USER MANUAL

FUNDUS CAMERA

Retina 400

UM RETINA400
V2- MARCH 2016

Contents

1. General warnings

These instructions describe the correct use of the system/instrument Fundus Camera Retina400.

ATTENTION!

Please read this manual carefully before using the equipment

All ESSILOR products are manufactured with maximum attention to reliability and safety. In order to use it efficiently and in complete safety we recommend reading this manual carefully before installation and use and heeding all the safety warnings contained in herein and reported on the exterior of the equipment. Even operators who have already used this type of instrument should verify their knowledge of the instructions contained in this manual. Keep this manual near the instrument for handy reference during use.

This device is considered a medical device. It should be utilized by authorized personnel only.

1.1 Symbols

Explanation of the graphic symbols used:

1) Applied parts classified as Type B in accordance with EN 60601-1 standard.
2) Device of class II (according to EN 60601-1). It means that the insulation to the power supply is highly trustworthy and there is therefore no need for earthing to guarantee security
3) General warning of the duty to read the instruction manual carefully before installing and using the equipment
4) "CE marking" that attests to product compliance with European Union Directive 93/42/EEC ("Medical Devices") and following amendments. Date of first Marking Jan 2014
5) Indicates the obligation to collect and separate disposal of electrical and electronic equipment, at the end of their useful life, according to 2012/19/EU
6) Manufacturer

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1.2 Intended use and instructions for use

Retina400 is an electro-medical system that allows for digitally retrieving, acquiring and processing of a retinal image, for use in ophthalmological diagnosis by medical specialists, and other uses inherent to the professional activity of other operators, optometrists and opticians, to the extent permitted by the laws and regulations for the exercise of their profession.

An absolute new entry in the field for retinal imaging, the instrument allows for a direct, 'live' monitoring on the computer screen, and capturing also in cases where the pupil diameter is extremely narrow. The instrument, with manual acquisition and electronically guided control guarantees high precision and repeatability of the measurements.

The dedicated software has the following characteristics:

- Manual guided acquisition system;

- Simultaneous visible ('white') light and IR acquisition;
- Panoramic analysis for enlarged field of view;
- Image processing, drawing and measuring
- Zoom effects
- Cup/disc horizontal and vertical;
- Image overlay;
- Edge enhancement;
- Contrast, brightness and RGB components settings and gamma correction;
- Image color splitting (grey-values, red free, channel separation);
- Color inversion and filter simulation;

For more detailed information on dedicated software, we refer to the User manual.

1.2.1 Classification

- Classification MEDICAL DEVICES
  Classification of the device according to rules as of appendix IX of Directive 93/42/EC and following amendments: class I
- Classification ELECTROMEDICAL DEVICES
  Class of protection against direct and indirect contact: class II
  Applied parts: Type B
  Compliance level for protection against humidity: Common devices (shell not protected) IP20
  Method of sterilization or disinfection: Disinfectable devices
  Compliance level for protection in the presence of inflammable anesthetics: No protection
  Degree of electrical connection between the unit and patient equipment with Patient Applied Part
  RETINA400 cameras fall into the category of class II, so the earth connection and the plug earth are functional earthing.

1.2.2 Environment conditions

As long as the system components remain in their original packing the equipment may be exposed to the environmental conditions listed below, for a maximum of 15 weeks during shipping and warehousing, without suffering damage.

Environment conditions for operation:
Temperature between -10 °C and +35 °C
atmospheric pressure between 800 hPa and 1060 hPa
relative humidity between 30% and 90%.

Environment conditions for warehousing:
Temperature between -10 °C and +55 °C
atmospheric pressure between 700 hPa and 1060 hPa
relative humidity between 10% and 95%.

Environment conditions for shipping:
Temperature between -40 °C and +70 °C
atmospheric pressure between 500 hPa and 1060 hPa
relative humidity between 10% and 95%.

