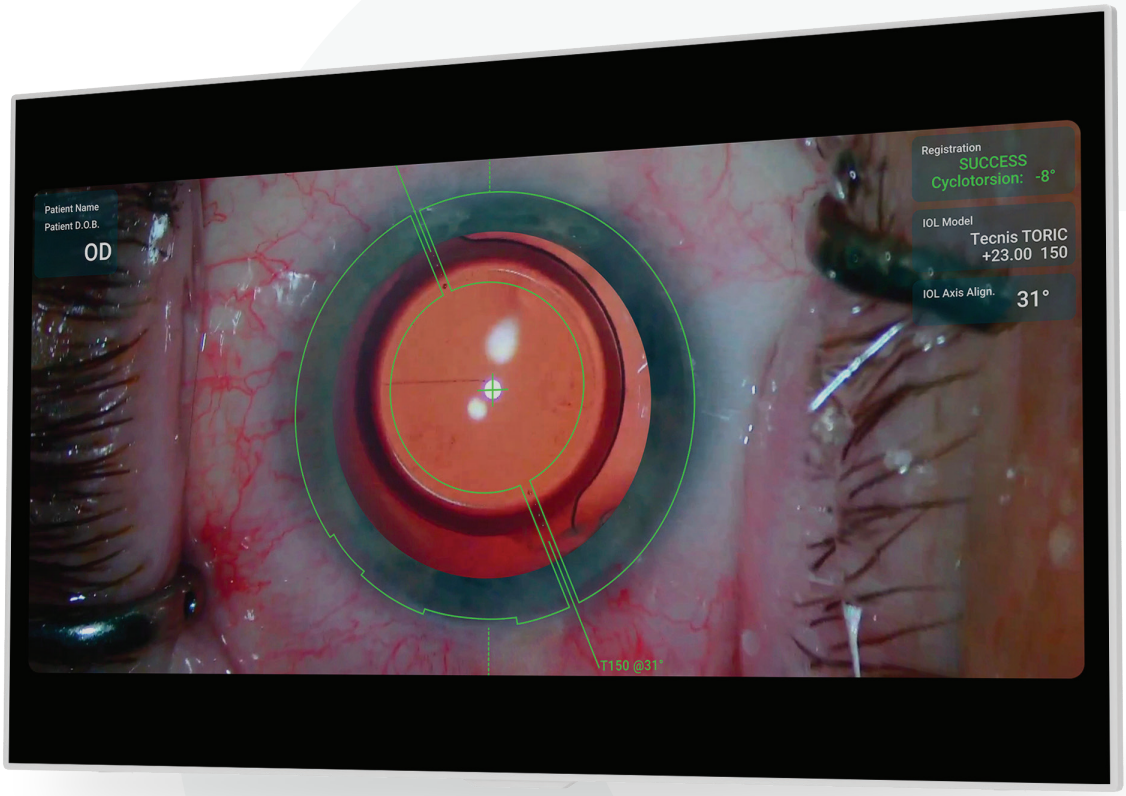
cassini
The world in vision

Cassini Guidance System

Instructions for Use



Device: Cassini Guidance System

Document ID – CGS-510-0005 V07

CE
0344

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1 INTRODUCTION

Cassini Guidance System (CGS) assists surgeons by providing recommendations during ophthalmic procedures. The solution provides graphical information to the surgeon as desired during surgery using pre-operative data and surgeon-selected, onscreen templates and guidance tools. Both onscreen templates and guidance tools can be toggled ON/OFF at any given time. Cassini Guidance System utilizes the surgeon's confirmation at each step to proceed and to position CGS's overlays accordingly. It does not make the decisions for surgeons but should be used only as guidance and support during surgery. It can be switched off without any surgical interruptions.

CGS is intended to be used by ophthalmic surgeons, ophthalmologists, or practitioners with equivalent education and/or experience.

This Instructions For Use (IFU) describes the use of Cassini Guidance System. Always keep this IFU at hand. For more information and news updates visit: www.cassini-technologies.com

WARNING

It is important to read these instructions carefully before using your Cassini Guidance System. The manufacturer cannot be held responsible for the results of using this device for any purposes other than described in these instructions for use. If any serious event occurs in relation to this device, this event should be reported to Cassini Technologies B.V. and to your local Competent Authority.

WARNING

If Cassini Guidance System causes any unknown negative side effects to the patient or user, please contact support, and inform the manufacturer of such events.

1.1. About these Instructions for Use

Before using Cassini Guidance System, you must read these Instructions for Use and strictly observe all **WARNING** and **CAUTION** notices. Pay special attention to all the information given and procedures described in the SAFETY section.

WARNING	**WARNING** alerts you to a potential serious outcome, adverse event, or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient.
CAUTION	**CAUTION** alerts you to where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and in a remote risk of more serious injury, and/or cause environmental pollution.
NOTE	**NOTE** highlights unusual points as an aid to the operator.

Table 1: Important messages

1.2. Symbols used

	Follow the instructions in the Instructions for Use. It is important that you read, understand, and observe the precautionary and operating instructions

	Name and contact information of the manufacturer
	Date of Manufacture
	Serial number used for identification of the device
	Caution! Consult Instructions for Use
	Consult Operating instructions
	Medical Device
	Unique Device Identification
	Reference Number

Table 2: Symbols use

2 INTENDED USE, INDICATIONS, CONTRA-INDICATIONS, PATIENT GROUP

2.1 Intended use, indications, contra-indications

Category	Definition
Intended purpose	The Cassini Guidance System assists surgeons by providing visual guides for incisions and lens placement during ophthalmic procedures using pre-operative data.
Medical Use	Medical Device Software (MDSW) intended to provide information which is used to take decisions with therapeutic purposes
Medical Indications	Cassini Guidance System is intended for surgeries for patients undergoing lens intra-ocular lens replacement procedures
Medical Condition	Patients undergoing lens replacement procedure
Contraindications	Not applicable
Side effects	Not applicable
Treatment type	Non-invasive
Treatment Parameters	Not applicable
Body part or tissue type for which an application or interaction is planned	Eye

Category	Definition
Duration of use	Temporary (< 60 minutes)
Intended environment	Hospital
Number of applications	Reuse without reprocessing

Table 3: Intended use

2.2 Intended users

Category	Definition
User age	Not relevant – professional education/training must be absolved
User gender	Not relevant
User size	Not relevant
User weight	Not relevant
Professional user or layperson	Ophthalmic surgeons, ophthalmologists, or practitioners with equivalent education and/or experience
Required training/background knowledge/education	Specialists in optometry and ophthalmology
Required language skills	English language
Required user training	Training upon set-up necessary. Additional training will be provided after new software release.
Possible restrictions of the user	Not relevant

2.3 Intended patient population

Category	Definition
Patient age	The device is intended for use in surgeries performed on adult patients.
Patient gender	Not applicable
Patient size	Not applicable
Patient weight	Not applicable
Nationality / ethnicity	Not applicable
Patient condition	There is no minimum or maximum level of health defined for patients imaged using the Cassini Guidance System for its intended purpose.
Self-application	Not applicable
Possible patient limitations	Not applicable
Criteria for patient selection	Undergoing inter-ocular lens placement procedure

Table 4: Intended patient

2.4 Operating Principle

Cassini Guidance System combines pre-operative measurement data, a treatment plan, surgeon-specific input and a microscope video feed to provide onscreen templates and guidance tools. This is achieved by processing the video frames from the microscope feed and matching them with pre-operative data, based on this the treatment plan can be rendered as live digital overlays over the live video feed on the control monitor.

3 CLINICAL BENEFITS

The intended CGS clinical benefit is to support surgeons in achieving greater accuracy in toric IOL alignment, to enhance refractive outcomes and reduce manual marking steps to increase time efficiency during an IOL replacement. For patients, these benefits translate to better visual outcomes, reduced procedure time, and a more comfortable surgical experience.

4 PERFORMANCE CHARACTERISTICS OF THE DEVICE

Cassini Guidance System does not have any essential performance functions as defined in IEC 60601-1.

5 CASSINI GUIDANCE SYSTEM COMPONENTS

With the Cassini Guidance System you will find enclosed:

- Instructions For Use (1×)

6 RESIDUAL RISK, CONTRA-INDICATIONS WHEN USING THE DEVICE

6.1 Residual risks

Residual risks are reduced as far as possible. From the known anomalies, please be aware of the following residual risks:

- Guidance cannot import cases with forward slash in the Patient ID. Do not use a / in the patient ID
- Cases are marked as "Finished" when cancelling the surgery workflow
- Surgery can be closed by pressing ESC button on a keyboard

The overall residual risk is estimated to have a probability of Unlikely and a severity of Minor. The overall residual risk is assessed as “Acceptable”.

6.2 Environmental conditions

WARNING

The Cassini Guidance System should only be used if the environmental conditions for use are met.

7 DEVICE SET-UP

7.1 Setup

When setting up, Cassini Guidance System does not require calibration.

7.2 Software Operating environment

Software Operating environment	
Operating System	Windows 11 Pro / IoT
Operating System Architecture	64-bit (x64)

Table 5: Software Operating environment

7.3 Hardware Operating environment

Cassini Guidance System requires a hardware set-up (computer) that meets the minimum requirements in Table 6. Hardware set-up is the responsibility of the user. Cassini Guidance System is compatible with any general consumer-grade computer meeting the minimum requirements specified below.

Category	Description
Processor	Modern 64-bit CPU, performance equivalent to Intel Core 5 (Meteor Lake, 28W-class) or better.
Hard disk space	NVMe SSD with >= 250 GB available for application, logs, and case data.
Physical Memory	≥ 16 GB RAM
GPU	Integrated GPU acceptable Must support the intended display
Display	Control monitor required; additional output display optional depending on site configuration.
Network	Ethernet ≥ 1 GbE
Capture card	DeckLink-compatible capture I/O with real-time playback support. Supports SDI and/or HDMI live video capture depending on the deployed configuration. Supports required video formats up to 1080i59.94/60, 1080p59.94/60, 2160p29.97/30, and 2160p59.94/60, subject to capture-card capability. Capture performance and latency shall be verified according to the approved hardware interoperability test protocol.

Table 6: Hardware specifications

7.4 Information and Communication Technology (ICT) requirements

ICT set-up is the responsibility of the user.

