



DEDICATED DRY EYE PLATFORM

Integrated diagnostic platform easy to use



June 2019
ver. 2 - 2019



THE COMPANY

We are an Italian company that operates in European and extra-European markets. The industrial activity of production of medical devices is the DNA of this Italian reality that over the years has been able to follow and anticipate the evolution of the markets, in terms of quality standards and demand for safety products for the medical world.

The managerial, commercial and administrative office manages the distribution of products in all markets promptly and efficiently, through a network of distributors or directly to public or private hospitals.

Our goal at Sbm Sistemi is to bring new systems in to the market to ensure that people who can't afford or benefit of these kind of instruments, can have access to primary healthcare and eye care. In countries where technology is not everywhere or wellness is not for everyone, villagers have to travel long distances and endure hardships to access basic eye care.



From a clean hospital room to a dirty tent in the desert. Our innovative and experienced team of scientists, physicians, researchers and business leaders have dedicated much of their lives to advancing treatments for eye diseases.

This team has worked together extensively and values having an environment of collaboration, transparency and trust that results in accelerated and needed innovation.

Sbm Sistemi incorporates the research and innovative technologies developed by a team of medical researchers in the diagnostic field.

The Sbm Sistemi Medical internal commitment to produce quality goes beyond internationally recognized standards and extends into the attitude of our highly trained production staff and dedicated Quality Team, who are always mindful that the products they manufacture are used to save lives in critical care applications both locally and across the world.

OUR OBJECTIVES

Sbm's mission is to overcome the complexity of adaptive optics, to make them practical and easy to use both for those who operate with ophthalmic devices and for patients themselves. All SBM Sistemi products offer fast and easy use.

CONTENTS

| | |
|--|----|
| HOW IS DRY EYE DIAGNOSED? | 04 |
| CLINICAL SCIENCE | 06 |
| INTEGRATED SYSTEM FOR OCULAR SURFACE ANALYSIS | 08 |
| DIAGNOSTIC | 10 |
| INTERFEROMETRY | 12 |
| TEAR MENISCUS HEIGHT MEASUREMENT | 14 |
| POSSIBILITY TO ACQUIRE UP TO 5 MEASURING POINTS | 15 |
| NIBUT | 16 |
| AUTO-NIBUT | 17 |
| MEIBOGRAPHY | 18 |
| MEIBOGRAPHY 3D | 20 |
| FITZPATRICK SCALE | 22 |
| CYLINDRICAL DANDRUFF AND BLEPHARITIS | 24 |
| BLINKING QUALITY | 26 |
| OTHER POSSIBLE EXAMINATIONS | 27 |
| MD. VIGO TREATMENT SUGGESTION | 28 |
| TREATMENT MANAGING | 30 |
| REPORT | 31 |
| COMPARISON OF THE SBM PRODUCTS FOR THE ASSESSMENT OF DRY EYE | 33 |
| PACKAGE CONTENTS | 34 |
| OTHER AVAILABLE ACCESSORIES | 35 |

THE EXAMS DESCRIBED IN THIS CATALOGUE REFER TO THE OSA TOOL, BUT SOME EXAMS ARE ONLY AVAILABLE ON THE OSA PLUS SOFTWARE VERSION



HOW IS DRY EYE DIAGNOSED?

OCULAR SURFACE WORKUP WITH AUTOMATED NON-INVASIVE MEASUREMENTS FOR THE DIAGNOSIS OF MEIBOMIAN GLAND DYSFUNCTION

Dry eye can be diagnosed through a comprehensive eye examination. Testing, with emphasis on the evaluation of the quantity and quality of tears produced by the eyes, may include:

- Patient history to determine the patient's symptoms and to note any general health problems, medications or environmental factors that may be contributing to the dry eye problem.
- External examination of the eye, including lid structure and blinking dynamics.
- Evaluation of the eyelids and cornea using bright light and magnification.
- Measurement of the quantity and quality of tears for any abnormality. Special dyes may be used in the eyes to better observe tear flow and to highlight any change to the outer surface of the eye caused by insufficient tearing.



CAUSES

- The natural aging process, notably menopause
- Diseases that affect the ability to produce tears, like Sjogren's syndrome, rheumatoid arthritis, and collagen vascular diseases
- Conjunctivitis
- Environmental conditions. Exposure to smoke, wind and dry climates can increase tear evaporation resulting in dry eye symptoms. Failure to blink regularly
- Problems that don't allow eyelids to close in the right way
- Treatment of cataract with faco-emulsification
- Treatment with medications including antihistamines, decongestants, blood pressure medications and antidepressants, can reduce tear production
- Other factors. Long-term use of contact lenses can be a factor in the development of dry eye
- Refractive eye surgeries, such as LASIK, can decrease tear production and contribute to dry eye.



REMEDIES

- Treatment with Artificial tears
- Steroid Eye drops
- Punctual plugs
- Intense Pulsed Light therapy has been used with positive results in case of Meibomian Gland dysfunction problems
- Use of a cool mist humidifier to add moisture to the air
- Drinking of water throughout the day to stay hydrated
- Warming of the Meibomian Glands with wet compresses on eyelids
- Specific diets.

From the Journal of Cornea and External Disease

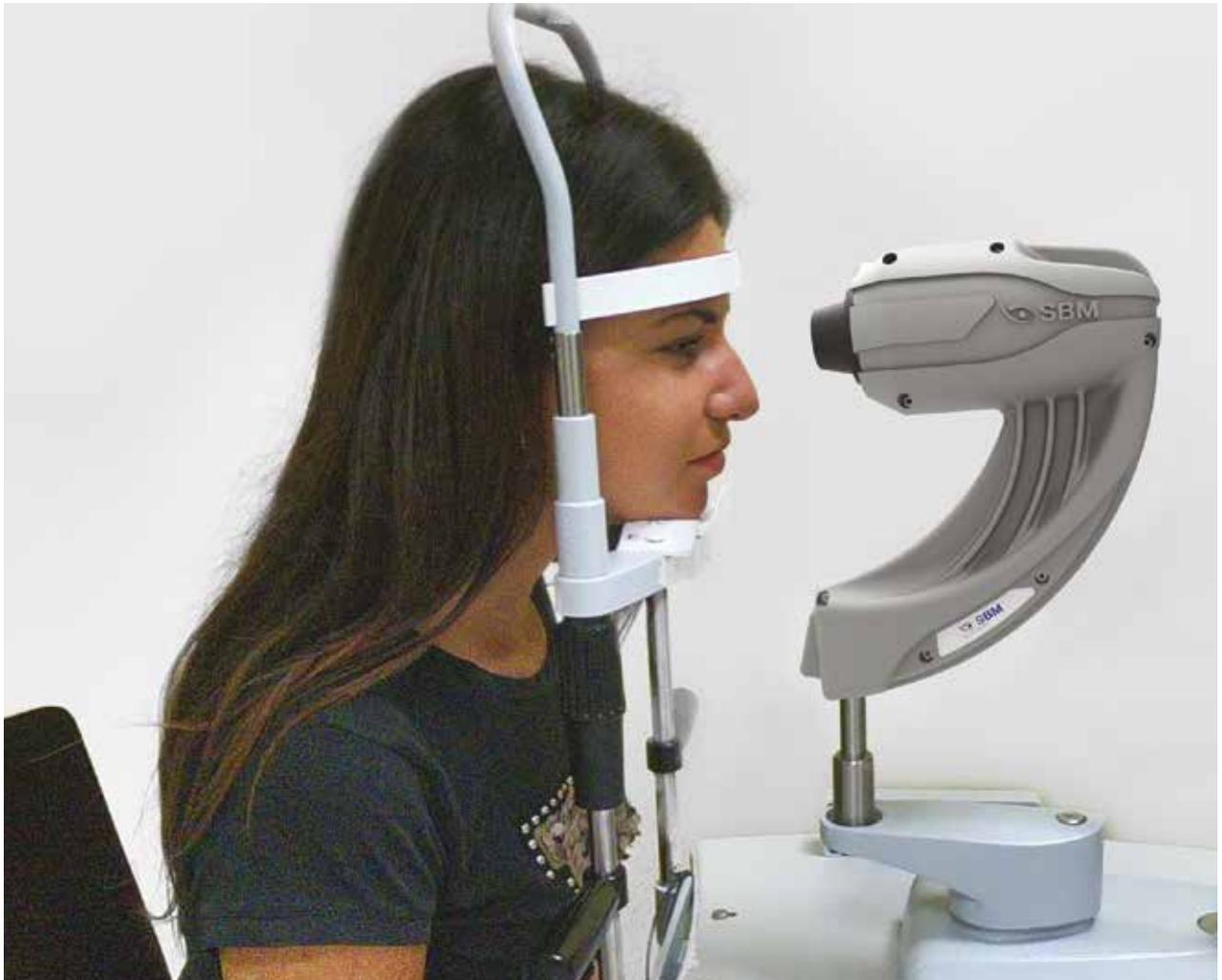
CLINICAL SCIENCE

OCULAR SURFACE WORKUP WITH AUTOMATED NON-INVASIVE MEASUREMENTS FOR THE DIAGNOSIS OF MEIBOMIAN GLAND DYSFUNCTION WITH THE SBM SISTEMI DEVICE.

