

DICOM Conformance Statement

CLARUS[™] 500 and CLARUS[™] 700

Version 1.1.3

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1 Conformance Statement Overview

CLARUS 500 and CLARUS 700 (both referred to as CLARUS in this document unless distinction is explicitly made) are non-contact, high-resolution imaging devices for invivo imaging of the human eye. Imaging modes include:

- True color reflectance imaging
- Infrared reflectance imaging (IR)
- Fundus autofluorescence with green or blue excitation (FAF-G and FAF-B)
- Fluorescein Angiography (FA) CLARUS 700 only
- IR is not available for all countries
- Stereo imaging
- External eye imaging

CLARUS consists of an image acquisition modality and review application. The acquisition modalities enables examination of patient's eye, while CLARUS review software enables you to view, analyze and manage CLARUS data on a personal computer. It provides all the CLARUS instrument functionality, except exam acquisition, in a remote location.

The CLARUS Application Software allows to:

- query modality worklist
- query patients and data
- create report
- perform exam
- store exam
- create report
- retrieve exam
- delete data
- DICOM file import
- DICOM file export
- merge of patients & reassign of exams

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

| Гable 1-1 | Network | Services | Supported |
|-----------|---------|----------|-----------|
|-----------|---------|----------|-----------|

| SOP Classes | User of Service (SCU) | Provider of Service (SCP) |
|--|-----------------------|---------------------------|
| Trans | fer | |
| Raw Data Storage | Yes | Yes ² |
| Ophthalmic Photography 8 Bit Image Storage | Yes | Yes ^{2, 4} |
| VL Photographic Image Storage | No ³ | Yes ² |
| Encapsulated PDF Storage | Yes | No |
| Workflow Ma | inagement | |
| Storage Commitment Push Model SOP Class | Yes | No |
| Modality Worklist Information Model - FIND | Yes | No |
| Query / R | etrieve | |
| Patient Root Query/Retrieve Information Model – FIND | Yes ¹ | No |
| Study Root Query/Retrieve Information Model – FIND | Yes ¹ | No |
| Study Root Query/Retrieve Information Model – MOVE | Yes | No |

¹Note: C-FIND extended negotiation is offered. Relational-query support is required by the SCP.

²Note: Only acts as SCP when a C-Move-RQ was initiated first and this association is still open.
 ³Note: CLARUS does not transmit VL Photographic Image IODs via DICOM network. It provides function to DICOM retrieve and import VISUCAM / VISPUPAC DICOM VL Photographic Image files from local, external or network drive.
 ⁴Note: CLARUS acts as Storage SCU for OP 8 Bit Images generated by CLARUS itself. However, it performs DICOM retrieve and file import only for those OP 8 Bit Images generated by VISUCAM / VISPUPAC.

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 |
| 1.2.840.10008.1.20.1 | Storage Commitment Push Model SOP Class | Workflow Management |
| 1.2.840.10008.5.1.4.1.1.66 | Raw Data Storage | Transfer |
| 1.2.840.10008.5.1.4.1.1.77.1.4 | VL Photographic Image Storage | Transfer |
| 1.2.840.10008.5.1.4.1.1.77.1.5.1 | Ophthalmic Photography 8 Bit Image Storage | Transfer |
| 1.2.840.10008.5.1.4.1.1.104.1 | Encapsulated PDF Storage | Transfer |
| 1.2.840.10008.5.1.4.1.2.1.1 | Patient Root Query/Retrieve Information Model - FIND | Query/Retrieve |
| 1.2.840.10008.5.1.4.1.2.2.1 | Study Root Query/Retrieve Information Model – FIND | Query/Retrieve |
| 1.2.840.10008.5.1.4.1.2.2.2 | Study Root Query/Retrieve Information Model – MOVE | Query/Retrieve |
| 1.2.840.10008.5.1.4.31 | Modality Worklist Information Model - FIND | Workflow Management |

CLARUS does not support Media Interchange.

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3.1 Revision History

Table 3-1 Revision History

| Document Version | Date | Changes |
|---------------------|------------|---|
| 01 | 2020-12-17 | Release for 1.1.2. Removed all references for ICG and FA- ICG simultaneous images, multi frame and movie |
| 02 | 2020-01-19 | Release for 1.1.2. Removed N/A from tables below. Removed EC REP. |
| 03 | 2022-05-16 | Release for 1.1.3. Update Address and Clarus version. |

3.2 Audience

This document is written for the people that need to understand how CLARUS 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 CLARUS 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 |
|--------------|--|
| ANAP | Attribute is not always present - applicable for type 3 attributes |
| AE | Application Entity |
| AET | Application Entity Title |
| APP | Application |
| AUTO | Automatically generated, cannot be modified by the operator |
| BRQ | Broad Query mode of Modality Worklist Query |
| CONFIG | Configurable parameter |
| CZM | Carl Zeiss Meditec |
| DEF | Default Value |
| DICOM | Digital Imaging and Communications in Medicine |
| ELE | Explicit Little Endian |
| EMR | Electronic Medical Record system |
| ILE | Implicit Little Endian |
| IM | Information Model |
| IOD | Information Object Definition |
| JPG-1 | JPEG Coding Process 1 transfer syntax; JPEG Baseline; ISO 10918-1 |
| JPG-LL | JPEG Lossless |
| J2K | JPEG 2000 Image Compression |
| J2K-LL | JPEG 2000 Image Compression |
| | (Lossless Only) |
| MWL | Modality Worklist |
| PBQ | Patient Based Query mode of Modality Worklist Query |
| PL | Pick list |

| Abbreviation | Definition |
|--------------|--|
| PLD | Pick list item details |
| PRQ | Patient Root Query |
| RNG | Range of values |
| SCP | Service Class Provider |
| SCU | Service Class User |
| SEL | Selection from a list of values |
| SOP | Service Object Pair, union of a specific DICOM service and related IOD. |
| SRQ | Study Root Query |
| TCP/IP | Transmission Control Protocol / Internet Protocol |
| UID | Unique Identifier |
| USER | User input |
| VNAP | Value not always present (attribute sent zero length if no value is present) - applicable for type 2 and 2C attributes |
| WF | Wide Field exam |
| UWF | Ultra Wide Field exam |
| MPG4-H | MPEG-4 AVC/H.264 High Profile / Level 4.1 |

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/)

Integrating the Healthcare Enterprise (IHE) EYECARE Technical Framework, rev 4.0, 2016 (available free at http://www.ihe.net/Technical_Framework/index.cfm).

4.1 Implementation Model

4.1.1 Application Data Flow

Figure 1 CLARUS Application Software as Acquisition Modality



Figure 2 CLARUS Application Software as Review Station



4.1.2 Functional Definition of AEs

4.1.2.1 Functional Definition of CLARUS

CLARUS is a non-contact, high-resolution imaging device for invivo imaging of the human eye. Imaging modes include:

- True color reflectance imaging
- Infrared reflectance imaging (IR)
- Fundus autofluorescence with green or blue excitation (FAF-Gand FAF-B)
- Fluorescein Angiography (FA) CLARUS 700 only
- Stereo imaging
- External eye imaging

The CLARUS consists of an image acquisition modality and review application. The acquisition modalities enables examination of patient's eye, while CLARUS review software enables you to view, analyze and manage CLARUS data on a personal computer. It provides all the CLARUS instrument functionality, except exam acquisition, in a remote location. The CLARUS Application Software allows to:

- query modality worklist
- query patients and data
- perform exam
- store exam
- create report
- retrieve exam
- delete data
- DICOM file import
- DICOM file export
- merge of patients & reassign of exams

The CLARUS 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 CLARUS 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.

| | Self delegation |
|---------------|------------------------------|
| ••••• | Asynchronous call |
| \rightarrow | Synchronous call |
| ← | Return from synchronous call |

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 Acquisition Modality activities

Query Modality Worklist

When the patient arrives at the CLARUS, the operator queries the worklist. The user can invoke this by simply selecting the "Today" Tab in the main view which lists all patients scheduled for today for this instrument (identified by the instrument's AE Title) and scheduled procedure step start date from today. The default parameters used for this "Today's" Query are configurable. See Table 4-38 Configuration Parameters for more details. For more specific worklist queries the "Advanced" and then "Scheduled Patients" button can be used.

In either way the operator can select a patient from the result list and furthermore select a requested procedure to proceed with data acquisition. According to the transferred data CLARUS creates an entry in the local database.

CLARUS does not support multiple Scheduled Procedure Steps in one Requested Procedure.

Note: In case of multiple Scheduled Procedure Steps within one Requested Procedure only the first Scheduled Procedure Step will be shown:

Scheduled Procedure Step Start Time1 = 2pm

Scheduled Procedure Step Start Time2 = 4pm

Only Scheduled Procedure Step scheduled for 2 pm will be shown.

Query patients and data

When the patient arrives at the CLARUS, the operator can search patients and data stored at a remote AE. This can be done by using the "Quick Search" in the main screen or by using "Advanced" and then the "All Patients" for a more detailed search. Any matching results will be listed in patient list. Only data supported by CLARUS will be listed (see chapter 4.2.1.3.4 for more details on supported data)

This activity generates an unscheduled case.

The operator can then select the patient for data acquisition or analysis.

Perform Exam

When a patient or worklist item is selected the operator selects an acquisition type and then performs the exam on the patient's eye. The Application Software allows users to review the acquired data, and elaborate the images before permanently saving the scan results.

Store Exam

Based on the selected Export Mode, the acquired data will be sent to the configured storage provider. If Export Mode "Session" is selected, CLARUS sends data acquired in the current session right after the acquisition session is completed. If "Shutdown" is selected, storage of all unarchived exam data is triggered during CLARUS shutdown.

When archiving to "FORUM/PACS Server", all Sensor data (Raw Data IOD), Elaboration Parameter (Raw Data IOD), and OP 8Bit Image IODs are sent.

When archiving to "DICOM EMR", only OP 8-Bit Image IODs can be sent.

Storage Commitment are requested only for Sensor Data (Raw Data IOD).

Sensor data (Raw Data IOD) is the data scanned by the instrument. Elaboration Parameter (Raw Data IOD) includes image processing parameters, annotations and comments that are generated by the device (default values) or added/modified by users during the review.

OP 8Bit Image IOD carries the image generated from the Sensor Raw Data for display purpose.

Create Reports

This is an optional on-demand activity. The operator can create and review a report based on the images displayed on the review screen. All the processing parameters and annotations are applied.

The reports are created on the fly. The user can print and/or save the created report. The application will send the report to the storage provider if it is configured.

Retrieve Exam

When a patient is selected from the main screen, CLARUS retrieves exams of the selected patient. It is to be noted that only Sensor data and Elaboration Parameter Raw Data IODs as well as VISUCAM Images (VL Photographic Images and OP 8 Bit Images) are retrieved.

Delete Data

The activity "Delete data" can either be invoked manually by the operator or triggered automatically by software application. Typically this can be invoked for single exam or complete patient data.

Manual invocation:

The operator can invoke this activity from the "Patient" screen by pressing the "Delete" button shown for a certain measurement, a complete group of measurements or a patient. When connected to a DICOM network, an instance or a patient cannot be removed from the modality until the storage to a remote AE is successfully completed and committed.

Optionally, the operator can select a patient, navigate to the Analyze screen to delete selected exams.

Manually triggered deletion of data is performed immediately.

Automatic invocation:

Automatically triggered deletion is done during the shutdown process and will be performed for any instance order than certain period (setting ExamCacheTime, default 14 days) where the storage to a remote AE is successfully completed and committed. Patient demographic data will only be deleted from the modality after all related storage instances have been successfully deleted.

DICOM File Import

This Activity allows import of exams from a disk attached to the device. After import those exams will be added to the local database.

The Operator can trigger "Import" from "Settings -> Data & Reports -> Import" at any time if no other activity is in progress.

During this activity, CLARUS imports Raw Data IODs (Sensor data and Elaboration Parameter) created by other CLARUS devices. It can also import VL Photographic Images created by VISUCAM.

DICOM File Export

This Activity allows export of exams to a local disk attached to the device.

The Operator can trigger "export" from "Settings -> Data & Reports -> Export", and export all exams of the selected patients. The User can also export selected exams of a patient from the Analyze screen.

During this activity, only exams created by CLARUS are exported.

Merge and Reassign

It is possible to merge a local patient into a patient imported via Modality Worklist or into a patient imported via Patient Root Query from a DICOM Query Provider.

The operator can also reassign a local exam to another patient.

4.1.3.2 Scheduled case with Acquisition Modality

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

• The examination can be scheduled in advance or at the moment the patient arrives and will be obtained by CLARUS via Modality Worklist query.

In either case all patient and study related information is available at the day the examination takes place. On CLARUS these patients appear in the "Todays" list in the main screen. This information is used to take the examination.

Figure 3 Scheduled Case



4.1.3.3 Unscheduled case

In the unscheduled case the patient arrives immediately at the instrument, so that the patient was not registered at the front desk or the software does not support DICOM modality worklist. Thus the examination is not scheduled in the Modality Worklist. Patient demographics and study specific information has to be generated at the instrument itself. The situation is akin to the case if the Modality Worklist AE could not be reached due to network issues.

Patient demographics can be queried from the Query Service Class Provider. However, this should be considered as an exceptional way to obtain patient demographics.

Figure 4 Unscheduled Case



4.2 AE Specifications

4.2.1 CLARUS AE Specification

4.2.1.1 SOP Classes

Table 4-1 SOP Classes for CLARUS 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 |
| Raw Data Storage | 1.2.840.10008.5.1.4.1.1.66 | Yes | Yes ² |
| VL Photographic Image Storage | 1.2.840.10008.5.1.4.1.1.77.1.4 | No ³ | Yes ² |
| Ophthalmic Photography 8 Bit Image Storage | 1.2.840.10008.5.1.4.1.1.77.1.5.1 | Yes | Yes ^{2, 4} |
| Encapsulated PDF Storage | 1.2.840.10008.5.1.4.1.1.104.1 | Yes | No |
| Patient Root Query/Retrieve Information Model - FIND | 1.2.840.10008.5.1.4.1.2.1.1 | Yes ¹ | No |
| Study Root Query/Retrieve Information Model – FIND | 1.2.840.10008.5.1.4.1.2.2.1 | Yes ¹ | No |
| Study Root Query/Retrieve Information Model – MOVE | 1.2.840.10008.5.1.4.1.2.2.2 | Yes | No |
| Modality Worklist Information Model - FIND | 1.2.840.10008.5.1.4.31 | Yes | No |

¹Note: C-FIND extended negotiation is offered. Relational-query support is required by the SCP.

²Note: Only acts as SCP when a C-Move-RQ was initiated first and this association is still open.

³Note: CLARUS does not transmit VL Photographic Images IODs via DICOM network. It provides function to DICOM retrieve and import VISUCAM / VISPUPAC DICOM VL Photographic Image files from local, external or network drive. ⁴Note: CLARUS acts as Storage SCU for OP 8 Bit images generated by CLARUS itself. However, it performs DICOM retrieve and file import only for those OP 8 Bit Images generated by VISUCAM / VISPUPAC.

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 depends on the usage profile. At a certain point of time there might be active simultaneously:

- 1 association for Verification
- 1 association for Storage
- 1 association for Storage Commitment
- 1 association for Query/Retrieve MOVE
- n associations for Modality Worklist FIND, depending on whether search criteria are changed while a previous query is still active (no response yet)

 n associations for Query/Retrieve - FIND, depending on whether search criteria are changed while a previous query is still active (no response yet)

Table 4-3 Number of associations as an Association initiator for CLARUS

Table 4-4 Number of Associations as an Association Acceptor for CLARUS

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

4.2.1.2.3 Asynchronous Nature

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

4.2.1.2.4 Implementation Identifying Information

Table 4-5 DICOM implementation class and version

| Implementation Class UID | 1.2.276.0.75.2.5.20 | |
|-----------------------------|---------------------|--|
| Implementation Version Name | NIM-2.13.2 | |

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 CLARUS 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 subsequent 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 as SCU

Table 4-6 Proposed Presentation Contexts for Activity Verify Communication

| Presentation Context Table | | | | | |
|--|----------------------|-----------|---------------------------|----------------------|------------------|
| Abstract Sy | /ntax | Trai | nsfer Syntax | Role | Ext. |
| Name | UID 1.2.840.10008 | Name List | UID List 1.2.840.10008 | _ | Neg. |
| Verification | 1.1 | ILE | 1.2 | BOTH | No |
| Storage Commitment Push Model | 1.20.1 | ILE | 1.2 | SCU | No |
| Raw Data Storage | 5.1.4.1.1.66 | ILE | 1.2 | BOTH ² | No |
| | | ELE | 1.2.1 | BOTH ² | No |
| VL Photographic Image Storage | 5.1.4.1.1.77.1.4 | ILE | 1.2 | SCP ² | No |
| | | ELE | 1.2.1 | SCP ² | No |
| | | JPG-1 | 1.2.4.50 | SCP ² | No |
| Ophthalmic Photography 8 Bit | 5.1.4.1.1.77.1.5.1 | ILE | 1.2 | BOTH ^{2, 4} | No |
| Image Storage | | ELE | 1.2.1 | BOTH ^{2, 4} | No |
| | | J2K-LL | 1.2.4.90 | BOTH ^{2, 4} | No |
| | | JPG-1 | 1.2.4.50 | BOTH ^{2, 4} | No |
| | | MPG4-H | 1.2.4.102 | SCU | No |
| Encapsulated PDF Storage | 5.1.4.1.1.104.1 | ILE | 1.2 | SCU | No |
| | | ELE | 1.2.1 | SCU | No |
| Patient Root Query/Retrieve IM – FIND | 5.1.4.1.2.1.1 | ILE | 1.2 | SCU | Yes ¹ |
| Study Root Query/Retrieve IM - FIND | 5.1.4.1.2.2.1 | ILE | 1.2 | SCU | Yes ¹ |
| Study Root Query/Retrieve IM - MOVE | 5.1.4.1.2.2.2 | ILE | 1.2 | SCU | No |
| Modality Worklist IM – FIND | 5.1.4.31 | ILE | 1.2 | SCU | No |

¹Note: C-FIND extended negotiation is offered. Relational-query support is required by the SCP.

²Note: Only acts as SCP when a C-Move-RQ was initiated first and this association is still open.

³Note: CLARUS does not transmit VL Photographic Image IODs via DICOM network. It provides function to DICOM retrieve and import VISUCAM / VISPUPAC DICOM VL Photographic Image files from local, external or network drive. ⁴Note: CLARUS acts as Storage SCU for OP 8 Bit Images generated by CLARUS itself. However, it performs DICOM retrieve and file import only for those OP 8 Bit Images generated by VISUCAM / VISPUPAC.

4.2.1.3.1.3 SOP Specific Conformance for Verification SOP Class

The CLARUS Application Software provides standard conformance.

4.2.1.3.2 Activity – Query Modality Worklist

The worklist contains scheduling information for patients. Query Modality Worklist is used to search for the right scheduling information for this instrument. An operator has two options to perform this activity.

4.2.1.3.2.1 Description and Sequencing of Activities

Option "Todays Patients query"

In this case, the Application Software performs a query with predefined query keys. These keys can be included/excluded in/from the worklist query by settings on "Settings -> EMR/PACS -> Manual Configuration Edit -> MWL" Settings For Today's List". The applied query keys are:

Table 4-7 Modality Worklist Query for Today's Patients

| Тад | Attribute Name | Description | Modality Worklist Query Settings For Today's List |
|--------------|--|-------------------------|--|
| (0040,0100) | Scheduled Procedure Step Sequence | | |
| >(0040,0001) | 40,0001) Scheduled Station Application Entity Title Uses the AE Title value as configured for the CLARUS | | Include/exclude with setting "Include AE Title". |
| | | instrument. | Default: Value as configured for the CLARUS instrument |
| >(0040,0002) | Scheduled procedure Step Start Date | Uses the date of today. | Include/exclude with setting "Include Today's Date". |
| | | | Default: Date of today |
| >(0008,0060) | Modality | "OP" | Include/exclude with setting "Include Modality". Default: "OP" |

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

This default query can be manually triggered by simply pressing the button in the header of the "Today" list. This default query is also triggered automatically in a configurable interval to keep the "Today" List up to date if option "Automatic MWL Update" is switched on.

