



# SMART HESS DIGITEST

Mod. 10.15.10

Rev. : A

Data : 01-09-2015

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## ELECTRONIC HESS SCREEN

Mod. 10.15.01

## PRODUCT SPECIFICATION



**Prodotto:** HESS DIGITEST Cod. 10.15.01 ID:1393676/R Cod. CND Z1212012004

**Company:** FG Elettronica

**Administration:** Studio Cocci Jonathan

Via Cesare Battisti N°53

50051 Castelfiorentino (FI) Italy

Tel: +39.05711721512

**Production :** Via Pistelli N°7

50051 Castelfiorentino (FI) Italy

Tel: +39.334.7520607 (Commercial)

Tel: +39.335.8044154 (technical)

Email: [commerciale@fgesnc.com](mailto:commerciale@fgesnc.com)

Web: [www.fgesnc.com](http://www.fgesnc.com)





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### 1. Scope

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

This instrument is manufactured in compliance with Para 2 regulations. It is intended for use in an orthopedic outpatient setting for examining ocular motility and all pathologies associated with it.

### 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 instrument 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: **Hess Dig. Cod: 10.15.01 ID 1393676/R**

#### 5. Introduction

The Hess DigiTest Code 10.15.01 replaces the previous model 10.15.00, in order to reduce the general dimensions of the instrument in order to make it more manageable and versatile, without however degrading in any way the performance in terms of angle of vision in order to guarantee the same 50 ° of ocular stimulation.

In addition to having a more versatile structure, Hess DigiTest 10.15.01 collects 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.

The tool is available in two versions:

*Basic Model:* Allows to perform Hess-Lancaster and Diplopia Field tests

*Plus Mode I:* Adds to the previous exams, the Campimeter Test, Binocular Scotometry, Worth Test and Schober Test.

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.

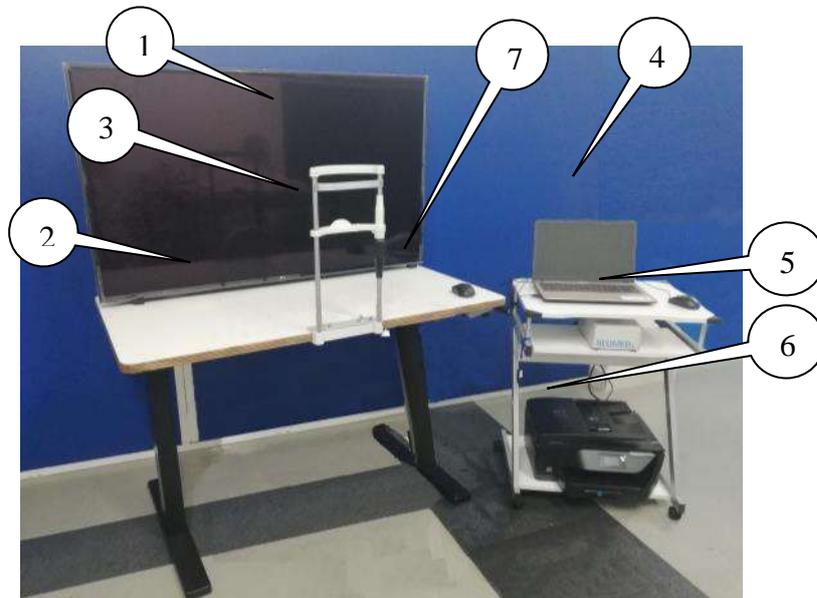
The instrument is aimed at those private or hospital ophthalmic surgeries that deal with the diagnosis of diplopia and strabismus.

