



# DTX Studio™ Clinic

Version 4.3

## **DICOM Conformance Statement**

# Conformance Statement Overview

The DTX Studio Clinic software release 4.3 is software that allows for tailored solutions in the dental imaging field. DTX Studio Clinic software provides the following DICOM data exchange features:

- DTX Studio Clinic can export and update DICOM File Sets to removable media; it thus serves as DICOM File Set updater (FSU).
- DTX Studio Clinic can browse through DICOM File Sets on removable media and can import images from these file sets; it thus serves as DICOM File Set Reader (FSR).

Table 1 provides an overview of the Media Storage Application profiles supported by DTX Studio diagnose.

Media storage application profile	Write files	Read files
<b>Compact Disk - Recordable</b>		
General purpose CD-R	Yes	Yes
<b>Magneto-Optical Disk</b>		
CT/MR 2.3 GB MOD	Yes	Yes
<b>DVD</b>		
General Purpose DVD-RAM	Yes	Yes
<b>BD</b>		
General Purpose BD Interchange	Yes	Yes
<b>USB and Flash Memory</b>		
General Purpose USB Media Interchange with JPEG	Yes	Yes

Table 1: Media services

# Table of Contents

<b>Conformance Statement Overview</b>	<b>2</b>
<b>Introduction</b>	<b>4</b>
Revision History	4
Audience	4
Scope and Field of Application	5
Remarks	5
References	5
<b>Terms and Definitions</b>	<b>6</b>
Abbreviations	8
<b>Media Interchange</b>	<b>9</b>
Implementation Model	9
Application Flow Diagram	9
Functional Definition of Application Entity (AE)	10
Sequencing of Real-world Activities	10
File Meta Information for Implementing Class and Version	10
AE Specifications	10
Application Entity Specification of the DTX Studio Clinic AE	10
Augmented and Private Profiles	12
Media Configuration	13
Extensions / Specializations / Privatizations	16
<b>Character Set Support</b>	<b>17</b>
<b>Security Profiles</b>	<b>18</b>

# Introduction

This chapter provides general information about the purpose, scope and contents of this Conformance Statement.

## Revision History

Revision	Date (yyyy-mm-dd)	Reason for change
008	2025-06-03	Update for version 4.3
007	2024-03-29	Update for version 4.2
006	2020-08-17	Update for version 1.8
005	2019-11-08	Update for version 1.7
004	2019-09-04	Update for version 1.6
003	2018-08-20	Update for version 1.4
002	2018-04-13	Update for version 1.3
001	2017-09-22	First draft

## Audience

This document is written for the people that need to understand how DTX Studio Clinic will integrate into their healthcare facility. This includes both those responsible for overall imaging network policy and architecture, 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.

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

Readers wishing to obtain more familiarity with the content and terminology of DICOM standard are encouraged to obtain and review the standard prior to reading this Conformance Statement. More information on acquiring this document and its updates on the DICOM standard may be found on the website of the National Electrical Manufacturer's Association (NEMA) at <http://dicom.nema.org>.

## Scope and Field of Application

The scope of this DICOM Conformance Statement is to facilitate data exchange with the DTX Studio Clinic software suite. This document specifies the compliance with the DICOM standard. It contains a short description of the applications involved and provides technical information about the data exchange capabilities of the equipment. The main elements describing these capabilities are: the supported DICOM Service Object Pair (SOP) Classes, Roles, Information Object Definitions (IOD) and Transfer Syntaxes.

The field of application is the integration of the DTX Studio Clinic software into an environment of other medical devices and hospital information systems. This Conformance Statement should be read in conjunction with the DICOM standard and its addenda.

## Remarks

The scope of this DICOM Conformance Statement is to facilitate integration between DTX Studio Clinic 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 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 conformant equipment.
- Test procedures should be defined and executed to validate the required level of interoperability with specific compatible DICOM equipment, as established by the healthcare facility.

