

## HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use EPIOXA™ HD and EPIOXA™ safely and effectively. See full prescribing information for EPIOXA HD and EPIOXA.

**EPIOXA HD (riboflavin 5'-phosphate ophthalmic solution) 0.239%, for topical ophthalmic use**  
**EPIOXA (riboflavin 5'-phosphate ophthalmic solution) 0.177%, for topical ophthalmic use**  
For use with the O<sub>2</sub>n™ System and Boost Goggles®  
Initial U.S. Approval: 2016

### INDICATIONS AND USAGE

EPIOXA HD and EPIOXA are photoenhancers indicated for use in epithelium-on corneal collagen cross-linking for the treatment of keratoconus in adults and pediatric patients aged 13 years and older, in conjunction with the O<sub>2</sub>n System and the Boost Goggles (1).

### DOSAGE AND ADMINISTRATION

- Apply topical anesthetic and insert a lid speculum (2).
- Using a cellulose spear sponge soaked with EPIOXA HD, remove the mucin layer from the corneal surface without debriding the corneal epithelium (epithelium-on) by swiping the sponge 4 to 10 times horizontally and vertically (2).
- Apply two drops of EPIOXA HD topically on the eye every 60 seconds for 4 minutes (STEP 1), followed by two drops of EPIOXA topically on the eye every 30 seconds for 6 minutes (STEP 2) (2).
- Gently rinse the corneal surface with approximately 5 mL of balanced salt solution (BSS) (2).
- Perform ultrasound pachymetry. If corneal thickness is less than 325 microns, irradiation should not be performed (2).
- Apply the Boost Goggles and turn on the oxygen flow. Refer to the *Boost Goggles User Guide* (2).
- Center the optical head of the O<sub>2</sub>n System over the cornea and irradiate the eye as per the instructions in the *O<sub>2</sub>n System Operator's Manual*. The O<sub>2</sub>n System automatically delivers irradiation to the eye for 11 minutes

6 seconds at 30 mW/cm<sup>2</sup> with an on/off cycle of 1 second UV-A on/ 1 second UV-A off at a wavelength of 365 nm (2).

- Instill BSS on the cornea every 2 minutes, or more frequently as needed, to maintain corneal hydration during UV-A irradiation (2).
- When the UV-A irradiation has stopped, shut off the oxygen flow and remove the Boost Goggles and lid speculum (2).
- Apply a bandage contact lens (2).

### DOSAGE FORMS AND STRENGTHS

- Ophthalmic solution: EPIOXA HD 0.239% in a single-dose glass syringe (3.1)
- Ophthalmic solution: EPIOXA 0.177% in a single-dose glass syringe (3.2)

### CONTRAINDICATIONS

- Hypersensitivity (4.1)
- Aphakic and pseudophakic patients without a UV-blocking intraocular lens (4.2)

### WARNINGS AND PRECAUTIONS

**Herpetic keratitis:** Use with caution in patients with a history of herpetic keratitis due to the potential for reactivation (5).

### ADVERSE REACTIONS

The most common adverse reaction was conjunctival hyperaemia (31%). Other adverse reactions, occurring in 5% to 25% of eyes included: corneal opacity (haze), photophobia, punctate keratitis, eye pain, eye irritation, increased lacrimation, corneal epithelium defect, eyelid oedema, corneal striae, visual acuity reduced, dry eye, and anterior chamber flare (6.1).

**To report SUSPECTED ADVERSE REACTIONS, contact GLAUKOS CORPORATION at 1-888-404-1644 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

See 17 for PATIENT COUNSELING INFORMATION

Revised: 10/2025

## FULL PRESCRIBING INFORMATION: CONTENTS\*

- INDICATIONS AND USAGE
- DOSAGE AND ADMINISTRATION
  - Important Administration Instructions
  - Recommended Dosage and Administration Instructions
- DOSAGE FORMS AND STRENGTHS
  - EPIOXA HD
  - EPIOXA
- CONTRAINDICATIONS
  - Hypersensitivity
  - Aphakic and Pseudophakic Patients
- WARNINGS AND PRECAUTIONS
  - Herpetic Keratitis
- ADVERSE REACTIONS
  - Clinical Trials Experience

- USE IN SPECIFIC POPULATIONS
  - Pregnancy
  - Lactation
  - Pediatric Use
  - Geriatric Use
- DESCRIPTION
- CLINICAL PHARMACOLOGY
  - Mechanism of Action
  - Pharmacodynamics
  - Pharmacokinetics
- NONCLINICAL TOXICOLOGY
  - Carcinogenesis, Mutagenesis, Impairment of Fertility
- CLINICAL STUDIES
- HOW SUPPLIED/STORAGE AND HANDLING
- PATIENT COUNSELING INFORMATION

\*Sections or subsections omitted from the full prescribing information are not listed.

## FULL PRESCRIBING INFORMATION

### 1 INDICATIONS AND USAGE

EPIOXA HD and EPIOXA are indicated in epithelium-on corneal collagen cross-linking for the treatment of keratoconus in adults and pediatric patients aged 13 years and older, in conjunction with the O<sub>2</sub>n System and the Boost Goggles.

### 2 DOSAGE AND ADMINISTRATION

#### 2.1 Important Administration Instructions

EPIOXA HD and EPIOXA are for topical ophthalmic use. **NOT** for injection or intraocular use.

EPIOXA HD and EPIOXA are supplied in single-dose syringes. Discard opened syringes after use.

EPIOXA HD and EPIOXA are for use with the O<sub>2</sub>n System and Boost Goggles only.

Refer to the *O<sub>2</sub>n System Operator's Manual* and *Boost Goggles User Guide* for device instructions.

#### 2.2 Recommended Dosage and Administration Instructions

Apply topical anesthetic and insert a lid speculum.

Using a cellulose spear sponge soaked with EPIOXA HD, remove the mucin layer from the corneal surface without debriding the corneal epithelium (epithelium-on) by swiping the sponge 4 to 10 times horizontally and vertically.

Apply two drops of EPIOXA HD topically on the eye every 60 seconds for 4 minutes (STEP 1), followed by two drops of EPIOXA topically on the eye every 30 seconds for 6 minutes (STEP 2).

Gently rinse the corneal surface with approximately 5 mL of balanced salt solution (BSS).

Perform ultrasound pachymetry. If corneal thickness is less than 325 microns, irradiation should not be performed.

Apply the Boost Goggles and turn on the oxygen flow as per the instructions in the *Boost Goggles User Guide*.

Center the optical head of the O<sub>2</sub>n System over the cornea and irradiate the eye as per the instructions in the *O<sub>2</sub>n System Operator's Manual*. The O<sub>2</sub>n System automatically delivers irradiation to the eye for 11 minutes 6 seconds at 30 mW/cm<sup>2</sup> with an on/off cycle of 1 second UV-A on/1 second UV-A off at a wavelength of 365 nm.

Instill BSS on the cornea every 2 minutes, or more frequently as needed, to maintain corneal hydration during UV-A irradiation.

When the UV-A irradiation has stopped, shut off the oxygen flow, and remove the Boost Goggles and lid speculum.

Apply a bandage contact lens.

### **3 DOSAGE FORMS AND STRENGTHS**

#### **3.1 EPIOXA HD**

Ophthalmic solution: 0.239% (2.39 mg/mL) of riboflavin 5'-phosphate in a clear, yellow, solution in a single-dose glass syringe.

#### **3.2 EPIOXA**

Ophthalmic solution: 0.177% (1.77 mg/mL) of riboflavin 5'-phosphate in a clear, yellow, solution in a single-dose glass syringe.

### **4 CONTRAINDICATIONS**

#### **4.1 Hypersensitivity**

EPIOXA HD and EPIOXA are contraindicated in patients with known hypersensitivity to benzalkonium chloride or any ingredients in EPIOXA HD and EPIOXA.

#### **4.2 Aphakic and Pseudophakic Patients**

Epithelium-on corneal collagen cross-linking is contraindicated in aphakic patients and pseudophakic patients without a UV-blocking intraocular lens.

### **5 WARNINGS AND PRECAUTIONS**

#### **5.1. Herpetic Keratitis**

Corneal collagen cross-linking should be used with caution in patients with a history of herpetic keratitis due to the potential for reactivation of herpes keratitis.

### **6 ADVERSE REACTIONS**

The following clinically significant adverse reactions are described elsewhere in the labeling:

Herpetic keratitis [*see Warnings and Precautions (5.1)*]

## **6.1 Clinical Trials Experience**

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of EPIOXA HD and EPIOXA in the epithelium-on corneal collagen cross-linking procedure with UV-A irradiation and supplemental oxygen was evaluated in two randomized, parallel-group, sham procedure/vehicle-controlled trials. Study eyes were randomized in a 2:1 treatment allocation to receive corneal collagen cross-linking (CXL) or sham procedure/vehicle control at the baseline visit. In both trials, CXL-treated eyes were followed for 12 months.

Safety data were obtained from a total of 389 CXL-treated eyes.

The most commonly reported adverse reaction in CXL-treated eyes was conjunctival hyperaemia (31%). Other adverse reactions occurring in 5% to 25% of CXL-treated eyes included: corneal opacity (haze), photophobia, punctate keratitis, eye pain, eye irritation, lacrimation increased, corneal epithelium defect, eyelid oedema, corneal striae, visual acuity reduced, dry eye, and anterior chamber flare.

## **8 USE IN SPECIFIC POPULATIONS**

### **8.1 Pregnancy**

#### Risk Summary

Animal development and reproduction studies have not been conducted with EPIOXA HD and EPIOXA with the O<sub>2</sub>n System and Boost Goggles. Since it is not known whether the epithelium-on corneal collagen cross-linking procedure can cause fetal harm or affect reproduction capacity, it should not be performed on pregnant women.

### **8.2 Lactation**

#### Risk Summary

There are no data on the presence of EPIOXA HD or EPIOXA in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for the EPIOXA HD and EPIOXA epithelium-on corneal collagen cross-linking procedure and any potential adverse effects on the breastfed child from the EPIOXA HD and EPIOXA epithelium-on corneal collagen cross-linking procedure or from the underlying maternal condition.

### **8.4 Pediatric Use**

The safety and effectiveness of EPIOXA HD and EPIOXA for the treatment of keratoconus have been established in pediatric patients aged 13 years and older.

## 8.5 Geriatric Use

No patients enrolled in the clinical trials were 65 years of age or older.

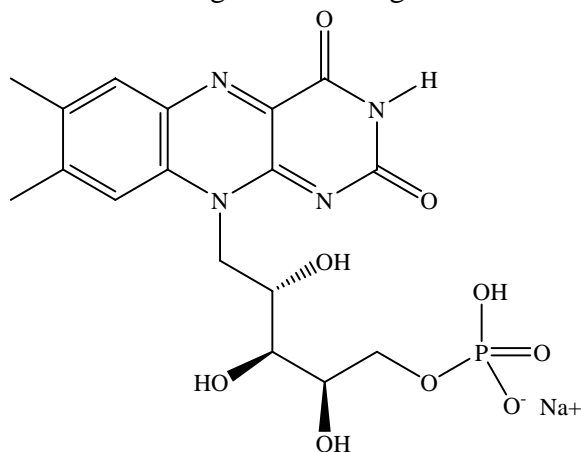
## 11 DESCRIPTION

EPIOXA HD (riboflavin 5'-phosphate ophthalmic solution) 0.239% and EPIOXA (riboflavin 5'-phosphate ophthalmic solution) 0.177% contain riboflavin 5'-phosphate, a photoenhancer, for topical ophthalmic use.

EPIOXA HD 0.239% is a clear, yellow, sterile buffered solution containing 2.39 mg/mL riboflavin 5'-phosphate. The pH of the solution is 6.7 to 7.7 and the osmolality is 200 mOsm/kg to 260 mOsm/kg. Each mL of solution contains 2.50 mg of riboflavin 5'-phosphate sodium (equivalent to 1.97 mg/mL riboflavin). Riboflavin 5'-phosphate sodium is a mixture of the sodium salts of riboflavin, riboflavin monophosphates, and riboflavin diphosphates. The inactive ingredients are hydroxypropyl methylcellulose, sodium chloride, dibasic sodium phosphate dihydrate, edetate disodium dihydrate, tromethamine, monobasic sodium phosphate dihydrate, benzalkonium chloride, and water for injection. Sodium hydroxide and/or hydrochloric acid may be added to adjust pH.

EPIOXA 0.177% is a clear, yellow, sterile buffered solution containing 1.77 mg/mL riboflavin 5'-phosphate. The pH of the solution is 6.5 to 7.5 and the osmolality is 330 mOsm/kg to 400 mOsm/kg. Each mL of solution contains 1.85 mg of riboflavin 5'-phosphate sodium (equivalent to 1.46 mg/mL riboflavin). Riboflavin 5'-phosphate sodium is a mixture of the sodium salts of riboflavin, riboflavin monophosphates, and riboflavin diphosphates. The inactive ingredients are sodium chloride, dibasic sodium phosphate dihydrate, tromethamine, monobasic sodium phosphate dihydrate, and water for injection. Sodium hydroxide and/or hydrochloric acid may be added to adjust pH.

The molecular formula for riboflavin 5'-phosphate sodium (Vitamin B2) is  $C_{17}H_{20}N_4NaO_9P$  with a molecular weight of 478.33 g/mol.



## **12 CLINICAL PHARMACOLOGY**

### **12.1 Mechanism of Action**

Riboflavin 5'-phosphate sodium (Vitamin B2) is the precursor of two coenzymes, flavin adenine dinucleotide and flavin mononucleotide, which catalyze oxidation/reduction reactions involved in a number of metabolic pathways.

Under the conditions used for corneal collagen cross-linking, riboflavin 5'-phosphate functions as a photoenhancer and generates singlet oxygen which is responsible for the cross-linking.

### **12.2 Pharmacodynamics**

The pharmacodynamics of EPIOXA HD and EPIOXA have not been characterized.

### **12.3 Pharmacokinetics**

The pharmacokinetics of EPIOXA HD and EPIOXA have not been characterized.

## **13 NONCLINICAL TOXICOLOGY**

### **13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

#### Carcinogenicity

Animal studies have not been conducted to determine the carcinogenic potential of photoexcited riboflavin.

#### Mutagenesis

Photoexcited riboflavin has been shown to be genotoxic in the Ames Salmonella reverse mutation assay and in the SOS/umu test system.

The genotoxicity of riboflavin, in the absence of photoexcitation has been examined in vitro in bacterial reverse mutation assays, sister chromatid exchange assay, chromosomal aberration assays and in vivo in a mouse micronucleus study. The overall weight of evidence indicates that riboflavin, in the absence of photoexcitation, is not genotoxic.

#### Impairment of Fertility

Animal studies to determine the effects of the EPIOXA HD and EPIOXA epithelium-on corneal collagen cross-linking procedure on fertility were not conducted.

## 14 CLINICAL STUDIES

Two prospective, randomized, parallel-group, sham procedure/vehicle-controlled trials (Study 1 [NCT03442751] and Study 2 [NCT05759559]) were conducted to evaluate the safety and efficacy of epithelium-on corneal collagen cross-linking (CXL) using riboflavin 5'-phosphate ophthalmic solutions with UV-A irradiation and supplemental oxygen in patients with keratoconus.

In both trials, eligible eyes were randomized to receive CXL treatment or sham procedure/vehicle control in a 2:1 treatment allocation at the baseline visit. Aphakic patients and pseudophakic patients without a UV-blocking intraocular lens were excluded. Both eyes of a patient could be enrolled in the trial; however, one eye was treated first, and the second eye was treated between 1 week and 3 months after the first eye. Eyes were evaluated at 1 day, 3 days, 1 week, and 1, 3, 6, and 12 months post-treatment.

In Study 1, eyes randomized to sham procedure/vehicle control were permitted to receive CXL treatment after month 6 and were followed an additional 6 months. The primary efficacy endpoint was at month 6 post-treatment and the secondary efficacy endpoint was at month 12 post-treatment. In Study 2, the primary efficacy endpoint was at month 12 post-treatment and the secondary efficacy endpoint was at month 6 post-treatment.

In Study 1, a total of 280 eyes of 201 patients were randomized into the trial, of which 279 eyes were treated: 189 eyes received CXL treatment and 90 eyes initially received sham procedure/vehicle control. A statistically significant treatment effect was demonstrated at month 6, based on the difference in change from baseline in maximum corneal curvature ( $K_{\max}$ ) between the CXL treatment group and sham procedure/vehicle control group (**Table 1**).

**Table 1. Study 1: Mean Baseline  $K_{\max}$  (D) and Change from Baseline  $K_{\max}$  (D)**

Visit	CXL Treatment (N=189)	Sham Procedure/Vehicle Control (N=90)	Treatment Difference (95% CI) P-value
Baseline <sup>a</sup>	59.4 (9.1)	59.3 (9.1)	
Month 6 <sup>b</sup>	-0.3 (-0.6, -0.0)	0.6 (0.2, 1.1)	-1.0 (-1.5, -0.4) <i>P</i> <0.01
Month 12 <sup>c</sup>	-0.4 (-0.7, -0.2)	0.7 (0.3, 1.1)	-1.1 (-1.6, -0.6) <i>P</i> <0.01

Randomized eyes that received study treatment

<sup>a</sup> Mean (standard deviation)  $K_{\max}$

<sup>b</sup> LS Mean change from baseline and corresponding 95% CIs obtained from a RMMM ANCOVA model with treatment as a factor and the baseline  $K_{\max}$  value and baseline keratoconus severity as covariates. Missing post-baseline  $K_{\max}$  data were handled by multiple imputation procedure for month 6.

<sup>c</sup> Missing post-baseline  $K_{\max}$  data were handled by last observation carried forward method for month 12 in Sham Procedure/Vehicle Control eyes that received CXL treatment after month 6.

In a subgroup analysis of patients in this trial at month 6, younger patients (< 29 years) experienced a treatment effect of -2.0 D, as a combination of improvement in the CXL treatment arm (-0.7 D) and deterioration in the sham procedure/vehicle control arm (1.3 D). Older patients ( $\geq$  29 years) did not experience improvement at month 6 in either arm.

In Study 2, a total of 312 eyes of 208 patients were randomized into the trial, of which 312 eyes were treated: 200 eyes received CXL treatment and 112 eyes received sham procedure/vehicle control. A statistically significant treatment effect was demonstrated at month 12, based on the difference in change from baseline in  $K_{\max}$  between the CXL treatment group and sham procedure/vehicle control group (**Table 2**).

**Table 2. Study 2: Mean Baseline  $K_{max}$  (D) and Change from Baseline  $K_{max}$  (D)**

Visit	CXL Treatment (N=200)	Sham Procedure/ Vehicle Control (N=112)	Treatment Difference (95% CI) P-Value
Baseline <sup>a</sup>	58.0 (8.0)	58.1 (8.6)	
Month 6 <sup>b</sup>	-0.4 (-0.6, -0.2)	0.1 (-0.1, 0.4)	-0.6 (-0.9, -0.2) <i>P</i> <0.01
Month 12 <sup>b</sup>	-0.5 (-0.7, -0.3)	0.4 (0.1, 0.8)	-1.0 (-1.3, -0.6) <i>P</i> <0.01

Randomized eyes that received study treatment

<sup>a</sup> Mean (standard deviation)  $K_{max}$

<sup>b</sup> LS Mean change from baseline and corresponding 95% CIs obtained from a RMMM ANCOVA model with treatment as a factor and the baseline  $K_{max}$  value and baseline keratoconus severity and age stratum as covariates. Missing post-baseline  $K_{max}$  data were handled by multiple imputation procedure.

In a subgroup analysis of patients in this trial at month 12, younger patients (< 30 years) experienced a treatment effect of -1.1 D, as a combination of improvement in the CXL treatment arm (-0.5 D) and deterioration in the sham procedure/vehicle control arm (0.5 D). Older patients ( $\geq$  30 years) in the CXL treatment arm experienced comparable improvement (-0.6 D) as younger patients (-0.5 D); however, in the sham procedure/vehicle control arm, older patients (-0.0 D) did not deteriorate as much as younger patients (0.5 D).

## 16 HOW SUPPLIED/STORAGE AND HANDLING

EPIOXA HD (riboflavin 5'-phosphate ophthalmic solution) 0.239%, and EPIOXA (riboflavin 5'-phosphate ophthalmic solution) 0.177%, are clear, yellow, ophthalmic solutions. EPIOXA HD and EPIOXA are co-packaged in an Epithelium-on Cross-linking Kit (NDC 25357-024-01) containing:

- One single-dose glass syringe containing 2 mL of EPIOXA HD 0.239% packaged in a foil pouch.
- One single-dose glass syringe containing 2 mL of EPIOXA 0.177% packaged in a foil pouch.

Store kit **refrigerated** at 2°C to 8°C (36°F to 46°F). Do not freeze. Minimize exposure of the syringes to light once removed from their protective packaging.

For topical ophthalmic use. Single-dose only. Discard syringes after use.

EPIOXA HD and EPIOXA are for use only with the O<sub>2</sub>n System, the single-use O<sub>2</sub>n System Treatment Activation Card, and Boost Goggles.

## 17 PATIENT COUNSELING INFORMATION

- Advise patients that there may be discomfort in the treated eye and that sunglasses may help with light sensitivity.
- Instruct patients that they should contact their physician immediately if they experience severe pain in the treated eye or any sudden decrease in their vision.

EPIOXA HD, EPIOXA, the O<sub>2</sub>n System, and Boost Goggles are marketed by:

Avedro, a Glaukos company  
30 North Avenue  
Burlington, MA 01803  
USA

Version:  
Issued MM/YYYY  
ML-000159

---

# GLAUKOS<sup>®</sup>

## O<sub>2</sub>n<sup>™</sup> System Operator's Manual

---

Model Number: 110-02725





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

## O<sub>2</sub>n™ System Operator's Manual

ML-000120 Rev. DRAFT

10/2025

© 2025 All rights reserved. Printed in the USA

### Patents, Trademarks, Copyrights

The O<sub>2</sub>n™ System may be covered by one or more patent applications issued or pending in the United States and worldwide.

The Glaukos logo design is a registered trademark of Glaukos Corporation. O<sub>2</sub>n™ and Epioxa™ are trademarks of Glaukos®. All software and documentation are subject to Glaukos Corporation copyrights. Boost Goggles® is a registered trademark of Avedro. Avedro is a wholly owned subsidiary of Glaukos Corporation.

Microsoft and Windows are registered trademarks and trademarks, respectively, of Microsoft Corporation. Any other trademarks contained within this manual are the property of their respective owners.

