SonoSite, Inc.   Bothell, Washington

Document Number: **D09360**
Revision: **A**
Title: **SonoSite® Workflow Solutions (SWS)**
                              DICOM Conformance Statement

CHANGE HISTORY:

Revision	Description of Change
A	Initial release. Version 1.1

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Conformance Statement Overview

The SWS application implements the necessary DICOM services to receive and store images transmitted from ultrasound systems.

Table 1-1 provides an overview of the network services supported by SWS.

Table 1-1 NETWORKING SERVICES

NETWORKING SOP CLASSES	USER OF SERVICE (SCU)	PROVIDER OF SERVICE (SCP)
TRANSFER		
Ultrasound Image Storage	No	Yes
Ultrasound Multi-Frame Image Storage	No	Yes
GENERAL		
Verification	No	Yes

Table 1.1-2 provides an overview of the media storage services supported by SWS.

Table 1.1-2   MEDIA STORAGE SERVICES

SOP CLASSES	ROLE
Media Storage Directory Storage	FSC/FSR
Ultrasound Image Storage	FSC/FSR
Ultrasound Multi-Frame Image Storage	FSC/FSR

1   INTRODUCTION

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

SWS is an ultrasound image storage system. The DICOM options of SWS provide a means to receive, store, and archive ultrasound images.

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 SWS application via its DICOM features.

1.2   DEFINITIONS

AE	Application Entity
ANSI	American National Standards Institute
DICOM	Digital Imaging and Communications in Medicine
FSC	File Set Creator
FSR	File Set Reader
IOD	Information Object Definition
PDU	Protocol Data Unit
PPS	Performed Procedure Step
SCU	Service Class User (Client)
SCP	Service Class Provider (Server)
SOP	Service – Object Pair
TCP/IP	Transmission Control Protocol/Internet Protocol
UID	Unique Identifier
US	Ultrasound
VR	Value Representation

1.3 REFERENCE DOCUMENTS

ACR-NEMA DICOM Standard Version 3.0 – 2007

2   IMPLEMENTATION MODEL

The SWS DICOM features incorporate the DICOM 3.0 standard for networked image storage functions. Performed Procedures[1] are transferred from an ultrasound system using standard network connections to be stored on SWS.

Images may be stored into SWS either via network transfer, or import of a DICOMDIR repository. Once studies have been transferred to SWS they may be reviewed, have reports created for them, and be archived via DICOMDIR.

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[1] Performed Procedures consist of images from the ultrasound system.

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2.1 APPLICATION DATA FLOW DIAGRAM