## References

NEMA Digital Imaging and Communications in Medicine (DICOM) Standard, available free at <http://dicom.nema.org/>

DTX Studio Clinic uses the DCMTK Toolkit™ to accomplish the DICOM Services.

# Terms and Definitions

Informal definitions are provided for the following terms used in this Conformance Statement. The DICOM Standard is the authoritative source for formal definitions of these terms.

**Abstract Syntax** – The information agreed to be exchanged between applications, generally equivalent to a Service/Object Pair (SOP) Class. Examples: Verification SOP Class, Modality Worklist Information Model Find SOP Class, Computed Radiography Image Storage SOP Class.

**Application Entity (AE)** – An end point of a DICOM information exchange, including the DICOM network or media interface software; i.e., the software that sends or receives DICOM information objects or messages. A single device may have multiple Application Entities.

**Application Entity Title** – The externally known name of an Application Entity, used to identify a DICOM application to other DICOM applications on the network.

**Application Context** – The specification of the type of communication used between Application Entities. Example: DICOM network protocol.

**Association** – A network communication channel set up between Application Entities.

**Attribute** – A unit of information in an object definition; a data element identified by a tag. The information may be a complex data structure (Sequence), itself composed of lower level data elements. Examples: Patient ID (0010,0020), Accession Number (0008,0050), Photometric Interpretation (0028,0004), Procedure Code Sequence (0008,1032).

**Information Object Definition (IOD)** – The specified set of Attributes that comprise a type of data object; does not represent a specific instance of the data object, but rather a class of similar data objects that have the same properties. The Attributes may be specified as Mandatory (Type 1), Required but possibly unknown (Type 2), or Optional (Type 3), and there may be conditions associated with the use of an Attribute (Types 1C and 2C). Examples: MR Image IOD, CT Image IOD, Print Job IOD.

**Joint Photographic Experts Group (JPEG)** – A set of standardized image compression techniques, available for use by DICOM applications. Media Application Profile – the specification of DICOM information objects and encoding exchanged on removable media (e.g., CDs)

**Module** – A set of Attributes within an Information Object Definition that are logically related to each other. Example: Patient Module includes Patient Name, Patient ID, Patient Birth Date, and Patient Sex.

**Negotiation** – First phase of Association establishment that allows Application Entities to agree on the types of data to be exchanged and how that data will be encoded.

**Presentation Context** – The set of DICOM network services used over an Association, as negotiated between Application Entities; includes Abstract Syntaxes and Transfer Syntaxes.

**Protocol Data Unit (PDU)** – A packet (piece) of a DICOM message sent across the network. Devices must specify the maximum size packet they can receive for DICOM messages.

**Security Profile** – A set of mechanisms, such as encryption, user authentication, or digital signatures, used by an Application Entity to ensure confidentiality, integrity, and/or availability of exchanged DICOM data.

**Service Class Provider (SCP)** – Role of an Application Entity that provides a DICOM network service; typically, a server that performs operations requested by another Application Entity (Service Class User). Examples: Picture Archiving and Communication System (image storage SCP, and image query/retrieve SCP), Radiology Information System (modality worklist SCP).

**Service Class User (SCU)** – Role of an Application Entity that uses a DICOM network service; typically, a client. Examples: imaging modality (image storage SCU, and modality worklist SCU), imaging workstation (image query/retrieve SCU).

**Service/Object Pair (SOP) Class** – The specification of the network or media transfer (service) of a particular type of data (object); the fundamental unit of DICOM interoperability specification. Examples: Ultrasound Image Storage Service, Basic Grayscale Print Management.

**Service/Object Pair (SOP) Instance** – An information object; a specific occurrence of information exchanged in a SOP Class. Examples: a specific X-ray image.

**Tag** – A 32-bit identifier for a data element, represented as a pair of four digit hexadecimal numbers, the “group” and the “element”. If the “group” number is odd, the tag is for a private (manufacturer-specific) data element. Examples: (0010,0020) [Patient ID], (07FE,0010) [Pixel Data], (0019,0210) [private data element]

**Transfer Syntax** – The encoding used for exchange of DICOM information objects and messages. Examples: JPEG compressed (images), little-endian explicit value representation.

