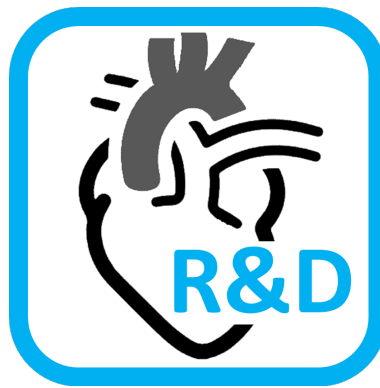


Segment - Installation Manual



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Software version 4.3.0.0

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<https://medviso.com/documents/segment/manual.pdf>

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1 Conventions and Trademarks

1.1 Typographic conventions



Caution used with the safety alert symbol, indicates a hazardous situation which, if not avoided, could result in minor or moderate injury or material damage.



Information intended to help the user achieve optimal use of the software. Includes usage considerations, limitations, or recommendations that do not relate to safety.



A reminder to the user of their responsibilities under applicable regulatory requirements.

A

Key A at the keyboard.

Ctrl-A

Control key. Hold down Ctrl key and A simultaneously.



Icon in toolbar.

*.mat

Filename extension.

C:/Program

Folder.

File

Menu, e.g. File menu.

File→Save As

Sub menu, e.g. under the File menu the item Save As is found.



Push/Toggle button in the graphical user interface.

2 Requirements

2.1 System requirements

- Operating System:
 - Windows 11
 - Windows Server 2019
- Processor: Any Intel or AMD x86-64 processor with a minimum of four logical cores
- Computer with 8 GB of memory or preferably 16 GB
- Harddisk with at least 5 GB of available space
- Graphics card supporting both DirectX and OpenGL
- To use the full functionality of the report function:
 - Microsoft Word
 - Adobe PDF reader
- To access full version of machine learning algorithms in Segment:
 - CUDA enabled NVIDIA graphics card with 4 GB memory or more
 - GPU architecture: Ampere, Turing, Volta, Pascal
- For users with additional modules not included in the free research version:
 - Internet connection for software license management and software download. We recommend a speed of at least 24 Mbit/s.

Recommendations

- Systems with two screens
- Using SSD disk for reading data

2.1.1 Mac OS users

Please refer to the section "I have a Mac" in our FAQ (www.medviso.com/faq).

2.2 Safety Instructions

Caution used with the safety alert symbol, indicates a hazardous situation which, if not avoided, could result in minor or moderate injury or material damage. Caution consists of the following elements:

- Information about the nature of a hazardous situation,
- Consequences of not avoiding a hazardous situation, and

- Methods of avoiding a hazardous situation.

The following cautions are valid for Segment:



CAUTION: The measurement results may not reflect the exact situation because the measurements are inaccurate.

Minor inaccuracy of value(s) in patient record. No harm to patient.

- Correct volumetric measurement and tissue characteristics values greatly depend on the final segmentation,
- Manually check and, if necessary, correct the algorithm segmentation results using your clinical knowledge,
- The automatic segmentation algorithms provides an initial assumption of contour definitions. It is the responsibility of the user to verify and correct the results,
- Review the patient report for errors prior transmitting the final result,
- Quantitative analysis is dependent on the quality and correctness of the image source data,
- The software may only be used by professionals trained in cardiac MR image analysis,
- Segment is a support tool that provides relevant clinical data as a resource to the clinician and is not intended to be a source of medical advice or to determine or recommend a course of action or treatment for a patient.



CAUTION: The automatic scar and MaR segmentation algorithms are developed for single vessel myocardial infarction or ischemia. They are not validated for multi-vessel myocardial infarctions or ischemia.

Extra work for user, since the user must do the segmentation manually for multi-vessel myocardial infarctions or ischemia. No harm to patient.

- Correct volumetric measurement and tissue characteristics values greatly depend on the final segmentation,
- Manually check and, if necessary, correct the algorithm segmentation results using your clinical knowledge,
- The automatic segmentation algorithms provides an initial assumption of contour definitions. It is the responsibility of the user to verify and correct the results,



CAUTION: The 4D flow analysis is only validated for Siemens data.

Extra work for user, since flow analysis for data from non-Siemens vendors must be done using the 2D flow analysis tools. No harm to patient.

- For 4D flow data acquired from non-Siemens vendors, perform flow analysis using validated 2D flow analysis tools instead of the 4D flow workflow.



CAUTION: The user reads a revision of the user manual that differs from their software revision, so the user gets incorrect information on how to use the software.

Extra work for user, since the software cannot be used. No harm to patient.

- Ensure the version number of your Instructions for Use corresponds to your software version number. The correct Instructions for Use for your software can always be found under the Help menu, while the latest can be found on the Medviso webpage.



