Avedro, Inc.
KXL System

Operator's Manual

Copyright 2017 All Rights Reserved

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.

"KXL" and the Avedro logo design are registered trademarks or trademarks of Avedro, Inc. All software and documentation is subject to Avedro, Inc. copyrights. All rights reserved 2017.

Microsoft and Windows are registered trademarks and trademarks, respectively, of Microsoft Corporation. Any other trademarks or service marks contained within this manual are the property of their respective owners.

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 0086

Table of Contents

1 Foreword 7
1.1 Intended Use of Manual 7
1.2 Intended Use / Indications for Use 7
1.3 Design Change Disclaimer 7
1.4 Reproduction Disclaimer 7
1.5 User Operation Assistance Statement 7
1.6 Contraindications, Warnings and Cautions 8
1.6.1 Contraindications 8
1.6.2 Warnings 8
1.6.3 Electrical Safety Warnings 8
1.7 Radiation Safety Warnings 10
1.8 Patient Safety 11
1.9 Additional Safety Considerations 11
1.10 FCC Compliance Notice 11
2 Introduction 13
2.1 System Overview 13
2.1.1 Major Components 14
3 System Operation 16
3.1 Touchpad/Keyboard Use 16
3.2 UV Energy (Dose) 19
3.3 Preparing the System 19
3.4 Important Steps before Turning on the System 20
3.5 Powering Up the System 20
3.6 Existing Patient Data 21
3.7 Add New Patient 21
3.8 Create New Treatment Plan 22
3.8.1 Select Eye to Treat 23
3.8.2 Select Treatment Type 23
3.8.3 Adjusting Treatment Parameters 24
3.9 Select Treatment Mode 26
3.9.1 Continuous UV Mode 26
3.9.2 Pulsed UV Mode 28
3.10 Starting a Treatment 28
3.10.1 Insert Treatment / RFID Activation Card 28
3.10.2 Single-use Activation Cards 29
3.10.3 Multi-use Activation Cards 30
3.10.4 RFID card controlled limits 32
3.10.5 Sync Alignment Remote 33

3.11 Preparing the Patient 35
3.11.1 Applying Riboflavin 36
3.12 Initiating Treatment 38
3.13 Monitoring Treatment 39
3.14 Pausing a Treatment 40
3.15 Cancelling Mid Treatment 41
3.16 Capturing Images 43
3.17 Treatment Complete 44
3.18 Reviewing Images 45
3.19 Deleting Photos 45
3.20 Patient Treatment Report 48
3.20.1 Adding Notes to a Patient Treatment Report 49
3.20.2 Exporting Treatment Report 50
3.20.3 Viewing a Treatment Report 53
3.21 Powering Down the System 57
3.22 Using the System Settings Menu 59
3.22.1 Service Settings 60
3.22.2 Editing System Language 60
3.22.3 Editing Alignment Crosshairs Intensity 60
3.22.4 Editing System Volume 61
3.22.5 Export Service Log 62
3.22.6 Editing Beep Intervals 63
3.22.7 Editing Camera White Balance 64
4 Maintenance / Service 66
4.1 Installation Policy 66
4.2 Customer Maintenance 66
4.3 Warranty Information 66
4.4 Service Contract Information 66
4.5 Per Patient Disposables 66
4.6 Trouble Shooting 67
4.7 Directions for Sterilization or Disinfection 68
4.8 Cleaning the System 68
4.9 Cleaning the Aperture 68
4.10 Articulating Arm Adjustment 68
4.11 Moving the System 68
4.12 Storing the System 69
4.13 Software 69
4.14 Identifying Risks Associated with Disposing of Waste Products 70
4.15 Performing a Visible Check 70
5 Equipment Classification 71
6 Symbol Library 72
7 Specifications 74

Table of Figures

Figure 2-1 Overview Illustration of System 14
Figure 2-2 System Illustrations with Callouts 15
Figure 2-3 Wireless Remote 15
Figure 3-1 Power Switch 20
Figure 3-2 Patient Database 21
Figure 3-3 Enter Patient Information 22
Figure 3-4 Create New Treatment Plan 22
Figure 3-5 Select Eye 23
Figure 3-6 Select Treatment Type 24
Figure 3-7 Adjusting Parameters 25
Figure 3-8 Adjusted Treatment Plan 26
Figure 3-9 Select Continuous Treatment Mode 27
Figure 3-10 Modifying Continuous Treatment Parameters 28
Figure 3-11 Insert Activation Card 29
Figure 3-12 Reading Tag 30
Figure 3-13 Card Balance: Treatments Remaining 30
Figure 3-14 Card Balance: 1 Treatment Remaining 31
Figure 3-15 No Treatments Left 31
Figure 3-16 Invalid Treatment Parameters 32
Figure 3-17 Invalid Treatment Parameters 33
Figure 3-18 Sync Remote 33
Figure 3-19 Sync process timed out 34
Figure 3-20 System Setup Status 35
Figure 3-21 Prepare Treatment: Apply Riboflavin 36
Figure 3-22 Align Crosshairs during induction 37
Figure 3-23 Remote Functions 38
Figure 3-24. Red Crosshairs X & Y Axes, Red Crosshairs Z Axis Alignment 38
Figure 3-25 Start UV Treatment 39
Figure 3-26 Treatment in Progress Screen 40
Figure 3-27 Treatment Paused Screen 41
Figure 3-28 Confirm Cancel Partial Treatment 42
Figure 3-29 Treatment Cancelled Confirmation 42
Figure 3-30 Partial Treatment Not Completed 43
Figure 3-31 Capturing Images 44
Figure 3-32 Treatment Complete Screen 45
Figure 3-33 Select Trash to delete 46
Figure 3-34 Select Yes to Delete 47
Figure 3-35 Select Done 47
Figure 3-36 Sample Treatment Report 48
Figure 3-37 Comments Icon 49
Figure 3-38 Comments Section 49
Figure 3-39 Exporting Treatment Report 50
Figure 3-40 Insert USB 51
Figure 3-41 USB Error 51
Figure 3-42 No space left on USB 52
Figure 3-43 Generating treatment report 52

Figure 3-44 Treatment report exported 53
Figure 3-45 Page 1 of 3: Treatment Details 54
Figure 3-46 Page 2 of 3: Comments 55
Figure 3-47 Page 3 of 3: Photos 56
Figure 3-48 Power Off 57
Figure 3-49 Power Off 58
Figure 3-50 Power Off Position 58
Figure 3-51 Press Options button 59
Figure 3-52 System Settings Menu 60
Figure 3-53 Edit System Language 60
Figure 3-54 Alignment Crosshairs Intensity 61
Figure 3-55 Edit Volume 62
Figure 3-56 Export Service log to USB 62
Figure 3-57 Export Service log in Progress 63
Figure 3-58 Select Beep Intervals 64
Figure 3-59. Edit Camera White Balance 65
Figure 4-1 Alignment Remote Lost Sync 67
Figure 4-2 Moving System Configuration 69

1 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

Neither this manual nor any part of it may be reproduced, photocopied, or electronically transmitted in any way without the advanced written permission of Avedro, Inc.

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

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

WARNING: No modification of this equipment is allowed.

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: 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

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.

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

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

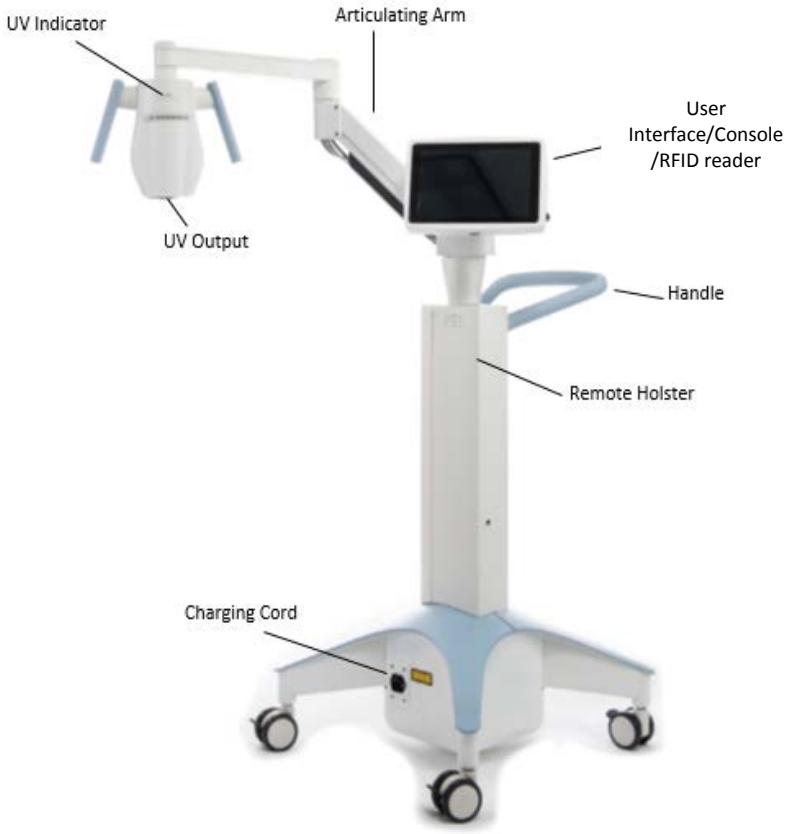


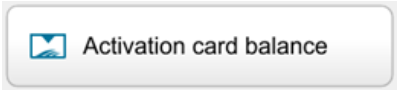
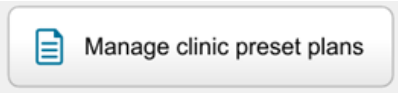
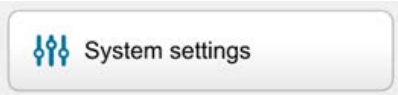
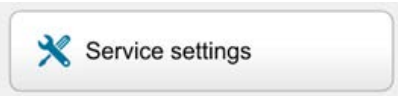
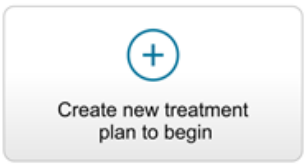
Figure 2-2 System Illustrations with Callouts

Figure 2-3 Wireless Remote

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 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

Touchpad Key	Icon	Description/Function
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.
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
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.
- Please see section 3.21 for Power Down sequence instructions.

Figure 3-1 Power Switch

- Press and release the power-on button on the side of the KXL display screen. The KXL System will begin a power-up sequence, loading the operating system and all configuration and reference files.

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

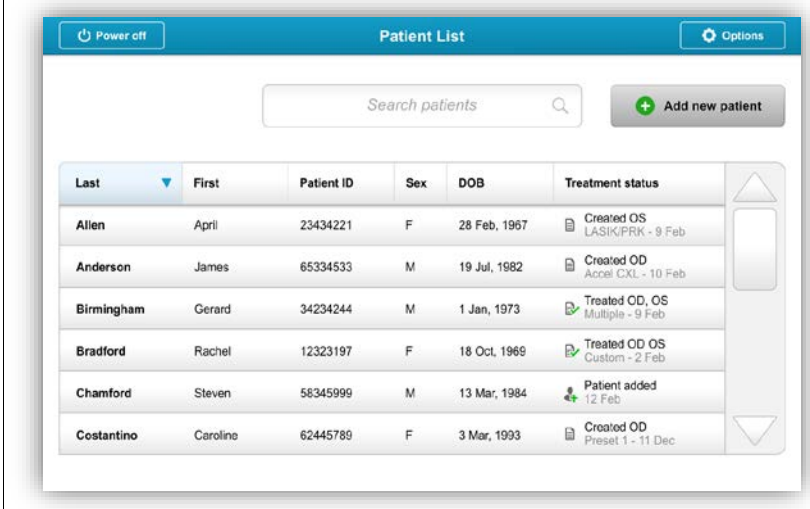


Figure 3-2 Patient Database

- The Patient database stores:
  - Previously treated patients
  - Untreated patients with saved treatment plans
  - New patients with no assigned treatment plans

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”
- If “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.

