



Merge PACS™

v. 6.6

DICOM CONFORMANCE STATEMENT MODALITY WORKLIST

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INDICATIONS FOR USE:

MERGE PACS is designed and marketed for soft copy reading, communication and storage of studies produced by digital modalities, to include Digital Mammography.

MERGE PACS receives images acquired from DICOM-compliant medical imaging systems, data from FDA-cleared Computer-Aided Detection systems and other FDA-cleared Image processing systems.

MERGE PACS imports images and render said images, upon request, within the viewer component utilizing both lossless (reversible) and lossy (irreversible) compression.

To support the diagnostic interpretation of Mammography studies, MERGE PACS will display the full fidelity DICOM image in a non-compressed format. Images will be rendered with patient and clinical information clearly displayed as part of the DICOM Overlay as required by MQSA, on monitors cleared by FDA for use in Digital Mammography. Lossy compressed mammography images and digitized film screen images must not be used for the purpose of primary diagnosis. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Within MERGE PACS, the MERGE Real Time Worklist offers real-time status of radiology activity and provides customizable workflow management capabilities. Communication of critical results is facilitated and documented through optional, and configurable, components within the Real Time Worklist.

MERGE PACS also offers the Patient Dashboard which provides a single view of all patient data, both imaging and non-imaging.

MERGE Reach is an optional component within MERGE PACS which provides clinicians secure, proactive communication and access to clinical reports and images.

Order and Report information generated by HIS/RIS and report creation systems are received and displayed in PACS via the transmission of HL7 messaging. For this data, MERGE PACS is not the creator, but instead the downstream recipient which relies on the validity of data from said systems.

MERGE PACS must be installed on suitable, commercial-standard hardware.

It is the user’s responsibility to ensure monitor quality, ambient light conditions and image compression ratios are consistent with the clinical application.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

CANADIAN DEVICE IDENTIFIER: Merge PACS



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Part	Date	Revision	Description
PAX-34566	10/13/2016	1	Update for 6.6.3.2

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Chapter 1. General

1.1. Executive Overview

The Merge PACS Web/Intranet Image Server IS Interface functions as the boundary between an Information System (IS), typically a Radiology Information System, and the digital modalities such as CT, MR, Ultrasound, etc. It provides scheduling information for diagnostic procedures as well as demographic information about the patient and the particular visit. This information is obtained by a HL7 interface, which is described in a separate interface specification. This device converts the protocol and information exchange from HL7 to DICOM and acts as a server for the clients (modalities) that support the DICOM Modality Worklist.

The most important characteristic of this device are the supported SOP Class and the respective roles (Service Class User or Provider, SCU/SCP or Both), a list of which is provided below:

SOP Class Name	SOP Class UID	Role
DICOM Modality Worklist Information Model - FIND	1.2.840.10008.5.1.4.31	SCP
Verification	1.2.840.10008.1.1	SCU/SCP

1.2. Abbreviations and ACRONYMS

The following acronyms and abbreviations are used throughout this document:

Abbreviation	Description
ASCII	American Standard Code for Information Interchange
AE	Application Entity
ANSI	American National Standards Institute
CR	Computerized radiography
CT	Computerized Tomography
DICOM	Digital Imaging and Communications in Medicine
HL7	Health Level 7
IE	Information Entity
IOD	Information Object Definition

Abbreviation	Description
ISO	International Standards Organization
MR	Magnetic Resonance
NEMA	National Electrical Manufacturers Association
NM	Nuclear Medicine
OSI	Open Systems Interconnection
PDU	Protocol Data Unit
RF	Radio Fluoroscopy
SC	Secondary Capture
SCP	Service Class Provider
SCU	Service Class User
SOP	Service-Object Pair
TCP/IP	Transmission Control Protocol/Internet Protocol
UID	Unique Identifier
US	Ultrasound
VM	Value Multiplicity
VR	Value Representation
XA	X-ray Angiography

Chapter 2. Scope

This DICOM Conformance statement documents the conformance of the *Merge PACS IS Interfaces* software with the Digital Imaging and Communications in Medicine (DICOM) standard. This document is essential in order to evaluate whether or not another DICOM compliant device can communicate with this software product. This statement is conformant with the recommended format as described in PS 3.2 of the DICOM Standard¹.

