

# **Avedro, Inc. KXL System**

---

## **Operator's Manual**

ML-00002

Revision A

Copyright 2010

All Rights Reserved

Printed in U.S.A.

## **Patents, Trademarks, Copyrights**

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

“KXL” and the Avedro logo design are registered trademarks or trademarks of Avedro, Inc. All software and documentation is subject to Avedro, Inc. copyrights. All rights reserved 2010.

Microsoft and Windows are registered trademarks and trademarks, respectively, of Microsoft Corporation.

Any other trademarks or service marks contained within this manual are the property of their respective owners.

### **For more information, contact:**

Your Local Avedro-authorized distributor



Avedro, Inc.  
230 Third Avenue  
Waltham, MA 02451

Authorized Representative

EMERGO EUROPE  
Molenstraat 15  
2513 BH, The Hague  
The Netherlands  
Phone: +31.70.345.8570  
Fax: +31.70.346.7299



# Table of Contents

<b>Chapter: 1</b>	<b>Foreword.....</b>	<b>1-1</b>
1.1	Intended Use of Manual.....	1-1
1.2	Intended Use .....	1-1
1.3	Design Change Disclaimer .....	1-1
1.4	Reproduction Disclaimer .....	1-1
1.5	User Operation Assistance Statement.....	1-1
1.6	Contraindications, Warnings and Cautions.....	1-2
1.6.1	Contraindications .....	1-2
1.6.2	Warnings .....	1-2
1.6.3	Electrical Safety Warnings.....	1-2
1.6.4	Grounding.....	1-3
1.6.5	Safety Instructions.....	1-3
1.7	Eye Protection.....	1-4
1.8	Patient Safety .....	1-4
1.9	Use Restrictions .....	1-5
1.10	Safety Design.....	1-5
1.11	Additional Safety Considerations .....	1-6
1.12	FCC Compliance Notice.....	1-6
1.13	Use in Presence of Flammable Mixtures .....	1-7
<b>Chapter: 2</b>	<b>Introduction.....</b>	<b>2-1</b>
2.1	System Overview.....	2-1
2.1.1	Major Components.....	2-2
<b>Chapter: 3</b>	<b>Procedure Guidelines.....</b>	<b>3-1</b>
3.1	UV Dose.....	3-1
3.2	Preparing the System .....	3-1
3.3	Select the Induction Period.....	3-1
3.4	Select the UV Treatment Parameters.....	3-2
3.5	Select and Prepare Accessories.....	3-2
3.6	Preparing the Patient.....	3-2
3.7	Starting Treatment .....	3-2
3.8	Alignment of Light Source .....	3-3
3.9	Monitoring Treatment.....	3-3
3.10	Stopping a Treatment.....	3-4
3.11	Resuming a Treatment.....	3-4
3.12	Canceling Treatment.....	3-4
3.13	Treatment Complete.....	3-4
<b>Chapter: 4</b>	<b>Treatment Guidelines.....</b>	<b>4-5</b>
4.1	Keratoconus / Post Lasik Ectasia.....	4-5

4.2	LASIK Xtra.....	4-5
<b>Chapter:</b>	<b>5            Operation.....</b>	<b>5-1</b>
5.1	Charging the KXL Battery.....	5-1
5.2	Software User Interface: Touchpad/Keyboard Use .....	5-1
5.3	Important Steps before Turning on the System .....	5-2
5.4	Software User Interface: Powering Up the System .....	5-3
5.5	Software User Interface: Setting Treatment Settings.....	5-4
5.6	Software User Interface: Starting Treatment.....	5-7
5.7	Software User Interface: Canceling a Treatment.....	5-12
5.8	Software User Interface: Using the Device Settings Menu .....	5-14
	5.8.1 Advanced Settings.....	5-14
	5.8.2 Country Code .....	5-15
	5.8.3 Editing System Volume .....	5-15
	5.8.4 Copying Treatment Data to USB .....	5-16
<b>Chapter:</b>	<b>6            Maintenance.....</b>	<b>6-1</b>
6.1	Customer Maintenance .....	6-1
6.2	Service and Diagnostic Requirements .....	6-1
6.3	Directions for Sterilization or Disinfection.....	6-1
6.4	Cleaning the System .....	6-1
6.5	Cleaning the Aperture.....	6-2
6.6	Performing Periodic Maintenance .....	6-2
6.7	Moving the System .....	6-2
6.8	Storing the System .....	6-2
6.9	Updating Software .....	6-2
6.10	Identifying Risks Associated with Disposing of Waste Products.....	6-2
6.11	Performing a Visible Check.....	6-3
<b>Chapter:</b>	<b>7            Customer Service Information .....</b>	<b>7-1</b>
7.1	Before Calling your local Avedro Representative for Help.....	7-1
7.2	Installation Policy .....	7-1
7.3	Warranty Information .....	7-1
7.4	Service Contract Information.....	7-1
7.5	Per Patient Disposables.....	7-1
<b>Chapter:</b>	<b>8            Symbol Library .....</b>	<b>8-1</b>
<b>Chapter:</b>	<b>9            Specifications.....</b>	<b>9-1</b>

# List of Figures

Figure 2-1. Overview Illustration of System .....	2-2
Figure 2-2. System Illustrations with Callouts .....	2-3
Figure 2-3. Wireless Remote .....	2-3
Figure 2-4: KXL Label.....	2-4
Figure 2-5: UV emitting Label.....	2-4
Figure 2-6: Laser Classification Label .....	2-4
Figure 5-1 Startup Test Screen.....	5-3
Figure 5-2. Welcome Screen .....	5-4
Figure 5-3. Induction Period Screen.....	5-4
Figure 5-4 Enter Treatment Parameters Screen.....	5-5
Figure 5-5 Populated Treatment Parameters Screen .....	5-5
Figure 5-6 Select UV Beam Diameter Screen.....	5-6
Figure 5-7 Confirm Treatment Parameters Screen.....	5-7
Figure 5-8 Scan Disposables Screen .....	5-7
Figure 5-9 System Setup Status.....	5-8
Figure 5-10 Prepare Patient Screen .....	5-8
Figure 5-11 .....	5-9
Figure 5-12 Induction Complete .....	5-9
Figure 5-13 Treatment Screen .....	5-10
Figure 5-14. Treatment Paused Screen.....	5-10
Figure 5-15. Treatment Complete Screen .....	5-11
Figure 5-16. Initial Confirm Cancel Session Screen .....	5-12
Figure 5-17. Confirm Cancel Partial Treatment.....	5-12
Figure 5-18. Partial Treatment Information .....	5-13
Figure 5-19. Device Settings Menu.....	5-14
Figure 5-20 Advanced Setting Access .....	5-14
Figure 5-21 Advanced Settings: Country Code.....	5-15
Figure 5-22. Device Settings Edit Volume.....	5-15
Figure 5-23. Device Settings Transfer to USB.....	5-16

This page is left blank intentionally.