INTRODUCTION

Dry eye disease was recently redefined as a “multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles.”¹ Meibomian Gland dysfunction (MGD) represents the leading cause of evaporative dry eye, the most common subtype of dry eye².

MGD is characterized by hyperkeratinization of the Meibomian Gland ductal epithelium, leading to obstruction and plugging of the gland orifice. Moreover, quantitative and qualitative changes in the meibum lipid composition lead to increased viscosity and reduced gland outflow onto the tear film. The stasis of meibum inside the gland promotes proliferation of bacteria, producing lipases and esterases that increase the viscosity and melting temperature of the meibum, thus setting up a vicious spiral. Hyposecretion of meibomian lipids causes thinning of the tear film lipid layer, with consequent tear film instability, increased evaporation rate, and dry eye onset.

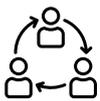
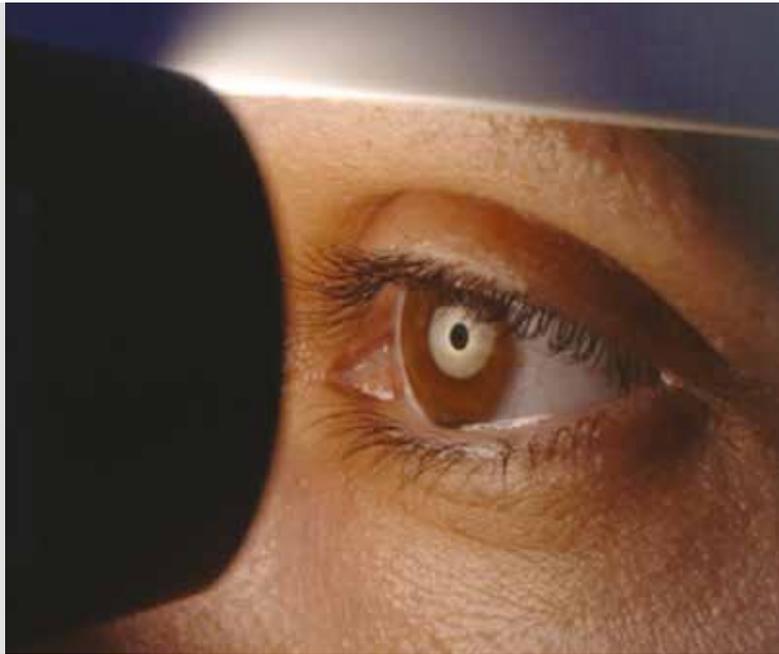




MATERIALS AND METHODS

Study Population

This cross-sectional study was conducted at Carones Ophthalmology Center (Milan, Italy) between September 2016 and July 2017. The study was performed in accordance with the principles of the Declaration of Helsinki and was approved by the local institutional review board. Written informed consent was obtained from all subjects before the examination.



DISCUSSION

The accurate diagnosis and classification of dry eye are complicated by the heterogeneous nature of the disease and the variability of signs and symptoms. Various diagnostic assessments have been proposed to qualitatively and quantitatively characterize the entire ocular surface system. However, to date, no universally accepted diagnostic workup for the diagnosis of MGD has been established. Several tests used routinely in daily practice require direct contact with the eye and/or the use of eye drops. The resulting alteration of the tear film volume and composition may not only influence the measured variable itself but also have disruptive effects on the results of subsequent tests. In addition, some tests require the clinician's judgment to reach a score and, therefore, are open to significant observer bias. Furthermore, measurements obtained using traditional tests are often affected by low values of repeatability and reproducibility. Recently, new automated non-invasive quantitative tests have been developed to overcome

these drawbacks. They include, among others, tear film interferometry, noncontact meibography, and tear osmolarity. In particular, interferometry is a technique that studies the surface reflection pattern and dynamics of the lipid layer of the tear film, thus allowing the measurement of the tear film stability and the thickness of the lipid layer. The measurement of BUT with a non-invasive technique eliminates the disturbance on the tear film caused by instillation of fluorescein dye. Meibography allows in vivo observation of the Meibomian Gland morphology; the gland structural changes may be graded with different scoring systems. In addition, new digital software allows automated calculation of the total meibomian gland area in the lower and upper eyelids. Tear film osmolarity has been reported as the single best metric to diagnose and grade severity of dry eye. However, some authors questioned its clinical utility because of the high variability of measurements and the lack of correlation with dry eye signs and symptoms.



IN CONCLUSION

The automated non-invasive ocular surface diagnostic workup used in the present study may represent a promising diagnostic tool for MGD diagnosis. Although no single test has been proved to be able to reach the diagnosis with sufficient accuracy, MGD may be strongly suspected when either NIBUT or Meibography combined in parallel are abnormal. Therefore, in case of positivity of either NIBUT or MGL, subsequent qualitative clinical tests should be performed to achieve a reliable diagnosis and a more precise characterization of MGD.

Giuseppe Giannaccare, MD, PhD,^{1*} Luca Vigo, MD,^{2*}
 Marco Pellegrini, MD,¹ Stefano Sebastiani, MD,¹
 Francesco Carones, MD²

¹ Ophthalmology Unit, DIMES, S.Orsola-Malpighi University Hospital, University of Bologna, Bologna, Italy

² Carones Ophthalmology Center, Milan, Italy

* The Authors contributed equally and should be considered co-first authors

INTEGRATED SYSTEM FOR THE ANALYSIS OF THE OCULAR SURFACE

The instrument is mounted in the slit lamp tonometer hole. It is designed to do all tear film tests, from the quality of tears to analysis of the meibomian glands using international grading scales.



TECHNICAL DATA

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

MINIMUM HARDWARE REQUIREMENTS

Intel® Pentium® Dual Core 2.00 Ghz

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



I.C.P. OSA registration number at the Ministry: 1556084/R

Invented and developed 100% in Italy

Medical instrument in CLASS I registered to 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 in any time and without notice.

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

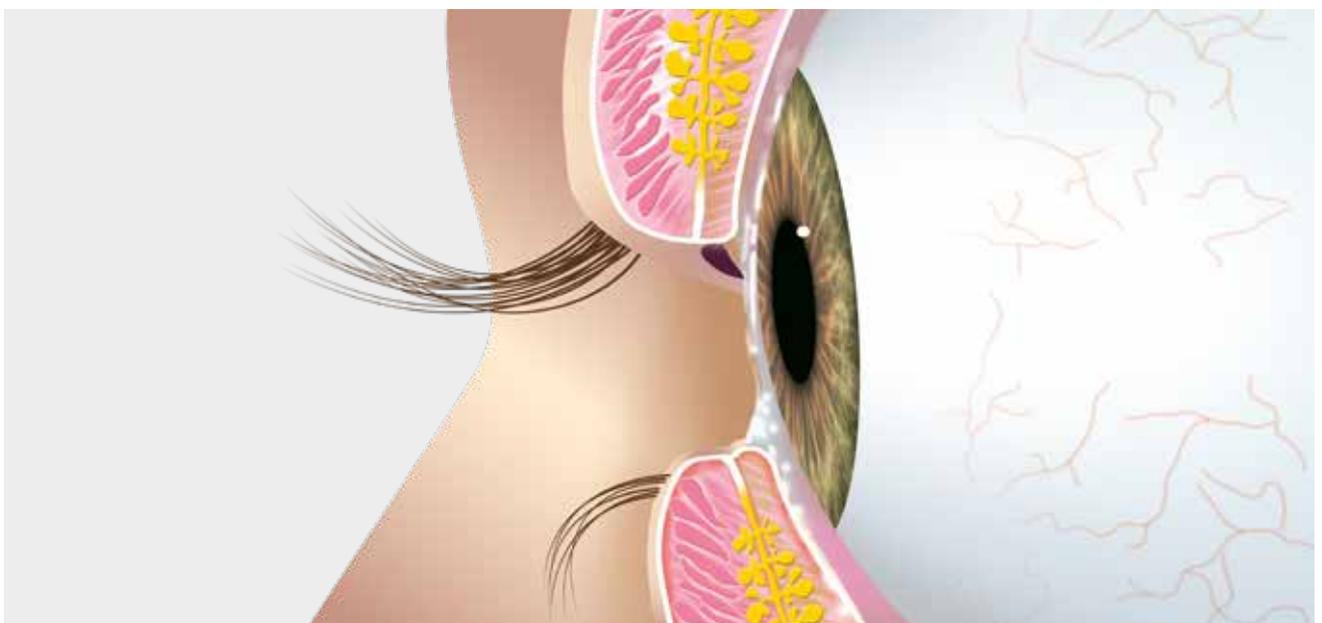
DIAGNOSTIC

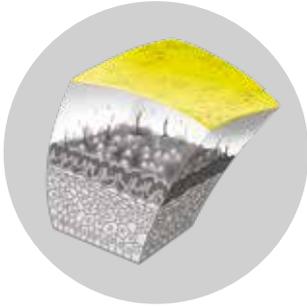
FUNCTIONS

The Sbm 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**.

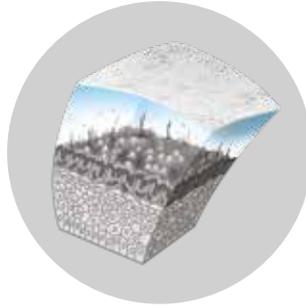
Thanks to the Sbm Device it is possible to identify the type of Dry Eye Disease (DED) and determine which components can be treated with a specific treatment, in relation to the type of deficiency.