2.1. How to Use this Document:

This statement consists of five important features that one should compare with other devices in order to determine connectivity:

___1. Implementation Model

The Implementation Model describes the functional relationship between the device, the so-called “real-world activities” which initiate certain DICOM functionality, and the DICOM services. A DICOM service is implemented on a device by a software process, which is called an “Application Entity” (AE). Each AE has a unique name called the AE Title, which is used to identify it to other AE’s. The AE Title is configurable to avoid two devices with the same name on a network. The “bubble diagram” (Application Data Flow Diagram) shows the interaction of the AE with the outside world across the dashed line, *i.e.*, the DICOM interface.

___2. AE Specifications

Each AE supports one or more Service-Object-Pair classes or SOP Class, which define the basic functionality. A SOP class consists of a combination of an Object or Information model with specific DICOM services. An example of such a SOP Class is the CT Image Storage Class, which consists of the combination of the DICOM C_STORE command with the CT Image object. Each of these classes is uniquely identified by an Unique Identification number (UID), which is issued by the NEMA. In addition, the “role” of the AE is specified, *i.e.*, User or Provider, which can be compared with acting as a Client or Server. In DICOM terms, this is called a Service Class User or Service Class Provider (SCU or SCP).

In order to interconnect with another device, the SOP classes as well as their role (SCU or SCP) have to be matched, *i.e.*, a SCU has to match a SCP at another device with an identical SOP class. Make sure to compare the SOP Class UID itself, not the description

¹ Digital Imaging and Communications in Medicine (DICOM) 3.0, NEMA PS 3.1-14, 1999

because there are SOP classes which have the same name, but support a different (newer) Object, which is identified by a different SOP Class UID.

3. Presentation Context

Each SOP class supports a particular presentation context, which is the combination of the SOP Class as specified under (2) and the Transfer Syntax. The Transfer Syntax defines the encoding of the DICOM basic elements, *i.e.*, its attributes and how the data is represented, *i.e.*, with a data type definition. The encoding of the data type as part of the message, or Value Representation (VR), can be done in two ways - implicitly or explicitly. If a device supports Explicit VR transfer syntax, it means that the transmitted data will include the VR information along with data and attribute tags. Implicit VR means that the VR information will not be included, and the receiving application must determine the VR type from the Attribute Tag. For example, when receiving the Attribute "Patient Name" in Explicit Transfer Syntax, there is an additional type code field (containing "PN" meaning "Person Name") to identify the Value Representation. In the case of Implicit Transfer Syntax, it is assumed to be known by the receiver and not explicitly specified that this attribute has a type of "Person Name".

The data can be communicated in the Intel or Motorola Byte ordering, AKA "Little Endian" or "Big Endian". This means that for certain 16 bit words; the two 8 bit Bytes might have to be swapped to be able to interpret the information by a device supporting a different byte ordering.

Lastly, compression can be applied, such as JPEG, which is specified in the transfer syntax. The Transfer Syntax of two devices must match in order for them to communicate.

4. Communication Profiles

This section specifies the communication options. In practice, each device always supports an Application level interface to the OSI level 4 (Transport layer), *i.e.*, TCP/IP stack. However, the Physical Media of two devices have to match for connectivity. Note that matching physical media can be achieved by standard off the shelf devices. For example, if one device supports standard Ethernet 10BaseT, it can be bridged to a Fast Ethernet, ATM, or whatever is supported.

5. Supported Attributes

Many devices specify which DICOM attributes they require and/or store in their internal database. It is important to compare these against the source of the information, particularly if a device requires certain attributes to accomplish specific functionality such as 3-D viewing, image processing, etc. A mismatch could have the effect that certain functionality or applications might fail.

2.2. WARNING to the Reader:

If another device matches this conformance statement based on the comparison with its own conformance statement, there is a chance, but no guarantee that they interoperate. DICOM only deals with communication, it does not specify what is needed for certain Applications to run on a device.

Chapter 3. Networking

3.1. Functional Overview

As shown in the Application Data Flow diagram below, the Merge PACS IS Interface software consists of a single Application Entity that deals with the DICOM communication. In addition to the Modality worklist function, there are four additional functions that are provided by the Application entity: Web access to images, archiving, auto routing and verification. These functions are described separately in the Merge PACS Web/Intranet Server DICOM conformance statement. The verification function is repeated in this conformance statement in addition to being specified in the Server DICOM conformance statement.