# Table of Contents

1	Foreword.....	8
1.1	Intended Use of Manual.....	8
1.2	Intended Use.....	8
1.3	Intended Patient Population.....	8
1.4	Intended Part of the Body or Type of Tissue Applied to or Interacted With.....	8
1.5	Intended User Profile.....	8
1.6	Intended Use Environment.....	9
1.7	Confidentiality Disclaimer.....	9
1.8	Reproduction Disclaimer.....	9
1.9	User Operation Assistance Statement.....	9
1.10	Adverse Event Reporting.....	9
1.11	Safety Definitions.....	9
1.12	Contraindications, Warnings and Cautions.....	10
1.12.1	Contraindications.....	10
1.12.2	Warnings.....	10
1.12.3	Electrical Safety Warnings.....	10
1.12.4	Radiation Safety Warnings and Cautions.....	13
1.13	Patient Safety.....	14
1.14	Additional Safety Considerations.....	14
1.15	Use in Specific Populations.....	14
1.16	FCC Compliance Notice.....	14
2	Introduction.....	16
2.1	System Overview.....	16
2.1.1	Major Components.....	17
3	System Operation.....	21
3.1	Touchpad/Keyboard Use.....	21
3.2	UV Dose.....	22
3.3	Preparing the System.....	23
3.4	Important Steps Before Turning On the System.....	23
3.5	Powering On the System.....	23
3.6	New Treatment.....	25
3.7	Insert Treatment (RFID) Activation Card.....	26
3.8	Select Eye and Confirm Treatment.....	27
3.9	Sync Alignment Remote.....	28
3.10	Prepare the Patient.....	30
3.11	Epioxa HD and Epioxa Induction.....	31
3.12	Perform Ultrasound Pachymetry.....	33
3.13	Fit Boost Goggles.....	34
3.14	Align Crosshairs to Cornea.....	35

3.15	Begin UV-A Treatment .....	37
3.16	Monitoring Treatment .....	39
3.17	Stopping a Treatment .....	39
3.18	Treatment Complete .....	40
3.19	Pausing or Canceling a Treatment .....	41
3.20	Powering Off the O <sub>2</sub> n System .....	43
3.21	Accessing the Options Menu .....	44
3.22	Using the System Settings Menu .....	45
	3.22.1 Audio Volume .....	45
	3.22.2 Altering Camera White Balance .....	46
	3.22.3 Altering Alignment Crosshairs Intensity .....	46
	3.22.4 Export Service Log .....	47
	3.22.5 Service Settings .....	48
	3.22.6 Demo Mode .....	48
4	Maintenance/Service .....	52
4.1	Installation Policy .....	52
4.2	Customer Maintenance .....	52
4.3	Warranty Information .....	52
4.4	Service Contract Information .....	52
4.5	Troubleshooting .....	53
	4.5.1 Error Message Table .....	53
	4.5.2 Wireless Remote .....	55
4.6	Directions for Sterilization or Disinfection .....	56
4.7	Cleaning the System .....	57
4.8	Cleaning the Aperture .....	57
4.9	Articulating Arm Adjustment .....	57
4.10	Moving the System .....	59
4.11	Preparing the System for Storage .....	60
4.12	Software .....	60
4.13	Identifying Risks Associated with Disposing of Waste Products .....	60
4.14	Performing a Visible Check .....	61
5	Equipment Classification .....	62
5.1	Essential Performance .....	62
5.2	Equipment Classification .....	63
5.3	EMC Guidance .....	64
5.4	RF Transmitters .....	70
	5.4.1 RFID Reader .....	70
	5.4.2 Wireless Remote Control .....	71
6	Symbols Library .....	74
7	Specifications .....	77
8	Cybersecurity .....	78
8.1	About Your Device .....	78

8.2	Installation and Storage.....	78
8.3	O <sub>2</sub> n System Secure Operation .....	78
8.4	O <sub>2</sub> n System Security Features.....	79
8.5	O <sub>2</sub> n System Back Up and Restore Features .....	79
8.6	O <sub>2</sub> n System Connectivity and Interfaces .....	80
8.7	Software Bill of Materials (SBOM) and Software Updates .....	81
8.8	O <sub>2</sub> n System Response to Security Events .....	81

## Table of Figures

Figure 2-1. Overview of O <sub>2</sub> n™ System .....	17
Figure 2-2. System Components Overview .....	18
Figure 2-3. Wireless Remote Control Overview .....	18
Figure 2-4. O <sub>2</sub> n System Label.....	19
Figure 2-5. UV Warning Label.....	19
Figure 2-6. Laser Classification Label.....	19
Figure 2-7. Laser Certification Label.....	20
Figure 3-1. Mains Power “On” Position.....	24
Figure 3-2. Power-on Button.....	24
Figure 3-3. Startup Screen.....	25
Figure 3-4. Start Treatment Screen .....	25
Figure 3-5. Reading Activation Card .....	26
Figure 3-6. Card Reading Completed.....	27
Figure 3-7. Treatment Confirmation Screen.....	28
Figure 3-8. Sync Remote.....	28
Figure 3-9. Sync Remote Timeout .....	29
Figure 3-10. Sync Remote Failure .....	29
Figure 3-11. Epioxa HD Induction .....	31
Figure 3-12. Epioxa Induction.....	32
Figure 3-13. BSS Rinse .....	33
Figure 3-14. Fitting Patient with Boost Goggles .....	34
Figure 3-15. Confirming Oxygen Saturation .....	35
Figure 3-16. Alignment of Red Crosshairs - X, Y, and X axes .....	36
Figure 3-17. Fine Tuning Alignment–Onscreen Controls.....	36
Figure 3-18. Fine Tuning Alignment–Remote Controls .....	37
Figure 3-19. Start Treatment.....	38

Figure 3-20. UV-A Treatment Screen.....	38
Figure 3-21. Treatment in Progress Screen .....	39
Figure 3-22. Treatment Paused Screen .....	40
Figure 3-23. Treatment Summary Screen.....	41
Figure 3-24. Confirm Cancel Treatment Screen .....	42
Figure 3-25. Confirm Treatment Not Completed .....	42
Figure 3-26. Select "Power Off" .....	43
Figure 3-27. Confirm Power Off .....	43
Figure 3-28. Mains Power "Off" Position .....	44
Figure 3-29. Accessing "Options" Menu.....	44
Figure 3-30. System Settings .....	45
Figure 3-31. Edit Volume .....	45
Figure 3-32. Edit Camera White Balance .....	46
Figure 3-33. Alignment Crosshairs Intensity.....	47
Figure 3-34. Export Service Log to USB .....	47
Figure 3-35. Export Service Log in Progress.....	48
Figure 3-36. Select Demo Mode .....	49
Figure 3-37. Confirm Demo Mode.....	49
Figure 3-38. Demo Mode is Indicated at Top of Screen .....	50
Figure 3-39. Treatment Summary Screen – Demo Mode.....	50
Figure 3-40. Exit Demo Mode.....	51
Figure 4-1. Access Battery Compartment.....	55
Figure 4-2. Remote Sync Lost Guidance .....	55
Figure 4-3. Remote Sync Failure Guidance.....	56
Figure 4-4. Position the Arm Parallel to the Floor .....	57
Figure 4-5. Loosen Counterbalance Set Screw A .....	58
Figure 4-6. Loosen Counterbalance Set Screw B .....	58
Figure 4-7. Set Arm Tension with Strength Adjustment Screw C .....	59
Figure 4-8. System Configuration for Moving and Storage .....	60

## Table of Tables

Table 3-1. Remote Indicator Light Status and Meaning .....	30
Table 5-1. Electromagnetic Emissions .....	64
Table 5-2. Electromagnetic Immunity .....	65
Table 5-3. Electromagnetic Immunity (continued).....	67

Table 5-4. Common Emitters, RFID AIM 7531731, Wireless Co-existence (ANSI C63.27).....69  
Table 5-5. Recommended Separation Distances.....69  
Table 5-6. Highest Emissions .....71

# 1 Foreword

---

## 1.1 Intended Use of Manual

This manual is designed to serve the operators of the O<sub>2</sub>n™ 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.

This manual does not include all the information needed to use EPIOXA™ HD and EPIOXA™ safely and effectively. See Full Prescribing Information for EPIOXA HD and EPIOXA.

## 1.2 Intended Use

The O<sub>2</sub>n™ System is intended for use with Epioxa™ HD (riboflavin 5'-phosphate ophthalmic solution) 0.239% and Epioxa™ (riboflavin 5'-phosphate ophthalmic solution) 0.177% and Boost Goggles® in epithelium-on corneal collagen cross-linking for the treatment of keratoconus in adults and pediatric patients aged 13 years and older.

## 1.3 Intended Patient Population

Patients who require epithelium-on corneal cross-linking procedures for the treatment of keratoconus.

## 1.4 Intended Part of the Body or Type of Tissue Applied to or Interacted With

Cornea, ocular tissue.

## 1.5 Intended User Profile

The intended users or system operators are trained medical professionals.



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

## 1.6 Intended Use Environment

The O<sub>2</sub>n 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, ambulatory surgical centers (ASCs), and hospitals.

## 1.7 Confidentiality Disclaimer

All patient data appearing in this document, including the sample screen graphics, are fictitious and representative only. No patient's confidentiality has been violated, with or without permission.

## 1.8 Reproduction Disclaimer

Neither this manual nor any part of it may be reproduced, photocopied, or electronically transmitted in any way without the advance written permission of Glaukos Corporation.

## 1.9 User Operation Assistance Statement

Should you experience any difficulty in running your O<sub>2</sub>n System, please contact your Glaukos authorized representative.

## 1.10 Adverse Event Reporting

Adverse events and/or serious incidents must be reported to Glaukos Corporation at [MedicalSafety@Glaukos.com](mailto:MedicalSafety@Glaukos.com).

## 1.11 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.

## 1.12 Contraindications, Warnings and Cautions

### 1.12.1 Contraindications

Aphakic and Pseudophakic Patients: Epithelium-on corneal collagen cross-linking is contraindicated in aphakic patients and pseudophakic patients without a UV-blocking intraocular lens.

### 1.12.2 Warnings

Herpetic Keratitis: Corneal collagen cross-linking should be used with caution in patients with a history of herpetic keratitis due to the potential for reactivation of herpes keratitis.

### 1.12.3 Electrical Safety Warnings

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

Portable and mobile RF communications equipment can affect medical electrical equipment such as the O<sub>2</sub>n System.

For Equipment Classifications please refer to Chapter 5.0 Equipment Classifications.



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

The System is designed for continuous operation using the external connector.



**WARNING:** This equipment is operated with hazardous voltages that can shock, burn, or cause death. To reduce the possibility of electrical shock, and inadvertent UV-A 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 service personnel.



WARNING: Power down the O<sub>2</sub>n 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 O<sub>2</sub>n System must be positioned so that it is not difficult to remove the power cord from the outlet.



WARNING: Do not operate the O<sub>2</sub>n System 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 O<sub>2</sub>n System near water and be careful not to spill liquids on any part of it.



WARNING: The Universal Serial Bus (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 O<sub>2</sub>n System in the presence of flammable mixtures or anesthetics.



WARNING: The remote contains replaceable batteries; if O<sub>2</sub>n System is not going to be used for an extended period remove the batteries.



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



WARNING: No modification of this equipment is allowed.



WARNING: Use of not-included accessories results in non-compliance of the System.



WARNING: The O<sub>2</sub>n System may be interfered with by other equipment even if that equipment complies with CISPR Emissions requirements. See Table 5-1.



WARNING: The O<sub>2</sub>n System shall not be serviced or maintained while in use with a patient.



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



WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the O<sub>2</sub>n System (110-02725), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

#### 1.12.4 Radiation Safety Warnings and Cautions



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



WARNING: UV emitted from this product. Avoid eye and skin exposure to unshielded products. Never direct the beam towards a person except for therapeutic purposes.



WARNING: UV emitted from this lamp. Skin or eye injury could result. Avoid exposure of eyes and skin to unshielded lamp.



CAUTION: UV emitted from this lamp. Skin or eye irritation. Minimize exposure.



CAUTION: 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 Patient Safety

The treatment should take place in a quiet atmosphere in order not to distract the attention of the patient.

- The patient should lie on a table or patient's chair in a supine position.
- The patient's head should rest comfortably in a headrest. It is imperative that the table or patient's chair and the System not be moved during the treatment procedure.



CAUTION: The O<sub>2</sub>n 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.

### 1.14 Additional Safety Considerations

- Any modification of the System's external light beam by means of optical elements is strictly prohibited.
- Plastic instrumentation such as speculums or eye shields may be damaged when impacted by the UV beam, possibly resulting in product degradation.

### 1.15 Use in Specific Populations

- The safety and effectiveness of corneal collagen cross-linking have been established in pediatric patients aged 13 years and older.

### 1.16 FCC Compliance Notice

This equipment has been tested and found to comply with the limits for a Class A 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 Glaukos® Customer Service for help. 781-768-3400

Properly shielded and grounded cables and connectors must be used to meet Federal Communication Commission (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 System.

NOTE: "Harmful interference" is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

# 2 Introduction

---

## 2.1 System Overview

The O<sub>2</sub>n System is an electronic medical device which delivers ultraviolet light (365-nm wavelength) in a round, broad-beam pattern onto the cornea after riboflavin 5'-phosphate ophthalmic solution (Epioxa HD and Epioxa) have been applied. Irradiating the riboflavin 5'-phosphate ophthalmic solution creates singlet oxygen, which forms intermolecular bonds in corneal collagen thereby 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 optical head houses the UV-A irradiation mechanism. The system emits UV-A radiation at a wavelength of 365 nm at an irradiance of 30 mW/cm<sup>2</sup> pulsed (1 second on, 1 second off) for 11 minutes, 6 seconds.

A fixed aperture mounted in the UV-A irradiation beam path is used to produce a circular area of irradiation at the treatment plane with a diameter of 9.0 mm. Alignment lasers are used to aid the user in focusing the beam on the patient's cornea. Fine alignment of the UV beam through observation of the alignment lasers is controlled by the user through a wireless remote.

The O<sub>2</sub>n System 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. The treatment parameters (Riboflavin Induction Period, Total UV Energy and UV Power) are confirmed through the user interface touch screen computer.

The O<sub>2</sub>n System is used in conjunction with Epioxa HD and Epioxa, Boost Goggles and a radio frequency identification (RFID) activation card.

NOTE: The depictions of the O<sub>2</sub>n System and user interface screenshots included in this manual are for demonstration purposes only.

## 2.1.1 Major Components

The O<sub>2</sub>n System part number includes the following major components:

- Optics Head with UV-A source
- Console with user interface
- Wireless remote control (with replaceable batteries)
- Hospital grade AC power cable (lockable/detachable)
- Epithelium-on Cross-linking Kit (disposable, supplied separately)
- Boost Goggles (disposable, supplied separately)



*Figure 2-1. Overview of O<sub>2</sub>n™ System*

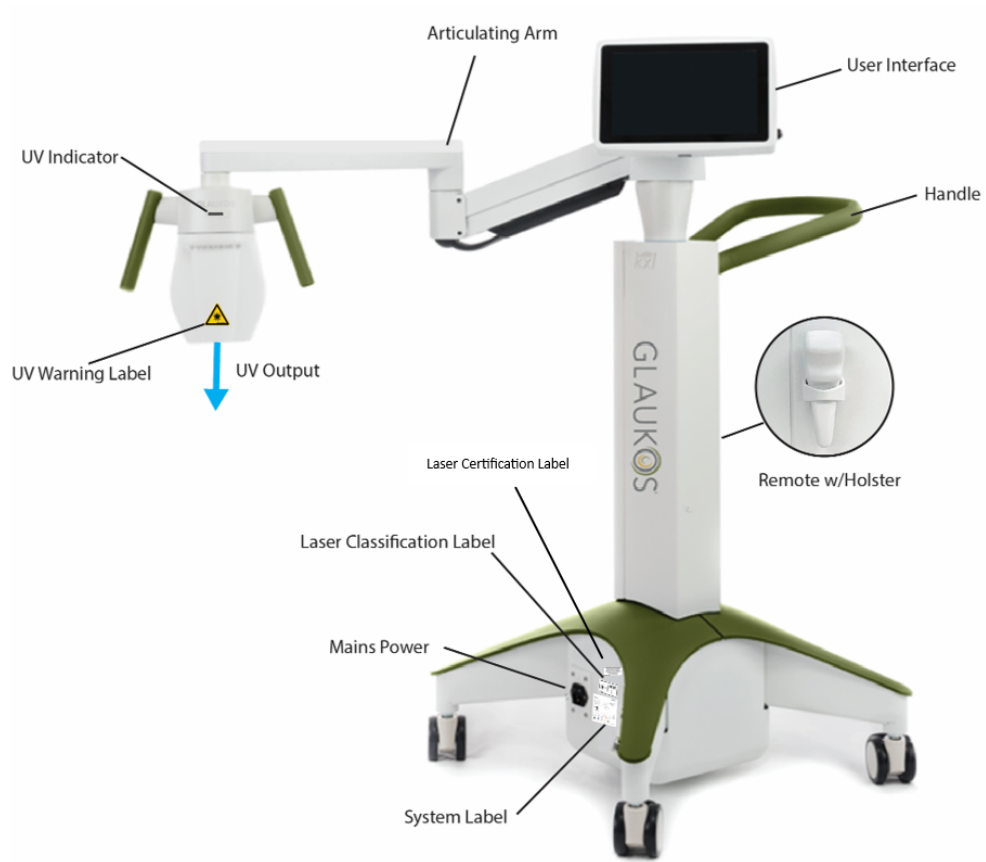


Figure 2-2. System Components Overview

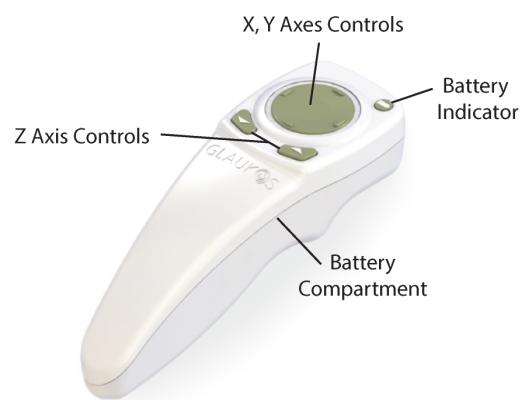


Figure 2-3. Wireless Remote Control Overview

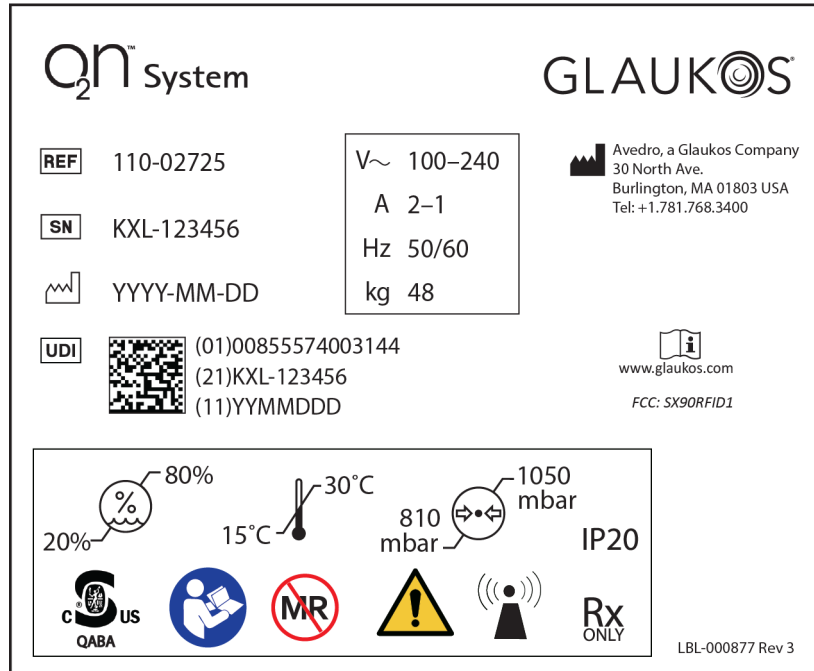


Figure 2-4. O<sub>2</sub>n System Label



Figure 2-5. UV Warning Label



Figure 2-6. Laser Classification Label

**Complies with FDA performance standards for laser products except for conformance with IEC 60825-1 Ed. 3., as described in Laser Notice No. 56, dated May 8, 2019.**



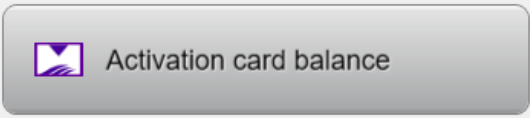
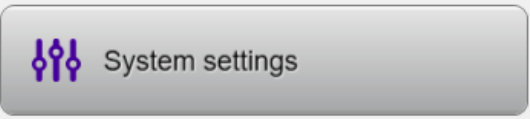
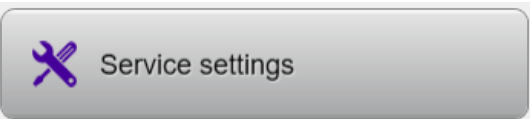


LBL-001036, Rev. 1




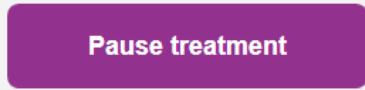

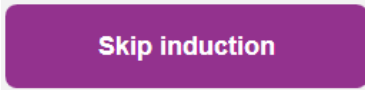

*Figure 2-7. Laser Certification Label*

# 3 System Operation

## 3.1 Touchpad/Keyboard Use

The table below identifies and describes important touchpad keys and icons unique to O<sub>2</sub>n System operation. Section 2.1.1 identifies the System's major components.

Touchpad Key	Icon	Description/Function
Power Off button (Initial screen)		Turns OFF electric power to the console.
Options button (Initial screen)		Displays system settings and demo mode.
Activation card balance button		Displays balance on Treatment Activation Card
System Settings		Device settings menu is displayed
Service settings		Ability to edit default parameters
OK button (various screens)		Directs the system to accept the current screen entries and to proceed to the next step.
Cancel button (various screens)		Cancels all the entries on a screen.

Touchpad Key	Icon	Description/Function
Done button (various screens)		Registers any changes on a screen or provides user with notifications and then returns to previous screen.
Start timer button		Starts treatment timer
Start treatment button (various Clinical Protocol screens)		Starts treatment
Pause treatment button		Pauses treatment
Resume treatment button		Resumes UV treatment from pause
Skip induction button		Skips riboflavin induction step
Fit Boost Goggles® button		Preparation step to allow patient to be fitted properly with Boost Goggles®



**CAUTION:** Only qualified and experienced personnel shall operate the UV-A System.

### 3.2 UV Dose

- UV Energy (Dose) is the product of UV Power (Irradiance) and UV Irradiation Time. UV Energy, UV Power and UV Irradiation Time are displayed on the user interface.
- The System tracks UV Energy, UV Power, UV Irradiation Time and Total Treatment Time during the treatment.
- The System's parameters are:
  - Induction Period: 4 minutes Epioxa HD  
6 minutes Epioxa

- Wavelength: 365 nm
- UV Energy: 10 J/cm<sup>2</sup>
- UV Power: 30 mW/cm<sup>2</sup> +/- 10%
- UV Irradiation Time: 11 minutes, 6 seconds with an on/off cycle of 1 second UV-A on/  
1 second UV-A off

### 3.3 Preparing the System

- Position the O<sub>2</sub>n System adjacent to the treatment table or chair. Lock the casters to secure the System's position.
- Check glass window of beam aperture for dust and dirt. See Section 4.7 and Section 4.8 for cleaning instructions.

### 3.4 Important Steps Before Turning On the System

- The user is responsible for assuring that the O<sub>2</sub>n System is functioning properly and is in good working condition before starting a treatment.
- To ensure the System is functioning properly, consider the following mandatory points:
  - Inspect the device, accessories, and connecting cables for visible damage.
  - Take into consideration your local regulations for use of portable electro-optical medical devices.

