

DICOM Conformance Statement

INTRABEAM[®] 600

Version 4.0

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1 Conformance Statement Overview

The INTRABEAM 600 is used for targeted radiotherapy treatment of a tumor or tumor bed in the form of a minimally invasive, intraoperative, interstitial, intracavitary technique or by means of contact in and on the entire body of a cancer patient.

By applying the radiation source in connection with different applicators, a prescription dose of low-energy X-ray radiation can be applied to the target volume. The emission of the radiation dose is controlled by the integrated control unit and software.

The INTRABEAM 600 includes several quality assurance components to ensure correct functioning of the X-ray source.

The INTRABEAM 600 is mobile; it can be manually moved into different treatment rooms.

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

Table 1-1 Network Services Supported

SOP Classes	User of Service (SCU)	Provider of Service (SCP)
Transfer		
Encapsulated PDF Storage	Yes	No
Query / Retrieve		
Patient Root Query/Retrieve Information Model – FIND	Yes	No
Workflow Management		
Verification SOP Class	Yes	Yes

The INTRABEAM does not support Media Interchange.

2 Table of Contents

1	Conformance Statement Overview	2
2	Table of Contents	3
3	Introduction	5
3.1	Revision History	5
3.2	Audience	5
3.3	Remarks	5
3.4	Definitions and Terms	5
3.5	Abbreviations	7
3.6	References	8
4	Networking	9
4.1	Implementation Model	9
4.1.1	Application Data Flow	9
4.1.2	Functional Definition of AEs	10
4.1.2.1	Functional Definition of INTRABEAM	10
4.1.3	Sequencing of Real-World Activities	10
4.1.3.1	Acquisition Modality activities	11
4.2	AE Specifications	12
4.2.1	INTRABEAM AE Specification	12
4.2.1.1	SOP Classes	12
4.2.1.2	Associations Policies	12
4.2.1.2.1	General	12
4.2.1.2.2	Number of Associations	13
4.2.1.2.3	Asynchronous Nature	13
4.2.1.2.4	Implementation Identifying Information	13
4.2.1.3	Association Initiation Policy	13
4.2.1.3.1	Activity – Verify Communication	13
4.2.1.3.2	Activity - Query remote AE for patients	14
4.2.1.3.3	Activity – Perform treatment	19
4.2.1.3.1	Activity – Create treatment report	19
4.2.1.3.2	Activity – Store treatment report	19
4.2.1.4	Association Acceptance Policy	22
4.2.1.4.1	Activity – Verify Communication	22
4.3	Network Interfaces	22
4.3.1	Physical Network Interface	22
4.3.2	Additional Protocols	22
4.3.3	IPv4 and IPv6 Support	22
4.4	Configuration	22
4.4.1	AE Title/Presentation Address Mapping	22
4.4.1.1	Local AE Titles	22
4.4.1.2	Remote AE Titles	23
4.4.2	Parameters	23
4.4.2.1	General Parameters	23
5	Media Interchange	24
6	Support of Character Sets	25
7	Security	26
8	Annexes	27
8.1	IOD Contents	27
8.1.1	Created SOP Instance(s)	27
8.1.1.1	Encapsulated PDF Information Object Definition	28
8.1.2	Usage of Attributes from Received IOD's	31
8.1.3	Attribute Mapping	31

8.1.4	Coerced/Modified Files	32
8.2	Data Dictionary of Private Attributes	32
8.3	Coded Terminology and Templates	32
8.4	Greyscale Image Consistency	32
8.5	Standard Extended / Specialized/ Private SOP Classes.....	32
8.6	Private Transfer Syntaxes	32

3 Introduction

3.1 Revision History

Document Version	Date	Author	Changes
1.0	2016-07-11	msmbe	Initial revision

3.2 Audience

This document is written for the people that need to understand how INTRABEAM 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 INTRABEAM 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 3-1 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
CONFIG	Configurable parameter
CZM	Carl Zeiss Meditec
DEF	Default Value
DICOM	Digital Imaging and Communications in Medicine
ELE	Explicit Little Endian
ILE	Implicit Little Endian
IM	Information Model
IOD	Information Object Definition
PL	Pick list
PLD	Pick list item details