# 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

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 permission or without permission.

## 1.4 Reproduction Disclaimer

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

## 1.5 User Operation Assistance Statement

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

## 1.6 Contraindications, Warnings and Cautions

### 1.6.1 Contraindications

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

- Corneal thickness < 300 microns at the time of treatment
- 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



**WARNING: This equipment is operated with hazardous voltages that can shock, burn, or cause death. To reduce the possibility of electrical shock, do not remove any fixed panels. Ensure that all service to the system is performed only by qualified Avedro service personnel.**



**WARNING: Remove the wall plug before servicing 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: Connect the equipment only to a grounded outlet.**



**WARNING: Never open the protective covers of the KXL System.**



**WARNING: Opening the covers exposes the user to electrical components, the UV light source, and possible UV radiation. Only Avedro-certified service engineers shall work inside components.**



**WARNING: Keep the area around the system dry.**



**WARNING: Do not operate the system if any of the cords are faulty or frayed.**



**WARNING: Unplug the power supply from the main power outlet before cleaning or maintaining the system.**

### 1.6.4 Grounding

Grounding is necessary for all KXL Systems when connect to a supply mains. (Note the KXL can operate on its own power through the internal battery system for 16 hours of normal operation. During extended periods of non-use connect the system to a supply mains.) Poor grounding might interfere with operation of the system. Service calls required by improperly grounded equipment are not covered under the warranty. All input power lines should be free of transients, spikes, sags, and surges. As a result, the KXL power should not be shared with other heavy variable loads such as elevators, air conditioning systems, large motors, etc. Operation close to radio towers, large generators, transformers, etc. should be avoided.



**WARNING: When connected to a supply mains the KXL System MUST be grounded for safety reasons; failure to ground the system properly could cause a potential hazard. Never bypass any grounding equipment or operate the KXL System when grounding is impaired.**

### 1.6.5 Safety Instructions

- National regulations for installation, starting up, and operation of medical products (respectively medical illumination) have to be considered in addition to the instructions given in this manual.
- The KXL System is an active medical device of class IIa according to European Medical Device Directive 93/42/EEC.
- Any LED system can cause physical harm if used improperly.
- The KXL System is a LED product (EN 62471). Created UV light leaves the housing of the device at the designated aperture.

- The targeting lasers are Class 1 (EN 60825-1) and eye safe under all operating conditions.
- Remember that reflective materials can deflect the UV-light haphazardly. Pay special attention to glass surfaces. Similarly, high-gloss polished metal surfaces within a few meters of the device can cause dangerous irradiation.
- Except for the therapeutic purpose, never look directly into the light beam or aperture.
- If the light beam is deployed for medical purposes, the user is responsible for assuring that all optical devices used for observation or adjustment are outfitted with appropriate protective filters.
- Check all system components prior to each treatment. Do not use the KXL System if any signs of damage to the equipment are observed.
- The system should undergo routine inspection and maintenance per Avedro's recommendations and institutional standards.

### 1.7 Eye Protection



**WARNING: The KXL System is a LED product; it conforms to the EN 62471 for LED devices. It emits UV light at 365 nm.**



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

### 1.8 Patient Safety

- The KXL System should be operated only by ophthalmic professionals who have been trained in its use and are capable of ensuring operation in accordance with this manual and regulations.
- 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.



**WARNING: The patient's compliance and the proper operation of the KXL System shall always be monitored by an ophthalmic professional during the treatment.**



**WARNING: Do not move the KXL System during treatment! Make sure that personnel do not bump into the table or patient's chair or against the device during the treatment procedure!**



**WARNING: The KXL System must be aligned to the patient's eye by the user.**

**NOTE:** Consult your nearest authorized Avedro dealer if you have any questions regarding the device and its application.

## 1.9 Use Restrictions

- Do not use the KXL System in combustible rooms and areas.
- Only use the KXL System in designated medical rooms in accordance with national and international guidelines and standards.
- The device has been tested for electromagnetic conformity (EMC) according to EN 60601-1-2 and EN 55011 (Class B). Despite adherence to all applicable EMC requirements, malfunctioning cannot be completely ruled out.
- The KXL System may be operated only in rooms with room temperatures between 10 °C to 40 °C and air humidity between 30% and 70% (non-condensing).
- Ask your Avedro representative if the system was exposed to any type of mechanical shock that could have caused a misalignment of the optical pathway. A safety check is necessary after any type of shock before any further treatments are performed.

Misalignment after a mechanical shock exposure could result in unsatisfying treatments.



**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.**

## 1.10 Safety Design

General specifications and standards relevant to design and manufacturing practices and procedures, such as those delineated in standards EN 60601, EN 62471, and EN 60825-1, were adhered to in the design and manufacture of the KXL System. The following protective measures are integrated into the system to achieve a high degree of safety and operating comfort:

- The device is controlled by an internal microprocessor. This processor is checked for proper working functions. In case of processor failure, no UV light is emitted due to the design of the device.
- The microprocessor unit controls the electrical current used to drive the UV-LED. This design allows the required UV light emission to remain constant over the life of the product.

- The KXL System detects and indicates internal errors of the device. UV emission is locked in such cases.

### 1.11 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.
- The KXL System is intended solely for physicians trained in the use of this instrument.
- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous UV radiation exposure.
- Operate the KXL System only from properly installed main electrical outlets.

### 1.12 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.

## 1.13 Use in Presence of Flammable Mixtures

The KXL System is not suitable for use in the presence of flammable mixtures or anesthetics.



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

This page is left blank intentionally.

# 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 ViBx has been applied. Irradiating the ViBx 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 30mW/cm<sup>2</sup>. A moving 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 7 mm, 9 mm or 11 mm, which is selected by the user selecting the corresponding aperture setting on the software user interface. 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<sup>2</sup> or more are prohibited by the software.

The KXL is a portable system with an articulating arm to allow infinite 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 (KXL Accelerated Crosslinking Treatment Kit) which has an RFID on it. The kit contains:

- ViBx ophthalmic solution is required for use with the KXL System while performing Crosslinking.
- UV-blocking disks ("UV Shields") are single-use, disposable accessories for use with the KXL System while performing Crosslinking.

These devices are available from Avedro or its local distributors.

