# Dry Eye dedicated clinical platform

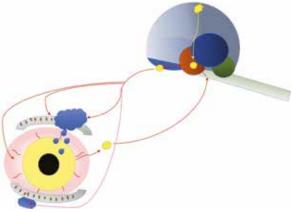
An integrated diagnostic platform easy to use anywhere and anytime. Connection to the most common telemedicine systems.



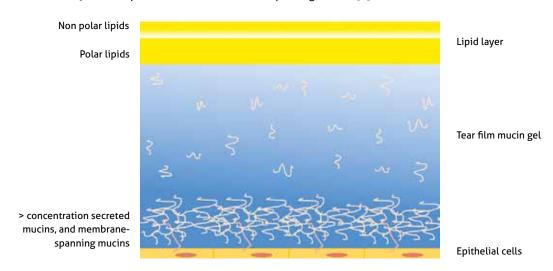


## The ocular surface – tear film integrated functional unit

Tear homeostasis is achieved reflexly by the lacrimal functional unit (LFU), which consists of the ocular surface, its secretory appendages and the connecting innervation. The trigeminal innervation of the ocular surface epithelia provides the afferent limb of the feedback loop. The parasympathetic secretomotor innervation of the lacrimal glands, meibomian glands and conjunctival goblet cells provides the efferent limb of this loop. [1]



The Tear Film (TF) is a hydrated mucin gel whose mucin concentration decreases with distance from the epithelial surface. It interacts with corneal and conjunctival epithelium via the membrane-spanning mucins. [2]





Mucins are secreted by the conjunctival goblet cells under autonomous nervous system control. Inflammatory mediators may stimulate mucin secretion and interfere with TF stability.

In most animals the lacrimal glands lie over the superior-temporal part of the globe and within the stroma of the third eyelid. Their secretion of water, electrolytes, proteins and mucins form the aqueous component of the TF.

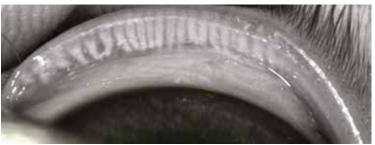
A superficial lipid layer, composed of polar and non-polar lipids, limits evaporation of the aqueous component of the TF. Tearscope examination allows to assess the characteristics of the TF lipid layer and interpret TF stability.

#### Meibomian glands

Meibomian glands are large sebaceous glands located in the eyelids. They produce an oily substance that is released in the eyelid margins and spread on the tear film thanks to blinking.

Noncontact infrared meibography is a noninvasive method to examine meibomian glands of animals





Lipids produced by the meibomian glands (MG) are the main component of the superficial lipid layer of the TF that protects it against evaporation of the aqueous phase and is believed also to stabilize the TF by lowering surface tension. Hence, meibomian lipids are essential for the maintenance of ocular surface health and integrity. [3]

Changes to the composition of mucins produced by the goblet cells and/or of lipids secreted by the meibomian glands alter the TF stability and increase TF evaporation, a frequent finding in animals' ocular surface disorders (OSD).

For the differential diagnosis of OSD it's mandatory to assess the MGs anatomical and functional characteristics and the TF stability and regularity. Hence an accurate diagnostic protocol should include meibography and tearscope examination.





## Meibomian Gland Dysfunction (MGD)

Meibomian Gland Dysfunction is a chronic alteration of the meibomian glands, commonly characterized by terminal duct obstruction and/or qualitative/quantitative changes in the glandular secretion.

MGD alters the lipid component of the tear film and may cause evaporative dry eye with the typical signs of eye irritation, clinically apparent inflammation and OSD.

In severe cases, MGD can cause blepharitis. Viceversa, in dogs and cats blepharitis is a frequent cause of MGD.



A more detailed diagnostic approach allows to better understand pathogenesis of OS diseases and choose the best treatment available. SBM-Sistemi developed handy instruments for veterinary use to help practitioners performing an accurate OS examination and researchers to investigate OS disorders.

A dedicated web connected platform allows to process all collected data, generate graphics and release documents to be added to the animal's clinical folder.