INTERFEROMETRY

The OSA can evaluate 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).



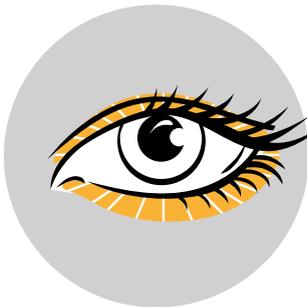
TEAR MENISCUS

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

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



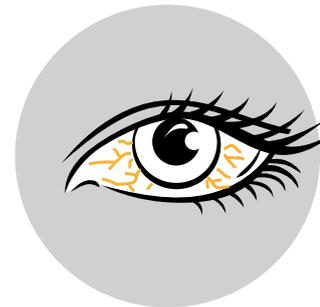
MEIBOGRAPHY

Meibography is the visualization of the glands through trans-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.



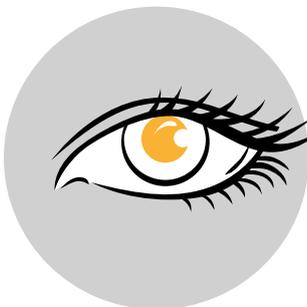
BLEPHARITIS

This test helps to detect 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.



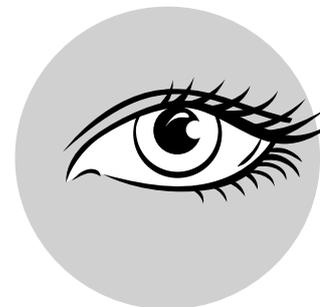
PUPILLOMETRY

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

INTERFEROMETRY



VALUES ARE DISPLAYED ON A USER-FRIENDLY GRADING SCALE THAT CAN BE USED TO EXPLAIN THE PATHOLOGY TO PATIENTS

OSA must be inserted in the support between slit lamp and biomicroscope. Its pin has been built in order to fit perfectly into the hole that you can see when the plate used for the tonometer is removed.

Sit the patient comfortably using the chin holder so the patient is still for the examination. The device must be kept as close to the eye as possible without touching.

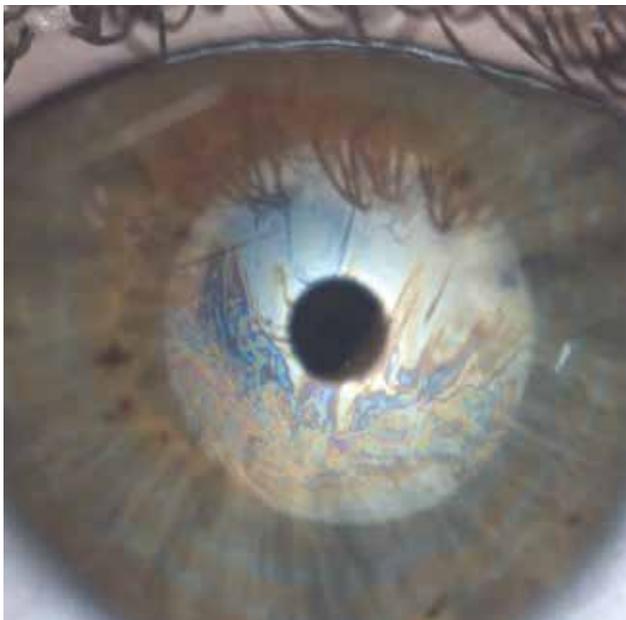
Closer the device is to the eye; broader the area is illuminated by the instrument. The light reflected from the tear film can be observed as a white circular area that almost completely covers the cornea.

Using the device, it is possible to do an interferometric analysis of the lipid layer in the tear film. The tear film plane must be focused, while the image of the bright circle must remain blurred.

Depending on its thickness and regularity, the lipid layer may appear like amorphous structure, marble appearance, wavy appearance, yellow, brown, blue or reddish interference fringes.

When the tool shows a matt white pattern, it means that there are no lipids; if it shows a white and quick movement of the image, so the lipid layer is present and in a borderline condition; when the resulting image is full of colors, it means there are many lipids.

This exam has fundamental importance, because most of the dry eye diseases are caused by an insufficiency of lipid layer quantity. In fact, aqueous layer evaporates without lipids and the eyes are more exposed to the risk of DED.



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.

LIPID LAYER ANALYSIS

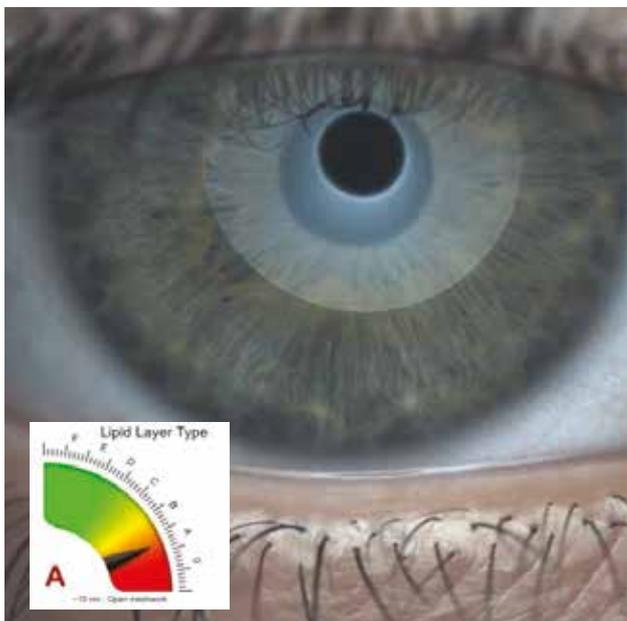
The Lipid analysis was good for OD with values greater than >80nm

The Lipid analysis for OS was <30nm

LIPID LAYER THICKNESS

It presents lipid layer thickness measurements in an easy to understand color-coded map.

The identification is done through the international grading scale of Dr. Guillon

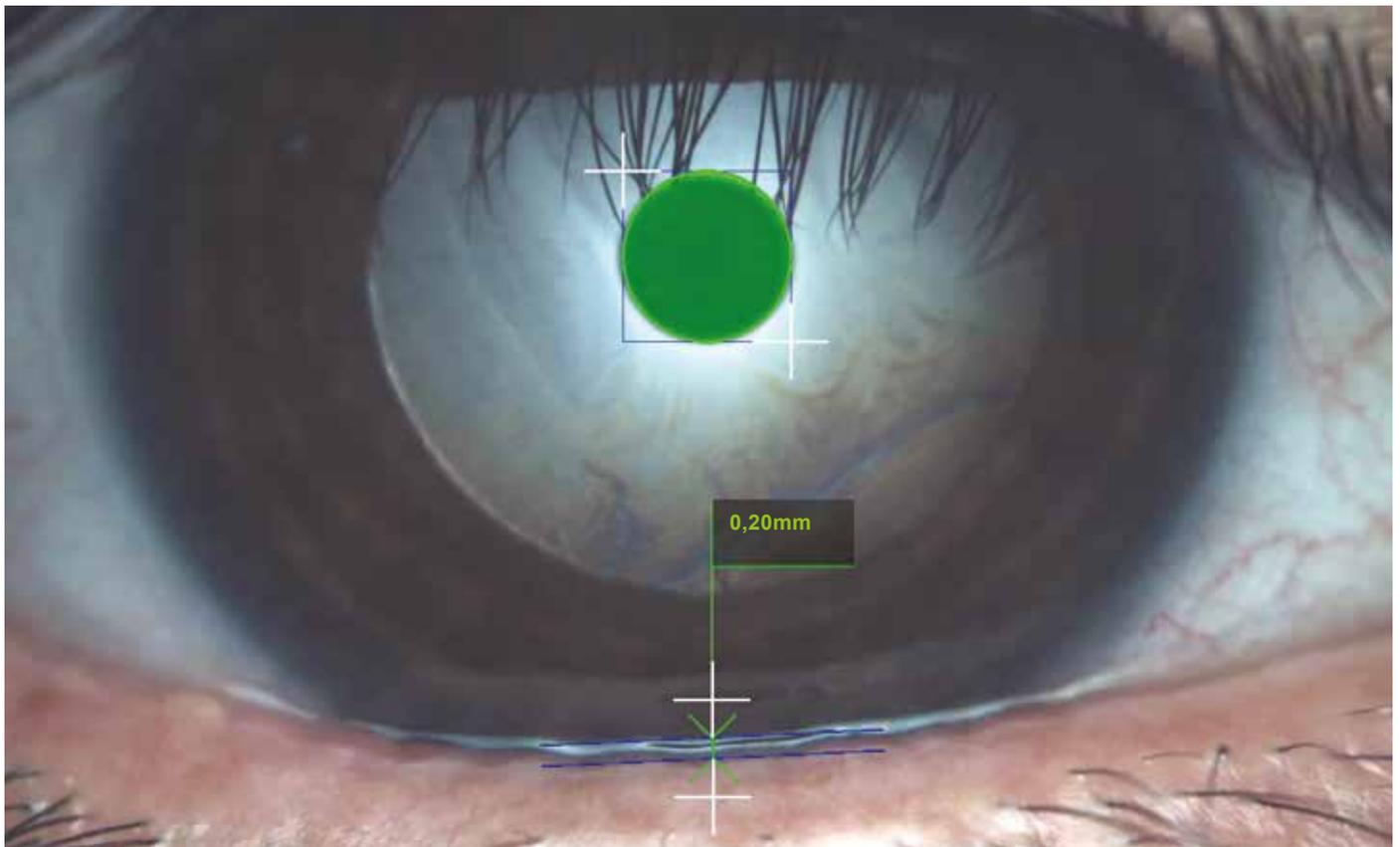


OS



OD

TEAR MENISCUS HEIGHT MEASUREMENT



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 available nowadays 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 is so a good indicator of tear production.

