

Practice Training

Oxygen-enriched Epithelium-on Cross-linking for Keratoconus

This content is intended for Healthcare Professionals only. If you are not a Healthcare Professional, please consult your doctor about the risks and benefits of Epioxa™. This presentation includes a demonstration of procedural techniques involved with the Oxygen-enriched Epithelium-on Cross-linking for Keratoconus. It is not intended to be used as a procedural training guide. Other surgeons may employ different techniques, and the steps demonstrated may not be the complete steps for the procedure. Individual surgeon preferences, experience, and patient needs should guide variations in procedural steps. Before using any pharmaceutical, including those demonstrated or referenced in this presentation, review all relevant package inserts, with particular attention to the indications, contraindications, warnings and precautions, and steps for use of the drug.

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GLAUKOS

PM-US-3220 Rev 2



Agenda



1 Products and Equipment

4 Procurement

2 Procedure Process

5 Practice FAQs

3 Troubleshooting

Products and Equipment

- **Glaukos Products**
- **Other Equipment and Supplies**



Procedure set-up



Before beginning the procedure:



- 1) Check all Glaukos products are ready.
- 2) Check all other equipment and supplies are ready.
- 3) Attach and test the oxygen supply and humidifier bottle connections.

**When all products, equipment, and supplies are ready,
start up the device and program the O₂n™ System treatment settings.**

Epioxa™ epithelium-on with O₂n™ System



- O₂n System

Accelerated pulsed UV treatment



- Epithelium-on cross-linking kit
 - ✓ Epioxa HD
 - ✓ Epioxa
 - ✓ RFID treatment activation card

Two-part ophthalmic solution for transepithelial delivery



- Boost Goggles® (single patient use)

Supplemental oxygen is delivered through Boost Goggles



- Glaukos humidifier hanger bracket

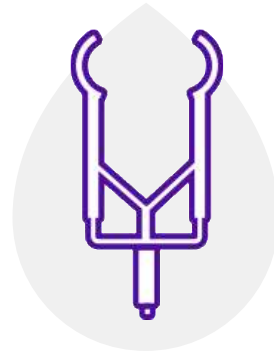
Other equipment and supplies



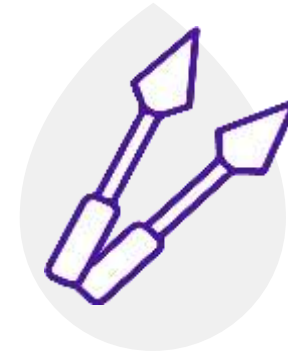
- Topical Anesthetic (eg, Proparacaine or Tetracaine)



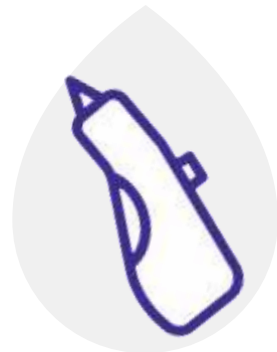
- Oxygen Meter (eg, Quantek 901 Handheld)



- Lid Speculum (eg, 45° Lieberman or Barraquer Wire Speculum)



- Surgical Sponge (eg, Weck-Cel Cellulose Eye Spear)



- Pachymeter



- Balanced Salt Solution (BSS)



- Gauze



- Oxygen Supply with Components

 Epioxa™
(riboflavin 5'-phosphate
ophthalmic solution)

Oxygen supply components, humidifier bottle with connector, and Boost Goggles[®]



Oxygen Regulator

- A. Flow-adjusting knob
- B. Barbed outlet port
- C. Cylinder contents indicator
- D. Pressure gauge



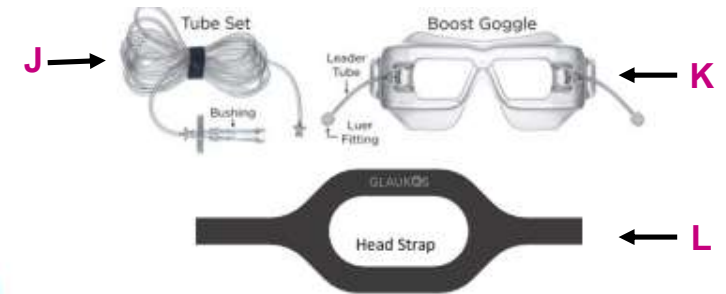
Humidifier Bottle

- E. Adapter inlet
- F. Relief valve
- G. Outlet barb w/snap trigger



Connector Tube

- H. Connector to oxygen source
- I. Threaded fitting to humidifier bottle



Boost Goggle Components

- J. Tubing Set
- K. Boost Goggles
- L. Goggles head strap

Prefilled humidifier bottle



Components of the prefilled humidifier bottle include

- Prefilled bottle directs oxygen through a reservoir of sterile water to humidify the oxygen stream and reduce dehydrating effects on the cornea
- Pressure relief valve, incorporated into the neck of the input, opens and emits a high-pitched whistle if the system pressure is too high, allowing detection of blocked lines
- Twist-off cap on the output nozzle breaks the seal and enables inspections for occlusions to the nozzle
- Yellow (or white) fitting connects directly to the output of the flow meter
- Boost Goggles[®] tubing connects directly to the output nozzle

