How to interpret tearcheck® examinations

Info Update Software Release 3.0.0

Interpretation Guide v3 01-2022

PATENTED TECHNOLOGY

tear check

tearcheck®

is intended for the investigation of dry eye syndrome and should be used by a licensed professional.

ESW vision

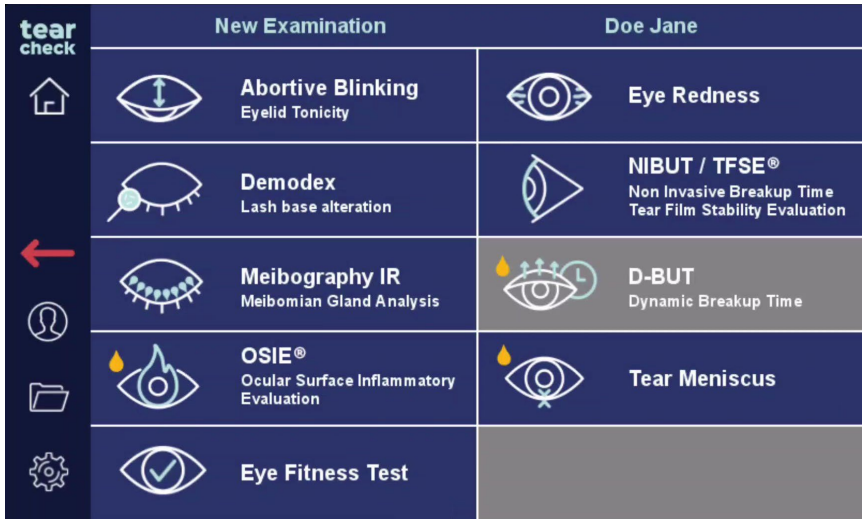
Interpretation Guide UPDATES v3

- All **exam screenshots** updated
- **Report diagramm** added to all exams
- **Eye Redness:** CCLRU-Score selection
- **Demodex:** Selection of demodex presence
- **NIBUT:** Breakup time calculation added
- OSDI renamed to **Eye Fitness Test** updated questionnaire
- **Report overview** added
- **Blink frequency** now displayed within Abortive Blinking

tearcheck® EXAMS

1. **EYE FITNESS TEST**
   Questionnaire to provide an overview of the patient's eye fitness in everyday life
2. **NIBUT / TFSE®**
   (Non-Invasive Breakup Time / Tear Film Stability Evaluation)
   Assesses the stability of the tear film
3. **EYE REDNESS**
   Displays the superficial blood vessels on the ocular surface
4. **ABORTIVE BLINKING / BLINK RATE**
   Detection of the structure of blinks to identify uncompleted ones
5. **MEIBOGRAPHY**
   Visualizes the Meibomian glands
6. **DEMODEX**
   Enlarged image capturing the base of the eyelashes to evaluate for signs of demodex
7. **D-BUT**
   Dynamic Breakup Time – COMING NEXT
8. **OSIE® (Ocular Surface Inflammatory Evaluation)**
   Detects areas on the ocular surface with increased inflammation risk
9. **TEAR MENISCUS**
   Calculates the tear meniscus height

EXAM OVERVIEW

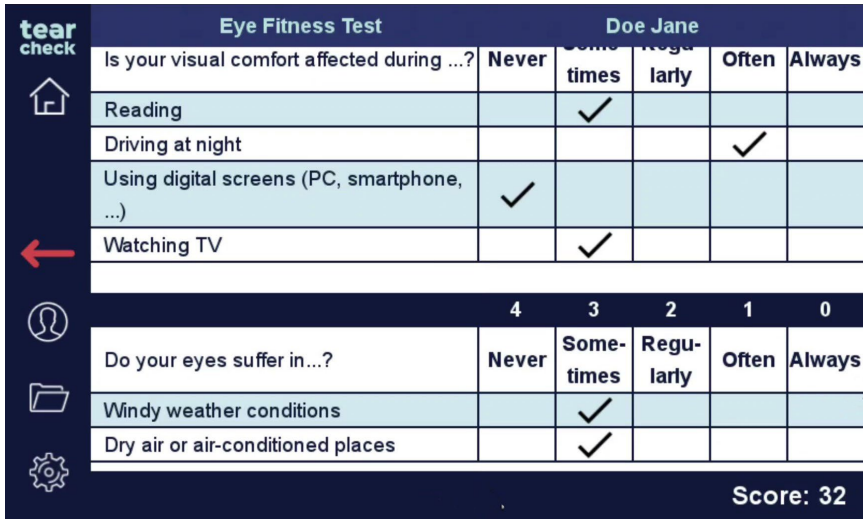


It is recommended to carry out all the exams in the proposed order.

The yellow drops indicate the exams which require a drop of fluorescein. In order not to influence the results of the other exams, the fluorescein exams must be carried out at the end.

Instructions on how to carry out each examination can be found in the tearcheck User Manual.

1. EYE FITNESS TEST



Eye Fitness Test	Doe Jane				
Is your visual comfort affected during ...?	Never	Some-times	Regu-larly	Often	Always
Reading		✓			
Driving at night				✓	
Using digital screens (PC, smartphone, ...)	✓				
Watching TV		✓			

	4	3	2	1	0
Do your eyes suffer in...?	Never	Some-times	Regu-larly	Often	Always
Windy weather conditions		✓			
Dry air or air-conditioned places		✓			

Score: 32

EYE FITNESS TEST
This questionnaire provides subjective patient feedback about the severity of dry eye symptoms.

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INTERPRETATION EYE FITNESS TEST			
NORMAL	MILD	MODERATE	SEVERE
44 - 35	34 - 29	28 - 25	24 - 0

Eye Fitness Test allows to evaluate the patient's subjective feeling about his/her daily vision comfort.

UPDATE v3 With the new software release 3.0.0 the name was changed into Eye Fitness Test. And the questions have been updated slightly, to track more information about the patient and habits, which could have impact on the visual comfort.

1. EYE FITNESS TEST

INSIGHTS

Eye Fitness Test is a questionnaire intended to be filled in by the patient and which provides an **overview on how the patient feels** about his/her ocular health in everyday life.

The information gathered through this questionnaire is fundamental insofar as it reflects the true perception of the patient.

Whatever information is given by diagnostic tools, whatever treatments are carried out, the essential thing must remain the patient's opinion and feelings.

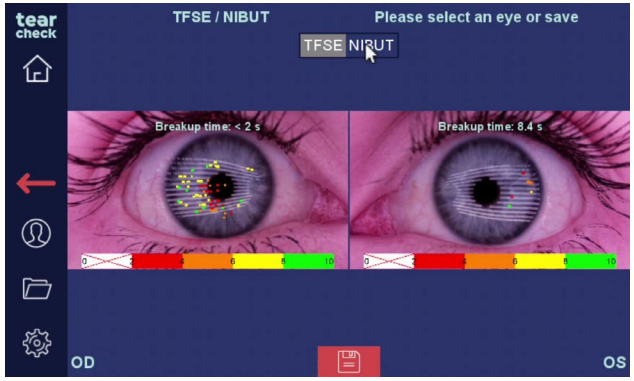
Even more than in many other syndromes, dry eye syndrome is characterized by complexity in diagnosis and management.