- 1. Stern ME et al. The role of the lacrimal functional unit in the pathophysiology of dry eye. Exp Eye Res, 78, 409-416, 2004
- 2. Pflugfelder SC et al. Management and therapy of dry eye disease: Report of the Management and Therapy Subcommittee of the International Dry Eye WorkShop. Ocular Surface, 5(2):163-178, 2007
- 3. Knop E et al. The International workshop of meibomian gland dysfunction: report of the subcommittee on anatomy, physiology and pathophysiology of the Meibomian gland. IOVS 52,4,1938-1978, 2011





ICP OSA-VET	ICP TEARVET-A	ICP MGA-VET
LIPID LAYER	LIPID LAYER	
INTERFEROMETRY	INTERFEROMETRY	
N.I.B.U.T	N.I.B.U.T	
TEAR MENISCUS	TEAR MENISCUS	
MEIBOGRAPHY		MEIBOGRAPHY
GRADING SCALE	GRADING SCALE	
REPORT	REPORT	REPORT

5

# > I.C.P. OSA-Vet

A full assessment of the ocular surface through a combination of tests for dry eye diagnosis, from tear break up time to the tear volume production test.





## Integrated system for the analysis of the ocular surface

This instrument is designed to perform all tear film tests and to analyse the meibomian glands. It allows to make various measurements and classifications according to international grading scales as well.

## OSA-Vet Meibography

Meibography allows to evaluate the morphology and drop out of the meibomian glands and to make the diagnosis of Meibomian Gland Dysfunction (MGD).

The software allows to analyze the functional and non functional areas, and to evaluate the extension of the affected area.

## Technical data

IMAGE RESOLUTION	5 mp
ACQUISITION MODE	Multi shot, video
FOCUS	Autofocus, manual focus
ISO MANAGEMENT	Variable
GRIDS	Placido disc, NIBUT grid
CAMERA	Full colour, sensitive to infrared (NIR)
LIGHT SOURCE	Infrared LED – Blue and white Led
OPERATIVE SYSTEM	For Windows System





Invented and developed 100% in Italy

 $\label{lem:medical model} \mbox{Medical instrument in CLASS I registered to the Ministry of Health}$ 

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 to visit the website www.sbmsistemi.com  $\,$ 





A convenient hand held device with two infrared filters and a built in camera. The OSA-Vet system captures and displays images of the meibomian glands straight on your computer.

#### Features:

- · Seamless and wireless capturing of images for added convenience
- Image capture button freezes live images which are instantly displayed on the computer
- Captured image enhancement tools: contrast, brightness and hue settings to improve and highlight captured images
- Define area for analysis and visible area of glands. Calculations of gland loss is then displayed graphically
- · Progression analysis provides a split screen for side by side image comparisons over time.

#### MG Analysis

Our device easily and efficiently integrates complex examinations such as meibography and tear film interferometry screening.

The Meibo-Scan shows the morphological changes in the glandular tissue when MGD occurs.

#### The I.C.P. allows to:

- · Calculate the percentage of functional glands in a selected area
- Point out through a change of colour the areas with and without glands,
- · Classify in 4 different degrees the loss of meibomian glands
  - A. Loss between 0 and 25 %: green
  - B. Loss between 25 and 50%: yellow
  - C. Loss between 50 and 75 %: orange
  - D. Loss between 75 and 100%: red
- Change the brightness of the images for a better evaluation

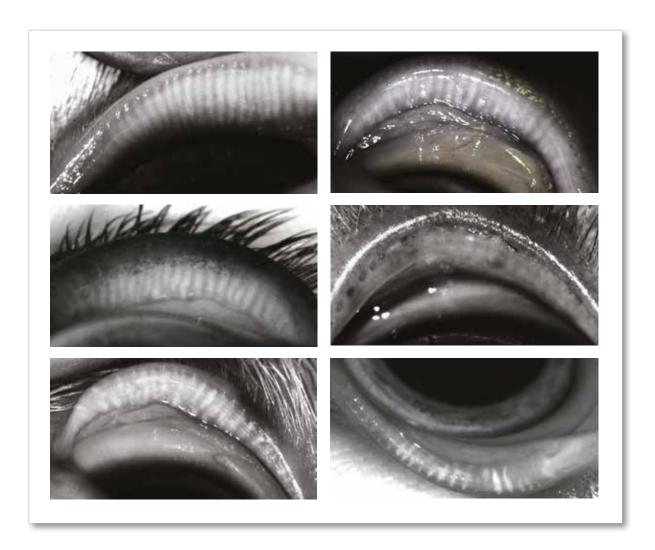


# Automatic detection of meibomian glands in selected areas

The I.C.P. (Integrated Clinical Platform) allows to record good quality images and to study the length and width of meibomian glands.

