Avedro, Inc.
KXL System

Operator's Manual

Printed in U.S.A.

Patents, Trademarks, Copyrights

The KXL System may be covered by one or more patent applications issued or pending in the United States and worldwide.

For more information, contact:

Your Local Avedro-authorized distributor

Avedro, Inc.
201 Jones Road
Waltham, MA 02451

EC REP

EMERGO EUROPE

Prinsessegracht 20

2514 AP, The Hague

The Netherlands

Phone: +31.70.345.8570

Fax: +31.70.346.7299

CE 2797

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Foreword

1.1 Intended Use of Manual

This manual is designed to serve the operators of the Avedro, Inc. KXL System. All operating instructions, product illustrations, screen graphics, troubleshooting/error messages, and other relevant information are contained in this manual. It is the operator's responsibility to ensure that all safety instructions in this manual are applied strictly.

1.2 Intended Use / Indications for Use

The KXL System delivers a uniform, metered dose of UVA light to a targeted treatment area for the intended use of illuminating the cornea during corneal cross-linking procedures stabilizing cornea which have been weakened by disease or by refractive surgery.

1.3 Design Change Disclaimer

- Due to design changes and product improvements, information in this manual is subject to change without notice. Avedro, Inc. (hereafter called "Avedro") reserves the right to change product design at any time without notice, which may subsequently affect the contents of this manual.
- Avedro assumes no responsibility for any errors that may appear in this manual. Avedro will make every reasonable effort to ensure that this manual is up to date and corresponds with the shipped KXL System.
- The computer display screens depicted in this manual are representative only. Depending on the software version of the system, minor differences may appear between the actual computer displays and those shown in this manual.
- All patient data appearing in this document, including the sample screen graphics, are fictitious and representative only. No patient's confidentiality has been violated, with or without permission.

1.4 Reproduction Disclaimer

1.5 User Operation Assistance Statement

Should you experience any difficulty in running your KXL System, please contact your local Avedro authorized representative.

1.6 Contraindications, Warnings and Cautions

1.6.1 Contraindications

This section describes situations in which the device should not be used because the risk of use clearly outweighs any possible benefit. Conditions that may contraindicate the use of the device include:

- Corneal thickness, with epithelium, of less than < 375 microns.
- Corneal melting disorders
- Aphakic patients
- Pseudophakic patients without UV blocking lens implanted
- Pregnant and nursing women
- Children

1.6.2 Warnings

Physicians should evaluate the potential benefits in patients with the following conditions:

- Herpes simplex, herpes zoster keratitis, recurrent corneal erosion, corneal dystrophy
- Epithelial healing disorders
- In this manual, Caution is defined as: a statement that alerts the user to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device or damage to other property. The caution statement includes the precaution that should be taken to avoid the hazard.
- In this manual, Warning is defined as: a statement that alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

1.6.3 Electrical Safety Warnings

- This equipment requires special precautions regarding electromagnetic compatibility (EMC). Installation and use should be carried out according to the EMC information provided in this manual.
- Portable and mobile RF communications equipment can affect medical electrical equipment such as the Avedro KXL System.

For Equipment Classifications please refer to Chapter 5.0 Equipment Classifications.

WARNING: Any repair or service must be carried out by Avedro trained personnel only.

WARNING: Do NOT modify this equipment without authorization of the manufacturer.

WARNING: To avoid the risk of shock this equipment must only be connected to a supply mains with protective earth.

To separate system connection to mains, grasp the power cord plug and pull it from outlet to disconnect.

The system is designed for continuous operation using the external connector.

WARNING: This equipment is operated with hazardous voltages that can shock, burn, or cause death. To reduce the possibility of electrical shock, and inadvertent UVA exposure do not remove any fixed panels. Ensure that all service to the system, beyond what is described in this manual, is performed only by qualified Avedro authorized service personnel.

WARNING: Power down system and remove the wall plug before servicing or cleaning (disinfecting) the equipment.

Never pull cords to remove the power cord from the outlet. Grasp the power cord plug and pull it from the outlet to disconnect.

The equipment must be positioned so that it is not difficult to remove the power cord from the outlet.

WARNING: Do not operate the equipment with a damaged power cord.

WARNING: Position the power cord so that it cannot be tripped over, walked on, rolled over, crimped, bent, pinched, or accidentally pulled from the wall outlet.

WARNING: Do not use the instrument near water and be careful not to spill liquids on any part of it.

WARNING: Do not operate the KXL System in the presence of flammable mixtures or anesthetics.

WARNING: Never look directly into the UV light beam. Never direct the beam towards a person except for therapeutic purposes.

WARNING: Ignoring local regulations on use of electro-optical medical devices may cause malfunction due to electromagnetic interference.

WARNING: The remote contains replaceable batteries; if system is not going to be used for an extended period of time remove the batteries.

WARNING: Use of not included accessories results in non-compliance of the device

WARNING: System may be interfered with by other equipment even if that equipment complies with CISPR Emissions requirements. See Table 5-1.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the Avedro KXL system (110-01019), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: System shall not be serviced or maintained while in use with a Patient.

WARNING: MR Unsafe – Keep away from magnetic resonance imaging equipment.

WARNING: Do not use a damaged or malfunctioning device. Use of such devices may harm the user and/or patient

1.7 Radiation Safety Warnings

WARNING: Use only laser grade instruments in order to prevent reflected UV radiation from smooth metallic surfaces.

WARNING: UV emitted from this product. Avoid eye and skin exposure to unshielded products. Never direct the beam towards a person except for therapeutic purposes.

1.8 Patient Safety

- The treatment should take place in a quiet and relaxed atmosphere in order not to distract the attention of the patient. The patient should lie on a table or patient's chair. The patient's head should rest comfortably in a headrest. It is imperative that the table or patient's chair or the system not be moved during the treatment procedure.

CAUTION: The KXL System is a medical device. It may be operated, therefore, only in health care facilities or medical areas under the supervision of medically trained personnel.

1.9 Additional Safety Considerations

- Any modification of the system's external light beam by means of optical elements is strictly prohibited.
- Plastic instrumentation such as speculums or eye shields may be damaged when impacted by the UV beam, possibly resulting in product degradation. Therefore, only Avedro recommended accessories or stainless-steel surgical instruments should be used.
- Smooth metallic surfaces can reflect despite the effort to blank them. Therefore, only laser grade instruments should be used.

1.10 FCC Compliance Notice

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or

television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an electrical outlet on a circuit different from that to which the receiver is connected.
- Consult Avedro Customer Service for help.
- Properly shielded and grounded cables and connectors must be used in order to meet FCC emission limits. Proper cables and connectors are available from Avedro. Avedro is not responsible for any radio or television interference caused by unauthorized changes or modifications to this equipment. Unauthorized changes or modifications could void the user's authority to operate the equipment.

2 Introduction

2.1 System Overview

The KXL System is an electronic medical device which delivers ultraviolet light (365 nm wavelength) in a circular pattern onto the cornea after a solution of Riboflavin has been applied. Irradiating the Riboflavin creates singlet oxygen, which forms intermolecular bonds in corneal collagen, stiffening the cornea through cross-linking. UV flux and irradiation time (that is, fluence) at the cornea are controlled by an onboard computer system.

The ***Optics Head*** houses the UVA irradiation mechanism and camera. The LED is preset by the manufacturer to emit UVA radiation at a wavelength of 365 nm at an intensity of 3 mW/cm^2 to 45 mW/cm^2.

A fixed aperture mounted in the UVA irradiation beam path is used to produce a uniform circular area of irradiation at the treatment plane with an approximate diameter of 9 mm. Alignment lasers are used to aid the user in focusing the beam on the patient's cornea. Fine alignment of the UV beam through observation of the alignment lasers is controlled through a wireless remote and an internal drive system. Treatment power is selectable by the user from 3 mW/cm^2 to 45 mW/cm^2 in 1 mW/cm^2 increments. Total Energy is selectable in 0.1 J/cm^2 increments on the user interface. However, actual limits to power and energy are controlled by the RFID treatment card.

The KXL is a portable system with an articulating arm to allow movement of the system for alignment of the UV Beam to the patient's cornea. The treatment parameters (Riboflavin Induction Period, Total UV Energy, UV Power and UV Pulse Cycle Times) are selected through the user interface touch screen computer.

The KXL System is used in conjunction with a Riboflavin solution and an RFID card.

2.1.1 Major Components

The major components of the KXL System include the following:

- Optics Head with UV source and Camera
- KXL console with user interface
- Wireless remote control (with replaceable batteries)
- KXL Accelerated Crosslinking Treatment Kit (disposable supplied separately)
- Hospital Grade AC power cable (Lockable/detachable)
- System Part Number: 110-01019

Figure 2-1. Overview Illustration of System

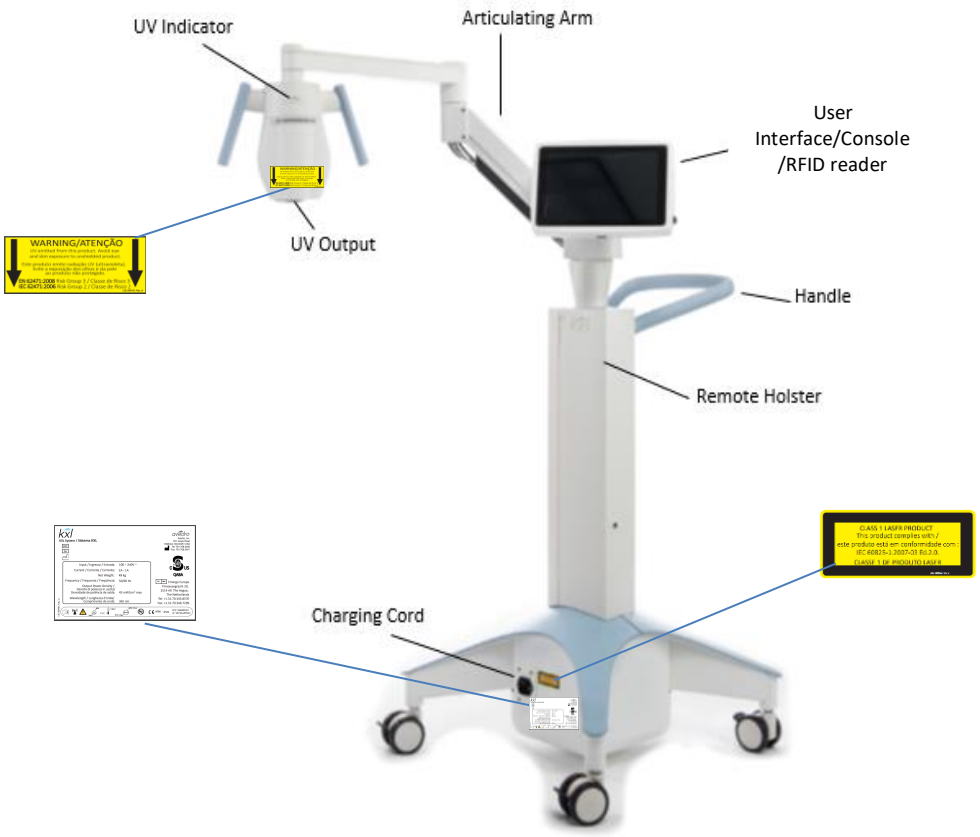


Figure 2-2. System Illustrations with Callouts

Figure 2-3. Wireless Remote

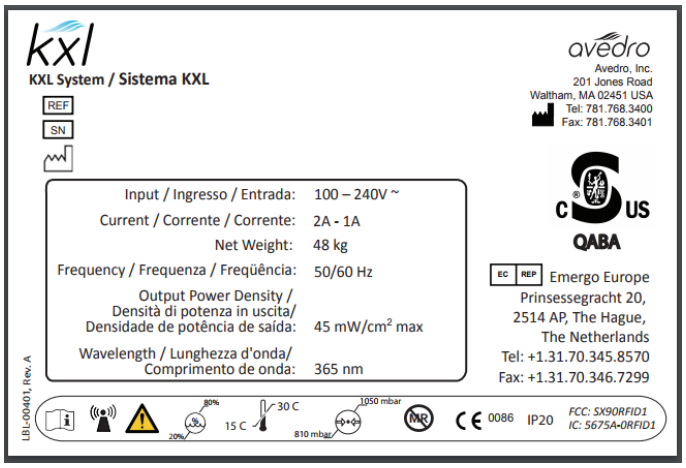


Figure 2-4. KXL Label

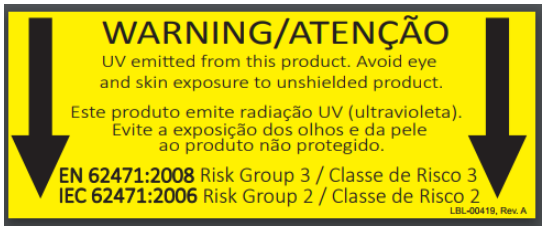


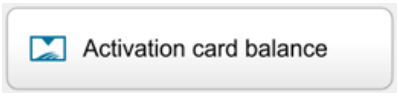
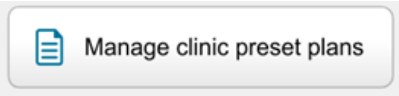
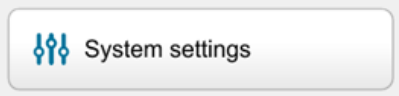
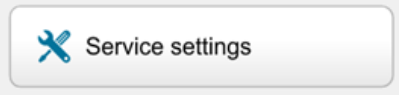
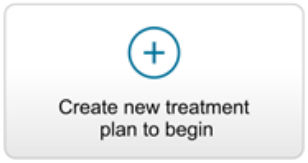
Figure 2-5. UV emitting Label

Figure 2-6. Laser Classification Label

3 System Operation

3.1 Touchpad/Keyboard Use

The table below identifies and describes important touchpad keys and icons unique to KXL System operation. Chapter 2 identifies and describes the KXL System's major components.

Touchpad Key	Icon	Description/Function
Power Off button (Initial screen)		Turns OFF electric power to the console.
Add new patient button (Initial screen)		Add patient information prior to treating the patient
Options button (Initial screen)		Displays system settings and managing preset plans
Activation card balance button		Displays balance on treatment card
Manage clinic preset plans		Modify parameters of preset treatment plan
System Settings		Device settings menu is displayed
Service settings		Ability to edit default parameters
Create new treatment plan to begin (Patient overview screen)		Starts preset or modified treatment plan for patient
UP arrow (various Clinical Protocol screens)		Increases the value of the current field.
DOWN arrow (various Clinical Protocol screens)		Decreases the value of the current field.

Touchpad Key	Icon	Description/Function
X button (various Device Settings screens)		Cancels all the entries on a screen and returns to the previous screen.
Checkmark button (various Clinical Protocol screens and Device Settings screen)		Directs the system to accept the current screen entries and to proceed to the next step.
Cancel button (various Clinical Protocol screens and Device Settings screen)		Cancels all the entries on a screen and returns to the previous screen.
Export button		Exports patient treatment report to USB
Add comment button (patient overview screen)		Add notes to a patient treatment report
Trash Can icon		Delete photos taken during treatment
Cancel Treatment button (various Clinical Protocol screens)		Cancels a treatment session for a patient.
Start timer button		Starts treatment timer
Change treatment type button		Changes treatment type
Perform treatment button(various Clinical Protocol screens)		Starts treatment

Touchpad Key	Icon	Description/Function

Return to Treatment button (Confirm Cancel Session screen)		Cancels the Cancel Session command and returns to the Treatment screen.
Return button (various Device Settings screen)		Returns to the Device Settings menu.
Restore to factory presets (manage clinic preset plans)		Presets restored to normal parameters

CAUTION: Only qualified and experienced personnel shall operate the KXL System.

