# Avedro, Inc.
# KXL System

# Operator's Manual

ML-00002 Revision N

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

## 1.3 Design Change Disclaimer

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

## 1.4 Reproduction Disclaimer

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

## 1.5 User Operation Assistance Statement

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

## 1.6 Contraindications, Warnings and Cautions

### 1.6.1 Contraindications

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

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

## 1.6.2 Warnings

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

- Herpes simplex, herpes zoster keratitis, recurrent corneal erosion, corneal dystrophy
- Epithelial healing disorders

## 1.6.3 Electrical Safety Warnings

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

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

**WARNING: No modification of this equipment is allowed.**

## 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

- 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 cross-linking. UV flux and irradiation time (that is, fluence) at the cornea are controlled by an onboard computer system.

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

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

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

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

## 2.1.1 Major Components

The major components of the KXL System include the following:

- **Optics Head with UV source**
- **KXL console with user interface**
- **Wireless remote control** (with replaceable batteries)
- **KXL Accelerated Crosslinking Treatment Kit** (disposable supplied separately)

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

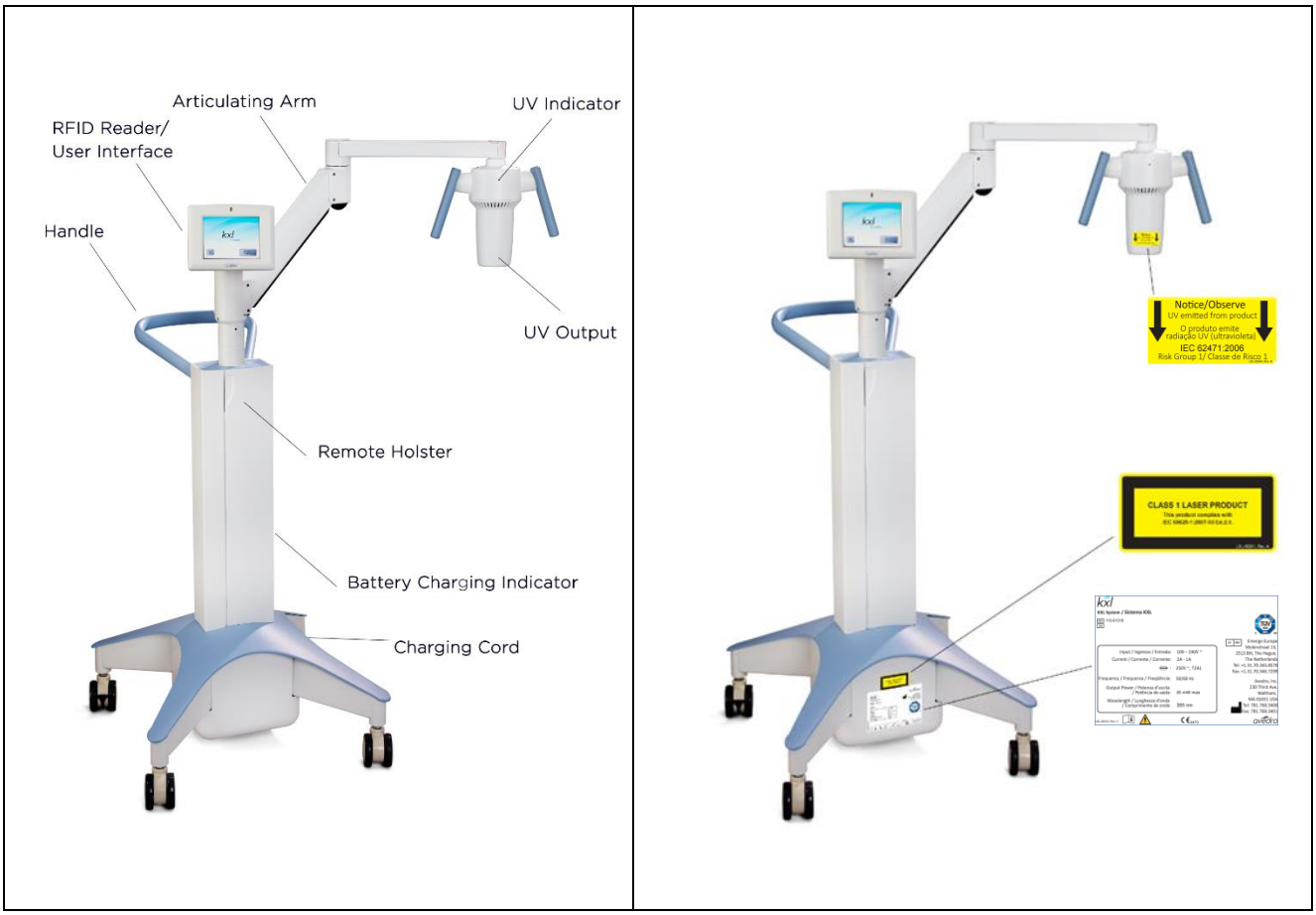



**Figure 2-2. System Illustrations with Callouts**

**Figure 2-3. Wireless Remote**

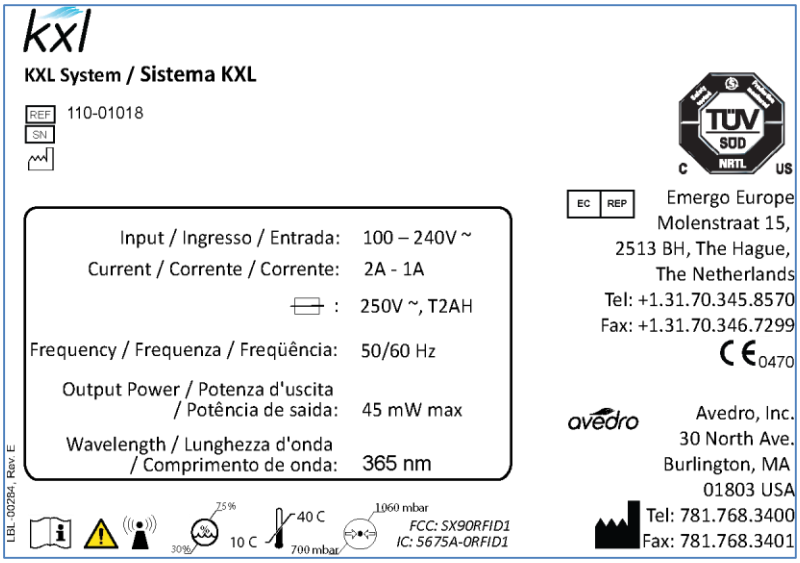



**Figure 2-4. KXL Label**

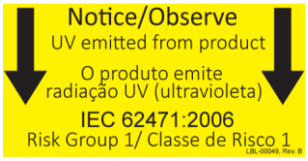



**Figure 2-5. UV emitting Label**

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

# 3 System Operation

## 3.1 Charging the KXL 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 supply mains at the end of each business day or 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.
    - Orange – low, charging
    - Yellow – charging
    - Green – fully charged
      NOTE: if the battery does not appear to be charging or retaining its charge, please contact your local Avedro Service Representative.

NOTE: the KXL battery should last for 16 hours during normal operation. The system software will notify the user when the battery needs to be charged. The KXL system prohibits a treatment if there is insufficient battery power to perform a treatment. (See chapter 4 Maintenance for more information on troubleshooting battery problems.)