Bottle set-up procedure

- Connect the top adapter by screwing into place and breaking the seal on the bottle input



Attaching the oxygen supply and humidifier bottle connections

- 1) Confirm oxygen meter and tank with sufficient pressure are available (between 500 and 2000 PSIG).
- 2) Attach the Glaukos humidifier bracket to the oxygen tank below the regulator.
- 3) Attach the humidifier bottle to the bracket and screw in the adaptor to the top of the bottle.
- 4) Screw in the 12-in connector tube to the top of the bottle and connect it to the regulator.
- 5) Snap off the trigger from the front of the bottle.
- 6) Turn on the oxygen flow rate to 1.0 L/m and confirm.
- 7) Connect the humidifier bottle tubing to the side of the goggles corresponding to the eye being treated.
- 8) Test the oxygen meter by testing the ambient oxygen or 20.9% and calibrate if necessary.



Assembled components

1. Oxygen/humidifier tube
2. Humidifier bracket (Glaukos)
3. Humidifier bottle
4. Oxygen Tank



1

2

3

4



Procedure Process

- **Patient Preparation and Device Set-up**
- **Riboflavin Application**
- **Oxygen Flow**
- **UV Treatment**
- **Treatment Completion**
- **Postoperative Care**



Starting up the device



1. Turn on the master power switch.



2. Press "Start" button on home screen.



3. Insert the activation card.



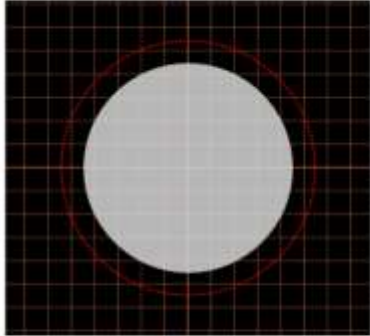
Confirming the settings



Treatment confirmation

Select the eye to treat

OS OD



Treatment parameters

Treatment shape:	Circle 9 mm (diameter)
Formulation:	EPIOXA™
Induction time:	EPIOXA™ HD: 4 min EPIOXA™: 6 min
UV irradiance:	30 mW/cm ²
Total UV dose:	10 J/cm ²
UV delivery:	Pulsed
Pulse duration:	On 1.0 sec Off 1.0 sec
Total UV treatment time:	11 min 6 sec

Cancel **Confirm**

Indicate right or left eye and press the “Confirm” button to confirm the treatment parameter settings are correct.