Figure 5 Today's Patients Query



Select Requested Procedure

The worklist item planned next according to its Scheduled Procedure Step Start Date and Time will be pre-selected. The operator can choose to either start the scan acquisition directly or choose another worklist item from the Today's list before continuing with the acquisition. If the operator proceeds to acquire without choosing any worklist item, the acquisition is associated with a worklist item with the earliest study date from the available worklist items.

Option "Interactive query"

The query keys of the "Interactive query" can be modified by the operator. To modify the query key the operator has to open the "Advanced" screen and use the tab "Scheduled Patients". This screen will provide all available search fields for the Modality Worklist search.

The operator can select the patient after the Modality Worklist search. In this case the patient will be added to the Today's Patients list and the operator can perform an acquisition.

Depending on the option "Automatic MWL Update" the workflow results in a scheduled or an unscheduled case.

Alternatively the operator can display the Modality Worklist Details for a selected patient. In the Details screen the operator can select a Requested Procedure or Scheduled Procedure Step and add the patient including the selected Requested Procedure / Scheduled Procedure Step information.

Figure 6 Interactive Query



Trigger "Query Modality Worklist"

The activity "Query Modality Worklist" can be triggered by the operator at any time if no other activity is in progress. To invoke the query the operator has to use the "Scheduled Patients" tab from the "Advanced" search screen. 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 "Station" is prefilled with the AE title configured for the Today's Modality Worklist Query (see Table 4-38 Configuration Parameters) and the "Schedule date" is predefined with today. All predefined values can be changed. 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.

Trigger query

The operator triggers the search after he 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. The Application Software will accept up to a configurable number of matches. If the number of received worklist items overstepped the configurable limit, the Application Software sends a C-CANCEL-RQ followed by a A-RELEASE-RQ to the service provider and a message is displayed. Despite this warning, the operator gets results in the result-list.

After receiving the response, the pick-list is updated. The result-list provides the most important information for a quick overview (see section 4.2.1.3.2.3 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 result-list

The operator can select a patient in the pick-list and return to the acquisition screen. Depending on the configuration of the predefined query keys and the "Automatic or manual MWL Update" the workflow results in an unscheduled or a scheduled case. Please refer to step "Show Patient in main screen" for further information.

Activate detailed view

The detailed view allows a closer look to all work items for the selected patient. Thus the operator can see more information about the patient, the Requested Procedures and the Scheduled Procedure Steps planned for the selected patient.

Select Requested Procedure

In the detailed view the operator has the option to select a dedicated Requested Procedure with the earliest associated Scheduled Procedure Step by clicking on the Select button of the highlighted Requested Procedure.

Show Patient in main screen

The operator can take over the selected item at any time. The data is stored in the list of "Today". After all that, the operator can start the examination of the patient and acquire scan data.

The transfer of the selected patient from the "Advanced" – "Scheduled Patients" screen will result in an unscheduled case.

The only exception is:

Predefined query keys for Today's List do match the selected Modality Worklist Item. The Patient is transferred to the main screen. Another MWL default query is triggered by manual or automatic Modality Worklist refresh, and the query results are displayed on Today's list.

Query conditions for Today's list is configurable in Settings -> EMR/PACS -> Manual Configuration Edit -> MWL.

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 ILE as SCU

| Presentation Context Table | | | | | |
|--|---|--------|---------------------------|---------------------|------------------|
| Abstract Sy | ıntax | Tran | sfer Syntax | Role | Ext. |
| Name | Name UID Name List UID List 1.2.840.10008 1.2.840.10008 1.2.840.10008 | | UID List 1.2.840.10008 | - | Neg. |
| Verification | 1.1 | ILE | 1.2 | BOTH | No |
| Storage Commitment Push Model | 1.20.1 | ILE | 1.2 | SCU | No |
| Raw Data Storage | 5.1.4.1.1.66 | ILE | 1.2 | BOTH ² | No |
| | | ELE | 1.2.1 | BOTH ² | No |
| VL Photographic Image Storage | 5.1.4.1.1.77.1.4 | ILE | 1.2 | SCP ² | No |
| | | ELE | 1.2.1 | SCP ² | No |
| | | JPG-1 | 1.2.4.50 | SCP ² | No |
| Ophthalmic Photography 8 Bit | 5.1.4.1.1.77.1.5.1 | ILE | 1.2 | BOTH ^{2,4} | No |
| image Storage | | ELE | 1.2.1 | BOTH ^{2,4} | No |
| | | J2K-LL | 1.2.4.90 | BOTH ^{2,4} | No |
| | | JPG-1 | 1.2.4.50 | BOTH ^{2,4} | No |
| | | MPG4-H | 1.2.4.102 | SCU | No |
| Encapsulated PDF Storage | 5.1.4.1.1.104.1 | ILE | 1.2 | SCU | No |
| | | ELE | 1.2.1 | SCU | No |
| Patient Root Query/Retrieve IM – FIND | 5.1.4.1.2.1.1 | ILE | 1.2 | SCU | Yes ¹ |
| Study Root Query/Retrieve IM - FIND | 5.1.4.1.2.2.1 | ILE | 1.2 | SCU | Yes ¹ |
| Study Root Query/Retrieve IM - MOVE | 5.1.4.1.2.2.2 | ILE | 1.2 | SCU | No |
| Modality Worklist IM – FIND | 5.1.4.31 | ILE | 1.2 | SCU | No |

Table 4-8 Proposed Presentation Contexts for Activity Query Modality Worklist

¹Note: C-FIND extended negotiation is offered. Relational-query support is required by the SCP.

²Note: Only acts as SCP when a C-Move-RQ was initiated first and this association is still open.

³Note: CLARUS does not transmit VL Photographic Image IODs via DICOM network. It provides function to DICOM retrieve and import VISUCAM / VISPUPAC VL DICOM VL Photographic Image files from local, external or network drive. ⁴Note: CLARUS acts as Storage SCU for OP 8 Bit Images generated by CLARUS itself. However, it performs DICOM retrieve and file import only for those OP 8 Bit Images generated by VISUCAM / VISPUPAC.

4.2.1.3.2.3 SOP Specific Conformance for Modality Worklist SOP Class

| Service Status | Further Meaning | Error Code | Behavior |
|----------------|--|------------|---|
| Failure | Refused: Out of Resources | A700 | Log message and display user alert message. |
| Failure | Identifier Does Not Match SOP Class | A900 | Log message and display user alert message. |
| Failure | Unable to process | C000-CFFF | Log message and display user alert message. |
| Failure | Refused: SOP class not supported | 0122 | Log message and display user alert message. |
| Cancel | Matching terminated due to Cancel request | FE00 | Log message. |
| Success | Matching is complete | 0000 | The Application Software processes the gathered search results and updates the pick list. |
| Pending | Matches are continuing – Current Match is supplied and any Optional Keys were supported in the same manner as Required Keys | FF00 | Log message. The Application Software checks whether the number of received worklist items overstepped the configurable limit. If yes applies, gathering is canceled (C- CANCEL-RQ is sent) and the partial search result gets displayed along with a message informing the user about more results being on the server. If no applies, gathering is continued. |
| Pending | Matches are continuing – Warning that one or more Optional Keys were not supported for existence and / or matching for this Identifier | FF01 | Log message. The Application Software checks whether the number of received worklist items overstepped the configurable limit. If yes applies, gathering is canceled (C- CANCEL-RQ is sent) and the partial search result gets displayed along with a message informing the user about more results being on the server. If no applies, gathering is continued. |
| Unknown | All other responses with unknown code meaning | хххх | Log message and display user alert message |

| Tag Tag Name | | Query Keys Matching | Mandatory Query Keys Return | Imported | Displayed | Copied to SOP Instance | |
|--------------------------------|---|------------------------|--------------------------------|----------|-----------|---------------------------|--|
| Scheduled Procedure Step (SPS) | | | | | | | |
| (0040,0100) | Scheduled Procedure Step Sequence | | х | | | | |
| >(0040,0001) | Scheduled Station Application Entity Title | BRQ, DEF* | | х | PLD | х | |
| >(0040,0003) | Scheduled Procedure Step Start Time | | х | Х | PLD | | |
| >(0040,0002) | Scheduled Procedure Step Start Date | BRQ, DEF*, SEL, RNG | x | Х | PLD | | |
| >(0008,0060) | Modality | BRQ, SEL, DEF* | | Х | PLD | x | |
| >(0040,0006) | Scheduled Performing Physicians Name | | | | | | |
| >(0040,0007) | Scheduled Procedure Step Description | | X ¹ | Х | PLD | х | |
| >(0040,0010) | Scheduled Station Name | | | | | | |
| >(0040,0011) | Scheduled Procedure Step | | | | | | |
| >(0040,0008) | Scheduled Protocol Code Sequence | | X ¹ | Х | | х | |
| >>(0008,0100) | Code Value | | X* | Х | | Х | |
| >>(0008,0102) | Coding Scheme Designator | | X* | Х | | Х | |
| >>(0008,0103) | Coding Scheme Version | | | Х | | Х | |
| >>(0008,0104) | Code Meaning | | | Х | PLD | Х | |
| >(0040,0012) | Pre-Medication | | | | | | |
| >(0040,0009) | Scheduled Procedure Step ID | | Х | Х | | Х | |
| >(0032,1070) | Requested Contrast Agent | | | | | | |
| Requested Pro | cedure | | | | | | |
| (0040,1001) | Requested Procedure ID | PBQ | Х | Х | PLD | Х | |
| (0032,1060) | Requested Procedure Description | | X ² | Х | PLD | Х | |
| (0032,1064) | Requested Procedure Code Sequence | | X ² | Х | | х | |
| >(0008,0100) | Code Value | | X* | Х | | Х | |
| >(0008,0102) | Coding Scheme Designator | | X* | Х | | Х | |
| >(0008,0103) | Coding Scheme Version | | | Х | | Х | |
| >(0008,0104) | Code Meaning | | | x | PLD | Х | |
| (0020,000D) | Study Instance UID | | Х | Х | | Х | |
| (0008,0020) | Study Date | | | | | | |
| (0008,0030) | Study Time | | | | | | |
| (0008,1110) | Referenced Study Sequence | | | Х | | Х | |

Table 4-10 Attributes involved in Modality Worklist C-FIND request and response

| Tag | Tag Name | Query Keys Matching | Mandatory Query Keys Return | Imported | Displayed | Copied to SOP Instance |
|-------------------|--|------------------------|--------------------------------|----------|-----------------|---------------------------|
| >(0008,1150) | Referenced SOP Class UID | | X* | х | | х |
| >(0008,1155) | Referenced SOP Instance UID | | X* | Х | | х |
| (0040,1003) | Requested Procedure Priority | | | | | |
| (0040,1004) | Patient Transport Arrangements | | | | | |
| (0040,1400) | Requested Procedure Comments | | | Х | PLD | х |
| Image Service | Request | | | | | |
| (0008,0050) | Accession Number | PBQ | | Х | PLD | х |
| (0032,1032) | Requesting Physician | | | | | |
| (0008,0090) | Referring Physicians Name | | | Х | PLD | х |
| Visit Identificat | ion | | • | | | |
| (0038,0010) | Admission ID | | | | | |
| Visit Status | | | | | | |
| (0038,0300) | Current Patient Location | | | | | |
| Visit Relations | nip | | • | | | |
| (0008,1120) | Referenced Patient Sequence | | | | | |
| >(0008,1150) | Referenced SOP Class UID | | | | | |
| >(0008,1155) | Referenced SOP Instance UID | | | | | |
| Patient Identific | cation | | | | | |
| (0010,0010) | Patients Name ^{1, 2} | PBQ | X | Х | PL, PLD, APP | Х |
| (0010,0020) | Patients ID | PBQ | х | Х | PL, PLD, APP | Х |
| (0010,0021) | Issuer of Patient ID | | | Х | PLD | х |
| (0010,1000) | Other Patient IDs | | | х | | х |
| Patient Demog | raphics | | | | | |
| (0010,0030) | Patients Birth Date | | | х | PL, PLD, APP | х |
| (0010,0040) | Patients Sex | | | х | PL, PLD, APP | х |
| (0010,1030) | Patients Weight | | | | | |
| (0040,3001) | Confidentiality Constraint on Patient Data Description | | | | | |
| (0010,2160) | Ethnic Group | | | Х | | х |
| (0010,4000) | Patients Comments | | | Х | | х |
| Patient Medical | ĺ | | | | | |
| (0038,0500) | Patient State | | | | | |
| (0010,2110) | Allergies | | | | | |
| (0010,21C0) | Pregnancy Status | | | | | |
| (0010,2000) | Medical Alerts | | | | | |
| (0038,0050) | Special Needs | | | | | |

Note 1: If the multicomponent group name representation is enabled the name component group configured with Priority 1 is shown in the pick list and in the patient's details. The search string entered in patient's last name or first name is sent in the alphabetic component group of the attribute (0010,0010) Patient's Name in the C-Find-RQ (see section 4.4.2.1 for the setting of multicomponent group names).

Note 2: Only patient's first name and last name are displayed in the GUI, but the entire name including all five components of all three component groups are imported and copied into the storage SOP Instance.

Note 3: All attributes with grey background are by default excluded from the list of Modality Worklist C-FIND-RQ return keys. If needed they can get activated by service personnel.

Note 4: All attributes with white background are by default included in the Modality Worklist C-FIND-RQ as return keys with the exception that sequences are sent zero-length (no sequence items included).

Values of column "Query Keys Matching":

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 |
| DEF* | The default value of the associated attribute can be configured in the Specific settings screen. |
| RNG SEL | The operator can apply a range as value for the query key. |
| - | The operator can select a value from a given list of values. |

Values of column "Query Keys Return":

Х

The tag shall be present in the Modality Worklist C-FIND response. If any required tag is missing the relevant Modality Worklist C-FIND response item (Scheduled Procedure Step) will be ignored and not imported by the application software.

Х*

The tag shall be present in the Modality Worklist C-FIND response if its enclosing sequence is present. If any required tag is missing the relevant Modality Worklist C-FIND response item (Scheduled Procedure Step) will be ignored and not imported by the application software.

X1

Either the Scheduled Procedure Step Description (0040,0007) or the Scheduled Protocol Code Sequence (0040,0008) or both shall be present in the Modality Worklist C-FIND response.

X2

Either the Requested Procedure Description (0032,1060) or the Requested Procedure Code Sequence (0032,1064) or both shall be present in the Modality Worklist C-FIND response.

Values of column "Imported":

Х

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:

Х

Values of marked tags will be stored in created SOP Instances. See section 8.1 "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 4-11 Modality Worklist query key details - Patient Based Query

| Тад | Tag Name | Description |
|-------------|----------------------------|---|
| (0010,0010) | Patients Name ¹ | The CLARUS Application Software supports family name and given name only. A "*" wildcard will automatically added at the end. |
| (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. |

Note 1: Even if the multicomponent group name representation is enabled the search string entered in patient's last name or first name as query key will always be sent in the Alphabetic group of the C-Find-RQ (see section 4.4.2.1 for the setting of multicomponent group names).

Table 4-12 Modality Worklist Query Key – Patient's Name - Wildcard Details

| Multicomponent Group Name Representation | | Search on Patient's Name: Search string entered in GUI: "Quincy" | Query key - Value in attribute (0010,0010) Patient's Name |
|---|--------------------------------|--|---|
| Disabled | | Last Name | Quincy* |
| | | First Name | *^Quincy* |
| Enabled | Priority 1 - he Ideographic | Last Name | *=Quincy* |
| (see section 4.4.2.1 for the | | First Name | *=*^Quincy* |
| group names). | Priority 1 - | Last Name | *=*=Quincy* |
| | Phonetic | First Name | *=*=*^Quincy* |
| | Priority 1 - | Last Name | Quincy* |
| | Alphabetic | First Name | *^Quincy* |

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.

| 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 to tomorrow, week and can even enter date ranges in the Advanced query. For "Today's patient" query, this key is included when "Include Today's Date" is ON. |
| >(0008,0060) | Modality | The operator can change the value and select one value of a predefined set of values including an empty string. Possible values are "OAM", "OP", "OPM", "OPT", "OPV", "IOL". For "Today's patient" query, this key is included when "Include Modality" is ON. |
| >(0040,0001) | Scheduled Station AE Title | The default value is given by the local AE Title as configured for the CLARUS The operator can enter the AE Title of another device or leave the field empty. For "Today's patient" query this key is included when "Include AE Title" is ON. |

Table 4-13 Modality Worklist query key details - Broad Query

4.2.1.3.3 Activity - Query Patients and Data

Query is used to get patient information and meta data of instances stored on a DICOM server.

4.2.1.3.3.1 Description and Sequencing of Activities

There are two ways for the user to trigger a query request. The "Quick Search" in the main screen will search in "Patient Given Name", "Patient Last Name", "Patient ID" and "Patient Birth Date" in parallel. The second way is the "Advanced" search. The user can select this search by clicking the "Advanced" button in the main screen.

Figure 7 Query for patients and data



Trigger "Query Patients and Data"

The activity "Query remote AE for patients and data" can be triggered by the operator by using the "Quick Search" or change to the "Advanced" screen.

Edit or modify query keys

The "Advanced Search – All Patients" screen offers a GUI for interactive query. The operator can change or fill in search criteria in the shown search fields.

The top-most search field in the main screen is the "Quick Search" field. Any value entered herein is applied to

- (0010,0010) Patient's Name Family Name
- (0010,0010) Patient's Name Given Name
- (0010,0020) Patient ID
- (0010,0030) Patient's Birth Date (only if the value entered is a date, format depends on the locale settings configuration)

The Query is issued as four separate requests. The entered value has automatically a trailing wildcard to fulfill the 'starts with' condition.

For more details on supported query keys see Table 4-20 Query key details.

Trigger query

The operator triggers the search after he or she filled in search criteria by either pressing the "Enter" key or click on the "Search button". The Application Software sends a Patient Root Query based DICOM C-FIND request which contains the entered search criteria. The Application Software waits for the response from the Query AE and accepts up to a configurable number of matches. If the number of matches exceeds this limit, the Application Software shows an information about truncated search results and a request to apply more specific query keys. Despite this warning, the operator gets results in the pick-list.

After receiving the response, the patient pick-list is updated. The patient pick-list provides the most important information for a quick overview.

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 patient entry.

Important note: For this activity it is required that the SCP supports the Relational query model since Application Software does not use the Hierarchical model.

Select patient(s) from patient list

If in Advanced Search the operator can select 1-n patients from the pick-list at the same time and import them into the application. See chapter 4.2.1.3.4 Activity – Retrieve Exam for activity details.

4.2.1.3.3.2 Proposed Presentation Contexts

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

- "Patient Root Query/Retrieve Information Model FIND" with Transfer Syntax ILE as SCU
- "Study Root Query/Retrieve Information Model FIND" with Transfer Syntax ILE as SCU

Important note: For this activity it is required that the SCP supports the Relational query model since Application Software does not use the Hierarchical model.

