Cardiovascular Suite

Cardiovascular Suite 4.5.1

Benutzerhandbuch und Gebrauchsanweisung

Dokumentnummer: TEC0002EN Rev. 21
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Cardiovascular Suite ist eine Software zur Abschätzung früher Marker des kardiovaskulären Risikos durch Ultraschallbildgebung des Gefäßlängsschnitts. Insbesondere besteht die Software aus zwei Hauptmessmodulen: 1) das FMD-Studio zur Messung der strömungsvermittelten Dilatation (FMD) der Brachialarterie durch Verarbeitung von Folgen von Ultraschallbildern; 2) das Carotid-Studio zur Messung der Intima-Media-Dicke (IMT) und des Durchmessers der Halsschlagader durch Verarbeitung von Ultraschallbildsequenzen, die in Kombination mit einer Druckschätzung Parameter der arteriellen Elastizität liefern. Bei Einzelbildern bietet die Software auch ein Werkzeug zur Messung geometrischer und statistischer Parameter an Teilen des Bildes, die vom Bediener manuell als Plaques erkannt werden. Das System kann in Dateien aufgezeichnete Bilder (oder Bildsequenzen) verarbeiten oder die Videoausgabe eines Ultraschallsystems in Echtzeit verarbeiten.

In Übereinstimmung mit den Anwendungsregeln von Kapitel 1.4 von Anhang IX der europäischen Richtlinie 93/42/EWG und nachfolgenden Änderungen und den Bestimmungen von Kapitel III von Anhang IX der europäischen Richtlinie 93/42/EWG und nachfolgenden Änderungen, Cardiovascular Suite-Software gehört zu den Medizinprodukten der Klasse IIa gemäß Regel 10. Das Produkt entspricht den gesetzlichen Anforderungen der Europäischen Richtlinie 93/42/EWG und nachfolgender Änderungen und Ergänzungen (Europäische Richtlinie 2007/47/EG) für Medizinprodukte. Diese Software darf in keinem Land ohne entsprechende behördliche Freigabe, Lizenz oder Registrierung verwendet werden, wie dies möglicherweise von den Aufsichtsbehörden des Landes verlangt wird.

Die Produktkennzeichnung für die Cardiovascular Suite umfasst das Handbuch und die Gebrauchsanweisung, den Anmeldebildschirm der Software sowie den Produktlizenzschlüssel und die Produktbeipackzettel.

Eine gedruckte Version des Benutzerhandbuchs und der Gebrauchsanweisung kann unter support@quipu.eu angefordert werden.

Adobe Acrobat Reader Ver. 6 oder höher wird empfohlen, um die PDF-Version des Benutzerhandbuchs und der Gebrauchsanweisung korrekt anzuzeigen.

MD CE 0476 Rx Only

QUIPU SRL
via Moruzzi 1, 56124 Pisa - Italy
+39.050.3152612 support@quipu.eu

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1 Hinweise zur Verwendung Sicherheitsinformationen

Bitte lesen Sie alle folgenden Anweisungen, Vorsichtsmaßnahmen und Warnungen vor der Verwendung sorgfältig durch.

Hinweise zur Verwendung

Die Cardiovascular Suite ist ein Softwareprogramm, das ausgebildete medizinische Fachkräfte bei der quantitativen Analyse von vaskulären Ultraschallbildern bei Erwachsenen unterstützen soll, insbesondere bei der Messung des Durchmessers und seiner Veränderungen an der A. brachialis, des Durchmessers und seiner Veränderungen an der Halsschlagader , die Karotis-Intima-Media-Dicke, und für die Carotis-Plaque-Analyse.

Kontraindikationen

Das Cardiovascular Suite-Gerät ist nicht für die Verwendung als Test, der eine direkte Diagnose einer Herz-Kreislauf-Erkrankung ermöglicht, vorgesehen. Es soll den Entscheidungsprozess des Arztes für Diagnose und Behandlung ergänzen, aber nicht ersetzen. Es sollte in Verbindung mit der Kenntnis der Krankengeschichte des Patienten und anderen klinischen Befunden verwendet werden.

Vorsichtsmaßnahmen und Warnhinweise

Nachfolgend finden Sie eine Liste mit Vorsichtsmaßnahmen und Warnhinweisen für die Cardiovascular Suite. Alle folgenden Punkte finden Sie auch in den entsprechenden Abschnitten in diesem Dokument.

Vorsichtsmaßnahmen

- VORSICHT: Der Computer muss ein medizinischer Computer gemäß der Norm EN 60601-1 für elektrische Isolierung und Sicherheit oder ein gewöhnlicher Personal Computer mit CE-Kennzeichnung (89/366/EWG) sein, der über einen medizinischen Trenntransformator, IEC 60601-1 Standard für elektrische Ableitung, an die Stromversorgung angeschlossen ist.
- VORSICHT: Das Betriebssystem des Computers, auf dem die Software verwendet wird, erfordert einen kontrollierten Zugriff mit Benutzername und Passwort. Außerdem wird in der Nutzersitzung des Betriebssystems, auf dem die Software ausgeführt wird, ein Timeout von 15 Minuten empfohlen.
- VORSICHT: Das Betriebssystem, auf dem die Software ausgeführt wird, muss aktualisiert werden.
- VORSICHT: Auf dem Computer, auf dem die Software ausgeführt wird, sollte ein aktualisierter Antiviren-/ Antimalware-Softwareschutz vorhanden sein.
- VORSICHT: Wenn der Computer mit dem Netzwerk verbunden ist, sollte eine Firewall verwendet werden, um Cyberangriffe zu verhindern.
- VORSICHT: Der Quipu License Key enthält Ihre Lizenz. Bewahren Sie es an einem sicheren Ort auf, um Verlust und/oder Diebstahl zu vermeiden.
- Bitte beachten Sie, dass eine Internetverbindung erforderlich ist, um die Evaluierungslizenz zu erhalten und zu verwenden
- VORSICHT: Das B-Mode-Fenster im Bild muss eine Mindestauflösung von 6 Pixel/mm haben. Falls vorhanden, muss die Größe des PWD-Fensters im Bild mindestens 200 x 100 Pixel betragen.
- VORSICHT: Das Ultraschallgerät muss für die Gefäßdarstellung geeignet und mit einer linearen Gefäßsonde mit einer Frequenz größer als 5 MHz ausgestattet sein.
- VORSICHT: Das Ultraschallgerät muss der europäischen Medizinprodukterichtlinie 93/42/EWG entsprechen oder von der zuständigen Aufsichtsbehörde freigegeben / registriert / lizenziert sein.
- VORSICHT: Wenn der Videokonverter mit einem AC/DC-Netzteil verwendet wird, muss es sich um ein medizinisches Netzteil gemäß IEC 60601-1, aktuelle Ausgabe, handeln.
- VORSICHT: Der Videokonverter muss direkt an einen USB-Anschluss Ihres Computers angeschlossen werden. Verwenden Sie keine Hubs oder die USB-Buchse an der externen Tastatur. Verwenden Sie USB 3.0, um die Leistung zu maximieren.
- VORSICHT: Stellen Sie sicher, dass der Videoausgangstyp und die Auflösung des Ultraschallscanners mit diesem Videokonverter kompatibel sind.

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- VORSICHT: Das AV.io HD muss mit der neuesten Firmware von Epiphan System Inc. aktualisiert werden.
- VORSICHT: Der Videokonverter muss direkt an einen USB-Anschluss Ihres Computers angeschlossen werden. Verwenden Sie keine Hubs oder die USB-Buchse an der externen Tastatur. Verwenden Sie USB 3.0, um die Leistung zu maximieren.
- VORSICHT: Schließen Sie alle Rauschunterdrückungsfilter aus (insbesondere zeitliche Filter).
- VORSICHT: Achten Sie darauf, dass sich nur das Ultraschallbild im ROI befindet. Bitte beachten Sie, dass die Verarbeitung durch Anmerkungen oder andere grafische Objekte, die das Bild überlagern, beeinträchtigt werden kann. Achten Sie insbesondere darauf, dass sich der Cursor des Doppler-Abtastvolumens nicht im ROI befindet.
- VORSICHT: Die Verarbeitung kann durch Anmerkungen oder andere grafische Objekte beeinträchtigt werden, die das Bild im Doppler-Fluss-ROI überlagern.
- VORSICHT: Die von Cardiovascular Suite erzeugten Daten werden während der Deinstallation der Software nicht gelöscht. Sie sollten manuell durch Löschen des Archivordners entfernt werden.
- VORSICHT: Die Sicherung des Archivordners wird empfohlen, bevor die Software deinstalliert/installiert wird.

Warnungen

- VORSICHT: Eine fehlgeschlagene / unvollständige / fehlerhafte Installation macht die Nutzung der Software nicht möglich.
- VORSICHT: Es wird empfohlen, regelmäßige Backups des Systems durchzuführen. Der Nichtdurchführung des Backups könnte zu einem dauerhaften Datenverlust führen.
- VORSICHT: Wenn auf dem Computer, auf dem die Software ausgeführt wird, ein Virus/eine Malware entdeckt wird, sollte der Benutzer geeignete Gegenmaßnahmen ergreifen, die das Entfernen unserer Software und deren Neuinstallation umfassen können.
- VORSICHT: Der Quipu -Lizenzschlüssel funktioniert nur auf dem Computer, auf dem er zum ersten Mal verwendet wird.
- VORSICHT: Der Mangel an Kalibrierung kann eine Fehlfunktion der Software erzeugen.
- VORSICHT: Die Verarbeitung kann durch Anmerkungen oder andere grafische Objekte beeinträchtigt werden, die das Bild im Doppler-Fluss-ROI überlagern.

Lebensdauer

Die Produktlebensdauer beträgt 2 Jahre nach dem Datum der Software -Erstellung. In diesem Zeitraum wird Quipu Sicherheitsaktualisierungen bereitstellen.

Beschriftung

Die Produktkennzeichnung für die Cardiovascular Suite umfasst das Handbuch und die Gebrauchsanweisung, den Anmeldebildschirm der Software sowie den Produktlizenzschlüssel und die Produktbeipackzettel.

Nachfolgend finden Sie eine Tabelle aller Kennzeichnungssymbole für die Cardiovascular Suite.

Tabelle der Kennzeichnungssymbole

Symbol	Meaning
℞ Only	Nur auf Rezept: Vorsicht: Das US-Bundesgesetz beschränkt dieses Gerät auf den Verkauf durch oder auf Anweisung eines Arztes oder Heilpraktikers.
MD	Gibt an, dass es sich bei dem Artikel um ein medizinisches Gerät handelt.

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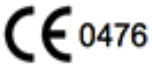
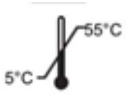
	Herstellerinformationen.
	Herstellungsjahr.
	Vorsicht. Weist darauf hin, dass der Benutzer die Gebrauchsanweisung für wichtige Warnhinweise wie Warnungen und Vorsichtsmaßnahmen konsultieren muss, die aus verschiedenen Gründen nicht auf dem Medizinprodukt selbst dargestellt werden können.
	Gebrauchsanweisung konsultieren.
	CE-Zeichen (Europäische Richtlinie). Das Produkt entspricht den gesetzlichen Anforderungen der Europäischen Richtlinie 93/42/EWG und nachfolgender Änderungen und Ergänzungen (Europäische Richtlinie 2007/47/EG) für Medizinprodukte.
	Nicht unter 5 °C oder über 55 °C lagern.
	Nicht unter 5 % Luftfeuchtigkeit oder über 95 % Luftfeuchtigkeit lagern.

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2 Empfehlungen

VORSICHT: Dieses Handbuch beschreibt die Anweisungen für die ordnungsgemäße Verwendung der Gerätesoftware Cardiovascular Suite. Bitte lesen Sie die Hinweise in diesem Dokument sorgfältig durch.

Die Software darf nur von geschultem und qualifiziertem Personal wie Labortechnikern, Krankenpflegern, Ärzten und/oder Sonographen verwendet werden, die Erfahrung in der Aufnahme und Analyse von vaskulären Ultraschallbildern haben. Es wird empfohlen, dass sich der Benutzer der Bedeutung der gemessenen und als Ergebnis vom Gerät zurückgegebenen Parameter bewusst ist. Es wird empfohlen, dass der Bediener keine ernsthaften Seh- und Hörprobleme hat. Erforderlich sind Kenntnisse der Muttersprache oder, für die Länder, die dies zulassen, der englischen Sprache.

Eine Sehbehinderung aufgrund bestimmter Umgebungsbedingungen, ein sehbehinderter Benutzer, eine nicht optimierte Helligkeit und/oder nicht optimierte Auflösung des Monitors können die korrekte Interpretation der bereitgestellten Ergebnisse beeinträchtigen.

Die vom Gerät durchgeführte Analyse kann bei jeder erwachsenen Person angewendet werden, die sich einer Ultraschalluntersuchung unterziehen kann. Es wird nicht empfohlen, das System zur Analyse von Personen mit einer verzerrten Anatomie des untersuchten arteriellen Segments zu verwenden.

Es wird empfohlen, das Gerät gemäß den internationalen Richtlinien zur Schätzung von Carotis-Biomarkern und brachialer flussvermittelter Dilatation (FMD) zu verwenden.

Die Software wird auf einem Computer installiert und kann in Verbindung mit einem Ultraschallgerät und einem Videokonverter verwendet werden. Für den korrekten Betrieb ist es ratsam, auf Umgebungseinflüsse zu achten, die den Betrieb dieser Geräte verändern können. Darüber hinaus wird empfohlen: i) die notwendigen Maßnahmen zu ergreifen, um Viren und Malware zu verhindern, und ii) eine regelmäßige Datensicherung durchzuführen. Einzelheiten finden Sie in den Anweisungen der einzelnen Hersteller.

Die Software wird über einen USB-Dongle-Schlüssel lizenziert. Verwenden Sie den USB-Dongle in einer Umgebung mit den folgenden Temperatur- und Feuchtigkeitsbedingungen: Betriebstemperatur: +5 ... +55 ° C (+41 ... +131 ° F), Feuchtigkeit: 5 ... 95%. Wir empfehlen, den USB-Dongle Key keinen Lösungsmitteln und brennbaren Medien auszusetzen. Es wird empfohlen, den USB-Dongle vor physischen Beschädigungen zu schützen.

Wenn Sie diese Software verwenden und personenbezogene sensible Daten verwalten, müssen Sie dies gemäß der Allgemeinen Datenschutzverordnung UE 2016/679 tun. Sensible Daten müssen auf eine Weise verarbeitet werden, die eine angemessene Sicherheit personenbezogener Daten gewährleistet, einschließlich des Schutzes vor unbefugter oder unrechtmäßiger Verarbeitung und vor versehentlichem Verlust, Zerstörung oder Beschädigung, unter Verwendung geeigneter technischer oder organisatorischer Maßnahmen.

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3 Installation

Cardiovascular Suite can be installed on Apple computer or on Microsoft Windows computer. Please see the minimum System requirements of the computer for a correct execution of Cardiovascular Suite.

> **CAUTION: The operating system of the machine where the software is used requires controlled access with user name and password. In addition, a time-out of 15 minutes is recommended in the user session of the operating system where the software runs.**

> **CAUTION: The operating system where the software runs must be updated.**

The software installer can be downloaded from the Quipu website www.quipu.eu

Please follow the correct instruction for the installation of the software on Apple computer and on Microsoft Windows computer respectively.

> **CAUTION: Failure / incomplete / incorrect installation makes it not possible to use the software.**

> **CAUTION: It is recommended to perform regular backups of the system. The non-operation of the backup could result in permanent data loss.**

> **CAUTION: if a virus/malware is detected in the computer where the software runs the user should adopt the suitable contro-measures that can include removing our software and re-installing it.**

Once installed, Cardiovascular Suite requires the activation of a License. The license is contained inside a Quipu License Key, which is a USB dongle key. The Quipu License Key must be plugged into the computer where the software is running. Please follow the instruction for Activating a license.

You can ask for a 14-days Evaluation license.

3.1 System requirements

Minimum Requirements

APPLE COMPUTER

- Apple Mac Computer with: Intel Core i5 5th generation 2.3 GHz Turbo Boost; 4GB RAM; 1GB free Hard Disk space*; 1280x800 monitor resolution.
- Mac OS X 10.12 - 10.15

MICROSOFT WINDOWS COMPUTER

- Intel Core i5 5th generation 2.3 GHz Turbo Boost; 4GB RAM; 1GB free Hard Disk space*; 1024x768 monitor resolution.
- OpenGL ES 2.1
- Microsoft Windows 7 64 bit, Windows 8.1 64 bit, Windows 10 64 bit

* 250GB free Hard Disk space is suggested for the Archive

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CAUTION: the computer must be a Medical Grade Computer in compliance with EN 60601-1 standard for electrical isolation and safety or a common CE marked personal computer (89/366/EEC) connected to power supply via Medical Grade Isolation Transformer that meets IEC 60601-1 standard for electrical leakage.

Optional video capture devices for on-line analysis:

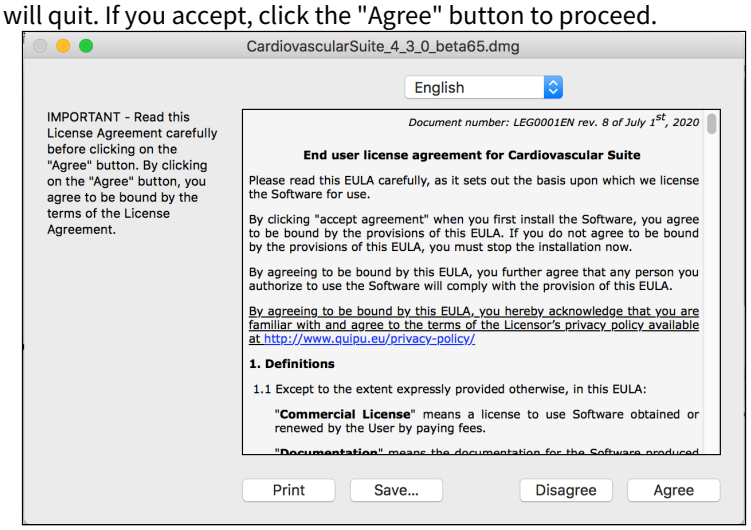
- Epiphan - AV.io HD hardware video capture (to connect your computer to DVI, VGA or HDMI video outputs)
- Magewell USB capture AIO (to connect your computer to DVI, VGA, HDMI, S-video and C-video outputs)

3.2 Apple computer

The software installation follows the usual procedure of installing software on Apple computers.

For information or support please contact Quipu support team at support@quipu.eu.

1. Double click on the Cardiovascular Suite disk image file (*.dmg file), a window with the software license will be shown. Read the License Agreement. If you don't accept the license agreement, please click "Disagree" and the installation will quit. If you accept, click the "Agree" button to proceed.



2. Drag the application's icon to your Applications folder.

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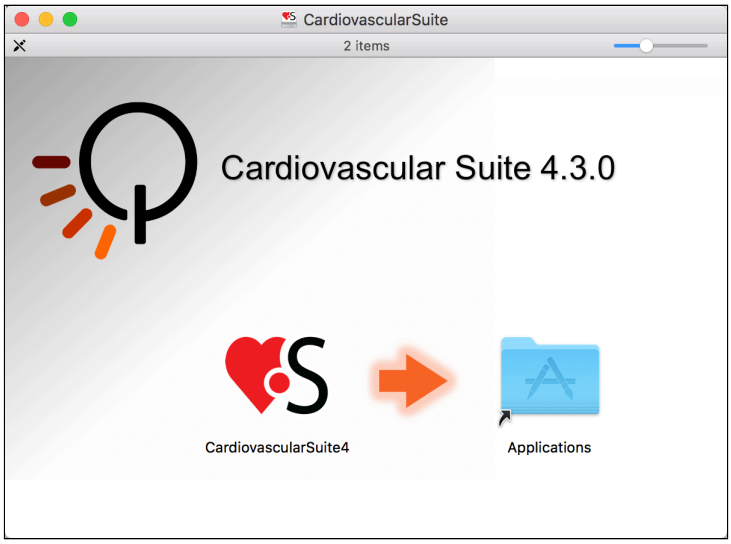
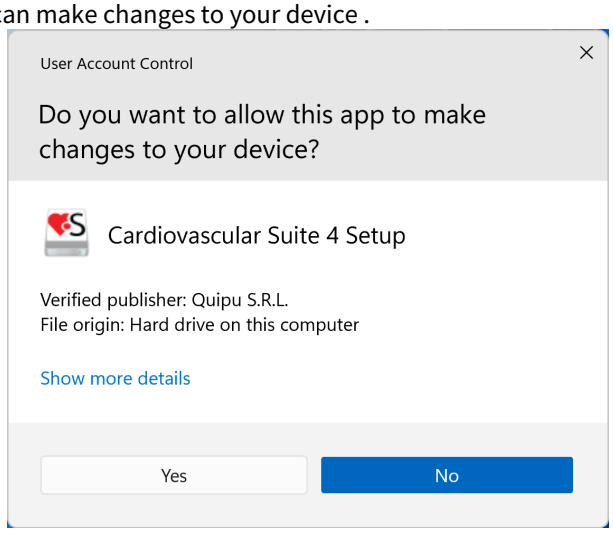


3.3 Microsoft Windows computer

The software installation follows the usual procedure of installing software on Microsoft Windows.

For information or support please contact Quipu support team at support@quipu.eu.

1. Confirm that the installer can make changes to your device .



2. Select the language that will be used during the installation.

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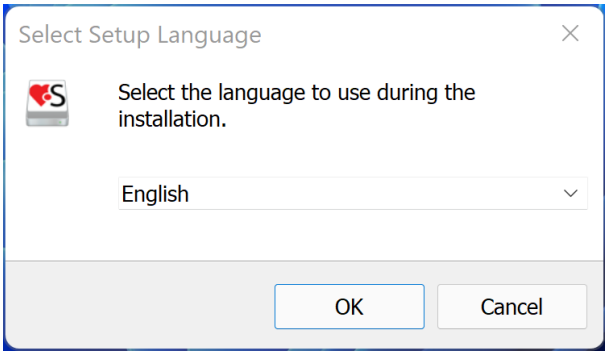
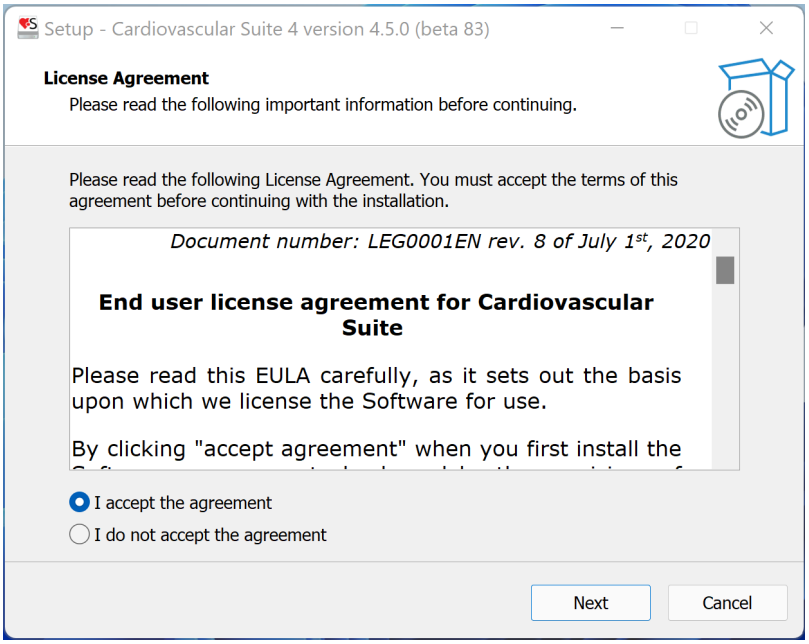


3. Read the License Agreement. If you don't accept the license agreement, please close the Cardiovascular Suite setup. If you accept, click the "Next" button to proceed.



4. Select the installation folder. In most cases, you can use the proposed installation folder. Click the "Next" button to proceed.

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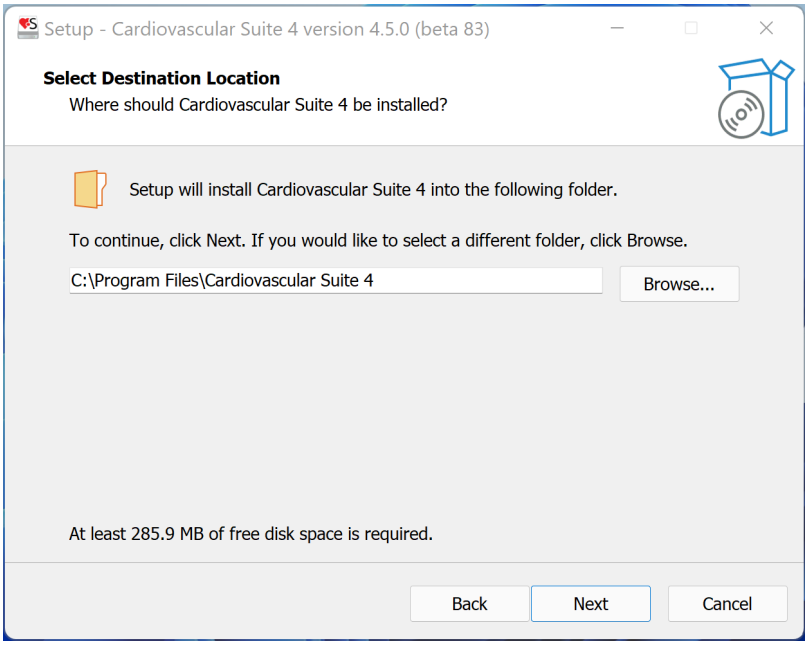
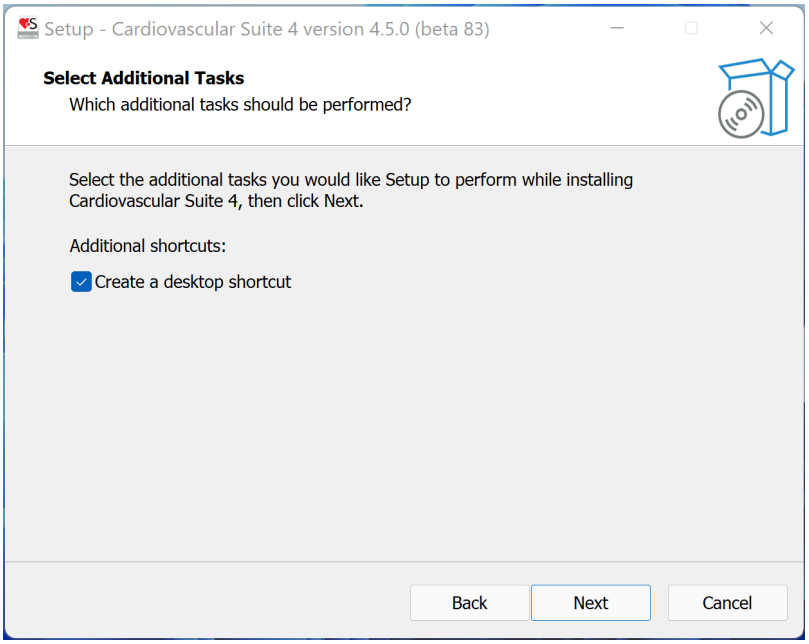


5. Select whether you want to create a Desktop Icon. Click the "Next" button to proceed.



6. Review the installation setting. Click the "Install" button to start installation. Cardiovascular Suite will be installed.

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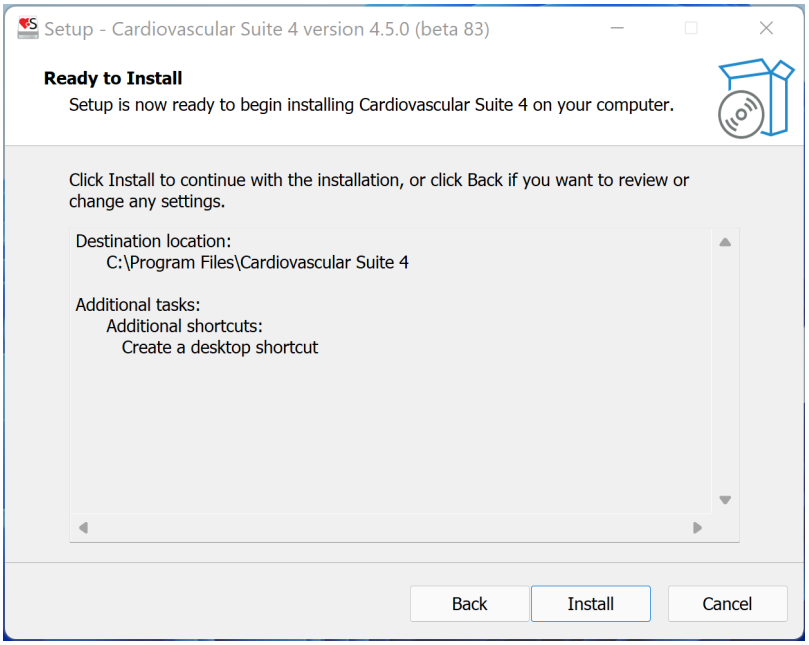
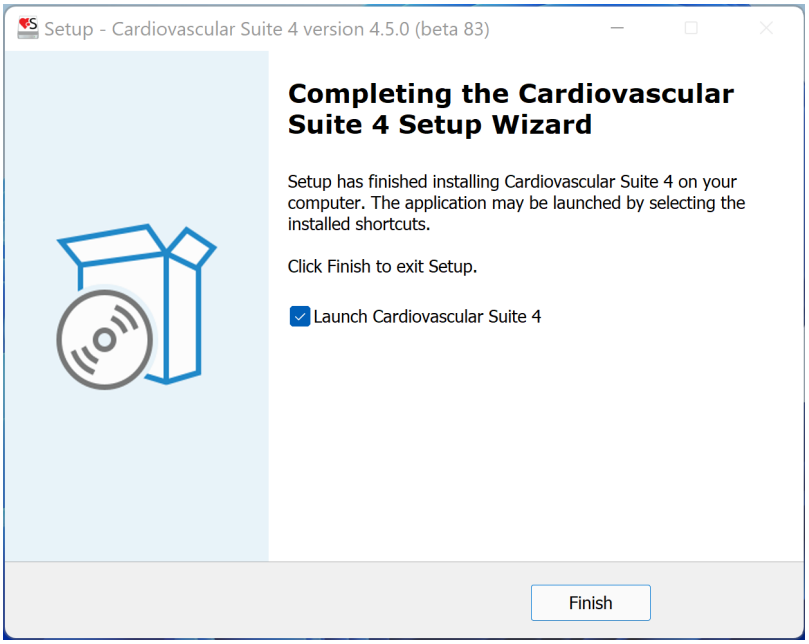


7. When the installation is completed, please click the "Finish" button.



3.4 Archive folder

When Cardiovascular Suite runs the first time, it creates the archive folder, where all the data will be stored. The archive folder is a local folder of the Windows/macOS user. This means that if Cardiovascular Suite is used by different Windows/macOS users on the same computer, each Windows/macOS user will have his/her own archive.

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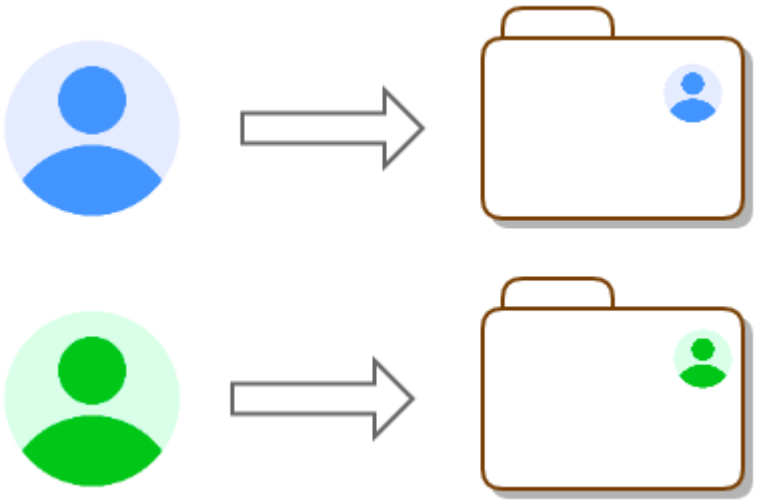

The archive folder is located at the following address:

- Apple Computers: ~/Library/Application Support/CardiovascularSuite4
- Windows Computers: %AppData%\..\Local\cardiovascular_suite4

> **CAUTION: It is recommended to perform regular backups of the system. The non-operation of the backup could result in permanent data loss.**

3.5 Moving to a new computer

The steps necessary to migrate Cardiovascular Suite to a new computer are:

1. Copy the archive folder(s)
2. Install Cardiovascular Suite
3. Migrate the license

3.5.1 Copying the archive folders

Copy the archive folder from the old computer to the new computer. The archive folder must be placed in the local folder of the Windows/macOS user who will use the software. If the old computer was used by more than one Windows/macOS users, you may have more than one archive folder to be copied in the new computer.

The archive folder is located at the following address:

- Apple Computers: ~/Library/Application Support/CardiovascularSuite4
- Windows Computers: %AppData%\..\Local\cardiovascular_suite4

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3.5.2 Installing Cardiovascular Suite

Install Cardiovascular Suite on the new computer. The last version of the software installer can be downloaded from the following links:

- Windows Computers: http://www.quipu.eu/download/CardiovascularSuiteWin.php
- Apple Computers: http://www.quipu.eu/download/CardiovascularSuiteMac.php

For previous versions of the software, please contact our support team at: support@quipu.eu

3.5.3 Migrating the license

If you have a Quipu License Key, plug it in the new computer. The license may not work because still locked to the old computer. In that case, an error message will be displayed when you run Cardiovascular Suite. Please contact the Quipu support team (support@quipu.eu) for migrating your license to the new computer.

3.6 Extraordinary maintenance

There are no updates of parts of the software. In case of correction of "bugs", the user is alerted via e-mail and the software can be re-installed in the usual manner described in the Installation instructions.

The last version of the software installer can be downloaded from the following links:

- Windows Computers: http://www.quipu.eu/download/CardiovascularSuiteWin.php
- Apple Computers: http://www.quipu.eu/download/CardiovascularSuiteMac.php

For previous versions of the software, please contact our support team at: support@quipu.eu

The archive of the software is not deleted when uninstalling/installing the software. The backup of the archive folder is recommended before uninstalling/installing the software. If you want to delete all the data previously created with Cardiovascular Suite, you must delete the archive folder.

The archive folder is located at the following address:

- Apple Computers: ~/Library/Application Support/CardiovascularSuite4
- Windows Computers: %AppData%\..\Local\cardiovascular_suite4

> ⚠ **CAUTION: the backup of the archive folder is recommended before uninstalling/installing the software.**

3.7 Decommissioning and disposal

The user can safely decommission and dispose the Cardiovascular Suite and the license key.

In particular, the software can be uninstalled following the usual procedure of uninstalling software on Apple computers or Windows computer. The uninstalling procedure does not delete the archive of the software. These data should be removed manually by deleting the archive folder that is located at the following address:

- Apple Computers: ~/Library/Application Support/CardiovascularSuite4
- Windows Computers: %AppData%\..\Local\cardiovascular_suite4

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The license key can be disposed according to the local regulation regarding the waste management.

> ⚠ **CAUTION: the data produced by Cardiovascular Suite are not deleted during the software uninstall procedure. They should be removed manually by deleting the archive folder.**

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4 License

Cardiovascular Suite is licensed under the EULA.

The two software modules (FMD Studio and Carotid Studio) are always present in Cardiovascular Suite, but each of them may be accessible or not by the user according to your software license.

You can choose between two types of license:

- **Perpetual License:** it is a license that never expires. With the Perpetual License you are entitled to run all the minor updates of the application. For example, if you have a perpetual license for FMD Studio ver. 4, you will be entitled to run FMD Studio ver. 4.0, 4.1, 4.2 and so on, but you will not be entitled to run FMD Studio ver. 5.0
- **Time License:** it is a time limited license. With this license, you are entitled to run any version of the application within the expiry day. After the expiry date, it is no longer possible to run the application or modify the stored data.

Cardiovascular Suite is licensed by the Quipu License Key, which is a USB dongle key.

Quipu License Key

When you receive the Quipu License Key, it will contain a not activated license. Please follow the instruction for Activating a license.

Once activated, your license will be stored inside your Quipu License Key.

> ⚠ **CAUTION : The Quipu License Key contains your license. Store it in a safe place in order to avoid loss and / or theft.**

The Quipu License Key must be plugged into the computer where the software is running. If you unplug the Quipu License Key while Cardiovascular Suite is running, the software will stop working.

You license will work only on the computer where the Quipu License Key is used for the first time (i.e. it will be locked to this computer). If you want to replace your computer, please contact the Quipu support team (support@quipu.eu) for instructions on how to move your license to the new computer. You are allowed to move your license in a new computer three times in a year.

> ⚠ **CAUTION : The Quipu License Key will work only on the computer where it is used for the first time.**

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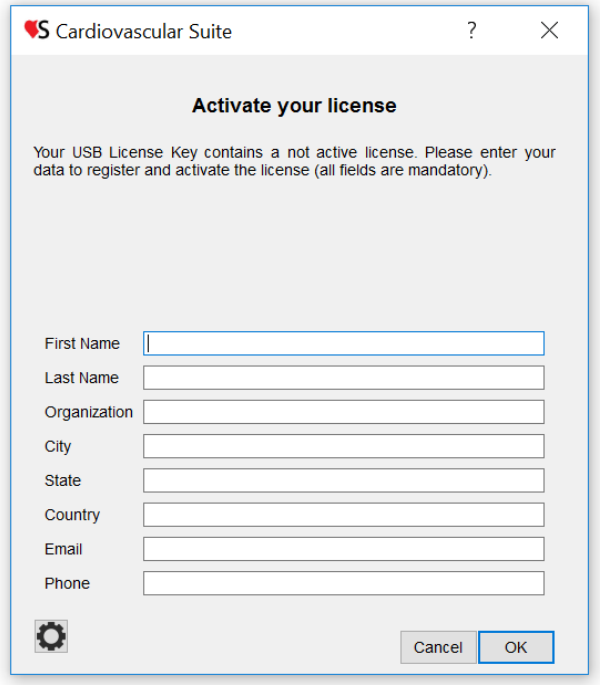
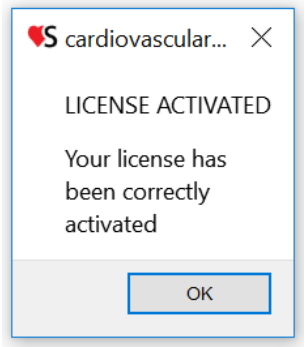
4.1 Activating a license

Plug the Quipu License Key into your computer and run Cardiovascular Suite.

The following form is shown. Please enter your data to register and activate the license (all fields are mandatory). Then, click on the OK button.



After a few seconds, a confirmation message will appear. CLick on the OK button and Cardiovascular Suite will start automatically.



If activation failed, proceed with offline activation by clicking the Offline button.

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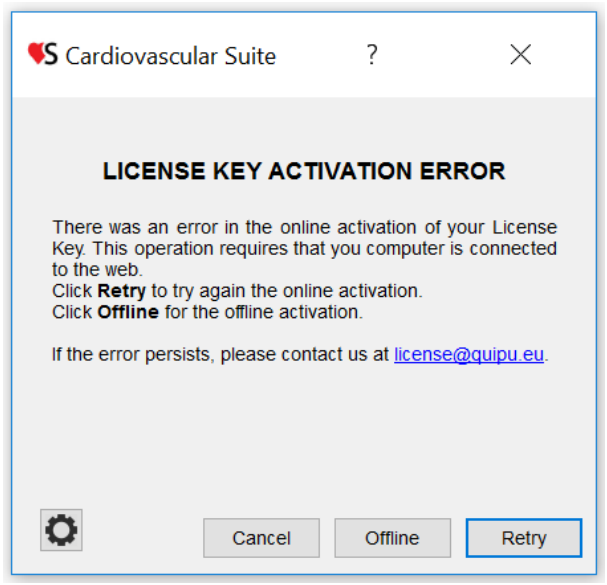
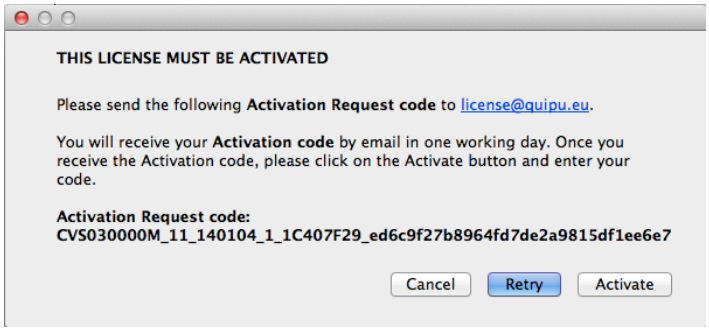


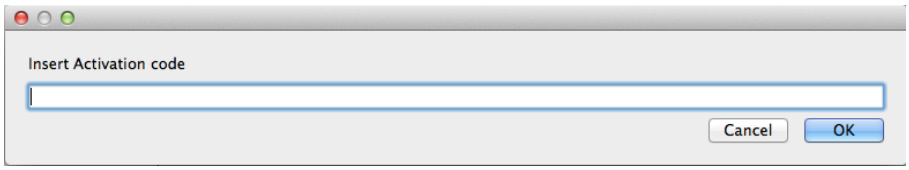
The following message will be shown:



Click on the license@quipu.eu; if you have a mail application on your computer, it will generate a pre-compiled email with your data (Name, Organization, City, Country) and the **Activation request code** that is displayed on the message. Otherwise, please send an email to license@quipu.eu containing your data (Name, Organization, City, Country) and the **Activation request code** that is displayed on the message.

Within a working day, you will receive an email with the **Activation Code**.