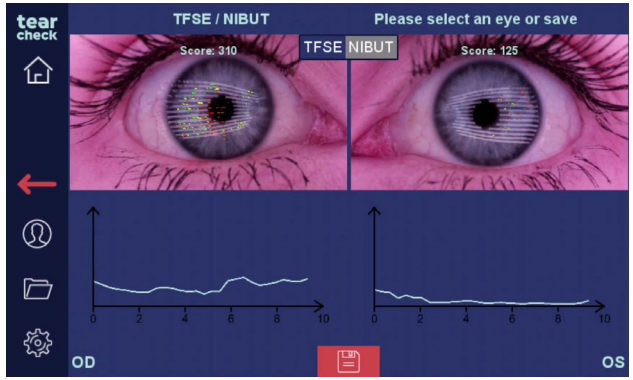
Indeed, there is no pathognomonic diagnosis of dry eye syndrome.

The opinion and feelings of the patient are therefore just as important as any examinations that can be carried out, however relevant they may be.

2. NIBUT / TFSE®

Non-Invasive Breakup Time / Tear Film Stability Evaluation





NIBUT / TFSE®
This examination evaluates the **stability and the breakup time of the tear film**.

NIBUT and TFSE® share the same imaging sequence.

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2. NIBUT / TFSE®

Non-Invasive Breakup Time / Tear Film Stability Evaluation

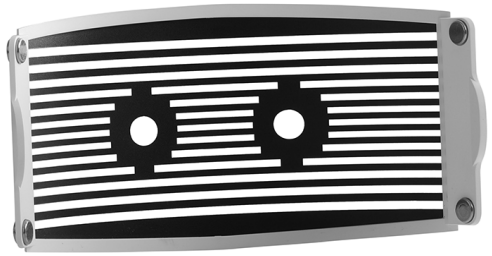
INSIGHTS

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

NIBUT and TSFE® share the same image acquisition sequence. Performing this exam requires the presence of the **line mask** on the device. The special feature of tearcheck® is, that it uses a mask with horizontal lines instead of the commonly used circular patterns.

The use of this screen with horizontal lines has several benefits:

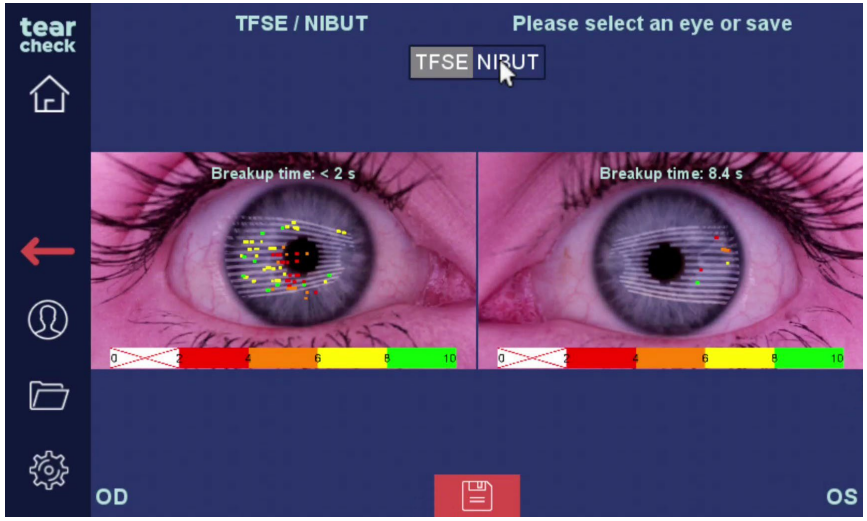
- A large measurement field on the cornea
- A substantially constant resolution on the measurement field
- Detection of tear film ruptures oriented uniformly over the entire field of observation in the natural direction of gravity.



line mask

2. NIBUT

Non-Invasive Breakup Time



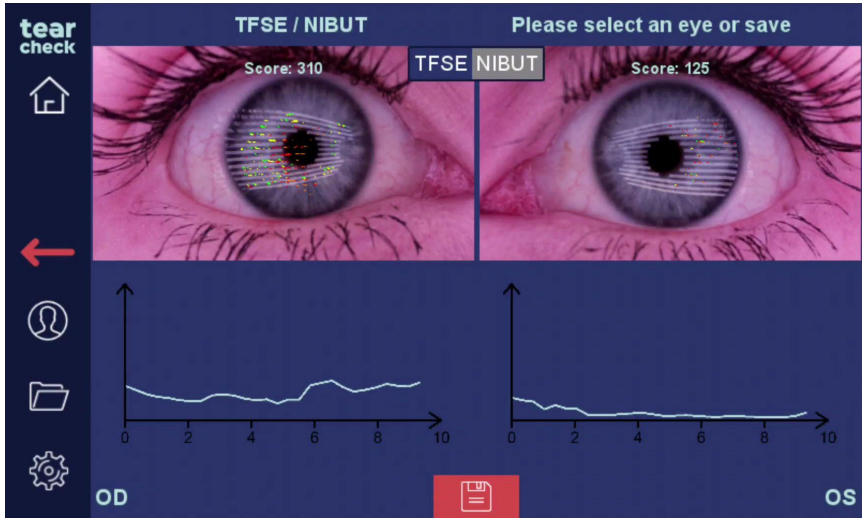
INTERPRETATION NIBUT			
NORMAL	MILD	MODERATE	SEVERE
> 10,0	10,0 - 6,0	5,9 - 2,0	< 2,0

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.

UPDATE v3 With the new software release 3.0.0, the **break-up time** is **calculated automatically** and displayed on top of the result image.

2. TFSE®

Tear Film Stability Evaluation



INTERPRETATION TFSE®			
NORMAL	MILD	MODERATE	SEVERE
< 100	100 - 250	251 - 500	> 500

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 syndrome**, 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** *(see the 4 standard curves - next page)*

2. TFSE®

Tear Film Stability Evaluation

INTERPRETATION TFSE®			
NORMAL	MILD	MODERATE	SEVERE
< 100	100 - 250	251 - 500	> 500

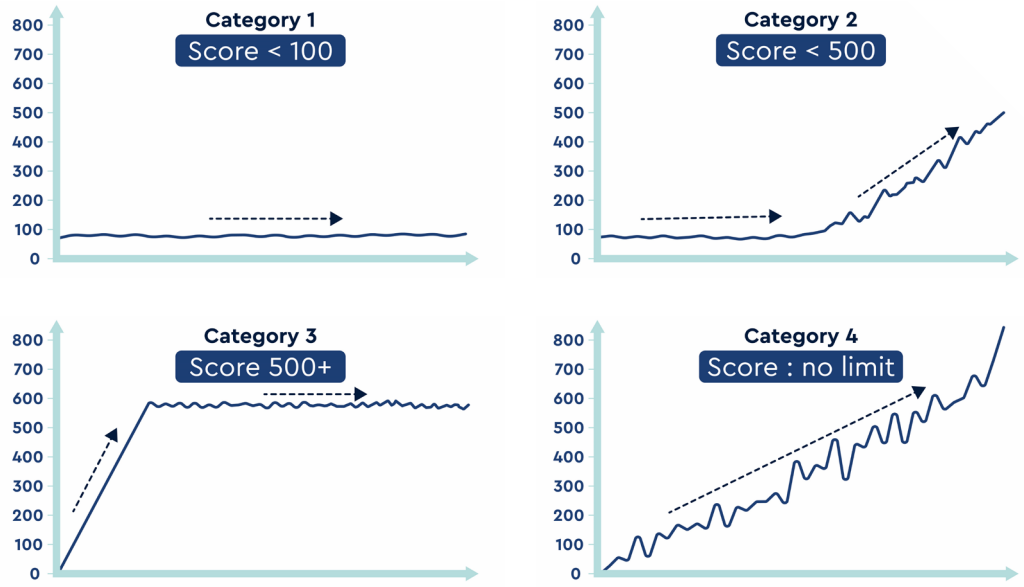
Category 1: healthy patient. Very few micro-movements and low intensity.