## 6. Intended use

**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: It consists of a 55 "high resolution LED screen that replaced the projector of the previous system, faithfully respecting the dimensions of the projected image in order to guarantee the same 50 ° of eye stimulation.
- 2- Height-adjustable table with support surface for the digital positioning device, like mouse or h-padh-pad operated by the patient.
- 3- Chin guard placed 50 cm from the center of the panel.
- 4- Laptop computer with Hess DigiTest sw
- 5- Power supply unit with electro medical isolation transformer
- 6- Printing device
- 7- Mouse



## 7. Functional Requirements

### 7.1 Hess Test

Hess Test	N° 4 preset sequences N° 1 manual sequence
Type of bright sight	Point or Line
Visual field coverage angle	50° ( ±25°) both horizontally and vertical
positioning resolution	±1mm
Measurement Accuracy	±0,5°
Data	error in prismatic diopters or angular degrees
examination management	automatic archiving in pdf file
Print	Color printing of Hess Grid with data table

### 7.2 Diplopia Field

Visual field coverage angle	50° horizontally, 40° 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 output	error in prismatic degrees or angular degrees
examination management	automatic archiving in pdf file
Print	Diplopia field print area with data table

### 7.3 Campimeter

Visual field coverage angle	50° horizontally, 40° vertically
Angular resolution	24 Sector of 15°
Type Peripheral Aim	Black color, sizes 4 and 12mm <sup>2</sup> 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	50° horizontally, 40° vertically
Angular resolution	24 Sector of 15°
Type Peripheral Aim	Circular Red / Green color with dimensions 4 e 12mm <sup>2</sup>
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

Power Supply :	115/230Vac
Frequency:	50÷60Hz
Absorbed power	<300VA
Input isolation transformer	IEC/EN60601-1

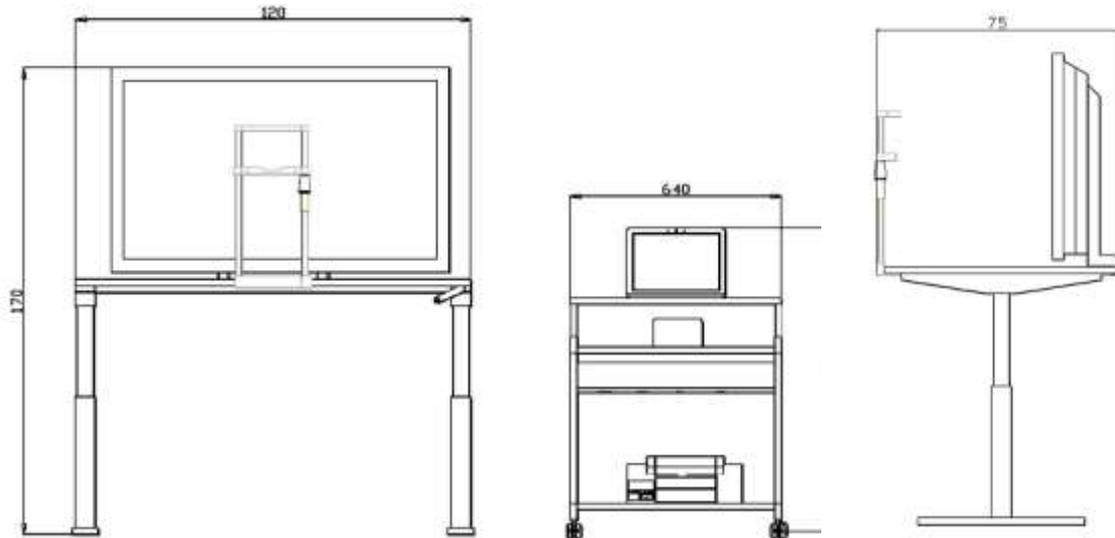
## 9. Environmental requirements

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

Dimensioni max: 120 x 170 x 75 cm



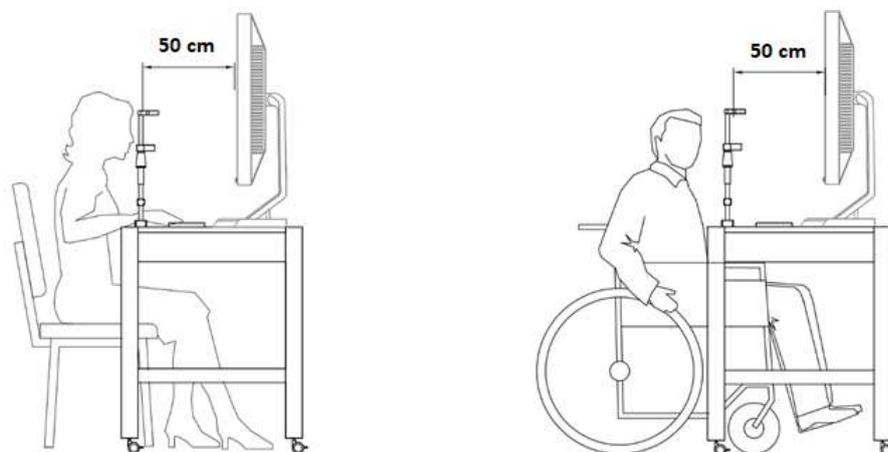
The instrument consists of a main table that supports the screen and the chin guard plus a second instrumentation table (computer, printer and isolation transformer).

