



materialise

innovators you can count on

Materialise Mimics Enlight

Medical 1.0

Instructions for Software Use



Description of Materialise Mimics Enlight Medical software

Materialise Mimics Enlight Medical is a workflow-based software interface for the transfer of medical images to an output file. The system provides visualization and measurement tools to enable the user to plan the procedure.

Materialise Mimics Enlight Medical reads DICOM compliant medical images from a medical scanner, supporting a wide range of scanners. The software provides different methods to visualize and segment anatomical structures. Based on the medical images and/or 3D reconstruction measurements can be created and visualized. This all will be saved in a digital output file which can be afterwards used as input data for a CAD or additive manufacturing system.

Indications for use

Materialise Mimics Enlight Medical is intended for use as a software interface and image segmentation system for the transfer of DICOM imaging information from a medical scanner to an output file.

It is also intended as a software to aid in reading and interpreting DICOM compliant images for structural heart and vascular treatment options. For this purpose, Materialise Mimics Enlight Medical provides additional visualization and measurement tools to enable the user to screen and plan the procedure.

The Materialise Mimics Enlight Medical output file can be used for the fabrication of physical replicas of the output file using traditional or additive manufacturing methods. The physical replica can be used for diagnostic purposes in the field of cardiovascular applications.

Materialise Mimics Enlight Medical should be used in conjunction with other diagnostic tools and expert clinical judgement.

Materialise Mimics Enlight Medical is not intended to predict the performance of a medical device.

Mimics Enlight Medical is not intended for mammography imaging or diagnosis.

Best-practice tips and precautions

The fluoroscopy tool can help plan C-arm angles; the planned angles will still need to be adapted during the procedure.

Further clinical investigations including a real clinical setting, linking the pre-operational planning with postop clinical data (neoLVOT area/blockage, survival) is needed to further confirm the clinical benefit.

Be advised that the quality of medical images determines the accuracy of the 3D model in Materialise Mimics Enlight Medical. Scanning protocols are left to the discretion of the user; however, we recommend that industry standards are referenced and followed. Only images obtained less than six months before should be used for evaluating surgical treatment options.



Please be aware that the Dicom coordinate system is reset for each Dicom series originating from all Hitachi scanners and from Siemens Symphony, Sonata and Harmony scanners with software versions older than Syngo MR B13.

Materialise Mimics Enlight Medical supports measurements with a precision of 0.01 mm. Please note that the measurements are limited by the resolution of the images.

Rx^{only} CAUTION: Federal law (USA) restricts this device to sale by or on the order of a Physician

Instructions for use

Starting Materialise Mimics Enlight Medical

After installing the software on your PC, double click the Materialise Mimics Enlight icon. You may also click on the **Start Button** → **All Programs** → **Materialise Software** → **Materialise Mimics Enlight Medical** to begin.

Materialise software is protected by a key file. When you start Materialise Mimics Enlight Medical for the first time or when your key has expired, the Key Request Wizard will automatically start up to assist you with the registration process. Available options are explained in the **User manual**. We recommend that you select '**instant activation**' in the Key Request Wizard. This will automatically renew your license Key File when it expires as long as you have internet access.

Minimum system requirements

Software	Hardware
Windows 7 – 64bit	Intel Core 2 Duo / AMD X2 AM2 or equivalent
Internet Explorer 8 and compatible	4 GB RAM
Adobe PDF viewer	DirectX 9.0c compliant graphics card with 512 MB RAM
	5 GB free hard disk space
	Resolution of 1280x1024

Note: Mac users can install Materialise Mimics Enlight Medical using Bootcamp in combination with a supported Windows OS

Preferred system requirements

Software	Hardware
Windows 7 - 64bit	Third generation Core i5/i7 or equivalent
Internet Explorer 8 and compatible	8 GB RAM
	DirectX 10.0 compliant ATI Radeon/nVidia GeForce card with 1GB RAM
	10 GB free hard disk space
	Resolution of 1680x1050 or higher

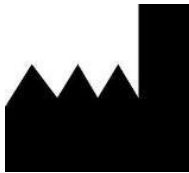
Note: Other qualifications may apply. When working with datasets larger than 1GB the system should comply with the recommended system requirements.



It is recommended to use our software within a hardware and/or network environment in which cyber security controls have been implemented including anti-virus and use of firewall.

Manufacturer contact details

Manufactured in August 2019 by:



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Materialise Mimics Enlight Medical is a CE-marked product.

Patent Notice

This product is covered by the following patents:

US9,943,373; US9,693,830

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