3.2 UV Energy (Dose)

- The UV Energy (Dose) is the product of the UV Power (Intensity) and the UV Irradiation Time. The UV Energy and UV Power are adjustable and the calculated UV Irradiation Time is displayed.
- The system tracks UV Energy, UV Power, UV Irradiation Time and Total Treatment Time during the treatment.
- These options are selectable by the user during the treatment plan mode. See Section 3.8.3
- There are two UV treatment modes available, Continuous and Pulsed.
    - Continuous Mode: UV output is constant for the duration of the UV treatment.

      Continuous Mode Parameters:

      Induction Period: 1 second – 30 minutes
      UV Energy*: 1 – 10.7 J/cm^2
      UV Power: 3 – 45 mW/cm^2
      **The user may select UV Energy in 0.1 J/cm^2 increments. The energy range is controlled by the RFID card.*
    - Pulsed Mode: UV output turns ON and OFF at user selected intervals.

      Pulsed Mode Parameters:

      Induction Period: 1 second – 30 minutes
      UV Energy*: 1 – 10.7 J/cm^2
      UV Power: 6 – 45 mW/cm^2
      UV ON Time: 1.0 – 4.0 Seconds
      UV OFF Time: 1.0 – 4.0 Seconds
      **The user may select UV Energy in 0.1 J/cm^2 increments. The energy range is controlled by the RFID card.*
- Please reference Riboflavin Instructions for Use (IFU) for formulation information.

3.3 Preparing the System

- Position the KXL System adjacent to the treatment table or chair. Lock the casters to secure the device's position.
- Make sure the system is turned ON.
- When system is in use, keep head away from bright lights, such as positioning in front of windows.
- Check glass window of beam aperture for dust and dirt. See Sections 4.7 and 4.8 for cleaning instructions.

3.4 Important Steps before Turning On the System

- The user is responsible for assuring that the KXL System is functioning properly before starting a treatment.
- To ensure the system is functioning properly, consider the following mandatory points:
    - Inspect the device, accessories, and connecting cables for visible damage.
    - Take local regulations for use of portable electro-optical medical devices into consideration.

3.5 Powering Up the System

- Turn ON the master power switch on the base of the KXL system, adjacent to the power cord plug. This switch provides AC mains power to the KXL system.
- Press and release the power-on button on the side of the KXL display screen. See Figure 3-1. The KXL System will begin a power-up sequence, loading the operating system and all configuration and reference files.

Figure 3-1. Power Switch

- NOTE: If there is a Start-up error, please note any error messages and contact your distributor or Customer Service.

- Please see section 3.21 for Power Down sequence instructions.
- The Patient database, shown in Figure 3.2, stores:
  - Previously treated patients
  - Untreated patients with saved treatment plans
  - New patients with no assigned treatment plans

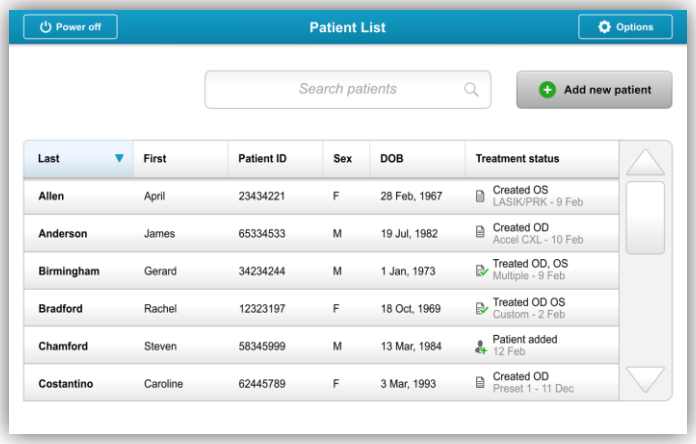


Figure 3-2. Patient Database

3.6 Existing Patient Data

- To search database for an existing patient, tap in the "search patients" box and a keyboard will generate. Type patients name in and results will populate.

3.7 Add New Patient

- To begin adding a new patient, select “Add new patient,” and the pop-up window shown in Figure 3-3 will appear.

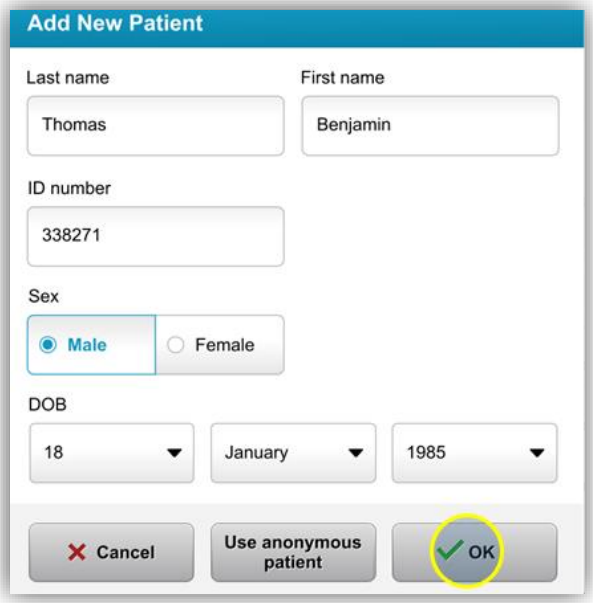


Figure 3-3. Enter Patient Information

- If “Use anonymous patient” is selected, last name field will populate as anonymous and an incrementing number will populate in “first name” field.
- Once the patient information is completed, the “OK” button will become available.
- Patients can be added at any time and are saved in the database once “OK” is pressed.

3.8 Create New Treatment Plan

- Select patient to treat from Patient Database
- Press "Create new treatment plan to begin"
- Treatment plans can be made and saved prior to patient's arrival

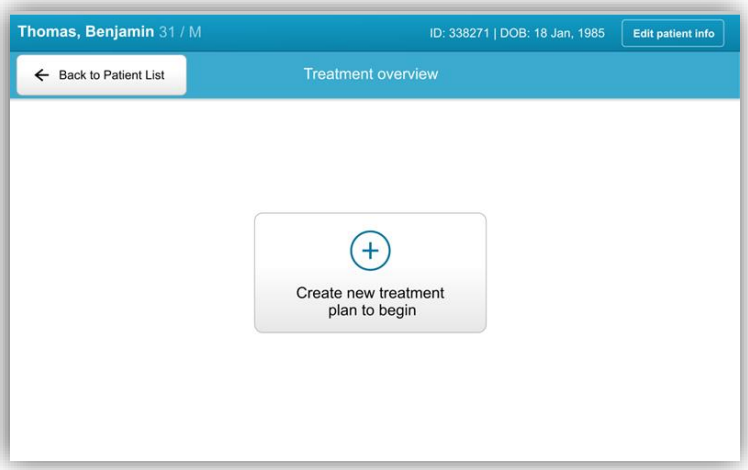


Figure 3-4. Create New Treatment Plan

3.8.1 Select Eye to Treat

- Choose the eye you wish to treat: OD or OS
- When eye is selected, the field will be outlined in blue as shown in Figure 3-5.

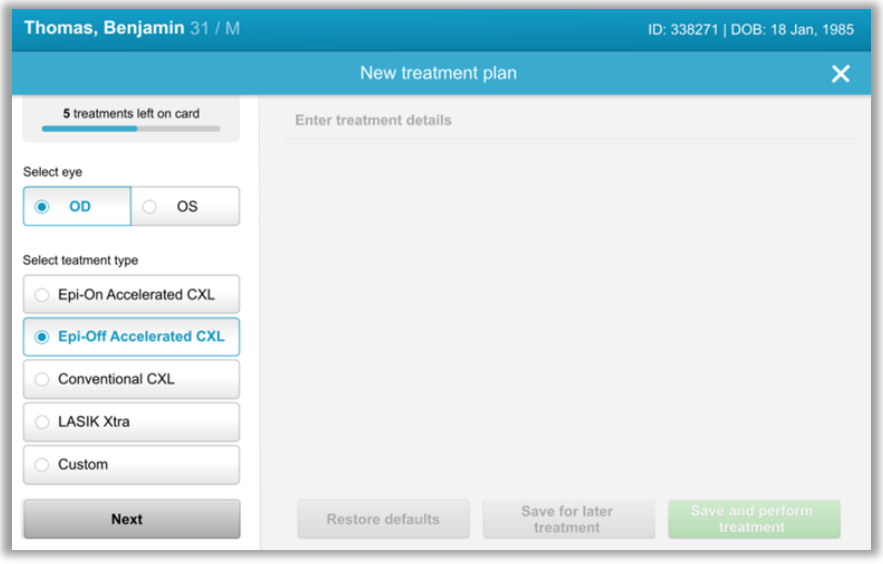


Figure 3-5. Select Eye

3.8.2 Select Treatment Type

- The system is pre-programmed with five preset treatment plans as shown in Figure 3-6:
  - Epi-On Accelerated CXL
  - Epi-Off Accelerated CXL
  - Conventional CXL
  - LASIK Xtra
  - Custom
- Saved formulations and parameters will auto-populate based on the chosen treatment plan.
- Any of the pre-set plans can be edited to change energy dose, irradiance or other treatment parameters then saved for future use.
- Select “Custom” treatment plan to create a new, custom plan.
- Once a pre-set treatment plan is chosen or a customizable treatment plan is saved, select “Next” to proceed.

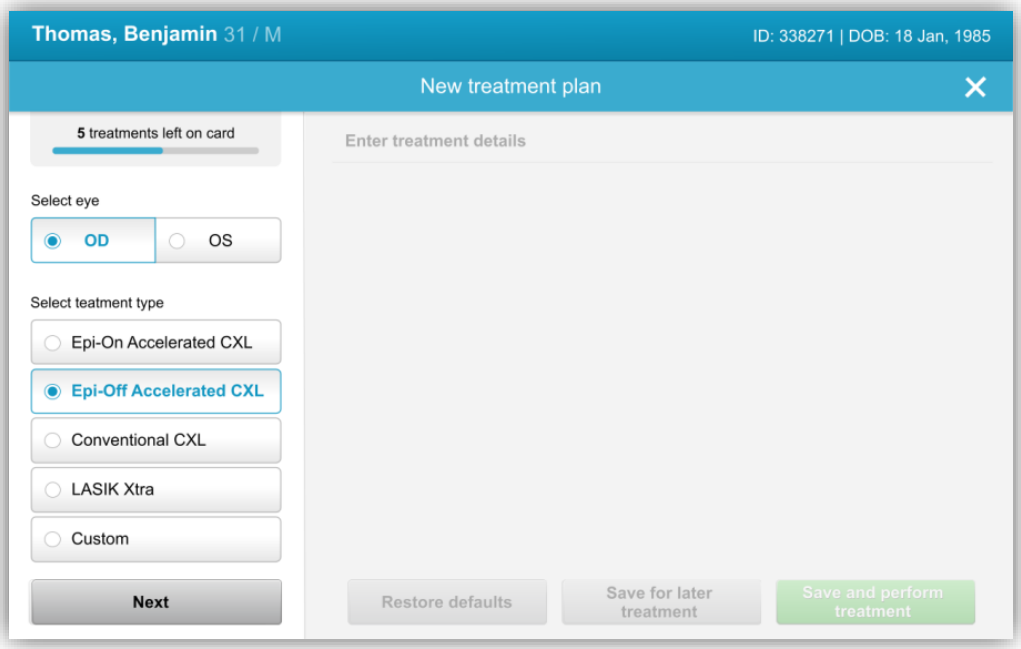


Figure 3-6. Select Treatment Type

3.8.3 Adjusting Treatment Parameters

- Review and confirm all treatment parameters within selected treatment plan. To edit individual parameters, press within the specific parameter and use the arrows to increase or decrease the desired field.

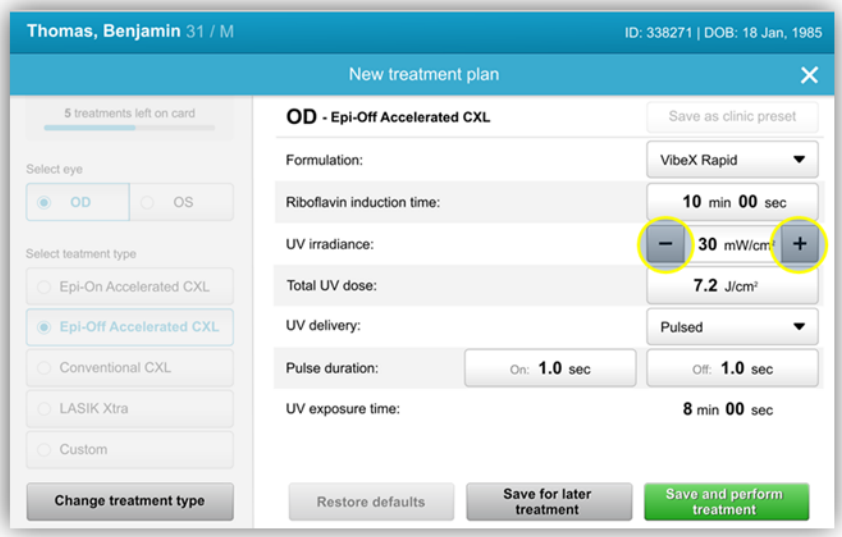


Figure 3-7. Adjusting Parameters

- When finished editing parameters, select "Save for later treatment" for future use, or "Save and perform treatment" for immediate use.
- If parameters were adjusted within any of the four presets, "Modified" will be displayed next to chosen treatment plan, as shown in Figure 3-8.

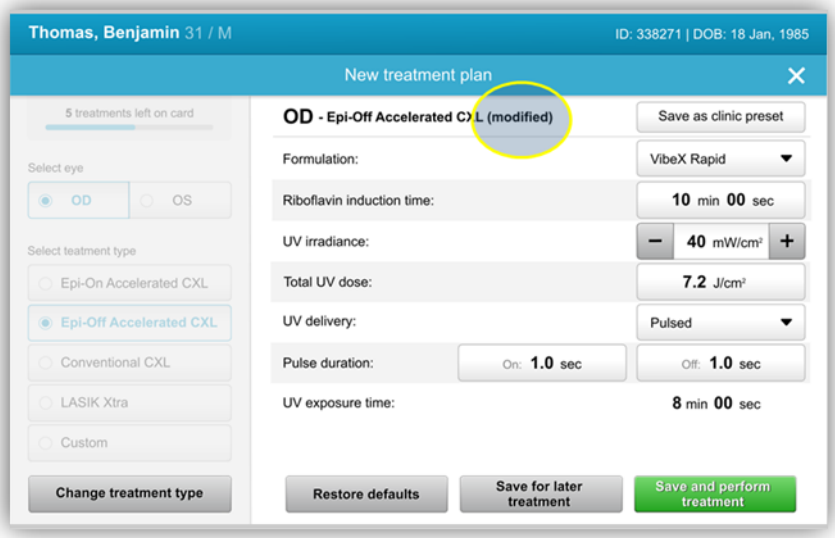


Figure 3-8. Adjusted Treatment Plan

3.9 Select Treatment Mode

There are two UV treatment modes available, Continuous and Pulsed.

- Continuous Mode: The UV output is constant for the duration of the UV treatment.
- Pulsed Mode: The UV output turns ON and OFF at user selected intervals.

3.9.1 Continuous UV Mode

To select Continuous treatment mode, select “Continuous” from the drop down menu to the right of “UV Delivery” as shown in Figure 3-9.

