I.C.P.

Portable Diagnostic System

SBM Sistemi

COMPANY TO THE PROFESSIONAL SERVICE

WHY CHOOSE I.C.P.

Dear professionals,

the aging of the population, the high expectations for a better quality of life and lifestyle of modern society require a better, more efficient and economically sustainable health care.

Crucial elements to meet these expectations are the progress in understanding of human body functioning at molecular and Nano metric scale, as well as the ability to intervene in a pre-symptomatic, acute or chronic stage of illness.

In diagnostics the ultimate goal is to identify the disease as early as possible, ideally at the level of its manifestation in a single cell. To achieve this, research and development activities must be undertaken in technologies field to improve the efficiency of diagnosis stage.

SBM Sistemi technologies can provide diagnostic tools with characteristics of sensitivity, specificity and reliability, plus the ability to record several measures or to integrate different analytical steps.

In general terms the mobile technology will have a great impact on the methodologies available for both the diagnosis of diseases and the discovery of new drugs. It will be possible to get early and reliable diagnosis using advanced detection systems.

Thanks to its evolution, the ophthalmology market is heading in increasingly innovative and decisive directions.

For some time now, in fact, has come the need to use portable and reliable equipment and diagnostic tools every time and everywhere, imited so far by their size and characteristics to be used only within the consulting room.

With SBM Sistemi unique innovation, designed and created entirely in Italy, from now on you can carry your own professionalism and examination room according to your needs.

We are pleased to announce the birth of the first portable refraction unit in fully digital platform that will allow you screening and diagnosis tests in the easiest and most innovative way ever designed.

With the unique I.C.P. App from SBM Sistemi (available on your Apple device) you will have the chance to manage medical records and examinations at any time of the day with a simple touch.

This is the first and only iPad app developed in the field of contact lens that allows you to show to the usual or first time wearer, as we see reality through the lenses chosen. They can then virtually evaluate the view between contact and ophthalmic lens in different situations.

A unique application for many screening…

Is necessary only a simple click to wear the instrument and to start the evaluation of your client. Every product that you will use, it will have at disposal a number of shared functions thanks the APP.

The simple ergonomic covers allow to insert and remove the tools in a few seconds, all the instruments are equipped with a convenient carrying case and its battery to use.

All products contained in this brochure answer to the community legislation CE, both for the mechanical optical features both electrical safety.

The practicality and cheapness of the product range allow you to make an ophthalmological visits and consultations at home and in all those problematic situations, like exams to handicapped or bedridden patients.

The products are supplied with rechargeable batteries that allow the use in environments devoid of electrical outlets.

The software functions present in all versions of the program

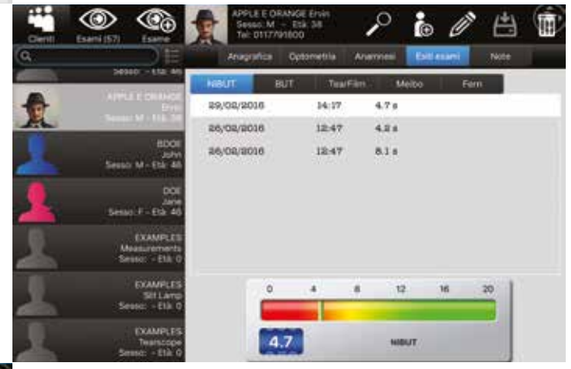
- Comparison of database's images
- Saving of images and movies comparing the situation before and post application
- Direct comparison with the taken images and the tables of Efron
- Direct comparison with the taken images and the tables of CCLRU
- Direct comparison with the taken images and the tables of Jenvis
- Possibility to point out and to show to your patient the pathology
- Evaluation of the visual acuity from a distance
- Evaluation of the visual acuity from close
- 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 and radiographs)
- 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

