Avedro, Inc.
KXL System

Operator's Manual

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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

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 crosslinking procedures.

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

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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.
- Prior corneal surgery
- Corneal melting disorders
- Aphakic patients
- Pseudophakic patients without UV blocking lens implanted

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

1.6.3 Electrical Safety Warnings

For Equipment Classifications please refer to chapter 6.0 Equipment Classifications

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

1.7 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.

1.8 Additional Safety Considerations

- UV irradiance of the KXL System is calibrated by the manufacturer and must be checked annually. 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.

1.9 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 crosslinking. 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 is preset by the manufacturer to emit UVA radiation at a wavelength of 365 nm at an intensity of 3 to 30 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 times are selectable by the user from 1 minute to 30 minutes in 1 second increments; power/time combinations that would result in a surface exposure of more than 5.4 J/cm^2 or more are prohibited by the software.

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 (induction period, UV exposure time, UV intensity, and beam diameter) are selected through the user interface touch screen computer.

The KXL System is used in conjunction with a disposable kit containing the Roboflavin, which has an RFID on it and is available from you local Avedro representative.

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)
- **KXL Accelerated Crosslinking Treatment Ki**t (disposable supplied separately)
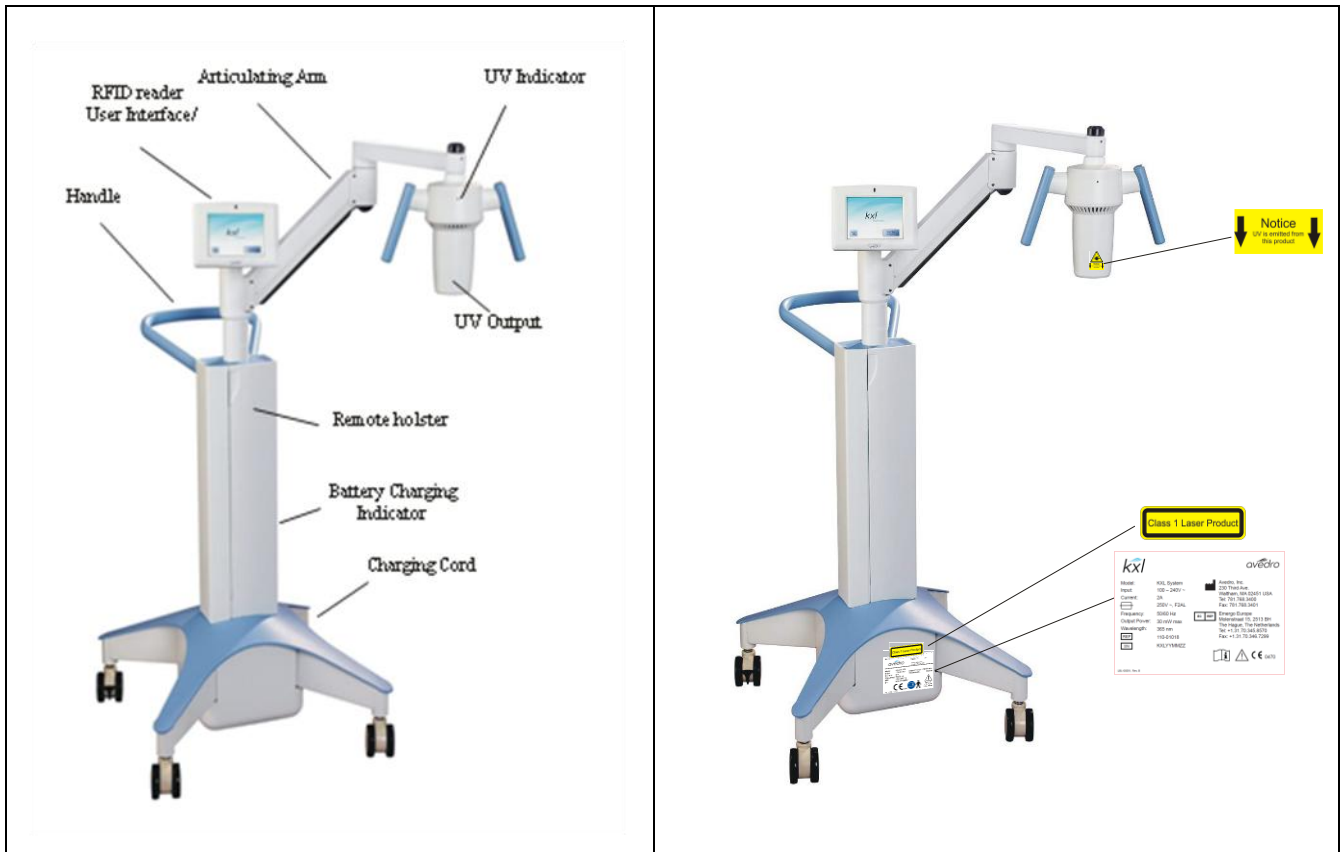