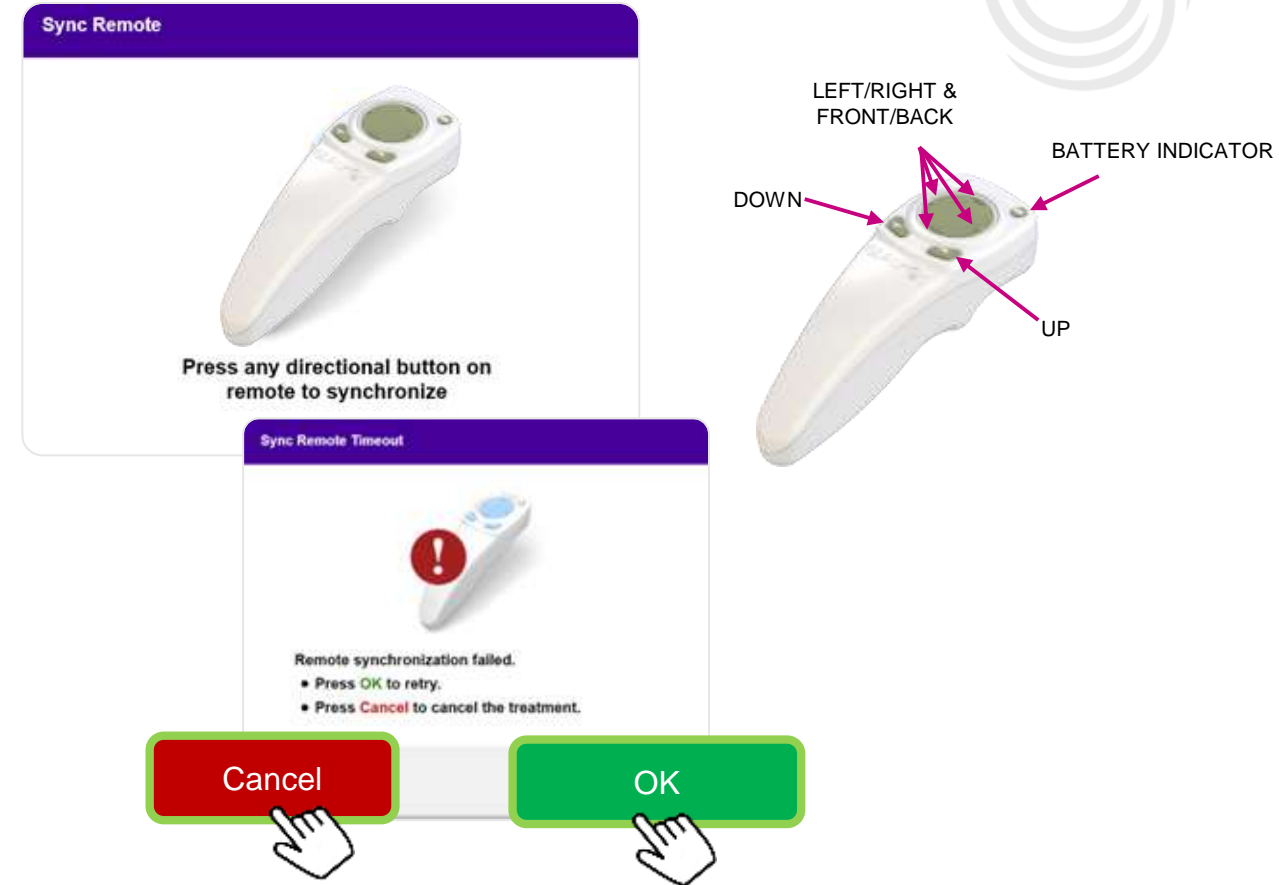


Synchronizing the remote

Synchronize (sync) the remote

Important: If you want to use the remote, you must sync the remote before beginning each procedure.

- Press any directional button to sync the remote. You have 15 seconds to sync the remote
- The system will beep every 2 seconds during the 15-second timeframe
- If a directional button is not pressed within the 15-second timeframe, the “Sync Remote Timeout” message appears onscreen
- Press “OK” to attempt to resync the remote or press “Cancel” to cancel the treatment



PATIENT PREP & SET-UP

EPIOXA HD

EPIOXA

OXYGEN

UV

TREATMENT COMPLETION

Preparing the cornea

Clear the surface mucin layer

- Instill topical anesthetic before insertion of the lid speculum
- Apply a small gauze to the temple area
- Insert the lid speculum
- Thoroughly moisten the surgical spear with Epioxa HD (Step 1 pouch)
- Gently clear the epithelial surface mucin layer with the moistened spear by making 4 to 10 gentle swipes each in both the horizontal and vertical meridians



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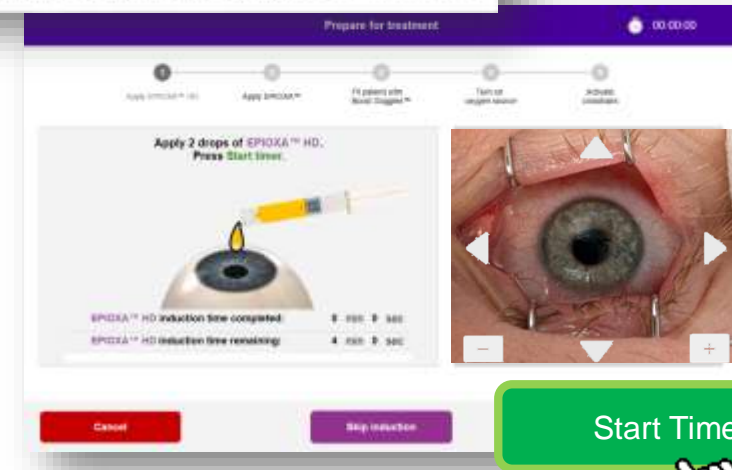
UV