The images are automatically classified.

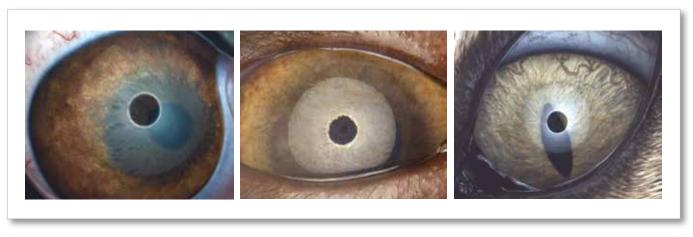
The position of the meibomiam glands in the eyelids is automatically detected.





The scattered light emitted by the OSA-Vet system allows to evaluate the interference patterns coming from the Lipid Layer (LL) of the tear film. The different patterns can be classified according to LL thickness and quality.

Thanks to the lipid layer observation, lacrimal abnormalities can be studied and a correct diagnosis can be made.







## ICP OSA-Vet dry eye analysis

OSA-Vet is an instrument available to veterinary ophthalmologists to evaluate the composition and stability of the Precorneal Tear Film (PTF).

It allows to better evaluate PTF qualitative deficiencies and make an accurate diagnosis of evaporative Dry Eye Disease (DED) due to imbalance of the three main PTF components:

- Lipids
- Aqueous
- Mucins

Thanks to OSA-Vet it is possible to identify the type of DED, determine which deficient layer is affected and select a specific treatment.

# OSA-Vet allows to quantify directly and indirectly each single tear film layer

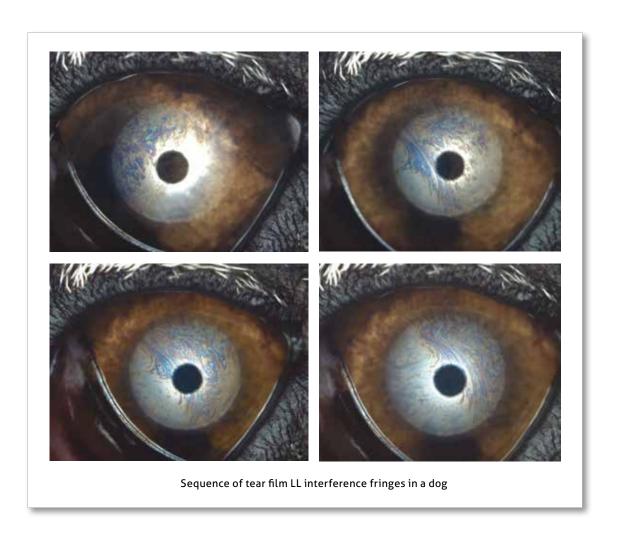
The white LED allows to show the phenomenon of interference fringes, that depends on the different thicknesses of the lipid layer of the tear film. Thanks to the white LED the ophthalmologist can study the Non-Invasive Break Up Time (NIBUT).

The blue LED allows to observe the ocular surface staining with fluorescein and to study the Break Up Time (BUT).



# Immediate interpretation and follow up

By using a dedicated lipid layer grading scale, each interference pattern may be examined in a simple and straightforward way





## Supplied accessories

The system is provided with a kit of useful grids to perform various screenings. All filters are already present in the OSA-Vet package.

- · A thick grid to observe the quality of the tear film
- A fine grid to evaluate the quality and the structure of tear film and measure the N.I.B.U.T.
- A Placido disc to highlight possible distortions or corneal and tear film irregularities.

## Lipid layer analysis

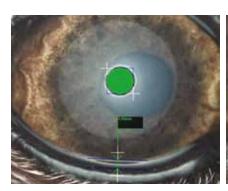
The lipid layer pattern depends on its thickness, which affects tear film evaporation. The colour and structure of the lipid layer is visible and can be recorded.

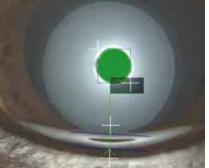
ICP OSA-VET allows to evaluate the thickness of the tear film lipid layer and to classify it in different categories in a quick and precise way. It is possible to refer to a grading scale for detailed classification and follow up.

