

User Manual

SimuLENS

Contents

1. GENERAL INFORMATION	2
2. INTENDED USERS	2
2.1. Professional user profile (fitters and laboratories)	2
2.2. Exclusions: use by patients or unqualified personnel	2
3. INDICATIONS AND CONTRAINDICATIONS	2
3.1. Indications for use	2
3.2. Clinical and technical contraindications	3
3.3. System limitations	3
4. TECHNICAL REQUIREMENTS	3
4.1. Minimum hardware and browser requirements	3
4.2. Connectivity and internet access	4
4.3. Network security and cybersecurity	4
5. INSTALLATION, ACCESS AND MAINTENANCE	4
5.1. Registration and user creation	4
5.2. Access to the online system	4
5.3. System maintenance and updates	4
5.4. Common access errors and resolution	5
6. SIMULENS® SYSTEM WORKFLOW	5
6.1 INTRODUCTION	5
6.2 PATIENT	6
6.3 DESIGN	9
6.4 ORDER	12
7. WARNINGS, PRECAUTIONS AND CLINICAL VALIDATIONS	12
7.1. Importance of validation by the professional	12
7.2. Risks if the suggested lens is not checked	13
7.3. Prior training recommendations	13
8. DATA MANAGEMENT AND USER PROTECTION	13
8.1. Access security and authentication	13
8.2. No local storage of clinical data	13
8.3. Safe-use recommendations (log out, do not share credentials)	14
9. FREQUENTLY ASKED QUESTIONS	14
10. COMPLAINTS AND INCIDENTS	15
11. CONTACT DETAILS	15

User Manual - SimuLENS®

Version: June 2026

1. GENERAL INFORMATION

Product name: SimuLENS

Version: v1.00.00.00.P

Manufacturer: SimuLENS Fitting S.L.

Address: Calle Yunque 1, 28914 Leganés, Madrid, Spain

CE marking: CE XXX

Issue date:

UDI code: 08437029426016

2. INTENDED USERS

2.1. Professional user profile (fitters and laboratories)

SimuLENS® is intended exclusively for eye-care professionals qualified to fit contact lenses, such as clinical optometrists, contact lens specialists and laboratory technicians. It is also intended 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 contact lens fitting. 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. It is designed for eye-care professionals

and laboratories that use corneal surface data (keratometry, topography) to select or design customized lenses, such as:

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

Its use makes it possible to digitally visualize the 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 contact with the patient 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 centration
- 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.
- The quality of the simulation depends on the quality of the input data (topography or keratometry).
- The 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 x 720 pixels
- Compatible browsers: Google Chrome, Mozilla Firefox, Microsoft Edge (latest updated versions)
- Standard processor and RAM 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
- Access allowed to the platform domains: *.simulens.net

4.3. Network security and cybersecurity

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

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

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. Access to the online system

Access is through the official web portal:

<https://app.simulens.net>

A stable internet connection and a compatible browser are required.

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

5.3. System maintenance and updates

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

Updates are performed automatically, without requiring user intervention.

For topographers connected through SimuLENS Connect, the local module will request its own update if new versions are available.

5.4. Common access errors and resolution

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

For any technical incident, it is recommended to contact the support team at: support@simulens.net

6. SIMULENS® SYSTEM WORKFLOW

6.1 INTRODUCTION

What is SimuLENS?

SimuLENS® is a digital platform that enables precise and efficient contact lens fitting. Thanks to its simulation engine, intuitive interface and direct connection with 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 manufacture of contact lenses.

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

Use of SimuLENS® improves contact lens fitting accuracy, reduces the number of physical trials required, and decreases total clinical time, improving the patient experience and reducing costs.

THE 3 KEYS TO USING SIMULENS

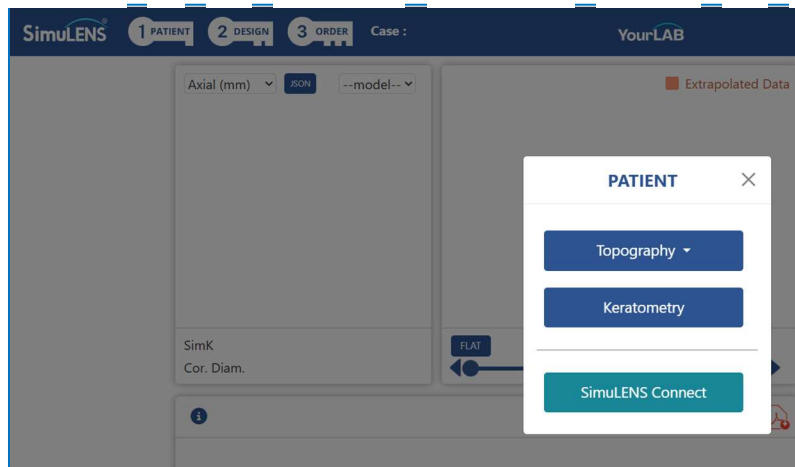
1. Select a patient and load the topographic data
2. Choose a lens design and view the simulation
3. Place the final order



