SonoSite, Inc.

Bothell, Washington

Document Number: D07914

Revision: C

Title: NanoMAXX

DICOM Conformance Statement

CHANGE HISTORY:

| Revision | Description of Change |
|----------|--|
| A | Initial release. |
| В | Updated to clarify specifics on private tag inclusion. |
| C | Add C-Store and Modality Worklist |

TABLE OF CONTENTS

| 1 | INTRODUCTION | |
|---|--|----|
| | 1.1 DICOM BACKGROUND | 6 |
| | 1.2 Definitions | 6 |
| | 1.3 REFERENCE DOCUMENTS | 7 |
| 2 | IMPLEMENTATION MODEL | 8 |
| _ | 2.1 APPLICATION DATA FLOW DIAGRAM | |
| | 2.2 FUNCTIONAL DEFINITIONS OF AE'S | |
| | 2.3 SEQUENCING OF REAL-WORLD ACTIVITIES | |
| | | |
| 3 | AE SPECIFICATIONS | |
| | 3.1 STORE AE – SPECIFICATION | |
| | 3.1.1 Association Establishment Policies | |
| | 3.1.1.1 General | |
| | 3.1.1.2 Number of Associations | |
| | 3.1.1.3 Asynchronous Nature | |
| | 3.1.1.4 Implementation Identifying Information | |
| | 3.1.2 Association Initiation by Real-World Activity | |
| | 3.1.2.1 Association Initiation by: Archive Exam | |
| | 3.1.2.2 Association Initiation By: Image Acquisition | |
| | 3.1.2.4 Association Initiation by: Get Status | |
| | 3.1.2.4 Association initiation by: Get status | |
| | 3.1.3.1 Verification SOP Class | |
| | 3.1.3.1 Verification SOF Class 3.1.3.2 Ultrasound Image Storage SOP Class | |
| | 3.1.3.3 Ultrasound Image Storage SOP Class (Retired) | |
| | 3.1.3.4 Secondary Capture Image Storage SOP Class | 20 |
| | 3.1.4 Common Composite Image IOD Module | |
| | 3.1.4.1 Patient Module | |
| | 3.1.4.2 General Study Module | |
| | 3.1.4.3 Patient Study Module | |
| | 3.1.4.4 General Series Module | |
| | 3.1.4.5 General Equipment Module | 24 |
| | 3.1.4.6 SC Equipment Module | 24 |
| | 3.1.4.7 General Image Module | |
| | 3.1.4.8 Image Pixel Module | |
| | 3.1.4.9 US Region Calibration Module | |
| | 3.1.4.10 US Image Module | |
| | 3.1.4.11 VOI LUT Module | |
| | 3.1.4.12 SOP Common Module | |
| | 3.1.5 Store AE Behavior to C-Store Status | |
| | 3.2 MODALITY WORKLIST AE – SPECIFICATION | |
| | 3.2.1 Association Establishment Policies | |
| | 3.2.1.1 General | |
| | 3.2.1.3 Asynchronous Nature | |
| | 3.2.1.4 Implementation Identifying Information | |
| | 3.2.2 Association Initiation by Real-World Activity | |
| | 3.2.2.1 Association Initiation by: Update Worklist | |
| | 3.2.2.2 Association Initiation by: Worklist Query | |
| | 3.2.2.3 Association Initiation by: Automatic Worklist Query | |
| | 3.2.2.4 Association Initiation by: Get Status | |
| | 3.2.3 Proposed Presentation Contexts to a Worklist Server | |
| | 3.2.3.1 Modality Worklist Information Model – FIND SOP Class | |
| | 3.2.3.2 Verification SOP Class | |
| | 3.2.4 Modality Worklist Attributes | 32 |
| | 3.2.4.1 Broad Worklist Query Matching Key Attributes | |
| | 3.2.4.2 Patient Based Query Matching Key Attributes | |
| | | |

| | 3.2.4.3 | Return Key Attributes | 33 |
|---|------------------|--|----|
| 4 | THIS A7 | TTRIBUTE FROM WORKLIST MAY BE TRUNCATED WHEN DISPLAYED IN THE | |
| N | | K USER INTERFACE. HOWEVER, THE VALUE CONTAINED IN THE ATTRIBUTE IS | |
| | | O IN FULL FIDELITY. | 35 |
| | 4.1.1 | Worklist AE Behavior to C-FIND Status | |
| | 4.2 MED | DIA EXPORT AE – SPECIFICATION | 35 |
| | 4.2.1 | Introduction | |
| | 4.2.2 | Implementation Model | |
| | 4.2.2.1 | Application Data Flow | |
| | 4.2.2.2 | Functional Definition of the AE | |
| | 4.2.2.3 | Sequencing of Real-World Activiities | |
| | 4.2.2.4 | File Meta Information Options (see PS 3.10) | |
| | | AE Specifications | |
| | 4.2.3.1 | File Meta Information for the Application Entity | |
| | 4.2.3.2 | Real-World Activities | |
| | | Augmented and Private Application Profiles | |
| | 4.2.5 | Media Configuration | |
| | 4.2.6 | Media Storage SOP Class | |
| | 4.2.7 4.2.7.1 | Information Module Definitions | |
| | 4.2.7.1 | File-set Identification Module | |
| | | · | |
| 5 | | UNICATION PROFILES | |
| | 5.1 TCP | P/IP STACK | 41 |
| 6 | EXTENS | SIONS/SPECIALIZATIONS/PRIVATIZATIONS | 42 |
| _ | | NDARD EXTENDED/SPECIALIZED/PRIVATE SOPS | |
| | | ATE TRANSFER SYNTAXES | |
| | | | |
| 7 | | GURATION | |
| | | ΓITLE/PRESENTATION ADDRESS MAPPING | |
| | | FIGURABLE PARAMETERS | |
| | 7.2.1 | NanoMAXX Configurable Parameters per Network Location | |
| | 7.2.2 | Configurable Parameters per Remote Device Instance | |
| | 7.2.3 | Other Configurable Parameters | 44 |
| 8 | SUPPOF | RT OF EXTENDED CHARACTER SETS | 45 |
| | | | |

LIST OF FIGURES

| Figure 2-1 | Implementation Model | 10 |
|--------------|---|----|
| Figure 2-2 | Sequencing Constraints - "During the Exam" Configuration | 13 |
| Figure 2-3 | Sequencing Constraints - "End of Exam" Configuration | 14 |
| Figure 3-1 | Media Export Data Flow | |
| | LIST OF TABLES | |
| Table 1-1 NE | TWORKING SERVICES | 5 |
| | ore AE SOP Class Support | |
| | ore AE Proposed Presentation Contexts to an Archiver | |
| Table 3-18 U | S Image IOD Modules | 19 |
| | C Image IOD Modules | |
| | atient Module Attributes | |
| | eneral Study Module Attributes | |
| | atient Study Module Attributes | |
| | eneral Series Module Attributes | |
| | eneral Equipment Module Attributes | |
| | C Equipment Module Attributes | |
| | eneral Image Module Attributes | |
| | nage Pixel Module Attributes | |
| | S Region Calibration Attributes | |
| | S Image Module Attributes | |
| | OI LUT Module Attributes | |
| | OP Common Module Attributes | |
| | ore AE Behavior to C-Store Status | |
| | odality Worklist AE SOP Class Support | |
| | Iodality Worklist AE Proposed Presentation Contexts to a Worklist Serverroad Worklist Query Matching Key Attributes | |
| | atient Based Query Matching Key Attributes | |
| | eturn Key Attributes | |
| | Vorklist AE Behavior to C-FIND Status | |
| | OP Classes and Transfer Syntaxes for Media Export | |
| | asic Directory IOD Modules | |
| | lle-Set Identification Module | |
| | irectory Information Module | |
| | ATIENT KEYS | |
| | ΓUDY KEYS | |
| | ERIES KEYS | |
| | MAGE KEYS | |
| | ivate Tags | |

Conformance Statement Overview

The NanoMAXX Ultrasound System implements the necessary DICOM services to download work lists from an information system, save acquired images to a network storage, and store DICOM files onto removable media.

Table 1-1 provides an overview of the network services supported by the NanoMAXX Ultrasound System.

Table 1-1 NETWORKING SERVICES

| NETWORKING SOP CLASSES | USER OF SERVICE (SCU) | PROVIDER OF SERVICE (SCP) | | | |
|------------------------------------|-----------------------|---------------------------|--|--|--|
| | TRANSFER | | | | |
| Ultrasound Image Storage | Yes | No | | | |
| Ultrasound Image Storage (Retired) | Yes | No | | | |
| Secondary Capture Image Storage | Yes No | | | | |
| WORKFLOW MANAGEMENT | | | | | |
| Modality Worklist | Yes | No | | | |
| GENERAL | | | | | |
| Verification | Yes | No | | | |

Table 1.1-2 provides an overview of the media storage services supported by the NanoMAXX Ultrasound System.

Table 1.1-2 MEDIA STORAGE SERVICES

| SOP CLASSES | ROLE |
|---------------------------------|------|
| Media Storage Directory Storage | FSC |
| Ultrasound Image Storage | FSC |
| Secondary Capture Image Storage | FSC |

1 INTRODUCTION

This document describes the SonoSite NanoMAXX® Ultrasound System's conformance to the ACR-NEMA DICOM (Digital Imaging and Communications in Medicine) standard and satisfies the DICOM requirement for a vendor conformance specification.

