cassini

SERVICE MANUAL

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• Adjusted section 9.2 for clarity
• Included new section "Calibration Tool Replacement Procedure"
• Updated Figures/Image number
• Updated company logo and document version

1 Introduction

This document is intended to provide guidance to ensure Cassini Customer Support can troubleshoot and ensure the safe and effective operation of Cassini.

This Service manual describes the troubleshooting, cleaning, maintenance instructions and the basis of service actions.

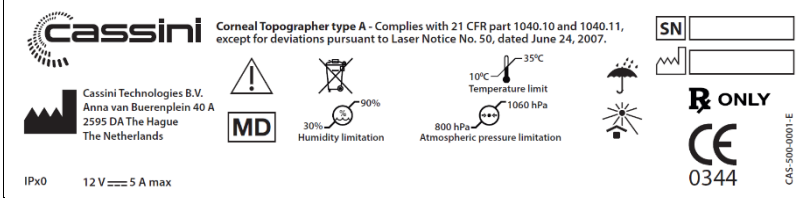
CAUTION

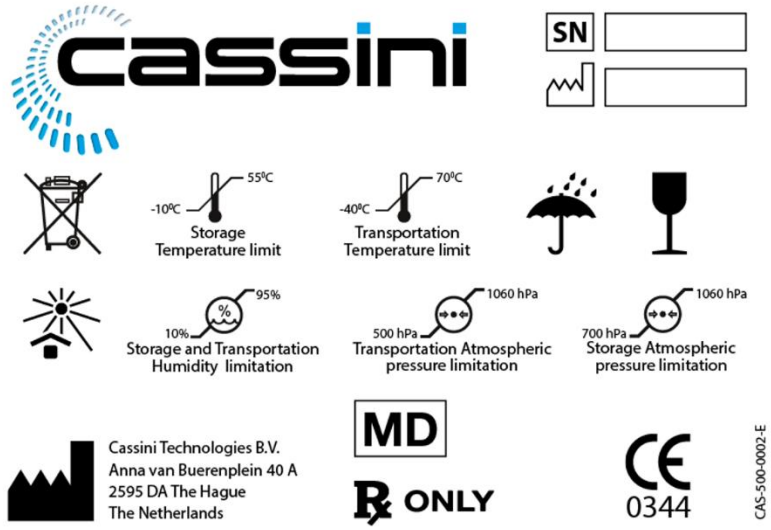
Before servicing Cassini, please read this instruction manual carefully to familiarize yourself with your Cassini and to ensure that you service it efficiently, properly, and safely.

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

1.1 Cassini labels

To ensure safety and to provide information, Cassini has several labels. If any of these labels are missing, contact Cassini Technologies BV.

LABEL	MEANING
	This label is placed on the side of Cassini and provides information about the type of Corneal Topographer, Laser safety certification, serial number, a general warning to exercise Caution, consult instructions for use, disposal indication, date of manufacture, manufacturer information, voltage and power input requirements, usage and storage conditions, electrical safety type and CE certification (by DEKRA).
	This label indicates that Cassini is a Class 1 laser product based on the laser light emitted from the device. The laser light emitted within the device has been classified as CLASS 3B. The laser radiation is class 3B near-IR. Cassini was classified according to IEC60825-1 entitled "Safety of laser products - Part 1: Equipment classification and requirements".

	This label is placed on the transport packaging. This label indicates the transport conditions.

1.2 About this Service Manual

Before providing service to the Cassini, please read these Instructions for Use, noting, and strictly observing all WARNINGS and CAUTION notices. Pay special attention to all the information given and procedures described in the SAFETY section (Chapter 2). Chapter 5 gives a complete list of the most important messages that can be displayed on the interface.

WARNING	A 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	A 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 personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury, and/or cause environmental pollution.
NOTE	NOTES highlight unusual points as an aid to the operator.

1.4 Product Information

The configuration of Cassini consists of base plate with on top of it a head support module and the actual device. The device consists of a system base with a joystick and an OD/OS detector and on top of that system base a LED dome. For an overview see Figure 1.

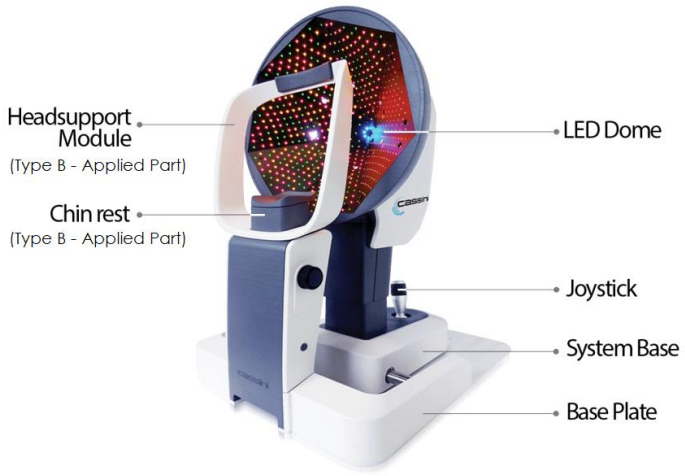


Figure 1 – Cassini main components (please note that the device you are servicing might look slightly different than the picture above)

The device is powered by a medical power supply (which is part of ME equipment) and connected by one USB3.0 cable to a specific computer which is delivered with Cassini.

The LED dome consists of 672 color LEDs (green, yellow, and red) and 7 blue 'anchor' LEDs, each one located on a LED panel and near the center hole of the dome. Inside the dome there is a color camera which will capture an image of the eye with these LEDs projected on it. That information will be used for image processing, meaning the reconstruction of the corneal surface. Additionally, Cassini has 7 white LEDs to illuminate the anterior segment of the eye.

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 as shown in Section 1, indicating that Cassini is a Class 1 laser product, and that radiation is emitted from the device.

CAUTION

Cassini has two embedded laser sources of Class 3B. Therefore, no protective covers may be removed from Cassini that may provide access to the enclosed laser beams and any exposure to the laser beams inside. If a cover is damaged or missing, exposure to the laser beams must be prevented.

1.5 Specifications of Cassini

Product details Cassini	
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
Dimensions	44(l)x32(w)x55(h) cm
Weight Cassini Device	15kg
OD/OS	Automatic detection
Colour	RAL 9010
Materials used	Type B Applied Parts: ColorRx® PC-2000RX Sabic Lexan HP4

Performance data Cassini	
Anterior Accuracy	Type A (according to 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)

Safety and Performance Standards	
Medical device Classification	Class IIa, according to Rule 10 (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

Hardware Specifications	
Processor	Intel Core Processors i5 or i7, Kaby Lake architecture, desktop versions (not energy efficient/budget lines).
Memory	8 GB DDR3 RAM
Hard disk space	1TB with 5400 RPM

Input Ports	1 LAN port, 3 USB Ports (of which 2 must be USB3). *The USB ports are not required to be powered.*
Screen Resolution	at least HD (1920 x 1080).
Graphics Card	Intel HD Graphics 4400
Software Requirements	
Operating System	Windows 10 Professional
Architecture	64 bit
OpenGL Support	OpenGL 2.1
DirectX Support	DirectX 11
Antivirus software	Any software that is compatible with windows pro. Recommended are McAffee, Nortonlifelock,Bitdefender

IT Network requirements for Healthcare provider - IT Security Requirements	
Network	Medical Grade or Clinical Network
Compliance	HIPAA (highly recommended)
Recommended Network Connection	See Chapter 11.2 Network Installation
Data transfer	Not Encrypted.

Table1: Specification of Cassini

For **Declaration of Conformity** of
Cassini Device: contact info@cassini-technologies.com
Computer (HP): contact info@cassini-technologies.com

2 Safety

Please read carefully through the Safety section, strictly following the signs and symbols mentioned throughout this Service Manual.

2.1 Important safety directions

Conditions for "normal use"

Cassini products are all designed to meet stringent safety standards. However, all medical electrical accessories require proper installation, operation, and maintenance, particularly regarding human safety.

It is vital to read, note, and where applicable, strictly observe all DANGER notices and safety markings on Cassini.

It is vital to follow strictly all safety directions under the heading SAFETY and all WARNINGS and CAUTIONS throughout this manual, to help ensure the safety of the technician.

Please note the following information given in the 'Introduction' section of this manual about the Intended use.

Only personnel trained by Cassini and with appropriate skill level (technician Level 4.2) may service the Cassini. In this context, qualified means those legally permitted to service this type of medical electrical device.

NOTE: Do not leave the device operating unattended.

2.2 Electrical and Mechanical

WARNING

Do not remove covers or cables from the accessories unless expressly instructed to do so in these Instructions for Use. Dangerous electrical voltages are present within the accessories. Removing covers or cables could lead to serious or fatal personal injury. Only a Technician Level 4.2 is allowed to remove the covers with extreme caution.

Covers or cables should only be removed by qualified- and authorized service personnel. In this context, qualified means those legally permitted to work on this type of medical electrical accessories in the jurisdiction(s) in which Cassini is being used, and authorized means those authorized by the operator of Cassini.

Shutting down the device can be done by removing and unplugging the mains connector and disconnecting the USB cables from the computer.

2.3 ESD – Electrostatic Discharge

Cassini is connected to a computer through a USB 3.0 port which supplies power to both the monochrome and the color camera as well as utilizing the data transfer.
Cassini unit complies with the safety requirements of IEC60601-2. However, when connected to a computer, the combination classifies as a Medical System and additional requirements are applicable. This is summarized in the following Caution statements:

CAUTION

Do not connect Cassini to its computer via a powered USB hub. Connection to its 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 Cassini computer as these can potentially affect the combined monochrome camera and color camera views on Cassini Graphical User Interface (GUI) when capturing images.

What is electrostatic discharge (ESD):

Electrostatic discharge (ESD) is the sudden flow of electricity between two objects with different charges and different numbers of electrons. This exchange of electrons creates a large electromagnetic field buildup, resulting in ESD.

ESD symbol as shown

Computer components that are sensitive to static electricity or ESD are motherboards, CPUs, expansion cards and memory devices.

NOTE That Cassini holds some of the same or similar PC components mentioned above. Therefore, extreme caution must be taken. You will see the ESD symbol throughout the Service Manual.

WARNING

Cassini must never be serviced without proper ESD equipment or certified ESD facility. Please see below for proper ESD equipment.

2.4 Handling sensitive Electronic Components

Some electronic components are very sensitive to static and the sudden discharge of electricity from your body to the component, which is harmless to humans, but can cause irreparable damage to the components or devices.

2.5 Antistatic Devices Explained

Anti-static devices help minimize the risk of damage caused by static by inhibiting the build-up of static electricity. This prevents the chance of a sudden discharge of electricity via the sensitive component, therefore protecting it from damage.

2.5.1 Antistatic Bag

An antistatic bag is used to store electronic components which are sensitive to static electricity. Conductive antistatic bags contain a layer of conductive metal, which forms a non-conductive barrier and a shield which protects the contents from the static charge using the Faraday cage effect.

2.5.2 Antistatic Bar

An antistatic bar removes static electricity from a production line, preventing issues including dust clinging to products, products clinging to themselves, rollers, machine beds or frames as well as materials jamming or tearing.

2.5.3 Antistatic Clothing

Antistatic clothing contains conductive threads, creating a wearable Faraday cage. Most antistatic garments need to be grounded, i.e. connected to the ground with a strap.

2.5.4 Antistatic Mat

An antistatic mat or ground mat allows electrostatic discharge to flow across the surface slowly, in a controlled manner, thus preventing the rapid discharge which can damage sensitive components. The mat is grounded by being connected to the mains plug outlet via an earth bonding plug. Both antistatic bench and floor mats are available for working with electronic components.

2.5.5 Antistatic Wrist Strap

An antistatic wrist strap or ESD wristband is used to ground a person who works on sensitive electronic components. It is worn around the wrist and connected to the mains plug outlet via an earth bonding plug.

2.6 Portable and Mobile Phones, and EMF

Cassini accessories comply with relevant international and national law and standards on EMC (electro-magnetic compatibility) for this type of product when used as intended. Such laws and standards define both the permissible electromagnetic emission levels from Cassini accessories and its required immunity to electromagnetic interference from external sources.


WARNING

Other electronic products exceeding the limits defined in such EMC standards could, under unusual circumstances, affect the operation of Cassini.

Medical electrical products need special precautions regarding EMC and need to be installed and put into service according to EMC information provided in the accompanying documents.

The use of accessories and cables, other than those specified may result in increased emission or decreased immunity levels.

The accessories should not be used adjacent to, or stacked with, other accessories. If adjacent or stacked use is necessary, the technician must verify that the accessories operate normally in the configuration in which it will be used.

2.7 Environmental conditions for use


WARNING

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

Temperature: +10 °C to +35 °C.
Humidity: max. 30 to 90% (non-condensing)
Maximum installation height: 2000m

2.8 Storage Conditions

Temperature: -10 °C to +55 °C.
Humidity: max. 10-95%(non-condensing)

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

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

2.9 Transport Conditions

Cassini within its packaging meets the transport simulation conditions according to ISO 15004-1:

Temperature: -40°C to +70 °C
Relative Humidity: 10% to 95%
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 sufficient padding and protection is used to prevent damage from shock, bump, vibrations, dust, or liquids.


WARNING

If the device or the transport box in which it has been transported has been clearly damaged, don't install it and please contact the local distributor and Cassini headquarters.

If the computer or the box in which it has been transported has been clearly damaged, don't install it and please contact the local distributor and Cassini headquarters.

If the calibration tool or the box in which it has been transported has been clearly damaged, don't use it and please contact the local distributor or Cassini Technical Support.

Please ensure that the device is realigned using the calibration tool after transport, see Section 9.

3 Safety Precautions Before Use

WARNING

Device must be placed in a dimmed room (during normal operations), not necessarily while Cassini device is being service.

CAUTION

To prevent Cassini from falling and to avoid injury, do not install Cassini on an uneven or unsteady surface, including a slope.

CAUTION

Cassini has two embedded laser sources of Class 1. Therefore, no protective covers may be removed from Cassini that may provide access to the enclosed laser beams and any exposure to the laser beams inside. If a cover is damaged or missing, exposure to the laser beams must be prevented.

CAUTION

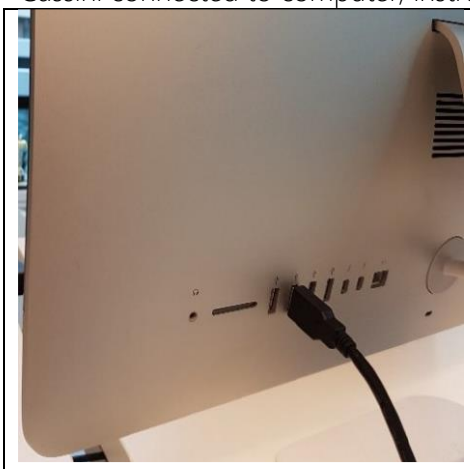
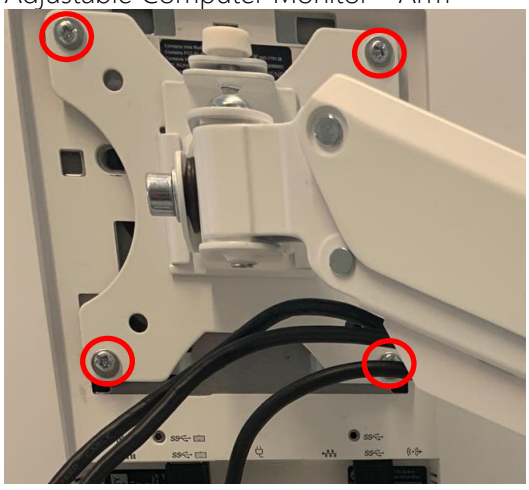
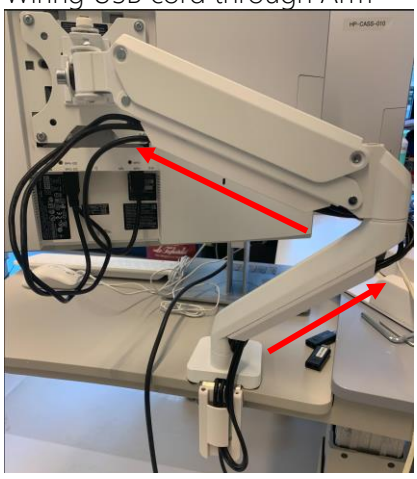
To avoid injury during carrying, Cassini should only be transported in box.


ESD Equipment or facility required.

4 Installation of Cassini

4.1 Connectivity of Cassini

Cassini connected to computer, instructions in below Table 2: Instructions for connectivity.

<table>
<tr><td> 
i-Mac</td><td> 
HP computer</td><td>The computer is connected to Cassini through one USB 3.0 cable.</td></tr>
<tr><td colspan="2"> 
Cassini power supply needs to be connected to the power cable of Cassini. The plug and socket provide suitable means for isolation from the supply mains hence they should be placed in a manner readily accessible when needed.</td><td> 
When Cassini is connected to the power supply, green light on top of the dome is turned on.</td></tr>
<tr><td>Adjustable Computer Monitor - Arm
  </td><td>Wiring USB cord through Arm
  </td><td>The adjustable computer monitor arm screws behind the HP computer using four screw, marked with red circles.

The USB 3.0 will need to be wired through the adjustable computer arm. The USB 3.0 cord will need to be connected behind the Hp using one of the four USB ports available.</td></tr>
</table>

CAUTION Be sure to plug the USB cable only in USB ports in a correct way. 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 Computer is to be established only in a direct manner and with observation of the above requirement. CAUTION No USB devices other than Cassini, mouse, and keyboard should be attached to computer as these can potentially affect the combined monochrome camera and color camera views on Cassini Graphical User Interface (GUI) when capturing images.		

Table 2: Instructions for connectivity

4.1.1 Adjustable Computer Monitor/Arm installation

The adjustable computer monitor arm will need to be mounted to the table. See image below as illustration. A rotating knob is used to C-Clamp the arm to the table. The arm must be tightly secure to the table with no movements.

Figure 2

4.1.2 Adjusting Computer Monitor Arm

The image below will show the direction in which to adjust the swivel rotation of the spring of the arm. Turning the spring screw towards the right, will make monitor arm movements quite loose. Turning the screw to the left will make the arm movement harder and more secure.

NOTE: With the computer mounted to the arm, always make sure the swivel screw is tightly secure.

CAUTION

DO NOT leave monitor arm loose with the computer mounted.

Figure 3

4.2 Network Installation

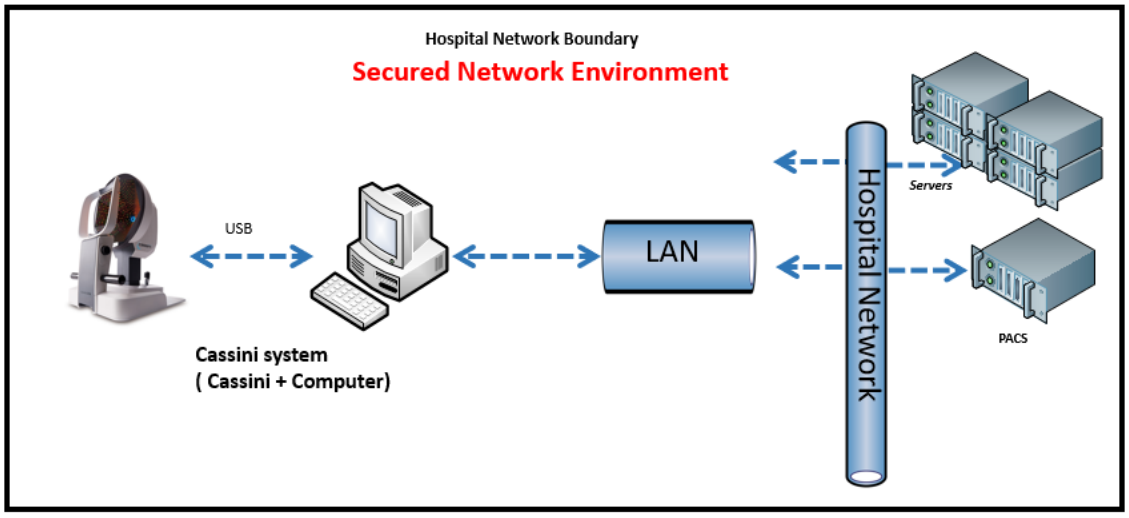


Figure 4: Secure network environment where security measures are in place to help protect from outside attackers.

Cassini device is connected to the Cassini 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 4.

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 is transmitted over a secure (end-to-end) connection. Cassini Technologies B.V. cannot be held liable for the loss or leaking of any data.

4.3 Software Installation

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

System time

When you receive a Cassini, computer and software, the system date and time are set to a certain region. Please change the setting to be in accordance with your region if required, otherwise the date and time stamp of the examinations shall contain incorrect information. Refer to the Windows 10 instructions about how to manage the regional settings.

Starting the Computer

At the first start of the computer connected to Cassini, you will have to log in with *username* Admin and *password* Admin. You will then see the following icon on the desktop:

Which is the icon of Cassini application. By double clicking on it you will start the application, and you will the main screen as displayed in Figure 5.

Figure 5 - Main screen

NOTE

Cassini is intended to be operated in a secured network environment. It is the responsibility of the user

- to ensure that the medical device contains only Cassini Software.
- for timely update of anti-virus software
- manage User-permissions and maintain audit trail of user actions.

4.4 About Cassini

The 'About Cassini…' option in the Help menu will show the "About Cassini" dialog box, which will show you the version of the software and device firmware.

4.5 Terminating Cassini software

Application can be terminated by clicking the red X button on the top right corner of the main screen (Figure 3: Main screen).

4.6 Software Licenses

Valid user licenses are required to operate Cassini software. These licenses can be obtained via Cassini support. Every license is valid during a determined period. USER is responsible for monitoring the date of license or licenses expiration. Please contact Cassini support or the local distributor for software license renewal.

5 Database Backup/Archiving/Restoring

CAUTION

Before attempting any service or repairs on Cassini computer, you must first back up the Cassini's database.

5.1 Export the database for backup/archiving

The complete database can be exported for several reasons e.g. archiving, moving to a different machine, for R&D purpose.

For Cassini 3.0/3.1 software, this can be done with the "ExportDB_v2.bat" script and the following steps:

The script files that are discussed in this document can be found under:

(\\ct-fs01) I:\Software\Sources\DatabaseScripts\v3.1.0\exportCassiniDB

Dependency: None

- Close application
- Open a command prompt
- Run the script "ExportDB_v2.bat"
- Type the password for the cassiniAdmin account, the script will produce output on the screen and should finish without any errors
- A folder with a timestamp and machine name will be created in the current working folder. The folder contains several "tar.gz" files, these files hold the database data.

In Cassini 3.2-3.4 software we have Database Archiving option in the software. Ensure you have a Service license to perform this function.

Go to Options→Settings→Service and click "Archive Database"

Select a proper location to store the files and click "Save".