PRQ	Patient Root Query
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

3.6 References

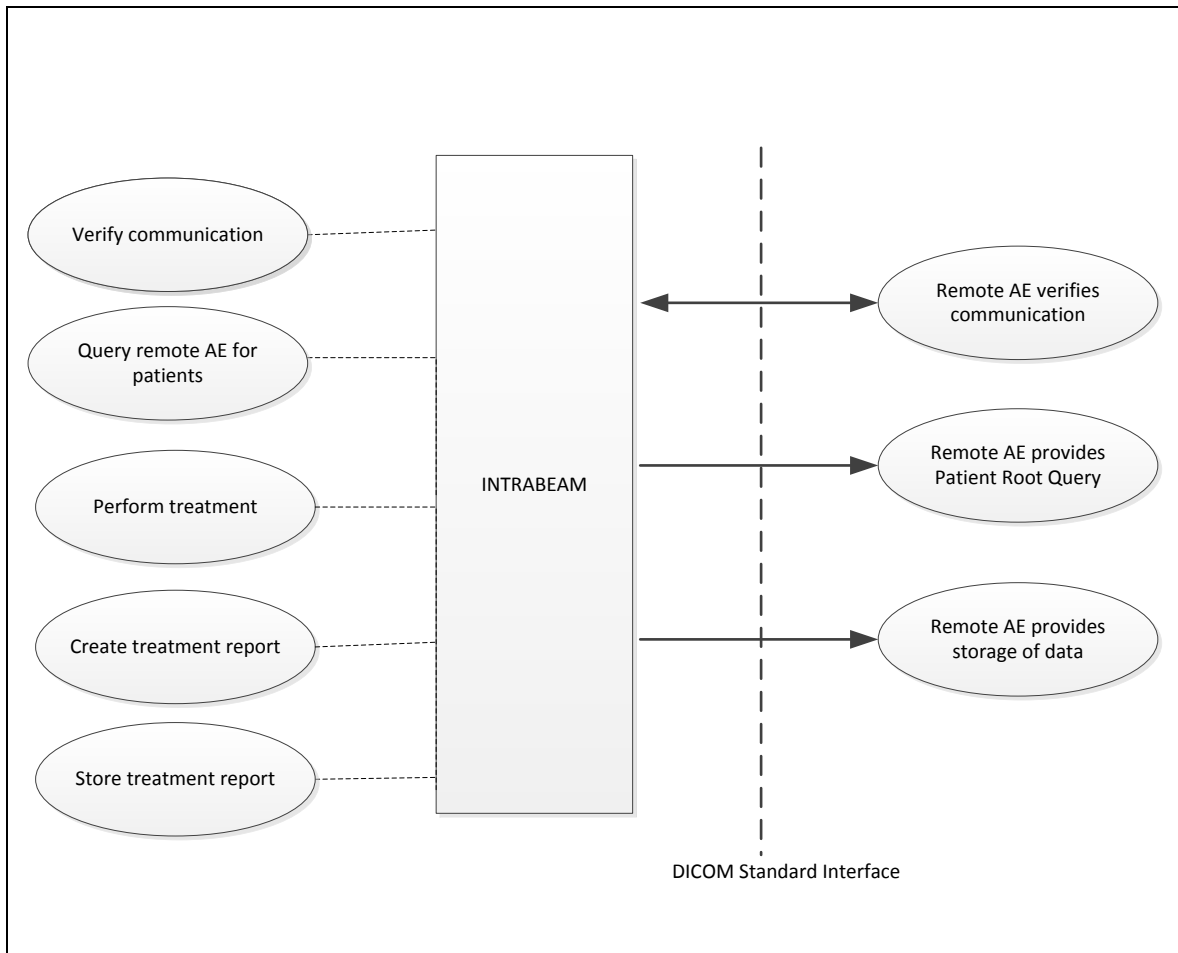
NEMA PS3 / ISO 12052, Digital Imaging and Communications in Medicine (DICOM) Standard, National Electrical Manufacturers Association, Rosslyn, VA, USA (available free at <http://medical.nema.org/>)

4 Networking

4.1 Implementation Model

4.1.1 Application Data Flow

Figure 4-1 INTRABEAM Application Software as Acquisition Modality



4.1.2 Functional Definition of AEs

4.1.2.1 Functional Definition of INTRABEAM

The INTRABEAM 600 is used for targeted radiotherapy treatment of a tumor or tumor bed in the form of a minimally invasive, intraoperative, interstitial, intracavitary technique or by means of contact in and on the entire body of a cancer patient.

The INTRABEAM Application Software allows to:

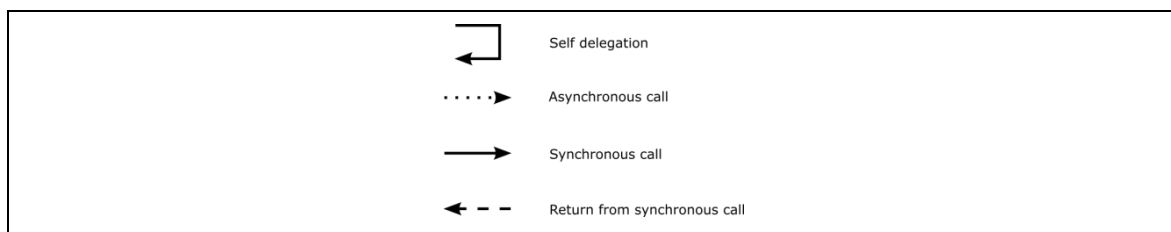
- query patient demographics
- export treatment reports

The INTRABEAM 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 INTRABEAM Software logs extensive information about the DICOM operations to its log file.

