



# HESS DIGITEST

Mod. 10.15.00

Rev. : A

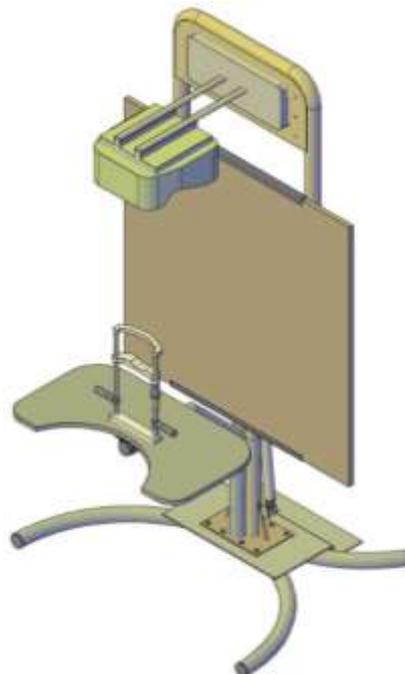
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## ELECTRONIC HESS SCREEN

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## PRODUCT SPECIFICATION



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### 1. Scope

This document describe the technical and functional characteristics of the System called "Electronic Hess Screen"

This System is used according to the European Standard listen at Para 2. And it is intended to be used in orthoptist or hospital environmental for examination of ocular motility and all pathologies connected to 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. Patents

The instrument is patented by the Italian "Ministry of Economic Development" with registration number No. 102015000058447



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#### 4. Commercial references

National Classification of Medical Devices CND Code Z1212012004  
Ministry of Health ID: Hess Dig. Cod: 10.15.00 ID 1393676 / R

#### 5. Introduction

The Hess-Lancaster screen is a test used to detect the presence of anomalies in the functioning of muscles responsible of ocular motility. Based on this assessment, in fact, the doctor determines the origin of a paralysis of the eyeballs, the diplopia or strabismus.

This type of test is indicated for the verification and control of ocular paresis or paralysis in various vascular pathologies, neurological, endocrinological, metabolic, cancer, traumatic, etc. orbitals.

In strabismus is useful for evaluating the type of ocular motility, particularly in research, when the changes of the muscular actions vary as in postural disorders, also associated with dental occlusion alterations and to proprioception's dent-alveolar periodontal and articular thus determining the entity the deviation and, above all, the state of the muscles affected by the problem, in addition to providing immediate evaluation parameters before / after during introductions of iatrogenic disturbing stimuli for diagnostic purposes.

To perform the classic Hess-Lancaster, the patient examination wearing a pair of glasses that has the red right lens and the left green, and is accommodated in front of a squared screen on which the doctor projects the red light of a torch, while the patient used another green. The test requires the patient overlaps the green light of his torch to the one projected by the doctor on the red checkered screen.

On completion of reuniting the points "seen" by the patient you will get a more or less regular shape square from which the doctor will extrapolate its diagnosis and then treatment to be followed for the correction of diplopia / squint.

The instrument "**Hess DigiTest**" automates this process by means of a special SW, which allows to optimize the examination eliminating human errors due to the manual of the old measurement method, also the data are captured and digitized, and then managed in electronic means for more effective and safe management of examinations.

To run the diagnostic test, the tool uses a high-resolution projector controlled by a computer and related SW, which projects a series of bars or points bright red (mire), according to the Hess-Lancaster scheme, and at the same time, the patient It using a pointing device like a mouse, touch pad, joystick, or other depending on the patient dexterity, projects the bright green bar or dot to superimpose the red sight.

When the patient will see overlap the two points (red and green), he will store the data pushing a button on the Touch-Pad.

At the end of the sequence the SW analyze the collected data and propose to the doctor, in addition to the Hess-Lancaster diagram a table with the data of the detected points, with the value of the deviation expressed in diopters and in angular degrees, which will help the doctor to perform diagnosis.

The substantial difference between the classic manual Test and this computerized method, is, as mentioned previously, in the exact determination of the alignment error, between the point commanded by the machine and the patient's response, identifying the misalignment even of a few millimeters.