User ITC Security Requirements	
Network (wired)	Medical Grade or Clinical Network
Compliance	HIPAA (highly recommended)
Data transfer	Encrypted

Table 7: User ITC set-up

8 TRAINING

Onsite and/or online training is provided for the safe use of Cassini Guidance System. A user can request a refresher training via the online training portal. The trainings will be updated with new material when required. Online portal can be accessed:

- Open your browser and browse to https://cassini.talentlms.com/
- Login using your user credentials. If you are a new user, sign up for a new user account.
- If you encounter any problems accessing the training materials, contact support@cassini-technologies.com.

Users of this device will be ophthalmic surgeons, ophthalmologists, or practitioners with equivalent education and/or experience. Their education level is being presumed to be such that they understand the basics of the English language, therefore a translation of graphical user interface (GUI) to their native language is not available.

9 INSTALLATION

WARNING

Cassini Guidance System is to be installed only by a technician authorized by Cassini Technologies B.V.

To power on and use the Cassini Guidance System:

1. Plug in the AC power cable into an electrical socket with functional ground
2. The system will automatically start its operating system
3. Launch the user software after logging in.

When CGS is launched and users can proceed to import, view cases and start surgery workflows. There are no consumable components that should be replaced periodically and no calibration required.

To power off the system:

1. Shut down the user application
2. Shut down the operating system
3. Unplug the AC power cable or disconnect it from the electrical socket

To power it back on:

1. Reconnect the AC power cable or reconnect it with the electrical socket
2. The system should automatically start again, launch the user software after logging in

The user should check if camera feed matches the expected orientation (up is up, down is down, etc.). If this is not the case (the image is flipped, mirrored or otherwise incorrect with respect to the observed orientation), consult user manual for the camera and/or microscope system.

NOTE

Cassini Guidance System requires correct camera feed for operation.

To validate the feed, after connecting camera with the computer, user should start Cassini Guidance System, check connection indicator and start surgery workflow. The user should then see the live surgical video stream live on the connected display. Move an object into the field of view of the camera from the top or bottom, and from the left or right side, and verify that the object enters the observed field of view in correct locations. In case of any discrepancy, consult the camera or microscope user manual.

10 MAINTENANCE AND SERVICING

10.1 Preventive maintenance - regular checks and usage

No maintenance is necessary unless identified by Cassini representative. If there are any issues with the software, user must reach out to local distributor or Cassini Technologies B.V. representative. Cassini Guidance System can be used continuously without any impact on general safety and performance.

11 INTEROPERABILITY

The Cassini Guidance System should not be used in combination with other products or components unless expressly recognized as compatible by Cassini Technologies B.V. Please contact Cassini Technologies B.V. for more information about compatibility:

Email: support@cassini-technologies.com
Web: www.cassini-technologies.com

For additional technical information you can contact Cassini Support:

Technical Support (USA – Toll free)	+1 888 660 6965
Technical Support (outside USA)	+31 (0)70 3993112

12 DISPOSAL

The software can be uninstalled with prior notification to local representative or Cassini Support.

13 OPERATING INSTRUCTIONS

NOTE

Some of the screenshots featured in the user manual may feature a ⚠ DEV. icon to clearly indicate a pre-release version of the software - an official release of the software does not have this indicator.

13.1 Application User Interface overview

The Cassini Guidance System can be launched via its shortcut, available on the desktop and/or start menu.

A splash screen will show up before the application is started in full screen mode and landing page opens.

NOTE

If instead of the application's landing page you are presented with an error "Error opening the database", you may have signed in with the wrong system user account. Please verify the correct user is logged in. Contact Cassini Support if the problem persists.

The user interface is segmented into 3 sections: the top menu bar, the side menu and the center frame. The top menu is always visible, but some elements may change depending on the state of the application. The landing page shows the application logo, page indicator (e.g. Landing Page), and various status indicators, i.e. icons and (optionally) a text description.

13.1.1 Status indicators

- ⚠ DEV. A pre-release software indicator, not present for official released software version.
- Connection indicator, showing a blue "Connected" icon when connected to an activate camera, and a red "Disconnected" icon otherwise.

13.1.2 Side menu

The right side of the main window is a context aware side menu, where the primary action for the given page is shown. On the landing page, these are "Import" and "View Cases", on the "View Cases" these may be "Start Surgery" or "Cancel".

There are shortcut icons which are always visible.

- Return to the Landing Page
- Open to the settings menu
- Open the about page, showing software version, UDI label, software licenses and copyright information. From this page, the user can access IFU corresponding to the current software version.

13.1.3 Center frame

The center frame features the primary content of each page. On the landing page, this shows the application branding, on the “View Cases” page this shows a table with planned cases, and during surgery it shows a live-video preview view with relevant overlays, as well as some action buttons.

13.2 Diagnostic Data Transfer – Import Cases

To use CGS, first export one or more cases from the Cassini Surgical Planning Software (CSPS).

Data transfer is typically done using a USB drive encrypted with industry-standard BitLocker encryption. In a secured network environment, a shared folder data transfer can be setup.

13.2.1 Import Cases -USB

- Insert the encrypted USB into the back of computer
- Unlock encryption with the configured or provided password. The system can be configured to auto-unlock the drive the next time it is inserted
- Select “Import” from the side menu

13.2.2 Import Cases – Shared data folder

- Go in the Settings to the General tab
- Check the Import files from shared folder box and click on Browse to select the folder
- Press Apply to submit the changes

13.2.3 Cases Imported

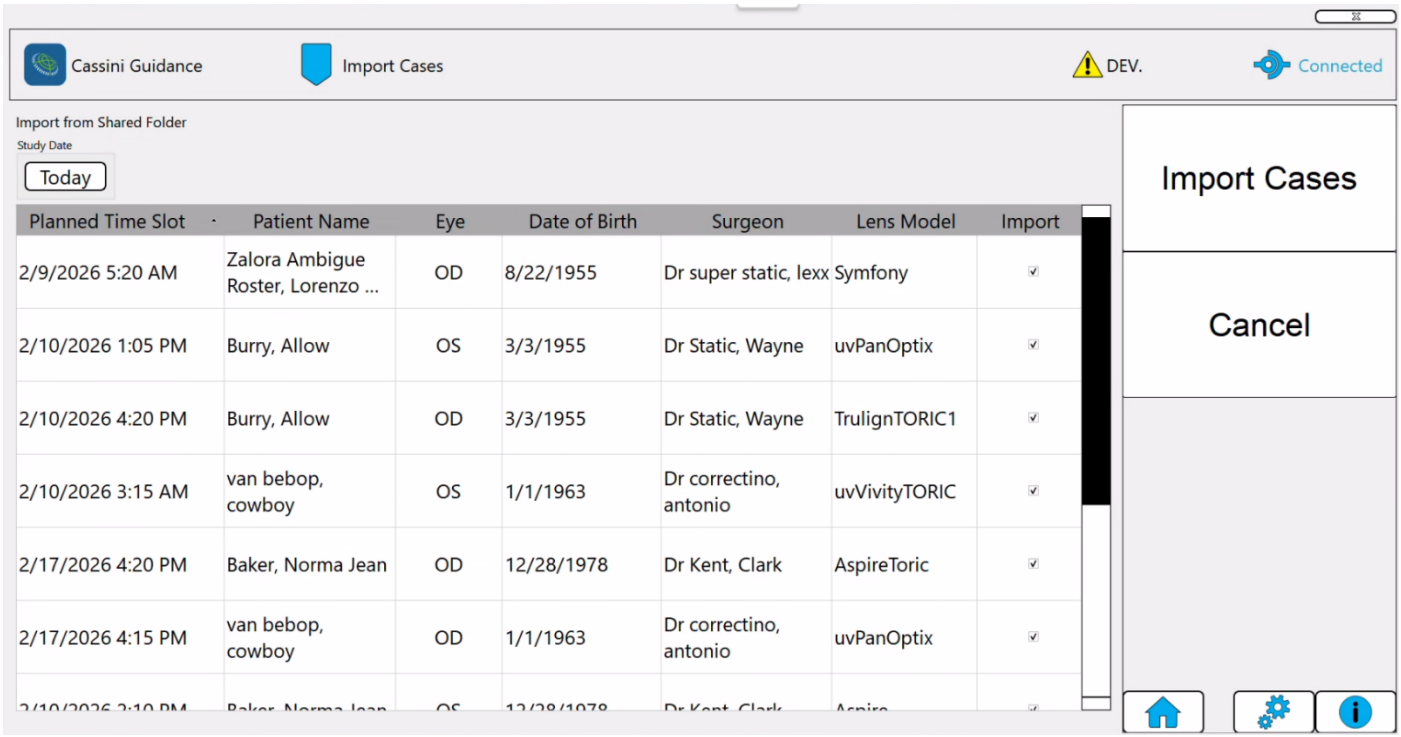

Figure 1: Import cases page

As cases are imported, please consider:

- All cases that can be imported will be shown in the “Import Cases” overview. Non-importable cases (e.g. duplicates) may either be hidden or shown with a different accent color
- These Importable cases will be automatically selected for import and cannot be deselected
- Non-importable cases are shown as deselected for Import and cannot be selected
- Already imported cases for which a newer import is available are deselected but can be manually selected
- Clicking on “Import Cases” will import all selected cases
- After the import process has been completed, the imported items from the USB drive will be automatically removed
- The imported cases are now available on the ‘View Cases’ page

13.3 View Cases

From the landing page, click ‘View Cases’. By default, the list is filtered to show Today’s cases, which may be a smaller subset than all cases imported.