Figure 2.1: Overview Illustration of System

Figure 2-1. System Illustrations with Callouts

Figure 2-2. Wireless Remote
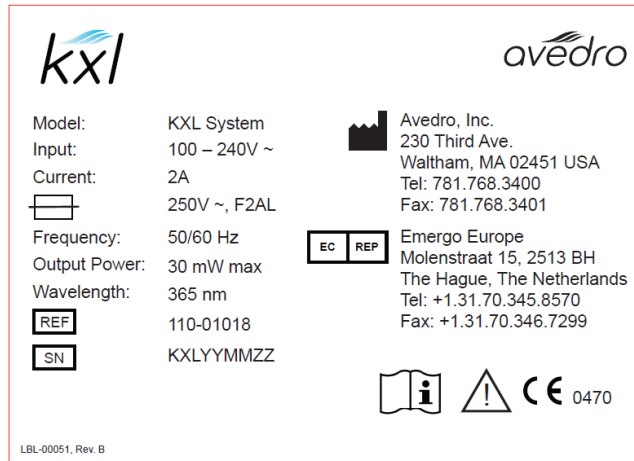
Figure 2-3: KXL Label

Figure 2-4: UV emitting Label

Figure 2-5: Laser Classification Label

3 Treatment Guidelines

3.1 Keratoconus / Post Lasik Ectasia

Avedro recommends the following KXL settings:

- Riboflavin Induction Period: 8 minutes

- UV Power: 30 mW/cm^2

- UV Treatment Time: 3 minutes

3.2 LASIK Xtra

Avedro recommends the following KXL settings:

- Riboflavin Induction Period: 1 minutes

- UV Power: 30 mW/cm^2

- UV Treatment Time: 3 minutes

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4 System Operation

4.1 Charging the KXL Battery

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

- If using the internal rechargeable battery, at the end of each business day or when not in use, the KXL should be connected to grounded supply mains to allow charging of the battery pack

- The change of the battery is identified by a light located on the column of the KXL, the following describes the battery charge.

  - o Orange – low, charging
  - o Yellow – charging
  - o Green – fully charged
    NOTE: if the battery does not appear to be holding a charge or charging please contact your local Avedro Service Representative.

  NOTE: the battery pack on the system should last for 16 hours during normal operation. The software system will notify the user when the battery needs to be charged. The KXL is designed to prohibit treatment if there is not sufficient battery power to perform a treatment. (See chapter 5.0 Maintenance for more information on troubleshooting battery problems)

4.2 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)	Power Off	Turns OFF electric power to the personal computer.
Start New Treatment button (Initial screen)	Start New Treatment	Directs the system to repeat the entire clinical treatment protocol so the physician can treat another 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 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)	Cancel Session	Cancels a treatment session for a particular patient. A prompt is then displayed to confirm your decision.
Return to Treatment button (Confirm Cancel Session screen)	Return to Treatment	Cancels the Cancel Session command and returns to the Treatment screen.
Return button (various Device Settings screen)	Return	Returns to the Device Settings menu.

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

4.3 UV Dose

- The UV irradiance dose is the product of the intensity of the irradiance and the exposure time. Both intensity of the irradiance and the exposure time are adjustable and displayed.

- The system tracks treatment time, intensity of irradiance and total dose during treatment.

  NOTE - The system's parameters are:

  Induction Period: 1 – 30 minutes
  Irradiance: 3 - 30 mW/cm^2
  Exposure Time: 1 - 30 minutes

  The maximum dose is 5.4 J/cm^2

  Riboflavin Formulation

  Riboflavin: 0.1 %
  Dextran T500   20.0%
  in isotonic NaCl-solution (pH 7.0)

4.4 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.

- Check glass window of beam aperture for dust and dirt. See sections 5.8 and 5.9 for cleaning instructions.

4.5 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:

  o   Inspect the device, accessories, and connecting cables for visible damage.

  o   Take local regulations for use of portable electro-optical medical devices into consideration.

