



USER MANUAL

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Dear Customer,

Thank you for choosing **tearcheck**, a revolution in Tearfilm Analysis. You have decided for a new standard of technology, developed and manufactured by E-Swin in France. Following the standards of our ISO13485 certification and the medical guidelines of directive 93/42/EEC, you will discover a product of high quality and performance.

Efforts are changing, and ease-of-use together with highly efficient exams and reliable results will set up new standards in your daily work with **tearcheck**. You will enjoy evaluating the tearfilm quality of your patients' eyes within a few minutes only.

You have my personal assurance, that the greatest care has been taken in the manufacturing of each **tearcheck**. Discover the convenience of use, when you start using **tearcheck**.

I hope that **tearcheck** will fully satisfy you and that you will choose to share your experience with us on our website www.keepeyeyesfit.com

With sincerest regards,

A handwritten signature in grey ink that reads "Yves Vincent". The signature is written in a cursive style and is positioned above the printed name and title.

Dr. Yves Vincent BROTTIER
Creator of **tearcheck**

OVERVIEW

tearcheck is intended for Dry Eye Symptom exploration and shall be used by professionals authorized according to the regulations of the country in which it is used.

» **tearcheck** PROVIDES THE FOLLOWING EXAMS

1. ABORTIVE BLINKING

In the abortive blinking examination, the blink pattern of all blinks is analysed over the duration of the examination (1 minute). This allows incomplete blinks to be detected, which may be the cause of incorrect tear film distribution on the ocular surface and deficient lipid secretion due to lack of pressure on the meibomian glands. As well the complete number of blinks per minute (blink rate) is calculated within the exam and displayed with the result.

2. EYE REDNESS – CONJUNCTIVAL HYPERHEMIA

This examination

- consists of images of the bulbar and palpebral conjunctiva.
- improves the contrast to improve the visibility and legibility of the superficial vascularization.

This examination will in particular make it possible to assess the hyperemia induced by the inflammatory phenomena consecutive to dry eye syndrome and to follow its evolution over the treatments delivered to the patient.

3. DEMODEX

The Demodex exam consists of an enlarged image capturing the base of the eyelashes.

The magnification factor of the image does not in itself allow direct visualization of the parasites, but it does make it possible to find and visualize the signs of the presence of the parasite.

4. NIBUT / TFSE

This examination is intended to assess the stability of the tear film.

NIBUT and TFSE are a combined exam and use the same imaging.
This exam requires the line mask to be present on the device.

4 steps will follow one another for data acquisition:

STEP 1 The patient, on the practitioner's order, must blink twice.

STEP 2 Data acquisition begins the moment the eyelids open. The patient should try to keep their eyes open for the duration of the acquisition.

STEP 3 The acquisition stops after 10 seconds or if the patient blinks before this time.

STEP 4 The practitioner then launches the calculation procedure on the basis of the acquired data. The results are then displayed on the screen.

NIBUT shows where and when the surface of the tear film ruptures. During the 10 second imaging, **tearcheck** evaluates the tear film surface 3 times per second. For better readability, the results are then grouped into 2 second increments. In addition the break-up time is calculated and displayed.

TFSE makes it possible to assess the micro-deformations appearing on the surface of the tear film. These micro-deformations reflect instability of the tear film. They are presented in number and in intensity.

During the 10 second imaging, the tear film of a healthy eye will show very few movements of low intensity. The eye of a patient with dry eye syndrom, that is linked to a deficiency of the lipid tear film component, shows higher micro-deformations the higher the deficiency is.

At the same time, the evolution of frequency and intensity of these micro deformations is observed over the entire imaging period.

In the end, it thus becomes possible to group patients into 4 categories:

CATEGORY 1 Healthy patient. Very few micro-deformations and low intensity.

CATEGORY 2 Patients with a significant number of micro-deformations but grouped towards the end of the 10 seconds of acquisition. No matter the intensity.

CATEGORY 3 Patients with micro-deformations of early onset but evolving very little over the rest of the acquisition time of 10 seconds

CATEGORY 4 Patients with micro-deformations of early onset and whose number and intensity will increase over the duration of acquisition.

Generally, the higher the category, the greater the lipid deficiency. Consequently, category 4 patients will be those who present the most significant discomfort and whose evolution over time will be the most unfavorable in the absence of treatment.

In summary, compared to NIBUT, the TFSE will allow us to see the fine evolution of the behavior of the tear film over time. In other words, NIBUT presents the major events appearing on the surface of the tear film (rupture) and the TFSE shows the finer nuances of the surface of the tear film.

The TFSE therefore remains a much richer examination than the classic NIBUT.

The evolution of this examination will be particularly interesting to follow during the different stages of the treatment.

OVERVIEW

5. MEIBOGRAPHY

Meibography makes it possible to visualize the Meibomian glands.

The exam is done in 5 steps:

- STEP 1** Taking an IR photograph of the inner side of the lower or upper eyelid (after flipping the eyelid).
- STEP 2** Once the image has been captured, the user will mark the area where Meibomian glands are present on the screen.
- STEP 3** The Meibomian glands are automatically detected within the selected area.
- STEP 4** The practitioner remains free to adjust the proposed result by adding or subtracting areas of the image where he considers that the Meibomian glands are present or not (refining step).
- STEP 5** The image is analyzed and a ratio is established between the area represented by the glands and the overall area of the selected area.

The results are shown through two parameters:

- The rate of loss of the glands compared to an individual with all the glands present.
- The morphology of the glands present.

Note that the accuracy of this examination is determined by the selections made by the practitioner as well as by the refinement.

6. OSIE (Ocular Surface Inflammatory Evaluation)

This exam takes place in 7 steps:

- STEP 1** The practitioner will instill fluorescein on the surface of the eye.
- STEP 2** Before the examination starts, one must wait 120 seconds.
- STEP 3** An image is captured in blue light.
- STEP 4** The cornea + bulbar conjunctiva is delimited by the practitioner on the screen.
- STEP 5** The calculation is launched and the device automatically recognizes areas with residual fluorescein.
- STEP 6** The practitioner can refine the result by using the 2 cursors on the screen.
- STEP 7** A ratio between the total surface selected and the surface of the fluorescent zones is established.

The principle of this examination resides in the fact that fluorescein will remain «attached» to areas of the eyeball exhibiting surface alteration in connection with an inflammatory process in the case of dry eye syndrome.

The evaluation of these inflammatory zones is carried out 120 seconds after instilling fluorescein, the time necessary for its natural elimination through the tear ducts:

- In a healthy patient, fluorescein will have disappeared from the surface of the eyeball. There will be 0% of surface presenting a residual fluorescence.
- In a patient with dry eye syndrome, the older the condition, the more the surface of the eyeball is suffering. The fluorescein will "materialize" these suffering zones by remaining fixed there beyond 120 seconds after instillation.

The accuracy of this examination is determined both by the selections made by the practitioner but also on the use of the adjustment sliders.

7. TEAR MENISCUS

This examination takes place in 4 stages and follows the OSIE examination:

STEP 1 A residual of the fluorescein instilled during the examination of the OSIE is present at the level of the lacrimal meniscus. A photographic acquisition of the meniscus area is carried out.

STEP 2 An identification of the meniscus area is carried out by the practitioner by marking the area on the screen.

STEP 3 The periphery of the iris is identified on the screen, its actual diameter being an input data previously evaluated by the practitioner.

STEP 4 The value of the thickest measurement and the measurement below the iris centre are thus established.

The accuracy of this examination depends on the reliability of the value of the diameter of the iris entered by the practitioner.

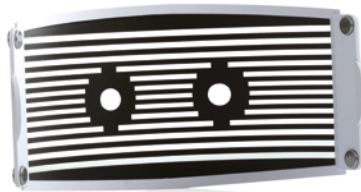
8. EYE FITNESS TEST

The Eye Fitness Test is a questionnaire intended to be filled in by the patient. It provides an overview of the patient's eye fitness in everyday life.

PACKAGE CONTENT tearcheck



tearcheck (table-version)



tearcheck line mask
(magnetic clip-in)



tearcheck eyelid flipping tool

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 **tearcheck** was delivered should therefore be carefully stored.



digital pen



power supply



power cord



clean spray



user manual

GLOSSARY





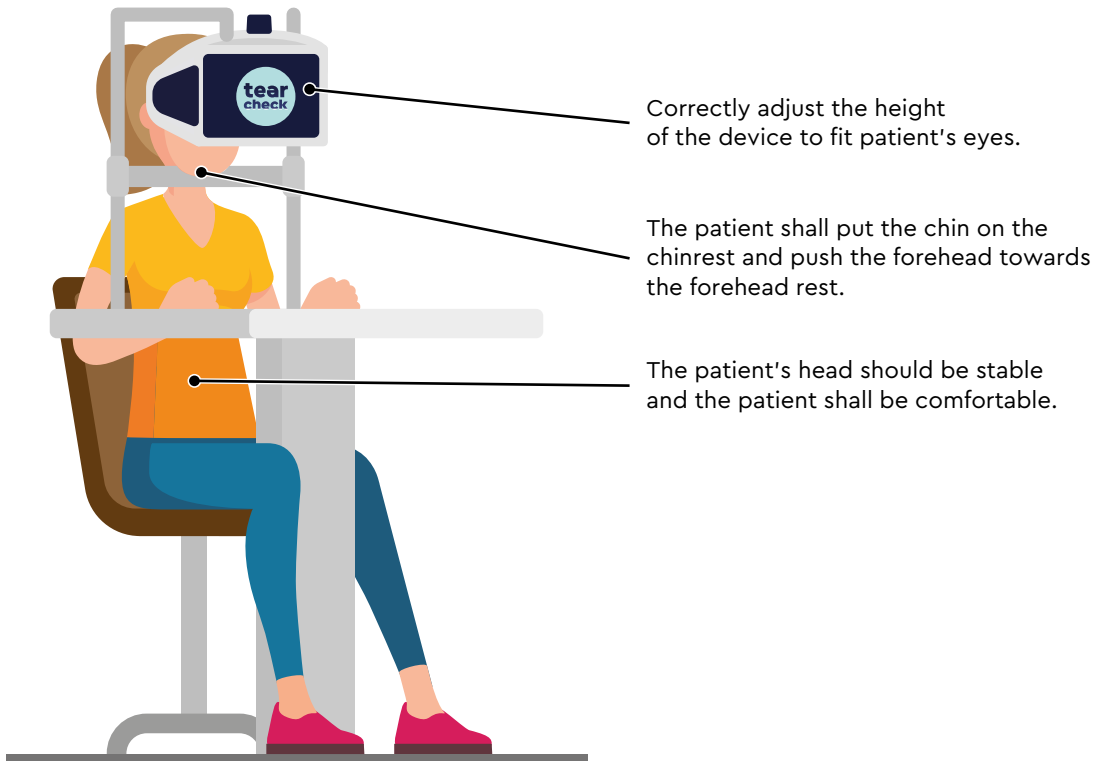


USING tearcheck

Before using **tearcheck**, read the following information carefully to ensure correct, easy and comfortable use.

» BEFORE EACH USE

INSTALL THE PATIENT



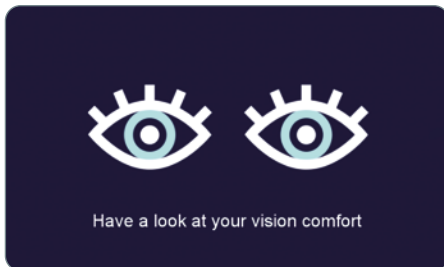
» STARTING **tearcheck**

STEP 1

Connect **tearcheck** to an external power supply.

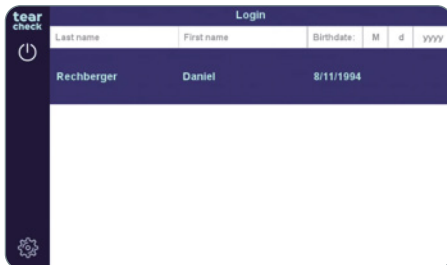
Connect the power supply to mains by using the power cord provided with the device.

tearcheck will start automatically.



STEP 2

Wait for the device to initialize.



