
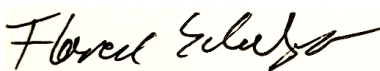




DICOM Conformance Statement - contextflow ADVANCE Chest CT

Approval

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contextflow GmbH
DICOM Conformance Statement

contextflow ADVANCE Chest CT ver. min. 2.0

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Edition

Version 1.0, May 2023

Product Identification

Product Name: **contextflow ADVANCE Chest CT**
Device Type: Medical Device Software (MDSW)
UDI-DI: (01)09120107330075

Manufacturer

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1 Overview

contextflow ADVANCE Chest CT is an Artificial Intelligence (AI)-based, Computer Aided Detection (CADe) system for 3D medical imaging data. *contextflow ADVANCE Chest CT* provides radiologists with complementary information for the identification and interpretation of lung-specific image patterns in Computed Tomography (CT) scans and is intended to support radiologists in objective image assessment and reporting.

This complementary information is computed based on DICOM CT Image objects and is made available as Secondary Capture, Encapsulated PDF and Enhanced SR DICOM objects. The application interacts with the PACS or the Modality via the DIMSE C-STORE service.

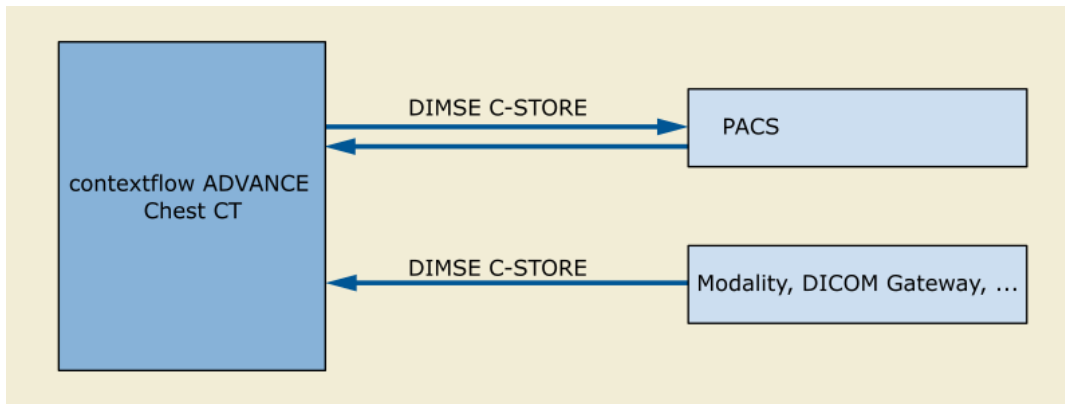


Figure 1-1. Overview of Implemented Services

1.1 Content and Transfer

Table 1-1 lists all Storage SOP Classes and the supported transfer mechanisms as well as the usage scenarios for those instances.

The "Transfer Syntax Set" column lists the sets of Transfer Syntaxes defined in Table 1-2 that are applicable to each SOP Class. The "DIMSE", "DICOM Web" and "Media Services" columns indicate the roles supported for each SOP Class.

The "Function" columns indicate how the instances are used by the system:

- Create: The system creates instances of the SOP Class. The type of the created SOP Class is indicated by one of the following abbreviations:
 - S: Standard SOP Class
 - SE: Standard Extended SOP Class
 - SP: Specialized SOP Class
 - P: Private SOP Class
- Display: The system displays the instances of the SOP Class to the user, either by displaying the SOP Instances natively or by applying instances of another suitable SOP Class to the image instances (e.g., a Presentation State or CAD SR).
- Process: The system processes the instances of the SOP Class to derive some further information that is made available to the user (e.g., a CAD processing algorithm, or a 3D Rendering).
- Archive: The system stores the instances of the SOP Class and makes them available again.

Table 1-1. Storage SOP Classes

SOP Classes		Transfer Syntax Set	DIMSE Services		DICOM Web Services		Media Services			Function			
			SCU	SCP	UA	OS	FSC	FSU	FSR	Create	Display	Process	Archive
CT Image Storage	1.2.840.10008.5.1.4.11.2	L,U	N	Y	N	N	N	N	N	N	Y	Y	N
Multi-frame True Color Secondary Capture Image Storage	1.2.840.10008.5.1.4.11.7.4	L	Y	N	N	N	N	N	N	S	N	N	N
Encapsulated PDF Storage	1.2.840.10008.5.1.4.11.104.1	NI	Y	N	N	N	N	N	N	S	N	N	N
Enhanced SR	1.2.840.10008.5.1.4.11.88.22	NI	Y	N	N	N	N	N	N	S	N	N	N

Table 1-2. Supported Transfer Syntaxes

Transfer Syntax Set	Transfer Syntax Name	Transfer Syntax UID	DICOM Web Service Bulkdata Media Type
Lossy Compressed Transfer Syntax Set (L)	JPEG Baseline (Process 1)	1.2.840.10008.1.2.4.50	image/jpeg
Uncompressed Transfer Syntax Set (U)	Explicit VR Little Endian	1.2.840.10008.1.2.1	application/octet-stream
	Implicit VR Little Endian	1.2.840.10008.1.2	N/A
Non-Image Transfer Syntax Set (NI)	Explicit VR Little Endian native	1.2.840.10008.1.2.1	application/octet-stream

1.1.1 Structured Reporting Root Template IDs

Table 1-3 lists all Template IDs (TID) of Root Templates that are supported by the system. The "Function" column indicates how the system uses the content of the DICOM SR:

- **CREATE:** The system creates instances using the specified TID.
- **RENDER:** The system displays the content of the SR, without using the data for any processing.
- **EXTRACT_DATA:** The system can extract structured data from the content and use the data for subsequent processing (e.g. reporting).
- **OVERLAY:** The system uses the information in the SR to display information directly on the images (e.g. Mammography CAD markers).
- **ARCHIVE:** The system stores instances for later retrieval

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The "SOP Class UID" column indicates which of the SR Storage SOP Classes are used to encode the information or to store it. If multiple SOP Classes are supported the "Condition" column describes the conditions for using the different SOP Classes.

