



# **DICOM Conformance Statement**

**PLEX<sup>®</sup> Elite 9000 Instrument and Review Software**

**Version 2.1**

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# 1 Conformance Statement Overview

For the Intended Use / Indications for Use, see the PLEX Elite 9000 Instructions for Use.

The PLEX Elite 9000 Application Software implements one single DICOM Application Entity which allows to:

- query modality worklist
- export evidence reports

This document is structured as suggested in the DICOM Standard (PS 3.2: Conformance).

**Table 1-1 Network Services Supported**

SOP Classes	User of Service (SCU)	Provider of Service (SCP)
<b>Transfer</b>		
Encapsulated PDF Storage	Yes	No
<b>Workflow Management</b>		
Modality Worklist Information Model - FIND	Yes	No
Verification	Yes	Yes

The SOP Classes are categorized as follows:

**Table 1-2 UID Values**

UID Value	UID Name	Category
1.2.840.10008.1.1	Verification	Workflow Management
1.2.840.10008.5.1.4.1.1.104.1	Encapsulated PDF Storage	Transfer
1.2.840.10008.5.1.4.31	Modality Worklist Information Model - FIND	Workflow Management

The PLEX Elite 9000 does not support Media Interchange.

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## 3 Introduction

### 3.1 Revision History

Table 3-1 Revision History

Document Version	Date	Author	Changes
EN_31_200_0194I	2020-04-28	Wing Leung	PLEX Elite Version 2.1 Addition of new procedure steps "ONH Angio (6mmx6mm) (100kHz)", "ONH Angio (6mmx6mm) (200kHz)", and "Angio (15mmx15mm) (200kHz)".

### 3.2 Audience

This document is written for the people that need to understand how PLEX Elite 9000 will integrate into their healthcare facility. This includes both those responsible for overall imaging network policy and architecture, as well as integrators who need to have a detailed understanding of the DICOM features of the product. This document contains some basic DICOM definitions so that any reader may understand how this product implements DICOM features. However, integrators are expected to fully understand all the DICOM terminology, how the tables in this document relate to the product's functionality, and how that functionality integrates with other devices that support compatible DICOM features.

### 3.3 Remarks

The scope of this DICOM Conformance Statement is to facilitate integration between PLEX Elite 9000 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 compatible DICOM equipment, as established by the healthcare facility.

### 3.4 Definitions and Terms

Informal definitions are provided for the following terms used in this Conformance Statement.

The DICOM Standard is the authoritative source for formal definitions of these terms.

#### Abstract Syntax

the information agreed to be exchanged between applications, generally equivalent to a Service/Object Pair (SOP) Class.

Examples: Verification SOP Class, Modality Worklist Information Model Find SOP Class, Computed Radiography Image Storage SOP Class.

**Application Entity (AE)**

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

**Application Entity Title**

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

**Application Context**

the specification of the type of communication used between Application Entities.

Example: DICOM network protocol.

**Association**

a network communication channel set up between Application Entities.

**Attribute**

a unit of information in an object definition; a data element identified by a tag. The information may be a complex data structure (Sequence), itself composed of lower level data elements.

Examples: Patient ID (0010,0020), Accession Number (0008,0050), Photometric Interpretation (0028,0004), Procedure Code Sequence (0008,1032).

**Information Object Definition (IOD)**

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

Examples: MR Image IOD, CT Image IOD, Print Job IOD.

**Joint Photographic Experts Group (JPEG)**

a set of standardized image compression techniques, available for use by DICOM applications.

**Media Application Profile**

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

**Module**

a set of Attributes within an Information Object Definition that are logically related to each other.

Example: Patient Module includes Patient Name, Patient ID, Patient Birth Date, and Patient Sex.

**Negotiation**

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

**Presentation Context**

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

**Protocol Data Unit (PDU)**

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

**Query Key**

A input value for a query process. Query Keys denote the set of DICOM tags that are sent from the SCU to SCP and thus control the query result.

**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 (SOP) Class**

the specification of the network or media transfer (service) of a particular type of data (object); the fundamental unit of DICOM interoperability specification.

Examples: Ultrasound Image Storage Service, Basic Grayscale Print Management.

**Service/Object Pair (SOP) Instance**

an information object; a specific occurrence of information exchanged in a SOP Class.

Examples: a specific x-ray image.

**Tag**

a 32-bit identifier for a data element, represented as a pair of four digit hexadecimal numbers, the “group” and the “element”. If the “group” number is odd, the tag is for a private (manufacturer-specific) data element.

Examples: (0010,0020) [Patient ID], (07FE,0010) [Pixel Data], (0019,0210) [private data element]

**Transfer Syntax**

the encoding used for exchange of DICOM information objects and messages.

Examples: JPEG compressed (images), little endian explicit value representation.

**Unique Identifier (UID)**

a globally unique “dotted decimal” string that identifies a specific object or a class of objects; an ISO-8824 Object Identifier.

Examples: Study Instance UID, SOP Class UID, SOP Instance UID.

**Value Representation (VR)**

the format type of an individual DICOM data element, such as text, an integer, a person’s name, or a code. DICOM information objects can be transmitted with either explicit identification of the type of each data element (Explicit VR), or without explicit identification (Implicit VR); with Implicit VR, the receiving application must use a DICOM data dictionary to look up the format of each data element.

## 3.5 Abbreviations

Table 3-2 Abbreviations used in this document

Abbreviation	Definition
AE	Application Entity
AET	Application Entity Title
DICOM	Digital Imaging and Communications in Medicine
ILE	Implicit Little Endian
ELE	Explicit Little Endian
EPDF	Encapsulated PDF
IM	Information Model
IOD	Information Object Definition

MWL	Modality Worklist
MPG2	Motion Picture Expert Group 2; Abbreviation and synonym for video encoding and compression transfer syntax.
OD	Oculus Dexter, the right eye
OS	Oculus Sinister, the left eye
OU	Oculus Uterque, both eyes
SCP	Service Class Provider
SCU	Service Class User
SOP	Service Object Pair, union of a specific DICOM service and related IOD.
TCP/IP	Transmission Control Protocol / Internet Protocol
UID	Unique Identifier
UI	User Interface

### 3.6 References

NEMA PS3 / ISO 12052, Digital Imaging and Communications in Medicine (DICOM) Standard, National Electrical Manufacturers Association, Rosslyn, VA, USA (available free at <http://medical.nema.org/>)

