ELECTRONIC HESS SCREEN

Mod. **10.15.11 / P**

PRODUCT SPECIFICATION

Product: SMART HESS DIGITEST   **Mod. 10.15.11**   **Cod: 10.15.11**   **ID 1690270**

Cod. CND Z1212012004

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1. Scope

This document describe the technical and functional characteristics of the System called "Smart Hess DigiTest".

Questo strumento è realizzato conformemente alla normative del Para 2. Ed è destinato ad essere utilizzato in ambiente ortottistico ambulatoriale per l'esame della motilità oculare e tutte le patologie connesse ad essa.

2. Documents and applicable Normative

1) directive 93/42/ECC del 14-06-93 plus amendment 2007/47/CE for medical device;
2) Legislative Decree n. 37 of 25 January 2010, "Implementation of the Directive 2007/47/CE concernment the medical dispositive ".
3) UNI CEI EN ISO 14971:2009-07 issue 2009-10—Application of risk management to medical devices; file 10036
4) CEI EN 60601-1 (2007-05) – Medical electrical equipment. Part 1-General requirements for safety;
5) CEI EN 60601-1-1 (2003-06) - Medical electrical equipment. Part 1: General requirements for safety .1. Collateral standard: Safety requirements for medical electrical systems;
6) CEI EN 60601-1-2 2010 + EC:2010 Gr.1 Cl.B - Medical electrical equipment. Part 1: General Requirements for Safety. 2 - Collateral standard: Electromagnetic compatibility - Requirements and tests
7) CEI EN 61000-3-2: 2015, CEI EN 61000-3-3: 2014 +/EC:2014, CEI 62304:2006, CEI 62366: 2007 CEI 62366-1:2015
8) UNI EN 1050 - Safety of machinery: Principles for risk assessment.
9) CEI EN 60601-1-4 - Medical electrical equipment. Part 1- General requirements for safety. 4. Collateral standard: Programmable electrical systems
10) CEI EN 60601-1-6 : 2010- electrical equipment Part 1- General requirements for basic safety and essential performance. Collateral standard: mobility.
11) CEI EN 60601-1-8 - electrical equipment Part 1- General safety regulations. Collateral standard: alarm systems - General requirements, tests and guidance for alarm systems used in equipment and medical electrical systems.
12) Risk Assessment Document

3. Patent

the tool is patented by the "*Italian Ministry of Economic Development* " with **N. 102015000058447**

4. Commercial references

National Classification of Medical Devices **Cod. CND Z1212012004**
Ministry of Health ID and MEPA: Smart Hess Dig. **Cod: 101511 ID 1690270**

5. Introduction

Hess DigiTest is a tool that gathers the main diagnostic tests in a single structure to evaluate the problems of strabismus, diplopia and / or ocular motility, in order to evaluate the therapeutic interventions following the pathology found.

These are the tests performed by the instrument:

Test Hess-Lancaster screen that allows to detect an anomaly of the alignment of the eyes (strabismus and / or forias), responsible for diplopia (splitting of the images). This examination allows you to identify which muscle or muscles are responsible for the disease.

Test of Diplopia field that detects the angle of diplopia in the entire visual field by highlighting and measuring the diplopia area both in monocular and binocular mode..

Campimeter is a diagnostic investigation that aims to assess the sensitivity of the retina by quantifying and detecting any absolute and relative functional losses and the integrity of the nerve pathways that originate from it.

Scotometry This Test differs from the Campimeter in that it measures the suppression scotoma in case of strabismus

Worth test used to evaluate a patient's flat fusion capacity, indicated when stereopsis is between 50 arc seconds, in patients with probable strabismus and in children of pediatric age.

**Schober test** for the simultaneous evaluation of vertical and horizontal ovens.

The instrument is aimed at those private or hospital ophthalmic surgeries that deal with the diagnosis of diplopia and strabismus

6. Intended use

Smart Hess DigiTest is an electro medical instrument for support to the orthoptist doctor, intended for a hospital outpatient clinic or doctor's office for ophthalmic diagnosis of diplopia and strabismus.

The instrument is designed to be used by the elderly or with mobility limitations forced on a standard wheelchair.

