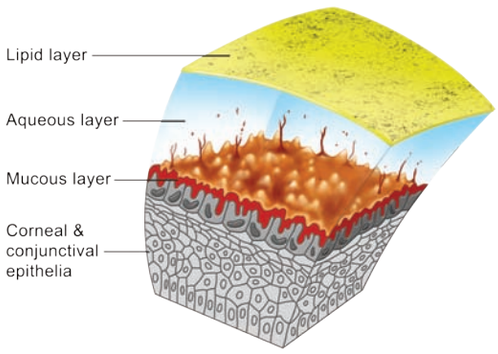
Ocular surface analyser

The scattered light emitted by the I.C.P. allows to evaluate the interference fringes caused by the "quality" of the tear film and to classify them in different pattern tear.

The observation of the 3 layers allows us to intervene in a targeted way, evaluating the use of a particular artificial tear, an integrator or the presence or not of lacrimal abnormalities.

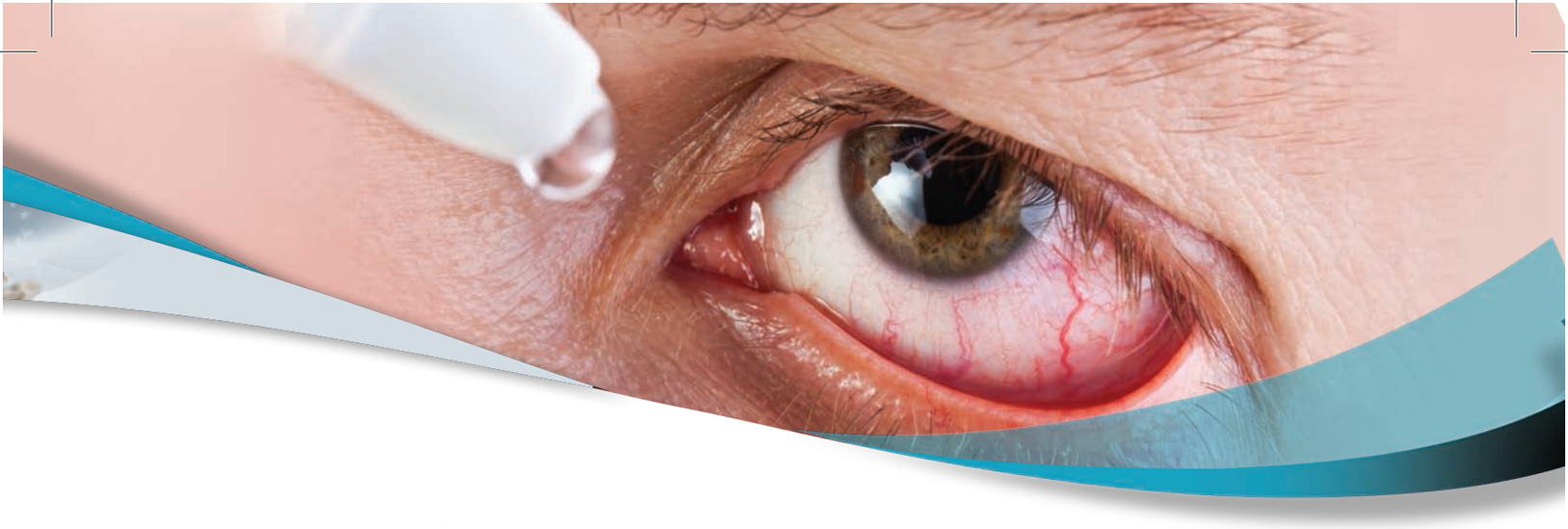
- Quantitative test that evaluate the quantity of basal and/or reflected secretion
- Qualitative test that evaluate the functionality and the stability of the tear film
- N.I.B.U.T.: the observation is made without the use of fluorescein.