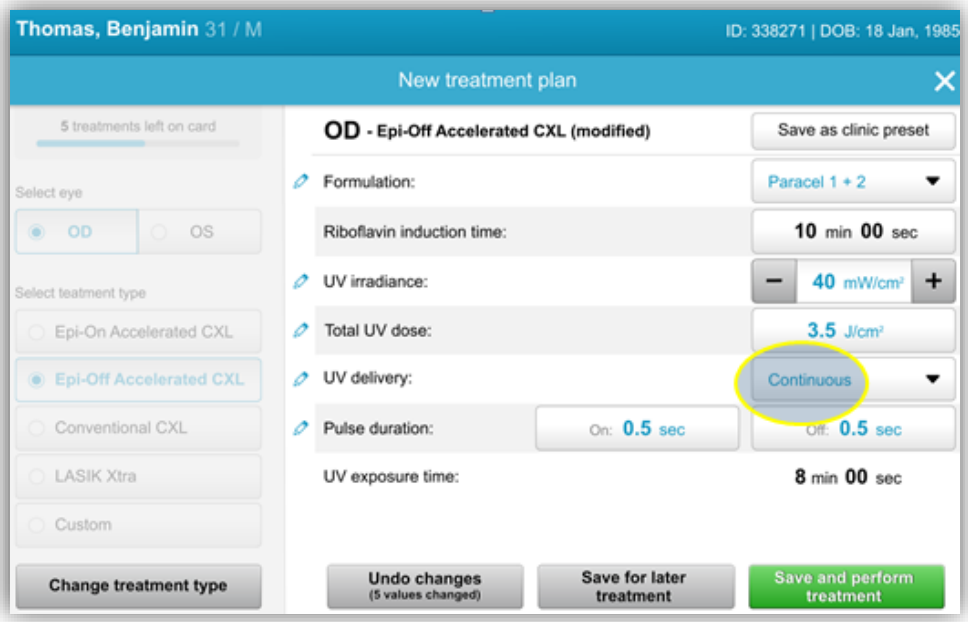


Figure 3-9. Select Continuous Treatment Mode

- Enter the desired UV treatment parameters:
  - Total Energy*
  - UV Power (3 – 45 mW/cm^2)

  NOTE: UV irradiation time is automatically calculated and displayed.

  * The user may select UV Energy in 0.1 J/cm^2 increments. The energy range is controlled by the RFID card.

- Review and confirm all treatment parameters by selecting **"**Save for later treatment" or "Save and perform treatment"; if the treatment parameters are not correct, select wrongful parameters and then re-enter the desired treatment parameters and save.

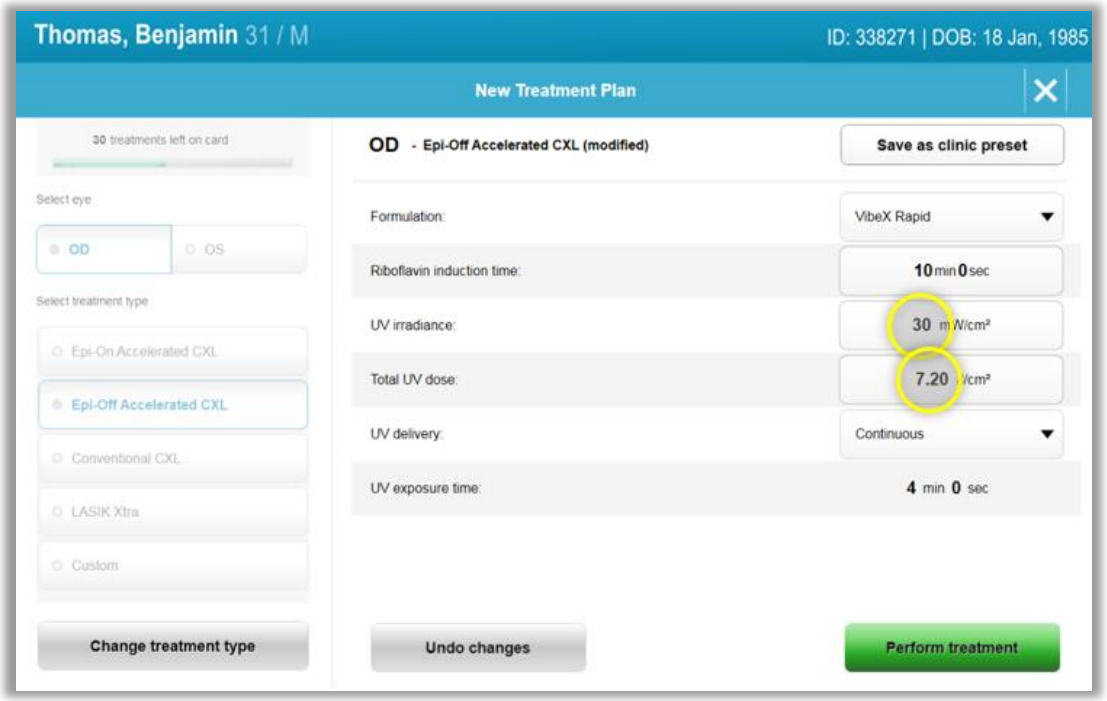


Figure 3-10. Modifying Continuous Treatment Parameters

3.9.2 Pulsed UV Mode

- To select Pulsed treatment mode, select "Pulsed" from the drop down menu to the right of "UV Delivery".

3.10 Starting a Treatment

- Choose patient from patient database.
- If a treatment plan was just created, select “Perform treatment”.

3.10.1 Insert Treatment / RFID Activation Card

- Insert the activation card all the way into the RFID slot and leave in place.

Figure 3-11. Insert Activation Card

3.10.2 Single-use Activation Cards

- Keep card in place until read is complete.

Figure 3-12. Reading Tag

- The “OK” button will illuminate when it is OK to remove the card.

3.10.3 Multi-use Activation Cards

- Once a multi-use activation card has been inserted, the display will show the number of treatments remaining on the card.
- Activation card can either be removed or remain in the RFID slot and stored for next use.

Figure 3-13. Card Balance: Treatments Remaining

- If treatment card only has one treatment left, the system will inform user to "Replace card before next treatment" as shown in Figure 3-14.

Figure 3-14. Card Balance: 1 Treatment Remaining

- If no treatments remain on the card, the system alerts the user to insert a different card or to save the treatment for later, as shown in Figure 3-15.

Figure 3-15. No Treatments Left

3.10.4RFID Card-controlled Limits

- If the user has programmed a UV Energy range that is outside the allowable value(s) controlled by the RFID card, the following message will appear after "Perform treatment" has been selected.

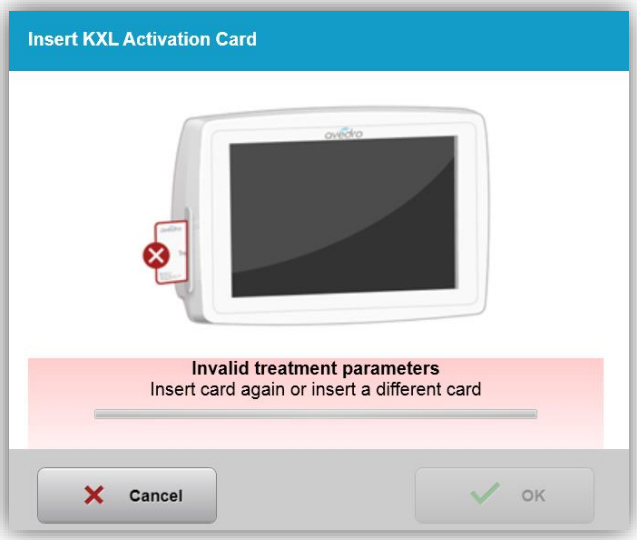


Figure 3-16. Invalid Treatment Parameters

- Go Back to Treatment Parameters to enter an appropriate parameter.

- If the user has the treatment card inserted while programming treatment parameters that are outside the allowable value(s) controlled by the RFID card, the following message will appear and "Perform treatment" will unable to be selected as shown in Figure 3-17.

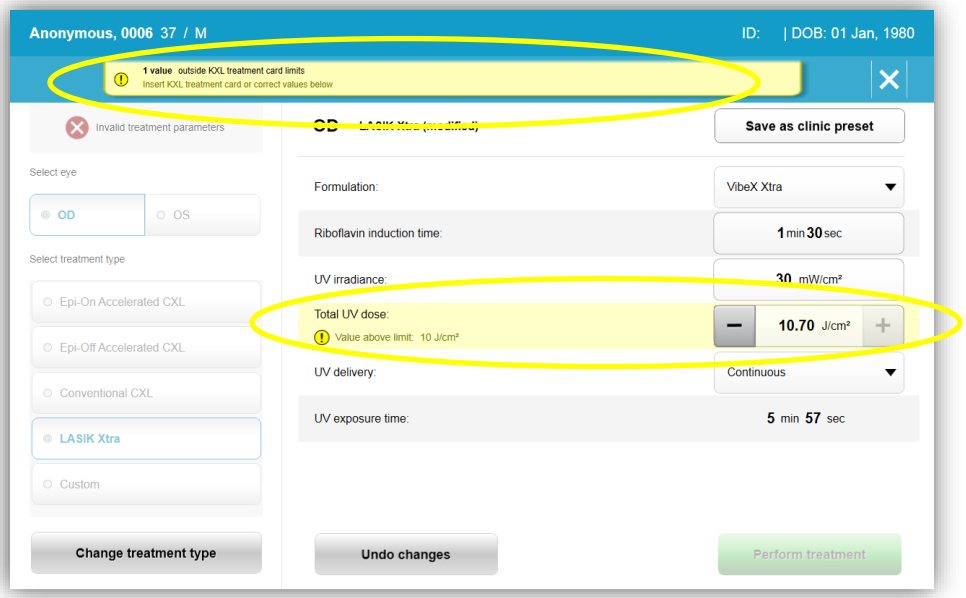


Figure 3-17. Invalid Treatment Parameters

3.10.5 Sync Alignment Remote

- The Sync alignment remote message will be visible on the screen for 15 seconds as shown in Figure 3-18.

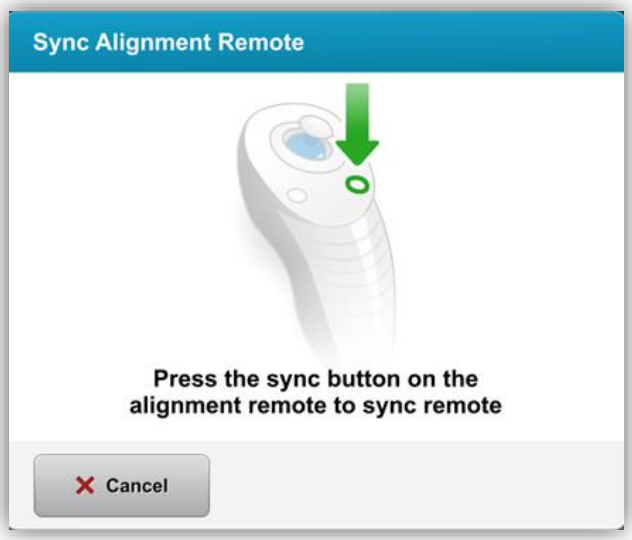


Figure 3-18. Sync Remote

- Press the sync button denoted with an “S” on the remote to synchronize the remote within the 15 second timeframe. See Figure 3-19 for sync button location. This is required for every procedure if use of the remote is desired.

Figure 3-19. System Setup Status

- The system will beep for the last 3 seconds of the 15 second sync timeframe.

- If the sync button is not pressed within the 15 second timeframe, a message stating "Alignment Remote Lost Sync" will appear onscreen as shown in Figure 3-20.
- Press "OK" to attempt to re-sync the remote, or choose to "Continue Without Remote."

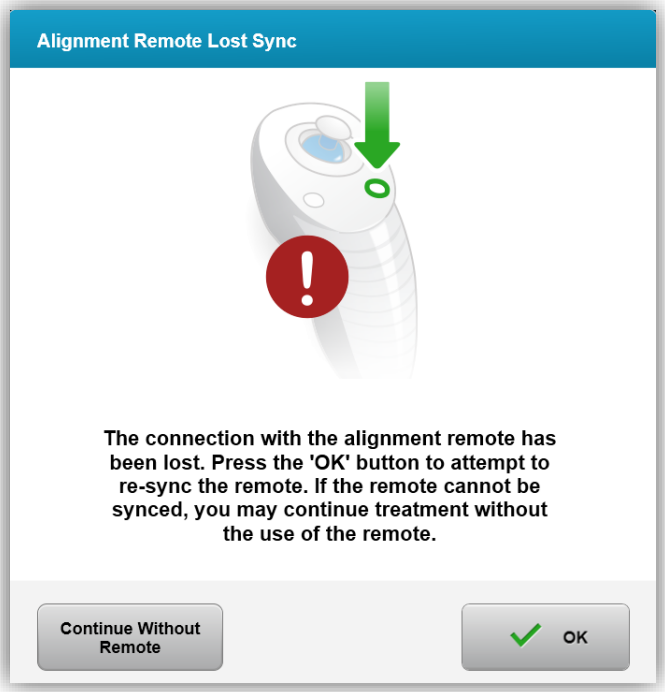


Figure 3-20. Sync Process Timed Out

- The various statuses of the remote Indicator Light are shown in Figure 3-21.
  - A constantly illuminated remote Indicator Light means that the remote is synchronized with the KXL.
  - If the Indicator Light is blinking constantly, replace batteries in the remote immediately to ensure proper operation.

Indicator Light Status	Meaning
ON	Actively Synchronized with the device
Blinking once per second for 10 seconds	Disconnecting Sync (After procedure)
Blinking constantly, twice per second	Replace batteries immediately (2 AAA)

Figure 3-21. Remote Indicator Light Status and Meaning

NOTE: The KXL system performs an internal self-test prior to each treatment to verify proper UVA calibration. The internal self-test uses a redundant set of optical sensors to ensure that accurate levels of UVA will be delivered for each treatment. If the internal self-test fails, an error message will be generated and the treatment cannot proceed. If this occurs, contact your distributor or Customer Service immediately.

3.11 Preparing the Patient

- Ensure that the patient is lying flat or reclined on a patient table or chair. His or her head should rest on a headrest.
- Adjust the table or chair and headrest so that the patient can rest comfortably for the duration of the treatment without head movement.
- Apply a lid speculum and optional drapes using standard clinical technique.

3.11.1 Applying Riboflavin, Induction, and Alignment

- Apply Riboflavin to the treatment eye in accordance with the Riboflavin Instructions for Use (IFU) and press “Start Timer.”

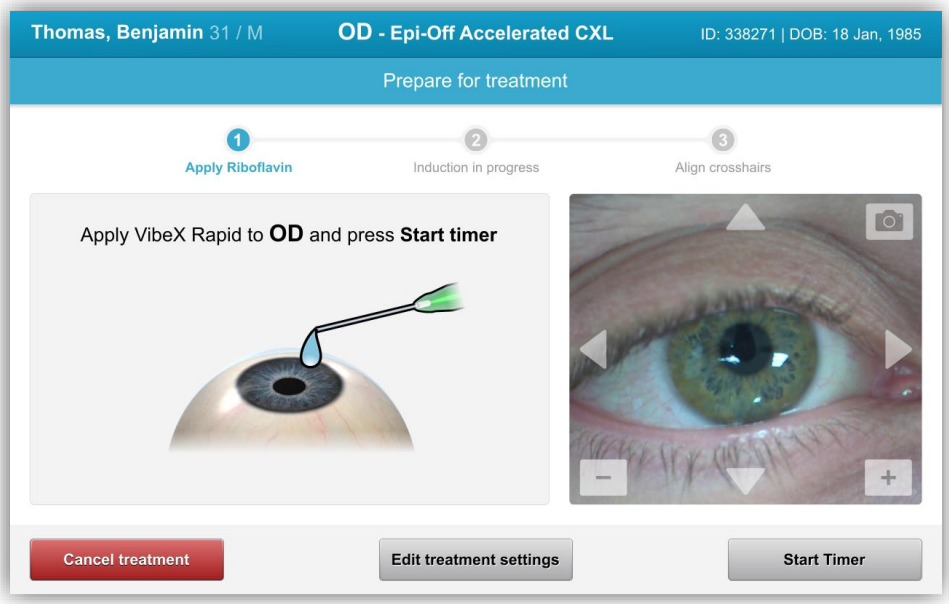


Figure 3-22. Prepare Treatment: Apply Riboflavin

CAUTION: Riboflavin (vitamin B2) is not a part of the KXL System described in this manual. For details , please refer to the Riboflavin’s Instructions for Use.