You can now click on the Activate button. The following message is shown:



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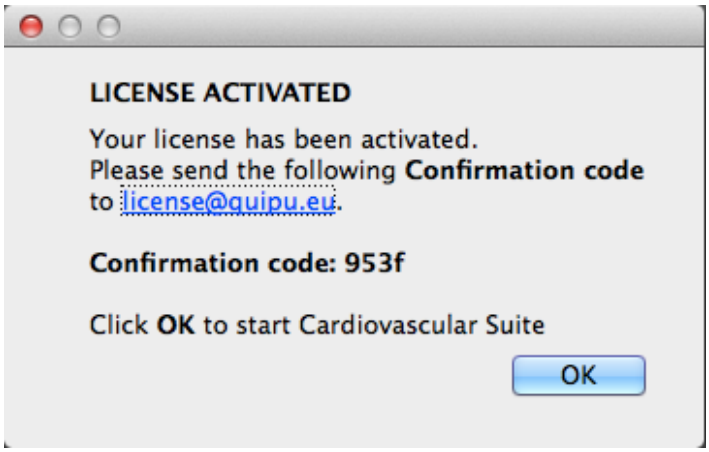
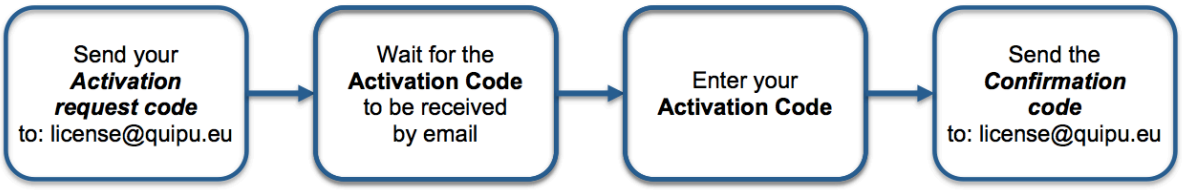
Enter your Activation code and click OK. A confirmation message is shown.



Please send the Confirmation Code to Quipu by email, then click OK to start Cardiovascular Suite.



4.2 Evaluation license

You can evaluate Cardiovascular Suite by a 14 days evaluation license.

With this license, you are entitled to use Cardiovascular Suite **only for EVALUATION PURPOSES**. If you wish to use the software for any other purpose, you must purchase a commercial license. If you do not purchase a commercial license, at the end of the 14 days your content will no longer be available to you.

You cannot use/publish/distribute data generated by the Cardiovascular Suite in the evaluation period unless you purchase a commercial license.

⚠ **Please, note that an Internet connection is needed to obtain and use the Evaluation License.**

⚠ **If you already have a Quipu License Key plugged in your computer, please remove it.**

After downloading and installing the software, run Cardiovascular Suite. The following message is displayed:

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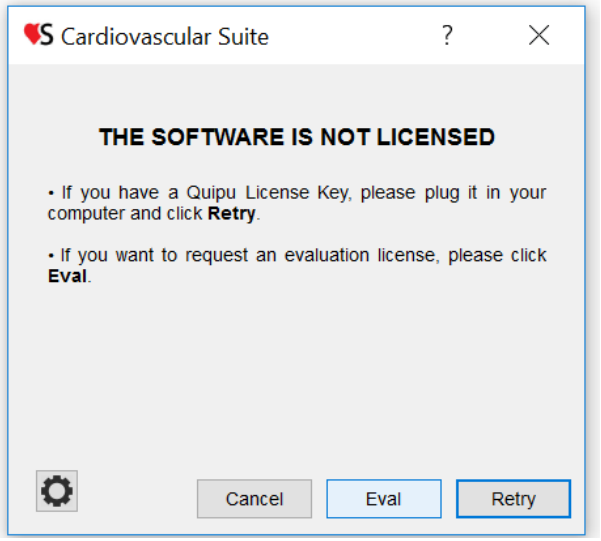
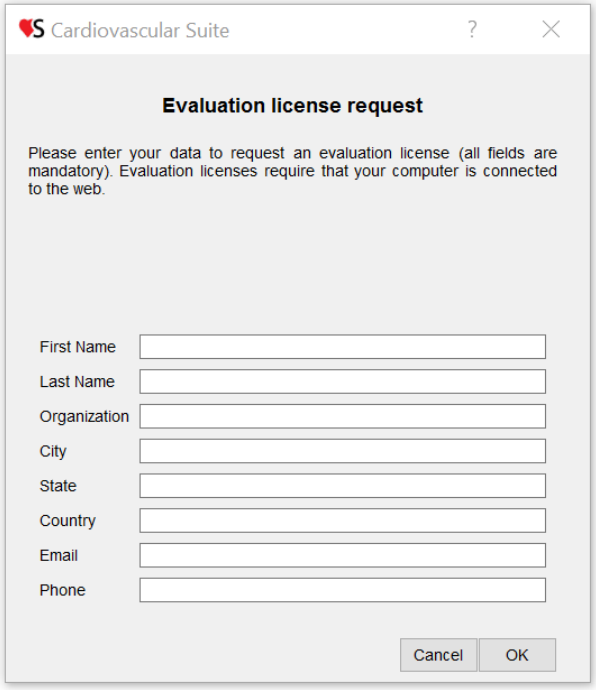


Click on the Eval button to request a fully functional 14-days Evaluation License. The following form is shown:



Please, enter your data to request an Evaluation License (all fields are mandatory). Then, click on the OK button. Please wait and after a few second the following confirmation message will be shown:

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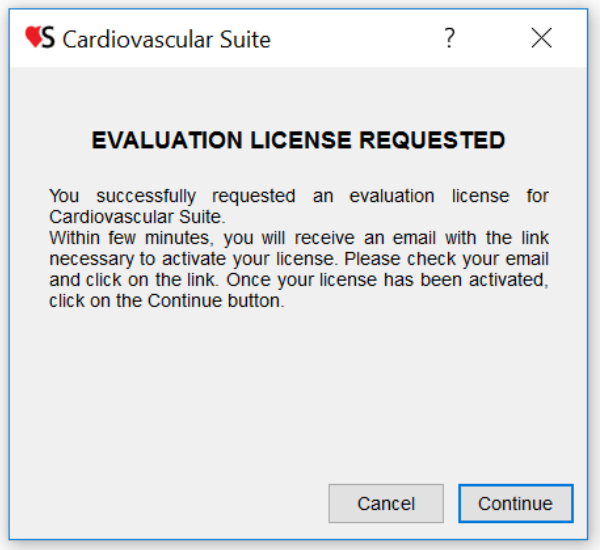
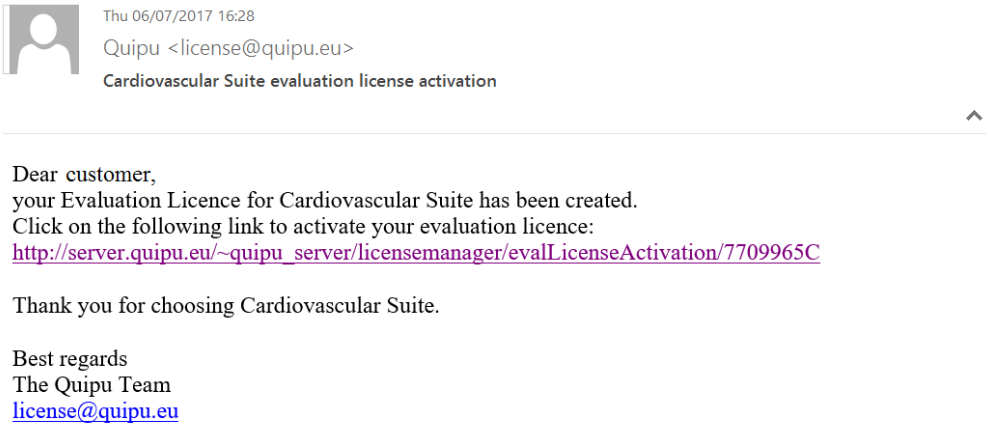
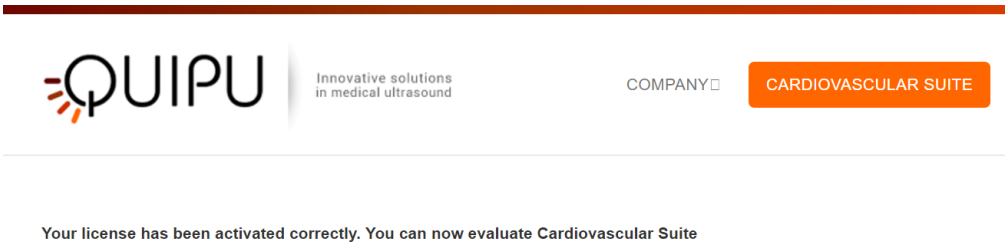


Within few minutes, you will receive an email with the **Activation link**.



Click on the **Activation link**. Your web browser will open the following web page and your license will be activated:



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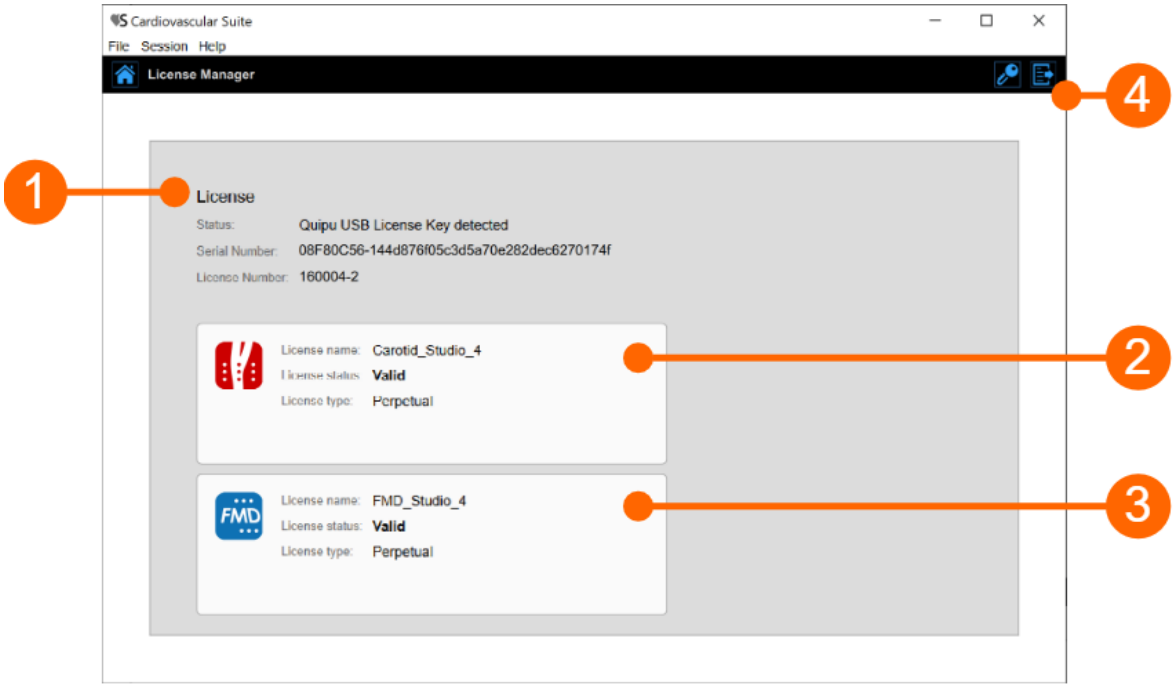
If you still have Cardiovascular Suite open with the "Evaluation License Requested" message, please click on the Continue button. Otherwise run again Cardiovascular Suite. Now, the software starts and the Login window is displayed.

If the Evaluation License Request failed or errors occurred, please contact our technical support by mail or Skype message (support@quipu.eu)

4.3 License manager

The license managers shows the status of your license and can be used to make updates to the license.



The section **(1)** shows some "general" license data:

Status: shows whether a USB License Key or a temporary License Key has been detected.

Serial Number: shows the serial number of Cardiovascular Suite.

License Number: shows the number of your License Key.

In the white frames **(2)** and **(3)** the data of the applications licenses are shown. Here you can see if your license is Valid or Not Valid, if it is Perpetual, Time or Evaluation and the expiry date (for time and evaluation only).

The buttons **(4)** can be used to enter the code that updates your license (Update Code) and to save your license data in a file that can be read by the Quipu support team. For more information, please contact support@quipu.eu

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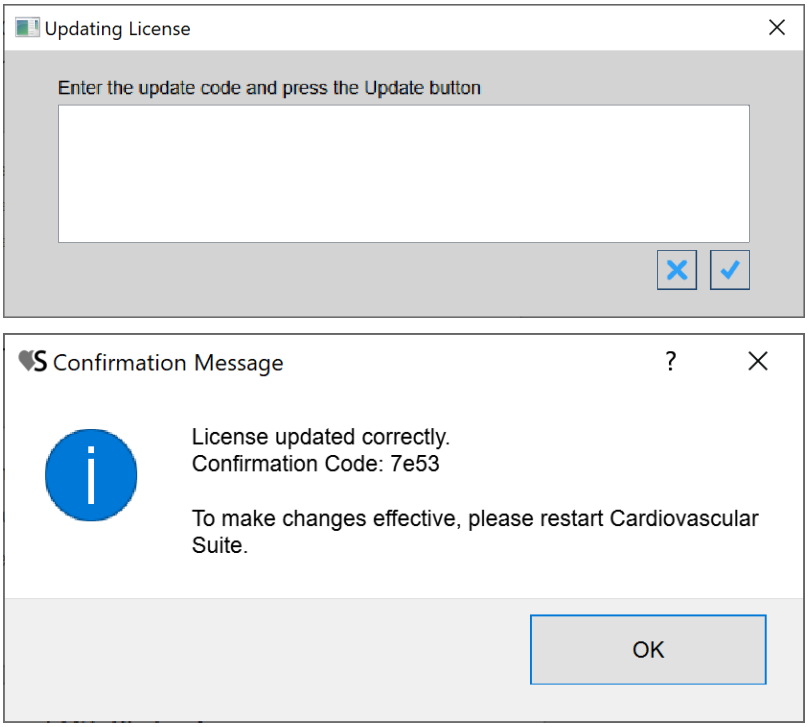

Update a license

- Click on the Update License button.
- Enter the Update Code provided by Quipu.
- Confirm with the Update button.
- A confirmation message will show the Confirmation Code. You must restart Cardiovascular Suite to make changes effective.

Export license data

Click on the Export License Data button to export the data of your license in a file that can be read by the Quipu support team. This can be useful when you encounter a problem with your license and you need support.

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5 Image and video sources

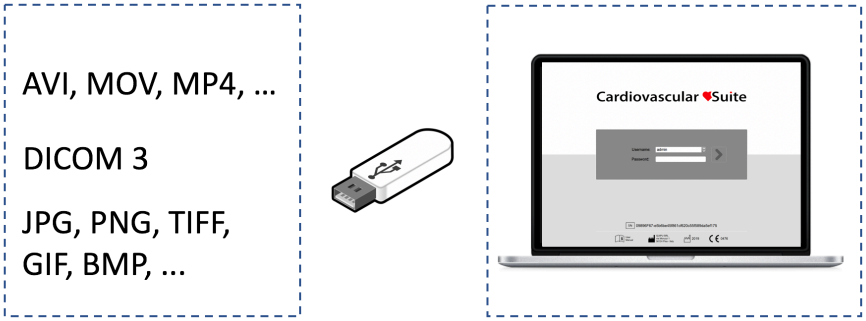
The software processes video images coming from a medical ultrasound equipment. It can work:

- **offline** by processing video clips or single images previously recorded on the ultrasound imaging device. See Using image or video clip for offline analysis.
- in **real-time** by processing the video output of the ultrasound imaging system. See Connecting your computer to the ultrasound system.

5.1 Using image or video clip for offline analysis

Video clips or single images recorded on the ultrasound imaging device can be moved on the computer using a digital medium (flash pen drive, hard disk, CD ROM). Video files can be in DICOM 3 or in all the most common video formats (AVI, MOV, MP4, ..). The images can be in all the most common image formats (JPG, PNG, TIFF, GIF, BMP, ..).

For more information on supported video formats, please contact support@quipu.eu



CAUTION: The B-mode window in the image must have a minimal resolution of 6 pixels/mm. If present, the size of the PWD window in the image must be at least 200x100 pixels.

5.2 Video and image player

The video and the images are displayed in a player like in the following figure.

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At the bottom of the video and image player, a control bar is present. The control bar contains different controls if the source is online or offline, and if a video or an image is played.

Control bar - online

The control bar contains the elapsed time and the Setting button.

Control bar - offline video

The control bar contains controls to manage the playback of a movie (Stop , Play /Pause , Step backward and Step forward buttons), the current and total time, and the Setting button.

Control bar - offline image

The control bar contains the Setting button.

5.2.1 Video and image settings

Click on the Setting button on the right of the video control bar. The Zoom controls and the Brightness and Contrast sliders will be shown.

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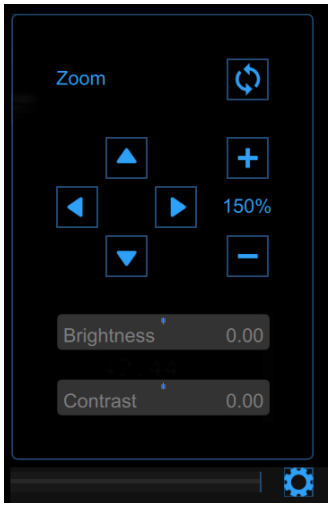


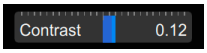
Click the Zoom in + / Zoom out − buttons to zoom in and out the image.

Click the Move up ▲ / Move down ▼ / Move Left ◀ / Move right ▶ button to move up / down / left / right the zoomed image.

Click the Reset zoom button ↻ to reset the image zoom.

Drag the brightness slider 

to adjust the brightness of the image.

Drag the contrast slider 

to adjust the contrast of the image.

5.3 Connecting your computer to the ultrasound system

You need a video capture device to connect the computer with the ultrasound system and perform real-time analysis. Quipu recommends two USB devices: the Epiphan AV.io HD or the Magewell USB Capture AIO.

If your ultrasound machine has a VGA/DVI/HDMI output (see next figure for reference), you can directly connect your ultrasound machine to the computer by using either the Epiphan AV.io HD or the Magewell USB Capture AIO video capture device. (See more...)

VGA

DVI

HDMI

If your ultrasound machine has a "legacy" video standard (S-Video or C-Video) output (see next figure for reference), you can directly connect your ultrasound machine to the computer by using the Magewell USB Capture AIO. If you want to use the Epiphan AV.io HD, you must first convert the video output to VGA, and then to acquire the VGA by the Epiphan AV.io HD. For the first video conversion, you can use any high-quality S-Video to VGA or C-Video to VGA converter. We suggest using the StarTech Video to VGA Converter v4.3 (See more ..)

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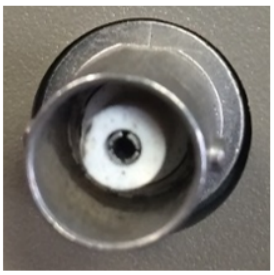
S-Video

C-Video (RCA)



C-Video (BNC)

	Epiphan AV.io HD	Magewell USB Capture AIO
VGA	Directly supported	Directly supported
DVI	Directly supported	Directly supported
HDMI	Directly supported	Directly supported
S-Video	Conversion to VGA is required	Directly supported
C-Video	Conversion to VGA is required	Directly supported

NOTE: Please, verify with the ultrasound machine technician that the video output of your ultrasound machine is active.

For information on the availability and the standard of the video output, please contact the manufacturer of the ultrasound system.

For additional technical information on how to connect the computer to the ultrasound apparatus and on the compatible video standards, please contact us at support@quipu.eu

CAUTION: The B-mode window in the video must have a minimal resolution of 6 pixels/mm. If present, the size of the PWD window in the image must be at least 200x100 pixels.

CAUTION: The ultrasound scanner must be in accordance with the European Medical Device Directive 93/42/EEC or cleared / registered / licensed by the appropriate regulatory authority.

CAUTION: If the video converter is used with an AC/DC power adapter, it must be a medical grade power adapter according to IEC 60601-1, current edition.

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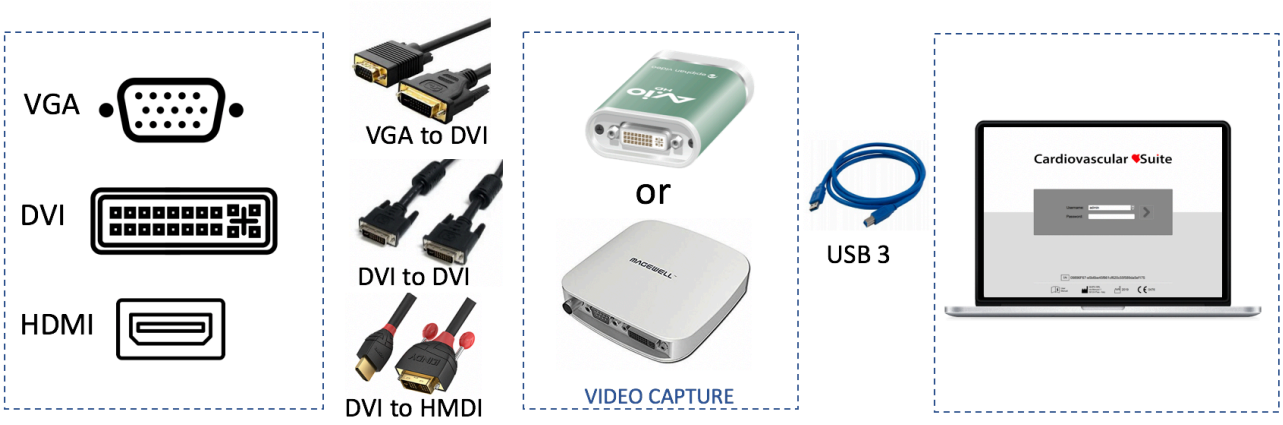
5.3.1 Using VGA/DVI/HDMI output

You can directly connect your ultrasound machine to the computer by using either the Epiphan AV.io HD or the Magewell USB Capture AIO video capture device.



Detail of the connections based on the output video format:

- **VGA video output**: use a VGA-to-DVI cable to connect your ultrasound machine to the Epiphan AV.io HD or the Magewell USB Capture AIO; then use the USB 3.0 cable to connect the video capture device to your computer.
- **DVI video output**: use a DVI cable to connect your machine to the Epiphan AV.io HD or the Magewell USB Capture AIO; then use the USB 3.0 cable for connecting the video capture device to your computer.
- **HDMI video output**: use an HDMI to DVI cable to connect your ultrasound machine to the Epiphan AV.io HD or the Magewell USB Capture AIO; then use the USB 3.0 cable to connect the video capture device to your computer.

See more about the Epiphan AV.io HD or the Magewell USB Capture AIO.

5.3.2 Using "legacy" video standard output

5.3.2.1 **Magewell USB Capture AIO**

You can directly connect your ultrasound machine to the computer by using the Magewell USB Capture AIO video capture device.

Detail of the connections based on the output video format:

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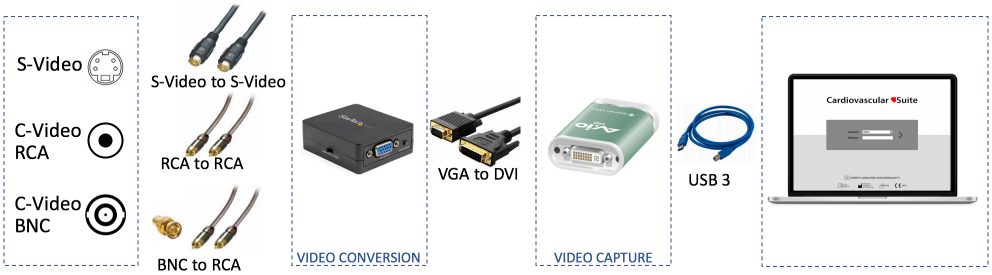
- **S-Video output**: use an S-Video cable to connect your ultrasound machine to the Magewell USB Capture AIO.
- **C-Video (RCA) output**: use an RCA cable to connect your ultrasound machine to the Magewell USB Capture AIO.
- **C-Video (BNC) output**: use a BNC-to-RCA adapter and then an RCA cable to connect your ultrasound machine to the Magewell USB Capture AIO.

Use the USB 3.0 cable to connect the video capture device to your computer. See more about Magewell USB Capture AIO.

5.3.2.2 **Epiphan Av.io HD**

You must first convert the video output to VGA by the StarTech Video to VGA Converter, and then to acquire the VGA by the Epiphan AV.io HD.



Detail of the connections based on the output video format:

1. First, connect your apparatus video output to the StarTech Video to VGA Converter.
    - **S-Video output**: use an S-Video cable to connect your ultrasound machine to the StarTech Video to VGA Converter.
    - **C-Video (RCA) output**: use an RCA cable to connect your ultrasound machine to the StarTech Video to VGA Converter.
    - **C-Video (BNC) output**: use a BNC-to-RCA adapter and then an RCA cable to connect your ultrasound machine to the StarTech Video to VGA Converter.
2. Once you have connected your apparatus to the StarTech Video to VGA Converter, you have to connect it to your computer by the Epiphan AV.io HD. You have to use the DVI-to-VGA cable to connect the Video Converter to the Epiphan AV.io HD. Then, use the USB 3.0 cable to connect the video capture device to your computer.

See more about the Epiphan AV.io HD.

See more about the About StarTech Video to VGA Converter.

5.3.3 About Magewell USB Capture AIO

The USB Capture AIO is a USB2.0/USB3.0 video capture device from Nanjing Magewell Electronics Co., Ltd, China.

The device can be used to connect your computer to DVI, VGA, HDMI, S-Video and Composite video outputs coming from the ultrasound system. See Connecting your computer to the ultrasound system for more details.

There's no software to install to use USB Capture AIO; simply connect the cables and go. It works on Microsoft Windows computers and Apple Mac OS X computers.

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Once you have connected your ultrasound apparatus to the USB Capture AIO, connect your computer to the video converter via the USB cable. The red LED (PWR) shows that the device is powered on. The green LED (ACT) shows the status of the device.

GREEN LED (ACT)	STATUS
Pulsing slowly	Idle
ON	Input signal connected
OFF	Input signal unconnected
Double blinks	Memory failed or FPGA configuration failed

The USB Capture AIO supports resolution up to 2048x2160. Performance may be limited by your computer features.

The Magewell USB Capture AIO supports both USB 3.0 and USB 2.0.

CAUTION: the video converter must be connected directly to a USB port on your computer. Do not use hubs or the USB socket on the external keyboard. Use USB 3.0 to maximize performances.

CAUTION: verify that the video output type and resolution of the ultrasound scanner are compatible with this video converter.

5.3.4 About Epiphan AV.io HD

The AV.io HD is a USB2.0/USB3.0 video capture device from Epiphan Systems Inc. Canada.

The device can be used to connect your computer to DVI, VGA or HDMI video outputs coming from the ultrasound system (or coming from a Video Converter if you use "legacy" standard video output). See Connecting your computer to the ultrasound system for more details.

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There's no software to install to use the AV.io HD; simply connect the cables and go. It works on Microsoft Windows computers and Apple Mac OS X computers.

1. Once you have connected your ultrasound apparatus to the AV.io HD, connect your computer to the video converter via the USB cable. The lighting of the **red** LED indicates that the device initializing.
2. After a few seconds, the LED turns **blue or green** to indicate proper connection between computers and video converter.
3. Connect the video converter to the ultrasound device via the VGA, DVI or HDMI cable.
4. The LED will be **blue or green** until you start capturing a video signal.
5. LED will be **blinking green** or **blinking blue** during the acquisition of a video signal.

LED COLOR	STATUS
OFF	Video converter not connected to the computer
Solid red	AV.io HD initializing
Blinking red	Adjustment to VGA input in progress
Solid green or blue	USB connection active
Blinking green or blue	Video and/or audio transferring successfully

The Epiphan AV.io HD supports resolution from 640x360 up to 1920x1200. Performance may be limited by your computer features.

The Epiphan AV.io HD supports both USB 3.0 and USB 2.0.

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CAUTION: the video converter must be connected directly to a USB port on your computer. Do not use hubs or the USB socket on the external keyboard. Use USB 3.0 to maximize performances.

CAUTION: the AV.io HD must be updated with the last firmware from Epiphan System Inc.

CAUTION: verify that the video output type and resolution of the ultrasound scanner are compatible with this video converter.

5.3.5 About StarTech Video to VGA Converter

The Video to VGA Converter from StarTech (Canada) will allow you to convert your S-Video or Composite Video output to a VGA.

	COMPONENT	FUNCTION
1	Video Input Selection Switch	Select the Source Device Video Signal
2	VGA Output Port	Connect a VGA Video Display Device
3	Resolution Selection Button	Select the Output Resolution
4	Power Port	Connect a Power Source

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5	Composite Video Input Port	Connect a Composite Video Source Device
6	S-Video Input Port	Connect an S-Video Source Device

5.3.5.1 How to use the StarTech Video to VGA Converter

- Determine if the Ultrasound system has a Composite or S-Video output. Toggle the Video Input Selection Switch **(1)** to match your Ultrasound system video output.
- Connect a Composite Video Cable to the Composite Video Input Port **(5)**, or Connect an S-Video Cable to the S-Video Input Port **(6)**.
- Connect the other end of the Composite Video Cable to the Composite output of the Ultrasound system, or Connect the other end of the S-Video Cable to the S-Video output of the Ultrasound system.
- Connect a VGA Cable to the VGA Output Port on the Video Converter **(2)**.
- Connect the other end of the VGA Cable to the Epiphan AV.io HD.
- Connect the Medical Grade USB Power Adapter to the Power Port **(4)**.
- Select the output resolution by pressing the Resolution Selection Button **(3)** until the desired resolution is met. Each time you press the Resolution Selection Button the new resolution settings will appear on the On Screen Display (OSD) in the upper right-hand corner of the screen. We suggest to use the following resolution: **800x600 P60**.

5.4 How to set up the ultrasound system

Cardiovascular Suite is based on image processing of a B-mode ultrasound scans. The quality of the results can depend on the quality of the ultrasound image supplied to the system.

The ultrasound device must have the following features:

- The ultrasound device must be suitable for vascular imaging and it must be equipped with a **vascular linear probe** with frequency >= 5MHz (a range 7-15 MHz is recommended)..
- The ultrasound device must have the **B-mode** imaging mode.
- For the shear-rate measurement, the ultrasound device must have the **Pulsed Wave Doppler** (PWD) mode, and the B-mode and the PWD must be shown and updated simultaneously on the image (Dual mode).
- For offline analysis, the ultrasound device must export in one of the following formats: **AVI, MOV, MP4, DICOM, PNG, JPG, BMP, TIF**. The size of the images must be <= 1920×1200 px.
- For online analysis, the ultrasound device must have a video output in one of the following formats: **S-Video** or **Composite Video** in PAL or NTSC; **VGA**, **DVI** or **HDMI** with a resolution up to 1920×1200 pixels.
- The B-mode in the image must have **minimal resolution** of 6 pixels/mm. If present, the size of the PWD window in the image must be at least 200x100 pixels.
- The **frame-rate** of the video must be >= 17 frames per second.

The general settings of the ultrasound system must be those suggested by the manufacturer of the apparatus. It is important, however, exclude any noise reduction filters that could degrade the performance of the edge detection algorithm. In particular, it is important to exclude any time filters that cause a smoothing effect on the images in motion. These filters may have different designations (the most common name is **persistence**) depending on the model of ultrasound equipment. Please contact the manufacturer of ultrasound apparatus for information on how to exclude this type of filter.

> ⚠ **CAUTION: The ultrasound device must be suitable for vascular imaging and it must be equipped with a vascular linear probe with frequency greater than 5MHz.**

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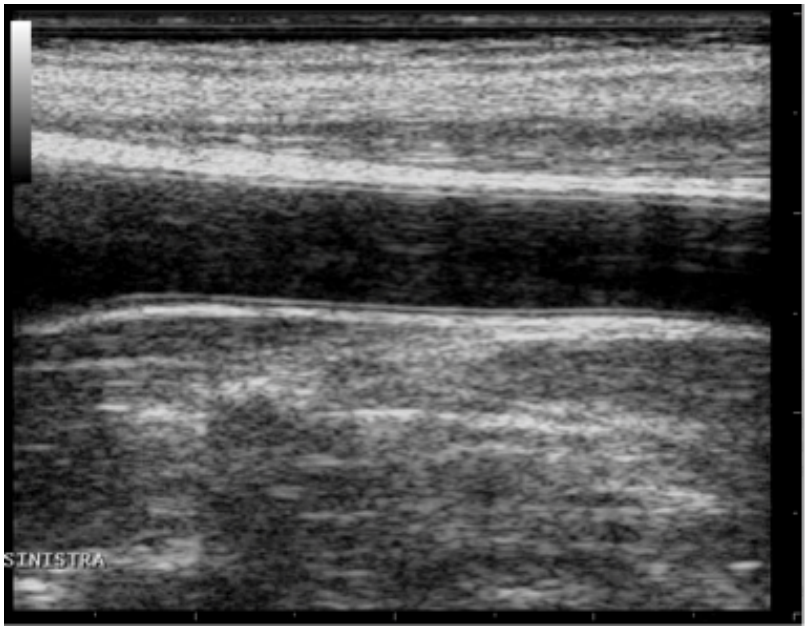
CAUTION: Exclude any noise reduction filter (especially temporal filters).

The artery should be viewed in longitudinal section and should be as horizontal as possible to the image. For Carotid Studio we recommend an image depth of 3-4 cm.



Example of carotid artery image

For FMD Studio we recommend an image depth of 2-3 cm. It is suggested also to choose a projection so that the vein is not visible (this normally appears immediately above the brachial artery). The algorithm for automatic tracking of the edges of the vessel could recognize the edge of the vein instead of the artery.

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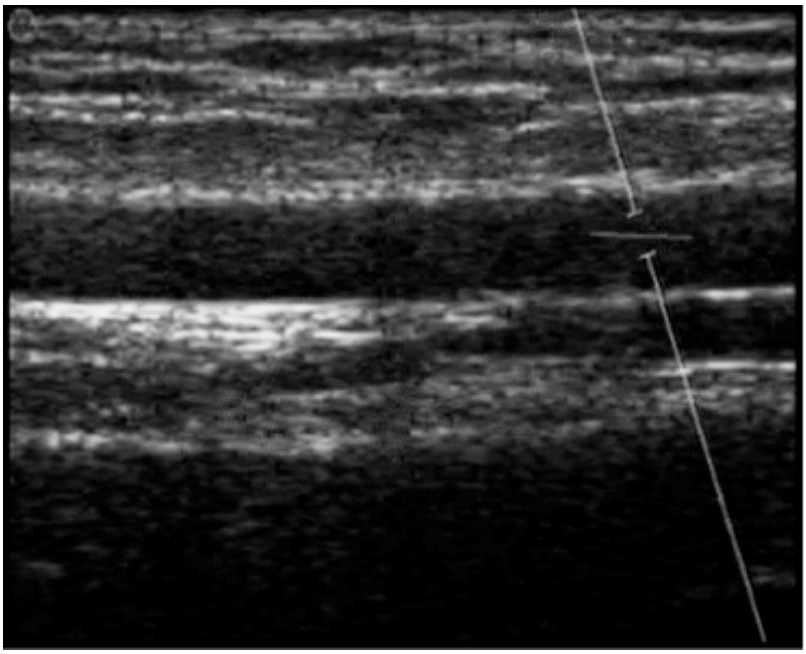

Example of brachial artery image

In addition, for FMD Studio, if you want to obtain both vessel diameter and shear rate, the ultrasound system must be in Duplex mode (simultaneous acquisition of B-mode and Doppler).

The angle between the Doppler beam and the vessel orientation should be ≤60 degrees. The sample volume should be as wide as possible but without encompassing the vessel walls and allowing for a slight margin for error in case of movement. Pay attention that the cursor of the doppler sample volume is not into the ROI where the diameter is computed. It is recommended that the sample volume is 5 - 15 mm apart from the ROI.

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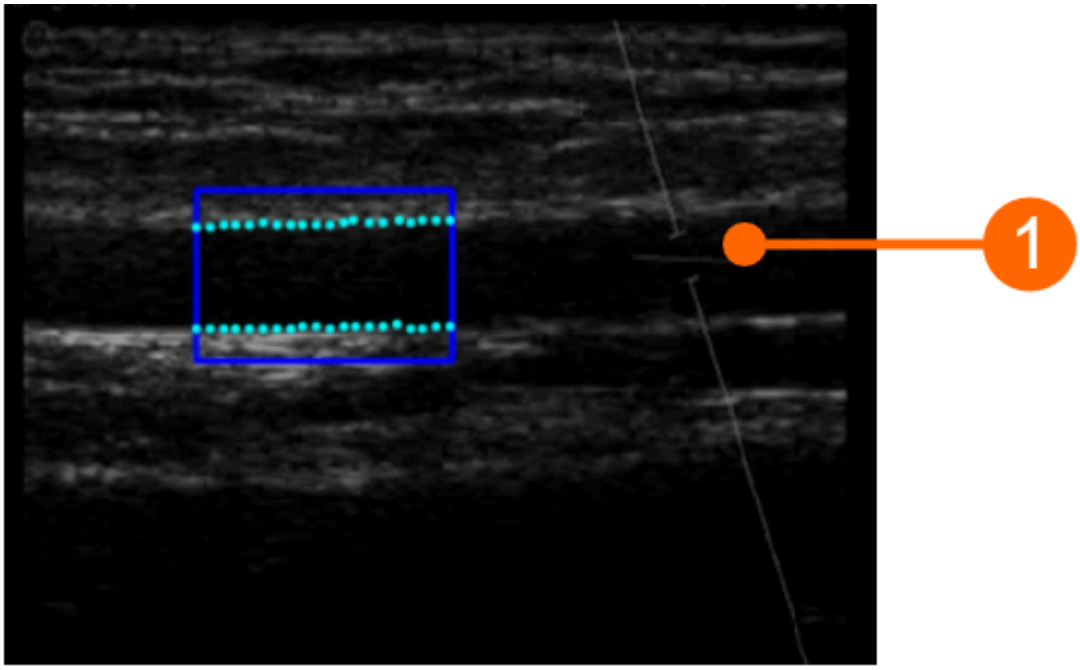

CAUTION: pay attention that nothing but the ultrasound image is into the ROI. Please note that the processing can be affected by annotations or any other graphical object that is superimposed to the image. In particular, pay attention that the cursor of the doppler sample volume is not into the ROI.

The scale of the Doppler flow profile should be set correctly on the ultrasound system. The vertical scale must be large enough to include the velocity profile during all the examination (in FMD measurements, greater velocity values are in reactive hyperemia). For the horizontal scale, we suggest a value of 3-4 seconds. Please note that the time average is computed over all the extend of the horizontal scale.

The Doppler Flow ROI must cover all the extent of the Doppler flow profile. The zero flow axis **(2)** must be included in the ROI: it will be automatically recognized and plotted in yellow. The vertical axis **(3)** must be external to the ROI. Please also ensure that any annotation **(4)** is outside the ROI since it could affect the flow analysis.

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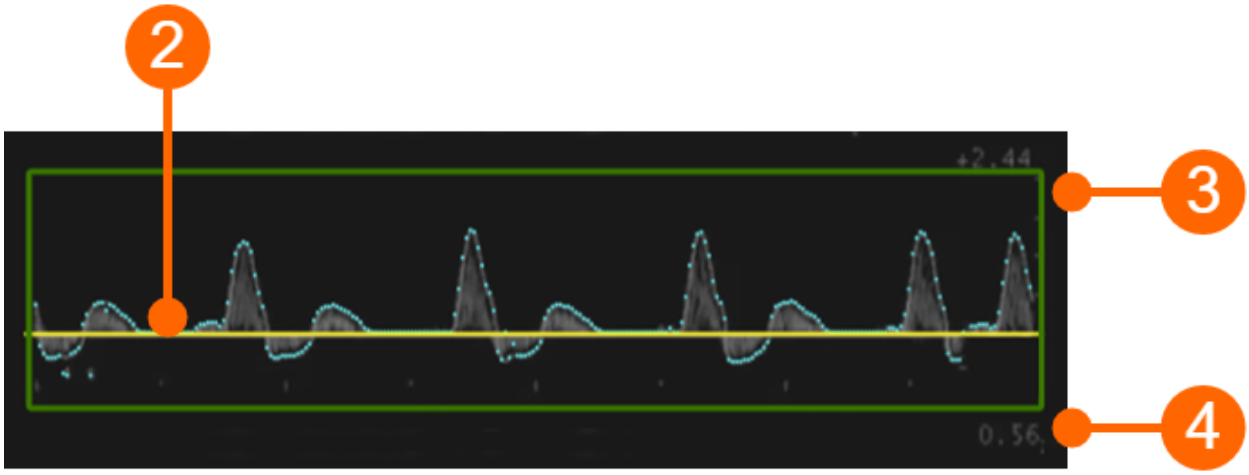

CAUTION: the processing can be affected by annotations or any other graphical object that is superimposed to the image into the Doppler Flow ROI.

Please remember that the tool for the calculation of the shear rate must be re-calibrated every time you change the size or scale of the Doppler flow profile. This calibration is present in FMD Studio analysis. It is recommended that the size or scale of the Doppler trace will be no longer changed once you have decided how to set up the ultrasound system.

FMD-Studio precision, expressed as coefficient of variation, is 10% for intra-observer intra-session measurements and 13% for intra-observer inter-session measurements of FMD%. For the Shear Rate measurement, the estimated precision is 2,3%.

Carotid Studio precision expressed as coefficient of variation is 2% for the diameter, 11% for the diameter variation during the cardiac cycle, 6% for IMT for intra-observer intra-session measurements and 3% for the diameter, 12% for the diameter variation during the cardiac cycle, 6% for IMT for intra-observer inter-session measurements. As regards geometric and statistics data the precision of the results expressed as coefficient of variation resulted lower than 10% for each measurement obtained on a single image by the same operator.

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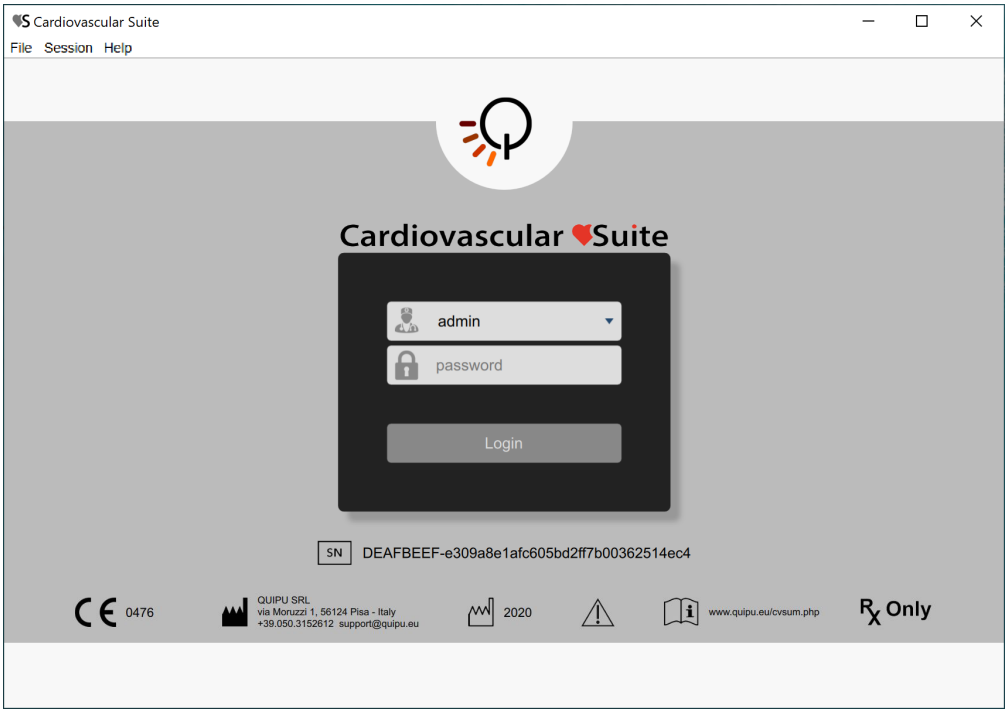
6 Login

When you run Cardiovascular Suite, you are asked to login with a Username and Password. Please enter your Username and Password, then click on the Login button to access the software.