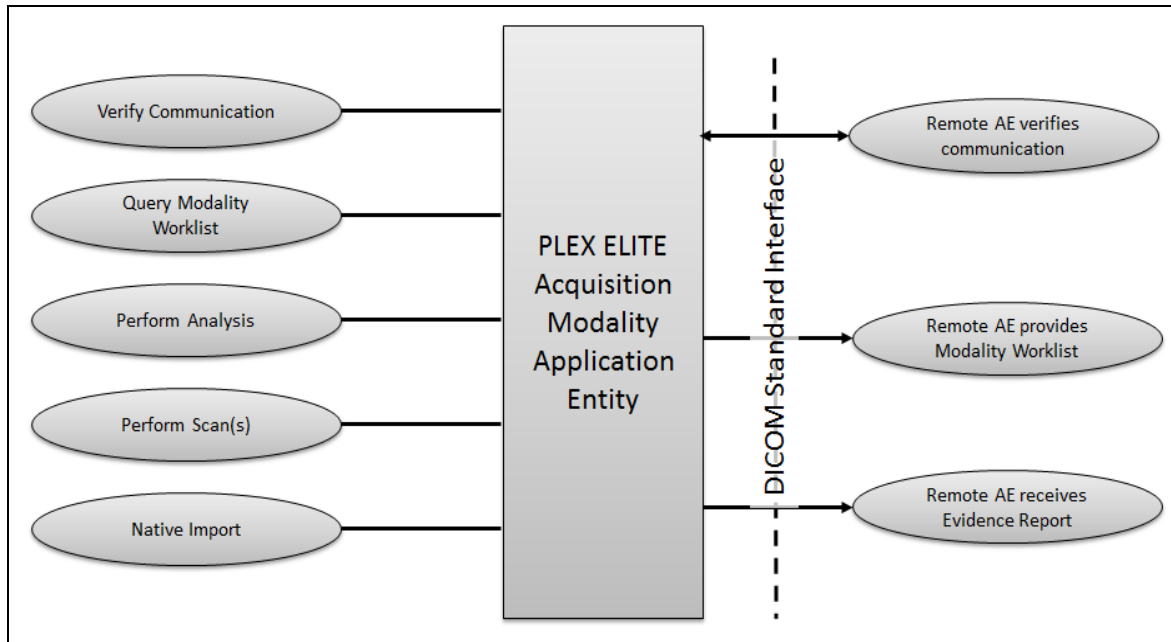


## 4 Networking

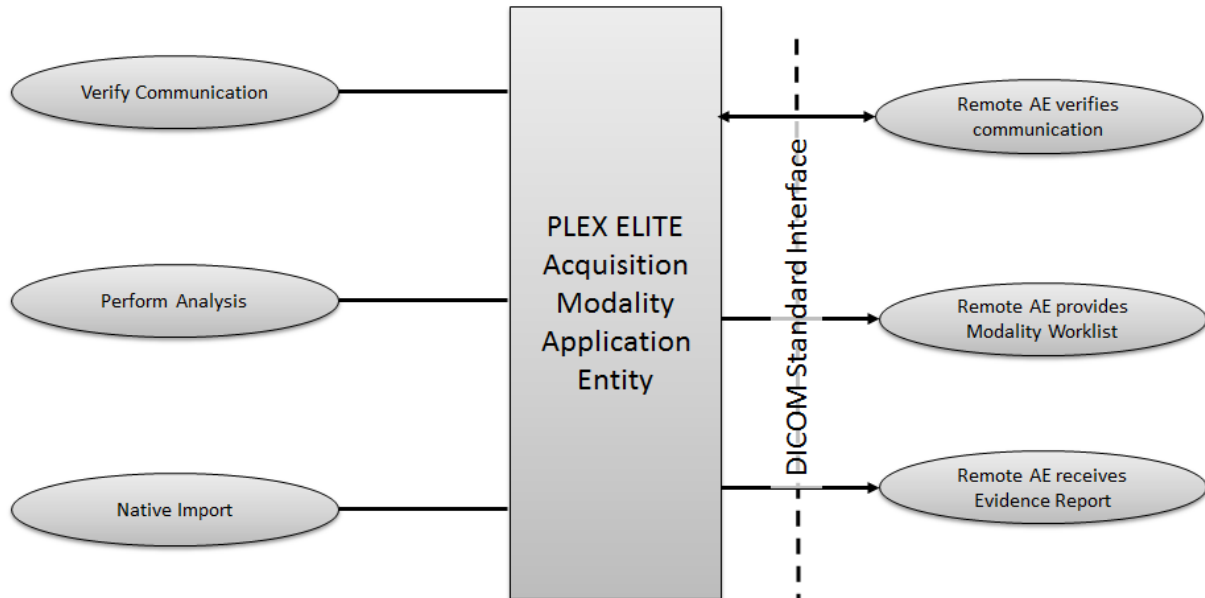
### 4.1 Implementation Model

#### 4.1.1 Application Data Flow

Figure 4-1 Functional Overview as Acquisition Modality



**Figure 4-2 Functional Overview as Review Station**



## 4.1.2 Functional Definition of AEs

### 4.1.2.1 Functional Definition of PLEX Elite 9000

For the Intended Use / Indications for Use, see the PLEX Elite 9000 Instructions for Use.

The PLEX Elite 9000 Application Software DICOM functionality allows to:

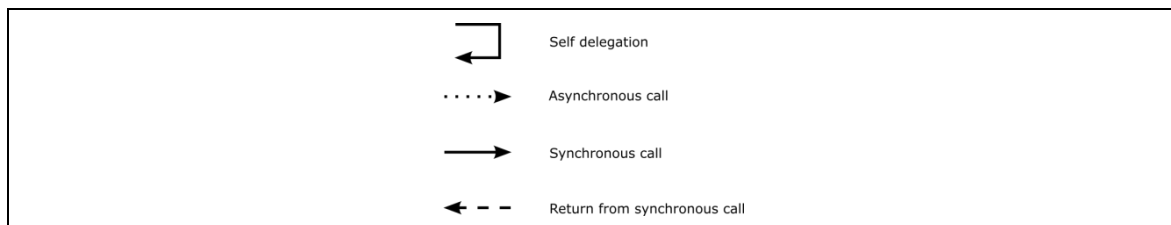
- query modality worklist
- export evidence reports

The PLEX Elite 9000 Software allows performing a verification of the configured AEs. The result of this verification contains information about the supported SOP Classes and Transfer Syntaxes.

The PLEX Elite 9000 Software logs extensive information about the DICOM operations to its log file.

### 4.1.3 Sequencing of Real-World Activities

To realize the real world activities, the different entities work together. The sequence diagrams shall depict the intended workflow.



The diagrams use slightly modified UML symbols. The asynchronous call is not depicted as suggested in UML. Some objects do have more than one dashed line. It symbolizes more than one thread.

#### 4.1.3.1 PLEX Elite 9000 Activities

##### Query Modality Worklist

When the patient arrives at the PLEX Elite 9000, the operator queries the worklist. He/she has two possibilities to do so:

Quick search: Selects the Today's Patients tab to perform a query with predefined query keys using the instrument's Scheduled Station AE Title and today's date.

Extended search capabilities: Invokes the query from the menu of the application software via "Search Worklist Patients". The operator types in search criteria and gets matching items back. The matches are listed in a table, from which the operator can select the correct item. According to the transferred data the PLEX Elite 9000 creates an entry in the local database and the operator can then select the patient for data acquisition.

##### Native import

This activity is optional.

The native import takes data into the system that has been created by other Application Software instances.

##### Perform scan(s)

The operator selects a scan acquisition protocol and then performs the scan on patient's eye. The Application Software allows the user to review the acquired scan data before permanently saving the scan result.

This activity creates scan data and analysis data.

##### Perform analysis

The operator can trigger this activity by selecting a specific analysis protocol. The applicable analysis depends on the available scan data. The user can adjust parameters to optimize the analysis result.

Analysis data that has been created within the analysis activity will be stored locally.

##### Sub-Activity: Export Evidence Report

The operator can invoke the creation of an evidence report by using the "Export to DICOM" option at any time within the analysis activity. Thus he or she can export several evidence reports during the analysis activity.

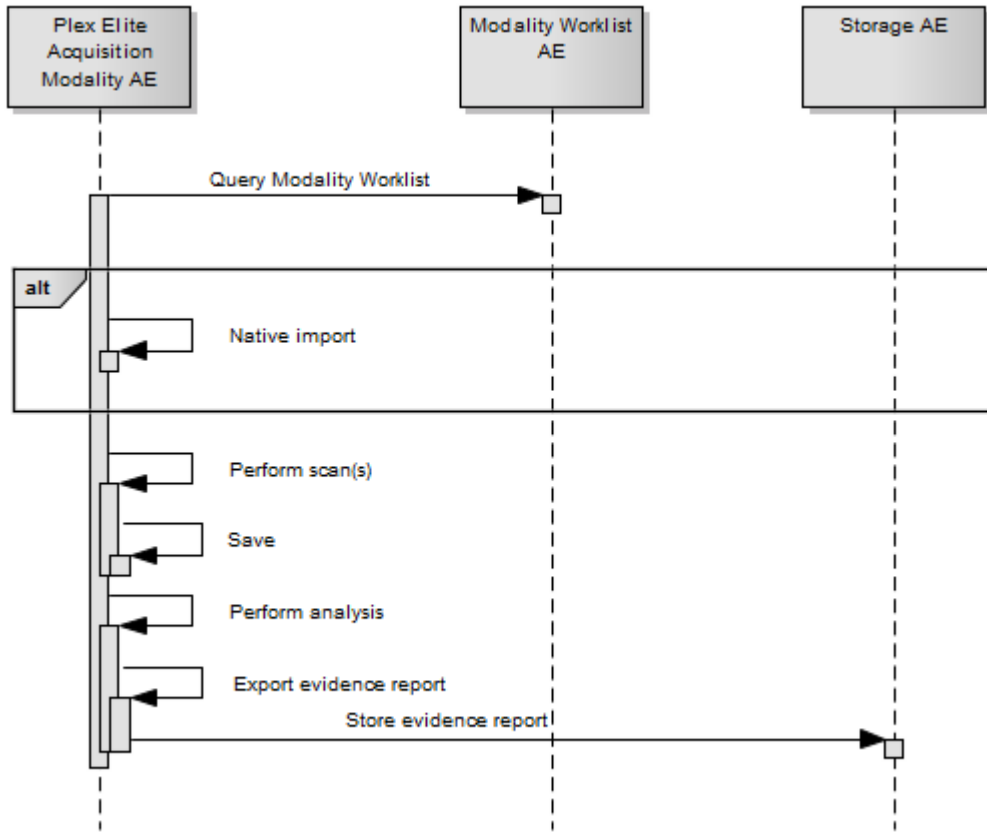
#### 4.1.3.2 Scheduled case with Acquisition Modality

The recommended case is that the patient arrives at the front desk. There could be two possibilities at this point:

- The examination can be scheduled for the instrument the moment the patient arrives
- The examination was scheduled in advance

In either case all patient and study related information is available at the moment the examination takes place. This information can then be used to decide which examination to take and to verify whether the acquired information will be attached to the correct patient. The operator at the instrument can trigger all activities listed below. An activity can be triggered if no other activity is currently active. The shown order of the activities is the recommended order. Details on DIMSE level will be explained in chapters after this.

**Figure 4-3 - Scheduled Case with Acquisition Modality**

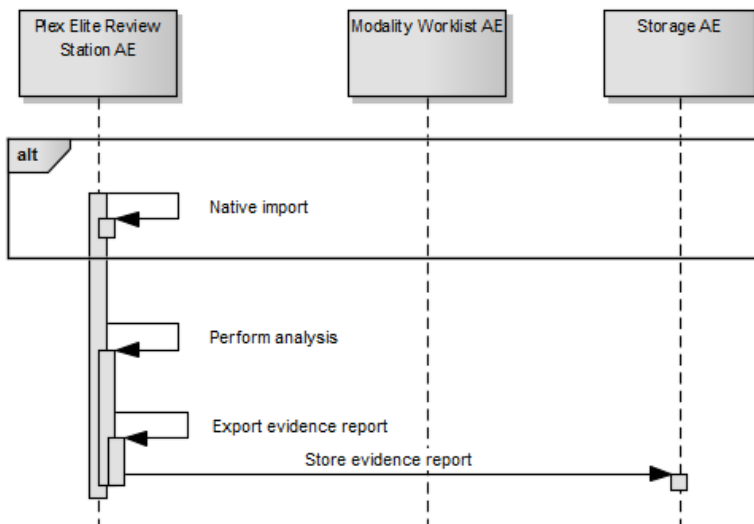


**4.1.3.3 Scheduled case with Acquisition Modality and Review Station**

Acquisition of scan data and its analysis can be performed separately in different locations. As before, the Acquisition Modality would be used to acquire scan data. The analysis can then be done at a separate Review Station. The Review Station is the PLEX Elite 9000 Application Software installed on a computer other than the Acquisition Modality. The Review Station has access to scan data and analysis parameters shared by the Acquisition Modality or via native import.

