

DICOM CONFORMANCE STATEMENT

SIMPLEWARE MEDICAL SYNOPSYS (NORTHERN EUROPE) LTD BRADNINCH HALL, CASTLE STREET EXETER, DEVON, EX4 3PL, UK

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1 Conformance Statement Overview

Simpleware provides an image processing software environment for converting 3D scan data (MRI, CT, micro-CT, FIB-SEM...) into computational models. The application supports searching for and loading DICOM images from a local file system or remote file server. Anonymisation options may be performed on DICOM metadata in conformance with the basic confidentiality profile outlined by the DICOM standard. A DICOM export feature allows a range of images to be saved to the local file system; this includes metadata from previously imported data. Single-frame grayscale image files may also be loaded and displayed. Additionally, a surface object can be encapsulated and exported as a DICOM file, with the active background metadata embedded into the exported file.

SOP Classes	User of Service (SCU)	Provider of Service (SCP)	
Transfer			
CT Image Storage	Yes	Yes	
Enhanced CT Image Storage	Yes	Yes	
MR Image Storage	Yes	Yes	
Enhanced MR Image Storage	Yes	Yes	
Secondary Capture Image Storage	Yes	Yes	
NM Image Storage	Yes	Yes	
Encapsulated STL Storage	Yes	Yes	
Encapsulated OBJ Storage	Yes	Yes	
Query/Retrieve			
Study Root Query/Retrieve Information Model – FIND	Yes	No	
Study Root Query/Retrieve Information Model – MOVE	Yes	No	
Study Root Query/Retrieve Information Model – GET	Yes	No	
Receipt of Images – STORE	No	Yes	
Verification			
Verification – ECHO	Yes	No	

1.1 Network Services

1.2 Media Services

Media Storage Application Profile	Write Files (FSC or FSU)	Read Files (FSR)	
Compact Disk - Recordable			
General Purpose CD-R	FSU Yes (excluding DICOMDIR)	Yes	
DVD			
General Purpose DVD-RAM	FSU Yes (excluding DICOMDIR)	Yes	
USB			
General Purpose USB Media Interchange	FSU Yes (excluding DICOMDIR)	Yes	

1.3 Supported Image SOP Classes

Name	UID
CT Image Storage	1.2.840.10008.5.1.4.1.1.2
Enhanced CT Image Storage	1.2.840.10008.5.1.4.1.1.2.1
MR Image Storage	1.2.840.10008.5.1.4.1.1.4
Enhanced MR Image Storage	1.2.840.10008.5.1.4.1.1.4.1
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7
NM Image Storage	1.2.840.10008.5.1.4.1.1.20
Encapsulated STL Storage	1.2.840.10008.5.1.4.1.1.104.3
Encapsulated OBJ Storage	1.2.840.10008.5.1.4.1.1.104.4

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3 Introduction

3.1 Audience

This document is written for people who need to understand what types of DICOM files and services Simpleware is compatible with. This includes both those responsible for overall imaging network policy and architecture, as well as integrators who must have a detailed understanding of the DICOM features of Simpleware. 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.

3.2 Remarks

The scope of this DICOM Conformance Statement is to facilitate integration between Simpleware 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 supposed 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 DICOM equipment, as established by the healthcare facility.

3.3 Terms and Definitions

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

Application Entity (AE)	A user or provider of one of more DICOM services. Simpleware can act as an Application Entity.
File-Set Creator (FSC) File-Set Reader (FSR) File-Set Updater (FSU)	A creator/reader/updater of DICOMDIR and DICOM files.
Information Object Definition (IOD)	An object-oriented abstract data model used to define the structure of specific types of DICOM files, for example, the structure of a DICOM file containing an MRI image.

PACS server	A Picture archiving and communication system server used for the
	storage and retrieval of DICOM images.
Service Class User (SCU)	An Application Entity that uses a service (a client).
Service Class Provider (SCP)	An Application Entity which provides a service (a server).
Service/Object Pair Class	An IOD and the operations that are applicable to it.
(SOP Class)	
Service/Object Pair Instance	An instance of an IOD pertaining to a SOP Class, for example, a specific
(SOP Instance)	MRI image.
Transport Layer Security	A cryptographic protocol designed to provide communications
(TLS)	security over a computer network.

3.4 Basics of DICOM Communication

This section describes terminology used in this Conformance Statement for the non-specialist. The key terms used in the Conformance Statement are highlighted in italics below. 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 a number of 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 *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).