The NanoMAXX system is an ultrasound imaging device. The DICOM options of the NanoMAXX system provide a means to query the Information System for scheduled procedures using Modality Worklist and send images to storage servers and removable USB media,.

Throughout this document DICOM storage servers will be referred to as archivers. For a device to be classified as an archiver it must be capable of receiving DICOM store commands. Archivers are primarily comprised of PACS.

This document is written with respect to ACR-NEMA DICOM version number 3.0 - 2007.

1.1 DICOM BACKGROUND

The DICOM information exchange specification provides a definitive structure of commands and information that allow for the inter-communication of medical imaging devices. Developed by the American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA), the DICOM standard strives to promote communication of image information through the use of a standardized set of command classes and information semantics.

The DICOM standard defines classes of information that are common to many modalities of medical imaging. However, to meet the specific needs of information content for such a diverse range of information, the DICOM specification defines structures for a multitude of medical data. To alleviate the need for applications to implement every aspect of the DICOM specification, a list of conformance tables for every modality was created to define the minimum set of information necessary for data exchanges. A requirement of the DICOM specification is to maintain a compliance document that outlines a subset of DICOM services and data classes that are supported by a device. The purpose of this document is to define a subset of DICOM for the exchange of information with the SonoSite NanoMAXX via its DICOM feature.

1.2 DEFINITIONS

AE Application Entity

ANSI American National Standards Institute

CW Continuous Wave

DICOM Digital Imaging and Communications in Medicine

DIMSE DICOM Message Service Element

FSC File Set Creator

HIS Hospital Information System

IE Information Entity

IOD Information Object Definition

kHz Kilohertz LUT Look Up Table

MPPS Modality Performed Procedure Step

| D07914 | Rev: C | NanoMAXX DICOM Conformance Statement | Page: 6 of 45 |
|--------|--------|--------------------------------------|----------------------|
| | | | |

PACS Picture Archive and Communication System

PW Pulsed Wave

PDU Protocol Data Unit

PPS Performed Procedure Step

RGB Red, Green, Blue

RIS Radiology Information System

SC Secondary Capture

SCU Service Class User (Client)

SCP Service Class Provider (Server)

SOP Service - Object Pair

SPS Scheduled Procedure Step

TCP/IP Transmission Control Protocol/Internet Protocol

UID Unique Identifier

US Ultrasound

USB Universal Serial Bus

UTC Coordinated Universal Time

VOI Value Of Interest

VR Value Representation

1.3 REFERENCE DOCUMENTS

ACR-NEMA DICOM Standard Version 3.0 – 2007

2 IMPLEMENTATION MODEL

The NanoMAXX DICOM feature incorporates the DICOM 3.0 standard for networked image storage and Modality Worklist functions. Scheduled Procedures are queried from the HIS/RIS Worklist SCP and presented to the operator for selection. Performed Procedures¹ are transferred from the NanoMAXX ultrasound system using standard network connections to be stored on a DICOM compatible archiver.

The behavior of how images are sent depends on which Transfer Images setting is selected during DICOM setup of locations. Two selections are offered, "During the exam" (in-progress transfer mode) or "End of exam" (batch transfer mode).

For batch transfer mode, NanoMAXX allows up to four archivers and one Worklist server to be selected at any given time. The devices are selected using DICOM Setup mode with all selected devices being placed into a destination list.

For in-progress transfer mode, NanoMAXX allows only one archive device and one Worklist server to be selected at any given time. Like batch transfer mode, the devices are selected using DICOM Setup mode with all selected devices annotated in the destination list.

A maximum of 200 Scheduled Procedures Steps may be queried from the selected Modality Worklist SCP. The Worklist is persisted to non-volatile memory so that it can be accessed during portable exams. Both manual and automatic queries are supported. Automatic queries are user configurable and are performed in the background at periodic intervals.

During an exam all saved images are written to internal storage. For batch transfer mode, when the exam completes all images associated with it are marked as Archive Pending for transfer to each device in the current destination list. If a network connection is present then transfer begins immediately.

Performed Procedures are Archived to devices in the destination list sequentially, starting with the first selected archiver. Exam images are sent to each destination device in batch transfer mode; an association is opened, all exam images are transferred in acquisition order, and the association is closed. Once an exam is successfully transferred to a device then all images in the exam are marked as Archive Complete to that destination. Archiving then continues with the next device in the destination list. Once all devices in the destination list have successfully received each exam image then the Exam Archive is complete.

For in-progress transfer mode, images are transferred immediately after acquisition provided there is a network connection present.

Acquired images are sent to the destination archive device; an association is opened if closed, the acquired image is transferred and the association is left open at the end of image transfer. The association is left open in anticipation of transferring another acquired image. If another image is not acquired within nominally 30 seconds, then the association is closed to preserve network resources. Any additional images acquired during the exam are sent on a subsequent association(s) using the sequence described above.

When a Get Status is performed the current destination list is used in the same manner as with Exam Archive. For batch transfer mode, the devices are accessed sequentially, starting with the first selected archiver. For each device an association is opened, status is returned, and the association is closed. Status is obtained from archiver and Worklist devices using DICOM Verify (C-Echo). Once status is successfully returned from all devices in the destination list then Get Status is complete.

¹ Performed Procedures consist of images from the ultrasound system.

| D07914 | Rev: C | NanoMAXX DICOM Conformance Statement | Page: 8 of 45 | |
|---|--------|--------------------------------------|----------------------|--|
| This document contains confidential information that is proprietary to SanoSite. Neither the document per the information | | | | |

This document contains confidential information that is proprietary to SonoSite. Neither the document nor the information contained therein should be disclosed or reproduced in whole or in part, without express written consent of SonoSite.

When a Get Status is performed during in-progress transfer mode, the archive device association is opened if closed, a C-Echo Request is issued and the C-Echo response status is reported. The association remains open while in DICOM Setup mode. Once DICOM Setup mode is exited the rules used for image acquisition apply to closing the association. This behavior allows an in-progress transfer with an open association to remain open through the Get Status process and allows subsequent image acquisition to be sent on the same association when acquisition constraints are met.

One or more completed exams may be selected from the exam list to have their images saved as DICOM files to the selected USB medium.

The user may choose to "Append" a completed exam. On the NanoMAXX system, this is treated as a new Series in the same Study as the original exam. The appended exam shows up as a separate line item in the Patient List form.

2.1 APPLICATION DATA FLOW DIAGRAM

The diagram in Figure 2-1 represents the relationship between the ultrasound system's real-world activities (circles on the left), the local AE's built into NanoMAXX (boxes in the center), and the remote AE's built into the devices NanoMAXX communicates with using DICOM (boxes on the right).

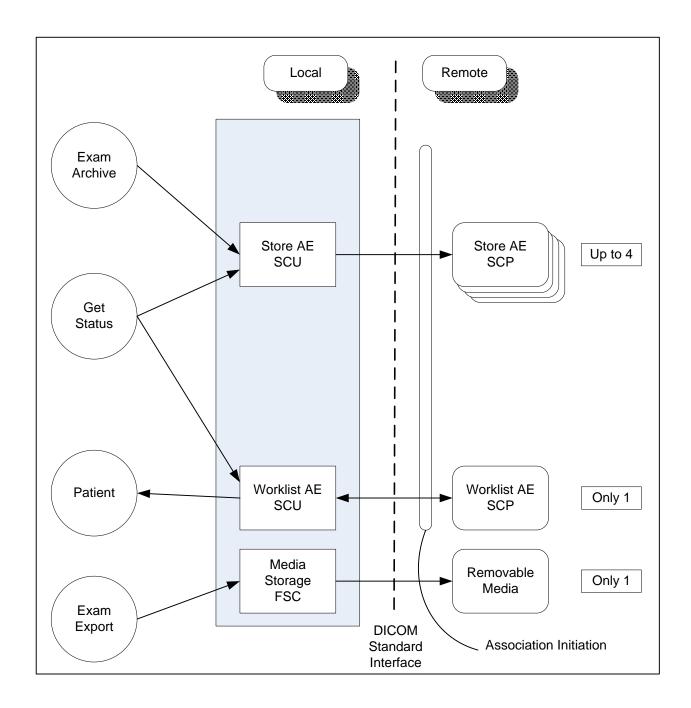


Figure 2-1 Implementation Model

The following are the conditions that invoke real-world activities associated with AE's.

| D07914 | Rev: C | NanoMAXX DICOM Conformance Statement | Page: 10 of 45 | |
|---|--------|--------------------------------------|-----------------------|--|
| This document contains confidential information that is proprietary to SonoSite. Neither the document nor the information | | | | |

Exam Archive

- For batch transfer mode, End Exam with one or more images saved on internal storage. Exam end occurs when the Delta key is pressed while configured to End Exam, or when Patient setup mode is entered and End Exam is pressed or any of the patient fields are changed and the saves committed or when New is pressed and you exit Patient setup.
- For in-progress transfer mode after an image acquisition is complete. Image acquisition occurs after the Save key is pressed.
- System startup with one or more images flagged as Archive Pending.

Get Status

Operator Verify command in DICOM Setup mode.

Patient

• User enters Patient Setup screen, enters search criteria, and presses the Query key. The Worklist screen is entered and a list of matching Scheduled Procedures Steps are returned and displayed.

Exam Export

 User selects one or more completed exams from the exam list and the images for those exams are written to the selected removable media.

