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### XI. QR Code 115
I. Introduction
The complete user manual is available on a web space.
To access other available languages, please scan the QR code at the end of this user manual > Chapter QR code (☞ p.116).
II. SAFETY
1. **DOCUMENTATION**

This usage and maintenance manual, together with the instructions on the label, reflects the information supplied by the manufacturer in accordance with Directive 93/42/EEC amended by 2007/47/EC.

The medical device must be accompanied by the information needed to ensure that it is used safely, taking the training and knowledge of potential users into account.

The manual is an integral part of the device, and therefore must be maintained with extreme care and always attached, in the event the product is transferred of to third parties.

It is addressed to operators, the owner, users and maintenance technicians.

The manual provides guidance on the technical characteristics, proper use of the device, transportation, storage, maintenance, disposal and security precautions.

Any changes to the manufacturer's instructions that prove relevant for patient and/or operator safety will be promptly communicated to the owners/users of the product through all channels useful for these purposes.

Any other changes and/or additions are excluded from the manufacturer's notification obligation.

If this manual, the device's labels and/or markings are even partially damaged, faded, illegible in part or in full, an additional copy must be immediately requested from the dealer or manufacturer.

2. **DEFINITIONS**

The terms referred to in this manual shall have the meaning given below:

**Medical device:** Device intended by the manufacturer to be used on human beings for care, diagnosis or the alleviation of disease.

**Patient:** The subject who undergoes a medical exam with the use of the device.

**Operator:** It is the person assigned to the use of the device according to the procedures reported in the intended use.
### 3. Symbols

The use of symbols is seen in this manual and on the device, whose meaning is described in the following table.

<table>
<thead>
<tr>
<th>Symbols</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="General prohibition" /></td>
<td>General prohibition</td>
</tr>
<tr>
<td><img src="image" alt="Forbidden operation" /></td>
<td>Forbidden operation</td>
</tr>
<tr>
<td><img src="image" alt="Refer to user manual follow the instructions" /></td>
<td>Refer to user manual follow the instructions</td>
</tr>
<tr>
<td><img src="image" alt="General mandatory action" /></td>
<td>General mandatory action</td>
</tr>
<tr>
<td><img src="image" alt="Symbol for compliant with CE marking i.e. with applicable European directives" /></td>
<td>Symbol for compliant with CE marking i.e. with applicable European directives</td>
</tr>
<tr>
<td><img src="image" alt="Serial No." /></td>
<td>Serial No.</td>
</tr>
<tr>
<td><img src="image" alt="Model" /></td>
<td>Model</td>
</tr>
<tr>
<td><img src="image" alt="ON/OFF switch (mean of isolation from the supply means)" /></td>
<td>ON/OFF switch (mean of isolation from the supply means)</td>
</tr>
<tr>
<td><img src="image" alt="This is the type B equipment" /></td>
<td>This is the type B equipment</td>
</tr>
<tr>
<td><img src="image" alt="This product complies with EU Directive 2012/19/EC. The crossed bin symbol on the device indicates that the product must be treated separately from household waste at the end of its useful life, it must be taken to a different collection point for electrical and electronic equipment, or returned to the seller when buying a new piece of equivalent equipment. The user is responsible for transporting the equipment to the appropriate collection facilities at the end of its life. Proper collection for the subsequent delivery of the device intended for recycling, treatment and environmentally compatible disposal helps prevent a negative impact on the environment and human health, and promotes the recycling of the materials from which the product is made. For more detailed information concerning available collection systems, contact your local waste disposal service" /></td>
<td>This product complies with EU Directive 2012/19/EC. The crossed bin symbol on the device indicates that the product must be treated separately from household waste at the end of its useful life, it must be taken to a different collection point for electrical and electronic equipment, or returned to the seller when buying a new piece of equivalent equipment. The user is responsible for transporting the equipment to the appropriate collection facilities at the end of its life. Proper collection for the subsequent delivery of the device intended for recycling, treatment and environmentally compatible disposal helps prevent a negative impact on the environment and human health, and promotes the recycling of the materials from which the product is made. For more detailed information concerning available collection systems, contact your local waste disposal service</td>
</tr>
<tr>
<td><img src="image" alt="Symbol for “manufacturer”" /></td>
<td>Symbol for “manufacturer”</td>
</tr>
<tr>
<td><img src="image" alt="Manufacturing date" /></td>
<td>Manufacturing date</td>
</tr>
<tr>
<td><img src="image" alt="General warning signal" /></td>
<td>General warning signal</td>
</tr>
<tr>
<td><img src="image" alt="Pay attention if this signal is shown" /></td>
<td>Pay attention if this signal is shown</td>
</tr>
<tr>
<td><img src="image" alt="Warning: dangerous voltage" /></td>
<td>Warning: dangerous voltage</td>
</tr>
<tr>
<td><img src="image" alt="Pay attention if this signal is shown" /></td>
<td>Pay attention if this signal is shown</td>
</tr>
<tr>
<td><img src="image" alt="Symbol for prescription only. U.S. Federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner" /></td>
<td>Symbol for prescription only. U.S. Federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner</td>
</tr>
<tr>
<td><img src="image" alt="Protective earth (ground)" /></td>
<td>Protective earth (ground)</td>
</tr>
</tbody>
</table>
4. Classification

Classification

This device is compliant with CE marking.

Date of first marking: September 2018

Class I medical device

The expected life of the device and its components is 4 years.

a. Technical features

<table>
<thead>
<tr>
<th>Technical data</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supply voltage</td>
<td>100-240 VAC</td>
</tr>
<tr>
<td>Rated frequency</td>
<td>50/60 Hz</td>
</tr>
<tr>
<td>Internal voltage</td>
<td>24 VDC - 12 VDC - 5 VDC</td>
</tr>
<tr>
<td>Maximum absorbed power</td>
<td>52 VA</td>
</tr>
<tr>
<td>Maximum absorbed current</td>
<td>400 mA</td>
</tr>
<tr>
<td>Safety class</td>
<td>I</td>
</tr>
<tr>
<td>Applied part</td>
<td>Type BF</td>
</tr>
<tr>
<td>Dimensions</td>
<td>340 x 430 x 460 mm</td>
</tr>
<tr>
<td>Weight</td>
<td>14.7 kg</td>
</tr>
<tr>
<td>Sensor resolution</td>
<td>2.1 mpixels</td>
</tr>
</tbody>
</table>

b. Environmental conditions

<table>
<thead>
<tr>
<th></th>
<th>Temperature</th>
<th>Humidity</th>
<th>Atmospheric pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use</td>
<td>[10°C ; 40°C]</td>
<td>Maximum 90 % without condensation</td>
<td>[800hPa ; 1060hPa]</td>
</tr>
<tr>
<td>Storage</td>
<td>[0°C ; 60°C]</td>
<td>Maximum 90 % without condensation</td>
<td>[700hPa ; 1060hPa]</td>
</tr>
<tr>
<td>Transportation</td>
<td>[-10°C ; 60°C]</td>
<td>Maximum 90 % without condensation</td>
<td>[500hPa ; 1060hPa]</td>
</tr>
</tbody>
</table>

Lighting: for a more successful result, it is recommended to perform the exam in a dimly lit area.

The device does not meet the temperature requirements of ISO 15004-1 for storage. Do not store the device in conditions where the temperature may exceed 60°C or drop lower than 0°C.
5. INDICATION FOR USE

This device is an automatic eye-fundus camera intended for taking digital images of a human retina without the use of a mydriatic agent.

