GLAUKOS®

KXL® System Operator's Manual

Model Number: 110-01019

Avedro, a Glaukos Company
30 North Ave.
Burlington, MA 01803 USA
Tel: +1.781.768.3400

EC REP EMERGO EUROPE B.V.
Wertervoortsedijk 60
6827 AT, Arnhem
The Netherlands
Tel: +1.31.70.345.8570

CE 2797

KXL® System Operator's Manual

ML-000157 Rev. 4
03/2025

Patents, Trademarks, Copyrights

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

KXL® is a registered trademark of Avedro, a Glaukos Company. All software and documentation are subject to Avedro, Inc. copyrights. Avedro is a wholly owned subsidiary of Glaukos® Corporation. Glaukos® is a registered trademark of Glaukos Corporation.

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.

About Manual

This manual is also provided in an electronic format and is available on the Glaukos website at www.glaukos.com. Adobe Acrobat is required. To obtain a paper copy of this manual at no additional cost, within 7 days, contact Glaukos Customer Service at: +1 (844) 528-3376 or orders@glaukos.com.

Information in this manual is subject to change without notice. For the latest manual, always refer to the Glaukos website. The depictions of the KXL System and operator interface screenshots included in this manual are for illustrative purposes only; actual product may vary.

Table of Contents

Table of Figures

1. FOREWORD

1.1. Intended Use of Manual

This manual is designed to serve the operators of the 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 strictly applied.

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. Intended Users

Intended users are trained licensed medical professionals.

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

1.4. Intended Use Environment

The KXL System is intended for use in a professional healthcare environment. It can be used in both inpatient and outpatient settings including physician's offices, clinics, and hospitals.

1.5. Intended Patient Population

Patients who require crosslinking procedures to stabilize the cornea which has been weakened by disease or by refractive surgery.

1.6. Contraindications

Use of the KXL system is contraindicated for the following conditions:

- 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

1.7. Precautions

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

1.8. Side Effects

Side effects are unintended, but predictable, symptoms that can develop while under therapy by taking a medication or using a medical device. They can happen at normal, recommended doses, and are unrelated to the intended purpose of the medication. Side effects are mostly foreseen by the physician and the patient should be instructed to be aware of the effects that could happen while on the therapy. Side effects typically resolve on their own with time. Side effects that may occur with KXL Corneal Cross-Linking include, but are not limited to:

- Conjunctival hyperemia
- Epiphora
- Blurred vision
- Stinging/burning sensation
- Foreign body sensation
- Pruritis

1.9. Adverse Event Reporting

Adverse events and/or serious incidents must be reported to Glaukos Corporation at MedicalSafety@glaukos.com.

1.10. Safety Definitions

Keyword statements may be used throughout the manual to emphasize important safety and critical information. These statements are defined below.

DANGER: A potentially hazardous situation which, if not avoided, will result in death or serious injury.

WARNING: A potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION: A potentially hazardous situation which, if not avoided, may result in minor or moderate injury or damage to the equipment or other property.

IMPORTANT: A note containing important information to aid in understanding or using the instructions.

NOTE: A note containing additional information to aid in understanding or using the instructions.

1.11. Electrical Safety Warnings

This equipment requires special precautions regarding electromagnetic compatibility (EMC). Installation and use should be carried out according to the EMC information provided in this manual.

Portable and mobile RF communications equipment can affect medical electrical equipment such as the Glaukos KXL System.

For equipment classifications please refer to Section 5: Equipment Classification.

Use only Glaukos products or Glaukos-approved products with your KXL System. Glaukos shall not be liable for damage to or malfunction of the system, caused by using unauthorized materials.

	Electrical Safety Warnings
1.	Any repair or service must be carried out by Glaukos trained personnel only. Do NOT modify this equipment without authorization of the manufacturer.
2.	To avoid the risk of shock this equipment must only be connected to a supply mains with protective earth. To separate system connection to mains, grasp the power cord plug and pull it from outlet to disconnect. The system is designed for continuous operation using the external connector.
3.	This equipment is operated with hazardous voltages that can shock, burn, or cause death. To reduce the possibility of electrical shock, and inadvertent UVA exposure do not remove any fixed panels. Ensure that all service to the system, beyond what is described in this manual, is performed only by qualified Glaukos authorized service personnel.
4.	Power down system and remove the wall plug before servicing or cleaning (disinfecting) the equipment. Never pull cords to remove the power cord from the outlet. Grasp the power cord plug and pull it from the outlet to disconnect. The equipment must be positioned so that it is not difficult to remove the power cord from the outlet.
5.	Do not operate the equipment with a damaged power cord.
6.	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.
7.	Do not use the instrument near water and be careful not to spill liquids on any part of it.
8.	Do not operate the KXL System in the presence of flammable mixtures or anesthetics.
9.	Never look directly into the UV light beam. Never direct the beam towards a person except for therapeutic purposes.
10.	Ignoring local regulations on use of electro-optical medical devices may cause malfunction due to electromagnetic interference.
11.	The remote control contains replaceable batteries. Remove the batteries if system is not going to be used for an extended period of time.
12.	Use of non-approved accessories results in non-compliance of the device.
13.	System may be interfered with by other equipment even if that equipment complies with CISPR Emissions requirements. See Section 5: Equipment Classification.
14	Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
15.	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the KXL system (110-01019), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
16.	System shall not be serviced or maintained while in use with a patient.
17.	MR Unsafe – Keep away from magnetic resonance imaging equipment.
18.	Do not use a damaged or malfunctioning device. Use of such devices may harm the user and/or patient.

1.12. Radiation Safety Warnings and Cautions

 **Radiation Safety Warnings**	
1.	Use only laser grade instruments to prevent reflected UV radiation from smooth metallic surfaces.
2.	UV emitted from this product. Avoid eye and skin exposure to unshielded products. Never direct the beam towards a person except for therapeutic purposes.
3.	UV emitted from this lamp. Skin or eye injury could result. Avoid exposure of eyes and skin to unshielded lamp.

 **Radiation Safety Cautions**	
1.	UV emitted from this lamp. Skin or eye irritation. Minimize exposure.
2.	UV emitted from this lamp. Possible skin or eye irritation can result from exposures exceeding 15 minutes in a day. Use appropriate shielding.

1.13. Additional Safety Considerations

Any modification of the system's external light beam by means of optical elements is prohibited.

Plastic instrumentation such as speculums or eye shields may be damaged when impacted by the UV beam, resulting in possible product degradation. Therefore, only Glaukos recommended accessories, or stainless-steel surgical instruments should be used.

1.14. 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 local Glaukos distributor help.
- Properly shielded and grounded cables and connectors must be used to meet FCC emission limits. Proper cables and connectors are available from Glaukos. Glaukos 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 round, broad-beam 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 KXL is a transportable system with an articulating arm to allow movement of the system for alignment of the UV Beam to the patient's cornea.

The optics head houses the UVA irradiation mechanism and camera. The system emits a UVA radiation at a wavelength of 365 nm (+/- 8 nm) at a variable irradiance between 3 mW/cm² to 45 mW/cm².

An aperture is used to produce a uniform circular area of irradiation in the intended treatment area 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 is controlled through a wireless remote control. User interface allows treatment irradiance and total energy to be selected by the user.

The KXL System is used in conjunction with a Riboflavin solution and an RFID treatment card. Each of the three treatment cards stores the number of treatments and the range of selectable treatment parameters for that particular treatment. The KXL System is compatible with the following riboflavin products:

Riboflavins	
Treatment/Treatment Card	**Formulation Brand**
Lasik Xtra® treatment	VibeX® Xtra
Accelerated Epi-off treatment	VibeX® Rapid
Trans-Epithelial treatment	Trans-Epithelial Kit: (ParaCel Part 1, ParaCel Part 2)
NOTE: Please reference riboflavin Instructions for Use (IFU) for formulation information.	

2.2. Major Components

The major components of the KXL System (Model Number: 110-01019) include the following:

- Optics head with UV source and camera
- KXL console with user interface
- Wireless remote control (with replaceable batteries)
- Hospital grade AC power cable (Lockable/detachable)

Figure 1. Overview of KXL System (Model Number: 110-01019)

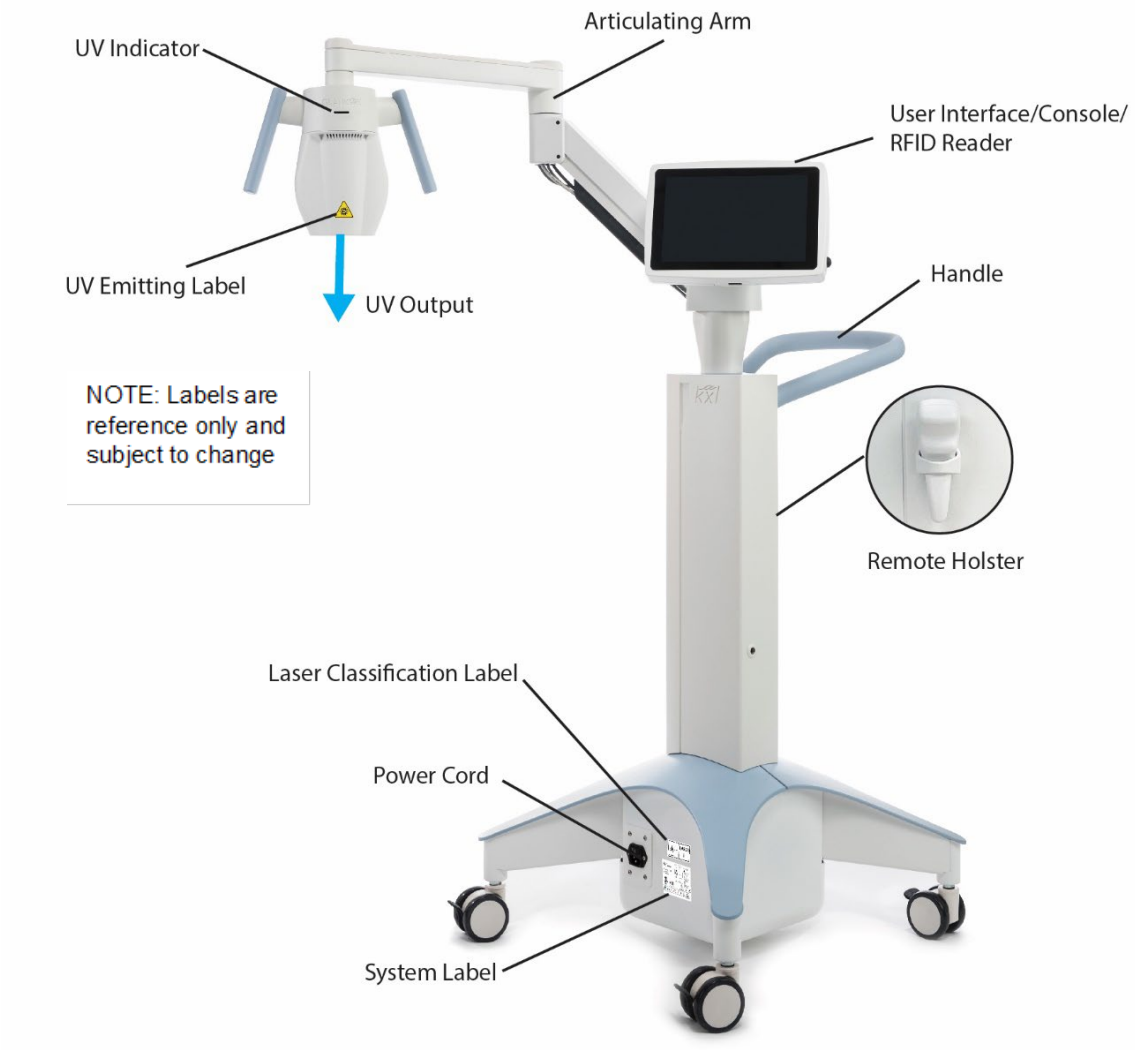


Figure 2. System Components and System Labeling Location

Figure 3. Wireless Remote Control

NOTE: If using legacy remote, refer to Appendix 1 for information on operation and troubleshooting.

