ENDOTHELIAL MICROSCOPE

MANUAL

PERSEUS

NOT SOLD IN US

EN

VIEWLIGHT
POWERED BY INNOVATION

Before use this instrument, be sure to read this manual

CONTENTS

INSTALLATION

1. GENERAL WARNINGS

- **These instructions describe how to use the PERSEUS endothelial microscope correctly.**

WARNING!
Please carefully readread this manual before using the device.

All our products have been manufactured with the greatest attention to safety. To use the device effectively and safely please read this user manual and the software's user manual carefully before installing and using the device, and follow the warnings reported in the manual and on the device. Operators who have used the device previously, should check again the instructions reported in this manual and in the software user manual.
The manual must be readily available for consultation.
The original text of this manual is in Italian.

1.1. SYMBOLS

Explanation of Symbols:

Type B applied parts, in compliance with EN 60601-1 standards.

Fuse

General Warning indicating the need to carefully read the user manual before installing and using the device.

CE 0051

Device classification in accordance with the rules set out in Annex IX of Directive 93/42/EEC and subsequent amendments: Class IIa.
The identification number relates to the Notified Body in charge of surveillance (IMQ)

Waste disposal symbol in accordance with Directives 2012/19/EU (WEEE - implemented with Leg. Decree 49/2014 dated 14/03/2014), and 2011/65/EU (RoHS 2 – implemented with Leg. Decree 27/2014 dated 4/03/2014).

Manufacturer

1.2. INTENDED USE AND OPERATING PROCEDURES

The PERSEUS specular microscope is an electromedical system for the detection, capturing and digital processing of an image of the corneal endothelium. It is designed to be used by eye specialists for ophthalmologic diagnosis and for other purposes related to the professional needs of operators, optometrists and opticians, in compliance with the laws and the regulations on the exercise of the profession.

PERSEUS enables mapping of the endothelial cells and the acquisition of a series of parameters to evaluate the cornea's health status.

The endothelium is the last layer of the cornea. It is about 5 µm thick and in a young individual it contains approximately 300,000 hexagonal cells.
The endothelium plays an important role in the correct functioning of the cornea and therefore its examination is fundamental for eye health diagnosis.
The most important characteristic of endothelial cells is that they do not replicate; furthermore, their number and shape can vary depending on the age, surgical treatments or use of contact lenses.
As mentioned above, endothelium's cells -which are hexagon-shaped in children and young adults- do not replicate and their shape and number affect the health of the cornea. At birth, human beings have approximately 4000 cells/mm2 and this number decreases over the years, thus changing the grating structure.
PERSEUS endothelial microscope enables to capture an electronic image of the endothelium without entering into contact with the patient. The image of the endothelium captured will then be used to calculate, using a complex mathematical formula, a number of clinically relevant parameters regarding the cells, including: cells number and density, shape, surface, average area, standard deviation, variance coefficient, percentage of cells with different shape, areas distribution histograms, pachymetry data.

PERSEUS endothelial microscope enables:

- non-invasive exam of the endothelial tissue;
- automatic focus of the endothelial layer;
- automatic calculation of cells centres and extensive statistical analysis based on the collected data;

PERSEUS endothelial microscope is first of all an essential instrument to determine the health status of the cornea. It is indispensable in pre- and post- transplant exams, and to follow-up on cataract surgery or to evaluate any traumatic damage of the cornea.

PERSEUS endothelial microscope allows for non-invasive non-contact examination. This translates into:

- No risk of transmission of infectious diseases;
- pain-free examination not requiring local anaesthesia.

1.2.1. CLASSIFICATION

- MEDICAL DEVICE classification device classification in accordance with the rules set out in Annex IX of Directive 93/42/EC and subsequent amendments: Class I.

- ELECTROMEDICAL DEVICES Classification.
  Type of protection against direct and indirect contact: Class 1
  Applied Parts: Type B.
  D egree of protection against humidity: Common device (no protection against water seepage) . IP20
  Sterilization method: Disinfectable device.
  Degree of protection when used with anaesthetics or flammable detergents: No protection.
  D egree of electrical connection between the device and the patient: Device with parts applied to the patient.