This manual has been drawn up taking the operator characteristics, knowledge, education level and training into account.

Operators using Retina800 must:

- Be adequately trained in the use of the device
- Be informed about the risks and side effects
- Be in possession of the qualifications required by law
- Read and understand every part of the user manual accompanying the device itself
- Carefully evaluate any contraindications performing an exam

Check the suitability of the environment prior to each use.

The operator is always entirely responsible for compliance and compatibility of the premises in which the product is used.

Like all electromedical devices, Retina800 requires special precautions as regards electromagnetic compatibility. The environment in which the device is used must comply with the characteristics set forth in the electromagnetic compatibility tables in the final section of the present document, and must also be connected to a compliant electrical system.

It is a class I medical device as in Annex IX to Directive 93/42/EEC amended by 2007/47/EC, is built in compliance with national and international regulations concerning medical devices.

The Retina800 medical device takes color photographs of the bottom of the retina with a retinal field of 45°. By means of the tablet, the doctor begins the automatic exam that results in a photo of the patient's retina, saved in the internal database of the device in .jpeg format. Retina800 is able to store acquired images and patient data in a local or remote database, through a secure data encryption system that complies with current privacy regulations.

The exam can be performed on all patients. The successful outcome of the exam (image quality of the retina) depends on the transparency of the optical channel that spans from the cornea to the retina (for example, this may be reduced in subjects with cataracts or crystalline lens with low transparency).

The use of this electromedical device on children and minors is prohibited without the assistance of adults.

Retina800 is comprised by a movable head equipped with optics, powered at 24 Vdc by means of an AC/DC adaptor (provided). To initiate the exam and view the image of the retina, a user interface is provided by a tablet (also included).

The device is only intended for exam of the retina as indicated herein.
It must be used within the limits and according to the procedures explicitly described by the manufacturer in this manual. The manufacturer is therefore deemed to be held harmless for all liability for damages resulting from misuse of the product by untrained persons, as well as any unauthorized modifications or interventions, including the use of parts other than those supplied directly by Essilor (or its authorized parties), exceptional events and the total or partial non-observance of the instructions in this manual.

**Where the device can be used**

The device can be used in hospitals, public and private health clinics and in public and private environments where eye or systemic and/or vision tests are carried out. The device can be used by medical personnel in collaboration with healthcare professionals and/or optometry professionals. Users must be adequately trained in the use of the device and informed about the risks and side effects and possess the qualifications required by law. The device, for the sole function of image acquisition and excluding the reporting (and clinical interpretation) part, can be used in self-acquisition mode by an appropriately trained person or assisted by appropriately trained personnel.

### 6. SAFETY REQUIREMENTS

**a. Contraindications**

No contraindication.

**b. Warnings**

This device is to be used for its intended use, according to the indicated instructions and directions for use. Essilor does not assume responsibility for damage to persons or property caused by improper use and/or misuse of the device, or for its use other than the function for which it was intended by its manufacturer.

The use of Retina800 assumes that the operator has knowledge of this manual and its user guide, as well as awareness of the risks related to improper use and misuse.

Therefore, it must not be used by persons who do not have adequate knowledge of the device and its methods/features of use, with the caveat that in the event of any questions and/or uncertainties about its operation and use, the operator will contact the authorized dealer and/or the manufacturer directly in order to acquire any clarifications and/or explanations, or, where necessary and expressly requested, specific assistance in the terms and procedures provided for in the receipts of purchase.

> Carefully read this manual and warnings before use the device.

The following must not be carried out, as they may compromise the compliance and/or the characteristics of the device:

- Incorrect installation
- Improper use
- Use of parts and/or third-party accessories that are not approved by the manufacturer
- Interventions and/or tampering by unauthorized personnel
- Lack of or improper maintenance
The warnings to be observed during installation, operation and maintenance of the device are contained below, in order to ensure the fulfilment of the requirements for operator and end-user safety as well as the proper functioning of the device.

- Any manipulation, replacement or operation performed on the device that is not carried out by Essilor personnel authorized shall void the warranty and exempt the manufacturer from any liability for direct and/or indirect damages that might be caused to persons or property.
- Use the power cord supplied with the product. Periodically check the integrity of the cable. Fully insert the plug into the mains socket on the rear side of the device.
- Use a power supply voltage between 100-240VAC 50/60Hz (not different from that listed on the plate).
- To avoid danger to persons or property, observe all nominal data and markings on the product. Consult the manual before making connections to the device.
- Avoid exposed circuitry. Do not touch exposed connections or components connected to power supply.
- Do not operate in the event of suspected fault or if cracks are present on the casing.
- If you suspect that the device is faulty and/or damaged, have it checked by specialized and approved personnel of the manufacturer.
- Avoid contact or penetration of liquids or powders into the device.
- Do not operate in a potentially explosive atmosphere and/or in the presence of flammable mixtures.
- Do not use Retina800 outdoors. It was designed and built for use in areas that are closed and protected from the elements.
- Use the device only with the original spare parts supplied by the manufacturer.
- Make sure that the features of the electric network comply with the power requirements of the device as indicated on its label and in this manual.
- Do not use devices other than Retina800 simultaneously on the patient.
- Do not use the device in environments with high electromagnetic fields that could cause Retina800 and other equipment in the surrounding area to malfunction. Do not keep mobile phones in the treatment area.
- The appliance must be installed and commissioned according to the EMC information contained in this manual.
- Portable and mobile radio communications equipment can affect the operation of the device.
- Do not operate near (within 1 m) of a device for short wave or microwave therapy.
- The use of accessories other than those supplied may adversely affect the electromagnetic compatibility performance of Retina800.
- Do not simultaneously connect the patient to a high frequency electrosurgical device.
- Caution: the use of controls and adjustments or the performance of procedures other than those specified herein may result in injury to the patient and the operator.
- It is recommended to use the device in dim room.

### Wifi

The minimum Wifi protocol requirements should be WPA-PSK o WPA2. It is excluded free network (without password) or WEP protocol because that are not safe against unauthorized access, malicious intent, and cyber-security threats.

The tablet is compatible with 2.4 GHz Wifi.
7. PRECAUTIONS

Retina800 may only be used by personnel trained to operate the device, and it is essential to carefully consider the following precautions.

- The device must only be operated and used by personnel trained on its usage techniques
- To prevent misuse by unauthorized personnel, the operator must log out of the management app at the end of each exam
- Perform cleaning and maintenance only after disconnecting the device from the mains and switching it off
- Perform maintenance of the device according to that indicated by the manufacturer

a. Special patient populations

The use of this electromedical device on children and minors is prohibited without the assistance of adults.

b. Adverse reactions

No adverse reactions.

c. Prescription devices

Caution: Federal (USA) laws restrict this device to sale by or on the order of a physician or a properly licensed practitioner.

The clinical interpretation of the images acquired by Retina800 is restricted to licensed eye care practitioners. The process of making a diagnosis using Retina800 results is the responsibility of the eye care practitioner. A device specific training is required for any operator to become able to use the system.

8. DISCLAIMER OF LIABILITY

The manufacturer assumes no liability for damages, accidents or injuries caused by failure to follow the requirements, directions and safety guidelines provided for in this manual.

Essilor will not cover any damages that may result from improper use and/or misuse of the product, nor will it respond in any way for any damage that may result from wear and tear, negligence, neglect, manipulation, incorrect/improper installation and/or connection of the products, or by improper use and/or misuse by the operator/end user of any third parties not authorized to use the device.
III. Supply Package
1. PACKAGING AND TRANSPORT

The device is contained in a cardboard box and adequately protected against vibration arising from a regular transport by means of specially shaped polyethylene foam. The box must be transported while maintaining it in the vertical position and avoiding bumps or jerks, and according to the environmental conditions of transport contained on the packaging.