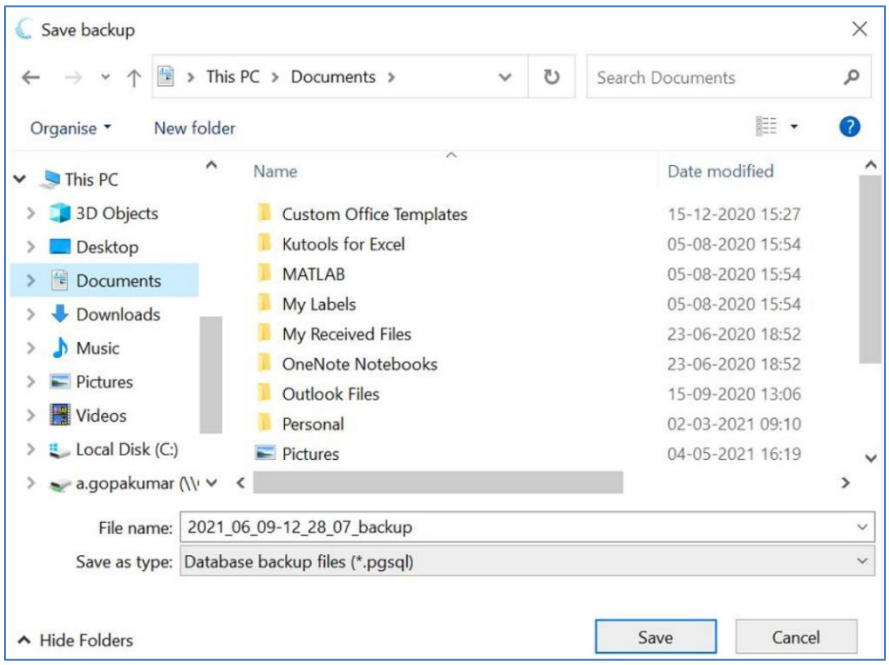


Figure 6

A progress bar will show up indicating the exporting process.

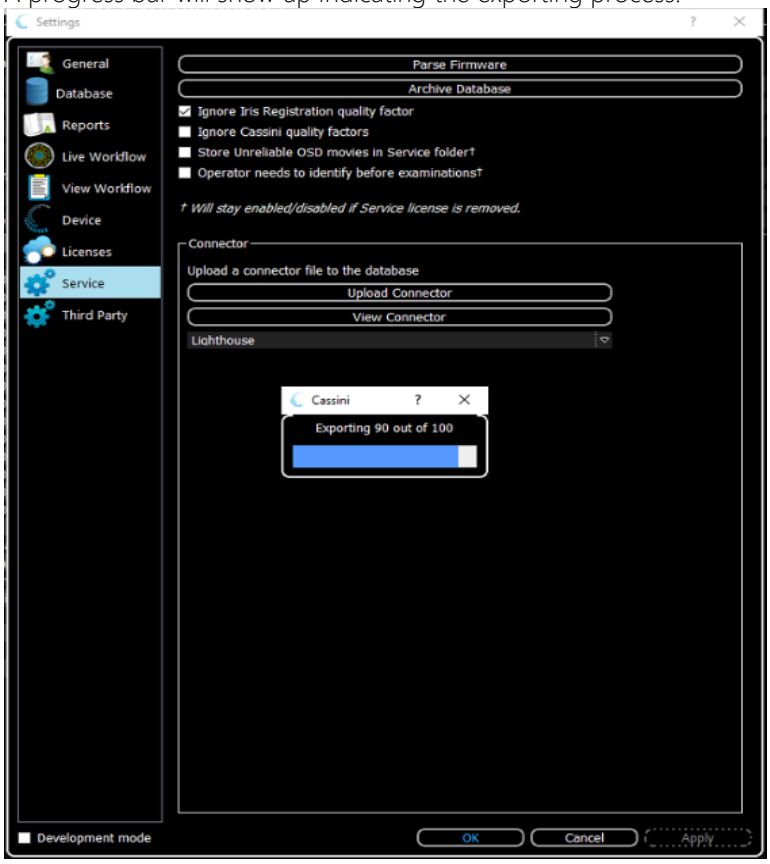


Figure 7

5.2 Import and restore the database

The archived database can be imported for several reasons e.g. moving to a different machine, for R&D purpose, etc.

For Cassini 3.0/3.1 software, this can be done with the "cleanCassiniEnv_v2.bat" and "ImportDB_v2.bat" scripts, and the following steps:

The script files that are discussed in this document can be found under:

(\\ct-fs01) I:\Software\Sources\DatabaseScripts\v3.1.0\ImportCassiniDB
(\\ct-fs01) I:\Software\Sources\DatabaseScripts\v3.1.0\cleanCassiniEnv

Dependency: None

- Close the Cassini application.
- Start the command prompt and run the scripts to proper import
- First: >> psql -U cassiniAdmin -d cassini -f cleanCassiniEnv_v2.sql
- Then: >> ImportDB_v2.bat %backupFileName%.pgsql
- You will have to enter the cassiniAdmin password once, then hit enter when prompted, then enter the password two more times.
- The import will take a few minutes.

Notes:
The first command will clean the database environment, backup the current database first if necessary. The Cassini application should not be running during the procedure.

Verify that the output to the command line shows that something is really imported, and no error is given (e.g. DROP SCHEMA, CREATE SCHEMA, pg_restore, ALTER DATABASE).

For Cassini 3.2-3.4 software, this can be done with the "cleanCassiniEnv_v2.bat" and "ImportDB_v3.bat" scripts, and the following steps:

The script files that are discussed in this document can be found under:

(\\ct-fs01) I:\Software\Sources\DatabaseScripts\v3.2.0\ImportCassiniDB
(\\ct-fs01) I:\Software\Sources\DatabaseScripts\v3.2.0\cleanCassiniEnv

Dependency: None

- Close the Cassini application.
- Start the command prompt and run the scripts to proper import
- First: >> psql -U cassiniAdmin -d cassini -f cleanCassiniEnv_v2.sql
- Then: >> ImportDB_v3.bat %backupFileName%.pgsql
- You will have to enter the cassiniAdmin password once, then hit enter when prompted, enter the password two more times.
- The import will take a few minutes.

Notes:
The first command will clean the database environment, backup the current database first if necessary. The Cassini application should not be running during the procedure.

Verify that the output to the command line shows that something is really imported, and no error is given (e.g. DROP SCHEMA, CREATE SCHEMA, pg_restore, ALTER DATABASE).

5.3 Database Management

In Development mode, Cassini software 3.5.0 and higher versions will offer the ability of database cleaning/deletion.

In Settings, in Database sections, one can perform several tasks for database management. One can see the store capacity and how much free space there is available. (Figure 8)

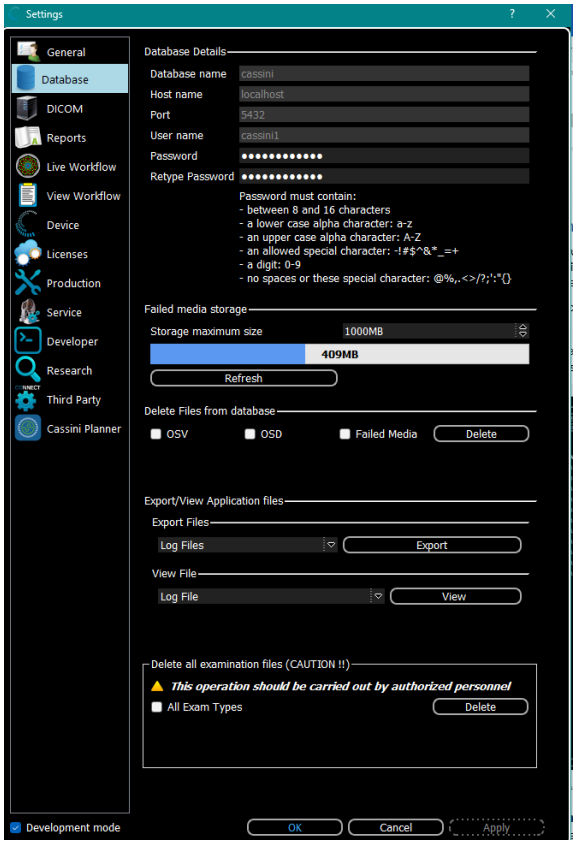


Figure 8 - Database settings screen

5.3.1 Deleting files from database

Unwanted Cassini OSV, OSD and Failed Media can be deleted from database to make room for more disk space. (Figure 9)

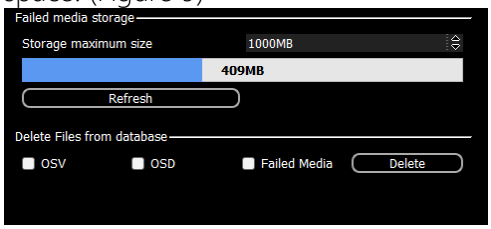


Figure 9

5.3.2 Deleting all Examinations

Under Development mode one can also delete the entire database. Archiving/backup of the entire database is highly recommended prior to performing a complete deletion of the database. (Figure 10)

WARNING

Deleting all exams should only be done if a customer has strictly requested to do so. One should confirm several times if the customer requests a a complete wipe, as they would be starting a new empty database. Archiving/backup of the entire database is highly recommended

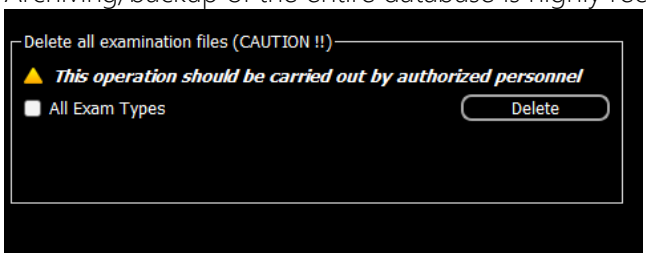


Figure 10 - Delete all Exams

5.3.3 Exporting of Logs, System Files, Camera Files and Failed Media Files

Development Mode also offers the ability to export all Cassini Logs, Camera Calibration files, Failed Media Files and System Files. These files are crucial for R&D purposes. The drop-down option will show the type of files to choose from for exporting or viewing. (Figure 11)

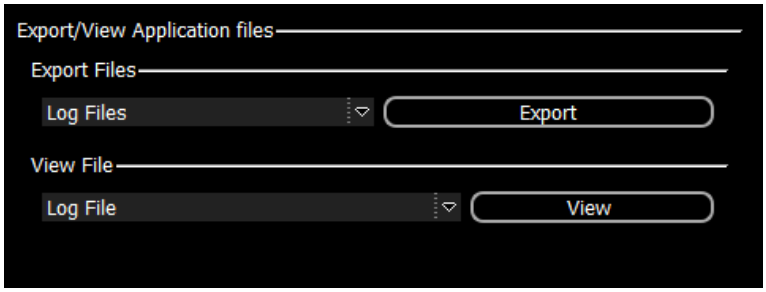


Figure 11 - Exporting Logs and other files

6 System and Error Messages

Cassini system will display numerous different types of Error messages. Please carefully read the Sections below (Section 6.1-6.3) to familiarize yourself with those messages and errors and how to properly troubleshoot them.

6.1 How to Handle System and Error Messages

When using Cassini sometimes system and error messages will pop up. Messages usually support with troubleshooting in order to do things better or to provide information how to solve a problem. There is no reason to worry about a device- or software malfunction since it is safe by design.

If a message appears on the screen, read it carefully and follow instructions or look into section 6.2-6.3 for explanation and troubleshooting.

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

6.2 Overview System and Error Messages

	Message	Suggestion
1	Fail to store scan in Database	Check if database is present and access rights are correct
2	Calibration File missing	Calibrate device
3	Unable to open device	Power cycle Cassini; restart application.
4	Unable to find printer	Please set the printer and try again. Connect printer. Check for latest printer drivers and install the associated drivers
5	Fail to open Database	Check if database is present and access rights are correct
6	Fail to find color camera ini file	Check if color camera ini file present and access rights are correct
7	Fail to find mono camera ini file	Check if mono camera ini file present and access rights are correct
8	timeout Executing command 0xXX	Powercycle Cassini; restart application
9	Database Query Error	Check if database is present and access rights are correct
10	USB Express call failed	Powercycle Cassini; restart application
11	There is an error with the USB connection to the device	Powercycle Cassini; restart application

12	Can't communicate with the device, please check theconnection	Check the USB connections and if necessary powercycle Cassini; restart application

6.3 Troubleshooting and Repair

	Problem	Suggestion
1	Poor scan results	• Recalibrate system and make sure the patient is well aligned • Make sure the patient's head is correctly positioned with his/her forehead against the head rest and his/her chin in the chinrest. • Make sure the patient does not blink when not told during scan or move during alignment • Tell the patient to widen both eyes maximally and let them blink just 1 second before the scan. Do not make the scan immediately after blinking! • Tell the patient to focus on the red fixation LED in the center of the dome with the eye which is to be scanned. If the Red fixation is too difficult to view by the patient, then have the patient focus in the center for the Blue LED's (Anterior Scan), as this means they are looking at the red fixation light • Tell the patient not to move/talk during scanning • If patient blinks often help patient with moving eyelid (close the other eye). When helping the patient in this way be sure not to use too much force which could deform the corneal surface • Tell the patient just to turn the head a bit so the shadow caused by the nose is less troublesome. • If turning the head does not work, then ask the patient to place chin on top of the chin rest. This technique will minimize the shadowing of the eyebrow and nose. • Do not move the joystick when pressing the trigger button
2	Calibration – processing of image is failing after right alignment	• Check if the calibration tool has scratches. If so, please contact thelocal distributor or Cassini Technical Support. • Check if the calibration tool has stains. If so, follow Section "Maintenance – Cleaning" to

	Problem	Suggestion
		carefully clean the calibration surface without making any scratches Dim all light sources. Try calibrating in a dark environment
3	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.
4	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 USB cable • Turn off / turn on the power of the Device by (un)plugging Cassini main power cable • Make sure there is a reflection surface (calibration target/eye) in front of the dome center • Check in calibration screen if the for indicators>0 Monochrome camera displays are usually dark, make sure you are close to focus
5	OD/OS indicator gives a wrong value	Check if this is working by moving the base in the extreme left and afterwards the extreme right position and monitor the value. Note: OD/OS relates to the eye of the patient (mirrored in operator's movement) If the above does not help, please contact the local distributor or Cassini Technical Support.
6	Unable to find work laser spots because of too many spots	This may happen if Cassini is too close to the eye. Please try to realign according to instructions.

	Problem	Suggestion
7	Unable to Calibrate	Calibration should always be done with the lights OFF in the room. If unable to turn lights OFF, then place the duct cover on top to cover Cassini head and perform calibration. Make sure the Calibration Tool glass part is not loose. If it feels loose, please tighten it. This may happen over time and the glass part will unscrew itself when rotating it out of its holder. If calibration is still difficult after trying the above steps, please proceed to the below steps as follow: • Clean Calibration Tool with cloth. • DO NOT use alcohol or abrasive chemicals on the Glass part of the calibration tool • Please try the thumb print technique by placing your thumb print slightly on the Glass part. The natural oils of the skin of the thumb will mimic a tear film, making calibration a lot easier and IR Dots (two white focus dots) easier to see. • Proceed to calibrating. Ensure that after the second calibration you have all Green Quality Factors and the difference between calibration verifications (the first and the second calibrations) is Radius of Curvature of 0.05D or below. • If any of the above does not help, please contact the local distributor or Cassini Technical Support.
8	Unable to find printer	Please make sure the printers are correctly installed under Windows. Please update any drivers associated with the printer by looking up the manufacture of the printer support website. If printer is directly connected via USB cord, then please try updating any drivers associated with the USB controller hub in Windows.

	Problem	Suggestion
9	Camera Icons grayed out (both Workflow and Calibration) 	If camera icons appear grayed out, please follow the troubleshooting steps below: • Make sure Cassini has power and green light on top of device is ON. • Ensure the camera USB cord is properly inserted. If the troubleshooting steps above are complete and icons remain grayed out, then follow steps below: • Ensure that the TCA licenses have Not expired. If they are expired, please reach out to Sales Team/ Cassini Technical Support regarding licenses renewal or extensions. • If Licenses Status is "OK" and icons are still grayed out, then proceed in performing a "Power Cycle" and computer restart. • If the camera icons remain grayed out after a Power Cycle and computer restart, then proceed to the Development portion of the Cassini Software to collect Error/Logs and contact Cassini Technical Support.

If (parts of) the system (have) has been damaged, please shutdown the system by unplugging Cassini mains cable and the computer mains cable from the power outlet and disconnect the USB cable. Shutdown the computer by closing Cassini application and selecting shutdown in the start menu of Windows.

During an examination, if the USB cable is disconnected from the computer in any way, then cancel the examination, restart Cassini software, power cycle Cassini device, reconnect the USB cable and repeat the scan.

WARNING

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

7 Maintenance and Disposal

7.1 Maintenance - Regular Checks and Usage

Inspect the instrument and components every two weeks. Missing accessories can be ordered from the Cassini Technologies BV authorized distributor or at www.cassini-technologies.com. Carefully inspect the calibration tool every day 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. Instructions for LED panel cleaning are given below.

NOTE The above procedure on Regular Checks is mentioned primarily for the Cassini user not particularly mentioned for Cassini Service Technicians. But all Cassini technicians should know the basis of maintaining a Cassini on daily basis.

CAUTION

When cleaning the LED panels or any other part of the device, make sure all power is disconnected from the device, meaning the main cable should be unplugged and USB cables should be disconnected.

For patient hygiene, make sure the chin- and headrest and handles are cleaned regularly with alcohol wipes.

For operator's hygiene, make sure the joystick and joystick button and computer and other peripherals are regularly cleaned.

After a period of not using Cassini, re-familiarize yourself with the important points of the manual before using it again.

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.

Don't install other software on the computer, which is provided with the system, running or storing other software could have a negative impact on the performance and security of Cassini software and patient database.

Software bug reports can be sent to support@cassini-technologies.com; they will be investigated for future software releases.

NOTE: The above procedure on Regular Checks is mentioned primarily for the Cassini user. But all Cassini technicians should know the basis of maintaining a Cassini on daily basis.

7.2 Maintenance - Cleaning

CAUTION

It is recommended that Cassini LED Panels are cleaned on a regular basis to prevent build-up of dirt, stains or dust that may reduce performance or operator and patient comfort. For proper LED detection, make sure that no fingerprints, dust or dirt are present on the LED panels.

CAUTION

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 both USB cables should be disconnected.

CAUTION

Care must be taken not to use any cleaning liquid or solvent inside the LED dome/for cleaning the LED panels 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. Don't use the same lens tissue for the cleaning of both calibration surface and LED panels and throw the lens tissues away after cleaning. When cleaning only touch the LED panels/calibration surface with the tissue; don't make direct contact by skin!

Cleaning of the parts which contact the patient or operator:

- All plastic covers including the operator control platform, the head support (head- and chinrest and handles), and any labels can be cleaned with a cloth and detergent or a common solvent such as alcohol. Common grade alcohol swabs or tissue can be used for this purpose.

- The LED panels can be cleaned with a clean dry lens tissue (Berkshire Lensx®90) which is provided with the system. Make sure that no objects are used which could cause scratching on the surface and make sure 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 with the system. Make sure that no objects are used which could cause scratching the surface and make sure that during cleaning direct contact between skin and calibration surface is prevented. Do not use a lot of pressure on the surface when cleaning and make sure the calibration surface never makes any other contact than with the foam of the box or the lens tissue to prevent scratches. After cleaning/calibration put the calibration tool immediately in the box again and close the cover to prevent dust getting in.

- For cleaning of the computer and its peripherals, please look at the instructions provided by the corresponding manufacturer.

7.3 Dust Free - Procedure

At any moment when the Cassini Technician exposes any of the internal components of the Cassini while opening any of the Protective Covers, dust must be cleared off from the Cassini. There should be no dust inside the Cassini to avoid dust particle falling inside the electronics components and in Mono/Color Cameras.

NOTE: After each service work done on a Cassini, please follow the Maintenance and Cleaning instructions mentioned above (7.1-7.2) so that the Cassini user receives their Cassini back cleaned and looking like new.

7.4 Disposing of the Product

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 Cassini. Return the product to Cassini Technologies BV for disposal and recycling

Cassini packaging materials consists of cardboards and plastics which can be recycled. Please handover these materials to the local recycling center or dispose them in an environment friendly manner.

8 Servicing Procedures

Please make sure to use proper ESD Equipment.

8.1 Rail Covers removal

To Remove the two rail covers, you'll need to locate 4 Star (Torx) screw, two in each rail covers. One screw in the front and one near the Chin Rest facing the back side of the Cassini.

A Torx size 10 screwdriver is needed to remove the 4 screws (T-10).

The covers will come loose by pulling slightly up and outwards exposing the Rails and the Base axel/wheels.

8.2 Assembly Introduction

Please make sure to use proper ESD Equipment. (see section 2.3)

This instruction describes the first part of the Cassini Device Assy structure. This section describes how the CSO base is converted, how the side plates are pre-assembled and wired and how the camera assembly is mounted. The result of this instruction is a basis for the device assembly on which the first check can be performed: the dust check

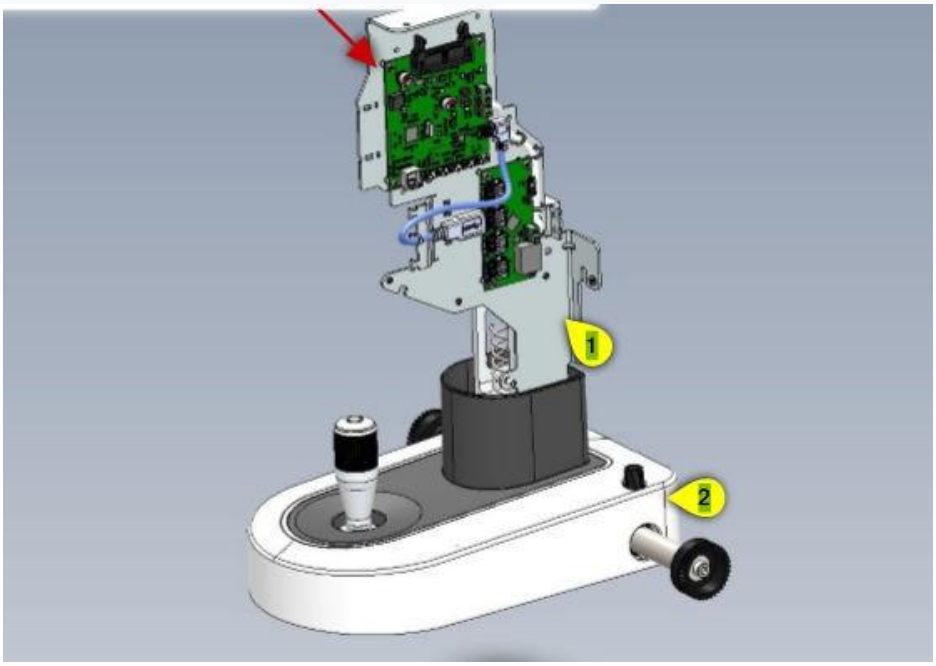


Figure 12 - Sideplate_assy-R on the Carriage Assy

1 - CAS-850-0002 Sideplate_assy-R
2 - 800-0157 carriage_assy

8.3 Cassini Base Assembly

Please make sure to use proper ESD Equipment. (see section 2.3)

The CSO base must be slightly modified so that it can be used in the Cassini. Unscrew the original adapter on the top of the CSO base.

NOTE: Below is a pressed spring

Take the CSO-BaseAssy and remove the following parts: the special screw with an O-ring underneath and the 'white neck. The 'white neck' is under pressure from a spring, so hold it when removing the screw!! Wipe off excess grease from the spring (Figure 7 on next page).

