



USER MANUAL

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Dear Client,

Thank you for your trust and confidence in our technology.

tearstim has been designed to ensure comfortable and safe use, providing reliable and convincing results.

tearstim, the pioneering IRPL® technology, specially certified to treat meibomian gland dysfunction and evaporative dry eye, will provide improved visual comfort and a better quality of life.

If you have any further questions, please do not hesitate to get in touch with us through our website:

<https://www.esw-vision.com/contact>

We would also like to invite you to share your experience and satisfaction to help us to continuously improve our products and services:

(EN): **<https://www.esw-vision.com>**

Your E-Swin Customer Service

After receiving your **tearstim**, you shall create your customer account and register your device here: <https://esw-connectplus.com/#/>.

Optic Cartridge use is controlled by two ways:

- An activation card provided with each Optic cartridge.
- An Optic cartridge activation code that enables use of a new cartridge.

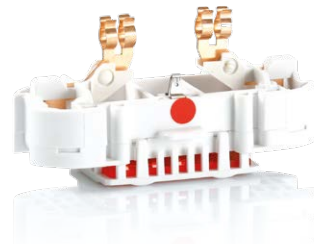
After registration of your **tearstim**, you will be able register your new Optic cartridges and get activation codes at <https://esw-connectplus.com/#/>.

Instruction for use are downloadable at: www.esw-vision.com/downloads

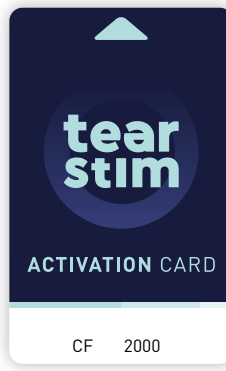
ACCESSORIES tearstim



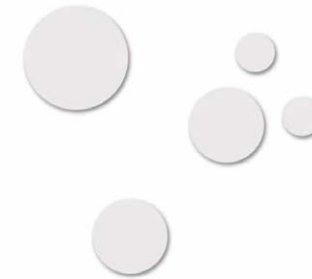
1 **tearstim** base unit and its applicator.



1 **optic**
Consumable cartridge
Part Number V036__010B__



1 activation card **tearstim**.
(delivered with **optic**)



patches
Self-adhesive patches
(self-adhesive patches per sheet).
Part Number: V000__020A__



stop
Guide plate.
Part Number: V000__016A__



Power cord.
Part Number: V036EU013A00A



gel
(flashing intended gel – 260 ml).
Part Number V000__007A01A



Pairs of **eye mask** protective
shells (in special packaging).
Part Number: V000__014A__



clean
Optical spray.
Part Number: V000__018A__
Any cleaning spray over 95% isopropyl
alcohol may be used.

The purpose of stickers (as known as patch) is to simplify the user to protect patients.
Any stickers with the same purpose can be used.



mask - Protective glasses.
Part Number : V000__012A__

Any glasses compliant to EN166 with a glass of
type 3: 8 to 18 % transmission may be used.



User manual.
Part Number: see on last page



NOTE: E-Swin SAS holds exclusive rights for the marketing of the **tearstim** and its accessories: **optic**, **clean**, **patches**, **stop**, **gel**, **mask**, **eye mask** etc. on its website at www.Keepyoureyesfit.com.

IMPORTANT: YOU MUST KEEP ALL THE ITEMS OF ORIGINAL PACKAGING (BOXES, PACKING BLOCKS, ETC.). The manufacturer's guarantee for parts and labour will only be valid if your device is returned in its complete original packaging. All items of original packaging in which your **tearstim** was delivered should therefore be carefully stored **tearstim**.

**tear
stim**



PRECAUTIONS FOR USE

» INDICATIONS

tearstim produce Intense pulsed light (IPL) in order to improve the dry eye syndrome caused by a deficiency in the oily layer of the cornea. The indication for IPL treatment is all adults, from phototypes I to V, suffering from Meibomian gland dysfunction (MGD).

Use of the **tearstim** device is associated with following benefits for the patient including (after 45 days of IPL treatment):

- Improvement of the meibomian gland function with a reduction of the lid margin of 73% (from 1.5/3 before treatment to 0.4/3) after 5 months and 24 days post-treatment,
- Stabilisation of the tear film with an increase for TBUT of 80% (from 4.02 before treatment to 7.95 seconds) after 1 month and 25 days post treatment,
- Less ocular surface inflammation with a CFS score reduction of 91% (from 1.1/12 before treatment to 0.1/12) after 7 months and 12 days post-treatment,
- Reduction of symptoms with a decrease of 63% (from 14.7/28 before treatment to 5.5/28) for SPEED questionnaire after 7 months and 12 days post-treatment,

No risk for the patient eyesight was claim by esw-vision.

» FOR YOUR SAFETY

Before using your **tearstim**, the following information should be read carefully:

- Service voltage: 100 – 240 V a.c.
- Rated frequency: 50–60 Hz.
- Maximum power consumption: 240 VA.
- Check that this voltage is consistent with the voltage rating of your installation. Any connection error may cause irreparable damage which is not covered by the guarantee.
- During normal use of **tearstim**, never disconnect the device by pulling on the power cord.
- Check that the power outlet to which **tearstim** is connected is not damaged, is in perfect working order, and will not prevent the correct use of **tearstim**.
- The power outlet must be easily accessible and can be used, in case of an emergency, to unplug tearstim from the power socket.
- Never use the **tearstim** with wet hands.
- The **tearstim** must not be used in any location in which the device might be exposed to water spray (on either the applicator or the base unit).
- Never immerse the **tearstim** base unit, its applicator or the **tearstim** Optic cartridge in water.

- The **tearstim** must not be used if it is damaged, in case of the display of a functional anomaly on the touch screen, or if the device has been dropped (concealed damage may jeopardize your safety and the safety of your client).
- This device can only be repaired using special tools. In case of any problems after delivery, contact us on our website at estore.esw-vision.com using your personal space. Any serious incident occurring in relation to the **tearstim** should be reported to esw-vision (<https://www.esw-vision.com/contact>) and the competent authority of the Member State in which the user and/or patient is established.
- **tearstim** Optic cartridges, and all accessories in general, must be ordered exclusively by visiting www.esw-vision.com/contact and choosing the applicable contact for your country. We cannot accept any liability associated with the use of consumable cartridges and accessories supplied by another manufacturer.
- During operation, the device must be positioned on a flat supporting surface, in a location where there is no risk of the device being dropped.
- E-Swin SAS cannot accept any liability for damage resulting from the incorrect use of the device, or from the use of the device other than as described in the present user manual.
- Attention – Using controls or setting or performance of procedures others than those specified in this user manual may result in exposure to dangerous optical radiation.
- Each of your clients must be supplied with a pair of EYE MASK protective shells. The protective shells EYE MASK must be worn through the operation of the device by the client.
- One pair of glasses MASK is supplied with the device: these glasses must be worn throughout the operation of the device by the professional user of the **tearstim**. Any other person in the vicinity during the operation of the **tearstim** must also wear these glasses.
- Once the **tearstim** is in service, it must not be brought into contact with the hair, the area covered by the EYE MASK protective shells, clothing or any other object, in order to avoid any risk of injury, obstruction or deterioration.
- The light emitting area of the applicator should not be in contact with the EYE MASK shells when the flash is triggered.
- The device must never be used in the proximity of an aerosol, in the proximity of a heat source, or in the proximity of the other electronic devices.
- The device must not be stacked on other electronic devices.
- Your **tearstim** is supplied with a mains lead (2 metres in length) and an applicator lead (2 metres in length). No extension cable, or any cable other than those supplied by E-Swin, should be used – the device may otherwise be rendered non-compliant for electromagnetic purposes.
- Wireless communication devices must be kept at a distance (approximately 3 metres), as these may impair the correct operation of the device.
- The device must be installed in an environment which is substantially free of electromagnetic interference (from computers, electrical solution appliances, etc.).
- **tearstim** can lead to undesirable side-effects such as blistering (lasting less than one week), cheek swelling, conjunctival cyst, floaters, hair loss at brow and forehead, light sensitivity and redness of face.