It is not suitable for patients with motor difficulties from the upper limbs, or mentally disturbed patients dependent, requiring, for a proper assessment procedures, of an effective interaction by the patient.
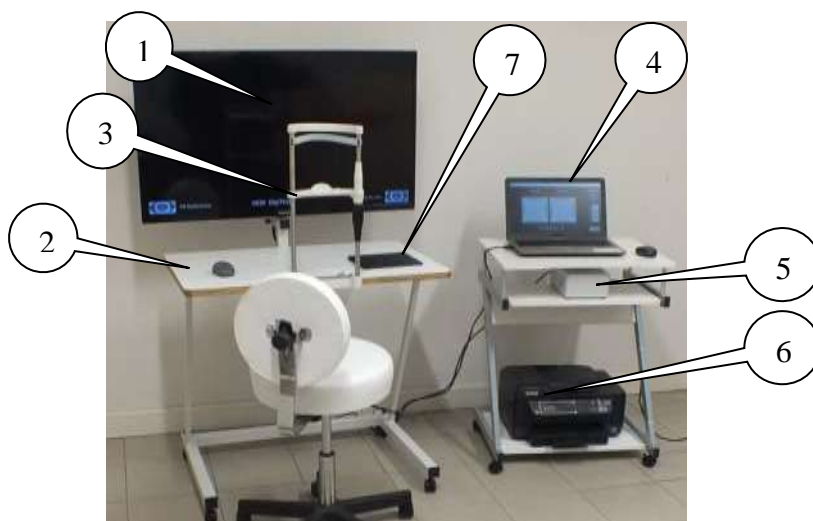
1- Screen HD 4K LED tecnology
2- Working plane for patient.
3- Chin located at 50 cm from the center panel.
4- Laptop computer with sw Hess DigiTest
5- Power Supply
6- Printer
7- Mouse

7. Functional Requirements

7.1 Test di Hess

Hess Test	N° 4 preset sequences
	N° 1 manual sequence
Visual field coverage angle	40° (±20°) both horizontally and vertical
positioning resolution	±1mm
Measurement Accuracy	±0,5°
Data	error in prismatic diopters
examination management	automatic archiving in pdf file
Print	Color printing of Hess Grid and data errors

7.2 Diplopia Field

Visual field coverage angle	40° horizontally, 30° vertically
Angular resolution	24 Sector of 15°
Type of bright sight	three dimension for Macular, Foveal or peripheral in white or red/green color for use with anaglyphic glasses.
positioning resolution	±1mm
Measurement Accuracy	±0,5°
Data	error in prismatic degrees
examination management	automatic archiving in pdf file
Print	Color printing of diplopia field and data errors

1.1 Campimeter

Visual field coverage angle	40° horizontally, 30° vertically
Angular resolution	24 Sector of 15°
Type Peripheral Aim	Black color, sizes 4 and 12mm2 and variable contrast from 25% to 100%
Type of Fixation Aim	Black, Green or Orange color with fixed or variable symbol
positioning resolution	±1mm
Measurement Accuracy	±0,5°
Data	"Blind area" in angular degrees or Prismatic Diopters
examination management	automatic archiving in pdf file
Print	Color printing of Visual field with data table

7.4 Scotometry

Visual field coverage angle	40° horizontally, 30° vertically
Angular resolution	24 Sector of 15°
Type Peripheral Aim	Circular Red / Green color with dimensions 4 e 12mm^2
Type of Fixation Aim	Red / Green color of fixed or variable shape with dim. 5 or 10mm.
positioning resolution	±1mm
Measurement Accuracy	±0,5°
Data	"Scotoma area" in angular degrees or Prismatic Diopters
examination management	automatic archiving in pdf file
Print	scotoma area print with data table

7.5 Worth Test

Distance of execution	50cm
Type of bright sight	circular 5 or 10mm
Data	detection of Exophoria, Exoforia and/or suppression.
examination management	automatic archiving in pdf file
Print	report with doctor's diagnosis

7.6 Schober Test

Distance of execution	50cm
Type of bright sight	circular with red cross
Data	detection of horizontal and vertical forias.
examination management	automatic archiving in pdf file
Print	report with doctor's diagnosis

8. Electrical Requirements

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Power Supply :	115/230Vac
Frequency:	50÷60Hz
Absorbed power	<500VA
Input isolation transformer	IEC/EN60601-1
Device with insulation Class ||	

9. Environmental requirements

The instrument has been developed and designed for use in both private and hospital outpatient setting.

Operative Temperature:	10°C ÷ +35°C (50°F ÷ 95°F)
Storage	-0°C ÷ +60°C (32°F ÷ 140°F)
Relative humidity:	0% up to 90%, non-condensing