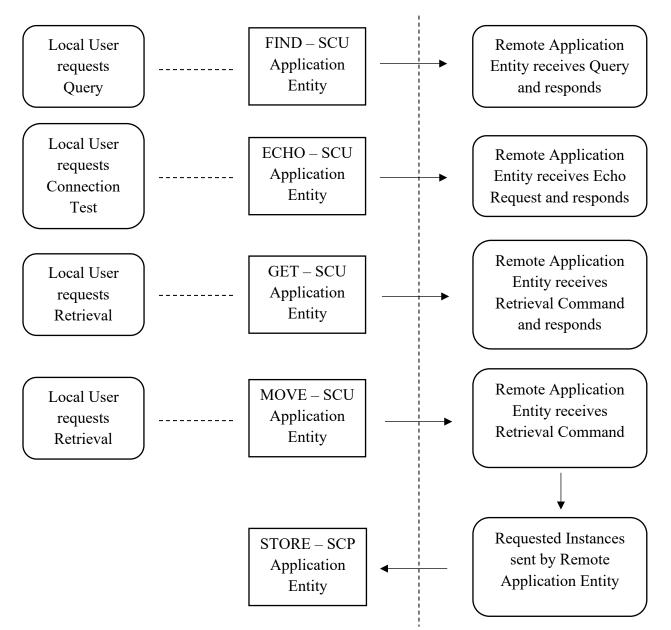
The Application Entities, having negotiated the Association parameters, may now commence exchanging data. Common data exchanges include queries for worklists and lists of stored images, transfer of image objects and analyses (structured reports), and sending images to film printers. Each exchangeable 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.

4 Networking

4.1 Implementation Model

4.1.1 Application Data Flow Diagram



DICOM Standard Interface

Simpleware is a single application that provides both a user interface and network communication (spawning additional threads as necessary to handle incoming connections), as well as media support.

Conceptually the network services may be modelled as the following separate AEs, though in fact all the AEs share a single (configurable) AE Title:

- FIND SCU, which sends queries and listens for a response.
- ECHO SCU, which sends echo requests and listens for a response.
- GET SCU, which retrieves studies to a temporary operating system directory.
- MOVE SCU, which requests the transfer of studies and waits for the remote system to initiate the transfer.
- STORE SCP, which accepts studies, as requested by MOVE SCU, and stores them in a temporary operating system directory.
- MOVE SCP, which initiates transfers of studies to a remote PACS server.

4.1.2 **Functional Definitions of AEs**

4.1.2.1 FIND – SCU

FIND – SCU is activated through the user interface when the user initiates a search in the PACS import wizard. Search terms include Modalities, Study date (range) and a free-form text field for matches to Patient Name, Patient ID, Accession Number or Study Description.

4.1.2.2 ECHO – SCU

ECHO – SCU is activated by the user when they want to test a connection to a PACS server.

4.1.2.3 GET – SCU

GET – SCU is activated when the user selects a study to download (previously identified by FIND – SCU) from a PACS server configured to use the C-GET protocol.

4.1.2.4 MOVE – SCU

MOVE – SCU is activated when the user selects a study to download (previously identified by FIND – SCU) from a PACS server configured to use the C-MOVE protocol.

4.1.2.5 STORE – SCP

STORE – SCP is activated when a remote server initiates the transfer of a study via the C-MOVE protocol in response to a request made by MOVE – SCU.

4.1.2.6 MOVE – SCP

MOVE – SCP is activated when the user selects a background to export to a PACS server.

4.1.3 Sequencing of Real-World Activities

All activities are sequentially initiated in the user interface, and another activity may not be initiated until the prior activity has completed.

4.2 AE Specifications

4.2.1 **FIND – SCU**

4.2.1.1 SOP Classes

This Application Entity provides Standard Conformance to the following SOP Class:

SOP Class Name	SOP Class UID	SCU	SCP
Study Root Query/Retrieve Information Model - FIND	1.2.840.10008.5.1.4.1.2.2.1	Yes	No

4.2.1.2 Association Policies

4.2.1.2.1 <u>General</u>

FIND-SCU initiates but never accepts associations.

4.2.1.2.2 Number of Associations

Number of Associations as an Association Initiator for FIND – SCU:

Maximum number of simultaneous associations	1
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4.2.1.2.3 Asynchronous Nature

FIND-SCU will only allow a single outstanding operation on an Association. Therefore, FIND-SCU will not perform asynchronous operations window negotiation.

4.2.1.2.4 Implementation Identifying Information

Implementation Class UID	1.2.276.0.7230010.3.0.3.6.6
Implementation Version Name	OFFIS_DCMTK_366

4.2.1.3 Association Initiation Policy

FIND-SCU attempts to initiate a new association when the user performs the query action from the user interface. If this involves recursive queries for lower query levels in the hierarchy, these will be performed on the same association.

4.2.1.3.1 Activity - Query Remote AE

4.2.1.3.1.1 Description and Sequencing of Activities

A single attempt will be made to query the remote AE. If the query fails, for whatever reason, no retry will be performed.

4.2.1.3.1.2 Proposed Presentation Contexts

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended
Name	UID	Name	UID List		Negotiation
		List			
Study Root	1.2.840.10008.5.1.4.1.2.2.1	Implicit	1.2.840.10008.1.2	SCU	None
Query/Retrieve		VR Little			
Information		Endian			
Model - FIND		Evolicit	1.2.840.10008.1.2.1		
		Explicit	1.2.840.10008.1.2.1		
		VR Little			
		Endian			
		Explicit	1.2.840.10008.1.2.2		
		VR Big			
		Endian			

4.2.1.3.1.3 SOP Specific Conformance

4.2.1.3.1.3.1 SOP Specific Conformance to C-FIND SOP Classes

FIND-SCU provides standard conformance to the supported C-FIND SOP Classes.

