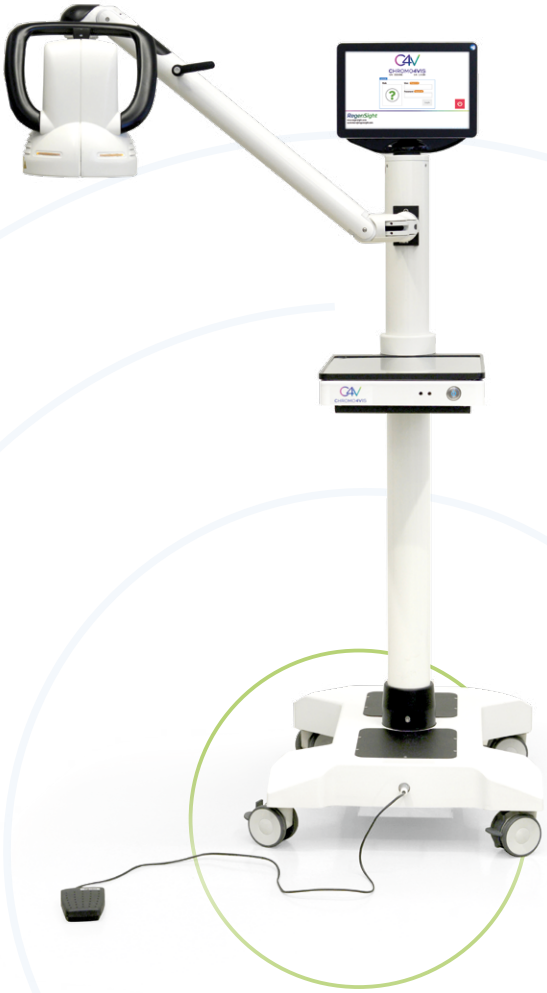
CHROMO4VIS

UV-A MEDICAL DEVICE FOR THERANOSTIC GUIDED CORNEAL CROSS-LINKING



TRANSFORMATIVE TECHNOLOGY

Scientifically and clinically validated Theranostics technology

EXPONENTIAL & KEY-ENABLING TECHNOLOGIES

- **Augmented reality** for precise corneal focusing (±0.2 mm) with integrated Placido disc technology
- **Internet Of Medical Things** for remote control and predictive maintenance (USB tethering or LAN connection)
- **Artificial intelligence** for the continuous improvement of device performance
- **Digital traceability** for clinical data storing and export

PRE-SET PROTOCOLS AND UNLIMITED ADD-ON OPTIONS

- UV-A energy dose: 3.6 J/cm² to 10.0 J/cm²
- UV-A power density: 3 mW/cm² to 40 mW/cm²
- UV-A irradiation mode: continuous or pulsed
- UV-A beam size from 5 mm to 9 mm diameter
- "Enhanced epi-on" algorithm

MAXIMUM RELIABILITY double monitoring system of UV-A power density (accuracy ±0.1 mW/cm²)

SUSTAINABLE TECHNOLOGY with optimized energy consumption

GRAPHIC USER INTERFACE on 10.1'' full HD touch screen with colour display

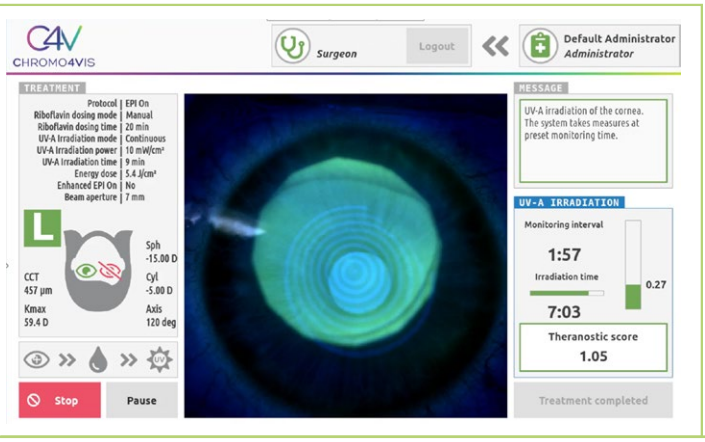
INTEGRATED INTERCONNECTION WITH PROPRIETARY CORNEAL IONTOPHORESIS

EASY HANDLING • Articulated and balanced arm (positioning accuracy: 0.2 mm)
• Wheeled cart

INDICATION OF USE Treatment of pathological conditions of the cornea with theranostic-guided corneal cross-liking procedures

EU MDR CERTIFICATION CE1936: class IIb active medical device

IP PROTECTION Patent Family ITUB20160237, EP3407920, US11612518 and CN108697814



THERANOSTIC PLATFORM

halts keratoconus progression and improves visual acuity with predictive personalization of the clinical outcome

TECHNICAL DATASHEET

RITSIGHT

0.22% RIBOFLAVIN OPHTHALMIC SOLUTION FOR CORNEAL CROSS-LINKING

UNIQUENESS THAT MEET THE SURGEONS' NEEDS

- 0.30% Riboflavin 5-phosphate (equivalent to 0.22% riboflavin base)
- Maximum stability of riboflavin for 36 months
- Hypotonic solution, viscoelastic-free
- 3.0 ml volume
- Storage at room temperature (4°C - 25°C)
- UDI with digital traceability (Data Matrix Code)

VERSATILE

Exclusive solution for all CXL protocols (epi-off, epi-on)

Indicated for thin corneas (minimum thickness 370 µm)

Indicated for manual application or with controlled corneal iontophoresis

INDICATION OF USE

Protection of the inner structures of the eye during corneal cross-linking procedures for treatment of ectatic corneal diseases, bullous keratopathy and infectious keratitis.

The only riboflavin validated for theranostic-guided corneal cross-linking

EU MDR CERTIFICATION CE0477: Class IIb sterile medical device

IP PROTECTION Patent Family IT201900011985, US20230131004 and CN114126650

DoRSight

CORNEAL IONTOPHORESIS CONTROLLED DELIVERY SYSTEM

For exclusive use with C4V CHROMO4VIS

INDICATION OF USE

Transepithelial application of riboflavin in the cornea prior to UV-A light irradiation with C4V CHROMO4VIS in theranostic-guided corneal cross-linking procedures.

UNIQUENESS

The integration of DoRSight with C4V CHROMO4VIS technology enables a sophisticated approach for **fast** and **precise patterned delivery** of riboflavin in the cornea, allowing, through theranostic-guided UV-A light photo-therapy, for:

- Enhancing precisely the regional tissue biomechanics
- Improving significantly the optical quality of the cornea

EU MDR CERTIFICATION CE1936:

Class IIa sterile accessory medical device

IP PROTECTION Patent Family IT102019000010341, EP3989895, US20220233842 and CN114025835

TECHNICAL DATASHEET

discover more at
www.regensight.com

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