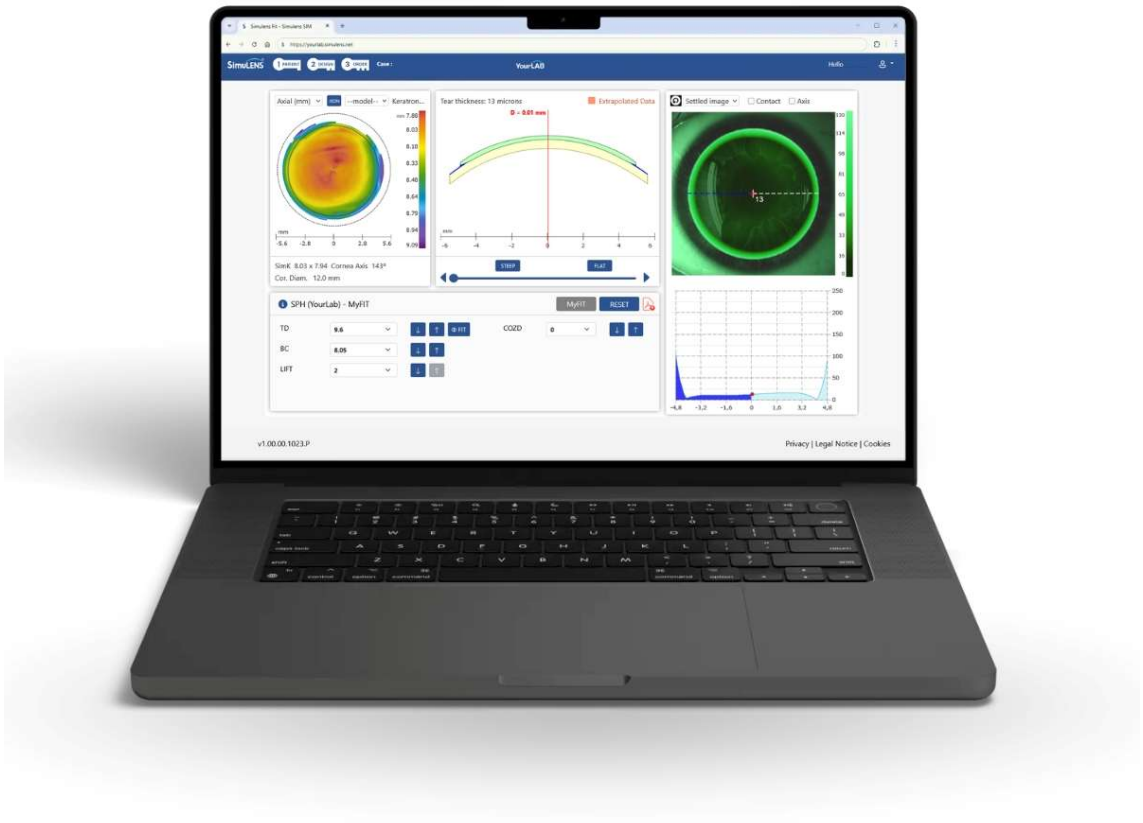


SimuLENS® User Manual

Contents

1. GENERAL INFORMATION

Product name: SimuLENS

Version: v1.00.00.00.P

Manufacturer: SimuLENS Fitting S.L.

Address: Yunque 1 Street, 28918 Leganés, Madrid, Spain

UDI code: 08437029426016

2. INTENDED USERS

2.1. Professional user profile (fitters and laboratories)

SimuLENS® is intended exclusively for vision care professionals qualified in contact lens fitting, such as clinical optometrists, contact lens specialists, ophthalmologists, specialized clinics, and laboratory technicians. It is also indicated for lens design and manufacturing laboratories that use the platform as a tool for calculation, simulation, and standardization of fittings.

2.2. Exclusions: Use by patients or unqualified personnel

This software is not designed to be used directly by patients or by personnel without specific training in advanced contactology. SimuLENS® must not be used as a substitute for clinical judgment or as a diagnostic or therapeutic tool without professional supervision.