1.2.2. ENVIRONMENTAL CONDITIONS

As long as the endothelial microscope is kept in its original packaging, it can be exposed to the following environmental conditions without being damaged, and for a maximum period of 15 weeks during shipping and storage:

Operating conditions of use:
Temperature between +10 °C and +35 °C;
Atmospheric pressure 800 hPa to 1060 hPa;
Relative humidity between 30% to 90%.

Storage conditions:
Temperature between -10 °C and +55 °C;
Atmospheric pressure between 700 hPa and 1060 hPa;
Relative humidity between 10% and 95%.

Transport conditions:
Temperature -40 °C to +70 °C;
Atmospheric pressure 500 hPa to 1060 hPa;
Relative humidity 10% to 95%.

Vibration, sinewave 10 Hz to 500 Hz, 0.5g
Shock 30g, time: 6ms
Bumb 10g. time: 6ms

1.2.3. REFERENCE STANDARDS

The following reference standards were applied in design, production, and testing of the product:

Community Directives

- DIRECTIVE 93/42/EEC “MEDICAL DEVICES ” of 14 JUNE 1993, amended by 07/47/EEC.
- DIRECTIVE 2002/96/EC “Waste Electrical and Electronic Equipment (WEEE).”

Quality Management System Standards

- UNI EN ISO 9001:2008 “Quality Management Systems – Requirements.”
- UNI EN ISO 13485:2012 “Medical Devices – Quality Management Systems - Clinical Requirements for Regulatory Compliance.”

Technical Standards

- EN 60601-1 - “MEDICAL ELECTRICAL EQUIPMENT – PART 1: GENERAL REQUIREMENTS FOR SAFETY.” 2006 edition as amended.
- EN 60601-1-2 - “Medical Electrical Equipment – Collateral Standard: Electromagnetic Compatibility.” 2001 edition.
- UNI EN ISO 15004-1 “Ophthalmologic Instruments – Fundamental Requirements and Test Methods – Part 1: General requirements applicable to all ophthalmic instruments.” 2007 edition
- UNI EN ISO 15004-2 “Ophthalmologic Instruments – Fundamental Requirements and Test Methods – Part 2: Light hazard protection” 2007 edition
- UNI EN ISO 14971:2012 “Risk Management for Medical Devices.”

1.2.4. WARRANTY

not be liable under the following circumstances:

- installation and commissioning are carried out without following the instructions and precaution warnings reported in the manual;
- the device is not used following the instructions and precaution warnings reported in the manual;
- accessories or spare parts are used other than those supplied or recommended by factory;
- repairs and safety controls are not carried out by skilled, qualified personnel, trained and authorised ;
- the electric system of the location where the device is installed does not comply with CEI standards and the law requirements in force.

We accepts no liability for direct or indirect consequences or for damages to property or harm to persons caused by the improper use of the device or by unsound clinical assumptions based on its use.

warrants this product for a period of 24 months as stated by the date of manufactu-ring. This warranty covers the replacement, at factory premises or at an authorised service centre, of components and materials, as well as the necessary working hours. Shipping and transportation charges shall be born by the customer.
This warranty does not cover consumable parts or parts likely to wear in normal operation (e.g. lamps and fuses) or faulty parts due to improper use or inadequate maintenance.
Parts subject to wear and/or deterioration in normal and parts damaged by improper use or maintenance performed by persons not authorized are not covered by this warranty.

OUT OF WARRANTY CONDITIONS

- Repairs of faults caused by natural disasters, mechanical shock (fall, impact, etc.), defects of the electrical system, neglect, improper use, maintenance or repairs carried out with non original material and/or by personnel not authorised
- Any use which is improper or falling out of the intended use as foreseen by the manufacturer.

We not be liable for any service deficiencies or inefficiencies due to causes or circu-mstances beyond its reasonable control. Under no circumstances, shall the customer be entitled to down time damages.

