

Software	Facad	SW version	3.8	Rev date	2016-02-12
Title	Facad DICOM Conformance Statement				

DICOM Conformance Statement

Facad Orthodontic Tracing software is manufactured by Ilexis AB.

DICOM Conformance Statement issued by Ilexis AB.

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1 DICOM Conformance Statement Overview

Facad® is a software program used for orthodontic tracing, cephalometric analysis, and visual diagnostic imaging, as well as for treatment planning with soft tissue profile prediction for both orthodontics and maxillo-facial surgery.

Tracing, cephalometric analysis, measurements, and imaging is performed on imported image files in several different image formats. The DICOM image file format is one of the accepted image formats. DICOM images are imported as individual DICOM files which may be stored at any Windows file system location. The application supports basic image viewing operations like zooming and adjusting image brightness and contrast. Changes made to the images, together with graphics overlaying the images, can be exported as image files (but not in DICOM format) and images can be exported to the system clipboard and/or an office (i.e., paper) printer.

Facad does not support DICOM printing nor is able to print to P2P film printers.

Supported Operating System (OS) are Windows 10, Windows 8.1, Windows 8, Windows 7, and Vista.

2 Introduction

The introduction specifies product and relevant disclaimers as well as any general information that the vendor feels is appropriate.

2.1 Revision History

The revision history provides dates and differences of the different releases.

Document version	Date of issue	Status	Description
00	2016-02-03	Not Auth	Initial version
01	2016-02-12	Authorized	Released version

2.2 Audience

This Conformance Statement is intended for:

- (Potential) customers
- System integrators of medical equipment
- Marketing staff interested in system functionality

It is assumed that the reader is familiar with the DICOM standard.

2.3 Remarks

The DICOM Conformance Statement is contained in chapter 4 through 8 and follows the contents and structuring requirements of DICOM PS 3.2.

2.4 Definitions, Terms and Abbreviations

Abbreviation/Term	Explanation
AE	Application Entity
CD	Compact disc
DICOM	Digital Imaging and Communications in Medicine
DVD	Digital Versatile Disc
FSC	File-set Creator
FSR	File-set Reader
FSU	File-set Updater
PACS	Picture Archiving and Communications System
RWA	Real-World Activity
SCU	Service Class User

2.5 References

[DICOM] Digital Imaging and Communications in Medicine, Parts 1 - 18 (NEMA PS 3.1- PS 3.18),
National Electrical Manufacturers Association (NEMA)
Publication Sales 1300 N. 17th Street, Suite 1752 Rosslyn, Virginia. 22209, United States of America
Internet: <http://medical.nema.org/>

3 Networking

Facad has no DICOM networking implementation, so no import or export of DICOM object data over network is possible.

4 Media Interchange

Facad is not intended to be used as a primary data storage medium for medical imaging data. As such, the operator should not rely on the software for permanent storage, but instead must rely on permanent storage at a separate location (i.e. PACS archive).

For hard drive, CD, DVD and USB device, Facad can perform the DICOM Media Storage service and File Format (DICOM Part 10, PS 3.10) as SCU, with capabilities for RWA Read Images (as FSR).

4.1 Implementation model

Application Data Flow Diagram

Facad implements the role of File Set Reader (FSR) when connected to a DICOM Part 10 Storage Medium, and will import images from the storage medium.

Facad supports images with the following DICOM photometric interpretations as shown in following table.

Photometric Interpretation	Import	Export	Viewing
MONOCHROME1	Yes	No	Yes
MONOCHROME2	Yes	No	Yes
RGB	Yes	No	Yes

4.2 AE Specifications

Facad supports the following Standard Application Profiles.

Description	Identifier
General Purpose CD-R Interchange	STD-GEN-CD
General Purpose Interchange on DVD-RAM Media	STD-GEN-DVD-RAM

File Meta Information for Facad

Not applicable, since Facad is neither FSC nor FSU.

Real-World Activities

Facad supports the following Real World Activities within the profile mentioned above.

