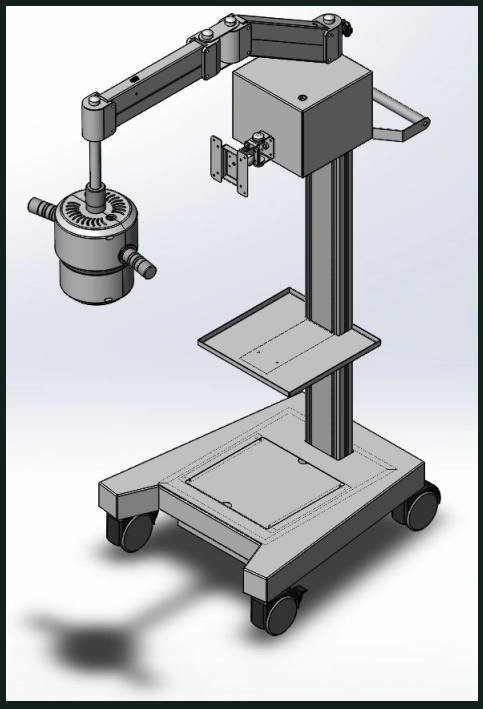
EVOptica

OPHTHALMIC INSTRUMENTS / ENGLISH EDITION

WaveLink

User Manual

TECHNICAL REVIEW EDITION



Full English translation of the supplied manual. Source inconsistencies are identified for technical review. This document is not a released clinical IFU for a new US configuration.

evoptica.com contact@evoptica.com

About this English edition

This edition translates the supplied original instructions and updates the corporate identity and contact details to EVOptica. It does not change instrument operation, calibration values, treatment parameters or the documented software behavior.

TECHNICAL REVIEW EDITION - NOT A RELEASED CLINICAL IFU

The supplied originals contain unresolved configuration differences, malformed values and, in places, text apparently copied from other instruments. These differences have been identified without guessing a correction. Manufacturer engineering and clinical review is required before releasing instructions for a specific product configuration.

Navigation and original references

Source section numbers below refer to pages in the supplied original. The English layout has its own footer page numbers. The linked section list and PDF bookmarks navigate this edition; original figure, table and contents references retain their source context.

Screenshots and interface labels

Illustrations document the original software interface. Portuguese button labels are retained where needed and paired with English descriptions. This translation does not imply that the underlying software has been localized or that obsolete operating systems and network settings are a new configuration recommendation.

The full configuration and source-review notes appear after the translated instructions. Resolve those notes before releasing this document for a specific instrument configuration.

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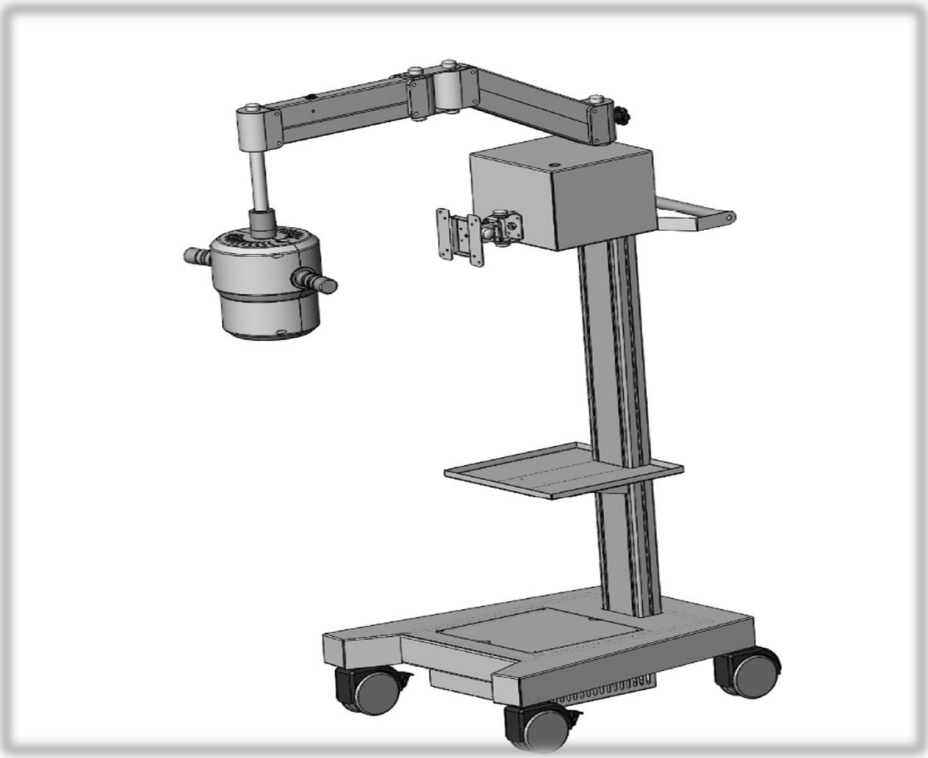
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SOURCE SECTION 1

WAVELINK User Manual

Version 01

Illustrations - source section 1



Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 2

Instructions for Use - User Manual

PRODUCT: WAVELINK - CROSS-LINK

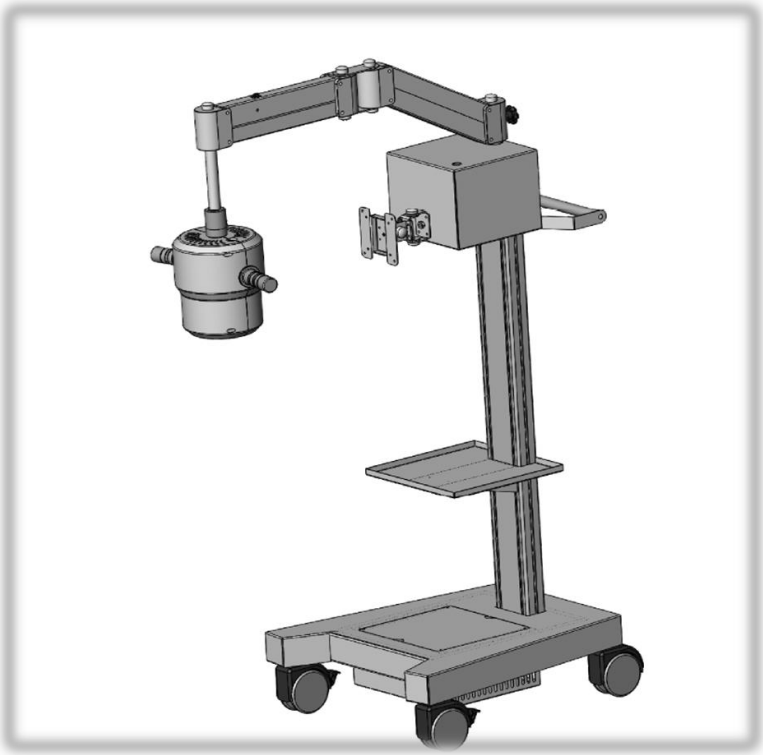
MODEL: WAVELINK 1.0

EVOptica. 221 S Main St, Fairport, NY 14450, USA. Call/text: +1-315-210-8976. contact@evoptica.com. https://evoptica.com. All rights reserved.

Partners

Our company's success owes much to the support of institutions and businesses.

Illustrations - source section 2



Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 3

We are therefore grateful to them and will continue to count on their support.

SOURCE SECTION 4

Conventions and Abbreviations Used in This Manual

USP: University of São Paulo.

UFSCar: Federal University of São Carlos.

IPD: Parqtec Design Institute.

PDF: Adobe Acrobat Reader document format (www.adobe.com).

SOURCE SECTION 5

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SOURCE SECTION 8

Introducing the Company

The original instrument manufacturer was a high-technology company, a spin-off of former students and professors from USP, UFSCar and UNIFESP, founded in 2006. With extensive scientific knowledge and a technical staff recruited from leading universities and technical schools such as SENAI, it described itself as changing the international landscape for the development and production of high-quality ophthalmic instruments. At publication, it had three successful instruments and was launching three additional advanced instruments that year, with American and European standards of finish. Its main aim was to produce high-quality ophthalmic instruments.

The original company was based in São Carlos, inland São Paulo, Brazil, a city of approximately 220,000 people known as the “Technology Capital.” The source describes São Carlos as having one of the world’s highest concentrations of PhDs, behind only certain centers of excellence in the USA and Europe. Its technological strength comes principally from campuses of two leading Brazilian universities (USP and UFSCar), approximately a dozen high-standard technical schools (SENAI, SENAC, Industrial School and others), and technology incubators such as ParqTec and Science Park, both managed by Prof. Dr. Sylvio Rosa.

WAVELINK - Intelligent Cross-Linking

Corneal cross-linking* using riboflavin and UV light is a modern, effective technique, primarily indicated for patients with keratoconus and other corneal ectasias, including certain post-LASIK cases. WAVELINK was conceived and developed by the original manufacturer in partnership with a renowned California company and introduced and manufactured in Brazil. The original source promised “permanent warranty and technical support throughout Brazil.” This is historical source language, not a current EVOptica U.S. warranty or service contract. Contact EVOptica for current terms.

SOURCE SECTION 9

1. Introduction to Cross-Linking

1.1. Corneal Cross-Linking with WAVELINK

Corneal cross-linking using riboflavin and UV light has been applied successfully since research began in Germany in the 2000s. It involves applying a riboflavin (vitamin B) solution to the eye and activating it with UV irradiation for periods ranging from 3 to 30 minutes. Once activated, riboflavin causes adjacent collagen bands to form new molecular bonds that restore and preserve corneal mechanical strength. The epithelium is usually removed to improve riboflavin penetration, although procedures without removal also exist.

This modern, effective technique is primarily indicated for keratoconus and other corneal ectasias, including certain post-LASIK cases. WAVELINK was conceived and developed by the original manufacturer in partnership with a renowned California company and introduced and manufactured in Brazil. The original source promised “permanent warranty and technical support throughout Brazil.” This is historical source language, not a current EVOptica U.S. warranty or service contract. Contact EVOptica for current terms.

SOURCE SECTION 10

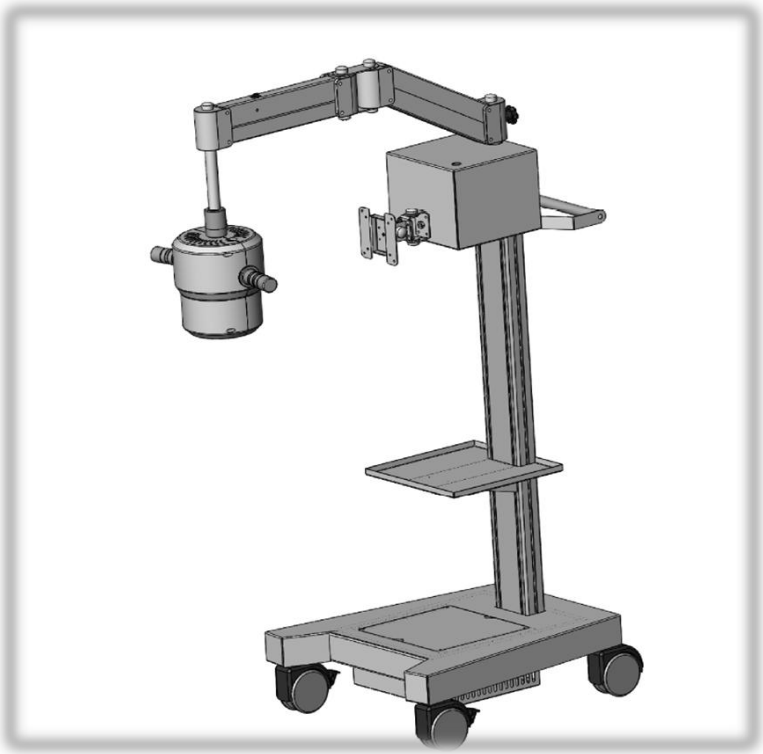
2. Revolutionary Optics

WAVELINK technology includes: a laser eye-alignment system with adjustable power, allowing quick, easy positioning of the eye optics; a fixation LED to help the patient maintain position throughout procedures lasting up to 30 minutes; and computerized adjustment of light-beam diameter from 4 mm to 11 mm.

3. Dedicated Riboflavin and High Return

WAVELINK procedures are easy to program and perform. Both instrument software and hardware are robust and reliable. This efficiency makes WAVELINK an ally for physicians and clinics in achieving a return on its use. Each procedure can be adjusted from 3 to 30 minutes, providing maximum treatment flexibility and allowing advance scheduling

Illustrations - source section 10



Original instrument or software illustration. See the English instructions and interface labels in this section.



SOURCE SECTION 11

of the ideal number of patients for each session. The riboflavin used with WAVELINK was developed for its specific characteristics and is sold by the company itself.

WARNING: Clinics and physicians must be adequately trained in the procedures before operating the Cross-Link equipment. This User Manual must be studied and understood before operating the equipment on any patient.

CAUTION: Use of controls, adjustments or procedures other than those specified here may result in exposure to hazardous radiation.

CAUTION: Any modification of the ophthalmic device will require equipment reclassification.

CAUTION: The source states that the law restricts sale of this device to a physician's order.

This Operator Manual contains confidential, proprietary manufacturer information.

EVOptica, 221 S Main St, Fairport, NY 14450, USA.

4. WAVELINK Requirements

This manual provides an overview of the safety and operating requirements of the corneal Cross-Link system.

Illustrations - source section 11



SOURCE SECTION 12

This manual is not intended to provide treatment-procedure instructions. Users are expected to have completed appropriate training before using the equipment. The source states that the manufacturer and distribution organization assumes responsibility for system use.

Every care was taken in preparing and checking this manual, but there is no guarantee that all information is correct. Information is subject to change without notice. The Cross-Link system may be used with approved accessories. The manufacturing and distribution organization is not responsible for loss or damage caused by unapproved accessories.

All maintenance and service work must be performed by trained, authorized service personnel. Only procedures described in the operator and service manuals are permitted. Maintenance by unauthorized persons voids all warranties.

Circuit diagrams and parts/component lists are not supplied. If technical documentation not provided here is needed, contact the manufacturer or local distributor in writing, explaining why it is needed; a service manual copy may then be supplied.

Before using the corneal Cross-Link system, read this manual carefully, paying particular attention to safety, operation and maintenance.

5. Safety

This corneal Cross-Link system was designed and tested to operate safely and correctly when used as directed here. DO NOT use it before reading and fully understanding this User Manual.

This manual provides the information required to operate the corneal Cross-Link system correctly. Its purpose is to familiarize the user with all equipment functions, demonstrate how to achieve the intended treatment and ensure patient safety. For assistance and guidance, contact technical support at contact@evoptica.com.

SOURCE SECTION 13

Only duly identified physicians, or persons under their supervision, may operate this equipment (the “user”). The user is responsible for understanding the complete protocol for equipment use, prescription and application to an individual patient, and the dosage of photosensitive medications administered to that patient.

The source states that the ultraviolet photosensitive light is not an integral part of the corneal Cross-Link system; its acquisition, storage and handling are the user’s responsibility.

5.1. Warnings and Precautions

The following warnings and precautions apply to WAVELINK and must always be observed by all users. Do not attempt maintenance or repairs beyond those included in this manual. Maintenance may only be performed by trained, authorized EVOptica personnel. Set the correct spot size and/or use the setting most appropriate for the power and procedure type. All modifications or repairs must be carried out by qualified professionals approved by EVOptica. For safety, unauthorized persons must never open the equipment, to avoid dangerous situations.

Always use nationally or internationally scientifically recognized clinical protocols. Correct operation depends on installation and selection of a suitable operating location. A grounded outlet, or connection of the grounding pin to the site’s earth connection, is specifically recommended. Unspecified controls, adjustments or procedures may expose the user to hazardous UV radiation. Read these instructions and always observe the specific requirements for the equipment’s indications.

Do not operate in the presence of flammable gases. Take particular care to avoid areas containing flammable or oxidizable anesthetic gases. The equipment is unsuitable for use near a flammable anesthetic mixture with air, oxygen or nitrous oxide. Do not direct the beam at flammable materials such as cotton.

SOURCE SECTION 14

Switch the equipment off when it is not in continuous use and secure the area against handling or use by unqualified persons. Do not obstruct the optical module ventilation grille. Clean only with the equipment switched off, using a clean, slightly damp cloth. DO NOT use solvents or abrasive cleaners. Avoid fire and/or explosion hazards when the light outlet is close to flammable materials. Local environmental regulations may govern disposal of toxic products. For disposal, contact the local distributor and/or EVOptica directly.

5.2. User Safety

WAVELINK is ultraviolet-emitting electromedical corneal equipment developed according to international safety standards. For UV-emitting equipment, avoid skin and eye exposure to the beam when treatment is not being performed. Operators must not look directly into the beam or point it at skin. Take special care to prevent reflected light from mirrored surfaces accidentally reaching the eyes. Protective eyewear against UV light is essential. Contact EVOptica technical support with questions.

Opening the equipment presents an electric-shock hazard. Only EVOptica-authorized technicians may open and maintain it. Use in areas with flammable gases, anesthetics or liquids is not recommended.