- Red alignment lasers will turn on 30 seconds before the end of the Induction period as shown in Figure 3-23.

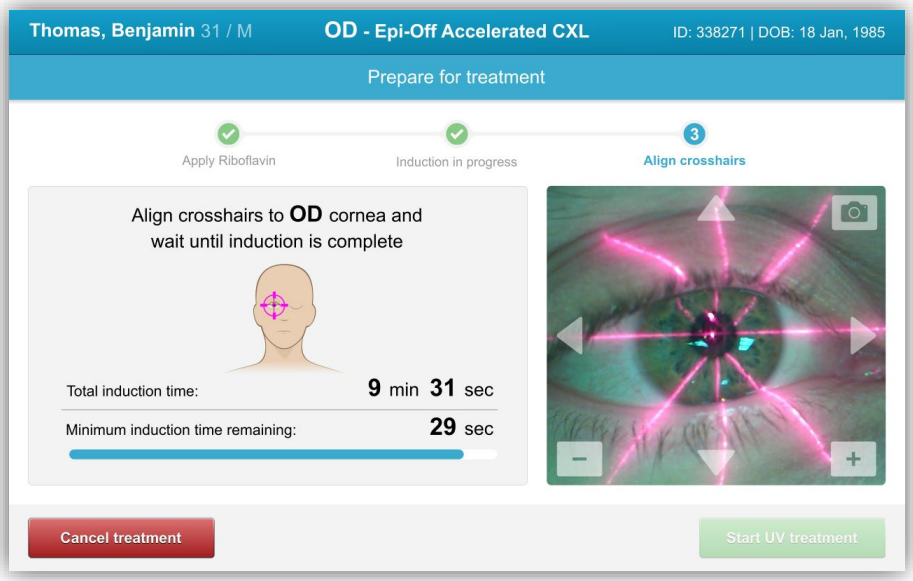


Figure 3-23. Align Crosshairs During Induction

- KXL has two alignment lasers as shown in Figure 3-24.
  - Red crosshair for X and Y axis positioning.
  - A second red crosshair for Z axis positioning.

    NOTE: Crosshairs may differ in appearance. They may appear thicker, thinner, longer or shorter.

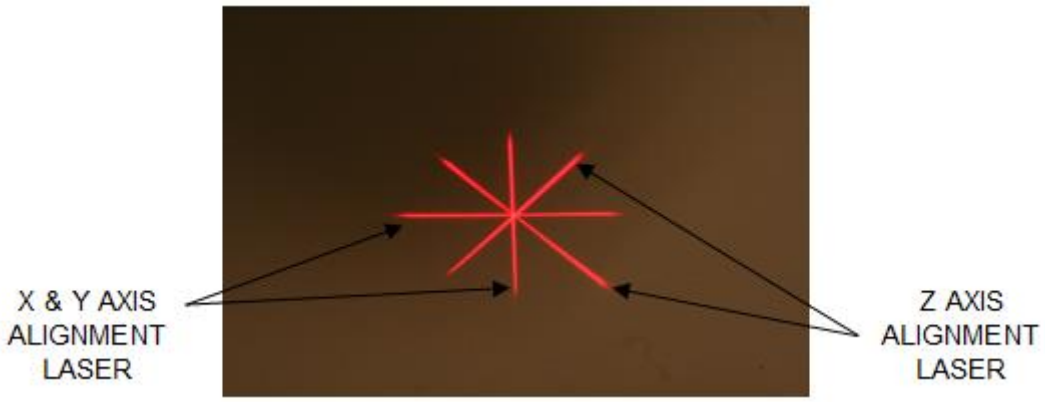


Figure 3-24. Alignment of Red Crosshairs – X & Y Axes and Z Axis

- When alignment lasers turn on, align the crosshairs over the eye to be treated.

- Manually move the KXL head back and forth and left and right until the X/Y axes' red crosshairs are aligned to the center of the pupil.
- Manually move the KXL head up and down to align the Z axis second red crosshair to the center of the first red crosshair.
- Fine tune the alignment as needed using the wireless remote or by pressing the onscreen arrows.

  NOTE: For correct alignment when using the remote, the Avedro logo on KXL head should face the user. Figure 3-25 displays the remote functions to use during the alignment process.

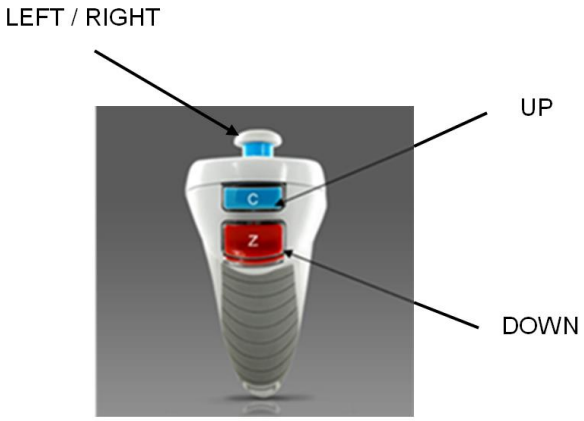


Figure 3-25. Remote Functions

3.12 Initiating Treatment

- Once the Riboflavin application, Induction, and Alignment of Crosshairs are complete, initiate treatment by pressing the "Start UV treatment" button as shown in Figure 3-26.

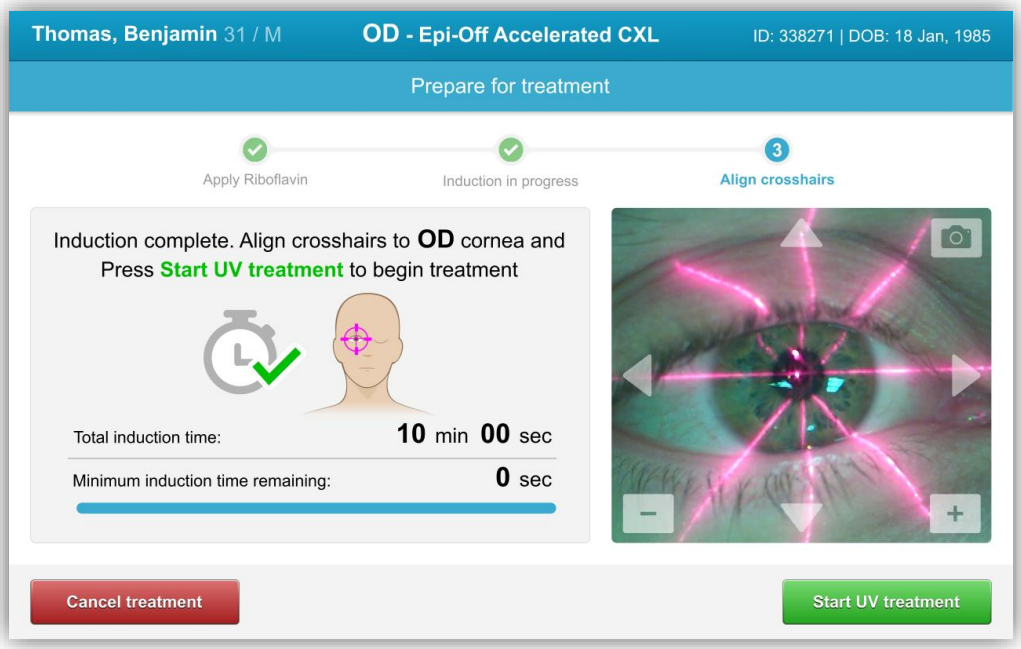


Figure 3-26. Start UV Treatment

- The patient should fixate on the red X & Y alignment crosshair throughout the treatment.
- Patients should remain still during the treatment.

WARNING: Start treatments only after the photosensitizer is applied.

CAUTION: UV light is emitted when the Avedro logo on the optical head flashes color from blue to green.

WARNING: Make sure that the KXL System and the patient's table or chair are secured and not moved after alignment and during treatment.

3.13 Monitoring Treatment

- Check continuously that the area of interest on the cornea is illuminated with the UVA light and adjust as necessary using the wireless remote or the onscreen arrows.

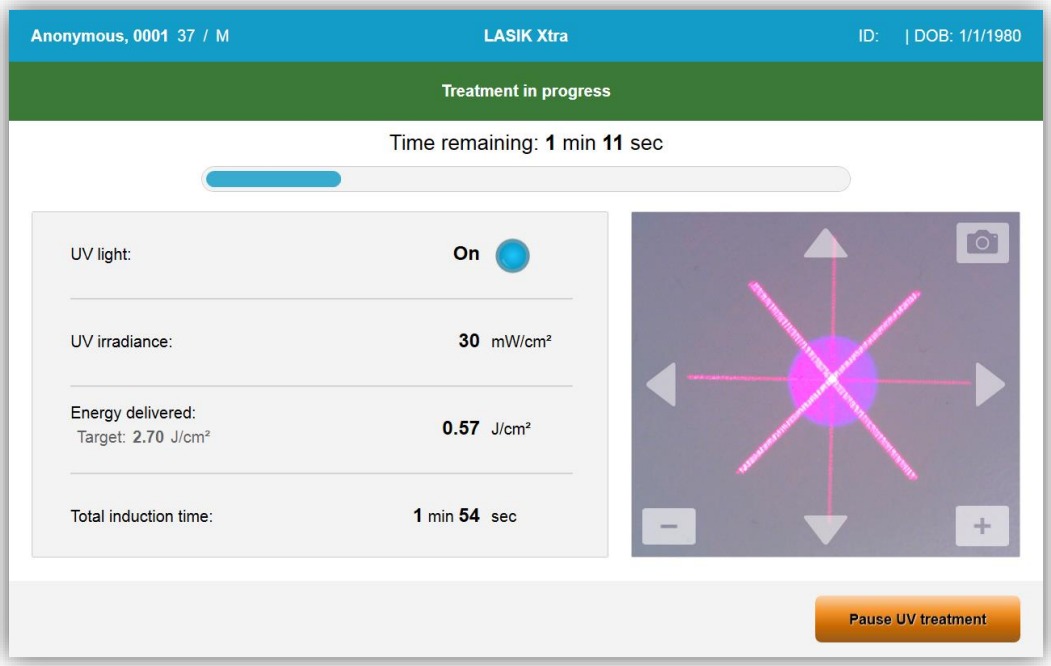


Figure 3-27. Treatment in Progress Screen

NOTE: When using Pulsed Treatment mode, UVA light will not be visible during the OFF periods. The User Interface will not change to “UV is OFF” during these cycles.

3.14 Pausing a Treatment

- The treatment stops automatically after the user-programmed timer expires.
- The user may decide to stop or interrupt the treatment. In such case, the UV light can be switched OFF by pushing the “Pause UV treatment” button.

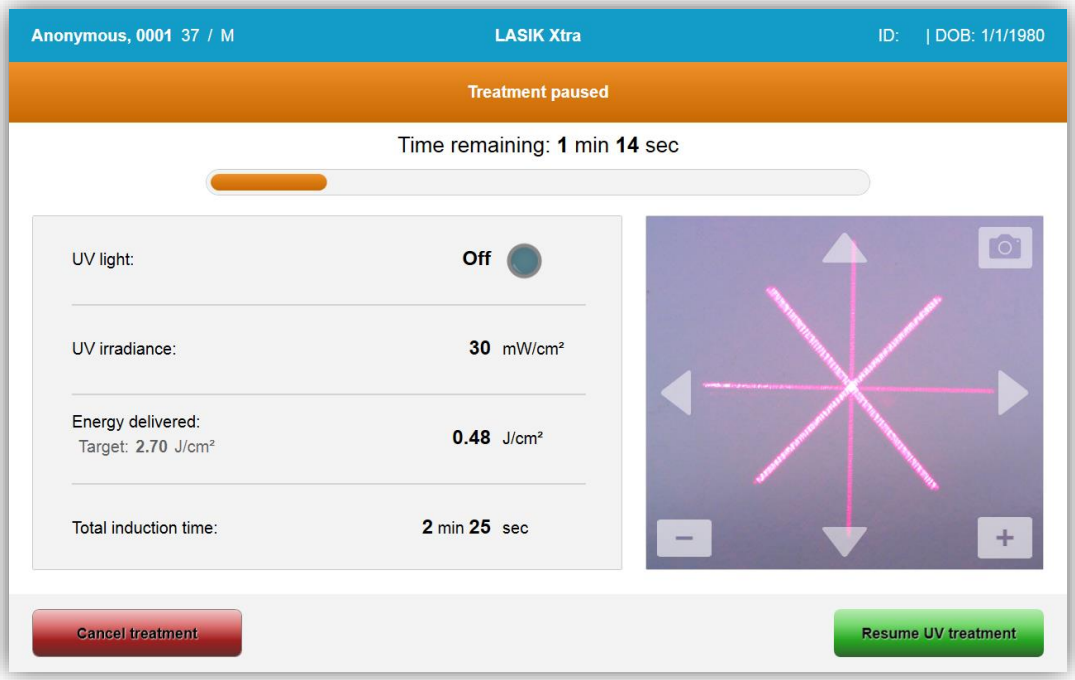


Figure 3-28. Treatment Paused Screen

- To cancel or resume treatment select "Cancel treatment" or "Resume UV treatment" respectively. See Section 3.15 if cancelling a session.

3.15 Cancelling Mid-Treatment

- A warning pop-up will appear when "Cancel treatment" is selected mid-treatment as shown in Figure 3-29.
- To confirm treatment cancellation, select "Yes".

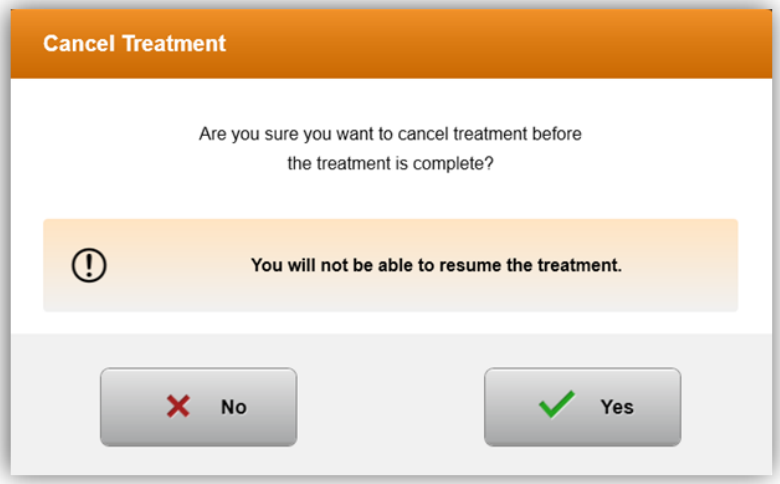


Figure 3-29. Confirm Cancel Partial Treatment

- If treatment cancellation was confirmed, an onscreen “Treatment Cancelled” message will appear as shown in Figure 3-30.