## 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**
- **KXL Accelerated Crosslinking Treatment Kit**



**Figure 2-1. Overview Illustration of System**

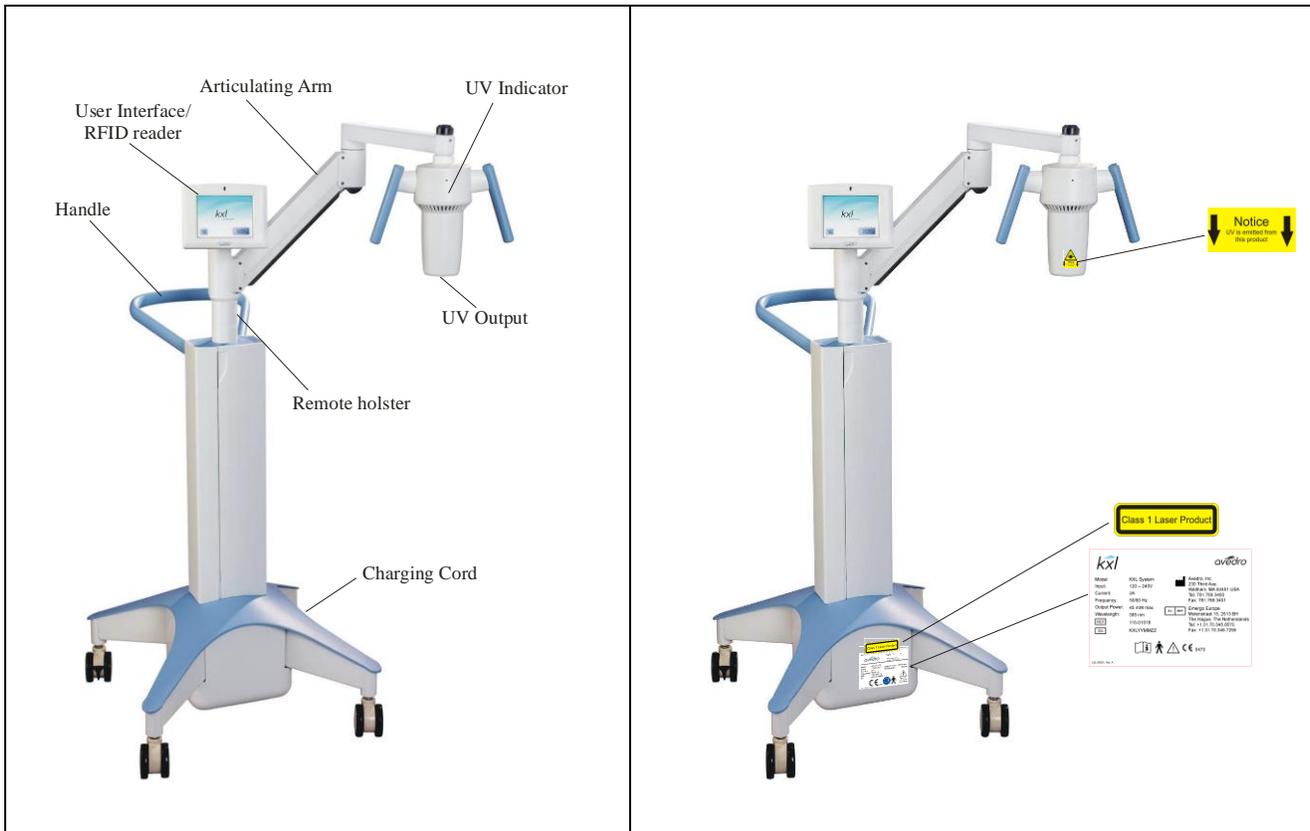
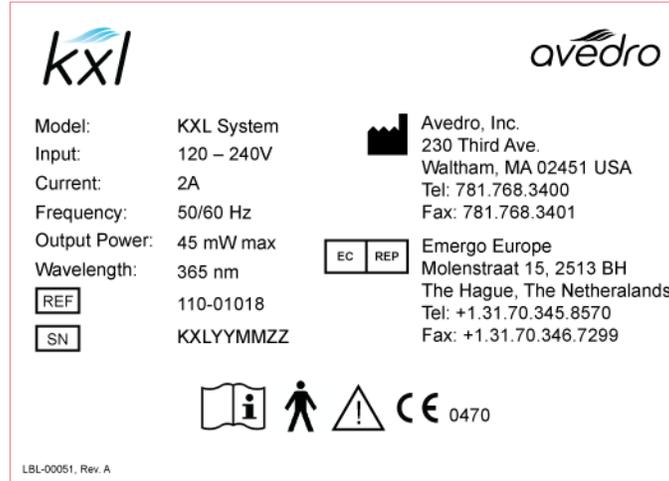


Figure 2-2. System Illustrations with Callouts



Figure 2-3. Wireless Remote

- The system is designed to be used in a treatment room, where the patient lies on the chair similar to that supplied with a typical excimer laser system.
- The system is operable by an ophthalmologist and a single assistant.
- The instrument includes a wireless remote control for activating treatment.



**Figure 2-4: KXL Label**



**Figure 2-5: UV emitting Label**



**Figure 2-6: Laser Classification Label**

# 3 Procedure Guidelines

---

## 3.1 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. Intensity of the irradiance, exposure time and UV irradiance dose are displayed.

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



**CAUTION: The UV dosage, and photosensitizer concentration have an influence on treatment results.**

*NOTE* - The system's parameters are:

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

The maximum dose is 5.4 J/cm<sup>2</sup>

**vīBx**

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

## 3.2 Preparing the System

1. Position the KXL System adjacent to the treatment table or chair. Lock the casters to secure the device's position.
2. Make sure the system is turned ON and tested successfully.
3. Check glass window of beam aperture for dust and dirt. See section 5.5 for cleaning instructions.



**CAUTION: Do not touch glass surface of the beam aperture.**

## 3.3 Select the Induction Period

1. Select the desired Induction Period by adjusting the setting on the Set Induction Period screen. See section 4.2 section 3 details.

## 3.4 Select the UV Treatment Parameters

1. Select the desired UV Treatment Parameters (UV Treatment Time, UV Power, and Beam Diameter) by adjusting the setting on the UV Treatment Parameters screen. See section 4.2 section 5 details.

## 3.5 Select and Prepare Accessories

1. Select appropriate accessories and scan RFID.



**CAUTION: vīBx (vitamin B2) and the UV Shield are not a part of the KXL System described in this manual. For details of component use, please refer to vīBx and UV Shield Directions for Use.**

## 3.6 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.

1. Adjust the table or chair and head rest so that the patient can rest comfortably for the duration of the treatment without head movement.
2. Apply a lid speculum and optional drapes using standard clinical technique.
3. ***Keratoconus and post-LASIK ectasia***: remove corneal epithelium using standard clinical technique.
  - a. Rinse single-use UV shield with hard contact lens solution and apply UV shield with opening centered over the treatment area. UV Shield maybe placed on the eye prior to VīBx application or after induction period based on standard clinical technique. (See UV Shield DFU for specific instructions on use.)
  - b. Place the UV Shield, centered on the cornea, covering the peripheral cornea and sclera.
4. ***LASIK Xtra*** is intended to be performed after the Excimer portion of the LASIK procedure is complete and with the corneal flap still removed.