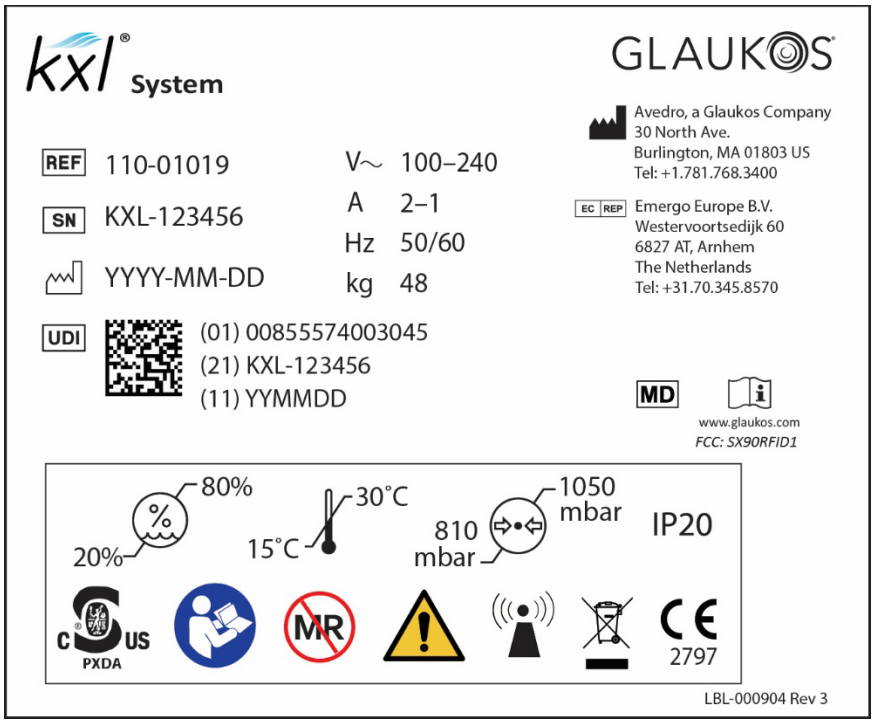


Figure 4 System Label

Figure 5. UV Label

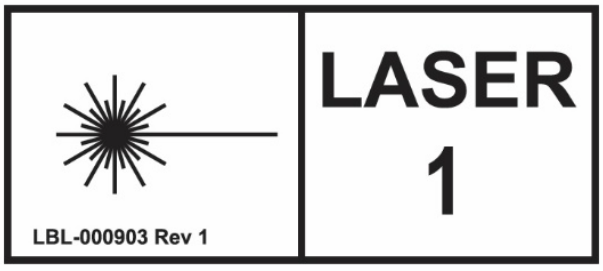
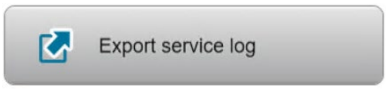
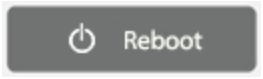
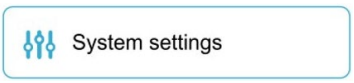
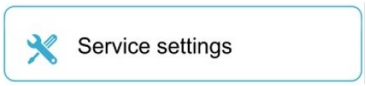
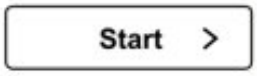


Figure 6. Laser Classification Label

3. SYSTEM OPERATION

3.1. Touchpad/Keyboard Use

The table below identifies and describes important touchpad keys and icons unique to KXL System operation. Section 2.2: Major Components identifies and describes the KXL System's major components.

Icon	Description/Function
	Export service logs.
	Reboot system if system start pretest is unsuccessful.
	Turns off electric power to the console.
	Display system settings. Options include system settings, service settings, demo mode.
	Device settings menu is displayed. Settings include audio volume, camera white balance, system language, export service log, alignment crosshairs intensity.
	Ability to edit default parameters. Settings include system diagnostics, manufacturing settings (head serial number, system serial number), UV calibration, change date and time. NOTE: Only available to service personnel.
	Launches system demo mode. NOTE: UV delivery is not accessible during demo mode.
	Starts preset or modified treatment plan for patient.
	Cancels all entries on a screen and returns to the previous screen. Cancels a treatment session for a patient.

Icon	Description/Function
Confirm	Directs the system to accept the current treatment parameters on the treatment confirmation screen and to proceed to the next step.
+	Increases the value of the current field.
−	Decreases the value of the current field.
Save as clinic preset	Allows user to save modified treatment parameters into clinical presets on system and moves user to manage clinic presets screen.
Delete	Deletes clinical preset with modified treatment parameters.
Close	Closes current screen without saving any changes.
Save	Saves modified treatment parameters into clinical presets on system.
OK	During remote control synchronization, allows user to retry remote control synchronization.
Start timer	Starts riboflavin induction timer.
Continue	If remote control synchronization fails, allows the treatment to continue without the remote control.
Start treatment	Once crosshairs are aligned, this button starts UV therapy.
Pause treatment	Pauses UV treatment. NOTE: Two pauses of two minutes each (four minutes total) are available per patient.

Icon	Description/Function
	Resumes UV treatment during pause.
	Exports treatment summary report.
	Completes treatment without exporting treatment summary report. Allows user to exit settings screens.
	Allows user to return to treatment summary screen to export treatment summary report.
	Allows user to complete treatment without exporting treatment summary report.
	Allows user to export treatment summary report onto user provided USB.

3.2. UV Energy (Dose)

The UV Radiant exposure (Dose) is the product of the UV Irradiance and the UV Irradiation Time. The Dose and UV Irradiance are adjustable, and the calculated UV Irradiation Time is displayed.

The System tracks Dose, UV Irradiance, UV Irradiation Time, and Total Treatment Time during the treatment

These options can be modified within the treatment confirmation screen. See Section 3.8 Modified Treatment.

There are two UV treatment modes available, Continuous and Pulsed. In Continuous mode UV output is constant for the duration of the treatment. In Pulsed mode, UV output turns on and off at user selected intervals.

For complete treatment parameters refer to the Section 7.2 Treatment Parameters including default setting and treatment range.

3.3. Before Powering on the System

The user is responsible for ensuring that the KXL System is functioning properly before starting a treatment.

To ensure the system is functioning properly, consider the following mandatory points:

- Inspect the device, accessories, and connecting cables for visible damage.
- Check glass window of beam aperture for dust and dirt. See Sections 4.6 and 4.7 for cleaning instructions.
- Consider local regulations for the use of portable electro-optical medical devices.

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.

Keep the optics head with UV source and camera away from bright lights (i.e., such as positioning in front of windows) when system is in use.

3.5. Powering Up the System

Power on the mains power switch on the base of the KXL System, adjacent to the power cord connection. This switch provides AC mains power to the KXL System. See figure below.

Press and release the on button on the side of the KXL display screen. figure below. The KXL System will begin a power-up sequence, which loads the operating system, launches the application, and runs a power-up test.

NOTE: If there is a start-up error, please refer to the Error Message Table in Troubleshooting System section 4.5 for more information.

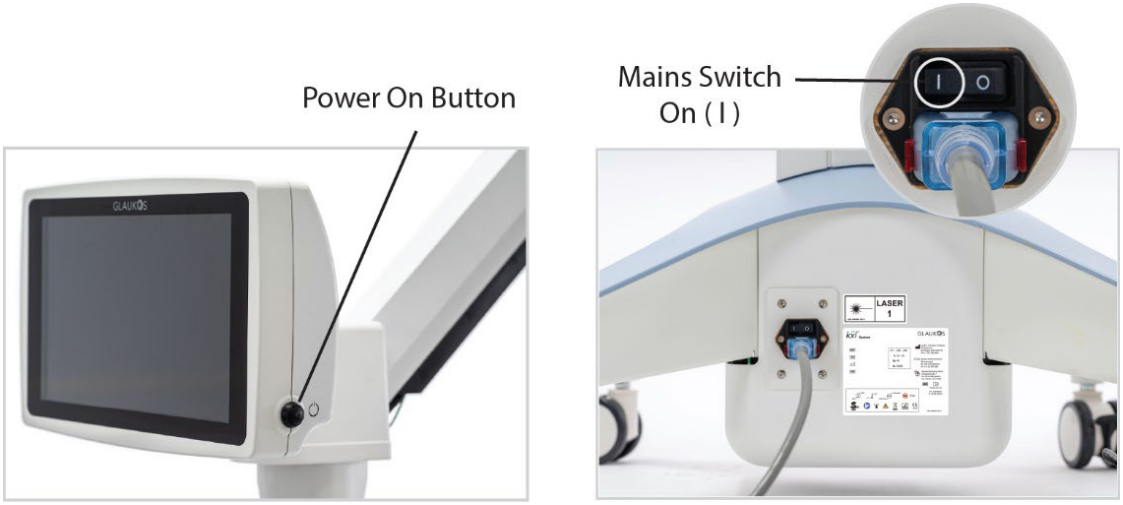


Figure 7. Power-on Button (left) and Mains Power Switch (right)

On the title screen, press Start to progress to the patient treatment screen.

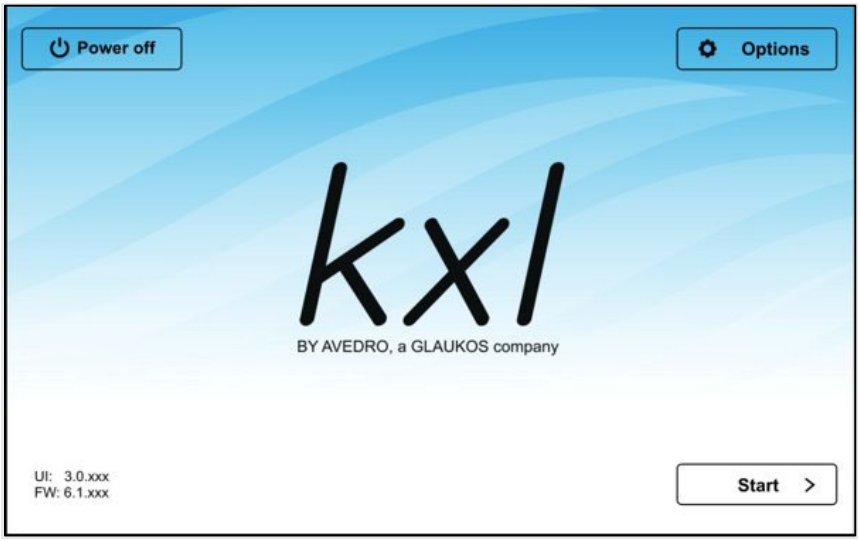


Figure 8. Title Screen

3.6. Treatment Activation Card

The treatment card is required to activate the system. KXL system treatment cards are included with the following riboflavin products.

Riboflavins	
Treatment/Treatment Card	**Formulation Brand**
Lasik Xtra® treatment	VibeX® Xtra
Accelerated Epi-off treatment	VibeX® Rapid
Trans-Epithelial treatment	Trans-Epithelial Kit
NOTE: Please refer to riboflavin Instructions for Use (IFU) for formulation information.	

Insert the treatment card into the RFID slot located to the left of the display screen.

NOTE: If there is a problem reading the card, rotate the card and then reinsert. Be sure to leave the card in the slot for at least 10 seconds.

Figure 9. Insert Treatment Card Screen

3.7. Treatment Confirmation

Once the treatment activation card has been inserted, select the eye to be treated: OS or OD.

NOTE: Be sure to select eye to treated or Confirm button will be unavailable.

The treatment confirmation screen will populate with the default parameters for the following treatment type, riboflavin formulation, and default treatment parameters.

NOTE: Default treatment parameters and full range of treatment parameters for the KXL System are available in Treatment Parameters Section 7.2 of this manual.

To use the default settings, press confirm to start remote control synchronization. To change treatment settings, see Modified Treatment section 3.8 below.