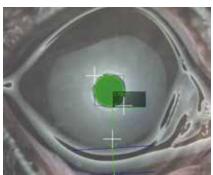
## Pre-corneal Tear Film thickness and Tear Meniscus height

In dogs and cats, the Pre-corneal Tear Film (PTF) is about 8 µm thick on the central cornea, but it is much thicker at the meniscus. By examining the meniscus, it is possible to evaluate the lacrimal glands aqueous production.

In the human beings the PTF reaches a 200 – 500 µm thickness at the meniscus (that equals 0,2 – 0,5 mm).









## N.I.B.U.T.

The OSA-VET allows to study the tear film Non Invasive Break Up Time (N.I.B.U.T.).

The Break Up Time (B.U.T.) test studies the tear film break up time with the use of fluorescein dye on the cornea. This test can cause reflex tearing and change tear film properties. On the contrary, the N.I.B.U.T. test is carried out without the use of fluorescein and is harmless and well tolerated in animals. In animals, the eye and third eyelid movements and lack of coopereation due to the animal's head restraint may interfere with both B.U.T. exams.



## White to white measurement

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



## Placido disc

To evaluate corneal topography and tear film defects by the projection of Placido rings on ocular surface.



Placido disc exam. Normal shaped cornea



Placido disc exam. Pigmented cornea in a KCS affected dog







## MGA-Vet Meibomian gland analyser-Vet

We developed a hand held device with two infrared filters and a built-in camera. Through WIFI connection, the MG device captures and displays images of the meibomian glands directly on your iPad.

Thanks to the modular double LED illumination, the images are clear and do not have reflections.

The instrument is portable and can be carried wherever you need it.

### Technical data

TYPOLOGY	Device for evaluation of the meibomian glands
CAMERA	Sensitive to infrared (NIR)
RESOLUTION	8 MPx
LIGHT SOURCE	Infrared LED
PART EXAMINED	Upper and lower eyelids
RATING	Calculation of the percentage of functional glands in selected areas
GRAPHIC RESULT	Pointing out by colour the areas with and without glands
TOOLS	Editor to highlight the area of the glands to be evaluated
OPERATIVE SYSTEM	For iPad - For Windows System







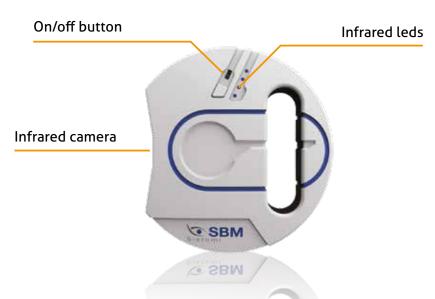
I.C.P. MGA-Vet Microsoft version by plug cable connetion IOS version by Wi-Fi connection

### Automatic detection of meibomian glands in selected areas

The I.C.P. (Integrated Clinical Platform) allows to record good quality images and to study the length and width of meibomian glands.

The images are automatically classified.

The position of the meibomian glands in the eyelids is automatically detected.

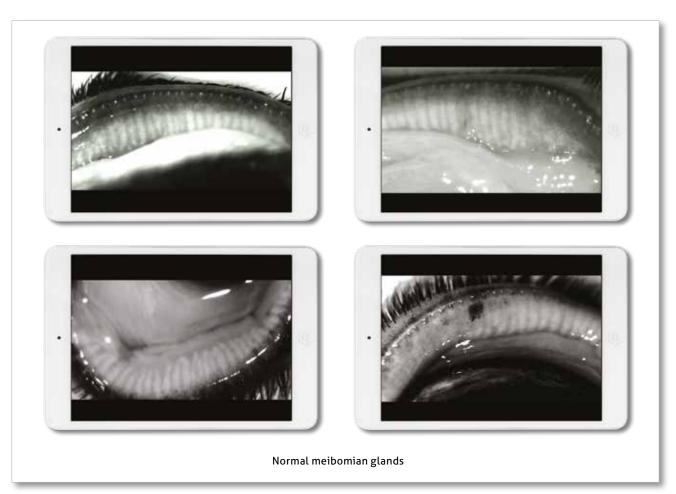


# System analysis of the images obtained through a sensitive infrared camera (NIR)

#### The I.C.P. allows to:

- Calculate the percentage of functional glands in a selected area
- · Point out the difference of colour of areas with and without glands
- Classify in 4 different degrees the loss of meibomian glands
  - A. Loss between 0 and 25 %: green
  - B. Loss between 25 and 50%: yellow
  - C. Loss between 50 and 75 %: orange
  - D. Loss between 75 and 100%: red
- Change the brightness of the images for a better evaluation