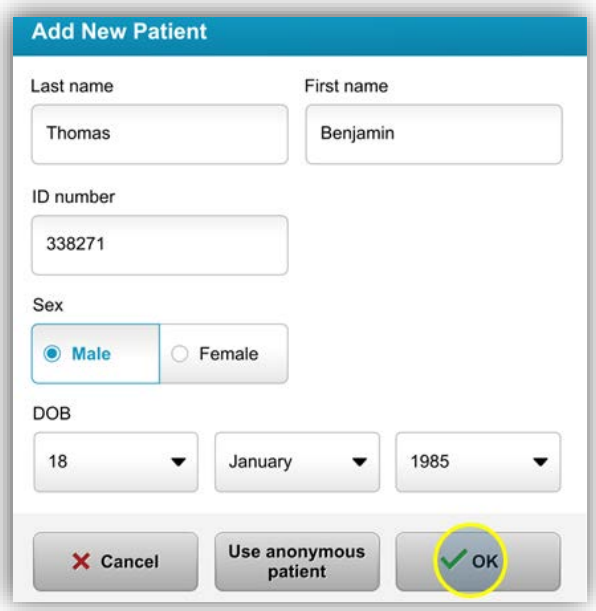


Figure 3-3 Enter Patient Information

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 patients arrival

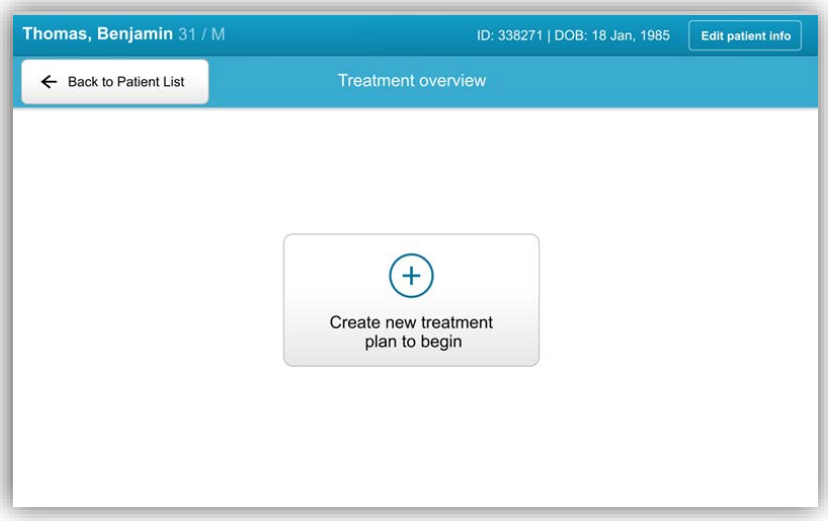


Figure 3-4 Create New Treatment Plan

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

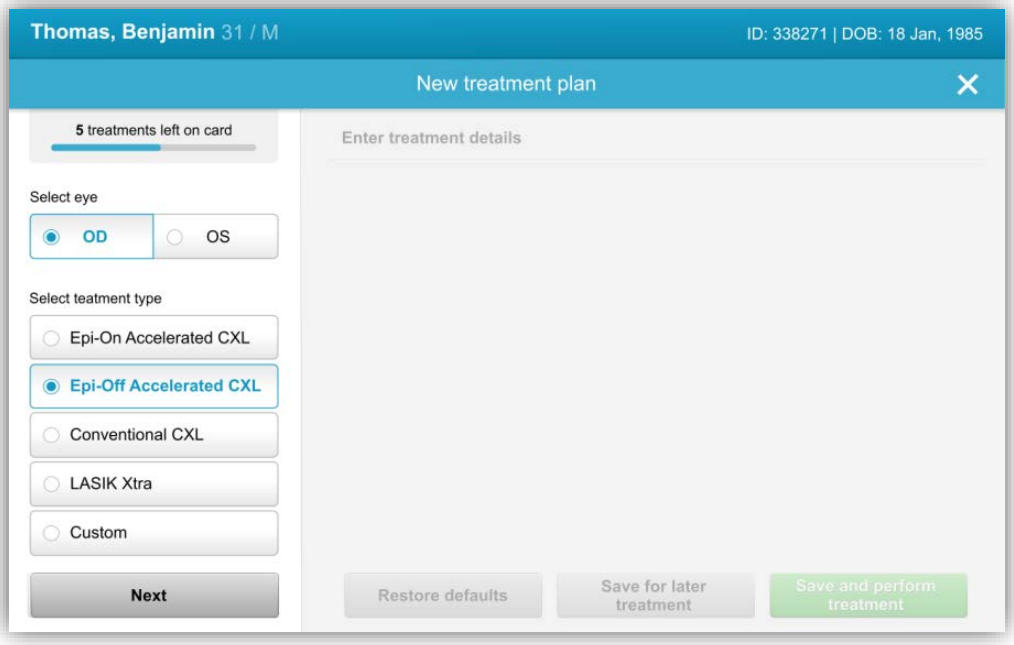


Figure 3-5 Select Eye

3.8.2 Select Treatment Type

- The system is pre-programmed with five preset treatment plans:
  - 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.

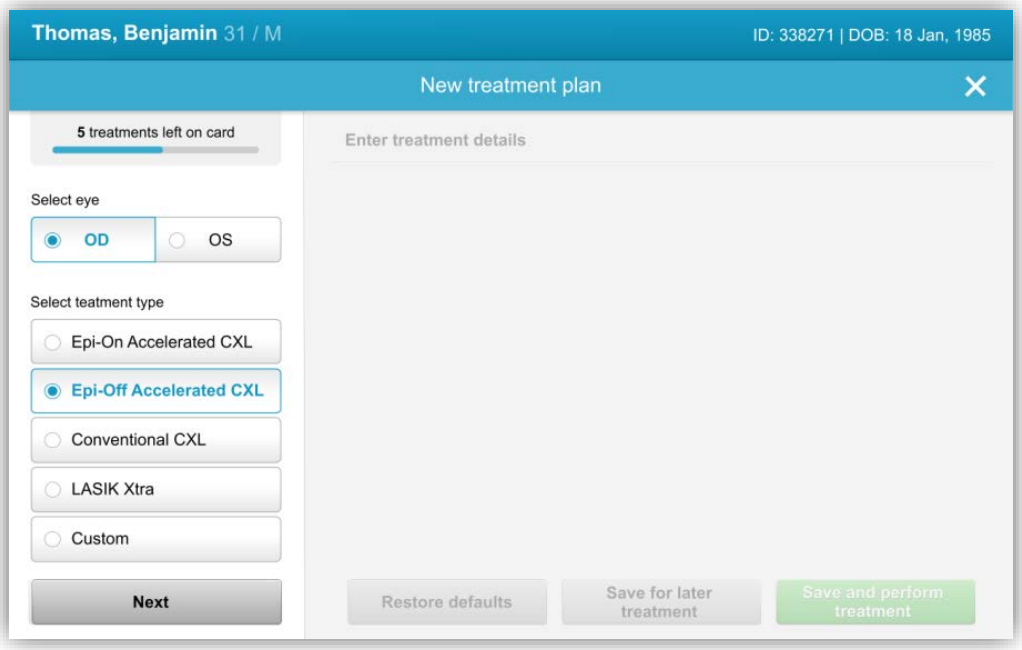


Figure 3-6 Select Treatment Type

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.

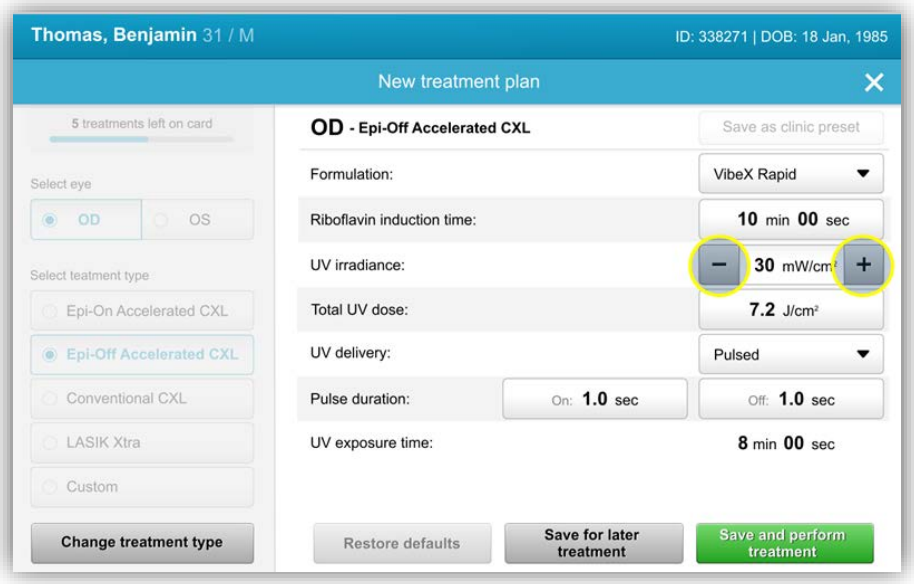


Figure 3-7 Adjusting Parameters

- 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.

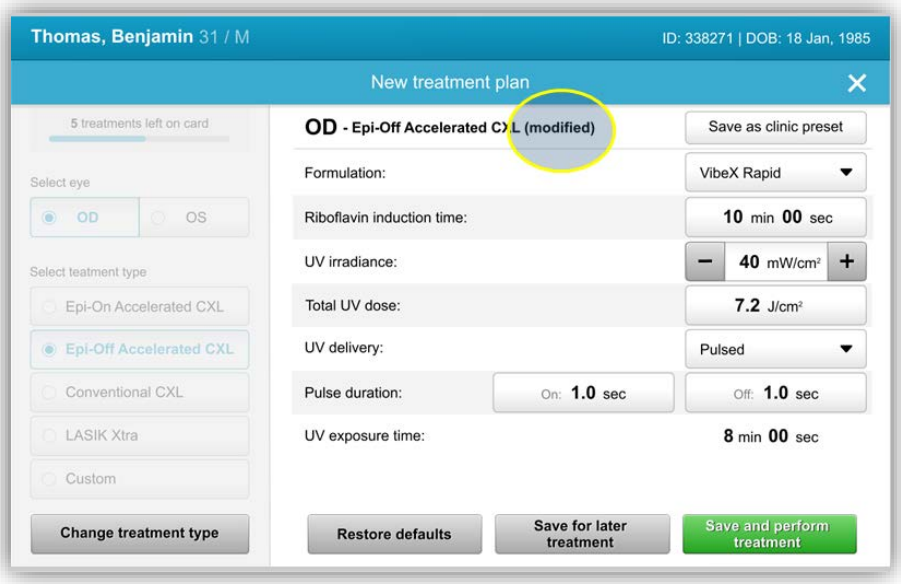


Figure 3-8 Adjusted Treatment Plan

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”.

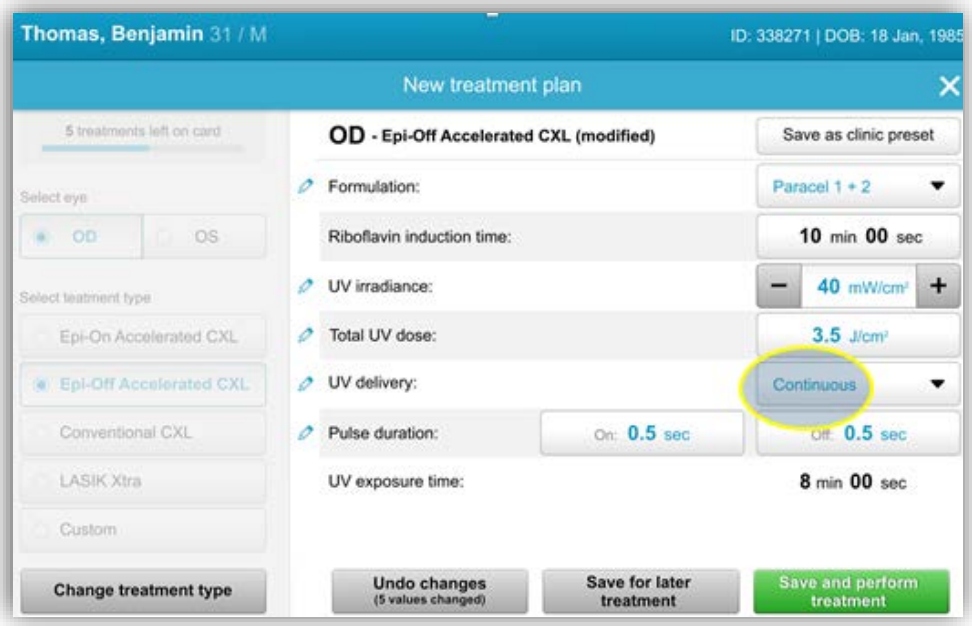


Figure 3-9 Select Continuous Treatment Mode

- 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.

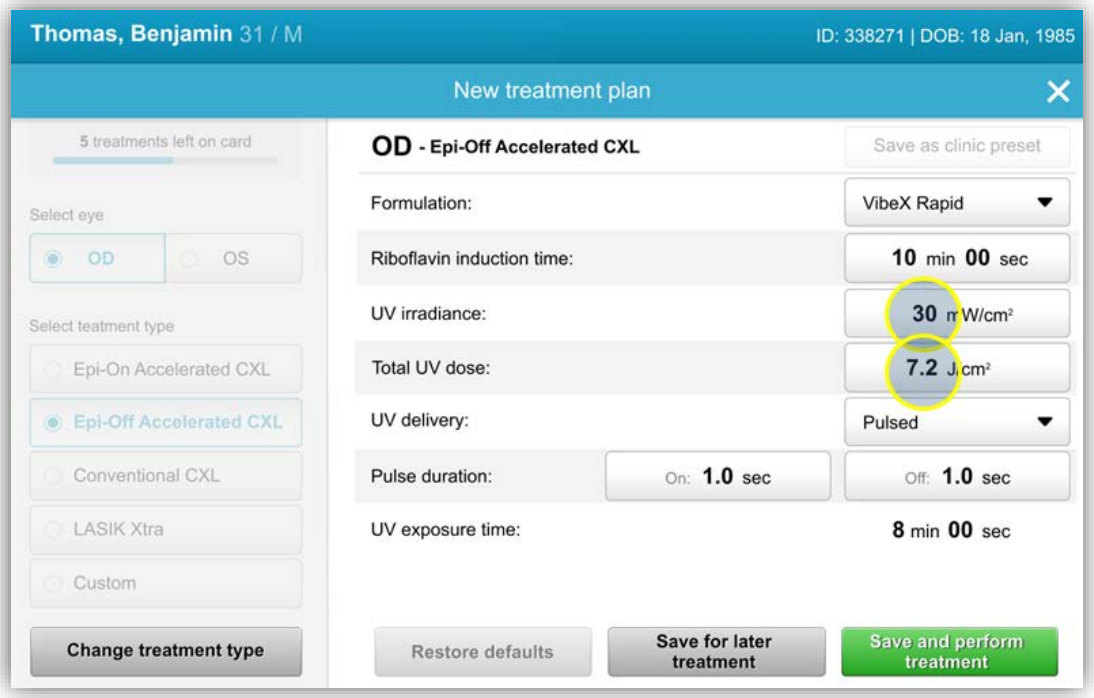


Figure 3-10 Modifying Continuous Treatment Parameters

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

Figure 3-12 Reading Tag

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".