Technical data

TYPOLOGY	Tear Film analisys
IMAGE RESOLUTION	From 8 to 12 mp
ACQUISITION MODE	Multi shot, video
FOCUS	Autofocus, manual focus
ISO MANAGEMENT	Variable
MAGNIFICATION	4x to 8x magnification with change via software
GRIDS	Placido disc, NIBUT grid
FILTERS	Yellow filter
LIGHTING	White led - Blue led
OPERATIVE SYSTEM	For iPad II, iPad, iPad Pro

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

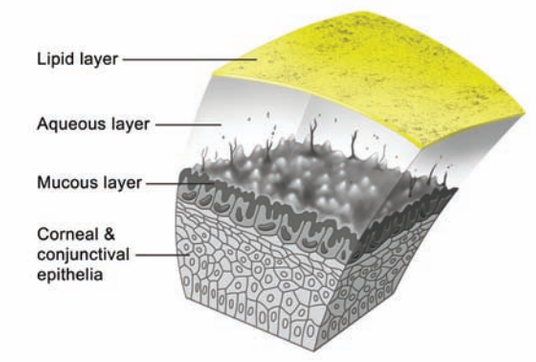


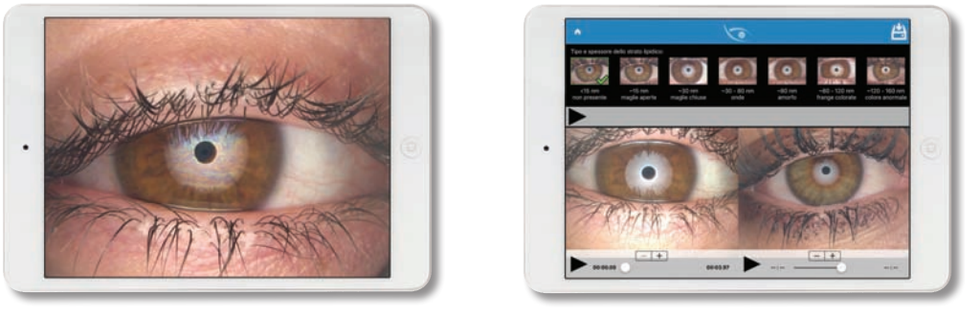
INTERFEROMETRY TEST

Analysis lipid layer

Through a quick and easy acquisition of a series of 3 blinks, ICP Tearscope allows to obtain the thickness of the single Lipid Layer of the tear film classifying it in 7 different categories in a quick and precise way the secretion of the lipids by the Meibomian Glands.

Presence of grading scale and comparison in the time for detailed and precise follow up.