**Unique Identifier (UID)** – A globally unique “dotted decimal” string that identifies a specific object or a class of objects; an ISO-8824 Object Identifier. Examples: Study Instance UID, SOP Class UID, SOP Instance UID.

**Value Representation (VR)** – The format type of an individual DICOM data element, such as text, an integer, a person’s name, or a code. DICOM information objects can be transmitted with either explicit identification of the type of each data element (Explicit VR), or without explicit identification (Implicit VR); with Implicit VR, the receiving application must use a DICOM data dictionary to look up the format of each data element.

# Abbreviations

AE	Application Entity
CD-R	Compact Disk Recordable
CR	Computed Radiography
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
DX	Digital X-ray
ECT	Enhanced Computed Tomography
FSU	File-Set Updater
FSR	File-Set Reader
IOD	Information Object Definition
IOS	International Organization for Standards
IO	Intraoral X-ray
JPEG	Joint Photographic Experts Group
OSI	Open Systems Interconnection
PDU	Protocol Data Unit
SC	Secondary Capture
SCP	Service Class Provider
SCU	Service Class User
SOP	Service-Object Pair
VL	Visible Light
VR	Value Representation



# Media Interchange

## Implementation Model

DTX Studio Clinic allows the user to read stand-alone DICOM files or from DICOM media and to import them to its local database. It also allows the user to select images of a patient for exporting to a disk in DICOM Media compatible format. It can process any instances of SOP classes listed in table 3.

### Application Flow Diagram

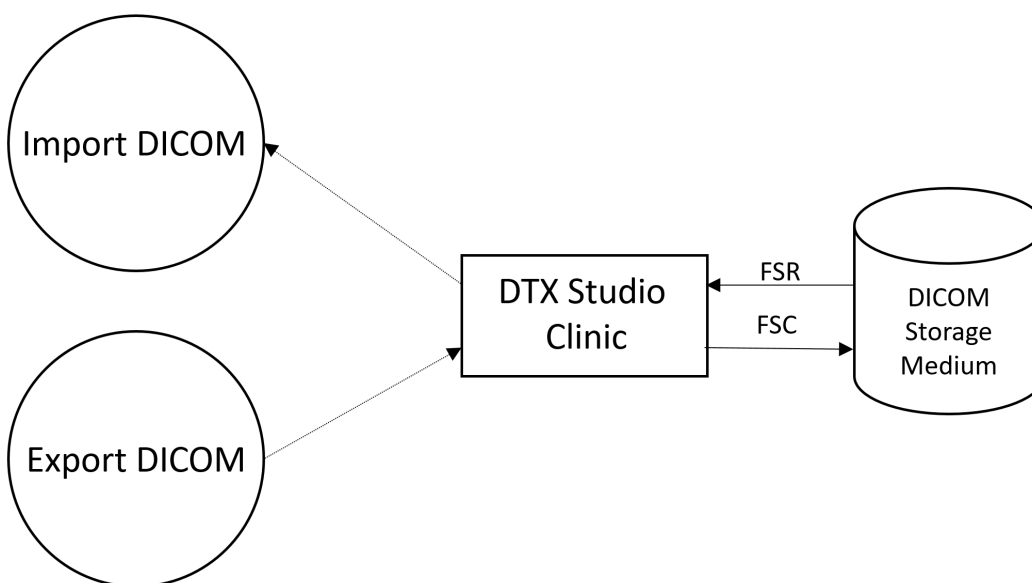


Fig. 1. – Media storage application data flow diagram

The DTX Studio Clinic application reads from Removable Media acting as an **FSR** to read in SOP instances as selected by the user when the “Import DICOM” command is used. The DTX Studio Clinic application will only display files that match the supported SOP Classes in the supported Application Profiles.