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.

Figure 3-15 No Treatments Left

3.10.4 RFID 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.

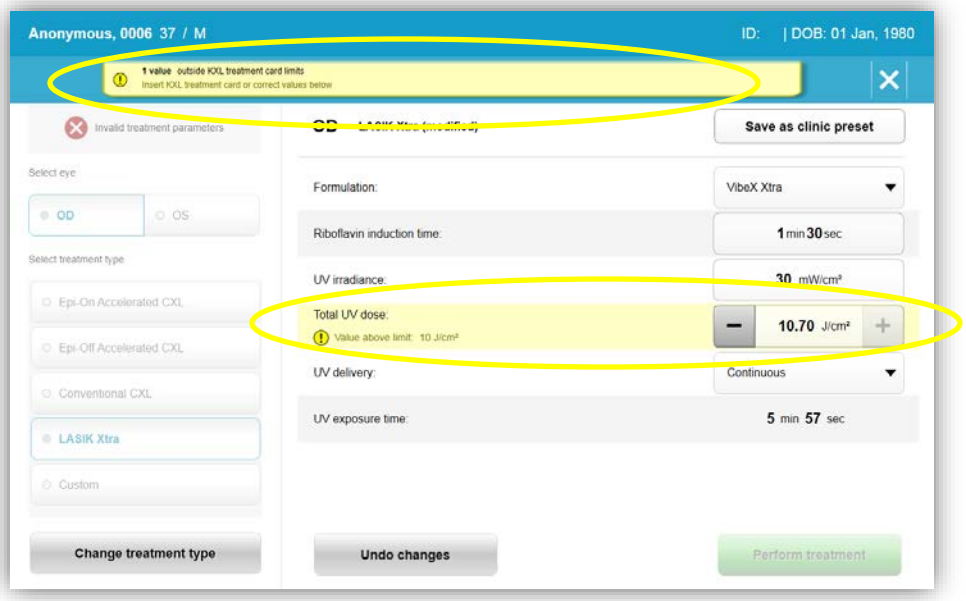


Figure 3-17 Invalid Treatment Parameters

3.10.5 Sync Alignment Remote

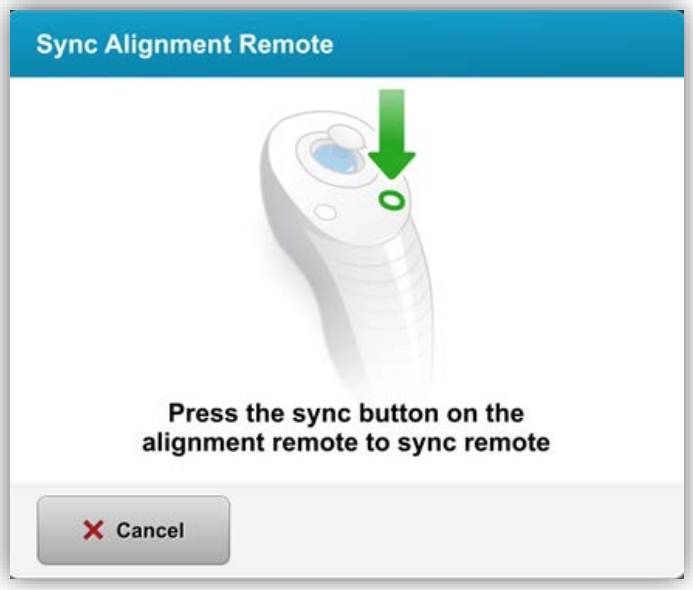


Figure 3-18 Sync Remote

- The Sync alignment remote message will be visible on the screen for 15 seconds
- When the timer gets to three seconds, it will beep for the remaining seconds
- If the sync button is not pressed within the timeframe, a message stating the sync process has timed out. However, you may choose to “Continue without remote”.

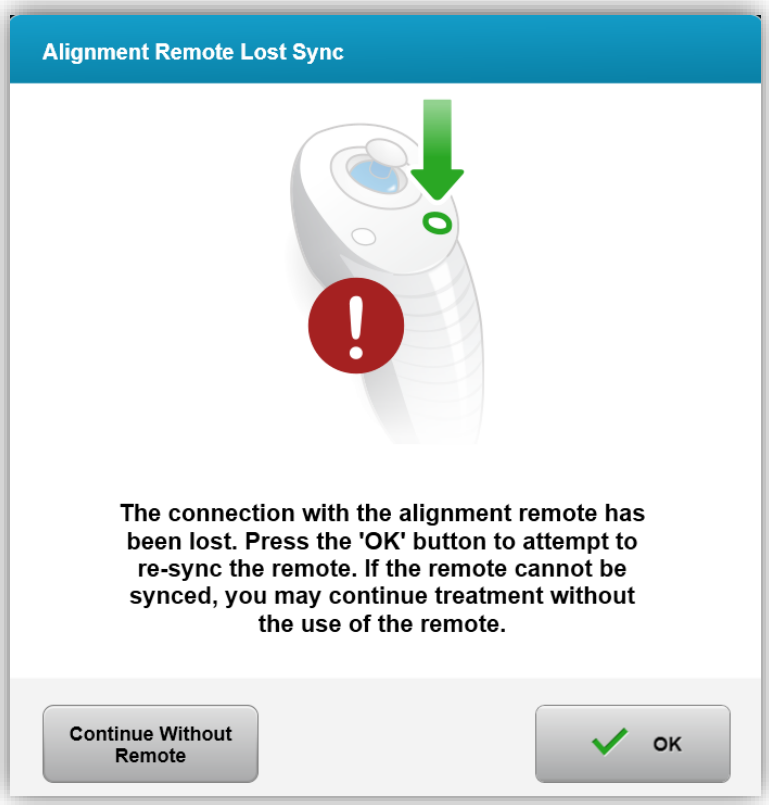


Figure 3-19 Sync process timed out

Figure 3-20 System Setup Status

- Press the "S" button on the remote to synchronize the remote within the 15 second window displayed on the screen. This is required for every procedure.

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)

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 in 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.
- Apply Riboflavin to the area of treatment in accordance with the Riboflavin Instructions for Use (IFU).

3.11.1 Applying Riboflavin

- Apply riboflavin drops on the eye per clinical protocol.
- Red lasers will turn on only 30 seconds before the induction period is over.
- When lasers turn on, align the crosshairs over eye to be treated.

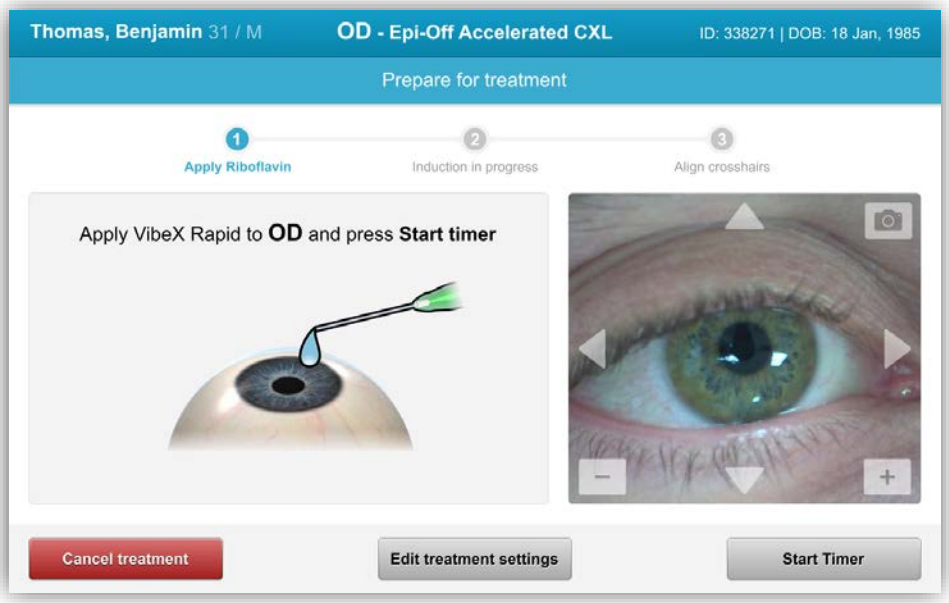


Figure 3-21 Prepare Treatment: Apply Riboflavin

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

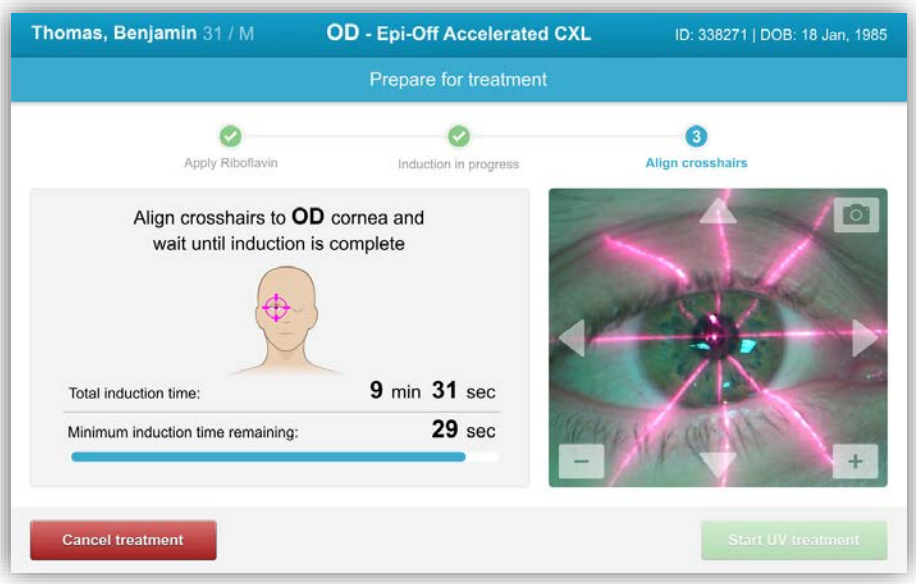


Figure 3-22 Align Crosshairs during induction

NOTE: Once the Riboflavin is applied to the eye, Start the induction by pressing the "Start UV Treatment" button.

- KXL has two alignment lasers.
  - Red crosshair for X and Y axis positioning.
  - A second Red crosshair for Z axis positioning.
  - Crosshairs may differ in appearance. They may appear thicker, thinner, longer or shorter.

Note: For correct alignment when using the Remote, the Avedro logo on optics head should face the user.

- Manually move the Optics 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 Optics 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 arrows on the motion stage.

Figure 3-23 Remote Functions

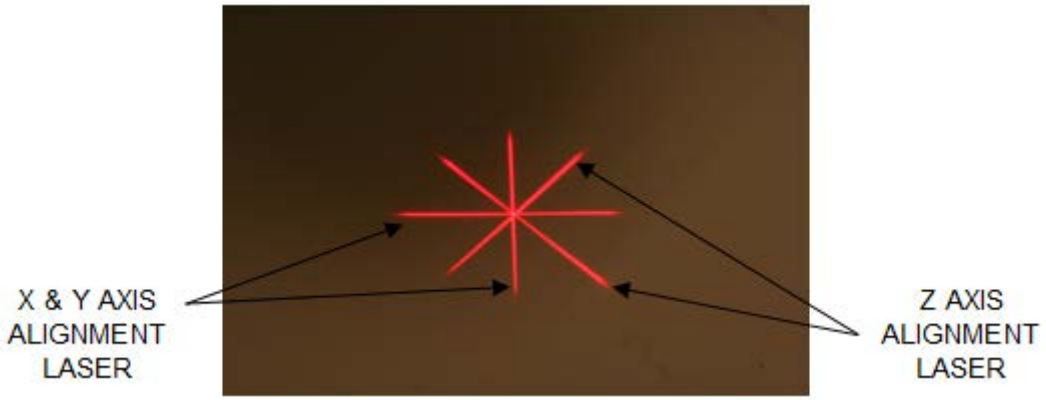


Figure 3-24. Red Crosshairs X & Y Axes, Red Crosshairs Z Axis Alignment

3.12 Initiating Treatment

- When the Induction Time is complete, Select the **"**Start UV Treatment**"** button to initiate treatment.