FULL MANAGEMENT PATIENT PRIVACY

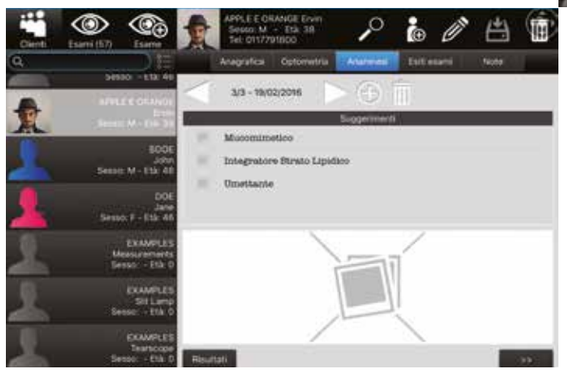
THE ELECTRONIC MEDICAL RECORD WITH THE ESSENTIAL REGISTRY OF THE PATIENT

EXAMS RESULTS

OPTOMETRIC SHEET



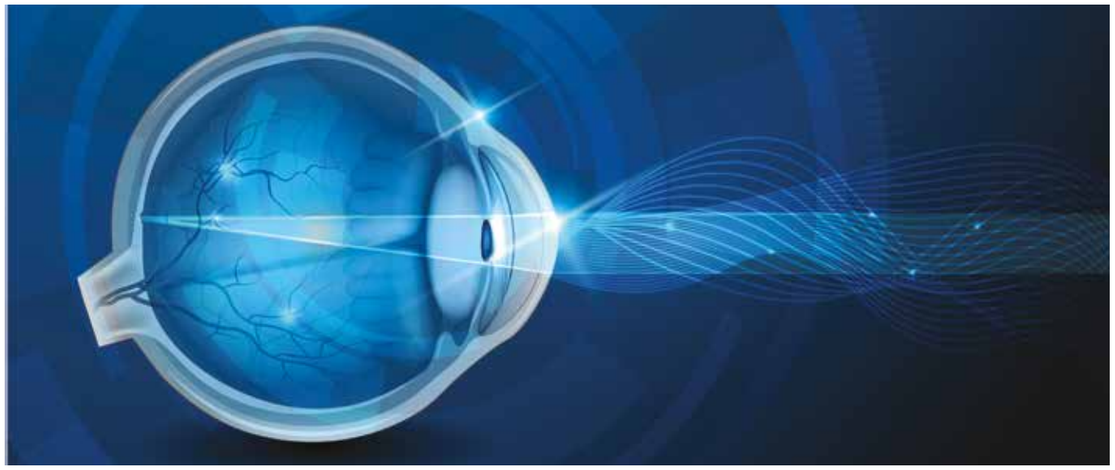
RESULTS PARAMETERIZED TEST



CONNECTING TO PHARMACEUTICAL CATALOGS

Type of exams

- Exam in slit lamp
- Exam in Fundus camera
- Exam in backlight
- Tearscope
- Analysis of Meibomian Glands
- Calculation of cyclotorsion's system for insertion of toric IOL
- Data analysis for the Oculoplastic surgery
- Ferning test
- Amsler test
- Optotype for visual acuity measurement



POSSIBILITY OF IMAGE MANIPULATION

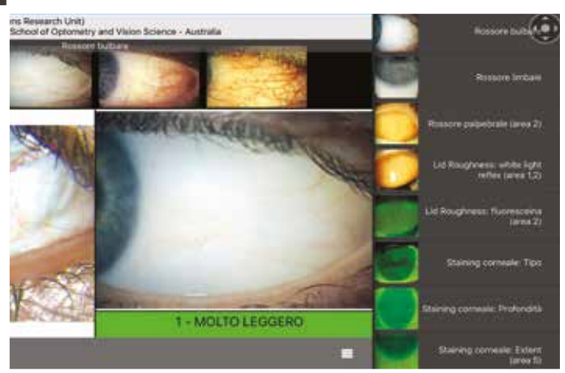
The captured image can be re-elaborated, allowing to highlight details of the patient's eye

VIDEO MANAGEMENT WITH THE EDITOR POSSIBILITY

Editor movie with possibility vision frame on frame, choose of image and possibility to save it.

USE OF THE TABLES OF EFRON, CCLRU, JENVIS

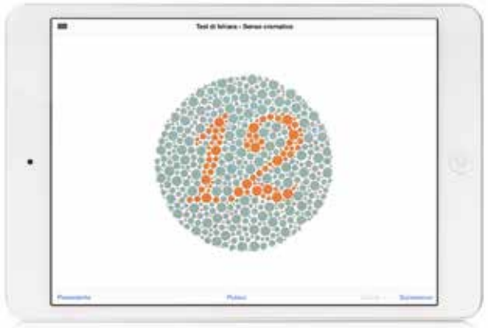
Comparison image of patient's eye with the respective rating scales of EFRON, CCLRU, JENVIS



OPTICAL CHART

An optotype in geometric progression with the following peculiarities

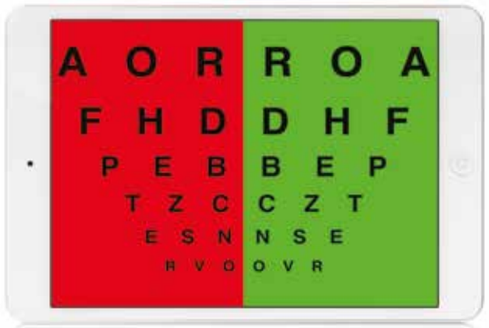
- Random presentation of images, numbers and letters
- Separated evaluation of the two eyes
- Contrast reversal
- For illiterate
- For children
- For simulators
- Read contrast
- Critical print Contrast



Various tests for visus are generated by an algorithm that, on the basis of the distance set, calculates the size of letters, the distance between the same and between individual rows.

For the other Optotypes, we visualize the single images chosen by catalogue that will be located and dimensioned based on the above criteria.

Read speed tests are characterized by a series of random sentences based on a distance of 40 cm.



The patients section allows the memorization of the patient data with their results

- LOG SEEDS
- LOG
- CROSS
- CLOCK
- NUMBERS
- CHILDREN
- ALBINI
- READ SPEED TEST 40 CM
- READ SPEED TEST WITH VARIABLE CONTRAST
- RED GREEN
- TEST FOR CLOSE 40 CM
- MESO/GLARE TEST
- COLOR VISION TEST LETTERS LARGE
- COLOR VISION TEST LARGE FIGURES
- COLOR VISION TEST SMALL LETTERS
- COLOR VISION TEST SMALL FIGURES
- S. CONTRAST LETTERS
- S. CONTRAST NUMBERS
- VARIOUS

The versatility of the remote control will allow the use of the application without to be close to the patient.

