



EYE
User manual

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Thank you for your trust.

The E-Eye is designed for simple, safe use. It provides reliable results for effective treatment.

Its innovative technology based on IRPL[®] (intense regulated pulsed light) is specially certified for the treatment of Meibomian gland dysfunction and evaporative dry eye. It contributes to improving your patients' visual comfort and quality of life.

For any questions, consult us on our website:

<https://esw-connectplus.com/#/contact>

Your opinion helps us to improve our products and services. Share your experience here: **<https://www.esw-vision.com>**

Your E-SWIN Customer Service

PACKAGE CONTENTS



E-EYE BASE AND ITS OPTICAL HEAD

The E-Eye is designed to emit IRPL® (intense regulated pulsed light) for therapeutic purposes to improve the symptoms of dry eye syndrome combined with tear film lipid layer deficiency.

The E-Eye is intended for eye care professionals such as ophthalmologists, optometrists, opticians and other professionals. It is only authorised for use in healthcare institutions, in accordance with local regulations.



MAINS POWER CORD

Your machine is delivered with a mains power cord adapted to the standard of your country. Take care not to bend it too sharply or trap it.



USER MANUAL

Please read all the information in this manual carefully.

As a healthcare professional, you must ensure that this treatment is only administered to people who satisfy the compatibility criteria.

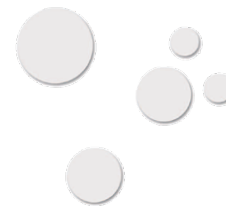
For any further information you may require, log into your user interface on esw-connectplus.com



SAFETY GLASSES

Safety glasses should be worn by anyone present when the treatment is administered to protect the eyes and ensure visual comfort. Clean them with the optic cleaning spray after each time they are used.

Any glasses which comply with EN166 with type 3 lenses (8 to 18% transmission) can be used.



SELF-ADHESIVE PATCHES

Self-adhesive patches are used to cover small areas which are not to be treated, such as moles. Apply them before applying the gel. Once in place, these areas can be treated without risk. Remove them at the end of the session.



PROTECTIVE EYE SHELLS

Protective eye shells must be worn by the person being treated and correctly adjusted to ensure optimum eye protection.



BARRIER PLATE

The barrier plate is made of material resistant to the flashes. It is used to cover any areas which you do not wish to expose to the treatment (e.g. tattoos). The glass tip of the applicator (optical guide) can be positioned overlapping the barrier plate and the skin.



OPTICAL HEAD EXTRACTION TOOL

The extraction tool is used to detach the optical head from the applicator to clean the optical parts or to change the optical cartridge.



OPTICAL CLEANING SPRAY

Optical cleaning spray is used to clean and maintain the optical components of the applicator and the touchscreen on the base.

Only use the cleaning spray when the machine is unplugged and the optical parts are cold.

After using the E-Eye, wait for the fan in the applicator to stop completely before unplugging the base. This ensures that the optical parts have completely cooled down.

Any optical cleaning product containing at least 95% isopropyl alcohol can be used.

CONSUMABLES

E-EYE OPTICAL CARTRIDGE PACK

The E-Eye Optical Cartridge Pack is a consumable which must be ordered separately from the machine. Its characteristics vary according to your mode of use. Contact your supplier to select the right reference.

The optical cartridge has a pre-programmed service life guaranteeing that the light emitted is of consistent quality from the first to the last flash. It is delivered with an activation card. These two components go together and must be replaced when the number of flashes available reaches zero.



E-EYE OPTICAL FILTER

The optical filter is essential to ensure the safety of the flashes emitted.

The filter (flat part made of red glass) must be intact with no cracks and perfectly smooth and flat.

It must be clean and dust-free.

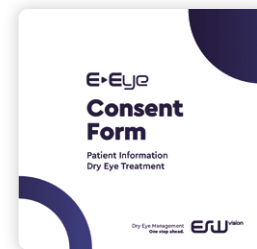
For optimum effectiveness, clean it prior to each use with the optical cleaning spray supplied in your pack.

A filter that is damaged due to insufficient maintenance is not covered by the warranty.



CONSENT FORM

This document can be given to the patient to inform them of the pathology, the treatment and the protocol.



OPTICAL GEL

The optical gel must be stored at room temperature.

Apply it in a very thick layer (1 cm thick).

Apply the gel progressively throughout the session to avoid it having dried out when the flash is applied.

The gel must not be reused on another area after it has been flashed. Once exposed to a flash, its optical characteristics are likely to have changed.

Ingredients (quantity % w/v): carbomer (0.5-2), Triethanolamine (0.5-2), Propylene glycol (0.5-2), dimethicone copolyol (0.1-1.0), isopropyl myristate (0.1-0.8), diazolidinyl urea (0.1-0.8), glycerol (1.0-5.0), aloe vera barbadensis (0.2-1.0), benzyl alcohol (and) methylchloroisothiazolinone (and) methylisothiazolinone (0.05 - 0.15), deionised water (qs 100). For external use only. Do not use on damaged, burnt or infected skin. Keep out of reach of children.



E-EYE OPTICAL HEAD

This component is the part of the E-Eye applied to the skin. Check its condition before each time it is used.

The glass tip must have no defects.

The coloured filter must be clean to guarantee maximum effectiveness.

Use the optical cleaning spray supplied with your E-Eye to maintain these components.

Change this assembly as soon as any mechanical defect appears or any damage is seen on the surface of the glass components.



The consumables are to be ordered in the form of a kit in your esw-connectplus.com space.

PRECAUTIONS FOR USE

FOR YOUR SAFETY

Before using your E-Eye, read the following information carefully:

- Working voltage: 100 - 240 V~.
- Rated frequency: 50-60 Hz.
- Maximum power consumption: 540 VA.
- Check that the working voltage of your machine is compatible with your electrical installation. Incorrect connection may cause irreversible damage which is not covered by the warranty.
- Ensure that the electrical socket used for your E-Eye is in good condition, is working properly and remains easily accessible for safe use.
- This machine is designed exclusively for use by eye care professionals in accordance with the local regulations.
- Never unplug the E-Eye by pulling on the power cord during normal use.
- Do not use the E-Eye with wet hands.
- Do not use the E-Eye in an environment where water could be splashed onto the machine (applicator or base).
- Never immerse the base of the E-Eye, its applicator or the E-Eye optical cartridge in water.
- Never use the E-Eye if it is damaged, if any malfunctions appear on the touchscreen or if it has fallen or been dropped. Damage which is not visible may be a risk to your safety and that of your patient.
- This machine can only be repaired using specific tools. In the event of problems after delivery, contact your customer service via the management interface on esw-connectplus.com
- Only order E-Eye optical cartridges and all consumables through your management interface esw-connectplus.com, selecting the contact corresponding to your country. You are liable if cartridges or accessories from another manufacturer are used. We do not guarantee their compatibility or safety.
- Always place the machine on a flat, stable surface to avoid any risk of it falling.
- In case of emergency, unplug the power cord at both ends to cut off the electricity supply to the E-Eye.