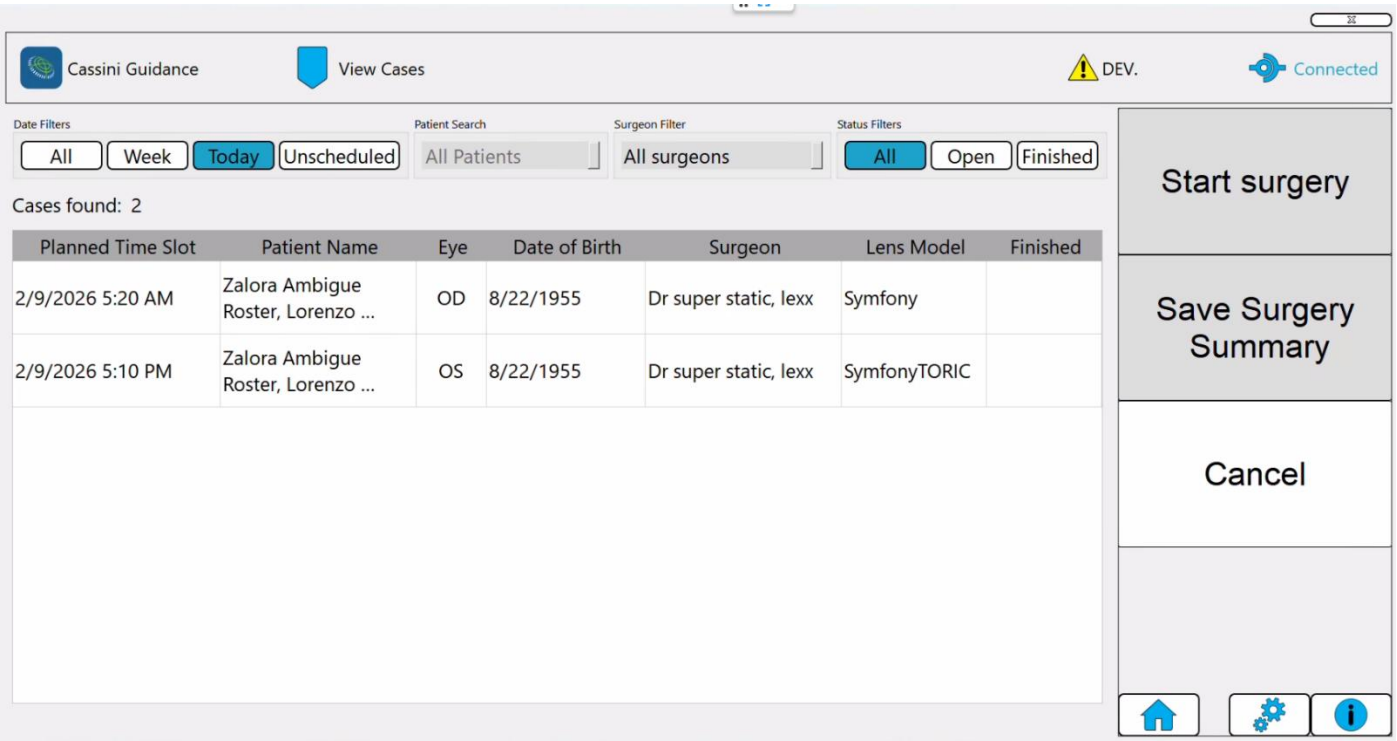

Figure 2: Cases filtered on Today

The filters can be adjusted by date, surgeon or case status (see Figure 3).

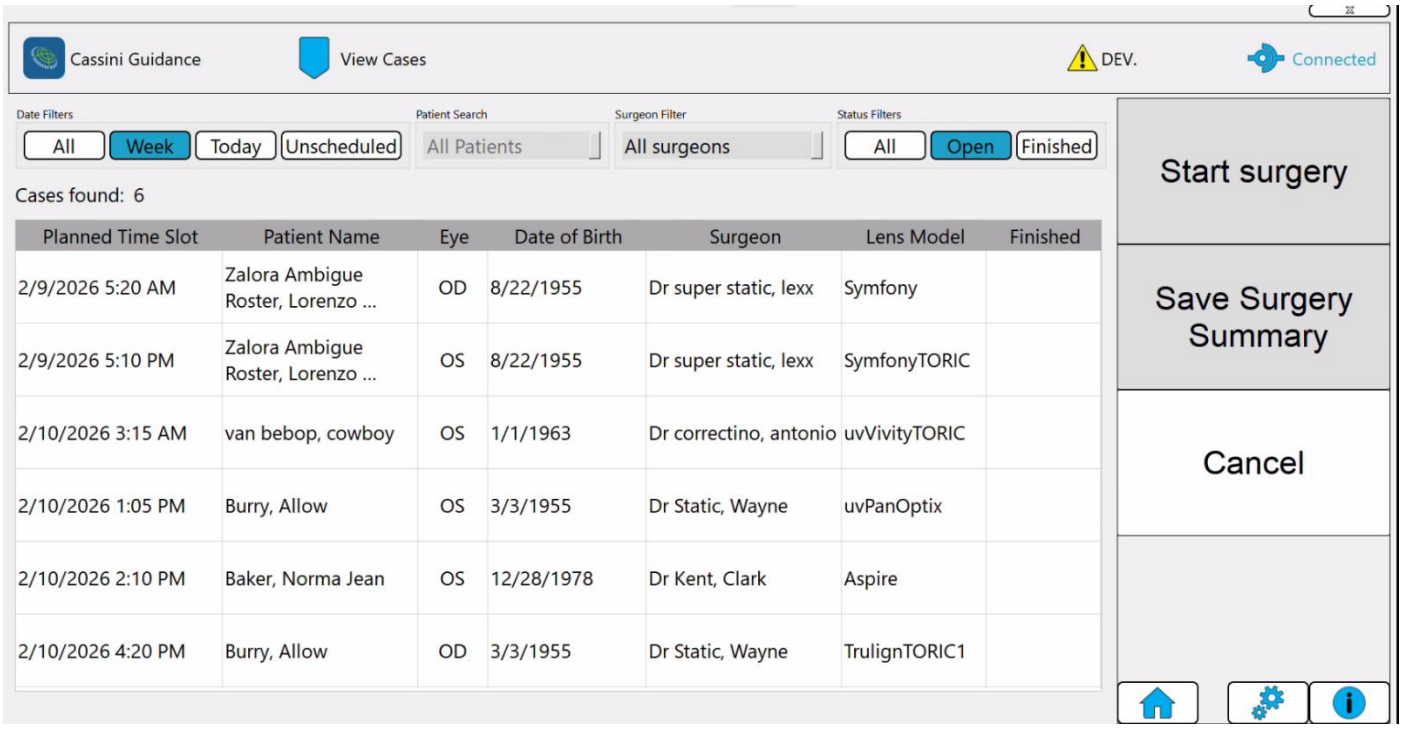

Figure 3: Cases filtered on Week

Search for a specific patient by entering (part of) the patient's first or last name and confirming with ENTER, or selecting any of the filters. Select a case, which will then be highlighted, and the "Start surgery" button becomes active (Figure 4). Finished surgeries cannot be selected. Once a case is selected, click "Start surgery".

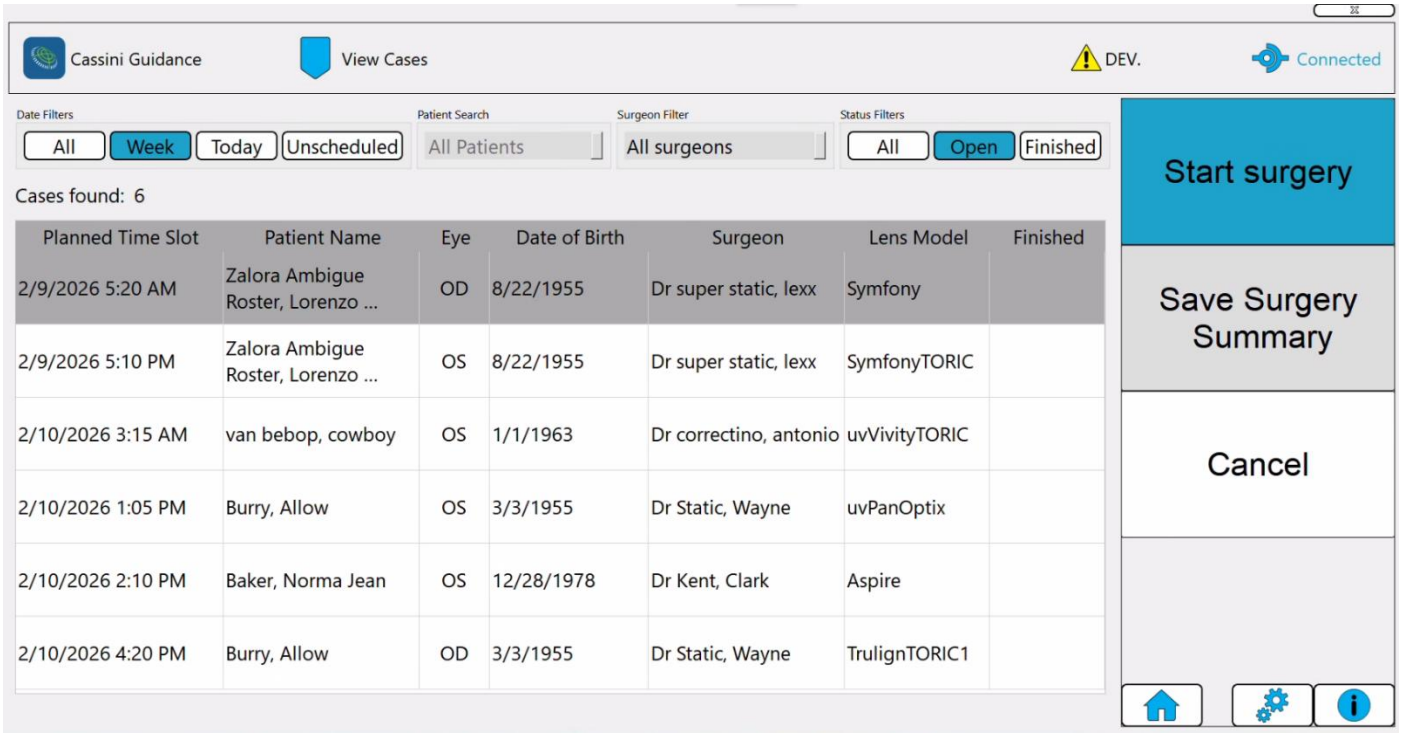

Figure 4: Start surgery

13.4 Surgery Workflow (WF) overview

During the surgery workflow, the application will show output on both the touchscreen monitor (also “control monitor”) and the video output display (also “external monitor”), if connected. The output in the central frame on the touchscreen monitor will look like a smaller version of the output to the video output display (Figure 5)

