cassini GUIDANCE

INSTRUCTION FOR USE

cassini

REVISION HISTORY

Device: Cassini Guidance System

Document ID – CGS-510-0005; Revision D

Issue Date: draft

Version	Change description
A	Initial release for SW 1.0.0
B	Added optional accessories. Revised chapter 8.3 Setup instructions and Chapter 6. Revised Chapter 10 Specification table Added chapter 12.2
C	Revised Chapter 1 - Introduction Added “Both onscreen templates and guidance tools can be toggled ON/OFF at any given time.” And “can be switched off without any surgical interruptions” in Chapter 2. Revised chapter 3.2 Revised Chapter 4. Revised chapter 5 Removed chapter on precautionary instructions Revised chapter 9 Revised Chapter 10 to align with SW rev 1.1.0 Revised chapter 13 to align with Terms & Conditions
D	Updated towards the latest standards CE mark with identification of the notified body added Updated clinical benefits, cybersecurity warning, included intended patient population.

Table 1 Revision History

CE 0344

Copyright:

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1. INTRODUCTION

The Cassini Guidance System 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.

The Cassini Guidance System 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. It includes operating procedures, troubleshooting-, cleaning-, and maintenance instructions.

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.

Always keep this IFU at hand. For more information and news updates visit: www.cassini-technologies.com

1.1. ABOUT THESE INSTRUCTIONS FOR USE

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

WARNING	A **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	A **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	**NOTES** highlight unusual points as an aid to the operator.

Table 2 Important messages

1.1 SYMBOLS USED

This index explains the symbols used on the device.

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

CE Marking

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

2.1INTENDED 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

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

2.2 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

3. CLINICAL BENEFITS

The Cassini Guidance System intended 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.

When Cassini Guidance System is connected to the network but it 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.

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It is the responsibility of the responsible organization / or user

- To ensure that no additional software is installed or existing software removed from the guidance computer provided by the manufacturer, and that the system is not tampered with.
- To maintain the hospital network free from cyberattacks.
- To ensure secure patient data management.

Follow the instructions given under the section “Cybersecurity” in this manual.

5. CASSINI GUIDANCE SYSTEM COMPONENTS

With the Cassini Guidance System you will find enclosed:

- Instructions For Use (1×)

Cassini Guidance System the latest software version is 1.1.0 and it is backwards compatible with 1.0.0 and 1.0.1. Moving forward, customer is entitled to software upgrades when they are made available for the period of Cassini Care contract. If not, do not install or use the software and contact your local distributor or Cassini Technologies B.V. Technical Support.

6. RESIDUAL RISK, CONTRA-INDICATIONS WHEN USING THE DEVICE

6.1 RESIDUAL RISKS

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

1. Guidance cannot import cases with forward slash in the Patient ID. Do not use a / in the patient ID.
2. Cases are marked as "Finished" when cancelling the surgery workflow
3. Surgery can be closed by pressing ESC button on a keyboard. Please prevent that during surgery by selecting the correct workflow.

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 and can be used for the period of 5 years after the initial installation to ensure software compatibility.

7.2. SOFTWARE OPERATING ENVIRONMENT

Software Operating environment	

Operating System	Windows 11 Professional
Operating System Architecture	64-bit
Windows version	2009

Table 1. Software Operating environment

7.3. HARDWARE OPERATING ENVIRONMENT

Cassini Guidance System requires a hardware set-up (computer system) that meets the minimum requirements in Table 2 to ensure continuous operation of the software. Hardware set-up is the responsibility of the user. The Cassini Guidance System is compatible with any general consumer-grade computer system meeting the minimum requirements specified below.

Hardware specifications	**Computer system**
Component Manufacturer	Intel Inc.
Model	NUC
Processors	Intel (R) Core (TM) 11th Gen i7-1185G7 @ 3.00 GHz
Hard disk space	2 TB SSD
Physical Memory	16 GB
GPU	Intel Iris Xe Graphics G7
Display	1080p Full HD

Table 2. Hardware specifications

7.4. INFORMATION AND COMMUNICATION TECHNOLOGY (ICT) REQUIREMENTS

ICT set-up is the responsibility of the user. In Table 3 recommended set-up is defined.

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

Table 3. User ITC set-up

8. TRAINING

As part of installation, onsite and/or online training is provided to the users about the safe use of Cassini Guidance System. Cassini Technologies B.V. provides online tutorials on Cassini Academy. A user can always request for a refresher training via the online training portal.

The objective of this material is to provide guidance and instructions on how to use the device. The training materials will be updated with new material frequently.

- Open your browser and browse to https://cassini.talentlms.com/
- Login using your user credentials. If you are a new user you can 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 and therefore a translation of the manual or graphical user interface (GUI) into the native language of the user 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 to an electrical socket with functional ground.
2. The system will automatically start its operating system.
3. Launch the user software after logging in.

When the Cassini Guidance System is launched and users can proceed to import, view cases and start surgery workflows and information is visible in control and secondary monitor, the device is installed properly. 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 at the electrical socket.

To power it back on:

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

10. MAINTENANCE AND SERVICING

10.1 PREVENTIVE MAINTENANCE - REGULAR CHECKS AND USAGE

No maintenance is necessary unless identified by Cassini Technologies B.V. representative. If there is any issues with the software, the 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 such other products or components are expressly recognized as compatible by Cassini Technologies B.V. Please contact Cassini Technologies B.V. for more information about compatibility:

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

For additional technical information you can contact Cassini Technical 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 the prior notification to your local representative or Cassini Technologies B.V. representative.

13. OPERATING INSTRUCTIONS

NOTE

All names and patient images displayed in the screenshots are fictional and generated solely for illustrative purposes; they do not depict real individuals or actual patients.

Some of the screenshots featured in this 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 Software can be launched via its shortcut, available on the desktop and/or start menu.

After launching the application via its shortcut, a splash screen will briefly show, before the application is started in full screen mode and opens on the Landing page.

NOTE

If instead of the application's landing page you are presented with an error dialog "Error opening the database" you may have inadvertently signed in with the wrong system user account. Please verify the correct user is logged in and contact customer support if the problem persists.

The user interface is segmented into 3 distinct sections: the top menu bar, the side menu (also application or actions menu) and the center frame (also primary output).

The top menu is always visible, but some elements may change depending on the state of the application and which page is currently active. On the landing page it shows the application logo, the current page indicator (e.g. Landing Page), and various status indicators indicated by icons and (optionally) a text description.

STATUS INDICATORS

- DEV. A pre-release software indicator, not present for official released software version.
- Recording time left indictor, showing the hours of recording time left, when Connected.
- Connection indicator, showing a blue "Connected" icon when connected to an activate camera and the guidance system video circuit switch is in the ON position, and a red "Disconnected" icon otherwise.
  For video circuit switch, ref 17 on installation diagram in chapter 9 INSTALLATION.

SIDE MENU

On the right side of the main application window is a context aware side menu where the primary action for the given page are shown. On the landing page these will be e.g. “Import” and “View Cases”, on the “View Cases” page these may be “Start Surgery” or “Cancel”. The functionality of the buttons is described in the relevant chapters below.

Additionally, there are some shortcut actions indicated by an icon which are always visible.

-  Return to the Landing Page (also “Home Screen”)
-  Open to the settings menu.
-  Open the about page, showing software version, the UDI label, software licenses and copyright information.
  From this page, the user may also access the IFU corresponding to the current software version.