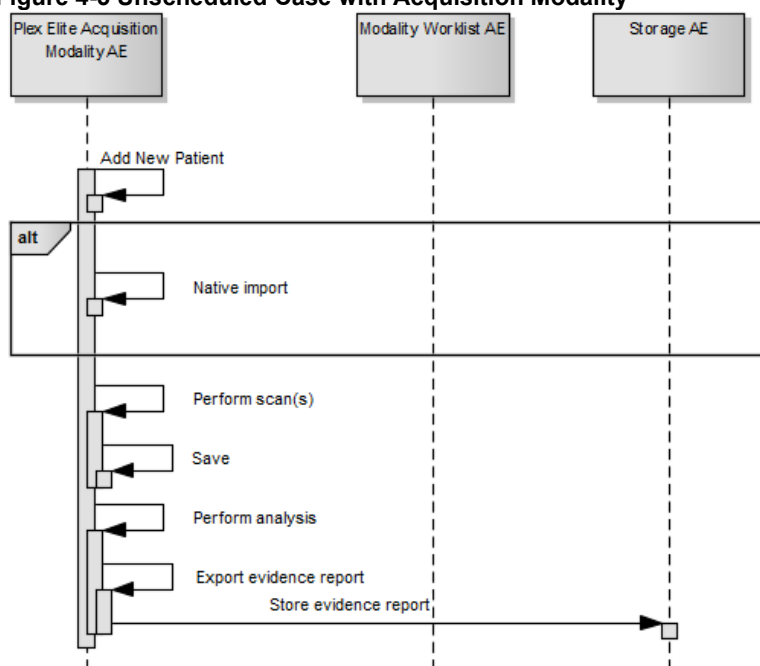
The Acquisition Modality would work as described in the chapter before. In the following sequence diagram the focus is on the functionality of the Review Station.

**Figure 4-4 - Review Station**



### 4.1.3.4 Unscheduled case

Figure 4-5 Unscheduled Case with Acquisition Modality



In the unscheduled case the patient arrives immediately at the instrument and has not been registered at the front desk. Thus the examination is not scheduled in advance and cannot be provided via the Modality Worklist. Patient demographics and study specific information has to be entered at the instrument itself.

## 4.2 AE Specifications

### 4.2.1 PLEX Elite 9000 Acquisition Modality AE Specification

#### 4.2.1.1 SOP Classes

Table 4-1 SOP Classes for PLEX Elite 9000 AE

SOP Class Name	SOP Class UID	SCU	SCP
Verification	1.2.840.10008.1.1	Yes	Yes
Storage Commitment Push Model SOP Class	1.2.840.10008.1.20.1	Yes	No
Encapsulated PDF Storage	1.2.840.10008.5.1.4.1.1.104.1	Yes	No
Raw Data Storage	1.2.840.10008.5.1.4.1.1.66	Yes	Yes
Study Root Query/Retrieve Information Model – FIND	1.2.840.10008.5.1.4.1.2.2.1	Yes	No
Patient Root Query/Retrieve Information Model - FIND	1.2.840.10008.5.1.4.1.2.1.1	Yes	No
Modality Worklist Information Model - FIND	1.2.840.10008.5.1.4.31	Yes	No
Study Root Query/Retrieve Information Model – MOVE	1.2.840.10008.5.1.4.1.2.2.2	Yes	No
Modality Performed Procedure Step SOP Class	1.2.840.10008.3.1.2.3.3	No	No

Modality Performed Procedure Step Notification SOP Class	1.2.840.10008.3.1.2.3.5	No	No
Ophthalmic Tomography Image Storage	1.2.840.10008.5.1.4.1.1.77.1.5.4	Yes	No
Multi-frame True Color Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7.4	No	No
Ophthalmic Photography 8 Bit Image Storage	1.2.840.10008.5.1.4.1.1.77.1.5.1	Yes	No

Note 1: The networking interface proposes more presentation contexts than actually supported by the application. All lines in grey are not supported by the PLEX Elite 9000 Application Software.

#### 4.2.1.2 Associations Policies

##### 4.2.1.2.1 General

The DICOM standard Application Context Name for DICOM 3.0 is always proposed:

**Table 4-2 DICOM Application Context**

Application Context Name	1.2.840.10008.3.1.1.1
--------------------------	-----------------------

##### 4.2.1.2.2 Number of Associations

The number of simultaneous associations can be two. At a time there may be one outgoing association and one incoming association.

**Table 4-3 Number of associations**

Maximum number of simultaneous associations	2
---	---

##### 4.2.1.2.3 Asynchronous Nature

PLEX Elite 9000 Application Software does not support asynchronous communication (multiple outstanding transactions over a single Association).

##### 4.2.1.2.4 Implementation Identifying Information

**Table 4-4 DICOM implementation class and version**

Implementation Class UID	1.2.276.0.75.2.5.20
Implementation Version Name	NIM-2.6.2

#### 4.2.1.3 Association Initiation Policy

##### 4.2.1.3.1 Activity – Verify Communication

###### 4.2.1.3.1.1 Description and Sequencing of Activities

This activity is available during the configuration phase. It facilitates the setup and management of the DICOM Application Entities.

The user can test the application level communication between instrument's software Application Entity and its peer DICOM Application Entities. During one test call, all peer DICOM Application Entities are contacted.

In the association request PLEX Elite 9000 Application Software proposes not only Verification SOP Class, but also all other SOP Classes as supported by the instrument's DICOM interface.

The association is established when the peer DICOM entity accepts the verification related presentation context. In a sub-sequent step a C-ECHO message is exchanged.

The results of the “Verify Communication” activity are shown to the user as success or failure. For e. g. a Storage Provider not only the Verification information is evaluated, but also the acceptance of the proposed presentation context comprising the respective Storage SOP Classes.

#### 4.2.1.3.1.2 Proposed Presentation Contexts

Following presentation contexts are offered for each initiated association. During this activity the Application Software uses only

- Verification" with Transfer Syntax ILE

**Table 4-5 Proposed Presentation Contexts for Activity Verify Communication**

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Ext. Neg.
Name	UID 1.2.840.10008. ...	Name List	UID List 1.2.840.10008. ...		
Verification	1.1	ILE	1.2	SCU	No
Modality Worklist IM - FIND	5.1.4.31	ILE	1.2	SCU	No
Study Root Q/R IM - FIND	5.1.4.1.2.2.1	ILE	1.2	SCU	Yes
Study Root Q/R IM - MOVE	5.1.4.1.2.2.2	ILE	1.2	SCU	No
Patient Root Q/R IM – FIND	5.1.4.1.2.1.1	ILE	1.2	SCU	Yes
Modality Performed Procedure Step	3.1.2.3.3	ILE	1.2	SCU	No
Modality Performed Procedure Step Notification	3.1.2.3.5	ILE	1.2	SCU	No
Encapsulated PDF Storage	5.1.4.1.1.104.1	ILE	1.2	SCU	No
		ELE	1.2.1	SCU	No
Raw Data Storage	5.1.4.1.1.66	ILE	1.2	SCU	No
		ELE	1.2.1	SCU	No
OP 8 Bit Image Storage	5.1.4.1.1.77.1.5.1	J2K	1.2.4.91	SCU	No
OPT Image Storage	5.1.4.1.1.77.1.5.4	J2K	1.2.4.91	SCU	No
Multi-frame True Color Secondary Capture Image Storage	5.1.4.1.1.7.4	RLE	1.2.5	SCU	No
		JPG-1	1.2.4.50	SCU	No
Storage Commitment Push Model	1.20.1	ILE	1.2	SCU	No

Note 1: The networking interface proposes more presentation contexts than actually supported by the application. All lines in grey are not supported by the PLEX Elite 9000 Application Software.

#### 4.2.1.3.1.3 SOP Specific Conformance for Verification SOP Class

The PLEX Elite 9000 Application Software provides standard conformance.

### 4.2.1.3.2 Activity – Query Modality Worklist

#### 4.2.1.3.2.1 Description and Sequencing of Activities

##### Option “Today’s Patients query”

In this case, the Application Software performs a query with predefined query keys. The operator cannot change the query key values. The applied query keys are:

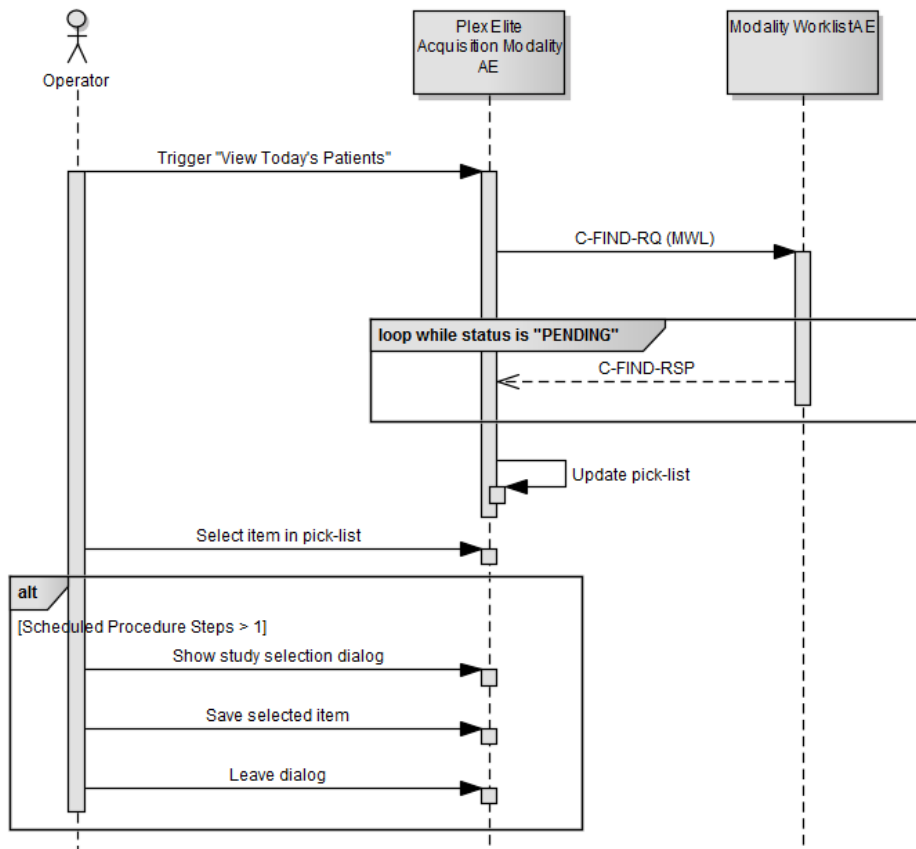
**Table 4-6 Modality Worklist Query for Today’s Patients**

Tag	Attribute Name	Description
(0040,0100)	Scheduled Procedure Step Sequence	N/A
>(0040,0001)	Scheduled Station Application Entity Title	Uses the value as configured in system preferences for the PLEX Elite 9000 instrument .
>(0040,0002)	Scheduled procedure Step Start Date	Uses the date of today.

All matching worklist items are subject to be imported into the local database.

Sequentially a broad Patient Root Query on Study level on the query key of today’s Study Date (0008,0020) follows which results in listing all Patients with existing studies from today’s date.

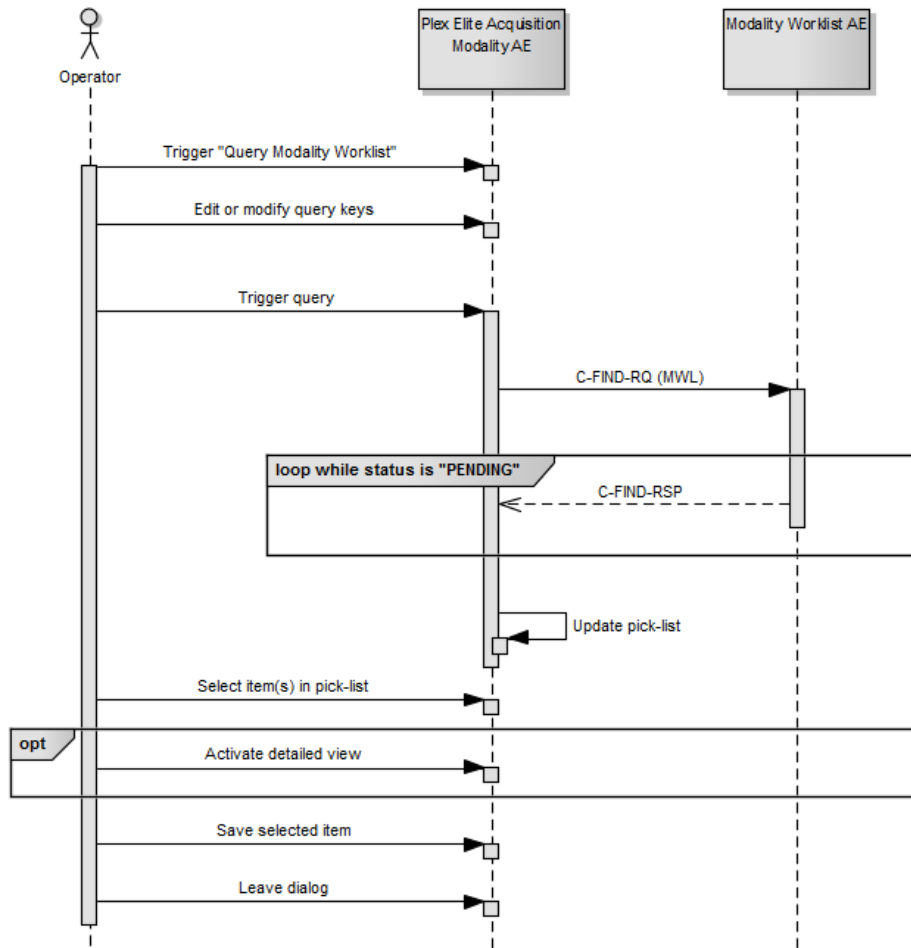
**Figure 4-6 Modality Worklist - Today’s Patient Query**





## Option “Interactive query”

Figure 4-7 - Modality Worklist - interactive query



### Trigger “Modality Worklist”

The activity “Query Modality Worklist” can be triggered by the operator at any time if no other activity is in progress. It is meaningful to perform the query when the patient arrives at the modality. Then the worklist contains latest information.

### Edit or modify query keys

The Modality Worklist query offers a GUI for interactive query. The GUI offers two sets of query keys. One set belongs to the so called "Patient Based Query", the other one belongs to the "Broad Query".

The operator can change or fill in search criteria in the shown dialog. For instance, the incomplete patient name or the patient ID can be used. For more details on supported query keys see Table 4-10 Modality Worklist Query Key Details - Patient Based Query and Table 4-11 Modality Worklist Query Key Details - Broad Query.

If the operator likes to use wildcards he may manually add the following wildcard characters:

\* signifies any number of characters (including none)

? signifies any one character

The application doesn't add wildcards automatically neither at the end of the search string nor at the beginning.

### Trigger query

The operator triggers the search after he or she filled in search criteria. The Application Software sends a DICOM C-FIND request, which contains the search

criteria. The Application Software waits for the response from the partner Application Entity. Application Software will accept up to a configurable number of matches. The Application Software checks whether the number of received worklist items overstepped the configurable limit. If the number of received worklist items overstepped the limit, then the Application Software sends a C-CANCEL-RQ, then an A-RELEASE-RQ to the service provider and a message is displayed. Despite this warning, the operator gets result in the pick-list.

After receiving the response, the pick-list is updated. The pick-list provides the most important information for a quick overview (see Table 4-9 Attributes involved in Modality Worklist C-FIND request and response for the supported set of tags).

The operator can start over, redefine query keys and trigger the query again. This can be performed as often as required, until he or she finds the correct worklist item.

#### **Select item in pick-list**

The operator can select one worklist item in the pick-list. The selected item becomes subject for a detailed view or it can be imported into the Application Software.

#### **Activate detailed view**

The detailed view allows a closer look to the currently selected worklist item. Thus the operator can see more information about patient information and schedule information (see Table 4-9 Attributes involved in Modality Worklist C-FIND request and response for the supported set of tags).

#### **Save selected item**

The operator can take over the selected item at any time. The data is stored in the list of today's patients.

The Application Software checks the local database for patient data with same combination of Patient ID and Issuer of Patient ID. If there is matching data, then the Application Software checks for differences in Patient's Name, Patient's Birth Date and Patient's Sex. In case of a difference, the Application Software presents the differences to the operator and asks whether to overwrite the data in the local database with the data from the Modality Worklist. The operator can also deny overwriting. For patients who do not relate to existing data, the Application Software prepares new data sets.

After saving the selected item, the operator can start over. By repeating this process the operator can take over several worklist items into the local database.

After all that, the operator can start the examination of the patient and acquire scan data.

#### **Leave dialog**

The operator finally finishes the worklist query by leaving the dialog.

#### **Multi Component Group Names Handling**

The PLEX Elite 9000 is capable to deal with the first component group of multi-component group names. When the operator triggers a search of a worklist containing multi-component group names the search will be performed using the first component group only. When the response from the modality worklist provider contains a multi-component group name the pick list will show only the first component group and the first component group information will be imported at the modality. An empty first component group in the worklist will result in an empty Patient Name attribute in the created DICOM IODs. The second and third component groups are ignored.

Note: PLEX Elite 9000 does not support multiple Scheduled Procedure Steps for the same requested procedure. It adapts the first scheduled procedure step in the receiving order.

#### 4.2.1.3.2.2 Proposed Presentation Contexts

Following presentation contexts are offered for each initiated association. During this activity the Application Software uses only

- "Modality Worklist IM - FIND" with Transfer Syntax IL

**Table 4-7 Proposed Presentation Contexts for Activity Query Modality Worklist**

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Ext. Neg.
Name	UID 1.2.840.10008. ...	Name List	UID List 1.2.840.10008. ...		
Verification	1.1	ILE	1.2	SCU	No
Modality Worklist IM - FIND	5.1.4.31	ILE	1.2	SCU	No
Study Root Q/R IM - FIND	5.1.4.1.2.2.1	ILE	1.2	SCU	Yes
Study Root Q/R IM - MOVE	5.1.4.1.2.2.2	ILE	1.2	SCU	No
Patient Root Q/R IM – FIND	5.1.4.1.2.1.1	ILE	1.2	SCU	Yes
Modality Performed Procedure Step	3.1.2.3.3	ILE	1.2	SCU	No
Modality Performed Procedure Step Notification	3.1.2.3.5	ILE	1.2	SCU	No
Encapsulated PDF Storage	5.1.4.1.1.104.1	ILE	1.2	SCU	No
		ELE	1.2.1	SCU	No
Raw Data Storage	5.1.4.1.1.166	ILE	1.2	SCU	No
		ELE	1.2.1	SCU	No
OP 8 Bit Image Storage	5.1.4.1.1.77.1.5.1	J2K	1.2.4.91	SCU	No
OPT Image Storage	5.1.4.1.1.77.1.5.4	J2K	1.2.4.91	SCU	No
Multi-frame True Color Secondary Capture Image Storage	5.1.4.1.1.7.4	RLE	1.2.5	SCU	No
		JPG-1	1.2.4.50	SCU	No
Storage Commitment Push Model	1.20.1	ILE	1.2	SCU	No

Note 1: The networking interface proposes more presentation contexts than actually supported by the application. All lines in grey are not supported by the PLEX Elite 9000.

