

Technical **Publications**

Direction 2391078-4-800 Revision 1

Seno Advantage 2.2 WorkStation

CONFORMANCE STATEMENT for DICOM

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REVISION HISTORY

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1. INTRODUCTION

1.1 OVERVIEW

This DICOM Conformance Statement describes only the services used by the Seno Advantage Application.

It is divided into Sections as described below:

Section 1 (Introduction), which describes the overall structure, intent, and references for this Conformance Statement.

Section 2 (Networking Conformance Statement), which specify the GEMS equipment compliance to the DICOM requirements for the implementation of networking features.

Section 3 (SC Information Object Implementation), which specify the GEMS equipment compliance to the DICOM requirements for the implementation of SC Information Object Implementation feature.

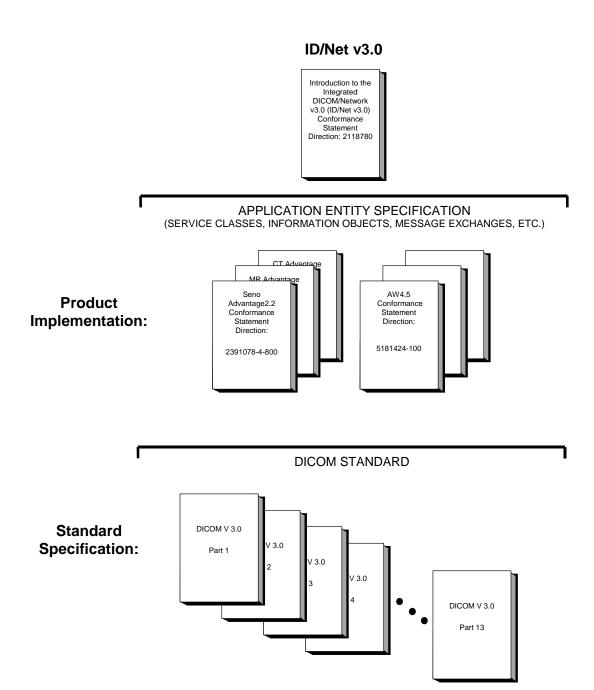
Section 4 (Basic Text SR Object Implementation), which specify the GEMS equipment compliance to the DICOM requirements for the implementation of Basic Text SR Information Object Implementation feature.

Section 5 (Digital Mammography XRAY Information Object Implementation), which specify the GEMS equipment compliance to the DICOM requirements for the support of Digital Mammography XRAY Information Object.

Section 6 (MAMMOGRAPHY CAD SR Information Object Implementation), which specify the GEMS equipment compliance to the DICOM requirements for the support of MAMMOGRAPHY CAD SR Information Object.

1.2 OVERALL DICOM CONFORMANCE STATEMENT DOCUMENT STRUCTURE

The Documentation Structure of the GEMS Conformance Statements and their relationship with the DICOM v3.0 Conformance Statements is shown in the Illustration below.



This document specifies the DICOM v3.0 implementation. It is entitled:

Seno Advantage 2.2 Workstation Conformance Statement for DICOM v3.0 Direction 2391078-4-800

This DICOM Conformance Statement documents the DICOM v3.0 Conformance Statement and Technical Specification required to interoperate with the GEMS network interface. Introductory information, which is applicable to all GEMS Conformance Statements, is described in the document:

Introduction to the Integrated DICOM/Network v3.0 (ID/Net v3.0) Conformance Statement Direction: 2118780.

This Introduction familiarizes the reader with DICOM terminology and general concepts. It should be read prior to reading the individual products' GEMS Conformance Statements.

The GEMS Conformance Statement, contained in this document, also specifies the Lower Layer communications, which it supports (e.g., TCP/IP). However, the Technical Specifications are defined in the DICOM v3.0 Part 8 standard.

For more information including Network Architecture and basic DICOM concepts, please refer to the Introduction.

For more information regarding DICOM, copies of the Standard may be obtained on the Internet at http://medical.nema.org. Comments on the Standard may be addressed to:

DICOM Secretariat NEMA 1300 N. 17th Street, Suite 1847 Rosslyn, VA 22209 USA

Phone: +1.703.841.3200

1.3 INTENDED AUDIENCE

The reader of this document is concerned with software design and/or system integration issues. It is assumed that the reader of this document is familiar with the DICOM v3.0 Standards and with the terminology and concepts, which are used in those Standards.

If readers are unfamiliar with DICOM v3.0 terminology they should first refer to the document listed below, then read the DICOM v3.0 Standard itself, prior to reading this DICOM Conformance Statement document.

Introduction to the Integrated DICOM/Network v3.0 (ID/Net v3.0) Conformance Statement Direction: 2118780

1.4 SCOPE AND FIELD OF APPLICATION

It is the intent of this document, in conjunction with the *Introduction to the Integrated DICOM/Network v3.0* (*ID/Net v3.0*) Conformance Statement, Direction: 2118780, to provide an unambiguous specification for GEMS implementations. This specification, called a Conformance Statement, includes a DICOM v3.0 Conformance Statement and is necessary to ensure proper processing and interpretation of GEMS medical data exchanged using DICOM v3.0. The GEMS Conformance Statements are available to the public.