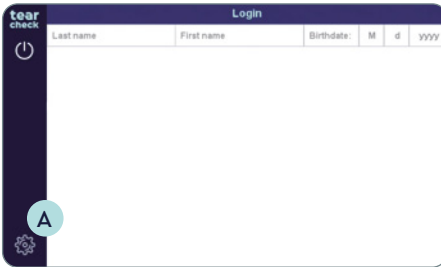
STEP 3

Login to the device by selecting the user.

-> Follow the instruction for FIRST USE on page 16.

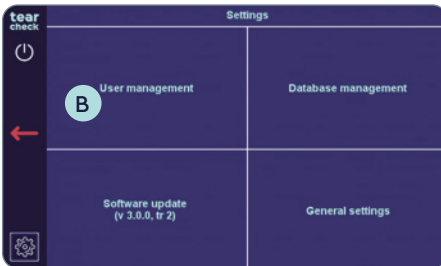
USING tearcheck

» FIRST USE



STEP 1

Press **Settings** **A** to open the Administration menu.

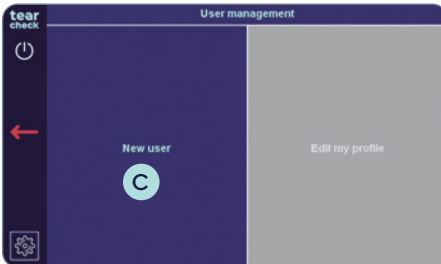


STEP 2

USER MANAGEMENT

At first use, there is no operator registered on the device. To start an examination, at least one operator must be created:

- Choose **User Management** **B**.



- Choose **New User** **C**.

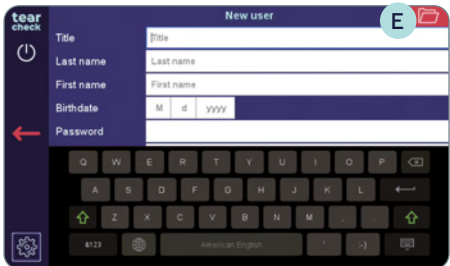
NOTE: Edit my profil is not accessible.



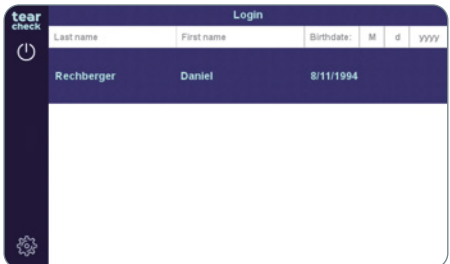
- Create a new operator by filling in the information fields in the **New User** menu.



NOTE: A virtual keyboard will appear when you touch a field **D**.



- Validate the operator creation by clicking on the **upper right icon** **E**.

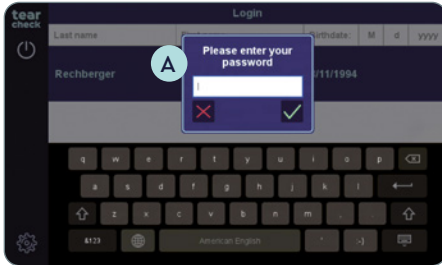


- The new operator will appear in the operator list.

USING tearcheck

» LOGIN

To use the device, an operator must be selected.

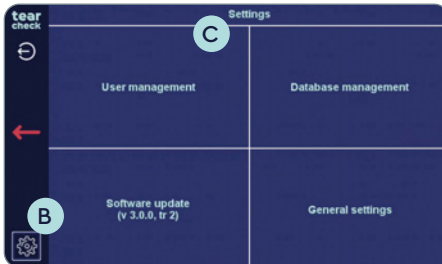


- Choose your name in the operator list; the **password** **A** must be entered.

NOTE: The header fields of the operator list allow to filter operators by lastname and/or firstname and/or birthdate.

» MANAGE YOUR PROFILE

Once you are logged in, you can manage your current profile.



STEP 1

- Go to **Settings** **B** and choose **User Management** **C**.



- Choose **Edit my profil** **D** (it is now accessible).

STEP 2

- Change title, last name, first name or birthdate if necessary.
- **Upload logo** **D** to customize reports.
- Validate the changes by clicking on the **upper right icon** **E**.

» PATIENT MANAGEMENT

When logged in, the operator can access the **patient management menu**.

You can start your examination by entering a New Patient, by selecting a Registered Patient or by using Anonymous Patient.

- Select **New Patient** **G** to create a new patient.

- Create a new patient by filling in the information fields in the **New Patient** menu.

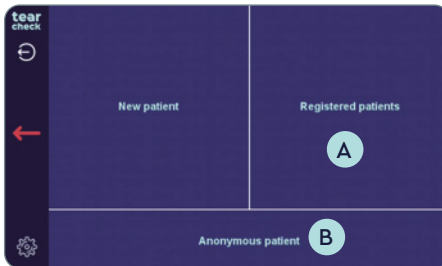
NOTE: Last name, first name and birthdate are mandatory.

- Validate the patient creation by clicking the **upper right folder icon** **H**. The patient is now listed in Registered Patients.

USING tearcheck

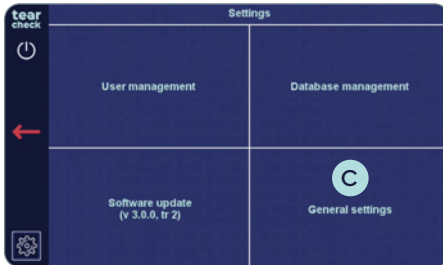
Last name	First name	Birthdate	M	d	yyyy
Caglar	Selin	2/6/1994			
Brenner	Victoria	2/16/1978			
Bruckmüller	Petra	6/23/1969			
Doe	Jane	1/1/2000			

- In the **Registered patients** list, all patients and operators will be displayed.

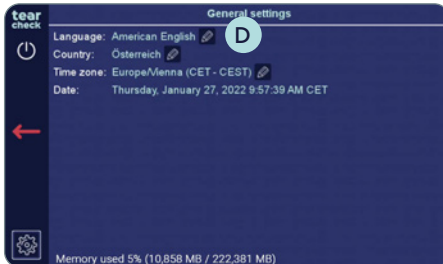


- Select **Registered Patient A** to start the examination of a patient already existing in your database.
- Select **Anonymous Patient B** if no patient information shall be registered. In this case also the report will not be stored at the end of the session.

» LANGUAGE SETTINGS



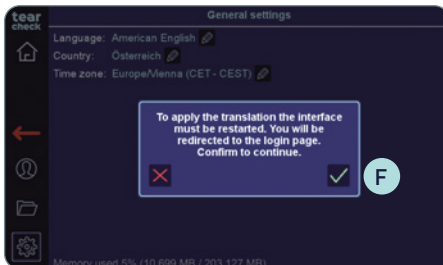
- Go to Settings and choose General settings **C**.



- Click on the pencil next to the currently selected language **D**.



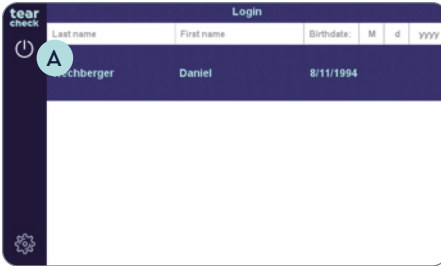
- Choose the language **E** you wish.



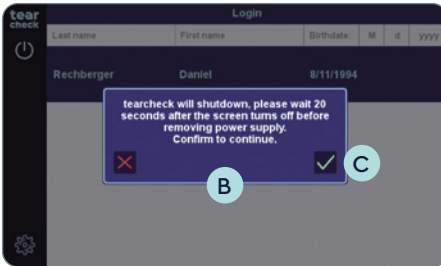
- A pop-up appears, telling you that the device will restart the interface to apply the translation. Confirm with the green check mark **F**. No further user interaction is required.

USING tearcheck

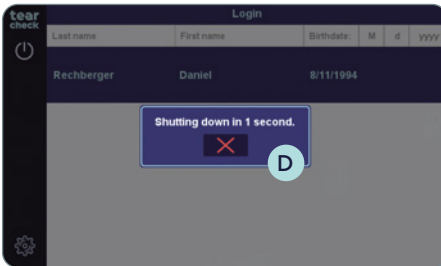
» SHUTTING OFF THE DEVICE



- Click on the power symbol **A** on the left.



- A pop-up **B** appears, telling you that **tearcheck** will shut down.
- Confirm with the green check mark **C** to shut down.

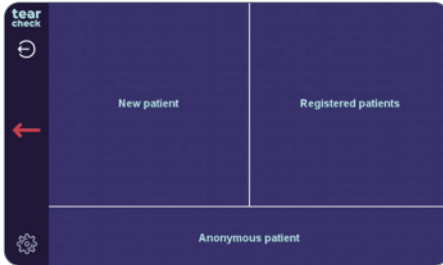


- The pop-up **D** tells you that the device will shut down in a few seconds.
- You must wait 20 seconds, before unplugging the device, after the screen turned black. If the device is unplugged too quickly, it may not be able to restart properly.



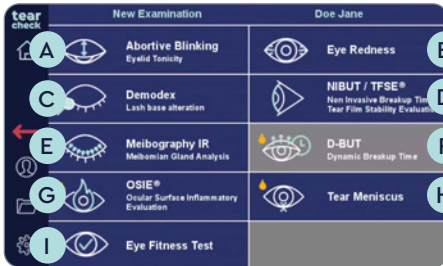
tearcheck EXAMINATIONS

» EXAMINATION MENU



After choosing a patient, an operator can access the examinations. The information on top of each screen will guide you through each exam.

NOTE: Examinations, which are displayed in gray, are not yet accessible. Any new examinations will be provided through regular software updates. More information on how to update your software can be found on page 57.



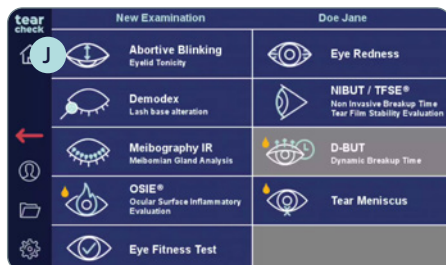
The following exams are available:

- Abortive Blinking **A**
- Eye Redness **B**
- Demodex **C**
- NIBUT / TFSE® **D**
- Meibography IR **E**
- D-BUT * (not yet accessible) **F**
- OSIE® * **G**
- Tear Meniscus * **H**
- Eye Fitness Test **I**

* fluorescein used for this exams

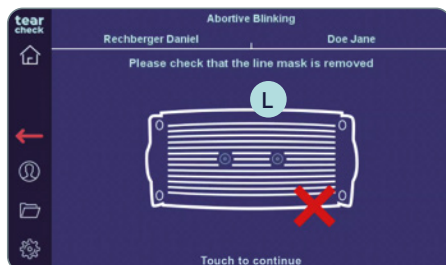
» ABORTIVE BLINKING

The exam analyses the blinking pattern of all blinks over the period of 60 seconds to determine complete and abortive blinks and also the full number of blinks per minute (blink rate).

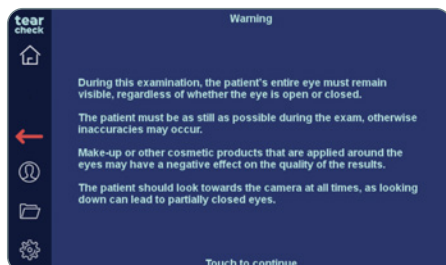


STEP 1

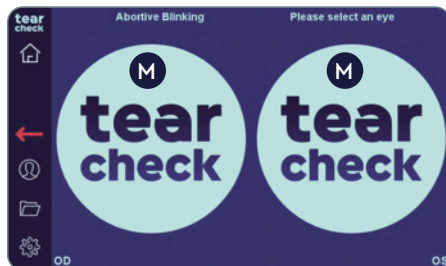
- Select Abortive Blinking examination **J** in the examination menu.



- Ensure that the **LINE MASK K** is removed (follow the instructions on the top of the screen), then click on the screen **L** to start.



- The instructions on the screen explain the procedure that needs to be followed.