#### 4.2.1.3.2.3 SOP Specific Conformance for Modality Worklist SOP Class

**Table 4-8 Modality Worklist C-FIND Response Status Handling Behavior**

Service Status	Further Meaning	Error Code	Behavior
Success	Matching is complete	0000	The Software Application stops receiving worklist items. It finally updates the pick list.
Pending	Matches are continuing	FF00, FF01	The Application Software checks whether the number of received worklist items overstepped the configurable limit. If the number of received worklist items overstepped the limit, then the Application Software sends a C-CANCEL-RQ,

			then an A-RELEASE-RQ to the service provider and a message is displayed.
Failure	Too Many Results	C001	If there are too many results the PLEX Elite 9000 application software throws a warning message "DICOM search returned too many records. Please narrow search" to the user and the status box is changed to yellow.
*	*	Any other status code	The user gets an error message.

**Table 4-9 Attributes involved in Modality Worklist C-FIND request and response**

Tag	Tag Name	Query Key Matching	Mandatory Query Keys Return	Imported	Displayed	Copied to SOP Instance
(0040,0100)	Scheduled Procedure Step Sequence	N/A	N/A	N/A	N/A	N/A
>(0040,0001)	Scheduled Station Application Entity Title	BRQ, DEF	N/A	N/A	PLD	N/A
>(0040,0003)	Scheduled Procedure Step Start Time	N/A	N/A	N/A	PL, PLD	N/A
>(0040,0002)	Scheduled Procedure Step Start Date	BRQ, DEF, RNG	N/A	N/A	PL, PLD	N/A
>(0008,0060)	Modality	BRQ, DEF, SEL	N/A	N/A	PLD	N/A
>(0040,0006)	Scheduled Performing Physicians Name	N/A	N/A	N/A	N/A	N/A
>(0040,0007)	Scheduled Procedure Step Description	N/A	N/A	N/A	PL, PLD	N/A
>(0040,0010)	Scheduled Station Name	N/A	N/A	N/A	N/A	N/A
>(0040,0011)	Scheduled Procedure Step Location	N/A	N/A	N/A	N/A	N/A
>(0040,0008)	Scheduled Protocol Code Sequence	N/A	N/A	N/A	N/A	N/A
>>(0008,0100)	Code Value	N/A	N/A	N/A	N/A	N/A
>>(0008,0102)	Coding Scheme Designator	N/A	N/A	N/A	N/A	N/A
>>(0008,0103)	Coding Scheme Version	N/A	N/A	N/A	N/A	N/A
>>(0008,0104)	Code Meaning	N/A	N/A	N/A	PLD	N/A
>(0040,0012)	Pre-Medication	N/A	N/A	N/A	N/A	N/A
>(0040,0009)	Scheduled Procedure Step ID	N/A	N/A	N/A	N/A	N/A
>(0032,1070)	Requested Contrast Agent	N/A	N/A	N/A	N/A	N/A
(0040,1001)	Requested Procedure ID	PBQ	N/A	X	PL, PLD	N/A
(0032,1060)	Requested Procedure Description	N/A	N/A	X	PLD	X
(0032,1064)	Requested Procedure Code Sequence	N/A	N/A	N/A	N/A	N/A

>(0008,0100)	Code Value	N/A	N/A	N/A	N/A	N/A
>(0008,0102)	Coding Scheme Designator	N/A	N/A	N/A	N/A	N/A
>(0008,0103)	Coding Scheme Version	N/A	N/A	N/A	N/A	N/A
>(0008,0104)	Code Meaning	N/A	N/A	N/A	PLD	N/A
(0020,000D)	Study Instance UID	N/A	X	X		X
(0008,1110)	Referenced Study Sequence	N/A	N/A	N/A	N/A	N/A
>(0008,1150)	Referenced SOP Class UID	N/A	N/A	N/A	N/A	N/A
>(0008,1155)	Referenced SOP Instance UID	N/A	N/A	N/A	N/A	N/A
(0040,1003)	Requested Procedure Priority	N/A	N/A	N/A	N/A	N/A
(0040,1004)	Patient Transport Arrangements	N/A	N/A	N/A	N/A	N/A
(0040,1400)	Requested Procedure Comments	N/A	N/A	N/A	N/A	N/A
(0008,0050)	Accession Number	PBQ	N/A	X	PL, PLD	X
(0032,1032)	Requesting Physician	N/A	N/A	N/A	N/A	N/A
(0008,0090)	Referring Physicians Name	N/A	N/A	X	PLD	X
(0038,0010)	Admission ID	N/A	N/A	N/A	N/A	N/A
(0038,0300)	Current Patient Location	N/A	N/A	N/A	N/A	N/A
(0008,1120)	Referenced Patient Sequence	N/A	N/A	N/A	N/A	N/A
>(0008,1150)	Referenced SOP Class UID	N/A	N/A	N/A	N/A	N/A
>(0008,1155)	Referenced SOP Instance UID	N/A	N/A	N/A	N/A	N/A
(0010,0010)	Patients Name	PBQ	X	X	PL, PLD, APP	X
(0010,0020)	Patients ID	PBQ	X	X	PL, PLD, APP	X
(0010,0021)	Issuer of Patient ID	N/A	N/A	X	N/A	X
(0010,1000)	Other Patient IDs	N/A	N/A	X	N/A	X
(0010,0030)	Patients Birth Date	N/A	X	X	PLD, APP	X
(0010,0040)	Patients Sex	N/A	N/A	X	PLD, APP	X
(0010,1030)	Patients Weight	N/A	N/A	N/A	N/A	N/A
(0040,3001)	Confidentiality Constraint on Patient Data Description	N/A	N/A	N/A	N/A	N/A
(0010,2160)	Ethnic Group	N/A	N/A	N/A	N/A	N/A
(0010,4000)	Patients Comments	N/A	N/A	X	N/A	X
(0038,0500)	Patient State	N/A	N/A	N/A	N/A	N/A

(0010,21C0)	Pregnancy Status	N/A	N/A	N/A	N/A	N/A
(0010,2000)	Medical Alerts	N/A	N/A	N/A	N/A	N/A
(0038,0050)	Special Needs	N/A	N/A	N/A	N/A	N/A

**Values of column “Query Key”:**

**PBQ**

A tag that is marked with PBQ is used as query key in the Patient Based Query mode of the interactive Modality Worklist Query Dialog.

**BRQ**

A tag that is marked with BRQ is used as query key in the Broad Query mode of the interactive Modality Worklist Query Dialog.

**DEF**

A tag that is marked with DEF has a value assigned when the interactive Modality Worklist Query Dialog is shown the first time or when the Reset button is pushed. Default values can get modified. The modifications will be stored for next use of Modality Worklist Query Dialog.

**RNG**

The operator can apply a range as value for the query key.

**SEL**

The operator can select a value from a given list of values.

**Values of column “Imported”:**

**X**

The value gets imported in the application. Thus this value may have influence in Information Objects which will be created as a result of the performed examination.

**Values of column “Displayed”:**

**PL**

Values of this tag are instantly visible in the pick list.

**PLD**

Values of this tag are visible in the details dialog of the current selected pick list item.

**APP**

Values of this tag are visible in the application.

**Values of column SOP Instance:**

**X**

Values of marked tags will be stored in created SOP Instances. See also table “mapping of attributes” in 8.1.3 Attribute Mapping.

Following set of tags can be used as query key in the so called “**Patient Based Query**”. The Patient Based Query is a working mode of the Modality Worklist Query Dialog.

**Table 4-10 Modality Worklist Query Key Details - Patient Based Query**

Tag	Tag Name	Description
(0010,0010)	Patients Name	The PLEX Elite 9000 Application Software supports family name and given name only. The operator can use '*' or '?' as wild cards.
(0010,0020)	Patient ID	The operator can enter a string which conforms to the Value Representation LO.
(0008,0050)	Accession Number	The operator can enter a string which conforms to the Value Representation SH.
(0040,1001)	Requested Procedure ID	The operator can enter a string which conforms to the Value Representation SH.

Following set of tags can be used as query key in the so called "**Broad Query**". The Broad Query is a working mode of the Modality Worklist Query Dialog.

**Table 4-11 Modality Worklist Query Key Details - Broad Query**

Tag	Tag Name	Description
(0040,0100)	Scheduled Procedure Step Sequence	This attribute is the container for the tags as listed below. The sequence contains one item.
>(0040,0002)	Scheduled Procedure Step Start Date	The default value is today's date. The operator can change the value and can even enter date ranges. It is also possible to search for all dates if the operator activates a check box.
>(0008,0060)	Modality	The default value is "OPT". The operator can change the value and select one value of a predefined set of values including an empty string. Possible values are "OP", "OPM", "OPT", "OPV", "OT" and empty string.
>(0040,0001)	Scheduled Station AE Title	The default value is set by configuration. The operator can enter the AE Title of another device or leave the field empty.

#### 4.2.1.3.3 Activity – Native import

Operator can trigger "Native import" at any time if no other activity is in progress.

This activity has no direct effect on DICOM messaging.