CENTER FRAME

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

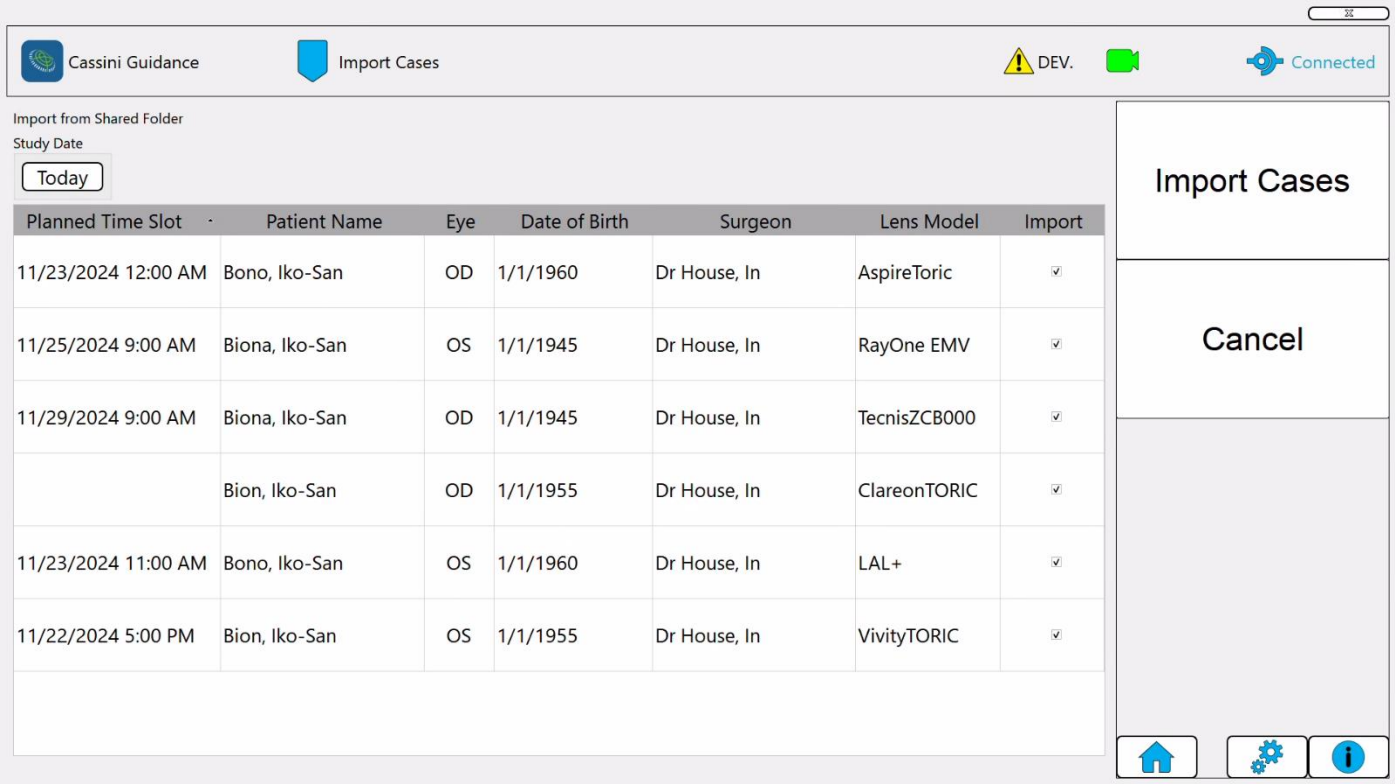
13.2 DIAGNOSTIC DATA TRANSFER – IMPORT CASES

To use the Cassini Guidance System, first export one or more cases from the Cassini Surgical Planning Software (CSPS). You can then import these cases as described in this chapter.

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 in consultation with customer support and a local IT administrator.

13.3 IMPORT CASES

a) Insert the (BitLocker) encrypted USB into the back of the Cassini Guidance System.
b) Unlock encryption with the configured or provided password. The system can be configured to auto-unlock the drive the next time it is inserted.
c) Select ‘Import’ action from the side menu.
d) Cases from the USB drive which can be imported will show up in the list on the “Import Cases” page.



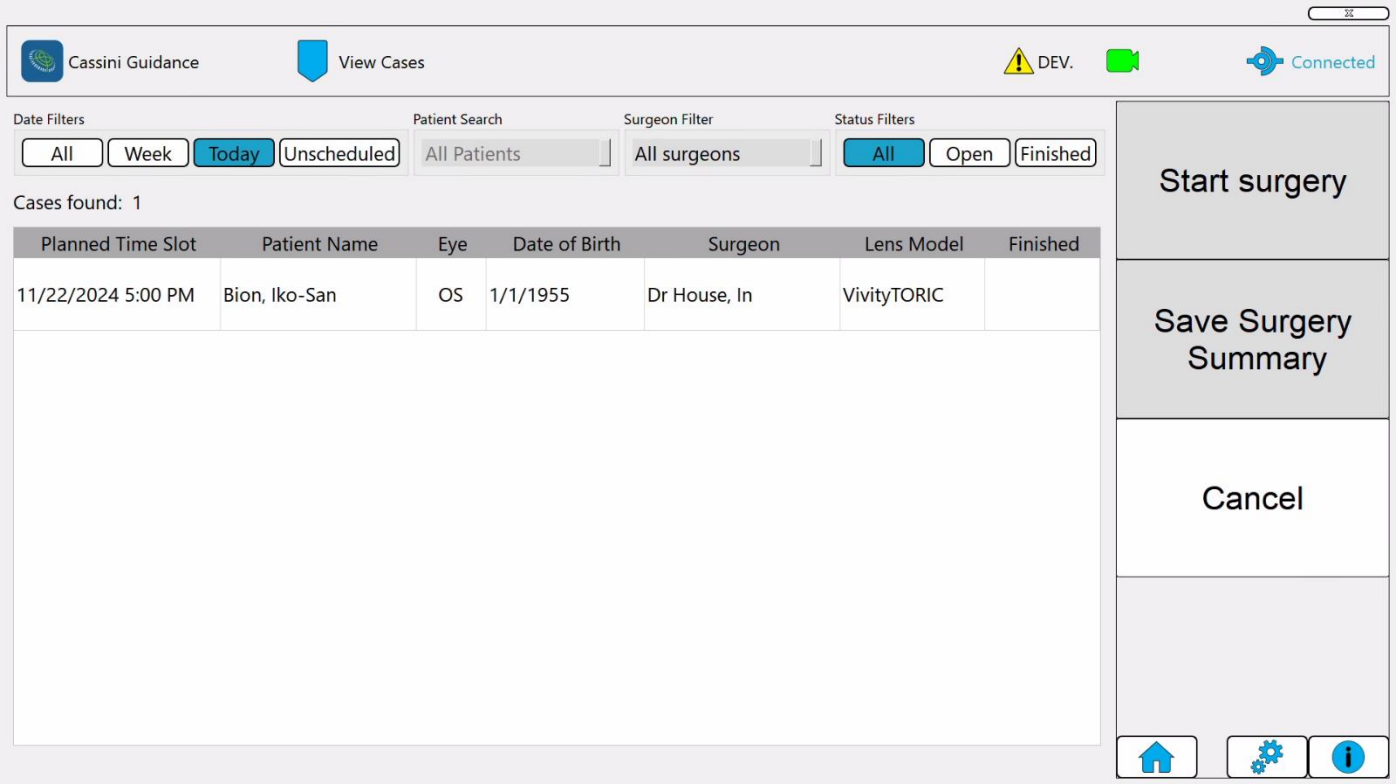
As cases are imported, the following considerations should be taken into account:

a) All cases that can be imported will be shown in the “Import Cases” list overview. Non-importable cases (e.g. duplicates) may either be hidden or shown with a different accent color.
b) These 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 export is available are deselected by default but can be manually selected.
c) When the ‘Import Cases’ button is pressed, all selected cases will be imported into the Cassini Guidance Database.
d) After the import process has been completed, the software will automatically attempt to remove the imported items from the USB drive.
e) The imported cases are now viewable from the ‘View Cases’ page.

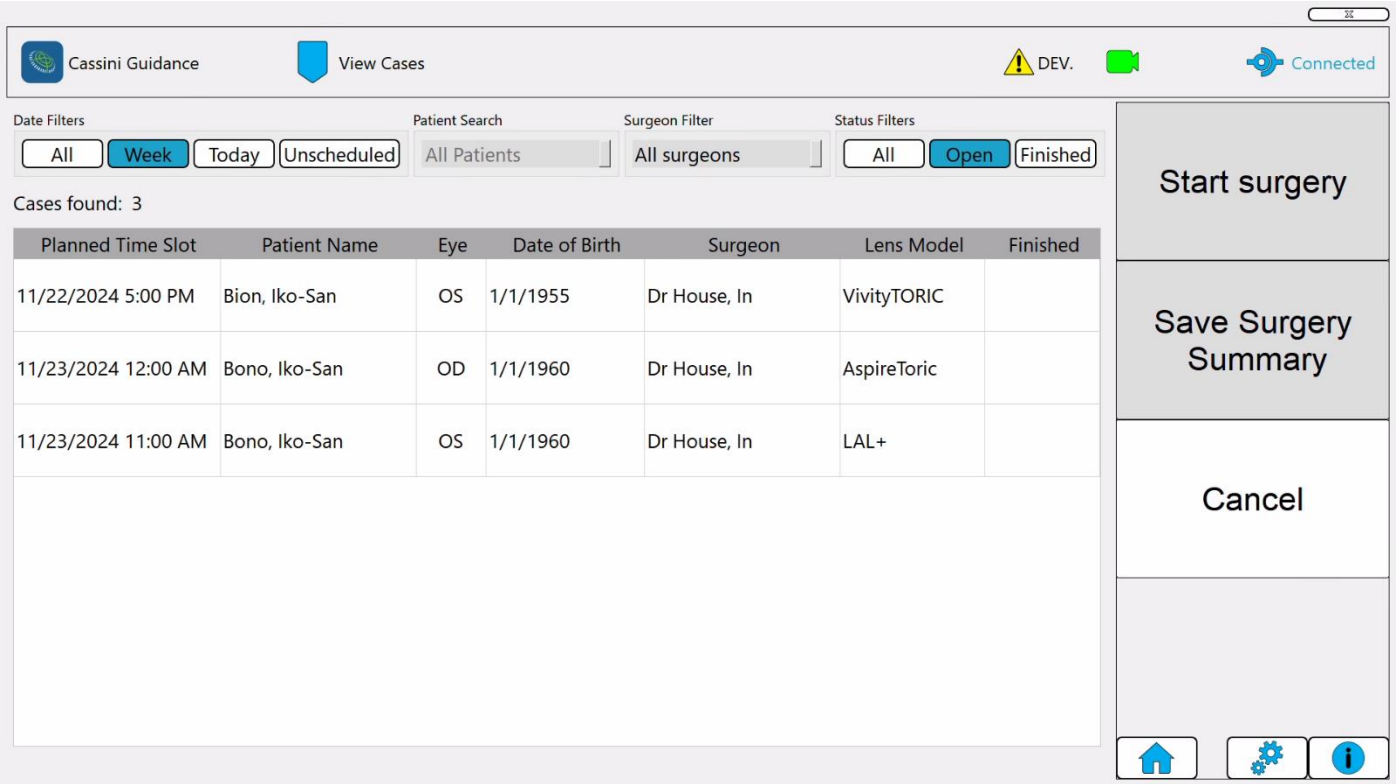
13.4 VIEW CASES

From the landing page (home screen), click on ‘View Cases’ to view imported cases.