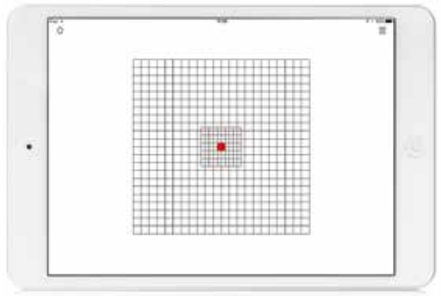
AMSLER TEST

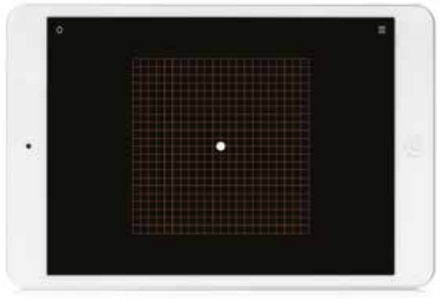
It is a very simple test that we can easily make at home at any time. The purpose of the test is to identify as early as possible the METAMORPHOPSIA that is the most typical symptom of the macular degeneration.

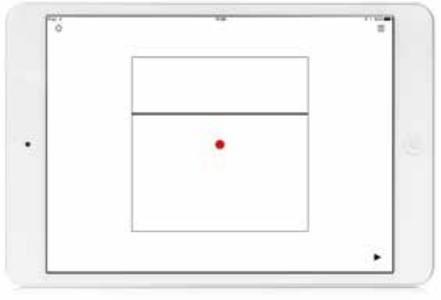
The metamorphopsia means the deformation, ripple, distortion of everything that is straight.

The grid is a diagnostic tool that helps to detect visual defects caused by retinal imperfections, optic nerve and transmission of visual impulses to the brain.

- STANDARD
- SCOTOMA COLOR
- HORIZONTAL METAMORPHOPSIA
- VERTICAL METAMORPHOPSIA
- CENTRAL
- HORIZONTAL MOVEMENT
- VERTICAL MOVEMENT





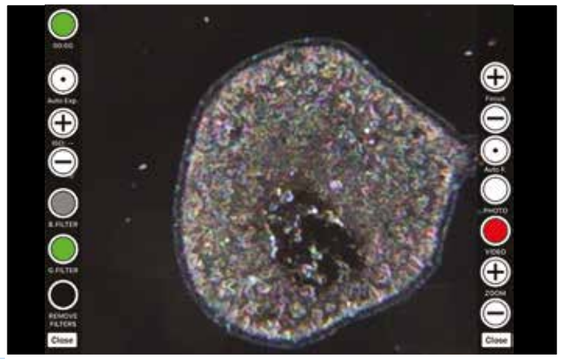


FERNING TEST

The test reflects the mucus conditions and indirectly provides indications about the osmolarity of the tears.

It is obtained a-traumatically with a micropipette, without anesthesia, is placed on a slide and is left to dry at room temperature (20-22°C).

The preparation is observed in contrast microscope at 40-100 final magnifications. The test is based on a feature common to all mucous secretions, the capacity of which is to crystallize, during drying, in the form of ferns (from here the name of Ferning Test), due to evaporation.



The levy is via a micro syringe with a tube at the level of the conjunctiva, and not in the bulb; with a quick movement in order to prevent subsequent tearing.

The removal of the tear would distort the test.

FERN CLASSIFICATION

Type I: contiguous ferning that denote a good protein carpet due to dense branching, in this case we know that in the film there is a fair amount of protein and that all parameters are respected, so we can apply all kinds of polymer.

Type II: The fern is still abundant, but begins to highlight gaps between the branches. The stability of the film is decreased, but we still have a good range of application for all types of lenses.

Type III: the ferning, due to proteins and precipitated salts, starts to rarefy; appear gaps and uniform conglomerates of mucin. For the lac application, the film must be partially reinstated, in case of hydrophilic polymer must be rehydrated. For contact lenses with continuous use, is used an artificial tears.

Type IV: the ferning phenomenon is absent and the sampled material does not show any organization, we see clusters and filaments of degenerated substances and probably also exfoliated cells.

DIGITAL SLIT LAMP

Visual screening

I.C.P. is a simple support that applies to your iPad.

Once applied the ICP, thanks to the application downloadable from iTunes, you will have the chance to make a lot of visual screening.

The I.C.P. can also enable health workers to send in real-time images or parts thereof to the experts for a more through diagnosis.

Dm_aa 1340861
Code 15003
Name Digital slit lamp
Classification CND z12120108
Class CE 1

RETINOSCOPY

Mydriatic and not Mydriatic

The instrument ICP Slit Lamp of SBM Sistemi will allow you to make an evaluation of the internal structures of the eyeball:

- Vitreous
- Retina
- Macula
- Optic nerve

Allowing you to save the analysis in digital format.