### 3.5 Powering On the System

- Turn ON the mains power switch on the base of the O<sub>2</sub>n System, adjacent to the power cord plug. This switch provides alternating current (AC) mains power to the O<sub>2</sub>n System.

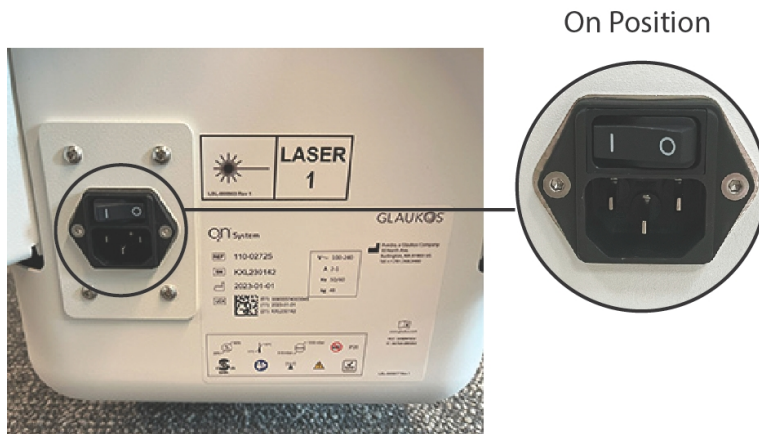


Figure 3-1. Mains Power "On" Position

- Press and release the power-on button on the side of the O<sub>2</sub>n display screen. See figure below. The O<sub>2</sub>n System will begin a power-up sequence, loading the operating system and all configuration and reference files.



Figure 3-2. Power-on Button

- The O<sub>2</sub>n System begins a power-up sequence, loading the operating system and all configuration and reference files. This initialization time is approximately 1 minute, 30 seconds.



Figure 3-3. Startup Screen

NOTE: If there is a start-up error, please note any error messages and see Error Message Table for follow-up action.

- Please see Section 3.20 for Power Down sequence instructions.

### 3.6 New Treatment

- Press “Start Treatment” button in lower right of Home Screen as shown in Figure 3-4.

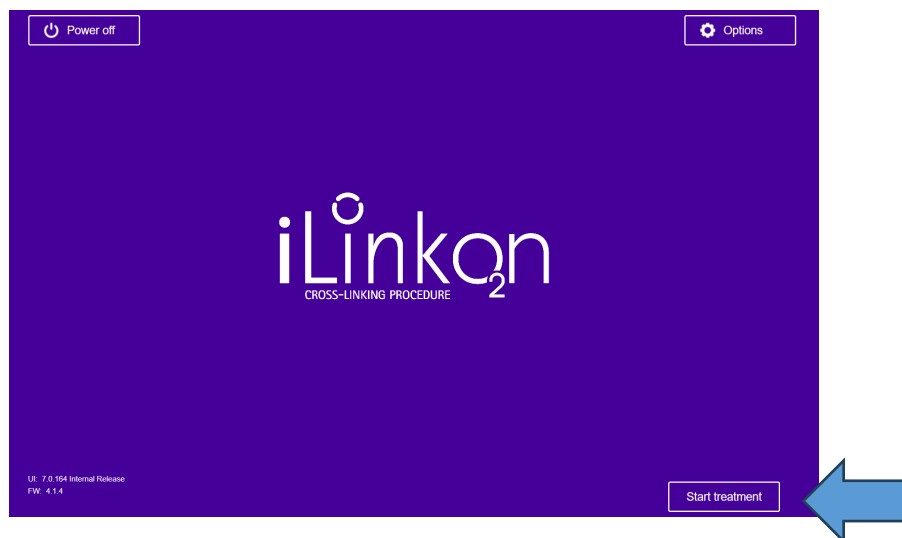
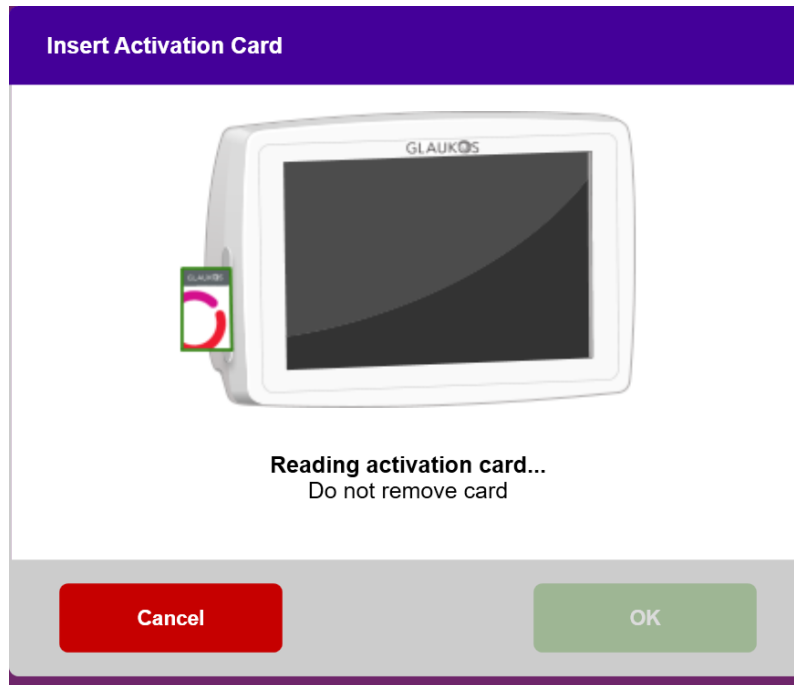


Figure 3-4. Start Treatment Screen

### 3.7 Insert Treatment (RFID) Activation Card

- The Treatment Activation Card is required to activate the system.  
NOTE: The Treatment Activation Card is programmed with parameters of 30 mW/cm<sup>2</sup> and 10 J/cm<sup>2</sup>.
- Insert the Treatment Activation Card into the RFID slot located to the left of the display screen until the system emits a beep.



*Figure 3-5. Reading Treatment Activation Card*

Keep the card inserted until reading is complete.

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

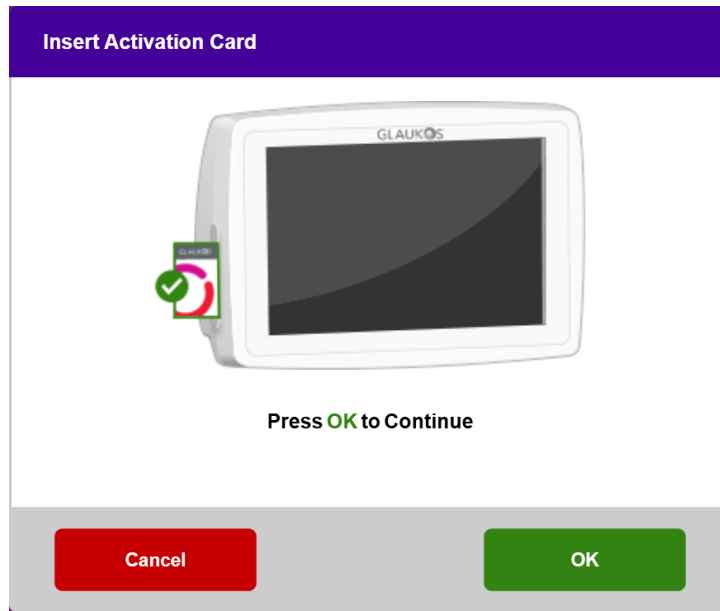


Figure 3-6. Treatment Activation Card Reading Completed

- The “OK” button will illuminate when the card has been read and treatment credit has been accepted by the System. Press “OK”. The user may remove the card at this time if desired.

### 3.8 Select Eye and Confirm Treatment

- Select eye to be treated by pressing either “OS” or “OD”.
- The Treatment confirmation screen is shown in Figure 3-7.
- Verify selection by pressing “Confirm”.

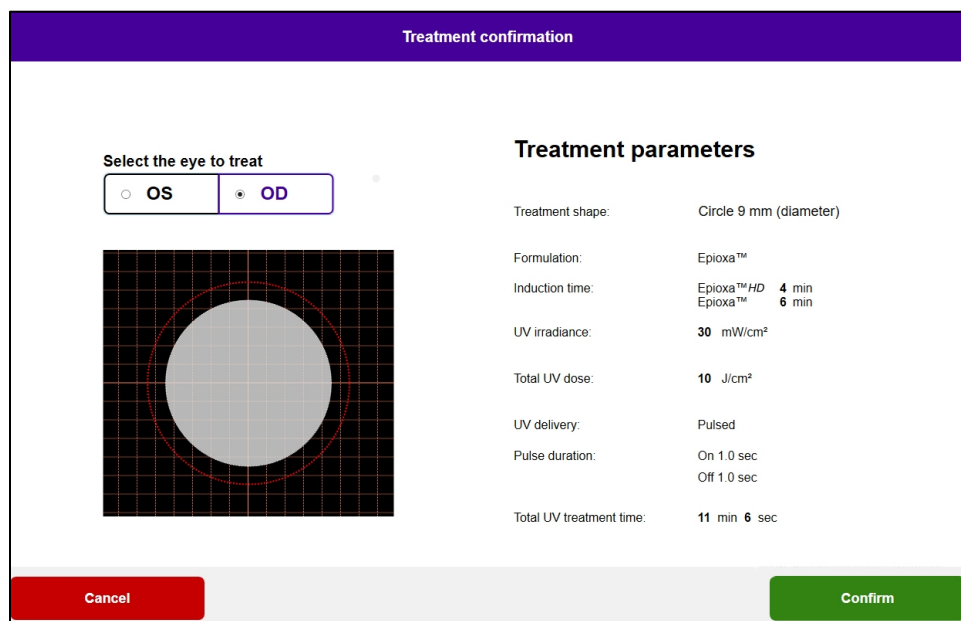


Figure 3-7. Treatment Confirmation Screen

### 3.9 Sync Alignment Remote

- The Sync alignment remote message will be visible on the screen for 15 seconds as shown in Figure 3-8.



Figure 3-8. Sync Remote

- Press any directional button to synchronize the remote within the 15-second timeframe. This is required for every procedure if use of the remote is desired.
- The system will beep every 2 seconds during the 15 second sync timeframe.
- If the sync button is not pressed within the 15 second timeframe, a message stating "Sync Remote Timeout" will appear onscreen.
- Press "OK" to attempt to re-sync the remote, or choose "Cancel" to cancel Treatment.

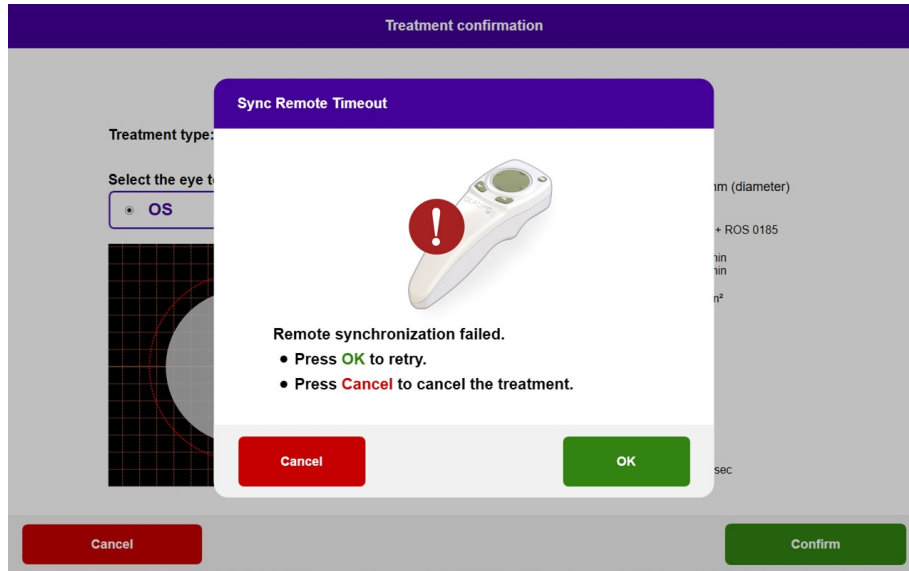


Figure 3-9. Sync Remote Timeout

- If the remote fails to sync a second time, The “Remote Sync Failure” screen will appear. Press “Continue” to continue treatment without the remote. Press “Cancel” to cancel the treatment.

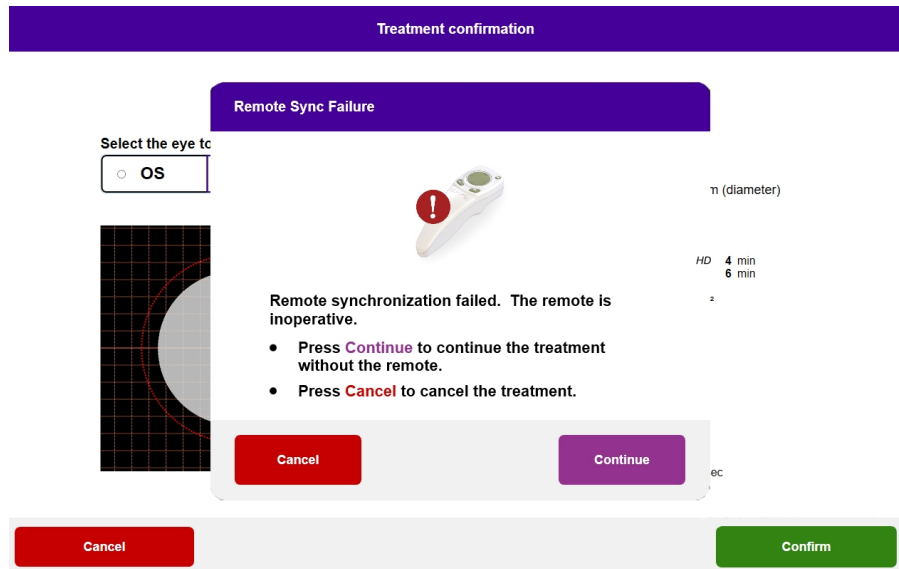


Figure 3-10. Sync Remote Failure

- The various statuses of the Remote Thumbpad Indicator Light and Battery Indicator Light are shown in Table 3-1.

Thumbpad Indicator Light Status	Meaning
No illumination	Off

Revolving blue light	Synchronizing
Steady blue light	Synchronized and Ready
Steady orange light	Lost synchronization
<b>Battery Indicator Light Status</b>	<b>Meaning</b>
No illumination	Off
Steady blue light	Battery is OK
Steady orange light	Less than 50% battery remaining
Flashing orange light	Less than 25% battery remaining

*Table 3-1. Remote Indicator Light Status and Meaning*

NOTE: The UV-A System performs an internal self-test prior to each treatment to verify proper UV-A calibration.

- The internal self-test uses a redundant set of optical sensors to ensure that accurate levels of UV-A 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, see Error Message Table for follow-up action.

### 3.10 Prepare the Patient

*This manual does not include all the information needed to use EPIOXA™ HD and EPIOXA™ safely and effectively. See Full Prescribing Information for EPIOXA HD and EPIOXA.*

- 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 topical anesthetic and insert a lid speculum.
- Using a cellulose spear sponge soaked with EPIOXA HD, remove the mucin layer from the corneal surface without debriding the corneal epithelium (epithelium-on) by swiping the sponge 4 to 10 times horizontally and vertically.

### 3.11 Epioxa HD and Epioxa Induction

*This manual does not include all the information needed to use EPIOXA™ HD and EPIOXA™ safely and effectively. See Full Prescribing Information for EPIOXA HD and EPIOXA.*

- STEP 1: Epioxa HD Induction  
Press “Start Timer” button and apply two drops of Epioxa HD topically on the eye every 60 seconds for 4 minutes.

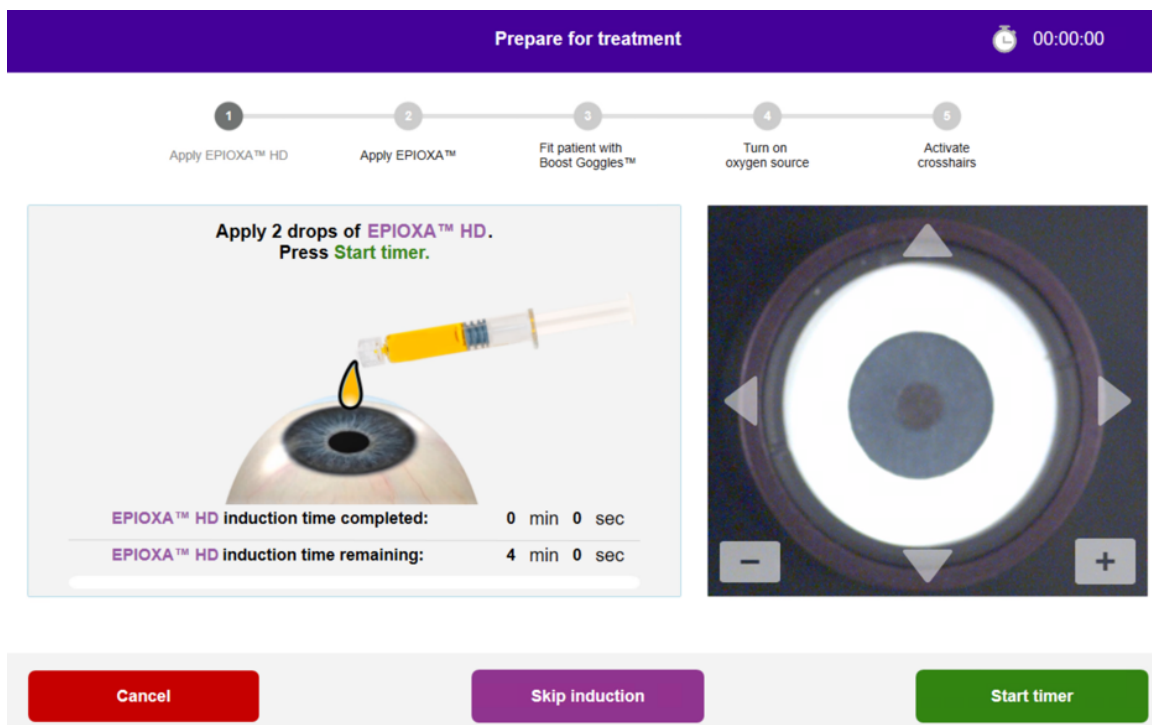


Figure 3-11. Epioxa HD Induction

- STEP 2: Epioxa Induction  
Press “Start Timer” button and apply two drops of Epioxa topically on the eye every 30 seconds for 6 minutes.

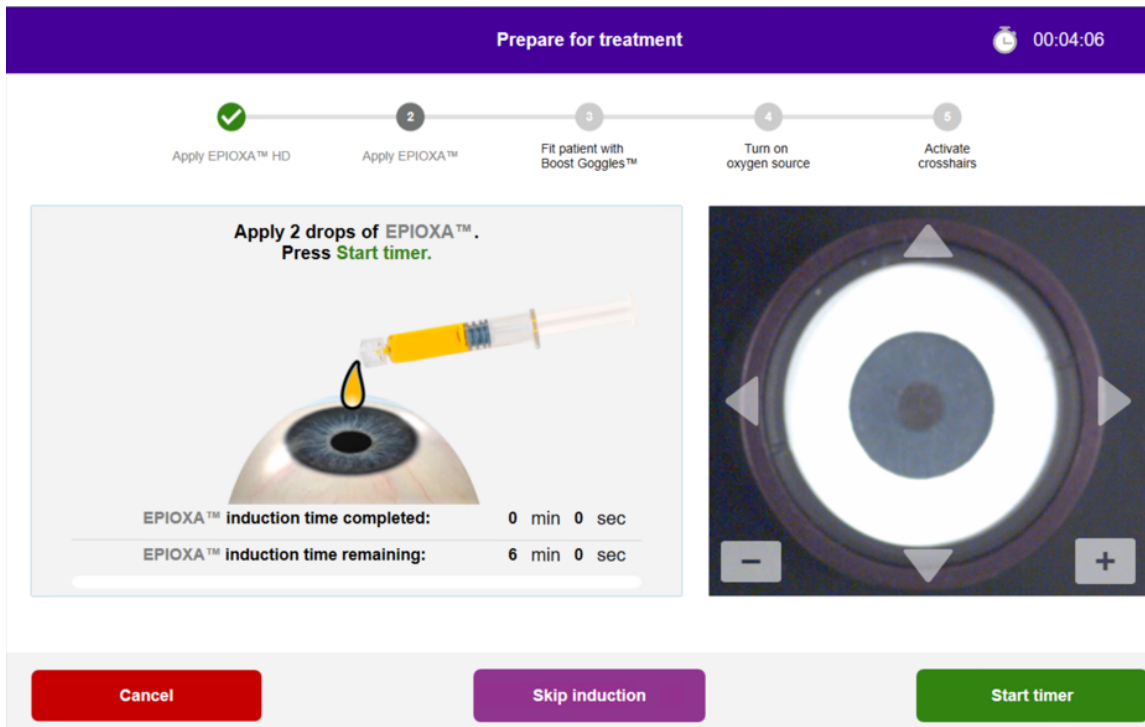


Figure 3-12. Epioxa Induction

- NOTE: If an error occurs and the system restarts, the user has the option to press skip induction. Refer to Troubleshooting Section 4.5 for more information on errors.
- Gently flush the corneal surface with approximately 5 mL of balanced salt solution (BSS). Then press “Fit Boost Goggles”.

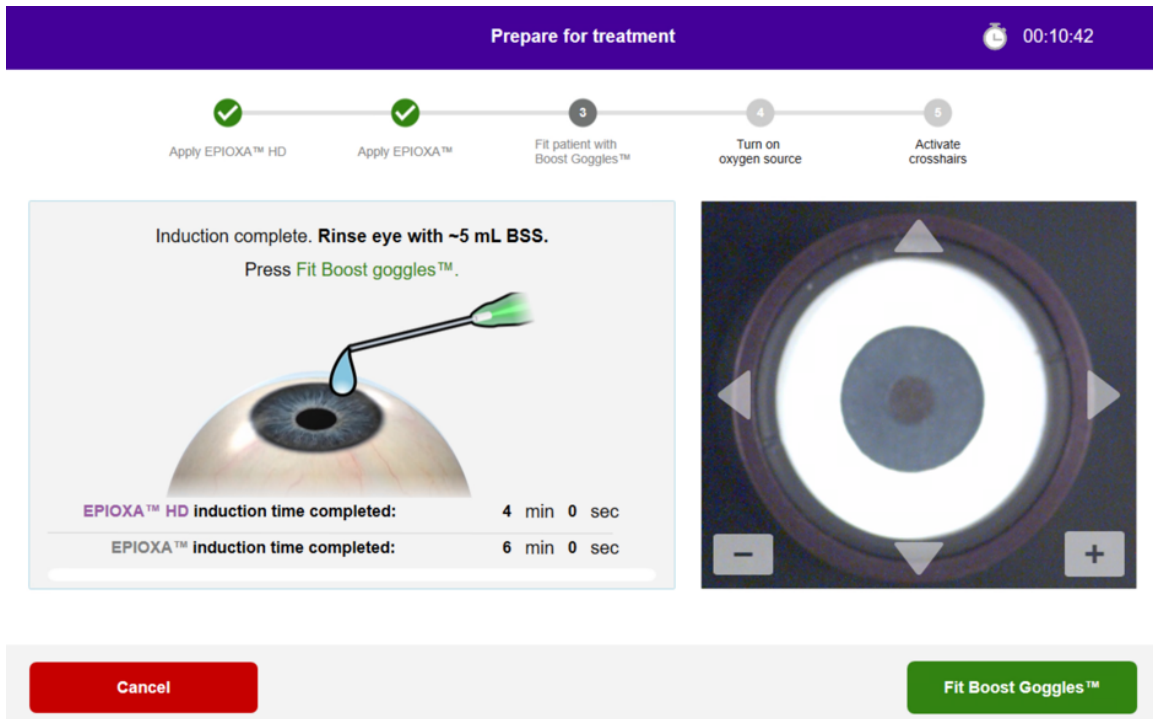


Figure 3-13. BSS Rinse

### 3.12 Perform Ultrasound Pachymetry

- If corneal thickness is less than 325 microns, irradiation should not be performed.