By default, this list is filtered to show Today's cases, which may be a smaller subset than the cases that were imported.

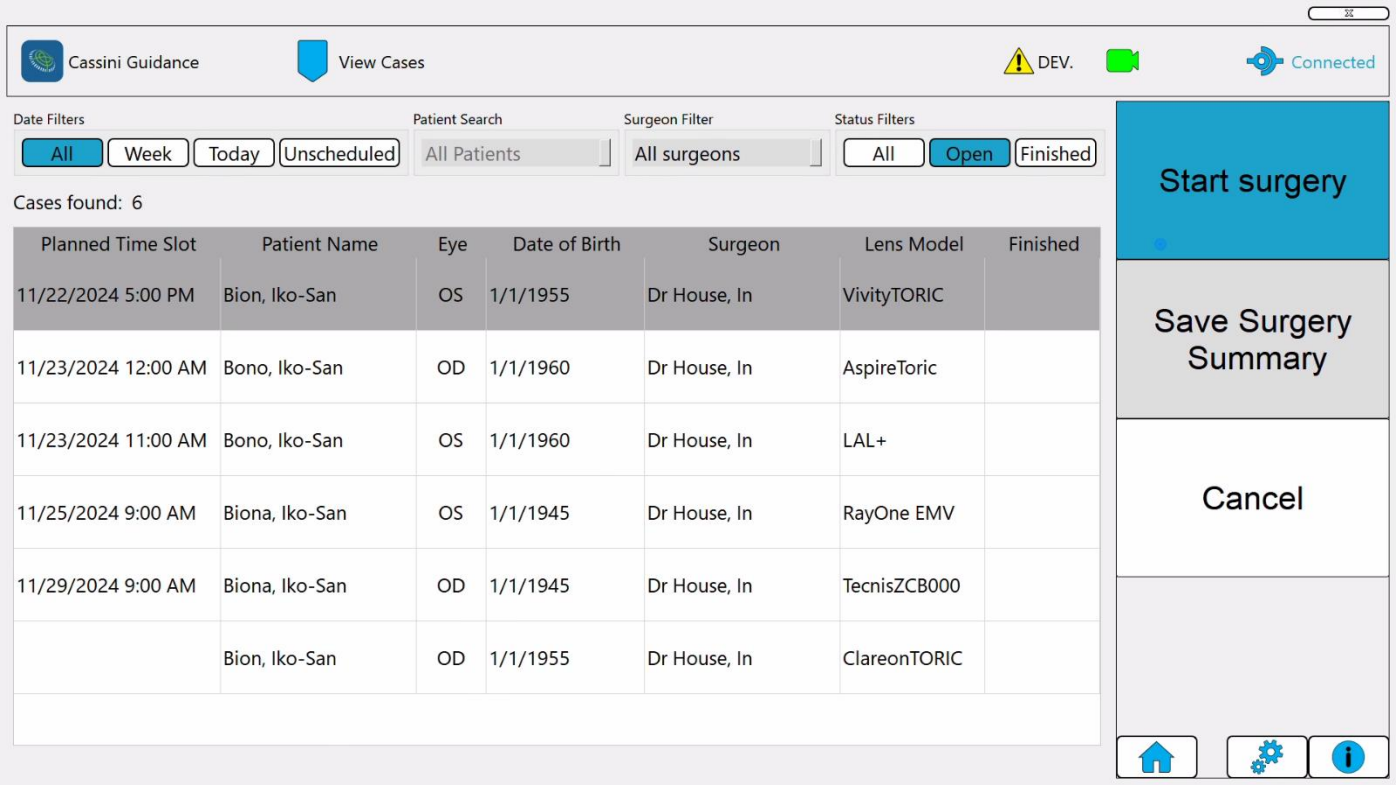


The filters can be changed to show a larger set of cases, by selecting all unscheduled cases, all cases for this week, or all cases, which can additionally be filtered by surgeon or status.



Additionally, the user may search for a specific patient by entering (part of) the first or last name of the patient and confirming with ENTER, or by pressing or toggling any of the filters.

Select a case by pressing unfinished entry in the table, which will then become highlighted, and the 'Start surgery' button becomes active.



After selecting a case (which then shows as highlighted) click or press "Start surgery" to start the surgical workflow.

13.5 SURGERY WORKFLOW (WF) - OVERVIEW

During the surgery workflow the application will show output on both the touch screen monitor (also "control monitor") and the video output display (also "external monitor"), if connected. The output in the central frame on the touch screen monitor will look like a smaller version of the output to the video output display. Below both outputs are depicted at one of the surgery workflow stages, the registration alignment stage, explained in more detail in subsequent chapters.

Figure 1. Touch screen monitor example on the left and video output display on the right

The first stage of the surgery workflow always consists of a patient time-out stage where the user confirms the right patient has been selected or immediately cancels the surgery workflow.

13.6 WF - PATIENT TIME OUT STAGE

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

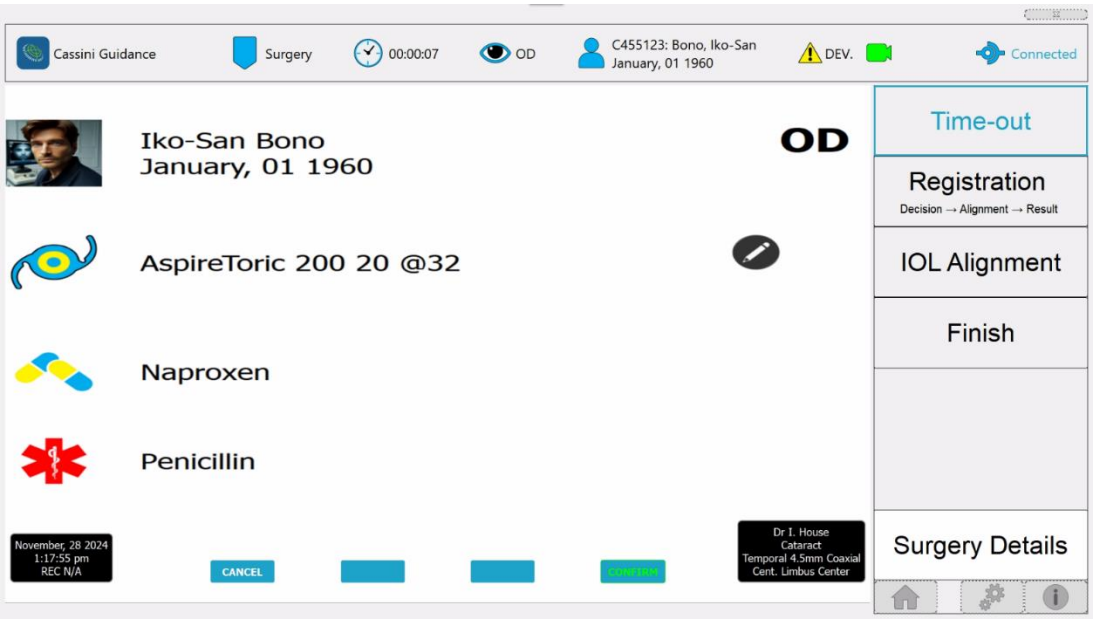


Figure 2. Time-out page example

The patient time out stage will show the following information, on both the touch screen monitor as well as the video out display.

- 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 medical details can be viewed when pressing the “Surgery Details” button on the touch screen monitor.

At the bottom left the current date and time are shown, along with the current recording status.

At the bottom left the surgeon's name, their selected surgery profile, and some key surgery workflow parameters are shown.

OVERLAY DETAILS: SURGERY SETTINGS – PROFILE & PARAMETERS

The bottom right of the corner boxes will show the following detailed information specified during surgical planning.