4.1.3 Sequencing of Real-World Activities

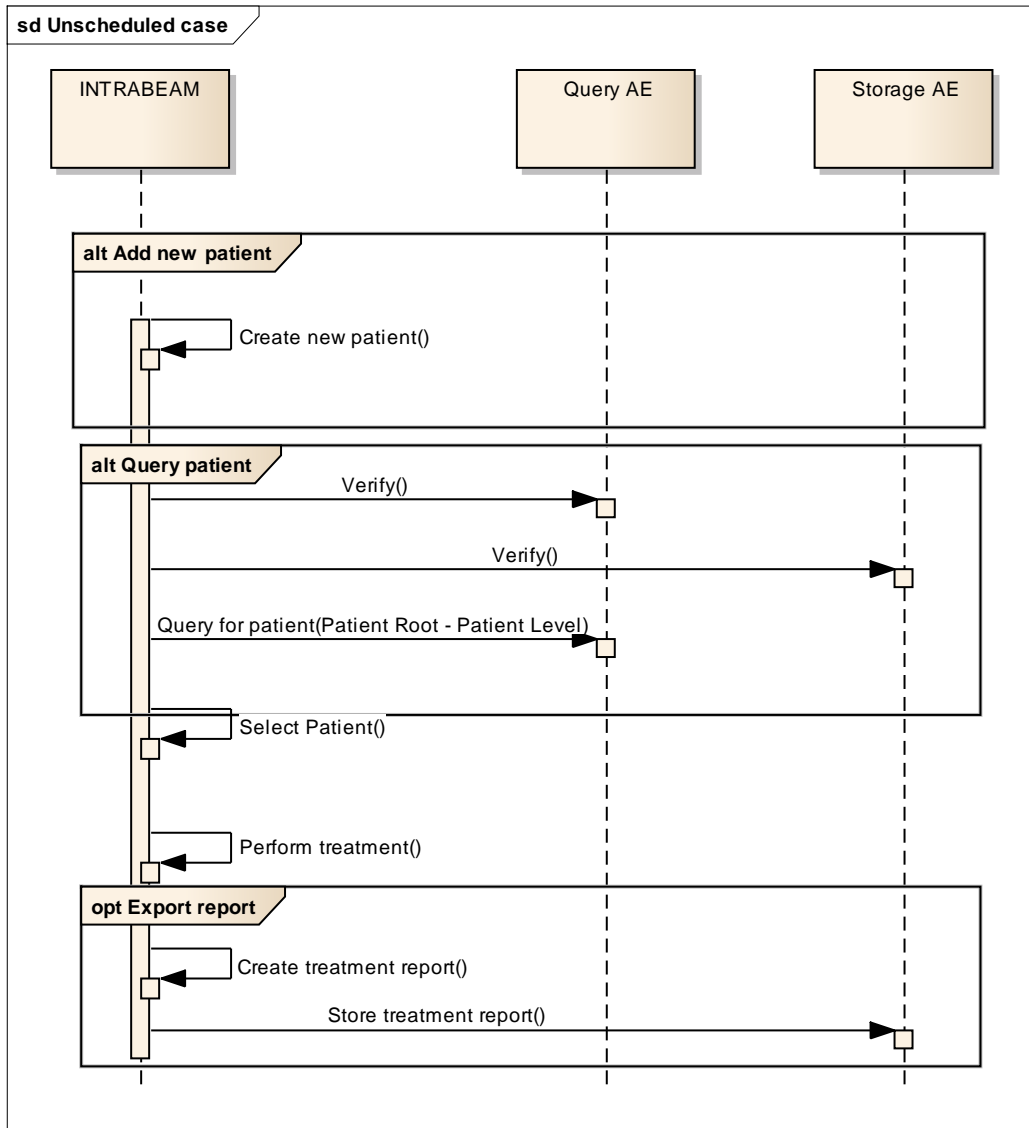
To realize the real world activities, the different entities work together. The sequence diagrams shall depict the intended workflow.



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

4.1.3.1 Acquisition Modality activities

Figure 4-2 Unscheduled Case



Query remote AE for patients

When the patient arrives at the device INTRABEAM, the operator can add manually a new patient or search for a patient at the remote AE. This can be done via the "Import Patient" screen providing search keys as described in 4.2.1.3.2.1.

Any matching results will be listed in the patient list.

This activity generates an unscheduled case.

The operator can select the patient for treatment and generate a treatment report afterwards.

Perform treatment

The operator can start "Perform treatment" at any time if no other activity is in progress and a valid system verification has been performed.

This activity has no direct relation to DICOM messaging.

The "Perform treatment" activity is started after selecting one item from the result lists of "Query remote AE for patients" or by entering new patient information in the "Patient" screen. Assigning a treatment prescription is a necessary prerequisite to treat the patient.

During this activity, the Application Software creates ongoing treatment data. Data created by this activity might become subject of the activity "Create treatment report".

Create treatment report

The operator can invoke the creation of a treatment report based on measured and prescribed data. This report can be saved in PDF format directly or archived as DICOM Encapsulated PDF IOD during activity "Store treatment to remote AE".

It is possible to create a full treatment report and a short form report. In case of any problem (communication problem with control console) a temporary full treatment report or a temporary short form report will be created.

Store treatment to remote AE

This activity can be triggered manually by the operator by selecting "Export report". The operator has the choice to export the full treatment report and/or the short form report. During this activity the treatment report is transferred to the configured Storage Provider.

4.2 AE Specifications

4.2.1 INTRABEAM AE Specification

4.2.1.1 SOP Classes

Table 4-1 SOP Classes for INTRABEAM AE

SOP Class Name	SOP Class UID	SCU	SCP
Verification	1.2.840.10008.1.1	Yes	Yes
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	No
Study Root Query/Retrieve Information Model – FIND ¹⁾	1.2.840.10008.5.1.4.1.2.2.1	Yes	No

¹⁾ The Study Root Query/Retrieve Information Model – FIND is negotiated but not used by the INTRABEAM application

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

4.2.1.2.3 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 Query/Retrieve - FIND

Table 4-3 Number of associations

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

4.2.1.2.4 Asynchronous Nature

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

4.2.1.2.5 Implementation Identifying Information

Table 4-4 DICOM implementation class and version

Implementation Class UID	1.2.276.0.75.2.5.20
Implementation Version Name	NIM-2.8.1

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 INTRABEAM Application Software proposes not only Verification SOP Class, but also all other SOP Classes as supported by the instrument's DICOM interface.