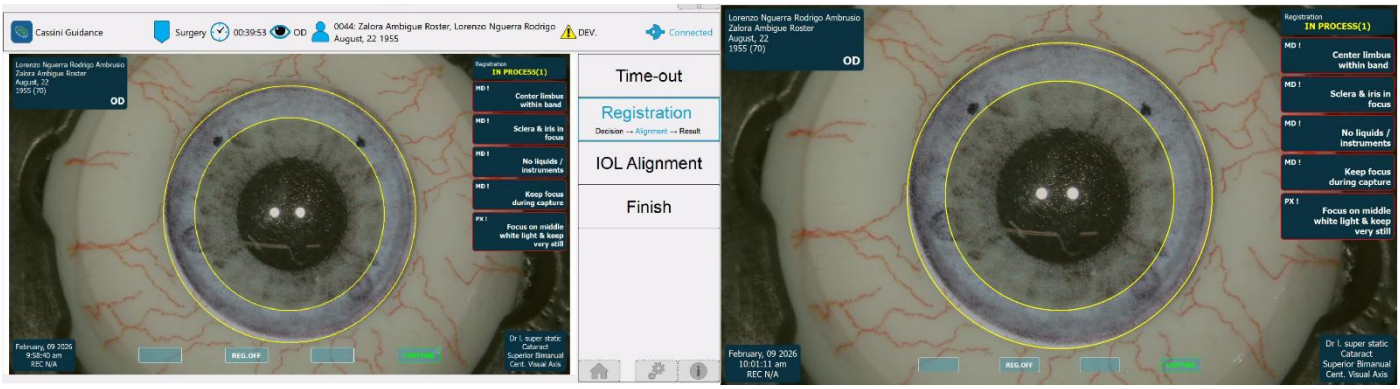

Figure 5: Touch screen monitor example on the left and video output display on the right

13.5 WF - Patient Time-Out stage

The surgery workflow always begins with the “Time-out” stage.

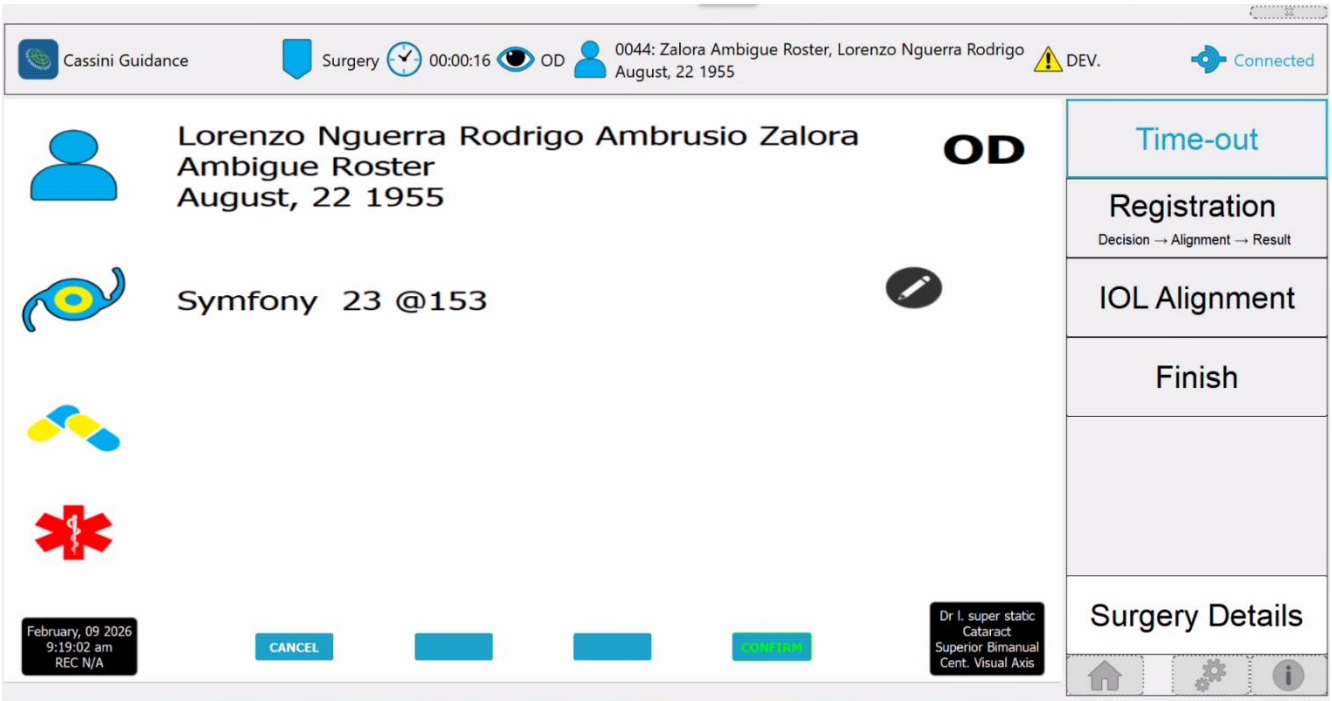

Figure 6: Time-out page example

The patient time-out stage shows the following:.

- Patient Name, (full) Date of Birth and eye type (left, **OS** or right, **OD**).
- The selected IOL Model and planned alignment angle (when applicable)
- Any medications entered during planning
- Any allergies entered during planning

Additional details can be viewed when pressing the “Surgery Details” on the touchscreen monitor.

At the bottom left, the date, time and current recording status is shown.

The bottom right of the corner boxes will show the following:

- Surgeon's initials and last name
- Selected Profile
- Incision location (Temporal/ Superior) Incision size in millimeters, phacoemulsification technique selected (Coaxial or Bimanual)
- Capsulorhexis Centration: Center of Limbus or Visual Axis

At the time-out stage, two primary actions are available, CANCEL and CONFIRM.

- CANCEL: returns to the "View Cases"
- CONFIRM: starts the surgery workflow

The next stage of the surgery workflow is the registration decision stage.

13.6 WF - Registration decision-making stage

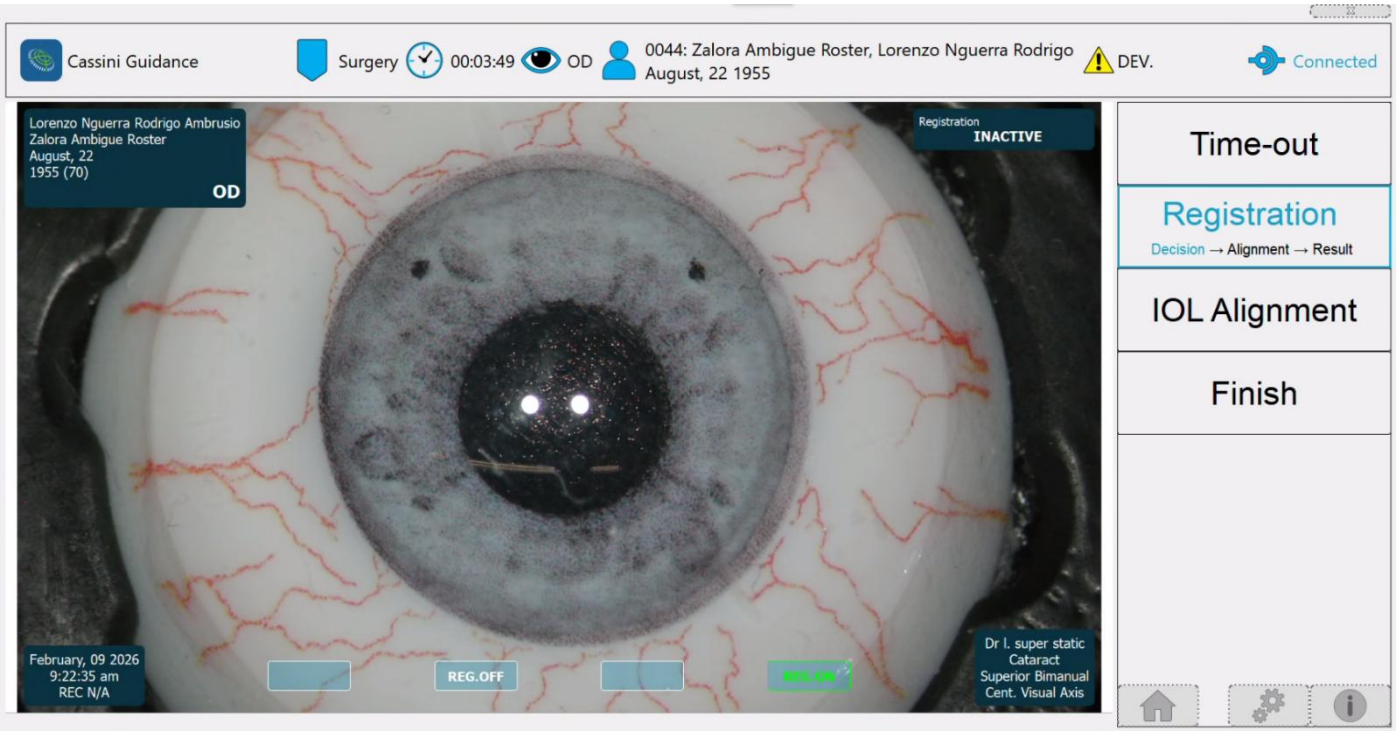

Figure 7: Registration decision stage

Depicted is the output on the touch screen monitor at the Registration decision stage. Visible in the top-right corner:

- Registration status: INACTIVE

Available action buttons:

- REG. OFF (white text): Continues without registration or guidance.
- REG. ON (green text): Proceeds to the next step and enables registration functionality

13.7 WF - Registration OFF Stage (REG.OFF)

If the user has selected REG. OFF, they will enter what will be the final stage of the workflow.