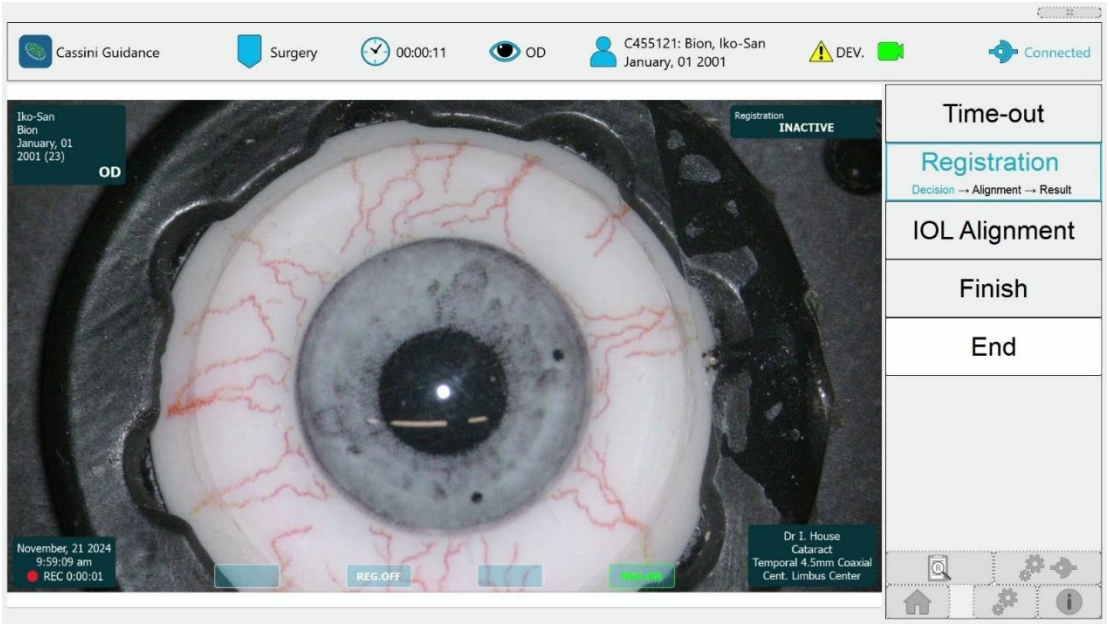
- Surgeon's first letter of first name and last name
- Selected Profile
- Incision location (Temporal/ Superior) Incision size in millimeters, phacoemulsification technique selected in Planning software (Coaxial or Bimanual)
- Capsulorhexis Centration: Center of Limbus or Visual Axis

At the Time out stage two primary actions are available, CANCEL and CONFIRM, using the buttons on the touch screen monitor.

- Press CANCEL and the user will be returned to the view cases overview.
- Press CONFIRM to start the surgery workflow and start the automatic recording of the case.

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

13.7 WF - REGISTRATION DECISION MAKING STAGE



Depicted is the output on the touch screen monitor at the first stage after Time out, the Registration decision stage, for the user to indicate whether to continue either with (REG.ON) or without (REG.OFF) registration (a pre-condition for guidance).

13.7.1 REGISTRATION DECISION SPECIFIC OVERLAY DETAILS

Visible in the top-right corner box:

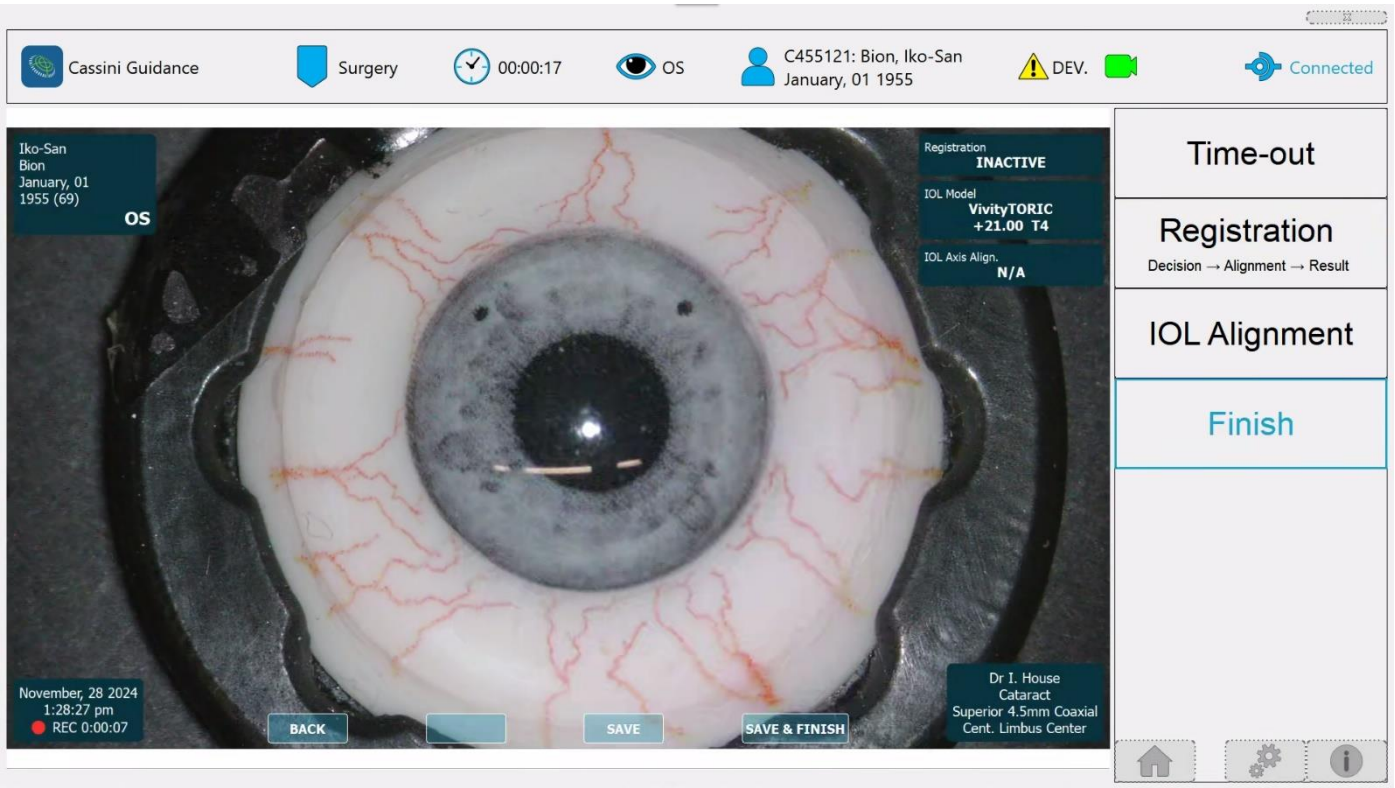
- Registration status: INACTIVE

Available action buttons:

- [2] REG. OFF (white text): enables the user to continue without registration or guidance; only with visualization and recording functionality
- [4] REG. ON (green text): guides the user to the next step and enables registration functionality

13.8 WF - REGISTRATION OFF STAGE (REG.OFF)

If the user has selected REG. OFF in the Time-out stage, they will immediately enter what will be the final stage of the workflow.



In this stage the software switches to a view without guidance information, which is limited to basic visualization and recording functionality. Conventional surgery can be performed in this mode, until the user chooses to save and/or finish the procedure. Or the user may go back, to registration stage and switch to the mode with additional guidance overlays enabled.

13.8.1 REGISTRATION OFF - SPECIFIC OVERLAY DETAILS

Visible in the top-right corner boxes:

- Registration status: INACTIVE
- IOL Model:
  - Name of model (selected in IOL Bank in Planning software)
  - Selected SE Power and Toric label, if available (selected in Planning software)
- IOL Axis Align: N/A

Assigned action buttons:

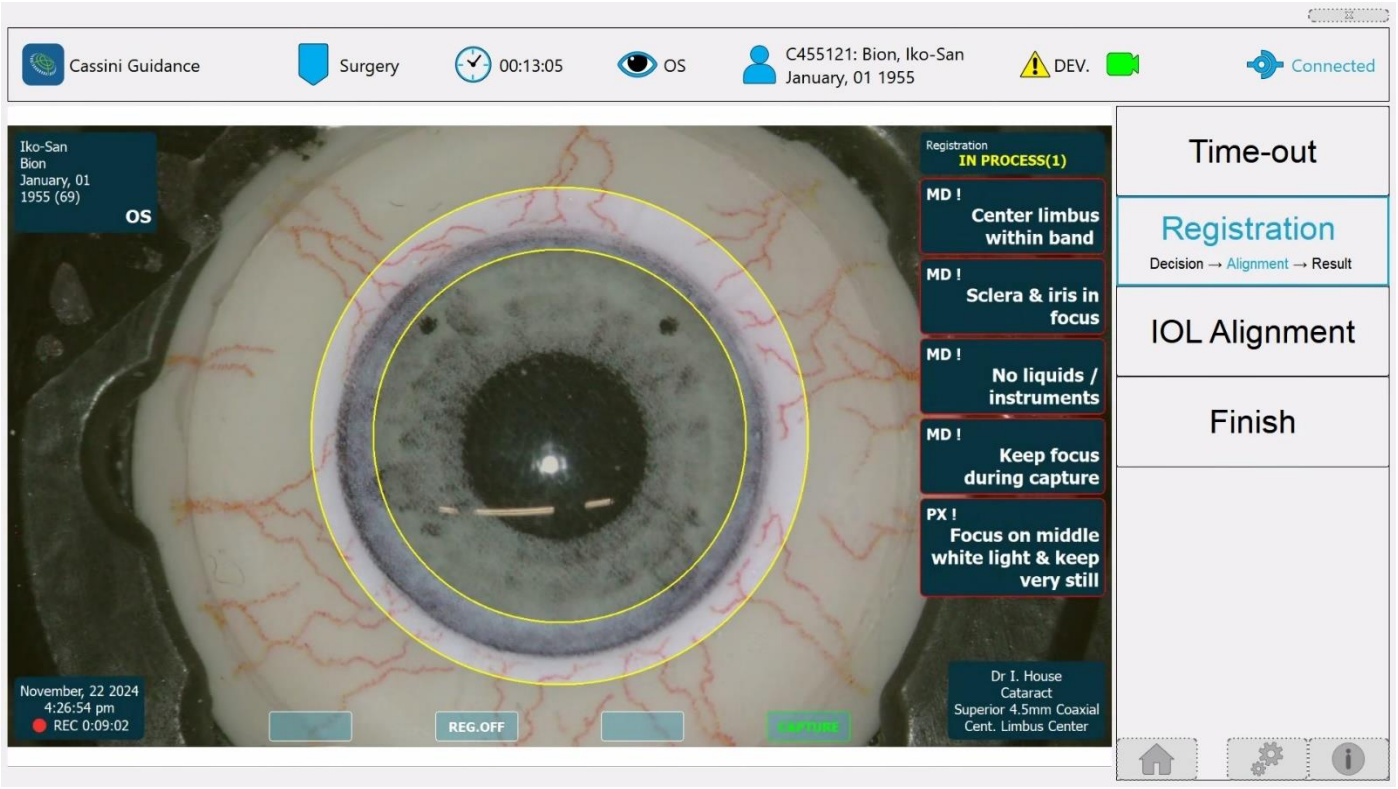
- [1] BACK: allows surgeon to revert to previous.
- [3] SAVE: save procedure, but not mark it as finished
- [4] SAVE & FINISH: save procedure, and mark it as finished.

13.9 WF - REGISTRATION ALIGNMENT

If the user selected REG. ON in the time out stage, they will enter the registration alignment stage.

Alignment instruction boxes appear on the right side of the live surgical video views. Instructions to the surgeon and staff are prefixed with MD, and instructions for the patient are prefixed with PX.

A semi-transparent drape will cover the screen, except for a clear band in the center of the screen. As per the on-screen instructions, 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.



To align the surgeon needs to adjust the zoom (Z-Axis) and move either the microscope or patient in such a manner that the limbus falls within the center (X/Y-Axes) of the clear band. Surgeons need to ensure clear focus and clarity of the sclera and iris upon the moment of capture. Once optimal alignment and sharpness has been achieved, then either the surgeon or nurse can click on 'CAPTURE'.

It is advisable not to have any instruments or fluid build-up during the capturing moment. The acquisition time is instantaneous.

The surgeon needs to instruct the patient to focus on the middle white light and to keep very still for a few seconds.

13.9.1 REGISTRATION ALIGNMENT - SPECIFIC OVERLAY DETAILS

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*

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Assigned action buttons:

- [2] REG. OFF: allows the surgeon to deactivate registration process for any reason
- [4] CAPTURE: allows surgeon or nurse to capture the frame used for registration

13.10 WF - REGISTRATION ANNOUNCEMENT STAGE

The Registration announcement stage will initiate automatically after registration has been identified. This registration process will take less than 2 seconds.

Three different registration outcomes are possible:

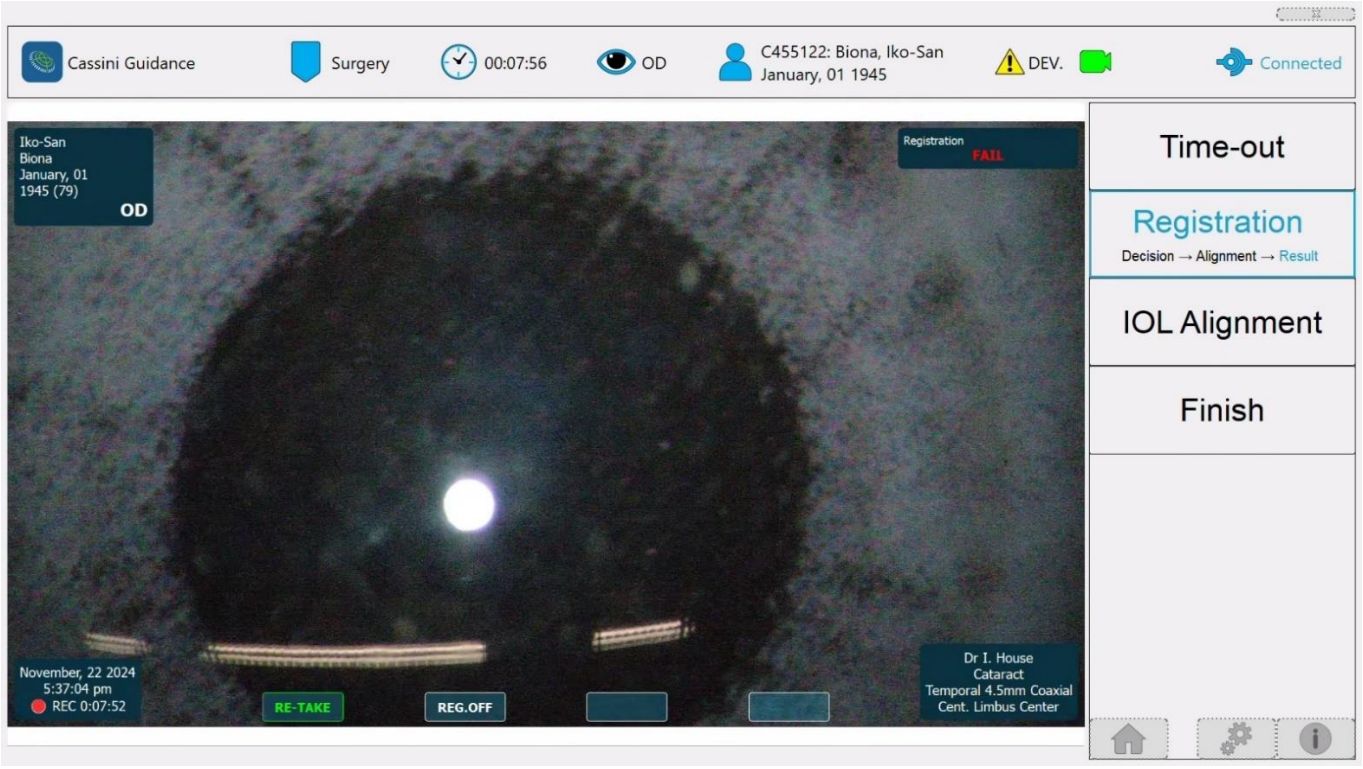
1. **SUCCESS**:
   >85% confidence on a registration accuracy within 3 degrees.
2. **MODERATE**:
   50%-85% confidence on registration accuracy within 3 degrees.
3. **FAIL**:
   <50% confidence on a registration accuracy within 3 degrees, or an inconclusive registration attempt.

As each registration outcome results in a different view, they will be described, in reverse order, in separate sections below.

13.10.1 FAIL - REGISTRATION - SPECIFIC OVERLAY DETAILS

If registration leads to FAIL state, no additional information will be shown, and the user has 2 options: re-take the registration frame (and re-aligning the system) or switching to registration off (REG.OFF.) mode.

In the example screenshot, the root cause was being too far zoomed in. Refer to the registration alignment chapter for correct alignment instructions.