Verify the integrity of the packaging upon receipt. If any damage to the packaging is noted, the operator who carried out the shipment must be immediately notified.

- If damage caused by transport is noted upon receipt of the device, the device must not be used and technical assistance must be contacted for an audit and revision of the device itself.
- The user must be fully aware of the contents of the manual and symbols.

2. UNPACKING AND STORAGE

It is necessary that the person unpacking the box has been trained as regards the risks of such operations.

To properly lift the box without jeopardizing the spine:

- Keep the back straight
- Keep the trunk upright
- Assume a squat position
- The weight lifted should be kept as close to the body as possible

Do not store the products above shoulder height.

The device must be stored in an area that complies with the environmental conditions for storage, as displayed on its packaging.

Bring the box to an area that is suitable for the extraction and installation of the machine's parts.

Open the package without the use of sharp objects that can damage its content.

Retain the packaging for reuse in the event of that the device needs to be shipped (such as for technical assistance), as the original packaging provides safe transportation.
### 3. Package Contents

Retina800 package contains the following items.

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device</td>
<td>![Device Image]</td>
</tr>
<tr>
<td>Tablet - Lenovo yoga with charger and micro USB cable</td>
<td>The tablet can store about 50000 images.</td>
</tr>
<tr>
<td>Mean well AC/DC adaptor GSM60A24 model</td>
<td>![Mean well AC/DC adaptor Image]</td>
</tr>
<tr>
<td>Detachable power cord</td>
<td>![Detachable power cord Image]</td>
</tr>
<tr>
<td>Lens cap</td>
<td>![Lens cap Image]</td>
</tr>
<tr>
<td>User manual</td>
<td>![User manual Image]</td>
</tr>
</tbody>
</table>
Optional accessory

Fundus adapter

Head

With:
1. Forehead rest*
2. Lens
3. Moveable head
4. Cheekbone rests*

*: Applied parts

Socket panel

1. LAN port
2. USB port
3. Battery connection port
4. ON/OFF button
IV. INSTALLATION OF THE DEVICE
1. **INSTALLATION**

Check the device for damage or dents that may have occurred during transport. If in doubt, contact your dealer or the manufacturer.

1. Place the contents of the box on a flat surface and check that all of the components are present and in good condition.

2. Connect the plug of the AC/DC adaptor into the socket on the base of Retina800 device.

3. Turn ON the tablet.

   If it does not turn ON, use the special charger and micro USB cable provided in its box.

4. Connect the AC/DC adaptor plug to a 100-240VAC, 50 / 60 Hz power supply.

   Or, that appropriate for the power requirements specified on the nameplate.

5. Press the power button (for about 3 seconds) until the corresponding green light comes on.
2. **Initial powering on**

Ensure that Retina800 is correctly mounted.

When powering ON for the first time, perform a device configuration. If there is a wireless network, enter the SSID and password; otherwise enter a SIM card enabled for traffic on the tablet.

Safety and patient well-being are the top priority during the use of Retina800. Follow the safety indications at the beginning of this manual, as well as all recommendations provided during the description of the device.

3. **First login**

Before you can use the device, a first connection procedure must be performed. It consists of creating an account (username and password), which will be required when turning on the tablet.

- [Username]: SerialNumber@essilor.fr
- [Password]: password

This password is temporary and you will be prompted to change it upon the first connection.

1. Go to the website https://retina800.essilor.com

> The following screen appears:

2. Fill in the fields.

Reminder:

- [Username]: SerialNumber@essilor.fr
- [Password]: password
3 Click on [LOGIN].

> A new password creation screen appears:

4 Create your own password and click [CONTINUE].

![Password creation screen]

Do not share your password, keep it carefully. The password allows you to log in to your account and see patients and exams performed.

> A PUK code is automatically generated.

![PUK code]

Make sure to save this code. This PUK code is required for all actions related to the account. It is the unique identifier for the product.

You will be asked for it in case of:

- A lost password
- Connection failure
- Tablet change
5. Click on [DOWNLOAD].

> The following screen appears:

![The following screen appears](image)

6. Enter the PUK code and click on [CONTINUE].

> The account is activated. You are logged in your reserved area.

4. **CHANGE PASSWORD**

1. Go to the website https://retina800.essilor.com

> The following screen appears:

![The following screen appears](image)

2. Fill in the fields.

Reminder:

- [Username]: username of your account
- [Password]: password of your account
3 Click on [LOGIN].

> The following screen appears:

![Login Screen]

4 Go on [PROFILE] section and click on [CHANGE PWD].

![Profile Screen]
The following screen appears:

- Fill the fields (current, new and confirm new password) and click on [SAVE].

- The password has been changed.
5. **RECOVER A LOST PASSWORD THROUGH THE PUK CODE**

1. Go to the website https://retina800.essilor.com

   >  The following screen appears:

   ![Login Screen]

2. Click on [forgot password? recover with your PUK].

   ![Forgot Password Screen]

3. Insert your username and click on [PROCEED].

   ![Recover PWD Screen]
The message [Request sent, check your mail for further details] appears.

You will receive the link to perform the change of your password.

The validity link is 24 hours.

Then, click on the link and fill the fields as shown below:

- [Username]
- [PUK code]
- [New Password]
- [Confirm new password]: insert again the new password and then click on [PROCEED]

> Your password has been changed.

6. **TURN ON/OFF THE TABLET**

a. **Switch ON the tablet and activate the APP**

The Retina800 user interface consists of the appropriate APP pre-installed in the supplied tablet, the various screens of the APP are shown below.

From each of the main screens you can immediately access all the other main screens using the menu on the left. From all the screens you can access the shutdown / log out feature using the round button at the top right.
1 Remove the tablet from the packaging and switch it ON with the power button located at the bottom left.

Navigation icons:

| ❯ Go back |
| Go to the first page (where you can set up): |
| • Wifi |
| • APN |
| • Date and time |
| • System language |

| ✗ Go to the first page (where you can set up): |
| • Wifi |
| • APN |
| • Date and time |
| • System language |

> A screen appears.
Click on the Essilor icon 🔄, enter your login and password and click on [SIGN IN].

After logging in with login and password, the [HOME] page will appear.

1. **[MACHINE]**
   Indicates whether Retina800 is ON or OFF.

2. **[DEVICE OUT RANGE]**
   Indicates whether Bluetooth communication between the tablet and the device is ON or OFF.
   If OFF, switch ON the Bluetooth communication of the tablet and/or bring the tablet closer to the device.

3. **[INTERNET CONNECTIVITY]**
   Indicates the tablet Wifi status.
4. **[PC SHARED FOLDER]**
   Allows the user to export retinal images from the tablet to a pc or to a server in an intranet Wifi environment.

5. **[DICOM CONNECTIVITY]**
   The connection with the DICOM interface is enabled and it is therefore possible to transmit the acquired images.

6. **[BATTERY]**
   Indicates the charge level of the tablet battery.

b. **Switch OFF**

1. Switch OFF with the power button located at the bottom left of the screen.
   > A message appears.

2. Click on [SHUTDOWN] or [LOGOUT].
   > The tablet is OFF.

3. Switch OFF the device pressing the green button and replace the cap on the front lens.
   > The device is OFF.

4. Leave the tablet under charge.
V. **Use of the Device**
1. **ENTER PATIENT**

To enter a patient click on [DO EXAM] by clicking on:

- The [HOME] page or,
- The side bar.