Category 2: patients with a significant number of micro-movements, but grouped towards the end of the 10 seconds of acquisition. No matter the intensity.

Category 3: patients with micro-movements of early onset but evolving very little over the rest of the acquisition time of 10 seconds.

Category 4: patients with micromovements of early onset and whose number and intensity increase over the duration of acquisition.

Generally, the higher the category, the greater the lipid deficiency. Category 4 patients will be those who will be the most uncomfortable 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 more finely the surface of the tear film. The TFSE® therefore remains a much richer examination than the classic NIBUT.
The evolution of this examination will particularly be interesting to follow during the different stages of treatment.

2. TFSE®

Tear Film Stability Evaluation

tear check

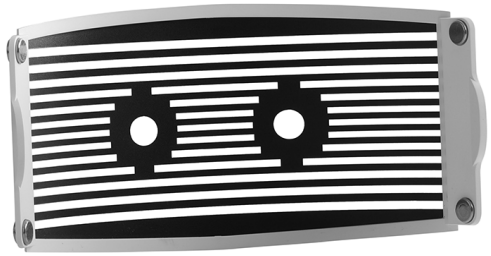
INSIGHTS

This examination was made possible in part by the use of the horizontal line mask. The horizontal lines respond to the gravity logic of the tear film and thus increase the sensitivity of detection of areas of the film with very small surface variations. It becomes possible **to detect film surface anomalies** much earlier and much more finely in comparison with all devices using circular lines.

In a healthy individual, after blinking the eyelids, over the duration of the 10 seconds of acquisition, the surface of the tear film will show very little movement and these movements will remain of low intensity.

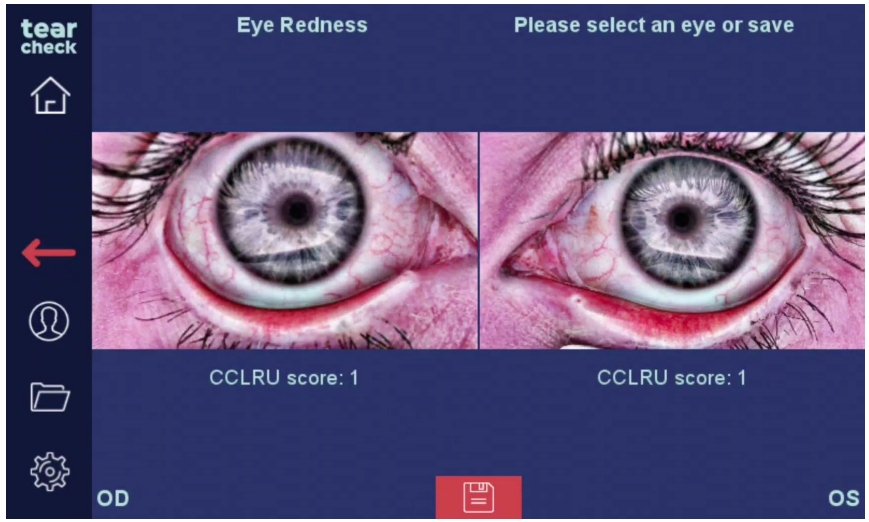
The eye of a patient with dry eye syndrome, that is linked to a deficiency of the lipid tear film component, shows more micro-deformations of higher intensity, the more severe the deficiency is. At the same time, it will be interesting to observe the evolution in the appearance of these micro-movements and the evolution of their intensity over the duration of the 10 seconds of acquisition.

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



line mask

3. EYE REDNESS



EYE REDNESS (CONJUNCTIVAL HYPEREMIA)
This examination captures images of the bulbar and palpebral conjunctivae.

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INTERPRETATION EYE REDNESS			
NORMAL	MILD	MODERATE	SEVERE
1	2	3	4

Improves contrast to enhance visibility and legibility of superficial vascularity.

This examination will in particular make it possible to assess hyperemia caused by dry eye induced inflammatory processes. It will be interesting to re-assess the patients as the treatment progresses.

UPDATE v3 The interpretation above is based on the **CCLRU-score**, which is specified on the next page.

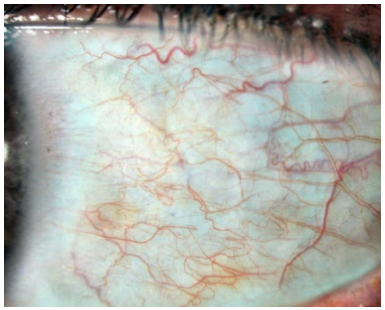
This examination consists of:

- **Capturing images of bulbar** and **eyelid conjunctivae**
- **Improving contrast** to accentuate the visibility and readability of superficial vascularization

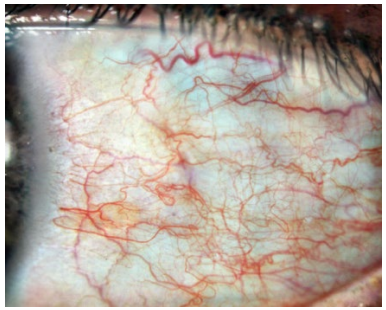
3. EYE REDNESS

UPDATE v3

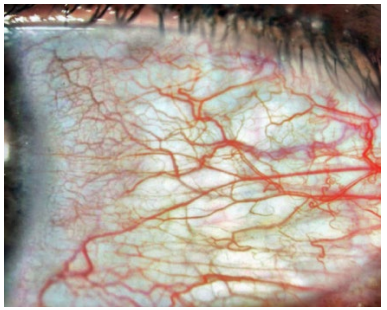
INSIGHTS



CCLRU-Score: 1



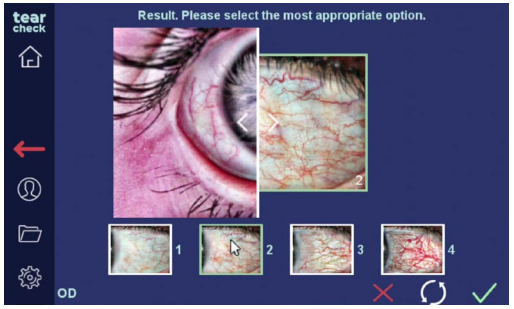
CCLRU-Score: 2



CCLRU-Score: 3

CCLRU-Score: 4

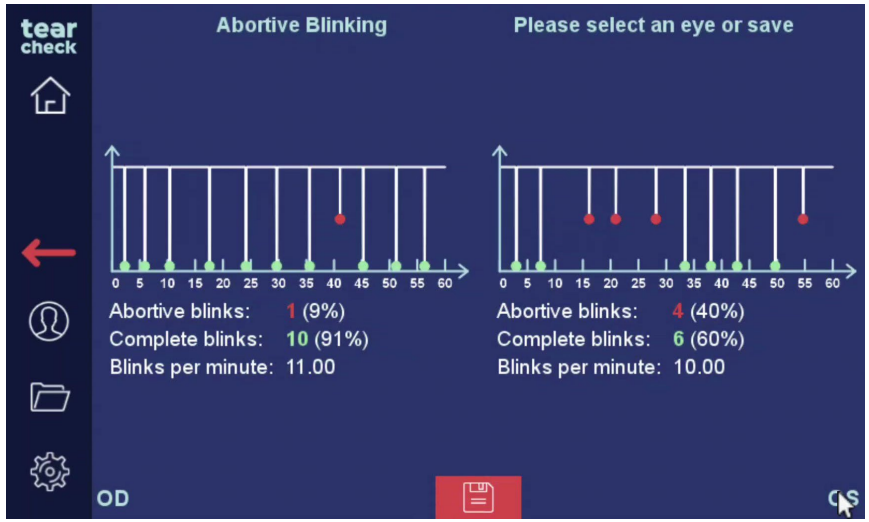
The **CCLRU-Score** makes it possible to classify the bulbar redness by comparing the tearcheck analysis with the reference photos (1-4) and choosing the most suitable option.



