

DICOM Conformance Statement for Implant Studio (1.2.0.1)

1. DICOM Conformance Statement Overview

Implant Studio has support for the reading of DICOM data sets such that CT scan data can be imported and used for implant planning and surgical guide design.

The limitation of only supporting CT scan data is reflected in the table of supported image SOP classes (see Table 1).

Table 1 - Supported Image SOP Classes

Name	UID
Computed Tomography (CT) Image Storage	1.2.840.10008.5.1.4.1.1.2
Enhanced Computed Tomography (CT) Image Storage	1.2.840.10008.5.1.4.1.1.2.1

Implant Studio has support for single-slice and multi-slice DICOM files, but does not currently support DICOMDIR files. Table 2 lists the currently supported transfer syntaxes. This means that if compression is used for transferring image data, it has to be JPEG Lossless, otherwise only uncompressed image data is supported.

Table 2 - Supported Transfer Syntaxes

Name	UID
Implicit VR Little Endian	1.2.840.10008.1.2
Explicit VR Little Endian	1.2.840.10008.1.2.1
JPEG Lossless, Non-Hierarchical, First-Order Prediction (Process 14 [Selection Value 1])	1.2.840.10008.1.2.4.70

Current DICOM data set restrictions in Implant Studio (some implied by the supported SOP classes and transfer syntaxes):

- Only CT/CBCT scan data.
- Patient Name (0010, 0010) must be present in DICOM file – but can be an empty string.
- Image data have to be 16 bit (for both compressed and non-compressed images).
- JPEG Lossless is only supported for single slice DICOM files.
- Slice Spacing cannot be larger than Slice Thickness.
- When a DICOM data set is spread across multiple DICOM files, Implant Studio will refuse to import the CT scan if the distances between- or the orientation of individual slices are inconsistent. In the case of a CT scan stored as individual slice files, one missing file would result in an import failure.

2. Table of Contents

1.	DICOM Conformance Statement Overview	1
2.	Table of Contents	2
3.	Introduction.....	3
1.	Revision History	3
2.	Audience	3
3.	Remarks	3
4.	Terms, Definitions and Abbreviations	3
5.	References	4
4.	Networking	4
5.	Media Interchange	4
6.	Implementation Model.....	4
1.	Application Data Flow.....	4
6.	Support of Character Sets.....	6
7.	Security	6
8.	Annexes	7
7.	IOD Contents	7
2.	Created SOP Instance	7
3.	Usage of Attributes from Received IOD	7
4.	Attribute Mapping.....	7
5.	Coerced/Modified Fields	7
8.	Data Dictionary of Private Attributes	7
9.	Coded Terminology and Templates.....	7
10.	Grayscale Image Consistency	7
11.	Standard Extended/Specialized/Private SOPs.....	7
12.	Private Transfer Syntaxes	7

3. Introduction

1. Revision History

Table 3 - Revision History

Document Version	Date of Issue	Author	Description
1.0	2014-02-21	AKN	Initial version.

2. Audience

This document is intended for persons needing to understand how Implant Studio will integrate into their healthcare facility. This includes both those responsible for overall imaging transferal, as well as integrators who need to have a detailed understanding of the DICOM features of the product. This document contains some basic DICOM definitions so that any reader may understand how this product implements DICOM features. However, integrators are expected to fully understand all the DICOM terminology, how the tables in this document relate to the product's functionality, and how that functionality integrates with other devices that support compatible DICOM features.

3. Remarks

The scope of this DICOM Conformance Statement is to facilitate integration between Implant Studio and other DICOM products. The Conformance Statement should be read and understood in conjunction with the DICOM Standard. DICOM by itself does not guarantee interoperability. The Conformance Statement does, however, facilitate a first-level comparison for interoperability between different applications supporting compatible DICOM functionality.

This Conformance Statement is not supposed to replace individual validation with other DICOM equipment to ensure proper exchange of intended information. In fact, the user should be aware of the following important issues:

- The comparison of different Conformance Statements is just the first step towards assessing interconnectivity and interoperability between the product and other DICOM equipment.
- Test procedures should be defined and executed to validate the required level of interoperability with specific DICOM equipment, as established by the healthcare facility.

4. Terms, Definitions and Abbreviations

Table 4 - Terms, Definitions and Abbreviations

Term / Definition / Abbreviation	Explanation
AE	Application Entity
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
FSC	File-Set Creator
FSR	File-Set Reader
FSU	File-Set Updater

DICOM equipment	Generic name for any none 3Shape DICOM system, being CBCT machines, DICOM compatible electronic patient journal systems etc..

5. References

[NEMA PS3]	Digital Imaging and Communications in Medicine (DICOM) Standard, available free at http://medical.nema.org/

4. Networking

Not applicable – since Implant Studio does not support importing or exporting of DICOM object data over network.