10. Physical Requirements

Dimension max: 150 x 150 x 65 cm
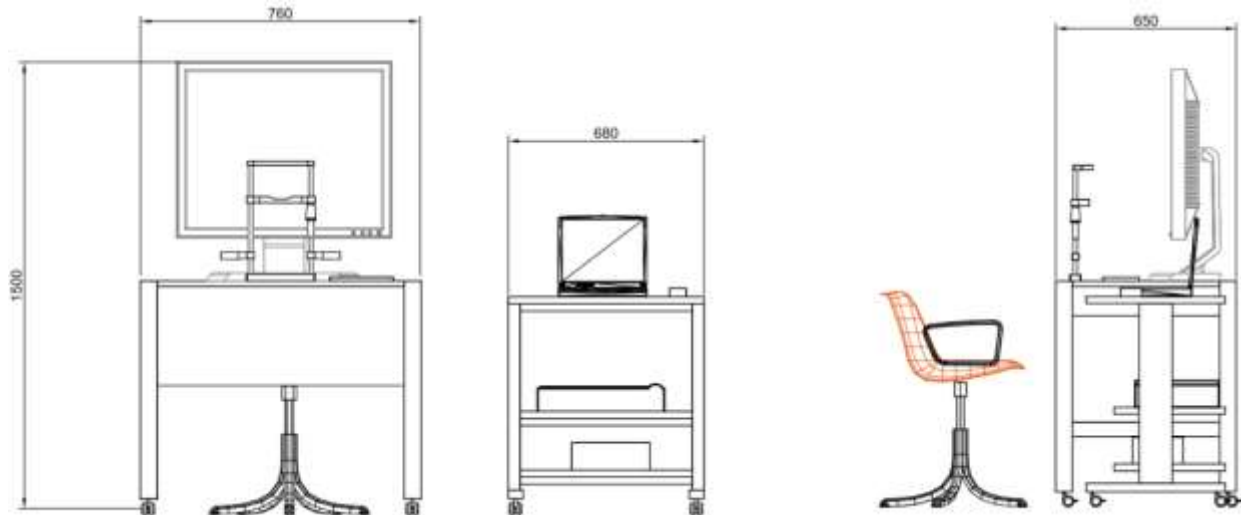
The instrument is classified as "portable," it meaning the ability to move from one room to another easily and without having to perform the setting-up procedures which may require the intervention of a skilled operator.

The instrument is allowed to transit in a doorway about the size of 2,00mt high and 1m wide.

The total weight of the instrument is light in order to be transported easily by medical personnel in safety.

The instrument is equipped with wheels for easy transport and / or handling lockable.

The design of the structure is installed according to ergonomic criteria and stability so as to provide safety and comfort to the patient during the examination.

There are no parts with shaping edge such as to generate risk of wounds or bruises on the part of users.

It is also prepared to accept patients with disability those needing a wheelchair for ambulation.
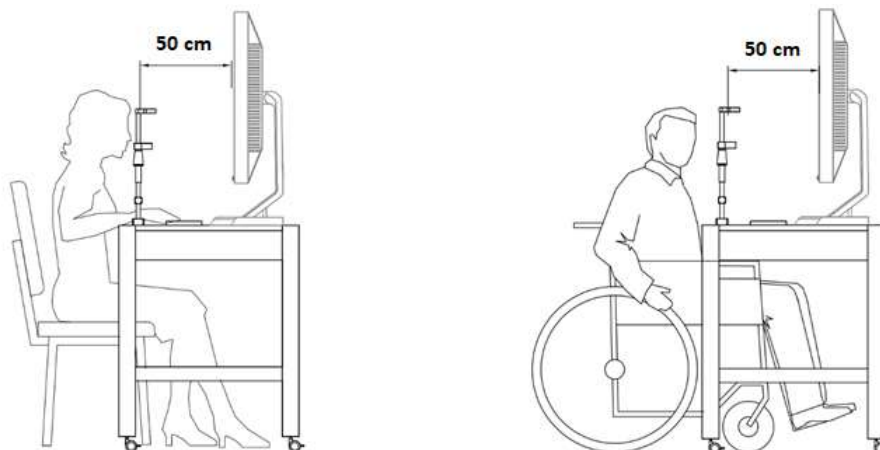
11. Functional Description

The instrument is composed of a Laptop type computer that controls a high resolution LED monitor via HDMI where the tests are projected. It is associated with a or Mouse for the patient's interaction of the light aims and the execution of the Test.

In addition, the DigiTest Smart Hess System is equipped with a printer, all powered by an isolation transformer compliant with the IEC / EN60601-1 standard for electro medical applications.

The operations that the tool performs to perform its function are summarized in two main phases:

- ✓ conduct examination according to the principle Hess
- ✓ patient data management
- ✓ Test Printout

11.1. Patient interface

The patient takes a seated position on the adjustable stool in front of the instrument, the doctor will position the patient by making him rest on the chin guard and adjust the height of the stool so that the patient is in a comfortable position so that he can perform the test in a relaxed way and without postural stress .

The patient will be made to wear special red / green lenses (anaglyphic glasses) and will be explained the test procedure and described the use of the pointing device (r mouse) with which he will have to interact.

The light targets related to the various Tests will be projected on the screen and the patient will have to interact with them according to the modalities of the Test used.