Only a single information model, Study Root, is supported.

All queries are initiated at the highest level of the information model (the STUDY level), and then for each response received, repeated at the next lower level (the SERIES level).

The following identifiers are supported in FIND – SCU queries:

Name	Тад	Types of Matching
Query Retrieve Level	(0008,0052)	"STUDY" or "SERIES"
STUDY Level		
Study Instance UID	(0020,000D)	Empty. For SCP to populate.
Patient's Birth Date	(0010, 0030)	Empty. For SCP to populate.
Study Time	(0008, 0030)	Empty. For SCP to populate.
Study Date	(0008,0020)	Date range
Patient's Name	(0010,0010)	Free-form string with wildcards
Patient's ID	(0010,0020)	Free-form string with wildcards
Accession Number	(0008,0050)	Free-form string with wildcards
Study Description	(0008,1030)	Free-form string with wildcards
Modalities in Study	(0008,0061)	If all available modalities are checked, this is
		left empty; else it contains the required
		modalities as a string. Modalities are
		separated with a '\' character.
SERIES Level		
Study Instance UID	(0020,000D)	A series is matched if it belongs to the
		queried study.
Series Instance UID	(0020, 000E)	Empty. For SCP to populate.
Series Date	(0008, 0021)	Empty. For SCP to populate.
Series Time	(0008, 0031)	Empty. For SCP to populate.

Name	Tag	Types of Matching
Series Description	(0008, 103E)	Empty. For SCP to populate.
Number of Series Related Instances	(0020, 1209)	Empty. For SCP to populate.
Modality	(0008,0060)	Empty. For SCP to populate. If the returned
		value is not a supported modality, then this
		field will appear blank in the user interface.

4.2.1.3.1.3.2 Supported Modalities

The following modalities are supported for search purposes:

СТ	Computed tomography
MR	Magnetic resonance
CR	Computed radiography
DX	Digital radiography
ES	Endoscopy
10	Intra-oral radiography
M3D	3D manufacturing model
MG	Mammography
NM	Nuclear medicine
OCT	Optical coherence tomography
PR	Presentation State
PT	Positron emission tomography
РХ	Panoramic X-ray
RF	Radio fluoroscopy
RG	Radiographic imaging
SR	SR document
US	Ultrasound
ХА	X-ray angiography
XC	External-camera photography
ОТ	Other

4.2.2 ECHO – SCU

4.2.2.1 SOP Classes

This Application Entity provides Standard Conformance to the following SOP Class:

SOP Class Name	SOP Class UID	SCU	SCP
Verification SOP Class	1.2.840.10008.1.1	Yes	No

4.2.2.2 Association Policies

4.2.2.2.1 <u>General</u>

ECHO-SCU initiates but never accepts associations.

4.2.2.2.2 Number of Associations

Number of Associations as an Association Initiator for ECHO – SCU:

Maximum number of simultaneous associations 1

4.2.2.2.3 Asynchronous Nature

ECHO-SCU will only allow a single outstanding operation on an Association. Therefore, ECHO-SCU will not perform asynchronous operations window negotiation.

4.2.2.2.4 Implementation Identifying Information

Implementation Class UID	1.2.276.0.7230010.3.0.3.6.6
Implementation Version Name	OFFIS_DCMTK_366

4.2.2.3 Association Initiation Policy

ECHO-SCU attempts to initiate a new association when the user requests a connection test from the user interface.

4.2.2.3.1 Activity – Test Connection with Remote AE

4.2.2.3.1.1 Description and Sequencing of Activities

A single attempt will be made to 'ping' the remote AE. If the query fails, for whatever reason, no retry will be performed.

Presentation Context Table					
Abstract Syntax		Transfer Syn	Transfer Syntax		Extended
Name	UID	Name List	UID List		Negotiation
Verification	1.2.840.10008.1.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCU	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Explicit VR Big Endian	1.2.840.10008.1.2.2		

4.2.2.3.1.3 SOP Specific Conformance

4.2.2.3.1.3.1 Specific Conformance to C-FIND SOP Classes

ECHO – SCU provides standard conformance to the Verification Service Class.

