Avedro, Inc.
KXL® System

Operator's Manual

Printed in U.S.A.

For software versions 6.0.0 and higher.

Patents, Trademarks, Copyrights

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

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

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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 is indicated for use with PHOTREXA (riboflavin 5'-phosphate ophthalmic solution) and PHOTREXA VISCOUS (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) in corneal collagen cross-linking for the treatment of progressive keratoconus and corneal ectasia after refractive surgery.

1.3 Confidentiality Disclaimer

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

None.

1.6.2 Warnings

Ulcerative keratitis can occur. Epithelial defects should be monitored until resolution.

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.

Even with the power cord removed, there is the potential for an electrical shock from the 12VDC internal power source.

The System is designed for continuous operation using the external connector or its internal rechargeable battery.

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, including to the rechargeable battery, is performed only by qualified Avedro service personnel.

WARNING: Remove the wall plug and turn off the power switch 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.

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: The USB port can only be used when the system is not in treatment mode, do not connect to the USB during treatment.

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

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

WARNING: Do not use adjacent to or stack with other equipment; if it is used adjacent to or stacked with other equipment, verify that the equipment behaves normally as intended.

WARNING: No modification of this equipment is allowed.

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

1.6.4 Radiation Safety Warnings

WARNING: Never look directly into the UV light beam nor direct the beam towards a person except for therapeutic purposes.

WARNING: Always wear UVA protective goggles when the KXL system is turned on.

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

1.7 Patient Safety

The treatment should take place in a quiet 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 and 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.

1.8 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.

1.9 Use in Specific Populations

- The safety and effectiveness of corneal collagen cross-linking has not been established in pediatric patients below the age of 14 years.

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 riboflavin phosphates ophthalmic solution (Photrexa Viscous and/or Photrexa) has been applied. Irradiating the riboflavin phosphates ophthalmic solution creates singlet oxygen, which forms intermolecular bonds in corneal collagen. 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. The LED emits continuous UVA radiation at a wavelength of 365 nm at an intensity of 3 mW/cm^2.

A fixed aperture mounted in the UVA irradiation beam path is used to produce a circular area of irradiation at the treatment plane with a diameter of 9.5 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 by the user through a wireless remote.

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. An internal battery powers the system; the battery is recharged by a System internal charger from any standard AC outlet. The treatment parameters (Riboflavin Induction Period, Total UV Energy and UV Power) are confirmed through the user interface touch screen computer.

The KXL System is used in conjunction with Photrexa Viscous and Photrexa and an RFID activation card.

NOTE: The depictions of the KXL System and user interface screenshots included in this manual are for demonstration purposes only. Actual product may vary.

2.1.1 Major Components

The major components of the KXL System include the following:

- Optics Head with UV source
- KXL console with user interface
- Wireless remote control (with replaceable batteries)

Figure 2-1. Overview Illustration of KXL System

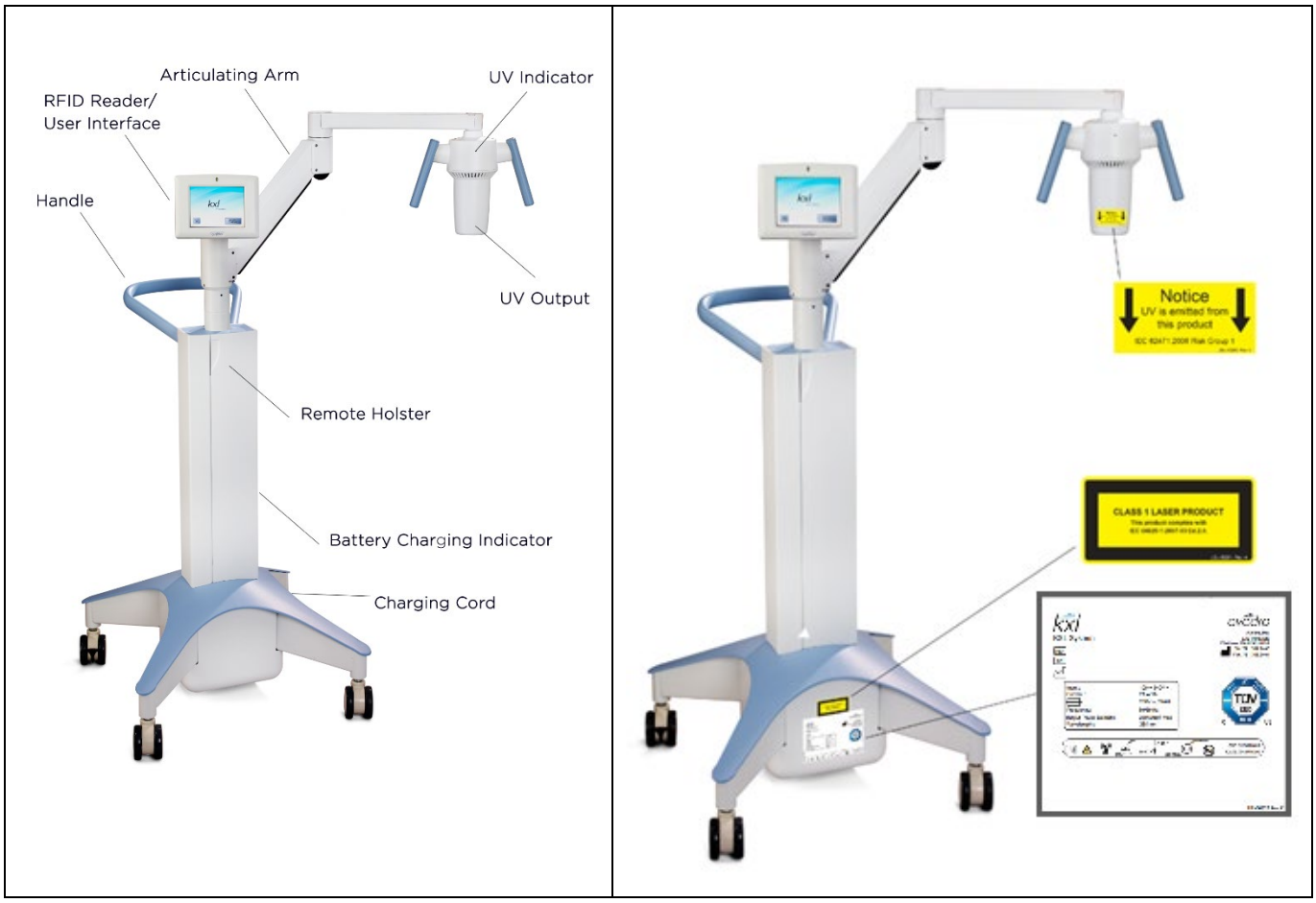


Figure 2-2. System Illustrations with Callouts

Figure 2-3. Wireless Remote

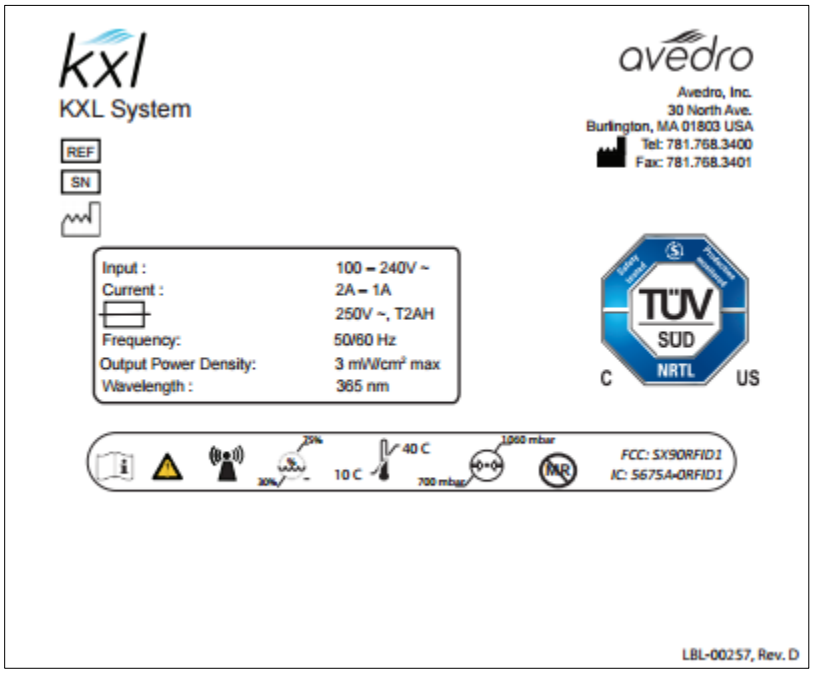


Figure 2-4. KXL Label

Figure 2-5. UV emitting Label

Figure 2-6. Alignment Laser Classification Label

3 System Operation

3.1 Charging the KXL System Battery

NOTE: Prior to initial use, the internal battery pack of the KXL must be charged overnight.

- In order to maintain battery charge, it is recommended that the KXL be connected to a grounded mains supply at all times or at the end of each business day, including when not in use.
- The charging status of the battery is identified by the color of the light located on the column of the KXL when the System is plugged in.
    - Red/Orange: Low, charging
    - Yellow: Charging
    - Green: Fully charged, ready for use
- The System software will notify the user when the battery needs to be charged as shown below in Figure 3.1.

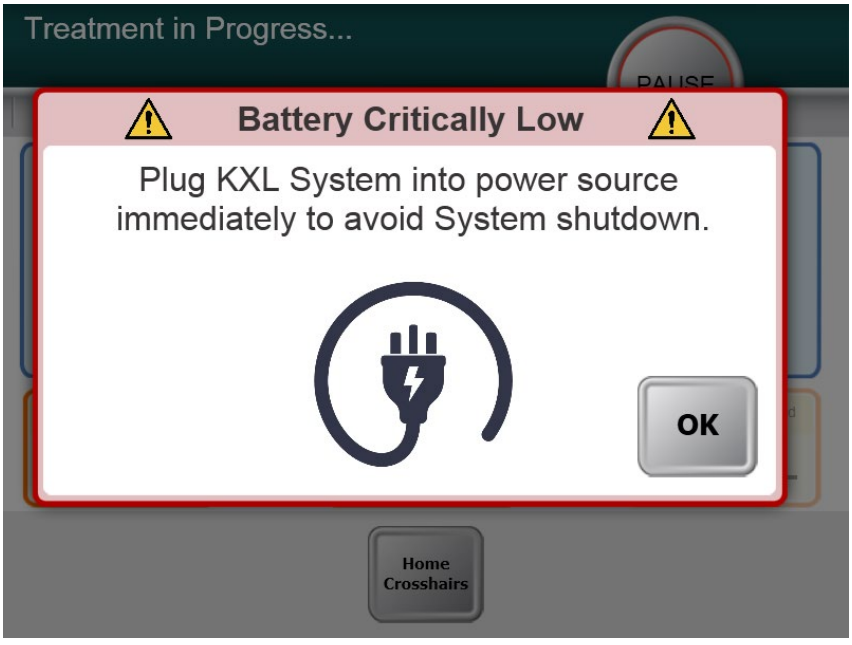


Figure 3-1. Power Switch

NOTE: The battery status indicator light is expected to turn green within 8 hours of being plugged in. If the light is not green within 8 hours, the System battery may be damaged, and it is recommended that you contact your local Avedro Service Representative.

3.2 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 internal computer.
Start New Treatment button (Initial screen)		Starts a new clinical treatment protocol.
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 particular 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 Session button (various Clinical Protocol screens)		Cancels a treatment session for a particular patient. A prompt is then displayed to confirm your decision.
Return button (various Device Settings screen)		Returns to the Device Settings menu.

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

3.3 UV Dose

- The UV Energy (Dose) is the product of the UV Power (Irradiance) and the UV Irradiation Time. The UV Energy, the UV Power and the UV Irradiation Time are displayed on the user interface.
- The System tracks UV Energy, UV Power, UV Irradiation Time and Total Treatment Time during the treatment.
- NOTE: The System's parameters are:
    - Induction Period: 30 minutes
    - Wavelength: 365 nm
    - UV Energy: 5.4 J/cm^2
    - UV Power: 3 ± 10% mW/cm^2
    - UV Irradiation Time: 30 minutes

3.4 Preparing the System

- Position the KXL System adjacent to the treatment table or chair. Lock the casters to secure the device's position.
- Check glass window of beam aperture for dust and dirt. See Sections 4.7 and 4.8 for cleaning instructions.