4.6 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.

- The KXL System begins a power-up sequence, loading the operating system and all configuration and reference files.
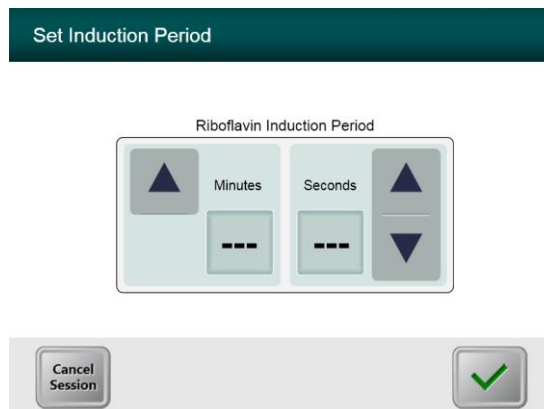
Figure 4-1. Startup Screen

- Press the **Power Off** button to turn the system off. If there is a Start-up error, please note any error messages and contact your distributor or Customer Service immediately.

4.7 Setting Treatment Settings

- To begin patient treatment, press the Start New Treatment button.

Figure 4-2. Induction Period Screen

- Specify the desired induction period (1 – 30 min) for the patient.

- When finished entering parameters, press the Checkmark button.

Figure 4-3 Enter Treatment Parameters Screen

- Specify the desired treatment parameters, in turn, for the patient as follows:

  o UV Treatment Time (1 – 30 minutes)

  o UV Power (3 – 30 mW/cm^2)

  NOTE: Total Energy will be displayed in the lower orange box. The maximum permissible Total Energy is than 5.4 J.
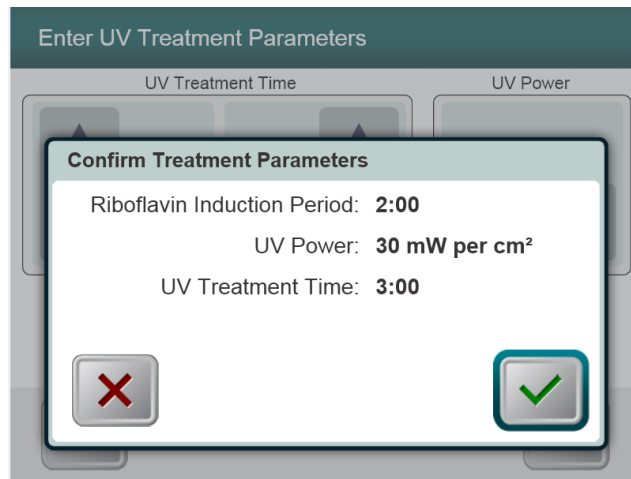


Figure 4-4 Populated Treatment Parameters Screen

- When finished entering treatment parameters, press the **Checkmark** button.

Figure 4-5 Confirm Treatment Parameters Screenn

- Confirm the specified treatment parameters by pressing the Checkmark; if the treatment parameters are not correct press the X and then re-enter the desired treatment parameters.