- E-SWIN SAS cannot be held liable for damage caused by incorrect use of the machine or use which does not comply with this manual.
- You must provide each patient with protective eye shells. The patient must wear them for the entire time that the machine is being used.
- A pair of protective glasses is provided with the machine. The professional using the E-Eye must wear them throughout the duration of the treatment.
- When the E-Eye is operating, it must not come into contact with the hair, the area around the protective eye shells, clothing or any other object to avoid any risk of injury, blockage or damage.
- The tip of the applicator must under no circumstances touch the protective eye shells when the flash is emitted.
- Never use the machine close to an aerosol, a heat source or any other electronic devices.
- Do not stack the E-Eye on top of other electronic devices.
- Your E-Eye is supplied with a mains power cord (2 metres long). Do not use any extension cable or other cables other than those supplied by E-SWIN as this may compromise the electromagnetic compliance of the equipment.
- Wireless communication equipment must be kept at a distance of approximately 3 metres to avoid any interference with the functioning of the machine.
- Install the machine in an environment with low electromagnetic pollution, away from computers and electrical treatment devices.
- The earth conductor is only used as a functional earth.
- Any serious incident linked to the E-Eye must be reported to the E-SWIN medical device vigilance department: regulatory@e-swin.com and to the competent authority in the country in which the user and/or patient is based.

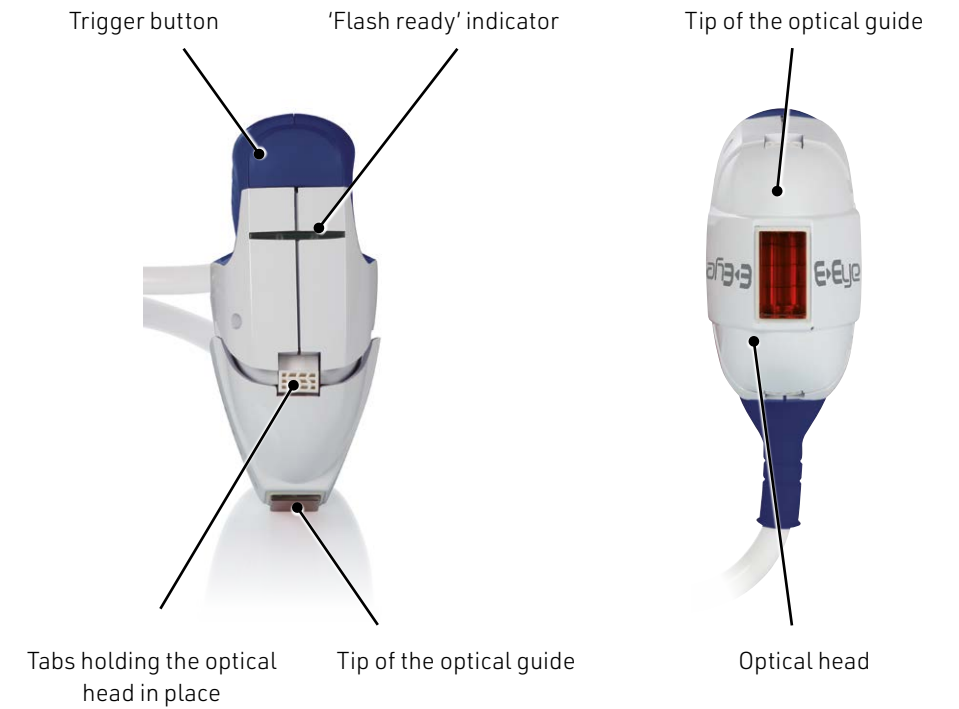
WARNING: The use of controls, adjustments or procedures which are not specified in this manual may lead to exposure to dangerous radiation.

GLOSSARY

BASE



APPLICATOR

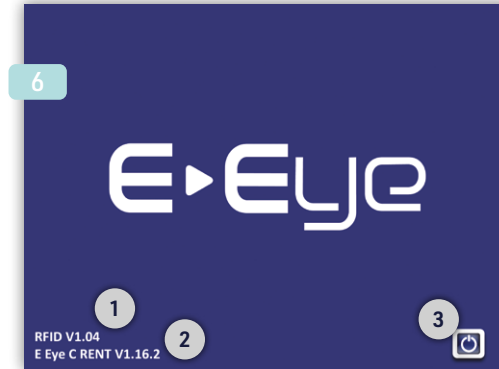


TOUCHSCREEN INTERFACE

6 HOME SCREEN

This menu is displayed when the machine is started up and provides the following information:

- (1) Version and presence of the RFID function.
- (2) Type of product, mode of use and software version.
- (3) Icon to switch the interface on and off.



7 MAIN MENU

The main menu is displayed after pressing icon (3) on the home page menu.

It is used to access the following menus:

- (8) Treatment.
- (9) Consumables and activations.
- (10) Machine settings.
- (11) Return to the previous screen.

It displays:

- (4) The temperature of the applicator.
- (5) The state of the day counter (it may or may not be present depending on the mode of use).
- (6) The state of the activation card and machine flash counters as well as the presence of an activation card.
- (7) The date & time.



Important information concerning the functioning of the counters (5) and (6):

(5) Day counter.

The day counter indicates the number of days remaining in your rental period. Its activation depends on the mode of use of the machine. If this function is active, a code to enter will be provided via your esw-connectplus.com space. It automatically goes down every 24 hours from when the code is entered. If the value is zero or negative, it will not be possible to access the treatment menu.

(6) Activation card and flash counter.

The machine flash counter is displayed on the first line of the icon. It is activated when you register your optical cartridge pack in your esw-connectplus.com space. It goes down each time the machine emits a flash.

The activation card counter is displayed on the second line of the icon. It displays the number of flashes available on the activation card supplied with your optical cartridge pack. It also goes down each time a flash is emitted.

If a value is zero or there is no activation card, it will not be possible to access the treatment menu.

When an activation card is inserted into the machine, the display in icon (6) changes and a beep is heard.



Example of the flash counters & card present display (6):

- | | |
|--|---|
| | <ul style="list-style-type: none">• Activation card: Present.• Machine flash counter: 4000.• Activation card counter: 989. |
| | <ul style="list-style-type: none">• Activation card: Present.• Machine flash counter: 4000.• Activation card counter: 0. |
| | <ul style="list-style-type: none">• Activation card: Absent.• Machine flash counter: 4000.• Activation card counter: Default value. |

8 TREATMENT MENU

The treatment menu is displayed after pressing icon (8).

It displays:

(21) (22) The selected fluence level (optical energy in J/cm²).

