*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, which can then be used in Mimics Medical for visualization, measuring, treatment planning and producing an output file to be used for additive manufacturing (3D printing). Mimics Medical also has functionality for linking to third party software packages.

Mimics Medical is not intended 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 medical imaging information to an output file. Mimics Medical is also intended for measuring and treatment planning.

The Mimics Medical output 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 orthopedic, maxillofacial and cardiovascular applications.

Mimics Medical should be used in conjunction with expert clinical judgement.

# 3  Contraindications

Please note that Mimics Medical is not intended for mammography imaging.

# 4  Warnings and recommendations

Mimics Medical should only be used by trained medical professionals. To engage in the experience, we recommend that all users participate in a training offered by a Materialise expert. 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.

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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.

# 5  Best-practice tips and precautions

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Mimics Medical can also be used by biomedical engineers or personnel equivalent by training or experience. Their results should be used in conjunction with expert clinical judgement.

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 planning and/or evaluating 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.

# 6  Instructions for use

## 6.1.  Starting Mimics Medical

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

## 6.2.  Minimum system requirements

| Software | Hardware |
|---|---|
| Windows® 10 – 64bit | Third generation Intel® Core™ i3 or equivalent |
| Internet Explorer® 11 or equivalent | 8 GB RAM |
| PDF viewer | DirectX® 11.0 compliant graphics card with 1 GB RAM |
| .NET framework 4.6.1 (or higher) | 15 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.

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
## 6.3. Preferred system requirements

| Software | Hardware |
|---|---|
| Windows® 10 – 64bit | Third generation Intel® Core™ i5/i7 or equivalent |
| Internet Explorer® 11 or equivalent | 16 GB RAM |
| PDF viewer | DirectX® 11.0 compliant AMD Radeon/NVIDIA® GeForce® card with 2 GB RAM |
| .NET framework 4.6.1 (or higher) | 20 GB free hard disk space |
| | Resolution of 1920x1080 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.

| | |
|---|---|
|  | Legal Manufacturer |
|  | Caution, please consult the instructions for use and the accompanying documentation |
|  | Consult instructions for use or consult electronic instructions for use |
|  | Date of manufacture |
| LOT | Batch code |
| MD | Medical device |
| UDI | Unique Device Identifier |

IFU for Mimics Medical is supplied in electronic form in PDF format on www.materialise.com/electronic-instructions-for-use. Paper version may be requested by emailing leaflet@materialise.be and will be provided within 7 calendar days at no additional cost.

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# 7  Manufacturer contact details

**Manufactured in September 2020 by:**
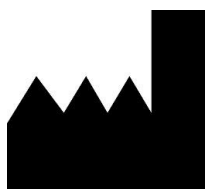
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http://www.materialise.com

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Mimics Medical is a CE-marked product

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