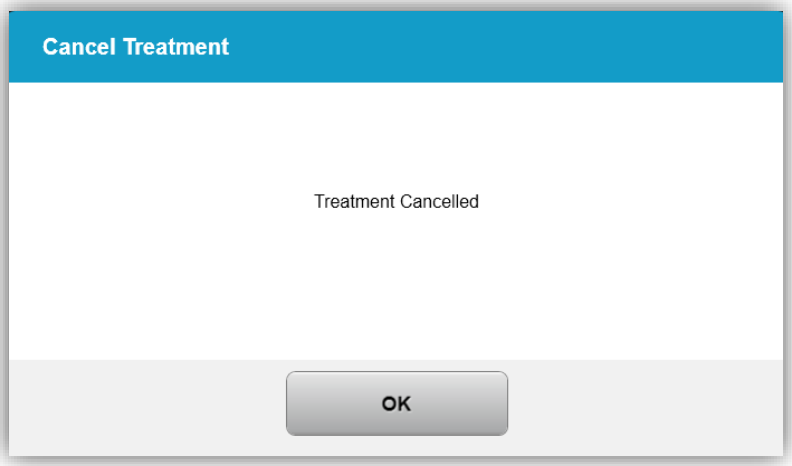


Figure 3-30. Treatment Cancelled Confirmation

- Select “OK” on the Cancel Treatment confirmation screen.
- Partial Treatment information will be displayed as shown in Figure 3-31.

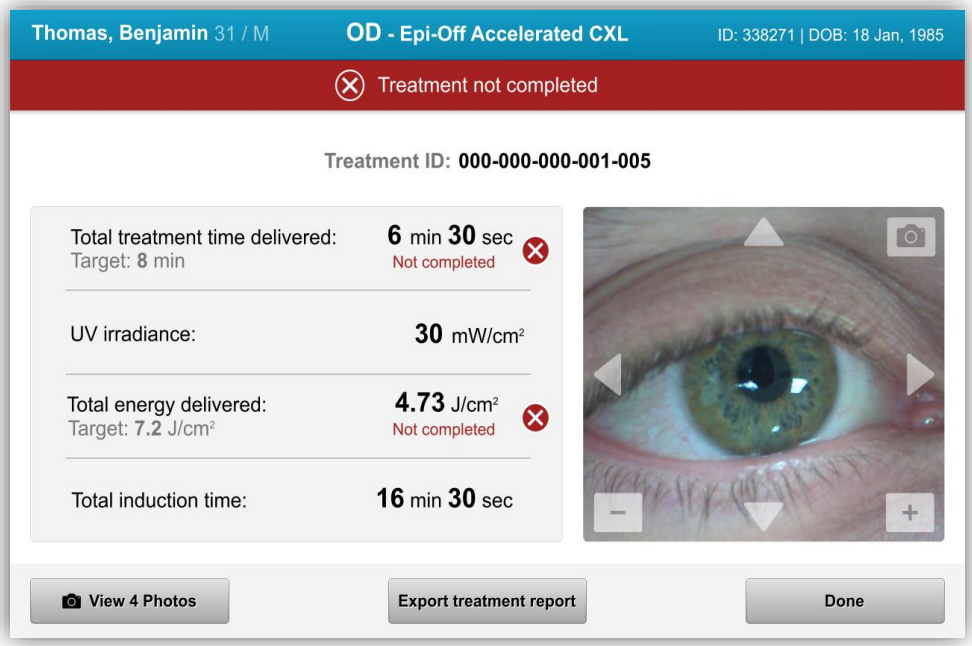


Figure 3-31. Partial Treatment Not Completed

3.16 Capturing Images

- Images can be taken at any stage throughout the treatment process.

- To capture an image, select the camera button in the top right hand corner of the eye image as shown in Figure 3-32.
- The image is automatically saved and available for review post-treatment.

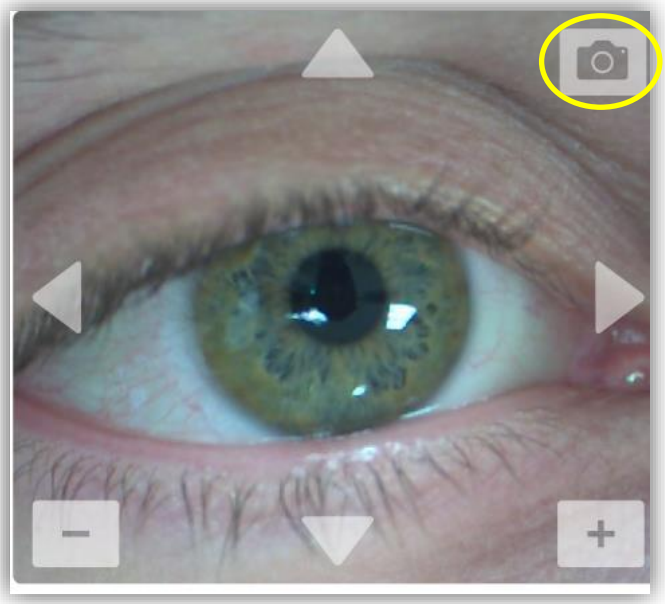


Figure 3-32. Capturing Images

3.17 Treatment Complete

- At the completion of a treatment, a summary of treatment parameters will be displayed, and the screen will show “Treatment complete” as shown in Figure 3-33.

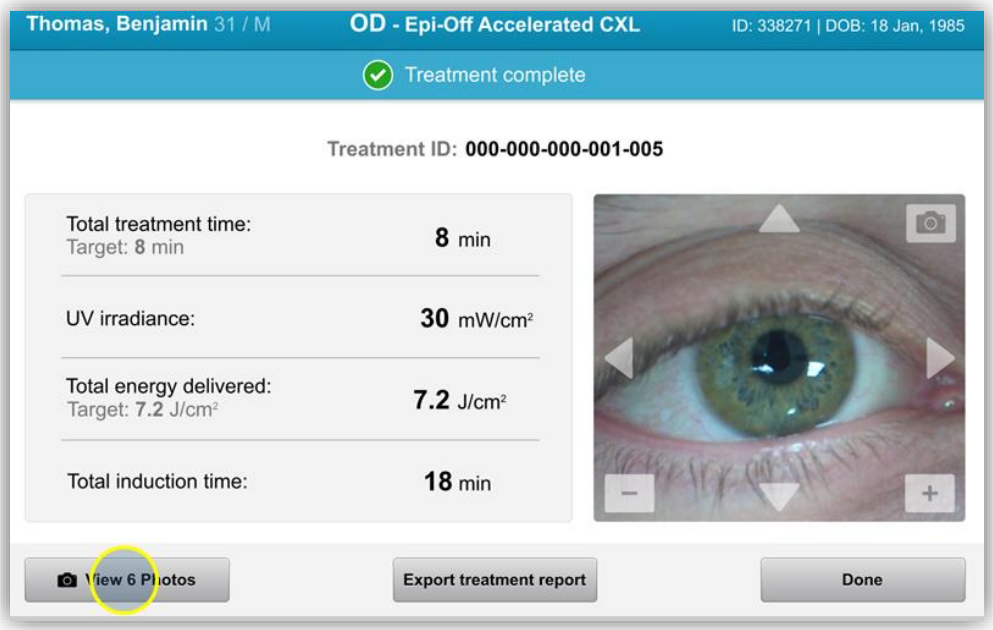


Figure 3-33. Treatment Complete Screen

- Carefully remove the device from the patient area.
- Follow up with normal post-op care.
- Remove speculum.

3.18 Reviewing Images

- All images taken throughout treatment are available for review post treatment.
- Select “View Photos” to enter the photo gallery as shown in Figure 3-33.

3.19 Deleting Photos

- Photos taken throughout treatment can be deleted.
- In the Photo Gallery, select the trash icon next to the photo to be deleted as shown in Figure 3-34.

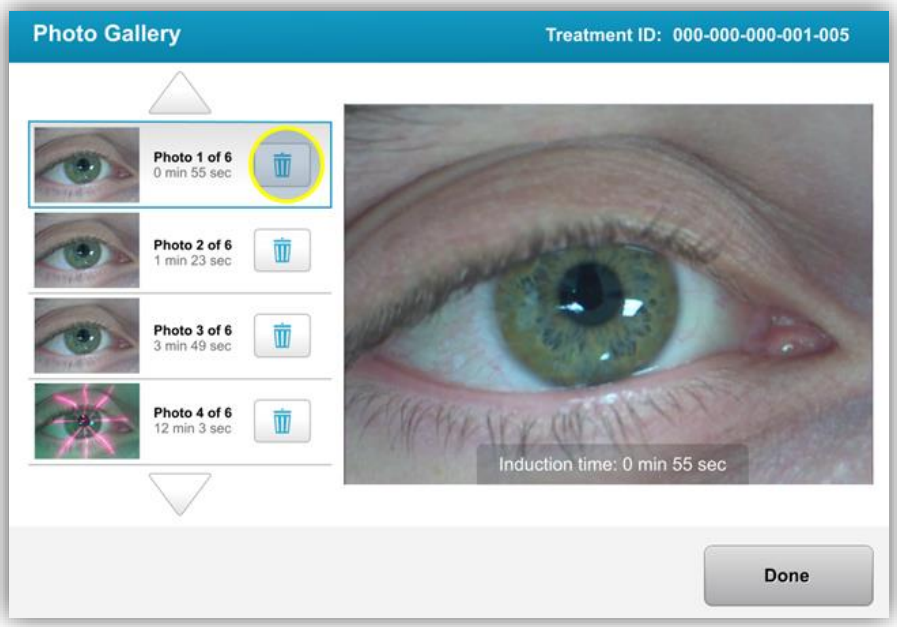


Figure 3-34. Select Trash to delete

- Once a photo is selected for deletion, select "Yes" to delete the photo, or select "No" to keep the image.

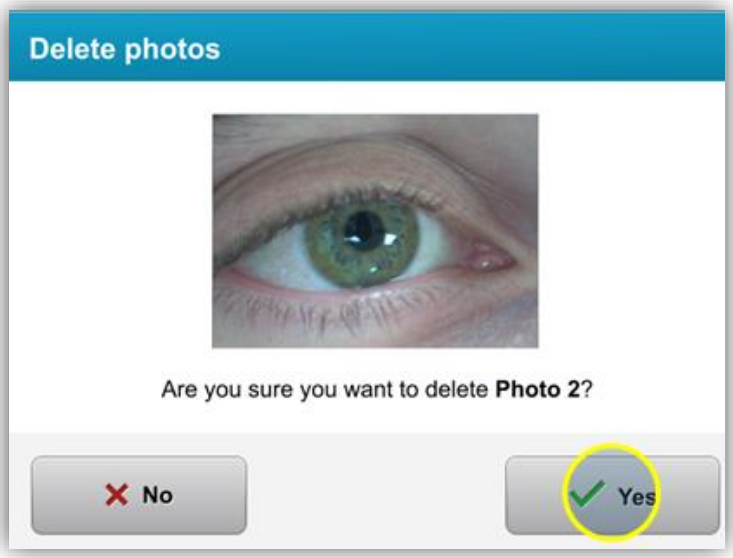


Figure 3-35. Select Yes to Delete

- Once deletion is confirmed, photo will not be retrievable.
- Select “Done” to confirm which photos will be displayed in the treatment report.

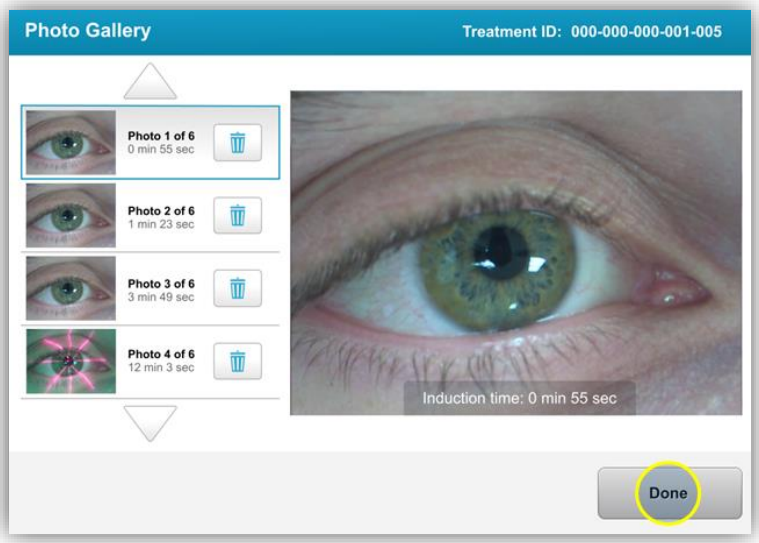


Figure 3-36. Select Done

3.20 Patient Treatment Report

- A treatment report is generated containing patient information, treatment details, photos taken throughout treatment, and notes. A sample report is shown in Figure 3-37.
- Treatment reports are generated even if treatments are paused or cancelled.
- A green checkmark will be listed next to completed phases.
- A red “X” mark will be listed next to incomplete phases.

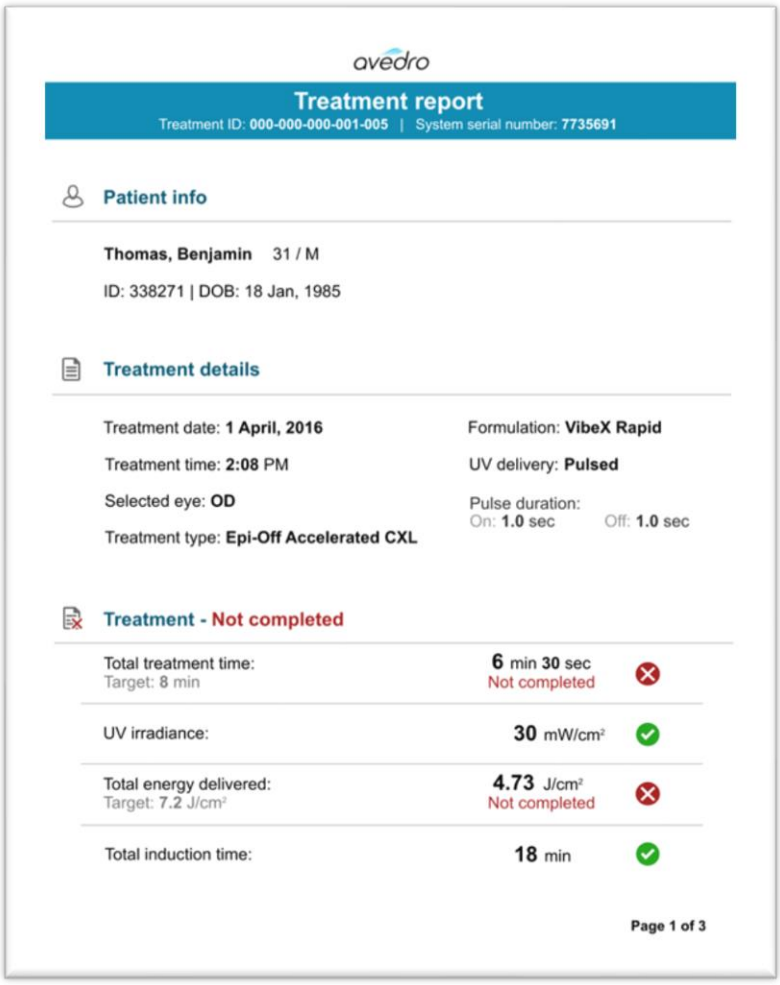


Figure 3-37. Sample Treatment Report

3.20.1 Adding Notes to a Patient Treatment Report

- From the Patient Database screen, select the patient's name.
- Press the message icon as shown in Figure 3-38 to enter comments about the patient's treatment.

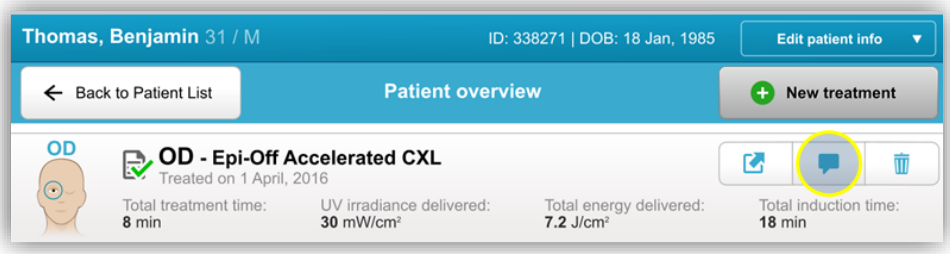


Figure 3-38. Comments Icon

- Keyboard will become available to make comments to the patient's report.