The reader of this DICOM Conformance Statement should be aware that different GEMS devices are capable of using different Information Object Definitions. For example, a GEMS CT Scanner may send images using the CT Information Object, MR Information Object, Secondary Capture Object, etc.

Included in this DICOM Conformance Statement are the Module Definitions, which define all data elements used by this GEMS implementation. If the user encounters unspecified private data elements while parsing a GEMS Data Set, the user is well advised to ignore those data elements (per the DICOM v3.0 standard). Unspecified private data element information is subject to change without notice. If, however, the device is acting as a "full fidelity storage device", it should retain and re-transmit all of the private data elements, which are sent by GEMS devices.

1.5 IMPORTANT REMARKS

The use of these DICOM Conformance Statements, in conjunction with the DICOM v3.0 Standards, is intended to facilitate communication with GE imaging equipment. However, by itself, it is not sufficient to ensure that interoperation will be successful. The user (or user's agent) needs to proceed with caution and address at least four issues:

- Integration The integration of any device into an overall system of interconnected devices goes beyond the scope of standards (DICOM v3.0), and of this introduction and associated DICOM Conformance Statements when interoperability with non-GE equipment is desired. The responsibility to analyze the applications requirements and to design a solution that integrates GE imaging equipment with non-GE systems is the user's responsibility and should not be underestimated. The user is strongly advised to ensure that such an integration analysis is correctly performed.
- Validation Testing the complete range of possible interactions between any GE device and non-GE devices, before the connection is declared operational, should not be overlooked. Therefore, the user should ensure that any non-GE provider accepts full responsibility for all validation required for their connection with GE devices. This includes the accuracy of the image data once it has crossed the interface between the GE imaging equipment and the non-GE device and the stability of the image data for the intended applications.
 - Such a validation is required before any clinical use (diagnosis and/or treatment) is performed. It applies when images acquired on GE imaging equipment are processed/displayed on a non-GE device, as well as when images acquired on non-GE equipment is processed/displayed on a GE console or workstation.
- Future Evolution GE understands that the DICOM Standard will evolve to meet the user's growing requirements. GE is actively involved in the development of the DICOM v3.0 Standard. DICOM v3.0 will incorporate new features and technologies and GE may follow the evolution of the Standard. The GEMS protocol is based on DICOM v3.0 as specified in each DICOM Conformance Statement. Evolution of the Standard may require changes to devices, which have implemented DICOM v3.0. In addition, GE reserves the right to discontinue or make changes to the support of communications features (on its products) reflected on by these DICOM Conformance Statements. The user should ensure that any non–GE provider, which connects with GE devices, also plans for the future evolution of the DICOM Standard. Failure to do so wills likely result in the loss of function and/or connectivity as the DICOM Standard changes and GE Products are enhanced to support these changes.
- **Interaction** It is the sole responsibility of the **non–GE provider** to ensure that communication with the interfaced equipment does not cause degradation of GE imaging equipment performance and/or function.

1.6 REFERENCES

A list of references, which is applicable to all GEMS Conformance Statements, is included in the *Introduction to the Integrated DICOM/Network v3.0 (ID/Net v3.0) Conformance Statement, Direction: 2118780.*

The information object implementation refers to DICOM PS 3.3 (Information Object Definition) and DICOM supplement 32: Digital X-Ray Supplement.

1.7 DEFINITIONS

A set of definitions which is applicable to all GEMS Conformance Statements is included in *the Introduction to the Integrated DICOM/Network v3.0 (ID/Net v3.0) Conformance Statement, Direction: 2118780.*

1.8 SYMBOLS AND ABBREVIATIONS

A list of symbols and abbreviations which is applicable to all GEMS Conformance Statements is included in the *Introduction to the Integrated DICOM/Network v3.0 (ID/Net v3.0) Conformance Statement, Direction: 2118780.*

2. NETWORKING CONFORMANCE STATEMENT

2.1 INTRODUCTION

This section of the DICOM Conformance Statement specifies the compliance to DICOM conformance requirements for the relevant **Networking** features on this GEMS product.

The Seno Advantage 2.2 Workstation is a medical image review station that allows easy selection; processing; filming and media interchange of multi-modality images from a variety of diagnostic imaging systems. When interpreted by a trained physician, mammography images displayed on the high-resolution B&W portrait monitors may be used as an element for diagnosis.

The Seno Advantage 2.2 Workstation uses the DICOM services to import images for possible further analysis or processing and to export images to other DICOM implementations, DICOM printers or DICOM Interchange media. It also uses the DICOM Storage Commitment service to transfer ownership of images to a remote workstation supporting storage commitment such as an archive system. All DICOM services are inherited from the AW4.5 Workstation. See the AW4.5 DCS manual ref. 5181424-100 applicable to the Seno Advantage 2.2 Workstation.

2.2 SUPPORTED DICOM INPUTS

The Seno Advantage 2.2 Workstation supports the following DICOM inputs.

SOP Class Name	SOP Class UID
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7 and the original modality (0008,0060) is MG
Digital Mammography X-Ray Image Storage - For Presentation	1.2.840.10008.5.1.4.1.1.1.2
Digital Mammography X-Ray Image Storage - For Processing	1.2.840.10008.5.1.4.1.1.2.1
RT Structure Set Storage (RTSS)	1.2.840.10008.5.1.4.1.1.481.3 and the manufacturer (0008,0070) is "R2", "CADx" or "iCAD, INC", and the modality (0008,0060) is MG
Mammography CAD SR	1.2.840.10008.5.1.4.1.1.88.50
Basic Text SR	1.2.840.10008.5.1.4.1.1.88.11 with the root node equal to "Mini Report Presentation"

2.3 GENERATED INPUTS

The Seno Advantage 2.2 Workstation can create specific Information Object Definitions that will be described in this conformance statement.

