



DEDICATED DRY EYE PLATFORM

Integrated and easy to use diagnostic platform



Sapphire
by EZER

INTEGRATED SYSTEM FOR THE ANALYSIS OF THE OCULAR SURFACE

The instrument is designed to perform tear film tests, from the quality of tears to the analysis of the Meibomian Glands.



TECHNICAL DATA

IMAGE RESOLUTION	5 MP
ACQUISITION MODE	Multi shot, video
FOCUS	Autofocus, manual focus
ISO MANAGEMENT	Variable
CONES	Main cone and Placid cone
CAMERA	Colored, sensitive to infrared (NIR), yellow-filtered
LIGHT SOURCE	Infrared LED – Blue, red and white LED

MINIMUM HARDWARE REQUIREMENTS

Intel® Core™ i7

SSD Drive

8 GB RAM

Screen resolution: 1600x900

1 available USB 3.0 port

1 other available USB port

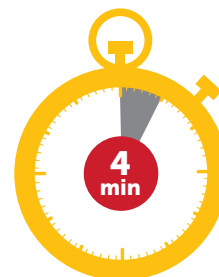
Microsoft® Windows® 8, 10 Professional (Pro) x64 (64 bit)

Considering the high quality of the videos, for optimal video recording and playback we suggest:

Intel® Core™ i7



DIAGNOSTIC TIME



Registration number at the Ministry:

Invented and developed 100% in Italy

Medical instrument in CLASS I registered at the Ministry of Health

Medical electrical equipment CLASS I complies with the norm En. 60601-1.

The technical features of the instrument and its accessories can be improved at any time and without notice.

To obtain an updated description we suggest visiting the website www.sbmsistemi.com

FUNCTIONS

The Device is the new instrument for the individual analysis of tear film that allows to carry out a quick detailed structural research of the tear composition.

Research on all the layers **(Lipid, Aqueous, Mucin) and Meibomian Glands**.

Thanks to the Us Ophthalmic Device it is possible to identify the type of Dry Eye Disease (DED) and determine which components can be treated with a specific treatment, in relation to the type of deficiency.

AUTO INTERFEROMETRY

The TFA automatically evaluates the quantity and quality of the lipid component on the tear film. The device highlights the lipid layer and the software analyses automatically Lipid Layer Thickness (LLT).

TEAR MENISCUS

The thickness of the tear meniscus that is observed on the eyelid margins provides useful information on the tear volume. The tear meniscus can be examined considering its height, regularity and shape.

NIBUT WITH MAP AND GRAPH

The stability of the mucin layer and the whole tear film is assessed through the study of non-invasive break up time (NIBUT), by using the Placido cone projected onto the cornea.

MEIBOGRAPHY

Meibography is the visualization of the glands through illumination of the eyelid with infrared light. It images the morphology of the glands in order to diagnose any meibomian gland drop out which would lead to tear dysfunction.

3D MEIBOGRAPHY

This new imaging system provides strong evidence to support the choice of a specific therapy (for example IPL treatment) and helps the patient to understand why a certain therapy is being recommended.

BLINK QUALITY

It has been established that efficient blinking plays an important role in ocular surface health including during contact lens wear and that it improves contact lens performance and comfort.

BLEPHARITIS

This test helps to visually see blepharitis and presence of Demodex. It can be performed on the outer surface of the eye and eyelids.

OCULAR REDNESS CLASSIFICATION

Once the image of the conjunctiva with its blood vessels is captured, it is possible to compare it with the classification sheets of bulbar and limbal redness degrees.

PUPILLOMETRY

Measurement of the pupil reaction to light with and without glare. Measurement mode: SCOTOPIC, MESOPIC, PHOTOPIC

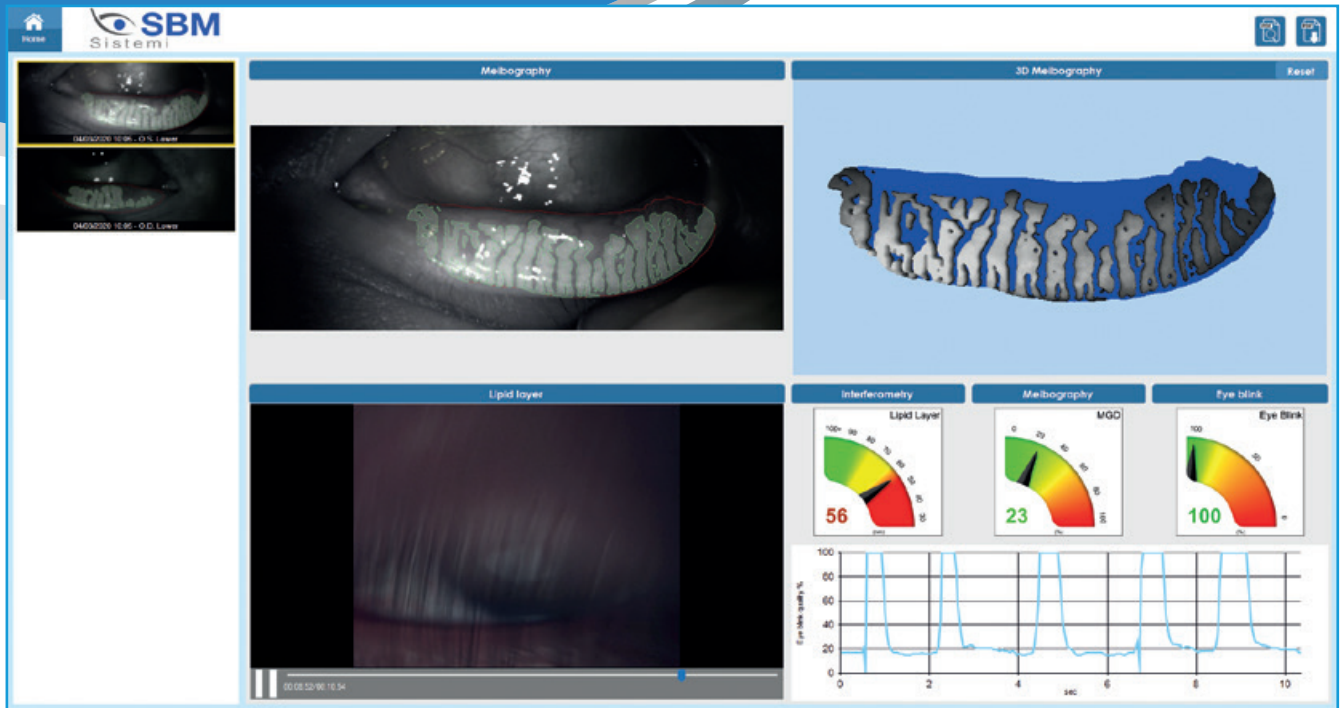
WHITE TO WHITE MEASUREMENT

Evaluation of corneal diameter from limbus to limbus (white-to-white distance, WTW).

ANTERIOR SEGMENT IMAGING

AUTO INTERFEROMETRY

COMPLETE MEIBO ANALYSIS: STRUCTURE AND SECRECTION VIEW



The evaluation of the lipid layer is part of your overall Dry Eye Assessment. Knowing what is causing Dry Eye will help determine the best treatment option.

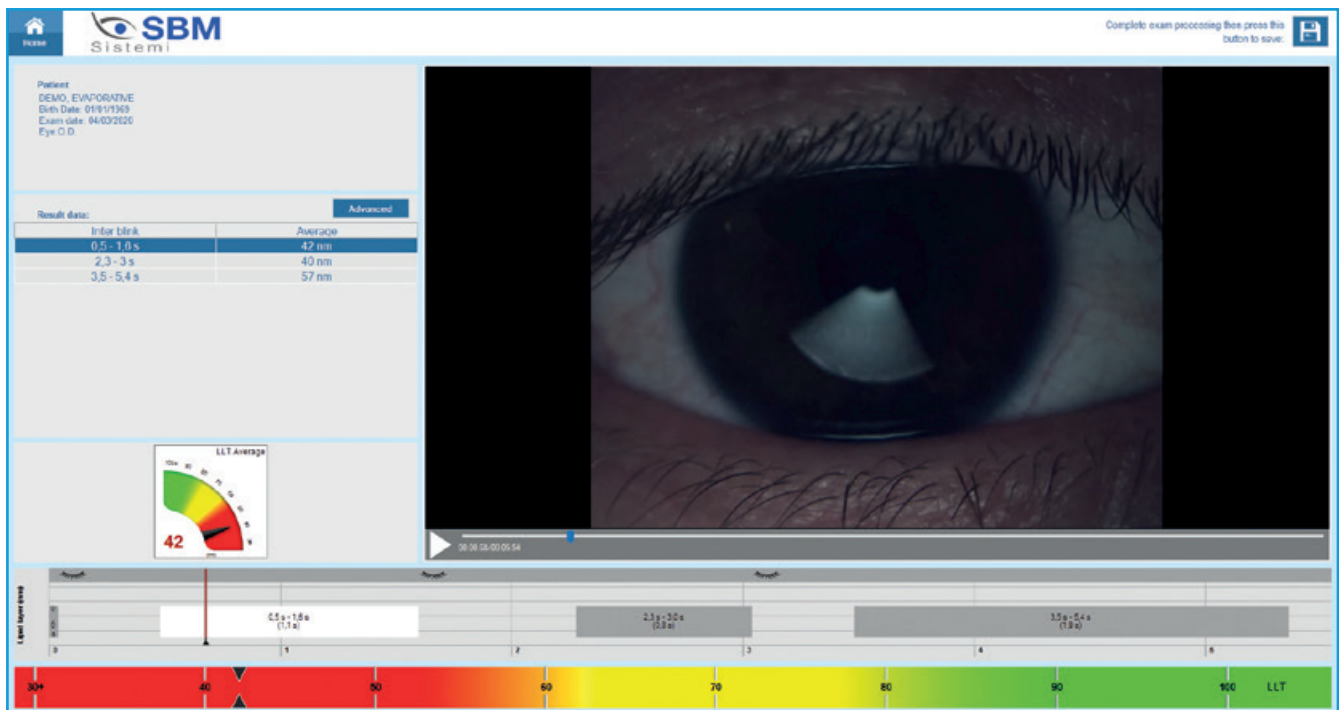
After your assessment is complete, the Optometrist will discuss your treatment options. Lipid pattern classification, incidence and clinical interpretation is adapted from Guillon & Guillon description incidence (%) with estimated thickness (nm).