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

The Sbm 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.

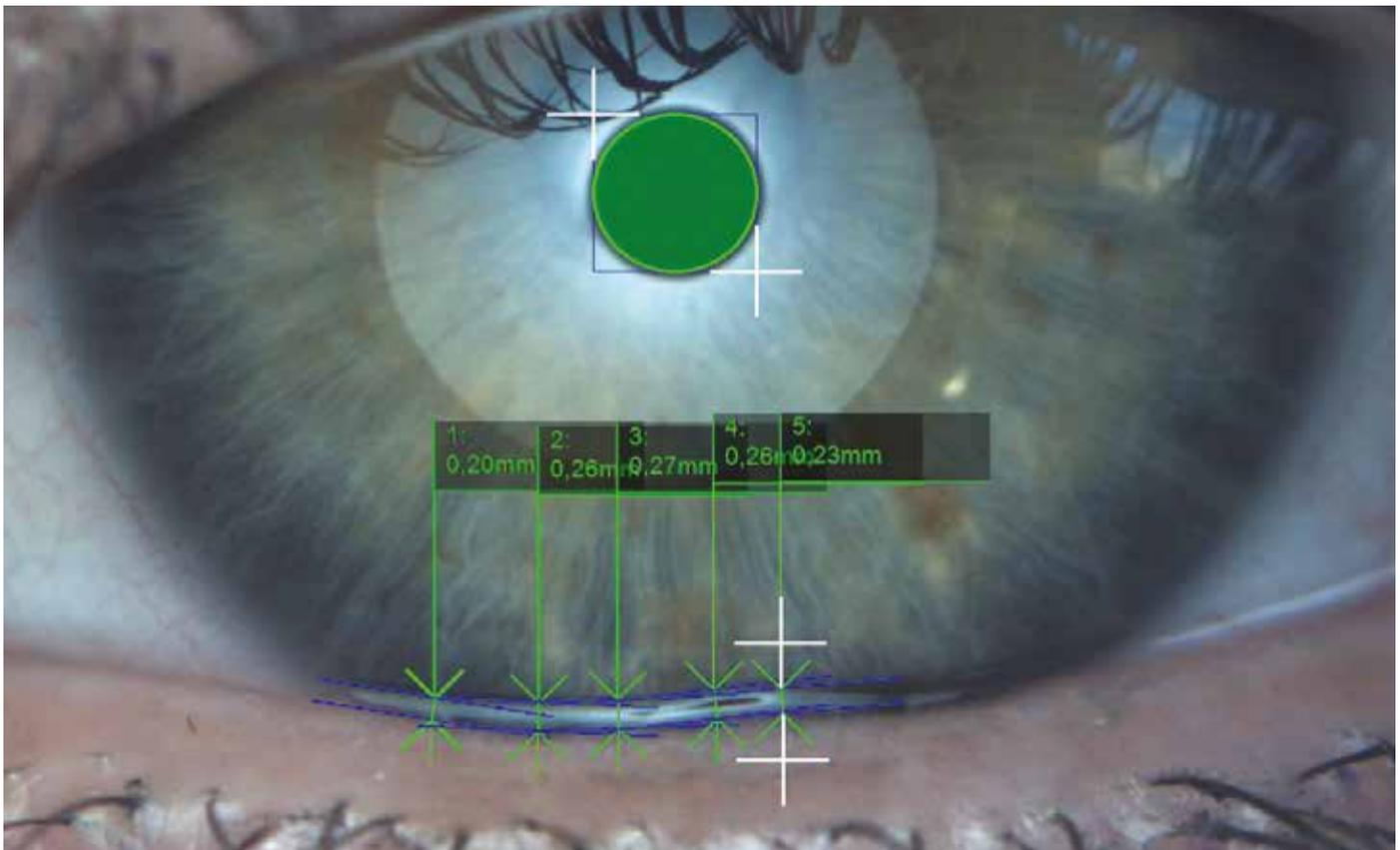
Recent advances and associated software have enabled the simultaneous imaging of both upper and lower meniscus, and real-time changes have been reported.

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.

POSSIBILITY TO ACQUIRE UP TO 5 MEASURING POINTS



Small tear volumes may result in dry eye symptoms, especially in aqueous tear deficiency (ATD). However, measuring the actual tear volume is difficult because the methods are invasive and irritative.

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.

The aqueous layer is evaluated through the non-invasive "Tear Meniscus" test, classifying it in different categories and possible issues related to this. The measurement (in mm) allows the direct evaluation of this layer quantity, and it is comparable to the Schirmer's Test with the difference that "Tear Meniscus" is without invasiveness and it does not take four minutes (only take a photo).

NIBUT



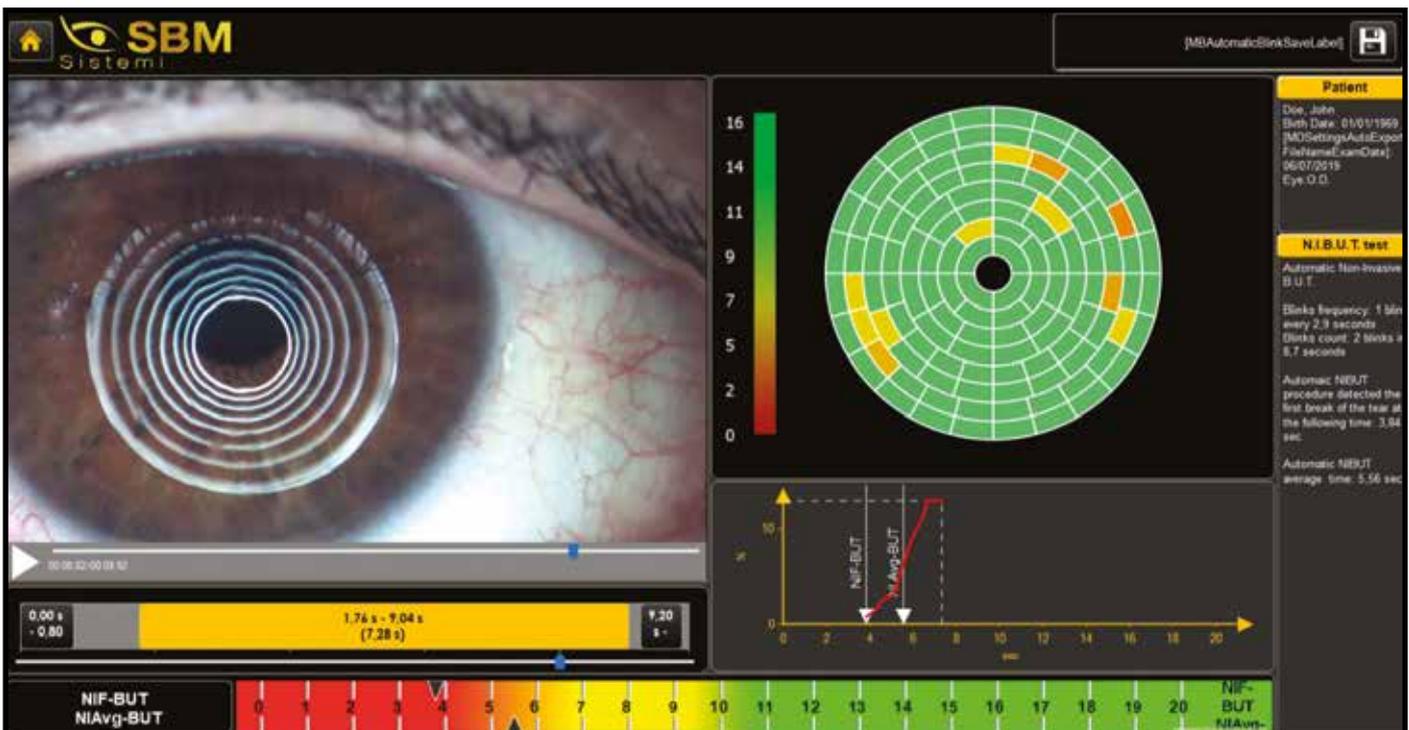
TEAR STABILITY EVALUATION

Through Placid disk projection on patients' cornea, ICP OSA automatically evaluates tear film stability.

The software checks periodically cornea's shape with the Placid 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.