Table 1-3. Supported Root SR Template IDs (TIDs)

Name	Root TID	Function	SOP Classes		Condition
Measurement Report	1500	CREATE	Enhanced SR	1.2.840.10008.5.1.4.1.1.88.22	N/A

1.2 DIMSE Services

1.2.1 Verification N/A

N/A

1.2.2 Storage

For details on supported Storage SOP Classes see Section 1.1.

1.2.3 Workflow Management N/A

N/A

1.2.4 Query/Retrieve N/A

N/A

1.2.5 Printing N/A

N/A

1.3 DICOM Web Services N/A

N/A

1.4 Media Services N/A

N/A

1.5 Real Time Video Service N/A

N/A

1.6 De-identification Profiles N/A

N/A

1.7 Specific Character Sets

The system can process the character sets in the Table 1-4. All DICOM objects generated by the system are using the character set ISO_IR 192 (UTF-8).

Table 1-4. Supported Specific Character Sets for reading

Defined Term	Description
Single-Byte Character Sets without Code Extensions	
ISO_IR 6	Default Repertoire
ISO_IR 100	Latin alphabet No. 1
ISO_IR 101	Latin alphabet No. 2
ISO_IR 109	Latin alphabet No. 3
ISO_IR 110	Latin alphabet No. 4
ISO_IR 144	Cyrillic
ISO_IR 127	Arabic
ISO_IR 126	Greek
ISO_IR 138	Hebrew
ISO_IR 148	Latin alphabet No. 5
ISO_IR 203	Latin alphabet No. 9
ISO_IR 13	Japanese
ISO_IR 166	Thai
Single-Byte Character Sets with Code Extension	
ISO 2022 IR 6	Default repertoire
ISO 2022 IR 100	Latin alphabet No. 1
ISO 2022 IR 101	Latin alphabet No. 2
ISO 2022 IR 109	Latin alphabet No. 3
ISO 2022 IR 110	Latin alphabet No. 4
ISO 2022 IR 144	Cyrillic
ISO 2022 IR 127	Arabic
ISO 2022 IR 126	Greek
ISO 2022 IR 138	Hebrew
ISO 2022 IR 148	Latin alphabet No. 5
ISO 2022 IR 203	Latin alphabet No. 9
ISO 2022 IR 13	Japanese
ISO 2022 IR 166	Thai

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Defined Term	Description
Multi-Byte Character Sets without Code Extensions	
ISO_IR 192	Unicode in UTF-8
GB18030	GB18030
GBK	GBK
Multi-Byte Character Sets with Code Extensions	
ISO 2022 IR 87	Japanese
ISO 2022 IR 159	
ISO 2022 IR 149	Korean
ISO 2022 IR 58	Simplified Chinese

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2 Introduction

2.1 Revision History

Revision	Date	Product Version(s)	Change
Rev-1	January 20, 2023 to May 8, 2023	min. contextflow ADVANCE Chest CT 2.0	Initial version

2.2 Audience

This document is intended for the audience listed below. It is assumed that the reader has a working knowledge of the DICOM Standard.

The document structure was designed for easier access to relevant information for different user groups:

- System Integrators can use information in Section N.6 during system installation and also information from Section 3 Service and Interoperability Description for details regarding the implemented services.
- Field Service Engineers can use the details from Section N.5 Service and Interoperability Description and from Section 5 Network and Media Communication Details for troubleshooting.
- Hospital IT staff focusing on security can use the details provided in Section 6 Security regarding implemented Security features.

2.3 Remarks

The scope of this DICOM Conformance Statement is to facilitate integration between *contextflow ADVANCE Chest CT* and other DICOM products. The Conformance Statement should be read and understood in conjunction with the DICOM Standard [1]. 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 should not replace validation with other DICOM equipment to ensure proper exchange of intended information. In fact, it is the user's responsibility to perform the following validation activities:
- The comparison of Conformance Statements from *contextflow ADVANCE Chest CT* and other DICOM conformant equipment is the first step towards assessing interconnectivity and interoperability between those systems.
- Test procedures should be defined and executed to validate the required level of interoperability with specific DICOM conformant equipment, as established by the healthcare facility.

contextflow ADVANCE Chest CT has participated in an industry-wide testing program sponsored by Integrating the Healthcare Enterprise (IHE). The IHE Integration Statement of *contextflow ADVANCE Chest CT* together with the IHE Technical Framework may facilitate the process of validation testing.

2.4 Terms and Definitions

The following list includes DICOM Terms, that are used throughout this Conformance Statement:

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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)	A representation of the external behavior of an application process in terms of DICOM Network Services, Web Services and/or media exchange capabilities implemented in one or more roles. A single device may have multiple Application Entities.
Application Entity Title (AET)	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. Example: DICOM network protocol.
Association	A network communication channel set up between Application Entities.
Attribute	A unit of information in an Information 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).
Data Element	A unit of information as defined by a single entry in the data dictionary. An encoded Information Object Definition (IOD) Attribute that is composed of, at a minimum, three fields: a Data Element Tag, a Value Length, and a Value Field. For some specific Transfer Syntaxes, a Data Element also contains a VR Field where the Value Representation of that Data Element is specified explicitly
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. Examples: MR Image IOD, CT Image IOD, Print Job IOD. The Attributes within an IOD 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).
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's Name, Patient ID, Patient' Birth Date, and Patient's Sex.

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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.
Origin Server	Refers to the program that can originate authoritative responses to HTTP requests for a given Target Resource. The term "server" refers to any implementation that receives a web service request message from a user agent.
Presentation Context	The set of DICOM Network Services used over an Association, as negotiated between Application Entities; includes Abstract Syntaxes and Transfer Syntaxes.
Private SOP Class	A SOP Class that is not defined in the DICOM Standard but is published in an implementation's Conformance Statement.
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.
Security Profile	A set of mechanisms, such as encryption, user authentication, or digital signatures, used by an Application Entity to ensure confidentiality, integrity, and/or availability of exchanged DICOM 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). Examples: Picture Archiving and Communication System (image storage SCP, and image query/retrieve SCP), Radiology Information System (modality worklist 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, and modality worklist SCU), imaging workstation (image query/retrieve SCU).
Service/Object Pair Class (SOP Class)	The specification of the network or media transfer (service) of a particular type of data (object) ; the fundamental unit of a DICOM interoperability specification. Examples: Ultrasound Image Storage Service, Basic Grayscale Print Management.
Service/Object Pair Instance (SOP Instance)	An information object; a specific occurrence of information exchanged in a SOP Class. E.g., a specific X-ray image.
Specialized SOP Class	A SOP Class that is derived from the Standard that is specialized by additional type 1, 1C, 2, 2C, or 3 Attributes, by enumeration of specific permitted Values for Attributes, or by enumeration of

