

FusionXD 2.1 DICOM Conformance Statement

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FusionXD 2.1 DICOM Conformance Statement

1 Introduction

1.1 References

| Reference | Document |
|-----------|--|
| REF1 | Digital Imaging and Communications in Medicine (DICOM) 2008, <i>National Electrical Manufacturers Association, USA</i> |

1.2 Integration and Features

The integration of medical devices may require functions that are beyond the scope of the DICOM standard. Consequently, using only the information provided by this Conformance Statement does not automatically guarantee interoperability. It is the user's responsibility to analyze application requirements and specify an integration solution for this equipment.

Our equipment has been tested to assure that the actual implementation of the DICOM interface corresponds with this Conformance Statement. If the Conformance Statements of a third-party product indicates that successful information exchange should be possible, additional interoperability tests may be necessary to ensure interoperability. It is the responsibility of the user (or user's agent) to specify the appropriate test suite and to carry out the additional interoperability tests.

Mirada Medical is committed to adapt its equipment to future versions of the DICOM Standard as much as possible. In order to do so, we reserve the right to make changes to our products or to discontinue them. The user should ensure that any third-party provider, connecting to our equipment, also adapts to future versions of the DICOM Standard. If not, the incorporation of DICOM enhancements into our equipment may lead to loss of connectivity.

Some of the features, described in this document are optional and may not be available in the product. For information on the user licensing please consult our sales representatives or the user documentation, supplied at the time of purchase.

1.3 Definitions, Acronyms and Abbreviations

| Definition | Description |
|------------|--|
| PACS | P icture A rchiving and C ommunication S ystem An information system which is able to store and archive medical data and radiology images in particular |

2 Services

The application can load and process objects stored in the hosting application.

The application can export result screens in the form of Secondary Capture images.

| SOP Classes Instance Transfer | User of Service (SCU) | Provider of Service (SCP) |
|----------------------------------|--------------------------|---|
| CT Image Storage | No | No Can load, process and view objects from the hosting application |
| MR Image Storage | No | No Can load, process and view objects from the hosting application |
| PET Image Storage | No | No Can load, process and view objects from the hosting application |
| Nuclear Medicine Image Storage | No | No Can load, process and view SPECT objects from the hosting application |
| Secondary Capture Image Storage | Yes | No |
| Verification | No | No |

Network Services

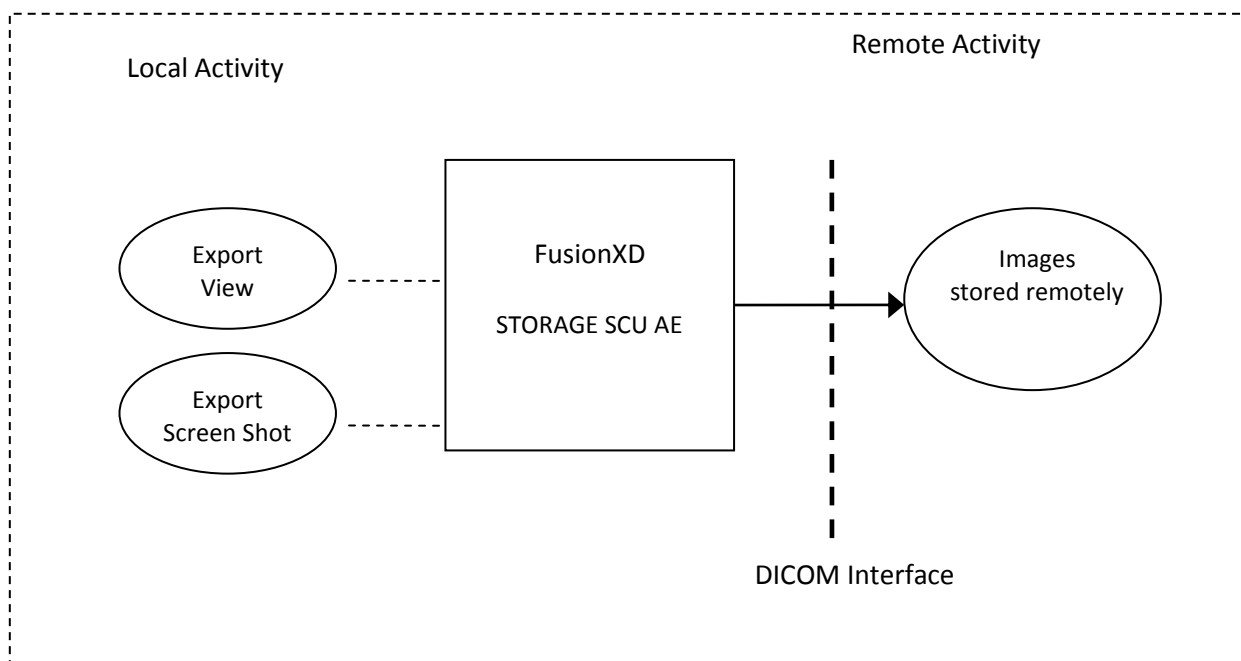
| Media Storage Application Profile | Write Files (FSC or FSU) | Read Files (FSR) |
|-----------------------------------|--|---|
| None supported in this edition | Writes (Exports) Media Part 10 compliant file contents | Reads (Imports) Media Part 10 compliant file contents |