AUTO-NIBUT



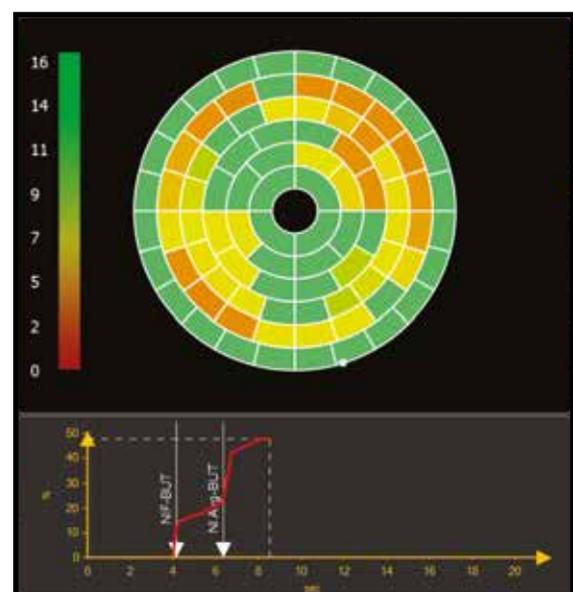
The Sbm Device allows to evaluate tear film stability and regularity, using non-invasive break up time measurement (NIBUT). This measures the number of seconds between one complete blinking and the appearance of the first discontinuity in the tear film.

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

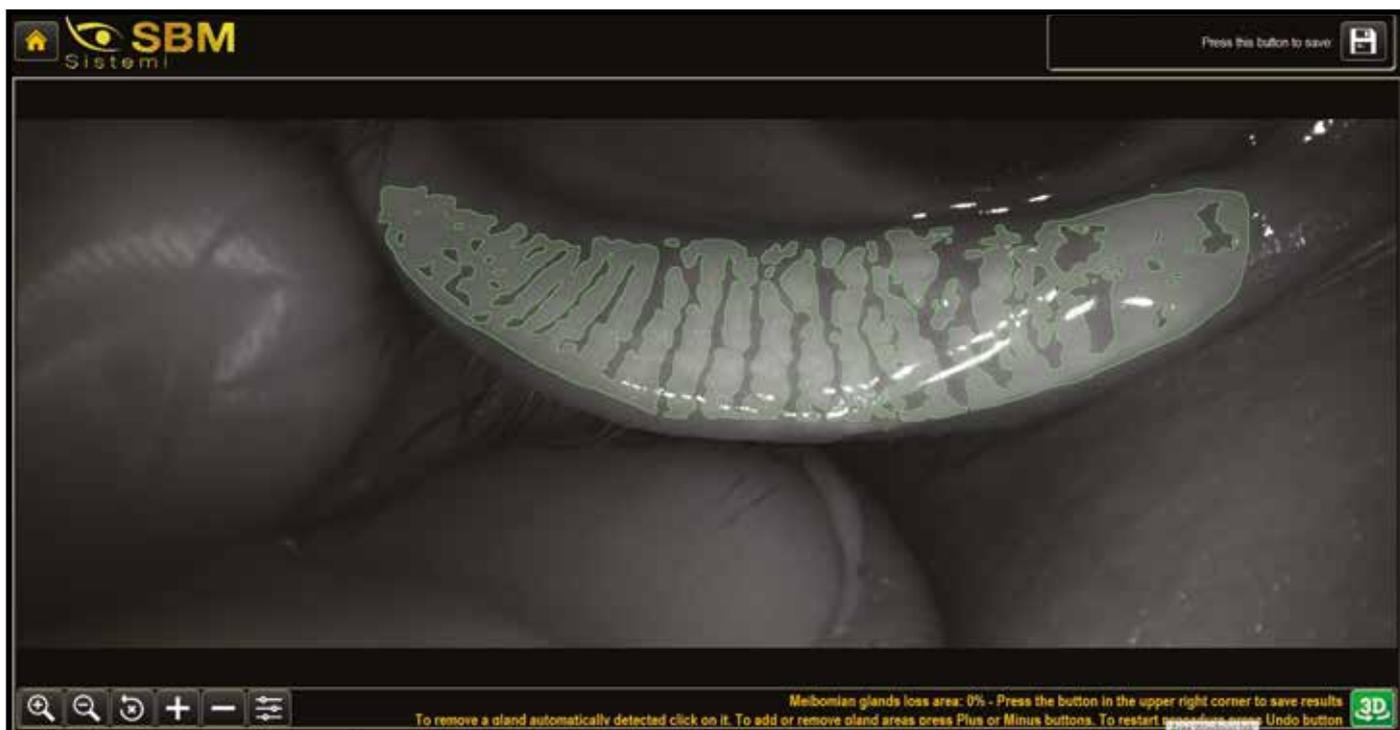
- Automatic NIBUT
- Average of more than one value
- Graph to understand the trend of tear film stability during the video
- Tear topography that shows all breaking the tear film during time.

Through the Placido rings, OSA automatically provides:

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



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 saccular 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 SBM 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.

AUTOMATIC LID DETECTION

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



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.

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 osmolarity 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.

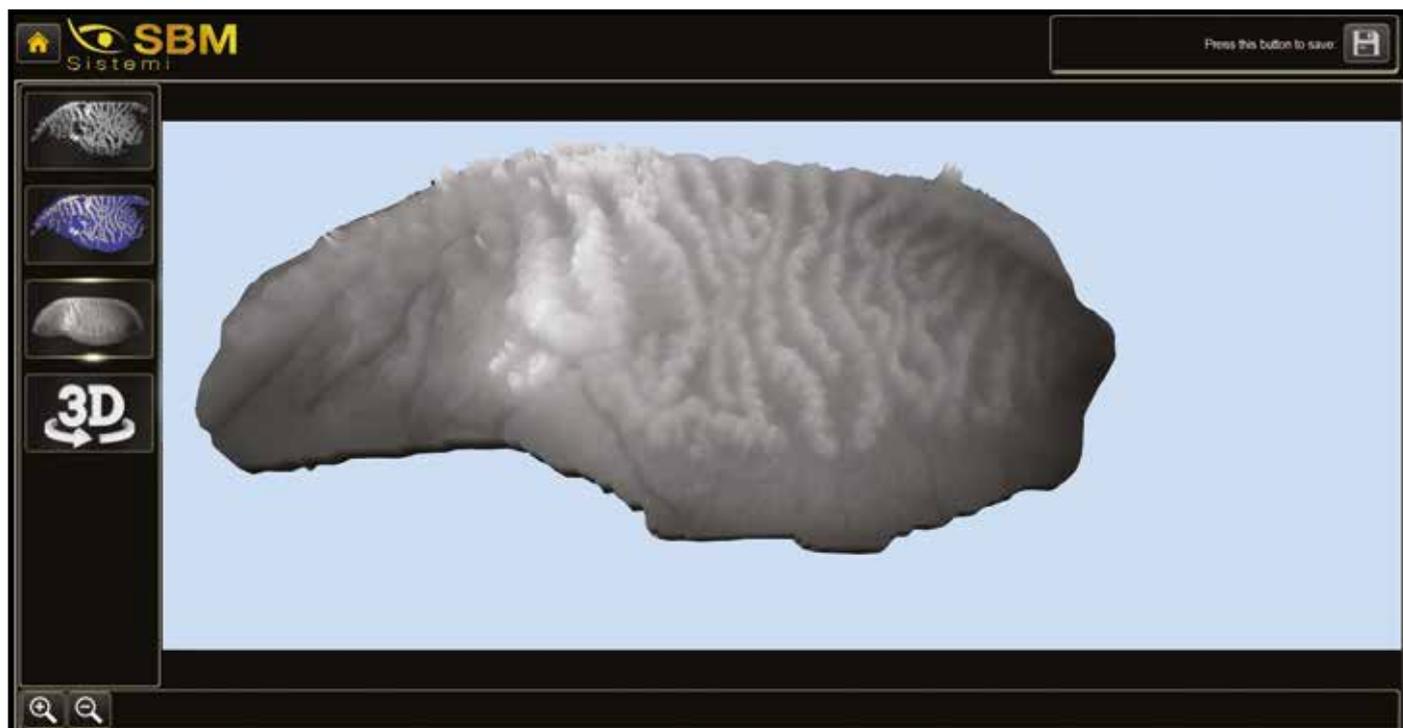
Different evaluations should be performed on Meibomian Glands in order to prescribe the most appropriate treatment, such as Intense Pulsed Light (IPL).

The Sbm Sistemi 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.



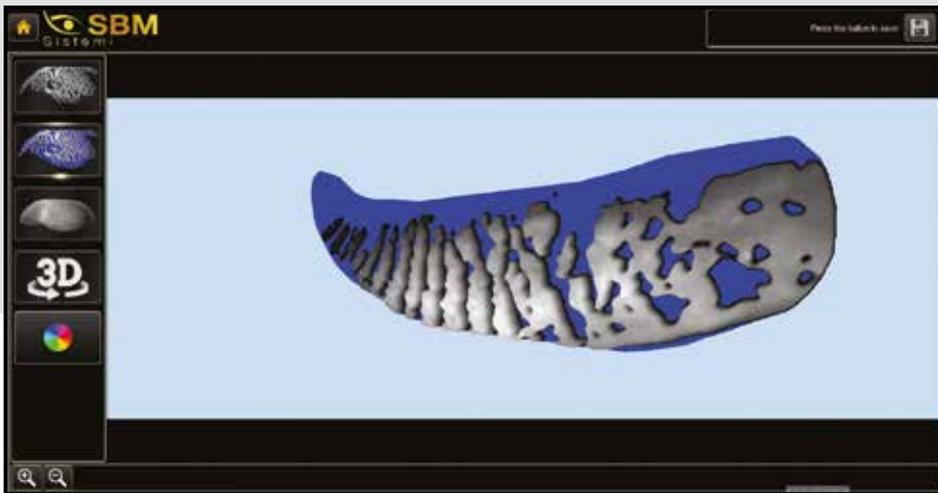
MEIBOGRAPHY 3D



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.

