

Title: Service Manual			<b>cassini</b> CONNECT O.R.
Device: Cassini Guidance System	Basic UDI-DI: 8720892096410100N2	Doc. ID: CGS 5.07.01	Ver. 02

## Change History

Version	Author	Changes
1.0	W. Bahadoer	Initial Release
2.0	J. Snellenburg	Added section on validating camera settings

## APPROVALS

Function	Name	Date	Signature
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## 1 Introduction

### 1.1 Purpose

This document serves as the comprehensive Service Manual for the Cassini Guidance System, designed specifically for Customer Service Engineers. It provides a detailed and practical guide for managing the application in clinical environments, covering routine and corrective maintenance, database management, audit log collection, and other essential support tasks performed at client sites.

The manual ensures consistency, accuracy, and efficiency in troubleshooting and maintaining system integrity, while also guiding qualified personnel through the processes necessary to verify and sustain safe and effective system operation. It aligns with key regulatory standards, including MDR and ISO 62304, ensuring that all service activities support compliance and uphold the highest standards of medical software safety and performance.

### 1.2 Scope

This Service Manual provides a comprehensive guide for maintaining and supporting the Cassini Guidance System version 1.1.0. It focuses exclusively on software modules and their functional interactions. These modules include those responsible for acquiring intraoperative video, processing and analyzing anatomical landmarks, managing data storage and access, presenting guidance overlays through the user interface, importing diagnostic information, and rendering outputs for surgical visualization.

The manual also outlines technical requirements for software servicing, system constraints related to operating environments, built-in cybersecurity measures, and risk mitigation protocols. These elements are maintained in compliance with MDR, ISO 62304, and other applicable regulatory frameworks.

In addition, this manual serves as a practical field guide for Customer Service Engineers, detailing the procedures, tools, and best practices required for:

- Application installation and upgrade after new release
- Performing database maintenance and health checks
- Collecting and analyzing audit logs for troubleshooting
- Managing application-level settings and configurations
- Addressing system performance or operational issues at client sites
- Executing other field-level application support activities

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It is intended for use by trained technical support personnel working on-site with clients and assumes a working knowledge of the application environment, system architecture, and standard troubleshooting practices.

### 1.3 Definitions and Acronyms

Term	Definition
CGS	Cassini Guidance System
DICOM	Digital Imaging and Communication in Medicine
PACS	Picture Archiving and Communication System
GUI	Graphical User Interface
IOL	Intraocular Lens
SSL	Secure Socket Layer
SHA256	Cryptographic hash function used for secure authentication

## 2 Specifications of Guidance Software

The CGS runs on Windows 11 (64-bit) operating system. Below is a detailed operational environment description for the CGS, listing the hardware requirement and third-party dependencies

### 2.1 Minimal hardware requirements

The system is designed to operate with the following minimal hardware specifications:

Component	Requirements
Processor (CPU)	Intel Core i7/i9 (11th Gen)
RAM	16 GB
Hard disk	2 TB
Graphics (GPU)	Intel Iris Xe Graphics G7
Display	1080p Full HD

## 3 System Overview

The Cassini Guidance System software operates as a modular, real-time application supporting surgical visualization and augmented reality guidance during ophthalmic procedures. The architecture is composed of the following software components:

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- **Input Component:** Captures and aggregates real-time data from imaging devices such as intraoperative microscope cameras.
- **Device Component:** The component processes incoming video data and ensures image quality optimization before forwarding it to the processing layer.
- **Processing Component:** Utilizes guidance algorithms to calculate real-time eye tracking data and detect anatomical landmarks such as the sclera, limbus, and pupil. The system applies advanced image processing algorithms, including segmentation, pattern recognition, and feature tracking to enhance precision.
- **GUI Component:** Provides an interactive graphical user interface (GUI) to visualize guidance overlays, surgical data, and workflow controls. The GUI is optimized for touch screen use, ensuring surgeons can easily access features without disrupting the surgical process. The interface is designed to minimize unnecessary user interactions.
- **Data Access Component:** Facilitates secure storage and retrieval of diagnostic and surgical data in a PostgreSQL database. The data access layer includes encryption features to ensure sensitive patient information remains protected both in transit and at rest.
- **External Import Component:** Manages the import of patient data through DICOM files . The component automatically validates incoming data for integrity and ensures seamless integration with diagnostic and planning data.
- **Output Component:** Displays augmented reality guidance layers on a secondary heads-up monitor, ensuring the surgeon can maintain visual focus on the surgical area while observing key guidance markers.

## 4 Safety and Performance requirements

The Cassini Guidance System software adheres to a Class B software classification as defined by IEC 62304. It complies with various standards for software applicable to SaMD (see Compliance Standards). Its safety features include encryption of patient-related data using AES-128, user authentication protocols based on SHA256-hashed credentials, and automatic session locking after periods of inactivity.

In addition to cryptographic protection, the system includes real-time performance monitoring, error-logging mechanisms, and secure access via SSL-encrypted communication. Critical functionalities such as surgical tracking and video overlay are designed to fail safely and report errors without system shutdown, ensuring uninterrupted operation during surgery.

## 5 Compliance Standards

Standard / Regulation	Title	Relevance to Manual
MDR (EU) 2017/745	Medical Device Regulation	Overall device and documentation compliance, post market surveillance.
FDA 21 CFR part 820	US FDA Quality System Regulation (QSR)	Quality and traceability for service interventions

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ISO 62304	Medical Device Software – Software Life Cycle Processes	Software servicing, maintenance, and update lifecycle
ISO 81001-5-1	Health Software and Health IT – Safety, Effectiveness, and Security	Secure servicing and software reliability
ISO 13485	Quality Management Systems for Medical Devices	Documentation and service process control

Table 1 Compliance Standards

## 6 Installation instructions

Installation of the Cassini Guidance System must be carried out exclusively by a certified service engineer authorized by Cassini Technologies B.V. Before initiating the installation, the engineer must verify that the host system meets the minimum hardware and operating system requirements (see section 2.1).

The installation procedure consists of several steps. First, the engineer must obtain the installation package from a secure, authenticated company data storage location within the Cassini Technologies environment. This package includes the executable installer, necessary drivers, and system configuration scripts.

Once the installer is launched with administrative privileges, the software installation wizard is displayed.

### 6.1 List of components

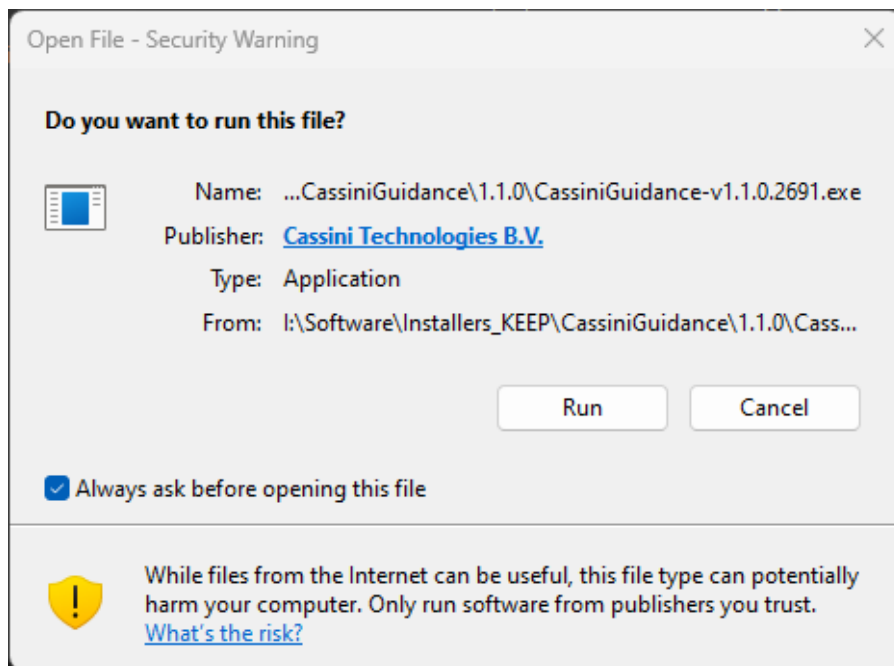
The Cassini Guidance System software installs the following components:

