

suiteHEART® Software

DICOM Conformance Statement

NeoSoft, LLC



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Manufacturer

NeoSoft, LLC
N27 W23910A Paul Road
Pewaukee, WI 53072 USA

Phone: 262-522-6120
website: www.neosoftllc.com

Sales: orders@neosoftmedical.com
Service: service@neosoftmedical.com

Table of Contents

1. OVERVIEW.....	1
2. INTRODUCTION	1
2.1 Abbreviations.....	1
2.2 Audience.....	2
2.3 Remarks.....	2
2.4 Terms and Definitions	2
2.5 Basics of DICOM Communication	4
2.6 Supported Character Sets	4
2.7 References	5
3. NETWORKING & MEDIA STORAGE.....	5
3.1 Networking.....	5
3.2 Media Storage.....	5
3.2.1 Implementation Model	5
3.2.2 Application Data Flow Diagram	5
3.2.3 Functional Definition of AEs.....	6
3.2.4 File Meta Information for Implementation Class and Version	6
3.3 AE Specifications	6
3.3.1 Real-World Activities	6
3.3.2 Media Storage Application Profiles.....	6
3.3.3 Options	6
3.4 Augmented and Private Application Profiles	7
3.5 Media Configuration.....	7
4. SECURITY.....	7
4.1 Security Profiles	7
4.2 Association Level Security.....	7
4.3 Application Level Security.....	7
5. ANNEXES.....	7
5.1 IOD Contents.....	7
5.1.1 Consumed SOP Instances.....	7
5.1.2 Created SOP Instances.....	9
5.1.3 SC Image IOD	10
5.1.4 Attribute Mapping	12
5.1.5 Coerced / Modified Fields	12
6. DATA DICTIONARY of PRIVATE ATTRIBUTES.....	13
6.1.1 Coded Terminology and Templates.....	13

6.1.2 Grayscale Image Consistency 13

6.1.3 Standard Extended / Specialized / Private SOP Classes 13

6.1.4 Private Transfer Syntaxes..... 13

1. OVERVIEW

suiteHEART® Software is intended to assist trained clinical personnel in the qualification and quantification of cardiac function. The software provides the tools to adjust the parameters of the DICOM images and provides presentation states where the user can appreciate various MRI acquired images of the heart and vasculature over time. Additionally, the software provides tools for measuring linear distances, areas, and volumes that can be used to quantify cardiac function. Finally, the software provides the tools for volumetric flow measurements and the ability to calculate flow values. Multiphase sequences of images can be displayed in cine mode to facilitate visualization.

The results of the measurement tools are interpreted by the physician and can be communicated to referring physicians.

When interpreted by a trained physician these tools may be useful in supporting the determination of a diagnosis.

2. INTRODUCTION

This DICOM Conformance Statement specifies the behavior and functionality of suiteHEART® Software, regarding supported DICOM networking SOP Classes and Media Storage Application Profiles.

2.1 Abbreviations

The following list illustrates all abbreviations that are used in this document.

AE	Application Entity
CD-R	Compact Disc - Recordable
DICOM	Digital Imaging and Communications in Medicine
DVD	Digital Versatile Disc
FSR	File - Set Reader
IOD	Information Object Definition
ISO	International Standards Organization
JPEG	Joint Photographic Experts Group
MR	Magnetic Resonance
PDU	Protocol Data Unit
SC	Secondary Capture
SCP	Service Class Provider
SCU	Service Class User
SOP	Service Object Pair
UID	Unique Identifier
VM	Value Multiplicity
VR	Value Representation
VNAP	Value Not Always Present

2.2 Audience

This document is written for the people that need to understand how suiteHEART® Software will integrate into their healthcare facility. This includes both those responsible for overall imaging network policy and architecture, as well as integrators who need to have a detailed understanding of the DICOM features of the product. This document contains some basic DICOM definitions so that any reader may understand how this product implements DICOM features. However, integrators are expected to fully understand all the DICOM terminology, how the tables in this document relate to the product's functionality, and how that functionality integrates with other devices that support compatible DICOM features.

