the device will be enabled to carry out treatment.
Once scanned, the code on the Riboflavin solution package will be stored by the device and may be used even after it is turned off, the next time it is switched on.
In the event of an already used or invalid UDI code, the message "NFC Invalid tag" will appear.

- In this case, press OK (F) and scan a new package.
- To manually enter the UDI code, press the "back" button (B).
- Press OK (F) to confirm.
- Enter the code manually, pressing "next" (E) to increase the value.
- Then press OK (F) to confirm the value and move to the next one.
- If an error occurs while typing, press the "back" button (B) and modify the value by using the "next" button (E).
- Press OK (F) to confirm.

4 Press "next" (E) or "back" (B) to select the type of procedure to be carried out:
   - Keratoconus
   - Keratitis
   - Refractive.

5 Press OK (F) to confirm.
Choose the protocol for the treatment to be carried out.

6 Scroll the menu by pressing the forward (E) or back (B) buttons.

The available protocols are:
Keratoconus 1: 3 mW/cm^2 for 30 minutes with continuous light (fluency 5.4 J/cm^2)
Keratoconus 2: 9 mW/cm^2 for 10 minutes with continuous light (fluency 5.4 J/cm^2)
Keratoconus 3: 18 mW/cm^2 for 5 minutes with continuous light (fluency 5.4 J/cm^2)
Keratoconus 4: 9 mW/cm^2 for 13 minutes and 12 seconds with continuous light (fluency 7.2 J/cm^2)
Keratoconus 5: 15 mW/cm^2 for 12 minutes with pulsed light (1" ON, 1"OFF) (fluency 5.4 J/ cm^2)
Keratoconus 6: 18 mW/cm^2 for 12 minutes and 58 seconds with pulsed light (1" ON, 1"OFF) (fluency 7.0 J/cm^2)
Keratoconus 7: 30 mW/cm^2 for 8 minutes with pulsed light (1" ON, 1"OFF) (fluency 7.2 J/cm^2)
Keratoconus 8: SUB 400 Micron. Enter the corneal thickness value using the "next" (E) and "back" (B) buttons, then press OK (F) to confirm.
Keratitis 1: 30 mW/cm^2 for 4 minutes with continuous light (fluency 7.2 J/cm^2)
Keratitis 2: 30 mW/cm^2 for 5 minutes and 33 seconds with continuous light (fluency 10 J/cm^2)
Refractive 1: 30 mW/cm^2 for 1 minute and 30 seconds with continuous light (fluency 2.7 J/cm^2)

7 Check the data relating to the chosen treatment on the display (D). Press OK (F) to confirm.
The background light of the UV button (A) lights up green.
8 Use the dial (G) to adjust the aperture of the diaphragm.
9 Check that the eye to be treated is correctly positioned in relation to the UV emitter of the device.
10 Start the treatment by pressing the UV button (A).
The background light of the UV button (A) lights up yellow.
- If it becomes necessary to stop the treatment, press the UV button (A).
The device pauses the treatment.
It is now possible to choose whether to stop the treatment or continue.
- To restart the treatment, press the UV button (A).

The background light of the UV button (A) lights up green.

- To abort the treatment, press the back button (B), then press OK (F).

5.9 HOW TO TURN OFF THE DEVICE

1 Press and hold down the ON/OFF button (C) of the device for a few seconds.

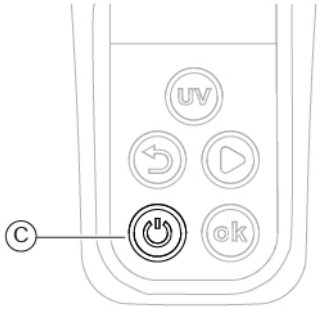


Fig. 68 - ON/OFF button

2 If connected, remove the USB power supply cable.
3 Clean the device with a soft and clean cloth.
4 Place the protective caps on the device.

6 ORDINARY MAINTENANCE

6.1 SAFETY WARNINGS

DANGER
Danger of electric shock. Unplug the USB power supply cable and the mains power supply unit and always switch off the device before disinfecting or cleaning the device and before any maintenance operation.

CAUTION
The device does not contain parts that requires the intervention of the user. Do not remove any parts of the device.

In case of operational faults or malfunctions or for every maintenance operation not mentioned in the instructions for use, speak to an authorised Service Centre or the device Manufacturer.