CAUTION: Antivirus software has not been installed or updated.

Patient stress and/or anxiety.

The computer where Segment is installed should have:

- Firewall,
- Anti-virus software installed and running,
- Back-up on patient data, and
- Personal login to access the software (in the preferences for Segment the user can activate user login to the device and user logging for the usage of the device.)



Each MRI scanner is unique and different phase contrast pulse sequences have to be individually validated for each scanner, as each scanner has individual sources of error that can affect flow quantification.



In the event that the use of Segment causes a serious incident, such that it results in physical OR psychological harm to the user and/or patient, this shall immediately be reported to Medviso AB (support@medviso.com), as well as the competent authority of your Member State (Ministries/Agencies of Health and/or Medicines).

3 IT Network and security

When installing and operating Segment on an IT network (a system or systems composed of communicating nodes), the following requirements must be met:

Technical specifications

Adequate protection against malware (malicious software) or similar threats must be implemented.

Information flow

Segment can connect to an organisation's PACS or other DICOM node. Ensure that network ports are available for communication. Adding Segment to the PACS whitelist can help ensure smooth information flow.

Hazardous situations

If the IT network does not comply with the requirements listed above, hazardous situations may occur.

These may include, for example:

- incorrect or delayed data transfer,
- system unavailability, or
- compromised data security.

3.1 Segment on an IT network

When Segment is installed and becomes part of an IT network, please be aware of the following:

1. Running Segment as part of an IT network may introduce risks to patients, users, or third parties that have not been previously identified.
2. It is the responsibility of the user to identify, analyse, evaluate, and control these risks before deployment.
3. Any subsequent changes to the IT network, may introduce new risks and may require additional analysis. Such changes to the IT network may include:
 - modifications to the IT network configuration,
 - addition of hardware, software platforms, or software applications,
 - removal of items from the IT network,
 - updates to hardware or software platforms or software applications,
 - upgrades to hardware or software platforms or software applications.

3.2 Adding Matlab website to Network firewall

If your organization is running a network firewall, it is need to bypass blocked connections to the MathWorks servers in order to install Matlab Runtime that is packaged together with Segment CMR in the installation process.

The MathWorks installer contacts MathWorks servers on the following ports and addresses:

- login.mathworks.com
- services.mathworks.com
- TCP ports 80 and 443

Your firewall needs to bypass blocked connections for both addresses over both ports. These servers do not use a Static IP Address and will resolve to a Dynamic IP Address. This means that users will not be able to white-list MathWorks servers via IP Address and will have to use the domain name. More information about possible solutions for unblocking the connection can be found in provided link below.

Source: <https://se.mathworks.com/matlabcentral/answers/92634-why-do-i-get-a-connection-error-when-installing-or-activating-matlab-or-another-mathworks-product>

3.3 Adding Licence Server to Network firewall

If your organization is running a network firewall, it is need to open network firewall for Medviso Licence Server in order to verify and update your Software licence.

Segment CMR contacts Medviso Licence Server on the following address and port:

- URL: <https://medviso.com>
- Port: 443

4 Installation guide

4.1 Installation and upgrading

To install or upgrade Segment, log in to our website (<https://medviso.com/download2/>) and download the installation file. Run the installation file under administrator privileges on the machine and follow the instructions in the figures below.

For more information on installation and network connectivity, please consult the separate installation manual found on our website (<https://medviso.com/user-manuals2/>). For assistance, please contact support@medviso.com.

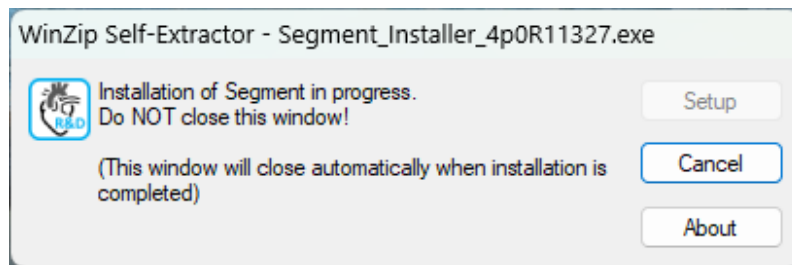


Figure 1: The installation starts automatically. Do not close this window, it will close automatically when the installation is completed.