Example of backlight

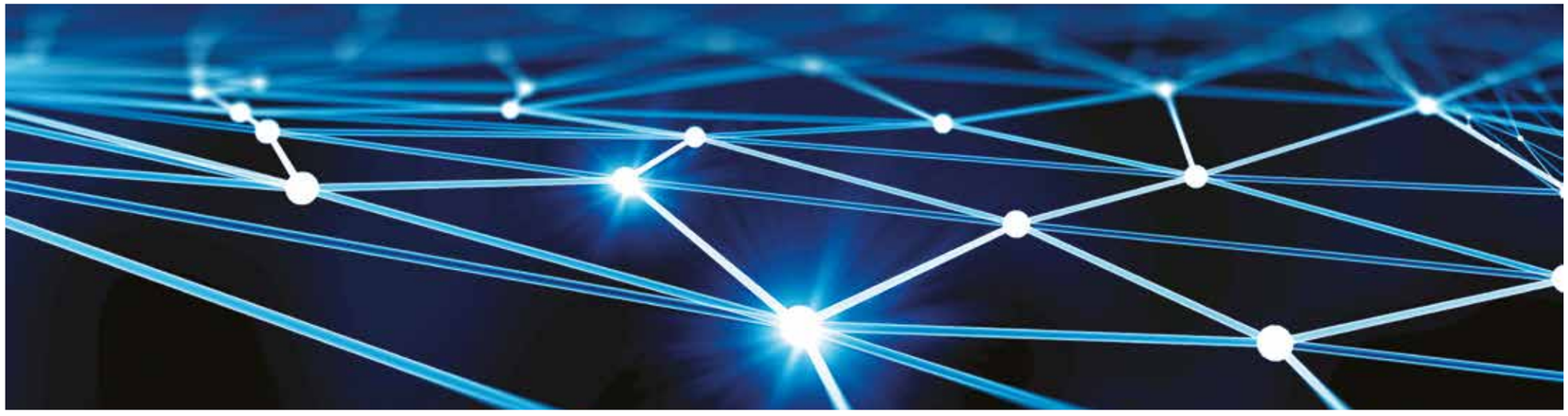
Back light of the crystalline

The increase of the contrast allows you to observe the indistinct particles present on the cornea. It is also suited to the observation of:

- Corneal alterations
- Metabolic alterations (leucomas, micro-cysts vacuoles)

It is obtained by observing the light reflected from the iris tissue directly on the cornea, through a rear light source.

Example of fundus without dilation



Technical features

IMAGE RESOLUTION
8.000.000

PHOTO RESOLUTION
3264x2448 in jpeg format

AUTOFOCUS SYSTEM

CAPTURE MODE
Multi shot, movie, autofocus, manual focus, variation of the iso for the acquisition with much ambient light.
The led illumination guarantees low consumption and a good reduction of color.

MAGNIFICATIONS
variable from 8x to 24x
change magnifications by software

FIELD OF VIEW
8x and 24 x

ILLUMINATION SYSTEM
slit width: adjustable up to 4 mm

ROTATION
90 - 180°

SLIT TILTING
20°

LIGHT BULB
Led 6V – 3watt corresponding to 30 W halogens

FILTERS
cobalt blue, green, grey

ILLUMINATION INTENSITY
adjustable from 0 to 100%

VERSION
with 30 – 45°
with 30 – 45 – 90°

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

TEARSCOPE (TEAR FILM SCREENING)

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.

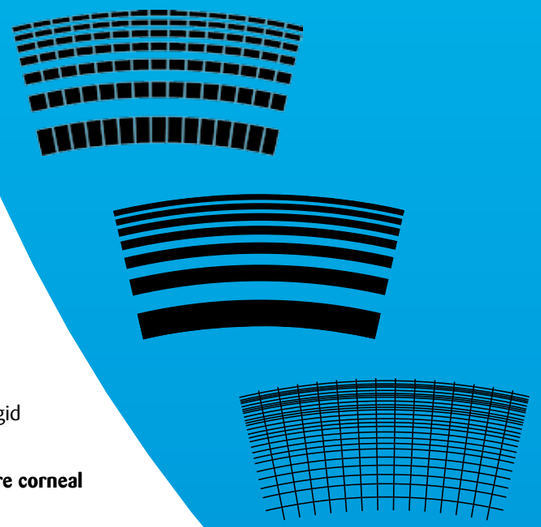
The observation of the lipid layer allows us to intervene in a targeted way, evaluating the use of a particular artificial tear, an integrator or the presence or not of lacrimal abnormalities.

- Dystrophies with Placido’s rings without fluorescein
- 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.

Dm_aa 1340864
Code 15002
Name Tearscope
Classification Z12120199
Class 1

Dynamic tear testing

- Observe the quality of the tear film non-invasively;
- Accurately measure the break up time and other important aspects of the tear film projecting directly into the surface of the patient's eye a white and homogeneous light source through a conical diffuser;
- Measure the height and the regularity of meniscus tear;
- Check the fluorescein pattern when applied to rigid contact lenses;
- Check the status of rigid lenses (scratches, deposits).



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.