4.2.3 **GET – SCU**

4.2.3.1 SOP Classes

GET-SCU provide Standard Conformance to the following SOP Class:

Name	UID	SCU	SCP
Study Root Query/Retrieve Information Model - GET	1.2.840.10008.5.1.4.1.2.2.3	Yes	No
CT Image Storage	1.2.840.10008.5.1.4.1.1.2	Yes	No
Enhanced CT Image Storage	1.2.840.10008.5.1.4.1.1.2.1	Yes	No
MR Image Storage	1.2.840.10008.5.1.4.1.1.4	Yes	No
Enhanced MR Image Storage	1.2.840.10008.5.1.4.1.1.4.1	Yes	No
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7	Yes	No
NM Image Storage	1.2.840.10008.5.1.4.1.1.20	Yes	No
Encapsulated STL Storage	1.2.840.10008.5.1.4.1.1.104.3	Yes	No
Encapsulated OBJ Storage	1.2.840.10008.5.1.4.1.1.104.4	Yes	No

4.2.3.2 Association Policies

4.2.3.2.1 <u>General</u>

GET-SCU initiates but never accepts associations.

4.2.3.2.2 <u>Number of Associations</u>

Maximum number of simultaneous associations	1
	1 I I I I I I I I I I I I I I I I I I I

4.2.3.2.3 Asynchronous Nature

GET-SCU will only allow a single outstanding operation on an Association. Therefore, GET-SCU will not perform asynchronous operations window negotiation.

4.2.3.2.4 Implementation Identifying Information

Implementation Class UID	1.2.276.0.7230010.3.0.3.6.6
Implementation Version Name	OFFIS_DCMTK_366

4.2.3.3 Association Initiation Policy

GET – SCU attempts to initiate a new association when the user performs the retrieve action from the user interface.

4.2.3.3.1 Activity - Retrieve Files from Remote AE

4.2.3.3.1.1 Description and Sequencing of Activities

For the study selected from the user interface to be retrieved, a single attempt will be made to retrieve it from the remote AE in question. If the retrieve fails, for whatever reason, no retry will be performed. As studies are received they are copied to a temporary operating system directory. Temporary files are removed once relevant data has been extracted into the Simpleware proprietary format, or if the operation is cancelled.

4.2.3.3.1.2 Proposed Presentation Contexts

Presentation Context Table						
Abstract Syntax		Transfer Syntax		Role	Extended	
Name	UID	Name List	UID List		Negotiation	
See Table 4.2.3.1-1	See Table 4.2.3.1-1	Implicit VR Little	1.2.840.10008.1.2	SCU	None	
		Endian				
		Explicit VR Little	1.2.840.10008.1.2.1			
		Endian				
		Explicit VR	1.2.840.10008.1.2.2			
		Big Endian				

4.2.3.3.1.3 SOP Specific Conformance

4.2.3.3.1.3.1 SOP Specific Conformance for SOP Classes

GET – SCU provides standard conformance to the supported C-GET SOP Classes.

Only a single information model, Study Root, is supported.

A retrieval will be performed at the STUDY level.

4.2.3.4 Association Acceptance Policy

GET-SCU does not accept associations.

4.2.4 **MOVE – SCU**

4.2.4.1 SOP Classes

MOVE-SCU provide Standard Conformance to the following SOP Class:

Name	UID	SCU	SCP
Study Root Query/Retrieve Information Model - MOVE	1.2.840.10008.5.1.4.1.2.2.2	Yes	No

4.2.4.2 Association Policies

4.2.4.2.1 <u>General</u>

MOVE-SCU initiates but never accepts associations.

4.2.4.2.2 Number of Associations

Maximum number of simultaneous associations	1
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4.2.4.2.3 Asynchronous Nature

MOVE-SCU will only allow a single outstanding operation on an Association. Therefore, MOVE-SCU will not perform asynchronous operations window negotiation.

4.2.4.2.4 Implementation Identifying Information

Implementation Class UID	1.2.276.0.7230010.3.0.3.6.6
Implementation Version Name	OFFIS_DCMTK_366

4.2.4.3 Association Initiation Policy

MOVE – SCU attempts to initiate a new association when the user requests the study delivery from the user interface.

4.2.4.3.1 Activity – Request File Delivery from AE

4.2.4.3.1.1 Description and Sequencing of Activities

For the study selected from the user interface to be delivered, a single attempt will be made to request it from the remote AE in question. If the request fails, for whatever reason, no retry will be performed.

4.2.4.3.1.2	Proposed Presentation Contexts
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Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended
Name	UID	Name	UID List		Negotiation
		List			
Study Root	1.2.840.10008.5.1.4.1.2.2.2	Implicit	1.2.840.10008.1.2	SCU	None
Query/Retrieve		VR Little			
Information		Endian			
Model - MOVE		E well eit	1 2 040 10000 1 2 1		
		Explicit	1.2.840.10008.1.2.1		
		VR Little			
		Endian			
		Explicit	1.2.840.1008.1.2.2		
		VR Big			
		Endian			

4.2.4.3.1.3 SOP Specific Conformance

4.2.4.3.1.3.1 SOP Specific Conformance for SOP Classes

MOVE – SCU provides standard conformance to the supported C-MOVE SOP Classes.

Only a single information model, Study Root, is supported.

A delivery request will be performed at the STUDY level.

4.2.4.4 Association Acceptance Policy

MOVE-SCU does not accept associations.