SOURCE SECTION 15

EVOptica is not directly or indirectly responsible for property damage, personal injury or financial losses arising from improper use. The user is responsible for taking all indicated precautions.

5.3. Patient Safety

WAVELINK must be operated by an ophthalmologist knowledgeable about corneal treatment. Position the patient lying on a comfortable reclining stretcher or bed in a calm environment without major distractions. Administer the photosensitive drug riboflavin and/or UV light carefully, in appropriate quantities, to avoid possible eye damage.

5.4. Safety Controls

WAVELINK must meet the various previously mentioned standard requirements. All safety features and controls must be engaged for correct system operation.

5.4.1. Emergency Stop

This switch rapidly shuts off UV light if a serious problem occurs. It is a red push switch that latches when pressed. In a power failure, manual intervention is unnecessary because WAVELINK has an automatic activation system.

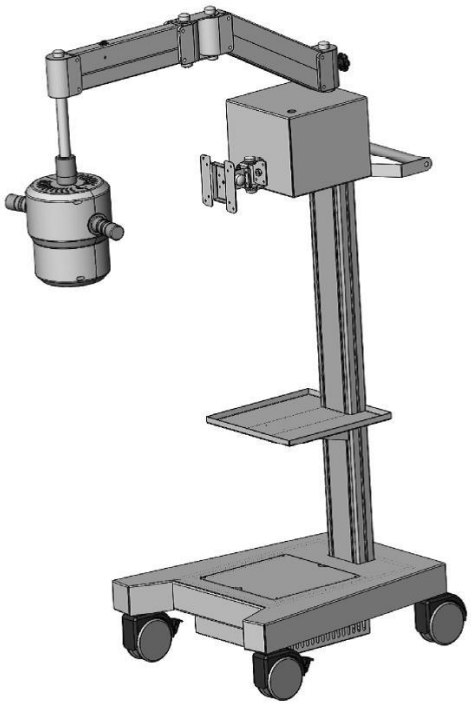
SOURCE SECTION 16

5.4.2. On/Off and Other Buttons

The on/off button is operated on the front equipment box. Power can only be activated using the buttons shown in the original illustration.

Emergency button. Figure 1 - Emergency button.

Illustrations - source section 16



Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 17

5.4.3. Important Notes

The safety control prevents the operator from inadvertently activating UV light. The UV system has protective housings that shield exposure to UV emissions. Special tools are needed to remove them; only authorized persons may do so. The UV system was designed to comply with safety standards, including earth leakage requirements. An audible warning sounds whenever UV light is emitted.

WAVELINK is a very safe instrument when correctly used as directed in this manual.

6. WAVELINK Product Labels

All WAVELINK labels must meet the previously mentioned regulatory standards. Labels fitted to the instrument are listed on the next page.

Figure 2 - WAVELINK front box. ON/OFF; EMERGENCY BUTTON; USB PORTS; RESET BUTTON; MAIN SWITCH.

Illustrations - source section 17



Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 18

Warranty label; electronic-system release-for-use labels; optical-system approval labels; company logo label; serial-number label.

7. Product Specifications

The WAVELINK specifications follow.

Specification	Value
Ultraviolet wavelength	365 nm ± 5 nm.
Ultraviolet light source	LED-cluster UV system.
Maximum power range	limited to 30 mW/cm².
Irradiance	adjustable, 0.05 mW/cm² - 30 mW/cm².
Energy monitoring	automatic, integrated power monitor with feedback loop.
Operating interface	10.4-inch color LCD touchscreen with built-in PC.
Pulse duration	adjustable, 10 s - 30 min.
Calibration	automatic.
Integrated energy meter	yes.
Output error - maximum power	<10%.
Spot sizes	module 4 - (10-13 mm), continuously variable; optional 11 mm.
Treatment-beam homogenizer	four ultra-efficient LEDs in a cluster system with twin homogenizer.
Working distance	55 mm.
Aiming beam	670 nm diode laser.
Aiming-beam power	<1.0 mW.
Video system	integrated high-resolution system with camera autofocus.

Source specification ambiguity: the spot-size entry is printed as “Module 4 - (10-13 mm), continuously variable & optional (11 mm).” This differs from the 4-11 mm range stated on source page 10 and remains unresolved.

SOURCE SECTION 19

Table 1 - Product specifications.

Specification	Value
Floor stand	height-adjustable with integrated pantographic arm.
Operating voltage	90-240 VAC, 50/60 Hz, Auto-Ranging & Opt. 30 min (as printed; the meaning of “Opt. 30 min” is unresolved).
Dimensions (cm)	130 cm (H) × 128 (W) × 40 cm (L).
Weight	48 kg.
Electrical input	single-phase, 100-230 VAC, 50/60 Hz.
Power	150 W.
Fuse (time-lag)	T3.15AH250V @ 100-230 VAC.
Temperature	transport -10 to 70 °C; operation 15 to 30 °C; storage -10 to 55 °C.
Relative humidity	operation 30%-85%, noncondensing; storage and transport up to 95%, noncondensing.
Atmospheric pressure	operation 800-1060 mbar; storage and transport 500-1060 mbar.
Cooling system	air-cooled.

The source lists operating voltage as 90-240 VAC and electrical input as 100-230 VAC. Both entries are retained without reconciliation.

SOURCE SECTION 20

8. Principles of Operation

8.1. General Description

The WAVELINK Cross-Link system was designed as a safe, highly sophisticated medical device. All modules are individually tested and calibrated to the highest standards and optimum accuracy. Only duly identified ophthalmologists or persons under their supervision (the “user”) may operate it. The user must know and understand the complete treatment protocol and how to administer the photosensitive solution (riboflavin) dosage.

The source describes four main parts and lists: wheeled base/control box; LCD touchscreen; UV light; arm; light head. The control box distributes the power supply. System software and touch controls are built into the LCD module. Wiring and connections are incorporated into the light arm.

UV light is generated by the UV head, which contains the control electronics, CCD camera, illumination and UV LEDs. Software controls and commands the UV head to initiate treatment light according to user preferences. It then communicates with and validates the installed system hardware before proceeding to processing.

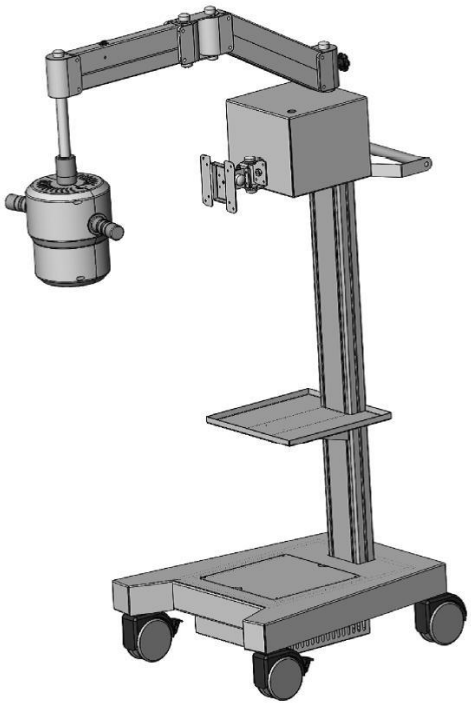
SOURCE SECTION 21

9. WAVELINK Controls and Displays

All WAVELINK controls are on the control box or touchscreen.

Figure 3 - Cross-Link controls diagram: OPTICAL HEAD; LCD TOUCHSCREEN; CONTROL BOX; PANTOGRAPHIC ARM; ON/OFF AND RESET BUTTON; EMERGENCY; MAIN SWITCH; WHEELS.

Illustrations - source section 21



Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 22

10. Wheeled Base and Control Box

All electronic components are brought together here, as described below.

(1) Connectors communicating with the optical head. (2) USB ports. (3) Main button. (4) Touchscreen monitor. (5) On/off and reset button. (6) Movable touchscreen support - left/right movement. (7) Emergency stop. (8) Instrument support. (9) Compartment: hard drive, power supply, latest-generation Intel processor and other computer-system components. (10) Swivel caster system - movement in all directions, with brakes for safety at the workstation.

Figure 4 - Wheeled base and control box.

Illustrations - source section 22



SOURCE SECTION 23

Notes

(1) Connectors beneath the control box provide all communication with the WAVELINK optical head.

(2) USB ports support accessories including mouse, keyboard and USB drive.

(3) The WAVELINK main button indicates power.

(4) The touchscreen eliminates the need for peripherals such as a mouse and keyboard.

(5) The on/off button switches the WAVELINK computer on and off.

(6) The movable support allows the touchscreen to be moved left or right.

(7) Emergency stop rapidly shuts down the UV-light system if a serious problem occurs. This red safety switch latches when pressed, removing all internal power in that position.

(8) The instrument support holds instruments and accessories needed during treatment.

(9) The compartment containing cables, hard drive and processor is sealed. Improper maintenance voids the WAVELINK warranty. Only EVOptica-authorized persons and specialized technicians may maintain WAVELINK.

(10) The caster system allows the physician to move the instrument between locations. Brakes secure it in the appropriate position.

SOURCE SECTION 24

11. Operating WAVELINK Software

11.1. Main Screen - Login

Figure 5 - Login.

A) List of registered physicians. B) Password field, if the selected physician has a password. C) After entering login details, click Enter (Entrar).

When first switched on, the main screen appears. A default user without a password is registered with Administrator privileges. Select the default user and click Enter to log in. The software menu then appears; see Figure 6.

Illustrations - source section 24



Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 25

11.2. Menu

Figure 6 - Menu. A) Logout ends the logged-in physician's session. B) Settings opens the menu shown in Figure 7. C) New Procedure (Novo Procedimento) opens the new-procedure screen. D) Review Procedure (Rever Procedimento) opens the completed-procedure review screen. E) Exit (Sair) closes the software.

Illustrations - source section 25



Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 26

Figure 7 - Settings. A) The Settings menu displays all software configuration options.

Illustrations - source section 26



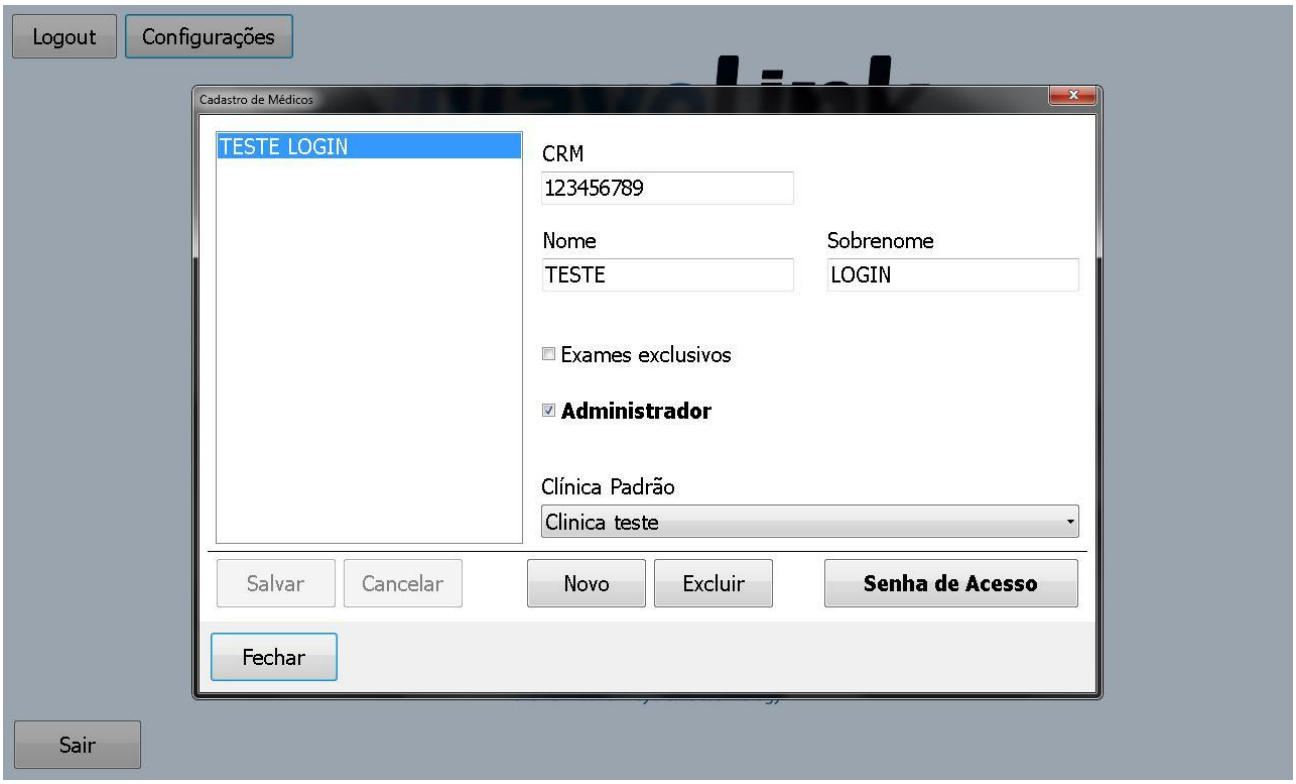
Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 27

11.3. Settings - Physician Registration

Figure 8 - Physician registration. A) All registered physicians: click a name to select it and view its details. B) Physician details: CRM registration number, FIRST NAME and SURNAME. C) Exclusive Examinations (Exames Exclusivos): when selected, only the physician who performed a procedure can view it. D) Administrator: when selected, the physician can modify and access every system function; nonadministrators cannot change settings. E) Select a default clinic to be preselected for report headers whenever this physician generates a report. F) Save (Salvar) saves all additions and changes. G) Cancel (Cancelar) cancels an addition or change in progress. H) New (Novo) enables the form for adding a physician. I) Delete (Excluir) removes the selected physician. J) Opens the form for adding or changing the login password; see Figure 9.

Illustrations - source section 27



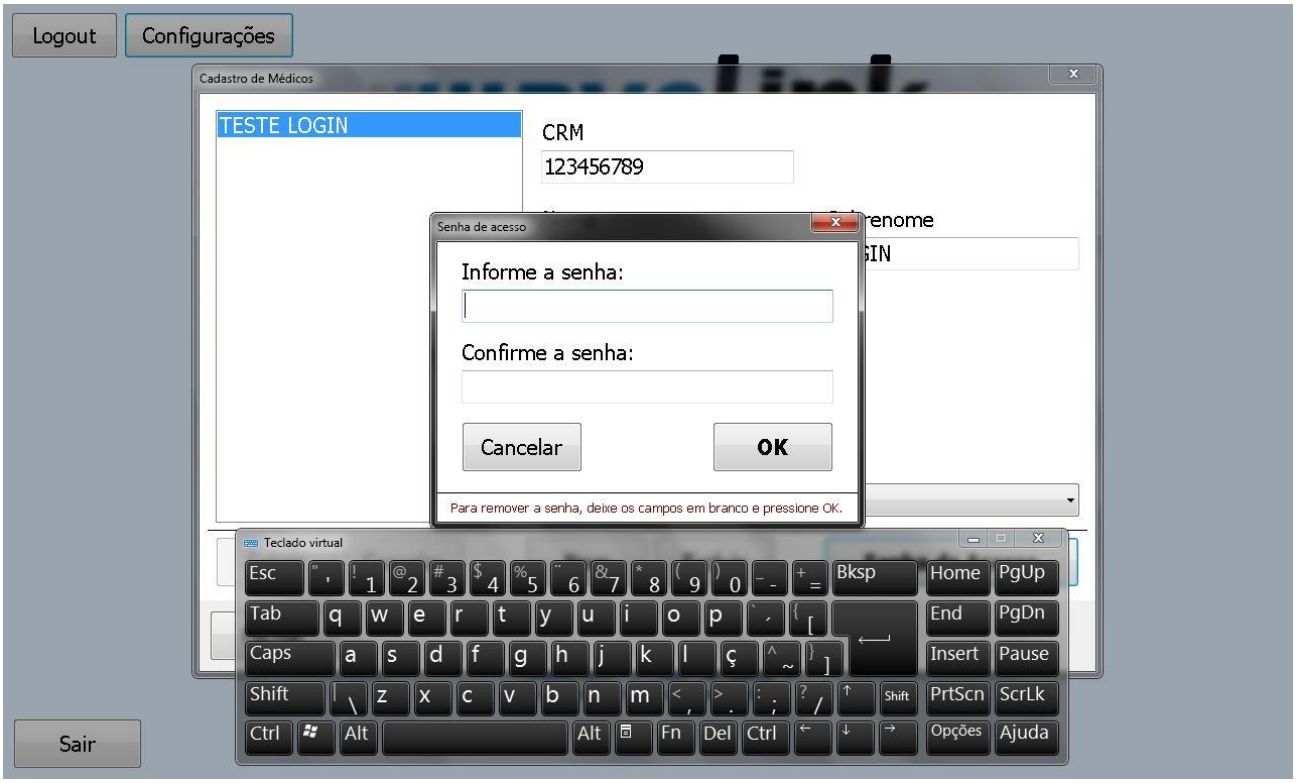
Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 28

K) Close (Fechar) closes physician registration and returns to the main menu.

