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| AUDIT TRAIL | | | | |
|-------------|--|-----------|--|--|
| Version | Change Description | Date | | |
| А | Initial version | Jan 2015 | | |
| В | Company name logo change to Brainlab | Feb 2016 | | |
| С | Periodic Review – Valid according to DICOM Standard 2019C | July 2019 | | |
| D | Periodic Review – Valid according to DICOM Standard 2020E | Feb 2021 | | |
| | | | | |

| Remarks: | | |
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| | Name | Position | Date | Signature |
|--------------|----------------|---------------------|------|-----------|
| Prepared By: | Roni Zenvirt | Software Specialist | | |
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| Approved By: | Yifat Mushkin | General Manager | | |

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1. Introduction

1.1. Overview

TraumaCad Mobile allows surgeons to evaluate digital images while performing various pre-operative surgical planning and evaluation of images. This software application enables surgeons to plan operations on screen, execute measurements, and facilitate the film-less orthopedic practice. The program features full PACS integration and an extensive, regularly updated library of digital templates from leading manufacturers. TraumaCad Mobile supports DICOM and enables the importing and exporting of image files from a central PACS system or Quentry.

TraumaCad Mobile has the following basic functions:

- <u>Select Source</u>: Upon successful login, the system will automatically detect for available sources (Quentry and Hospital PACS Systems) which are accessible to the user for Querying and Retrieving DICOM images from that source.
- <u>Search</u>: Search for patients and/or studies. The matching search results will show-up, the user can choose the series he wants to work on and select the patient image.
- <u>Calibrate</u>: Automatically or manually calibrate the image, define the image orientation and planning side.
- <u>Planning</u>: By selecting the appropriate templates and by using measurement tools the user can do his planning on the image.
- <u>Save</u>: Saving the planning back to the image source (Hospital PACS or Quentry).

1.2. Intended Audience

This conformance statement is intended for existing or potential users of TraumaCad Mobile, system administrators of institutions using TraumaCad Mobile, as well as developers of systems wishing to communicate with TraumaCad Mobile using the DICOM protocol.

It is assumed that the reader of this Conformance Statement is familiar with the DICOM standard.

1.3. References

Digital Imaging and Communications in Medicine (DICOM) standard by the National Electrical Manufacturers Association (NEMA).

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1.4. **Definitions**

| AE | DICOM Application Entity |
|--------|---|
| AET | Application Entity Title |
| DICOM | Digital Imaging and Communications in Medicine |
| FSC | File Set Creator |
| IOD | DICOM Information Object Definition |
| PDU | Protocol Data Unit |
| SCP | Service Class Provider |
| SCU | Service Class User |
| SOP | Service Object Pair |
| TCP/IP | Transmission Control Protocol/Internet Protocol |
| UID | Unique Identifier |
| | |

Quentry Gateway Service to upload and to download data to and from Quentry

1.5. Important Note

The fact that equipment is compatible according to this Conformance Statement, does not in itself guarantee interoperability. Though compatibility with the DICOM standard has been thoroughly tested, interoperability conflicts may arise when trying to use Quentry Gateway with other devices. Interoperability does not lie within the scope of the DICOM standard.

TraumaCad Mobile uses Quentry Gateway for all DICOM communication; it allows download of data via DICOM Query/Retrieve and storage of DICOM data. It provides standard conformance to the SOP Classes as described below.

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2. Implementation Model

2.1. Application Data Flow Diagram

2.1.1. Query

The user may initiate a DICOM C-FIND operation as shown in Figure 2.1-1.

This operation may be repeated as necessary to query recursively down to study, series or image level.



2.1.2. Retrieve

Following the above procedure, the user may select a displayed study, series or image entry to initiate a C- MOVE operation, as in Figure 2.1-2. For this purpose, Quentry Gateway acts as an SCP of the C-STORE service class.





2.1.3. Commit

Once required operations have been completed, the user may press the Save button to initiate a C-STORE of the generated secondary capture image to a remote SCP, as shown in Figure 2.1-3.





2.2. Functional Definitions of Application Entity (AE's)

TraumaCad Mobile using Quentry Gateway is capable of receiving images through standard DICOM Query/Retrieve services.

After processing, calibration and other operations selected by the user, a new secondary capture image is generated, which may be sent to a C-STORE SCP.

2.3. Sequencing of Real-World Activities

Images must be acquired either through DICOM Query/Retrieve before they can be sent to the remote storage SCP. TraumaCad Mobile using Quentry Gateway only acts as a C-STORE SCP for the duration of an outgoing C-MOVE request.

3. AE Specifications

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Although multiple instances of TraumaCad Mobile may be running simultaneously, each represents the same Application Entity.