4.8 Starting Treatment
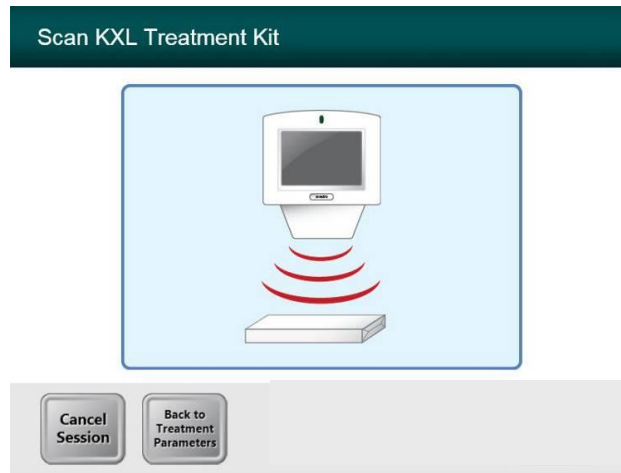
Figure 4-6 Scan Disposables Scree

- Scan the disposable kit (which is unique for each patient) on the RFID reader.
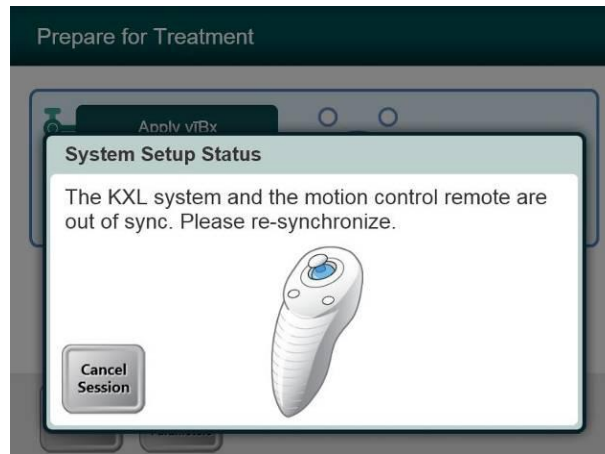
Figure 4-7 System Setup Status

- Press the "S" button on the remote to synchronize the remote. This is required for every procedure.

     NOTE: 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. (see chapter 5 Maintenance section of this manual for additional information)

4.9 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 head rest.

- Adjust the table or chair and head rest 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.

- *Keratoconus and post-LASIK ectasia*: remove corneal epithelium using standard clinical technique.

  - Rinse single-use UV shield with hard contact lens solution and apply UV shield with opening centered over the treatment area. UV Shield can be placed on the eye prior to Riboflavin application or after induction period based on standard clinical technique. (See UV Shield DFU for specific instructions on use.)

  - Place the UV Shield, centered on the cornea, covering the peripheral cornea and sclera.

  - Apply Riboflavin to the area of treatment.

  - Start the induction by pressing the "Riboflavin Applied: Start Timer" button.

  - The induction timer begins to count and the alignment lasers illuminate.

- *LASIK Xtra* is intended to be performed after the Excimer portion of the LASIK procedure is complete and with the corneal flap still removed.

  - Rinse single-use UV shield with hard contact lens solution.

  - Apply Riboflavin onto the corneal bed and then to the underside of the corneal flap. Replace corneal flap using standard clinical technique.

  - Place the UV Shield, centered on the cornea, covering the peripheral cornea and sclera. (See UV Shield DFU for specific instructions on use.)

  - Start the induction by pressing the "Riboflavin Applied: Start Timer" button.
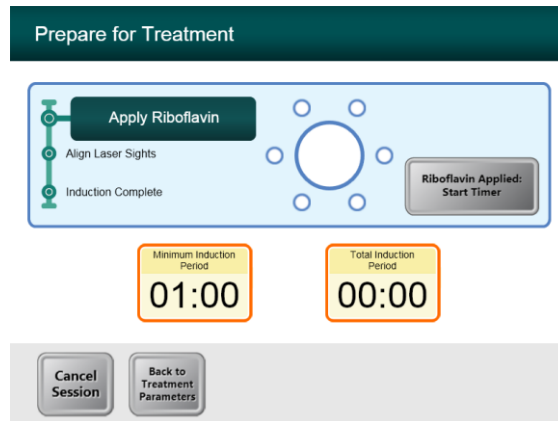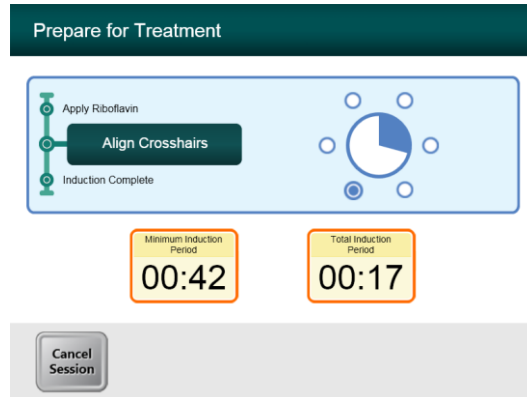
Figure 4-8 Prepare Patient Screen

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

Figure 4-9 Align Crosshairs during induction

- Move the Optics head until the red crosshairs are aligned to the center of the target area, then adjust the treatment head up and down to align the green dot to the center of the cross. Fine tune the alignment as needed using the wireless remote

4.10   Initiating Treatment

When the Induction Time is complete the "Begin UV Treatment" button will appear. Press the "**Begin UV Treatment**" button to initiate treatment.
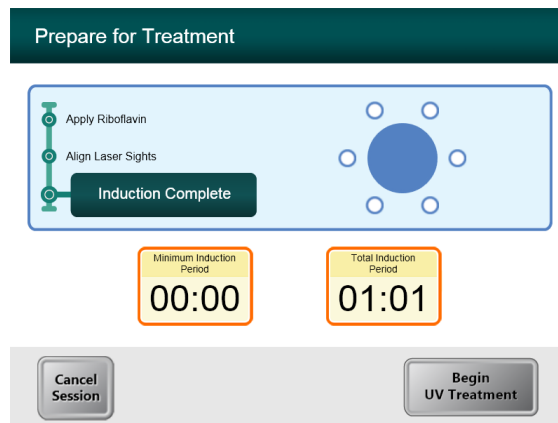
Figure 4-10 Induction Complete

WARNING: Start treatments only after the photosensitizer is applied.