The table is adjustable in height by means of a simple knob, which allows you to move the top from 72cm to 120cm from the ground, in order to adapt to any patient or seat height.

Although it is not equipped with wheels, it can be easily moved from one room to another without having to perform alignment procedures that require the intervention of a specialized operator.

The structure is made taking into account the ergonomic and safety requirements for the operator and the patient, the design has been created taking care to eliminate angular parts and with such shapes as to generate the risk of injuries or bruises by users.

it is also designed to accept patients with disabilities such as those who need a wheelchair for walking.





## 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 Keyboard or Mouse for the patient's interaction of the light aims and the execution of the Test.

In addition, the DigiTest 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 ( 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 management and print

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

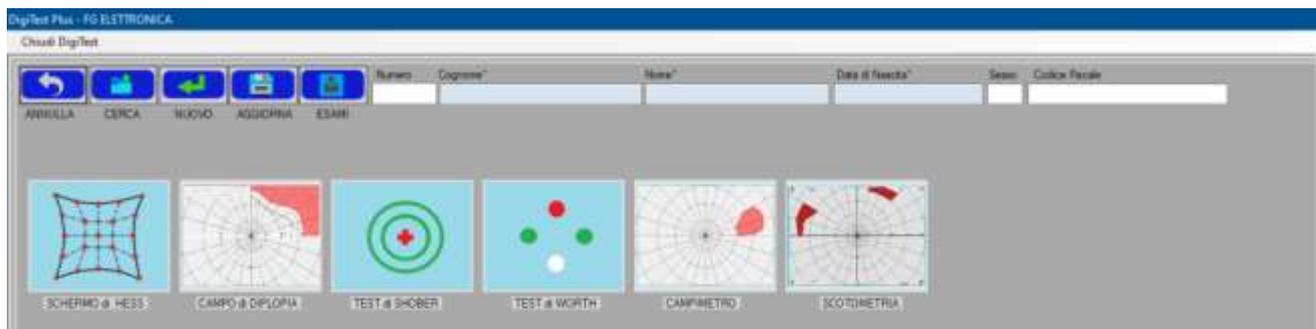
The instrument allow to execute the following examination:

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

### 12.1. Main Panel

Tutto l'avvio dell'applicativo è presente il pannello di seguito riportato dove si accede a tutto l'archivio Pazienti dal quale si crea il nuovo paziente o si carica uno esistente, oltre che segnalato e / o monitorato i precedenti.

Tramite le "icone" si seleziona lo stesso da eseguire, nell'esempio sono riportate alcune icone relative agli esami per la diplopia, ma possono essere aggiunti altri esami opzionali.



### 12.2. Test of Hess-Lancaster

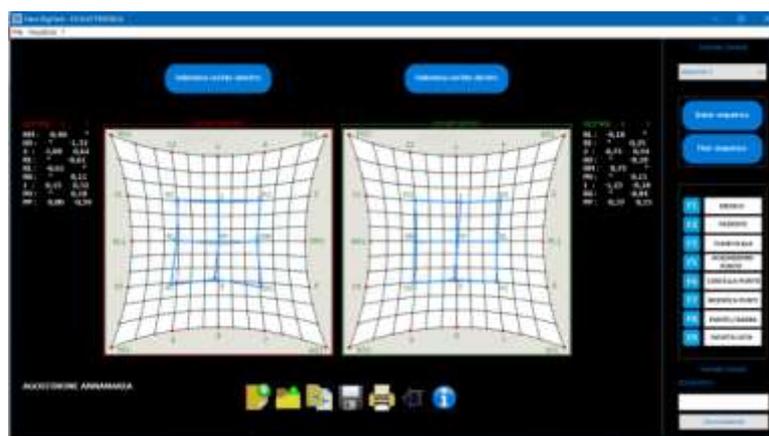
The **Hess-Lancaster screen** is a test that is used to detect abnormalities of ocular motility. It is indicated for the verification and control of eye paresis in the various vascular, neurological, endocrinological, metabolic, tumor, traumatic, orbital pathologies, etc. Thanks to this examination,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