When you first run Cardiovascular Suite, the default user account is:

Username: admin

Password: admin



In the lower part of the Login window, the labeling of the device is shown.

In particular, on the right of the SN symbol you can find the Serial Number of your software.

Operators

A user account (username and password) is associate to each **operator** of Cardiovascular Suite (an operator is a person who uses Cardiovascular Suite). When the software starts, the operator must login with its user account.

Two classes of operator are available in Cardiovascular Suite:

1. **Users**. They have full access to the software.
2. **Read-only users**. These users can only read the archive and the documents.

An operator is characterized also by a **status** that can be **active** or **disabled.** If an operator has been disabled, he/she cannot access to the software.

It is possible to modify a user account and to add a new one in the Operators management panel.

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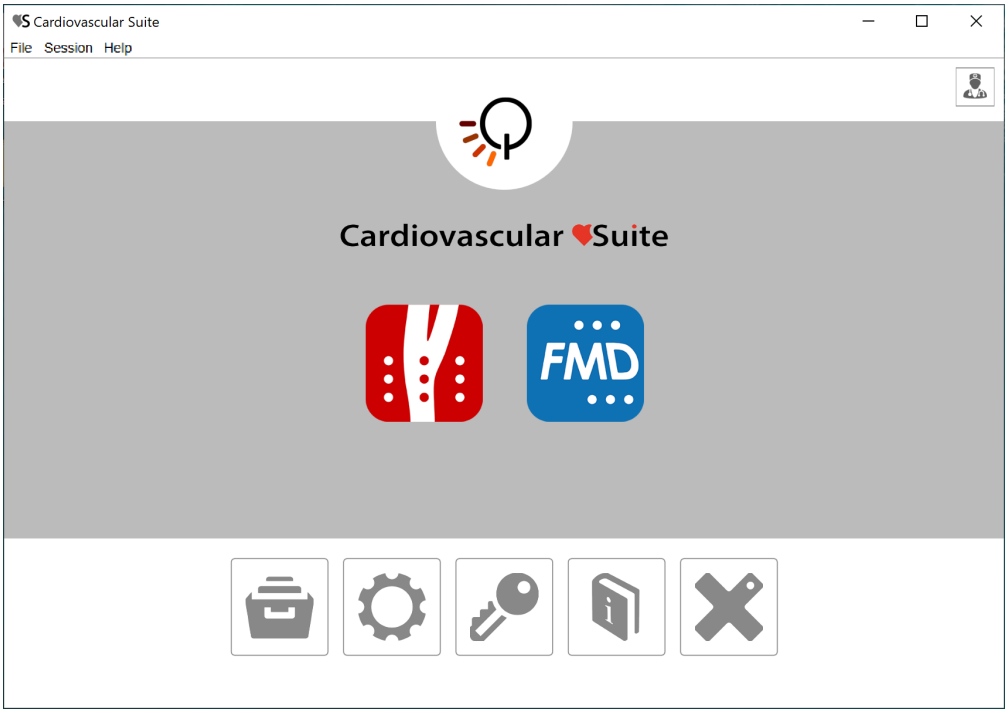
7 Home



The Home Screen contains the main controls of the software.

The Carotid Studio and the FMD Studio buttons start a new study with Carotid Studio and FMD Studio respectively.

If a lock icon is present inside the button, this means that you don't have a valid license for this application.

The buttons in the lower part of the Home Screen are:

- **archive**: opens the Archive window.
- **settings**: opens the Settings manager window.
- **license**: opens the License manager window.
- **manual**: opens this User Manual in an external browser.
- **exit**: quit Cardiovascular Suite.

On the top right of the Home Screen, clicking on the operator icon, you can find the name of the logged user and the logout button.

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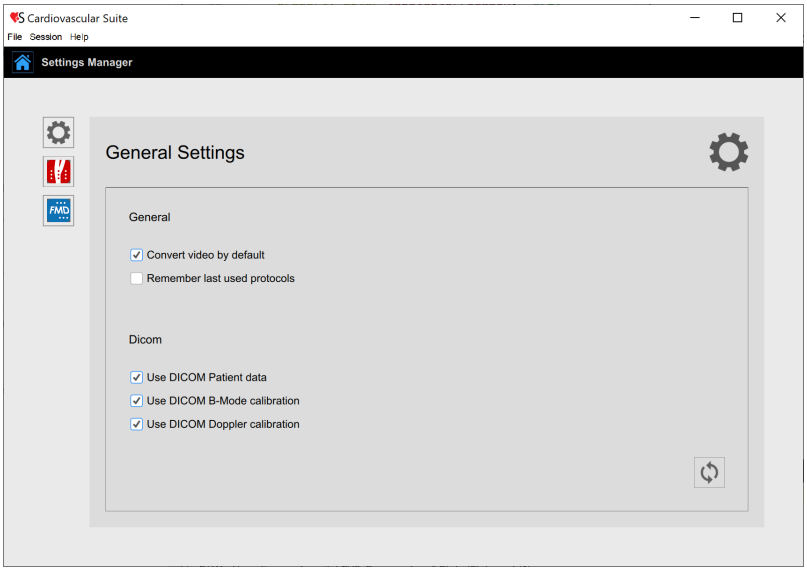
8 Settings manager

The Settings manager contains the settings of Cardiovascular Suite.

1. General settings
2. Carotid Studio settings
3. FMD Studio settings

8.1 General settings



The following settings are available:

General

- **Convert video by default**: if set, when creating a new study, the "Convert video" checkbox is set by default.
- **Remember last used protocol**: if set, when creating a new study, the study will be associated by default with the last used protocols.

Dicom

- **Use DICOM Patient data**: if set, when opening a DICOM file, the patient data are obtained from the file metadata.
- **Use DICOM B-mode calibration**: if set, when opening a DICOM file, B-mode calibration is obtained from the file metadata.
- **Use DICOM Doppler calibration**: if set, when opening a DICOM file, Doppler calibration is obtained from the file metadata.

Every time a change is performed, the software automatically saves it. Click the Restore button to restore the default options.

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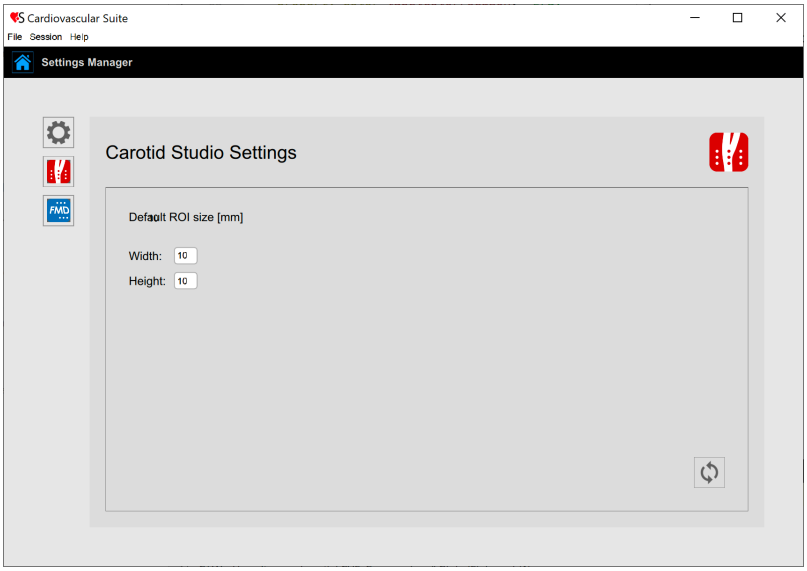
8.2 Carotid Studio settings



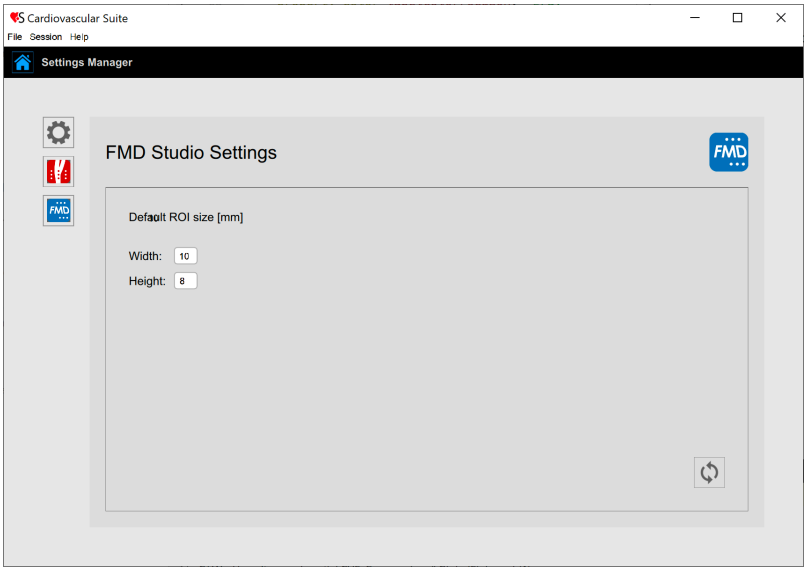
The following settings are available:

Default ROI size

- **Width**: width of the default ROI.
- **Height**: height of the default ROI.

Every time a change is performed, the software automatically saves it. Click the Restore button to restore the default options.

8.3 FMD Studio settings



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The following settings are available:

Default ROI size

- **Width**: width of the default ROI.
- **Height**: height of the default ROI.

Every time a change is performed, the software automatically saves it. Click the Restore  button to restore the default options.

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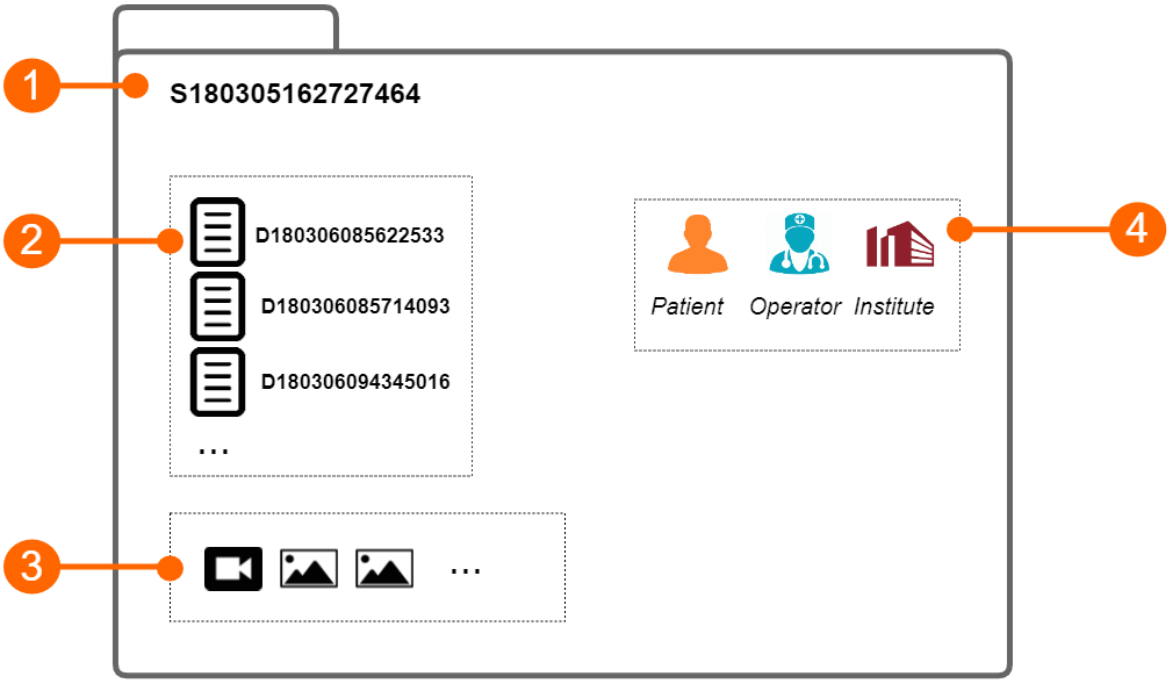
9 Archive

The Archive is made up by several tabs, that manage:

- the studies and their documents;
- the patients;
- the operators;
- the institutes;
- the protocols;
- the tags.

9.1 *STUDIES AND DOCUMENTS*



The study **(1)** contains the results generated by a software application. These results are organized into documents **(2)**. Each document contains the results of the analysis of a video clip or an image. The study instead may contain one or more media files (video clip or images).

Each study has a unique study identification number (study ID), which is a string starting with the letter "S" and followed by 15 numeric digits. Analogously, each document has a unique document identification number (document ID), which is a string starting with the letter "D" and followed by 15 numeric digits.

Each study can be associated with one or more protocols and each document can be associated with one or more tags.

9.2 *PATIENTS*

The patient is the person who undergo the examination.

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The archive can contain the following patient data:

- Patient ID
- First name
- Middle name
- Last Name
- Sex (it can be: "Unspecified", "Female" or "Male")
- Birth date (it can be set or "unspecified")
- Address (Street, number, City, ZIP, State/Region, Country)
- Telephone
- E-mail

You can enter no data of the patients. The only mandatory field is the patient ID. If you don't enter patient ID, a random value will be automatically proposed, which is a string starting with the letter "P" and followed by 15 numeric digits.

9.3 *OPERATORS*

The operator is the person who make the examination.

The archive can contain the following operator data:

- First name
- Middle name
- Last Name
- Birth date (it can be set or "unspecified")
- Telephone
- E-mail

You can also set a picture of the operator.

9.4 *INSTITUTES*

The institute is the organization where the examination is performed.

The archive can contain the following institute data:

- Name
- Address (Street, number, City, ZIP, State/Region, Country)
- Telephone
- Fax
- E-mail

You can also set a picture of the institute.

9.5 *PROTOCOLS*

The protocol is a particular experiment or proceeding which a study or more than one may be associated with.

The archive can contain the following protocol data:

- Name
- Description

You can also set a picture of the protocol.

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9.6 ***TAGS***

The tag is a particular label which a document, or more than one, may be associated with.

Cardiovascular Suite has two types of tags:

1. **System tags**, which are already defined in the software and are used to specify which documents will be included in the study report.
2. **Custom tags**, which are defined by the user and are used to better identify a document.

Only one system tag can be associated to a document.

Custom tags contain the following tag data:

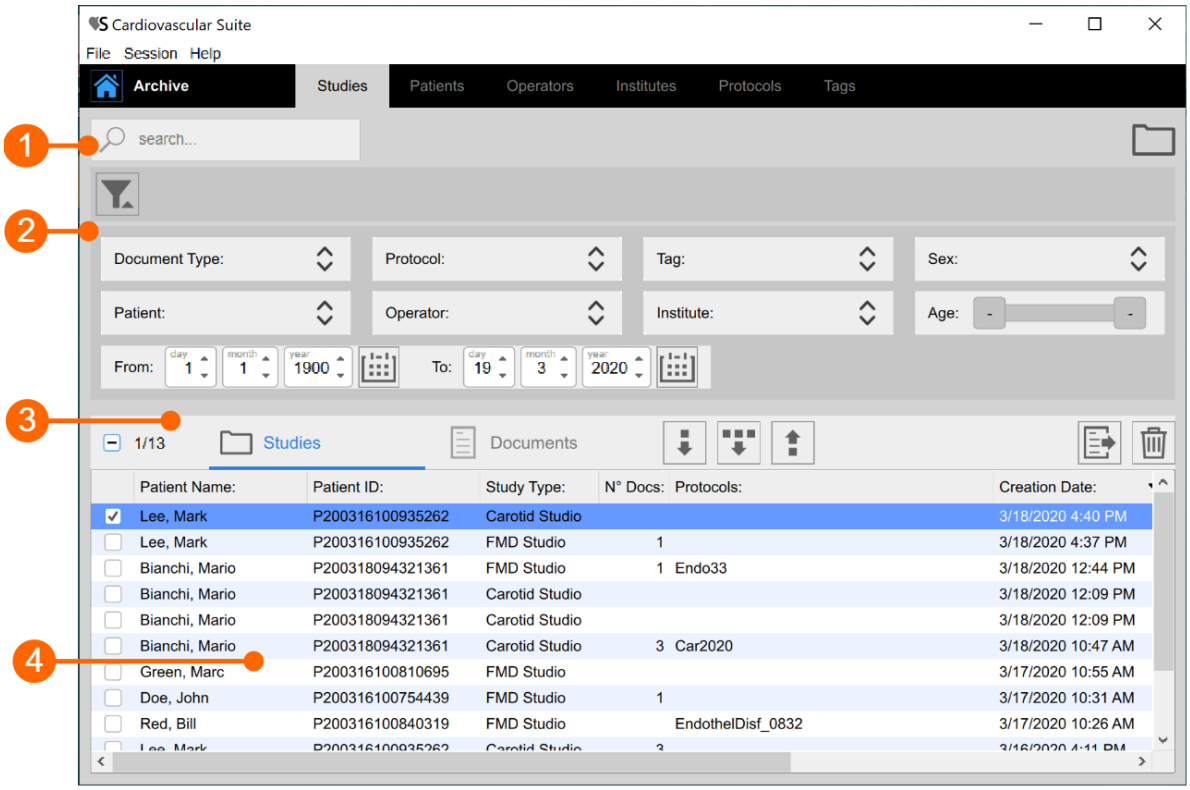
- Name
- Description

You can also set a picture of the custom tag.

9.7 Studies management

In the Studies and Documents panel, it is possible to manage studies and documents.

This panel is made up by a search field **(1),** the filter management panel **(2)**, the control buttons **(3)** and a table **(4)** for showing the study list (or the document list), depending on the selected tab (Studies or Documents) from the control buttons.



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9.7.1 Searching and filtering

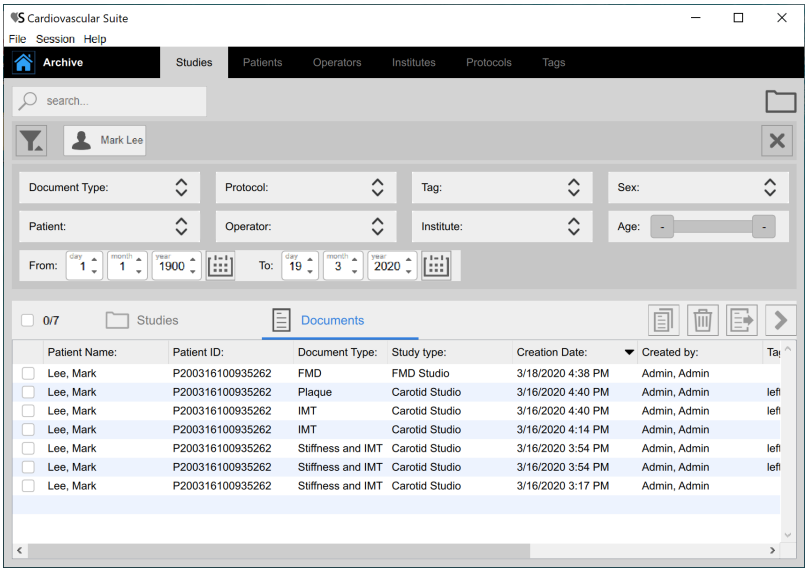
It is possible to perform a textual search in the Studies or Documents table thanks to the search field on the top **(1)**.

The filter management panel **(2)** allows the possibility to add and remove filters. By clicking on the  icon, the following filters can be added:

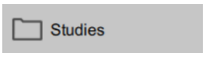
- Document type
- Patient
- Operator
- Institute
- Patient Sex
- Patient Age
- Patient Birthdate
- Document Tag
- Study Protocol

In addition, it is possible to filter the studies by patient, operator, and institute by going to their panels and double clicking on one of them.

Once the filter panel is visible, it is sufficient to choose one or more filters using the dropdown menu and the table is automatically filtered. It is possible to remove one filter at a time by clicking on it, or to remove all the filters at the same time by clicking on the  icon, as show in the following picture.



9.7.2 Management of Studies Table

Selecting the Studies tab 

, the Studies table is shown where you can find the list of all the studies performed and stored into the Archive.

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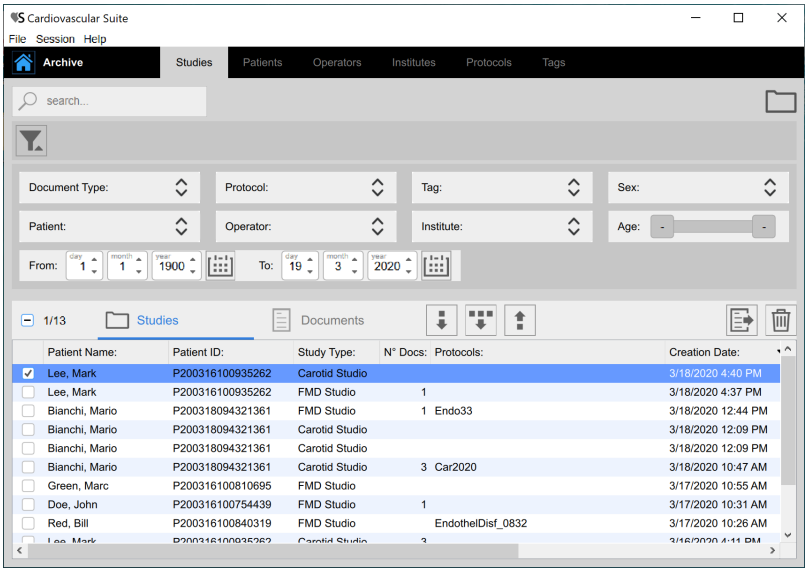

Import a study:

- Click on the Import Study button that is placed on the top of the Studies Table.
- Select the folder that contains the study to be imported, then press Open.

Import more than one study:

- Click on the Multiple Import Study button that is placed on the top of the Studies Table.
- Select the folder that contains the studies to be imported, then select the studied and press Open.

Export a study:

- In table **(4)**, click on the study to be exported.
- Click on the Export Study button that is placed on the left of the Studies Table.
- Select the destination path where you want to save your exported study, then press Save.

A report file in CVS format is created in the destination folder. It contains the details of the exported study.

Delete a study:

- In table **(4)**, click on the study to be deleted.
- Click on the Delete Study button that is placed above the Studies Table, on the right.

Multiple selection:

In Studies Table multi-select feature is available. You can select more than one study and perform export and delete operation on selected studies.

In table **(4)**, select the studies through the check-box. The label over the table shows how many studies are selected from the available ones.

After you have selected studies you can export them (clicking on multiple Export button, placed above the Studies Table) or delete them (clicking on Delete button, placed above the Studies Table, on the right).

Advanced export:

It is possible to export documents of selected study/studies as CSV, TSV or PDF file.

- In table **(4)**, select the study/studies to be exported

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- Click on the Export Documents  button that is placed on the top of Studies Table. A drop-down menu appears:
  - *Export Document Results*: it exports a TSV/CSV file containing information about the study, the document, and the computed results. You can also export a PDF report of the document.
  - *Export Document Data*: it exports a TSV/CSV file containing the results of the study and the instantaneous data.
- Select the destination path where you want to save your exported documents, then press Save.

9.7.2.1 Study view

It is possible to open the study view by double clicking on it from the Studies Table **(4)**. A new window containing the study ad its files is opened, as shown in the following picture. Some buttons are also available to operate the study:

- Click the next  or to the previous  study button to navigate among the studies.
- Click the Generate study report  button to create a PDF report of the study (available for Carotid Stdio only, see Study report).
- Click the Export the Study  button to export the current study.
- Click the Delete the Study  button to delete the current study.

The study view contains:

- a panel with information regarding the study and the patient **(5).**
- a panel for adding and removing protocols to the study **(6).**
- a note text field **(7)** where it is possible to add comments to the study.
- a media file container **(8)** which collects all the media files of the study (clicking on the media file icon new window for showing the file is opened).
- a table containing all the study documents and the buttons **(9)** for managing them.

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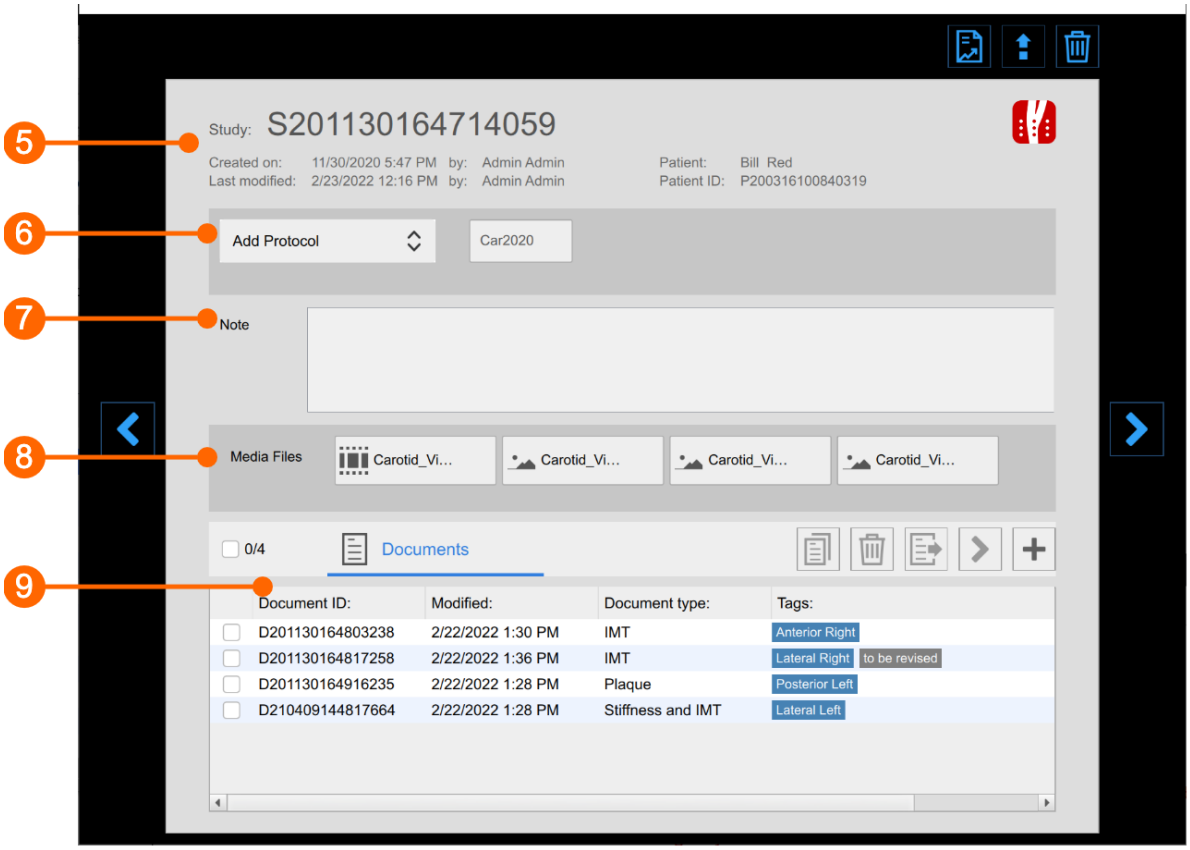

It is possible to click on a document of the table to see some information about the document itself.

From the documents table **(9)** it is also possible to create a new document related to that study, by clicking on the + button. You can select one or more document and duplicate one of them using the duplicate button. For selected documents, it is also possible to export and delete them. In addition, by clicking on the › icon it is possible to view the review of that document.

9.7.3 Management of Documents Table

Selecting the Documents tab Documents, the Documents table is shown.

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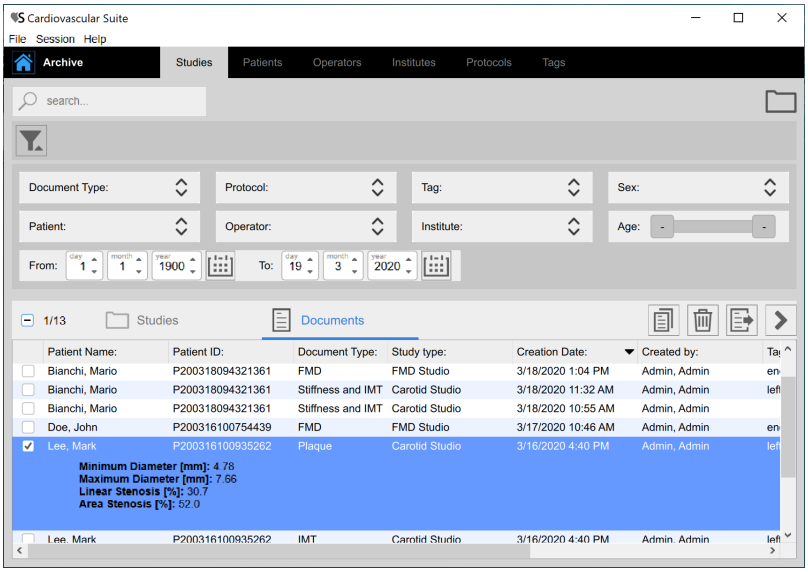

Open a document:

- Click on the document to be open.
- Click on the Go button in document preview and the document will open in the application that created it or,
- Double click on the document to be open.
- The document will open in the application that created it.

Duplicate a document:

- In the Documents table, click on the document to be duplicated.
- Click on the Duplicate Document button placed above the table.

Delete a document:

- In the Documents table, click on the document to be deleted.
- Click on the Delete Document button placed above the table.

Export a document:

It is possible to export one or more documents as CSV, TSV or PDF file.

- In the Documents table, select the document to be exported.
- Click on the Export Document button, placed above the Documents table. A drop-down menu appears:
- *Export Document Results*: it exports a TSV/CSV file containing information about the study, the document, and the computed results. You can also export a PDF report of the document.
- *Export Document Data*: it exports a TSV/CSV file containing the results of the study and the instantaneous data.
- *Export Aggregated Results* (available only if more than a document is selected): it is also possible to export aggregated results of different documents in a single CSV or TSV file (please note that selected studies should all be of the same type).

- Select the destination path where you want to save your exported documents, then press Save.

Multiple selection:

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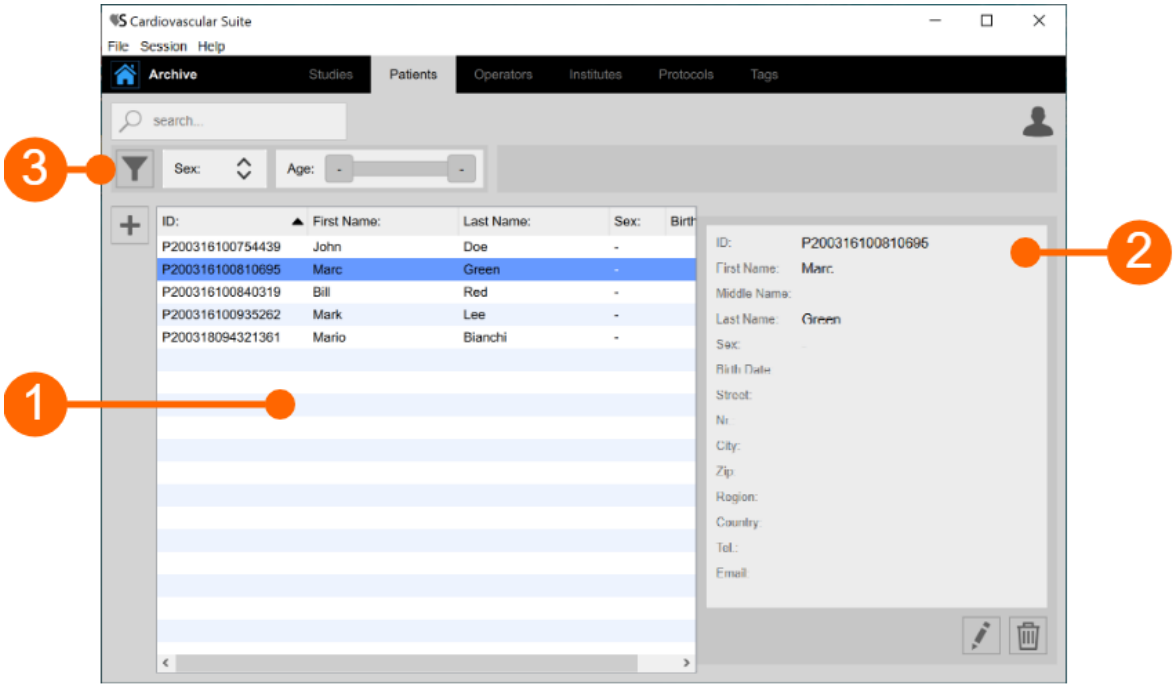
In Documents Table multi-select feature is available. You can select more than one document and perform export and delete operation on selected documents.

In table, select the documents through the check-box. The label over the table shows how many documents are selected from the available ones.

After you have selected documents you can export them (clicking on Export button) or delete them (clicking on Delete button).

9.8 Patients management

Allows you to manage patients.



The patient list is given in table **(1)**. Once you select one of patients, detailed information are shown in the frame **(2)**.

In the frame **(3)** you can perform textual research and add and remove filters. The following filter can be used:

- Sex
- Age

In addition, with a double click on a patient, the list of the study related to that patient is shown in the Studies management window:

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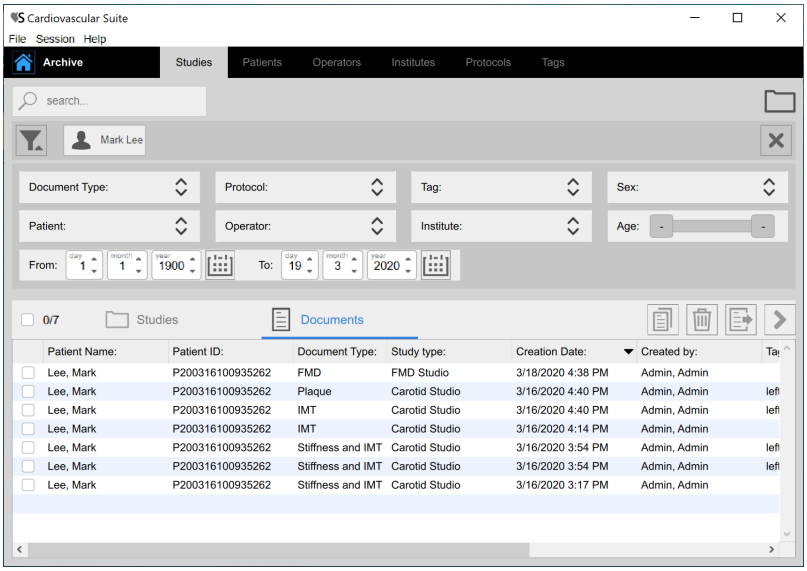

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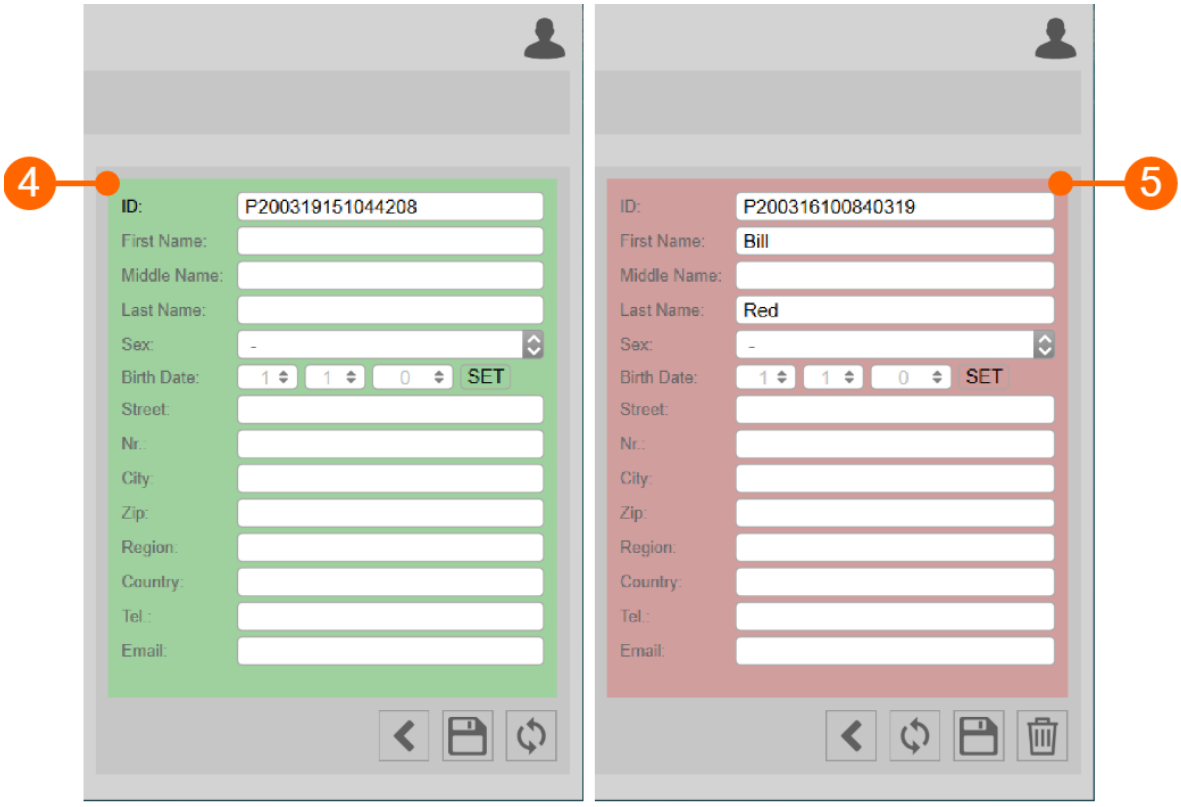

Add a new patient:

- Click on the Add New Patient button.
- In the new patient frame **(4)**, enter the patient data. The only mandatory field is the patient ID and the software automatically creates a new one.
- Click on the Save button to save the patient data.

Modify a patient:

- Select the patient to be modified.
- Click on the Edit button.
- Modify the patient data in the frame **(5)**.
- Click on the Save button to save the data.
- You can use the Restore button to restore data.

Delete a patient:

- Select the patient to be deleted.
- Click on the Delete button.
- Confirm deletion with the OK button.

> ⓘ You cannot delete a patient that is associated with existing studies.

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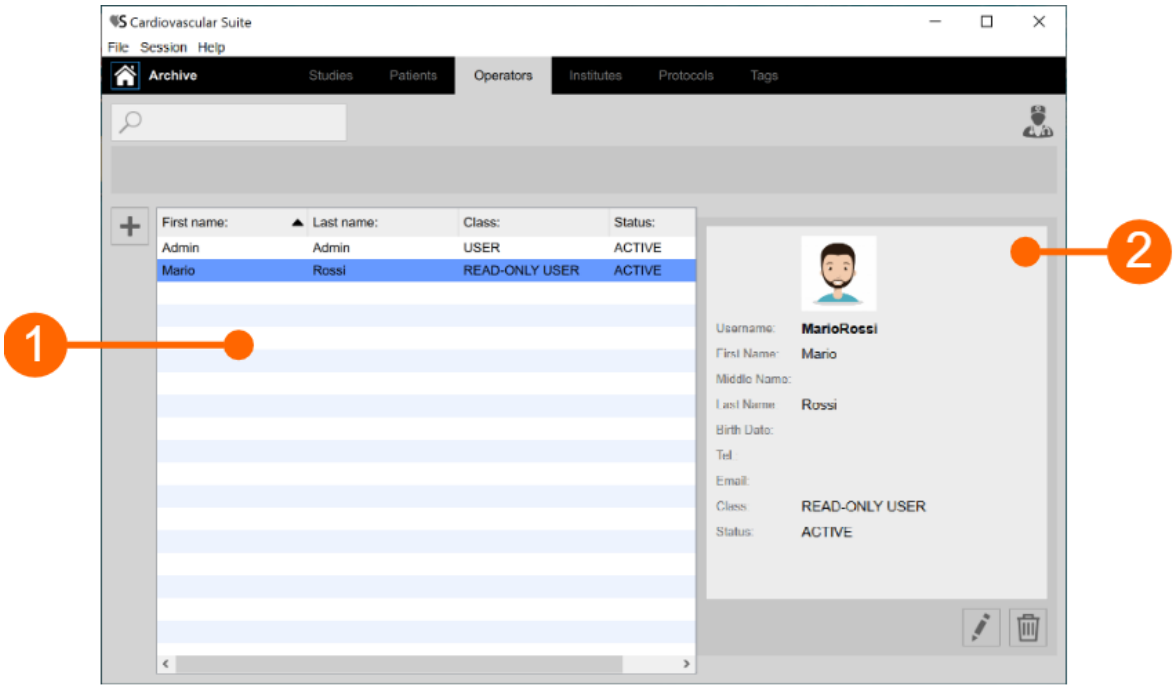
9.9 Operators management

Allows you to manage operators.



The operators list is given in the table above **(1)**. Once you select one of the operators, detailed information are shown in the frame **(2)**.

You can double click on the operator in table **(1)** to show the studies performed by this operator in the Studies management window.