It is used to access:

(23) (24) Fluence level selection.

(25) Validation of the selected level.



9 CONSUMABLE AND ACTIVATION MENU

The consumable and activation menu is displayed after pressing icon (9) in the main menu.

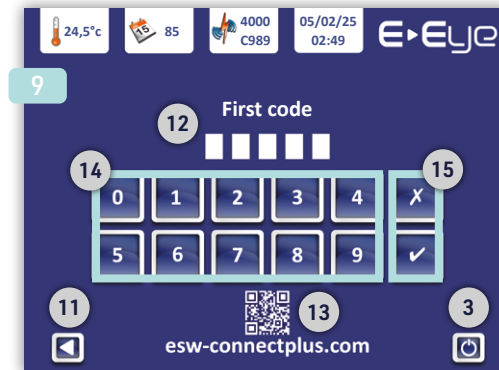
It is used to enter the codes obtained via your interface on esw-connectplus.com

(12) Code input zone. Another screen will open after validation to enter a second code.

(13) Link to your management interface.

(14) Keypad to enter the codes.

(15) Deletion and correction.



10 MACHINE SETTINGS MENU

The machine settings menu is displayed after pressing the icon (10) in the main menu.

It is used to access the following menus:

(16) Lock code management.

(17) Language selection.

(18) Definition of the date and time.

(19) Maintenance, access restricted to E-SWIN services only.

(20) Selection of the screen brightness and sound levels.



16 LOCK CODE MENU

The lock code menu is displayed after pressing icon (16) in the machine settings menu.

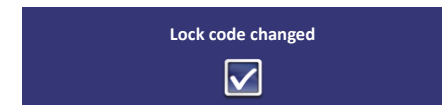
This menu enables you to protect access to the machine's functions using a four-digit code if you wish.

The default code is 0000 and does not affect accessibility.

To personalise the lock code:

- Enter the current lock code and validate.
- Enter the desired lock code and validate.

A message confirms that the lock code has been changed.



IMPORTANT: Note down your lock code carefully.

If you forget it, you will not be able to use your E-Eye and the machine will have to be returned to us to be reset. Only our technical department can carry out this operation. This operation is not covered by the warranty.

TOUCHSCREEN INTERFACE

19 MAINTENANCE MENU

The maintenance menu is displayed after pressing icon (19) in the machine settings menu.

Access to this menu is limited exclusively to authorised E-SWIN personnel.

The error codes SECU04 and SECU05 cause this screen to appear. In this case, contact your customer service via the management interface on esw-connectplus.com

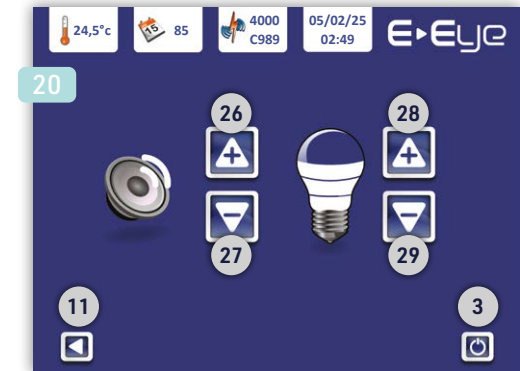


20 MENU TO SELECT THE SCREEN BRIGHTNESS AND SOUND LEVELS

The menu to select the screen brightness and sound levels is displayed after pressing icon (20) in the machine settings menu.

It is used to adjust:

- (26) (27) The sound level of your machine.
- (28) (29) The screen brightness.



17 LANGUAGE SELECTION INTERFACE

The language selection menu is displayed after pressing icon (17) in the machine settings menu.

It is used to:

- (30) Select the language used.
- (31) (32) Scroll through the languages available.

A message confirms that the language has been changed.



18 DATE AND TIME MENU

The date and time menu is displayed after pressing icon (18) in the machine settings menu.

It is used to:

- (33) Set the date: dd/mm/yy.
- (34) Set the time: hh:mm.
- (35) Validate the selection.



Language change confirmed



START-UP

UNWRAP YOUR PACK

Carefully unwrap all the components in your pack and remove the protection films.

Keep all the original packaging in a safe place.

The manufacturer's warranty (parts and labour) is only valid if the machine is returned in its original packaging.

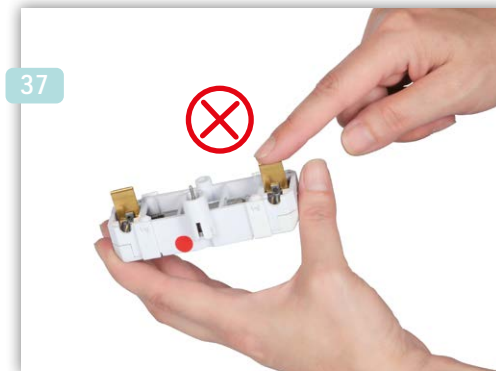
ASSEMBLING THE OPTICAL CARTRIDGE

PRECAUTIONS: During the entire procedure, under no circumstances must you touch:

36 The flash lamp or its reflector.



37 The cartridge electrodes.



IMPORTANT: If you have inadvertently touched these components, contact your supplier immediately.

38 Grasp the applicator with the E-Eye logo facing you and the cord connecting the applicator to the base on your left.



39 Insert the extraction tool between the optical head and the fixed side casing of the applicator. Push it in as far as it will go.

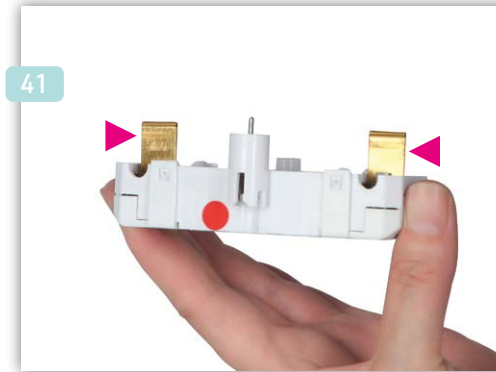


40 Hold the extraction tool in this position and simultaneously press on the two side tabs (pink arrows) retaining the optical head and remove it. Place the optical head on a clean flat surface.



START-UP

41 Check which way round your optical cartridge should be inserted by identifying the two electrodes (pink arrows) and the red dot on one of its sides.



42 Find the red dot on the applicator. Align the two red dots to insert the cartridge correctly.



43 Insert the cartridge as far as it will go in the applicator.



44 Check that it is correctly positioned. It must be parallel with the end of the fixed part of the applicator.

If the cartridge is not in the correct position, it has not been inserted properly. Remove it and check:

- that the red dots are aligned.
- the condition of the electrodes.

If the electrodes are deformed, do not insert the cartridge into the applicator to avoid damaging the machine. Contact your supplier immediately.



45 Position the optical head, aligning the red dot on the fixed part of the applicator with the red dot inside the optical head (turquoise arrows).