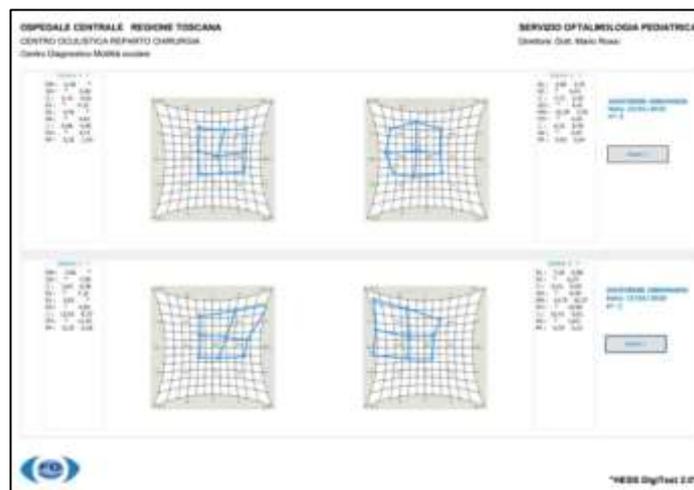
Doctor interface

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.

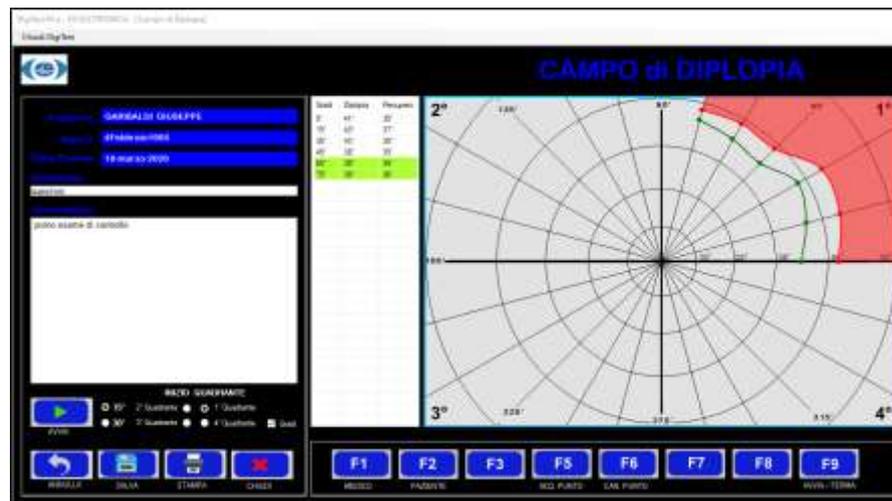
at the end of the exam, the instrument creates a map divided into sectors of 15 ° where the diplopia area highlighted in red and the recovery area indicated in green are represented.

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 are 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.



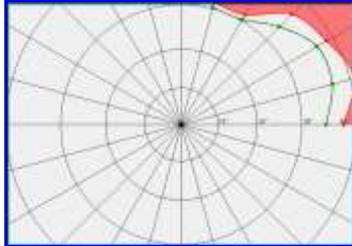
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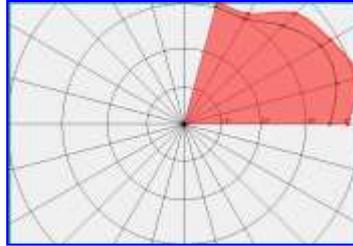
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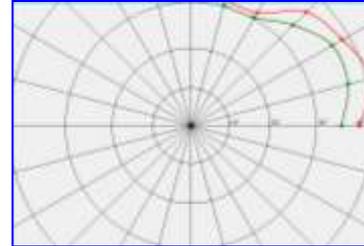
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External Diplopia



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.