We shall not be liable for any service deficiencies or inefficiencies due to causes or circumstances beyond its reasonable control. Under no circumstances, shall the customer be entitled to down time damages.
For maintenance or technical information on the device, please contact at:

VIEWLIGHT LLC

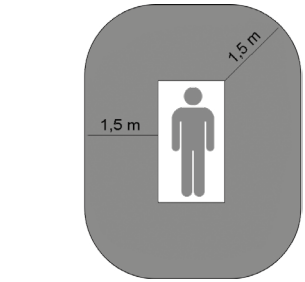
8380 NW 64 ST
Miami Fl 33166 USA
phone: +305-406-3915 - fax +305-938-5012
email: **customerservice@viewlightusa.com**
web: **www.viewlightusa.com**

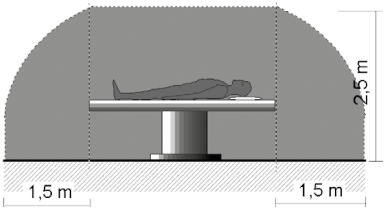
1.3. SAFETY PRECAUTIONS

ATTENTION!

- matches the voltage indicated on the computer data label. If the voltage does not match, contact the customer service or the manufacturer itself. (see chapter on INSTALLATION). The whole system must comply with CEI or IEC standards (standards for electrical systems in medical environments). Should you have any doubts, please contact the electrical installation and maintenance company in charge of your electrical system.
- The power source must have a differential circuit breaker (IΔn= 30 mA) and a thermal magnetic circuit breaker (Vn=230V) to protect the device. The power socket must be close and easily accessible.
- Do not use multiple sockets, adapters or extension cables to connect the device plug to the mains socket. Do not perform any repairs or maintenance work on the instrument or the electrical system beyond what is explained in this manual.
- To disconnect the device from the power supply, also in case of emergency, grab the plug of the power cable; do not pull the power cable to unplug the device.
- Never touch the computer mains power cable with wet hands; make sure the mains power cable is not walked on or trapped under weights; do not tie the mains power cable.
- A damaged power cable can cause fire or electric shock. It must be checked frequently. If the supplied computer power cable needs to be replaced, please contact the supplier.
- Do not attempt any technical intervention on the device or system unless specified in this manual.
- Do not use the device in the proximity of water and avoid liquid spillage on any surface of the device. Avoid humid or dusty places or places which are subject to rapid fluctuations in temperature and humidity.
- Unplug the device from the power socket before cleaning and/or disinfecting.
- The device does not generate or receive electromagnetic interferences when operated near other devices; no preventive or corrective action is necessary.
- Any peripheral device (printer, scanner, CD player, etc) connected to the analogical or digital interface of the system must comply with the following standards: In the

THE PERSONAL COMPUTER AND ALL PERIPHERAL DEVICES SHOULD BE PLACED OUTSIDE THE PATIENT AREA





The patient area is the volume defined as shown in the figure, within which the patient may come into contact (intentionally or unintentionally, directly or through contact with the operators) with medical electrical and other devices making up the system

United States of America:
- » UL 1950 for ITE equipment;
- » UL 2601-1 for medical electrical equipment;

In Europe:
- » EN 60950 for ITE equipment;
- » EN 60601-1 for electromedical equipment.

- After connecting all the necessary equipment, make sure the electromedical system complies with EN 60601-1-1 "Collateral standards. Safety measures for electromedical systems".
- If leakage current values exceed the regulatory limits, further safety measures must be adopted, as indicated in the EN 60601-1-1 standards.

In this case, the overall system must be powered through a safety isolation transformer.

- Be careful when examining children or patients whose cornea is not sufficiently transparent; with these subjects it might not be possible to capture an image of the endothelium.
- Always make sure that the patient is positioned correctly with his/her chin against the chinrest and his/her forehead against the head rest.
- Some endothelia are difficult to capture and results can be contradictory. This might be the case with: patients with irregularly-shaped corneas, recently medicated and/or operated eyes (3-4 days before), patients with keratoconus disorder.
- Be extra careful when the patient's eye is covered by the eyelid or by the eyelashes, or when there is a tear on the eye surface, eyelid or eyelashes. If that is the case, help the patient to completely open the eyelid or to remove the tear before proceeding with the exam.
- With intraocular lenses, capturing can be performed in MANUAL mode adopting the adequate precautions.
- The data collected must however always be examined by an eye specialist.