Figure 3-39. Comments Section

3.20.2 Exporting Treatment Report

- Select "Export treatment report" as shown in Figure 3-40 to save report to a USB stick.
- Report will be exported as PDF.

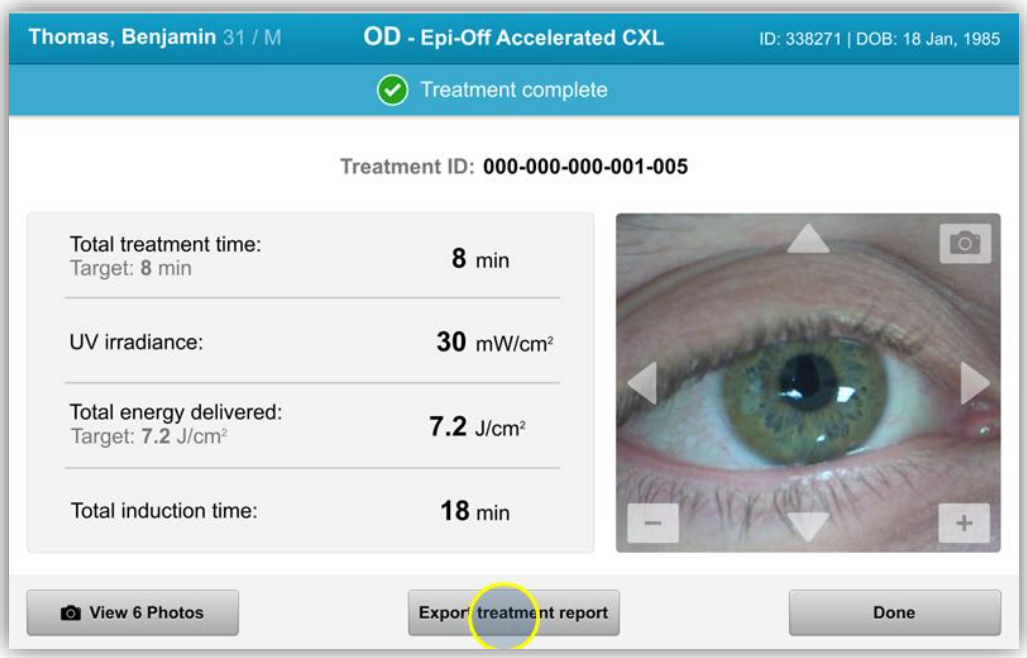


Figure 3-40. Exporting Treatment Report

- The screen will prompt to insert USB drive as shown in Figure 3-41.

NOTE: Avedro does not supply USB drive for storing patient data

Figure 3-41. Insert USB

- If the USB is full or the system is unable to read the USB, an error message will be displayed as shown in Figure 3-42.

Figure 3-42. USB Error and No Space Left on USB

- If there is no issue with the USB, a message will appear stating "Generating treatment report."

Figure 3-43. Generating treatment report

- When the treatment report is exported, a confirmation message will appear as shown in Figure 3-44.

Figure 3-44. Treatment report exported

3.20.3 Viewing a Treatment Report

- Full treatment report can be reviewed on system or USB (if exported).
- Any photos or comments added will be included in report.

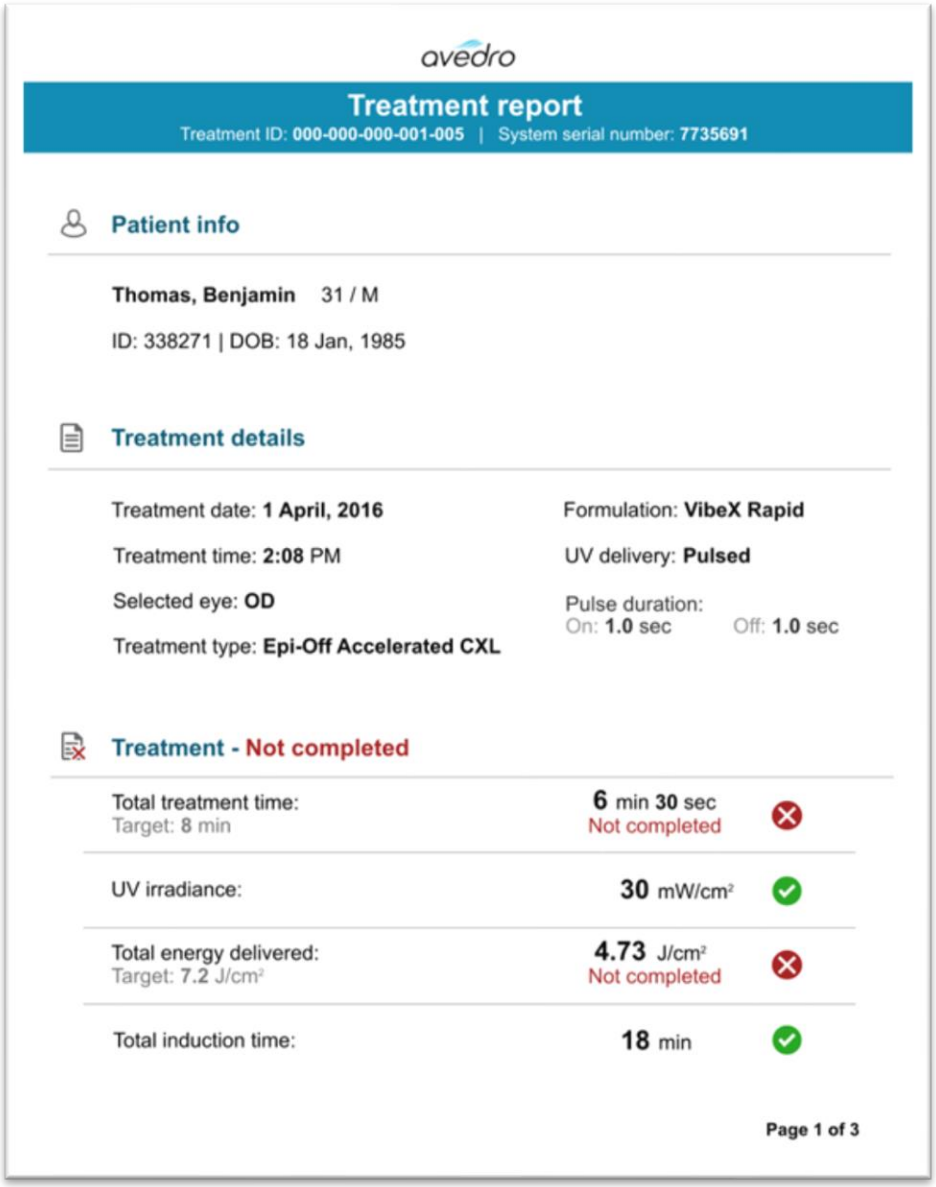
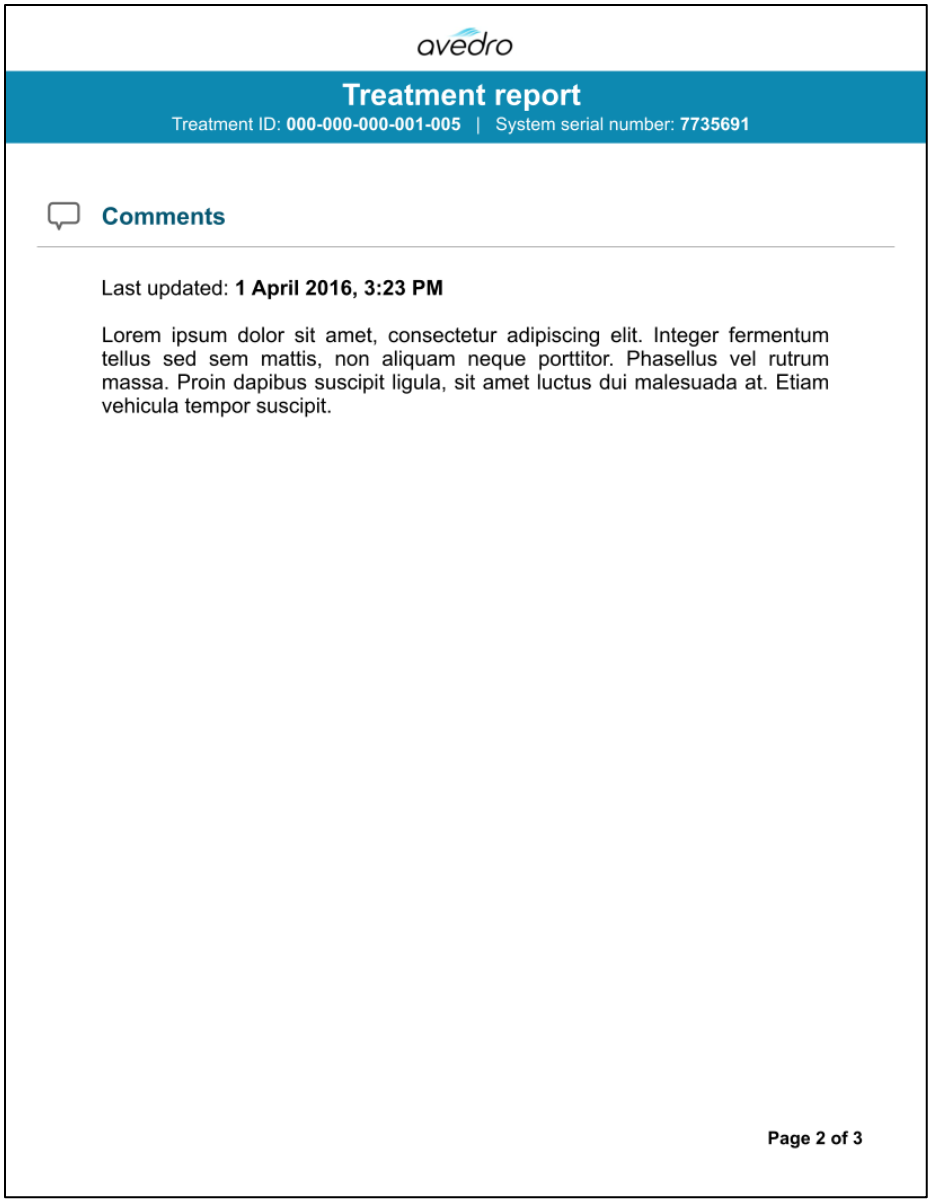


Figure 3-45. Page 1 of 3: Treatment Details


avedro

Treatment report

Treatment ID: **000-000-000-001-005** | System serial number: **7735691**

Comments

Last updated: **1 April 2016, 3:23 PM**

Lorem ipsum dolor sit amet, consectetur adipiscing elit. Integer fermentum tellus sed sem mattis, non aliquam neque porttitor. Phasellus vel rutrum massa. Proin dapibus suscipit ligula, sit amet luctus dui malesuada at. Etiam vehicula tempor suscipit.

Page 2 of 3

Figure 3-46. Page 2 of 3: Comments

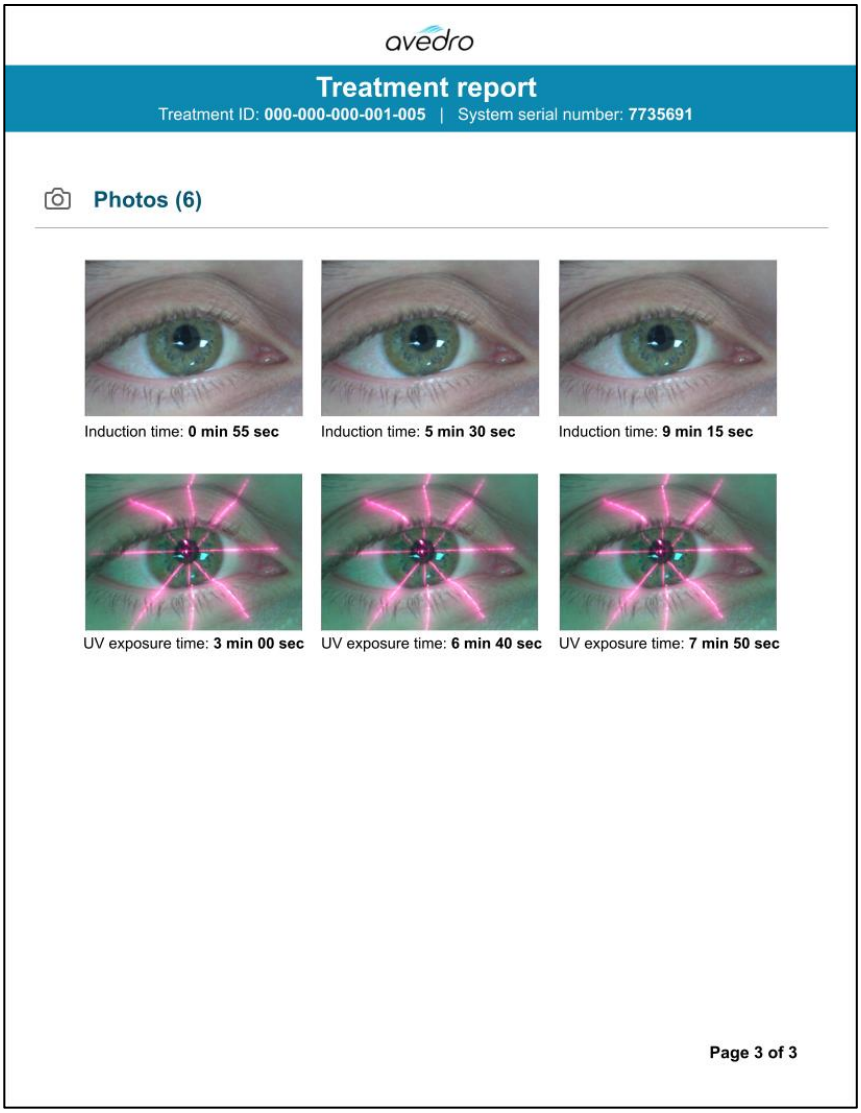


Figure 3-47. Page 3 of 3: Photos

3.21 Powering Down the KXL System

- Select “Power Off” on the Patient List homescreen as shown in Figure 3-48.

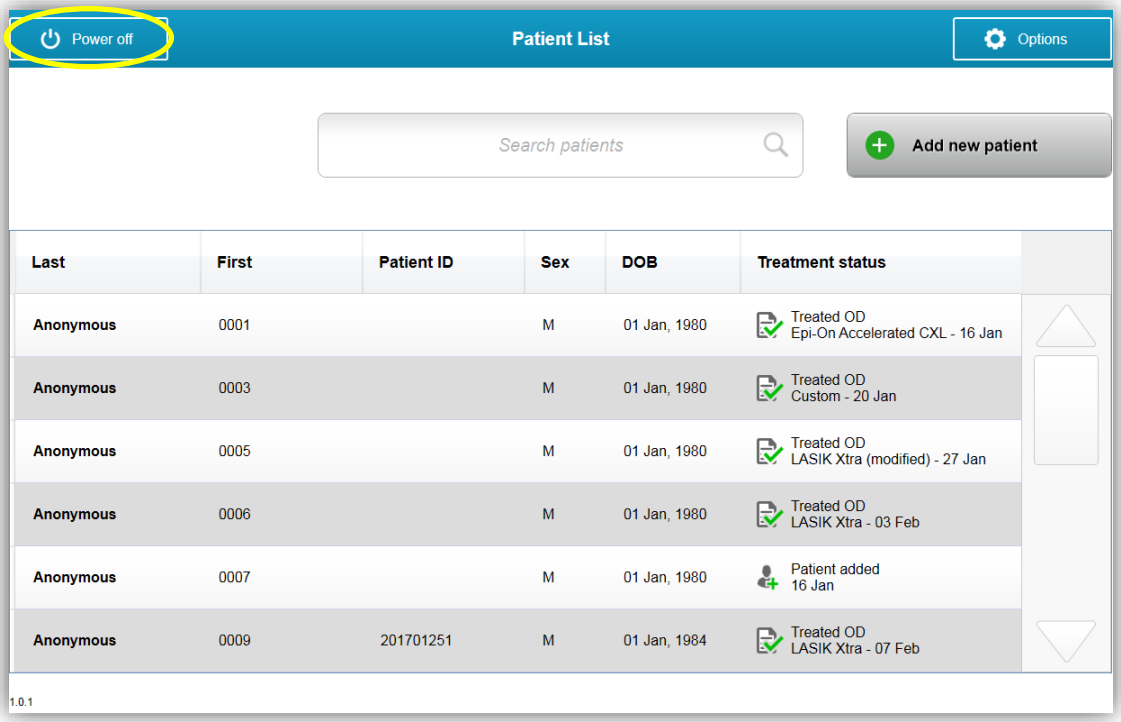


Figure 3-48. Select “Power Off”

- Confirm powering off system by selecting “Yes” as shown in Figure 3-49.