Vibration, sinusoid 10 Hz @ 500 Hz, 0.5g
Shock 30g, duration 6ms
Bumb 10g. duration 6ms

1.2.3 Reference standards

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

EU Directives

- **DIRECTIVE 93/42/EEC "MEDICAL DEVICES " , amended by 2007/47/EC.**
- **DIRECTIVE 2012/19/UE "Waste Electrical and Electronic Equipment (WEEE)."**
- **DIRECTIVE 2011/65/UE: "ROHS Directive"**

Standards concerning Quality Management Systems :

- **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." 2007 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."**
- **Guidance for Industry and FDA Staff - Guidance for the submission of Premarket Notifications for Medical Image Management Devices (July 27, 2000)**
- **Guidance for Industry and FDA Staff - Guidance for the content of premarket submissions for software contained in medical devices (May 11, 2005)**
- **UNI EN ISO 9001:2008 "Quality Management Systems – Requirements."**
- **UNI EN ISO 13485:2012 "Medical Devices – Quality Management Systems - Clinical Requirements for Regulatory Compliance."**

1.2.4 Warranty

The Manufacturer is responsible for compliance with Directive 93/42/CE as amended by 2007/47/CE, its performance, safety and reliability, and the CE marking. Device lifetime : 10 years

Nevertheless Manufacturer denies such responsibility when:

- the installation and commissioning are not made in accordance with the instructions and precautions given in this manual;
- the device is not used in accordance with the instructions and precautions in this manual;
- spare parts and accessories not supplied or recommended by Manufacturer are used;
- repairs and safety checks are not carried out by competent personnel, qualified, trained and authorized by Manufacturer;

- the electrical installation of the room in which the appliance is not in compliance with CEI and
  laws and regulations.

Manufacturer disclaims any liability for direct or indirect consequences or damages to persons or property, resulting from improper use or incorrect clinical evaluation of its use

Parts subject to wear and/or deterioration in normal and parts damaged by improper use or maintenance performed by persons not authorized by Manufacturer are not covered by this warranty.

To request technical assistance with maintenance, please contact directly your local technical center or your distributor.

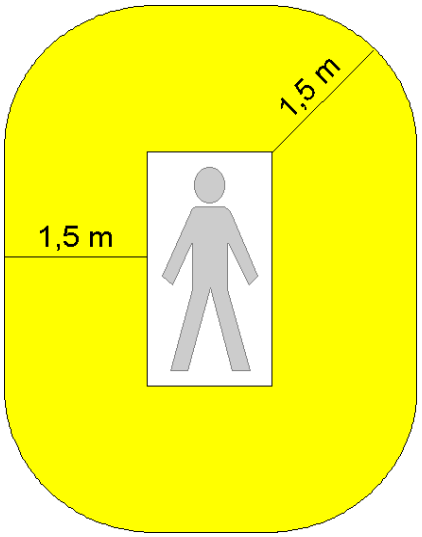
1.3 Safety precautions

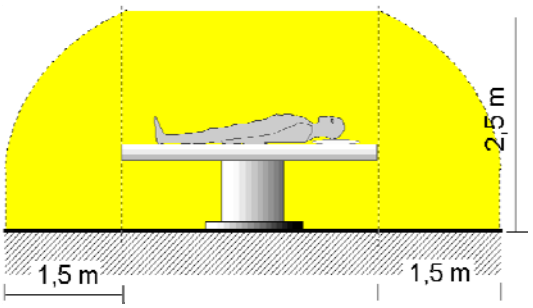
ATTENTION!

- Never touch the power cord with wet hands. Check frequently that the cord is so placed as not to be stepped on or crushed by weights. Never knot the cord.
- A damaged power cord can cause fires or electrical shocks. Check frequently that it is in good condition. If it becomes necessary to replace the power cord originally supplied with the instrument, contact your supplier.
- Do not perform any repairs or maintenance work on the instrument or the electrical system beyond what is explained in this manual.
- Do not use the instrument near water and be careful not to spill liquids on any part of it. Avoid damp and dusty locations and locations subject to brusque changes in temperature and humidity.
- Disconnect the instrument from the main power supply before cleaning and/or disinfecting.
- The equipment neither generates nor receives electromagnetic interference when used in proximity to other devices; no preventive or corrective measures need therefore be taken in this regard.
- No precautions are required in case of change in the device's performance
- In the standard configuration supplied by Manufacturer, the system includes components that do not classify as medical electrical equipment (PC or portable computer, etc.) besides the fundus camera as such. The resulting system is in any case tested in accordance with EN 60601-1 (3rd edition), in particular according to the requirements described in chapter 16. Since the unit in question can include other instruments, medical electrical and not, Manufacturer is unable to test compliance of all possible configurations.
- The configuration verified by Manufacturer is the one with the PC outside of the patient area.
- Any other accessories (printer, scanner, etc.) connected to the analog or digital interfaces of the system must be certified in accordance with the standards listed below.
  - EN 60950 for ITE equipment (safety regulations for information technology equipment), or
  - EN 60601-1 for medical electrical devices.