1.4. Disposal at the end of life

Under Directives 2002/95/EC, 2002/96/EC and 2003/108/EC, on the restriction of hazardous substances in electrical and electronic equipment and on their disposal".
The device purchased is manufactured using special materials and substances. The device may contain hazardous substances potentially harmful to the environment or to human health if improperly disposed of into the environment.
To prevent any hazardous substances from being discharged into the environment and to promote the conservation of natural resources, the manufacturer -should the user want to get rid of the used device at endof- life- facilitates the possible reuse of the device and the recovery and recycling of its materials.
Public authorities adopt adequate measures to make sure that users, distributors and manufacturers contribute to the collection of electrical and electronic equipment, setting legal requirements for reusing, recovering or recycling said equipment.

In the case of disposal of the device, specific provisions of European and national law apply, and provide that:

- the device shall not be disposed of as urban waste, it shall be collected separately, by contacting a company specialising in the disposal of electrical/electronic equipment or the public authorities responsible for waste management;
- in the event that a new piece of equipment is purchased from the same manufacturer to replace an old one placed on the market before 13 August 2005, equivalent and with the same functions of the new equipment, the distributor or manufacturer is legally required to collect the old piece of equipment;
- if the user wants to get rid of a used piece of equipment, placed on the market after 13 August 2005, the distributor or manufacturer is legally required to collect it;
- the manufacturer shall take care of the transport, handling, recovery and/or disposal of the old equipment collected at its own charge;
- the potentially harmful effects to the environment or human health due to any hazardous substance contained in electrical and electronic equipment or to the improper use of said equipment or its parts shall be taken into account. The device described in this user manual is made of metal mechanical components, plastic material, electrical components and electronic boards. The manufacturer will provide the users with any information regarding the hazardous substances contained in the device and on the recovery and recycling of said substances, as well as on the possible reuse of the used device.

Violations shall be punished by the current legislation with serious administrative sanctions.

2. SUPPLY PACKAGE

The device is composed of one endothelial microscope with built-in chinrest module; with uninterruptible power supply (UPS).

Peripherals and auxiliary devices:

1. Laser printer compliant with EN 60950 standards;
2. Isolation transformer 230V –230V for use in the operating theatre (leakage currents limitator) compliant with EN 60742;
3. Motorised adjustable elevating table with telescopic lifter, brand SCHUMO AG with wooden top; electro medical device compliant with EN 60601:1 standards, purchased from VIEWLIGHT and not modified.

Accessories:

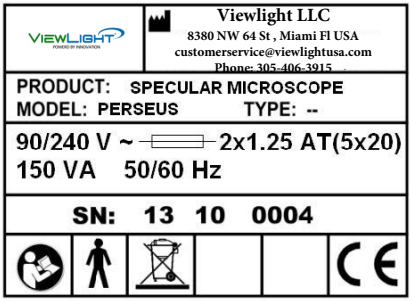
The device is supplied with the following accessories:

- one protection cover;
- one set of chinrest papers;
- two protection fuses;
- the user manual;
- UPS;
- management software.

2.1 IDENTIFICATION NAMEPLATE

Data reported on the nameplates:

- Manufacturer's name.
- Device name.
- Serial number.
- Month and year of manufacture.



3. ROUTINE MAINTENANCE

All repair operations described in this chapter must be performed with the power cable of the unit disconnected from the mains outlet. In the event of faults that cannot be solved with the operations described below, please contact the installer company.

Protection against dust.

When not in use, protect the system against dust with the dust cover supplied. Dust accumulating on the device must be regularly removed with a soft cloth or blower.

Replacing the mains fuses.

To replace power fuses follow these instructions:

- Remove the fuse box (11). Before taking any action, isolate the device from the electrical system by unplugging the mains supply;
- Replace the fuses making sure that the fuse voltage matches the voltage indicated on the transformer nameplate;
- Plug in the mains supply cable into the mains socket.

WARNING!
Do not use any thinners or solvents.

WARNING!
If the product needs maintenance, contact the Technical Service authorised .

WARNING!
To avoid the risk of electrical shock, this device must only be connected to power supply systems with protective earth.

4. USAGE

Launch the software.