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

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

4.2.1.3.1.2 Proposed Presentation Contexts

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

- Verification with Transfer Syntax ILE as SCU

Table 4-5 Presentation Contexts proposed by the INTRABEAM AE

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Ext. Neg.
Name	UID 1.2.840.10008. ...	Name List	UID List 1.2.840.10008. ...		
Verification	1.1	ILE	1.2	BOTH	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
Study Root Query/Retrieve Information Model – FIND ¹⁾	1.2.840.10008.5.1.4.1.2.2.1	ILE	1.2	SCU	Yes

¹⁾ The Study Root Query/Retrieve Information Model – FIND is negotiated but not used by the INTRABEAM application

4.2.1.3.1.3 SOP Specific Conformance for Verification SOP Class

The INTRABEAM Application Software provides standard conformance.

4.2.1.3.2 Activity - Query remote AE for patients

Query is used to get patient information from a DICOM server.

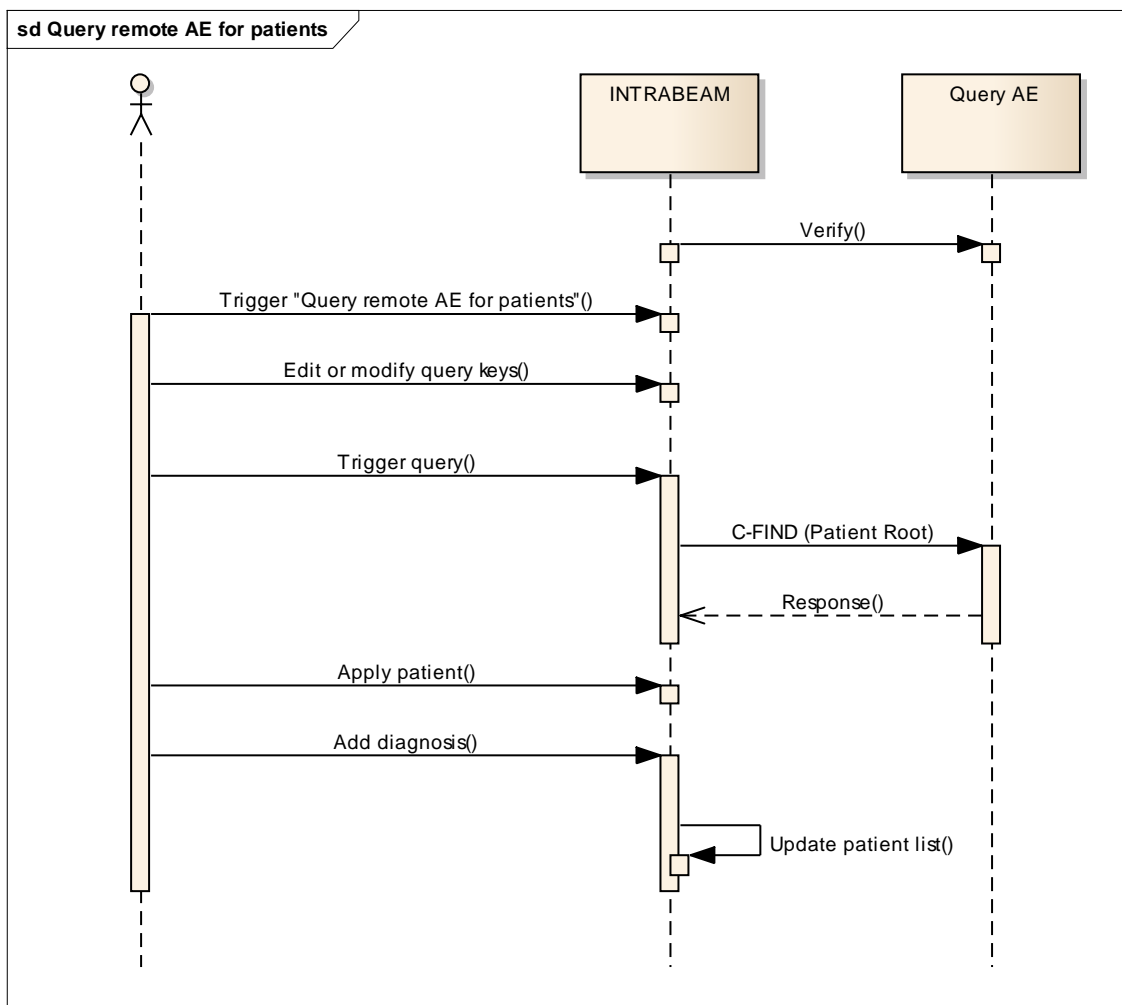
4.2.1.3.2.1 Description and Sequencing of Activities

The query request can be triggered via “Import patient” menu. The operator can specify the following search keys:

- “Patient Given Name”
- “Patient Last Name”
- “Patient ID”
- "Patient Birth Date"
- “Patient Sex”

After the desired patient was found on the query provider the operator can import the patient into the INTRABEAM device.

Figure 4-3 Query remote AE for patients



Trigger “Query remote AE for patients”

The activity “Query remote AE for patients” can be triggered by the operator by using the “Import Patient”.

Edit or modify query keys

The search screen offers a GUI for interactive query. The operator can change or fill in search criteria in the shown search fields.

- (0010,0010) Patient’s Name – Family Name
- (0010,0010) Patient’s Name – Given Name
- (0010,0020) Patient ID
- (0010,0030) Patient’s Birth Date (The Patient’s Birth Date has to be entered in the following format: YYYY-MM-DD)
- (0010,0040) Patient’s Sex

In case of patient’s name the user must explicitly use “*” for wild card matching. User must use “Sm*” to match “Smith”. “Sm” query will not match “Smith”.