- Cassini Guidance System 1.1.0 software (main component); build number: v1.1.0.2691
- PostgreSQL v15.4
- Cassini DICOM Interface Software v1.2.0.3776

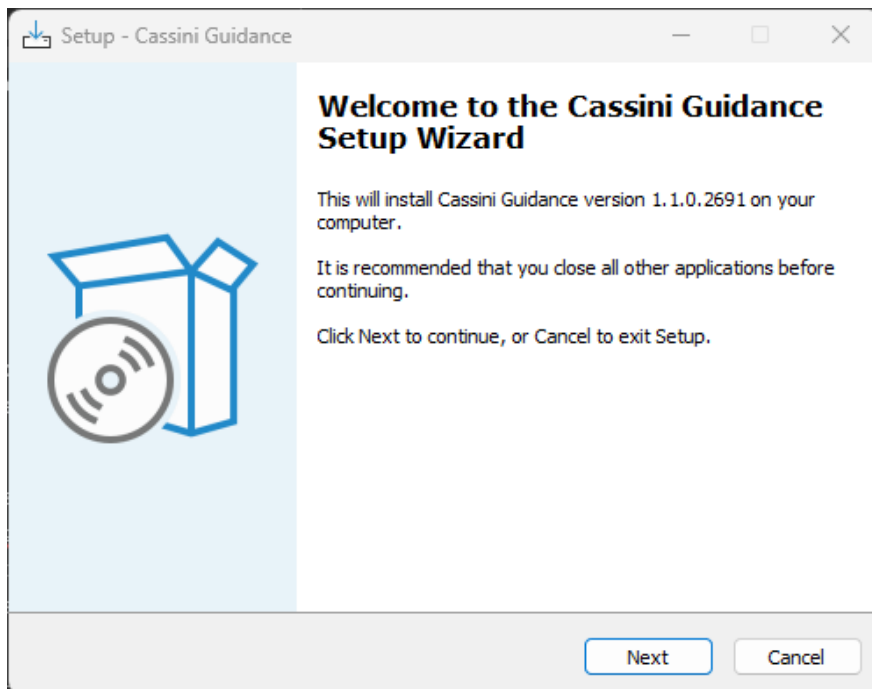
### 6.2 Installation wizard

**Step 1 – Windows security warning dialog:** The engineer must click "**Run**" to proceed with the installation. This step ensures that the user acknowledges the potential risks of running executable files and confirms trust in the software publisher

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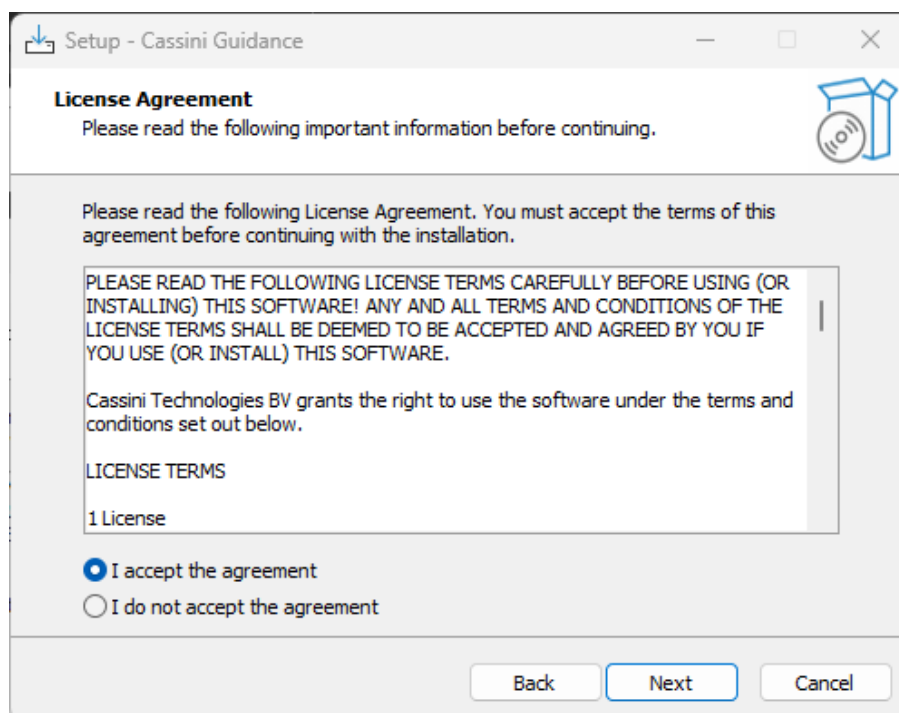


**Step 2 – Welcome Screen:** The wizard welcomes the engineer and confirms that all pre-installation checks (hardware, OS version) have passed. The engineer clicks "**Next**" to proceed.

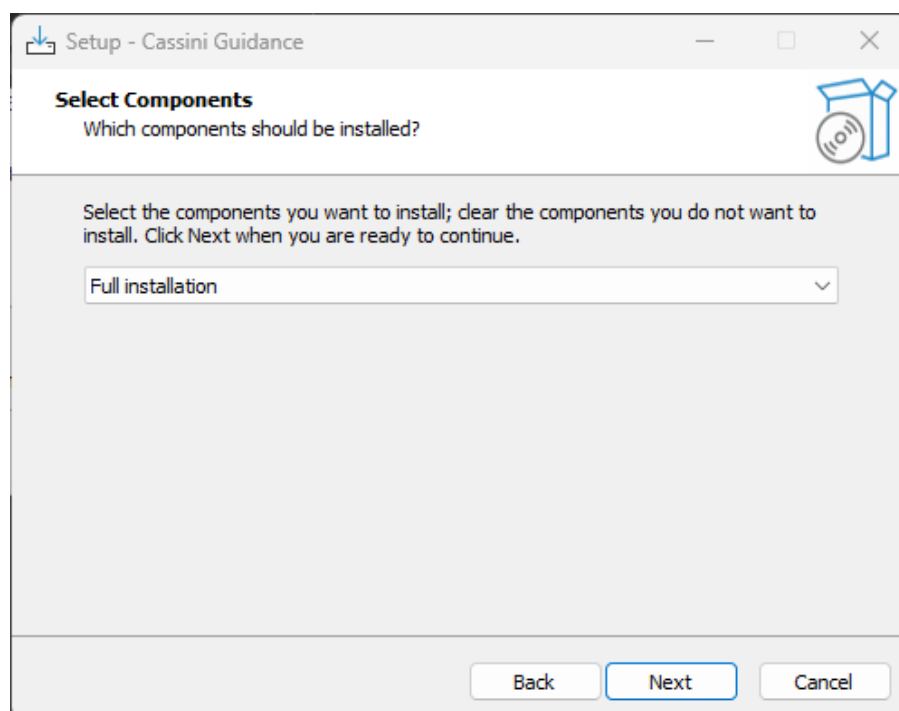


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**Step 3 – License Agreement:** The installer displays the software license agreement. The engineer must review and accept the terms by clicking **Next**.