The system stores all the points and at the end creates the measurement report representing the reading chart of the exam or the doctor's comments or diagnosis, which can be printed or managed as a common * .pdf file.

11.2. Doctor interface

The operating SW for each type of test, creates a control panel on the computer screen where the doctor can command and manage the examination course.

The first operation of the doctor is to open the patient's card by looking for it in the "Patients" archive or generate a new card in case the patient is on the first examination.

11.3. Patient data management and printing

The tool creates an archive that allows the management of patients and their examinations over time. The Data Base is organized as follows:

A named "Folder" is created for each patient, named with: Surname, Name, Date of Birth. Within each "Patient Folder" all the tests performed by that specific patient are saved, in the case of multiple tests of the same type on the same day, a progressive number is added to the exam.

Exam reports are saved in pdf format for easy management and export.

The print format is in color, on A4 paper size.

At the top there is a "header" field of adequate proportions (max 2 ÷ 3 cm including page border) for the insertion of a Company logo and / or name of the doctor's office or hospital that holds the measuring instrument, this field is editable and customizable with the standard Windows tool.

12. Description of exams

The instrument allow to execute the following examination:

- **Test of Hess-Lancaster**
- **Diplopia Field**
- **Campimeter**
- **Scotometry**
- **Worth Test**
- **Schober Test**

12.1. Main Panel

When starting the application, the following panel is displayed where you can access to the Patient archive where you can create the new patient or load an existing one, as well as view and / or print previous exams.

Using the "icons" you select the exam to be performed, in the example there are some icons related to the exams for diplopia ad strabismus, but other optional exams may be added.
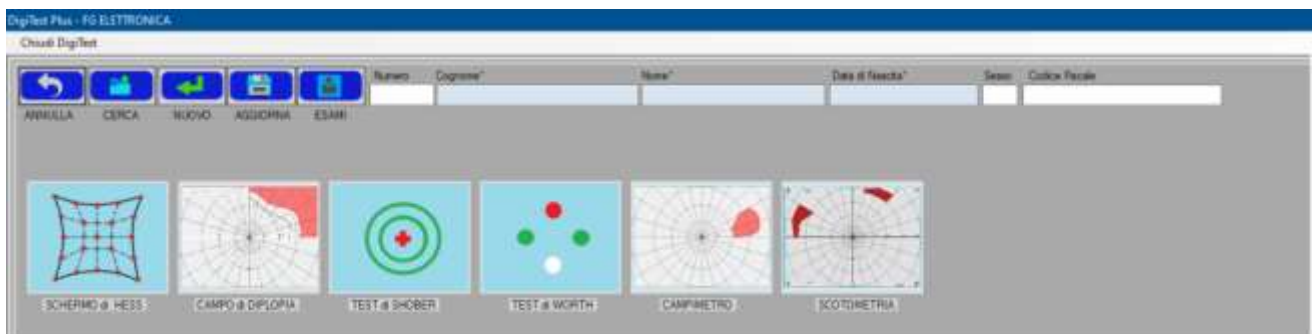
12.2. Test of Hess-Lancaster

The **Hess-Lancaster screen** is a test that is used to detect abnormalities of ocular motility. It is indicated for the verification and control of eye paresis in the various vascular, neurological, endocrinological, metabolic, tumor, traumatic, orbital pathologies, etc. Thanks to this examination, the doctor determines the origin of a paralysis of the eyeballs, diplopia or strabismus.

To perform the Hess-Lancaster examination, the patient wears anaglyphic glasses with red/green lenses to facilitate dissociation and is seated in front of a squared screen on which the doctor projects the red light of a torch, while the patient uses another green light. The test requires the patient to superimpose the green light of his flashlight on the red light projected by the doctor on the squared screen.

At the end of the examination, by bringing together the points "seen" by the patient, a more or less regular square will be obtained from which the doctor will extrapolate his diagnosis and consequently the therapy to be followed for the correction of diplopia / strabismus.

The "DigiTest" tool automates this procedure by means of a special control SW, which allows you to optimize the examination by eliminating human errors due to the manual dexterity of the old measurement method, in addition the data are acquired and digitized and then managed electronically for a more effective and safe exam management.