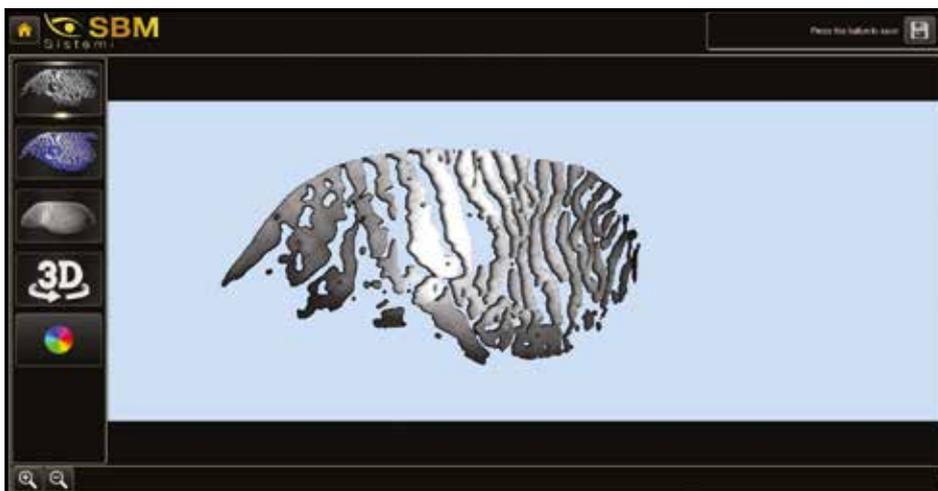
Moreover, this new imaging system provides strong evidence to support the choice of a specific therapy (for example IPL treatment) and helps the patient to understand why a certain therapy is being recommended.

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



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:

- Ability to view the presence of abnormal gland structures in a high-resolution 3D image
- To be able to compare 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.

FITZPATRICK SCALE

THE FITZPATRICK SCALE AND THE RISK FOR THE USE OF THE IPL TREATMENT

IPL stands for Intense Pulsed Light, also known as photo-rejuvenation or photofacial. This treatment is performed at doctor's offices and can be effective in treating Meibomian Gland Dysfunction.

Briefly, IPL treats the skin with quick and powerful flashes of light. The light energy then penetrates below the skin's surface.

For this reason, it is important to evaluate the photo type of the skin to avoid damage.

Nowadays some devices are configurable via screen and allow the physician to evaluate the type of treatment based on the skin colour.

Some products cannot treat certain photo types, or inflamed skin. Therefore, this assessment is very important.





CYLINDRICAL DANDRUFF AND BLEPHARITIS

THIS EXAM IS AVAILABLE ONLY WITH THE PURCHASE OF THE APPOSITE ADDITIONAL LENS FOR CYLINDRICAL DANDRUFF IMAGING (LOOK AT PAGE 31)



The human skin surface is known to house millions of bacteria, though some people have more than the average number. 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 Sbm 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

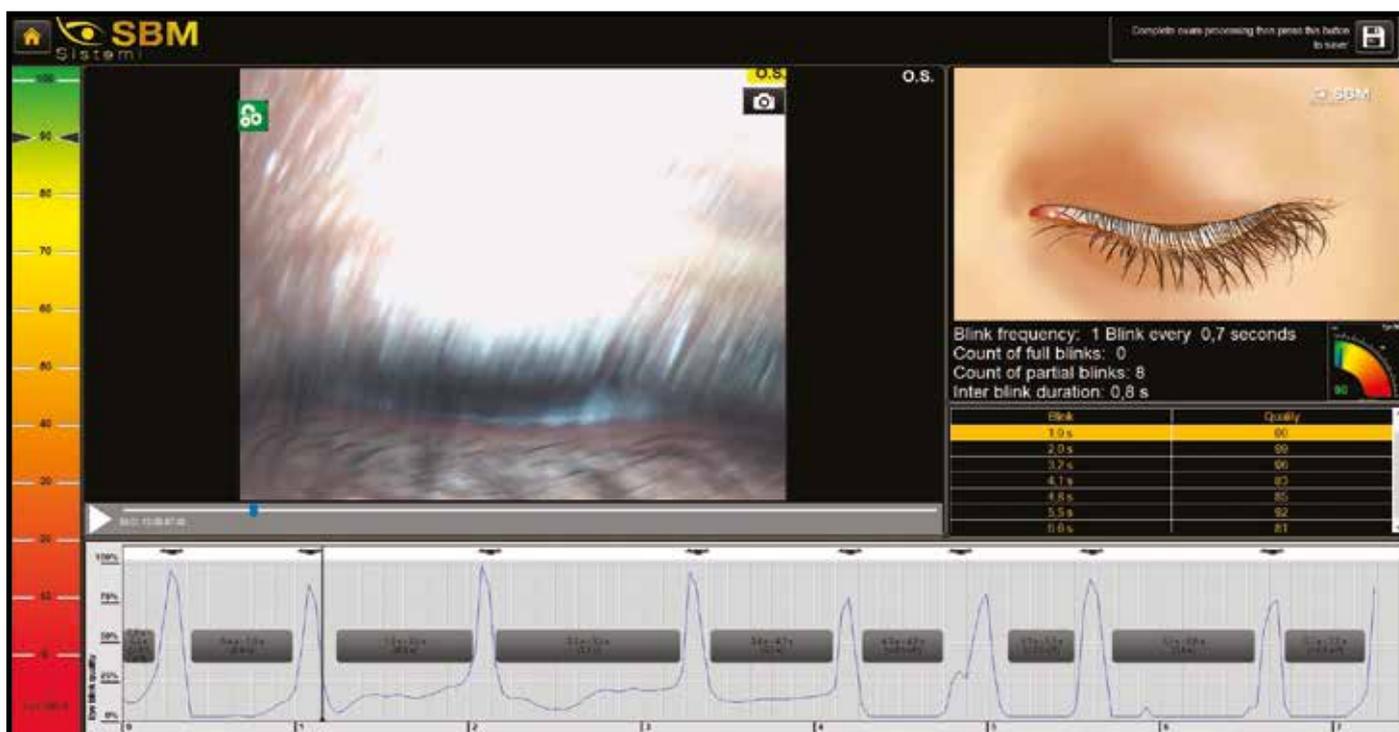
The symptoms of D. brevis are similar to those of D. folliculorum. The key difference is their location.

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 of 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.

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 is 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.

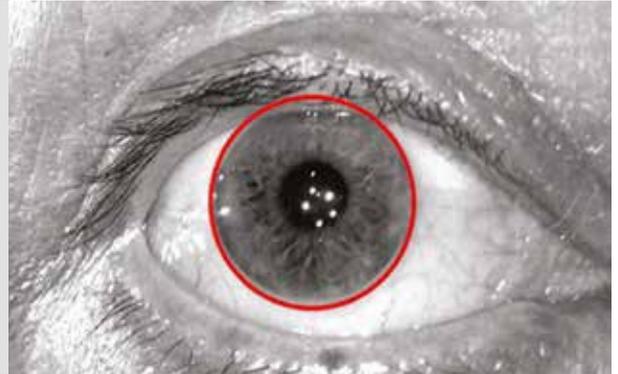
Inefficient blinking during contact lens wear may be related to a low blinking rate or incomplete blinking and can often be a reason for dry eye symptoms or ocular surface staining.

OSA automatically detects and analyses blinking, determining its quality.

OTHER POSSIBLE EXAMINATIONS

WHITE TO WHITE MEASUREMENT

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



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.