  The connected accessories should be placed outside of the patient area.

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

- The operator should make sure, once all the equipment has been assembled, that the resulting medical electrical system complies with the prescriptions of EN 60601-1 (exact prescriptions are given in chapter 16 of the aforementioned standard)
- Should the measured leakage current values be outside of permissible limits, further safety measures as suggested by EN 60601-1 (3rd edition) should be adopted. In this case the entire system should be powered through an appropriate separate transformer or an insulating transformer.
- The transformer is absolutely indispensable when it is difficult to keep the computer and other non-medical electrical devices outside of the patient area.

ATTENTION!

Only those units bearing the Manufacturer trademark and the external power supply (AC/DC Adapter MEAN WELL Mod. MES3OB-3P1J) of the "CONTROL BOX" may be placed and used inside the patient area.

The following parts of the system must be placed outside the patient area:

- Computer (PC or portable), with relative accessories (monitor, keyboards, mouse, etc.),
- Printers,
- Other auxiliary units that do not classify as medical electrical equipment (power supplies / battery chargers, modems, etc.).

If the system needs to be connected to a network (LAN / WAN) it is suggested to take whatever precautions necessary to avoid the importing of hazardous voltages coming from remote devices, by means of the connected cables. It might be necessary to use data transmission devices that ensure 'GALVANIC ISOLATION'.

Manufacturer disclaims all liability for the safety of the patient and the operator for electrical connections between computers and other external devices (peripherals) or LANs, not provided by Manufacturer.

1.4 End-of-life disposal information

In accordance 2012/19/UE concerning reduction of use of dangerous substances in electrical and electronic equipment and disposal of electrical and electronic waste.

The instrument you have purchased is made using particular materials and substances. It may also contain substances having potentially dangerous effects on the environment and human health if released into the environment by improper disposal.

To avoid releasing dangerous substances into the environment and in order to promote conservation of natural resources, and should the user decide to dispose of an end-of-life instrument, the Manufacturer will facilitate re-use and recovery and recycling of the materials it contains.

Governments agencies have adopted measures obliging users, distributors, and manufacturers to contribute to collection of waste electrical and electronic equipment (WEEE) and prescribes that such equipment find re-use or be recovered or recycled.

When disposing of the instrument, remember that disposal is regulated by precise European and national laws and regulations that prescribe the following:

- **Do not dispose of the instrument as ordinary municipal waste**. For **separate collection** contact a company specialized in disposal of waste electrical and electronic equipment or your local waste disposal agency for information.
- If a new instrument is purchased from the same Manufacturer to replace an end-of-life instrument put on the market before 13 August 2005, of an equivalent type and performing the same functions as the new device, the distributor or Manufacturer is required by law to take back the end-of-life device.
- If the user intends to dispose of a used device put on the market after 13 August 2005, the distributor or Manufacturer is required by law to take back the device.
- The Manufacturer is responsible for transporting, treating, and recovering and/or recycling any used equipment collected and for all relevant expenses.
- **Do not forget that dangerous substances present in waste electrical and electronic equipment and/or improper use of same or parts of same can have potentially adverse effects on the environment and human health**. The instrument described in this manual contains metal and plastic mechanical parts, electrical components, and electronic circuit cards. The Manufacturer is at user's complete disposition for any information requested regarding the dangerous substances contained in the instrument and recovery and recycling procedures and/or the possibility of re-using the end-of-life instrument.