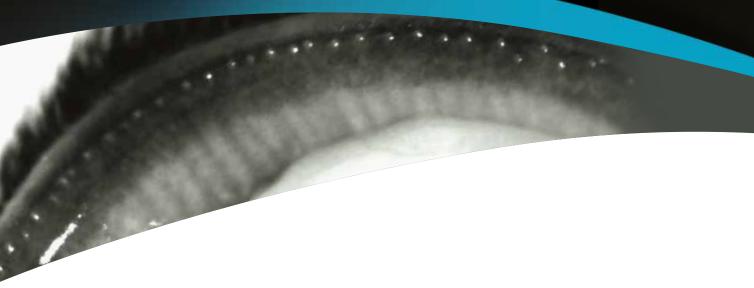




# MGA-Vet Meibography

Meibography allows to evaluate the morphology and drop out of the meibomian glands and to make the diagnosis of Meibomian Gland Dysfunction (MGD).

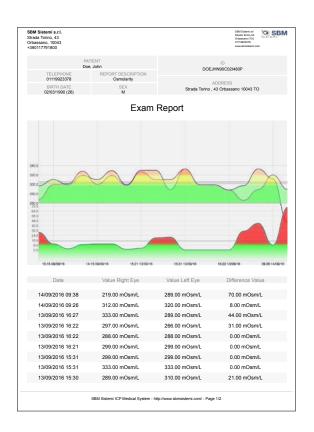
The software allows to analyze the functional and non functional areas, and to evaluate the extension of the affected area.



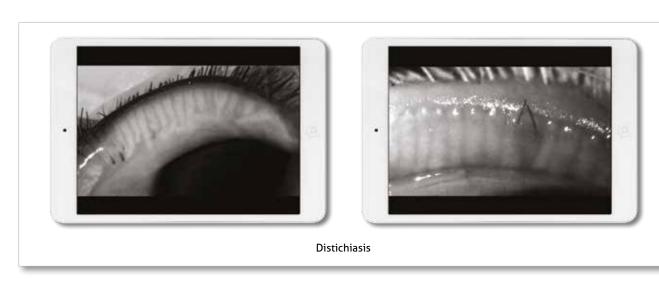
A convenient hand held device with two infrared filters and a built in camera. Utilising WIFI connectivity the MGD device captures and displays images of the meibomian glands straight on to your iPad.

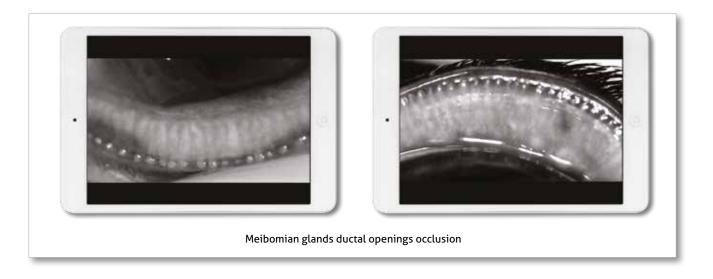
#### Features:

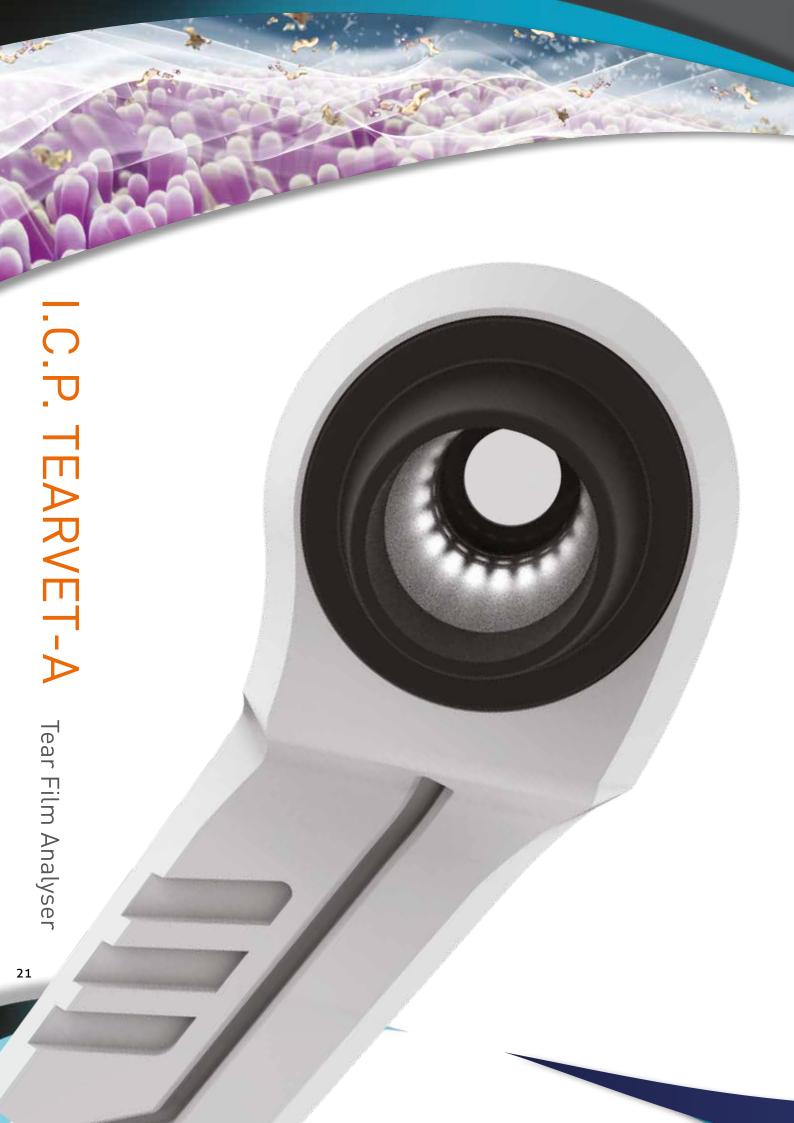
- · Seamless and wireless capturing of images for added value
- Freezing live images, instantly displayed on the iPad via the image capturing button
- Captured image enhancement tools: contrast, brightness and colour settings to improve and highlight images
- Possibility to delimit one area for the study of the glands. The calculation of gland loss is displayed graphically on the screen
- Possibility to split the screen, for side by side image comparisons over time













## Tear film lipid layer examination

The scattered light emitted by the Tearvet-A system allows to evaluate the interference patterns of the tear film Lipid Layer (LL). The different patterns can be classified according to LL thickness and quality.

By examining the LL it's possible to detect lacrimal abnormalities and make a correct diagnosis.

## Technical data

TYPOLOGY	Tear Film analysis
IMAGE RESOLUTION	From 8 to 12 MP
<b>ACQUISITION MODE</b>	Multi shot, video
FOCUS	Autofocus, manual focus
ISO MANAGEMENT	Variable
MAGNIFICATION	4x to 8x magnification with change via software
MAGNIFICATION GRIDS	4x to 8x magnification with change via software Placido disc, NIBUT grid
GRIDS	Placido disc, NIBUT grid





On/off button

Blue led - White led

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 to visit the website www.sbmsistemi.com



## ICP TEARVET-A dry eye analysis

TEARVET-A is an instrument available to veterinary ophthalmologists to evaluate the composition and stability of the Precorneal Tear Film (PTF).

It allows to better evaluate PTF qualitative deficiencies and make an accurate diagnosis of evaporative Dry Eye Disease (DED) due to imbalance of the three main PTF components:

- Lipids
- Aqueous
- Mucins

Thanks to TEARVET-A it is possible to identify the type of DED, determine which deficient layer is affected and select a specific treatment.





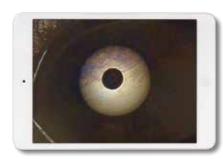


Lipid layer examination

# Tearvet-A allows to quantify directly and indirectly each single tear film layer

The white LED allows to show the phenomenon of interference fringes, that depends on the different thicknesses of the lipid layer of the tear film. Thanks to the white LED the ophthalmologist can study the Non-Invasive Break Up Time (NIBUT).

The blue LED allows to observe the ocular surface staining with fluorescein and to study the Break Up Time (BUT).







Coloured interference fringes



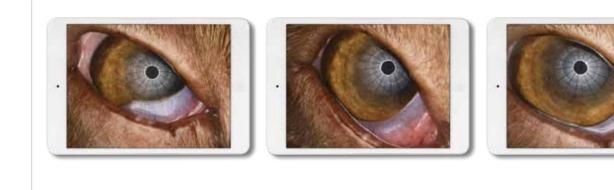
### Immediate interpretation and follow up

By using a dedicated lipid layer grading scale, each interference pattern may be examined in a simple and straightforward way.