- 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

The I.C.P. and its accessories allow you to make a depth review of the pre corneal tear film that is divided into 5 parts:

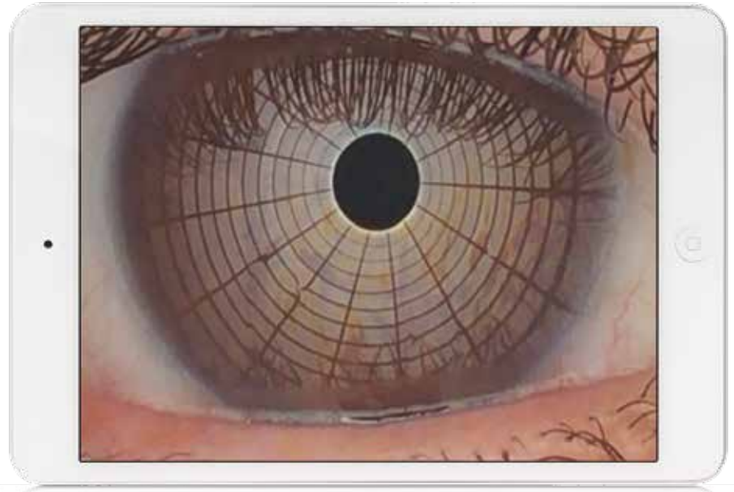
- Observation and classification of lipid layer
- Observation of blink sequence, with visualization of a map of the rupture's area with relative times calculated automatically.
- Measurement of BLACK LINE (MLMI)
- Observation of Meibomian glands (also with infrared camera optional)
- Evaluation of the 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)

Thanks to quantitative tests, that evaluate the quantity of basal and/or reflected secretion, to qualitative tests, that evaluate the functionality and the stability of the tear film, we can obtain OBJECTIVE and repeatable measurements about the situation of our patient.

With this system we believe to bring to the Optical Centre, Medical Studies and Pharmacies an innovative, simple, ingenious product that always suggests THE BEST PRODUCT to our customer.

Not only, but thanks to the integrated statistical system, we will have the possibility to evaluate the investment made by your company at the medical center concerned.

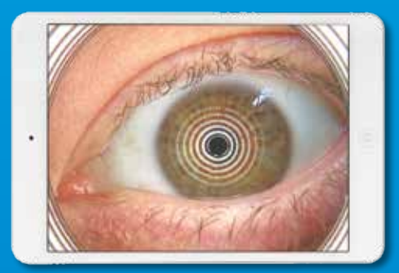


NIBUT ANALYSIS (BREAK UP TIME OF TEAR FILM)

Possibility to evaluate the BUT without the use of the fluorescein with a simple acquisition of 10s.

ANALYSIS OF LIPID LAYER

It allows to evaluate the stability of the tear, the disposition on the entire cornea and the actual thickness of the layer according to the Dr. Guillon studies.



Corneal distortion screening

Through the use of some Placido's discs, is possible to evaluate a possible deformation.

ANALYSIS OF MEIBOMIAN GLANDS MGD

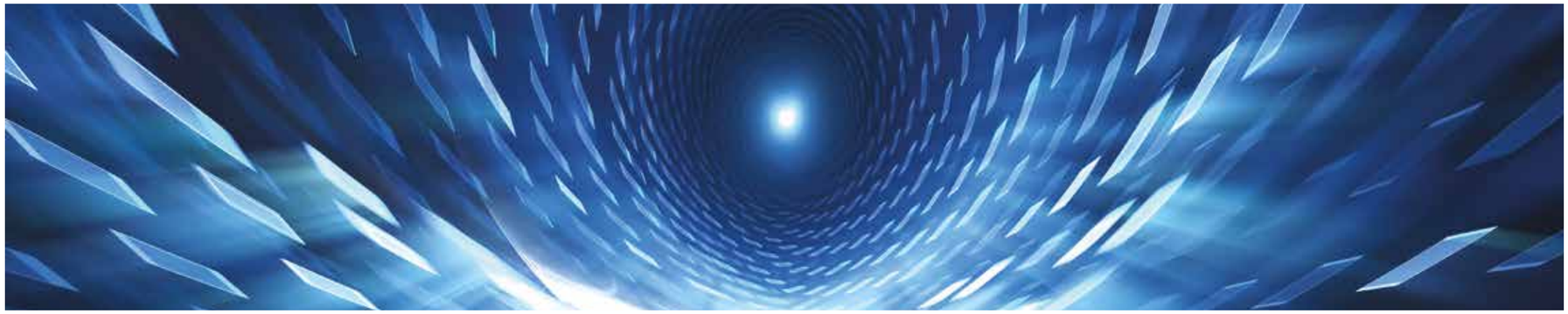
Through an acquisition of color images, or by infrared camera, it allows the evaluation of the gland.

The criticality is made through five-level scale.
The evaluation scales are an essential instrument for the registration and for the clinical monitoring of the modifies to the ocular tissues.

These scales are used to evaluate the gravity of a wide range of conditions, included those associated to the contact lenses.

The dysfunction of the Meibomian Glands (MGD, Meibomian Gland Dysfunction) is caused by a chronic alteration of the sebaceous glands that are located inside of the eyelids.