Current legislation provides severe sanctions in the case of failure to respect disposal laws and regulations in force.

2 System Components

The principal units making up the system are the:

Fundus camera whole unit, designed and built by Manufacturer, is composed of:

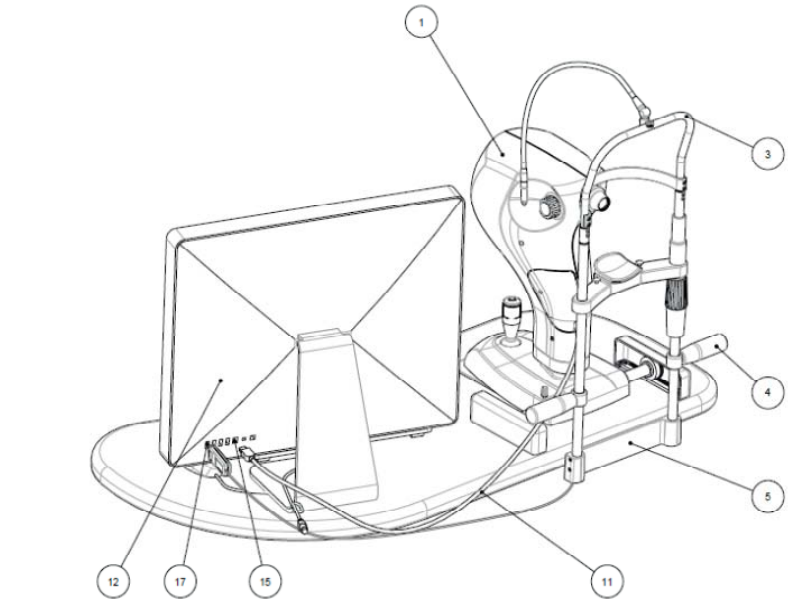
1. Fundus Camera instrument
2. Personal Computer (as option)
3. Dedicated software
4. Chinrest with illuminated fixation point and USB attachment