TREATMENT COMPLETION

Step 1: Epioxa HD drop protocol

Instill Epioxa HD

- Instill 2 drops of Epioxa HD from the prefilled syringe in Step 1 pouch and press “Start Timer”.
- Instill 2 drops of Epioxa HD every 60 sec for 4 min:
- After the fourth instillation, prepare the Epioxa syringe in the Step 2 pouch



Step 2: Epioxa drop protocol

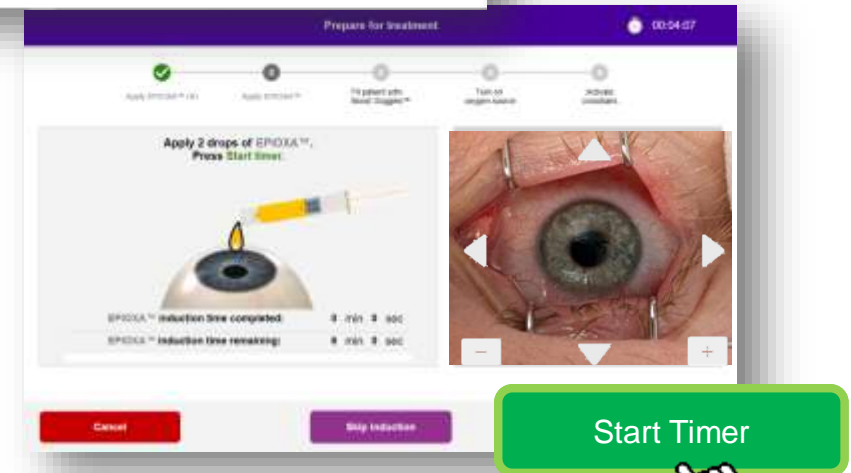
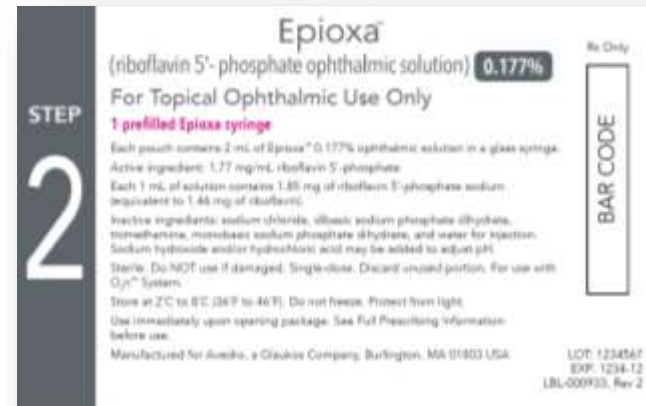


Instill Epioxa

- Instill 2 drops of Epioxa from the prefilled syringe in Step 2 pouch and press “Start Timer”.
- Instill 2 drops of Epioxa every 30 sec for 6 min
- After induction, gently and thoroughly flush riboflavin with BSS (>5 mL) to remove all residual Epioxa

Measure ultrasound pachymetry

- Apply anesthetic and measure pachymetry to ensure $\geq 325 \mu\text{m}$



Fitting the Boost Goggles[®]



Fit and level the goggles

- To fit and level the goggles, press the “Fit Boost Goggles” button
- Apply the goggles. Tighten both straps to “swim-goggle tight.” Press all the way around the edges of the goggles to ensure a smooth seal
- Avoid disrupting the seal of the goggles or blocking the diffuser ports with multiple layers of gauze or other materials
- Ensure that the goggles are level in both planes. A pad may need to be placed under the patient’s head