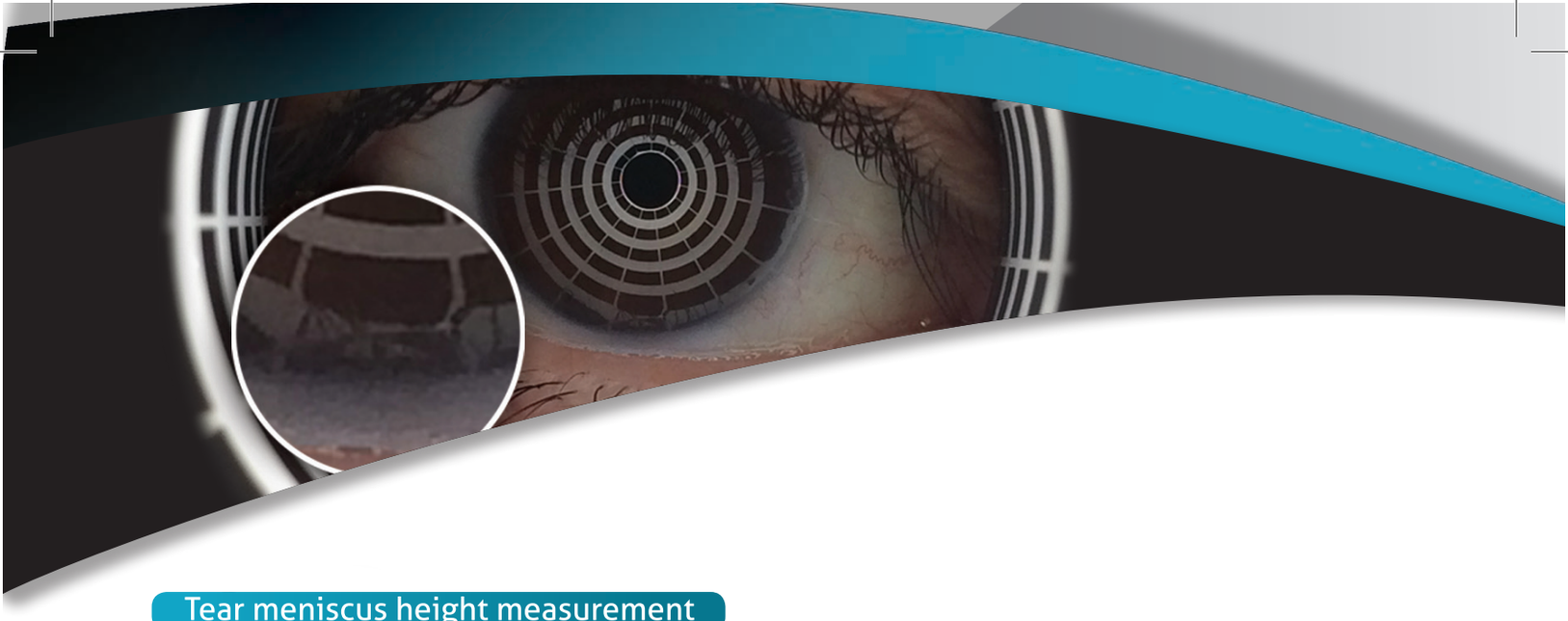
Analysis stability and calculation of the lipid layer thickness

ICP Dry eye analysis

I.C.P. Tearscope the new instrument of individual analysis of lacrimal layers that allow with a quick detailed structural research of the tear composition.
Possibility of researsch on the single layers:

- Lipid
- Aqueous
- Mucin

Thanks to ICP Tearscope is possible to identify the type of DED (Dry Eye Desease) and determine which deficient layers can be treated with a specific treatment.

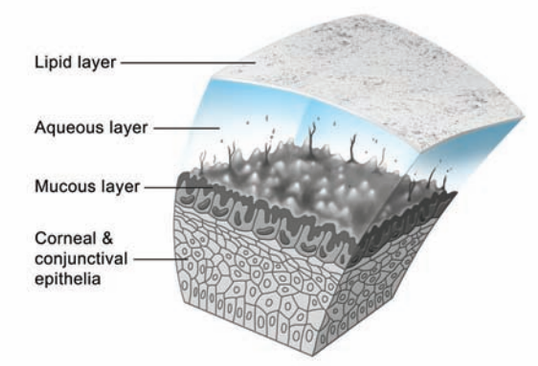


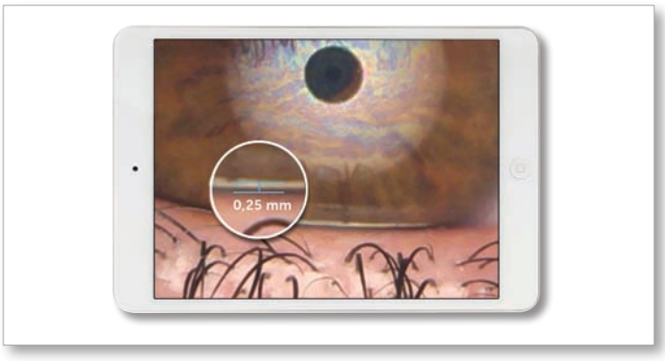
Tear meniscus height measurement

The tear film is the thin layer of liquid (about 8 µ, its thickness is variable on basis the considered portion and it results at maximum at cornea level) composed 98% of water and for the remaining 2% by protein and lipids, that is continuously and uniformly distributed on the ocular surface of the closing of the eyelids and that performs irreplaceable functions for our sight.