## 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 personal computer. |
| Start New Treatment button (Initial screen) | | Starts a clinical treatment protocol so the physician can treat patients. |

| 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) | | 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) | | Cancels the Cancel Session command and returns to the Treatment screen. |
| 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 Energy (Dose)

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

    ***Continuous Mode Parameters:***

    | | |
    |---|---|
    | Induction Period: | 1 second – 30 minutes |
    | UV Energy*: | 1 – 10.7 J/cm$^2$ |
    | UV Power: | 3 – 45 mW/cm$^2$ |

    * The user may select UV Energy in 0.1 J/cm$^2$ increments. The energy range is controlled by the RFID card.
  - Pulsed Mode: UV output turns ON and OFF at user selected intervals.

    ***Pulsed Mode Parameters:***

    | | |
    |---|---|
    | Induction Period: | 1 second – 30 minutes |
    | UV Energy*: | 1 – 10.7 J/cm$^2$ |
    | UV Power: | 15 – 45 mW/cm$^2$ |
    | UV ON Time: | 1.0 – 4.0 Seconds |
    | UV OFF Time: | 1.0 – 4.0 Seconds |

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

**Please reference Riboflavin Instructions for Use (IFU) for formulation information.**

# 3.4 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 4.8 and 4.9 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 local regulations for use of portable electro-optical medical devices into consideration.

## 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 3-1. Power Switch**

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

**Figure 3-2. Startup Screen**

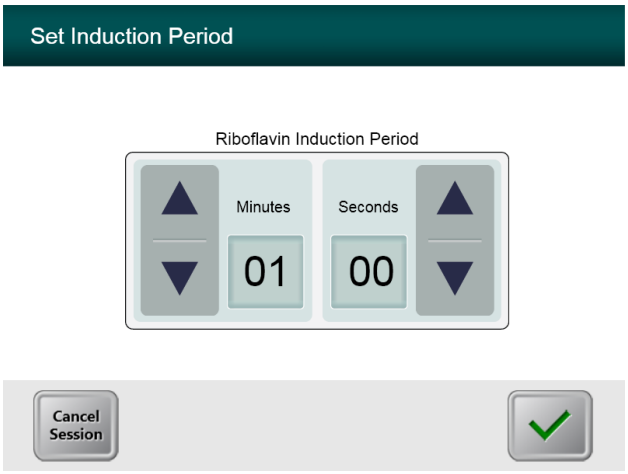
- To begin patient treatment, press the Start New Treatment button.
- Please see section 3.16 for Power Down sequence instructions.

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

# 3.7 Set Riboflavin Induction Period

- Specify the desired Riboflavin Induction Period (1 sec – 30 min).
- When finished entering parameters, press the Checkmark button.

**Figure 3-3. Induction Period Screen**




**NOTE: Default treatment parameters will auto-populate user selectable fields but are adjustable. Defaults settings can be changed (see section 3.16.5, Editing Default Treatment Parameters Screen).**

# 3.8 Select Treatment Mode

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

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

## 3.8.1 Continuous UV Treatment Mode

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

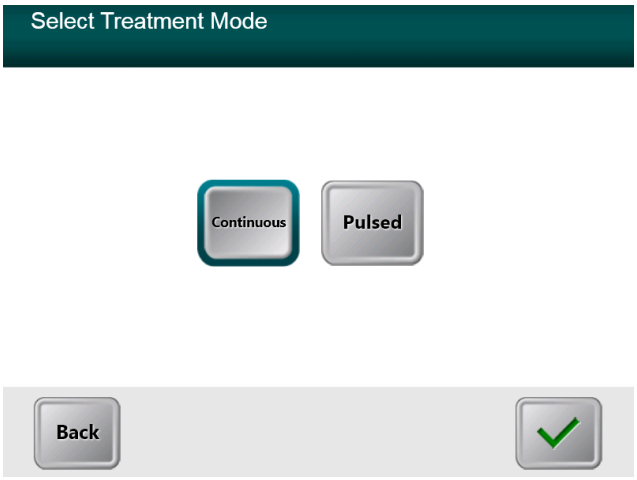



**Figure 3-4. Select Continuous Treatment Mode Screen**

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

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

  * The user may select UV Energy in 0.1 J/cm$^2$ increments. The energy range is controlled by the RFID card.
- When finished entering treatment parameters, press the **Checkmark** button.

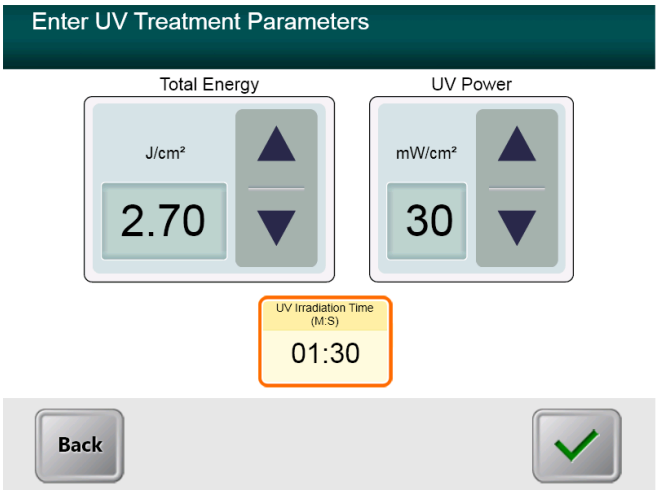



**Figure 3-5. Continuous Treatment Parameters Screen**

- 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.

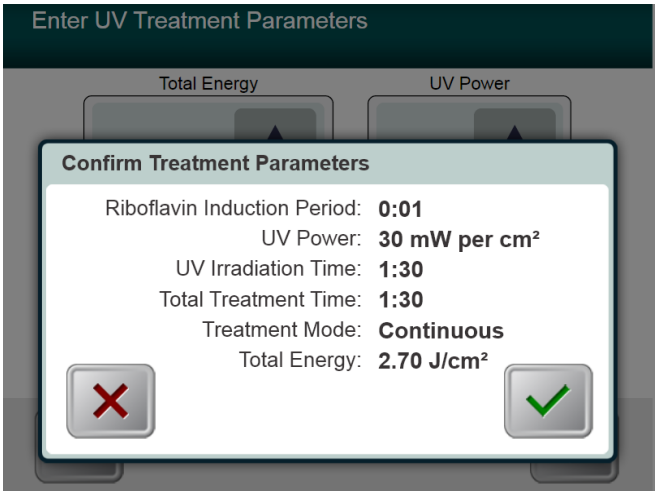



**Figure 3-6. Confirm Continuous Treatment Parameters Screen**

## 3.8.2 Pulsed UV Exposure

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

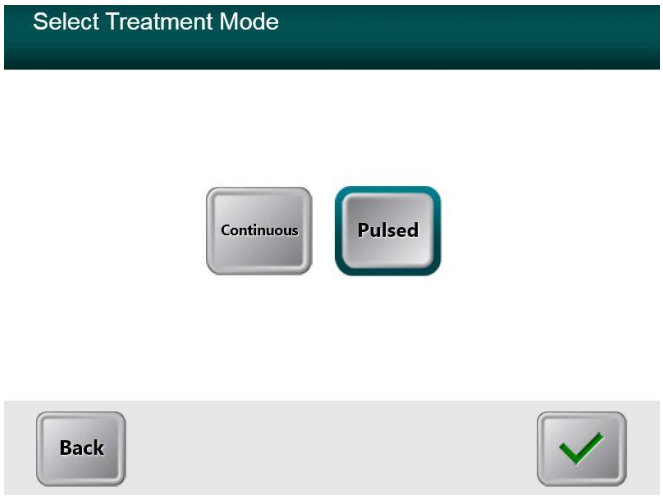



**Figure 3-7. Select Pulsed Treatment Mode Screen**

- Enter the desired UV treatment parameters:
  - Total Energy*
  - UV Power (15 – 45 mW/cm$^2$)
  - NOTE: UV irradiation time is automatically calculated and displayed in the orange box.