**CAUTION: UV dose, photosensitizer concentration, and the corneal thickness of the patient's eye have an influence on treatment results.**

## 3.7 Starting Treatment

1. ***Keratoconus and post-LASIK ectasia***: Apply VīBx to the area of treatment.
  - a. Start the induction by pressing the **VīBx Applied** button.

- 
- b. The induction timer begins to count and the alignment lasers illuminate.
  2. ***LASIK Xtra***: Apply vīBx onto the corneal bed and then to the underside of the corneal flap. Replace corneal flap using standard clinical technique.
    - a. Place the UV Shield, centered on the cornea, covering the peripheral cornea and sclera.
    - b. Start the induction by pressing the **ViBx Applied** button.

### 3.8 Alignment of Light Source

1. Center the red cross on 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. This defines the correct position.
2. Align the optics head, and fine tune the alignment using the wireless remote
3. When alignment is complete and the Induction time is complete press the **UV On** button.

Yellow lights indicate the UV emission.



**WARNING: Start treatments only after the photosensitizer is applied.**



**CAUTION: UV light is emitted as long as the yellow 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.**

### 3.9 Monitoring Treatment

- Verify the UV light is aligned properly and fine 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.
- Check continuously that the area of interest on the cornea is illuminated all the time. Visible control is sufficient.



**WARNING: Visual control of the centration of the illuminated area with respect to the area of interest on the cornea is required during each treatment.**

## 3.10 Stopping a Treatment

- The treatment stops automatically after the user-programmed time treatment is started with the **UV On** button.
- 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.

## 3.11 Resuming a Treatment

- To resume a treatment, press the **Resume** button. This action restarts a treatment and the safety timer. The UV emission now runs and starts the timer from where it was paused.

## 3.12 Canceling Treatment

1. From the Treatment Pause screen the treatment can be ended by clicking **Cancel Session**. This button asks the user for multiple confirmations of cancelation and then displays the Partial Treatment Information.

## 3.13 Treatment Complete

2. 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.
3. If treatments are complete Power OFF the system using the “Power Off” button on the New Treatment Screen.
4. Carefully remove the device from the patient.
5. Remove the UV Shield and discard.
6. Apply antibiotic ointment on the cornea and then cover cornea with a bandage contact lens
7. Remove speculum
8. Give post-op medication using a regimen similar to after photorefractive keratectomy(PRK): pain medication, steroids, antibiotics.

**NOTE:** For storage or transportation, please use the transportation case delivered with the KXL System.

---

# 4 Treatment Guidelines

---

## 4.1 Keratoconus / Post Lasik Ectasia

Avedro recommends the following KXL settings:

- vīBx Induction Period: 8 minutes
- UV Power: 30 mW/cm<sup>2</sup>
- UV Treatment Time: 3 minutes

## 4.2 LASIK Xtra

Avedro recommends the following KXL settings:

- vīBx Induction Period: 1 minutes
- UV Power: 30 mW/cm<sup>2</sup>
- UV Treatment Time: 3 minutes

This page is left blank intentionally.

# 5 Operation

---

## 5.1 Charging the KXL Battery

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

1. Using supplied power cord plug KXL into a grounded supply mains when the system is not in use or overnight.
2. At the end of each business day the KXL should be connected to grounded supply mains to allow charging of the battery pack

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.

## 5.2 Software User Interface: 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 personal computer..
Start New Treatment button (Initial screen)		Directs the system to repeat the entire clinical treatment protocol so the physician can treat another patient.
UP arrow (various Clinical Protocol screens)		Increases the value of the current field
DOWN arrow (various Clinical Protocol screens)		Decreases the value of the current field

Touchpad Key	Icon	Description/Function
X button (various Device Settings screens)		Cancels all the entries on a 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 displays to confirm your decision.
Return to Treatment button (Confirm Cancel Session screen)		Cancels the Cancel Session command and returns to the Treatment screen.
Return button (various Device Settings screen)		Returns you to the Device Settings menu.



**CAUTION: Only qualified and experienced personnel shall operate the KXL System. A setup and functional check of the system should be performed only by an ophthalmic professional trained in setup and use of the device.**

## 5.3 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:

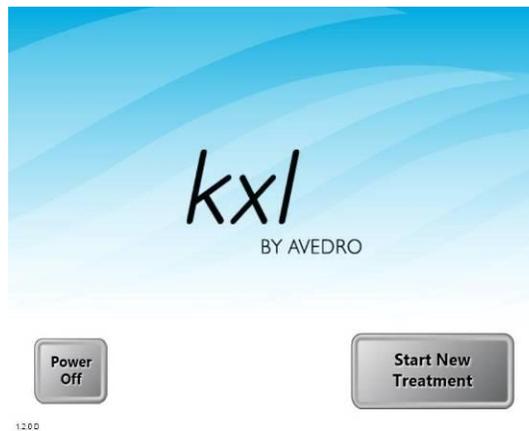
- Inspect the device, accessories, and connecting cables for visible damage.
- Take local regulations for use of portable electro-optical medical devices into consideration.

## 5.4 Software User Interface: Powering Up the System

3. 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.

The system then displays the Startup Test screen.



**Figure 5-1 Startup Test Screen**

4. 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.

The Welcome screen then displays following a successful start-up test.

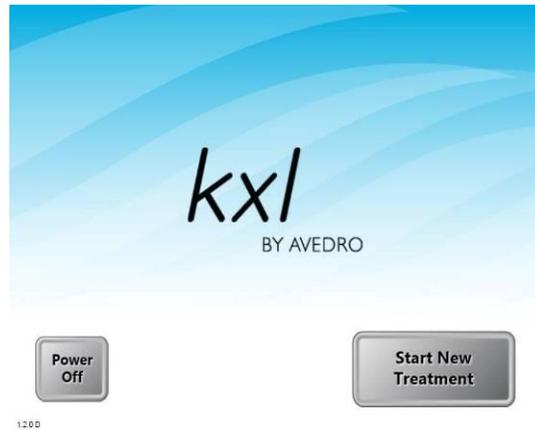


Figure 5-2. Welcome Screen

## 5.5 Software User Interface: Setting Treatment Settings

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

The Set Induction Period screen displays.

