cassini
The world in vision

Cassini Ambient

Instructions for Use

Cassini Technologies B.V.
Anna van Buerenplein 40a
2595 DA Den Haag
The Netherlands

Tel: +31 (0)70-399 3112 / +1 202 590 9150
Email: support@cassini-technologies.com
Web: www.cassini-technologies.com
Support portal: support.cassini-technologies.com

Device: Cassini
Trade name: Cassini Ambient
Basic UDI-DI: 871932605963.0YL
Cassini Instructions for Use
Revision: **CAS-510-0001-V19**
Revision Date: 01-12-2025

℞ ONLY

CE
0344

CONTENTS

1 INTRODUCTION

Cassini Ambient is a topographer to deliver point sharp accuracy and measure the angle of astigmatism of the anterior and posterior surface of the cornea. Both measurements are combined into Total Corneal Astigmatism using optical ray-tracing models.

This manual describes the use of Cassini. It includes operating procedures, troubleshooting, cleaning, and maintenance instructions.

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

If Cassini causes any unknown negative side effects to the patient or user, contact support and inform the manufacturer.

Always keep this instruction manual at hand.
For more information visit: www.cassini-technologies.com

1.1 About Instructions for Use

Before using Cassini, read the 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 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 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 injury or damage to the product or other property, and a remote risk of more serious injury, and/or cause environmental pollution.
NOTE	**NOTE** highlights unusual points as an aid to the user.

Table 1: Important messages

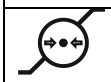
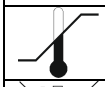
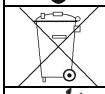
1.2 Definitions

Concept	Definition
Focus	Defined by the sharpness of the image and controlled by a forward and backward movement of Cassini.
Centration	Defined by the left/right and up/down position of Cassini.
Work distance	The distance between the apex and the objective lens. The quality of the surface reconstruction is based on this distance; it is important to focus the system correctly before capturing an image.
Work distance lasers	These are the two lasers used to determine the optimal focus of Cassini. When the patient's head is placed in the headrest, focus is done by moving the Cassini in the direction of the eye. The corneal diffused laser reflections on the eye, also defined as the work distance laser spots, will

	cross each other when moving the dome forwards and backwards. If they are on top of each other, the system is properly in focus.
Calibration tool	The tool supplied with the system should always be kept in the vicinity of the system for frequent calibrations. It is a 'perfect' (yet unique) sphere which is used as the baseline for the surface reconstruction (calibration).

Table 2: Specific terminology

1.3 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
	TYPE B applied part
	Indicates the range of atmospheric pressure to which the medical device can be safely exposed
	Indicates the range of humidity to which the medical device can be safely exposed
	Indicates the temperature limits to which the medical device can be safely exposed
	This is an electronic or electrical device. Dispose of this product according to local regulations. This will help to recycle
	Keep dry
	Keep away from sunlight
	Fragile
	Caution! Consult Instructions for Use
	Consult Operating instructions
	Direct current

IPX0	Degree of protection against contamination. Cassini is protected against solid foreign objects of 12,5 mm Ø and greater. There is no protection provided for the ingress of liquid.
	Cassini uses a Class I Laser safety sign
CE 0344	Product conforms with the European Council of Medical Device Directive (93/42/EEC)
℞ ONLY	Prescription only - device restricted to use by or on the order of a physician
MD	Medical Device
UDI	Unique Device Identification
REF	Reference Number

Table 3: Symbols used

2 INTENDED PURPOSE AND INTENDED USE

2.1 Intended purpose

Category	Definition
Intended purpose	Cassini is intended to be used for the diagnosis of corneal abnormalities, as well as planning for refractive and cataract treatments
Medical Use	Cassini measures the shape of the cornea, which can be used in general corneal diagnostics, as well as planning for refractive and cataract treatments
Medical Indications	Cassini is intended to be used on patients suffering from poor vision that may potentially be due to corneal abnormalities or cataracts
Medical Condition	Patients with corneal abnormalities or cataracts
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 or clinical environment (EM (Electro Magnetic) Environment: Home healthcare environment according to 60601-1-2:2014)
Number of applications	Reuse without reprocessing

Table 4: Intended use and purpose

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	Ophthalmologists, Optometrists, Opticians, Ophthalmic Technicians, 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 is necessary. Additional training will be provided after the new software release
Possible restrictions of the user	Not relevant

Table 5: Intended users

2.3 Intended patient population

Category	Definition
Patient age	Not applicable
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 examined using Cassini for its intended purpose
Self-application	Not applicable
Possible patient limitations	Not applicable
Criteria for patient selection	Patients undergoing corneal diagnostics

Table 6: Intended patients

3 CLINICAL BENEFITS

Accurate and precise diagnostic parameters that are used for planning cataract surgery treatment:

- Anterior keratometry values
- Posterior keratometry values
- Total Corneal Astigmatism keratometry values
- Refined Higher Order Aberration display
- Iris images for accurate astigmatism correction during cataract surgery

Optimal corneal diagnostic display:

- Detailed topographical mapping of the cornea
- Relevant corneal shape parameters (e.g., astigmatism, asphericity)
- Posterior corneal measurement

- Screening parameters for corneal abnormalities (e.g. SRI, SAI) allowing for general corneal diagnostics, as well as informed adaptation of refractive treatment plans

4 ESSENTIAL PERFORMANCE AND PRINCIPLES OF OPERATION

4.1 Essential Performance

The essential performance functions are defined as the performance of clinical functions, other than those related to basic safety, where loss or degradation beyond the limits results in an unacceptable risk. Cassini does not have any Essential Performance Functions.

4.2 Principles of Operation

Cassini provides diagnostic information necessary for medical condition evaluation and medical treatment planning. Cassini is a reflection-based corneal topographer that measures the shape of the anterior (front) and posterior (back) surfaces of the cornea using multiple LEDs. Cassini provides feedback on the accuracy of each measurement by a set of quality factors (Focus & Centration).

The front surface of the cornea is measured using a multi-color-coded LED pattern consisting of 679 LEDs (7 blue, 224 red, 224 yellow, and 224 green). The back surface is measured using multiple infrared LEDs ranging from 7 to 35, depending on the Cassini and software version number. Cassini is also optically equipped with white LEDs for background illumination, two aiming lasers to position the cornea correctly in front of the device, and a fixation target for the patient.

Light from the LEDs reflects on the cornea into the optical system of Cassini and is projected on a camera using a set of lenses (Figure 1). The visible LEDs are projected on a color camera, and the infrared LEDs are projected on a mono camera. The position of the LEDs on the camera relates to the shape of the cornea. The shape of the cornea is determined through a algorithm based on tracing rays from the object towards the sensor. Per LED, the shape of the cornea is changed iteratively to match the angle of incidence to the angle of reflection. The back surface of the cornea is measured in the same way using the shape of the front surface in its model, a fixed central corneal thickness, and refraction.

NOTE

A calibration method with a known target (sphere with radius of curvature of 8.0 mm) is used to determine the location of each LED in the object plane. The coordinates of these LEDs (object) are used in the raytracing model. As a result, it is required to keep the calibration tool with its paired Cassini. Regular calibration (at least once a week) is required to ensure measurement accuracy.

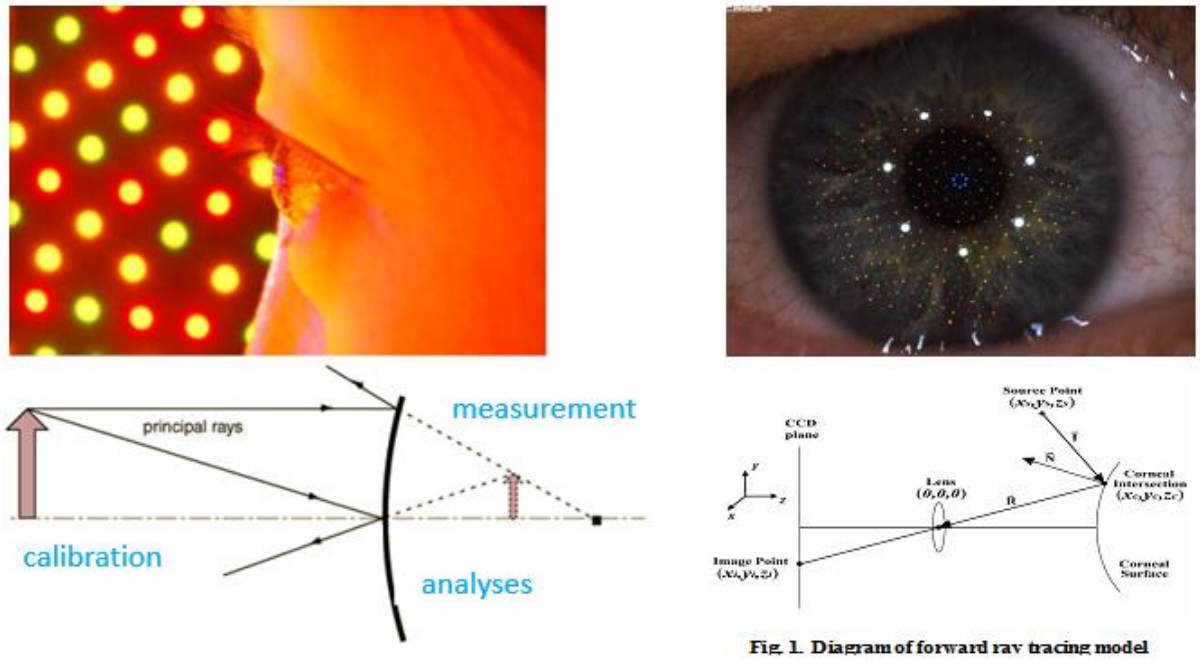


Figure 1: Overview of measurement principles

5 DEVICE COMPONENTS

Cassini consists of a base plate with a head support on top of it and the device. The device consists of a system base with a joystick and an OD/OS detector. On top of the system base is an LED dome (Figure 2)

Figure 2: Cassini main components (your device might look slightly different than pictured above)

The device is powered by a medical power supply and connected to a computer with one USB3.0 cable.

The LED dome consists of 672 color LEDs (green, yellow, and red) and 7 blue LEDs, each located on an LED panel and near the center hole of the dome. Inside the dome is a color camera for capturing an image of the eye with LEDs projected on it.

Radiation details:

Nature, type, intensity, and distribution of applied radiation: Cassini uses two infrared laser diodes, operating at 850 nm. The laser beams project spots on the cornea. Cassini has laser radiation warnings labels indicating that Cassini is a Class 1 laser product and that radiation is emitted from the device.

CAUTION

Use the fixation guard if the device is not directly in use.

With Cassini, :

- Calibration tool (1x)

Also included:

- Cassini User Manual (1×)
- Power supply (1x) for powering the Cassini device
- Power cables (1x*US 2,5m length or 1x*EU 2,5m length)
- USB 3.0 cable (length 3m)
- Medical isolation transformer (1x) (optional)
- Table (1x) (optional)
- Computer (1x) (optional)
- Dry lens cleaning tissues for cleaning the LED panels and the calibration surface
- Dust Cover (1x)

Make sure that after unpacking, all the above standard Cassini parts are included. If not, do not install the device and contact your distributor or Cassini Support.

WARNING

The use of cables other than those specified or provided by the manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

6 RESIDUAL RISK AND CONTRA-INDICATIONS

6.1 Contra-Indications

Cassini does not have any contra-indications.

6.2 Residual Risks

All residual risks have been reduced to Medium or Low or have had risk controls implemented to reduce the probability of occurrence of harm to the lowest levels of “Improbable” or “Remote”. The most severe harmful event could be an electrical shock due to misuse. However, the probability of electrical shock has been reduced to the lowest level of “Improbable”, and the device is designed to comply with applicable safety standards such as IEC60601-1.

7 DEVICE SET-UP

Installation by a technician authorized by Cassini Technologies B.V. is required.

7.1 Unpacking

The unit weighs 15 kg (approx.).

7.2 Inspection

Upon unpacking the unit, check if the package contains all items listed in the section 5 and for any damage. In case of damage, contact your Cassini Support or your distributor. To dispose the packaging material, refer to the instructions provided in the section 17.

7.3 Setup

Check section 7.4 to make sure the mains supply complies with the technical specifications of the device. Check section 7.5 to make sure the environment complies with the environmental conditions for use of the device.

NOTE

Avoid exposure to direct sunlight.

7.4 Device specifications

Mains Voltage	100-240 VAC
Mains Frequency	50/60 Hz
Output Voltage	12VDC
Output current	5A max
Maximum Power	60W
Chinrest movement	Vertical: 55 mm
Maximum load allowed on Chinrest	Max 10kg
Dimensions	44(l)x32(w)x55(h) cm
Weight Cassini Device	15kg
OD/OS	Automatic detection
Color	RAL 9010
Materials used	Type B Applied Parts: ColorRx® PC-2000RX Sabic Lexan HP4

Table 7: Product details

Anterior Accuracy	Type A (according ISO 19980:2012)
Anterior Precision (Power & Astigmatism)	< 0.1D
Anterior Angle of Astigmatism Precision	< 3.0 degrees
Total Corneal Precision (Astigmatism)	< 0.15D
Total Corneal Angle of Astigmatism Precision	< 6.0 degrees
Corneal Coverage Inner Diameter	< 0.5 mm (for RoC of 8mm)
Corneal Coverage Outer Diameter	> 10.0 mm (for RoC of 8mm)

Table 8: Performance data

Medical device Classification	Class IIa, according to Rules 10 and 11 (MDD 93/42/EEC). Class 1, as per 21 CFR 820
Electrical Safety	Class I
Applied parts	Type B

IP classification (Ingress Protection):	IPX0
Laser Product Classification	Class 1
Overvoltage Category	II (2500 V)
Altitude	<2000 m
Pollution degree	2 (non-conductive pollution - office)
Electromagnetic Compatibility (EMC)	CISPR11 Group 1 Class B
Mode of Operation	Continuous

Table 9: Safety and Performance Standards

Minimum computer Specifications	
Processor	Processor Architecture: Intel families Coffee Lake, Alder Lake, Raptor Lake, Arrow Lake Total cores: ≥8 (P-cores + E-cores for hybrid architectures) Base frequency: ≥1.7 GHz
Memory	16 GB DDR4 RAM
Hard disk space	512GB SSD
USB Ports	3 USB Ports (of which 2 must be USB3). *The USB ports are not required to be powered.*
Screen Resolution	1280 x 1024 (HD)
Graphics Card	Intel UHD Graphics 630 or equivalent NVIDIA Card
Software Requirements	
Operating System	Microsoft Windows 11 Pro
Architecture	64 bit
OpenGL Support	OpenGL 2.1
DirectX Support	DirectX 11
Antivirus software	Any antivirus software that is compatible with Windows 11 Pro

Table 10: Hardware and Software specification

Capability SECURITY LEVEL (SL-C) of Cassini	2
IT Security Requirements	
Network	The medical-grade or clinical network protected by firewalls and network access controls. It must operate only within trusted and segmented networks managed by the hospital's IT department.
Recommended Network Connection	See section 9.2 for configuration details. Remote access (if needed for service) must be temporary and secured using MFA-protected channels.
Data transfer	Data transfers (e.g., DICOM or USB) occur within secured HIPAA-compliant environments.
Local Storage	All local data, including the PostgreSQL database, is stored on BitLocker-encrypted drives. Database connections are limited to localhost only.
User Authentication	Access to the Windows operating system and Cassini software is limited to authorized users.

	Local admin credentials are managed by Cassini or disabled when joined to the domain.
Software Integrity	Installation of unauthorized or unapproved software on the Cassini system is prohibited. Only Cassini-approved updates may be applied.
System Hardening	BIOS password protection, Secure Boot, and restricted boot order must remain active.
Logging and Audit	The system relies on standard Windows Event Logging for system activities. Hospitals are responsible for monitoring within their IT policies

Table 11: IT Network requirements for Healthcare provider

For **Declaration of Conformity** for the Cassini or computer when provided by Cassini Technologies B.V., contact qara@cassini-technologies.com

7.5 Environmental conditions

WARNING

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

7.5.1 Operating Conditions

- Temperature: +10 °C to +35 °C
- Humidity: max. 30 to 90%(non-condensing)
- Atmospheric pressure: 800 to 1060 hPa

7.5.2 Storage conditions

- Temperature: -10 °C to +55 °C
- Humidity: max. 10 to 95%(non-condensing)
- Atmospheric pressure: 700 to 1060 hPa

When storing the Cassini, ensure that the following conditions are met:

- Store it in its commercial packaging in a dry, ventilated room and away from sunlight
- Do not store on an uneven surface or in an area where it is subject to vibrations
- Do not store where chemicals are stored or gas may be generated

7.5.3 Transport conditions

- Temperature: -40°C to +70 °C
- Relative Humidity: 10% to 95% (non-condensing)
- Atmospheric pressure: 500 hPa to 1060 hPa
- Vibration, sinusoidal 10 Hz to 500 Hz: 0,5 g
- Shock 30 g, duration 6 ms, bump 10 g, duration 6 ms

When transporting Cassini, ensure that enough padding and protection is used to prevent damage from shock, bump, vibrations, dust, or liquids. If the device is moved and not sufficient protection is provided, the manufacturer is not responsible for any damage.

WARNING

DO NOT install or use the device if the device is broken or the packaging is damaged!

8 TRAINING

During installation, training is provided to the users about the safe use of Cassini. A user can request refresher training. User education level is presumed to be such that they understand the basics of the English language; therefore, a translation of the GUI to their native language is not available.

8.1 Online Training Material

Cassini provides online tutorials on Cassini Academy. The objective of the tutorials is to provide the user with insight into the use of Cassini. The training materials will be updated when required.

- Open your browser and browse to https://cassini.talentlms.com/
- Login using your credentials. If you are a new user, you can request access via support@cassini-technologies.com.
- If you encounter any problems, contact support@cassini-technologies.com

9 INSTALLATION

9.1 Cassini connectivity

 Example of computer connectivity	The computer is connected to Cassini with a USB 3.0 cable.

<table>
<tr>
<td>  </td>
<td>Cassini power supply must be connected to Cassini power cable.
The power supply must be connected to a Protective Earth/earthed mains socket.

The plug and socket provide suitable means for isolation from the supply mains and should be placed in a readily accessible location when needed.</td>
<td>When Cassini is connected to the power supply, the green light on top of the dome is turned on.

  </td>
</tr>
<tr>
<td colspan="3">CAUTION
Be sure to plug the USB cable only in USB ports. Connectors can break, or the computer can be damaged when the wrong ports are used. Reduced performance may be experienced if the USB-cables are placed on the same USB-hub.

CAUTION
Do not connect Cassini to its computer via a powered USB hub. Connection to the Computer is to be established only in a direct manner and with observation of the above requirement.

CAUTION
No USB devices other than Cassini should be attached to computers, as these can potentially affect the combined monochrome camera and color camera views on the GUI when capturing images.</td>
</tr>
</table>

Table 12: Instructions for connectivity

9.2 Network Installation

Cassini is intended to be installed in a hospital or healthcare facility with a secure network environment only. Cassini is connected to the computer where examinations and patient data are stored. Data can be transferred through the hospital network to the servers or PACS, as shown in Figure 3.

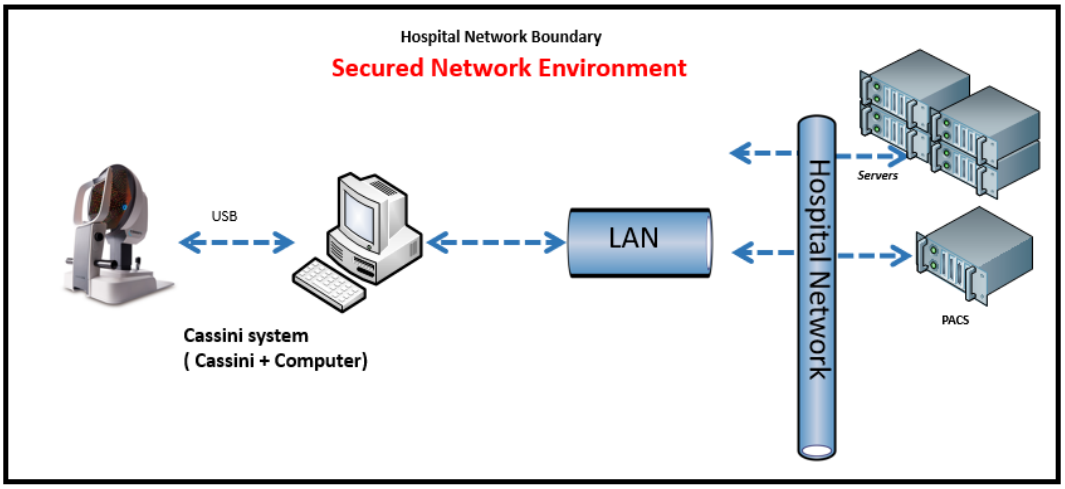


Figure 3: Secure network environment where security measures are in place

NOTE

The capability SECURITY LEVEL (SL-C) of Cassini is 2. It is the responsibility of the organization (Hospital Network Administrator) to configure the SL-T and SL-A required for their network.

WARNING

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

9.3 Software installation

Cassini software is pre-installed on the computer supplied with a Cassini and runs on Windows.

When you receive the device, the system date and time are set to a certain region. If your region is different, you must change the setting in accordance with your region; otherwise, the date and time stamp of the examinations shall contain incorrect information. Refer to the Windows 11 instructions for managing the regional settings.

Starting the Computer

WARNING

Do not touch the computer and the patient at the same time. This is to prevent electric shocks from excessive leakage currents during single-fault conditions.

When you first start Cassini, you will then see the following icon on the desktop:

This is the Cassini application icon. Double-clicking on it will start the application and you will see the main screen (Figure 4).

Figure 4: Main screen

9.4 About Cassini

The 'About Cassini' option in the 'Help' menu will show you a dialog box which shows the version of the software and firmware.

9.5 Terminating Cassini software

Application can be closed by clicking the red 'X' on the top right corner of the main screen (Figure 4).

9.6 Software Licenses

Valid user licenses are required to operate Cassini. These licenses can be obtained via Cassini Support. Every license is valid for a determined period. Users are responsible for monitoring the license's expiration date. Contact support@cassini-technologies.com or your distributor for the renewal.

10 INTEROPERABILITY

10.1 Compatibility

Cassini should not be used in combination with other products or components unless expressly recognized as compatible by Cassini Technologies B.V.. Contact Cassini for more compatibility information: support@cassini-technologies.com

Changes and/or additions to Cassini should be carried out by Cassini or authorized 3rd parties. Any changes and/or additions must comply with all applicable laws and regulations.

11 CALIBRATION

Before you start making scans, the device must be calibrated with the calibration tool delivered with the system. Make sure the device is calibrated at least once a week. If the device has been relocated or moved, calibration before measuring is necessary.

NOTE

To ensure accurate measurements, the device must be calibrated weekly. You will receive a reminder to verify the calibration of your Cassini on a weekly basis.

