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

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1 Description of Mimics AA

Materialise Mimics® Automatic Algorithms module, briefly AA, is a software module for segmenting medical images (such as CT and MRI). Mimics AA is used as a medical device, within the limits of the described below intended use statement. Mimics AA may be used to process stacks of 2D images in the .mcs format. Once images are processed, they can be used in Mimics Medical for numerous applications of Engineering on Anatomy including measuring, designing, modeling and 3D printing.

The algorithms offered by Mimics AA are:

- Mimics AA Heart CT 1.5.2
- Mimics AA CMF CT 1.3.1
- Mimics AA Knee CT 3.0.1
- Mimics AA Knee MRI 2.1.3

2 Indications for use

Mimics Automatic Algorithms are intended for use as an image segmentation system for the transfer of medical imaging information to a Mimics output file.

Additional information:

The automatic algorithms interfaces with the Mimics Viewer platform.

It enables MIS users to upload .mcs files to SurgiCase Drive (ie. case management part of Mimics Viewer platform) and request an automatic segmentation. Users are informed once the segmentation has finished (successfully or not) and can then view or download the files in question if no failure was reported.

Mimics AA can only be used for clinical use, if:
- the users are using the software in countries where regulatory clearance has been obtained.
- and the user has a lawful license to Mimics Medical
Both conditions need to be met to use Mimics AA for clinical use. Currently EU, US, Canada and Japan meet these conditions.

Mimics AA is not for clinical use in following countries;
Australia, Colombia, Ecuador, Singapore, Saudi Arabia, South Korea, Taiwan, Thailand, Turkey, Israel

3 Contraindications

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

4 Warnings and recommendations

Mimics AA 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 AA 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 AA is used, is disclaimed. The output of automatic segmentation functionality in Mimics AA should always

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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. Accuracy of measurements is limited by the pixel size of the images.

5 Best-practice tips and precautions

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Mimics AA 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 AA. Recommended scan protocols can be found in the technical descriptions, located in the Mimics Viewer "Help" section. 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 AA

1. Import images to Mimics Medical version 18 or later
2. Navigate to https://mimicsviewer.materialise.com/ to begin.
3. Log in
4. Create a new case & upload a mimics project
5. Initiate the automatic segmentation with Mimics AA
6. Download the Mimics project file for reviewing & editing the segmentation in Mimics Medical

6.2. System requirements

Following operating systems are supported:

- Latest version of iOS
- Latest version of Mac OS
- Windows® 7 Service Pack 1 (SP1) (32-bit or 64-bit)
- Windows 10

Following Browsers are supported:

Browser with WebGL support and WebGL enabled.

- Google Chrome on Windows OS desktop, Mac OS X
- Microsoft Edge on Windows OS desktop
- Mozilla Firefox on Windows OS desktop
- Apple Safari on Mac OS X, iOS Oss

Internet connection

- 3G or higher

Application window resolution

- WXGA or higher

Screen size

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- 7 inches or more

Memory

- 2GB RAM or more

CPU

- Dual Core processor or better

Graphics card

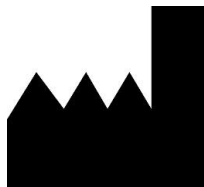- Please refer to the following list describing black/white lists for graphic cards:
https://www.khronos.org/webgl/wiki/BlacklistsAndWhitelists

Security

- Anti-virus and anti-malware software
- Firewall 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
LOT	Batch code
MD	Medical device
UDI	Unique Device Identifier

IFU for Mimics AA 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 January 2021 by:

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innovators you can count on