PRECAUTIONS FOR USE

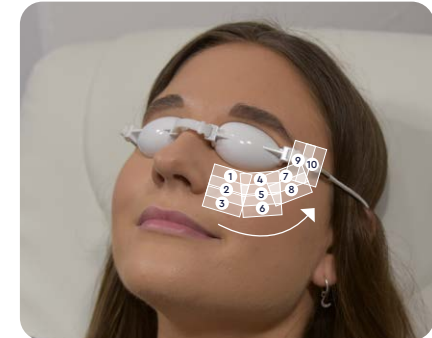
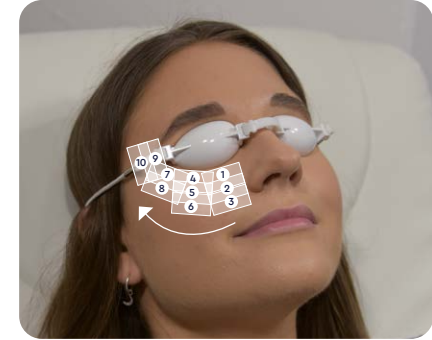
» COMPATIBILITY CRITERIA

tearstim must be contra-indicated for persons who are unsuitable for pulsed light procedure; specifically, where one of the following criteria are fulfilled:

- On pregnant women.
- On black skin (phototype VI).
- On sunburned skin which has healed within the last month.
- In case of a previous history of sunlight allergy.
- On skin that has been exposed to high pressure UV for less than ten days.
- On persons who have applied a self-tanning product (cream, dietary supplement) for less than two months ago.
- On an injured, burned, or infected skin.
- On skin lesions of unusual appearance, which will require investigation.
- On high-risk areas (blemishes, birthmarks, warts, unhealed wounds...).
- On persons suffering from a skin condition (eczema, inflammation, acne...).
- On moles: if they are located on the zone to be solutioned, they must first be protected, for example by covering them with the self-adhesive patches provided with your **tearstim**.
- On eyelids with permanent tattoos.
- On tattooed areas: permanent make-up, or cosmetic tattoos, of whatever colour. In this case, use the stop delimitation plate.
- On eyelids with make-up applied.
- On persons undergoing photo-sensitising procedure: depending upon medical opinion, these persons may not be accepted for solution with the **tearstim**.
- On persons with a previous history of cutaneous pathology.
- On diabetics, hemophiliac, epileptics, persons suffering of tardive cutaneous porphyria.
- On persons wearing a pacemaker or cardiac defibrillator.
- On animals.

» **tearstim** PROCEDURES

- Unperfumed micellar cleansing water is used to remove any cosmetic residues (make-up) from the skin.
- Zone concerned:
 - Apply 8-10 flashes on the cheekbone and left temporal area according the drawing on your right.
 - Repeat the same procedure under the right side.
- After flash procedure, the application of cosmetic products is possible.
- The specific **tearstim** protocol consists of 3 sessions as follows :
 - Day 0
 - Day 15
 - Day 45
 - (Day 75 optional)



IN NEED OF HELP?

To contact our sales department or technical department, go to your client space on www.Keepyoureyesfit.com, and click on the tab «Contact us and After-Sales Service».



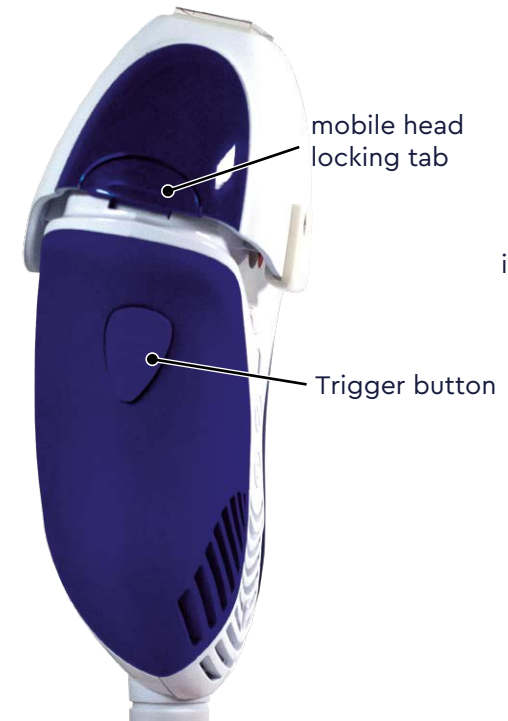
Only the GEL, the self-adhesive PATCHES and the EYE MASK protective shells supplied with your **tearstim** must be used. The use of any other product may give rise to the risk of skin burns.

GLOSSARY

» BASE



» APPLICATOR



INFORMATION PROVIDED BY THE **tearstim**'S TOUCHSCREEN

ON / OFF OF THE DEVICE

- 1 On/off switch.