Visible in the top-right corner box:

- Registration status: FAIL

Assigned action buttons:

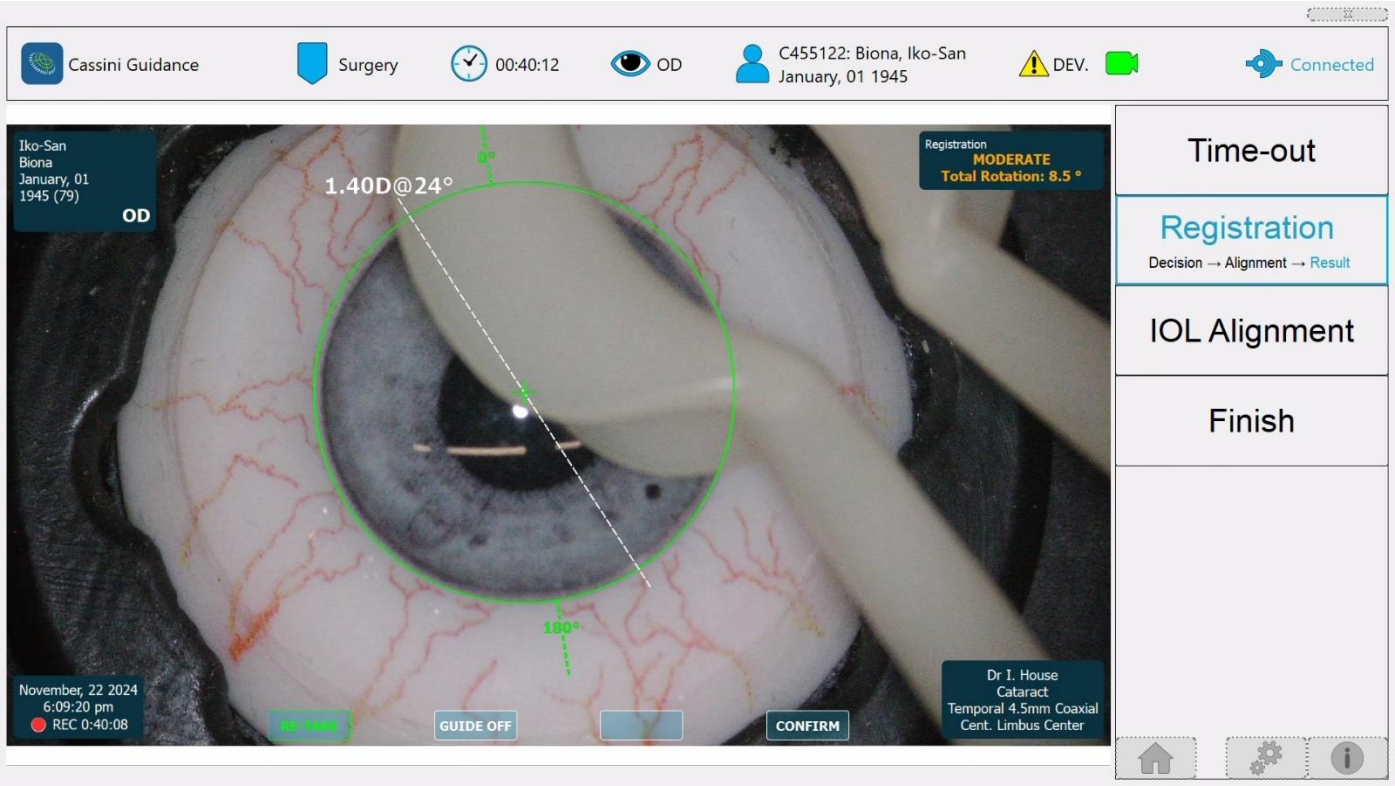
- [1] RE-TAKE (green text): allows the user to retake and repeat the registration process
- [2] REG. OFF (white text): allows the surgeon to deactivate registration process and proceed without guidance

13.10.2 MODERATE - REGISTRATION - SPECIFIC OVERLAY DETAILS

A moderate registration is always sub-optimal so the default (recommend) action in such a case is always RE-TAKE rather than CONFIRM, however the result is not necessarily incorrect. As such, the registration outcome (what total rotation was found) is still reported.

In the example screenshot below, the cause for a moderate registration score is an instrument obscuring a large part of the (artificial) eye. This in and of itself would be grounds to re-take, but the outcome can still be assessed in relation to **subsequent** registration attempts.

It is highly recommended not accept the first moderate registration outcome without careful deliberation. The user should re-take (several times) to either confirm multiple moderate results with the same outcome or obtain a SUCCESS outcome.



Visible in the top-right corner box:

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

Guidance overlay tool 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). The source of the information are the pre-op diagnostics data, and the placement
- A dashed white line drawn across the eye with the pre-op astigmatism steep axis. This can be the anterior or total astigmatism measured by the Cassini Ambient, or a custom axis, selected in the Cassini Surgical Planning Software. The magnitude and axis of astigmatism will be indicated along this pre-op steep axis line.

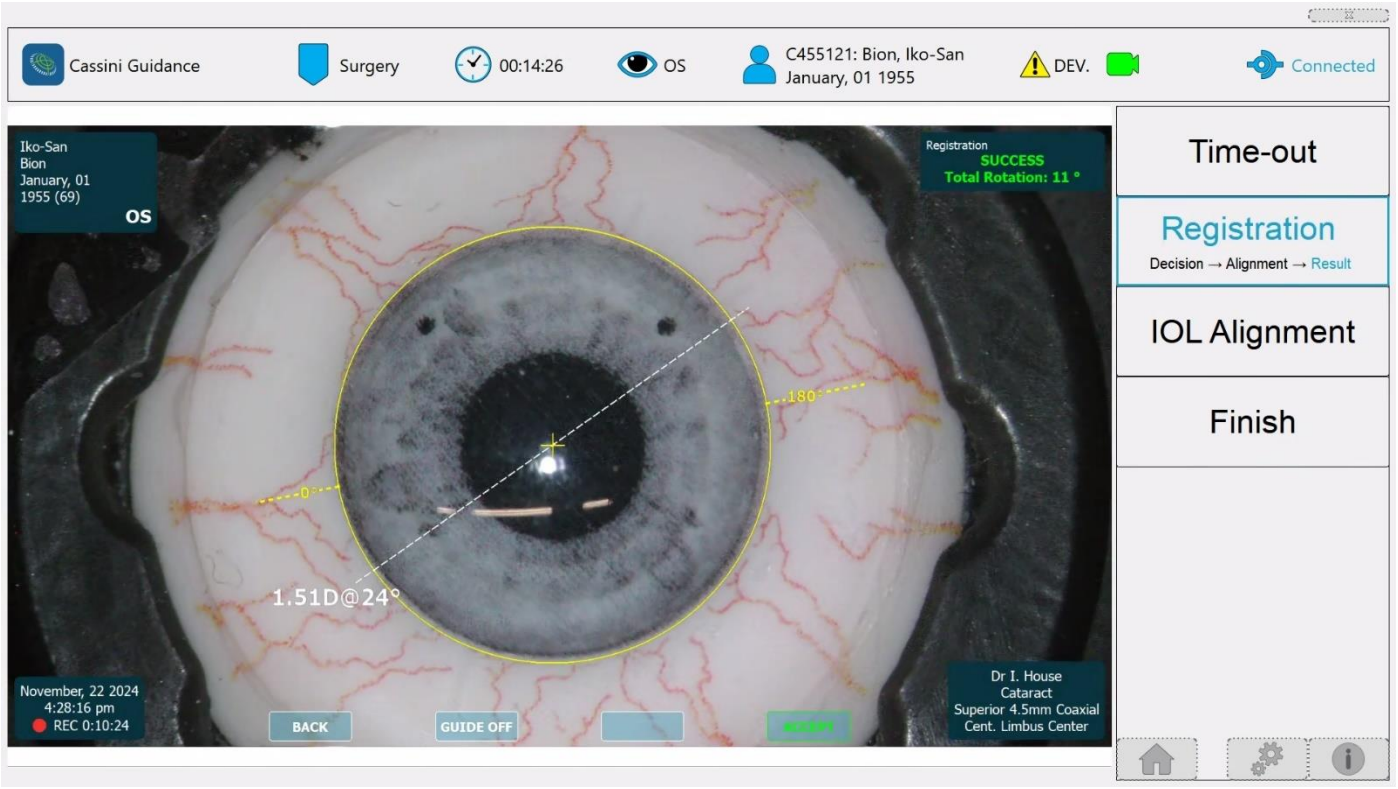
Assigned action buttons:

- [1] RE-TAKE (green text): allows the user to retake and repeat the registration process.
- [2] REG. OFF (white text): allows the user to deactivate the registration process.
- [3] ACCEPT (white text): allows the user to move forward to the next stage, despite the moderate registration (e.g. after several moderate, but reasonable and consistent, registrations)

13.10.3 SUCCES - REGISTRATION - SPECIFIC OVERLAY DETAILS

A SUCCES registration is always the goal, as in this case there is a high likelihood that the correct registration has been found. With repeated SUCCESS registrations that produce a consistent result the likelihood of a correct registration can be further increased.

In the example below, the surgeon has selected yellow as the color of the overlays, instead of green. The overlay color can be customized in the surgeon's profile in the Cassini Surgical Planning Software.



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 tool information is showing the same information as for a moderate registration:

- 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.