Observation of blinking frequency and completeness should also be considered - while listening to history and symptoms can be an ideal time to observe this.

A typical blink pattern can be observed as approximately one blink every five seconds, ie 11 blinks per minute. Incomplete blink can often be observed in contact lens wearers, and frequent blink may be a result of an attempt to maintain a relatively thin lipid layer.

AUTO DETECTION OF:

Average thickness of the Lipid layer
Blinking rate



AUTOMATED LIPID LAYER ANALYSIS

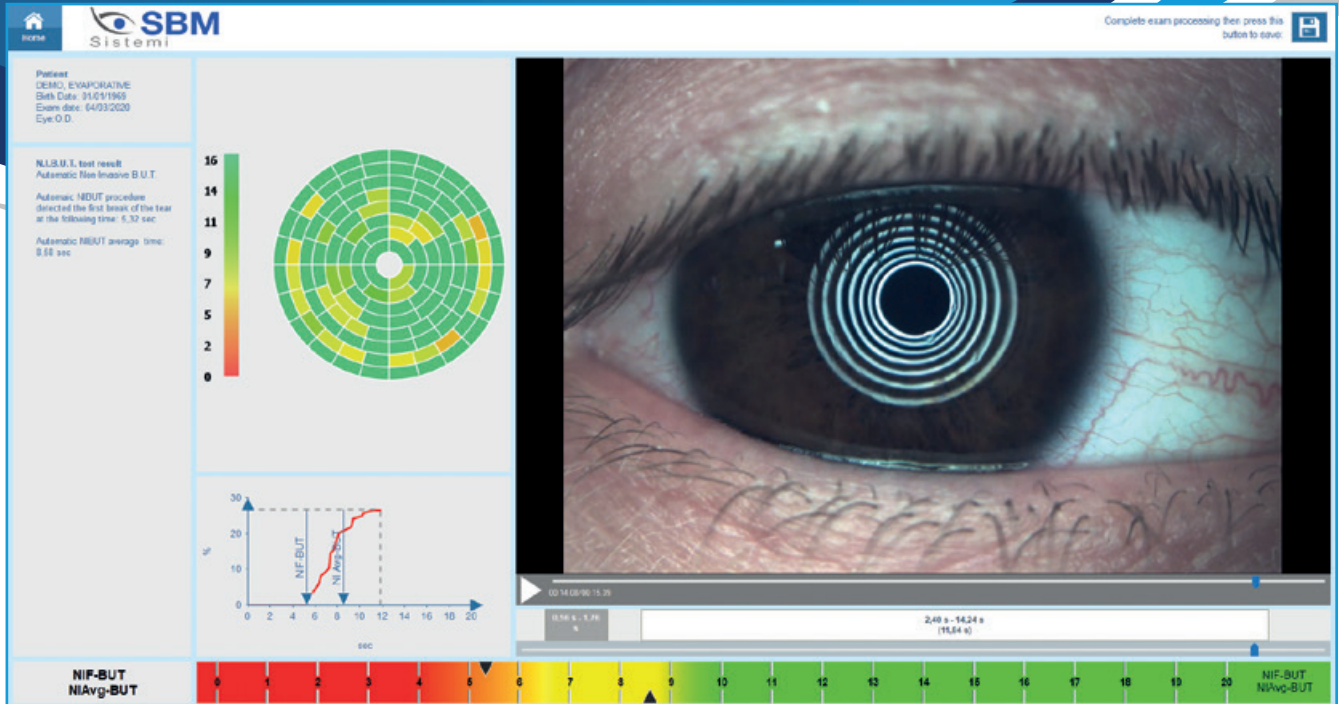
The TFA software analyses lipid layer thickness and allows to understand the functionality of Meibomian Glands. It is possible to carry out a follow up after MG treatment detecting an increase in secretion.

Using the new Us Ophthalmic, Interferometry gets easy, quick and automatic.

The software automatically detects the coloured lipids on the patient's eye and determines lipid layer thickness (LLT).

In a few seconds it is possible to get automatically relevant data to understand functionality of Meibomian Glands such as average LLT.

AUTO-NIBUT



The Device allows to evaluate tear film stability and regularity, using non-invasive break up time measurement (NIBUT). This measures the number of seconds between one complete blinking and the appearance of the first discontinuity in the tear film.

With the Us Ophthalmic Device, thanks to one single video, the physician can gain lots of information:

- Automatic NIBUT
- Average of more than one value
- Graph to understand the trend of tear film stability during the video
- Tear topography that shows all breaking the tear film during time.

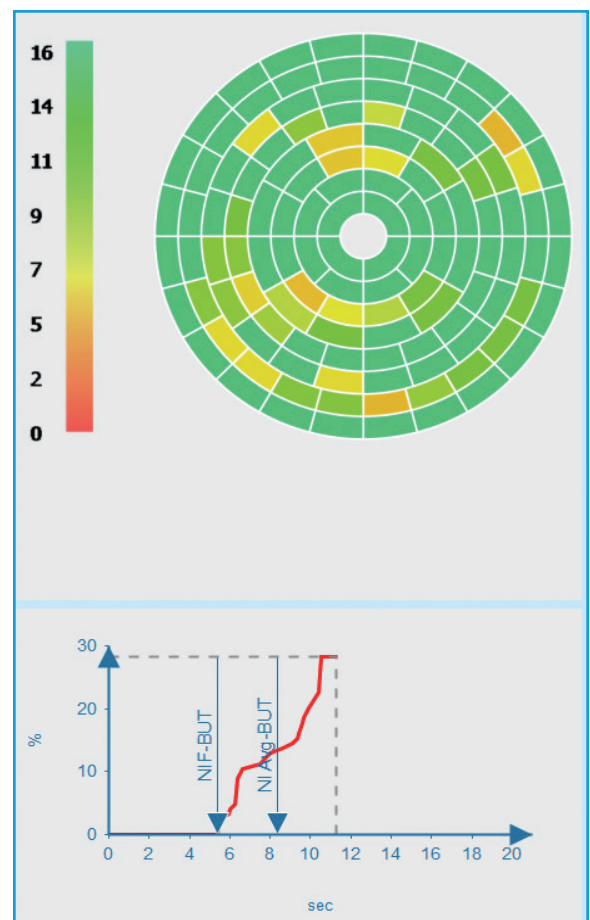
TEAR STABILITY EVALUATION

Through Placido disk projection on patients' cornea, TFA automatically evaluates tear film stability.