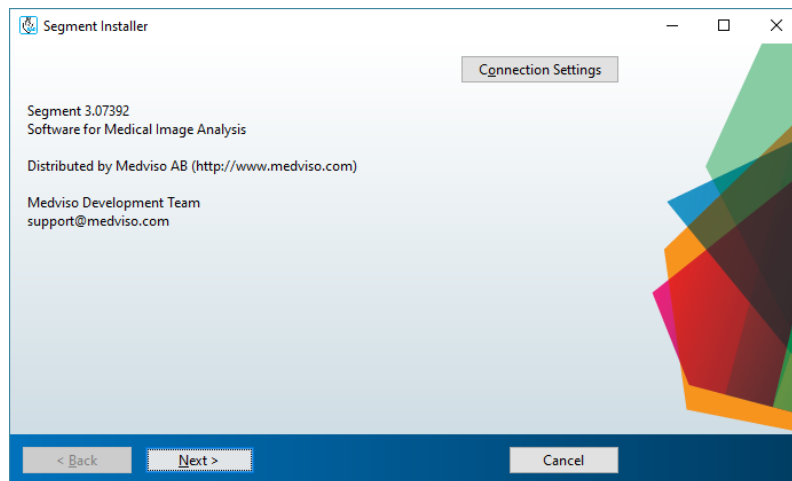


Figure 2: Click on Next.

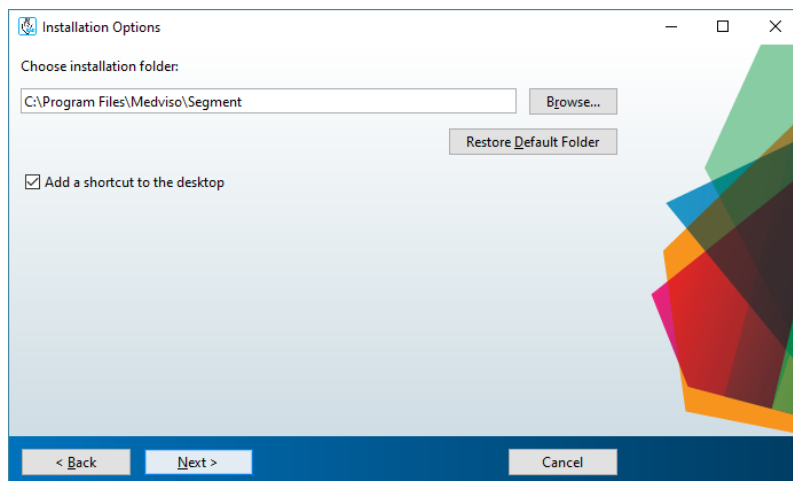


Figure 3: Select Add a shortcut to the desktop. Click on Next.

For first time installation, Matlab Compiler Runtime (MCR) needs to be installed according to Figure 4 - 7. For upgrading, continue according to Figure 8.

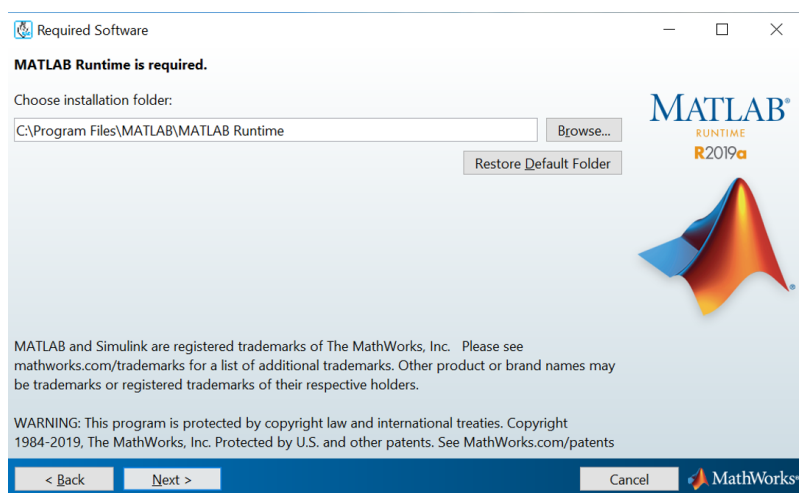


Figure 4: Click on Next.

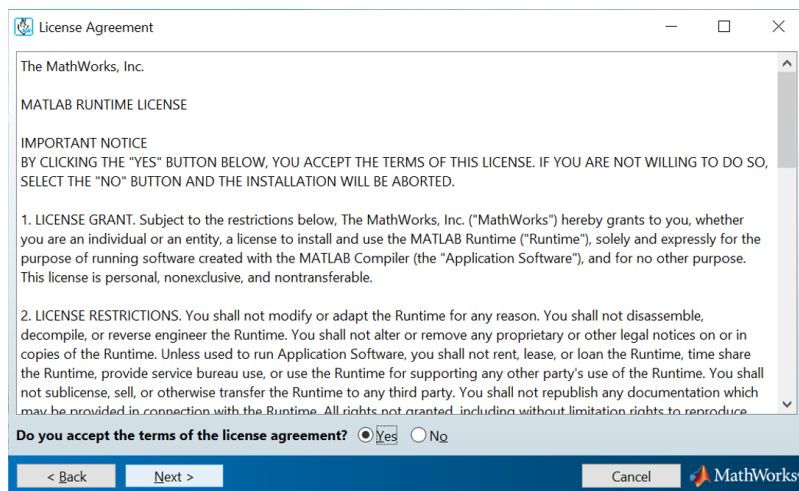


Figure 5: Select Yes. Click on Next.