The DTX Studio Clinic application can export DICOM file Sets to removable media; it thus serves as DICOM File Set Creator (FSC) using the “Export DICOM” command. If the images are not internally stored in DICOM file format, they are converted when exported. The SOP instances written/updated will be limited to instances that match the criteria of one of the supported Application Profiles listed in Table 3.

## Functional Definition of Application Entity (AE)

DTX Studio Clinic Application Entity can perform following functions:

### Import / FSR

- It can **display** a directory listing of the File-set on a piece of media.
- It can **read** a DICOM File set on a piece of media and **copy** SOP instances from piece of media to its local storage.
- It can browse through DICOM File Sets on removable media and can **import** images from these file sets.

### Export / FSC

- It can **initialize** a piece of media, **writing** a new DICOM File-set onto the media.
- 2D images are exported as .dcm files
- 3D volumes can be exported as single-slice DICOM File Set (i.e. with slice number in file name and .dcm file suffix) or as multi-frame DICOM File Set (i.e. a single file with .dcm as suffix).

## Sequencing of Real-world Activities

There are no sequencing requirements.

## File Meta Information for Implementing Class and Version

The implementation information in the File Meta Header in each file is:

Implementation Class UID	1.2.528.56.1005.1.2
Implementation version name	DTXStudio4_3_23

# AE Specifications

## Application Entity Specification of the DTX Studio Clinic AE

The DTX Studio Clinic Application Entity provides conformances to the Media Storage Service Class according to the following table.

Supported application profiles	Real-world activity	Role	Service class option
STD-GEN-CD	Import DICOM	FSR	Interchange
STD-GEN-CD	Export DICOM	FSC	Interchange

Table 1. – Application profiles, activities and roles

### File meta information for the application entity

When File Meta Information is created the DTXStudio4\_3\_23 source AE Title is used. Private information is not used in the application profile.

### Real-world Activities

#### Activity: Import DICOM

The DTX Studio Clinic Application acts as an FSR when copying from the DICOM Media CD to local storage.

DTX Studio Clinic shall copy any SOP Instance files defined for the Application Profile specified in table 2 or Storage SOP class and transfer syntaxes listed in table 3 selected from a DICOM Media CD Directory list from the media to the local storage upon user request.

### Media Storage Application Profiles

The DTX Studio Clinic AE supports the SOP Classes listed in the table below:

Information Object definition	SOP Class UID
Media Storage Directory Storage	1.2.840.10008.1.3.10
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
Computed Radiography Image Storage	1.2.840.10008.5.1.4.1.1.1
Digital X-Ray Image Storage – For Presentation	1.2.840.10008.5.1.4.1.1.1.1
Digital X-Ray Image Storage – For Processing	1.2.840.10008.5.1.4.1.1.1.1.1
Digital Intraoral X-Ray Image Storage - For Presentation	1.2.840.10008.5.1.4.1.1.1.3
Digital Intra-oral X-Ray Image Storage - For Processing	1.2.840.10008.5.1.4.1.1.1.3.1
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7
Multi-frame Grayscale Byte Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7.2
Multi-frame Grayscale Word Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7.3

Table 3: IODs, SOP classes and transfer syntaxes for DTX Studio Clinic

The DTX Studio Clinic AE supports the following Transfer Syntaxes listed in the table below when importing DICOMs:

Transfer Syntax UID	Transfer syntax
1.2.840.10008.1.2	Implicit VR Endian: Default Transfer Syntax for DICOM
1.2.840.10008.1.2.1	Explicit VR Little Endian
1.2.840.10008.1.2.5	RLE Lossless
1.2.840.10008.1.2.4.50	JPEG Baseline: Default Transfer Syntax for Lossy JPEG 8-bit Image Compression
1.2.840.10008.1.2.4.51	JPEG Baseline: Default Transfer Syntax for Lossy JPEG 12-bit Image Compression
1.2.840.10008.1.2.4.57	JPEG lossless, Non-Hierarchical
1.2.840.10008.1.2.4.70	JPEG Lossless, Non-Hierarchical, First Order Prediction. The default transfer syntax for lossless JPEG.
1.2.840.10008.1.2.4.90	JPEG 2000 Image Compression (Lossless Only)
1.2.840.10008.1.2.4.91	JPEG 2000 Image Compression