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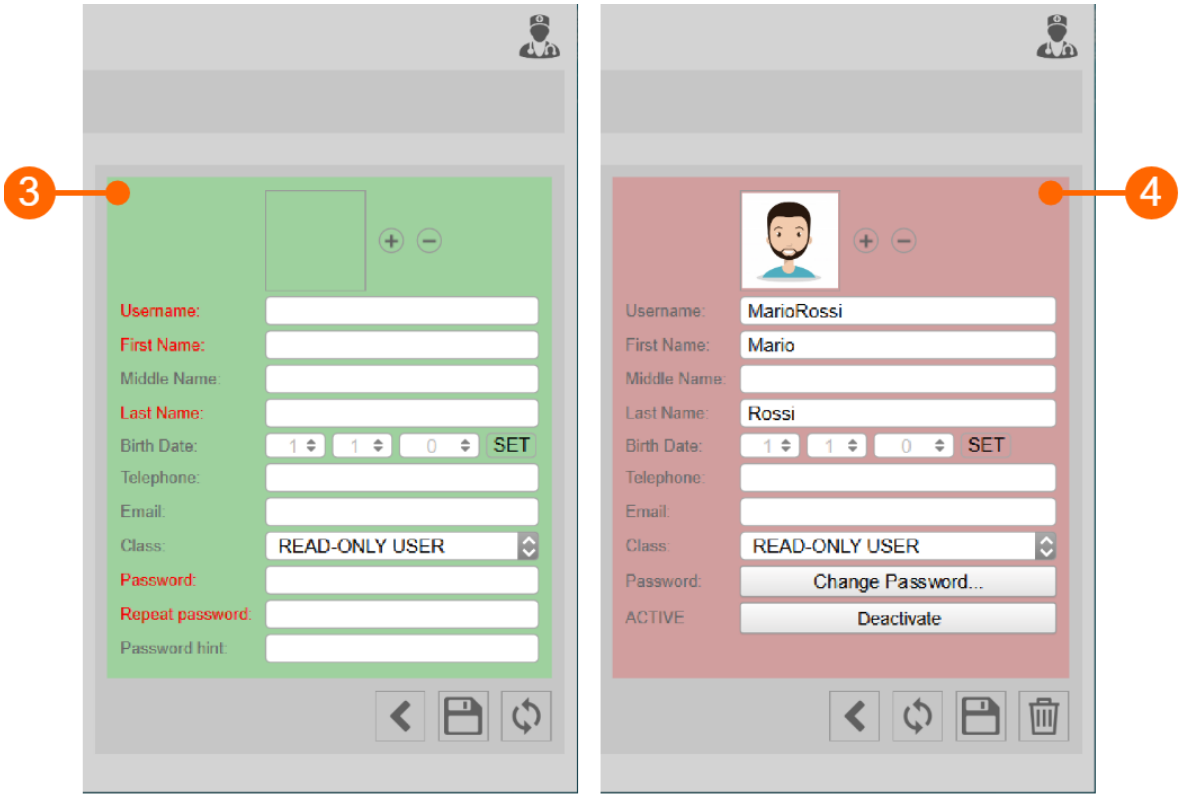

Add a new operator:

- Click on the Add New Operator button.
- In the new operator frame **(3)**, enter the operator data. Labels of mandatory fields (First Name, Last Name) are red.
- Click on the Save button to save the operator data.

Modify an operator:

- Select the operator to be modified.
- Click on the Edit button.
- Modify the operator data in the frame **(4)**.
- Click on the Save button to save the data.
- You can use the Restore button to restore data.

Delete an operator:

- Select the operator to be deleted.
- Click on the Delete button.
- Confirm deletion with the OK button.

> You cannot delete an operator that is associated with existing studies.

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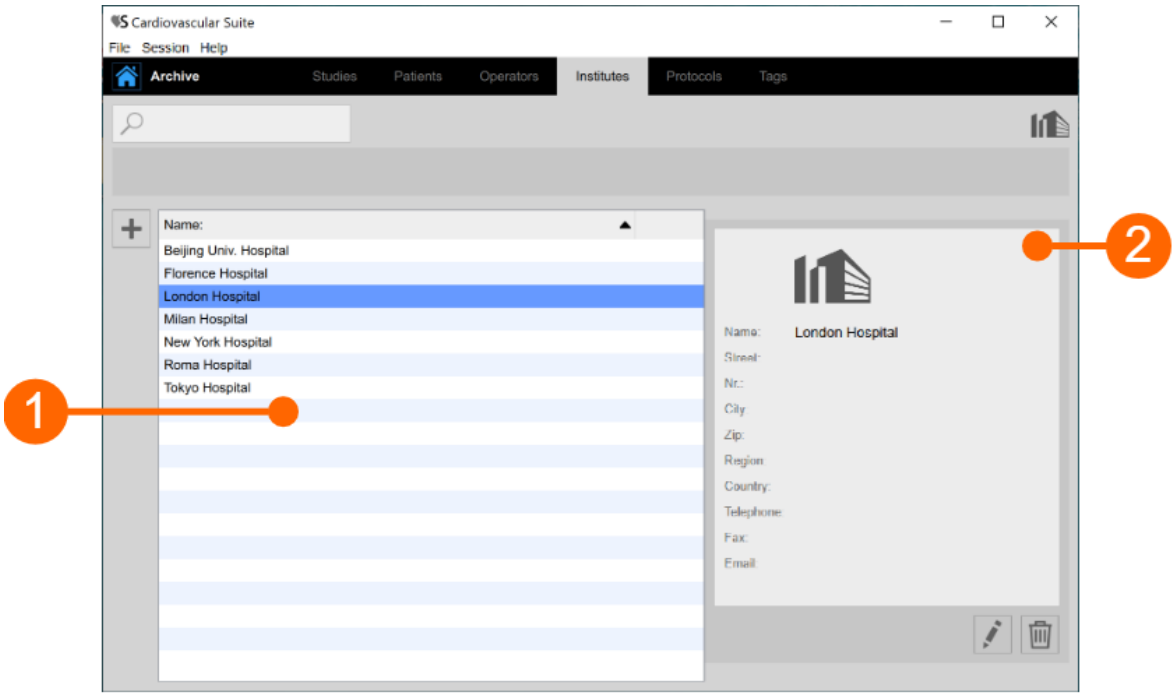
9.10 Institutes management

Allows you to manage institutes.



The institutes list is given in table **(1)**. Once you select one of the institutes, detailed information are shown in the frame **(2)**.

You can double click on the institute in table **(1)** to show the studies performed within this institute in the Studies management window.

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Add a new institute:

- Click on the + button for adding a new institute.
- In the new institute frame **(3)**, enter the institute data. The mandatory field (Name) is in red.
- Click on the Save button to save the institute data.

Modify an institute:

- Select the institute to be modified.
- Click on the Edit button.
- Modify the institute data in the frame **(4)**.
- Click on the Save button to save the data.
- You can use the Restore button to restore data.

Delete an institute:

- Select the institute to be deleted.
- Click on the Delete button.
- Confirm deletion with the OK button.

> ⓘ You cannot delete an institute that is associated with existing studies.

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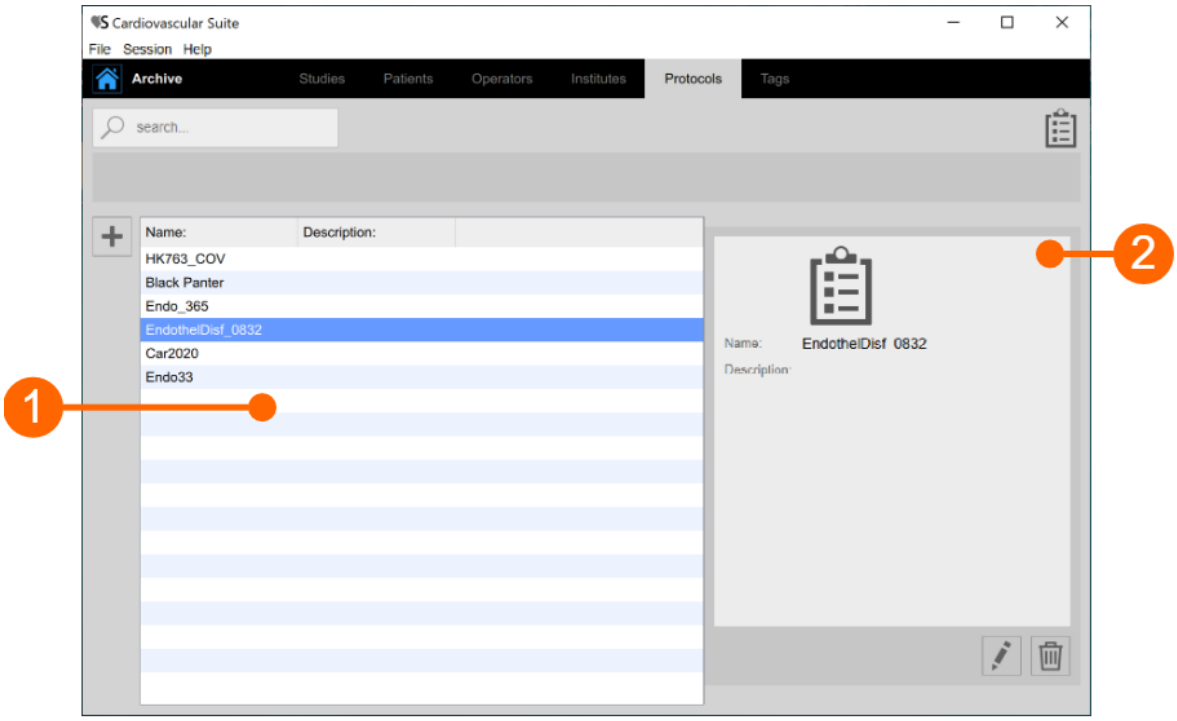
9.11 Protocols managements

Allows you to manage protocols.



The protocols list is given in table **(1)**. Once you select one of the protocols, detailed information are shown in the frame **(2)**. At the top of the screen there is a search field to perform a textual research for protocols in the list.

You can double click on the protocol in table **(1)** to show the studies performed within this protocol in the Studies management window.

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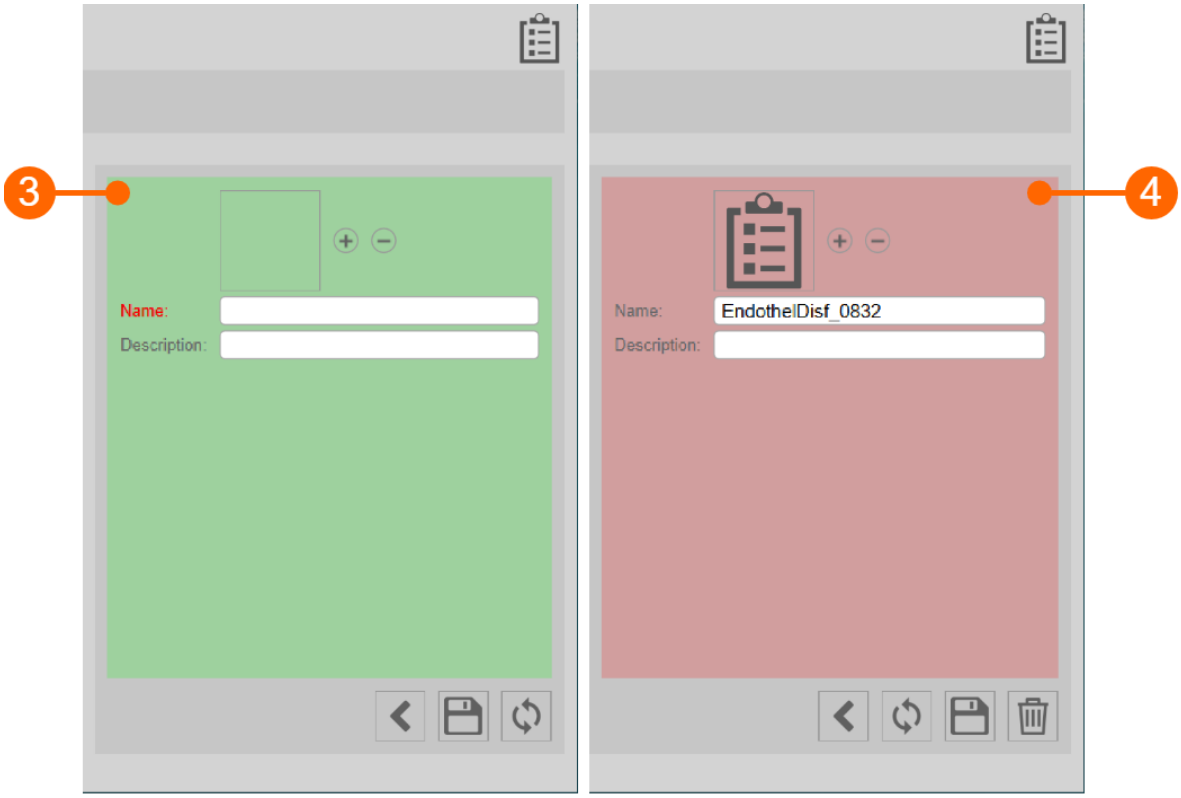

Add a new protocol:

- Click on the + button for adding a new protocol.
- In the new protocol frame **(3)**, enter the protocol data. The mandatory field (Name) is in red.
- Click on the Save button to save the protocol data.

Modify a protocol:

- Select the protocol to be modified.
- Click on the Edit button.
- Modify the protocol data in the frame **(4)**.
- Click on the Save button to save the data.
- You can use the Restore button to restore data.

Delete a protocol:

- Select the protocol to be deleted.
- Click on the Delete button.
- Confirm deletion with the OK button.

> You cannot delete a protocol that is associated with existing studies.

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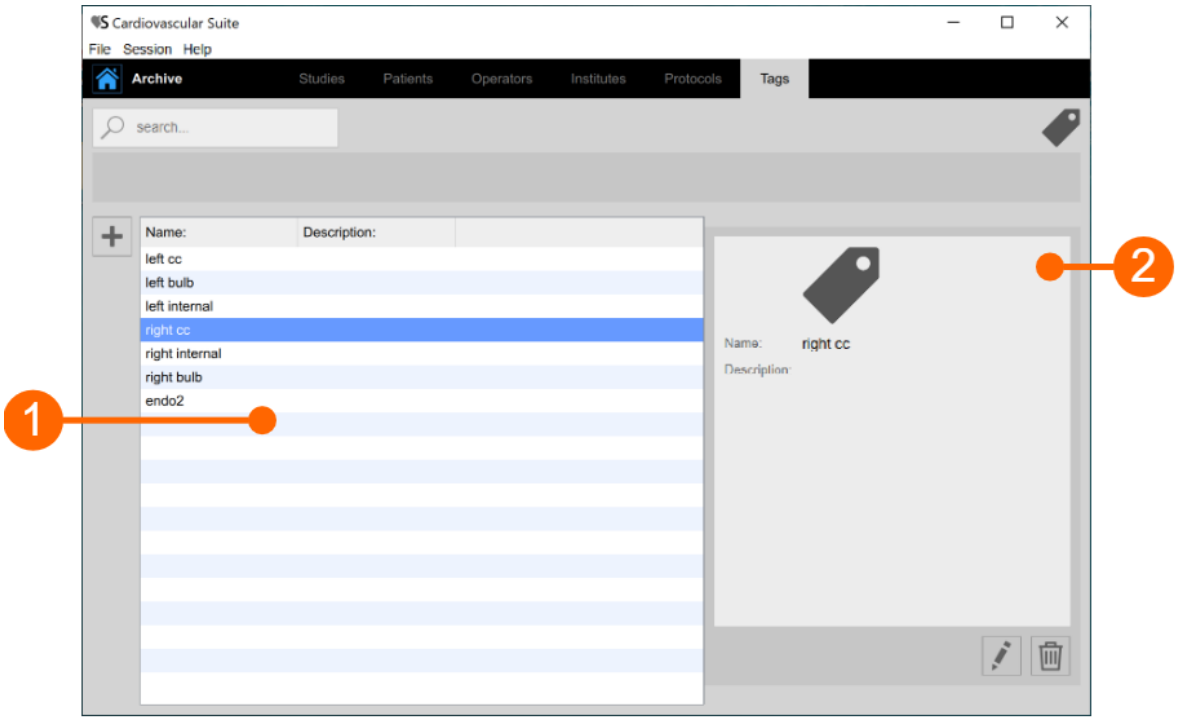
9.12 Tags management

The Archive Tags section allows you to manage the custom tags.



The tags list is given in table **(1)**. Once you select one of the tags, detailed information are shown in the frame **(2)**. At the top of the screen there is a search field to perform a textual research for tags in the list.

You can double click on the tag in table **(1)** to show the documents associated to this tag in the Studies management window.

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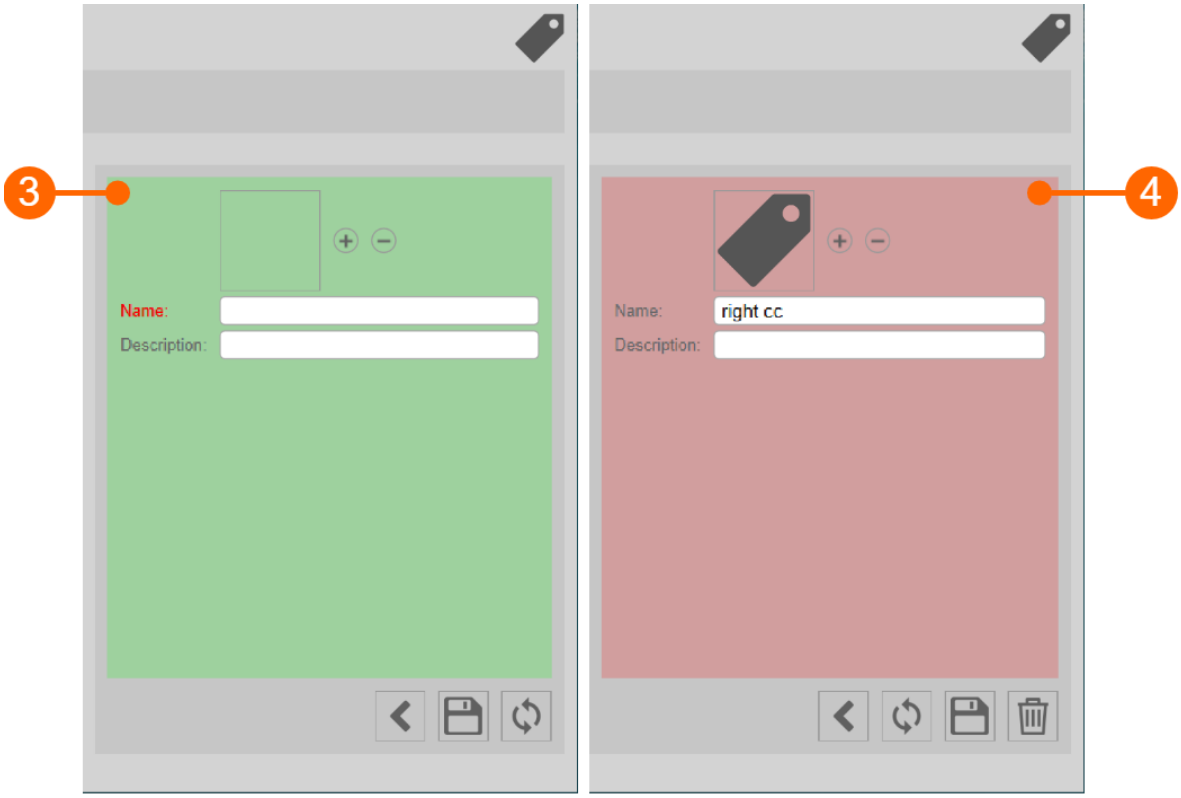

Add a new tag:

- Click on the + button for adding a new tag.
- In the new tag frame **(3)**, enter the tag data. The mandatory field (Name) is in red.
- Click on the Save button to save the tag data.

Modify a tag:

- Select the tag to be modified.
- Click on the Edit button.
- Modify the tag data in the frame **(4)**.
- Click on the Save button to save the data.
- You can use the Restore button to restore data.

Delete a tag:

- Select the tag to be deleted.
- Click on the Delete button.
- Confirm deletion with the OK button.

> You cannot delete a tag that is associated with existing docuements.

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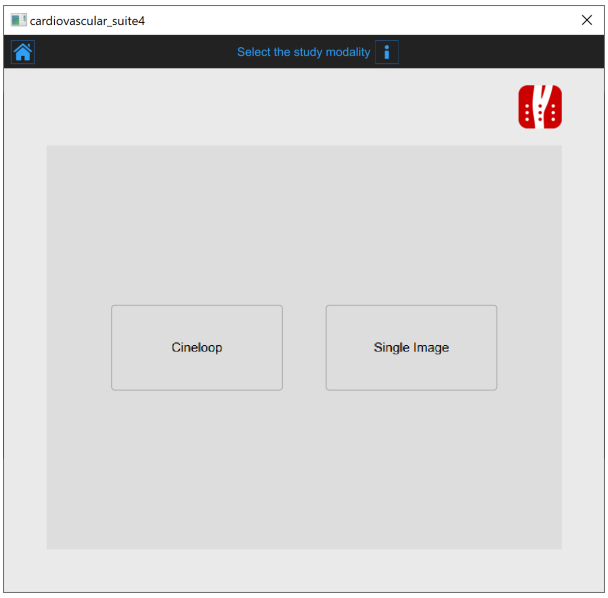
10 Carotid Studio

Carotid Studio is a software for the measurement of the Intima Media Thickness (IMT), the carotid diameter, and the stiffness parameters by processing sequences of ultrasound images. On single images, the software also provides a tool for the measurement of geometric and statistic parameters on plaques that are recognized manually by the operator.

10.1 Create a new study

When you start Carotid Studio, a procedure guides you in the creation of a new study. The steps are:

10.1.1 Select the study modality



In this tab, you can select the study modality. Carotid Studio allows to analyze through "Cineloop" modality (loading a video clip) and "Single Image" modality (processing a single frame coming from a video or loaded as image).

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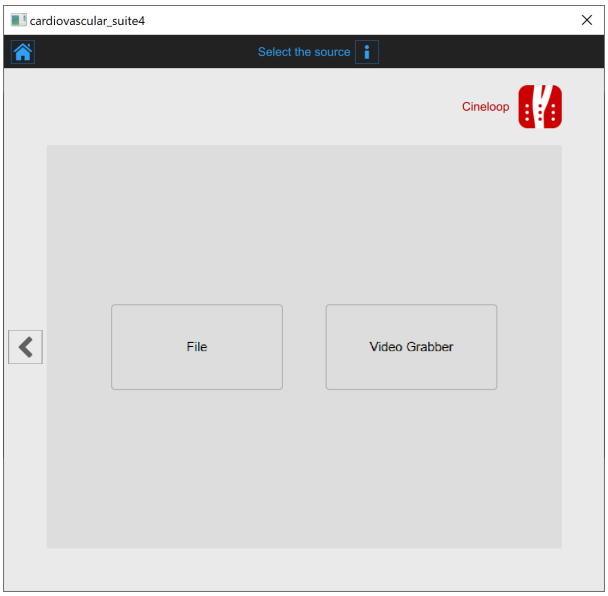
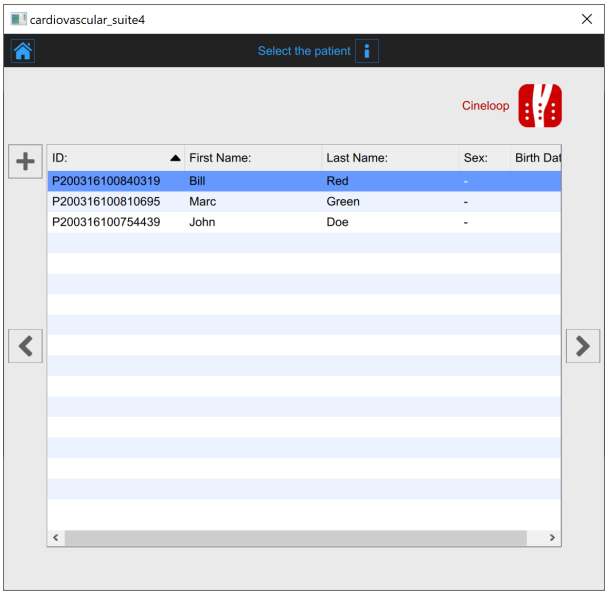
10.1.2 **Select the source**



In this tab, you can select the study video source. With the "Cineloop" modality, Carotid Studio processes video sources (Video File or a DICOM File) while with "Single Image" it also processes images. Both the modalities allow to work in real-time by processing images directly coming from the ultrasound equipment thanks to a video converter.

10.1.3 Select the patient

> For DICOM files, the patient data are obtained by the file metadata and this window is skipped (see Settings). You can anyhow edit the patient data from the Review window.



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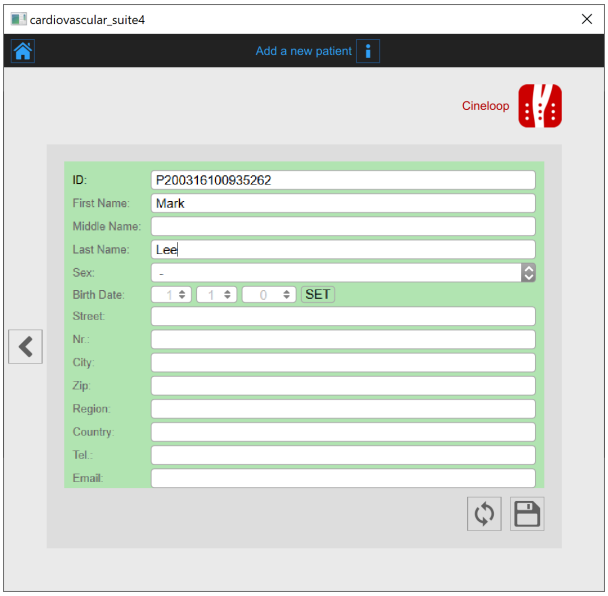
In this tab, you can select the patient among the ones already present in the Archive. Select the patient and click on the Next button (you can simply double-click on the patient to proceed). If you want to create a new patient, click of the Add New Patient button.
In the Add new patient frame, enter the patient data. The only mandatory field is the patient ID (a random value is automatically proposed). Click on the Save button to save the patient data.



10.1.4 Select the institute

If it is the first time you create a study, after selecting the patient you will also need to select the institute. If you have already created at least one study, the software remembers the institute used for the previous study and after selecting the patient shows you automatically the final review (where you can still make changes before starting the new study).

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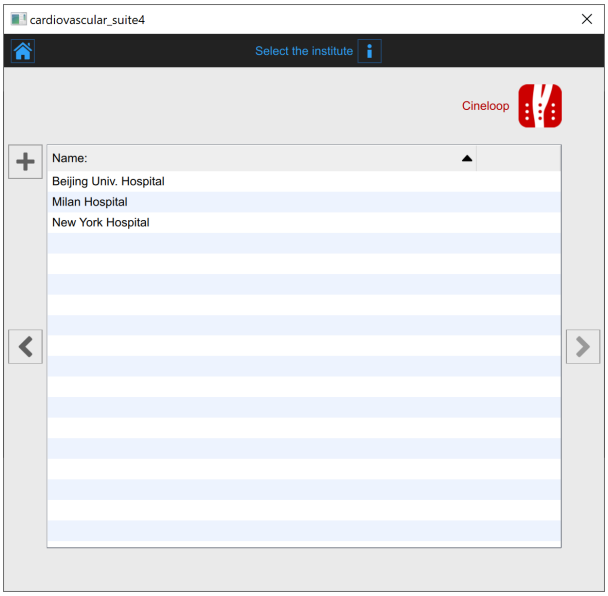
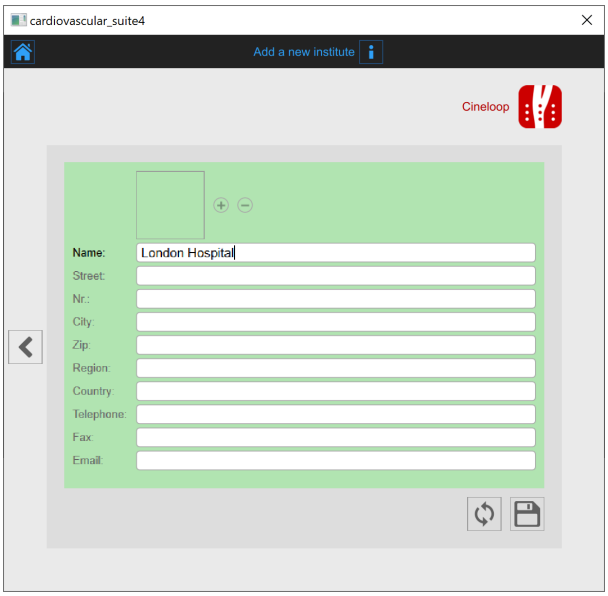


In this tab, you can select the institute among the ones already present in the Archive. Select the **institute and click on the Next button (you can simply double-click on the institute to proceed).**

If you want to create a new institute, click of the Add New Institute button.
In the Add new institute frame, enter the institute data. The mandatory field (Name) is in red until you have filled in the Name blank. Click on the Save button to save the institute data.



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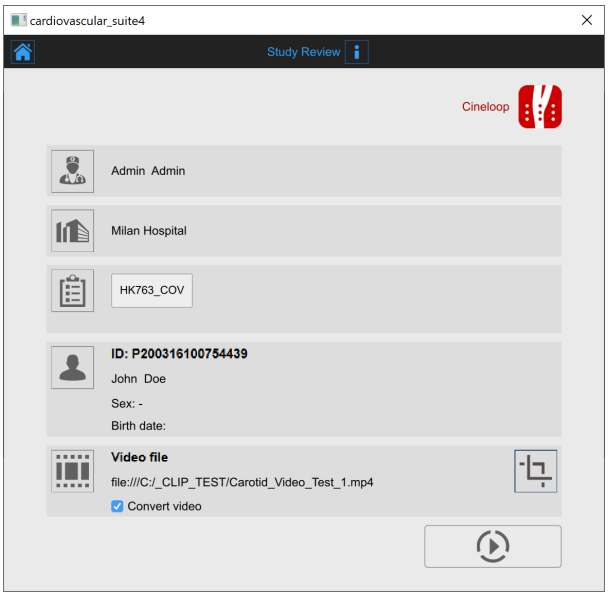
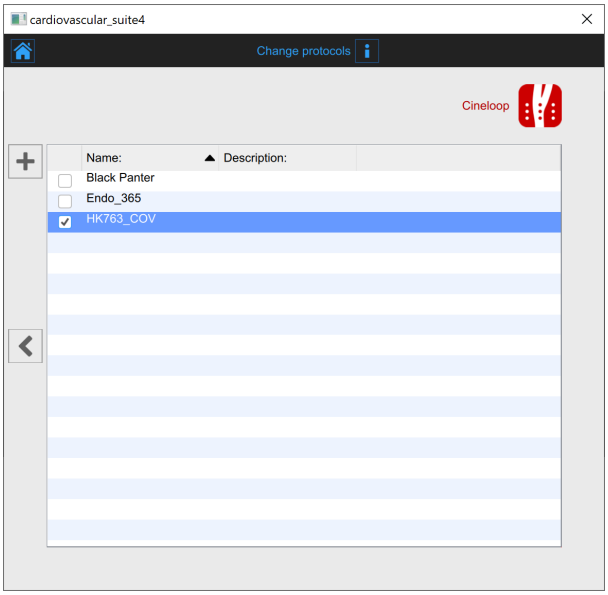
10.1.5 **Review**



In this tab you can review your selection (you can also change Patient and Institute by clicking on their buttons). It is possible also to change the selected source for this study by clicking on the icon that represents the source.

Here, the user has the possibility to associate the study to one or more existing protocols, by clicking on the protocols icon .



In the Protocols tab, you can associate the study to one or more than one protocols already present in the Archive. Put a tick on the protocol you want to associate the study with. If you want to create a new protocol, click of the Add New protocol button. In the Add new protocol frame, enter the protocol data. The mandatory field (Name) is in red until you have filled in the Name blank. Click on the Save button to save the protocol data.

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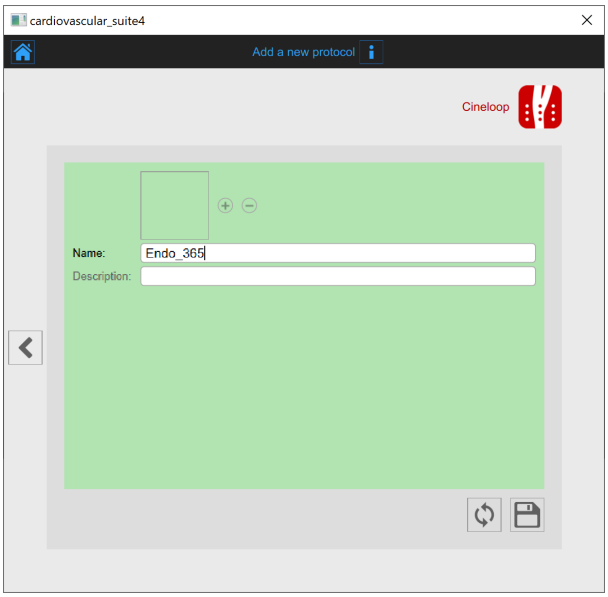

Click on the Previous button to go back to the review window.

> If in the Settings manager the option "Remember last used protocols" is checked, the study will be associated by default with the last used protocols.

In addition, if you have chosen a video file as source, in the review window, it is possible to convert the video file to be optimized for the analysis with Carotid Studio. This operation may take few minutes.

> The default value of the "Convert video" checkbox is set by the "Convert video by default" option in the Settings manager.

You can also crop the images by clicking the Crop button in the source panel. In this case, a new window opens; it is possible to select a region to be used for the analysis. Click on the Confirm button after you have drawn the region.

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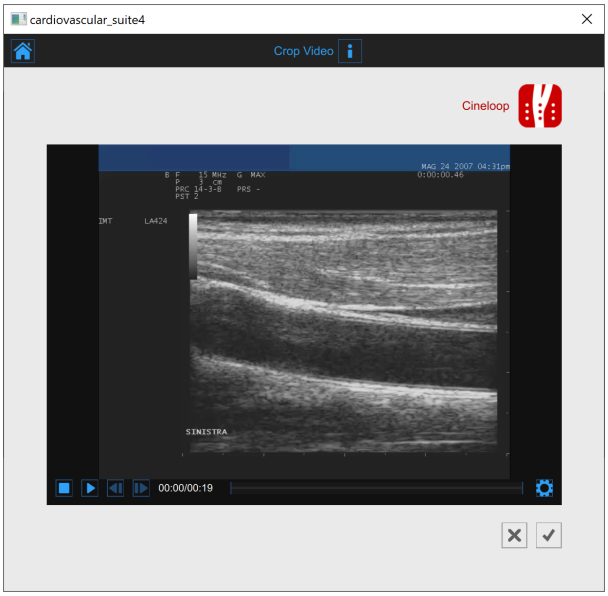
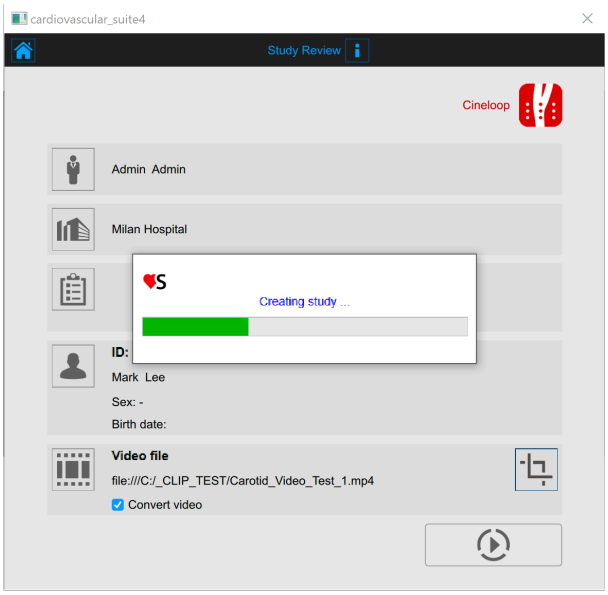


Click on the Start the Study button to proceed. A progress bar, as shown in the following picture, will show you the progression of the study creation.



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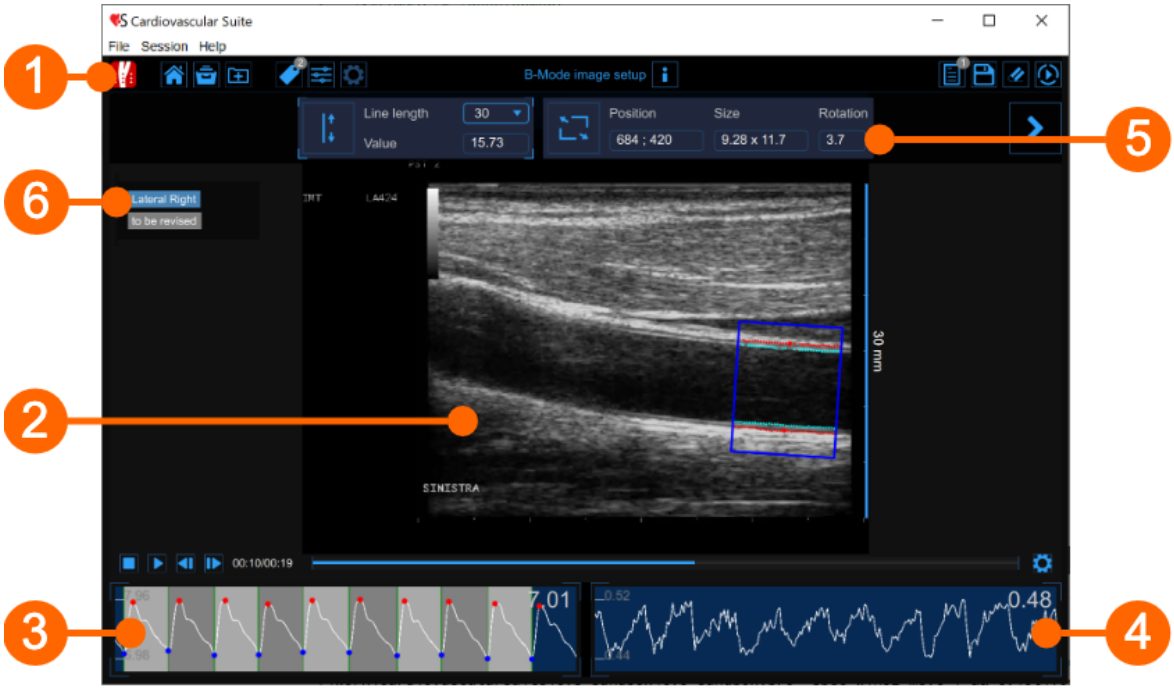
10.2 Cineloop study analysis

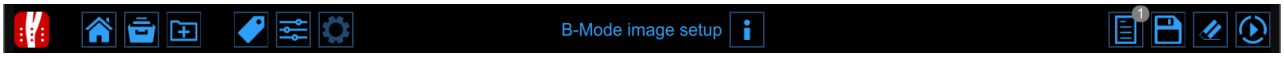


The analysis window contains the following components:

1. Top bar
2. Video window
3. Diameter chart
4. IMT chart
5. Setup panel
6. Tags

10.2.1 Top bar

The top bar contains some essential information for the navigation. Several icons are displayed.



The Carotid Studio  button shows information about the study and about Cardiovascular Suite. Regarding the study, the number identification (ID) is displayed together with information about patient and the institute. Information about the software such as version and type of license are shown in the upper part of the windows, as the following figure:

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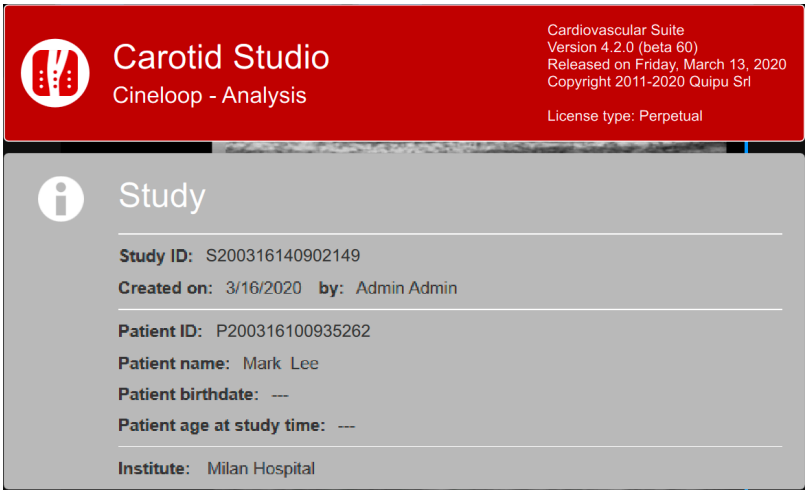

The Home button closes the Carotid Studio application and returns to the home screen of Cardiovascular Suite.

The Archive button closes the Carotid Studio application and returns to the archive of Cardiovascular Suite.

The New video button allow to open a new video for the analysis.

The Tags Management button opens the tag management panel as described in Tags.

The Preset Management button opens the preset management panel as described in Presets.

The Setup Panel button is used to show the setup panel when it is hidden.

The Info button shows information about active controls (calibration lines, ROI, etc.).

The Start Exam button starts the examination. While the analysis is collecting data, a red led advises that the recording is in progress.

The Save button saves a document of the study. With the Cancel button it is possible to cancel the analysis and delete data in the Diameter and IMT charts.

The Review Documents button allows to suspend the analysis and to review the documents saved in the current analysis session. The button is only activated if you saved at least one document.

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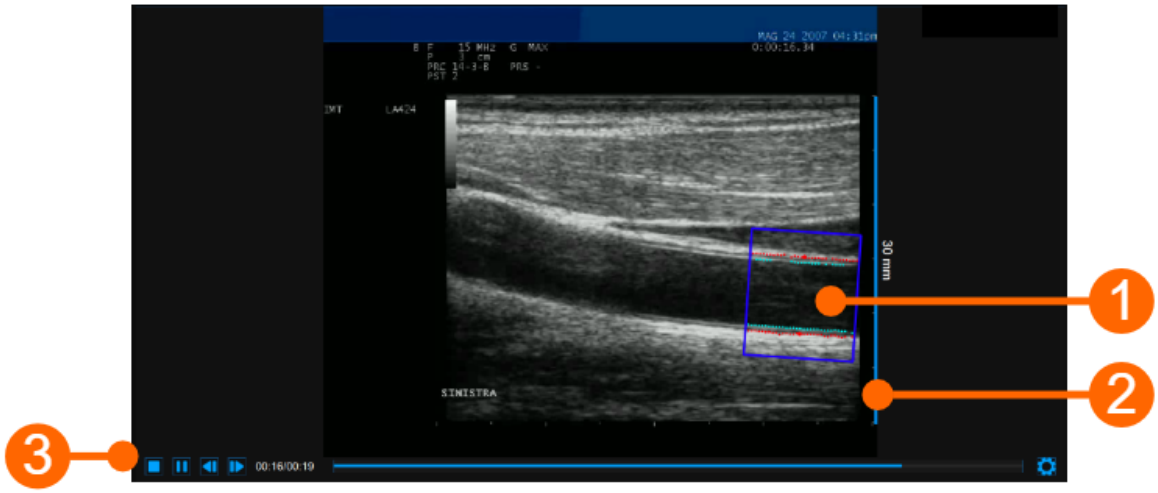
10.2.2 Video window

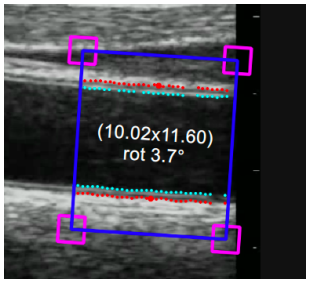


The video window shows the video signal from your ultrasound system. A ROI **(1)** can be traced in the video windows, where both the IMT and the diameter are computed.