Table 4-14 Proposed Presentation Contexts for Activity Query Patients and Data

| Presentation Context Table | | | | | | |
|----------------------------|----------------------|--|------|------|------|--|
| Abstract | Transfer Syntax | | Role | Ext. | | |
| Name | UID 1.2.840.10008 | Name List UID List 1.2.840.10008 | | | neg. | |
| Verification | 1.1 | ILE | 1.2 | BOTH | No | |

| Presentation Context Table | | | | | |
|--|----------------------|-----------|---------------------------|----------------------|------------------|
| Abstract | t Syntax | Tran | sfer Syntax | Role | Ext. |
| Name | UID 1.2.840.10008 | Name List | UID List 1.2.840.10008 | _ | Neg. |
| Storage Commitment Push Model | 1.20.1 | ILE | 1.2 | SCU | No |
| Raw Data Storage | 5.1.4.1.1.66 | ILE | 1.2 | BOTH ² | No |
| | | ELE | 1.2.1 | BOTH ² | No |
| VL Photographic Image Storage | 5.1.4.1.1.77.1.4 | ILE | 1.2 | SCP ² | No |
| | | ELE | 1.2.1 | SCP ² | No |
| | | JPG-1 | 1.2.4.50 | SCP ² | No |
| Ophthalmic Photography 8 Bit | 5.1.4.1.1.77.1.5.1 | ILE | 1.2 | BOTH ^{2, 4} | No |
| Image Storage | | ELE | 1.2.1 | BOTH ^{2, 4} | No |
| | | J2K-LL | 1.2.4.90 | BOTH ^{2, 4} | No |
| | | JPG-1 | 1.2.4.50 | BOTH ^{2, 4} | No |
| | | MPG4-H | 1.2.4.102 | SCU | No |
| Encapsulated PDF Storage | 5.1.4.1.1.104.1 | ILE | 1.2 | SCU | No |
| | | ELE | 1.2.1 | SCU | No |
| Patient Root Query/Retrieve IM – FIND | 5.1.4.1.2.1.1 | ILE | 1.2 | SCU | Yes ¹ |
| Study Root Query/Retrieve IM - FIND | 5.1.4.1.2.2.1 | ILE | 1.2 | SCU | Yes ¹ |
| Study Root Query/Retrieve IM - MOVE | 5.1.4.1.2.2.2 | ILE | 1.2 | SCU | No |
| Modality Worklist IM – FIND | 5.1.4.31 | ILE | 1.2 | SCU | No |

¹Note: C-FIND extended negotiation is offered. Relational-query support is required by the SCP.

²Note: Only acts as SCP when a C-Move-RQ was initiated first and this association is still open.

³Note: CLARUS does not transmit VL Photographic Image IODs via DICOM network. It provides function to DICOM retrieve and import VISUCAM / VISPUPAC DICOM VL Photographic Image files from local, external or network drive. ⁴Note: CLARUS acts as Storage SCU for OP 8 Bit Images generated by CLARUS itself. However, it performs DICOM retrieve and file import only for those OP 8 Bit Images generated by VISUCAM / VISPUPAC.

4.2.1.3.3.3 SOP Specific Conformance for Patient Root and Study Root Query/Retrieve SOP Class as SCU

Table 4-15 Query C-FIND Response Status Handling Behavior

| Service Status | Further Meaning | Error Code | Behavior |
|----------------|--|------------|---|
| Failure | Refused: Out of Resources | A700 | Log message and display user alert message. |
| Failure | Identifier does not match SOP Class | A900-A9FF | Log message and display user alert message. |
| Failure | Unable to process | C000-CFFF | Log message and display user alert message. |
| Failure | Refused: SOP class not supported | 0122 | Log message and display user alert message. |
| Cancel | Matching terminated due to Cancel request | FE00 | Log message. |

| Service Status | Further Meaning | Error Code | Behavior |
|----------------|---|------------|--|
| Success | Matching is complete – No final Identifier is supplied | 0000 | The Application Software processes the gathered search results and updates the pick list. |
| Pending | Matches are continuing – Current Match is supplied and any Optional Keys were supported in the same manner as Required Keys | FF00 | Log message. The Application Software checks whether the number of received query result items overstepped the configurable limit. If yes applies, gathering is canceled (C- CANCEL-RQ is sent) and the partial search result gets displayed along with a message informing the user about more results being on the server. If no applies, gathering is continued. |
| Pending | Matches are continuing – Warning that one or more Optional Keys were not supported for existence and / or matching for this Identifier. | FF01 | Log message. The Application Software checks whether the number of received query result items overstepped the configurable limit. If yes applies, gathering is canceled (C- CANCEL-RQ is sent) and the partial search result gets displayed along with a message informing the user about more results being on the server. If no applies, gathering is continued. |
| Unknown | All other responses with unknown code meaning | хххх | Log message and display user alert message. |

Table 4-16 PATIENT level keys for the Patient Root Query/Retrieve Information Model (request and response)

| Тад | Tag Name | Query Keys Matching | Query Keys Return | Imported | Displayed | Copied into SOP Instance |
|-------------|-----------------------------|---------------------------|-------------------------|----------|-----------|--------------------------------|
| (0010,0010) | Patient's Name ¹ | Х | | Х | Х | Х |
| (0010,0020) | Patient ID | Х | Х | Х | Х | Х |
| (0010,0021) | Issuer of Patient ID | | | Х | | Х |
| (0010,0030) | Patient's Birth Date | RNG | | Х | Х | Х |
| (0010,0040) | Patient's Sex | | | Х | Х | Х |
| (0010,1000) | Other Patient IDs | | | Х | | Х |
| (0010,2160) | Ethnic Group | | | Х | | Х |
| (0010,4000) | Patient Comments | | | Х | | Х |

¹ Note: Even if the multicomponent group name representation is enabled the search string entered in patient's last name or first name as query key will always be sent in the Alphabetic group of the C-Find-RQ (see section 4.4.2.1 for the setting of multicomponent group names).

Table 4-17 STUDY level keys for the Patient Root Query/Retrieve Information Model (request and response)

| Тад | Tag Name | Query Keys Matching | Query Keys Return | Imported | Displayed | Copied into SOP Instance |
|-------------|---------------------------------|------------------------|----------------------|----------|-----------|-----------------------------|
| (0008,0020) | Study Date | | | | | |
| (0008,0030) | Study Time | | | | | |
| (0008,0050) | Accession Number | х | | | | |
| (0008,0061) | Modalities in Study | | | | | |
| (0008,0090) | Referring Physician's Name | Х | | | | |
| (0008,0090) | Study Description | | | | | |
| (0008,1080) | Admitting Diagnoses Description | | | | | |
| (0020,0010) | Study ID | | | | | |
| (0020,000D) | Study Instance UID | | | | | |

Table 4-18 SERIES level keys for the Patient Root Query/Retrieve Information Model (request and response)

| Тад | Tag Name | Query Keys Matching | Query Keys Return | Imported | Displayed | Copied into SOP Instance |
|-------------|-------------------------------------|---------------------------|-------------------------|----------|-----------|--------------------------------|
| (0008,0021) | Series Date | | | | | |
| (0008,0031) | Series Time | | | | | |
| (0008,0060) | Modality | SEL | | | | |
| (0008,103E) | Series Description | | | | | |
| (0008,1050) | Performing Physician's Name | | | | | |
| (0008,1090) | Manufacturer's Model Name | | | | | |
| (0020,000E) | Series Instance UID | | | | | |
| (0020,0011) | Series Number | | | | | |
| (0020,0060) | Laterality | | | | | |
| (0040,0244) | Performed Procedure Step Start Date | | | | | |
| (0040,0245) | Performed Procedure Step Start Time | | | | | |
| (0040,0275) | Request Attributes Sequence | | | | | |

Table 4-19 IMAGE level keys for the Patient Root Query/Retrieve Information Model (request and response)

| Тад | Tag Name | Query Keys Matching | Query Keys Return | Imported | Displayed | Copied into SOP Instance |
|--------------|------------------------------|------------------------|----------------------|----------|-----------|--------------------------------|
| (0008,0008) | Image Type | | | | | |
| (0008,0012) | Instance Creation Date | | | | | |
| (0008,0013) | Instance Creation Time | | | | | |
| (0008,0016) | SOP Class UID | | | | | |
| (0008,0018) | SOP Instance UID | | | | | |
| (0008,002A) | Acquisition DateTime | RNG | | | | |
| (0008,114A) | Referenced Instance Sequence | | | | | |
| >(0008,1150) | Referenced SOP Class UID | | | | | |
| >(0008,1155) | Referenced SOP Instance UID | | | | | |
| (0020,0013) | Instance Number | | | | | |
| (0020,0062) | Image Laterality | | | | | |

Values of column "Query Keys Matching":

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.

Х

The value is included in the query request if not empty.

AUTO

The value cannot be modified by the operator.

Values of column "Query Keys Return":

Х

The tag shall be present in the Patient Root Query/Retrieve C-FIND response. If any required tag is missing the relevant Patient Root Query/Retrieve C-FIND response item will be ignored and not imported by the application software.

Values of column "Imported":

Х

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":

Х

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

Values of column SOP Instance:

х

Values of marked tags will be stored in created SOP Instances. See section "mapping of attributes" in 8.1.3 Attribute Mapping.

Table 4-20 Query key details

| Tag | Tag Name | Description |
|-------------|---|--|
| (0010,0010) | Patient's Name ¹ | The default value is empty string. |
| | | Only family name and given name can be used as query keys. |
| | | A trailing wildcard "*" is automatically added at the end of the specified search string. |
| | | This is a DICOM Standard query key on Patient level. |
| (0010,0020) | Patient ID | The default value is empty string. |
| | | The operator can enter each value that conforms to the Value Representation LO. |
| | | This is a DICOM Standard query key on Patient level. |
| (0010,0030) | Patient's Birth Date | The default value is empty date. |
| | | The operator can enter a specific value that conforms to the Value Representation DA. The operator can also select from a range of dates. |
| | | This is a DICOM Optional query key on Patient level, thus the effect of this query key on the query depends on Service Provider implementation. |
| (0008,0050) | Accession Number | The default value is empty string. |
| | | The operator can enter each value that conforms to the Value Representation SH. This is a DICOM Standard query key on Study level. |
| (0008,0090) | Referring Physician's Name ² | The default value is empty string. |
| | | Only family name can be used as query key. |
| | | This is a DICOM Optional query key on Study level, thus the effect of this query key on the query depends on Service Provider implementation. |
| (0008,0060) | Modality | The default value is empty string. |
| | | The operator can select from a list of pre-defined values and the application software will convert the selection to a value that conforms to the Value Representation CS. |
| | | This is a DICOM Standard query key on Series level. |

Note 1: Even if the multicomponent group name representation is enabled the search string entered in patient's last name or first name as query key will always be sent in the Alphabetic group of the C-Find-RQ (see section 4.4.2.1 for the setting of multicomponent group names).

Note 2: The search string is always sent in the Alphabetic part of the multicomponent group name of the query key.

Table 4-21 Query Key – Patient's Name - Wildcard Details

| Multicomponent Group Name Representation | | Search on Patient's Name – Search string entered in GUI: "Quincy" | Query key – Value in attribute (0010,0010) Patient's Name |
|--|-----------------------------|---|---|
| Disabled | | Last Name | Quincy* |
| | | First Name | *^Quincy* |
| Enabled | Priority 1 - Ideographic | Last Name | *=Quincy* |
| (see section 4.4.2.1 for the setting of multicomponent | | First Name | *=*^Quincy* |
| group names). | Priority 1 - Phonetic | Last Name | *=*=Quincy* |
| | | First Name | *=*=*^Quincy* |
| | Priority 1 - | Last Name | Quincy* |
| | Alphabetic | First Name | *^Quincy* |

4.2.1.3.4 Activity – Retrieve Exam

When the user selects a patient, two stage study root query shall be triggered.

- 1) Query on Modalities in Study (OP/XC) on Study Level
- 2) Several Study Root Queries on Study Date (depending on the response of first query) on Image level to get the exam metadata of CLARUS Sensor Raw Data and VISUCAM images.

In this query, Modalities in Study (0008, 0061) with value OP or XC are used as query keys, and the results are filtered using CLARUS UID Root and Manufacturer's Model Name (0008, 1090) for VISUCAM.

Following two stage query another Study Root query is triggered to find the instances of related image Elaboration Parameter Raw Data. In this case, RAW Data SOP Class UID and Modality OT are used as query keys.

After CLARUS collects relevant information from the Query provider, Retrieve requests are sent to get CLARUS Sensor data, Elaboration Parameter Raw Data and VISUCAM images.
4.2.1.3.4.1 Description and Sequencing of Activities

Figure 8 Retrieve Exam



Select patient from patient list

The operator can select one patient entry from the patient list. Once the item is selected the Application Software sends a Study Root based instance level DICOM C-FIND request, which uses all patient level return values as query keys. The Application Software synchronizes the local database with the query results information. If any synchronization problems appear the DICOM server is the leading system.

In general the combination of patient id and issuer of patient id is assumed to be unique for a patient. In case of a conflict, (the same patient id and issuer of patient id is used for a different patient), the application will only show the patient coming from the DICOM server. The application will trigger a storage request for the data of the conflicting local patient as this patient will become hidden and be deleted later on.

This behavior only applies when the instrument is in fully connected mode, which requires Modality Worklist, Query, Storage and Retrieve Provider connection.

Important note: For this activity it is required that the SCP supports the Relational query model since Application Software does not use the Hierarchical model.

The CLARUS Sensor Raw Data and VISUCAM images are retrieved only when they are not already cached in local system.

For each CLARUS Sensor Raw Data object, the latest Image Elaboration Parameter Raw Data, if newer than the local version, is also retrieved.

4.2.1.3.4.2 Proposed Presentation Contexts

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

- Study Root Q/R Information Model FIND" with Transfer Syntax ILE as SCU
- Study Root Q/R Information Model MOVE" with Transfer Syntax ILE as SCU
- "Raw Data Storage" with Transfer Syntax ELE or ILE as SCP
- OP 8 Bit Image Storage with Transfer Syntax ELE, ILE, J2K-LL and JPG-1 as SCP
- VL Photographic Image Storage with Transfer Syntax ELE, ILE and JPG-1 as SCP

Table 4-22 Proposed Presentation Contexts for Activity Retrieve Exam

| Presentation Context Table | | | | | | | | |
|--|----------------------|-----------|---------------------------|----------------------|------------------|--|--|--|
| Abstract Syntax | ĸ | Tran | sfer Syntax | Role | Ext. | | | |
| Name | UID 1.2.840.10008 | Name List | UID List 1.2.840.10008 | | Neg. | | | |
| Verification | 1.1 | ILE | 1.2 | BOTH | No | | | |
| Storage Commitment Push Model | 1.20.1 | ILE | 1.2 | SCU | No | | | |
| Raw Data Storage | 5.1.4.1.1.66 | ILE | 1.2 | BOTH ² | No | | | |
| | | ELE | 1.2.1 | BOTH ² | No | | | |
| VL Photographic Image Storage | 5.1.4.1.1.77.1.4 | ILE | 1.2 | SCP ² | No | | | |
| | | ELE | 1.2.1 | SCP ² | No | | | |
| | | JPG-1 | 1.2.4.50 | SCP ² | No | | | |
| Ophthalmic Photography 8 Bit Image | 5.1.4.1.1.77.1.5.1 | ILE | 1.2 | BOTH ^{2, 4} | No | | | |
| Storage | | ELE | 1.2.1 | BOTH ^{2, 4} | No | | | |
| | | J2K-LL | 1.2.4.90 | BOTH ^{2, 4} | No | | | |
| | | JPG-1 | 1.2.4.50 | BOTH ^{2, 4} | No | | | |
| | | MPG4-H | 1.2.4.102 | SCU | No | | | |
| Encapsulated PDF Storage | 5.1.4.1.1.104.1 | ILE | 1.2 | SCU | No | | | |
| | | ELE | 1.2.1 | SCU | No | | | |
| Patient Root Query/Retrieve IM – FIND | 5.1.4.1.2.1.1 | ILE | 1.2 | SCU | Yes ¹ | | | |
| Study Root Query/Retrieve IM - FIND | 5.1.4.1.2.2.1 | ILE | 1.2 | SCU | Yes ¹ | | | |
| Study Root Query/Retrieve IM - MOVE | 5.1.4.1.2.2.2 | ILE | 1.2 | SCU | No | | | |
| Modality Worklist IM – FIND | 5.1.4.31 | ILE | 1.2 | SCU | No | | | |

¹Note: C-FIND extended negotiation is offered. Relational-query support is required by the SCP.

²Note: Only acts as SCP when a C-Move-RQ was initiated first and this association is still open.

³Note: CLARUS does not transmit VL Photographic Image IODs via DICOM network. It provides function to DICOM retrieve and import VISUCAM / VISPUPAC DICOM VL Photographic Image files from local, external or network drive. ⁴Note: CLARUS acts as Storage SCU for OP 8 Bit Images generated by CLARUS itself. However, it performs DICOM retrieve and file import only for those OP 8 Bit Images generated by VISUCAM / VISPUPAC.

4.2.1.3.4.3 SOP Specific Conformance for Patient Root and Study Root Query/Retrieve SOP Class as SCU

| Service Status | Further Meaning | Error Code | Behavior |
|----------------|--|------------|---|
| Failure | Refused: Out of Resources | A700 | Log message and display user alert message. |
| Failure | Identifier does not match SOP Class | A900-A9FF | Log message and display user alert message. |
| Failure | Unable to process | C000-CFFF | Log message and display user alert message. |
| Failure | Refused: SOP class not supported | 0122 | Log message and display user alert message. |
| Cancel | Matching terminated due to Cancel request | FE00 | Log message. |
| Success | Matching is complete – No final Identifier is supplied | 0000 | The Application Software processes the gathered search results and updates the pick list. |
| Pending | Matches are continuing – Current Match is supplied and any Optional Keys were supported in the same manner as Required Keys | FF00 | Log message. The Application Software checks whether the number of received query result items overstepped the configurable limit. If yes applies, gathering is canceled (C- CANCEL-RQ is sent) and the partial search result gets displayed along with a message informing the user about more results being on the server. If no applies, gathering is continued. |
| Pending | Matches are continuing – Warning that one or more Optional Keys were not supported for existence and / or matching for this Identifier. | FF01 | Log message. The Application Software checks whether the number of received query result items overstepped the configurable limit. If yes applies, gathering is canceled (C- CANCEL-RQ is sent) and the partial search result gets displayed along with a message informing the user about more results being on the server. If no applies, gathering is continued. |
| Unknown | All other responses with unknown code meaning | хххх | Log message and display user alert message. |

Table 4-23 Query C-FIND Response Status Handling Behavior

Table 4-24 Retrieve C-MOVE Response Status Handling Behavior

| Service Status | Further Meaning | Error Code | Behavior |
|----------------|---|------------|---|
| Failure | Refused: Out of Resources – Unable to calculate number of matches | A701 | Log message and retry C-MOVE. If error persists display user alert message. |
| Failure | Refused: Out of Resources – Unable to perform sub-operations | A702 | Log message and retry C-MOVE. If error persists display user alert message. |
| Failure | Refused: Move Destination unknown | A801 | Log message and do not retry C-MOVE. Display user alert message. |
| Failure | Identifier does not match SOP Class | A900-A9FF | Log message and do not retry C-MOVE. Display user alert message. |
| Failure | Unable to Process | C000-CFFF | Log message and do not retry C-MOVE. Display user alert message. |
| Failure | Refused: SOP class not supported | 0122 | Log message and do not retry C-MOVE. Display user alert message. |
| Cancel | Sub-operations terminated due to Cancel Indication | FE00 | Not applicable because of single instance retrieve. |
| Warning | Sub-operations Complete – One or more Failures | B000 | Log message and do not retry C-MOVE. |

| Service Status | Further Meaning | Error Code | Behavior |
|----------------|---|------------|---|
| Success | Matching is complete – No final Identifier is supplied | 0000 | None. |
| Pending | Matches are continuing – Current Match is supplied and any Optional Keys were supported in the same manner as Required Keys | FF00 | Not applicable because of single instance retrieve. |
| Unknown | All other responses with unknown code meaning | хххх | Log message and do not retry C-MOVE. Display user alert message. |

Table 4-25 STUDY level keys for the Study Root Query/Retrieve Information Model (request and response)

| Тад | Tag Name | Query Keys Matching | Query Keys Return | Imported | Displayed | Copied into SOP Instance |
|-------------|---------------------------------|------------------------|----------------------|----------|-----------|-----------------------------|
| (0010,0010) | Patient's Name ¹ | AUTO | | Х | | |
| (0010,0020) | Patient ID | AUTO | Х | Х | | |
| (0010,0021) | Issuer of Patient ID | AUTO | | Х | | |
| (0010,0030) | Patient's Birth Date | AUTO | | Х | | |
| (0010,0032) | Patient's Birth Time | | | | | |
| (0010,0040) | Patient's Sex | AUTO | | Х | | |
| (0010,1000) | Other Patient IDs | | | | | |
| (0010,2160) | Ethnic Group | | | | | |
| (0010,4000) | Patient Comments | | | | | |
| (0008,0020) | Study Date | AUTO | | Х | | |
| (0008,0030) | Study Time | | | Х | | |
| (0008,0050) | Accession Number | | | Х | | |
| (0008,0061) | Modalities in Study | AUTO | | | | |
| (0008,0090) | Referring Physician's Name | | | Х | | |
| (0008,1080) | Admitting Diagnoses Description | | | | | |
| (0020,0010) | Study ID | | | Х | | |
| (0020,000D) | Study Instance UID | | Х | Х | | |
| (0008,1030) | Study Description | | | Х | | |

¹Note: If the multicomponent name representation is enabled than all three name components are used as C-Find-RQ query key (Alphabetic, Ideographic and Phonetic) (see section 4.4.2.1 for the setting of multicomponent group names).