CAUTION: UV light is emitted as long as the blue indication light is ON.

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

Figure 4-11 Treatment Screen

4.11 Monitoring Treatment

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

- The patient has to fixate on the center of the light beam aperture throughout the treatment.

- Patients should remain still during the treatment.

4.12 Stopping 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.
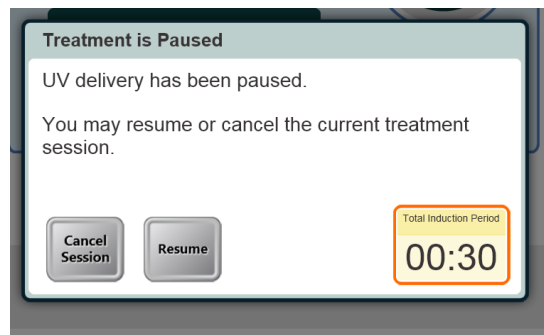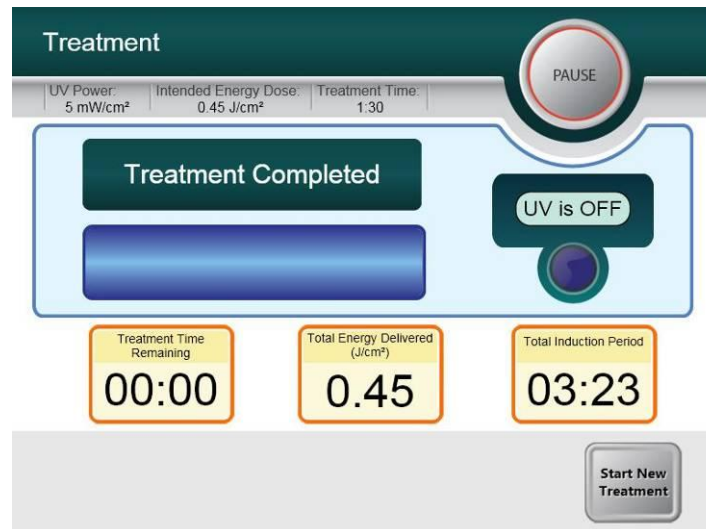

Figure 4-12. Treatment Paused Screen

- To cancel or resume treatment press appropriately. See section 4.13 if canceling a session.

4.13 Treatment Complete

- At the completion of a treatment the Total Treatment Parameters will be displayed and the screen will show Treatment complete. Press **Start New Treatment** to initiate next treatment.

Figure 4-13. Treatment Complete Screen

- To exit treatment and / or start a new treatment press **Start 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.

- Apply antibiotic ointment on the cornea and then cover cornea with a bandage contact lens

- Remove speculum

- Give post-op medication using a regimen similar to after photorefractive keratectomy(PRK): pain medication, steroids, antibiotics.

4.14 Pausing or Canceling a Treatment

If session is **Canceled** screen displays with **Confirm Cancel Session**.
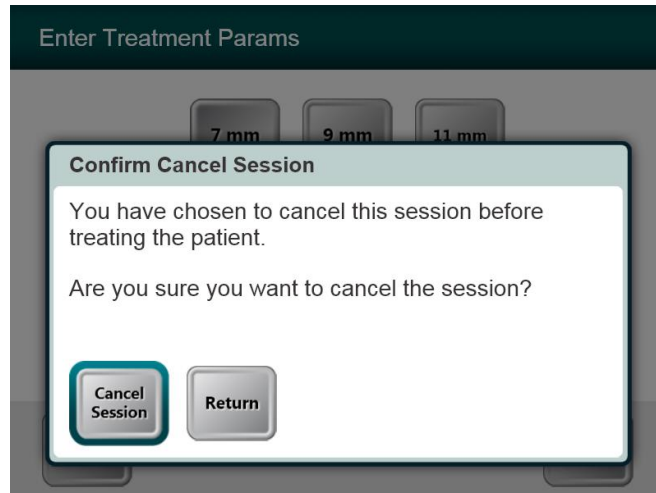
Figure 4-14. Initial Confirm Cancel Session Screen

- To cancel session press **Cancel Session**.