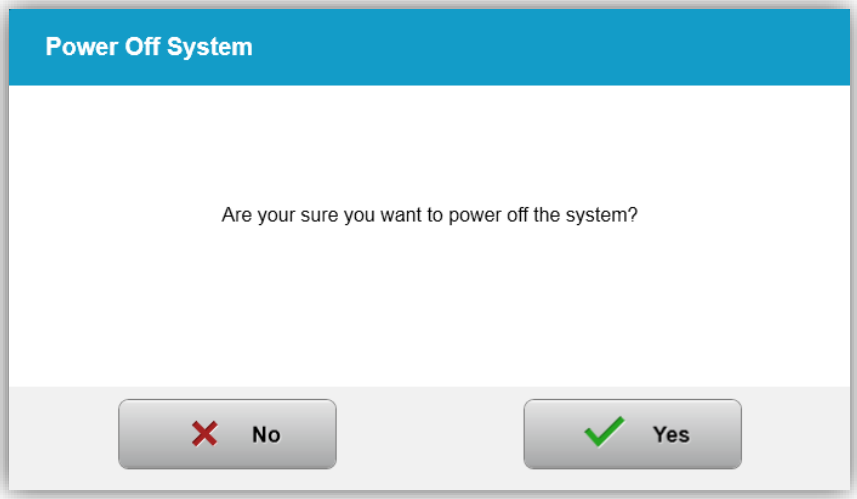


Figure 3-49. Confirm “Power Off”

- Wait for the software to shut down and the screen to go blank.
- Turn the master power switch on the KXL base to the "Off" position as shown in Figure 3-50.

Figure 3-50. Power Off Position

3.22 Accessing the System Settings Menu

- From the Patient List homescreen, press the "Options" button, then press "System Settings" as shown in Figures 3-51 and 3-52.

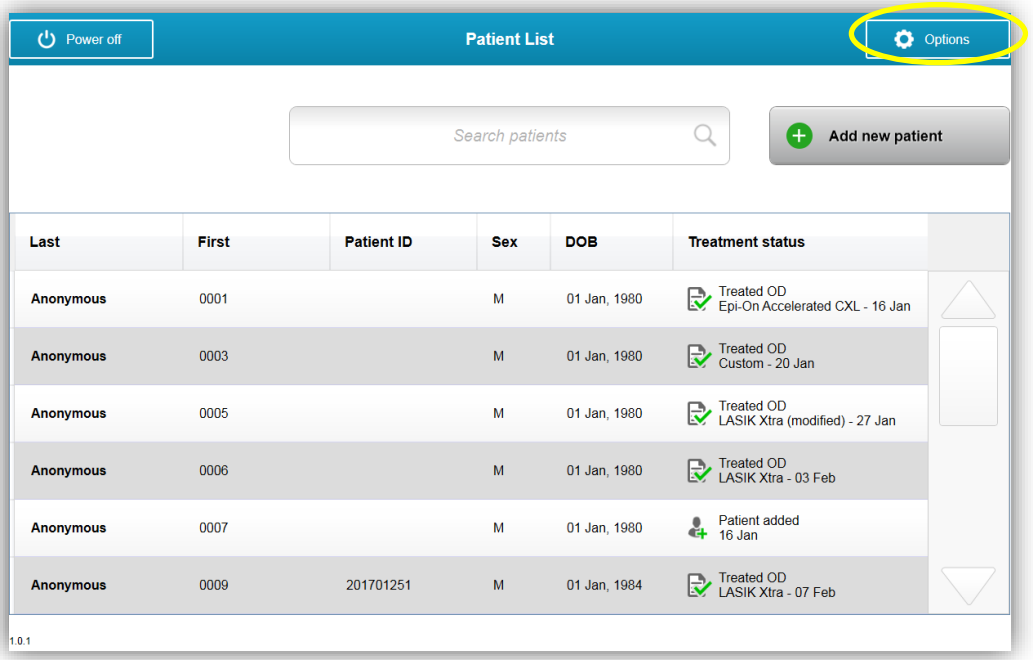


Figure 3-51. Press the "Options" button

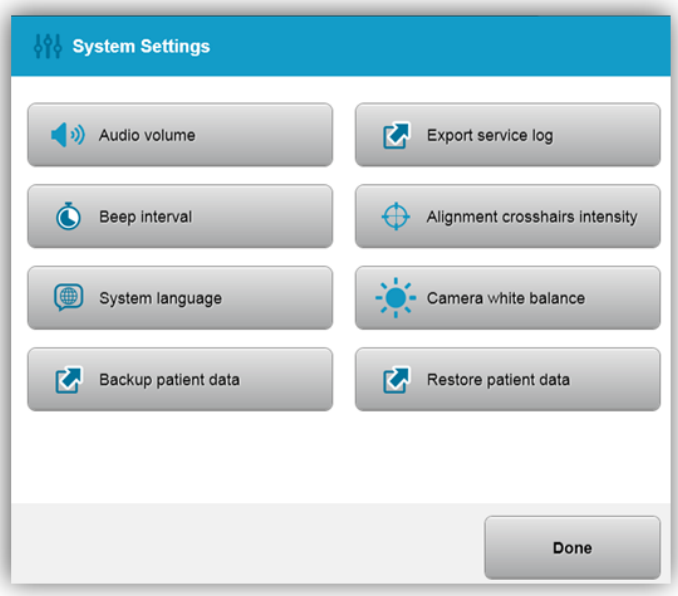


Figure 3-52. System Settings Menu

3.22.1 Service Settings

- Service Settings are only available to Avedro and Service personnel with a KXL Advanced Settings access card.
- If selected the user will be prompted to scan an access card.

3.22.2 Selecting a Different System Language

- Select “System Language” to change the language of the Graphical User Interface.
- Select the desired language from the menu as shown in Figure 3-53.

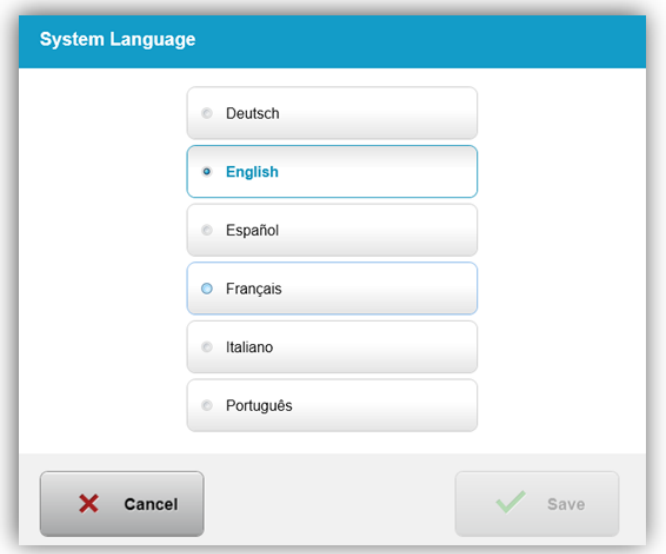


Figure 3-53. Edit System Language

3.22.3 Altering the Intensity of Alignment Crosshairs

- Select "Alignment Crosshairs Intensity" from the System Settings menu to alter the brightness of the alignment crosshairs. The screen shown in Figure 3-54 will appear.
- Adjust crosshair brightness and select "Save."

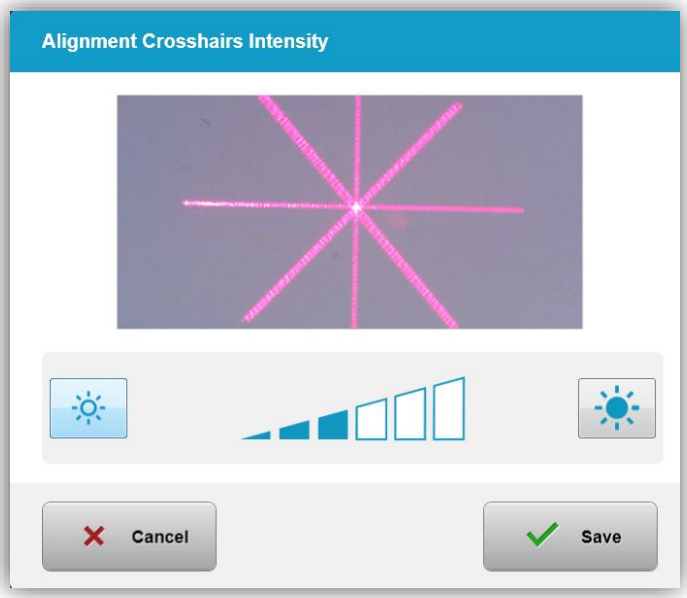


Figure 3-54. Alignment Crosshairs Intensity

3.22.4 Altering the System Volume

- Select “Audio Volume” from the System Settings menu to alter the sound volume level.

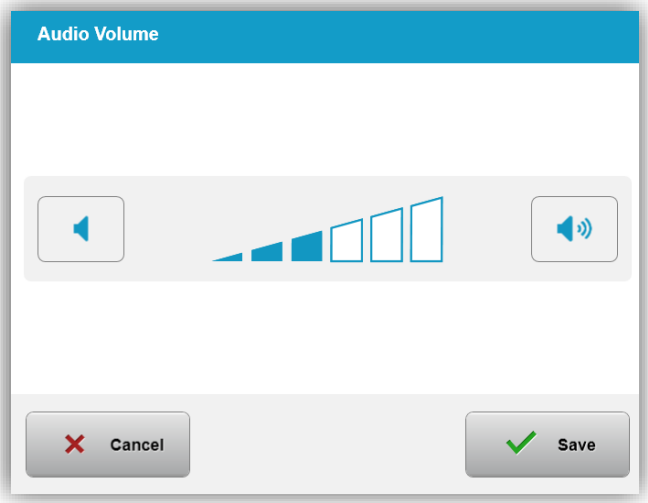


Figure 3-55. Edit Volume

3.22.5 Export Service Log

- Select “Export service log” from the System Settings menu.
- Follow onscreen instructions to insert a USB drive to the USB port as shown in Figure 3-56.

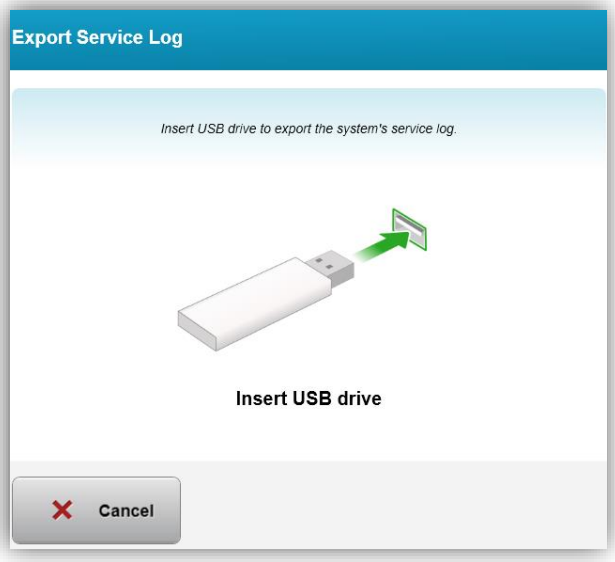


Figure 3-56. Export Service Log to USB

- The system automatically begins transferring the service log and shows a progress bar of the transfer process as shown in Figure 3-57.

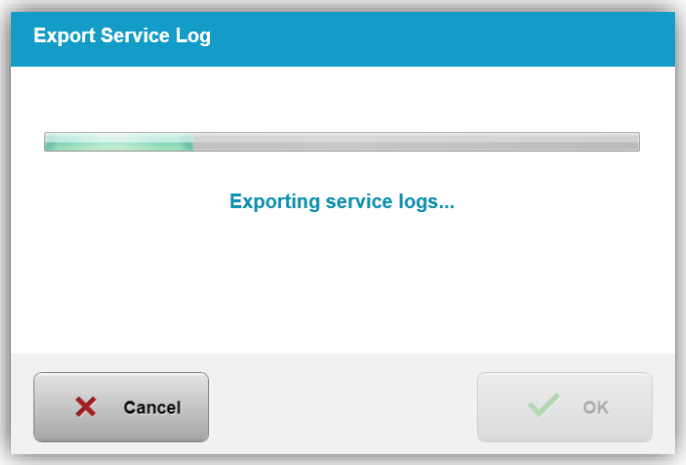


Figure 3-57. Export Service Log in Progress

- Once the export is complete, press the "OK" button to return to the System Settings menu.

3.22.6 Altering Audible Beep Intervals

- Select "Beep interval" from the System Settings menu to alter the time between audible beeps while induction is in progress.
- Click the minute and second icons to increase or decrease time, then press save to return to the System Settings menu.

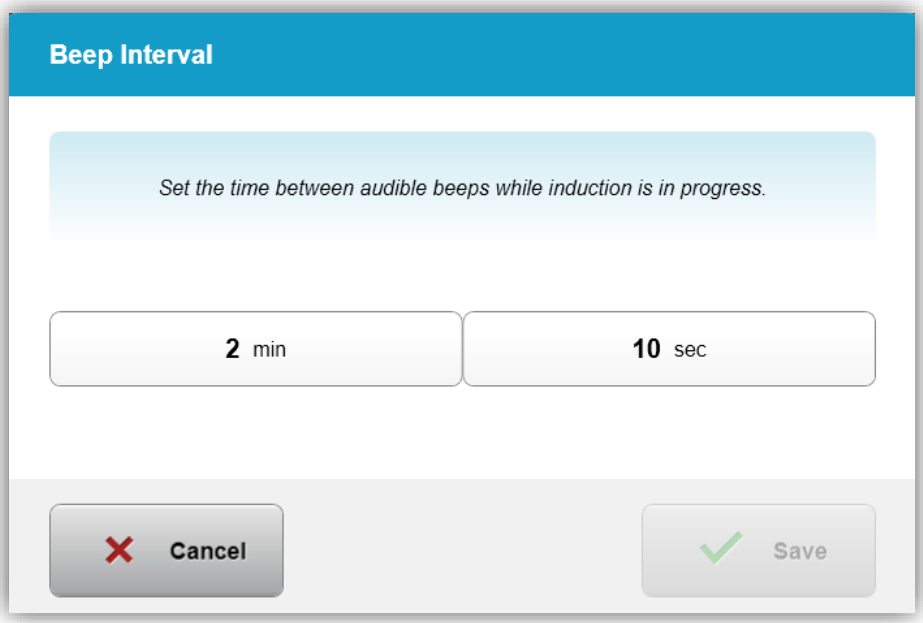


Figure 3-58. Select Beep Intervals

3.22.7 Altering Camera White Balance

- Select "Camera white balance" from the System Settings menu to change the light conditions within the console.
- Select desired white balance and click "Save" to return to the System Settings menu.