WARNING

Cassini is supplied with a unique calibration tool. The calibration tool is sensitive to scratches and stains, making it useless for calibration. Handle it with care and store it in the box in which it has been delivered. Do not use the calibration tool to calibrate a system that was not supplied with. Make sure never to touch the calibration surface (stains!) and follow the cleaning instructions carefully if cleaning is necessary. Only take it out of the specially designed box containing foam with a cut-out for the calibration procedure. After calibrating, immediately put the tool carefully in the box again and close the cover to prevent dust from getting in the box. If the surface has fallen from the table or shows scratches, contact your distributor or Cassini Support.

The calibration workflow consists of two parts:

- The workflow used to calibrate your Cassini for the very first time
- The workflow used to verify if your Cassini has been calibrated correctly

11.1 First Calibration

The system must be calibrated with the calibration tool. Remove the original chin rest top. Place the calibration tool in the chin rest module at the height of the eye height indicator.

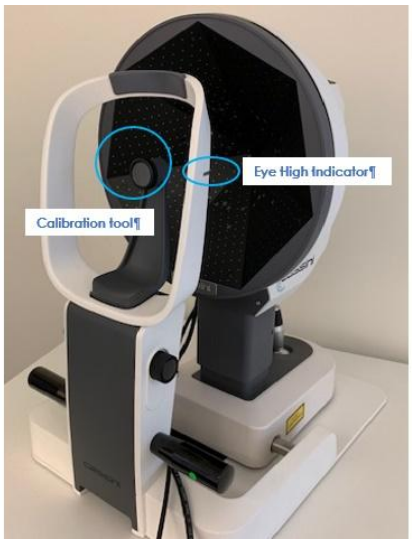


Figure 5: Calibration tool placement

Open the calibration procedure by clicking calibration icon  on the main screen. Click on 'Calibrate device' in the menu. The calibration screen displays two windows. The window on the left shows the livestream images of the color camera, and the window on the right shows the livestream of the monochrome camera (Figure 6).

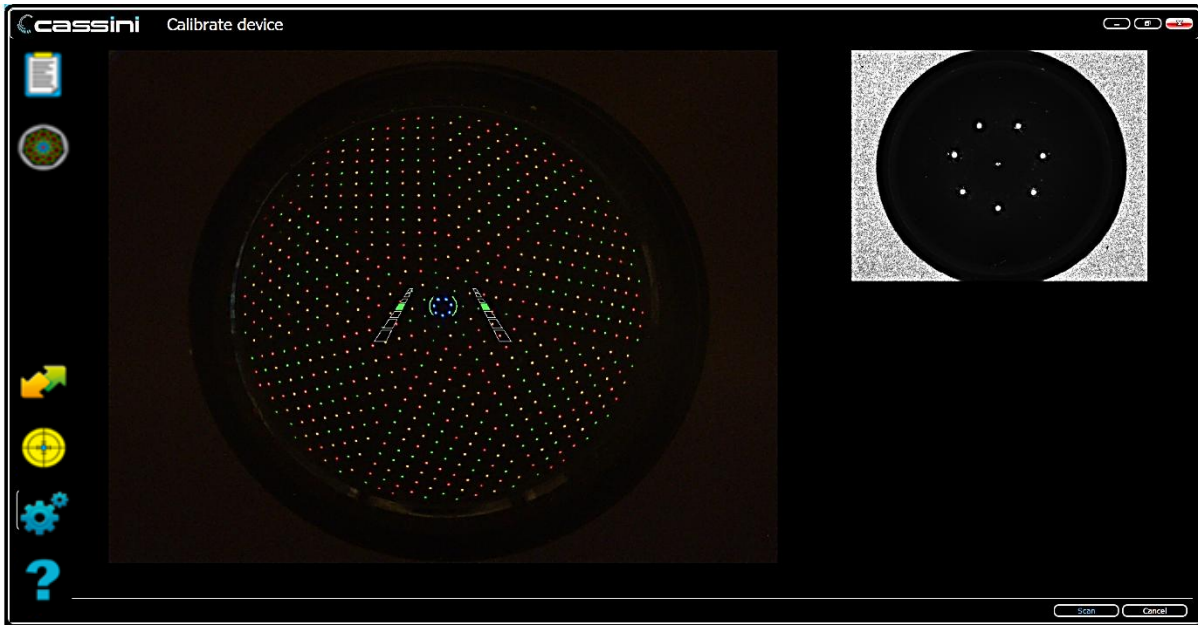


Figure 6: Calibration screen

Move Cassini forward and backward (and left/right) until the colored LEDs reflect from the calibration tool. Due to its sensitivity, we recommend using both hands – one holding the joystick and another fixed on the base (Figure 7).

Figure 7: Positioning Cassini

Alignment of Cassini in front of the calibration tool is correct if (Figure 8):

- The blue LEDs are centered within the blue arcs, and the Centration arcs become green
- The focus rails are green OR – if the rails do not respond to forward/backward movement - the two laser spots on the right image (very faintly visible) are on top of each other

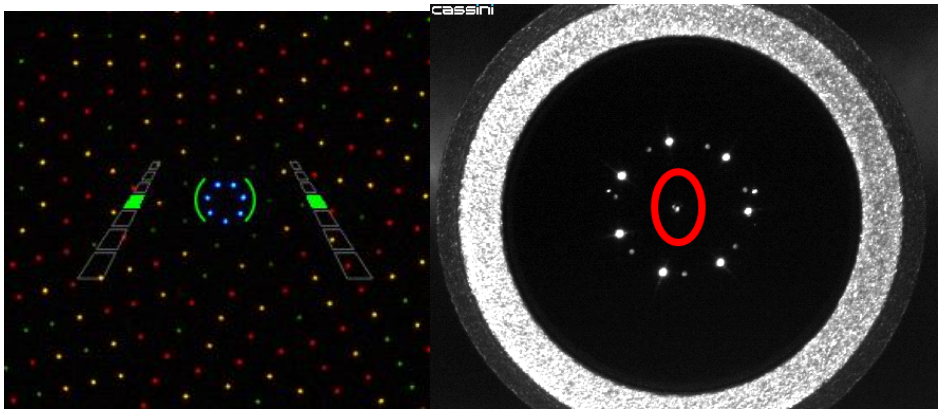


Figure 8: Example of a proper alignment. Note, the red circle on the right window is placed there for clarity only

CAUTION

Be aware that false calibrations will result in inaccurate measurements. Our advice is to calibrate if Cassini has been moved or if you suspect consistently wrong measurements.

Table 13 shows examples of incorrect alignments and recommendations for calibration.

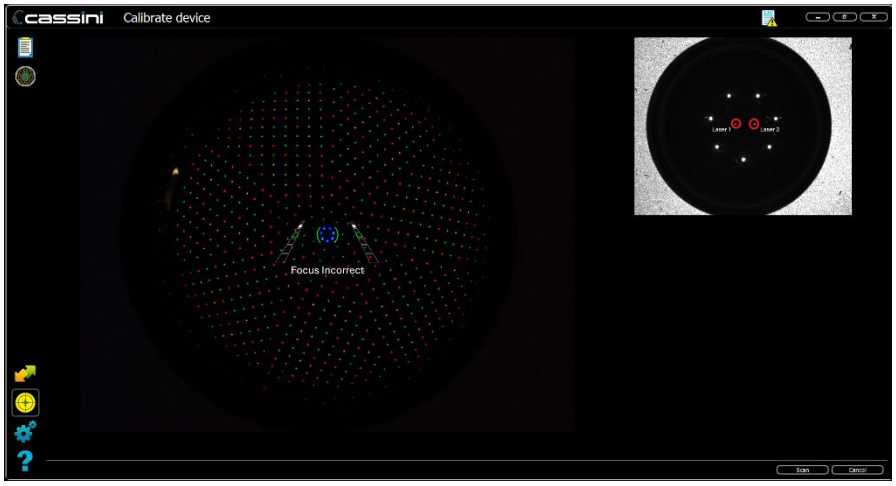
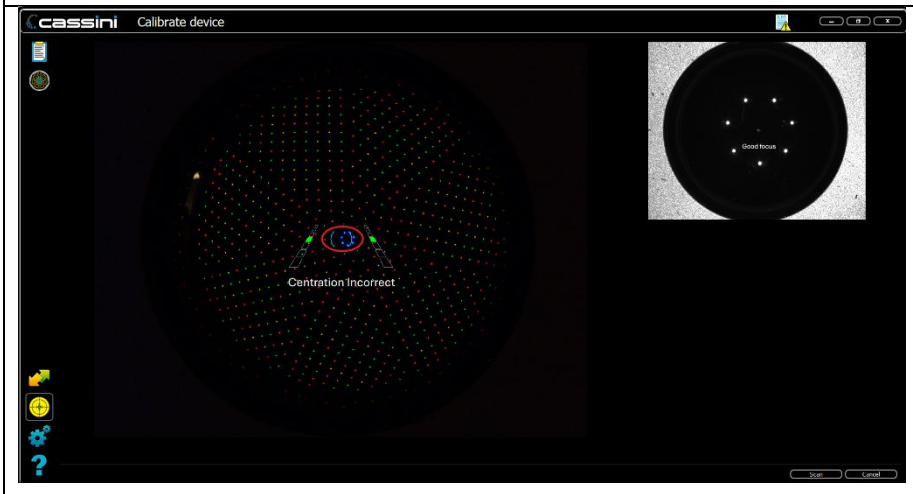
	**Out of focus:** work distance spots are not on top of each other. Move the device more forward/ backward
	**Centration incorrect.** Move the device to the right for proper alignment.

Table 13: Alignment with the calibration tool explained

When the alignment requirements are met, calibration can start by pressing the “Scan” button or the trigger button on the joystick. Then Cassini displays Quality Factors and provides a recommendation to continue or to retake the image (Figure 9)

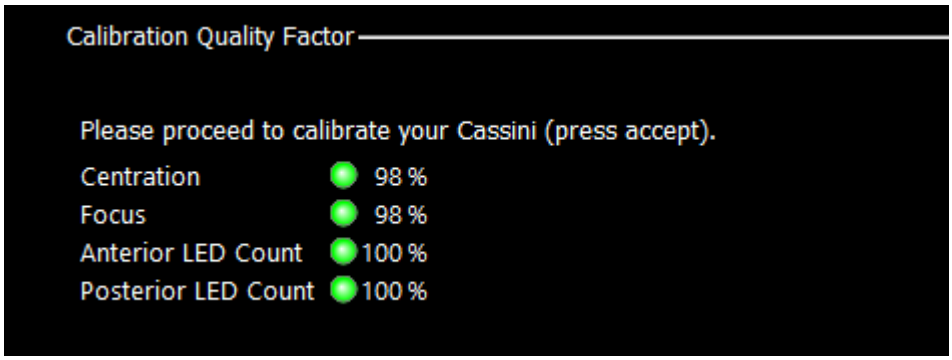


Figure 9: Quality Factors indicators

Accept; then, calibration has been stored.

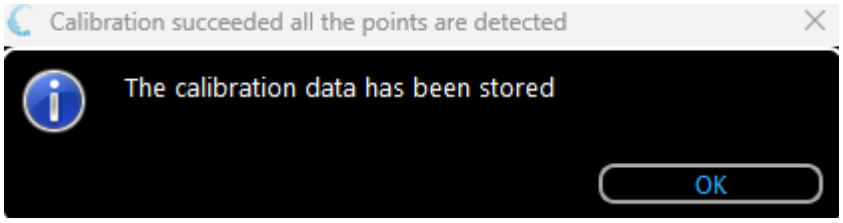


Figure 10: Pop-up indicating that the calibration has been stored

11.2 Calibration verification

The calibration verification workflow will indicate if Cassini has been calibrated correctly. This part of the workflow will only appear if the device has already been calibrated for the first time and/or if the calibration target has potentially been damaged.

CAUTION

Try to relocate Cassini as little as possible; relocation could have a negative impact on the quality of the optical path, which is very sensitive and on which the measurements are being based. Heavy mechanical shocks due to the relocation of the Cassini Device may lead to the displacement of internal components. This may lead to unstable focusing rails and poor timing of the Auto Capture trigger. If this happens, call support for recalibration of your Cassini.

- Repeat steps in the section 11.1
- Instead of storing the calibration data, Cassini provides an overview of the calibration data and verifies if the radius of curvature is correct. Cassini recommends whether calibration should be stored or if any other action should take place (Figure 11)

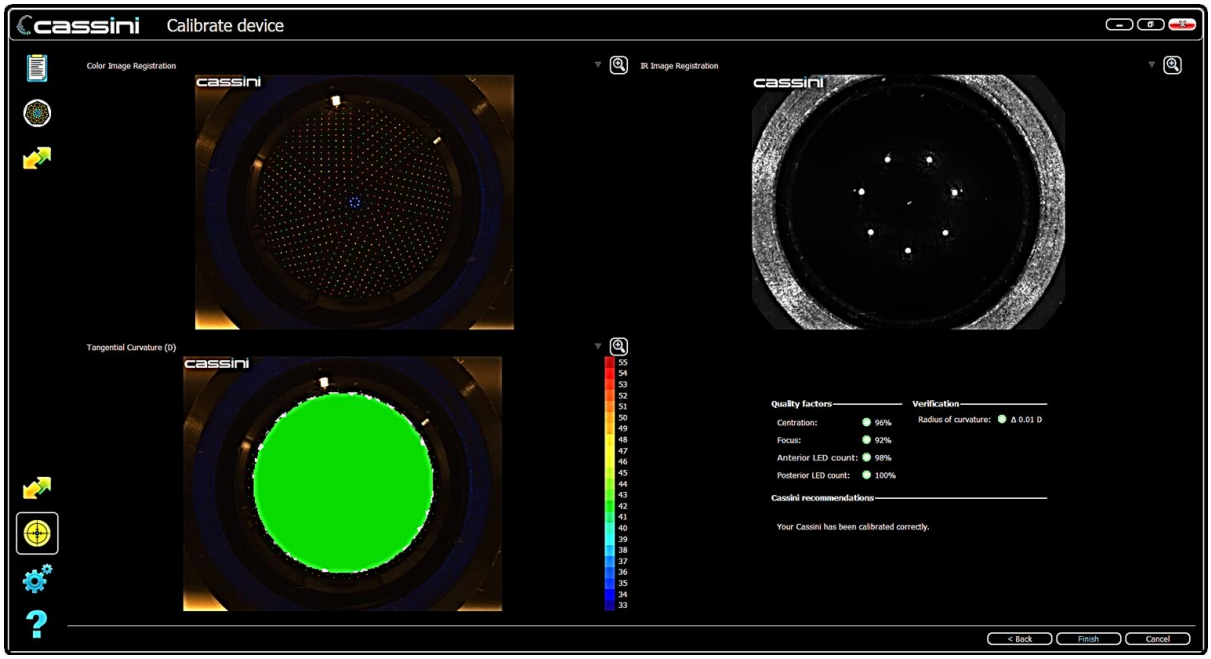


Figure 3: Calibration verification

12 PATIENT MANAGEMENT

By clicking on Management, then on the  patient management icon and selecting patient management, the patient management screen opens, consisting of a patient list (see section 12.1).

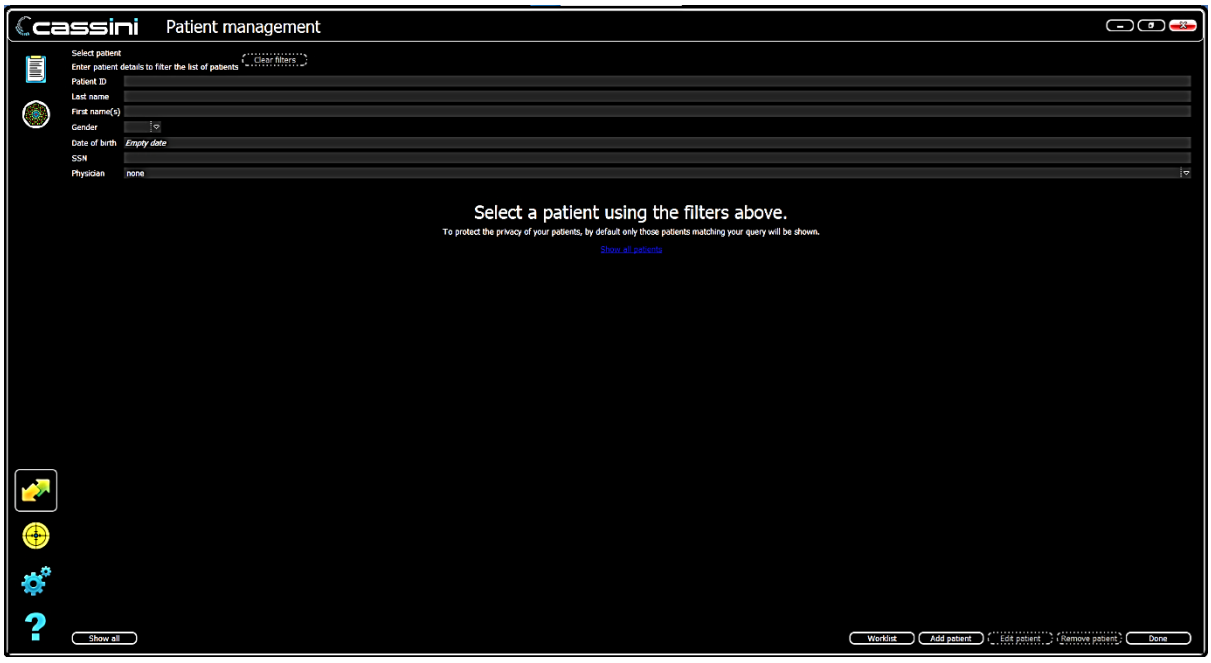


Figure 4: Patient selection

The user can add and delete patients from the list and edit and enter patient data. For privacy reasons, the patient names are hidden by default. Click on *Show Patient List,* and all patient names become available. Refer to the settings to switch the privacy option off.

By clicking on the column labels in the patient list, one can sort the patients. Click “Add patient” to add a new patient. A pop-up will appear in which you can fill out the patient data, such as gender, name, SSN, and more. Obligatory fields (as per active software licenses) are marked by * (see Figure 5).

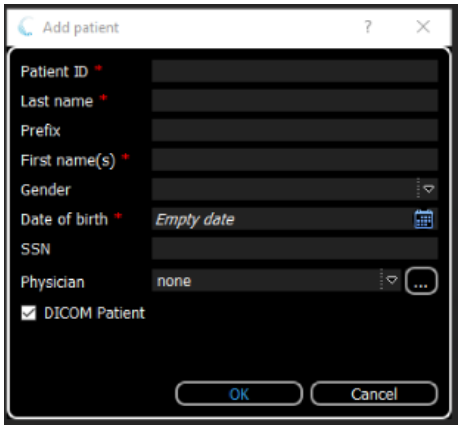


Figure 5: Add Patient menu

Physician management allows you to link the physician to a patient. The physician's name will be displayed on the print layout. By default, the physician name list is empty.

To add a Physician, click on  . The physician manager pop-up will appear (Figure 14). Enter name and code in the correct fields. By clicking “OK”, you add a new Physician to the database. Clicking **Save & Close** memorizes the list and returns you to the patient list.

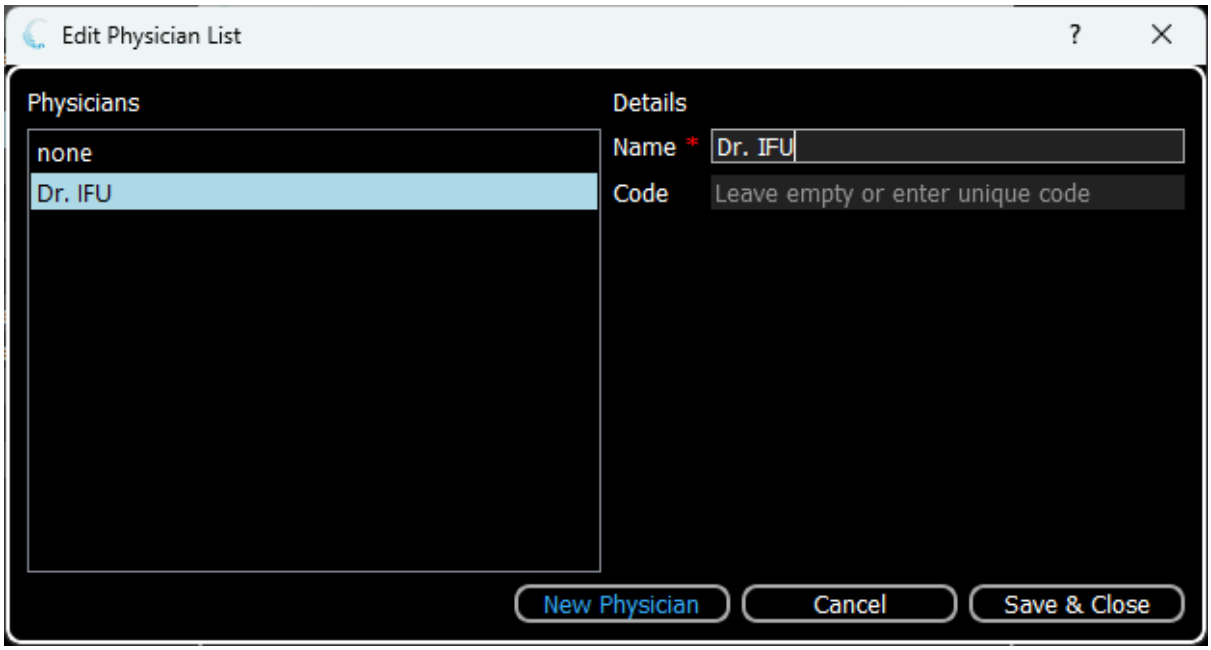


Figure 6: Add Physician menu

By clicking on a patient's name in the list, you select a patient. You can edit its data by clicking on the “Edit patient” or remove the patient from the list by clicking “Remove patient”. If you have finished the patient management, you can return to the main screen by clicking “Done”.

12.1 DICOM connectivity

For the clinics where the DICOM connectivity is available, we can offer a DICOM license. It allows importing patients from the DICOM list and should always be enabled (see Figure 7).

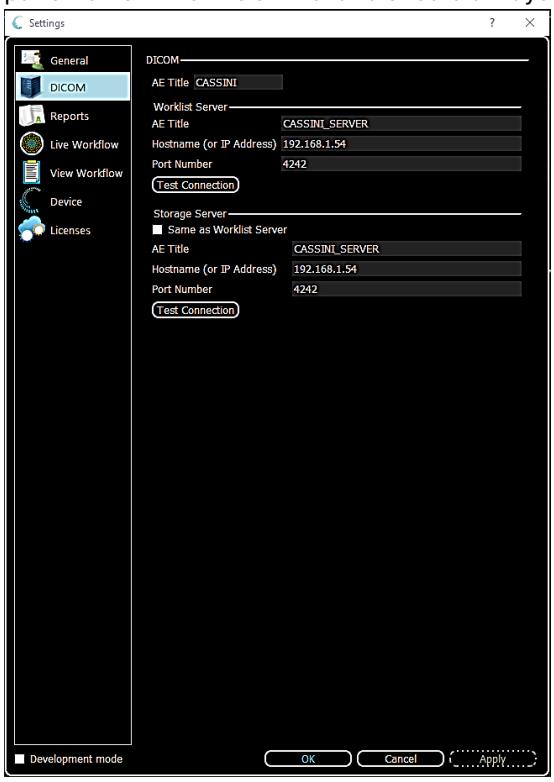


Figure 7: DICOM settings

After the settings are set, it is possible to import a selection of patients or a single patient from the DICOM list. Use the “Worklist” at the bottom of the patient management page.

