



Mimics Innovation Suite

Dicom Conformance Statement

Introduction

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.

Definition and abbreviation

The following symbols and abbreviations are used in this document:

DICOM	Digital Imaging and Communications in Medicine
FSC	File-set Creator
FSR	File-set Reader
UID	Unique Identifier
SOP	DICOM service-Object Pair

Implementation Mode

Mimics' Dicom interface implementation supports the DICOM File Format as described in "Digital Imaging and Communications in Medicine (DICOM) 3.0 – 1999, National Electrical Manufacturers Association (NEMA), PS3.1-14. Testing and validation of Media Storage Interface was performed to ensure correspondence with this DICOM Conformance Statement. Mimics does not support any network services such as query/retrieve or other network transfer functionalities.

Mimics is used for the visualization, analysis and segmentation of medical images. Provided with a Storage Media device, Mimics reads and writes CT and MRI, as well as X-Ray and 3D ultrasound images when using the Research Edition of the software.

Data Flow Diagram

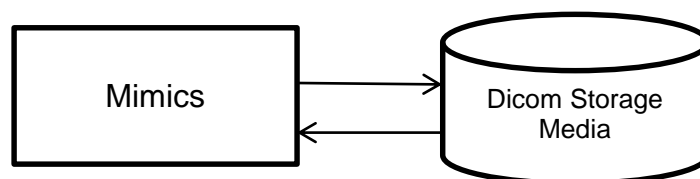


Figure 1. Mimics displays and exports Dicom information

Functional Definitions of Application Entities

- Mimics displays information of DICOM files on the medium
- Mimics exports DICOM files onto a medium

/ Storage provider AE

Not applicable

/ Query/Retrieve user AE

Not applicable

/ Media storage AE

Mimics provides Standard Conformance to the following DICOM 3.0 Storage SOP Classes.

Name	UID
CR image storage	1.2.840.10008.5.1.4.1.1.1
CT Image Storage	1.2.840.10008.5.1.4.1.1.2
Enhanced CT Image Storage	1.2.840.10008.5.1.4.1.1.2.1
MR Image Storage	1.2.840.10008.5.1.4.1.1.4
Enhanced MR Image Storage	1.2.840.10008.5.1.4.1.1.4.1
HP_LIVE_3D_02	1.2.840.113543.6.6.1.3.10002

In order to import images correctly the following mandatory attributes are required.

IOD	Attribute Name	Tag
Serie	Modality	0008,0060
Series	Series number	0020,0011
Equipment ¹	Manufacturer	0008,0070
Equipment ¹	Manufacturer's model name	0008,1090
Equipment ¹	Software Version Number	0018,1020
Image	Pixel Spacing	0028,0030

Image	Image Orientation (Patient)	0020,0013
Image	Image Position (Patient)	0020,0032
Image	Image Type	0008,0008
Image	Lossy image compression	0028,2110
Pixel	Photometric interpretation	0028,0004
Pixel	Rows	0028,0010
Pixel	Columns	0028,0011
Pixel	Bits Allocated	0028,0100
Pixel	Bits Stored	0028,0101
Pixel	High bit	0028,0102
CR ²	Imager Pixel Spacing	0018,1164
LUT	Rescale Intercept	0028,1052
LUT	Rescale Slope	0028,1053
LUT	Rescale Type	0028,1054

¹ required for Siemens Symphony and Sonata with software versions MR A40 or earlier and Hitachi MRI scanners

² required for X-ray images

Regulatory Information:

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. It is also used as pre-operative software for simulating /evaluating surgical treatment options.

Mimics Research is intended only for research purposes. It is intended as a software interface and image segmentation system for the transfer of imaging information from a variety of imaging sources to an output file. It is also used as software for simulating, measuring and modeling in the field of biomedical research. Mimics Research must not be used, and is not intended to be used, for any medical purpose whatsoever.

Materialise Belgium – Technologielaan 15 – 3000 Leuven – Belgium

CE ¹⁶³⁹ Mimics Medical is a CE-marked product. Copyright 2014 Materialise N.V – L-10122 revision 1, 04/2014