2.2 FUNCTIONAL DEFINITIONS OF AE'S

Store

This AE handles sending ultrasound images to an archiver using the DICOM store SCU services. Steps taken to Get Archiver Status:

```
A-ASSOCIATE
C-ECHO command
A-RELEASE
```

Steps taken to Send Exam to Archiver, batch transfer mode:

Steps taken to Send Exam to Archiver, in progress transfer mode:

Worklist

This AE handles querying a Worklist SCP for a list of scheduled procedures using the DICOM Modality Worklist SCU services.

Steps taken to Get Worklist Status:

| D07914 | Rev: C | NanoMAXX DICOM Conformance Statement | Page: 11 of 45 | |
|---|--------|--------------------------------------|-----------------------|--|
| This decrement contains confidential information that is magnifecture to ConcCite. Notifice the decrement nor the information | | | | |

```
A-ASSOCIATE
C-ECHO command
A-RELEASE

Steps taken to Query a Worklist SCP:
A-ASSOCIATE
SEND C-FIND Request command
{
    RECEIVE C-FIND Response
} While C-FIND status == pending AND responses <= 200
A-RELEASE
```

2.3 SEQUENCING OF REAL-WORLD ACTIVITIES

All real world activities that initiate communication to remote AE's operate asynchronously with respect to each other and Workflow activities.

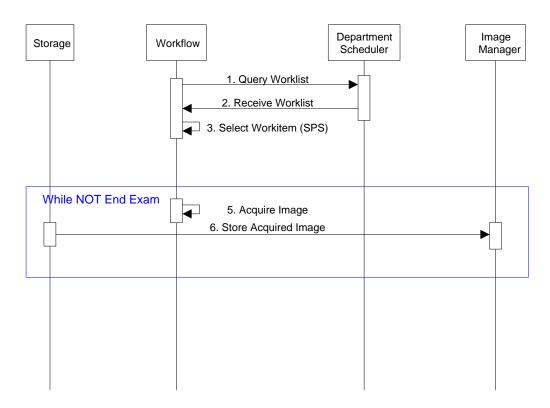


Figure 2-2 Sequencing Constraints - "During the Exam" Configuration

Under normal scheduled workflow conditions the sequencing constraints illustrated apply:

- 1. Worklist Query is initiated.
- 2. List of Scheduled Procedure Steps (SPS) are returned.
- 3. SPS item is selected from the Worklist and the Exam begins.
- 4. Image is acquired.
- 5. Association is opened with the Image Manager and the acquired image is stored. Subsequent image acquisitions are stored under the same association, if the acquisition completes within 30 seconds of the last Store operation. After 30 seconds of inactivity, the association is closed.

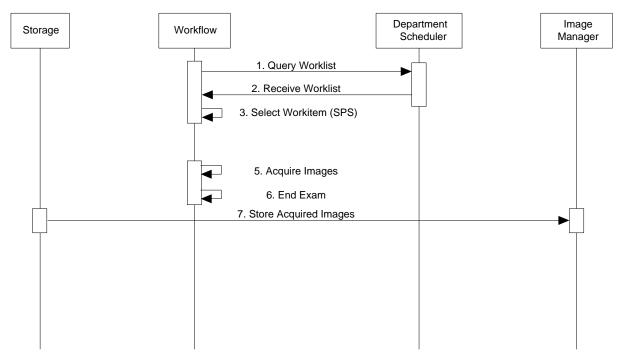


Figure 2-3 Sequencing Constraints - "End of Exam" Configuration

Under normal scheduled workflow conditions the sequencing constraints illustrated apply:

- 1. Worklist Query is initiated.
- 2. List of Scheduled Procedure Steps (SPS) are returned.
- 3. SPS item is selected from the Worklist and the Exam begins.
- 4. Images are acquired.
- 5. Exam is ended.
- 6. Image SOP instances acquired during the exam are stored to the Image Manager.

3 AE SPECIFICATIONS

3.1 STORE AE - SPECIFICATION

The Store AE provides conformance to the following DICOM V3.0 SOP Classes as an SCU:

Table 3-1 Store AE SOP Class Support

| SOP Class Name | SOP Class UID | Conformance Level |
|------------------------------------|-----------------------------|-------------------|
| Verification | 1.2.840.10008.1.1 | Standard |
| Ultrasound Image Storage | 1.2.840.10008.5.1.4.1.1.6.1 | Standard |
| Ultrasound Image Storage (Retired) | 1.2.840.10008.5.1.4.1.1.6 | Standard |
| Secondary Capture Image Storage | 1.2.840.10008.5.1.4.1.1.7 | Standard |

3.1.1 Association Establishment Policies

The Store AE will initiate an association to a device in response to the following real-world activities; Archive Exam or Image Acquisition, Review Archive, and Get Status.

3.1.1.1 **GENERAL**

Maximum PDU size offered to SCP: 32,768 bytes

This is the maximum PDU size the Store AE can receive and is the value offered for the maximum PDU size in the Association Request command. Once the Association is open if the Store AE receives a PDU that is larger than this value then the Association will be aborted.

Minimum PDU size accepted from SCP: 1,024 bytes

This is the minimum PDU size the Store AE can be configured to send. If the Store AE receives a maximum PDU size in the Association Accept response that is smaller than this value then the Association will be aborted immediately.

Maximum PDU size sent by SCU: 32,768 bytes

This is the maximum PDU size the Store AE can be configured to send. The maximum PDU size sent on any Store AE Association will be the smaller of the configured value and the maximum PDU size received in the Association Accept response.

3.1.1.2 NUMBER OF ASSOCIATIONS

Number of simultaneous associations for the Store AE: 1

3.1.1.3 ASYNCHRONOUS NATURE

The Store AE will not use asynchronous operations.

3.1.1.4 IMPLEMENTATION IDENTIFYING INFORMATION

Implementation Class UID: "1.2.840.114340.3" Implementation Version name: "Tiller_SV500"

Note: "114340" is registered by SonoSite with ANSI. Version name will be used initially as shown, but is subject to change with new versions of the DICOM capable application software.

3.1.2 Association Initiation by Real-World Activity

| D07914 | Rev: C | NanoMAXX DICOM Conformance Statement | Page: 16 of 45 |
|--------|--------|--|-----------------------|
| TEL: 1 | | the state of the s | 4 . 6 |

The Store AE will open associations to the storage devices listed in the current destination list in response to the following real-world activities; Archive Exam or Image Acquisition, Review Archive, and Get Status.

3.1.2.1 ASSOCIATION INITIATION BY: ARCHIVE EXAM

The Archive Exam real-world activity if configured for batch transfer mode will cause the Store AE to open associations to each storage device listed in the current destination list.

3.1.2.2 ASSOCIATION INITIATION BY: IMAGE ACQUISITION

The Image Acquisition real-world activity if configured for in-progress transfer mode will cause the Store AE to open an association to the selected storage device .

3.1.2.3 ASSOCIATION INITIATION BY: REVIEW ARCHIVE

The Archive command real-world activity while in Review mode will cause the Store AE to open associations to each storage device listed in the current destination list.

3.1.2.4 ASSOCIATION INITIATION BY: GET STATUS

The Get Status real-world activity will cause the Store AE to open associations to each archiver listed in the current destination list.

3.1.3 Proposed Presentation Contexts to an Archiver

Table 3-2 Store AE Proposed Presentation Contexts to an Archiver

| Presentation Context Table | | | | | | | | |
|--|-----------------------------|--|--|----------|-------------|--|--|--|
| A | Abstract Syntax | Transfer S | Role | Extended | | | | |
| Name | UID | Name List | UID List | | Negotiation | | | |
| Verification | 1.2.840.10008.1.1 | Implicit VR Little Endian | 1.2.840.10008.1.2 | SCU | None | | | |
| Ultrasound Image Storage | 1.2.840.10008.5.1.4.1.1.6.1 | Implicit VR Little Endian Explicit VR Little Endian JPEG Baseline (Process 1) ¹ | 1.2.840.10008.1.2 1.2.840.10008.1.2.1 1.2.840.10008.1.2.4.50 | SCU | None | | | |
| Ultrasound Image Storage (Retired) | 1.2.840.10008.5.1.4.1.1.6 | Implicit VR Little Endian Explicit VR Little Endian | 1.2.840.10008.1.2 1.2.840.10008.1.2.1 | SCU | None | | | |
| Secondary Capture Image Storage | 1.2.840.10008.5.1.4.1.1.7 | Implicit VR Little Endian Explicit VR Little Endian | 1.2.840.10008.1.2 1.2.840.10008.1.2.1 | SCU | None | | | |
| | | | | | | | | |

¹ This Transfer Syntax is the only one proposed if JPEG Compression is configured.

3.1.3.1 VERIFICATION SOP CLASS

The Store AE provides standard conformance to the Verification SOP Class as an SCU. The remote SCP must support Verification in the same association as the Store Command (C-Store).