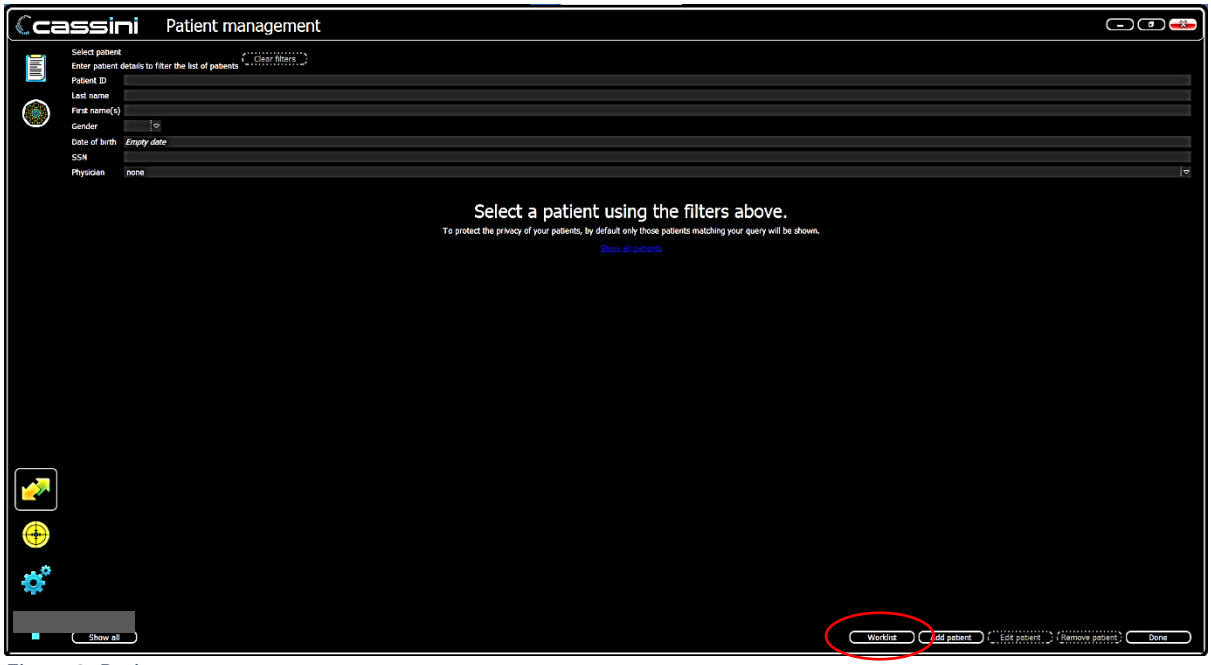


Figure 8: Patient management page

The patient worklist allows selection of the patients to import (Figure 17):

1. Import a selection by date patient list

2. Import the patient scheduled for today
3. Import the complete patient list available in DICOM

Figure 9: Worklist patient

After selecting the date, click "Import List". The "Patients imported" will popup.

12.1.1 Upload patient data to DICOM server

To export Patient data through DICOM, go to View Examination, click on “Report”, select one report to be exported, select the "Send to DICOM", and click “Create and Upload to DICOM server”. After the progress bar is full, the report is uploaded to the server.

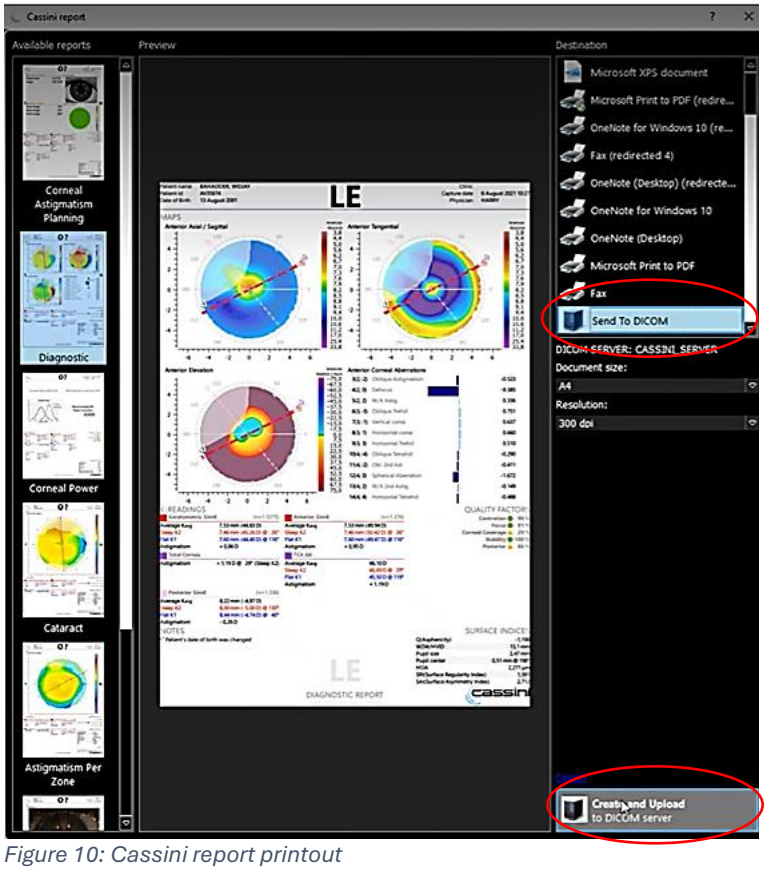


Figure 10: Cassini report printout

NOTE

Patients that will be exported to DICOM storage server must have a valid Patient ID and are flagged as a DICOM patient. This patient ID can only be entered in the Add or Edit patient form (Figure 12)

13 EXAMINATION

WARNING

The accuracy of the examinations is expressed by the Quality Factors FOCUS, CENTRATION, and POSTERIOR (for SMART only).

WARNING

The repeatability of the measurements should be sufficient if ALL Quality Factors are above 85% and if the surface of the cornea is stable. However, circumstances like tear film fluctuations, involuntary movements, micro-saccades, or sudden blinks affect the outcomes of the measurement significantly. Cassini does not control these natural instabilities. Cassini advises users to take 3 measurements per eye to identify the presence of these effects. The Quality Factors STABILITY and CORNEAL COVERAGE help to identify movement and blinks.

When taking an examination, consider the following:

1. Make sure the patient's head is placed correctly in the head support unit
2. Make sure the patient looks at the fixation target
3. Make sure the patient blinks regularly during alignment to ensure optimal ocular surface quality
4. Make sure the patient's eye is opened as wide as possible
5. Avoid unnecessary device movement during acquisitions and ensure the surface on which the device is placed is stable

WARNING

Do not apply external force on the eye when keeping the eye open. This may lead to inaccurate measurements.

13.1 Positioning Patient

Adjust the appropriate height of the chinrest needed for each patient by rotating the right column of the chinrest, see Figure 11.

NOTE

Maximum load that can be placed on the chinrest is 10kg.

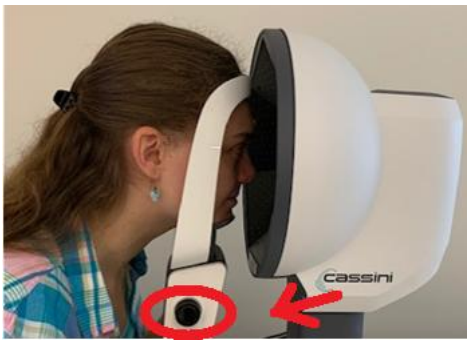


Figure 11: Patient positioning and Chinrest adjustment knob

13.2 Examination Types

NOTE

All examinations are activated through a license key. Contact Cassini Support for more information.

CAUTION

It is advised to inform patients on the measurement sequence to avoid wrong measurements.

Examination Type	High-Level Functionality
SMART	Performed in sequence: • Mesopic scan • Photopic scan • Posterior scan • Anterior, incl. External Ocular Photography scan
Corneal Topography	Measures the shape of the anterior surface of the cornea
External Ocular Photography	Captures a high-resolution color image of the anterior segment
Ocular Surface Visualization	Visualizes the Tear Film Dynamics

Table 14: Examinations

The examinations are shown when clicking the examination icon in the side bar menu.

Figure 12: Examination types

A reminder will be visible when there are installed licenses that are due for renewal.

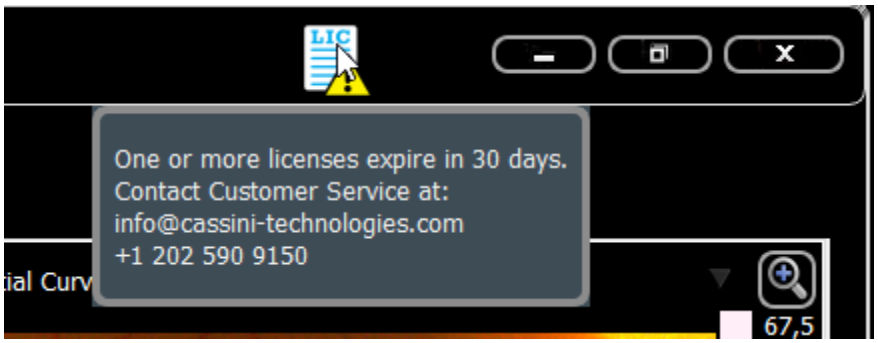


Figure 13: License renewal reminder

13.3 Auto capture

The auto capture functionality is set up to maximize the measurement quality. Manual refinements are required for auto capture to trigger.

Auto capture triggers if the Quality Factors are met: for Focus (Z Axis), Centration (X and Y Axes), and Corneal Coverage, all higher than 85% at acquisition time. When auto capture is triggered, instantaneous acquisition is simulated in the live image, followed by the text notification “auto capture” to indicate successful acquisition. Auto capture functionality is applicable for the SMART and Corneal Topography workflows. It can be enabled from the settings menu (Figure 22):

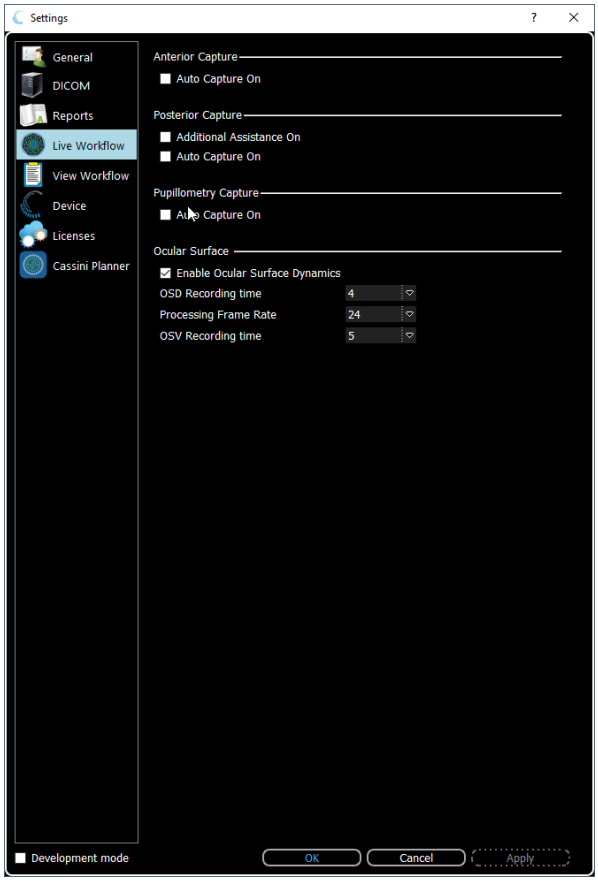


Figure 14: Enable auto capture

CAUTION

Auto Capture does not take movement or the blink sequence into account.. It may be possible that the Auto Capture triggers at an inconvenient movement. Cassini advises qualifying the captured image before accepting it. Movement during the examination is characterized by smeared, elliptically shaped LEDs that point in one/multiple direction(s). The quality of the ocular surface is highly dependent on the crispness/sharpness of the LEDs' reflections.

To get the best result and avoid unwanted movements, it is recommended to utilize auto capture:

1. Between acquisitions, move the device slightly backwards (towards the user, away from the patient) to ensure a good starting position to focus the device

2. Center the camera's view on the patient's eye and adjust the device so that the ring of blue LEDs appears in the center of the patient's eye. Every time the blue arcs turn green, the device is centered, and the CENTRATION condition of Auto Capture is met

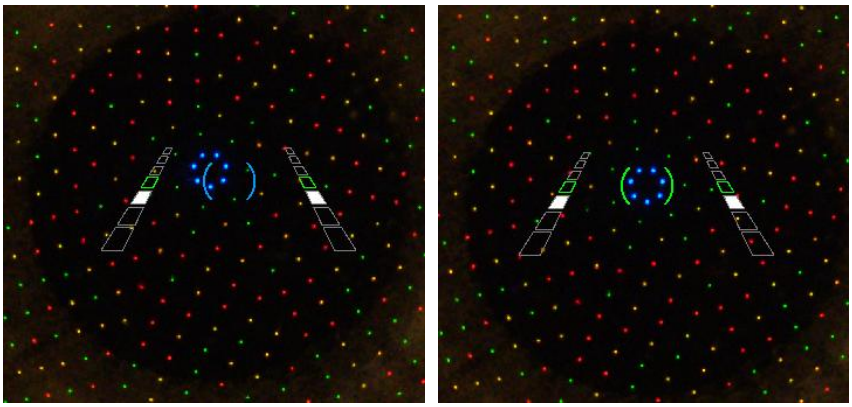


Figure 15: Centration for auto capture (left: not centered; right: correctly centered)

3. Slowly move the device forward and backward as needed until the focus rails become active (white squares are visible). When the white squares fill the green rectangles in the focus rails, the FOCUS condition of Auto Capture is met

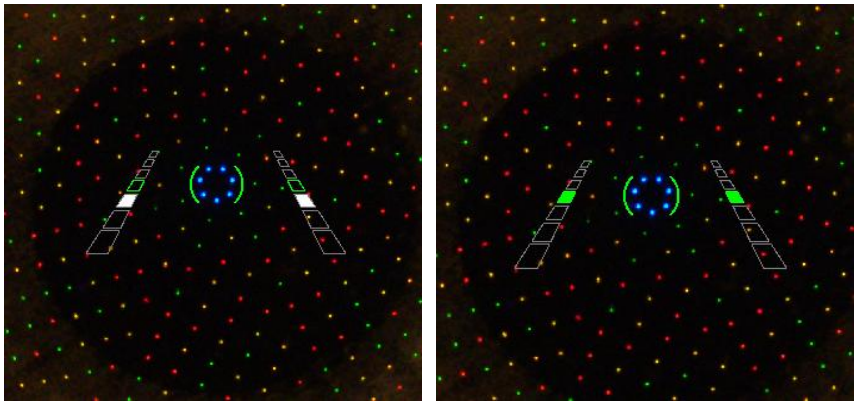


Figure 16: Focus for auto capture (left: out of focus, right: correctly focused)

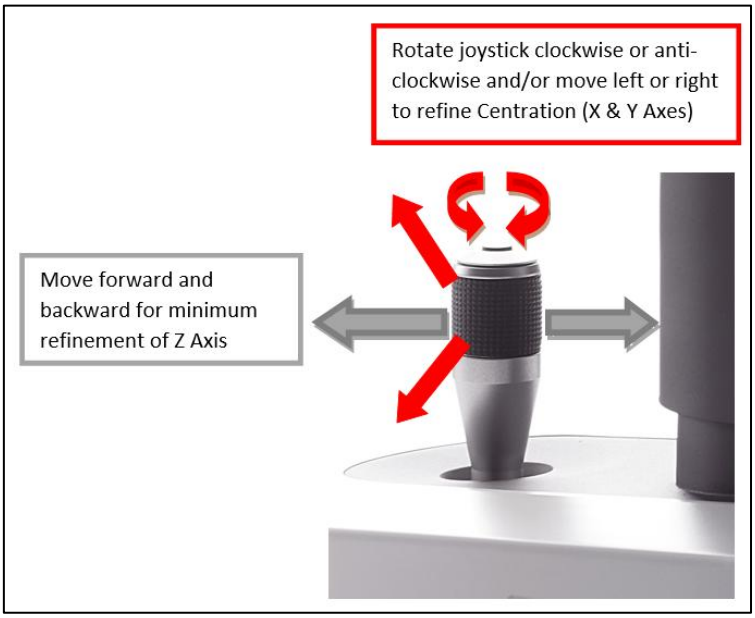


Figure 17: Joystick movement description

4. Ask the patient to blink and open their eyes wide

5. Fine-tune alignment, first Centration, then Focus until the auto capture initiates
6. The user needs to inspect all Quality Factors and click the joystick button to accept the acquisition. The topographical reconstruction of the images and parameters display will follow after accepting the acquisition

13.4 Quality Factors

The Quality Factors help users to judge if the data from the captured examination is accurate. Focus, Centration, and the Corneal Coverage affect the accuracy of the measurement. The Focus and Centration Quality Factors are directly related to the measurement accuracy.

If the Quality Factors vary significantly (more than ~30%) between measurements, or if the corneal surface changes, repeatability decreases. Variation in readings may result from tear-film instability, eye movements (micro-saccades), or physiological factors such as heartbeat. The tear film is particularly unstable immediately after a blink or during tear film break-up, which can distort measurements. Artificial tears and other topical eye drops may also alter results and should be used with caution before imaging.

The Quality Factors are:

Focus	Related to the distance between the cornea and Cassini and represented by the alignment rails. Also, optically known as the Z-axis
Centration	Related to the in-plane (enface) position of Cassini in front of the eye. This alignment is represented by the position of the blue LEDs within the blue arcs and the white arcs in the SMART workflow. Also, optically known as X-Y Axes
Corneal Coverage	Related to the number of LEDs present on the cornea within the area of the white LEDs
Stability	Related to any movement present during the image acquisition
Posterior	Related to the number of LEDs detected

Table 15: Quality factors

NOTE

The Posterior Quality Factor is only available if the SMART workflow has been activated.

The following rules apply to all anterior Quality Factors (Focus, Centration, Coverage, Stability):

1. GREEN CIRCLE QF ≥ 85%
2. ORANGE TRIANGLE QF < 85%

The Posterior Quality Factor only turns GREEN at 100%.

13.5 SMART

The SMART workflow comprises the following:

1. Mesopic scan
2. Photopic scan
3. Posterior scan
4. Anterior [incl. External Ocular Photography] scan

To acquire SMART, follow the next steps:

1. To start an examination, click “SMART”
2. Select or Add a Patient as described in the section 12

Image capture:

1. In the SMART workflow, the image capture can be performed via Auto Capture or through manual capture
2. If Auto Capture is enabled, position the device close to the user and move forward to the patient's eye until the Auto Capture is triggered. Refer to section 13.3 for more information
3. If manual capture is enabled, Ask the patient to blink a few times and open their eyes wide

Click the joystick button when:

1. Focus rails and arcs are green
2. 7 white lights are sharp

Press "Accept" or click the joystick button and proceed to the next workflow within SMART.

13.5.1 Mesopic Scan

1. In the large window, Cassini shows the live stream images from the mono camera. Align Cassini in front of the eye and ask the patient to look at the red fixation target in Cassini.

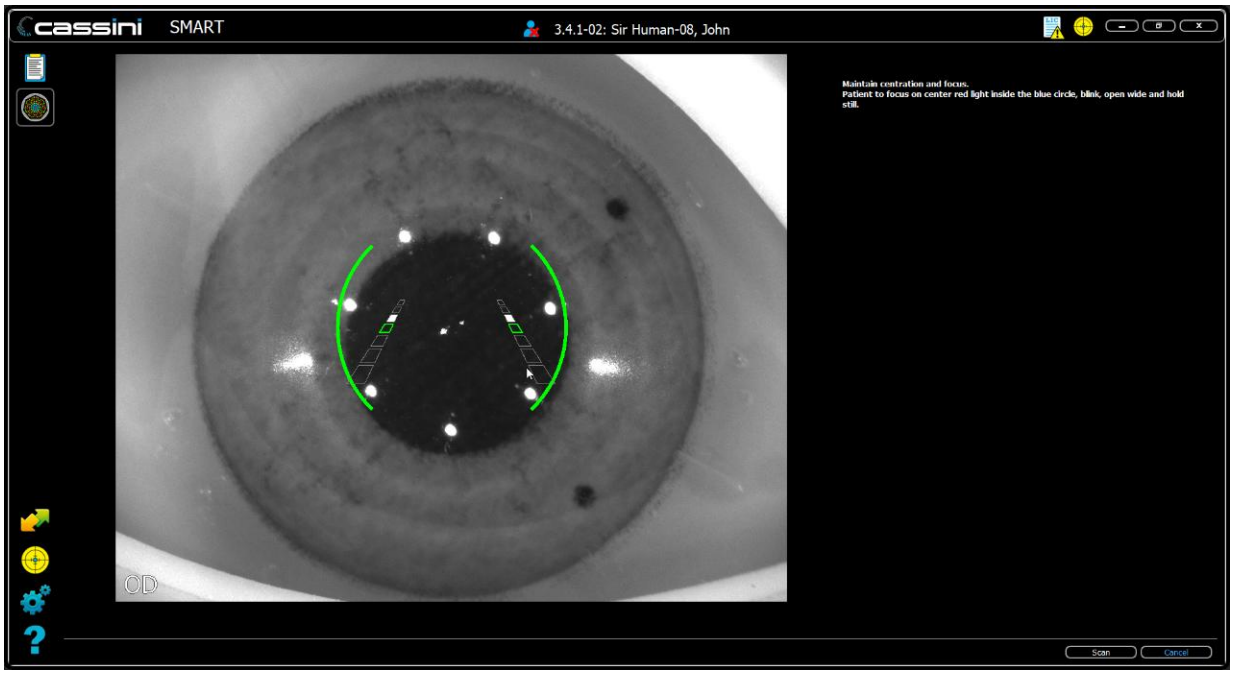


Figure 18: Live view of Mesopic scan

2. Capture the image either through Auto Capture or manually via the joystick
3. Proceed to Photopic if the image Quality Factor is green. If not, retake the acquisition
4. The results are displayed as shown in Figure 28

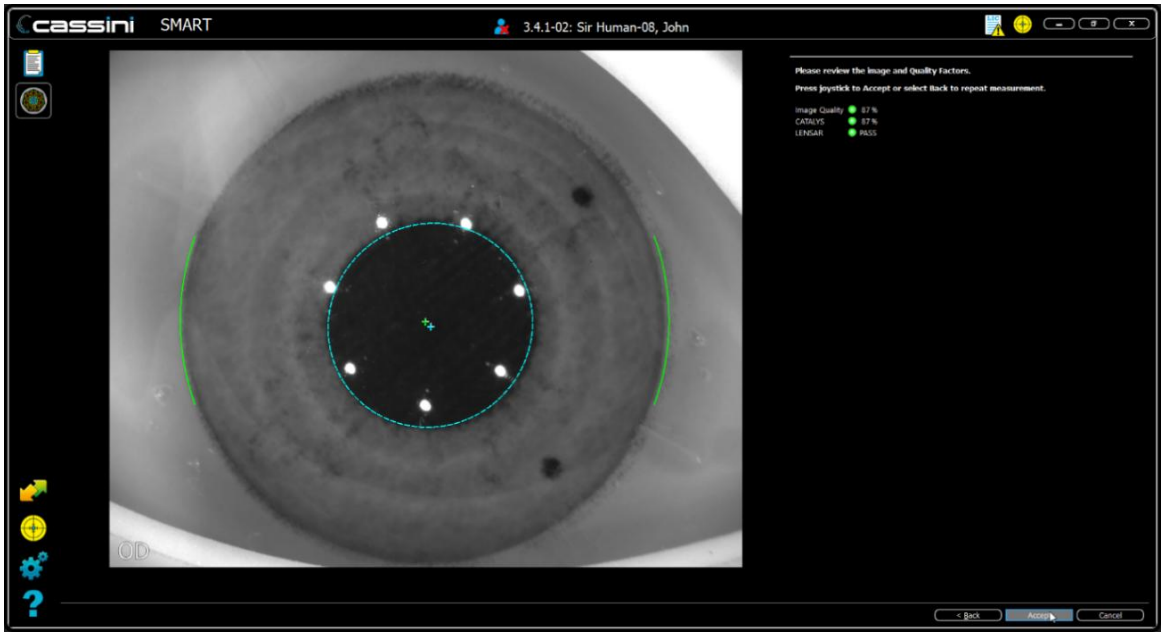


Figure 19: Results of Mesopic

NOTE

If you have Femtosecond Laser licenses installed for third parties such as CATALYS or LENSAR, then the mesopic will calculate quality factors of those devices. If LENSAR fails, the user will be able to continue after the 3rd attempt, provided the CATALYS quality factor remains green.