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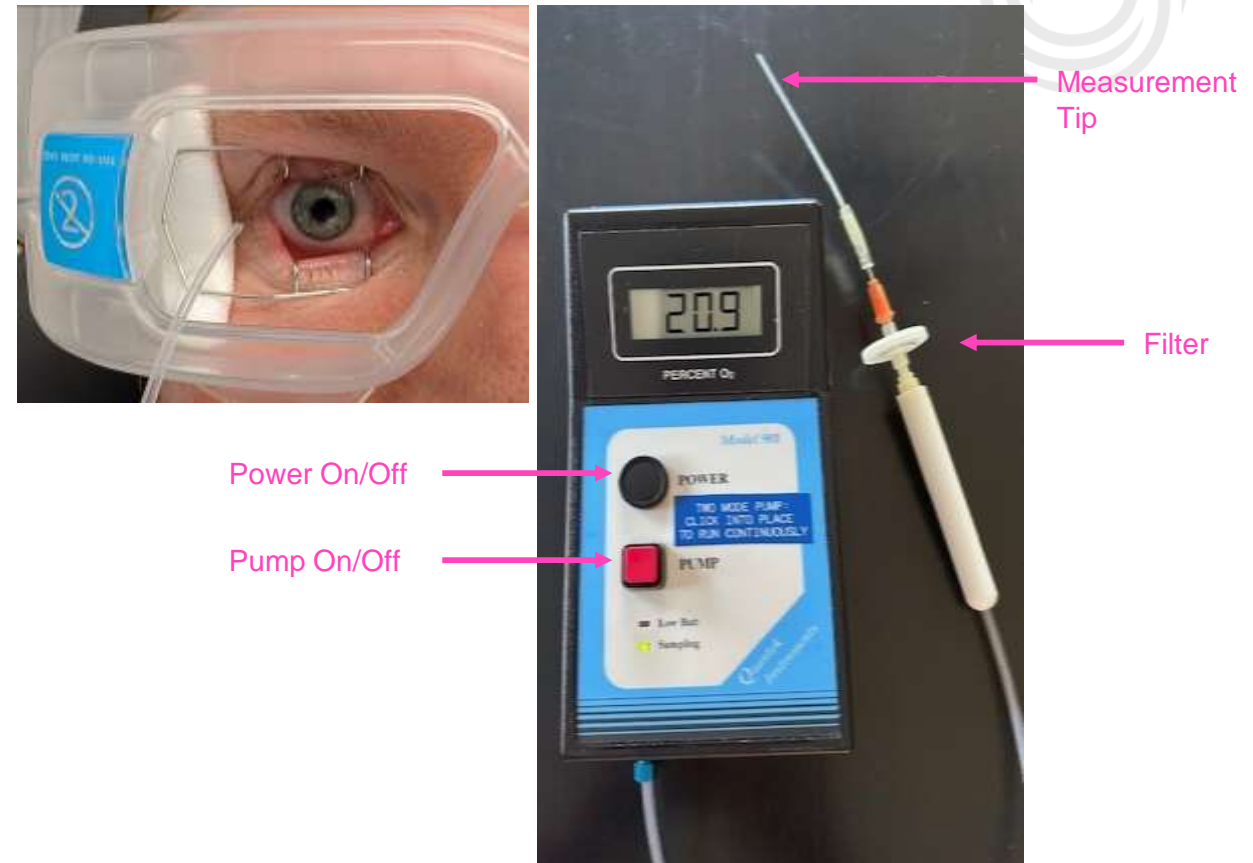
TREATMENT COMPLETION

Setting up the oxygen flow

Measure the oxygen concentration

- Press the “Turn on Oxygen Flow” button and turn the tank regulator to 1 L/min
- Turn on the power to the oxygen meter. Be sure the pump is activated and confirm 20.9% ambient oxygen
- Insert the measurement tip within the goggles, near the cornea at the lateral canthus, without contacting the patient
- Allow 30 to 60 sec for the oxygen level to reach $\geq 90\%$. Adjust the goggle fit and head position if necessary

Note: Allow 2 minutes to elapse from the start of oxygen flow before initiation of UV.



PATIENT PREP & SET-UP

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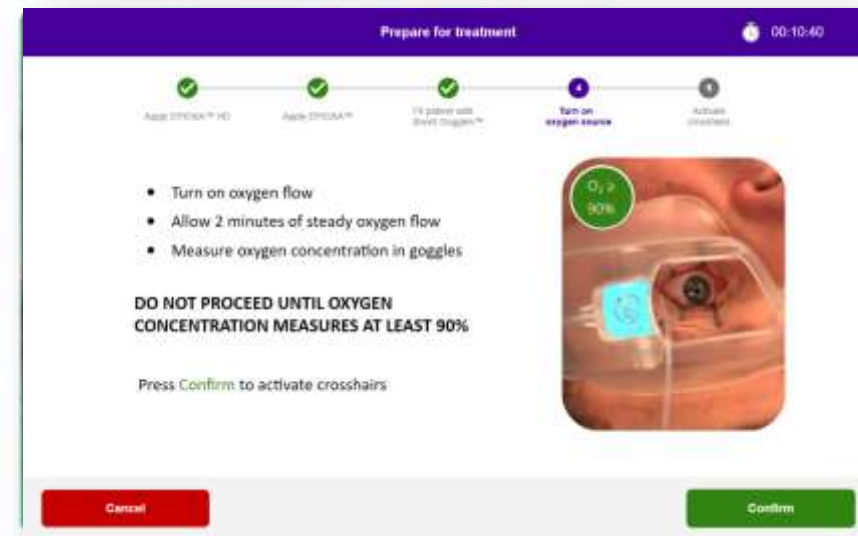
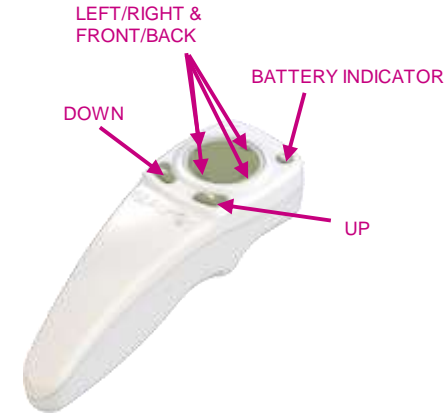
UV