Table 4: IODs, SOP classes and transfer syntaxes for DTX Studio Clinic

### Activity - Export DICOM

DTX Studio Clinic AE acts as an FSC using the interchange option when requested to copy SOP Instances from the local data base to the CD-R. DTX Studio Clinic AE copies the SOP Instances to the media and creates a corresponding multi-frame DICOM file (2D images or 3D volumes) or single-slice DICOM files (3D volumes). It is up to the user to finalize the physical volume at the completion of the write session.

### Media Storage Application Profiles

The application entity supports the same SOP Classes and Transfer Syntaxes as the Import to Local Storage Activity, see Table 3.

## Augmented and Private Profiles

DTX Studio Clinic does not support any augmented or private application profiles.

# Media Configuration

The DTX Studio Clinic software converts 3D DICOM sets to a multi-frame DICOM set if they are imported as single-slice datasets. The DTX Studio Clinic software converts 2D DICOM sets during import to PNG format and stores the content of the DICOM tags.

No conversion is done by DTX Studio Clinic to export **3D DICOM sets** from the external database (DTX Studio™ Core), however following SOP class attributes are updated in the exported DICOM file:

Attribute name	Tag
Implementation Class UID	0002, 0012
Implementation Version Name	0002, 0013
Patient ID	0010, 0020

Table 5: Updated SOP class attributes

When exporting 2D images or 3D DICOM sets as DICOM, DTX Studio Clinic supports the same SOP Classes and Transfer Syntaxes as the Import DICOM Activity, see Table 3. The following SOP class Attributes are included in the exported DICOM file:

Attribute name	Tag
Implementation Class UID	0002, 0012
Implementation Version Name	0002, 0013
Patient ID	0010, 0020
Patient's Name	0010, 0010
Patient's Birth Date	0010, 0030
Patient's Sex	0010, 0040
Institution Name	0008, 0080
Institution Address	0008, 0081
Institution Department Name	0008, 1040
Referring Physician's Name	0008, 0090
Specific Character Set	0008, 0005
Study Instance UID	0020, 000D
Study ID	0020, 0010
Series Number	0020, 0011
Instance Number	0020, 0013
Series Instance UID	0020, 000E
Study Date	0008, 0020
Study Time	0008, 0030

Attribute name	Tag
Study Description	0008, 1030
SOP Instance UID	0008, 0018
Pregnancy Status	0010, 21C0
X-Ray Tube Current	0018, 1151
X-Ray Tube Current in $\mu\text{A}$	0018, 8151
X-Ray Tube Current in mA	0018, 9330
Exposure Time	0018, 1150
Exposure Time in ms	0018, 9328
Exposure Time in $\mu\text{s}$	0018, 8150
Exposure	0018, 1152
Exposure in $\mu\text{As}$	0018, 1153
KVP	0018, 0060
Image and Fluoroscopy Area Dose Product	0018, 115E
Detector ID	0018, 700a
Gantry/Detector Tilt	0018, 1120
Tube Angle	0018, 9303
Convolution Kernel	0018, 1210
Series Instance UID	0020, 000E
Series Number	0020, 0011
Series Date	0008, 0021
Series Time	0008, 0031
Acquisition DateTime	0008, 002A
Acquisition Date	0008, 0022
Acquisition Time	0008, 0032
Patient Position	0018, 5100
Image Orientation (Patient)	0020, 0037
Number of Frames	0028, 0008
Accession Number	0008, 0050
Bits Stored	0028, 0101
Columns	0028, 0011