Dm_aa 1392897
Code 15006
Name ICP MGD
Classification Z12120199
Class 1



ACQUISITION OF THE IMAGE THROUGH INFRARED CAMERA

DETECTION OF THE AFFECTED AREA WITH WIZARD FOR THE GENERATION OF THE AREA CALCULATION

These glands produce oily lipid substances that are released at level of the eyelid margins and reach the tear film thanks to winks eyelid. The oily lipid substances float on the surface of the tear film and serve to reduce evaporation.

The MGD alters the lipid component of the tear film and this can cause the appearance of an evaporative dry eye with its characteristic symptoms.

In several cases the MGD can cause also an inflammation of the eyelid margins called posterior blepharitis.

System analysis of the images obtained through a sensitive infrared camera (NIR) in order to locate automatically:

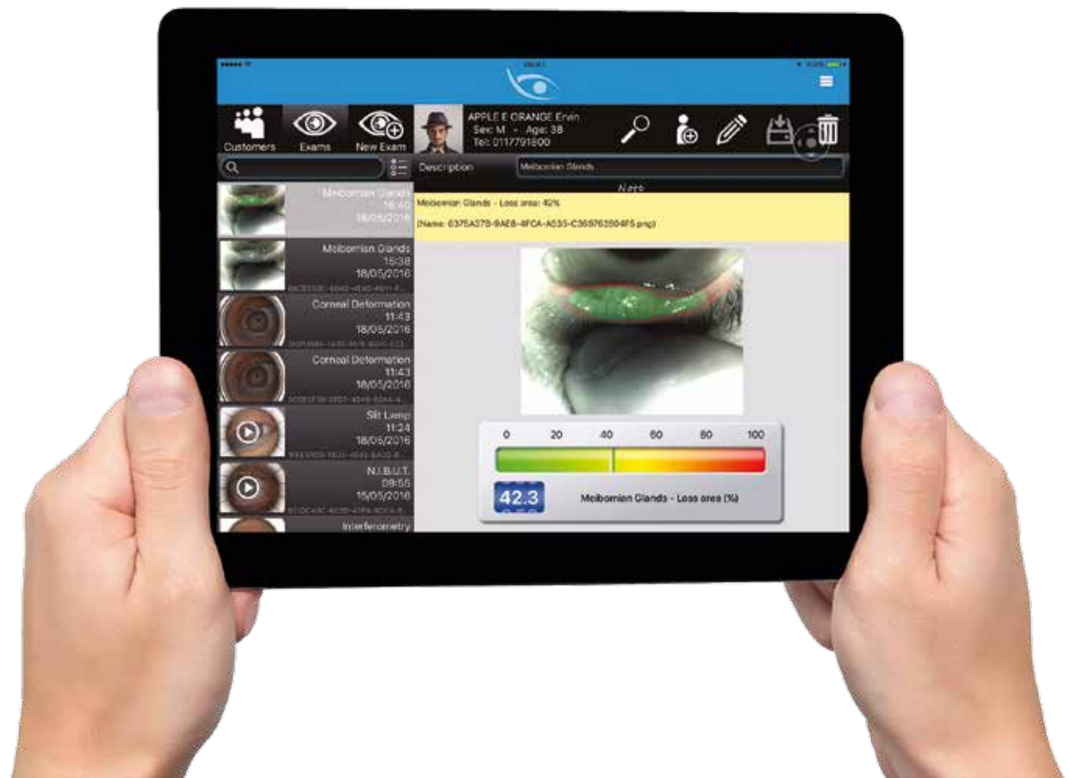
- The position detected from the image, valid both for the superior both for the inferior part of the eye
- Calculating percentage of the extension in area of the present glands, taken by the operator
- Calculating percentage of the area of the missing glands
- Absent and present coloring area
- Classification in 4 different degrees
- Loss of less than 15%
- Loss between 15 and 30% in yellow
- Loss between 30 and 50% in orange
- Loss of over 50% in red
- Through the editor system is possible to modify the brightness of the picture for a better evaluation

Meibography

It serves to build the morphology, diagnosis and drop out of the Meibomian Glands and for the diagnosis of the vital dysfunctions.

Meiboscopy is the visualization of the glands through trans-illumination of the eyelid with infrared light.

The software allows to analyze the working and not working areas, and to compare the glands of the patient with the diagnostic evaluation scales.



Problematic evaluation of the dry eye

For dry eye diagnosis are recommended a series of exams:

- Measurement of the winking frequency and calculation of the inter wink interval
- Measurement of the height of the lower tear meniscus
- Measurement of the tear osmolarity (if available)
- Calculation of the tear film break up time (TFBUT) and the index of ocular protection (OPI)
- Classification of the corneal and conjunctival coloration with fluorescein
- Schirmer Test or alternative test (phenol red test)
- Quantification of the morphological characteristics of eyelids
- Squeezing: quantification of the squeezability and of the quality of the lipid component
- Meibography: quantification of atrophy.