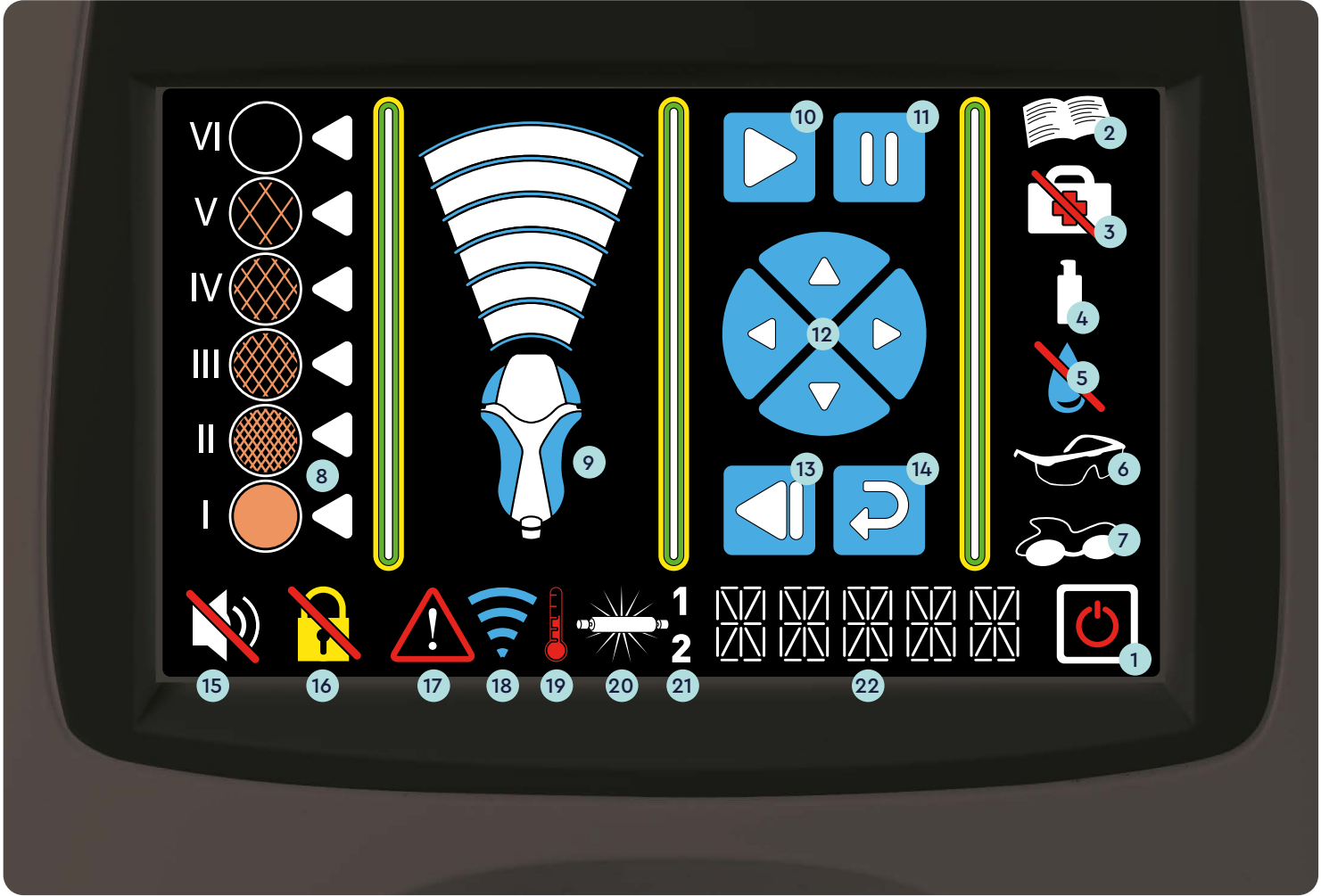
SAFETY ICONS

- 2 Reading the instruction manual.
- 3 **tearstim** must not be used in certain physiological or medicated contexts (pregnancy, photosensitising medication ...).
- 4 the application of gel is mandatory.
- 5 Spillage of water on any part of the device.
- 6 Wearing the safety glasses **māsk** is recommended.
- 7 Wearing the **elye māsk** protective shells is mandatory.

HOW TO SET UP A SESSION

- 8 The skin colour. This area allows to select the colour of the skin, from lightest (bottom) to darkest (top).
- 9 Intensity level. The visual filling gauge represents the 6 levels of intensity of the released flash. Intensity level can be adjusted by pressing the gauge area.
- 10 Play. Enables to switch from « on hold mode » to « activ mode » to continue dry eye session.
- 11 Pause. This icon is displayed on the touch screen throughout the duration of the dry eye session. Pressing it allows you to put the device in pause mode.

THE BASE OF **tearstim** IS EQUIPPED WITH A TOUCH SCREEN



BROWSING AREA

- 12 These buttons enable you to move from one character to another (22), and to increase or decrease the digits of each character.
- 13 Go back to the previous menu. This icon enables you to modify any selection made previously. It is available only when icons 16 and 20 have been selected.
- 14 Validation of input data (22).

INFORMATION IN REAL TIME

- 15 Volume activation/deactivation.
- 16 Lock / unlock. This icon enables you to secure your **tearstim** with a PIN code.
- 17 Warning. A number is displayed on the touch screen when this icon is active; it corresponds to an error message.
- 18 Detection of the activation card.
- 19 Temperature of the applicator. This icon is not active during normal functioning of the device. If it blinks, please refer to the corresponding error message.
- 20 Cartridge tube. When it is blinks, it means that you can flash.
- 21 Numbers 1 and 2 correspond respectively to the first input, then to the second input that confirms the secure PIN.
- 22 All these characters enables you to enter the secure PIN code of **tearstim**, and also to show the remaining number of flashes at any moment.

**tear
stim**



SOLUTION TO IMPROVE DRY EYE USING THE tearstim

» BEFORE EACH USE

VERIFICATION

- Check the power cord (must not be pinched or crushed, wire must not be bare).
- Check the cable connecting the base to the applicator (no visible impairment).
- Check the external optical parts of **tearstim**. Check that the glass tip of the applicator (opticalguide) is intact, and if this is not the case, changing the mobile head is essential. This component can be ordered by visiting www.esw-vision.com/contact and choosing the applicable contact for your country.
- Verification and maintenance of the internal optical parts.
 - In all cases, before you start disassembling of the mobile head, the device must be unplugged.
 - Before each use, and before plugging-in **tearstim**, you must check the integrity of the internal optical parts: tube, filter (Flat red piece made of glass), and optical guide. The filter must be cleaned systematically before each dry eye session with **tearstim**. It must be clean and free of dust.

To check :

- Unscrew mobile head screw **1** with tools and lay onto a flat surface.
- Wiggle the locking part **2** to release it while holding it.
- Press simultaneously both locking tabs **3** of both sides of the mobile head while holding the locking part.
- Gently remove the mobile head.
- Carefully place the mobile head and the locking part onto a flat surface **4**.
- Removing the optic cartridge with filter (video available on your personal customer page).
 - Once the mobile head is removed, the optic cartridge with filter appears in the applicator **5**.



- Remove the cartridge from the applicator: firmly grip on the cartridge body **6** and pull it out **7**. The optic cartridge with filter is now removed **8** ; Only hold the optic cartridge by the plastic part at either end.

- Cleaning of the internal optical parts.
 - Once the filter cartridge is removed, the transparent optical glass is also available **9**.
 - Select the **CLEAN** spray: spray it on a lint-free cloth beforehand **10**.

NOTE: Never spray directly on the optical parts.

- Afterwards clean only the accessible side of the filter with this cloth **11**. Repeat the same procedure for the accessible part of optical glass **12**.

NOTE: The filter must never be separated from its optic cartridge.

- When cleaning is done, take the optic cartridge **13** and align it with the applicator with the help of the red dots **14**. Push it into the slide way of the applicator by pressing on it, so as to ensure that it is properly maintained **15**.
- Position the locking part of the applicator before putting back the mobile part of the applicator **16**.
- Then, assemble the mobile part of the applicator with the locking part **17**.
- Press down the head towards the applicator by pressing simultaneously both locking tabs of the mobile head **18**.
- Ensure that both parts are tucked securely verrouillage **19** while making sure to align the internal red dot of the head with the red dot of the applicator. Finally, screw back tightly the locking part screw with a suitable tool.



Once your session is complete, before switching the device off and unplugging it, you must wait for the fan to come to a complete stop (it may take more than 10 minutes). This procedure enables the optical parts to cool down. The other fans, located in the base of **tearstim**, will only stop when the device is unplugged.

NOTE: For better efficiency of **tearstim**, it is recommended to clean the filter before each use with the clean spray provided when you purchased **tearstim**. Any damaged filter due to non-compliance with the procedure for use is not covered by the manufacturers warranty.

SOLUTION TO IMPROVE DRY EYE USING THE tearstim

» STAGE 1

PREPARING THE PERSON RECEIVING THE SESSION

- The person has to be settled in an examination and treatment chair lying or sitting.
- The skin must be clean, dry and free of any cosmetic products.
- Check that no cream, moisturizing lotion, oil or any other substance has been applied to the skin beforehand.

» STAGE 2

NOTE: Before using the activation card, make sure your **tearstim** have been registered on the website: <https://esw-connectplus.com/#/> and you have entered the activation codes for your "OPTIC cartridge". (See the instruction on the section "CHANGING THE **tearstim** OPTIC CARTRIDGE" (page 30).

USING THE ACTIVATION CARD

tearstim operates with an activation card.

This card is specific to the OPTIC cartridge with which it has been delivered.

- Take the activation card of your OPTIC cartridge.
- Insert the card as far as it goes into the lateral slot (A and B).
- Leave the card in this slot throughout the entire dry eye session.
- At the end of the session, remove the activation card, take care not to damage it, and store it in its case.
- Follow the procedure to switch off the device.



SOLUTION TO IMPROVE DRY EYE USING THE tearstim

» STAGE 3

STARTING AND SETTING UP tearstim

• Connect tearstim to its power cord.

tearstim issues three beep sounds; the screen is black **A**. Just press anywhere on the screen to enable all icons to appear **B**. These icons are explained on pages 16 and 17. The display of all menus is temporary. Only the safety icons keep blinking.

• Unlock the safety features **C**.

It is mandatory to validate each safety feature by pressing on each safety icon one by one (the order of validation does not matter).

Once all the safety icons are validated, all the other settings icons for the flash will be available.

If an icon has not been validated, it will continue to blink. You will not be able to set up or use your **tearstim** if all the safety features have not validated.

• Setting up operational modes

- If you bought the device (owner mode):

- ▶ You will have full access to using the device, a code for flash credit is still required.