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CENTRO DI OCULISTICA REPARTO CHIRURGIA  
AMBULATORIO DI ORTOTTICA  
Via Giuseppe Garibaldi N° 1000

SSIT Servizio Sanitario della Toscana

Medico	Dott. BIANCHINI	Data esame	19-febbraio-2020
PAZIENTE	GARBALDI GIUSEPPE	M	Data di Nascita 2 gennaio 2020
ID	00 63	CF : GIUSEPPEGARBALDI	

ESAME : CAMPO DI DIPLORIA  
Esito : primo esame di controllo

Gradi	Diplopia	Angolo
0	41°	33°
15	43°	33°
30	43°	38°
45	38°	35°
60	38°	35°
75	38°	38°
90		
105		
120		
135		
150		
165		
180		
195		
210		
225		
240		
255		
270		
285		
300		
315		
330		
345		
360		

FG Elettronica - Via C. Galvani 53, Castelbrenno (FI), Tel. 057172512P.L. 0611110484  
Email: commerciale@fganc.com



### **12.4. 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  $\pm 50^\circ$ , the instrument at the end of the examination, creates a map divided into sectors of  $15^\circ$  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 4mm<sup>2</sup> or 12mm<sup>2</sup> 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)



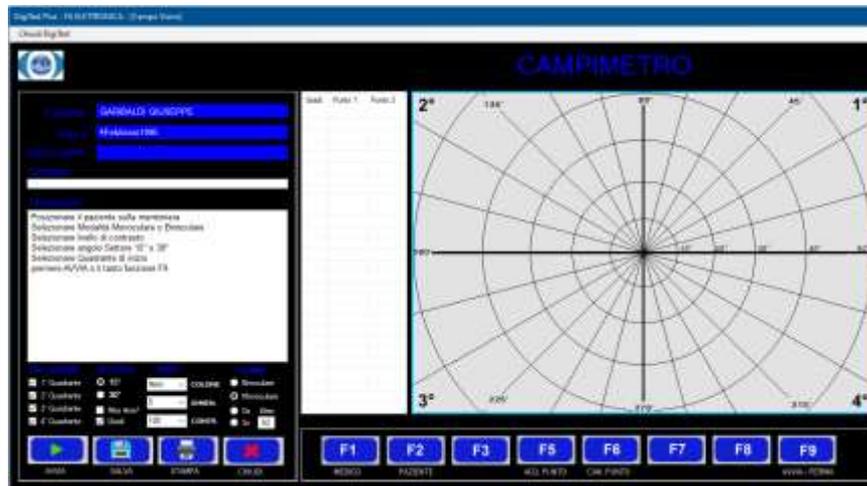
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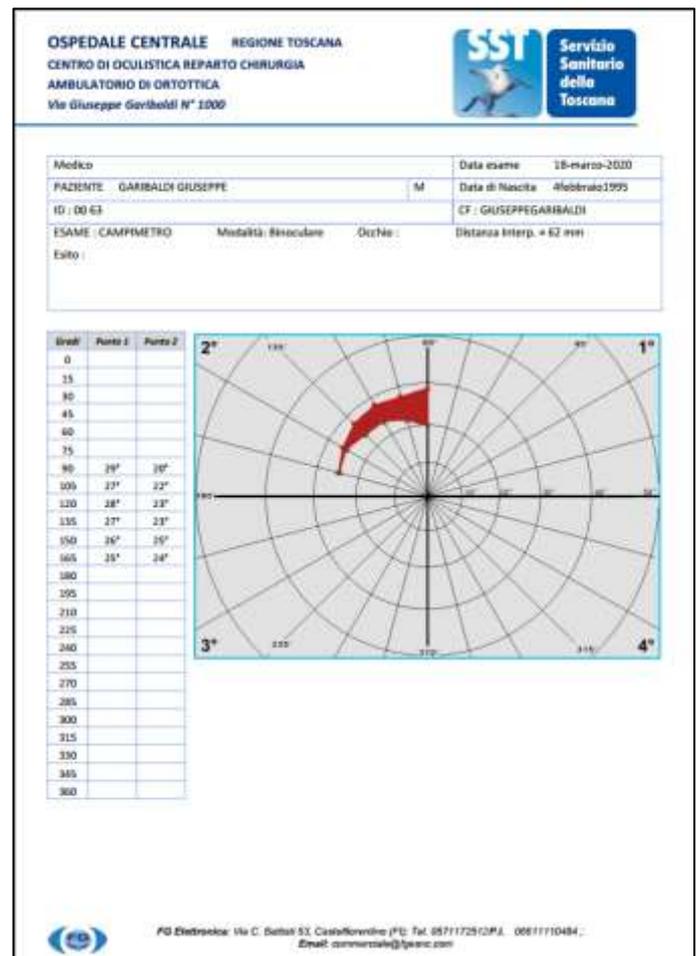
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The Campimeter application provides an examination report where the "blind" area or areas are represented by measuring the start and end angle expressed in angular degrees for each sector of 15 or 30 °