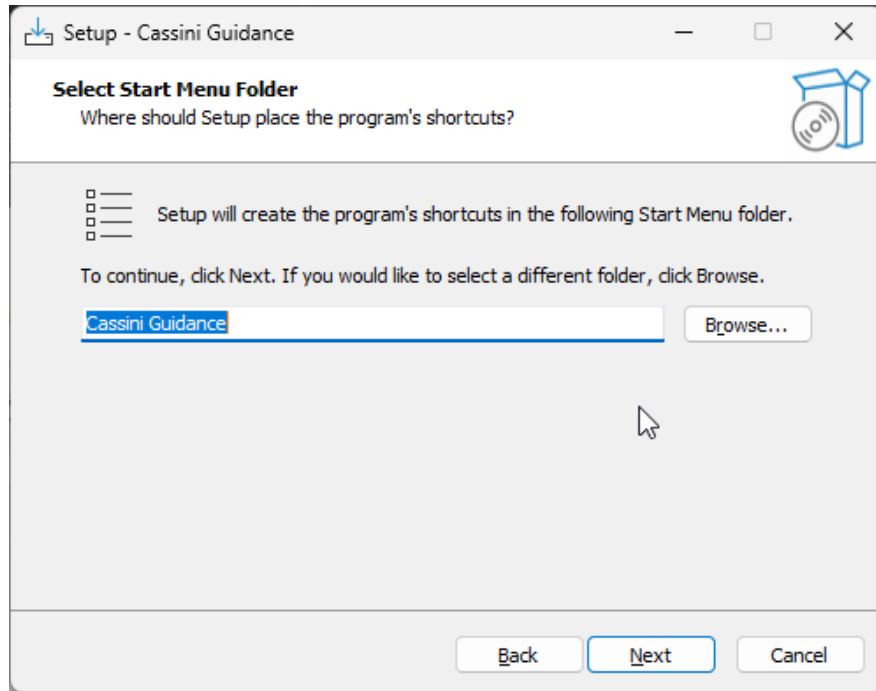
**Step 4 – Select Components:** This installation step allows the engineer to select which components of Cassini Guidance System to install. The default and only option is "**Full installation**", the engineer selects this by clicking **Next**.



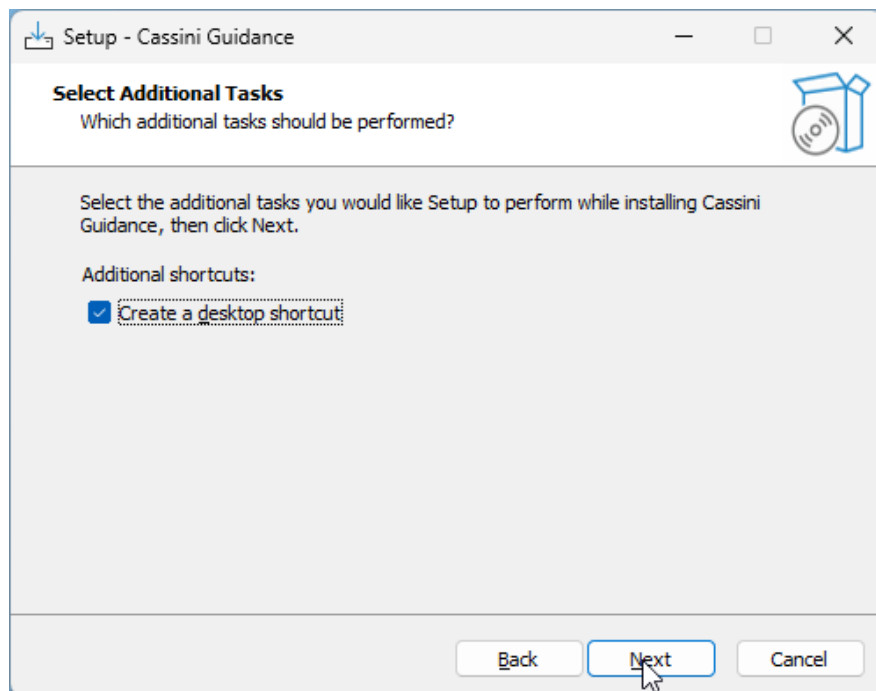


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**Step 5 – Destination Folder:** This step allows selection of the installation directory. It is recommended to use the default path unless otherwise specified by the IT administrator

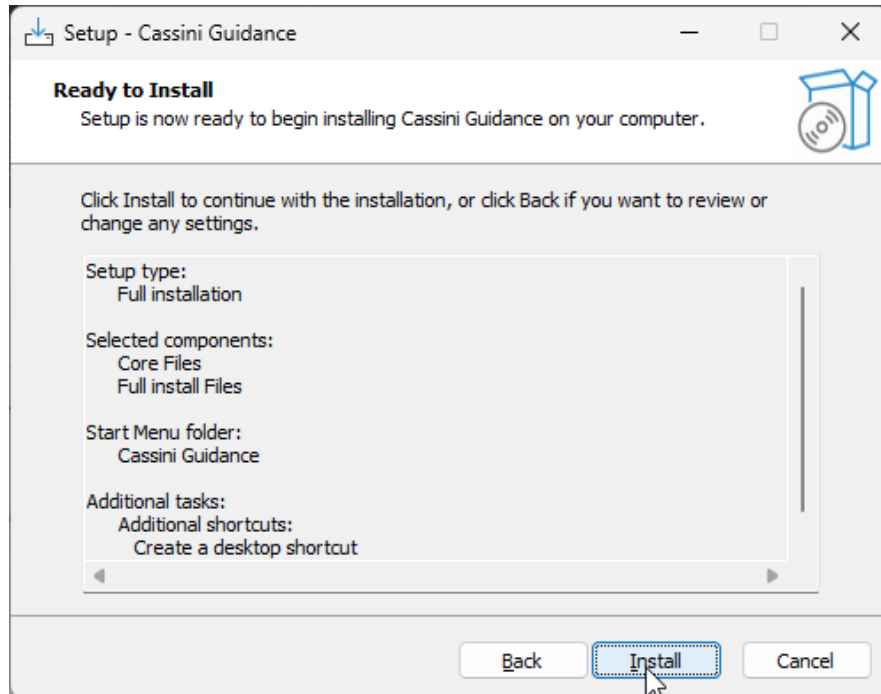


**Step 6 – Additional Tasks:** This installation step allows the engineer to select additional tasks, such as creating a desktop shortcut for Cassini Guidance System. The engineer can check the desired options before clicking **Next** to continue with the setup.

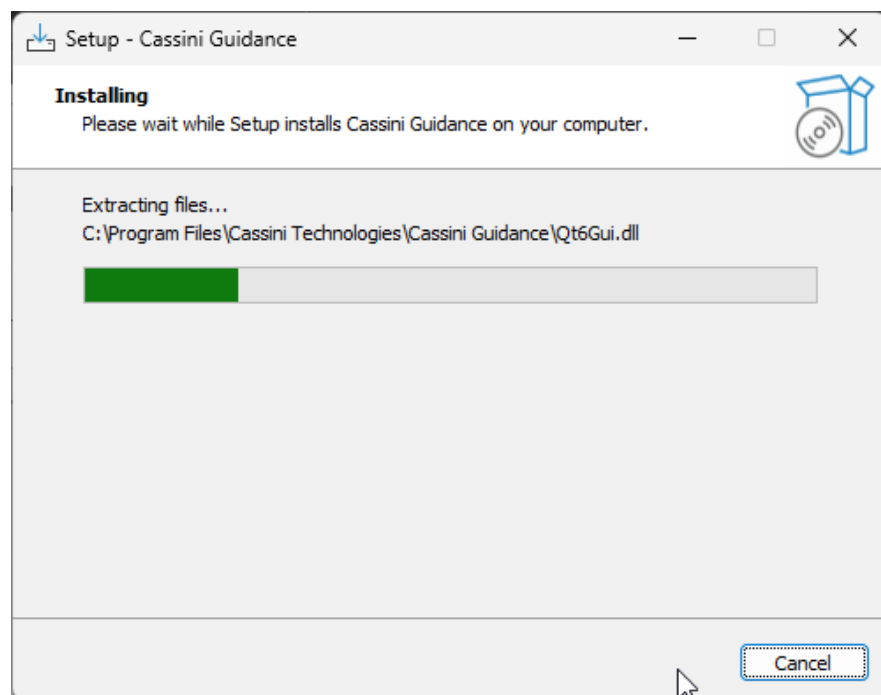


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**Step 7 – Install overview:** This step marks the beginning of the actual installation process for Cassini Guidance. It provides an overview of the selected setup options—such as components, start menu folder, and additional tasks—before the engineer clicks **Install** to proceed.