SOP Class Name	SOP Class UID
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7 and the original modality (0008,0060) is MG
Basic Text SR	1.2.840.10008.5.1.4.1.1.88.11 with the root node equal to "Mini Report Presentation"

3. SC INFORMATION OBJECT IMPLEMENTATION

3.1 INTRODUCTION

This section specifies the use of the DICOM SC Image IOD to represent the information included in SC images produced by this implementation. Corresponding attributes are conveyed using the module construct. The contents of this section are:

- 3.2- SC ENTITY-RELATIONSHIP MODEL
- 3.3- SC-IOD MODULE TABLE
- 3.4- SC-INFORMATION MODULE DEFINITIONS
- 3.5- PRIVATE DATA DICTIONARY

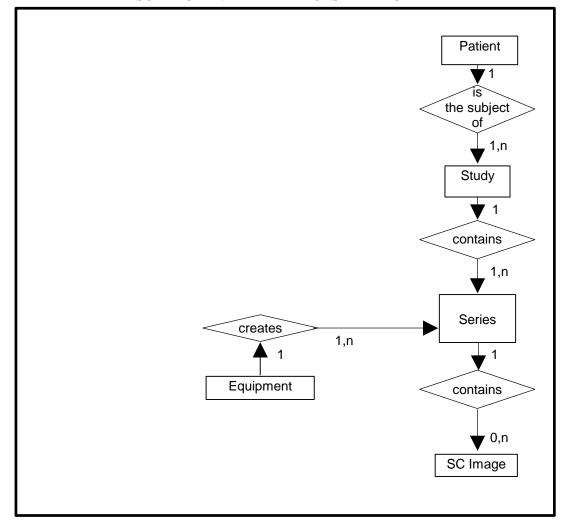
3.2 SC ENTITY-RELATIONSHIP MODEL

The Entity-Relationship diagram for the SC Image interoperability schema is shown in **Illustration 3.2.1.** In this figure, the following diagrammatic convention is established to represent the information organization:

- each entity is represented by a rectangular box
- each relationship is represented by a diamond shaped box.
- the fact that a relationship exists between two entities is depicted by lines connecting the corresponding entity boxes to the relationship boxes.

The relationships are fully defined with the maximum number of possible entities in the relationship shown. In other words, the relationship between Series and Image can have up to n Images per Series, but the Patient to Study relationship has 1 Patient for each Study (a Patient can have more than one Study on the system, however each Study will contain all of the information pertaining to that Patient).

ILLUSTRATION 3.2-1
SC IMAGE ENTITY RELATIONSHIP DIAGRAM



3.2.1 ENTITY DESCRIPTIONS

Please refer to DICOM Standard Part 3 (Information Object Definitions) for a description of each of the entities contained within the SC Information Object.

3.2.2 Seno Advantage Mapping of DICOM entities

TABLE 3.2-1
MAPPING OF DICOM ENTITIES TO SENO ADVANTAGE ENTITIES

DICOM	Seno Advantage Entity
Patient	Patient
Study	Exam
Series	Series
Image	Image

3.3 SC-IOD MODULE TABLE

Within an entity of the DICOM v3.0 SC IOD, attributes are grouped into related set of attributes. A set of related attributes is termed a module. A module facilitates the understanding of the semantics concerning the attributes and how the attributes are related with each other. A module grouping does not infer any encoding of information into datasets.

Table 3.3.1 identifies the defined modules within the entities, which comprise the DICOM v3.0 SC IOD. Module Name identifies modules.

See DICOM v3.0 Part 3 for a complete definition of the entities, modules, and attributes.

TABLE 3.3.1 SC IMAGE IOD MODULES

Entity Name	Module Name	Reference
Patient	Patient	3.4.1.1
Study	General Study	3.4.2.1
	Patient Study	3.4.2.2
Series	General Series	3.4.3.1
Equipment	General Equipment	3.4.4.1
	SC Equipment	3.4.9.1
Image	General Image	3.4.5.1
	Image Pixel	3.4.5.2
	SC Image	3.4.9.2
	Modality LUT	3.4.7.2
	VOI LUT	3.4.7.1
	SOP Common	3.4.8.1

3.4 SC-INFORMATION MODULE DEFINITIONS

Please refer to DICOM v3.0 Standard Part 3 (Information Object Definitions) for a description of each of the entities and modules contained within the SC Information Object.

The following modules are included to convey Enumerated Values, Defined Terms, and Optional Attributes supported. Type 1 & Type 2 Attributes are also included for completeness and to define what values they may take and where these values are obtained. It should be noted that they are the same ones as defined in the DICOM v3.0 Standard Part 3 (Information Object Definitions). The Attributes, which are not listed in the following modules, are not sent.

3.4.1 Common Patient Entity Modules

3.4.1.1 Patient Module

This section specifies the Attributes of the Patient that describe and identify the Patient who is the subject of a diagnostic Study. This Module contains Attributes of the patient that are needed for diagnostic interpretation of the Image and are common for all studies performed on the patient.