6.2 PATIENT

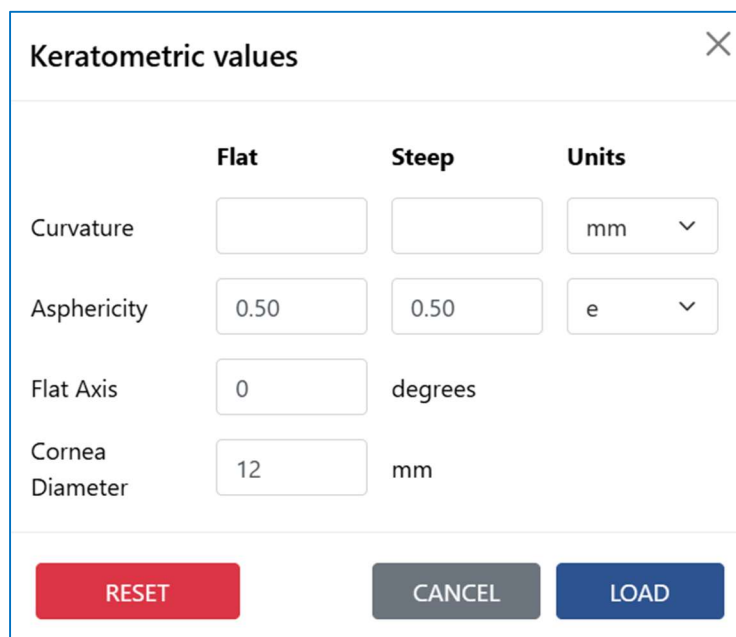
Create patient

1. Access the Patient tab from the main menu.



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

a) Keratometry:



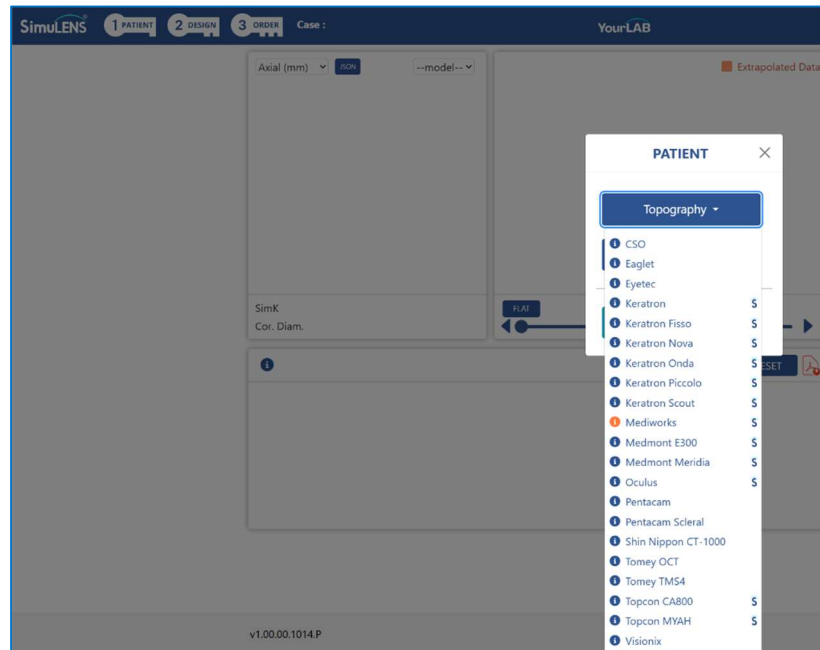
	Flat	Steep	Units
Curvature	<input type="text"/>	<input type="text"/>	mm
Asphericity	0.50	0.50	e
Flat Axis	0	degrees	
Cornea Diameter	12	mm	