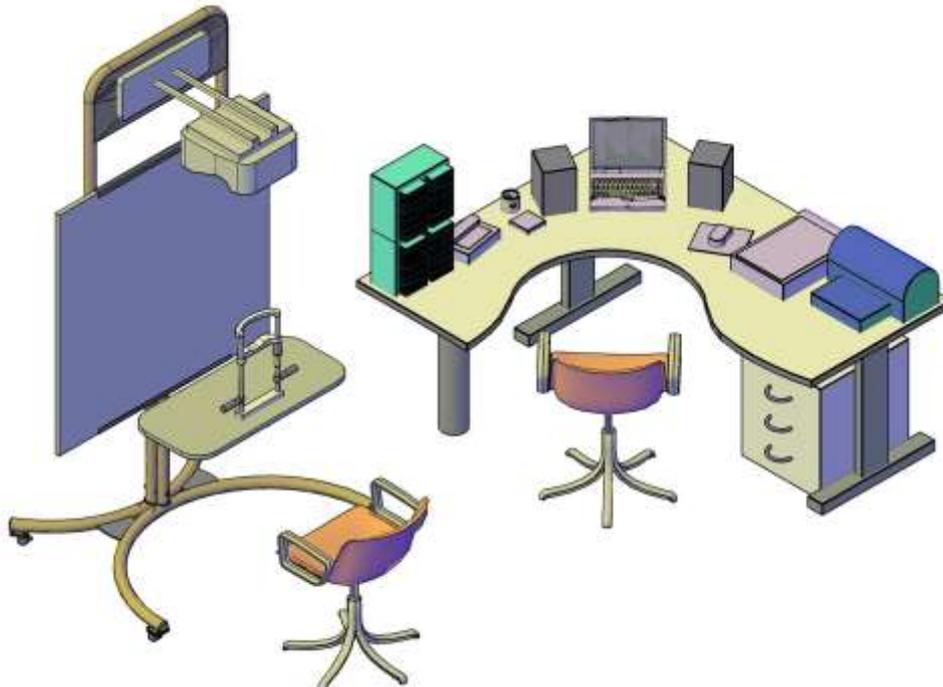
Another essential advantage is that to creating a database of all act examinations to verify the course of a therapy or simply for statistics or therapeutic evaluations.

## 6. Intended use

The Electronic Hess Screen 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.





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### 7. Functional Requirements

Hess Test	N° 3 preset sequences N° 1 manual sequence
Visual field coverage angle	50° ( ±25°) both horizontally and vertical
positioning resolution	±1mm
Measurement Accuracy	±1mm
Data	error in angular position and error in prismatic diopters
examination management	automatic archiving in pdf file
Print	Color printing of Hess Grid and data errors

### 8. Electrical Requirements

Power Supply :	115/230Vac
Frequency:	50÷60Hz
Absorbed power	<800VA
Input isolation transformer	IEC/EN60601-1

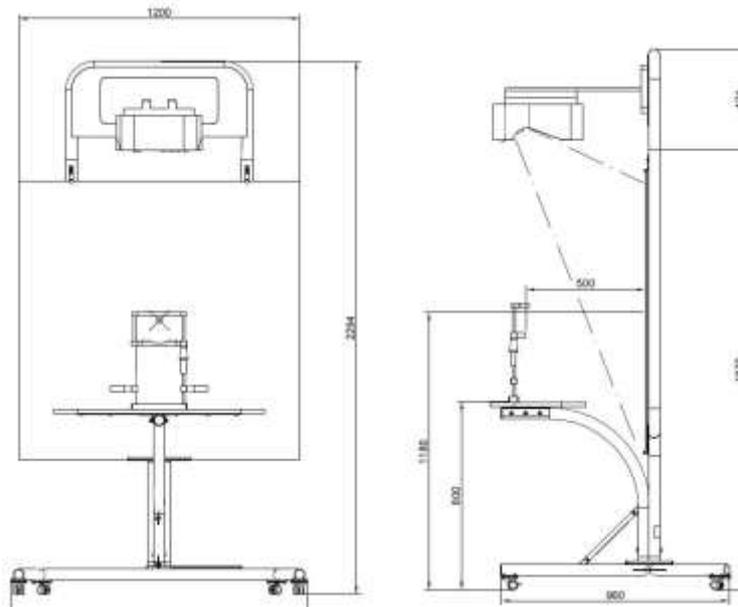
### 9. Environmental requirements

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

Dimension max: 230 x 120 x 960 cm



The instrument is classified as "semi-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.