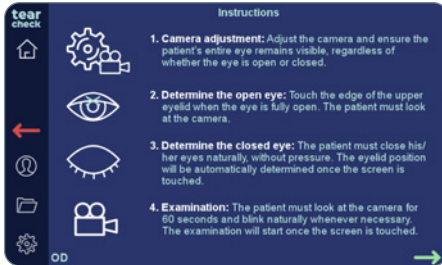


STEP 2

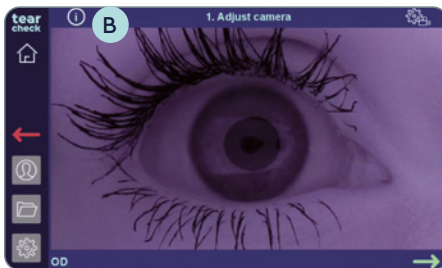
- Select the right or left eye and start the exam by clicking on the **tearcheck** logo **M**.

NOTE: The **tearcheck** logo will appear, if no examination has been done yet.

tearcheck EXAMINATIONS



- The individual steps of this examination are explained in detail on this page.



STEP 3

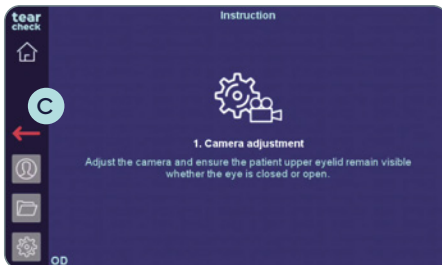
CAMERA ADJUSTMENT

- After choosing an eye (OD = oculus dexter – right eye / OS = oculus sinister - left eye), adjust the camera and ensure the patient's entire eye remains visible, regardless of whether the eye is open or closed.
- The image can be adjusted by using the focus wheel **A** on top of the device.
- The detailed instructions for the current step can be reviewed by clicking on the info-button **B** on the top-left.





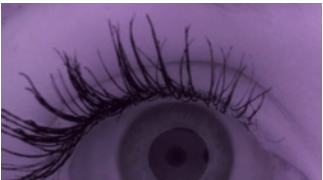

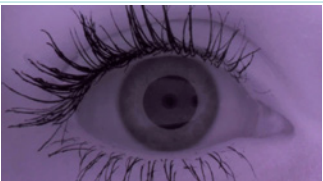
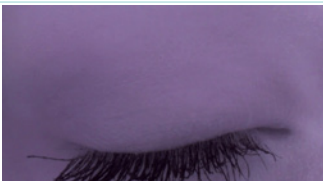
NOTE: Detailed instructions on the camera adjustment (positioning and focusing) can be found on the next page.



- To close the detailed instruction page, click anywhere on this page or click on the red arrow **C** to get back.



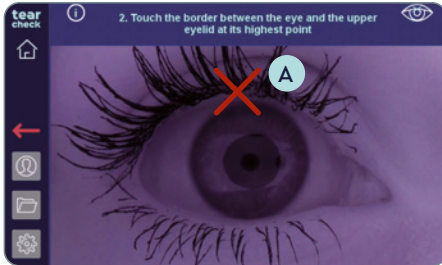
CAMERA ADJUSTMENT: POSITIONING

OPEN EYE	CLOSED EYE	SUITABLE	REASON
		NO	Eye is too far on one side, the eyelid will be difficult/impossible to detect.
		NO	Eye is too high and there's too much space below the eye, the user can't touch the border between the eye and the upper eyelid.
		NO	Eye is too low, the eyelid will be difficult to detect, when the eye is fully closed.
		YES	Good centering, the eyelid remains visible whether the eye is closed and or open AND there is some margin below the eyelid when the eye is closed.

CAMERA ADJUSTMENT: FOCUS

The eyelid must be as sharp as possible. However, this examination is rather tolerant to a bad focus, as long as the patient is positioned correctly.

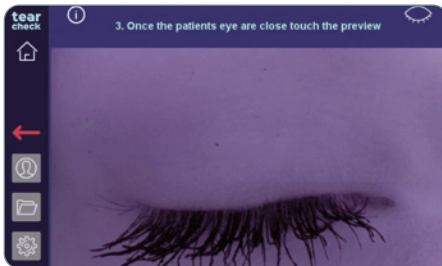
tearcheck EXAMINATIONS



STEP 4

DETERMINE OPEN EYE

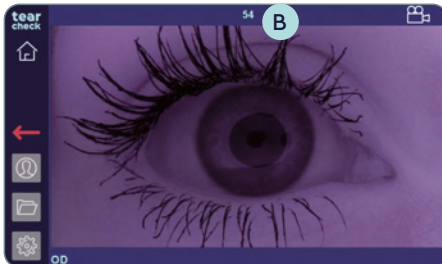
- Touch the edge of the upper eyelid when the eye is fully open, to mark the open eye (see red cross in the picture) **A**. The patient must look at the camera.



STEP 5

DETERMINE CLOSED EYE

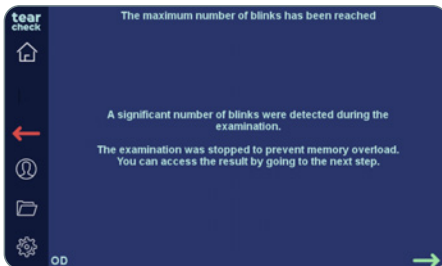
- The patient must close his/her eyes naturally, without pressure. The eyelid position will be automatically determined once the screen is touched.



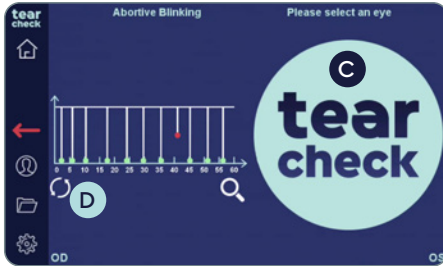
STEP 6

EXAMINATION

- The patient must look at the camera for 60 seconds and blink naturally whenever necessary. The examination will start once the screen is touched.
- The timer **B** on top shows the remaining time.



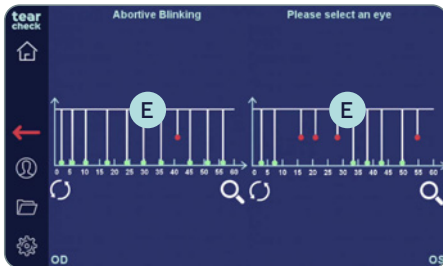
- The examination will stop, if too many blinks are detected. If this situation occurs an appropriate warning is displayed.
- The analysis screen and/or the results screen are also accessible if the examination has not taken the entire 60 seconds.



STEP 7

- Continue with the second eye by clicking on the **tearcheck** logo **C**, or restart the examination of the first eye by clicking on the redo-button **D** below the image of the eye.

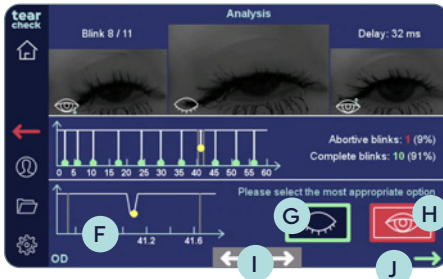
NOTE: The examination result is not yet stored.



STEP 8

ANALYSE EXAM

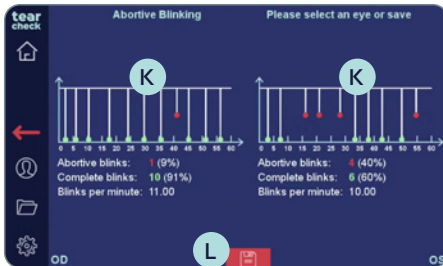
- If abortive blinks have been detected, they need to be re-checked and confirmed. Click on one of the graphs **E** to get to the analysis screen.
- If no abortive blinks have been detected, the result will be available immediately.
- The graph on the bottom **F** shows the currently selected blink in more detail.
- Select completed blink (green button) **G** or abortive blink (red button) **H** for the currently selected blink.
- Switch between the blinks with the white arrows **I** on the bottom centre or select a blink by clicking on one of the points in the upper graph (only the abortive blinks are accessible).
- After reviewing and confirming abortive or completed blinks the analysis can be confirmed by clicking on the green arrow **J**.



STEP 9

RESULT OF ANALYSIS

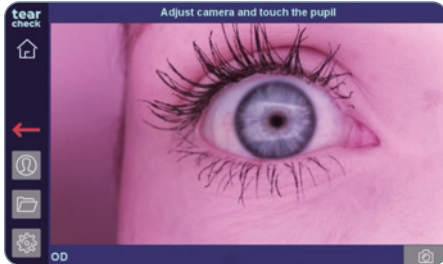
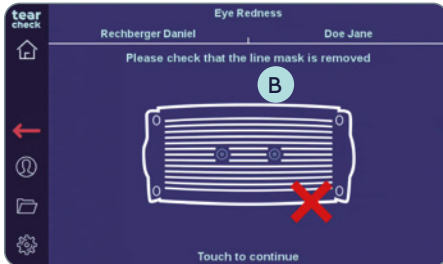
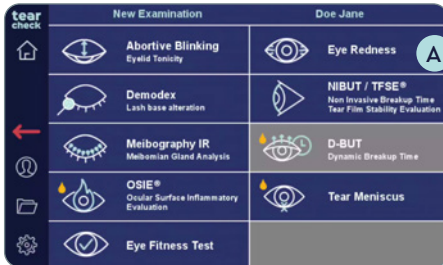
- The examination results for both eyes are shown by a graph and by numbers. The result for one eye can be displayed in full-screen by clicking on one of the result previews **K**.
- Save the examination results of the patient by clicking on the disk icon **L**.



tearcheck EXAMINATIONS

» EYE REDNESS

Eye Redness is detected by displaying the small vessels on the ocular surface.



STEP 1

- Select **Eye Redness** **A** examination in the examination menu.

STEP 2

- Ensure that the **LINE MASK** **C** is removed (follow the instructions on the top of the screen), then click on the screen **B** to start.

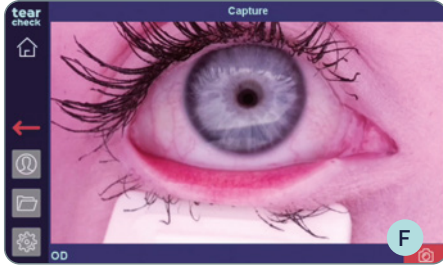


- Select the right or left eye and start the exam by clicking on the **tearcheck** logo **D**.

NOTE: The **tearcheck** logo will appear, if no examination has been done yet.

STEP 3

- After choosing an eye (OD = oculus dexter – right eye / OS = oculus sinister – left eye), **click on the patient's eye** to adjust the image.

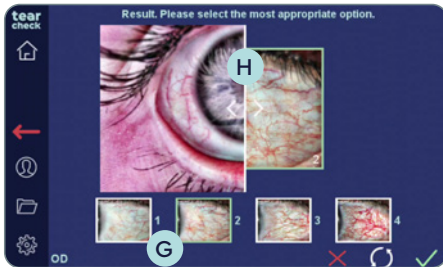


- It is recommended to use the **EYELID FLIPPING TOOL** **E** to pull down or flip the eyelid. This can help to achieve even more revealing results.
- **Capture the image** of the eye by clicking on the red camera icon **F**.



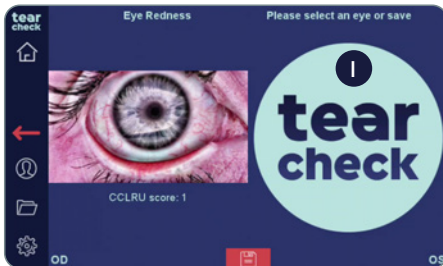
STEP 4

ANALYSIS OF EXAM

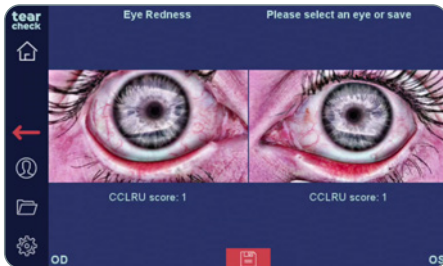


- Select the most appropriate option (1-4) for the captured image based on the reference images **G**.
- The reference images can be enlarged by clicking on an image and moving the vertical bar **H** to the left.
- Confirm the selection by clicking on the green arrow, restart the capture by clicking on the redo-button, or delete the image by clicking on the red cross.