### 3.13 Fit Boost Goggles

- Gently apply Boost Goggles® to patient's face and secure with head strap.

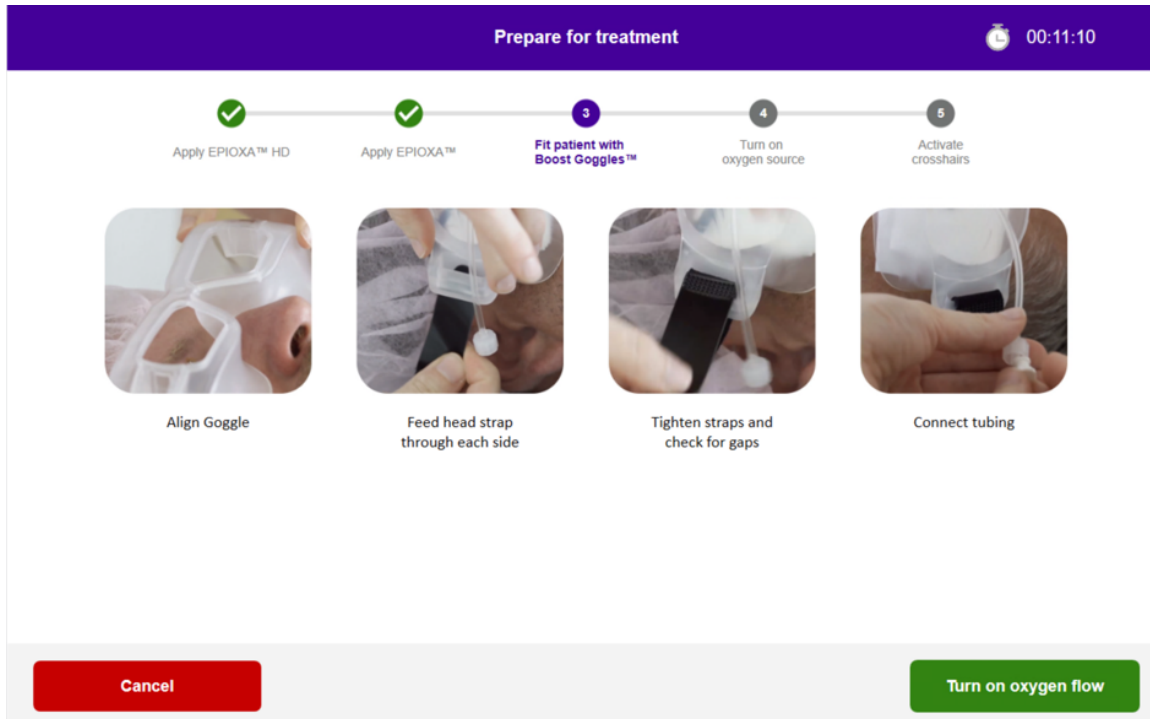


Figure 3-14. Fitting Patient with Boost Goggles

- Connect tubing to oxygen source and turn on oxygen flow as per the instructions in the *Boost Goggles User Guide*.
- Measure oxygen concentration temporarily by oxygen port, near corneal surface. Ensure saturation is at least 90%.



**WARNING:** Do not proceed until oxygen concentration measures at least 90%.

- Press “Confirm”.

The screenshot shows a medical device interface with a purple header bar containing the text "Prepare for treatment" and a timer "00:11:48". Below the header is a progress bar with five steps: 1. Apply EPIOXA™ HD (checked), 2. Apply EPIOXA™ (checked), 3. Fit patient with Boost Goggles™ (checked), 4. Turn on oxygen source (active), and 5. Activate crosshairs. To the right of the progress bar is a circular inset image showing a patient's eye with a device and a green overlay indicating "O<sub>2</sub> ≥ 90%". Below the progress bar are three bullet points: "Turn on oxygen flow", "Allow 2 minutes of steady oxygen flow", and "Measure oxygen concentration in goggles". Below these is a bold instruction: "DO NOT PROCEED UNTIL OXYGEN CONCENTRATION MEASURES AT LEAST 90%". Below the instruction is the text "Press Confirm to activate crosshairs". At the bottom of the screen are two buttons: a red "Cancel" button on the left and a green "Confirm" button on the right.

Figure 3-15. Confirming Oxygen Saturation

### 3.14 Align Crosshairs to Cornea

- UV-A has two alignment lasers as shown in the figure below.
  - Red crosshair for X and Y axes positioning.
  - A second red crosshair for Z axis positioning.
- NOTE: Crosshairs may differ in appearance. They may appear thicker, thinner, longer or shorter.

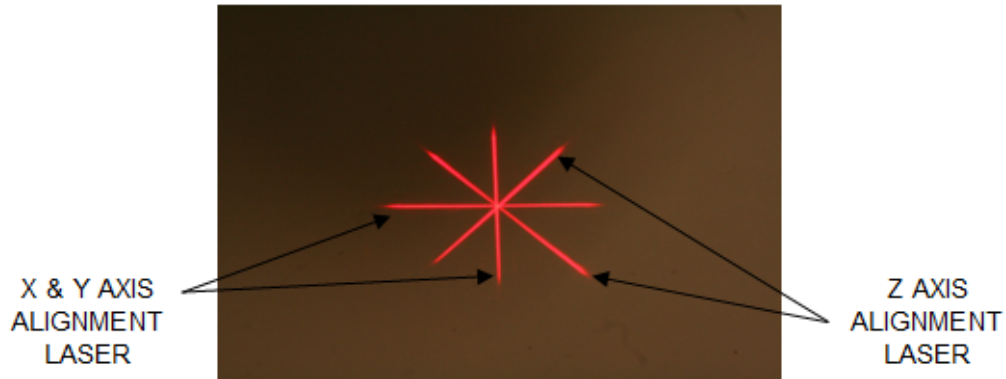


Figure 3-16. Alignment of Red Crosshairs - X, Y, and Z axes

- When alignment lasers turn on, align the crosshairs over the eye to be treated.
  - Manually move the UV-A head forward and back and left and right until the X/Y axes' red crosshairs are aligned to the center of the pupil.
  - Manually move the UV-A head up and down to align the Z axis second red crosshair to the center of the first red crosshair.
  - Fine tune the alignment as needed using the wireless remote or by pressing the onscreen arrows.

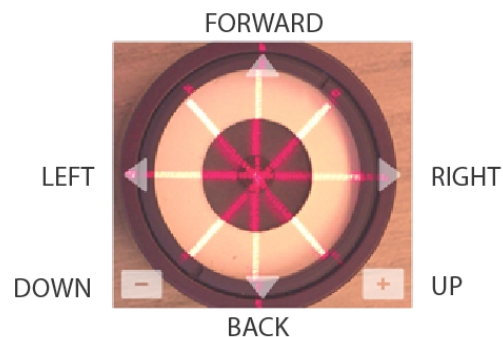


Figure 3-17. Fine Tuning Alignment—Onscreen Controls

- NOTE: For correct alignment when using the remote, the Glaukos logo on UV-A head should face the user. The figure below displays the controls used during the alignment process.

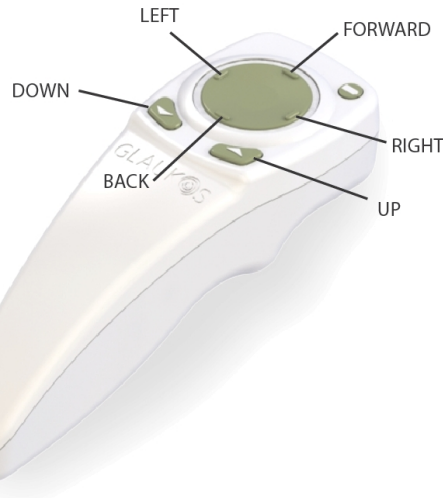


Figure 3-18. Fine Tuning Alignment–Remote Controls

### 3.15 Begin UV-A Treatment

- Press “Start treatment” button shown in Figure 3-20. The screen in Figure 3-21 will display “Treatment in Progress” as shown. Treatment time remaining will count down from 11 minutes, 6 seconds.

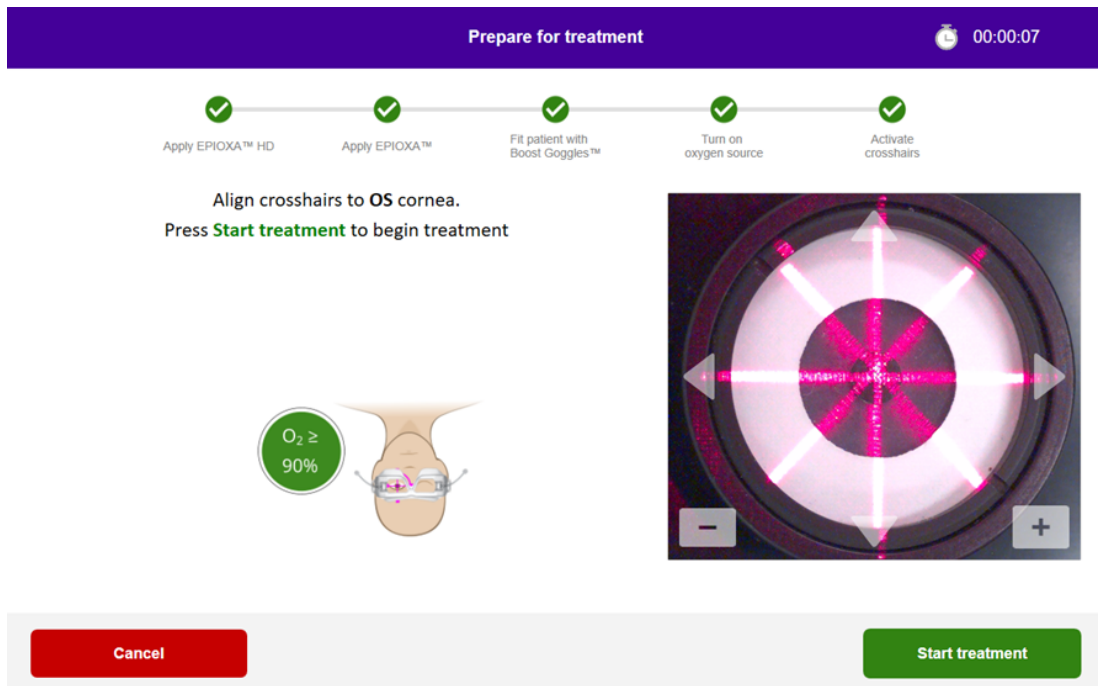


Figure 3-19. Start Treatment

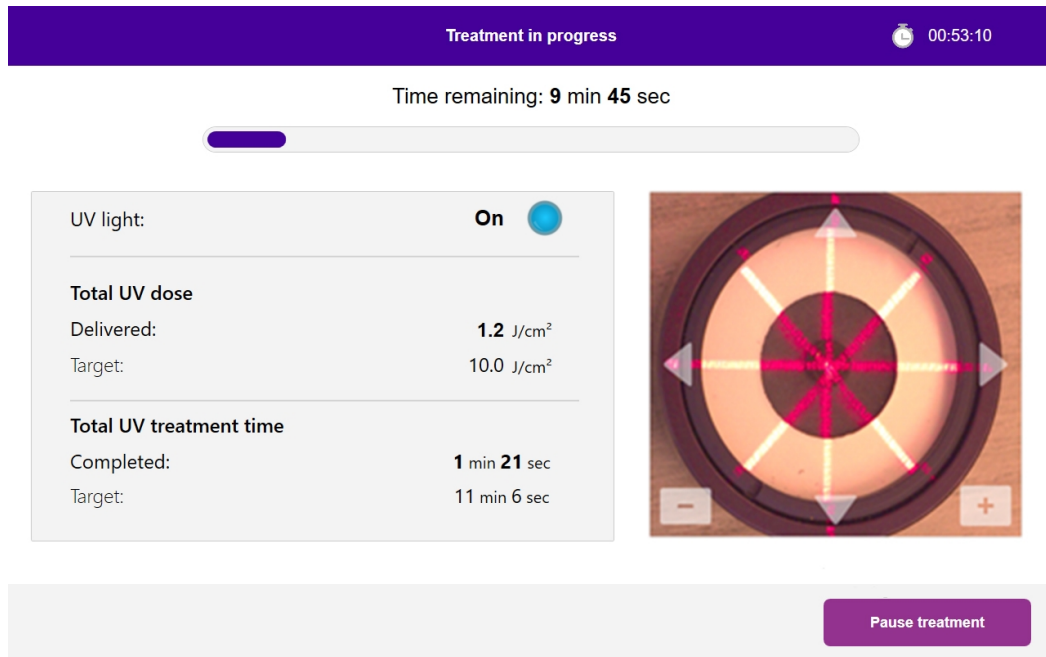


Figure 3-20. UV-A Treatment Screen

NOTE: The O<sub>2</sub>n system continuously monitors UV levels during treatment.

- The internal monitor uses a redundant set of optical sensors to ensure that accurate levels of UV-A are delivered throughout the treatment.
- If the UV-A levels deviate from the intended values, an error message will be generated, and the treatment cannot proceed. If this occurs, see Error Message Table for follow-up action.



WARNING: Avoid direct illumination of the corneal limbus.



WARNING: Make sure that the O<sub>2</sub>n System and the patient's table or chair are secured and not moved after alignment and during treatment.



CAUTION: UV light is emitted when the status indicator under the Glaukos logo on the optical head changes color from blue to green.

### 3.16 Monitoring Treatment

- Check continuously that the intended area of the cornea is illuminated with the UV-A light and adjust as necessary using the wireless remote or onscreen arrows.

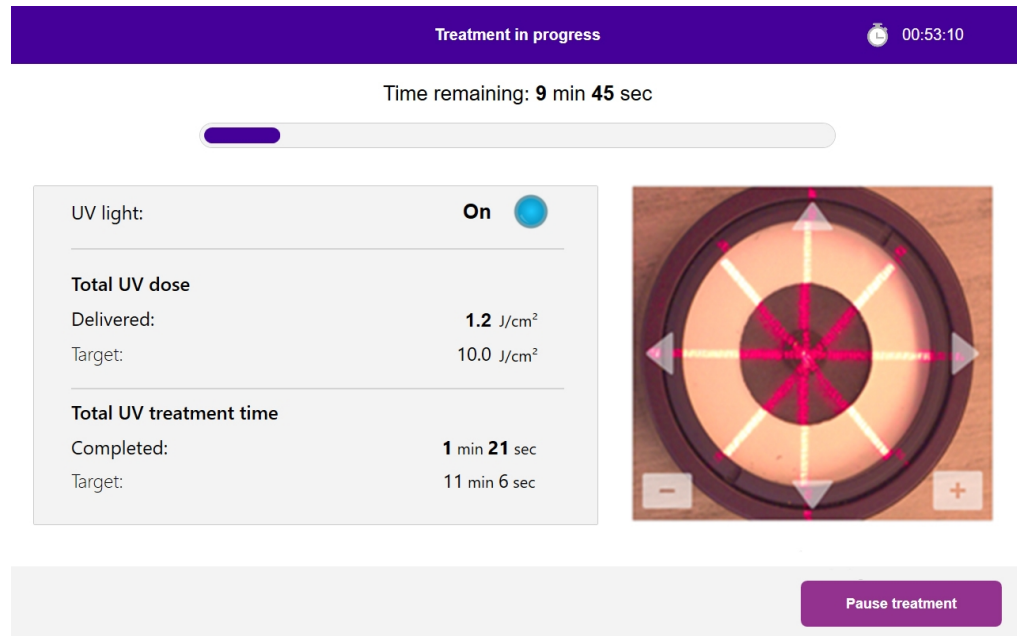


Figure 3-21. Treatment in Progress Screen

- The patient should attempt to fixate on the red X & Y alignment crosshair throughout the treatment.
- BSS should be instilled on the cornea every 2 minutes, or more frequently as needed, to maintain corneal hydration during UV-A irradiation.
- Patients should remain still during the treatment.

### 3.17 Stopping a Treatment

- The treatment stops automatically after the treatment timer expires.
- The user may decide to stop or interrupt the treatment. In such case, the UV-A light can be switched OFF by pushing the “Pause treatment” button.
- If treatment is Paused, the system will emit a double beep every few seconds as a reminder.

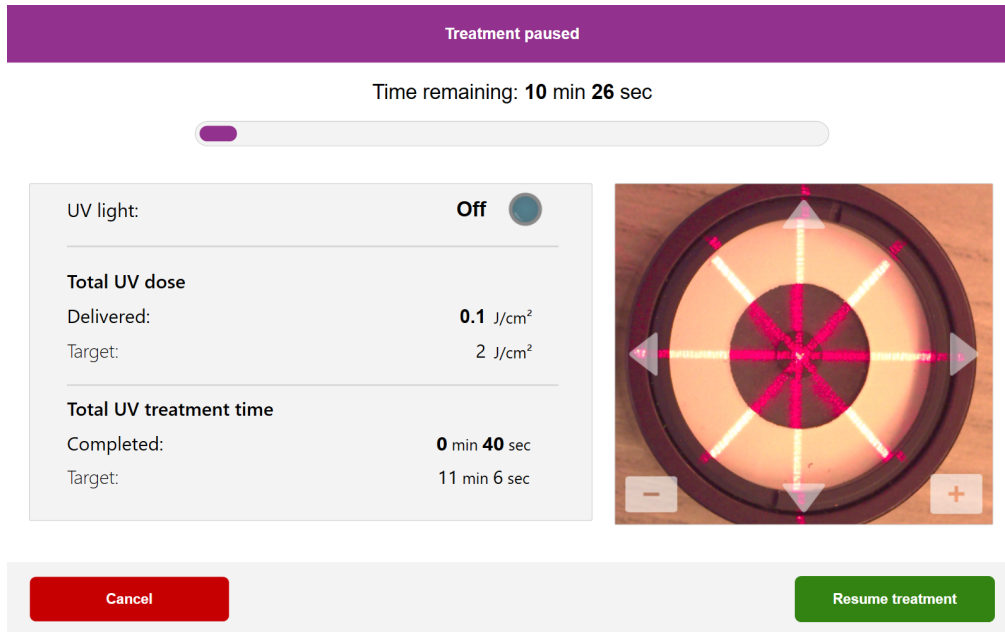


Figure 3-22. Treatment Paused Screen

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

### 3.18 Treatment Complete

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

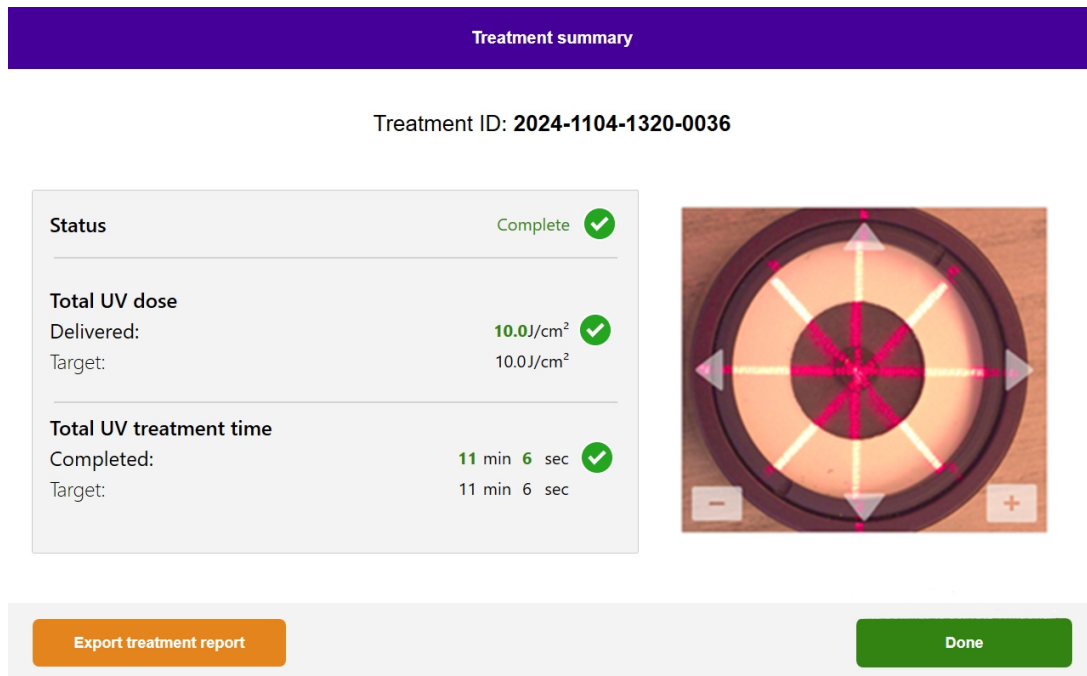


Figure 3-23. Treatment Summary Screen

- Press “Done” to exit treatment and/or start a new treatment. Press Export Treatment Summary to export a treatment report.
- When treatments are complete, power OFF the system using the “Power Off” button on the Main Screen.
- Carefully remove the device from the patient area.
- Measure oxygen concentration temporarily by oxygen port, near corneal surface.
- Shut off oxygen flow. Disconnect oxygen from Boost Goggles.
- Remove Boost Goggles from patient.
- Remove lid speculum.
- Apply a bandage contact lens.

### 3.19 Pausing or Canceling a Treatment

Treatment may be paused at the discretion of the physician. If a session is canceled the following screen displays to confirm cancel treatment.