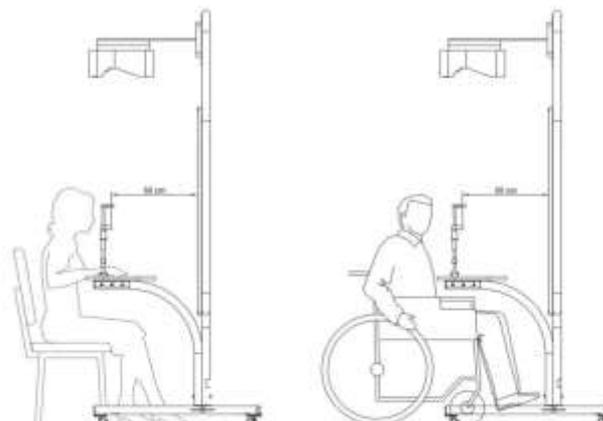
The total weight of the instrument is light in order to be transported easily by medical personnel in safety.

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.





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### 10. Functional Description

The instrument is composed by a Laptop computer that commands via HDMI, a LCD short throw projector which projects on a panel the points or bright aims according to the grid defined by the screen by Hess, with it is then associated a touchpad for handling by the patient the luminous green aims and a mouse for control of the instrument by the medical user.

In addition, the Hess DigiTest system is equipped with a color printer Deskjet type, all powered by an isolation transformer complies with IEC / EN60601-1 rules relating to electro-medical applications.

The operations that the instrument performs to perform its function can be summarized in two main phases:

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

#### 10.1. Patient interface

The patient takes a sitting position on the adjustable stool in front of the instrument, the doctor will position the patient making him lean on the chin and adjust the height of the stool so that the patient is in a comfortable position so that it can run the test in a relaxed manner and without postural stress . To the patient will be made to wear special red / green lenses and will explain the test procedure and described the use of the Touch-Pad which will position the green light sights.

A projector will create in sequence of bright red points (sights) on the panel and the patient must place the Green bright spot, controlled via the Touch-Pad on top of them.

The system stores all the points and at the end creates the exam reading chart, which can be printed or managed as a common file \* .pdf.

#### 10.2. Doctor interface

The operating SW creates a control panel on the computer screen from where the doctor can control and manage the examination.

The doctor may select from various pre-set sequences in addition to all the functions for saving and managing for results.

The first operation of the doctor is to open the patient's record by searching the archive "patients" or create a new tab in the event that the patient is the first examination.

#### 10.3. Patient Data Management and printing

The tool creates a Data Base to allow the management of patients and their examinations in time. The Data Base is organized as follows:

It creates a "folder" for each registered patient, (in the case of homonymous users should differentiate the two patients with an extra argument against the name). Within each "Patient Folder" you will create a "subfolder" appointed by the exam date, within which will be stored in PDF format all examinations and documents relating to that day.



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The size of the print is in color on A4 page in landscape orientation.

At the top is arranged a field of "header" an appropriate scale (max 2 to 3 cm including board page) for inserting a company logo and / or name of the doctor's office or hospital that holds the measuring instrument.