3.1.3.2 ULTRASOUND IMAGE STORAGE SOP CLASS

The Ultrasound Image Storage SOP Class uses the Common Composite Image IOD Modules as shown in Table 3-3

Table 3-3 US Image IOD Modules

| IE | Module | Reference | Usage |
|--------------------|-------------------------------|-----------|-------|
| Patient | Patient | 3.1.4.1 | M |
| Patient | Clinical Trial Subject | Not Used | U |
| | General Study | 3.1.4.2 | M |
| Study | Patient Study | 3.1.4.3 | U |
| | Clinical Trial Study | Not Used | U |
| Series | General Series | 3.1.4.4 | M |
| Series | Clinical Trial Series | Not Used | U |
| Frame Of Reference | Frame Of Reference | Not Used | U |
| Frame Of Reference | Synchronization | Not Used | U |
| Equipment | General Equipment | 3.1.4.5 | M |
| | General Image | 3.1.4.7 | M |
| | Image Pixel | 3.1.4.8 | M |
| | Contrast/Bolus | Not Used | С |
| Torres | Palette Color Lookup Table | Not Used | С |
| Image | US Region Calibration | 3.1.4.9 | U |
| | US Image | 3.1.4.10 | M |
| | Overlay Plane | Not Used | U |
| | VOI LUT | 3.1.4.11 | U |
| | SOP Common | 3.1.4.12 | M |

3.1.3.3 ULTRASOUND IMAGE STORAGE SOP CLASS (RETIRED)

The Ultrasound Image Storage SOP Class (Retired) uses the Common Composite Image IOD.

3.1.3.4 SECONDARY CAPTURE IMAGE STORAGE SOP CLASS

The Secondary Capture Image Storage SOP Class uses the Common Composite Image IOD Modules as shown in Table 3-4.

Table 3-4 SC Image IOD Modules

| IE | Module | Reference | Usage |
|---------------|------------------------|-----------|-------|
| Patient | Patient | 3.1.4.1 | M |
| ratient | Clinical Trial Subject | Not Used | U |
| General Study | | 3.1.4.2 | M |
| Study | Patient Study | 3.1.4.3 | U |
| | Clinical Trial Study | Not Used | U |
| Series | General Series | 3.1.4.4 | M |
| Series | Clinical Trial Series | Not Used | U |
| Equipment | General Equipment | 3.1.4.5 | U |
| Equipment | SC Equipment | 3.1.4.6 | M |
| | General Image | 3.1.4.7 | M |
| | Image Pixel | 3.1.4.8 | M |
| | SC Image | Not Used | M |
| Image | Overlay Plane | Not Used | U |
| | Modality LUT | Not Used | U |
| | VOI LUT | 3.1.4.11 | U |
| | SOP Common | 3.1.4.12 | M |

3.1.4 COMMON COMPOSITE IMAGE IOD MODULE

The section defines the Modules that are common to the Ultrasound, Ultrasound (Retired), and Secondary Capture Storage SOP Classes.

3.1.4.1 PATIENT MODULE

Table 3-5 specifies the attributes used from the Patient Module. These attributes are used by the Ultrasound, Ultrasound (Retired), and Secondary Capture Image Storage SOP Classes. Attributes not listed are not used.

Table 3-5 Patient Module Attributes

| Attribute Name | Tag | Type | Attribute Description |
|-----------------------------------|-------------|------|---|
| | | | From Worklist or manually entered on Patient |
| Patient's Name ¹ | (0010,0010) | 2 | Setup screen (Last, First and Middle fields). All 5 |
| 1 attent 5 Name | (0010,0010) | | Person Name Components are preserved when |
| | | | name comes from Worklist. |
| Patient ID ¹ | (0010 0020) | 2 | From Worklist or manually entered on Patient |
| ratient 1D | (0010,0020) | 2 | Setup screen (ID field) |
| Dation Va Birth Date 1 | (0010,0030) | 2 | From Worklist or manually entered on Patient |
| Patient's Birth Date ¹ | | | Setup screen (Date of birth fields) |
| Patient's Sex ¹ | (0010,0040) | 2 | From Worklist or manually entered on Patient |
| Patient's Sex 1 | | | Setup screen (Gender pick list) |
| Other Patient IDs | (0010,1000) | 3 | From Worklist |
| Ethnia Croup | (0010,2160) | 2 | Manually entered on Patient Setup screen. Only |
| Ethnic Group | | 3 | sent for IMT Exam Types. |

¹This attribute cannot be modified by the user when coming from DICOM Worklist.

3.1.4.2 GENERAL STUDY MODULE

Table 3-6 specifies the attributes used from the General Study Module. These attributes are used by the Ultrasound, Ultrasound (Retired), and Secondary Capture Image Storage SOP Classes. Attributes not listed are not used.

Table 3-6 General Study Module Attributes

| Attribute Name | Tag | Type | Attribute Description |
|------------------------------------|-------------|------|--|
| Study Instance UID | (0020,000D) | 1 | From Worklist or automatically generated |
| Study Date | (0008,0020) | 2 | Procedure start date |
| Study Time | (0008,0030) | 2 | Procedure start time |
| Referring Physician's Name | (0008,0090) | 2 | From Worklist or manually entered on Patient Setup screen (Referring Dr. field) Note: Only last name component will be sent when manually entered. |
| Study ID | (0020,0010) | 2 | From Worklist (mapped from Requested Procedure ID attribute) or manually entered for unscheduled procedures. If no value is provided via worklist or manual entry, then a value will be automatically generated. |
| Accession Number ² | (0008,0050) | 2 | From Worklist or manually entered on Patient Setup screen (Accession field) |
| Study Description | (0008,1030) | 3 | From Worklist ¹ or selected manually on Patient Setup screen (Procedure Type pick list) |
| Referenced Study Sequence | (0008,1110) | 3 | From Worklist. Not sent if procedure was unscheduled. |
| >Referenced SOP Class UID | (0008,1150) | 1C | |
| >Referenced SOP Instance UID | (0008,1155) | 1C | |
| Procedure Code Sequence | (0008,1032) | 3 | Mapped from Worklist Requested Procedure Code Sequence, if performed. Not sent if procedure was unscheduled. |
| >Code Value | (0008,0100) | 1C | _ |
| >Coding Scheme Designator | (0008,0102) | 1C | |
| >Code Meaning | (0008,0104) | 1C | |
| Name of Physician(s) Reading Study | (0008,1060) | 3 | Entered on Patient Setup screen. (Reading Dr. field) Note: Only last name component will be sent when manually entered |

Mapped from Scheduled Procedure Step Description (0040,0007) if it exists. Otherwise, Study Description is set to value of Requested Procedure Description (0032,1060) if it exists. If Requested Procedure Description (0032,1060) is also empty, Study Description is set to Requested Procedure Code Sequence (0032,1064) Code Meaning (0008,0104).

3.1.4.3 PATIENT STUDY MODULE

Table 3-7 defines attributes used from the Patient Study Module. These attributes are used by the Ultrasound, Ultrasound (Retired), and Secondary Capture Image Storage SOP Classes. Attributes not listed are not used.

| D07914 Rev: C NanoMAXX DICOM Conformance Statement Page: 22 of 45 |
|---|
|---|

² This attribute cannot be modified by the user when coming from DICOM Worklist.

Table 3-7 Patient Study Module Attributes

| Attribute Name | Tag | Type | Attribute Description |
|------------------------------|-------------|------|--|
| Patient's Size | (0010,1020) | 3 | Only sent for Cardiac Exam types. |
| Patient's Weight | (0010,1030) | 3 | Only sent for Cardiac Exam types. |
| Additional Patient's History | (0010,21B0) | 3 | From Worklist of manually entered on Patient Setup screen (Indications field). |

3.1.4.4 GENERAL SERIES MODULE

Table 3-8 specifies the attributes used from the General Series Module. These attributes are used by the Ultrasound, Ultrasound (Retired), and Secondary Capture Image Storage SOP Classes. Attributes not listed are not used.

Table 3-8 General Series Module Attributes

| Attribute Name | Tag | Type | Attribute Description |
|---|-------------|------|---|
| Modality | (0008,0060) | 1 | "US" |
| Series Instance UID | (0020,000E) | 1 | Automatically generated |
| Series Number | (0020,0011) | 2 | "1" |
| Laterality | (0020,0060) | 2C | Zero Length |
| Series Date | (0008,0021) | 3 | Procedure start date |
| Series Time | (0008,0031) | 3 | Procedure start time |
| Protocol Name | (0018,1030) | 3 | Zero length |
| Series Description | (0008,103E) | 3 | Same as Performed Procedure Step Description |
| Operator's Name | (0008,1070) | 3 | Entered on Patient Setup screen (User field). The User's initials are transmitted in the last name component |
| Request Attributes Sequence | (0040,0275) | 3 | Only sent if the procedure originated from a Worklist Scheduled Procedure Step |
| >Requested Procedure ID | (0040,1001) | 1C | From Worklist |
| >Scheduled Procedure Step ID | (0040,0009) | 1C | From Worklist |
| >Scheduled Procedure Step Description | (0040,0007) | 3 | From Worklist |
| >Scheduled Protocol Code Sequence | (0040,0008) | 3 | From Worklist |
| >>Code Value | (0008,0100) | 1C | |
| >>Coding Scheme Designator | (0008,0102) | 1C | |
| >>Code Meaning | (0008,0104) | 1C | |
| Performed Procedure Step ID | (0040,0253) | 3 | From Worklist (mapped from Scheduled Procedure Step ID) or Generated by NanoMAXX |
| Performed Procedure Step Start Date | (0040,0244) | 3 | Procedure start date |
| Performed Procedure Step Start Time | (0040,0245) | 3 | Procedure start time |
| Performed Procedure Step Description | (0040,0254) | 3 | Mapped from Worklist SPS description, if performed, or selected manually on Patient Setup screen (Procedure Type pick list) |
| Performed Protocol Code Sequence | (0040,0260) | 3 | Mapped From Worklist Scheduled Protocol Code sequence, if performed. Otherwise sent as zero length sequence. |

| D07914 Rev: C NanoMAXX DICOM Conformance Statement Page: 23 of 45 |
|---|
|---|

| Attribute Name | Tag | Type | Attribute Description |
|---------------------------|-------------|------|-----------------------|
| >Code Value | (0008,0100) | 1C | |
| >Coding Scheme Designator | (0008,0102) | 1C | |
| >Code Meaning | (0008,0104) | 1C | |

3.1.4.5 GENERAL EQUIPMENT MODULE

Table 3-9 specifies the attributes used from the General Equipment Module. These attributes are used by the Ultrasound, Ultrasound (Retired), and Secondary Capture Image Storage SOP Classes. Attributes not listed are not used.

