

1 Description of Mimics software

Materialise's Interactive Medical Image Control System (MIMICS) is a software tool for visualizing and segmenting medical images (such as CT and MRI) and rendering 3D objects. The software comes in two editions: Research and Medical. Only the Medical edition may be used as a medical device, within the limits described in the intended use statements of these editions. The Research edition is intended for research only.

Mimics 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 Base 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.

2 Indications for use

Mimics Medical (hereafter 'Mimics') 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 is not intended to be used for mammography imaging.

3 Warnings and recommendations

Mimics software should only be used by trained professionals. We recommend that all users participate in a training offered by a Materialise expert for best results. Outputs intended to treat or diagnose patients must be checked by the responsible clinician who can compare the 3D reconstructions with the slice images to verify quality. It is the clinician's ultimate obligation to exercise his/her professional judgment as to whether the treatment planned using the medical device software (Mimics) should be performed. 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. For bone related applications, we advise you to reconstruct the medical images in a window optimized for bone.

Mimics supports measurements with a precision of 0.0001 mm/degree. Please note that the measurements are limited by the resolution of the images.

4 Best-practice tips and precautions

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

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

Materialise software is protected by a key file. When you start Mimics 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 **Reference 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
	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
	20 GB free hard disk space
	Resolution of 1680x1050 or higher

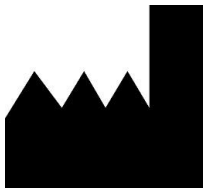
Note: Other qualifications may apply. When working with datasets larger than 1GB the system should comply with the recommended system requirements. Advanced segmentation tools such as Smart Expand and Coronary segmentation require hardware as specified in the recommended requirements even for smaller datasets.

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

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CE⁰¹²⁰ Mimics Medical is a CE-marked product.

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