Media Services

3 Networking

3.1 Implementation Model

3.1.1 Application Data Flow Diagram



3.1.2 Functional Definitions of AE's

Conceptually the network services may be modelled as the following Application Entities:

3.1.2.1 STORAGE-SCU AE

“**FusionXD_SCU**” AE provides the ability to export data to appropriately configured Storage SCP. An appropriate Presentation Context is determined and association proposed for the transfer of images to the target SCP. The status of the transfer is presented and should an error condition occur it is reported.

3.1.3 Sequencing of Real-World Activities

A set of image sets are selected in the hosting application [REF1] and then **FusionXD** is launched. These image sets are loaded, processed and displayed by **FusionXD** according to different rules, based on the time points in which images had been originally acquired. The display then can be captured in a secondary capture image and exported to a DICOM Storage SCP. For details of the layout, the user interface and the image processing capabilities, refer to the user documentation.

User transactions from **FusionXD** and the hosting application are automatically synchronised and sequenced with the data processing and network operations so consistency of data is guaranteed.

3.2 AE Specifications

3.2.1 STORAGE-SCU

3.2.1.1 SOP Classes

STORAGE-SCU provides Standard Conformance to the following SOP Classes:

| SOP Class Name | SOP Class UID | SCU | SCP |
|-------------------------|---------------------------|-----|-----|
| Secondary Capture Image | 1.2.840.10008.5.1.4.1.1.7 | Yes | No |

Table 2.2.2-1
SOP Classes supported by STORAGE-SCU

3.2.1.2 Association Policies

3.2.1.2.1 General

STORAGE-SCU initiates but never accepts associations.

| | |
|---------------------------|-------------|
| Maximum PDU size received | 16384 bytes |
|---------------------------|-------------|

Table 2.2.2-2
Maximum PDU size received for STORAGE-SCU

3.2.1.2.2 Number of Associations

| | |
|---|-----------|
| Maximum number of simultaneous associations | unlimited |
|---|-----------|

Table 2.2.2-3
Number of Associations for STORAGE-SCU

3.2.1.2.3 Asynchronous Nature

STORAGE-SCU will only allow a single outstanding operation on an Association. Therefore, STORAGE-SCU will not perform asynchronous operations window negotiation.

3.2.1.2.4 Implementation Identifying Information

| | |
|-----------------------------|------------------------------|
| Implementation Class UID | 1.2.826.0.1.3680043.8.691.18 |
| Implementation Version Name | as released |

Table 2.2.2-4
DICOM Implementation Class and Version for STORAGE-SCU

3.2.1.3 Association Initiation Policy

3.2.1.3.1 Activity – Export View

3.2.1.3.1.1 Description and Sequencing of Activities

An image is captured from a pre-selected view. For each image captured from the user interface, a single attempt will be made to transmit it to the selected remote AE. If the send fails, for whatever reason, no retry will be performed, and the whole export job will be aborted.