Table 3-9 General Equipment Module Attributes

| Attribute Name | Tag | Type | Attribute Description |
|---------------------------|-------------|------|---|
| Manufacturer | (0008,0070) | 2 | "SonoSite, Inc." |
| Institution Name | (0008,0080) | 3 | Entered on Patient Setup screen (Institution) |
| Station Name | (0008,1010) | 3 | Host Name for current location |
| Manufacturer's Model Name | (0008,1090) | 3 | Model name (maps to product line) |
| Software Versions | (0018,1020) | 3 | ARM Firmware Version |

3.1.4.6 SC EQUIPMENT MODULE

Table 3-10 describes the attributes used from the SC Equipment Module. These attributes are used by the Secondary Capture Image Storage SOP Class. Attributes not listed are not used.

Table 3-10 SC Equipment Module Attributes

| Attribute Name | Tag | Type | Attribute Description |
|-----------------|-------------|------|-----------------------|
| Conversion Type | (0008,0064) | 1 | "WSD" |
| Modality | (0008,0060) | 3 | "US" |

3.1.4.7 GENERAL IMAGE MODULE

Table 3-11 specifies the attributes used from the General Image Module. These attributes are used by the Ultrasound, Ultrasound (Retired), and Secondary Capture Image Storage SOP Classes. Attributes not listed are not used.

Table 3-11 General Image Module Attributes

| Attribute Name | Tag | Type | Attribute Description |
|-------------------------|-------------|------|---|
| Instance Number | (0020,0013) | 2 | A number that identifies this image |
| Patient Orientation | (0020,0020) | 2C | Zero Length |
| Content Date | (0008,0023) | 2C | Image acquisition date |
| Content Time | (0008,0033) | 2C | Image acquisition time |
| Derivation Description | (0008,2111) | 3 | "RGB to MONOCHROME2 conversion" - Sent for MONOCHROME2 images "RGB to JPEG Baseline 1 conversion" - Sent for JPEG Lossy compressed images. |
| Lossy Image Compression | (0028,2110) | 3 | 01=Lossy Compressed - Only sent for MONOCHROME2 and JPEG Lossy Compressed images. |

| D07914 Rev: C NanoMAXX DICOM Conformance Statement Page: 24 of 45 |
|---|
|---|

| Attribute Name | Tag | Type | Attribute Description |
|----------------------------------|-------------|------|--|
| Lossy Image Compression Ratio | (0028,2112) | 3 | Set to 3 for MONOCHROME2 images. The approximate compression ratio is sent for JPEG Lossy Compressed images. |

3.1.4.8 IMAGE PIXEL MODULE

Table 3-12 specifies the attributes used from the Image Pixel Module. These attributes are used by the Ultrasound, Ultrasound (Retired), and Secondary Capture Image Storage SOP Classes. Attributes not listed are not used.

Table 3-12 Image Pixel Module Attributes

| Attribute Name | Tag | Type | Attribute Description |
|----------------------------|-------------|------|---|
| Samples per Pixel | (0028,0002) | 1 | MONOCHROME2=1, RGB=3, YBR_FULL_422 = 3 |
| Photometric Interpretation | (0028,0004) | 1 | Configurable in DICOM Setup mode. Valid settings defined by archiver type and Transfer Syntax being used. MONOCHROME2, RGB or YBR_FULL_422 |
| Rows | (0028,0010) | 1 | 480 |
| Columns | (0028,0011) | 1 | 640 |
| Bits Allocated | (0028,0100) | 1 | 8 |
| Bits Stored | (0028,0101) | 1 | 8 |
| High Bit | (0028,0102) | 1 | 7 |
| Pixel Representation | (0028,0103) | 1 | 0 |
| Pixel Data | (7FE0,0010) | 1 | Used – Basic Offset Table is set to zero length for encapsulated multi-frame images. |
| Planar Configuration | (0028,0006) | 1C | 0=Color-by-pixel - Only sent for RGB and YBR_FULL_422 images |

3.1.4.9 US REGION CALIBRATION MODULE

Table 3-13 specifies the attributes used from the US Region Calibration Module. These attributes are used by Ultrasound, and Ultrasound (Retired) Image Storage SOP instances created by the NanoMAXX system. Attributes not listed are not used.

Table 3-13 US Region Calibration Attributes

| Attribute Name | Tag | Type | Attribute Description |
|-------------------------------------|-------------|------|--|
| Sequence of Ultrasound Regions | (0018,6011) | 1 | Used |
| >Region Location Min x ₀ | (0018,6018) | 1 | Automatically generated |
| >Region Location Min y ₀ | (0018,601A) | 1 | Automatically generated |
| >Region Location Max x ₁ | (0018,601C) | 1 | Automatically generated |
| >Region Location Max y ₁ | (0018,601E) | 1 | Automatically generated |
| >Physical Units X Direction | (0018,6024) | 1 | |
| >Physical Units Y Direction | (0018,6026) | 1 | Automatically generated |
| >Physical Delta X | (0018,602C) | 1 | Automatically generated |
| >Physical Delta Y | (0018,602E) | 1 | Automatically generated |
| >Reference Pixel x ₀ | (0018,6020) | 3 | Only sent in Spectral Doppler regions. |
| >Reference Pixel y ₀ | (0018,6022) | 3 | Only sent in Spectral Doppler regions. |
| >Ref. Pixel Physical Value X | (0018,6028) | 3 | Only sent in Spectral Doppler regions. |
| >Ref. Pixel Physical Value Y | (0018,602A) | 3 | Only sent in Spectral Doppler regions. |
| >Region Spatial Format | (0018,6012) | 1 | Automatically generated |
| >Region Data Type | (0018,6014) | 1 | Automatically generated |
| >Region Flags | (0018,6016) | 1 | Automatically generated |

| D07914 | Rev: C | NanoMAXX DICOM Conformance Statement | Page: 26 of 45 |
|--------|--------|--------------------------------------|-----------------------|
| | | | |

3.1.4.10 US IMAGE MODULE

Table 3-14 specifies the attributes used from the US Image Module. These attributes are used by Ultrasound, and Ultrasound (Retired) Image Storage SOP instances created by the NanoMAXX system. Attributes not listed are not sent.

Table 3-14 US Image Module Attributes

| Attribute Name | Tag | Type | Attribute Description |
|----------------------------|-------------|------|---|
| Samples Per Pixel | (0028,0002) | 1 | MONOCHROME2=1, RGB=3, YBR_FULL_422 = 3 |
| Photometric Interpretation | (0028,0004) | 1 | Configurable in DICOM Setup mode Valid settings defined by archiver type and Transfer Syntax being used. MONOCHROME2, RGB or YBR_FULL_422 |
| Bits Allocated | (0028,0100) | 1 | 8 |
| Bits Stored | (0028,0101) | 1 | 8 |
| High Bit | (0028,0102) | 1 | 7 |
| Planar Configuration | (0028,0006) | 1C | 0=Color-by-pixel - Only sent for RGB and YBR_FULL_422 images |
| Pixel Representation | (0028,0103) | 1 | 0 |

| Attribute Name | Tag | Type | Attribute Description |
|-------------------------|-------------|------|---|
| Image Type | (0008,0008) | 2 | RGB = "ORIGINAL\PRIMARY\ <examtype>\nnnn" YBR_FULL_422 or MONOCHROME2 = "DERIVED\PRIMARY\<examtype>\nnnn" Possible values for <examtype>: ABDOMINAL BREAST CHEST ENDOCAVITARY ENDORECTAL ENDOVAGINAL EPICARDIAL FETAL HEART GYNECOLOGY HEPATIC IMT INTRACARDIAC INTRAOPERATIVE INTRAVASCULAR MUSCULOSKELETAL NEONATAL HEAD NERVE OBSTETRICAL OPHTHALMIC ORBITAL PEDIATRIC PELVIC RETROPERITONEAL SCROTAL SMALL PARTS SUPERFICIAL TTE US BIOPSY VASCULAR VENOUS nnnn=bit map designating the image mode:</examtype></examtype></examtype> |
| Lossy Image Compression | (0028,2110) | 1C | MONOCHROME2 and JPEG Lossy Compressed |

| D07914 Rev: C NanoMAXX DICOM Conformance Statement Page: 28 of 45 |
|--|
|--|

| Attribute Name | Tag | Type | Attribute Description |
|----------------------------------|-------------|------|---|
| Ultrasound Color Data Present | (0028,0014) | 3 | 00=Color data not present in image 01=Color data is present in image Not sent with Ultrasound (Retired) Images. |
| Heart Rate | (0018,1088) | 3 | |
| Transducer Data | (0018,5010) | 3 | |

3.1.4.11 VOI LUT MODULE

Table 3-15 specifies the attributes used from the VOI LUT module. These attributes are used by the Ultrasound, Ultrasound (Retired), and Secondary Capture Image Storage SOP Classes. Attributes not listed are not used.