Attribute name	Tag
Rows	0028, 0010
Pixel Spacing	0028, 0030
Imager Pixel Spacing	0018, 1164
Number of Slices	0054, 0081
Slice Thickness	0018, 0050
Slice Location	0020, 1041
Table Position	0018, 9327
Reconstruction Target Center (Patient)	0018, 9318
Revolution Time	0018, 9305
Manufacturer's Model Name	0008, 1090
Manufacturer	0008, 0070
Device Serial Number	0018, 1000
Modality	0008, 0060
Pixel Representation	0028, 0103
Bits Allocated	0028, 0100
Bits Stored	0028 0101
High Bit	0028, 0102
Samples per Pixel	0028, 0002
Photometric Interpretation	0028, 0004
Window Center	0028, 1050
Window Width	0028, 1051
Image Type	0008, 0008
Frame Type	0008, 9007
Source Image Sequence	0008, 2112
Scan Options	0018, 0022
Lossy Image Compression	0028, 2110
Rescale Type	0028, 1054
Rescale Slope	0028, 1053
Rescale Intercept	0028, 1052
Coding Scheme Designator	0008, 0102

Attribute name	Tag
Code Value	0008, 0100
Code Meaning	0008, 0104
Anatomic Region Sequence	0008, 2218
Primary Anatomic Structure Sequence	0008, 2228
Presentation Intent Type	0008, 0068
Image Laterality	0020, 0062
Burned in Annotation	0028, 0301
Pixel Intensity Relationship	0028, 1040
Pixel Intensity Relationship Sign	0028, 1041
Presentation LUT Shape	2050, 0020
Patient Orientation	0020, 0020
Detector Type	0018, 7004

Table 6: SOP class attributes

## Extensions / Specializations / Privatizations

In accordance with DIN 6862-2 the following CT and DVT tags are missing because they are either technically not available or not applicable:

Attribute name	Tag
Acquisition Type	0018, 9302
Single Collimation Width	0018, 9306
Total Collimation Width	0018, 9307
Spiral Pitch Factor	0018, 9311
Table Feed per Rotation	0018, 9310
Exposure Modulation Type	0018, 9323
CTDIvol	0018, 9345
CTDI Phantom Type Code Sequence	0018, 9346
Fluoroscopy Flag	0018, 9334
CT Additional X-Ray Source Sequence	0018, 9360
Volume Based Calculation Technique	0008, 9207

Table 7: Unavailable tags



# Character Set Support

This implementation supports the following extended character set:

- ISO-IR-6 – default character set
- ISO-IR 100 – Latin alphabet No. 1, supplementary set
- ISO-IR 192, UTF-8

# Security Profiles

No DICOM communication is performed in DTX Studio Clinic. Therefore, the DTX Studio Clinic software does not conform to any defined DICOM Security Profiles.



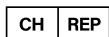
Nobel Biocare AB  
Box 5190, 402 26  
Västra Hamngatan 1,  
411 17 Göteborg,  
Sweden

[www.nobelbiocare.com](http://www.nobelbiocare.com)

**Distributed in Australia by:**

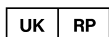
Nobel Biocare Australia Pty Ltd  
Level 4/7 Eden Park Drive  
Macquarie Park, NSW 2114  
Australia

Phone: +61 1800 804 597



**CH importer/representative:**

Nobel Biocare Services AG  
Balz Zimmermann-Strasse 7  
8302 Kloten  
Switzerland



**UK responsible person:**

Nobel Biocare UK Ltd.  
4 Longwalk Road  
Stockley Park  
Uxbridge UB11 1FE  
United Kingdom

**Distributed in New Zealand by:**

Nobel Biocare New Zealand Ltd  
33 Spartan Road  
Takanini, Auckland, 2105  
New Zealand

Phone: +64 0800 441 657

**Distributed in Turkey by:**

EOT Dental  
Sağlık Ürünleri ve Dış Ticaret A.Ş  
Nispetiye Mah. Aytar Cad.  
Metro İş Merkezi No: 10/7  
Beşiktaş İSTANBUL  
Phone: +90 2123614901