The diagram in Figure 2-1 represents the relationship between SWS's real-world activities and the remote AE's built into the ultrasound systems that SWS communicates with using DICOM.
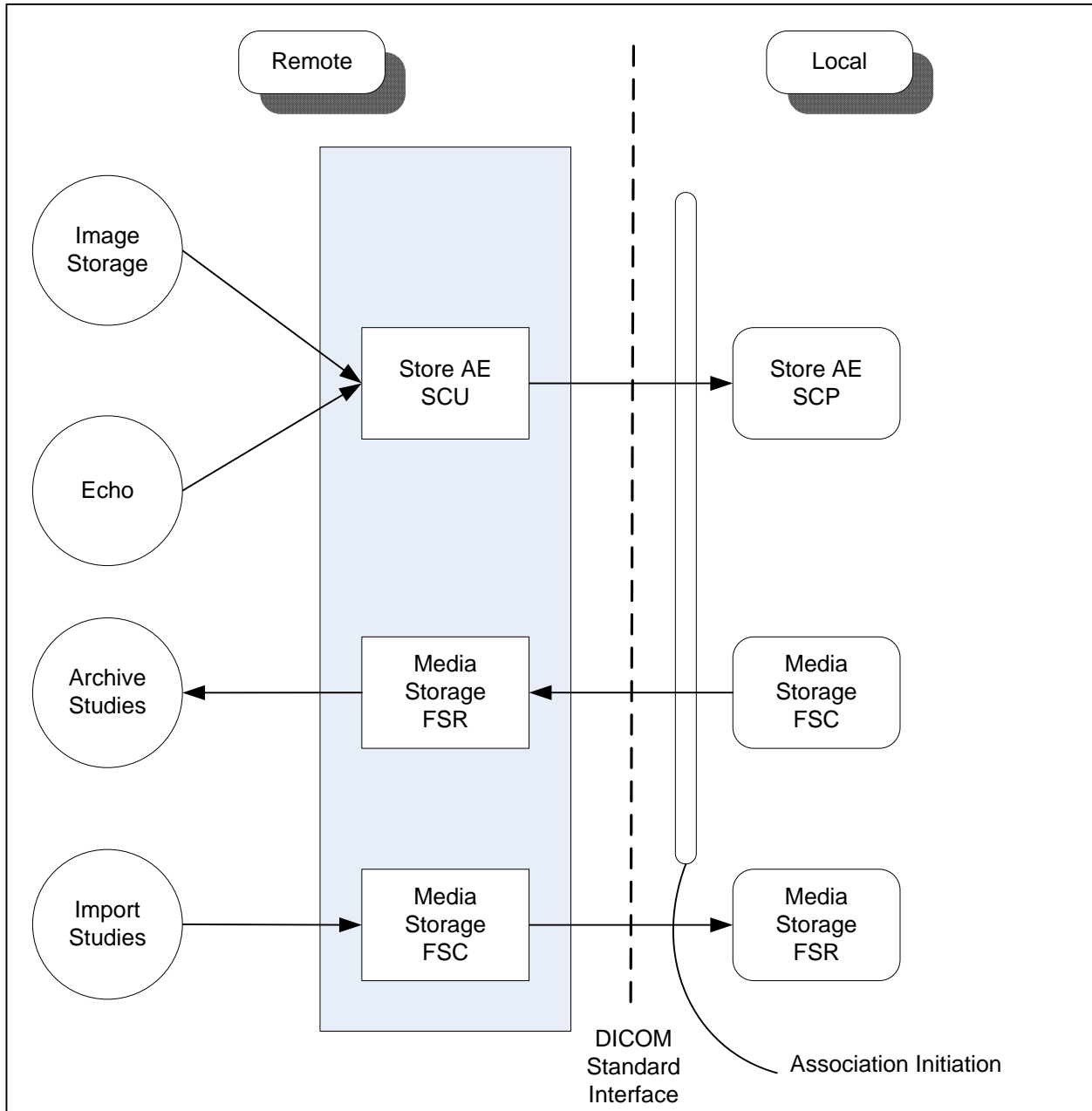
Figure 2-1   Implementation Model

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

Image Storage
- Ultrasound system transfers images via C-Store.

Echo
- Ultrasound system initiates C-Echo.

Archive Studies
- SWS Administrator selects one or more studies to be archived via DICOMDIR

Import Studies
- SWS user selects one or more completed studies residing in a DICOMDIR repository to be imported into SWS.

2.2 FUNCTIONAL DEFINITIONS OF AE'S

Store
This AE handles receiving ultrasound images from an ultrasound system using the DICOM store SCP services.
Steps taken for Echo operation:
        A-ASSOCIATE
        C-ECHO command
        A-RELEASE

Steps taken for image storage operation:
        A-ASSOCIATE
        for each exam image
        {
                C-STORE Image SOP Instance
        }
        A-RELEASE