Figure 9 - Entering the password. A) Fields for entering and confirming the password. B) Cancel discards changes and returns to physician registration. C) OK saves the password for the selected physician.

Illustrations - source section 28



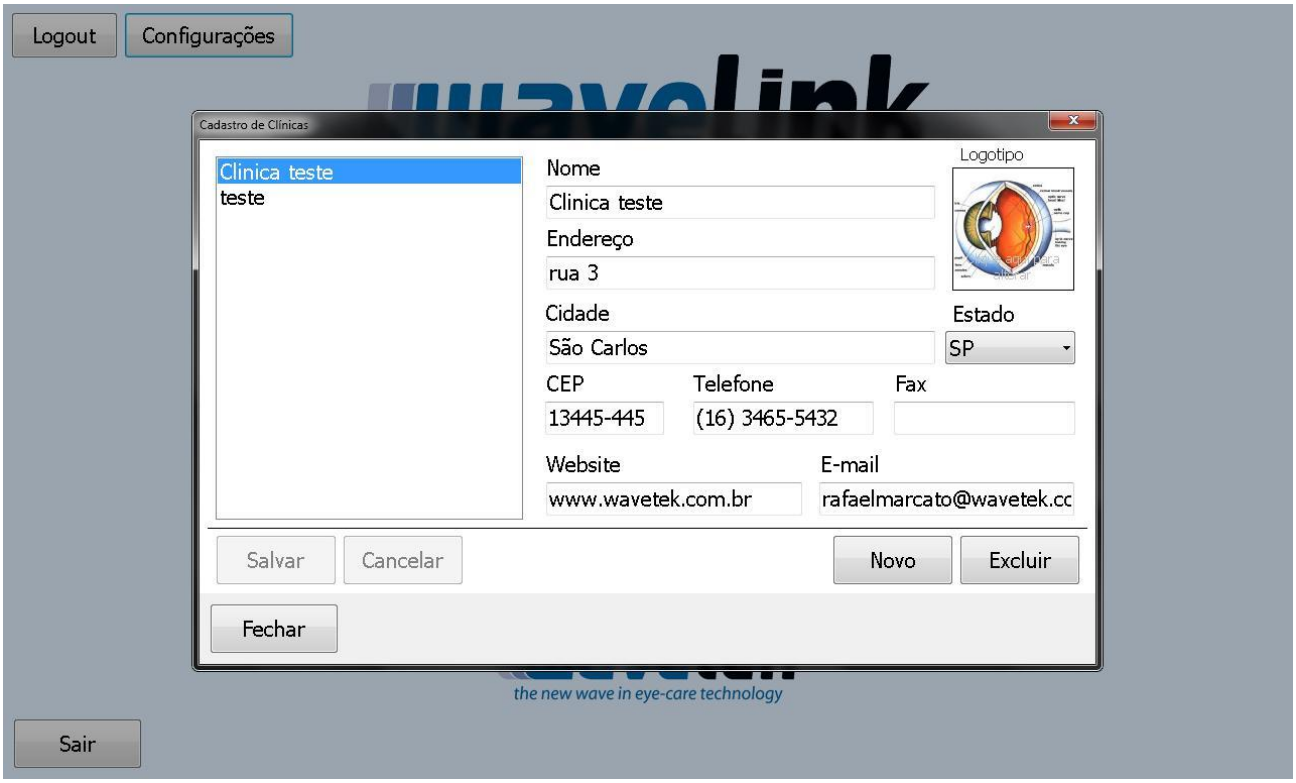
Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 29

11.4. Settings - Clinic Registration

Figure 10 - Settings, riboflavin registration (caption as in source). A) All registered clinics: click a name to select it and view details. B) Clinic details: NAME, ADDRESS, CITY, STATE, POSTAL CODE, TELEPHONE, FAX, WEBSITE and EMAIL. C) Save saves all additions and changes. D) Cancel cancels an addition or change in progress. E) New enables the form for adding a new physician (wording in source). F) Delete removes a selected physician (wording in source). G) Close closes clinic registration and returns to the main menu.

Illustrations - source section 29



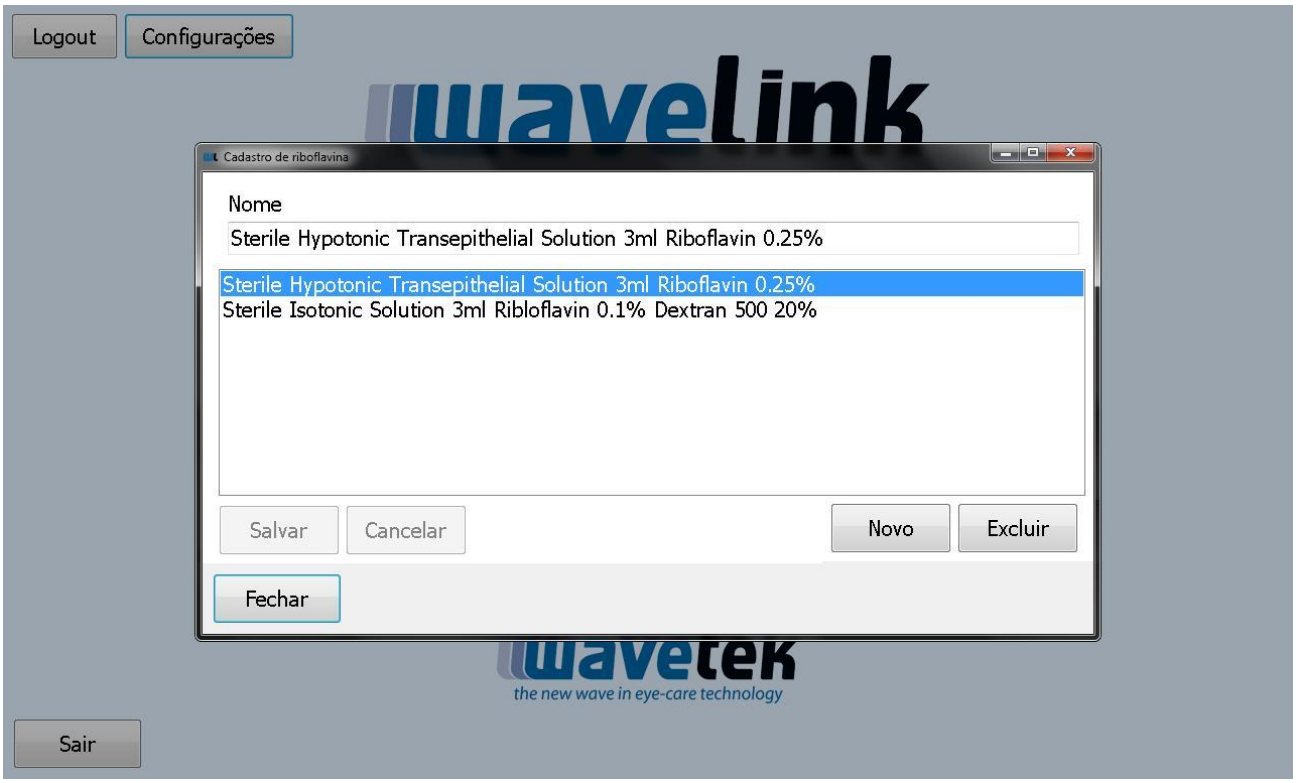
Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 30

11.5. Settings - Riboflavin Registration

Figure 11 - Riboflavin registration. A) All registered riboflavins: click a name to select it and view details. B) Riboflavin details: NAME. C) Save saves all additions and changes. D) Cancel cancels an addition or change in progress. E) New enables the form for adding a new physician (wording in source). F) Delete removes a selected physician (wording in source). G) Close closes riboflavin registration and returns to the main menu.

Illustrations - source section 30



Original instrument or software illustration. See the English instructions and interface labels in this section.

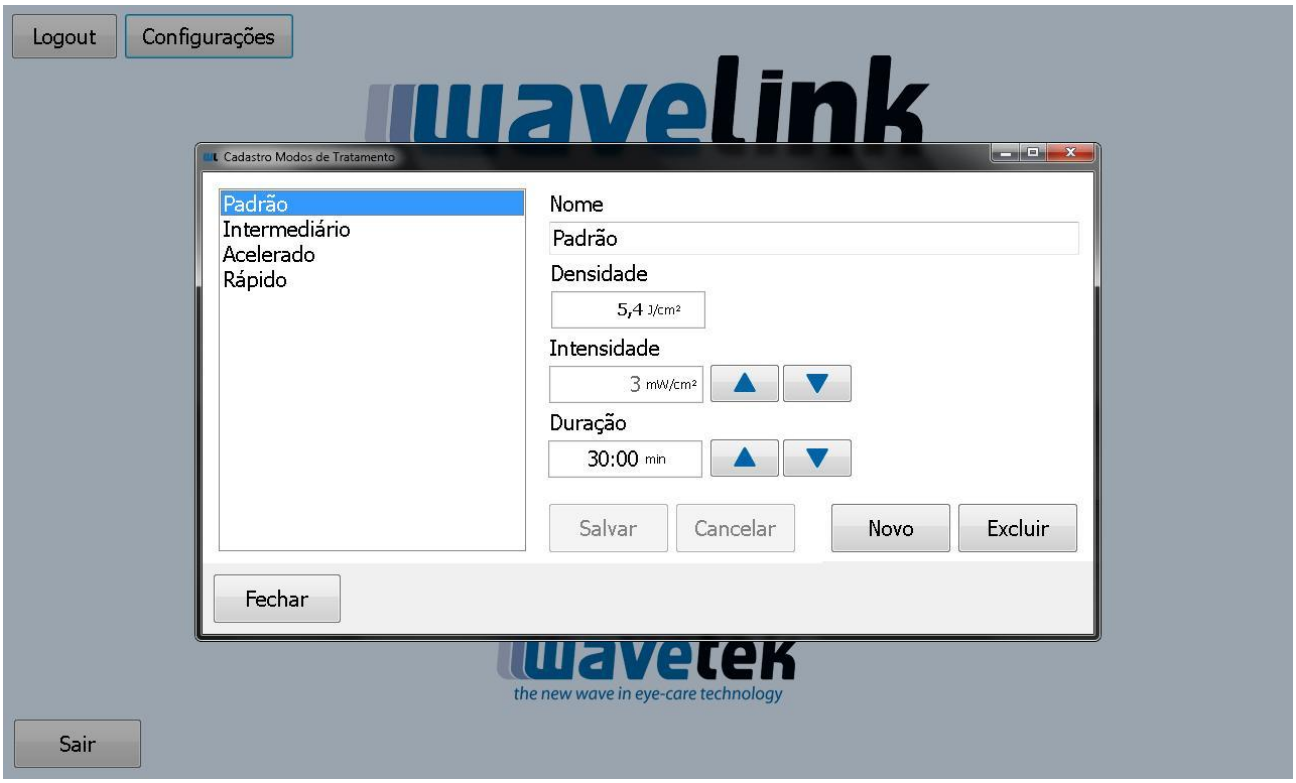
SOURCE SECTION 31

11.6. Settings - Treatment Mode Registration

Figure 12 - Treatment mode registration. A) All registered treatment modes: click a name to select it and view details. B) Treatment mode details: NAME, DENSITY, INTENSITY and DURATION. C) Save saves all additions and changes. D) Cancel cancels an addition or change in progress. E) New enables the form for adding a new physician (wording in source). F) Delete removes a selected physician (wording in source). G) Close closes treatment mode registration and returns to the main menu.

Density is calculated automatically from intensity and duration.

Illustrations - source section 31



Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 32

11.7. General Settings

Figure 13 - General settings. A) Live image and zoom settings, X-axis zoom and Y-axis zoom. B) Default Camera (Câmera Padrão), used throughout the procedure to view the patient's eye. C) Close returns to the main menu. D) Save saves all changes. E) Image brightness adjustment tool. F) Image contrast adjustment tool.

Illustrations - source section 32



Original instrument or software illustration. See the English instructions and interface labels in this section.

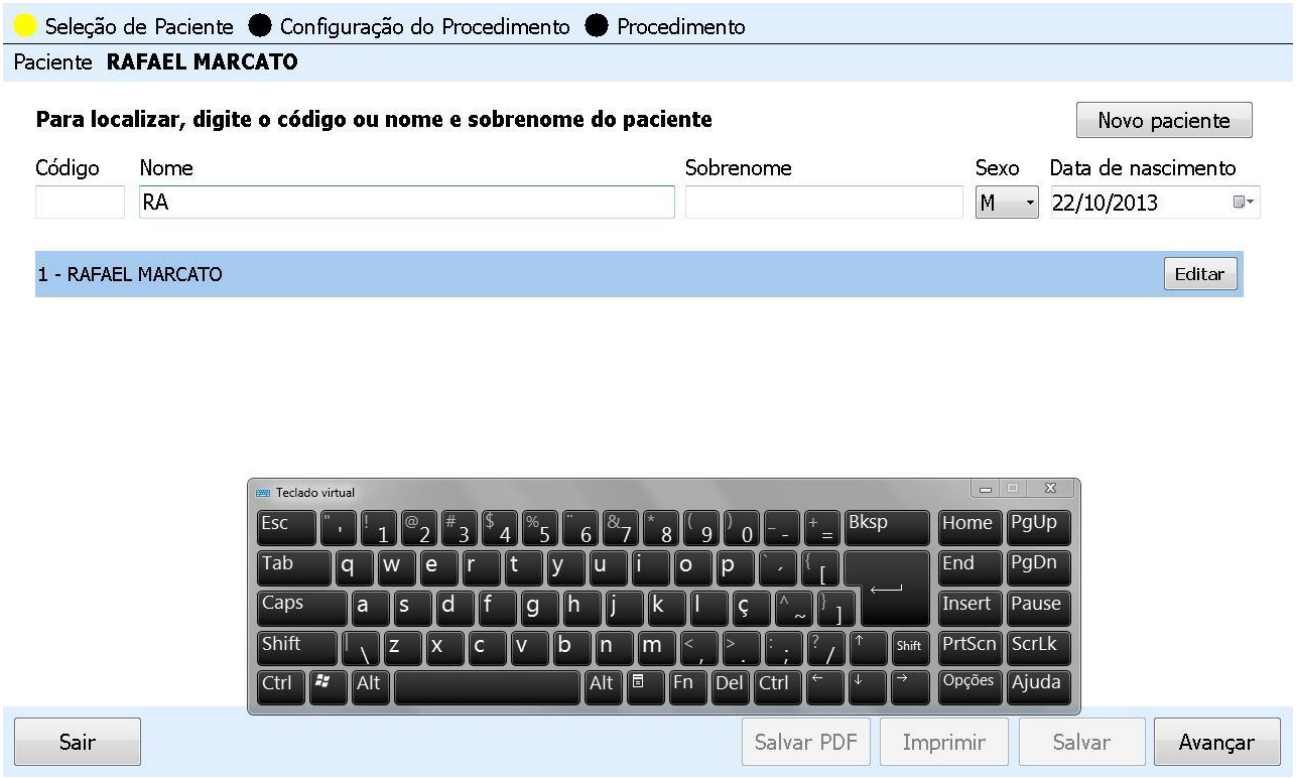
SOURCE SECTION 33

11.8. New Procedure or Review Procedure - Patient Selection

Figure 14 - New procedure, patient selection. A) Patient details: CODE, FIRST NAME, SURNAME, SEX, DATE OF BIRTH. B) Patient list: search results. C) New Patient (Novo paciente) enables the patient detail fields; fill them in and click Next (Avançar) to add a patient. D) Edit (Editar) opens the selected patient's editing menu; see Figure 15. E) Exit returns to the main menu; see Figure 6. F) After selecting a patient, Next displays the next step: Figure 16 for a new procedure or Figure 25 for review.

To find a registered patient, enter the code or first name and surname. Searching occurs automatically as characters are typed, and results appear in the patient list.