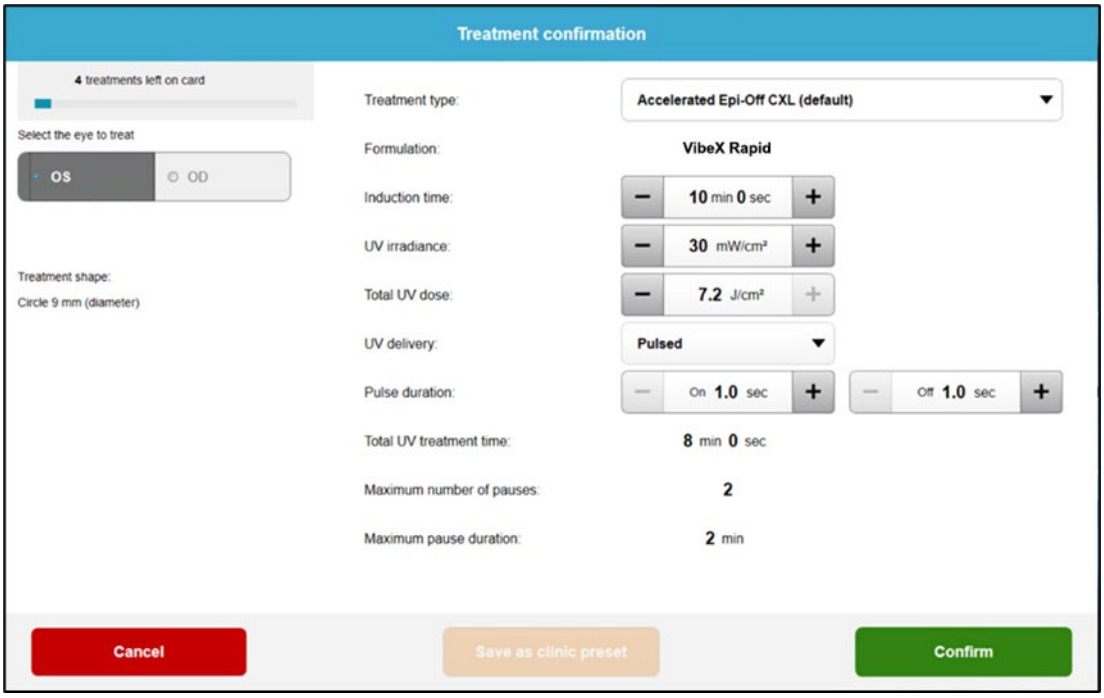


Figure 10. Save Modified Treatment as Clinical Presets

3.8. Modified Treatment

The following default parameters may be adjusted to create a modified treatment by pressing the up (+) and down (-) keys, see Figure 11:

- Induction time
- UV irradiance
- Total UV dose
- UV delivery (pulsed or continuous) If pulsed UV delivery is selected, pulse duration can also be adjusted.

NOTE: While parameters can be adjusted, the total UV dose is controlled by the treatment activation card limits.

After settings are modified, press confirm to start remote control synchronization, or if desired you may save the modified setting as a preset for future use. See Setting Presets on the following page.

Setting Presets

Presets allow the user to save four clinical presets for each treatment type. To save a clinical preset, press to select an available preset; then press save.

Presets may be deleted if no longer needed.

NOTE: Presets are stored and available on Treatment Confirmation Screen under the Treatment type drop down.

Figure 11. Save Modified Treatment as Clinical Presets

3.9. Remote Control Synchronization

Once settings have been selected, press confirm on the treatment confirmation screen. The system will give 15 seconds to synchronize the remote control.

Figure 12. Sync Remote Screen

Press any directional button on the remote to synchronize the remote within the 15-second timeframe. This is required for every procedure if use of the remote is desired.

The KXL system will beep every 2 seconds during the 15-second sync timeframe.

If the sync button on the remote control is not pressed within the 15-second timeframe, the sync remote timeout screen will be displayed.

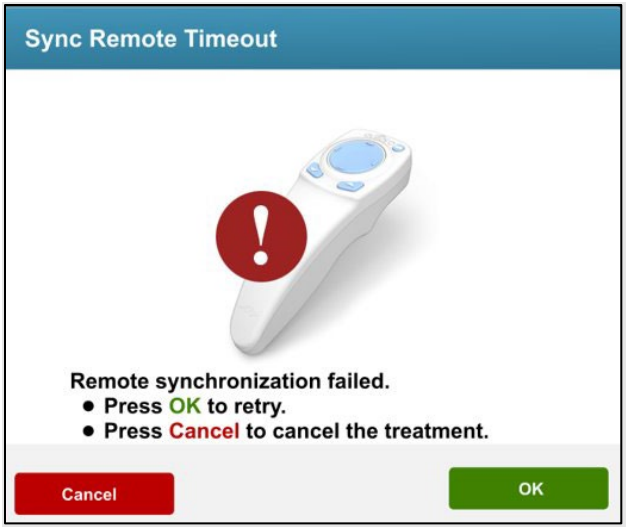


Figure 13. Sync Remote Timeout Popup Screen

If this problem occurs, see Remote Control Status Indicators on the following page for possible battery issues.

The user may attempt to resynchronize the remote twice. If the synchronization is unsuccessful, the system will give the option to continue the treatment without the remote or cancel the treatment.

IMPORTANT: The user can still use onscreen controls for adjusting UV alignment without the remote.

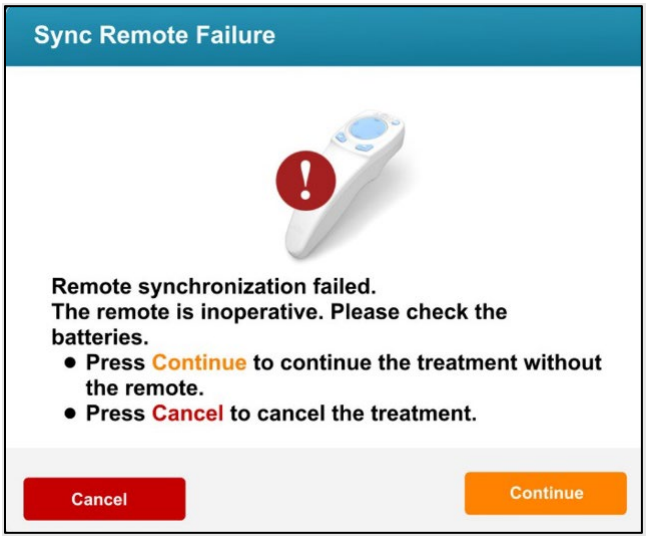


Figure 14. Sync Remote Failure

Remote Control Indicators

The remote control has two indicator lights that provide status information about the remote and battery. The thumbpad light illuminates around the thumbpad and the battery light illuminates around the battery button. If there is a problem syncing to the system or with the battery, refer to the table below for help.

Remote Indicators	
'Thumbpad Light' Indicator	**Meaning**
No illumination	Off
Revolving blue light	Synchronizing
Steady blue light	Synchronized and ready
Steady orange light	Lost synchronization
'Battery Light' Indicator	**Meaning**
No illumination	Off
Steady blue light	Battery is ok
Steady orange light	Battery needs replacing
Steady blue light	Battery must be replaced (2 AA)

3.10. KXL System Internal Self-Test

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 occurs, and the treatment cannot proceed. If this happens, please note any error message and use the error messages table for follow-up action.

3.11. Prepare the Patient

Ensure that the patient is lying flat in a supine position on a treatment table or reclining treatment chair. The patient's head should rest on 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.

- Epithelium Off: If an "epithelium off" procedure is being performed, remove the corneal epithelium prior to application of riboflavin.
- Epithelium On: If an "epithelium on" procedure is being performed, do not remove the corneal epithelium prior to application of riboflavin.
- Lasik Xtra: If a "Lasik Xtra" procedure is being performed, apply riboflavin to the exposed stromal bed immediately following excimer laser ablation prior to repositioning the corneal flap.

3.12. Riboflavin Induction

Riboflavin application shall be in accordance with the appropriate riboflavin instructions for use (IFU). For further information on KXL supported riboflavin formulations, refer to the appropriate riboflavin IFU.

Prepare for Treatment

After the patient's eye has been prepped with the initial application of riboflavin, press start timer to start the riboflavin induction.

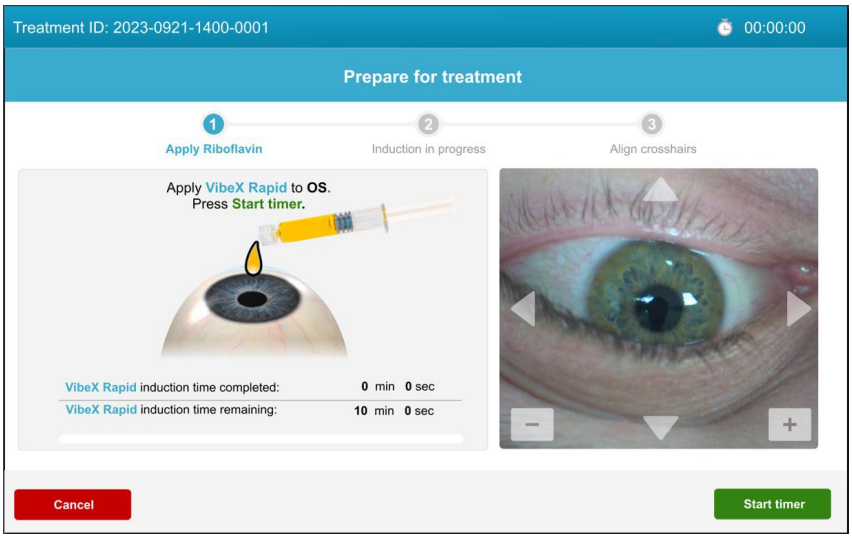


Figure 15. Prepare for Riboflavin Induction Screen

Riboflavin Induction

The KXL system will provide audible and visual guidance for timed riboflavin application during the induction period.

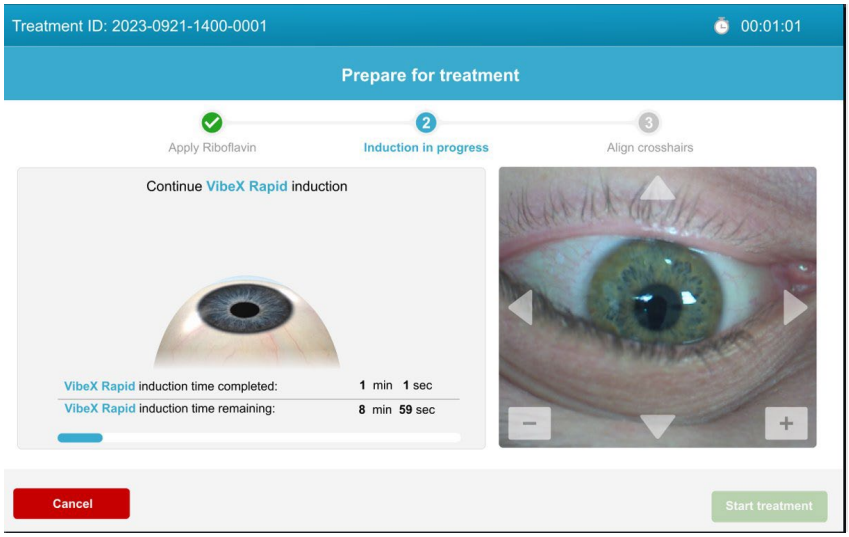


Figure 16. Induction in Progress Screen

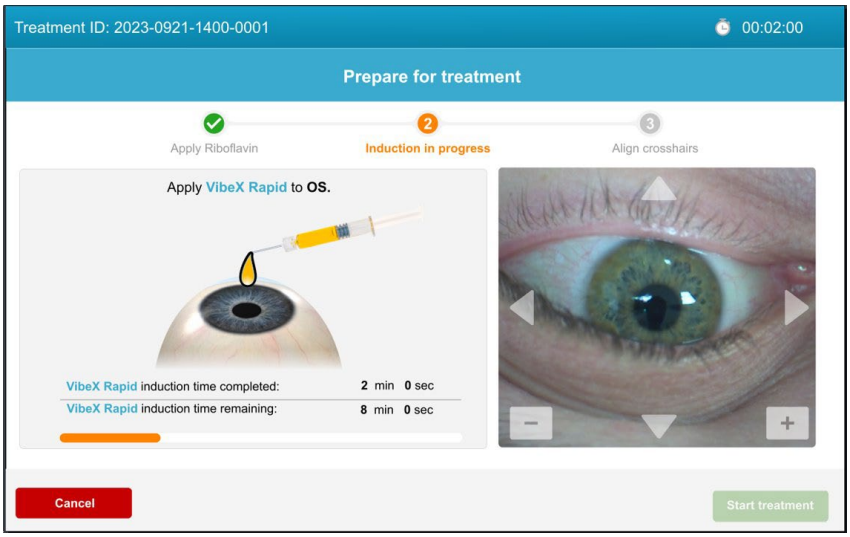


Figure 17. Visual Guidance During Riboflavin Induction Period

3.13. Align Crosshairs to Patient's Cornea

NOTE: Red alignment lasers will turn on 60 seconds before the end of the riboflavin induction period.