Table 3-15 VOI LUT Module Attributes

| Attribute Name | Tag | Type | Attribute Description |
|----------------|-------------|------|----------------------------------|
| Window Center | (0028,1050) | 3 | 128 - Only sent with Monochrome2 |
| Window Width | (0028,1051) | 1C | 256 - Only sent with Monochrome2 |

3.1.4.12 SOP COMMON MODULE

Table 3-16 specifies the attributes used from the SOP Common module. These attributes are used by the Ultrasound, Ultrasound (Retired), and Secondary Capture Image Storage SOP Classes. Attributes not listed are not used.

Table 3-16 SOP Common Module Attributes

| Attribute Name | Tag | Type | Attribute Description |
|------------------------|-------------|------|-------------------------------------|
| SOP Class UID | (0008,0016) | 1 | Automatically generated |
| SOP Instance UID | (0008,0018) | 1 | Automatically generated |
| Specific Character Set | (0008,0005) | 1C | ISO_IR 100 |
| Instance Number | (0020,0013) | 3 | A number that identifies this image |

3.1.5 STORE AE BEHAVIOR TO C-STORE STATUS

Table 3-17describes the behavior for C-Store response status returned from the Storage SCP. All image SOP classes supported by the Store AE exhibit the same behavior.

Table 3-17 Store AE Behavior to C-Store Status

| Service | Further Meaning | Status | Store AE Behavior |
|---------|-----------------------------------|--------|--|
| Status | | Codes | |
| Success | | 0000 | Continue without user notification |
| Refused | Out of Resources | A7xx | Association terminated. User notified. |
| Error | Data Set does not match SOP Class | A9xx | Association terminated. User notified. |
| Error | Cannot understand | Cxxx | Association terminated. User notified. |
| | Coercion of data elements | B000 | Ignored - Message logged. |
| Warning | Data set does not match SOP class | B007 | Ignored - Message logged. |
| | Elements discarded | B006 | Ignored - Message logged. |

3.2 MODALITY WORKLIST AE - SPECIFICATION

The Modality Worklist AE provides conformance to the following DICOM V3.0 SOP Classes as an SCU:

Table 3-18 Modality Worklist AE SOP Class Support

| SOP Class Name | SOP Class UID | Conformance Level |
|--|------------------------|-------------------|
| Verification | 1.2.840.10008.1.1 | Standard |
| Modality Worklist Information Model - FIND | 1.2.840.10008.5.1.4.31 | Standard |

3.2.1 ASSOCIATION ESTABLISHMENT POLICIES

The Modality Worklist AE will initiate an association to a device in response to the following real-world activities;

- 1. The user initiates a manual Update Worklist (Broad Query).
- 2. The user initiates a specific Worklist Query (Patient Based Query).
- 3. The system initiates an Automatic Worklist Query (Broad Query).

In all cases a C-FIND command is issued to the Modality Worklist server. After the requested data is returned, the association is closed.

3.2.1.1 GENERAL

Maximum PDU size offered to SCP: 32,768 bytes

This is the maximum PDU size the Modality Worklist AE can receive and is the value offered for the maximum PDU size in the Association Request command. Once the Association is open if the Modality Worklist AE receives a PDU that is larger than this value then the Association will be aborted.

Minimum PDU size accepted from SCP: 1,024 bytes

This is the minimum PDU size the Modality Worklist AE can be configured to send. If the Modality Worklist AE receives a maximum PDU size in the Association Accept response that is smaller than this value then the Association will be aborted immediately.

Maximum PDU size sent by SCU: 32,768 bytes

| D07914 | Rev: C | NanoMAXX DICOM Conformance Statement | Page: 30 of 45 | | |
|--------|--------|--------------------------------------|-----------------------|--|--|
| | | | | | |

This is the maximum PDU size the Modality Worklist AE can be configured to send. The maximum PDU size sent on any Modality Worklist AE Association will be the smaller of the configured value and the maximum PDU size received in the Association Accept response.

3.2.1.2 NUMBER OF ASSOCIATIONS

Number of simultaneous associations for the Modality Worklist AE: 1

3.2.1.3 ASYNCHRONOUS NATURE

The Modality Worklist AE will not use asynchronous operations.

3.2.1.4 IMPLEMENTATION IDENTIFYING INFORMATION

Implementation Class UID: "1.2.840.114340.3" Implementation Version name: "Tiller_SV500"

Note: "114340" is registered by SonoSite with ANSI. Version name will be used initially as shown, but is subject to change with new versions of the DICOM capable application software.

3.2.2 ASSOCIATION INITIATION BY REAL-WORLD ACTIVITY

The Modality Worklist AE will open associations to the configured Worklist SCP in response to the following real-world activities; Update Worklist, Query Worklist, Automatic Worklist Query, and Get Status.

3.2.2.1 ASSOCIATION INITIATION BY: UPDATE WORKLIST

The Update Worklist real-world activity initiated in Worklist screen will cause the Modality Worklist AE to open an association with the Worklist SCP, configured in the current Location.

3.2.2.2 ASSOCIATION INITIATION BY: WORKLIST QUERY

The Query Worklist command real-world activity initiated in Patient Setup screen will cause the Modality Worklist AE to open an association with the Worklist SCP, configured in the current Location.

3.2.2.3 ASSOCIATION INITIATION BY: AUTOMATIC WORKLIST QUERY

The Automatic Worklist Query real-world activity initiated by the system at periodic intervals will cause the Modality Worklist AE to open an association with the Worklist SCP, configured in the current Location.

3.2.2.4 ASSOCIATION INITIATION BY: GET STATUS

The Get Status real-world activity will cause the Modality Worklist AE to open an association to the Modality Worklist SCP configured in the current Location.

3.2.3 Proposed Presentation Contexts to a Worklist Server

Table 3-19 Modality Worklist AE Proposed Presentation Contexts to a Worklist Server

| Presentation Context Table | | | | | | | |
|---|------------------------|---------------------------|-------------------|-----|-------------|--|--|
| Abs | tract Syntax | Transfer Syntax | | | Extended | | |
| Name | UID | Name List | st UID List | | Negotiation | | |
| Verification SOP Class | 1.2.840.10008.1.1 | Implicit VR Little Endian | 1.2.840.10008.1.2 | SCU | None | | |
| Modality Worklist Information Model – FIND | 1.2.840.10008.5.1.4.31 | Implicit VR Little Endian | 1.2.840.10008.1.2 | SCU | None | | |

3.2.3.1 MODALITY WORKLIST INFORMATION MODEL - FIND SOP CLASS

The Modality Worklist AE provides standard conformance to the Modality Worklist Information Model – FIND SOP Class as an SCU.

3.2.3.2 VERIFICATION SOP CLASS

The Modality Worklist AE provides standard conformance to the Verification SOP Class as an SCU.

3.2.4 MODALITY WORKLIST ATTRIBUTES

3.2.4.1 Broad Worklist Query Matching Key Attributes

Table 3-20 specifies the Matching Key attributes used by Automatic Worklist C-FIND requests and manual Update Worklist C-FIND requests for Broad queries initiated by the user from the Worklist screen.

Table 3-20 Broad Worklist Query Matching Key Attributes

| Attribute Name | Tag | Type | Notes |
|--|-------------|------|---|
| Modality | (0008,0060) | R | Selectable from list provided by User Interface |
| Scheduled Station AE-Title | (0040,0001) | R | Configurable – Sent as either; 1) NanoMAXX's AE Title 2) Universal Matching. |
| Scheduled Procedure Step Start Date | (0040,0002) | R | Configurable – Sent as either; 1) Today's date 2) Yesterday, Today and Tomorrow date range 3) Universal Matching |

3.2.4.2 PATIENT BASED QUERY MATCHING KEY ATTRIBUTES

Table 3-21 specifies the Matching Key attributes used for Worklist C-FIND requests for Patient Based queries initiated by the user from the Patient Setup screen.

Table 3-21 Patient Based Query Matching Key Attributes

| Attribute Name | Tag | Type | Notes |
|----------------------------|-------------|------|---|
| Modality | (0008,0060) | R | Selectable from list provided by User Interface |
| Scheduled Station AE-Title | (0040,0001) | R | Configurable – Sent as either; 1) NanoMAXX's AE Title 2) Universal Matching. |

| D07914 | Rev: C | NanoMAXX DICOM Conformance Statement | Page: 32 of 45 | | |
|--------|--------|--------------------------------------|-----------------------|--|--|
| | | | | | |

| Attribute Name | Tag | Type | Notes | |
|--|---------------|------|---|--|
| Scheduled Procedure Step Start Date | (0040,0002) R | | Configurable – Sent as either; 1) Today's date 2) Yesterday, Today and Tomorrow date range 3) Universal Matching | |
| Patient's Name | (0010,0010) | | Entered on Patient Setup screen. A wild card is appended to Last, First and Middle name component. | |
| Patient ID (0010,0020) | | R | Entered on Patient Setup screen. Single value matching only. | |
| Accession Number (0008,0050) | | О | Entered on Patient Setup screen. | |
| Requested Procedure ID (0040,1001) | | О | Entered on Patient Setup screen. | |

3.2.4.3 RETURN KEY ATTRIBUTES

Table 3-22 specifies the Return Key attributes that are included in all Worklist C-FIND requests.