3.5 Important Steps Before Turning on the System

- The user is responsible for assuring that the KXL System is functioning properly and is in good working condition 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 into consideration your local regulations for use of portable electro-optical medical devices.

3.6 Powering Up the System

- Turn ON the single power switch on the front of the KXL console. This switch turns on all the system components.

Figure 3-2. Power Switch

- The KXL System begins a power-up sequence, loading the operating system and all configuration and reference files.
- Ensure that the System battery status indicator light is green.

  NOTE: If the System has been plugged in and fully charged, and then the System is moved to another location and plugged in, the battery status indicator light will not be green initially. The System may be used for treatments.

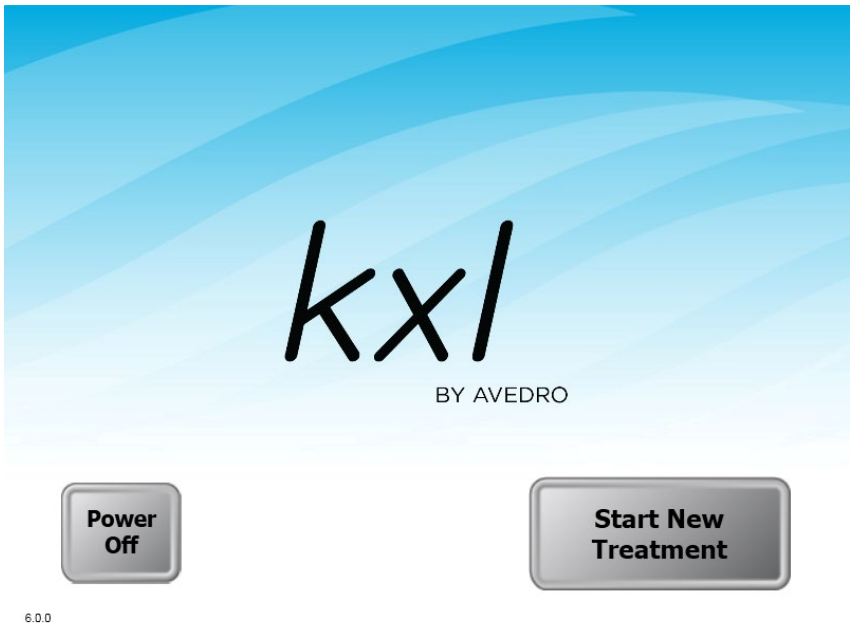


Figure 3-3. Startup Screen

- Please see Section 3.20 for Power Down sequence instructions.

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

3.7 Confirm Riboflavin Induction Period

- To begin patient treatment, press the Start New Treatment button.
- Confirm the length of the induction period (30 min) for the patient.
- To proceed, press the Checkmark button.

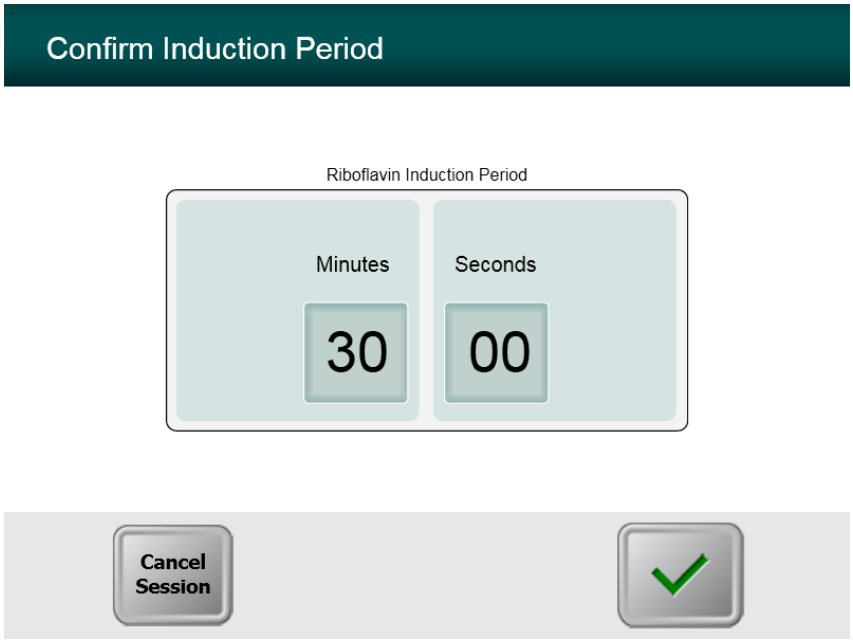


Figure 3-4. Induction Period Screen

3.8 Confirm UV Treatment

3.8.1 Confirm UV Dose

- Confirm the desired UV treatment parameters by pressing the Checkmark button:
    - Total Energy (5.4 J/cm^2)
    - UV Power (3 mW/cm^2)

NOTE: UV irradiation time is displayed in the orange box.

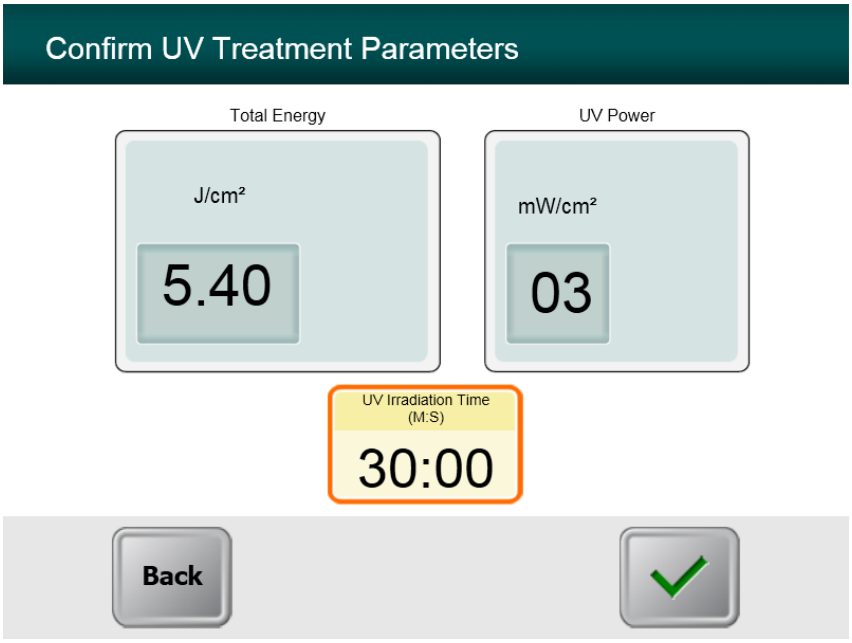


Figure 3-5. UV Energy Dose

WARNING: The Treatment Activation Card is pre-programmed with above parameters and will only confirm the above energy and power dose.

- Confirm the specified treatment parameters by pressing the Checkmark.

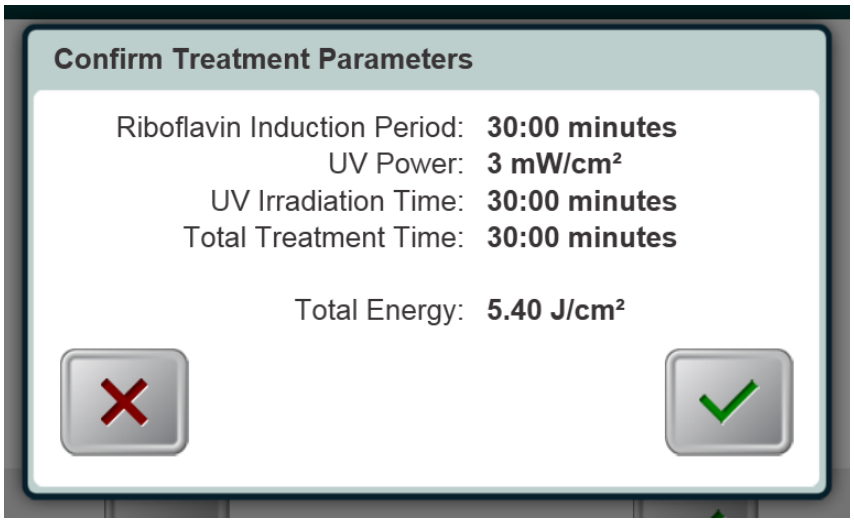


Figure 3-6. Confirm Treatment Parameters Screen

3.9 Starting Treatment

- Place the activation card on the RFID reader and hold in place until the system emits a beep.

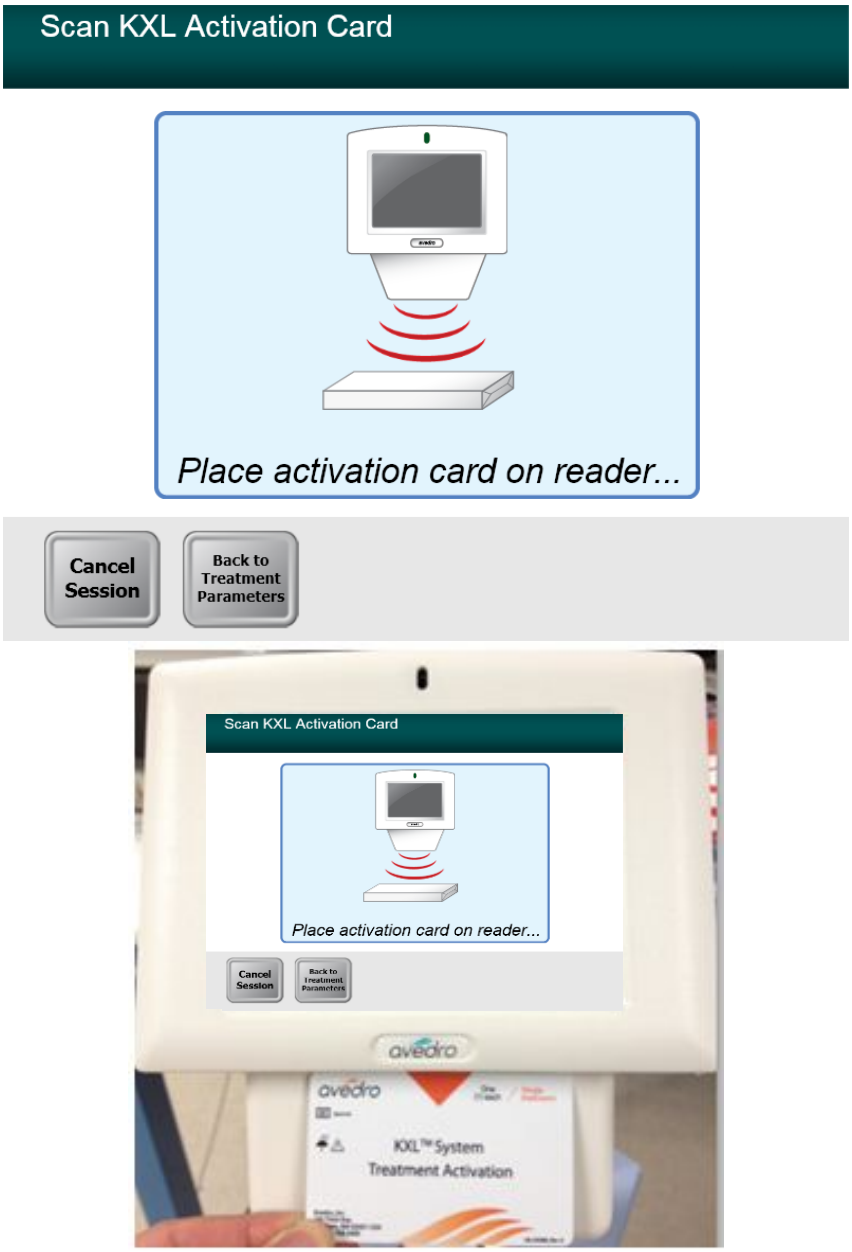


Figure 3-7. Reading Activation Card

WARNING: The Treatment Activation Card is pre-programmed with stated parameters of 3 mW/cm² and 5.4 J/cm².