After the riboflavin induction has been completed, align laser crosshairs to the patient's cornea.

Manually move the KXL head back and forth and left and right until the X/Y axes' red crosshairs are aligned to the center of the pupil to be treated.

Manually move the KXL head up and down to align the Z axis second red crosshair to the center of the first red crosshair.

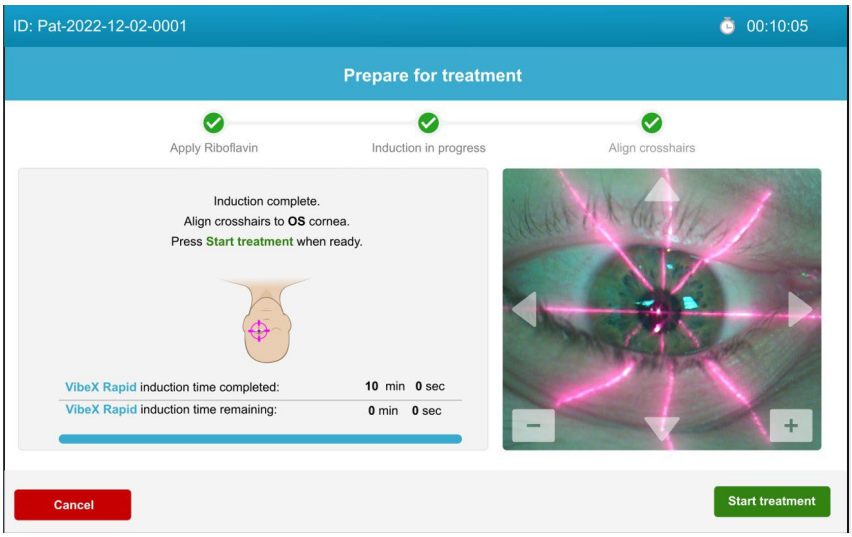


Figure 18. Red Alignment Crosshairs on Patient's Cornea

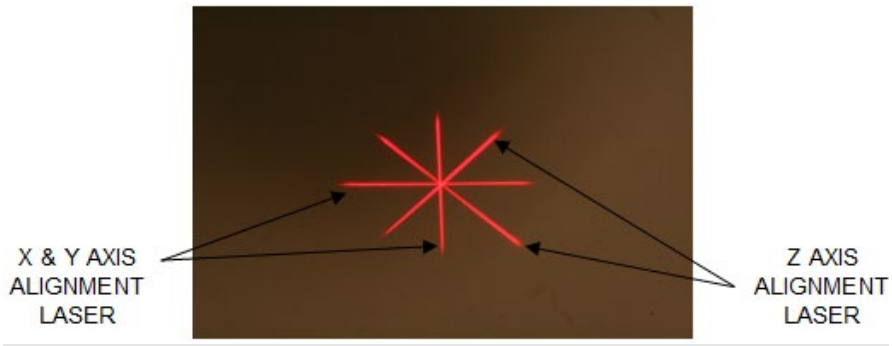


Figure 19. Alignment of Red Crosshairs

Fine adjustments to alignment can be achieved using the wireless remote or by pressing the onscreen arrows.

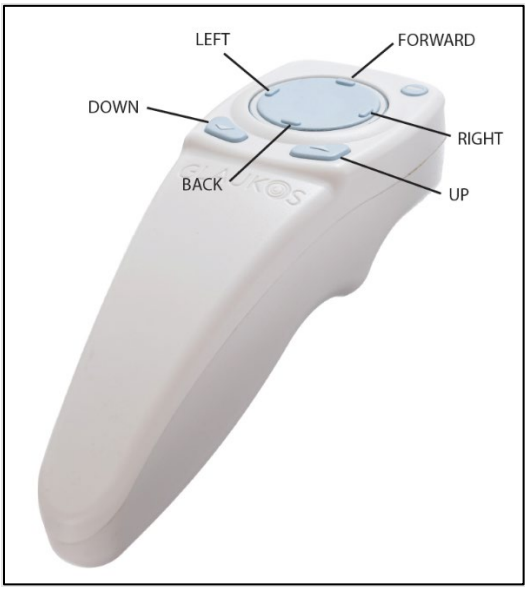


Figure 20. Remote Alignment Functions

If the remote is deactivated, fine alignment may be also achieved manually using the onscreen arrows (left, right, forward, back) and up (+) and down (-) keys.

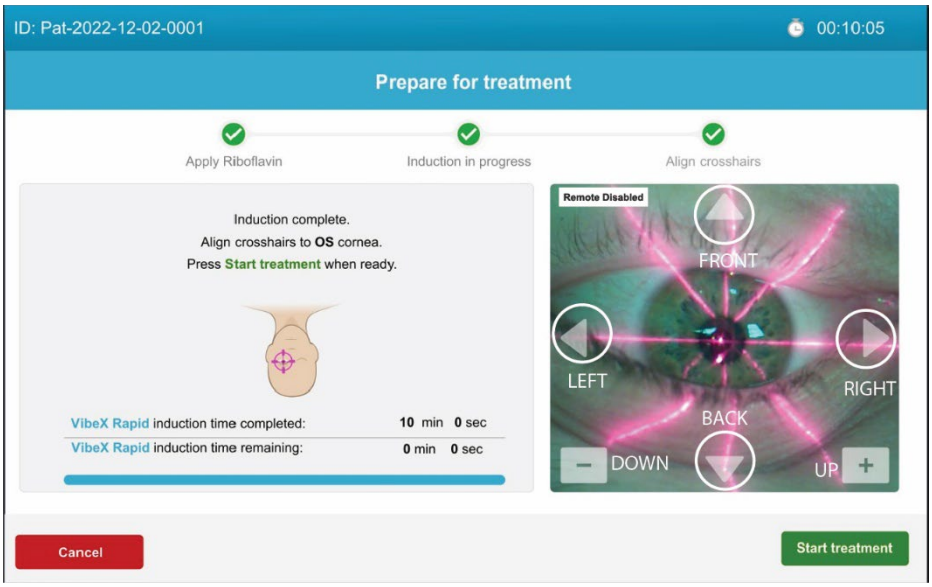


Figure 21. Fine Alignment Onscreen

3.14. Start UV Treatment

Initiate UV treatment by pressing start treatment.

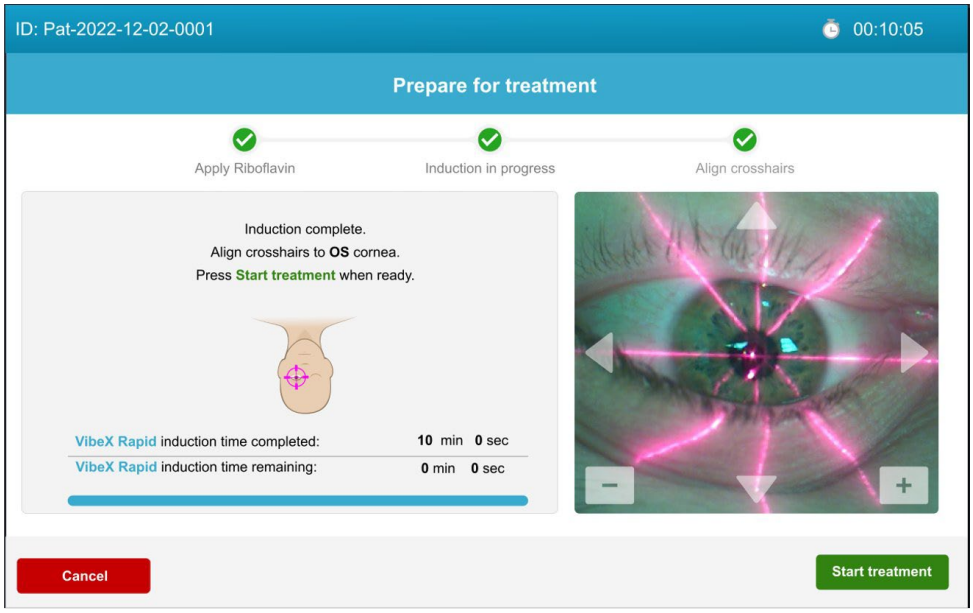


Figure 22. Start UV Treatment

Advise the patient to remain still and fixate on the red X and Y alignment crosshairs throughout the treatment.

Warnings	
1.	Start treatments only after the riboflavin is applied.
2.	Make sure that the KXL System and the patient's table or chair are secured and not moved after alignment and during treatment.

Caution	
1.	UV light is emitted when the UV light indicator window located on the optical head flashes color from blue to green.

3.15. Monitoring UV Treatment

Check continuously that the intended treatment area on the cornea is illuminated with the UVA light and adjust as necessary using the wireless remote or the onscreen arrows.

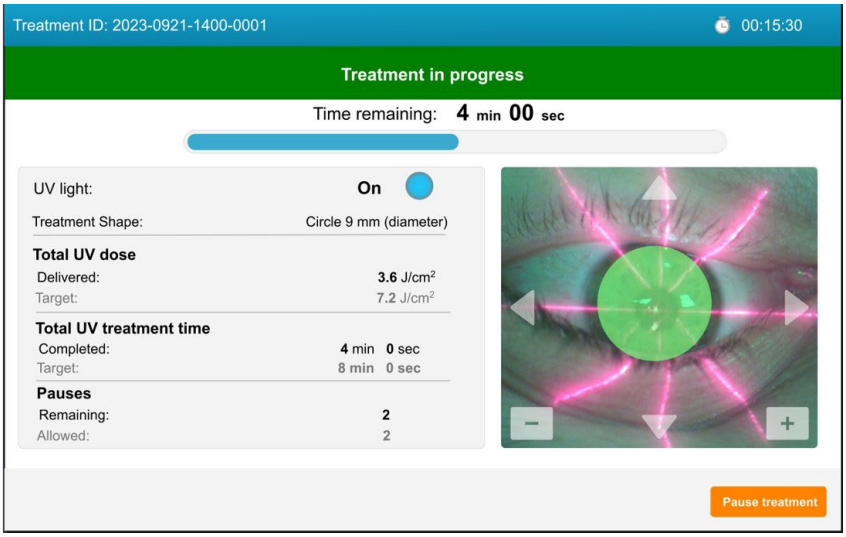


Figure 23. Treatment in Progress Screen

NOTE: When using pulsed treatment mode, UVA light will not be visible during the OFF periods. The operator interface will not change to "UV light: OFF" during these cycles.

3.16. Pausing a UV Treatment

Should the UV treatment need to be paused, the KXL System allows for each treatment to be paused twice, and each pause may last up to two minutes for a total of four paused minutes.

Press resume treatment, to continue the treatment from the same point in the treatment.

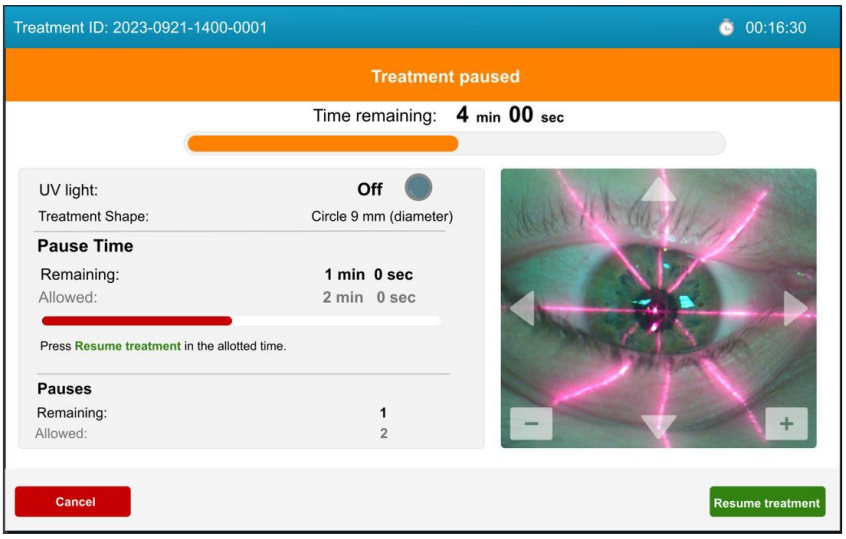


Figure 24. Paused UV Treatment

IMPORTANT: During the UV treatment, if both pauses (totaling four minutes) are exhausted the treatment can no longer be resumed. The UV treatment will have to be cancelled. Press Cancel to end treatment.