Table 3-22 Return Key Attributes

| Attribute Name | Tag | Type | Notes |
|---|-------------|------|---|
| Study Instance UID | (0020,000D) | 1 | |
| Accession Number ⁴ | (0008,0050) | 2 | Displayed on Patient Setup screen |
| Referring Physician's Name | (0008,0090) | 2 | Displayed on Patient Setup screen |
| Patient's Name ⁴ | (0010,0010) | 1 | Displayed on Patient Setup screen. All 5 name components are preserved but only Last, First and Middle name components are displayed. |
| Patient ID ⁴ | (0010,0020) | 1 | Displayed on Patient Setup screen |
| Patients Birth Date | (0010,0030) | 2 | Displayed on Patient Setup screen |
| Patient's Sex | (0010,0040) | 2 | Displayed on Patient Setup screen |
| Other Patient Ids | (0010,1000) | 3 | |
| Additional Patient History | (0010,21B0) | 3 | Displayed on Patient Setup screen as Indications |
| Admitting Diagnoses Description | (0008,1080) | 3 | Displayed on Patient Setup screen as Indications if Additional Patient History is not returned. |
| Last Menstrual Date | (0010,21D0) | 2 | Displayed on Patient Setup screen with OB/GYN exam type only. |
| Scheduled Procedure Step Sequence | (0040,0100) | 1 | |
| >Modality | (0008,0060) | 1 | |
| >Scheduled Station AE Title | (0040,0001) | 1 | |
| >Scheduled Procedure Step Start Date | (0040,0002) | 1 | |
| >Scheduled Procedure Step Start Time | (0040,0003) | 1 | |
| >Scheduled Procedure Step Description ⁴ | (0040,0007) | 1C | |
| >Scheduled Protocol Code Sequence | (0040,0008) | 1C | |
| >>Code Value | (0008,0100) | 1C | |
| >>Coding Scheme Designator | (0008,0102) | 1C | |
| >>Code Meaning | (0008,0104) | 3 | |
| >Scheduled Procedure Step ID | (0040,0009) | 1 | |
| Requested Procedure ID ⁴ | (0040,1001) | 1 | Displayed on Patient Setup screen. |

| D07914 | Rev: C | NanoMAXX DICOM Conformance Statement | Page: 33 of 45 |
|--------|--------|--------------------------------------|-----------------------|
| | | | |

| Attribute Name | Tag | Type | Notes |
|---|-------------|------|-------|
| Requested Procedure Description ⁴ | (0032,1060) | 1C | |
| Requested Procedure Code Sequence | (0032,1064) | 1C | |
| >Code Value | (0008,0100) | 1C | |
| >Coding Scheme Designator | (0008,0102) | 1C | |
| >Code Meaning ⁴ | (0008,0104) | 3 | |
| Referenced Study Sequence | (0008,1110) | 2 | |
| >Referenced SOP Class UID | (0008,1150) | 1C | |
| >Referenced SOP Instance UID | (0008,1155) | 1C | |

4 THIS ATTRIBUTE FROM WORKLIST MAY BE TRUNCATED WHEN DISPLAYED IN THE NANOMAXX USER INTERFACE. HOWEVER, THE VALUE CONTAINED IN THE ATTRIBUTE IS PRESERVED IN FULL FIDELITY.

4.1.1 WORKLIST AE BEHAVIOR TO C-FIND STATUS

Table 4-1 specifies the response status codes, which an SCP may return following the SCU's C-FIND request, along with the Worklist AE's associated behavior. Only those status responses that indicate some form of error condition are presented to the user. Related fields are not used.

Table 4-1 Worklist AE Behavior to C-FIND Status

| Service Status | Further Meaning | Status Codes | Worklist AE Behavior |
|-------------------|--|-----------------|--|
| Refused | Out of resources | A700 | The association is terminated. The user is notified of the failure. |
| Foiled | Identifier does not match SOP Class | A900 | The association is terminated. The user is notified of the failure. |
| Failed | Unable to process | Cxxx | The association is terminated. The user is notified of the failure. |
| Cancel | Matching terminated due to Cancel request | FE00 | The association is terminated. The user is notified that the query was incomplete. |
| Success | Matching is complete – No final Identifier is supplied. | 0000 | The Modality Worklist AE will continue operation without user notification. |
| Donding | Matches are continuing – Current Match is supplied and any Optional Keys were supported in the same manner as Required Keys. | FF00 | The Modality Worklist AE will continue operation without user notification. |
| Pending | Matches are continuing – Warning that one or more Optional Keys were not supported for existence for this Identifier. | FF01 | The Modality Worklist AE will continue operation without user notification. |

4.2 MEDIA EXPORT AE - SPECIFICATION

4.2.1 Introduction

This section of the conformance statement specifies the NanoMAXX compliance to DICOM Media Storage. It details the roles supported by this product.

NanoMAXX is able to export DICOM images to removable USB media stick memory. Any reference to USB in this document refers to "USB media stick memory".

4.2.2 IMPLEMENTATION MODEL

| D07914 | Rev: C | NanoMAXX DICOM Conformance Statement | Page: 35 of 45 | | | |
|--------|--------|--------------------------------------|-----------------------|--|--|--|
| | | | | | | |

The Media Export AE saves Ultrasound images to a USB storage device. It is associated with the local real-world activity "Export to USB". "Export to USB" is performed upon user request for selected patient series.

4.2.2.1 APPLICATION DATA FLOW



Figure 4-1 Media Export Data Flow

4.2.2.2 FUNCTIONAL DEFINITION OF THE AE

NanoMAXX can perform the following functions:

- Create a new DICOM file-set on the USB medium
- Add to an existing DICOM file-set previously created by the NanoMAXX system

4.2.2.3 SEQUENCING OF REAL-WORLD ACTIVITIES

Not applicable.

4.2.2.4 FILE META INFORMATION OPTIONS (SEE PS 3.10)

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

Implementation Class UID: "1.2.840.114340.3" Implementation Version Name: "Tiller_SV500"

Note: "114340" is registered by SonoSite with ANSI. Version name will be used initially as shown, but is subject to change with new versions of the DICOM capable application software.

4.2.3 AE SPECIFICATIONS

4.2.3.1 FILE META INFORMATION FOR THE APPLICATION ENTITY

The Source Application Entity Title included in the file header is configurable. The default value set in the File Meta Information for this AE is: "DICOM Media".

4.2.3.2 REAL-WORLD ACTIVITIES

4.2.3.2.1 REAL-WORLD ACTIVITY – "EXPORT TO USB"

"Export to USB" saves the selected DICOM SOP instances to the USB medium and creates a DICOM File Set. If a DICOM File Set created by the NanoMAXX exists on the medium, any new files selected for export will be added to the existing files. The Media Export AE acts as a File Set Creator when requested to export SOP instances from the internal storage to a USB medium. If there is insufficient space on the medium, the user will be prompted with an informative message.

Limitations: The user cannot review or manipulate DICOM files written to the USB medium on the system.

4.2.3.2.1.1 Media Storage Application Profile for the real-world activity "Export to USB" Not applicable [FUTURE]

4.2.3.2.1.1.1 Options

This Application Entity supports the SOP Classes and Transfer Syntaxes listed below in Table 4-2:

| Abstract S | yntax | Transfe | er Syntax |
|---------------------------------|-----------------------------|---------------------------|------------------------|
| Name | UID | UID Name List | |
| Media Storage Directory Storage | 1.2.840.10008.1.3.10 | Explicit VR Little Endian | 1.2.840.10008.1.2.1 |
| Ultrasound Image Storage | 1.2.840.10008.5.1.4.1.1.6.1 | Explicit VR Little Endian | 1.2.840.10008.1.2.1 |
| Olirasoulid Illiage Storage | 1.2.840.10008.3.1.4.1.1.0.1 | JPEG Baseline (Process 1) | 1.2.840.10008.1.2.4.50 |
| | | Evplicit VP Little Endian | 1 2 840 10008 1 2 1 |

Table 4-2 SOP Classes and Transfer Syntaxes for Media Export

1.2.840.10008.5.1.4.1.1.7

Sec. 3.2.4 Common Composite Image IOD Module describes image module usage by NanoMAXX.

JPEG Baseline (Process 1)

1.2.840.10008.1.2.4.50

4.2.4 AUGMENTED AND PRIVATE APPLICATION PROFILES

Not applicable.

Secondary Capture Image Storage

| D07914 | Rev: C | NanoMAXX DICOM Conformance Statement | Page: 37 of 45 | | | |
|--|--------|--------------------------------------|-----------------------|--|--|--|
| This document contains confidential information that is magnifecture to ConcCita. Neither the document new the information | | | | | | |

4.2.5 MEDIA CONFIGURATION

The Application Entity Titles configurable for Media Services are listed below:

Application Entity: "Media Export" Default AE Title: "DICOM Media"

4.2.6 MEDIA STORAGE SOP CLASS

The following diagram illustrates the relationship between directory entities in the Basic Directory module produced by NanoMAXX. It is based on the basic DICOM entity relationship model.

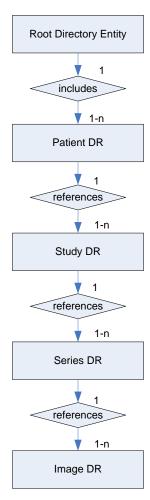


Figure 3-2 NanoMAXX Directory Entity Relationship Diagram

The Media Storage SOP Class uses the Basic Directory IOD Modules as shown in Table 4-3.