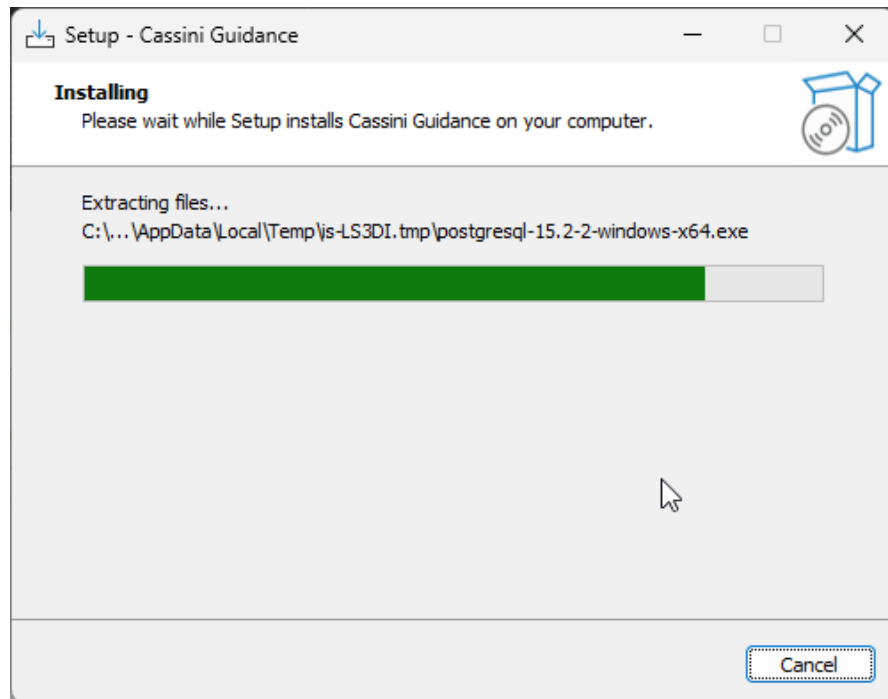


**Step 8 – Installation:** This step shows the **installation progress** of the Cassini Guidance System software. A progress bar indicates that files are being copied and installed, with the current file path displayed to keep the engineer informed.

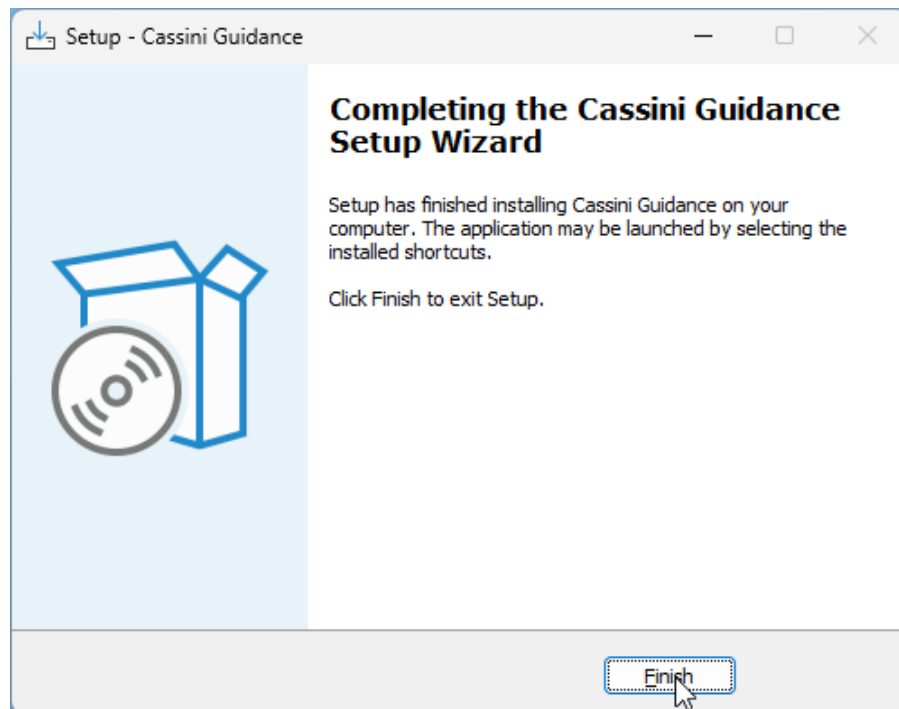


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**Step 9 – Database Installation:** PostgreSQL 15 is automatically installed as part of the CGS software suite.



**Step 9 – Finish:** This is the final step of the Cassini Guidance System installation process. It confirms that the setup has been completed successfully, and the engineer can now launch the application via the installed shortcuts. Clicking **Finish** exits the setup wizard.



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### 6.3 Base Registry Key

The Cassini Guidance System software requires a registry to be manually created in the user environment before the start of the application. A registry key of type **string** must be created in:

***HKEY\_CURRENT\_USER\Software\Cassini Technologies\Cassini Guidance***

the name of the key must be:

***BaseFunctionalityEnabled***

and the value must be set to **true**.

### 6.4 Database account configuration

After the installation is complete, the engineer must configure the PostgreSQL database. While most configuration steps are handled by the Guidance software installation, the service engineer must manually enter credentials for two database accounts: the cassiniGuidanceAdmin account and a user account used by the Cassini application.

This process begins when the application is launched for the first time. A configuration dialog will appear, prompting the engineer to enter the password for the cassiniGuidanceAdmin database account. Additionally, the engineer must define a new database user account with an associated password, which will be used by the Cassini Guidance System application.

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Dialog - [Preview]

Choose a password for the database administrator account

Password :

Confirm password :

Add a unique Cassini database account with a password

Username :

Password :

Confirm password :

Passwords must contain :

- between 8 and 16 characters
- a lower case alpha character : a-z
- an upper case alpha character : A-Z
- an allowed special character : ! @ # \$ % ^ & \* \_ - = +
- a digit : 0-9
- no spaces or these special characters : [ , . < > / ? ; ' : " { } ]

Username must start with [Cc]assini and contain :

- between 7 and 12 characters
- a digit : 0-9
- no spaces or these special characters : [ , . < > / ? ; ' : " { } ! @ # \$ % ^ & \* \_ - = + ]

☐ show password

OK Cancel

Figure 1 Database configuration dialog

The configuration dialog prompts the engineer to input the required account credentials (see Figure 1). These credentials are essential for securing access to the database and enabling proper application functionality.

#### 6.4.1 Superuser account

The Cassini Guidance System software uses a dedicated PostgreSQL superuser account named **cassiniGuidanceAdmin**, which has full administrative privileges. This account is primarily used for database recovery and advanced maintenance tasks.

- username must always remain "**cassiniGuidanceAdmin**" across all installations.

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- A unique, secure password must be chosen for each client site.
- The password must comply with the complex rules defined in the configuration dialog.
- A screenshot of the credentials window, showing the password, must be stored securely for future reference, especially in case of system recovery needs.

#### 6.4.2 Cassini application account

In addition to the superuser account, a separate application account is required. This account is used by the CGS software to authenticate the database on behalf of the end users.

- The username must be unique within each client's environment.
- It should always begin with "**cassiniGuidance**", followed by a number.
- The username must not contain any restricted characters as specified in the dialog.
- This account and its credentials must never be shared with the end user.