A user can request images to be sent to multiple destinations. Each request is forwarded to the job queue and processed individually. Only one job will be active at a time. If the C-STORE Response from the remote Application contains a status other than Success or Warning, the Association is aborted. No retry will be performed, and the whole export job will be aborted.

3.2.1.3.1.2 Proposed Presentation Contexts

| Abstract Syntax | | Transfer Syntax | | Role | Extended Negotiation |
|-------------------|-------------------|---------------------------|---------------------|------|----------------------|
| Name | UID | Name | UID | | |
| See Table 2.2.2-1 | See Table 2.2.2-1 | Implicit VR Little Endian | 1.2.840.10008.1.2 | SCP | None |
| See Table 2.2.2-1 | See Table 2.2.2-1 | Explicit VR Little Endian | 1.2.840.10008.1.2.1 | SCU | None |

Table 2.2.2-5
Proposed Presentation Contexts for STORAGE-SCU and EXPORT IMAGES

3.2.1.3.1.3 SOP Specific Conformance to Storage SOP Classes

STORAGE-SCU provides standard conformance to the Storage Service Class.

The actual image is formed by a set of modules specific to the given SOP class, in accordance with the DICOM standard. The IOD content is listed in Annex 7.1.

In order to transfer an image STORAGE SCU will connect to the specified port of the remote host and send an associate request. Any errors will be reported to the user, indicating the specific cause of the problem. Possible errors are:

| Error | Reason |
|-------|--------|
|-------|--------|

| Error | Reason |
|--|--|
| Connection refused | if the remote host does not listen on the specified TCP/IP port |
| Remote SCP rejected association request | if the remote SCP rejects the initial request |
| Remote SCP aborted association request | if the remote SCP aborts the initial request |
| Transfer syntax not supported | if the remote SCP does not support any of the proposed transfer syntaxes |
| Acknowledge rejected- no reason specified | if the acknowledge was rejected without specifying a reason |

Once the associate request is successfully acknowledged, STORAGE SCU sends C-STORE requests and reads the corresponding C-STORE responses. Images from one series are transferred on a single association.

STORAGE-SCU will behave as described in Table 2.2.2-6 in response to the status returned in the C-STORE response command message.

| Service Status | Further Meaning | Error Code | Behaviour |
|----------------|-----------------------------------|-----------------------|--|
| Success | Success | 0000 | The SCP has successfully stored the SOP Instance. If all SOP Instances in a send job have status success then the job is marked as complete. |
| Refused | Out of Resources | A700- A7FF | The Association is aborted using ABORT-RQ and the send job is marked as failed. The status meaning is logged and the job failure is reported to the user via the job control application. This is a transient failure. |
| Error | Data Set does not match SOP Class | A900- A9FF | The Association is aborted using ABORT-RQ and the send job is marked as failed. The status meaning is logged and the job failure is reported to the user via the job control application. |
| Error | Cannot Understand | C000- CFFF | The Association is aborted using ABORT-RQ and the send job is marked as failed. The status meaning is logged and the job failure is reported to the user via the job control application. |
| Warning | Coercion of Data Elements | B000 | Image transmission is considered successful but the status meaning is logged. |
| Warning | Data Set does not match SOP Class | B007 | Image transmission is considered successful but the status meaning is logged. |
| Warning | Elements Discarded | B006 | Image transmission is considered successful but the status meaning is logged. |
| * | * | Any other status code | The Association is aborted using ABORT-RQ and the send job is marked as failed. The status code is logged and the job failure is reported to the user via the job control application. |

Table 2.2.2-6
Response Status for STORAGE-SCU and Export images

3.2.1.3.2 Activity – Export Screen Shot

The behaviour for this activity is the same as for the activity “Export View”. The difference is that the captured data is coming from all views of the screen.

3.2.1.4 Association Acceptance Policy

STORAGE-SCU does not accept associations.

3.3 Network Interfaces

3.3.1 Physical Network Interface

The application is indifferent to the physical medium over which TCP/IP executes; which is dependent on the underlying operating system and hardware.

3.3.2 Additional Protocols

When host names rather than IP addresses are used in the configuration properties to specify presentation addresses for remote AEs, the application is dependent on the name resolution mechanism of the underlying operating system.