In case the Patient Last Name, Patient Given Name or Patient ID search field is empty the software automatically inserts [*] wildcard in the respective DICOM attribute.

For more details on supported query keys see Table 4-9 Query key details.

Trigger query

The operator triggers the search after he or she filled in search criteria by clicking on the "Search button". The Application Software sends a Patient Root 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 result list is updated.

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.

Apply patient

The operator can verify the imported patient and add additional "Insurance ID" and "Other ID". After this step the patient can be applied.

Add diagnosis

To completely store the patient into the local database the operator has to fill in the diagnosis. The diagnosis has to be at least three characters long.

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

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

Table 4-6 Proposed Presentation Contexts by the INTRABEAM AE

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Ext. Neg.
Name	UID 1.2.840.10008. ...	Name List	UID List 1.2.840.10008. ...		
Verification	1.1	ILE	1.2	BOTH	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
Study Root Query/Retrieve IM – FIND ¹⁾	5.1.4.1.2.2.1	ILE	1.2	SCU	Yes

¹⁾ The Study Root Query/Retrieve Information Model – FIND is negotiated but not used by the INTRABEAM application

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

Table 4-7 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 and display user alert 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	xxxx	Log message and display user alert message.

Table 4-8 PATIENT level keys for the Patient Root Query/Retrieve Information Model (request and response)

Tag	Tag Name	Query Key	Imported	Displayed	Modifiable	SOP Instance
(0010,0010)	Patient's Name	X	X	X		X
(0010,0020)	Patient ID	X	X	X		X
(0010,0021)	Issuer of Patient ID					
(0010,0030)	Patient's Birth Date	X	X	X		X
(0010,0032)	Patient's Birth Time					
(0010,0040)	Patient's Sex	X	X	X		X
(0010,1000)	Other Patient IDs					

(0010,2160)	Ethnic Group					
(0010,4000)	Patient Comments					

Values of column “Query Key”:

X

The value is included in the query request if not empty. Empty attributes act as return keys.

Values of column “Imported”:

X

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

Values of column “Displayed”:

X

Values of this tag are instantly visible in the GUI.

Values of column “Modifiable”:

X

A value which has been imported to the application might be modified inside the application.

Values of column SOP Instance:

X

Values of marked tags will be stored in created SOP Instances.

Table 4-9 Query key details

Tag	Tag Name	Description
(0010,0010)	Patient's Name	The default value is empty string. If empty the software automatically adds “*”. Only family name and given name can be used as query keys. The operator can use '*' or '?' as wild cards. This is a DICOM Standard query key on Patient level.
(0010,0020)	Patient ID	The default value is empty string. If empty the software automatically adds “*”. 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. 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	The default value is empty string. The operator can select value from the drop

		down list (Value Representation CS). This is a DICOM Standard query key on Patient level.
--	--	--

4.2.1.3.3 Activity – Perform treatment

The operator can start “Perform treatment” at any time if no other activity is in progress and a valid system verification has performed.

This activity has no direct relation to DICOM messaging.

The Perform treatment activity is started after selecting one item from the result lists of "Query remote AE for patients" or by entering new patient information in the "Patient" screen. Assigning a treatment prescription is a necessary prerequisite to treat the patient.

During this activity, the Application Software creates ongoing treatment data. Data created by this activity might become subject of the activity "Create treatment report".

4.2.1.3.1 Activity – Create treatment report

The operator can invoke the creation of a treatment report based on measured and prescribed data. This report can be saved in PDF format directly or archived as DICOM Encapsulated PDF IOD during activity “Store treatment to remote AE”.