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	specific permitted Templates. The additional Attributes may either be drawn from the Data Dictionary in PS3.6 or may be Private Attributes.
Standard SOP Class	A SOP Class defined in the Standard, and that is implemented and used without any modifications.
Standard Extended SOP Class	A SOP Class that is defined in the standard, and that is extended by additional type 3 Attributes. The additional Attributes may either be drawn from the DICOM Data Dictionary in PS3.6 or may be Private Attributes.
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.
TLS-Secured Port	TCP port on which an implementation accepts TLS connections to exchange DICOM information.
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.
User Agent	A client in a network protocol used in communications within a client-server distributed computing system. In particular, the Hypertext Transfer Protocol (HTTP) identifies the client software originating the request, using a user-agent header, even when the client is not operated by a user.
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 Abbreviations

Abbreviations that are used in this DICOM Conformance Statement are listed here.

AE	Application Entity
AET	Application Entity Title

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CAD	Computer Aided Detection
CDA	Clinical Document Architecture
CID	Context Identifier
DCS	DICOM Conformance Statement
DHCP	Dynamic Host Configuration Protocol
DICOM	Digital Imaging and Communications in Medicine
ELE	Explicit VR Little Endian
FSC	File-Set Creator
FSU	File-Set Updater
FSR	File-Set Reader
IANA	Internet Assigned Numbers Authority
IHE	Integrating the Healthcare Enterprise
ILE	Implicit VR Little Endian
IOD	Information Object Definition
IPv4	Internet Protocol version 4
IPv6	Internet Protocol version 6
ISO	International Organization for Standardization
MPPS	Modality Performed Procedure Step
MWL	Modality Worklist
NEMA	National Electrical Manufacturers Association
NTP	Network Time Protocol
OID	Object Identifier
OS	Origin Server
PDU	Protocol Data Unit

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PHI	Protected Health Information
PPS	Performed Procedure Step
QIDO-RS	Query based on ID for DICOM Objects by RESTful Services
RTV	Real Time Video
SCP	Service Class Provider
SCU	Service Class User
SDP	Service Description Protocol
SOP	Service-Object Pair
SPS	Scheduled Procedure Step
SR	Structured Reporting
STOW-RS	STore Over the Web by RESTful Services
TCP/IP	Transmission Control Protocol/Internet Protocol
TID	Template Identifier
UA	User Agent
UI	User Interface
UID	Unique Identifier
UL	Upper Layer
UPS	Unified Procedure Step
UPS-RS	Unified Procedure Step by RESTful Services
VR	Value Representation
WADO-RS	Web Access to DICOM Objects by RESTful Services
WADO-URI	Web Access to DICOM Objects by URI

2.6 References

- [1] National Electrical Manufacturers Association (NEMA), Rosslyn, VA USA. *PS3 / ISO 12052 Digital Imaging and Communications in Medicine (DICOM) Standard*. <http://www.dicomstandard.org> .

3 Implementation Model

The product *contextflow ADVANCE Chest CT (version min. 2.0)* is implemented within three major components each of which covering different system requirements: The application frontend is the user-interface implemented as a Web Application, components implementing the AI functionality and the backend, which is responsible for preparing incoming datasets for examination, managing query execution, combining query results and presenting this functionality in an API which is used by the application frontend. The backend is implemented following a micro service architecture, with the DICOM Report Service (DRS) generating DICOM data objects and the Medical Data Gateway (MDG) service providing all DICOM Networking related functionality.

The MDG service has one Application Entity (AE) called CTXFLW, which implements DIMSE C-STORE functionality.

3.1 Application Entities and Data Flow

The network and media interchange application model for the *contextflow ADVANCE Chest CT* is shown in Figure 3-1 *contextflow ADVANCE Chest CT* Application Data Flow Diagram. The arrows represent the DIMSE C-STORE service.

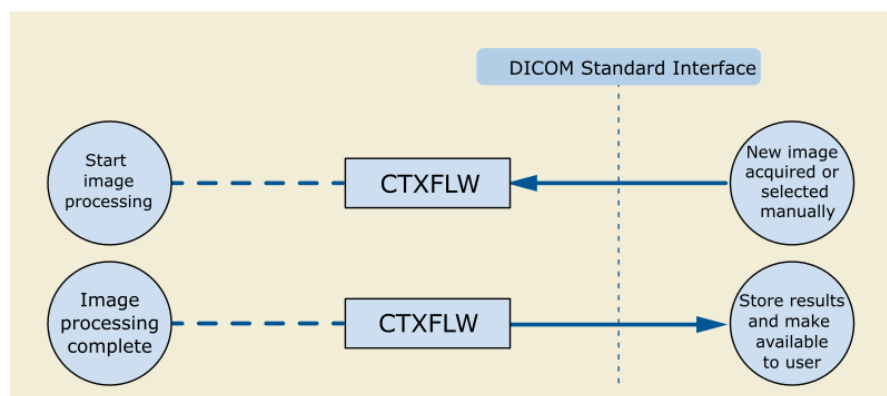


Figure 3-1. contextflow ADVANCE Chest CT Application Data Flow Diagram

3.1.1 Functional Definition of CTXFLW

The sole AE CTXFLW receives CT Images as a DIMSE C-STORE Service Class Provider (SCP) from the customer and sends Secondary Capture, Enhanced SR and Encapsulated PDF DICOM objects as a DIMSE C-STORE Service Class User (SCU) to a configurable customer DIMSE peer (usually the PACS).

4 Service and Interoperability Description

4.1 Mapping of Services to Application Entities

Table 4-1 provides an overview of the Application Entities and the Services supported by each AE.