3. INDICATIONS AND CONTRAINDICATIONS

3.1. Indications for use

SimuLENS® is indicated as clinical support software for the digital simulation of special contact lens fitting. SimuLENS® is designed for vision care professionals and laboratories that use corneal surface data (keratometry, topography) to select or design custom lenses, such as:

- Conventional RGP lenses
- Ortho-k lenses
- Scleral and corneo-scleral lenses
- Other customized rigid or soft lens designs

Its use enables digital visualization of lens geometry and its interaction with the cornea, as a validation tool prior to the final order.

3.2. Clinical and technical contraindications

Although SimuLENS® has no direct patient contact and does not generate a diagnosis, it must not be used in the following cases without additional clinical validation.

- Topographies with poor quality, artifacts, or incorrect centering
- Lenses with parameters outside the design range defined by the laboratory
- Use of the system without prior training in contact lens fitting

3.3. System limitations

- SimuLENS® does not replace the professional's clinical judgment.
- The simulation is geometric, not physiological: it does not represent dynamic phenomena such as blinking, tear retention, or eyelid pressure.
- Simulation quality depends on the quality of the input data (topography or keratometry).
- Results obtained must be verified with clinical tests on the patient.

4. TECHNICAL REQUIREMENTS

4.1. Minimum hardware and browser requirements

For optimal operation of SimuLENS®, the following technical requirements are recommended:

- Minimum screen resolution: 1280 × 720 pixels
- Compatible browsers: Google Chrome, Mozilla Firefox, Microsoft Edge (latest updated versions)
- Processor and RAM standard for current office computers (Intel i3 or higher, 4 GB RAM or more)

4.2. Connectivity and internet access

SimuLENS® is an online platform. Therefore, it requires:

- Stable internet connection
- Recommended bandwidth: minimum 2 Mbps download / 1 Mbps upload
- Allowed access to the platform domains: *.simulens.net

4.3. Network security and cybersecurity

- SimuLENS® runs under the secure HTTPS protocol
- Each user has unique credentials for access
- No clinical data are stored on the user's local device
- It is recommended to sign out after each use and not to share the password

If unauthorized access is suspected, the user must contact the SimuLENS technical support team immediately.

5. INSTALLATION, ACCESS AND MAINTENANCE

5.1. Registration and user creation

SimuLENS® is a web platform. It does not require local software installation. To get started, the associated laboratory must provide a license and access to the fitting professional.

Each registered user receives personal, non-transferable credentials.

5.2. Online system access

Access is through the official web portal: https://app.simulens.net

It requires a stable internet connection and a compatible browser.

On first access, the system may request that a new password be set.

5.3. System maintenance and updates

SimuLENS® is updated periodically to add new features, improve the user experience, and strengthen security.

Updates are performed automatically, without requiring user intervention. For topographers connected via SimuLENS Connect, the local module will request its own update if new versions are available.

5.4. Common access errors and troubleshooting

- Activation email not received: check the spam folder or contact support
- Username/password error: check uppercase and lowercase; “Forgot your password?” option available
- Loading issues or slowness: check the internet connection or update the browser

For any technical issue, contact the support team at: support@simulens.net

6. SIMULENS® SYSTEM WORKFLOW

6.1 Introduction

SimuLENS® is a digital platform that enables precise and efficient contact lens fitting. Thanks to its simulation engine, intuitive interface, and direct connection to topographers, it reduces fitting times and improves clinical outcomes.

SimuLENS® is intended exclusively for qualified professional users, including fitters and laboratories specialized in the design, fitting, or manufacturing of contact lenses.

Use of the platform requires knowledge of corneal topography, special lens fitting, and understanding of geometric design parameters.

Using SimuLENS® helps improve fitting precision, reduce the number of physical trials required, and decrease total chair time, improving the patient experience and reducing costs.