PUPILLARY PARAMETERS DETECTION

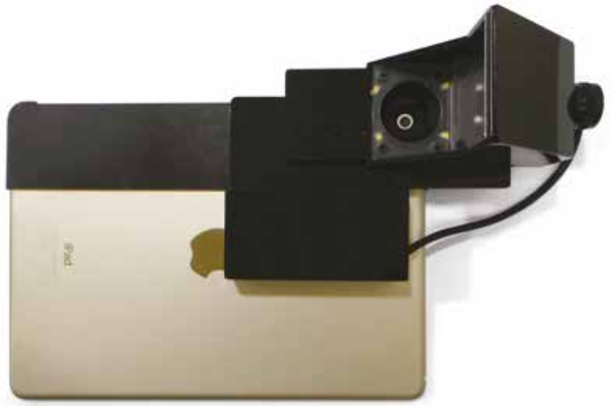
Oculoplastic surgery

The oculoplastic surgery is specializes in the treatment of eyelids pathologies, the portion of the face around the eyes, the tear system and the orbits (deep structures that surrounding the eye).

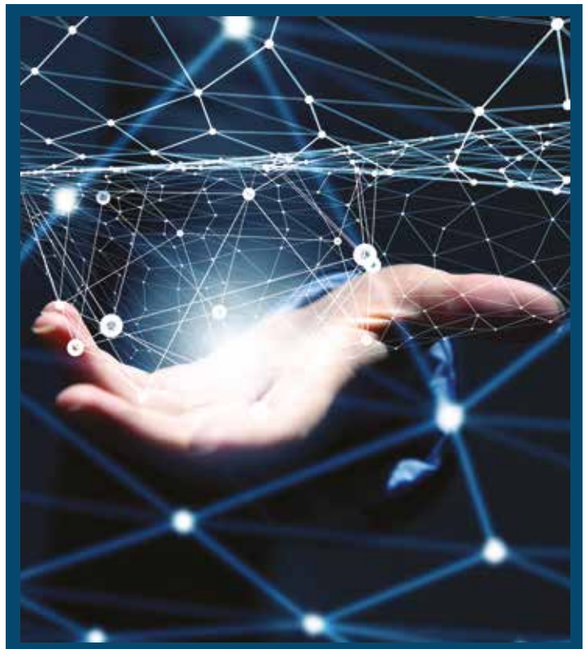
The oculoplastic surgeons are Doctors Ophthalmologists that made a specific surgical training for this discipline, they have a depth knowledge of the eyelids, of the eye and of all orbital structures.

In addition they also have neuro-ophthalmologic knowledge that allow to manage the diseases to the border between neurology and ophthalmology.

Surgery is concerned with abnormalities of the eyelids or of the surrounding tissues, like the position and profile anomalies (for example eyelid ptosis or descent of the eyelids), of the distiroidea pathology (Basedow), of the eyes that weep as in the occlusion of the lacrimal streets, of the removal of cysts and tumors and of the installation and/or management of ocular prostheses.



Dm_aa 1340865
Code 15001
Name ICP
Classification Z12120199
Class 1



Portable system useful for the measurement to detect

- Visible horizontal iris diameter (HVID) that can be used to choose the total initial diameter of the trial lens
- The average and maximum diameter of the pupil that will affect the choice of BOZD.
- The vertical eyelid opening width (VPA), in both cases to support the choice of TD and also as basic initial measurement.

In condition

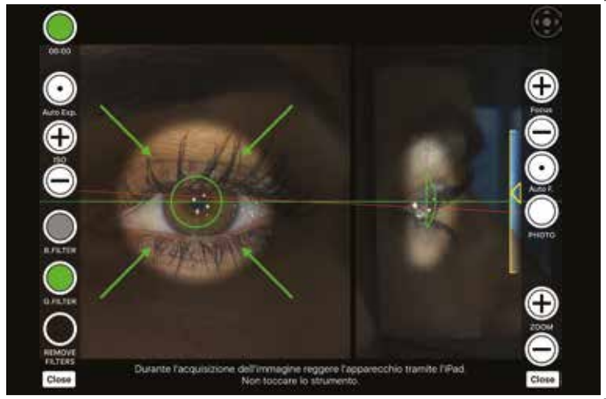
- Mesopic (4 lux)
- Photopic (50 lux)

Demonstration of the lens in the eye diameter of the wearer with the various light conditions.

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

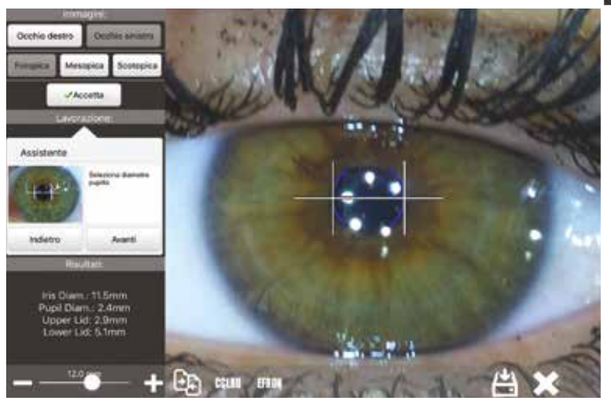
SIMULTANEOUS ACQUISITION FRONTAL-LATERAL

It allows the frontal visualization of the eye and simultaneously its profile.