3.9.1 Single-use Disposables

- Hold until read is complete and discard tag or activation card.

3.9.2 Multi-use Disposables

- Once a multi-use activation card has been scanned, the display will show the number of treatments remaining on the card.

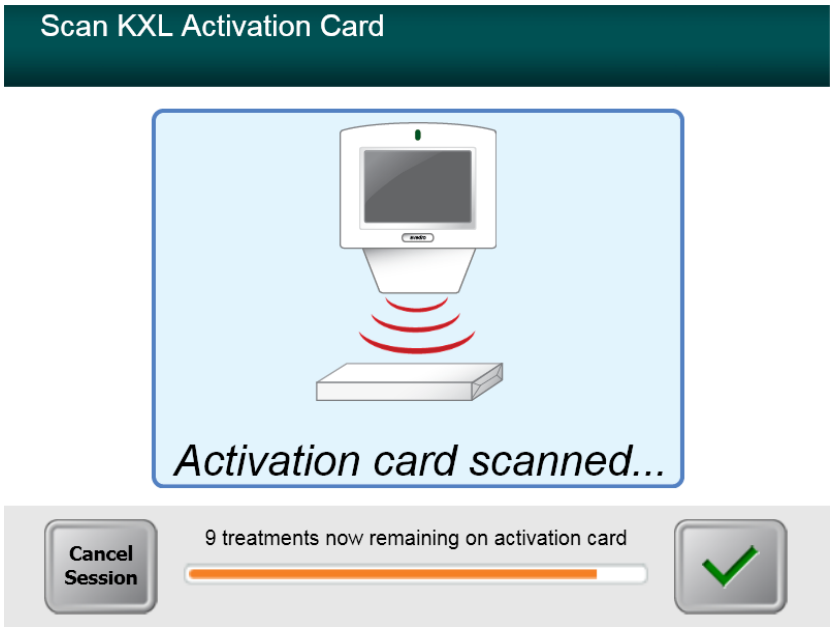


Figure 3-8. Treatments Remaining

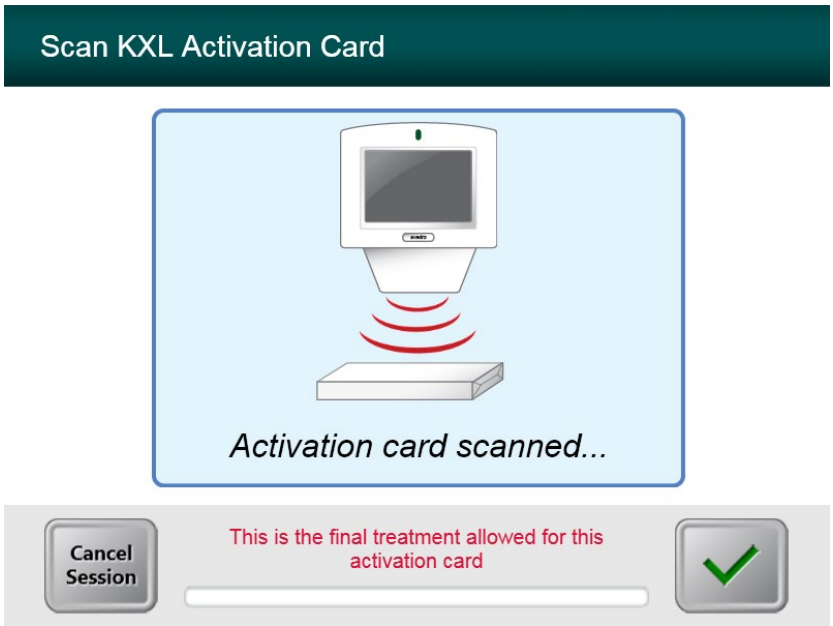


Figure 3-9. Final Treatment

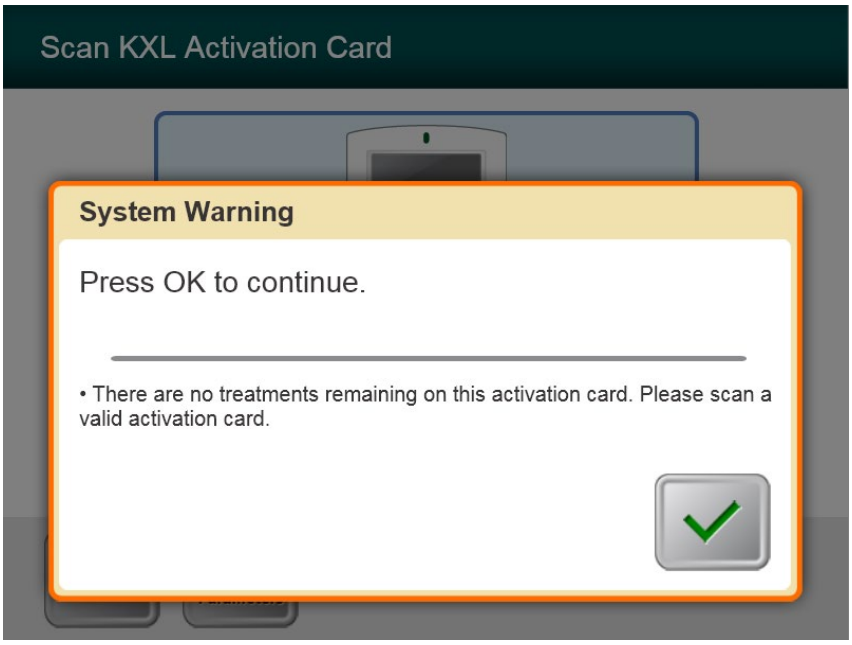


Figure 3-10. No Treatments Remaining

3.9.3 Sync Alignment Remote

- A Sync Alignment Remote window will appear before transitioning to the "Prepare for Treatment" window.
- 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.

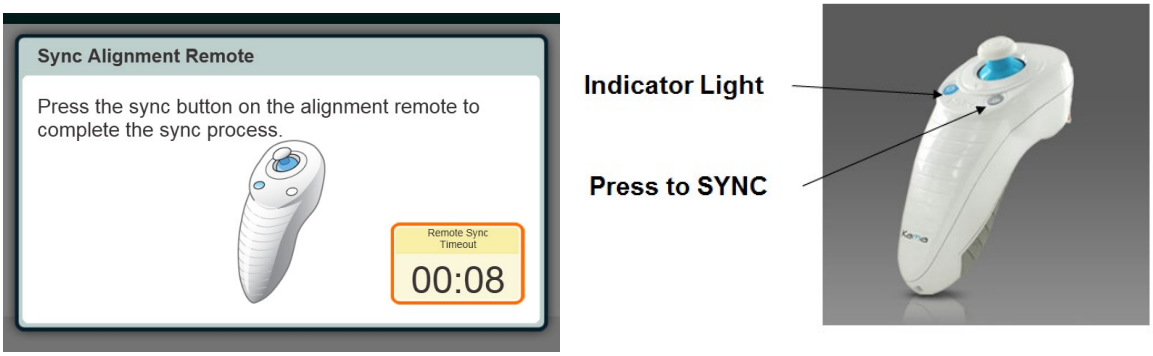


Figure 3-11. Remote Sync Status

Remote Indicator Light Status	Meaning
ON	Actively synchronized with the device
Blinking once per second for 10 seconds	Disconnection sync (after procedure)
Blinking constantly, twice per second	Replace remote batteries immediately (2 AAA)

- If the sync button is not pressed within the allotted 15 seconds or the process is unsuccessful, re-enable the synchronization process by pressing the green checkmark as shown below in Figure 3-12.

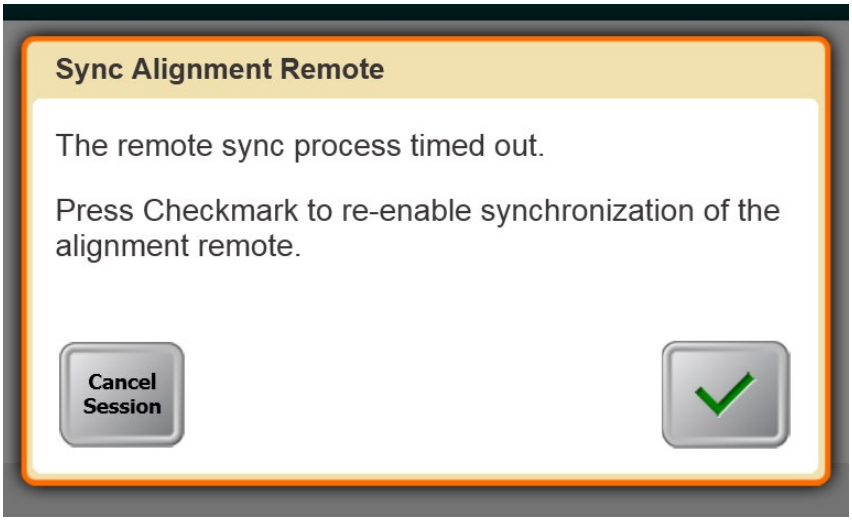


Figure 3-12. Re-enable Remote Sync Process

- If the synchronization process is unsuccessful after a second attempt, the user may opt to continue the treatment without the remote by clicking “Continue Without Remote.”

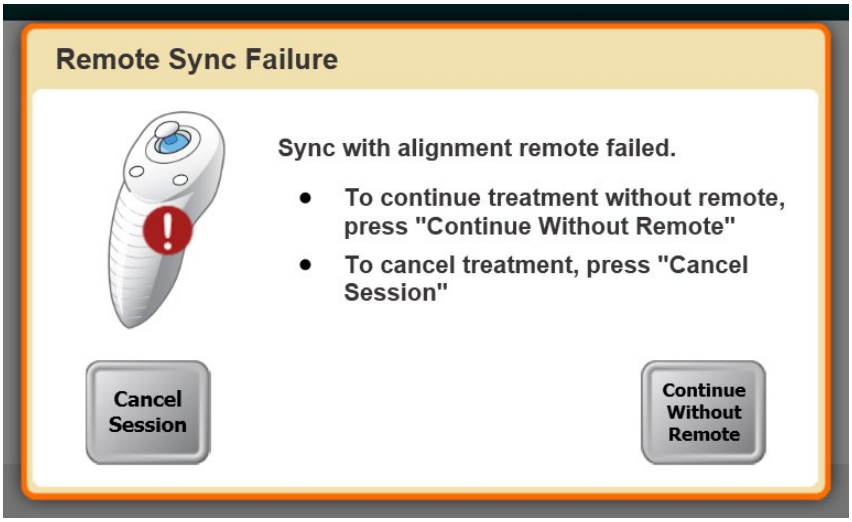


Figure 3-13. Continue Treatment Without Remote

- If the user selects to continue without remote, the touchscreen will indicate "Remote disabled."

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 local Avedro technical service representative.
- Annual preventative maintenance of the KXL System is not required because the System performs an internal self-test prior to each eye being treated.

3.10 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.
- Using topical anesthesia, debride the epithelium to a diameter of approximately 9 mm using standard aseptic technique.

3.11 Administration of Photrexa Viscous

- Post epithelial debridement, instill 1 drop of PHOTREXA VISCOUS topically on the eye every 2 minutes for 30 minutes.
- Once the Photrexa Viscous is applied to the eye, start the induction by pressing either the "Use External Induction Timer" or "Start KXL Induction Timer" button.