<table>
<thead>
<tr>
<th>[Home] page</th>
<th>Side bar</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Home page screenshot" /></td>
<td><img src="image2.png" alt="Side bar screenshot" /></td>
</tr>
</tbody>
</table>

> The following screen appears.

![New patient entry screen](image3.png)

2. From here, click on [ENTER NEW PATIENT].
Choose whether to proceed with:

1. **[QUICK ENTRY]**
   To be used when complete patient information is not necessary.

2. **[FULL ENTRY]**
   To be used when complete patient information is necessary.

3. **[IMPORT]**
   Select the import mode.
Verify that the device is positioned in a dim place and make sure that the front lens cap has been removed. The patient will position the head as shown, with forehead and cheekbones resting on the silicon parts.

With:
1. Forehead rest
2. Cheekbone rests

The patient’s eye must be positioned in the center of the cheekbone rests at the height of the blue bar.

To ensure greater comfort, the patient can place his/her hands on the areas at the bottom of the device.
2. **Perform an Exam**

To perform an exam:

1. On the [HOME] page click on [PATIENTS].
   
   > A list of patients appears.

2. Then click on [DO EXAM] icon.

3. Select the eye (left and/or right) and the type of fixation that you want to examine.
Then, click on [START].

> The machine will move by itself and when the exam is completed (after about 20 seconds), it will show the image of the retina.

> You can reject or accept the image. If you accept, the image will be saved in the tablet's memory.

3. APPLICABLE FEATURES

Retinal images can be filtered in different ways depending on what needs to be highlighted most. A more complete and detailed vision will thus allow to deepen the sections of the retina that are being examined.

In the image view section, the following features can be selected at the bottom left:

- [ACTIONS]
- [FILTERS]
- [COMPARE IMAGES]
a. [Actions]

On the [ACTIONS] tab you can choose between:

- [PATHOLOGIES]
- [REMOVE]
- [PRINT]
- [MOSAIC]
- [SEND EMAIL]
- [DRAW MANUAL CDR]
[Pathologies]
A doctor can enter and edit diagnostic notes using the [NOTE OD] and [NOTE OS].

1. Click on [ACTIONS] then [PATHOLOGIES].

The following screen appears:

2. Select the pathologies by checking the boxes and click on [UPDATE].
[Remove]

Remove definitively the image from the tablet.

1. Click on [ACTIONS] then [REMOVE].

> The image is removed from the tablet.

[Print]

Print the image selected.

By clicking here you can enter the print format, where you will be able to update the information on the patient or the doctor by entering the notes. It is possible to insert additional images, up to a maximum of 2, from those shown alongside.

1. Click on [ACTIONS] then [PRINT].
The following screen appears.

Click on [SELECT RETINAS].
The following screen appears.

Drag and drop the images of the exam performed.
4 Then click on [PRINT].

> The exam will then be sent to the printer that will have to be connected to the same network of the tablet and compatible with the android print drivers.

> Then, the printer selection it is shown.

5 Select paper size A4.

![Image of paper size selection]

The choice of the correct paper size is mandatory.

6 Then click on .
The mosaic functionality is used to merge together from a minimum of 2 to a maximum of 7 images of the different fixations previously acquired.

To perform the mosaic functionality, it is necessary to take at least 2 fixation images for each eye.

1. Click on [ACTIONS] then [MOSAIC].

The following screen appears.

The mosaic can be created from a minimum of 2 images to a maximum of 7.
2 Drag and drop the chosen images to make the mosaic.

3 Then, click on [CREATE MOSAIC].
The mosaic creation starts.

At the end, the mosaic appears.

You can reject or accept the image.
If you choose to accept the image it is possible to apply filters or compare images. For example:

> Mosaic image with [VASCULAR] filter:

Click on [FILTERS] > [VASCULAR]  
Then, click on [UPDATE]

> Mosaic image with [CHOROIDAL] filter:

Click on [FILTERS] > [CHOROIDAL]  
Then, click on [UPDATE]

> Mosaic image with [NERVE FIBRE] filter:

Click on [FILTERS] > [NERVE FIBRE]  
Then, click on [UPDATE]
> Mosaic image with [RED FREE] filter:

<table>
<thead>
<tr>
<th>Click on [FILTERS] &gt; [RED FREE]</th>
<th>Then, click on [UPDATE]</th>
</tr>
</thead>
</table>

[Send email]

To configure the email address, please go to the [Settings] chapter.

1. Click on [ACTIONS] then [SEND EMAIL].
The following screen appears.

2. Drag the images you want to send.

⚠️ The maximum size allowed to send images is 5MB.
Then, click on [WRITE EMAIL].

It is possible to edit the fields:

- Email
- Phone
- Subject
- Email text

If you had set the configuration of your email, the fields will be filled automatically. You can still edit the fields and who will receive the email but, the default settings described in the previous points will remain unchanged.

Then, click on [SEND].
> The user will then receive an e-mail of the type.

In order to view and download the images, it is necessary to click on [Click here to download].

> This will open a default browser window with the password entry request (the password is the phone number entered in the previous step, before clicking [SEND] on the tablet) and then click [SEND].

> The images obtained are then shown. Click on them to download them on your PC.
[Draw manual CDR]

You can modify the first drawing of CDR.

1. Click on [ACTIONS] then [DRAW MANUAL CDR].

For more information you can consult the filters section.

b. [Filters]

On the [FILTERS] tab you can choose to apply filters:

- [VASCULAR]
- [CHOROIDAL]
- [AUTOMATIC CDR]
- [MANUAL CDR]
- [NERVE FIBRE]
- [RED FREE]
Original image acquired by the device without any filter.

[Vascular]
Allows you to view images using a green filter.

Click on [FILTERS] > [VASCULAR]  
Then, click on [UPDATE]

[Choroidal]
Allows you to view images using a red filter.

Click on [FILTERS] > [CHOROIDAL]  
Then, click on [UPDATE]
[CDR] - Cup to disk

The functionality of the cup to disc allows to evaluate the excavation of the optic nerve, allowing the doctor to estimate the possible presence of glaucoma.

You can select two functions in isolation or in combination with the applicable filters.

1. [Automatic CDR]: the user interface itself proposes the creation on the image of the two ellipses cup and disc.
2. [Manual CDR]: the user himself performs the sizing of the two ellipses (cup and disc).

[Automatic CDR]

Click on [FILTERS] > [AUTOMATIC CDR] Then, click on [UPDATE]

![Automatic CDR](image)

[Manual CDR]

Click on [FILTERS] > [MANUAL CDR] Then, click on [UPDATE]

![Manual CDR](image)

If you choose:

- [DISC] > you can modify the dimensions and perform the rotation of the disc ellipse (circled in green)
- [CUP] > you can modify the dimensions and perform the rotation of the cup ellipse (circled in blue)
Then, the image with the modifications is displayed.

Filters on "Cup to disk"

It is possible to combine cup to disc feature with the other image filter and also to compare images with cup to disc and filters.

Please find below examples with the [Manual CDR] filter.

In both cases (automatic or manual), you just have to select the type of filter and click on [UPDATE].