The window also contains the calibration line **(2)** for the B-mode image once it has been calibrated. The video controls bar **(3)** is located at the bottom of the window. For more information on the video controls, see Video and image player.

10.2.2.1 ROI

The Region of Interest (ROI) is the portion of the image where both the diameter and the IMT are calculated. The points of the Lumen-Intima interface and the Media-Adventitia interface are displayed within the ROI in cyan and red color respectively. The ROI can be moved, resized, and/or rotated. Each time you change the position, size and/or inclination of the ROI, the analysis is re-initialized.



Draw a new ROI:

You can manually draw the diameter ROI with the desired size and position. If the image is already calibrated, you can also more quickly draw a diameter ROI with the default sizes set in Carotid Studio settings (a star in the Set ROI button will indicate that the default ROI can be drawn). The default ROI is also automatically rotated so to be parallel to the carotid artery.

default ROI drawing

- Click on the Set ROI button in the Setup panel (the button remains active)
- Click in the video window in the center of the carotid artery.

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- A ROI of the default ROI sizes will be automatically initialized.

manual drawing

- Click on the Set ROI button in the Setup panel (the button remains active).
- Click inside the video window and drag until the ROI is complete (the size of the ROI is shown in the Setup panel and graphically within the ROI).
- When you release the mouse, the analysis is initialized.

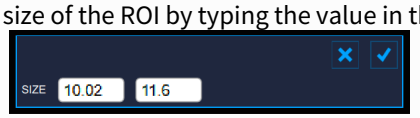
Rotate the ROI:

- Click on the upper side of the ROI and use the special cursor that indicates a rotation.
- Hold inside the ROI, drag the rectangle by rotating it to the desired angle.

> As an alternative, you can modify the position of the ROI by typing the value in the Setup panel.
>
> 
>

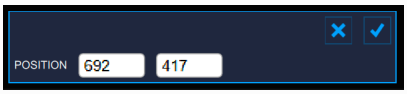
Resize the ROI:

- Click on one of the sides or one of the corners of the ROI.
- Drag to change the size of the the ROI.

> An alternative, you can modify the size of the ROI by typing the value in the Setup panel.
>
> 
>

Move the ROI:

- Click and hold inside the ROI.
- Drag the ROI to the location of interest.

> As an alternative, you can modify the position of the ROI by typing the value in the Setup panel.
>
> 
>

Re-initialize the ROI:

- Double click inside the Diameter ROI to re-initialize the position and the rotation of the ROI

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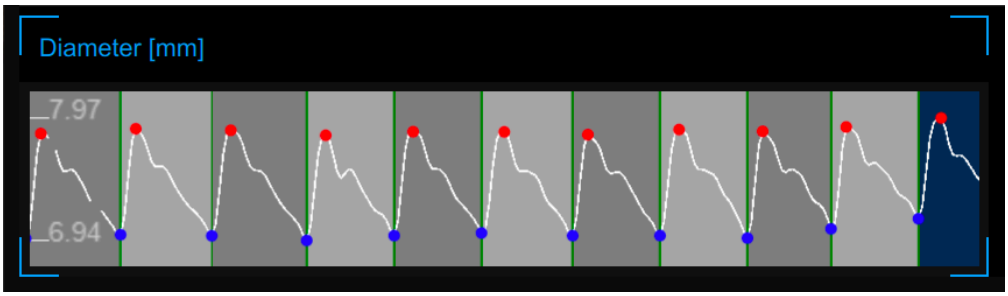
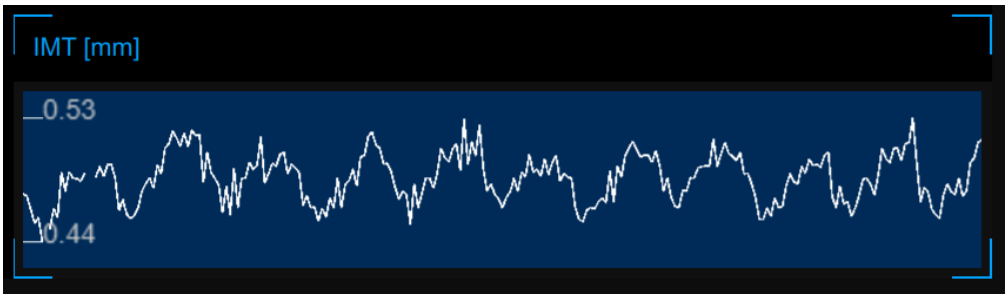
10.2.3 Diameter chart



The chart shows the trend of the diameter during the examination. During the analysis, Carotid Studio recognizes the heart cycles that are shown in dark and light gray alternatively. The red points in the chart are the systolic diameters and the blue points are the diastolic diameters.

10.2.4 IMT chart



The chart shows the trend of the IMT during the examination.

10.2.5 Setup panel

The setup panel must be used to set the recording data length, to Calibrate the B-mode image, to set the ROI, the *sensitivity* of the algorithm and the systolic and diastolic blood pressures.

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10.2.5.1 B-mode image setup

Calibration

The Set Calibration  button is used to Calibrate the B-mode image.

The drop-down menu **(1)** shows the length of the line used for the calibration.

The numeric display **(2)** shows the calibration value.

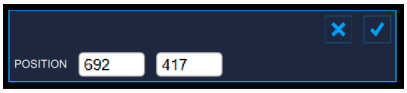
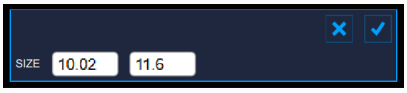
> If you click in the value field, you are allowed to manually enter the calibration value in the editable field (if you already know the value). The click the Save button to enter the values.
>
> 
>

ROI

The Set ROI  button is used to set the ROI.

The numeric display **(3)** shows the center position, in pixels, of the ROI.

The numeric display **(4)** shows the size (width x height), in pixels, of the ROI.

> If you click in the value field, you are allowed to manually enter the ROI position and size values in the editable fields (if you already know the values). The click the Save button to enter the values.
>
> 
>
>
> 
>

The numeric displays **(8)** show the degree of rotation of the ROI.

> If you click in the value field, you are allowed to manually enter the degree value of rotation.
>
> 
>

Sensitivity

The slider **(5)** sets the sensitivity of the algorithm. Adjust this value in order to have a better detection of the intima-media border and the media-adventitia border.

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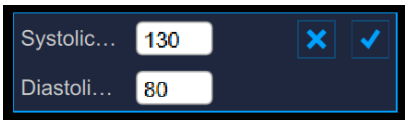
10.2.5.2 Recording Data Length

The drop-down menu **(6)** shows the time length of the diameter and IMT data recording.

10.2.5.3 Blood Pressure

The numeric displays **(7)** show the values of systolic and diastolic blood pressure. If you click in the value field, you are allowed to manually enter the values of systolic and diastolic blood pressure. The click the Save button to enter the values.



If present, these values will be used to compute the stiffness parameters. For this purpose, the local carotid pressure should be used: in this case the carotid waveform is obtained by tonometer or similar device and it is generally calibrated by brachial measurement (sphygmomanometer) assuming that mean and diastolic values are constant along the arterial tree. For more information you can see:

"Reference values for local arterial stiffness. Part A: Carotid artery", Engelen L, Bossuyt J, Ferreira I et al., *J Hypertens.* 2015 Oct;33(10):1981-96

"Expert consensus document on arterial stiffness: methodological issues and clinical applications.", S. Laurent, J. Cockcroft, L. Van Bortel et al., *Eur Heart J.* 2006 Nov;27(21):2588-605

Once you have calibrated the B-Mode image and set the ROI, click on the Next button to proceed to set the recording the data length and the blood pressure. Alternatively, you can click on the Start study button to start the analysis.

10.2.6 Tags

The Tags Management button opens a panel that allows to associate a tag to the document, or create a new tag. Carotid studio can use two types of tags:

1. System tags, which are already defined in Cardiovascular Suite. System tags are used to specify which segment of the Carotid artery is analysed, and are necessary to include the document data in the study report. Only one system tag can be associated to a document.
2. Custom tags, which are defined by the user and are used to better identify a document.

Custom tags can also be managed through the Tags management into the Archive.

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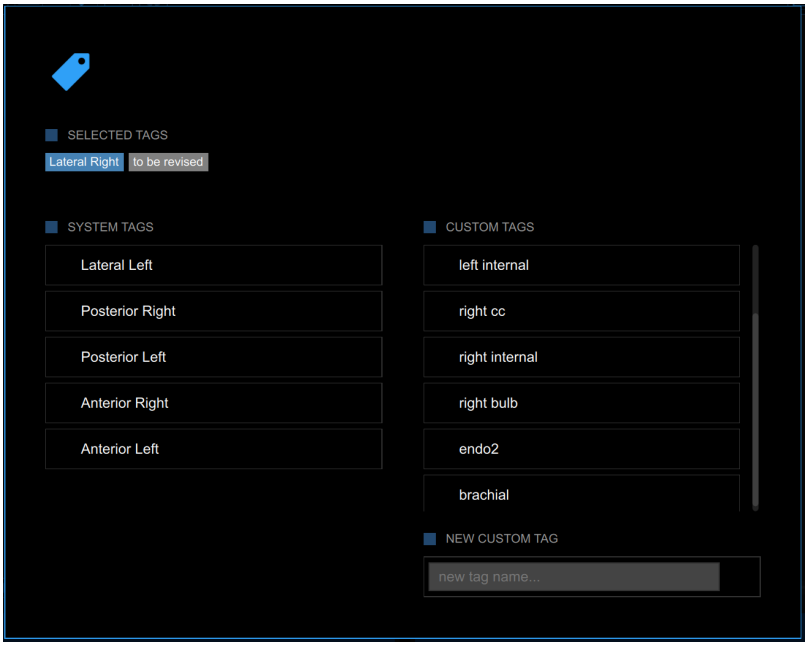

The selected tags are visible in a special area of the Analysis window. The tags area can me moved by right clicking and dragging.

10.2.7 Presets

The preset management  button opens the preset management panel that allows to manage presets. In particular, it allows to remember the settings of:

- B-mode image calibration
- B-mode image ROI (size, position, and rotation)
- recording time

A preset can be saved and reused for following studies.

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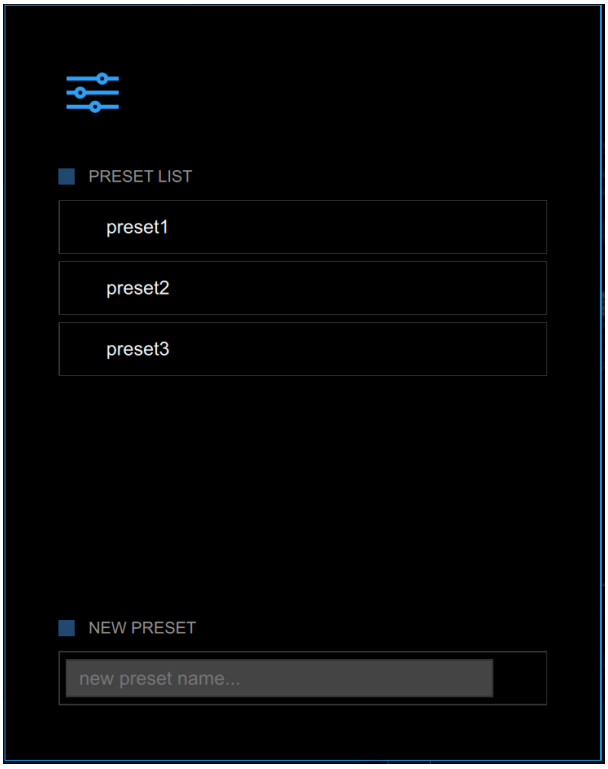
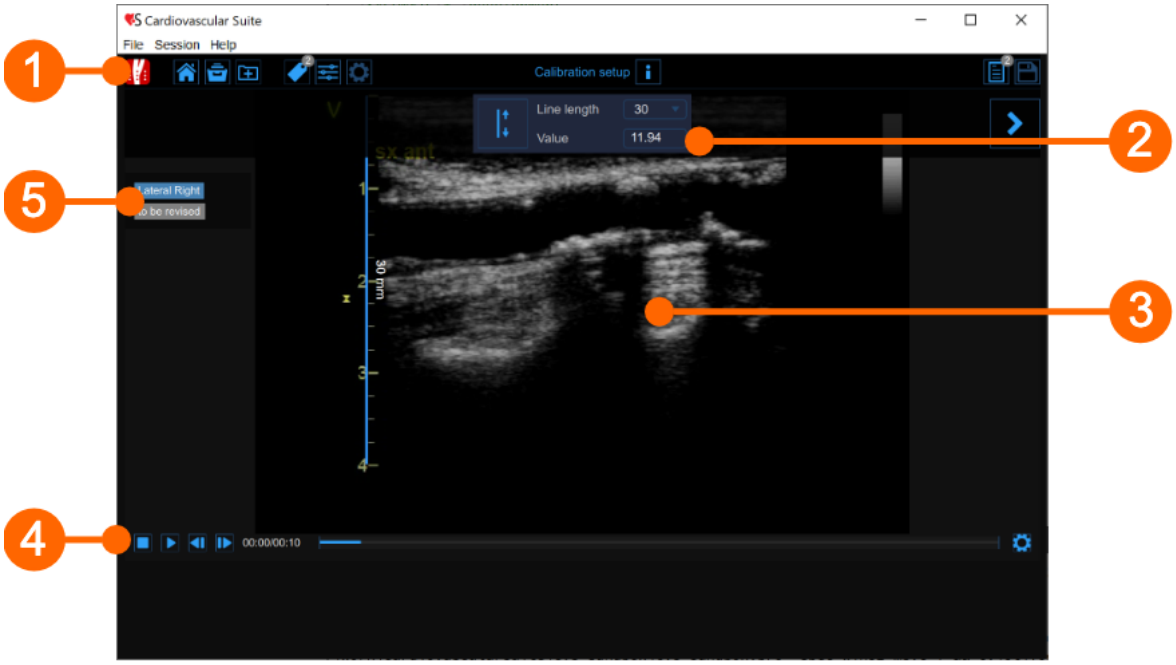


10.3 Single image study analysis



Carotid Studio single image modality analyses image files or a single image selected from a video file and allows to perform two different types of analysis:

- IMT analysis

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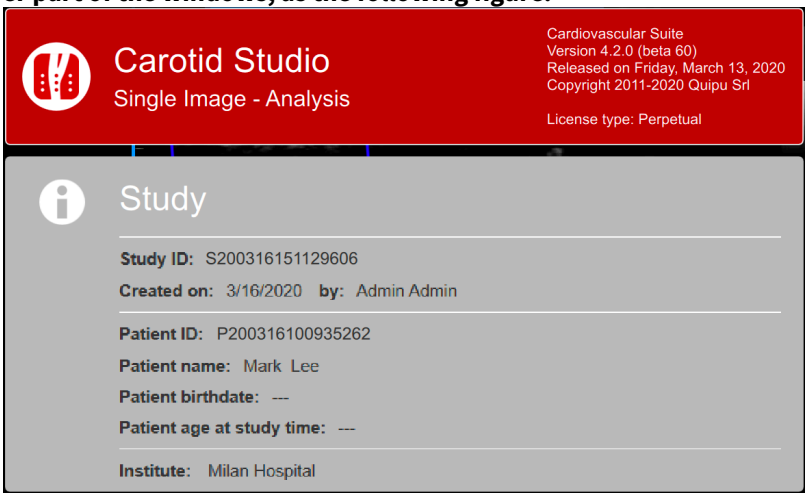
- Plaque analysis

The single image analysis window contains the following components:

1. **Top bar**

The top bar contains some essential information for the navigation. Several icons are displayed.

The Carotid Studio button shows information about the study and about Cardiovascular Suite. Regarding the study, the number identification (ID) is displayed together with information about patient and the institute. Information about the software such as version and type of license are shown in the upper part of the windows, as the following figure:



The home button closes the Carotid Studio application and returns to the home screen of Cardiovascular Suite.

The Archive button closes the Carotid Studio application and returns to the archive of Cardiovascular Suite.

The New video/image button allow to open a new video/image for the analysis.

The Tags Management button opens the tag management panel as described in Tags.

The preset management button opens the preset management panel as described in Presets.

The Info button shows information about active controls (calibration lines, ROI, etc.). The icon is used to show the setup panel when it is hidden.

The Freeze/Run / button suspends and resume the image acquisition (present in real-time analysis only).

The Save button saves a documents of the study.

The Review Documents button allows to suspend the analysis and to review the documents saved in the current analysis session. The button is only activated if you saved at least one document.

2. **Setup panel**
The setup panel must be used to Calibrate the B-mode image.

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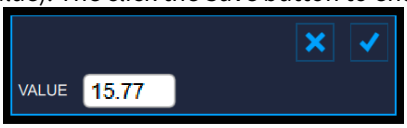
Calibration

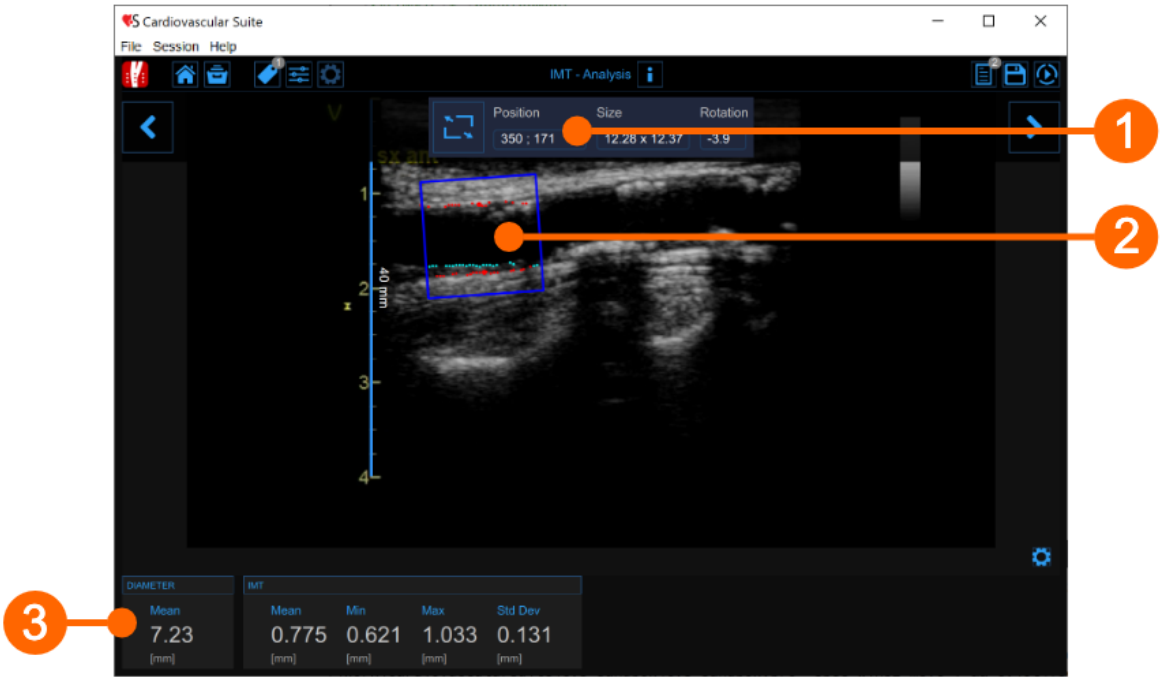
The Set Calibration button is used to Calibrate the B-mode image. The drop-down menu shows the length of the line used for the calibration. The numeric display shows the calibration value.

> If you click in the value field, you are allowed to manually enter the calibration value in the editable field (if you already know the value). The click the Save button to enter the values.
>
> 
>

3. **Image window**
   The media window shows the media file that is analyzed.

4. **Image window control bar**
   The media window control bar is at the bottom of the media window and contains controls to manage the playback of a movie (only in case of video file) and the brightness and contrast adjustment.
5. **Tags Area**
   The selected tags are visible in this area. The tags area can me moved by right clicking and dragging.

10.3.1 IMT analysis



The IMT analysis window contains the following components:

1 Setup panel

The Set ROI button is used to set the ROI.

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The numeric display "Position" shows the position, in pixels, of the ROI (central point). The numeric display "Size" shows the size (width x height), in pixels, of the ROI. The numeric display "Rotation" shows the degree of rotation of the ROI (degrees).

NOTE: if you click in the value fields, you are allowed to manually enter the ROI position, the size, and the rotation in the editable fields (if you already know the values). The click the Save button to enter the values.

2 ROI

The Region of Interest (ROI) is the portion of the image where both the diameter and the IMT are calculated. The points of the Lumen-Intima interface and the Media-Adventitia interface are displayed within the ROI in cyan and red color respectively. The ROI can be moved, resized, and/or rotated. Each time you change the position, size and/or inclination of the ROI, the analysis is re-initialized.

Draw a new ROI:

You can manually draw the diameter ROI with the desired size and position. If the image is already calibrated, you can also more quickly draw a diameter ROI with the default sizes set in Carotid Studio settings (a star in the Set ROI button will indicate that the default ROI can be drawn). The default ROI is also automatically rotated so to be parallel to the carotid artery.

default ROI drawing

- Click on the Set ROI button in the Setup panel (the button remains active)
- Click in the video window in the center of the carotid artery.
- A ROI of the default ROI sizes will be automatically initialized.

manual drawing

- Click on the Set ROI button in the Setup panel (the button remains active).
- Click inside the video window and drag until the ROI is complete (the size of the ROI is shown in the Setup panel and graphically within the ROI).
- When you release the mouse, the analysis is initialized.

Rotate the ROI:

- Click immediately outside the ROI (a special cursor that indicates a rotation is shown)
- Hold inside the ROI, drag the rectangle by rotating it to the desired angle

> As an alternative, you can modify the position of the ROI by typing the value in the Setup Panel.

Resize the ROI:

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- Click on one of the sides or one of the corners of the ROI.
- Drag to change the size of the ROI.

> As an alternative, you can modify the size of the ROI by typing the value in the Setup Panel.

Move the ROI:

- Click and hold inside the ROI.
- Drag the ROI to the location of interest.

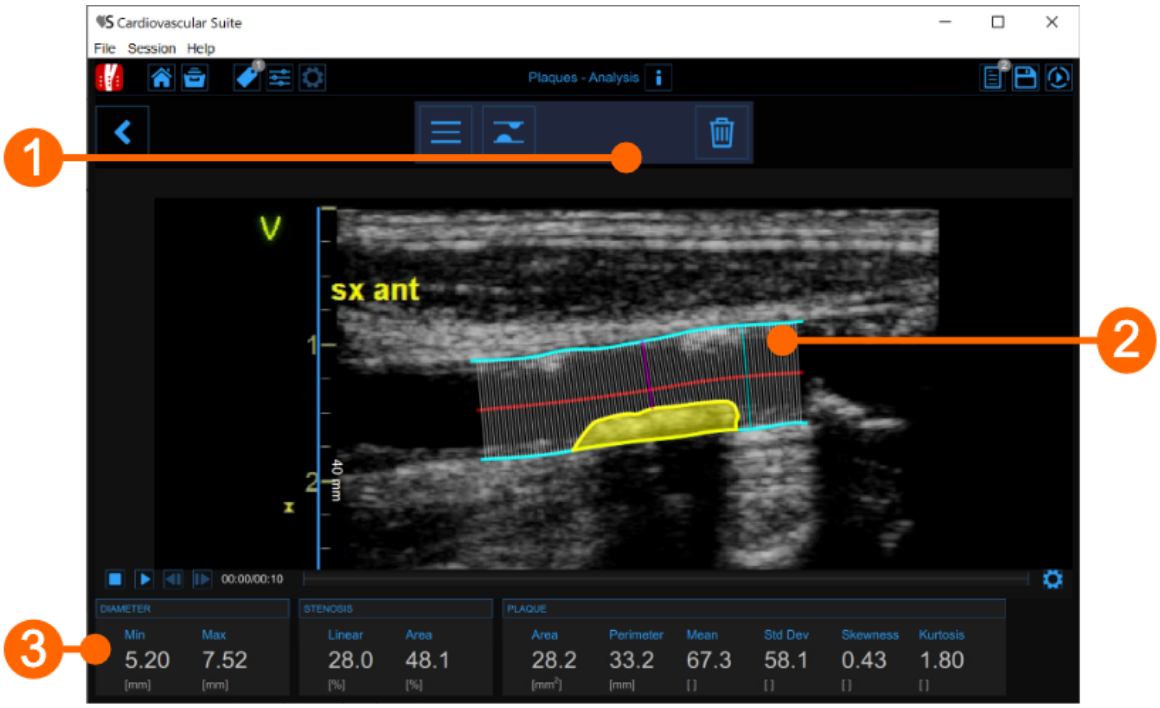
> As an alternative, you can modify the position of the ROI by typing the value in the Setup Panel.

Re-initialize the ROI:

- Double click inside the Diameter ROI to re-initialize the position and the rotation of the ROI.

3 Data panel
This panel contains the computed values. In particular, it shows the mean diameter value and minimum, maximum, mean, and standard deviation of IMT.

10.3.2 Plaque analysis



The plaque analysis window contains the following components:

1. **Setup panel**
   It contains the controls for tracing of the vessel borders, drawing a plaque and delete it.

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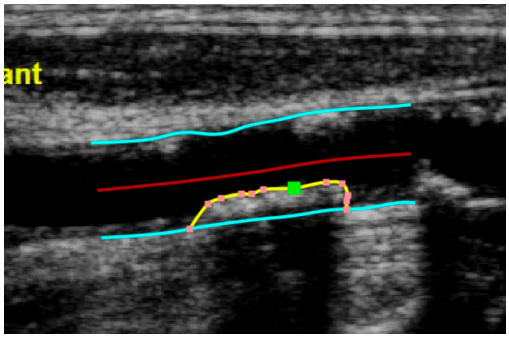
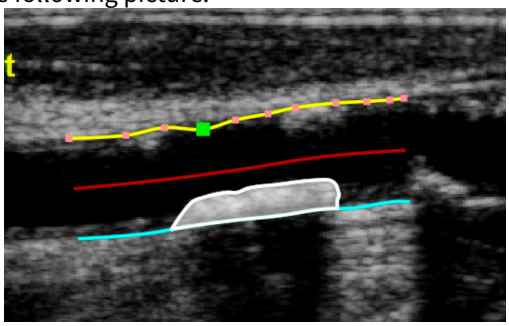
2. **Plaque analysis tool**
   The Trace borders  button is used to manually trace the borders of the vessel. The user has to trace point-by-point the vessel edges and the software interpolates them. It is possible to modify the points by dragging them, as shown in the following picture.



   After the two borders are traced, the software automatically compute the minimum and maximum values of the diameter and the linear and circular values of the stenosis. The Draw plaque  button is used to manually draw the profile of a plaque. The user has to trace point-by-point the plaque profile and the software interpolates them. Also in this case, it is possible to modify the points by dragging them and to delete a plaque, as shown in the following picture.



   After the plaque is drawn, the software automatically computes its area, perimeter, and the mean, standard deviation, skewness, and kurtosis of its grey level.

3. **Data panel**
   This panel contains the computed values. In particular, it shows the minimum and maximum values of the diameter and the linear and circular values of the stenosis. In addition, if a plaque has been drawn, it also displays its area and perimeter, and the mean, standard deviation, skewness, and kurtosis value of its grey level.

10.3.3 Tags

The Tags Management  button opens a panel that allows to associate a tag to the document, or create a new tag. Carotid studio can use two types of tags:

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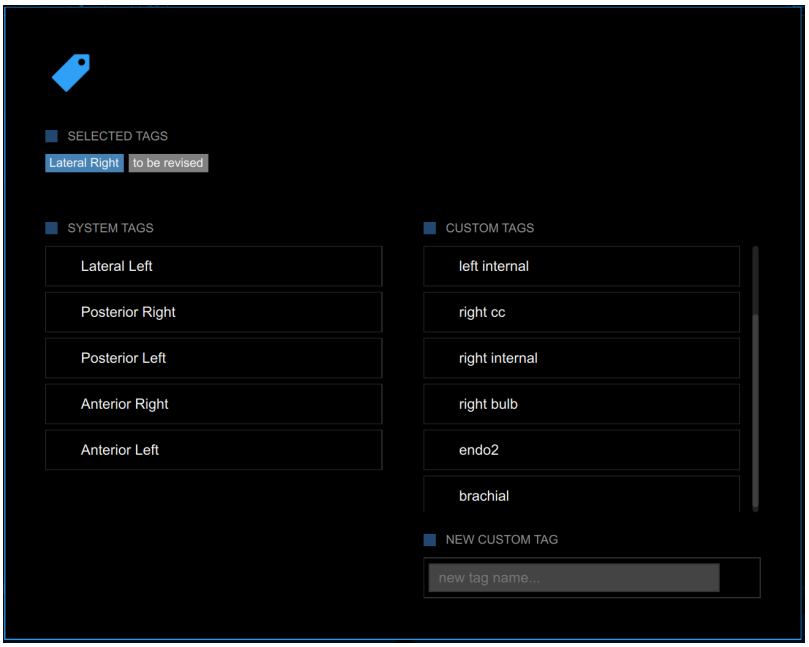
1. System tags, which are already defined in Cardiovascular Suite. System tags are used to specify which segment of the Carotid artery is analysed, and are necessary to include the document data in the study report. Only one system tag can be associated to a document.
2. Custom tags, which are defined by the user and are used to better identify a document.

Custom tags can also be managed through the Tags management into the Archive.



The selected tags are visible in a special area of the Analysis window. The tags area can me moved by right clicking and dragging.

10.3.4 Presets

The preset management  button opens the preset management panel that allows to manage presets. In particular, it allows to remember the settings of:

- B-mode image calibration
- B-mode image ROI (size, position, and rotation)

A preset can be saved and reused for following studies.

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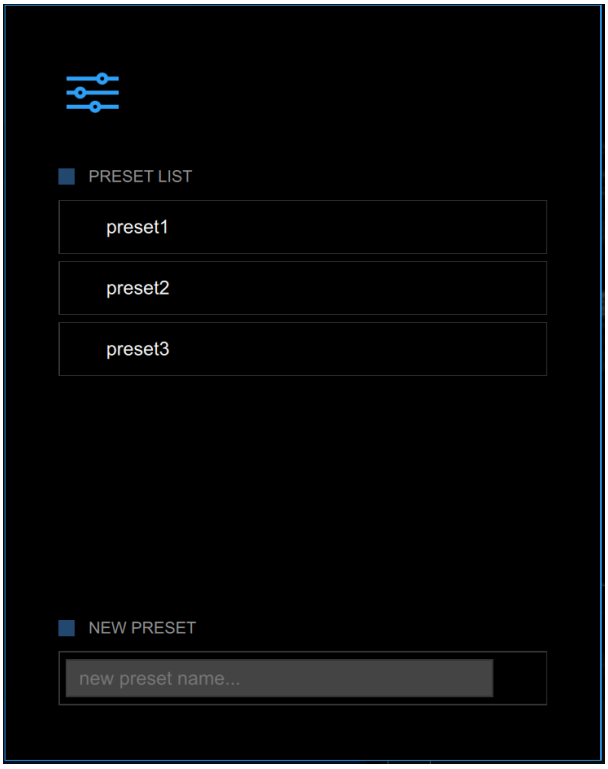
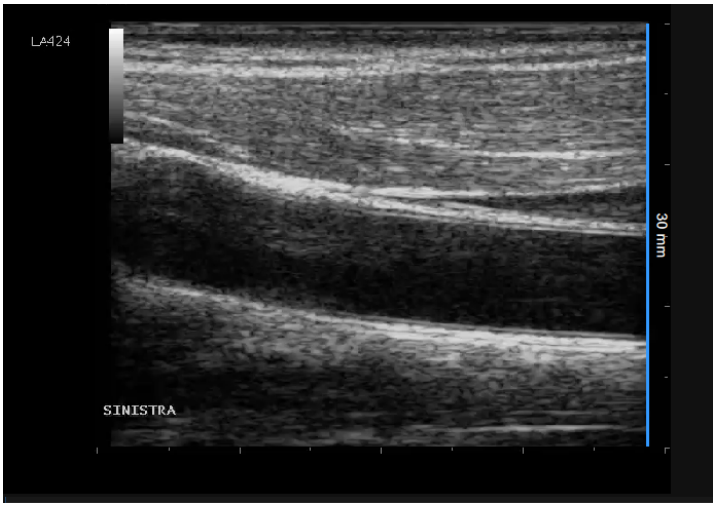


10.4 Calibrate the B-mode image

The calibration of the images must be done before starting a new examination because it is necessary to provide information about the size of the image generated by ultrasound system. The calibration factor changes depending on the settings of your ultrasound machine. You should check the calibration at each new examination.

> **CAUTION: the lack of calibration can generate a software malfunction.**



- Locate, in ultrasound image, a range of known distance (30 mm. in the example of figure).

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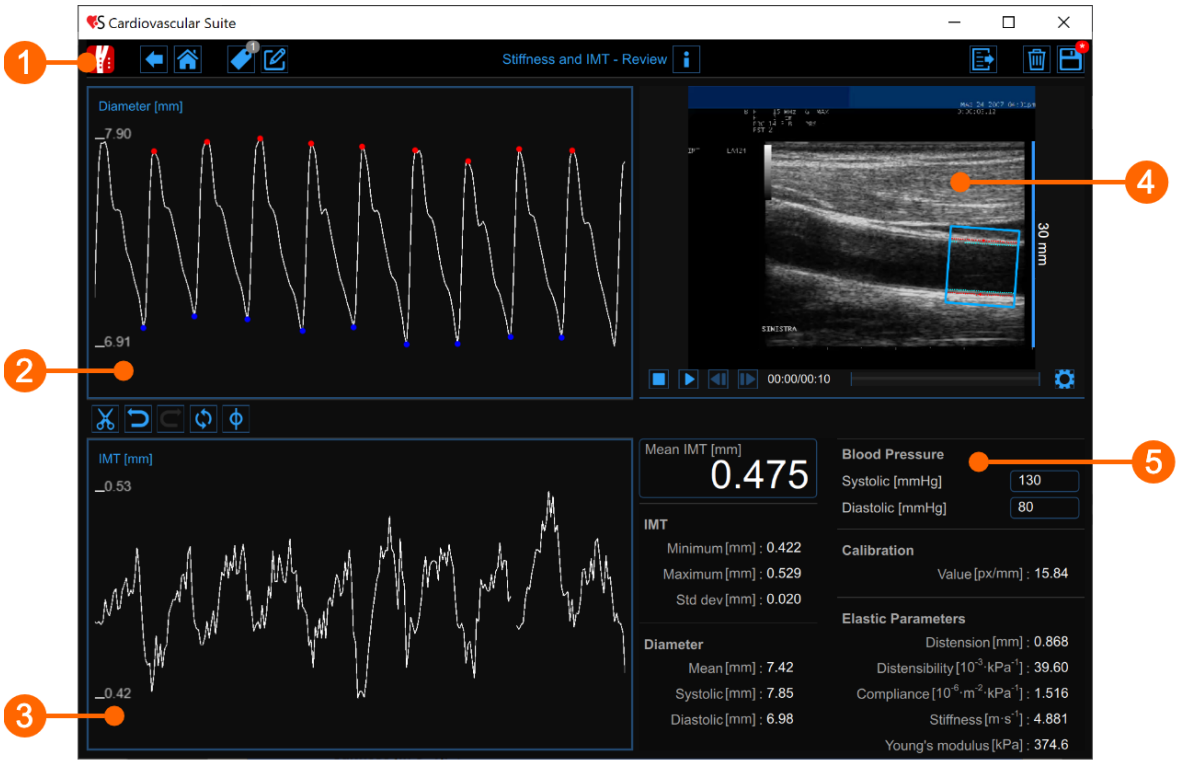
- In the B-mode setup panel, select from the drop-down menu, the distance specified above.
- In the B-mode setup panel, click on the Set B-Mode Calibration button (button remains active).
- Draw a line on the image corresponding to the known distance: click on one end and drag the mouse to the other extreme (press the Shift key or CTRL Shift keys on your keyboard if you want the line to be not vertical or horizontal).

For DICOM files, when present, the B-mode calibration is be obtained automatically by the file metadata (see Settings). You can anyhow modify the calibration value.

You can directly type the calibration value in the Calibration factor field of the B-mode setup panel if you already know the value.

10.5 Cineloop study review



The Review window shows the result of the analysis and allows you to remove piece of data that are considered to be "outliers". In the Review window you can review both the images and the result of the analysis and decide to remove the data that were generated in this time interval.

The Review window contains the following components:

1. Top bar
2. Diameter chart
3. IMT chart
4. Video window

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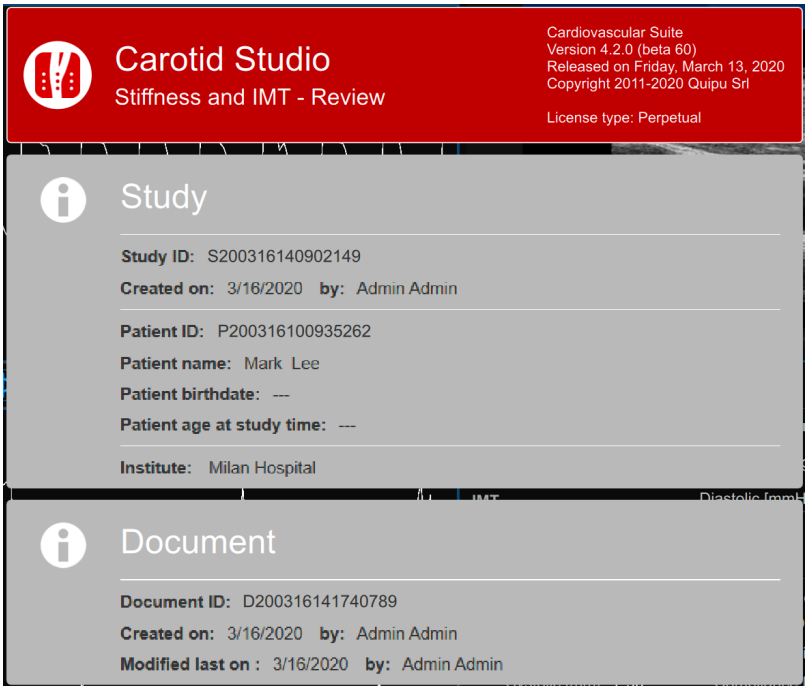
5. Results panel

10.5.1 Top bar

The top bar contains some essential information for the navigation.

The Carotid Studio button shows a panel containing some information about Cardiovascular Suite, about the current study and the current document. Regarding the study, the study ID is displayed together with information about the patient and the institute. In addition, info regarding the current document are provided. Information about the software, such as version and type of license, are shown in the upper part of the panel.



The home button closes the Carotid Studio application and returns to the home screen of Cardiovascular Suite. The back button closes the Carotid Studio application and comes back to the Archive.

The Tags Management button opens a panel (see the following picture) that allows to create a new tag and associate it or an existing tag to the document. Tags can be managed through the Tags management into the Archive.

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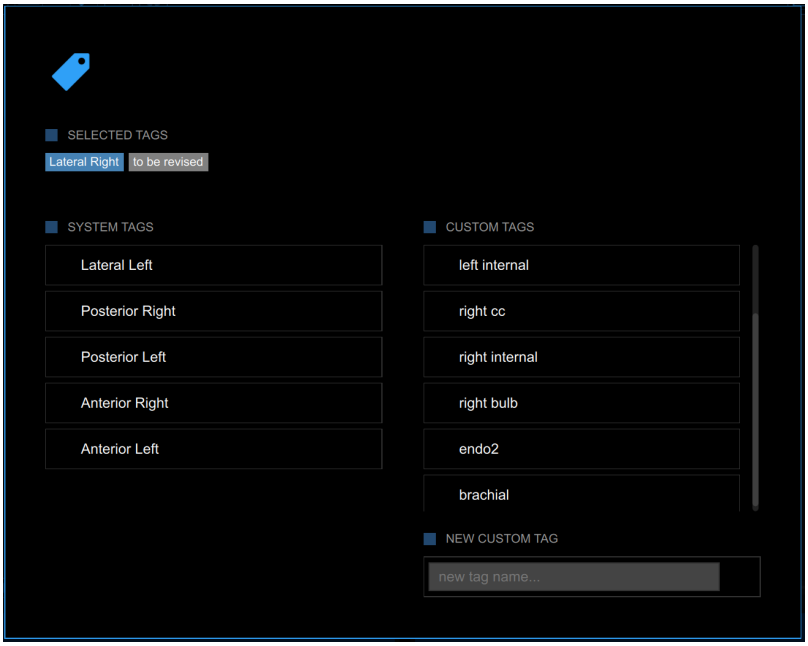
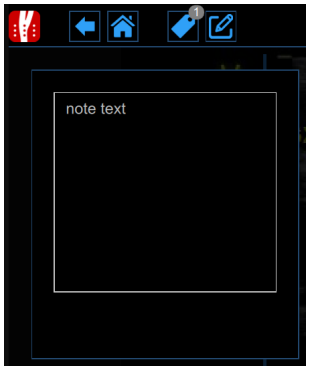


The Notes button can be used to enter a note in the document.



The Save button is used to save your changes to the document, once you have edited the data.

The Delete the document button is used to delete the current document.

The Export button is used to export your data. You can export the Document Results and the Document Data.

The **Document Results** contains all the results of the analysis and all the information about the study, the document and the patient.

The **Document Data** contains all the Document Results, a list of the Diameter and the IMT values computed at each frame.