3.4 Configuration

All configurations are performed using file(s) stored in pre-defined locations that are specific to the underlying operating system.

3.4.1 AE Title/Presentation Address Mapping

The mapping of the logical name by which remote AEs are described in the user interface to Called AE Titles as well as presentation address (hostname or IP address and port number) is configurable.

3.4.2 Parameters

The following parameters can be configured for the STORAGE SCU AE:

- AE Title
- A list of remote (C-STORE target) AEs, each with its AE Title, IP Address/ Host Name and Port

4 Media Interchange

The application can read (Import) and write (Export) Media Part 10 compliant file contents on any available media, supported by the system on which the hosting application is deployed.

No DICOMDIR or any of the Media Interchange Profiles are supported.

5 Support of Character Sets

No extended character sets are supported

6 Security

6.1 Security Profiles

None of the DICOM security profiles is supported. Security is achieved by other means.

6.2 Association level security

None supported.

Any Calling AE Titles and/or IP addresses may open an Association.

6.3 Application level security

None supported.

7 Annexes

7.1 IOD contents

7.1.1 Created SOP Instances

7.1.1.1 SC Image IOD

7.1.1.1.1 SC Image IOD Modules

| IE | Module | DICOM Part 3 Reference | DICOM Usage |
|-----------|------------------------|------------------------|--------------|
| Patient | Patient | C.7.1.1 | M |
| | Clinical Trial Subject | C.7.1.3 | U (not used) |
| Study | General Study | C.7.2.1 | M |
| | Patient Study | C.7.2.2 | U |
| | Clinical Trial Study | C.7.2.3 | U |
| Series | General Series | C.7.3.1 | M |
| | Clinical Trial Series | C.7.3.2 | U (not Used) |
| Equipment | General Equipment | C.7.5.1 | U |
| | SC Equipment | C.8.6.1 | M |

| IE | Module | DICOM Part 3 Reference | DICOM Usage |
|-------|---------------|------------------------|-------------|
| Image | General Image | C.7.6.1 | M |
| | Image Pixel | C.7.6.3 | M |
| | SC Image | C.8.6.2 | M |
| | Overlay Plane | C.9.2 | U |
| | Modality LUT | C.11.1 | U |
| | VOI LUT | C.11.2 | U |
| | SOP Common | C.12.1 | M |

7.1.1.1.2 Patient Module

| Attribute Name | Tag | Type | Content | Comment |
|----------------------|-------------|------|---------|-------------------------------|
| Patient's Name | (0010,0010) | 2 | COID | Copied from the primary study |
| Patient ID | (0010,0020) | 2 | COID | Copied from the primary study |
| Patient's Birth Date | (0010,0030) | 2 | COID | Copied from the primary study |
| Patient's Sex | (0010,0040) | 2 | COID | Copied from the primary study |

Note: Screen data from more than one patient can be captured in the image.

7.1.1.1.3 General Study

| Attribute Name | Tag | Type | Content | Comment |
|----------------------------|-------------|------|---------|-------------------------------|
| Study Instance UID | (0020,000D) | 1 | COID | Copied from the primary study |
| Study Date | (0008,0020) | 2 | COID | Copied from the primary study |
| Study Time | (0008,0030) | 2 | COID | Copied from the primary study |
| Referring Physician's Name | (0008,0090) | 2 | COID | Copied from the primary study |
| Study ID | (0020,0010) | 2 | COID | Copied from the primary study |
| Accession Number | (0008,0050) | 2 | COID | Copied from the primary study |
| Study Description | (0008,1030) | 3 | COID | Copied from the primary study |

Note: Screen data from more than one study can be captured in the image.

7.1.1.1.4 Patient Study

| Attribute Name | Tag | Type | Content | Comment |
|------------------|-------------|------|---------|-------------------------------|
| Patient's Age | (0010,1010) | 3 | COID | Copied from the primary study |
| Patient's Size | (0010,1020) | 3 | COID | Copied from the primary study |
| Patient's Weight | (0010,1030) | 3 | COID | Copied from the primary study |

Note: Screen data from more than one patient and/or study can be captured in the image.