5. Media Interchange

6. Implementation Model

1. Application Data Flow

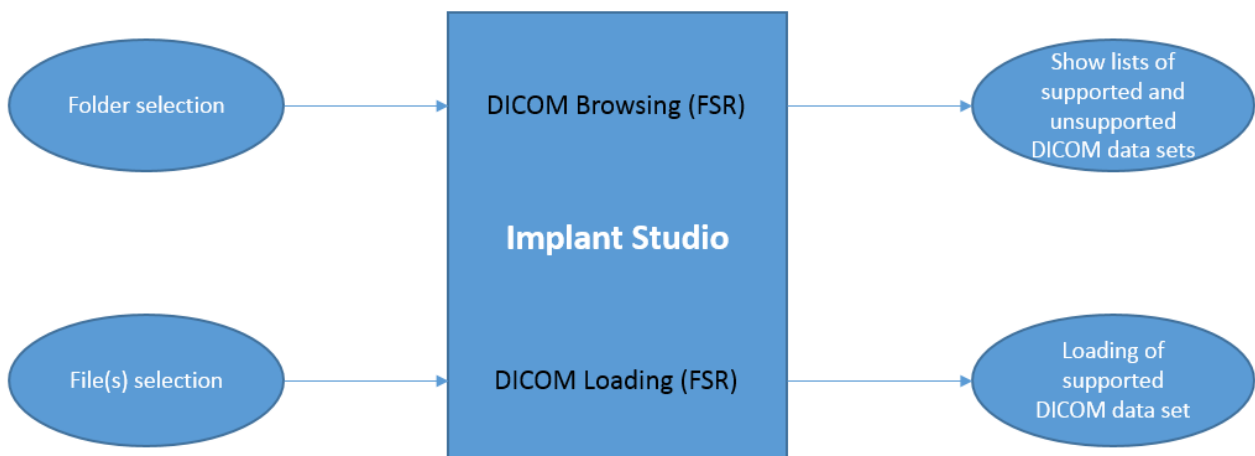


Figure 1 - Application Data Flow Diagrams

As shown in Figure 1 - Application Data Flow Diagrams, Implant Studio provides one application entity with two real-world activities:

- **DICOM Browsing (FSR):** The application can, if provided with a folder, process a folder and show a list of supported and a list of unsupported DICOM data sets contained in the folder. Based on user selection from the list of supported DICOM data sets the application will add the DICOM data set to an order.

- DICOM Loading (FSR): The application can, if provided with a user selected file or set of files, load a supported DICOM data set.

Implant Studio is media-neutral, since the user is required to browse and locate the folder containing DICOM files.

2. Functional Definition of AE's

DICOM Browsing (FSR)

DICOM Browsing is activated through the user interface where folder selection is possible. DICOM Browsing acts as a filtering step for *DICOM Loading (FSR)*.

DICOM Loading (FSR)

DICOM Loading happens in the background when a user tries to open an order for which a DICOM data set has previously been added.

3. Sequencing of Real-World Activities

When setting up an order in Implant Studio the user is requested to attach a DICOM data set by selecting it from the list of supported DICOM data sets using the *DICOM Browsing (FSR)*. Having attached the DICOM data set to the order, the user is allowed to open/start the order. When loading an order, Implant Studio will use the *DICOM Loading (FSR)* to read in all information from the supported DICOM data set.

7. AE Specifications

4. Implant Studio – Specification

Implant Studio only supports the use of data from CT scanners and therefore limited to the use of the application profiles listed in Table 5 (the application is media neutral and dependent on the underlying hardware).

Table 5 - Supported Application Profiles

Supported Application Profile	Real-World Activity	Role
STD-CTMR-CD	DICOM Browsing + DICOM Loading	FSR
STD-CTMR-DVD	DICOM Browsing + DICOM Loading	FSR
STD-CTMR-DVD-RAM	DICOM Browsing + DICOM Loading	FSR

File Meta Information for the Application Entity

Not applicable, since Implant Studio is neither FSC nor FSU.

Real World Activities

DICOM Browsing (FSR)

DICOM Browsing is activated through the user interface where folder selection is possible. DICOM Browsing can read all DICOM PS 3.10 compliant files.

After processing of the selected folder a list of supported as well as a list of unsupported DICOM data sets is made visible. Unsupported DICOM data sets are shown together with a relevant description of why they

are not supported. Support for a DICOM data set is based on the restrictions for the *DICOM Loading (FSR)* – see the following section.

When selecting a supported DICOM data set (CT scan) the patient name, scan time and scanner name is shown. The selected supported DICOM data set can be attached to the Implant Studio order.

DICOM Loading (FSR)

DICOM Loading happens in the background when a user tries to open an order for which a DICOM data set has previously been added. Implant Studio has due to its usage only support for CT scans.

Table 6 shows the supported image SOP classes.

Table 6 - Supported Image SOP Classes

Name	UID
Computed Tomography (CT) Image Storage	1.2.840.10008.5.1.4.1.1.2
Enhanced Computed Tomography (CT) Image Storage	1.2.840.10008.5.1.4.1.1.2.1

Table 7 shows the supported transfer syntaxes. Implant Studio has support for single-slice and multi-slice DICOM files, but NOT for DICOMDIR files.

Table 7 - Supported Transfer Syntaxes

Name	UID
Implicit VR Little Endian	1.2.840.10008.1.2
Explicit VR Little Endian	1.2.840.10008.1.2.1
JPEG Lossless, Non-Hierarchical, First-Order Prediction (Process 14 [Selection Value 1])	1.2.840.10008.1.2.4.70

6. Support of Character Sets

Implant Studio only supports the default character repertoire.

7. Security

Not applicable.

8. Annexes

8. IOD Contents

5. Created SOP Instance

Not applicable, since Implant Studio does not create any SOP instances.

6. Usage of Attributes from Received IOD's

See DICOM Conformance Statement Overview.

7. Attribute Mapping

Not applicable.

8. Coerced/Modified Fields

Implants Studio does not coerce or modify any fields.

9. Data Dictionary of Private Attributes

Not applicable.

10. Coded Terminology and Templates

Not applicable.

11. Grayscale Image Consistency

Not applicable.

12. Standard Extended/Specialized/Private SOPs

Not applicable.

13. Private Transfer Syntaxes

Not applicable.