13.5.2 Photopic Scan

1. The patient should focus on the red fixation target in the center of the LED dome
2. Capture the image either through Auto Capture or manually via the joystick
3. Proceed to Posterior if the image Quality Factor is green; if not, retake the acquisition

Figure 20: Live view of Photopic

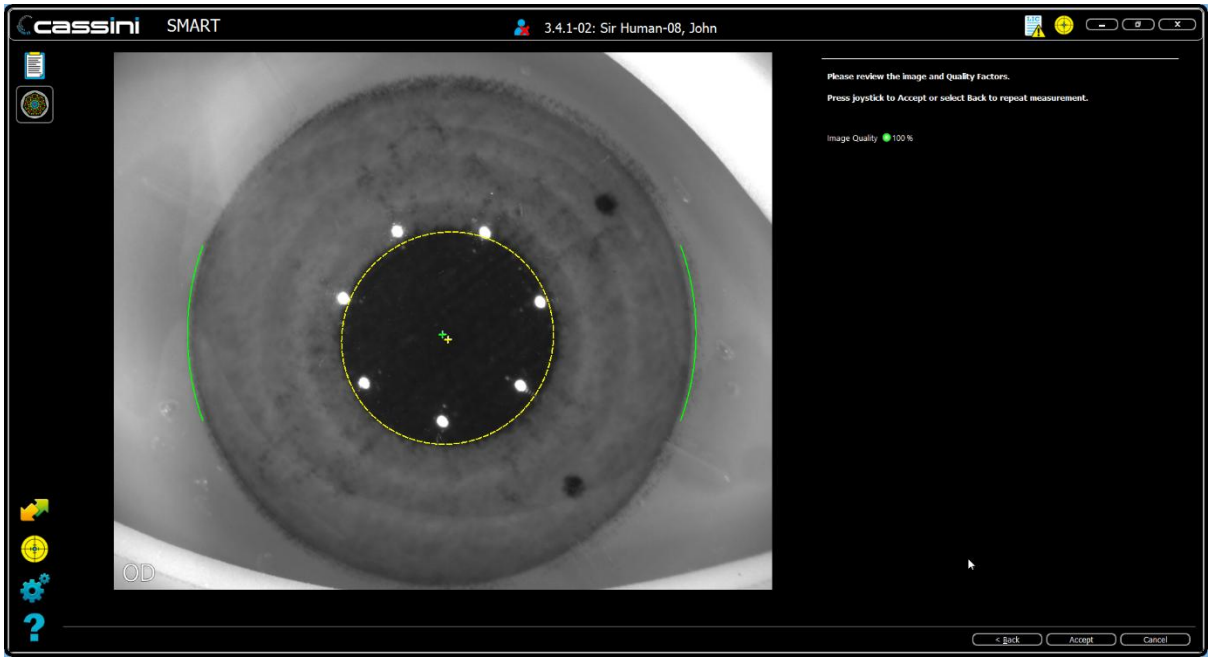


Figure 21: Results of Photopic

NOTE

Cassini advises asking the patient to blink, open their eyes, and sit steady before scanning.

13.5.3 Posterior Scan

1. Align Cassini in front of the eye and ask the patient to look at the red fixation target. The alignment is correct if the setup is as per Figure 31.

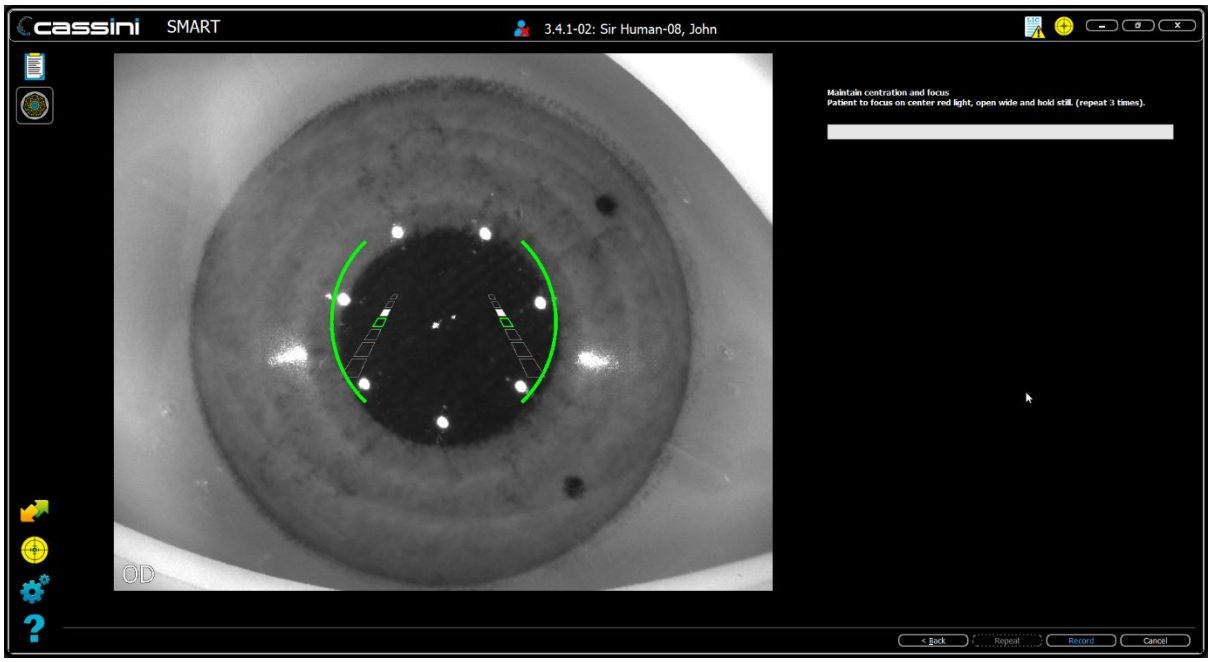


Figure 22: 7 white reflected IR LEDs are visible and not blocked by the nose or eyebrows. Focus rails must be green

NOTE

During the capture, the patient should sit still and avoid blinking.

2. After the first capture, Cassini will go back into live mode, and the user will have to repeat the steps minimum two times in a row. The progression bar will fill up once a new capture has been made

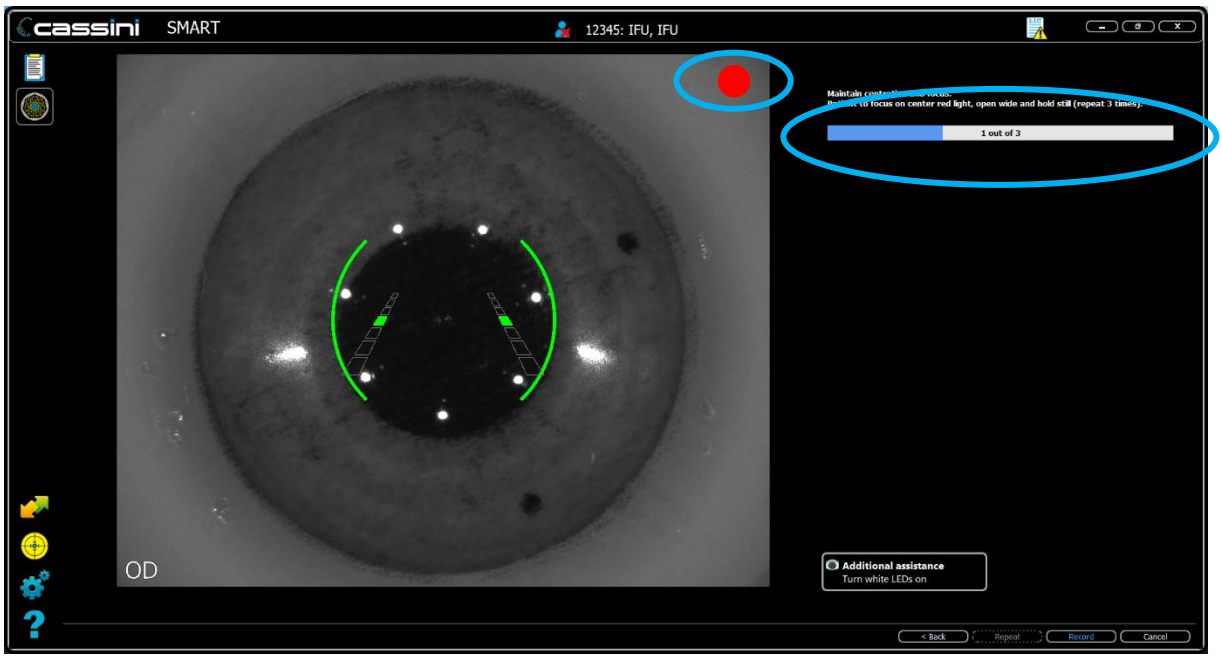


Figure 23: Image Capture

3. After 3 consecutive posterior captures, Cassini will process the information and provide feedback on the quality of the examination.

NOTE

Cassini recommends repeating the measurement until a posterior Quality Factor of 100% has been achieved to ensure accurate measurements.

The posterior Quality Factor is affected by:

1. Low LED count due to shadowing effects (must see all 7 LEDs during capture)
2. Pupil edge covers the faint reflections for the posterior surface
3. Movement and blinks
4. Severe misalignment

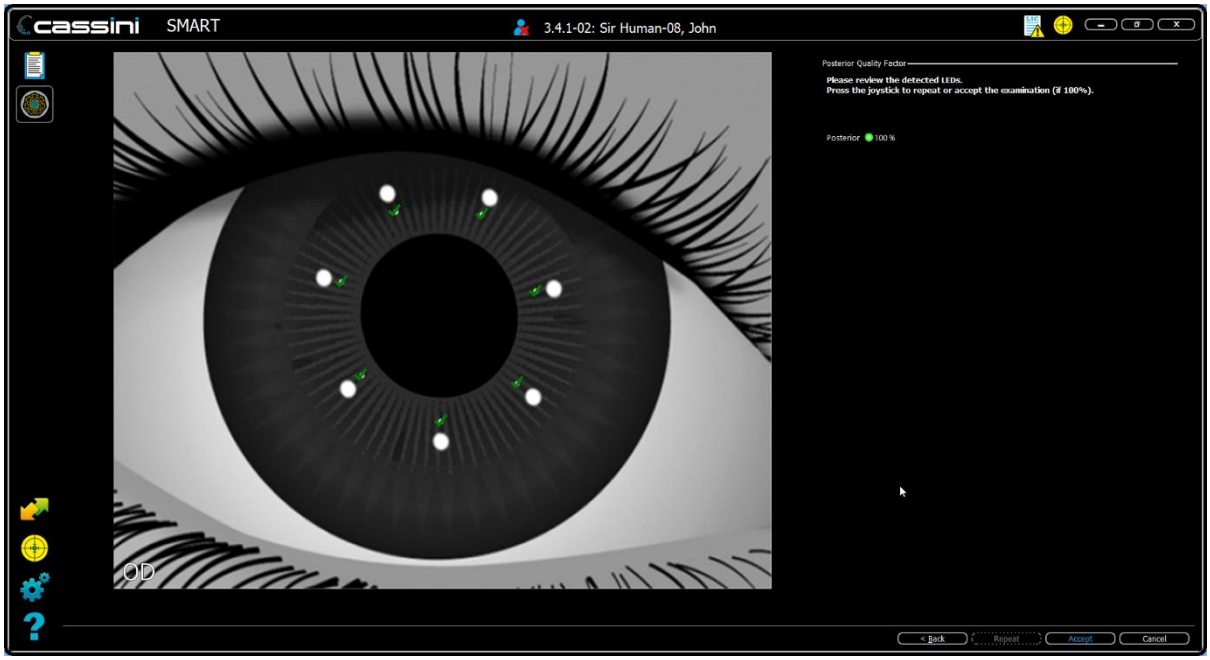


Figure 24: The Result page is shown after the first three (3) captures. A green checkmark indicates a P2 reflection has been detected. If a red cross is available, it indicates the P2 reflection is missing.

If P2 reflections are missing (see Figure 33), also indicated by a Quality Factor lower than 100%, the user can add more captures by pressing the joystick button or by pressing “Repeat. During live view, the user can focus on the missing P2 reflection: ask the patient to blink and open their eyes widely until the P2 spot appears.

NOTE

Visibility of the 2nd Purkinje reflections may vary due to blinks and pupil size.

NOTE

A maximum number of 12 posterior captures can be made.

Sometimes the measurement fails because the faint reflections from the posterior surface (2nd Purkinje image) overlap with the pupil edge. The software will display: "The recommendation is to turn the white lights ON for this patient." This option will force the pupil to a smaller size. “Additional assistance Turn white LEDs on” can be turned on automatically in settings.

13.5.4 Anterior Scan

1. Ask the patient to blink a few times and open their eyes wide for the anterior image capture
2. Capture the image either through Auto Capture or manually via the joystick

NOTE

It is advised to ask the patient to blink, open their eyes, and sit steady before scanning.

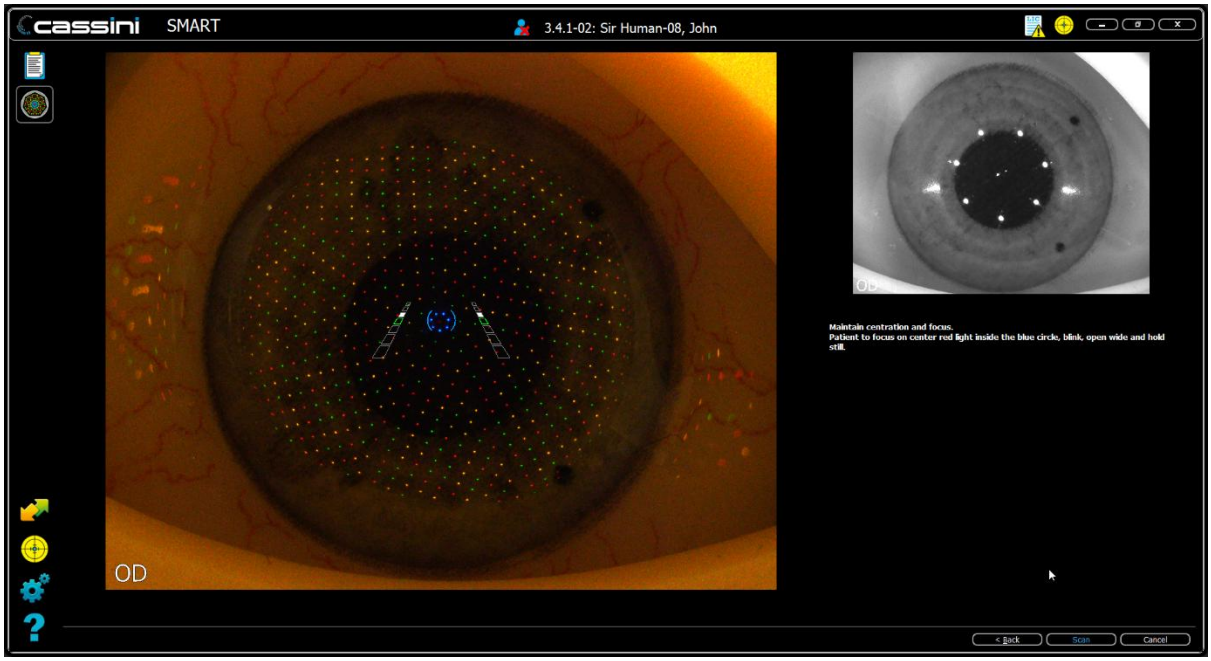


Figure 25: Live view of Anterior

3. After anterior acquisition has been completed, the Quality Factors can be reviewed before proceeding

NOTE

In some patients it might be difficult to trigger auto-capture. In such case, manually click the joystick button for acquisition. Click "Back" to retake the acquisition if necessary.

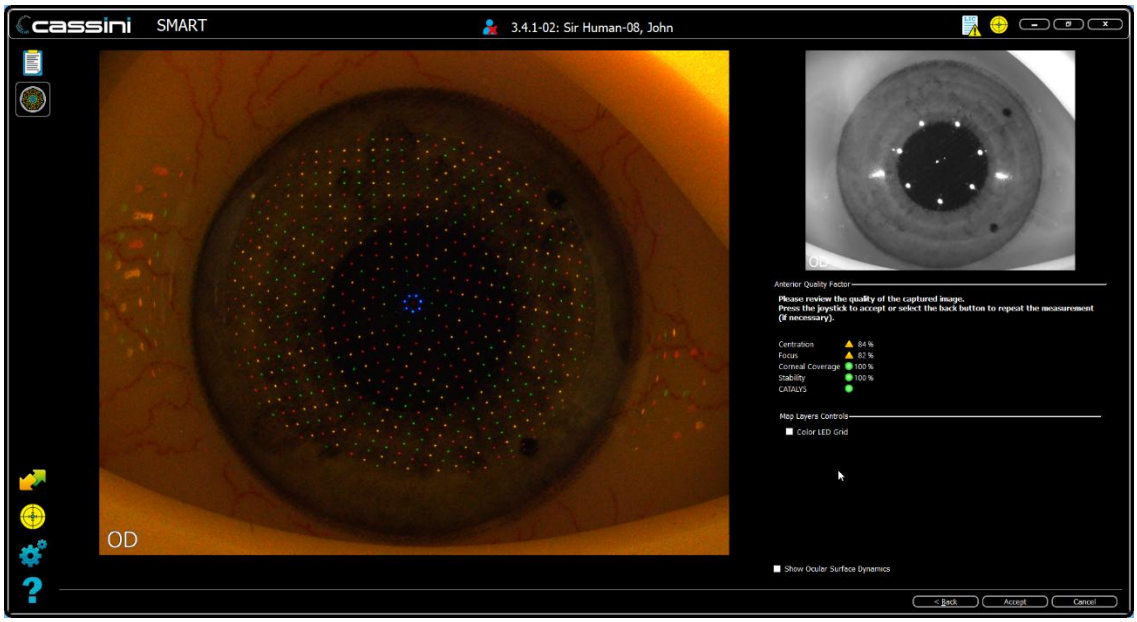


Figure 26: Results of Anterior

4. Click "Accept" ONLY if all the QF are in green

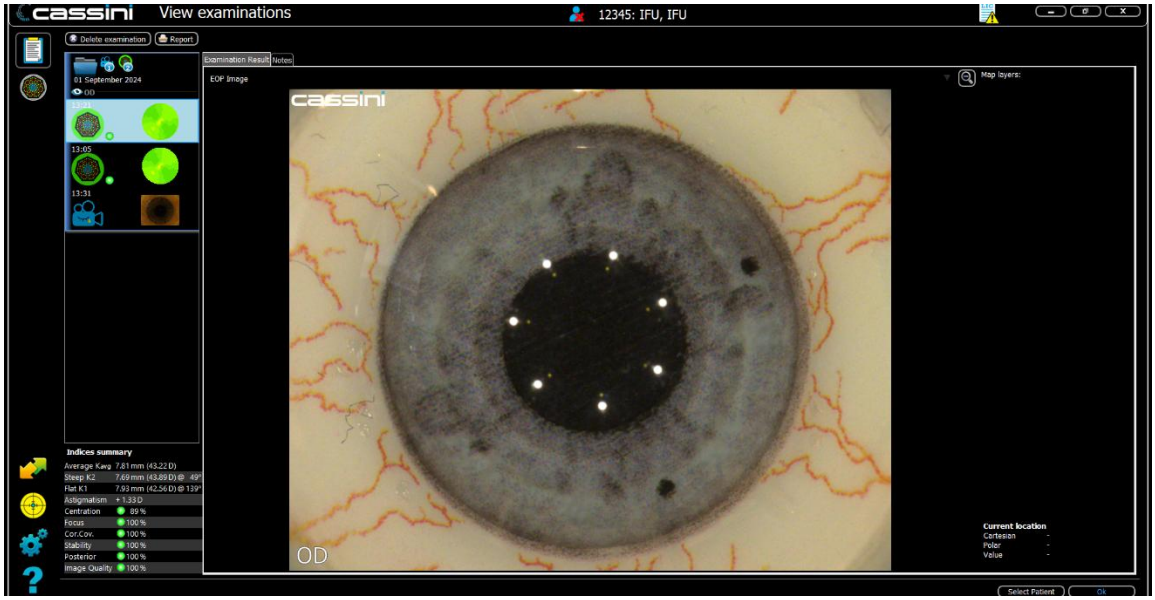


Figure 27: Result SMART examination (1-Up)

The user can switch to the 6-Up view as Figure 28.

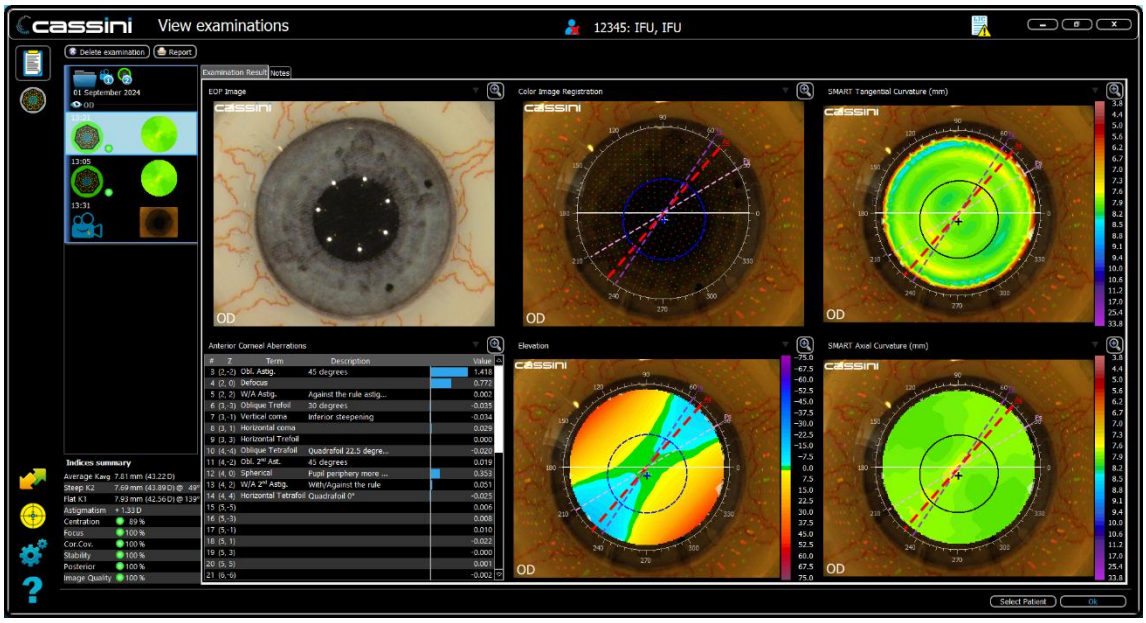


Figure 28: Result SMART (6-Up)

Based on images captured, the user can create reports and print them out (see Figure 38).