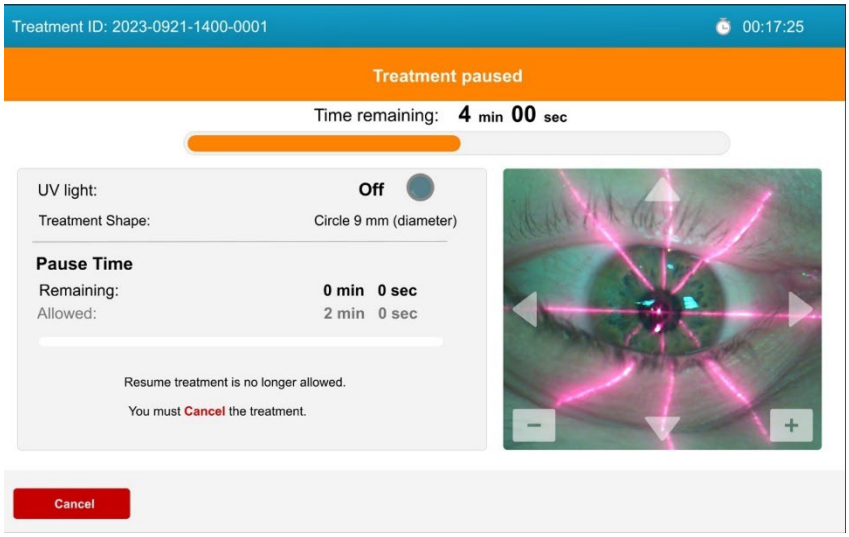


Figure 25. Treatment Pauses Exhausted

3.17. Cancelling a UV Treatment in Progress

At any time during a UV treatment in progress may be cancelled.

From the ‘Treatment in progress’ screen press Pause, and then press Cancel from the ‘Treatment Paused’ screen.

A warning pop-up will appear next, confirming that the user wants to cancel the treatment.

Figure 26. Cancellation of In-Progress UV Treatment

3.18. Completed UV Treatment

After the UV treatment is completed, the system will display the treatment summary.

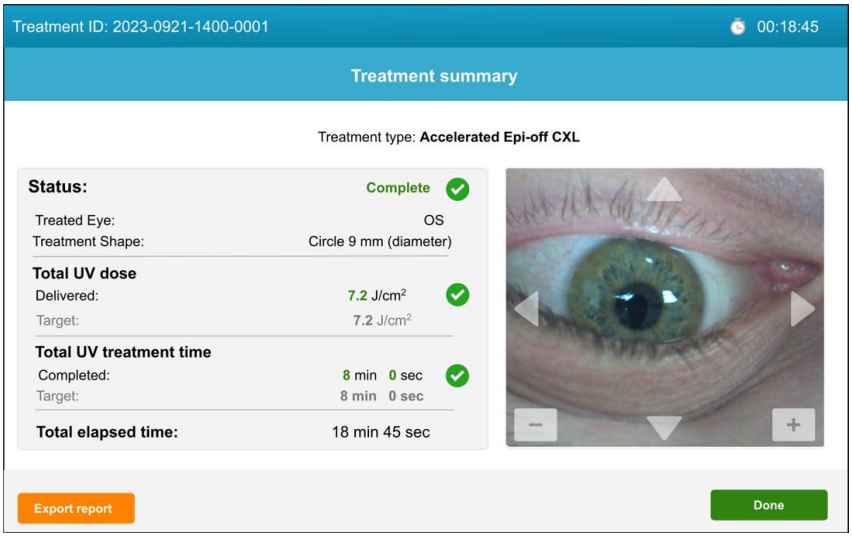


Figure 27. Completed Treatment Summary Screen

NOTE: Cancelled treatments/incomplete treatments will also be displayed in the treatment summary.

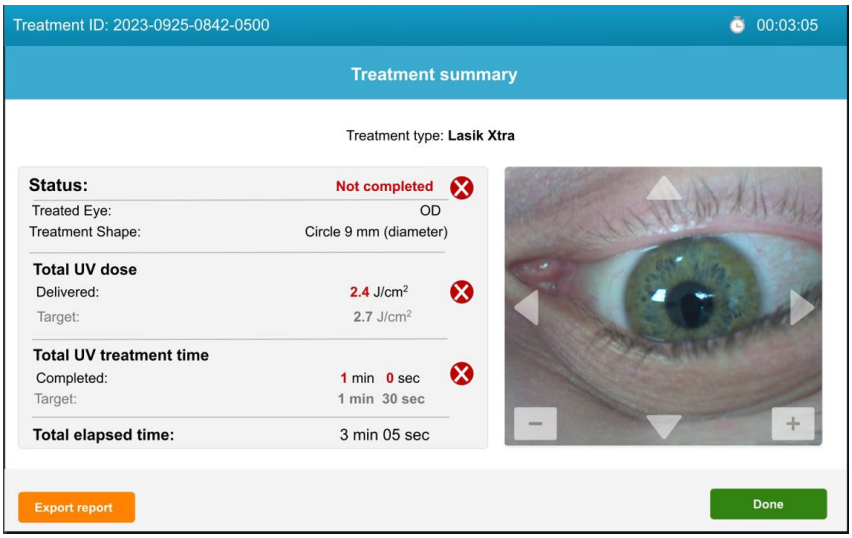


Figure 28. Incomplete Treatment Summary Screen

3.19. Export Treatment Summary Report

Treatment summary reports can be exported from the KXL System onto a customer provided USB.

- Press export report on the treatment summary screen.
- Press export on the popup screen.
- Insert customer supplied USB.

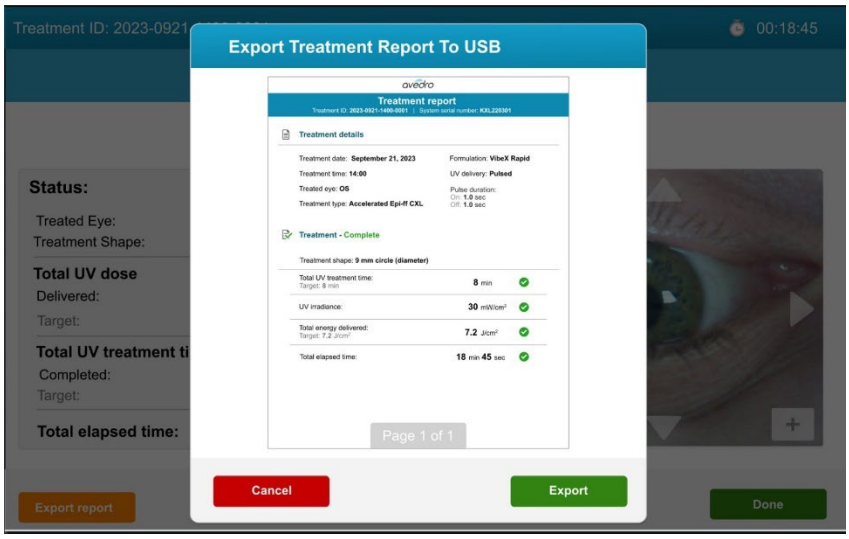


Figure 29. Export Treatment Report to USB

Figure 30. Insert USB Drive to Export Report

Treatments may also be completed without exporting the treatment summary report.

NOTE: Users can end a treatment without exporting the treatment summary report by pressing done from the treatment summary screen and then confirming the selection.

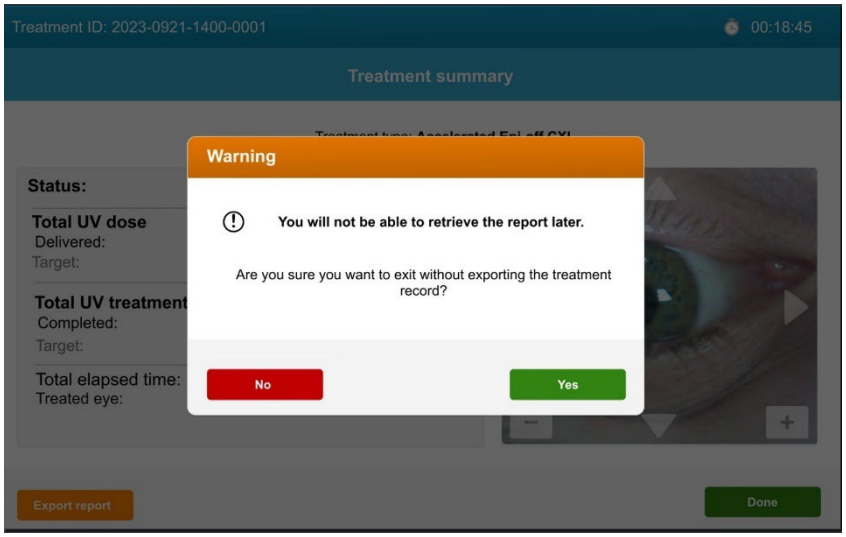


Figure 31. Completing a Treatment Without Exporting the Treatment Report

3.20. Powering Down the KXL System

After the treatment is complete, the system will return to the title screen.

Press power off to shut down to the KXL System.

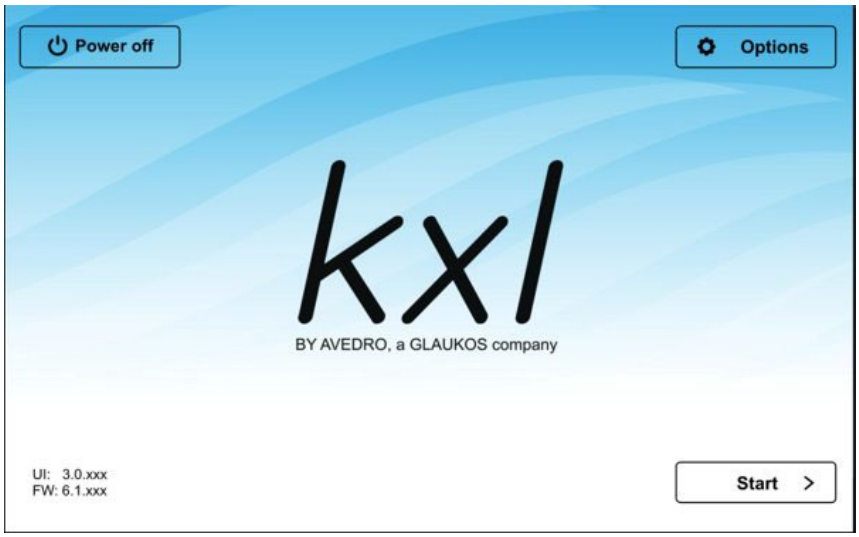


Figure 32. Power Off from Title Screen

Press yes to confirm power of the system.

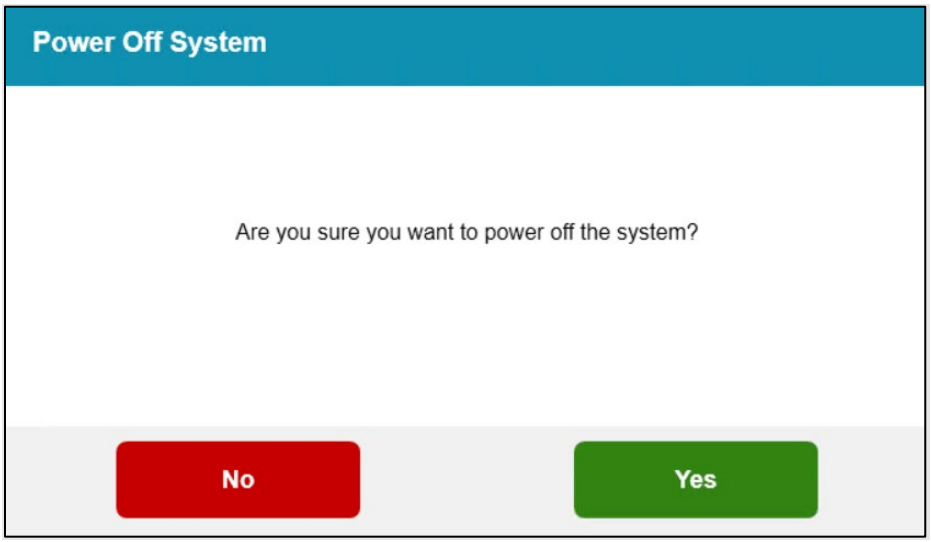


Figure 33. Confirm KXL System Power Off

Wait for the software to shut down and the screen to go blank.