In fact it is able to improve the optic quality of the image regularizing the corneal surface (it has an index of refraction of 1,33, very close to that of the cornea); it allows an adequate lubrication reducing the friction of the eyelids, it allows the transport and the diffusion of molecules (oxygen, carbon dioxide, ions, mucins, lipids with a slightly alkaline pH 7,3/7,8), vital elements for the survival of the epithelia and of the cornea, it has strong antibacterial activity thanks to the presence of some enzymes and it guarantees the parts and keeps the ocular surface clean removing impurities from the environment, the waste of metabolism and exfoliated cells.

In the photos (on the left) is possible to recognize the diffraction of light on the lipid layer, on the right is possible to see the meniscus composed by tear film between the edge of the eyelid and the cornea (normal if its height is included between 0.22-0.5 mm).

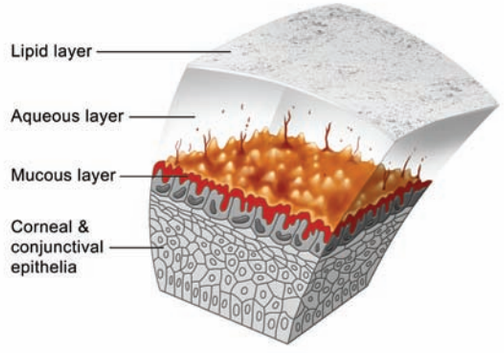




N.I.B.U.T.

Evaluation of tear film break-up time non invasive and fully automatic.
In the B U T test the presence of fluorescein in the tears may stimulate reflex tearing and may also result in changes to the tear film properties.

To overcome these potential limitations, using a non-invasive procedure because the eye is not touched.