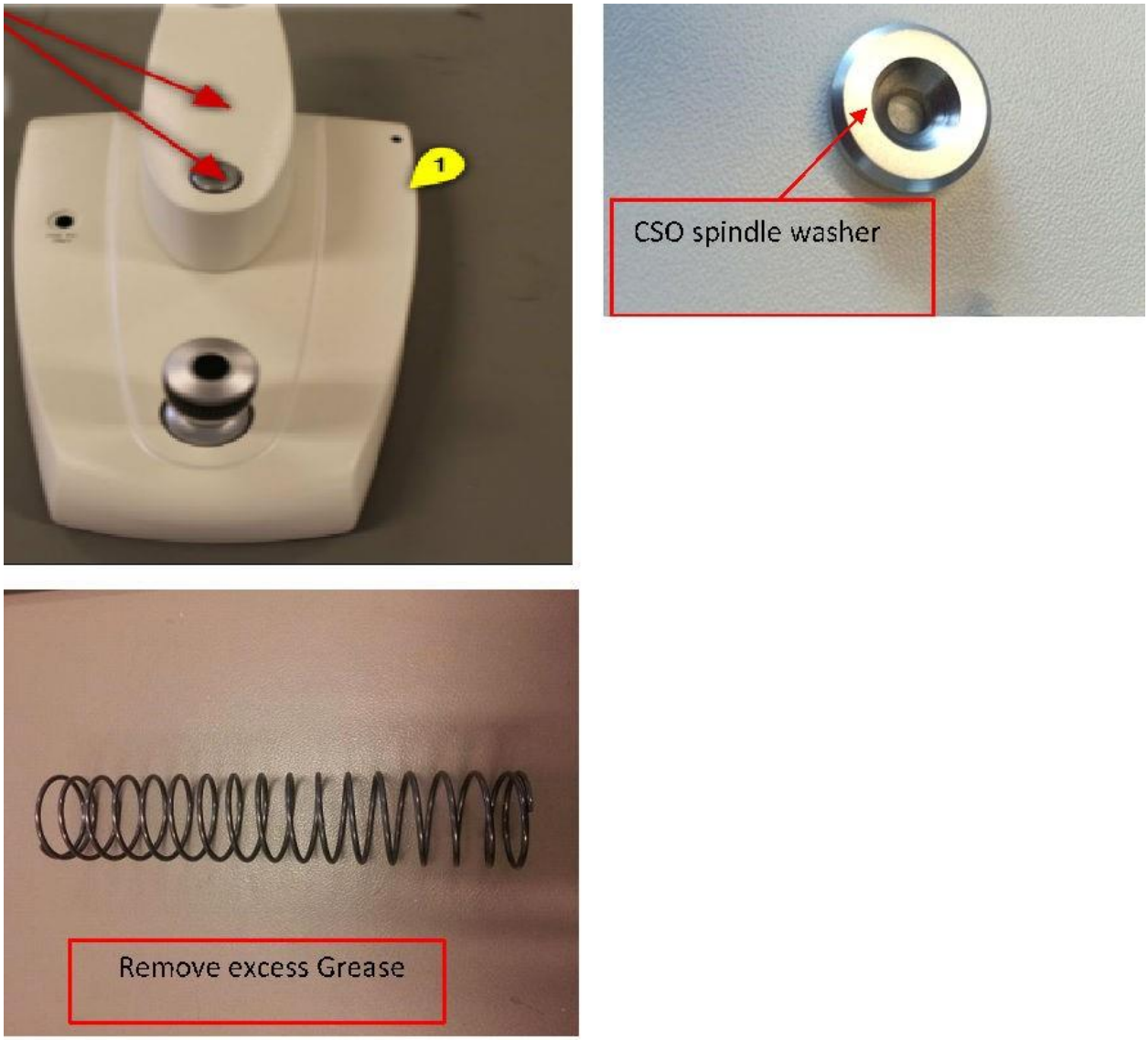


Figure 13 - CSO Base

Place the CSO to system-board cable (800-0020) and place a ferrite core around the CSO cable. Fix the ferrite core with hotmelt. In addition, check that the screws shown in Figure 8 (next page) are properly tightened, screw them if they are not. After this the lid can be placed again. Clean the base with a cloth with alcohol

Please make sure to use proper ESD Equipment. (see section 2.3)

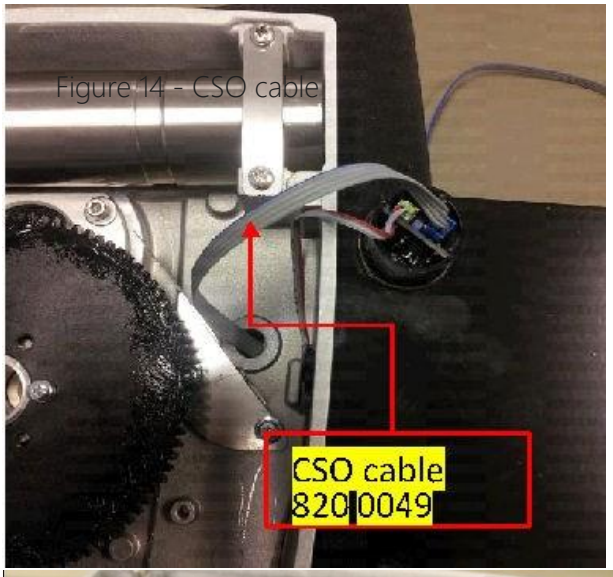
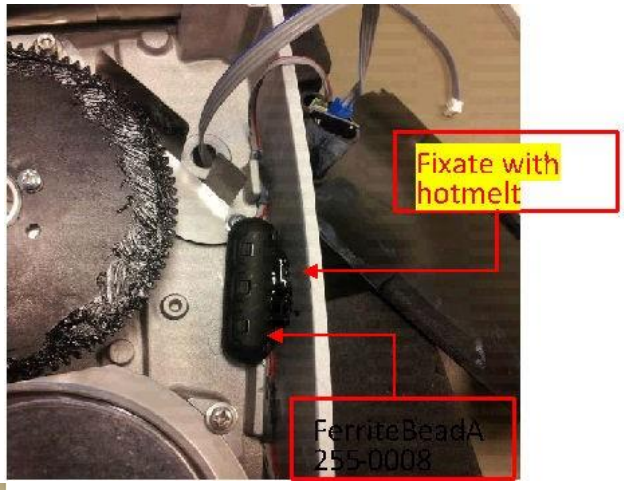
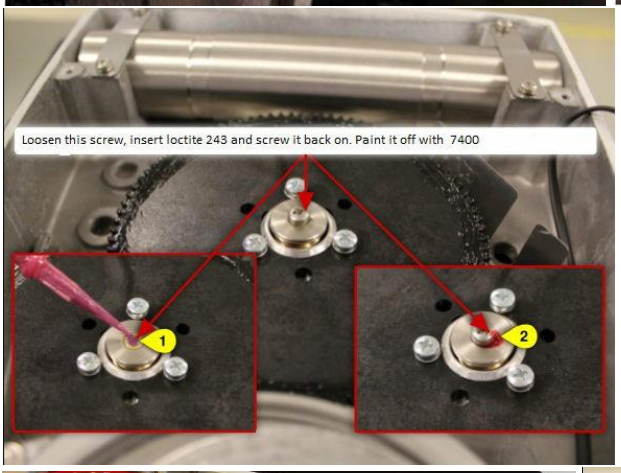
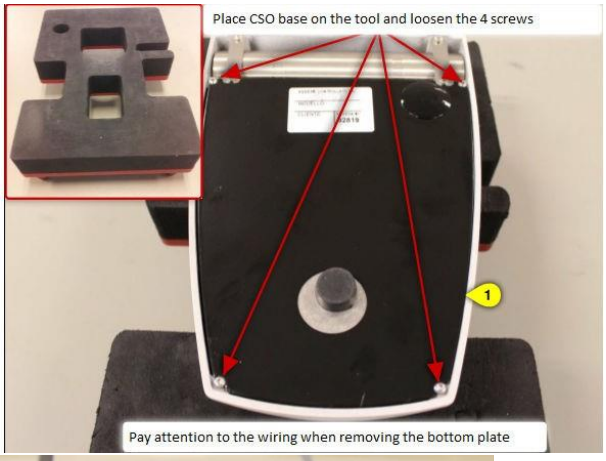
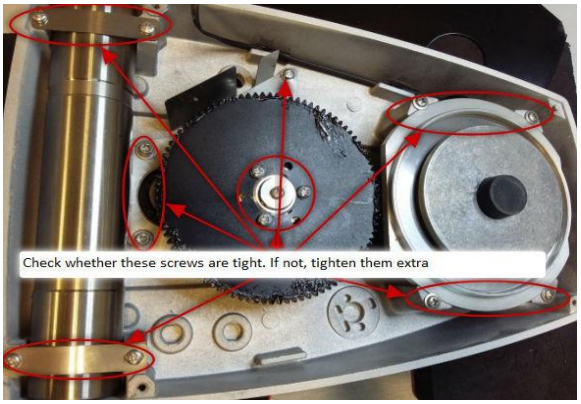


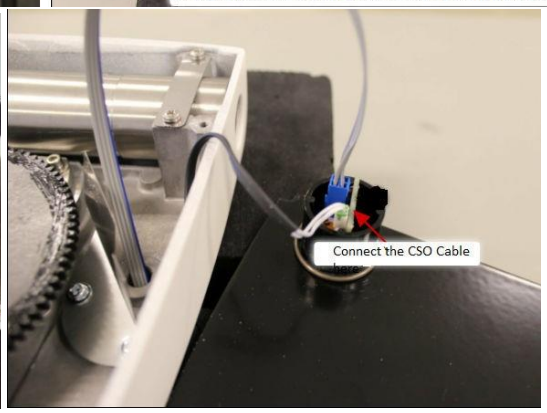
Figure 14 - CSO cable











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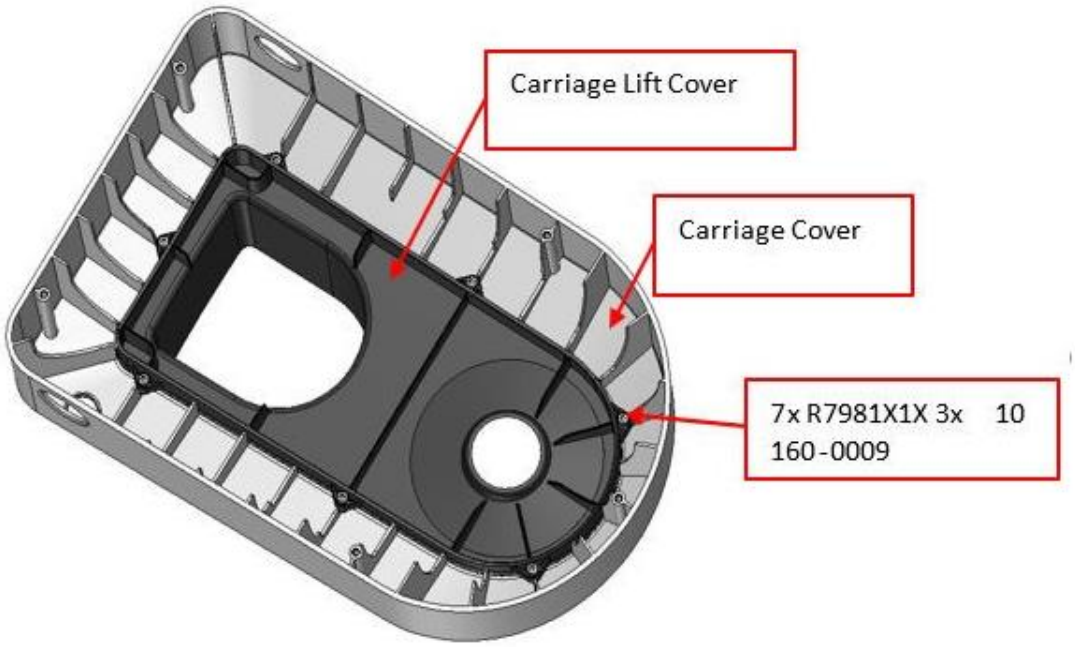


Figure 15 – Carriage cover

I

Please make sure to use proper ESD Equipment. (see section 2.3)

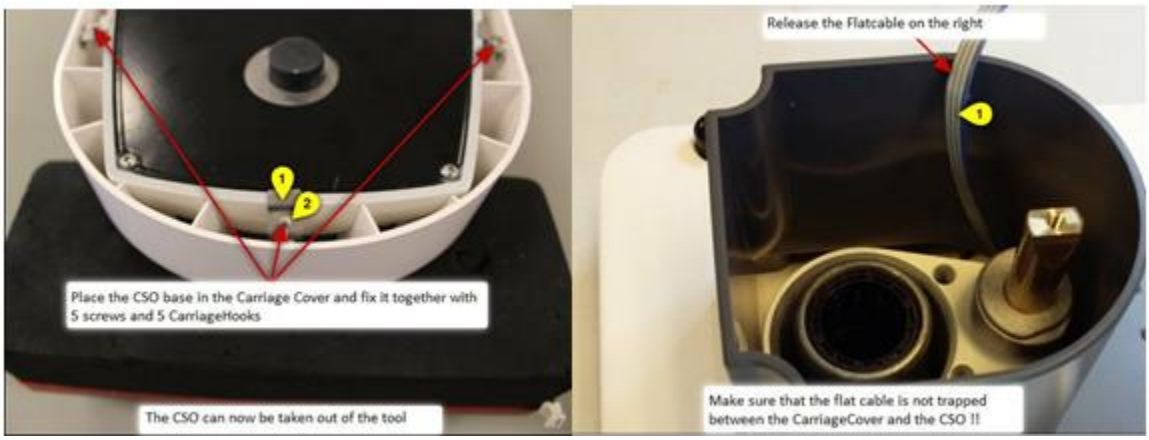


Figure 16

Place the CSO Carriage in the Carriage cover and screw it in place (Figure 17). Note that the axle must temporarily leave to place this assy.

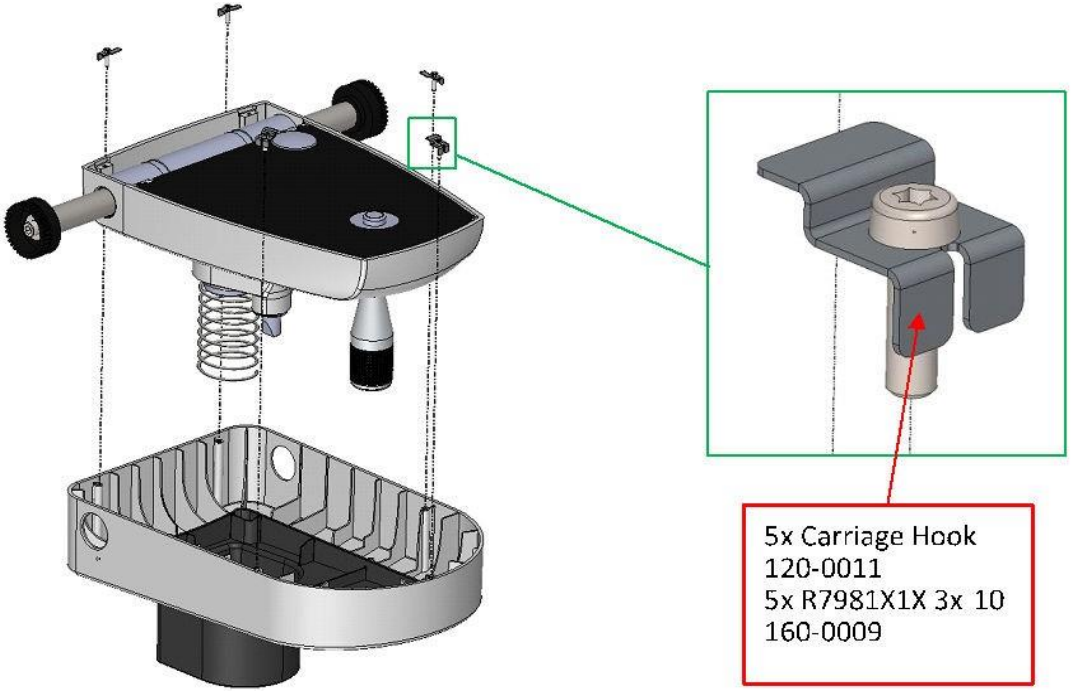
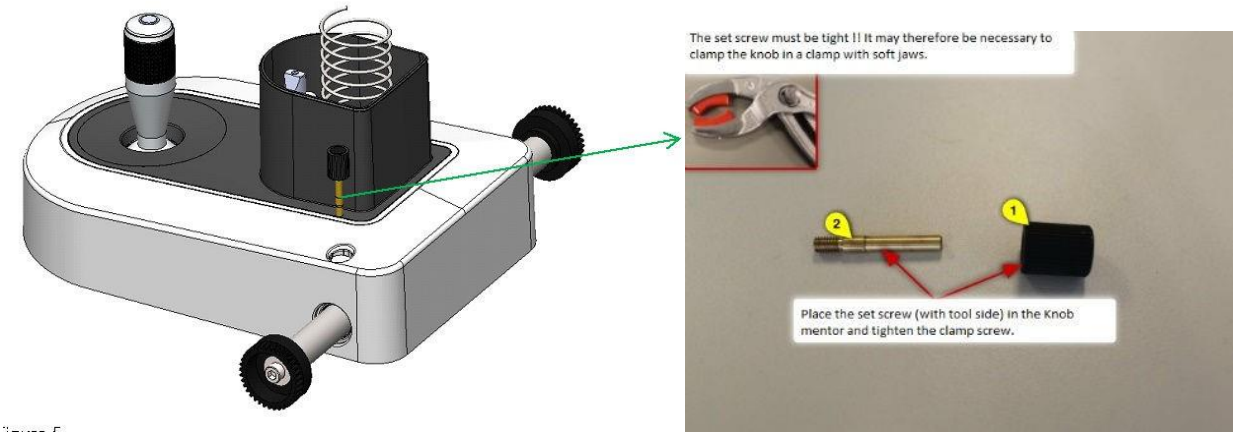
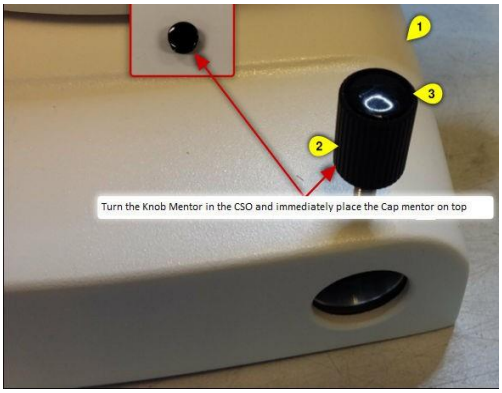


Figure 17 – Placing CSO base over carriage cover

Turn the assembly over and place the button (Figure 18).
The set screw is placed into the knob mentor and placed on the CSO after its being tightened.





Finally place the CSO spindle washer with 1x DIN7991 M4x20 (160-0533) on the shaft. Do not tighten this yet, this step only ensures that the washer cannot get lost. See Figure 18.

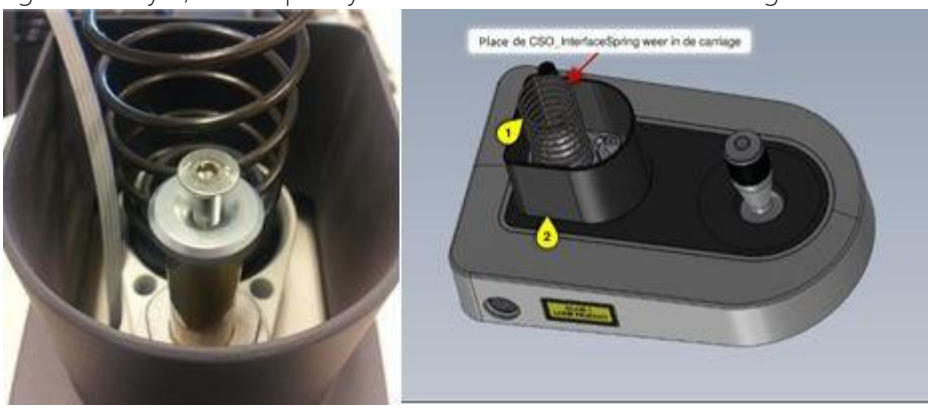


Figure 18 – Placement of spindle washer into the shaft

After this, the pre-assembling of the side plates will be continued. The CSO base will be further worked on later in the sections below.

8.4 Cabling to Plate – Right

First connect the 2 PCA system boards and the USB hub on the side plate. The flat cable is connected to the top circuit board and then tied to the back of side plate.