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

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

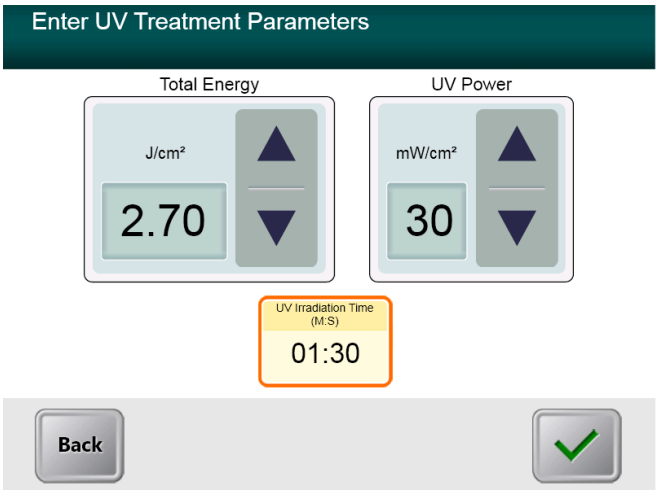



**Figure 3-8. Pulsed Treatment Parameters Screen**

- Select the desired times in which the UV is cycled ON and OFF
- When finished entering treatment parameters, press the **Checkmark** button.

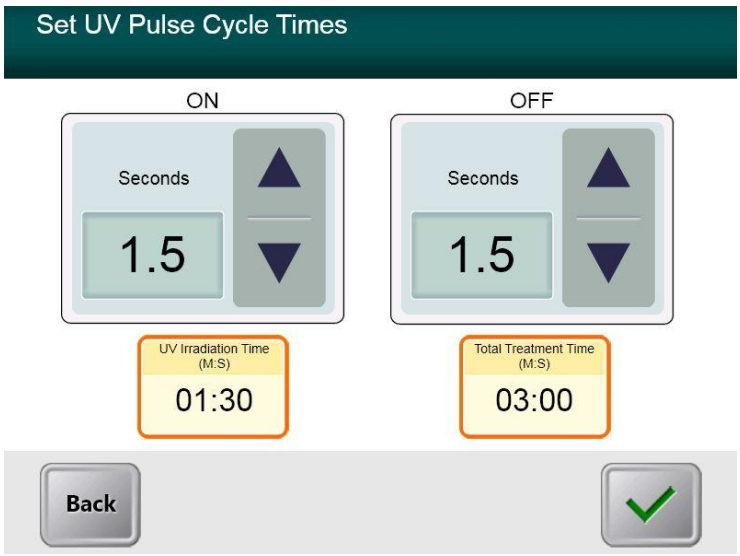



**Figure 3-9. Set UV Pulse Cycle Times Screen**

- 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.

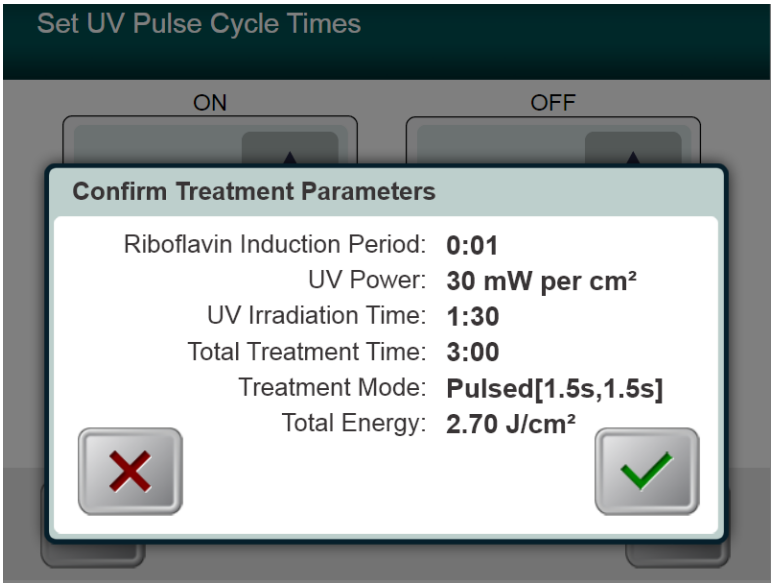



**Figure 3-10. Confirm Pulsed Treatment Parameters Screen**

# 3.9 Starting Treatment

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

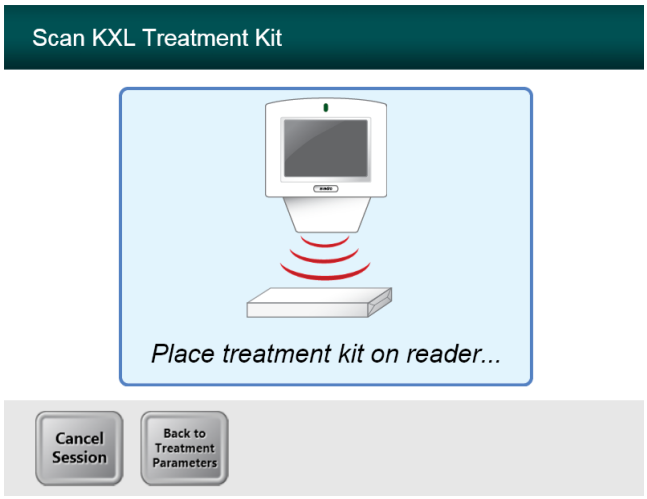


**Figure 3-11. Reading Disposables**

## 3.9.1 Single-use disposables

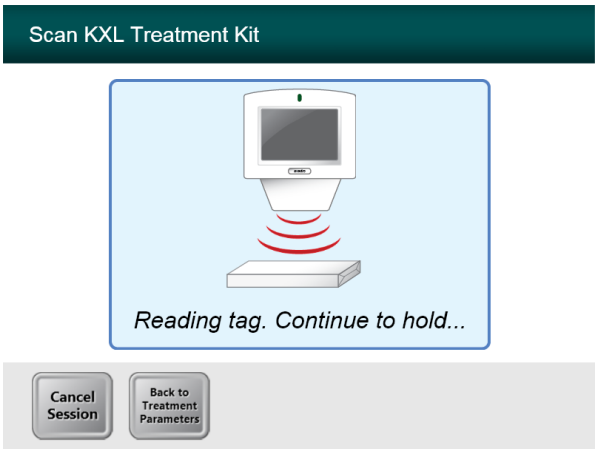



**Figure 3-12. Reading Tag Screen**

- 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.