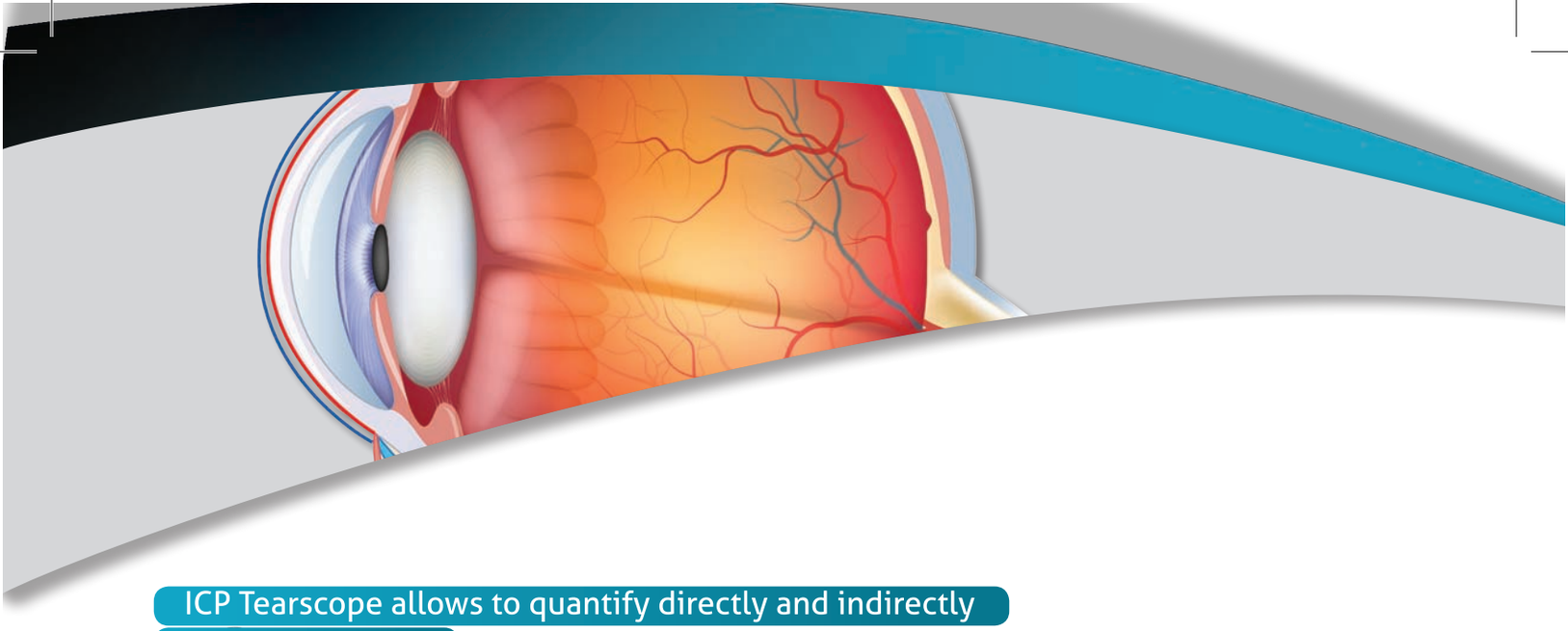
Supplied accessories

The system is provided with a kit of useful grids to perform various screening, all filters are already present in the system software and includes tests to evaluate and diagnose dry eye problems and can recommend artificial tears.

- Measurement of BLACK LINE (MLMI)
- Evaluation of the integrity of cornea and ascertaining the presence of corneal scars and bruises.

The product is already ready for the connection to Digital Imaging and Communications in Medicine (DICOM)

- Blue and white Led
- A thick grid to observe the quality of the tear film and measure the N.I.B.U.T.
- A fine grid to evaluate the quality and the structure of tear
- A Placido's disc to highlight possible distortions or corneal irregularities
- A yellow and cobalt blue filter via software for applicative evaluation of rigid contact lenses.



ICP Tearscope allows to quantify directly and indirectly each single layer

With white LED slighting displays in vivo the phenomenon of interference fringes possible to assess the thickness of the lipid component of the tear and run the NiBUT.

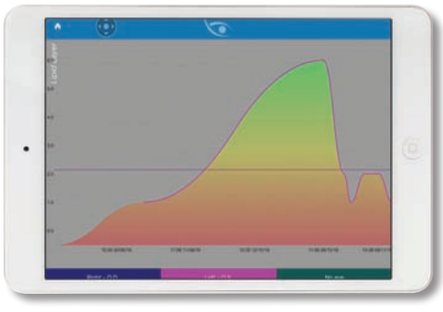
With blue LED slighting (with the fluorescein) creates a large area and allows you to perform the BUT and look fluorescein of large diameter scleral and mini scleral contact lenses type.

Mucin layer and water layer analysis

The layer watery is evaluated on the meniscus tear categorizing in different categories and possible issues related this. The measurement in mm allows without invasiveness the direct evaluation of the quantity.

Immediate interpretation and follow up

Through the use of GRADING SCALE dedicated to each value obtained from the exams, the interpretation of the obtained data results easy and immediate making the iPad a real platform dedicated to the analysis of dry eye with detailed temporal graphics that allow to demonstrate in simple steps the need of the treatments and then the effective functioning of these!



Graphic pre and post treatment with easy interpretation for the patient

All Dry Eye with scales and classified parameters on basis of standard

Registration made
in the following extra
cee countries

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 the fact that the products they manufacture are used to save lives in critical care applications both locally and worldwide.

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 standard specifically 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 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

I Cloud

The system allows you to securely access all your data from iPad to PC and from PC to iPad.