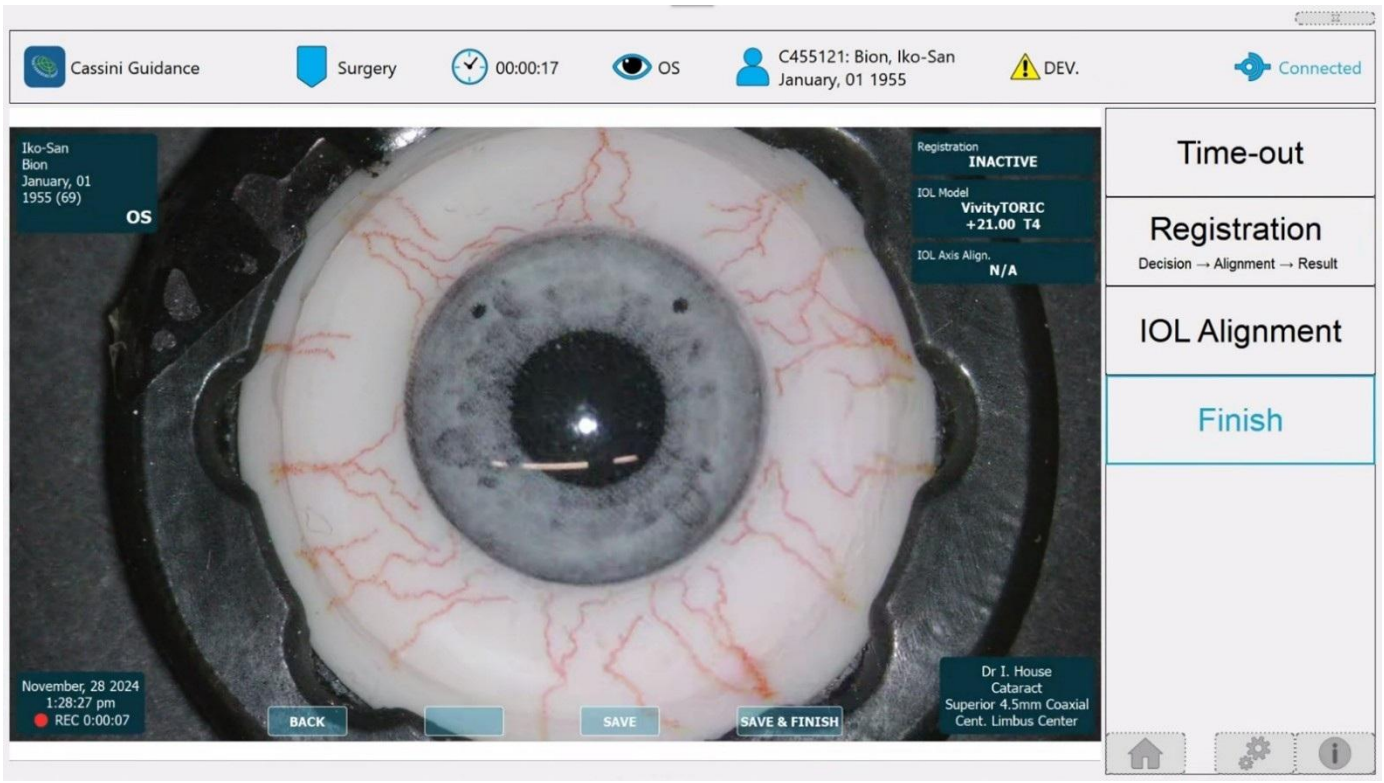

Figure 8: Registration OFF selected

In this stage, the software switches to a view without overlays. The user may go back to registration stage and switch to the mode with additional guidance overlays.

Visible in the top-right corner boxes:

- Registration status: INACTIVE
- IOL Model:
  - Name of model
  - Selected SE Power and Toric label, if available
- IOL Axis Align: N/A

Assigned action buttons:

- BACK: Reverts to previous
- SAVE: Saves procedure but does not mark it as finished
- SAVE & FINISH: Saves procedure and marks it as finished

13.8 WF - Registration alignment

If the user selected REG. ON they will enter the registration alignment stage.

Alignment instruction boxes appear on the right side of the live surgical video view. Instructions to the surgeon and staff are prefixed with MD, and instructions for the patient are prefixed with PX. The patient's eye should be aligned with respect to the camera, such that the **limbus** falls within this clear band in the center of the screen.

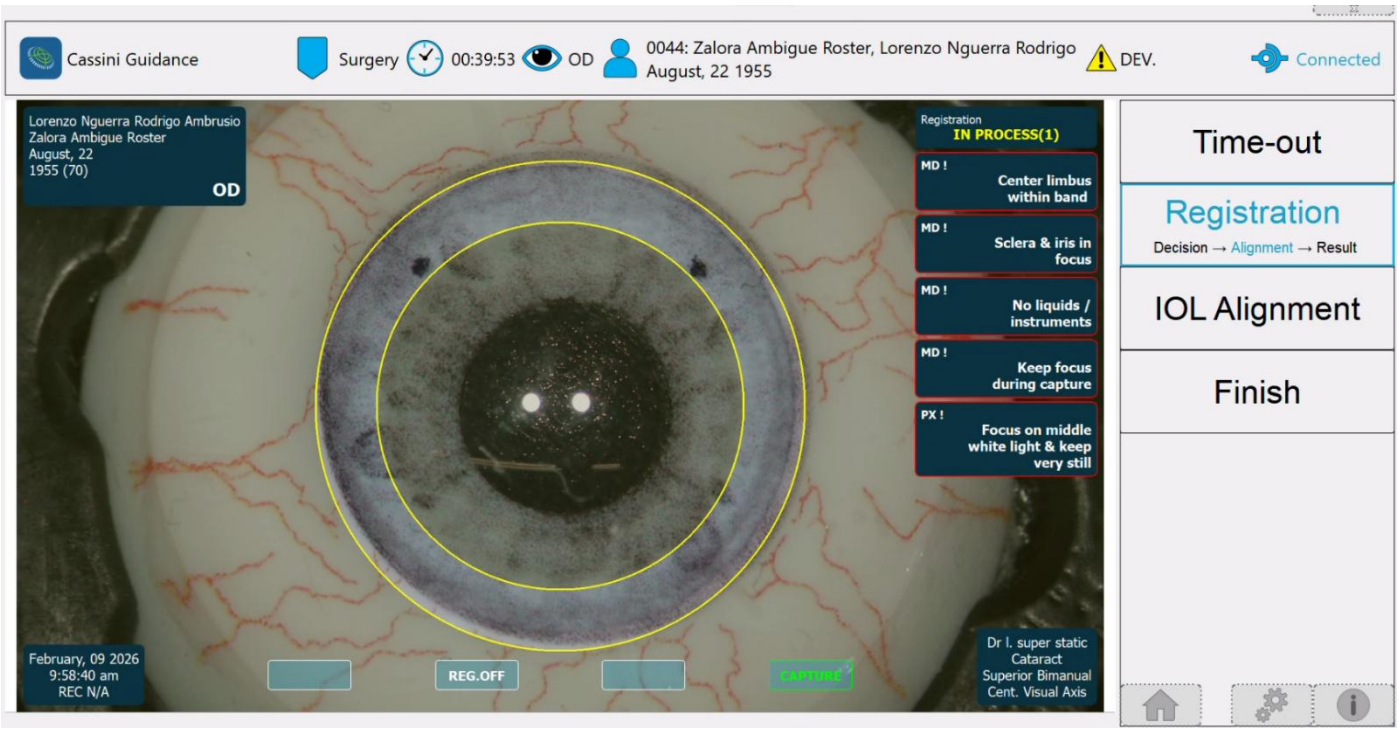

Figure 9: Registration alignment stage

To align, adjust the zoom (Z-Axis) and move either the microscope or patient so that the limbus falls within the center (X/Y-Axes) of the clear band. Ensure clear focus and clarity of the sclera and iris for the capture. Once optimal alignment and sharpness is achieved, click 'CAPTURE'.

Cassini recommends not to have any instruments or fluid build-up during the capture. The acquisition is instantaneous. The surgeon needs to instruct the patient to focus on the middle white light and to keep still for a few seconds.

Visible in the top-right corner boxes:

- Registration status: IN PROCESS
- MD! - *Center limbus within band*
- MD! - *Sclera & iris in focus*
- MD! - *No liquids / instruments*
- MD! - *Keep focus for during capture*
- PX! - *Focus on middle white light & keep very still*

Assigned action buttons:

- REG. OFF: Deactivates registration process
- CAPTURE: Captures the frame used for registration

13.9 WF - Registration announcement stage

The registration announcement stage will start automatically after registration. This registration process takes less than 2 seconds. Three different registration outcomes are possible:

- **SUCCESS**:
  >85% confidence on a registration accuracy within ±30 degrees
- **MODERATE**:
  50%-85% confidence on registration accuracy within ±30 degrees
- **FAIL**:
  <50% confidence on a registration accuracy within ±30 degrees, or an inconclusive registration attempt

13.9.1 FAIL Registration – specific overlay details

If registration leads to FAIL, no additional information will be shown (Figure 10). The user has two options: re-take the registration (and re-aligning the system) or switch to REG.OFF. mode. Refer to the registration alignment chapter for correct alignment instructions.