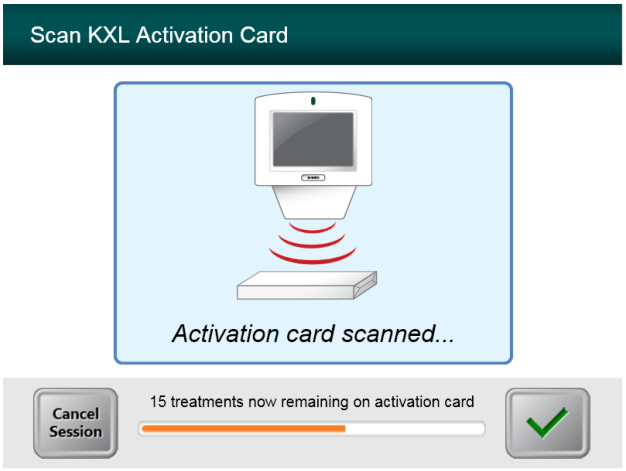



**Figure 3-13. Treatments Remaining**

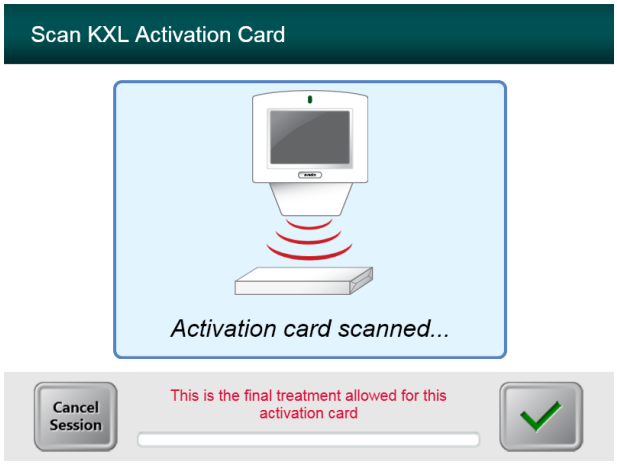



**Figure 3-14. Final Treatment**

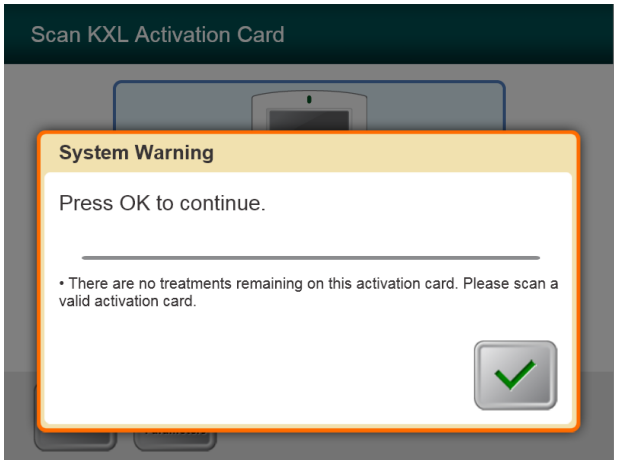



**Figure 3-15. No Treatments Remaining**

## 3.9.3 RFID card controlled limits

- If the user has previously programmed an UV Energy range that is outside the allowable value(s) controlled by the RFID card the following message will appear.

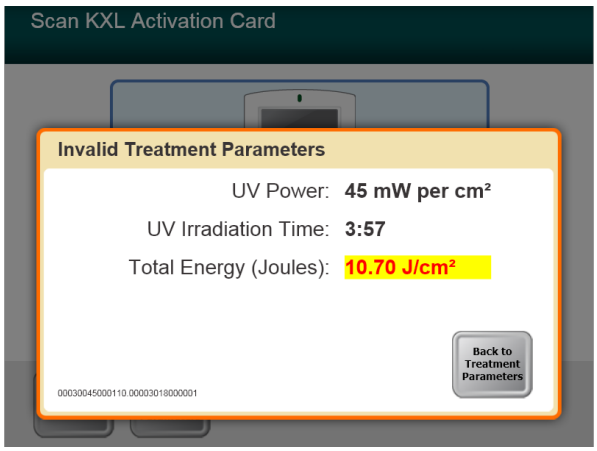



**Figure 3-16. Invalid Treatment Parameters**

- Press Back to Treatment Parameters to enter the appropriate parameter.

## 3.9.4 Sync Alignment Remote

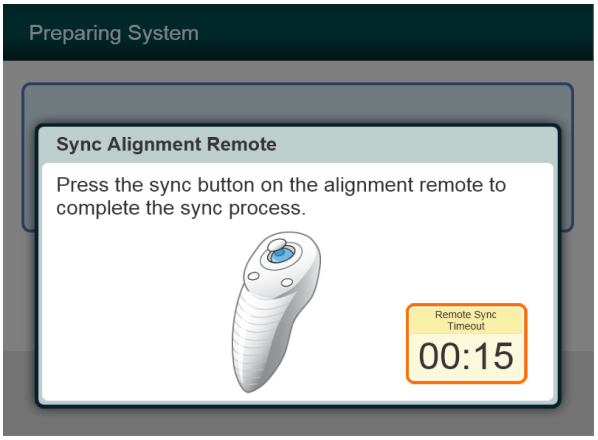


**Figure 3-17. System Setup Status**

- 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. This is required for every procedure.
    - Note: Pressing the Sync button is necessary even though the window prompting the Sync disappears.

| Indicator Light Status | Meaning |
|---|---|
| ON (Solid Blue) | Synchronized with system |
| OFF | Lost synchronization with system |

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

# 3.10 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.
- Apply Riboflavin to the area of treatment in accordance with the Riboflavin Instructions for Use (IFU).

**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.**

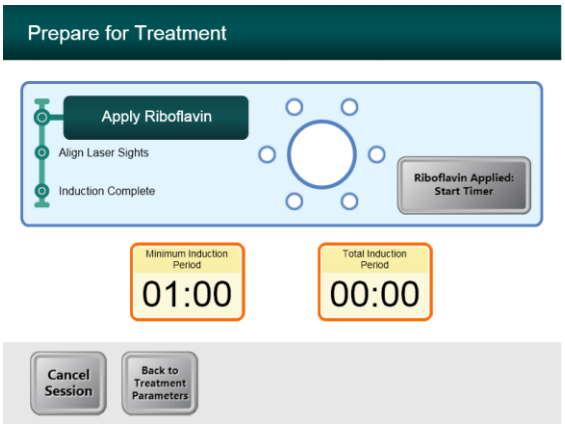



**Figure 3-18. Prepare Patient Screen**

**NOTE: Once the Riboflavin is applied to the eye, Start the induction by pressing the "Riboflavin Applied: Start Timer" button.**

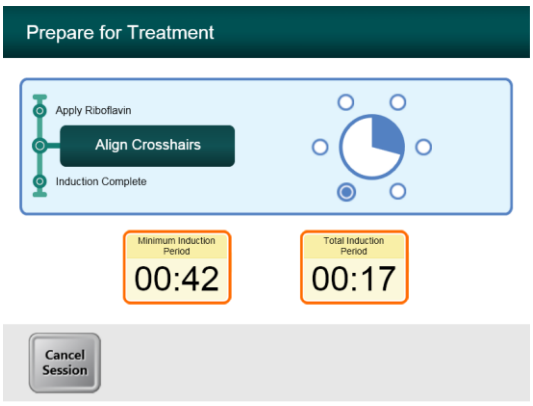



**Figure 3-19. Align Crosshairs during induction**

- KXL has two alignment lasers.
    - Red crosshair for X and Y axis positioning.
    - Green dot or a second Red crosshair for Z axis positioning.
- ***Note: For correct alignment when using the Remote, the Avedro logo on optics head should face the user***
- Manually move the Optics head back and forth and left and right until the X/Y axes' Red crosshairs are aligned to the center of the pupil.
- Manually move the Optics head up and down to align the Z axis green dot or second red crosshair to the center of the first red crosshair.
- Fine tune the alignment as needed using the wireless remote.