During this activity, the Application Software imports scan data and analysis data that has been created in Application Software instances other than this instance. The imported data is subject to be archived within next "Archive data"-activity call.

#### 4.2.1.3.4 Activity – Perform scan(s)

Operator can trigger "Perform scan(s)" at any time if no other activity is in progress.

This activity has no direct effect on DICOM messaging.

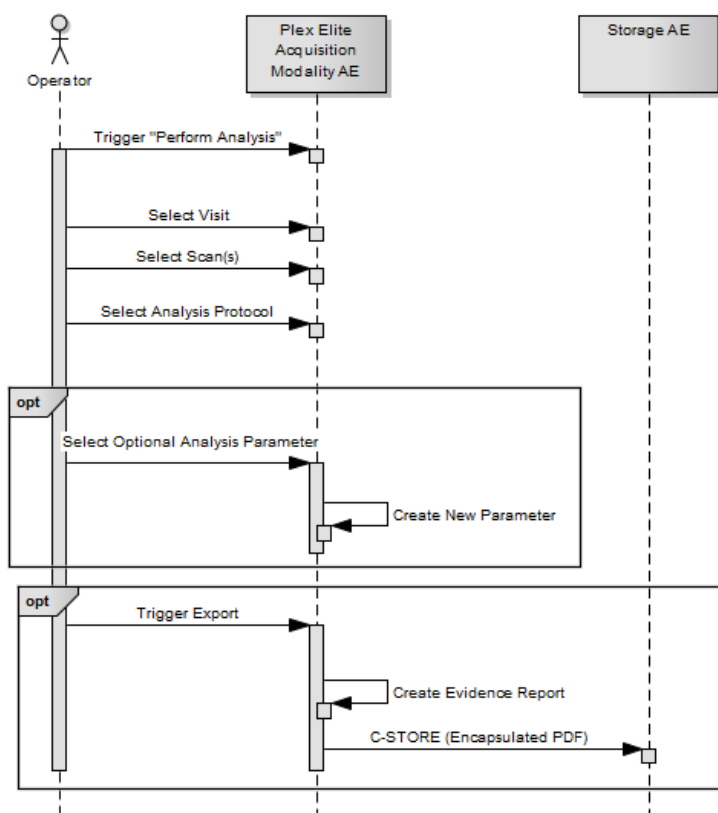
During this activity, the Application Software creates scan data. It also creates default parameters for an analysis. Scan and analysis data will be stored in local archive.

#### 4.2.1.3.5 Activity – Perform analysis

Operator can trigger "Perform analysis" at any time if no other activity is in progress.

#### 4.2.1.3.5.1 Description and Sequencing of Activities (Analysis)

Figure 4-8 - Perform Analysis



#### Trigger "Perform Analysis"

The activity can be triggered by selecting a patient from the pick list and clicking the analyse button.

#### Select a Visit

Operator can select a visit to perform an analysis.

#### Select Scan(s)

The operator selects one or more scans to include in the report. The Application Software enables applicable analysis types.

#### Select Analysis Protocol

The operator selects one analysis type.

Optionally the application software perform an analysis based on multiple prior scans

#### Select Optional Analysis Parameter

This is an optional step. The operator can adjust the parameters and thus, modify the analysis. Adjusting the parameters causes the creation of a new set of parameters. That set of parameters will be stored in local archive.

#### Export Evidence Report

At any time the operator can create an evidence report. The Application Software sends evidence reports to the configured Storage Application Entity.



Evidence reports won't be stored or archived on the instrument itself.

The created evidence report contains the information that was presented on screen when the operator triggered the export. Usually the evidence report contains one to three pages.

#### 4.2.1.3.5.2 Proposed Presentation Contexts

Following presentation contexts are offered for each initiated association. During this activity the Application Software uses only

- Encapsulated PDF with Transfer Syntax ELE or ILE

**Table 4-12 Proposed Presentation Contexts for Activity Perform Analysis**

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Ext. Neg.
Name	UID 1.2.840.10008. ...	Name List	UID List 1.2.840.10008. ...		
Verification	1.1	ILE	1.2	SCU	No
Modality Worklist IM - FIND	5.1.4.31	ILE	1.2	SCU	No
Study Root Q/R IM - FIND	5.1.4.1.2.2.1	ILE	1.2	SCU	Yes
Study Root Q/R IM - MOVE	5.1.4.1.2.2.2	ILE	1.2	SCU	No
Patient Root Q/R IM – FIND	5.1.4.1.2.1.1	ILE	1.2	SCU	Yes
Modality Performed Procedure Step	3.1.2.3.3	ILE	1.2	SCU	No
Modality Performed Procedure Step Notification	3.1.2.3.5	ILE	1.2	SCU	No
Encapsulated PDF Storage	5.1.4.1.1.104.1	ILE	1.2	SCU	No
		ELE	1.2.1	SCU	No
Raw Data Storage	5.1.4.1.1.66	ILE	1.2	SCU	No
		ELE	1.2.1	SCU	No
OP 8 Bit Image Storage	5.1.4.1.1.77.1.5.1	J2K	1.2.4.91	SCU	No
OPT Image Storage	5.1.4.1.1.77.1.5.4	J2K	1.2.4.91	SCU	No
Multi-frame True Color Secondary Capture Image Storage	5.1.4.1.1.7.4	RLE	1.2.5	SCU	No
		JPG-1	1.2.4.50	SCU	No
Storage Commitment Push Model	1.20.1	ILE	1.2	SCU	No

Note 1: The networking interface proposes more presentation contexts than actually supported by the application. All lines in grey are not supported by the PLEX Elite 9000.

#### 4.2.1.3.5.3 SOP Specific Conformance for Encapsulated PDF Storage SOP Class as SCU

**Table 4-13 C-STORE Response Status Handling Behavior**

Service Status	Further Meaning	Status Code	Behavior
Success	Success	0000	The Application Software returns from this activity, prompting a success message.
Refused	Out of Resources	A700 – A7FF	An error message is shown to the operator. The Application Software logs this event and returns.
Error	Data Set does not match SOP Class	A900 – A9FF	
Error	Cannot Understand	C000 – CFFF	
Warning	Coercion of Data Elements	B000	
Warning	Data Set does not match SOP Class	B007	
Warning	Elements Discarded	B006	
*	*	Any other status value	

**Table 4-14 C-STORE Communication Failure Behavior**

Exception	Behavior
DIMSE response timeout	The Association is aborted using A-ABORT. The reason is written to the log file. A user alert message is displayed.
Network Timeout	The Application Software is unable to connect to the remote Application Entity. The reason is written to the log file. A user alert message is displayed.
Maximum Association Idle Time exceeded	The Artim timer expires and the socket is closed. The reason is written to the log file.

#### 4.2.1.4 Association Acceptance Policy

##### 4.2.1.4.1 Activity – Verify Communication

The activity can be performed at any time. The service is available as soon as the Application Software has been started.

##### 4.2.1.4.1.1 Description and Sequencing of Activities

The Software AE responds to verification requests made by remote AEs.

##### 4.2.1.4.1.2 Accepted Presentation Contexts

Table 4-15 Acceptable Presentation Context for Activity Verify Communication

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Ext. Neg.
Name	UID	Name List	UID List		
	1.2.840.10008. ...		1.2.840.10008. ...		
Verification	... 1.1	ILE	... 1.2	SCP	No

##### 4.2.1.4.1.3 SOP Specific Conformance for Verification SOP Class as SCP

The Application Software AE provides standard conformance.

### 4.3 Network Interfaces

#### 4.3.1 Physical Network Interface

The physical network interface is not visible for the instrument application. The instrument application uses the communication stack as offered by the Operating System.

#### 4.3.2 Additional Protocols

Both IP addresses and host names are supported and get resolved. Else no additional protocols are supported.

#### 4.3.3 IPv4 and IPv6 Support

Application software supports IPv6 features through configuration preference settings. This will also require that the instrument or review station installed specific IPv6 protocol and its required attributes via networking configuration for each network interface card.

### 4.4 Configuration

Local application entity and remote application entity information can be configured with the DICOM Gateway Configuration Tool. There is only one single Application Entity Title used for the instrument Software Application. It is also possible to configure timeout, institution, and query response item limit parameters via the DICOM Gateway Configuration Tool..

#### 4.4.1 AE Title/Presentation Address Mapping

The mapping from AE Title to TCP/IP addresses and ports is configurable and set at the time of installation by Installation Personnel.

#### 4.4.1.1 Local AE Titles

The IP is not configurable by the Configuration Tool. The IP is administrated by the Operating System. If the Application Software is running on a host with more than one network connection, the user should select the loopback adapter from the list of IP addresses.

**Table 4-16 AE Title Configuration Table**

<b>Application Entity</b>	<b>Default AE Title</b>	<b>Default TCP/IP Port</b>
PLEX Elite 9000 AE	GW_[timestamp] [timestamp] : the time the DICOM Gateway Configuration Tool is started.	11112

In case AutoConnect™ is enabled in both PLEX Elite 9000 and FORUM, the Local AE configuration is registered automatically in the FORUM AE Title Administration.

#### 4.4.1.2 Remote AE Titles

The mapping of external AE Titles to TCP/IP addresses and ports is configurable. The PLEX Elite 9000 Application Software allows setting up a remote Application Entity for each service (Modality Worklist, Storage, Storage Commitment, Query and Retrieve). For all Application Entities, the host name or IP, the Port and the Application Entity Title must be known.

In case AutoConnect is enabled in both PLEX Elite 9000 and FORUM, the configuration of the Remote Application Entities can be performed automatically using the AutoConnect button.