#### 6.4.3 Application (user) data

The application's database authentication details are stored in the Windows Registry at:

**HKCU\Software\Cassini Technologies\Database**

- This registry location is accessible to the end user.
- All data except the password is stored in plain text and is human-readable.
- The password is securely encrypted to prevent user access or manipulation.

### 6.5 Windows Update Management

To prevent disruption of surgical procedures and ensure uninterrupted system performance, it is critical that Windows Update is not allowed to execute while the Cassini Guidance Software is in use. Service engineers must ensure that Windows Update is configured to operate manually.

During installation or servicing, the engineer must access the Windows Update settings and set the update mode to 'Pause' or 'Manual'. Automatic restarts, background installations, and update scheduling must be disabled. The recommended configuration uses Group Policy or local administrative settings to restrict automatic downloads and to prevent the system from rebooting without explicit user approval.

Windows Update should only be applied during scheduled service windows, when the application is not in active use and a full backup has been completed. Any updates applied to the operating system must be followed by a system validation check to confirm continued functionality of the Cassini Guidance Software.

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## 6.6 Reinstallation or Upgrade

Reinstallation or upgrade of the Cassini Guidance System software must be performed by a service engineer. This process is required when restoring a damaged installation or deploying a new software version. It is essential that PostgreSQL database contents, registry keys, and software licenses remain intact during the operation.

### Reinstallation Steps:

1. Backup Confirmation (Optional but Recommended):  
Before proceeding, verify that the PostgreSQL database is functional and backed up using pg\_dump. Confirm that the current registry keys are intact and accessible.
2. Uninstallation:  
Use the Windows Control Panel or the designed uninstaller tool to remove the existing Cassini Guidance System software. Ensure that the PostgreSQL service is not removed or reconfigured during this process. The registry and user data should remain untouched.
3. Preparation:  
Confirm that the latest or identical version of the Cassini Guidance System software is available from a verified source (SharePoint or USB). Ensure administrative privileges for installation.
4. Installation:  
Launch the installation wizard and proceed as outlined in Section 4.1. The installer will detect the existing PostgreSQL instance and use existing configuration and credentials
5. Validation:  
After installation, start the application to ensure that it connects properly to the existing database and registry settings. Run tests to confirm that all overlays and modules behave as expected.

## 6.7 Application startup

Following completion of the installation wizard, the service engineer must confirm that the installation has been completed successfully by launching the Cassini Guidance System software application.

Upon startup, the software should open without errors and display the main menu screen (figure 2). The engineer must connect all hardware peripherals and ensure they are correctly recognized by the software. This includes verifying that the UltraStudio Recorder is transmitting a live video feed from the microscope, and that the ATEM switcher is routing the overlay output to the external display.

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Figure 2 Main menu

Once the video stream is visible in the GUI, the engineer should test the application with test case data from Cassini Planner. This test generates overlays and guidance markers, which must render correctly on both the control monitor and the heads-up display. The tracking, segmentation, and registration features should respond as expected, with no noticeable delay, distortion, or misalignment.

The final step in the validation process is to review the system logs for errors or warnings and to confirm that the database is actively logging system events. If all systems pass the checks, the installation is considered successful, and the engineer may proceed to complete and submit the installation verification report.

## 7 Maintenance & Updates

### 7.1 Application Maintenance

Routine maintenance of the Cassini Guidance System is essential to ensure its operational integrity and consistent performance in a clinical environment. This involves a combination of functional checks, data management, and system validation tasks.

Key servicing activities include:

- **Application Functionality:**  
Verify that the software launches correctly and that the user interface is responsive.
- **Database Integrity:**  
Confirm that the PostgreSQL database is operational. At the client's request, back up the database using the `pg_dump` utility and store the encrypted archive securely.



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- **Simulation Testing:**  
Use exports from the Cassini Planner (e.g., prosthetic eye cases) to simulate surgical sessions and validate the performance of tracking and segmentation modules.
- **Overlay and UI Validation:**  
Ensure overlays render correctly and that all modules respond as expected during simulated workflows.
- **Audit Log Review:**  
Check audit logs for completeness and investigate any recurring or recent error patterns.
- **Data Cleanup:**  
With client approval, purge temporary files and obsolete patient case data in accordance with the clinic's data retention policy.

These steps help maintain the reliability and safety of the system in a clinical setting while supporting compliance with operational and regulatory standards.

## 7.2 Health Checks and Logs

System health checks are performed by reviewing the internal log files generated by the CGS application and PostgreSQL database engine. These logs can be accessed directly from the filesystem in the application's log directory. Key indicators to review include error entries in cassiniGuidance.log, synchronization latency, database access events, and overlay rendering anomalies.

Audit logs should also be checked to confirm that access to sensitive operations such as user authentication, case deletion, and database modification are being properly recorded. These logs help track usage trends and provide forensic insight into system issues.

When an issue occurs with the Cassini Guidance System software, the service engineer should gather application logs using the following steps:

- The engineer needs to navigate to the "C:\Users\%username%\AppData\Local\Temp\Cassini Guidance" folder
- Select the file with "log" extension.
- Save the log to a designated folder for further analysis.

To gather Windows OS logs, the service engineer should follow these steps:

- Open the Event Viewer by typing eventvwr in the Run dialog (Win + R).
- Navigate to "Windows Logs" and select "Application" and "System."
- Right-click each log and select "Save All Events As..."
- Save the logs to a designated folder for further analysis.

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## 8 Troubleshooting

### 8.1 Common Issues and Solutions

- Issue: Application fails to launch  
Solution: Verify that PostgreSQL services are running and configuration files have not been altered. Restart the application and examine the latest log entries for error tags.  
  
Solution: Base registry key is missing
- Issue: Missing overlays in simulation mode  
Solution: Recheck tracking and segmentation configurations. Ensure test case data is loaded properly and the registered eye angle does not exceed the threshold of 12 degrees
- Issue: GUI freezes during startup  
Solution: Perform a clean boot of the system. Check logs for UI initialization failures.
- Issue: Loss of video stream  
Solution: Check system for overheating and perform a system reboot  
  
Solution: Check for power surge and suggest using a UPS if necessary  
  
Solution: Check system for damaged components and plan a replacement
- Issue: System is not performing as expected  
Solution: Check if Windows update is running, pause the update procedure if running  
  
Solution: Check the Windows Task Manager to determine which process is consuming a lot of resources, terminate those tasks

### 8.2 Error Codes

The Cassini Guidance System software logs error codes in cassiniGuidance.log. Each log line starts with the Date Time stamp and contains an error log level indicator

- Info: Indicates informational messages
- Warning: Indicates a warning that might lead to a failure
- Fatal: Indicates a non-recoverable error.

### 8.3 Overview System and Error Messages

Message	Suggestion
Fail to store scan in Database	Check if database is present and access rights are correct
Unable to open device	Power cycle device and restart application

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Fail to open Database	Check if database is present and access rights are correct
Database Query Error	Check if database is present and access rights are correct
Can't communicate with the device, please check the connection	Power cycle device
Unable to create sub directories	Check if the user had write-permissions to this target location
Cannot read .dcm file	Check the .dcm file in a DICOM viewer, format error should be visible
Unexpected handler called	Restart application

*Table 2 Common Error Messages*

For critical errors, restart the machine using the Windows Services control panel. If the Issue persists, escalate to Cassini Technologies for support.

#### 8.4 Reinstallation or Recovery

If a full reinstall is required, first create a backup of the PostgreSQL database using pg\_dump. Then, uninstall the current version via the Windows Control Panel without deleting user settings or database files. Reinstall the software using the verified installation package. After installation, reconnect the application to the existing database and validate functionality via simulation mode.

### 9 Access and Security

#### 9.1 Admin Access and Roles

The Cassini Guidance System software includes role-based access control (RBAC). Administrative access is limited to authorized users with elevated privileges for configuration, audit access, and software update deployment. Admin roles are provisioned via the installation wizard and managed through the PostgreSQL backend or GUI security settings.