Table 4-26 SERIES level keys for the Study Root Query/Retrieve Information Model (request and response)

| Тад | Tag Name | Query Keys Matching | Query Keys Return | Imported | Displayed | Copied into SOP Instance |
|--------------|-----------------------------|------------------------|----------------------|----------|-----------|-----------------------------|
| (0008,0021) | Series Date | | | Х | | |
| (0008,0031) | Series Time | | | Х | | |
| (0008,0060) | Modality | AUTO | Х | Х | | |
| (0020,0011) | Series Number | | | Х | | |
| (0020, 000E) | Series Instance UID | | Х | Х | | |
| (0008, 103E) | Series Description | | | Х | | |
| (0008,1050) | Performing Physician's Name | | | Х | | |

| Tag | Tag Name | Query Keys Matching | Query Keys Return | Imported | Displayed | Copied into SOP Instance |
|-------------|-------------------------------------|------------------------|----------------------|----------|-----------|-----------------------------|
| (0008,1090) | Manufacturer's Model Name | | Х | Х | | |
| (0020,0060) | Laterality | | | | | |
| (0040,0244) | Performed Procedure Step Start Date | | | Х | | |
| (0040,0245) | Performed Procedure Step Start Time | | | Х | | |
| (0040,0275) | Request Attributes Sequence | | | | | |

Table 4-27 IMAGE level keys for the Study Root Query/Retrieve Information Model (request and response)

| Тад | Tag Name | Query Keys Matching | Query Keys Return | Imported | Displayed | Copied into SOP Instance |
|--------------|------------------------------|------------------------|----------------------|----------|-----------|-----------------------------|
| (0008,0008) | Image Type | | | | | |
| (0008,0012) | Instance Creation Date | | | | | |
| (0008,0013) | Instance Creation Time | | | | | |
| (0008,0016) | SOP Class UID | AUTO | Х | Х | | |
| (0008,0018) | SOP Instance UID | | Х | Х | | |
| (0020,0013) | Instance Number | | | Х | | |
| (0008,0023) | Content Date | | | Х | | |
| (0008,002A) | Acquisition DateTime | | | Х | | |
| (0008,114A) | Referenced Instance Sequence | | | | | |
| >(0008,1150) | Referenced SOP Class UID | | | | | |
| >(0008,1155) | Referenced SOP Instance UID | | | | | |
| (0020,0062) | Image Laterality | | | Х | | |

Values of column "Query Keys Matching":

Х

The value is included in the query request if not empty.

AUTO

The value cannot be modified by the operator.

Values of column "Query Keys Return":

Х

The tag shall be present in the Study Root Query/Retrieve C-FIND response. If any required tag is missing the relevant Study Root Query/Retrieve C-FIND response item will be ignored and not imported by the application software.

X¹

The sequence attribute is included in the query request as return key containing zero items.

X*

The tag shall be present in the Study Root Query/Retrieve C-FIND response if its enclosing sequence is present. If any required tag is missing the relevant Study Root Query/Retrieve C-FIND response item will be ignored and not imported by the application software.

Values of column "Imported":

Х

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":

Х

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

Values of column SOP Instance:

Х

Values of marked tags will be stored in created SOP Instances. See section "mapping of attributes" in 8.1.3 Attribute Mapping.

| Table 4-28 | Query | key | details |
|------------|-------|-----|---------|
|------------|-------|-----|---------|

| Tag | Tag Name | Description |
|-------------|-------------------------|--|
| (0010,0010) | Patient's Name¹ | This attribute is used as query key automatically when the operator selects a patient from the patient list and the application starts querying the remote AE for "Visits" and "Exams". |
| | | The value assigned conforms to the value gathered from the previous Patient Root Query. |
| | | This is a DICOM Standard query key on Patient level. |
| (0010,0020) | Patient ID | This attribute is used as query key automatically when the operator selects a patient from the patient list and the application starts querying the remote AE for "Visits" and "Exams". |
| | | The value assigned conforms to the value gathered from the previous Patient Root Query. |
| | | The value conforms to the Value Representation LO. |
| | | This is a DICOM Standard query key on Patient level. |
| (0010,0021) | Issuer of Patient ID | This attribute is used as query key automatically when the operator selects a patient from the patient list and the application starts querying the remote AE for "Visits" and "Exams". |
| | | The value assigned conforms to the value gathered from the previous Patient Root Query. |
| | | This is a DICOM Optional query key on Patient level, thus the effect of this query key on the query depends on Service Provider implementation. |
| (0010,0030) | Patient's Birth Date | This attribute is used as query key automatically when the operator selects a patient from the patient list and the application starts querying the remote AE for "Visits" and "Exams". |
| | | The value assigned conforms to the value gathered from the previous Patient Root Query. |
| | | The value conforms to the Value Representation DA. This is a DICOM Optional query key on Patient level, thus the effect of this query key on the query depends on Service Provider implementation. |
| (0010,0040) | Patient's Sex | This attribute is used as query key automatically when the operator selects a patient from the patient list and the application starts querying the remote AE for "Visits" and "Exams". |
| | | The value assigned conforms to the value gathered from the previous Patient root Query. The value conforms to the Value Representation CS. |
| | | This is a DICOM Optional query key on Patient level, thus the effect of this query key on the query depends on Service Provider implementation. |
| (0008,0016) | SOP Class UID | This attribute is used as query key automatically when the operator selects a patient from the patient list and the application starts querying the remote AE for Elaboration Parameter Raw Data IODs. |
| | | The value is 1.2.840.10008.5.1.4.1.1.66. |
| | | This is a DICOM Optional query key on Image level, thus the effect of this query key on the query depends on Service Provider implementation. |
| (0008,0060) | Modality | This attribute is used as query key automatically when the operator selects a patient from the patient list and the application starts querying the remote AE for Elaboration Parameter Raw Data IODs. |
| | | The value is OT. |
| (0008,0061) | Modalities in Study | This attribute is used in first of the two stage query as query key automatically when the operator selects a patient from the patient list and the application starts querying the remote AE for studies. |
| | | The value are OP\XC. |
| | | This is a DICOM Optional query key on study level, thus the effect of this query key on the query depends on Service Provider implementation. |

¹ Note: If the selected patient's name contains several component groups, all available name component groups are also provided in the Study Root Query C-Find-RQ data set (Alphabetic, Ideographic and Phonetic).

4.2.1.3.5 Activity – Perform Exam

The operator can trigger "Acquire" at any time if no other activity is in progress.

This activity has no direct relation to DICOM messaging.

During this activity, the Application Software creates scan data. It also creates default image elaboration parameters. Sensor scanned image and elaboration parameters will be stored as Raw Data SOP Instances. The created data is subject to be archived within the next "Store Exam"-activity call.

4.2.1.3.6 Activity – Store Exam

This activity is triggered automatically or manually to send acquired data to the pre-configured storage provider.

4.2.1.3.6.1 Description and Sequencing of Activities

Figure 9 Store Exam



Trigger "Store Exam"

This activity is triggered automatically in the background when:

Export Mode is "Session": acquisition is completed and user navigated away from acquisition screen (to review or main screen). The exams acquired during this session are sent to configured storage provider.

Export Mode is "Shutdown": All un-archived exams are sent to configured storage provider as part of the shutdown activities.

Alternatively, the user can trigger "Resend" manually, and export all unarchived exams.

When archiving to "FORUM/PACS Server", all Sensor data (Raw Data IOD), Elaboration Parameter (Raw Data IOD), and OP 8 Bit Image IODs are sent. For montage images created from user selected images, the constituent images are duplicated from the source. Both the constituent and the montaged images are sent to the storage provider.

When the archive destination is set to "DICOM EMR", Raw Data IODs will not get archived. OP 8 Bit Image IODs will be sent if Export OP Data to DICOM EMR is ON.

Request Commitment for stored but uncommitted instances

To verify that the data has been safely archived, the Application Software can be set up to request the configured Storage Commitment AE in a configurable interval to commit the storage of instances.

Storage Commitments are requested for CLARUS Sensor data (Raw Data) IODs only.

Data that has been successfully archived (stored and successfully committed) might be subject to be deleted at shutdown after a configurable caching time.

4.2.1.3.6.2 Proposed Presentation Contexts

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

- Raw Data Storage with Transfer Syntax ELE (Transfer Syntax ILE as fallback) as SCU
- Raw Data Storage with Transfer Syntax J2K as SCU
- OP 8 Bit Image Storage with Transfer Syntax J2K-LL as SCU
- OP 8 Bit Image Storage with Transfer Syntax JPG-1 as SCU
- OP 8 Bit Image Storage with Transfer Syntax MPG4-H as SCU
- Storage Commitment Push Model with Transfer Syntax ILE as SCU

| Presentation Context Table | | | | | | | | |
|---------------------------------------|----------------------|-----------|---------------------------|----------------------|------------------|--|--|--|
| Abstract Syntax | | Tran | sfer Syntax | Role | Ext. | | | |
| Name | UID 1.2.840.10008 | Name List | UID List 1.2.840.10008 | | Neg. | | | |
| Verification | 1.1 | ILE | 1.2 | BOTH | No | | | |
| Storage Commitment Push Model | 1.20.1 | ILE | 1.2 | SCU | No | | | |
| Raw Data Storage | 5.1.4.1.1.66 | ILE | 1.2 | BOTH ² | No | | | |
| | | ELE | 1.2.1 | BOTH ² | No | | | |
| VL Photographic Image Storage | 5.1.4.1.1.77.1.4 | ILE | 1.2 | SCP ² | No | | | |
| | | ELE | 1.2.1 | SCP ² | No | | | |
| | | JPG-1 | 1.2.4.50 | SCP ² | No | | | |
| Ophthalmic Photography 8 Bit Image | 5.1.4.1.1.77.1.5.1 | ILE | 1.2 | BOTH ^{2, 4} | No | | | |
| Storage | | ELE | 1.2.1 | BOTH ^{2, 4} | No | | | |
| | | J2K-LL | 1.2.4.90 | BOTH ^{2, 4} | No | | | |
| | | JPG-1 | 1.2.4.50 | BOTH ^{2, 4} | No | | | |
| | | MPG4-H | 1.2.4.102 | SCU | No | | | |
| Encapsulated PDF Storage | 5.1.4.1.1.104.1 | ILE | 1.2 | SCU | No | | | |
| | | ELE | 1.2.1 | SCU | No | | | |
| Patient Root Query/Retrieve IM – FIND | 5.1.4.1.2.1.1 | ILE | 1.2 | SCU | Yes ¹ | | | |

Table 4-29 Proposed Presentation Contexts for Activity Store Exam

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| Presentation Context Table | | | | | | | |
|-------------------------------------|----------------------|-----------|---------------------------|------|------------------|--|--|
| Abstract Syntax | | Trans | sfer Syntax | Role | Ext. | | |
| Name | UID 1.2.840.10008 | Name List | UID List 1.2.840.10008 | | neg. | | |
| Study Root Query/Retrieve IM - FIND | 5.1.4.1.2.2.1 | ILE | 1.2 | SCU | Yes ¹ | | |
| Study Root Query/Retrieve IM - MOVE | 5.1.4.1.2.2.2 | ILE | 1.2 | SCU | No | | |
| Modality Worklist IM – FIND | 5.1.4.31 | ILE | 1.2 | SCU | No | | |

¹Note: C-FIND extended negotiation is offered. Relational-query support is required by the SCP.

²Note: Only acts as SCP when a C-Move-RQ was initiated first and this association is still open.

³Note: CLARUS does not transmit VL Photographic Image IODs via DICOM network. It provides function to DICOM retrieve and import VISUCAM / VISPUPAC DICOM VL Photographic Image files from local, external or network drive. ⁴Note: CLARUS acts as Storage SCU for OP 8 Bit Images generated by CLARUS itself. However, it performs DICOM retrieve and file import only for those OP 8 Bit Images generated by VISUCAM / VISPUPAC.

4.2.1.3.6.3 SOP Specific Conformance for Storage SOP Classes

| Table 4-30 | Storage C-STORE | Response Status | Handling Behavior |
|------------|-----------------|-----------------|--------------------------|
|------------|-----------------|-----------------|--------------------------|

| Service Status | Further Meaning | Status Code | Behavior |
|----------------|---|-------------|--|
| Failure | Refused: Out of Resources | A700-A7FF | Log message and retry c-store. If error persists then display user alert message. |
| | | | After initial failure the storage request will be repeated two more times. Afterwards it will be taken up by the Background Storage Activity until successful completion. |
| Failure | Error: Data Set does not match SOP Class | A900-AFF | Log message and do not retry c-store. Display user alert message. |
| Failure | Error: Cannot understand | C000-CFFF | Log message and do not retry c-store. Display user alert message. |
| Failure | Refused: SOP class not supported | 0122 | Log message and do not retry c-store. Display user alert message. |
| Warning | Coercion of data Elements | B000 | Log message. |
| Warning | Data Set does not match SOP Class | B007 | Log message. |
| Warning | Elements Discarded | B006 | Log message. |
| Success | Successful Storage | 0000 | The Application Software flags the data as successfully stored. |
| Unknown | All other responses with unknown code | хххх | Log message and do not retry c-store. Display user alert message. |

4.2.1.3.6.4 SOP Specific Conformance for Storage Commitment SOP Class

4.2.1.3.6.4.1 Storage Commitment Operations (N-ACTION)

The Application Software will request storage commitment for instances of the acquired Sensor Raw Data if the Remote AE is configured as Storage Commitment Provider and a presentation context for the Storage Commitment Push Model has been accepted.

The Storage Commitment Request addresses at least one SOP Instance and at maximum 500 SOP instances.

The behavior of the Application Software when encountering status codes in an N-ACTION response is summarized in the table below:

| Service Status | Further Meaning | Status Code | Behavior |
|----------------|--|-------------|--|
| Failure | Class-instance conflict | 0119 | Log message and display user alert message. |
| Failure | Duplicate invocation | 0210 | Log message. |
| Failure | Invalid argument value | 0115 | Log message and display user alert message. |
| Failure | Invalid SOP Instance | 0117 | Log message and display user alert message. |
| Failure | Mistyped argument | 0212 | Log message and display user alert message. |
| Failure | No such action | 0123 | Log message and display user alert message. |
| Failure | No such argument | 0114 | Log message and display user alert message. |
| Failure | No such SOP class | 0118 | Log message and display user alert message. |
| Failure | No such SOP Instance | 0112 | Log message. |
| Failure | Processing failure | 0110 | Log message and display user alert message. |
| Failure | Resource limitation | 0213 | Log message. |
| Failure | Unrecognized operation | 0211 | Log message and display user alert message. |
| Success | Success | 0000 | The Application Software will wait for an incoming N- EVENT-REPORT. |
| Unknown | All other responses with unknown code meaning. | хххх | Log message and display user alert message. |

Table 4-31 Storage Commitment N-ACTION Response Status Handling Behavior

4.2.1.3.6.4.2 Storage Commitment Communication Failure Behaviour

If the Application Software runs in a timeout or if the association is aborted by the provider or network layer, or if waiting duration for Storage Commitment N-EVENT-REPORT oversteps a configurable time limit then the related SOP Instance is considered as not being committed. Then the SOP Instance is subject of a future Storage Commitment service call. It will be included again within next call of this activity.

In addition to that, the Application Software writes the SOP Instance UID to the log file, together with the failure reason.

4.2.1.3.7 Activity – Create Report

The operator can select exams from the analyze screen, and "Review" the selected images. After the image elaboration (e.g. putting annotation, adjust brightness/contrast, etc.) is finished, the operator can press the "Report" button to create and preview the report.

The operator can select to print and/or save the report to a PDF file or send it to the storage provider if Report Export Format is ePDF.

4.2.1.3.7.1 Description and Sequencing of Activities

Figure 4-10 Create Report



4.2.1.3.7.2 Proposed Presentation Contexts

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

Encapsulated PDF Storage Transfer Syntax ILE or ELE as SCU

| Table 4-32 Proposed Presentatio | n Contexts for | Activity | Archive da | ata |
|---------------------------------|----------------|----------|------------|-----|
|---------------------------------|----------------|----------|------------|-----|

| Presentation Context Table | | | | | | |
|------------------------------------|----------------------|-----------|---------------------------|----------------------|------|--|
| Abstract Syntax | | Trar | nsfer Syntax | Role | Ext. | |
| Name | UID 1.2.840.10008 | Name List | UID List 1.2.840.10008 | | Neg. | |
| Verification | 1.1 | ILE | 1.2 | BOTH | No | |
| Storage Commitment Push Model | 1.20.1 | ILE | 1.2 | SCU | No | |
| Raw Data Storage | 5.1.4.1.1.66 | ILE | 1.2 | BOTH ² | No | |
| | | ELE | 1.2.1 | BOTH ² | No | |
| VL Photographic Image Storage | 5.1.4.1.1.77.1.4 | ILE | 1.2 | SCP ² | No | |
| | | ELE | 1.2.1 | SCP ² | No | |
| | | JPG-1 | 1.2.4.50 | SCP ² | No | |
| Ophthalmic Photography 8 Bit Image | 5.1.4.1.1.77.1.5.1 | ILE | 1.2 | BOTH ^{2, 4} | No | |
| Storage | | ELE | 1.2.1 | BOTH ^{2, 4} | No | |
| | | J2K-LL | 1.2.4.90 | BOTH ^{2, 4} | No | |
| | | JPG-1 | 1.2.4.50 | BOTH ^{2, 4} | No | |
| | | MPG4-H | 1.2.4.102 | SCU | No | |

| Presentation Context Table | | | | | | |
|--|----------------------|-------------|---------------------------|------|------------------|--|
| Abstract Syntax | Tran | sfer Syntax | Role | Ext. | | |
| Name | UID 1.2.840.10008 | Name List | UID List 1.2.840.10008 | | Neg. | |
| Encapsulated PDF Storage | 5.1.4.1.1.104.1 | ILE | 1.2 | SCU | No | |
| | | ELE | 1.2.1 | SCU | No | |
| Patient Root Query/Retrieve IM – FIND | 5.1.4.1.2.1.1 | ILE | 1.2 | SCU | Yes ¹ | |
| Study Root Query/Retrieve IM - FIND | 5.1.4.1.2.2.1 | ILE | 1.2 | SCU | Yes ¹ | |
| Study Root Query/Retrieve IM - MOVE | 5.1.4.1.2.2.2 | ILE | 1.2 | SCU | No | |
| Modality Worklist IM – FIND | 5.1.4.31 | ILE | 1.2 | SCU | No | |

¹Note: C-FIND extended negotiation is offered. Relational-query support is required by the SCP.