RESET CANCEL LOAD

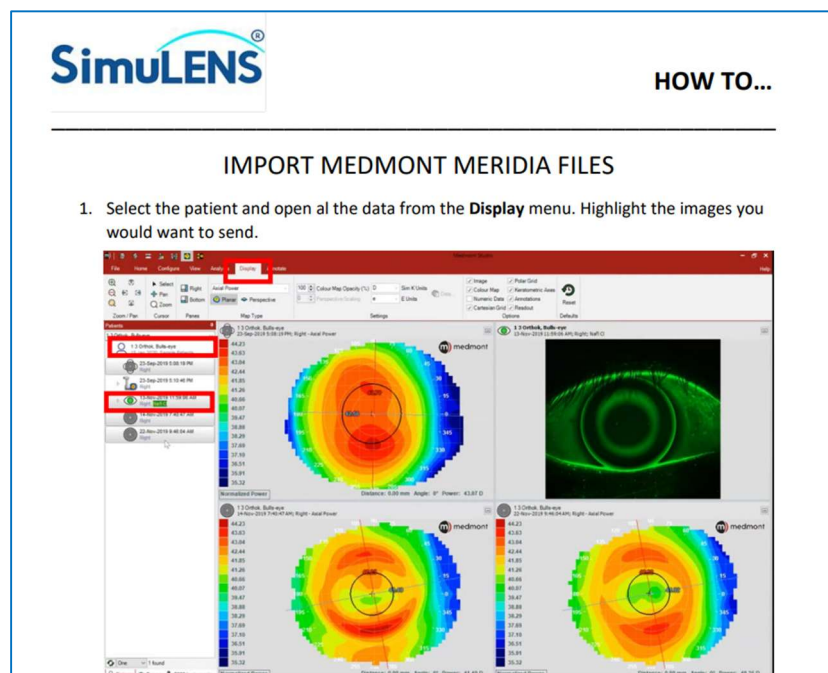
b) Exported topography:

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

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

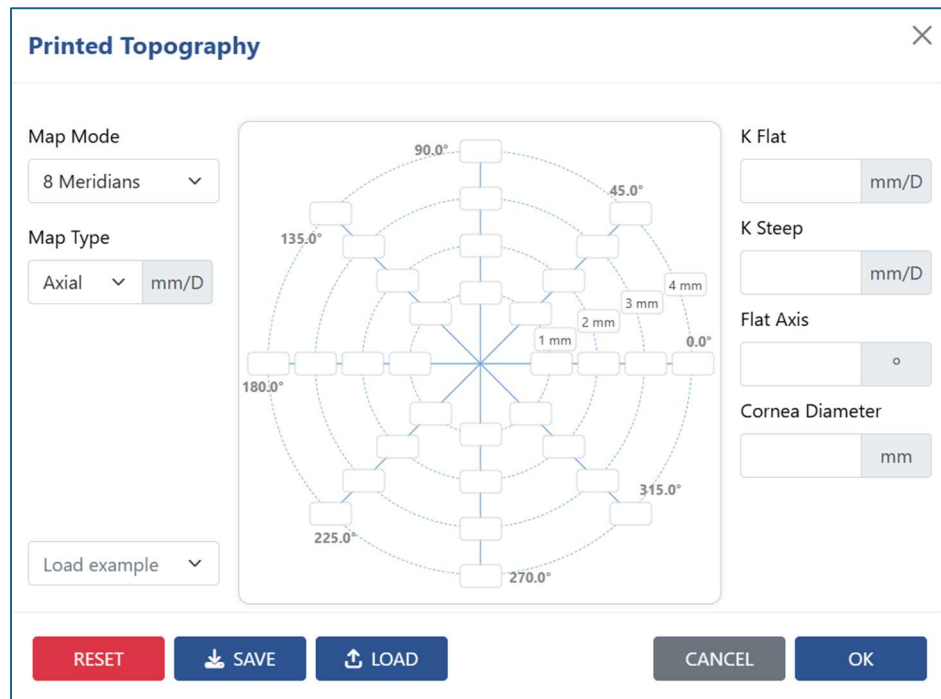


Example of a Medmont export guide:



c) Printed topography:

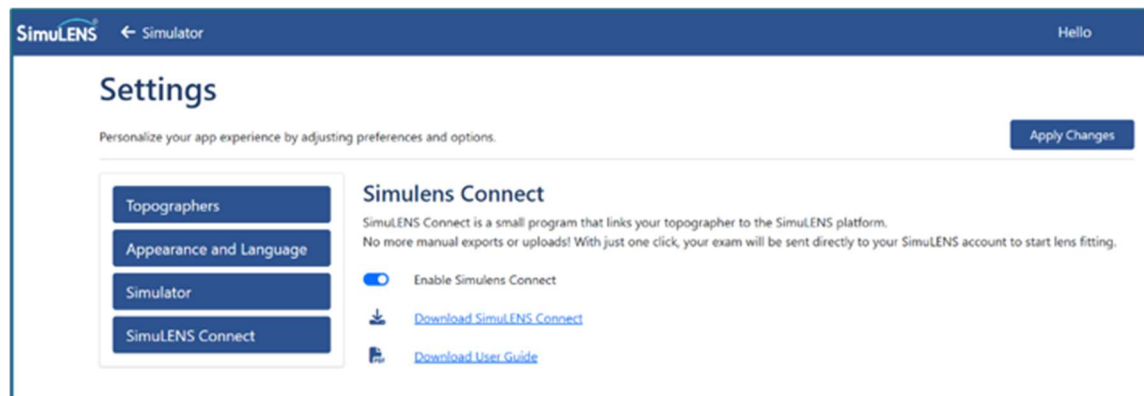
Click Topography, select Printed Topography and enter the topography data on the following screen:



d) SimuLENS Connect:

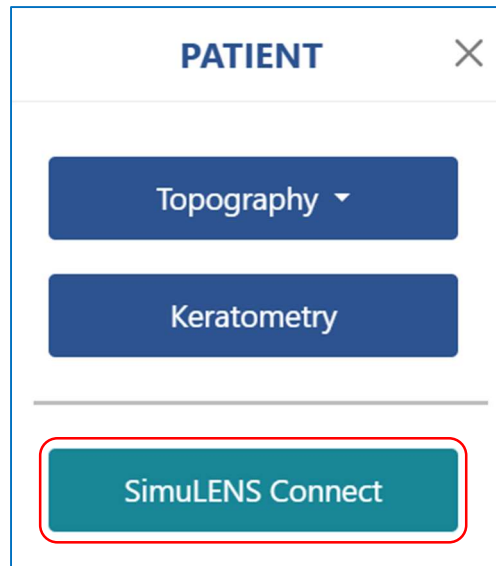
This software allows you to connect your topographer directly.

Access Tools from the drop-down menu and select SimuLENS Connect:

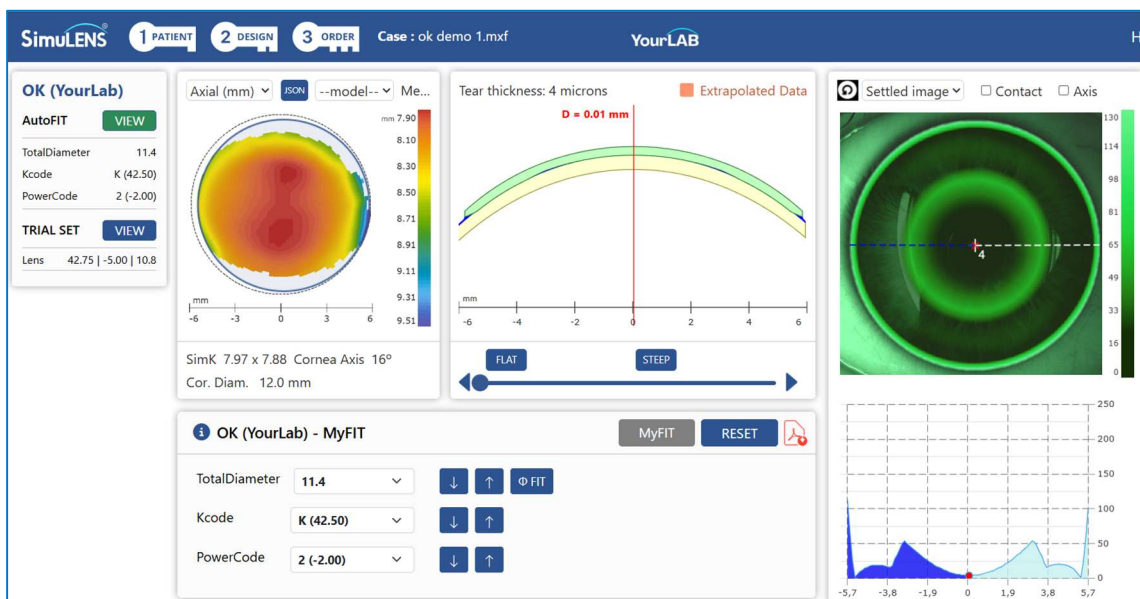


Download SimuLENS Connect and follow the steps in the User Guide to install it.