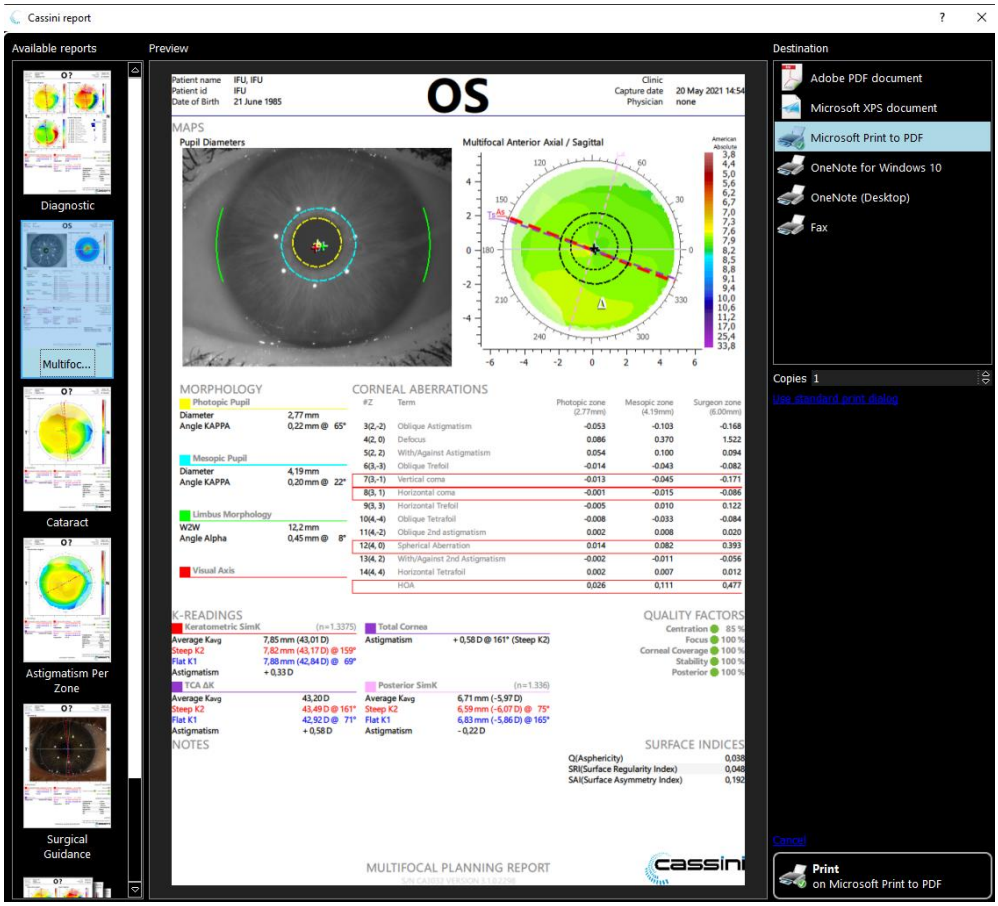


Figure 29: SMART report

13.5.4.1 Ocular Surface Dynamics

This feature is available in SMART anterior acquisition by enabling the option in the Settings page.

The Ocular Surface Dynamics (OSD) provides a quick 2-second recording so that the surgeon can understand more about the stability of the tear film. After the anterior acquisition has been completed, you can review all the Quality Factors before proceeding.

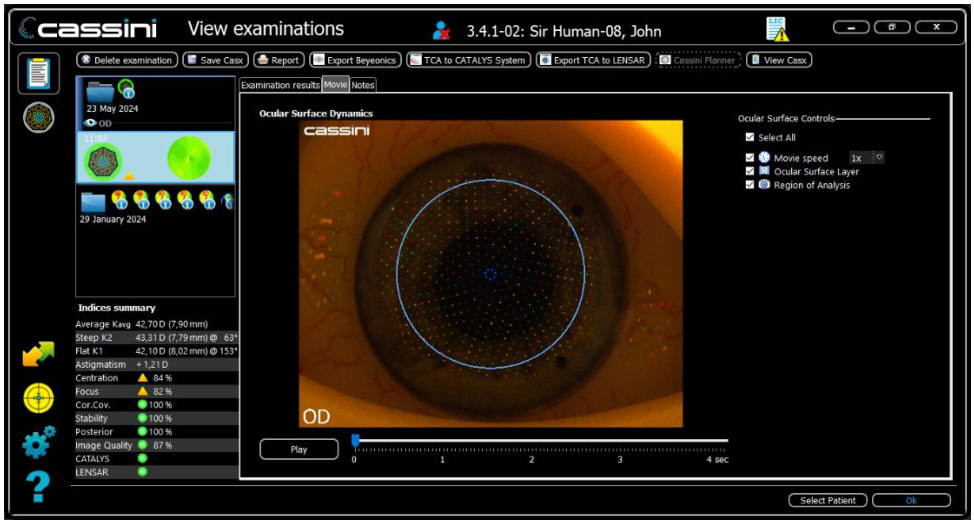


Figure 30: OSD Results

13.5.4.2 External Ocular Photography (EOP)

This feature within the SMART anterior scan allows the user to capture high-resolution images of the anterior segment of the eye. The difference between SMART EOP and the separate EOP examination is the image field of view. The field of view is larger for the separate EOP examination.

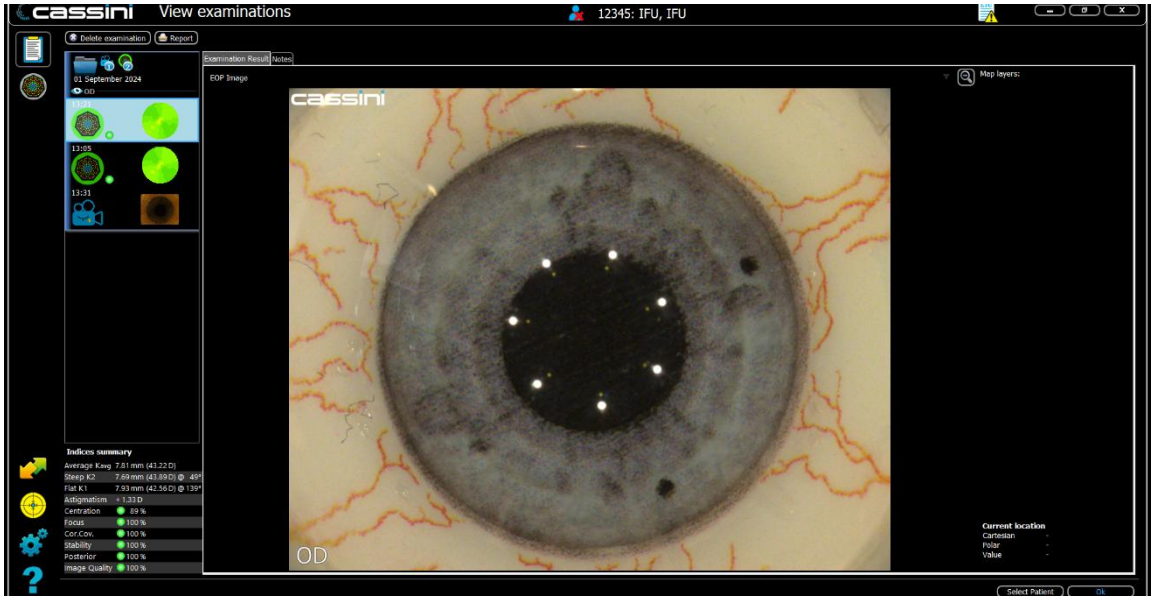


Figure 31: Result SMART EOP

13.6 Corneal Topography

Corneal Topography measures the shape of the anterior surface of the cornea using color LED technology.

To acquire Corneal Topography, follow the next steps:

1. To start an examination, click “Corneal Topography”
2. Select or Add a Patient as described in the section 12
3. In the large window, Cassini shows the live stream of the color camera, and in the small window, the live stream of the mono camera. Align the Cassini in front of the eye and ask the patient to look at the red fixation target. Alignment is correct if you meet the following criteria:
    - Focus Rails must be green – placing the laser spots on top of each other (small window)
    - Centration Arcs must be green – Blue LEDs should be placed inside the arcs
    - All 7 white LEDs must be visible (small window)
4. Capture the image using auto capture, the joystick button, or the “Scan” button.
5. After the triggering, the captured image is shown together with an initial Quality Factor indicator (Figure 42)
6. Click accept with the mouse or use the joystick to confirm the measurement. The results are displayed as shown in Figure 43
7. By pressing the joystick again, Cassini will go into live mode for a second examination (OS/OD)

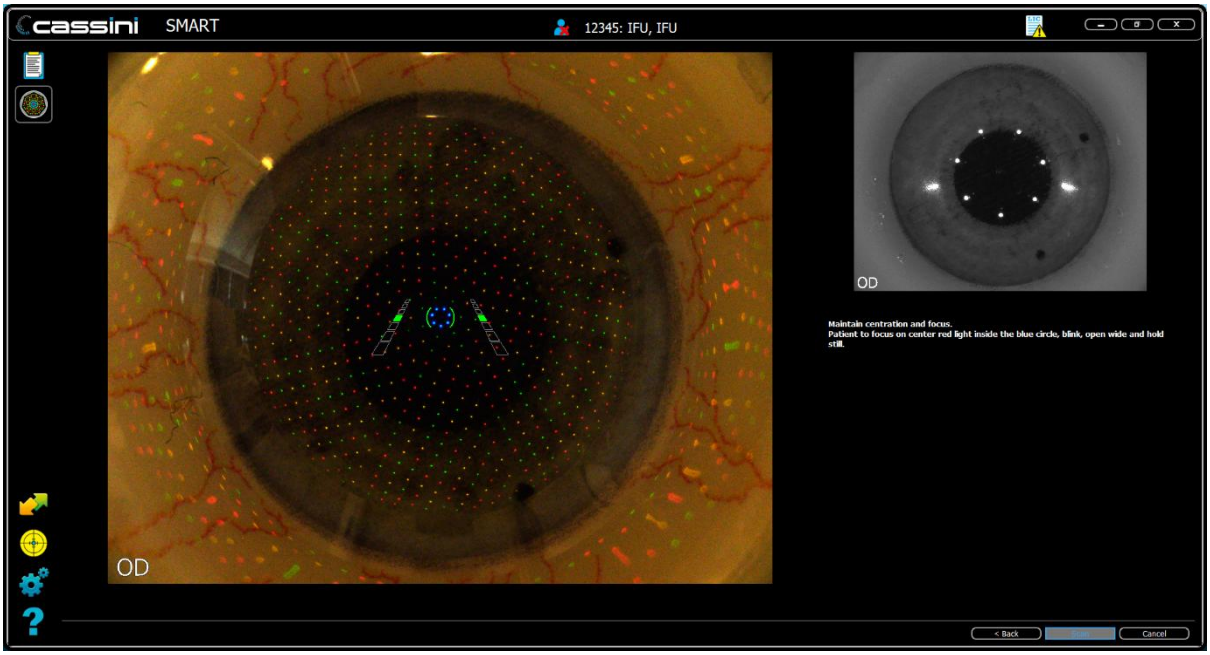


Figure 32: Good alignment (Focus, Centration, and Coverage)

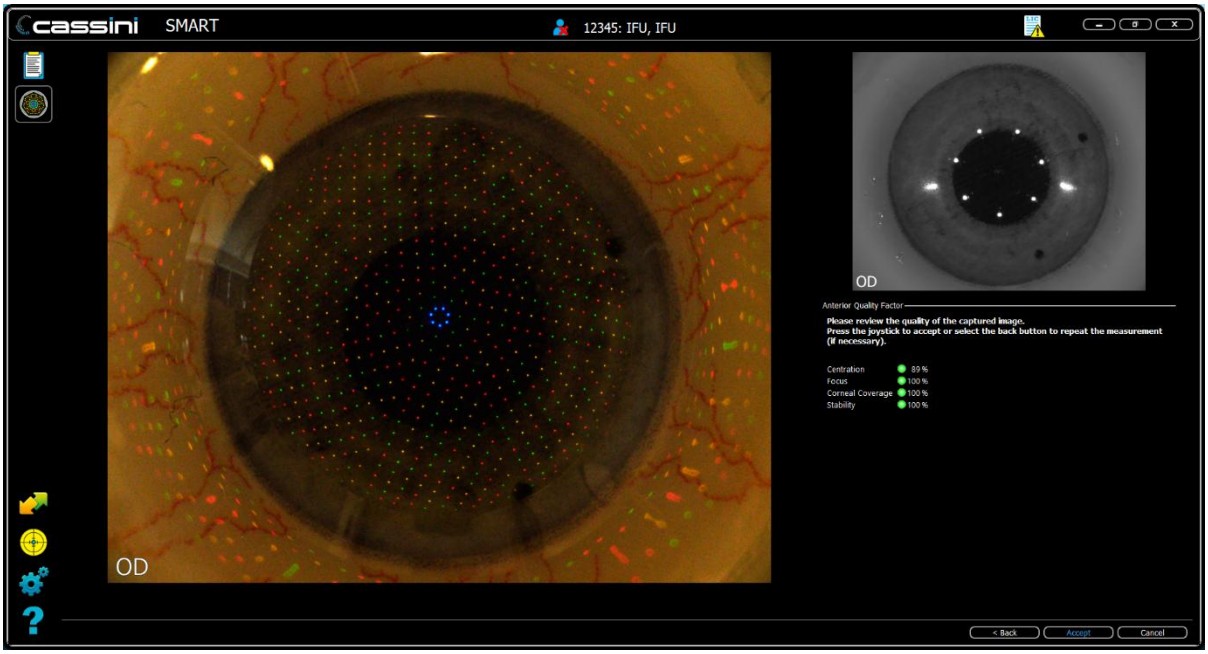


Figure 33: Capture with Quality Factor indicator

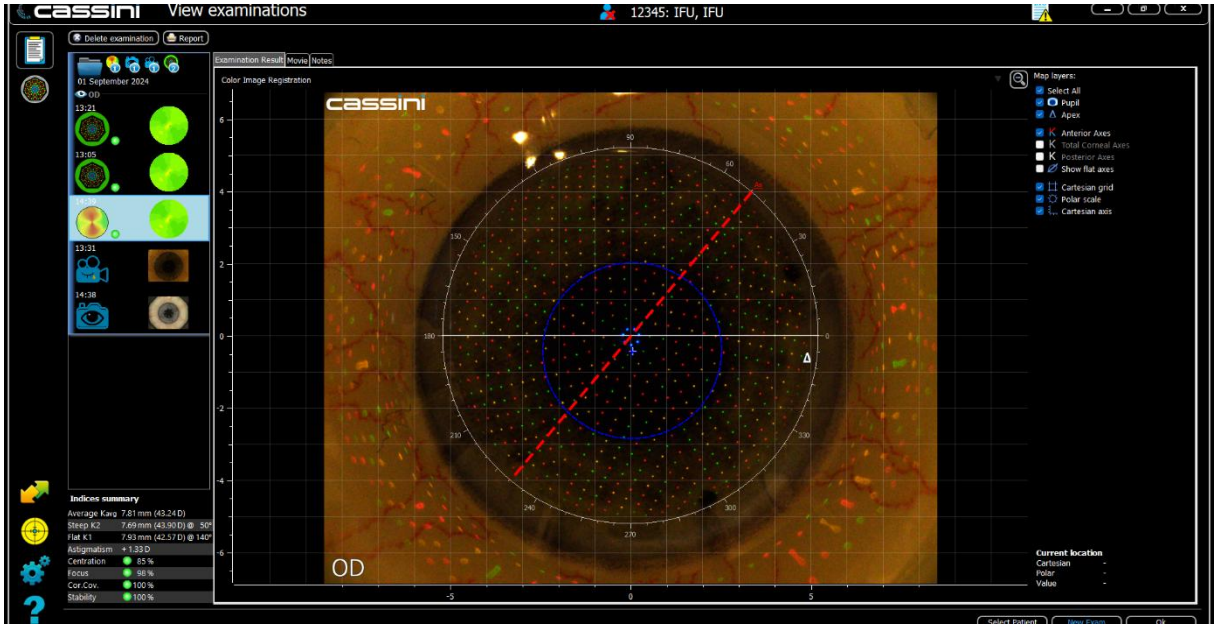


Figure 34: Results Corneal Topography (1-Up)

NOTE

The joystick button can be used to click through the entire examination workflow as well as to restart the same examination type. The feature will speed up the workflow and reduce patient chair time when taking multiple examinations of the same eye or when taking measurements for both eyes.

13.7 External Ocular Photography

External Ocular Photography allows to capture high-resolution images of the anterior segment of the eye. Unlike other workflows, this one does not provide feedback on the distance between the cornea and Cassini. The user has full freedom to align Cassini in front of the eye. This is helpful if the surgeon wants to capture an image of certain parts of the sclera or eyelids. The benefit of this workflow is to store and achieve high-resolution, full-color images of the anterior segment of the eye.

To acquire External Ocular Photography, follow the next steps:

1. To start an examination, click “External Ocular Photography”
2. Select or Add a Patient as described in the section 12
3. In the large window, Cassini shows the live stream images from the color camera
4. Align Cassini in front of the eye. The fixation target is turned on for support if necessary

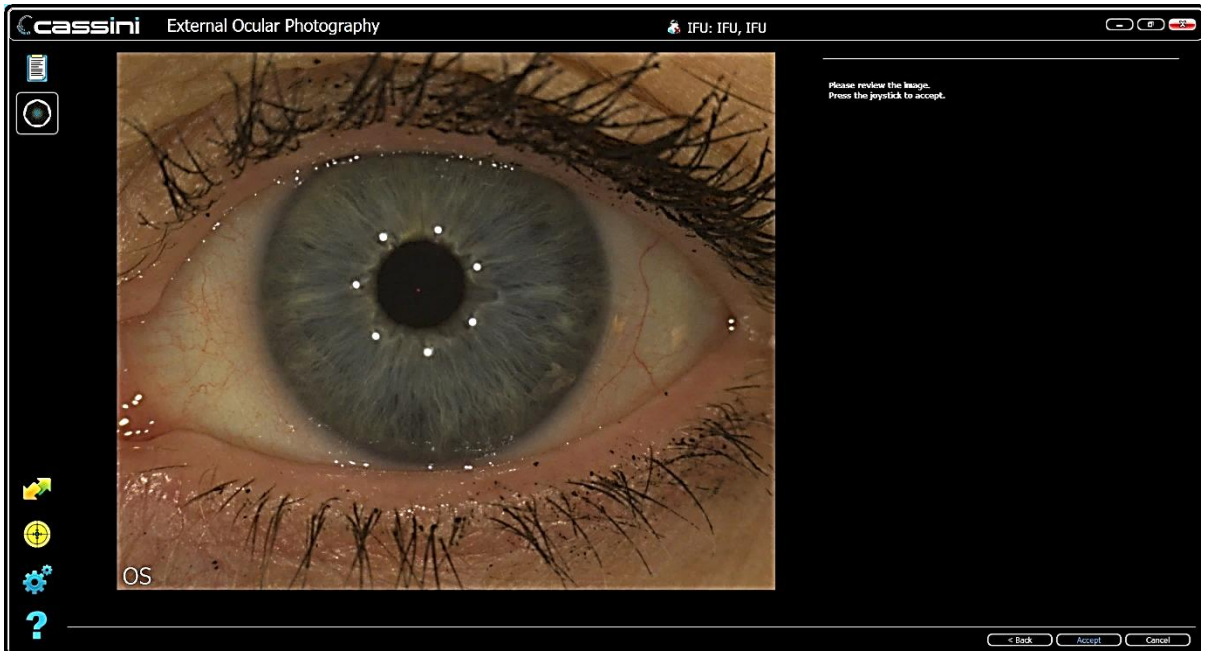


Figure 35: Live of External Ocular Photography

5. Make sure the target feature is in focus
6. Capture the image using the joystick or “Scan” button.
7. Click “Accept”
8. The results are displayed as in Figure 45

Figure 36: Results External Ocular Photography

13.8 Ocular Surface Visualization (OSV

OSV is a workflow that allows Tear Film Dynamics visualization by recording tear film and displaying the recording. The recording shows the status of the tear film for 5, 7, or 10 seconds. The OSV recording time can be selected in the Settings (Figure 38).

To acquire Ocular Surface Visualization, follow the next steps carefully:

1. To start an examination, click “Ocular Surface Visualization.”

2. Select or Add a Patient as in the section 12
3. In a large window, Cassini shows the live stream images from the color camera. Align Cassini in front of the eye and ask the patient to look at the red fixation target.
4. Click the joystick button when the focus rails and crosshairs are green

The results are displayed as in Figure 49.