Illustrations - source section 33



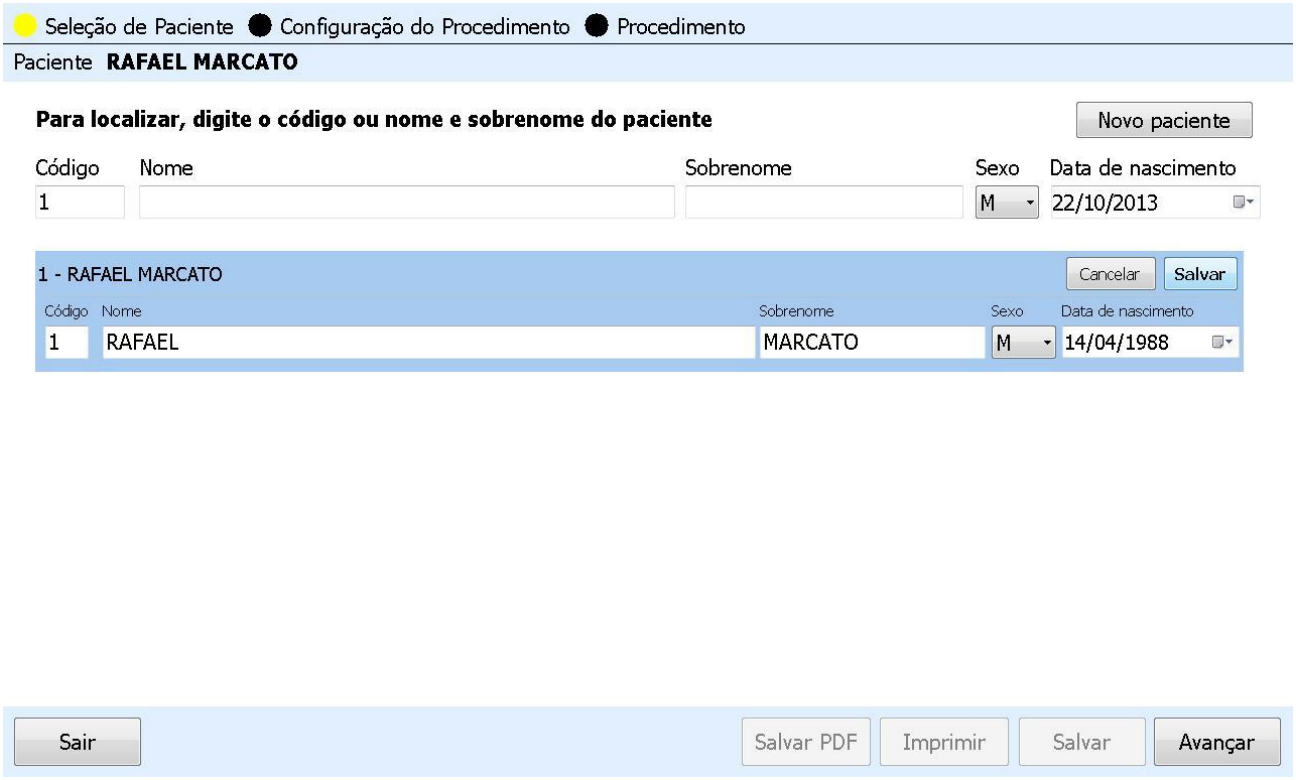
Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 34

11.9. New Procedure or Review Procedure - Editing Patient Details

Figure 15 - Editing patient details. A) Patient details: CODE, FIRST NAME, SURNAME, SEX, DATE OF BIRTH. B) Cancel discards changes. C) Save saves all changes.

Illustrations - source section 34



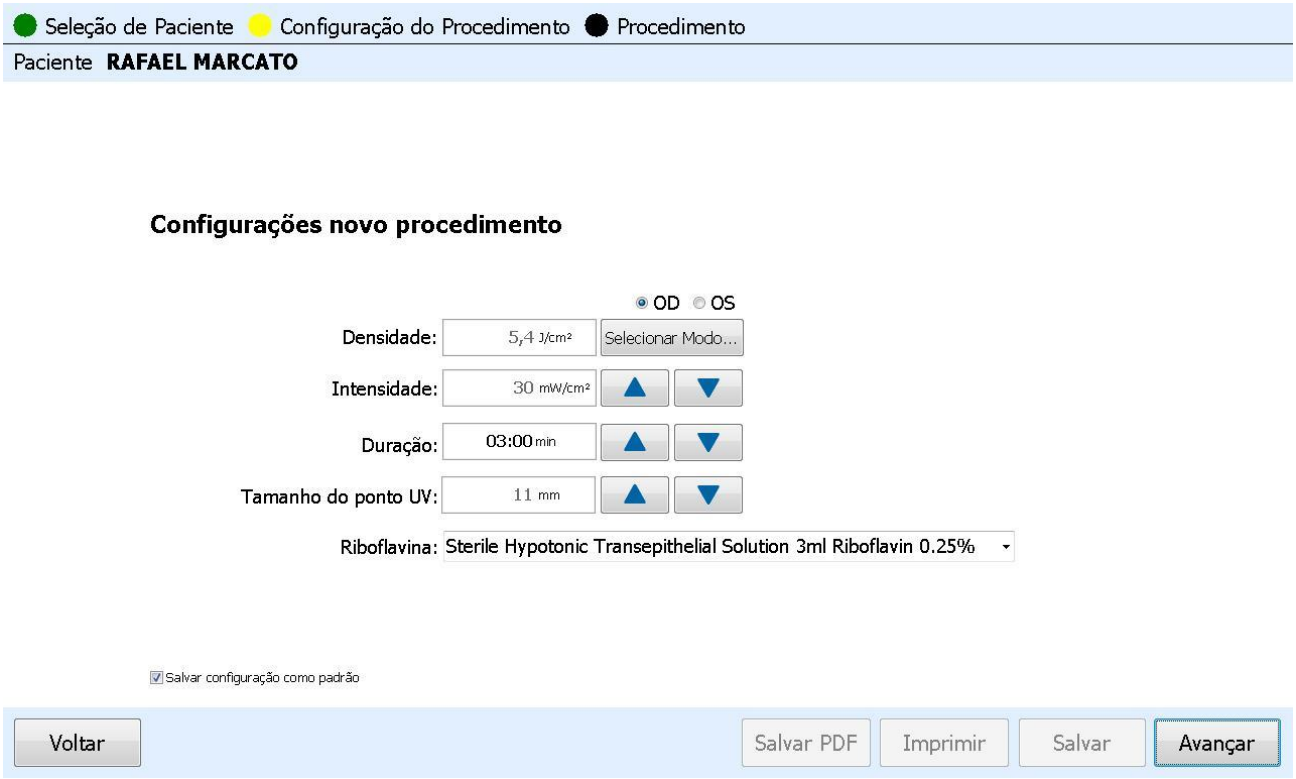
Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 35

11.9.1. New Procedure - Settings

Figure 16 - New-procedure settings. A) New-procedure parameters: DENSITY, INTENSITY, DURATION, UV SPOT SIZE, RIBOFLAVIN. B) Select Mode (Selecionar Modo) opens the menu for selecting a previously registered treatment mode; see Figure 17. C) Save Settings as Default (Salvar configurações como padrão): when selected, all parameters in this step are stored and shown next time as default field values to speed up the procedure. D) Back (Voltar) returns to patient selection. E) Next advances to the following step; see Figure 18.

Illustrations - source section 35



Original instrument or software illustration. See the English instructions and interface labels in this section.

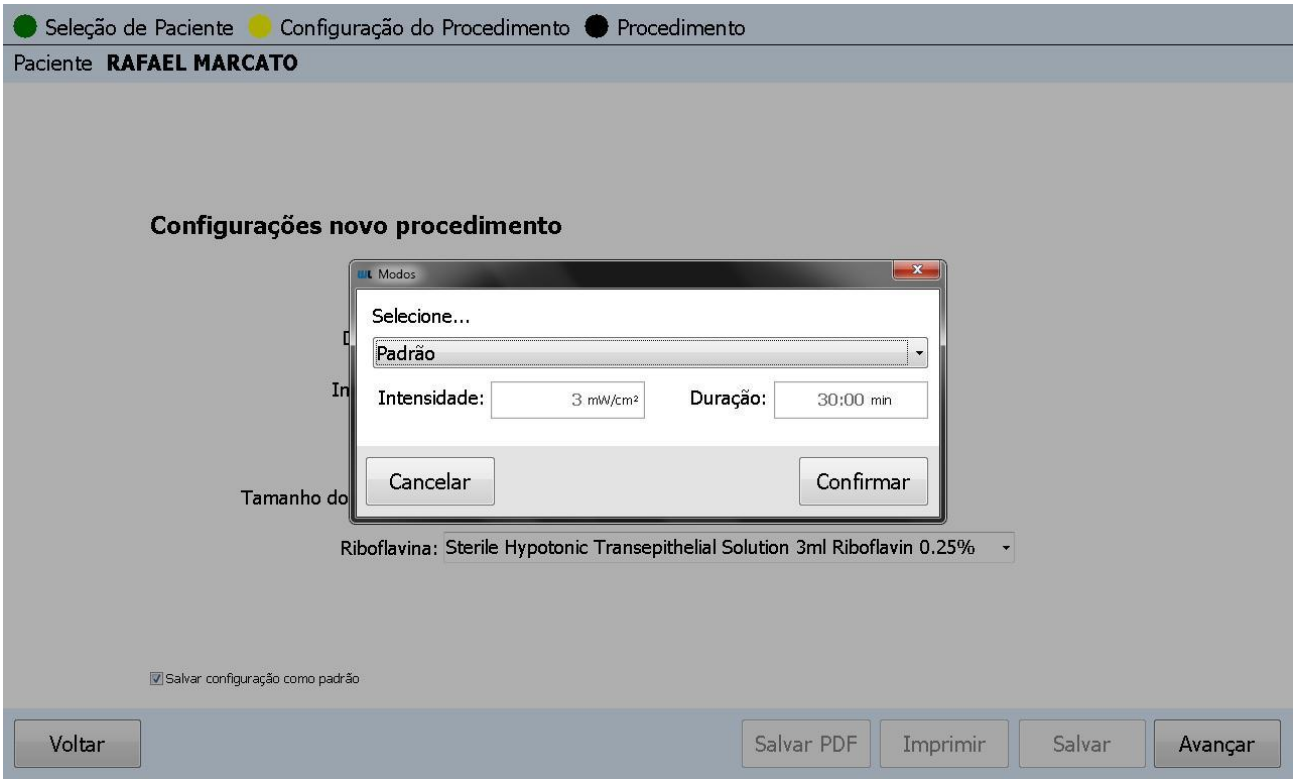
SOURCE SECTION 36

11.9.2. New Procedure - Select Treatment Mode

Figure 17 - Select treatment mode. A) Treatment mode details: NAME, INTENSITY and DURATION. B) Cancel closes the treatment mode selection screen. C) Confirm (Confirmar) closes the selection screen and fills the corresponding settings fields (Figure 16) with the selected mode.

To select another mode, click the mode-name combo box to display all previously registered treatment modes.

Illustrations - source section 36



Original instrument or software illustration. See the English instructions and interface labels in this section.

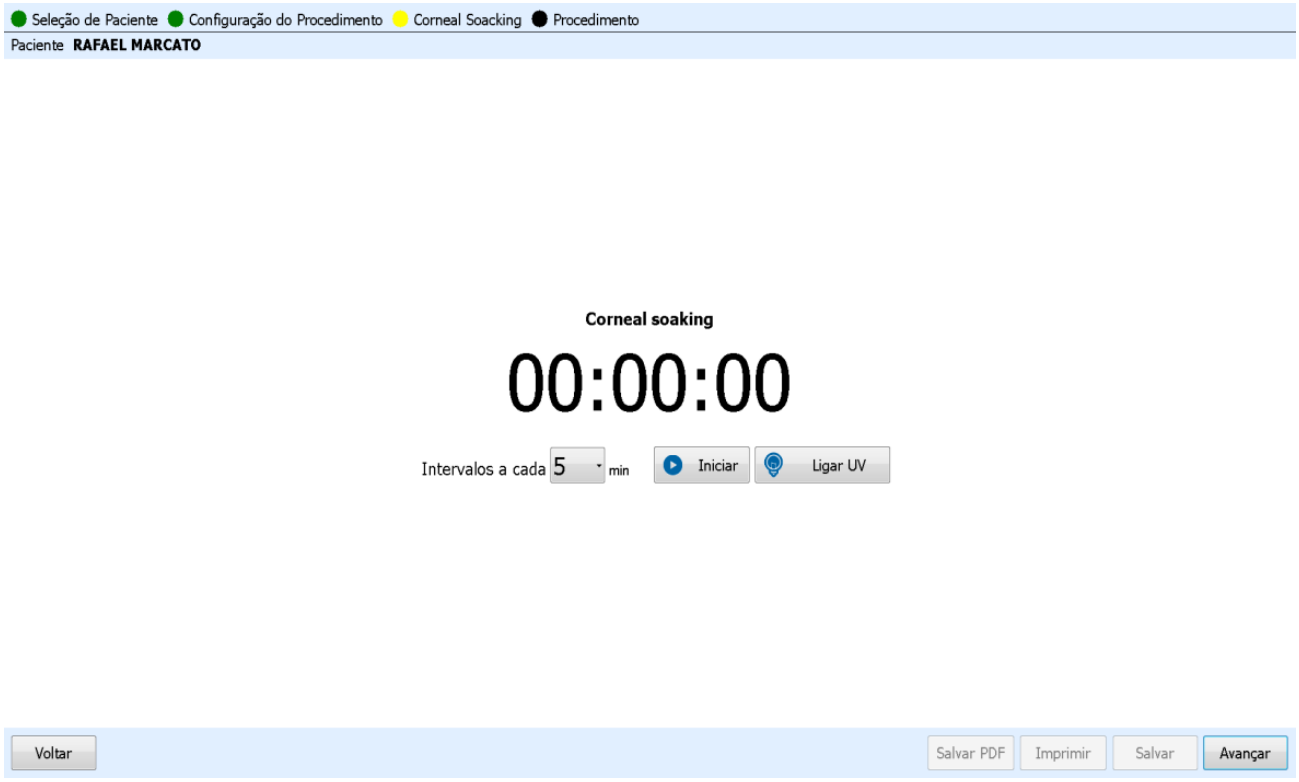
SOURCE SECTION 37

11.10. New Procedure - Corneal Soaking

A) Timer; emits a beep when activated. B) Interval specified by the physician. Every “X” minutes, the timer pauses and beeps as a notification. C) Starts and pauses the timer. D) Switches UV light on and off.

Figure 18 - New procedure, corneal soaking.

Illustrations - source section 37



Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 38

12. New Procedure - Procedure

Figure 19 - Procedure. A) Procedure information: remaining DENSITY to be applied and remaining DURATION. B) Displays a millimeter grid as a reference for measuring pupil size; see Figure 19. C) Processing parameters: ALIGNMENT INTENSITY, LIGHT INTENSITY, CENTERING SPOT INTENSITY, APPLICATION INTERVAL, APPLICATION TIME and PUPIL. D) Capture Image captures a live camera image and displays a small preview with Delete and Save options; see Figure 20. E) Automatic examination restart after riboflavin application time: enabled restarts automatically; disabled pauses the procedure. F) Start initiates the procedure and changes its name to Pause; pressing it again while active pauses the procedure. G) Live image of the patient's eye to assist the procedure. H) Back returns to a preceding step.

Illustrations - source section 38



Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 39

I) Save Settings as Default: when selected, all parameters chosen in this step are stored and shown next time as default field values to speed up the procedure. J) Once the examination is saved, Save Report as PDF is enabled. K) Once saved, Print Report is enabled. L) Save: after completing the procedure, opens a screen for additional information (Figure 21); afterward you may Cancel or Save the procedure to the database. M) Pulsed Mode opens settings for UV-light on and pause times.

SOURCE SECTION 40

12.1. New Procedure - Procedure - Millimeter Grid

Figure 20 - Procedure, millimeter grid.

Illustrations - source section 40



Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 41

12.2. New Procedure - Procedure - Save Image

A) Capture Image displays a preview with options to save or cancel the image capture.

Only two (2) captured images are saved per procedure. The source describes the sequence as follows: after capture of the second image, the first is removed, the second becomes the first, and the third becomes the second. Each newly captured and saved image repeats the replacement process; at the end, the last two (2) captured images are saved.

Figure 21 - Procedure, save image.

Illustrations - source section 41



Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 42

12.3. New Procedure - Procedure - Save with Additional Information

Figure 22 - Save with additional information. A) Additional procedure information field: Notes (Observações). After notes are entered, the virtual keyboard closes and Cancel or Save to Database becomes visible. The notes field may also be left blank.