Table 4-3 Basic Directory IOD Modules

| Module | Reference | Usage |
|-------------------------|-----------|-------|
| File-set Identification | 3.1.4.1 | M |

| D07914 | Rev: C | NanoMAXX DICOM Conformance Statement | Page: 38 of 45 | | |
|---|--------|--------------------------------------|-----------------------|--|--|
| This document contains confidential information that is proprietary to SonoSite. Neither the document nor the information | | | | | |

This document contains confidential information that is proprietary to SonoSite. Neither the document nor the information contained therein should be disclosed or reproduced in whole or in part, without express written consent of SonoSite.

| Module | Reference | Usage |
|-----------------------|-----------|-------|
| Directory Information | 3.4.7.2 | U |

4.2.7 Information Module Definitions

4.2.7.1 FILE-SET IDENTIFICATION MODULE

Table 4-4 specifies the attributes used from the File-set Identification Module.

Table 4-4 File-Set Identification Module

| Attribute Name | Tag | Type | Attribute Description |
|---|-------------|------|-----------------------|
| File-set ID | (0004,1130) | 2 | "SONO_EXPORT" |
| File-set Descriptor ID | (0004,1141) | 3 | Not Used |
| Specific Character Set of Fileset Descriptor File | (0004,1142) | 1C | Not Used |

4.2.7.2 DIRECTORY INFORMATION MODULE

Table 4-5 specifies the attributes used from the Directory Information Module.

Table 4-5 Directory Information Module

| Attribute Name | Tag | Type | Attribute Description |
|---|-------------|------|---|
| Offset of the First Directory Record of the Root Directory Entity | (0004,1200) | 1 | See PS 3.3 |
| Offset of the Last Directory Record of the Root Directory Entity | (0004,1202) | 1 | See PS 3.3 |
| File-set Consistency Flag | (0004,1212) | 1 | See PS 3.3 |
| Directory Record Sequence | (0004,1220) | 2 | See PS 3.3 |
| >Offset of the Next Directory Record | (0004,1400) | 1C | See PS 3.3 |
| >Record In-use Flag | (0004,1410) | 1C | NanoMAXX sets all created records to 0xFFFF |
| >Offset of Referenced Lower- Level Directory Entity | (0004,1420) | 1C | See PS 3.3 |
| >Directory Record Type | (0004,1430) | 1C | NanoMAXX Supported Values: PATIENT, STUDY, SERIES, IMAGE |
| >Referenced File ID | (0004,1500) | 1C | See PS 3.3 |
| >Referenced SOP Class UID in File | (0004,1510) | 1C | See PS 3.3 |
| >Referenced SOP Instance UID in File | (0004,1511) | 1C | See PS 3.3 |
| >Referenced Transfer Syntax in UID in File | (0004,1512) | 1C | See PS 3.3 |

4.2.7.2.1 PATIENT KEYS

Table 4-6 specifies the additional keys used for directory records of type PATIENT.

| D07914 | Rev: C | NanoMAXX DICOM Conformance Statement | Page: 39 of 45 | | | |
|---|--------|--------------------------------------|-----------------------|--|--|--|
| This document contains confidential information that is proprietary to SonoSite. Neither the document nor the information | | | | | | |

Table 4-6 PATIENT KEYS

| Attribute Name | Tag | Type | Attribute Description |
|----------------|-------------|------|-----------------------|
| Patient's Name | (0010,0010) | 2 | Reference 3.2.4.1 |
| Patient ID | (0010,0020) | 1 | Reference 3.2.4.1 |

4.2.7.2.2 STUDY KEYS

Table 4-7 specifies the additional keys used for directory records of type STUDY.

Table 4-7 STUDY KEYS

| Attribute Name | Tag | Type | Attribute Description |
|--------------------|-------------|------|-----------------------|
| Study Date | (0008,0020) | 1 | Reference 3.2.4.2 |
| Study Time | (0008,0030) | 1 | Reference 3.2.4.2 |
| Study Description | (0008,1030) | 2 | Reference 3.2.4.2 |
| Study Instance UID | (0020,000D) | 1C | Reference 3.2.4.2 |
| Study ID | (0020,0010) | 1 | Reference 3.2.4.2 |
| Accession Number | (0008,0050) | 2 | Reference 3.2.4.2 |

4.2.7.2.3 **SERIES KEYS**

Table 4-8 specifies the additional keys used for directory records of type SERIES.

Table 4-8 SERIES KEYS

| Attribute Name | Tag | Type | Attribute Description |
|---------------------|-------------|------|-----------------------|
| Modality | (0008,0060) | 1 | Reference 3.2.4.4 |
| Series Instance UID | (0020,000E) | 1 | Reference 3.2.4.4 |
| Series Number | (0020,0011) | 1 | Reference 3.2.4.4 |

4.2.7.2.4 IMAGE KEYS

Table 4-9 specifies the additional keys used for directory records of type IMAGE.

Table 4-9 IMAGE KEYS

| Attribute Name | Tag | Type | Attribute Description |
|-----------------|-------------|------|-----------------------|
| Instance Number | (0020,0013) | 1 | Reference 3.2.4.7 |

5 COMMUNICATION PROFILES

5.1 TCP/IP STACK

The TCP/IP protocol is used.

6 EXTENSIONS/SPECIALIZATIONS/PRIVATIZATIONS

6.1 STANDARD EXTENDED/SPECIALIZED/PRIVATE SOPS

SonoSite uses the tag range of (0019,XXXX) for private tags in US Image Storage objects. These tags include additional report and image metadata intended for use by SonoSite applications, and are included only when the "Include private tags" option is selected on the system.

Table 6-1 Private Tags

| Tag | VR | Attribute Description |
|-------------|----|--|
| (0019,0010) | LO | Private Data |
| (0019,1010) | UT | Private Data (only present in first image in series) |
| (0019,1020) | UT | Private Data (only present in first image in series) |
| (0019,1030) | UT | Private Data (only present in first image in series) |
| (0019,1040) | UT | Private Data (only present in first image in series) |
| (0019,1050) | UT | Private Data |
| (0019,1060) | UT | Private Data |

6.2 PRIVATE TRANSFER SYNTAXES

None

7 CONFIGURATION

7.1 AE TITLE/PRESENTATION ADDRESS MAPPING

The NanoMAXX AE Title and networking parameters are configurable in DICOM Setup Mode. Port number 104 is the default used for DICOM communication..

7.2 CONFIGURABLE PARAMETERS

7.2.1 NANOMAXX CONFIGURABLE PARAMETERS PER NETWORK LOCATION

The NanoMAXX system can be configured to operate in multiple network locations. The NanoMAXX local device settings and remote device settings (e.g. Archivers/Worklist) can be configured for each location. These parameters are intended to be configured by a network/DICOM administrator.

Configurable NanoMAXX Networking and DICOM parameters:

- DHCP (default = disabled)
- Hostname (Name field)
- DICOM AE Title
- IP Address (disabled if DHCP is selected)
- Subnet Mask (disabled if DHCP is selected)
- Default Gateway (disabled if DHCP is selected)
- Network Write Timeout
- Network Read Timeout
- Network speed (Auto, 100Mb/10Mb, Full/Half duplex)
- Transfer Images (End of exam, During the exam)
- Port (default = 104)
- Wireless properties (see NanoMAXX User Guide for detailed configuration information)

7.2.2 CONFIGURABLE PARAMETERS PER REMOTE DEVICE INSTANCE

Every archiver and Modality Worklist device that NanoMAXX is setup to communicate with has a set of parameters that are configurable in Setup mode. These parameters are intended to be configured by a network/DICOM administrator.

Configurable parameters for each device instance:

- DICOM AE Title
- Hostname (Name field)
- IP Address
- Port Number

Configurable parameters for each Archiver device instance:

SOP Class Ultrasound / Ultrasound Retired / Secondary Capture

• Photometric Interpretation Monochrome2 / RGB / YBR_FULL_422 (used for JPEG Baseline)

Transfer Syntax ELE/ILE or JPEG Baseline

• Send Images Only Selection

• Max Retries

- Retry Interval
- Inclusion of private tags

Configurable parameters for the Worklist SCP device instance:

| D07914 Rev: C NanoMAXX DICOM Conformance Statement Page: 43 of | D07914 |
|--|--------|
|--|--------|

Automatic Query Enable On/Off

• Automatic Query Interval Selection = 30 minutes, 1, 2, 4, 8, 12, 24 hours

Automatic Query Start Time Selection = 0:00 to 23:00 hours
 Modality Selectable from list in user interface

 Scheduled Station AE Title This NanoMAXX system only or universal matching (used for Broad & Patient Based Queries)

• SPS Date Today; "Yesterday, Today & Tomorrow"; or universal matching (Used for Broad & Patient Based Queries)

7.2.3 OTHER CONFIGURABLE PARAMETERS

These settings apply independent of network configuration:

• Photometric Interpretation (removable media) Monochrome2 / RGB / YBR_FULL_422

8 SUPPORT OF EXTENDED CHARACTER SETS

The NanoMAXX system supports the ISO 8859 Latin 1 (ISO-IR 100) character set family.

The Specific Character Set key attribute (0008,0005), a type 1C attribute, may be returned by an SCP if that device supports any character set encodings beyond the ISO_IR 6. If the tag is not present in the Worklist query result, the default (i.e. ISO_IR 6, i.e. ASCII) is assumed. If the tag is present, only ISO_IR 6 (ASCII) or ISO_IR 100 (Latin Alphabet # 1) are supported by the NanoMAXX system. All other character set encodings are unsupported and will cause the system to issue a C-Find Cancel. All query results data acquired up to the first detection of an unsupported character set encoding are retained and presented to the user.