²Note: Only acts as SCP when a C-Move-RQ was initiated first and this association is still open.

³Note: CLARUS does not transmit VL Photographic Image IODs via DICOM network. It provides function to DICOM retrieve and import VISUCAM / VISPUPAC DICOM VL Photographic Image files from local, external or network drive. ⁴Note: CLARUS acts as Storage SCU for OP 8 Bit Images generated by CLARUS itself. However, it performs DICOM retrieve and file import only for those OP 8 Bit Images generated by VISUCAM / VISPUPAC.

4.2.1.3.7.3 SOP Specific Conformance for Storage SOP Classes

Please refer to section 4.2.1.3.6.3 for details.

4.2.1.3.8 Activity – Merge and Reassign

The operator has the possibility to merge a local patient into a patient imported via Modality Worklist or into a patient imported via Patient Root Query from a DICOM Query Provider.

CLARUS allows users to reassign a selected study of a patient to another patient.

4.2.1.3.9 Activity - DICOM File Import

This Activity allows import of exams from disk attached to the device. The imported exam is added to the local database. It has no effect on DICOM messaging.

The Operator can trigger "Import" from "Settings -> Data & Reports -> Import" at any time if no other activity is in progress. During this activity, CLARUS imports Raw Data IODs (Sensor data and Elaboration Parameter) created by other CLARUS devices. It can also import VL Photographic Images and OP 8 Bit Images created by VISUCAM.

4.2.1.3.10 Activity - DICOM File Export

This Activity allows export of exams to a local disk attached to the device. It has no effect on DICOM messaging.

The Operator can trigger "export" from "Settings -> Data & Reports -> Export", and export all exams of the selected patients. User can also export selected exams of a patient from the Analyze screen.

During this activity, the application software exports only exams (Raw Data and OP 8 Bit Images) created by CLARUS devices. All Sensor data (Raw Data IOD), Elaboration Parameter (Raw Data IOD), and OP 8 Bit Image IODs are exported to the same location specified by the user.

Optionally, the user can choose to de-identify the exported IODs. The setting is available on "Settings -> Data & Reports - > Export" De-Identify patient data. Please refer to 7.1.1 for the modified attributes.

4.2.1.3.11 Activity – Delete data

Delete Patient

The patient deletion can either be invoked manually by the operator or triggered automatically by software application. A patient is deleted from the CLARUS' local database by deleting all demography and exam data. Knowledge of this deletion is not forwarded to any leading system.

| | Standalone Mode | Connected Mode |
|-------------------------------------|---|---|
| Manual Deletion | Patients can be deleted from the patient list. Deletion will be immediate. | Not available |
| Automatic Deletion Not available | The following activities will be performed during the shutdown process: | |
| | | |
| | | If storage commitment is enabled , committed exams older than 14 days (ExamCacheTime default) will be deleted. |
| | Not available | If storage commitment is <u>disabled</u> , <u>archived</u> exams older than 14 days (ExamCacheTime default) will be deleted. |
| | | Delete Series |
| | | Series without any exams will be deleted |
| | | Delete Study |
| | | Studies without any series will be deleted |
| | | Delete Patient |
| | | Patients without any studies will be deleted |

Manual invocation: In standalone mode, the operator can invoke this activity from the "Patient" screen by pressing the "Delete" button. Manually triggered deletion of data is performed immediately. **Automatic invocation**: Automatically triggered deletion is done as part of the Database Cleanup

Activity which occurs during the shutdown process.

In case storage commitment is disabled, it will be performed for any exam older than 14 days (ExamCacheTime default) whose storage to a remote AE is successfully completed.

In case storage commitment is **enabled**, it will be performed for any exam older than 14 days (ExamCacheTime default) whose storage to a remote AE is successfully completed **and** committed. Patient demographic data will only be deleted from the modality after all related storage instances have been successfully deleted.

Delete Exam

The operator can right-click to delete the selected exams from the Analyze screen where the list of thumbnails are displayed. The exam data is deleted from the CLARUS's local database only, leading systems are not notified of the deletion(s). This function allows operator to remove poorly performed exams.

Furthermore the software application provides configurable options (Settings -> EMR/PACS -> Manual Configuration Edit -> Advanced -> Storage Commitment section) for automatic deletion of data in case of certain error conditions:

Delete Exam when "Instance not found": When configured with Delete Exam, the affected instance that cannot be found anymore on the remote AE, is flagged for deletion as soon as the Storage Commitment report contains a failure reason "instance not found" for this particular instance. The deletion of the instance happens on next shutdown.

Re-Archive when "Instance not found": When configured with Re-Archive, the affected instance is re-archived immediately when storage commitment reports a failure reason "Instance not found". New Storage Commitment will be requested in a future Storage Commitment call. In case the new Storage Commitment fails again it will be retried until the maximum number of retries (3 Storage Commitment calls) is reached.

Delete when "Failed Instances": When the user hits the Delete Button all instances which are in Storage Commitment error status (any error or failure reason other than "Instance not found") will be marked for deletion when the maximum number of retries (3 Storage Commitment calls) is reached.

Deletion happens on next shutdown.

Reset when "Failed Instances": When the user hits the Reset Button all instances which are in Storage Commitment error status (any error or failure reason other than "Instance not found") will be marked as already archived, but not storage committed.

The status for these instances will be reset as if no storage commitment has been ever requested before. In a future Storage Commitment call the Application Software will request again storage commitment for these particular instances and retries any future failed storage commitment until the maximum number of retries (3 Storage Commitment calls) is reached.

4.2.1.4 Association Acceptance Policy

4.2.1.4.1 Activity – Verify Communication

The activity can be performed from the network settings screen when an exam is not being performed.

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 4-33 Acceptable Presentation Context for Activity Verify Communication

| Presentation Context Table | | | | | | |
|----------------------------|----------------------|-----------------|---------------------------|------|------|--|
| Abstrac | | Transfer Syntax | Role | Ext. | | |
| Name | UID 1.2.840.10008 | Name List | UID List 1.2.840.10008 | | Neg. | |
| Verification | 1.1 | ILE | 1.2 | BOTH | No | |

4.2.1.4.1.3 SOP Specific Conformance for Verification SOP Class as SCP

The Application Software AE provides standard conformance.

4.2.1.4.2 Activity – Store Exam

This chapter describes the aspect of association acceptance of the activity "Store Exam". The activity sends Sensor Raw Data, Elaboration Parameter Raw Data and OP 8 Bit Image SOP Instances to the configured storage provider. Storage commitment is requested for Sensor Raw Data afterwards.

4.2.1.4.2.1 Description and Sequencing of Activities

The description and sequencing of activities is covered by chapter "4.2.1.3.6Activity – Store Exam".

4.2.1.4.2.2 Accepted Presentation Contexts

Table 4-34 Acceptable Presentation Contexts for Activity Store Exam

| Presentation Context Table | | | | | | |
|-------------------------------|----------------------|--------------|---------------------------|------|------|--|
| Abstract Syntax Tran | | | ansfer Syntax | Role | Ext. | |
| Name | UID 1.2.840.10008 | Name List | UID List 1.2.840.10008 | | Neg. | |
| Verification | 1.1 | ILE | 1.2 | BOTH | No | |
| Storage Commitment Push Model | 1.20.1 | ILE | 1.2 | SCU | No | |

4.2.1.4.2.3 SOP Specific Conformance for Storage SOP Class as SCP

The Application Software AE provides standard conformance.

4.2.1.4.2.4 SOP Specific Conformance for Storage Commitment SOP Class

4.2.1.4.2.4.1 Storage Commitment Operations (N-EVENT-REPORT)

The Application Software is capable of receiving an N-EVENT-REPORT notification if it has successfully negotiated a Presentation Context for the Storage Commitment Push

The behavior of Application Software when receiving Event Types within the N-EVENT-REPORT is summarized in the table below.

| Service Status | Further Meaning | Status Code | Behavior |
|----------------|---|-------------|--|
| Failure | Processing Failure | 0110 | Log message and retry Storage Commitment for the failed SOP Instance(s). |
| | | | A failed Storage Commitment request will be repeated two more times. |
| Failure | No such object instance | 0112 | Log message. The SOP Instance(s) is also considered as not being committed. The application will re-archive or delete the local instance based on a setting (see section 4.4.2.1 General Parameters). The default setting is to re-archive the exam. |
| Failure | Resource limitation | 0213 | Log message and retry Storage Commitment for the failed SOP Instance(s). A failed Storage Commitment request will be repeated two more times. |
| Failure | Referenced SOP Class not supported | 0122 | Log message. |
| Failure | Class / Instance conflict | 0119 | Log message. A failed Storage Commitment request will be repeated two more times. |
| Failure | Duplicate transaction UID | 0131 | Log message and retry Storage Commitment for the failed SOP Instance(s). A failed Storage Commitment request will be repeated two more times |
| Unknown | All other responses with unknown code meaning | xxxx | Log message and retry Storage Commitment for the failed SOP Instance(s). A failed Storage Commitment request will be repeated two more times. |

 Table 4-35 Storage Commitment N-EVENT-REPORT Request Failure Reasons

If the N-EVENT-REPORT contains failed instances the behavior of the application depends on the failure reason associated with the failed instances (see table above). In general retry means a retry for 2 times, no retry will set the error counter to maximum. A reset of the error counter is possible in the application settings screen (Networking).

4.2.1.4.3 Activity – Create Report

This chapter describes the aspect of association acceptance of the activity "Create Report". The activity sends ePDF Instances to configured storage provider.

4.2.1.4.3.1 Description and Sequencing of Activities

The description and sequencing of activities covered by chapter "4.2.1.3.7 Activity - Create Report"

4.2.1.4.3.2 Accepted Presentation Contexts

| Presentation Context Table | | | | | | |
|----------------------------|-----------------|------|---------------|------|------|--|
| Abstract Synta | Transfer Syntax | | Role | Ext. | | |
| Name | UID | Name | UID List | | Neg. | |
| | 1.2.840.10008 | List | 1.2.840.10008 | | | |
| Verification | 1.1 | ILE | 1.2 | BOTH | No | |

Table 4-36 Acceptable Presentation Contexts for Activity Create Report

4.2.1.4.3.3 SOP Specific Conformance for Storage SOP Class as SCP

The Application Software AE provides standard conformance.

4.2.1.4.4 Activity – Retrieve Exam

This chapter describes the aspect of association acceptance of the activity "Retrieve Exam". The activity retrieves exam data and image elaboration parameters belonging to a selected patient.

4.2.1.4.4.1 Description and Sequencing of Activities

The description and sequencing of activities covered by chapter "4.2.1.3.4 Activity - Retrieve Exam"

4.2.1.4.4.2 Accepted Presentation Contexts

Table 4-37 Acceptable Presentation Contexts for Activity Retrieve Exam

| Presentation Context Table | | | | | | |
|-------------------------------|----------------------|-----------|---------------------------|---------------------|-----------|--|
| Abstract Syntax | | Trar | nsfer Syntax | Role | Ext. Neg. | |
| Name | UID 1.2.840.10008 | Name List | UID List 1.2.840.10008 | | | |
| Verification | 1.1 | ILE | 1.2 | BOTH | No | |
| Raw Data Storage | 5.1.4.1.1.66 | ILE | 1.2 | SCP ¹ | No | |
| | | ELE | 1.2.1 | SCP ¹ | No | |
| VL Photographic Image Storage | 5.1.4.1.1.77.1.4 | ILE | 1.2 | SCP ^{1, 2} | No | |
| | | ELE | 1.2.1 | SCP ^{1, 2} | No | |
| | | JPG-1 | 1.2.4.50 | SCP ^{1, 2} | No | |
| Ophthalmic Photography 8 Bit | 5.1.4.1.1.77.1.5.1 | ILE | 1.2 | SCP ^{1, 3} | No | |
| Image Storage | | ELE | 1.2.1 | SCP ^{1, 3} | No | |
| | | J2K | 1.2.4.91 | SCP ^{1, 3} | No | |
| | | J2K-LL | 1.2.4.90 | SCP ^{1, 3} | No | |
| | | JPG-1 | 1.2.4.50 | SCP ^{1, 3} | No | |

¹Note: Only acts as SCP when a C-Move-RQ was initiated first and this association is still open.

²Note: CLARUS does not transmit VL Photographic Image IODs via DICOM network. It provides function to DICOM retrieve and import VISUCAM / VISPUPAC DICOM VL Photographic Image files from local, external or network drive. ³Note: CLARUS acts as Storage SCU for OP 8 Bit Images generated by CLARUS itself. However, it performs DICOM retrieve and file import only for those OP 8 Bit Images generated by VISUCAM / VISPUPAC.

4.2.1.4.4.3 SOP Specific Conformance for Storage SOP Class as SCP

The Application Software AE provides standard conformance.

4.3 Network Interfaces

4.3.1 Physica/ 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

The CLARUS supports IPv4 as well as IPv6 Addresses.

4.4 Configuration

Local application entity and remote application entity information can be configured in the Application Settings -> Network Configuration screen.

For AutoConnect[™]-enabled systems from ZEISS the configuration can be performed automatically using the AutoConnect button.

It is also possible to configure timeout, institution, and worklist item limit parameters via Application Software Settings -> Network Configuration screen.

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 address is configurable via the Settings -> Network -> Network Configuration screen. Any changes in this screen will update the Operating System settings. The Application Entity Title as well as the port number are configurable in Local Application Entity section of the same configuration screen. The default port number is 11112.

4.4.1.2 Remote AE Titles/Presentation Address Mapping

The mapping of external AE Titles to TCP/IP addresses and ports is configurable. The CLARUS Application Software allows setting up a remote Application Entity for each service. For all Application Entities, the host name or IP, the Port and the Application Entity Title must be known.

4.4.2 Parameters

4.4.2.1 General Parameters

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

Table 4-38 Configuration Parameters

| Parameter | Configurable (Yes/No) | Default Value |
|----------------------------|-----------------------|---------------|
| General Para | meters | |
| DIMSE RSP Timeout | Yes | 40 sec |
| | (10 – 60 sec.) | |
| Network Timeout | Yes | 20 sec. |
| | (5-20 sec.) | |
| Max. Association Idle Time | Yes | 30 sec |
| | (10 – 60 sec.) | |

| Parameter | Configurable (Yes/No) | Default Value | |
|---|--|---|--|
| TCP IP port | Yes (1-65535) | 11112 | |
| Network log level | Yes | Error | |
| | (debug, info, warning, error) | | |
| Storage Commitment for failed instances | Yes | Re-archive | |
| (0008,0080) Institution Name | Yes | EMPTY | |
| (0008,1040) Institutional Department Name | Yes | EMPTY | |
| (0008,0081) Institution Address | Yes | EMPTY | |
| (0008,1010) Station Name | Yes | EMPTY | |
| (0010,0021) Issuer of Patient ID | Yes | CLARUS 500 / CLARUS 700 | |
| Use multiple character sets | Yes | Disabled | |
| AE Specific Pa | rameters | | |
| Number of simultaneous Associations by Service and/or SOP Class | s? | 1 | |
| AE Title | Yes | CLARUS | |
| Modality Worklist SC | U Parameters | · · | |
| Maximum Query Responses (Modality Worklist IM, Patient Root Q/R IM and Study Root Q/R IM) | Yes (10-999) | 200 | |
| Automatic MWL update | Yes | Enabled | |
| Today's Patient List Refresh Rate (Modality Worklist Polling Interval) | Yes (Min. – Max.) | 5 min. | |
| (0040,0001) Scheduled Station Application Entity Title (Today's Patient Worklist Query) | Yes (include/exclude from query) | Value as configured for the CLARUS instrument | |
| (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) | "OP" | |
| Patient Root Q/R and Study Ro | oot Q/R SCU Parameters | | |
| Maximum Query Responses (Modality Worklist IM, Patient Root Q/R IM and Study Root Q/R IM) | Yes (10-999) | 200 | |
| Unconstraint query | | | |
| Extended Negotiation – relational query support negotiation (Patient Root Q/R IM and Study Root Q/R IM) | Yes | Yes | |
| Storage Commitment Storage Commitment | SCU Parameters | | |
| 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). | - | - | |
| Storage Commitment enable/disable | Yes | Enabled | |
| Reaction to "instance not found" | Yes ("delete Exam", "re-archive") | "re-archive" | |
| Storage SCU Pa | irameters | 1 | |
| Archive to (Settings -> EMR/PACS -> Manual Configuration Edit -> Advanced -> FORUM/PACS Server/DICOM EMR section -> EMR / PACS option) | Yes (FORUM/PACS Server / DICOM EMR) | FORUM/PACS Server | |

| Parameter | Configurable (Yes/No) | Default Value |
|---|---|---------------|
| OP Data Transfer Syntax | JPEG Baseline/JPEG 2000 Compression (Lossless Only)/MP4 | JPEG Baseline |
| Export OP Data to DICOM EMR | Yes (Enable/Disable) | Enabled |
| Storage SCP Pa | irameters | |
| 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). | | |
| Verification SCP I | Parameters | |
| 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). | | |
| DICOM File Export | Parameters | |
| De-Identify patient data | Yes (Enable/Disable) | Disabled |
| Keep DateTime | Yes (Enable/Disable) | Disabled |
| Compress Data | Yes (Enable/Disable) | Disabled |

5 Media Interchange

Media Interchange is not scope of this document since Media Interchange is not supported by CLARUS 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

7.1 Security Profiles

7.1.1 Basic Application Level Confidentiality Profile

The application provides partial conformance to the Basic Application Level Confidentiality Profile for de-identification when IODs are exported as DICOM files. The profile applies to Sensor data (Raw Data IOD), Elaboration Parameter (Raw Data IOD), and OP 8 Bit Image IOD. The option to turn ON/OFF de-identification is configurable via "Settings -> Data & Reports -> De-Identify patient data". The following describes the application's de-identification conformance:

- Supports the "Retain UID option"
- Supports "Retain Safe Private Option" and retain private attributes in Sensor and Elaboration Parameter Raw Data IODs.
- Support Retain Longitudinal Temporal Information With Full Dates Option. This is an option that can be turned on/off via "Keep DateTime" (Settings -> Data & Reports -> Keep DateTime)
- Does not automatically obscure text or features in pixel data
- Does not obscure information in ePDF embedded in the data set.
- Sets the Patient Identity Removed (0012,0062) attribute and the Deidentification Method Code Sequence (0012, 0064).
- Whenever application export annotation raw data, it sets current date time to Acquisition and content date time irrespective of identification or de-identification mode.