- If the session is **Paused** the screen displays **Confirm Cancel Partial Treatment**.
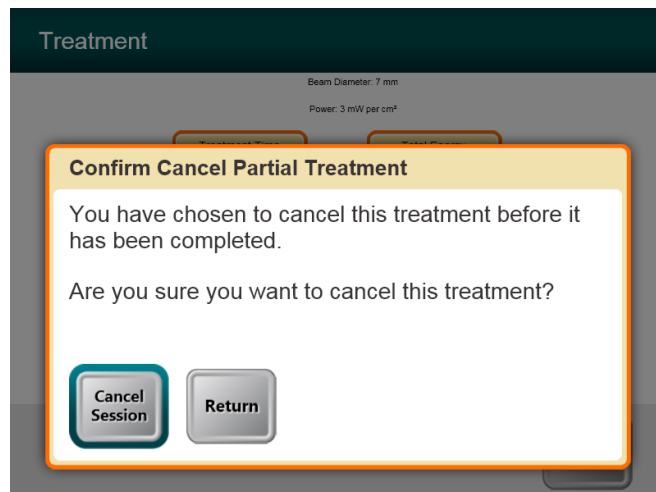
Figure 4-15. Confirm Cancel Partial Treatment

1. To cancel session press **Cancel Session**.

The screen displays **Partial Treatment Information**

Figure 4-16. Partial Treatment Information

4.15   Using the Device Settings Menu

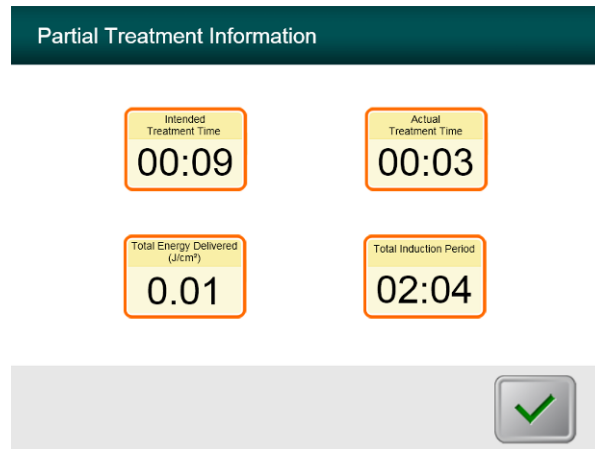* With the Initialization screen (New Patient Start) displayed, press and hold the KXL on the touch screen.

Figure 4-17. Device Settings Menu

4.15.1   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.
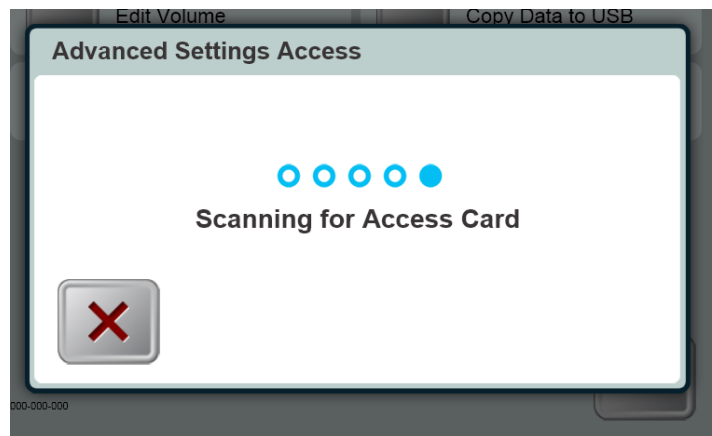
Figure 4-18 Advanced Setting Access

4.15.2   Country Code
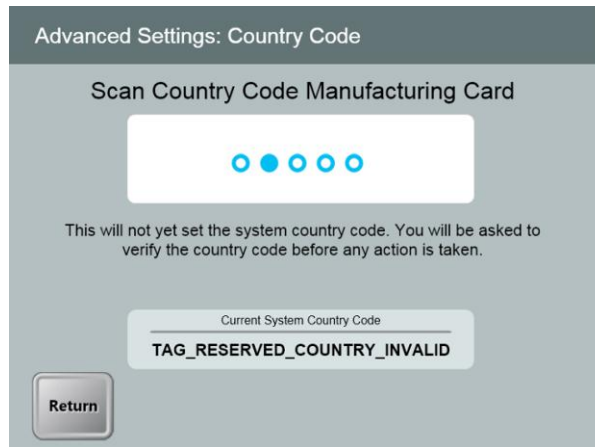
Figure 4-19 Advanced Settings: Country Code

- Country Code selection is only available prior to initial setup and is configured by service personnel.