7.1.1.1.5 General Series

| Attribute Name | Tag | Type | Content | Comment |
|-------------------------------|-------------|------|-------------------------|---|
| Modality | (0008,0060) | 3 | See SC Equipment | |
| Series Instance UID | (0020,000E) | 1 | generated automatically | One Series Instance UID is generated for one image. |
| Series Number | (0020,0011) | 2 | Set to 1 | |
| Series Date | (0008,0021) | 3 | generated automatically | Set to the date of when the export is performed |
| Series Time | (0008,0031) | 3 | generated automatically | Set to the time of when the export is performed |
| Performing Physician's Name | (0008,1050) | 3 | Supplied by the user | |
| Series Description | (0008,103E) | 3 | Supplied by the user | |
| Operator's Name | (0008,1070) | 3 | Supplied by the user | |
| Patient Position | (0018,5100) | 2C | Not present | Patient position descriptor relative to the Equipment For SC this may or may not be present. The application does not store this attribute because the capture is an image from two or more acquisitions which may have different patient positions |
| Request Attribute Sequence | (0040,0275) | 3 | Not Present | |
| > Requested Procedure ID | (0040,1001) | | | |
| > Scheduled Procedure Step ID | (0040,0009) | | | |

7.1.1.1.6 General Equipment

| Attribute Name | Tag | Type | Content | Comment |
|----------------|-------------|------|---------|-------------------------------|
| Manufacturer | (0008,0070) | 2 | COID | Copied from the primary study |

| Attribute Name | Tag | Type | Content | Comment |
|---------------------------|-------------|------|---------|-------------------------------|
| Manufacturer's Model Name | (0008,1090) | 3 | COID | Copied from the primary study |

7.1.1.1.7 SC Equipment

| Attribute Name | Tag | Type | Content | Comment |
|--|-------------|------|------------|---|
| Conversion Type | (0008,0064) | 1 | WSD | Workstation |
| Modality | (0008,0060) | 3 | OT | The capture is a fused image from two modalities, so no generic modality is expressed |
| Secondary Capture Device Manufacturer | (0018,1016) | 3 | 'Mirada' | |
| Secondary Capture Device Manufacturer's Model Name | (0018,1018) | 3 | 'FusionXD' | |
| Secondary Capture Device Software Version | (0018,1019) | 3 | 'm.n.o.p' | Set to the software version number (build number) |

7.1.1.1.8 General Image

| Attribute Name | Tag | Type | Content | Comment |
|---------------------|-------------|------|--|---------|
| Instance Number | (0020,0013) | 2 | see SOP Common Module Attributes | |
| Content Date | (0008,0023) | 2C | Set to the date of when the export is performed | |
| Content Time | (0008,0033) | 2C | Set to the date of when the export is performed | |
| Image Type | (0008,0008) | 3 | "DERIVED/PRIMARY/" | |
| Acquisition Number | (0020,0012) | 3 | Set to same value as instance number. | |
| Patient Orientation | (0020,0020) | 2C | Calculated from the image orientation of the view from the screen that is being exported. May be empty if the orientation cannot be calculated | |

7.1.1.1.9 Image Pixel

| Attribute Name | Tag | Type | Content | Comment |
|----------------|-----|------|---------|---------|
|----------------|-----|------|---------|---------|

| Attribute Name | Tag | Type | Content | Comment |
|----------------------------|-------------|------|--|---------|
| Samples per Pixel | (0028,0002) | 1 | 3 | |
| Photometric Interpretation | (0028,0004) | 1 | RGB | |
| Rows | (0028,0010) | 1 | Set to the number of rows of the original image that the exported image is derived from | |
| Columns | (0028,0011) | 1 | Set to the number of columns of the original image that the exported image is derived from | |
| Bits Allocated | (0028,0100) | 1 | 8 | |
| Bits Stored | (0028,0101) | 1 | 8 | |
| High Bit | (0028,0102) | 1 | 7 | |
| Pixel Representation | (0028,0103) | 1 | Set to 0000H (pixel values are unsigned) | |
| Pixel Data | (7FE0,0010) | 1 | Set to the pixel data of the exported image | |
| Planar Configuration | (0028,0006) | 1C | Set to 0 (colour-by-pixel) | |
| Pixel Aspect Ratio | (0028,0034) | 1C | Present if the aspect ratio is not 1\1. May not be present otherwise | |