Table 4-1. Service to AE Mapping

Application Entity	Supported Services	Role								
		DIMSE		DICOM Web		DICOM Media			Real-Time Video	
		SCU	SCP	Origin Server	User Agent	FSC	FSU	FSR	SCU	SCP
CTXFLW	Storage	Y	Y	N	N	N	N	N	N	N

4.2 Supported DIMSE Services

4.2.1 Basic Worklist Management Service N/A

N/A

4.2.2 Modality Performed Procedure Step Service N/A

N/A

4.2.3 Unified Worklist and Procedure Step Service N/A

N/A

4.2.4 Instance Availability Notification Service N/A

N/A

4.2.5 Storage Service

4.2.5.1 SCU of the Storage SOP Classes

As a Service Class User of the Storage Service Class, *contextflow ADVANCE Chest CT* uses the C-STORE-RQ message to request storage of DICOM objects by a remote SCP. See Section 1.1 Content and Transfer in the Overview for the list of supported SOP Classes.

For details regarding the content of SOP Instances that are created by the system, see Section N.9, which describes the underlying IOD of the supported SOP Classes.

The storage requests are triggered automatically as soon as the analysis of a previously received study is complete and the instances containing the results have been generated. These instances are created within new series inside the study that was analyzed.

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4.2.5.1.1 Transcoding of Transfer Syntaxes N/A

N/A

4.2.5.2 SCP of the Storage SOP Classes

As a Service Class Provider of the Storage Service Class, *contextflow ADVANCE Chest CT* receives the C-STORE-RQ message from remote SCUs. See Section 1.1 *Content and Transfer* in the *Overview* for the list of supported SOP Classes.

Table 4-2 defines the conformance levels of *contextflow ADVANCE Chest CT*.

Table 4-2. Levels of Conformance

Levels of Conformance	2
Level of Digital Signature Support	1

contextflow ADVANCE Chest CT does not coerce any Attributes upon receiving them from other systems.

Table 4-3 lists any limitations on displaying or processing instances, e.g., display or processing of the respective SOP Instances is prevented by an unsupported Value for an Attribute or the absence of that Attribute.

The "Effect" column describes what happens if the limitation is encountered. The following Values are used:

- ND: Display is not possible
- LD: Display is limited
- NP: Processing is not possible
- LP: Processing is limited
- OT: Other effects described in the "Comments" column

Table 4-3. Display and Processing Limitations for Storage SCP

Limitation Case			Effect	Comments
Attribute Name	Tag	Value		
CT Image Storage (1.2.840.10008.5.1.4.1.1.2)				
Rows	(0028,0010)	Not: 512	NP	Only 512x512 images can be processed.
Columns	(0028,0011)			
Transfer Syntax UID	(0002,0010)	Not one of: 1.2.840.10008.1.2.4.50 1.2.840.10008.1.2.1 1.2.840.10008.1.2	NP	Only uncompressed or JPEG Baseline images can be processed.

Table 4-4 lists the actions performed upon receiving instances from a remote AE and the system behavior when certain conditions are encountered

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Table 4-4. Behavior when storing Instances

Action upon Receiving	Condition	System Behavior
Attempt to process one series of a study	No further instances from a study were received for a configurable duration.	The system selects one of the received series based on the image dimensions, slice spacing and slice thickness and attempts to process it. If successful, the analysis results for the study are based on this series.
Add series to an existing study	No previously received series was processed successfully.	An attempt is made to process the new series. If successful, the analysis results for the study are based on this series.
Ignore series	A previously received series has been processed successfully.	No action is performed and the analysis results for the study are based on the previously received series.

Table 4-5 describes how the SCP handles compression for stored instances.

The following Values are used in the "Behavior" column:

- AS_IS: Images are stored as received.
- CONFIGURATION: Images are compressed based on internal configuration settings.
- OTHER: All other conditions, which are further described in the "Comments" column.

The Transfer Syntax is used to describe the compression mechanism applied.

Table 4-5. Image Compression by Storage SCP

SOP Class	Behavior	Transfer Syntax		Comments
All SOP Classes	AS_IS			

4.2.6 Storage Commitment Service N/A

N/A

4.2.7 Query/Retrieve Service Class N/A

N/A

4.2.8 Print Management Service N/A

N/A

4.3 Supported DICOM Web Services N/A

N/A

4.4 Media Service N/A

N/A

4.5 Real Time Video Service N/A

N/A

4.6 Cross Service Considerations N/A

N/A

4.7 Specific Character Sets

For Specific Character Sets supported in addition to the default character repertoire, refer to Section 1.7 for the Values for Specific Character Set (0008,0005).

5 Configuration

The system is configured entirely based on configuration files that are managed by contextflow operators.

Throughout all subsections the following Values can be used in the "Configurable" column:

- USER: The parameter is configurable by the user.
- SERVICE: The parameter is configurable by service personnel.
- FIXED: The parameter is not configurable (it has a fixed Value). The Value is required for the configuration of the remote system.
- N/A: The parameter is not applicable for the local or the remote system.

5.1 General Configuration Parameters

Table 5-1 lists general configuration parameters applicable across all supported DICOM Services.

Table 5-1. General Configuration Parameters

Parameter	Configurable	Default Value	Comments
Max PDU	NO	16384	
Timeout waiting for instances before a study is considered complete	SERVICE	20 seconds	

5.2 Configuration of DIMSE Services

The tables in the following subsections show the configuration parameters required for DIMSE Services. In order to identify whether contextflow DETECT Lung CT is an SCP and / or an SCU, the following applies:

- SCP: The (Secured) Local Called AET and Remote Calling AET parameters are present.
- SCU: The (Secured) Local Calling AET and Remote Called AET parameters are present.