> The image appears.
<table>
<thead>
<tr>
<th>Click on [FILTERS] &gt; [CHOROIDAL] &gt; [MANUAL CDR]</th>
<th>Then, click on [UPDATE]</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Image of choroidal filter]</td>
<td>![Image of choroidal filter with update]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Click on [FILTERS] &gt; [MANUAL CDR] &gt; [NERVE FIBRE]</th>
<th>Then, click on [UPDATE]</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Image of nerve fibre filter]</td>
<td>![Image of nerve fibre filter with update]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Click on [FILTERS] &gt; [MANUAL CDR] &gt; [RED FREE]</th>
<th>Then, click on [UPDATE]</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Image of red free filter]</td>
<td>![Image of red free filter with update]</td>
</tr>
</tbody>
</table>
[Nerve fibre]

Allows you to view images using a blue filter.

Click on [FILTERS] > [NERVE FIBRE]  
Then, click on [UPDATE]

[Red free]

Allows you to view images using a 50% blue and 50% green filter.

Click on [FILTERS] > [RED FREE]  
Then, click on [UPDATE]

c. [Compare images]

Allows comparisons of retinal images of the same patient.

Check the box [COMPARE IMAGES] to compare two images.
Then, select the image to be compared by choosing between the images on the right. The comparison of the two images is displayed.

It is also possible to combine the two functions shown above (comparison of images and filters applicable).

For example:

<table>
<thead>
<tr>
<th>Click on [FILTERS] &gt; [VASCULAR]</th>
<th>Then, click on [UPDATE]</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Click on FILTERS &gt; VASCULAR" /></td>
<td><img src="image2" alt="Then, click on UPDATE" /></td>
</tr>
</tbody>
</table>
4. CONSULT PATIENT RECORDS

1. To consult the record of a patient, on the [HOME] page click on [PATIENTS].

   > Then, the patients list appears.

2. Click on a patient’s name.

   > A screen appears, where in the lower section all the exams carried out can be scrolled using the grey arrows.

3. To enter an individual exam, click on it.

   > The images concerning that exam will appear.
VI. Settings
1. **DATE AND TIME**

On the [HOME] page, click on [DATE AND TIME].

> The user can set the date and time of the tablet.
2. Language

a. Change system language

1. On the [HOME] page, click on [SYSTEM LANGUAGE].

   > A list of available languages appears.

2. You can choose the desired system language from the list.

   > Click on it, the language will change.
b. Change APP language

1. On the [HOME] page, click on [ACCOUNT] and open the drop-down [LANGUAGE] menu.

2. You can choose the desired system language from the list.

3. Click on it, then on [UPDATE].

   > The language will change.

c. Change language on the tablet keyboard

1. At login, click either in the username field or in the password field, so that the keyboard is shown.
2. Hold the icon on the keyboard.

   > The following window will appear:

3. To add a language to those shown, click on [LANGUAGE SETTINGS].

   > A window appears, click on [ADD KEYBOARD].
You can choose the desired system language from the list.

The chosen language will then appear in the list.

Click on the icon to return to the App screen.
Click on the icon `@` on the keyboard.

The desired language will be set.

In all the screens in which a text field is inserted, the chosen language will be retained.

If you want to change the keyboard language, click on the icon `@` once if you want to set a language already on the list, or repeat the procedure described above to add a new language.
3. How to set ...

1. On the [HOME] page, click on [SETTINGS].

   > The following screen appears:

   ![Settings Screen]

2. You can now choose to set:

   - [RETINAS SHARING]
   - [PC SHARED FOLDER]
   - [DICOM]
   - [AI] - Artificial Intelligence
   - [Email Sending]

   a. ... [Retinas sharing]

   You can choose to:

   - Save images with patient information on the image file's name
   - Save images in json recognition format

   ![Retinas Sharing Setting Screen]
b. ... [PC shared folder]

Shared folder function allows you to export retinal images from the tablet to a PC or to a server in an intranet Wifi environment.

1. Create a shared folder on a Windows PC.

Example on Windows 7:

- Create a new folder by right-clicking the mouse where you want the folder to appear and selecting [New -> folder].
- Then right-click on the folder and select [Share with -> specific people...].
- Choose the username by using the combo box near the [Add] button, and press [Add].
  > The selected username should appear on the list under the button.
- Set the permission level to read/write and click on [Share], then [Done].
  > To check if everything is correct, right-click on the folder and select [properties -> sharing -> advanced sharing -> permissions]
  > Full control should be allowed (if it isn't, click the [allow] checkbox).
  > You can get more detailed, OS-specific instructions (OS is for Operating System) by googling for [Windows < your windows version > share folder].

For Windows 10: since the release of version 1709 (April 2018), a critical component has been disabled by default, and must be re-enabled by the user.

Go to [Control Panel -> Programs and Features -> Windows Features] and check the item [SMB 1.0 / CIFS File Sharing Support].

2. Take note of the name of the PC, the name of the shared folder, the username and the password. The password is the same that the user needs to log into Windows.

Try accessing the shared folder from another PC.

Examples: \192.168.1.100\FolderName or \JOHNDOE-PC\Test, with username and password chosen during step 1.

3. Try writing/deleting some files in that folder to make sure the remote PC has read/write permissions.
Take the tablet, make sure that it’s on the same network as the PC with the shared folder, and log in with the personal credentials (username and password).

- You should see an icon [PC SHARED FOLDER] on dashboard.
- At first the icon will be red (OFF).

⚠️ If there is no icon, try log out and then back in.

On the [HOME] page, click on [SETTINGS] and choose what kind of sharing you need:

- Either .jpg images with the patient’s info in the file name or,
- A combination of .jpg and .json files, the latter holding the patient’s info.

By selecting the [IMAGES WITH PATIENT INFO IN IMAGE FILE NAME] checkbox, you also get to choose what kind of information to display, and in what order, by using the combo boxes elements.

Below the combo boxes you also get an example of the resulting filename.

The option [IMAGES WITH PATIENT INFO IN THE JSON FILE] don’t have this kind of option, because all the patient’s info are contained in the .json: it’s up to the program that reads it to pick the information that it needs.
A combination of the above save mode solution is allowed.

If the DICOM server is set, you can also transfer the images in DICOM format (.DCM) in addition to the .jpg / .png format.

By scrolling up a bit, you will see a section titled [PC SHARED FOLDER].
The user can fill the fields using the data from step 1.

- **[HOST]**
- **[FOLDER NAME]**
- **[USERNAME]**
- **[PASSWORD]**
- **[DOMAIN]** (optional)

- **[HOST]** is the name or the IP address of the PC that contains the shared folder (i.e. laptopo-7gu05p3u or 192.168.1.100).
- **[FOLDER NAME]** refers to the name of the shared folder (i.e. FolderName or [Shared]).

Click on **[UPDATE]**.

Log out and then log in using your credentials.

- The active connections are shown in the **[HOME]** page.
> The icon [SHARED FOLDER] should turn green (ON).

From now on, every exam performed using this tablet should create a .jpg file and/or a .json in the shared folder on the PC.

If you need to re-send one or more exams:

1. On the [HOME] page, click on [PATIENTS] > [NEW PATIENTS].
   > You should see a column of checkboxes on the right (one for every patient).
2. Check the patients that you want to re-send.
3. Drop-down the menu at the top right and choose [SEND TO SHARED FOLDER].
   > The selected patients should appear as a set of .jpg and/or .json files on the shared folder.

Wait until the transfer is complete.
c. ... [DICOM]

You can set the DICOM server.

1. On the [HOME] page, click on [SETTINGS].

![settings page]

2. Enter the reference to fill in the fields.

3. Then, click on [UPDATE].

   > The settings are updated.

   > The active connections are shown in the [HOME] page.