Turn the mains power switch on the KXL base to the off position.

Figure 34. Mains Power Switch in Off Position

3.21. Options Menu

There are additional system settings that can be accessed from the main title screen. Press options to access the Options Menu. Three selections are available from the options menu:

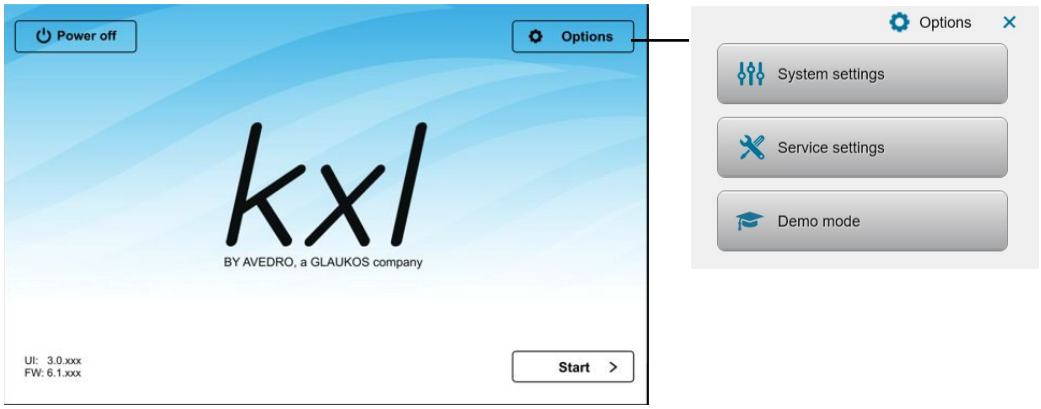


Figure 35. Options Menu

- System Settings: Five system settings that can be adjusted to user preferences.
- Service Settings: For use by Glaukos and service personnel only and requires a service access card.
- Demo Mode: Allows user training on system without using UV light or treatment cards.

3.22. System Settings Menu

Below are the system settings menu options and functionality.

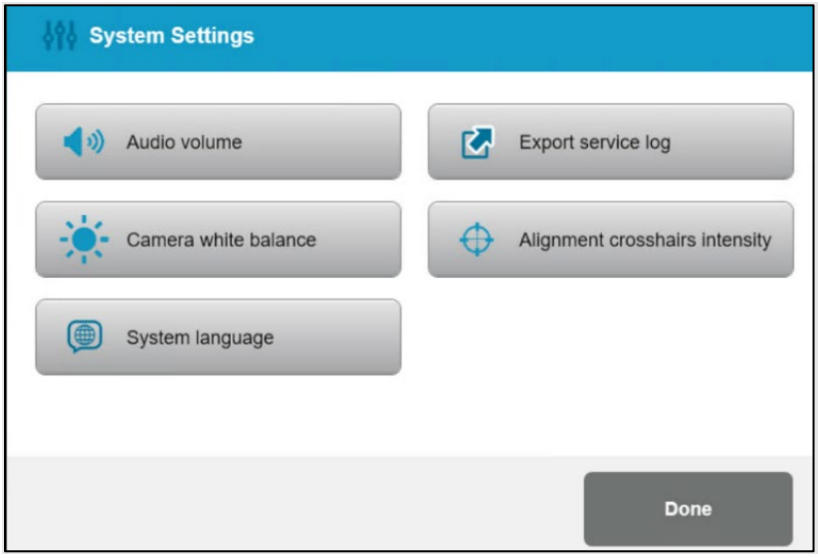


Figure 36. System Settings

- Audio volume: Allows adjustments to system's volume level.
- Camera white balance: Allows light selection between three settings: Tungsten 2800K (default), Daylight 5000K or Daylight 6500
- System language: Allows the user to change the user interface from English to one of five languages.
- Export service log: Allows the user to export service logs onto a USB (not provided).
- Alignment crosshairs intensity: Allows adjustment of alignment crosshair brightness.

4. MAINTENANCE / SERVICE

Definitions	
Maintenance	Maintenance refers to those non-technical procedures an everyday operator must perform to keep the system working properly.
Service	Service 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, a Glaukos trained/authorized personnel installs and sets up the system, and verifies the system is operating properly.

Per the KXL System user service agreement, any further hardware adjustment, other than what is specified for normal operation, should be performed by, or with the guidance of, an Glaukos-authorized distributor.

4.2. User Maintenance

The following user maintenance is recommended. Continued regular maintenance will help maintain the KXL System and its functionality.

Before each treatment:

- Inspect the device, accessories and connecting cables and power cord for visible damage; do not use if damaged.
- Check glass window of beam aperture for dust and dirt. See section 4.7 for cleaning instructions for the aperture.

Periodically inspect the KXL System and if needed clean surfaces as instructed in section 4.6.

4.3. Warranty Information

A warranty is supplied separately with the purchasing information.

4.4. Service Contract Information

A service contract is available for all KXL Systems. The contract provides regularly scheduled service and field upgrades, as well as any non-scheduled service calls that may be needed. All service must be performed by a qualified service representative while under service contract. If you have trouble with your system, refer to the Troubleshooting System section 0 for possible remediation steps.

4.5. Troubleshooting System

System Errors

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

If the event of a system error, please refer to the Error Message Table that lists errors, cause and action needed to resolve the error.

Should you experience any other difficulty that cannot be resolved while operating the KXL System, please contact your local Glaukos authorized representative.

Error Message Table			
No.	**Errors**	**Cause**	**Action**
1	UNKNOWN_ERROR	General unhandled exception handler	Contact your distributor or customer service
2	SYSTEM_SETTINGS_COULD_NOT_BE_SAVED	File io error	Contact your distributor or customer service
3	VALID_CALIBRATION_DATA_NOT_FOUND	file corruption	Contact your distributor or customer service
4	REQUEST_TO_PRIMARY_BOARD_TIMED_OUT	Loss of communication	Restart system; if error persists contact your distributor or customer service
5	COULD_NOT_CONTROL_ALIGNMENT_LASERS	HW malfunction	Contact your distributor or customer service
6	ERROR_IN_UPDATE_TREATMENTCARDUSAGE	Error communicating with RFID tag	Use another card; contact your distributor or customer service if persists
7	NOT_SAME_CARD_MESSAGE	Card was changed between treatment confirmation and induction	Use same card that started the treatment confirmation.
8	SYSTEM_ERROR	Handled exception	Restart system, if error persists contact your distributor or customer service
9	UV_TREATMENT_COULD_NOT_BE_STARTED	Start treatment rejected by FW	Contact your distributor or customer service
10	UV_COULD_NOT_BE_PAUSED	Pause command rejected by FW	Contact your distributor or customer service
11	TREATMENT_COULD_NOT_BE_COMPLETED	Complete treatment command rejected by FW	Contact your distributor or customer service
12	Packet reception failed	Loss of communication	Contact your distributor or customer service
13	Packet transmit failed	Loss of communication	Contact your distributor or customer service
14	SYSTEM_CONNECTION_HAS_BEEN_LOST_DURING_TREATMENT_TREATMENT_HAS_BEEN_HALTED	Loss of communication	Contact your distributor or customer service
15	SYSTEM_FAILED_TO_CONNECT_WITH_DEVICE	Loss of communication	Contact your distributor or customer service
16	ERROR_UVMON_PD1_H	PD1 is >10% higher than the target calibration value	Contact your distributor or customer service
17	ERROR_UVMON_PD1_L	PD1 is >10% lower than the target calibration value	Contact your distributor or customer service

Error Message Table			
No.	**Errors**	**Cause**	**Action**
18	ERROR_UVMON_TRMT_TIME_H	Treatment exceeded the expected time by >3 seconds	Contact your distributor or customer service
19	ERROR_UVMON_TRMT_TIME_L	Treatment ended >3 seconds before expected time	Contact your distributor or customer service
20	ERROR_UVMON_OVERTEMP	UV diode temperature >50 deg C	Contact your distributor or customer service
21	ERROR_UVMON_PD2_H	PD2 is >10% higher than the target calibration value	Contact your distributor or customer service
22	ERROR_UVMON_PD2_L	PD2 is >10% lower than the target calibration value	Contact your distributor or customer service
23	ERROR_WATCHDOG_FAILURE	UV Watchdog tripped.	Contact your distributor or customer service
24	ERROR_DTR_DISABLED_UNEXPECTEDLY	DTR disabled.	Contact your distributor or customer service
25	ERROR_UV_DISABLED_BY_FW_UNEXPECTEDLY	UV disabled by firmware unexpectedly	Contact your distributor or customer service
26	SELFTEST_FAILED UV_DTR_ERROR	The UV was not enabled by the UIC via the DTR signal.	Contact your distributor or customer service
27	SELFTEST_FAILED UV_WATCHDOG	The watchdog hardware could not be enabled.	Contact your distributor or customer service
28	SELFTEST_FAILED UV_CALIBRATION_CHECKSUM_ERROR	The calibration CRC check failed indicating that the data may be corrupted	Contact your distributor or customer service
29	SELFTEST_FAILED UV_OUT_OF_RANGE	PD1 indicated that the UV exceeded the +/-10% range when tested.	Contact your distributor or customer service
30	SELFTEST_FAILED MOTION_CONTROL_MOTOR_ERROR	The 3-axis motors could not be homed.	Contact your distributor or customer service

NOTE: Should you experience any difficulty that cannot be resolved by the suggested actions in this table, please contact your local Glaukos authorized representative

Replacing the Wireless Remote Batteries

The KXL System uses a remote control with replaceable batteries. To change the batteries in the remote control, slide the front of the remote backward while holding and sliding the back of the remote in the opposite direction. See Figure 38.

If using legacy remote, refer to Appendix 1.

Figure 37. Access Battery Compartment

Troubleshooting Remote Control Connection Issues

If using legacy remote, refer to Appendix 1.

If the batteries run low, the system will lose its connection with the remote. Press “OK” to synchronize the remote again.

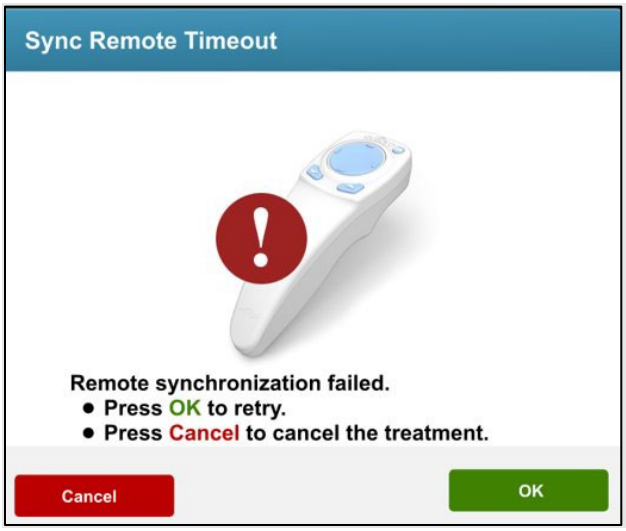


Figure 38. Remote Sync Timeout

If the remote fails to synchronize and two attempts, press “continue” to the complete the treatment without the remote.