NOTE: The examination result is not yet stored.



- **Continue with the second eye** by clicking on the **tearcheck** logo **I**.



STEP 5

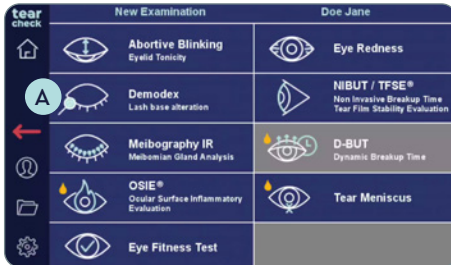
RESULT OF EXAM

- **Save** the examination results of the patient by clicking on the disk icon **C**.

tearcheck EXAMINATIONS

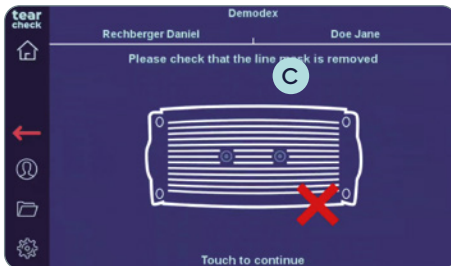
» DEMODEX

The **Demodex** detection is displayed by a zoom image of the eye lashes on the edge of the eyelids.



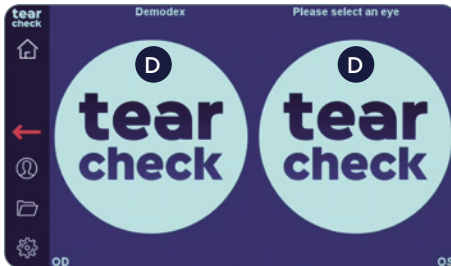
STEP 1

- Select **Demodex** A examination in the examination menu.



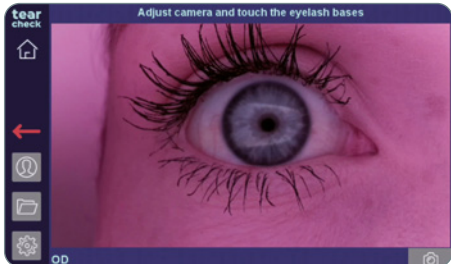
STEP 2

- Ensure that the **LINE MASK** B is removed (follow the instructions on the top of the screen), then click on the screen C to start.



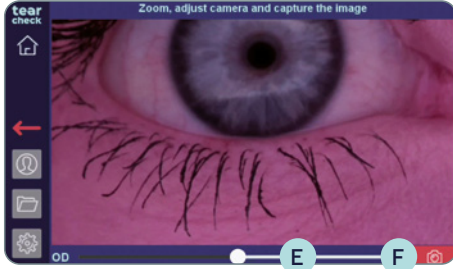
- Select the right or left eye and start the exam by clicking on the **tearcheck** logo D.

NOTE: The **tearcheck** logo will appear, if no examination has been done yet.



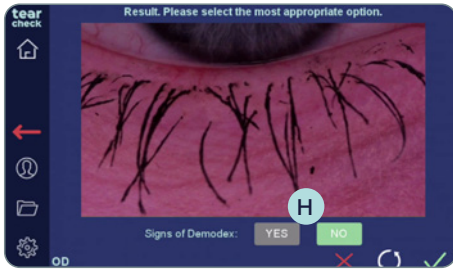
STEP 3

- After choosing an eye (OD = oculus dexter – right eye / OS = oculus sinister – left eye), **click on the patient's eye** to adjust the focus.



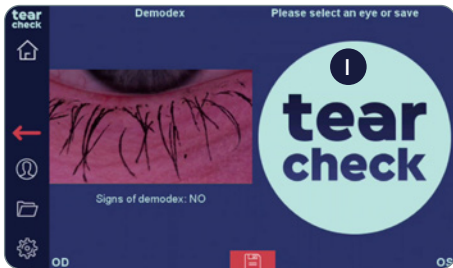
STEP 4

- Use the slider **E** on the bottom to zoom, adjust the image and **capture the image of the eye** by clicking on the camera icon **F**.
- The image can be adjusted by using the **focus wheel G** on top of the device.

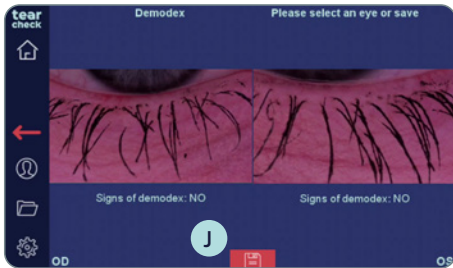


STEP 5

- **Select YES or NO H**, depending on visible signs of Demodex in the captured image.
- **Confirm the selection** by clicking on the green arrow, restart the capture by clicking on the redo-button, or delete the image by clicking on the red cross.



- **Continue with the second eye** by clicking on the **tearcheck** logo **I**.



STEP 6

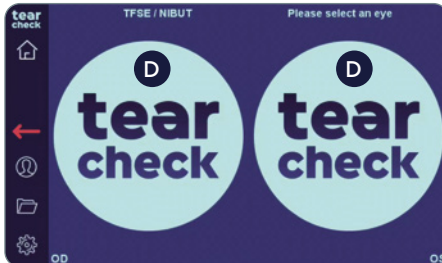
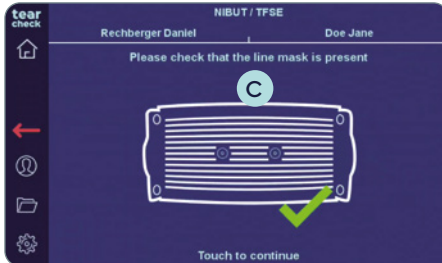
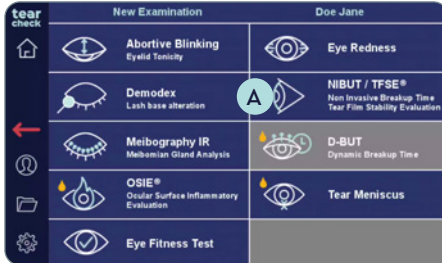
RESULT OF EXAM

- **Save the examination results** of the patient by clicking on the disk icon **J**.

tearcheck EXAMINATIONS

» NIBUT / TFSE®

Tearfilm Stability Evaluation (TFSE®) and **Non-Invasive Break-up-Time (NIBUT)** are a combined exam for which a 10 second video of each eye is taken.



STEP 1

- Select **NIBUT/TFSE®** **A** examination in the examination menu.

- Ensure that the **LINE MASK** **B** is present (follow the instructions on the top of the screen), then click on the screen **C** to start.



STEP 2

- Select the right or left eye and start the exam by clicking on the **tearcheck** logo **D**.

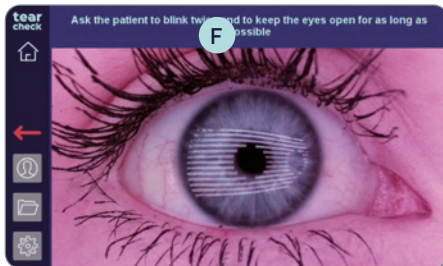
NOTE: The **tearcheck** logo will appear, if no examination has been done yet.

STEP 3

- After choosing an eye (OD = oculus dexter – right eye / OS = oculus sinister – left eye), **click on the patient's pupil** to adjust the image.

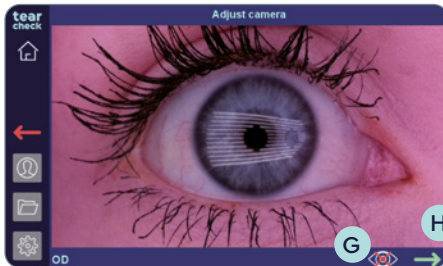


- The image can be adjusted by using the **focus wheel E** on top of the device.



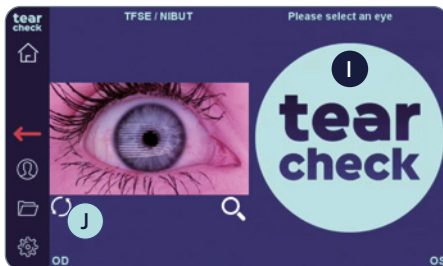
STEP 4

- Instruct the patient to **blink twice to start** the recording automatically.
- A timer **F** starts counting down from 10 to 0 during the recording of the exam.



- Start the recording manually by clicking on the **eye icon G** on the bottom of the screen and then on the **green arrow H**, if the blinking cannot be detected.

NOTE: The recording stops in both cases after 10 seconds, or if the patient blinks during the exam. The recorded eye is then shown in the exam menu.

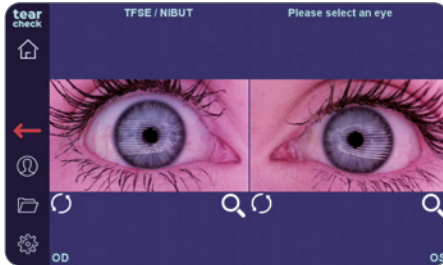


STEP 5

- **Continue with the second eye** by clicking on the **tearcheck logo I**, or **restart** the examination of the first eye by clicking on the redo-button **J** below the image of the eye.

NOTE: The examination result is not yet stored.

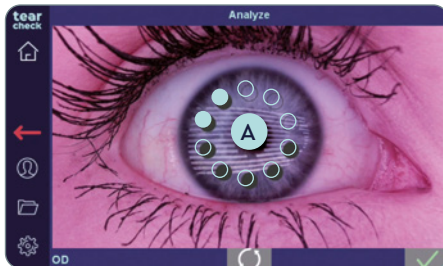
tearcheck EXAMINATIONS



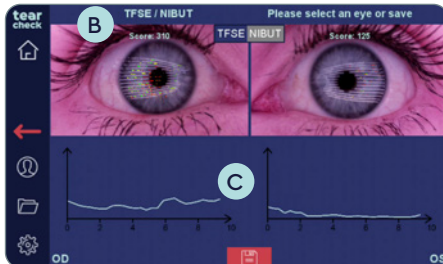
STEP 6

ANALYSE EXAM

- Each eye can now be analyzed by clicking on the image.



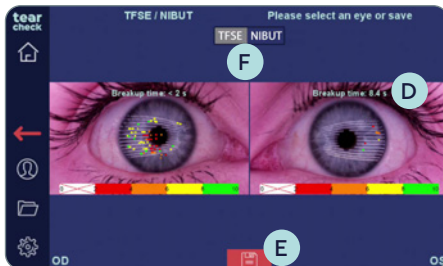
- The analysis of the image starts automatically and takes only a few seconds. During the analyses a circle of ice-blue dots **A** is shown in the center of the image.



STEP 7

RESULT OF ANALYSIS

- **TFSE:** The examination results for both eyes are shown by a **score B** on top of the image and a **scale C** below the image.

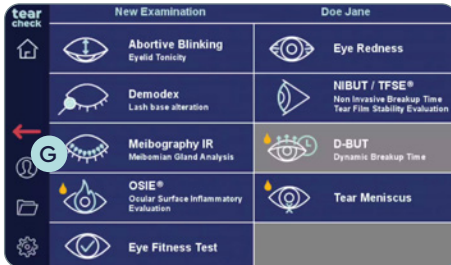


- **NIBUT:** The examination results for both eyes are shown by dots in different colours in the captured image and the calculated break-up time in seconds **D**.
- **Store the examination results** of the patient by clicking on the disk icon **E**.

NOTE: Display changes according to the selection of TFSE®/NIBUT **F**.

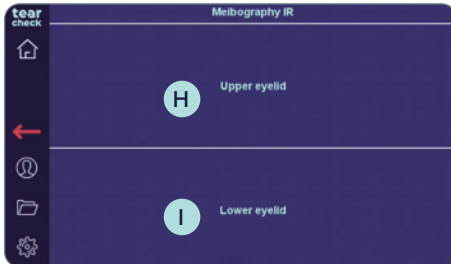
» MEIBOGRAPHY IR

The **examination of the Meibomian Glands** shows the loss of glands through 3 types of images (real imaging, 2D image and 3D rendering).