TABLE 3.4-1
PATIENT MODULE ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description
Patient's Name	(0010,0010)	2	Original
Patient ID	(0010,0020)	2	Original
Patient's Birth Date	(0010,0030)	2	Original
Patient's Sex	(0010,0040)	2	Original

3.4.2 Common Study Entity Modules

The following Study IE Modules are common to all Composite Image IODs, which reference the Study IE. These Modules contain Attributes of the patient and study that are needed for diagnostic interpretation of the image.

3.4.2.1 General Study Module

This section specifies the Attributes which describe and identify the Study performed upon the Patient.

TABLE 3.4-2 GENERAL STUDY MODULE ATTRIBUTES

Attribute Name	Tag	Type	Notes
Study Instance UID	(0020,000D)	1	Original
Study Date	(0008,0020)	2	Original
Study Time	(0008,0030)	2	Original
Referring Physician's Name	(0008,0090)	2	Original
Study ID	(0020,0010)	2	Original
Accession Number	(0008,0050)	2	Original
Study Description	(0008,1030)	3	Original

3.4.2.2 Patient Study Module

This section defines Attributes that provide information about the Patient at the time the Study was performed.

TABLE 3.4-3
PATIENT STUDY MODULE ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description
Patient's Age	(0010,1010)	3	Original

3.4.3 Common Series Entity Modules

The following Series IE Modules are common to all Composite Image IODs, which reference the Series IE.

3.4.3.1 General Series Module

This section specifies the Attributes, which identify and describe general information about the Series within a Study.

TABLE 3.4-4
GENERAL SERIES MODULE ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description
Modality	(0008,0060)	1	Original
Series Instance UID	(0020,000E)	1	Generated from GE Based UID: 1.2.840.113619.6.264.
Series Number	(0020,0011)	2	Generated
Series Description	(0008,103E)	3	Screen Save

3.4.4 Common Equipment Entity Modules

The following Equipment IE Module is common to all Composite Image IODs, which reference the Equipment IE.

3.4.4.1 General Equipment Module

This section specifies the Attributes, which identify and describe the piece of equipment, which produced a Series of Images.

TABLE 3.4-5
GENERAL EQUIPMENT MODULE ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description
Manufacturer	(0008,0070)	2	Original
Institution Name	(0008,0080)	3	Original
Institution Address	(0008,0081)	3	Original
Station Name	(0008,1010)	3	Original
Manufacturer's Model Name	(0008,1090)	3	Original
Software Versions	(0018,1020)	3	Original

3.4.4.1.1 General Equipment Attribute Descriptions

3.4.4.1.1.1 Pixel Padding Value

Not used

3.4.5 Common Image Entity Modules

The following Image IE Modules are common to all Composite Image IODs, which reference the Image IE.

3.4.5.1 General Image Module

This section specifies the Attributes, which identify and describe an image within a particular series.

TABLE 3.4-6
GENERAL IMAGE MODULE ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description
Image Number	(0020,0013)	2	Generated
Patient Orientation	(0020,0020)	2C	Original
Image Date	(0008,0023)	2C	Original
Image Time	(0008,0033)	2C	Original
Image Type	(0008,0008)	3	See 3.4.5.1.1.1.
Burned In Annotation	(0028,0301)	3	Not sent

3.4.5.1.1 General Image Attribute Descriptions

3.4.5.1.1.1 Image Type

This type is set to:

DERIVED\SECONDARY\<Originaltype>\SCREEN SAVE in case of Screen Save.

3.4.5.1.1.2 Derivation Description and Source Image Sequence

This sequence is not encoded.

3.4.5.1.1.3 Lossy Image Compression

Not Supported. But Seno Advantage can display Digital Mammography X-Ray images with lossy compression. In that situation an annotation is displayed in the image and burnt into the pixels of the generated SCPT to avoid misdiagnosis, see Multi-Vendor support table

3.4.5.2 Image Pixel Module

This section specifies the Attributes that describe the pixel data of the image.

TABLE 3.4-7
IMAGE PIXEL MODULE ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description
Samples per Pixel	(0028,0002	1	1
Photometric Interpretation	(0028,0004)	1	MONOCHROME1 or MONOCHROME2
Rows	(0028,0010)	1	Generated
Columns	(0028,0011)	1	Generated
Bits Allocated	(0028,0100)	1	Original
Bits Stored	(0028,0101)	1	Original
High Bit	(0028,0102)	1	Original
Pixel Representation	(0028,0103)	1	Original
Pixel Data	(7FE0, 0010)	1	Generated

3.4.6 Common Overlay Modules

This module is not implemented for this IOD.

3.4.7 Common Lookup Table Modules

3.4.7.1 VOI LUT module

This section specifies the Attributes that describe the VOI LUT.

TABLE 3.4-8 VOI LUT MODULE ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description
Window Center	(0028,1050)	3	One value is set.
			This value is derived from the Window Center present in the image when the operator asked for the Screen Save.
Window Width	(0028,1051)	1C	One value is set.
			This value is derived from the Window Width present in the image when the operator asked for the Screen Save.

3.4.7.2 Modality LUT module

This section specifies the Attributes that describe the Modality LUT.