#### 9.2 Secure Field Access

Service engineers should authenticate using designated service credentials. Remote sessions, if necessary, must occur via secured, hospital-approved remote access solutions. All access activities are logged and should comply with local IT security protocols and Cassini's internal field servicing policy.

#### 9.3 Patch / Vulnerability Handling

Security patches and vulnerability fixes are issued by Cassini Technologies as digitally signed packages. Patch validation includes checksum verification, sandbox testing, and simulation validation. Service engineers must verify patch integrity before deployment and document update outcomes as part of the site's service report.

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## 10 Decommissioning

### 10.1 Uninstall Instructions

Uninstallation is performed through the Windows Control Panel. It is critical not to delete the PostgreSQL database unless decommissioning is final. Use administrative rights to remove the application and verify that all application services have stopped.

### 10.2 Data Removal / Archival

If full removal is required, back up and archive all database content using pg\_dump. Exported patient data must be stored securely in accordance with GDPR and HIPAA compliance where applicable. Once archived, database directories and registry keys should be purged using the provided clean-up script.

## 11 Service Tools

### Console Script Execution Policy:

To protect the integrity of the client environment, only scripts officially approved by the development team may be executed. Running unauthorized console scripts can cause severe damage to the database and may result in irrecoverable data loss.

### 11.1 Restore Application Password

Since the registry section containing database credentials is accessible to the user, there's a possibility that data may be accidentally deleted. If this occurs, the application password can be restored using the restoreAppPassw.bat script.

Dependency: None

- Close the Cassini application
- Open a command box
- Run the script "restoreAppPassw.bat"
- Type the password for the cassiniGuidanceAdmin account, the script should finish without any errors

### 11.2 Clean Cassini application environment

In specific scenarios, such as resetting a demo unit, it is advisable to fully clean the Cassini Guidance System application environment and initiate a fresh installation state. This can be done using the cleanCassiniEnv.bat script

Dependency: cleanCassiniEnv\_v2.sql

- Close the Cassini application
- Open a command box

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- Make sure the files that this script depends on are present in the same folder as the script .bat file
- Run the script “cleanCassiniEnv.bat”
- Type the password for the cassinGuidanceAdmin account, the script should finish without any errors
- Restart the application and you should see the “Database configuration dialog”

### 11.3 Exporting Database

The complete database can be exported for several reasons, such as archiving, moving to a different machine, or for R&D purposes. This can be done with the ExportDB.bat script using the following steps:

Dependency: None

- Close application (not mandatory)
- Open a command box
- Run the script “ExportDB.bat”
- Type the password for the cassiniGuidanceAdmin 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 directory
- The folder contains several “tar.gz” files, these files hold the database data.

### 11.4 Importing Database

**Important:** This process will erase the existing database before importing.

Import operations must be performed in a clean environment as merging with existing data is not currently supported.

The import process uses the ImportDB.bat script and a folder containing the exported database files.

Dependency: ImportDB\_v3.sql

- Close application
- Open a command box
- Make sure the files that this script depends on are present in the same folder as the script .bat file
- Run the script “ImportDB.bat”
- When prompted:

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- Enter the cassiniGuidanceAdmin password **to** wipe the existing database. Wait for the script to complete this step.
- Enter the password again to start the import process. Depending on the size of the database, this may take several minutes.
- Enter the password a final time to set the database version.

## 12 Validating Camera Settings

Although the Cassini Guidance System is (microscope) camera agnostic it is important that the camera settings are validated to be correct for both our application as well as downstream use.

There are 4 main criteria to validate: image orientation, video format, (auto) gain, (auto) white balance.

- Video format (Resolution 1080i/p, Frame Rate 50-60Hz)
- Image orientation (up is up, down is down, left is left and right is right)
- Auto Gain (Automatic, adapts to low and high light exposure)
- White Balance is configured correctly (either automatic: AWB; or appropriate manual setting)

Below these settings are discussed in the context of a popular medical grade camera, the Leica HD C100. Generally every medical grade camera will have the same or at least a subset of these features under control, when in doubt always consult the user manual for the specific microscope and/or camera module.

### 12.1 Example 1: Leica HD C100

*The Leica HD C100 is only used as an illustrative example, the principles apply generally.*

The Leica HD C100 Camera comes with its own camera control module depicted below. This camera control module determines the output of the camera which is sent to the Cassini Guidance System. If this module is configured incorrectly it is possible that the Cassini Guidance system doesn't detect an input, or an input is detected but the system doesn't function correctly (e.g. registration doesn't work).

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Figure 3. Leica HD C100 Control Module Front Panel Controls. Refer to the manual for a detailed explanation of the control functions.

#### 12.1.1 Video Format (Resolution / Frame Rate)

*This section is about validating the video format (resolution and frame rate).*

This is the most critical setting to validate because if the setting is incorrect, the Cassini Guidance System may not detect an input signal. Furthermore, even a setting that is detected by the Cassini Guidance System may subsequently not work with video equipment downstream. A field service engineer should verify that the given setting works for all systems in the chain: the Cassini guidance system, video displays and/or TV connected to the loopback interface and/or those downstream from the guidance system outputs.

On the HDC100 this setting is summarized as the VIDEO FORMAT, depicted below as 1080p50 (which means a resolution of 1920x1080, progressive mode, at 50Hz).

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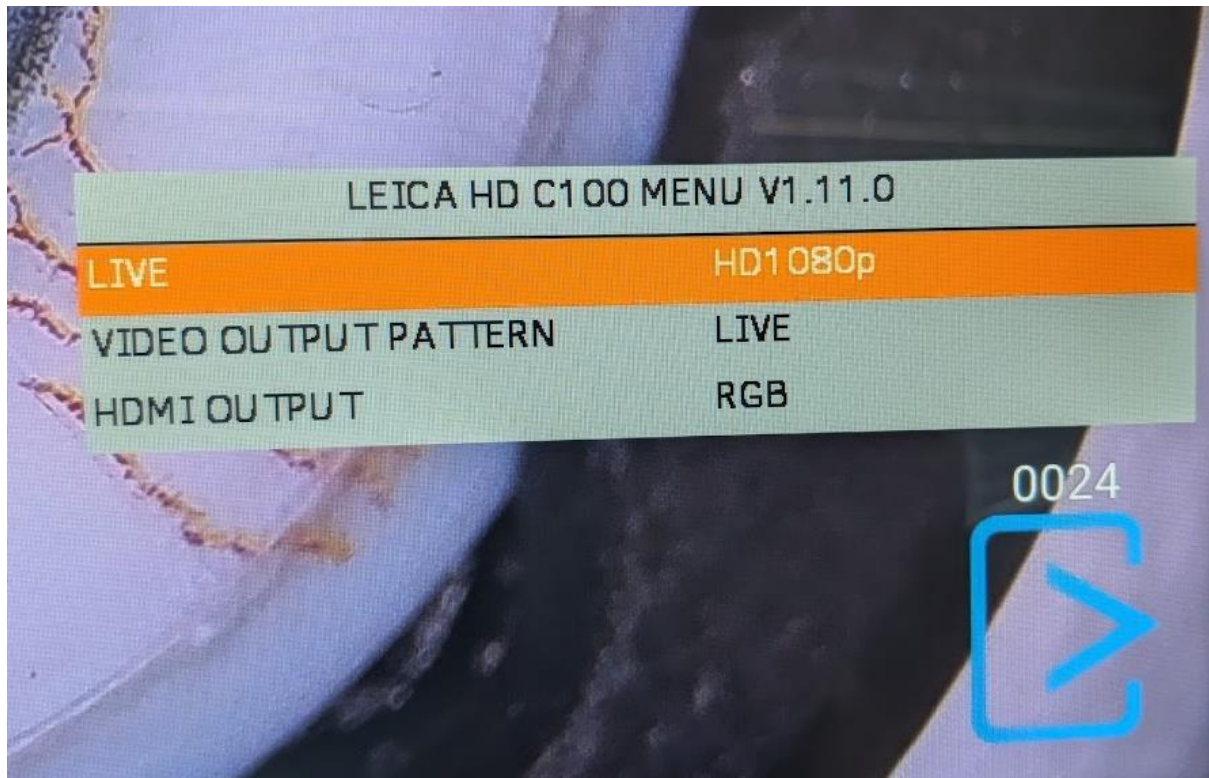


Figure 4. Leica HDC100 On-Screen Menu to control video format. Selected is HD1080p.

