

1 Description of 3-matic Medical software

Materialise 3-matic Medical is a software that combines CAD tools with pre-processing (meshing) capabilities. To do this, it works on triangulated (STL) files which makes it suitable for freeform 3D data, like the anatomical data coming from the segmentation of medical images (from Mimics Medical). As such, 3-matic Medical can be seen as a tool that allows Anatomical CAD or what Materialise has coined 'Engineering on Anatomy'. 3-matic Medical may be used as a medical device, within the limits of the described below intended use statement.

3-matic Medical may be used to import anatomical data and other 3D objects in STL format or in numerous CAD formats including: CATIA, IGES, STEP, etc. Once objects have been loaded, they can be used for many applications of 'Engineering on Anatomy' including measuring, designing, modeling and 3D printing.

The modules that can be obtained for 3-matic Medical enable the users to do thorough 3D measurements and analyses, design an implant or surgical guide, or prepare the mesh for finite element modeling.

2 Indications for use

3-matic Medical is intended for use as software for computer assisted design and manufacturing of medical exo- and endo-protheses, patient specific medical and dental/orthodontic accessories and dental restorations.

3 Warnings and recommendations

3-matic Medical software should only be used by trained 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 3-matic 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 3-matic Medical is used, is disclaimed.

3-matic Medical displays measurements with 4 digits behind the decimal point. Accuracy of measurements is limited by the data source.

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 3-matic Medical should be re-validated by the user before being applied with the present version.

4 Best-practice tips and precautions

Be advised that the quality and resolution of your triangle mesh can influence the result of design or analysis operations. For best results, we recommend that industry standards are referenced and followed.

5 Instructions for use

5.1. Starting 3-matic Medical

After installing the software on your PC, double click the 3-matic Medical icon on your desktop. You may also click on the **Start Button** → **All Programs** → **Materialise** → **3-matic Medical** to begin. Be sure to select the *Medical edition* for clinical applications.

Materialise software is protected by a key file. When you start 3-matic 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 **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® 10 – 64bit Version 1607	Third generation Intel® Core™ i5 or equivalent
Microsoft Edge® 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 1920x1080

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® 10 – 64bit Version 1909	Third generation Intel® Core™ i7 or equivalent
Microsoft Edge® 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

*Other qualifications may apply.



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.

5.4. Description of Symbols used in the About Box of the software

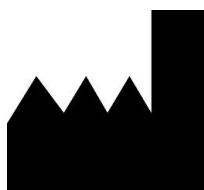
	Legal Manufacturer
	Caution, please consult the instructions for use and the accompanying documentation
	Consult instructions for use or consult electronic instructions for use
	Date of manufacture
	Batch code
	Medical device
	Unique Device Identifier

IFU for Materialise 3-matic 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.



6 Manufacturer contact detail

Manufactured in June 2021 by:



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3-matic Medical is a CE-marked product.

Australian Sponsor:

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