This document contains the basic 'Instructions for Use' of Materialise Mimics Medical.
Detailed instructions can be found in the 'User Guide'.
English is the language used in the Mimics Medical software interface.

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1 Description of Mimics Medical software

Materialise Mimics Medical, briefly 'Mimics Medical', is a software tool for visualizing and segmenting medical images (such as CT and MRI) and rendering 3D objects. Mimics Medical may be used as a medical device, within the limits of the described below intended use statement.

Mimics Medical may be used to load and process stacks of 2D images from numerous formats including: Dicom 3.0 format, BMP, TIFF, JPG and raw images. Once images are processed, they can be used for numerous applications of Engineering on Anatomy including measuring, designing, modeling and 3D printing.

Mimics Medical enables users to control and correct the segmentation of medical images such as CT and MRI-scans. A trained software user can easily and accurately define 3D models for visualization and/or production. The software also provides a way to remove image artifacts that may appear due to a patient's metal implants.

Additional modules provide more extensive capabilities such as the ability to perform CAD operations (for designing custom prosthesis or optimizing new devices based on image data) or preparing finite element meshes.

Mimics Medical is not intended to create physical replicas of anatomical models for diagnostic use or to predict the performance of a medical device.

2 Indications for use

Mimics Medical is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance Imaging scanner to an output file. It is also used as pre-operative software for simulating/evaluating surgical treatment options.

Mimics Medical is not intended to be used for mammography imaging.

3 Warnings and recommendations

Mimics Medical should only be used by trained medical professionals. We recommend that all users participate in a training offered by a Materialise expert for best results. As stipulated in the End User License Agreement, Materialise warrants during the Warranty Period that Mimics Medical shall operate substantially in accordance with the functional specifications in the Documentation. Any other warranty, whether express or implied, including but not limited to any warranty regarding fitness for purpose, safety, performance or effectiveness aspects of the medical application or device for which Mimics Medical is used, is disclaimed. The output of (semi-)automatic segmentation functionality in Mimics Medical should always be verified by the user before being used for any purpose.

Inter-slice and in-slice distance of less than 1mm are recommended for treatment decisions based on 3D reconstructions for pre-operative planning or 3D printing.

Mimics Medical displays measurements with 4 digits behind the decimal point. Accuracy of measurements is limited by the pixel size of the images.

Python scripts written by the user should always be validated by the user before being used for any purpose. Python scripts written for previous versions of Mimics Medical should be re-validated by the user before being applied with the present version.

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4 Best-practice tips and precautions

Be advised that the quality of medical images determines the accuracy of the 3D model in Mimics 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 simulating and/or 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.

5 Instructions for use

5.1. Starting Mimics Medical

After installing the software on your PC, double click the Mimics Medical icon on your desktop. You may also click on the **Start Button → All Programs → Materialise → Mimics Medical** to begin. Be sure to select the *Medical edition* for clinical applications.

Materialise software is protected by a key file. When you start Mimics 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 Guide**. 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.

5.2. Minimum system requirements

Software	Hardware
Windows® 7 SP1 – 64bit	Intel® Core™ 2 Duo / AMD Athlon™ X2 AM2 or equivalent
Internet Explorer® 10	4 GB RAM
PDF viewer	DirectX® 11.0 compliant graphics card with 1 GB RAM
.NET framework 4.5.2 (or higher)	5 GB free hard disk space
	Resolution of 1280x1024

Note: Mac® users can install the MIS using Boot Camp® in combination with a supported Windows OS.

5.3. Preferred system requirements

Software	Hardware
Windows® 7 SP1 – 64bit	Third generation Intel® Core™ i5/i7 or equivalent
Internet Explorer® 10	16 GB RAM
PDF viewer	DirectX® 11.0 compliant AMD Radeon/NVIDIA® GeForce® card with 2 GB RAM
.NET framework 4.5.2 (or higher)	20 GB free hard disk space

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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. Advanced segmentation tools such as Smart Expand and Coronary segmentation require hardware as specified in the recommended requirements even for smaller datasets. When working with 4D or multi stack data, the amount of RAM needed increases as you import more image series into the project.

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.

6 Manufacturer contact details

Manufactured in January 2019 by:
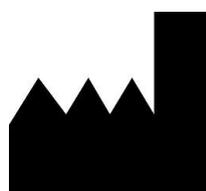
Materialise NV

Technologielaan 15

3001 Leuven, Belgium

Phone: +32 16 39 66 11

http://www.materialise.com

CE 0120 Mimics Medical is a CE-marked product.

Australian Sponsor:
Emergo Australia; Level 20, Tower II Darling Park; 201 Sussex Street; Sydney NSW 2000; Australia