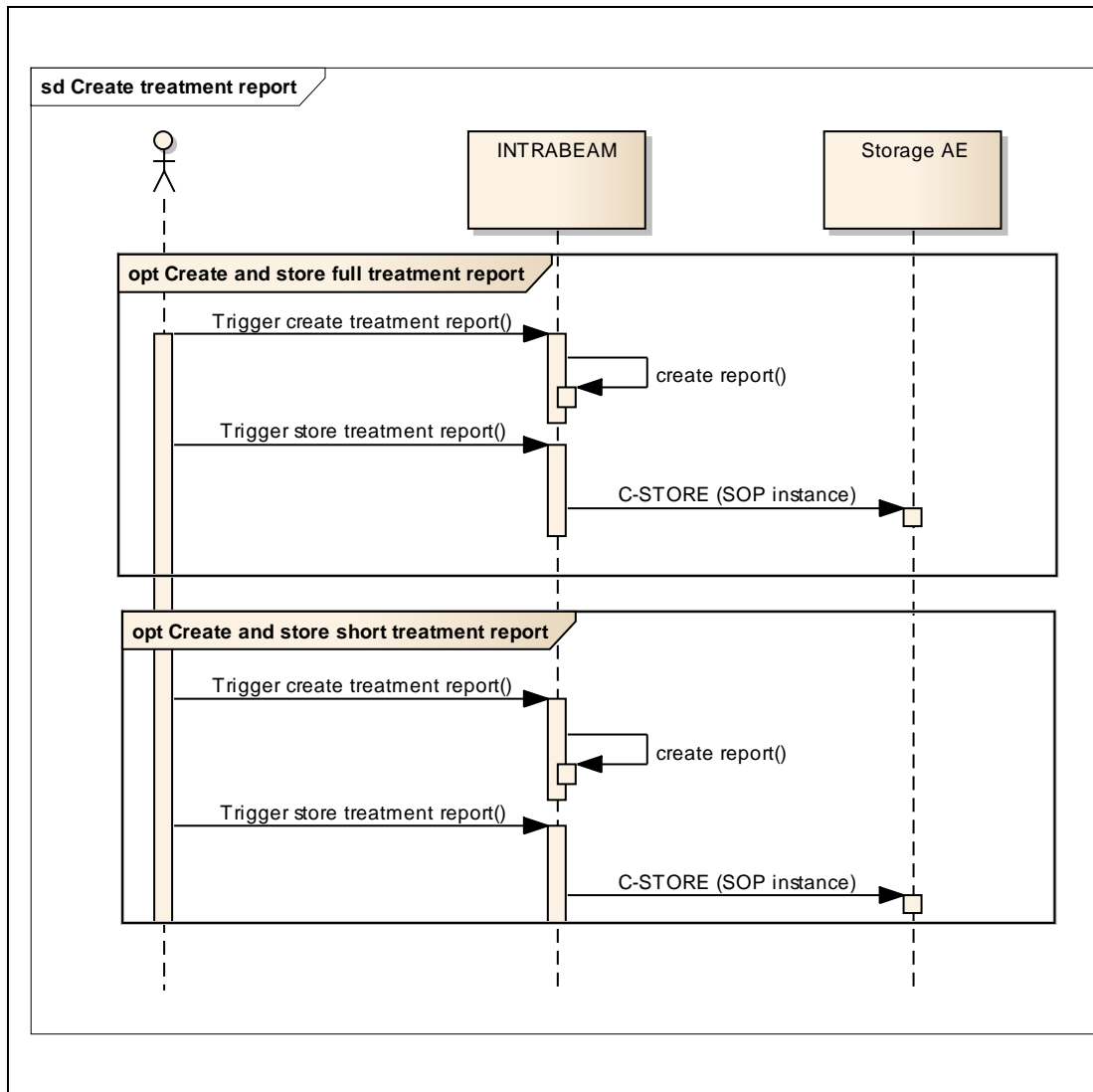
It is possible to create a full treatment report and a short form report. In case of any problem (communication problem with control console) a temporary full treatment report or a temporary short form report will be created.

4.2.1.3.2 Activity – Store treatment report

This activity is triggered manually by the operator by selecting “Export report”. The operator has the choice to export the full treatment report and/or the short form report. During this activity the treatment report is transferred to the configured Storage Provider.

4.2.1.3.2.1 Description and Sequencing of Activities

Figure 4-4 Archive data



Trigger “Store treatment report”

This activity can be triggered in the “Treatment review – Load patient” by clicking either on the “Single treatment” or “Short Form” button. “Single treatment” triggers a full treatment report. Once triggered, the application software transfers the selected treatment report to the configured Storage AE.

4.2.1.3.2.2

4.2.1.3.2.3 Proposed Presentation Contexts

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

- Encapsulated PDF with Transfer Syntax ELE (Transfer Syntax ILE as fallback) as SCU

Table 4-10 Presentation Contexts proposed by INTRABEAM AE

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Ext. Neg.
Name	UID 1.2.840.10008. ...	Name List	UID List 1.2.840.10008. ...		
Verification	1.1	ILE	1.2	BOTH	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
Study Root Query/Retrieve IM – FIND ¹⁾	5.1.4.1.2.2.1	ILE	1.2	SCU	Yes

¹⁾ The Study Root Query/Retrieve Information Model – FIND is negotiated but not used by the INTRABEAM application

4.2.1.3.2.4 SOP Specific Conformance for Storage SOP Classes

Table 4-11 Storage C-STORE Response Status Handling Behavior

Service Status	Further Meaning	Status Code	Behavior
Failure	Refused: Out of Resources	A700-A7FF	Log message and display user alert message.
Failure	Error: Data Set does not match SOP Class	A900-AFF	Log message and display user alert message.
Failure	Error: Cannot understand	C000-CFFF	Log message and display user alert message.
Failure	Refused: SOP class not supported	0122	Log message and 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	xxxx	Log message and display user alert message.

4.2.1.4 Association Acceptance Policy

4.2.1.4.1 Activity – Verify Communication

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

4.2.1.4.1.1 Description and Sequencing of Activities

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

4.2.1.4.1.2 Accepted Presentation Contexts

Table 4-12 Presentation Context accepted by the INTRABEAM AE

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Ext. Neg.
Name	UID	Name List	UID List		
Verification	1.2.840.10008. 1.1	ILE	1.2.840.10008. 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.

4.3 Network Interfaces

4.3.1 Physical Network Interface

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

4.3.2 Additional Protocols

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

4.3.3 IPv4 and IPv6 Support

The INTRABEAM supports IPv4 as well as IPv6 Addresses.

4.4 Configuration

Local application entity and remote application entity information can be configured with the Networking Configuration Tool. It is also possible to configure timeout, institution, and query item limit parameters via Application Software, configuration tool, and configuration file.