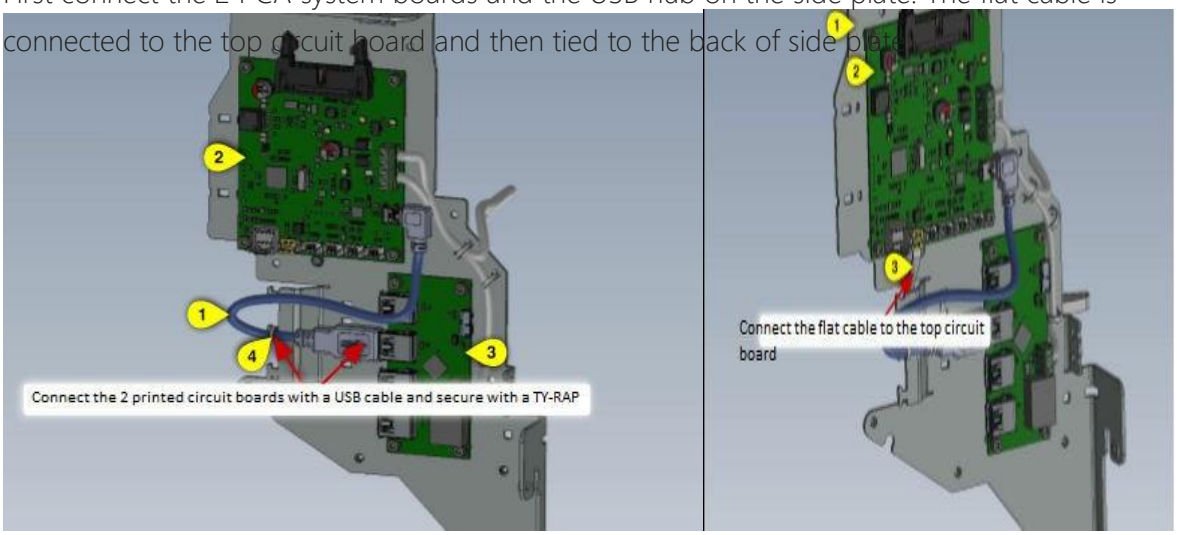


Figure 19 – PCA System board

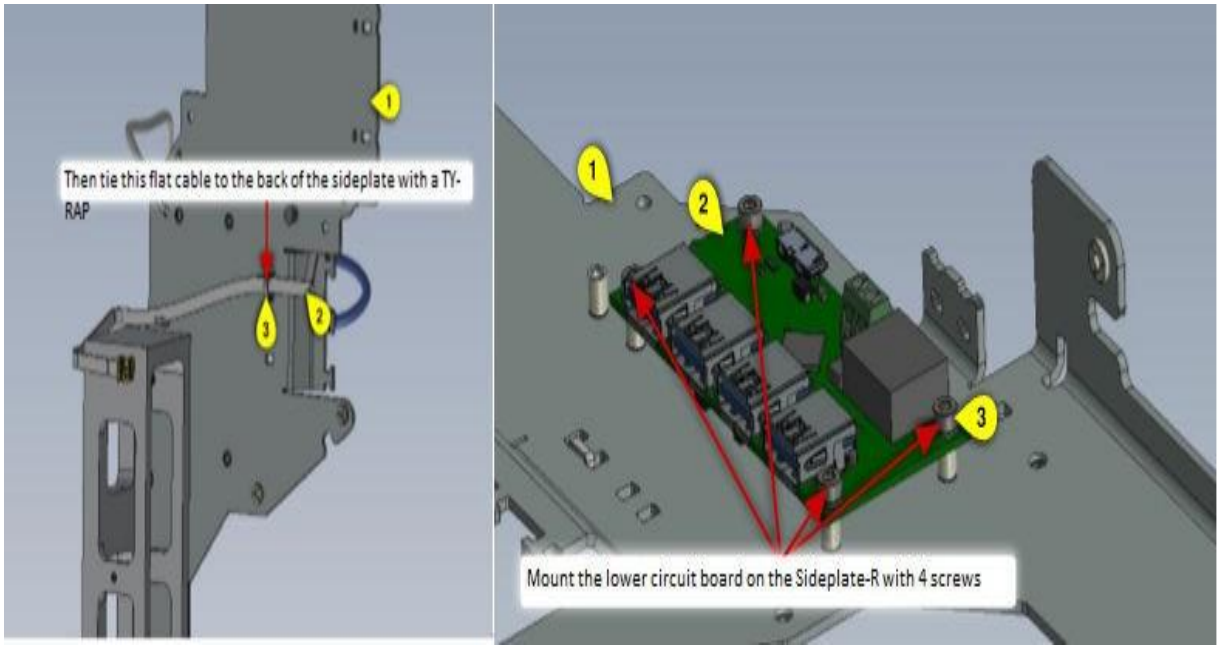


Figure 20

Now mount the lower circuit board with three screws on the side plate (Figure 20)

Attach the internal power cables to the printed circuit boards with TY-RAP '

Internal power cord

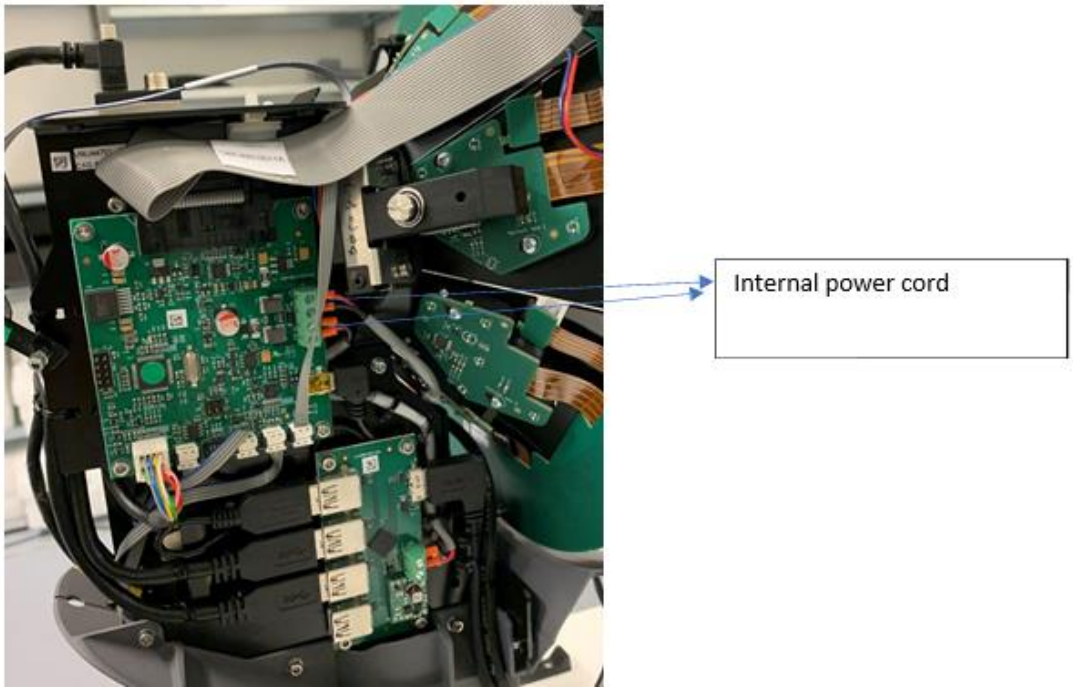


Figure 21

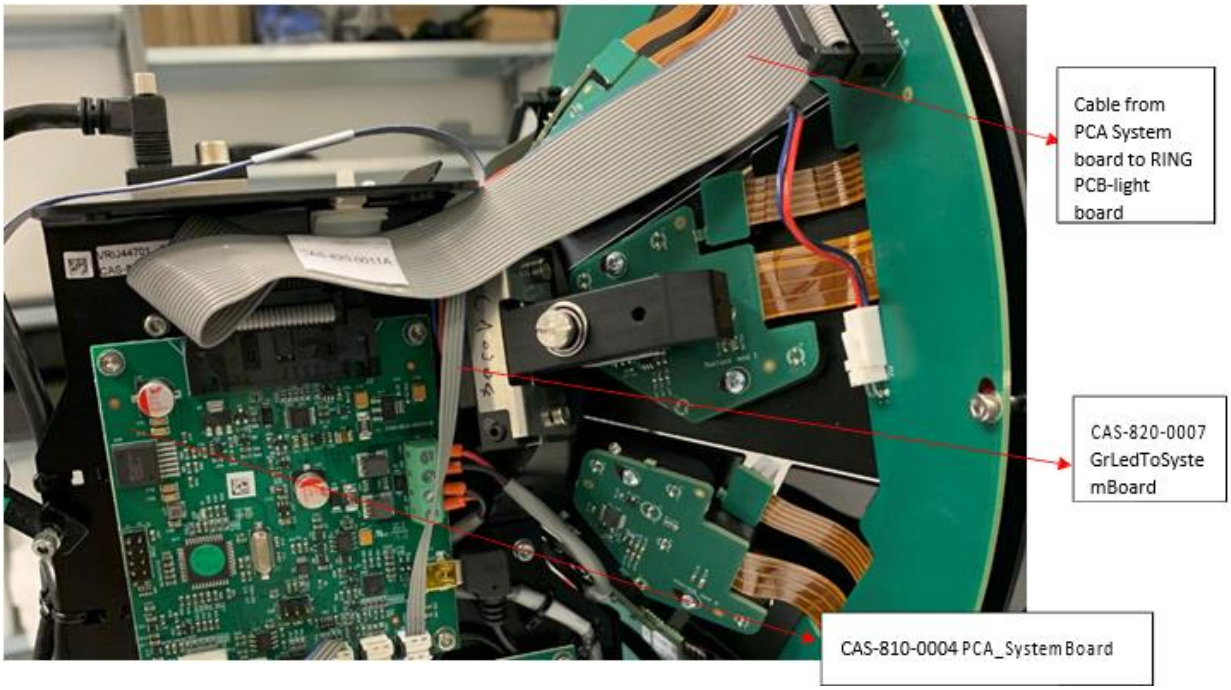


Figure 22

Connect the cable to the PCA_SystemBoard and the RingPCB-light board.

8.5 Mounting of CSO Base

Both side plates are now pre-assembled and ready to be mounted on the CSO Base. First remove the rubber cap under the CSO base (Figure 23).

Before the side plates can be mounted, the housing bottom assembly must also be placed, because this part cannot be pushed over the side plates. This part does not need to be attached yet (Figure
23).

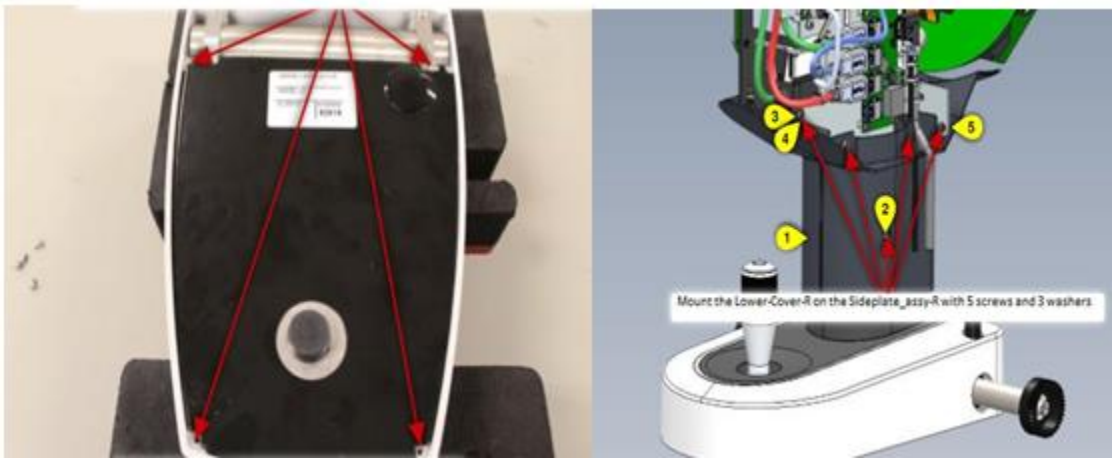


Figure 23

Now mount the side plate to the adapter, and then mount it on the CSO base. Start by placing the two dowel pins. Then attach the camera pin to the lift adapter then attach the Housing lid mount
plate. (Figure 23)

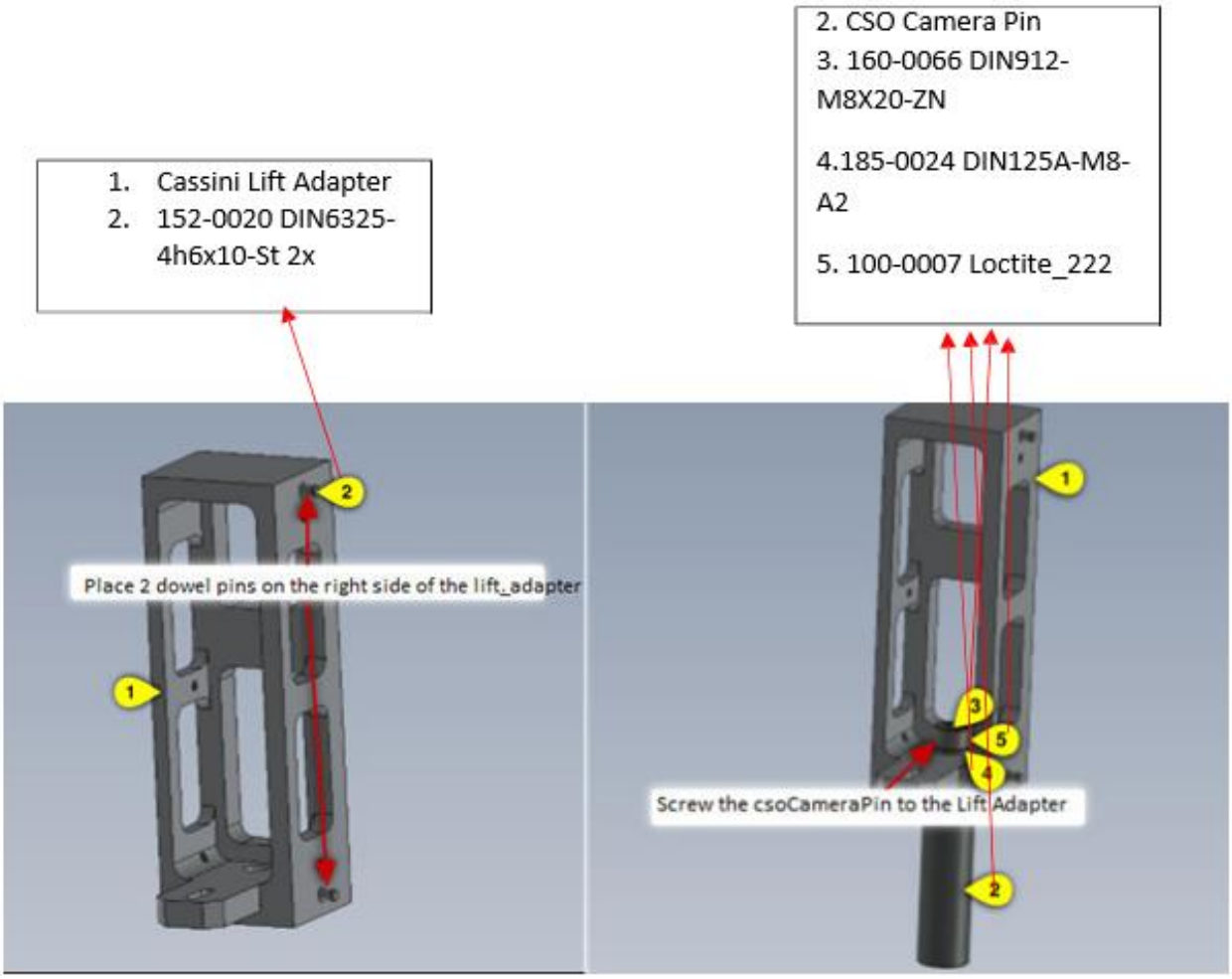


Figure 24

First, the Side plate right assembly can be placed on the CSO base (Figure 19). The Side plate left will be placed later: when the Camera assembly is mounted.

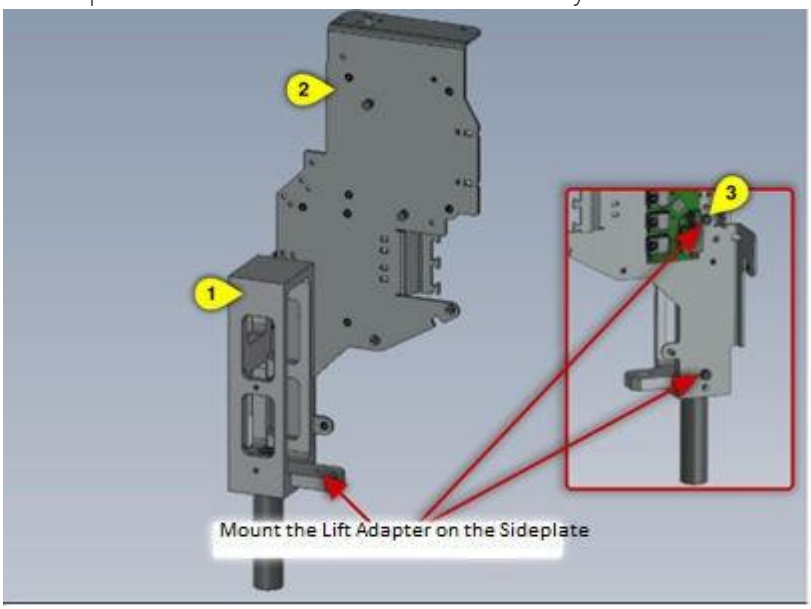
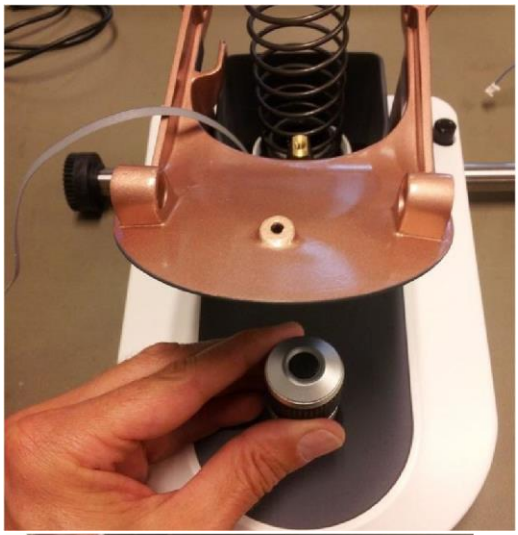
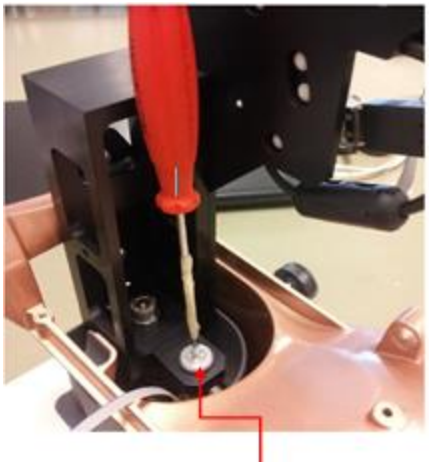


Figure 25

Take the CSO washer and the countersunk screw from the CSO base. Then place the Lift Adapter assembly on the CSO Carriage. Screw it into place with the countersunk screw using the CSO Spindle Washer as shown in Figure 25.

NOTE: Check that the spring is properly seated in the notch of the lift adapter





1x DIN7991 M4 x 20

160-0533

1x CSO spindle washer

185-0048

Loctite 243

Figure 26

8.6 Cabling Device

Please make sure to use proper ESD Equipment. (see section 2.3)

If the cameras are checked and clean, the LED control PCB can be placed. First connect the power cable to J16. Then connect the internal Power cord to J15 and the 'board to board' cable (CBL 8) to J4. See the illustrations below for the routing. If these cables are connected, the PCB can be snapped and screwed down. (Figure 27)

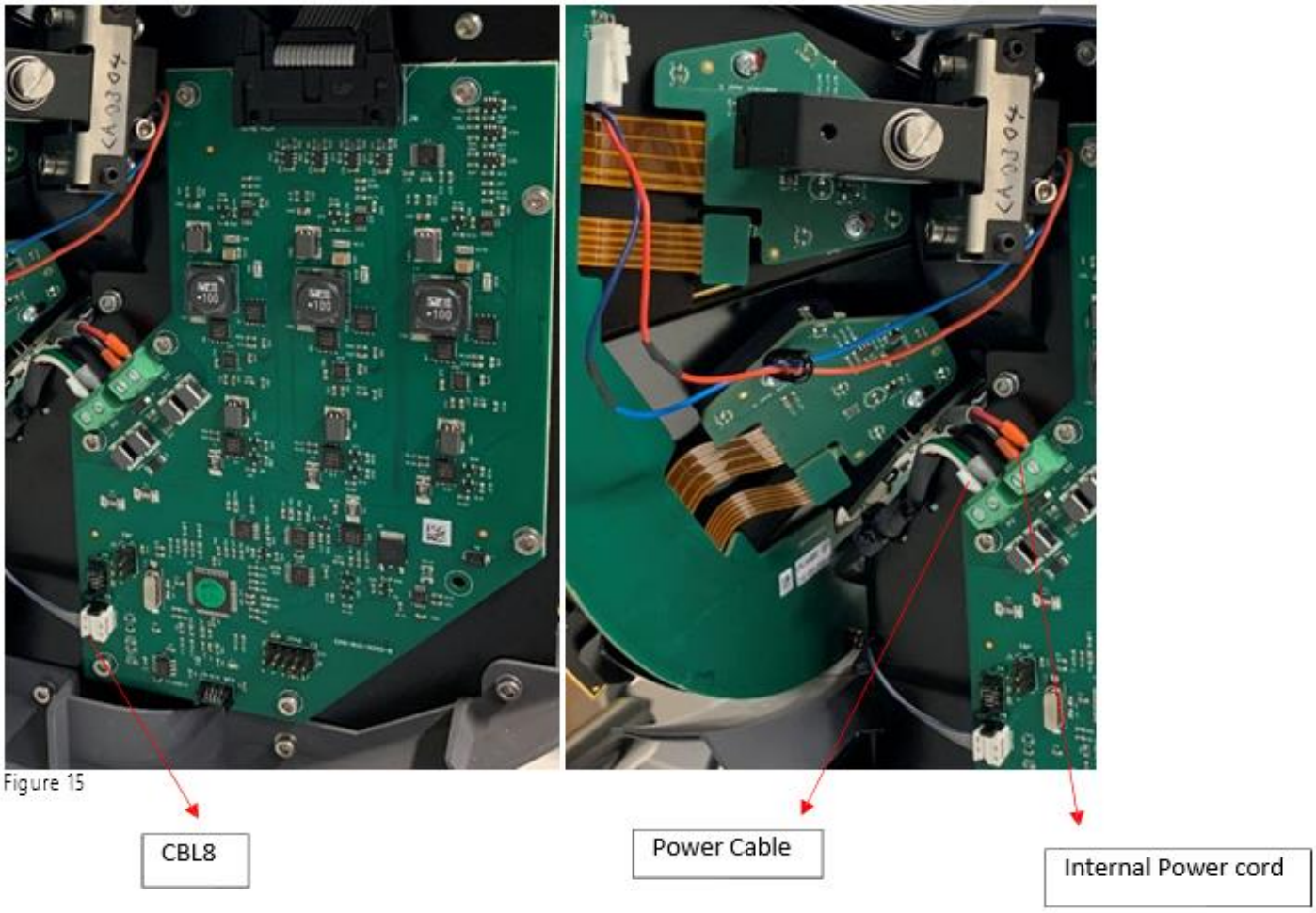


Figure 27 – PCA Led Control board

The exact cable routing is crucial for fitting the caps. Connect the cable from PCA_LedControl to the RingPCB-light_assy. The LED cable leads to the 7 LED domes. (Figure 28)

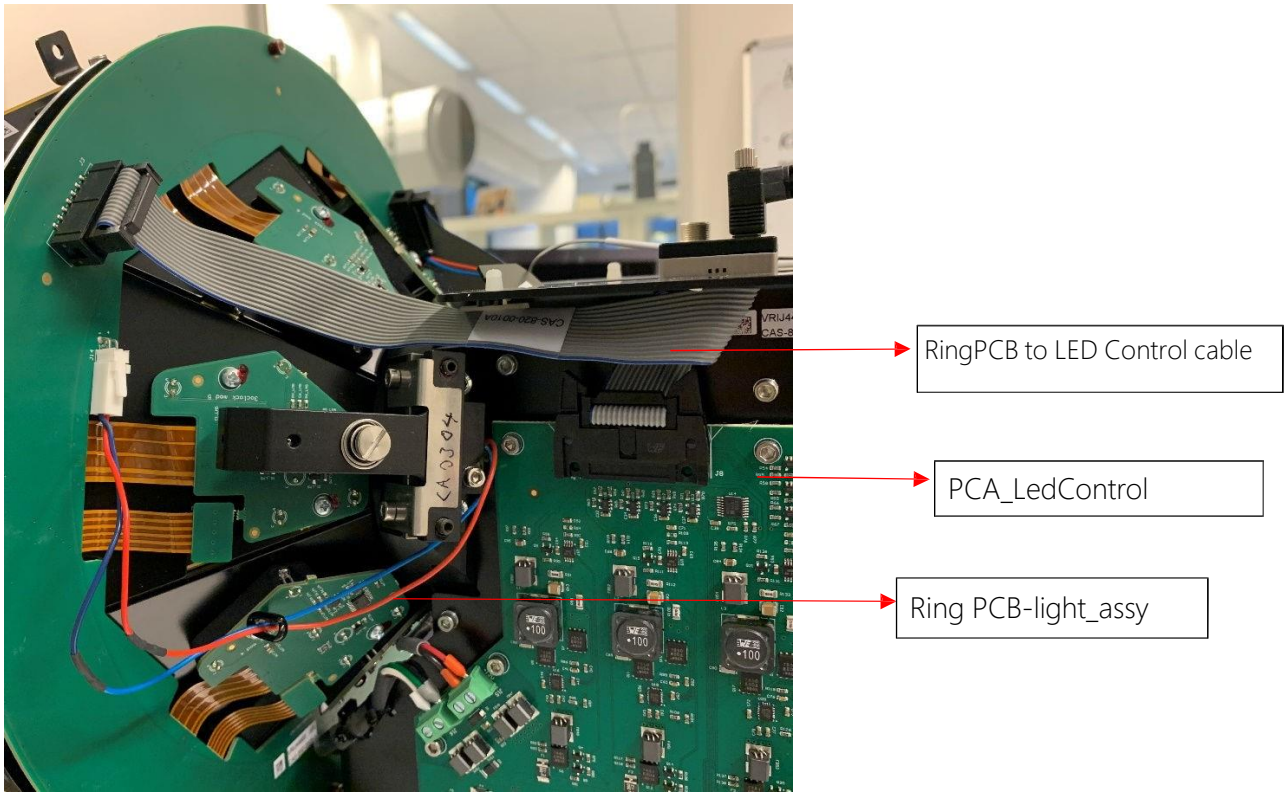


Figure 28

Connect the cable from PCA_Led Control to Ring PCB-light_assy

Please make sure to use proper ESD Equipment. (see section 2.3)

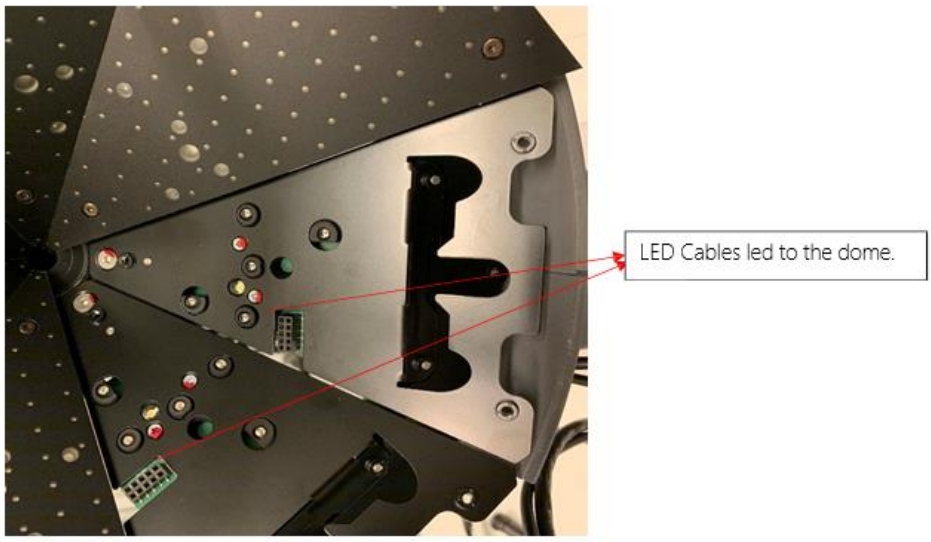


Figure 29

The PCO_USB3.0Hub is connected to the BMicroRA_2M and earthing wire.