Eye Redness CCLRU selection

Using the eyelid flipping tool to pull down or flip the eyelid, helps to achieve even more revealing results.

4. ABORTIVE BLINKING / BLINK RATE



ABORTIVE BLINKING / BLINK RATE
This exam shows all blinks identified within 60 seconds to determine complete and abortive blinks.

UPDATE v3 In addition, the full number of blinks per minute is calculated and displayed.

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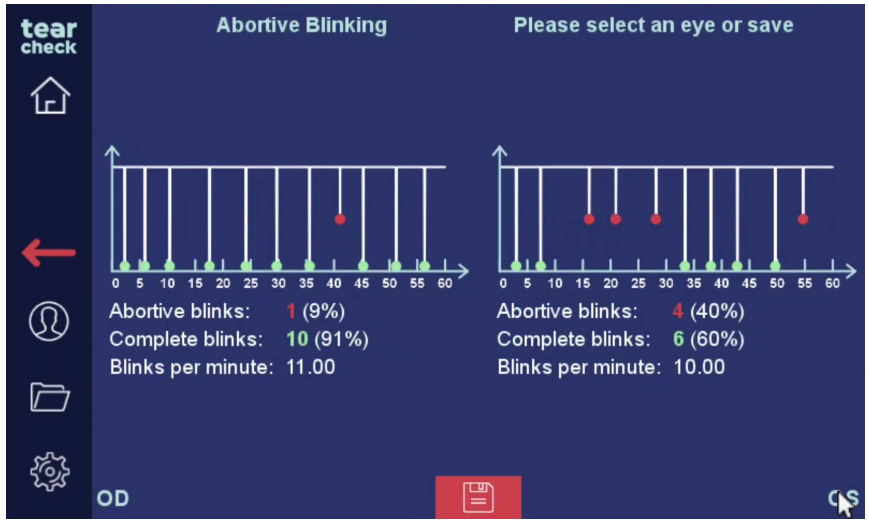
4. ABORTIVE BLINKING



ABORTIVE BLINKING
The exam shows all blinks identified within 60 seconds to determine complete and abortive blinks.

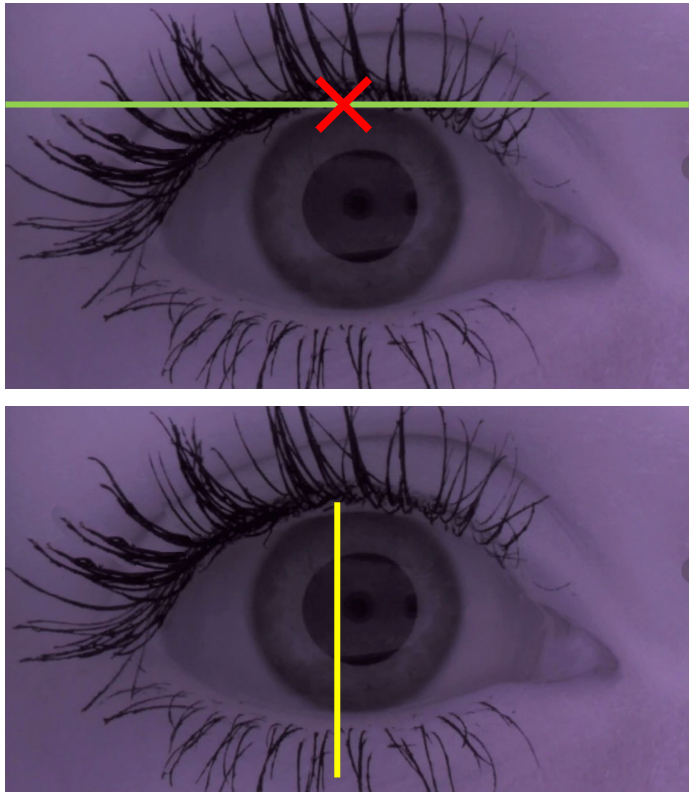
INTERPRETATION ABORTIVE BLINKING			
NORMAL	MILD	MODERATE	SEVERE
< 15%	15% - 25%	26% - 50%	> 50%

The software identifies all the blinks over the acquisition time (expected 1 minute) and determines the structure of the identified blinks: complete or incomplete blinks. This reveals an incomplete blink, which leads to an uneven distribution of the tear film, especially the lipid tear film component. Since the eyelids are not fully closed, the pressure on the meibomian glands is not sufficient to release enough lipid.

The higher the number of blinks and the higher the number of abortive (incomplete) blinks, the more severe the effects on the quality of the tear film will be.

This is especially concerning for elderly people, as with age, the eyelids are less toned and the contraction quality decreases.

4. ABORTIVE BLINKING



INSIGHTS

DETERMINE OPEN EYE

- The edge of the upper eyelid needs to be touched when the eye is fully open (see red cross in the photo on the left).
- tearcheck® then knows that the eyelid will not move higher than the green line in the picture.

DETERMINE CLOSED EYE

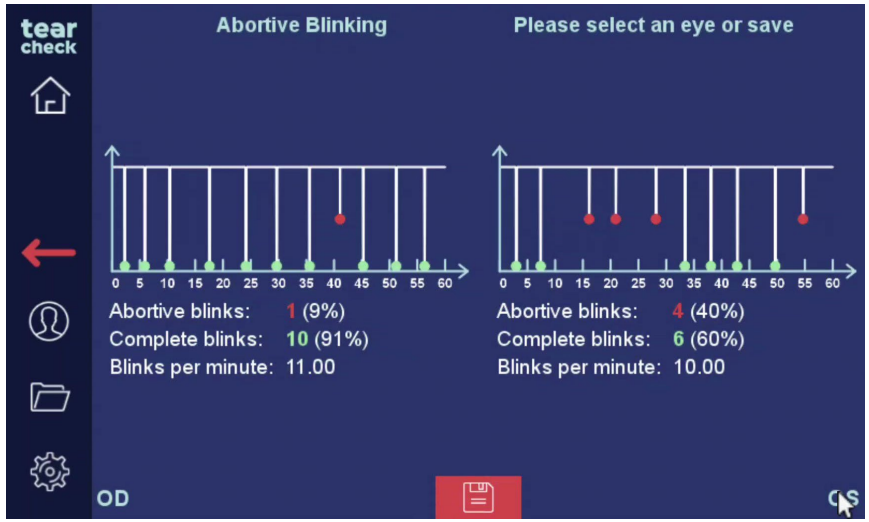
- The patient must close the eye naturally, without pressure. The eyelid position will automatically be detected once the screen is touched.