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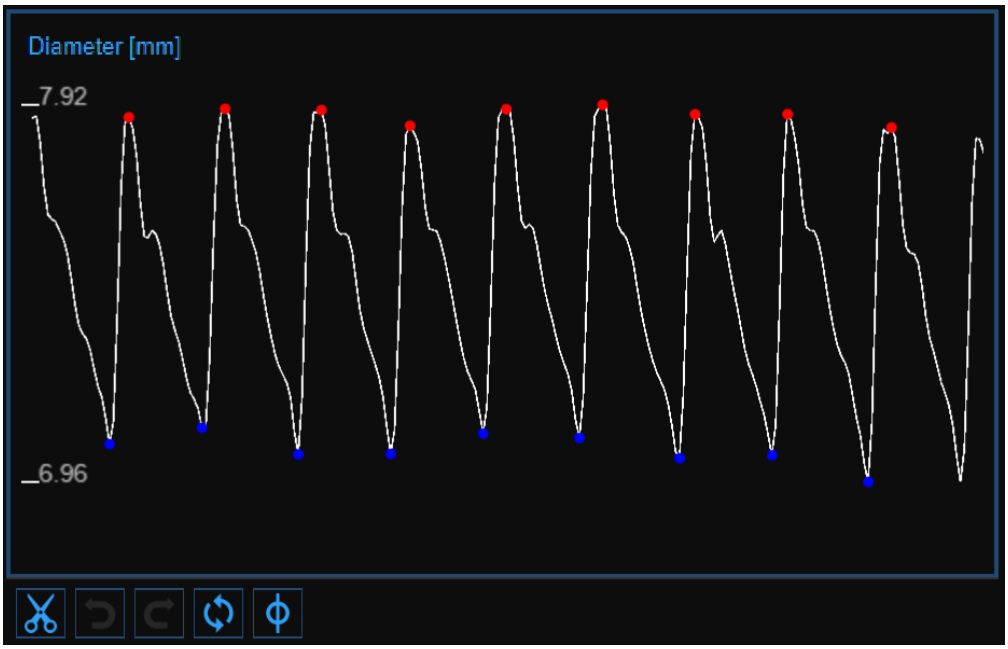
10.5.2 Diameter chart



The chart shows the trend of the diameter. The buttons on the bottom can be used for editing the chart and removing the outliers.

10.5.2.1 Remove the outliers

- Click on the Cut button. The heart cycle will be highlighted in the diameter chart.
- Click on the cardiac cycles you want to remove.
- Once you have removed the outliers, the data on the Results panel will be automatically updated.

You can use the undo and redo buttons to cancel and restore your changes. The Restore button cancels all your changes and restore original data.

Click on the Save button in the Top Bar to save your changes to the document.

10.5.2.2 Graph cursors

As shown in the following figure, the Cursor button **(1)** activates a cursor **(2)** on the Diameter chart that shows the current time position on the graph according to the images shown in the Video window. The coordinates (diameter value in millimeters and time value in the format *minutes:seconds.milliseconds*) of the cursor are dynamically updated and shown in **(3)**. When the Cursor button is active, it is also possible to know the coordinates of an exact point in the graph; it is only needed to hover over the chart and a second cursor **(4)** is displayed. It follows the mouse movements and the exact coordinates of the point are shown in the label **(5)** (diameter value is expressed in millimeters and the time value has the format *minutes:seconds.milliseconds*).

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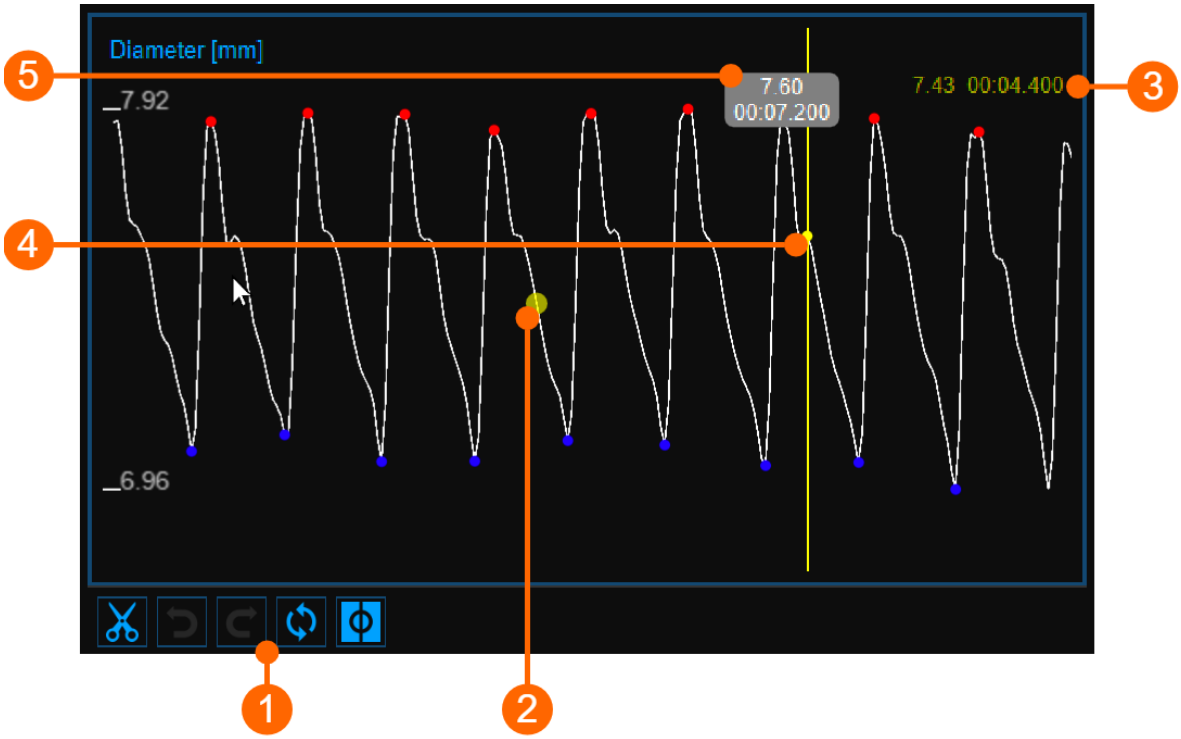
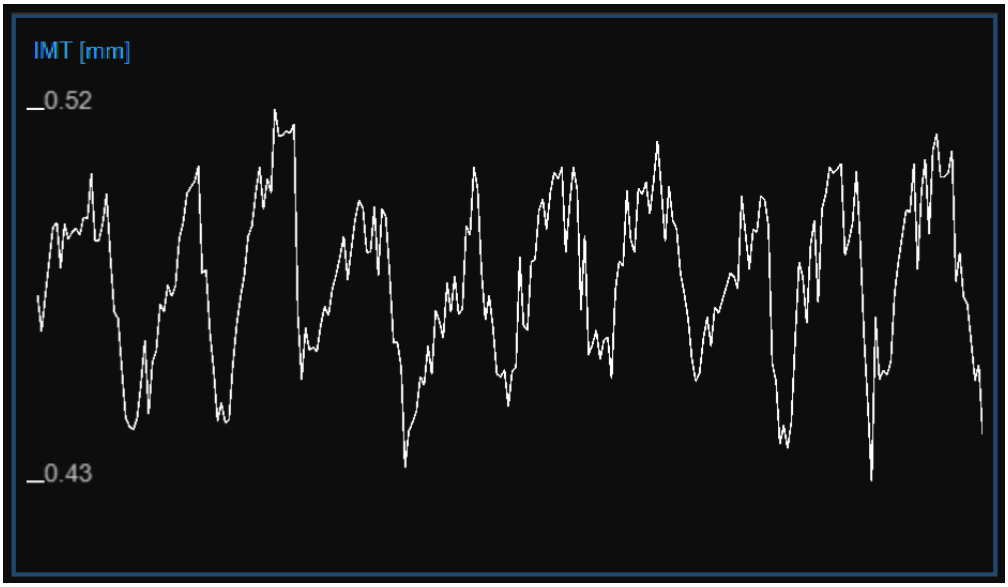


10.5.3 IMT chart



The chart shows the trend of the IMT. The buttons at the top can be used for editing the chart and removing the outliers.

10.5.3.1 Remove the outliers

- Click on the Cut button.

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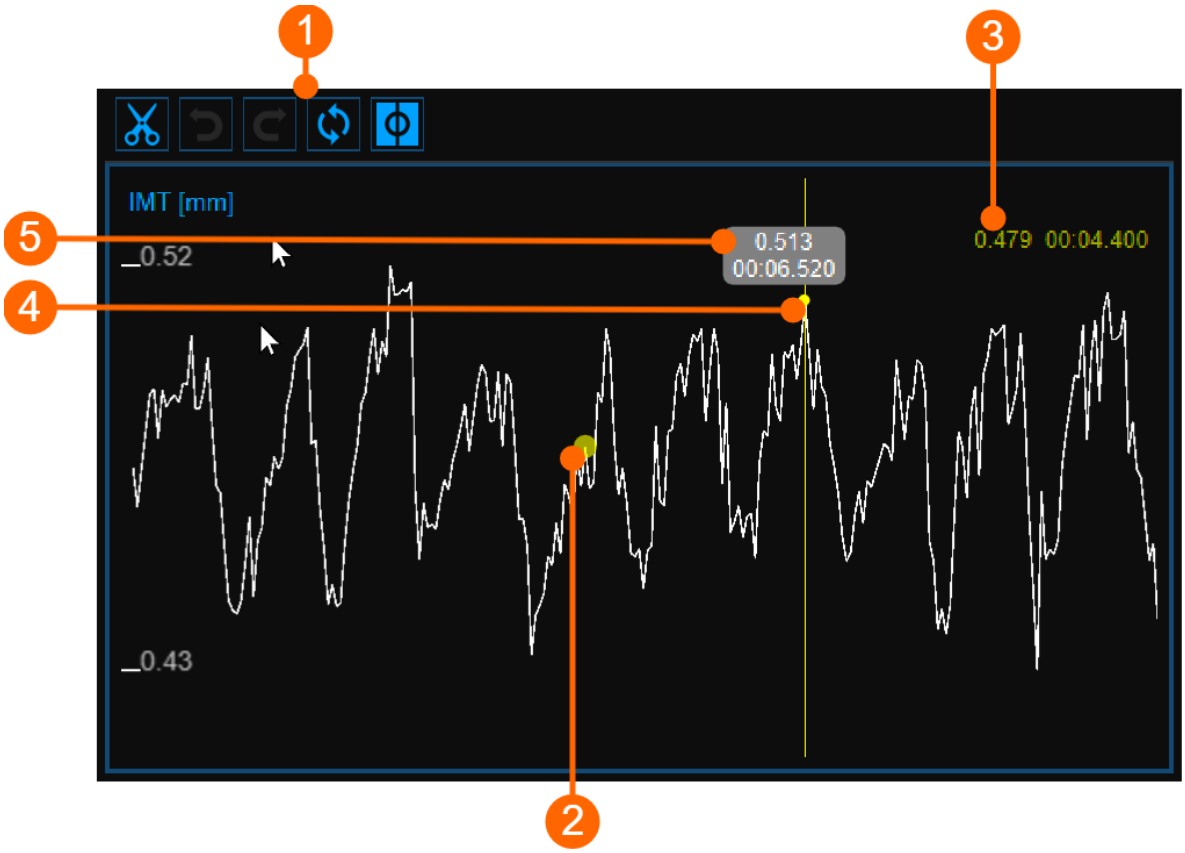
- In the IMT chart, click on one of the two extremes of the range to be deleted.
- Drag the mouse horizontally to the other extreme of the range to be deleted.
- Once you have removed the outliers, the data on the Results panel will be automatically updated.

You can use the undo and redo buttons to cancel and restore your changes. The restore button cancels all your changes and restore original data.

Note: Click on the Save button in the Top bar to save your changes to the document.

10.5.3.2 Graph cursors

As shown in the following figure, the Cursor button **(1)** activates a cursor **(2)** on the IMT chart that shows the current time position on the graph according to the images shown in the Video window. The coordinates (IMT value in millimeters and time value in the format *minutes:seconds.milliseconds*) of the cursor are dynamically updated and shown in **(3)**. When the Cursor button is active, it is also possible to know the coordinates of an exact point in the graph; it is only needed to hover over the chart and a second cursor **(4)** is displayed. It follows the mouse movements and the exact coordinates of the point are shown in the label **(5)** (IMT value is expressed in millimeters and the time value has the format *minutes:seconds.milliseconds*).



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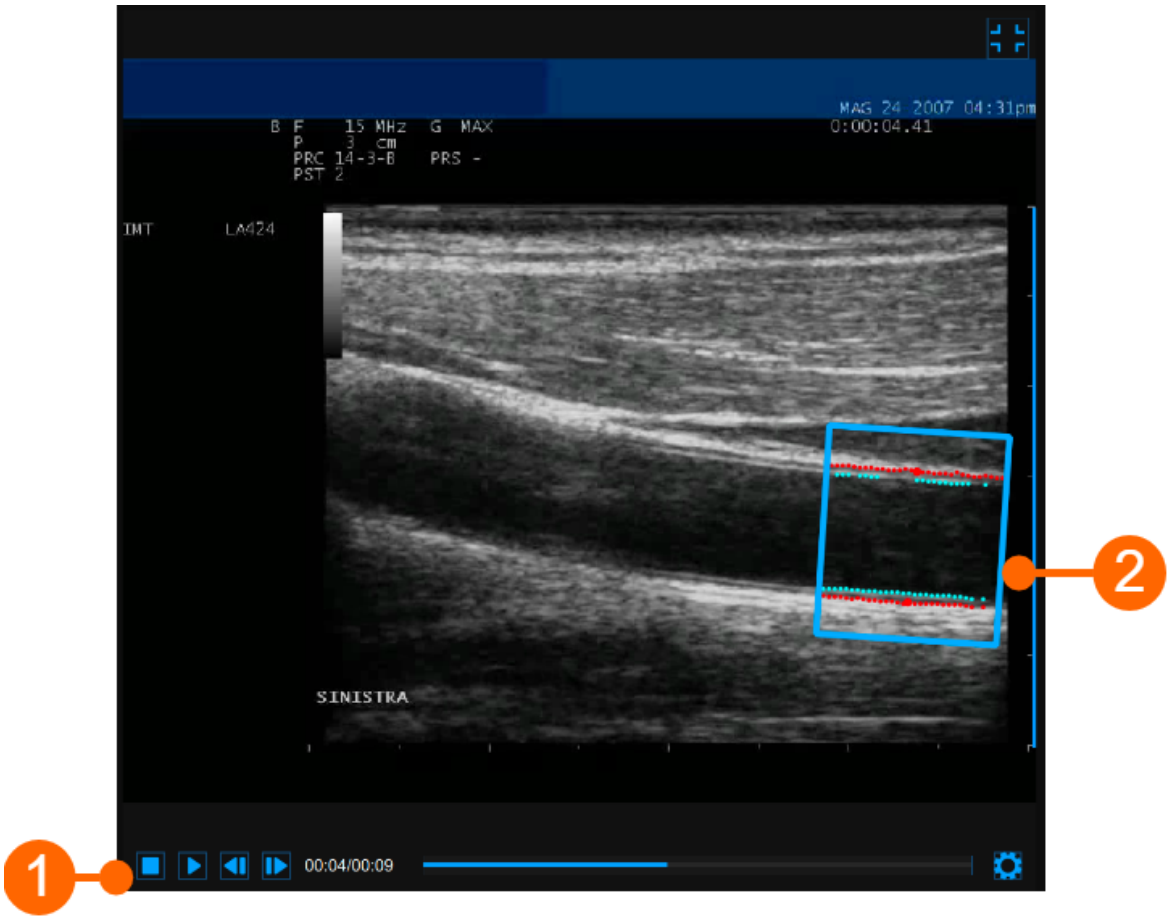
10.5.4 Video window



The video window shows the video signal from your ultrasound system. The points of the Lumen-Intima interface and the Media-Adventitia interface are displayed within the ROI **(2)** in cyan color.

The video control bar **(1)** is located at the bottom of the window.

If you want to expand the video window, you have to click on the Enlarge button.

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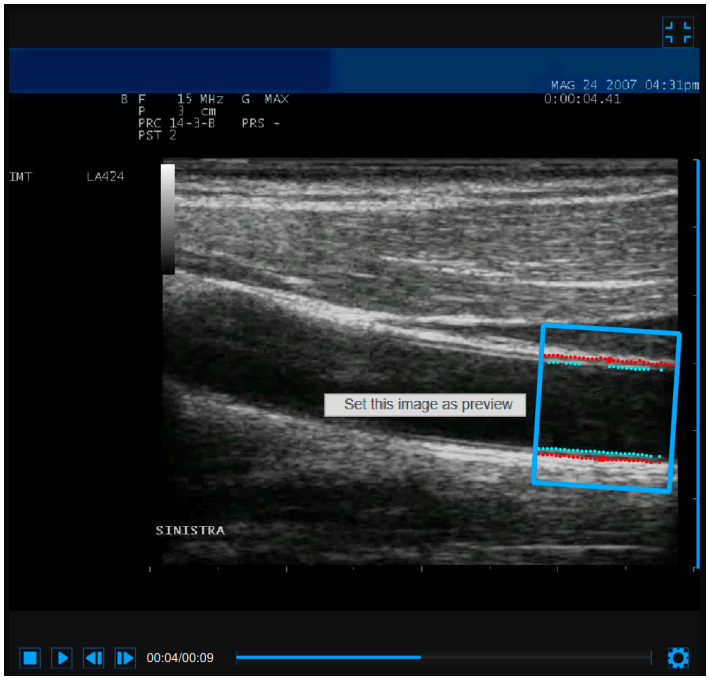
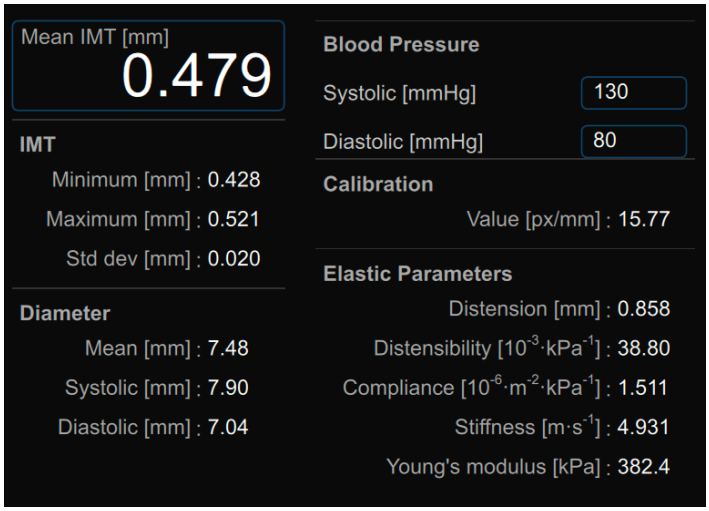


If you perform right click on the video window and click on "Set this image as preview" the current frame will be saved and displayed in the Documents Table as document preview (see Studies management).

10.5.5 Results panel



The panel shows the results of the analysis. The following data are displayed:

- ***Calibration value [px/mm]***
- ***Mean IMT [mm]***: Intima Media Thickness. It is computed as an average value of the data present in the IMT chart.
- ***Minimum IMT [mm]***: minimum value of Intima Media Thickness. It is computed on the data present in the IMT chart.

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- ***Maximum IMT [mm]***: maximum value of Intima Media Thickness. It is computed on the data present in the IMT chart.
- ***Std. dev IMT [mm]:*** standard deviation of Intima Media Thickness. It is computed on the data present in the IMT chart.
- ***Mean diameter [mm]***: value of the average diameter. It is computed as an average value of the diameter data present in the Diameter chart.
- ***Systolic diameter [mm]***: value of the diameter in systole. It is computed as an average value of the systolic diameters present in the Diameter chart.
- ***Diastolic diameter [mm]***: value of the diameter in diastole. It is computed as an average value of the diastolic diameters present in the Diameter chart.
- ***Blood pressure [mmHg]***: diastolic pressure and systolic pressure.
- ***Distension [mm]***: stroke change in diameter.

$$Distension = \Delta D = D_s - D_d$$

- ***Compliance [10^{-6}·m^2·kPa^{-1}]***: absolute change in lumen area for a given pressure change.

$$Compliance = \frac{\Delta A}{\Delta P} = \frac{\pi}{4} \cdot \frac{D_s^2 - D_d^2}{P_s - P_d}$$

- ***Distensibility [10^{-3}· kPa^{-1}]***: relative change in lumen area during systole for a given pressure change.

$$Distensibility = \frac{1}{A_d} \cdot \frac{\Delta A}{\Delta P} = \frac{1}{D_d^2} \cdot \frac{D_s^2 - D_d^2}{P_s - P_d}$$

- ***Carotid Stiffness [m·s^{-1}]***: Stiffness value computed by Bramwell-Hill equation.

$$Stiffness = \frac{1}{\sqrt{\rho \cdot Distensibility}} = \sqrt{\frac{A_d \cdot \Delta P}{\rho \cdot \Delta A}} = \sqrt{\frac{D_d^2 \cdot (P_s - P_d)}{\rho \cdot (D_s^2 - D_d^2)}}$$

- ***Young's elastic modulus [kPa]***:

$$Young's\ Modulus = \frac{3}{Distensibility} \cdot \left(1 + \frac{A_d}{WCSA}\right)$$

where:

D_e = External Diameter (between the media-adventitia interfaces) measured in diastole.

D_i = Internal Diameter (between the lumen-intima interfaces) measured in diastole.

D_s = Systolic Diameter (external).

D_d = Diastolic Diameter (external), $D_d = D_e$

WCSA = Wall Cross Section Area

$$WCSA = \frac{\pi}{4} \cdot (D_e^2 - D_i^2)$$

ΔA = Stroke change in lumen area.

$$\Delta A = \frac{\pi}{4} \cdot (D_s^2 - D_d^2)$$

A_d = Diastolic Area.

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$$A_d = \frac{\pi}{4} \cdot D_d^2$$

P_s = Systolic Pressure.

P_d = Diastolic Pressure.

$\Delta P = P^s - P^d$

ρ = Blood density: is assumed to be constant and equal to 1.06 g/cm^3.

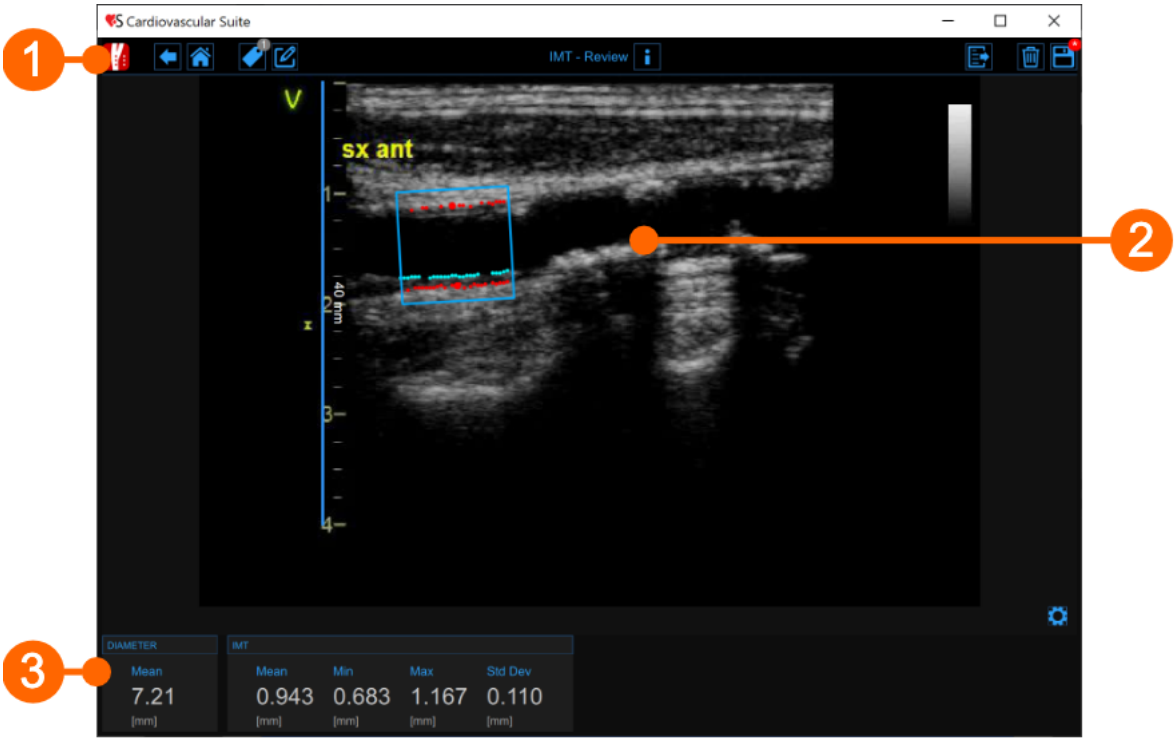
These data can be exported in the Document Data. See here for export details.

10.6 Single image study review

Carotid Studio single image modality, depending on the performed analysis, generates two different types of documents:

1. IMT document
2. Plaque document

10.6.1 IMT review



The Review window contains the following components:

1. Top bar

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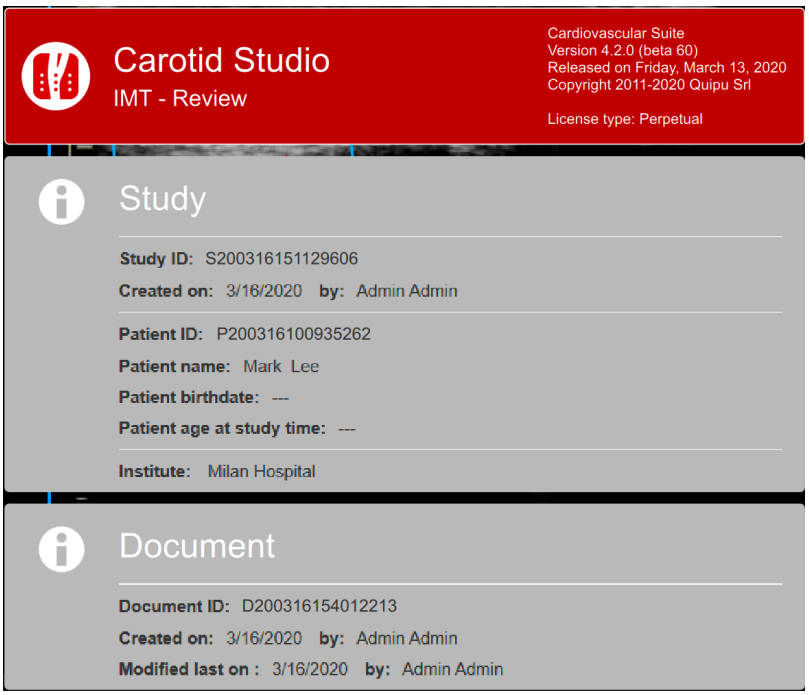
The top bar contains some essential information for the navigation.

The Carotid Studio button shows a panel containing some information about Cardiovascular Suite, about the current study and the current document. Regarding the study, the study ID is displayed together with information about the patient and the institute. In addition, info regarding the current document are provided. Information about the software, such as version and type of license, are shown in the upper part of the panel.



The home button closes the Carotid Studio application and returns to the home screen of Cardiovascular Suite. The Back button closes Carotid Studio and goes back to the Archive.

The Tags Management button opens a panel (see the following picture) that allows to create a new tag and associate it or an existing tag to the document. Tags can be managed through the Tags management into the Archive.

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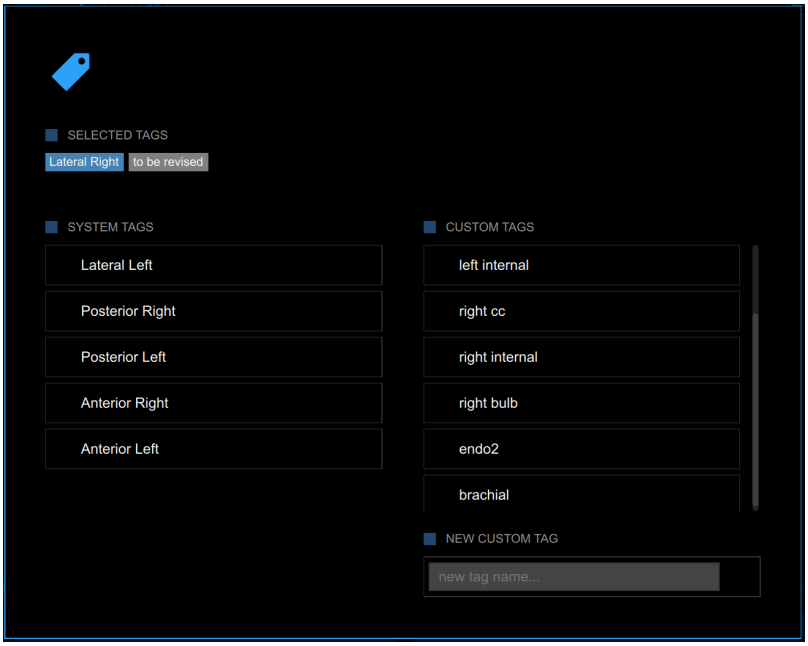
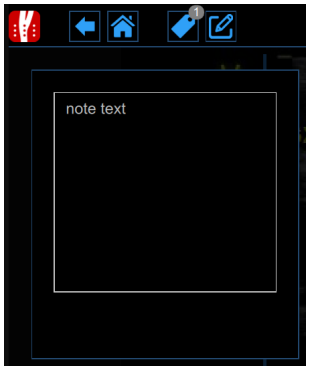


The Notes button can be used to enter a note in the document.



The Save button is used to save your changes to the document, once you have edited the data.

The Delete the document button is used to delete the current document.

The Export button is used to export your data. You can export the **Document Results** that contains all the results of the analysis and all the information about the study, the document and the patient.

2. Image window

The image window shows the media file that has been analysed. It shows also the ROI and the calibration line used.

3. Results panel

The panel shows the results of the analysis. The following data are displayed:

- ***Mean diameter [mm]***: value of the average diameter. It is computed as an average value of the data present in the ROI.
- ***Mean IMT [mm]***: Intima Media Thickness. It is computed as an average value of the data present in the ROI.

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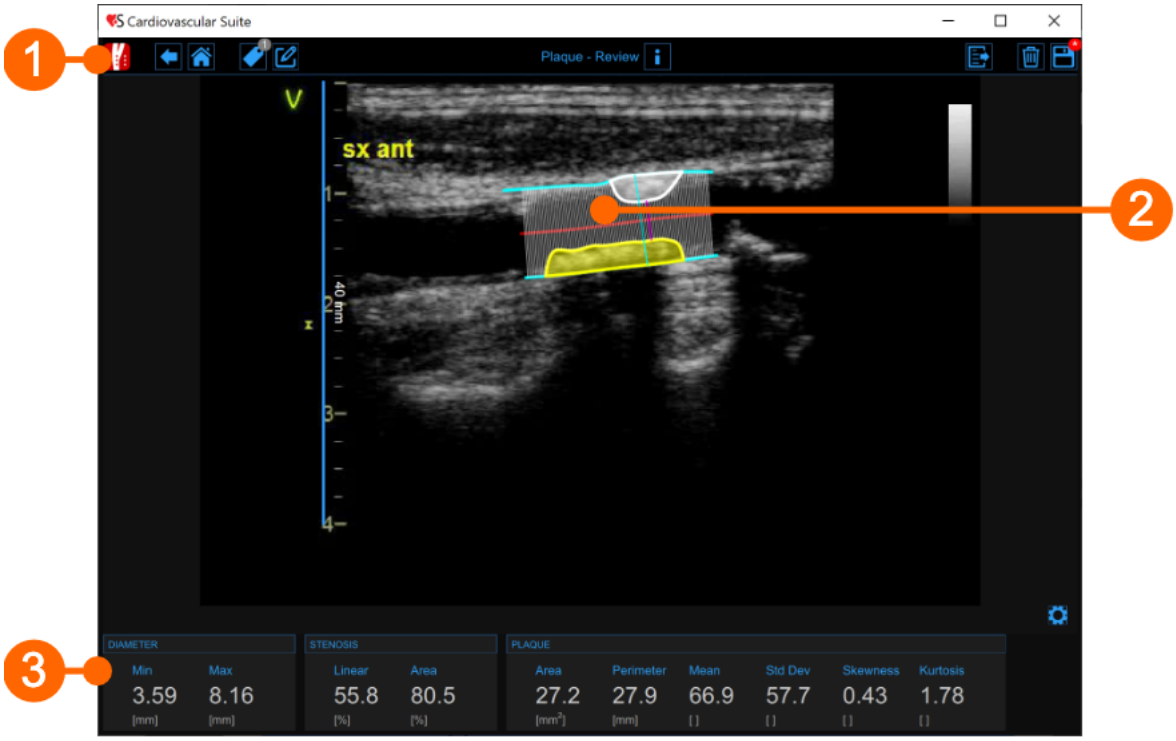
- ***Minimum IMT [mm]***: minimum value of Intima Media Thickness. It is computed on the data present in the ROI.
- ***Maximum IMT [mm]***: maximum value of Intima Media Thickness. It is computed on the data present in the ROI.
- ***Std. dev IMT [mm]:*** standard deviation of Intima Media Thickness. It is computed on the data present in the ROI.

10.6.2 Plaque review



The Review window contains the following components:

1. Top bar

The top bar contains some essential information for the navigation.

The Carotid Studio button shows a panel containing some information about Cardiovascular Suite, about the current study and the current document. Regarding the study, the study ID is displayed together with information about the patient and the institute. In addition, info regarding the current document are provided. Information about the software, such as version and type of license, are shown in the upper part of the panel.

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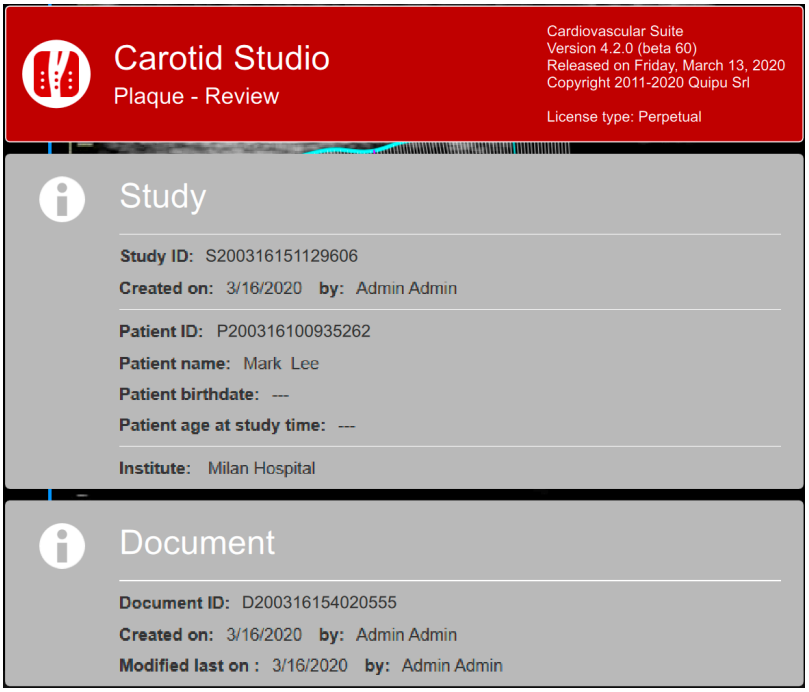
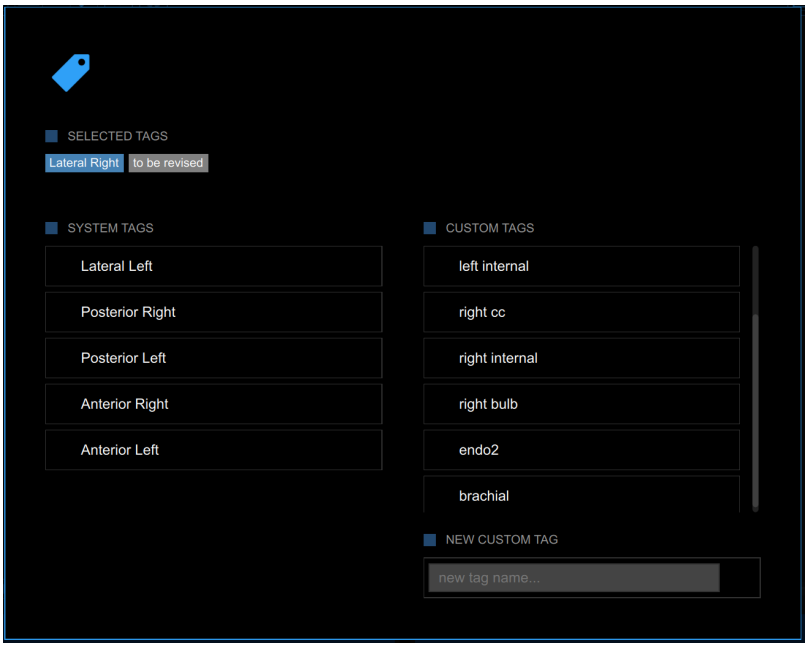


The Home button closes the Carotid Studio application and returns to the home screen of Cardiovascular Suite. The Back button closes Carotid Studio and goes back to the Archive.

The Tags Management button opens a panel (see the following picture) that allows to create a new tag and associate it or an existing tag to the document. Tags can be managed through the Tags management into the Archive.



The Notes button can be used to enter a note in the document.

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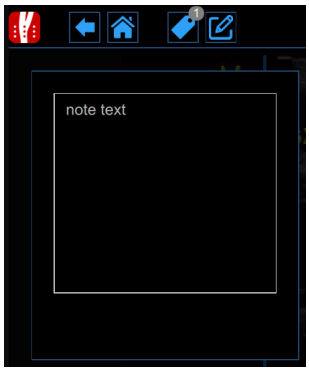

The Save button is used to save your changes to the document, once you have edited the data.

The Delete the document button is used to delete the current document.

The Export button is used to export your data. You can export the **Document Results** that contains all the results of the analysis and all the information about the study, the document and the patient.

2. Media window
The media window shows the media file that has been analysed. It shows the plaque analysis tool and the calibration line used. It displays also the drawn plaques.

3. Results panel

The panel shows the results of the analysis. The following data are displayed:

- ***Min diameter [mm]***: minimum value of the diameter.
- ***Max diameter [mm]***: maximum value of the diameter.
- ***Linear stenosis [%]***: percent of linear stenosi (computed on the diameter)
- ***Area stenosis [%]***: percent of area stenosi (computed on the cross section area)
- ***Plaque area [mm^2]***: area of the plaque
- ***Plaque perimeter [mm]***: perimeter of the plaque
- ***Plaque mean []***: mean value of the grey levels in the plaque
- ***Plaque std dev []***: standard deviation of the grey levels in the plaque
- ***Plaque skewness []***: skewness of the grey levels in the plaque
- ***Plaque kurtosis []***: kurtosis of the grey levels in the plaque

10.7 Study report

The study report summarises the results of the documents of the study.

The report includes only the study documents that have a system tag. This is because the tag is necessary to identify the scan view (lateral, posterior or anterior) and the carotid artery (left or right).

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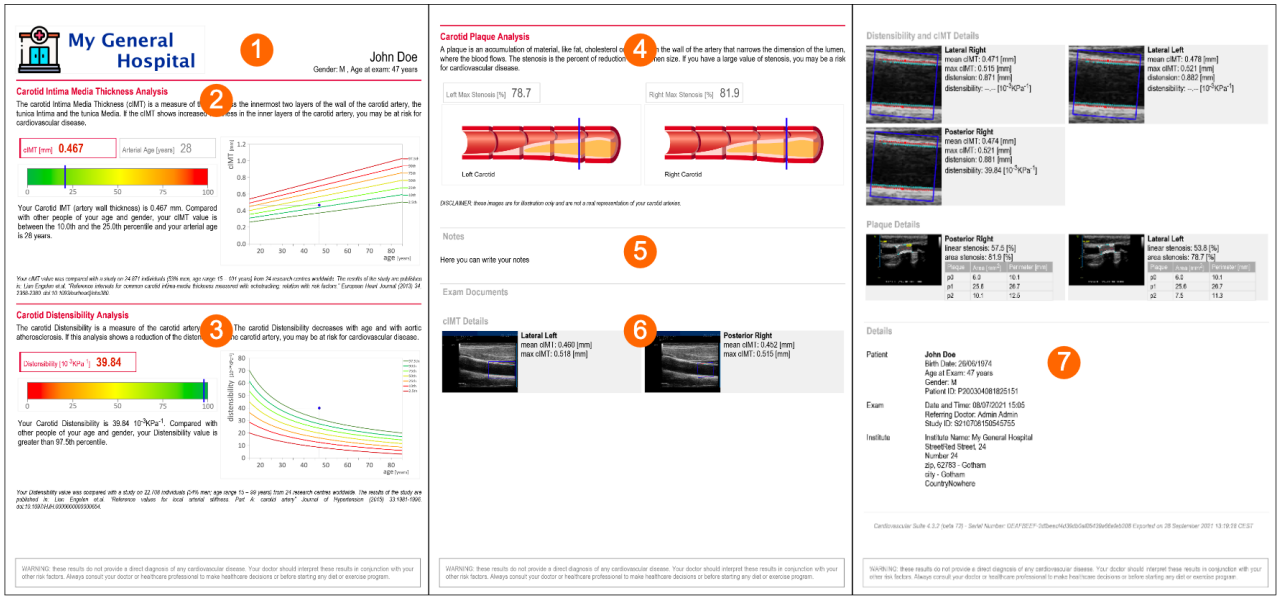

The report has te following sections:

1. Header
2. Carotid Intima Media Thickness Analysis
3. Carotid Distensibility Analysis
4. Carotid Plaque Analysis
5. Notes
6. Exam documents
7. Details

10.7.1 Header

The header contains the patient Name, gender and age, and the logo of the institute. The logo can be set in Institute s management.

10.7.2 Carotid Intima Media Thickness Analysis

This section reports a **mean value** of carotid IMT that is obtained as the average of the IMT values contained in the documents included in the report. Both documents of "IMT" type and "Stiffness and IMT" type are used to compute this value. The carotid IMT value is compared with reference values published in Lian Engelen et.al. “Reference intervals for common carotid intima media thickness measured with echotracking: relation with risk factors.” European Heart Journal (2013) 34, 2368-2380. The percentile of the carotid IMT value is reported. The arterial age value, which is calculated as the value at which the IMT value corresponds to the 50-th percentile of the reference population, is also reported.

This section will be present in the report only if data are available, i.e. if the report includes documents of "IMT" type and/or "Stiffness and IMT" type.

10.7.3 Carotid Distensibility Analysis

This section reports a **mean value** of carotid distensibility that is obtained as the average of the distensibility values contained in the documents included in the report. Documents of "Stiffness and IMT" type are used to compute this value. The carotid distensibility value is compared with reference values published in Lian Engelen et.al. "Reference

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values for local arterial stiffness. Part A: carotid artery" J Hypertension 2015 Oct. 33(10):1981-96. The percentile of the carotid distensibility value is reported.

This section will be present in the report only if data are available, i.e. if the report includes documents of "Stiffness and IMT" type, where the distensibility is computed.