46 Insert the optical head by pressing gently on the two retention tabs (pink arrows).



START-UP

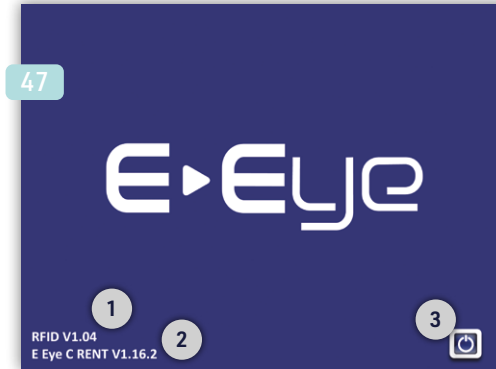
PLUGGING YOUR MACHINE INTO THE MAINS

Use the mains power cord supplied with your pack to connect your machine to the electricity supply.

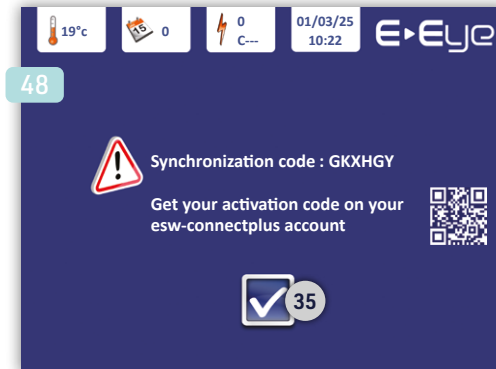
It should correspond to the standard in your country. If this is not the case, contact your supplier.

HOME SCREEN AND ACTIVATION OF THE MODE OF USE

47 If your mode of use was activated by your supplier, the home screen is displayed when the power is switched on.

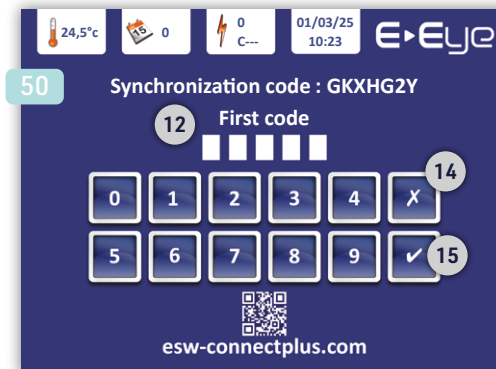


48 If it was not activated, a screen with your synchronisation code appears. Log into your esw-connectplus.com account to activate your machine. Press the validation button (**35**) to access the screen to enter the code generated via esw-connectplus.com



50 Enter the first series of five digits. After validating, a second screen will appear to enter the second part of the code. Validate to finalise activation.

51 During these input stages, a message will appear to inform you of the status of the code:



51 code already used Code refused Code accepted

MAIN MENU AND UTILISATION CODE

52 The main menu appears. The treatment menu is unavailable. Your flash counter needs to be topped up.

Go to your esw-connectplus.com space to register your cartridge pack and obtain its utilisation code.

Use icon (**9**) to access the code input interface.

Enter the two series of five digits you have obtained. Validate and your flash counter is credited (**6**).

If your Days counter (**5**) displays '0' or a negative value, your mode of use needs to be activated or your rental period needs to be renewed.

- Log into your esw-connectplus.com space to obtain your activation code.
- Enter the two series of five digits obtained.
- Validate. Your rental period will be activated or renewed.

53 Insert the activation card into the slot provided for this purpose on the outside left side of your machine.

When the activation card is inserted, the machine detects its presence and:

- Emits a beep.
- Changes the status of the icon.
- Displays the number of flashes available ('Cnnnn') on your activation card.

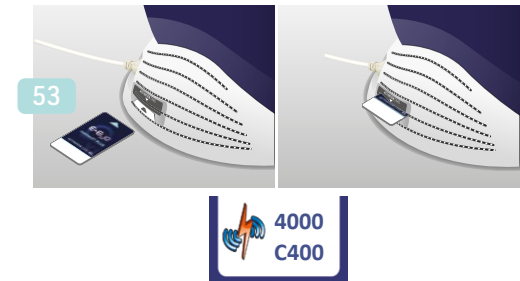
54 Your machine is now ready to use. The treatment menu (**8**) is available.

IMPORTANT: The machine cannot be used without the activation card. This prevents any unauthorised use.

STANDBY

The machine goes into standby after 7 seconds of inactivity. In this mode, the E-Eye screen goes black. However, it is still possible to emit flashes.

To exit this mode, simply touch the touchscreen.



TREATMENT

CONTRAINDICATIONS

Do not use the E-Eye in the following situations:

- Pregnancy.
- Phototype VI (very dark skin).
- Skin which is injured, burnt or infected.
- Sunburn which has healed within the last month.
- A history of sun allergy.
- Exposure to high-pressure UV light less than ten days ago.
- Use of self-tanning products (cream, food supplement) less than two weeks ago.
- Skin lesions with an unusual appearance (medical advice should be sought).
- Moles and freckles in the area to be treated (protect them with the self-adhesive patches provided).
- Tattoos (use the barrier plate provided).
- Photosensitising treatment in progress (medical advice should be sought to decide if the treatment is compatible with pulsed light treatment).
- A history of skin diseases.
- Diabetes, haemophilia, epilepsy or porphyria cutanea tarda.
- Pacemaker or cardiac defibrillator.
- Do not use on animals.

MEDICAL INDICATIONS

The E-Eye machine is designed and manufactured by E-Swin (France).

This machine is a Class IIb health device. In accordance with this regulation, it bears the CE 0197 marking.

The E-Eye is suitable for use on adult patients (phototypes I to V) with Meibomian gland dysfunction (MGD). This disease is associated with tear film lipid layer deficiency, leading to dry eye syndrome.

No risk to the patient's sight has been observed by E-SWIN.

E-Eye is designed for eye care professionals, ophthalmologists, optometrists, opticians and other professionals according to the local regulations for use in healthcare institutions only.

The E-Eye can lead to adverse effects such as blisters (lasting less than one week), swollen cheeks, a conjunctival cyst, floating bodies, hair loss from the eyebrows and forehead, sensitivity to light and facial redness.

Essential instructions for use:

- Read this manual carefully before use.
- The gel, self-adhesive patches; barrier plate, protective eye shells and safety glasses provided with your E-Eye pack must be used. Using other products may lead to skin burns.
- The patient must wear protective eye shells.
- Only apply the gel after the protective eye shells have been put on.
- The gel must never penetrate under the shells.
- The user must wear safety glasses.

PROTOCOL

The protocol consists of three sessions performed as follows:

- Day 1
- Day 15
- Day 45
- Day 75 (optional)

The treatment is applied to the temporal area of each eye and on the cheekbones.