2.3 SEQUENCING OF REAL-WORLD ACTIVITIES

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

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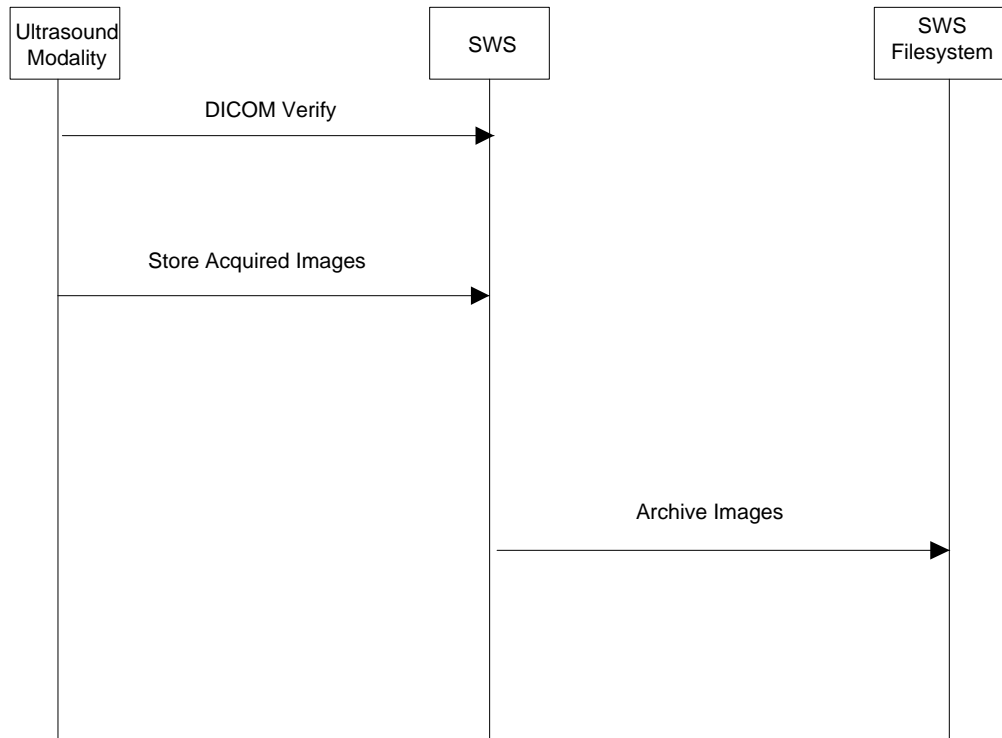
Figure 2-2   SWS Sequencing of Real World Activities

Under normal conditions the sequencing constraints illustrated apply:
1. DICOM Verify conducted to ensure proper system setup.
2. Images transferred from Ultrasound System
3. Image Archive creates DICOMDIR on SWS filesystem

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3   AE SPECIFICATIONS

3.1 STORE AE – SPECIFICATION

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

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 Multi-Frame Image Storage	1.2.840.10008.5.1.4.1.1.3.1	Standard

3.1.1 ASSOCIATION ESTABLISHMENT POLICIES

The Store AE will accept an association from a device in response to the following real-world activities:
Image Storage or Verify.

3.1.1.1 GENERAL

Maximum PDU size the Store AE can receive: 16,352 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.

Maximum PDU size the Store AE can send: 65,535 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: 5

3.1.1.3 ASYNCHRONOUS NATURE

The Store AE does not use asynchronous operations.

3.1.1.4 IMPLEMENTATION IDENTIFYING INFORMATION

Implementation Class UID: "1.2.840.114340.100"
Implementation Version name: "saa-dcm4che-2.0.20"

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 POLICY

The Store AE does not initiate Associations.

3.1.3 ASSOCIATION ACCEPTANCE POLICY

The Store AE will accept Associations from remote ultrasound systems based on the real world activities
particular to that system.

3.1.3.1 EXTERNAL AE REQUESTS ULTRASOUND IMAGE STORAGE

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The Image Storage real-world activity initiated by an ultrasound system will cause the Store AE to accept associations and respond accordingly.

3.1.3.2 EXTERNAL AE REQUESTS VERIFICATION

The Echo command real-world activity initiated by an ultrasound system will cause the Store AE to accept associations and respond accordingly.

3.1.4 ACCEPTED PRESENTATION CONTEXTS

Table 3-2 Store AE Accepted Presentation Contexts

Presentation Context Table					
Abstract Syntax		**Transfer Syntax**		**Role**	**Extended Negotiation**
Name	**UID**	**Name List**	**UID List**		
Verification	1.2.840.10008.1.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	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)	1.2.840.10008.1.2 1.2.840.10008.1.2.1 1.2.840.10008.1.2.4.50	SCP	None
Ultrasound Multi-Frame Image Storage	1.2.840.10008.5.1.4.1.1.3.1	Implicit VR Little Endian Explicit VR Little Endian JPEG Baseline (Process 1)	1.2.840.10008.1.2 1.2.840.10008.1.2.1 1.2.840.10008.1.2.4.50	SCP	None

3.1.4.1 VERIFICATION SOP CLASS

The Store AE provides standard conformance to the Verification SOP Class as an SCP.

3.1.4.2 ULTRASOUND IMAGE STORAGE SOP CLASS

The Store AE provides standard conformance to the Ultrasound Image Storage SOP Class as an SCP.

3.1.4.3 ULTRASOUND MULTI-FRAME IMAGE STORAGE SOP CLASS

The Store AE provides standard conformance to the Ultrasound Multi-Frame Image Storage SOP Class as an SCP.