EXAMINATION

- The eyelid position will then be tracked along the yellow line (between the highest position of the eyelid and the lowest position of the eyelid).

4. BLINK RATE

UPDATE v3



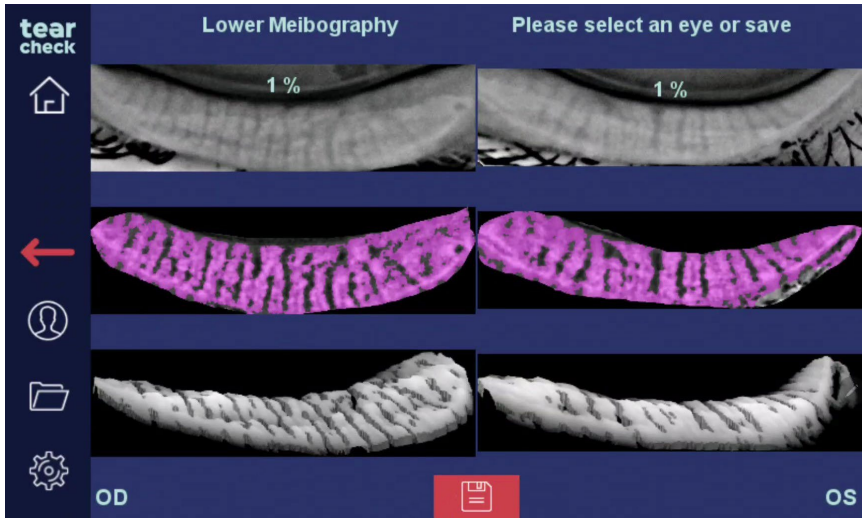
BLINK RATE

Within the calculation of Abortive Blinking, also all blinks per minute (no matter if complete or abortive) are calculated and displayed.

INTERPRETATION BLINK RATE			
NORMAL	**MILD**	**MODERATE**	**SEVERE**
< 20	20 - 25	26 - 32	> 32

If the Number of Blinks per minute is less than 5, the exam needs to be repeated.

5. MEIBOGRAPHY



MEIBOGRAPHY
Meibography makes it possible to visualize the Meibomian Glands.

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INTERPRETATION MEIBOGRAPHY			
NORMAL	MILD	MODERATE	SEVERE
< 20%	20% - 35%	36% - 50%	> 50%

The results offer to evaluate the following two parameters:

1. The **rate of gland loss** (in %) compared to an individual with all of the glands present.
2. The **morphology** of the glands present.

UPDATE v3 With the new software release 3.0.0, the meibography images have been improved, to allow even better visualization of the meibomian glands in all of the available views.

5. MEIBOGRAPHY

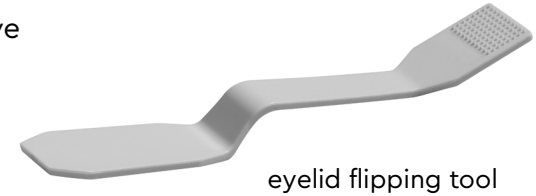
INSIGHTS

Meibography makes it possible to visualize the meibomian glands. This visualization is useful in explaining the anatomical structure responsible for the production of the lipid film to the patient.

We sought to "transcend" the final image obtained, considering that patients still have difficulty understanding raw medical imagery.

2 display modes have been developed:

- A **2D mode** in color, the glands appearing in pink on a background of shades of gray;
- A **3D mode**, particularly effective for highlighting areas where the glands have disappeared.



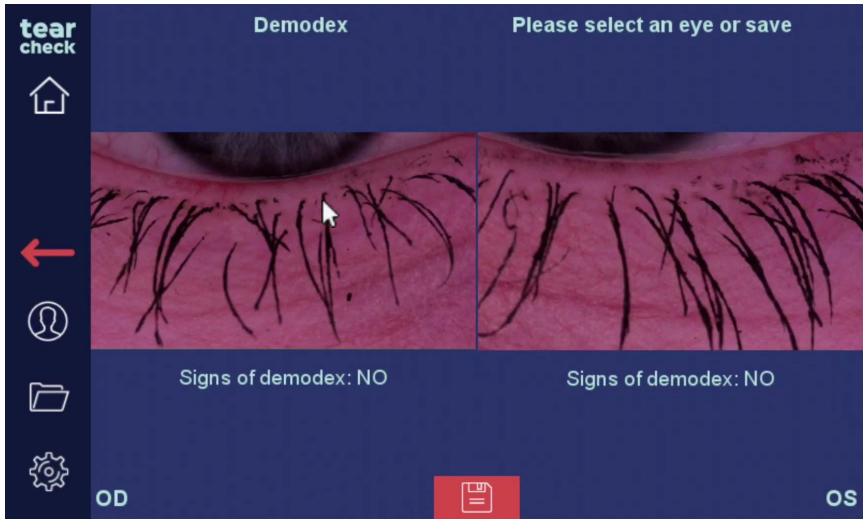
eyelid flipping tool

The results thus obtained make it possible to assess mainly **2 parameters**:

- The **rate of loss** of glands compared to an individual with all glands present.
- The **morphology of the glands present** (dilated glands or not, a sign of potential retention of secretions due to blocked ducts).

The accuracy of this examination is determined by the selections made by the practitioner as well as the selection refining step.

6. DEMODEX



DEMODEX
The Demodex exam consists of an enlarged image capturing the base of the eyelashes to evaluate for signs of demodex.

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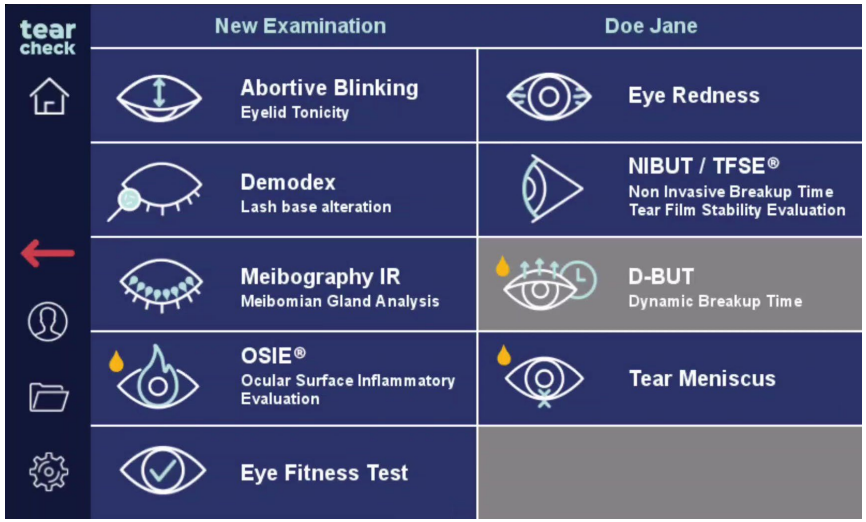
INTERPRETATION DEMODEX			
NORMAL	**MILD**	**MODERATE**	**SEVERE**
No	No	Yes	Yes

The magnification factor of the image does not in itself allow direct visualization of the parasites. Instead it makes it possible to trace and visualize signs of demodex presence.