The "Hess Screen" application has a "user" interface for the doctor that allows you to manage patient data, select the sequence of points to be projected and manage the examination as it proceeds. (*see operating manual*)
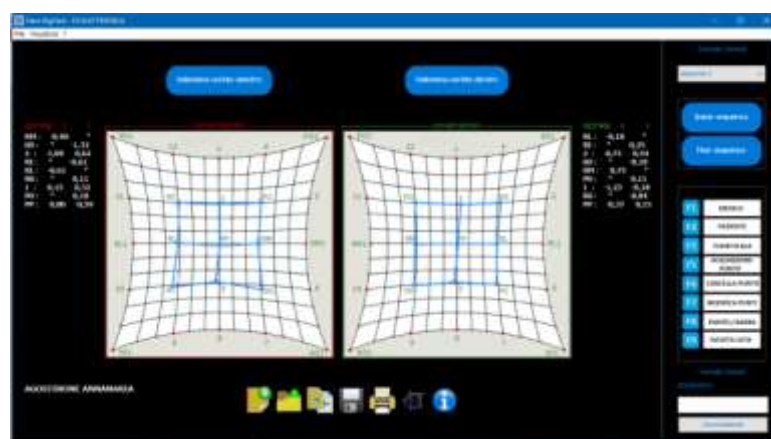

Doctor interface

The Hess Screen application provides an examination report where the points detected by the patient are represented with a table showing the deviation in Prismatic Diopters and in angular degrees, with respect to the projected target.
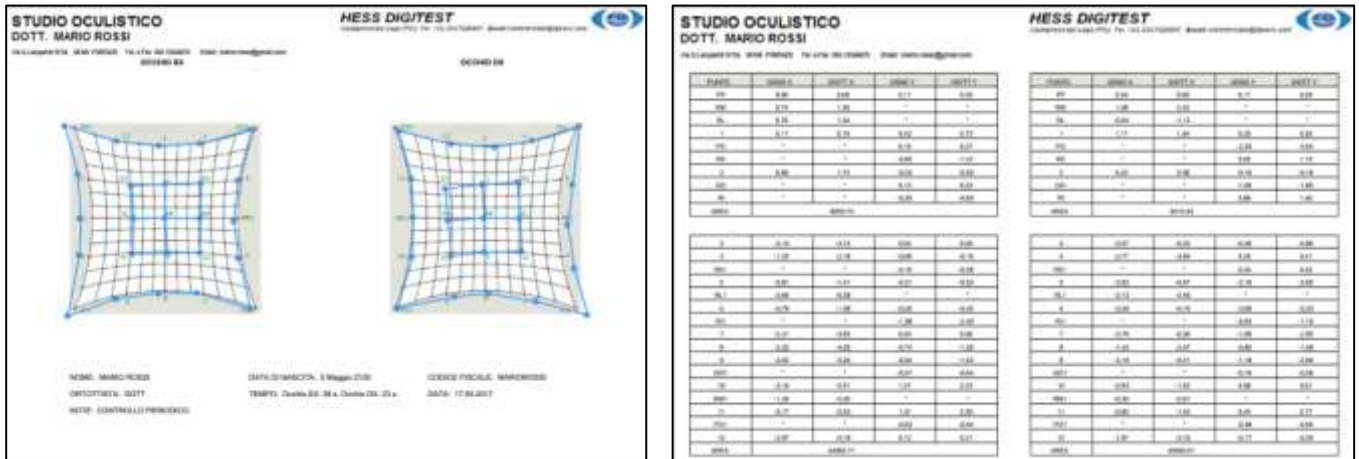
Example of an exam report

The application has a "Comparison" function between an exam and a previous one in order to evaluate the progress of a pathology or the course of a therapy.
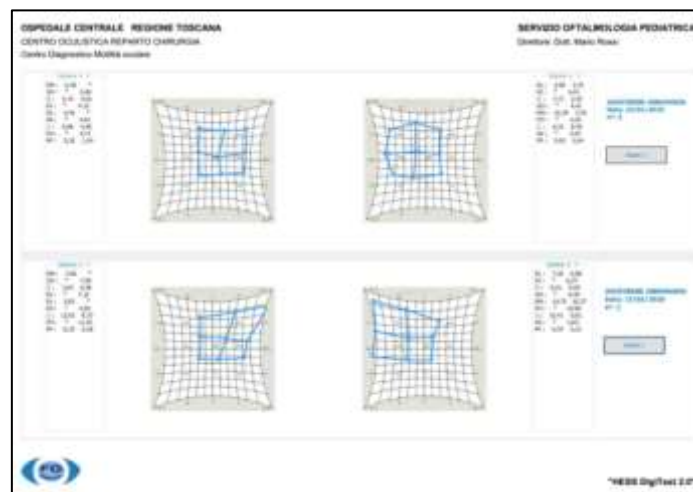
Comparison between two exams

12.3. Diplopia Field

This is a quick exam that allows you to check the problems of diplopia, or doubling of the image seen, of the patient in the entire field of view, in binocular mode.

at the end of the exam, the instrument creates a map divided into sectors of 15 ° where the diplopia area highlighted in red and the recovery area indicated in green are represented.

The examination is performed at a distance of 50 cm from the screen, positioning the patient on the chin guard aligned on the center of the screen and, keeping the head in a fixed position, the patient will have to follow with his eyes a bright target that is slid from the center towards the external from the patient himself, using the mouse wheel, when the patient sees the double target, he will have to "click" on the left button of the mouse to memorize the point of the split.