3.1.5 STORE AE BEHAVIOR TO C-STORE STATUS

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

Service Status	Further Meaning	Status Codes	Store AE Behavior
Success		0000	The Composite SOP Instance was successfully received and stored in the system repository.
Error	Processing Failure	0110	This status is returned due to internal errors such as a processing failure response from the internal database or a filesystem operation. The appropriate Status will be sent in the C-STORE Response. Error indication message is output to the Service Log.
Warning	Coercion of data elements	B000	This status is returned if one or more Attribute values were coerced/ modified on reception. Image transmission is considered successful. The appropriate SUCCESS Status will be sent in the C-STORE Response. Warning indication message is output to the Service Log.
	Data set does not match SOP class	B007	This status is returned if the C-STORE Request specifies Attributes that are not specific as part of the Storage SOP class. Image transmission is considered successful. The appropriate SUCCESS Status will be sent in the C-STORE Response. Warning indication message is output to the Service Log.

3.2 MEDIA EXPORT AE – SPECIFICATION

3.2.1 INTRODUCTION

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

SWS is able to export DICOM images to a specified file location.

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3.2.2 IMPLEMENTATION MODEL

The Media Export AE saves Ultrasound images to a specified file location. It is associated with the local real-world activity "Archive Studies". "Archive Studies" is performed upon administrator request for selected patient studies.

3.2.2.1 APPLICATION DATA FLOW

Figure 3-1   Media Export Data Flow

3.2.2.2 FUNCTIONAL DEFINITION OF THE AE

SWS can perform the following functions:
- Create a new DICOM file-set
- Import from an existing DICOM file-set

3.2.2.3 SEQUENCING OF REAL-WORLD ACTIVIITIES

Not applicable.

3.2.2.4 FILE META INFORMATION OPTIONS (SEE PS 3.10)

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

Implementation Class UID: "1.2.840.114340.100"
Implementation Version name: "saa-dcm4che-2.0.20"

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.

3.2.3 AE SPECIFICATIONS

3.2.3.1 REAL-WORLD ACTIVITIES

3.2.3.1.1 REAL-WORLD ACTIVITY – "ARCHIVE STUDIES"

"Archive Studies" saves the selected studies to the selected file path and creates a DICOM File Set. A new, datestamped folder will be created by SWS each time an archive operation is initiated, so there will never be any overwriting or updating of a preexisting dataset. The Media Export AE acts as a File Set Creator when requested to export SOP instances from internal storage.

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

3.2.3.1.1.1 Media Storage Application Profile for the real-world activity "Archive Studies"

Not applicable [FUTURE]

3.2.3.1.1.1.1 Options

This Application Entity supports the SOP Classes and Transfer Syntaxes listed below in Table 3-4:

Table 3-4 SOP Classes and Transfer Syntaxes for Media Export

Abstract Syntax		Transfer Syntax	
Name	UID	Name List	UID 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 JPEG Baseline (Process 1)	1.2.840.10008.1.2.1 1.2.840.10008.1.2.4.50
Ultrasound Multi-Frame Image Storage	1.2.840.10008.5.1.4.1.1.3.1	Explicit VR Little Endian JPEG Baseline (Process 1)	1.2.840.10008.1.2.1 1.2.840.10008.1.2.4.50

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

3.2.4 AUGMENTED AND PRIVATE APPLICATION PROFILES

Not applicable.

3.2.5 MEDIA CONFIGURATION

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

Application Entity: "Media Export"

3.2.6 MEDIA STORAGE SOP CLASS

The following diagram illustrates the relationship between directory entities in the Basic Directory module produced by SWS. It is based on the basic DICOM entity relationship model.
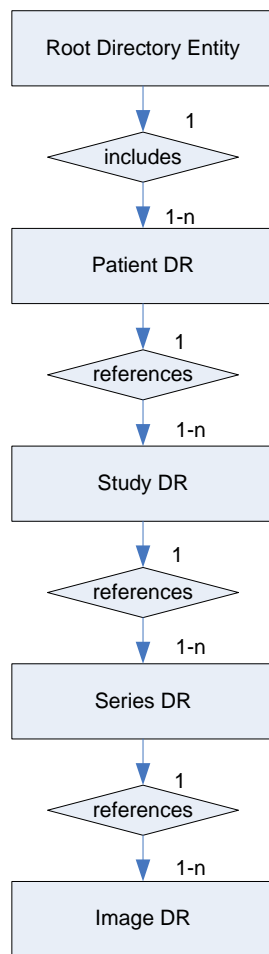
Figure 3-2   SWS Directory Entity Relationship Diagram

The Media Storage SOP Class uses the Basic Directory IOD Modules as shown in Table 3-5.