UPDATE v3 Based on the captured image, the user is asked to subjectively select whether there are signs of demodex visible or not.

FLUORESCEIN EXAMS



For the next 3 examinations the presence of fluorescein is required.

It is recommended to use liquid fluorescein. If this is not available, it is possible to use fluorescein strips. Therefore moisten them with a little normal saline or anesthetic drops and gently touch the inside of the lower eyelid with the moistened strip.

Note the right timing for each exam to achieve proper results:

6. **D-BUT**
   exam can start right after instilling fluorescein
7. **OSIE®**
   directly after D-BUT / or 2 minutes after instilling fluorescein *(watch the timer on top of the screen)*
8. **Tear Meniscus**
   directly after D-BUT or OSIE® / or 2 minutes after instilling fluorescein

7. D-BUT

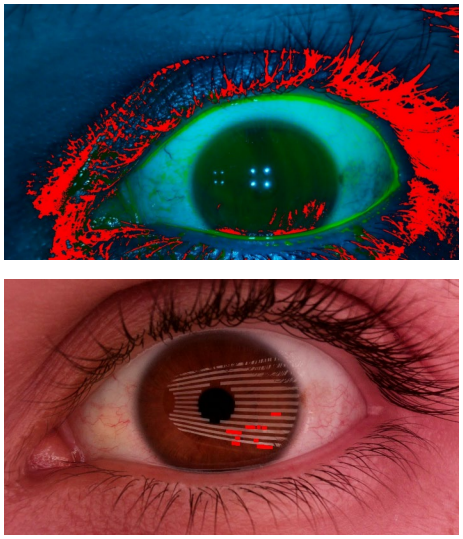
Preview / Coming next ...

Dynamic Breakup Time

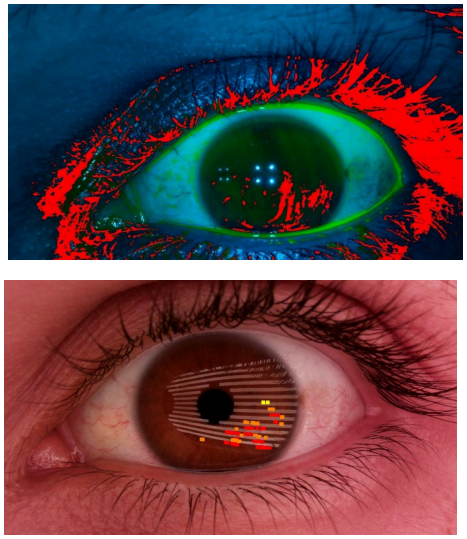
Comparison between tearcheck® NIBUT and D-BUT to show the accuracy of tearcheck®

The upcoming D-BUT exam is taken with a drop of fluorescin. Each raw image is captured at a given time after an eye blink.
The images show the development of the elevations within the captured time :

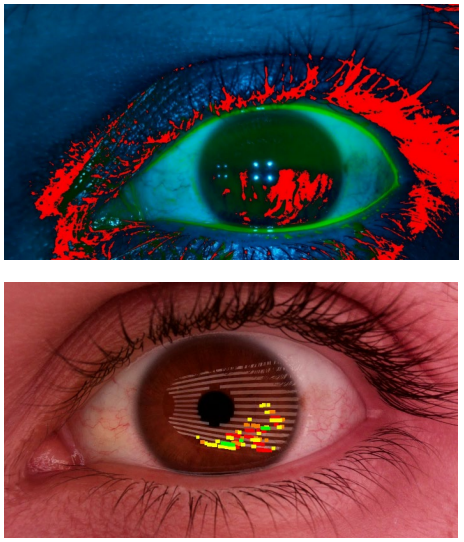
- The same image where break-up under fluorescein is highlighted in red
- The incremental result of tearcheck® NIBUT analysis.



D-BUT + NIBUT 3 seconds after eyeblink



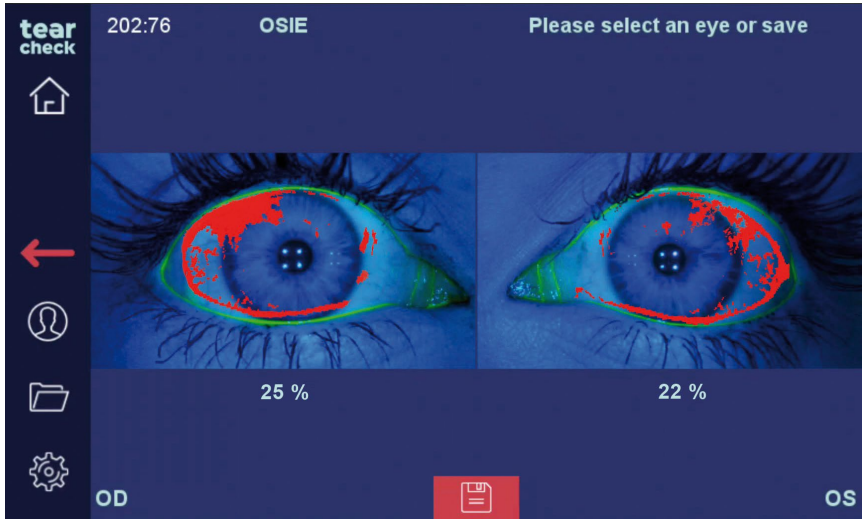
D-BUT + NIBUT 6 seconds after eyeblink



D-BUT + NIBUT 8 seconds after eyeblink

8. OSIE®

Ocular Surface Inflammatory Evaluation



OSIE®: 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.

INTERPRETATION OSIE®			
NORMAL	MILD	MODERATE	SEVERE
< 10%	10% - 25%	26% - 40%	> 40%

The analysis of these inflammatory zones is carried out 2 minutes after instilling fluorescein, the time necessary for its natural elimination through the lacrimal 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 the 120 seconds after instillation.

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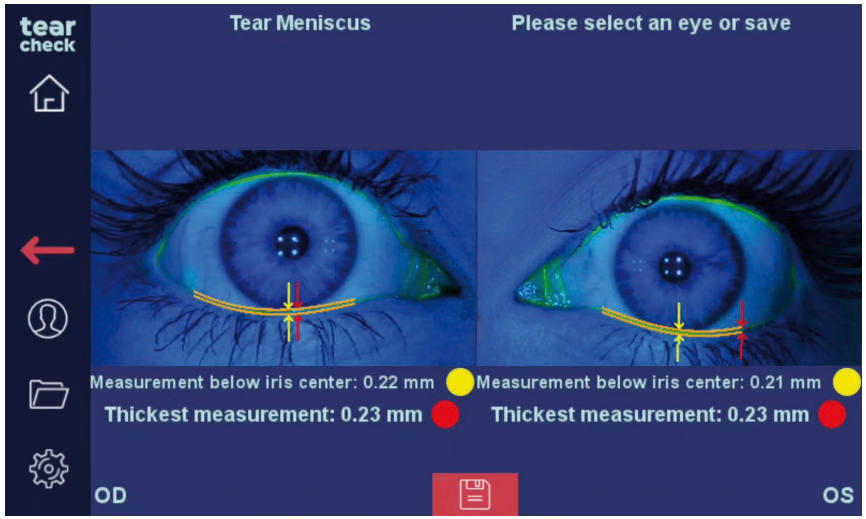
9. TEAR MENISCUS



TEAR MENISCUS
This examination shows the height of the tear meniscus.

