

Parks Medical Electronics, Inc.

Sonova Software DICOM Conformance Statement

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1. Introduction

This document describes the conformance to the DICOM 3.0 standard for the Flo-Lab vascular data acquisition and reporting systems from Parks Medical Electronics, Inc.

It shall establish the conformance specifications for the Flo-Lab system only, and does not apply to other products offered by Parks Medical Electronics, Inc.

1.1. DICOM and Sonova Software

The DICOM standard provides a well-defined set of structures and protocols that allow inter-operability of a wide variety of medical imaging devices.

Sonova Software provides support for connectivity to DICOM service class providers (SCP's). Sonova Software will not support all features supported by the DICOM standard. This document clearly states the DICOM services and SOP classes that are supported by the Sonova Software application included with the Flo-Lab.

This document is written with respect to the adopted portions of the DICOM standard, Revision 3. The following sections of this document follow the outline specified in the DICOM Standard NEMA publication PS3.2.

Sonova Software supports the Ultrasound Image Storage SOP as a Service Class User (SCU) and Modality Work List info Model Find SOP as a Service Class User (SCU).

1.2. Definitions, terms, and abbreviations

AE - **A**pplication **E**ntity - The program(Sonova) which implements DICOM.

DICOM - The **D**igital **I**maging and **C**ommunications in **M**edicine standard.

DICOM files on the media.

DIMSE - **D**ICOM **M**essage **S**ervice **E**lement

Media - the storage media – hard disk

NEMA - **N**ational **E**quipment **M**anufacturer's **A**ssociation

PDU - **P**rotocol **D**ata **U**nit

RWA - **R**eal **W**orld **A**ctivity

SCP - **S**ervice **C**lass **P**rovider

SCU - **S**ervice **C**lass **U**ser

SOP - **S**ervice **O**bject **P**air

TCP/IP - **T**ransmission **C**ontrol **P**rotocol/**I**nternet **P**rotocol

UID - **U**nique **I**dentifier

MWL - **M**odality **W**ork **L**ist

2. Implementation Model

The Implementation Model identifies the Sonova DICOM Application Entity (AE) and its relation to the Real World Activities (RWA's).

This statement covers the storage of DICOM images to networked DICOM Storage SCP devices, and local or network accessible hard disks, as specified by DICOM 3.0 specification, parts 3, 4, 5, 6, 10, 11, and 12.

2.1. Application Data Flow Diagram

The diagram in figure 1 represents the relationship between the Sonova Application Entity (rectangle) and a remote DICOM storage SCP AE (circle right).

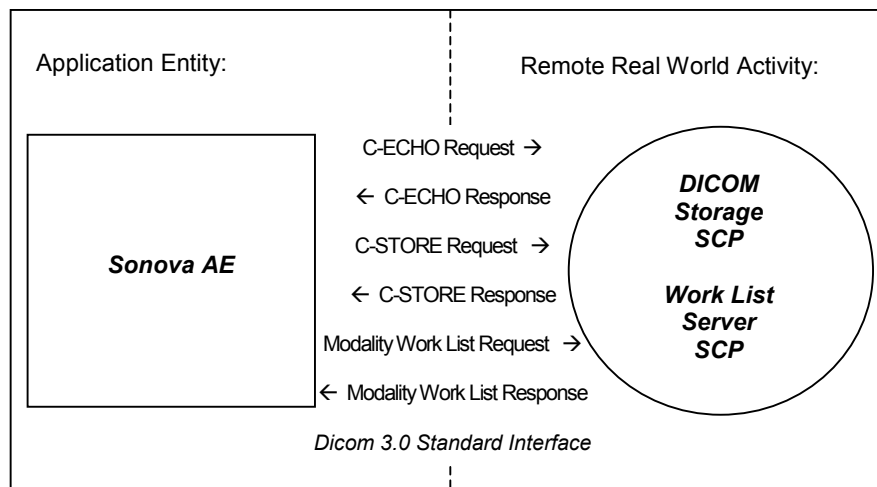


Figure 1 - Implementation Model

2.2 Functional Definition of Sonova Application Entity

- Create DICOM Part 10 file (US-MF IOD) images from native report format.
- Verify remote SCP Server and its status.
- Send DICOM image files to remote DICOM SCP.
- Basic Modality Work List Service Class

2.2.1. Verification of Remote Real-World Activities

Sonova AE performs the Verification Service Class as SCU to determine the ability of an application on a remote node to receive DICOM messages (C-ECHO DIMSE).

The Sonova AE initiates an association to the Store SCP Server and verifies its on-line status when the user selects "DICOM" and "Send (F12)".

2.2.2. Remote Real-World Activities

Sonova AE performs all of the functions to transmit images and associated data to DICOM SCP's (network servers and/or workstations). The Sonova AE supports the Ultrasound Image Storage SOP class as an SCU and Modality Work List Info Model find SOP as an SCU.