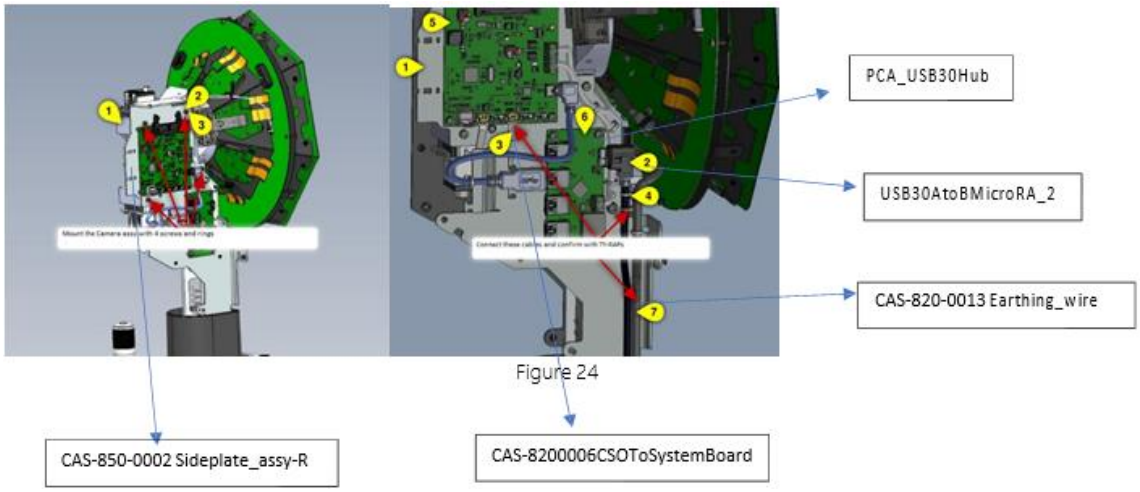
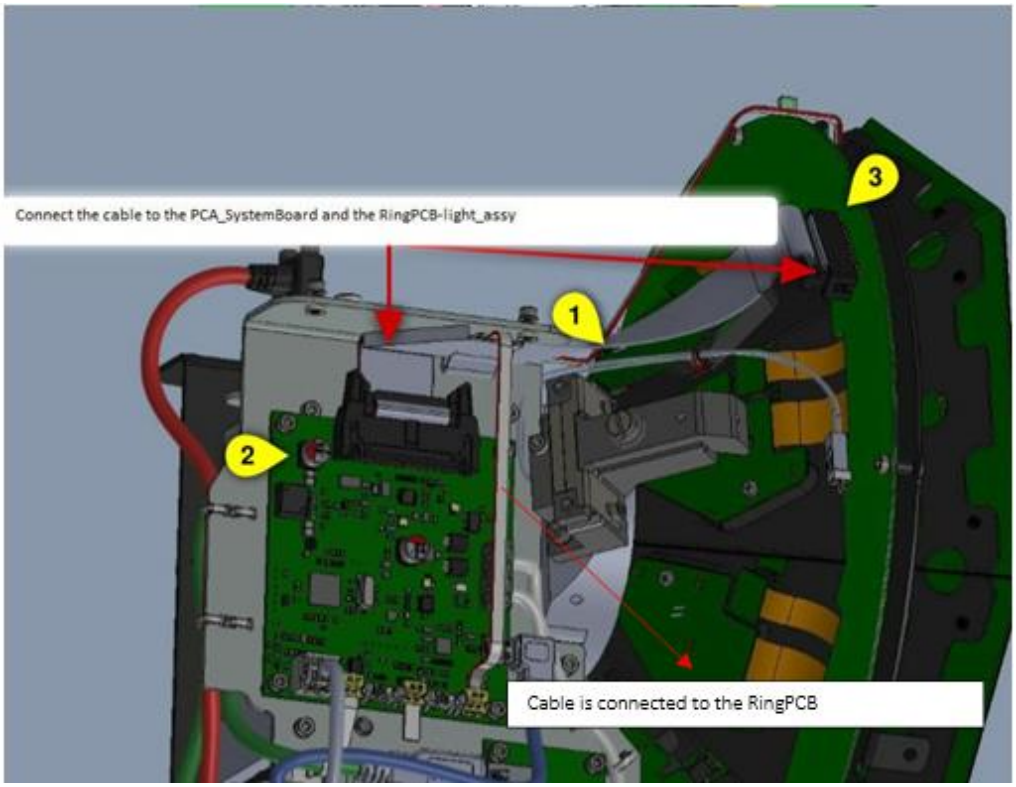


Figure 24

Figure 30

Unlike previous models with several cables going to the light module, we have only one cable from the system board connected to the Ring PCB.



Please make sure to use proper ESD Equipment. (see section 2.3)

Connect the cable of the Fixation Target to port J9 of System PCB 2. Pay attention to the routing, see Figure 32 (yellow line)

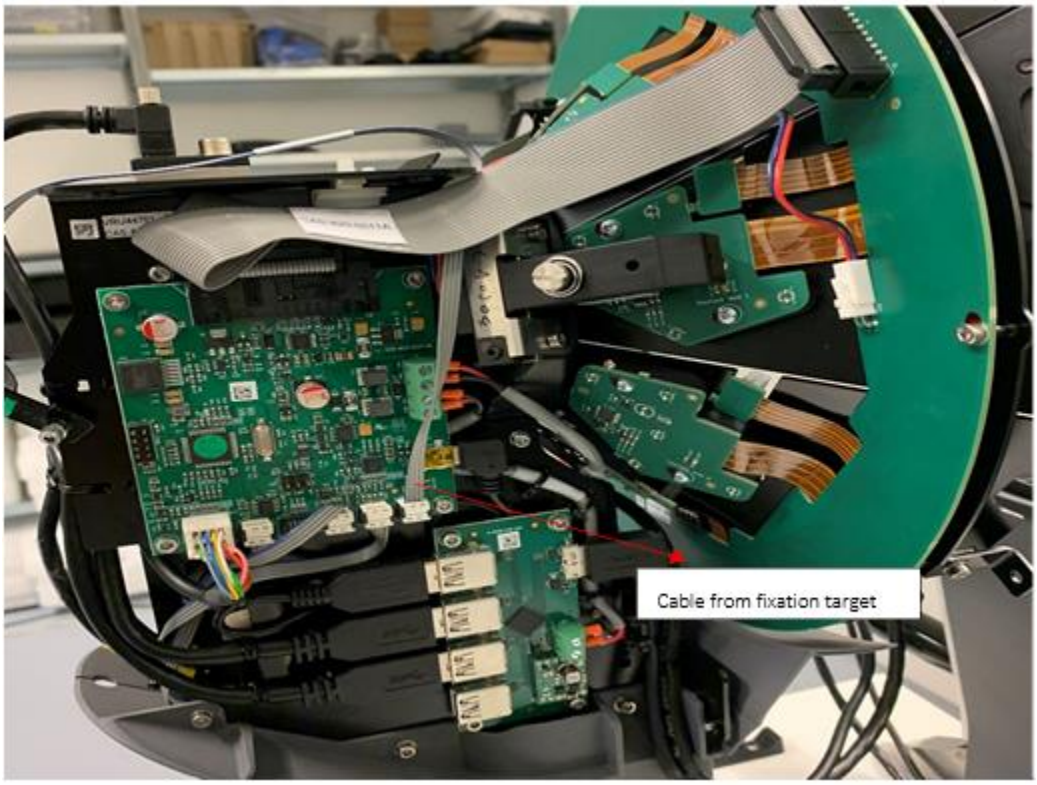


Figure 32

Connect the cable of the LED, which is in the cover, to connector J19 of System PCB 2

Please make sure to use proper ESD Equipment. (see section 2.3)

8.7 Housing Assembly

Assemble Covers The covers, or "Housing Cover Assy" can now be placed over the Cassini.

The first step is to place the Housing-Bottom (130-0103). First, make them dust-free with compressed air.

CAUTION

Never blast air in the direction of the Cassini Device.

The Housing Bottom is screwed directly against the Dome Ring: this is the starting point for the alignment of the covers. First start with the screws at the front (see Figure 33)

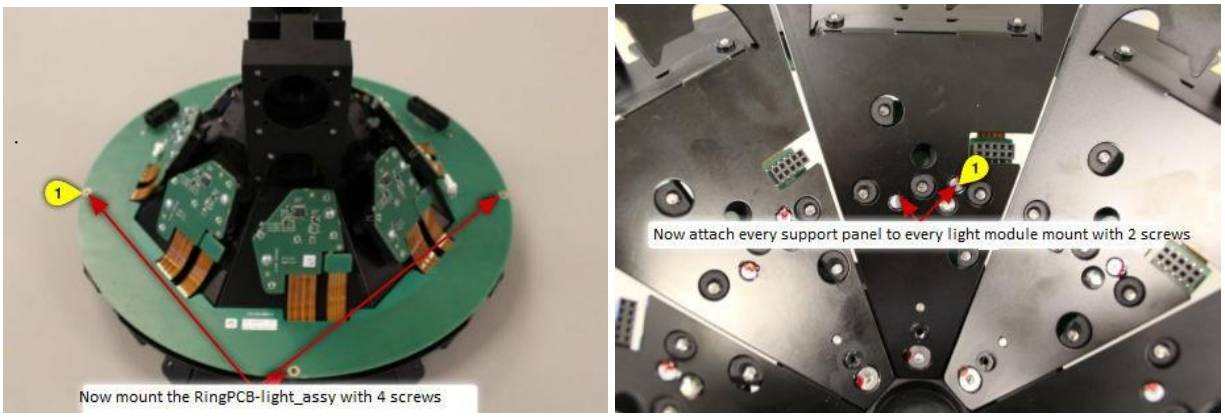


Figure 33

Please make sure to use proper ESD Equipment. (see section 2.3)

The Side plate is mounted on the Lower cover-L with 5 screws and 3 washers(Figure 28)

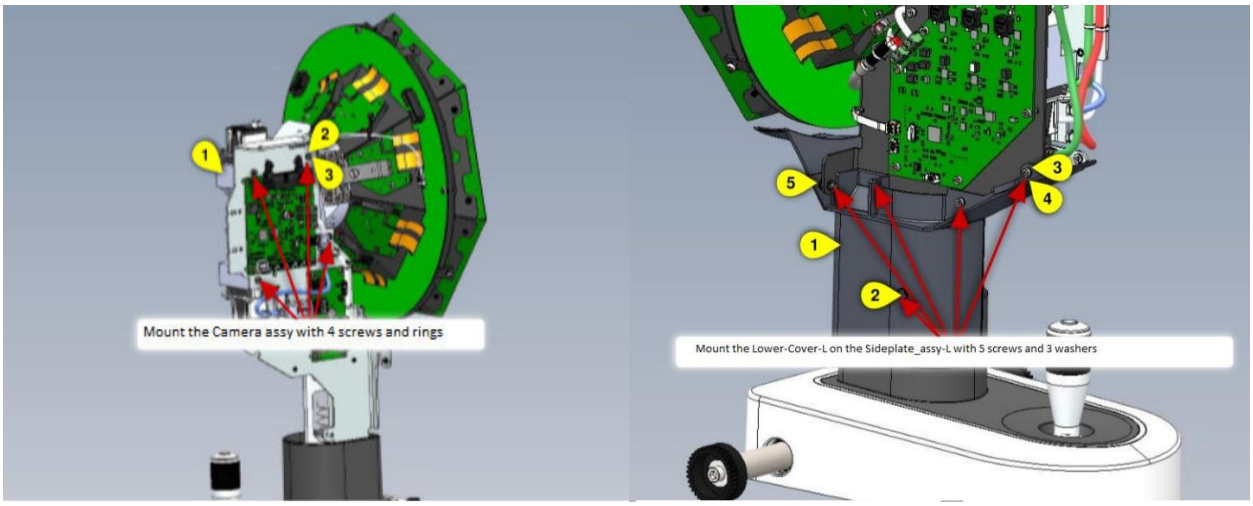


Figure 34

Please make sure to use proper ESD Equipment. (see section 2.3)

The next part that can be placed is the Housing-Dome-Left-Assembly (800-0162).

NOTE

Do not tighten this screw completely yet, aiming the caps should be done afterwards.

Figure 35

The cover is then mounted on the front with screws. The hood has a small clearance on the mounting holes, so the hood can be adjusted. If the hood nicely aligns with the 7-plane, these screws can be fastened. (Figure 36).

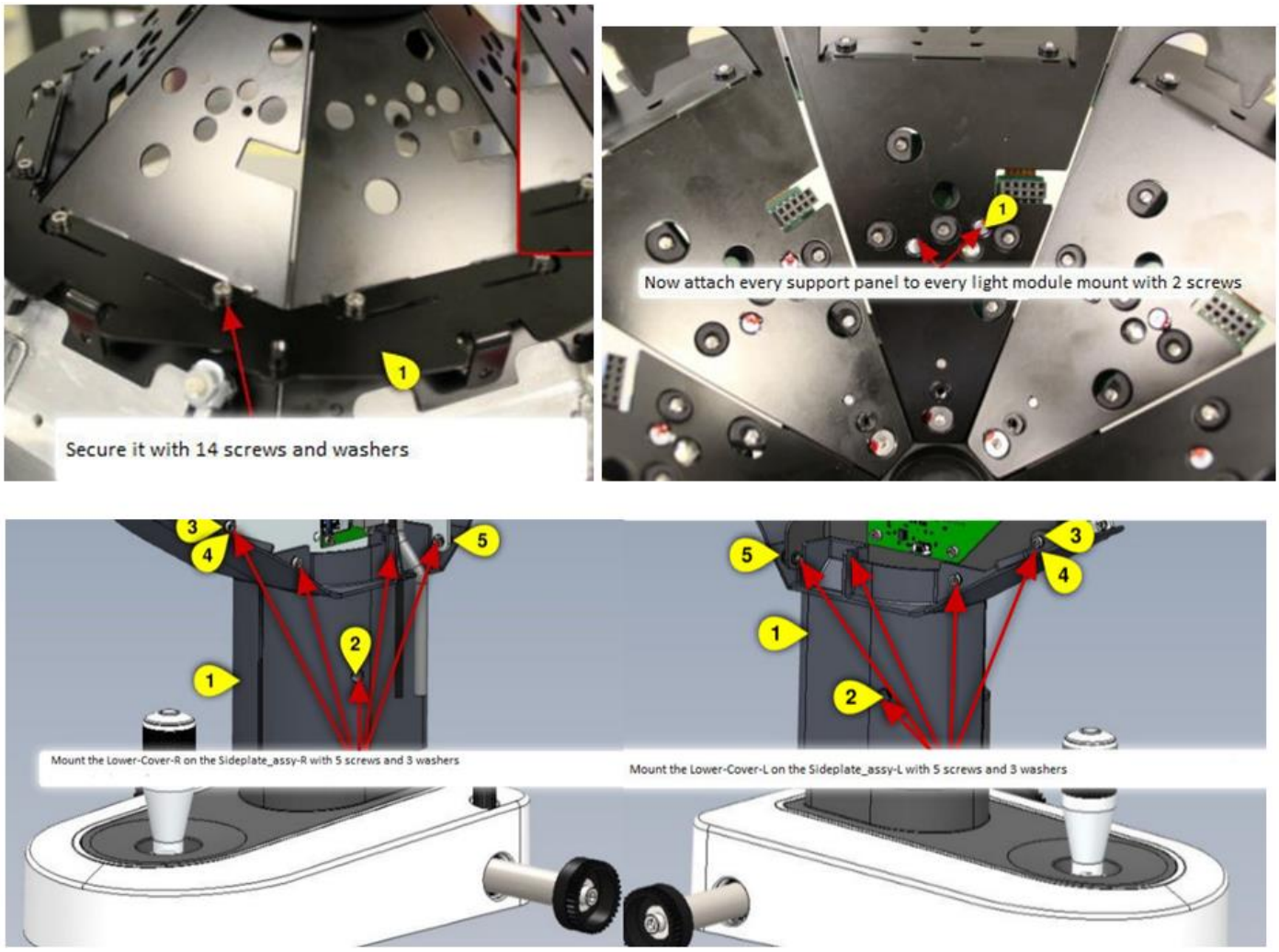


Figure 36

Please make sure to use proper ESD Equipment. (see section 2.3)

The next part that can be placed is the Housing-Dome-Right-Assy (800-0161). This hood is first mounted with one screw at the rear. (see Figure 37).

NOTE

Do not tighten this screw completely yet, aiming the caps should be done afterwards.

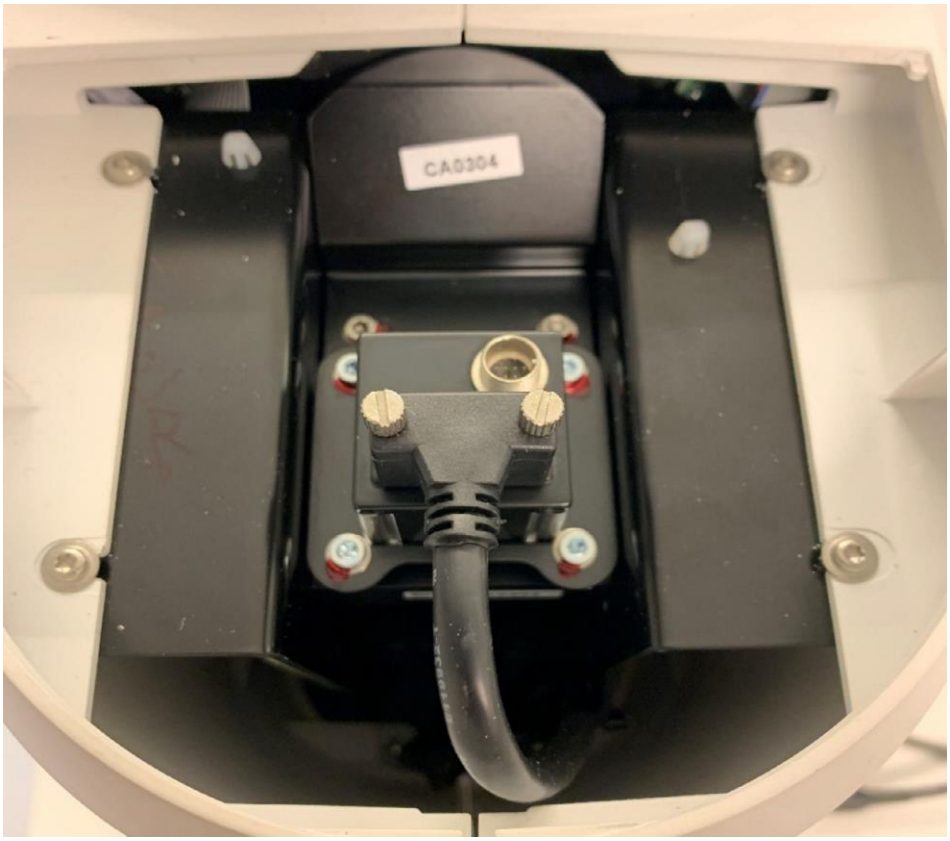


Figure 37

The cover is then mounted on the front with the screws. The hood has a small clearance on the mounting holes, so the hood can be adjusted. If the hood nicely aligns with the 7-plane, these screws can be fastened. (Figure 38

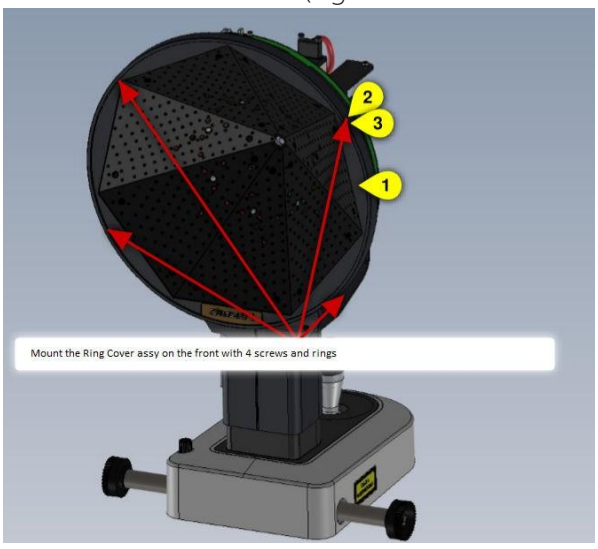


Figure 38

Check that the dividing line between the cap is continuous. If this is not the case, this can be adjusted with the screws in the slotted holes and the torx flange screws.