The field service engineer should check for a given setting if (1) the Cassini Guidance System receives inputs, (2) the system is correctly passed on to downstream devices (if any). They should start with the best possible supported setting (e.g. 1080p60 for a HD Camera system) and then move down until a setting is found that works (1080p60 -> 1080p50 -> 1080i60 -> 1080i50 -> 1080p30). Going lower than 1080i50 *\*not\** advised but in some cases 1080p30 may be the only mode supported by (older) downstream equipment and may still be acceptable to the user. This is to be determined on a case by case target but the **goal** should always be a resolution of at least 1920x1080 and a frame rate of 50-60Hz.

#### 12.1.2 Image Orientation

*This section is about validating the image orientation between camera input and reality.*

The second setting which must be correct is image orientation, that is when the microscope is over a target (e.g. a fake eye) and **positioned as the surgeon would use it** then the image is right-side-up and oriented correctly. Meaning that if a finger is brought in from the top of the target, it also appears in the video image from the top. If a finger is brought in from the left of the target it is also appears in the video image from the left.

The setting which controls this in this case is the FLIP IMAGE setting, which can be set to MIRROR, FLIP, MIRROR+FLIP, etc. Because each camera can be **physically** mounted differently, the right setting should be **empirically** be determined.



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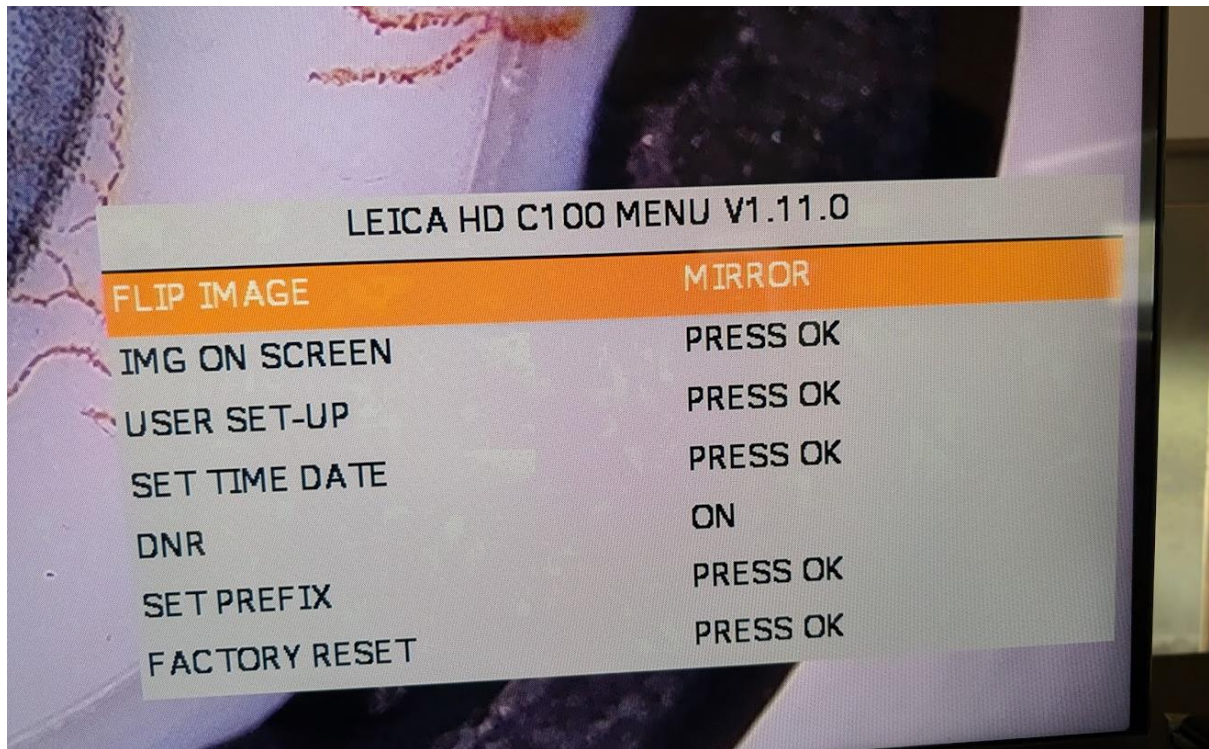


Figure 5. Leica HD C100 OSD Menu showing image orientations; selected is FLIP IMAGE. The *\*correct\** setting should be determined per system.

### 12.1.3 Exposure Settings (Auto Gain)

*This section is about validating the camera's exposure (auto gain) settings.*

The right exposure setting ensures that the image is visible under both low light and high light output settings of the microscope's light sources. Ideally, the camera's exposure setting is set to automatic, which works to balance the exposure from the lowest to the highest light output setting which the attached microscope supports, or at least the full operable range.

It is **not** advisable to use a manual exposure setting; if exposure is left manual, then the guidance system may only function properly under a limited range of light intensities.

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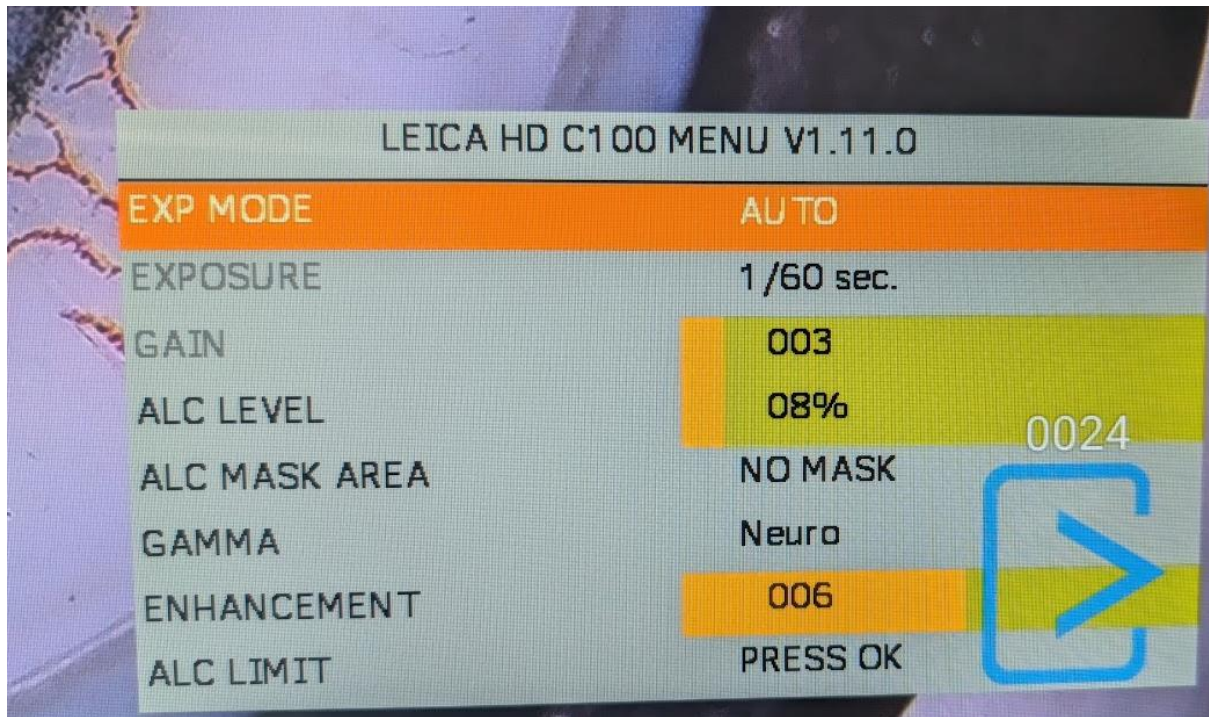


Figure 6. Leica HDC100 On-Screen Menu controlling exposure/gain. Auto mode selected.