2.2.3. Sequencing of Remote Real World Activities:

In order for remote processes to be able to provide the Real World Activity SCP services, the appropriate association must first be successfully opened. Sonova AE initiates an association to the Store SCP Server when the user selects "DICOM" and "Send (F12)". If an association cannot be opened then the "Send (F12)" process will be aborted.

Once an association has been made (post "Send (F12)" initiation), Sonova AE will create a DICOM part 10 cine image file from the native report format and transfer the DICOM file to the remote DICOM SCP (C-STORE). Once the transfer completes the (Sonova AE –remote SCU AE) association will be closed.

Pressing Alt-M will query the Work List Server and then receive a list of matching patients and studies. A patient can be selected from the list and the type of study, patient demographics and accession number will be placed in the patient's record. The operator may configure the query to receive only the patients desired.

3. Application Entity Specifications

The Sonova AE provide Standard **Conformance** to the following **DICOM V3.0** SOP Classes as an SCU:

Information Object Definition	SOP Class UID	Transfer Syntax	Transfer Syntax UID
Ultrasound Image Storage	1.2.840.1008.5.1.4.1.1.6.1	Implicit VR Little Endian Uncompressed	1.2.840.1008.1.2
		Explicit VR Little Endian Uncompressed	1.2.840.1008.1.2.1
		JPEG Lossy (baseline)	1.2.840.1008.1.2.4.50
		JPEG Lossless	1.2.840.1008.1.2.4.57
Modality Work List Info Model Find	1.2.740.1008.5.1.4.31		

Table 3.0-1: Supported SOP Classes

3.1. Association Establishment Policies

The Sonova AE uses TCP/IP. The Maximum Length PDU negotiation is included in all association establishment requests. The maximum length PDU offered for an association initiated by Sonova AE is: 64k

3.1.1. Number of Associations

The maximum number of simultaneous associations for the Sonova AE is one. A separate association will be negotiated for each image transferred.

3.1.2. Asynchronous Nature

Asynchronous operations are not supported.

3.1.3. Implementation Identifying Information

Implementation Class UID: "1.2.826.0.1.3680043.2.827"

Implementation Version Name: "SONOVA V3"

3.2. Association Acceptance Policy

The Sonova AE does not accept associations.

3.2.1. Application Entity Title

The default AE Title used is "SONOVA" but this can be modified in the DICOM Configuration Dialog.

3.3. Required and optionally applied Attributes

The following table denotes the attributes included in the Ultrasound Image Object as implemented in the Sonova AE. Attributes not listed are not used.

Tag	Attribute	Notes
0008,0008	Image Type	Set to "ORIGINAL\PRIMARY".
0008,0012	Instance Creation Date	Set to date file was created
0008,0013	Instance Creation Time	Set to time file was created
0008,0014	Instance Creator UID	Unique Id (Sonova assigned UIDRoot or user assigned UIDRoot)
0008,0016	SOP Class UID	Set to US Image 1.2.840.10008.5.1.4.1.1.6.1
0008,0018	SOP Instance UID	System assigned
0008,0020	Study Date	Set to the date that the study started
0008,0023	Image Date	Set to the date the image file was created
0008,0030	Study Time	Set to the time that the study started

0008,0033	Image Time	Set to the time the image was created
0008,0050	Accession Number	User assigned
0008,0060	Modality	Set to 'US'
0008,0070	Manufacturer	Set to "Parks Medical Electronics, Inc."
0008,0080	Institution Name	Default is zero length
0008,0081	Institution Address	Default is zero length
0008,0090	Referring Physician's Name	Default is zero length
0008,1010	Station Name	Not used at this time - zero length
0008,1030	Study Description	Set to Sonova study type + study date + study time
0008,1040	Institutional Department Name	Not used at this time - zero length
0008,1060	Name of Physician(s) Reading Study	Default is zero length
0008,1070	Operators Name	Default is zero length
0008,1090	Manufacturer's Model Name	Set to Simulation or Flo-Lab 2100SX depending on device used to generate image.
0010,0010	Patient's Name	This field must be filled in by the user and is required
0010,0020	Patient ID	Set to unique system assigned Pat_Id
0010,0021	Issuer of Patient ID	Issuing authority institution name
0010,0030	Patient's Birth Date	Default is zero length
0010,0040	Patient's Sex	Default is zero length
0010,1010	Patient's Age	Default is zero length
0018,1000	Device Serial Number	Default is zero length
0018,1020	Software Version	Set to the Sonova AE version number
0020,000D	Study Instance UID	System assigned
0020,000E	Series Instance UID	System assigned
0020,0010	Study ID	Set to unique system assigned Study_Id
0020,0011	Series Number	System Assigned
0020,0013	Image Number	Image number for study series
0028,0004	Photometric Interpretation	Set to RGB
0032,4000	Study Comments	default is zero length