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Table 3-5 Basic Directory IOD Modules

Module	Reference	Usage
File-set Identification	**Error! Reference source not found.**	M
Directory Information	3.2.7.2	U

3.2.7 INFORMATION MODULE DEFINITIONS

3.2.7.1 FILE-SET IDENTIFICATION MODULE

Table 3-6 specifies the attributes used from the File-set Identification Module.

Table 3-6 File-Set Identification Module

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

3.2.7.2 DIRECTORY INFORMATION MODULE

Table 3-7 specifies the attributes used from the Directory Information Module.

Table 3-7 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	See PS 3.3
>Offset of Referenced Lower-Level Directory Entity	(0004,1420)	1C	See PS 3.3
>Directory Record Type	(0004,1430)	1C	SWS 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

3.2.7.2.1 PATIENT KEYS

Table 3-8 specifies the additional keys used for directory records of type PATIENT.

Table 3-8 PATIENT KEYS

Attribute Name	Tag	Type	Attribute Description
Patient's Name	(0010,0010)	2	See PS 3.3
Patient ID	(0010,0020)	1	See PS 3.3
Patient's Birth Date	(0010,0030)	3	See PS 3.3
Patient's Sex	(0010,0040)	3	See PS 3.3

3.2.7.2.2 STUDY KEYS

Table 3-9 specifies the additional keys used for directory records of type STUDY.

Table 3-9 STUDY KEYS

Attribute Name	Tag	Type	Attribute Description
Study Date	(0008,0020)	1	See PS 3.3
Study Time	(0008,0030)	1	See PS 3.3
Study Description	(0008,1030)	2	See PS 3.3
Study Instance UID	(0020,000D)	1C	See PS 3.3
Study ID	(0020,0010)	1	See PS 3.3
Accession Number	(0008,0050)	2	See PS 3.3

3.2.7.2.3 SERIES KEYS

Table 3-10 specifies the additional keys used for directory records of type SERIES.

Table 3-10 SERIES KEYS

Attribute Name	Tag	Type	Attribute Description
Modality	(0008,0060)	1	See PS 3.3
Institution Name	(0008,0080)	3	See PS 3.3
Series Instance UID	(0020,000E)	1	See PS 3.3
Series Number	(0020,0011)	1	See PS 3.3

3.2.7.2.4 IMAGE KEYS

Table 3-11 specifies the additional keys used for directory records of type IMAGE.

Table 3-11 IMAGE KEYS

Attribute Name	Tag	Type	Attribute Description
Image Type	(0008,0008)	3	See PS 3.3
Instance Number	(0020,0013)	1	See PS 3.3
Rows	(0028,0010)	3	See PS 3.3
Columns	(0028,0011)	3	See PS 3.3

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Attribute Name	Tag	Type	Attribute Description
Lossy Image Compression Ratio	(0028,2112)	3	See PS 3.3

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4   COMMUNICATION PROFILES

4.1   TCP/IP STACK

The TCP/IP protocol is used.

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5 EXTENSIONS/SPECIALIZATIONS/PRIVATIZATIONS

5.1 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.

Table 5-1 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

5.2 PRIVATE TRANSFER SYNTAXES

None

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6   CONFIGURATION

6.1   AE TITLE

The SWS AE Title and networking parameters are configurable in the network setting page. Port number 11112 is the default used for DICOM communication.

6.2   CONFIGURABLE PARAMETERS

6.2.1   SWS CONFIGURABLE PARAMETERS

These parameters are intended to be configured by a network/DICOM administrator.

- DICOM AE Title (default = SWS)
- Port (default = 11112)

6.2.2   OTHER CONFIGURABLE PARAMETERS

These settings apply independent of network configuration:

- Archive directory (location on the server where DICOMDIR will be created)

7 SUPPORT OF EXTENDED CHARACTER SETS

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

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