NOTE: Typical office lighting is under 5000K. As a result, the System default setting is Tungsten 2800K. If a different light source is used, it may be useful to edit the white balance condition.

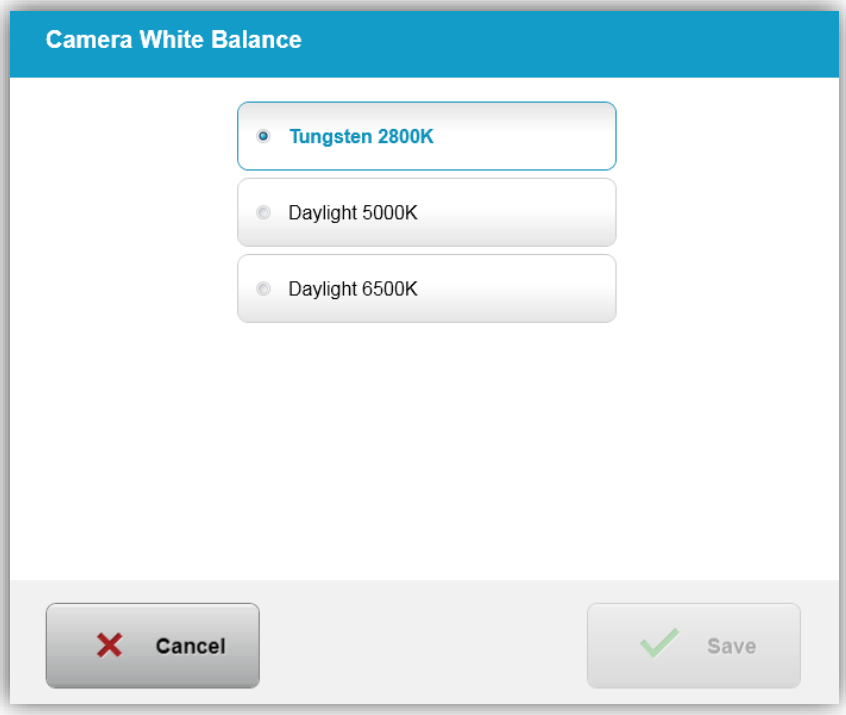


Figure 3-59. Edit Camera White Balance

4 Maintenance / Service

By definition, “maintenance” refers to those non-technical procedures an everyday operator must perform to keep the system working properly. The word “service,” by contrast, refers to tasks that are intended to be performed only by a qualified service representative.

4.1 Installation Policy

- For each new KXL System customer, an Avedro trained or authorized personnel provides a full initial installation and start-up of the system. Following initial installation and once the system is operating properly, this Avedro representative may also provide basic training to a designated operator about the basic operation of the KXL System.
- Consequently, this manual does not include any specific instructions relating to installation or set-up of the system. Per your service agreement, any further hardware adjustment, other than what is specified for normal operation, should be performed by, or with the guidance of, an Avedro-authorized distributor.

4.2 Customer Maintenance

- In general, there is no customer maintenance required for The KXL System. All technical maintenance or service will be performed by a qualified service representative while under service contract. If you have trouble with your system, refer to the Troubleshooting section below or call your local Avedro Representative.

4.3 Warranty Information

- A Warranty is supplied separately with the purchasing information.

4.4 Service Contract Information

- A service contract is available on all KXL Systems. The contract provides for regularly scheduled service and field upgrades. It also provides for any non-scheduled service calls that may be necessary.

4.5 Per Patient Disposables

- Per Patient Disposables can be ordered from Avedro or your Avedro-authorized distributor. **Use only Avedro products or Avedro-approved products with your KXL System**. Avedro shall not be liable for damage to or malfunction of the system, which it deems, was caused by the use of unauthorized materials.

4.6 Trouble Shooting

- The KXL System checks its status at start-up automatically. If the status is incorrect, the software prevents the operator from initiating treatments.

4.6.1 Wireless Remote

- The KXL System uses a remote control with replaceable batteries. If the batteries run low, the system will lose its connection with the remote and notify the user of the need to either re-synchronize or "Continue Without Remote."

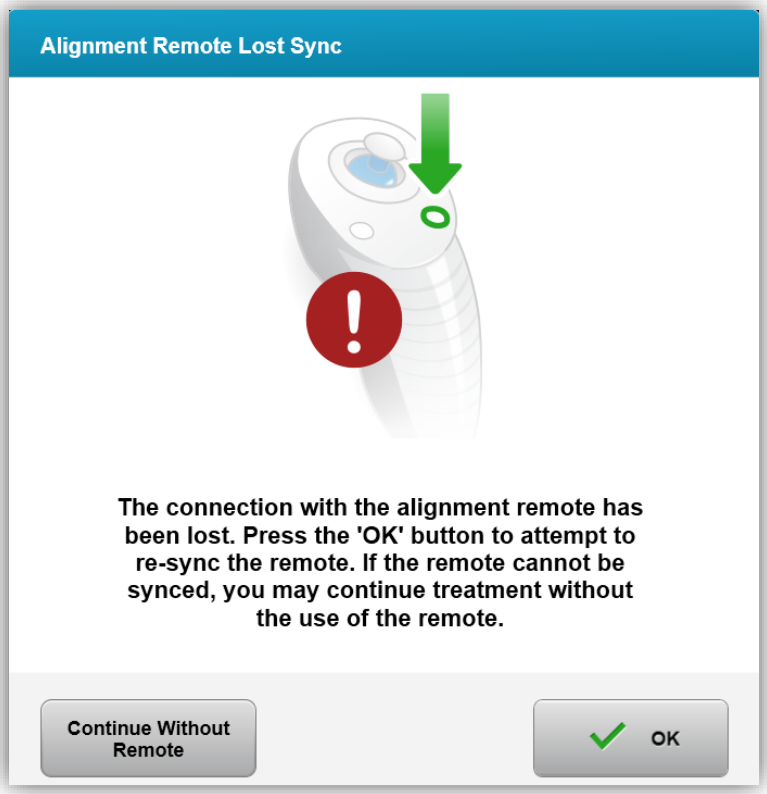


Figure 4-1. Alignment Remote Lost Sync

- If light on the remote is flashing two times per second, the remote's batteries need to be changed.
- If the light on the remote is flashing once per second, then it is not synchronized.
- If the remote does not re-synchronize by pressing the "Sync" button, replace the batteries.
- If replacing the batteries does not allow the system to synchronize, contact your local Avedro Service Representative.

4.7 Directions for Disinfection

- No components of the KXL System are designed to be sterilized by the operator.
- ONLY external cleaning and disinfection is recommended.
  - For disinfection purposes, use only 70% isopropyl alcohol preparations or 10% bleach solutions. Use soft fiber-free wipes.

4.8 Cleaning the System

- Use a soft damp cloth to clean the KXL System.
- The exterior of the System can be cleaned using a lint-free cloth dampened with dilute bleach, soapy water, or isopropyl alcohol.
- A 70% isopropyl alcohol or 10% chlorine bleach solution can also be used if necessary.
- DO NOT submerge the System in liquid or pour liquid onto the system.

CAUTION: Power down the system and remove the power supply cord from the main outlet prior to any cleaning procedure.

CAUTION: The glass window of the beam aperture must not under any circumstances be in contact with any aggressive cleaning agents.

- While cleaning the surfaces of the device, ensure that cleaning fluids do not seep inside the device, as this leakage can damage the device.
- Use a lint-free cloth dampened with isopropyl alcohol to clean the remote control.

4.9 Cleaning the Aperture

- Check the beam aperture routinely prior to treatment.
- Use camera lens wipes or compressed air to remove dust and particles from the glass surface of the aperture.

4.10 Articulating Arm Adjustment

- If the articulating arm does not hold the KXL Head in a fixed vertical position, contact your local Avedro service representative.

4.11 Moving the System

- The KXL is designed as a movable system within an office environment. If it ever proves necessary to transport or ship the KXL System, for any reason, contact your local Avedro representative. Packing and transporting the system should be performed only by Avedro trained and authorized personnel.
- Prior to moving the KXL System from one room to another, the monitor should be moved sideways, and the KXL Head should be positioned close to the cart handle with the elbow protruding at the back. The system can then be easily pushed by the cart handle through the door frame.

Figure 4-2. Moving System Configuration

4.12 Storing the System

- Follow all the storage temperature and humidity range specifications as listed in Chapter 7.0 - Specifications.
- Close all panels on the system to prevent dust and moisture from entering; this is mandatory.
- Turn OFF all the components and switch off the master power switch as well. Disconnect the power cord from its electrical outlet Remove the batteries from the wireless remote.
- Do not disassemble any part of the system as this could cause misalignment or damage.

4.13 Software

- Should the software become corrupted and fail to work correctly, call your local Avedro service representative. Software updates will only be carried out by Avedro service representatives.

4.14 Risks Associated with Disposing of Waste Products

- When disposing of waste products, follow all applicable local regulations.

4.15 Performing a Visible Check

- Check all components of the device routinely for damage or malfunction prior to each treatment.

5 Equipment Classification

According to EN60601-1 Medical Device Electrical Standard

- Protection against electrical shock
  - Class 1 (external electrical power source)
- Degree of protection against electric shock
  - Not classified, equipment not provided with applied part
  - Ingress protection: IP20 (No protection against ingress of water)
- Method of sterilization or disinfection
  - Disinfect-able device
- Degree of protection for use in the presence of a flammable as aesthetic mixture
  - No protection
- Use conditions
  - Continuous service

According to FCC Part 15, EN55011 and EN60601-1-2

- Class B

According to EN60825-1 Safety of laser productions

- Alignment lasers are Class 1 Laser Product

According to EN62471 Photobiological safety of lamps and lamp systems

- IEC 62471:2006 Risk Group 2
- EN 62471:2008 Risk Group 3
- UVA LED is Risk Group 3

According to Annex II.3 of Directive 93/42/EEC

- Class IIa

EMC Requirements

The KXL System requires special precautions regarding electromagnetic compatibility (EMC). Installation and use should be carried out according to the EMC information provided in this manual. Portable and mobile RF communications equipment may affect the KXL System.

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

Guidance and manufacturer's declaration — electromagnetic immunity			
The KXL System is intended for use in the electromagnetic environment specified below. The customer or the user of the KXL System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not Applicable Input /Output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT (100 % dip in UT) for 0.5 cycle 0% UT (100% dip in UT) for 1 cycles 70% UT (30% dip in UT) for 25/30 cycles 0% UT (100 % dip in UT) for 5 sec	0 % UT (100 % dip in UT) for 0.5 cycle 0% UT (100% dip in UT) for 1 cycles 70% UT (30% dip in UT) for 25/30 cycles 0% UT (100 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment, If the user of the KXL System requires continued operation during power mains interruptions, it is recommended that the KXL System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity
The KXL System is intended for use in the electromagnetic environment specified below. The customer or the user of the KXL System should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the KXL System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3V/m	$d = 1{,}2\sqrt{P}$ $d = 2{,}3\sqrt{P}$ 80 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:
Proximity fields from RF wireless communications equipment (IEC 61000-4-3:2006 A1:2007 A2:2010)	15 specific frequencies. Immunity level 9-28V/m	15 specific frequencies. Immunity level 9-28V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the KXL System is used exceeds the applicable RF compliance level above, the KXL System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the KXL System.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the KXL System
The KXL System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the KXL System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the KXL System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $\boldsymbol{d = 2.3\sqrt{P}}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

The KXL System contains an RFID function which transmits and receives at the 13.56 MHz frequency. This functionality may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.

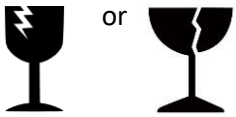
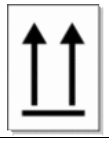
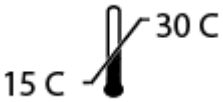
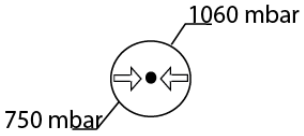
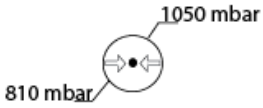
The KXL System contains the following RF transmitters:
RFID Reader

• 13.56MHz Reader/Writer • Integral Antenna: Maximum 4” Read Range • Max output power is 200mW • Meets: ISO18000-3, ISO15693

WiFi Adapter		
Frequency Modulation	**5 GHz (802.11a/n)**	**2.4 GHz (802.11b/g/n)**
Frequency band	5.15 GHz - 5.85 GHz (dependent on country)	2.400 - 2.4835 GHz (dependent on country)
Modulation	BPSK, QPSK, 16 QAM, 64 QAM	CCK, DQPSK, DBPSK
Wireless Medium	5 GHz UNII: Orthogonal Frequency Division Multiplexing (OFDM)	2.4 GHz ISM: Orthogonal Frequency Division Multiplexing (OFDM)
Channels	4 to 12 (dependent on country)	Channel 1-11 (US only) Channel 1-13 (Japan, Europe)
Max Output Power	< 100mW	<100mW

6 Symbol Library

Text Symbol	Symbol Illustration	Definition
1. No AP symbol in presence of flammable anesthetics		Danger, Risk of Explosion. Not for use
2. AC symbol		Alternating current
3. "I" in a book		Attention: Consult ACCOMPANYING DOCUMENTS
4. Ground symbol in circle		Protected earth (ground)
5. Ingress Protection Symbol	IP20	Ingress Protection solids under 12.5 mm and no protection against water)
6. Power button		Standby
7. Power Switch	I	ON
8. Power Switch	O	OFF
9. CE Mark		Conformity mark
10. Manufacturer		Name and address of the manufacturer
11. ! in a Triangle		Caution specific warning in operators manual
12. Net Weight (kgs) Gross Weight (kgs)	NW GW	Weight
13. Umbrella with raindrops		Keep Dry: Store protected from moisture (symbol is with or without rain drops)

Text Symbol	Symbol Illustration	Definition
14. Broken glass		Contents are fragile, handle with care
15. Two up arrows		Keep arrows on carton pointing up
16. Water drop in a box		Humidity limits (percentages below symbol are the acceptable range for humidity)
17. Operating Temperature limits		Operating Temperature limits
18. Storage Temperature limits		Storage Temperature limits
19. MR crossed in a circle		MR Unsafe – Keep away from magnetic resonance imaging (MRI) equipment
20. Storage Pressure limits		Storage Atmospheric pressure limits
21. Operating Pressure limits		Operating Atmospheric pressure limits
22. Signal emitted		RF transmitted through device

7 Specifications

Specification	Description
Electrical	Line voltages 100 – 240 volts AC Current 2A – 1A Single Phase RMS, 50/60 Hz Remote 2x AAA batteries
List of cables and Accessories	Wireless Remote Hospital Grade AC power cable (Lockable/Detachable)
Energy Delivery	UV Radiation 3 – 45 mW/cm^2 365 nm
UVA LED Light Source	UV Radiation 365 nm
External Interfaces	USB 2.0
Physical Dimensions	No larger than 60 x 60 x 150 cm (Length x Width x Height)
Weight (crated system)	NW 48 Kg GW 120 Kg
Remote Battery Life (normal operating conditions)	18 hours
Remote and Dongle FCC ID and Operating Frequencies	FCC ID: SXJ87027-TX 2.405-2.475 GHz.
Environmental Operating Conditions	The system operates under the following atmospheric conditions (no condensation).
Ambient temperature	+15 to +30 ºC
Relative humidity	20% to 80% , non-condensing
Atmospheric pressure	810 to 1050 mbar
Transport and Storage Conditions	The instrument withstands the following transport and storage conditions without damage or performance deterioration.
Ambient temperature	-15 to +60 ºC
Relative humidity	10% to 80% non-condensing
Atmospheric pressure	750 to 1060 mbar