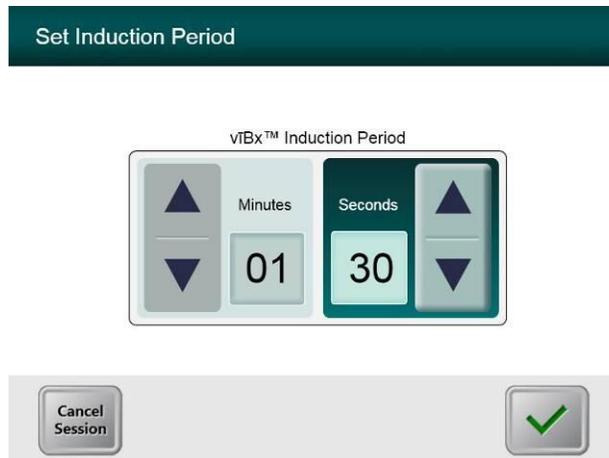
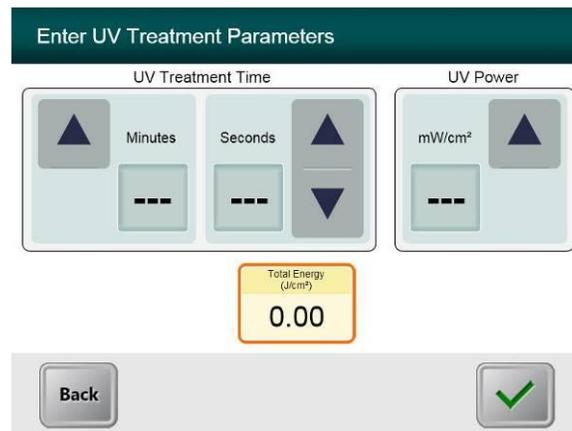


Figure 5-3. Induction Period Screen

2. Specify the desired induction period (1 – 30 min) for this patient.
3. When finished entering parameters, click the **Checkmark** button.

The Enter Treatment Parameters screen displays.

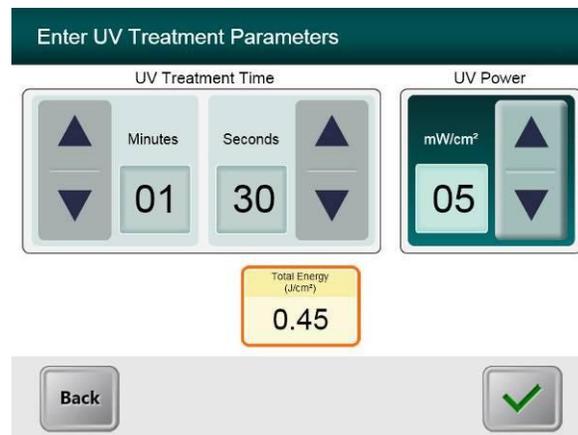


**Figure 5-4 Enter Treatment Parameters Screen**

4. Specify the desired treatment parameters, in turn, for this patient as follows:

- UV Treatment Time (1 – 30 minutes)
- UV Power (3 – 30 mW/cm<sup>2</sup>)

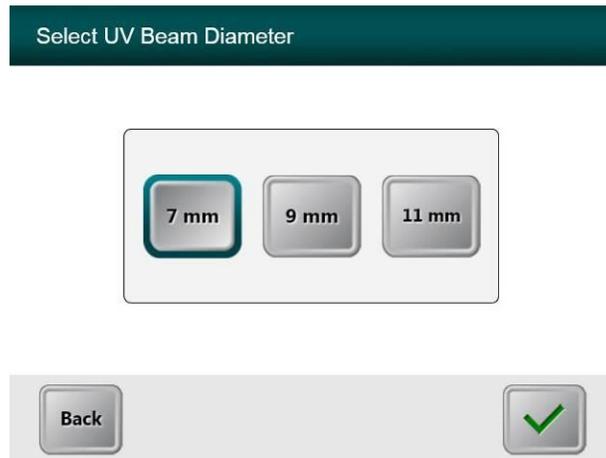
NOTE: Total Energy will be displayed in the lower right orange box. The maximum permissible Total Energy is than 5.4 J.



**Figure 5-5 Populated Treatment Parameters Screen**

5. When finished entering treatment parameters, click the **Checkmark** button.

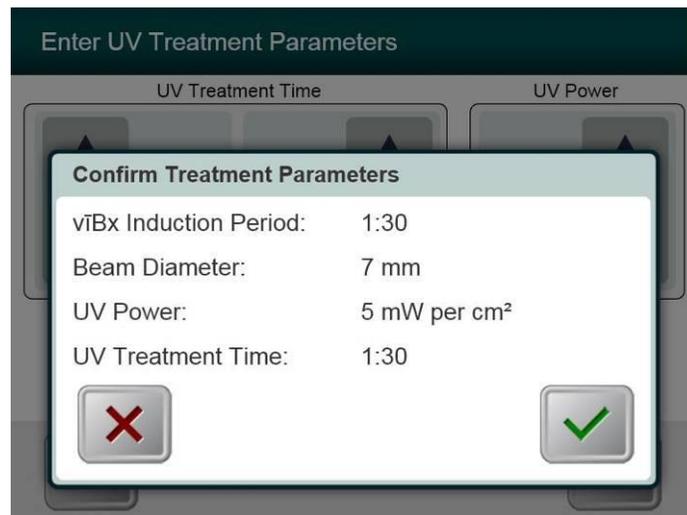
The Select UV Beam Diameter screen displays:



**Figure 5-6 Select UV Beam Diameter Screen**

6. Specify the Beam diameter for this patient as follows:
  - Beam diameter (7, 9, 11mm)
7. When finished entering treatment parameters, click the Checkmark button.

The Confirm Treatment Parameters screen displays.

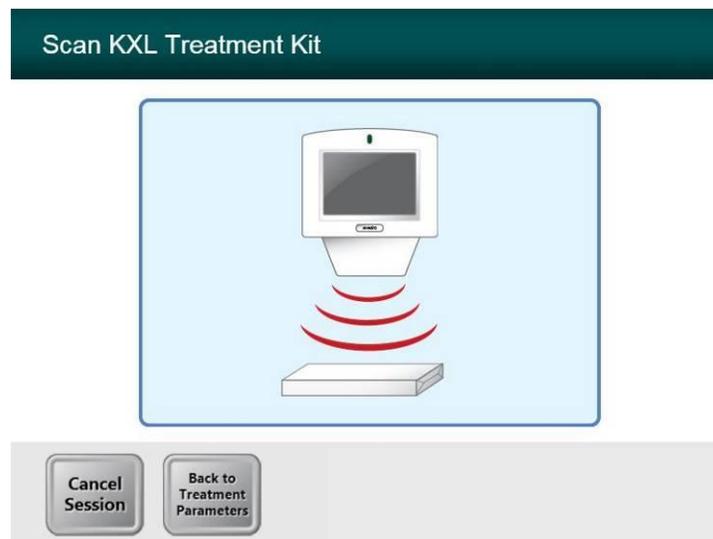


**Figure 5-7 Confirm Treatment Parameters Screen**

8. Confirm the specified treatment parameters by clicking the **Checkmark**; if the treatment parameters are not correct click the **X** and then re-enter the desired treatment parameters.