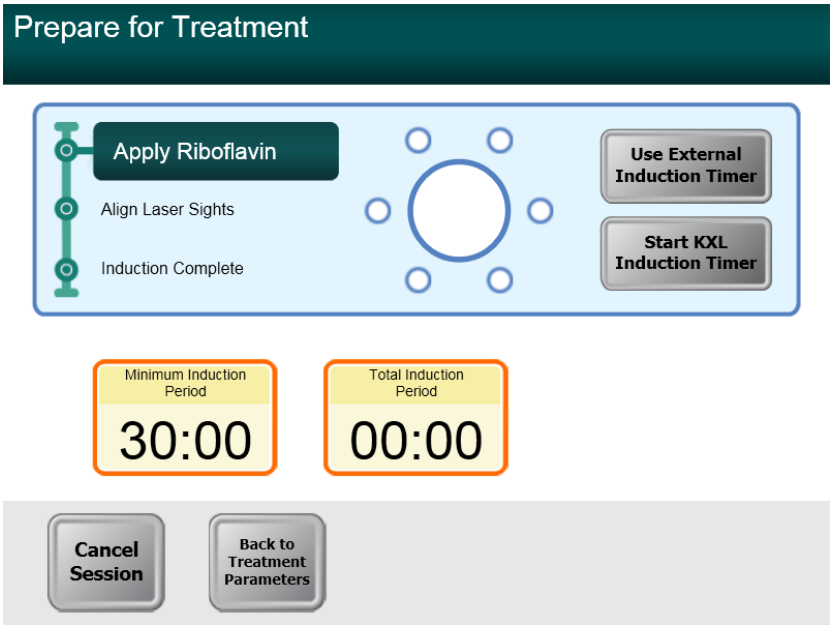


Figure 3-14. Prepare Patient Screen

- If "Use External Induction Timer" is chosen, the internal KXL Induction timer will be disabled and user is responsible for monitoring Induction time using an alternative method. See Figure 3-15.
- If "Start KXL Induction Timer" is chosen, the internal KXL Induction timer will be enabled and the system will show the timer for riboflavin induction.

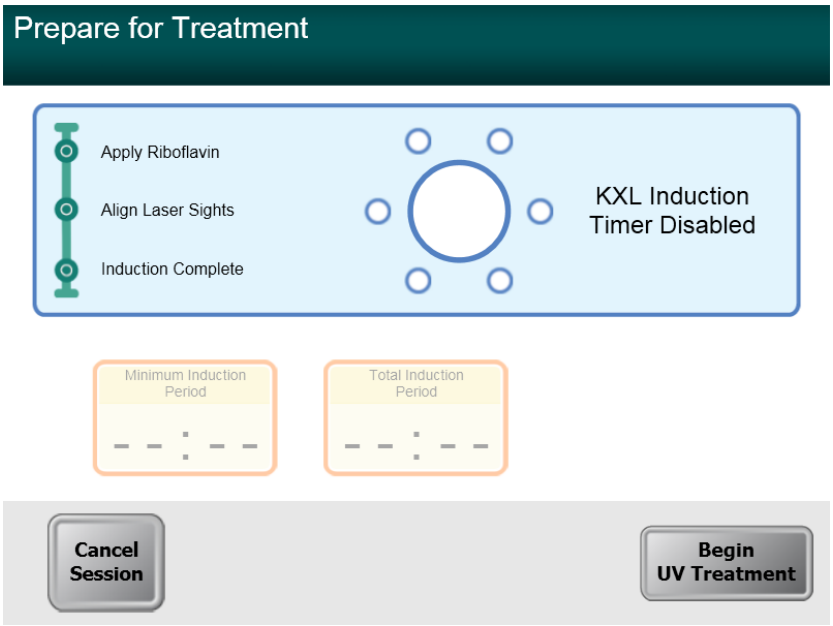


Figure 3-15. Prepare Patient Screen: KXL Timer Disabled

3.12 Confirm Riboflavin Absorption

When the Induction Time is complete the "Begin UV Treatment" button will appear. Prior to initiating treatment:

- Examine the eye under the slit lamp for the presence of a yellow flare in the anterior chamber.
- If the yellow flare is not detected, instill 1 drop of PHOTREXA VISCOUS every 2 minutes for an additional 2 to 3 drops and recheck for the presence of a yellow flare. This process can be repeated as necessary.

3.13 Confirm Corneal Thickness

- Once the yellow flare is observed, perform ultrasound pachymetry.
- If corneal thickness is less than 400 microns, instill 2 drops of PHOTREXA every 5 to 10 seconds until the corneal thickness increases to at least 400 microns.
- If unable to achieve corneal thickness of at least 400 microns, abort procedure.

3.14 Alignment of the Device

- KXL has two alignment lasers.
    - Red crosshair for X and Y axis positioning.
    - A second red crosshair for Z axis positioning.
- Ensure that the alignment lasers are visible prior to performing a treatment.

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 red crosshairs are aligned to the center of the pupil.
- Manually move the Optics head up and down to align the Z axis or second red crosshair to the center of the first red crosshair.
- Fine tune the alignment as needed using the wireless remote.
- The patient should attempt to fixate on the red X & Y alignment crosshair throughout the treatment.

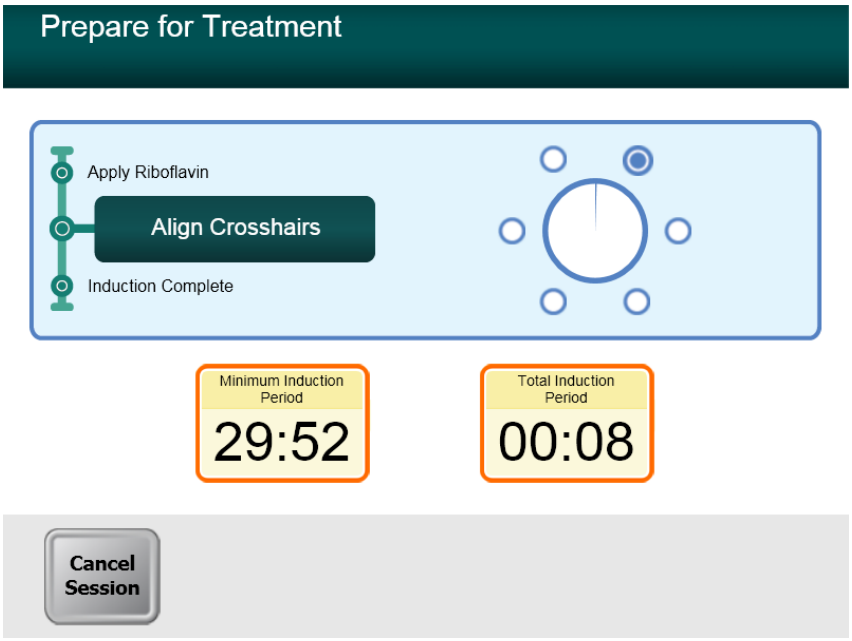


Figure 3-16. Align Crosshairs During Induction

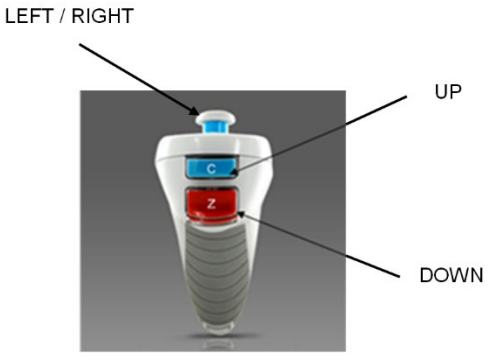


Figure 3-17. Remote Functions

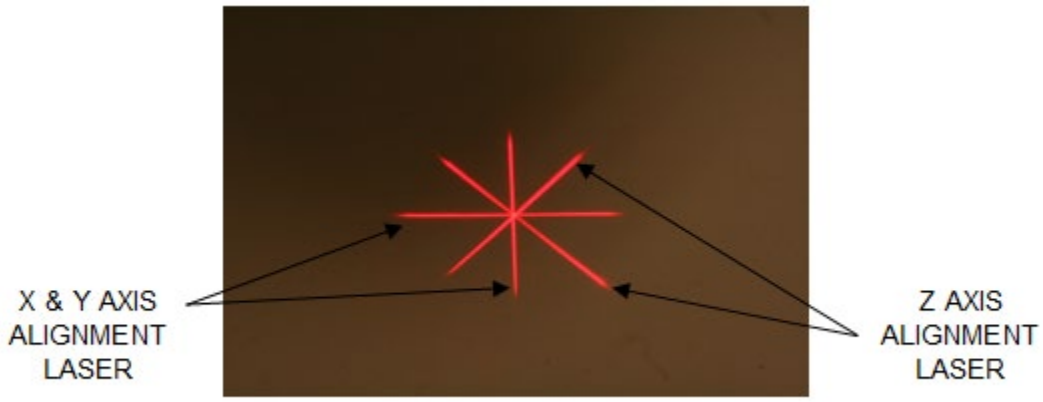


Figure 3-18. Red Crosshairs X & Y Axes, Red Crosshairs Z Axis Alignment

3.15 Initiating Treatment

CAUTION: Irradiation should not be performed unless the 400 micron corneal thickness threshold is met.

- Press the **"Begin UV Treatment"** button to initiate treatment.
- During irradiation, continue topical instillation of PHOTREXA VISCOUS onto the eye every 2 minutes for the 30-minute irradiation period.

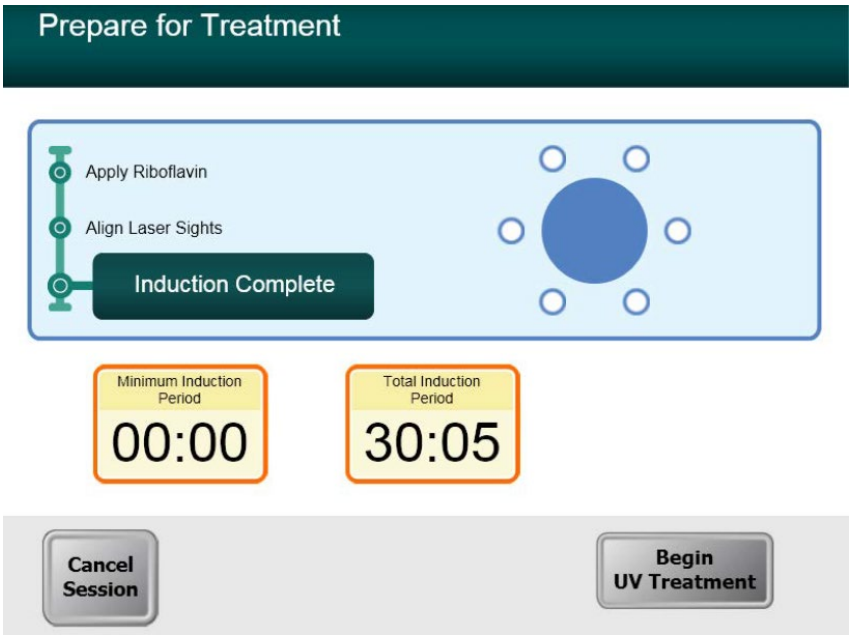


Figure 3-19. Induction Complete

NOTE: The KXL system continuously monitors UVA levels during treatment.

- The internal monitor uses a redundant set of optical sensors to ensure that accurate levels of UVA are delivered throughout the treatment.
- If the UVA levels deviate from the intended values, an error message will be generated, and the treatment cannot proceed. If this occurs, contact your Avedro sales representative or Customer Service immediately.

WARNING: Avoid direct illumination of the limbus.

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

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

3.16 Monitoring Treatment

- Check continuously that the area of debridement on the cornea is illuminated with the UV light and adjust as necessary using the wireless remote.
- If the patient moves during UV treatment and crosshairs cannot be easily returned to alignment, press the "Home Crosshairs" button to restart alignment.