10.7.4 Carotid Plaque Analysis

This section reports the maximum value of the linear stenosis for both the left and the right carotid. Documents of "Plaque" type are used to compute this value.

This section will be present in the report only if data are available, i.e. if the report includes documents of "Plaque" type.

10.7.5 Notes

This section contains the study notes that can be set in the Study view window (see Studies management).

10.7.6 Exam documents

This section contains a summary of the results of all the documents included in the report.

Details

This section contains details on the Patient, Study and Institute data.

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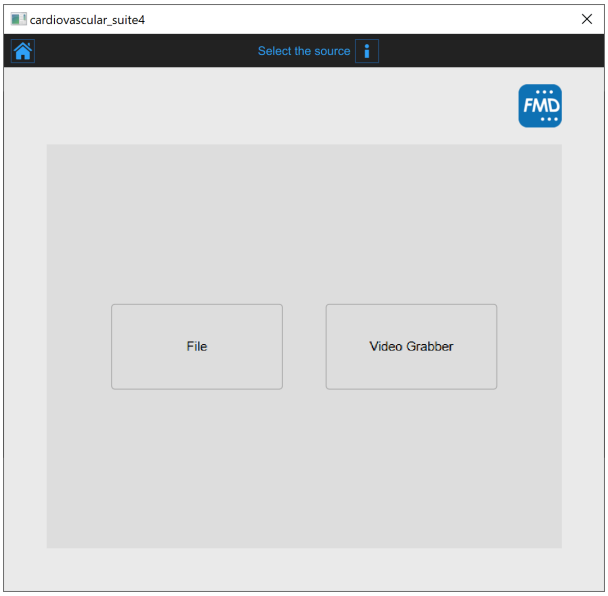
11 FMD Studio

FMD Studio is a software for the measurement of the Flow-Mediated Dilation (FMD) or other general Vasodilation of the brachial artery.

11.1 Create a new study

When you start FMD Studio, a procedure guides you in the creation of a new study. The steps are:

11.1.1 Select the source



In this tab, you can select the study video source. FMD Studio processes video sources and can work in offline modality by processing a Video File or a DICOM File or in real time by processing images directly coming from the ultrasound equipment thanks to a video converter.

11.1.2 Select the patient

> For DICOM files, the patient data are obtained by the file metadata and this window is skipped (see Settings). You can anyhow edit the patient data from the Review window.

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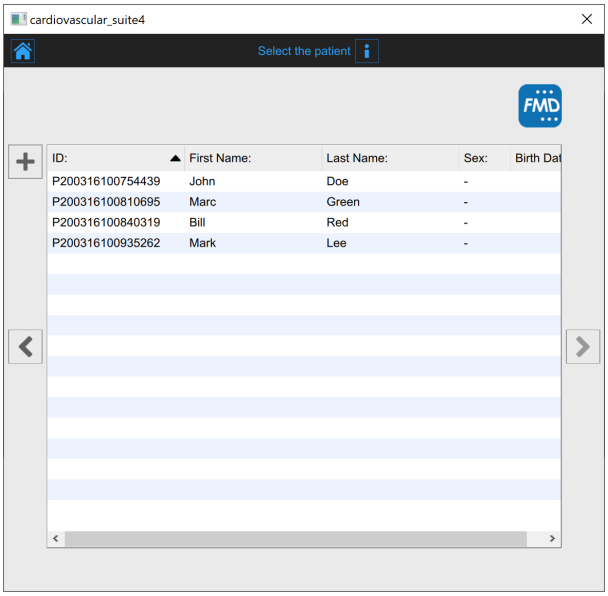
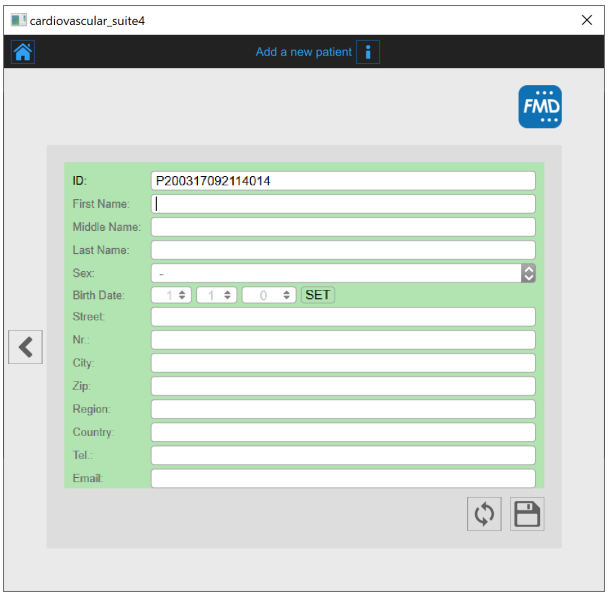


In this tab, you can select the patient among the ones already present in the Archive. Select the patient and click on the Next button (you can simply double-click on the patient to proceed).

If you want to create a new patient, click on the Add New Patient button. In the Add new patient frame, enter the patient data. The only mandatory field is the patient ID. If you don't enter patient ID a random value is automatically proposed. Click on the Save button to save the patient data.



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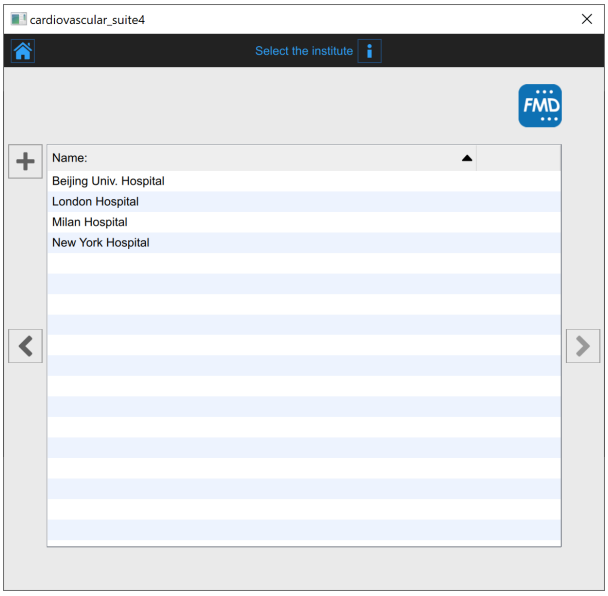
11.1.3 Select the institute

If it is the first time you create a study, after selecting the patient you will also need to select the institute. If you have already created at least one study, the software remembers the institute used for the previous study and after selecting the patient shows you automatically the final review (where you can still make changes before starting the new study).



In this tab, you can select the institute among the ones already present in the Archive. Select the institute and click on the Next button (you can simply double-click on the institute to proceed).

If you want to create a new institute, click on the Add New Institute button. In the Add new institute frame, enter the institute data. The only mandatory field is the Name. Click on the Save button to save the institute data.

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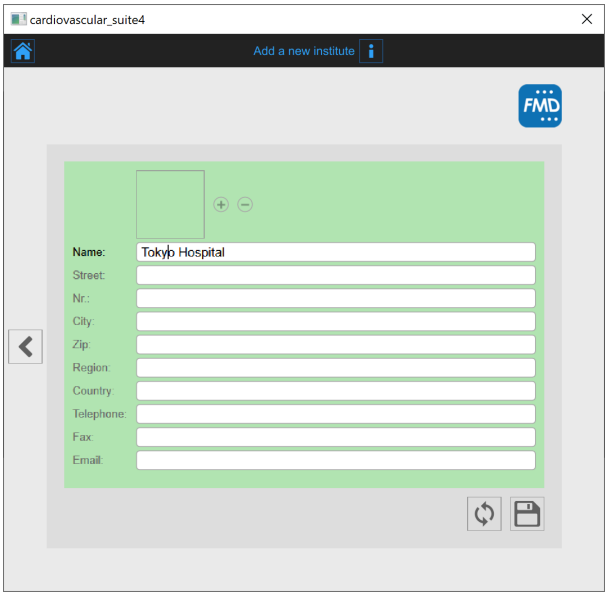
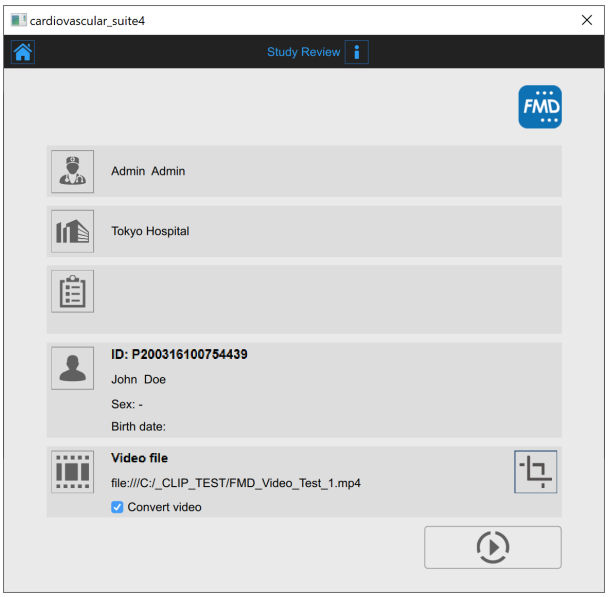


11.1.4 Review



In this tab you can review your selection (you can also change Patient and Institute by clicking on their buttons). It is possible also to change the selected source for this study by clicking on the icon that represents the source.

Here, the user has the possibility to associate the study to one ore more existing protocols, by clicking on the protocols icon .

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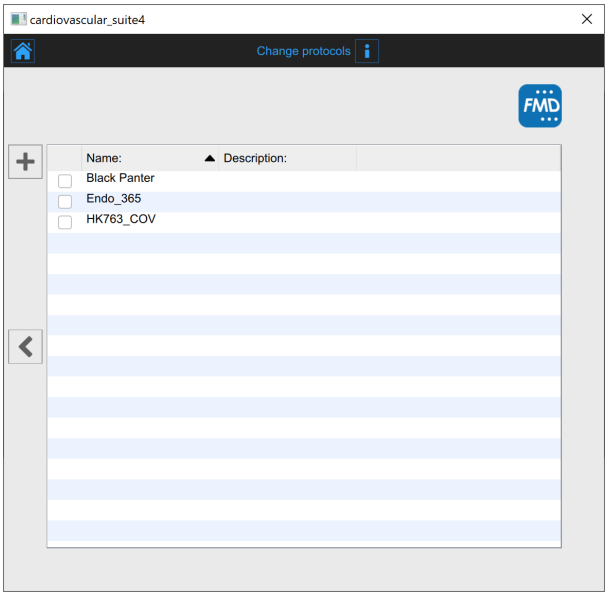
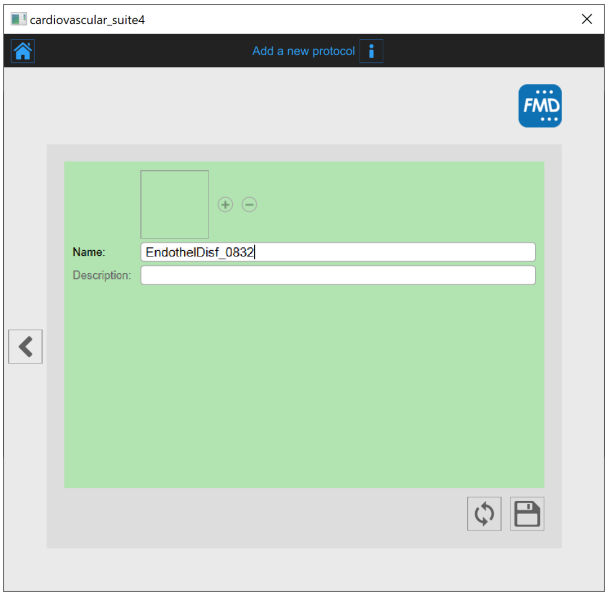


In the Protocols tab, you can associate the study to one or more than one protocols already present in the Archive. Put a tick on the protocol you want to associate the study with. If you want to create a new protocol, click of the Add New protocol button. In the Add new institute frame, enter the protocol data. The mandatory field (Name) is in red until you have filled in the Name blank. Click on the Save button to save the protocol data.



Click on the Previous button to go back to the review window.

> If in the Settings manager the option "Remember last used protocols" is checked, the study will be associated by default with the last used protocols.

In addition, if you have chosen a video file as source, in the review window, it is possible to convert the video file to be optimized for the analysis with Carotid Studio. This operation may take few minutes.

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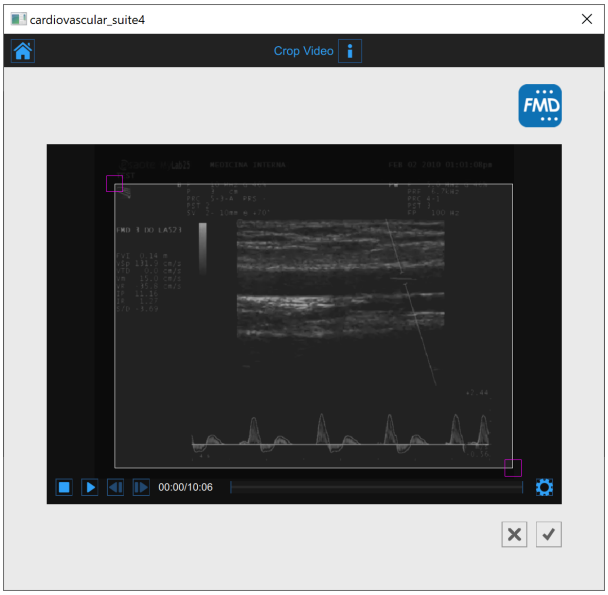
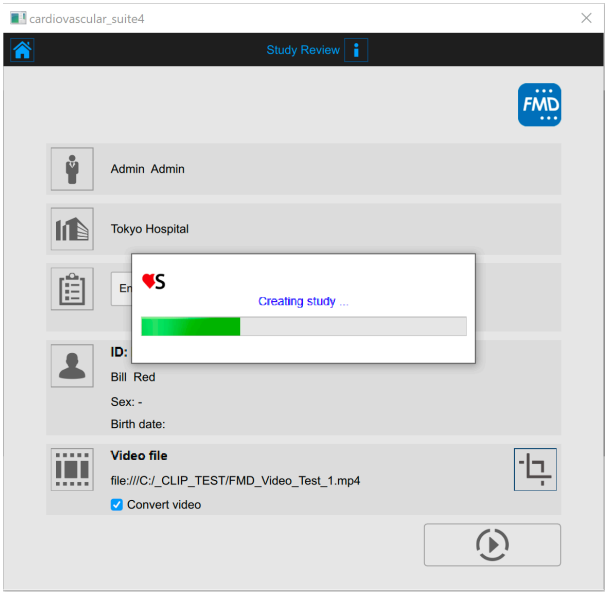
The default value of the "Convert video" checkbox is set by the "Convert video by default" option in the Settings manager.

You can also crop the images by clicking the Crop button in the source panel. In this case, a new window opens; it is possible to select a region to be used for the analysis. Click on the Confirm button after you have drawn the region.



Click on the Start the Study button to proceed. A progress bar, as shown in the following picture, will show you the progression of the study creation.



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11.2 Analysis

The Analysis window contains the following components:

1. Top bar
2. Video window
3. Mean diameter chart
4. Shear rate chart
5. Instantaneous diameter chart
6. Setup panel
7. Tags

11.2.1 Top bar

The top bar contains some essential information for the navigation.

The FMD Studio button shows a panel containing some information about Cardiovascular Suite and about the current study. Regarding the study, the study ID is displayed together with information about the patient and the institute. Information about the software, such as version and type of license, are shown in the upper part of the panel.

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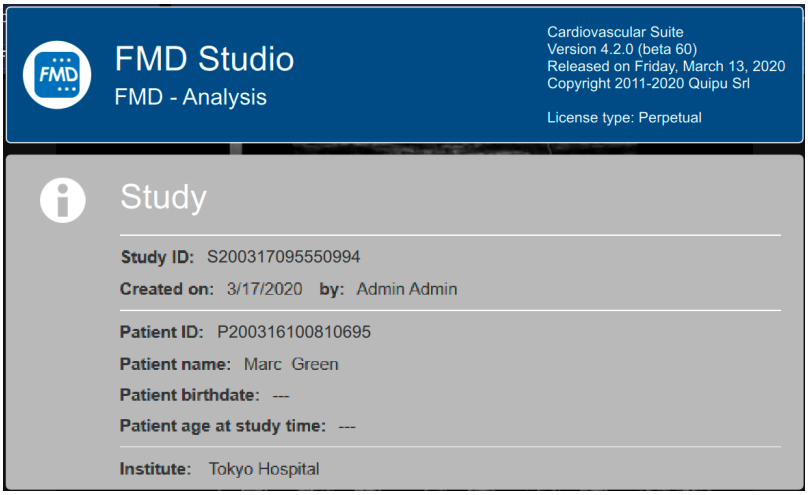

The home button closes the FMD Studio application and returns to the home screen of Cardiovascular Suite.

The Archive button closes the FMD Studio application and returns to the archive of Cardiovascular Suite.

The New video button allow to open a new video for the analysis.

The Tags Management button opens the tag management panel as described in Tags.

The preset management button opens the preset management panel as described in Presets.

The Setup Panel button is used to show the setup panel when it is hidden.

The Info button shows information about active controls (calibration lines, ROI, etc.).

The start/pause and save buttons works in a different way for offline analysis and real-time analysis:

- In **offline analysis**, the Start the Analysis / Pause the Analysis button starts and suspend the image analysis. The Save the Document button, saves the document.
- In **real-time analysis**, the Start Recording / Pause Recording button starts and suspend both the image recording and the image analysis. The Stop Recording ad Save button, stops the image recording (i.e. stops the examination) and saves the document.

The Cancel the analysis button discard the data that have been collected so far.

The Review Documents button allows to suspend the analysis and to review the documents saved in the current analysis session. The button is only activated if you saved at least one document.

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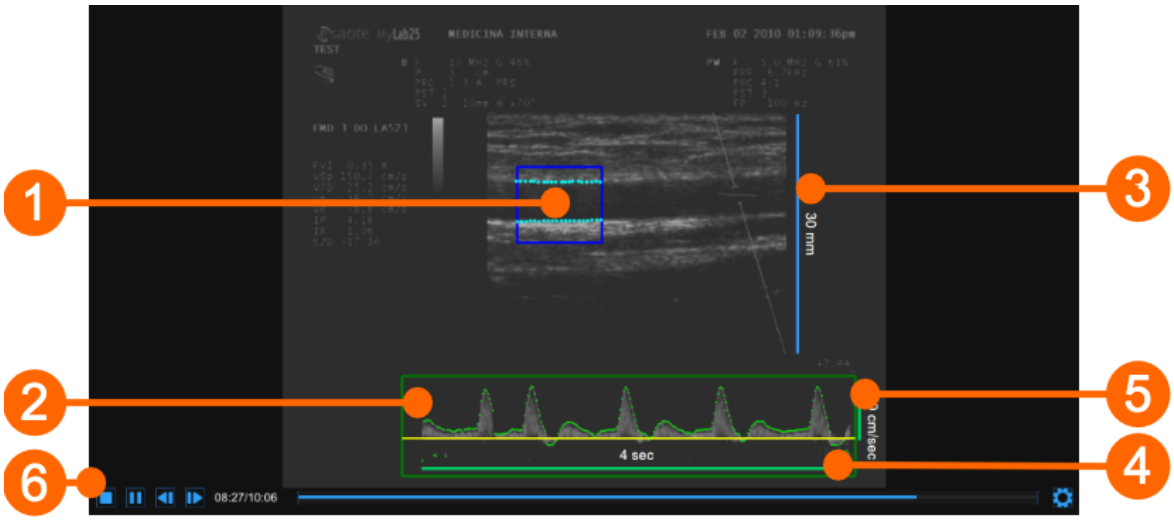
11.2.2 Video window



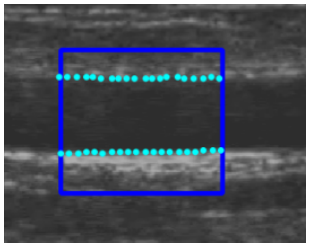
The video window shows the video signal from your ultrasound system. Two ROIs can be present in the window: the diameter ROI in blue **(1)** and the Doppler flow ROI in green **(2)**.

The window contains also the calibration lines for the B-mode image **(3)** and for the Doppler flow **(4)(5)**, once these have been calibrated.

The video controls bar **(6)** is located at the bottom of the window. For more information on the video controls, see Video and image player.

11.2.2.1 **Diameter ROI**

The Diameter Region of Interest (ROI) is the portion of the image where the diameter is calculated. The edges of the vessel obtained by the algorithm of edge detection are displayed within the ROI. The ROI can be moved and/or resized. Each time you change the position and/or size of the ROI, the contours of the vessel are re-initialized.



Draw a new diameter ROI:

You can manually draw the diameter ROI with the desired size and position. If the image is already calibrated, you can also more quickly draw a diameter ROI with the default sizes set in FMD Studio settings (a star in the Set ROI button will indicate that the default ROI can be drawn).

default ROI drawing

- Click on the Set ROI button in the Setup panel (the button remains active).
- Click in the video window in the center of the brachial artery.
- A ROI of the default ROI sizes will be automatically initialized.

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manual drawing

- Click on the Set B-Mode ROI button in the Setup panel (the button remains active).
- Click inside the video window and drag until the Diameter ROI is complete (the size of the ROI is shown in the Setup panel).
- When you release the mouse, the contours are initialized.

Modify the diameter ROI:

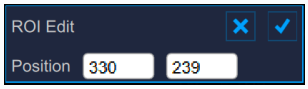
- Click on one of the sides or one of the corners of the diameter ROI.
- Drag to change the size of the the diameter ROI.

As an alternative, you can modify the size of the diameter ROI by typing the value in the Setup panel.

Move the diameter ROI:

- Click and hold inside the diameter ROI.
- Drag the diameter ROI to the location of interest.

As an alternative, you can modify the position of the diameter ROI by typing the value in the Setup panel.



Re-initialize the edge detection algorithm:

- Click inside the Diameter ROI.

11.2.2.2 Doppler flow ROI

The Doppler Flow Region of Interest (ROI) is the portion of the image that includes the Doppler Flow waveform.

The algorithm for the Doppler Flow analysis, automatically locates the zero line, which is displayed in yellow, and the waveform, which is displayed in green.

The Doppler Flow ROI can be moved and resized. Each time you change the position and size of the ROI, the algorithm is re-initialized and the zero line is re-localized.

For more information on ultrasound setting for Doppler analysis, please see how to Calibrate the Doppler flow image.

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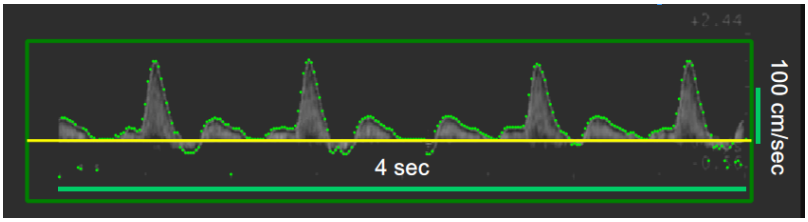


Draw a new Doppler flow ROI:

- Click on the Set Doppler Flow ROI button in the Setup panel (the button remains active).
- Click inside the video window and drag until the Doppler Flow ROI is complete (the size of ROI is shown in the Setup panel).
- When you release the mouse, the algorithm for the Doppler Flow analysis is initialized.

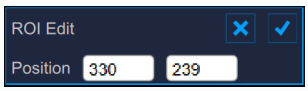
Modify the Doppler flow ROI:

- Click on one of the corners of the Doppler Flow ROI.
- Drag to change the size of the the Doppler Flow ROI (the size of ROI is shown in the Setup panel).

> As an alternative, you can modify the size of the Doppler flow ROI by typing the value in the Setup panel.
>
> 
>

Move the Doppler Flow ROI:

- Click and hold inside the Diameter ROI.
- Drag the Doppler Flow ROI to the location of interest.

> As an alternative, you can modify the position of the Doppler flow ROI by typing the value in the Setup panel.
>
> 
>

Re-initialize the algorithm for the Doppler Flow analysis:

- Click inside the Doppler Flow ROI.

Re-initialize the ROI:

- Double click inside the Diameter ROI to re-initialize the position of the ROI

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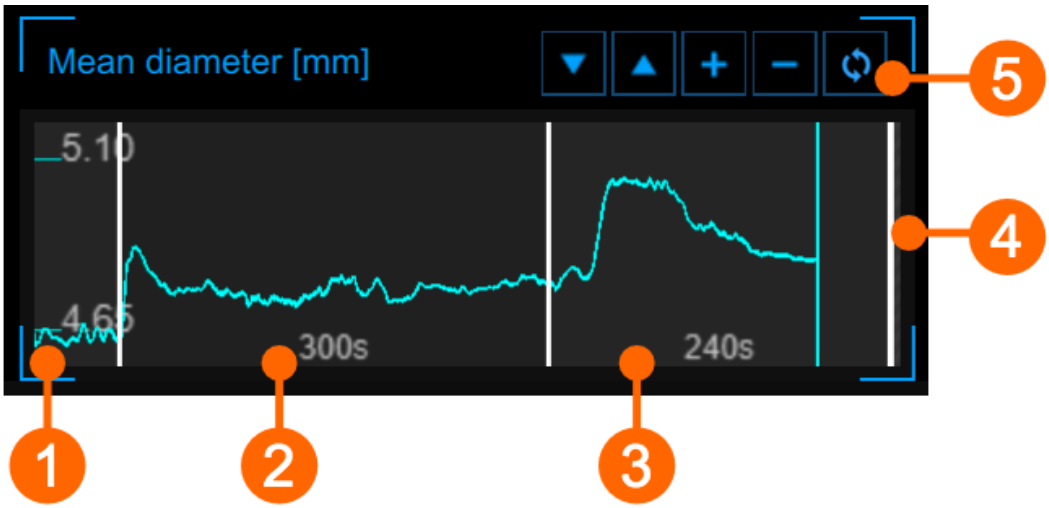
11.2.3 Mean diameter chart

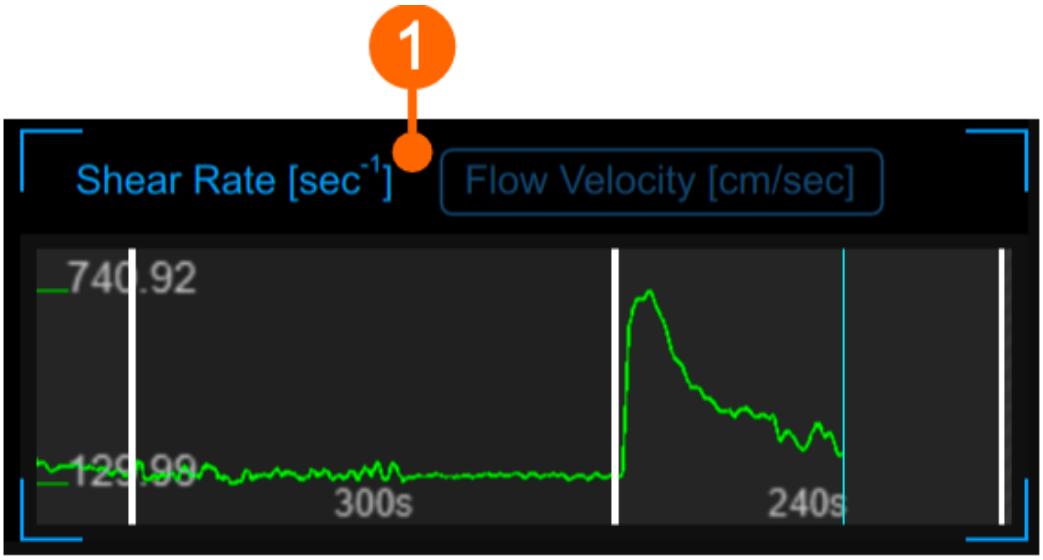


The chart shows the trend of the mean diameter during the examination. The chart is divided into three or two parts, according to the study modality. You have basal **(1)**, ischemia **(2)** and vasodilation **(3)** in FMD; ischemia is missing in vasodilation modality. In offline mode, a fourth part **(4)** may be present if the time length of the video is greater than the sum of the basal + (ischemia) + vasodilation.

The time length of the three (two) parts is set in the Timeline panel. You can set the timeline also by moving the three (two) vertical cursors that are present at end-baseline, end-ischemia and end-vasodilation.

Using the buttons at the top right **(5)** you can move up ▲ or down ▼ the chart, enlarge + or reduce − the vertical scale or restore ↻ the default view.

11.2.4 Shear rate chart



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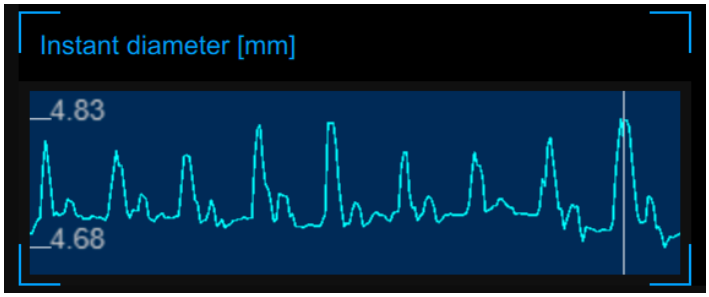
The graph shows the trend of the time averaged positive Shear Rate or the time averaged positive Flow Velocity during the examination. You can switch between the two view by the selector **(1)**.

The chart is divided into time intervals in a similar manner to the Mean diameter chart.

> The chart is enabled if the Doppler analysis has been enabled in the Setup panel.

11.2.5 Instantaneous diameter chart

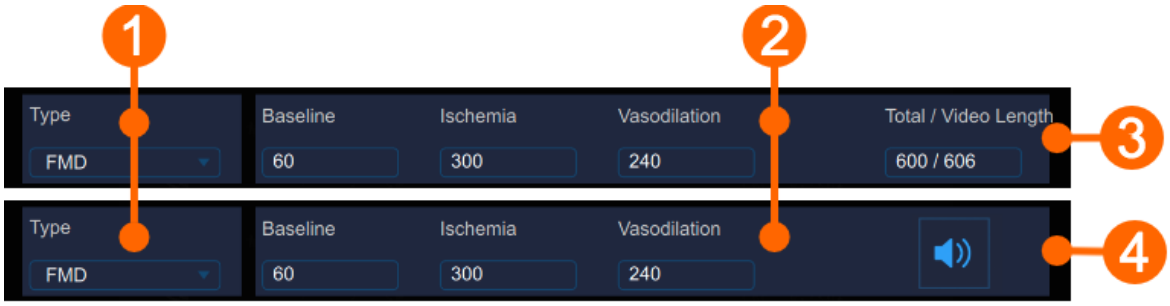


This chart shows the diameter changes within the cardiac cycle. The correct form of this chart is an index of measurement quality. The chart axes will automatically scale.

11.2.6 Setup panel

The setup panel contains the commands to set the timeline of the exam, to calibrate the B-mode and the Doppler flow images, to set the diameter and Doppler flow ROIs and to choose the sensitivity of the algorithm. You can move among the panels by using the Next button and the Previous button. The Next button is enabled only if you have set all the mandatory field in the panel.

11.2.6.1 Study modality and timeline setup



In **(1)**, you can select the study types. FMD Studio can work in two modalities: "FMD" and "Vasodilation". The two modalities differ in how the timeline of the examination is organized.

In **FMD modality**, the timeline is divided into three parts:

1. Baseline, where the software computes the baseline diameter and the baseline shear-rate.
2. Ischemia, which is not used for the analysis.
3. Vasodilation, where the software computes the maximum diameter, the recovery diameter, the maximum shear-rate and the area under the curve of the shear-rate.

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In **Vasodilation modality**, the timeline is divided into two parts:

1. Baseline, where the software computes the baseline diameter and the baseline shear-rate.
2. Vasodilation, where the software computes the maximum diameter, the maximum shear-rate and the area under the curve of the shear-rate.

The time length of the timeline parts can be set in the Time panel **(2)**. In the Time Panel, you can choose the time length of baseline, ischemia and vasodilation (ischemia is present only in "FMD" modality) intervals.

In Offline analysis **(3)**, the Time panel shows the total length of baseline + ischemia + vasodilation, and the video length. In Online analysis **(4)**, the panel contains the control indicating if the acoustic alert is Enabled or Disabled (click on the icon to change its status). In enabled, an acoustic signal is played at the end of the baseline and the ischemia time interval.

Once the time lengths have been set, click on the Next button to proceed.

Timeline management

User can set and modify the time length entering values into the Text Fields (see previous picture) but also dragging one of the vertical cursors in graphs, as shown in the following picture:

FMD Studio allows the users to manage the timeline in a flexible way able to meet their clinical and/or research needs. There are constraints on the timeline in terms of minimum and maximum allowed values for each interval (you can not set values outside the allowed range and, if the video modality is "Offline analysis", the sum of the intervals cannot be grater than the time length of the video file under examination). There are also suggested minimum values: if the user decides to ignore this advice, the analysis will be performed anyway but there will be a yellow alert icon ( ) next to the values that may not be reliable in that configuration. In the following table allowed and suggested values are shown:

Timeline constraints (in seconds)			
	Baseline	*Ischemia*	*Vasodilation*
FMD	5* - 180	0 - 420	5** - 1200
Vasodilation	5* - 300	-	5 - 1500

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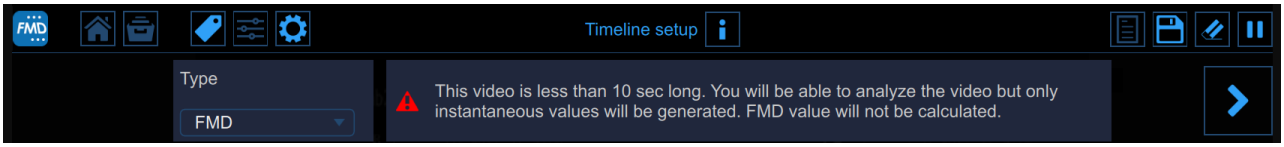
* we suggest a basal period of at least 20 sec.

** we suggest a vasodilation period of at least 120 sec.

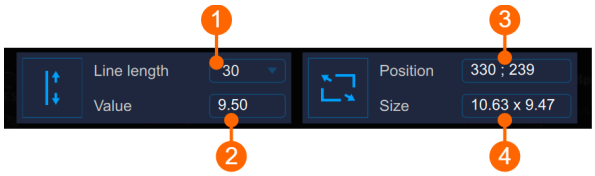
If the user uploads a video clip (for offline analysis) with a lower duration than the minimum allowed values (it means 10 seconds; 5 for baseline and 5 for vasodilation) an error message will appear: "This video is less than 10 sec long. You will be able to analyse the video but only instantaneous values will be generated. FMD value will not be calculated."



In this configuration user cannot set the timeline and characteristics parameters (e.g. FMD, FMDr, baseline diameter,...) will not be computed but only instantaneous values will be generated.

You can hover over the yellow icon ( ) or the red one ( ) and an informative message about the warning or error situation will be displayed.

11.2.6.2 B-mode image setup



The B-Mode Panel must be used to Calibrate the B-mode image and to set the diameter ROI.

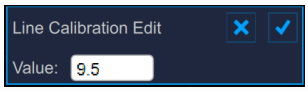
Calibration

The Set B-Mode Calibration button is used to Calibrate the B-mode image.

The drop down menu **(1)** shows the length of the line used for the calibration.

The numeric display **(2)** shows the calibration value.

If you click in the value field, you are allowed to manually enter the calibration value in the editable field (if you already know the value). Then click the Save button to save the values.



ROI

The Set B-Mode ROI button is used to set the diameter ROI.

The numeric display **(3)** shows the center position, in pixels, of the diameter ROI.

The numeric display **(4)** shows the size (width x height), in mm, of the diameter ROI.

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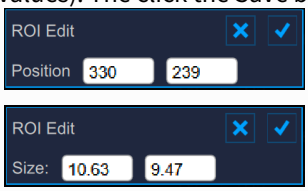
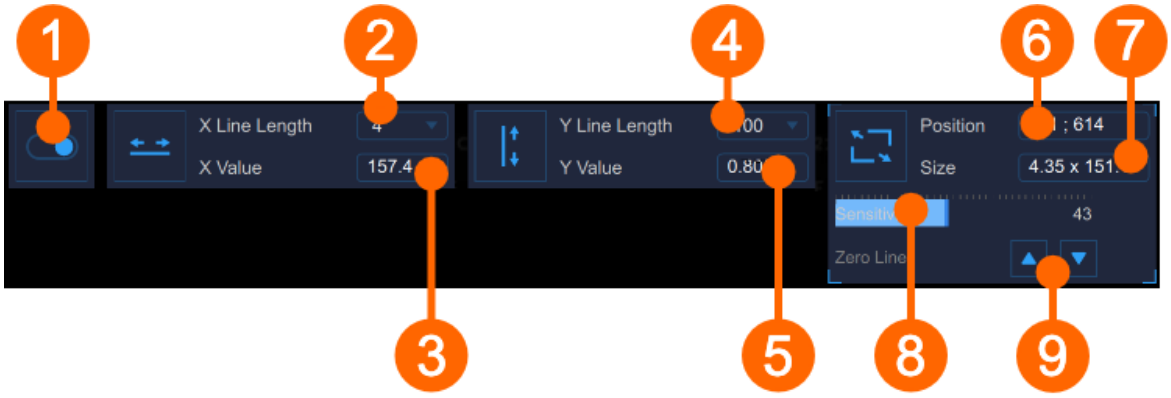
If you click in the value field, you are allowed to manually enter the ROI position and size values in the editable fields (if you already know the values). The click the Save button to enter the values.



Once you have calibrated the B-Mode image and set the Diameter ROI, click on the Next button to proceed.

11.2.6.3 Doppler Setup



The Doppler Panel must be used to Calibrate the Doppler flow image and to set the Doppler flow ROI.

The switch **(1)** enables and disables the Doppler Flow analysis.

Calibration

The Set Doppler X-Calibration button is used to calibrate the x-axis (time).

The drop down menu **(2)** shows the length of the line used for the calibration (sec).

The numeric display **(3)** shows the x-calibration value (pix/sec).

The Set Doppler Y-Calibration button is used to calibrate the y-axis (velocity).

The drop down menu **(4)** shows the length of the line used for the calibration (cm/sec).

The numeric display **(5)** shows the y-calibration value (pix/cm/sec).

ROI

The Set Doppler Flow ROI button is used to set the Doppler flow ROI.

The numeric display **(6)** shows the center position, in pixels, of the Doppler flow ROI.

The numeric display **(7)** shows the size (width x height), in pixels, of the Doppler flow ROI.

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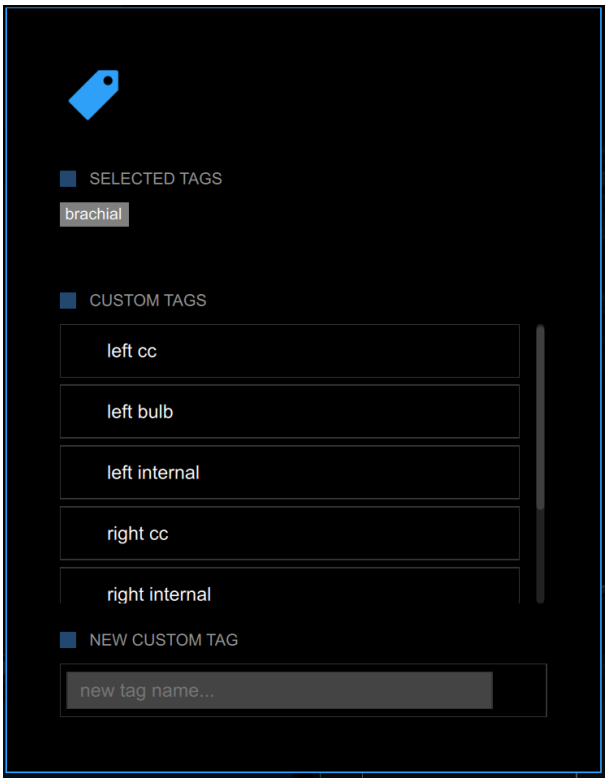
The sensitivity of the Doppler Flow analysis algorithm is set by the slider **(8)**.

The position of the zero line can be adjusted by the buttons **(9)**.

Once you have calibrated the B-Mode image and set the Diameter ROI, click on the Next button to proceed.

11.2.7 Tags

The Tags Management button opens a panel that allows to associate a tag to the document, or create a new tag. Tags can also be managed through the Tags management into the Archive.



The selected tags are visible in a special area of the Analysis window. The tags area can me moved by right clicking and dragging.

11.2.8 Presets

The preset management button opens the preset management panel that allows to manage presets. In particular, it allows to remember the settings of:

- timeline (baseline, ischemia and vasodilation)
- B-mode image calibration
- B-mode image ROI (size and position)
- Doppler calibration (X and Y calibration)
- Doppler ROI (size and position)

A preset can be saved and reused for following studies.

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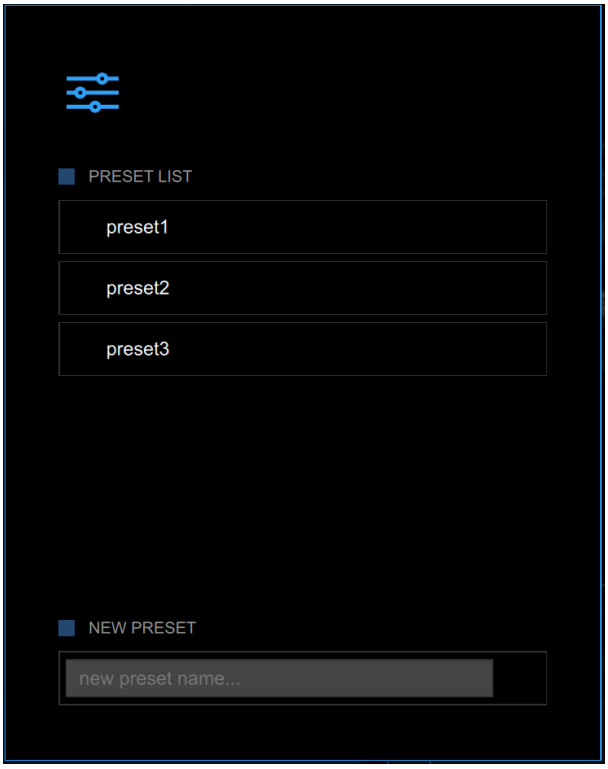
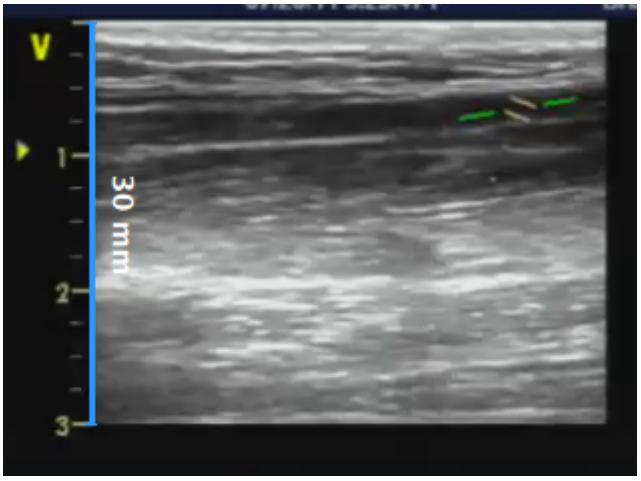


11.2.9 Calibrate the B-mode image

The calibration of the images must be done before starting a new examination because it is necessary to provide information about the size of the image generated by ultrasound system. The calibration factor changes depending on the settings of your ultrasound machine. You should check the calibration at each new examination.