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 Tools -> Administration -> Select – Preferences -> DICOM 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

The mapping of external AE Titles to TCP/IP addresses and ports is configurable. The INTRABEAM 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 4-13 Configuration Parameters Table

Parameter	Configurable (Yes/No)	Default Value
General Parameters		
DIMSE RSP Timeout	Yes (10 – 60 sec.)	20 sec
Network Timeout	Yes (5-20 sec.)	20 sec.
Max. Association Idle Time	Yes (10 – 60 sec.)	30 sec
Network log level	Yes	Warning
(0008,0080) Institution Name	Yes	EMPTY
(0008,1010) Station Name	Yes	EMPTY
Patient Root Q/R SCU Parameters		
Maximum Query Responses (Patient Root Q/R IM)	Yes (1-999)	100
Unconstraint query	Yes	Yes (if query keys are left empty)
Extended Negotiation – relational query support negotiation (Patient Root Q/R IM)	No	No
Verification SCP 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).		

5 Media Interchange

Media Interchange is not scope of this document since Media Interchange is not supported by INTRABEAM Application Software.

6 Support of Character Sets

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

Table 6-1 Supported Character Set

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

7 Security

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

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

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

8 Annexes

8.1 IOD Contents

8.1.1 Created SOP Instance(s)

Abbreviations used for presence of values:

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:

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.

8.1.1.1 Encapsulated PDF Information Object Definition

IE	Module	Usage	Presence of Module
Patient			
	Patient	MANDATORY	ALWAYS
	ClinicalTrialSubject	OPTIONAL	NEVER
Study			
	GeneralStudy	MANDATORY	ALWAYS
	PatientStudy	OPTIONAL	NEVER
	ClinicalTrialStudy	OPTIONAL	NEVER
Series			
	EncapsulatedDocumentSeries	MANDATORY	ALWAYS
	ClinicalTrialSeries	OPTIONAL	NEVER
	CzmEncapsulatedPdfSeriesExtension	OPTIONAL	NEVER
Equipment			
	GeneralEquipment	MANDATORY	ALWAYS
	ScEquipment	MANDATORY	ALWAYS
EncapsulatedDocument			
	EncapsulatedDocument	MANDATORY	ALWAYS
	SopCommon	MANDATORY	ALWAYS
	CzmEncapsulatedPdfInstanceExtension	OPTIONAL	NEVER

Table 8-1 Encapsulated PDF IOD - Module "Patient"

Tag	Type	VR	Name	Description	PoV	Source
(0010,0010)	2	PN	Patient's Name	Patient's full name.	ALWAYS	PRQ, USER
(0010,0020)	2	LO	Patient ID	Primary hospital identification number or code for the patient.	ALWAYS	PRQ, USER
(0010,0030)	2	DA	Patient's Birth Date	Birth date of the patient.	ALWAYS	PRQ, USER
(0010,0040)	2	CS	Patient's Sex	Sex of the named patient. Enumerated Values: M = male F = female O = other	ALWAYS	PRQ, USER

Table 8-2 Encapsulated PDF IOD - Module "General Study"

Tag	Type	VR	Name	Description	PoV	Source
(0020,000D)	1	UI	Study Instance UID	Unique identifier for the Study. <i>INTRABEAM uses a constant prefix of "1.2.276.0.75.2.7.10.1.1." followed by a date/time stamp and machine specific</i>	ALWAYS	AUTO

				<i>identifier.</i>		
(0008,0020)	2	DA	Study Date	Date the Study started.	ALWAYS	AUTO
(0008,0030)	2	TM	Study Time	Time the Study started. <i>Time of first fraction treatment</i>	ALWAYS	AUTO
(0008,0090)	2	PN	Referring Physician's Name	Name of the patient's referring physician	EMPTY	AUTO
(0020,0010)	2	SH	Study ID	User or equipment generated Study identifier. <i>16 characters alpha-numeric value</i>	ALWAYS	AUTO
(0008,0050)	2	SH	Accession Number	A RIS generated number that identifies the order for the Study.	EMPTY	AUTO

Table 8-3 Encapsulated PDF IOD - Module "Encapsulated Document Series"

Tag	Type	VR	Name	Description	PoV	Source
(0008,0060)	1	CS	Modality	The modality appropriate for the encapsulated document. This Type definition shall override the definition in the SC Equipment Module. See section C.7.3.1.1.1 for Defined Terms. Note: SR may be an appropriate value for an Encapsulated CDA document with a structured XML Body. <i>Always "RTRECORD" (RT Treatment Record)</i>	ALWAYS	AUTO
(0020,000E)	1	UI	Series Instance UID	Unique identifier of the Series. <i>INTRABEAM uses a constant prefix of "1.2.276.0.75.2.7.10.1.2." followed by a date/time stamp and machine specific identifier.</i>	ALWAYS	AUTO
(0020,0011)	1	IS	Series Number	A number that identifies the Series.	ALWAYS	AUTO
(0008,103E)	3	LO	Series Description	Description of the Series <i>User entered Diagnosis.</i>	ALWAYS	AUTO

Table 8-4 Encapsulated PDF IOD - Module "General Equipment"

Tag	Type	VR	Name	Description	PoV	Source
(0008,0070)	2	LO	Manufacturer	Manufacturer of the equipment that produced the composite instances. <i>Always "Carl Zeiss Meditec"</i>	ALWAYS	AUTO
(0008,0080)	3	LO	Institution Name	Institution where the equipment that produced the composite instances is located. <i>User entered Institution Name</i>	ANAP	CONFIG
(0008,1010)	3	SH	Station Name	User defined name identifying the machine that produced the composite instances. <i>User entered Station Name</i>	ALWAYS	CONFIG
(0008,1090)	3	LO	Manufacturer's Model Name	Manufacturer's model name of the equipment that produced the composite instances. <i>Always "INTRABEAM"</i>	ALWAYS	AUTO