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INTERPRETATION TEAR MENISCUS			
NORMAL	MILD	MODERATE	SEVERE
> 0,20	0,20 – 0,15	0,15 – 0,10	< 0,10

The tear meniscus is evaluated in the lower eyelid and shows, if there is sufficient tear production before the next eye blink.

Two values are calculated:

- Yellow: tear meniscus measurement below iris center
- Red: Thickest measurement of the tear meniscus

Tear meniscus should be done directly after OSIE® or D-BUT to use remaining fluorescein.

9. TEAR MENISCUS

INSIGHTS

This exam takes place:

- Either after completing the OSIE® exam
- Or 2 minutes after instilling a drop of fluorescein in each eye.

In both cases, the time lapse between instillation of fluorescein and measurement of the height of the meniscus is sufficient for the excess fluid brought by the fluorescein drop to be eliminated naturally through the tear ducts.

IMPORTANT:

- Fluorescein must be supplied in the form of drops and not through papers impregnated with fluorescein (this is to avoid irritation by friction which would increase tear secretion by reflex route).
- The tear ducts must be permeable to avoid any abnormal retention of tears in the meniscus (make sure to remove any punctum plugs if present)

Carried out in this form, the examination will prove to be much more reliable than a measurement of the meniscus in white light and without colouring: in fact, the natural shape of the meniscus and in particular the shape of the area of its connection with the eyeball make very difficult real optical identification of the upper edge of the meniscus. Measurements made in this way are most likely to be distorted.

The presence of dye will remove all optical artifacts and thus make the measurement much more reliable.

9. TEAR MENISCUS

INSIGHTS

For any measurement of a real dimension using an imaging tool, it is always necessary to have a frame of reference within the image that allows a relationship to be created between pixels and millimetres.

Here, we have chosen the **diameter of the iris as the benchmark**, unlike other devices which have chosen the diameter of the pupil.

The reason is simple:

Regardless of the ambient lighting, which may vary depending on the exam environment, the diameter of the iris, unlike the diameter of the pupil, does not vary.

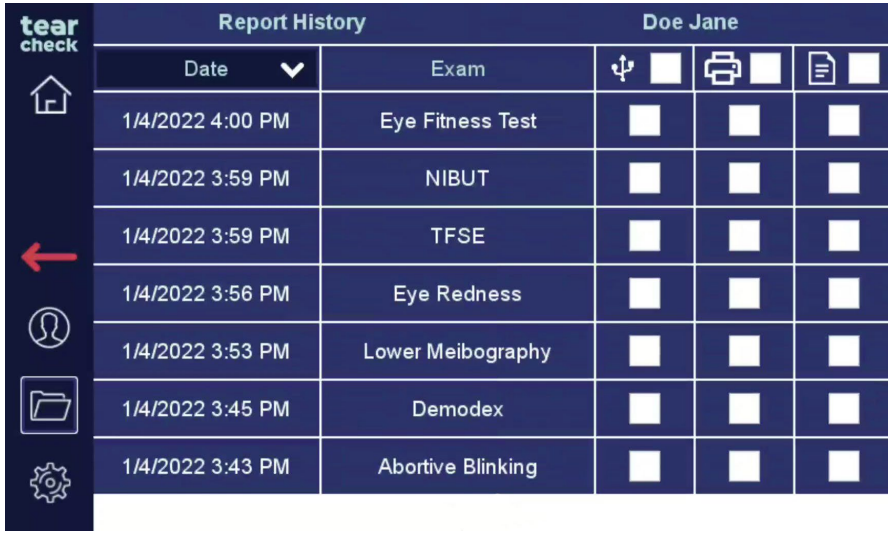
A device which would use the diameter of the pupil as a reference would give totally different values for the same meniscus depending on the surrounding light pollution. This type of device would therefore not be reliable.

According to the fact that the full tear meniscus is not visible under white illumination, we prefer to proceed by utilizing fluorescein remaining after BUT or ocular surface inflammatory evaluation.

After a few times, excess liquid is evacuated by the tear ducts and the tear meniscus is not modified in its height. The tear meniscus is nevertheless loaded by fluorescein and thus becomes fluorescent under blue light.

Tear meniscus acts as a green light source and its imaging is not impaired by the lighting source shape. To get access to the physical dimension (in mm), the iris size is used as a reference as iris diameter does not vary.

REPORT HISTORY

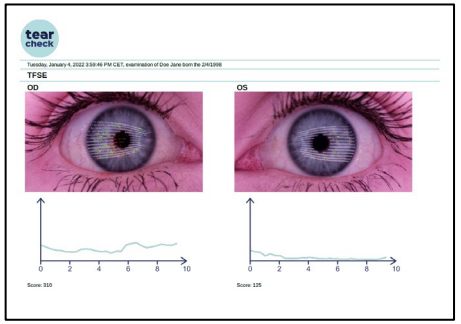


The whole report per patient will be stored. That makes it possible to compare different results from same examination or to regard all selected exams.

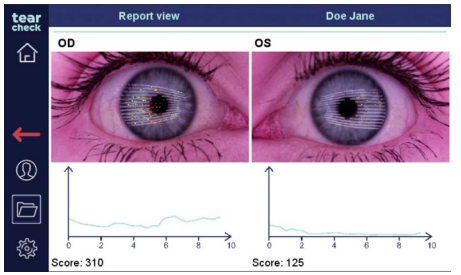
The report history can be filtered by date or by exam.

tearcheck® REPORT
The report is available for print, to show on the screen or to export by USB.