- You will always have the most up-to-date version of your patients' data at the right time.
- From the iPad device you will have the ability to send all patient records and related exams, or parts of them to the Windows system.
- All patient examinations, or part of them, can be sent to the iOS device
- The system allows you to save space on the iPad, having the ability to only preserve patients who are going to be visited in portability
- Data storage
- share all information inside the clinic
- Possibility to recive exams from assistants allover the world for referral or sharing

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 that includes:

- Essential patient registry
- Medical history
- Formula of the current therapeutic cycle
- Archive of images
- Report

With this module is possible to manage the database of patient, his medical history, the medical examinations and their Follow Up.
It follows that, through a unique screen, will be possible to visualize the whole clinical history of the patient and will be made all related prints.
The doctor has then, at the end of the visit, the possibility to print and deliver to the patient a report that presents only the data of the clinical cartel that he considers appropriate, inserting also a textual discursive section. He can also choose to send these documents via email.
Multisite/multi iPad with synchronization between them to visualize all medical reports from a computer.
External memory to download exams when the memory of the various supports is finished.
Backup and recovery of the achieve.
Working also in background.
Saving photo and video on FTP instead that on the device to safeguard the space.

The software functions present in all versions of the program

- Comparison of database's images
- Saving of images and movies comparing the situation before and post application
- Direct comparison with the taken images and the tables of Efron
- Direct comparison with the taken images and the tables of CCLRU
- Direct comparison with the taken images and the tables of Jenvis
- Possibility to point out and to show to your patient the pathology
- Evaluation of the visual acuity from far
- Evaluation of the visual acuity from near
- Show visually with the help of the iPad the difference between the use of the lac and the use of the ophthalmic lens
- Database dedicated and structured for the saving of the sensible data and of the made exams during the time
- Technical follow up targeted to the LAC application
- The electronic medical record with the essential registry of the Patient
- The medical history of the patient
- Optometric data
- Results of examinations
- Privacy management
- The archive of images and movies (photographs)
- Test and results
- Follow up visits allowing the simultaneous visualization of images related the next visits. With this function is possible to evaluate the upgradability of the pathology through direct comparison
- Reporting and printing up to 10 printable reports.

CLASS 1
MEDICAL
DEVICE

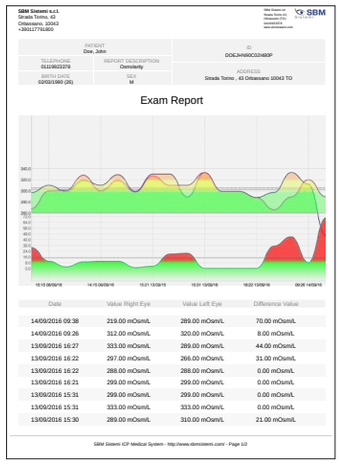
New results and exams

These values have been grouped in a new section in the exam results screen with all these new values.
All values from "Grading scales" were deliberately put together in a single section later providing the ability to filter the values seeing only those of interest (Redness, Staining, ...)

Daily report

with all exams values of a given day

Report with values and graph of a specific exam value (nibut, osdi, osmolarity)



Osmolarity

Values and graph of osmolarity values

N.I.B.U.T.

Values and graph of nibut values

History

The SBM was founded in 1984. The core activity of the new company is to produce software for optical centers.

The territorial development begins with the opening of new distribution facilities on the Italian territory, especially to offer services and assistance. In the '90s,
the company began its real growth path that is still the main goal for the future.

Thanks to large investments and sacrifices in those years began working for production.
Later in time also starts working as a provider of information technology services and optics and ophthalmology instrumentation.

After more than twenty years these services are still carried out at the office of our customers or our operating offices on the Italian territory and abroad.

The experience achieved over the years with important and prestigious brands allows us to be present on the market as a serious and reliable partners for Strategic Outsourcing services or part of them.

Production

A good product must be made from a precise projecting including a careful materials choice.
The final difference consists in availability of personalized solutions for every need.

SBM Sistemi customers have a complete post-sale support. Any request related to the software is solved with remote assistance from local partners or directly by the SBM company. Any need related to the hardware can be managed by our local partners all-over the world that, in constant contact with SBM company, have the opportunity to ship the instrument for complete check-up.

All SBM Sistemi products are realized with hi-precision by factory technicians. Pre-sale checks and verifications consist in 24 hours non-stop test session to ensure the quality of the components.

Only after this task an instrument can be packaged and considered ready for delivery.