At this point, always turning the mouse wheel, it will go back with the target towards the center until the target remains split and, when the target returns to be a single point, "click" again on the left button of the mouse to store the recovery point.

The program will advance autonomously to the next sector up to the completion of the entire visual field.

The "Diplopia Field" application has a "user" interface for the doctor that allows you to manage the exam. (see operating manual).
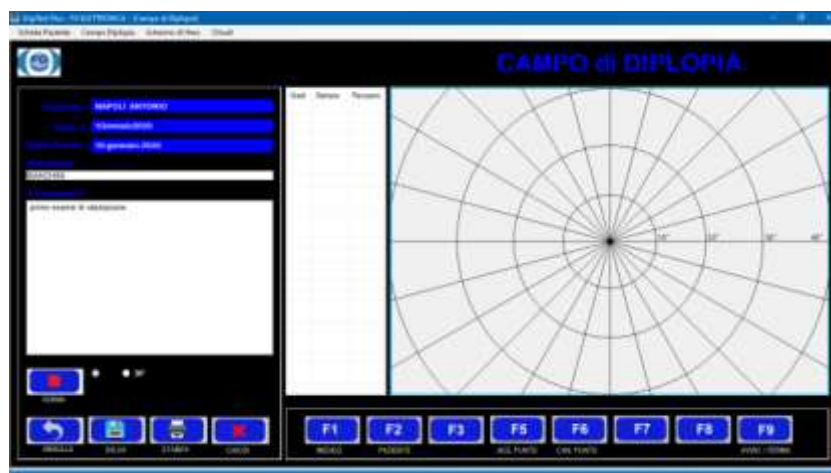
graphical interface to the doctor

The Diplopia Field application provides an examination report where the area or areas of diplopia is represented by measuring for each sector of 15 or 30 °, the angle at which the splitting begins (diplopia) and the recovery angle expressed in angular degrees.

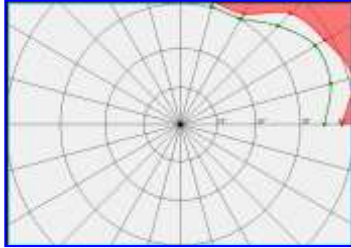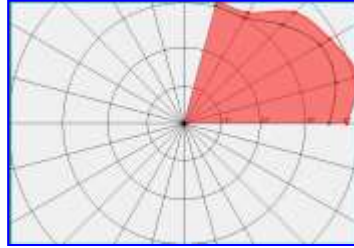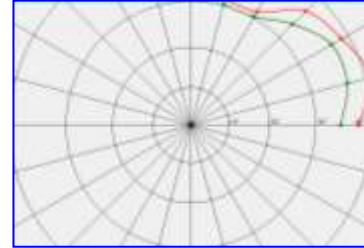*External Diplopia*

Internal diplopia

No filling

The examination report is created on a single page which contains the patient's personal data, the date of the examination and the graphic representation of the patient's diplopia field with the associated diplopia angles table.

The report is in standard .pdf format which can be read and printed on any device.

11.1. Campimeter

The Campimeter is a diagnostic investigation that aims to assess the sensitivity of the retina by quantifying and detecting any absolute and relative functional losses and the integrity of the nerve pathways that originate from it.

This application, supporting the diplopia investigation, analyzes the visual field within ± 50 °, the instrument at the end of the examination, creates a map divided into sectors of 15 ° where the "scotomatous area" is shown highlighted in red.

The examination is performed in Binocular or Monocular mode, at a distance of 50 cm from the screen, positioning the patient on the chin guard with the head in a fixed position, the patient must keep his gaze on a central luminous target in the screen, consisting of a symbol which can vary in shape and color randomly in order to draw the patient's attention, and using peripheral vision he will have to observe (without moving his gaze from the central target) a bright spot, called peripheral aim, that he or the doctor himself , it will move from the far end of the screen to the center. The peripheral aim of a fixed size of 4mm2 or 12mm2 and can vary in contrast from 100% to 25% (the greater the contrast of the aim, the greater the activation of the affected retinal area and therefore and therefore will make the test easily visible, while a low contrast aim will help to highlight the scotomatous area.

When the patient sees the Mira disappear (scotoma area) he will have to memorize the point with a click of the mouse, then continue with the movement of the luminous point until he sees it reappear, at which point he will memorize the point again with a click of the mouse.

The program will advance autonomously to the next sector up to the completion of the entire visual field.

In the Monocular mode, the inter-pupillary distance is considered in the position of the central aim in order to obtain a correct perpendicularity of the visual axis with respect to the screen.