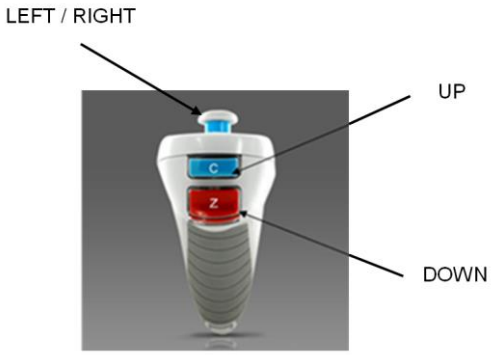



**Figure 3-20. Remote Functions**

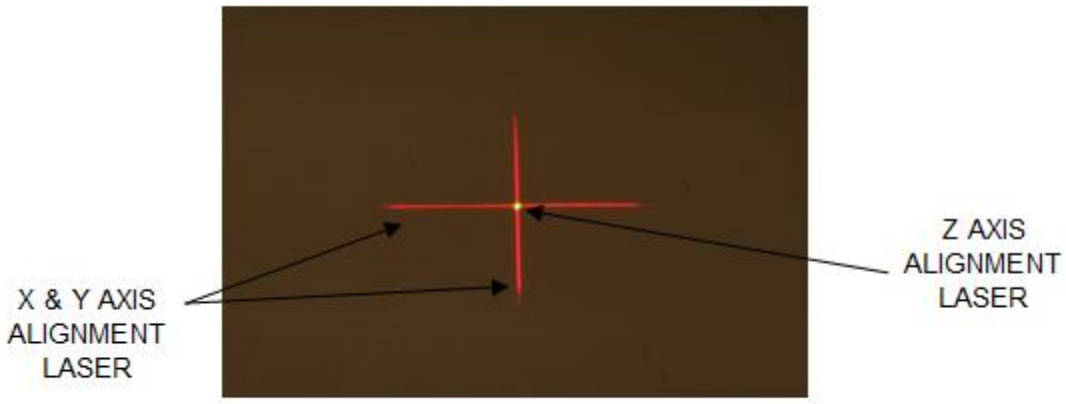



**Figure 3-21. Red Crosshairs X & Y Axes, Green Dot Z Axis Alignment**

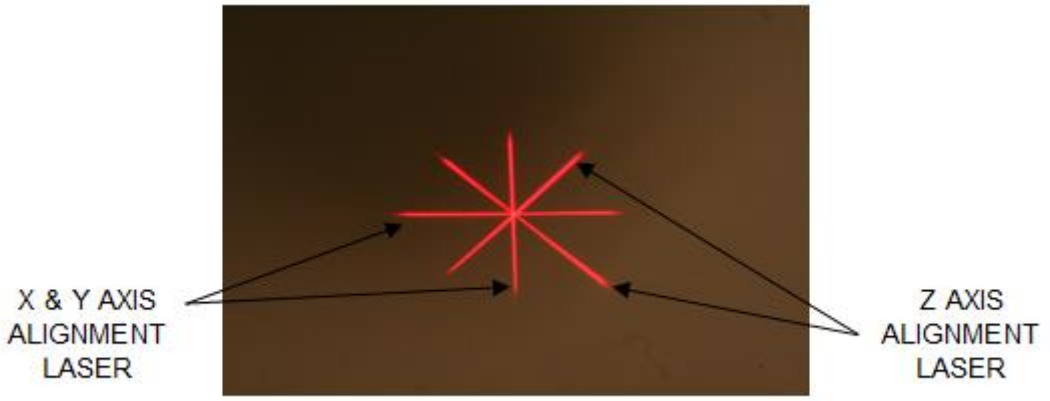



**Figure 3-22. Red Crosshairs X & Y Axes, Red Crosshairs Z Axis Alignment**

## 3.11 Initiating Treatment

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

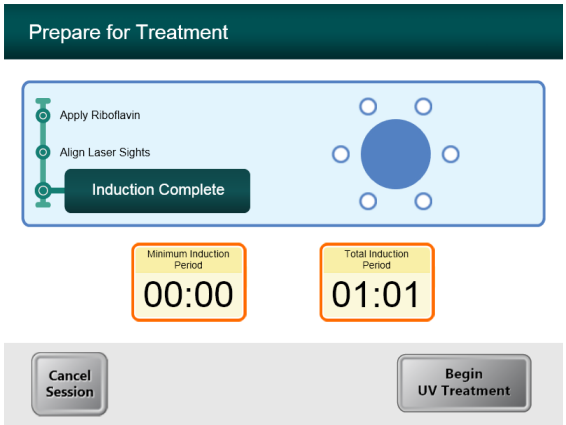



**Figure 3-23. Induction Complete**

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

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

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

# 3.12 Monitoring Treatment

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

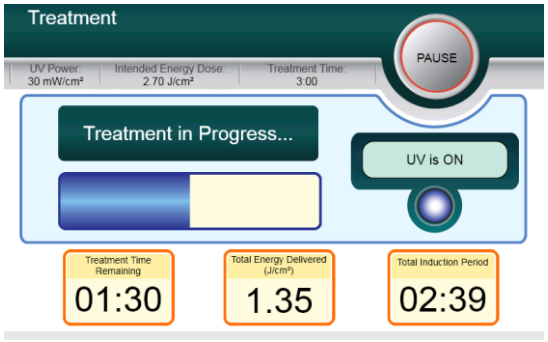



**Figure 3-24. Treatment Screen**

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

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

# 3.13 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.

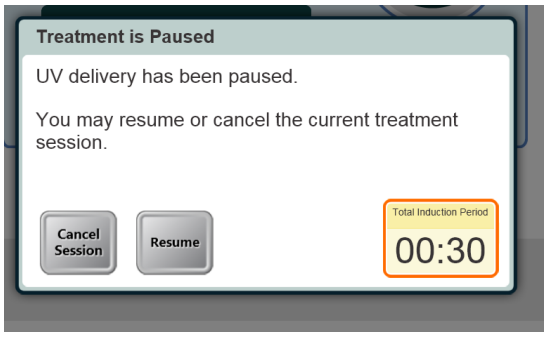



**Figure 3-25. Treatment Paused Screen**

- To cancel or resume treatment press appropriately. See section 3.16 if canceling a session.