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



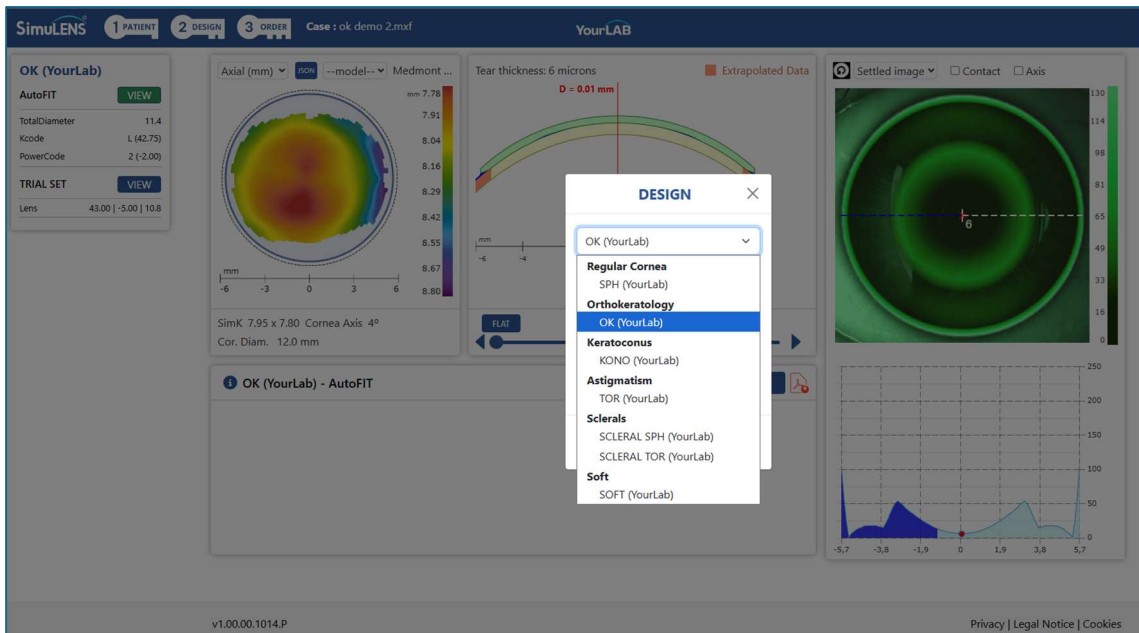
Once the desired option has been selected, the data will appear on the main screen:



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 from 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:
- o Click MyFIT to view the parameter selection:



Main options:

- MyFIT: Displays the lens parameters
- Fluorogram: Check the tear microns at each point of the lens
 - o View the contact points by clicking ?Contact?
 - o Mark the axes by selecting ?Axis?
- Tear profile: Shows the tear film thickness in a sagittal section.

- Lens profile: Displays the complete geometry of the lens (curves, diameters, thicknesses) and how it adapts to 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 complete, click Order.
2. Enter additional details if necessary (clinical comments, instructions, etc.).
3. The system will generate:
 - o PDF with the topography, fluorogram and lens information

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

ORDER

Patient: patient_1 Laboratory Email: demo_lab@microsoft.com

LENS PARAMETERS

Design	KONO (YourLab)
DIAMETER	9.1
BC	7.50
EDGE	75
P-TORICITY	0

SPECTACLE RX

Sph		D
Cyl		D
Axis		°
Vertex dist.	▼	mm

TESTED LENS

Back Curve		mm
Center Power		D

OVER-REFRACTION

Sph		D
Cyl		D
Axis		°
Vertex dist.	▼	mm

COMMENTS

Notes...

ATTACHMENTS

No files attached

SELECT

SEND

Before confirming the order, the professional must verify that the simulated lens meets 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.

The final choice of the lens and its clinical validation are the exclusive responsibility of the fitting professional.

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

7.2. Risks if the suggested lens is not checked

Fitting contact lenses without clinical verification may lead to:

- Selection of unsuitable geometry
- Poor alignment with the ocular surface
- Possible discomfort or low visual effectiveness

SimuLENS® does not replace clinical lens trial 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 special lenses (RGP, ortho-k, scleral, etc.)
- Clinical interpretation of simulated results

8. DATA MANAGEMENT AND USER PROTECTION

8.1. Access security and authentication

Each SimuLENS® user has personal and 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.

Clinical data are not stored on the user's local device, which minimizes the risk of information leakage.

The data entered during the simulation are only kept while the session is actively being used.

8.3. Safe-use recommendations (log out, do not share credentials)

To ensure a secure experience, it is recommended to:

- Log out after each use, especially on shared computers
- Do not share credentials with other users
- Use secure 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 it is sent?

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 the laboratory rules.

Can I work with several laboratories from the same account?

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

Is it possible to fit lenses without topography?

Yes. SimuLENS® allows you to 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 the values extracted from a printed topography

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

Is any type of 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 accuracy 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 the use of 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. However, if any anomaly, malfunction or unexpected result that could have clinical consequences is detected during use of the system, 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, systematic error or unexpected system behavior that could contribute to an incorrect clinical decision is detected, please notify the manufacturer via support@simulens.net.