2.3 Remarks

The scope of this DICOM conformance statement is to facilitate integration between suiteHEART® Software and other DICOM products. The conformance statement should be read and understood in conjunction with the DICOM Standard. DICOM by itself does not guarantee interoperability. The Conformance Statement does, however, facilitate a first-level comparison for interoperability between different applications supporting compatible DICOM functionality. This Conformance Statement is not meant to replace validation with other DICOM equipment to ensure proper exchange of intended information. In fact, the user should be aware of the following important issues:

- The comparison of different Conformance Statements is just the first step towards assessing interconnectivity and interoperability between the product and other DICOM conformant equipment.
- Test procedures should be defined and executed to validate the required level of interoperability with specific compatible DICOM equipment, as established by the healthcare facility.

2.4 Terms and Definitions

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

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

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

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

Application Context - the specification of the type of communication used between Application Entities (e.g. DICOM network protocol).

Association - a network communication channel set up between Application Entities.

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

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

Joint Photographic Experts Group (JPEG) - a set of standardized image compression techniques, available for use by DICOM applications.

Media Application Profile - the specification of DICOM information objects and encoding exchanged on removable media (e.g., CDs).

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

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

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

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

Secondary Capture(SC) - suiteHEART® Software uses SC images to store its custom data.

Service Class Provider (SCP) - role of an Application Entity that provides a DICOM network service, typically a server that performs operations requested by another Application Entity (Service Class User). Example: Picture Archiving and Communication System (image storage SCP, and image query/retrieve SCP).

Service Class User (SCU) - role of an Application Entity that uses a DICOM network service, typically a client. Examples: imaging modality (image storage SCU), imaging workstation (image query/retrieve SCU)

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

Service/Object Pair (SOP) Instance - an information object; a specific occurrence of information exchanged in a SOP Class. Examples: a specific MRI image.

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

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

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

Value Representation (VR) - the format type of an individual DICOM data element, such as text, an integer, a person's name, or a code. DICOM information objects can be transmitted with either explicit identification of the type of each data element (Explicit VR), or without explicit identification (Implicit

VR); with Implicit VR, the receiving application must use a DICOM data dictionary to look up the format of each data element.

2.5 Basics of DICOM Communication

This section describes terminology used in this Conformance Statement for the non-specialist. This section is not a substitute for training about DICOM, and it makes many simplifications about the meanings of DICOM terms.

Two Application Entities (devices) that want to communicate with each other over a network using DICOM protocol must first agree on several things during an initial network "*handshake*." One of the two devices must initiate an *Association* (a connection to the other device) and ask if specific services, information, and encoding can be supported by the other device (*Negotiation*).

DICOM specifies several network services and types of information objects, each of which is called an *Abstract Syntax* for the Negotiation. DICOM also specifies a variety of methods for encoding data, denoted as *Transfer Syntaxes*. The Negotiation allows the initiating Application Entity to propose combinations of Abstract Syntax and Transfer Syntax to be used on the Association; these combinations are called *Presentation Contexts*. The receiving Application Entity accepts the Presentation Contexts it supports.

For each Presentation Context, the Association Negotiation also allows the devices to agree on *Roles* - which one is the Service Class User (*SCU - client*) and which is the Service Class Provider (*SCP - server*). Normally the device initiating the connection is the SCU, i.e., the client system calls the server, but not always.

The Association Negotiation finally enables exchange of maximum network packet (PDU) size, security information, and network service options (called *Extended Negotiation information*).

The Application Entities, having negotiated the Association parameters, may now commence exchanging data. Common data exchanges include queries for worklists and lists of stored images, transfer of image objects and analyses (structured reports), and sending images to film printers. Each exchangeable unit of data is formatted by the sender in accordance with the appropriate Information Object Definition and sent using the negotiated Transfer Syntax. There is a Default Transfer Syntax that all systems must accept, but it may not be the most efficient for some use cases. Each transfer is explicitly acknowledged by the receiver with a Response Status indicating success, failure, or that query or retrieve operations are still in process.

Two Application Entities may also communicate with each other by exchanging media (such as a CD-R). Since there is no Association Negotiation possible, they both use a Media Application Profile that specifies "pre-negotiated" exchange media format, Abstract Syntax, and Transfer Syntax.