The "Campimeter" application has a "user" interface for the doctor that allows you to manage the exam. (see operating manual)
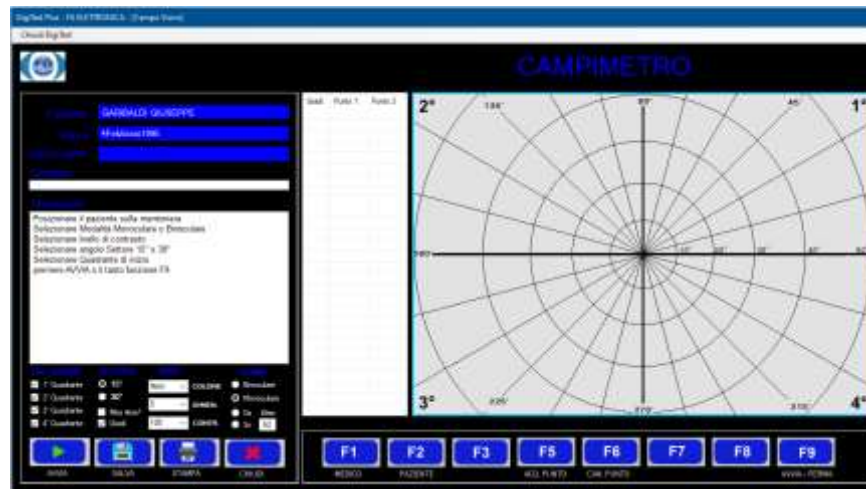
The Campimeter application provides an examination report where the "blind" area or areas are represented by measuring the start and end angle expressed in angular degrees for each sector of 15 or 30 °

The examination report is created on a single page which contains the patient's personal data, the date of the examination and the graphic representation of the patient's diplopia field with the associated diplopia angles table.

The report is in standard .pdf format which can be read and printed on any device.

12.5. Binocular scotometry

This application, which supports the Hess screen, analyzes the visual field within ± 50 °, the instrument at the end of the examination, creates a map divided into sectors of 15 ° where the "scotomatous area" is highlighted in red

The Scotometry Test differs from the Campimeter in that it measures the suppression scotoma in case of strabismus.

Suppression is a regional phenomenon in that it affects only a portion of the eye's visual field, in fact, the entire field of vision of the deviated eye is not suppressed. The amplitude and location of the scotomes are influenced by the direction, amplitude, variability and intermittence of the deviation.

This examination is useful in anticipation of surgery or prismatic correction.

The examination is performed in Binocular mode, at a distance of 50 cm from the screen, positioning the patient on the chin guard with the head in a fixed position (as for the Campimeter), then the patient wears the Red / Green anaglyphic glasses. The Scotometry application projects a central fixation target of red color (initially) that can vary in shape randomly in order to attract the patient's attention, and using peripheral vision he will have to observe (without moving the gaze from the central target) a green peripheral sight with a fixed size of 4mm2.

When the patient sees the Green Mire disappear (scotoma area) he will have to memorize the point with a click of the mouse, then continue with the movement of the luminous point until he sees it reappear, at which point he will memorize the point again with a click of the mouse . The program will advance autonomously to the next sector up to the completion of the entire visual field.

At the end the color of the central Fixation Target is inverted with the Peripheral one and the filter of the Red / Green anaglyphic glasses is inverted and the Test repeated.

The "Scotometry" application has a "user" interface for the doctor that allows you to manage the exam in all its functions. (see operating manual)
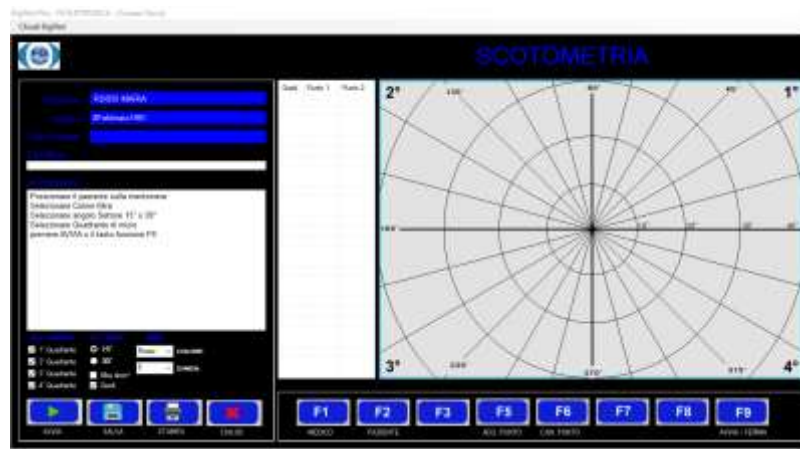
The Scotometry application provides an examination report where the area or areas of scotoma is represented by measuring, for each sector of 15 or 30 °, the start and end angle expressed in angular degrees or prismatic diopters.