## 4.4.2 Parameters

### 4.4.2.1 General Parameters

The general parameters are shared for associations to any of the configured AE.

**Table 4-17 Configuration Parameters Table**

Parameter	Configurable (Yes/No)	Default Value
<b>General Parameters</b>		
DIMSE RSP Timeout	Yes (10 – 60 sec.)	20 sec
Network Timeout	Yes (5-20 sec.)	20 sec.
Max. Association Idle Time	Yes (10 – 60 sec.)	30 sec
(0008,0080) Institution Name	Yes	empty
(0008,1040) Institutional Department Name	No	N/A
(0008,0081) Institution Address	No	N/A
(0008,1010) Station Name	Yes	empty
(0008,1070) Operator's Name	Yes	Logged in user
(0010,0021) Issuer of Patient ID (used locally created patients)	Yes	Auto generated number
Today Patients As Default (Query for Today's Patients at Startup)	Yes (in Records-> Preferences-> Display Options)	No
Enable IP_V6	Yes	IP_V4
<b>AE Specific Parameters</b>		
Maximum number of simultaneous associations is 2.		
<b>Verification SCU Parameters</b>		
C-ECHO Interval	No	Only on demand
<b>Modality Worklist SCU Parameters</b>		
Maximum Query Responses (Modality Worklist IM, Patient Root Q/R IM and Study Root Q/R IM)	Yes (10-4999)	999
Today's Patient List Refresh Rate (Modality Worklist Polling Interval)	No	Only on demand
(0040,0001) Scheduled Station Application Entity Title (Today's Patient Worklist Query)	Yes (include/exclude from query)	Empty
(0040,0002) Scheduled procedure Step Start Date	Yes (include/exclude from query)	Uses the date of today
(0008,0060) Modality	Yes (include/exclude from query)	"OPT"
<b>Verification SCP Parameters</b>		
No specific configuration required The configuration of port number and Application Entity Title are part of the Local Application Entity setup (see 4.4.1.1 Local AE Titles).	N/A	N/A

## 5 Media Interchange

Media Interchange is not scope of this document since Media Interchange is not supported by PLEX Elite 9000 Application Software.

## 6 Support of Character Sets

All application entities described in the previous chapters support UTF-8 character set.

**Table 6-1 Supported Character Set**

Supported Specific Character Set	
Character Set Description	Defined Term
UTF-8 encoded Unicode	ISO_IR 192

## 7 Security

The DICOM capabilities of the PLEX Elite 9000 Application Software do not support any specific security measures.

It is assumed that PLEX Elite 9000 Application Software is used within a secured environment. It is assumed that a secured environment includes at a minimum:

- Firewall or router protections to ensure that only approved external hosts have network access to PLEX Elite 9000 Application Software
- Firewall or router protections to ensure that PLEX Elite 9000 Application Software only has network access to approved external hosts and services.
- Any communication with external hosts and services outside the locally secured environment use appropriate secure network channels (e.g. such as a Virtual Private Network (VPN))

Other network security procedures such as automated intrusion detection may be appropriate in some environments. Additional security features may be established by the local security policy and are beyond the scope of this conformance statement.



## 8 Annexes

### 8.1 IOD Contents

#### 8.1.1 Created SOP Instance(s)

##### Abbreviations used for Presence of Values (PoV):

**VNAP**

Value Not Always Present (attribute sent zero length if no value is present) – Applicable for Type 2, 2C.

**ANAP**

Attribute is not always present – Applicable for Type 3

**ALWAYS**

Attribute is always present with a value – Applicable for Type 1

**EMPTY**

Attribute is sent without a value – Applicable for Type 2

##### Abbreviations used for Sources of Data (Source):

**USER**

The attribute value source is from User input

**AUTO**

The attribute value is generated automatically

**MWL, MPPS, etc.**

The attribute value is the same as the value received using a DICOM service such as Modality Worklist, Modality Performed Procedure Step, etc.

**CONFIG**

The attribute value source is a configurable parameter

**ACQUISITION**

The sources of data come from data acquisition process. Include Image and data relate to Image

**ANALYSIS**

The sources of data come from data generate by application or add/edit/update by user when images are analysed.

The tables below show “full blown” IODs.

Some cells have grey background color. In the template the grey background color exists because there is no related CZM-XML Element or because Network Integration Manager (NIM) does handle the attribute.

The text as given by column Value contains the description as given by the DICOM Standard for the IOD. Named references relate to the DICOM Information Object Definitions, as specified in PS 3.3: DICOM Information Object Definitions.

For the rest, please fill in text for Value, Presence of Value and Source. Please verify the descriptions in red. You may add more specific descriptions. Please do not delete any row.

Cells with orange background require special attention. It is the instruments responsibility to decide whether the conditions for each attribute require the attributes to be present or not. If the attributes are never included in the IOD the cells shall be grayed out.

### 8.1.1.1 Encapsulated PDF Information Object Definition

**Table 8-1 Encapsulated PDF IOD – Module Overview**

IE	Module	References	Usage
Patient			
	Patient	Table 8-2 Module “Patient” of Created	ALWAYS
Study			
	General Study	Table 8-3 Module “General Study” of Created	ALWAYS
Series			
	Encapsulated Document Series	Table 8-4 Module “Encapsulated Document Series” of Created Encapsulated PDF SOP Instances	ALWAYS
	Czm Encapsulated Pdf Series Extension	Table 8-5 Module “Czm Encapsulated Pdf Series Extension” of Created Encapsulated PDF SOP Instances	ALWAYS
Equipment			
	General Equipment	Table 8-6 Module “General Equipment” of Created	ALWAYS
	Sc Equipment	Table 8-7 Module “SC Equipment” of Created Encapsulated PDF SOP Instances	ALWAYS
Encapsulated Document			
	Encapsulated Document	Table 8-8 Module “Encapsulated Document” of Created Encapsulated PDF SOP Instances	ALWAYS
	Sop Common	Table 8-9 Module “Sop Common” of Created Encapsulated PDF SOP Instances	ALWAYS
	CZM NIM Internal	Table 8-10 Module “CZM NIM Internal” of Created Encapsulated PDF SOP Instances	ALWAYS

**Table 8-2 Module “Patient” of Created Encapsulated PDF SOP Instances**

Attribute Name	Tag	VR	Value	PoV	Source
Patient's Name	(0010,0010)	PN	Patient's full name.	ALWAYS	MWL, USER
Patient ID	(0010,0020)	LO	Primary hospital identification number or code for the patient.	ALWAYS	MWL, USER
Issuer of Patient ID	(0010,0021)	LO	Copied from MWL response in the scheduled case.  In the unscheduled case uses value as configured in Institution Edit dialog.	ANAP	MWL, CONFIG
Patient's Birth Date	(0010,0030)	DA	Birth date of the patient.	ALWAYS	MWL, USER
Patient's Sex	(0010,0040)	CS	Sex of the named patient. Enumerated Values: M = male F = female O = other	VNAP	MWL, USER
Other Patient IDs	(0010,1000)	LO	N/A	N/A	N/A
Patient Comments	(0010,4000)	LT	User-defined additional information about the patient.	ANAP	MWL, USER

**Table 8-3 Module “General Study” of Created Encapsulated PDF SOP Instances**

Attribute Name	Tag	VR	Value	PoV	Source
Study Instance UID	(0020,000D)	UI	Unique identifier for the Study. Uses value as given by the Modality Worklist service in scheduled case.  The software creates the UID in the unscheduled case. Then it uses “1.2.276.0.75.2.2.44.” as constant prefix for generated UIDs for PLEX Elite 9000.  Uses value as given by the source Raw Data when it is originated from other devices.	ALWAYS	MWL, AUTO
Study Date	(0008,0020)	DA	Date the Study started.	ALWAYS	AUTO
Study Time	(0008,0030)	TM	Time the Study started.	ALWAYS	AUTO
Referring Physician's Name	(0008,0090)	PN	Name of the patient's referring physician. Value does not exist in unscheduled case.	VNAP	MWL
Study ID	(0020,0010)	SH	User or equipment generated Study identifier.	ALWAYS	AUTO
Accession Number	(0008,0050)	SH	A RIS generated number that identifies the order for the Study. Value does not exist in unscheduled case.	VNAP	MWL

Study Description	(0008,1030)	LO	<p>Institution-generated description or classification of the Study (component) performed.</p> <p>In scheduled case, the source attribute for this value is Requested Procedure Description.</p> <p>Value does not exist in unscheduled case.</p>	ANAP	MWL
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**Table 8-4 Module “Encapsulated Document Series” of Created Encapsulated PDF SOP Instances**