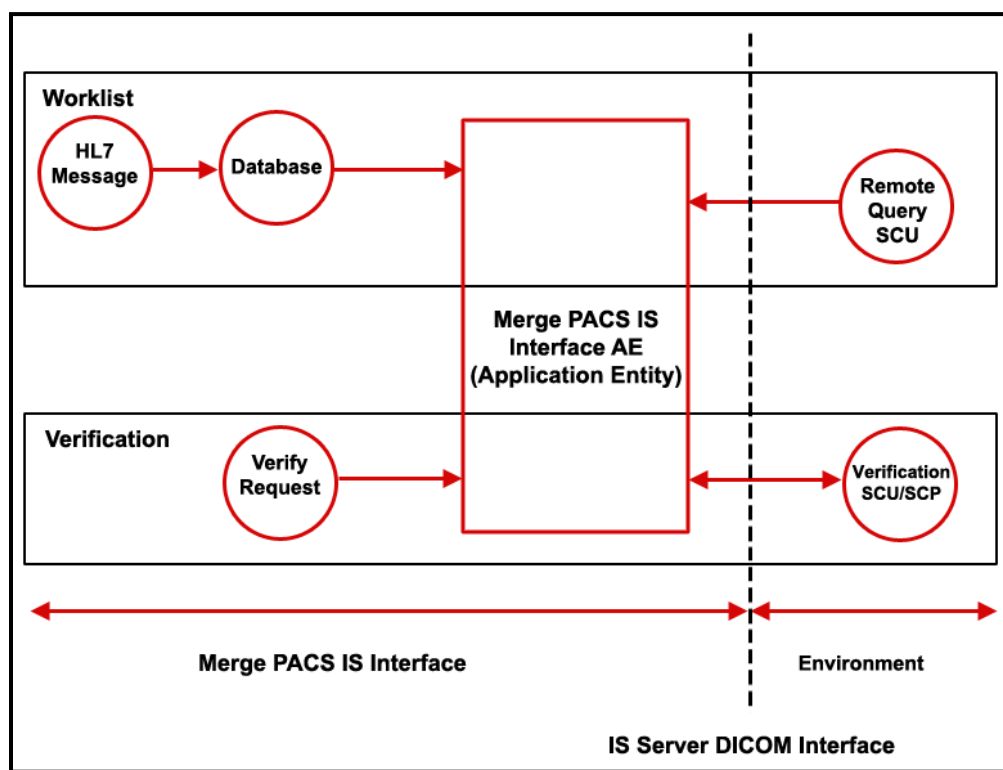


Figure 1: Implementation Model

The Worklist function listens to unsolicited events initiated by an Information System (IS) using the HL7 protocol. These HL7 events are used to generate and/or modify a schedule of diagnostic procedures in a database. A Client (Remote Query SCU) initiates a Query that causes the AE to retrieve scheduling information from the database. The AE acts as a Server, sending the scheduling information back to the Remote Query SCU Client.

The Verification function will either initiate a Verification to an external device to find out whether another AE can respond, or will respond to a Verification Request.

3.2. Functional Definition of Merge PACS Worklist AE

3.2.1. Sequencing of Real-World Activities

Work list entries provided to a modality, pertaining to requested procedures will be removed from the work list immediately upon establishment of a linkage between a study received by the image server and the requested procedure. Such linkage is established automatically if one of the following is true:

1. The received study contains a Referenced Study Sequence attribute matching the Referenced SOP Class UID and Referenced Study Instance UID supplied for the procedure by Merge PACS via the Modality Work list.
2. The received study's Study Instance UID matches the Study Instance UID supplied for the procedure by Merge PACS via the Modality Work list.
3. The received study's Accession Number matches the Accession Number supplied for the procedure by Merge PACS via the Modality Work list.

Such linkage can also be established manually by means of HL7 messages from the IS to Merge PACS. The user interface for performing manual linkage is usually provided by the IS system as an Order-Exam matching function to be performed by the technologist as part of the post-exam processing step.

The actual data for the requested procedure will be retained in the database for a configurable period of time following passage of the latest Scheduled Procedure Start Time for a procedure. The default retention time is 7 days.

Should the linkage between a received study and a requested procedure be removed, the Modality Work list entries pertaining to the requested procedure will once again appear in the work list.

Removal of the linkage can be effected by means of HL7 messages from the IS to Merge PACS.