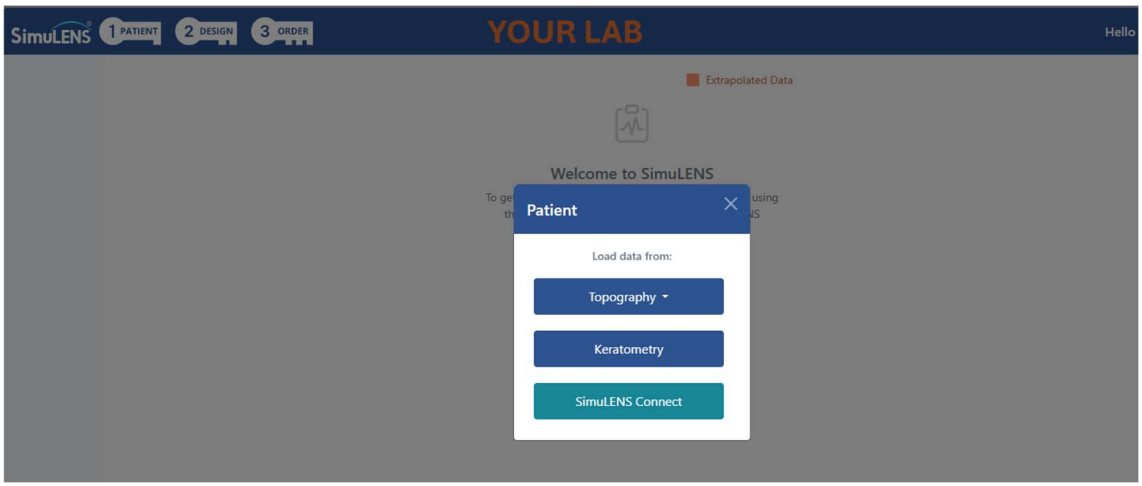
THE 3 KEYS TO USING SIMULENS

1. Select a patient and load their topographic data
2. Choose a lens design and view the simulation
3. Place the final order

6.2 Patient

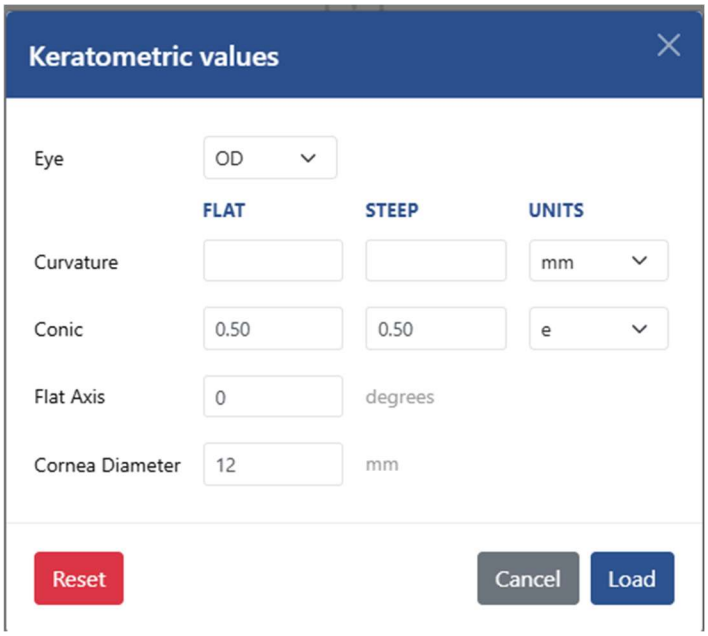
Create patient

1. Go to the Patient tab from the main menu.



2. Choose how you want to enter patient data; there are 4 ways:

a) Keratometry:

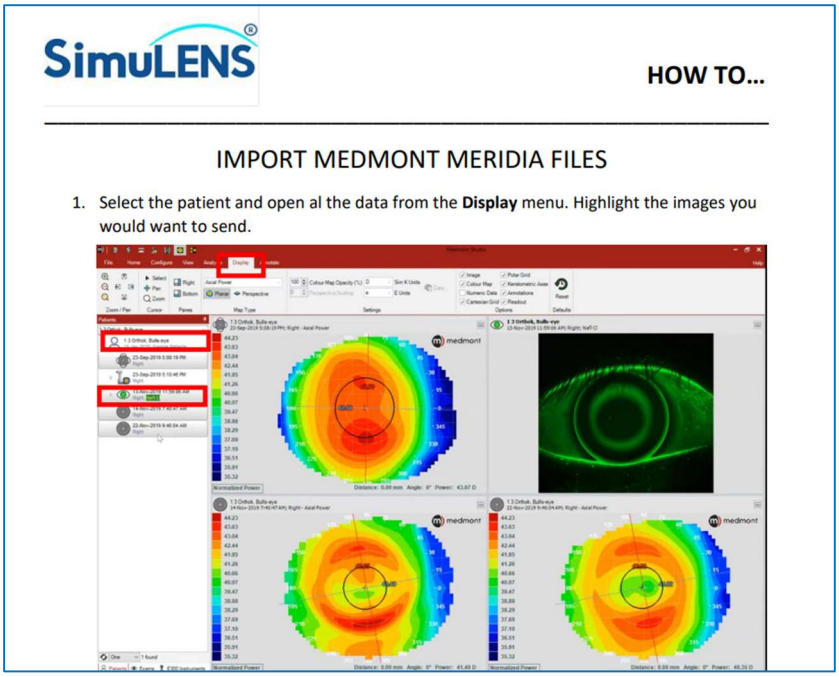


b) Exported topography:

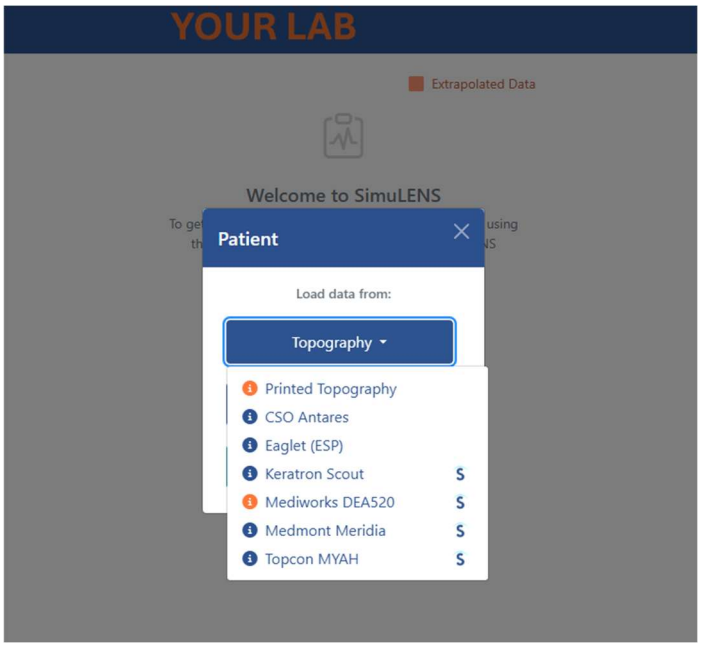
1. Export the topography from your topographer using the information guide available under the "information" icon

Medmont Meridia

Example of Medmont export guide:

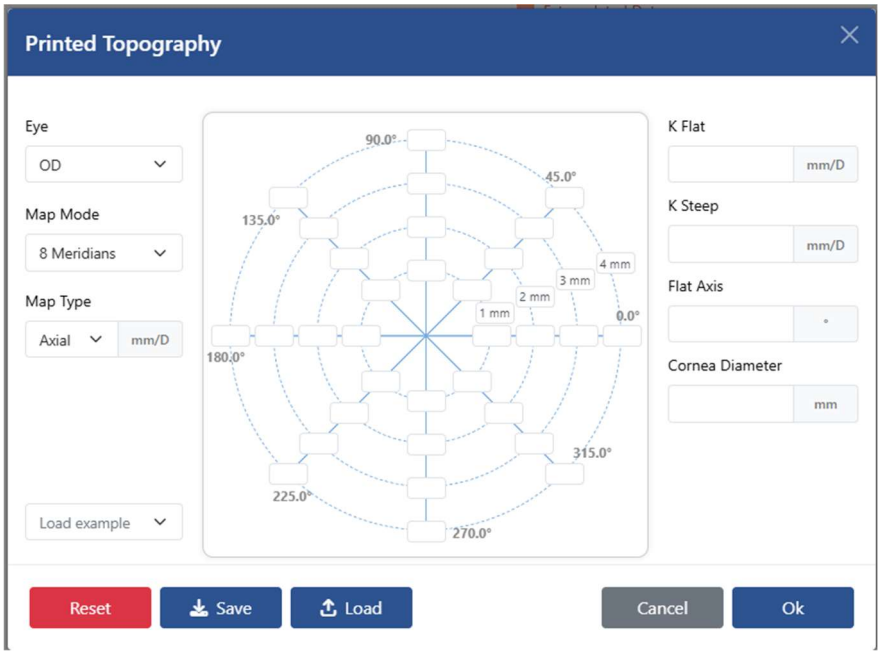


2. Select your topographer and select the previously saved files.



c) Printed topography:

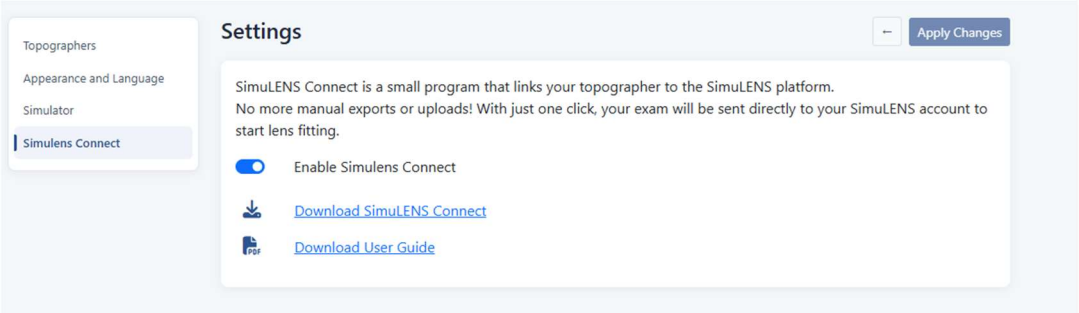
Click Topography, select Printed Topography, and enter the topography data on the next screen:



d) SimuLENS Connect:

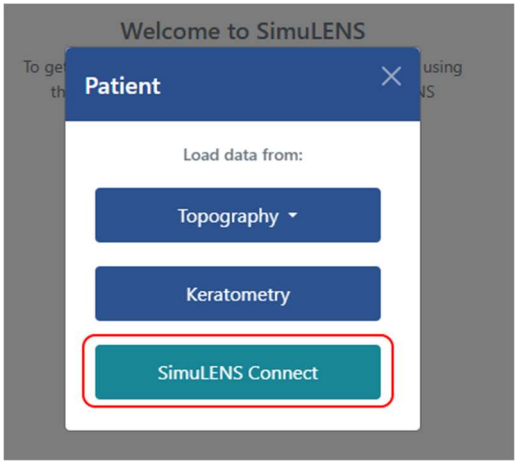
This software allows you to connect your topographer directly to Simulens.

Go to App Settings from the drop-down menu and select SimuLENS Connect:

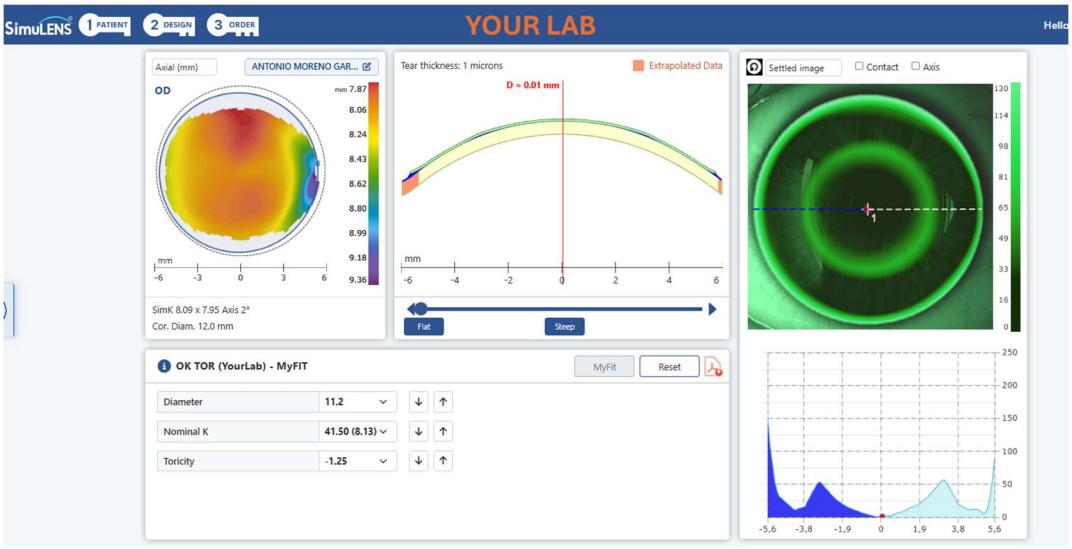


Download SimuLENS Connect and follow the steps in the User Guide to install it.

Once installed, in the PATIENT menu click SimuLENS Connect and the topography selected from the topographer will be uploaded automatically.



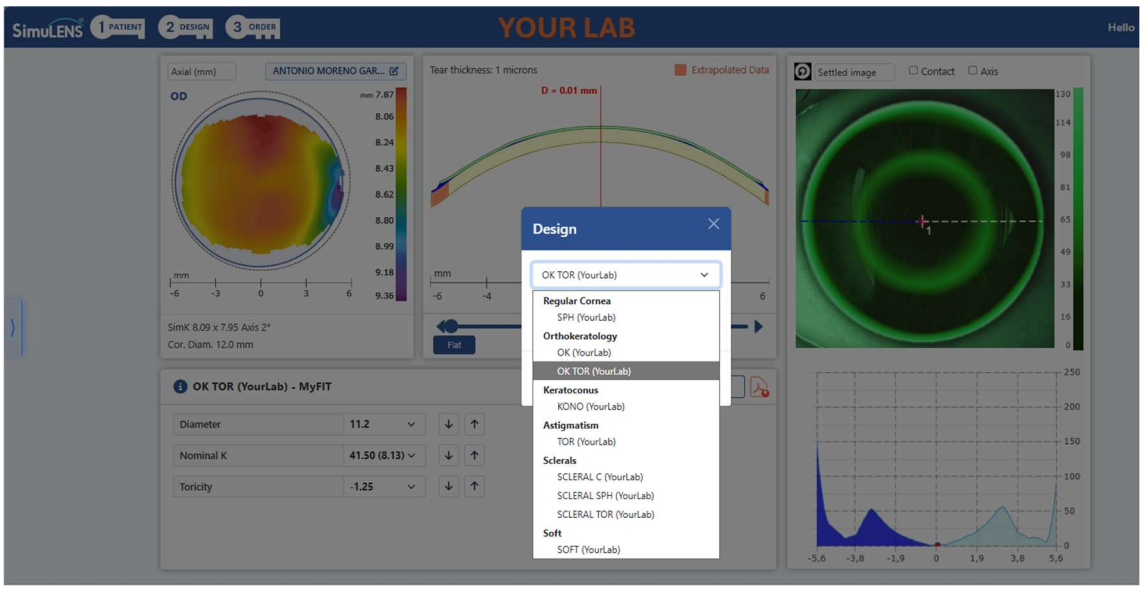
Once the desired option is selected, the data will appear on the main screen:



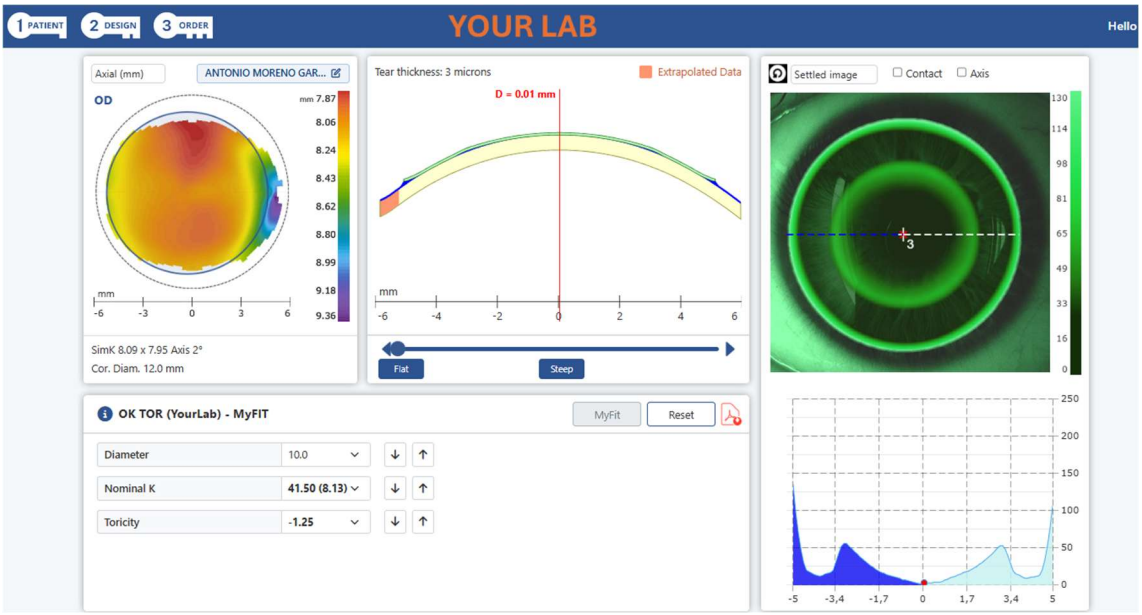
SimuLENS is compatible with topographers that allow export in .zrn, .dat, .txt or similar formats. To ensure full compatibility, it is recommended to follow the export guides available under the help icon. SimuLENS does not guarantee results with non-validated devices.

6.3 Design

1. Select the design you want to simulate from the drop-down list (the designs for each laboratory will be available).



2. In a few seconds SimuLENS calculates the best lens:
    - Click MyFIT to view the parameter selection:



Main options:

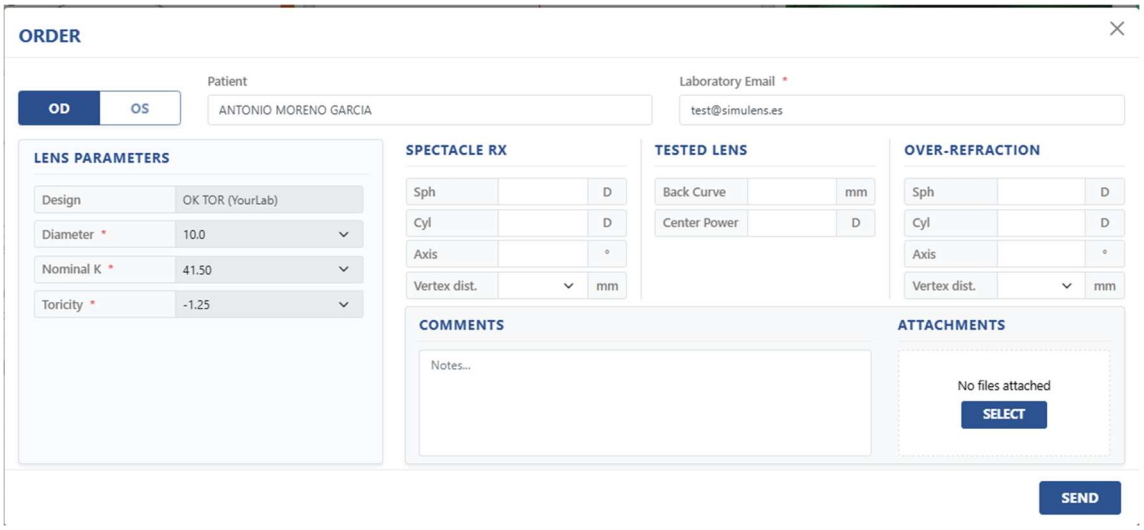
- **MyFIT:** Displays the lens parameters
- **Fluorogram:** Check tear microns at each point on the lens
    - View contact points by clicking “Contact”
    - Mark the axes by selecting “Axis”
- **Tear profile:** Shows tear film thickness in a sagittal cross-section.
- **Lens profile:** Visualizes the full lens geometry (curves, diameters, thicknesses) and how it fits on the corneal surface.

Note: the fitting simulation is based on a geometric prediction derived from topography. Interpretation must be performed by the professional according to clinical judgment.