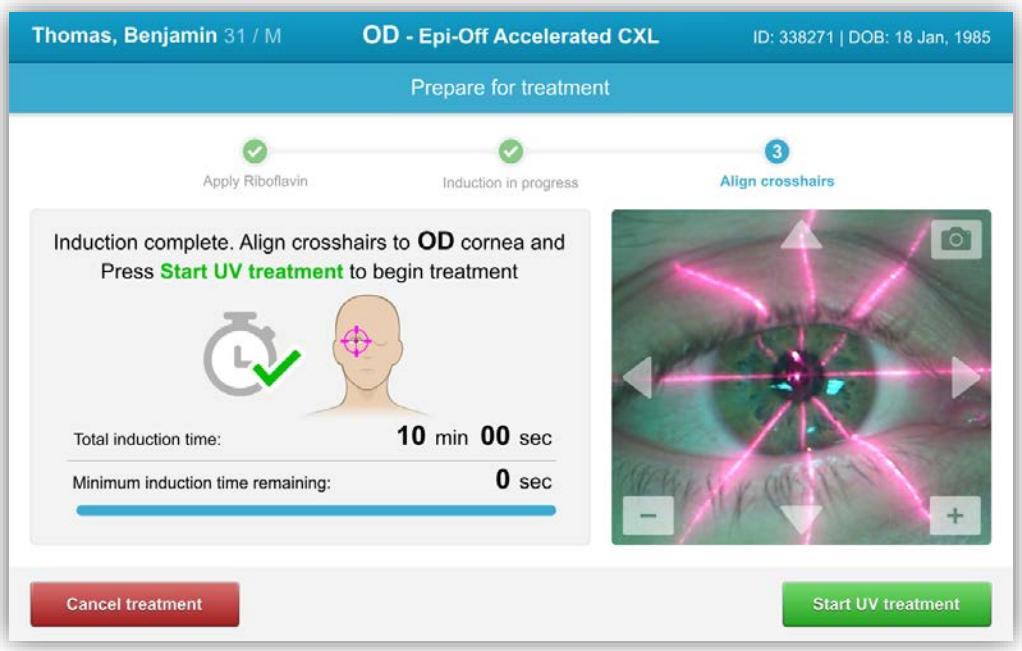


Figure 3-25 Start UV Treatment

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 arrows on motion stage.

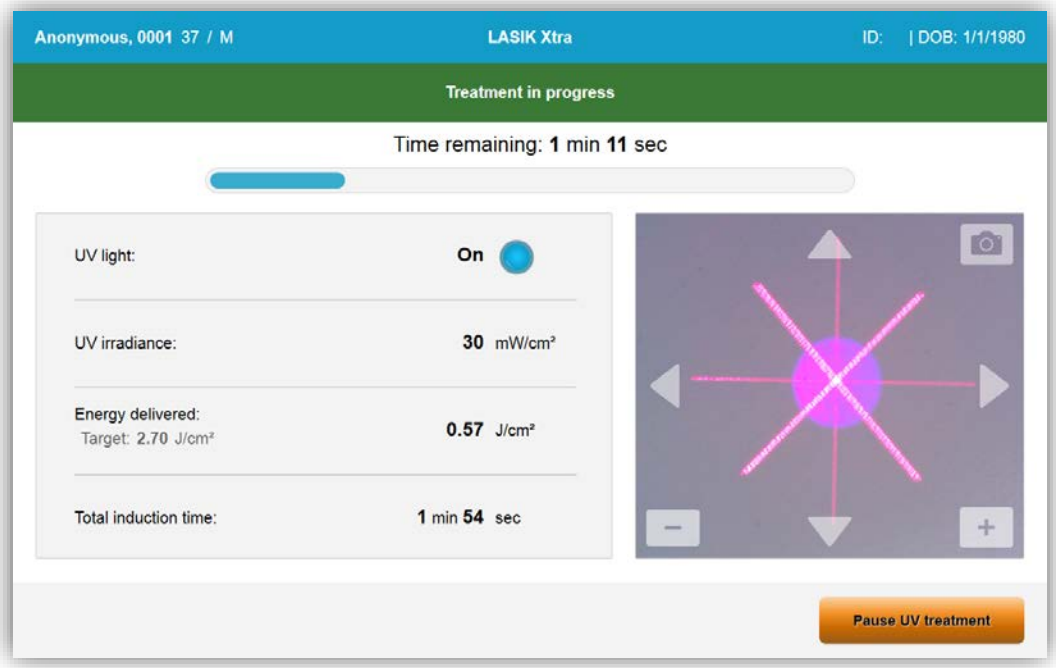


Figure 3-26 Treatment in Progress Screen

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.

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

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 button.

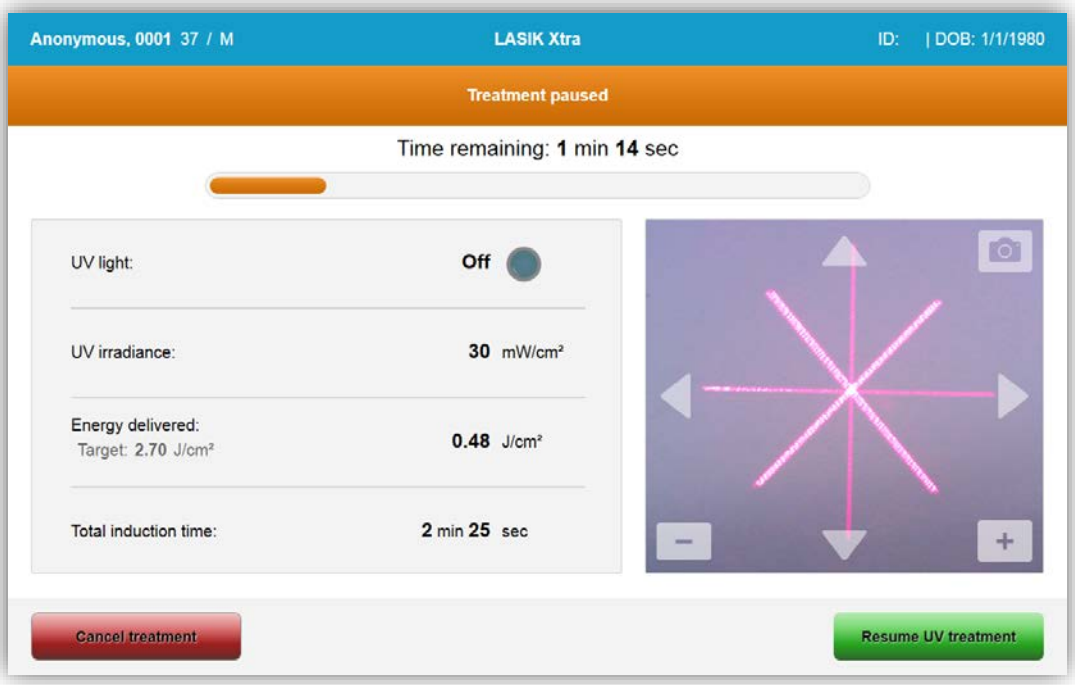


Figure 3-27 Treatment Paused Screen

- To cancel or resume treatment select “Cancel Treatment” or “Resume UV treatment” respectively. See section 3.14 if canceling a session.

3.15 Cancelling Mid Treatment

- If treatment is cancelled mid treatment, screen displays with Confirm cancelling treatment before it is complete
- To cancel session, select “Yes”.

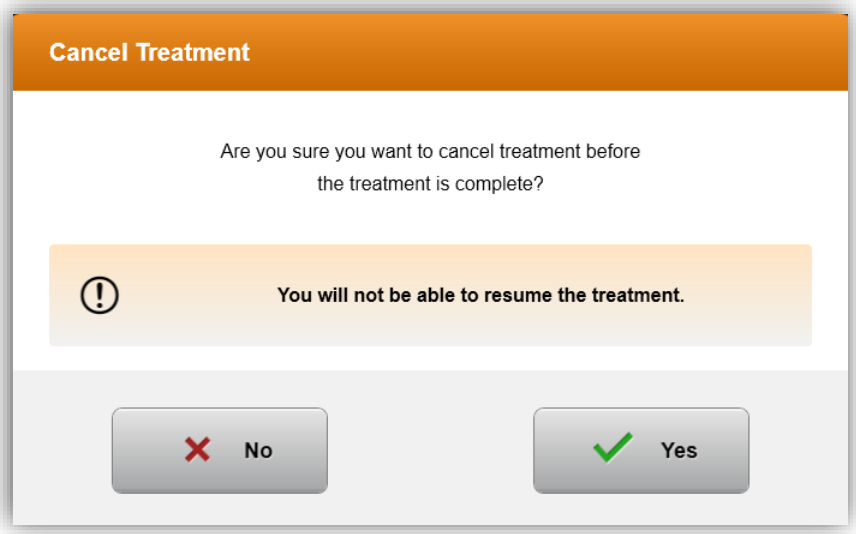


Figure 3-28 Confirm Cancel Partial Treatment

- If cancelling treatment was confirmed, the screen displays confirmation

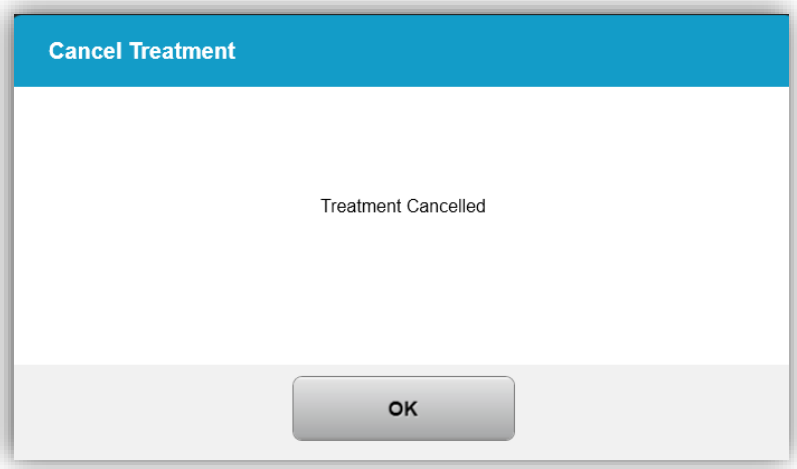


Figure 3-29 Treatment Cancelled Confirmation

- Once cancelled, the screen displays Partial Treatment Information**.**

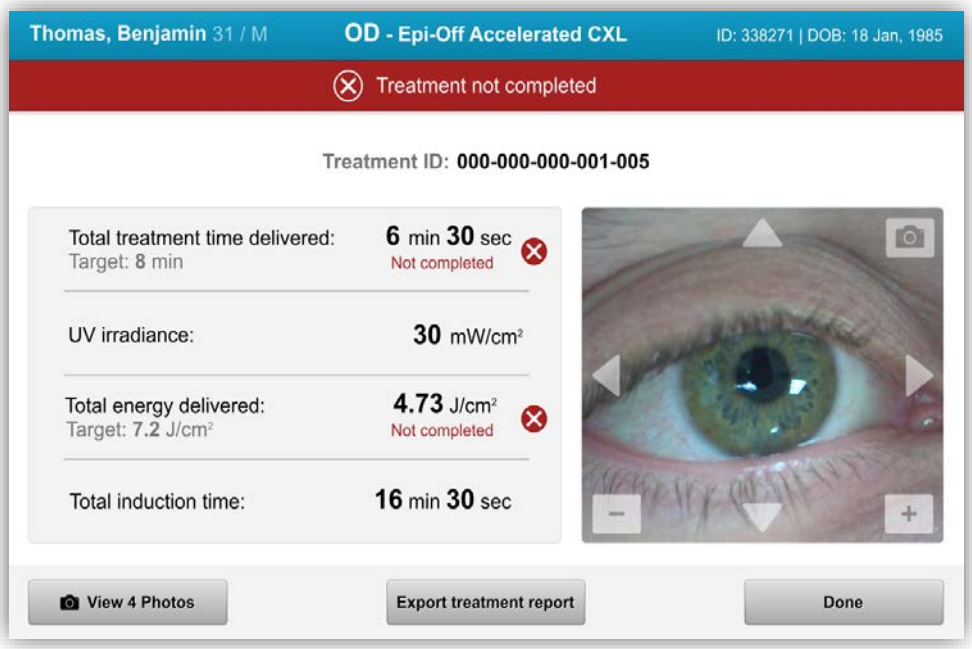


Figure 3-30 Partial Treatment Not Completed

3.16 Capturing Images

- Images can be taken at each stage throughout the treatment process.
- To capture an image, select the camera button in the top right hand corner of eye image.
- The image is automatically saved and available for review post treatment.

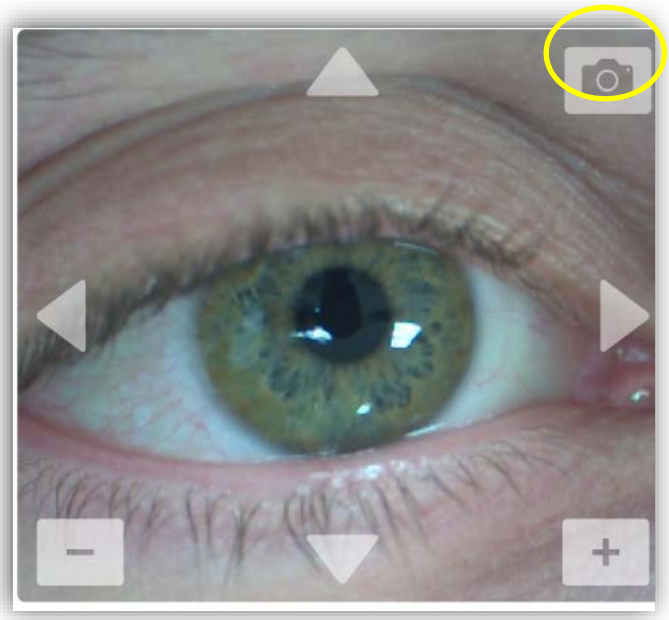


Figure 3-31 Capturing Images

3.17 Treatment Complete

At the completion of a treatment the Total Treatment Parameters will be displayed and the screen will show Treatment complete.