3.2.2. SOP Classes

This application entity provides standard conformance to the following DICOM SOP classes:

SOP Class Name	SOP Class UID	SCU	SCP
Verification	1.2.840.10008.1.1	YES	YES
Modality Worklist Information Model - FIND	1.2.840.10008.5.1.4.31	-	YES

3.3. Association Initiation

3.3.1. General

A verification request will be initiated upon a user action such as for testing purposes. (Never automatically or gratuitously.)

3.3.2. Application Context

The DICOM standard application context name, which is always proposed, is DICOM 3.0:

Application context name	1.2.840.10008.3.1.1.1
---------------------------------	-----------------------

The PDU size is configurable and ranges from 4096 - 2**32-1 with as default value 65536.

SOP Class extended negotiation is not supported.

3.3.3. Number of Associations

Only one Association will be initiated at a time.

3.3.4. Asynchronous Nature

Asynchronous mode of operation is not supported.

3.3.5. Implementation Identifying Information

The implementation Information of this application is:

Information	Description
Implementation Class UID	1.2.840.113837.7.7.2000
Implementation version name	2.3WIN32-12MAY00

3.3.6. Association Initiation Policy

The association will be released immediately following the execution of a single Verify request when used for testing purposes.

3.3.7. Proposed Presentation Contexts

SOP Class Name	Abstract Syntax		Transfer Syntax		Role
	SOP Class UID	Name	UID		
Verification	1.2.840.10008.1.1	DICOM Implicit VR Little Endian Transfer Syntax	1.2.840.10008.1.2		SCU

3.4. Association Acceptance

3.4.1. General

The following (external) real-World activities will cause a request for an association acceptance:

- Remote Query request
- Remote Verification request

If a TCP/IP connection is made by a requestor and not followed up by a DICOM association request within a certain time period, the acceptor will drop the association. This period is configurable (“ARTIM”).

When the association has been established, there is also a time-out value for a command to be received. When there is no activity within this time, an A_Release-RQ will be issued to release the association. This time period is configurable (“MAX Incoming association lifetime”).

3.4.2. Number of Associations

The number of simultaneous associations depends on the hardware resources such as available memory, CPU speed, etc. As a minimum, it consists of 20 for a typical configuration (note that the same AE also functions as a server, therefore, there might be other outstanding associations outside those of the work list).

3.4.3. Asynchronous Nature

Asynchronous mode of operation is not supported.

3.4.4. Accepted Presentation Context Table

The AE accepts as SCP for its SOP classes all presentation contexts containing the following transfer syntax:

Abstract Syntax		Transfer Syntax		Role
SOP Class Name	SOP Class UID	Name	UID	
Modality Worklist Information Model – FIND	1.2.840.10008.5.1.4.31	DICOM Implicit VR Little Endian Transfer Syntax	1.2.840.10008.1.2	SCP
		DICOM Explicit VR Little Endian Transfer Syntax	1.2.840.10008.1.2.1	SCP
Verification	1.2.840.10008.1.1	DICOM Implicit VR Little Endian Transfer Syntax	1.2.840.10008.1.2	SCP

Extended negotiation is not supported; relational query is not accepted.

Explicit VR transfer syntax is preferred: When offered both the Implicit and Explicit VR transfer syntax, the Explicit will be accepted.

3.5. SOP Specific Conformance for FIND SOP Class as a SCP

Wildcards are not affected by normalization of the query key. Thus, case-, space-, and punctuation-insensitive matching is performed for such attributes.

Attribute Name	Notes	Attribute (Group, Element)
Patient Identification		

Patient Name		(0010, 0010)
Patient ID	K	(0010, 0020)
Patient ID Issuer		(0010, 0021)
Other Patient IDs		(0010, 1000)
Patient Demographic		
Patient Birth Date		(0010, 0030)
Patient Sex		(0010, 0040)
Confidentiality Constraint on Patient Data		(0040, 3001)
Patient Address		(0010, 1040)
Patient Telephone Numbers		(0010, 2154)
Patient Medical		
Patient State		(0038, 0500)
Pregnancy Status		(0010, 21c0)
Medical Alerts		(0010, 2000)
Contrast Allergies		(0010, 2110)
Patient Weight		(0010, 1030)
Special Needs		(0038, 0050)
Imaging Service Request		
Accession Number	K, 1	(0008, 0050)
Requesting Physician		(0032, 1032)
Referring Physician		(0008, 0090)
Visit Comments		(0038, 4000)
Placer Order Number / Imaging Service Request		(0040, 2016)
Filler Order Number / Imaging Service Request		(0040, 2017)
Visit Identification		
Admission ID		(0038, 0010)
Visit Status		
Current Patient Location		(0038, 0300)
Visit Relationship		
Referenced Patient Sequence		(0008, 1120)
> Referenced SOP Class UID		(0008, 1150)
> Referenced SOP Instance UID		(0008, 1155)
Requested Procedure		
Requested Procedure Comments		(0040, 1400)
Requested Procedure Description		(0032, 1060)
Requested Procedure Code Sequence		(0032, 1064)
> Code Value		(0008, 0100)