> **CAUTION: the lack of calibration can generate a software malfunction.**



- Locate, in ultrasound image, a range of known distance (30 mm. in the example of figure).
- In the B-mode setup panel, select from the drop-down menu, the distance specified above.

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- In the B-mode setup panel, click on the Set B-Mode Calibration button (button remains active).
- Draw a line on the image corresponding to the known distance: click on one end and drag the mouse to the other extreme (press the Shift key or Ctrl+Shift keys on your keyboard if you want the line to be not vertical or horizontal).

For DICOM files, when present, the B-mode calibration is be obtained automatically by the file metadata (see Settings). You can anyhow modify the calibration value.

You can directly type the calibration value in the Calibration factor field of the B-mode setup panel, if you already know the value.

11.2.10 Calibrate the Doppler flow image

The calibration of the Doppler Flow analysis must be done before starting a new examination because it is necessary to provide information about the size of the Doppler waveform generated by ultrasound system. The calibration factor changes depending on the settings of your ultrasound machine. You should check the calibration at each new examination.

CAUTION: the lack of calibration can generate a software malfunction.

- Locate, on the x axis of the Doppler flow profile, a known time length (1 sec in the example in figure).
- In the Doppler setup panel, select from the "x-line length" drop-down menu, the time length specified above.
- In the Doppler setup panel, click on the Set Doppler X-Calibration button (button remains active).
- Draw a line on the image corresponding to the known distance: click on one end and drag the mouse to the other extreme (press the Shift key on your keyboard if you want the line to be not horizontal).
- Locate, on the y axis of the Doppler flow profile, a known flow velocity value (200 cm/sec in the example in figure).
- In the Doppler setup panel, select from the "y-line length" drop-down menu, the flow velocity value specified above.
- In the Doppler setup panel, click on the Set Doppler Y-Calibration button (button remains active).
- Draw a line on the image corresponding to the known distance: click on one end and drag the mouse to the other extreme (press the Shift key on your keyboard if you want the line to be not vertical).

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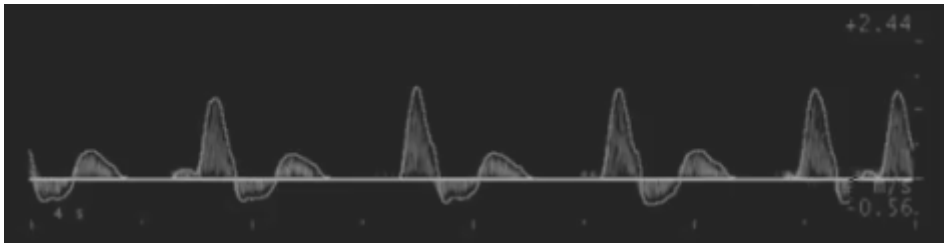
For DICOM files, when present, the Doppler calibration is be obtained automatically by the file metadata (see Settings). You can anyhow modify the calibration values.

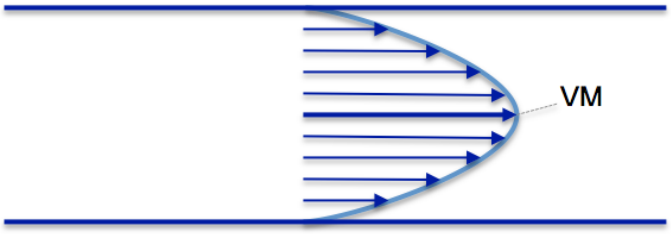
You can directly type the calibration values in the X value and Y value fields of the Doppler setup panel (if you already know the values).

11.2.11 Doppler flow analysis

FMD Studio computes the envelope of the Doppler flow velocity waveform over the time interval defined by the Doppler flow ROI. The result is used to compute the Time Average Wall Shear Rate.



We assume the velocity profile to be parabolic and we assume that the Doppler flow velocity waveform provides the maximum value (VM) of the velocity profile (i.e. the maximum spatial velocity). In fact, the analysis is based only on the Doppler flow envelope because the video image data does not give information on the velocity profile of the vessel.



Velocity Profile in a vessel

With this assumptions, the Shear Rate (SR) can be computed as:

$$SR = \frac{4 \cdot V}{d}$$

where d is the diameter of the vessel.

FMD Studio computes two values for velocity:

V_{TAP} : time averaged of the positive values of V.

V_{TAN} : time averaged of the negative values of V.

Both the averages are computed over the Doppler flow ROI.

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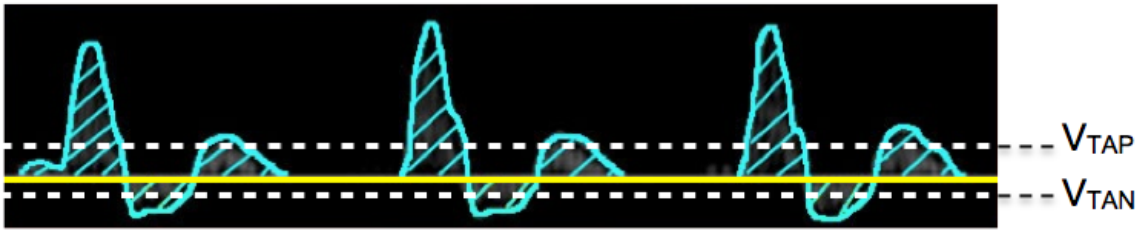
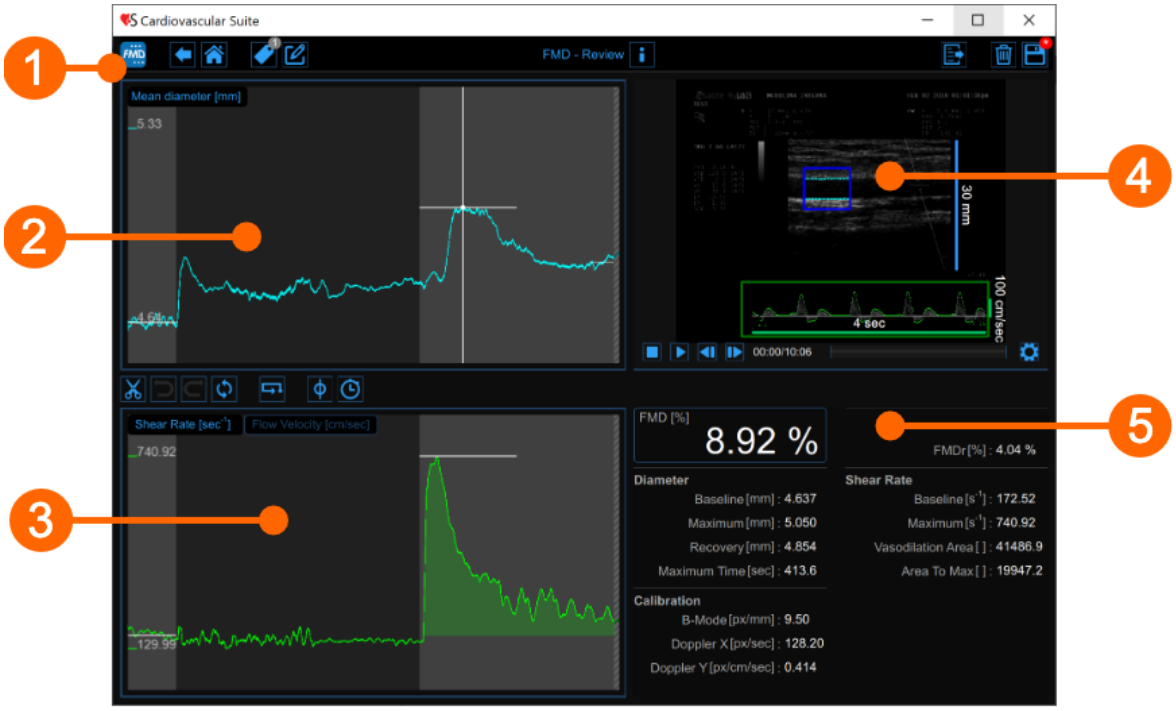


These two values are used to compute the Shear Rate as:

SR_{TAP} : Time Average Positive wall Shear Rate.

SR_{TAN} : Time Average Negative wall Shear Rate.

11.3 Review



The Review window shows the result of the analysis and allows you to remove piece of data that are considered to be "outliers". This can happen, for example, if in a short time interval the patient did move and the brachial artery was not correctly displayed. In the Review window you can review both the images and the result of the analysis and decide to remove the data that were generated in this time interval.

The Review window contains the following components:

1. Top bar
2. Mean diameter chart
3. Shear rate chart
4. Video window
5. Results panel

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11.3.1 Top bar

The top bar contains some essential information for the navigation.

The FMD Studio button shows a panel containing some information about Cardiovascular Suite, about the current study and the current document. Regarding the study, the study ID is displayed together with information about the patient and the institute. In addition, info regarding the current document are provided. Information about the software, such as version and type of license, are shown in the upper part of the panel.

The Home button closes the FMD Studio application and returns to the home screen of Cardiovascular Suite.

The back button closes the FMD Studio application and comes back to the Archive.

The Tags Management button opens a panel (see the following picture) that allows to create a new tag and associate it or an existing tag to the document. Tags can be managed through the Tags management into the Archive.

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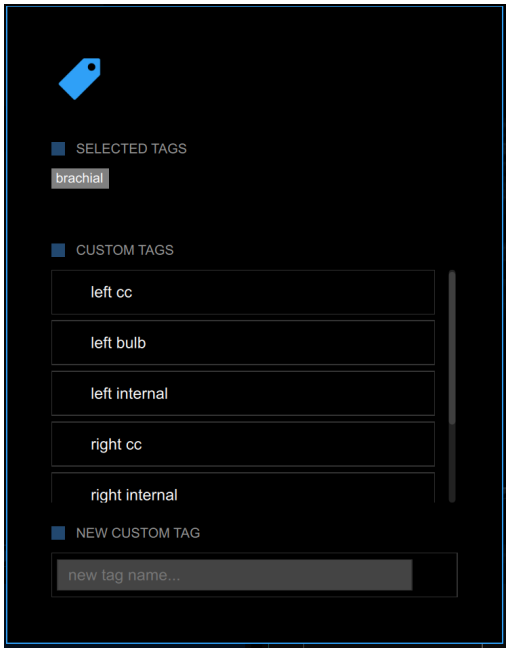
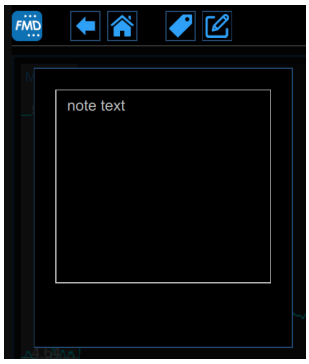


The Notes button can be used to enter a note in the document.



The Save button is used to save your changes to the document once you have edited the data.

The Delete the document button is used to delete the current document.

The Export button is used to export your data. You can export the Document Results and the Document Data.

The **Document Results** contains all the results of the analysis and all the information about the study, the document, and the patient.

The **Document Data** contains all the Document Results, a list of the Mean Diameter, the Shear Rate, and the Doppler Velocity (one value per second) and the Diameter and the Doppler Velocity values computed at each frame.

> Only the diameter values are actual instantaneous values because they are computed on the single images. The Doppler Velocity is actually a Time averaged value. In fact, despite it is calculated on the single image, it is computed in the time interval defined by the Doppler flow ROI. For more info, please see Doppler flow analysis.

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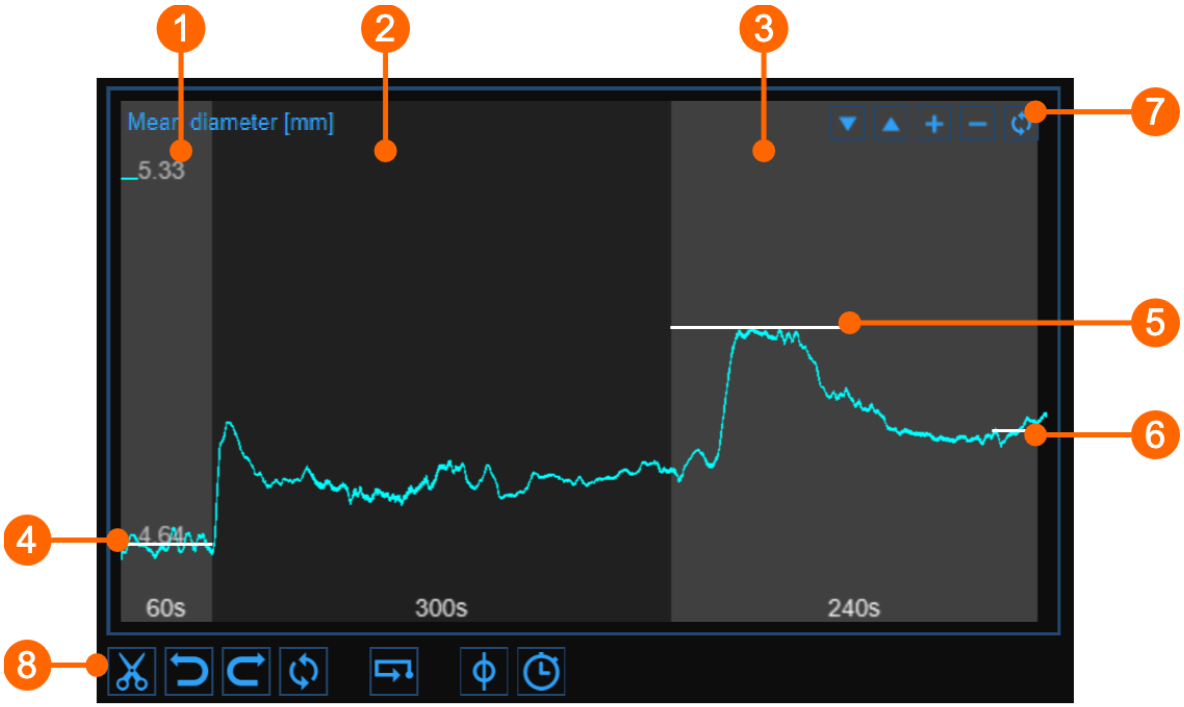
11.3.2 Mean diameter chart



The chart shows the trend of the mean diameter during the examination. The chart is divided into three or two parts, according to the study modality. You have basal **(1)**, ischemia **(2)** and vasodilation **(3)** intervals in FMD; ischemia is missing in vasodilation modality.

In the chart, three cursors are present (two cursors in "Vasodilation" study mode): the first one **(4)** is places at the baseline diameter value; the second one **(5)** is placed at the maximum diameter value in vasodilation; the third one **(6)** is placed at the post baseline (this cursors is absent in "Vasodilation" study modality). Cardiovascular Suite places the cursors at the position automatically computed at the end of the analysis. You can manually place these values if you see that some outliers have affected the automatic analysis.

These values are shown in the Results panel.

Using the buttons at the top right **(7)** you can move up or down the chart, enlarge or reduce the vertical scale or restore the default view.

The buttons under the chart **(8)** can be used for editing the chart in order to remove the outliers, for activating the graph cursor, and for modifying the timeline.

11.3.2.1 Remove the outliers

- Click on the Cut button.
- In the Mean diameter chart, click on one of the two extremes of the range to be deleted.
- Drag the mouse horizontally to the other extreme of the range to be deleted (see next paragraph for removal constraints).
- Once you have removed the outliers, click on the recompute button if you want to re-analyze the data on the edited chart.

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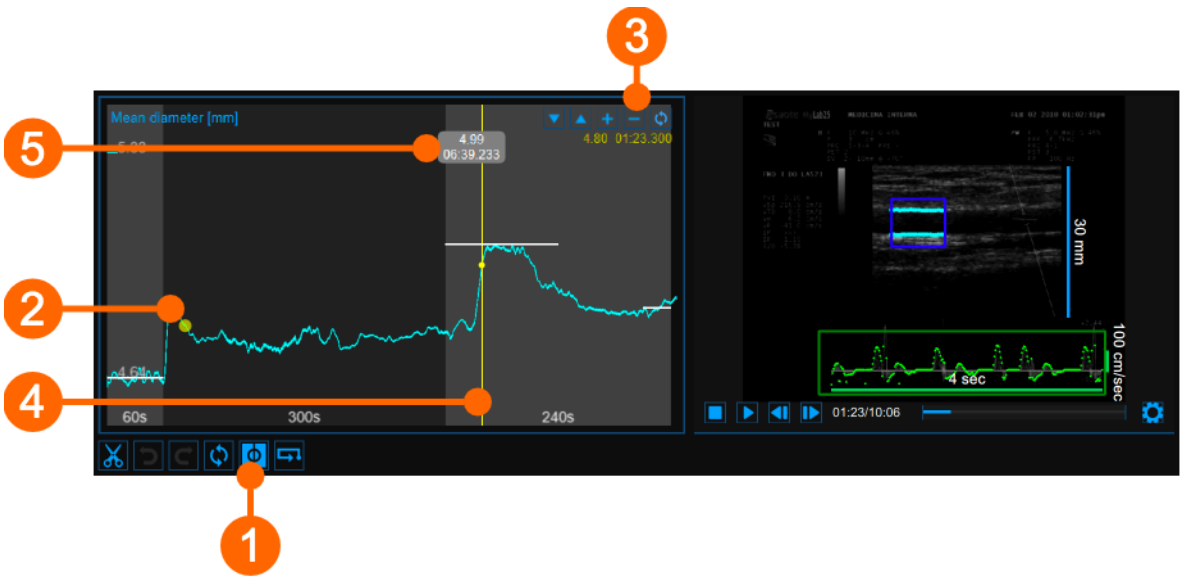
You can use the undo and redo buttons to cancel and restore your changes. The restore button cancels all your changes and restore original data.

Click on the Save button in the Top bar to save your changes to the document.

11.3.2.2 Graph cursors

As shown in the following figure, the Cursor button **(1)** activates a cursor **(2)** on the Mean Diameter chart that shows the current time position on the graph according to the images shown in the Video window. The coordinates (diameter value in millimeters and time value in the format *minutes:seconds.milliseconds*) of the cursor are dynamically updated and shown in **(3)**. When the Cursor button is active, it is also possible to know the coordinates of an exact point in the graph; it is only needed to hover over the chart and a second cursor **(4)** is displayed. It follows the mouse movements and the exact coordinates of the point are shown in the label **(5)** (diameter value is expressed in millimeters and the time value has the format *minutes:seconds.milliseconds*).



11.3.2.3 Modify the timeline

- Click the Timeline button **(4)**.
- Move the vertical cursors that are place at the end-baseline **(1)**, end-ischemia **(2)** and end-vasodilation **(3)**.

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11.3.2.4 Alerts

In FMD Studio Review you can cut and delete data from the mean diameter chart. Please, note that timeline constraints are already valid (see ***Timeline management*** paragraph in Setup panel).

After data removal, if there are intervals with a duration lower than the suggested value or than the allowed value, a yellow ( ) or red ( ), respectively, alert icon will appear next to the parameters that can be affected by the too short time interval. In addition, if the intervals do not meet the minimum duration allowed value some parameters will not be calculated. You can hover over the icons and an informative message about the warning or error situation will be displayed.

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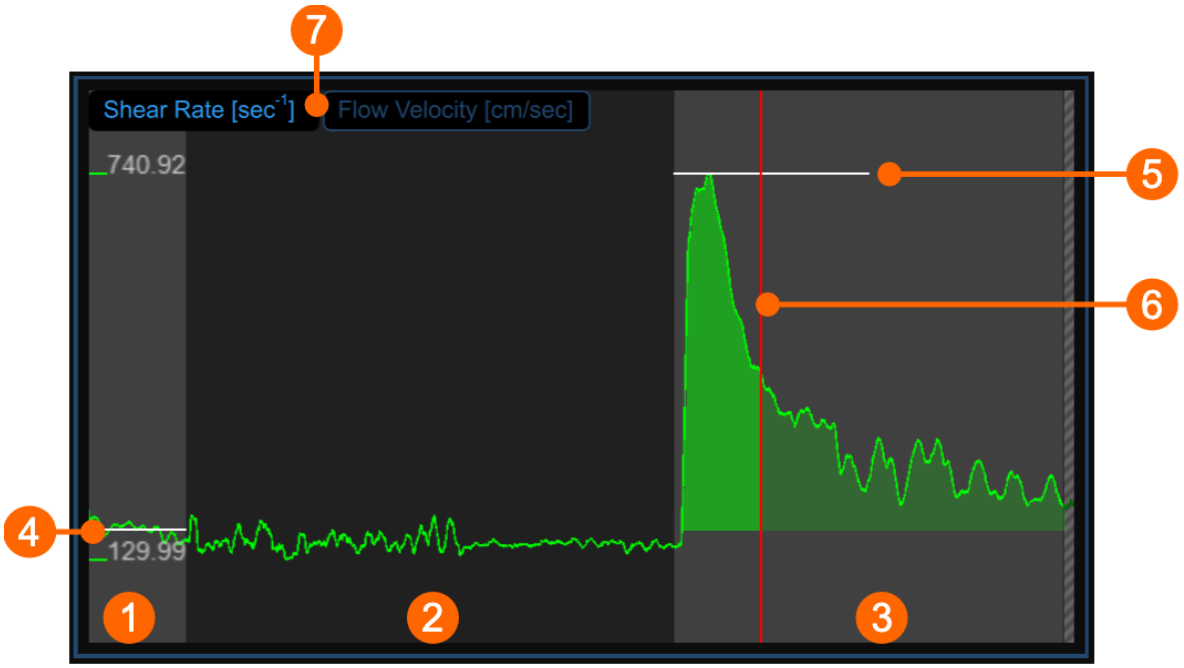
11.3.3 Shear rate chart



The chart shows the trend of the time averaged positive Shear Rate (or the time averaged positive Flow Velocity, according to selector **(7)**) during the examination. The chart is divided into three or two parts, according to the study modality. You have basal **(1)**, ischemia **(2)** and vasodilation **(3)** intervals in FMD; ischemia is missing in vasodilation modality.

In the chart, two cursors are present: the first one **(4)** is placed at the baseline value; the second one **(5)** is placed at the maximum value in vasodilation. A third cursors **(6)** is shown at the time value corresponding to the maximum value of the diameter when the same cursor is selected in the Mean diameter chart. Cardiovascular Suite places the cursors at the position automatically computed at the end of the analysis. You can manually place these values if you see that some outliers have affected the automatic analysis.

These values are shown in the Results panel.

11.3.3.1 Graph cursors

As shown in the following figure, the Cursor button at the bottom of the Mean diameter chart activates a cursor **(1)** on the Shear Rate chart that shows the current time position on the graph according to the images shown in the Video window. The coordinates (shear rate value in s^{-1} and time value in the format *minutes:seconds.milliseconds*) of the cursor are dynamically updated and shown in **(2)**. When the Cursor button is active, it is also possible to know the coordinates of an exact point in the graph; it is only needed to hover over the chart and a second cursor **(3)** is displayed. It follows the mouse movements and the exact coordinates of the point are shown in the label **(4)** (shear rate value is expressed in s^{-1} and the time value has the format *minutes:seconds.milliseconds*).

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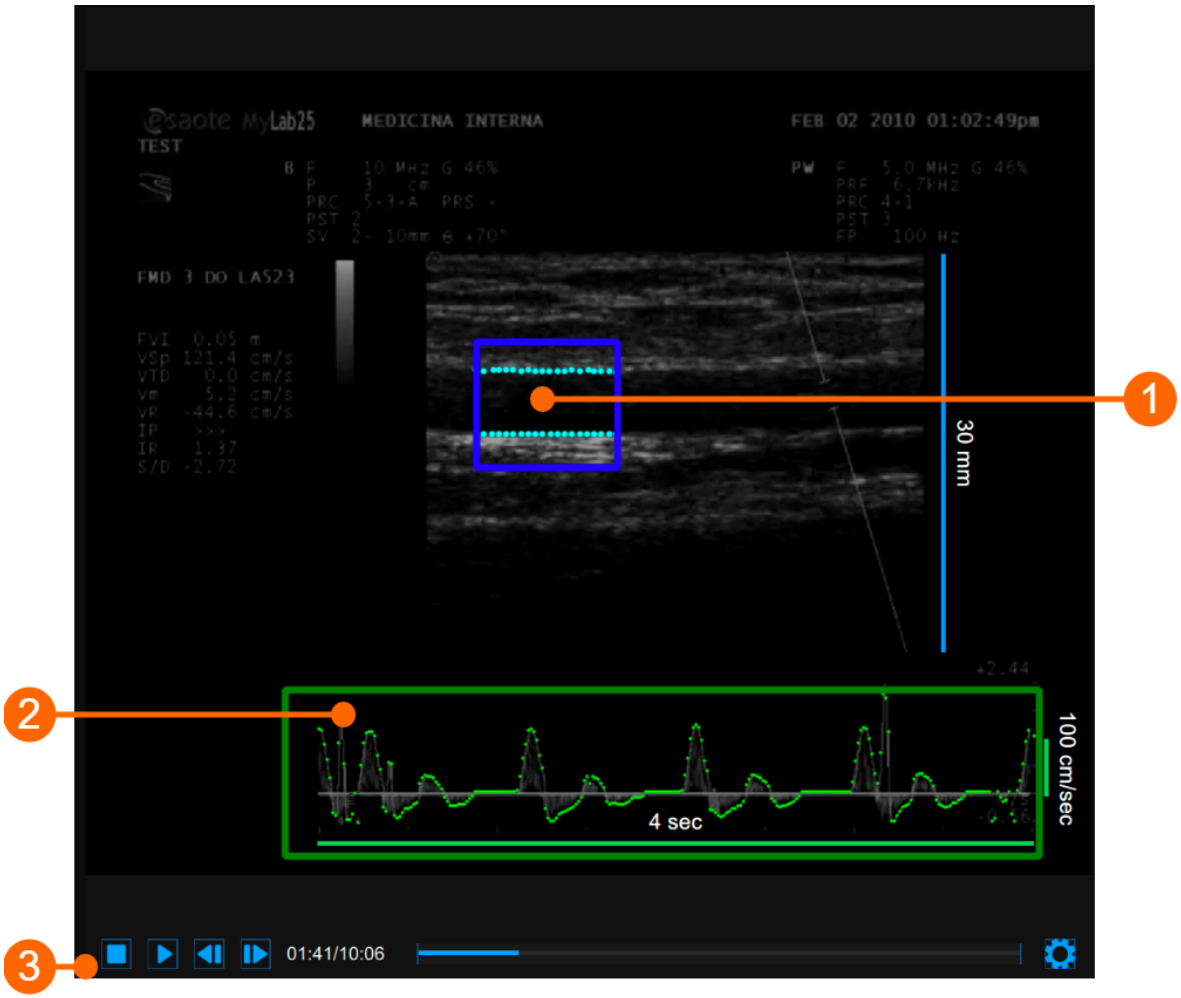
11.3.4 Video window



The video window shows the video signal from your ultrasound system. Two ROIs can be present in the window: the diameter ROI in blue **(1)** and the Doppler flow ROI in green **(2)**.

The Video control bar **(3)** is located at the bottom of the window.

If you want to expand the video window, you have to click on the Enlarge button.

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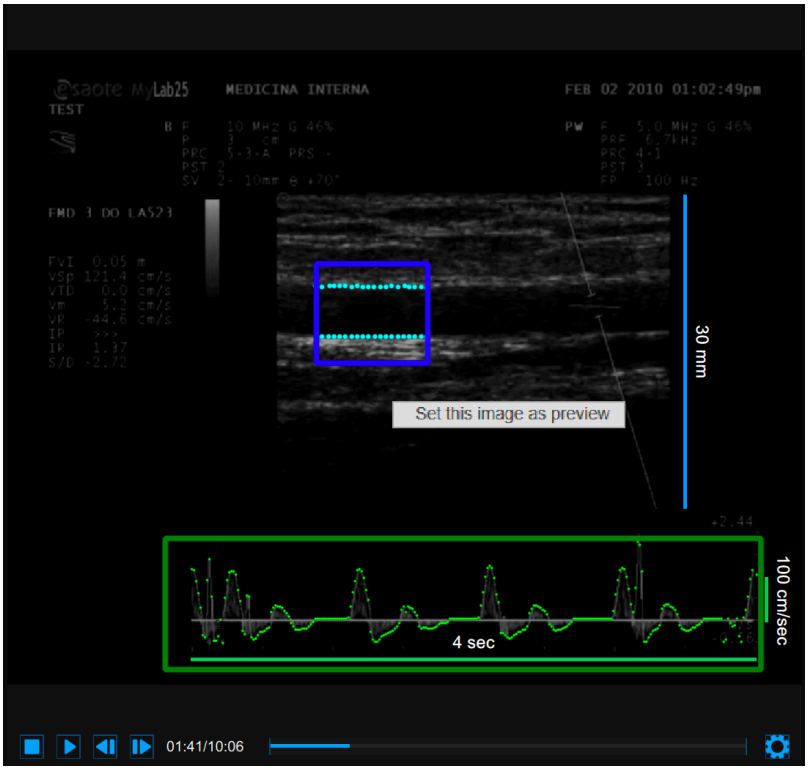
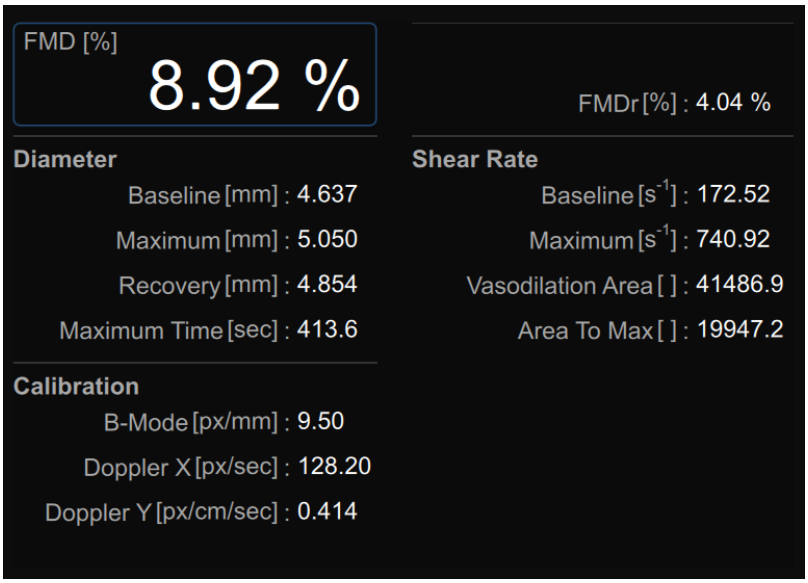


If you perform right click on the video window and click on "Set this image as preview" the current frame will be saved and displayed in the Documents Table as document preview (see Studies management)

11.3.5 Results panel



The panel shows the results of the analysis. The following data are displayed:

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- ***FMD [%]: Flow Mediated Dilation***

$$FMD = \frac{Maximum\ Diameter - Baseline\ Diameter}{Baseline\ Diameter}$$

- ***FMDr [%]: Flow Mediated Dilation with respect to the Recovery Diameter***

$$FMD_r = \frac{Maximum\ Diameter - Recovery\ Diameter}{Recovery\ Diameter}$$

Diameter

- ***Baseline Diameter [mm]***: mean of the diameter values in the "Baseline" time interval.
- ***Maximum Diameter [mm]***: maximum diameter value in the "Vasodilation" time interval.
- ***Recovery Diameter [mm]***: mean of the last 30 seconds of diameter values available in the "Vasodilation" time interval.
- ***Maximum Time [sec]***: time of the maximum diameter value in the "Vasodilation" time interval.

Calibration

- ***B-Mode calibration value [px/mm]:*** value of the calibration of the B-mode image
- ***Doppler X calibration value [px/sec]:*** value of calibration of the x axis (time) of PW Doppler
- ***Doppler Y calibration value [px/cm/sec]:*** value of calibration of the y axis (velocity) of PW Doppler

Shear Rate *(visible when the shear rate chart is visible)*

- ***Baseline Shear Rate [s^{-1}]***: mean of the shear rate values in the Baseline time interval.
- ***Maximum Shear Rate [s^{-1}]***: maximum of the shear rate values in the Vasodilation time interval.
- ***Vasodilation Area [dimensionless]***: area under the curve of the shear rate in the Vasodilation time interval, calculated with reference to the baseline shear rate value (Fig. 1).
- ***Area to Max [dimensionless]***: area under the curve of the shear rate in the time interval that begins with the Vasodilation and ends at the time of the Maximum Diameter, calculated with reference to the baseline shear rate value (Fig. 2).

Flow Velocity *(visible when the flow velocity chart is visible)*

- ***Baseline Flow Velocity [cm/sec]***: mean of the flow velocity values in the Baseline time interval.
- ***Maximum Flow Velocity [cm/sec]***: maximum of the flow velocity values in the Vasodilation time interval.
- ***Vasodilation Area [cm]***: area under the curve of the flow velocity in the Vasodilation time interval, calculated with reference to the baseline flow velocity value (Fig. 1).
- ***Area to Max [cm]***: area under the curve of the flow velocity in the time interval that begins with the Vasodilation and ends at the time of the Maximum Diameter, calculated with reference to the baseline flow velocity value (Fig. 2).

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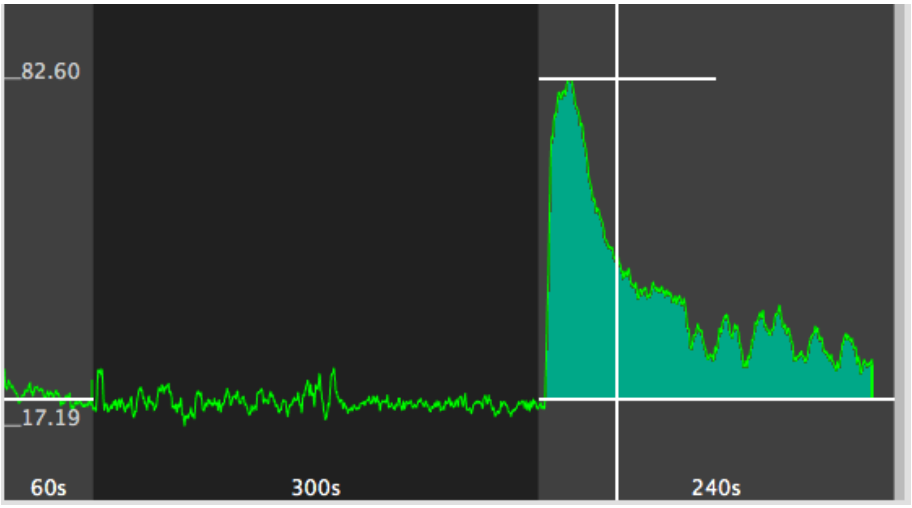

Figure 1 - Area

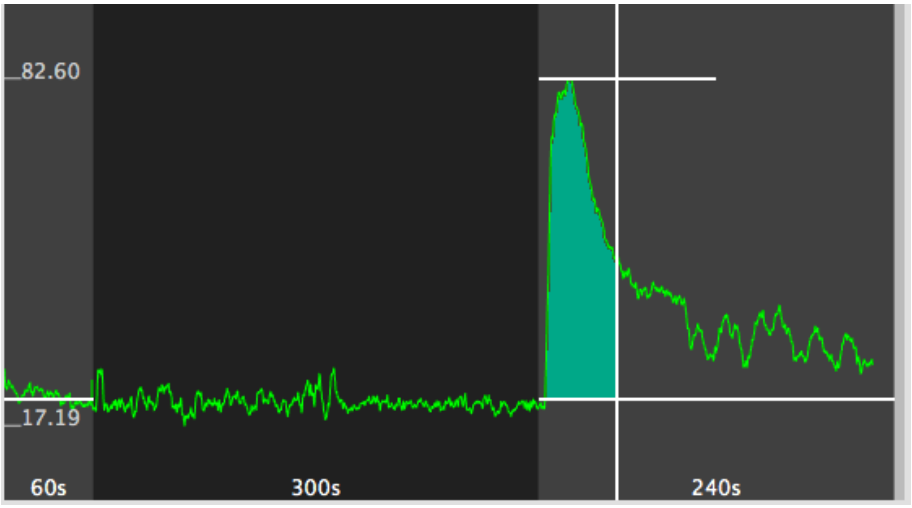

Figure 2 - Area to Max

These data can also be exported in different formats. See here for export details.

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12 Warnings

This software may provide incorrect results in the following cases:

- if recommendations regarding type of analysed images, adopted ultrasound equipment and experience of the operator are not followed;
- if the user does not perform the basic operations required, such as calibration and proper tracking of initial contours.

Essential requirement for a correct analysis is the operation of the device. In case of a fault:

- close and reopen the application software, or
- restart the computer where the software is installed and open the application again
- contact your dealer for assistance.

Any malfunction of the device, however, does not affect the state of health of the patient.

The user has the responsibility to check the accuracy of the external ultrasound images to avoid the possibility of generating an incorrect result.

The software device must be used in an environment that allows optimal visibility of the screen.

The software device has a 2 years warranty in which Quipu will provide security updates.

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13 References

- Gemignani V, Faita F, Ghiadoni L, Poggianti E, Demi M.

"A system for real-time measurement of the brachial artery diameter in B-mode ultrasound images."

IEEE Trans Med Imaging. 2007 Mar;26(3):393-404.

- Gemignani V, Bianchini E, Faita F, Giannarelli C, Plantinga Y, Ghiadoni L, Demi M.

"Ultrasound measurement of the brachial artery flow-mediated dilation without ECG gating"

Ultrasound Med Biol. 2008 Mar;34(3):385-91. Epub 2007 Oct 26.

- Faita F, Gemignani V, Bianchini E, Giannarelli C, Ghiadoni L, Demi M.

"Real-time measurement system for evaluation of the carotid intima-media thickness with a robust edge operator."

J Ultrasound Med. 2008 Sep;27(9):1353-61

- Bianchini E, Bozec E, Gemignani V, Faita F, Giannarelli C, Ghiadoni L, Demi M, Boutouyrie P, Laurent S.

"Assessment of carotid stiffness and intima-media thickness from ultrasound data: comparison between two methods."

J Ultrasound Med. 2010 Aug;29(8):1169-75.

- E. Bianchini, A. Corciu, L. Venneri, F. Faita, C. Giannarelli, V. Gemignani, M. Demi.

"Assessment of Cardiovascular Risk Markers from Ultrasound Images: System Reproducibility."

Computers in Cardiology 2008;35:105−108.

- Faita F, Masi S, Loukogeorgakis S, Gemignani V, Okorie M, Bianchini E, Charakida M, Demi M, Ghiadoni L, Deanfield JE.

"Comparison of two automatic methods for the assessment of brachial artery flow-mediated dilation."

J Hypertens. 2011 Jan;29(1):85-90.

- Ghiadoni L, Faita F, Salvetti M, Cordiano C, Biggi A, Puato M, Di Monaco A, De Siati L, Volpe M, Ambrosio G, Gemignani V, Muiesan M, Taddei S, Lanza GA, Cosentino F.

"Assessment of Flow-Mediated Dilation Reproducibility: a Nationwide Multicenter Study".

J Hypertens. 2012 Jul;30(7):1399-405

- Charakida M, Masi S, Lüscher TF, Kastelein JJ, Deanfield JE.

"Assessment of atherosclerosis: the role of flow-mediated dilatation."

Eur Heart J. 2010 Dec;31(23):2854-61. Epub 2010 Sep 23.

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- Yeboah J, Crouse JR, Hsu FC, Burke GL, Herrington DM.

  “Brachial flow-mediated dilation predicts incident cardiovascular events in older adults: the Cardiovascular Health Study.”

  Circulation. 2007 May 8;115(18):2390-7. Epub 2007 Apr 23.

- O'Leary DH, Bots ML.

  “Imaging of atherosclerosis: carotid intima-media thickness.”

  Eur Heart J. 2010 Jul;31(14):1682-9. Epub 2010 Jun 11.

- Amato M, Veglia F, de Faire U, Giral P, Rauramaa R, Smit AJ, Kurl S, Ravani A, Frigerio B, Sansaro D, Bonomi A, Tedesco CC, Castelnuovo S, Mannarino E, Humphries SE, Hamsten A, Tremoli E, Baldassarre D; IMPROVE study group.

"Carotid plaque-thickness and common carotid IMT show additive value in cardiovascular risk prediction and reclassification."

Atherosclerosis. 2017 Aug;263:412-419.

- Mattace-Raso FU, van der Cammen TJ, Hofman A, van Popele NM, Bos ML, Schalekamp MA, Asmar R, Reneman RS, Hoeks AP, Breteler MM, Witteman JC.

  “Arterial stiffness and risk of coronary heart disease and stroke: the Rotterdam Study.”

  Circulation. 2006 Feb 7;113(5):657-63.

- Lian Engelen, Isabel Ferreira, Coen D Stehouwer, Pierre Boutouyrie, Stéphane Laurent, Reference Values for Arterial Measurements Collaboration

  "Reference intervals for common carotid intima-media thickness measured with echotracking: relation with risk factors"

  Eur Heart J. 2013 Aug;34(30):2368-80. Epub 2012 Nov 27.

- Lian Engelen, Jelle Bossuyt, Isabel Ferreira, Luc M van Bortel, Koen D Reesink, Patrick Segers, Coen D Stehouwer, Stéphane Laurent, Pierre Boutouyrie, Reference Values for Arterial Measurements Collaboration

  "Reference values for local arterial stiffness. Part A: carotid artery"

  J Hypertens. 2015 Oct;33(10):1981-96.

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14 Contacts

Quipu S.r.l.

Address:

via Moruzzi 1

I-56124 Pisa Italy

Telephone:

(+39) 050 315 2612

Web:

www.quipu.eu

info@quipu.eu

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