- If you joined the Connect + program:

- ▶ You will have a commitment with Eswin, a code for days credit is required. The codes for flash credit will be provided for each flash lamp cartridge.

• Setting up your dry eye session.

Simply complete suitable parameters on each flashing icon in order to prepare the dry eye session.

Each and every setting must be configured in order to use **tearstim**. If any of them has not been set, the icon will keep on blinking.



IDENTIFY THE COLOUR OF THE SKIN **D**

Choose the colour of the skin **8** from the lightest (bottom) to the darkest (top).



ADJUST THE DESIRED INTENSITY LEVEL **E**

Press the the filling gauge icon **9** to set up the desired intensity level. The arcs indicates the intensity level or power of issued flash.



Press the intensity level icon until it gradually reaches the desired intensity level. Each time the icon is touched, the energy level is updated accordingly on the alphanumeric display.



The desired setting must be validated using the icon **10** (see picture **F**).



NOTE: Very dark skin is not represented here because it is not compatible with **tearstim**.

SOLUTION TO IMPROVE DRY EYE USING THE tearstim

TEARSTIM READY FOR USE **G**.

Once all settings are validated, the pause icon **11** located on the browsing area becomes visible.

The lamp icon **20** is now blinking, the device is ready to flash.

The signal icon **18** shows the activation card detection. If the icon is on, it means that the activation card has been detected by tearstim.

The area **22** is showing two digits displays, one after another :

➤ The first display shows a 4 digits number representing how many flashes are left on the **tearstim** optic cartridge until it needs to be changed **H**.

➤ The second display shows a 4 digits number preceded by the letter Cxxxx. It represents the number of available flashes left on the activation card **I**.



» STAGE 4

FLASH SESSION

- The **eye mask** should be correctly adjusted on the eyes of the person receiving the session and must be worn throughout the whole session .
- Any beauty spots should be covered using the **patches**.
- Apply the **gel** in a generous layer (minimum 1cm thick) on the cheekbone and the temporal areas, making sure that the **gel** does not get under the **eye mask**.
- Locate your **mask** and put them on. If there are other persons close to you during the operation of **tearstim**, they will also be required to wear **mask** glasses.
- If necessary, use the **stop** plate to mask a substantial area which is not to receive flash (tatoos, beard).
- Position the end 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 button located of the side of the applicator.
- Release the trigger button.
- Move the optical guide to the next area to be flashed, moving from the inner canthus towards the temporal area of the eye.
- Generate the next flash.



The applicator button must not be pressed until the green indicator light is illuminated. If the button is pressed too early (before the green indicator light is illuminated), a flash may not be generated.

NOTE: The **gel**, the self-adhesive **patches**, the guide plate **stop**, the **mask** goggles and the **eye mask** protective shells used must be those supplied with your **tearstim**. The use of any other product may result in the risk of skin burns, and will invalidate the guarantee of your device.



IMPORTANT: No flash should be triggered if the **eye mask** protective shells are not in place. Do not apply **gel** on the area to be flashed until the **eye mask** protective shells are in place on the person benefiting from the session. Under no circumstances should the **gel** penetrate under the **eye mask** protective shells.

SOLUTION TO IMPROVE DRY EYE USING THE tearstim



» STAGE 5

ENDING THE SESSION

- Press key **1**.
- Once the fan located inside the applicator is off (after 10 minutes or so), the power cord can be unplugged. The other fans, located inside the base of **tearstim** will only stop when the device is unplugged.
- Clean the glass tip of the applicator (optical guide) with a damp cloth.
- Finish cleaning the optical guide with the spray clean (images **A** and **B**).



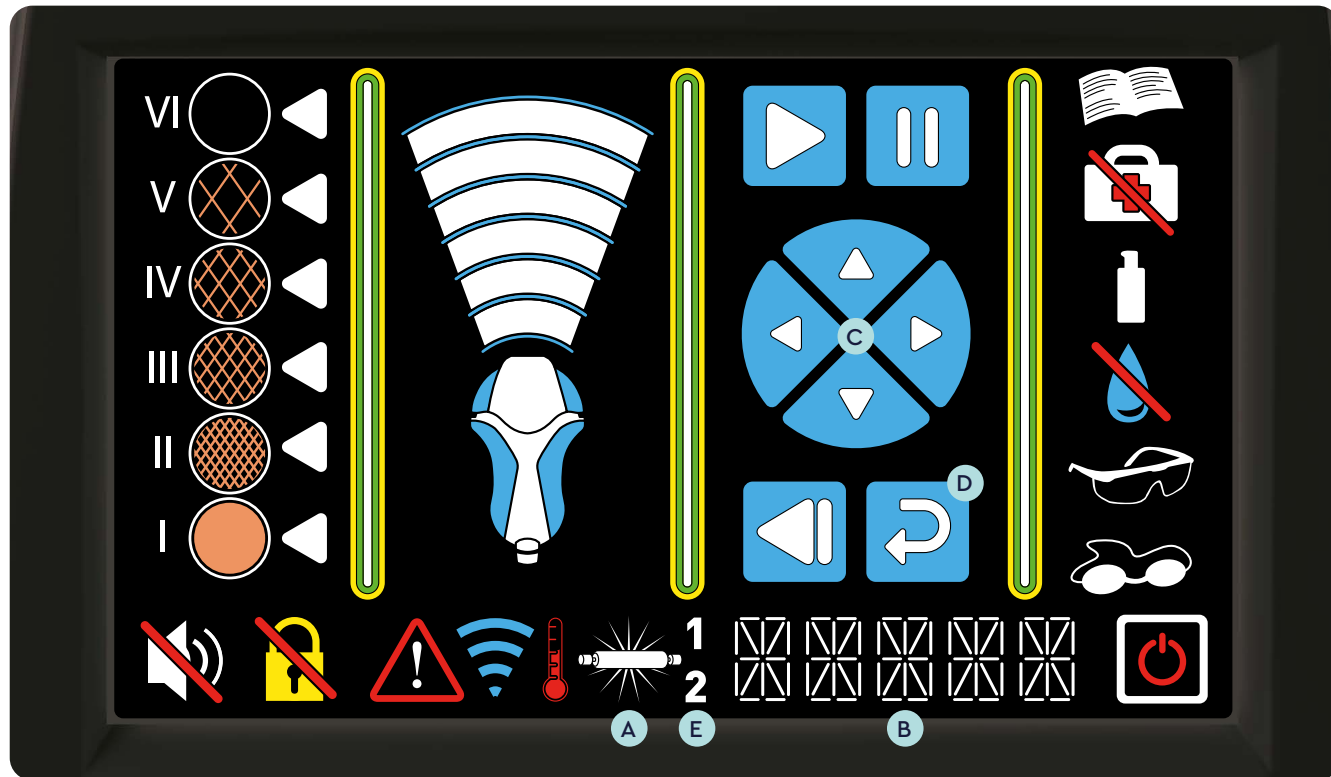
For any intervention after using **tearstim**, you must wait for the fans located inside the applicator to turn off completely. This enables, among other things, the optical parts to cool down. The fans located in the base, for their part, only stop when the device is unplugged.

Once the dry eye programme has started, the device charges itself. Vertical bars scroll at the bottom of the touch screen, from right to left (where icon **22** is located). It also charges after each flash and precedes the display of the number of remaining flashes on the optic cartridge. If the device is idle for 15 minutes, it will automatically go into «pause» mode.



CHANGING THE tearstim OPTIC CARTRIDGE

This step must be performed with utmost caution. Importer handling can result in permanent damage to the applicator and to **tearstim** in a more general way. The warranty does not cover importer handling. We therefore recommend you to be very attentive to the following procedure



INFORMATION IN REAL TIME

- A** Cartridge tube. When it is blinks, it means that you can flash.
- B** All these characters enables you to enter the secure PIN code of **tearstim**, and also to show the remaining number of flashes at any moment.