BULBAR REDNESS CLASSIFICATION

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



COMPARISON WITH THE MAIN INTERNATIONAL GRADING SCALES

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

MD. VIGO TREATMENT SUGGESTION

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



DATA RESULTS VIEW

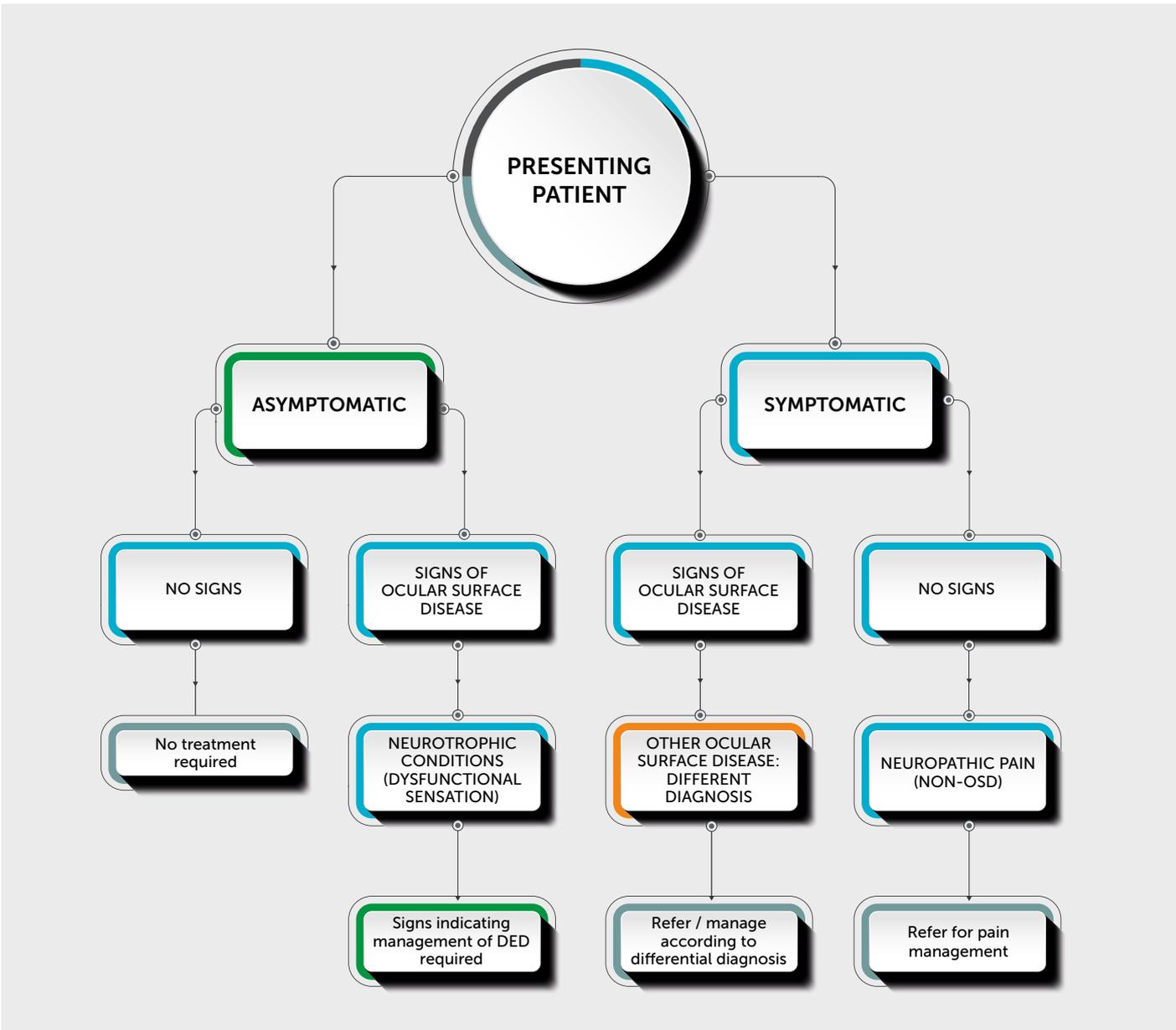
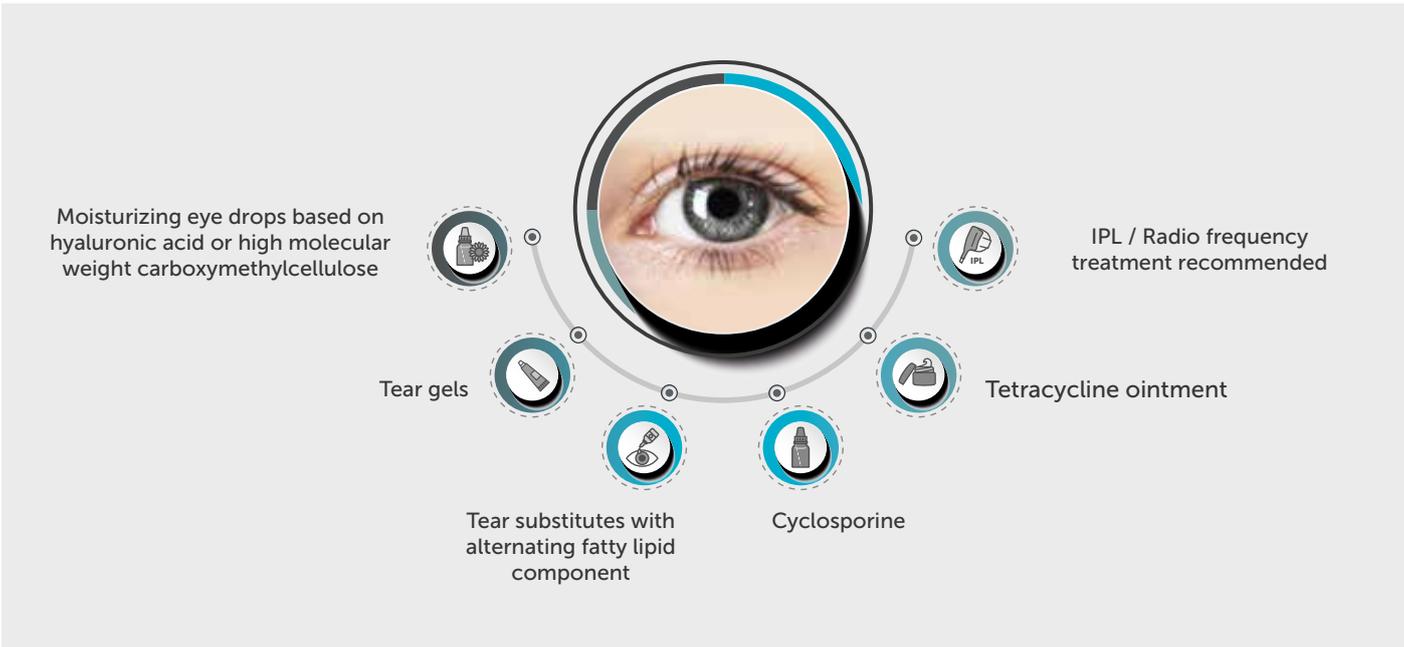
A complete and dry eye-focused database allows to understand and properly diagnose the dry eye patient. With the useful data result tab, the ophthalmologist can check the complete tear film assessment, determining all deficiencies that cause the pathology and, in the meantime, understanding which treatment is needed to approach each case.

DIAGNOSIS SUGGESTION

Ocular surface data and pathology classification

Thanks to Studio Medico Carones with MD. Luca Vigo's experience, OSA includes a suggestion algorithm able to share a possible treatment approach for each patient.

All suggestions can be useful for diagnosis and treatment.



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, 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 (e.g.: Bausch+Lomb Hyaluronic Acid 3 times/day every 8 hours, or Bausch+Lomb Hyaluronic Acid daily every hour for 3 months).

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 (e.g.: IPL, 2 sessions already done and 1 missing).



IPL - Both eyes

IPL repeated in 15 and 30 days
Treatment start date: 16/05/2019.



Cyclosporine - Both eyes

Cyclosporine oral capsule 25 mg
Treatment start date: 16/05/2019. 1.25 mg/kg, two times per day. Duration (Days): 90.



Systane Idra Drops - Right eye

Idratation drops
Treatment start date: 16/05/2019. 5 drops, 2 times per day (morning and evening). Duration (Days): 30.

REPORT

The screenshot displays the SBM Systems software interface. At the top, there are navigation tabs: Patients (24), Exams (139), New Exams, Advanced Search, Tutorial, Settings, Transfer, Menu, and Remote Support. The main area is filled with various eye health charts, including a large one showing a value of 8,6. A central dialog box titled 'Click on the report type to choose the print option:' is open, offering several report types: 'Report by date', 'Exam report', 'Protocol report', 'Report of a single value', and 'Diastereal report'. Below these options, there are checkboxes for 'Print all reports in one single file' and buttons for 'Save PDF' and 'Open PDF'. In the bottom left, a table lists patient data:

| Eye | Date | Vel |
|------|---------------------|------|
| O.D. | 05/02/2019 11:30:58 | 8,0 |
| O.D. | 01/02/2019 15:44:05 | 7,2 |
| O.D. | 31/01/2019 10:42:45 | 8,0 |
| O.D. | 31/01/2019 10:40:52 | 8,0 |
| O.D. | 31/01/2019 10:40:36 | 8,5 |
| O.D. | 31/01/2019 10:40:00 | 7,0 |
| O.D. | 31/01/2019 09:53:32 | 14,2 |
| O.D. | 28/11/2019 12:20:05 | 5,0 |

DIFFERENT REPORTS AVAILABLE

The OSA 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.

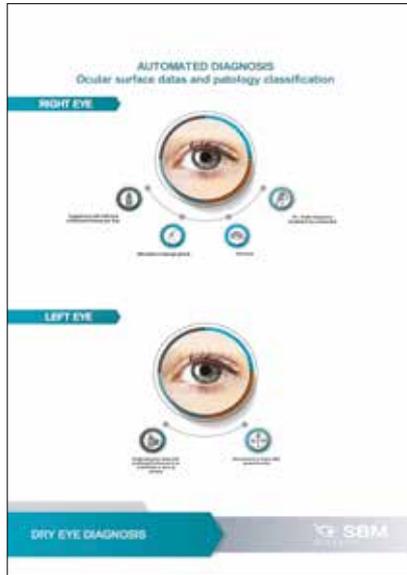
For customer satisfaction, it is often advisable to provide technical documentation relating to the exams taken.