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  $\pm 50^\circ$ , the instrument at the end of the examination, creates a map divided into sectors of  $15^\circ$  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 4mm<sup>2</sup>.

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)



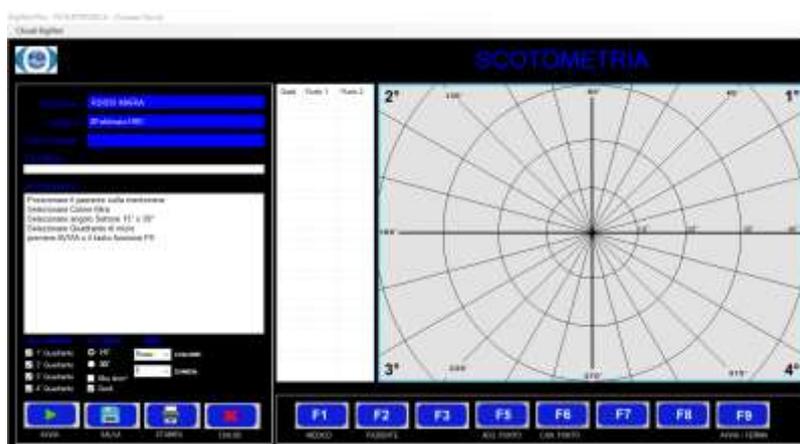
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The Scotometry application provides an examination report where the area or areas of scotoma is represented by measuring, for each sector of 15 or 30 °, the start and end angle expressed in angular degrees or prismatic diopters.

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

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CENTRO DI OCULISTICA REPARTO CHIRURGIA  
AMBULATORIO DI ORTOPTICA  
Via Giuseppe Garibaldi N° 1000

SSIT Servizio Sanitario della Toscana

Medico	Data esame		18-marzo-2000	
PAZIENTE	GARIBALDI GIUSEPPE	M	Data di nascita	4 febbraio 1995
ID : 00 63			CF : GIUSEPPEGARIBALDI	
ESAME : SCOTOMETRIA	Modaltà: Binoculare			
Esito :				

Grad	Punto 1	Punto 2
0	45°	36°
15	43°	33°
30	42°	34°
45	39°	34°
60		
75		
90		
105		
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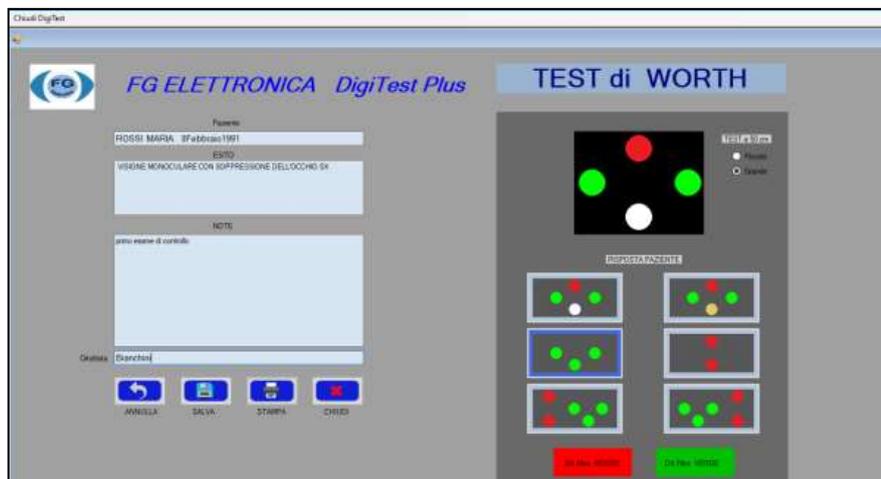
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### 12.6. Worth Test