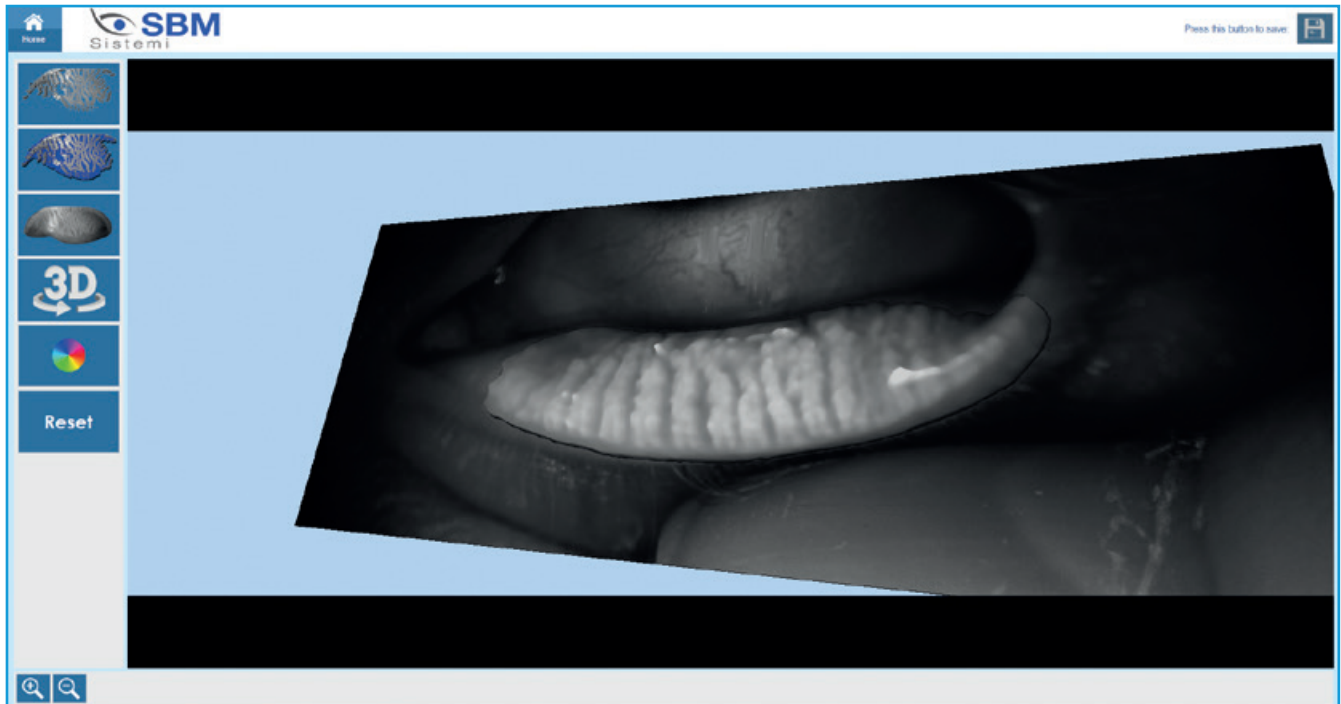
The software checks periodically cornea's shape with the Placido rings and detects any deviation, providing break up time values in an easy and understandable way. AVG BUT is provided with normograms and, after different analysis, shows the trend line for a useful follow up after treat.

Through the Placido rings, TFA automatically provides:

- First BUT
- Avg BUT
- Stability graph
- Tear topography



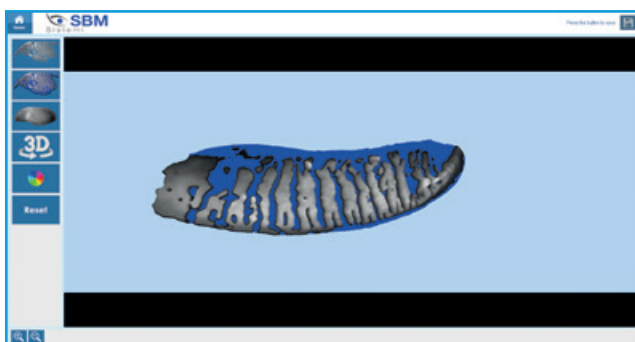
MEIBOGRAPHY 3D



AN OUTSTANDING DIAGNOSTIC EVALUATION IS NEEDED TO DEMONSTRATE THE EFFECTIVENESS OF THE IPL TREATMENT TO PATIENTS

The revolutionary introduction of the 3D Meibomian Gland imaging gives two big advantages. Firstly, it enables to confirm the presence of abnormal glands compared to a healthy subject in a 3D view; secondly, it provides a clear image to share with the patients, to help explain the potential reason of their discomfort.

Moreover, this new imaging system provides strong evidence to support the choice of a specific therapy (for example IPL treatment) and helps the patient to understand why a certain therapy is being recommended.



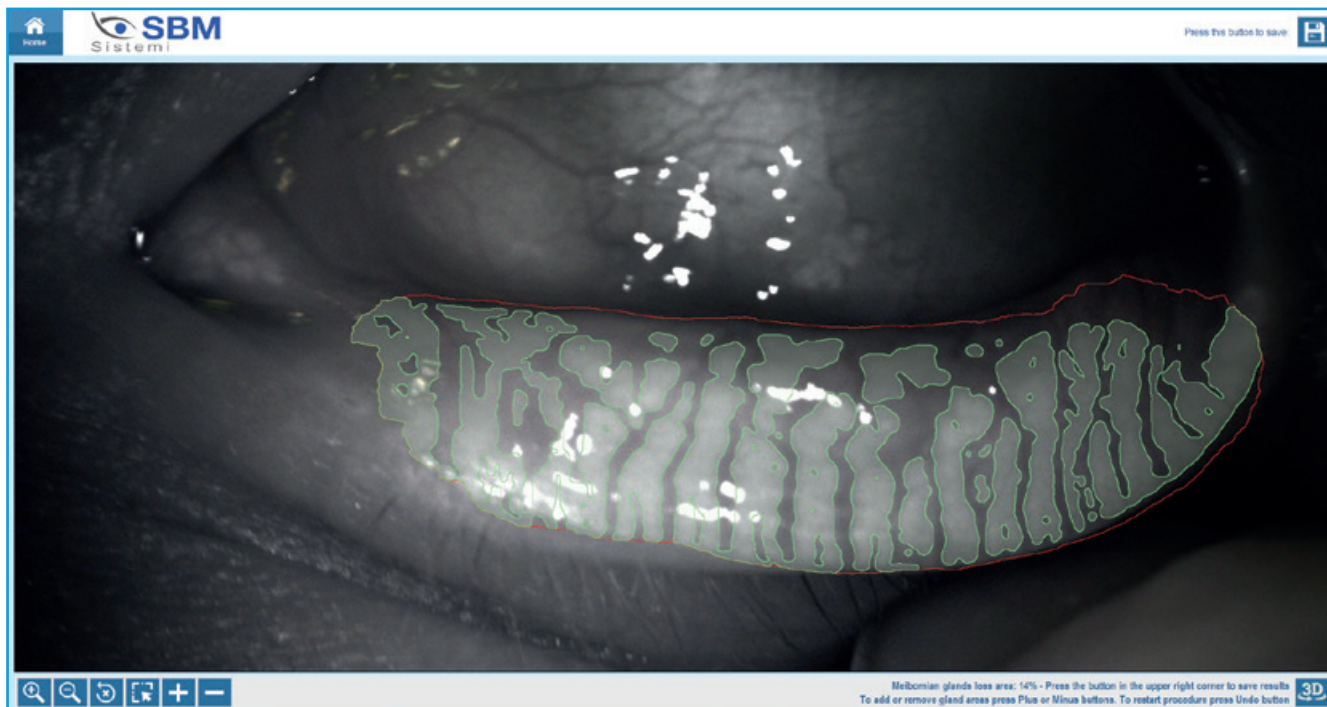
BENEFITS FOR PATIENTS:

- For the first time, a 3D image can help to understand the structure of the eyelids. It can show possible diseases of Meibomian Glands and differences with healthy MGs.
- Patients can see for themselves why they are getting eye discomfort and fluctuating vision
- Patients can understand why a specific treatment is suggested.

ADVANTAGES FOR THE PHYSICIAN:

- Viewing the presence of abnormal gland structures in a high-resolution 3D image
- Comparing a normal patient gland profile with that of an MGD patient
- Evidence that supports the diagnosis in the case of evaporative dry eye disease and the explanation of the reasons for the choice of MGD therapy (including IPL)
- Compelling evidence to help the patient visualise what is happening to the Meibomian Glands
- Providing the reassurance that MGD is a contributory factor in the diagnosis of evaporative dry eye disease.

MEIBOGRAPHY



MEIBOMIAN GLAND AUTO DETECTION ON UPPER AND LOWER EYELIDS

Meibomian Glands (MGs) play a significant role in tear quality by producing lipids (meibum) that are part of the superficial tear film. Dysfunction of the MGs destabilizes tear composition resulting in evaporative dry eye.

The posterior lamella of the eyelid hosts a fleet of parallel MGs situated between the palpebral conjunctiva and tarsal plate. A normal Meibomian Gland is approximately linear and 3–4 mm in length, traversing the posterior eyelid perpendicularly to the lid margin. Closer inspection of a Meibomian Gland demonstrates a tubulo-acinar architecture with sacular arrangements of acini and a ductal system that communicates with orifices near the muco-cutaneous junction of the eyelid.

Glandular acini contain clusters of modified sebaceous cells called meibocytes (functional unit of the Meibomian Gland).

These cells synthesize and secrete lipids (meibum) into the pre-corneal tear film. Meibum permeates the tear surface where it serves several important functions. It prevents tear evaporation and thus desiccation of the ocular surface; it acts as a physical and hydrophobic barrier to the inward movement of environmental and organic agents; and it lubricates the ocular surface to prevent irritation while promoting a clear ocular image. Consequently, tear physiology is dependent upon the proper functioning of the MGs.

THE US OPHTHALMIC DEVICE CAN DETECT THE LENGTH AND WIDTH OF MEIBOMIAN GLANDS SHOWN THROUGH INFRARED MEIBOGRAPHY WITHOUT REQUIRING ANY INPUT FROM THE USER. THE IMAGES ARE THEN AUTOMATICALLY CLASSIFIED.

HOW IT WORKS

The System automatically analyses the images taken through a sensitive infrared camera (NIR) to locate the Meibomian Glands in a guided way:

- An exam valid both for the upper and the lower eyelids;
- Automatic percentage of the extension of MGs in the chosen area
- Automatic percentage of the Meibomian Gland loss area

If the operator prefers, it is also possible to manually compare the images taken with three different related grading scales.

AUTOMATIC LID DETECTION

To decrease evaluation time, the software automatically detects the lid margin for MG analysis.