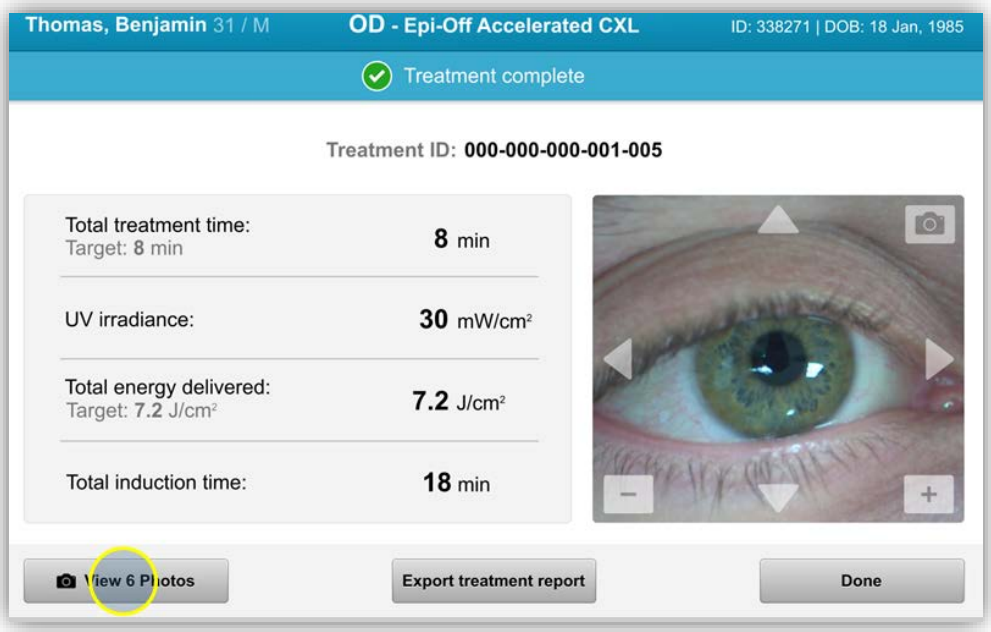


Figure 3-32 Treatment Complete Screen

- If treatments are complete, select “Done” and Power OFF the system using the “Power Off” button on the Main 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 photo gallery.
-

3.19 Deleting Photos

- Photos taken throughout treatment can be deleted.
- Select the trash icon to delete a photo.

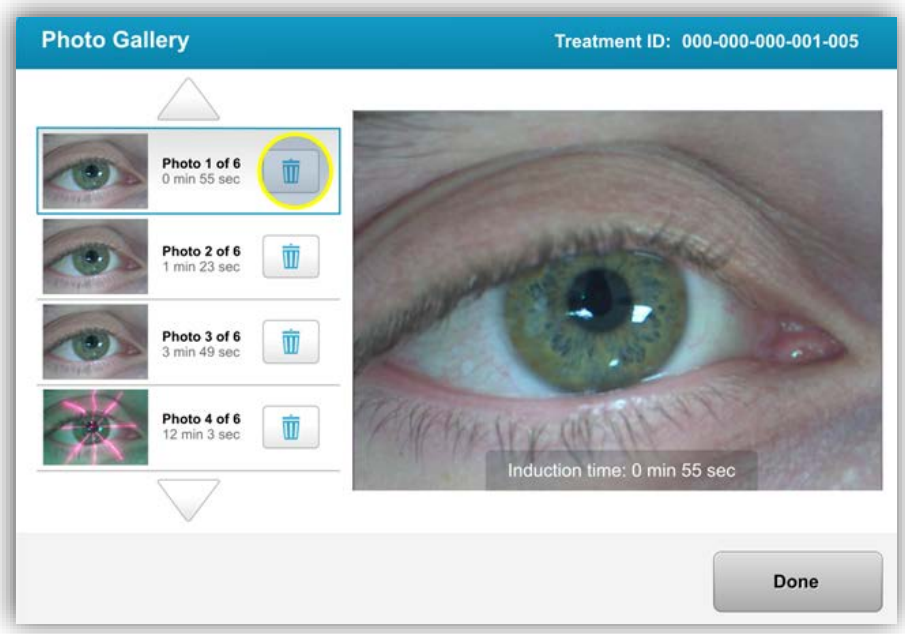


Figure 3-33 Select Trash to delete

- Once a photo is selected for deletion, select “yes” to delete photo or select “no” to keep the image.
- Once deletion is confirmed, photo will not be retrievable.

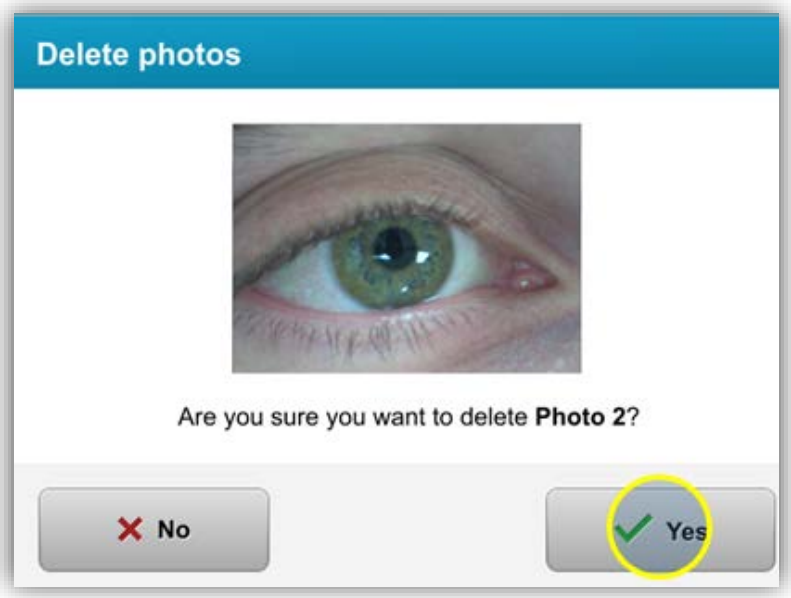


Figure 3-34 Select Yes to Delete

- Select “Done” to confirm which photos will be displayed in the treatment report.

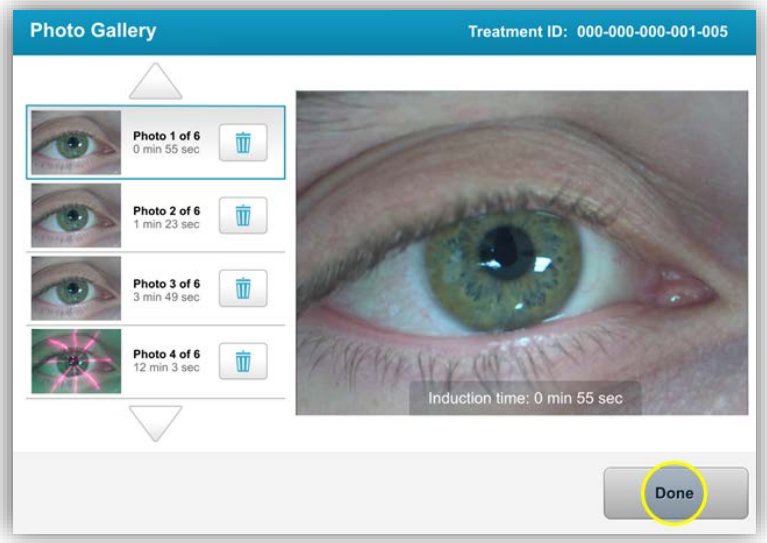
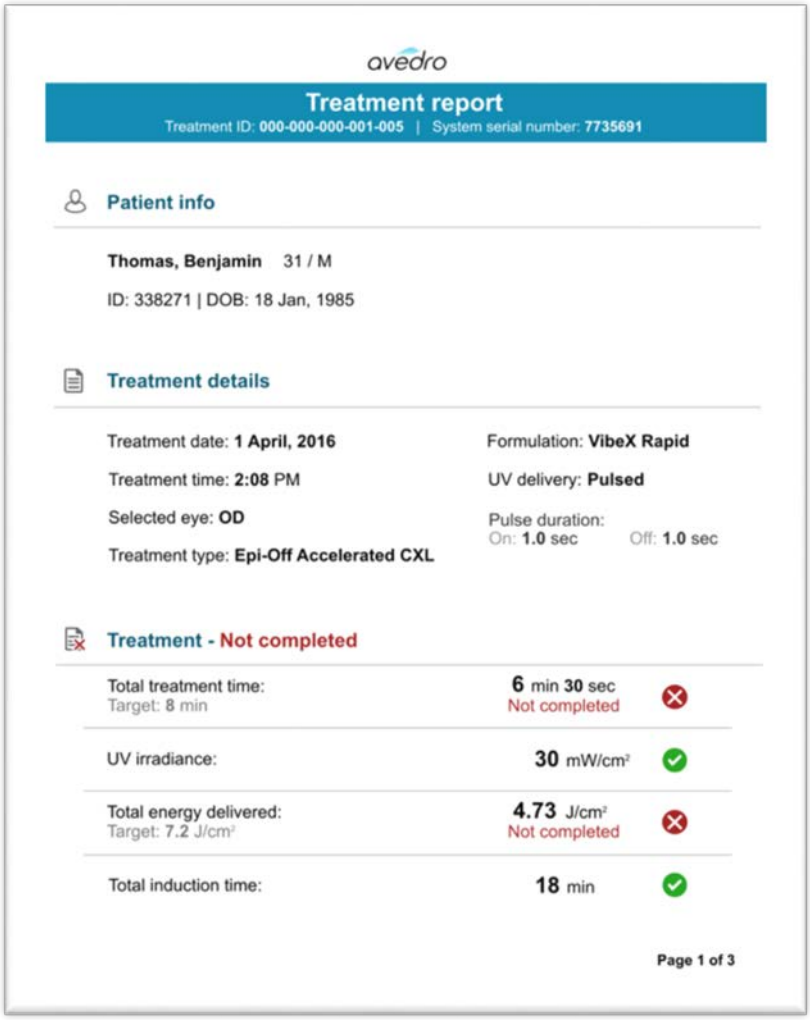


Figure 3-35 Select Done

3.20 Patient Treatment Report

- A treatment report is generated containing patient information, treatment details, photos taken throughout treatment and a notes section.
- 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.



avedro

Treatment report

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

Patient info

Thomas, Benjamin 31 / M

ID: 338271 | DOB: 18 Jan, 1985

Treatment details

Treatment date: **1 April, 2016**

Treatment time: **2:08** PM

Selected eye: **OD**

Treatment type: **Epi-Off Accelerated CXL**

Formulation: **VibeX Rapid**

UV delivery: **Pulsed**

Pulse duration:
On: **1.0** sec Off: **1.0** sec

Treatment - Not completed

Total treatment time: Target: 8 min	**6** min **30** sec Not completed	✗
UV irradiance:	**30** mW/cm²	✓
Total energy delivered: Target: **7.2** J/cm²	**4.73** J/cm² Not completed	✗
Total induction time:	**18** min	✓

Page 1 of 3

Figure 3-36 Sample Treatment Report

3.20.1 Adding Notes to a Patient Treatment Report

- From the Patient Database screen, select the patients name.
- Press the message icon to enter comments about the patient's treatment.

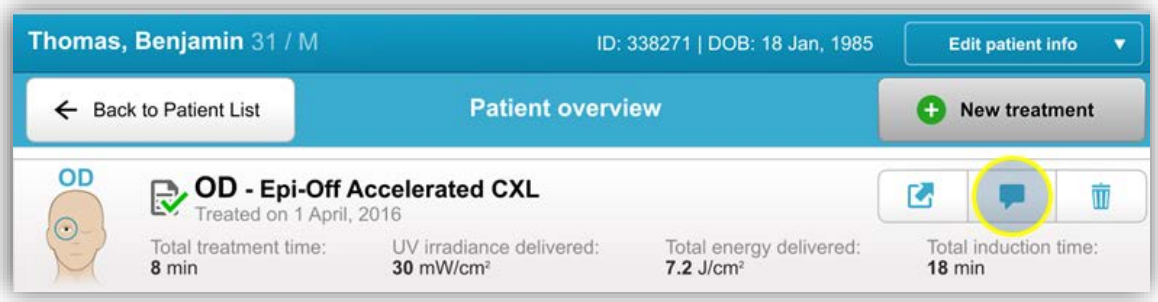


Figure 3-37 Comments Icon

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

Figure 3-38 Comments Section

3.20.2 Exporting Treatment Report

- Select “Export treatment report” to save report to a USB stick.
- Report will be exported as PDF.