3.4. Modality Work List SOP Class Filtering, Requesting and Return Elements

Filtering Query Attributes

Tag	Attribute	Notes
0010,0020	Patient ID	
0010,0010	Patient Name	
0010,0050	Accession Number	
0008,0060	Modality	
0032,1060	Requested Procedure Description	

0040,0002	Scheduled Procedure Step Start Date	
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Returned Attributes

Tag	Attribute	Notes
0010,0020	Patient ID	
0010,0010	Patient Name	
0010,0030	Patient Birthdate	
0010,0040	Gender	
0008,0050	Accession Number	
0040,0002	Scheduled Procedure Start Date	
0040,0003	Scheduled Procedure Start Time	
0008,0060	Modality	
0020,000D	Study Instance UID	
0040,0001	Scheduled Station AE Title	
0032,1060	Requested Procedure Description	

4. Communication Profiles

4.1. Supported Configuration Stacks (parts 8, 9)

The Sonova AE provides DICOM V3.0 TCP/IP Network Communication Support as defined in PS 3.8.

4.2. TCP/IP Stack

The Sonova AE inherits the TCP/IP stack from the Windows operating system upon which it executes. Port number 104 is used as a default for DICOM communication but can be configured to use any port.

4.2.1. Physical Media Support

The Sonova SCU is indifferent to the physical medium over which TCP/IP executes; it inherits this from the Windows operating system upon which it executes.

5. Configuration

5.1. Ultrasound Image Storage Configuration

Sonova AE can be configured to send DICOM images to a DICOM SCP store or send images for storage to a local or network available hard disk. The user can configure the storage type by selecting “Utilities” and “System Setup” and “DICOM Configuration”. The default storage type is “Local/Network Drive”.

5.1.1. SCP Server File Storage Type

When the user selects file storage “SCP Server” they need to provide additional configuration settings for Sonova AE to communicate with a remote DICOM SCP (refer to figure 1).

5.1.1.1. SCP Server AE Title / Presentation Address Mapping

The Sonova DICOM Configuration is used for mapping of an Application Entity Title to a Presentation Address. A Presentation Address consists of a host name or IP address and port number. The information obtained in the Sonova DICOM Configuration Dialog is used to establish associations to remote Application Entities.

5.1.1.1.1. DICOM SCP Configuration - Use

These radio buttons determine whether DHCP (Dynamic Host Configuration Protocol) is used to configure the network IP address, or a user specified IP address is used.

5.1.1.1.2. DNS Name

The DNS Name field is used to configure the remote computer name for the system that Sonova AE will be sending DICOM images to.

5.1.1.1.3 IP Address

The IP Address field is used to configure the network IP address for the system that Sonova AE will be sending DICOM images to.

5.1.1.1.4 Port

This field is used to configure the port number that the remote DICOM Store SCP application will be listening to for messages from Sonova AE. The factory default is **104**.

5.1.1.1.5. SCP AE Title

The SCP AE Title field is used to configure the Application Entity title for the remote DICOM Store SCP application that Sonova AE will be sending images to.

5.1.1.1.6. Sonova AE Title

The Sonova AE Title field is used to configure the Application Entity title used by Sonova when requesting services from an SCP.

5.1.2. Local/Network Drive File Storage Type

When the user selects file storage "Local/Network" they need to provide drive and file path for Sonova AE (refer to figure 1).

5.1.2.1. Local/Network File Path

The user can select the drive and file path using the "Change Path" button.

5.1.2.2. Change Path Dialog

The user can use this dialog to provide an available drive and path to where the images will be stored.

5.1.3. Root UID Prefix

The UIDRoot prefix field is used to change the unique ID Root prefix that is used to create file names for images. If this edit is blank the Sonova AE will use the system assigned unique UIDRoot.

5.2. Modality Work List Configuration

5.2.1. IP Address

The IP address is used to configure the network IP address for the system that Modality Work List will be requesting information from.

5.2.2. Port

The port is used to configure the port number that the Modality Work List Server will be listening to.

5.2.3. SCP AE Title (Called AE)

The SCP AE title is the title of the Modality Work List Server that Work List will request patient information from.

5.2.4. Modality Work List AE Title (Calling AE)

The Modality Work List AE title is the title used by Modality Work List when requesting information from the Work List Server.

Note: If the called AE title is "DEMO", Modality Work List will not attempt to query the Work List Server but will instead display a list of local patients for demonstration purposes.

6. Support of Extended Character Sets

The ISO IR 100 specific Character Set is supported.

7. Codes and Controlled Terminologies

The Sonova SCU AE does not support any additional Codes or Controlled Terminologies.