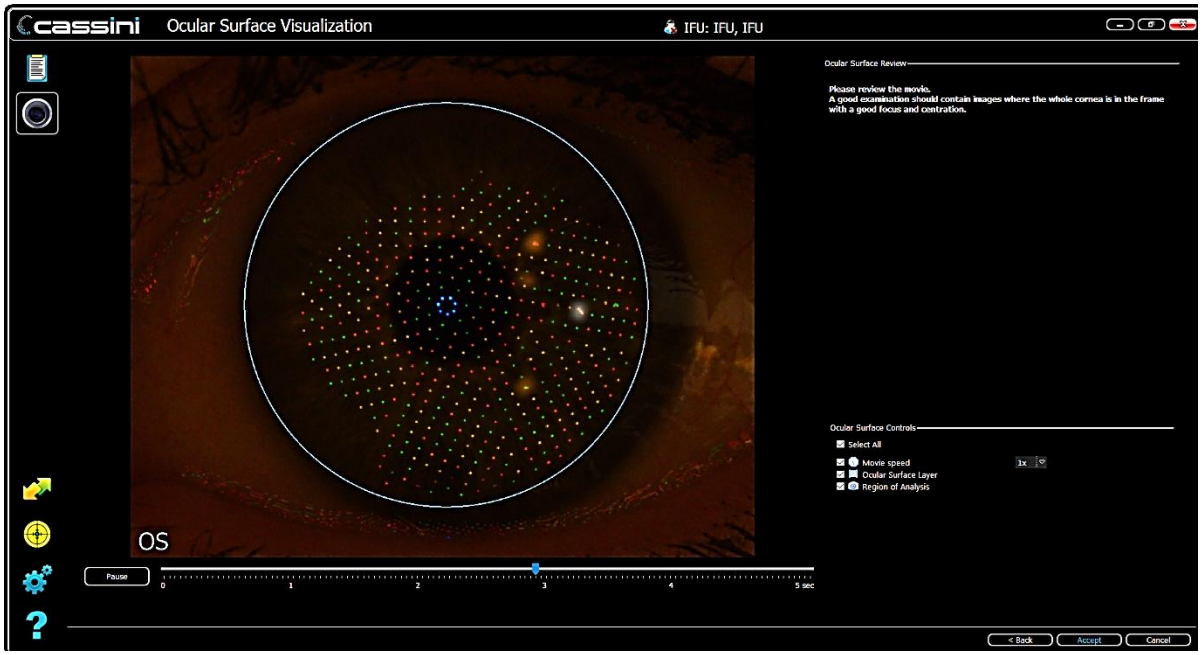


Figure 37: Ocular Surface Visualization Video playing

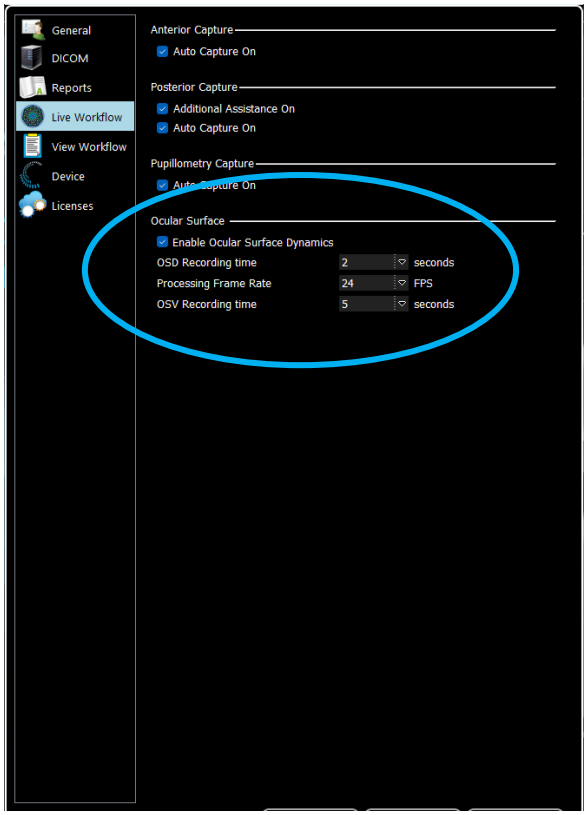


Figure 38: Settings

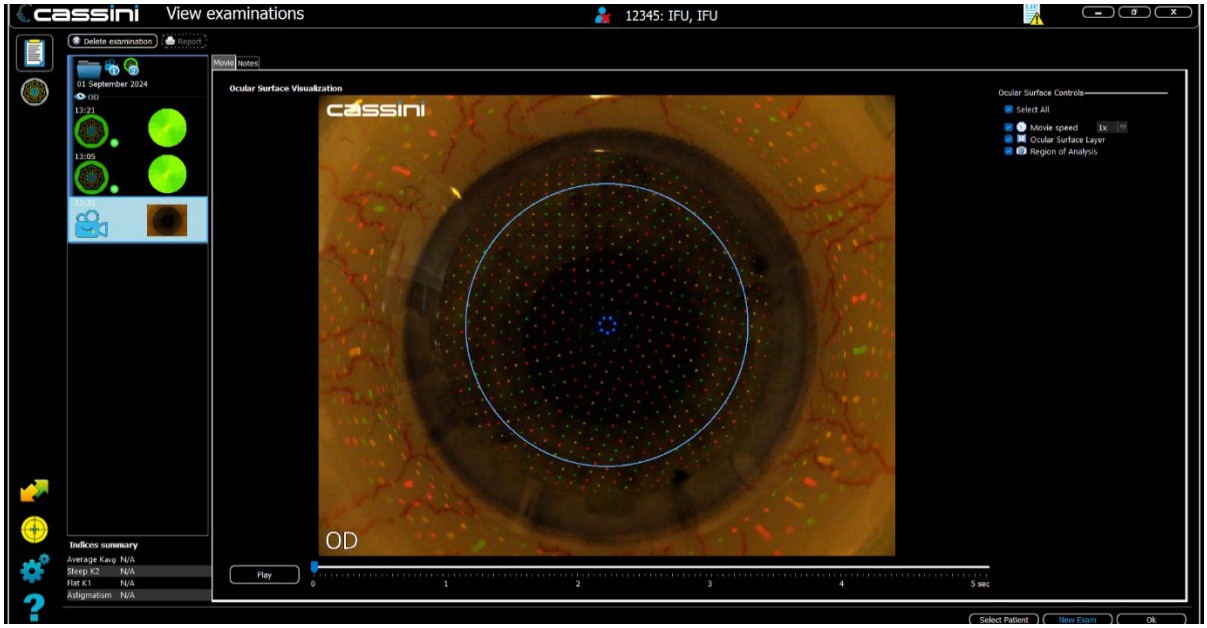


Figure 39: Movie displaying the results

14 VIEW EXAMINATIONS

14.1 View Examination

Figure 40: Cassini main menu

- Click “View examinations” to view an examination

Figure 41: Select a patient

- The patient list will open; to see all patients, click “Show all”
- Select a patient
- A list of examinations and the results will be shown

“View Examinations” displayed as in Figure 52 and contains the following:

- Examination Overview Field: patient’s examinations organized by:
  - Date : Latest examination on top
  - Eye Type OD on top, followed by OS
  - Examination Type Listed in Table 7
- Examination Result Window: The configuration of this window depends on the examination type.
- Indices Summary: summary of the keratometric data for Corneal Topography and Total Corneal Astigmatism

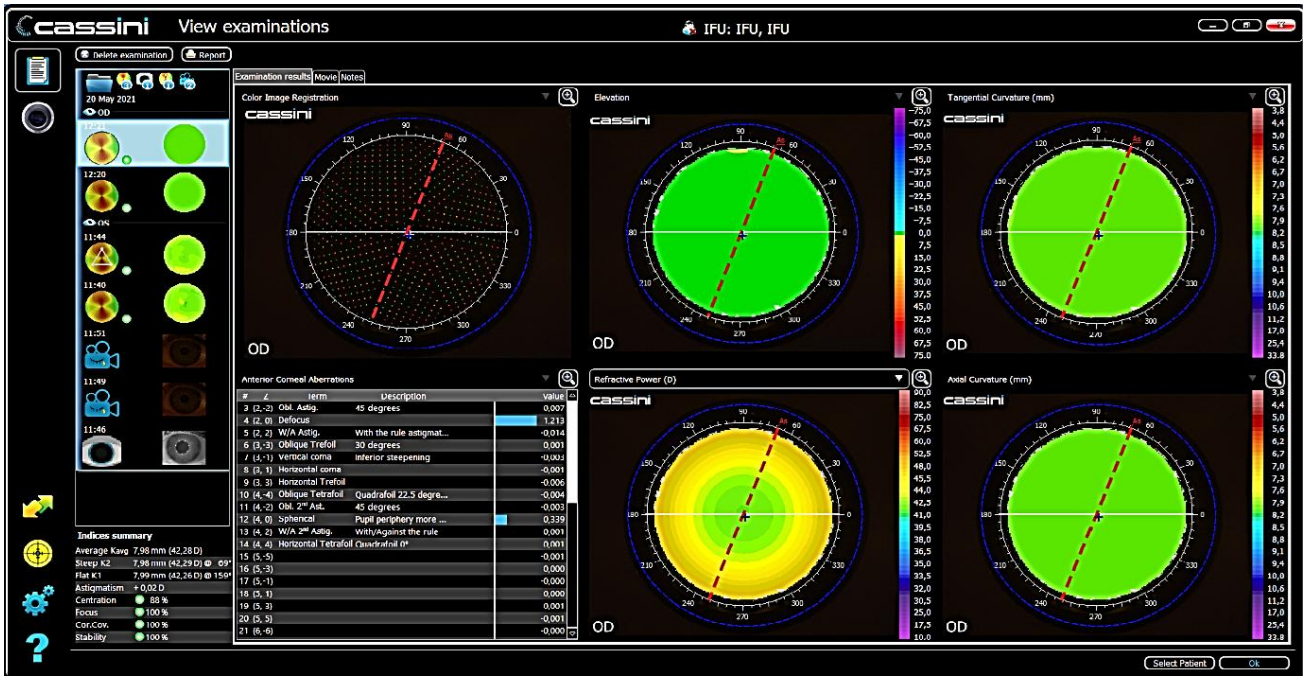


Figure 42: View Examinations view

14.2 SMART

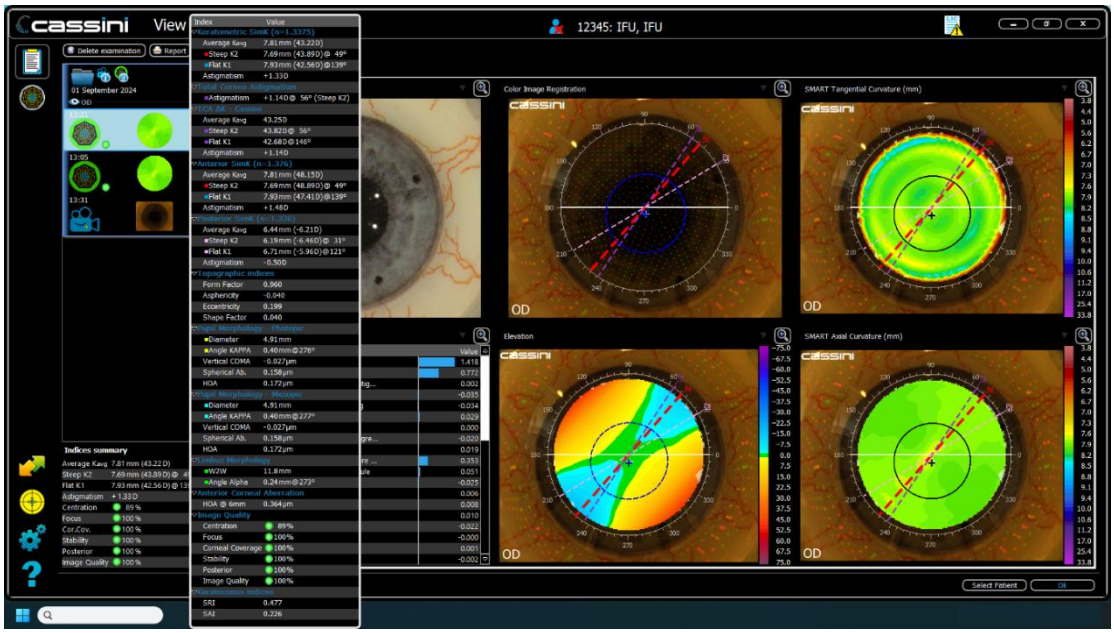


Figure 43: View examination results - SMART

Data presented in SMART is the Total Cornea Astigmatism data. Data related to the posterior surface and total corneal astigmatism are labelled in the indices and maps.

14.2.1 Maps

The axes are displayed using the following color coding:

- Anterior Red for Steep and Blue for Flat
- Posterior Pink for both Steep and Flat
- Total Cornea Purple for both Steep and Flat

Figure 44: Steep Axis of Astigmatism for Anterior, Posterior, and Total Corneal

Labels of the axis are on the right and can be turned off, if necessary. The flat axes are on but can be turned off. This can improve the identification of the axis, especially for ATR and oblique cases.

14.2.2 Indices

This indices menu is extended with the K-reading for anterior, posterior, and total cornea (see Figure 59).

Index	Value
Keratometric SimK (n=1.3375)	
Average Kavg	42,70D (7,90mm)
Steep K2	43,31D (7,79mm)@ 63°
Flat K1	42,10D (8,02mm)@153°
Astigmatism	+1,21D
Total Cornea Astigmatism	
Astigmatism	+1,26D@ 64° (Steep K2)
TCA ΔK - Cassini	
Average Kavg	43,59D
Steep K2	44,22D@ 64°
Flat K1	42,96D@154°
Astigmatism	+1,26D
Anterior SimK (n=1.376)	
Average Kavg	47,57D (7,90mm)
Steep K2	48,25D (7,79mm)@ 63°
Flat K1	46,90D (8,02mm)@153°
Astigmatism	+1,35D
Posterior SimK (n=1.336)	
Average Kavg	-5,04D (7,93mm)
Steep K2	-5,10D (7,84mm)@ 48°
Flat K1	-4,99D (8,02mm)@138°
Astigmatism	-0,12D
Topographic indices	
Form Factor	0,964
Asphericity	-0,036
Eccentricity	0,189
Shape Factor	0,036
Pupil Morphology - Photopic	
Diameter	4,97mm
Angle KAPPA	0,42mm@291°
Vertical COMA	0,003µm
Spherical Ab.	0,178µm
HOA	0,277µm
Pupil Morphology - Mesopic	
Diameter	4,98mm
Angle KAPPA	0,42mm@291°
Vertical COMA	0,003µm
Spherical Ab.	0,179µm
HOA	0,278µm

Figure 45: Indices menu for SMART

The list has been extended by three sets of SimK readings: anterior, posterior, and total cornea. All three sets are based on the real refractive indices of the cornea, i.e., 1.376 for the corneal tissue and 1.336 for the aqueous humor. The refractive index is used to convert the radius of curvature (in millimeters) to the optical power (in diopters) using the following equation:

$$Power\ (Diopter) = (n_1 - n_2)R\ (in\ mm$$

This is illustrated in the following example:

	Radius of Curvature	Power
Anterior Surface	8.0 mm	$\frac{(1.376-1.0)}{0.008}$ =47.0 D
Posterior Surface	6.7 mm	$\frac{(1.336-1.376)}{0.0067}$ = - 5.97 D

Table 18: Optical power example

The total corneal astigmatism is derived from the anterior and posterior measurements using a ray tracing model. Total Corneal Astigmatism is calculated according to the Layman's terms for vectoring 2 cylinders.

The original SimK from the anterior surface is based on a fixed relation between the anterior and posterior surfaces using Gullstrand's definition. The real refractive index has been replaced by pseudo index 1.3375, which we call "keratometric index". Using this value, the estimated total refraction of the cornea based upon the anterior measurement only is 42.19D (for 8.0 mm).

14.3 Corneal Topography

The view of the corneal topography examination is visible in Figure 53.

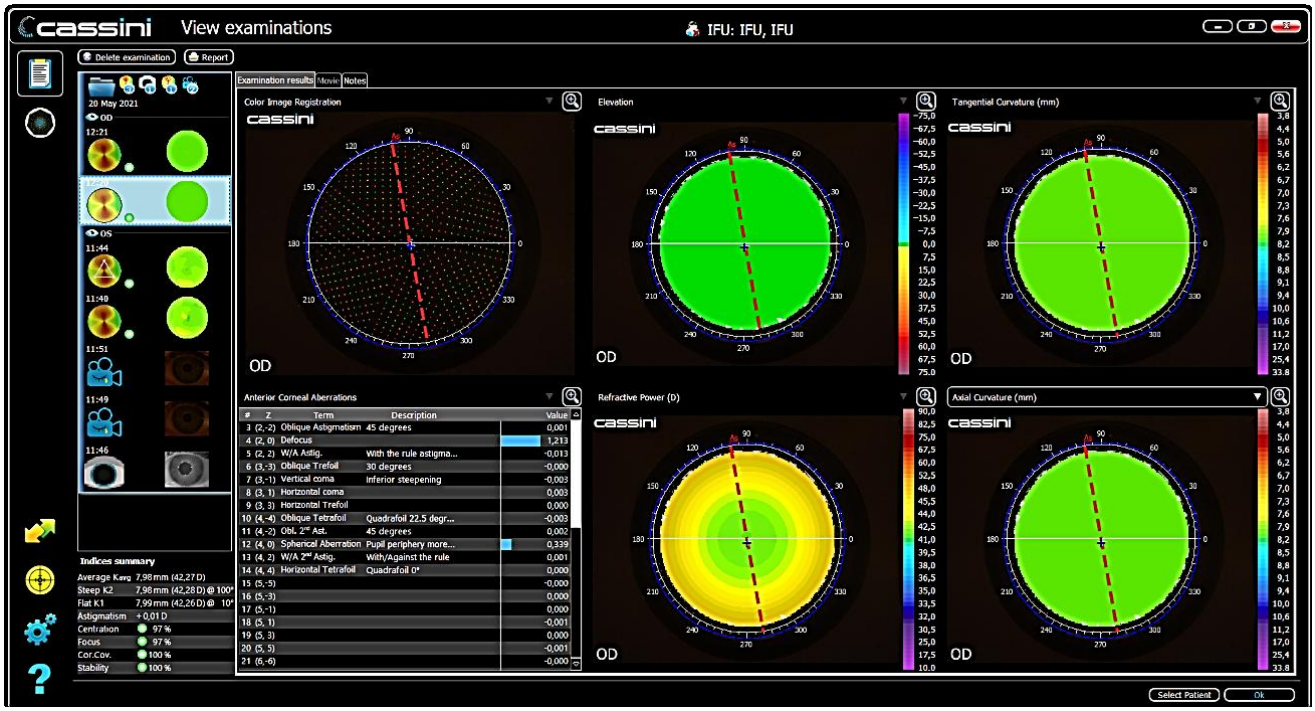
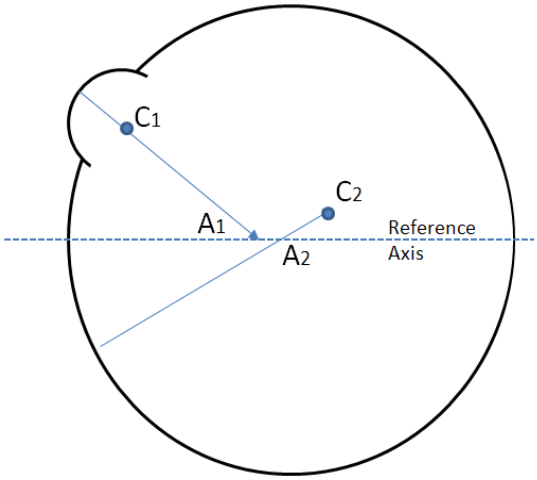


Figure 46: View the corneal topography examination

The examination window contains the examination result, the movie, and the notes tab. The examination result tab shows 6 small windows (6-up), each displaying a particular map. The arrangement of the maps can be customized using the dropdown list above every window. The chosen configuration will be stored

automatically and applied to every examination. The notes tab allows to add information for the surgeon (e.g., suspected dry eyes, movement during examination, poor fixation, etc.). This information will also be printed in the reports

Type	Description
Color image registration	Color image registration is a high-resolution image of the cornea and surrounding tissue. The image contains qualitative information related to the quality captured image and the status of the eye during capture. Movement during the examination is characterized by smeared elliptic shaped LEDs that point in one direction. The quality of the ocular surface is smooth if the LEDs' reflections are in focus. Coverage is related to the number of LEDs present on the cornea within the area of the white LEDs. The image also indicates the location of the reflected pattern in relation to the iris and pupil. The axis of astigmatism overlay is helpful to determine the position of the axes in relation to the eye. The axis may cross clear landmarks on the iris or point to distinct blood vessels on the sclera. Effects like cyclorotation can be corrected if these landmarks are used in surgery.
Axial Curvature	The axial (sagittal) curvature map is based on axial distance from a point on the cornea to the reference axis along the normal to the curve of that point. As in the image below, C1 and C2 represent the centers of curvature for the two radii of curvature, and A1 and A2 represent the endpoints of the distance from these points to the given reference axis (axial axis). Axial distance will underestimate the steep curvatures and overestimate flat curvatures. For those reasons, the axial curvature has a smoothing function and provides a more global description of shape. The reference axis is defined as the optical axis of the system, i.e., the center of the color image. The axial distances are expressed in millimeters and converted to diopters using the keratometric (1.3375) or refractive (1.376) index. 
Tangential Curvature Map	The Tangential (Instantaneous / Local) Curvature Map represents the true Radius of Curvature. It is derived from real curvature at every point on the cornea (see illustration) and does not include any reference axis like the Axial curvature maps. This will give a more detailed representation. The radius of the curvature is expressed in millimeters and converted to diopters using the keratometric (1.3375) or refractive (1.376) index.

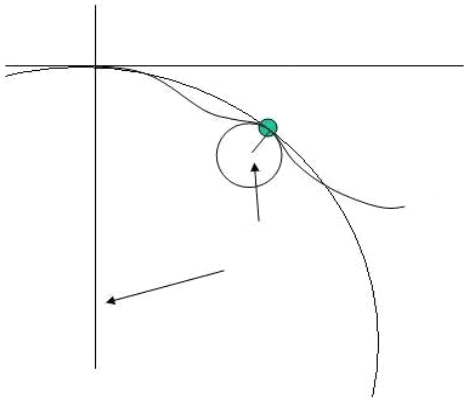
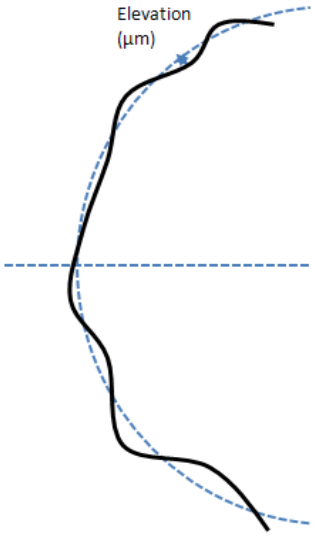
	
Elevation Map	Elevation map displays the distances from a reference plane to the corneal surface. The reference plane is defined as the *best-fit sphere* for that surface. The corneal surface has hills above the sphere and valleys below the sphere. The elevation maps are expressed in microns. 
Refractive Power Map	Refractive Power is expressed in diopters and refers to the refractive properties of the cornea. The axial and tangential curvature maps are only accurate in the central region (1 – 2 mm) since the equations used to convert from millimeters to diopter scale are very simplistic. The refractive power map shows a representation of the power of the cornea along the full cornea. The calculations are based on the height data using n=1.3375 (keratometric index).
Aberrations	The aberrations table displays the optical aberrations of the front surface of the cornea using the Zernike definition. Cassini uses Zernike order N=8, giving a total of 45 coefficients. Among these, the most important Zernike coefficients are astigmatism, coma, and spherical aberration. Defocus (myopia or hyperopia) and Astigmatism are marked as lower-order aberrations, and the rest (Z>5) are higher-order aberrations. The Zernike aberrations are calculated on a diameter of 6 mm and displayed in microns. Interpretation of the first terms is given by Cassini and is in line with the international standard ISO 24157:2008.

Table 16: Explanations

For more details, the magnifying glass icon above every window can be used to zoom in.