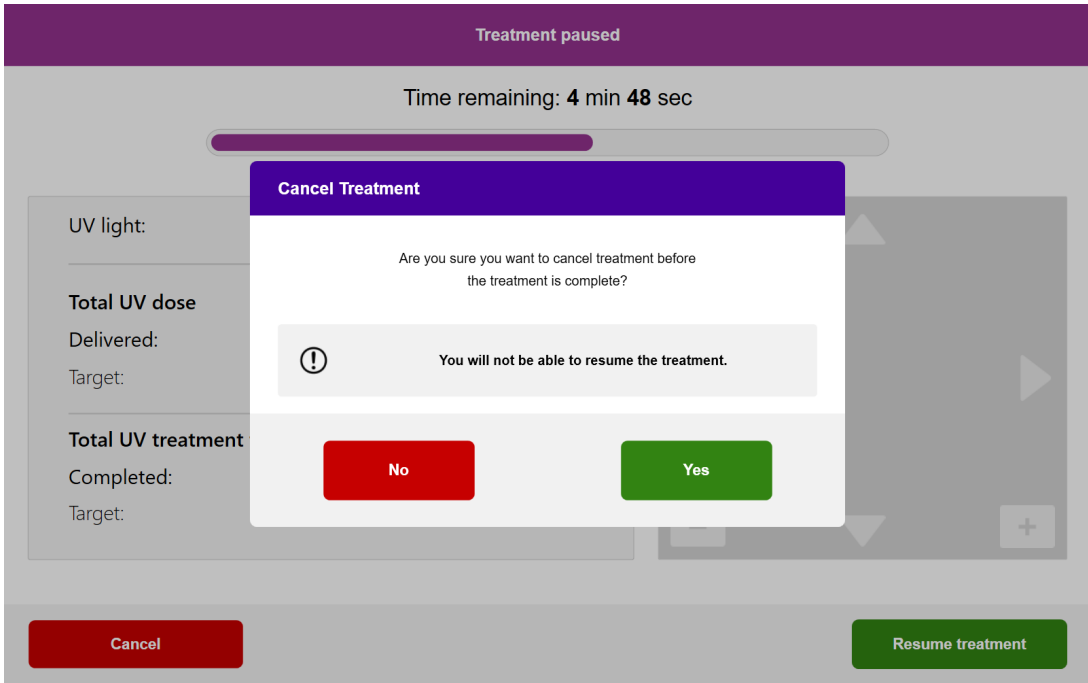


Figure 3-24. Confirm Cancel Treatment Screen

- To cancel a treatment, press "Yes".
- If the treatment is canceled, the screen displays "Treatment not completed".

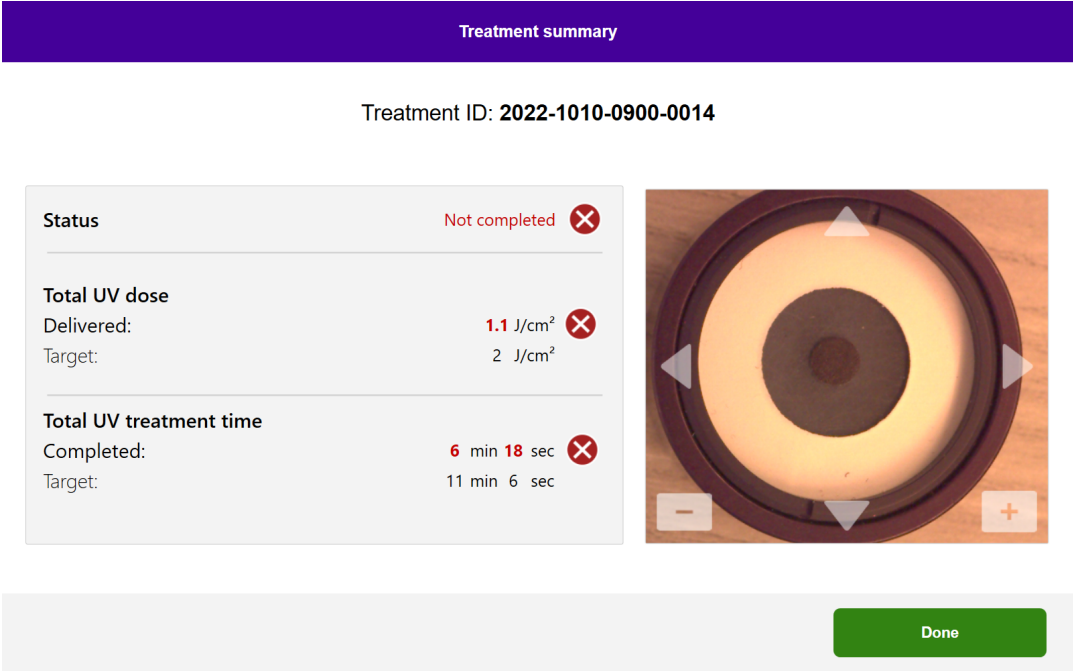


Figure 3-25. Confirm Treatment Not Completed

- To cancel the session, press "Done".
- System will return to home screen.

### 3.20 Powering Off the O<sub>2</sub>n System

- Select "Power Off" on the Patient List home screen as shown in Figure 3-26.

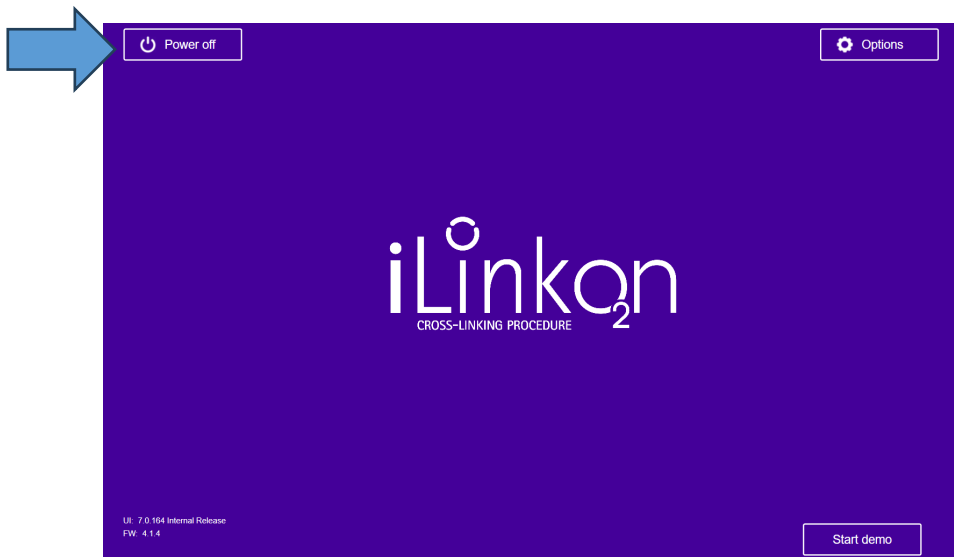


Figure 3-26. Select "Power Off"

- Confirm powering off system by selecting "Yes" as shown in Figure 3-27.

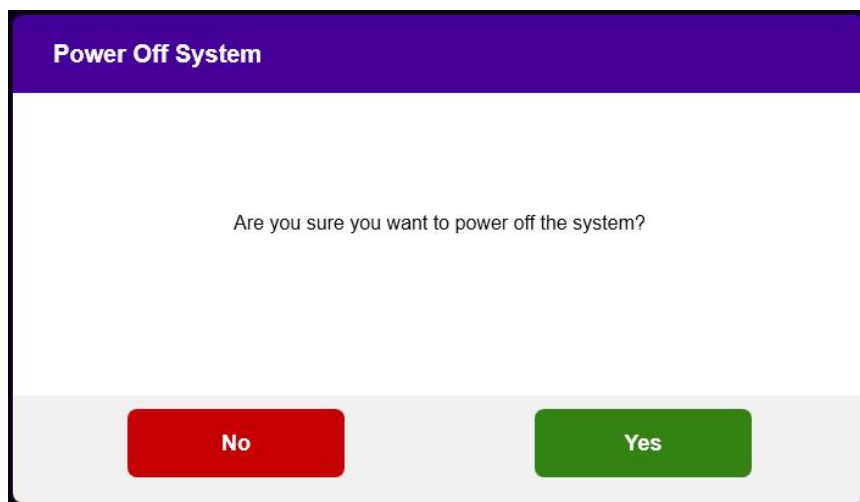


Figure 3-27. Confirm Power Off

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

- Turn the mains power switch on the UV-A base to the “Off” position as shown in Figure 3-28.

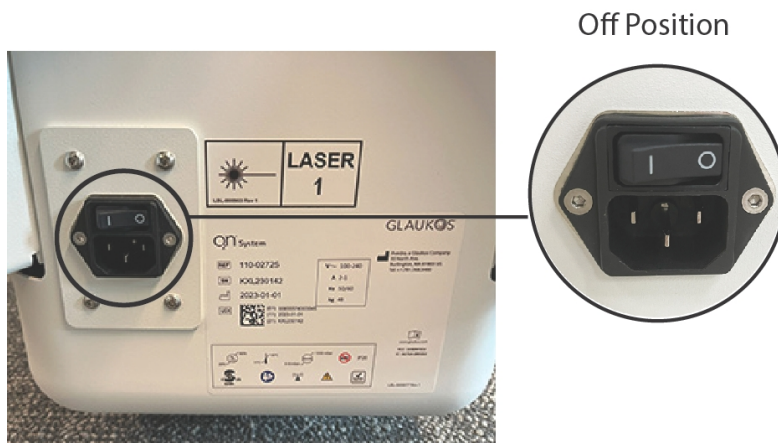


Figure 3-28. Mains Power “Off” Position

- NOTE: If the software becomes unresponsive, the System can be shut down by holding down the power button on the right side of the display screen.

### 3.21 Accessing the Options Menu

- From the Patient List home screen, press the “Options” button to display the 4 Options menu as shown in Figure 3-29.

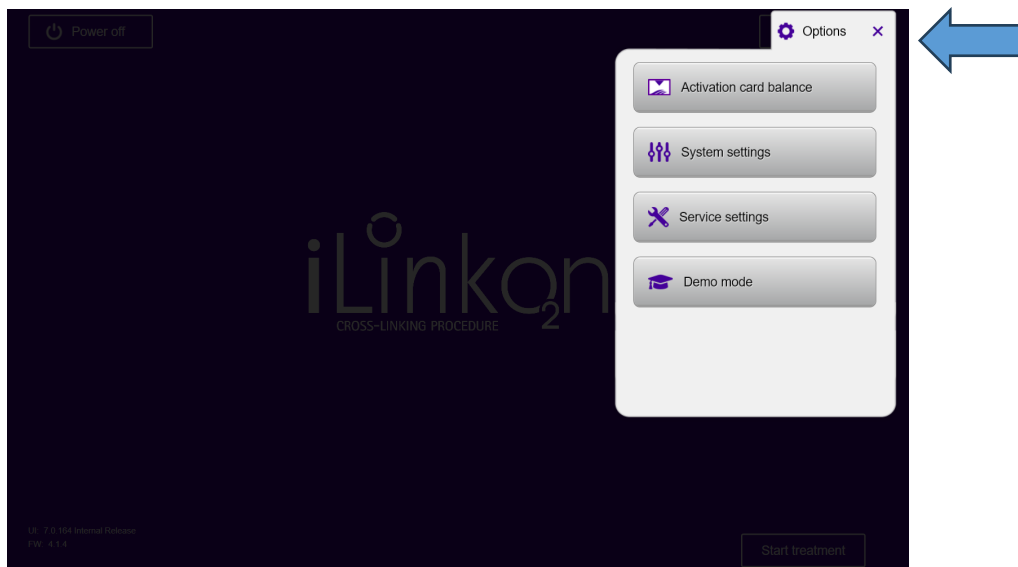


Figure 3-29. Accessing “Options” Menu

## 3.22 Using the System Settings Menu

- Select “System Setting” from the options menu to access the system settings shown in Figure 3-30.

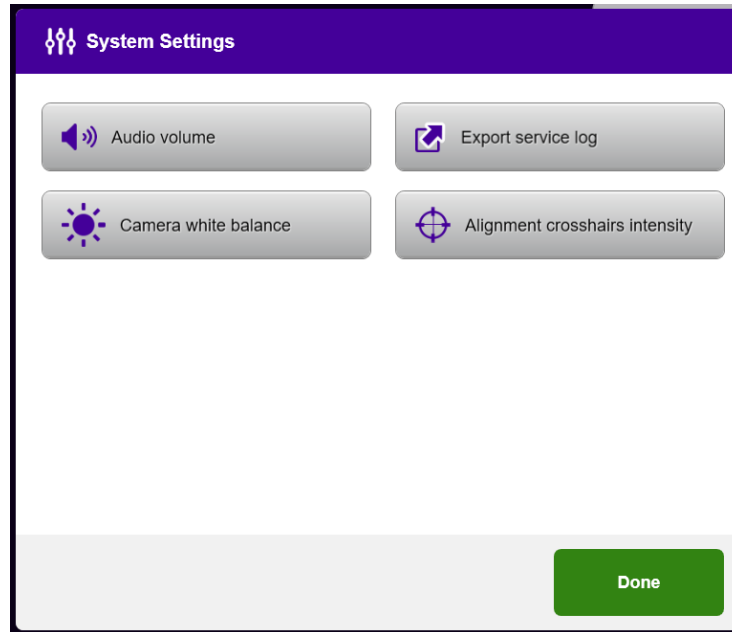


Figure 3-30. System Settings

### 3.22.1 Audio Volume

- Select “Audio Volume” from the System Settings menu to alter the sound volume level.

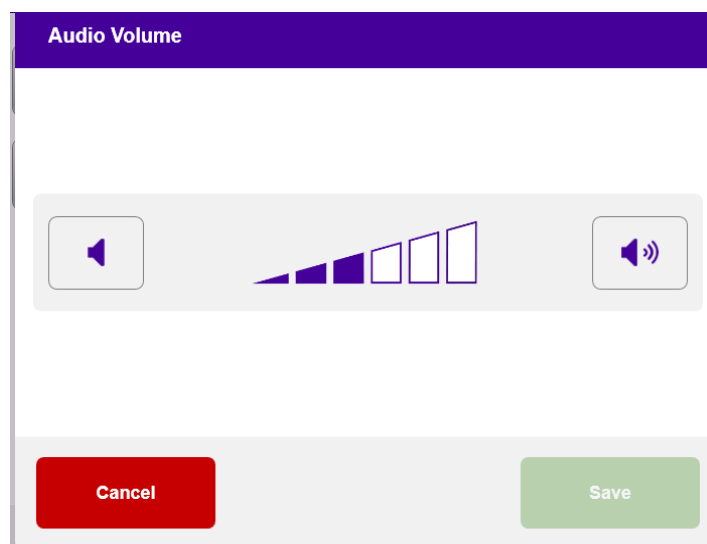


Figure 3-31. Edit Volume

### 3.22.2 Altering Camera White Balance

- Select "Camera White Balance" from the System Settings menu to change the light conditions within the console.
- Select desired white balance and click "Save" to return to the System Settings menu.

NOTE: Typical office lighting is under 5000K. As a result, the System default setting is Daylight 5000K. If a different light source is used, it may be useful to edit the white balance condition.

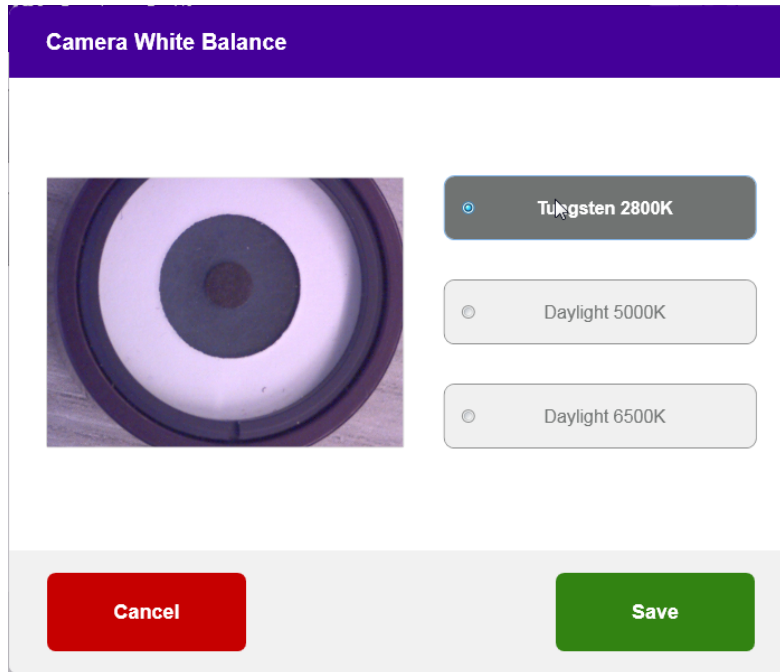


Figure 3-32. Edit Camera White Balance

### 3.22.3 Altering Alignment Crosshairs Intensity

- Select "Alignment Crosshairs Intensity" from the System Settings menu to alter the brightness of the alignment crosshairs. The screen shown in Figure 3-33 will appear.
- Adjust crosshair brightness and select "Save."

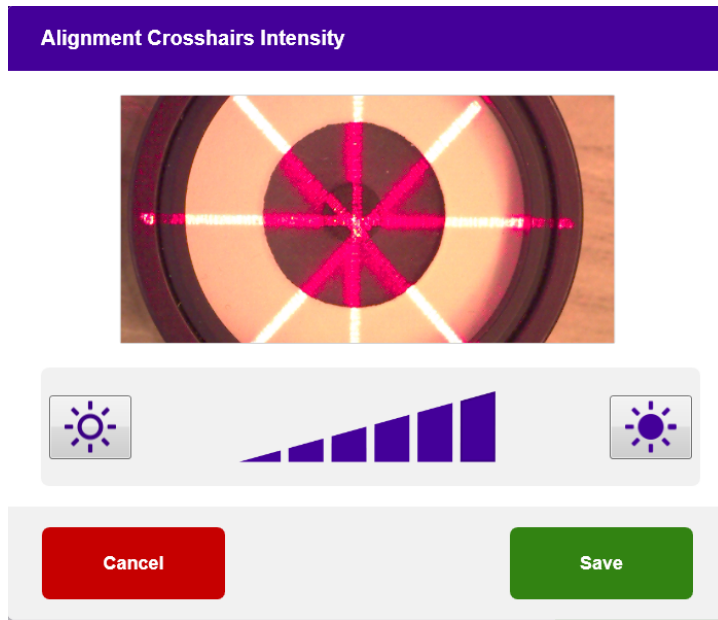


Figure 3-33. Alignment Crosshairs Intensity

### 3.22.4 Export Service Log

- Select "Export Service Log" from the System Settings menu.
- Follow onscreen instructions to insert a USB drive to the USB port as shown in Figure 3-34.

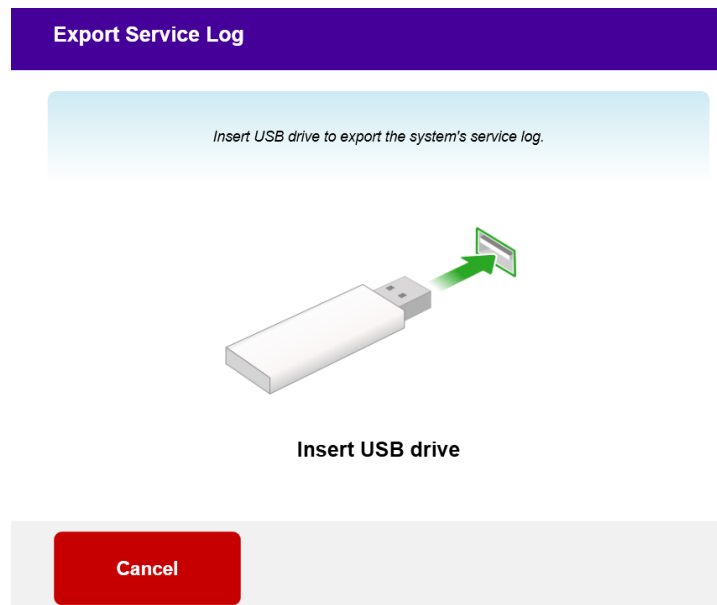
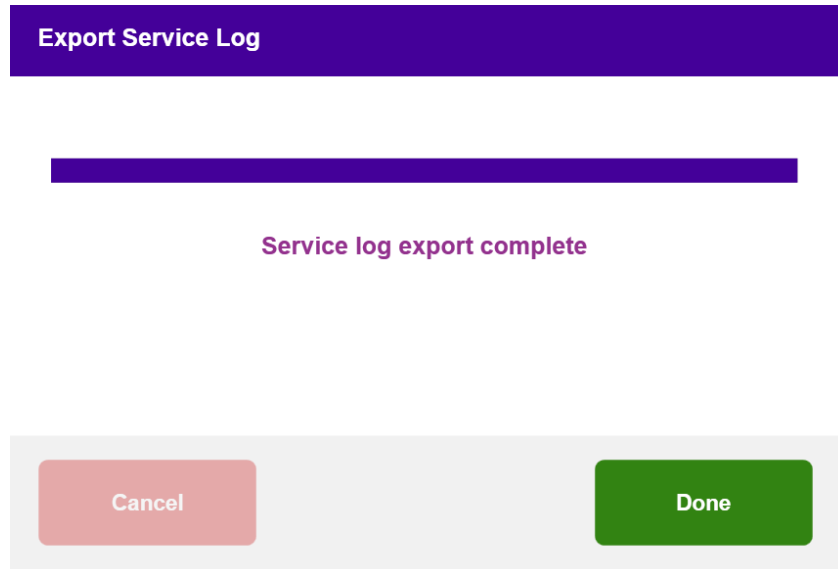


Figure 3-34. Export Service Log to USB

- The System automatically begins transferring the service log and shows a progress bar of the transfer process as shown in Figure 3-35.



*Figure 3-35. Export Service Log in Progress*

- Once the export is complete, press "Done" to return to the System Settings menu.

### 3.22.5 Service Settings

- Service Settings are only available to Glaukos® Service personnel.
- If selected, the user will be prompted to scan an access card.