TABLE 3.4-9
MODALITY LUT MODULE ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description
Rescale Intercept	(0028,1052)	1C	0
Rescale Slope	(0028,1053)	1C	1
Rescale Type	(0028,1054)	1C	US

3.4.8 General Modules

The SOP Common Module is mandatory for all DICOM IODs.

3.4.8.1 SOP Common Module

This section defines the Attributes, which are required for proper functioning and identification of the associated SOP Instances. They do not specify any semantics about the Real-World Object represented by the IOD.

TABLE 3.4-10 SOP COMMON MODULE ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description
SOP Class UID	(0008,0016)	1	1.2.840.10008.5.1.4.7
SOP Instance UID	(0008,0018)	1	Generated from GE Based UID: 1.2.840.113619.6.264.
Specific Character Set	(0008,0005)	1C	 If non present in the original image, and if the new Patient Name contains non English character(s), set to "ISO_IR 100" Original value otherwise

3.4.9 SC Modules

This Section describes SC Equipment, and Image Modules. These Modules contain Attributes that are specific to SC Image IOD.

3.4.9.1 SC Equipment Module

This Module describes equipment used to convert images into a DICOM format.

TABLE 3.4-11 SC IMAGE EQUIPMENT MODULE ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description
Conversion Type	(0008,0064)	1	WSD
Modality	(0008,0060)	3	Original
Secondary Capture Device ID	(0018,1010)	3	Station name
Secondary Capture Device Manufacturer	(0018,1016)	3	GE MEDICAL SYSTEMS
Secondary Capture Device Manufacturer's Model Name	(0018,1018)	3	A.W.4.1
Secondary Capture Device Software Version	(0018,1019)	3	Build information: <date and="" creation="" of="" software="" time=""></date>

3.4.9.2 SC Image Module

The table in this Section contains IOD Attributes that describe SC images.

TABLE 3.4-12 SC IMAGE MODULE ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description
Date of Secondary Capture	(0018,1012)	3	Creation date of the Secondary Capture
Time of Secondary Capture	(0018,1014)	3	Creation time of the Secondary Capture

3.5 PRIVATE DATA DICTIONARY

No private elements are being used for this IOD.

4. BASIC TEXT SR INFORMATION OBJECT IMPLEMENTATION

4.1 INTRODUCTION

This section specifies the use of the DICOM Basic Text SR IOD to represent the information included in Basic text SR produced by this implementation. Corresponding attributes are conveyed using the module construct. The contents of this section are:

- 4.2 BASIC TEXT SR ENTITY-RELATIONSHIP MODEL
- 4.3 BASIC TEXT SR-IOD MODULE TABLE
- 4.4 BASIC TEXT SR-INFORMATION MODULE DEFINITIONS
- 4.6 EXAM NOTE PRESENTATION TEMPLATE

Note: The Basic Text DICOM SR produced by this implementation is also named: "Exam Note"

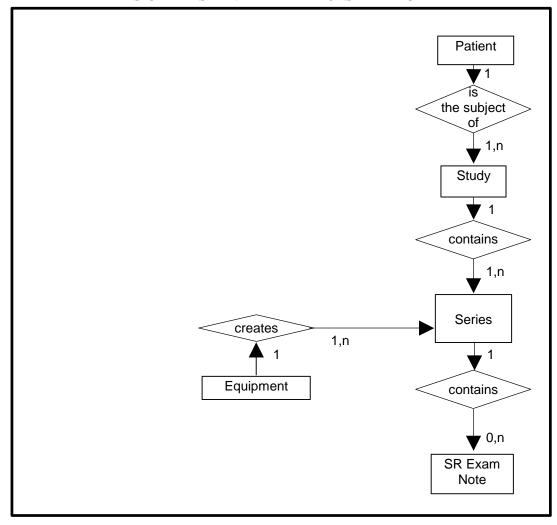
4.2 BASIC TEXT SR ENTITY-RELATIONSHIP MODEL

The Entity-Relationship diagram for the Basic Text SR interoperability schema is shown in **Illustration 4.2.1.** In this figure, the following diagrammatic convention is established to represent the information organization:

- each entity is represented by a rectangular box
- each relationship is represented by a diamond shaped box.
- the fact that a relationship exists between two entities is depicted by lines connecting the corresponding entity boxes to the relationship boxes.

The relationships are fully defined with the maximum number of possible entities in the relationship shown. In other words, the relationship between Series and Image can have up to n Images per Series, but the Patient to Study relationship has 1 Patient for each Study (a Patient can have more than one Study on the system, however each Study will contain all of the information pertaining to that Patient).

ILLUSTRATION 4.2-1
BASIC TEXT SR ENTITY RELATIONSHIP DIAGRAM



4.2.1 ENTITY DESCRIPTIONS

Please refer to DICOM Standard Part 3 (Information Object Definitions) for a description of each of the entities contained within the Basic Text SR Information Object.

4.2.2 Seno Advantage Mapping of DICOM entities

TABLE 4.2-1
MAPPING OF DICOM ENTITIES TO SENO ADVANTAGE ENTITIES

DICOM	Seno Advantage Entity
Patient	Patient
Study	Exam
Series	Series
SR Document	SR Document

4.3 BASIC TEXT SR-IOD MODULE TABLE

Within an entity of the DICOM v3.0 BASIC TEXT SR IOD, attributes are grouped into related set of attributes. A set of related attributes is termed a module. A module facilitates the understanding of the semantics concerning the attributes and how the attributes are related with each other. A module grouping does not infer any encoding of information into datasets.