Meibomian Gland dysfunction (MGD) is characterised by chronic, diffuse abnormalities of the Meibomian Glands and altered secretion and chemical composition of meibum. MGD leads to increased tear evaporation, increased tear osmolality and an increased susceptibility to ocular surface inflammation, epithelial damage and discomfort. MGD is the leading cause of dry eye disease and affects most of the population.

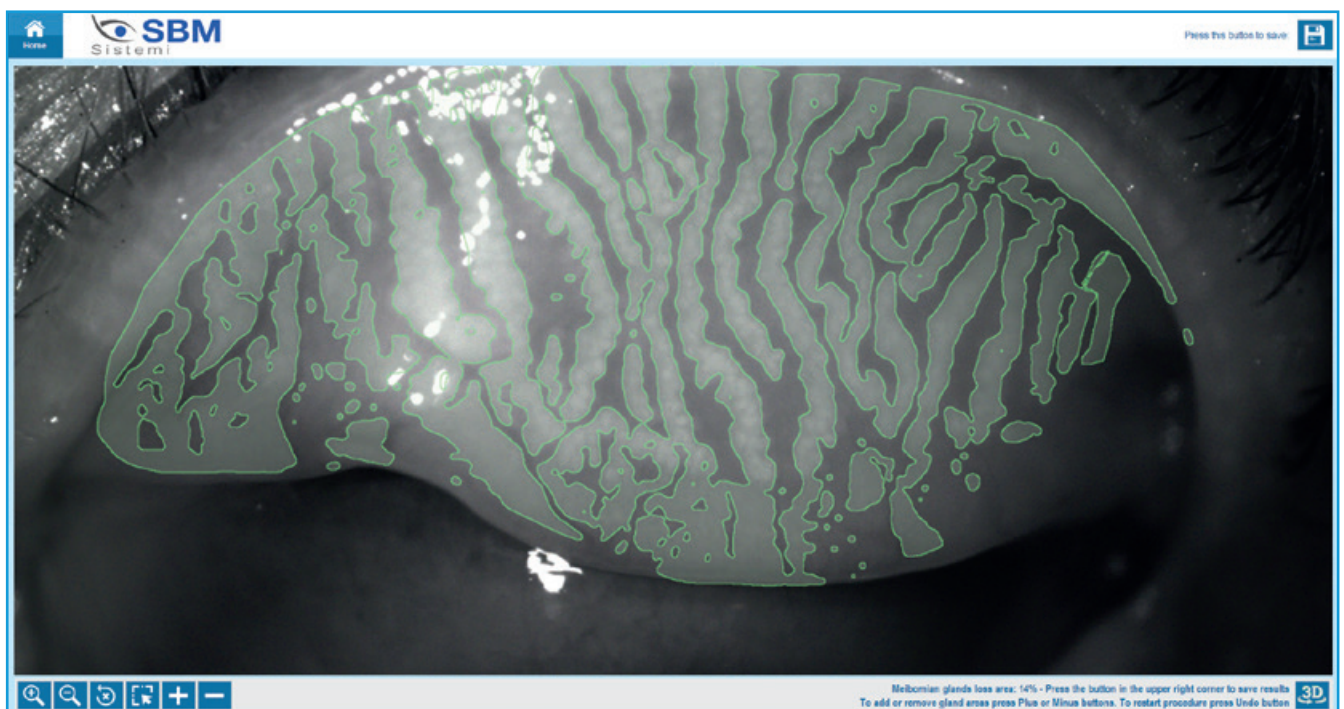
Blepharitis is a common eyelid condition that can lead to symptoms ranging from burning, to itching, flaking, eyelid discharge, eyelid redness, and the occurrence of frequent "pink eye"-like flare ups.



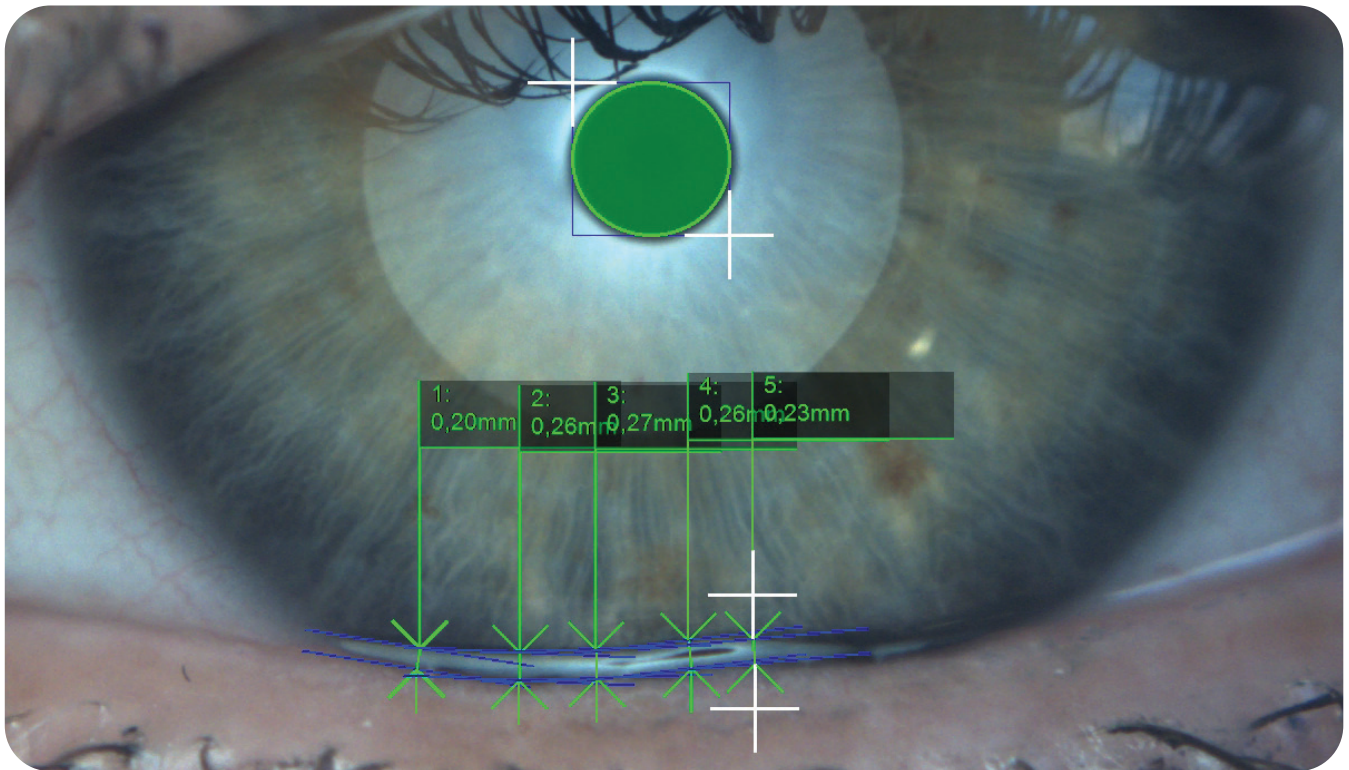
Different evaluations should be performed on Meibomian Glands in order to prescribe the most appropriate treatment, such as Intense Pulsed Light (IPL). The Us Ophthalmic tools allow an accurate comprehension of the ocular surface and especially the Meibomian Glands. The acquired images are processed and transformed into 3D pictures.

Thanks to scientific algorithms it is possible for the physician to see these 3D images, and to show them and explain abnormalities to the patients.

It will therefore be easier for the physician to recommend a specific treatment even if it is more expensive. It will also be possible to evaluate the efficacy of periocular intense pulsed light therapy on MGs.



TEAR MENISCUS HEIGHT MEASUREMENT



UP TO 5 MEASURING POINTS

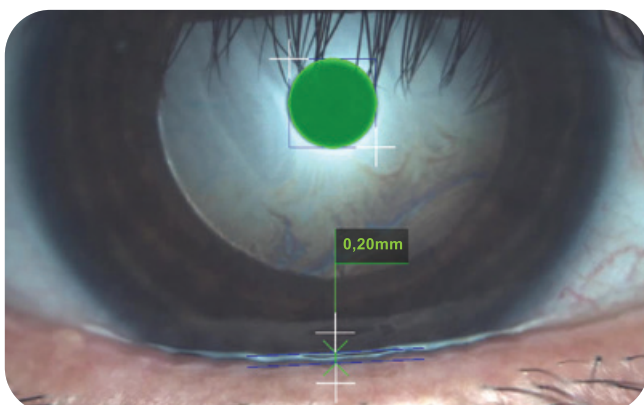
Low tear production may result in aqueous tear deficiency (ATD) and cause dry eye symptoms. However, measuring the tear volume is difficult since the methods normally used are invasive and irritating. Reflex tear production can be induced, giving an overestimation of basal tear flow and volume. The sizes of the tear meniscus are related to the tear secretion rate and tear stability, and they are good indicators of the overall tear volume. Tear meniscus height is related to the tear secretion rate and tear stability and for this reason it's a good indicator of tear production.

The aqueous layer is evaluated through the non-invasive "Tear Meniscus" test and is then classified into different categories.