4.2.5 **STORE – SCP**

4.2.5.1 Classes

STORE-SCP provide Standard Conformance to the following SOP Classes:

Name	UID	SCU	SCP
CT Image Storage	1.2.840.10008.5.1.4.1.1.2	No	Yes
Enhanced CT Image Storage	1.2.840.10008.5.1.4.1.1.2.1	No	Yes
MR Image Storage	1.2.840.10008.5.1.4.1.1.4	No	Yes
Enhanced MR Image Storage	1.2.840.10008.5.1.4.1.1.4.1	No	Yes
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7	No	Yes
NM Image Storage	1.2.840.10008.5.1.4.1.1.20	No	Yes
Encapsulated STL Storage	1.2.840.10008.5.1.4.1.1.104.3	No	Yes
Encapsulated OBJ Storage	1.2.840.10008.5.1.4.1.1.104.4	No	Yes

4.2.5.2 Association Policies

4.2.5.2.1 <u>General</u>

STORE-SCP accepts but never initiates associations.

4.2.5.2.2 <u>Number of Associations</u>

Maximum number of simultaneous associations	1
---	---

4.2.5.2.3 Asynchronous Nature

STORE-SCP will only allow a single outstanding operation on an Association. Therefore, STORE-SCP will not perform asynchronous operations window negotiation.

4.2.5.2.4 Implementation Identifying Information

Implementation Class UID	1.2.276.0.7230010.3.0.3.6.6
Implementation Version Name	OFFIS_DCMTK_366

4.2.5.3 Association Initiation Policy

STORE-SCP does not initiate associations.

4.2.5.3.1 Activity – Accept File from Remote AE

4.2.5.3.1.1 Description and Sequencing of Activities

As instances are received, they are copied to a temporary operating system directory. Temporary files are removed once relevant data has been extracted into the Simpleware proprietary format, or if the operation is cancelled.

4.2.5.3.1.2 Proposed Presentation Contexts

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended
Name	UID	Name List	UID List		Negotiation
See Table 4.2.5.1-1	See Table 4.2.5.1-1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Explicit VR Big Endian	1.2.840.10008.1.2.1		

4.2.5.3.1.3 SOP Specific Conformance

4.2.5.3.1.3.1 SOP Specific Conformance to C-FIND SOP Classes

STORE-SCP provides standard conformance to the Storage Service Class.

4.2.6 **MOVE – SCP**

4.2.6.1 Classes

MOVE-SCP provide Standard conformance to the following SOP Classes:

Name	UID	SCU	SCP
CT Image Storage	1.2.840.10008.5.1.4.1.1.2	No	Yes
Enhanced CT Image Storage	1.2.840.10008.5.1.4.1.1.2.1	No	Yes
MR Image Storage	1.2.840.10008.5.1.4.1.1.4	No	Yes
Enhanced MR Image Storage	1.2.840.10008.5.1.4.1.1.4.1	No	Yes
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7	No	Yes
NM Image Storage	1.2.840.10008.5.1.4.1.1.20	No	Yes
Encapsulated STL Storage	1.2.840.10008.5.1.4.1.1.104.	3 No	Yes
Encapsulated OBJ Storage	1.2.840.10008.5.1.4.1.1.104.4	4 No	Yes

4.2.6.2 Association Policies

4.2.6.2.1 <u>General</u>

MOVE-SCP initiates but never accepts associations.

4.2.6.2.2 <u>Number of Associations</u>

Maximum number of simultaneous associations	1
---	---

4.2.6.2.3 Asynchronous Nature

MOVE-SCP will only allow a single outstanding operation on an Association. Therefore, MOVE-SCP will not perform asynchronous operations window negotiation.

4.2.6.2.4 Implementation Identifying Information

Implementation Class UID	1.2.276.0.7230010.3.0.3.6.6
Implementation Version Name	OFFIS_DCMTK_366

4.2.6.3 Association Initiation Policy

4.2.6.3.1 Activity – Send File to Remote AE

4.2.6.3.1.1 Description and Sequencing of Activities

As instances are sent, they are copied to a temporary operating system directory. Temporary files are removed once sent to the remote AE, of if the operation is cancelled.

4.2.6.3.1.2 Proposed Presentation Contexts

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended
Name	UID	Name List	UID List		Negotiation
See Table 4.2.5.1-1	See Table 4.2.5.1-1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Explicit VR Big Endian	1.2.840.10008.1.2.1		

4.2.6.3.1.2.1 SOP Specific Conformance to C-FIND SOP Classes

MOVE-SCP provides standard conformance to the Storage Service Class.

4.3 Network Interfaces

4.3.1 **Physical Network Interface**

The application is indifferent to the physical medium over which TCP/IP executes, which is dependent on the underlying operating system and hardware.

4.3.2 Additional Protocols

When host names rather than IP addresses are used in the configuration properties to specify presentation addresses for remote AEs, the application is dependent on the name resolution mechanism of the underlying operating system.