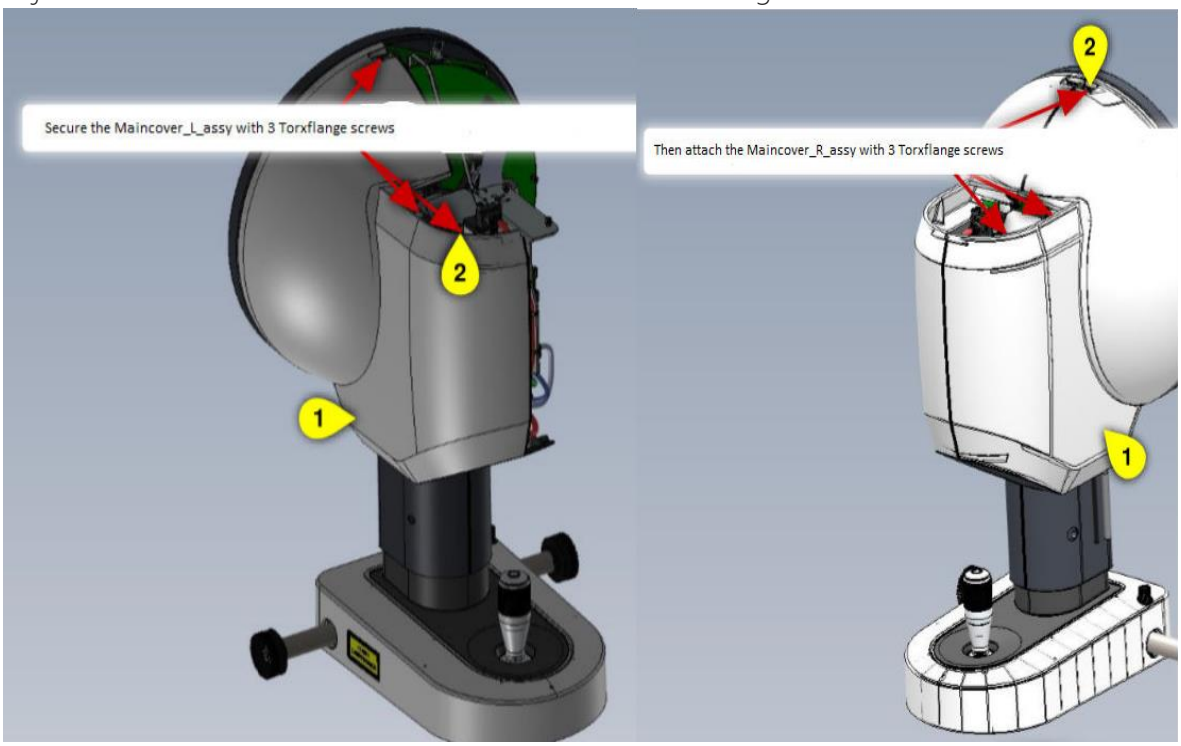


Figure 39 – Attaching Cassini Main cover with torx screws

Finally, check whether the cover is free of the CSO base by turning this highest and lowest position

Please make sure to use proper ESD Equipment. (see section 2.3)

8.8 Placing LED panels

The LED Dome Panels are mounted after the caps have been installed. There are two types of this, recognizable by the number of holes. See Table 1 and Figure 40.

Table 1

Name	Number	Characteristics	Number	Positions
LED Dome Panel A	800-0083	3 Holes	5	1, 5, 6, 7 and 11 o'clock
LED Dome Panel B	800-0084	4 Holes	2	3 and 9 o'clock

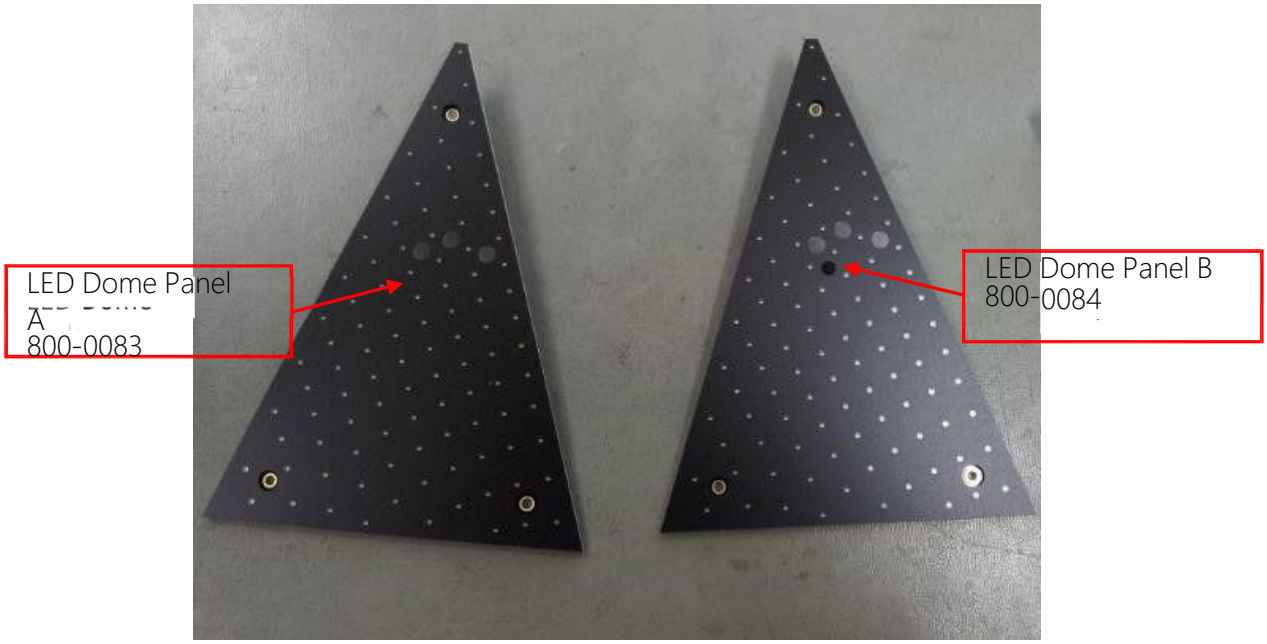


Figure 40

Please make sure to use proper ESD Equipment. (see section 2.3)

Start by installing the lower LED dome (6 o'clock). This is a Panel A. Connect the cable and use three screws as shown in Figure 41. Do not tighten the screws completely yet, so that it can be slided a little
later. Always start at the bottom to prevent screws from falling into the device.

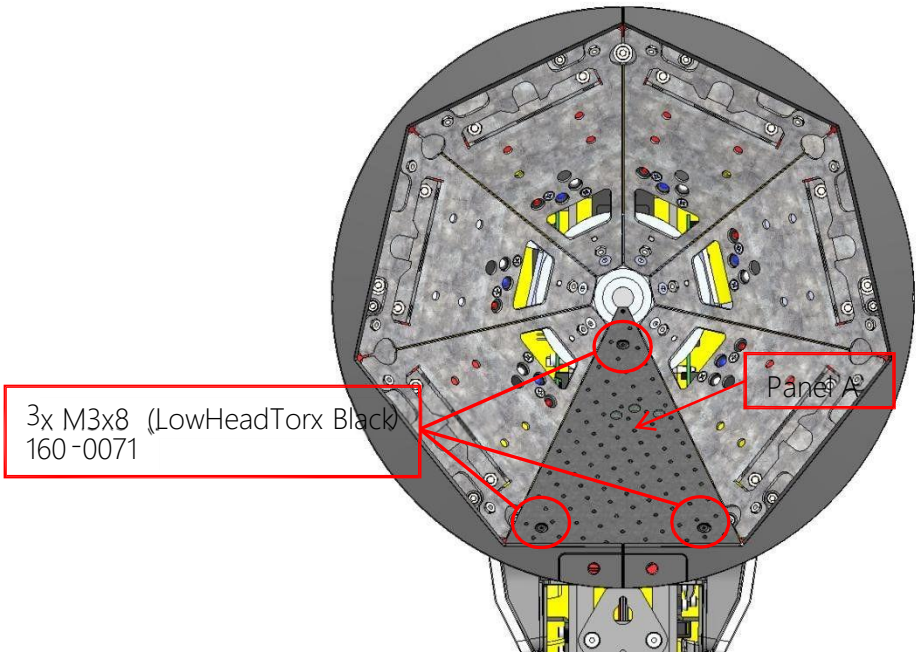


Figure 41

Please make sure to use proper ESD Equipment. (see section 2.3)

Then place the two LED panels of 5 o'clock and 7 o'clock. These are also Panel A attached with three screws each (160-0071). Now place the two LED panels of 3 o'clock and 9 o'clock. Note that this is the other type, Panel B. Again, use three screws (160-0071). Finally, place the remaining two LED panels of 1 o'clock and 11 o'clock. These are again type Panel A. For each of these three screws (160-0071) are used. (see Figure 42)

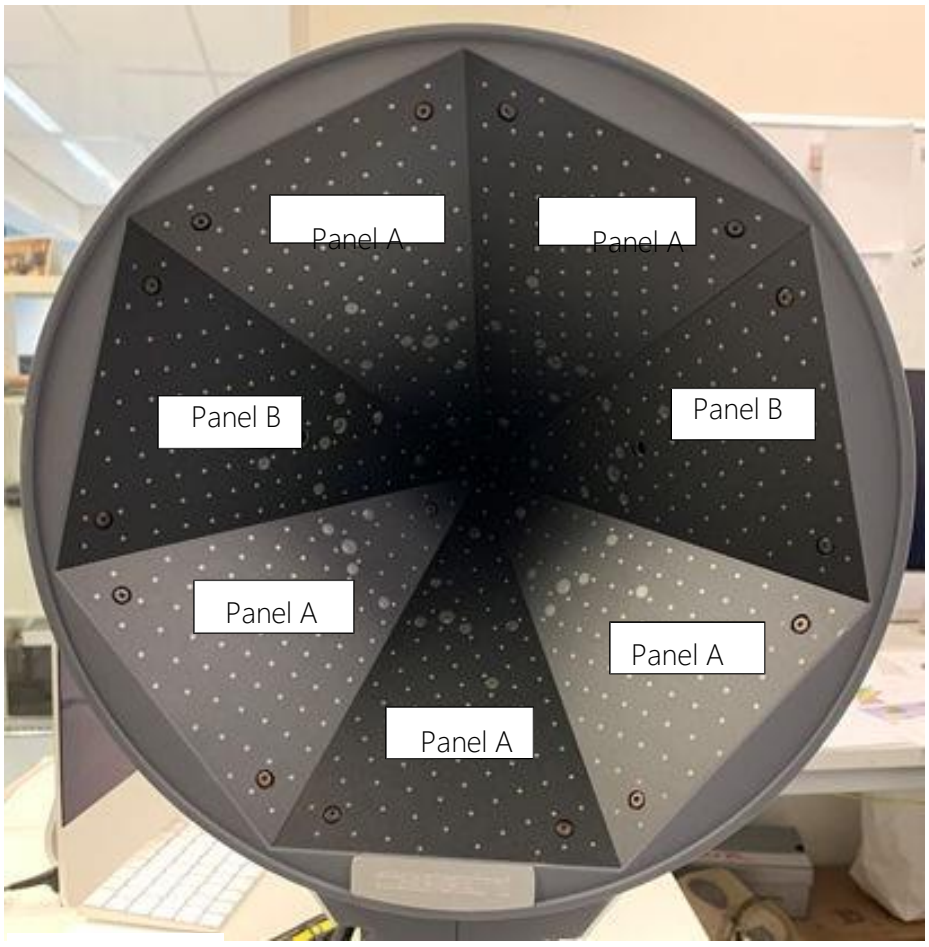


Figure 42

Finally tighten all 21 screws of the LED Dome Panels. Ensure that play on the panels is evenly distributed

Please make sure to use proper ESD Equipment. (see section 2.3)

The last step is to place the Housing-Bottom-Lid

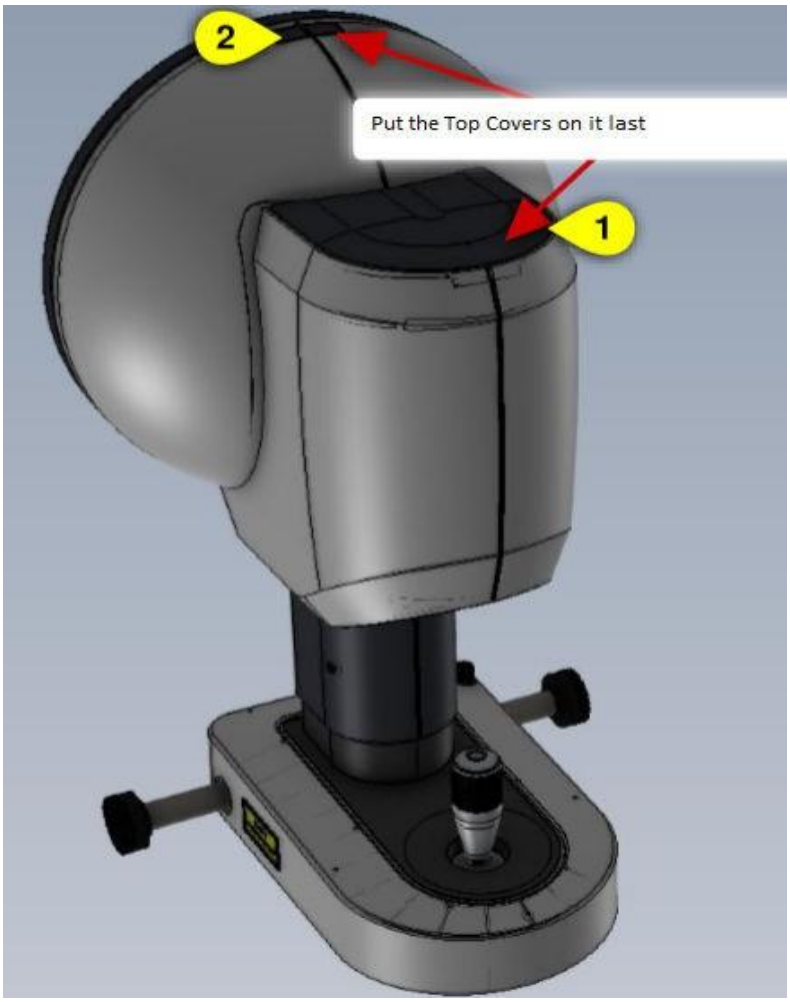


Figure 43

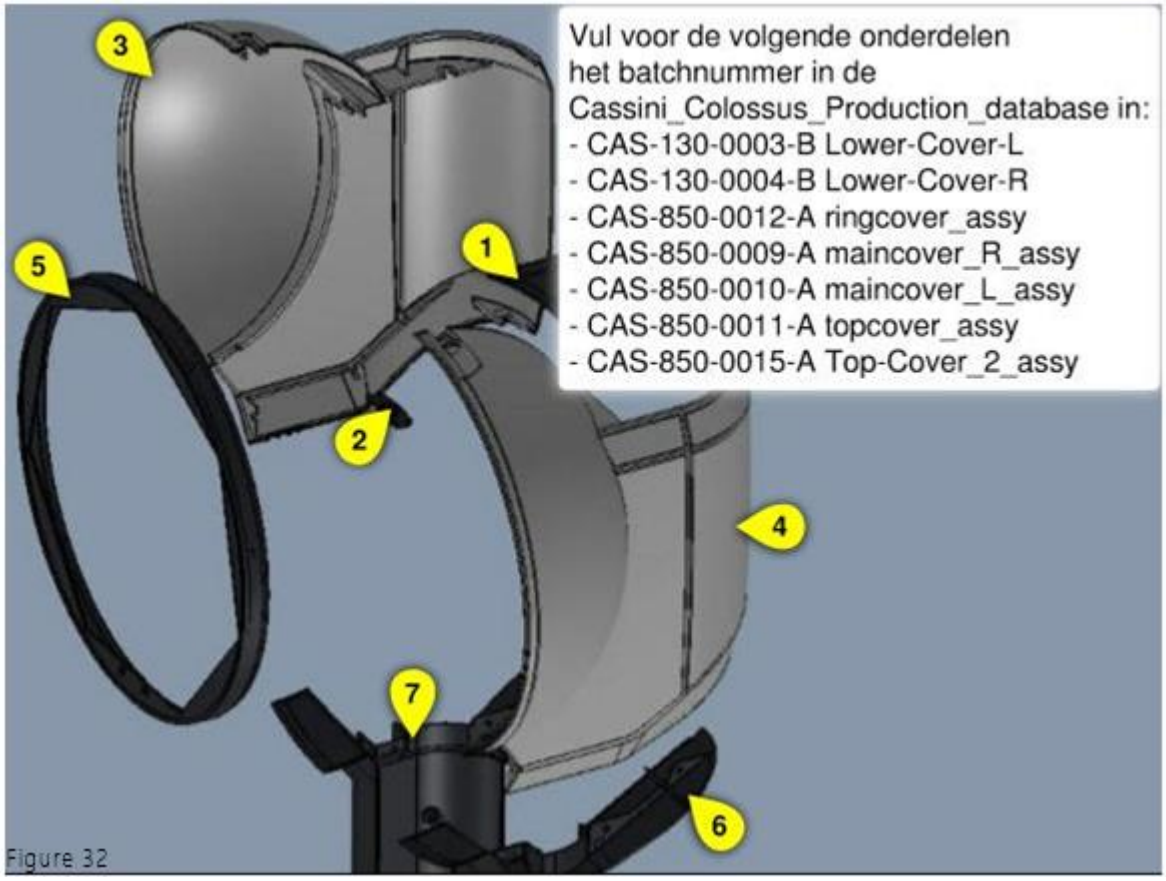


Figure 44

8.9 Sub-Module is ready

The Cassini must then pass a final test before it can be packed. If the Cassini cannot be tested immediately, make sure that the Cassini is stored safely. Make sure that the Housing-bottom-lid-assembly (800-0163) and the Housing-top (130-0104) are placed before it is stored.

Points of attention are:
- Dust
- Fingerprints
- Damage to and through the cables

Roll up the cables and place them in anti-static bubble film. Then place an antistatic bag over the Cassini to protect it from dust. (Figure 45 and Figure 46)

Figure 45

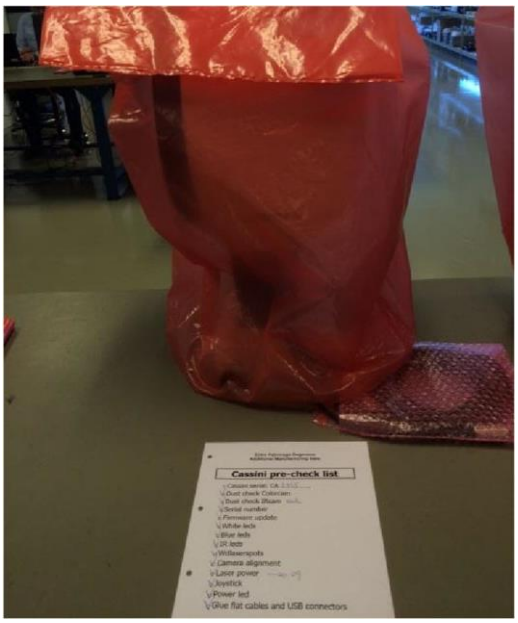
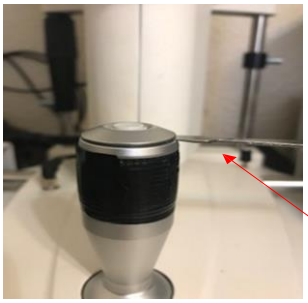


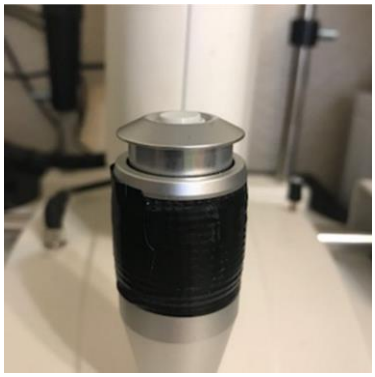
Figure 46

8.10 Joystick Button Assembly

Please make sure to use proper ESD Equipment. (see section 2.3)



With thin flat tool, simply pry upwards evenly and slowly



NOTE

Taking extreme care not to pull completely upwards fast nor rotating the top portion of the joystick. Doing so could potentially break the
wires inside.

Please make sure to use proper ESD Equipment. (see section 2.3)

After you have slowly and carefully pulled the top portion (please see side picture on how it should look) ...you then grab the black connector and pull straight out being careful not to bend or break the two Gold Pins.

NOTE

To install the new part...simply follow the instructions backwards

CAUTION

Again, Never Rotate the Silver button piece.

9 Calibrations

9.1 Laser Alignment Calibration (LAC)

CAUTION

LAC can only be done by Service Technician Level 4.2

Please follow the guidelines below on how to properly perform the LAC

NOTE: LAC must be done after Cassini has been moved around or after each Service/Repair. The below instructions are especially for Laser alignment calibration in software 3.1.

Step 1: Select the Service LAC option from the Cassini home page.