» STAGE 1

In normal use the remaining number of flashes is displayed in area **B**.

Two counters will be alternately displayed:

- Beginning by the C letter is the number of flashes remaining in the activation card,
- The other counter, beginning by a space, indicates the number of flashes still available in the **tearstim**.

The cartridge tube icon **A** indicates:

- When **tearstim** flash count is higher than 20, the cartridge tube icon **A** lights up.
- When **tearstim** flash counter display is below 20, the cartridge tube icon **A** starts blinking. The cartridge may be replaced and a new cartridge activation code may be entered, or the remaining flash credit can be used entirely.
- When **tearstim** flash counter display reaches 0, the cartridge tube icon **A** lights off and flash emission is no longer authorized.

The cartridge must be replaced and a new cartridge activation code must be entered.

- When **tearstim** activation card counter display reaches 0, the cartridge tube icon **A** lights off and flash emission is no longer authorized. The activation card must be replaced. An activation card is provided with each cartridge.

Note that a new activation code cannot be entered when tearstim flash counter display is higher than 20.

» STAGE 2

Before turning off and unplugging your device, you must wait for the fan located inside the applicator to stop operating completely (this may take several minutes). This procedure enables the optical parts of the applicator to cool down; the other fans located inside the base of **tearstim**, will only stop once the device is unplugged.

» STAGE 3

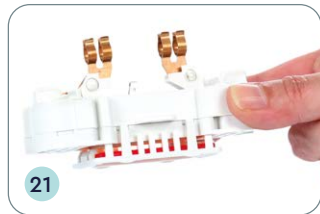
- Turn off the device.
- Unplug the power cord from the device.

CHANGING THE tearstim OPTIC CARTRIDGE

» STAGE 4

REMOVING THE OPTIC CARTRIDGE

- Unscrew mobile head screw 14 with tools and lay onto a flat surface.
- Wiggle the locking part to release it while holding it.
- Press simultaneously both locking tabs of both sides of the mobile head while holding the locking part 15.
- Gently remove the mobile head.
- Carefully place the mobile head and the locking part onto a flat surface 16.
- Once the mobile head is removed, the optic cartridge and its filter are accessible 17.
- To remove the optic cartridge from the applicator: firmly grab the cartridge body part 18 and pull it out 19.



The optic cartridge with filter is now out of the applicator 20, and must only be held by the plastic parts at either end of the optic cartridge 21.



The filter must never be separated from its optic cartridge. Caution: optic cartridge filter may be hot.

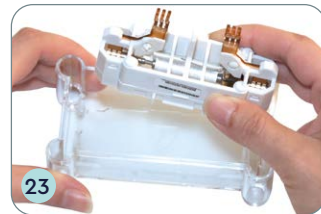
» STAGE 5

RECEPTION OF THE NEW OPTIC CARTRIDGE AND UNPACKING

Remove the new optic cartridge from the plastic box 22 & 23.

» STAGE 6

Before repositioning the mobile head of the applicator, you must always clean the filter (located directly on the optic cartridge) with the spray clean, but use it only on its accessible surface. It is strictly forbidden to spray clean spray directly on the filter. It must be spray beforehand on a clean, dry cloth, and then use this cloth to clean the accessible surface of the filter 31.



NOTE: The cartridges are not symmetrical. They must therefore be inserted in a specific way and not differently. To ensure that it is inserted properly, the cartridge shows a red dot on its side. This red dot must be oriented to match the side of the applicator where the ventilation grid is, also marked by a red dot. Therefore, the two red dots must be aligned. Do not remove the red stickers.

» STAGE 7

INSERTING A NEW OPTIC CARTRIDGE

(video available on your personal client page)

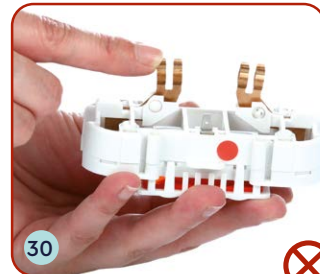
- Take the new optic cartridge and check the direction of insertion of this new cartridge.
- Align the optic cartridge with the applicator using the red dots as guides 24.
- Push it into the applicator slide by pressing down on both sides, to ensure it is held properly 25.
- Once the cartridge is in place, ensure it is aligned with the fixed part of the applicator.



If you twisted the electrodes, do not insert your optic cartridge in your **tearstim** as it may cause serious damage to your device. You will need to send us back the damaged cartridge and order another one.

PRECAUTIONS: During the entire procedure of changing the optic cartridge, you must under no circumstance touch the electrodes of the tube 30. If you accidentally touch the tube or its reflector, we urge you to send us back your cartridge to proceed to an exchange.

- Position the locking part of the applicator before putting back the mobile part of the applicator 26.
- Then, assemble the mobile part of the applicator with the locking part 27. Press down the head towards the applicator by pressing simultaneously both locking tabs of the mobile head 28. Ensure that both parts are tucked securely 29 while making sure to align the internal red dot of the head with the red dot of the applicator. Finally, screw back tightly the locking part screw with a suitable tool.



WARNING: It is strictly prohibited to make any modification of any kind to your **tearstim**.

CHANGING THE tearstim OPTIC CARTRIDGE

» STAGE 8

Re-attach the mobile head by pressing delicately as indicated on image to the right ³².

» STAGE 9

When the number of flashes expires, you must replace the optic cartridge. It will be delivered with its activation card. The warranty does not cover improper handling. We therefore recommend you to be very attentive to the procedure to follow.

» STAGE 10

ENTERING AN ACTIVATION CODE

Register your optic cartridge here:

<https://esw-connectplus.com/#/> and get your optic cartridge activation code.

This code is valid for a **tearstim** serial number and an optic cartridge serial number pair.

The code contains 10 digits in two 5 digits groups.



TO ENTER THE CODE IN THE TEARSTIM:

» STEP 1:

Touch the display area ^B. You will get the following answer:

- The first character is a blinking 0
- The number 1 appear on the icon ^E

You are ready to enter the first 5 digits of activation code.

» STEP 2:

Use the arrow pad ^C to enter the digits

- Up and down arrows allow you to increase and decrease the digit value
- Left and right arrow allow you to go to next or previous digit

» STEP 3:

As soon as you entered the 5 first digit of the activation code, double check the data you entered and validate with the symbol ^D

You will see the following answer:

- The number 2 appear on the icon ^E, meaning that you are ready to input the second part of activation code

» STEP 4:

Enter the last 5 digit of activation code using arrow of icon ^C as per step2

» STEP 5:

Double check the data you entered and validate with the symbol ^D

» STEP6:

If you succeeded entering the code, you will the following answer:

- The **Tearstim** flash counter will be updated
- The Cartridge tube icon ^A is now on.



SOFTWARE OPTIONS

» SOFTWARE OPTIONS

PIN CODE

It is possible to secure your **tearstim** by entering a PIN code. As long as a specific PIN code has not been entered, a red bar will appear on the lock icon (16). This means that the device is not locked; there is no code to enter.

By default, the PIN code is 0000. If you do not act on the PIN, you will not be asked for one when you boot the device. If, on the other hand, you change the default PIN code (0000), you will need to enter the new PIN code each time you restart **tearstim**.

• Change the PIN code

To change the PIN code, you must:

- Click on the lock icon 16. The number 1, located next to the lamp icon 20 will blink: you must therefore enter the first digit of your new code.
- Enter the PIN code (4 digits) with the help of the browsing icons 12. They will enable you to change the digit of each segment (vertical arrows) and to move from one segment to another (horizontal arrows). Once the 4-digit code is entered, validate them by clicking on icon 14. The number 2, located next to icon 20 will blink: you must enter the second digit of your new code.
- Enter your code a second time (confirmation entry) and revalidate (validation icon 14).

When the input is complete, you will automatically go back to the previous menu.

However, if the second code entered is different from the first code, the warning icon 17 will blink and the error message no.14 will be displayed. You must press the validation icon 14 and redo the entire procedure (enter the PIN code, then re-enter the same PIN code for confirmation).