2.6 Supported Character Sets

suiteHEART® Software supports the following character sets for both reading in primary images and writing out secondary data: ISO-IR 6, ISO-IR 100, ISO-IR 192, and ISO 2022 IR 100.

2.7 References

[DICOM] NEMA Standards Publication PS 3.1--18, Digital Imaging and Communications in Medicine (DICOM), 2011, available at <http://medical.nema.org/>

3. NETWORKING & MEDIA STORAGE

3.1 Networking

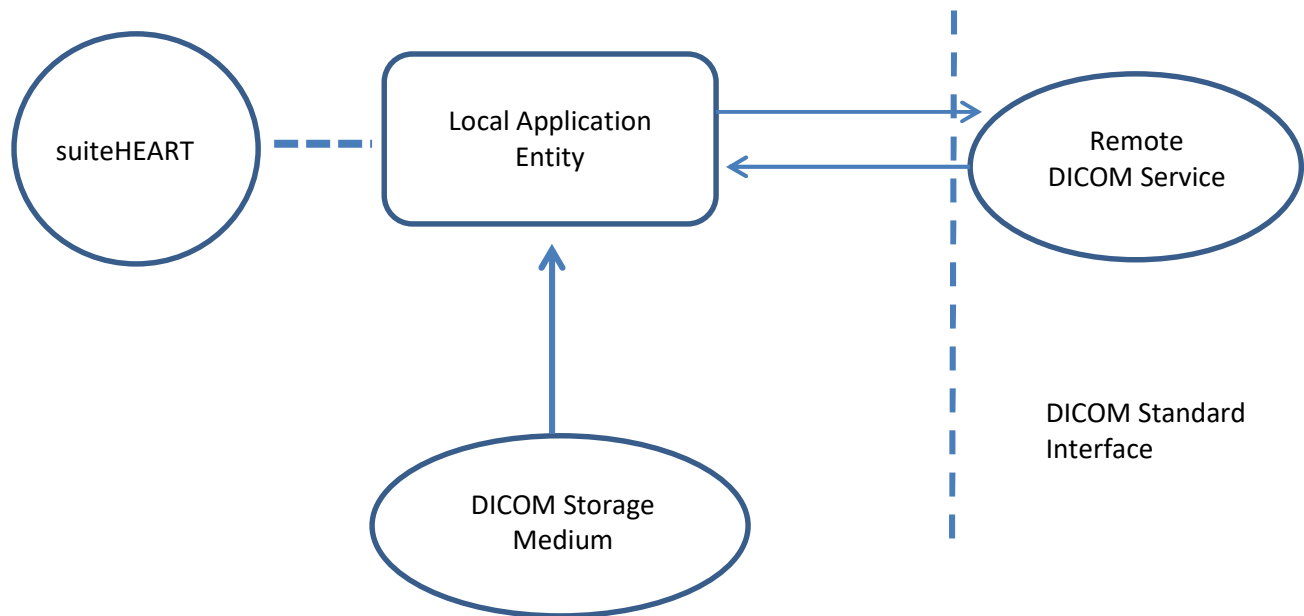
The suiteHEART® Software application works on DICOM files accessible in the local computers file system and does not send or retrieve DICOM data from the network.

In case there is a need for DICOM data to be pulled and pushed to network DICOM services, NeoSoft's application suiteDXT is used to perform this task. The following figure shows the data flow.

3.2 Media Storage

3.2.1 Implementation Model

Figure 1: Application Data Flow Diagram



3.2.2 Application Data Flow Diagram

The suiteHEART® Software application works on DICOM files available in the local system.

If there is a need for the DICOM data to be pulled and pushed to network DICOM services, another NeoSoft application, suiteDXT, is used to perform this task. Figure 1 shows the data connection

3.2.3 Functional Definition of AEs

suiteHEART® Software is accessed through the suiteDXT application with a user selected study, which is in the local AE system. The application can also be started with a product configuration file that tells the location of the study, which can be any accessible directory through the computer's file system. In either case, if a study (a group of DICOM MRI images) could not be found, an error is given, and the application will quit.

3.2.4 File Meta Information for Implementation Class and Version

Not applicable.