Report Export / Print

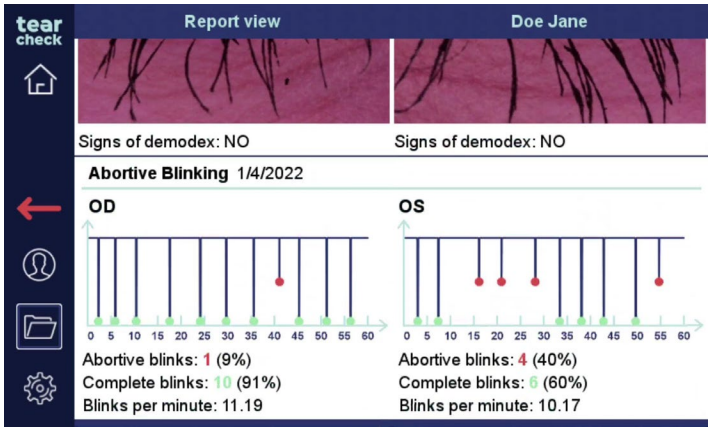


Report on the Screen

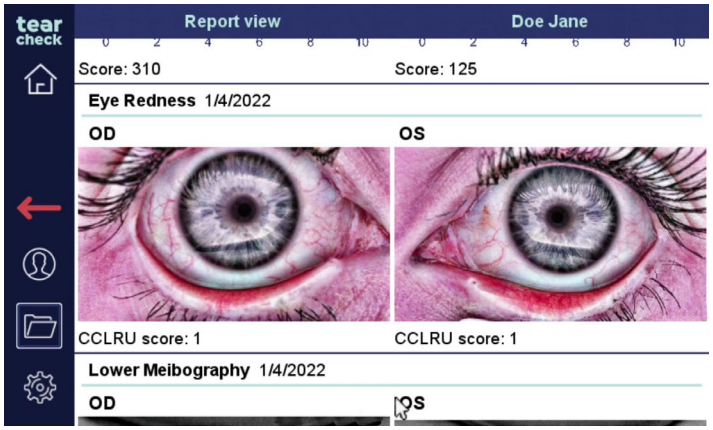


REPORTS OF EXAMS

ABORTIVE BLINKING Report



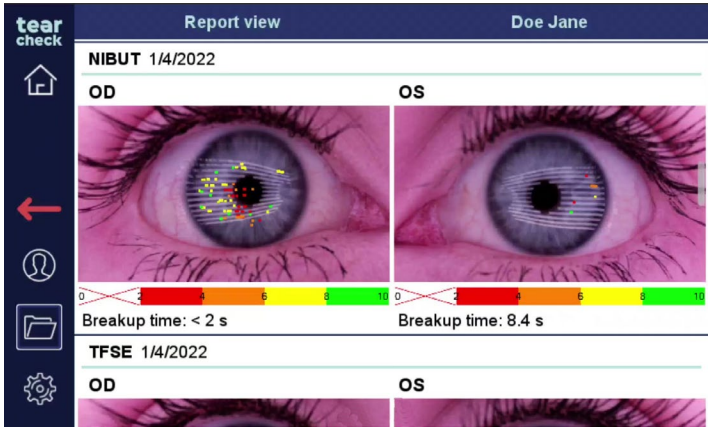
EYE REDNESS Report



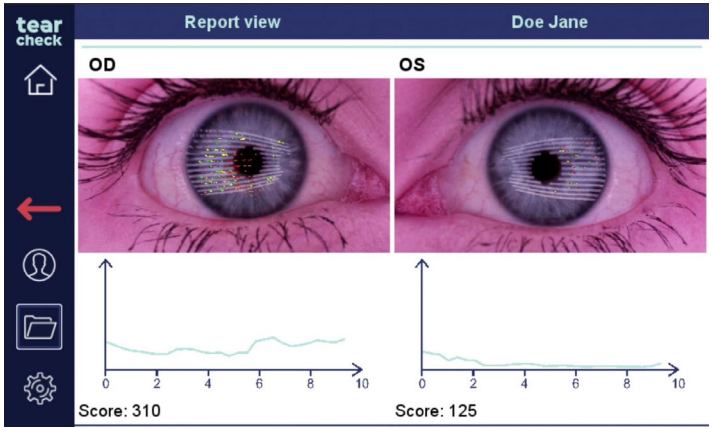
DEMODEX Report

REPORTS OF EXAMS

NIBUT Report



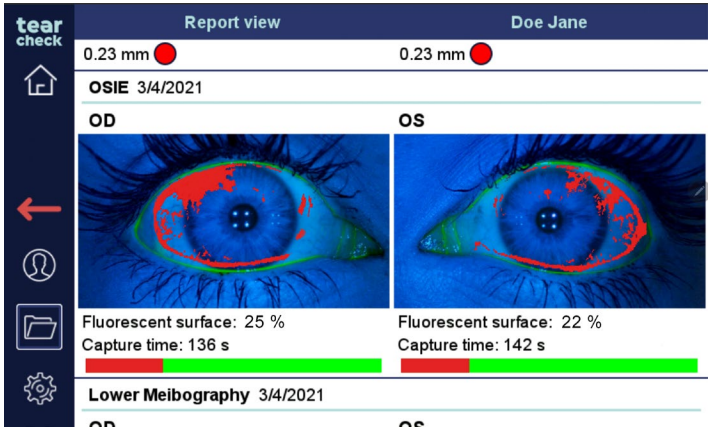
TFSE® Report



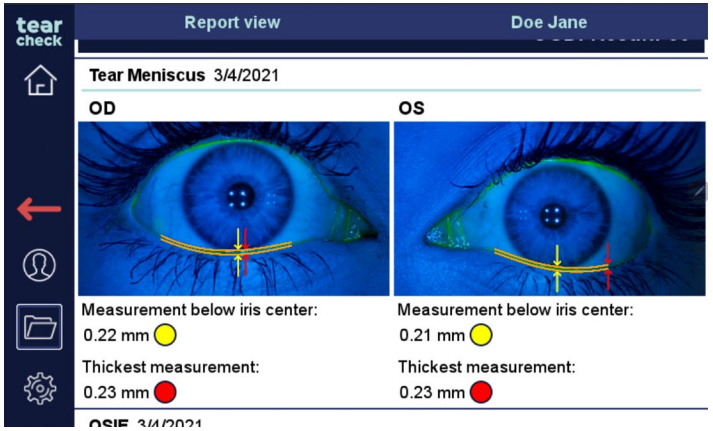
MEIBOGRAPHY Report

REPORTS OF EXAMS

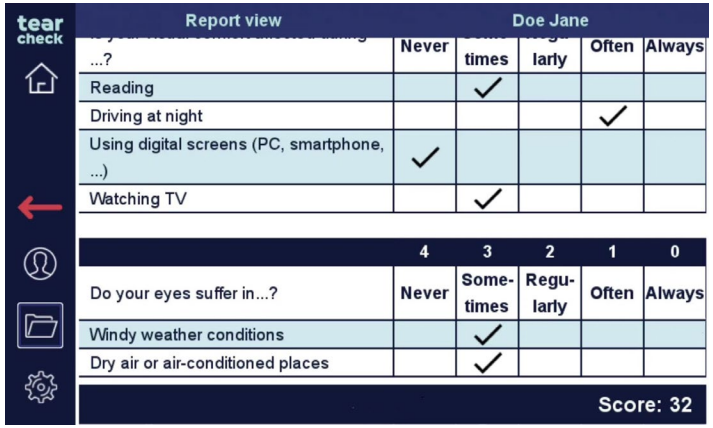
OSIE® Report



TEAR MENISCUS Report



EYE FITNESS TEST Report



REPORT OVERVIEW

UPDATE v3

tearcheck® REPORT OVERVIEW
The report overview shows on one page an overview of the results of all exams and the corresponding category per exam (normal / mild / moderate / severe).

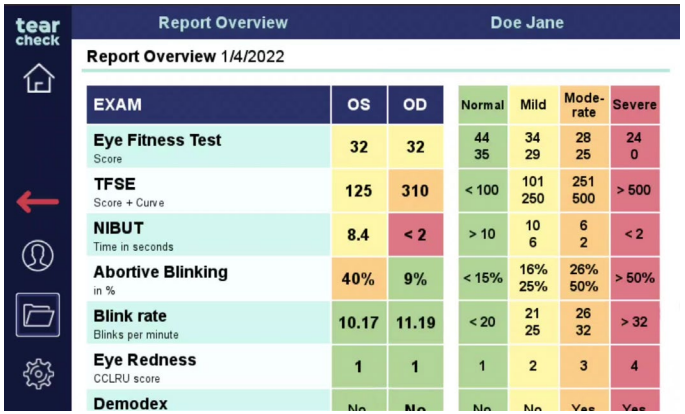
NOTE: Guidelines for smart Dry Eye analysis can be found in the **NEW Smart Screening document.**

This new feature makes it possible to easily present the outcomes of the exams to the patient and also compare with results of previous examinations.

The user can either select a full day, to view the results of all exams, or also unfold all exams of one day, to unselect those that are not needed.

The report overview is available for print, to show on the screen or to export by USB.

Report Overview of all exams per day



tear check

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Register your device on our platform to get the latest product insights:

gateway.esw-vision.com

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ESW vision