4.3.2.1 BCP195 TLS Secure Transport Connection Profile

Simpleware conforms to the BCP195 TLS Secure Transport Connection Profile (for details see section 7.1.1: DICOM BCP195 TLS Secure Transport Connection Profile).

4.3.3 IPv4 and IPv6 Support

This product supports IPv4 only.

4.4 Configuration

All configuration is performed in the PACS section of the Simpleware Preferences dialog. Refer to the Simpleware built-in help system for details.

4.4.1 AE Title/Presentation Address Mapping

The AE Title of the local application is configurable in the Simpleware preferences dialog and is shared by all the AEs listed in section 4.1 Implementation Model. The mapping of the logical name by which remote AEs are described in the user interface to presentation address (hostname or IP address and port number) is configurable in the preferences dialog.

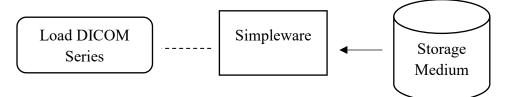
Parameter	Configurable (Yes/No)	Default Value
General Parameters		
PDU Size	No	16kB
Time-out waiting for acceptance or rejection Response to an Association Open Request. (Application Level timeout)	No	30 seconds
General DIMSE level time-out values	No	None (0)
Time-out waiting for response to TCP/IP connect() request. (Low-level timeout)	No	None
Time-out waiting for acceptance of a TCP/IP message over the network. (Low-level timeout)	No	None
Time-out for waiting for data between TCP/IP packets. (Low-level timeout)	No	None
Any changes to default TCP/IP settings, such as configurable stack parameters.	No	None
AE Specific Parameters (all AEs)		
Size constraint in maximum object size	No	None
Maximum PDU size the AE can receive	No	16kB
Maximum PDU size the AE can send	No	16kB
AE specific DIMSE level time-out values	No	None (0)
Number of simultaneous Associations by Service and/or SOP Class	No	1
SOP Class support	No	All supported SOP Classes always proposed and accepted
Transfer Syntax support	No	All supported Transfer Syntaxes always proposed and accepted

4.4.2 **4.4.2 Parameters**

5 Media Interchange

5.1 Implementation Model

5.1.1 Application Data Flow Diagram



5.1.2 Functional Definitions of AEs

Simpleware provides media support as a File Set Reader. The user may select a series of singleframe image files from a directory, or a multi-frame image file, to be loaded for display and further processing. The reading and display of the contents of DICOMDIR files is supported to help identify series for loading.

5.1.3 Sequencing of Real-World Activities

All FSR activities are sequentially initiated in the user interface or through commands in a script. Another activity may not be initiated until the prior activity has completed.

5.2 AE Specifications

5.2.1 Simpleware - Specification

Application Profiles, Activities, and Roles for Simpleware		
Application Profiles Supported	Real World Activity	Role
STD-GEN-CD	Load directory or file	FSR
	Export DICOM series	FSU
STD-GEN-DVD-RAM	Load directory or file	FSR
	Export DICOM series	FSU
STD-CTMR-CD	Load directory or file	FSR
	Export DICOM series	FSU
STD-CTMR-DVD	Load directory or file	FSR
	Export DICOM series	FSU

5.2.1.1 File Meta Information for Simpleware

Simpleware will add the meta information to files on export as an FSU.

5.2.1.2 Real World Activities

5.2.1.2.1 Load Directory or File

When the user selects the DICOM import operation, a wizard will be displayed allowing an operating system directory or a DICOMDIR file to be selected. Once selected, a browser will be displayed from which a DICOM series may be chosen and in turn imported into the software. The user can examine relevant DICOM elements prior to import.

5.2.1.2.2 Export DICOM Series

When the user selects the DICOM export operation, a dialog will be displayed, from which options can be selected to export a range of slices, compress the files and anonymise the DICOM elements. The user can then select a destination to export a sequence of DICOM files.

When file compression is specified the format will be lossless JPEG2000.

When exporting a Simpleware background that has no existing DICOM data, the following set of tags will be generated and added to each 'dcm' file to be exported:

Attribute name	Tag	Comments	
Tag group 08			
SOP Class UID	(0008,0016)	A value is generated.	
SOP Instance UID	(0008,0018)	A value is generated.	
Study Date	(0008,0020)	The date when exported.	
Study Time	(0008,0030)	Set as an empty string.	
Accession Number	(0008,0050)	Set as an empty string.	
Modality	(0008,0060)	Set to CT – Computed Tomography.	
Conversion Type	(0008,0064)	Set to WSD – Workstation.	
Referring Physician's Name	(0008,0090)	Set as an empty string.	
Tag group 10			
Patient's Name	(0010,0010)	Set as an empty string.	
Patient's ID	(0010,0020)	Set as an empty string.	
Patient's Birth Date	(0010,0030)	Set as an empty string.	
Patient's Sex	(0010,0040)	Set as an empty string.	
Tag group 18			
Spacing Between Slices	(0018,0088)	Populated according to the image spacing.	
Nominal Scanned Pixel	(0018,2010)	Populated according to the image spacing.	
Spacing			
Tag group 20			
Study Instance ID	(0020,000D)	A value is generated.	
Study Instance ID	(0020,000E)	A value is generated.	
Study ID	(0020,0010)	Set as an empty string.	
Series Number	(0020,0011)		
Instance Number	(0020,0013)	Set as a one-based index for each exported file.	
Patient Orientation	(0020,0020)	Set as an empty string.	
Frame of Reference UID	(0020,0020)	A value is generated.	
Slice Location	(0020,1041)	Position data set for each exported file.	
Tag group 28			
Samples per Pixel	(0028,0002)	Populated according to the image type being exported.	
Photometric Interpretation	(0028,0004)	Populated according to the image type being exported.	
Rows	(0028,0010)	Populated according to the image type being exported.	
Columns	(0028,0011)	Populated according to the image type being exported.	
Pixel Spacing	(0028,0030)	Populated according to the image type being exported.	
Bits Allocated	(0028,0100)	Populated according to the image type being exported.	
Bits Stored	(0028,0101)	Populated according to the image type being exported.	
High Bit	(0028,0102)	Populated according to the image type being exported.	
Pixel Representation	(0028,0103)	Populated according to the image type being exported.	
Rescale Slope	(0028,1053)	Populated according to the image type being exported.	
Rescale Type	(0028,1054)	Populated according to the image type being exported.	

5.3 Augmented and Private Profiles

5.3.1 Augmented Profiles

None.

5.3.2 Private Profiles

None.

5.4 Media Configuration

None.

6 Support of Character Sets

6.1 Overview

Support extends to correctly decoding and displaying the correct symbols in the supported character sets for all strings read from DICOM files.

No specific support for sorting of strings other than in the default character set is provided in the browsers.

6.2 Character Sets

Simpleware supports the following character sets:

Character Set Description	Defined Term
Default repertoire	n/a
Latin alphabet No. 1	ISO_IR 100
Latin alphabet No. 2	ISO_IR 101
Latin alphabet No. 3	ISO_IR 109
Latin alphabet No. 4	ISO_IR 110
Cyrillic	ISO_IR 144
Arabic	ISO_IR 127
Greek	ISO_IR 126
Hebrew	ISO_IR 138
Latin alphabet No. 5	ISO_IR 148
Japanese	ISO_IR 13
Thai	ISO_IR 166
Japanese (JIS X 0208: Kanji)	ISO 2022 IR 87
Japanese (JIS X 0212: Supplementary Kanji set)	ISO 2022 IR 159
Korean	ISO 2022 IR 149
Simplified Chinese	ISO 2022 IR 58
Unicode in UTF-8	ISO_IR 192
GB18030	GB18030
GBK	GBK

Multiple character sets specified for a single string (ISO 2022) are not supported, when this occurs, or an otherwise unsupported character set is encountered, Simpleware loads the raw bytes interpreting them using the operating system's locale.

7 Security

7.1 Security Profiles

7.1.1 DICOM BCP195 TLS Secure Transport Connection Profile

Secure communication is a mode of operation of Simpleware supported by the implementation of the DICOM BCP195 TLS Secure Transport Connection Profile. This functionality is used by network nodes that can authenticate each other before they can exchange any DICOM information.

For secure communication, the TLS protocol v1.2 is used which provides message authentication, integrity, confidentiality and replay protection.

Simpleware uses the following cipher suites:

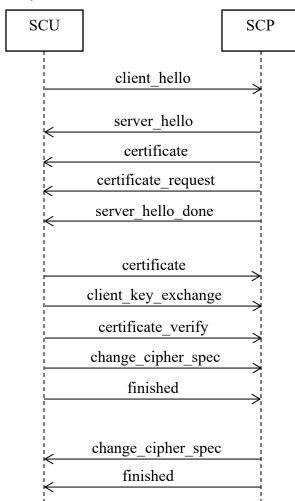
 TLS_DHE_RSA_WITH_AES_128_GCM_SHA256 	(0x00, 0x9E)
 TLS_ECDHE_RSA_WITH_AES_128_GCM_SHA256 	(0xC0, 0x2F)
 TLS_DHE_RSA_WITH_AES_256_GCM_SHA384 	(0x00, 0x9F)
 TLS_ECDHE_RSA_WITH_AES_256_GCM_SHA384 	(0xC0, 0x30)
TLS_RSA_WITH_AES_128_CBC_SHA	(0x00, 0x3C)
 TLS_RSA_WITH_3DES_EDE_CBC_SHA 	(0x00, 0x0A)

The BCP195 TLS Secure Transport Connection Profile is backward compatible with older security profiles. When Simpleware tries to establish a secure connection with a network node using an older security profile, the connection will fall back to using TLS protocol v1.1 or 1.0, in which case these cipher suites are used:

٠	TLS_RSA_WITH_AES_128_CBC_SHA	(0x00, 0x3C)
•	TLS_RSA_WITH_3DES_EDE_CBC_SHA	(0x00, 0x0A)

Simpleware supports X.509 certificates. Trusted certificates can only be read from the local machine trusted certificate stores. It is the responsibility of the user to setup and maintain certificate stores and trust chains. This includes the removal of revoked certificates and certificate updates prior to their expiration dates. In case of a security breach, the whole certificate chain will need to be replaced.