Illustrations - source section 42



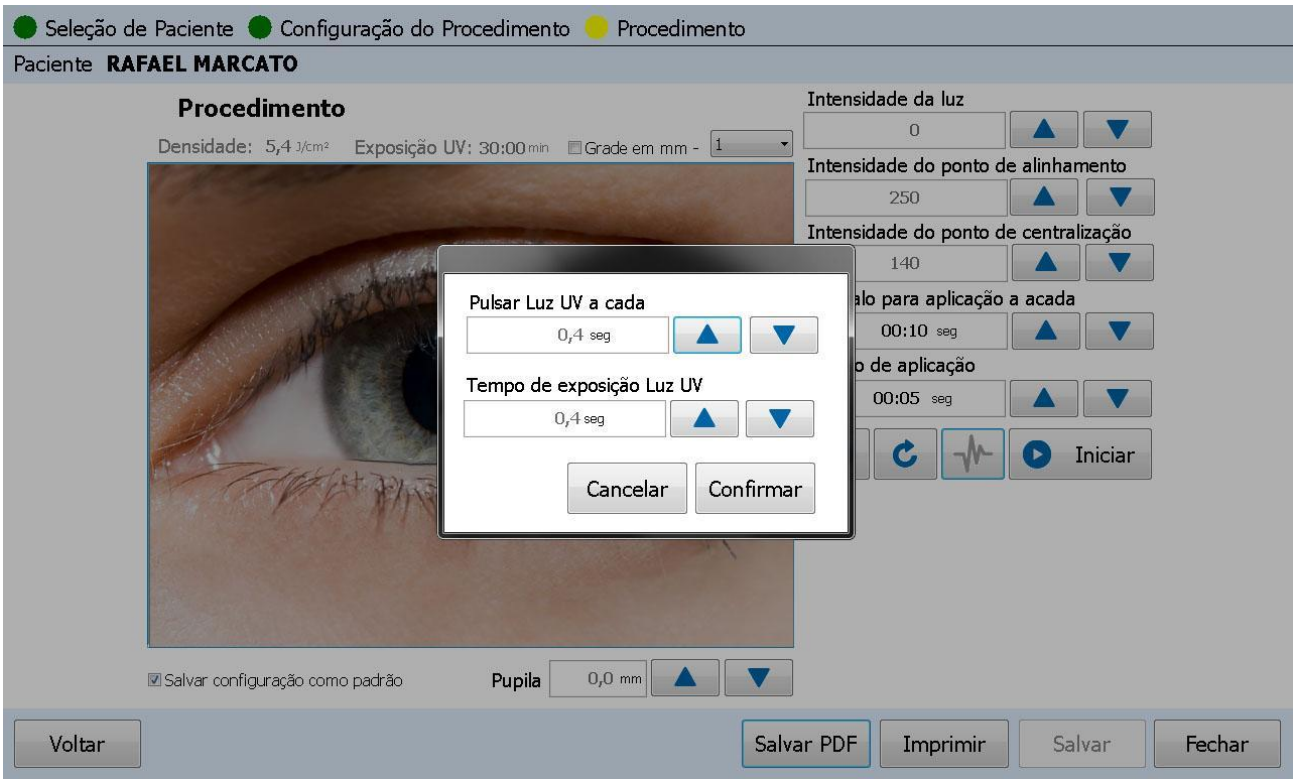
Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 43

12.4. New Procedure - Procedure - Pulsed Mode

A) Timing options for the UV-light interval and exposure time. B) Buttons to Cancel pulsed mode or Confirm to activate the selected settings.

Illustrations - source section 43



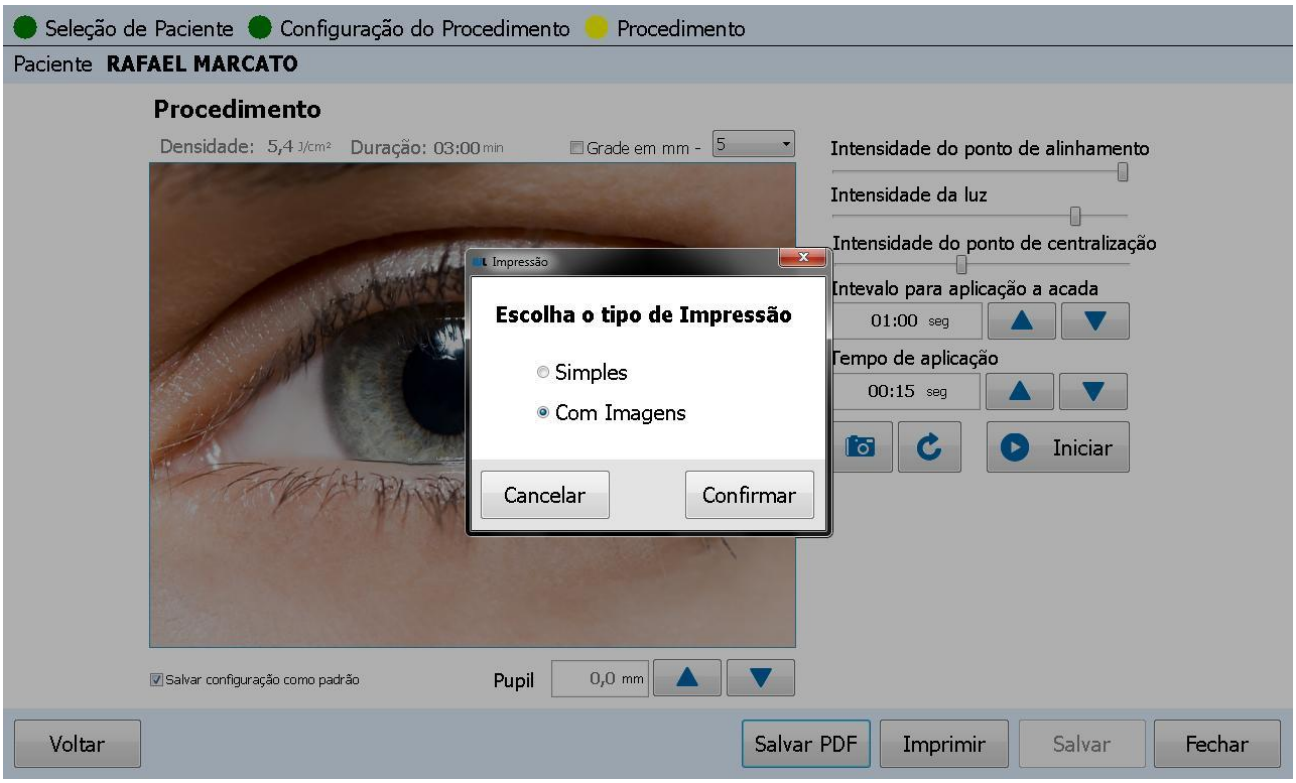
Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 44

13. New Procedure - Print or Save as PDF

Figure 23 - Print or save as PDF. Pressing Print or Save as PDF opens the print-type selection screen. A) Two report types: Simple (Simples), Figure 30; and With Images (Com Imagens), Figure 29. The image report option is enabled only when one or two images were saved during the procedure. B) Cancel cancels the current process. C) Confirm confirms the selection and opens the screen for choosing the clinic shown on the report.

Illustrations - source section 44



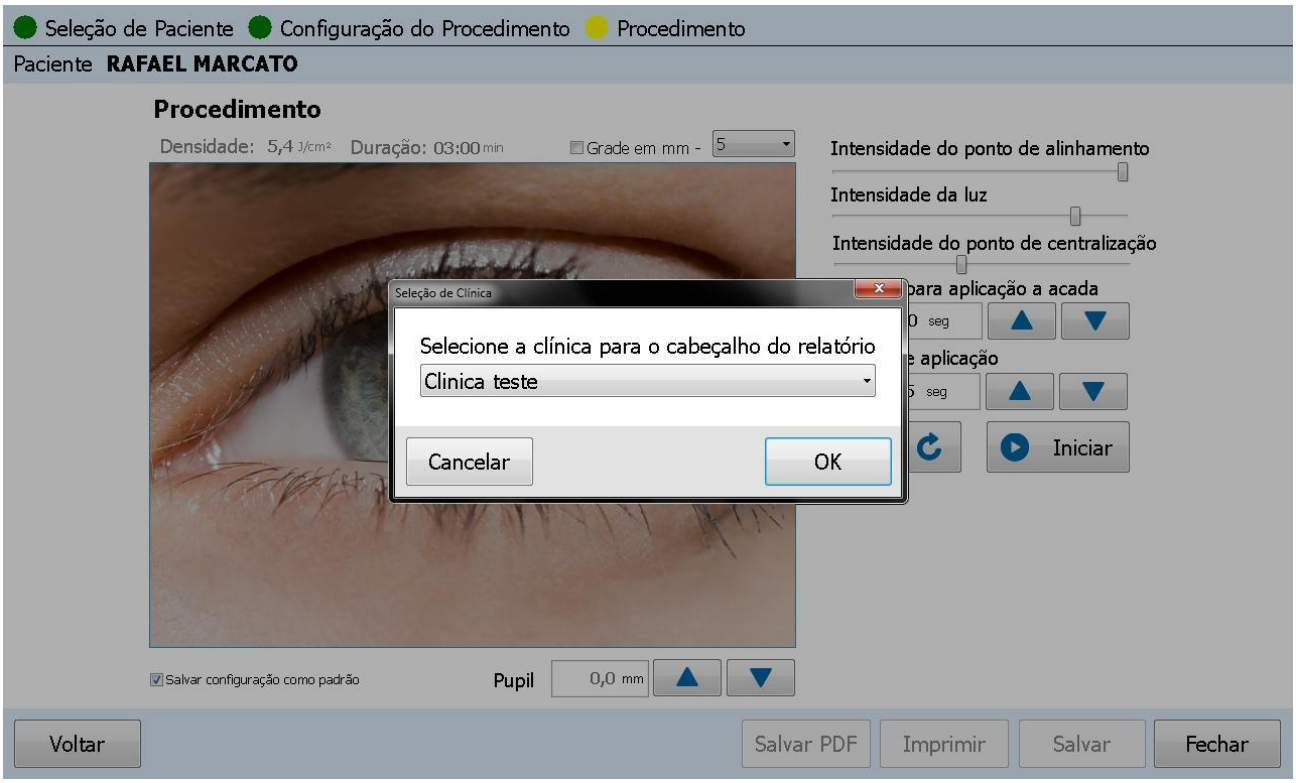
Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 45

13.1. New Procedure - Print or Save as PDF - Select Clinic

Figure 24 - Select clinic. A) Select the clinic to appear on the report by name. B) Cancel cancels the current process. C) OK completes print/PDF setup and displays or saves the report; see Figure 23.

Illustrations - source section 45



Original instrument or software illustration. See the English instructions and interface labels in this section.

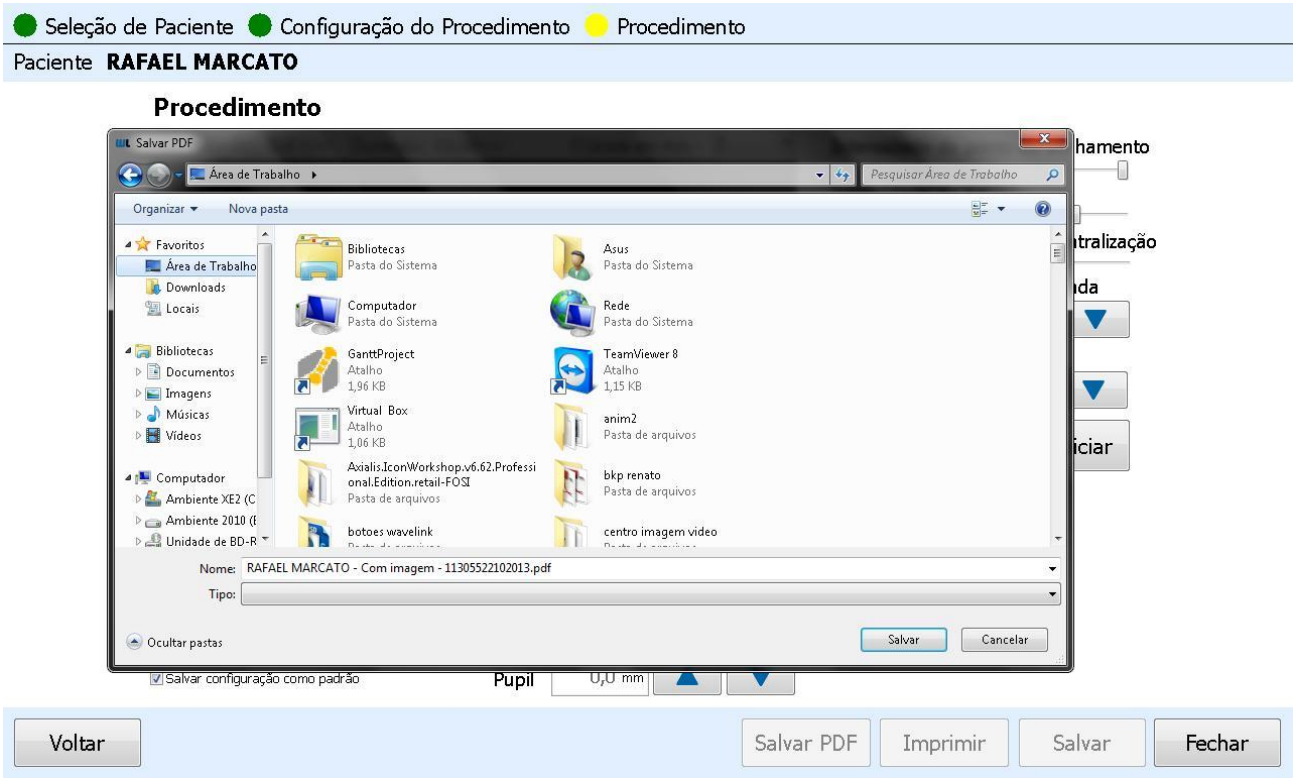
SOURCE SECTION 46

13.2. New Procedure - Save as PDF

Figure 25 - Save as PDF. A) After selecting a clinic, the PDF Save dialog opens, allowing selection of the report destination, for example a USB drive. B) Save saves the PDF report in the selected location. C) Cancel cancels saving.

After Save or Cancel, return to the procedure screen with Save as PDF, Print and Close enabled. Close returns to the main software menu.

Illustrations - source section 46



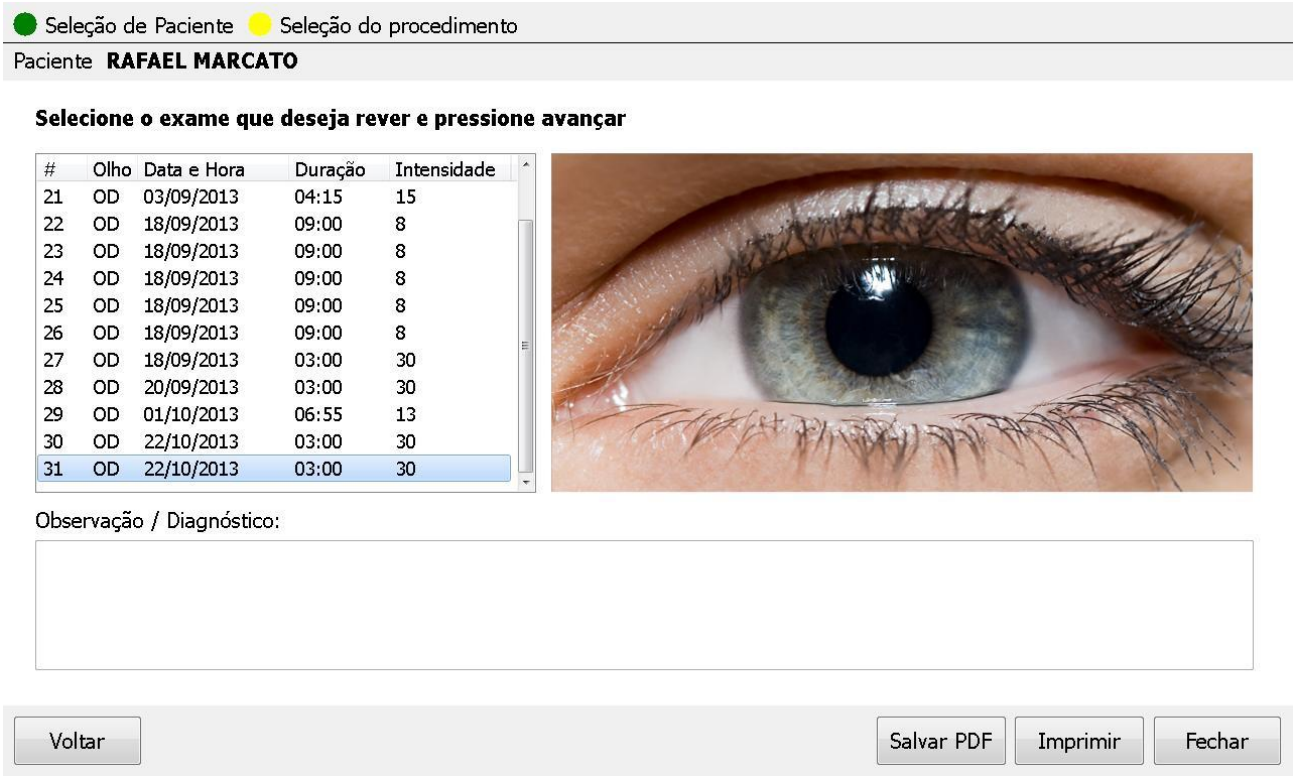
Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 47

14. Review Procedure - Procedure Selection

Figure 26 - Procedure selection. A) List of completed procedures and their details for the selected patient. B) Preview of the first image saved during the procedure, if any. C) Back returns to patient selection. D) Save Report as PDF saves the report. E) Print prints the report. F) Close returns to the main menu.