### 3.22.6 Demo Mode

NOTE: Not for use in treating patients

- Demo mode allows users to train on use of the UV-A System without requiring a Treatment Activation Card and without using UV-A light.
  - Select "Demo Mode" from Options Menu

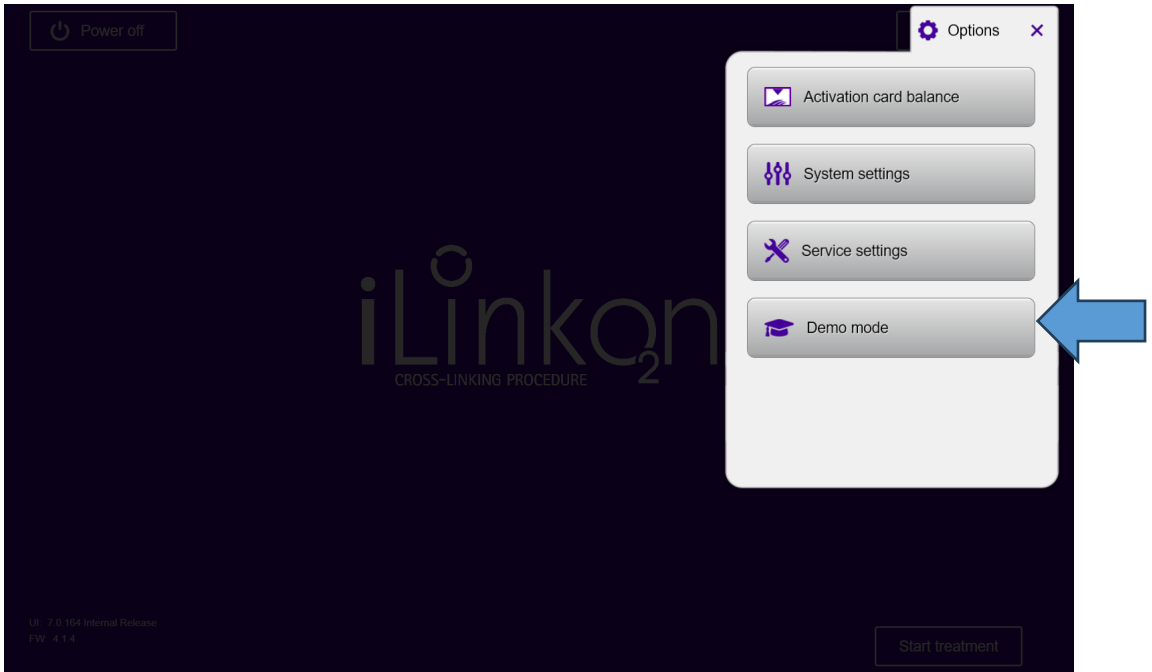


Figure 3-36. Select Demo Mode

- Select "Confirm" to use the System in Demo Mode

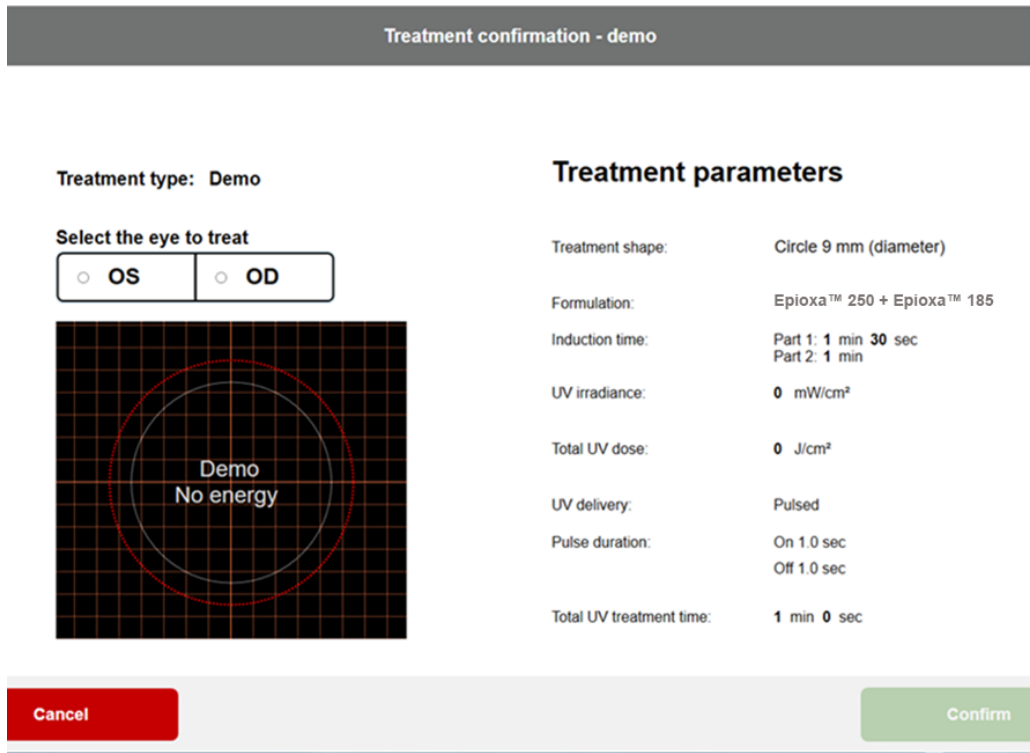


Figure 3-37. Confirm Demo Mode

- The O<sub>2</sub>n™ System demo mode will step through the same steps as outlined previously in the manual.

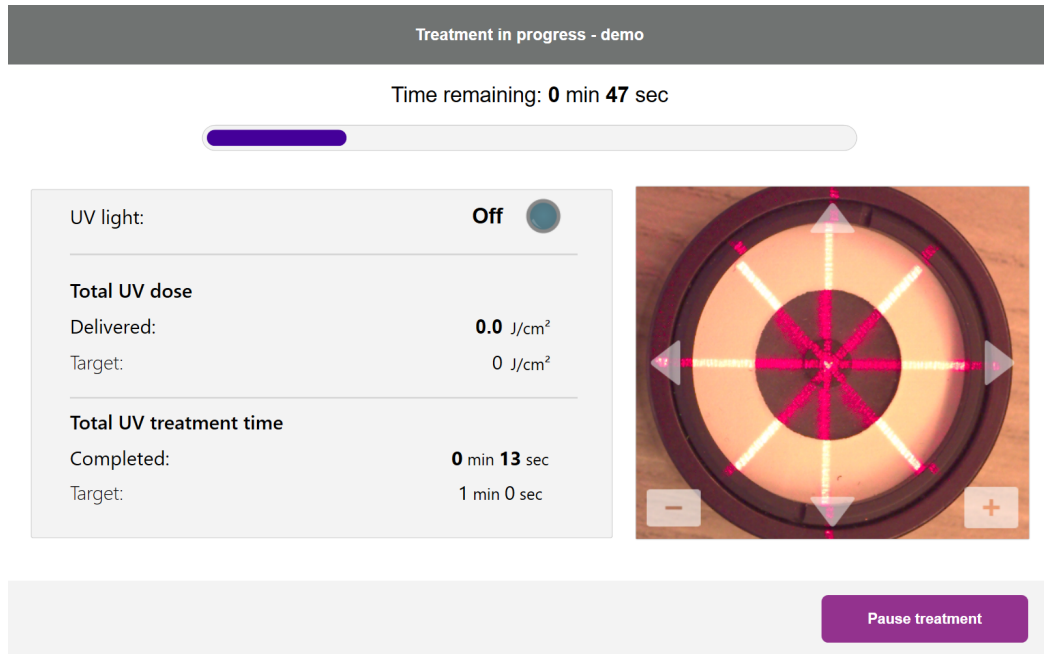


Figure 3-38. Demo Mode is Indicated at Top of Screen

When completed, a Treatment Summary screen will be shown indicating the demo mode has finished. Press "Done" to return to the main menu.

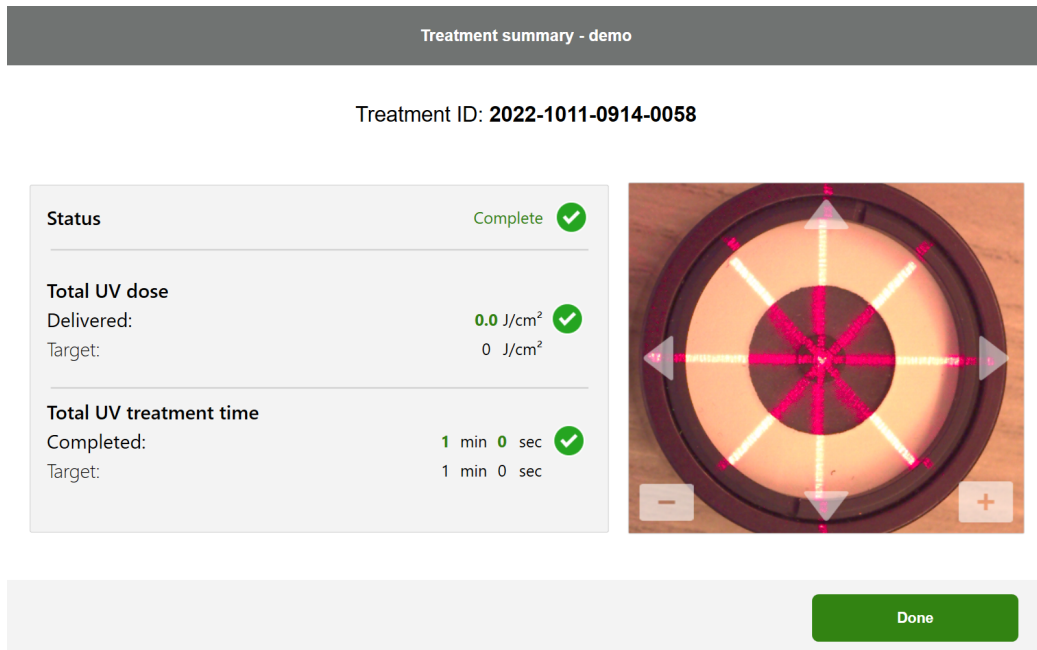


Figure 3-39. Treatment Summary Screen – Demo Mode

- To exit "Demo Mode," select "Exit Demo Mode" from the Options screen.

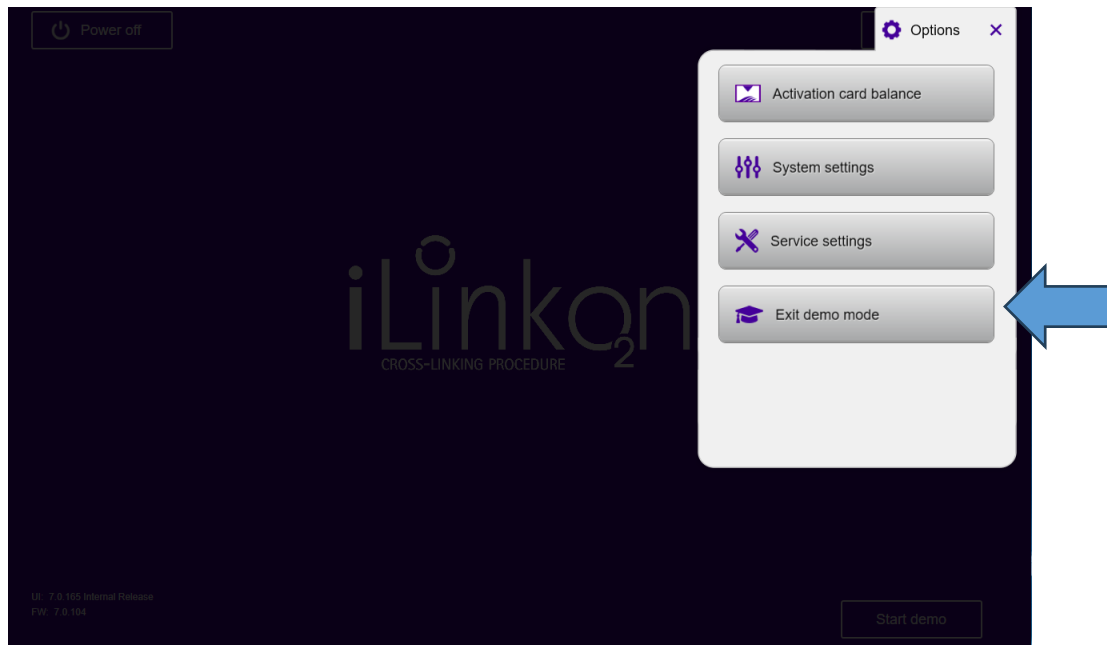


Figure 3-40. Exit Demo Mode

# 4 Maintenance/Service

---

Maintenance refers to those non-technical procedures an everyday operator must perform to keep the system working properly. Service refers to tasks to be performed only by a qualified service representative.

## 4.1 Installation Policy

- For each new O<sub>2</sub>n System, a person trained by Glaukos can perform a full initial installation and start-up of the System. Following initial installation and once the System is operating properly, the Glaukos representative may also provide basic training to a designated operator about the basic operation of the O<sub>2</sub>n 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, a Glaukos authorized representative.

## 4.2 Customer Maintenance

- In general, there is no customer maintenance required for the O<sub>2</sub>n 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 Troubleshooting Section 4.5 or call your local Glaukos Representative.
- There are no customer maintenance requirements due to EM disturbances to ensure the device remains safe and performs as intended throughout the expected service life.

## 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 O<sub>2</sub>n Systems. The contract includes regularly scheduled maintenance, as well as any non-scheduled service calls that may be necessary.

## 4.5 Troubleshooting

### 4.5.1 Error Message Table

Errors	Cause	Action
UNKNOWN_ERROR	General unhandled exception handler	Contact your distributor or customer service
SYSTEM_SETTINGS_COULD_NOT_BE_SAVED	File io error	Contact your distributor or customer service
VALID_CALIBRATION_DATA_NOT_FOUND	file corruption	Contact your distributor or customer service
REQUEST_TO_PRIMARY_BOARD_TIMED_OUT	Loss of communication	Restart system, if repeated contact your distributor or customer service
COULD_NOT_CONTROL_ALIGNMENT_LASERS	HW malfunction	Contact your distributor or customer service
ERROR_IN_UPDATE_TREATMENT_CARD_USAGE	Error communicating with RFID tag	Use another card, contact your distributor or customer service if persists
SYSTEM_ERROR	Handled exception	Restart system, if repeated contact your distributor or customer service
UV_TREATMENT_COULD_NOT_BE_STARTED	Start treatment rejected by FW	Contact your distributor or customer service
UV_COULD_NOT_BE_PAUSED	Pause command rejected by FW	Contact your distributor or customer service
TREATMENT_COULD_NOT_BE_COMPLETED	Complete treatment command rejected by FW	Contact your distributor or customer service
Packet reception failed	Loss of communication	Contact your distributor or customer service
Packet transmit failed	Loss of communication	Contact your distributor or customer service
SYSTEM_CONNECTION_HAS_BEEN_LOST_DURING_TREATMENT_TREATMENT_HAS_BEEN_HALTED	Loss of communication	Contact your distributor or customer service
SYSTEM_FAILED_TO_CONNECT_WITH_DEVICE	Loss of communication	Contact your distributor or customer service
ERROR_UVMON_PD1_H	PD1 is >10% higher than the target calibration value	Contact your distributor or customer service
ERROR_UVMON_PD1_L	PD1 is >10% lower than the target calibration value	Contact your distributor or customer service
ERROR_UVMON_TRMT_TIME_H	Treatment exceeded the expected time by >3 seconds	Contact your distributor or customer service
ERROR_UVMON_TRMT_TIME_L	Treatment ended >3 seconds before expected time	Contact your distributor or customer service

ERROR_UVMON_OVERTEMP	UV diode temperature >50 deg C	Contact your distributor or customer service
ERROR_UVMON_PD2_H	PD2 is >10% higher than the target calibration value	Contact your distributor or customer service
ERROR_UVMON_PD2_L	PD2 is >10% lower than the target calibration value	Contact your distributor or customer service
ERROR_WATCHDOG_FAILURE	UV Watchdog tripped.	Contact your distributor or customer service
ERROR_DTR_DISABLED_UNEXPECTEDLY	DTR disabled.	Contact your distributor or customer service
ERROR_UV_DISABLED_BY_FW_UNEXPECTEDLY	UV disabled by firmware unexpectedly	Contact your distributor or customer service
SELFTTEST_FAILED UV_DTR_ERROR	The UV was not enabled by the UIC via the DTR signal.	Contact your distributor or customer service
SELFTTEST_FAILED UV_WATCHDOG	The watchdog hardware could not be enabled.	Contact your distributor or customer service
SELFTTEST_FAILED UV_CALIBRATION_CHECKSUM_ERROR	The calibration CRC check failed indicating that the data may be corrupted	Contact your distributor or customer service
SELFTTEST_FAILED UV_OUT_OF_RANGE	PD1 indicated that the UV exceeded the +/- 10% range when tested.	Contact your distributor or customer service
SELFTTEST_FAILED MOTION_CONTROL_MOTOR_ERROR	The 3-axis motors could not be homed.	Contact your distributor or customer service
ERROR_IN_CONFIRM_OXYGEN_FLOW_COMMAND_ROUNTINE	Internal Exception	Contact your distributor or customer service
ERROR_IN_START_OXYGEN_FLOW_COMMAND_ROUNTINE	Internal Exception	Contact your distributor or customer service
NO_RESPONSE_FROM_PRIMARY_DURING_REMOTE_SYNC_C	Loss of communication	Contact your distributor or customer service
Cannot commit the Treatment info for cancellation	Internal Exception	Contact your distributor or customer service
<Variable message text coming from an exception is also possible>	Internal Exception	Contact your distributor or customer service

- The O<sub>2</sub>n System performs a status check at start-up automatically. If the status is incorrect, the software prevents the operator from initiating treatments.

## 4.5.2 Wireless Remote

- The O<sub>2</sub>n System uses a remote control with replaceable batteries. To access the battery area, slide the top of the remote in one direction while securing and moving the bottom of the remote in the opposite direction. See Figure 4-1.



Figure 4-1. Access Battery Compartment

- If the batteries run low, the system loses its connection with the remote and notifies the user of the need to resynchronize, see Figure 4.2. Press "OK" to resync or press "Continue" without the remote.

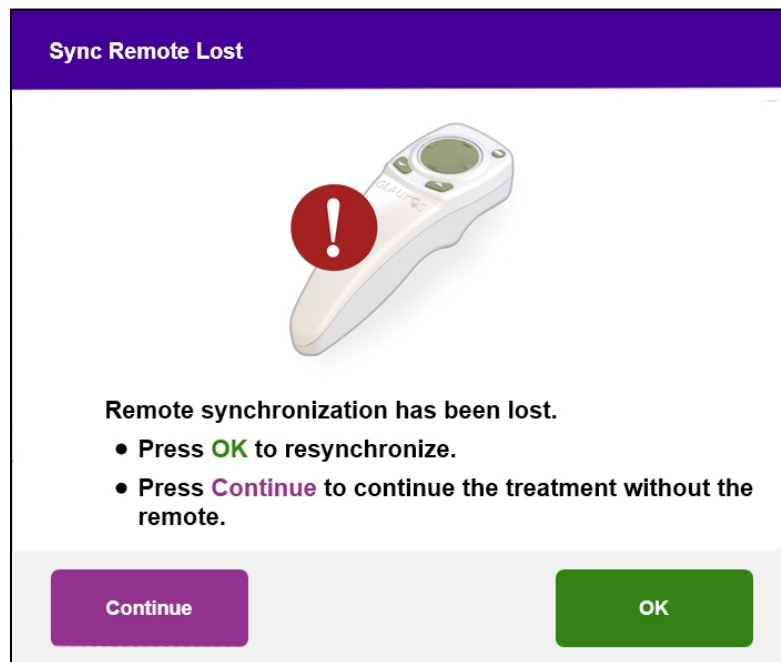


Figure 4-2. Remote Sync Lost Guidance

- If after two tries, the remote fails to re-sync, the following screen appears, see Figure 4-3. Select “Continue” to continue treatment without the remote or press “Cancel” to cancel treatment.

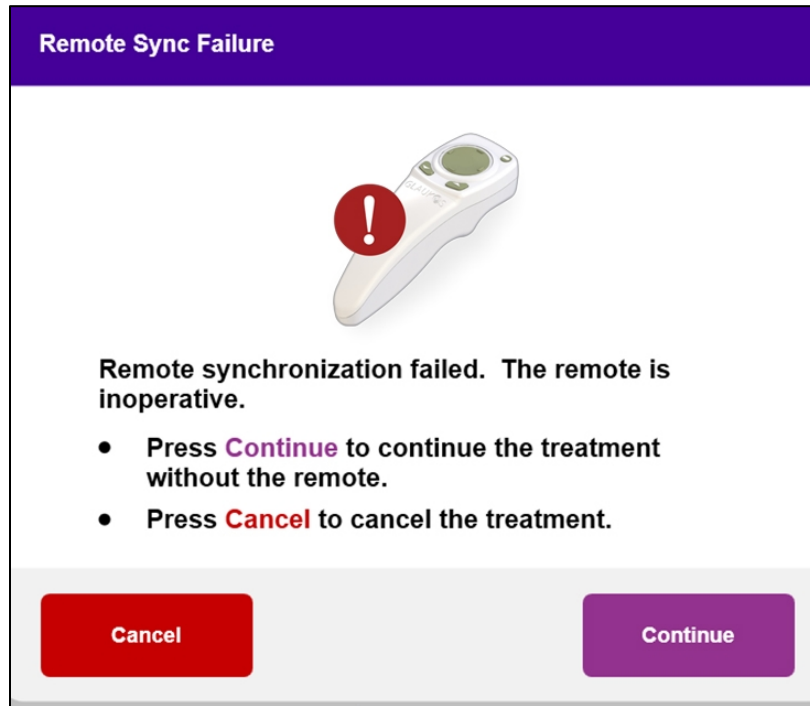


Figure 4-3. Remote Sync Failure Guidance

- If battery status light is orange, the remote’s batteries need to be changed shortly.
- If the battery status light is flashing orange, the remote’s batteries need to be changed immediately. There is not enough power to complete a treatment with the remote.
- If replacing the batteries does not allow the System to synchronize, contact your local Glaukos® Service Representative.

## 4.6 Directions for Sterilization or Disinfection

- No components of the O<sub>2</sub>n System are designed to be sterilized by the operator. External cleaning and disinfection ONLY are recommended. For disinfection purposes, use only 70% isopropyl alcohol spray or preparations. Use small amounts of liquid and soft lint-free wipes.

## 4.7 Cleaning the System



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

- Use a soft damp cloth to clean the system.
- The exterior of the O<sub>2</sub>n System can be cleaned using a lint-free cloth dampened with isopropyl alcohol.
- DO NOT submerge the system in liquid or pour liquid onto the system.
- While cleaning the surfaces of the device, ensure that cleaning fluids do not seep inside the device, as this leakage can damage the device.
- Use a lint-free cloth dampened with isopropyl alcohol to clean the remote control.

## 4.8 Cleaning the Aperture



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

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

## 4.9 Articulating Arm Adjustment

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

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

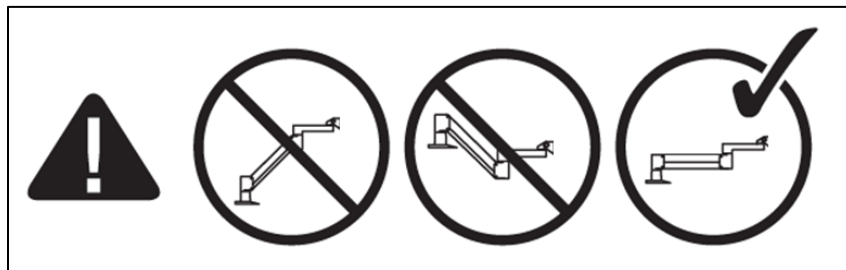


Figure 4-4. Position the Arm Parallel to the Floor

- If the arm drifts downward, lift the arm to the top of its range and loosen Counterbalance Set Screw A by turning the screw at least a ½ turn. Use a 3/32 Allen Wrench. See Figure 4-5.

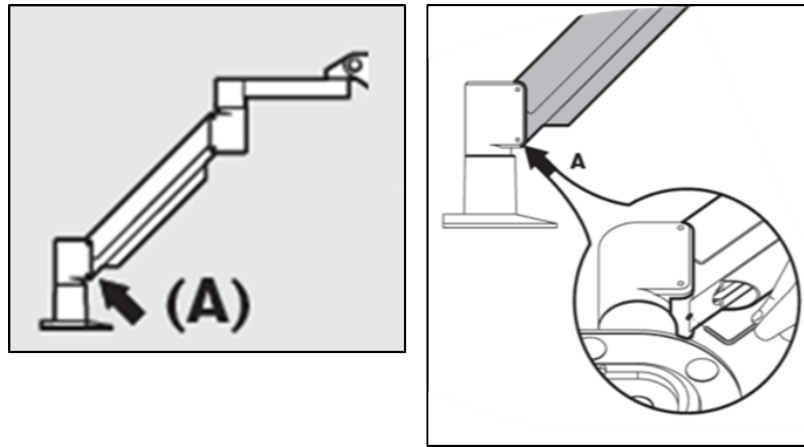


Figure 4-5. Loosen Counterbalance Set Screw A

- Reposition the arm horizontally. Loosen the upper Counterbalance Set Screw B by turning the screw at least a ½ turn. Use a 3/32 Allen Wrench. See Figure 4-6.