7.1.1.1.10 SC Image

| Attribute Name | Tag | Type | Content | Comment |
|---------------------------|-------------|------|---|---------|
| Date of Secondary Capture | (0018,1012) | 1 | The date the Secondary Capture Image was produced | |
| Time of Secondary Capture | (0018,1014) | 3 | The time the Secondary Capture Image was produced | |

7.1.1.1.11 SOP Common

| Attribute Name | Tag | Type | Content | Comment |
|------------------|-------------|------|---|--|
| SOP Class UID | (0008,0016) | 1 | 1.2.840.10008.5.1.4.1.1.7 | |
| SOP Instance UID | (0008,0018) | 1 | Generated automatically | A new SOP Instance UID is generated for each image capture |
| Instance Number | (0020,0013) | 3 | An integer number that identifies an object instance; Set to the internal slice index of the image to be exported | |

7.1.2 Usage of attributes from received IODs

7.1.2.1 NM Image

7.1.2.1.1 Loading

The following requirements must be met for images to be successfully loaded and processed:

| Attribute | Tag | Requirement |
|-------------------------------|-------------|----------------------------|
| Image Type Value 3 | (0008,0008) | RECON TOMO |
| Detector Information Sequence | (0054,0022) | present |
| > Image Position | (0020,0032) | present with value |
| > Image Orientation | (0020,0037) | present with value |
| Spacing Between Slices | (0018,0088) | present with value |
| Photometric Interpretation | (0028,0004) | Not equal to PALETTE COLOR |

7.1.2.2 PET Image

7.1.2.2.1 Loading

The following requirements must be met for images to be successfully loaded and processed:

| Attribute | Tag | Requirement |
|--------------------|-------------|---------------------------|
| Image Type Value 2 | (0008,0008) | Not equal to REPROJECTION |

7.1.2.2.2 PET Quantification

PET SUV quantification can only be enabled if the currently selected dataset fulfils **all** the following conditions;

1. the "SOP Class UID" tag (0008,0016) is equal to 1.2.840.10008.5.1.4.1.1.128
2. the "Modality" tag (0008,0060) is present and equals PT
3. the "Counts Source" tag (0054,1002) is present and equals EMISSION
4. the "Decay Correction" tag (0054,1102) is present and equals either START or ADMIN
5. the "Units" tag (0054,1001) is present and equals BQML
6. the "Radiopharmaceutical Start Time" tag (0018,1072) is present and not empty
7. Acquisition start time is later than the Radiopharmaceutical Start Time. The Acquisition start time is defined as the earliest Acquisition Time (0008,0032) value across all images (each image has one acquisition time).
8. the "Radiopharmaceutical Half Life" tag (0018,1075) is strictly positive
9. the "Radionuclide Total Dose" tag (0018,1074) is strictly positive
10. the "Patient's Weight" tag (0010,1030) is strictly positive

These conditions are required for SUV based on Body Weight. In addition to these requirements, the following is required

- For PET SUV based on Body Surface Area:
 - “Patient’s Size” tag (0010,1020) must be present and strictly positive
- For PET SUV based on Lean Body Mass
 - “Patient’s Sex” tag (0010,0040) must be present and is set to “M” or “F”

7.1.3 Attribute Mapping

Not applicable

7.1.4 Coerced/Modified Instances

The following IODs define the derived instances

7.2 Data Dictionaries

No private attributes in the exported standard objects are used.

7.3 Coded terminology

The value for Code Meaning will be displayed for all code sequences. No local lexicon is provided to look up alternative code meanings.

7.4 Greyscale Image Consistency

Calibration to the Greyscale Standard Display Function (GSDF) is outside of the scope of this document

7.5 Standard extended SOPs

None

7.6 Private SOPs

Private SOPs are outside of the scope of this document.

7.7 Private Transfer Syntaxes

None