> Coding Scheme Designator		(0008, 0102)
> Code Meaning		(0008, 0104)
Requested Procedure ID	K, 2	(0040, 1001)
Study Instance UID (generated)		(0020, 000D)
Referenced Study Sequence		(0008, 1110)
> Referenced SOP Class		(0008, 1150)
> Referenced Study Instance UID		(0008, 1155)
Requested Procedure Reason		(0040, 1002)
Requested Procedure Priority		(0040, 1003)
Patient Transport Arrangements		(0040, 1004)
Scheduled Procedure Step		
Scheduled Procedure Step Sequence		(0040, 0100)
> Scheduled Station AE Title		(0040, 0001)
> Scheduled Procedure Step Start Date		(0040, 0002)
> Scheduled Procedure Step Start Time		(0040, 0003)
> Scheduled Procedure Step Location		(0040, 0011)
> Scheduled Procedure Step Status		(0040, 0020)
> Modality		(0008, 0060)
> Scheduled Performing Physician's Name		(0040, 0006)
> Scheduled Procedure Step ID	K, 3	(0040, 0009)
> Scheduled Station Name		(0040, 0010)
> Scheduled Protocol Code Sequence		(0040, 0008)
>> Code Value		(0008, 0100)
>> Coding Scheme Designator		(0008, 0102)
>> Code Meaning		(0008, 0104)
> Scheduled Procedure Step Description		(0040, 0007)
Scheduled Procedure Step Comments		(0040, 0400)

Notes:

K - This attribute is used as a unique key.

1 - Guaranteed unique within the context of a Patient.

2 - Guaranteed unique within the context of an Imaging Service Request

3 - Guaranteed unique within the context of a Requested Procedure

All attributes listed above may be used as matching keys. Certain attributes are indexed for better query performance. It is recommended to supply at least one of the indexed attributes as a key. The list of attributes that are indexed for enhanced query performance is configurable. The standard list follows:

Attribute Name	Attribute (Group, Element)
Patient ID	(0010, 0020)
Accession Number	(0008, 0050)
Requested Procedure ID	(0040, 1001)
Scheduled Procedure Step ID	(0040, 0009)
Modality	(0008, 0060)
Scheduled Procedure Start Date	(0040, 0002)
Scheduled Station AE Title	(0040, 0001)

It is strongly recommended, but not required, that all queries contain at least one non-null matching value for one of the indexed attributes. Indexes may be added by customer support to solve specific site-related query problems.

All available items matched will be returned. A configurable limit on the maximum number of rows returned in a query response is implemented. The default value is 5000 rows. If a query would produce more than the limit an error response is returned. This limit can be set to infinity.

Depending on the capabilities and characteristics of the Information system, it is feasible to specify multiple Requested Procedures resulting in multiple Scheduled Procedure steps, all as a single Image Service Request, consistent with the information model as specified in the DICOM standard

3.5.1. Timing

Changes appear on the work list typically within a second after an applicable HL7 command has been received; only the typical computer program processing time is required.

3.5.2. Error handling

The following errors will be returned upon unsuccessful C-FIND processing:

Status Code	Error Comment	Meaning	Invalid Elements List (0000, 0901) Returned?
0110	Internal SCP error	A program error was detected while processing the query (e.g. program logic error, etc.).	No.
0110	Unable to connect to local database.	The SCP is unable to establish a connection to its underlying RDBMS.	No.