It is forbidden to carry out any maintenance operation on the device not indicated in the instructions for use.

6.2 ELECTRICAL SAFETY CHECK

DANGER
Electrical danger due to age and wear.
The electrical safety of the device may decrease with age and wear.
Follow and comply with the regulations in force in the country of use regarding electrical tests on devices.
Otherwise, have an electrical safety test performed at least once a year in accordance with IEC 62353 by the manufacturer or a qualified technician. Follow the procedure indicated in the technical manual issued by the manufacturer.
Record and keep evidence of the tests and measurements taken during tests.
The test ends with a device operation test. This operation must be performed by a person familiar with the device application.

6.3 CLEANING AND DISINFECTION

CAUTION
Carefully follow the instructions for cleaning and disinfection described in this manual, in order to avoid any damage to the device and accessories.

CAUTION
A correct cleaning and disinfection procedure, together with appropriate operating procedures, is essential to preventing the spread of infections or cross contamination.

CAUTION
Danger of material damage. Do not use spray products.
Do not use excessively wet cloths, as they may drip.
If needed, use a damp and well wrung out cloth.
Make sure no liquid penetrates into the device.

Cleaning and disinfection procedures must be carried out regularly.

Device parts that do not come into direct contact with the patient must be cleaned at least once a day.
Device parts that do come into direct contact with the patient must be thoroughly cleaned and disinfected after each use.

This section describes the procedures to be carried out during use and maintenance in order to ensure proper cleaning and disinfection of the device and its accessories.

6.3.1 RECOMMENDED PRODUCTS FOR CLEANING AND DISINFECTION

CAUTION

Danger of material damage. Do not use solvents, acidic or basic solutions (pH <4,5 or >8,0), abrasive or caustic substances, chlorine-based and chlorine-derived products.

The Manufacturer is not liable for any damage caused by using disinfectant products not indicated in this manual.

The choice of the most suitable product and procedures for the cleaning and disinfection of the device must take into account both the sensitivity of the device to specific substances and the effectiveness of the product.

For the cleaning and disinfection procedures, use products approved by the FDA or EC for medical devices or medical-surgical devices.

Use the products as listed below, divided by category:

Detergents	Use polyenzymatic solutions or neutral surfactant-based solutions.
Disinfectants and decontaminating products	Use products for disinfecting surfaces (containing or not containing aldehyde) or formaldehyde-free surface disinfectants (i.e. Kohrsolin FF). Alternatively, you may use ethyl alcohol, 70% v/v alcohol or isopropyl alcohol.

For information about the use of the chosen product, follow the instructions provided by the manufacturer.

6.3.2 CLASSIFICATION OF THE CRITICALITY OF THE DEVICE

CAUTION
The device supplied is not sterile and must not be sterilised prior to use.

This device is classified as "non-critical" since it is only used on intact skin and therefore has a low infectious risk**.**
For devices classified as non-critical, regular cleaning or low-level disinfection is sufficient.
However, when the patient's condition is transmissible by direct contact or in case of accidental exposure to body fluids, the device must be disinfected with a higher-level disinfectant after cleaning.

6.3.3 DEVICE CLEANING

CAUTION
Carefully follow the cleaning instructions described in this section in order to avoid damage to the device and its accessories.

CAUTION
Danger of material damage. Clean using a non-abrasive cloth to avoid damaging the surface.

The device must be regularly cleaned.

Clean the outer parts of the device using a damp, non-abrasive cloth and a rinse-free cleaning solution.

For more information about suitable cleaning products, read paragraph **"Recommended products for cleaning and disinfection" on page 64.**

6.3.4 CLEANING THE APPLIED PARTS

CAUTION
Danger of material damage. Only use detergent and disinfectant products specifically approved for medical devices or medical-surgical devices.

The applied parts that come into direct contact with the patient during the examination must be thoroughly cleaned after each use with a disinfectant approved for the purpose.

1 Turn off the device and unplug it from the power socket.
2 Clean the applied parts using products suitable for surface disinfection (they may contain aldehyde).
Alternatively, use a non-abrasive cloth soaked in a solution of water, ethyl alcohol (70% maximum) or isopropyl alcohol.

For more information about suitable cleaning products, read paragraph **"Recommended products for cleaning and disinfection" on page 64.**

6.3.5 CLEANING THE OPTICAL COMPONENTS

CAUTION
Danger of material damage. The device is equipped with optical components. The optical components of the device are precision and pressure-sensitive parts. Clean using a non-abrasive cloth to avoid damaging the surface.