TREATMENT COMPLETION

Aligning the O₂n™ System

Align the crosshairs

- Press the “Confirm” button to turn on the crosshairs
- Position the O₂n System alignment crosshairs over the cornea as shown
 - First red crosshair for x- and y-axis positioning
 - Second red crosshair for z-axis positioning
- Use the arrows on the screen or the remote to accurately align the crosshairs on the patient’s eye



PATIENT PREP & SET-UP

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EPIOXA

OXYGEN

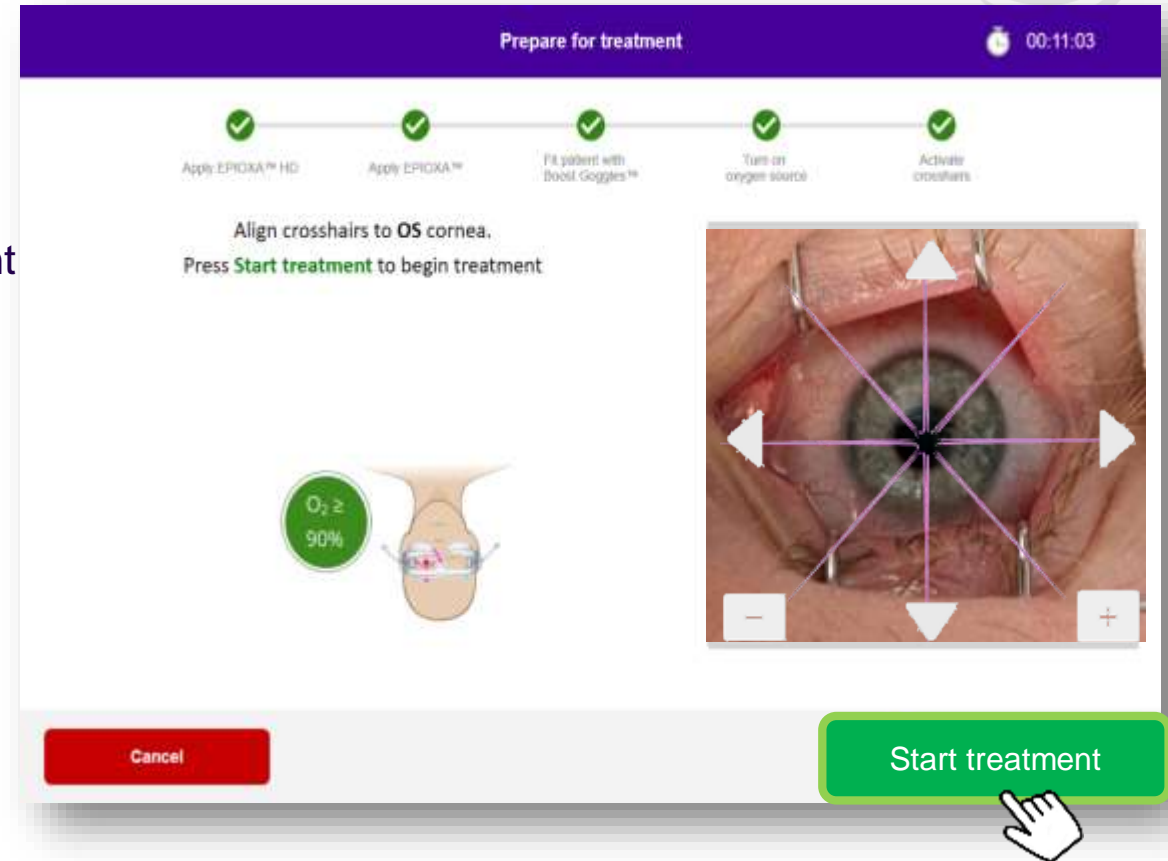
UV

TREATMENT COMPLETION

Starting the UV-A treatment

Start the UV-A treatment

- Press the “Start Treatment” button to initiate the UV-A treatment
- Instill drops of BSS at 2-min intervals, or more frequently as needed, to maintain hydration during the UV treatment
- Use the arrows on the screen or the remote to adjust the beam position on the patient’s eye if needed during treatment
- When treatment has ended, measure the oxygen concentration again
- Turn off the oxygen flow following the completion of the programmed irradiation time
- Remove the goggles and then the speculum