The following table describes the attributes modified during de-identification:

Table 7-1 Attributes Modified During De-Identification

| Attribute | Tag | Action | Keep DateTime Enabled |
|-------------------------------|-------------|--|-----------------------|
| Accession Number | (0008,0050) | Z | |
| Acquisition Context Sequence | (0040,0555) | Z | |
| Acquisition Datetime | (0008,002A) | Raw Data IOD: X OP 8 Bit Image IOD: D | К |
| Content Date | (0008,0023) | D | К |
| Content Time | (0008,0033) | D | К |
| Device_serial_number | (0018,1000) | Х | |
| Ethnic Group | (0010,2160) | Х | |
| Institution_address | (0008,0081) | X | |
| Institution_name | (0008,0080) | Х | |
| Institutional_department_name | (0008,1040) | Х | |
| Issuer of PatientID | (0010,0021) | Х | |
| Operators Name | (0008,1070) | Х | |
| Other Patient IDs | (0010,1000) | Х | |
| Patient Birth Date | (0010,0030) | Z | |
| Patient Comments | (0010,4000) | Х | |
| Patient Sex | (0010,0040) | Z | |
| Patients Birth Time | (0010,0032) | Х | |
| Patietn ID | (0010,0020) | D | |
| Patient Name | (0010,0010) | D | |

| Attribute | Тад | Action | Keep DateTime Enabled |
|--------------------------------------|-------------|--------|-----------------------|
| Performed Procedure Step Description | (0040,0254) | X | |
| Performed Procedure Step Start Date | (0040,0244) | Х | К |
| Performed Procedure Step Start Time | (0040,0245) | Х | К |
| Protocol Name | (0018,1030) | X | |
| Referring Physician Name | (0008,0090) | Z | |
| Request Attributes Sequence | (0040,0275) | Х | |
| Requested Procedure Description | (0032,1060) | Х | |
| Requested Procedure ID | (0040,1001) | Х | |
| Scheduled Procedure Step Description | (0040,0007) | Х | |
| Series Date | (0008,0021) | Х | К |
| Series Description | (0008,103E) | Х | |
| Series Time | (0008,0031) | Х | К |
| Station_name | (0008,1010) | Х | |
| Study Date | (0008,0020) | Z | К |
| Study Description | (0008,1030) | Х | |
| Study ID | (0020,0010) | D | |
| Study Time | (0008,0030) | Z | К |

The following action codes are used in the above table:

D – Replace with a non-zero length value that may be a dummy value and consistent with the VR

 \mathbf{K} – Keep

Z - Replace with a zero length value, or a non-zero length value that may be a dummy value and consistent with the VR

X - Remove

7.1.2 ASSOCIATION LEVEL SECURITY

None supported.

7.1.3 APPLICATION LEVEL SECURITY

The DICOM capabilities of the CLARUS Application Software do not support any specific security measures.

- It is assumed that CLARUS 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 CLARUS Application Software
- Firewall or router protections to ensure that CLARUS Application Software only has network access to approve 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.

8.1 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 analyzed.

SRQ

The attribute value is same as the value received using a DICOM service such as Study Root Query.

| IE | Module | Reference | Usage |
|------------------|--|---|---------------------|
| Patient | | | |
| | Patient | Table 8-1 Module "Patient" of Created SOP | ALWAYS |
| | Clinical Trial Subject | | OPTIONAL – Not Used |
| Study | | | |
| | General Study | Table 8-2 Module "General Study" of Created SOP Instances | ALWAYS |
| | Patient Study | | OPTIONAL – Not used |
| | Clinical Trial Study | | OPTIONAL – Not used |
| Series | | | |
| | General Series | Table 8-4 Module "General Series" of Created OP 8 Bit Image SOP Instances | ALWAYS |
| | Ophthalmic Photography Series | Table 8-5 Module "Ophthalmic Photography Series" of Created OP 8 Bit Image SOP Instances | ALWAYS |
| | Clinical Trial Series | | OPTIONAL – Not used |
| FrameOfReference | | | |
| | Synchronization | Table 8-8 Module "Synchronization" of Created OP 8 Bit Image SOP Instances | ALWAYS |
| Equipment | | | |
| | General Equipment | Table 8-3 Module "General Equipment" of Created SOP Instances | ALWAYS |
| Image | | | |
| | General Image | Table 8-10 Module "General Image" of Created OP 8 Bit Image SOP Instances | ALWAYS |
| | | | ALWAYS |
| | Image Pixel | Table 8-11 Module "Image Pixel" of Created OP 8 Bit Image SOP Instances | |
| | Enhanced Contrast Bolus | Table 8-12 Module "Enhanced Contrast Bolus" of Created OP 8 Bit Image SOP Instances | OPTIONAL (FA) |
| | Cine | Table 8-13 Module "Cine" of Created OP 8 Bit Image SOP Instances | ALWAYS |
| | Multi Frame | Table 8-14 Module "Multi Frame" of Created OP 8Bit Image SOP Instances | ALWAYS |
| | Device | | OPTIONAL – Not used |
| 156 | Acquisition Context | Table 8-15 Module "Acquisition Context" of Created OP 8 Bit Image SOP Instances | ALWAYS |
| | Ophthalmic Photography Image | Table 8-16 Module "Ophthalmic Photography Image" of Created OP 8 Bit Image SOP Instances | ALWAYS |
| | Ocular Region Imaged | Table 8-17 Module "Ocular Region Imaged" of Created OP 8 Bit Image SOP Instances | ALWAYS |
| | Ophthalmic Photography Acquisition Parameters | Table 8-18 Module "Ophthalmic Photography Acquisition Parameters" of Created OP 8 Bit Image SOP Instances | ALWAYS |
| | Ophthalmic Photographic Parameters | Table 8-19 Module "Ophthalmic Photographic Parameters" of Created OP 8 Bit Image SOP Instances | ALWAYS |
| | Icc Profile | | OPTIONAL – Not used |

8.1.1.1 Ophthalmic Photography 8 Bit Image Information Object Definition

| IE | Module | Reference | Usage |
|----|------------------|---|---------------------|
| | Sop Common | Table 8-20 Module "Sop Common" of Created OP 8 Bit Image SOP Instances | ALWAYS |
| | Frame Extraction | | OPTIONAL – Not used |

8.1.1.2 Encapsulated PDF Information Object Definition

| IE | Module | References | Usage |
|----------------------|--|--|---------------------|
| Patient | | | |
| | Patient | Table 8-1 Module "Patient" of Created SOP Instances | ALWAYS |
| | Clinical Trial Subject | | OPTIONAL - not used |
| Study | | | |
| | General Study | Table 8-2 Module "General Study" of Created SOP Instances | ALWAYS |
| | Patient Study | | OPTIONAL – not used |
| | Clinical Trial Study | | OPTIONAL – not used |
| Series | | | |
| | Encapsulated Document Series | Table 8-7 Module "Encapsulated Document Series" of Created ePDF Instances | ALWAYS |
| | Clinical Trial Series | | OPTIONAL – not used |
| | Czm Encapsulated Pdf Series Extension | | OPTIONAL – not used |
| Equipment | | | |
| | General Equipment | Table 8-3 Module "General Equipment" of Created SOP Instances | ALWAYS |
| | Sc Equipment | Table 8-9 Module "SC Equipment" of Created ePDF SOP Instances | AWLAYS |
| EncapsulatedDocument | | | |
| | Encapsulated Document | Table 8-24 Module "Encapsulated Document" of Created ePDF SOP Instances | ALWAYS |
| | Sop Common | Table 8-25 Module "Sop Common" of Created ePDF SOP Instances | ALWAYS |
| | Czm Encapsulated Pdf Instance Extension | | OPTIONAL – not used |

8.1.1.3 Raw Data Information Object Definition

| IE | Module | Reference | Usage | |
|---------|--|---|---------------------|--|
| Patient | | | | |
| | Table 8-1 Module "Patient" of Created SOP Instances | Table 8-1 Module "Patient" of Created SOP Instances | ALWAYS | |
| | Clinical Trial Subject | | OPTIONAL – Not used | |
| Study | | | | |
| | General Study | Table 8-2 Module "General Study" of Created SOP Instances | ALWAYS | |
| | Patient Study | | OPTIONAL – Not used | |
| | Clinical Trial Study | | OPTIONAL – Not used | |
| Series | | | | |
| | GeneralSeries | Table 8-6 Module "General Series" of Created Raw Data SOP Instances | ALWAYS | |

| IE | Module | Reference | Usage |
|------------------|-----------------------------|---|--------------------------------|
| | ClinicalTrialSeries | | OPTIONAL – Not used |
| FrameOfReference | | | |
| | FrameOfReference | | OPTIONAL – Not used |
| | Synchronization | | CONDITIONAL – Not used |
| Equipment | | | |
| | General Equipment | Table 8-3 Module "General Equipment" of Created SOP Instances | ALWAYS |
| Raw Data | | | |
| | AcquisitionContext | Table 8-21 Module "Acquisition Context" of Created Raw Data SOP Instances | ALWAYS (ONLY for Image RAW) |
| | Specimen | | OPTIONAL – Not used |
| | Raw Data | Table 8-22 Module "Raw Data" of Created Raw Data SOP Instances | ALWAYS |
| | SopCommon | Table 8-23 Module "Sop Common" of Created Raw Data SOP Instances | ALWAYS |
| | CzmRawDataInstanceExtension | | OPTIONAL – Not used |

8.1.1.4 Common Modules

Table 8-1 Module "Patient" of Created SOP Instances

| Attribute Name | Тад | VR | Value | PoV | Source |
|--|-------------|----|---|--------|-------------------------|
| Patient's Name | (0010,0010) | PN | Patient's full name. Multicomponent group names are supported. NOTE: If CLARUS is set up for ID as Identification mode (Settings -> General -> Patients), then no patient demographic is required and value may not be available. | VNAP | USER, MWL, SRQ |
| Patient ID | (0010,0020) | LO | When a patient record is created locally, the patient ID can be assigned by user or generated automatically. | ALWAYS | USER, MWL, SRQ, AUTO |
| Issuer of Patient ID | (0010,0021) | LO | Configuration value applies when a patient record is created locally. The value is configurable in General Settings. | ANAP | MWL, SRQ, CONFIG |
| Patient's Birth Date | (0010,0030) | DA | Birth date of the patient. | ALWAYS | MWL, USER, SRQ |
| Patient's Sex | (0010,0040) | cs | Sex of the named patient. Enumerated Values: M = male F = female O = other | VNAP | MWL, USER, SRQ |
| Other Patient IDs | (0010,1000) | LO | Present only when value is available | ANAP | MWL, SRQ |
| Ethnic Group | (0010,2160) | SH | Present only when the value is available | ANAP | MWL, SRQ |
| Patient Comments | (0010,4000) | LT | Present only when the value is available | ANAP | MWL, SRQ |
| Patient Identity Removed | (0012,0062) | cs | Present only when De-Identify Patient Data is ON. Set to YES | ANAP | AUTO |
| De-identification Method Code Sequence | (0012,0064) | SQ | Present only when De-Identify Patient Data is ON. | ANAP | AUTO |
| > Include 'Code Sequence Macro'. | | | The following items are present: ("113100", "DCM", "Basic Application Confidentiality Profile") ("113110", "DCM", "Retain UIDs Option") ("113111", "DCM", "Retain Safe Private Option") for Raw Data IOD only This item is present when Keep DateTime is enabled: ("113106", "DCM", "Retain Longitudinal Temporal Information With Full Dates Option") | | |

Table 8-2 Module "General Study" of Created SOP Instances

| Attribute Name | Tag | VR | Value | PoV | Source |
|-------------------------------------|-------------|----|---|--------|--------------|
| Study Instance UID | (0020,000D) | UI | The software creates the UID in the unscheduled case. Then it uses "1.2.276.0.75.2.2.70.0.1 as DICOM root prefix for generated UIDs. OP 8 Bit Image IOD: The value is the same as study UID of the related image RAW data set. RAW Data: For the image Elaboration Parameter Raw Data, the value is the same as study UID of the related image RAW data set. | ALWAYS | AUTO, MWL |
| Study Date | (0008,0020) | DA | The date the study is created in CLARUS. | ALWAYS | AUTO |
| Study Time | (0008,0030) | ТМ | The time the study is created in CLARUS. | ALWAYS | AUTO |
| Referring Physician's Name | (0008,0090) | PN | Present only when the value is available from MWL | VNAP | MWL |
| Study ID | (0020,0010) | SH | In scheduled case: Copied from Requested Procedure ID. For unscheduled case, the value is generated from the study datetime. The value is the same as Study ID of the related image RAW data set. For the image elaboration parameter RAW, the value is the same as Study ID of the related image RAW data set. | ALWAYS | AUTO, MWL |
| Accession Number | (0008,0050) | SH | For the scheduled case via MWL. For the unscheduled case empty. | VNAP | MWL |
| Study Description | (0008,1030) | LO | Copied from Requested Procedure Description. | ANAP | MWL |
| Referenced Study Sequence | (0008,1110) | SQ | Present only when the value is available from MWL | ANAP | MWL |
| > Referenced SOP Class UID | (0008,1150) | UI | Uniquely identifies the referenced SOP Class. | ALWAYS | MWL |
| > Referenced SOP Instance UID | (0008,1155) | UI | Uniquely identifies the referenced SOP Instance. | ALWAYS | MWL |
| Procedure Code Sequence | (0008,1032) | SQ | Present only when the value is available from MWL | ANAP | MWL |
| > Include 'Code Sequence Macro'. | | | | ALWAYS | MWL |

Table 8-3 Module "General Equipment" of Created SOP Instances

| Attribute Name | Тад | VR | Value | PoV | Source |
|-------------------------------|-------------|----|--|--------|--------|
| Manufacturer | (0008,0070) | LO | Always "Carl Zeiss Meditec" | ALWAYS | AUTO |
| Institution Name | (0008,0080) | LO | Value is configurable in "General Settings" | ANAP | CONFIG |
| Institution Address | (0008,0081) | ST | Value is configurable in "General Settings" | ANAP | CONFIG |
| Station Name | (0008,1010) | SH | Value is configurable in "General Settings" | ANAP | CONFIG |
| Institutional Department Name | (0008,1040) | LO | Value is configurable in "General Settings" | ANAP | CONFIG |
| Manufacturer's Model Name | (0008,1090) | LO | Set to "CLARUS 500" or "CLARUS 700" | ALWAYS | AUTO |
| Device Serial Number | (0018,1000) | LO | The serial number of CLARUS instrument. For review software, the value is set to 000-0000 | ALWAYS | AUTO |
| Software Version(s) | (0018,1020) | LO | For CLARUS version | ALWAYS | AUTO |

| | | | 1.0: "1.0.0.23635" | | |
|--------------------------|-------------|----|---|--------|------|
| | | | Higher versions "1.0.x.y" | | |
| | | | For CLARUS version 1.1: 1.1.0.39000 | | |
| | | | Higher versions: "1.1.x.y" | | |
| Date of Last Calibration | (0018,1200) | DA | Date when the CLARUS device was calibrated. | ALWAYS | AUTO |
| Time of Last Calibration | (0018,1201) | ТΜ | Time when the CLARUS device was calibrated. | ALWAYS | AUTO |

8.1.1.5 Modules "Series" of Created OP 8 Bit Image SOP Instances

| Table 8-4 Module | "General Series | " of Created OP | 8 Bit Image SOP | Instances |
|------------------|-----------------|-----------------|-----------------|-----------|
| | | | • = | |

| Attribute Name | Tag | VR | Value | PoV | Source |
|---|-------------|----|---|--------|--------|
| Series Instance UID | (0020,000E) | UI | "1.2.276.0.75.2.2.70.0.2" constant prefix for generated UIDs A new series and UID is created from its Raw Data source. | ALWAYS | AUTO |
| Series Number | (0020,0011) | IS | A number generated from the series instance UID. | ALWAYS | AUTO |
| Series Date | (0008,0021) | DA | The date the series is created in CLARUS. | ALWAYS | AUTO |
| Series Time | (0008,0031) | тм | The time the series is created in CLARUS. | ALWAYS | AUTO |
| Protocol Name | (0018,1030) | LO | Present only when value is available from MWL | ANAP | MWL |
| Operators' Name | (0008,1070) | PN | The username of the current CLARUS user. | ALWAYS | AUTO |
| Request Attributes Sequence | (0040,0275) | SQ | Present only in scheduled case. | ANAP | MWL |
| > Requested Procedure ID | (0040,1001) | SH | Copied from MWL. See section 8.1.3 "Attribute Mapping". | ANAP | MWL |
| > Requested Procedure Code Sequence | (0032,1064) | SQ | Present only when value is available from MWL | ANAP | MWL |
| >> Include 'Code Sequence Macro'. | | | | ALWAYS | MWL |
| > Scheduled Procedure Step ID | (0040,0009) | SH | Present only when value is available from MWL | ANAP | MWL |
| Scheduled Procedure Step Description | (0040,0007) | LO | Present only when value is available from MWL | ANAP | MWL |
| > Scheduled Protocol Code Sequence | (0040,0008) | SQ | Present only when value is available from MWL | ANAP | MWL |
| >> Include 'Code Sequence Macro'. | | | | ALWAYS | MWL |
| 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) | ТМ | Time on which the Performed Procedure Step started. | ALWAYS | AUTO |
| Performed Procedure Step Description | (0040,0254) | LO | Copied from MWL. See section 8.1.3 "Attribute Mapping". | ANAP | MWL |

Table 8-5 Module "Ophthalmic Photography Series" of Created OP 8 Bit Image SOP Instances

| Attribute Name | Тад | VR | Value | PoV | Source |
|----------------|-------------|----|------------|--------|--------|
| Modality | (0008,0060) | CS | Always: OP | ALWAYS | AUTO |

8.1.1.6 Modules "Series" of Created Raw Data SOP Instances

Table 8-6 Module "General Series" of Created Raw Data SOP Instances

| Attribute Name | Тад | VR | Value | PoV | Source |
|---|-------------|----|---|--------|--------|
| Modality | (0008,0060) | cs | OP" for Image RAW "OT" for Elaboration Parameter RAW | ALWAYS | AUTO |
| Series Instance UID | (0020,000E) | UI | "1.2.276.0.75.2.2.70.0.2" constant prefix for generated UIDs. Image and Elaboration Parameter Raw Data are in different series and have different Series Instance UIDs. | ALWAYS | AUTO |
| Series Number | (0020,0011) | IS | A number generated from the series instance UID. | ALWAYS | AUTO |
| Series Date | (0008,0021) | DA | Date the Series started. | ALWAYS | AUTO |
| Series Time | (0008,0031) | тм | Time the Series started. | ALWAYS | AUTO |
| Protocol Name | (0018,1030) | LO | Present only when value is available from MWL | ANAP | MWL |
| Operators' Name | (0008,1070) | PN | The username of the current CLARUS user. | ALWAYS | AUTO |
| Request Attributes Sequence | (0040,0275) | SQ | Copied from MWL. See section 8.1.3 "Attribute Mapping". | ANAP | MWL |
| > Requested Procedure ID | (0040,1001) | SH | Copied from MWL. See section 8.1.3 "Attribute Mapping". | ANAP | MWL |
| > Requested Procedure Description | (0032,1060) | LO | Copied from MWL. See section 8.1.3 "Attribute Mapping". | ANAP | MWL |
| > Requested Procedure Code Sequence | (0032,1064) | SQ | Copied from MWL. See section 8.1.3 "Attribute Mapping". | ANAP | MWL |
| >> Include 'Code Sequence Macro'. | | | Copied from MWL. See section 8.1.3 "Attribute Mapping". | ALWAYS | MWL |
| > Scheduled Procedure Step ID | (0040,0009) | SH | Copied from MWL. See section 8.1.3 "Attribute Mapping". | ANAP | MWL |
| Scheduled Procedure Step Description | (0040,0007) | LO | Copied from MWL. See section 8.1.3 "Attribute Mapping". | ANAP | MWL |
| > Scheduled Protocol Code Sequence | (0040,0008) | SQ | Copied from MWL. See section 8.1.3 "Attribute Mapping". | ANAP | MWL |
| >> Include 'Code Sequence Macro'. | | | | ALWAYS | MWL |
| 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) | ТМ | Time on which the Performed Procedure Step started. | ALWAYS | AUTO |
| Performed Procedure Step Description | (0040,0254) | LO | Copied from MWL. See section 8.1.3 "Attribute Mapping". | ANAP | MWL |