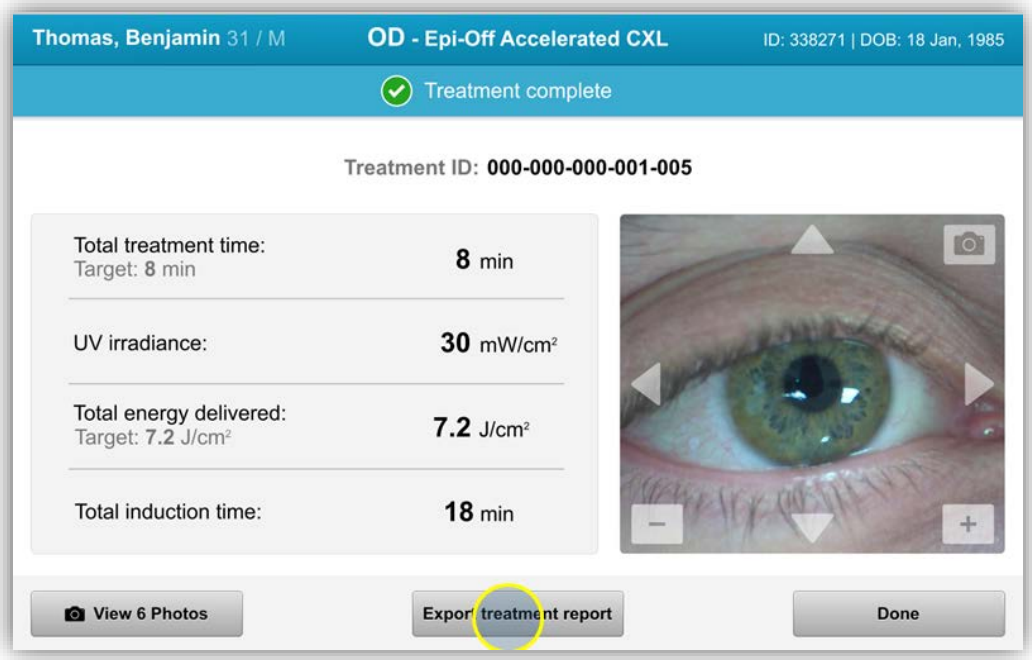


Figure 3-39 Exporting Treatment Report

- The screen will prompt to insert USB drive.
- Avedro does not supply USB drive for storing patient data

Figure 3-40 Insert USB

- If the USB is full or the system is unable to read the USB, a message indicating the error will be displayed.

Figure 3-41 USB Error

Figure 3-42 No space left on USB

- Once USB is entered, "Generating treatment report" message will appear

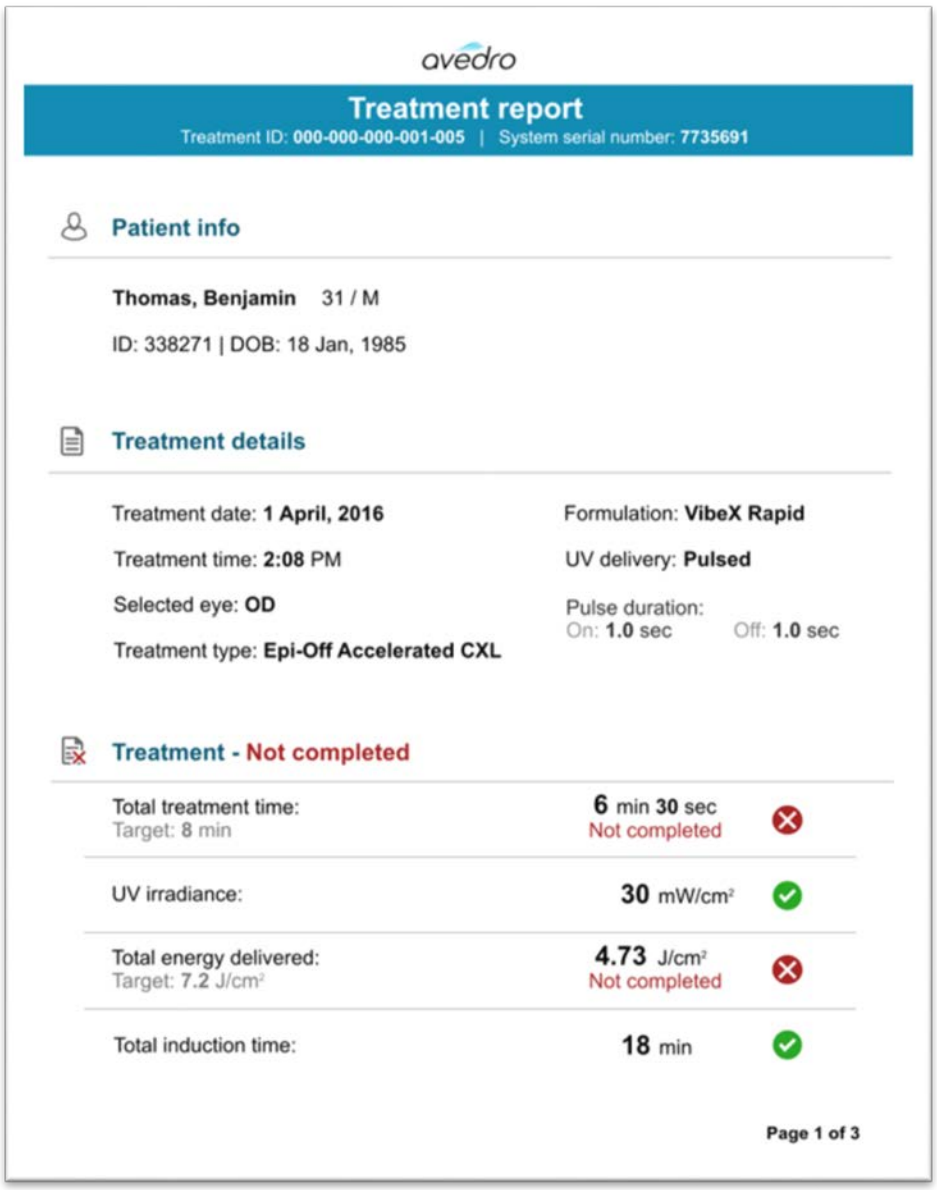
Figure 3-43 Generating treatment report

- When Treatment report is exported, a confirmation message will appear

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.



avedro

Treatment report

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

Patient info

Thomas, Benjamin 31 / M

ID: 338271 | DOB: 18 Jan, 1985

Treatment details

Treatment date: **1 April, 2016**

Treatment time: **2:08** PM

Selected eye: **OD**

Treatment type: **Epi-Off Accelerated CXL**

Formulation: **VibeX Rapid**

UV delivery: **Pulsed**

Pulse duration:
On: **1.0** sec Off: **1.0** sec

Treatment - Not completed

Total treatment time: Target: 8 min	**6** min **30** sec Not completed	✗
UV irradiance:	**30** mW/cm²	✓
Total energy delivered: Target: 7.2 J/cm²	**4.73** J/cm² Not completed	✗
Total induction time:	**18** min	✓

Page 1 of 3

Figure 3-45 Page 1 of 3: Treatment Details

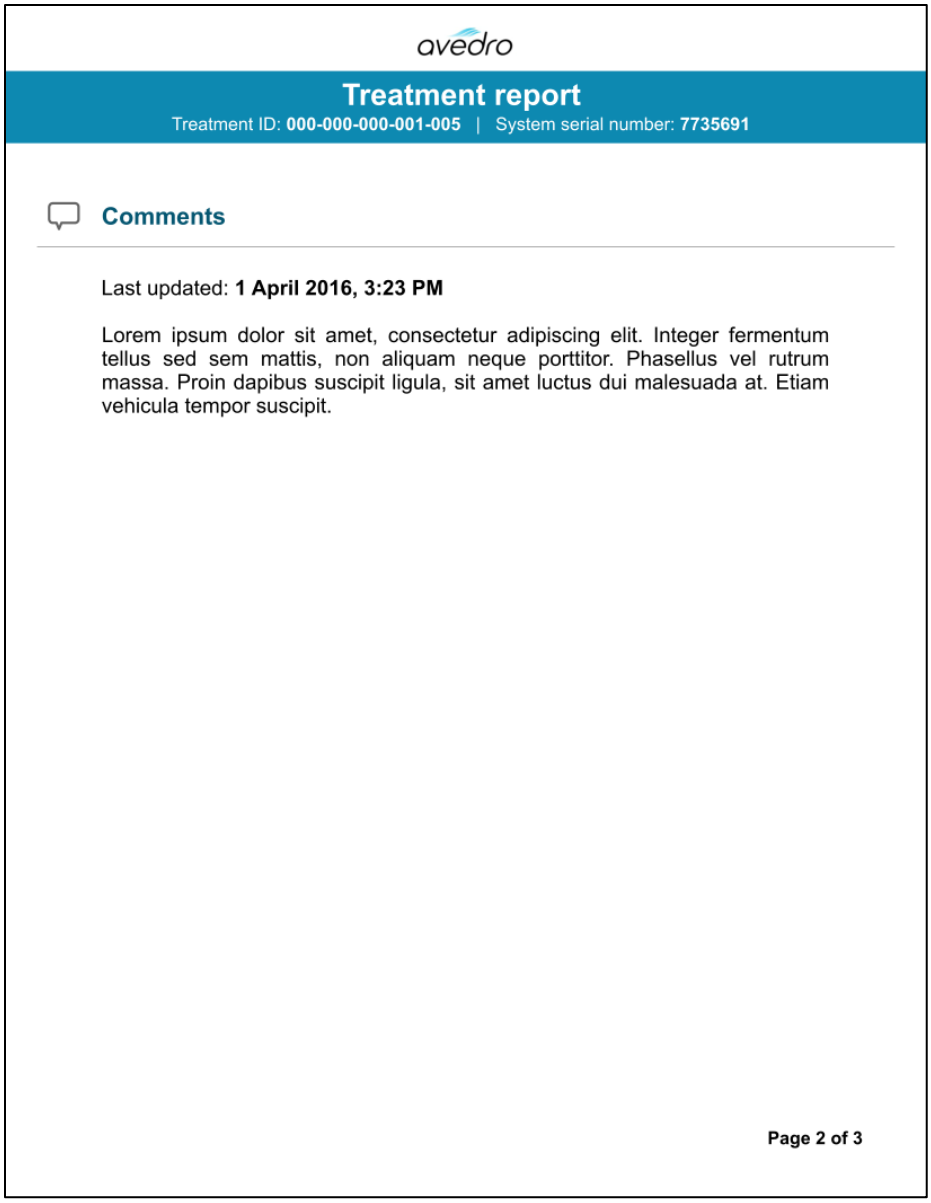


Figure 3-46 Page 2 of 3: Comments

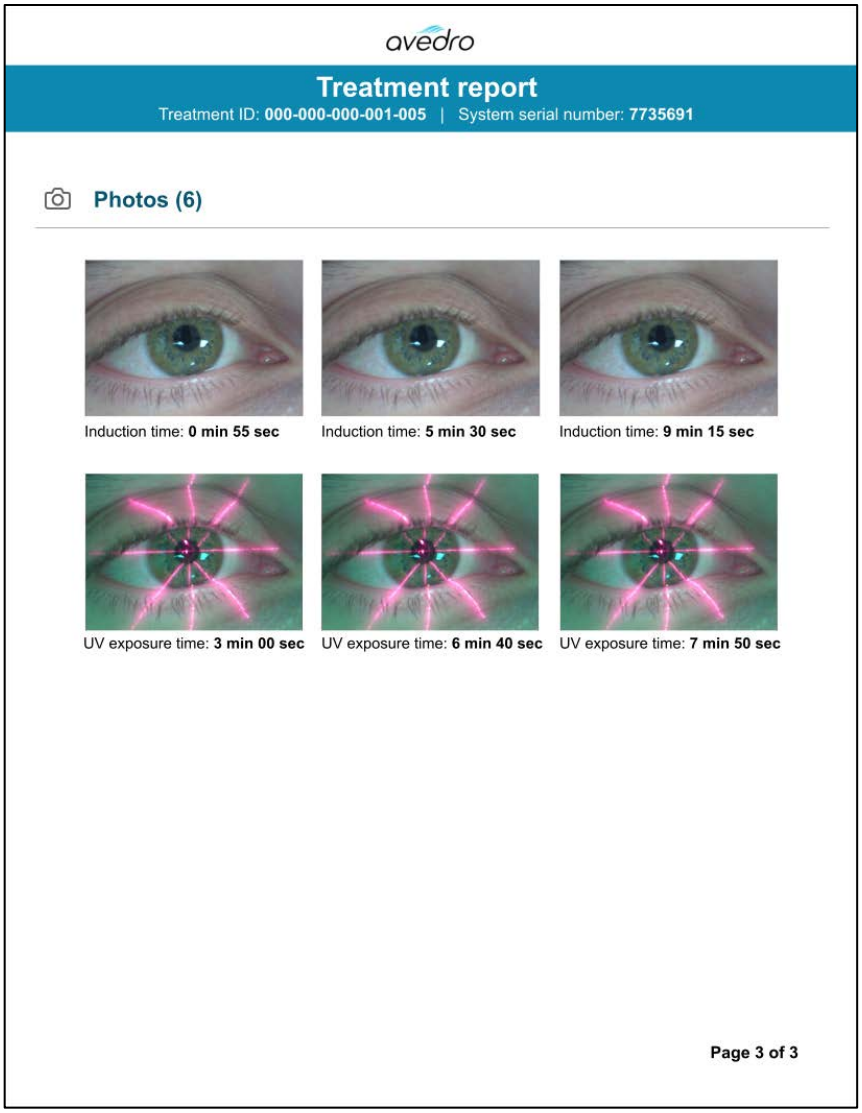


Figure 3-47 Page 3 of 3: Photos

3.21 Powering Down the System

- Select the “Power Off” on the console.