Pausing the treatment



The user may decide to stop or interrupt the treatment. In such a 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
- To resume the treatment, press the “Resume treatment” button
- To cancel the treatment, press the “Cancel” button

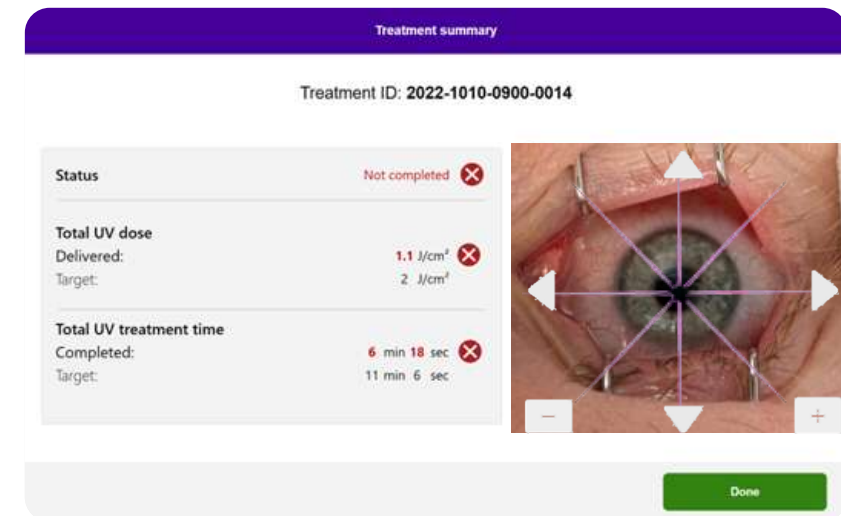
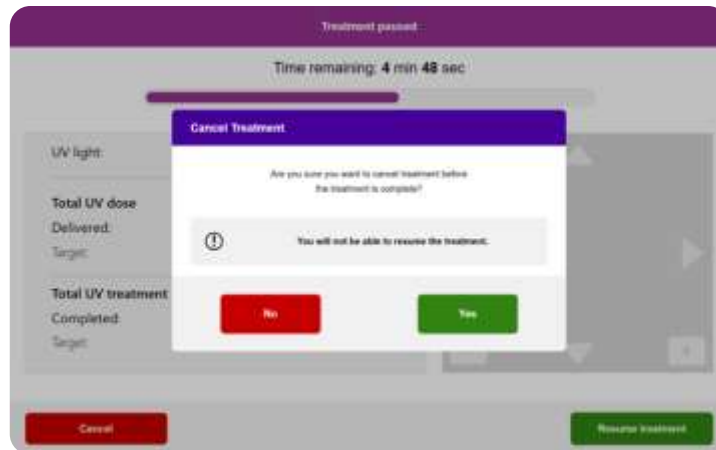


Canceling a treatment while the treatment is paused



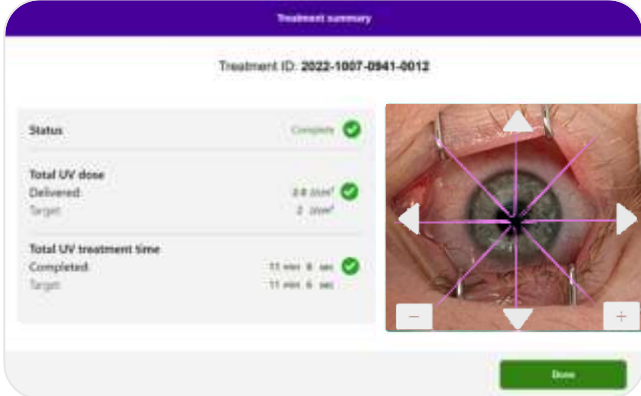
Pressing “Cancel” during a paused treatment

- If the “Cancel” button is pressed during a paused session, a “Cancel Treatment” screen appears
- To cancel a treatment, press the “Yes” button
- If the treatment is canceled, the screen displays a “Not completed” status message under “Treatment summary”
- To cancel the session, press the “Done” button
- The system then returns to the home screen