## Supplied accessories

The system is provided with a kit of useful grids to perform various screenings. All filters are already present in the Tearvet-A package.

- · A thick grid to observe the quality of the tear film
- A fine grid to evaluate the quality and the structure of tear film and measure the N.I.B.U.T.
- A Placido disc to highlight possible distortions or corneal and tear film irregularities.



## Lipid layer analysis

Tearvet-A allows to evaluate the thickness of the tear film lipid layer and to classify it in different categories in a quick and precise way.

It is possible to refer to a grading scale for detailed classification and follow up.

For a detailed interpretation of tear stability, Tearvet-A allows to examine the lipid layer and the non invasive break up time. By matching the two exams it's possible to better evaluate the stability of the precorneal tear film.

By using the fluorescein stain, it's possible to perform the classic BUT.

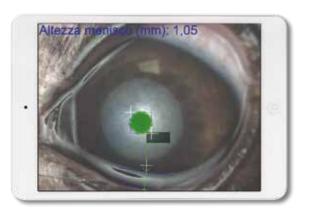


## Pre-corneal Tear Film thickness and Tear Meniscus height

By examining the meniscus, it is possible to evaluate the lacrimal gland aqueous production.

In dogs and cats, the PTF is about 8  $\mu$ m thick on the central cornea, but it is much thicker at the meniscus. In the human beings the PTF reaches a 200 – 500  $\mu$ m thickness at the meniscus (that equals 0,2 – 0,5 mm)









#### Medical certificate

All SBM Sistemi medical products are marked EC under the Medical Device 93/42 / EEC Directive and also conform to a set of international standards as applicable.

However, the interior of the medical commitment SBM Sistemi for product quality goes beyond the adherence of internationally recognized standards and extends in the attitude of our highly skilled production staff and the quality dedicated team, who are always aware of the fact that the products they manufacture are used to diagnose ocular surface diseases, restore and maintain human and animal welfare.

ID registration BD/RDN

I.C.P. IOL registration number at the Ministry: 1340867/R

I.C.P. SLIT LAMP registration number at the Ministry: 1340861/R

I.C.P. SLIT LAMP PLUS registration number at the Ministry: 1340862/R

I.C.P. TEARSCOPE registration number at the Ministry: 1340864/R

I.C.P. MEASUREMENT registration number at the Ministry: 1340865/R

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

Furthermore, all devices are certified CE and are accordant to the European regulations in force.

Electro medical test – photobiological test – etc

ISO 13485 Quality Management System for Medical Devices

ISO 13485ISO 13485 is a quality management system specifically made for the medical devices industry, which encompasses aspects of the ISO 9001 standard, plus additional industry-specific medical device requirements.

ISO 13485: 2003 has been harmonized against the three EU Medical Devices Directives (Medical Devices, In-vitro Diagnostic Devices and Active Implantable Devices), so certification to this standard by an accredited certification body such as ECM automatically demonstrates compliance with specific clauses in these directives.

The certification of a quality management system, specifically made for medical devices, to ISO 13485 is essential, for medical companies which export their products to the global market. In the European Union, the fulfilment of EU Directives (e.g., Active Implantable Medical Devices Directive, Medical Devices Directive and In Vitro Diagnostic Directive) allows the free trade of medical devices. A significant portion of demonstrating compliance with the EU directive requirements is the establishment and independent assessment of the quality system.

uni en iso 9001:2015 Nr. 8631/0 uni cei en iso 13485:2012 Nr. 8632/0











"Unlike words, and their interpretation, the image is a neutral constant a benchmark reference frozen in time.

It becomes the quintessentially unbiased witness to the condition at the moment of capture".

## The software functions present in all versions of the program

The software functions in all versions of the program are:

- · Comparison of database images
- · Saving of images and videos in order to compare the clinical aspects before and after treatment
- · Direct comparison between the recorded images and the grading scales
- · Possibility to point out and show the clinical aspects of the pathology to the client
- Dedicated database that is structured to save images, in order to record sensible data
- · Electronic medical record with the essential data of the animal
- · Possibility to record the medical history of the animal
- · Showing the results of examinations
- Privacy management
- · Storage of images and videos
- · Showing tests and results
- Follow up of examinations allowing the simultaneous visualization of previously taken images.
   Thanks to this function it is possible to evaluate the changes of the clinical status through direct comparison of images taken in different time-lapses
- · Reporting and printing reports.