8.1.1.7 Module "Series" of Created ePDF SOP Instances

| Attribute Name | Тад | VR | Value | PoV | Source |
|--|-------------|----|--|--------|--------|
| Modality | (0008,0060) | CS | Always "OP". | ALWAYS | AUTO |
| Series Instance UID | (0020,000E) | UI | "1.2.276.0.75.2.2.70.0.2" constant prefix for generated UIDs | ALWAYS | AUTO |
| Series Number | (0020,0011) | IS | The value is generated from series datetime. | ALWAYS | AUTO |
| Request Attributes Sequence | (0040,0275) | SQ | Copied from MWL. See section 8.1.3 "Attribute Mapping". | ANAP | MWL |
| > Requested Procedure ID | (0040,1001) | SH | Copied from MWL. See section 8.1.3 "Attribute Mapping". | ANAP | MWL |
| > Requested Procedure Description | (0032,1060) | LO | Copied from MWL. See section 8.1.3 "Attribute Mapping". | ANAP | MWL |
| > Requested Procedure Code Sequence | (0032,1064) | SQ | Copied from MWL. See section 8.1.3 "Attribute Mapping". | ANAP | MWL |
| >> Include 'Code Sequence Macro'. | | | Copied from MWL. See section 8.1.3 "Attribute Mapping". | ALWAYS | MWL |
| > Scheduled Procedure Step ID | (0040,0009) | SH | Copied from MWL. See section 8.1.3 "Attribute Mapping". | ANAP | MWL |
| > Scheduled Procedure Step Description | (0040,0007) | LO | Copied from MWL. See section 8.1.3 "Attribute Mapping". | ANAP | MWL |
| > Scheduled Protocol Code Sequence | (0040,0008) | SQ | Copied from MWL. See section 8.1.3 "Attribute Mapping". | ANAP | MWL |
| >> Include 'Code Sequence Macro'. | | | | ALWAYS | MWL |
| 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) | тм | Time on which the Performed Procedure Step started. | ALWAYS | AUTO |
| Performed Procedure Step Description | (0040,0254) | LO | Copied from MWL. See section 8.1.3 "Attribute Mapping". | ANAP | MWL |

| Table 8-7 Module "Encapsulated Document Series" of | f Created ePDF Instances |
|--|--------------------------|
|--|--------------------------|

8.1.1.8 Module "Frame of Reference" of Created OP 8 Bit Image SOP Instances

Table 8-8 Module "Synchronization" of Created OP 8 Bit Image SOP Instances

| Attribute Name | Тад | VR | Value | PoV | Source |
|---|-------------|----|--|--------|--------|
| Synchronization Frame of Reference UID | (0020,0200) | UI | Value: 1.2.276.0.75.2.2.70.0.5.YYMMDDHHMMSSmmm. MACAddress.random_number | ALWAYS | AUTO |
| Synchronization Trigger | (0018,106A) | CS | Always "NO TRIGGER" | ALWAYS | AUTO |
| Acquisition Time Synchronized | (0018,1800) | CS | Always "N" | ALWAYS | AUTO |

8.1.1.9 Module "Equipment" of Created ePDF SOP Instances

| Attribute Name | Тад | VR | Value | PoV | Source |
|-----------------|-------------|----|--------------|--------|--------|
| Conversion Type | (0008,0064) | CS | Set to "SYN" | ALWAYS | AUTO |

Table 8-9 Module "SC Equipment" of Created ePDF SOP Instances

8.1.1.10 Modules "Image" of Created OP 8 Bit Image SOP Instances

PoV VR Value Attribute Name Tag Source AUTO **Patient Orientation** (0020,0020)CS Set to L/F ALWAYS **Referenced Image Sequence** (0008, 1140)SQ This attribute present when the image is part of a stereo pair. ANAP AUTO > Referenced SOP Class UID (0008, 1150)UI Set to 1.2.840.10008.5.1.4.1.1.77.1.5.1 ALWAYS AUTO > Referenced SOP Instance For Stereo: SOP Instance UID of another image in the stereo UI ALWAYS AUTO (0008, 1155)UID pair. > Purpose of Reference Code For stereo pair: Set to ("121315", "DCM", "Other image of SQ ALWAYS AUTO (0040,A170) stereoscopic pair") Sequence >> Include 'Code Sequence ALWAYS AUTO Macro'.

Table 8-10 Module "General Image" of Created OP 8 Bit Image SOP Instances

Table 8-11 Module "Image Pixel" of Created OP 8 Bit Image SOP Instances

| Attribute Name | Тад | VR | Value | PoV | Source |
|----------------|-------------|-------|--------------------------------|--------|--------|
| Rows | (0028,0010) | US | Number of rows in the image. | ALWAYS | AUTO |
| Columns | (0028,0011) | US | Number of columns in the image | ALWAYS | AUTO |
| Bits Allocated | (0028,0100) | US | Always "8" | ALWAYS | AUTO |
| Bits Stored | (0028,0101) | US | Always "8" | ALWAYS | AUTO |
| High Bit | (0028,0102) | US | Always "7" | ALWAYS | AUTO |
| Pixel Data | (7FE0,0010) | OW OB | Pixel data of the image | ALWAYS | AUTO |

Table 8-12 Module "Enhanced Contrast Bolus" of Created OP 8 Bit Image SOP Instances

| Attribute Name | Tag | VR | Value | PoV | Source |
|---|-------------|----|---|--------|--------|
| Contrast/Bolus Agent Sequence | (0018,0012) | SQ | For FA only | ANAP | AUTO |
| > Include 'Code Sequence Macro'. | | | For FA Set to ("C-B02CC", "SRT", "Fluorescein") | ALWAYS | AUTO |
| > Contrast/Bolus Agent Number | (0018,9337) | US | Always "1" | ALWAYS | AUTO |
| Contrast/Bolus Administration Route Sequence | (0018,0014) | SQ | For FA only | ANAP | AUTO |
| >> Include 'Code Sequence Macro'. | | | Set to ("G-D101", "SRT", "Intravenous Route") | ALWAYS | Αυτο |

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| Attribute Name | Tag | VR | Value | PoV | Source |
|---|-------------|----|---|--------|--------|
| > Contrast/Bolus Ingredient Code Sequence | (0018,9338) | SQ | | EMPTY | AUTO |
| > Contrast/Bolus Volume | (0018,1041) | DS | Always "0" | ALWAYS | AUTO |
| Contrast/Bolus Ingredient Concentration | (0018,1049) | DS | Always "0" | ALWAYS | AUTO |
| Contrast Administration Profile Sequence | (0018,9340) | SQ | For FA only | ALWAYS | AUTO |
| >> Contrast/Bolus Volume | (0018,1041) | DS | Always "0" | ALWAYS | AUTO |
| >> Contrast/Bolus Start Time | (0018,1042) | тм | Set to injection start time. | ALWAYS | AUTO |
| >> Contrast Flow Duration | (0018,1047) | DS | Set to angio time spam in seconds since injection (i.e. Acquisition DateTime – Injection DateTime) | ALWAYS | AUTO |

Table 8-13 Module "Cine" of Created OP 8 Bit Image SOP Instances

| Attribute Name | Тад | VR | Value | PoV | Source |
|----------------|-------------|----|-----------|--------|--------|
| Frame Time | (0018,1063) | DS | Set to 0. | ALWAYS | AUTO |

Table 8-14 Module "Multi Frame" of Created OP 8 Bit Image SOP Instances

| Attribute Name | Тад | VR | Value | PoV | Source |
|----------------------------|-------------|----|---|--------|--------|
| Number of Frames | (0028,0008) | IS | Single frame image: Set to 1. | ALWAYS | AUTO |
| Frame Increment Pointer | (0028,0009) | AT | Always "00181063" which is intended to refer to Frame Time DICOM tag. | ALWAYS | AUTO |

Table 8-15 Module "Acquisition Context" of Created OP 8 Bit Image SOP Instances

| Attribute Name | Tag | VR | Value | PoV | Source |
|-----------------------------------|-------------|----|--|--------|--------|
| Acquisition Context Sequence | (0040,0555) | SQ | Please refer to section 8.3.3 for the code items in the sequence. | ALWAYS | AUTO |
| > Value Type | (0040,A040) | cs | Please refer to section 8.3.3 for the code values types in the sequence. | ALWAYS | AUTO |
| > Concept Name Code Sequence | (0040,A043) | SQ | Please refer to section 8.3.3 for the codes in the sequence. | ALWAYS | AUTO |
| >> Include 'Code Sequence Macro'. | | | | ALWAYS | AUTO |
| > Numeric Value | (0040,A30A) | DS | Please refer to section 8.3.3 for the codes with value type NUMERIC. | ALWAYS | AUTO |
| > Measurement Units Code Sequence | (0040,08EA) | SQ | Please refer to section 8.3.3 for the codes with value type NUMERIC. | ALWAYS | AUTO |
| >> Include 'Code Sequence Macro'. | | | | ALWAYS | AUTO |
| > Text Value | (0040,A160) | UT | Please refer to section 8.3.3 for the codes with value type TEXT. | ALWAYS | AUTO |
| > Concept Code Sequence | (0040,A168) | SQ | Please refer to section 8.3.3 for the codes with value type CODE. | ALWAYS | AUTO |
| >> Include 'Code Sequence Macro'. | | | | ALWAYS | AUTO |

| Attribute Name | Tag | VR | Value | PoV | Source |
|----------------------------------|-------------|----|---|--------|--------|
| Image Type | (0008,0008) | cs | Value 1: "DERIVED" Value 2: PRIMARY Value 3: "MONTAGE" for UWF, Montage and AutoMontage image; "STEREO L" or STEREO R" for stereo images; "CORRECTED" for others Value 4: One of the following value according to the scan type: COLOR: Color FAFGREEN: FAF Green FAFBLUE: FAF Blue IR: IR FA: FA Value 5: One of the following value according to the exam type: WF, STEREO, UWF, MONTAGE , AUTOMONTAGE, ANTERIORSEGMENT | ALWAYS | AUTO |
| Instance Number | (0020,0013) | IS | A number generated from the OP Instance UID | ALWAYS | AUTO |
| Samples per Pixel | (0028,0002) | US | Value: "3" if the scan type is Color ; "1" otherwise | ALWAYS | AUTO |
| Photometric Interpretation | (0028,0004) | cs | Value: "RGB" if the scan type is Color and OP Data Transfer Syntax is JPEG2000; "YBR_FULL_422" if scan type is Color and OP Data Transfer Syntax is JPEG Baseline;"MONOCHROME2" otherwise | ALWAYS | AUTO |
| Pixel Representation | (0028,0103) | US | Enumerated Values: 0000H = unsigned integer. 0001H = 2's complement Enumerated value: 0 | ALWAYS | AUTO |
| Planar Configuration | (0028,0006) | US | Enumerated value: 0 Attribute present only when the scan type is Color (Samples per pixel is 3) | ANAP | AUTO |
| Content Time | (0008,0033) | тм | The date the image pixel data creation started | ALWAYS | AUTO |
| Content Date | (0008,0023) | DA | The time the image pixel data creation started | ALWAYS | AUTO |
| Acquisition Datetime | (0008,002A) | DT | The date and time that the acquisition of data started. | ALWAYS | AUTO |
| Source Image Sequence | (0008,2112) | SQ | For UWF, Montage and AutoMontage exams: constituent images. For others: Raw image it derived from. | ALWAYS | AUTO |
| > Referenced SOP Class UID | (0008,1150) | UI | 1.2.840.10008.5.1.4.1.1.77.1.5.1 for UWF, Montage and AutoMontage exams; 1.2.840.10008.5.1.4.1.1.66 for others | ALWAYS | AUTO |
| > Referenced SOP Instance UID | (0008,1155) | UI | The SOP instance UID of the source instance. | ALWAYS | AUTO |

Table 8-16 Module "Ophthalmic Photography Image" of Created OP 8 Bit Image SOP Instances

| Attribute Name | Тад | VR | Value | PoV | Source |
|---|-------------|----|---|--------|--------|
| > Purpose of Reference Code Sequence | (0040,A170) | SQ | The purpose that the image is referenced as a source. | ALWAYS | AUTO |
| >> Include 'Code Sequence Macro'. | | | ("121329", "DCM", "Source image for montage") \rightarrow for UWF, Montage and AutoMontage exams | ALWAYS | AUTO |
| Lossy Image Compression | (0028,2110) | CS | Depends on Import/Export Settings→ OP Data Transfer Syntax: JPEG Baseline: Value set to 01 JPEG 2000 Compression (Lossless Only): Value set to 00 | ALWAYS | AUTO |
| Lossy Image Compression Ratio | (0028,2112) | DS | The ratio of the lossy compression. Present only when OP Data Transfer Syntax setting is set to "JPEG Baseline" | ANAP | AUTO |
| Lossy Image Compression Method | (0028,2114) | cs | Set to "ISO_10918_1" | ANAP | AUTO |
| Presentation LUT Shape | (2050,0020) | cs | Enumerated Values: IDENTITY | ANAP | AUTO |
| Burned In Annotation | (0028,0301) | CS | Value: NO | ALWAYS | AUTO |

Table 8-17 Module "Ocular Region Imaged" of Created OP 8 Bit Image SOP Instances

| Attribute Name | Тад | VR | Value | PoV | Source |
|-------------------------------------|-------------|----|---|--------|--------|
| Image Laterality | (0020,0062) | cs | Enumerated Values: $R = right eye L = left eye B = both left and right eye$ | ALWAYS | AUTO |
| Anatomic Region Sequence | (0008,2218) | SQ | Anatomic region of interest in this Instance | ALWAYS | AUTO |
| > Include 'Code Sequence Macro'. | | | Always ("T-AA000", "SRT", "Eye") | ALWAYS | AUTO |

Table 8-18 Module "Ophthalmic Photography Acquisition Parameters" of Created OP 8 Bit Image SOP Instances

| Attribute Name | Тад | VR | Value | PoV | Source |
|-----------------------------------|-------------|----|--|-------|--------|
| Patient Eye Movement Commanded | (0022,0005) | cs | Information is unavailable, and the value is set to empty. | EMPTY | AUTO |
| Horizontal Field of View | (0022,000C) | FL | The value is set to 135 for UWF and AutoMontage 90 for others Not available for Montage | VNAP | AUTO |
| Refractive State Sequence | (0022,001B) | SQ | Information is unavailable, and the value is set to empty. | EMPTY | AUTO |
| Emmetropic Magnification | (0022,000A) | FL | Information is unavailable, and the value is set to empty. | EMPTY | AUTO |
| Intra Ocular Pressure | (0022,000B) | FL | Information is unavailable, and the value is set to empty. | EMPTY | AUTO |
| Pupil Dilated | (0022,000D) | cs | Enumerated Values: YES, NO Set to empty. Note: Myd scan type on the GUI could also be used when patient has naturally large pupils. | EMPTY | AUTO |
| Table 8-19 Module | "Ophthalmic Photographic | Parameters" of Created OP | 8 Bit Image SOP Instances |
|-------------------|--------------------------|---------------------------|---------------------------|
|-------------------|--------------------------|---------------------------|---------------------------|

| Attribute Name | Tag | VR | Value | PoV | Source |
|--|-------------|----|--|--------|--------|
| Acquisition Device Type Code Sequence | (0022,0015) | SQ | Type of acquisition device | ALWAYS | AUTO |
| > Include 'Code Sequence Macro'. | | | Always ("R-1021B", "SRT", "External Camera") | ALWAYS | AUTO |
| Illumination Type Code Sequence | (0022,0016) | SQ | Set to empty. | EMPTY | AUTO |
| Light Path Filter Type Stack Code Sequence | (0022,0017) | SQ | Set to empty. | EMPTY | AUTO |
| Image Path Filter Type Stack Code Sequence | (0022,0018) | SQ | Set to empty. | EMPTY | AUTO |
| Lenses Code Sequence | (0022,0019) | SQ | Set to empty. | EMPTY | AUTO |
| Detector Type | (0018,7004) | CS | Set to empty. | EMPTY | AUTO |
| Camera Angle of View | (0022,001E) | FL | The value is set to 135 for UWF and AutoMontage 90 for othres Not available for Montage | ANAP | AUTO |

Table 8-20 Module "Sop Common" of Created OP 8 Bit Image SOP Instances

| Attribute Name | Tag | VR | Value | PoV | Source |
|---|-------------|----|--|--------|--------|
| SOP Class UID | (0008,0016) | UI | "1.2.840.10008.5.1.4.1.1.77.1.5.1" | ALWAYS | AUTO |
| SOP Instance UID | (0008,0018) | UI | "1.2.276.0.75.2.2.70.0" constant prefix for generated UIDs | ALWAYS | AUTO |
| Specific Character Set | (0008,0005) | CS | Set to "ISO_IR 192" | ALWAYS | AUTO |
| Instance Creation Date | (0008,0012) | DA | Date the SOP Instance was created. | ALWAYS | AUTO |
| Instance Creation Time | (0008,0013) | ТΜ | Time the SOP Instance was created. | ALWAYS | AUTO |
| Contributing Equipment Sequence | (0018,A001) | SQ | Present only when De-Identify Patient Data is ON. | ANAP | AUTO |
| > Purpose of Reference Code Sequence | (0040,A170) | SQ | Purpose for which the related equipment is being reference | ALWAYS | AUTO |
| >> Include 'Code Sequence Macro'. | | | Set to ("109104", "DCM", "De-identifying Equipment") | ALWAYS | AUTO |
| > Manufacturer | (0008,0070) | LO | Always "Carl Zeiss Meditec" | ALWAYS | AUTO |
| > Manufacturer's Model Name | (0008,1090) | LO | Set to: "CLARUS 500" or "CLARUS 700" | ALWAYS | AUTO |
| > Software Version(s) | (0018,1020) | LO | For CLARUS version 1.0: "1.0.0.23635" Higher versions "1.0.x.y" For CLARUS version 1.1: 1.1.0.39000 Higher versions: "1.1.x.y" | ALWAYS | AUTO |
| > Date of Last Calibration | (0018,1200) | DA | Date when the device is last calibrated. | ALWAYS | AUTO |
| > Time of Last Calibration | (0018,1201) | ТΜ | Time when the device is last calibrated. | ALWAYS | AUTO |
| Longitudinal Temporal Information Modified | (0028,0303) | cs | Enumerated value: UNMODIFIED Present only when De-Identify Patient Data and Keep DateTime are both ON. | ANAP | Αυτο |

8.1.1.11 Modules "Raw Data" of Created Raw Data SOP Instances

| Attribute Name | Тад | VR | Value | PoV | Source |
|---------------------------------|-------------|----|--|------|--------|
| Acquisition Context Sequence | (0040,0555) | SQ | Please refer to section 8.3.3 for the code items in the sequence. For Sensor Raw Data: Always present and filled; Empty when de-identitied. For Elaboration Parameter: Always empty | VNAP | AUTO |

Table 8-21 Module "Acquisition Context" of Created Raw Data SOP Instances

| Attribute Name | Тад | VR | Value | PoV | Source |
|--------------------------------------|-------------|----|--|--------|--------|
| > Value Type | (0040,A040) | cs | Please refer to section 8.3.3 for the code values types in the sequence. | ALWAYS | AUTO |
| > Concept Name Code Sequence | (0040,A043) | SQ | Please refer to section 8.3.3 for the codes in the sequence. | ALWAYS | AUTO |
| >> Include 'Code Sequence Macro'. | | | | ALWAYS | AUTO |
| > Text Value | (0040,A160) | UT | Please refer to section 8.3.3 for the codes with value type TEXT. | ALWAYS | AUTO |
| > Concept Code Sequence | (0040,A168) | SQ | Please refer to section 8.3.3 for the codes with value type CODE. | ALWAYS | AUTO |
| >> Include 'Code Sequence Macro'. | | | | ALWAYS | AUTO |