Supported Application Profiles	Real World Activity	Role	Service Class Option
STD-GEN-CD	Read image(s) from CD Disk	FSR	Interchange
STD-GEN-DVD-RAM	Read image(s) from DVD Disk	FSR	Interchange

4.3 Read images from hard drive / CD disk / DVD disk

Facad will act as a FSR when reading selected images from the medium. Selection of an image file is made manually and by browsing. The user may select an image from the directory to be imported into Facad. When a DICOM image file is imported, the DICOM image file is copied from the hard drive or media into the organized Facad data area. Read Image will then read image data of the selected image, and displays image data in Facad. When importing, the images stored are an exact copy of the images from the medium.

The user is able to display relevant DICOM information from patient and image data for the currently displayed image and information for (non-private) DICOM attributes by selecting the function *Image information*.

The images should belong to one of the following SOP classes:

Supported SOP Classes

Name	UID
Computed Radiography (CR) Image Storage	1.2.840.10008.5.1.4.1.1.1
Digital X-Ray (DX) Image Storage – for Presentation	1.2.840.10008.5.1.4.1.1.1.1
Digital X-Ray (DX) Image Storage – for Processing	1.2.840.10008.5.1.4.1.1.1.1.1
Secondary Capture Image (SC) Storage	1.2.840.10008.5.1.4.1.1.7

Note that Facad shall ignore all unsupported DICOM SOP classes and unsupported (private) DICOM attributes.

Supported Transfer Syntaxes

Name	UID	Comments
DICOM Implicit VR Little Endian	1.2.840.10008.1.2	Default Transfer Syntax
Explicit VR Little Endian	1.2.840.10008.1.2.1	
DICOM Explicit VR Big Endian	1.2.840.10008.1.2.2	
Lossy JPEG Image Compression	1.2.840.10008.1.2.4.50	JPEG coding Process 1 for 8-bit images
DICOM Deflated Explicit VR Little Endian	1.2.840.10008.1.2.1.99	

Note that Facad shall ignore all unsupported DICOM and Private Transfer Syntaxes.

Export

The user shall not be able to Export a selected image from Facad to a DICOM Node or DICOM Media.

Storage

The user shall not be able to store a selected image from Facad to a DICOM Storage.

Printing

The user shall not be able to print a selected image from Facad to a DICOM Printer. The user shall not be able to print to P2P film printers.

Patient List

Facad shall present an overview of the patients in a patient list. The displayed Attributes in the Patients list shall allow the user to select a patient for further investigation.

Patient list shall display:

Attribute	VR	Tag
Patient's Name	PN	(0010,0010)
Patient's ID	LO	(0010,0020)
Patient's Birth Date	DA	(0010,0030)
Patient's Sex	CS	(0010,0040)

4.4 Media Configuration

Not applicable.

5 Extensions / Specializations / Privatizations

5.1 Standard Extended / Specialized / Private SOPs

Facad does not implement any extended/specialized or private SOPs.

5.2 Private Transfer Syntaxes

Facad does not support any private transfer syntaxes.

6 Support of Character Sets

Facad will correctly read international person names and descriptive text received in DICOM format. This applies to text found in DICOM files imported from hard drives, CD's or other media.

7 Security

The system shall provide the following security measures:

Data Consistency (Hazard)

The system shall not modify any persistent image and/or patient data.

Image Processing

The system shall be able to display images with the following image types and presentation types.

Image Brightness and Contrast

The system shall apply a linear brightness and contrast functionality.

7.1 Security Profiles

Not applicable.

7.2 Association Level Security

Not applicable.

7.3 Application Level Security

Not applicable.

8 Annexes

8.1 IOD Contents

Created SOP Instance

Not applicable, since Facad does not create any SOP instances.

Usage of Attributes from Received IOD

Facad will only accept IOD's from DICOM valid media.

Attribute Mapping

Not applicable.

Coerced/Modified fields

Facad will not coerce or modify any fields.

8.2 Data Dictionary of Private Attributes

Not applicable.

8.3 Coded Terminology and Templates

Not applicable.

8.4 Grayscale Image consistency

Not applicable.

8.5 Standard Extended/Specialized/Private SOPs

Facad supports Standard Extended, Specialized, and Private SOP classes as per Table 13.

8.6 Private Transfer Syntaxes

Facad does not support any private transfer syntaxes.