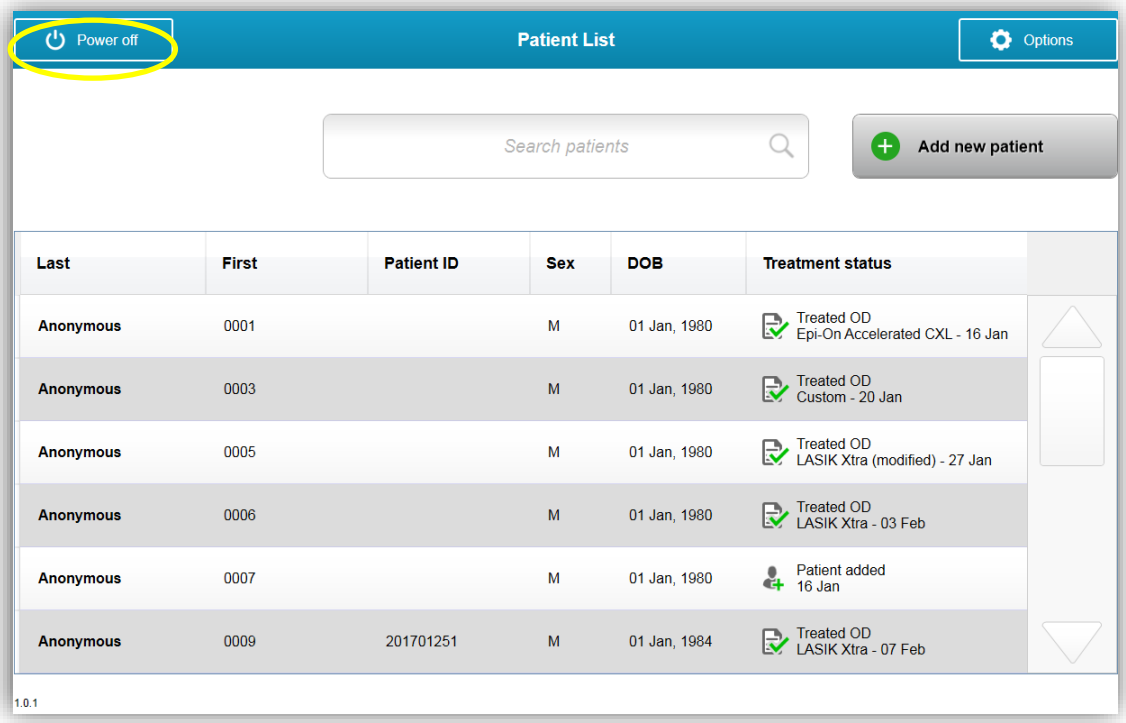


Figure 3-48 Power Off

- Confirm powering off system

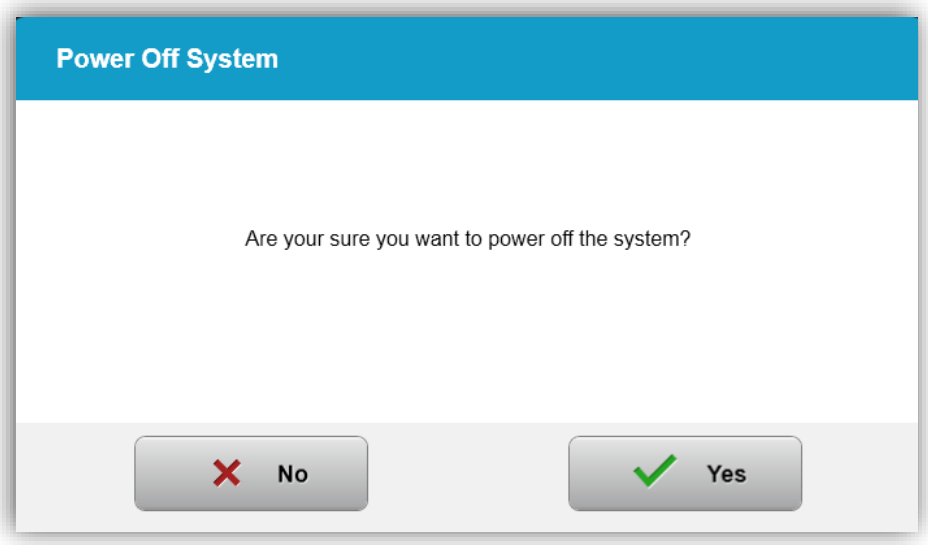


Figure 3-49 Power Off

- Wait for the software to shut down - the screen will be blank.
- After the screen is blank and software shuts down, turn the master power switch to the “Off” position.

Figure 3-50 Power Off Position

3.22 Using the System Settings Menu

- With the Patient database displayed, press the “Options” button, then press ‘System Settings”

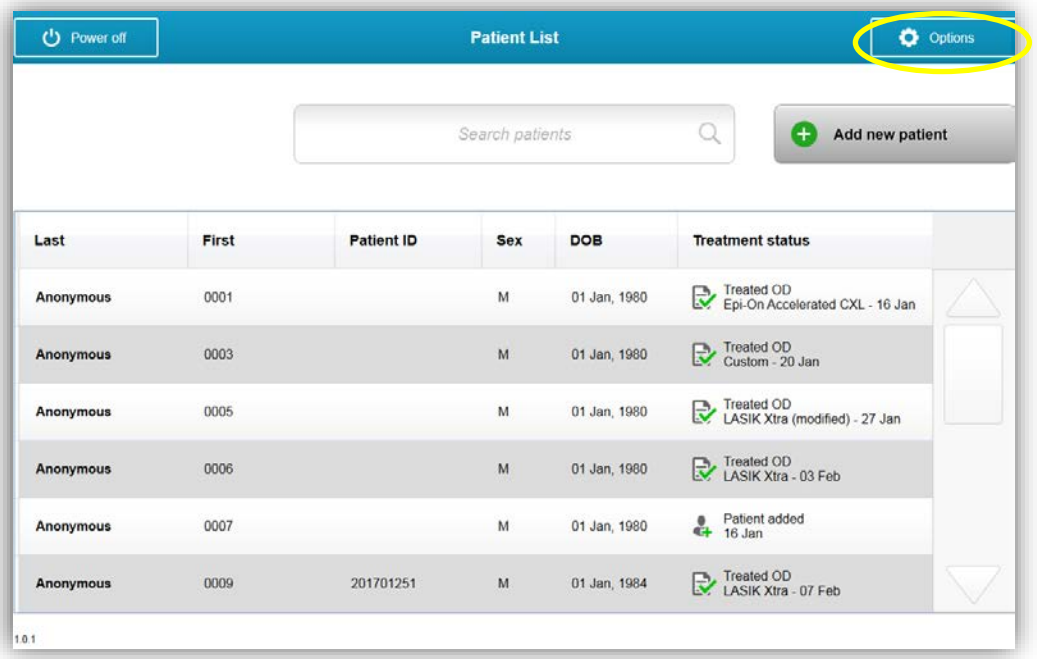


Figure 3-51 Press Options button

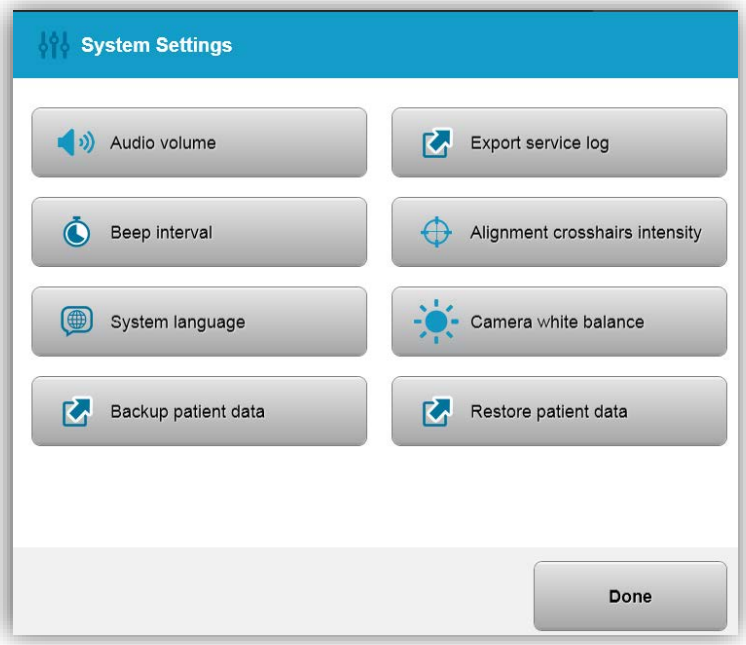


Figure 3-52 System Settings Menu

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 Editing System Language

- The System Language option allows a user to select the language of the Graphical User Interface.
- Select the desired language from the menu.

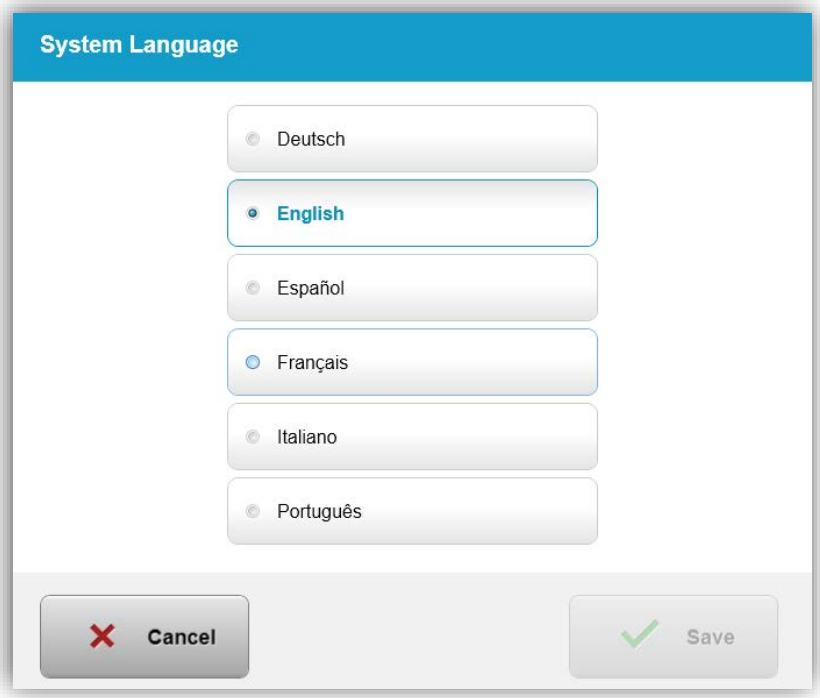


Figure 3-53 Edit System Language

3.22.3 Editing Alignment Crosshairs Intensity

- The Alignment Crosshairs Intensity option allows a user to edit the brightness of the alignment crosshairs.
- Select the Alignment Crosshairs Intensity button on the Device Settings menu.

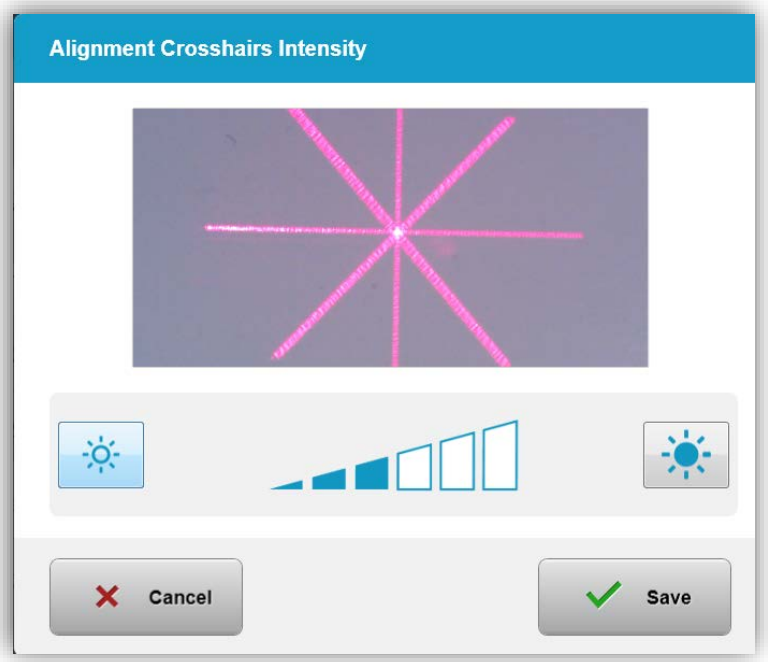


Figure 3-54 Alignment Crosshairs Intensity

3.22.4 Editing System Volume

- The Edit Volume option allows a user to edit the system volume level.
- Select the Audio Volume button on the Device Settings menu.