3.3 AE Specifications

3.3.1 Real-World Activities

All activities of suiteHEART® Software are sequentially initiated in the user interface. Application data, including temporary analysis state data, signed report data, and custom series, are stored as DICOM secondary capture data in the computer file system. The application DICOM data then can be pushed to remote DICOM service using suiteDXT or imported by other DICOM service application.

Table 1: SOP Classes for AE STORAGE-SCP

SOP Class Name	SOP Class UID	SCU	SCP
MR Image Storage	1.2.840.10008.5.1.4.1.1.4	NA	NA
MR Enhanced Image Storage	1.2.840.10008.5.1.4.1.1.4.1	NA	NA
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7	NA	NA

3.3.2 Media Storage Application Profiles

suiteHEART® Software supports write access to the computer's file systems per the user's permission. It does not support direct writing to CD or DVD drive.

3.3.3 Options

suiteHEART® Software supports the following SOP classes and transfer syntaxes. It writes its own application data using secondary capture DICOM data class, with AE entity (0x0002,0x0016) same as read from the study.

Table 2: IODS, SOP Classes and Transfer Syntaxes for AE MEDIA-FSR

Information Object Definition	SOP Class UID	Transfer Syntax	Transfer Syntax UID
MR Image Storage	1.2.840.10008.5.1.4.1.1.4	Implicit VR Little Endian, Explicit VR Little Endian, Explicit VR Big Endian, JPEG Lossless JPEG Lossless	1.2.840.10008.1.2 1.2.840.10008.1.2.1 1.2.840.10008.1.2.2 1.2.840.10008.1.2.4.70

MR Enhanced Image Storage	1.2.840.10008.5.1.4.1.1.4.1	Implicit VR Little Endian, Explicit VR Little Endian, Explicit VR Big Endian, JPEG Lossless	1.2.840.10008.1.2 1.2.840.10008.1.2.1 1.2.840.10008.1.2.2, 1.2.840.10008.1.2.4.70
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7	Explicit VR Little Endian, Implicit VR Little Endian	1.2.840.10008.1.2.1 1.2.840.10008.1.2

3.4 *Augmented and Private Application Profiles*

Not applicable.

3.5 *Media Configuration*

Not applicable.

4. *SECURITY*

4.1 *Security Profiles*

suiteHEART® Software does not support any security profiles.

4.2 *Association Level Security*

Not applicable.

4.3 *Application Level Security*

suiteHEART® Software does not support any application level security.

5. *ANNEXES*

5.1 *IOD Contents*

suiteHEART® Software reads & writes the following tags to understand and analyze images.

5.1.1 *Consumed SOP Instances*

suiteHEART® Software relies on the tags shown in the following table to perform its functions.

Table 3: IOD Tags for SOP Instances

Module	Attribute Name	Tag
FILE META INFORMATION	AE Title	(0002,0016)
MULTI-FRAME FUNCTIONAL GROUPS MODULE	Stack Position Number	(0020,9057)

FRAME OF REFERENCE MODULE	Frame Of Reference UID	(0020,0052)
GENERAL EQUIPMENT MODULE	Manufacturer	(0008,0070)
	Institution Name	(0008,0080)
GENERAL IMAGE MODULE	Image Type	(0008,0008)
	Content Time	(0008,0033)
	Acquisition Number	(0020,0012)
	Instance Number	(0020,0013)
	Images In Acquisition	(0020,1002)
GENERAL SERIES MODULE	Modality	(0008,0060)
	Series Description	(0008,103E)
	Patient Position	(0018,5100)
	Series Instance UID	(0020,000E)
	Series Number	(0020,0011)
GENERAL STUDY MODULE	Study Date	(0008,0020)
	Accession Number	(0008,0050)
	Referring Physician Name	(0008,0090)
	Study Description	(0008,1030)
	Study Instance UID	(0020,000D)
	Study Id	(0020,0010)
IMAGE PIXEL MODULE	Samples Per Pixel	(0028,0002)
	Photometric Interpretation	(0028,0004)
	Planar Configuration	(0028,0006)
	Rows	(0028,0010)
	Columns	(0028,0011)
	Bits Stored	(0028,0101)
	High Bit	(0028,0102)
	Pixel Representation	(0028,0103)
	Pixel Min Value	(0028,0106)
	Pixel Max Value	(0028,0107)
	Pixel Data	(7FE0,0010)
IMAGE PLANE MODULE	Slice Thickness	(0018,0050)
	Image Position	(0020,0032)
	Image Orientation	(0020,0037)
	Slice Location	(0020,1041)
	Pixel Spacing	(0028,0030)
MR IMAGE MODULE	Scanning Sequence	(0018,0020)
	Sequence Variant	(0018,0021)
	Scan Options	(0018,0022)
	Sequence Name	(0018,0024)
	Repetition Time	(0018,0080)
	Echo Time	(0018,0081)