STEP 1

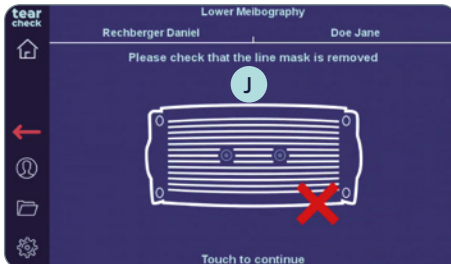
- Select **Meibography IR** **G** examination in the examination menu.



STEP 2

- Choose Upper **H** or Lower Eyelid **I** for the examination.

NOTE: It is sufficient to exam the lower eyelid.



- Ensure that the **LINE MASK** **J** is **removed** (follow the instructions on the top of the screen), then click on the screen **K** to start.

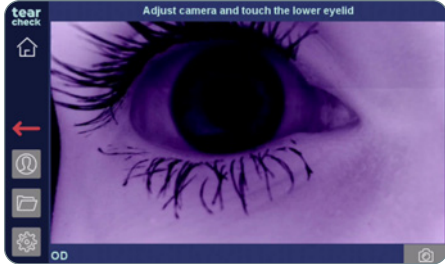


STEP 3

- Select the right or left eye and start the exam by clicking on the **tearcheck** logo **L**.

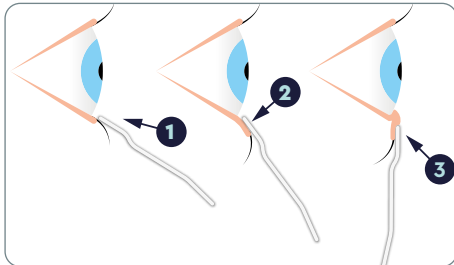
NOTE: The **tearcheck** logo will appear, if no examination has been done yet.

tearcheck EXAMINATIONS



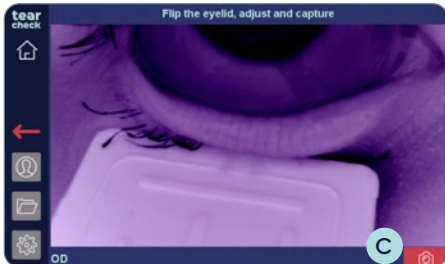
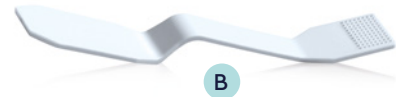
STEP 4

- After choosing an eye (OD = oculus dexter – right eye / OS = oculus sinister – left eye), **click on the patient's eyelid** to adjust the image.
- The image can be adjusted by using the **focus wheel A** on the top of the device.



STEP 5

- Use the **EYELID FLIPPING TOOL B** to flip the eyelid:
 - 1 place the eyelid flipping tool below the lash line,
 - 2 pull down,
 - 3 push towards the eye.

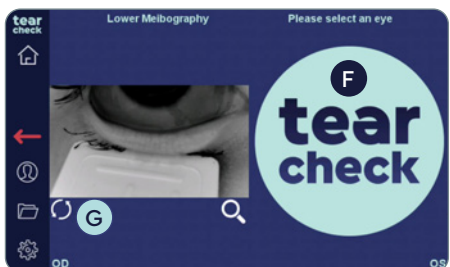


STEP 6

- **Capture** the image of the eyelid image by clicking on the red camera icon **C**.

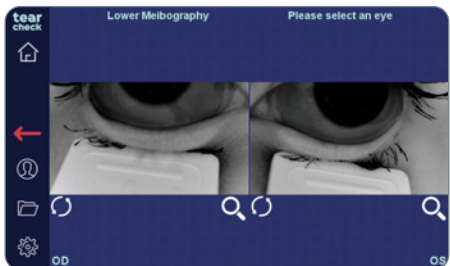


- **Validate** with the green check **D** mark or **restart** with the redo-button icon **E**.



- **Continue with the second eye** by clicking on the **tearcheck** logo **F**, or **restart** the examination of the first eye by clicking on the redo-button **G** below the image of the eye.

NOTE: The examination result is not yet stored.

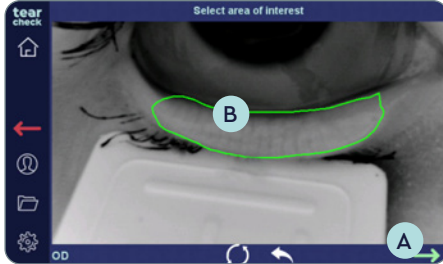


STEP 7

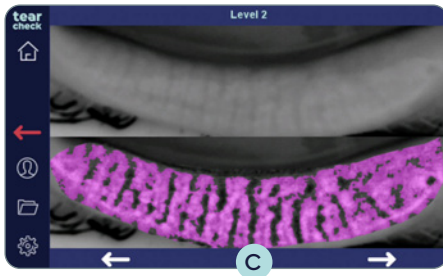
- Click on the image to **clip the area of interest**.
- Mark the area of interest (area with Meibomian glands) with the **DIGITAL PEN H** or with your finger directly on the screen or on the optional tablet.



tearcheck EXAMINATIONS



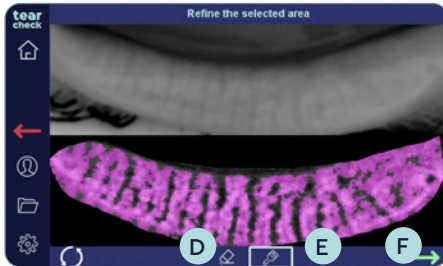
NOTE: The marking can be corrected by restarting the whole marking process or by restarting the last line (double-tap). The validation arrow (green) **A** can only be selected when the mark (polygon) **B** is closed.



STEP 8

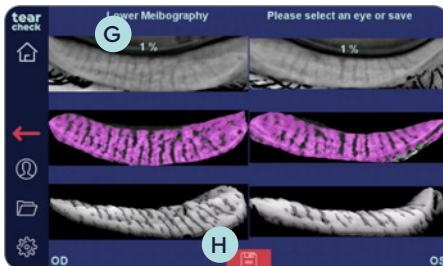
DETECTION OF MEIBOMIAN GLANDS

- After clicking the validation arrow, choose the most representative Meibomian Gland detection.
- Left and right arrows **C** allow to switch between the 3 suggested results.



After validating one of the suggested results, the **area of interest can be refined:**

- By removing some pixels with the rubber icon **D**.
- By adding some pixels with the brush icon **E**.
- After the refinement, proceed by clicking on the green arrow **F**.



STEP 9

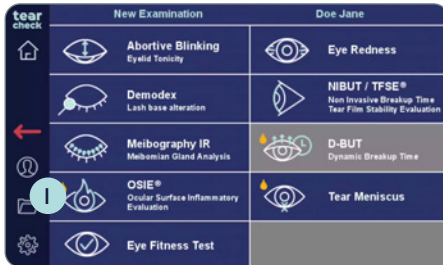
RESULT OF ANALYSIS

The examination result for both eyes is shown through a gland loss ratio **G** and a 3D greyscale rendering of the area of interest.

- **Save the examination results** of the patient by clicking on the disk icon **H**.

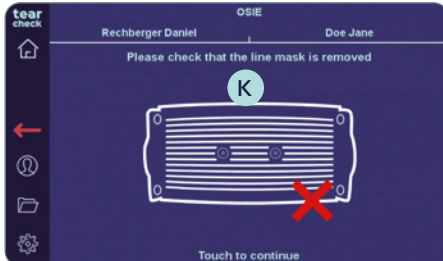
» OSIE®

Ocular Surface Inflammatory Evaluation (OSIE®) is using blue light to detect areas on the ocular surface that are subject to an increased inflammation risk.



STEP 1

- Select **OSIE®** **I** examination in the examination menu.

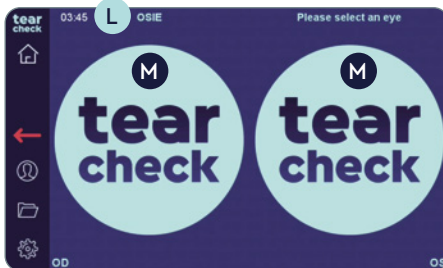


STEP 2

- Ensure that the **LINE MASK** **J** is removed (follow the instructions on the top of the screen), then click on the screen **K** to start.



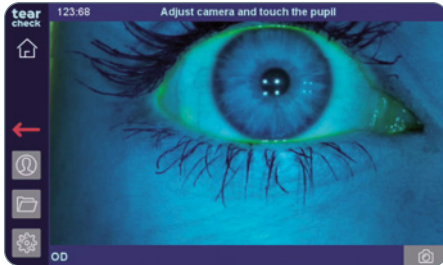
- Follow the OSIE® process as shown on top of the screen by instilling a drop of **fluorescein** in each eye.
- Click on the screen and wait 2 minutes before capturing the image.



- A timer **L** appears at the top of the screen.
- Select the right or left eye and start the exam by clicking on the **tearcheck** logo **M**.

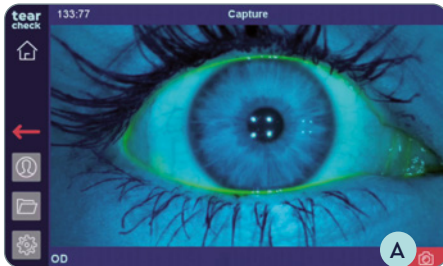
NOTE: The **tearcheck** logo will appear, if no examination has been done yet.

tearcheck EXAMINATIONS

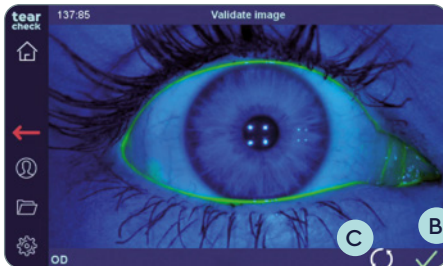


STEP 3

- After choosing an eye (OD = oculus dexter – right eye / OS = oculus sinister – left eye), **click on the patient's pupil** to adjust the image.
- The pupil should be centered in the image.

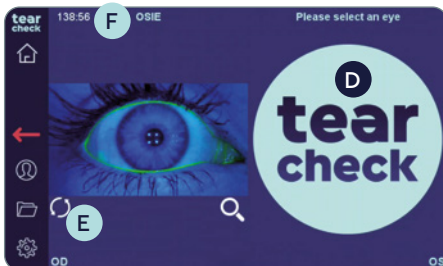


- **Capture the image of the eye** by clicking on the camera icon **A**.



- **Validate B** or **restart C** the capture.

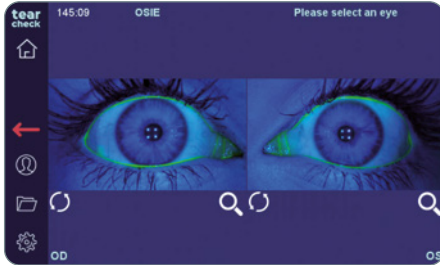
NOTE: An error message will be displayed if the iris is not found due to inappropriate camera adjustment, and most likely due to bad centering of the eye in the image.



STEP 4

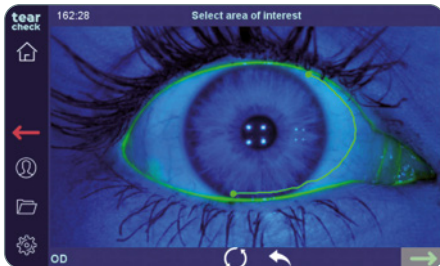
- **Continue with the second eye** by clicking on the **tearcheck** logo **D**, or **restart** the examination of the first eye by clicking on the redo-button **E** below the image of the eye.

NOTE: The timer **F** is showing how long fluorescein is already instilled. The examination result is not yet stored.