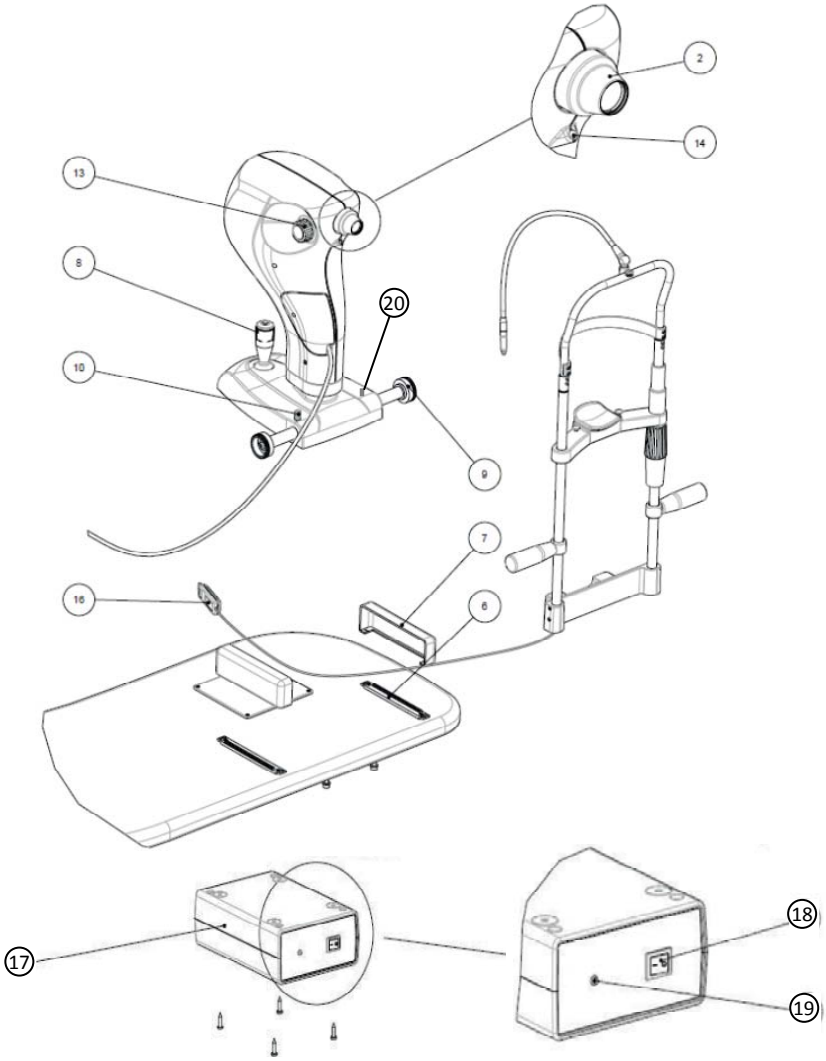
Standard accessories

The system is supplied complete with the accessories listed below:

- two guards for the advancement guides
- one dust cover
- one set Allen wrenches
- one pack chin rest papers
- two fuses

1) *Instrument*
2) *Optical lens*
3) *Chin rest*
4) *Chin rest hand held*
5) *Chin rest support*
6) *Toothed guides Unit control box*
7) *Guide guards*
8) *Joystick with acquisition button*
9) *Toothed wheels*
10) *Base slide lock knob*
11) *USB3 cable*
12) *Personal computer*
13) *Focus adjustment handle*
14) *LED illumination*
15) *USB3 Socket*
16) *Fixation point power supply (USB)*
17) *USB socket*
18) RETINA400 External power supply
19) Power supply name plate
20) Power supply switch
21) External power input

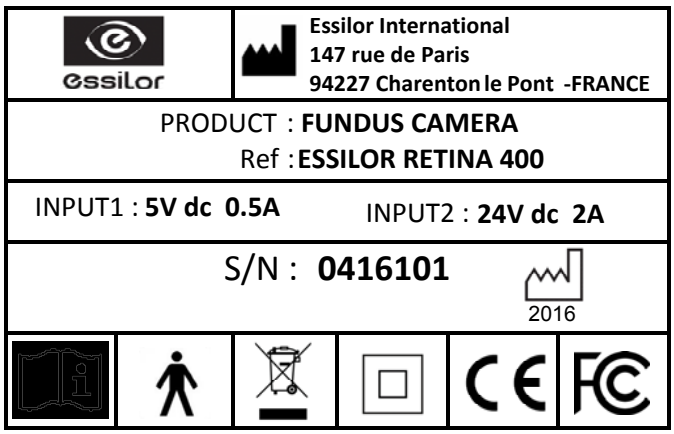




2.1 ID PLATE

Data on the plate :

- Name & Address of the legal Manufacturer.
- Name of the equipment.
- Serial number.
- year of manufacturing



CAUTION:

Federal law restricts this device to sale by or on the order of a physician 21CFR 801.109

3 Routine maintenance

The system requires no particular routine maintenance.

Clean the external surfaces of the instrument with a cloth slightly dampened with water. Do not use thinners or solvents.

Protection from Dust

When the instrument is not in use, protect it from dust by replacing it in the carrying case. Periodically remove any dust that has accumulated on the instrument with a very soft cloth or a hand-operated pump.

Unscheduled maintenance (repairs, replacement of components, checking internal parts, etc.) is the exclusive competence of the Manufacturer technical assistance service

Attention

On request, the Manufacturer will supply diagrams, components lists, and particular technical instructions for maintenance and calibration use by authorized and previously-trained personnel

ATTENTION!
Do not use solvents or thinners

ATTENTION!
In case of need for maintenance, contact the technical service authorized by Manufacturer

4 Instructions for use

a) Enter the program dedicated software ; first instructions for the dedicated software are the following:
b) After inserting the patient or the necessary new exam, the software will prepare for acquisition;
c) Make the patient sit comfortably with chin on the chin rest and forehead against the relative support;
d) Raise or lower the chin rest using the wheel available on the chin rest support, in order to center the patient's eye on the output channel (computer monitor);
e) Move the focus knob in the default position.
f) Move the unit so that this is in a position of about 5 cm from the eye
g) Tell the patient to fixate the fixation target;
h) Slowly advance the instrument towards the eye, using the monitor for maintaining alignment and focus, until the retinal image appears;
i) Make micro-adjustments with the joystick to maximize image quality in terms of homogeneity and illumination and field of view;
j) Optionally adjust focus with the focus adjustment handle;
k) It is possible to acquire more than one image per exam;
l) The images will be shown immediately afterwards on the main gallery.