The software required to operate PERSEUS endothelial microscope is already installed on the instrument built-in computer. No other software can be installed on this computer. Do not install any software for any other purpose on this computer to preserve its high performance and avoid jeopardizing its correct functioning.
Switch on the instrument by pressing the button (1).
Important: make sure to use only your fingers or touch-screen pens . Never use regular pens or any other pointed object.

Capturing instructions.

For data capturing without entering the patient's data, use the button on the side.

For data capturing after entering patient's data, use button on the side.

Please refer to the software user manual for all following operations.

5. FUNCTIONAL FEATURES

PERSEUS endothelial microscope is the result of a long research carried out by recognized professionals to bring new technology, quality and design together to the highest level.

The system designed exploits innovative solutions which make it unique for some of its features. Among these:

1) Absence of a photo-sensor or of a linear sensor along the return optical path. Software-managed and performed acquisition, guaranteeing higher reliability (reduced number of electronic components used), lower manufacturing cost and more flexible use.
2) The CCD digital photo camera enables to capture well-defined top-quality images.
3) Patients, exams and images acquired are stored inside the report database, enabling post-exam mana gement of collected data.
4) The system is equipped for data exchange using other applications in Intranet/Internet environment.
5) Further developments could lead to remote diagnosis and automated exams without operator.
6) The measurement software is fully automatic and it calculates parameters which other systems do not always provide.

Software features.

The software can analyse all relevant data produced by the endothelial exam. This includes cell size summary data (polymegathism), such as:

- Number of cells in the area measured;
- Cell density;
- Cell average area;
- Standard deviation of analysed cells;
- Variance coefficient;
- Average median error;
- Cell size occurrence histogram.

This also includes cell shape summary data (pleomorphism), such as:

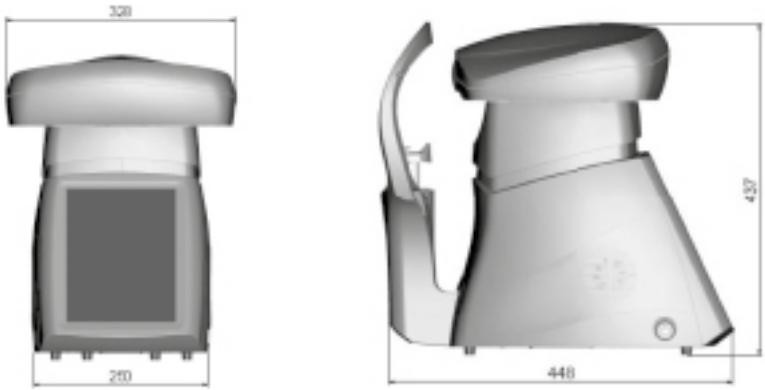
- Hexagonal deviation (percentage of hexagonal cells);
- Shape factor;
- Cell shape occurrence histogram.

The images presented are top-quality and cell count is completely automatic. Where necessary, manual editing is available. This system counts up to 400 cells in automatic mode with one acquisition: the large number of cells analysed produces statistically relevant and highly repeatable data. Endothelial data analysis and the images can be saved in an archive with the patient's personal data. This archive can then be integrated with software solutions for corneal topography (PHOENIX) and for the digital slit lamp.

6. TECHNICAL FEATURES

Photographic method	Contactless
Photographic field	0.54 mm x 0.27 mm
Measurement accuracy	±10 µm
Video camera	CCD video camera
LED	LED
Power supply voltage	100V-120V ac ±10% 60 Hz 230V-240V ac ±10% 50 Hz
Fuses	Mains socket unit: 5x20 mm 2x 1.25AT
Power absorbed	200 VA
Weight (only instrument)	15 Kg approx.
Power cable	Three-core cable (with protective earth), conductors minimum cross-section 1 mm^2

Dimensions:



7. GUIDANCE AND MANUFACTURER 'S DECLARATION
7.1. ELECTROMAGNETIC EMISSION

TABLE 1 - Guidance and manufacturer's declaration – electromagnetic emission		
The equipment Perseus is intended for use in the electromagnetic environment specified be-low. The customer or the end user of the Perseus should assure that it is used in such an environ-ment.		
Emission test	compliance	Electromagnetic environment - guidance
RF emission – CISPR 11	Group 1	The PERSEUS uses RF energy only for its internal function. Therefore its emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emission – CISPR 11	Class B	The PERSEUS is suitable for use in all establishments including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes
Harmonic emission IEC 61000-3-2	Class A	The PERSEUS is suitable for use in all establishments including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes
Voltage fluctuation/flicker emission IEC 61000-3-3	Complies	The PERSEUS is suitable for use in all establishments including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes