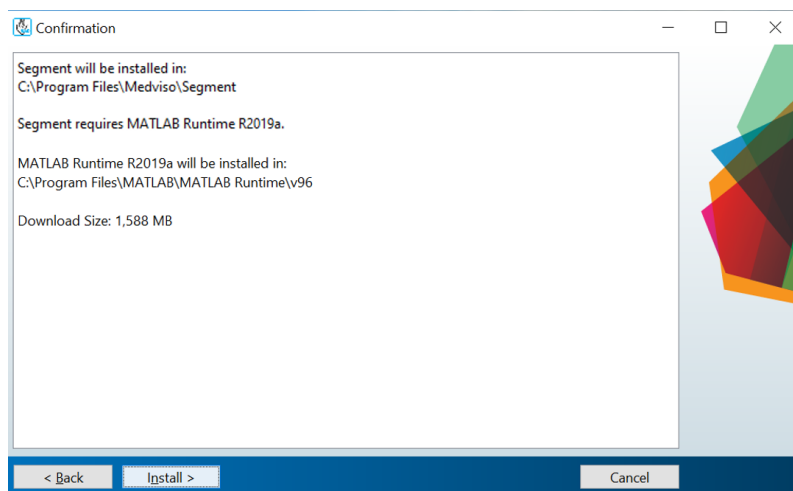


Figure 6: Click on Install.

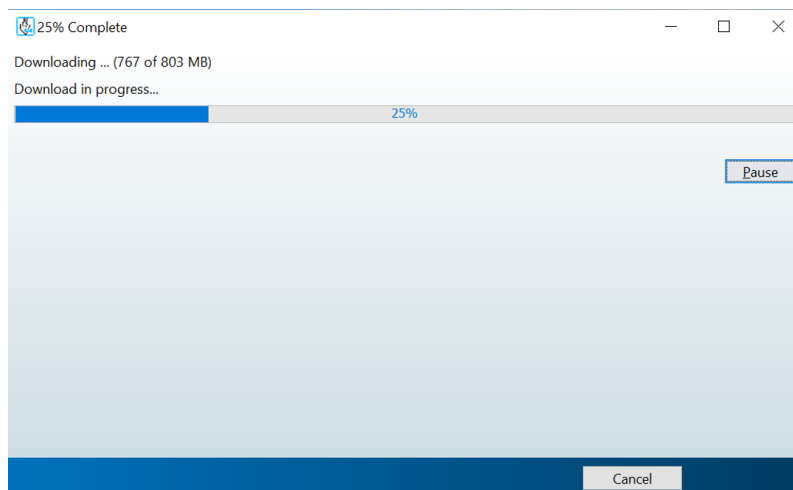


Figure 7: Wait for completed process.

For upgrading, only install Segment according to Figure 8 - 9.

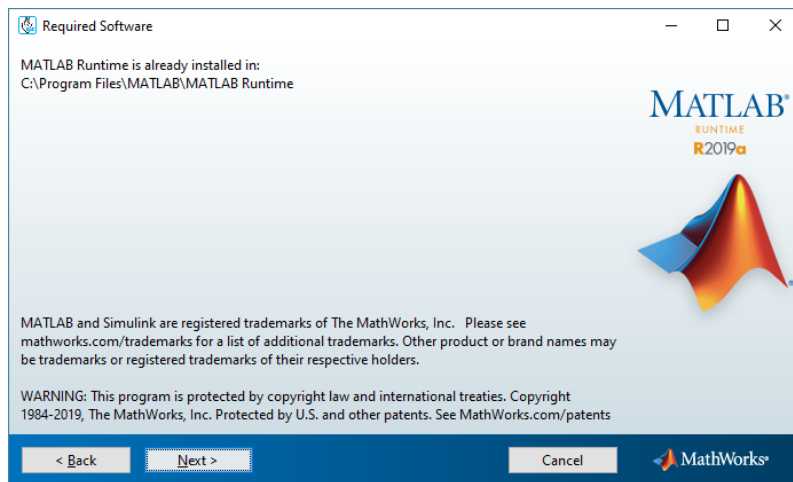


Figure 8: Click on Next.