## 5.6 Software User Interface: Starting Treatment

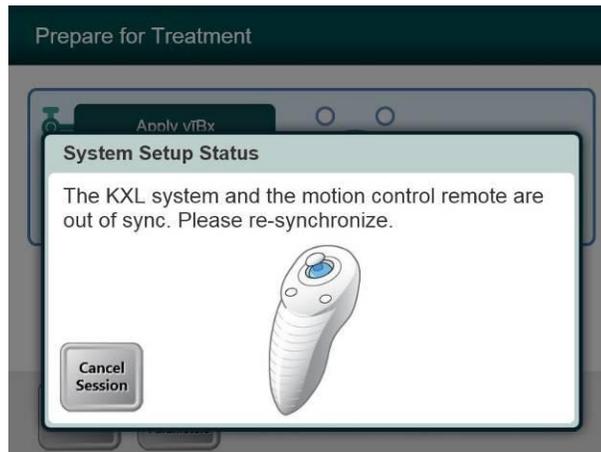
The Scan Disposables screen displays.



**Figure 5-8 Scan Disposables Screen**

9. Scan the disposable kit (which is unique for each patient) on the RFID reader.

### System Setup Status

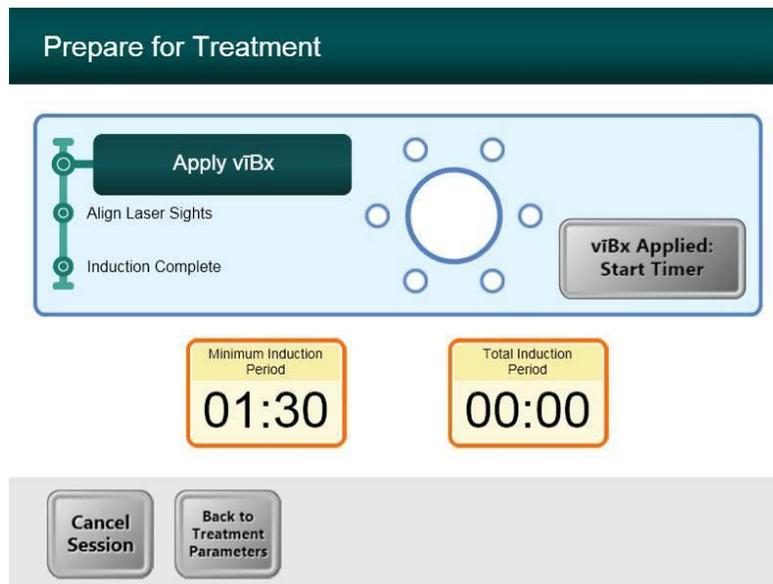


**Figure 5-9 System Setup Status**

10. Press the “S” on the remote to synchronize the remote. This is required for every procedure.

NOTE: If light on remote continues 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.

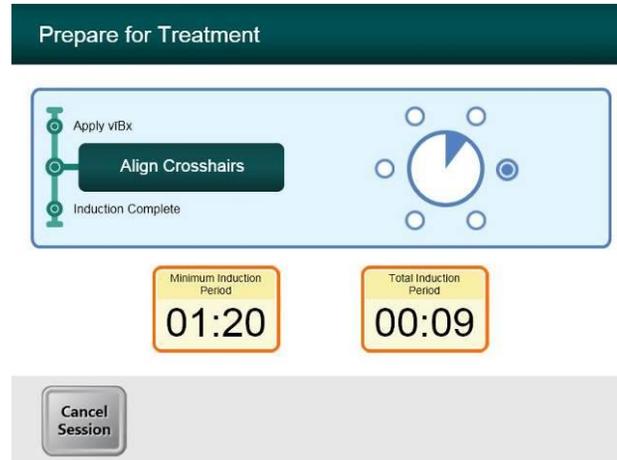
The Prepare for Treatment screen displays.



**Figure 5-10 Prepare Patient Screen**

11. Apply the **V**iBx per its instructions for use, and then click the **V**iBx **A**pplied button.

12. Place a cleaned UV Shield on the patient’s eye prior to **ViBx** application or after induction period using standard clinical practice as directed by the UV Shield’s Directions for Use.
13. Prepare for Treatment screen shows



**Figure 5-11**

14. The software counts down the induction time.
15. While the system is counting down the induction time align the crosshairs to the patient’s eye by adjusting the optics head and fine tuning with the remote.

NOTE: A properly aligned system has the crosshair laser aligned to the center of treatment and the dot laser aligned to the center of the crosshair. This ensures that the UV beam will be centered and focused on the treatment area of interested

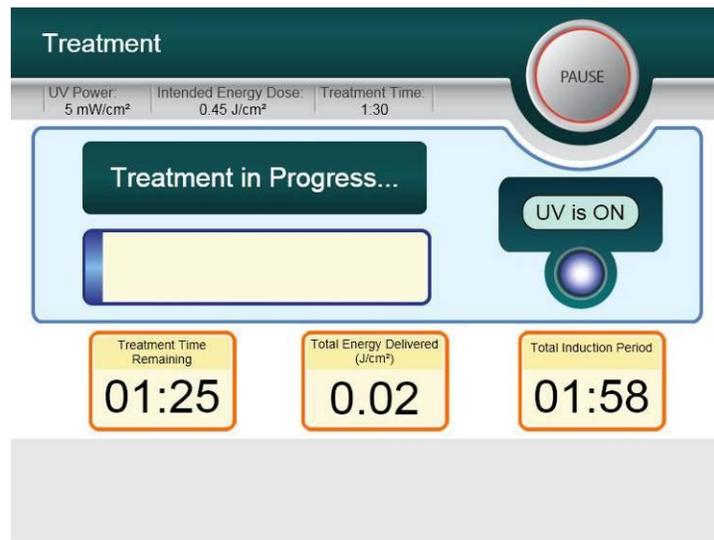
Prepare Patient screen displays Induction Complete and **UV On** button is displayed.



**Figure 5-12 Induction Complete**

16. Click **Begin UV Treatment** to initiate treatment.

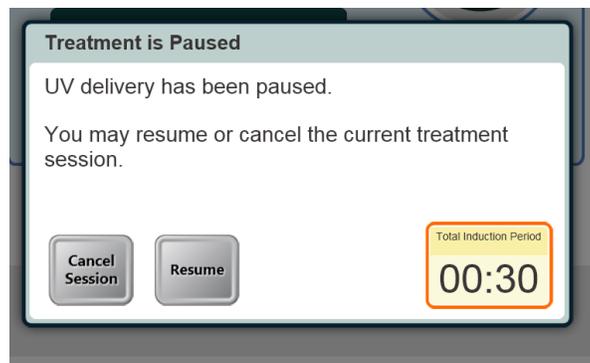
The Treatment screen displays.