## 10. Hess Screen Exam Description

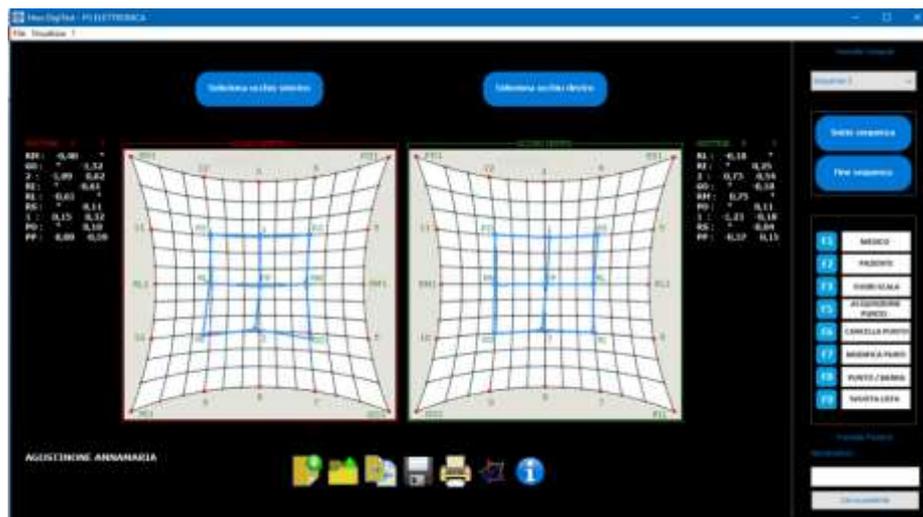
The Hess-Lancaster scheme is a test that is used to detect abnormalities of ocular motility. It is indicated for the verification and control of eye paresis in the various vascular, neurological, endocrinological, metabolic, tumor, traumatic, orbital pathologies, etc. Thanks to this examination, the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

To perform the Hess-Lancaster examination, the patient wears a pair of 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)



*Example of graphical interface for the doctor*



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BUTTON	FUNCTION
Select sequence	It allows the doctor to select between various standard or customized sequences.
Start Sequence	to start the Test by following the specified sequence.
End of sequence	End of the Test.
Patient Name	It allows the doctor to enter the patient's name or code by creating a new tab for each exam.
Search Patient	It allows the doctor to search the patient's name or code already entered or to recall previous tests.
Select Right or Left eye	It allows the doctor to select the test for the left or right eye.
Out of Range	It allows the doctor to store a point seen by the patient outside of the screen
Acquire Point	It allows the doctor to store a point in place of the patient, when the patient has movement difficulty
Delete or modify Point	It allows the doctor to undo the last or a previous revelation of the measure in the case of measurement error or deliberate repetition
Point or Bar	It allows the doctor to select representation of bright point as Bars or Points.

bottom are icons for shortcuts:

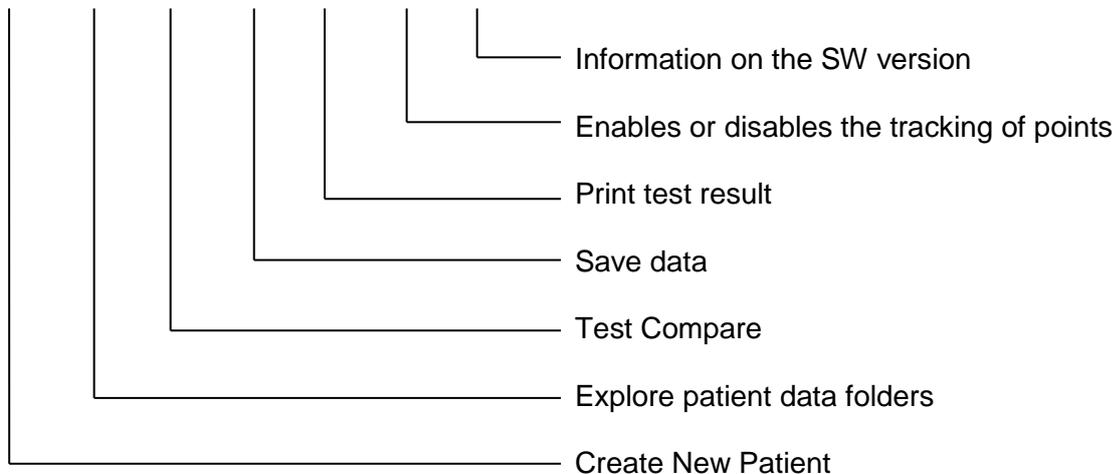


Figure 6. Toolbar

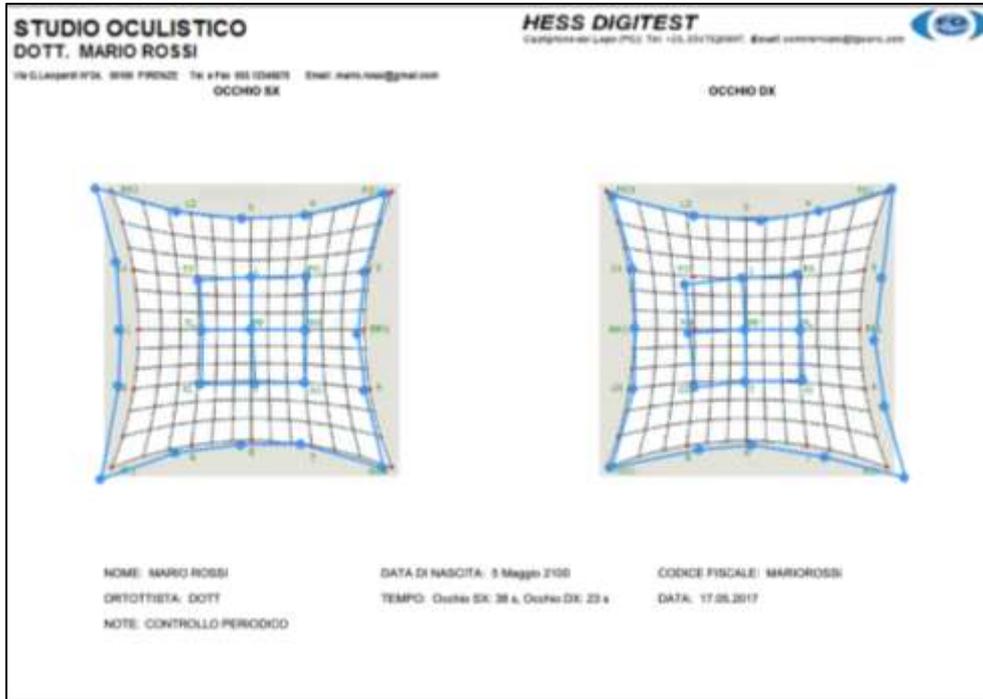


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The Hess Screen application provides an examination report where the points detected by the patient are represented with a table that reports the deviation in Prismatic Diopters and in angular degrees, with respect to the projected target.



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PUNTO	GRADI X	GRADI Y	GRADI X	GRADI Y
PP	0.00	0.00	0.11	0.20
RM	0.74	-1.20	*	*
RL	0.75	-1.24	*	*
1	0.71	0.19	0.40	0.75
PD	*	*	0.16	0.27
RS	*	*	-0.09	-1.47
2	0.06	1.74	-0.03	-0.03
SD	*	*	0.10	0.20
SL	*	*	-0.09	-0.09
AREA	804.75			

PUNTO	GRADI X	GRADI X	GRADI Y	GRADI Y
PP	0.24	0.00	0.11	0.20
RM	1.28	2.42	*	*
RL	-0.69	-1.12	*	*
1	1.17	1.89	0.20	0.38
PD	*	*	-2.03	-2.04
RS	*	*	0.00	1.12
2	0.22	0.38	-0.10	-0.18
SD	*	*	-1.89	-1.89
SL	*	*	0.00	1.40
AREA	810.00			

PUNTO	GRADI X	GRADI Y	GRADI X	GRADI Y
0	-0.74	-0.72	0.00	0.00
4	-1.29	-2.19	-0.09	-0.10
8D1	*	*	-0.16	-0.28
8	-0.81	-1.41	-0.21	-0.04
16L1	-0.86	-0.28	*	*
8	-0.76	-1.38	-0.28	-0.45
16H1	*	*	-1.28	-0.40
7	-0.21	-0.86	0.00	0.00
8	-0.20	-4.00	-0.74	-1.20
8	-0.00	-0.28	-0.04	-1.03
16D1	*	*	-0.27	-0.04
16	-0.36	-0.61	1.27	1.23
16H1	-1.26	-0.20	*	*
11	-0.17	-0.22	1.21	1.20
16D1	*	*	-0.04	-0.04
12	-0.07	-0.18	0.12	0.21
AREA	4880.71			