Illustrations - source section 47



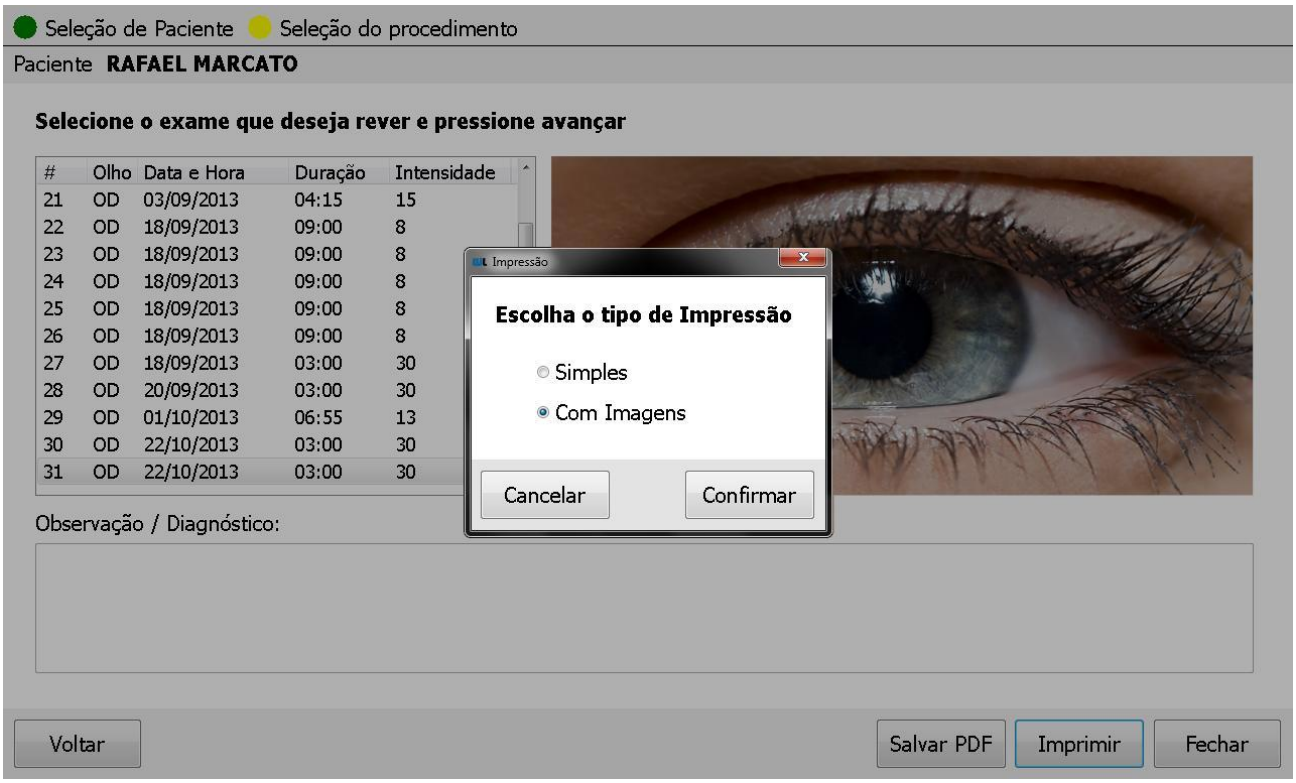
Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 48

14.1. Review Procedure - Print or Save as PDF

Figure 27 - Print or save as PDF. Clicking Print or Save as PDF opens the print-type screen. A) Two report types: Simple, Figure 30; and With Images, Figure 29. With Images is enabled only if one or two images were saved during the procedure. B) Cancel cancels the current process. C) Confirm confirms the selection and opens clinic selection for the report.

Illustrations - source section 48



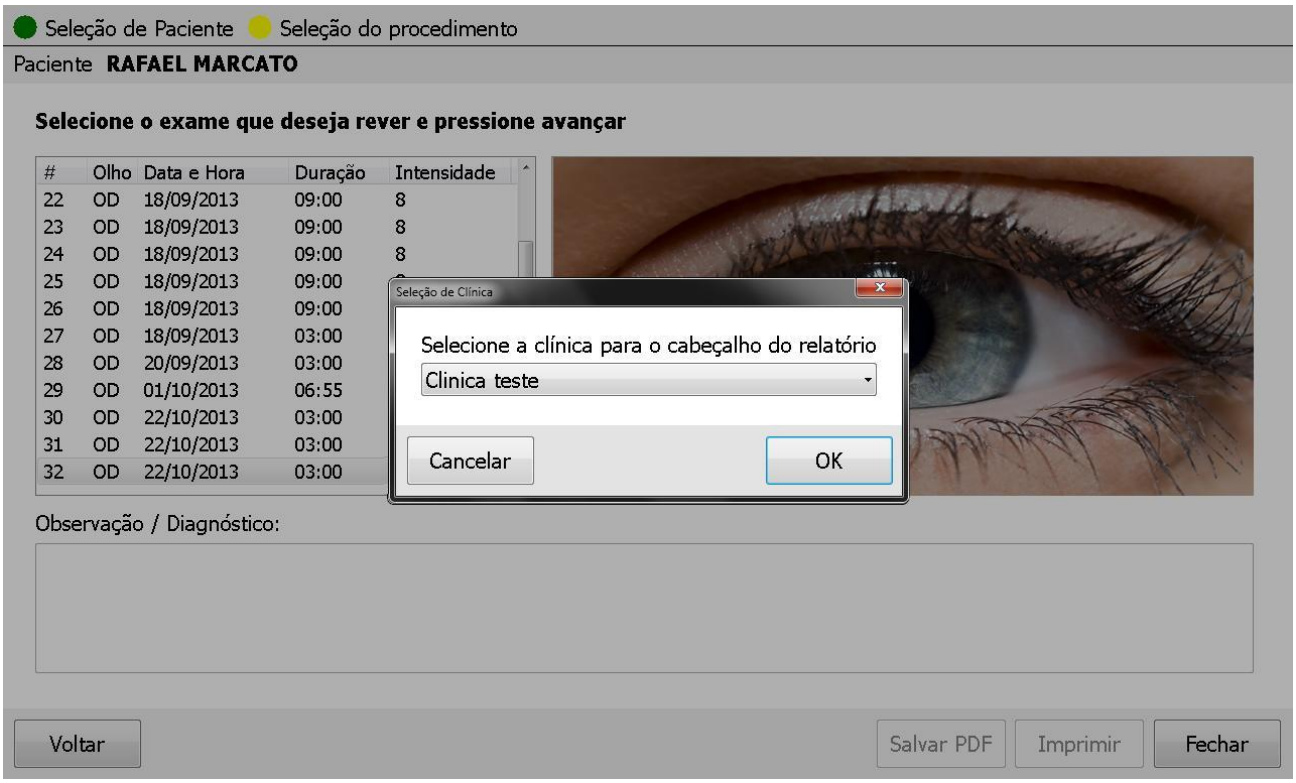
Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 49

14.2. Print or Save as PDF - Select Clinic

Figure 28 - Select clinic. A) Select the clinic for the report by name. B) Cancel cancels the current process. C) OK completes print/PDF setup and displays or saves the report; see Figure 28.

Illustrations - source section 49



Original instrument or software illustration. See the English instructions and interface labels in this section.

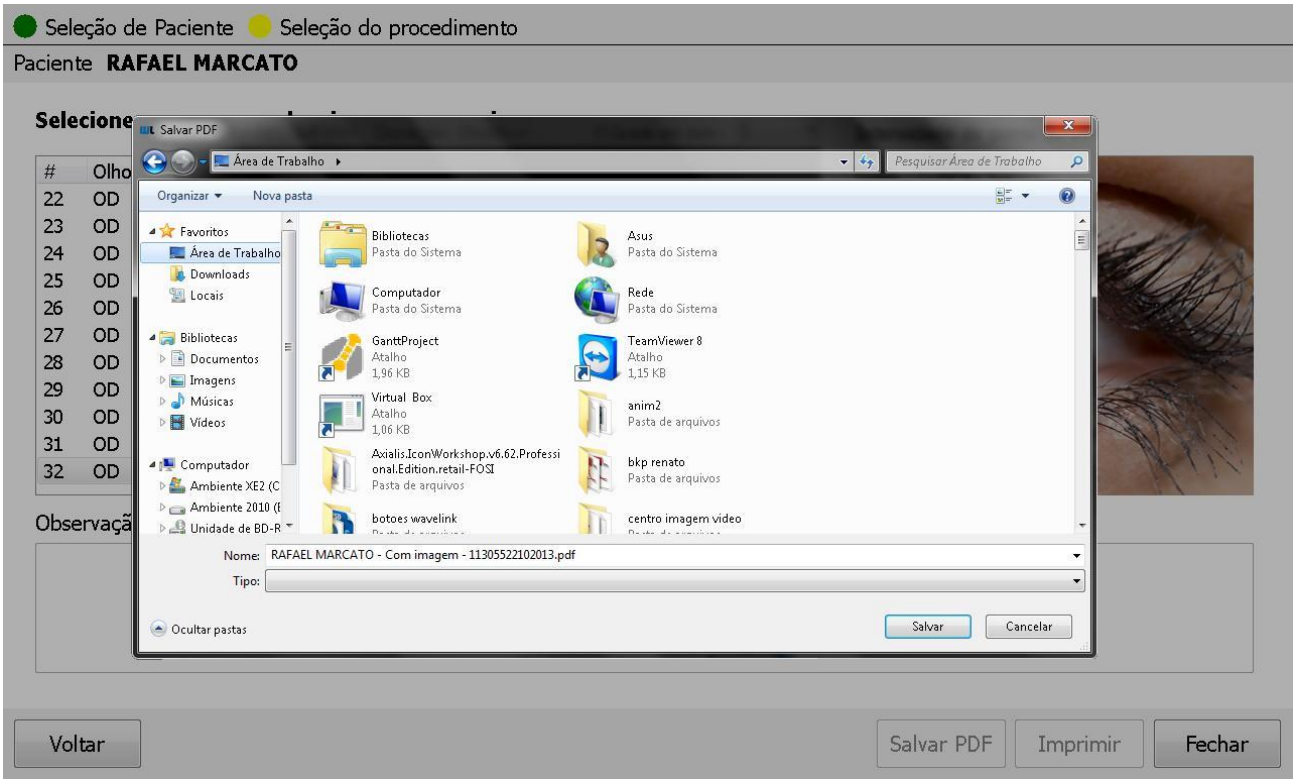
SOURCE SECTION 50

14.3. Review Procedure - Save as PDF

Figure 29 - Save as PDF. A) After selecting a clinic, the PDF Save dialog opens, allowing selection of the report destination, for example a USB drive. B) Save saves the PDF report in the selected location. C) Cancel cancels saving.

After Save or Cancel, return to the Review Procedure screen with Save as PDF, Print and Close enabled. Close returns to the main software menu.

Illustrations - source section 50



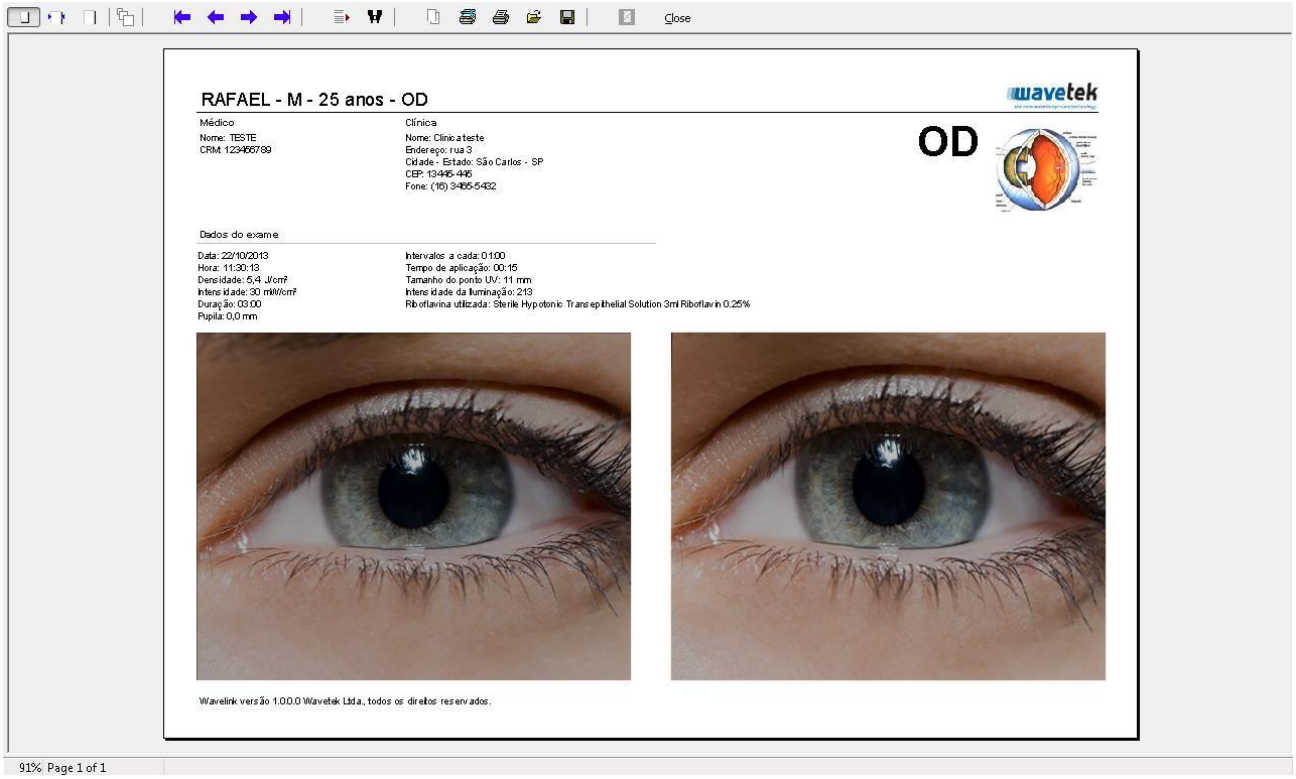
Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 51

15. Report with Images

Figure 30 - Report with images. A) Options bar: buttons for printing, printer setup, report positioning (size as a percentage relative to the monitor), saving as PDF and closing to return to procedure selection. B) Report information: physician, clinic, procedure data, and EVOptica logo and company information. The image report is configured for A4 paper.

Illustrations - source section 51



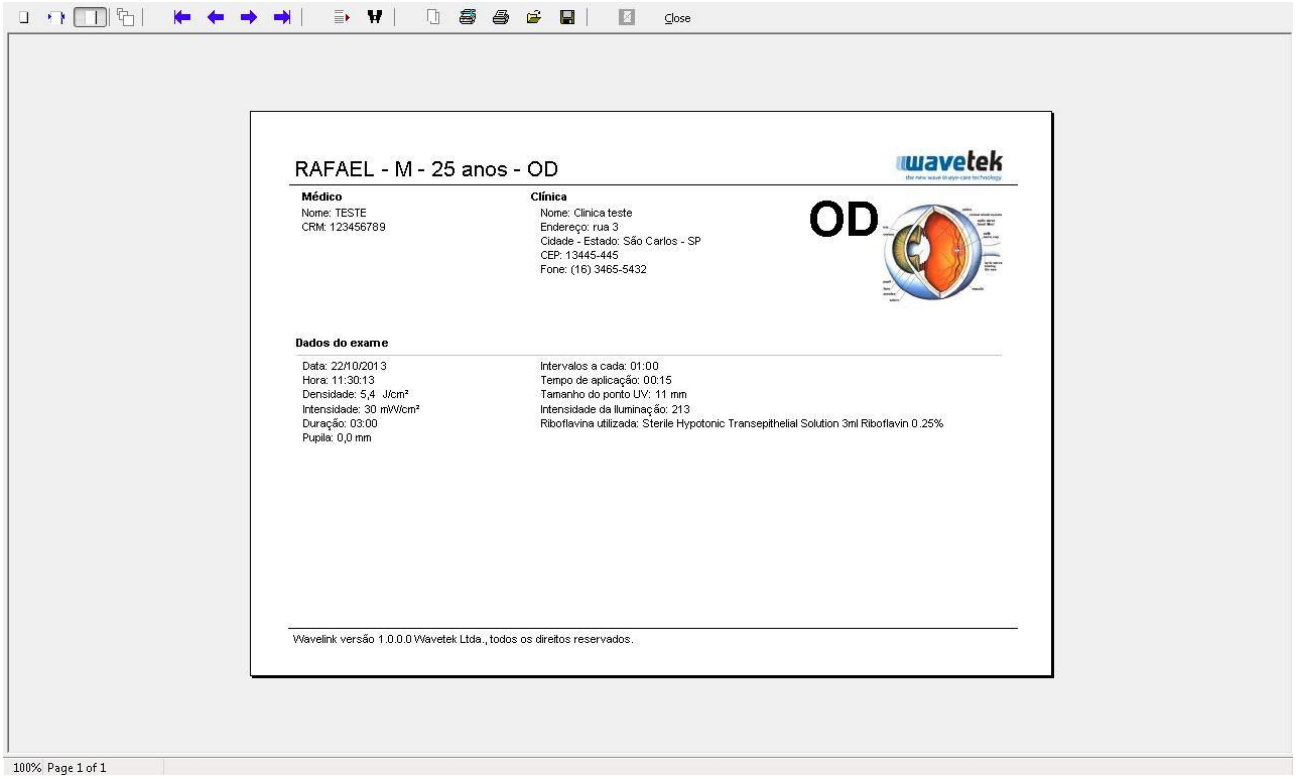
Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 52

16. Simple Report

Figure 31 - Simple report. A) Options bar: buttons for printing, printer setup, report positioning (size as a percentage relative to the monitor), saving as PDF and closing to return to procedure selection. B) Report information: physician, clinic, procedure data, and EVOptica logo and company information. The simple report is configured for A3 paper.