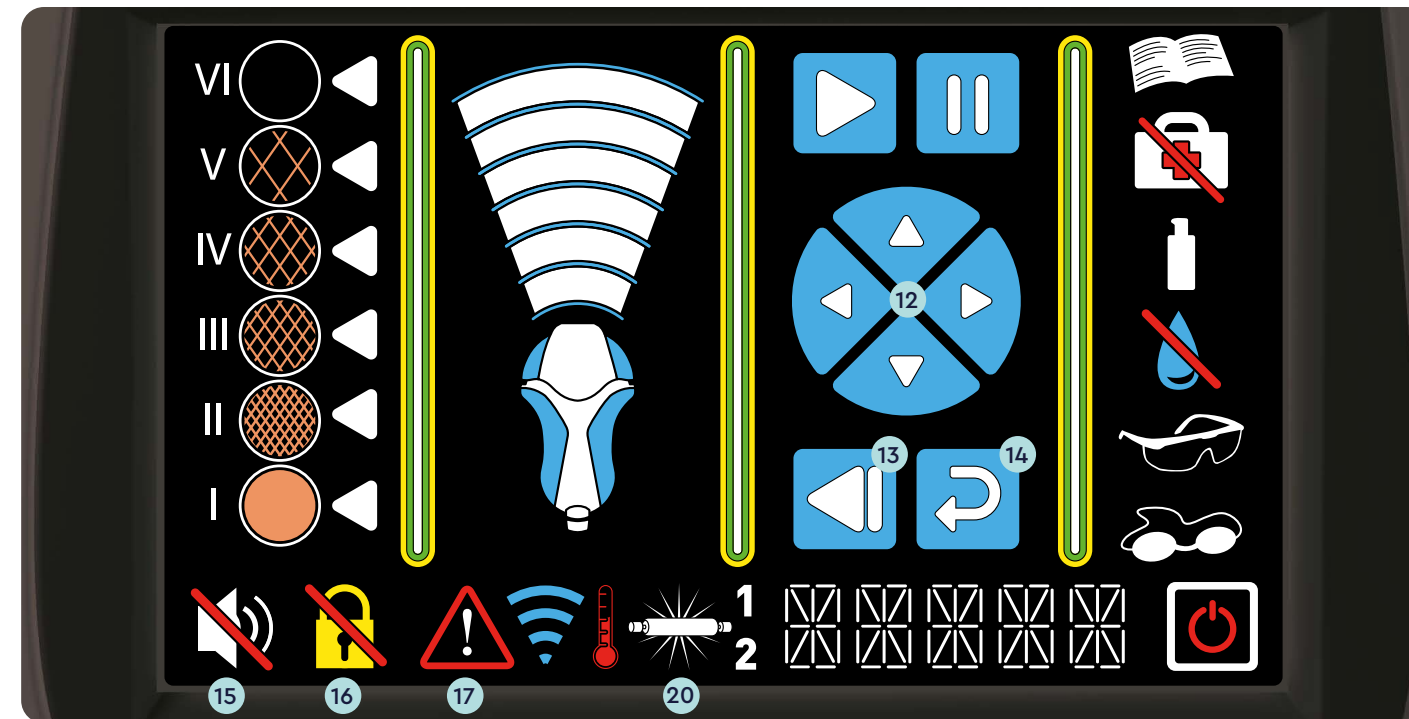
When turning on your device, you will then be asked to enter the PIN code. The unlock icon 16 blinks (it is no longer crossed out by a red line). You must enter the PIN code (only once). If the code is correct, the safety icons will be displayed. If the code is not correct, the warning icon 17 will blink and the error message no.13 will be displayed.

• Disable the PIN code

Disabling the PIN code is possible only when **tearstim** is already running, i.e. the PIN code you want to change has already been entered at start-up. You must then click once on the unlock icon 16, and enter the PIN code once.

• Modify an existing PIN code

Modifying an existing PIN code, while a former code already exists, is possible but only when **tearstim** is already running, i.e. the PIN you want to change has already been entered at start-up. You must click once on the lock icon 16 and enter the current code once, then validate it (validation icon 14). The device is unlocked; the red line on appears the lock icon 16. It is then possible to enter a new PIN code by following the same steps as those described previously.



NOTE: If you have mistakenly selected the lock icon 16, and that you do not wish to enter a personalised PIN code, click on the go back icon 13.

IMPORTANT: If you cannot remember the PIN code you have entered, you must send us back your **tearstim** to allow our technical department to unlock your device. This service is not included in the warranty; you will therefore be billed for it.

BEEP KEYS

By default, the «Beep keys» are activated but it is possible to disable it 15.

PROHIBITED OPTIONS

» HERE IS A LIST OF SOME ACTIONS THAT ARE PROHIBITED WHEN USING YOUR **tearstim** (non-exhaustive)

These actions are prohibited on the grounds that they might expose you to danger or entail the risk of irreparable damage to your device.



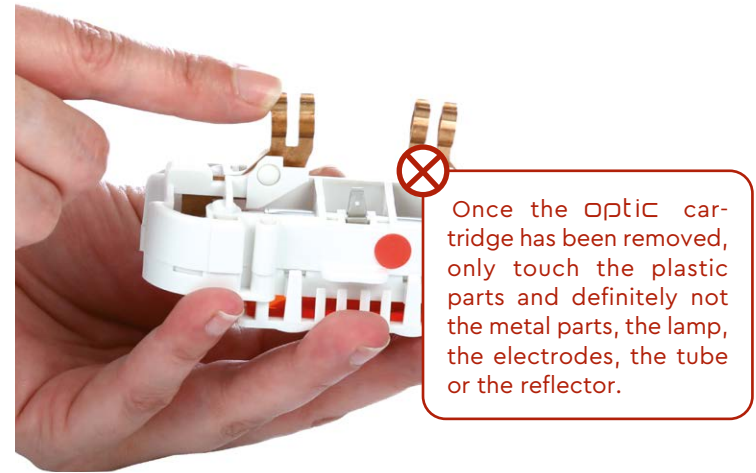
Do not cover the ventilation grid located on the applicator, with your hands or in any manner whatsoever.



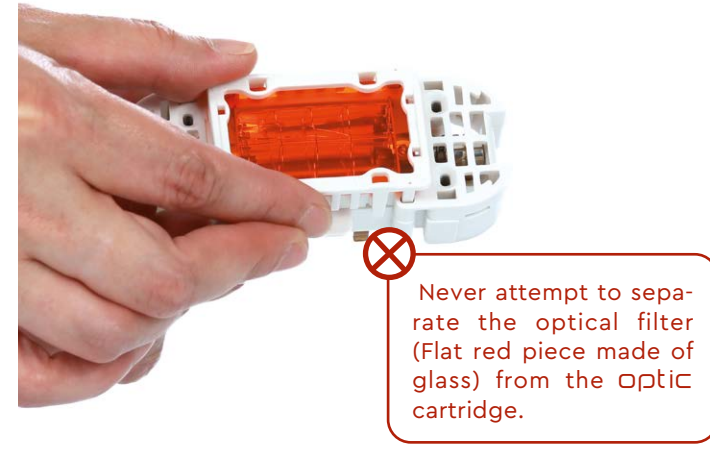
Do not to block the ventilation grid located on the upper part by covering the base of **tearstim** with a cloth.



Do not place the base of **tearstim** on a soft surface (such as a towel) as it will lead to a possible obstruction of the lower ventilation grid.



Once the optic cartridge has been removed, only touch the plastic parts and definitely not the metal parts, the lamp, the electrodes, the tube or the reflector.



Never attempt to separate the optical filter (Flat red piece made of glass) from the optic cartridge.



Never spray clean directly on the optical filter.

! Do not attempt to open your **tearstim** device: all interventions must be carried out by people duly authorised by the manufacturer.
NOTE: Unlike the fans located inside the applicator, the other ones located inside the base of **tearstim**, will only stop when the device is unplugged.