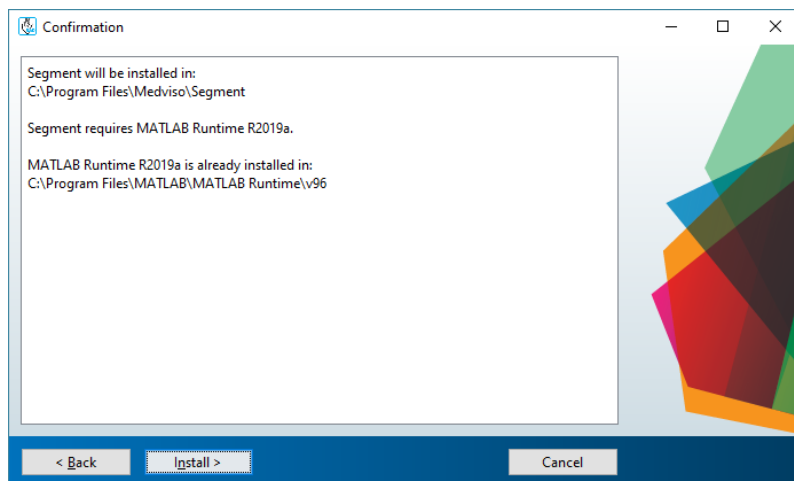


Figure 9: Click on **Install**.

For first time installation or upgrading, continue according to Figures 10 - 11.

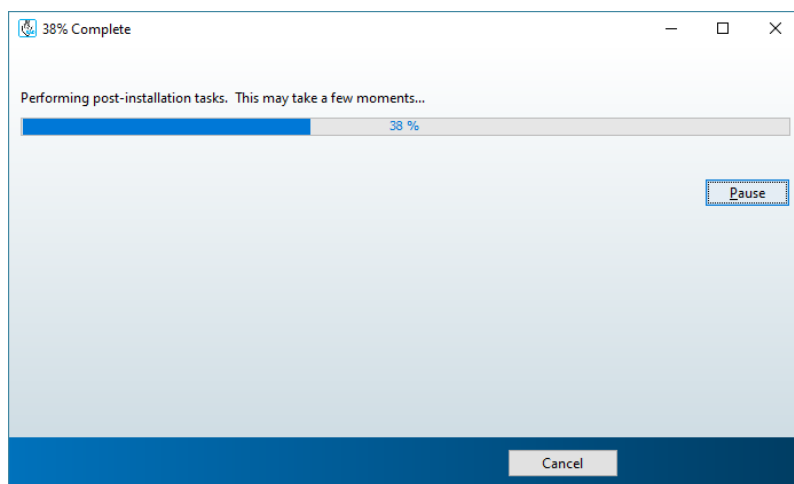


Figure 10: Wait for completed process.

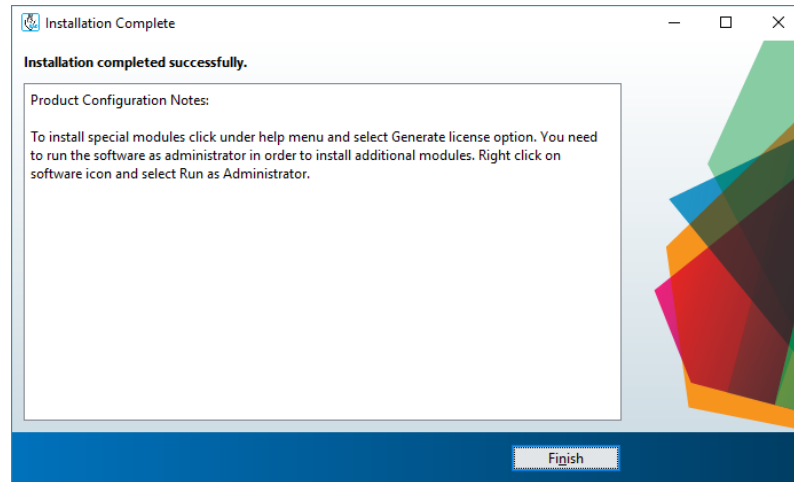


Figure 11: Click on Finish.


4.2 First time running Segment

The first time you run the software to configure it you need to run the software as Administrator. Right click on the shortcut to the software and select Run as administrator. Note that it is not sufficient to be logged in as administrator on the computer.

The first time Segment is started, it runs a setup process which can take a while, so be patient. When starting the software, the image in Figure 12 should be displayed. If it is not displayed, then the software is not correctly installed.