Apply a series of five flashes per eye during each session. All treatments must be performed outside the orbital rim. Treatments inside the orbital rim are prohibited.

VERIFICATION BEFORE TREATMENT

Before each time the machine is used, check:

- the power cord (ensure it is not trapped or compressed and there are no exposed wires).
- the cord connecting the base to the applicator (no visible damage).
- that the components of the optical head are intact (page no.30).
- that your activation card is inserted in your E-Eye and that it has been detected by the machine.
- that the number of flashes displayed by your E-Eye is sufficient to perform the treatment.
- that your rental period is still active (if applicable).
- that the optical gel, the protective eye shells and the safety glasses are in good condition and available.

PATIENT PREPARATION

Installation:

- The patient is lying or sitting on an examination chair.

Skin preparation:

- Check that no cream, oil, moisturiser or other substance has been applied to the skin.
- Clean the skin using fragrance-free micellar water to remove any cosmetic residues.
- Ensure the skin is clean and dry.

Eye protection:

- Check that the protective eye shells are clean.
- Fit them correctly on the patient's eyes.
- They must remain in place for the entire duration of the session.

Protection of sensitive areas:

- Cover moles using the self-adhesive patches.

Gel application:

- Apply the gel in a thick layer (at least 1 cm thick) on the cheekbones and temporal area.
- Make sure that no gel penetrates under the protective eye shells.

TREATMENT

ENERGY LEVEL SELECTION

55

Select icon (8) in the main menu. The energy level selection menu appears.

56

There is a white bar (57) in the lower part of the display area to remind you what stage you are at on this screen and on every screen concerning the treatment.

This menu is used to select the fluence delivered by the flash.

The selected energy level, or fluence (21), is indicated in joules per square centimetre (J/cm²).

The E-Eye offers six predefined energy levels.

The fluence must be selected according to the patient's phototype.

You are reminded that people with phototype VI must not be treated with this machine.

Maximum authorised values according to the patient's phototype.

'Fitzpatrick phototype'	Maximum fluence in J/cm ²
I	13
II	12.2
III	11.4
IV	10.6
V	9.8
VI	X

58

Select the level using buttons (23) and (24).

Validate using button (25).

12.2 J/cm² is the value selected in this example.



59

The safety icon validation menu is displayed. Press on each greyed-out icon to confirm that:

- (60) you are wearing the safety glasses provided to ensure your visual comfort during the session.
- (61) you have applied gel to the whole of the area to be treated.
- (62) you have read the user manual, in particular the general recommendations and the contraindications.
- (63) you have checked that the E-Eye is not being used in an unsuitable medical or physiological context (pregnant women, photosensitising medication, etc.).
- (64) your patient is wearing their protective eye shells as a compulsory requirement during the entire session.
- (65) you have checked that no water can splash onto the E-Eye.

Once all the safety precautions have been validated, the validation icon (25) becomes accessible.

66

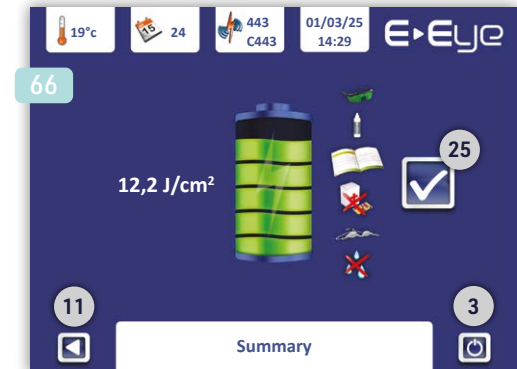
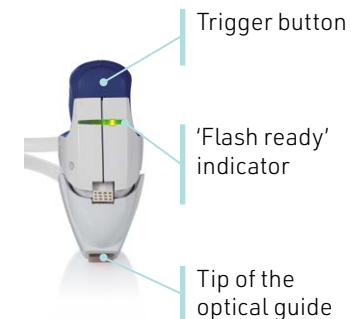
After validation, a summary of your selection choices appears on the screen.

You are reminded that you can return to the previous screen at any time by pressing button (11) and you can return to the home screen by pressing button (3).

67

Press icon (25) to start charging the selected energy level. The energy gauge flashes during this phase.

When the flashing stops, a beep is emitted and the 'flash ready' indicator on the applicator turns green once this phase is ended.



TREATMENT

TREATMENT

- Wear your safety glasses. Anyone in the vicinity should also wear safety glasses.
- If necessary, use the barrier plate provided to cover any fairly large area which must not be treated (e.g. tattoo).
- Place the tip of the optical guide on the gel. The optical guide must be in full contact with the gel but not with the skin.
- Trigger a flash by pressing the trigger button on the front of the applicator.
- Release the button. The machine switches to the charging phase.

68

- Move the optical guide on the half-face from the inner canthus to the outer canthus.
- As soon as the beep is emitted and the 'ready to flash' indicator is green you can administer a new flash by pressing the trigger button.

69

- Repeat the operation until you have administered five flashes per half-face.

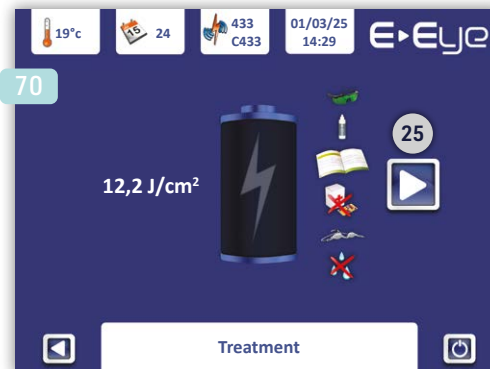
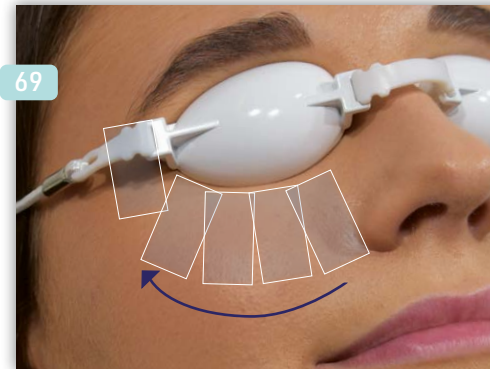
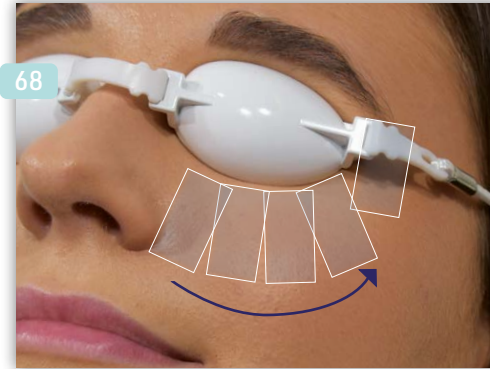
IMPORTANT: All treatments must be performed outside the orbital rim. Treatments inside the orbital rim are prohibited.