# 3.14 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.

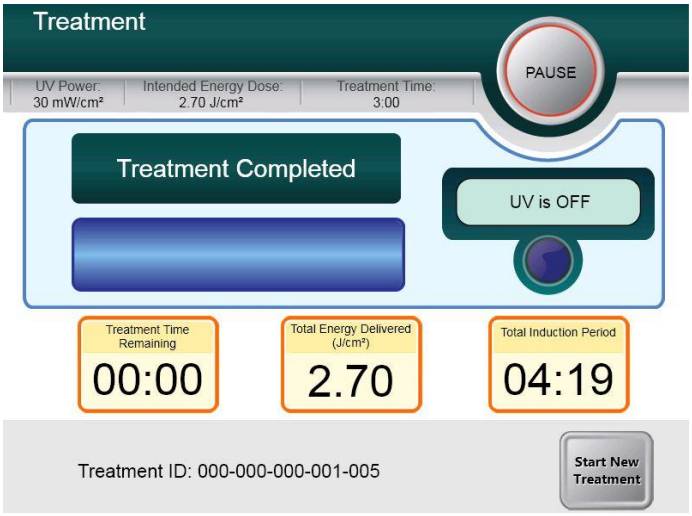



**Figure 3-26. Treatment Complete Screen**

- 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.

# 3.15 Pausing or Canceling a Treatment

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

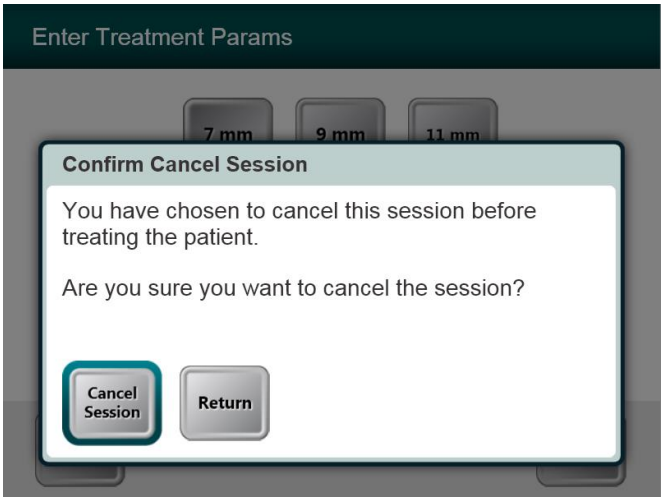



**Figure 3-27. Initial Confirm Cancel Session Screen**

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

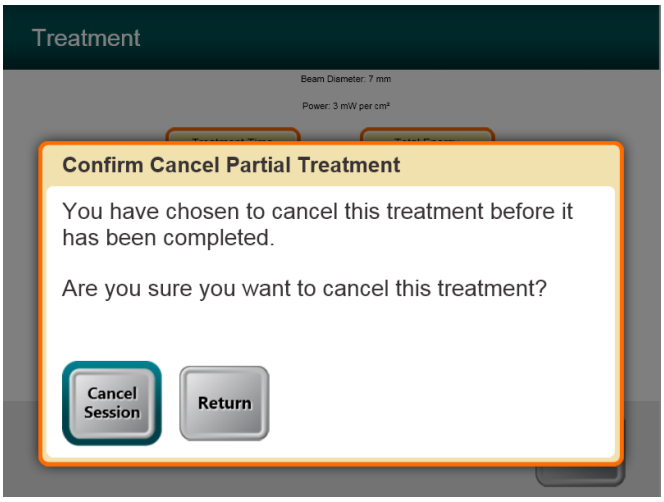



**Figure 3-28. Confirm Cancel Partial Treatment**

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

The screen displays **Partial Treatment Information**

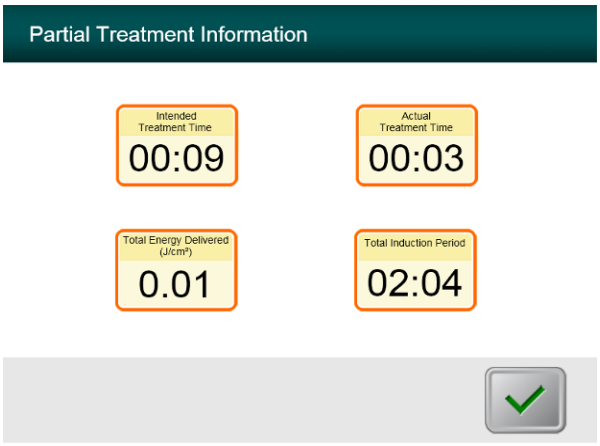



**Figure 3-29. Partial Treatment Information**

## 3.16 Powering Down the System

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

In order to maintain battery charge, it is recommended that the KXL be connected to a grounded supply mains at the end of each business day or when not in use.

**Figure 3-30. Power Off**

- Press the "Power Off" on the touch screen monitor.
- Wait for the software to shut down - the screen will be blank.

**Figure 3-31. Power Off Position**

- After the screen is blank and software shuts down, turn the system power switch to the "Off" position.

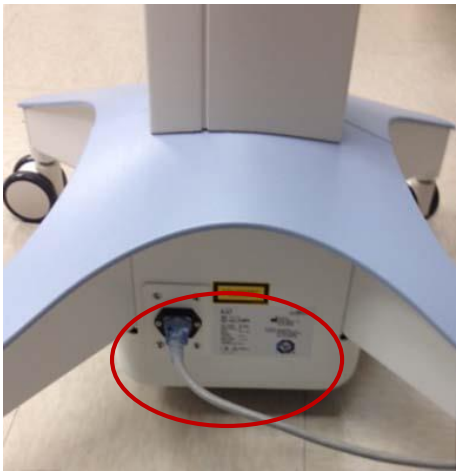


**Figure 3-32. KXL System Plug**

- Plug the KXL System in to an electrical outlet until next use.