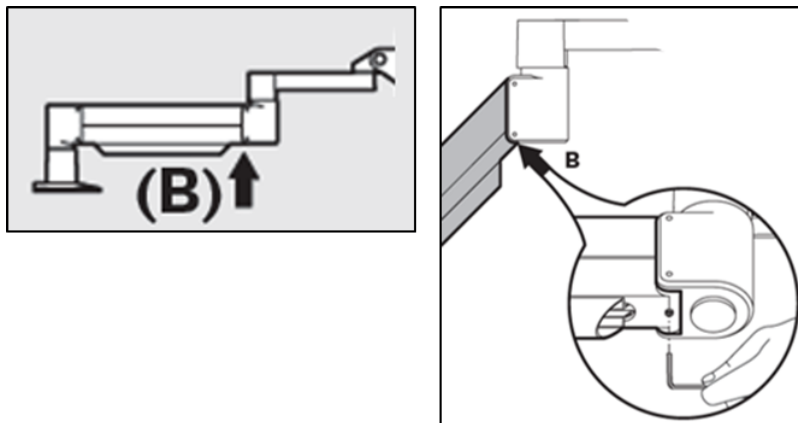


Figure 4-6. Loosen Counterbalance Set Screw B

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

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

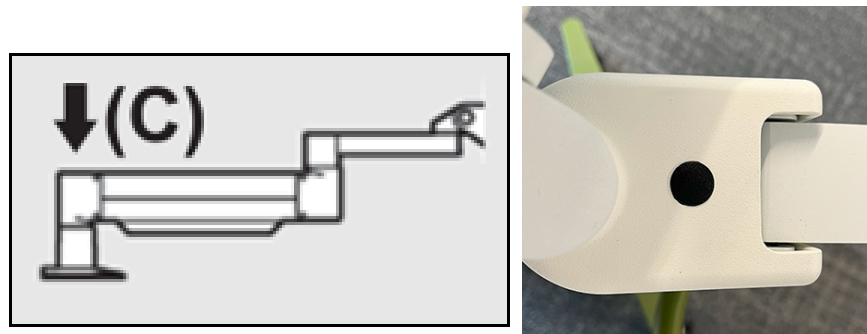


Figure 4-7. Set Arm Tension with Strength Adjustment Screw C

- Turn Strength Adjustment Screw C clockwise for two full revolutions.
- Ensure that the arm is stationary or barely moving upward.
- Raise the arm to the highest position and tighten Counterbalance Set Screw A until contact is made, then tighten  $\frac{1}{2}$  to  $\frac{3}{4}$  max revolutions. See Figure 4-5.
- Position the arm horizontally and tighten Counterbalance Set Screw B until contact is made, then tighten  $\frac{1}{2}$  to  $\frac{3}{4}$  revolutions. See Figure 4-6.
- 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  $\frac{1}{4}$ -revolution at a time until it no longer rises on its own.

#### 4.10 Moving the System

- The O<sub>2</sub>n System is designed as a movable system within a hospital, ASC, clinic or office environment .
- Before moving, position the system as shown in Figure 4-8. Lower the articulated arm to its lowest position. Position the optics head 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.

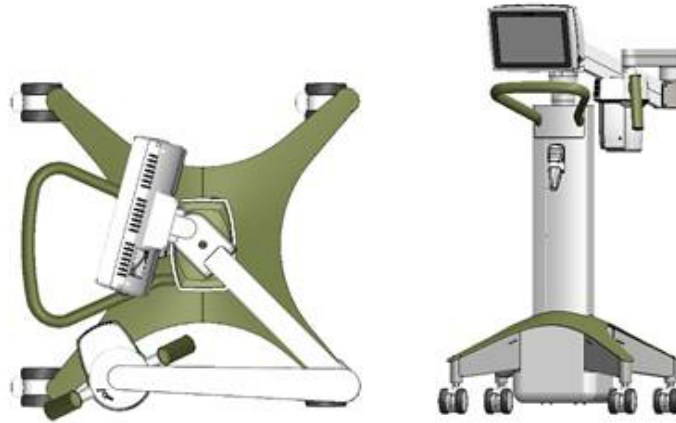


Figure 4-8. System Configuration for Moving and Storage

#### 4.11 Preparing the System for Storage

- Follow all the storage temperature and humidity specifications, as listed in Specifications Section 7.
- Turn OFF the system via the power button or display. Next, turn off the AC mains switch at the power inlet. Disconnect the power cord physically from the wall outlet.
- Position the system as shown in Figure 4-8, and then drape the AC power cord with the system for future use.
- Remove the batteries from the wireless remote (if long-term storage is intended).
- Be sure to store the system in a secure area with access limited to trained, authorized personnel only.

**IMPORTANT:** If transport or shipping of the O<sub>2</sub>n System is ever required, contact your local Glaukos representative. Packing and transporting the system should be performed only by Glaukos trained and authorized personnel.

#### 4.12 Software

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

#### 4.13 Identifying Risks Associated with Disposing of Waste Products

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

#### 4.14 Performing a Visible Check

- Check all components of the device routinely for damage or malfunction prior to each treatment.

**WARNING:** Do not use a damaged or malfunctioning device. Use of such devices may harm the user and/or patient.

# 5 Equipment Classification

---

## 5.1 Essential Performance

The O<sub>2</sub>n system delivers to the cornea UV-A radiation of nominally 365 nm wavelength at an irradiance of 30 mW/cm<sup>2</sup> over an exposure period of up to 11 minutes 6 seconds to deliver a total energy density of up to 10 J/cm<sup>2</sup>.

Note: If the O<sub>2</sub>n System experiences a loss or degradation in functionality or performance due to electromagnetic (EM) disturbances, the head indicator will turn blue and an error message will appear on the user interface. Please refer to Section 4.5.1 - Error Message Table for guidance or contact Glaukos for assistance.

### User Expectation:

Essential Performance: The system must maintain the programmed intensity of the emitted light while in treatment mode.

### Performance Criteria:

Green light on optical head must stay 'ON' during treatment. Blue light emitted from optical head must stay 'ON' during idle, and computer screen must be active.

### Description of How Basic Safety and Essential Performance Can Be Monitored During Each Test:

Green light on the optical head must stay 'ON' during treatment. The blue light emitted from the optical head must stay 'ON' during idle, and computer screen must be active. If the remote synchronization fails, the user may continue treatment without the remote or re-synchronize the remote.

### How to Observe Essential Performance:

The UV intensity is monitored by the system. If the intensity falls out of the accepted range, the light in the optical head will be blue, the user interface will display an error message, and the UV LED will shut off.

- Fault Condition:
  - The O<sub>2</sub>n System shall not deliver energy in excess of 110% of the targeted fluence. Internal monitoring of the fluence rate (intensity) is designed to trigger an error condition if the intensity falls outside of the 10% acceptable tolerance. Internal monitoring is performed via a first photodiode (PD1) monitoring the output of the UV source directly. A second photodiode (PD2) monitors the output after the optical imaging chain, prior to exiting the optical head window as a secondary protection to ensure output is maintained within expected and acceptable conditions.

## 5.2 Equipment Classification

According to IEC60601-1 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
  - Ingress protection: IP20
  - Updated remote ingress protection: IP53
- Boost Goggles Type B applied part. (No electrical connection)
- Method of sterilization or disinfection
  - Disinfectable device
- Degree of protection for use in the presence of a flammable anesthetic mixture
  - No protection
- Use conditions
  - Continuous service

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

- Class A

According to IEC60825-1 Safety of laser productions

- Alignment lasers are Class 1 Laser Product

According to IEC62471 Photobiological safety of lamps and lamp systems

- IEC 62471: 2006 Risk Group 1

### 5.3 EMC Guidance



The O<sub>2</sub>n 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 O<sub>2</sub>n System. Any equipment to be used in proximity with the O<sub>2</sub>n System that exceeds the tested EMC levels below may impact the performance of the O<sub>2</sub>n System.

Guidance and manufacturer's declaration - electromagnetic emissions		
The O <sub>2</sub> n™ System is intended for use in the electromagnetic environment specified below. The customer or the user of the O <sub>2</sub> n™ 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 O <sub>2</sub> n 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 A	The O <sub>2</sub> n System is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:  WARNING: 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 emissions  IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions  IEC 61000-3-3	Complies	

Table 5-1. Electromagnetic Emissions


**Guidance and manufacturer's declaration — electromagnetic immunity**

The O<sub>2</sub>n™ System is intended for use in the electromagnetic environment specified below. The customer or the user of the O<sub>2</sub>n™ 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	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not Applicable Input /Output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4remote sync-11	0 % UT (100 % dip in UT) for 0.5 cycle 0% UT (100% dip in UT) for 1 cycle 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 45	0 % UT (100 % dip in UT) for 0.5 cycle 0% UT (100% dip in UT) for 1 cycle 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 45	Mains power quality should be that of a typical commercial or hospital environment, If the user of the O <sub>2</sub> n System requires continued operation during power mains interruptions, it is recommended that the O <sub>2</sub> n System be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity Magnetic Fields IEC 61000-4-39	9KHz- 150Khz, 150Khz-26MHz	9KHz- 150Khz, 150Khz-26MHz	Proximity magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE:  $U_T$  is the a.c. mains voltage prior to application of the test level.

Table 5-2. Electromagnetic Immunity

Guidance and manufacturer's declaration — electromagnetic immunity			
The UV-A UV Illumination System is intended for use in the electromagnetic environment specified below. The customer or the user of the UV-A UV Illumination System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz plus 6Vrms for ISM bands	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the UV-A UV Illumination System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$  $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 80 MHz to 2.7 GHz  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, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol:  
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	
Proximity fields from RF wireless communications equipment (IEC 61000-4-3:2006 A1:2007 A2:2010)	15 specific frequencies. Immunity level 9-28V/m		
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>NOTE 3 The O<sub>2</sub>n system was tested in accordance with the recommendations of IEC TS 60601-4-2:2024, Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems. The ELECTROMAGNETIC phenomena and IMMUNITY TEST LEVELS with which the O<sub>2</sub>n system complied were defined according to the recommendations of IEC TS 60601-4-2:2024.</p> <p>NOTE 4 The O<sub>2</sub>n system has no performance associated with intended use that is not safety related (i.e., was not already tested as either Basic Safety or Essential Performance during IEC 60601-1-2 testing).</p>			
<p><sup>a</sup> 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 UV-A UV Illumination System is used exceeds the applicable RF compliance level above, the UV-A UV</p>			

Illumination System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the UV-A UV Illumination System.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

*Table 5-3. Electromagnetic Immunity (continued)*

Guidance and manufacturer's declaration — Common Emitters, RFID AIM 7351731 and Wireless Co-existence (ANSI C63.27)

The UV-A UV Illumination System is intended for use in the electromagnetic environment specified below.  
 The customer or the user of the UV-A UV Illumination System should assure that it is used in such an environment.

Immunity test	Test level			Compliance level	Electromagnetic environment — guidance										
RFID AIM 7351731	RFID Specification	Frequency	Test Level (RMS)	<table border="1"> <tr><th>Compliance Level</th></tr> <tr><td>65 A/m</td></tr> <tr><td>7.5 A/m</td></tr> <tr><td>7.5 A/m</td></tr> <tr><td>5 A/m</td></tr> <tr><td>3 V/m</td></tr> <tr><td>12 A/m</td></tr> <tr><td>54 V/m</td></tr> <tr><td>54 V/m</td></tr> <tr><td>54 V/m</td></tr> </table>	Compliance Level	65 A/m	7.5 A/m	7.5 A/m	5 A/m	3 V/m	12 A/m	54 V/m	54 V/m	54 V/m	
	Compliance Level														
	65 A/m														
	7.5 A/m														
	7.5 A/m														
	5 A/m														
	3 V/m														
	12 A/m														
	54 V/m														
	54 V/m														
54 V/m															
ISO 14223, Type A	134.2kHz	65 A/m													
ISO 14443-3, Type A	13.56 MHz	7.5 A/m													
ISO 14443-4, Type B	13.56 MHz	7.5 A/m													
ISO 15693-3	13.56 MHz	5 A/m													
ISO 18000-7	433.92 MHz	3 V/m													
ISO 18000-3 Mode 3	13.56 MHz	12 A/m													
ISO 18000-63	860-960 MHz	54 V/m													
ISO 18000-63	860-960 MHz	54 V/m													
ISO 18000-4	2.4 GHz	54 V/m													
Common Emitters	EMI Source	Frequency	Test Level (RMS)	<table border="1"> <tr><th>Test Level (RMS)</th></tr> <tr><td>50 V/m</td></tr> <tr><td>500 V/m</td></tr> <tr><td>400 V/m</td></tr> <tr><td>81.5 dBuA/m</td></tr> <tr><td>35-90 dBuA/m</td></tr> <tr><td>30 dBm</td></tr> <tr><td>15-30 dBm</td></tr> </table>	Test Level (RMS)	50 V/m	500 V/m	400 V/m	81.5 dBuA/m	35-90 dBuA/m	30 dBm	15-30 dBm	Maintain a minimum distance as reference in warning between the system and EM emitters, especially those operating in or near tested frequency ranges. Please note: there are currently no recognized standards for this testing and therefore the testing was performed on an ad hoc basis.		
	Test Level (RMS)														
	50 V/m														
	500 V/m														
	400 V/m														
	81.5 dBuA/m														
	35-90 dBuA/m														
	30 dBm														
15-30 dBm															
Diathermy	1.7 MHz - 2.3 MHz	50 V/m													
Electrosurgical Cut	1.7 MHz	500 V/m													
Electrosurgical Coagulate	1.7 MHz	400 V/m													
NFC	13.56 MHz	81.5 dBuA/m													
Wireless Power Transfers	104.7, 113.0, 128.3, 134.7, 149.3, 160.4, 175.3, 488.2, 805.7, 1100.2, 1430.4, 1750.7, 2040.0, 2172.0, 2299.5, 4025.0, 4197.5, 4372.5, 4547.5, 4722.5, 4897.5, 6120.0, 6470.0, 6800.0 KHz	35-90 dBuA/m													
5G Cellular (FR1)	660, 742, 842, 1909.9, 1923.264, 2560, 3610, 3905, 6050 MHz	30 dBm													
5G Cellular (FR2)	24.5, 25.75, 27.25, 29.00, 28.15, 38.05, 39.5 GHz	15-30 dBm													
Wireless Co-existence (C63.27)	Specification	Frequency	Test Level (RMS)	Compliance to IEEE/ANSI C63.27	WARNING: To ensure proper operation of this device, maintain a minimum separation distance of 30cm from RF transmitting devices										
	ISO/IEC 14443B, I-Block	13.56 MHz	7.5 A/m, 10cm												
	ISO/IEC 15693, Stay Quiet	13.56 MHz	5 A/m, 10cm												

	ISO-IEC 18000-3, Mode 3 Inventory	13.56 MHz	12 A/m, 10cm		such as cell phones, Wi-Fi routers, and Bluetooth devices. Failure to do so may result in wireless communication disruption or data loss.
	ISO IEC 14443A, Select	13.56 MHz	7.5 A/m, 10cm		
	Unintended IEEE 802.11n signal protocol	Per C63.27 guidance	Per C63.27 guidance		
NOTE 1 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 UV-A UV Illumination System is used exceeds the applicable RF compliance level above, the UV-A UV Illumination System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the UV-A UV Illumination System.					
b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.					

Table 5-4. Common Emitters, RFID AIM 7531731, Wireless Co-existence (ANSI C63.27)

Recommended separation distances between portable and mobile RF communications equipment and the UV-A UV Illumination System			
The UV-A UV Illumination System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the UV-A UV Illumination System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the UV-A UV Illumination System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in 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.			

Table 5-5. Recommended Separation Distances

## 5.4 RF Transmitters

### 5.4.1 RFID Reader

- RFID reader allows authorization of treatment via RFID-enabled cards. RFID is a wireless communication technology that uses radio waves. This device emits radio signals to power the tag (in passive systems), receive data, and send it to a backend system for processing. Should the RFID reader fail to recognize an authentic Treatment Activation Card, treatment may be delayed. The RFID Reader is only able to recognize an encrypted, signed Treatment Activation Card or service card.
  - Quality of Service
    - Data Integrity: RFID cards contain a valid, Glaukos created signature
    - Data Latency: 2 s maximum
    - Accessibility:  $\leq 4$  inches
    - Signal Priority: N/A (only able to read one Treatment Activation Card at a time)
- 13.56 MHz Reader/Writer
- Receiver Bandwidth: 13.110 MHz to 14.010 MHz
- No modulation defined in data sheet
- Integral Antenna: Maximum 4" Read Range
- US/FCC number SX90RFID1
- Max output power is 200mW
- Complies with ISO 15693
- The transmitter module must not be co-located with any other transmitter or antenna
- For more information, please visit <https://fcc.gov/oet/ea/fccid> and search for FCC ID SX90RFID1

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

Fundamental	Frequency (MHz)	Level (dB $\mu$ V/m) at 30 m	Limit (dB $\mu$ V/m) at 30 m	Limit ( $\mu$ V/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 $\mu$ V/m)	Limit (dB $\mu$ V/m)	Margin (dB)
-------	-----------------	----------------------	----------------------	-------------

Harmonics	27.12 (peak)	-5.2	29.5	-34.7
Spurious	200.6 (peak)	34.5	40.0	-5.5
Conducted	0.199 (avg)	38.8	54.6	-15.8

Table 5-6. Highest Emissions

#### 5.4.1.1 Information addressing RFID Wireless Issues

The RFID Reader is required to activate the O<sub>2</sub>n System. Upon activation, the treatment available on the Treatment Activation Card will be consumed. The RFID reader's functionality is considered minimal to negligible during the treatment phase. If RFID functionality is not working, a treatment cannot be started. If there is a problem reading the card, rotate the card and then reinsert. Be sure to leave the card inside the reader for at least 10 seconds. If this does not resolve the issue, please contact Glaukos support.

#### 5.4.2 Wireless Remote Control

- Remote control and receiver board are used for aligning the optical assemblies with the treatment area. The remote uses the Nordic Semiconductor proprietary Gazelle protocol in the 2.4 GHz frequency band.
- Remote Control
  - Quality of Service
    - Data Integrity: 128 bit AES encryption
    - Data Latency: 15ms maximum
    - Accessibility: Able to sync up to 5 feet, shall remain connected up to 10 feet
    - Signal Priority: N/A (only one remote able to be paired at a time)
  - FCC ID SXJ87027-TX
  - RF IC: Nordic Semiconductor NRF52810
  - Input rated: 3.0 VDC
  - Maximum power output: -5 dbmW at 3m
  - GFSK modulation
  - Antenna type: Chip antenna, peak gain 0.8 dbi
- Receiver Board
  - Quality of Service
    - Data Integrity: 128 bit AES encryption

- Data Latency: 15ms maximum
- Accessibility: Able to sync up to 5 feet, shall remain connected up to 10 feet
- Signal Priority: N/A (only one remote able to be paired at a time)
- FCC ID: 2AVGK-KXLRX
- RF IC: Nordic Semiconductor NRF52810
- Input rated: 3.3 VDC
- Maximum power output: -8dbmW at 3m
- 2402 MHz to 2480 MHz: 40 channels
- GFSK modulation
- Antenna type: Chip antenna, peak gain 0.8 dbi
- Maximum Range: 5'
- Emissions Compliant with 47 CFR Part 15
- The remote control and receiver board and its antenna must not be co-located or operated in conjunction with another antenna or transmitter

For more information please visit <https://www.fcc.gov/oet/ea/fccid> and search for FCC ID 2AVGK-KXLTX and 2AVGK-KXLRX

The highest emissions generated by the remote control are:

Type	Frequency (MHz)	Peak Output Power (dBm)	Average Output Power (dBm)	Limit (dBm)
Output power	2402	-4.33	-4.93	30
	2442	-4.06	-4.66	
	2480	-4.24	-4.94	

The highest emissions for the remote receiver board are:

Type	Frequency (MHz)	Peak Output	Average Output	Limit (dBm)
------	-----------------	-------------	----------------	-------------

		Power (dBm)	Power (dBm)	
Output power	2402	-6.13	-7.15	30
	2442	-6.72	-7.91	
	2480	-6.84	-8.28	

#### 5.4.2.1 Information Addressing Wireless Remote Issues

The wireless remote control assists users in maneuvering the optical head and camera. However, its functional wireless performance (FWP) is not critical during standard care, as the system can alternatively be operated via the touchscreen or by manually adjusting the optical head in the event of a disconnection.

- If unintended motion of the head or camera occurs without user input—potentially due to a jammed or stuck button or other malfunction of the wireless remote control— please follow the steps below:
  1. Open the back cover of the wireless remote control.
  2. Remove the batteries.
  3. The treatment will automatically pause.
  4. You may then choose one of the following options:
    - Option 1: Replace the batteries and resume treatment.
    - Option 2: Continue the treatment without using the wireless remote control.











Note: Refer to *Section 3.9 – Sync Alignment Remote* for instructions on how to either re-sync the remote control or proceed with the treatment without it.















OR

- If unintended motion of the head or camera occurs without user input—potentially due to EM disturbances - please follow the steps below:
  1. Refer to Section 4.5.1 Error Message Table OR
  2. Refer to Section 1.12.3 Electrical Safety Warnings OR
  3. Contact your distributor or customer service
- During live video operation/treatment, head motor control shall always be available via on-screen controls as an alternative to the wireless remote.

# 6 Symbols Library

The following symbols may be found on the O<sub>2</sub>n System, labeling or packaging.

Symbol	Definition	Location
	Alternating Current	system label
	Attention: Consult instructions for use	system label
	Protected earth; protective ground	on system
	Stand by	on system
I	ON (power to mains)	on system
O	OFF (power to mains)	on system
	Caution	system label, manual
	UV light hazard (Refer to section 1.12.4 for warnings)	on system
	Keep away from rain	crate
	Fragile	crate
	This way up	crate
	Do not stack	crate

Symbol	Definition	Location
	Humidity limits	system label
	Temperature limits	system label
	Magnetic Resonance Unsafe	system label
	Atmospheric Pressure limits	system label
	Non-ionizing electromagnetic radiation	system label
	Catalogue number	system label
	Serial number	system label
	Quantity	crate
	Manufacturer	system label
	Date of Manufacture	system label
	Refer to Instruction Manual/Mandatory	system label
	Unique Device Identifier	system label
	Prescription Device	system label
	RFID symbol	system

Abbreviations			
A	ampere	nm	nanometer
EMC	electromagnetic compatibility	NW	net weight
FW	firmware	OD	right eye
GW	gross weight	OS	left eye
IP	Ingress Protection	RFID	Radio Frequency Identification
J/cm <sup>2</sup>	Joules per square centimeter	sec	second
kg	kilogram	UI	user interface
LED	light-emitting diode	UV	Ultraviolet light
mbar	millibar	UV-A	Ultraviolet A
min	minute	V	Volt
mW/cm <sup>2</sup>	milliwatt per square centimeter		

# 7 Specifications

Specification	Description
Electrical	Line voltages 100 – 240 volts AC Current: 2A – 1A Single Phase RMS, 50/60 Hz Remote 2x AA batteries
List of Cables and Accessories	Wireless Remote Hospital-Grade AC Power Cable (lockable/detachable)
Energy Delivery	UV Radiation 30 mW/cm <sup>2</sup> +/- 10% 365 nm
UV-A LED Light Source	UV Radiation 365 nm
Alignment Laser	Class I Laser 650nm
External Interfaces	USB 2.0
Physical Dimensions (Shipping, Storage, Transport)	Length: 24.5 in (62.2 cm) Width: 26.5 in (67.4 cm) Height: 46.6 in (118.5 cm)
Physical Dimensions (Full-extension Nominal Maximum)	Length: 50.1 in (127.2 cm) Width: 47.4 in (120.4 cm) Height: 55.5 in (140.9 cm)
Weight (crated system)	NW 106 lb. (48 kg) GW 190 lb. (86 kg)
Remote Battery Life (normal operating conditions)	18 hours
Environmental Operating Conditions	The system operates under the following atmospheric conditions (no condensation).
Ambient temperature	15°C to 30°C (59°F to 86°F)
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°C to 60°C (5°F to 140°F)
Relative humidity	10% to 80% non-condensing

Atmospheric pressure	750 to 1060 mbar
----------------------	------------------

# 8 Cybersecurity

---

Please review the instructions below to ensure the O<sub>2</sub>n System remains secure as intended by the manufacturer.