USE OF ACCESSORIES

The **OPTIC** cartridge has a pre-programmed service life which guarantees the consistent quality of light emitted, from the first flash to the very last. The cartridge is supplied together with its activation card. The **OPTIC** cartridge and its card must be replaced once the number of available flashes is expired.



Made in France

OPTIC

The **GEL** must be stored at room temperature. It is used in a very thick layer (5 – 6 mm in thickness), and is applied progressively throughout the session, in order to avoid any drying of **GEL** on the skin. Once used on the skin and subject to flash exposure, the **GEL** must not, under any circumstances, be recovered and used on a different zone. Flash exposure of the **GEL** is liable to result in the modification of its optical characteristics. At the end of the session, it is removed from the surface of the skin using a paper towel or a wet compress. The **GEL** is removed from the optical components and the moving part of the applicator using a damp cloth, followed by the application of the **CLEAN** spray.



Made in Europe

GEL

Active ingredients: Methylisothiazolinone and Methylchloroisothiazolinone (MCI/MI). The content of these ingredients, in a ratio of 3:1, is 0.0008%. Contains no formic aldehydes. Keep out of the light – For external use only. Not to be used on broken, burned or infected skin.

These glasses **mask** must be worn by all persons who are present during flash procedures, in order to prevent dazzling during sessions. After each use, they should be cleaned using the **CLEAN** spray.



Made in China

mask

These protective shells **eye mask** must be worn by persons under procedure, and must be adjusted correctly. They protect the eyes of the person. Disinfect the shells after each session.



Made in China

eye mask

The **SPRAY CLEAN** is used to clean and maintain:

- The optical parts of the mobile head of the applicator:
 - External optical parts: spray directly and wipe with a dry cotton cloth.
 - Internal optical parts: Never spray directly on the internal optical parts. Take a dry cotton cloth and spray on the cloth, and then clean the filter (flat red part made of glass) with this dampened cloth. Finish cleaning with a dry part of the cloth.
- The device's touchscreen: Never spray directly on the touchscreen. Take a dry cotton cloth and spray on the cloth, and then wipe the screen with this dampened cloth. Finish cleaning with a dry part of the cloth.

The **SPRAY CLEAN** must only be used once the device is unplugged and the optical parts are cold.

If you intervene after using the **tearstim**, you must wait for the fan of the device to come to a complete stop before unplugging the base. This enables, among other things, the optical parts to cool down properly.



Made in France

CLEAN

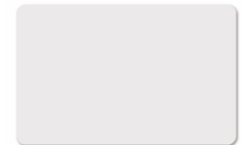
These self-adhesive **patches** are used to mask small areas (such as beauty spots) which are not to be exposed to flashing. The **patches** must be positioned before the gel is applied. It will then be possible to administer flashing to the entire zone, regardless of the presence of beauty spots. **patches** are removed at the end of the session.



Made in France

patches

The **STOP** plate is constructed of a flash-resistant material. It is used to mask an area where flash procedure is not to be applied (for example, tattoos). The glass end of the applicator (optical guide) may also be positioned to overlap the **STOP** plate and the skin.



Made in France

STOP

All these products can be ordered through

the applicable contact for your country.

MAINTENANCE

Check that your **tearstim** is unplugged when you are undertaking its maintenance. If you intervene after using **tearstim**, you must wait for the fan of the device to come to a complete stop before unplugging the base. This enables, among other things, the optical parts to cool down properly.

NOTE: Unlike the fans located inside the applicator, the ones located inside the base of **tearstim** only stop when the device is unplugged.

tearstim does not require periodic maintenance by the manufacturer. There is not sterile part or accessories required for use of the **tearstim**.

» BASE

PLASTIC PARTS

All plastic parts of **tearstim** must be cleaned with a clean cloth, dampened with water (without any additives).

TOUCHSCREEN

The screen must be cleaned with a clean cloth that has been dampened with the spray **clean** (never spray directly on the touch screen).

POWER CORD

Check its perfect condition (must not be pinched or crushed, no bare wires). Clean with a cloth that has been dampened with water (without any additives).

» APPLICATOR

MOBILE HEAD

Cleaning the optical parts (internal and external) of the mobile head with the spray **clean** before and after each use maintains your **tearstim**'s effectiveness. Never spray directly on the internal parts of the applicator.

BODY OF THE APPLICATOR

All plastic parts of the applicator must be cleaned with clean cloth that has been dampened with water (without any additives).

» BASE CABLE TO APPLICATOR

This cable must always stay clean without any visible impairment. You must never bend it strongly or get it stuck. If in doubt about the cable's condition, you must stop using your **tearstim** immediately.

» THE AIR VENTS OF THE BASE AND THE APPLICATOR

The applicator and the base are ventilated. The grids are found on both the applicator and the base, on its lower and upper back part. You must check that all of these grids are clean and that there are no elements likely to clog them.

IMPORTANT: Be careful not to drop liquid into the ventilation grid located on the lower casing.

» STORAGE

- Store your **tearstim** and its accessories in its box.
- Place your **tearstim** in a room where the room temperature does not exceed 25°C (for immediate use), away from excessive moisture (e.g. bathroom) and in a place where it cannot be subjected to vibrations (e.g. placed on a washing machine).
- If the device suffers from an impact, it will be necessary to check the optical parts in their entirety.
- Any visible damage to the optical parts: filter (flat red part made of glass), optical guide, tube, etc. must lead to an immediate cessation of use of the device.

REMINDER:

Storage temperature: -5 ° C to + 65 ° C.

Storage temperature for immediate use: +5 ° C to +25 ° C.

Use and store in a place where the relative humidity is under 93 %.

ASSISTANCE

» TECHNICAL DEPARTMENT

In case of doubt about the use of **tearstim**, contact our technical department. Visit your customer page at www.esw-vision.com and click on "My E-Swin contacts".

» ERROR MESSAGES
















In addition to its own number (see table below), each error message is notified by the blinking of the warning icon **17**.

SCREEN DISPLAY	MEANING	WHAT TO DO?
01	No flash detected.	Contact our technical department. Visit your customer page at www.keepyoureyesfit.com and click on "My E-Swin contacts".
03 04 05 08	Your device is blocked.	Unplug your device and plug it back. If the problem persists, contact our technical department. Visit your customer page at www.keepyoureyesfit.com and click on "My E-Swin contacts".
06 (and blinking of the temperature icon 19)	Temporary blocking.	Wait for the procedure that cools down the optical parts of the applicator to finish.
10 (and blinking of the icon that detects the activation card (18))	Loss of connection with the activation card.	Check that the activation card is present and running smoothly. Re-insert it again.
13	You have inserted the wrong PIN code (when you started the device, the PIN code entered was different to the one previously recorded).	Follow the instructions about entering the code.
14	You have inserted the wrong PIN code (the 2 consecutive PIN codes entered are not identical).	Contact our technical department. Visit your customer page at www.keepyoureyesfit.com and click on "My E-Swin contacts".



MARKING

» MARKING

REF : tearstim	Reference to dry eye solution using the tearstim device.
SN	Unique serial number of your tearstim .
 E-SWIN Rue des Côtes d'Orval ZA de la Prévôté 78550 Houdan - FRANCE	Year of manufacture of your device and address of the manufacturer.
IP 2X	Device protected against solid foreign body of 12,5 mm in diameter or more (IP rating).
	Logo corresponding to a degree of protection against electric shock for parts that are applied onto the person (Part to be applied - Type BF).
	Device must be used indoors.
	Keep the device dry.
	Keep away from light and heat.
	It is compulsory to refer to the instructions in the user manual.
100 - 240 V~ 50-60 Hz 240 VA	Operating conditions - supply voltage (alternating current), frequency of the mains voltage, power.
	Warning, dangerous voltage device.
	Global safety mark for electrical devices.
	Optical radiation aperture
	Respect the upper and lower temperature limits indicated beside this logo.
	Atmospheric pressure Limits.
	Relative humidity Limits.
	Do not use this product after the deadline specified beside this logo (gel).
LOT	The batch number of the product is indicated beside this logo (gel).
	It is compulsory to refer to the instructions in the manual.
	Electromedical Equipment of Class II rating.
MD	This equipment is a medical device.
CE ₀₁₉₇	Complies with mdr eu2017/745 requirements.
UDI	Unique device identifier.