#### I Cloud

- The system allows you to securely have access to all your data from your iPad and your PC
- You will always have the most up-to-date version of your patients' data at the right time
- You can send your client records from your iPad to the Windows system or to your iOS device
- Data storage
- You can share your data with the computer system of your clinic
- · You can receive examinations and exchange ideas with colleagues from all over the world for referral and sharing



#### **OUR PROJECT IN TELEMEDICINE**

We are planning an innovative web tele-diagnostic application dedicated to the world of vision.

Our mission is to make the main ocular surface diagnostic tests available to interested practitioners with the support of board certified veterinary ophthalmologists.

Examinations acquired by SBM-Sistemi instruments and all medical records will be transferred via web to a specialist for a referral. The data will be analysed and a report will follow shortly.

Thanks to a free mobile app (compatible with iOS, Android and Windows Mobile), the client will be able to save his pets' exams on his personal account without any loss, to share them with his family vet or ask for a second opinion to a veterinary ophthalmologist.

The website has been developed with the latest IT technology, ensuring technical reliability and operational safety in the management and storage of data. Moreover, it guarantees privacy to the client in compliance with the current legislation.

#### Windows system

A practical personal archive to bring always with you and with the possibility to share the archive by Wi-Fi with the various ICP medical instrumentation

The electronical medical cartel includes:

- An essential patient history
- A medical history
- The current therapeutic cycle
- An archive of images
- A report

With this system it is possible to manage the database of the patient, his medical history, the medical examinations and their follow up. It is possible to visualize the whole clinical history of the patient in one screenshot and to print it.

The system can be connected to an external hard disk in order to increase memory, make backups of the archive. You can save files on a File Transfer Protocol (FTP).



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#### Scientific advisor

# Claudio Peruccio, DVM, SCMPA, DipECVO, Hon DipACVO, MRCVS EBVS® European & RCVS Specialist in Veterinary Ophthalmology

DVM, Specialist Small Animal Diseases (SCMPA). Associate Professor at the Faculty of Veterinary Medicine, University of Torino, Italy until 2006. Diplomate European College of Veterinary Ophthalmologists (ECVO) and founding member since 1993. Honorary Diplomate of the American College of Veterinary Ophthalmologists (ACVO). Member and Specialist of the Royal College of Veterinary Surgeons (MRCVS).

From 1974 his main interests are veterinary and comparative ophthalmology.

He studied at the Veterinary Colleges in Illinois, Pennsylvania, Florida and held the office of Adjunct Associate Professor at the Department of Clinical Medicine, College of Vet. Med., University of Illinois, Usa.

In 1997 he has been awarded the World Small Animal Veterinary Association (WSAVA) / WALTHAM Internation Award for Service to the Profession.

October 19, 2014 he has been nominated Honorary Diplomate of the American College of Veterinary Ophthalmologists (ACVO).

Speaker and lecturer in many meetings in Italy and other Countries, author of many scientific publications, chapters and textbooks.

Founder editor of international and national journals and newsletters: Progress in Veterinary and Comparative Ophthalmology, Progress in Veterinary Neurology, Veterinaria, Ippologia, Orizzonti Veterinari, Hereditary Eye Disease, The Globe.

Founder member and member of the board of the following international and national organizations:

- European College of Veterinary Ophthalmologists (ECVO, President 2014-2016)
- International Society of Veterinary Ophthalmology (ISVO, President 1991-93)
- Italian Small Animal Veterinary Association (AIVPA, President 1982-84)
- Italian Companion Animal Veterinary Society (SCIVAC, Vice-president 1985-87)
- Italian Society of Veterinary Ophthalmology (SOVI, President 1989-98)
- Italian Society of Veterinary Neurology (SINVET, Vice-president 1989-92)

#### Present ongoing offices:

- Director CVITGroup Academy
- Editor of The Globe, ISVO Newsletter
- Consultant at Veterinary Ophthalmology Referrals in Torino, Milano, Samarate (Italy)

At present the main area of interest is Ocular Surface focusing on new diagnostic techniques and treatments.

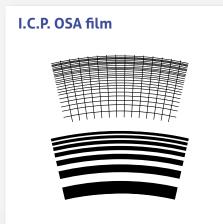


## Accessory













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