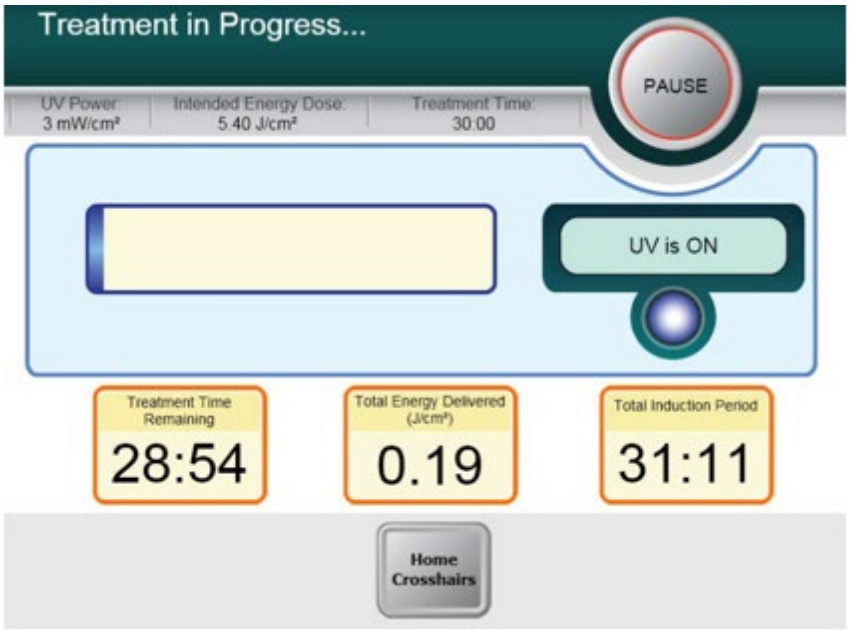


Figure 3-20. Treatment Screen

- The patient should attempt to fixate on the red X & Y alignment crosshair throughout the treatment.
- Patients should remain still during the treatment.
- Every two minutes the status bar illuminates in orange and displays the "Apply Riboflavin" reminder and the system beeps.

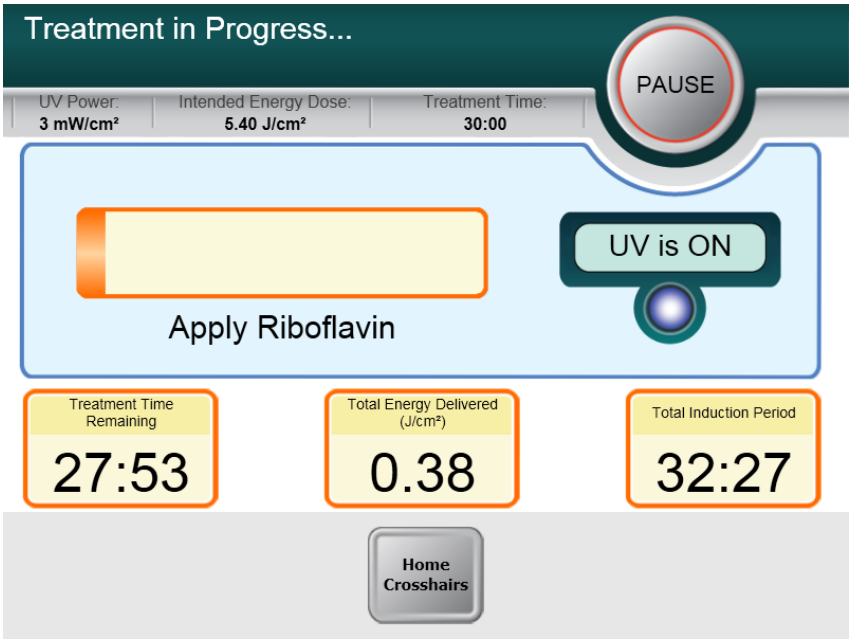


Figure 3-21. Apply Riboflavin Reminder Screen

3.17 Stopping a Treatment

- The treatment stops automatically after the treatment 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.
- If treatment is **Paused,** the system will emit a double beep every few seconds as a reminder

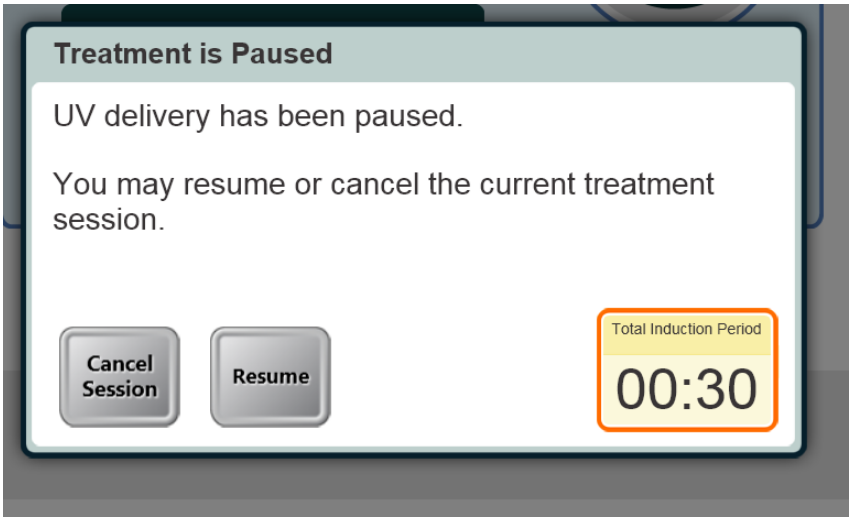


Figure 3-22. Treatment Paused Screen

- To cancel or resume treatment press “Cancel Session” or “Resume” as appropriate. See Section 3.19 if canceling a session.

3.18 Treatment Complete

- At the completion of a treatment the Total Treatment Parameters will be displayed, and the screen will show “Treatment Completed.”

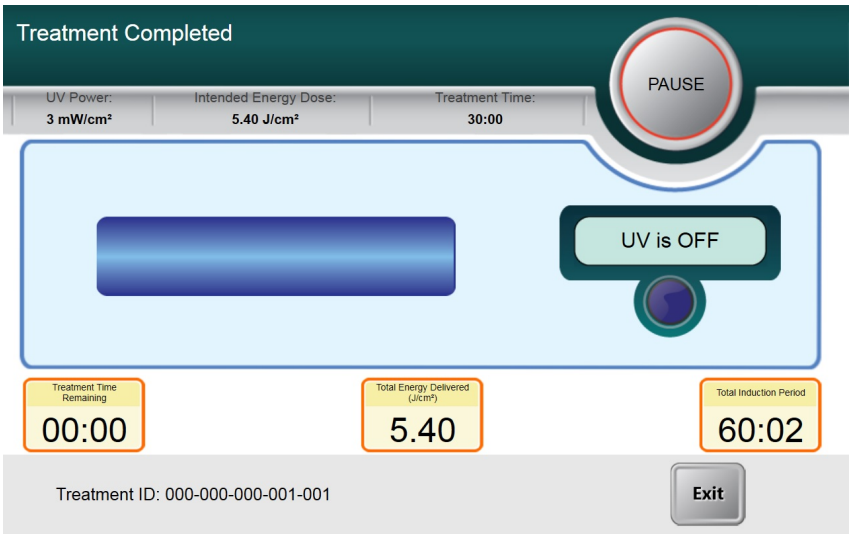


Figure 3-23. Treatment Complete Screen

- Press “Exit” to exit treatment and / or start a new treatment.
- If treatments are complete, Power OFF the system using the “Power Off” button on the Main Screen.
- Carefully remove the device from the patient area.
- Remove speculum.

3.19 Pausing or Canceling a Treatment

Treatment may be paused at the discretion of the physician. If a session is **canceled** the following screen displays with "**Confirm Cancel Session**."

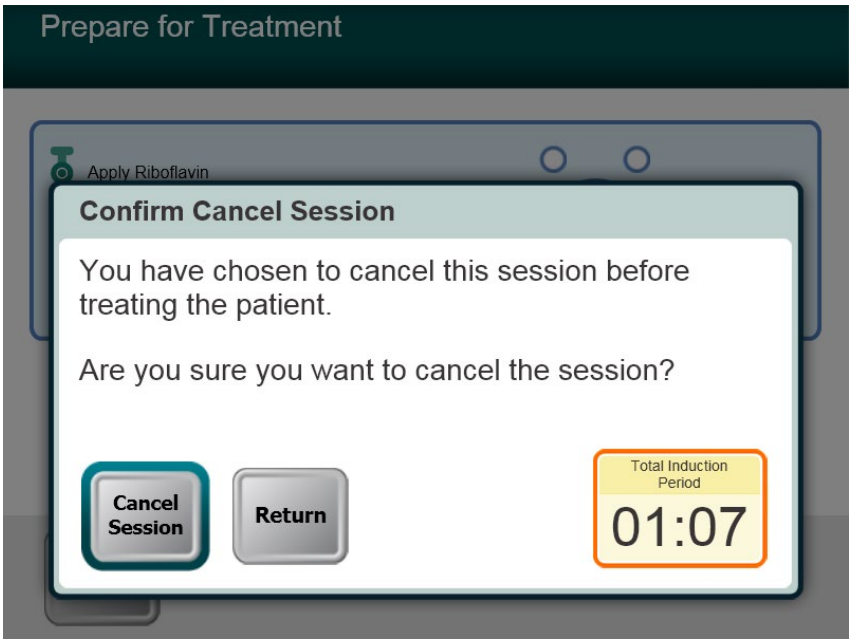


Figure 3-24. Confirm Cancel Session Screen

- To cancel a session, press "**Cancel Session**."
- If the session is **Paused,** the screen displays "**Confirm Cancel Partial Treatment**."

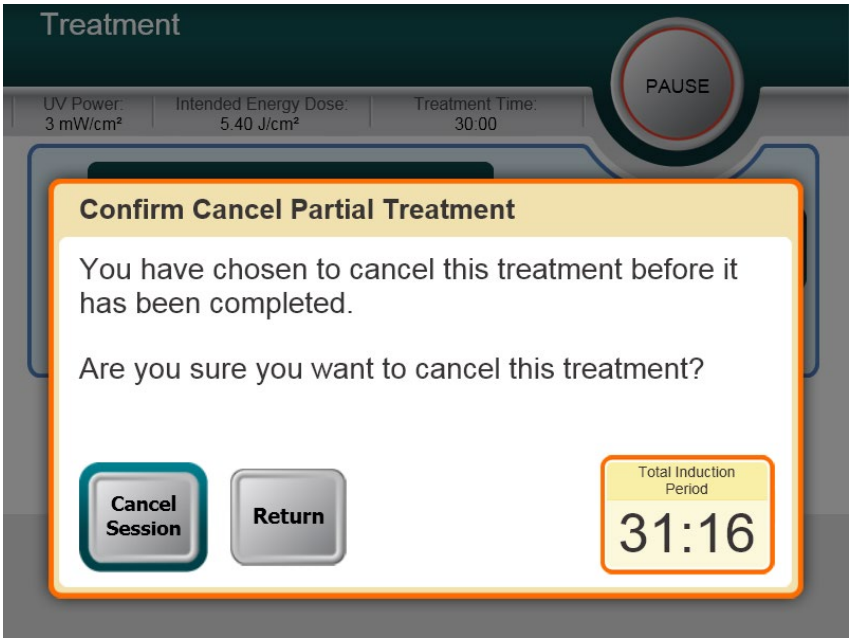


Figure 3-25. Confirm Cancel Partial Treatment

- To cancel the session, press “Cancel Session.”
- The screen displays “Partial Treatment Information.”

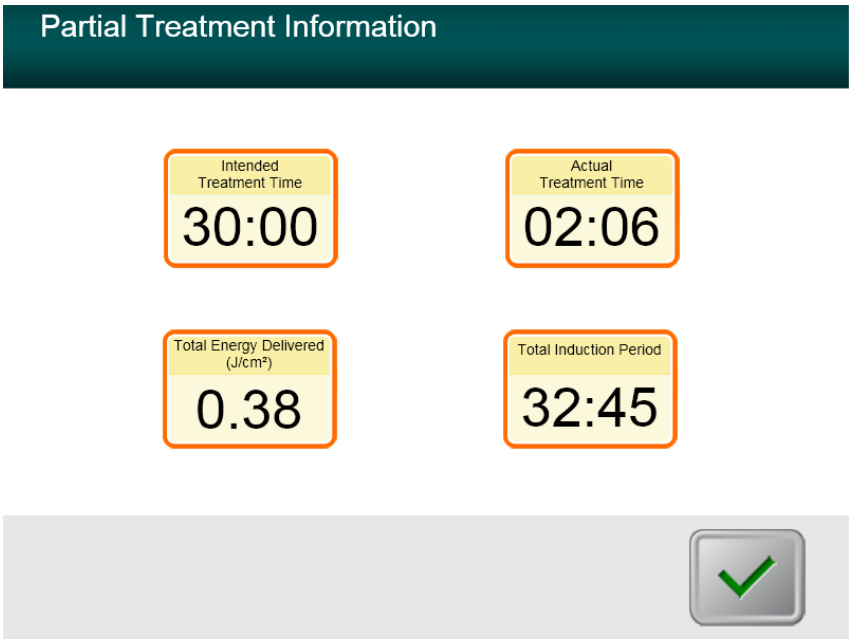


Figure 3-26. Partial Treatment Information

- If External Induction Timer was used, the **“Total Induction Period”** box will be faded out.