4.15.3   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 4-20. Device Settings Edit Volume

4.15.4 Copying Treatment Data to USB

- The Copy Treatment Data to USB option is for Service use only.

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.

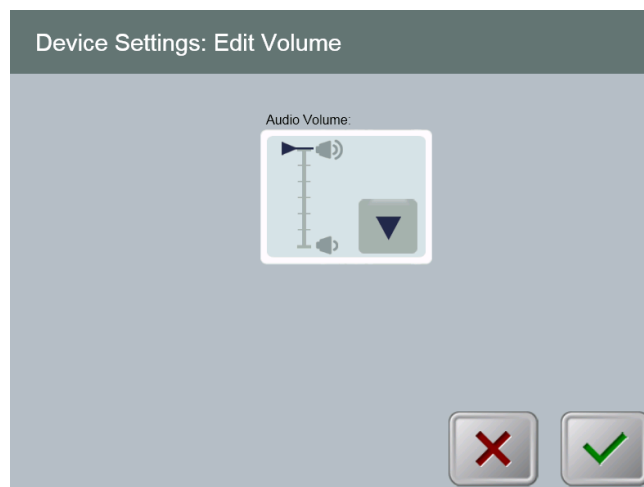*NOTE:* The current patient's treatment data are cleared from the screen at the end of the treatment sequence and the data are no longer available on the system. They are NOT stored in the system's permanent storage.

- Select the **Copy Treatment Data to USB** button on the Device Settings menu.
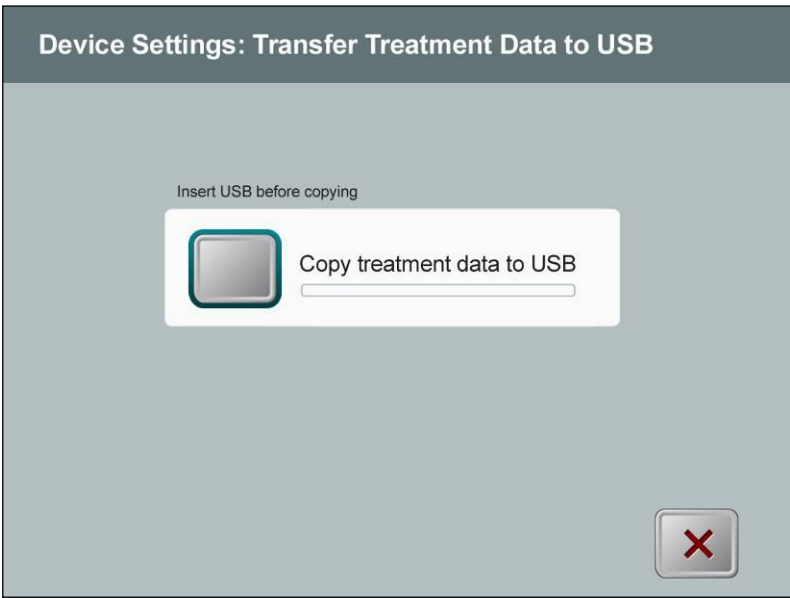
Figure 4-21. Device Settings Transfer to USB

- 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.

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5 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.

5.1 Installation Policy

- For each new KXL System customer, your Avedro-authorized distributor provides 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 distributor.

5.2 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.

5.3 Warranty Information

- A Warranty is supplied separately with the purchasing information.

5.4 Service Contract Information

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

## 5.5 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.

5.6 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 when the system is in the normal operating state.

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 not allow the user 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.
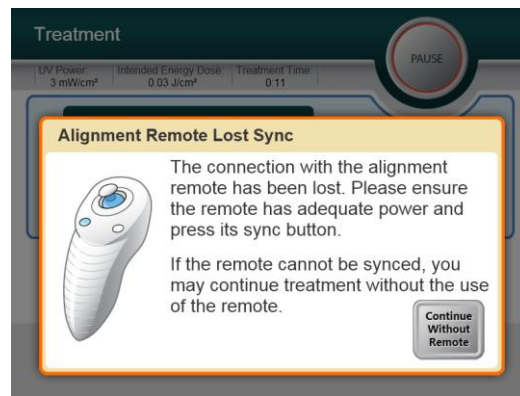
Figure 5-1 Remote Lost Sync

   o 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

   o If the remote does not re-synchronize by pressing the "Sync" button, replace the batteries.

   o If replacing the batteries does not allow the system to synchronize contact your local Avedro Service Representative.