## 8.1 About Your Device

The O<sub>2</sub>n System utilizes Windows 10 IoT Enterprise LTSC 2021 as the operating system (OS). This OS supports a 10-year lifecycle with service ending January 13, 2032.

## 8.2 Installation and Storage

- During on-site installation, a Glaukos Service Engineer will provide the user with a USB drive containing a cryptographic key (“USB key”) that will be required to be inserted by the user into the O<sub>2</sub>n System at each power up.
- Store the USB key and password in a safe, secure location. If lost, a Field Service call will be required to replace the USB key.
- Do not leave the O<sub>2</sub>n System unattended or unsecured.
- When not in use, store the O<sub>2</sub>n System in a secure manner (e.g., powered off in a locked room) to prevent unauthorized use or physical tampering.
- Store all Epithelium-On Cross-linking Kits in a secure location (e.g., locked storage cabinet) to prevent unauthorized access to encrypted and cryptographically signed Treatment Activation Cards.

## 8.3 O<sub>2</sub>n System Secure Operation

- Contact Glaukos if the O<sub>2</sub>n System authorized user login password is forgotten.
- The device will need to be returned to Glaukos to reset the password, if forgotten.
- Treatment can only be delivered if the user successfully scans an encrypted and cryptographically signed Treatment Activation Card.
- The user is provided with a USB key that is required to be inserted into the O<sub>2</sub>n System at each power up.
- The O<sub>2</sub>n System is unable to be used without an encrypted cryptographically signed Treatment Activation Card. These cards are shipped separately and therefore the O<sub>2</sub>n System is considered secure during shipment.
- Contact Glaukos to arrange for device decommissioning and sanitizing.

## 8.4 O<sub>2</sub>n System Security Features

- The O<sub>2</sub>n System employs the following features to protect critical use and functionality:
  - The O<sub>2</sub>n System is not capable of interfacing with private or public networks, including the internet. This design eliminates the risk of remote cyberattacks by preventing external wired, or wireless, network connectivity.
  - A USB key is required to gain access to the O<sub>2</sub>n System.
  - Treatments can only be delivered if the user successfully scans an encrypted and cryptographically signed Treatment Activation Card.
  - All communication ports are designed for specific and local communication only.
  - The LAN connector is disabled.
  - Software and firmware updates can only be completed by Glaukos at an authorized facility.
  - Treatment history data are encrypted.
  - No patient identifying information is collected or stored.
  - All drives are encrypted (BitLocker).
  - Unauthorized applications cannot be executed (AppLocker).
  - The authorized O<sub>2</sub>n™ System user must log in to unlock the device to allow an Authorized Glaukos Field Service Engineer to work on the system.
  - Service functions can only be accessed with an encrypted and cryptographically signed service card.
  - BIOS is accessible only through a strong, unique BIOS password set during manufacturing.

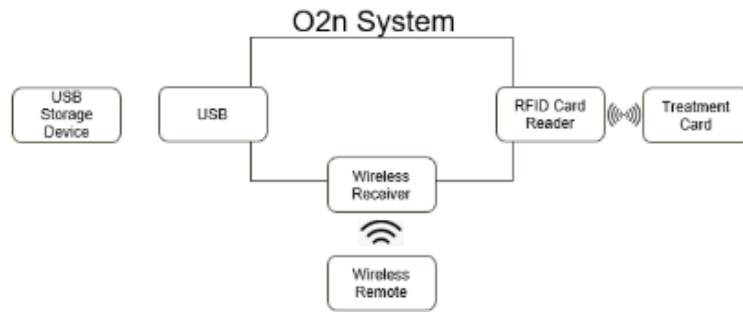
## 8.5 O<sub>2</sub>n System Back Up and Restore Features

- The O<sub>2</sub>n System offers the following user selected configurations:
  - Audio volume
  - Camera white balance
  - Alignment crosshairs intensity
- Auto-backup and restore features are not available for these settings. It is the user's responsibility to adjust these settings to their preference if the system is restored.

## 8.6 O<sub>2</sub>n System Connectivity and Interfaces

NOTE: The O<sub>2</sub>n System offers no user-initiated network destination endpoints. It is not capable of interfacing with private or public networks, including the internet. There are no exposed surfaces on the O<sub>2</sub>n System.

- The diagram below shows all intended secure interfaces of the O<sub>2</sub>n System:



- The O<sub>2</sub>n System does not:
  - Allow 3rd party RFID cards.
  - Allow 3rd party wireless devices.
- The O<sub>2</sub>n™ System requires multifactor authentication.
- There are no special infrastructure requirements required for the O<sub>2</sub>n System to operate as intended.
- This O<sub>2</sub>n System design eliminates the risk of remote cyberattacks by preventing external wired, or wireless, network connectivity.
- The O<sub>2</sub>n System device includes the following interfaces:

Interface	Description
USB	<p>USB interfaces have the following approved bidirectional endpoints:</p> <ul style="list-style-type: none"> <li>Internal connectivity for the camera and RFID reader.</li> <li>External connectivity with mass storage device for encrypted log files.</li> </ul> <p>NOTE: The USB interfaces have no external networking capability.</p>
RFID	<p>The RFID reader is bidirectional and used solely for the purpose of reading valid Treatment Activation Cards and service cards, and for designating the treatment card as consumed to prevent reuse.</p> <ul style="list-style-type: none"> <li>Treatment cannot be initiated without a valid, signed Treatment Activation Card.</li> </ul>

	<ul style="list-style-type: none"> <li>• A Treatment Activation Card cannot be reused once consumed.</li> <li>• Service functions are not accessible without a valid, signed Service Card.</li> </ul> <p>NOTE: The RFID reader has no external networking capability</p>
Wireless Interface	<p>The wireless interface exists solely for the purpose of bidirectional pairing and receiving input from the Glaukos wireless remote.</p> <ul style="list-style-type: none"> <li>• The wireless interface will not pair with unauthorized devices.</li> <li>• The wireless interface has no external networking capability</li> </ul>
LAN Connector	<p>The internally located LAN connector is disabled at the time of manufacture and is not capable of providing internal or external communication or data transfer. There is no authorized communication to or from the LAN connector.</p>

## 8.7 Software Bill of Materials (SBOM) and Software Updates

- A machine-readable and a human readable version of the O<sub>2</sub>n System SBOMs may be downloaded from the Glaukos website:  
<https://github.com/Glaukos-Corneal-Health/110-02725-iLink-2/tree/main/v2.1/sbom>
- Glaukos will notify the user in writing when software and firmware updates are available.
- Since the O<sub>2</sub>n System is not capable of interfacing to private or public networks, including the internet, the system must be returned to Glaukos for installation of authorized software and firmware updates.
- Do not allow unauthorized personnel to attempt to install new software or firmware.

## 8.8 O<sub>2</sub>n System Response to Security Events

- The O<sub>2</sub>n™ System automatically monitors attempted use of unauthorized, or fraudulent, Treatment Activation Cards. If detected, the system will display an error message and log the event. The system will prevent treatment from being delivered without a valid, cryptographically signed Treatment Activation Card.
- The O<sub>2</sub>n System automatically monitors attempted use of unauthorized, or fraudulent, Service Card. If detected, the system will display an error message and log the event.

- Windows Defender continuously monitors for security events. If a security event is detected, the system will be rendered inoperable.
- You should immediately stop using the O<sub>2</sub>n System if unauthorized use, or suspicious activity, is suspected. Return the device immediately to Glaukos for a full inspection.
- Windows security event logs, and AppLocker security logs are encrypted, exported, and available for review by trained and authorized Glaukos employees.
- Whenever on-site, a Glaukos Service Engineer will review the export the system log and promptly send to Glaukos for review of any suspicious behavior.

The user should immediately stop using the O<sub>2</sub>n System if unauthorized use, or suspicious activity, is suspected. Contact Glaukos immediately for a Field Service Visit or return the device to Glaukos for a full inspection.

## Items Needed

Before treatment, have the following items available:

- Medical grade oxygen source with pressure regulator and flow meter (recommend an aluminum size D or E with integrated valve and regulator and metered flow rate of 1 liter per minute (LPM))
- Humidifier with pressure relief valve and tapered barb fitting
- Humidifier connector tube, 15"
- Humidifier bottle bracket
- Lid speculum
- Oxygen sensing meter, such as Quantek Model 901 or equivalent

## Intended Use

The Boost Goggles® are intended for use with Epioxa™ HD (riboflavin 5'-phosphate ophthalmic solution) 0.239% and Epioxa™ (riboflavin 5'-phosphate ophthalmic solution) 0.177% and the O<sub>2</sub>n™ System in epithelium-on corneal collagen cross-linking for the treatment of keratoconus in adults and pediatric patients aged 13 years and older.

## Contraindications and Warnings

### Contraindications

Aphakic and Pseudophakic Patients: Epithelium-on corneal collagen cross-linking is contraindicated in aphakic patients and pseudophakic patients without a UV-blocking intraocular lens.

### Warnings

Herpetic Keratitis: Corneal collagen cross-linking should be used with caution in patients with a history of herpetic keratitis due to the potential for reactivation of herpes keratitis.

## Intended User

Intended users are trained, licensed medical professionals.

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

### Intended Patient Population/Use Environment

Patients who require epithelium-on corneal cross-linking procedures for the treatment of keratoconus.

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

## Cautions

Please read these instructions before using the product.

Refer to manufacturers' instructions regarding proper set up and use of third-party components.

Images used in this manual are for guidance only and may not be exact depictions of the device.

Boost Goggles are intended for single patient use only. Do not re-use. Discard after use.

Boost Goggles must be used with a humidified medical grade oxygen source with a flow rate of 1 LPM, required to achieve ≥90% oxygen concentration.

Check that the procedure area is free from ignition sources and open flames while medical grade oxygen source is in use.

Verify that there is sufficient oxygen in the cylinder for completion of treatment before use.

Ensure that the oxygen tank is secured to tank cart or wall during use and storage.

Check ambient oxygen levels of use environment with oxygen meter prior to therapy. Ambient oxygen reading should be 20.9% oxygen.

## Connect Oxygen Source to Humidifier Bottle

1. Unpackage the humidifier bottle and prepare per manufacturer's instructions (i.e., secure humidifier bottle adapter inlet [A] to humidifier bottle and tighten, snap trigger upward [B] from humidifier outlet barb to remove. After snapping trigger from humidifier outlet barb [B], ensure the opening is unobstructed. NOTE: The humidifier and humidifier connector tube are single use only. Use in accordance with manufacturer's instructions.

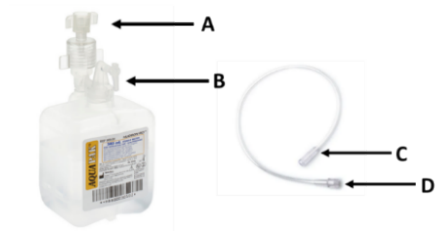


Figure 1: Humidifier Bottle with Tubing

Item	Humidifier Items Description
A	Humidifier bottle adapter inlet
B	Humidifier bottle trigger/ barbed outlet
C	Humidifier connector tube bushing end
D	Humidifier connector tube threaded fitting end

2. Connect 15" humidifier connector tube threaded fitting end [D] to humidifier bottle adapter inlet [A].
3. Connect 15" humidifier connector tube bushing end [C] to barbed outlet of oxygen source equipped with pressure regulator and flow meter.
4. Hang humidifier bottle from oxygen cylinder using bracket.



Figure 2: Humidifier Bottle Installed

5. Turn on oxygen source and set oxygen flow rate to 1 LPM. Ensure there is no leakage around the connections as follows. Look for bubbles in the humidifier bottle. Occlude the humidifier bottle outlet barb [B] with a gloved finger and listen for the whistle alarm while oxygen is flowing.



Figure 3: Humidifier Leakage Check

6. Turn off oxygen source.

## Open Boost Goggles

1. Unpackage the goggle tray, head strap, and tube set, and then discard packaging.

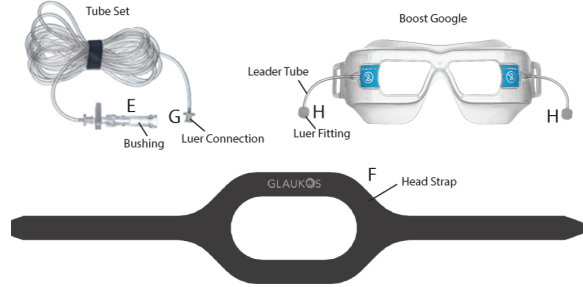


Figure 4- Boost Goggles Overview

Item	Description
E	Boost Goggle tube set bushing end
F	Boost Goggle head strap
G	Boost Goggle tube set luer fitting connection
H	Boost Goggle leader tube luer fitting

2. Connect the bushing end [E] of the Boost Goggle tube set to the output of the humidifier bottle [B].
3. Push the bushing end [E] firmly onto the humidifier bottle barbed fitting [B] to ensure proper attachment and seal without leakage.  
NOTE: Reserve the tie band around the Boost Goggle tube set to secure excess tubing.



Figure 5: Bushing End of Tube Set to Humidifier Bottle

## Prepare Patient

1. Prior to the patient lying on the table/chair, place head strap on the head rest with the logo facing up [F].
2. Instruct the patient to lie in a supine position. Guide the back of the head onto the center of the head strap. The hook and loop ends should exit near the top of the patient's ear with both ends being the same length.
3. Place gauze on the temporal side of the eye being treated and then tape down in place. This is to absorb excess fluid.
4. Carefully insert lid speculum.

## Align Goggles and Attach to Head Strap

1. Place the goggles so they are comfortably positioned on the bridge of the nose and align the goggle openings over the center of each eye.
2. Attach the head strap to the goggles by threading the strap ends one at a time through the side slots on the goggles and tighten the two straps simultaneously to avoid decentering the goggles.
3. Confirm that the goggles remain centered over the eyes, and the patient's head is flat in side-to-side and head-to-toe axes.
4. Minimize any gaps between the goggle and the patient's skin and ensure the goggle is level in both planes.

## Connect Tubing to Goggles

Connect the Boost Goggle tube set [G] to the Boost Goggle leader tube luer fitting [H] on the side of the eye to be treated with a ¼ twist in the clockwise direction.

NOTE: The reserved tie band is recommended for use to secure excess tubing during setup and use.

## Turn on Oxygen

NOTE: The humidifier and humidifier connector tube are single use only. Use in accordance with manufacturer's instructions.

1. Turn on the oxygen sensing meter and ensure ambient oxygen in procedure room is 20.9%.
1. Slowly turn on the oxygen source, starting the flow of humidified oxygen. Set the flow to 1 LPM. Adjust if necessary.
2. Allow two minutes of steady oxygen flow to ensure that the eye is under an oxygen rich environment.
3. Confirm ≥90% oxygen concentration near the cornea with oxygen meter. If concentration is below 90%, check for leaks in tubing connections and fit of goggles on patient.

WARNING: Do not proceed until oxygen concentration measures at least 90%.

4. After two minutes of steady oxygen flow, the eye is ready for UV irradiation.
5. After UV irradiation is complete, reconfirm ≥90% oxygen concentration near the cornea with oxygen meter to ensure steady oxygen flow throughout treatment.
6. Turn off the oxygen sensing meter.
7. If treating one eye of patient, proceed to section, "Remove Goggles".

## Bilateral Treatment

1. If performing bilateral treatment, turn off the oxygen source and carefully remove the goggles from the patient.
2. Remove speculum from patient's eye.
3. Disconnect the Boost Goggle tube set [G] from the Boost Goggle leader tube Luer fitting [H] with a ¼ twist in the counterclockwise direction.
4. Repeat steps from section "Prepare Patient" through section "Turn on Oxygen."

## Remove Goggles

1. At the end of the treatment, turn off the oxygen source and carefully remove the goggles from the patient.
2. Goggles can be gently removed from the patient's face by releasing the hook and loop straps on each side of the goggle, and then lifting the goggles from the patient's face, treated eye first.

Remove speculum and gauze from patient's eye.

3. Disconnect the Boost Goggle tubing bushing end [E] from the humidifier bottle outlet barb [B].
4. Disconnect the humidifier connector tube bushing end [C] from the oxygen tank barbed outlet.
5. Once removed, discard the Boost Goggle tubing, the Boost Goggles, the head strap, humidifier, and humidifier connector tube.

NOTE: The humidifier and humidifier connector tube are single use only. Use in accordance with manufacturer's instructions.

## Troubleshooting

### Oxygen Supply – Bubbler Alarms

The pressure valve has tripped on the humidifier bottle (i.e., a hiss can be heard).

1. Check oxygen source flow rate. Ensure flow rate is set to 1 LPM.
2. Check if Boost Goggle tubing is coiled, bent, or crushed. If the tubing has been damaged due to being coiled, bent, crushed, then replace with new goggles and tubing.
3. Disconnect Boost Goggle tubing from humidifier bottle. If humidifier outlet barb [B] is clogged or occluded, prepare a new humidifier bottle (i.e., snap trigger upward [B] from humidifier outlet barb to remove). Run 1 LPM of oxygen through the humidifier to ensure that the outlet is not clogged or occluded.
4. Disconnect Boost Goggle tubing from filter (C07) in Figure 6. If humidifier whistle alarm is still present, then replace with new goggles and tubing.

### Oxygen Measurement – Low Reading

The oxygen reading on Quantek Model 901 oxygen-sensing meter is low (i.e., below 90% oxygen).

1. Check setup:
  - Flow rate is set to 1 LPM.
  - At least 500 psi available in oxygen tank, check pressure gauge reading on tank.
  - Oxygen meter probe at corneal plane.
2. Check tubing connections, see figure below.
  - Check hand-tightened connections; should not be overtightened: C02, C03, C06, C10.
  - Check push fit connections are fully seated: C01, C04, C05, C07, C08, C09, C11, C12.
  - Check oxygen port is seated properly. If not, press until fully seated or flush with the Boost Goggle: C13.

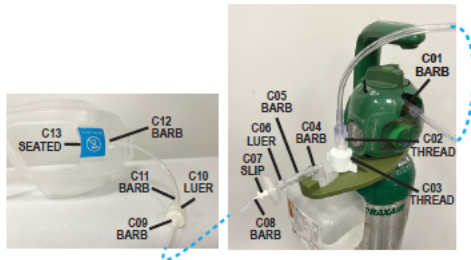


Figure 6: Tubing Connections

3. Check the oxygen sensing meter for the following conditions:
  - Continuous Mode On: indicated by the red button on and the sound of meter pump running.
  - Oxygen meter should run for at least 2 minutes before first measurement on treatment day. Oxygen meter should be in the treatment room for at least 30 minutes prior to measurement.
  - If the low battery warning light is on during treatment, replace batteries. Charge oxygen meter the night prior to treatment. Do not charge meter during treatment.
  - Be sure oxygen service is up to date.
  - Ambient oxygen setting should be 20.9%. If not, adjust oxygen meter at SPAN port using a screwdriver. While monitoring oxygen reading, turn clockwise to increase oxygen value or turn counterclockwise to decrease oxygen value.



Figure 7: Oxygen Meter Adjustment at Span Port

4. Check for the following conditions near patient/goggles:
  - Air movement near goggle eye opening. Place palm of hand near opening and feel for air movement. If there is air movement, search and remove the source. Common air sources might be an air conditioning or heating vent, talking too closely to patient (<30 cm), door opening near patient.

- Delivery leaks. Listen for audible hissing sound (i.e., leak at connection points) and tighten appropriate connection or replace goggle and tubing set if tightening connection points does not remove leak.
- Check fit of Boost Goggles to patient's face, as follows.
  - Ensure there are no gaps between the patient's face and the goggles.
  - Gaps in the temporal area (near ear) must be eliminated while gaps around the nose bridge must be minimized.
  - If gaps persist, close gaps with surgical tape.

#### Boost Goggles Check

Check goggle oxygen flow issues in the connections.

1. Connect goggles to tubing and set oxygen flow to 1 LPM. Position oxygen meter probe in the center of the oxygen port.



Figure 8: Oxygen Meter Probe Centered

2. With oxygen meter probe in position, use a finger to seal most of the oxygen port, while leaving a small opening at one corner for oxygen to release from the chamber.

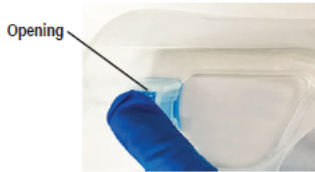


Figure 9: Small Opening for Oxygen Release

3. Oxygen concentration reading will be  $\geq 90\%$  within 30–60 seconds.  
NOTE: If after performing these steps a  $\geq 90\%$  oxygen reading is not achieved, check fit of Boost Goggle to patient's face for gaps as detailed in Step 4 of the previous section.

### Storage Conditions

Temperature -15°C to 55°C

Humidity 10% to 80%














### Operating Conditions

Temperature 15°C to 30°C

Humidity 20% to 80%

### Symbol Library

The following symbols may be used on the device, device packaging or in this User Guide.

Symbol	Definition
	Do not reuse
	Consult instructions for use
	Manufacturer
	Non-sterile
	Caution
	Keep away from rain
	Prescription Device
4. 	Catalog Number
5. 	Lot Number
6. 	Use by Date
7. 	Unique Device Identifier
8. 	Temperature limits
9. 	Humidity limits



## Boost Goggles® User Guide



Avedro, a Glaukos Company  
30 North Ave  
Burlington, MA 01803 USA  
Tel: +1.781.768.3400  
Fax: +1.781.768.3401  
[orders@glaukos.com](mailto:orders@glaukos.com)

ML-000158 Rev 4

10/2025

© 2025 All rights reserved.

Boost Goggles® is a registered trademark of Avedro, a Glaukos Company. Epioxa™ and O<sub>2</sub>n™ are trademarks of Glaukos Corporation. Glaukos® is a registered trademark of Glaukos Corporation.

Adverse events and/or serious incidents must be reported to Glaukos Corporation at [MedicalSafety@Glaukos.com](mailto:MedicalSafety@Glaukos.com).