Illustrations - source section 52



Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 53

17. WAVELINK Installation

17.1. Introduction and Requirements

It is strongly recommended that the manufacturer or its authorized agent install WAVELINK at the operator's site to ensure correct operation, alignment and calibration to specifications. After initial installation, the operator must ensure correct UV-system operation whenever the UV light is moved or relocated.

Follow these procedures for successful installation. Complete the checklist and report form and send a copy to EVOptica for the WAVELINK product history record. If the report is not sent, the manufacturer reserves the right to refuse subsequent warranty claims. The installer should retain a copy, and the customer may retain one as well.

Take all cautions during corneal Cross-Link installation to prevent exposing yourself or others to hazardous UV radiation. Always wear UV safety eyewear suitable for this specific wavelength.

Installation requirements: grounded AC mains supply, 100-230 V, 50 or 60 Hz, single-phase outlet capable of supplying up to 280 W. The original manufacturer supplied a Brazilian-standard power cord. A suitable room providing a safe working environment is required, as for other ophthalmic equipment.

SOURCE SECTION 54

To relocate the system, unlock all casters on the wheeled base and carefully move it to the new location. For transfer to another facility, consider repacking it in its original packaging to prevent damage. After the move, verify correct UV-system operation according to the following steps in this User Manual.

SOURCE SECTION 55

18. Unpacking and Customer Receiving Inspection

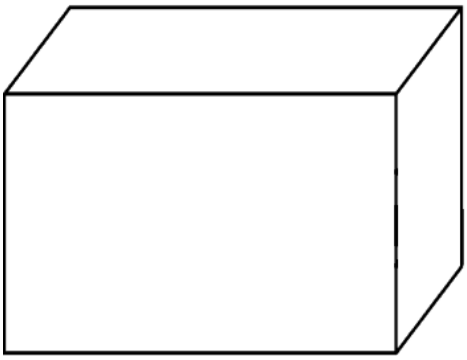
The UV system usually arrives in one cardboard box containing the wheeled base, control box, LCD touchscreen, UV head, arm assembly and other accessories.

Inspect the package for signs of mishandling on receipt, and report product damage to the package handler. The manufacturer reserves the right to refuse warranty claims involving unauthorized maintenance, so it is essential that the carrier accept full responsibility for any shipping damage. If the outer carton is undamaged, continue removing the internally packed assemblies.

Shipping fields: RECIPIENT; ADDRESS; NUMBER; CITY; STATE; CNPJ/CUSTOMER.

Figure 32 - EVOptica box.

Illustrations - source section 55




wavetek
wavetek
wavelink

SOURCE SECTION 56

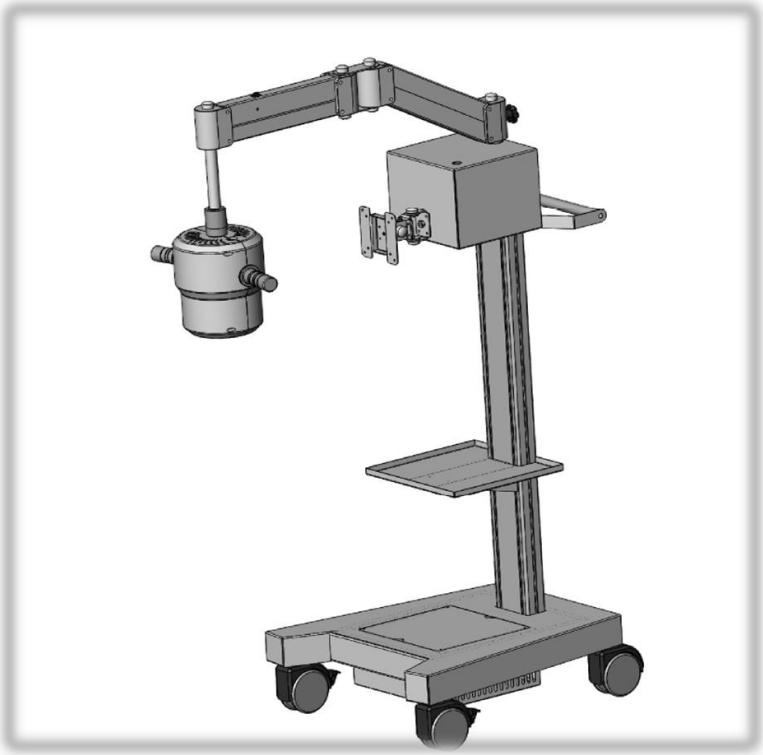
19. Care of WAVELINK Parts

Unpack all items from their boxes and cases and inspect their general condition and for shipping damage. Take extreme care not to touch lenses or optical parts, and ensure all items are present.

Four main parts: casters; control base with LCD touchscreen box; UV pantographic arm; optical head.

Figure 33 - Components: caster assembly for instrument movement; pantographic arm; control base; optical head.

Illustrations - source section 56



Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 57

19.1. WAVELINK Reassembly Process

The EVOptica technician uses suitable tools to fit WAVELINK parts and components. Follow the procedures below. Position the wheeled base and control box appropriately on a level surface. Lock the wheels to prevent sliding. Only the company technician may install WAVELINK. Installation by unauthorized persons voids the warranty.

The technician fits the pantographic arm, touchscreen and optical head, and completes the WAVELINK electronic-system checklist. Fit four screws to the rear of the LCD display as illustrated.

Figure 35 - Fitting the monitor. Figure 34 - Correct fitting of the pantographic arm.

Illustrations - source section 57





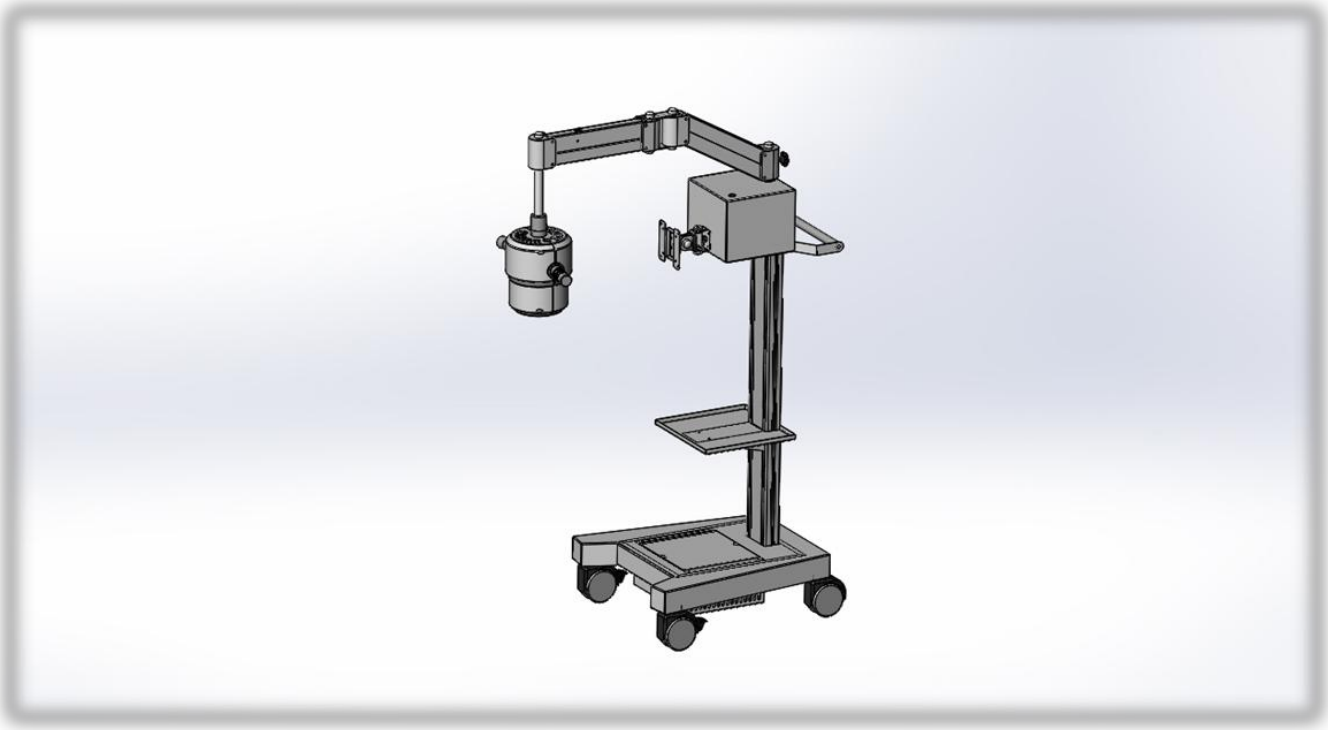
Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 58

Carefully place the pantographic arm onto the WAVELINK control box for assembly. Ensure the UV head is securely attached to the pantographic arm and can swing around for stability testing. Always verify that the cover is locked before integrity or stability tests.

Figure 36 - Optical head and pantographic arm illustration. Pantographic arm; optical head.

Illustrations - source section 58



Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 59

20. Starting the Equipment

Before switching on, ensure all connectors and connections are in place and the electrical supply meets system specifications. Startup procedures: release the emergency button; connect the interlock plug at the rear of the control box; check the computer connection cables work; use a 110 V voltage stabilizer for ATX power-supply longevity; verify appropriate voltage at the installation site.

WARNING: WAVELINK is dual voltage. See the product specifications in this manual.

SOURCE SECTION 60

21. Installation Record Sheet

PRODUCT NAME: Corneal Cross-Link System. MODEL: WAVELINK. MANUFACTURER: EVOptica. SERIAL NUMBER: _____.

1. SYSTEM CONFIGURATION (mark OK). □ 1.1 All parts received and verified OK. □ 1.2 Equipment packaging undamaged. □ 1.3 Cables fitted and clamps etc. installed. □ 1.4 Electrical power cord connected. □ 1.5 System assembly completed.

2. UV SYSTEM CHECK. □ 2.1 UV light switched ON, indicated by LED display. □ 2.2 UV system performs startup self-checks. □ 2.3 Check whether error messages are displayed. □ 2.4 All display-panel controls and monitors operate correctly. □ 2.5 Aiming beam visible, intensity adjustable.

INSTALLER NAME: _____ DATE: ____/____/____. DISTRIBUTOR NAME: _____ DATE: ____/____/____. CUSTOMER NAME: _____ DATE: ____/____/____.

The company technician sends this installation record for inclusion in the product history record.

SOURCE SECTION 61

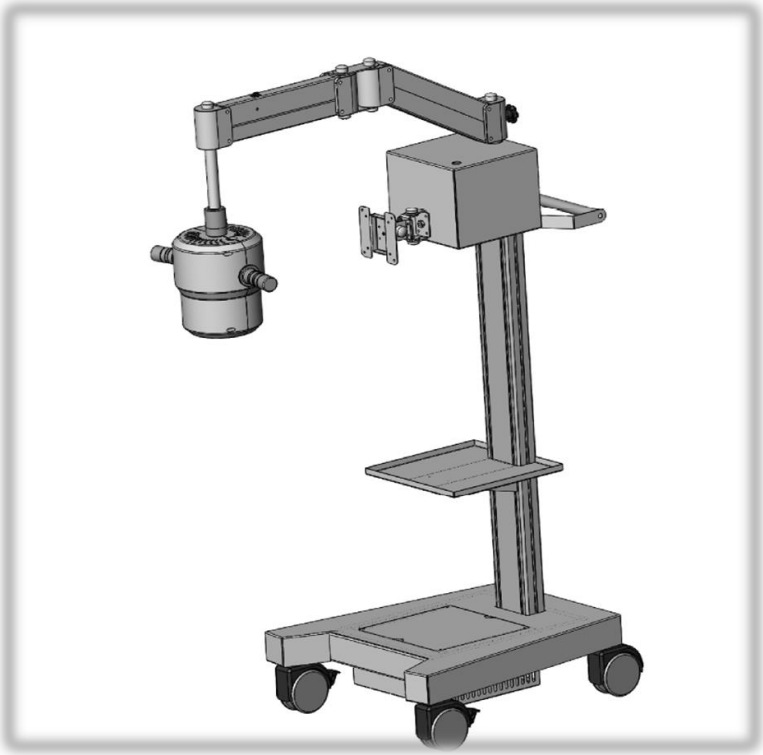
22. Clinical Use

22.1. Introduction

The corneal Cross-Link system is a specialized medical device controlled by sophisticated software in its integrated computer. It emits low-level 365 nm UV-A light from a UV LED (light-emitting diode) cluster through a specialized optical module, producing a homogeneous spot with controllable beam power for delivery to the corneal surface. It is intended to allow noninvasive treatment of corneal disorders using controllable UV light in the referenced process.

Figure 37 - WAVELINK components: (1) pantographic arm; (2) control box; (3) optical head; (4) casters; (5) instrument tray; (6) controllable pantographic-arm movement; (7) movable touchscreen support; (8) software interface on an LCD touchscreen.

Illustrations - source section 61



Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 62

22.2. Main Indications for Use

The source describes the WAVELINK Cross-Linking system as an increasingly recognized innovative, revolutionary surgical procedure for numerous corneal diseases, including keratoconus, iatrogenic ectasia, post-LASIK ectasia and pellucid marginal degeneration.

22.3. Riboflavin - Use of the WAVELINK Cross-Link System

The process combines UV-A corneal irradiation from the Cross-Link system with separately supplied riboflavin (vitamin B2). The solution acts as a stimulant, photosynthesized by UV-A on corneal tissue, and also as a safety filter, creating a superficial barrier over the cornea to prevent UV-A reaching the internal retina. Riboflavin is administered as drops on the corneal surface and is essential to every corneal cross-linking procedure.

It is available and is to be applied in two formulations: isotonic solution, riboflavin 5-phosphate (0.1%) + 20% dextran T500; hypotonic solution, riboflavin 5-phosphate (0.1%).

The isotonic or hypotonic solution is administered according to corneal thickness to ensure optical treatment safety in accordance with corneal cross-linking treatment protocols. The physician must measure and assess corneal thickness before each procedure using additional diagnostic equipment.

Figure 38 - Riboflavin, use of the Cross-Link system.

Illustrations - source section 62



SOURCE SECTION 63

22.4. Riboflavin Supplies

22.4.1. Riboflavin Source

Riboflavin must be manufactured under completely aseptic conditions by a Class II manufacturer accredited for GMP. Generic solution is commercially and readily available from various manufacturers suitable for use with the Cross-Link device. The physician is not restricted to one supplier.

The original manual states that many markets worldwide classify and register riboflavin as a device rather than a pharmaceutical agent, acting as a filter to protect the retina from UV-A. It further states that some markets do not recognize riboflavin as a device (CE), but as a pharmaceutical agent because an element of pharmacological action is present. These are original-market references, not a statement of current US clearance.

It is therefore essential and commercially viable for the company not to restrict itself or customers to a particular riboflavin supplier or impose a package model. The company offers riboflavin for the surgical procedure.

Figure 39 - Supplying riboflavin to all customers.

Illustrations - source section 63



SOURCE SECTION 64

22.5. Mechanisms of Action

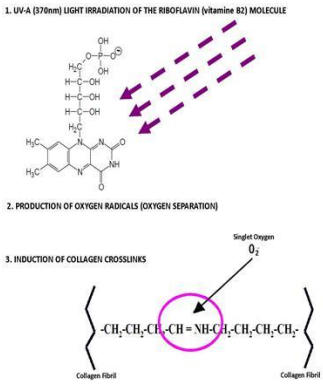
Riboflavin combined with ultraviolet irradiation induces a photopolymerization process that increases corneal biomechanical strength by forming new interfibrillar covalent bonds in corneal collagen. UV-A-activated riboflavin stimulates singlet oxygen production[2], helping physically form new cross-links between adjacent collagen strands in the stroma.

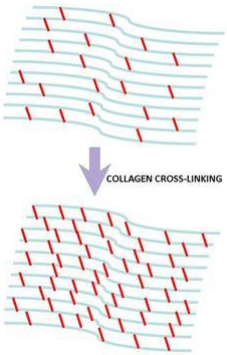
UV-A irradiation disrupts the internal chemical equilibrium of riboflavin molecules, producing free oxygen radicals at the point where the riboflavin molecule is unstable. It becomes stable only when bound to two collagen fibrils, creating a bridge between fibers (a cross-link) and strengthening the cornea overall.

The source reports that evidence from ongoing clinical research shows successful recovery of corneal mechanical strength, arrest of keratoconus progression and an increase in corneal stiffness of up to 320%.

Figure 40 - Mechanism of action.