Status Code	Error Comment	Meaning	Invalid Elements List (0000, 0901) Returned?
0120	Missing required keys/values: <list>	One or more type 0 attributes were missing in the request. <list> in the error comment is replaced by a list of the missing attributes.	Yes. List of missing or empty required attributes.
C001	Query error.	Unspecified error while processing query.	No.
C002	Internal program error at CFind service provider.	Internal program error in query processor e.g. null pointer, etc.	No.
C007	Query/Retrieve level missing from request.	The query did not specify the query/retrieve level: attribute (0008, 0052) was missing or empty.	Yes. (0008, 0052)
C008	Unrecognized Q/R level (<level>) requested.	The SCU specified an unrecognized (i.e. not "PATIENT", "STUDY", "SERIES", or "IMAGE") query/retrieve level in attribute (0008, 0052). <level> in the error comment is replaced by the invalid value specified by the SCU.	Yes. (0008, 0052)
C009	Invalid Q/R level (<level>) requested.	The query level specified by the SCU is not valid for the query model being used (e.g. PATIENT query level specified while using the Study Root query model). <level> in the error comment is replaced by the invalid value specified by the SCU.	Yes. (0008, 0052)
C010	Internal error - Invalid query passed to QueryDatabase().	Internal program error. The query translator produced an empty SQL query.	No.
C011	Internal error - Invalid argument to QueryDatabase().	Internal program error. The query translator produced an invalid SQL query.	No.
C012	Internal error - Invalid database schema on SCP.	Internal program error. The configurable database schema cannot be processed.	No.
C013	Internal SCP error - SQL query preparation failed.	Internal program error. The query translator produced an invalid SQL query or a database error occurred.	No.
C014	Internal SCP error - SQL bind failed.	Internal program error. The query translator produced an invalid SQL query or a database error occurred.	No.
C015	Internal SCP error - SQL query error.	Internal program error. The query translator produced an invalid SQL query or a database error occurred while executing query.	No.
C016	Internal error - SQL result retrieval failure on SCP.	Internal program error. An error occurred while reading query results from the database.	No.
C017	Internal error - Result set encoding failure on SCP.	Internal program error. An error occurred while encoding query results into DICOM dataset	No.

Status Code	Error Comment	Meaning	Invalid Elements List (0000, 0901) Returned?
C018	Error in local database configuration (device map).	Internal program error. Storage device map misconfigured.	No.
FE00		Matching terminated due to Cancel request.	No.
FF00		Matching continues. Current match is supplied. Any optional keys were supported in the same manner as required keys.	No.
FF01		Matching continues. Current match is supplied. Warning that one or more optional keys were not supported for existence and/or matching for this identifier.	Yes. List of optional requested attributes not supported for matching or return.

3.6. Communication Profiles

3.6.1. Supported Communication Stacks

DICOM Upper Layer over TCP/IP is supported.

3.6.2. OSI and point to point

OSI and the point to point stack are not supported.

3.6.3. TCP/IP Stack

The TCP/IP stack is inherited from the underlying operating system

- **API:** The application makes use of the Berkeley Sockets interface on Unix and of the WinSock interface on Win32 platforms.
- **Physical Media Support:** DICOM is indifferent to the physical medium over which TCP/IP executes. When a complete system (hardware as well as software) is provided, Merge PACS will provide at a minimum Ethernet (10/100/1000 Mbitsec). It is strongly recommended to consult your reseller and/or Merge Healthcare Support for detailed information.

3.7. Configurable Parameters

- Maximum PDU size: (4096 - $2^{32}-1$ (default = 65536)) separately configurable for incoming and outgoing PDUs, DICOM rules strictly followed
- Time out values:
 - ARTIM: Association request, Reject, Release Timer (ARTIM): This timer starts when a TCP/IP connection has been made by the requestor and causes a time-out when no Associate request is received within the time specified. It is also used to monitor the time for the receiver to close the connection. The default value is 180 seconds.
 - MAX incoming association lifetime: Time-out for waiting for a command on an open association. Default value is 12 hours. A value of 0 sets it to infinity.
 - MAX read/write time: This is used to monitor the time it takes for a read/write operation on sockets. Default value is 5 minutes; a value of 0 sets it to infinity.
- Local AE title
- Remote AE Title fields
- List of accepted calling AE titles (default = any)
- Local IP address and Netmask (listens on all interfaces; uses IP addresses assigned to underlying system)
- Responding TCP/IP ports and addresses (listen port configurable; listens on all interfaces)
- List of accepted abstract syntaxes
- List of attributes extracted from stored SOP instances and cataloged in RDBMS to support DICOM Q/R

3.8. Support of Extended Character Sets

This application supports only ISO_IR 100 (ISO 8859-1 Latin 1) as extended character set.