5.2.1 Basic Worklist Management Service Configuration N/A

N/A

5.2.2 Modality Performed Procedure Step Service Configuration N/A

N/A

5.2.3 Unified Worklist and Procedure Step Service Configuration N/A

N/A

5.2.4 Instance Availability Notification Service Configuration N/A

N/A

5.2.5 Storage Service Configuration

Table 5-2 lists Storage Service configuration parameters:

Table 5-2. Storage Service Parameters

Local Configuration Parameters - Storage Service			
Parameter	Configurable	Default Value	Comments
Calling AE Title (SCU)	SERVICE	CTXFLW	
Called AE Title (SCP)	SERVICE	CTXFLW	
Port high priority	SERVICE	1104	
Port low priority	SERVICE	1105	Data received over the low priority port is only processed when no high priority data is available
Supported Transfer Syntax as SCP	FIXED	See Table 1-2	
Supported storage SOP classes as SCP	FIXED	See Table 1-1	

5.2.6 Storage Commitment Service Configuration N/A

N/A

5.2.7 Query/Retrieve Service Configuration N/A

N/A

5.2.8 Print Management Service Configuration N/A

N/A

5.3 Configuration of DICOM Web Services N/A

N/A

5.4 Configuration of Media Storage Service N/A

N/A

5.5 Configuration of Real Time Video Service N/A

N/A

5.6 Configuration of Audit Trail - Syslog N/A

N/A

6 Network and Media Communication Details

6.1 General

Since there is only one AE, there are no cross interactions. The real world activities of the AE CTXFLW are depicted in the diagram below.

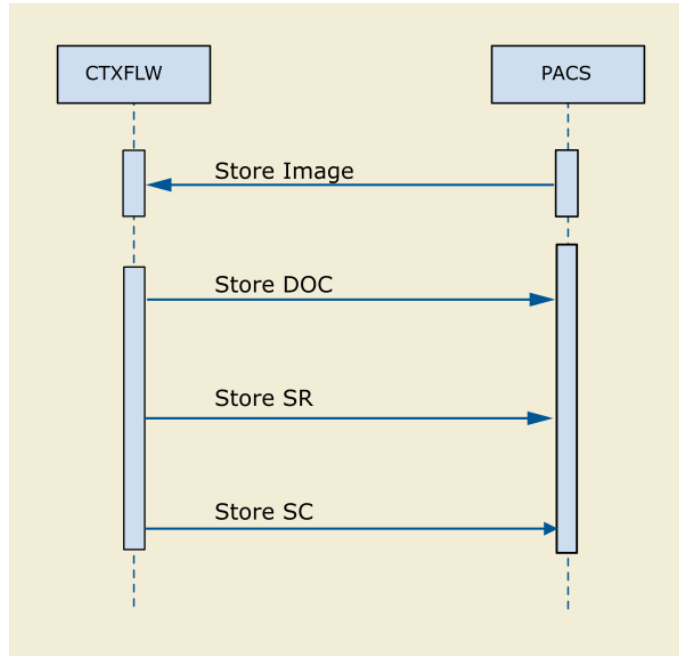


Figure 6-1. Real-World Activity

7 Security

7.1 Introduction

The security section describes security features implemented by this product. It includes descriptions of non-DICOM network protocols, information to configure firewalls and application whitelists, lists of supported DICOM security profiles as well as Web Security features. Additionally, secured media storage, VPN, etc. are also specified in this security section.

7.2 External Network Requirements N/A

N/A

7.3 TCP Port Configuration

See Section 5 *Configuration* for information on the usage of ports for DICOM and other protocols. This section contains helpful information for product administrators to configure firewalls, application whitelists, etc.

The system requires the following open ports for inbound connections:

- 22 (SSH)
- 80 (HTTP)
- 443 (HTTPS)
- 1104 (DIMSE)

7.4 DICOM Security Profiles Support

7.4.1 Secure Use and User Identity Profiles N/A

N/A

7.4.2 Secure Transport Connection Profiles N/A

N/A

7.4.3 Media Storage Security Profiles N/A

N/A

7.4.4 Attribute Confidentiality Profiles N/A

N/A

7.4.5 Digital Signature Profiles N/A

N/A

7.4.6 Additional DICOM Security Profiles N/A

N/A

7.5 User Identity Negotiation Support N/A

N/A

7.6 Web Services Security Features

- Audit control mechanism used
User interaction With PHI related datasets is logged for audit purpose.
- Personal authentication mechanisms
User access is granted by user name and password authentication. Additionally a trusted external component (usually the PACS) can implement a token URL generation which authenticates the user without the need to provide username and password.
- Certification management tools and process
TLS certificates must be provided by the client since the system is generally installed within the clients network.

7.7 Other Security Features

7.7.1 Media Storage Security N/A

N/A

7.7.2 Network Security

It is the responsibility of the client who owns the network our system operates in provide or allow Network Security components.

Annex A Information Object Definitions (IODs)

This section describes all the SOP Instances natively created by *contextflow ADVANCE Chest CT*, i.e., all SOP Classes that are marked in the "Created" column in Table 1-1.

In the "Source" column, the following Values can be used:

- **FIXED:** The Value is pre-defined and cannot be modified.
- **GENERATED:** The Value is generated by the system.
- **CONFIGURATION:** The Value is copied from the system configuration.
- **MWL:** The Value is copied from a Modality Worklist entry.
- **QUERY:** The Value is determined by performing a query of any of the supported Query/Retrieve Services.
- **USER:** The Value is entered by the user.
- **SCANNED:** The Value is read from a barcode scanner or similar device.
- **EMPTY:** The Attribute is sent with a zero-length Value.
- **SRC_INSTANCE:** The Value is copied from previously created/received SOP Instances.

The "Presence" columns reflect the usage of the Module, Functional Group Macro, Attributes, or Value in the *contextflow ADVANCE Chest CT* Implementation and is not necessarily the same as defined in the DICOM Standard. For the "Presence" column the following Values can be used:

- **ALWAYS:** the module, functional group macro, Attributes or Value is always present.
- **CONDITIONAL:** the presence of the module, functional group macro, Attributes or Value is dependent on a condition. The condition must be listed in the "Conditions" column.
- **SRC_COPY:** The presence of the Attributes and Values depends on the availability of these in the source instances, which are used for copying this information.
- **EMPTY:** The Attribute is present but without a Value (zero length).

A.1 Information Shared Across Multiple IODs

A.1.1 Common Modules

All SOP Instances generated by the system use the common modules listed in Table A-1 to Table A-10 or a subset of them, as defined in the IOD specific subsections below.