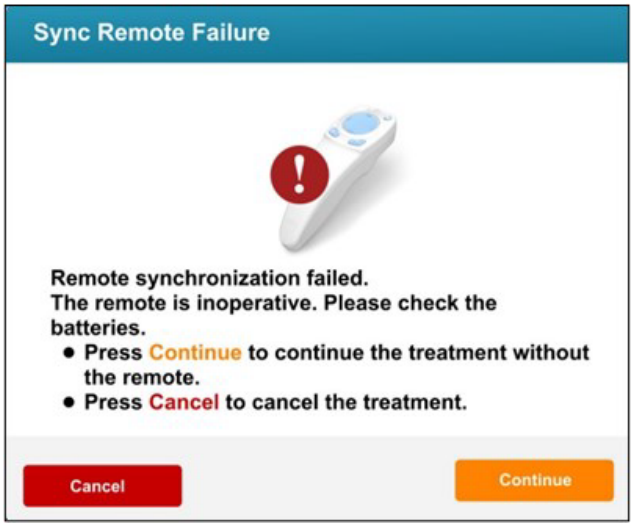


Figure 39. Remote Sync Failed

4.6. Cleaning the System

Prior to cleaning be sure the system is powered off and the mains power cord is disconnected. It is recommended that the system and components be cleaned in the following manner.

KXL System: Use a fiber-free wipe dampened with isopropyl alcohol to wipe down the system. While cleaning the surface of the device, ensure that cleaning fluids do not seep inside the device, as this can damage the device.

Remote: Use a fiber-free wipe dampened with isopropyl alcohol to clean the remote control.

To clean the aperture, refer to Section 4.7.

DO NOT submerge the system in liquid or pour liquid onto the system.

No components of the KXL System are designed to be sterilized by the operator.

Caution	
1.	Power down the system and remove the power supply cord from the main outlet prior to any cleaning procedure.
2.	The glass window of the beam aperture must not under any circumstances be in contact with any aggressive cleaning agents.

4.7. Cleaning the Aperture

Inspect the beam aperture prior to treatment for dust and particles.

If cleaning is needed, wipe the glass surface of the aperture using a camera lens wipe or use compressed air to remove debris from the aperture.

4.8. Articulating Arm Adjustment

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

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

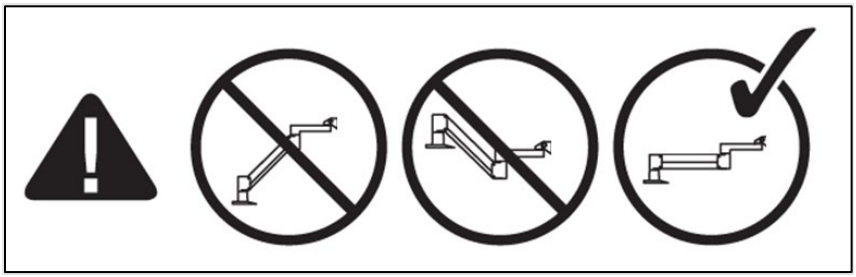


Figure 40. Position the Arm Parallel to the Floor

If the arm drifts downward, lift the arm to the top of its range and loosen Counterbalance Set Screw A by turning the screw at least a 1/2 turn. Use provided 3/32 Allen Wrench. See Figure 41.

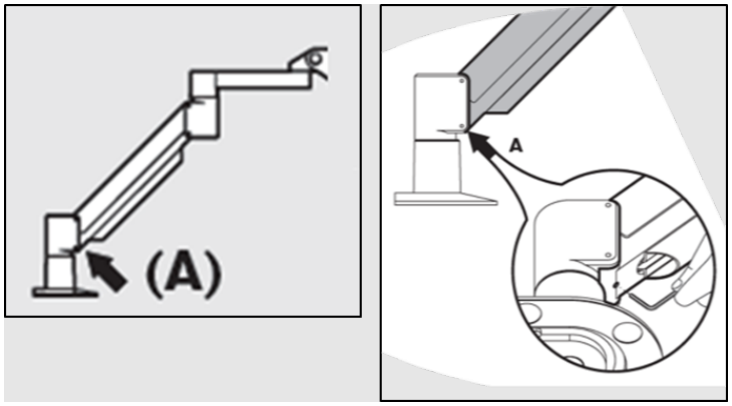


Figure 41. Loosen Counterbalance Set Screw A

Reposition the arm horizontally. Loosen the upper Counterbalance Set Screw B by turning the screw at least a 1/2 turn. Use provided 3/32 Allen Wrench. See Figure 42.

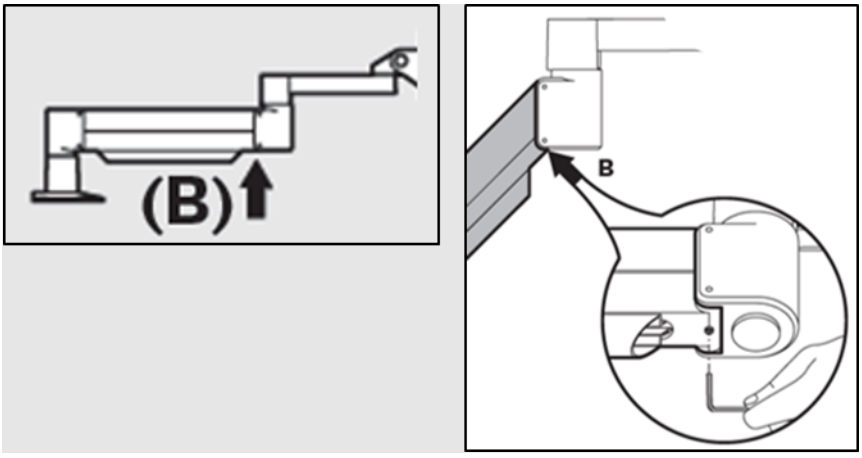


Figure 42. Loosen Counterbalance Set Screw B

Maintain the horizontal arm position by supporting load as needed.

Using the 7/32 Allen Wrench (why equivalent OUS), set the arm tension with the Strength Adjustment Screw C. Turn the Screw C counterclockwise until the arm begins to move slowly upward. There should be a slight bounce-back when the arm is lightly tapped down after adjustment. See Figure 43.

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

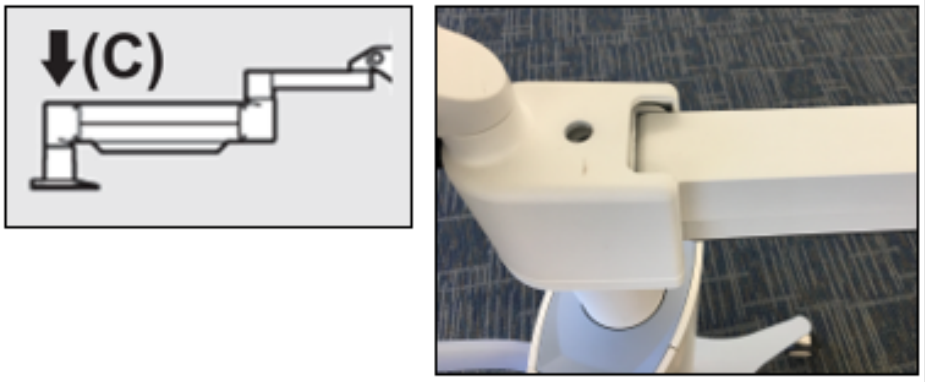


Figure 43. Set Arm Tension with Strength Adjustment Screw C

Turn Strength Adjustment Screw C two full revolutions in the clockwise direction.

Ensure that the arm is stationary to barely creeping upward.

Raise the arm to the highest position and tighten Counterbalance Set Screw A until contact is made, then tighten ½ to ¾ max revolutions. See Figure 41.

Position the arm horizontally and tighten Counterbalance Set Screw B until contact is made, then tighten ½ to ¾ revolutions. See Figure 42.

Cycle the arm up and down through its full range of motion. Ensure there is not upward or downward drift. NOTE: If the arm drifts upward from any position, return to horizontal and turn Strength Adjustment Screw C clockwise ¼-revolution at a time until it no longer rises on its own.

4.9. Moving the System

The KXL System is designed as a movable system within an office environment.

IMPORTANT: If it is necessary to transport or ship the system, for any reason, contact your local Glaukos representative. Packing and transporting the system should be performed only by Glaukos trained and authorized personnel.

Before moving the system from one room to another, the head should be positioned close to the cart handle with the elbow protruding at the back. See Figure 44 for positioning. The system can be easily pushed by the cart handle through the door frame.

Figure 44. System Configuration for Moving and Storage

4.10. Storing the System

Store system as you would if moving per section 4.9 per the Follow all the storage temperature and humidity range specifications as listed in Section 7: Specifications.

Do not disassemble any part of the system as this could cause misalignment or damage.

Turn OFF all the components and switch off the mains power switch. Disconnect the power cord from its electrical outlet. Remove the batteries from the wireless remote if storing for an extended time.

4.11. Software

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

4.12. Risks Associated with Disposing of Waste Products

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

5. EQUIPMENT CLASSIFICATION

5.1. According to EN60601-1 Medical Device Electrical Standard

Protection against electrical shock

- Class 1 (external electrical power source)

Degree of protection against electric shock

- Not classified, equipment not provided with applied part
- System ingress protection: IP20 (No protection against ingress of water)
- Updated remote ingress protection: IP53

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

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

Class B

5.3. According to EN60825-1 Safety of Laser Productions

Alignment lasers are Class 1 Laser Product

5.4. According to EN62471 Photobiological Safety of Lamps and Lamp Systems

IEC 62471:2006 Risk Group 2

EN 62471:2008 Risk Group 3

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

Class IIa

5.6. EMC Requirements

The KXL System requires special precautions regarding electromagnetic compatibility (EMC). Installation and use should be carried out according to the EMC information provided in this manual. Portable and mobile RF communications equipment may affect the KXL System.

Guidance and manufacturer's declaration - electromagnetic emissions		
The KXL System is intended for use in the electromagnetic environment specified below. The customer or the user of the KXL System should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment — guidance**
Conducted disturbance (Conducted emissions) CISPR 11 EN55011	Group 1	The KXL System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Electromagnetics radiation disturbance (Radiated emissions) CISPR 11 EN55011	Class B	The KXL System is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. Warning: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic current emissions IEC 61000-3-2	Class A	
Voltage changes, fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The KXL System is intended for use in the electromagnetic environment specified below. The customer or the user of the KXL System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment — guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	Repeat Freq 100Khz +/- 2 kV for power supply lines and +/- 1 kV for input/output lines	+/- 2 kV for power supply lines Not Applicable Input /Output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0 % UT (100 % dip in UT) for 0.5 cycle 0% UT (100% dip in UT) for 1 cycles 70% UT (30% dip in UT) for 25/30 cycles 0% UT (100 % dip in UT) for 5 sec For 0.5 at each phase angle 0-315 separated by	0 % UT (100 % dip in UT) for 0.5 cycle 0% UT (100% dip in UT) for 1 cycles 70% UT (30% dip in UT) for 25/30 cycles 0% UT (100 % dip in UT) for 5 sec For 0.5 at each phase angle 0-315 separated by	Mains power quality should be that of a typical commercial or hospital environment, If the user of the KXL System requires continued operation during power mains interruptions, it is recommended that the KXL System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 Proximity Magnetic Fields IEC 61000-4-39	30 A/m 9KHz- 150Khz, 150Khz-26MHz	30 A/m 9KHz- 150Khz, 150Khz-26MHz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Proximity magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			
Conducted Disturbance induced by RF fields (Conducted Disturbance) IEC61000-4-6	3 Vrms 150 kHz to 80 MHz plus 6Vrms for ISM bands	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the KXL System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance.** $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$

Guidance and manufacturer's declaration - electromagnetic immunity			
The KXL System is intended for use in the electromagnetic environment specified below. The customer or the user of the KXL System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment — guidance**
Radiated RF Electromagnetic field IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3V/m	$d = 1{,}2\sqrt{P}$ $d = 2{,}3\sqrt{P}$ 80 MHz to 2.7 GHz
Proximity fields from RF wireless communications equipment (IEC 60601-1-2 Table 9)	15 specific frequencies. Immunity level 9-28V/m	15 specific frequencies. Immunity level 9-28V/m	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range.[b.] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the KXL System is used exceeds the applicable RF compliance level above, the KXL System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the KXL System. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the KXL System			
The KXL System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the KXL System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the KXL System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **NOTE 1**: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **NOTE 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

The KXL System contains an RFID function which transmits and receives at the 13.56 MHz frequency. This functionality may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.