The Us Ophthalmic Device is an excellent method of screening for dry-eye patients, to measure the upper and lower tear meniscus in patients with aqueous tear deficiency (ATD) dry eye and to determine the most effective meniscus variables for the diagnosis of dry eye. Normal tear volume is important for the maintenance of ocular surface physiology and ocular comfort.

The total tear volume is composed of the tear meniscus, which contains 75% to 90% of the tears, the pre-ocular film and the cul-de-sac.

Recent advances and associated software have enabled the simultaneous imaging of both upper and lower meniscus, and real-time changes have been reported.

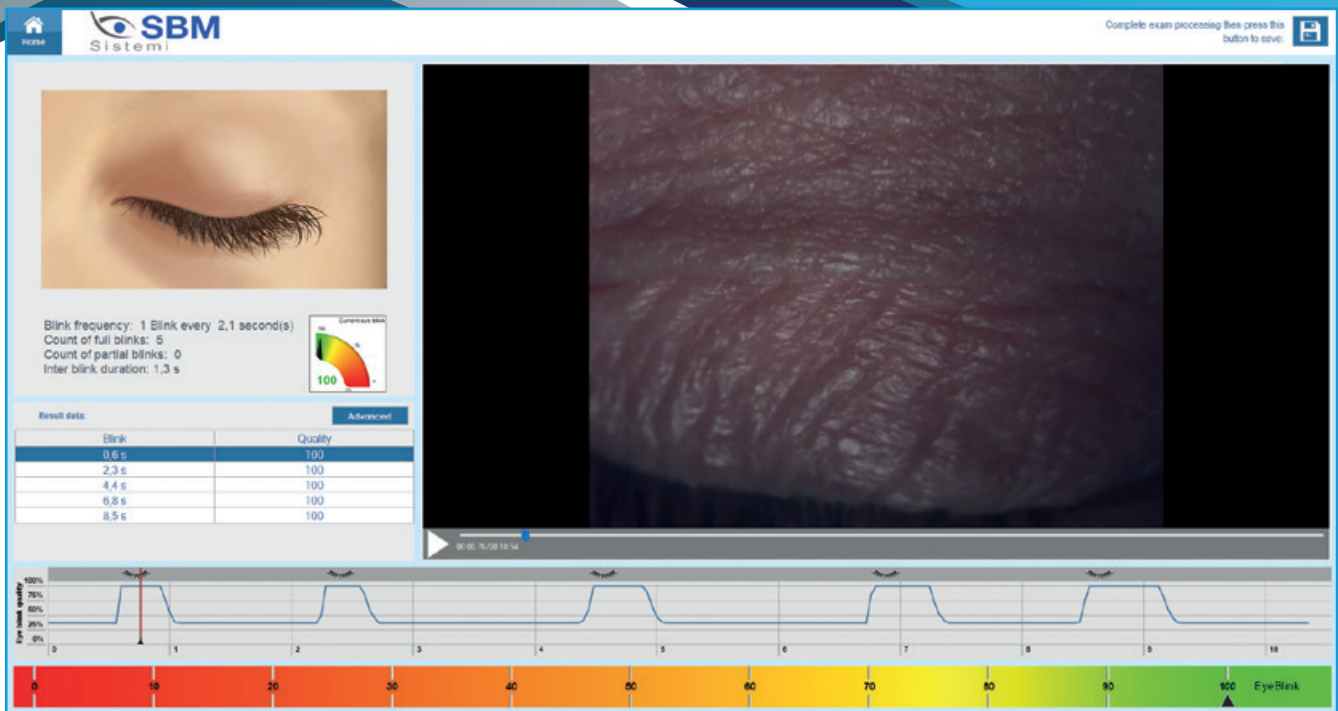


Evaluation of the tear film quantity.

With the various magnification tools, it is possible to measure the tear meniscus height on the lower eyelid and evaluate its characteristics.

The result of this exam is comparable to the Schirmer's Tear Test 1 (STT1), with the difference that it is not invasive and lasts 3 seconds instead of several minutes.

BLINKING QUALITY



A healthy person should be expected to show periodic blinking, by closing the eyelids briefly.

Most blinks are spontaneous, occurring regularly with no external stimulus. However, a reflex blink can occur in response to external stimuli such as a bright light, a sudden loud noise, or an object approaching towards the eyes.

A voluntary or forced blink is another type of blinking in which the person deliberately closes the eyes and the lower eyelid raises to meet the upper eyelid.

A complete blink, in which the upper eyelid touches the lower eyelid, contributes to the health of the ocular surface by providing a fresh layer of tears as well as maintaining optical integrity thanks to a smooth tear film over the cornea.

The rate of blinking and its completeness vary depending on the task undertaken during blink assessment, the direction of gaze, the emotional

state of the subjects and the method under which the blink is measured.

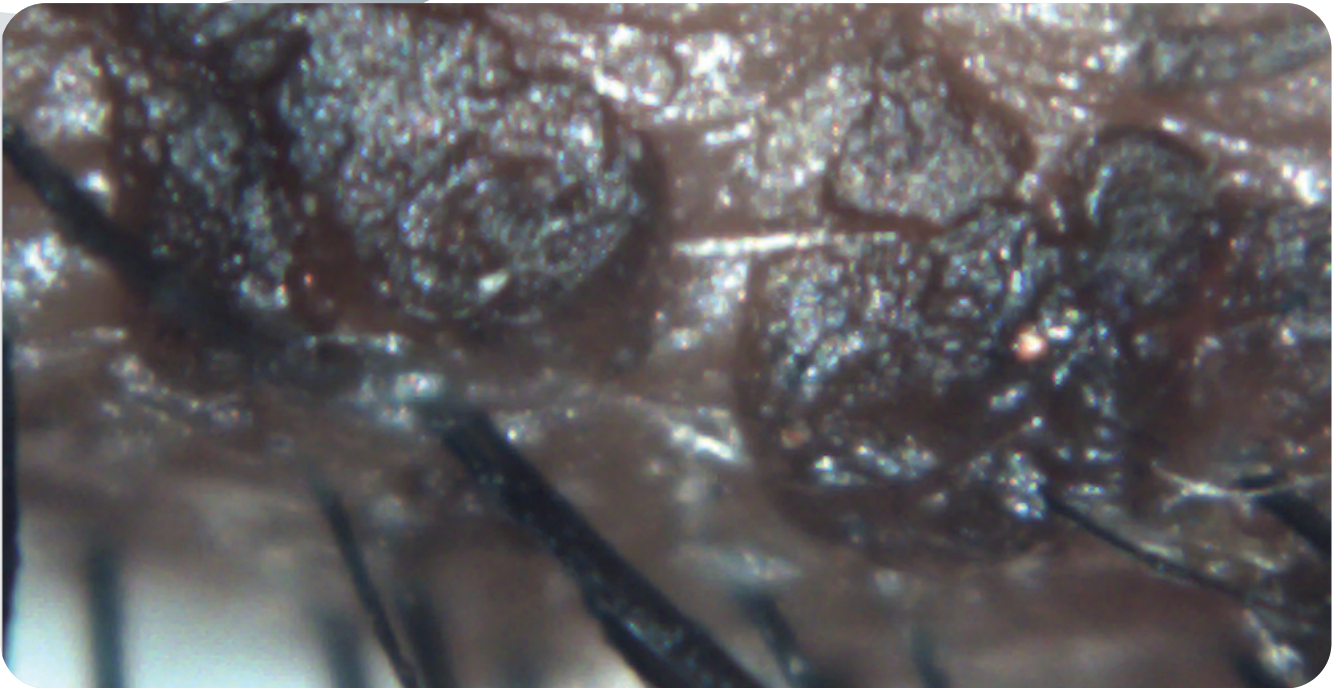
It is also well known that wearing contact lenses (both rigid and soft lenses) can induce significant changes in blinking rate and completeness.

It has been established that efficient blinking plays an important role in ocular surface health during contact lens wear and that it improves contact lens performance and comfort.

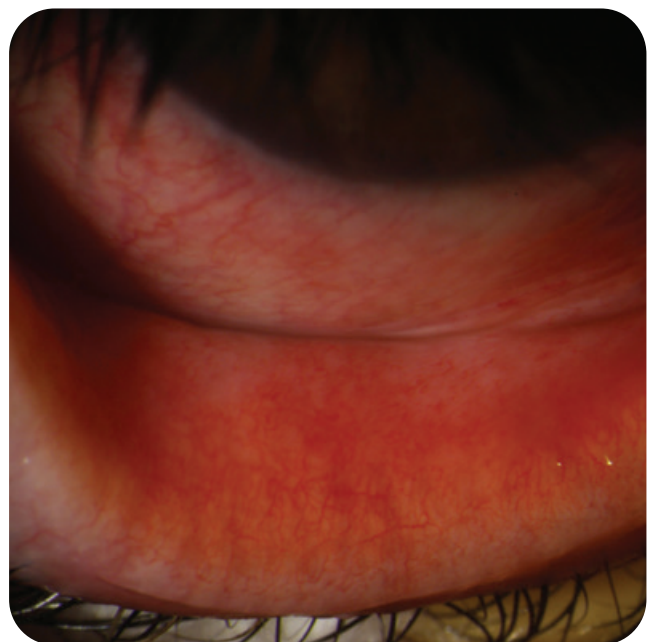
Inefficient blinking during contact lens wear may be related to a low blinking rate or incomplete blinking and can often be a reason for dry eye symptoms or ocular surface staining.