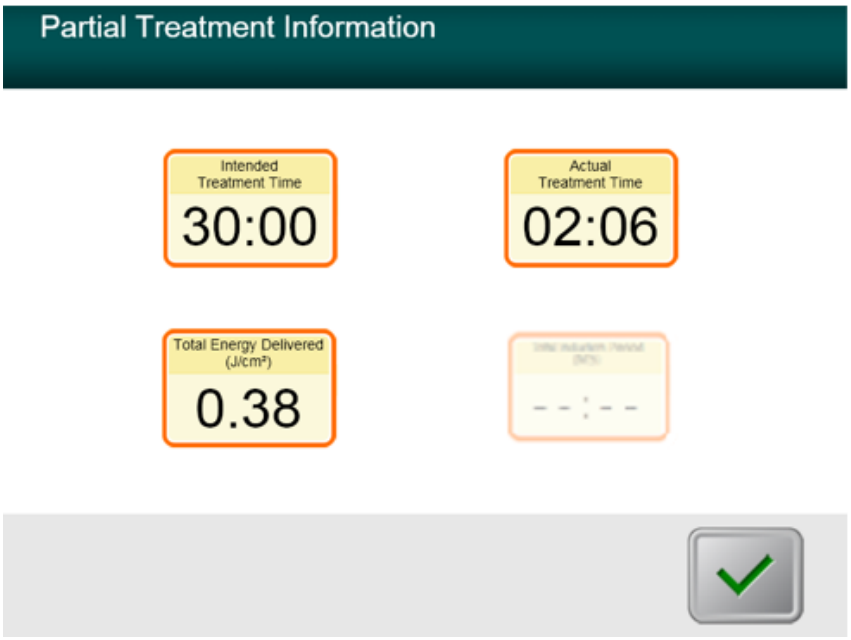


Figure 3-27. Partial Treatment Information – External Timer

3.20 Powering Down the System

NOTE: It is recommended that the KXL System be plugged into an electrical outlet when not in use or when stored.

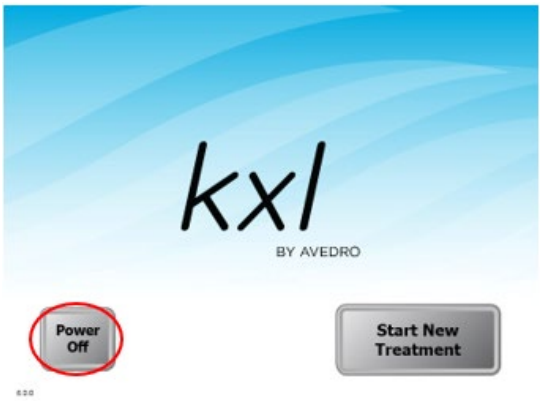


Figure 3-28. Power Off

- Press the "Power Off" on the touch screen monitor.

Figure 3-29. Power Off Position

- Turn the system power switch to the "Off" position.

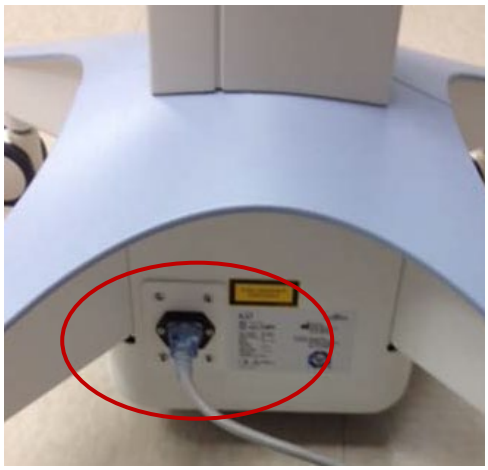


Figure 3-30. KXL System Plug

- If the KXL System is not already plugged in, plug the KXL System into an AC outlet until next use.

3.21 Checking KXL System Battery Function after Storage

If the KXL System has not been plugged into an AC outlet or used for a period of 3 months or more, perform the following diagnostic test to determine the status of the KXL System battery:

- With the System fully powered down, plug the System into an AC outlet for up to 8 hours.
- Within 8 hours of charging, observe the charge indicator LED light on the side of the device main body.
- If the indicator light does not turn green within 8 hours, the battery may be damaged. **Do not use the System to treat patients.** Contact your Avedro Service Representative.

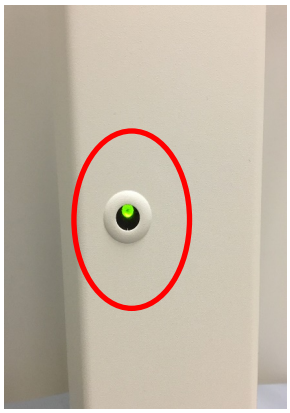


Figure 3-31. KXL System Battery Status Indicator

3.22 Using the Device Settings Menu

- With the Initialization screen (Start New Patient) displayed, press and hold the KXL logo on the touch screen.

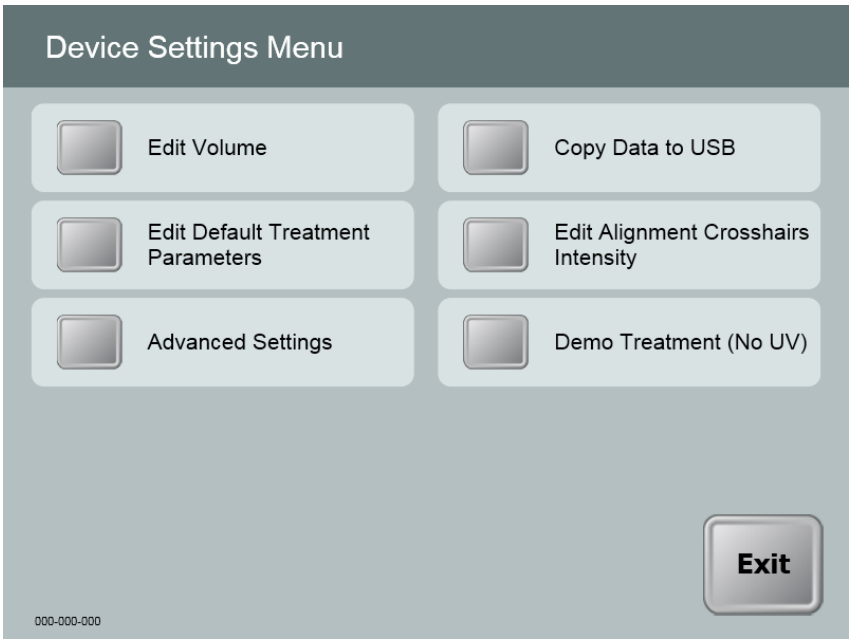


Figure 3-32. Device Settings Menu

3.22.1 Advanced Settings

- Advanced 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 Alignment Crosshairs Intensity

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

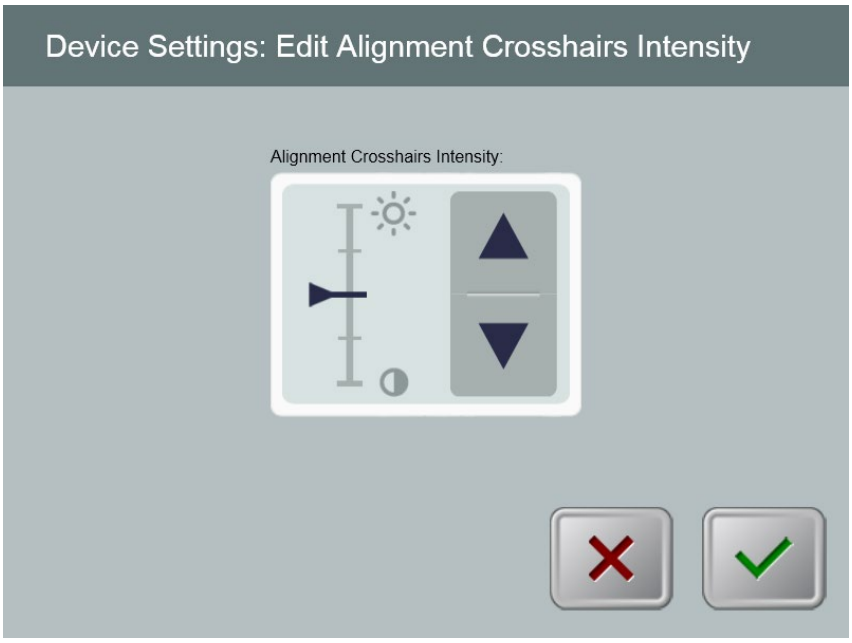


Figure 3-33. Edit Alignment Crosshairs Intensity

3.22.3 Editing System Volume

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

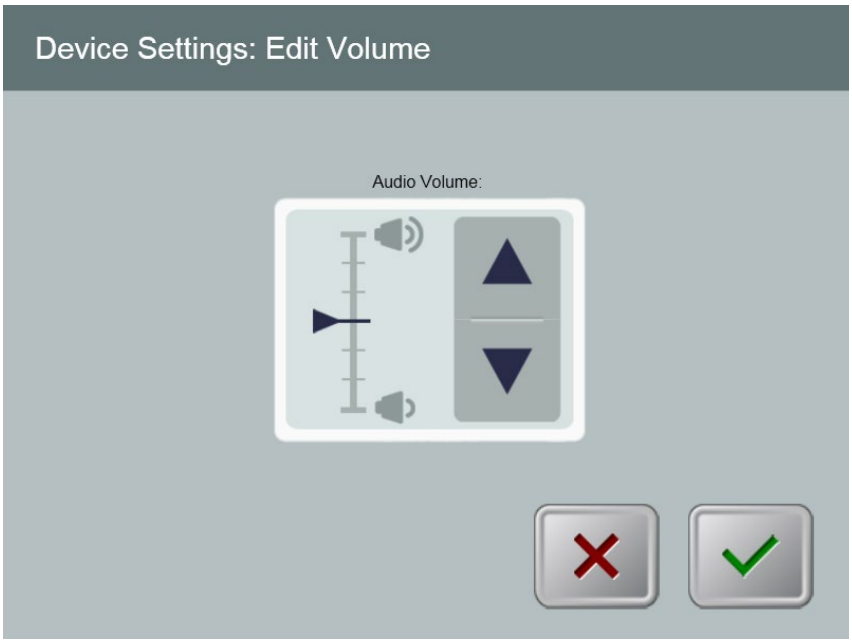


Figure 3-34. Edit Volume

3.22.4 Copying Treatment Data to USB

WARNING: The USB port can only be used when the system is not in treatment mode. Do not have items connected to the USB during treatment.

- Select the Copy Treatment Data to USB button on the Device Settings menu.