Illustrations - source section 64





SOURCE SECTION 65

23. Clinical Guidelines

23.1. Disclaimer

The following information is based on results of various clinical studies and is provided only as general guidance. The original manual describes corneal collagen cross-linking with riboflavin as a revolutionary, emerging technique under clinical investigation. The ophthalmologist must become familiar with the latest recommended treatment techniques.

23.2. Eligibility and Exclusion Criteria

The source states that publications and ongoing clinical studies demonstrate riboflavin corneal cross-linking as safe and effective for grades I and II keratoconus, iatrogenic post-LASIK ectasia and pellucid marginal degeneration. Preoperative assessment remains necessary to determine whether a patient with keratoconus or another corneal disorder is a suitable candidate.

Main contraindications described in the source: patients with corneal thickness below 350 µm after epithelial removal, to avoid retinal UV exposure; severe corneal scarring, because irregular scar tissue may cause hot spots or UV penetration to the retina; keratometry above 58 diopters, because the cornea may not flatten sufficiently to make the procedure worthwhile; history of severe corneal herpes simplex infection, because UV-A may reactivate the virus.

SOURCE SECTION 66

Patients with pre-existing severe dry-eye disease require preoperative treatment because it can delay epithelial healing after corneal collagen cross-linking.

23.3. Treatment Steps (Based on the Conventional Protocol)

NOTE: This protocol was suggested by the Paulista School of Medicine. Technical responsibility for the procedures does not rest with EVOptica. Each treating physician must obtain additional information about the riboflavin type, actual technique and specific treatment objectives.

23.3.1. Step A - Corneal Abrasion

Apply one drop of topical anesthetic. Check corneal thickness with a pachymeter at the thinnest location, described in the source by the unclear term “cantered,” and inferiorly in keratoconus patients. Thickness is generally >450 µm; if lower, expect a thin cornea after epithelial removal.

Insert the eye speculum. Looking through a microscope (optional), place the corneal marker firmly and directly on the cornea and administer several drops of 20% alcohol for 30 seconds; then absorb the alcohol with an eye sponge. Perform epithelial abrasion, normally 8-9 mm. Using a new corneal sponge, carefully remove the fragile epithelium, normally approximately 50 µm thick.

Measure corneal thickness again. If >400 µm, proceed with riboflavin with dextran only. The ISOTONIC solution helps maintain the cornea or slightly swell it, up to 2%.

SOURCE SECTION 67

If the cornea is <400 µm, also prepare riboflavin without dextran. The HYPOTONIC solution should swell and enlarge the cornea.

23.3.2. Step B - Corneal Soaking with Riboflavin

Continue administering one riboflavin drop every 5 minutes for 30 minutes total (6 drops). At the end of 30 minutes, measure thickness again using the pachymeter.

NOTE: If corneal thickness is <400 µm, start riboflavin without dextran (hypotonic) every “2, 3 minutes” (source wording) for approximately 10 minutes total, until the cornea swells to equal or greater than 400 µm; the source prints the symbol “>”. Confirm by remeasuring thickness. Check riboflavin diffusion into the anterior chamber with a slit lamp, if available.

23.3.3. Step C - Corneal Irradiation (UV Application)

Confirm correct WAVELINK settings, aiming the X, Y and Z positioning beam, and instruct the patient to look at the fixation target throughout the procedure.

NOTE: Working distance is 55 mm. Adjust it by focusing the two aiming beams into a single beam at its sharpest profile.

Select the correct aperture, treatment spot size 6, 8 or 10 mm. Ensure UV light does not contact the limbus.

NOTE: The treatment beam should be as large as possible but smaller than the limbal diameter to avoid stem-cell destruction.

SOURCE SECTION 68

Set the desired treatment type. Cross-Link includes four treatment modes (protocols):

Mode	Intensity as printed in source	Exposure	Total
A. STANDARD	3.0 MW/cm^2	30 min exposure	5.4 J/cm^2
B. INTERMEDIATE	9.0 mW/cm^2	10 min exposure	5.4 J/cm^2
C. ACCELERATED	18 MW/cm^2	5 min exposure	5.4 J/cm^2
D. RAPID	30 mW/cm^2	3 min exposure	5.4 J/cm^2

NOTE: Each option maintains the same total delivered exposure of 5.4 J/cm^2, called “total overall irradiance” in the source. The source describes this as the upper UV-A safety factor in WAVELINK corneal Cross-Link treatment. WAVELINK also has closed-loop output-power control and a built-in energy meter to maintain safer, more accurate energy.

INSTRUCTIONS: Continue administering one drop of riboflavin until the procedure ends: every 3-5 minutes in standard mode; every 1.5-2 minutes in intermediate mode; every 1 minute in accelerated mode; every 0.5-1 minute in rapid mode. Ensure the UV-A instrument remains centered and focused throughout treatment.

NOTE: The riboflavin administration timer can be set on WAVELINK. WAVELINK automatically switches off UV-A irradiation. The source states that the pre-irradiation treatment period is 3-30 minutes.

Source unit ambiguity: the standard and accelerated entries print “MW,” while intermediate and rapid entries print “mW.” Capitalization is reproduced here; the inconsistency remains unresolved and is not a validated treatment setting.

SOURCE SECTION 69

23.3.4. After Treatment

NOTE: This protocol was suggested by the Paulista School of Medicine. Technical responsibility for the procedures does not rest with EVOptica. Each treating physician must obtain additional information about the riboflavin type, actual technique and specific objectives.

Immediate aftercare: administer antibiotic eye drops, generally one drop in each treated eye; apply a therapeutic contact lens to the treated eye; antibiotic drops and topical steroids for four days, four times daily; analgesics if needed; daily follow-up and contact-lens removal on day four; Fluoromethocone eye drops (source spelling).

23.3.5. Side Effects

The original source reports that data from various Cross-Link studies indicated safe, effective treatment without significant side effects recorded at publication. Intraocular safety was extensively assessed; it states that “keratinocytes” are depleted to a depth of 300 µm and regenerate over 6 months. The corneal endothelium, crystalline lens and retina are preserved if a minimum corneal thickness of 400 µm is respected. UV dosage is designed to prevent damage to the corneal endothelium and other intraocular structures.

Postoperatively, there may be light sensitivity and mild discomfort during the first week, similar to photorefractive keratectomy (PRK). Other consequences include inability to wear contact lenses for several weeks. Changes in corneal shape require contact-lens refitting or changes in visual correction.

SOURCE SECTION 70

As with many treatments, unidentified long-term risks may exist. Increased corneal stiffness may diminish over time, requiring periodic additional treatment. The source reports clinical research data suggesting repetition of corneal cross-linking every seven years.

24. Maintenance

WAVELINK requires minimal maintenance. Apart from several simple routine operator procedures, no operator maintenance is required. EVOptica recommends servicing by an authorized company service agent. The instrument has a 12-month warranty.

During preventive maintenance, verify system calibration, alignment and general UV-light functions. WAVELINK has a calibrated power meter; earth leakage current and earth resistance are measured according to NBR 60601-1. Only an authorized company service agent may perform these procedures.

If there are any questions about operation, calibration or alignment, contact an authorized representative or EVOptica Technical Support to determine the appropriate action.

24.1. Operator/User Maintenance

An annual inspection by the authorized company representative is recommended. Contact authorized service for technical and commercial terms: contact@evoptica.com. EVOptica cannot be held responsible if equipment is opened and/or modified by unauthorized persons.

SOURCE SECTION 71

Use other than specified by Engineering automatically cancels the warranty. Read operating conditions carefully; contact Technical Support if uncertain.

24.2. Cleaning

Use a lint-free cloth dampened with a nonabrasive cleaning solution, for example water and mild detergent. Do not use organic solvents such as gasoline, alcohol or kerosene on the exterior. Clean the display with a soft cloth to minimize LCD scratching. Do not turn WAVELINK upside down while cleaning, as this may damage electrical safety systems.

If liquid is spilled on the instrument, clean it immediately with a suitable absorbent, lint-free cloth. After cleaning, ensure no liquid remains at the electrical socket, as it could short-circuit contacts. Clean the socket with cotton and wait one hour before plugging in.

Switch off and unplug WAVELINK during cleaning. After cleaning, wait at least 1 minute before connecting to the outlet; use dry cloths in this case. WAVELINK is a high-precision instrument and requires every possible care during cleaning.

SOURCE SECTION 72

24.3. Repairs

For a long useful life, have the authorized distributor or company technical service periodically inspect the device and replace parts as needed. For any WAVELINK defect, contact an authorized company distributor immediately. Repairs and replacement of spare parts are reserved for the authorized distributor.

24.4. Periodic Maintenance

Annual inspections are recommended, including software verification and adjustment and calibration of mechanical and electronic systems.

SOURCE SECTION 73

25. Troubleshooting

The full list of WAVELINK problems and solutions follows.

Problem	Cause	Action / Solution
Interlock	Interlock plug not connected	Check the interlock connection. If the problem persists, contact authorized service or the manufacturer.
Motor movement	Motor is moving	Wait for the motor to be ready. If the problem persists, contact authorized service or the manufacturer.
Communication failure	Computer is not switched off	Switch off the touchscreen-panel computer. If the problem persists, contact authorized service or the manufacturer.
Motor failure	Motor operation failure	Restart the system. If the problem persists, contact authorized service or the manufacturer.
UV high current	UV LED electrical current out of range or beyond tolerance	Contact authorized service or the manufacturer.
UV light failure	Aiming-beam deficiency or UV-light intensity >1 mW, as described in the source	Contact authorized service or the manufacturer.
Power too high	Energy exceeds the preset value by 20%	Contact authorized service or the manufacturer.
Light power too low	UV-light power is at 30% of the preset energy value	Contact authorized service or the manufacturer.
Communication error	No communication between optical driver and console within the 300 ms frame time (continued on next source page)	Restart the system. If the problem persists, contact authorized service or the manufacturer.

SOURCE SECTION 74

Communication error cause, continued: within the 300 ms frame time.

Table 2 - Troubleshooting.

Problem	Cause	Action / Solution
Calibration	System is not calibrated	Contact authorized service or the manufacturer.
System error	System failed the software integrity test	Restart the system. If the problem persists, contact authorized service or the manufacturer.
Safety system	System indication (source wording: “Acusação do Sistema”)	Restart the system. Contact authorized service or the manufacturer.

SOURCE SECTION 75

26. Technical Support

26.1. EVOptica Technical Support

EVOptica has a technical support department for customer needs and qualified technicians to address technical problems related to its products. All products are installed by authorized persons. Depending on the service and agreed estimate, service may be provided at the customer's office, clinic or hospital.

Request technical service by call/text at +1-315-210-8976 or email contact@evoptica.com. https://evoptica.com. Specialized maintenance support for all EVOptica equipment customers.

Illustrations - source section 75





Original instrument or software illustration. See the English instructions and interface labels in this section.

SOURCE SECTION 76

27. Warranty Terms

INVOICE NUMBER: _____. PURCHASED BY: _____. MANUFACTURE DATE: _____. DELIVERY RESPONSIBLE PERSON: _____. INSTRUMENT SERIAL NUMBER: _____. O.P.: _____. CNPJ: _____. CUSTOMER NAME: _____. CUSTOMER ADDRESS: _____.

EVOptica warrants WAVELINK against manufacturing defects for one (1) year from purchase. Service requires that the claim fall within this period and that the product serial number match this certificate.

27.1. Factors Voiding the Warranty

Failure to observe manual recommendations for transport, installation, use and maintenance; accident, dropping, improper installation or damage caused by incorrect use or natural agents; tampering, repairs, modification or alteration of equipment or parts by persons not authorized by EVOptica. After the warranty period, all service, parts and expenses are charged under current company policy.

SOURCE SECTION 77

27.2. Ongoing Technical Support

WARNING: Maintenance by means other than EVOptica service is expressly prohibited because it can adversely affect WAVELINK operation. Evidence of third-party or unauthorized maintenance voids the warranty. Breaking safety labels or equipment seals also voids it.

27.3. Warranty Exclusions

Labor for reinstallation if required; transport to warranty repair (freight paid by the customer); new training or retraining for technicians and office staff absent on installation day.

27.4. Loss of Warranty

The warranty is void if: the instrument is connected to incorrect voltage and/or the User Manual technical specifications and recommendations are disregarded; the equipment is tampered with (a seal must not be opened by unauthorized persons); damage results from mechanical shocks, falls or impacts, moisture, salt air, excessive heat or incorrect handling; intervention or repair is performed by persons or companies not accredited by EVOptica;

SOURCE SECTION 78

or devices, parts, equipment, accessories or software that prevent correct operation are installed by the user or by a person/company not accredited by EVOptica.

I acknowledge receipt of the Warranty Certificate for the equipment with the serial number stated in this certificate. Date: ____/____/____.

Fairport, _____.

Company representative signature: _____. Consumer signature: _____.

SOURCE SECTION 79

27.5. Responsibility Statement

Original instrument responsibility statement: the original Brazilian manufacturer, represented by its Technical Manager, Eng. Elizeu Ramos, and Legal Representative, Luis Alberto Vieira de Carvalho, signed below, assumed full technical and legal responsibility for the product and declared that all WAVELINK information in these Instructions for Use was true. These original instrument references do not establish current US clearance.

Legal Representative: Prof. Dr. Luis Alberto V. de Carvalho. CPF/MF 168601838-11. Signature: _____.

Technical Manager: Eng. Elizeu Ramos. CREA-SP 5061454507. Signature: _____.

Configuration and source-review notes

Source limitations requiring technical review

Source section 8: Corrected in QA: pages8-9 now quote the original 'permanent warranty and technical support throughout Brazil' promise expressly as historical source language, not a current EVOptica U.S. warranty or service contract.

Source section 12: Source manufacturer/distributor sentence says 'assumes any responsibility,' likely missing a negation given context. Translation accurately preserves responsibility wording with source attribution; do not silently add 'not'.

Source section 13: Source says 'ultraviolet photosensitive light' is not part of the system and its acquisition/storage is user responsibility, likely confused drug/light terminology. Literal wording retained, not corrected to a medication.

Source section 15: Power-failure paragraph says no manual intervention is needed because of automatic activation, without explaining safe recovery/irradiation behavior. Translation retained ambiguity; do not infer automatic restart authorization.

Source section 18: Beam spot entry malformed as 'module4 - (10-13mm), continuously variable; optional11mm'; page10/brochure describe4-11mm. Aiming system also differs: manual670nm diode laser versus brochure two670nm red LEDs plus laser prose. Values preserved separately.

Source section 19: Source voltage90-240VAC and electrical input100-230VAC conflict. 'Auto-Ranging & Opt.30min' is unresolved in manual; brochure describes optional30-minute battery. No inferred battery substituted into manual.

Source section 65: Contraindication threshold below350µm after epithelial removal conflicts with treatment steps requiring400µm on pages66-67 and preservation claim on69. Both thresholds retained; not reconciled into a clinical protocol.

Source section 67: Hypotonic-riboflavin interval printed '2,3 minutes' is ambiguous between decimal and range. Translation quotes '2, 3 minutes'; ≥400µm prose versus > symbol discrepancy preserved.

Source section 68: Standard and accelerated protocols print MW/cm^2 while intermediate/rapid print mW/cm^2. Translation preserves capitalization with explicit source-unit warning. All four rows retain3/9/18/30 intensity numerals,30/10/5/3minutes and5.4J/cm^2 totals. Source also incorrectly calls J/cm^2 total irradiance. No clinical dose correction applied.

Source section 69: Drug spelling 'Fluoromethocone' and cell term 'keratinocytes' retained as source wording rather than guessed pharmacology/anatomy. Original safety/efficacy statements are historical clinical claims, not validated current IFU content.

Source section 71: Cleaning says wait one hour after cleaning a wet electrical socket, then at least one minute after general cleaning. Both conditions and prohibitions on alcohol/organic solvents, upside-down cleaning and energized cleaning are preserved; do not merge waiting periods.

Source section 73: Troubleshooting source says computer is not switched off and action is switch off, not restart; preserved. Low power is 'at30%' of preset energy, not30% below; preserved. UV-light-failure threshold >1mW is an unresolved source unit/beam identification issue.

Source section 74: All three continued troubleshooting rows retained; 'Acusação do Sistema' remains unclear and is identified as source wording. Communication-error300ms cause is completed on73 and repeated as continuation on74.

EVOptica

Ophthalmic instruments. Science, engineering and experience connected.

Contact sales, distribution and product support

evoptica.com

contact@evoptica.com

Call or text +1-315-210-8976

221 S Main St
Fairport, NY 14450
United States

Explore WaveLink resources

Request a demonstration or quotation

Configuration and market information

US regulatory clearance is in progress. The original ophthalmic product line held clearances in South American markets. Contact EVOptica for the product configuration, documentation and availability relevant to your destination market.

This is a full English technical-review edition of the supplied source document. It preserves source procedures, warnings, values and unresolved source differences. It is not a manufacturer-released clinical IFU for a new US product configuration.

Document information

English EVOptica edition: 05 November 2026.

Source revision: Version 01

Original technical illustrations are retained for traceability. Some legacy interface screenshots show Portuguese controls; English instructions and label glossaries accompany them. Product and software names are retained. Third-party marks identify their respective owners.