(0018,1000)	3	LO	Device Serial Number	Manufacturer's serial number of the equipment that produced the composite instances. Note: This identifier corresponds to the device that actually created the images, such as a CR plate reader or a CT console, and may not be sufficient to identify all of the equipment in the imaging chain, such as the generator or gantry or plate. <i>Always System S/N</i>	ALWAYS	AUTO
(0018,1020)	3	LO	Software Version(s)	Manufacturer's designation of software version of the equipment that produced the composite instances. See Section C.7.5.1.1.3. <i>"4.0.8" or higher version of "4.0.x.y"</i>	ALWAYS	AUTO

Table 8-5 Encapsulated PDF IOD - Module "SC Equipment"

Tag	Type	VR	Name	Description	PoV	Source
(0008,0064)	1	CS	Conversion Type	Describes the kind of image conversion. Defined Terms: DV = Digitized Video DI = Digital Interface DF = Digitized Film WSD = Workstation SD = Scanned Document SI = Scanned Image DRW = Drawing SYN = Synthetic Image <i>Always "SYN" for Synthetic Image.</i>	ALWAYS	AUTO

Table 8-6 Encapsulated PDF IOD - Module "Encapsulated Document"

Tag	Type	VR	Name	Description	PoV	Source
(0020,0013)	1	IS	Instance Number	A number that identifies this SOP Instance. The value shall be unique within a series. <i>There could be several types of report – full fraction report, short form fraction report, temporary full fraction report.</i> <i>The instance number is depending on the report type and can have the following values:</i> <i>1 (final full report)</i> <i>2 (short form report)</i> <i>3 (temporary full report)</i> <i>4 (temporary short report)</i>	ALWAYS	AUTO
(0008,0023)	2	DA	Content Date	The date the document content creation was started. <i>Date that the report file is generated.</i>	ALWAYS	AUTO
(0008,0033)	2	TM	Content Time	The time the document content creation was started. <i>Date that the report file is generated.</i>	ALWAYS	AUTO
(0008,002A)	2	DT	Acquisition Datetime	The date and time that the original generation of the data in the document started. <i>Treatment start date/time</i>	ALWAYS	AUTO
(0028,0301)	1	CS	Burned In Annotation	Indicates whether or not the encapsulated document contains sufficient burned in annotation to identify the patient and date the data was acquired. Enumerated Values: YES NO Identification of patient and date as text in an encapsulated document (e.g., in an XML attribute or element) is equivalent to "burned in annotation".	ALWAYS	AUTO

				A de-identified document may use the value NO. <i>Always "YES".</i>		
(0042,0010)	2	ST	Document Title	The title of the document. Note: In the case of a PDF encapsulated document, this may be the value of the "Title" entry in the "Document Information Directory" as encoded in the PDF data. <i>Always "Treatment Record"</i>	ALWAYS	AUTO
(0040,A043)	2	SQ	Concept Name Code Sequence	A coded representation of the document title. Zero or one item may be present. <i>Always zero items</i>	EMPTY	AUTO
(0042,0012)	1	LO	MIME Type of Encapsulated Document	The type of the encapsulated document stream described using the MIME Media Type (see RFC 2046). <i>Always "application/pdf"</i>	ALWAYS	AUTO
(0042,0011)	1	OB	Encapsulated Document	Encapsulated Document stream, containing a document encoded according to the MIME Type.	ALWAYS	AUTO

Table 8-7 Encapsulated PDF IOD - Module "SOP Common"

Tag	Type	VR	Name	Description	PoV	Source
(0008,0016)	1	UI	SOP Class UID	Uniquely identifies the SOP Class. See C.12.1.1.1 for further explanation. See also PS 3.4. <i>Always "1.2.840.10008.5.1.4.1.1.104.1" for Encapsulated PDF IOD.</i>	ALWAYS	AUTO
(0008,0018)	1	UI	SOP Instance UID	Uniquely identifies the SOP Instance. See C.12.1.1.1 for further explanation. See also PS 3.4. <i>INTRABEAM uses a constant prefix of "1.2.276.0.75.2.7.10.1.3." followed by a date/time stamp and machine specific identifier.</i>	ALWAYS	AUTO
(0008,0005)	1C	CS	Specific Character Set	Character Set that expands or replaces the Basic Graphic Set. Required if an expanded or replacement character set is used. See C.12.1.1.2 for Defined Terms. <i>Always "ISO_IR 192" for UTF-8 encoded Unicode.</i>	ALWAYS	AUTO
(0008,0012)	3	DA	Instance Creation Date	Date the SOP Instance was created. <i>Date that this message is sent</i>	ALWAYS	AUTO
(0008,0013)	3	TM	Instance Creation Time	Time the SOP Instance was created. <i>Time that this message is sent</i>	ALWAYS	AUTO

8.1.2 Usage of Attributes from Received IOD's

Not applicable.

8.1.3 Attribute Mapping

Not applicable.

8.1.4 Coerced/Modified Files

Not applicable.

8.2 Data Dictionary of Private Attributes

The Application Software AE does not define Private Attributes.

8.3 Coded Terminology and Templates

Not applicable.

8.4 Greyscale Image Consistency

Not applicable.

8.5 Standard Extended / Specialized/ Private SOP Classes

Not applicable.

8.6 Private Transfer Syntaxes

No Private Transfer Syntax is supported.

The product meets the essential requirements stipulated in Annex I of the 93/42/EEC Directive governing medical devices. The product is labeled with:



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