IRIS DIAMETER

Valutazione del diametro pupillare direttamente sull'occhio del paziente.

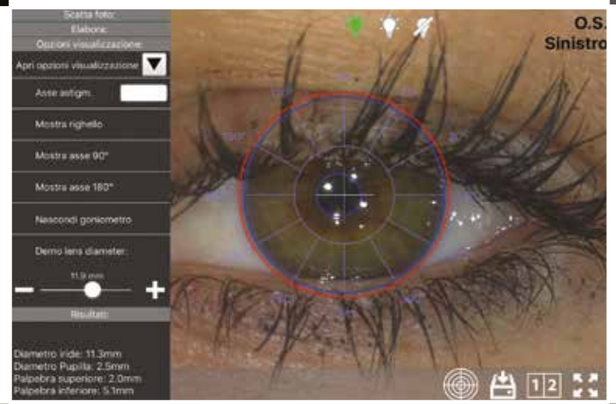


PUPIL DIAMETER

evaluation of the pupillary diameter directly on the patient's eye.

RESULTS

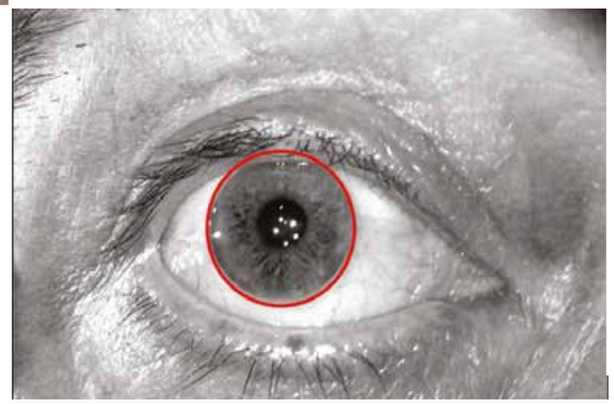
shows all the parameters obtained from the made evaluations on the patient's eye: iris diameter, pupil diameter, eye opening.



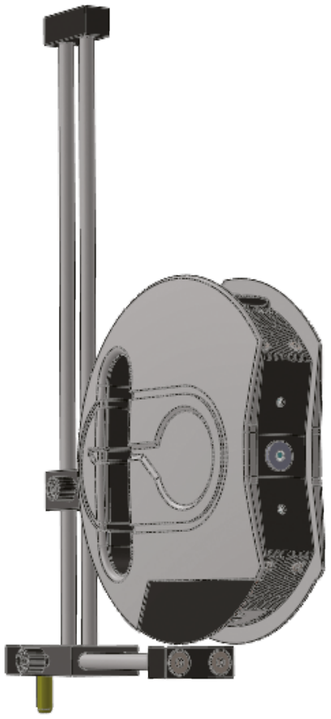
MEASUREMENT WITH TOOLS

WHITE TO WHITE MEASUREMENT

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



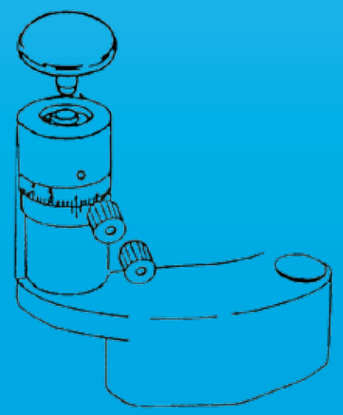
ACCESSORIES



Support

Is possible to use a valid support in case you use the instrument in your medical studies.

From today your support unit will be enriched by a new and effective aid to the visual screening.



holder for refraction unit, usable on any slit lamp graft the tool support the analysis of Meibomian glands, Tearscope etc

Big:
Dimension: 52x41x25 cm

Briefcase

Bags, resistant material to large stresses, have the particularity to be watertight with IP 67 impermeability and the perfect seal for liquids and dust, this is ensured by a rubber seal along the entire closure profile; is also present in all models a balancing valve of the internal and external pressure. Customizations are possible such as bespoke interior, screen prints or stickers.

Medium:
Dimension: 42,6x29x15,9 cm

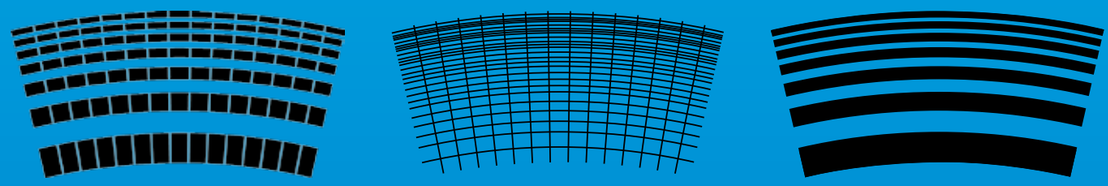
Small:
Dimension: 34x30x15 cm

Battery

Features

- Cells at polymers: more thin and more light
- FAST CHARGE: thanks to 1.5A charging output it loads at maximum speed even more powerful devices
- Ultra-light: it weighs only 72 grams
- Ultrathin: only 8 mm thick
- Input 5V DC 1000mA
- Micro USB charging cable included.

Tear scope films



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