TFA automatically detects and analyses blinking, determining its quality.

CYLINDRICAL DANDRUFF AND BLEPHARITIS



The human skin surface is known to house millions of bacteria, though some people have more than the normal and healthy quantity. Blepharitis is an inflammation caused by some bacteria that lie at the base of eyelashes. They produce dandruff-like flakes in the skin, which lead to infection and inflammation. Problems with the Meibomian Glands (meibomianitis) in the eyelids can also cause blepharitis. The development of inflammation is also associated with risk factors such as dandruff, dry eye, acne rosacea, or bacteria. Blepharitis is a common eye disorder affecting all age groups. The eye must be evaluated using a specialized tool such as the Us Ophthalmic magnifying device. This tool highlights inflammation in the eye and the existence of bacteria/fungi/viruses. If signs of infection are found during close monitoring, the ophthalmologist wipes the eye and collects any discharge as a sample. This is then evaluated under a microscope. Comprehensive Eye Examinations.



BLEPHARITIS AND CYLINDRICAL DANDRUFF

This test helps in the detection of blepharitis. It can be performed on the outer surface of the eyeball and eyelids.

The process includes:

- Analysis of the patient's history.
- Extrinsic detection of the eye structure, skin texture, and appearance of eyelashes.
- Examining the openings of the Meibomian Glands, base of the eyelashes, and eyelid margins using a bright light.
- Checking for abnormalities by evaluating the quantity and quality of tears.

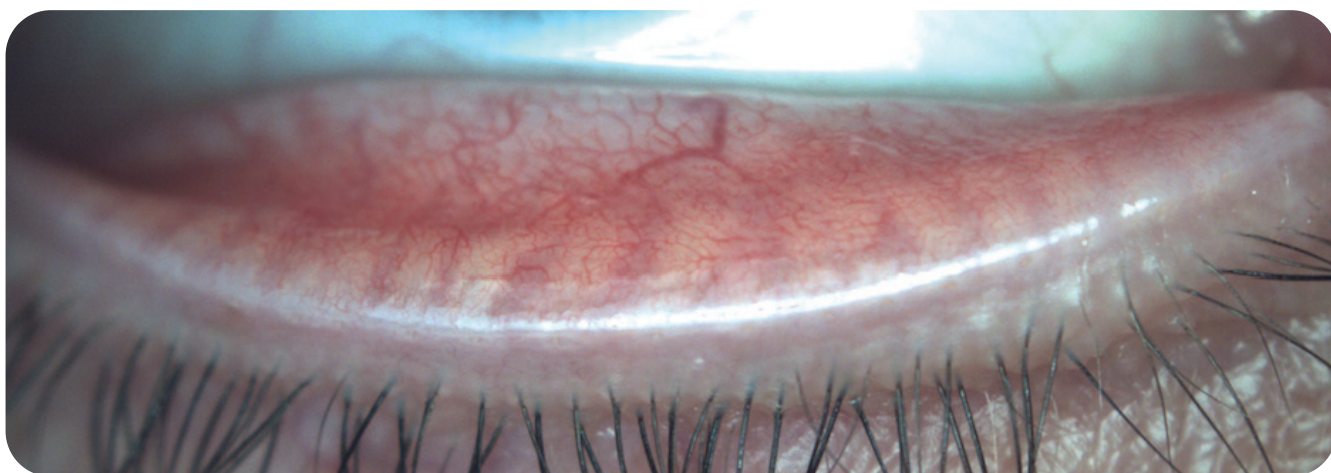
The type of blepharitis can be determined based on the appearance of the eyelid edges. If the symptoms frequently exhibited by the patients are mildly sticking eyelids, thickened lid margins, and missing/misdirected eyelashes, then the type of blepharitis is diagnosed as Staphylococcal.

If the patients show mild redness of the eyelids or scales around the base of eyelashes, then it is diagnosed as a Seborrheic blepharitis.

When the patient is found with blockage of the Meibomian Glands in the eyelids, poor quality of tears, and redness of the lining of the eyelids, Meibomian blepharitis is diagnosed.

If a hard, matted crust is formed on the eyelashes, and after its removal small sores appear on the skin, Ulcerative blepharitis is diagnosed.

In this case, patients may experience distortion of the front edges of the eyelids, loss of eyelashes, and chronic tearing. In severe conditions, keratitis is also present.



WHAT IS DEMODEX BREVIS?

Demodex brevis is a kind of mite found on the skin of humans. Like its counterpart Demodex folliculorum, D. brevis is naturally occurring. D. brevis is so small that mites can't be seen macroscopically.

The average mite causes noticeable reactions and problems in people largely infested.

Symptoms of D. brevis usually only occur in case of large infestations. Signs might include:

- Red skin
- Rough or tough skin
- Scaly or patchy skin

The symptoms of D. brevis are similar to those of D. folliculorum. The key difference is their location.

While D. folliculorum tends to stay on the face, D. brevis can distribute all over the body. Chest and neck are common areas of D. brevis infestation.

Once in the skin, D. brevis feeds on the product of the sebaceous glands. These glands are connected to hair follicles underneath the skin's surface.

Infestations of D. brevis aren't common in young children, but their numbers naturally grow with age. The mites may also be spread between humans.

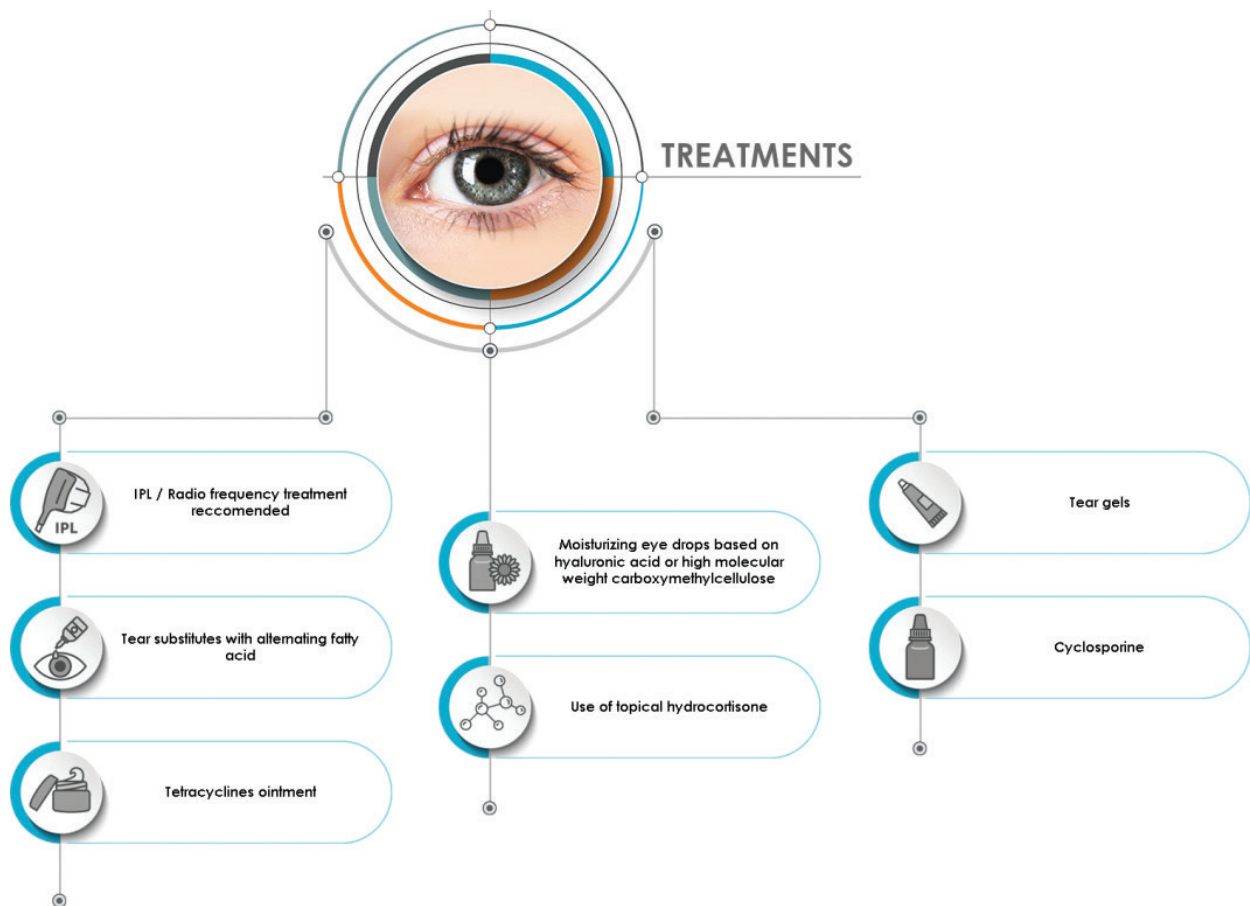
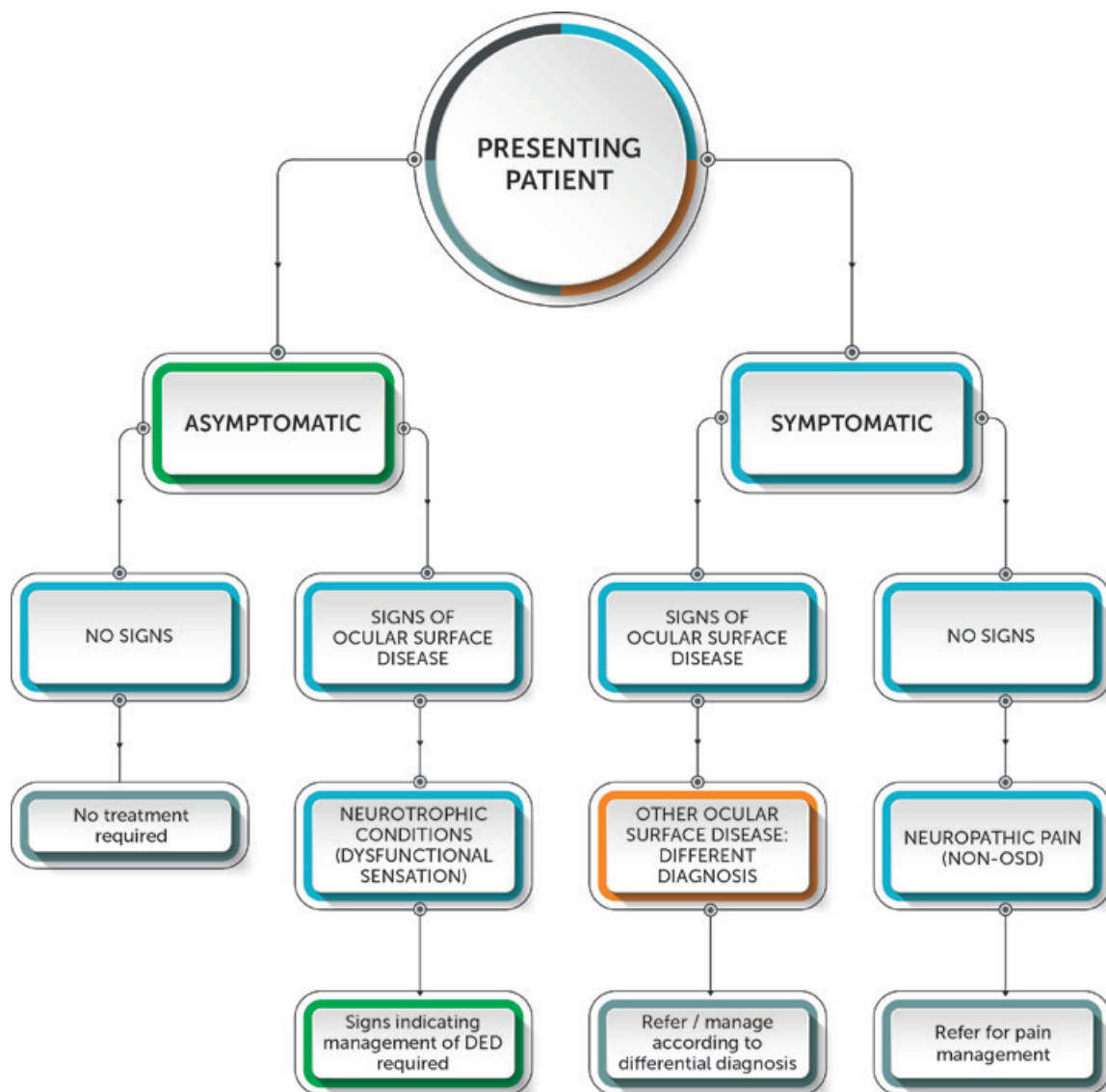
**SUGGESTIONS FOR DIAGNOSIS AND
TREATMENT BASED ON CLINICAL
PROCEDURE BY DR. LUCA VIGO
AND STUDIO CARONES
(MILAN, ITALY)**