The KXL System contains the following RF transmitters: **RFID Reader**
• 13.56MHz Reader/Writer • Integral Antenna: Maximum 4” Read Range • Max output power is 200mW • Meets: ISO18000-3, ISO15693

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

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

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

Original Wireless Remote Control, P/N

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

Updated Wireless Remote Control

- FCC ID 2AVGK-KXLTX
- Frequency Range 2402MHz to 2480MHz
- Emissions Compliant with CFR Part 15

6. SYMBOLS/ABBREVIATIONS

The following symbols may be found on the KXL system, labeling or packaging.

Symbol	Definition	Standard	Location
	Alternating Current	IEC 60417	system label
	Consult instructions for use	ISO 15223-1	system label
	Protected earth; protective ground	IEC 60417	system
	On	ISO 60417	system
	Off	ISO 60417	system
	Stand-by	ISO 60417	system
	CE Mark	93/465/EC Annex B (c)	system label
	Caution: On equipment near placement	ISO 7000	system label
	UV Light Hazard (Refer to section 1.12 for warnings)	ISO 7010	on system
	Keep away from rain	ISO 15223-1	carton/crate
	Fragile	ISO 15223-1	carton/crate
	This way up	ISO 7000	carton/crate
	Do not stack	ISO 7000	carton/crate

Symbol	Definition	Standard	Location
	Humidity limits	ISO 15223-1	system label
	Temperature limits	ISO 15223-1	system label
	Atmospheric Pressure limits	ISO 15223-1	system label
	Magnetic Resonance Unsafe	ASTM F2503-13	system label
	Non-ionizing electromagnetic radiation	ISO 7000	system label
	Medical device	ISO 15223-1	system label
	WEEE symbol	IEC 60417	system label
	Catalogue number	ISO 15223-1	system label
	Serial number	ISO 15223-1	system label
	Manufacturer	ISO 15223-1	system label
	Date of Manufacture	ISO 15223-1	system label
	Refer to Instruction Manual/booklet mandatory	ISO 7010	system label
	Authorized Representative in the European Community	ISO 15223-1	system label
	Unique Device Identifier	ISO 15223-1	system label
	Quantity: Refers to the quantity of device(s) contained within a package	User defined	carton/crate label

Abbreviations			
ºC	degree Celsius	min	minute
A	ampere	mW/cm^2	milliwatt per square centimeter
CX	corneal cross-linking	nm	nanometer
EMC	electromagnetic compatibility	OD	right eye
FW	firmware	OS	left eye
Hz	hertz	sec	second
IP	Ingress Protection	UI	user interface
J/cm^2	Joules per square centimeter	UV	Ultraviolet light
kg	kilogram	UVA	Ultraviolet A
LED	light-emitting diode	V	Volt
mbar	millibar		

7. SPECIFICATIONS

7.1. System Specifications

Specification	Description
Electrical	Line voltages 100 – 240 volts AC Current 2A – 1A Single Phase RMS, 50/60 Hz Original Remote 2x AAA batteries Updated Remote 2x AA batteries
List of cables and Accessories	Wireless Remote Hospital Grade AC power cable (Lockable/Detachable)
Energy Delivery	UV Radiation 3 – 45 mW/cm² +/- 10% 365 nm +/- 8 nm
UVA LED Light Source	UV Radiation 365 nm +/- 8 nm
External Interfaces	USB 2.0
Physical Dimensions	Length: 60 in (152 cm) Width: 58 in (147 cm) Height: 118 in (300 cm)
Physical Dimensions w/Full Arm Articulation	Length: 129 in (328 cm) Width: 110 in (279 cm) Height: 150 in (381 cm)
Weight (crated system)	NW 48 kg GW 89 kg
Remote Battery Life (normal operating conditions)	18 hours
Remote and Dongle FCC ID and Operating Frequencies	FCC ID: SXJ87027-TX (original remote) FCC ID: 2AVGK-KXLTX (updated remote) 2.405-2.475 GHz.
Remote Ingress Protection (solids under 12.5 mm and no protection against water)	IP20 (Original Remote) IP53 (Updated Remote)
Environmental Operating Conditions	The system operates under the following atmospheric conditions (no condensation).
Ambient temperature	+15 to +30 ºC
Relative humidity	20% to 80%, non-condensing
Atmospheric pressure	810 to 1050 mbar
Transport and Storage Conditions	The instrument withstands the following transport and storage conditions without damage or performance deterioration.
Ambient temperature	-15 to +60 ºC
Relative humidity	10% to 80% non-condensing
Atmospheric pressure	750 to 1060 mbar

7.2. Treatment Parameters

Treatment Parameters				
Treatment Type		**Lasik Xtra®**	**Accelerated Epi-Off CXL**	**Trans-Epithelial**
Formulation		VibeX® Xtra	VibeX® Rapid	ParaCel Part 1, ParaCel Part 2
Induction Time/ Soak Time	Default	1 minute 30 seconds	10 minutes	4 minutes (Part 1) 6 minutes (Part 2)
	Range	15 seconds– 30 minutes	60 seconds – 30 minutes	60 seconds– 4 minutes (Part 1) 60 seconds– 30 minutes (Part 2)
UV Irradiance	Default	30 mW/cm²	30 mW/cm²	45 mW/cm²
	Range*	*3 mW/cm²–45 mW/cm²	*3 mW/cm²–45 mW/cm²	*3 mW/cm²–45 mW/cm²
Total UV Dose	Default	2.7 J/cm²	7.2 J/cm²	10 J/cm²
	Range**	**1 J/cm²–4.1 J/cm²	**1 J/cm² –7.2 J/cm²	**1 J/cm² –10 J/cm²
UV Delivery	Default	CW	Pulsed	Pulsed
	Range	CW and Pulsed	CW and Pulsed	CW and Pulsed
Pulse Duration	Default	N/A	1 second on, 1 second off	1 second on, 1 second off
	Range	1 second on/off– 4 seconds on/off	1 second on/off– 4 seconds on/off	1 second on/off– 4 seconds on/off

NOTES:
* For CW treatment 3mW/cm² is minimum; for Pulsed treatment 6mW/cm² is minimum.
** The user may select Total UV Dose in 0.1 J/cm² increments.

8. APPENDIX 1

8.1. Legacy Remote Control

In prior KXL system releases, the legacy remote control shown below was provided. If you are still using the legacy remote control, please refer to the instructions in this appendix for operation and other important troubleshooting information.

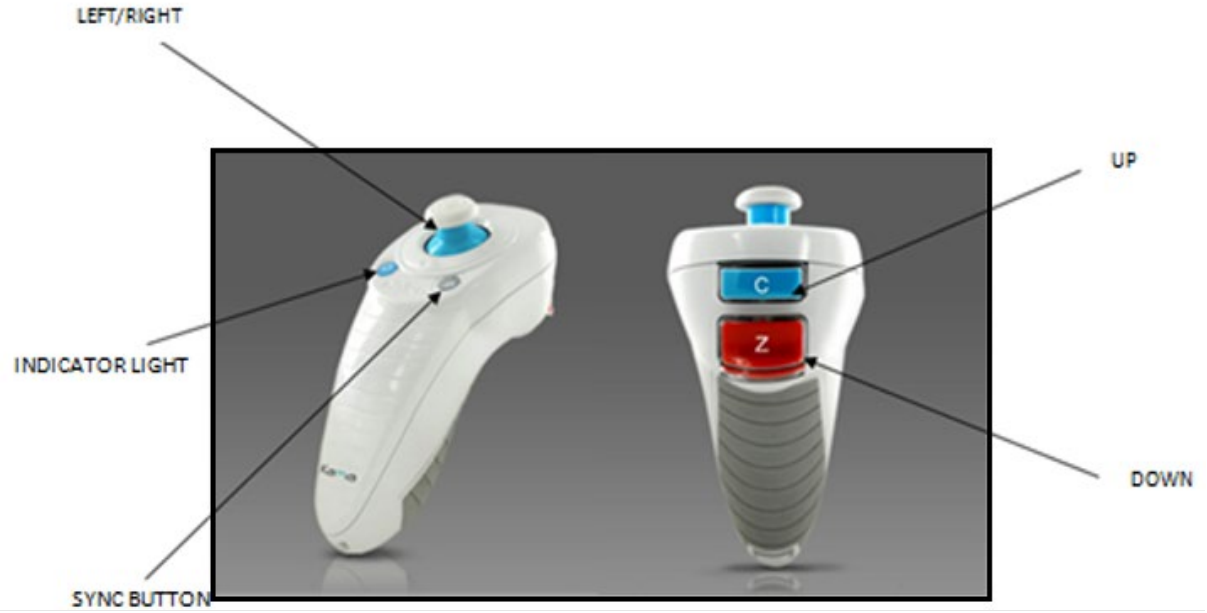


Figure 45. Legacy Remote Control–Overview

8.2. Legacy Remote Synchronization

NOTE: When using the remote control, synchronization is required for each procedure.

After settings have been selected, press confirm on the treatment confirmation screen. The system will allow 15 seconds to synchronize the remote control.

Press the sync button denoted with an “S” on the remote control to synchronize the remote control within the timeframe, as shown in figure below. The KXL system will beep every 2 seconds during the synchronization.

Figure 46. Legacy Remote–Sync Remote Screen

If the sync button on the remote control is not pressed within the 15-second timeframe, the sync remote timeout screen will be displayed. Press OK to retry. If a problem occurs again, see Troubleshooting Legacy Remote on the following page for possible battery issues.

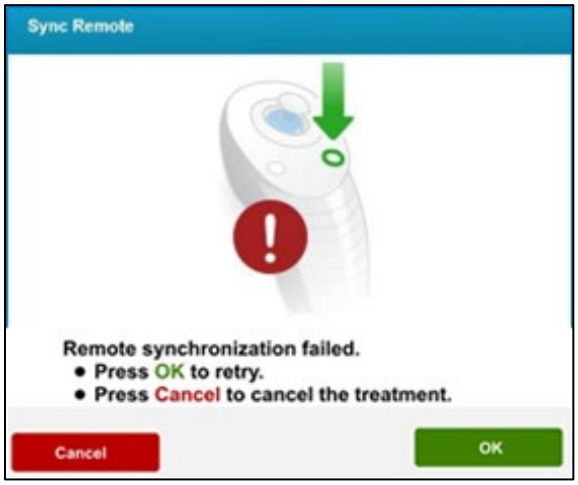


Figure 47. Legacy Remote–Sync Timeout

If the remote fails after multiple attempts to sync or becomes inoperative at any time, treatment can still be continued without the remote. Press, “Continue” to continue treatment without the remote.

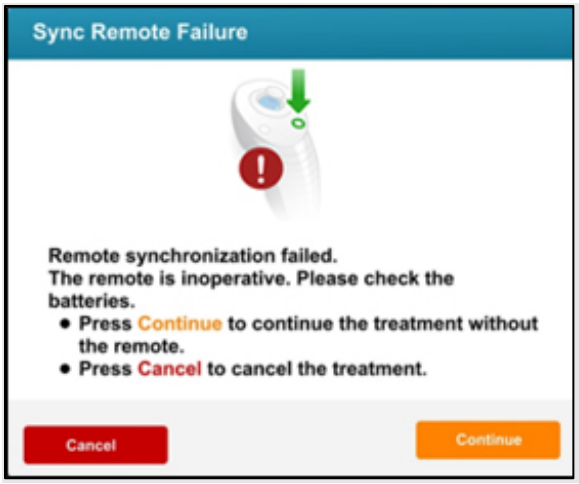


Figure 48. Legacy Remote–Sync Failure

8.3. Troubleshooting Legacy Remote

The legacy remote has as indicator light that communicates its status as detailed in the table below.

Legacy Remote Control Indicators	
Indicator Light Status	**Meaning**
On	Actively synchronized with the device
Blinking once per second for 10 seconds	Disconnecting sync (after procedure)
Blinking constantly, twice per second	Replace batteries immediately (2 AAA)

8.4. Replacing Legacy Remote Batteries

The legacy remote has replaceable batteries. To change the batteries in the remote control, lift the tab on the rear of the remote to access the battery compartment. Replace the batteries. Insert panel and snap back into place.

Intentionally left blank