Table 4.3.1 identifies the defined modules within the entities, which comprise the DICOM v3.0 Basic Text SR IOD. Module Name identifies modules.

See DICOM v3.0 Part 3 for a complete definition of the entities, modules, and attributes.

TABLE 4.3.1
BASIC TEXT SR IOD MODULES

Entity Name	Module Name	Reference
Patient	Patient	4.4.1.1
Study	General Study	4.4.2.1
Series	SR Document Series	4.4.3.1
Equipment	General Equipment	4.4.3.2
Document	SR Document General	4.4.4.1
	SR Document Content	4.4.4.2
	SOP Common	4.4.5.1

4.4 BASIC TEXT SR-INFORMATION MODULE DEFINITIONS

Please refer to DICOM v3.0 Standard Part 3 (Information Object Definitions) for a description of each of the entities and modules contained within the Basic Text SR Information Object.

The following modules are included to convey Enumerated Values, Defined Terms, and Optional Attributes supported. Type 1 & Type 2 Attributes are also included for completeness and to define what values they may take and where these values are obtained. It should be noted that they are the same ones as defined in the DICOM v3.0 Standard Part 3 (Information Object Definitions). The Attributes, which are not listed in the following modules, are not sent.

4.4.1 Common Patient Entity Modules

4.4.1.1 Patient Module

This section specifies the Attributes of the Patient that describe and identify the Patient who is the subject of a diagnostic Study. This Module contains Attributes of the patient that are needed for diagnostic interpretation of the Image and are common for all studies performed on the patient.

TABLE 4.4-1
PATIENT MODULE ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description
Patient's Name	(0010,0010)	2	Copy of the patient name of the most recent exam if present, empty string otherwise
Patient ID	(0010,0020)	2	Copy of the patient ID of the most recent exam if present, empty string otherwise
Patient's Birth Date	(0010,0030)	2	Copy of the patient birth date of the most recent exam if present, empty string otherwise
Patient's Sex	(0010,0040)	2	Copy of the patient sex of the most recent exam if present, empty string otherwise

4.4.2 Common Study Entity Modules

The following Study IE Modules are common to all Composite Image IODs, which reference the Study IE. These Modules contain Attributes of the patient and study that are needed for diagnostic interpretation of the image.

4.4.2.1 General Study Module

This section specifies the Attributes, which describe and identify the Study performed upon the Patient.

TABLE 4.4-2 GENERAL STUDY MODULE ATTRIBUTES

Attribute Name	Tag	Type	Notes
Study Instance UID	(0020,000D)	1	Copy of the study instance UID of the most recent exam
Study Date	(0008,0020)	2	Copy of the study date of the most recent exam if present, empty string otherwise
Study Time	(0008,0030)	2	Copy of the study time of the most recent exam if present, empty string otherwise
Accession Number	(0008,0050)	2	Copy of the accession number of the most recent exam if present, empty string otherwise
Referring Physician's Name	(0008,0090)	2	Copy of the physician name of the most recent exam if present, empty string otherwise
Study Description	(0008,1030)	3	Copy of the study description of the most recent exam if present, not defined otherwise
Study ID	(0020,0010)	2	Copy of the study ID of the most recent exam if present, empty string otherwise

4.4.3 SR Document Series entity Modules

The following SR Document Series IE Modules are common to all Composite Image IODs that reference the SR Document Series IE.

4.4.3.1 SR Document Series Module

This section specifies the attributes that identify and describe general information about the SR Document Series within a Study.

TABLE 4.4-3
SR DOCUMENT SERIES MODULE ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description
Modality	(0008,0060)	1	SR
Series Instance UID	(0020, 000E)	1	Generated from GE Based UID:
			1.2.840.113619.2.198
Series Number	(0020, 0011)	1	Generated
Series Description	(0008, 103E)	3	Free text filled by the end user
Referenced Performed Procedure step	(0008, 1111)	2	Empty
Sequence			

4.4.3.2 General Equipment Module

This section specifies the Attributes, which identify and describe the piece of equipment which produced a Series of Images.

TABLE 4.4-4
GENERAL EQUIPMENT MODULE ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description
Manufacturer (0008,0070) 2		2	GE MEDICAL SYSTEMS
Station Name	(0008,1010)	3	Not present
Manufacturer's Model Name	(0008,1090)	3	Seno Advantage version.

4.4.4 SR Document Entity Modules

The following SR document Modules are common to all Composite Image IODs, which reference the Image IE.

4.4.4.1 SR Document General Module

This section specifies the Attributes, which identify and describe the SR Document.