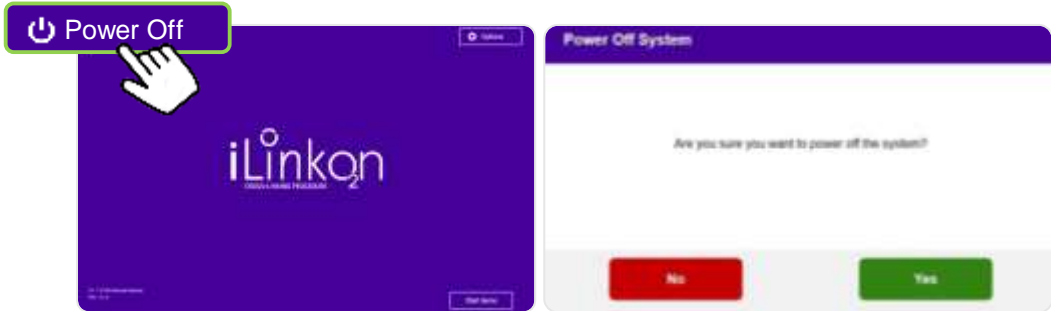
Completing the treatment procedure



- At the completion of a treatment, all the treatment parameters are displayed on the screen under “Treatment Summary”

Turning the power off

- If the treatment is complete, turn the power off for the system by pressing the “Power Off” button on the main screen
- Confirm powering off the system by pressing the “Yes” button
- Carefully remove the device from the patient area



Postoperative care

Postoperative medications may include

- Oral NSAID
- Topical NSAID
- Broad spectrum topical antibiotic
- Preservative-free artificial tears



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TREATMENT COMPLETION

Troubleshooting

- **Oxygen Supply**
- **Oxygen Measurement**



Oxygen supply



The pressure relief valve has tripped on the humidifier bottle

- Confirm that the output of the humidifier bottle is free of occlusion.
- Confirm that the tubing has not been bent, crushed or coiled too tightly.
- Confirm that the regulator is not set to greater than 1.0 L/min.

No oxygen is flowing to the Boost Goggles

- Confirm that the output of the humidifier bottle is free of occlusion.
- Confirm that the tubing has not been bent, crushed or coiled too tightly.
- Confirm that the oxygen pressure is between 500 and 2000 PSIG and that the flow meter is on and adjusted to 1.0 L/min.
- Confirm that the Boost Goggles have not been used multiple times*, possibly leading to a blocked filter.

*Boost Goggles are intended for single patient use only.

Oxygen measurement



The oxygen reading is low

- Confirm the pump is activated on the meter, that the air filter installed correctly and the “Low Battery” warning light is not illuminated.
- Confirm that the meter properly calibrated to 20.9% ambient oxygen.
- Confirm that the tip of the probe is well inside the Boost Goggles® and minimize talking or movement near the face.
- Check for supply leaks.
- Confirm a tight seal to the face all the way around.
- Confirm that the overhead HVAC is not disrupting the oxygen flow.



IMPORTANT SAFETY INFORMATION

Contraindications

EPIOXA™ HD and EPIOXA are contraindicated in patients with known hypersensitivity to benzalkonium chloride (BAC) or any ingredients in EPIOXA HD and EPIOXA. Epithelium-on corneal collagen cross-linking is contraindicated in aphakic and pseudophakic patients without a UV-blocking intraocular lens.

Warnings and Precautions

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.

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.

INDICATIONS AND USAGE

EPIOXA™ HD (riboflavin 5'-phosphate ophthalmic solution) 0.239% and EPIOXA™ (riboflavin 5'-phosphate ophthalmic solution) 0.177% 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 O2n™ System and the Boost Goggles®.

Please see full [Prescribing Information](#) for EPIOXA HD and EPIOXA.

You are encouraged to report all side effects to the FDA. Visit www.fda.gov/medwatch, or call [1-800-FDA-1088](tel:1-800-FDA-1088). You may also call Glaukos at [1-888-404-1644](tel:1-888-404-1644).

Medical Information and Adverse Event Reporting

(844) 528-3376 x 1

MedicalSafety@Glaukos.com



Customer Service and Account Information

(844) 528-3376 x 2

USAOrders@Glaukos.com

Technical Support and Field Service

(844) 528-3376 x 3

EpioxaCareConnect

(for questions about coding, billing, claims submissions or payer coverage)

(855) 5-EPIOXA

This training does not replace the Prescribing Information/ Operators Manual.

Refer to the Prescribing Information/ O₂n System Operator's Manual before performing Corneal Cross-Linking.

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Epioxa[™]
(riboflavin 5'-phosphate
ophthalmic solution)