To complete the setup, set preferences and window positions as described in Sections 4.2.1 and 4.2.2.

4.2.1 Setting preferences

It is recommended to set the preferences of which folders to use to avoid browsing each time you want to load or save a file. It is invoked by using the  icon (p). Set Data, Export and CD folders.

4.2.2 Setting window positions

The position of the main window for Segment can be set by dragging the window to an optional position and size. The size and position will be saved so that next time Segment is launched the same position will be used. In case where one have switched to another monitor, Segment may move outside the screen. In this case you could press **Ctrl-0** to reset GUI positions. This is also available under the File menu (a).

4.2.3 PACS connection

This module is an commercial available module, that is not included in the free research version. Please contact Medviso Sales team (sales@medviso.com) for more information and

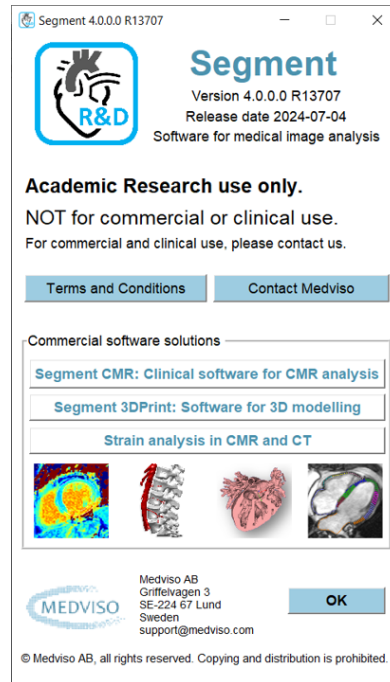


Figure 12: Startup window for Segment.

a quote.

Setting up PACS connection and Segment Server usually requires help from your local PACS support, and we recommend that you contact us to setup a telephone / web-based video conference to make this process as smooth as possible. The Database and PACS connection manual and the Sectra PACS plugin manual is found at Medviso AB homepage (<https://medviso.com/user-manuals>). The Sectra PACS plugin may require additional Microsoft Visual C++ components that can be downloaded from Medviso AB homepage (<https://medviso.com/download2/>).

4.3 Add software license code

This section only applies if you have a commercial purchased license for Segment, for the free research version no license is needed. For new installations you need to add your license code for Segment. Add your license code after installation by starting Segment and select **Setup License** under the **Settings** menu in Segment. Note that you have to run the software as Administrator to be able to add the license code in Segment. If you have lost the license code, please contact sales@medviso.com.

4.4 Uninstallation

To uninstall Segment, go to Control Panel and select **Uninstall a program** (Figure 13). Search for Segment in the programs list, right-click on it and select **Uninstall/Change**. Do the same

steps for uninstalling MATLAB Runtime, but select MATLAB Runtime in the programs list.

User preferences are stored in `AppData`, in the subfolder `Segment` under each user account.

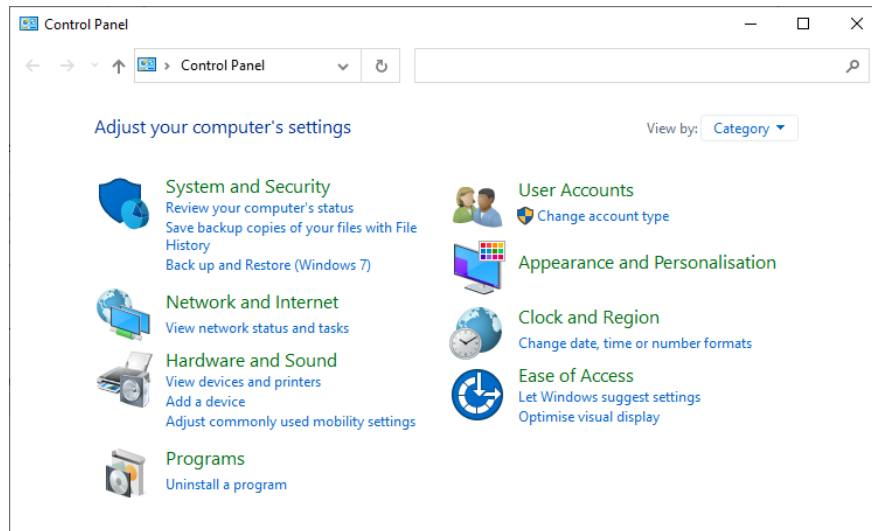


Figure 13: Control Panel

4.5 Software overview

An overview of Segment is given in Figure 14.

To learn more about each tool, hold the mouse over the icon in the software and a help text will be displayed. To exit the software, simply press the x-button in the top right corner.