Clean the optical components carefully using a dry, non-abrasive, lint-free cloth.

6.4 CHECK-UV

Perform the CHECK-UV procedure on the device regularly in order to ensure accurate measurements. Follow the procedure described in paragraph **"How to perform the CHECK-UV procedure" on page 48.**

6.5 RECHARGING THE BATTERIES

Recharge the batteries before each start-up or after a long period of non-use. Follow the procedure described in paragraph **"How to charge the device batteries" on page 44.**

6.6 ALARM RESOLUTION

Alarms are divided into two categories:

- Messages: you may continue to use the device when a message appears.
- Errors: the device stops when an error occurs.

6.6.1 MESSAGES

Device positioned on the C-BASE accessory.

Message	Cause	Solution
UV emission LOW	UV emission LOW.	Check that the lens of the UV emitter is clean. If the problem persists, contact an authorised Service Centre.
CHECK–UV not completed	The CHECK–UV procedure has not been completed.	Place the device on the C-BASE accessory and wait for the CHECK-UV procedure to complete.

When the device is turned on. Prior to starting the treatment.

Message	Cause	Solution
Battery too low	The battery charge level is too low.	Recharge the batteries. Follow the procedure described in paragraph **"How to charge the device batteries" on page 44.**
Factory Calibration Required	The device is outside the recommended calibration range.	Contact the authorised Service Centre.
UV check required	Perform the CHECK-UV procedure.	Place the device on the C-BASE accessory and wait for the CHECK-UV procedure to complete.
NFC Invalid tag	The NFC tag is invalid.	Use valid Riboflavin contained in the C-eye Procedure Kit.

For further details, contact the authorised Service Centre.

6.6.2 ERRORS

Device positioned on the C-BASE accessory.

Error	Cause	Solution
UV emissions out of range	UV emissions out of range.	Contact the authorised Service Centre.
C-BASE Hardware error	Hardware error in the C-BASE accessory.	Disconnect and reconnect the USB power supply cable. If the problem persists, contact an authorised Service Centre.

When the device is turned on. Prior to starting the treatment.

Error	Cause	Solution
NFC Error	Error.	Restart the device. If the problem persists, contact an authorised Service Centre.
Battery not Present	The device does not detect the presence of the batteries.	Contact the authorised Service Centre.
Battery life Expired	The batteries need to be replaced.	Contact the authorised Service Centre.

During the treatment.

Error	Cause	Solution
UV emissions out of range	The UV LED emission is too high or too low.	The treatment is interrupted. Contact the authorised Service Centre.
Hardware error	Internal hardware error.	The treatment is interrupted. Contact the authorised Service Centre.

6.7 LIST OF SPARE PARTS AND ACCESSORIES

Code	Description
105005A00	C-eye device
105005300	C-ST accessory
105005400	C-SL1 accessory (For slit lamp with illumination from above)
105005401	C-SL2 accessory (For slit lamp with illumination from above)
105005600	C-BASE accessory
3020500	Mains power supply
3020840	USB power supply cable
30110212010	Panasonic BK80AAAB batteries (4 pieces)
205005526_ASE	Disassembly accessory

For spare parts or accessories not included in the list, ask the authorised Service Centre.

6.8 TROUBLESHOOTING

Issue	Cause	Solution	Note
The device does not switch on.	The batteries are exhausted.	Recharge the batteries. Follow the procedure described in paragraph **"How to charge the device batteries" on page 44.**	If the problem persists, contact an authorised Service Centre.
	The batteries need to be replaced.	Contact the authorised Service Centre.	
The device does not generate any light.	The treatment was not started correctly.	Check that the button to start the treatment has been pressed correctly.	If the problem persists, contact an authorised Service Centre.
The measured power density is outside the specified limits.	The voltage of the power grid to which the device is connected is not correct.	Check the power grid voltage.	Correct values: 100-240V 50-60Hz
	The USB power supply cable is not connected properly.	Check that the USB power supply cable has been properly connected.	Check that the base of the device has been correctly positioned on the magnetic adapter of the C-BASE accessory.
	The UV emitter lens is dirty.	Clean the device with a soft and clean cloth.	

For further details, contact the authorised Service Centre.

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