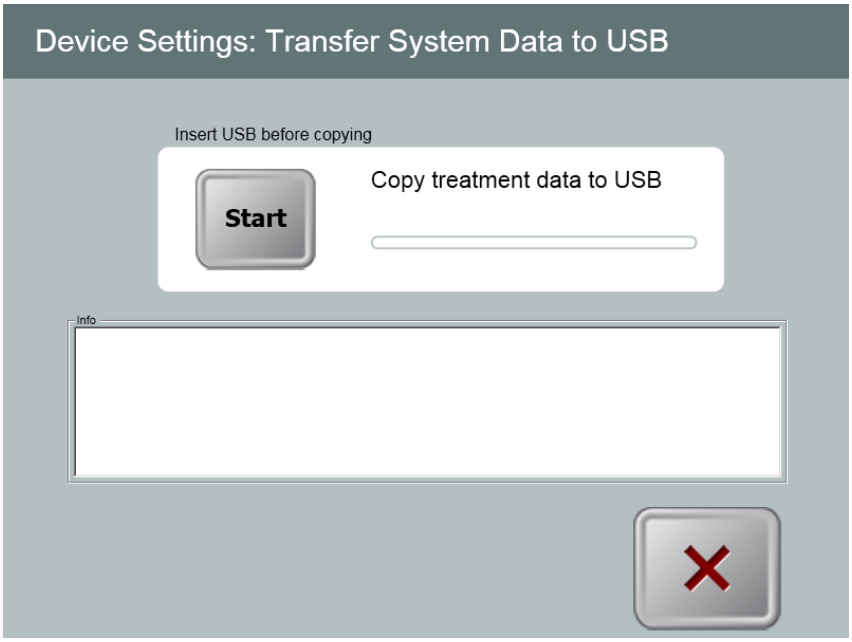


Figure 3-35. Data Transfer to USB

- Insert a USB device to a USB port and then press the Copy treatment data to USB button. The system begins transferring the treatment data and shows a progress bar of the transfer process as shown in the screen below.
- Once complete press the Return button. The System will return you to the Device Settings menu.

3.22.5 Confirming Treatment Settings

- The Device Settings: Treatment Parameters option allows a user to confirm the treatment parameters that are displayed on that System.

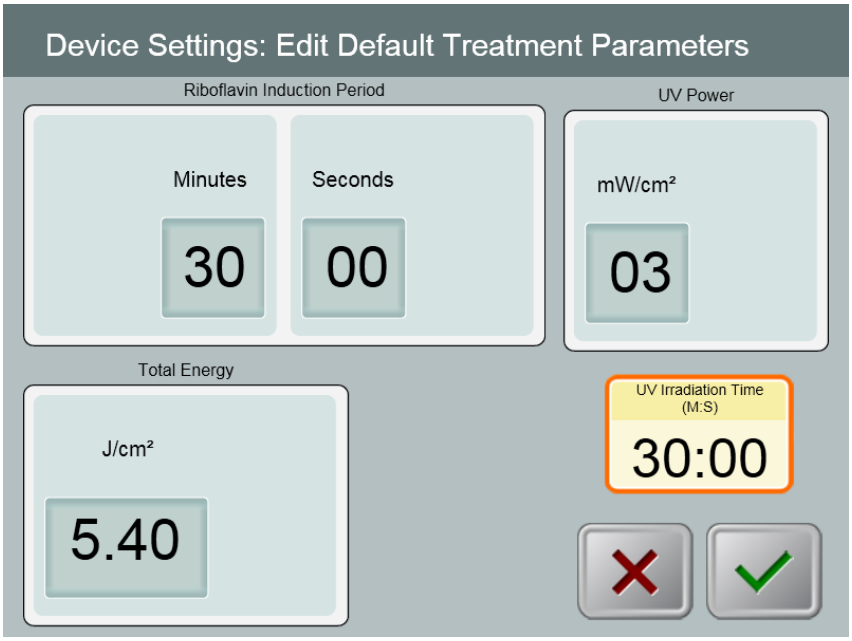


Figure 3-36. Edit Default Treatment Parameters

- When treatment parameters are confirmed, press the Checkmark button to exit these Settings.

3.22.6 Demo Mode

NOTE: Not for use in treating patients

- Demo mode allows users to train on use of the KXL System without requiring treatment cards and without using UV light.
    - Select “Demo Mode”
    - Select “Start” to use the System in Demo Mode
- The KXL System screens will indicate that the System is currently in “Demo Mode” as shown in Figure 3-37 and Figure 3-38.
- To exit “Demo Mode,” select “Exit Demo Mode” from the System main screen.

Figure 3-37. Mainscreen Indicates Demo Mode

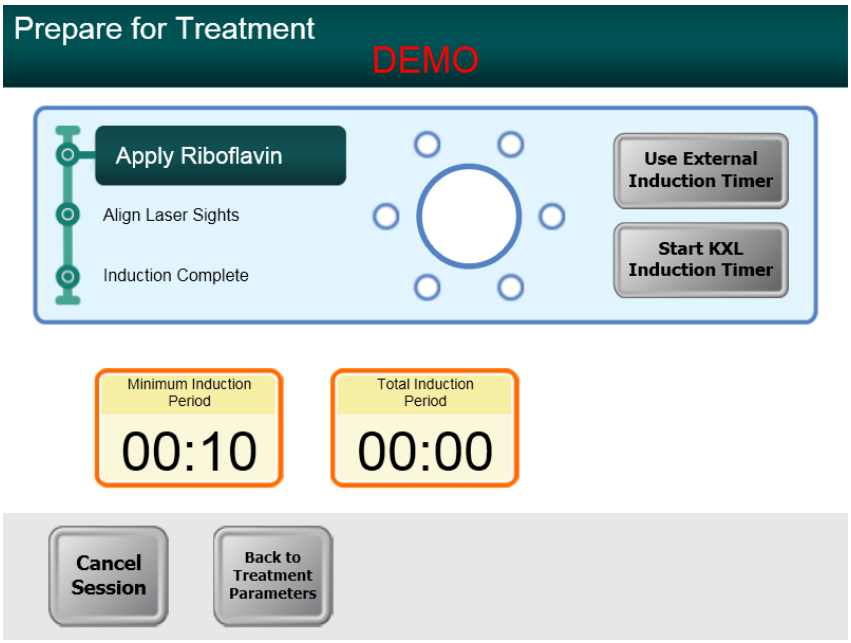


Figure 3-38. Demo Mode is Indicated at Top of Screen

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, a person trained by Avedro can perform a full initial installation and start-up of the System. Following initial installation and once the System is operating properly, the 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 representative.

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 maintenance. It also provides for any non-scheduled service calls that may be necessary.

4.5 Troubleshooting

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

4.5.1 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 re-synchronize. The user will not be able to initiate a procedure.
- 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.

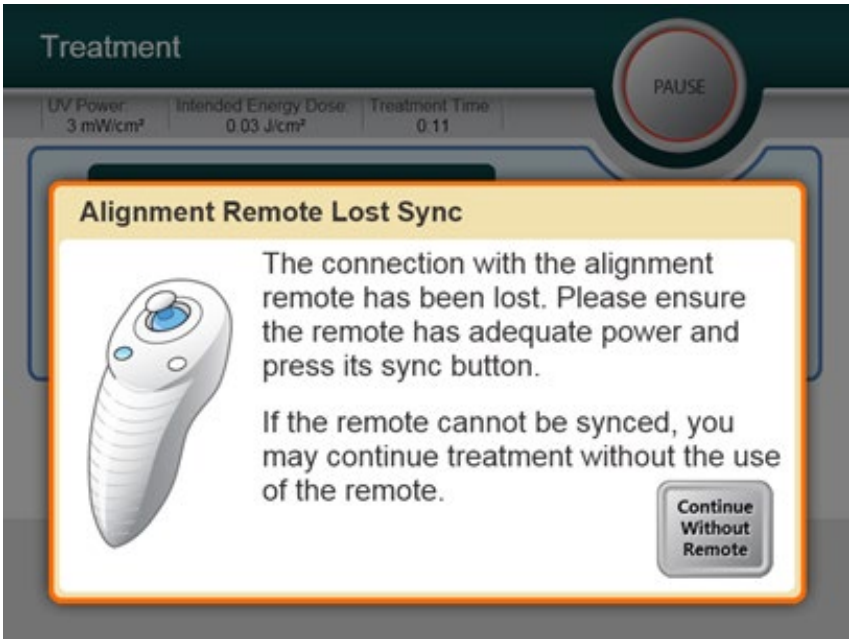


Figure 4-1. Alignment Remote Lost Sync

- 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.

4.5.2 Internal Rechargeable Battery

- The KXL System is supplied with a rechargeable battery. If the System does not appear to be turning on, ensure that the battery is charged by plugging it into an outlet and checking the battery status indicator light on the column of the System.
    - If the indicator is green, and the System still does not turn on, contact your local Avedro service representative.
    - If the indicator is orange, wait until it turns green before turning the System on. If the System still does not turn on or the indicator does not go green within 8 hours, contact your local Avedro service representative.
- If the KXL System has been stored unplugged for a period of 3 or more months, refer to Section 3.21 for recommended diagnostic test procedure.

4.6 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 small amounts of liquid and soft fiber-free wipes.

4.7 Cleaning the System

CAUTION: Remove the power supply cord from the main outlet and turn off the power switch prior to any cleaning procedure.

- Use a soft damp cloth to clean the system.
- The exterior of the KXL System can be cleaned using a lint-free cloth dampened with isopropyl alcohol.
- DO NOT submerge the system in liquid or pour liquid onto the system.
- 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.

4.8 Cleaning the Aperture

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

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

4.9 Articulating Arm Adjustment

If the articulating arm does not hold the Optical Head in a fixed vertical position, follow the steps outlined below to counterbalance the articulating arm.

- Cycle the arm up and down through its full range of motion and set the arm horizontal, i.e. approximately parallel to the floor.

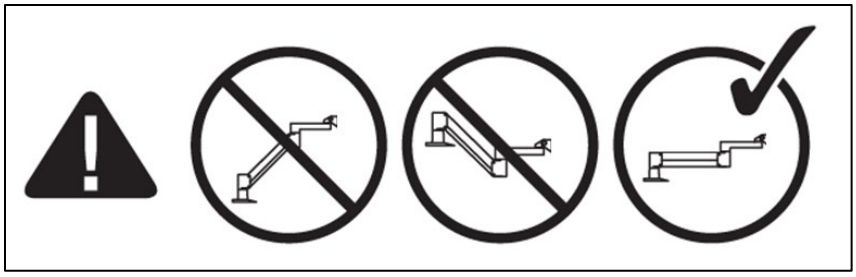


Figure 4-2. Position the Arm Parallel to the Floor

- If the arm drifts downward, lift the arm to the top of its range and loosen Counterbalance Set Screw A by turning the screw at least a ½ turn. Use a 3/32 Allen Wrench. See Figure 4-3.

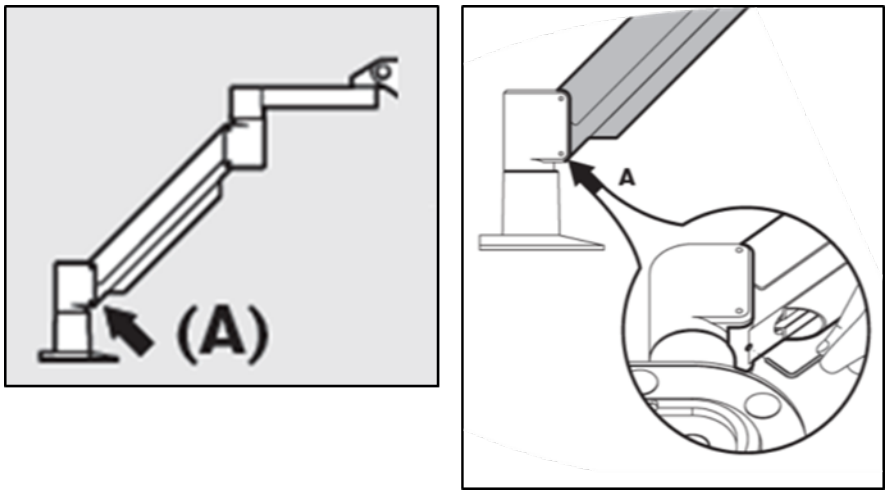


Figure 4-3. Loosen Counterbalance Set Screw A

- Reposition the arm horizontally. Loosen the upper Counterbalance Set Screw B by turning the screw at least a ½ turn. Use a 3/32 Allen Wrench. See Figure 4-4.