70

After approximately one minute of inactivity in treatment mode, the E-Eye switches to standby. Simply press icon (25) to resume treatment.

REMINDER: During the treatment phase, the machine may switch to standby but it is still possible to emit flashes.

28



END OF THE SESSION

71

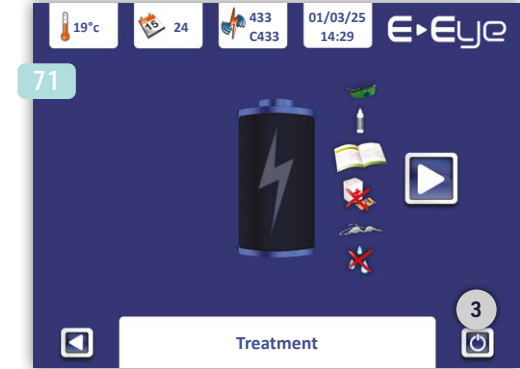
- Press the on/off button (3) on the machine.
- The applicator fans continue to operate for approximately two minutes. Do not unplug the mains power cord until they have stopped. This ensures that the optical parts have cooled down (the fans in the base will continue to operate until the mains power cord is unplugged from the machine).
- Remove your safety glasses.
 - Wipe the remaining gel off your patient's face, then clean their skin with micellar water.
 - Remove the protective eye shells from your patient's eyes. The shells must be cleaned.

72

- Spray the optical cleaning spray onto a lint-free cloth and clean the glass tip of the applicator (optical guide).

73

- The applicator bracket can also be cleaned.
- Lift off the translucent black base by grasping it by its two wings.
 - Rinse it with water and ensure it is completely dry before refitting it.



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MAINTENANCE & CHANGING THE CARTRIDGE

WARNINGS

IMPORTANT:

- Wait for the fans in the applicator to completely stop before carrying out any work on the machine. This ensures that the optical parts have completely cooled down.
- The fans in the base will continue to operate until the mains power cord is unplugged.
- Before any maintenance work, disconnect the machine by unplugging the power cord at both ends.
- Never spray the optical cleaning spray directly on the optical components or the touchscreen. Apply it to a dry, lint-free cloth first.
- Never allow any liquid to run into the ventilation holes in the base or the applicator.
- Never attempt to open the machine. All work must be performed solely by a technician authorised by the manufacturer.

BASE MAINTENANCE

PLASTIC PARTS

- Do not clean the inside of the activation card slot.
- Clean the plastic surfaces using a clean cloth slightly dampened with clean water (with no additives).

TOUCHSCREEN

- Use a clean cloth soaked with optical cleaning spray.
- Never spray directly on the touchscreen.

MAINS POWER CORD

- Disconnect both ends before cleaning it.
- Wipe it with a damp cloth soaked in clean water only (with no additives).

VENTILATION HOLES

- Check that the ventilation holes underneath and on the back are clean.
- Ensure that nothing is blocking them.



APPLICATOR BRACKET

- Lift off the translucent black plastic base by grasping it by its two wings.
- Rinse it with water and ensure it is completely dry before refitting it.



APPLICATOR MAINTENANCE

APPLICATOR BODY

Clean the plastic surfaces using a clean cloth slightly dampened with clean water (with no additives).

OPTICAL HEAD

- Before each time the machine is used, clean and check the optical parts of the optical head.
- Refer to the 'Assembling the optical cartridge' section (page no.18) for how to remove the optical cartridge.

74

- Hold the optical head with the optical filter facing you.



75

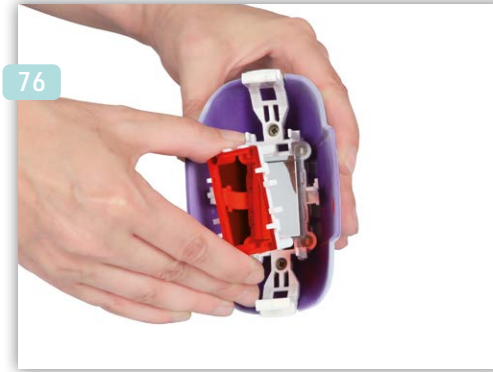
- Gently push the retention clips outwards.



MAINTENANCE & CHANGING THE CARTRIDGE

76

- Carefully remove the filter and place it on a clean, flat surface.



77

- Spray the optical cleaning spray on a dry, lint-free cloth. Repeat this stage to clean each component.



78

- Clean the inside of the optical guide and check its condition. It must not be chipped and its surface must be smooth and flat. Carefully put down the optical head on a flat surface.



79

- Clean both sides of the optical filter and check its condition. There must be no cracks and it must be perfectly flat.



80

- Refit the optical filter in the optical head and attach it by inserting it into the retention clips.



81

- Clean the outside of the optical guide and check its condition. It must not be chipped and its surface must be smooth and flat.



MAINTENANCE & CHANGING THE CARTRIDGE

APPLICATOR CABLE

- Check that the cable is in perfect condition. Ensure it is not trapped or compressed and there are no exposed wires.
- If you have any doubts concerning the condition of this cord, you must stop using your machine immediately.
- This cable must always remain clean.
- Clean it with a cloth dampened beforehand with water (with no additives).

VENTILATION HOLES

The applicator has ventilation holes. Ensure they remain clean and that nothing is blocking them.

CHANGING THE OPTICAL CARTRIDGE

- Wait for the fans in the applicator to completely stop.
- Unplug the machine from the mains by disconnecting the power cord at both ends.
- Note the 22 characters of the serial number on the wrapping and/or on the cartridge. At least one of the two will be required to obtain your utilisation code on esw-connectplus.com
- Refer to the 'Assembling the optical cartridge' section (page no.18) for how to remove the old optical cartridge and install the new one with care.
- Plug the machine into the mains using the power cord.
- The home screen appears. Press icon (3).
- Follow the instructions in the 'main menu and utilisation code' section (page no.23) to enter your utilisation code obtained via your user space on esw-connectplus.com
- Insert the activation card provided with your cartridge pack.

Your machine is now ready to use.

REMINDER: You can follow your flash consumption in real time on icon (5). You can also follow the remaining number of days of your rental period on icon (6).



PROHIBITED ACTIONS

HERE IS A LIST OF PROHIBITED ACTIONS ON YOUR E-Eye (NON-EXHAUSTIVE)

These actions are prohibited because they put you in danger or may irreversibly damage your machine.