	Inversion Time	(0018,0082)
	Number Of Averages	(0018,0083)
	Image Frequency	(0018,0084)
	Slice Spacing	(0018,0088)
	Echo Numbers	(0018,0086)
	Magnetic Field Strength	(0018,0087)
	Echo Train Length	(0018,0091)
	Pixel Bandwidth	(0018,0095)
	Percent Phase Field Of View	(0018,0094)
	Trigger Time	(0018,1060)
	Norminal Interval	(0018,1062)
	Heart Rate	(0018,1088)
	Receive Coil Name	(0018,1250)
	Acquisition Matrix	(0018,1310)
	Phase Encode Direction	(0018,1312)
	Flip Angle	(0018,1314)
	Temporal Position Identifier	(0020,0100)
	Bits Allocated	(0028,0100)
MR PULSE SEQUENCE MODULE	Philips Phase Contrast	(0018,9014)
MULTI-FRAME MODULE	Number Of Frames	(0028,0008)
PATIENT MODULE	Patient Name	(0010,0010)
	Patient Id	(0010,0020)
	Patient Birth Date	(0010,0030)
	Patient Sex	(0010,0040)
	Patient Age	(0010,1010)
	Patient Size	(0010,1020)
	Patient Weight	(0010,1030)
MULTI-FRAME FUNCTIONAL GROUPS MODULE	Rescale Intercept	(0028,1052)
	Rescale Slope	(0028,1053)
	Rescale Type	(0028,1054)
SOP COMMON MODULE	Specific Char Set	(0008,0005)
	Sop Class UID	(0008,0016)
	Sop Instance UID	(0008,0018)
VOI LUT MODULE	Window Center	(0028,1050)
	Window Width	(0028,1051)
NEOSOFT PRIVATE DATA MODULE	Secondary Capture Data	(0099,1001)

5.1.2 Created SOP Instances

suiteHEART® Software uses secondary captured (SC) storage class for this application data and report. The actual data is stored in private tag (0099,1001).

5.1.3 SC Image IOD

suiteHEART® Software creates SC Image objects showing the results of a quantitative evaluation in a graphical presentation (e.g. polar map, diagram). Table 4 describes the modules and attributes of the underlying IOD. Most attributes that are never present in a created SOP instance are omitted from the tables in order to increase the readability.

Table 4: Modules and Attributes of Underlying IOD

Module	Attribute Name	Tag	VR	Value	Presence of Value
FILE META INFORMATION	File Meta Information	(0002,0001)	OB	First byte set to 0 and second byte set to 1	Always
	Implementation Class UID	(0002,0012)	UI	1.2.826.0.1.3680043.9.1400.2.0.2	Always
	Implementation Version Name	(0002,0013)	SH	Software version	Always
	Source Application Entity Title	(0002,0016)	AE	Value from original patient study AE Title.	Always
PATIENT MODULE	Patient Name	(0010,0010)	PN	From original DICOM image	Always
	Patient ID	(0010,0020)	LO	From original DICOM image	Always
	Patient Birth Date	(0010,0030)	DA	From original DICOM image, if available else Blank	Always
	Patient Sex	(0010,0040)	CS	User selected, if selection performed, or from original DICOM image	Always
GENERAL STUDY MODULE	Study Date	(0008,0020)	DA	From original DICOM image	Always
	Study Time	(0008,0030)	TM	From original DICOM image	Always
	Accession Number	(0008,0050)	SH	From original DICOM image, if available else Blank	Always
	Referring Physician's Name	(0008,0090)	PN	From original DICOM image	Always
	Study Instance UID	(0020,000D)	UI	From original DICOM image	Always
	Study ID	(0020,0010)	SH	From original DICOM image	Always
	Study Description	(0008,1030)	LO	From original DICOM image	Always
GENERAL SERIES MODULE	Series Instance UID	(0020,000E)	UI	Automatic	Always
	Series Number	(0020,0011)	IS	Automatic	Always
	Patient Position	(0018,5100)	CS	From original DICOM image, if available else "FFS" image	Always
	Modality	(0008,0060)	CS	From original DICOM image	Always
	Series Description	(0008,103E)	LO	Automatic	Always
GENERAL EQUIPMENT MODULE	Manufacturer	(0008,0070)	LO	"NeoSoft LLC" or from original DICOM image (during custom series creation)	Always