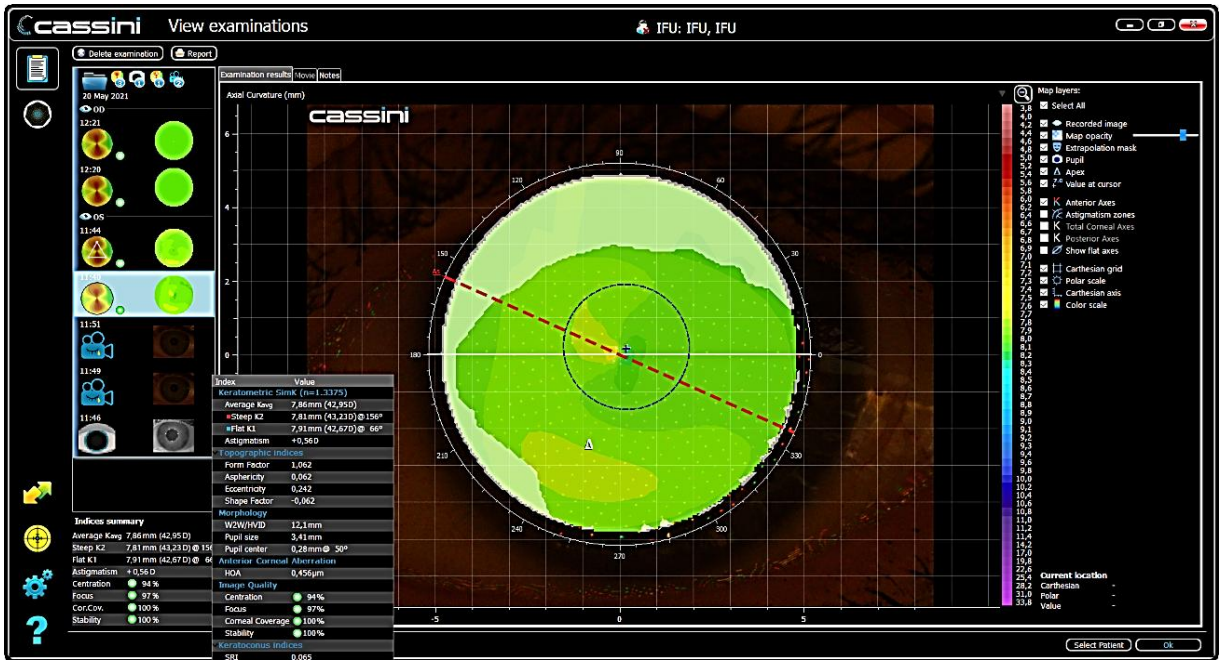


Figure 47: Corneal Topography 1-up

Overlays provide additional information on the examination and can be switched on/off if needed. The list of overlays is:

- Color image registration
- Map opacity for setting the transparency of the maps. This may be useful to relate the underlying image to the location of topographic features. To differentiate between actual measurement data and extrapolated data, Cassini covers the extrapolated data with a semi-transparent white layer
- Astigmatism axis
- Astigmatism per zone (3, 5, 7, and 9 mm) – by default off
- Pupil position and dimension (based on an elliptic fit)
- Apex
- Value of the cursor when hovering over the maps
- Cartesian grid and axis in millimeter scale
- Polar grid
- Color legend

NOTE

Extrapolated mask indicating the “measured” and “extrapolated” area. Missing areas might be caused by shadowing effects or missing LEDs.

Click on the Sim-K values to see the indices menu.

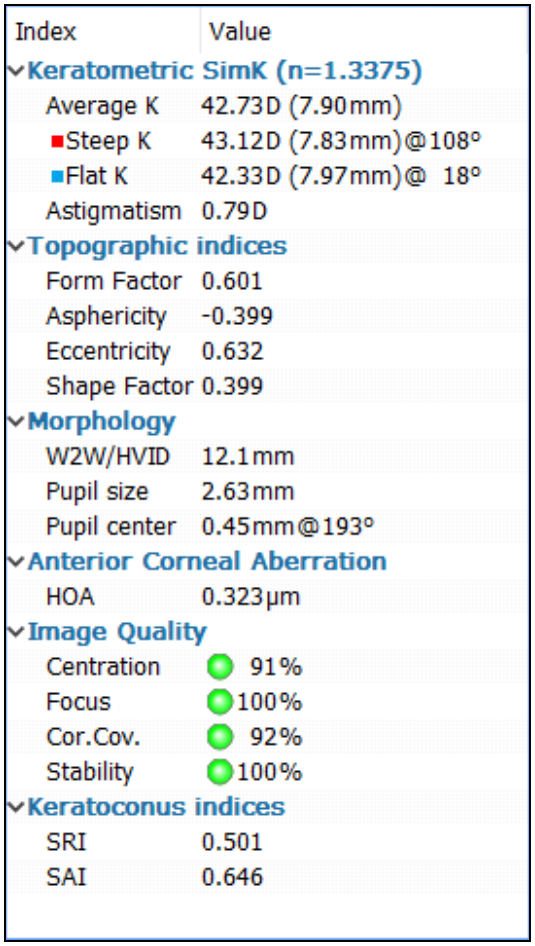


Figure 48: Indices fields

Indices	Definition
Steep K	Curvature oriented along steep axis (Diopters or millimeters). Measurement based on a 3 mm zone.
Flat K	Curvature oriented along flat axis (Diopters or millimeters). Measurement based on a 3 mm zone.
Astigmatism	Steep K minus Flat K (Diopters)
Shape Factor (E)	Corneal Shape Factor. The sign of E is a convention to signify whether an ellipse takes a prolate or oblate orientation. ($E=e^2$)
Eccentricity (e)	Parameter indicating the deviation from a spherical shape
Asphericity (Q)	Equal to k minus 1. (Q=-E)
Form Factor (p)	Indicates the shape of the cornea. A form factor of 1 means a spherical shape. This parameter is equal to 1 minus the eccentricity (e) squared. (p=1 - E). Sometimes this parameter is identified as k instead of p.
HOA	RMS of the higher-order terms N=3 to N=6
W2W/HVID	White-to-white or the Horizontal Visible Iris Diameter
Pupil Size	The average diameter of the pupil is based on an elliptic fit.

Pupil Centre	The center of the pupil relative to the center of the measurement data (center of the blue LEDs)
Quality Factor	See section 13.4
SAI	Surface Asymmetry Index. A measure of asymmetry through the center of the cornea. SAI is often higher than normal in keratoconus, penetrating keratoplasty, decentered myopic refractive surgical procedures, trauma, and contact lens warpage.
SRI	Surface Regularity Index. The regularity of the surface (smoothness). When SRI is elevated, the corneal surface ahead of the entrance pupil will be irregular. High SRI values are found with dry eyes, contact lens wear, trauma, and penetrating keratoplasty.

Table 17: Definition of Indices

14.4 External Ocular Photography

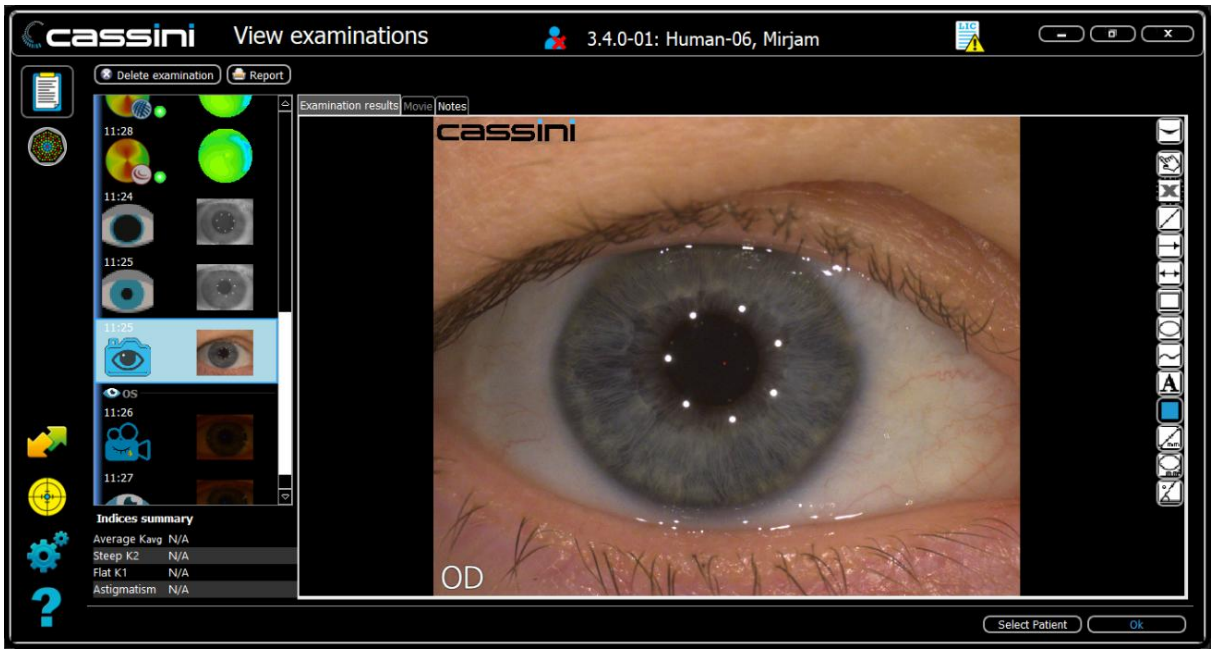


Figure 49: View examination - EOP

This attribute allows the user to indicate and measure features on the image. The attributes are displayed on the right.

14.5 Report

Reporting functionality is available for Corneal Topography, External Ocular Photography, and SMART. The report dialog appears after clicking “Report” (see Figure 60).

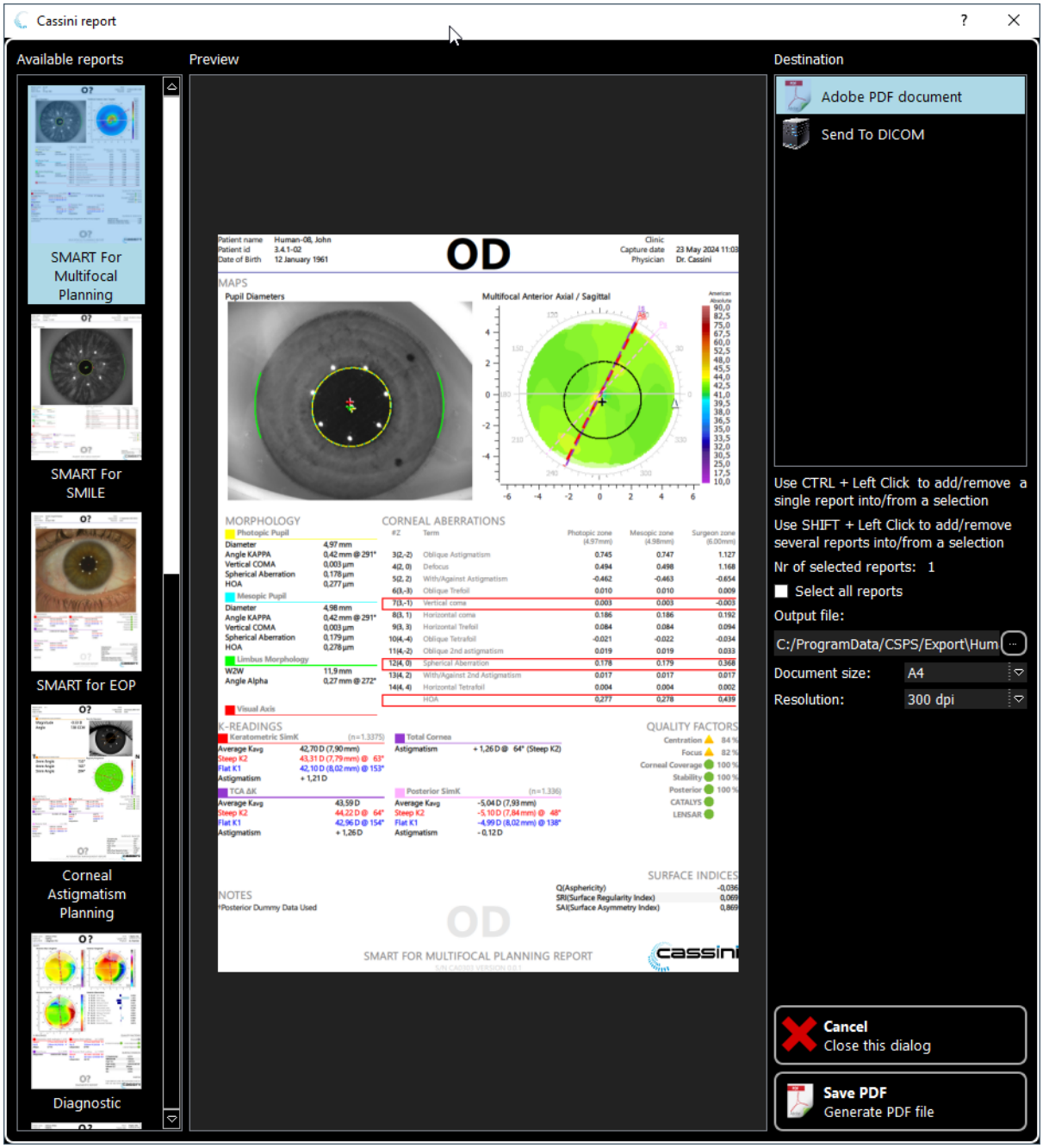


Figure 50: Report dialog

Cassini provides multiple report types.

- The Diagnostic Report contains three maps to show insight into the shape and irregular features of the anterior surface of the cornea. The corneal aberrations chart gives insight into the existence of higher-order aberrations. The K-readings, Qualify Factors, Surface Indices, and Notes are displayed in the lower half of the report.
- The Cataract Report contains a large map with a clear projection of the steep axis of astigmatism for reference. The surgical guidance template is designed to be used in the OR. The steep axis of astigmatism is projected on top of the Color image registration. Natural landmarks such as the scleral vessels or distinct iris structures can be used during surgery to provide additional feedback while aligning toric IOL.
- "Combined" Report is an option that allows the user to print all reports at once.

- The SMART Report contains information about the diameter and the angle values of the pupil and limbus. This report consists of Mesopic, Photopic images, Corneal aberrations, Multifocal IOL qualifiers, K-readings, Quality Factors, and Surface indices (see Figure 61).
- Other reports, such as FLACS print report, EOP report, Astigmatism planning print report, are optional reports that will be available based on customer requests.

When viewing this report, click on (+) next to the “Pupil Image” to view the diameter and the angle values of the pupil and limbus on the “View Examinations” page.

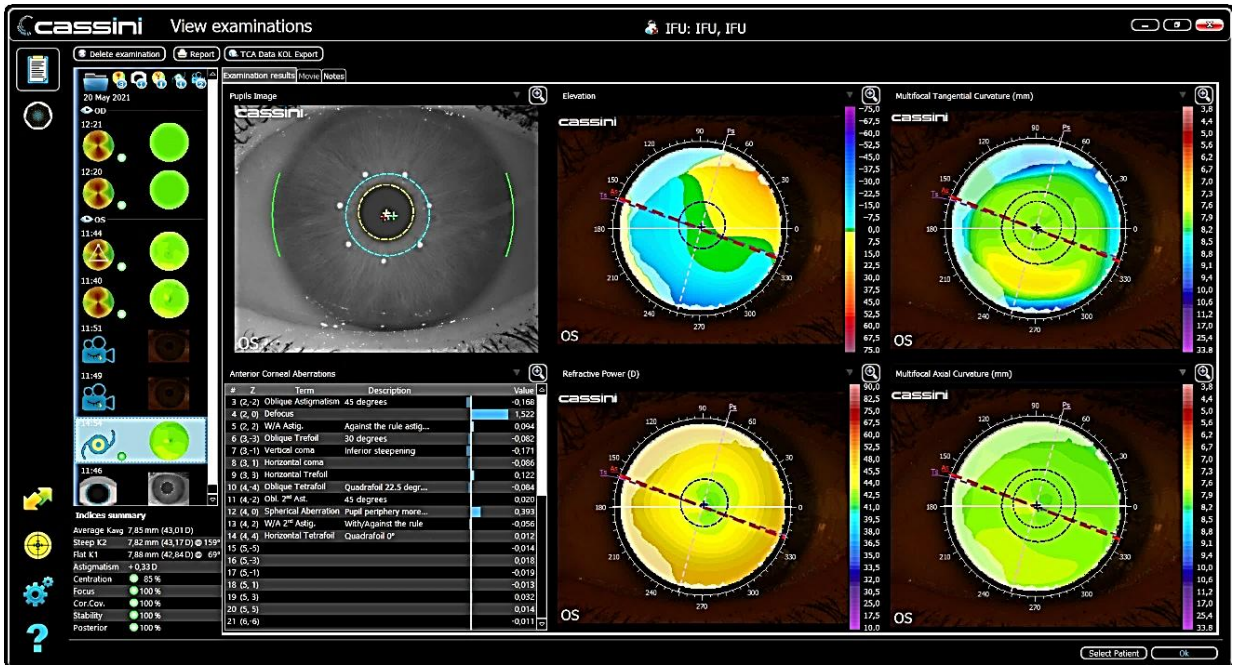


Figure 51: SMART 6-ups

Reports can be exported in PDF, printed, or sent to DICOM (see 12.1) according to the chosen destination (listed on the left of the dialog page).

14.6 Third Party Export

Measurement data from the corneal topography examination and the total corneal astigmatism examination can be exported to a third-party software. A corresponding valid license is required to enable the third-party export. Once the license key is entered, an export button appears in the view screen after a link with a third party has been set up (see Figure 64). Contact Cassini Support or your distributor for more information.

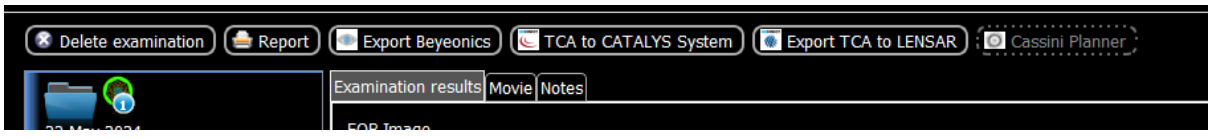


Figure 52: Third-party export buttons

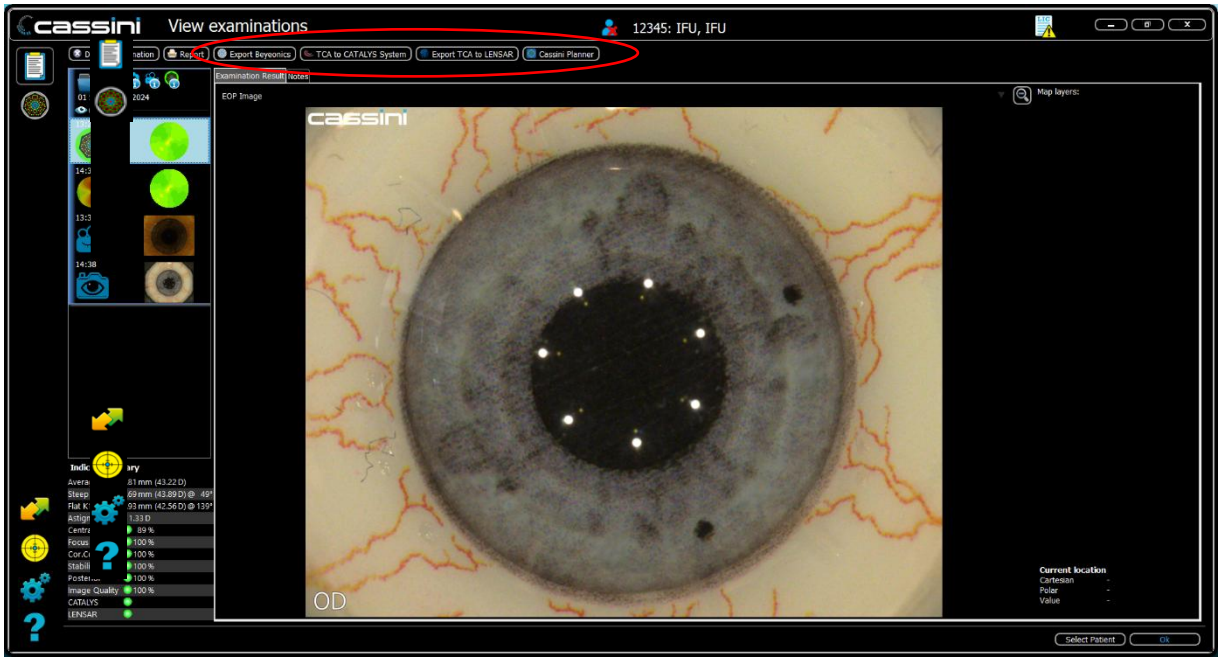
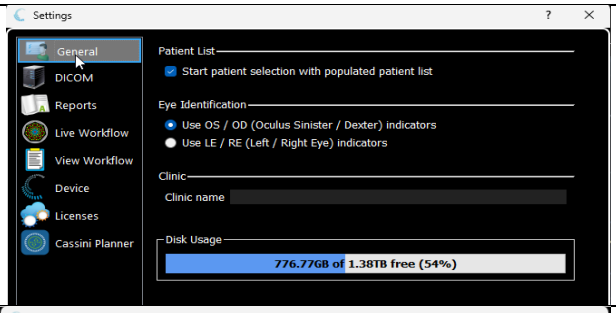
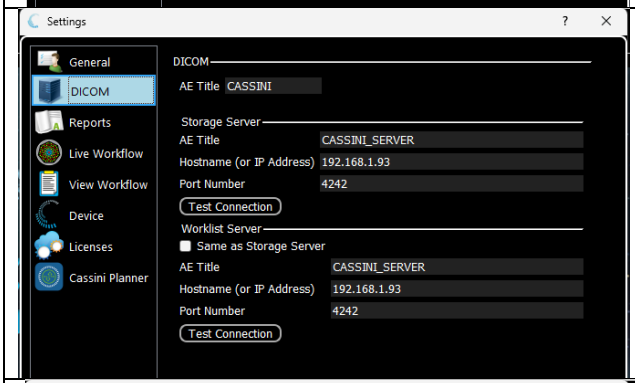
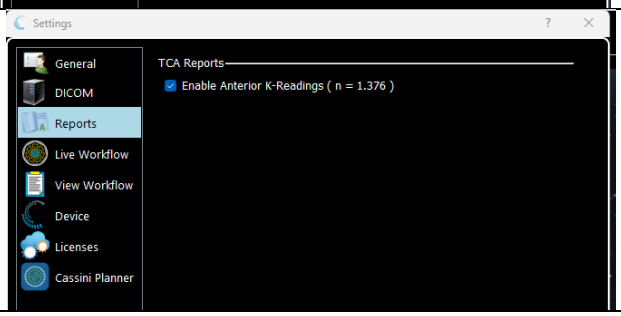


Figure 53: Placement of the Third-Party Export Button on the View Page

14.7 Settings

By selecting Options in the main menu, you can modify user-, device-, and other settings.

	In 'General', the following can be configured: • Notation of the Eye Indicator – OS/OD or N/T • Name of the Clinic It also displays the disk usage indicator to inform the user of the remaining free space on the system.
	the 'DICOM' settings page allows the user to enter the DICOM Worklist and Storage data.
	'Reports' allows removing true anterior readings for the print-out. We recommend to leave these readings on the print-out as they give insightful information about TCA (in combination with the posterior readings).