Table 8-22 Module "Raw Data" of Created Raw Data SOP Instances

| Attribute Name | Тад | VR | Value | PoV | Source |
|-------------------------------------|-------------|----|--|--------|--------|
| Instance Number | (0020,0013) | IS | A number created from SOP instance UID. | ALWAYS | AUTO |
| Content Date | (0008,0023) | DA | eation started AL | | AUTO |
| Content Time | (0008,0033) | тм | he time the image pixel data reation started | | AUTO |
| Acquisition Datetime | (0008,002A) | DT | The date and time that the acquisition of data started. | ALWAYS | AUTO |
| Image Laterality | (0020,0062) | CS | Enumerated Values: $R = right L = left U = unpaired B = both left and right$ | ALWAYS | AUTO |
| Creator-Version UID | (0008,9123) | UI | For CLARUS 1.0 : 1.2.276.0.75.2.2.70.0.6.1.0.x.y For CLARUS 1.1: 1.2.276.0.75.2.2.70.0.6.1.1.x.y | ALWAYS | AUTO |
| Referenced Instance Sequence | (0008,114A) | SQ | For Image Raw Data: This sequence presents only when the image is created as Montage, AutoMontage or UWF (ultra wide field). In these cases, the Raw Data IOD is generated from other constituent Raw Data instances. For Elaboration Parameter: Always present and refers to the annotated Sensor data. | ANAP | AUTO |
| > Referenced SOP Class UID | (0008,1150) | UI | Set to 1.2.840.10008.5.1.4.1.1.66 | ALWAYS | AUTO |
| > Referenced SOP Instance UID | (0008,1155) | UI | SOP instance UID of the constituent images | ALWAYS | AUTO |

Table 8-23 Module "Sop Common" of Created Raw Data SOP Instances

| Attribute Name | Tag | VR | Value | PoV | Source |
|----------------|-------------|----|-------------------------------------|--------|--------|
| SOP Class UID | (0008,0016) | UI | Always "1.2.840.10008.5.1.4.1.1.66" | ALWAYS | AUTO |

| Attribute Name | Tag | VR | Value | PoV | Source |
|---|-------------|----|--|--------|--------|
| SOP Instance UID | (0008,0018) | UI | "1.2.276.0.75.2.2.70.0.3" 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) | тм | Time the SOP Instance was created. | ALWAYS | AUTO |
| Contributing Equipment Sequence | (0018,A001) | SQ | Present only when De-Identify Patient Data is ON. | ANAP | AUTO |
| > Purpose of Reference Code Sequence | (0040,A170) | SQ | Purpose for which the related equipment is being referenced | ALWAYS | AUTO |
| >> Include 'Code Sequence Macro'. | | | Set to ("109104", "DCM", "De-identifying Equipment") | ALWAYS | AUTO |
| > Manufacturer | (0008,0070) | LO | Always "Carl Zeiss Meditec" | ALWAYS | AUTO |
| > Manufacturer's Model Name | (0008,1090) | LO | Set to: "CLARUS 500" or "CLARUS 700" | ALWAYS | AUTO |
| > Software Version(s) | (0018,1020) | LO | For CLARUS version 1.0: "1.0.0.23635" Higher versions "1.0.x.y" For CLARUS version 1.1: 1.1.0.39000 Higher versions: "1.1.x.y" | ALWAYS | AUTO |

8.1.1.12 Modules "Ecapsulated Document" of Created ePDF SOP Instances

| Attribute Name | Тад | VR | Value | PoV | Source |
|--|-------------|----|--|--------|--------|
| Instance Number | (0020,0013) | IS | A number generated from SOP Instance UID | ALWAYS | AUTO |
| Content Date | (0008,0023) | DA | The date the document content creation was started. | ALWAYS | AUTO |
| Content Time | (0008,0033) | тм | The time the document content creation was started. | ALWAYS | AUTO |
| Acquisition Datetime | (0008,002A) | DT | The date and time that the original generation of the data in the document Al tarted. | | AUTO |
| Image Laterality | (0020,0062) | CS | Enumerated Values: R = right L = left U = unpaired B = both left and right | ALWAYS | AUTO |
| Burned In Annotation | (0028,0301) | cs | Always "YES" | ALWAYS | AUTO |
| Source Instance Sequence | (0042,0013) | SQ | Contains always one or more sequence item, depending on the number of exams which has been involved for the creation of this evidence report. One for each exam is included in the report. | | AUTO |
| > Referenced SOP Class UID | (0008,1150) | UI | Always "1.2.840.10008.5.1.4.1.1.66" for the Raw Data SOP Class. | ALWAYS | AUTO |
| > Referenced SOP Instance UID | (0008,1155) | UI | The value of the actual referenced SOP Instance. | ALWAYS | AUTO |
| Document Title | (0042,0010) | ST | Created from the creation date time. Format: "Report " + yyyy-MM-dd HH-mm-ss-fff | ALWAYS | AUTO |
| Concept Name Code Sequence | (0040,A043) | SQ | Zero items for CLARUS | ALWAYS | AUTO |
| MIME Type of Encapsulated Document | (0042,0012) | LO | Always "application/pdf". | ALWAYS | AUTO |
| Encapsulated Document | (0042,0011) | ОВ | Encapsulated Document stream, containing a document encoded according to the MIME Type. | ALWAYS | AUTO |

Table 8-24 Module "Encapsulated Document" of Created ePDF SOP Instances

Table 8-25 Module "Sop Common" of Created ePDF SOP Instances

| Attribute Name | Тад | 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 | "1.2.276.0.75.2.2.70.0.3" 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. Date report was generated. | ALWAYS | AUTO |
| Instance Creation Time | (0008,0013) | тм | Time the SOP Instance was created. Time report was generated. | ALWAYS | AUTO |

8.1.2 Usage of Attributes from Received IOD's

Each Application that depends on certain fields to function correctly should specify which ones are required for it to perform its intended function.

The CLARUS Application Software provides standard conformance.

The usage of attributes of Modality Worklist IODs is described in chapter 4.2.1.3.2 Activity – Query Modality Worklist. The case of patient data collision is outlined in chapter of Study Root Query/Retrieve SOP Class.

8.1.3 Attribute Mapping

In scheduled case, the following attributes are mapped from Modality Worklist to instances of Ophthalmic Photography 8 Bit IOD, Raw Data IOD, and Encapsulated Pdf IOD.

Table 8-26 Attribute Mapping

| | Modality Worklist | | Instance IOD | Editable |
|--------------|--------------------------------------|-----------------------------|--|----------|
| (0010,0010) | Patient's Name | (0010,0010) | Patient's Name | No |
| (0010,0020) | Patient ID | (0010,0020) | Patient ID | 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 |
| (0010,0030) | Patient's Birth Date | (0010,0030) | Patient's Birth Date | No |
| (0010,0040) | Patient's Sex | (0010,0040) | Patient's Sex | No |
| (0010,2160) | Ethnic Group | (0010,2160) | Ethnic Group | No |
| (0010,4000) | Patient Comments | (0010,4000) | Patient Comments | No |
| (0008,0050) | Accession Number | (0008,0050) | Accession Number | No |
| (0008,0090) | Referring Physicians Name | (0008,0090) | Referring Physicians Name | No |
| | | (0020,0010) | Study ID | No |
| (0040,1001) | Requested Procedure ID | (0040,0275) >(0040,1001) | Request Attributes Sequence > Requested Procedure ID | No |
| | | (0008,1030) | Study Description | No |
| (0032,1060) | Requested Procedure Description | (0040,0275) >(0032,1060) | Request Attributes Sequence > Requested Procedure Description | No |
| | | (0018,1030) | Protocol Name | No |
| | | (0040,0254) | Performed Procedure Step Description | No |
| (0032,1064) | Requested Procedure Code Sequence | (0008,1032) | Procedure Code Sequence | No |
| >(0008,0100) | Code Value | >(0008,0100) | Code Value | No |
| >(0008,0102) | Coding Scheme Designator | >(0008,0102) | Coding Scheme Designator | No |
| >(0008,0103) | Coding Scheme Version | >(0008,0103) | Coding Scheme Version | No |
| >(0008,0104) | Code Meaning | >(0008,0104) | Code Meaning | No |
| (0020,000D) | Study Instance UID | (0020,000D) | Study Instance UID | No |
| (0008,1110) | Referenced Study Sequence | (0008,1110) | Referenced Study Sequence | No |
| >(0008,1150) | Referenced Sop Class UID | >(0008,1150) | Referenced Sop Class UID | No |
| >(0008,1155) | Referenced Sop Instance UID | >(0008,1155) | Referenced Sop Instance UID | No |

| | Modality Worklist | | Instance IOD | Editable |
|---------------|---|-----------------------------|---|----------|
| (0040,0100) | Scheduled Procedure Step Sequence | | | No |
| >(0040,0007) | Scheduled Procedure Step Description | (0040,0275) >(0040,0007) | Request Attributes Sequence > Scheduled Procedure Step Description | No |
| >(0040,0008) | Scheduled Protocol Code Sequence | (0040,0275) >(0040,0008) | Request Attributes Sequence > Scheduled Protocol Code Sequence | No |
| >>(0008,0100) | Code Value | >(0008,0100) | Code Value | No |
| >>(0008,0102) | Coding Scheme Designator | >(0008,0102) | Coding Scheme Designator | No |
| >>(0008,0103) | Coding Scheme Version | >(0008,0103) | Coding Scheme Version | No |
| >>(0008,0104) | Code Meaning | >(0008,0104) | Code Meaning | No |
| >(0040,0009) | Scheduled Procedure Step ID | (0040,0275) >(0040,0009) | Request Attributes Sequence > Scheduled Procedure Step ID | 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 CLARUS Application Software.

8.2 Data Dictionary of Private Attributes

Table 8-27 Private Dictionary Group (2C03,00xx) = "99CZM_SAM_ImageElaboration"

Occurs in: RAW Data SOP Instance

| Тад | Attribute Name | VR | VM |
|-------------|------------------------------|----|----|
| (2C03,00xx) | Private Creator | LO | 1 |
| (2C03,xx01) | Parameters Schema Version | SH | 1 |
| (2C03,xx02) | Image Elaboration Parameters | OB | 1 |

Table 8-28 Private Dictionary Group (2C05,00xx) = "99CZM_SAM_Equipment"

Occurs in: RAW Data SOP Instance

| Тад | Attribute Name | VR | VM |
|-------------|-----------------|----|----|
| (2C05,00xx) | Private Creator | LO | 1 |
| (2C05,xx01) | Sensor Name | LO | 1 |

Table 8-29 Private Dictionary Group (2C07,00xx) = "99CZM_SAM_Image"

Occurs in: RAW Data SOP Instance

| Тад | Attribute Name | VR | VМ |
|-------------|------------------------|----|----|
| (2C07,00xx) | Private Creator | LO | 1 |
| (2C07,xx01) | WF Rows | US | 1 |
| (2C07,xx02) | WF Columns | US | 1 |
| (2C07,xx03) | WF Pixel Data Sequence | SQ | 1 |
| (2C07,xx04) | Pixel Data | ОВ | 1 |

| Тад | Attribute Name | VR | ∨м |
|-------------|--|----|-----|
| (2C07,xx05) | WF Image Type | CS | 2-n |
| (2C07,xx06) | WF Samples Per Pixel | US | 1 |
| (2C07,xx07) | WF Photometric Interpretation | CS | 1 |
| (2C07,xx08) | WF Number of Frames | IS | 1 |
| (2C07,xx09) | WF Distortion Correction Source | LO | 1 |
| (2C07,xx0A) | WF Grouping Key | LO | 1 |
| (2C07,xx0B) | WF Favorite Image | CS | 1 |
| (2C07,xx0C) | WF Pixel Width | FL | 1 |
| (2C07,xx0D) | WF Pixel Height | FL | 1 |
| (2C07,xx0E) | WF Cine Sequence | SQ | 1 |
| (2C07,xx0F) | Frame Time | DS | 1 |
| (2C07,xx10) | Start Trim | IS | 1 |
| (2C07,xx11) | Stop Trim | IS | 1 |
| (2C07,xx12) | Frame Delay | DS | 1 |
| (2C07,xx13) | Effective Duration | DS | 1 |
| (2C07,xx14) | Actual Duration | IS | 1 |
| (2C07,xx15) | WF Contrast Bolus Agent Sequence | SQ | 1 |
| (2C07,xx16) | Contrast Bolus Agent Number | US | 1 |
| (2C07,xx17) | Contrast Bolus Administration Profile Sequence | SQ | 1 |
| (2C07,xx18) | Contrast Bolus Start Time TI | | 1 |
| (2C07,xx19) | Contrast Bolus Stop Time | тм | 1 |
| (2C07,xx1A) | Contrast Bolus Agent Code | cs | 1 |
| (2C07,xx1B) | Contrast Bolus Administration Route Code | cs | 1 |
| (2C07,xx1C) | WF Patient Eye Movement Commanded | cs | 1 |
| (2C07,xx1D) | WF Patient Eye Movement Commanded Code | cs | 1 |
| (2C07,xx1E) | WF Focus Aid | | 1 |
| (2C07,xx1F) | WF Auto Focus | | 1 |
| (2C07,xx20) | WF Focus Position | | 1 |
| (2C07,xx21) | WF Fixation Protocol | | 1 |
| (2C07,xx22) | WF Fixation Position X | | 1 |
| (2C07,xx23) | WF Fixation Position Y | FD | 1 |
| (2C07,xx24) | WF Fovea Position X | US | 1 |
| (2C07,xx25) | WF Fovea Position Y | US | 1 |

| Тад | Attribute Name | VR | VМ |
|-------------|----------------------------|----|----|
| (2C07,xx26) | WF Montage Sequence No | US | 1 |
| (2C07,xx27) | WF Fixation Mode | US | 1 |
| (2C07,xx28) | WF ONH Position X | FD | 1 |
| (2C07,xx29) | WF ONH Position Y | FD | 1 |
| (2C07,xx2A) | WF Ophthalmic FOV | FL | 1 |
| (2C07,xx2B) | WF ONH Identification Mode | CS | 1 |
| (2C07,xx2C) | WF Suggested White Level | US | 1 |
| (2C07,xx2D) | WF Suggested Black Level | US | 1 |
| (2C07,xx2E) | WF Default Max White Level | US | 1 |

Table 8-30 Private Dictionary Group (2201,00xx) = "99CZM_NIM_INTERNAL_01"

Occurs in: ALL IODs

| Тад | Name | VR | VM |
|-------------|-----------------------------------|----|----|
| (2201,00xx) | Private Creator | LO | 1 |
| (2201,xx00) | lod_name_meta_info | LT | 1 |
| (2201,xx01) | Czm_xml_version I | | 1 |
| (2201,xx02) | private_module_names_and_versions | LT | 1 |

8.3 Coded Terminology and Templates

8.3.1 Context Groups

The following context groups are used in CLARUS:

| Context Group | Default Value Set | Configurable | Use |
|--|-------------------|--------------|--|
| Ophthalmic Anatomic Structure Imaged | CID 4209 | Extensible | Uses in Anatomic Region Sequence (0008,2218) to specify detailed information on the anatomic region that was examined. |
| | | | Bit |
| Ophthalmic Photography Acquisition Device | CID 4202 | Extensible | Uses in Acquisition Device Type Code Sequence (0022,0015) to specify detailed information on the type of acquisition device. Occurs in Image Ophthalmic Photography 8 Bit |
| Ophthalmic Imaging Agent | CID 4200 | Extensible | Uses in Contrast/Bolus Agent Sequence (0018,0012) to specify detailed information on the contrast agents administered prior to or during the acquisition. Occurs in Image Ophthalmic Photography 8 |
| | | | Bit - FA, only |
| Route of Administration | CID 11 | Extensible | (0018,0012) to specify detailed information on the route of administration of contrast agent. |
| | | | Occurs in Image Ophthalmic Photography 8 Bit - FA only |
| Contributing Equipment Purposes of | CID 7005 | Extensible | Uses in Contributing Equipment Sequence (0018,A001) to specify the purpose for which the equipment is being referenced. |
| Kelerence | | | Occurs in Image RawData, ImageElaboration RawData and Ophthalmic Photography 8 Bit |
| De-Identification Method | CID 7050 | Extensible | Used in De-identification Method Code Sequence (0012,0064) to specify the method used. |
| | | | Occurs in Image RawData and ImageElaboration RawData |
| Referenced Image Purposes of Reference | CID 7201 | Extensible | Used in Referenced Instance Sequence (0008,114A) to specify the other image of a stereoscopic pair. |
| | | | Occurs in Ophthalmic Photography 8 Bit |
| Source Image Purposes of Reference | CID 7202 | Extensible | Used in Referenced Instance Sequence (0008,114A) and Source Image Sequence (0008,2112) to specify the source of processed or montaged image. |
| | | | Occurs in Image RawData and Ophthalmic Photography 8 Bit |
| Purpose of Reference to Object | CID 3407 | Extensible | Used in Referenced Instance Sequence (0008,114A) to specify the purpose of reference. |
| | | | Occurs in ImageElaboration RawData |

8.3.2 Template Specifications

CLARUS does not use any extended or private template.

8.3.3 Private Code Definitions

In the scheduled case, CLARUS uses codes that are available via the MWL provider. The Requested Procedure Code sequence (0032,1064) and Scheduled Protocol Code Sequence (0040,0008) will be transmitted from MWL C-FIND response to instances of Ophthalmic Photography 8 Bit, Raw Data.

CLARUS uses the following codes in the Acquisition Context Sequence to specify the acquisition parameters. Occurs in Image RAW and Ophthalmic Photography 8 Bit IOD.

| Code Value | Coding Scheme Designator | Coding Type | Meas. Units Code / Values | Code Meaning |
|-------------------------------|-----------------------------|----------------|--|-------------------------------------|
| WFOPPUPILDILATED ¹ | 99CZM | CODE | Values: True; False | Pupil Dilated |
| WFOPPROJXMIN | 99CZM | TEXT | | ProjectedXMin |
| WFOPPROJYMIN | 99CZM | TEXT | | ProjectedYMin |
| WFOPPROJXMAX | 99CZM | TEXT | | ProjectedXMax |
| WFOPPROJYMAX | 99CZM | TEXT | | ProjectedYMax |
| WFOPPROTNAME ² | 99CZM | TEXT | Values: Initial, Freehand; AutoFixation | Protocol Name |
| WFOPFIXPOSX ² | 99CZM | TEXT | | Fixation pos X |
| WFOPFIXPOSY ² | 99CZM | TEXT | | Fixation pos Y |
| WFOPFOVEAPOSX ² | 99CZM | NUMERIC | Unit: pixel | Fovea pos X |
| WFOPFOVEAPOSY ² | 99CZM | NUMERIC | Unit: pixel | Fovea pos Y |
| WFOPBIASCORRSRC ² | 99CZM | ТЕХТ | Values: UNDEFINED FIXATION_POSITION FOVEA_POSITION CENTER_POSITION | DistCorrectSrc |
| WFOPGRPKEY ² | 99CZM | TEXT | | GroupingKey |
| WFOPFAVORITE ² | 99CZM | CODE | Values: True; False | FavoriteImage |
| WFOPSEQUENCENO | 99CZM | NUMERIC | Unit: none | Sequence number of images acquired. |

Table 8-31 Coded Values used in Acquisition Context Sequence

¹Note: Only occurs in Image RAW Data IOD.

²Note: Only occurs in Ophthalmic Photography 8 Bit IOD.

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).

8.6 Private Transfer Syntaxes

No Private Transfer Syntax is supported.



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