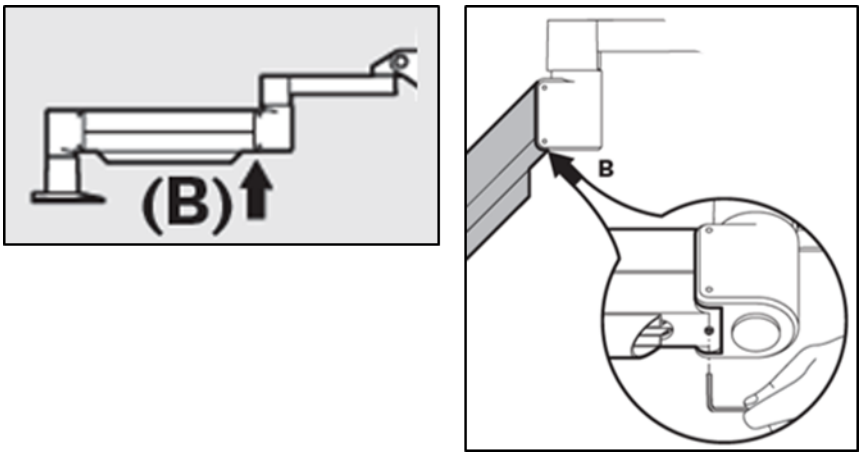


Figure 4-4. Loosen Counterbalance Set Screw B

- Maintain the horizontal arm position by supporting load as needed.
- Set the arm tension with the Strength Adjustment Screw C. Use a 7/32 Allen Wrench and turn the Screw C counter clockwise until the arm just begins to move slowly upward. There should be a slight bounce-back when the arm is lightly tapped down after adjustment. See Figure 4-5.

  NOTE: 15-20 turns may be needed. If the arm continues to droop and the screw cannot be turned further, contact your local Avedro service representative.

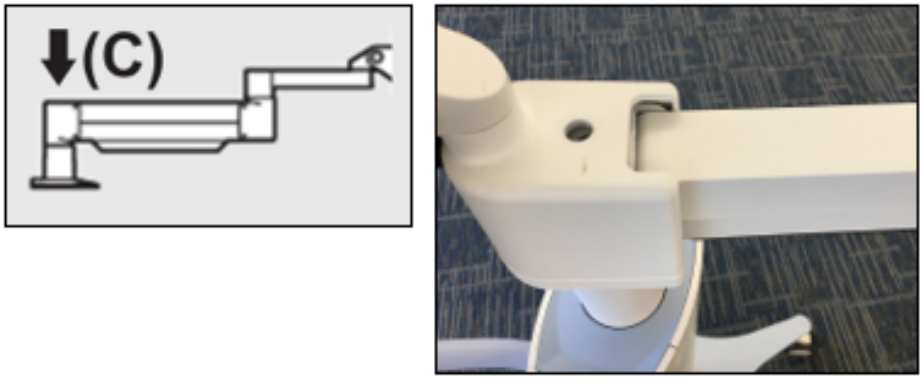


Figure 4-5. Set Arm Tension with Strength Adjustment Screw C

- Turn Strength Adjustment Screw C two full revolutions in the clockwise direction.
- Ensure that the arm is stationary to barely creeping upward.

- Raise the arm to the highest position and tighten Counterbalance Set Screw A until contact is made, then tighten ½ to ¾ max revolutions. See Figure 4-3.
- Position the arm horizontally and tighten Counterbalance Set Screw B until contact is made, then tighten ½ to ¾ revolutions. See Figure 4-4.
- Cycle the arm up and down through its full range of motion. Ensure there is no upward or downward drift.

  NOTE: If the arm drifts upward from any position, return to horizontal and turn Strength Adjustment Screw C clockwise ¼-revolution at a time until it no longer rises on its own.

4.10 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.

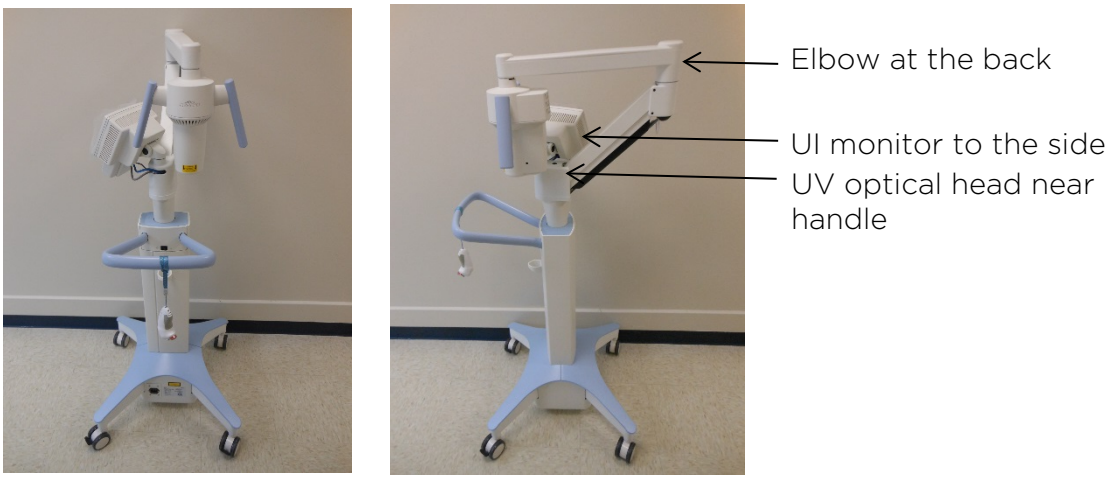


Figure 4-6. Edit Default Treatment Parameters

4.11 Storing the System

- Follow all the storage temperature and humidity range specifications as listed in the Specifications, Section7.
- Close all panels on the system to prevent dust and moisture from entering; this is mandatory.
- Turn OFF all the components and the main power supply as well. It is recommended that the System remain plugged into an electrical outlet if not being used for more than 3 months.
- Remove the batteries from the wireless remote.
- Cover the touch screen LCD display and keyboard with its original cover or packaging to prevent any damage.
- Do not disassemble any part of the system as this could cause misalignment or damage.

4.12 Software

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

4.13 Identifying Risks Associated with Disposing of Waste Products

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

4.14 Performing a Visible Check

- Check all components of the device routinely for damage or malfunction prior to each treatment.
- Do not use a damaged or malfunctioning device. Use of such devices may harm the user and/or patient.

5 Equipment Classification

5.1 Essential Performance

The KXL system delivers to the cornea UV-A radiation of nominally 365 nm wavelength at an irradiance of 3 mW/cm^2 over an exposure period of up to 30 minutes to deliver a total energy density of up to 5.4 J/cm^2.

5.2 Equipment Classification

According to IEC60601-1 Medical Device Electrical Standard

- Protection against electrical shock
    - Class 1 (external electrical power source)
    - Internally powered equipment (internal battery operation)
- 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 anesthetic mixture
    - No protection
- Use conditions
    - Continuous service

According to FCC Part 15, IEC55011 and IEC60601-1-2

- Class B

According to IEC60825-1 Safety of laser productions

- Alignment lasers are Class 1 Laser Product

According to IEC62471 Photobiological safety of lamps and lamp systems

- UVA LED is Risk Group 1

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

- Class IIa

5.3 EMC Guidance

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">The KXL UV Illumination System is intended for use in the electromagnetic environment specified below. The customer or the user of the KXL UV Illumination System should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment — guidance</th></tr>
<tr><td>RF emissions

CISPR 11</td><td>Group 1</td><td>The KXL UV Illumination 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.</td></tr>
<tr><td>RF emissions

CISPR 11</td><td>Class B</td><td rowspan="3">The KXL UV Illumination System is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:

Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the KXL UV Illumination System or shielding the location.</td></tr>
<tr><td>Harmonic emissions

IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions

IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Table 5-1. Electromagnetic Emissions

Guidance and manufacturer's declaration — electromagnetic immunity			
The KXL UV Illumination System is intended for use in the electromagnetic environment specified below. The customer or the user of the KXL UV Illumination 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	±6 kV contact ±8 kV air	±6 kV contact ±8 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	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	0% U_T for 0.5 cycles 40% U_T for 5 cycles 70% U_T for 25/30 cycles 0% U_T for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment, If the user of the KXL UV Illumination System requires continued operation during power mains interruptions, it is recommended that the KXL UV Illumination System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 5-2. Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The KXL UV Illumination System is intended for use in the electromagnetic environment specified below. The customer or the user of the KXL UV Illumination System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the KXL UV Illumination System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 80 MHz to 2.5 GHz
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
			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 meters (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: 
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 UV Illumination System is used exceeds the applicable RF compliance level above, the KXL UV Illumination 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 UV Illumination System. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 5-3. Electromagnetic Immunity (continued)

Recommended separation distances between portable and mobile RF communications equipment and the KXL UV Illumination System			
The KXL UV Illumination System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the KXL UV Illumination System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the KXL UV Illumination 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 $d = 2.3\sqrt{P}$
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.			

Table 5-4. Recommended Separation Distances

5.4 RF Transmitters

5.4.1 RFID Reader

- 13.56MHz Reader/Writer
- Integral Antenna: Maximum 4" Read Range
- US/FCC number SX90RFID1
- Max output power is 200mW
- Meets: ISO18000-3, ISO15693

The highest emissions generated by the above equipment are listed below:

Fundamental	Frequency (MHz)	Level (dB µV/m) at 30 m	Limit (dB µV/m) at 30 m	Limit (µV/m) at 30 m	Margin (dB)
Paragraph 15.225(a)	13.56 (peak)	29.8	84	15,848	-54.2

Other	Frequency (MHz)	Level (dB µV/m)	Limit (dB µV/m)	Margin (dB)
Harmonics	27.12 (peak)	-5.2	29.5	-34.7
Spurious	200.6 (peak)	34.5	40.0	-5.5
Conducted	0.199 (avg)	38.8	54.6	-15.8

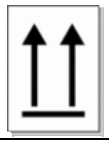
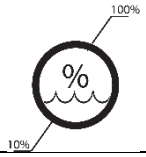
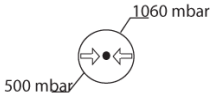
Table 5-5. Highest Emissions

5.4.2 Wireless Remote Control

- FCC ID SXJ87027-TX
- Frequency Range 2405MHz to 2475MHz
- Emissions Compliant with 47 CFR Part 15

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. Power Switch		ON
6. Power Switch		OFF
7. Fuse symbol		Fuse
8. Manufacturer		Name and address of the manufacturer
9. ! in a Triangle		Caution specific warning in operators manual
10. Net Weight (kgs) Gross Weight (kgs)	NW GW	Weight
11. Umbrella with raindrops		Keep Dry: Store protected from moisture (symbol is with or without rain drops)
12. Wine glass with crack on it	 or	Contents are fragile, handle with care

Text Symbol	Symbol Illustration	Definition
13. Two up arrows		Keep arrows on carton pointing up
14. Water drop in a box		Humidity limits (percentages below symbol are the acceptable range for humidity)
15. Temperature limits		Temperature shipment limits
16. MR crossed in a circle		MR Unsafe – Keep away from magnetic resonance imaging (MRI) equipment
17. Signal emitted		This device includes RF transmitters
18. Pressure limits		Atmospheric pressure limits (storage / operating)

7 Specifications

Specification	Description
Electrical	Battery Powered: 12V 35 Ah SLA Line voltages 100 – 240 volts AC Current: 2A – 1A Single Phase RMS, 50/60 Hz Remote 2x AAA batteries
User accessible Fuses	250 V~ T2AH
Energy Delivery	UV Radiation 3 mW/cm^2 ±10% 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^3 (Length x Width x Height)
Weight (crated system)	NW 45 Kg GW 120 Kg
System Battery Life (normal operating conditions)	16 hours
Remote Battery Life (normal operating conditions)	18 hours
Environmental Operating Conditions	The system operates under the following atmospheric conditions (no condensation).
Ambient temperature	+10 to +40 ºC
Relative humidity	30% to 75%, non-condensing
Atmospheric pressure	700 to 1060 mbar
Transport and Storage Conditions	The instrument withstands the following transport and storage conditions without damage or performance deterioration.
Ambient temperature	-15 to +70 ºC
Relative humidity	10% to 100% non-condensing
Atmospheric pressure	500 to 1060 mbar