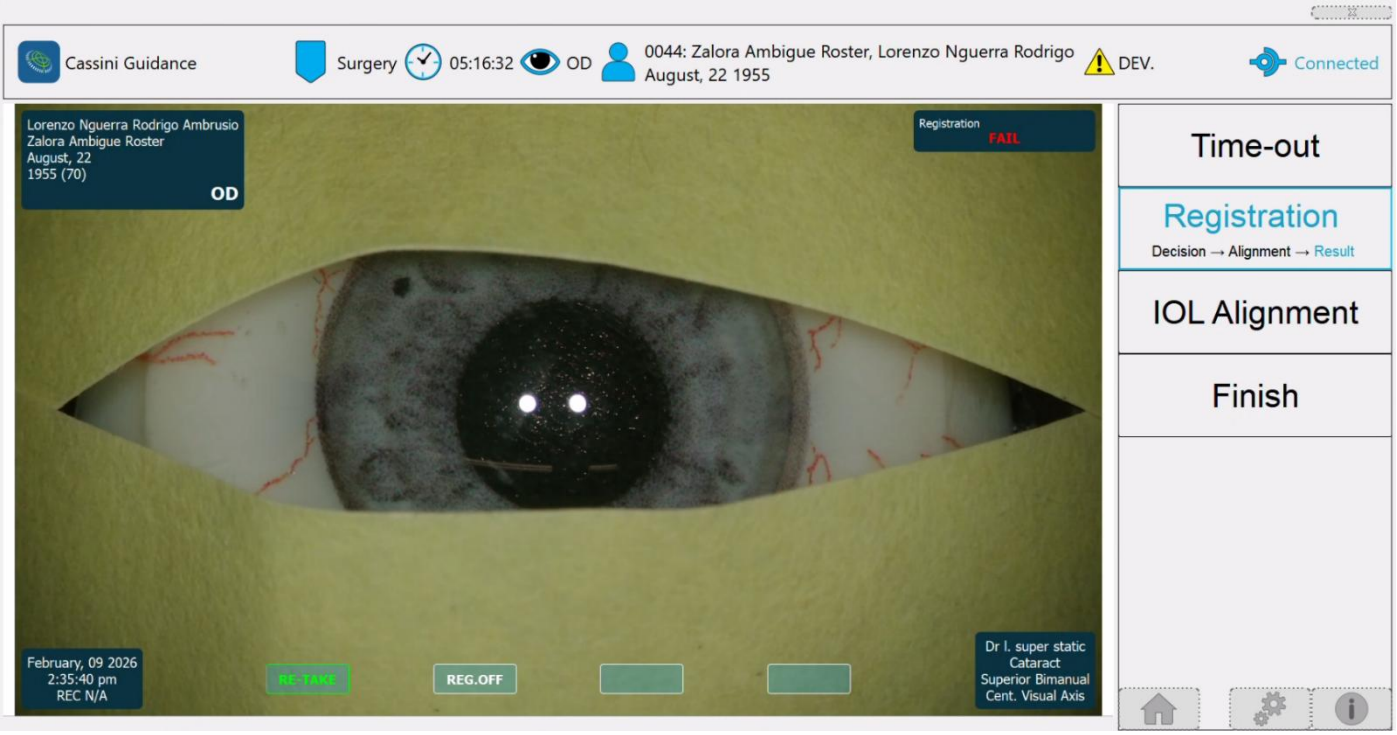

Figure 10: Failed registration

Visible in the top-right corner box:

- Registration status: FAIL

Assigned action buttons:

- RE-TAKE (green text): Retakes and repeats the registration process
- REG. OFF (white text): Deactivates registration process and proceeds without guidance

13.9.2 MODERATE Registration – specific overlay details

A moderate registration is always sub-optimal. Cassini recommends to RE-TAKE rather than CONFIRM. However, the result is not necessarily incorrect. Thus, the registration outcome (the total rotation was found) is still reported.

In Figure 11, the cause for a moderate registration score is an instrument obscuring a large part of the eye. This would be grounds to re-take, but the outcome can still be assessed in relation to **subsequent** registration attempts.

Cassini recommends not to accept the first moderate registration outcome without careful consideration. The user should re-take (several times) to either confirm multiple moderate results or obtain a SUCCESS outcome.

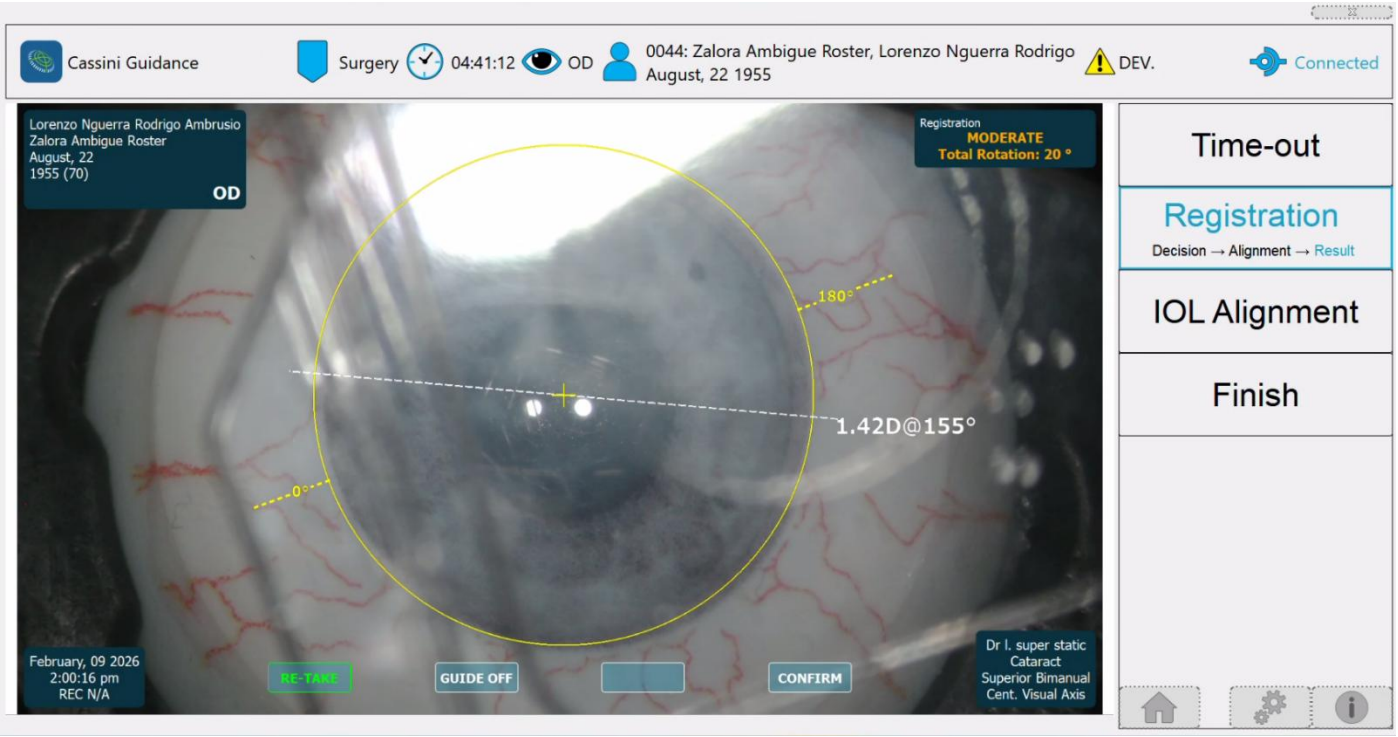

Figure 11: Moderate registration

Visible on the top-right corner box:

- Registration status: MODERATE
- Total Rotation: total registration angle in degrees in relation to pre-op diagnostics

Guidance overlay information:

- A colored circle which will be fitted to the limbus
- Two colored dashed lines indicate the 0°-180° pre-op diagnostic horizon
- A colored centration cross which indicates the desired alignment center: Visual Axis or Angle Alpha (center of the limbus)
- A dashed white line across the eye with the pre-op astigmatism steep axis. It can be the anterior, total astigmatism, or a custom axis. The magnitude and axis of astigmatism will be indicated along this pre-op steep axis line.

Assigned action buttons:

- RE-TAKE (green text): Retakes and repeats the registration process
- REG. OFF (white text): Deactivates the registration process
- ACCEPT (white text): Moves forward to the next stage despite the moderate registration

13.9.3 SUCCESS Registration – specific overlay details

In Figure 12, yellow has been selected as the overlay color, instead of green. It can be customized if required.

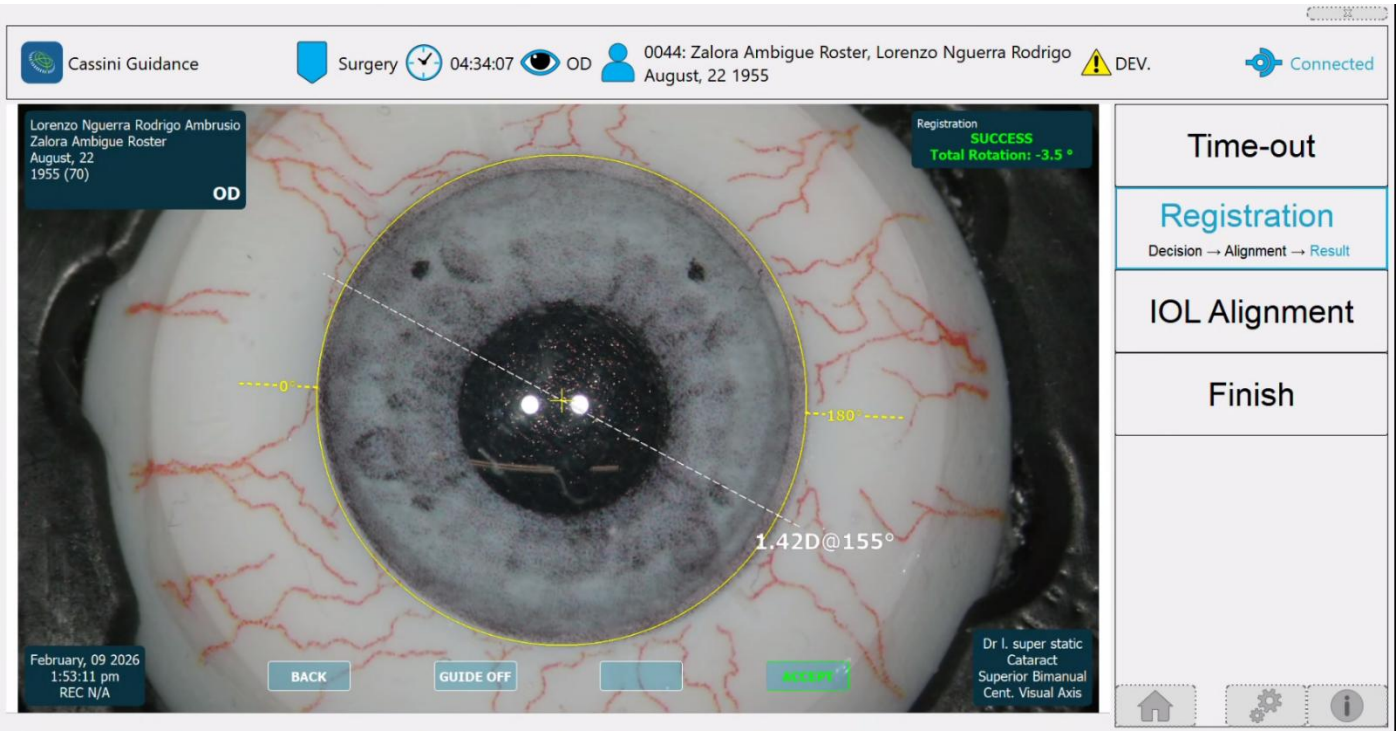

Figure 12: SUCCESS registration

Visible in the top-right corner box:

- Registration status: SUCCESS
- Total Rotation: total registration angle in degrees in relation to pre-op diagnostics

The guidance overlay information has the same information as for a moderate registration.