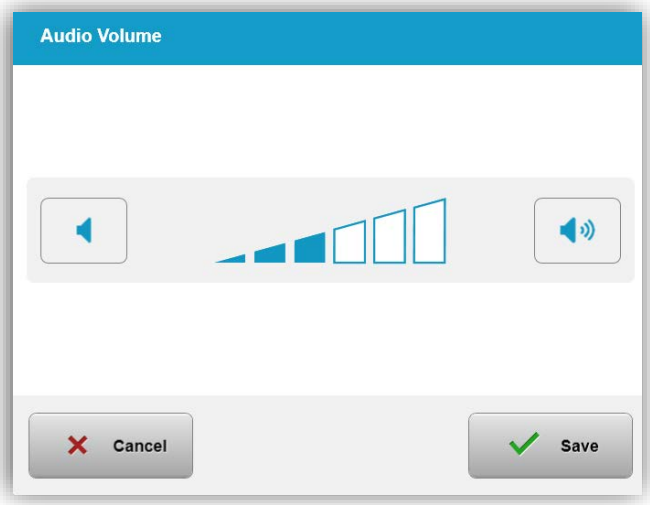


Figure 3-55 Edit Volume

3.22.5 Export Service Log

- Select the Export Service log button on the Device Settings menu.

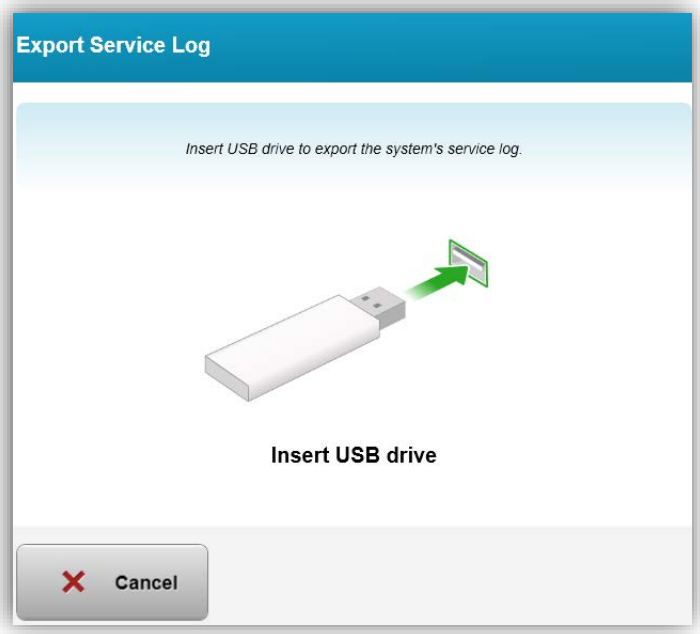


Figure 3-56 Export Service log to USB

- Insert a USB drive to the USB port. The system automatically begins transferring the service log and shows a progress bar of the transfer process as shown in the following figure.

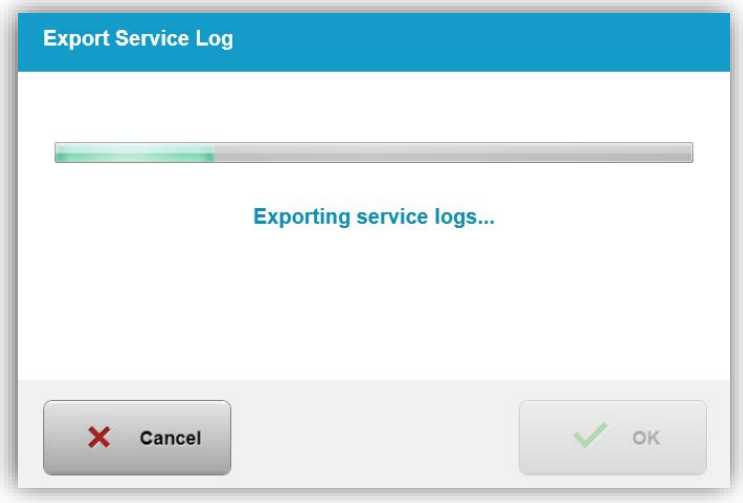


Figure 3-57 Export Service log in Progress

- Once complete press the “OK**”** button. The system will return you to the System Settings menu.

3.22.6 Editing Beep Intervals

- The Editing beep intervals option allows a user to set the default time between audible beeps while induction is in progress.
- Click the minute and second icons to increase or decrease time, then press save.

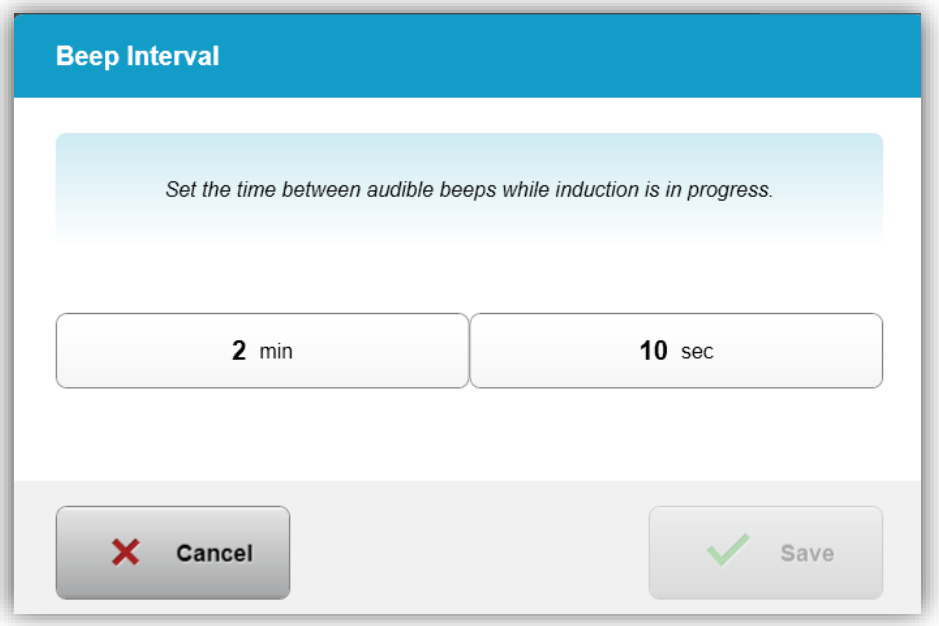


Figure 3-58 Select Beep Intervals

3.22.7 Editing Camera White Balance

- The Camera White Balance option allows a user to change the light conditions within the console. Typical office lighting is under 5000K. As a result, the default setting is Tungsten 2800K. If a different light source is used, it may be useful to edit the white balance condition.

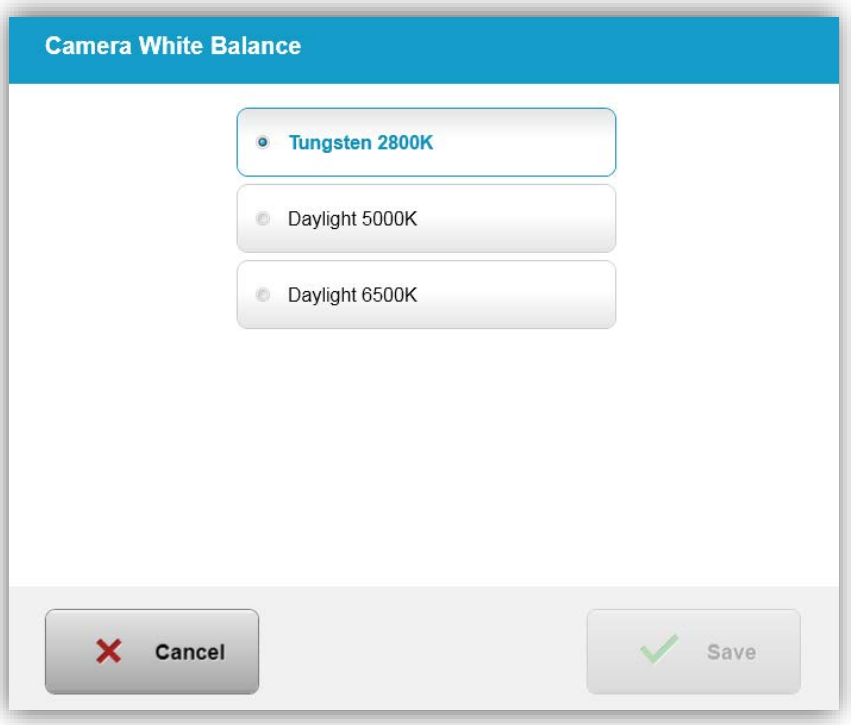


Figure 3-59. Edit Camera White Balance

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.

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 re-synchronize and will ask user to "Continue without remote" . If the remote synchronization is lost during a treatment the user will be prompted to determine if they want to continue the treatment without the remote.

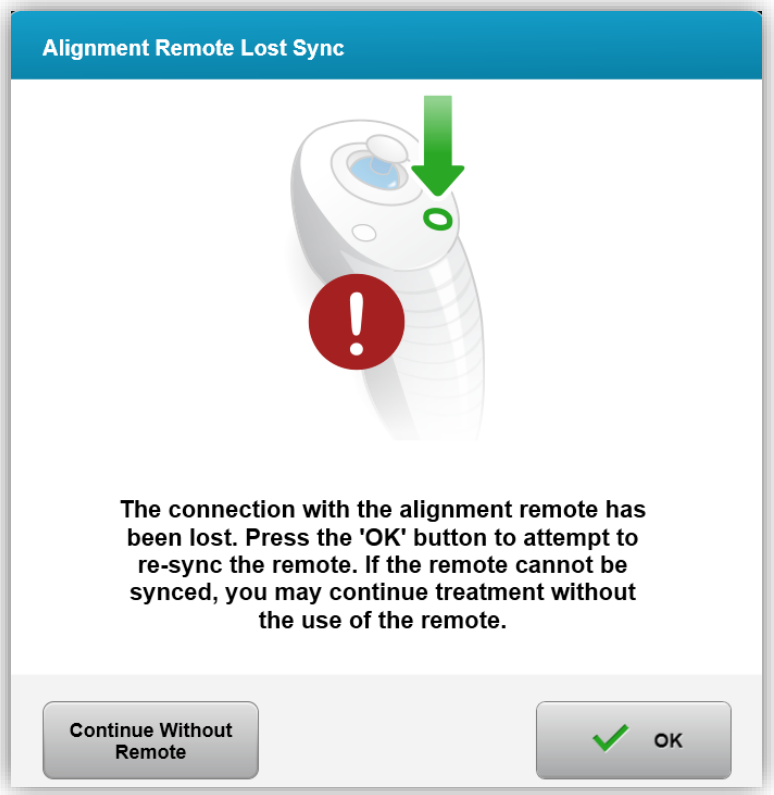


Figure 4-1 Alignment Remote Lost Sync

- 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 Sterilization or Disinfection

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

4.8 Cleaning the System

- Use a soft damp cloth to clean the 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 Optical Head in a fix 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 optics 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.

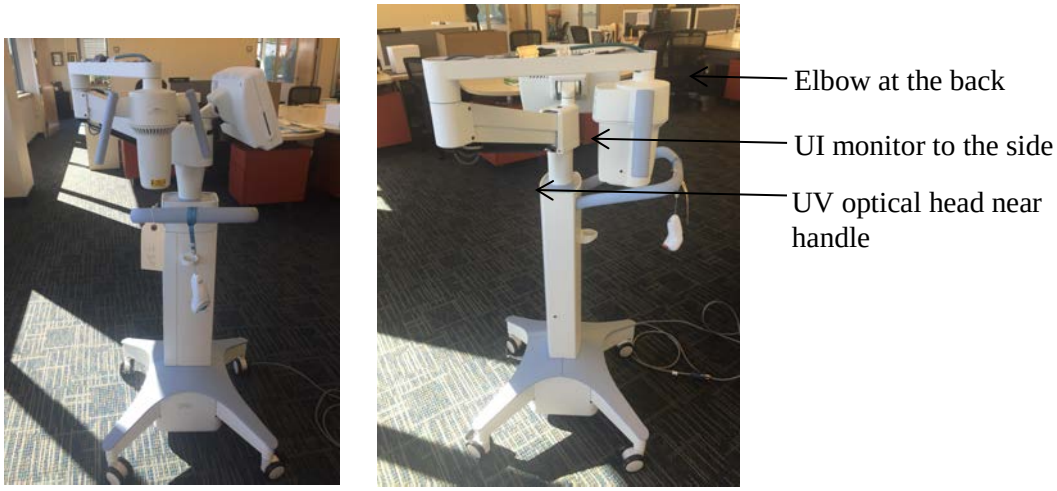


Figure 4-2 Moving System Configuration

4.12 Storing the System

- Follow all the storage temperature and humidity range specifications as listed in the Specifications chapter 7.0.
- 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 Identifying 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
- 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

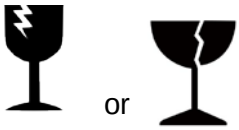
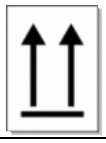
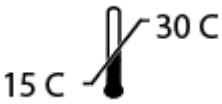
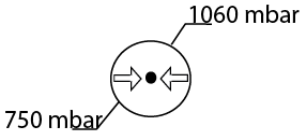
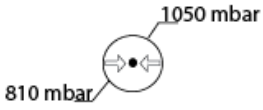
- IEC 62471:2006 Risk Group 2
- EN 62471:2008 Risk Group 3
- UVA LED is Risk Group 3

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

- Class IIa

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

Text Symbol	Symbol Illustration	Definition
13. Umbrella with raindrops		Keep Dry: Store protected from moisture (symbol is with or without rain drops)
14.		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 shipment 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
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