#### 12.1.4 White Balance (or Color Balance)

*This section is about validating the camera's white balance (color gain) settings.*

A proper white balance setting is important because the image from Cassini Ambient which the registration is done with is also properly white balanced. An imbalanced white balance on the microscope side may lead to a reduction of the probability of successful registration. A field engineer should validate that appears properly white balanced and/or make sure that auto white balance (AWB) or auto white calibration (AWC) is readily available as needed.

What is important is that white in reality looks white in the image, and is not tainted by a yellow/red/blue 'haze'. If in doubt place a test target with white, red and blue under the microscope and compare this to the same image from the Cassini Ambient (EOP Image), these should look visually comparable if not identical.



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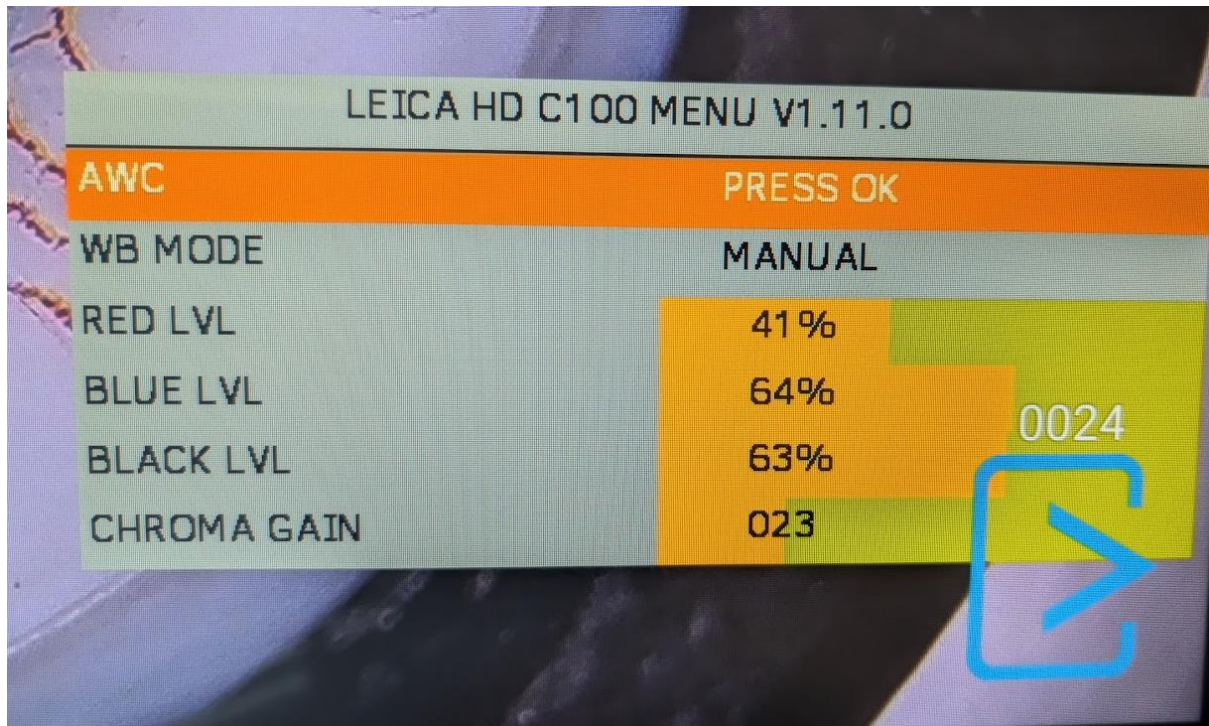


Figure 7. Leica HDC100 On-Screen Menu controlling color balance. Although set to manual, a suitable color profile is selected (validated via a test eye).

## 12.2 Final Checks

*This setting describes the general checks to be performed for any combination of hardware.*

Always make sure that the image from the microscope can be observed by the Cassini Guidance System, as observed in the GUI on the control monitor, and that this image is passed downstream (e.g. to a connected TV) as well.

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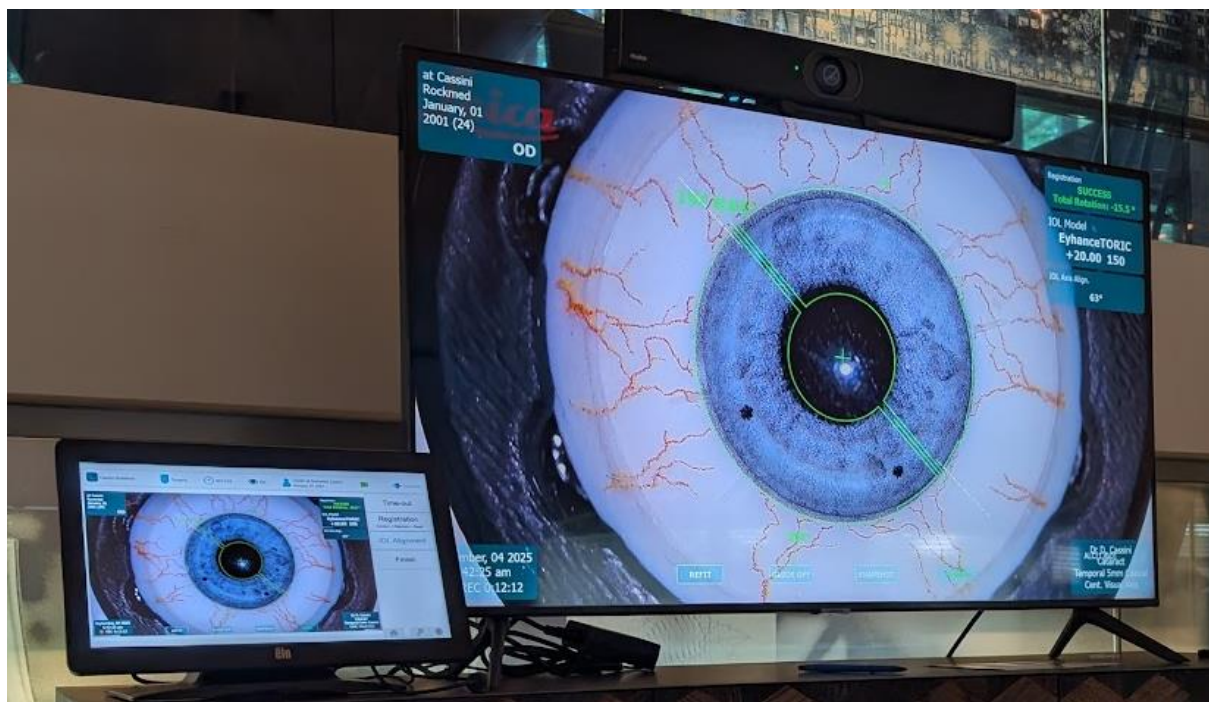


Figure 8. Side-by-side view of the Cassini Guidance System's control monitor showing the input as well as the primary video display out on a secondary screen (a TV in this instance).

If the microscope has its own monitor (as is often the case) make sure that the image appears *\*identical\** as observed by the Cassini Guidance system (same colors, same image orientation).



Figure 9. Microscope Camera feed on the microscope's own (control) monitor and/or existing display. Validated to match the Cassini's color and image orientation.












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Final Audit Report

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