Assigned action buttons:

- RE-TAKE (white text): Retakes and repeats the registration process
- REG. OFF (white text): Deactivates registration process
- ACCEPT (green text): Confirms and accepts the registration and proceeds to the next stage

13.9.4 SUCCESS but with large Total Rotation

It's important to note that the total rotation is not limited to cyclotorsion. The total rotation is the sum of **all** apparent rotation inducing effects (e.g. cyclotorsion, patient head tilt, camera rotation) while accounting for the planned sitting position. Operating in a superior position, with all stable, the expected rotation between pre-op and surgery is 180**°,** which results in a total rotation of 0°. Or, if the patient eye manifests 10 degrees cyclotorsion and the camera was rotated an additional 5°, the total rotation could be 15°.

Assuming a typical range of cyclotorsion ±20**°** and some compounding effects, the expected total rotation is set to be within the range of **±30°.** Outside of this range, a moderate registration will be considered a FAIL, and a SUCCESS registration should be considered with caution – at least until the source of the large total rotation has been justified by the surgeon.

In Figure 13, the registration is SUCCESS, but the total rotation is abnormally large (98°), yet repeatedly consistent. Here, although the surgical plan was to operate superior, due to circumstances, the procedure is taking place in a temporal sitting position, explaining the extra ~90° offset.

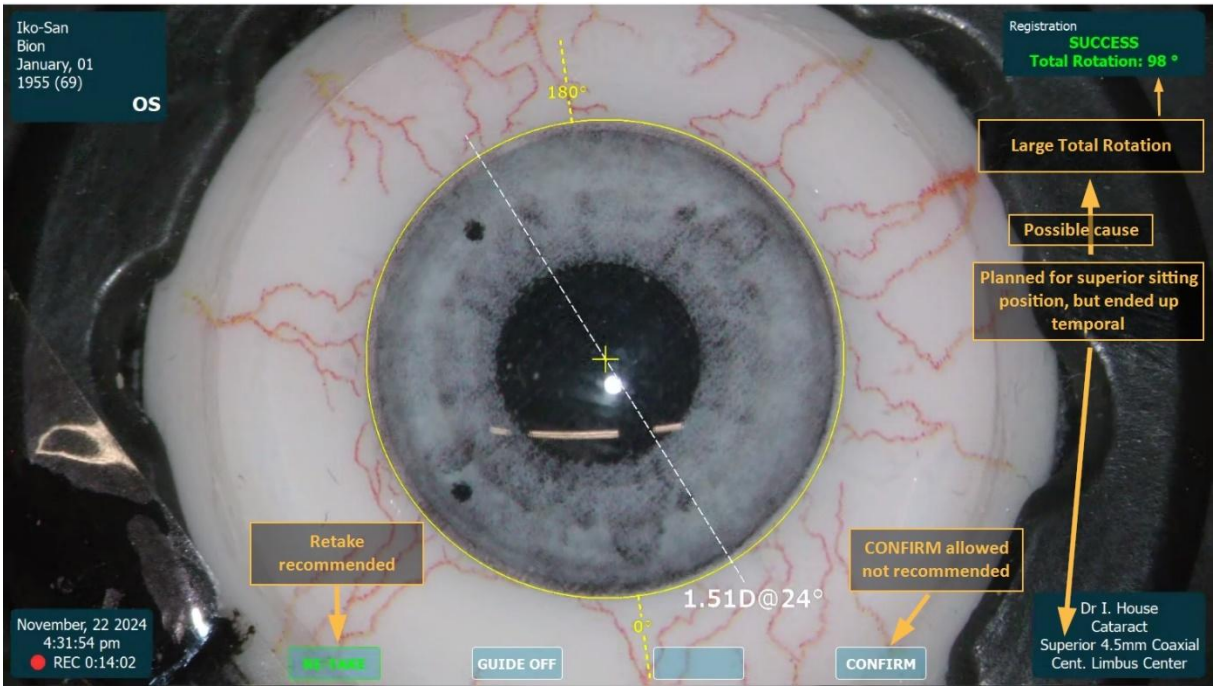

Figure 13: Large total rotational

13.10 WF – IOL Alignment Stage

After confirming the registration outcome, the workflow moves to the IOL Alignment stage. This differs if a toric or non-toric lens was selected during planning.

The IOL Alignment stage has "REFIT" button. This action should **only** be used if tracking has been lost due to changed conditions of the eye (e.g. bleedings). The action should **only** be used **after** the eye has been allowed to return to the initial registration position (alignment, magnification and focus).

WARNING

Use "Refit" only if you can reposition the patient's eye to the same orientation and plane that registration was performed on.

13.10.1 IOL Alignment – Toric Lens – specific overlay details

The toric IOL alignment guide features specific elements to aid in the alignment – centration and rotation – of the toric IOL.

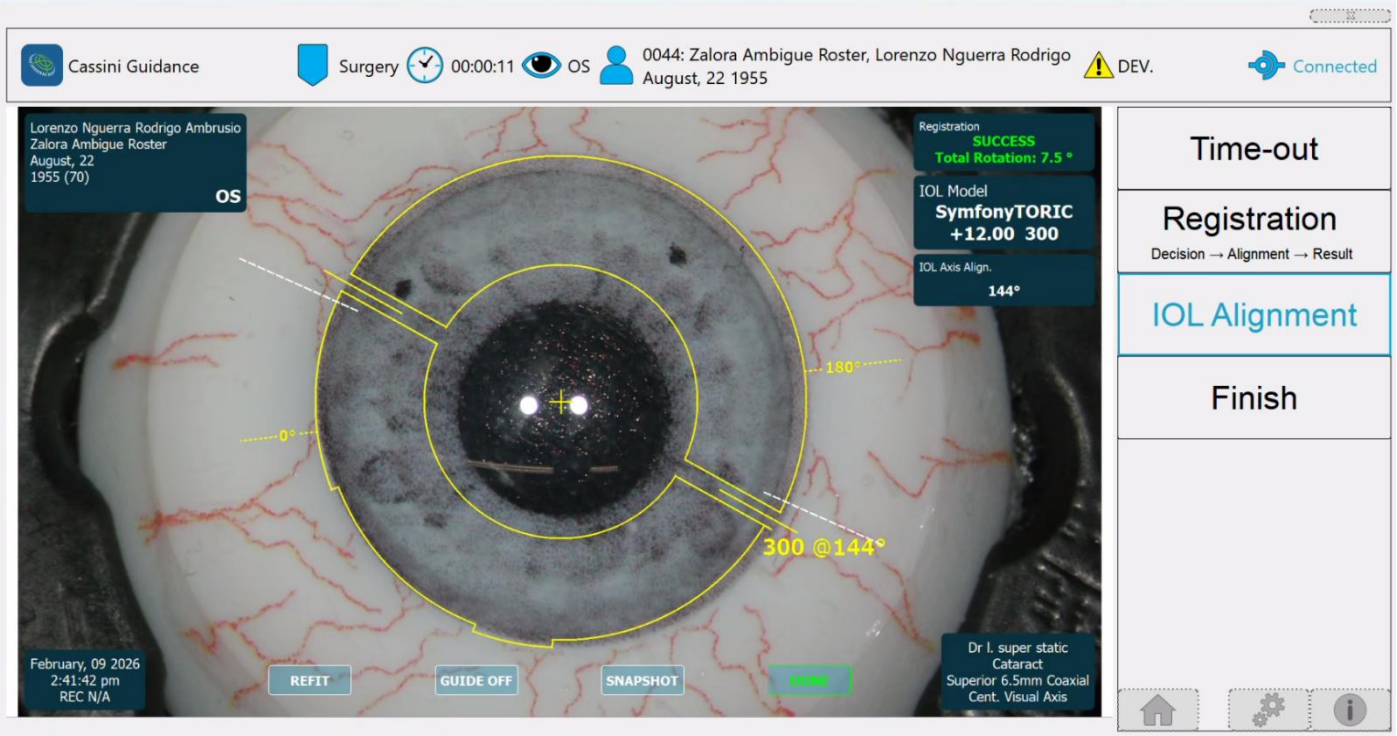

Figure 14: Toric IOL alignment

Visible in the top-right corner boxes:

- Registration status: SUCCESS
  Total Rotation: total registration angle in degrees in relation to pre-op diagnostics
- IOL Model:
  - Name of model
  - Selected SE Power and Toric label
- IOL Axis Align:
  - Toric IOL Alignment target axis, in degrees

Guidance overlay information:

- A colored circle fitted to the limbus
- Two colored dashed lines indicate the 0°-180° pre-op diagnostic horizon
- A colored cross centered on the visual axis or limbus center
- A dashed white line drawn across the eye with the pre-op astigmatism steep axis.
- A smaller colored circle to indicate the planned Capsulorhexis (diameter size and centration predefined), centered around the center cross
- A solid line starting just outside the capsulotomy zone and ending just outside the limbus zone representing the IOL target axis
- Main incision indicator with a retracting notch toward the inside of the limbus (size and location predefined)
- Similarly to the main incision, a secondary incision location indicator (paracentesis)

Assigned action buttons:

- REFIT: Runs the refit and updates the layers
- GUIDE. OFF: Hides the guide overlay. GUIDE. ON then turns it back on
- SNAPSHOT: Creates a snapshot and stores it
- DONE (green text): Ends the IOL Alignment stage and proceeds to the Finish stage of the workflow