4.6 Software upgrade

When upgrading to new software version you can just install a new version over the old version. The versions are always backwards compatible and settings are kept. If you have activated services for Segment to work as a DICOM node, then these services need to be stopped during the upgrade process. How to do this is illustrated in Figure 15. The services may also be stopped directly with Windows service manager by typing `services.msc` in the Windows search box.

The services can be restarted after upgrade is complete. The services will also be automatically restarted when the computer is restarted.

4.7 Trouble shooting

To trouble shoot the installation you can see if the Segment installation program actually was successfully started by checking for the existence of `.log` files. Segment cre-

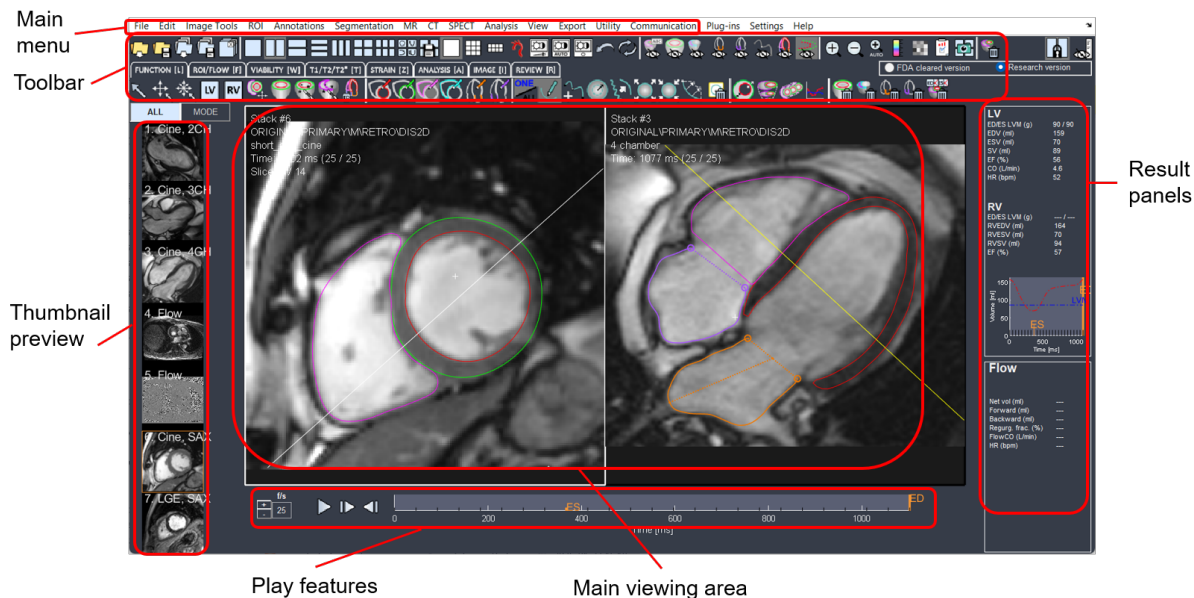


Figure 14: Main graphical user interface.

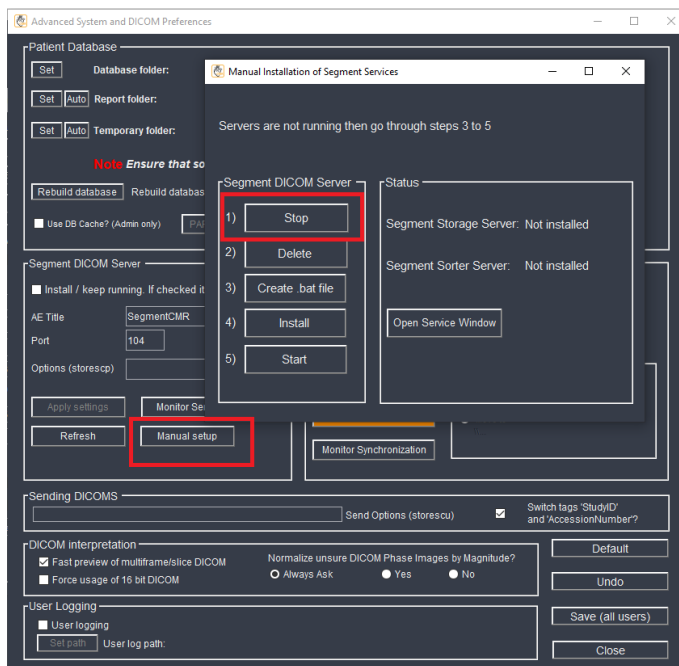


Figure 15: Stop services button in the Manual Installation of Segment Services window.

ates a log file during installation, this file is stored in the user folder (i.e Documents and Settings/Username and Application Data and the subfolder Segment. Note that this folder by default is hidden. If you have problems installing Segment, please send this log-file to support@medviso.com together with a description on what problems where encountered.