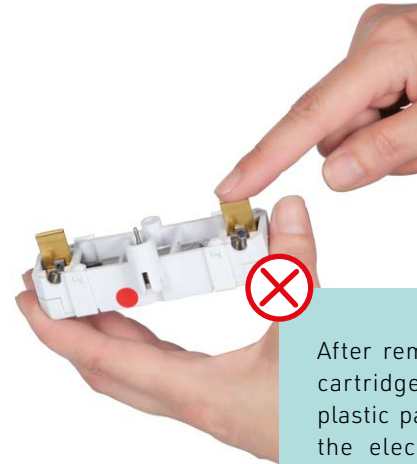
If you have any doubts concerning the functioning of your machine, contact your supplier by logging into your esw-connectplus.com space.



Never cover the ventilation holes on the applicator with your hand or any other object.



Never cover the base of the E-Eye with a cloth as this will block the upper ventilation holes.



After removing the optical cartridge, only touch the plastic parts. Do not touch the electrodes, the flash lamp or the reflector.



Never attempt to dismantle the applicator.



Never place the E-Eye base on a non-rigid surface (e.g. a towel) to avoid blocking the lower ventilation holes.



Never touch the flash lamp or the reflector with your fingers or any other object.



Never touch the contacts.



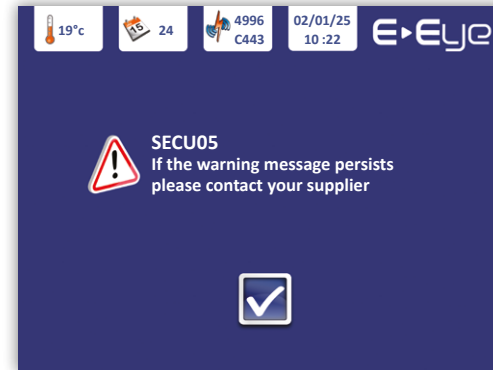
- Do not open the E-Eye machine. All work must be performed solely by a technician authorised by the manufacturer.
- A manual discharge device may be activated after the machine is opened by a person authorised to carry out repairs by the manufacturer.

TECHNICAL SUPPORT & SOFTWARE UPDATES

If you have any doubts concerning the use or functioning of your machine, contact your supplier by logging into your esw-connectplus.com space.

In your space, you will also have access to the active software version for your E-Eye and to the electronic version of its user manual. To ensure an appropriate level of cybersecurity when downloading, make sure that all the security updates for your computer's operating system are installed. You are also advised to use an up-to-date antivirus and firewall.

This manual is applicable to software versions 1.16 x and higher.



WARNING MESSAGE












The appearance of a warning message means that you must contact your supplier by logging into your esw-connectplus.com space.












SCREEN DISPLAY	MEANING	WHAT TO DO
SECU02	The optical head or the optical cartridge is not detected.	Check that both components are present and correctly positioned.
SECU06	The internal temperature of the applicator is too high.	Wait for the applicator's ventilation system to lower its internal temperature.
SECU09	The date displayed on your E-Eye is earlier than 01/01/2010.	Change the date via the date and time definition menu.
SECU14	Loss of connection with the activation card.	Check the state of the activation card.
SECU 04 SECU 05 SECU 07	Your machine is blocked.	Unplug your E-Eye from the mains and contact your supplier.



TECHNICAL CHARACTERISTICS

MARKING

	Reference of the medical device.
	Unique serial number of the medical device.
 E-SWIN Rue des Côtes d'Orval ZA de la Prévôté 78550 Houdan - France	Symbol indicating the name and address of the manufacturer. The date of manufacture is indicated in the serial number of the machine. Characters fifteen to eighteen in the number represent the year and week, YYWW.
 0197	Medical device satisfying the requirements of MDR EU 2017/745, certified by an independent body.
IP2X	Device protected against solid foreign objects larger than 12.5 mm in diameter (IP rating).
	Functional earth terminal.
	Logo corresponding to a degree of protection against electric shock for the parts in contact with the patient (type BF applied part).
	Class II medical electrical equipment.
	The machine must be used indoors.
	Store the machine in a dry place.
	Keep away from light and heat.
	Indicates the need for the user to consult the instructions for use.

100 - 240 V~ 50 - 60 Hz 540 VA	Operating conditions (supply voltage (alternating current), mains voltage frequency, power).
	Warning: electrical hazard.
	Warning: general safety sign.
	Warning: hazardous optical radiation.
	Comply with the upper and lower temperature limits shown on each side of this logo.
	Indicates the atmospheric pressure range to which the medical device can be exposed in complete safety.
	Indicates the humidity range to which the medical device can be exposed in complete safety.
	Symbol indicating 'unique device identifier'
	Symbol indicating that the E-Eye is a medical device
	Do not use the product after the date shown under this symbol (gel).
	The batch number of the product (gel) is shown next to this logo.
 IEC 60601-2-57:2011 Risk Level: Group 3 WARNING: The light emitted may result in eye injury. Do not look at the light source. Maximum fluence: 13 J/cm² Pulse duration: 170 ms Wavelength range: 580 - 1625 nm	Warning label in accordance with standard IEC60601-2-57.

SPECIFICATIONS

Technology	IRPL® (Intense Regulated Pulsed Light).
Wavelength	> 580 nm
Charging time/Energy source	Continuous operation
Dimensions (L x W x H)	Max 345 x 320 x 440 mm
Weight	Max 11.5 kg.
Dimensions with packaging (L x W x H)	Max 735 x 445 x 632 mm
Gross weight	Max 16.7 kg
Sound level	Max 83 dBA
Electrical installation required	100 - 240 VAC
Maximum consumption	540 VA
Frequency	50/60 Hz
Temperature	Operating: +5 to +25°C Storage: -5 to +65°C
Relative humidity	<93%
Atmospheric pressure	70-106 kPa

RECYCLING AND PROCESSING



Instructions relative to the processing of used products: the Waste Electrical and Electronic Equipment Directive 2012/19/EC was introduced to ensure that products are recycled using the best possible processing, recovery and recycling techniques and thus contribute to protecting the environment and human health.

Your product is designed and manufactured with high-quality components and materials which can be recycled and reused.

E SWIN SAS is affiliated with an eco-organisation which collects and processes end-of-life products.

TECHNICAL CHARACTERISTICS

DIRECTIVES AND MANUFACTURER'S DECLARATION

RADIO-FREQUENCY EMISSIONS

The E-Eye is equipped with a 13.56 MHz radio frequency transmitter using ASK modulation and with a field strength level of less than 42 dB(μ A/m).

The radio frequency transmitter can access the activation card for which the internal counter gives the information concerning the number of flashes remaining before the optical cartridge needs to be replaced.

ELECTROMAGNETIC EMISSIONS

The E-Eye is designed to be used in the electromagnetic environment specified below. The user must ensure it is used in this environment.