Table A-1. Patient Module

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Patient's Name	(0010,0010)	SRC_INSTANCE	ALWAYS	SRC_COPY			
Patient ID	(0010,0020)	SRC_INSTANCE	ALWAYS	ALWAYS			
Patient's Birth Date	(0010,0030)	SRC_INSTANCE	ALWAYS	SRC_COPY			
Patient's Sex	(0010,0040)	SRC_INSTANCE	ALWAYS	SRC_COPY			

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Table A-2. General Study Module

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Study Instance UID	(0018,000D)	SRC_INSTANCE	ALWAYS	ALWAYS			
Study Date	(0008,0020)	SRC_INSTANCE	ALWAYS	SRC_COPY			
Study Time	(0008,0030)	SRC_INSTANCE	ALWAYS	SRC_COPY			
Referring Physician's Name	(0008,0090)	SRC_INSTANCE	ALWAYS	SRC_COPY			
Study ID	(0020,0010)	SRC_INSTANCE	ALWAYS	SRC_COPY			
Accession Number	(0008,0050)	SRC_INSTANCE	ALWAYS	SRC_COPY			

Table A-3. General Series Module

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Modality	(0008,0060)	FIXED	ALWAYS	ALWAYS	CT, SR, DOC		Value fixed for each IOD
Series Instance UID	(0020,000E)	GENERATED	ALWAYS	ALWAYS			
Series Number	(0020,0011)	FIXED	ALWAYS	ALWAYS	11335		
Series Description	(0008,103E)	CONFIGURATION	ALWAYS	ALWAYS	See A.2 - A.3		Value configured for each IOD

Table A-4. Frame of Reference Module

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Frame of Reference UID	0020,0052)	SRC_INSTANCE	ALWAYS	SRC_COPY			

Table A-5. General Equipment Module

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Manufacturer	(0008,0070)	FIXED	ALWAYS	NEVER			

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Table A-6. General Image Module

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Comments
Instance Number	(0020,0013)	GENERATED	ALWAYS	ALWAYS	1, ..., n	The i-th instance in a series has instance number i.

Table A-7. Image Pixel Module

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Samples per Pixel	(0028,0002)	FIXED	ALWAYS	ALWAYS	3		
Photometric Interpretation	(0028,0004)	FIXED	ALWAYS	ALWAYS	YBR_FULL_422		
Planar Configuration	(0028,0006)	FIXED	ALWAYS	ALWAYS	0		
Rows	(0028,0010)	GENERATED	ALWAYS	ALWAYS			Image dimensions depend on the number of analyzed patterns
Columns	(0028,0011)						
Bits Allocated	(0028,0100)	FIXED	ALWAYS	ALWAYS	8		
Bits Stored	(0028,0101)	FIXED	ALWAYS	ALWAYS	8		
High Bit	(0028,0102)	FIXED	ALWAYS	ALWAYS	7		
Pixel representation	(0028,0103)	FIXED	ALWAYS	ALWAYS	0		

Table A-8. Multi-Frame Functional Groups Module

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Shared Functional Groups Sequence	(5200,9229)	FIXED	ALWAYS	ALWAYS			
>Plane Orientation Sequence	(0020,9116)	FIXED	ALWAYS	ALWAYS			
>>Image Orientation (Patient)	(0020,0037)	SRC_INSTANCE	ALWAYS	ALWAYS			

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Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Per-frame Functional Groups Sequence	(5200,9230)	FIXED	ALWAYS	ALWAYS			
>Plane Position Sequence	(0020,9113)	FIXED	ALWAYS	ALWAYS			
>>Image Position (Patient)	(0020,0032)	SRC_INSTANCE	ALWAYS	ALWAYS			

Table A-9. Multi-Frame Dimension Module

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Dimension Organization Sequence	(0020,9221)	GENERATED	ALWAYS	ALWAYS			
>Dimension Organization UID	(0020,9164)	GENERATED	ALWAYS	ALWAYS			
Dimension Index Sequence	(0020,9222)	FIXED	ALWAYS	ALWAYS			
>Dimension Index Pointer	(0020,9165)	FIXED	ALWAYS	ALWAYS	0020,0032		
>Functional Group Pointer	(0020,9167)	FIXED	ALWAYS	ALWAYS	5200,9230		

Table A-10. SOP Common Module

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Specific Character Set	(0008,0005)	FIXED	ALWAYS	ALWAYS	ISO_IR 192		
SOP Class UID	(0008,0016)	FIXED	ALWAYS	ALWAYS			Value matches SOP Class of generated object
SOP Instance UID	(0008,0018)	GENERATED	ALWAYS	ALWAYS			
Instance Creation Date	(0008,0012)	GENERATED	ALWAYS	ALWAYS			
Instance Creation Time	(0008,0013)	GENERATED	ALWAYS	ALWAYS			

A.1.2 Common Functional Group Macros N/A

N/A

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A.1.3 Common Private Modules N/A

N/A

A.1.4 Coded Values

Table A-11 lists Coded Values referenced from the "Value" column of the tables above.

Table A-11. Values and Code Sets shared across IODs

Attribute Name	Tag	Value/Code	Condition	Comments
Specific Character Set	(0008,0005)	ISO_IR 192	Unicode in UTF-8	
Photometric Interpretation	(0028,0004)	YBR_FULL_422	JPEG compressed Images	

A.2 Multi-frame True Color Secondary Capture Image IOD

Table A-12 defines the structure of Multi-frame True Color Secondary Capture Image IOD.

Table A-12. Multi-frame True Color Secondary Capture Image IOD

IE	Module Name	Presence (Module)	Condition	Reference
Patient	Patient Module	ALWAYS		Table A-1
Study	General Study Module	ALWAYS		Table A-2
Series	General Series Module	ALWAYS		Table A-3
Frame Of Reference	Frame of Reference	ALWAYS		Table A-4
Equipment	General Equipment Module	ALWAYS		Table A-5
	SC Equipment	ALWAYS		Table A-13
Image	General Image Module	ALWAYS		Table A-6
	Image Pixel Module	ALWAYS		Table A-7
	Multi Frame Module	ALWAYS		Table A-16
	Multi-Frame Dimension Module	ALWAYS		Table A-9
	Multi-Frame Functional Groups Module	ALWAYS		Table A-8
	SC Multi-frame Image	ALWAYS		Table A-14
	SC Multi-frame Vector	ALWAYS		Table A-15

A.2.1 Multi-frame True Color Secondary Capture Image IOD Specific Modules

The following tables list Modules and Attributes specific for Multi-frame True Color Secondary Capture Image IOD.