Assigned action buttons:

- [1] RE-TAKE (white text): allows the user to retake and repeat the registration process.
- [2] REG. OFF (white text): allows the user to deactivate registration process.
- [3] ACCEPT (green text): allows to confirm and accept the registration and proceed to the next stage

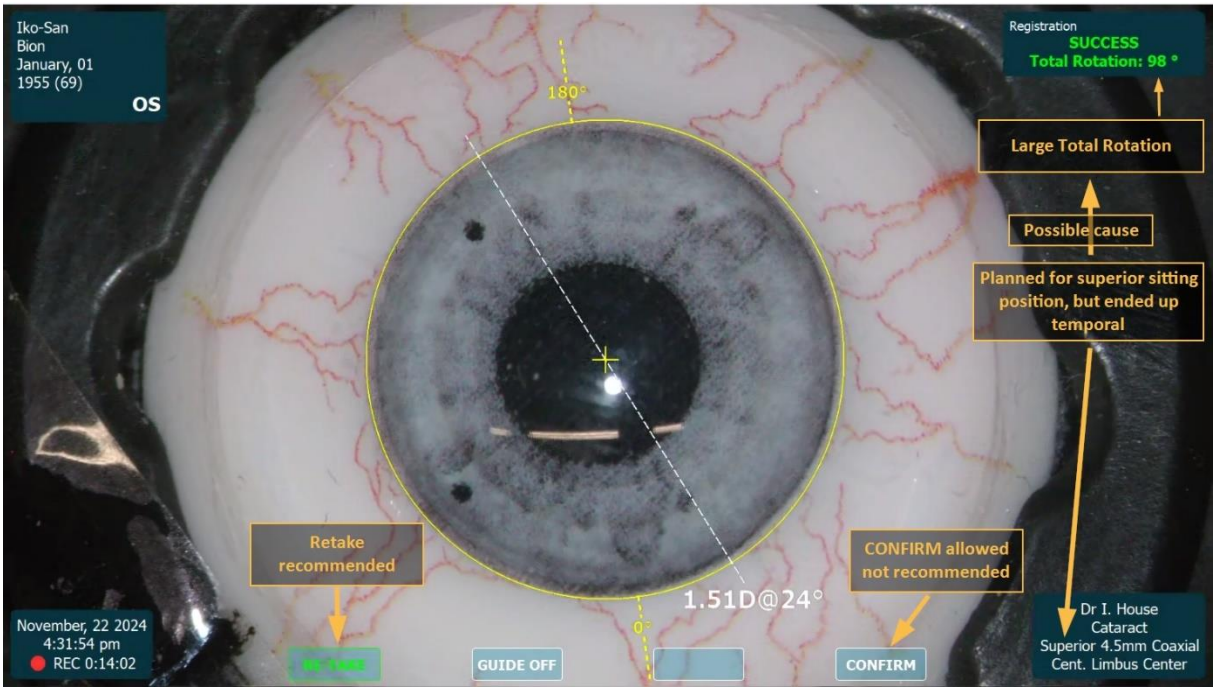
13.10.4 SUCCES BUT WITH LARGE TOTAL ROTATION

It's important to note that the total rotation is not merely 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.

As an example, the registration is SUCCESS, but the total rotation is abnormally large (98°), yet repeatedly consistent. In this case, 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° of offset.



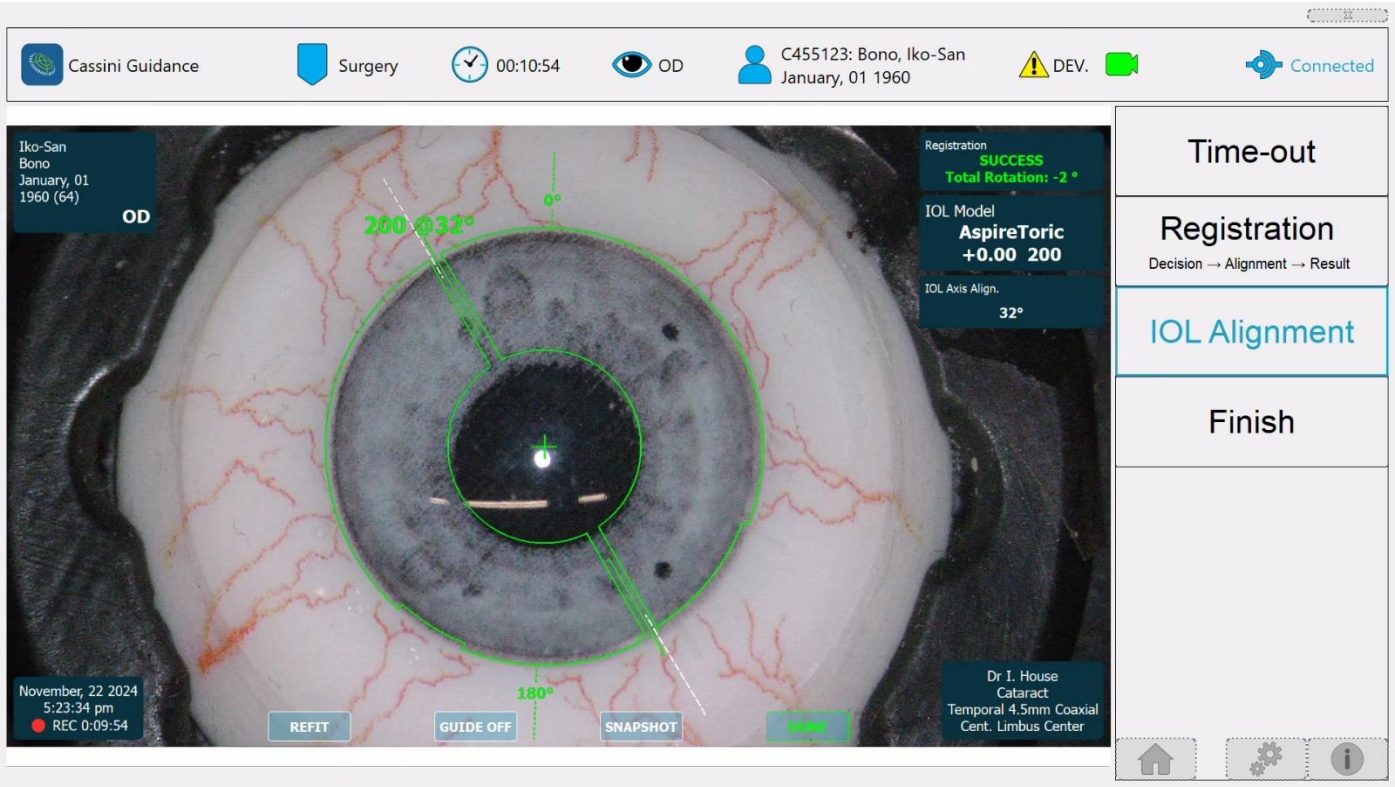
13.11 WF – IOL ALIGNMENT STAGE

After accepting or confirming the registration outcome the workflow moves on to the IOL Alignment stage, which is slightly different depending on whether a toric or a non-toric lens was selected during planning.

The IOL Alignment stage comes with a special ‘refit’ action (button). This action should **only** be used if the guide is no longer being update (tracking has been lost) due to significantly changed conditions of the eye (e.g. bleedings), and the action should **only** be used **after** the eye has been allowed to return to the initial registration position (alignment, magnification and focus). If used under other circumstances, the accuracy of the guidance overlays may be reduced.

IOL ALIGNMENT – TORIC LENS - SPECIFIC OVERLAY DETAILS

The toric IOL alignment guide features specific elements to aid in the alignment – centration as well as rotation – of the toric IOL, for the best possible outcomes.



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 with:
  - Name of model (as selected in Planning SW)
  - Selected SE Power and Toric label
- IOL Axis Align:
  - Toric IOL Alignment target axis, in degrees

Guidance overlay tool information:

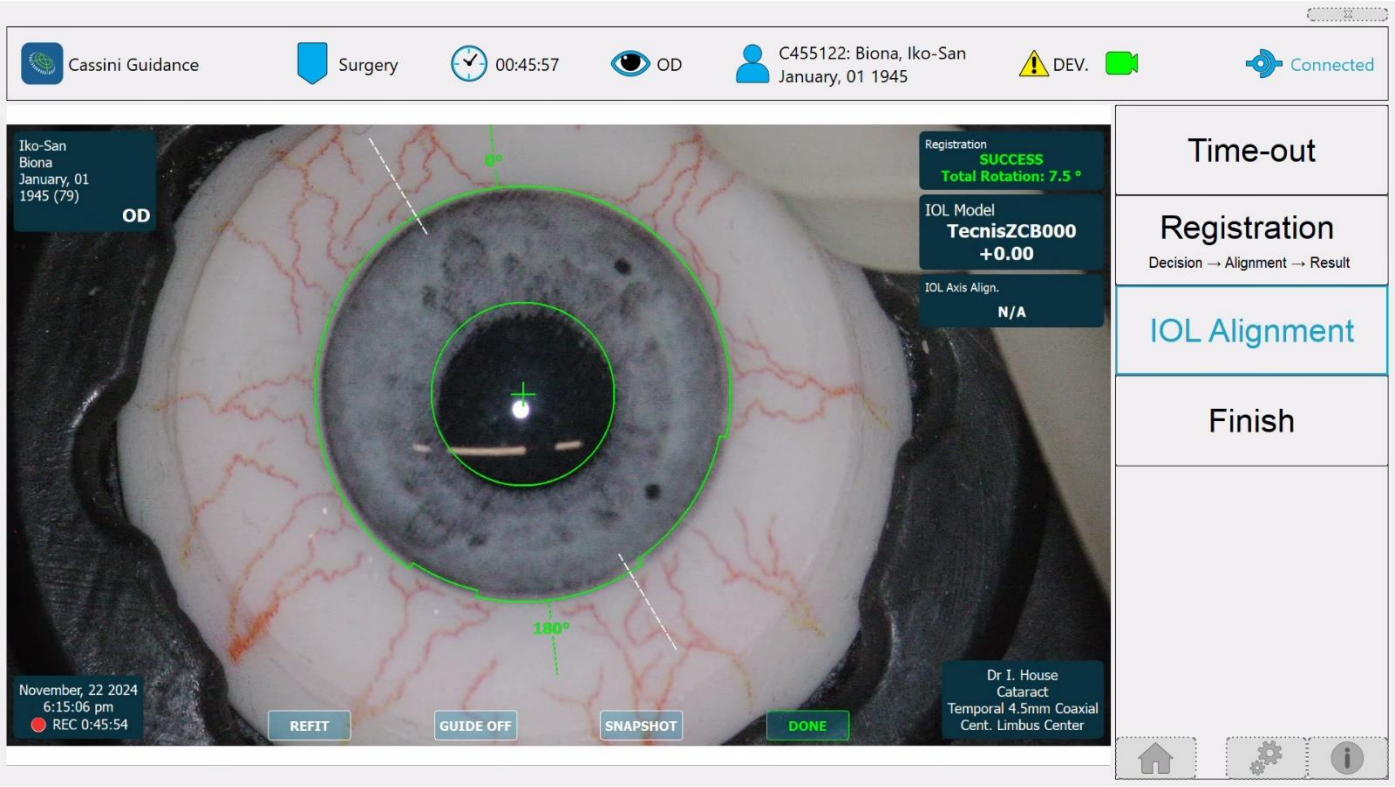
- A colored circle fitted to the limbus
- Two colored dashed lines indicate the 0°-180° pre-op diagnostic horizon
- A colored cross centered on the visual axis or limbus center
- A dashed white line drawn across the eye with the pre-op astigmatism steep axis.

- A smaller colored circle to indicate the planned Capsulorhexis (diameter size and centration predefined in Planning software), 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 location indicator with a retracting notch toward the inside of the limbus (size and location selected in the planning software)
- Similarly to the main incision, a secondary incision location indicator (paracentesis)

Assigned action buttons:

- [1] REFIT: Runs the refit algorithm and updates the layers
- [2] GUIDE. OFF: Hides the guide overlay. GUIDE. ON then turns it back on.
- [3] SNAPSHOT: create a snapshot and store it
- [4] DONE (green text): end the IOL Alignment stage and proceed to the finish stage of the workflow

IOL ALIGNMENT – NON-TORIC LENS - SPECIFIC OVERLAY DETAILS



The Guidance overlay tool information for the non-toric lens is very similar, except that the IOL Target axis is not shown.

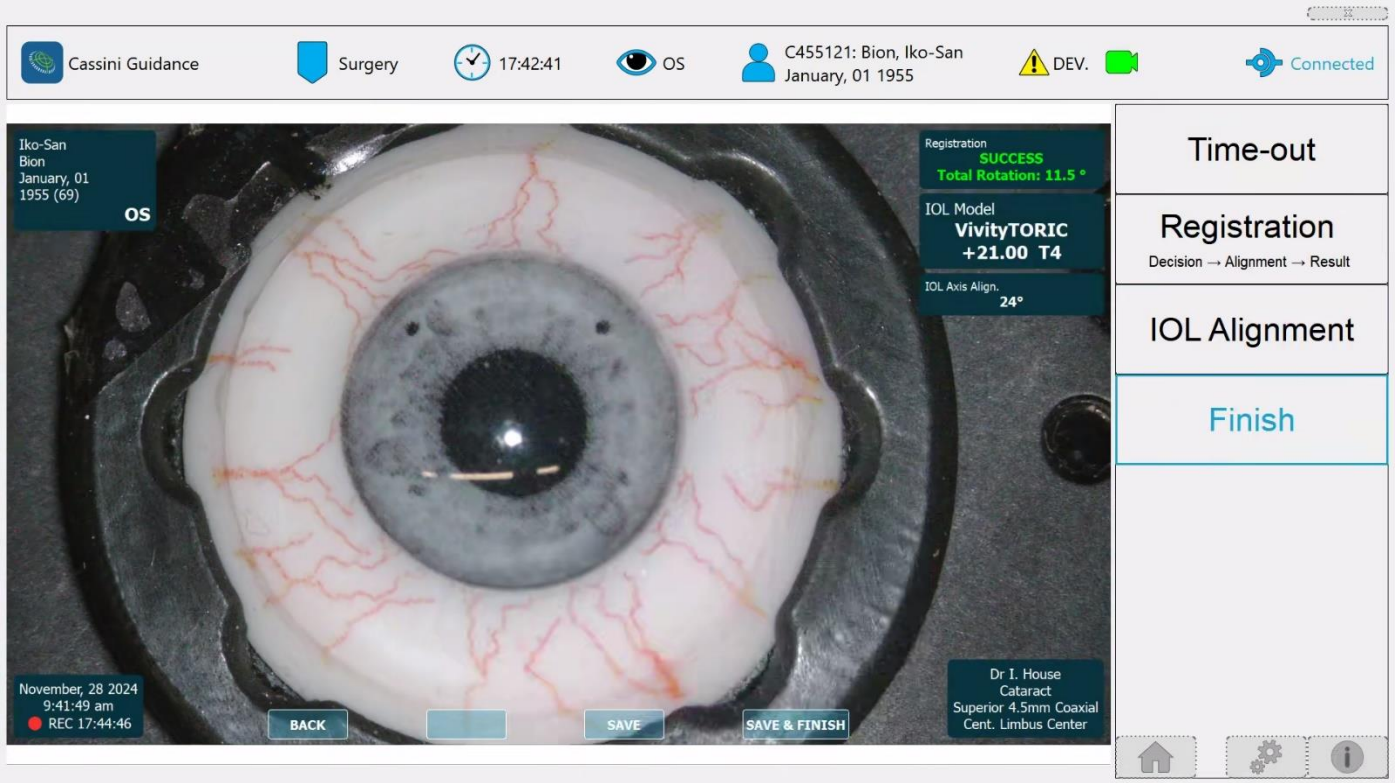
The registration information is identical, and the IOL Model section is similar, but describing a non-toric IOL.

The action buttons are identical to the those described in the previous section.

13.12 WF - FINAL STAGE

At this stage all the alignment guides will be switched off, but the recording will continue. As such there is time to administer eyedrops and perform a final inspection.

FINISH STAGE - SPECIFIC OVERLAY DETAILS



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:

- [1] BACK: Return to the previous (IOL Alignment) stage
- [3] SAVE: End the surgery workflow and save the case but does not mark it as finished.
- [4] SAVE & FINISH: End the surgery workflow, save the case and mark it as finished.

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

Upon clicking on 'SAVE & FINISH', the recording will stop, and the user will be returned to the "View Cases" page of the application. From there they can start the next case.

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 Cassini messages (notification, warning, and error) and Windows messages. The error messages are of the highest severity messages but recoverable and with limited impact on the patient safety or surgery process. Contact Cassini Technologies B.V when you encounter such messages.

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WARNING

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

14.2 WHAT TO DO IN THE EVENT OF A POWER SURGE

In the event of a power surge, the system 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 application. Optionally resume the previous case if the surgery is still on-going.

If the system does not restart automatically after reconnecting it, there may be permanent damage. In that case the surgeon is advised to revert to the surgical procedure prior to integrating Cassini Guidance into Clinic's workflow (e.g., using binoculars or directly connecting the camera inputs to a heads-up display). Surgical guidance and recording functionality will then not be available. Additionally contact customer 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 (Email and Contact numbers mentioned above for Technical Support) and/or its authorized representative.

14.4 SERVICE

The expected service life of Cassini Guidance System is 5 years.

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

The hardcopy of this user manual can be requested free of charge through the above-mentioned toll-free numbers. It shall be delivered to you within 7 calendar days.

15. CYBERSECURITY

Do not install unauthorized software on Cassini Guidance System; It could have a negative impact on the performance and security of Cassini Guidance System. Contact Cassini Technologies B.V. support before installing any software.

It is the responsibility of the responsible organization and or user to:

- Manage 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.

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 (end-to-end) 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. For power-down instructions, refer to Section 9 INSTALLATION. Users should then contact Customer Support. An authorized technician from Cassini Technologies B.V. will assess the impact of the breach and determine whether system restoration is possible. Please note that the system does not support user-initiated reset functionality; any recovery actions are coordinated exclusively through authorized support services.

16. LICENSE TERMS AND CONDITIONS

Please read the terms & conditions that was shared separately before using this software! All terms and 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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