![home page with connections]

   > If the status of the DICOM is [ON] the captured images are automatically sent to the DICOM server while still keeping the copy on tablet and server.
At any time, you can send the images to the DICOM server by clicking [PATIENTS] on the side bar and [DICOM UPLOAD] on the drop-down menu at the top right.

Then, wait until the transfer is complete.

---

d. ... AI (Artificial Intelligence) sharing images for software

To perform the correct setting in order to transfer the images on a user PC to be processed by a third-party software (not supplied by Essilor), proceed as follows:

1. On the [HOME] page, click on [SETTINGS].
2 Set the shared folder on PC.

3 Fill the fields.
   - [HOST]: PC name
   - [USERNAME]: PC account in which the folder in which the images will be transferred is created
   - [PASSWORD]: PC account
   - [FOLDER NAME]: name of the user's PC folder in which the images will be transferred

4 Click on [UPDATE].

⚠️ The folder on the PC must have enabled the "Advanced sharing", "Share folder" setting to transfer the images.

5 Then, click on [PATIENTS] > [NEW PATIENT].

6 Click on [SEND TO AI] to select the desired patients on the drop-down menu at the top right.

7 Wait until the transfer is complete.

   > On the PC folder, on the shared folder (set as shared folder) the AI folder will automatically be created with the images of the selected patients.
e. ... [Email Sending]

First, you have to set the email box configuration:

1. Go to the website https://retina800.essilor.com

   The following screen appears:

   ![Login Screen]

2. Fill in the fields.

   Reminder:
   - [Username]: username of your account
   - [Password]: password of your account

3. Click on [LOGIN].

   The following screen appears:
On the [PROFILE] section, click on [Email Template].

A window appears:

Fill the fields:

- [SUBJECT]: subject of the email
- [BODY]: body of the email
- [SIGNATURE]: signature that you can attach
- [ATTACHMENT]: file to be attached (pdf)
Then, click on [SAVE].

On the [HOME] page, click on [SETTINGS].

Go to [EMAIL SENDING] section.

From here you can edit the subject and text of the email.

Then, click on [UPDATE].
On [PATIENTS] section, choose a patient from the list and click on [EDIT].

> A window will open showing the user’s details.

Fill [EMAIL] and [PHONE].

It is necessary that both e-mail and phone number are inserted, as they are essential to proceed with the following steps.

Then click on [UPDATE].
Example:

1. Select the desired image.

   Click on [ACTIONS] then [SEND EMAIL].

   > The following screen appears.
2 Drag the images you want to send.

⚠️ The maximum size allowed to send images is 5MB.

3 Then, click on [WRITE EMAIL].

> It is possible to edit the fields:

- Email
- Phone
- Subject
- Email text
Automatically appear email, phone, subject and text of the email set in the previous steps. You can still edit the fields and who will receive the email but, the default settings described in the previous points will remain unchanged.

4 Then, click on [SEND].

> The user will then receive an e-mail of the type.

In order to view and download the images, it is necessary to click on [Click here to download].

> This will open a default browser window with the password entry request (the password is the phone number entered in the previous step, before clicking [SEND] on the tablet) and then click [SEND].
The images obtained are then shown. Click on them you can download them on your PC.

4. REMOTE SUPPORT (TEAMVIEWER) - OPTIONAL

This feature is used by both Essilor service personnel and the distributor in case it has been authorized by Essilor to perform remote support from a tablet. In the event that the distributor takes care of the remote support, he must have purchased the license of TeamViewer necessary to provide this type of support to its customers.

On the [HOME] page, click on ?.

The following screen appears:
2. Click on [TEAMVIEWER].
   
   > The QuickSupport TeamViewer will open.

3. Wait for the ID number.

   The ID must be communicated to the service personnel.
Once the ID has been communicated, the following screen appears:

4 Click on [ALLOW].

> A notification appears on the tablet.

> The sharing of the screen between your device and the staff is activate.
5. **Cloud access**

The access to the cloud allows you to:

- Have access to the patient datas and retina’s images from any web access.
- Make, save, download and print picture and report.

⚠️ You can’t perform exam from this website.

1. Go to the website https://retina800.essilor.com

   > The following screen appears:

   ![Login screen]

2. Fill in the fields.

   > The following screen appears:

   ![Patient information screen]
To add a new patient

1. On the [PATIENTS] section, click on clicking [Add new Patient].

> The following screen appears:

2. Fill in the fields and click on [SAVE].

> It is possible to modify the patient informations by clicking on the [PROFILE] section.
To modify or delete patient information

1. On the [PATIENTS] section, move the mouse over a patient line.
   - 2 icons appears:

2. Click on:

   - , to modify patient data. Then, click on [SAVE] to update patient data.

   - , to delete a patient. Then, enter your password and click on [CONFIRM] to delete the patient.
To edit a pathology

1. On the [PATIENTS] section, click on the patient name.

> The following screen appears:

2. Click on [EDIT PATHOLOGIES] to edit pathologies and proceed with the others images.

⚠️ You can add only 2 pathologies maximum per eye.

> The following screen appears:

> The pathologies will appear on the medical report.
To open an exam

1. Click on the date of the exam.

The following screen appears:

You can also select pathologies from here by clicking on the drop down menu on the right.
Then, select a filter by clicking on [FILTERS] at the bottom of the retina image.

The list of the filters appears.

Select a filter and click on [UPDATE].

To edit a report

Click on [REPORT].
The following screen appears:

Select each image you want to put on the report.

Only 1 image on the left and 1 image on the right image.

It is also possible to apply filter.
Then, click on [DOWNLOAD].

The report is downloaded on your device.

6. Telemedicine

The device provides its own telemedicine platform.

It is possible to setup a network made of several Retina800 units and one "Eye Doctor" which remotely makes the referrals on images taken with the device.

You need special credential to have telemedicine account.

Go to the website https://retina800.essilor.com

The following screen appears:

Fill in the fields.
3. Click on [LOGIN].

> The following screen appears:

![Login Screen]

⚠️ Each line corresponding to one Retina800 device.

4. Select the Retina800 whose you want to analyse images by clicking on the corresponding line.

> The exam datas appears.

Personal data are encrypted, telemedicine accounts have no access to them. Telemedicine account can see the patient's images by clicking on patient's code

> Click on the patient's code to see the patient image of the exam.
The following screen appears.

Click on [EDIT PATHOLOGIES] to edit pathologies and proceed with the others images.

You can add only 2 pathologies maximum per eye.

The following screen appears:
Once the evaluation is done the icon turns from grey to green.

On the [HOME] page click on [PATIENTS].

A list of patients appears.

At the end, on the column [REPORTING STATUS], the circle will be checked in green:
7. Retina800 Adapter - Optional Accessory

a. Overview

The Retina800 adapter is an optional accessory that allows you to download images acquired from a Retina800 to a PC.

The adapter is viewed from the USB PC with a maximum capacity of 7 Gbytes, enough to store around 40,000 images.

The images are transferred as soon as they are acquired by the device, as the tablet and adapter are within range. If they are too far apart, the images are put on hold until they are approached; when this happens, the transfer automatically precedes.

b. Initial configuration

1. Connect the USB cable of the adapter to any USB port on the user’s PC.

   If this is the first time you use the adapter, wait until the PC loads the appropriate drivers (which happens automatically).

> You will see a new Wifi network.
If the tablet is within range of the adapter, the corresponding icon on the [HOME] page turns green. In case the adapter is out of range, the actual image transfer will be put on hold.

The name of the .jpg images is taken from the patient's data; default is: "name + last name + NS code + date of the exam".