Table A-13. SC Equipment Module for Multi-frame True Color Secondary Capture Image IOD

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Modality	(0008,0060)	FIXED	ALWAYS	ALWAYS	CT		
Conversion Type	(0008,0064)	FIXED	ALWAYS	ALWAYS	WSD		

Table A-14. SC Multi-frame Image Module for Multi-frame True Color Secondary Capture Image IOD

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Frame Increment Pointer	(0028,0009)	FIXED	ALWAYS	ALWAYS	0018,2005		
Pixel Spacing	(0028,0030)	SRC_INCREMENTANCE	ALWAYS	ALWAYS			
Burned In Annotation	(0028,0301)	FIXED	ALWAYS	ALWAYS	NO		

Table A-15. SC Multi-frame Vector Module for Multi-frame True Color Secondary Capture Image IOD

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Slice Location Vector	(0018,2005)	GENERATED	ALWAYS	ALWAYS			

Table A-16. Multi-frame Module for Multi-frame True Color Secondary Capture Image IOD

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Number of Frames	(0028,0008)	GENERATED	ALWAYS	ALWAYS			
Frame Increment Pointer	(0028,0009)	GENERATED	ALWAYS	ALWAYS			

A.2.2 Multi-frame True Color Secondary Capture Image IOD Coded Values

Table A-17 lists Coded Values referenced from the "Value" column of the tables above for Multi-frame True Color Secondary Capture Image IOD:

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Table A-17. Values and Code Sets for Multi-frame True Color Secondary Capture Image IOD

Attribute Name	Tag	Value/Code	Condition	Comments
Conversion Type	(0008,0064)	WSD	Workstation	

A.3. Encapsulated PDF IOD

Table A-18 defines the structure of Encapsulated PDF IOD.

Table A-18. Encapsulated PDF IOD

IE	Module Name	Presence (Module)	Condition	Reference
Patient	Patient Module	ALWAYS		Table A-1
Study	General Study Module	ALWAYS		Table A-2
Series	Encapsulated Document Series Module	ALWAYS		Table A-19
Equipment	General Equipment Module	ALWAYS		Table A-5
	SC Equipment	ALWAYS		Table A-13
Encapsulated Document	Encapsulated Document Module	ALWAYS		Table A-20
	SOP Common Module	ALWAYS		Table A-10

A.3.1 Encapsulated PDF IOD Specific Modules

The tables below list Modules and Attributes used in Encapsulated PDF IOD:

Table A-19. Encapsulated Document Series Module used in Encapsulated PDF IOD

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Modality	(0008,0060)	FIXED	ALWAYS	ALWAYS	DOC		
Series Instance UID	(0020,000E)	GENERATED	ALWAYS	ALWAYS			
Series Number	(0020,0011)	FIXED	ALWAYS	ALWAYS	11335		
Series Description	(0008,103E)	CONFIGURATION	ALWAYS	ALWAYS	contextflow ADVANCE Chest CT - Insights PDF Report		

Table A-20. Encapsulated Document General Module used in Encapsulated PDF IOD

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Instance Number	(0020,0013)	FIXED	ALWAYS	ALWAYS	1		
Content Date	(0008,0023)	GENERATED	ALWAYS	ALWAYS	Current date		

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Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Content Time	(0008,0033)	GENERATED	ALWAYS	NEVER	empty		
Acquisition DateTime	(0008,002A)	SRC_INSTANCE	ALWAYS	NEVER	empty		
Burned In Annotation	(0028,0301)	FIXED	ALWAYS	ALWAYS	YES		
Document Title	(0042,0010)	FIXED	ALWAYS	ALWAYS	contextflow ADVANCE Chest CT - Insights PDF Report		
Concept Name Code Sequence	(0040,A043)	FIXED	ALWAYS	NEVER	empty		
MIME Type of Encapsulated Document	(0042,0012)	FIXED	ALWAYS	ALWAYS	application/pdf		
Encapsulated Document	(0042,0011)	GENERATED	ALWAYS	ALWAYS			

A.4. Enhanced SR IOD

Table A-21 defines the structure of Enhanced SR IOD.

Table A-21. Enhanced SR IOD

IE	Module Name	Presence (Module)	Condition	Reference
Patient	Patient Module	ALWAYS		Table A-1
Study	General Study Module	ALWAYS		Table A-2
Series	SR Document Series Module	ALWAYS		Table A-22
Equipment	General Equipment Module	ALWAYS		Table A-5
Document	SR Document General Module	ALWAYS		Table A-23
	SR Document Content	ALWAYS		Table A-24
	SOP Common Module	ALWAYS		Table A-10

A.4.1 Enhanced SR IOD Specific Modules

The tables below list Modules and Attributes used in Enhanced SR IOD:

Table A-22. SR Document Series Module used in Enhanced SR IOD

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Modality	(0008,0060)	FIXED		ALWAYS	SR		

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Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Referenced Performed Procedure Step Sequence	(0008,1111)	FIXED	ALWAYS	NEVER	empty		
Series Instance UID	(0020,000E)	GENERATED	ALWAYS	ALWAYS			
Series Number	(0020,0011)	FIXED	ALWAYS	ALWAYS	11335		

Table A-23. SR Document General Module used in Enhanced SR IOD

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Instance Number	(0020,0013)	FIXED	ALWAYS	ALWAYS	1		
Completion Flag	(0040,A491)	FIXED	ALWAYS	ALWAYS	COMPLETE		
Verification Flag	(0040,A493)	FIXED	ALWAYS	ALWAYS	UNVERIFIED		
Content Date	(0008,0023)	GENERATED	ALWAYS	ALWAYS	Current date		
Content Time	(0008,0033)	GENERATED	ALWAYS	ALWAYS	Current time		

Table A-24. SR Document Content Module used in Enhanced SR IOD

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Value Type	(0040,A040)	FIXED	ALWAYS	ALWAYS	CONTAINER		
Continuity of Content	(0040,A050)	FIXED	ALWAYS	ALWAYS	SEPARATE		
Content Template Sequence	(0040,A504)	FIXED	CONDITION	ALWAYS	See Annex B for encoding on supported TIDs	Present if the object follows a template	
Content Sequence	(0040,A730)	GENERATED	ALWAYS	ALWAYS			

Annex B Structured Report Content Encoding

This section provides the detailed content encoding for all TIDs supported by *contextflow ADVANCE Chest CT*.