# 3.17 Using the Device Settings Menu

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

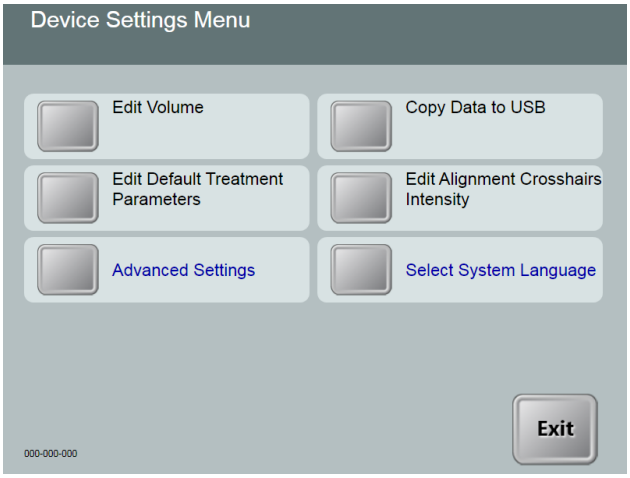



**Figure 3-33. Device Settings Menu**

## 3.17.1 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.

## 3.17.2 Editing System Language

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

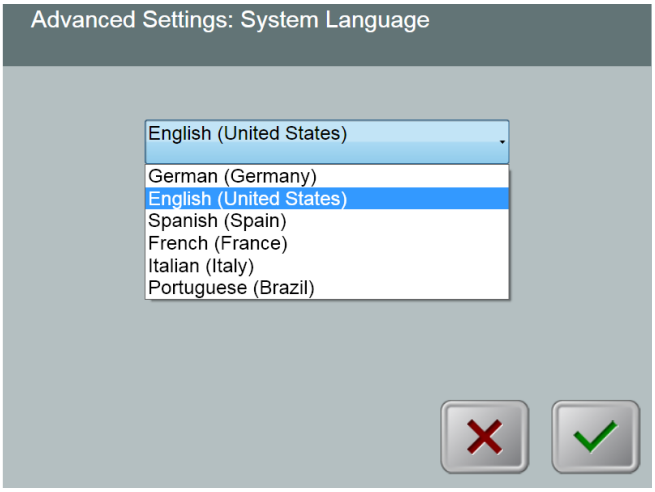



**Figure 3-34. Edit System Language**

## 3.17.3 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.

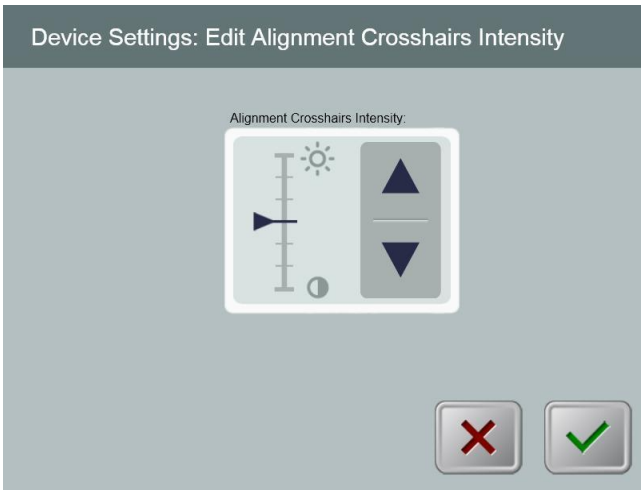



**Figure 3-35. Edit Alignment Crosshairs Intensity**

## 3.17.4 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.

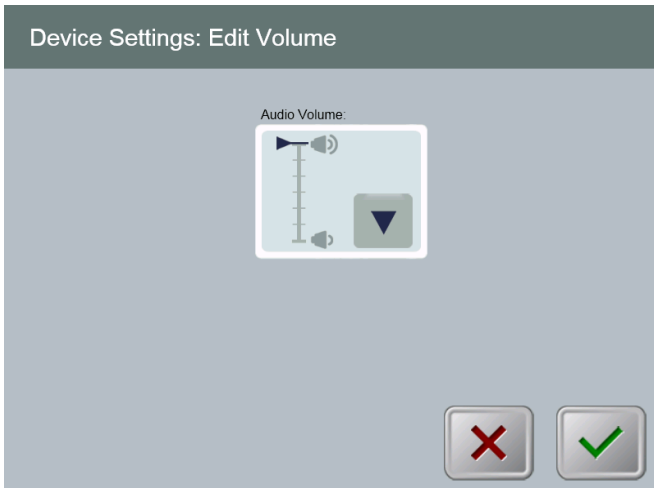



**Figure 3-36. Edit Volume**

## 3.17.5 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.

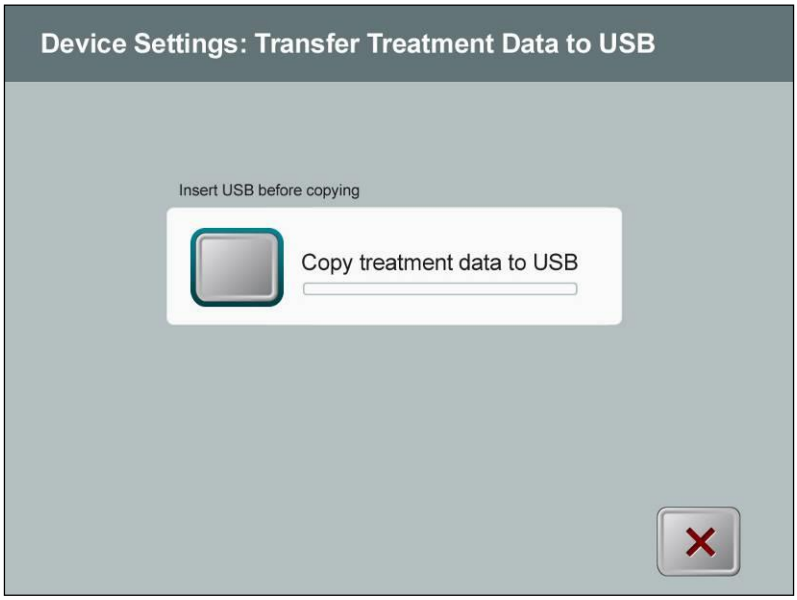



**Figure 3-37. Device Settings Transfer to USB**

- 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.

## 3.17.6 Editing Default Treatment Parameters Screen

- The Edit Default Treatment Parameters option allows a user to set the default treatment parameters that are displayed on entry to the Set Induction Time and Set UV Parameters screens.

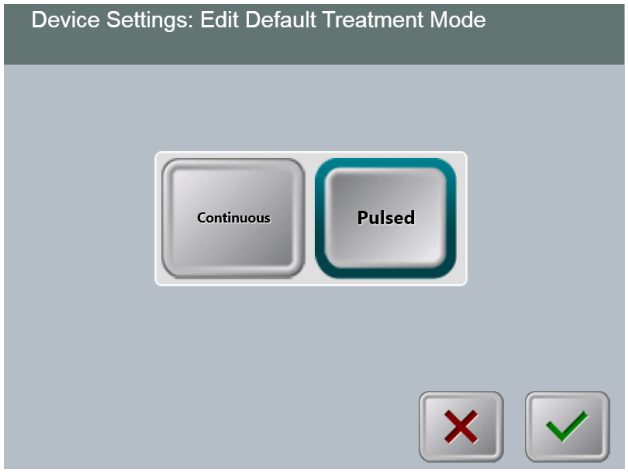



**Figure 3-38. Select Default Treatment Mode**

- Press the **Checkmark** button to continue.