In case the software runs then you can access the log-files under the Help menu and Open Folder with Log Files .

4.7.1 Segment fails to install

The most probable cause is not to run the installation software as administrator. Another problem may be that have no Internet connection during installation.

4.7.2 Segment fails to start after installation

If the software fails to start after installation without or with error messages, that means that the installation process was not completed successfully Please refer to the section "Program won't start" in our FAQ (www.medviso.com/faq) for further support.

4.7.3 No compatible GPU configuration detected

Segment fails to find a compatible NVIDIA graphics card. Firstly check that the card is correctly installed and meet the performance. We recommend to download the tool GPU-Z from Techpowerup for this purpose (www.techpowerup.com/download/techpowerup-gpu-z). If you have one card installed that should match the requirements on possible cause may be that your operating system is blocking GPU usage either for compability reasons or power saving reasons.

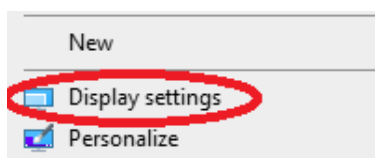


Figure 16: Select display settings by right click on desktop.

4.7.4 Sudden software crash

This is most likely caused by old NVIDIA graphics driver, please see Section 4.7.5. For getting help general crashes please send log-files to support@medviso.com. See details on where to

4.7.5 Update NVIDIA graphics driver to latest version

Please note that although you use Windows update and this process claims all drivers to be updated this is likely not the case for the NVIDIA graphics card driver. To install a new

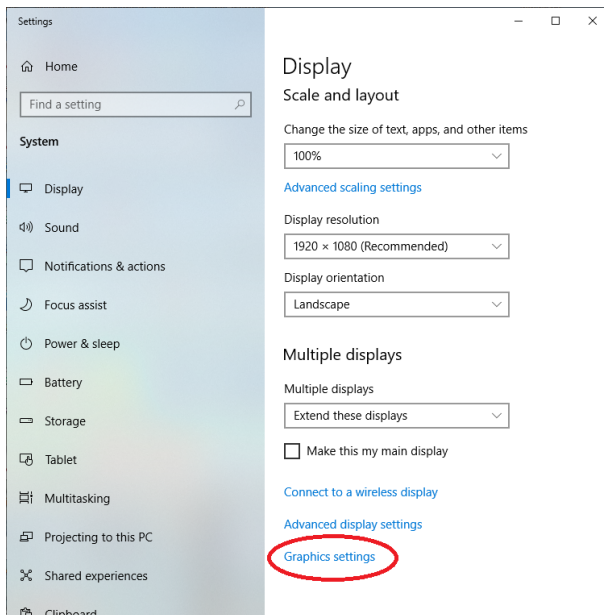


Figure 17: Select Graphics settings.

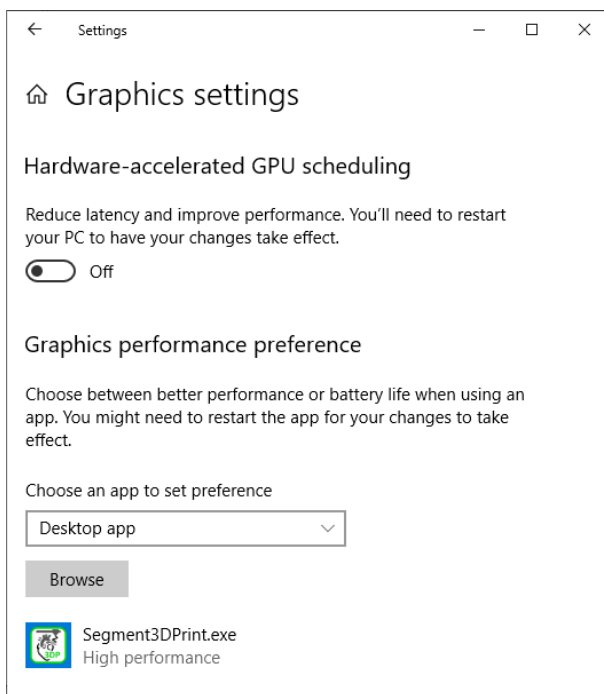


Figure 18: Select Browse, and select folder where Segment is installed. Select application. Select High Performance.

version, go to <http://nvidia.co.uk/Download/index.aspx>. Select your graphics card details and press Search. Follow instructions on how to download and install. See also under

Section 4.7.3 on how to see GPU details and driver version details.