TABLE 4.4-5
SR DOCUMENT GENERAL MODULE ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description
Instance Number	(0020, 0013)	1	1
Completion flag	(0040, A491)	1	COMPLETE
Verification flag	(0040, A493)	1	VERIFIED

Content Date	(0008, 0023)	1	Date of creation
Content Time	(0008, 0033)	1	Time of creation
Verifying Observer Sequence	(0040, A073)	1C	
> Verifying Observer Name	(0040, A075)	1	Name of the user that currently is logged on the station
> Verifying Observer Identification Code Sequence	(0040, A088)	2	Empty
> Verifying Organization	(0040, A027)	1	Same as Institution Name (0008,0080) of General Equipment Module
> Verifying Date Time	(0040, A030)	1	Date and time of creation
Performed Procedure Code Sequence	(0040, A372)	2	Empty

4.4.4.2 SR Document Content Module

This section specifies the attributes that identify and describe the SR content

TABLE 4.4-6
SR DOCUMENT CONTENT MODULE ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description
Content Template Sequence	(0040, A504)	1C	
> Template identifier	(0040, DB00)	1	SA2_0 MINIREPORT
> Mapping Resource	(0008, 0105)	1	PRIVATE

4.4.5 General Modules

The SOP Common Module is mandatory for all DICOM IODs.

4.4.5.1 SOP Common Module

This section defines the Attributes, which are required for proper functioning and identification of the associated SOP Instances. They do not specify any semantics about the Real-World Object represented by the IOD.

TABLE 4.4-7
SOP COMMON MODULE ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description	
SOP Class UID	(0008,0016)	1	BASIC TEXT SR:	
			1.2.840.10008.5.1.4.1.1.88.11	
SOP Instance UID	(0008,0018)	1	Generated from GE Based UID: 1.2.840.113619.2.198	
Specific Character Set	(0008,0005)	1C	 If non present in the original image, and if the new Patient Name contains non English character(s), set to "ISO_IR 100" Original value otherwise 	

4.5 PRIVATE DATA DICTIONARY

No private elements are being used for this IOD.

4.6 EXAM NOTE - PRESENTATION TEMPLATE

This template describes how the SR Document Content Module of the Basic Text SR Information Object Definition is constrained for the purpose of implementing the Exam Note.

4.6.1 TID SA2_0 MINIREPORT: Exam Note Presentation

NL	Rel with	VT	Concept Name	VM	Req	Condition	Value Set Constraint
	Parent				Type		
1		CONTAINER	EV (SA2-MR-0001, 99GEMS,	1	M		Document title
			"Mini Report Presentation")				
2>	HAS OBS	INCLUDE	DTID (1003) "Person observer	1	M		
	CONTEXT		identifying attributes"				
3>	CONTAINS	TEXT	EV (SA2-MR-0002, 99GEMS,	1	M		
			"Findings, diagnostic")				

4.6.2 TID 1003 Person observer identifying attributes

	NL	Rel with	VT	Concept Name	VM	Req	Condition	Value Set Constraint
		Parent				Type		
1			PNAME	EV (121008,DCM, "Person Observer Name")	1	M		Name of the user that currently is logged on the station
2			TEXT	EV (121009,DCM, "Person Observer's Organization Name")	1	U		"no name"

4.7 PRIVATE CODED ENTRIES

The private coded entries that are required for implementing the Exam Note DICOM SR object are listed below (these are referred into the Exam Note Presentation Template).

Coded Entries						
Coding Scheme Designator Code Value Code Meaning						
(0008,0102)	(0008,0100)	(0008,0104)				
99GEMS	SA2-MR-0001	Mini Report Presentation				
99GEMS	SA2-MR-0002	Findings, diagnostic				

5. DIGITAL MAMMOGRAPHY XRAY INFORMATION OBJECT IMPLEMENTATION

Seno Advantage Application supports DICOM MG images as input created by any vendor.

5.1 SPECIFIC BEHAVIOR BASED ON DICOM INPUTS

The Seno Advantage Viewer provides many features, which allow the end user to display, manipulate and process Mammography images. Some of these features do not apply or apply differently to images, which are not GE images.

The purpose of this section is to detail differences in the behavior of features due to the image vendor source: **GE** vendor, and other vendors (**non-GE**).

5.1.1 Multi-Vendor support table

The following table details the Seno Advantage Viewer features, which do not support or support with limitation the non-GE images.

All other Seno Advantage Viewer features, which are not listed, support both GE images and non-GE images the same way.

Feature	GE Images	Non-GE Images		
Loading/displaying an Image on Screen.	Overlays defined in (7FE0, 0010) and (60xx, 3000) are not supported. A warning message is displayed to explain the limitation.	Overlays defined in (7FE0, 0010) and (60xx, 3000) are not supported. A warning message is displayed to explain the limitation.		
Loading/displaying an Image on Screen.	GE Images acquired with non-square pixels are displayed. A warning message is displayed to explain the limitation on measurement. Measurement values are in pixels or pixels ² .	Non-GE Images acquired with non-square pixels are displayed. A warning message is displayed to explain the limitation on measurement. Measurement values are in pixels or pixels ² .		
Loading/displaying an Image on Screen.	GE images compressed with loss are displayed with a warning annotation.	Non-GE images compressed with loss are displayed with a warning annotation.		
View Name definitions	View name computation is based on the following GE acquisition limitations:	View name computation is based on the following GE acquisition limitations:		
	Standard view names:	Standard view names:		
	Image laterality: L or R	Image laterality: L or R		
	• View code: ML, MLO, LM, LMO, CC, FB or SIO.	• View code: ML, MLO, LM, LMO, CC, FB or SIO.		
	• View modifier code: One of RL, RM, ID, S, TAN and M if Mag view is applied.	View modifier code: One of RL, RM, ID, S, TAN and M if Mag view is applied.		
	Special view names:	Special view names:		
	• CV	• CV		
	• (R or L)AT	• (R or L)AT		
	• (R or L)XCC	• (R or L)XCC		
	• (R or L)XCCM	• (R or L)XCCM		
	• (R or L)XCCL	• (R or L)XCCL		
	Means, Images only with above View Name combinations are supported.	Means, Images only with above View Name combinations are supported.		
Fit to Breast	Applies to GE images.	Not applicable on non-GE images unless the DICOM tags Pixel Padding Value (0028,0120) or Pixel Padding		