TECHNICAL CHARACTERISTICS

» SPECIFICATIONS

Impact points, specifications	2 cm x 3.75 cm (7,5 cm ²)	
Speed	1 pulse each 2,2 to 5 seconds	
Technology	Intense pulsed light	
Wavelength	>580 - 1200 nm	
Charging time / energy source	Continuous operation	
Dimensions (L x W x H)	270 x 320 x 380 mm max	
Weight	6,5 kg max	
Shipping dimensions (L x W x H)	615 x 325 x 537 mm	
Shipping weight	10,3 kg max	
Noise	83 dBA max	
Electrical installation requirements	100 - 240 VAC	
Maximum power consumption	240 VA	
Frequency	50/60 Hz	
Temperature	Working	+5 to +25°C
	Stockage	-5 to +65°C
Relative working humidity (non-condensing)	30 - 93 %	
Atmospheric pressure	70-106 kPa	

» RECYCLING AND PROCESSING



Instructions for the processing of end-of-life products: the WEEE Directive (Waste Electrical and Electronic Equipment) 2012/19/UE has been implemented to ensure that products are recycled by the application of optimum techniques for processing, exploitation and recycling, thereby contributing to the protection of the environment and human health.

Your product has been designed and manufactured using high-quality products, which are suitable for recycling and re-use.

E-Swin SAS is affiliated to an eco-organization, which undertakes the collection and processing of end-of-life products.

TECHNICAL CHARACTERISTICS

» GUIDANCE AND MANUFACTURER'S DECLARATION

ESSENTIAL PERFORMANCE

tearstim has no essential performance.

RADIO FREQUENCY EMISSIONS

tearstim is equipped with a radio-frequency transmitter at 13.56 MHz in an ASK modulation and at a power lower than 42 dBμA/m.

Radio-frequency transmitter is used to access the activation card, whose internal counter gives the information of the remaining number of flash remaining **before replacement of the flash lamp cartridge**.

ELECTROMAGNETIC EMISSIONS

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

The **tearstim** device is intended for use in the electromagnetic environment specified below.
The user should assure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its radiated emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings uses for domestic purpose.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Passed	

ELECTROMAGNETIC IMMUNITY

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The **tearstim** device is intended for use in the electromagnetic environment specified below.
The user of the device should assure that it is used in such an environment.

IMMUNITY TEST	IEC60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient / burst IEC 61000-4-4	± 2 kV 100 kHz	± 2 kV 100 kHz	Mains power quality should be that of a typical public low voltage power supply network.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical public low voltage power supply network.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT for 0.5 cycle at 0,45,90,135,180,225,270,315° 0% Ut for 1 cycle at 0° 70% for 25/30 cycle at 0° 0% for 250/300 cycle, any angle	0 % UT for 0.5 cycle at 0,45,90,135,180,225,270,315° 0% Ut for 1 cycle at 0° 70% for 25/30 cycle at 0° 0% for 250/300 cycle, any angle	Mains power quality should be that of a typical public low voltage power supply network. If the user of the device requires continued operation during power mains interruption, it is recommended that device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location of a typical location connected to public low voltage power supply network.

NOTE: UT is the ac mains voltage prior to application of the test level.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The **tearstim** device is intended for use in the electromagnetic environment specified below.
The user of the device should assure that it is used in such an environment.

IMMUNITY TEST	IEC60601 TEST LEVEL	COMPLIANCE LEVEL
Conducted RF • IEC 61000-4-6	3Vrms • 150 kHz to 80MHz 6 V for ISM band • 3V/m	3Vrms • 150 kHz to 80MHz 6 V in ISM bands between 150 kHz to 80MHz
Radiated RF • IEC 61000-4-3	80 MHz to 2.7 GHz	3V/m • 80 MHz to 2.7 GHz

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption an reflection from structures, objects and peoples.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast 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 Device is used exceed the applicable RF compliance level above, the Device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Device.

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

TECHNICAL CHARACTERISTICS

ELECTROMAGNETIC IMMUNITY

GUIDANCE AND MANUFACTURER'S DECLARATION – IMMUNITY TO PROXIMITY FIELDS FROM RF WIRELESS COMMUNICATIONS EQUIPMENT

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

TEST FREQUENCY (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	1700–1990	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	2	0,3	28
1845						
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						
5785						

NOTE : 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 1 m test distance is permitted by IEC 61000-4-3.

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

b) The carrier shall 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 worst case.

LIGHT EMISSION

tearstim is classified under risk group 3 related to "thermic retinal" danger.

The inhomogeneity of lighting on the applied surface is below to 20%.

The ocular risk is negligible from a distance, between the eye and the surface of emission, of 7,40 meters.

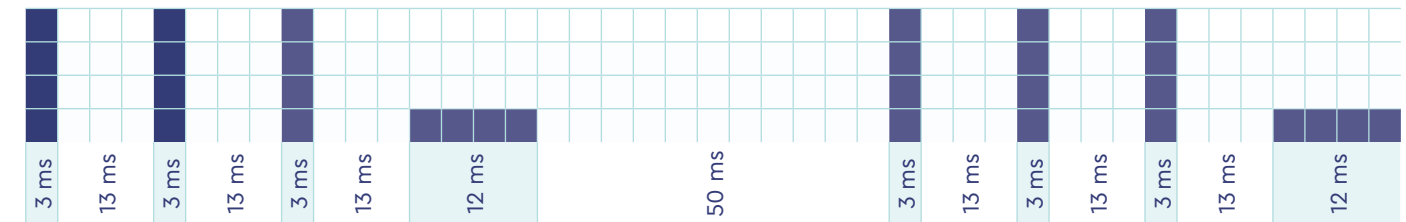
Pulse train overall duration: 170 ms.

Output energy on the flashing area versus user's selection:

ENERGY SETTING	FLUENCE (J/cm ²)
1	9,0
2	9,8
3	10,6
4	11,4
5	12,2
6	13,0

Pulse train contains 8 pulses defined by:

PULSE NUMBER	PULSE DURATION (in ms)	DELAY TO NEXT PULSE (in ms)
1	3	13
2	3	13
3	3	13
4	12	50
5	3	13
6	3	13
7	3	13
8	12	End of pulse train



PRECAUTIONS FOR USE

Never bring the base unit or the applicator into contact with water. Do not open the base unit or the applicator, as you may risk exposure to high voltages. Never use cartridges and accessories other than those designated and sold by E-Swin SAS for use with the **tearstim**.

ENVIRONMENTAL PROTECTION

You must abide by local regulations for the disposal of packaging and consumables. Insofar as possible, recycling should be encouraged.

Your device is guaranteed for professional use.

The term of this guarantee is associated with legislation in force in each country.

Any error in connection, any incorrect handling, any use of the device other than for dry eye procedure and, in general, any use of the device which fails to observe the conditions described in this manual will invalidate the guarantee.

The company E-Swin SAS will not accept liability for any accident arising from failure to observe the instructions contained in this manual, or from differences in the information provided by the labelling or the touch screen of **tearstim**.

The manufacturer's guarantee for parts and labour will only be valid if the device is returned in all the items of its original packaging (boxes, packing blocks, etc.).

All the packaging in which your **tearstim** was supplied should therefore be carefully stored.

CONTACT



For more information contact: contact@esw-vision.com
or visit: www.KeepYourEyesFit.com

E-SWIN

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www.Keepyoureyesfit.com