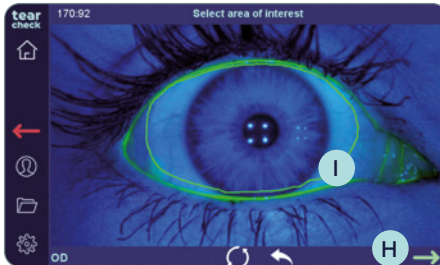


STEP 5

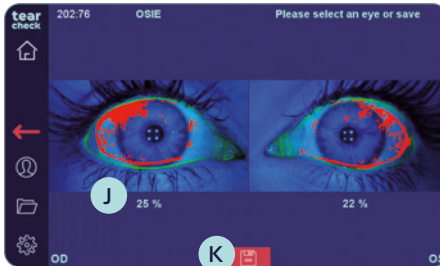
- Click on the image to clip the area of interest.



- **Mark the area of interest** (whole ocular surface) with the **DIGITAL PEN G** or with your finger directly on the screen or on the optional tablet.



NOTE: The marking can be corrected by restarting the whole marking process or by restarting the last line (double-tap). The validation arrow (green) **H** can only be selected when the mark (polygon) **I** is closed.



STEP 6

RESULT OF EXAM

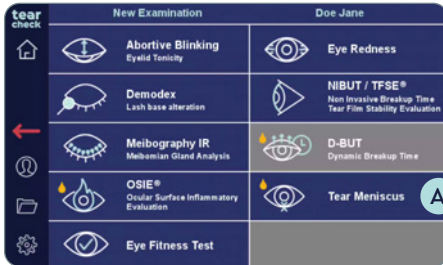
The area with increased inflammation risk is indicated in red and a percentage **J** is showing the inflammation ratio.

- **Save** the examination results of the patient by clicking on the disk icon **K**.

tearcheck EXAMINATIONS

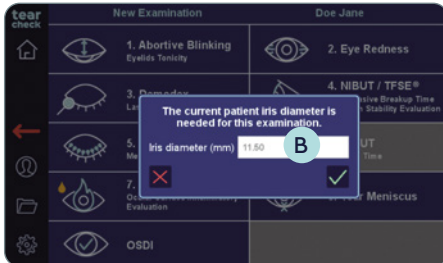
▶▶ TEAR MENISCUS

Tear Meniscus height is detected by quantifying the height of the tearfilm in the middle of the lower eye lid. This will typically be run after OSIE to benefit of remaining fluorescein.



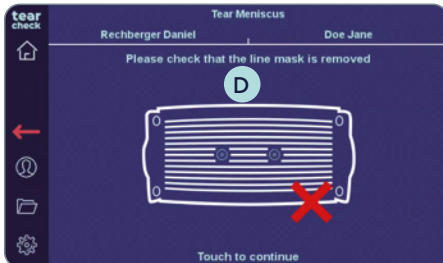
STEP 1

- Select **Tear Meniscus** **A** examination in the examination menu.



STEP 2

- If it has not been filled in with the patient information, fill in the eye iris diameter (in millimeter) of the patient and confirm by clicking the check mark **B**.

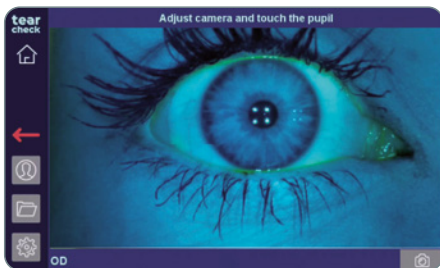


- Ensure that the **LINE MASK** **C** is removed (follow the instructions on the top of the screen), then click on the screen **D** to start.



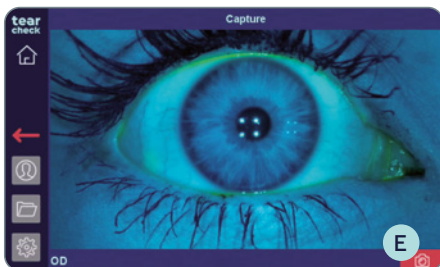
- Select the right or left eye and **start the exam** by clicking on the **tearcheck** logo **D**.

NOTE: The **tearcheck** logo will appear, if no examination has been done yet.

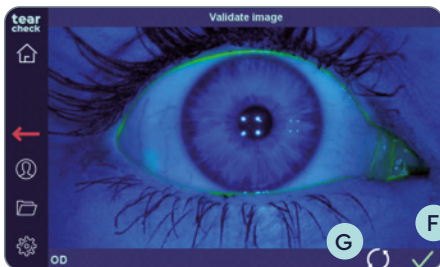


STEP 3

- After choosing an eye (OD = oculus dexter – right eye / OS = oculus sinister – left eye), **click on the patient's pupil** to adjust the image.



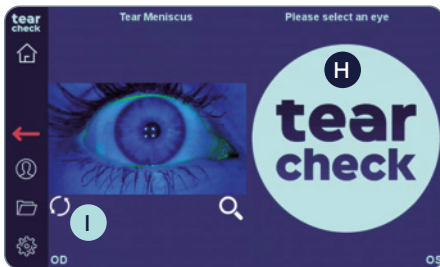
- **Capture the image of the eye** by clicking on the camera icon **E**.



STEP 4

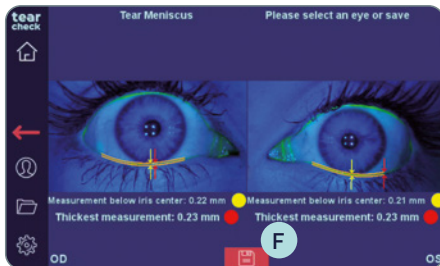
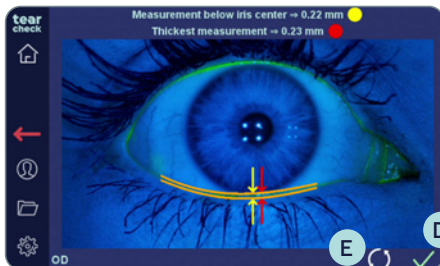
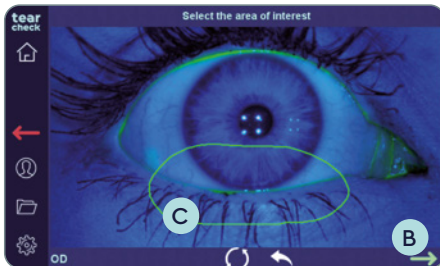
- **Validate** **F** or **restart** **G** the capture.

NOTE: An error message will be displayed, if the iris is not found due to inappropriate camera adjustment.



- **Continue with the second eye** by clicking on the **tearcheck** logo **H**, or **restart** the examination of the first eye by clicking on redo-button **I**.

tearcheck EXAMINATIONS



STEP 5

- Click on the image to **clip the area of interest**.
- **Mark the area of interest** (lower eyelid) with the **DIGITAL PEN** **A** or with your finger directly on the screen or on the optional tablet.



NOTE: The marking can be corrected by restarting the whole marking process or by restarting the last line (double-tap). The validation arrow (green) **B** can only be selected when the mark (polygon) **C** is closed.

After validation, the analysis is done and the tear meniscus height is displayed in millimeters.

- Click on the check mark **D** to **confirm** or **restart** with the redo-button **E** icon.

NOTE: An error message will be displayed if the meniscus is not found. This can be due to an insufficient amount of fluorescein, a poor distribution of it or if the tear meniscus is too thin. Narrowing the selection may solve the issue.

RESULT OF EXAM

Two values are calculated:

- Measurement below the iris center (yellow)
- Thickest measurement (red)
- **Save the examination results** of the patient by clicking on the disk icon **F**.

» EYE FITNESS TEST

The **Eye Fitness Test** is a questionnaire to evaluate the score (0–44) of subjective signs and symptoms.

New Examination		Doe Jane	
	Abortive Blinking Eyelid Tonicity		Eye Redness
	Demodex Lash base alteration		NIBUT / TFSE* Non Invasive Breakup Time Tear Film Stability Evaluation
	Meibography IR Meibomian Gland Analysis		D-BUT Dynamic Breakup Time
	OSIE* Ocular Surface Inflammatory Evaluation		Tear Meniscus
	Eye Fit G st		

STEP 1

- Select **Eye Fitness Test** **G** in the examination menu.

Eye Fitness Test		Doe Jane	
General well-being:			
Do you feel good today?	Yes	No	
Are you under medical treatment with an ophthalmologist or optometrist?			
Are you especially sensitive to light?			
Are you pregnant?			
Are you using eye drops?			
Do you blink more frequently to help improve comfort?			
Do you rub your eye frequently?			
Are you wearing contact lenses?			
Analysis of eye fitness:			
Do you feel or notice the following	4	3	2
	Some-	Regu-	

STEP 2

- Start the questionnaire. The patient can enter replies directly through the tablet.

NOTE: Validation of the score is only possible, if all questions are answered.

- If required, the answers can be changed by clicking in another field.

Eye Fitness Test		Doe Jane	
Reading			
Driving at night			
Using digital screens (PC, smartphone, ...)	✓		
Watching TV		✓	
Do your eyes suffer in...?			
	4	3	2
	Never	Some-	Regu-
		times	larly
			Often
			Always
Windy weather conditions		✓	
Dry air or air-conditioned places		✓	
Completed: 19/19			
H ✓			

STEP 3

- After completing all questions, click on the check mark **H** to get the result.

Eye Fitness Test		Doe Jane	
Is your visual comfort affected during ...?	Never	Some-	Often
		times	larly
			Always
Reading		✓	
Driving at night			✓
Using digital screens (PC, smartphone, ...)	✓		
Watching TV		✓	
Do your eyes suffer in...?			
	4	3	2
	Never	Some-	Regu-
		times	larly
			Often
			Always
Windy weather conditions		✓	
Dry air or air-conditioned places		✓	
Score: 32			

STEP 4

RESULT OF EYE FITNESS TEST

A score from 0 (severe dry eye) to 44 (normal eye) will be displayed.

The Eye Fitness Test report is automatically saved.

tearcheck EXAMINATIONS

» OTHERS

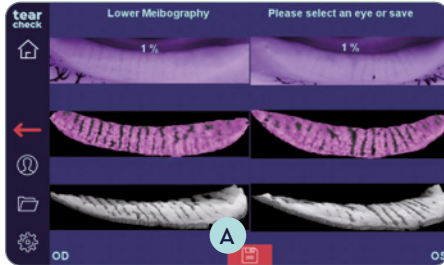
If new or updated examinations are available, a software update will be provided.
The update can be downloaded directly in your client account on gateway.esw-vision.com.

NOTE: Register your device after receipt on gateway.esw-vision.com to get automatic access to available software updates.



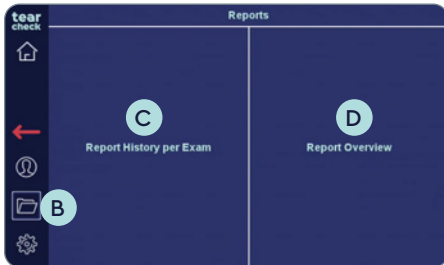
tearcheck RESULTS

» SAVE EXAMINATION RESULTS



- When an examination is finished, **save the results** by clicking on the disk icon at the bottom center of the screen **A**.
- A message indicates that the report is saved.

» REPORTS



STEP 1

- Examination **reports can be viewed** by clicking on the folder icon **B** on the left bar.

NOTE: This icon **B** is accessible when a patient has been selected. It is not accessible for Anonymous Patient.

There are two different options for reports available:

- **Report History per Exam** **C**
Makes it possible to access all saved reports per patient with all details and captured images.
- **Report Overview** **D**
Shows on one page an overview of the results of all exams and the corresponding category per exam (normal / mild / moderate / severe).

STEP 2

- Select either Report History per Exam or Report Overview.

» REPORT HISTORY PER EXAM

Date	Exam	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1/4/2022 4:00 PM	Eye Fitness Test	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1/4/2022 3:59 PM	NIBUT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1/4/2022 3:59 PM	TFSE	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1/4/2022 3:56 PM	Eye Redness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1/4/2022 3:53 PM	Lower Meibography	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1/4/2022 3:45 PM	Demodex	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1/4/2022 3:43 PM	Abortive Blinking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

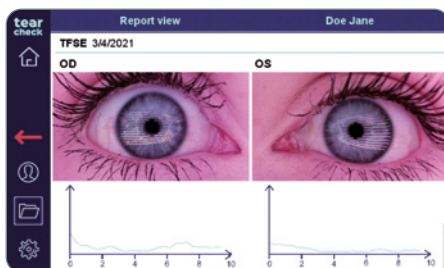
- When examinations have been saved, the **list of reports** is displayed in the **Report History** with examination date, type and export options.
- This list may be sorted by date or exam by clicking on the corresponding header **E**.