The examination report is created on a single page that contains the patient's personal data, the date of the examination and the graphic representation of the patient's scotometry areas with the associated table of start and end angles.

The report is in standard .pdf format which can be read and printed on any device

12.6. Worth Test

The Worth test is used to evaluate the fusion capacity, and consists of the projection of four colored discs on a black background placed crosswise: one red at the top, two green horizontally, and one white at the bottom. The eyes of the examined subject are covered by anaglyphic filters. In this way, the condition is created in which each eye sees the discs of the color of its filter and in addition the white disc. The situation is of partial fusional dissociation, as the simultaneous vision of the white disk keeps the stimulus to melt.

The examination is performed at a distance of 50 cm from the screen, positioning the patient on the chin guard with the head in a fixed position, the patient using the anaglyphic glasses, will have to observe the bright sights and report to the doctor his chromatic perception of the sights according to the which the application determines the type of foria and the doctor performs the diagnosis.

The "Campimeter" application has a "user" interface for the doctor that allows you to manage the exam. (see operating manual)

The examination report is created on a single page which contains the patient's personal data, the date of execution and the description of the diagnosis.

The report is in standard .pdf format which can be read and printed on any device.

12.7. Schober Test

The Schober test is used to simultaneously evaluate both horizontal and vertical holes. Two colored filters (anaglyphic glasses) are used, one red and the other green.

The examination is performed at a distance of 50 cm from the screen, on which a green circle and a red cross will be projected, the patient is positioned on the chin guard and using the low ambient light anaglyphic glasses to facilitate dissociation. patient will have to move the cross with the mouse, positioning it in the center of the circles.

The position taken by the cross with respect to the circle will allow the application to establish the type of foria present.

The "Campimeter" application has a "user" interface for the doctor that allows you to manage the exam. (see operating manual)

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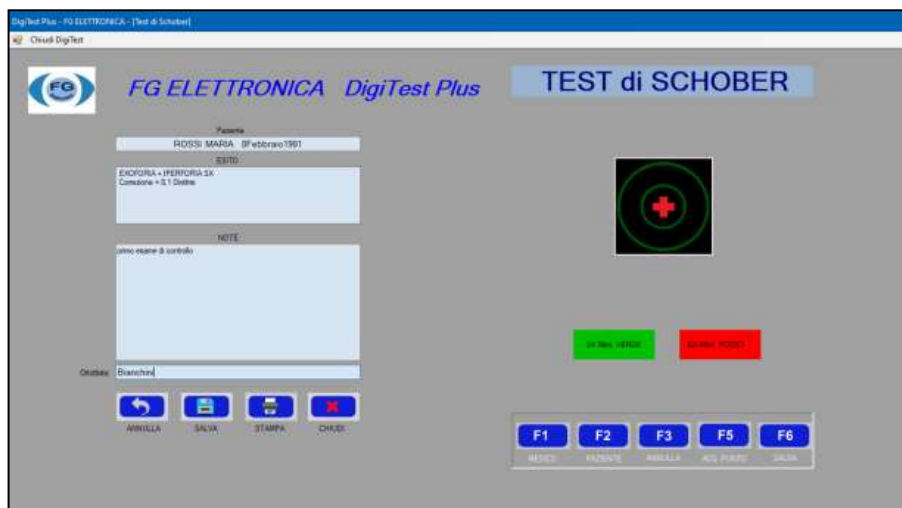
The examination report is created on a single page which contains the patient's personal data, the date of execution and the description of the diagnosis.

The report is in standard .pdf format which can be read and printed on any device.

13. Publications and awards

Below are some publications and reports from hospitals and / or private medical practices that have experimented and used the Hess DigiTest tool with positive results.

1. Hess DigiTest was also presented by the "*Sacro Cuore" - Negrar - VR - Italy Hospital* at the "***ARVO 2017 Annual meeting***" held in Baltimore (USA), where it achieved great success interest as a new computerized alternative tool to the classic Hess Lancaster exam.

2. The Hess DigiTest screen has been studied and evaluated by the University of Ferrara, comparing it with the classic manual examination, checking the differences in terms of performance, ease of use and reliability of the measured data .

   The results of this analysis are reported in the thesis "*Low tech versus high tech: the Hess-Lancaster Screen*" presented for the 2015/2016 academic year by Dr. Gaia Giacomello.

   The full text of the thesis is available online at the institutional sites of the University of Ferrara.

3. Dr. Giovanni Battista Marcon Registered in the Order of Surgeons and Dentists of the province of Vicenza and owner of the homonymous medical practice, specialized in strabismus surgery, he has successfully experimented and contributed to the development of the instrument.