PUNTO	GRADI X	GRADI X	GRADI Y	GRADI Y
0	-0.07	-0.22	0.00	-0.00
4	-0.77	-4.84	0.21	0.41
8D1	*	*	0.24	0.42
8	-0.82	-0.87	0.10	-0.00
16L1	-0.73	-0.46	*	*
8	-0.01	-0.10	-0.02	-0.23
16H1	*	*	-0.02	-1.10
7	-0.76	-0.06	-1.09	-0.00
8	-1.42	-0.47	-0.01	-1.48
8	-0.10	-0.41	-1.18	-0.00
16D1	*	*	-0.10	-0.28
10	-0.01	-1.02	0.00	0.01
16H1	-0.20	-0.01	*	*
11	-0.82	-1.42	0.04	0.77
16D1	*	*	-0.00	-0.00
12	-1.01	-0.10	-0.17	-0.20
AREA	4080.01			

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

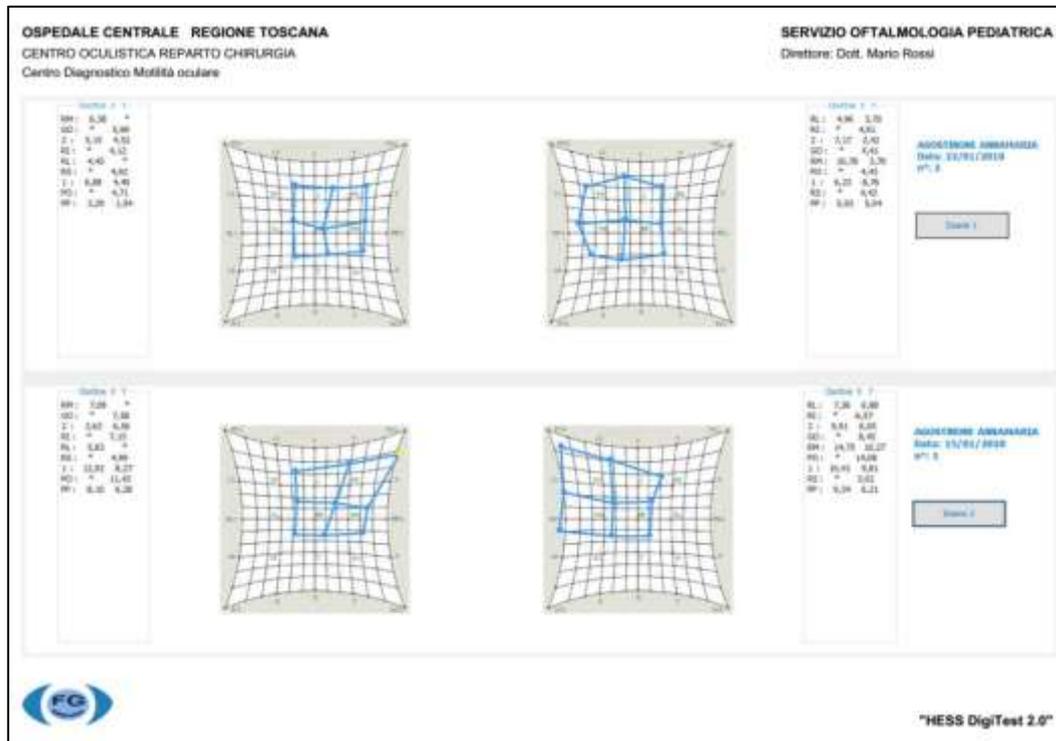


Fig 7. Test Compare

## 11. Publications and references

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 - Hospital (VR)*, at the "**Annual ARVO 2017**" meeting held in Baltimore (USA), where it achieved great success interest as a new computerized alternative tool to the classic Hess Lancaster.
2. The Hess DigiTest screen has been the subject of study and evaluation 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 office, specialized in strabismus surgery, has successfully experimented and contributed to the development of the instrument.