**Figure 5-13 Treatment Screen**

17. Treatment is initiated when this screen displays
18. To pause the treatment click **Pause**.

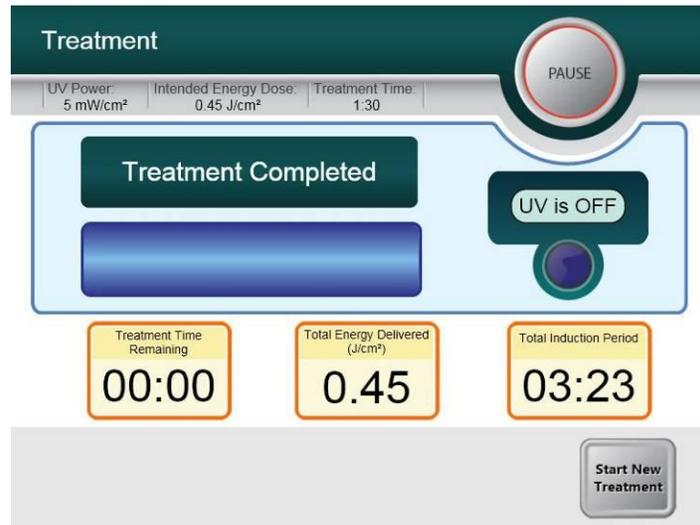
The Treatment is Paused screen displays.



**Figure 5-14. Treatment Paused Screen**

19. To cancel or resume treatment click appropriately. See section 3.7 if canceling a session.

When Treatment is complete the Treatment screen displays with **Treatment Complete**.



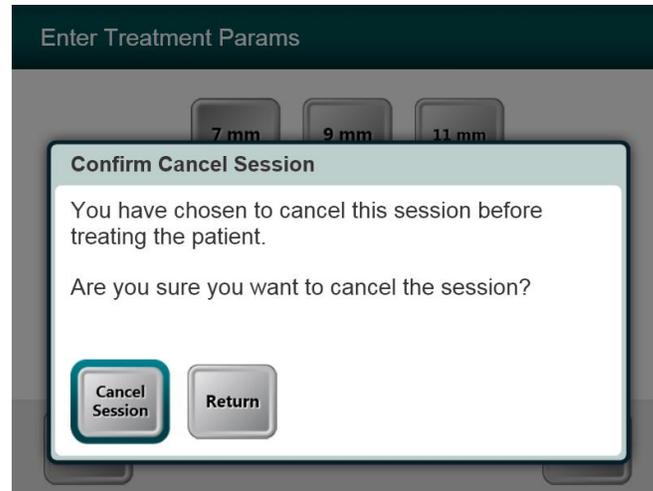
**Figure 5-15. Treatment Complete Screen**

20. To exit treatment and / or start a new treatment click **Start New Treatment**.

## 5.7 Software User Interface: Canceling a Treatment

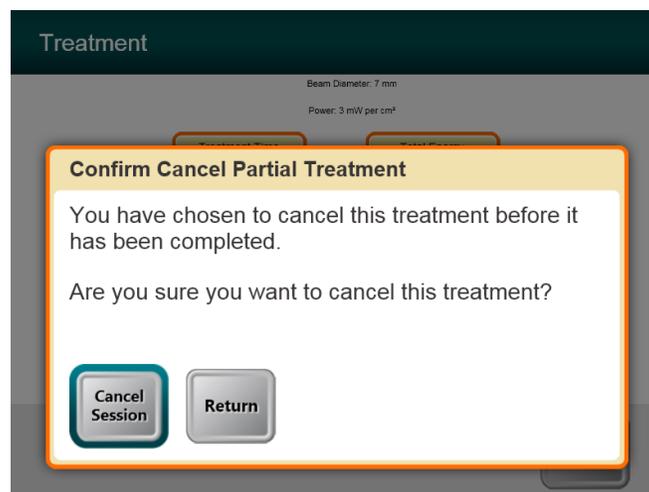
If session is canceled screen displays with **Confirm Cancel Session**.

**Figure 5-16. Initial Confirm Cancel Session Screen**



21. To cancel session click **Cancel Session**.

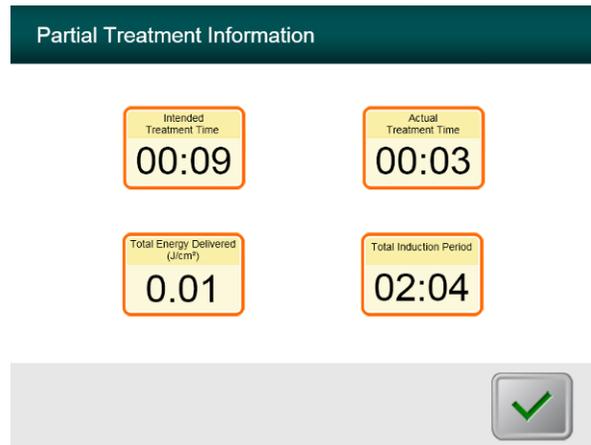
The screen displays **Confirm Cancel Partial Treatment**.



**Figure 5-17. Confirm Cancel Partial Treatment**

22. To cancel session click **Cancel Session**.

The screen displays **Partial Treatment Information**

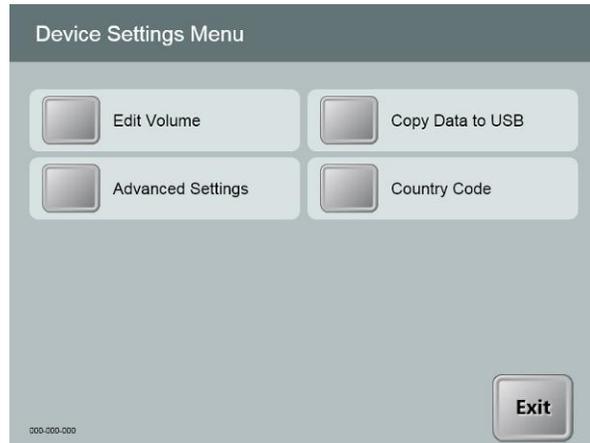


**Figure 5-18. Partial Treatment Information**

## 5.8 Software User Interface: Using the Device Settings Menu

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

The Device Settings Menu displays.