The examination at this point is to be considered complete.

For more detailed information on dedicated software, we refer to the User manual of the software

ATTENTION!

Do not turn of the PC, nor disconnect the connection cable between PC and instrument while the instrument is used

ATTENTION!

To turn of the system it is sufficient to follow standard procedures for exiting a software program and turn of the power supply for the PC

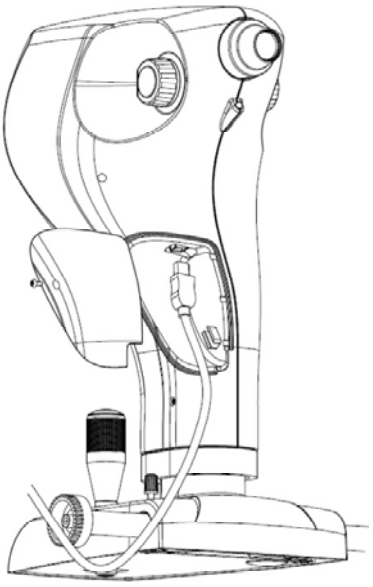
TO ISOLATE (and obtain a condition of absolute safety) YOU SHOULD UNPLUG THE COMPUTER'S POWER CORD

5 Technical specifications

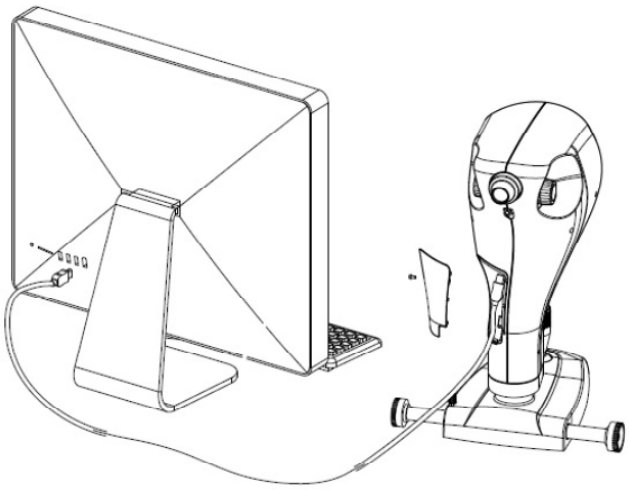
	5MP
Working distance (mm)	20
Image resolution	2448 x 2051
Power Supply (instrument)	Specific external power supply 24V dc 2A and USB3 5vdc 0.5A
Power Supply PC	See Computer data plate
Weight (kg)	ca. 10
Dimensions (mm) (H x L x D)	300 x 400 x 410
Shelf size (mm)	380 x 500
Classification according to safety standard EN60601-1 (3rd ed.)	
Class of protection against direct and indirect contact	class II
Applied Parts	Type B
Compliance level for protection against humidity	Common devices (shell not protected) IP20
Method of sterilization or disinfection	Disinfectable devices
Compliance level for protection in the presence of inflammable anesthetics	No protection
Use conditions	Continuous service
Classification according to standard ISO 10940	
Center of the field	≥ 60 line pairs/ mm
Midfield (r/2)	≥ 40 line pairs/ mm
Periphery of the field (r)	≥ 25 line pairs/ mm
Pixel pitch	6 µm
Field of view	50 ° x 42°

6 Installation

The USB3 cable is removable. You can access the connector the cable by removing the cover located on the front of the instrument.



Retina400 Connection on computer with USB3



This Device is compliant with CE marking. Date of first marking: March 2016

Essilor Instruments USA
8600 W. Catalpa Avenue, Suite 703
Chicago, IL 60656
Phone: 855.393.4647
Email: info@essilorinstrumentsusa.com
www.essilorinstrumentsusa.com