7.2. ELECTROMAGNETIC IMMUNITY.

TABLE 2 - Guidance and manufacturer's declaration – electromagnetic immunity			
The equipment PERSEUS is intended for use in the electromagnetic environment specified below. The customer or the end user of the PERSEUS should assure that it is used in such an enviroment			
Immunity	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 KV contact ±8 KV air	±6 KV contact ±8 KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical Fast Transient/Burst IEC 61000-4-4	±2 KV for power supply lines ±1 KV for I/O lines	±2 KV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 KV differential mode ±2 KV common mode	±1 KV differential mode ±2 KV common mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage Dips, Short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% Ut for 0,5 cycle 40% Ut for 5 cycles 70% Ut for 25 cycles <5% Ut for 5 sec	<5% Ut for 0,5 cycle 40% Ut for 5 cycles 70% Ut for 25 cycles <5% Ut for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user requi-res continued operation during power mains interruptions, it is recommended that the PERSEUS be powered from an Uninterruptible Power Supply or Battery
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Note: Ut is the AC mains voltage prior to application of the test level

TABLE 3 - Guidance and manufacturer's declaration – electromagnetic immunity

The equipment PERSEUS is intended for use in the electromagnetic environment specified be-low.
The customer or the end user of the PERSEUS should assure that it is used in such an environ-ment

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communication equipment should be used no closer to any part , including cables, than the recommen-ded separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3Vrms 150KHz to 80MHz	3 V rms	Recommended separation distance. d=1,167*sqrt (P)
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2,5 GHz	3 V/m	d=1,167*sqrt (P) 80 MHz to 800 MHz d=2,333*sqrt(P) 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and d is the recommen-ded separation distance in metres (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: at 80 MHz and 800 MHz, the higher frequency range applies
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

B1. INSTALLATION AND COMMISSIONING

All equipment is always delivered packaged in optimal conditions to withstand standard transport and storage conditions. In the event that, when removing the device from its packaging, damages due to transport are detected, please contact the installer company or the manufacturer directly.

Figura 1

Connect the device.

To connect the device, follow the instructions below:

- Position the instrument as shown in figure 3 making sure that the resting surface is clean;
- Verify that the power socket voltage selector is set to the desired voltage for use with the device. If necessary, take out the flaps and turn until the correct voltage value is displayed;
- Plug cable 8 into power outlet 11;
- Fix the cable in the correct position with cable ties 12 and 13;
- Bring the instrument back into operating position.

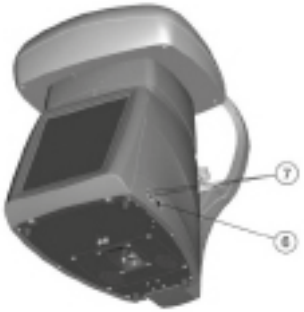


Figura 2

Follow the instructions and warnings described in paragraph 1.3 SAFETY WARNINGS to ensure proper use of the device.

Legend.

1) Start button;
2) Headrest;
3) Chinrest.
4) Optical Unit;
5) Chinrest paper pins;
6) Ethernet port;
7) 2 USB ports;
8) Power cable;
9) Fuses;
10) Fuse box;
11) Power supply outlet;
12) Cable tie;
13) Cable set screw;
14) Supporting surface;
15) Nameplate;

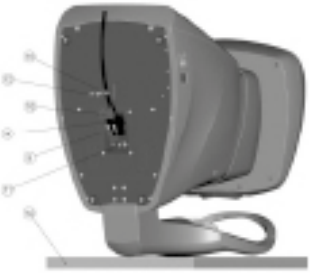


Figura 3


VIEWLIGHT
POWERED BY INNOVATION

VIEWLIGHT®

POWERD BY INNOVATION

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