Figure 47 – Service LAC in 3.1 software

Step 2: Click on the arrow to expand the process, select Device Configuration and click on Open

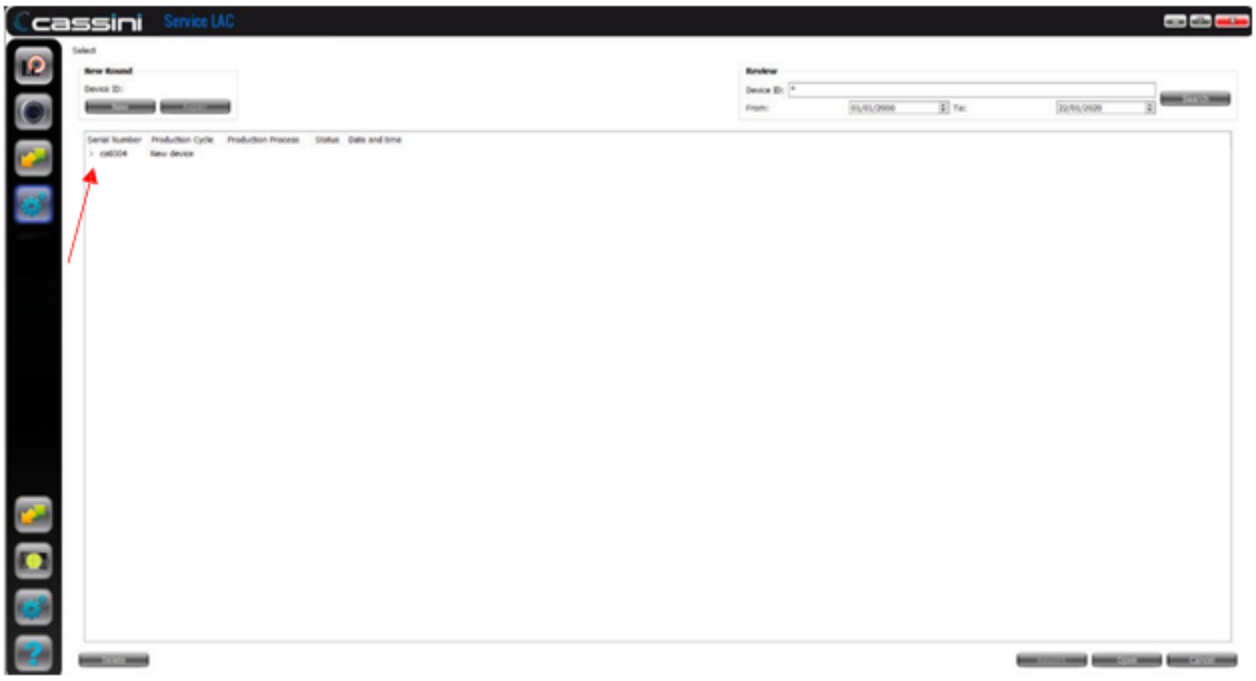


Figure 48

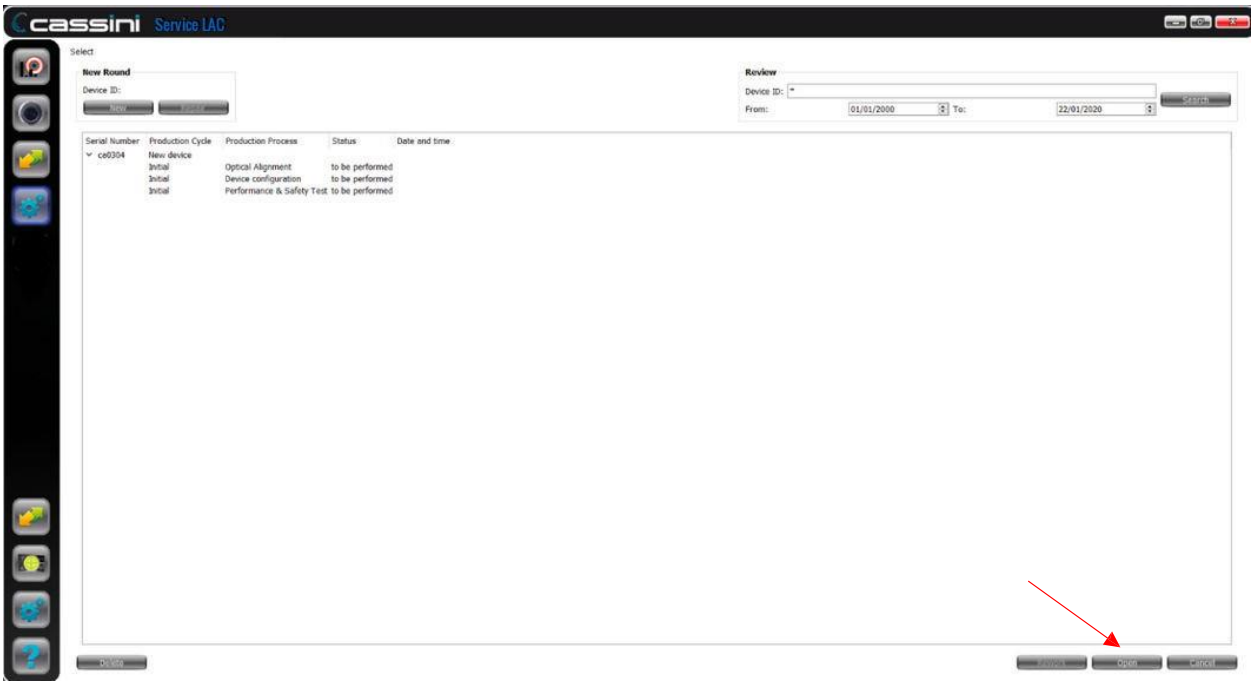


Figure 49

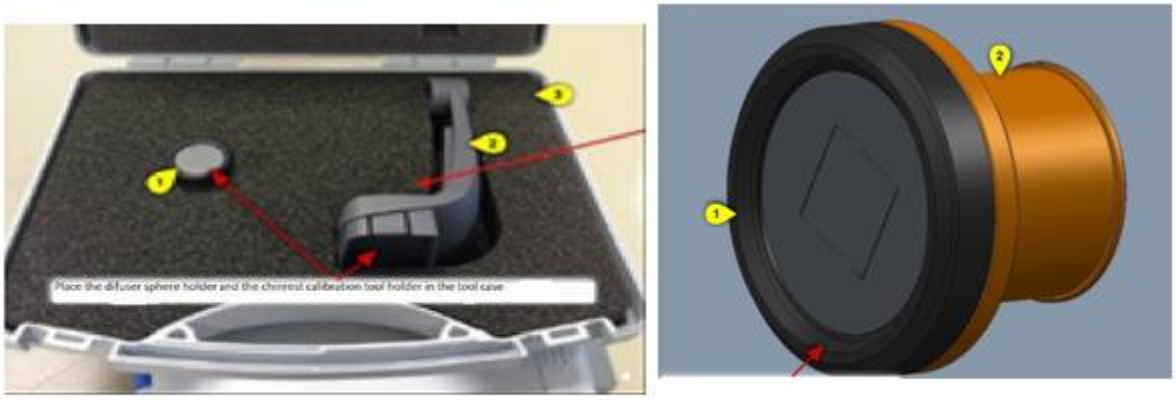


Figure 50 – Calibration target

Position the Calibration Tool in front of the Cassini

Aim the Cassini on the metal plate

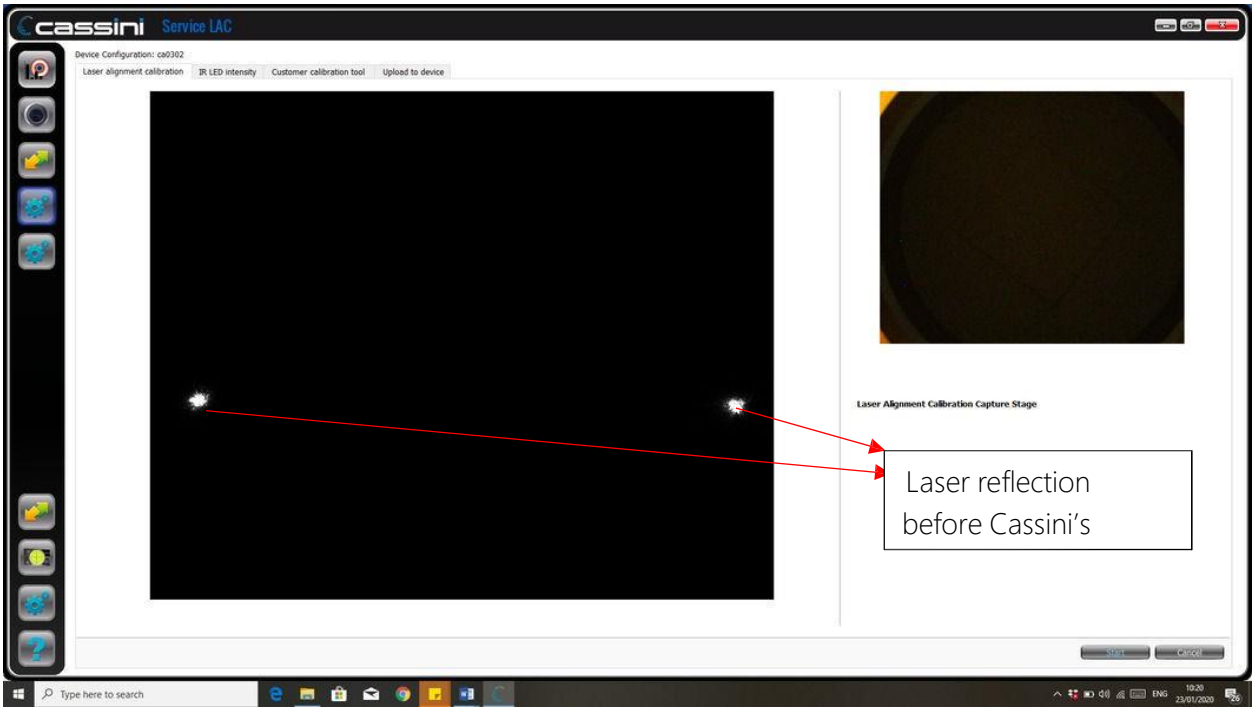


Figure 51 - Laser spots in Lac procedure

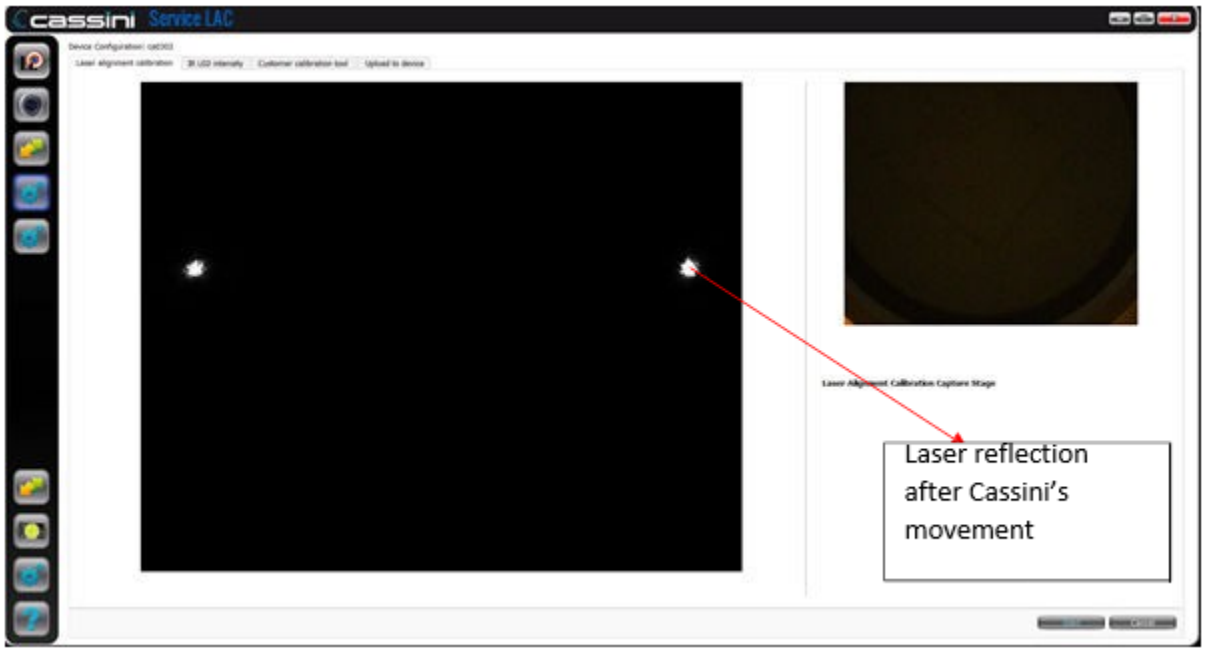


Figure 52

Test whether Cassini is placed correctly by moving Cassini forward and verify if both laser spots are always visible (no shadowing effects).

- The laser spots are supposed to move in the direction of the red arrows. If the spots are nicely visualized along this line, Cassini is positioned properly.
- Align the Cassini system in front of the metal plate in such a way that both lasers are in the LOWER part of the image.
- Click "Start" and move the Cassini gently forward and backward until the image on screen looks as depicted below. The Stop option is not enabled until the progress bar turns blue.

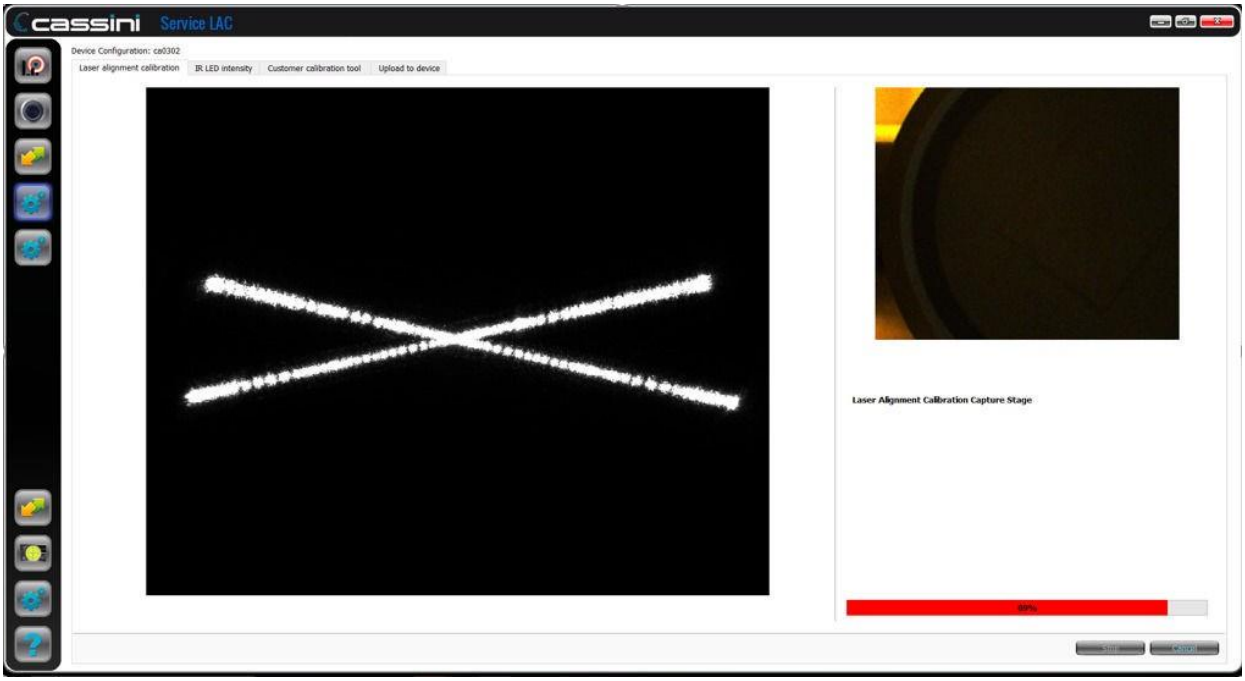


Figure 53

Click "Stop" when the progress bar turns blue.

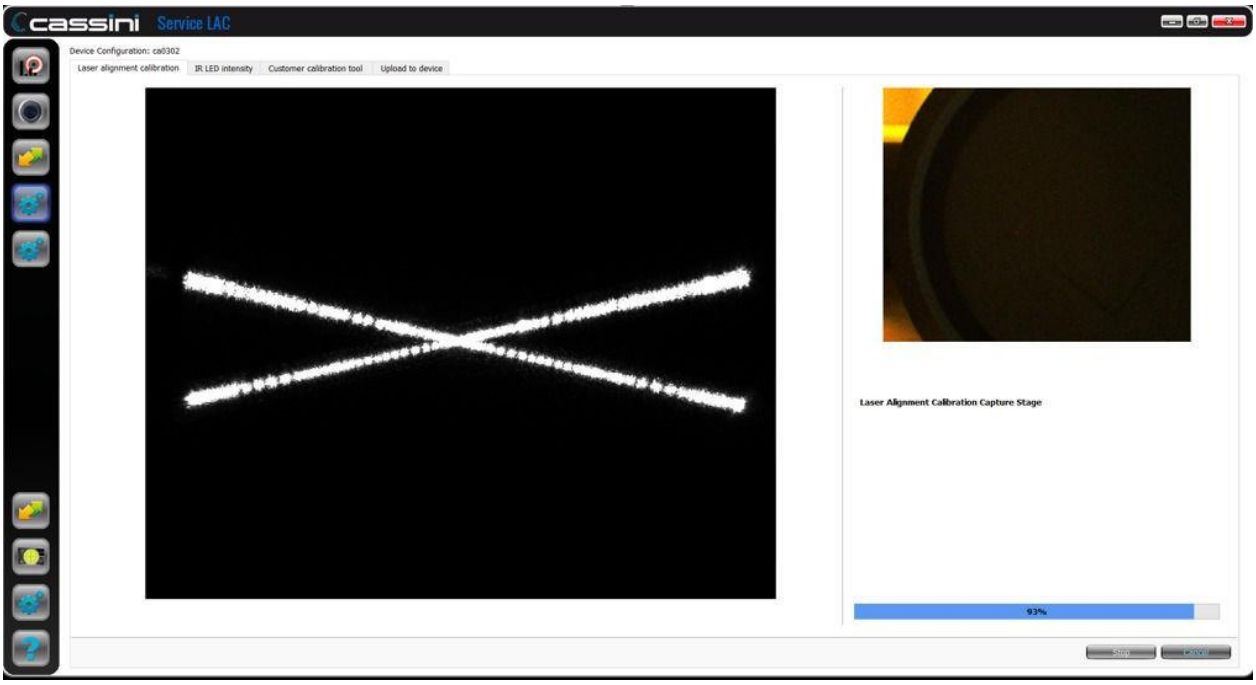


Figure 54

Click Accept if you see a message "Calibration Ok".

Figure 55

Do Not click UPLOAD. Copy the Lac values.

Figure 56

Go to Development Device options. Enter the values under IR laser alignment and click Save.

Figure 57

Once LAC is finished, proceed to calibration.

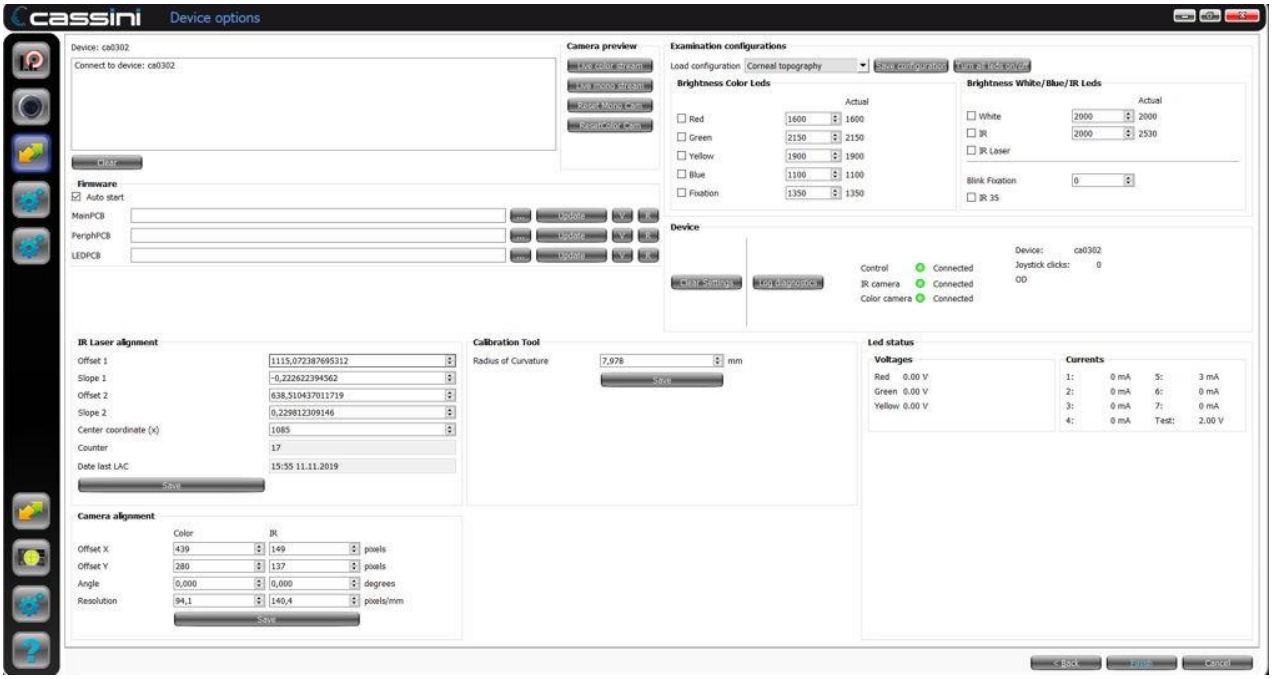


Figure 58

9.1.1 Laser alignment calibration in Cassini 3.4/3.5 software

Step 1: Select the Service→Service LAC option from the Cassini home page.

Figure 59 – Service Lac in 3.4/3.5 software

Step 2: Position the Calibration Tool in front of the Cassini. Aim the Cassini on the metal plate.

Step 3: Align the Cassini system in front of the metal plate in such a way that both lasers are in the LOWER part of the image.

Step 4: Click "Start" and move the Cassini gently forward and backward until the image on screen looks as depicted below. The Stop option is not enabled until the progress bar turns blue.

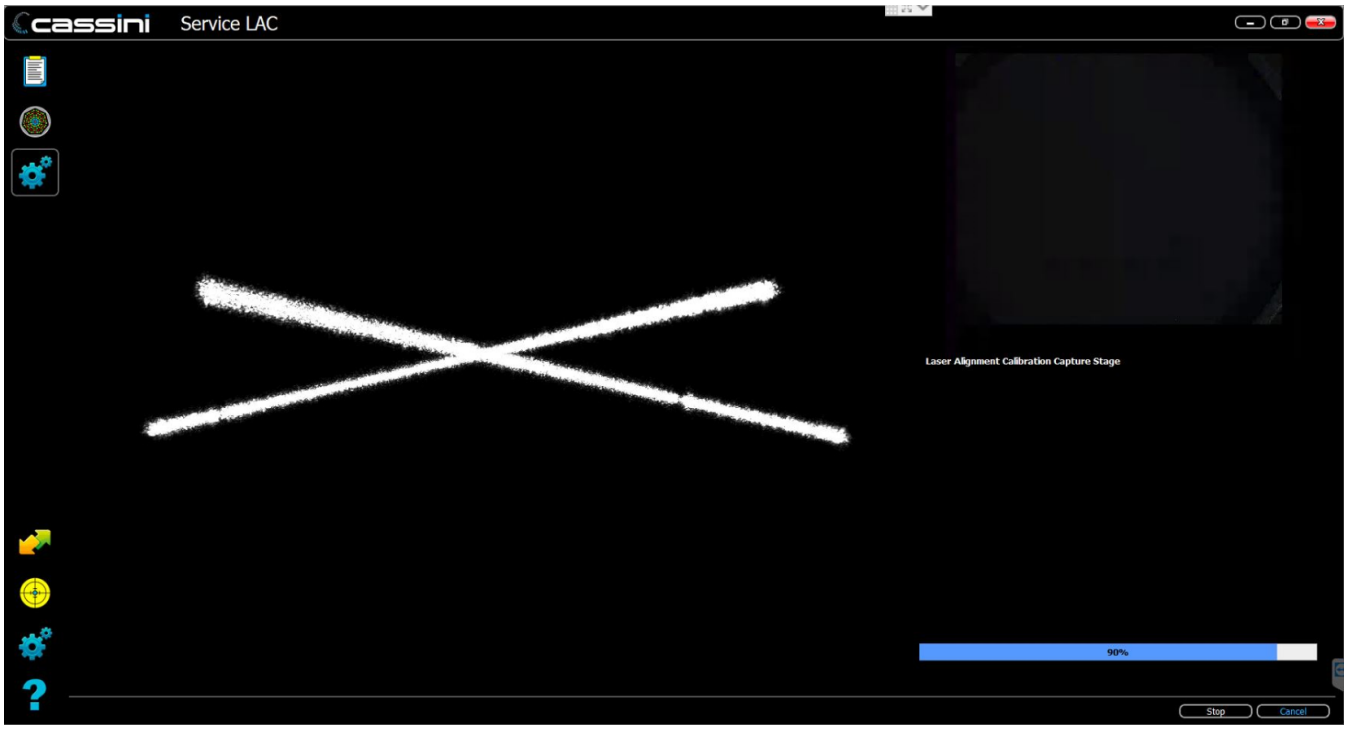


Figure 60

Step 5: Click "Stop" when the progress bar turns blue.
Click Accept if you see a message "Calibration OK".