Date	Exam	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1/4/2022 4:00 PM	Eye Fitness Test	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1/4/2022 3:59 PM	NIBUT	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1/4/2022 3:59 PM	TFSE	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1/4/2022 3:56 PM	Eye Redness	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/4/2022 3:53 PM	Lower Meibography	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1/4/2022 3:45 PM	Demodex	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1/4/2022 3:43 PM	Abortive Blinking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- Check the corresponding box to view reports on the screen, print reports or export to a USB device **F**. Select the requested reports per column and validate by clicking on the check mark **G**.

The selected reports will then

- be displayed on the screen.
- generated and sent to the remote printer, if one is available.
- generated and copied to a USB device, if one is available.



NOTE: Multiple reports can be chosen to be displayed, printed or exported. In this case, reports are displayed one after the other on the screen and printed/exported on separated pages for each exam..

tearcheck RESULTS

» REPORT OVERVIEW

Date	Exam	
1/4/2022	all Exams	<input checked="" type="checkbox"/>

- Access the report overview of all exams of one day by checking a full day in the right column **A**.

Date	Exam	
1/4/2022	all Exams	<input checked="" type="checkbox"/>
4:00:33 PM CET	Eye Fitness Test	<input checked="" type="checkbox"/>
3:59:46 PM CET	NIBUT	<input checked="" type="checkbox"/>
3:59:46 PM CET	TFSE	<input checked="" type="checkbox"/>
3:56:58 PM CET	Eye Redness	<input type="checkbox"/>
3:53:37 PM CET	Lower Meibography	<input type="checkbox"/>
3:45:25 PM CET	Demodex	<input type="checkbox"/>
3:43:31 PM CET	Absortive Blinking	<input type="checkbox"/>

- Single exams within one day can be selected by unfolding **B** all exams of one day and then ticking only the desired exams.

Date	Exam	
1/4/2022	all Exams	<input checked="" type="checkbox"/>
4:00:33 PM CET	Eye Fitness Test	<input checked="" type="checkbox"/>
3:59:46 PM CET	NIBUT	<input checked="" type="checkbox"/>
3:59:46 PM CET	TFSE	<input checked="" type="checkbox"/>
3:56:58 PM CET	Eye Redness	<input type="checkbox"/>
3:53:37 PM CET	Lower Meibography	<input type="checkbox"/>
3:45:25 PM CET	Demodex	<input type="checkbox"/>
3:43:31 PM CET	Absortive Blinking	<input type="checkbox"/>

- Select USB export **C**, print **D** or display on the screen **E** for the selected report overview and confirm with the green check mark.

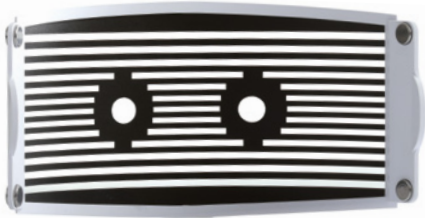
EXAM	OS	OD	Normal	Mild	Moderate	Severe
Eye Fitness Test Score	32	32	44 36	34 29	28 25	24 0
TFSE Score + Curve	125	310	<100	101 250	251 500	>500
NIBUT Time in seconds	8.4	<2	>10	10 6	6 2	<2

NOTE: Exams carried out within one day are displayed in one report overview. If exams from different days are selected, a separate report overview for each day will be created.



USE OF tearcheck ACCESSORIES

» LINE MASK



The **tearcheck LINE MASK** is an innovative solution to detect interruptions in the tearfilm over a wide area on the ocular surface.

The **LINE MASK** is mandatory for TFSE® and NIBUT examination.

» EYELID FLIPPING TOOL



The **tearcheck EYELID FLIPPING TOOL** is used to flip the eyelid for Meibomian Gland detection. The special tool was developed for "contact-free" imaging of the glands.

To be used for Meibography and Eye Redness detection.

NOTE: all **tearcheck** accessories can be ordered by visiting www.esw-vision.com/contact and choosing the applicable contact for your country.



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MAINTENANCE

tearcheck does not require periodic maintenance by the manufacturer.

» REPLACEABLE PARTS

The following part are replaceable by the user:

- The external power supply. Power supply may be ordered under the reference V040__017A00A.
- The power cord. Power cord may be ordered under the reference V040EU013A01A.

For your safety, use only replacement parts provided by the manufacturer.

» CLEANING

The **LINE MASK** cannot be cleaned. It shall be replaced when transparent areas are dirty or when scratches are visible in dark areas.

Plastic parts of **tearcheck** housing may be cleaned with a clean cloth which has been slightly moistened with water without any additional product.

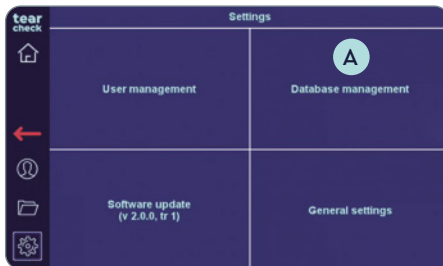
Both lenses and display screen of **tearcheck** may be cleaned with a clean cloth which has been slightly impregnated with the Clean spray (never apply the clean spray directly on the device).

The chinrest and forehead stop must be disinfected by the practitioner, and under his responsibility, with products he has selected in accordance with the medical context in which he works.

The **EYELID FLIPPING TOOL** is intended for a single use and shall be discarded after each patient.

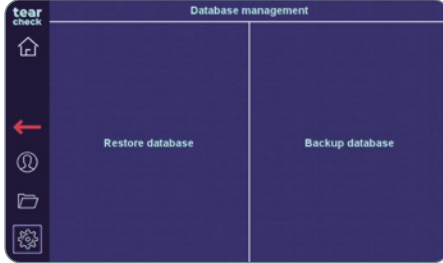
There is not sterile part or accessories required for use of the **tearcheck**.

» DATA BASE MANAGEMENT

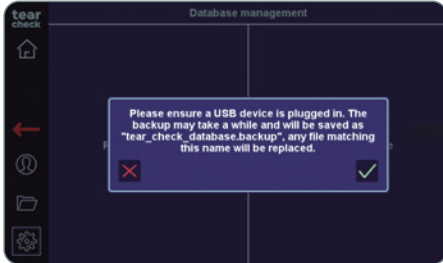


STEP 1

- Click on **Database Management** **A** in the Settings menu

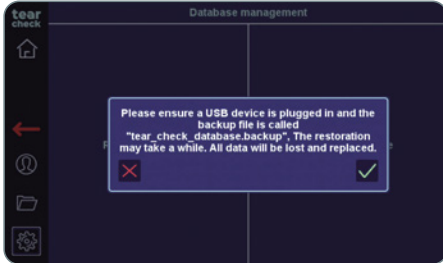


It is possible to **RESTORE** or to **BACKUP** the **tearcheck** Database.

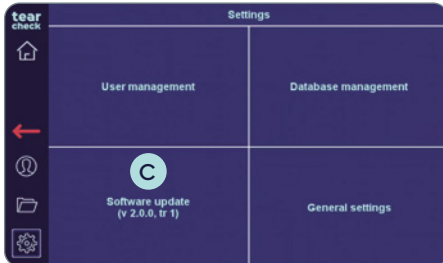


STEP 2

- To **backup the database**, insert a **USB key/device B** and click on Backup Database: a binary file named "tear_check_database.backup" will be copied on the USB key/device.
- To **restore database**, insert the **USB key/device B** with file named "tear_check_database.backup" and click on Restore Database: your current database will be erased.



» SOFTWARE UPDATE

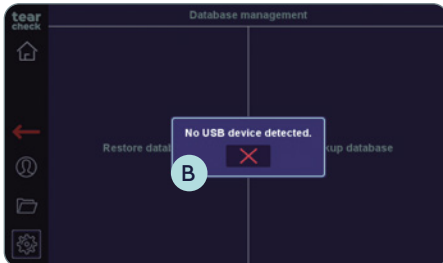
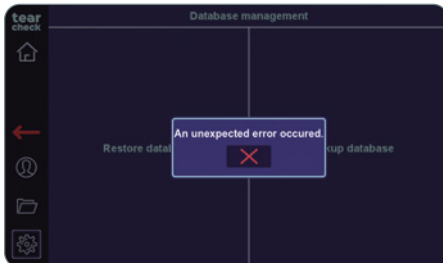
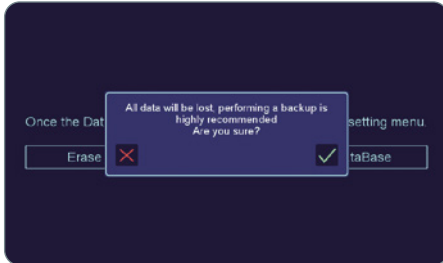
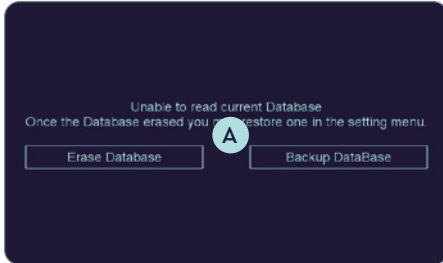


STEP 1

- Click on **Software Update C** in the Settings menu
- Insert a valid **USB key/device B**, the software update is starting automatically.
- A message is displayed when the update was successful and invites to reboot the device.

MAINTENANCE

» WARNING AND MESSAGES



DATABASE MESSAGES

AT STARTUP

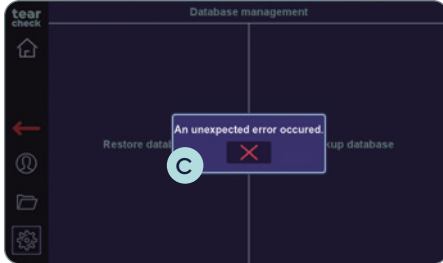
- In case of a **database corruption** when the user starts the device, a message **A** is displayed to the user.
- The user may erase the database if a recent backup is available.
- User will be asked to confirm database deletion.

- Otherwise, the user may **backup the database** and send a copy to the manufacturer. If possible, the corrupted database will be repaired.

DURING DATABASE BACKUP

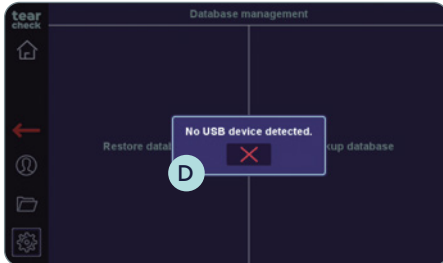
- During the database backup, this message indicates that the **USB stick is probably disconnected or unusable**.
- In this case retry the backup with another USB stick.

- Trying to achieve a backup while **no USB stick is present** will generate this message **B**.
- The user should retry after checking the connected USB stick.

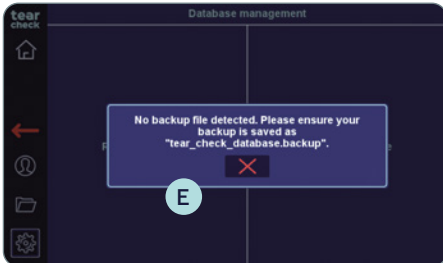


DURING DATABASE RESTORE

- If the **USB stick is disconnected** during a database restore, the following message **C** will be displayed.
- The user shall retry with another USB stick.

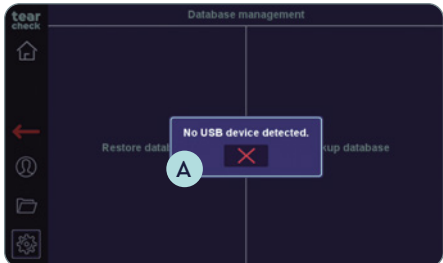


- Trying to **restore a database without connecting an USB stick** will generate this message **D**.
- The user shall retry after connecting a USB stick.