6.4 Order

1. When the calculation is finished, click **Order**.
2. Enter additional details if needed (clinical comments, instructions, etc.).
3. The system will generate:
    - PDF with the topography, fluorogram, and lens information

You can save the files or send them directly to the laboratory.



Before confirming the order, the professional must verify that the simulated lens matches the patient's clinical needs. SimuLENS provides an indicative simulation, not a definitive diagnosis.

7. WARNINGS, PRECAUTIONS AND CLINICAL VALIDATIONS

7.1. Importance of validation by the professional

SimuLENS® is a simulation system that proposes a lens geometry based on the corneal data entered.

Final lens selection and clinical validation are the exclusive responsibility of the fitting professional.

It is always recommended to verify consistency between the lens suggested by the system and the patient's clinical reality.

7.2. Risks if the suggested lens is not checked

Fitting contact lenses without clinical verification may result in:

- Selection of an inadequate geometry
- Poor alignment with the ocular surface
- Possible discomfort or reduced visual performance

SimuLENS® does not replace clinical trial with a lens or patient follow-up.

7.3. Prior training recommendations

Although SimuLENS® has been designed with an intuitive interface, it is recommended that the user have prior training in:

- Corneal topography and map reading
- Basic and advanced contact lens parameters
- Design and fitting of specialty lenses (RGP, ortho-k, sclerals, etc.)
- Clinical interpretation of simulated results

8. DATA MANAGEMENT AND USER PROTECTION

8.1. Access security and authentication

Each SimuLENS® user has personal, non-transferable credentials. Access is protected by the secure HTTPS protocol and requires a username and password.

If credentials are forgotten, recovery can be requested by email.

8.2. No local storage of clinical data

SimuLENS® is a cloud-based system.

No clinical data are stored on the user's local device, which minimizes the risk of information leakage.

Data entered during simulation are retained only while actively working in the session.

8.3. Secure use recommendations (sign out, do not share credentials)

To ensure a secure experience, it is recommended to:

- Sign out after each use, especially on shared computers
- Do not share credentials with other users
- Use strong passwords and update them periodically
- Contact technical support if unauthorized access is suspected

In the event of a security incident, immediately contact the support team at: support@simulens.net

9. FREQUENTLY ASKED QUESTIONS

What happens if the map does not load after sending it?

Verify that you clicked the SimuLENS Connect button within the correct patient. Only the last map sent is loaded.

Can I modify the parameters manually?

Yes. Most designs allow all parameters to be modified. Some are locked according to laboratory rules.

Can I work with several laboratories from the same account?

Yes. You can use the same account across different laboratories, but each has its own access URL. You only need to enter from each laboratory's specific web address.

Is it possible to fit lenses without topography?

Yes. SimuLENS® allows work without a direct connection to a topographer. If you do not have a digital file, you can:

- Enter manual keratometries (flat K and steep K)
- Use values taken from a printed topography

Although the system can work without a digital map, simulation precision is higher when working with complete topographies in digital format.

Is any training required before using SimuLENS?

Although it does not require local installation, prior training on corneal topography, lens parameters, and design rules is recommended for optimal use of the system.

Can it be used with scleral lenses?

Yes. SimuLENS® is compatible with scleral, corneo-scleral, and large-diameter designs. Simulation precision will depend on the quality and type of topography available, especially for lenses that cover areas beyond the limbus.

Where do I request support?

If you experience technical errors, access problems, or questions about using the system, you can contact the SimuLENS support team at: **support@simulens.net**

10. COMPLAINTS AND INCIDENTS

SimuLENS® is software intended exclusively for professionals and does not come into direct contact with the patient. Nevertheless, if during use of the system any anomaly, malfunction, or unexpected result is detected that could have clinical consequences, it must be reported immediately to: **support@simulens.net**.

11. CONTACT DETAILS

Official website: https://simulens.net
Demo or support form: https://simulens.net/how-to-subscribe
Email: support@simulens.net

Incident notification

SimuLENS® is a simulation tool that requires clinical validation by the healthcare professional.

If inappropriate use, a systematic error, or unexpected system behavior is detected that could contribute to an incorrect clinical decision, please notify the manufacturer via **support@simulens.net**.