DIAGNOSIS SUGGESTION

Ocular surface data and pathology classification

All suggestions can be useful for diagnosis and treatment.



OTHER POSSIBLE EXAMINATIONS

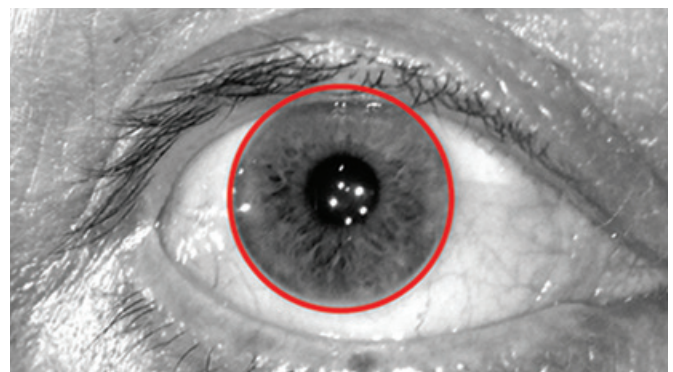
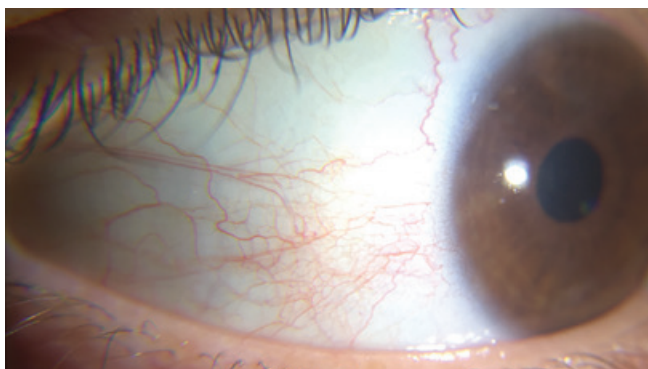


AN ASSESSMENT OF GRADING SCALES FOR MEIBOGRAPHY IMAGES

The evaluation of the Meibomian Gland dysfunction appears to be of increasing interest in research and clinical practice. Consequently, the evaluation of MGs morphology using Meibography is of high interest for both researchers and clinicians.

WHITE TO WHITE MEASUREMENT

Evaluation of corneal diameter from limbus to limbus (white-to-white distance, WTW).

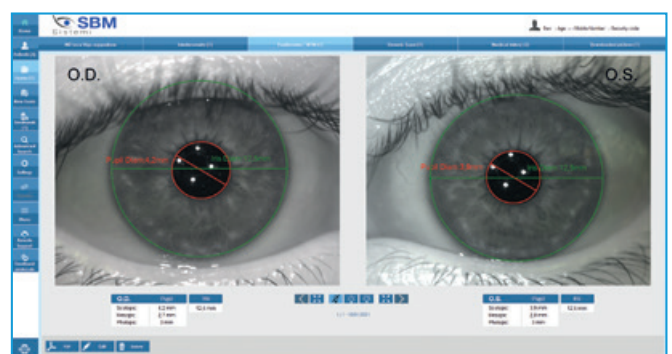
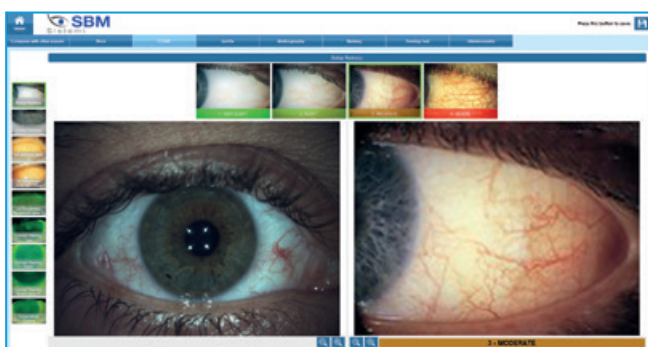


BULBAR REDNESS CLASSIFICATION

Acquiring an image of the conjunctiva, it will be possible to compare the patient's condition with different international grading scales.

PUPILLOMETRY

The measurement of the pupil diameter has become increasingly important in the field of refractive surgery. Larger scotopic pupil sizes may be partially responsible for the occurrence of postoperative symptoms such as halos, glare, and monocular diplopia. Refractive surgeons also need an accurate scotopic pupil measurement to determine appropriate treatment zones for excimer laser, corneal, and intraocular surgery.



COMPARISON WITH THE MAIN INTERNATIONAL GRADING SCALES

EFRON - CCLRU - JENVIS - GLAUCOMA -
FERNING TEST - MEIBOGRAPHY

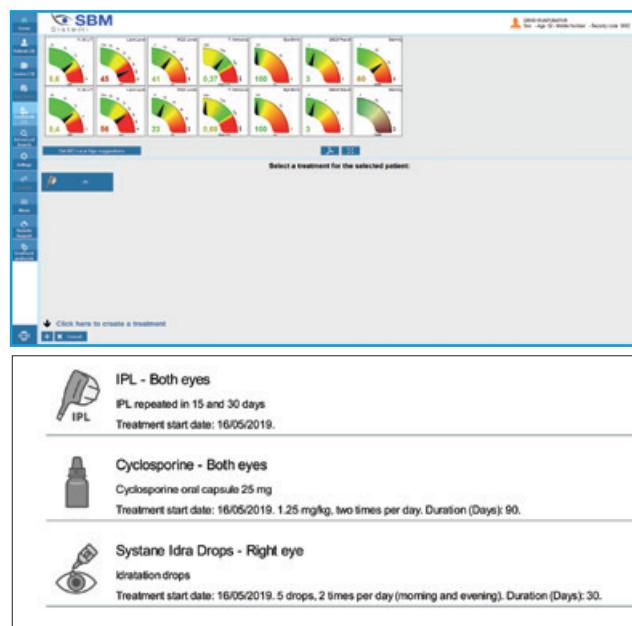
TREATMENT MANAGING

Through TREATMENT MANAGING tab, the software allows the physician to fill in the database with all drugs, integrators and treatments available in his practice.