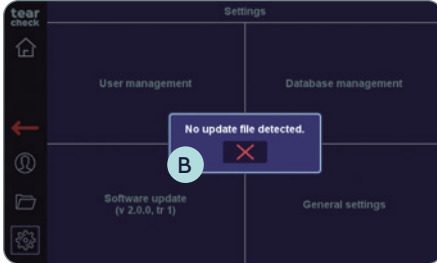
- If the software is **unable to find a valid database file** on the USB stick, this message **E** will appear.
- The user shall check the content of the USB stick.

MESSAGES DURING SOFTWARE UPDATE

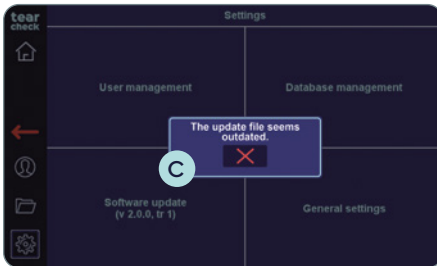


- If **no USB stick** is connected during the attempted **software update**, the following message **A** will appear.
- The user shall try again after connecting a USB stick.

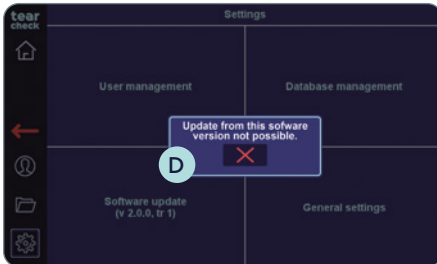
MAINTENANCE



- If the software is **unable to find a valid update file** on the USB stick, this message **E** will appear.
- The user shall check the content of the USB stick.



- An attempt to update the device with an **outdated update file** will generate this message **B**.
- The user shall contact the manufacturer to get the latest update package.

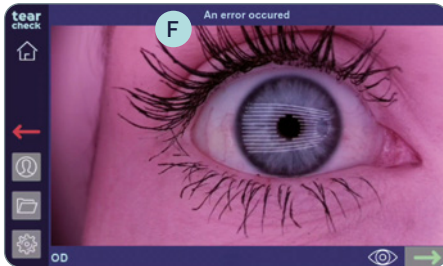


- If the **current version of software is too old** with regards to the to latest version, the following message **C** appears.
- The user shall install the new software updates as soon as they are available. If a user has disregarded several software updates, it is likely that an update in one step is impossible **D**. In this case, the user shall contact the manufacturer.



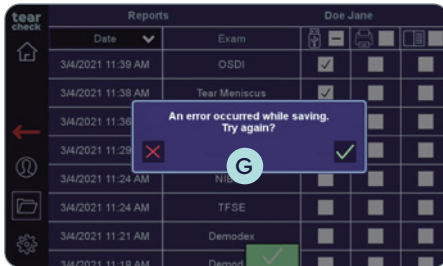
- If an update package is available on the USB stick, the following message **E** will be displayed if the **file is corrupted**.

MESSAGES GENERATED DURING AN EXAM



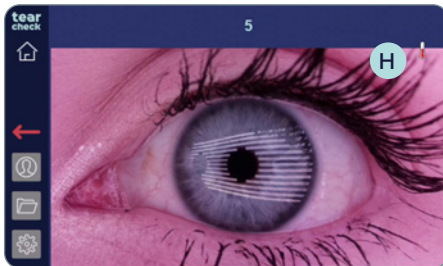
- During image processing the following message **F** may appear, meaning that **captured data may not be processed**.
- The user shall retry to perform the exam.
- In case of failure, the user shall contact the manufacturer.

MESSAGES DURING REPORT DOWNLOAD

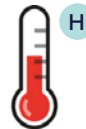


- When a user is attempting to save a report on a USB stick, the following message **G** will appear if **no USB stick is connected** or it does not work properly.
- The user shall retry using another USB stick.

TEMPERATURE WARNING



- If the temperature symbol **H** is displayed, the processor slows down to avoid overheating.
- Verify that you use **tearcheck** in environmental conditions compliant to specifications.



SUPPORT

» TECHNICAL SERVICE



If technical support is required please contact your **tearcheck** distribution partner or contact our service department through our contact form on www.esw-vision.com

» COMMERCIAL SERVICE



For user assistance, please contact your **tearcheck** distribution partner or our commercial service through our contact form on www.esw-vision.com

» ERROR MESSAGES



If **tearcheck** is blocked, plug-off the device and dis-connect the power cord. Restart the device again. If the device remains blocked, please contact our technical service.

» TRAINING



Training is **not required** to use the product.






















**tear
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TECHNICAL DATA

» MARKING

 REF : tearcheck	Reference of the tearcheck device.
 SN	Unique serial number of the tearcheck device.
 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.
	It is compulsory to refer to the instructions in the user manual.
	This symbol invites the reader to consult the operating instructions for any information necessary for proper use of the device.
	Electromedical Equipment of Class II rating
	Device must be used indoors.
	Keep the device dry.
	Keep away of light and heat.
 LOT	The batch number of the product is indicated next to this logo.
	Connector Polarity
	Direct Current
	Respect the upper and lower temperature limits indicated next to this logo.
	Atmospheric pressure Limits
	Relative humidity Limits
	Global safety mark for electrical devices.
IP 20	Device is protected against solid foreign bodies of 12,5 mm in diameter or more (IP rating).
IP 4X	Device is protected against solid foreign bodies of 1 mm in diameter or more (IP rating).
	Waste Electrical and Electronic Equipment
	Device is compliant to European regulation
	UL recognized part
EFFICIENCY LEVEL VI	Energy Star efficiency classification

» SPECIFICATIONS

Energy Source	100–240V 50–60Hz external power supply
DC power supply input characteristic	12V DC 5A
Dimensions (L x W x H)	240 × 195 × 190 mm (active part only)
Weight	Active part: 1800 g Fastening and chinrest: 1900 g
Shipping Dimensions (L x W x H)	815 × 520 × 355 mm
Shipping Weight	12.5 kg
Maximum Power Consumption	60 W max
Temperature (Working)	+5 to +35 °C
Temperature (Storage)	-5 to +65 °C
Relative Humidity (Non-Condensing)	30 to 93%
Atmospheric pressure (use)	760–1060 hPa
Atmospheric pressure (storage and transport)	760–1060 hPa
Applied parts	Chinrest and Forehead stop

» RECYCLING AND PROCESSING



Instructions for the treatment of used products: the WEEE (Waste Electrical and Electronic Equipment) Directive 2002/96/CE has been implemented to ensure that the products are recycled by using the best techniques for treatment, recovery and recycling, and thus to contribute to the protection of environment and human health.

Your product has been designed and manufactured with components and high quality materials that can be recycled and reused.

E-Swin SAS is affiliated to an eco organization that is responsible for collecting and processing of end-of-life products.

TECHNICAL DATA

» GUIDANCE AND MANUFACTURER'S DECLARATION

RADIO FREQUENCY EMISSIONS

tearcheck incorporates a radio frequency transmitter at 2.5 GHz.

ELECTROMAGNETIC EMISSIONS

tearcheck is intended for use in the electromagnetic environment specified below. The user of **tearcheck** should ensure that it is used in such environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF emissions CISPR 11	Group 1	tearcheck 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	tearcheck 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	

FOR YOUR SAFETY

- No modification of this equipment is allowed, only use the power supply and accessories delivered with the device.
- Never use **tearcheck** if damaged, never use in case of a functional anomaly appearing on the touchscreen, or following a fall.
- This device can only be repaired with special tools. For any problem after delivery please contact us in our website on www.e-swin-pro.com
- USB port of **tearcheck** is dedicated to connection of an USB stick. Connection of other devices is strictly prohibited.
- Contraindications: there is no contraindications in the use of **tearcheck**.

ELECTROMAGNETIC IMMUNITY

tearcheck is intended for use in the electromagnetic environment specified below. The user of **tearcheck** should ensure that it is used in such 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 % U_T for 0.5 cycle at 0,45,90,135,180,225,270,315° 0% U_T for 1 cycle at 0° 70% for 25/30 cycle at 0° 0% for 250/300 cycle, any angle	0 % U_T for 0.5 cycle at 0,45,90,135,180,225,270,315° 0% U_T 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: U_T is the AC mains voltage prior to application of the test level.			
Conducted RF • IEC 61000-4-6	3Vrms 150 kHz to 80MHz 6 V for ISM band	3Vrms 150 kHz to 80MHz 6 V in ISM bands between 150 kHz to 80MHz	
Radiated RF • IEC 61000-4-3	3V/m 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 or reflection from structures, objects and peoples.

- a 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 DATA

RECOMMENDED SEPARATION BETWEEN PORTABLE AND MOBILE RF COMMUNICATION EQUIPMENT AND **tearcheck**

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

The Device 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

Immunity test:			IEC 61000-4-3			
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	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	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.

TO AVOID ELECTROMAGNETIC SUSCEPTIBILITY ISSUES ON THE **tearcheck** AND ITS SURROUNDED DEVICES, USER SHALL FOLLOW THE FOLLOWING RULES FOR INSTALLATION

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of **tearcheck**, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

TECHNICAL DATA

LIGHT EMISSION

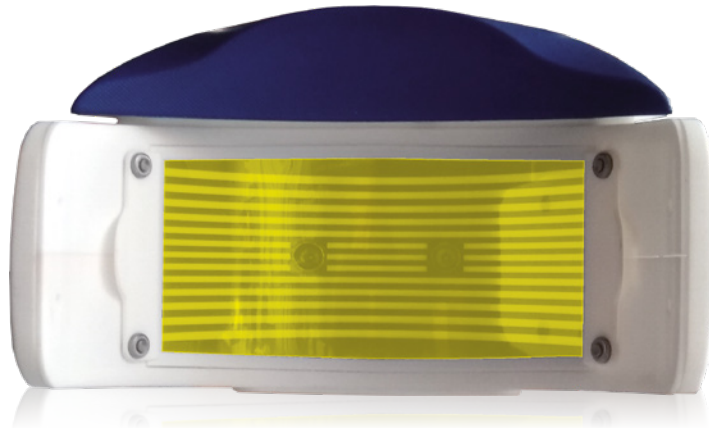
tearcheck is classified in the no risk group in term of light emission according to IEC60601-2-57:2011. There is no need for skin or eye protection of patient neither operator.

Maximum light emission versus wavelength:

WAVELENGTH	MAXIMUM EXPOSURE
White spectrum	$< 2.8 \cdot 10^5 \text{ W m}^{-2} \text{ sr}^{-1}$
Blue light (465 nm)	$< 10^5 \text{ W m}^{-2} \text{ sr}^{-1}$
Near Infrared light (850 nm)	$< 3200 \text{ W m}^{-2}$ on cornea

Exposure uniformity: better than $\pm 20 \%$ in the eye plane limited by camera field of view.

Light emission area is shown as the yellow area in the picture below:

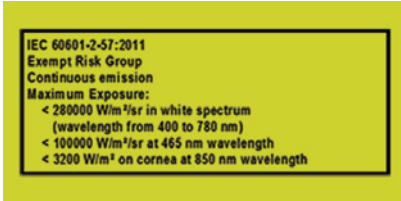


tearcheck is intended to be used by authorized people only. User shall log out from its session to avoid use of the device by unauthorized people.

CAUTION: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Adjustements allowed to the user are image focusing and chinrest vertical movement.

Warning label according to IEC60601-2-57:2011:



SEPARATION FROM MAINS

If needed **tearcheck** shall be separated from mains by disconnecting the IEC C7 plug from external power supply. The power cord must remain accessible during use of the product.

» STANDARDS

CERTIFICATION

E-SWIN SAS, the company that is the exclusive manufacturer of the device **tearcheck** has been awarded an ISO 13485:2016 certification.

» CONFORMITY

E-SWIN hereby declares that **tearcheck** meets the essential requirements of the 93/42/EEC directive Annex II, article 3.

WARRANTY

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 analysis 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 **tearcheck**.

The manufacturer's guarantee for parts and labor 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 **tearcheck** was supplied should therefore be carefully stored.

CONTACT



For more information visit: www.esw-vision.com

E-SWIN

ZA de la Prévôté
Rue des Côtes d'Orval
78550 Houdan
FRANCE
01 30 46 37 61



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