Thanks to the various press reports of the Sbm 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.



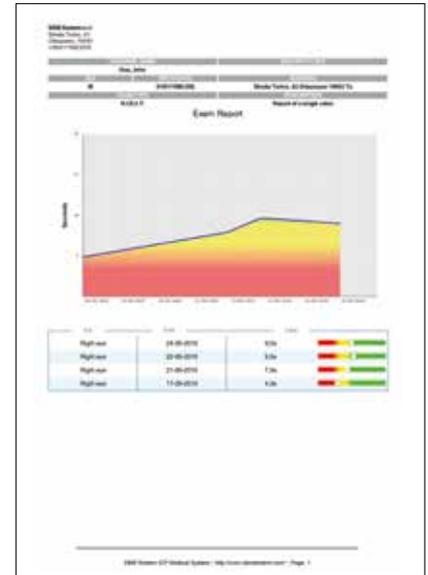
COMPLETE REPORT

Complete report with all results and pictures used to explain to the patient any dry eye category.



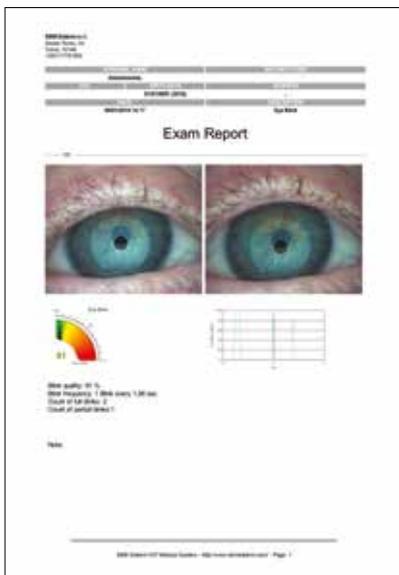
TREATMENT REPORT

Patient oriented report explaining causes of pathology and recommended treatments.



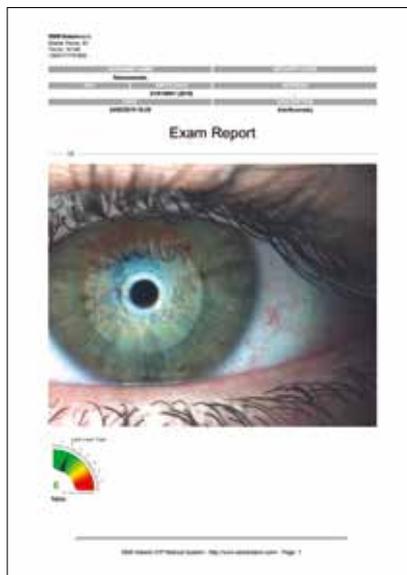
FOLLOW UP REPORT

For each value it is possible to show the trend line before/during/after treatment.



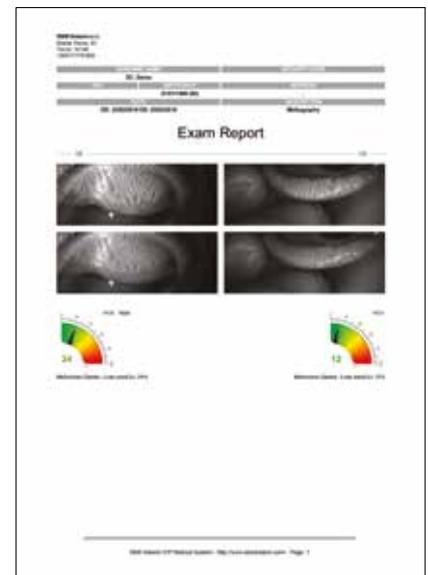
BLINKING QUALITY

You have the possibility to save the results of Eye Blinking quality and quantity with the related graph.



MONOCULAR REPORT

To save and print one only interesting examination.



BINOCULAR REPORT

To save in a single pdf the same examination of both eyes.



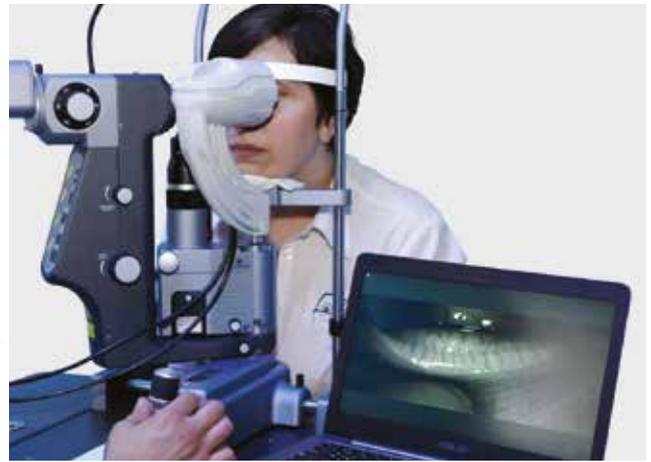
SBM SISTEMI DEVICE'S COMPARATIVE SHEET



| | | |
|---|---|--|
| AUTO-INTERFEROMETRY TEST Automatic evaluation of the lipid layer | INTERFEROMETRY TEST Manual evaluation of lipid layer | INTERFEROMETRY TEST Manual evaluation of the lipid layer |
| TEAR MENISCUS-HEIGHT Estimation of the tear film quantity up to 5 values | TEAR MENISCUS-HEIGHT Estimation of the tear film quantity up to 5 values | TEAR MENISCUS-HEIGHT Evaluation of the tear film quantity |
| AUTONIBUT Evaluation of tear film break-up time. Non-invasive and fully automatic with tear topography and graphic of tear stability | AUTONIBUT Evaluation of tear film break-up time. Non-invasive and fully automatic with tear topography and graphic of tear stability | AUTONIBUT Evaluation of tear film non-invasive break-up time: non-invasive and fully automatic |
| MEIBOGRAPHY Auto detection of MGs thanks to infrared leds and percentage of loss area | MEIBOGRAPHY Auto detection of MGs thanks to infrared leds and percentage of loss area | MEIBOGRAPHY Auto detection of MGs thanks to infrared leds and percentage of loss area |
| 3D MEIBOGRAPHY The revolutionary introduction of 3D Meibomian Gland imaging. This new imaging system provides strong evidence to support your choice of therapy for your patient. | 3D MEIBOGRAPHY The revolutionary introduction of 3D Meibomian Gland imaging. This new imaging system provides strong evidence to support your choice of therapy for your patient. | |
| EYE BLINKING DETECTION | EYE BLINKING DETECTION | |
| BUT TEST - STAINING TEST With the use of a yellow filter and a blue led | | |
| BLEPHARITIS AND CYLINDRICAL DANDRUFF With automatic magnification | BLEPHARITIS AND CYLINDRICAL DANDRUFF With an appropriate additional lens | BLEPHARITIS AND CYLINDRICAL DANDRUFF With an appropriate additional lens |
| PUPILLOMETRY AND WHITE TO WHITE MEASUREMENT In scotopic, mesopic and photopic light | PUPILLOMETRY AND WHITE TO WHITE MEASUREMENT In scotopic, mesopic and photopic light | PUPILLOMETRY AND WHITE TO WHITE MEASUREMENT In scotopic, mesopic and photopic light |
| MD. VIGO TREATMENT SUGGESTION Possibility to print a report with suggested diagnosis and treatment | MD. VIGO TREATMENT SUGGESTION Possibility to print a report with suggested diagnosis and treatment | MD. VIGO TREATMENT SUGGESTION Possibility to print a report with suggested diagnosis and treatment |
| REPORT Different typologies of reports to be printed | REPORT Different typologies of reports to be printed | REPORT Different typologies of reports to be printed |
| TREATMENT MANAGING | TREATMENT MANAGING | TREATMENT MANAGING |
| LIFESTYLE QUESTIONNAIRE | LIFESTYLE QUESTIONNAIRE | LIFESTYLE QUESTIONNAIRE |
| COMPARISON WITH ALL INTERNATIONAL GRADING SCALES (Efron, CCLRU, Jenvis) | COMPARISON WITH ALL INTERNATIONAL GRADING SCALES (Efron, CCLRU, Jenvis) | COMPARISON WITH ALL INTERNATIONAL GRADING SCALES (Efron, CCLRU, Jenvis) |

PACKAGE CONTENTS

- OSA
- GRIDS TO EVALUATE NIBUT OR PLACID CONE
- BRIEFCASE



OTHER AVAILABLE ACCESSORIES



COMPLETE HOLDER



FOOT PEDAL USB

USB connection



PLACIDO DISK CONE



TABLE



TABLE HOLDER



LENS FOR CYLINDRICAL DANDRUFF IMAGING



DRY EYE DISEASE

Dry Eye Syndrome and the consequent diseases commonly occur together. Patients may have irksome symptoms, but not associate them with dry eye syndrome.



- Glaucoma
- Contact lens wear
- Cataract and refractive surgery
- Diabetes
- Prevalence of Dry Eye Disease in Rheumatoid Arthritis Patients
- Blepharitis

DEALER

www.sbmsistemi.com

Strada Torino, 43 - 10043 Orbassano (Torino) Italy
Tel. +39.011.19923378 - info@sbmsistemi.com