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.

OSPEDALE CENTRALE REGIONE TOSCANA		SSIT Servizio Sanitario della Toscana		
CENTRO DI OCULISTICA REPARTO CHIRURGIA AMBULATORIO DI ORTOTTICA Via Giuseppe Garibaldi N° 1000				
Medico	Dott. Bianchini	Data esame	12/02/2020	
PAZIENTE	ROSSI MARIA	F	Data di nascita	02/02/1991
ID	0064	CF	MARIAROSI	
ESAME : TEST di WORTH				
Esito : VISIONE MONOCULARE CON SOPPRESSIONE DELL'OCCHIO SX				
Note: primo esame di controllo				



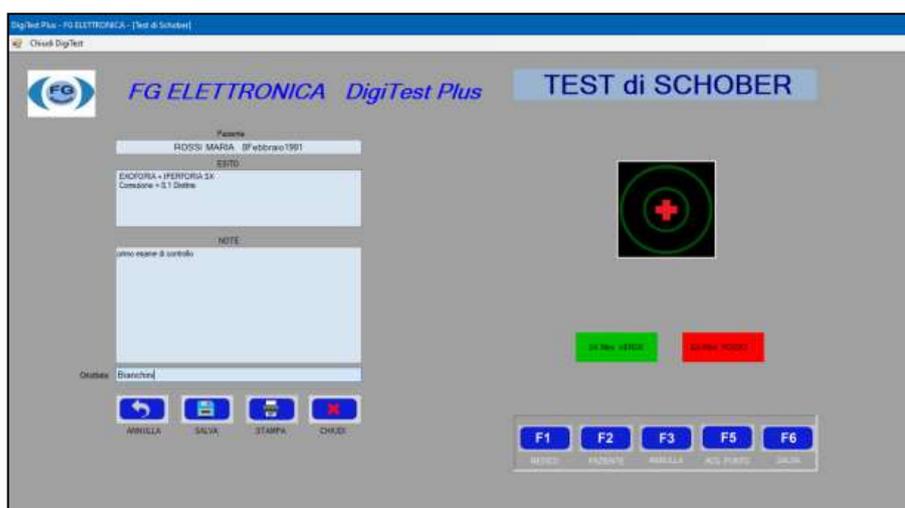
### 12.7. Schober Test

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)



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 attached some publications and reports from hospitals and/or private medical offices 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. Lo schermo di Hess DigiTest è stato oggetto di studio e valutazione da parte dell'Università di Ferrara mettendolo a confronto con il classico esame svolto in modo manuale, verificando le differenze in termini di prestazioni, facilità d'uso e affidabilità dei dati misurati .  
I risultati di questa analisi sono riportati nella tesi di laurea "Tecnologia low tech contro high tech: lo schermo di Hess-Lancaster", pubblicato per l'anno accademico 2015/2016 dalla Dott.sa Gaia Giacomello.  
Il testo completo della Tesi è disponibile online presso i siti istituzionali dell'Università degli studi della città di Ferrara.
3. Il Dott. Giovanni Battista Marcon Iscritto all'Ordine dei Medici Chirurghi e Odontoiatri della provincia di Vicenza e titolare dello studio medico omonimo, specializzato in chirurgia degli strabismi, ha sperimentato con successo e ha contribuito allo sviluppo dello strumento.