If you want to change it:

On the [HOME] page, click on [SETTINGS].

The following screen appears:
The settings page allows you to choose which data to use and in which order.

The only requirement is that you must enter the patient's first and last name and date of the exam.

The settings page will also show you an example of the name of the final file.
> Alternatively, you can share images in json format, by selecting the option.

c. Transfer of the image

The presence of the adapter does not change the way the device is normally used. Each accepted image will be transferred to the adapter and will be displayed in the USB folder.

1. From the [HOME] page, click on [PATIENTS].

> The list of patients appears.
Then select the patient whose data you want to export.

> You can choose one or more patients by selecting the appropriate check boxes.

You can also choose to select all the patients by clicking the checkboxes:
3. Then, click on [SEND TO RETINA800 ADAPTER] on the drop-down menu at the top right.

Wait until the transfer is complete.

Then, on the computer, select the adapter.

The patient's data appears in the adapter folder.

As soon as the adapter is connected to the PC, Windows may display an alert.

Recommendations

1. Always select "Safely Remove hardware" before disconnecting the adapter.
2. The USB memory of the adapter must be considered temporary.
   Once the transfer from the tablet is complete, you need to move the images to a PC hard disk for security reasons.
3. Do not use the adapter as a normal USB stick to store personal files or to create new directories.
VII. MAINTENANCE
This section shows the maintenance operations permitted for the operator to perform.

Maintenance must be carried out with the device turned OFF and the cable disconnected from the mains.

1. **Cleaning the device**

Cleaning of plastic parts and the casing must be done with a damp soft cloth. Always avoid directly spraying the parts of the device.

   a. **Cleaning the lens**

   Particular attention must be paid to the cleaning of the front lens in order to not remove the anti-reflection coating, decreasing its exam performance. "Berkshire Bluesorb® 750" cloth moistened with 96% neutral pure ethyl alcohol or moistened lens cleaning wipes can be used.

   b. **Cleaning the cheekbone and forehead rests**

   All parts in contact with the patient must be disinfected after each exam with a cloth moistened with a common disinfectant.

   ![No symbol] The use of jets or sprays of water or other substances that can damage the surfaces is not permitted.

2. **Periodic checks**

The integrity of the power cord and any cracks on the casing of the device or AC/DC adaptor must be checked on a weekly basis. In the event of breakage, immediately contact your service representative.
VIII. TROUBLESHOOTING
<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>The device does not switch ON</td>
<td>AC/DC adaptor is not plugged in</td>
<td>Connect the AC/DC plug adaptor to a power outlet with suitable power supply</td>
</tr>
<tr>
<td></td>
<td>The device is not connected to the AC/DC adaptor</td>
<td>Connect the jack of the AC/DC adaptor into the socket on the device</td>
</tr>
<tr>
<td>The tablet does not switch ON</td>
<td>Tablet batteries are not charged</td>
<td>Connect the tablet's charger and its micro USB cable to a power outlet with suitable power supply</td>
</tr>
<tr>
<td>Unable to log in on the initial screen of the tablet</td>
<td>No internet connection</td>
<td>If:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• the tablet is connected to a Wifi network, ensure that the network name and password are correct</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• the tablet is equipped with a SIM card, verify the remaining credit</td>
</tr>
<tr>
<td></td>
<td>Incorrect username and/or password</td>
<td>Ensure that the username and password are correct. If they have been forgotten, go to the Essilor website and follow the password recovery procedures</td>
</tr>
<tr>
<td>The device does not respond to commands sent via tablet</td>
<td>Wifi connection between tablet and the device failed</td>
<td>Connect the product to the Wifi network via tablet</td>
</tr>
<tr>
<td></td>
<td>The tablet is too far away from the device</td>
<td>Move the tablet closer to the device</td>
</tr>
<tr>
<td>The device's optical head continues to rotate without getting close to the patient</td>
<td>The device is unable to identify the patient's pupil</td>
<td>Remove the lens cover, if any</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ensure the correct positioning of the patient’s forehead and cheekbones on the appropriate rests</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ask the patient to keep the eye wide open during the exam</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The environment is too bright; turn OFF the lights in the room or reduce their brightness</td>
</tr>
<tr>
<td>The optical head slowly approaches the patient, then stops and turns back</td>
<td>The patient is blinking too frequently</td>
<td>Ask the patient to keep the eye wide open during the exam</td>
</tr>
<tr>
<td></td>
<td></td>
<td>This behavior is normal if it only occurs once or twice; otherwise it is possible that the patient has moved</td>
</tr>
<tr>
<td>The optical head quickly approaches the patient, then stops and turns back</td>
<td></td>
<td>Ask the patient to remain still for the duration of the exam</td>
</tr>
</tbody>
</table>
### List of error codes

<table>
<thead>
<tr>
<th>Code number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ERR 4</td>
<td>An error occurs retrieving your profile, please retry later</td>
</tr>
<tr>
<td>ERR 5</td>
<td>Change the default password in the web portal to access the application</td>
</tr>
<tr>
<td>ERR 6</td>
<td>Confirm the PUK in the web portal to access the application</td>
</tr>
<tr>
<td>ERR 7</td>
<td>Please check your credentials and retry</td>
</tr>
<tr>
<td>ERR 8</td>
<td>An error occurred while logging in</td>
</tr>
<tr>
<td>ERR 11</td>
<td>Check your internet connection</td>
</tr>
<tr>
<td>ERR 13</td>
<td>Please check your connection with the APP</td>
</tr>
<tr>
<td>ERR 14</td>
<td>An error occurred while inserting the patient</td>
</tr>
<tr>
<td>ERR 15</td>
<td>An error occurred while updating the patient</td>
</tr>
<tr>
<td>ERR 18</td>
<td>Session expired. Please log in again</td>
</tr>
<tr>
<td>ERR 19</td>
<td>An error occurred while updating the profile</td>
</tr>
<tr>
<td>ERR 21</td>
<td>An error occurred while checking for updates. If the problem persists, contact the support service</td>
</tr>
<tr>
<td>ERR 26</td>
<td>An error occurred while transferring images to shared folder. Check network connection, parameters needed for connection in Settings section and disk space availability on shared folder and then retry</td>
</tr>
<tr>
<td>ERR 34</td>
<td>An error occurred while sending email</td>
</tr>
<tr>
<td>ERR 35</td>
<td>An error occurred while exporting to the shared folder. Check network connection, parameters needed for connection in Settings section and disk space availability on shared folder and then retry. If the problem persists, contact the support service</td>
</tr>
</tbody>
</table>

⚠️ If the device continues to present any anomaly which limits (even in part) the correct operating conditions despite of the verifications and interventions listed above, it is compulsory for the operator and user to immediately contact the authorized technical assistance of the dealer or manufacturer.
IX. ASSISTANCE, NOTIFICATION, ALERT AND LABEL
1. **ASSISTANCE**

Never attempt to modify or disassemble this product yourself. It can result in malfunction or fire.

In case of malfunction, please contact your local Essilor technical support.

2. **NOTIFICATION & ALERT**

Any accident, malfunction and/or dysfunction, deterioration in the characteristics and performance of the device that has caused or may potentially be liable to cause harmful events for the operator/patient must be promptly reported by contacting the manufacturer, in order to take all appropriate measures, including recalls.

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FRANCE

3. **ID PLATE**

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4. **LABEL**

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This is the AC/DC switching adaptor identifying label.
X. GUIDANCE AND MANUFACTURER'S DECLARATION
1. **Electromagnetic Emission**

**Guidance and manufacturer’s declaration – electromagnetic emission**

Retina800 is intended for use in the electromagnetic environment specified below.