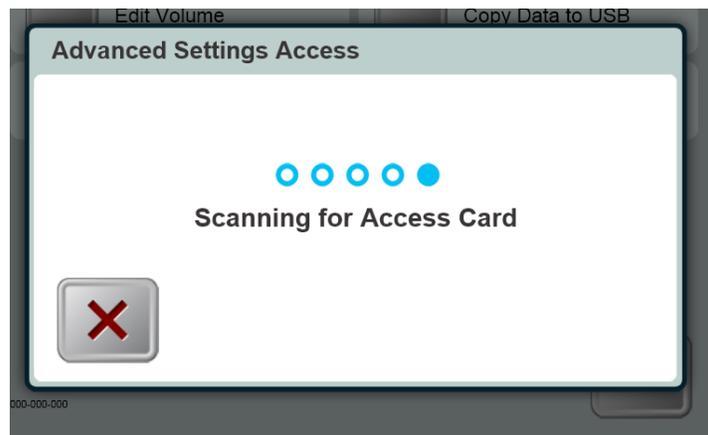


**Figure 5-19. Device Settings Menu**

2. Refer to sections 3.7.1 – 3.7.2 for details on the available options.

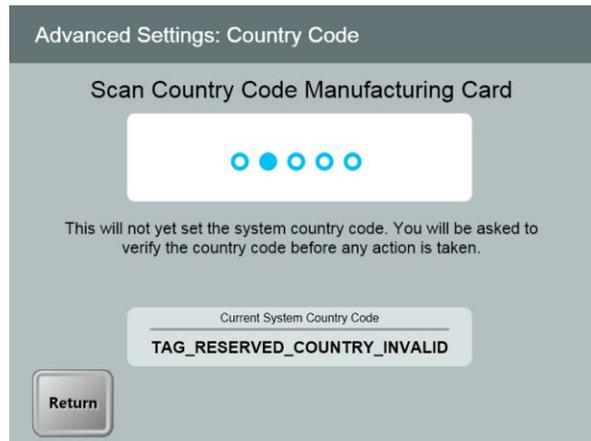
### 5.8.1 Advanced Settings

1. 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 5-20 Advanced Setting Access**

## 5.8.2 Country Code



**Figure 5-21 Advanced Settings: Country Code**

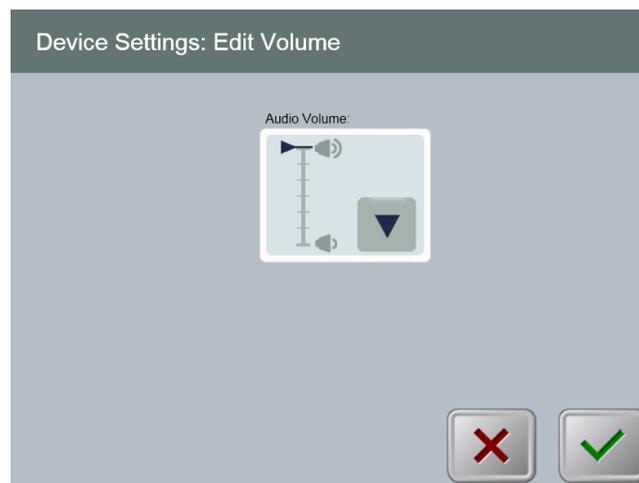
1. Country Code selection is only available prior to initial setup and the user will be prompted to scan a Country Code Setup card to set the country code.

## 5.8.3 Editing System Volume

The Edit Volume option allows a user with the appropriate security level to edit the system volume level.

1. Select the **Edit Volume** button on the Device Settings menu.

The Device Settings: Edit Volume screen displays.



**Figure 5-22. Device Settings Edit Volume**

## 5.8.4 Copying Treatment Data to USB

The Copy Treatment Data to USB option permits a user to copy treatment data from the KXL System computer's hard drive to a connected USB device via a USB port.

**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. Consequently, if you wish to integrate patient treatment data with your facility's Patient Information and Billing system, you **MUST** copy the treatment data to a USB device with this option.

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

The Device Settings: Transfer Treatment Data to USB screen displays.



**Figure 5-23. Device Settings Transfer to USB**

2. 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.
3. Once complete press the **Return** button.

You return to the Device Settings menu.

# 6 Maintenance

---

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.

## 6.1 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 in Chapter 6 or call your local Avedro Representative.

## 6.2 Service and Diagnostic Requirements

- 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.

## 6.3 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.

## 6.4 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 submerge the system in liquid or pour liquid onto the system.



**CAUTION: Remove the power supply cord from the main outlet 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.

## 6.5 Cleaning the Aperture

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

## 6.6 Performing Periodic Maintenance

Interval	Specific Task
Annual	Calibration by Avedro trained personnel.

## 6.7 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.

## 6.8 Storing the System

- Follow all the storage temperature and humidity range specifications as listed in the Specifications chapter (Chapter 9).
- 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.
- 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.

## 6.9 Updating Software

- Should the software become corrupted and fail to work correctly at some point, call your local Avedro service representative.

## 6.10 Identifying Risks Associated with Disposing of Waste Products

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

## 6.11 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.

This page is left blank intentionally.

# 7 Customer Service Information

---

## 7.1 Before Calling your local Avedro Representative for Help

Whenever you experience difficulty using the KXL System, before **calling your Avedro-authorized distributor for help, first follow the information contained in this chapter.**

1. Write down the time and date that the problem occurred, or when you first noticed the problem. Also, note what the system was doing when the problem occurred or was first noticed. Note all other relevant information.
2. Attempt to isolate the problem.
3. Issue a complaint

## 7.2 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.

## 7.3 Warranty Information

A Warranty is supplied separately with the purchasing information.

## 7.4 Service Contract Information

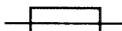
A service contract is available on all KXL Systems. The contract provides for regularly scheduled maintenance and field upgrades. It also provides for any non-scheduled service calls that may be necessary.

## 7.5 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.

This page is left blank intentionally.

# 8 Symbol Library

Text Symbol	Symbol Illustration	Definition
1. Man in a box		Type BF "Body Floating" applied part
2. No AP symbol in presence of flammable anesthetics		Danger, Risk of Explosion. Not for use.
3. AC symbol		Alternating current
4. ! in triangle		Attention: Consult ACCOMPANYING DOCUMENTS
6. Ground symbol in circle		Protected earth (ground)
7. "I" on Power Switch		ON
8. "0" on Power Switch		OFF
9. Fuse symbol		Fuse
10. Lightning bolt in triangle		Dangerous Voltage
14. CE Mark		Conformity mark
14. CE Mark		Standby

This page is left blank intentionally.

# 9 Specifications

---

Specification	Description
Software Version	System 1.0
Electrical	Battery Powered: 12V 35 Ah Charging: Line voltages 100, 115, 22, 240 volts AC, ± 10% RMS, 50/60 Hz, ± 5%
Energy Delivery	UV Radiation
External Interfaces	USB 2.0
Environmental Operating Conditions	The system operates under the following atmospheric conditions (no condensation).
Ambient temperature	+15 to +40 °C
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 °C
Relative humidity	10% to 100% including condensation
Atmospheric pressure	500 to 1060 mbar
Device Classification per MDD 93/42/EEC	Class IIa
Physical Dimensions	No larger than 60 x 60 x 150 cm <sup>3</sup> (Length x Width x Height)
Weight (crated system)	At least 120 Kg
Battery Life (normal operating conditions)	16 hours