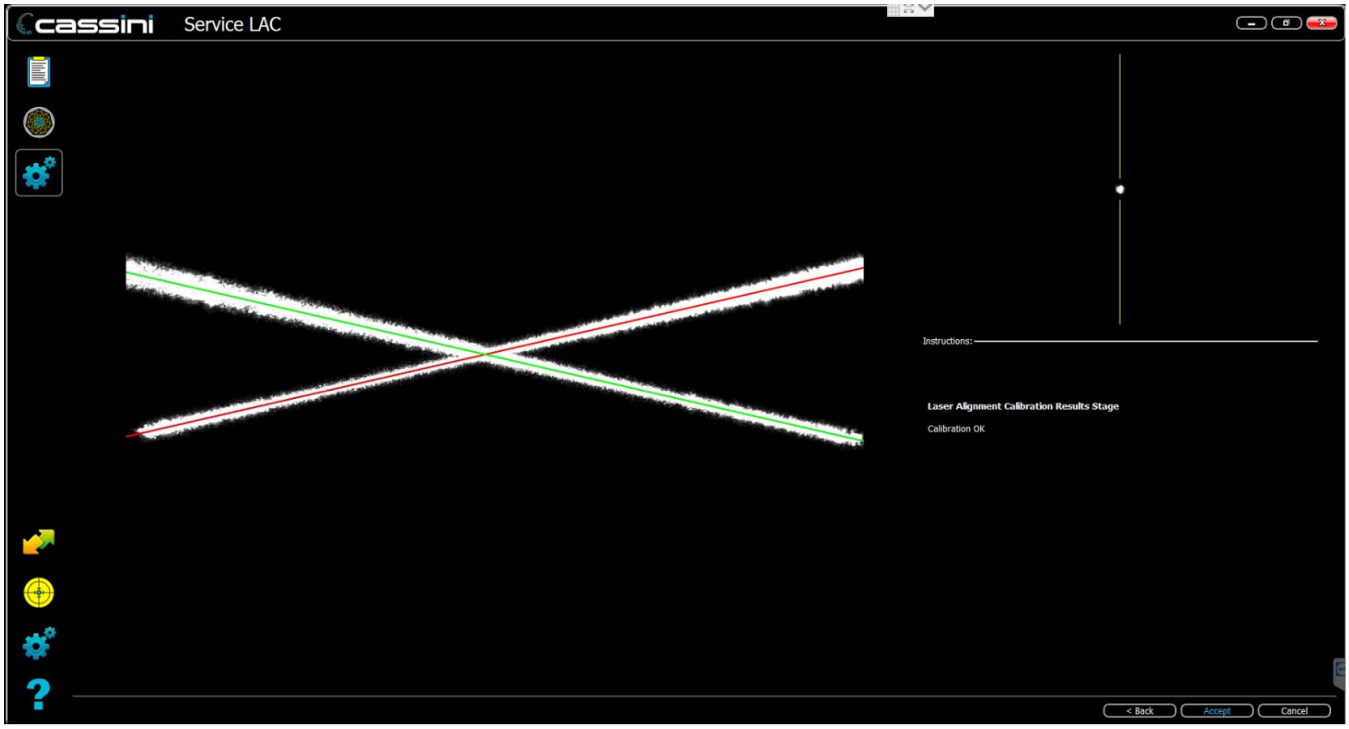


Figure 61

Step 6: Click Upload to add values to the IR Laser alignment page in device options.

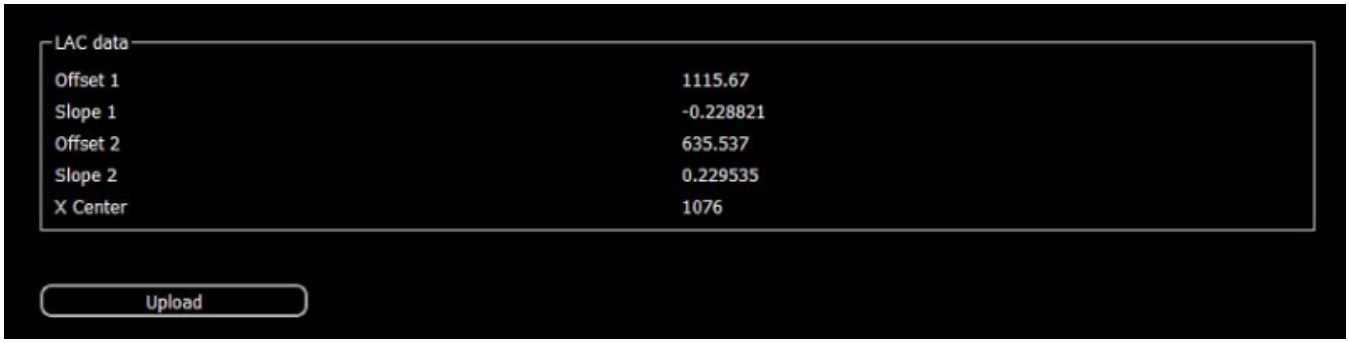


Figure 62 – Uploading values directly to device options page

9.2 Calibration

Before you start making scans the device has to be calibrated with it's proper calibration tool. If the device has been relocated or moved, calibration before measuring is always necessary.

CAUTION

Every Cassini is supplied with a unique calibration tool. The calibration tool is sensitive to scratches and stains making it useless for calibration. Therefore, handle it with care and store it always in the box in which it has been delivered. Do not use the calibration tool to calibrate a system which it wasn't supplied with. Make sure never to touch the calibration surface (stains!). 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 getting in the box. If the Calibration Tool has fallen from the table or shows scratches, please contact the local distributor or Cassini Technical Support.

The calibration workflow consists of two parts:

A. The first workflow is to calibrate the Cassini for the very first time.
B. The second run through the workflow is to *verify* if the Cassini has been calibrated correctly.

First Calibration Run

1. The system must be calibrated with the calibration tool. It should be clamped between the two rods of the headrest on the height of the eye height indicator or (for Cassini II) placed on top of the chin rest.

Figure 63: Calibration tool clamped in headrest (please note that the Cassini may look a bit different)

2. Open the calibration procedure by moving the mouse to the calibration icon  in the main

screen. Click on "calibrate device" in the unfolded 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 infrared camera (Figure 64).

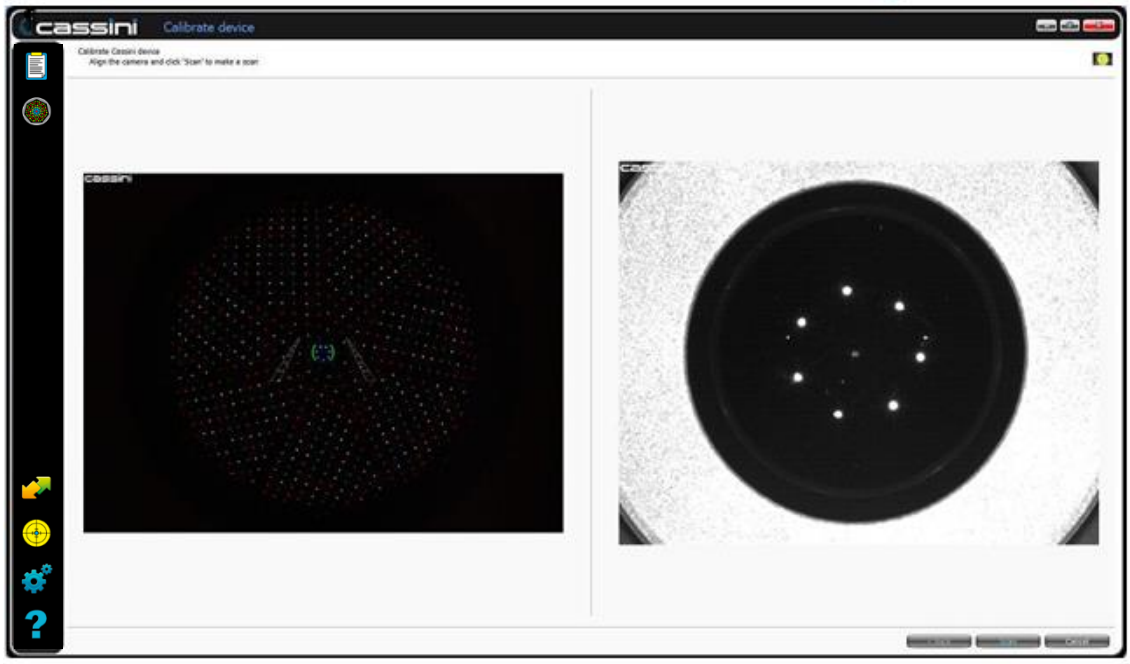


Figure 64: Calibration screen

3. Cassini should be aligned correctly in front of the calibration tool. Please move Cassini forward and backward (and left/right) until the colored LEDs reflect nicely from the calibration tool.
   Due to the sensitivity of Cassini, it is advised to align Cassini with both hands – one holding the joystick and one fixation the base (Figure 65).

Figure 65: positioning Cassini (please use the non-joystick hand to increase control over the base if necessary)

4. The alignment of Cassini in front of the calibration tool is correct if (Figure 60):
    a. The blue LEDs are centered within the blue arcs, and the centration arcs become green.
    b. The focus rails are green OR – if the rails do not respond on forward/backward movement - the two laser spots in the left image (very faintly visible) are on top of each other.

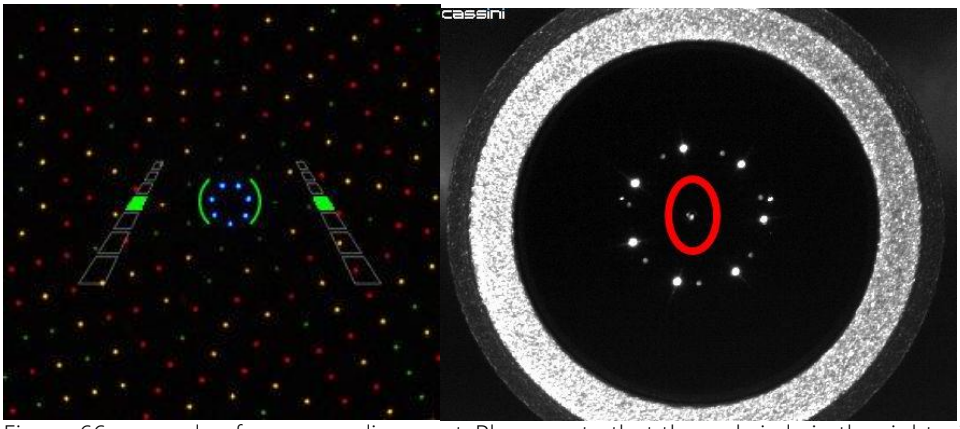


Figure 66: example of a proper alignment. Please note that the red circle in the right window is placed there for clarity (not present in the actual software).

CAUTION

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

Figure 67 shows examples of wrong alignments and hints on aspects you should be aware of when aligning.

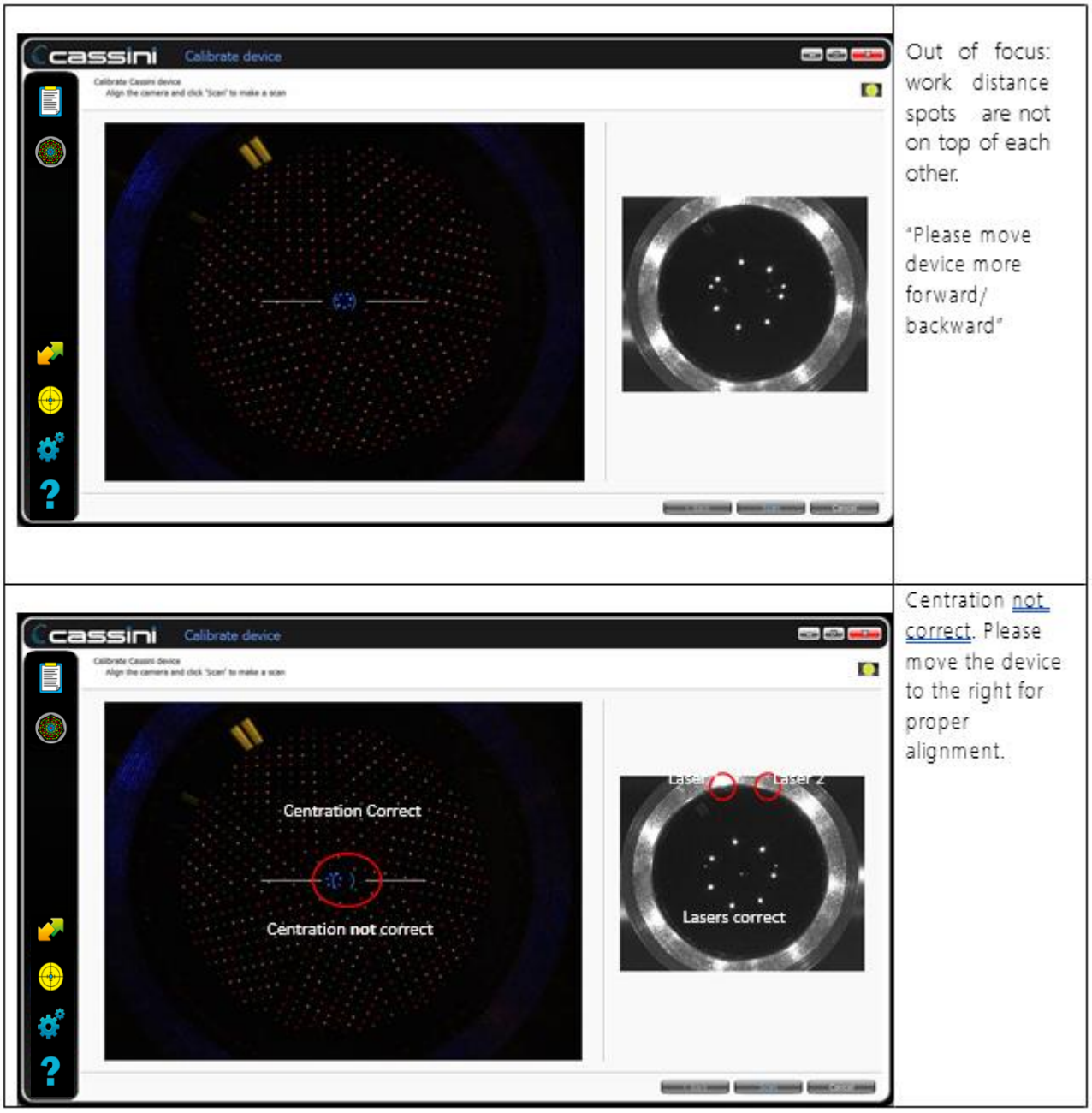


Figure 67

5. When the right alignment requirements have been met one can make a calibration by pressing the scan button in the GUI or the trigger button on the joystick. Next, the Cassini displays the quality factors and provides a recommendation to continue or to retake an image (Figure 68).

Figure 68: Quality Factors indicate if the capture image for calibration has the right quality. Cassini recommends continuing or retake an image.

6. Please accept and calibration has been stored.

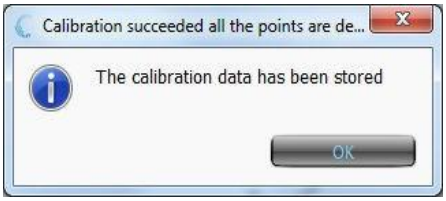


Figure 69

CAUTION

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

7. Please repeat steps 1 to 6.

8. Instead of storing the calibration data (step 6), Cassini provides an overview of the calibration data and verifies if the radius of curvature is correct. Cassini recommends if calibration should be stored or if any other action should take place (Figure 70).

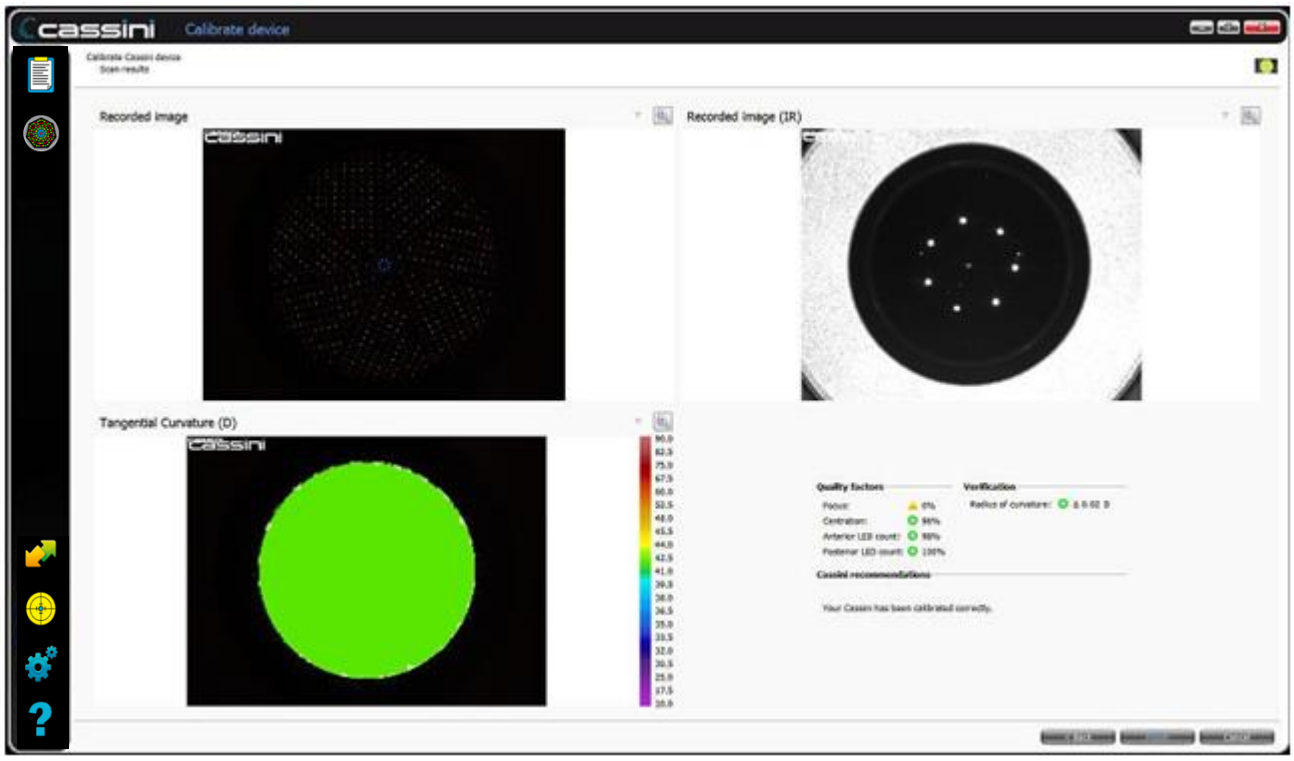

cassini
Calibrate device
Recorded image
Recorded image (IR)
Tangential Curvature (D)
Quality factors
Verification
Cassini recommendations
Your Cassini has been calibrated correctly.

Figure 70

10 Calibration Tool Replacement Procedure

Each Calibration Tool is uniquely paired with its respective Cassini device prior to shipping.

- Every Calibration Tool is affixed with a **label indicating its Radius of Curvature (ROC)** and the **serial number of the Cassini device** with which it was originally paired.
- The ROC can be located on **two labels**: one affixed directly to the Calibration Tool and one located on the Calibration Toolbox (see Figures 71 and 72).

Figure 71

Figure 72

- **NOTE**: Digits **7.977** (for illustration purposes only, the number can differ per calibration tool) represent the Radius of Curvature (ROC)

If a Calibration Tool requires replacement, the following procedure must be completed **before Color Calibration is performed; only after Color Calibration the device can be used on a patient**:

1. **Verify Replacement Tool**
    - Confirm that the replacement Calibration Tool has a label specifying its ROC.
    - **Note:** A backup or replacement Calibration Tool may not display a Cassini serial number as the tool is not part of the originally shipped configuration (See Figures 73 and 74)

Figure 73

Figure 74

NOTE: The replacement tool does not show a Cassini serial number, e.g. CA3123. The digits 7.975 will represent the Radius of Curvature (ROC)

2. Update Cassini Software Settings
    - Place the Cassini software into **Development Mode** (requires a valid Development License).
    - Navigate to **Development** > **Device Options > Calibration Tool**.
    - Update the ROC value in the software to match the ROC value indicated on the Calibration Tool label.
    - Select **Save** and then **Finish** (bottom right of screen) to confirm the update. This ensures the Cassini gets properly calibrated using the changes. (see Figures 75, 76 and 77)

Figure 75

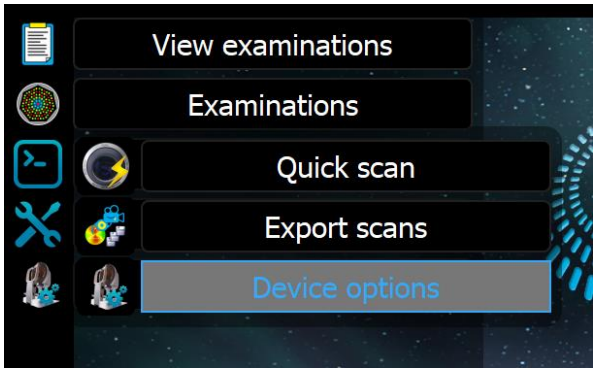


Figure 76

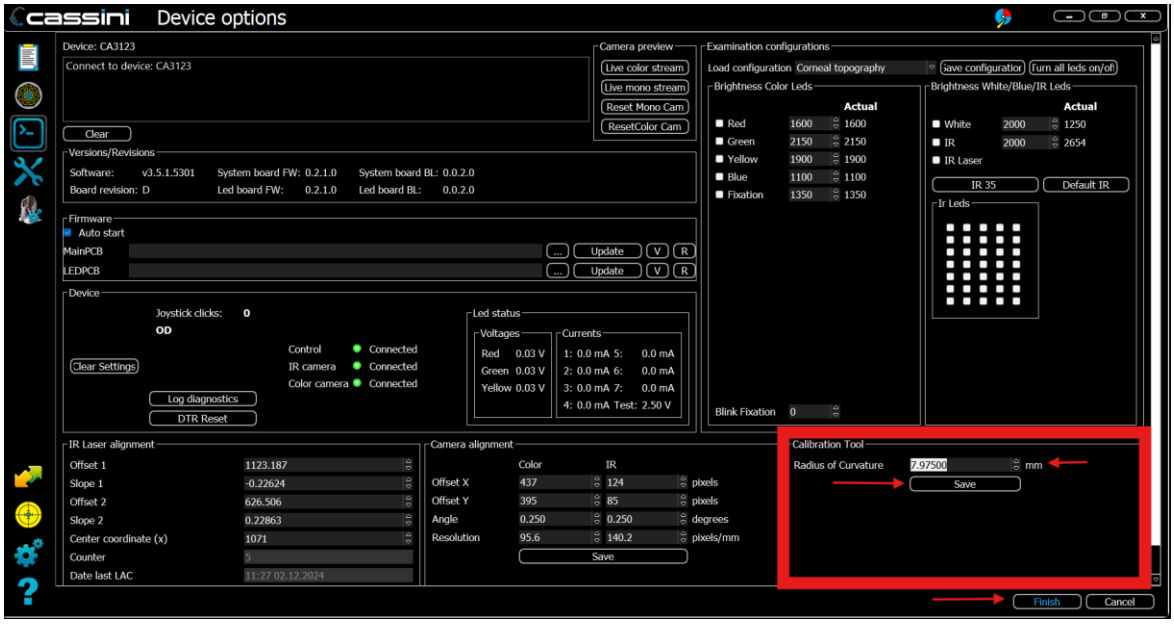


Figure 77

3. Perform System Calibration
    - Complete the **LAC/Color Calibration procedure** as outlined in the calibration section of this SOP. (See Section 9 Calibration)
4. Document the Replacement
    - Record the change(s), including the ROC of the replacement Calibration Tool, device serial number, in the **Device History Record (DHR)** for full traceability.

11 Contact

Please contact Cassini Technologies BV headquarters for further assistance or service-related questions or concerns

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