Throughout the tables listed in Section N.10 the following codes are used for the "Source" and "Presence of Content Item" columns.

In the "Source" column, the following Values can be used:

- **FIXED:** The Value is pre-defined and cannot be modified.
- **GENERATED:** The Value is generated by the system.
- **CONFIGURATION:** The Value is copied from the system configuration.
- **MWL:** The Value is copied from a Modality Worklist entry.
- **QUERY:** The Value is determined by performing a query of any of the supported Query/Retrieve Services.
- **USER:** The Value is entered by the user.
- **SCANNED:** The Value is read from a barcode scanner or similar device.
- **EMPTY:** The Attribute is sent with a zero-length Value.
- **SRC_INSTANCE:** The Value is copied from previously created/received SOP Instances.

In the "Presence of Content Item" the following Values can be used:

- **ALWAYS:** the module, functional group macro, Attributes or Value is always present.
- **CONDITIONAL:** the presence of the the module, functional group macro, Attributes or Value is dependent on a condition. The condition must be listed in the "Comments" column.
- **SRC_COPY:** The presence of the Attributes and Values depends on the availability of these in the source instances, which are used for copying this information.
- **EMPTY:** The Attribute is present but without a Value (zero length).

B.1 Nodule Detection SR (TID 1500)

Table B-1 shows the encoding of content of a Nodule Detection SR (TID 1500).

Table B-1. Nodule Detection SR (TID 1500)

NL	Rel with Parent	VT	Concept Name	Source	Presence of Content Item	Values	TID	Comments
		CONTAINER	(126000,DCM,"Imaging Measurement Report")		ALWAYS		1500	
>	HAS OBS CONTEXT	CODE	(121005,DCM,"Observer Type")	FIXED	ALWAYS	(121007,DCM,"Device")		
>	HAS OBS CONTEXT	TEXT	(121014,DCM,"Device Observer Manufacturer")	FIXED	ALWAYS	contextflow GmbH		

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NL	Rel with Parent	VT	Concept Name	Source	Presence of Content Item	Values	TID	Comments
>	HAS OBS CONTEXT	TEXT	(121015,DCM,"Device Observer Model Name")	FIXED	ALWAYS	contextflow ADVANCE Chest CT		
>	CONTAINS	CONTAINER	(126010,DCM,"Imaging Measurements")		ALWAYS			
>>	HAS CONCEPT MOD	TEXT	(111001,DCM,"Algorithm Name")	FIXED	ALWAYS	contextflow ADVANCE Chest CT		
>>	HAS CONCEPT MOD	TEXT	(111001,DCM,"Algorithm Version")	FIXED	ALWAYS			
>>	HAS CONCEPT MOD	TEXT	(111001,DCM,"Algorithm Parameters")	FIXED	ALWAYS			
>>	CONTAINS	CONTAINER	(125007,DCM,"Measurement Group")		ALWAYS		1411	Multiple entries can be present
>>>	HAS OBS CONTEXT	TEXT	(112039,DCM,"Tracking Identifier")	GENERATED	ALWAYS			
>>>	HAS OBS CONTEXT	UIDREF	(112040,DCM,"Tracking Unique Identifier")	GENERATED	ALWAYS			
>>>	CONTAINS	CODE	(121071,DCM,"Finding")	FIXED	ALWAYS	(27925004, SCT,"Nodule")		
>>>	CONTAINS	SCoord	(111030,DCM,"Image Region")	GENERATED	ALWAYS	POINT{X,Y}		
>>>>	SELECTED FROM	IMAGE	(260753009,SCT,"Source")	SRC_INSTANCE	ALWAYS	Source SOP Instance UID		
>>>	CONTAINS	NUM	(103340004,SCT,"Short Axis")	GENERATED	ALWAYS	X (mm,UCUM,"millimeter")		
>>>>	INFERRED FROM	SCoord	(121055,DCM,"Path")	GENERATED	ALWAYS	POLYLINE {X1,Y1,X2,Y2}		
>>>>>	SELECTED FROM	IMAGE	(260753009,SCT,"Source")	SRC_INSTANCE	ALWAYS	Source SOP Instance UID		
>>>	CONTAINS	NUM	(103339001,SCT,"Long Axis")	GENERATED	ALWAYS	X (mm,UCUM,"millimeter")		
>>>>	INFERRED FROM	SCoord	(121055,DCM,"Path")	GENERATED	ALWAYS	POLYLINE {X1,Y1,X2,Y2}		
>>>>>	SELECTED FROM	IMAGE	(260753009,SCT,"Source")	SRC_INSTANCE	ALWAYS	Source SOP Instance UID		

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NL	Rel with Parent	VT	Concept Name	Source	Presence of Content Item	Values	TID	Comments
>>>	CONTAINS	NUM	(YEKZ,IBSI,"Volume from Voxel Summation")	GENERATED	ALWAYS	X (mm3,UCUM,"cubic millimeter")		

B.1.1 Code Sets

The following tables list specific code sets referenced from the Nodule Detection SR (TID 1500).

Table B-2. Nodule Detection SR Codes

Coding Scheme Designator	Code Value	Code Meaning
DCM	126000	Imaging Measurement Report
DCM	121007	Device
DCM	121005	Observer Type
DCM	121014	Device Observer Manufacturer
DCM	121015	Device Observer Model Name
DCM	126010	Imaging Measurements
DCM	111001	Algorithm Name
DCM	111003	Algorithm Version
DCM	111002	Algorithm Parameters
DCM	125007	Measurement Group
DCM	112039	Tracking Identifier
DCM	112040	Tracking Unique Identifier
DCM	121071	Finding
SCT	27925004	Nodule
DCM	111030	Image Region
SCT	260753009	Source
SCT	103339001	Long Axis
UCUM	mm	millimeter
DCM	121055	Path
SCT	103340004	Short Axis
YEKZ	IBSI	Volume from Voxel Summation
UCUM	mm3	cubic millimeter

Annex C Security Details N/A

N/A

Annex D Mapping of Attributes N/A

N/A

Annex E Code Set Usage N/A

N/A