The customer or the end user of the Retina800 should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emission test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emission – CISPR 11</td>
<td>Group 1</td>
<td>Retina800 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.</td>
</tr>
<tr>
<td>Emission – CISPR 11</td>
<td>Class B</td>
<td>Retina800 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.</td>
</tr>
<tr>
<td>Harmonic emission</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td>Complies</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuation/flicker emission</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>
2. Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity

Retina800 is intended for use in the electromagnetic environment specified below. The customer or the end user of the Retina800 should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 Test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>±8 kV contact ±2, 4, 8, 15 kV air</td>
<td>±8 kV contact ±2, 4, 8, 15 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Transient/sequence of rapid electrical pulses IEC 61000-4-4</td>
<td>±2 kV for power supply lines ±1 kV for I/O lines</td>
<td>±2 kV for power supply lines Not applicable</td>
<td>The quality of the mains voltage should be that of a typical commercial or hospital environment. In case of 2 kV bursts on the power supply line, a malfunctioning of the selected fixation LED may occur, move the power supply to a free socket to which no other devices are connected.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±1 kV between phases ±2 kV between the phase(s) and the ground</td>
<td>±1 kV between phases ±2 kV between the phase(s) and the ground</td>
<td>The quality of the network voltage should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</td>
<td>0% U_T for 0,5 cycle 0% U_T for 1 cycle 70% U_T for 25 cycles 0% U_T for 250 cycles</td>
<td>0% U_T for 0,5 cycle 0% U_T for 1 cycle 70% U_T for 25 cycles 0% U_T for 250 cycles</td>
<td>The quality of the mains voltage should be that of a typical commercial or hospital environment. If the Retina800 user requires continued operation during mains power outages, it is recommended to use Retina800 with an uninterruptible power supply or batteries.</td>
</tr>
<tr>
<td>High frequency (50/60Hz) magnetic field IEC 61000-4-8</td>
<td>30 A/m</td>
<td>Not applicable, the device does not contain components susceptible to magnetic fields.</td>
<td>Magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

Note: U_T is the mains voltage in AC before applying the test level.
Guidance and manufacturer’s declaration – electromagnetic immunity

Retina800 is designed to work in the electromagnetic environment specified below. Retina800’s customer or user should ensure that it is used in that environment.

Portable and mobile RF communications equipment should not be used closer to any part of, including cables, than the recommended separation distance calculated with the equation applicable to the transmitter frequency.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 Test level</th>
<th>Compliance level</th>
<th>Recommended separation distance d:</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Conduct</td>
<td>3 Veff from 150kHz to 80 MHz</td>
<td>3 Veff</td>
<td>d= 30 cm</td>
</tr>
<tr>
<td>RF Irradiated</td>
<td>3 V/m from 80 MHz to 2,5 GHz</td>
<td>3 V/m</td>
<td>d= 30 cm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Immunity to proximity fields by wireless RF communication devices</th>
<th>IEC 60601 Test level</th>
<th>Compliance level</th>
<th>Recommended separation distance d:</th>
</tr>
</thead>
<tbody>
<tr>
<td>TETRA 400 380 – 390 MHz, GMRS 460 430 – 170 MHz, LTE Band 13, 17 704 – 787 MHz, GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 800 960 MHz, GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 5 1700 – 1990 MHz, Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 70 2400 – 2570 MHz, WLAN 802.11 a/n 5100 – 5800 MHz</td>
<td>27 V/m</td>
<td>27 V/m</td>
<td>d= 30 cm</td>
</tr>
</tbody>
</table>

FCC radio module

Retina800 device contains a radio module that complies with regulations of the USA:

FCC ID: TFB-TIWI1-01

These devices comply with part 15 of the FCC rules.

As reported on the labeling, "Contains Transmitter Module FCC ID: TFB-TIWI1-01".
XI. QR Code
The complete user manual is available on the web. To access it, please scan the QR code below using a dedicated application.
A teljes használati útmutató megtalálható a webes felületen. A hozzáféréshez, kérjük, olvassa le a lenti QR-kódot a megfelelő alkalmazás használatával.

Panduan pengguna yang lengkap tersedia di web space. Untuk mengaksesnya, silakan pindai kode QR berikut dengan menggunakan aplikasi khusus.

Il manuale utente completo è disponibile su uno spazio Web. Per accedervi, scansionare il codice QR seguente mediante un'applicazione dedicata.

ユーザーマニュアル完全版はウェブサイト内で閲覧いただけます。それにアクセスするには、専用アプリケーションを使用して以下のQRコードをスキャンしてください。

Pilnā lietotāja instrukcija ir pieejama tīmekļi. Lai tai pieklūtu, lūdzu, noskenējiet tālāk redzamo QR kodu, izmantojot tam paredzētu lietojumprogrammu.

Išsamaus naudotojo vadovo ieškotie interneto svetainėje. Kad jį atvertumėte, specialia programėlę nuskaitykite toliau pateiktą QR kodą.

Manual pengguna yang lengkap boleh didapati di ruangan web. Untuk akses, sila imbas kod QR di bawah menggunakan aplikasi yang berkena.

Den komplette brukerhåndboken er tilgjengelig på et webområde. For å få tilgang, må du skanne QR-koden nedenfor ved hjelp av en dedikert applikasjon.

De volledige gebruikershandleiding is beschikbaar op een website. U kunt de handleiding bereiken door de QR-code hiernaast te scannen met een geschikte applicatie.

Kompletna instrukcja użytkownika jest dostpna na stronie internetowej. Aby uzyskać dostęp, zeskanuj poniższy kod QR przy użyciu dedykowanej aplikacji.

O manual do utilizador completo está disponível num espaço web. Para aceder, queira digitalizar o QR code seguinte com a ajuda de uma aplicação dedicada.

Celá uživatelská příručka je k dispozici na webu. Pro přístup k ní oskenujte níže uvedený QR kód pomocí specializované aplikace.

Versiunea integrală a manualului de utilizare este disponibilă pe un site web. Pentru a-l accesa, scanați codul QR de mai jos cu ajutorul unei aplicații dedicate.

Полное руководство пользователя доступно на сайте. Чтобы получить к нему доступ, сканируйте QR-код ниже с помощью специального приложения.
Potpuno korisničko uputstvo je dostupno na vebu. Da biste mu pristupili, skenirajte QR kód u nastavku pomoću namenske aplikacije.

Celý používateľský manuál je dostupný na internete. Aby ste sa k nemu dostali, naskenujte QR kód nižšie pomocou to určené aplikácie.

Celoten uporabniški priročnik je na voljo na spletnem mestu. Za dostop do njega skenirajte spodnjo kodo QR z uporabo namenske aplikacije.

Den fullständiga handboken finns på en plats på Internet. Skanna QR-koden nedan med en lämplig app för att få åtkomst till den.

มีคู่มือผู้ใช้ฉบับสมบูรณ์ให้ที่เว็บไซต์ เพื่อเข้าถึงข้อมูล กรุณาสแกน QR ด้านล่างนี้โดยใช้แอปพลิเคชั่นเฉพาะงาน


Повний посібник користувача доступний на сайті. Щоб отримати до нього доступ, скануйте QR-код нижче за допомогою спеціального додатку.

Câm nang hương dân sử dụng hoan chinh hiện có trên không gian web. Để truy cập, vui lòng quét mã QR bên dưới sử dụng ứng dụng chuyển dung.