13.10.2 IOL Alignment – NON-Toric Lens – specific overlay details

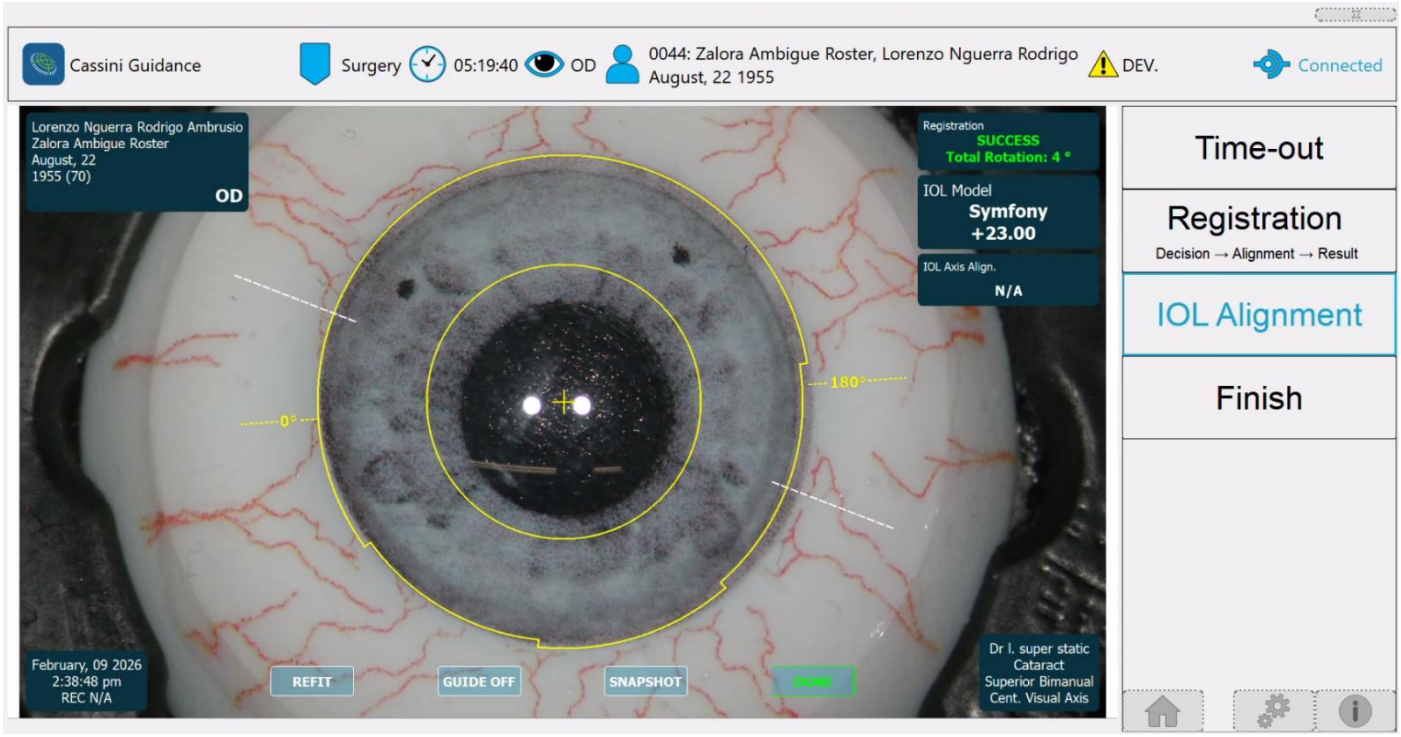

Figure 15: Non-toric IOL alignment

The Guidance overlay information for non-toric lens is same, except IOL Target axis is not shown. The registration information is identical, and the IOL Model section is similar but describing a non-toric IOL.The action buttons are identical as in the previous section.

13.11 WF - Final stage

In this stage, all the alignment guides will be switched off.

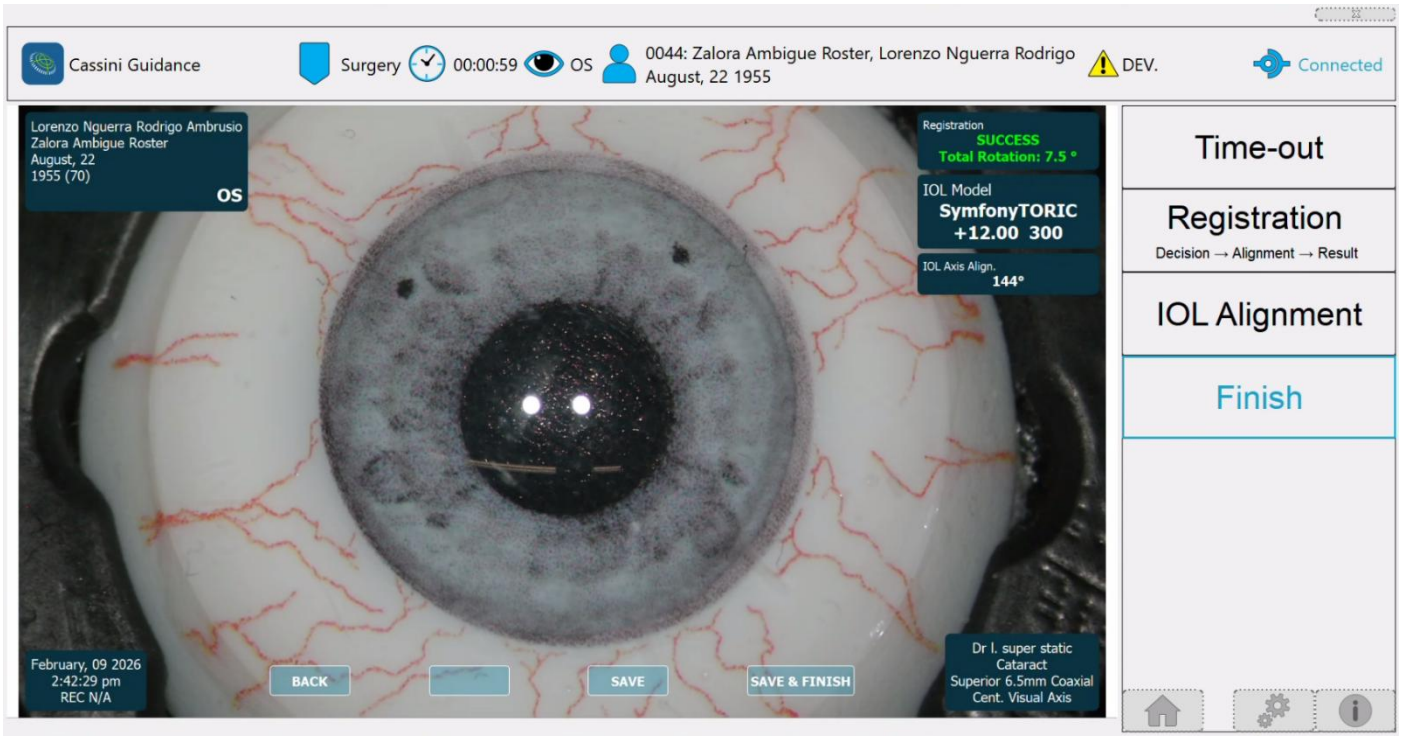

Figure 16: Finish stage

Visible in the top-right corner boxes:

- Registration status unchanged from previous stage
- IOL Model: unchanged from previous stage
- IOL Axis Align: unchanged from previous stage

Assigned action buttons:

- BACK: Returns to the previous (IOL Alignment) stage
- SAVE: Ends the surgery workflow and saves the case but does not mark it as finished
- SAVE & FINISH: Ends the surgery workflow, saves the case and marks it as finished

The 'SAVE' functionality gives the user an option to redo the surgery but should **only** be used if no surgery has been performed yet. If the case is restarted, registration must be redone.

Click on 'SAVE & FINISH' to finish the surgery and return to "View Cases" page.

14 TROUBLESHOOTING, COMPLAINTS AND INCIDENTS

14.1 How to handle system and error messages

When using Cassini Guidance System, system and error messages can pop up.

There are three types of messages (notification, warning, and error) and Windows messages. Error messages are of the highest severity but recoverable with limited impact on the patient safety or surgery process. Contact Cassini Support. when you encounter such messages.

WARNING

DO NOT attempt to repair the system but contact your local distributor or Cassini Technologies B.V.

14.2 Power surge of computer

In the event of a power surge, the computer may shut off. To recover, disconnect the system from the wall outlet and reconnect it once the electricity grid is back to normal. The system should restart normally. After the restart, log in and launch the software. Optionally, resume the previous case if the surgery is still ongoing.

If the software does not restart automatically, there may be permanent damage. In that case, the surgeon is advised to revert to the other surgery procedure methods (e.g., using binoculars or directly connecting the camera inputs to a heads-up display). Additionally, contact Cassini Support to assess the extent of the damage.

14.3 Regulatory compliance – Complaints and Incidents

If during the use of this device or as a result of its use, a malfunction or serious incident has occurred, please report it to the manufacturer (support@cassini-technologies.com) and/or local distributor.

14.4 Service

Email: support@cassini-technologies.com

Web: www.cassini-technologies.com

Technical Support (USA – Toll free)	+1 888 660 6965
Technical Support (outside USA)	+31 (0)70 3993112

15 CYBERSECURITY

When Cassini Guidance System is connected to the network but is not being used in a secured network environment, cybersecurity attacks are possible, resulting in loss of patient data from the hospital network or Cassini device.

It is the responsibility of the responsible organization and/or user for:

- Management of the operating system user rights and policies
- Periodic data backup to prevent any data loss
- Encryption of the exported data

Any software issues can be sent to support@cassini-technologies.com.

When Cassini Guidance System is connected to the network but is not being used in a secured network environment, cybersecurity attacks are possible, resulting in loss of patient data from the hospital network or Cassini device.

WARNING

DO NOT Install any other software on the Cassini Guidance System other than the software provided by the manufacturer!

It is the user's responsibility to ensure that data exported or imported by Cassini Guidance System happens in a secure and isolated environment, and when transported, is transmitted over a secure connection. Cassini Technologies B.V. cannot be held liable for the loss or leaking of any data.

Back-up and restoration of lost information due to a security breach is the responsibility of the customer. In the event of a security breach, users should shut down the software and power off the hardware on which it is installed. Users should then contact Customer Support and/or local distributor. Cassini assess the impact of the breach and determine whether system restoration is possible.

NOTE

The system does not support user-initiated reset functionality; any recovery actions are coordinated exclusively through authorized support services.

16 LICENSE TERMS & CONDITIONS

Please read the Terms & Conditions that was shared separately before using this software! All Terms & Conditions of the license terms shall be deemed to be accepted and agreed by you if you use (or install) this software.

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