Attribute Name	Tag	VR	Value	PoV	Source
Modality	(0008,0060)	CS	The modality appropriate for the encapsulated document. This Type definition shall override the definition in the SC Equipment Module. See NEMA PS3.3 Section C.7.3.1.1.1 for Defined Terms. Note: SR may be an appropriate value for an Encapsulated CDA document with a structured XML Body. Default “OPT”, but can be configured to be “OP” for systems that don’t support “OPT”.	ALWAYS	CONFIG
Series Instance UID	(0020,000E)	UI	Unique identifier of the Series. “1.2.276.0.75.2.2.44” extended by machine identifier and time information.	ALWAYS	AUTO
Series Number	(0020,0011)	IS	Always 1.	ALWAYS	AUTO
Series Description	(0008,103E)	LO	Description of the Series. Same value as for Performed Procedure Step Description (0040,0254).	ALWAYS	AUTO
Performed Procedure Step Start Date	(0040,0244)	DA	Date on which the Performed Procedure Step started	ALWAYS	AUTO
Performed Procedure Step Start Time	(0040,0245)	TM	Time on which the Performed Procedure Step started	ALWAYS	AUTO
Performed Procedure Step Description	(0040,0254)	LO	Institution-generated description or classification of the Procedure Step that was performed. For Objects generated by PLEX Elite 9000 SW versions 2.1.0.x one of the following values will be set: Cube (12mmx12mm) (512x512) (100kHz) Cube (12mmx12mm) (800x800) (100kHz) Cube (12mmx12mm) (1024x1024) (100kHz) HD Spotlight 1 (100kHz) UHD Spotlight 1 (200kHz) Angio (3mmx3mm) (100kHz) Angio (6mmx6mm) (100kHz) Angio (9mmx9mm) (100kHz) Angio (12mmx12mm) (100kHz) Angio (15mmx9mm) (100kHz) HD Angio (12mmx12mm) (200kHz) ONH Angio (6mmx6mm) (100kHz) HD 51 Line (6mm) (100kHz) HD 51 Line (12mm) (100kHz) Cube (12mmx12mm) (512x512) (200kHz) Cube (12mmx12mm) (800x800) (200kHz) Cube (12mmx12mm) (1024x1024) (200kHz) Angio (3mmx3mm) (200kHz)	ALWAYS	AUTO

			Angio (6mmx6mm) (200kHz) Angio (9mmx9mm) (200kHz) Angio (12mmx12mm) (200kHz) Angio (15mmx9mm) (200kHz) Angio (15mmx15mm) (200kHz) ONH Angio (6mmx6mm) (200kHz)		
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**Table 8-5 Module “Czm Encapsulated Pdf Series Extension” of Created Encapsulated PDF SOP Instances**

Attribute Name	Tag	VR	Value	PoV	Source
Laterality	(0020,0060)	CS	Laterality of (paired) body part examined. Enumerated Values: R = right, L = left, B = both	ALWAYS	AUTO

**Table 8-6 Module “General Equipment” of Created Encapsulated PDF SOP Instances**

Attribute Name	Tag	VR	Value	PoV	Source
Manufacturer	(0008,0070)	LO	Manufacturer of the equipment that produced the composite instances. Always “Carl Zeiss Meditec”	ALWAYS	AUTO
Institution Name	(0008,0080)	LO	Institution where the equipment that produced the composite instances is located. Value as configured in Institution Edit dialog.	ANAP	CONFIG
Station Name	(0008,1010)	SH	User defined name identifying the machine that produced the composite instances. As configured in Equipment Edit dialog.	ANAP	CONFIG
Manufacturer's Model Name	(0008,1090)	LO	Manufacturer's model name of the equipment that produced the composite instances. As configured at installation time using configuration file. Always “PLEX ELITE 9000”	ALWAYS	CONFIG
Device Serial Number	(0018,1000)	LO	The serial number of the instrument in case of an Acquisition Modality. The model number plus license certificate number in case of a Review Station.	ALWAYS	AUTO
Software Version(s)	(0018,1020)	LO	Manufacturer's designation of software version of the equipment that produced the composite instances. See NEMA PS3.3 Section C.7.5.1.1.3. Always <acquisition software version><generated software version> Where <generated software version> is “2.1.0.x”	ALWAYS	AUTO

**Table 8-7 Module “SC Equipment” of Created Encapsulated PDF SOP Instances**

Attribute Name	Tag	VR	Value	PoV	Source
Conversion Type	(0008,0064)	CS	Always “SYN” for Synthetic Image	ALWAYS	AUTO

**Table 8-8 Module “Encapsulated Document” of Created Encapsulated PDF SOP Instances**

Attribute Name	Tag	VR	Value	PoV	Source
Instance Number	(0020,0013)	IS	A number that identifies this SOP Instance. The value shall be unique within a series. Always “1” since there is always only one instance per series.	ALWAYS	AUTO
Content Date	(0008,0023)	DA	The date the document content creation was started.	ALWAYS	AUTO
Content Time	(0008,0033)	TM	The time the document content creation was started.	ALWAYS	AUTO
Acquisition Datetime	(0008,002A)	DT	The date and time the original scan (source) data was acquired, where the report was derived from.	ALWAYS	AUTO
Burned In Annotation	(0028,0301)	CS	Always “YES” since there is enough information to identify the patient.	ALWAYS	AUTO
Document Title	(0042,0010)	ST	<p>The title of the document. Note: In the case of a PDF encapsulated document, this may be the value of the "Title" entry in the "Document Information Directory" as encoded in the PDF data.</p> <p>There are 2 choices available here for Document Title: For OU Cube Report analysis use the naming convention: “OU Cube Report”</p> <p>For all other analysis, use the following naming convention: &lt;eye site&gt;+ “ + &lt;analysis name&gt;, where &lt;eye site&gt; can be one of values: “OD” “OS” “OU” &lt;analysis name&gt; can be one of values: “Angiography Analysis” “Cube Report” “Enface Report” “SpotLight Report” “High Definition Images” “Advanced RPE Analysis”</p>	ALWAYS	AUTO
Concept Name Code Sequence	(0040,A043)	SQ	A coded representation of the document title. Zero or one item may be present. Always empty.	ALWAYS	AUTO
MIME Type of Encapsulated Document	(0042,0012)	LO	The type of the encapsulated document stream described using the MIME Media Type (see RFC 2046).	ALWAYS	AUTO

			Always "application/pdf"		
Encapsulated Document	(0042,0011)	OB	Encapsulated Document stream, containing a document encoded according to the MIME Type.	ALWAYS	AUTO



**Table 8-9 Module “Sop Common” of Created Encapsulated PDF SOP Instances**

Attribute Name	Tag	VR	Value	PoV	Source
SOP Class UID	(0008,0016)	UI	Always “1.2.840.10008.5.1.4.1.1.104.1”	ALWAYS	AUTO
SOP Instance UID	(0008,0018)	UI	“1.2.276.0.75.2.2.44” as constant prefix for generated UIDs	ALWAYS	AUTO
Specific Character Set	(0008,0005)	CS	Always “ISO_IR 192” for UTF-8 encoded Unicode.	ALWAYS	AUTO
Instance Creation Date	(0008,0012)	DA	Date the SOP Instance was created.	ALWAYS	AUTO
Instance Creation Time	(0008,0013)	TM	Time the SOP Instance was created.	ALWAYS	AUTO

**Table 8-10 Module “CZM NIM Internal” of Created Encapsulated PDF SOP Instances**

Attribute Name	Tag	VR	Value	PoV	Source
Private Creator	(2201,00xx)	LO	99CZM_NIM_INTERNAL_01	ALWAYS	AUTO
Iod_name_meta_info	(2201,xx00)	LT	EncapsulatedPdf	ALWAYS	AUTO
Czm_xml_version	(2201,xx01)	LT	2.8	ALWAYS	AUTO

### 8.1.2 Usage of Attributes from Received IOD's

The usage of attributes of Modality Worklist IODs is described in chapter 4.2.1.3.2 Activity – Query Modality Worklist.

### 8.1.3 Attribute Mapping

In scheduled case, the following attributes are mapped from Modality Worklist to SOP instances of Encapsulated PDF IOD.

**Table 8-11 Attribute Mapping**

Modality Worklist			Instance IOD	Editable
(0020,000D)	Study Instance UID	(0020,000D)	Study Instance UID	No
(0008,0050)	Accession Number	(0008,0050)	Accession Number	No
(0032,1060)	Requested Procedure Description	(0008,1030)	Study Description	No
(0010,0021)	Issuer of Patient ID	(0010,0021)	Issuer of Patient ID	No
(0010,1000)	Other Patient IDs	(0010,1000)	Other Patient IDs	No
(0008,0090)	Referring Physicians Name	(0008,0090)	Referring Physicians Name	No
(0010,0010)	Patients Name	(0010,0010)	Patients Name	No
(0010,0020)	Patient ID	(0010,0020)	Patient ID	No
(0100,0030)	Patients Birth Date	(0010,0030)	Patients Birth Date	No
(0010,0040)	Patients Sex	(0010,0040)	Patients Sex	No
(0010,4000)	Patient Comments	(0010,4000)	Patient Comments	No

### 8.1.4 Coerced/Modified Files

Those tags are listed in chapter 4.2.1.3.2 Activity – Query Modality Worklist. Other attributes get lost and are not available in the PLEX Elite 9000 Application Software.

## 8.2 Data Dictionary of Private Attributes

The Private Attributes added to created SOP Instances are listed in the Tables below. PLEX Elite 9000 reserves blocks of private attributes in group 2201.

**Table 8-12 Private Dictionary Group (2201,00xx) = “99CZM\_NIM\_INTERNAL\_01”**

Occurs in: all SOP Instances created by PLEX Elite 9000

Tag	Attribute Name	VR	VM
(2201,00xx)	Private Creator	LO	1
(2201,xx00)	lod_name_meta_info	LT	1
(2201,xx01)	Czm_xml_version	LT	1

## 8.3 Coded Terminology and Templates

No codes are used.

### 8.3.1 Context Groups

N/A

### 8.3.2 Template Specifications

N/A

### 8.3.3 Private Code Definitions

N/A

## 8.4 Greyscale Image Consistency

Not applicable.

## 8.5 Standard Extended / Specialized/ Private SOP Classes

The following standard extensions are used in the IODs described in Chapter 8.1.1 Created SOP Instance(s).

Table 8-5 Module “Czm Encapsulated Pdf Series Extension” of Created Encapsulated PDF SOP Instances

Table 8-10 Module “CZM NIM Internal” of Created Encapsulated PDF SOP Instances

## 8.6 Private Transfer Syntaxes

No Private Transfer Syntax is supported.



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