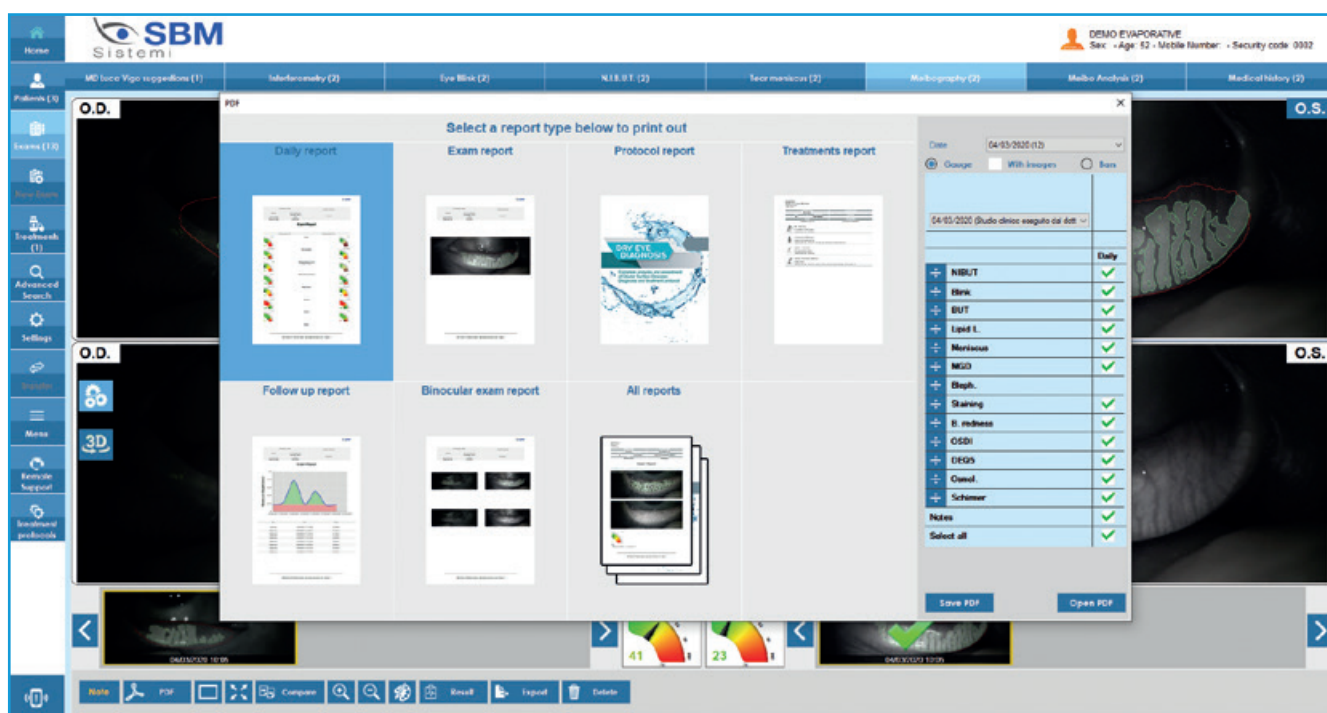
Any treatment as vitamins, Omega-3, eye drops, hot packs and IPL/Radiofrequency and many more, can be loaded on the software to prescribe the products of the brands that the doctor prefers.

The whole report with the diagnosis and treatment suggested by the ophthalmologist will be printed directly. Moreover, it is possible to store and reuse the treatments with other patients.

It is also possible to check and follow up the patient's treatment, in order to understand the clinical situation, the time spent from the initial examination, the progresses achieved.



REPORT

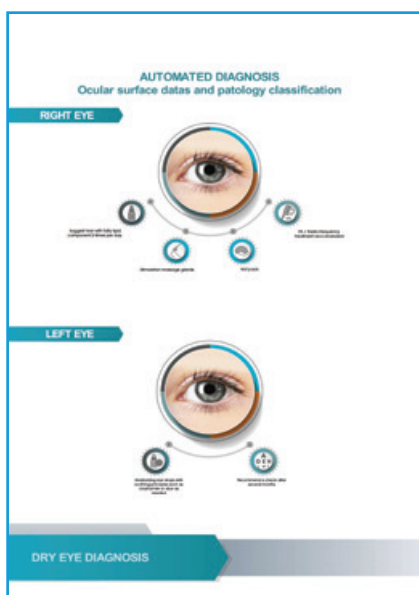
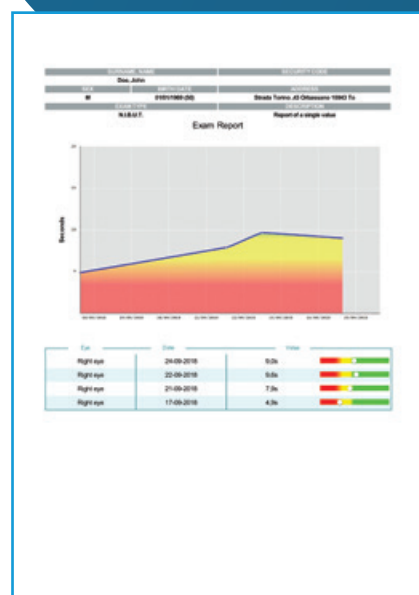
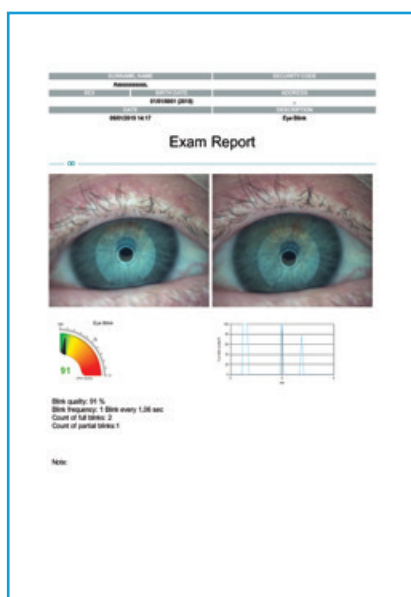
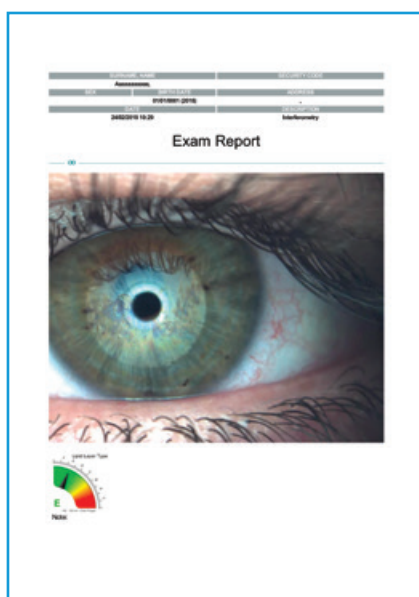
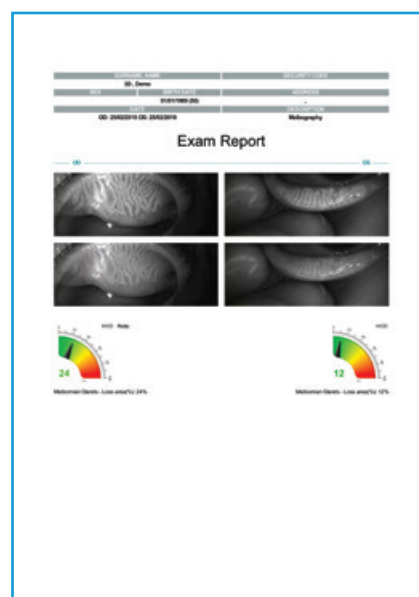


DIFFERENT REPORTS AVAILABLE

The TFA software is a dedicated platform for dry eye and allows, in addition to helping in the diagnosis and classification of diseases, to print and save various medical reports, offering the most professional and clinical solutions to patients.

For customer satisfaction, it is often advisable to provide technical documentation relating to the exams taken.

Thanks to the various print reports of the US Ophthalmic device, you will have the possibility to visually explain and simply demonstrate the pathology situation. Furthermore, it's possible to explain how the pathology has changed over time.



PACKAGE CONTENTS

- TFA
- FOOT PEDAL
- MAIN CONE
- PLACIDO CONE
- BRIEFCASE



OTHER AVAILABLE ACCESSORIES

TABLE HOLDER



**SLIT LAMP
ADAPTER**



**COMPLETE
HOLDER**



TABLE



DRY EYE MANAGEMENT

Check on our website our full range
of devices to diagnose and treat patients
affected by Dry Eye Syndrome.



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