		Value (0028,0120) and Pixel Padding Range Limit (0028,0121) are present.
Quadrant Zoom	On GE images, it applies the Smart Quadrant function.	On non-GE images, it applies the normal <i>Quadrant Zoom</i> function unless the DICOM tags Pixel Padding Value (0028,0120) or Pixel Padding Value (0028,0120) and Pixel Padding Range Limit (0028,0121) are present.
VOI LUT	Gamma LUT is always used for GE images including SCPT images. The VOI LUT (0028,3010) if present is not used.	Gamma LUT is used for non-GE images if DICOM tag VOI LUT function (0028,1056) is SIGMOID. Linear LUT is used for non-GE images if the tag VOI LUT description is not present in the image or is present but not equal to SIGMOID.
Inverse Video	On GE images, it applies the <i>smart</i> invert function.	On non-GE images, it applies the normal inverted video unless the DICOM tags Pixel Padding Value (0028,0120) or Pixel Padding Value (0028,0120) and Pixel Padding Range Limit (0028,0121) are present.
Auto Windowing	Multi-valued windowing (Standard, High, Low and User) available on GE images.	Multi-valued windowing not available on non-GE images. If multiple windowing values are available in the non- GE image then the only first windowing is used.
Measurement	On GE images, the imager pixel spacing (0018, 1164) is used for measurements. For any kind of view including the magview the measures are adjusted with the estimated radiographic magnification factor (0018,1114). Mag images with measures are displayed with a warning annotation.	On non-GE images, the imager pixel spacing (0018, 1164) is used for measurements. For any kind of view including the mag-view the measures are adjusted with the estimated radiographic magnification factor (0018,1114) if present. Mag images with measures are displayed with a warning annotation.

6. MAMMOGRAPHY CAD SR INFORMATION OBJECT IMPLEMENTATION

Seno Advantage Application supports DICOM Mammography CAD SR as input created by any vendor. For legacy purpose Seno Advantage supports also RT Structure Set Storage (RTSS) created by the manufacturer (0008,0070) is "R2", "CADx" or "iCAD, INC", and the modality (0008,0060) is MG.

6.1 SPECIFIC BEHAVIOR BASED ON DICOM INPUTS

The Seno Advantage Viewer provides many features, which allow the end user to display the result of the CAD processing. Some of these features do not apply or apply differently according to the CAD vendor.

The purpose of this section is to detail differences in the behavior of features due to the CAD vendor source.

6.1.1 Multi-Vendor support table

6.1.1.1 Supported CAD markers

The Seno Advantage supports different marker shapes, representing the findings displayed on the images, according to the CAD vendor:

When the manufacturer (0008,0070) is "R2":

- a triangle indicating the position of the micro calcifications
- a star indicating the position of the masses

Otherwise:

RT structure sets and the manufacturer (0008,0070) is "CADx":

- a rectangle wrapping around micro calcifications
- an ellipse wrapping around masses

Mammography CAD SR:

- an outline of type polyline, ellipse or circle wrapping around micro calcifications and masses if present
- otherwise a cross indicating the position of the micro calcifications or the masses

6.1.1.2 CAD information

The Seno Advantage displays information and statistics data stored in the Mammography CAD SR, resulting from the CAD processing and corresponding to each findings displayed on the image, according to the CAD vendor:

Common CAD information:

Content Date (0008,0023) and Content Time (0008,0033)

For each finding:

- Marker number (generated by Seno Advantage or a number as defined in (112039, DCM, "Tracking Identifier"))
- Finding type (i.e. breast density or cluster of micro calcifications)
- Algorithm name as defined in (111001, DCM, "Algorithm Name")
- Algorithm version as defined in (111003, DCM, "Algorithm Version")

When the manufacturer (0008,0070) is "iCAD, inc"

General information for the selected image if present:

- Percent glandular tissue
- Breast composition

For each breast density if present:

- CAD Operating point description or number
- Certainty of finding
- Longest Axis
- Selected Region Description
- Distance from Nipple
- Distance from Chest wall
- Area

For each cluster of micro calcifications if present:

- CAD Operating point description or number
- Certainty of finding
- Longest Axis
- Number of micro calcifications in the cluster
- Selected Region Description
- Distance from Nipple
- Distance from Chest wall
- Area
- The Average calcification distance in a calcification cluster
- The Standard deviation distance of calcifications in a cluster

6.1.1.3 Two view positives

The Seno Advantage displays close to each marker, representing the findings displayed on the images, the numbers being defined in (112039, DCM, "Tracking Identifier") in the Mammography CAD SR and the manufacturer (0008,0070) is "iCAD, inc". When the CAD system identifies the same detection on different images, then the same number is used for the findings to ease the correlation between multiple images.