SC EQUIPMENT MODULE	Conversion Type	(0008,0064)	CS	"DRW"	Always
GENERAL IMAGE MODULE	Instance Number	(0020,0013)	IS	Sequential number increased for each instance within a series	Always
	Content Date	(0008,0023)	DA	Creation Date	Always
	Content Time	(0008,0033)	TM	Creation Time	Always
	Patient Orientation	(0020,0020)	CS	Blank	Always
	Burned In Annotation	(0028,0301)	CS	"YES" filled for color RGB image(s) only	VNAP
suiteHEART® PRIVATE DATA MODULE	Owner of private tag	(0099,0010)	CS	"SUITEHEART"	Always
	Workspace Stream	(0099,1001)	OB	Application Data	Always
IMAGE PIXEL MODULE	Samples Per Pixel	(0028,0002)	US	1 for MONOCHROME2 and 3 for RGB	Always
	Photometric	(0028,0004)	CS	"MONOCHROME2" or "RGB"	Always
	Interpretation				
	Planar	(0028,0006)	US	0, filled for MONOCHROME2 only	VNAP
	Configuration				
	Rows	(0028,0010)	US	Automatic	Always
	Columns	(0028,0011)	US	Automatic	Always
	Bits Allocated	(0028,0100)	US	16 for MONOCHROME2 and 8 for RGB	Always
	Bits Stored	(0028,0101)	US	16 for MONOCHROME2 and 8 for RGB	Always
	High Bit	(0028,0102)	US	15 for MONOCHROME2 and 7 for RGB	Always
	Pixel Representation	(0028,0103)	US	0, filled for MONOCHROME2 only	VNAP
	Pixel Data	(7FE0,0010)	OW or OB	Automatic (OW for MONOCHROME2 and OB for RGB)	Always
SOP COMMON MODULE	Specific Character Set	(0008,0005)	CS	From original DICOM image	Always
	SOP Class UID	(0008,0016)	UI	"1.2.840.10008.5.1.4.1.1.7"	Always
	SOP Instance UID	(0008,0018)	UI	Automatic	Always

5.1.4 Attribute Mapping

suiteHEART® Software does not use any attribute mapping.

5.1.5 Coerced / Modified Fields

suiteHEART® Software does not modify any fields of existing DICOM object it reads.

6. DATA DICTIONARY of PRIVATE ATTRIBUTES

The private attributes added to created SOP instances are listed in Table 5. suiteHEART® Software uses blocks of private attributes. Further details on the usage of these private attributes are described in “IOD Contents.”

Table 5: Data Dictionary of Private Attributes in Created SOP INSTANCES

Tag	Attribute Name	VR	VM	Attribute Description
(0099,0010)	Private Tag Owner	CS	1	Product ID (suiteHEART) that creates the DICOM

6.1.1 Coded Terminology and Templates

suiteHEART® Software does not use any coded terminology or templates.

6.1.2 Grayscale Image Consistency

suiteHEART® Software does not make use of the DICOM Grayscale Standard Display Function.

6.1.3 Standard Extended / Specialized / Private SOP Classes

The system does not support any other specialized or private SOP classes beside MR SOP, Enhanced MR SOP classed and its own SC class data.

6.1.4 Private Transfer Syntaxes

suiteHEART® Software does not use any private transfer syntaxes.