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 charging indicator on the column of the system. If the light is orange or yellow the system is charging, if it is green it is fully charged.

   o If the indicator is green or yellow and the system still does not turn on contact your local Avedro service representative.

o   If the indicator is orange wait until it turns yellow or green and try turning the system on, if it still does not turn on or the indicator does go yellow or green within 8 hours contact your local Avedro service representative.

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

5.8 Cleaning the System

* 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 dilute bleach, soapy water, or isopropyl alcohol.

* A 70% alcohol or 10% chlorine bleach solution can also be used if necessary.

* DO NOT submerse the system in liquid or pour liquid onto the system.

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

CAUTION: Aggressive cleaning agents, especially those containing abrasives or aggressive solvents can damage component surfaces.

* The glass window of the beam aperture must not under any circumstances be in contact with any of the aforementioned substances.

* While cleaning the surfaces of the device, ensure that cleaning fluids do not seep inside the device, as this leakage can damage the device.

5.9 Cleaning the Aperture

* 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.

5.10   Articulating Arm Adjustment

If the articulating arm does not hold the Optical Head in a fix vertical position contact your local Avedro service representative.

5.11 Performing Periodic Maintenance

Interval	Specific Task
Annual	Calibration by Avedro trained personnel.

5.12 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.

5.13 Storing the System

- Follow all the storage temperature and humidity range specifications as listed in the Specifications chapter 8.0.

- 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. Disconnect the power cord physically from its electrical outlet.

- 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.

5.14 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.

5.15 Identifying Risks Associated with Disposing of Waste Products

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

5.16 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.

6 Equipment Classification

According to EN60601-1 Medical Device Electrical Standard

- o Protection against electrical shock

    - ▪ Class 1 (external electrical power source)

    - ▪ Internally powered equipment (internal battery operation)

- o Degree of protection against electric shock

    - ▪ Not classified, equipment not provided with applied part

- o Degree of protection against ingress of water

    - ▪ Common Devices IP20 (No protection against ingress of water)

- o Method of sterilization or disinfection

    - ▪ Disinfect able device

- o Degree of protection for use in the presence of a flammable as aesthetic mixture

    - ▪ No protection

- o Use conditions

    - ▪ Continuous service

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

- o Class B

According to EN60825-1 Safety of laser productions

- o Alignment lasers are Class 1 Laser Product (<0.39 microwatts)

According to EN62471 Photobiological safety of lamps and lamp systems

- o UVA LED is Risk Group 1

According to Annex II.3 of Directive 93/42/EEC as amended by 2007/47/EC

- o Class IIa

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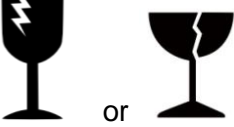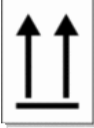
Text Symbol	Symbol Illustration	Definition
1. No AP symbol in presence of flammable anesthetics		Danger, Risk of Explosion. Not for use.
2. AC symbol		Alternating current
3. "I" in a book		Attention: Consult ACCOMPANYING DOCUMENTS
4. Ground symbol in circle		Protected earth (ground)
5. Power Switch	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

Text Symbol	Symbol Illustration	Definition
13. Wine glass with crack on it	or	Contents are fragile, handle with care.
14. Two up arrows		Keep arrows on carton pointing up
15. Water drop in a box	10-100%	Humidity limits (percentages below symbol are the acceptable range for humidity)
16. Temperature limits	70 C -15 C	Temperature shipment limits.

8 Specifications

Specification	Description
Software Version	System 1.0
Electrical	Battery Powered: 12V 35 Ah SLA
	Line voltages 100-240 volts AC, ± 10%
	Current 2A
	Single Phase
	RMS, 50/60 Hz, ± 5%
	Remote 2x AAA batteries
User accessible Fuses	250 V~ F2AL
Energy Delivery	UV Radiation
	3-30 mW/cm^2
	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
Battery Life (normal operating conditions)	16 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%
Atmospheric pressure	900 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% including condensation
Atmospheric pressure	500 to 1060 mbar