The following diagram represents the message flow of a TLS handshake as supported by Simpleware:



7.1.2 Attribute Confidentiality Profiles

7.1.2.1 Basic Application Level Confidentiality Profile

Simpleware supports the Basic Application Level Confidentiality Profile as specified in the DICOM standard, Part 15, Annex E.2.

7.1.2.1.1 Attributes Removed or Replaced

Refer to the table Application Level Confidentiality Profile Attributes in the DICOM standard, Part 15, Annex E.2. Each attribute is assigned one or more action codes that define if the attribute should be removed or replaced.

Additionally, the software provides an option for the user to remove all private DICOM tags.

7.1.2.1.2 Inserted Dummy Values

The following values are used as dummy values when an attribute needs to be replaced:

Value Representation (VR)	Dummy Value
DA	10000101
DT	10000101000000.000000
TM	00000.00000
LO	Anonymised
SH	Anonymised
SQ	Anonymised

7.1.2.1.3 Encrypted Attributes Data Sets

Encryption of attributes for later re-identification is not supported.

7.1.2.1.4 Scope of Referential Integrity of Replacement Values for UIDs

Replacement UIDs are derived from the original UID values by creating name-based UUIDs as specified in RFC 4122: A Universally Unique Identifier (UUID) URN Namespace. The software implementation uses a SHA-1 hash of the original UID and encodes the hash into a valid UUID, which is then represented as a single integer. The root value of "2.25" is prepended to the resulting value.

As a result, original UIDs of equal values in different DICOM objects, such as different DICOM studies or series are replaced by new UIDs of equal values.

7.2 Association Level Security

None supported.

7.3 Application Level Security

Simpleware allows the use of either a conventional (non-secure) connection or a secure connection, based on the Transport Layer Security (TLS) protocol, for importing DICOM information. When configured, Simpleware supports security measures for:

- Secure authentication of a network node
- Integrity and confidentiality of transmitted data
- Replay protection

8 Annexes

8.1 IOD Contents

8.1.1 Created SOP Instances

None.

8.1.2 Usage of Attributes from Received IODs

No SOP Class specific fields are required.

Simpleware makes use of the conventional identification attributes to distinguish patients, studies, series and instances. In particular, during import, if an operating system directory is chosen to be scanned for DICOM series, they are grouped by Series instance UID, Series Number, Sequence Name, Slice Thickness, Rows, Columns and Image Type. The operator may additionally specify Study Description, Series Description, Patient's Name, Protocol Name and Acquisition Number if the default grouping is not satisfactory.

8.1.3 Attribute Mapping

Not applicable.

8.1.4 **Coerced/Modified Fields**

Attribute name	Тад	Modification	Reason
All sequence tags	N/A	Removed	Exporting sequence tags is not supported.
Pixel Spacing	(0028,0030)	Generated	Generated on export
Spacing between	(0018,0088)	Generated	Generated on export
Slices			
SOP Instance	(0008,0018)	Removed	To allow interoperability with some third-
			party software.
Study Time	(0008,0030)	Created and	To keep a consistent time across all slices for
		zeroed if	compatibility with some third-party software.
		absent.	
Instance Number	(0020,0013)	Generated	Generated on export.
Slice Location	(0020,0032)	Generated	Generated on export.
Image Position	(0020,0032)	Generated	Generated on export.
(Patient)			
Specific	(0008,0005)	Removed	String data may be re-encoded on import.
Character Set			Therefore, this tag is not reflective of the data
			and is removed on export.

No coercion is performed on imported data. For export, the following modifications are performed:

8.2 Data Dictionary of Private Attributes

Existing private attributes are loaded and then optionally re-exported. As part of anonymisation options, private tags can be removed on export.

8.3 Coded Terminology and Templates

Not applicable.

8.4 Grayscale Image Consistency

Not applicable.

8.5 Standard Extended/Specialized/Private SOP Classes

None.

8.6 Private Transfer Syntaxes

None.

Regulatory Information:

Simpleware Medical is intended for use as a software interface and image segmentation system for the transfer of medical imaging information to an output file. The software is intended to inform clinical management by improving confidence in clinical decision-making and presurgical planning through use of patient-specific 3D models (virtual 3D models and 3D printed anatomical models) created from medical imaging. Outputs from the software must be reviewed for clinical suitability by expert clinicians working on specific patient cases.

Please see <u>https://www.synopsys.com/simpleware/resources/regulatory.html</u> for more details of clearances.

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