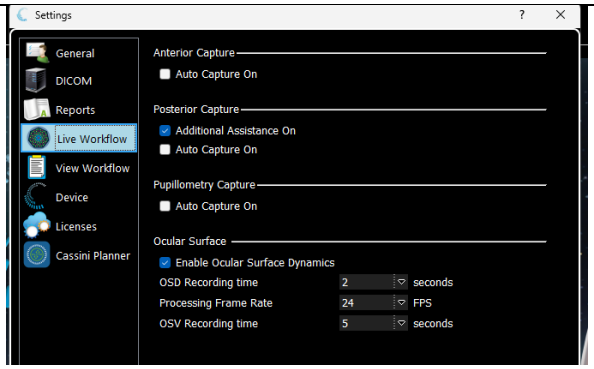
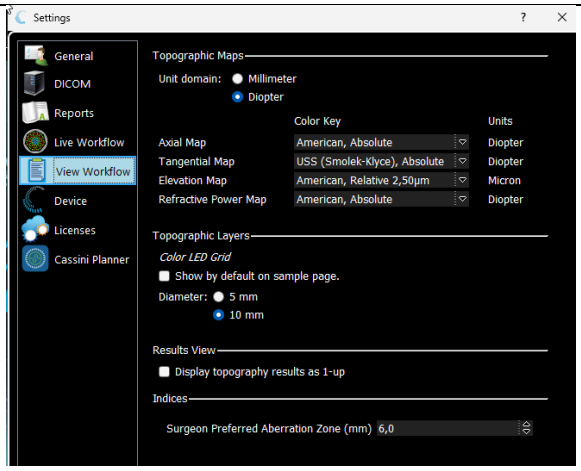
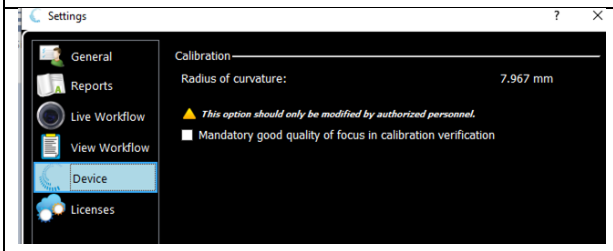
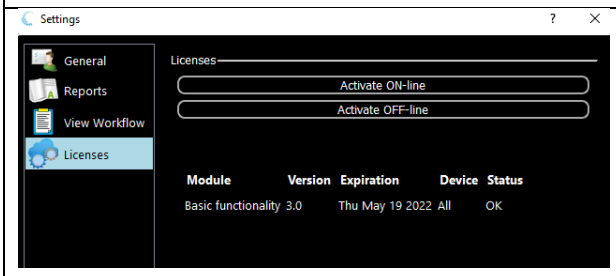
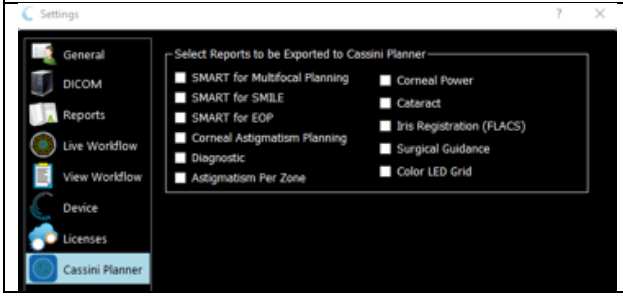
	‘Live Workflow’ allows enabling • the auto capture functionality for the anterior stage • the auto capture functionality for the posterior stage • the auto capture functionality for the Pupillometry stages it also allows the configuration of the Ocular Surface feature.
	'View Workflow' allows configuration of • the map display and the unit used for K-readings. The default setting is the American Color Key. • the 'Color LED Grid' feature and its zone • the default view on the Results page for topography scans • the Surgeon Preferred Aberration Zone
	‘Calibration’ provides insight into the radius of curvature of the artificial eye.
	‘Licenses’ allows viewing the list of activated licenses, including their status. The user can add new licenses by clicking “Activate Online” or “Activate Offline”.
	The report type can be selected to report to Cassini Planner.

Table 23: System settings

14.8 Planning for IOL

After completing the capture process, move on to the "View Examination" window, where the "Cassini Planner" button will be visible. Proceed by clicking "Cassini Planner". This is an additional Cassini module assisting the surgeon with IOL selection. The license for Cassini Planner should be enabled.

15 COLOR KEYS

The color representation of the maps depends on the selected color scale and its range. Cassini offers five color scales with four ranges for curvature and power maps. For the elevation maps, Cassini offers four color scales and four ranges.

CAUTION

The appearance of the maps depends on the selected scale and range. Normal structures may look abnormal and vice versa. It is advised to select a scale and range that you understand.

15.1 Curvature & Power

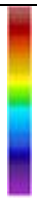
Name Color Scale		Range (Diopters)	Range (Millimeters)
European		Absolute (0 – 90) Relative (0.25, 0.50, 1.0)	Absolute (33.8 – 3.8) Relative (0.05, 0.1, 0.25)
American (Default)		Absolute (0 – 90) Relative (0.25, 0.50, 1.0)	Absolute (33.8 – 3.8) Relative (0.05, 0.1, 0.25)
TMS		Absolute (0 – 90) Relative (0.25, 0.50, 1.0)	Absolute (33.8 – 3.8) Relative (0.05, 0.1, 0.25)
USS (Smolek Klyce)		Absolute (30 – 67.5)	Absolute (11.20 – 4.95D)
Standard Scale (ISO19880 and the ANSI aliged)		Relative (0.50, 1.0)	Relative (0.1, 0.2)

Table 19: Curvature & power color scale

"European" is characterized by a large number of colors, greyish color tints for very steep curvatures, and yellowish colors in the 'normal' range of 41 – 43 Diopter, and greenish colors for flatter corneas.

"American" is the typical scale starting with dark red for steep curvatures, via green (normal) to blue/purple for flatter regions.

"TMS" is defined to resemble the graphical conventions used by Tomey Topographers.

"Universal Standard Scale (USS)" is based on the power distribution of a wide variety of different cornea's including normal contact lens wearers, different stages of keratoconus, etc.

"Standard Scale" follows the definitions outlined in ISO19880 and the ANSI.

The absolute range is defined by a static minimum (10D) and maximum (90D) in the power maps value and a varying size across the entire range of the scale: the step size in the center is small (0.5D) and in the periphery is large (2.5D). The relative range uses a central value (41D) and a fixed step size towards the lower and higher ranges.

15.2 Elevation

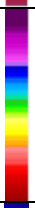
Name Color Scale		Range (micron meters)
European		Relative (2.5, 5, 10, 25)
American		Relative (2.5, 5, 10, 25)
Intuitive		Relative (2.5, 5, 10, 25)
Standard Scale		Relative (2.5, 5, 10, 25)

Table 20: Elevation color scale

"American" is defined by green in the center, blue towards negative, and red towards positive values. "Intuitive" contains the typical RYGBP scale, while "Standard" and "European" are similar to the scales from the curvature maps, except in the European scale, green is 0 micron.

16 TROUBLESHOOTING, COMPLAINTS, AND INCIDENTS

You must follow all the directions under the **SAFETY**, **WARNINGS,** and **CAUTIONS** headings throughout this manual to ensure the safety of both patients and users.

16.1 Electrical and Mechanical

WARNING

Only personnel trained by Cassini and with an appropriate skill level may operate the device.

16.2 Electrostatic discharge

Cassini is connected to multimedia equipment and complies with IEC60601-1-2.

16.3 Portable and mobile phones, and EMC

Cassini complies with CISPR11 (Ed 4.1) standards on EMC (electro-magnetic compatibility). This standard defines both the permissible electromagnetic emission levels from Cassini and its required immunity to electromagnetic interference from external sources. Other electronic products exceeding the limits defined in this EMC standard could, under unusual circumstances, affect the operation of Cassini.

Cassini is classified as Group 1, Class B ISM equipment.

Group 1 contains all ISM equipment in which there is intentionally generated and/or used conductively coupled radio-frequency energy, which is necessary for the internal functioning of the equipment itself.

Class B equipment is an equipment suitable for use in domestic establishments and in establishments directly connected to a low-voltage power supply network, which supplies buildings used for domestic purposes.

Cassini needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this chapter.

WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of Cassini. Otherwise, degradation of the performance of this equipment could result. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

16.4 System and error messages

When using Cassini, system and error messages can pop up. These messages usually help with troubleshooting to perform functions properly or to inform how to solve a problem. If a message appears on the screen, read it carefully and follow the instructions below for troubleshooting.

There are three types of Cassini messages (notification, warning, and error) and Windows messages. Error messages are of the highest severity but usually recoverable.

16.5 Overview system and error messages

	Message	Suggestion
1	Failed to store scan in the Database	Check if the database service is running
2	Calibration File missing	Calibrate device
3	Unable to open device	Power cycle Cassini; restart the application and check the USB connection
4	Unable to find printer	See your printer and try again

5	Failed to open the Database	Check if the database is present and db service is running
6	Failed to find the color camera ini file	Check if the color camera ini file is present and access rights are correct
7	Failed to find mono camera ini file	Check if the DB service is running
8	Timeout Executing command 0xXX	Powercycle Cassini; restart application; disconnect USB
9	Database Query Error	Check if database is present and db service is running
10	USB Express call failed	Powercycle Cassini; restart application
11	There is an error with your USB connection to the device	Powercycle Cassini; restart application
12	Cannot communicate with the device, please check your connection	Check the USB connections and, if necessary powercycle Cassini; restart the application
13	Failed to load the system settings file	Check if db service is running
14	Storage Server connection: ERROR	Check the DICOM configuration with your DICOM vendor
15	Worklist Server connection: ERROR	Check the DICOM configuration with your DICOM vendor

Table 21: System and error messages

16.6 Troubleshooting and repair

Problem	Suggestion
Poor scan results	• Recalibrate the system and ensure the patient is well aligned • Ensure the patient's head is positioned with their forehead against the headrest and their chin in the chinrest • Ensure the patient does not blink when not told during the scan or move during alignment • Ensure both eyes are maximally open and let them blink just 1 second before scanning. Do not take the scan immediately after blinking • Tell the patient to focus on the red fixation LED in the center of the dome. If the red fixation is too difficult for them to view, have the patient focus on the center of the blue LEDs (Anterior Scan) • Tell the patient not to move during scanning • Tell the patient to turn their head just a bit so that the shadow caused by their nose is less troublesome • If turning their head does not work, then ask them to place their chin on top of the chinrest. This technique will minimize the shadowing of the eyebrow and nose. • Do not move the joystick when pressing the trigger button
Calibration – processing of the image is failing after the right alignment	• Check if the calibration tool has scratches. If so, contact your distributor or Cassini Support. • Check if the calibration tool has stains. If so, follow Section "Maintenance – Cleaning" to clean the calibration surface without making any scratches. • Dim all light sources. Try calibrating in a dark environment.

Alignment not possible	• Monochrome camera displays are white due to overexposure to light sources. Dim all other light sources. Try aligning in a dark environment. • Work distance laser spots are not present; make sure you are in focus by looking at the LEDs displayed in the color camera display.
The camera seems not to be working / dark images in the display of the color camera / monochrome camera	• Make sure the USB cable is connected • Disconnect and reconnect the USB cable • Turn off / turn on the power of the Device by (un)plugging the Cassini mains power cable • Ensure there is a reflection surface (calibration target/eye) in front of the dome center • Check in the calibration screen if the for indicators > 0 • Monochrome camera displays are usually dark; make sure you are close to focus.
OD/OS indicator gives a wrong value	• Move the base to the extreme left and then, the extreme right position and monitor the value. Note, OD/OS relates to the eye of the patient • If the above does not help, contact your distributor or Cassini Support
Unable to find work laser spots because of too many spots	This may happen if Cassini is too close to the eye. Try to realign according to the instructions
Unable to find printer	• Ensure the printers are correctly installed • Update any drivers associated with the printer by looking up the printer support website • If a printer is directly connected via USB cord, try updating any drivers associated with the USB controller hub on Windows
Unable to Calibrate	Make sure the glass part of the calibration tool is not loose. If it feels loose, tighten it. This may happen over time, and the glass part may unscrew itself when rotating out of its holder. If calibration is still difficult after trying the above, proceed with the following: • Clean the calibration tool with a cloth • DO NOT use alcohol or abrasive chemicals on the Glass part of the calibration tool • Apply the *thumbprint* technique by placing your thumbprint slightly on the clear curved part of the calibration tool. Your fingerprint will create an opaque background • Proceed with calibrating Ensure that after calibration, you have all Green Quality Factors, and the Radius of Curvature is 0.05D or below.

	Repeat the calibration process twice if the radius of curvature is above 0.05D. If it remains above 0.05D, contact your distributor or Cassini Support.

Table 22: Troubleshooting

If (parts of) the system (have) is damaged, shutdown the system by unplugging the Cassini main cable and the computer main cable from the power outlet and disconnect the USB cable. Shutdown the computer by closing the Cassini application and selecting shutdown in the Start menu of Windows.

During an examination, if the USB cable is disconnected from the computer, cancel your examination, restart the Cassini software, power cycle Cassini, reconnect the USB cable, and repeat the scan.

CAUTION

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

16.7 Regulatory compliance

Serious Incident Reporting (EU) for a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation (EU) 2017/745 on Medical Devices). If, during the use of this device or due to its use, a serious incident occurred, report it to the manufacturer (support@cassini-technologies.com) and/or its authorized representative and to your national authority.

16.8 Service

Cassini will not need servicing. However, if you have any concerns about the performance of your Cassini, contact Cassini Support. The expected service life of Cassini is 5 years.

- Email: support@cassini-technologies.com
- Web: www.cassini-technologies.com
- Support USA – Toll-free: +1 888 660 6965
- Support outside USA: +31 (0)70 3993112

17 Maintenance and Servicing

17.1 Preventive maintenance - regular checks and usage

Inspect the instrument and components every two weeks to ensure there is no degradation in the performance of physical components before scanning patients. Damage or missing components can be ordered from Cassini Support.

Carefully inspect the calibration tool for scratches and stains before calibrating the device. For proper LED detection, make sure that no fingerprints, dust, or dirt are present on the LED panels. For instructions for LED panel cleaning, see the section 19.

18 Cybersecurity

WARNING

Do not install unauthorized software on the computer that is provided with Cassini. It could have a negative impact on the performance and security of the Cassini software and patient database. Contact Cassini Support before installing any software.

It is the responsibility of you and/or your organization to:

- Timely updates of anti-virus software
- Management of the operating system user rights and policies
- Periodic data backup to prevent any data loss
- Encryption of the exported data

To ensure secure use of the Cassini, follow these cybersecurity requirements:

- Remote Desktop Access
  - Remote Desktop (RDP) must remain disabled in all deployed systems.
  - If remote access is required for service, it must only be enabled temporarily and exclusively through a secure, MFA-protected remote support channel.
- BIOS / UEFI Security
  - A supervisor (admin) password must be configured.
  - Secure Boot must remain enabled.
  - The boot order must be restricted to the internal SSD only.
  - BIOS rollback protection must be enabled.
- BitLocker Configuration
  - Users must not leave the system unattended in public areas
  - BitLocker with PIN protection must remain enabled.
- Local Administrator Accounts
  - When systems are joined to a domain, the local administrator account must be disabled.
  - If a standalone system is used, a strong password must be configured.
  - Hospitals must enforce password complexity and account lockout policies consistent with their IT security policies.
  - Default passwords should not be used
- Application Permissions
  - Limit user access to non-administrative accounts only.
- Driver and Network Controls
  - Network configuration changes at the login screen must be restricted according to the user's IT policies.
  - Wireless adapters should be disabled if not required.
- Network Name Resolution
  - LLMNR and NetBIOS should be disabled.
- Local Access and Privileges
  - Local administrative access is restricted to authorized personnel.
- Database and Communication Security
  - Database and DICOM communication occur only within the hospital's secure HIPAA-compliant network.
  - Database access is limited to localhost; external connections are not permitted
  - Data transfers via USB or other removable devices should use encrypted or controlled media.

In case of a cybersecurity vulnerability or incident, disconnect the device from the network and document the incident. User organization IT and security teams should be informed as per the organization's policies.

User must promptly notify Cassini Support (support@cassini-technologies.com) and follow the instructions provided for cybersecurity risk management. In case of a cybersecurity incident or vulnerability, Cassini Technologies will:

- Perform a risk assessment to determine the scope of the vulnerability or incident and evaluate potential threats to patient safety or device functionality
- Apply security protocols such as installing patches or disconnecting the device from the affected network, and engage external experts if necessary
- User is responsible for data back-up and recovery

WARNING

For Cybersecurity reasons, the user is responsible for the installation and maintenance of the anti-virus software!

19 CLEANING AND DISINFECTION

CAUTION

Do not remove any parts of the device, as this might result in exposing internal parts and introducing the risk of electric shock.

CAUTION

It is recommended that Cassini LED Panels be cleaned regularly to prevent the build-up of dirt, stains, or dust that may reduce performance or user and patient comfort. For LED detection, make sure that no fingerprints, dust, or dirt are present on the LED panels. When cleaning the LED panels or any other part of the device, make sure all power is disconnected from the device, meaning the mains cable should be unplugged and the USB cable should be disconnected.

Care must be taken not to use any cleaning liquid or solvent inside the LED dome or for cleaning the calibration tool. Only the dry lens tissues supplied with the system should be used for cleaning the LED panels and calibration surface. Do not use the same lens tissue for the cleaning of both the calibration surface and the LED panels. When cleaning, only touch the LED panels/calibration surface with the tissue; do not make direct contact with skin!

To avoid infection, it is recommended to use the cleaning techniques below to clean the parts that are in contact with the patient or user.

- All plastic covers, including the user control platform, the head support (head- and chinrest and handles), and labels, can be cleaned with a cloth and a common solvent such as alcohol. Common grade alcohol swabs or tissue can be used for this purpose. They should be cleaned ahead of every new patient and/or user use.
- The LED panels can be cleaned with a clean dry lens tissue (Berkshire Lensx®90), which is provided. Ensure that no object that could scratch the surface is used. Ensure that during cleaning, no particles disappear between the LED panels or into the hole in the center of the dome.
- The calibration tool can be cleaned with a clean dry lens tissue (Berkshire Lensx®90), which is provided. Ensure that no object that could scratch the surface is used, and avoid direct contact between skin and calibration surface during cleaning. Do not use a lot of pressure on the surface when cleaning. To prevent scratches, ensure that the calibration surface does not make contact with anything other than the foam of the box or the lens tissue. After cleaning/calibration, put the calibration tool in the box and close the cover to prevent dust from getting in.
- If unsuccessful with cleaning the LED panels, contact your dealer or Cassini Support.

20 DISPOSAL

20.1 Cassini device

CAUTION

To avoid potential negative consequences for the environment and possibly human health, this instrument should be disposed of for EU member countries in accordance with WEEE (Directive on Waste Electrical and Electronic Equipment), for all other countries, in accordance with local disposal and recycling laws. Hence, DO NOT dispose of Cassini. Return the product to Cassini Technologies B.V. for disposal and recycling

20.2 Cassini packaging materials

Cassini packaging materials can be recycled. Give these materials to your local recycling center or dispose of them in an environmentally friendly manner.

21 SOFTWARE LICENSE TERMS

Please read the Terms & Conditions before using this software! Any and all Terms & Conditions shall be deemed to be accepted and agreed to by you if you use (or install) this software.

22 PRODUCT LIABILITY

22.1 Warranty disclaimer & limited liability

Refer to Terms & Conditions for the detailed overview of warranties and liabilities.

22.2 Responsibilities

Cassini Technologies B.V. is not responsible for any damages due to fire, earthquakes, actions by third persons, and other accidents, or damages due to negligence and misuse by the user under unusual conditions. Cassini Technologies B.V. is not responsible for damages derived from instability to properly use this instrument, such as loss of business profit and suspension of business. Cassini Technologies B.V. is not responsible for damages caused by using this instrument in a manner other than described in this user manual. Diagnoses made shall be the responsibility of the pertaining doctors, and Cassini Technologies B.V. is not responsible for the results of such diagnoses. Printed images are not for diagnostic purposes, and printing quality depends on the quality and type of printer and paper. Cassini Technologies B.V. is not responsible for any patient harm or loss of patient data in case of any violation of the instructions provided under the section “cybersecurity”.

23 DECLARATION OF CONFORMITY - EMC

Guidance and Manufacturer’s declaration-electromagnetic emissions

Cassini is intended for use in the electromagnetic environment specified below. The customer or the user should ensure that it is used in the following environment:		
Emissions Test	**Compliance**	**Electromagnetic Environment - guidance**
RF emissions CISPR11	Group 1	Cassini does not intentionally generate/ use RF energy. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	Cassini is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	Not applicable. Rated power is less than 75W.
Voltage Fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
Cassini is intended for use in the electromagnetic environment specified below. The user should assure that it is used in the following environment:			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment - guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±8 kV contact ±15kV air	±8 kV contact ±15 kV air	Floors should be made of wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical\fast transient/burst immunity test IEC/EN 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge immunity test IEC/EN 61000-4-5	Line(s) to line 1 kV Line to ground 2kV	Line(s) to line1 kV Line to ground 2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency magnetic field immunity test IEC/EN 61000-4-8	N/A	N/A	Cassini does not contain components which are sensitive to magnetic fields.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - guidance
Immunity to conducted disturbances, induced by radio-frequency fields IEC/EN 61000-4-6	0.15-80 MHz 3V 6V in ISM bands	0.15-80 MHz 3V 6V in ISM bands	
Voltage dips, short interruptions and voltage variations immunity test IEC/EN 61000-4-11	0% UT for 0,5 and 1 cycle 70% UT for 25/30 cycles 0% UT for 250/300 cycles	0% UT for 0,5 and 1 cycle 70% UT for 25/30 cycles 0% UT for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of Cassini requires continued operation during power mains interruptions, it is recommended that Cassini be powered from an uninterruptible power supply or a battery.
Radiated RF EM fields IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz	10 V/m 80 MHz to 2,7 GHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See the table below.	See the table below.	Recommended separation distance: $E = \frac{6}{d}\sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in (m), and E is the IMMUNITY TEST LEVEL in V/m.
Close proximity magnetic fields testing EN 60601-1-2	9kHz – 13.56 MHz	Not applicable	EUT does not contain components that are sensitive to magnetic fields

Test frequency (MHz)	Band a) (MHz)	Service (a)	Modulation (b)	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380 - 390	TETRA 400	Pulse modulation b)18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b)217 Hz	0,2	0,3	9
745						
780						

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulationb)	Maximum power (W)	Distance (m)	Immunity test level (V/m)
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b)18 Hz	2	0,3	28
1720 1845 1970	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b)217 Hz	2	0,3	28
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b)217 Hz	2	0,3	28
5240 5500 5785	5100 – 5800	WLAN 802.11 a/n	Pulse modulation b)217 Hz	0,2	0,3	9
NOTE If necessary, to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.						
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because, while it does not represent actual modulation, it would be the worst case.						

Cassini Technologies B.V.
Anna van Buerenplein 40A
2595 DA Den Haag, Netherlands

P: +31 70 399 31 12
E: info@cassini-technologies.com

cassini
The world in vision