EMISSION TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - DIRECTIVES
RF emissions - CISPR 11	Group 1	The E-Eye machine only uses RF energy for its internal functions. Therefore, its radiation emissions are very low and are not likely to cause interference in any electronic devices nearby.
RF emissions - CISPR 11	Class B	The E-Eye machine can be used in all environments, including residential environments and in establishments directly connected to a low-voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions - IEC 61000-3-2	Class A	
Voltage fluctuations Flicker - IEC 61000-3-3	Compliant	

WARNING: The use of accessories, transducers and cables other than those specified or supplied by the manufacturer of this equipment could lead to an increase in electromagnetic emissions or a reduction in the electromagnetic immunity of this equipment, and cause malfunctions.

WARNING: Portable RF communication equipment (including peripherals such as antenna cables and external antenna) must not be used closer than 30 cm (12 inches) to any part of the E-Eye, including the cables specified by the manufacturer. Otherwise the performance of this equipment may deteriorate.

WARNING: Using this equipment adjacent to or stacked on other equipment must be avoided as this may lead to malfunctions. If such use should be necessary, this equipment and the other equipment must be checked to make sure it is functioning correctly.

ELECTROMAGNETIC IMMUNITY

The E-Eye is designed to be used in the electromagnetic environment specified below. The user of the device must ensure it is used in such an environment.

IMMUNITY TEST	TEST LEVEL ACCORDING TO IEC 60601	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT DIRECTIVES
Electrostatic discharge (ESD). IEC 61000-4-2	± 8 kV in contact ± 15 kV in air	± 8 kV in contact ± 15 kV in air	Floors should be made of wood, concrete or ceramic tiles. If floors are covered in synthetic materials, the relative humidity must be at least 30%.
Fast transients in bursts. IEC 61000-4-4	± 2 kV 100 kHz	± 2 kV 100 kHz	The electronic power supply quality should be that of the public network.
Surges. IEC 61000-4-5	± 1 kV between phases ± 2 kV between phase and earth	± 1 kV in differential mode ± 2 kV in common mode	The electronic power supply quality should be that of the public network.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	0% U_T on 0.5 cycles at 45, 90, 135, 180, 225, 270, 315° 0% U_T on one cycle at 0° 70% for 25/30 cycles at 0° 0% for 250/300 cycles, all angles	0% U_T on 0.5 cycles at 45, 90, 135, 180, 225, 270, 315° 0% U_T on one cycle at 0° 70% for 25/30 cycles at 0° 0% for 250/300 cycles, all angles	The electronic power supply quality should be that of the public network. If the user of the E-Eye requires continuous operation during power supply interruptions, it is recommended that the E-Eye be powered from an uninterruptible power supply or battery.
Magnetic fields at power frequencies 50 and 60 Hz. IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at power frequency should be at levels characteristic of those of the public network.
Conducted RF disturbances IEC 61000-4-6	3 Vrms 150 kHz at 80 MHz 6V for the ISM band	3 Vrms 150 kHz at 80 MHz 6V in ISM bands between 150 kHz and 80MHz	
Radiated RF disturbances IEC 61000-4-3	3 V/m 80 MHz at 2.7 GHz	3 V/m 80 MHz at 2.7 GHz	

NOTE 1: U_T is the voltage of the AC power supply before the application of the test level.

NOTE 2: At 80 MHz and at 800 MHz, the highest frequency range applies.

NOTE 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the E-Eye is used exceeds the applicable RF compliance level above, the E-Eye should be observed to check that it is operating normally. If abnormal performance is observed, additional measures may be necessary, such as reorienting or repositioning the E-Eye.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

TECHNICAL CHARACTERISTICS

IMMUNITY TO PROXIMITY FIELDS FROM RF WIRELESS COMMUNICATIONS EQUIPMENT

The E-Eye machine is intended to be used in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the machine can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the machine, as recommended below, according to the maximum transmission power of the communications equipment.

Immunity test: IEC 61000-4-3

FREQUENCY TEST (MHz)	BAND a) (MHz)	SERVICE a)	MODULATION b)	MAXIMUM POWER (W)	DISTANCE (m)	IMMUNITY TEST LEVEL (V/m)
385	380 - 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE band 13, 17	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900; TETRA 800; iDEN 820; CDMA 850; LTE band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28
870						
930						
1720						
1845	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28
1990						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
5500						
5,785						

N.B. If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The test distance of 1 m is authorised by standard IEC 61000-4-3.

^{a)} For some services, only the uplink frequencies are included.

^{b)} The carrier must be modulated using a 50% duty cycle square wave signal.

^{c)} As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be the worst-case scenario.

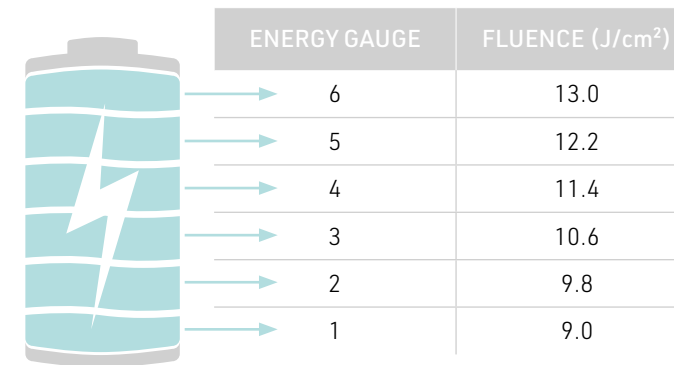
LIGHT EMISSION

The E-Eye is classed in risk group 3 for the 'retinal thermal' risk.

The non-homogeneity of the illumination on the applied surface is below to 20%.

The ocular risk is negligible from a distance between the eye and the surface of emission greater than 7.40 metres.

Energy delivered on the area to be treated according to the user's selection:



CERTIFICATIONS

E-SWIN SAS, the exclusive manufacturer of the E-Eye machine, is ISO 13485 certified.

COMPLIANT

E-SWIN hereby declares that the E-Eye complies with the general safety and performance requirements of regulation 2017/745 appendix I, and has the CE marking under the responsibility of TÜV Rheinland.

ENVIRONMENTAL PROTECTION

Please comply with local regulations when disposing of packaging and consumables. Wherever possible, try to promote recycling.

Your device is guaranteed for professional use.

The duration of this warranty is linked to the legislation in force in each country.

The warranty is rendered void in case of:

- connection error or incorrect handling.
- improper use, particularly if it is used for any other purpose than that of its medical indication.
- failure to comply with the conditions described in this manual.

E-SWIN SAS will not be held responsible for any accident that may occur due to improper use or non-compliance with the instructions in this manual or the information provided through the labelling or the touchscreen of the E-Eye.

The manufacturer's warranty (parts and labour) is only valid if the machine is returned in all the parts of its original packaging (boxes, inserts, etc.).

All parts of the original packaging of your E-Eye must therefore be kept in a safe place.



For further information, go to [esw-connectplus.com](https://www.esw-connectplus.com)

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