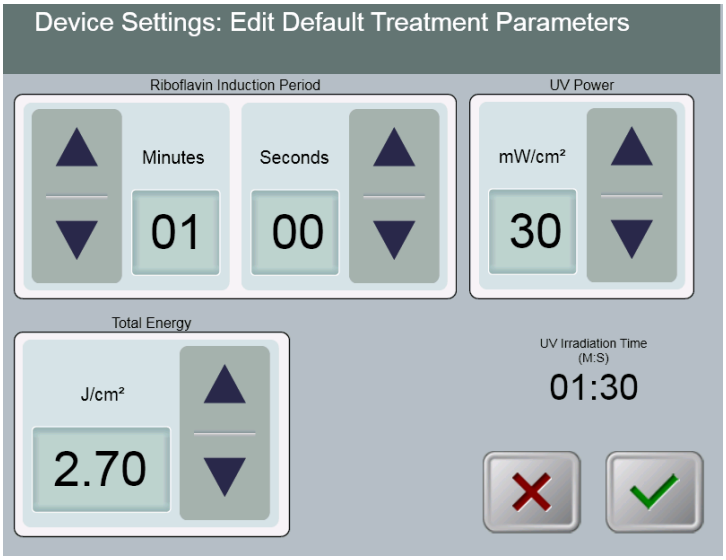



**Figure 3-39. Edit Default Treatment Parameters (Continuous & Pulsed)**

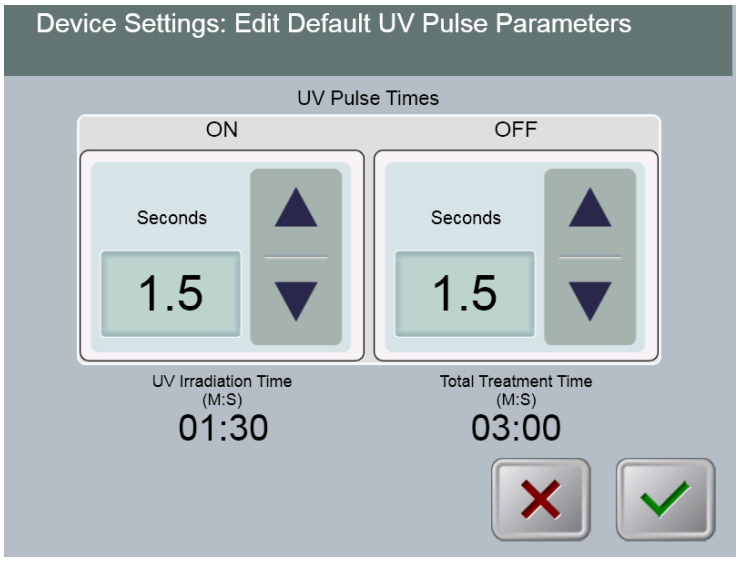



**Figure 3-40. Edit Default UV Pulse Parameters (Pulsed Only)**

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

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# 4 Maintenance / Service

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

## 4.1 Installation Policy

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

## 4.2 Customer Maintenance

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

## 4.3 Warranty Information

- A Warranty is supplied separately with the purchasing information.

## 4.4 Service Contract Information

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

## 4.5 Per Patient Disposables

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

# 4.6 Trouble Shooting

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

**Wireless Remote**

- The KXL System uses a remote control with replaceable batteries. If the batteries run low the system will lose its connection with the remote.
    - If light on the remote does not turn on or goes off, the remote's batteries may need to be changed. Replace the batteries prior to initiating a treatment.
    - If replacing the batteries does not allow the system to synchronize contact your local Avedro Service Representative.
    - If the remote loses sync during a treatment, the KXL head can be manually manipulated for manual alignment.

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

# 4.7 Directions for Sterilization or Disinfection

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

# 4.8 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 isopropyl alcohol.
- 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: The glass window of the beam aperture must not under any circumstances be in contact with any aggressive cleaning agents.**

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

## 4.9 Cleaning the Aperture

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

## 4.10 Articulating Arm Adjustment

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

## 4.11 Moving the System

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

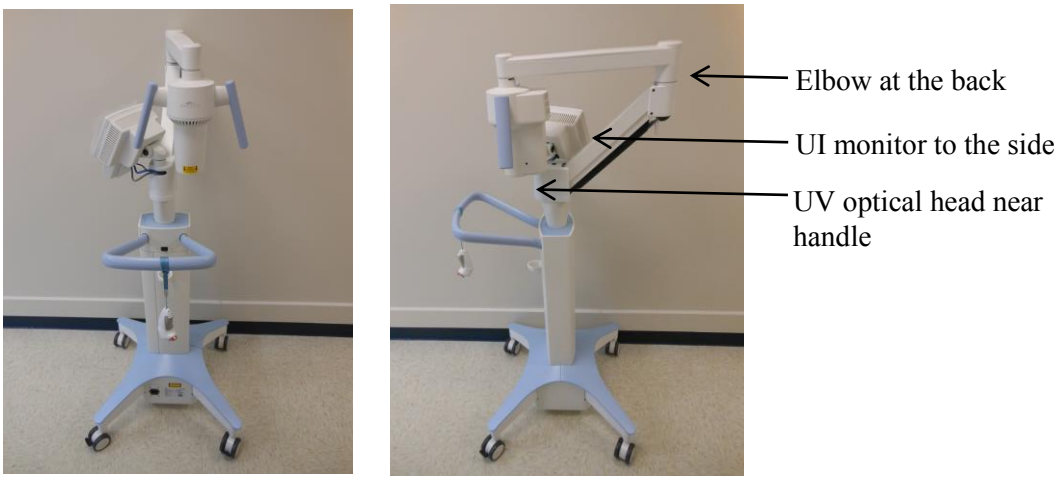



**Figure 4-1 Moving System Configuration**

## 4.12 Storing the System

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

- Close all panels on the system to prevent dust and moisture from entering; this is mandatory.
- Turn OFF all the components and 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.
- If systems are left unused for more than 6 months, the system battery should be charged. See Section 3.1 for charging instructions.

## 4.13 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.

## 4.14 Identifying Risks Associated with Disposing of Waste Products

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

## 4.15 Performing a Visible Check

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

# 5 Equipment Classification

**According to EN60601-1 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 as aesthetic mixture
  - No protection
- Use conditions
  - Continuous service

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

- Class B

**According to EN60825-1 Safety of laser productions**

- Alignment lasers are Class 1 Laser Product

**According to EN62471 Photobiological safety of lamps and lamp systems**

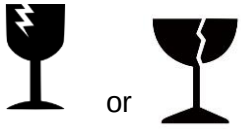
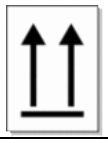
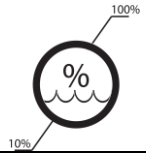
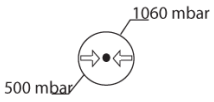
- UVA LED is Risk Group 1

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

- Class IIa

# 6 Symbol Library

| Text Symbol | Symbol Illustration | Definition |
|---|---|---|
| 1. No AP symbol in presence of flammable anesthetics | | Danger, Risk of Explosion. Not for use |
| 2. AC symbol | | Alternating current |
| 3. “I” in a book | | Attention: Consult ACCOMPANYING DOCUMENTS |
| 4. Ground symbol in circle | | Protected earth (ground) |
| 5. 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)<br>Gross Weight (kgs) | NW<br>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 |   | Contents are fragile, handle with care |
| 14. Two up arrows |  | Keep arrows on carton pointing up |
| 15. Percentage sign over wave with limits |   | Humidity limits (percentages on either side of symbol are the acceptable range for humidity) |
| 16. Temperature limits | | Temperature storage/operating limits |
| 17. Pressure limits |   | Atmospheric pressure limits (storage / operating) |
| 18. Signal emitted | | RF transmitted through device |

# 7 Specifications

| Specification | Description |
|---|---|
| **Electrical** | Battery Powered: 12V 35 Ah SLA<br>Line voltages 100 – 240 volts AC<br>Current 2A – 1A<br>Single Phase<br>RMS, 50/60 Hz<br>Remote 2x AAA batteries |
| **User accessible Fuses** | 250 V~ T2AH |
| **Energy Delivery** | UV Radiation<br>3 – 45 mW/cm$^2$<br>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<br>GW 120 Kg |
| **Battery Life**<br>**(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% , 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 |