3.1. TraumaCad Mobile Specification

TraumaCad Mobile using Quentry Gateway provides Standard Conformance to the following DICOM V3.0 SOP Classes as an SCU:

| SOP Class Name | SOP Class UID |
|--|-----------------------------|
| Verification SOP class | 1.2.840.10008.1.1 |
| Secondary Capture Image Storage | 1.2.840.10008.5.1.4.1.1.7 |
| Study Root Query/Retrieve Information Model – FIND | 1.2.840.10008.5.1.4.1.2.2.1 |
| Study Root Query/Retrieve Information Model – MOVE | 1.2.840.10008.5.1.4.1.2.2.2 |
| Digital X-Ray Image Storage – For Presentation | 1.2.840.10008.5.1.4.1.1.1.1 |
| Computed Radiography Image Storage | 1.2.840.10008.5.1.4.1.1.1 |

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And to the following DICOM V3.0 SOP Classes as an SCP:

| SOP Class Name | SOP Class LIID |
|--|-----------------------------|
| | 301 61033 010 |
| Verification SOP class | 1.2.840.10008.1.1 |
| Computed Radiography Image Storage | 1.2.840.10008.5.1.4.1.1.1 |
| Digital X-Ray Image Storage – For Presentation | 1.2.840.10008.5.1.4.1.1.1.1 |
| Secondary Capture Image Storage | 1.2.840.10008.5.1.4.1.1.7 |

Note: SCP functionality is only present for the duration of an outgoing C-MOVE operation.

3.1.1 Association Establishment Policies

3.1.1.1. General

TraumaCad Mobile using Quentry Gateway will attempt to establish associations whenever it is invoked with appropriate parameters. Each SOP instance is transferred in a separate association.

TraumaCad Mobile using Quentry Gateway listens for incoming associations when a C-MOVE operation is initiated, and responds as described elsewhere in this document. The maximum PDU size which TraumaCad Mobile Gateway will use is 64K.

3.1.1.2. Number of Associations

There are no inherent limitations on the total number of simultaneous associations which the Application Entity represented by TraumaCad Mobile using Quentry Gateway can maintain.

3.1.1.3. Asynchronous Nature

TraumaCad Mobile using Quentry Gateway will not perform asynchronous operations window negotiation.

3.1.1.4. Implementation Identifying Information

TraumaCad Mobile using Quentry Gateway will provide an Implementation Class UID of "1.2.276.0.20.4.1.4.3.x.x.x.". TraumaCad will provide an implementation version name of "QuentryGateway". The 4 last components represented by x.x.x.x in the above identifying strings changes in different versions of the program, to reflect the current version number.

3.1.2. Association Initiation by Real-World Activity

TraumaCad Mobile using Quentry Gateway attempts to initiate new associations as documented in section 2.1 above

| 3.1.2.1.1. | Associated Real-World Activity |
|------------|--|
| | The User initiates the Query Command |
| 3.1.2.1.2. | Proposed Presentation Contexts |
| | TraumaCad Mobile using Quentry Gateway will only propose a single |
| | Presentation Context in each association, and the proposed Transfer Syntaxes |
| | will be as shown in Table 3.1.2-1 |

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 Table 3.1.2-1: Proposed Presentation Contexts for Application Entity TraumaCad Mobile and Real-World

 Activity Query

| Abstract Syntax | UID | | Transfer Synt | tax UID | Role | Extended |
|---|-----------------------------|---|---|-------------------------|------|-------------|
| Name | | | Name List | | List | Negotiation |
| Study Root Query/Retrieve Information | 1.2.840.10008.5.1.4.1.2.2.1 | | Implicit VR Little Endian | 1.2.840.10008.1.2 | SCU | None |
| Model – FIND | | | Explicit VR Little Endian | 1.2.840.10008.1.2. 1 | SCU | None |
| 3.1.2.2. | Retrieve | | | | | |
| | 3.1.2.2.1. | Associated Real-World Activity The User selects a study, series or image in the query results. | | | | |
| | 3.1.2.2.2. | Proposed Pr TraumaCad Presentation will be as sh | osed Presentation Contexts naCad Mobile using Quentry Gateway will only propose a single entation Context in each association, and the proposed Transfer Syntaxe are as shown in Table 3.1.2-2 | | | |

| Table 3.1.2-2: Proposed Presentation Contexts for Application Entity TraumaCad Mobile and Real-World Activit | ÿ |
|--|---|
| Retrieve | |

| Abstract Syntax Name | UID | Transfer Synt Name List | tax UID | Role List | Extended Negotiation |
|---|-----------------------------|---------------------------------|-------------------------|--------------|-------------------------|
| Study Root Query/Retrieve Information | 1.2.840.10008.5.1.4.1.2.2.2 | Implicit VR Little Endian | 1.2.840.10008.1.2 | SCU | None |
| Model – MOVE | | Explicit VR Little Endian | 1.2.840.10008.1.2. 1 | SCU | None |
| 3.1.2.3. | Commit | | | | |

| 3.1.2.3.1. | Associated Real-World Activity |
|------------|---|
| | The User, having created a new image with templating information on it, |
| | selects the Commit button |
| 3.1.2.3.2. | Proposed Presentation Contexts |
| | TraumaCad Mobile using Quentry Gateway will only propose a single |

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Presentation Context in each association, and the proposed Transfer Syntaxes will be as shown in Table 3.1.2-3

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| Table 3.1.2-3: Proposed Presentation Contexts for Application Entity TraumaCad Mobile and Real-World Activity |
|---|
| Commit |

| Abstract Syntax | | Transfer Syntax | חווח | Role | Extended |
|---|---------------------------------|--|------------------------|------|-------------|
| Name | 010 | Name List | | List | Negotiation |
| Secondary 1.2.840.10008.5.1.4.1.1.7 Capture Image Storage | Explicit VR Little Endian | 1.2.840.10008.1.2.1 | SCU | None | |
| | | Implicit VR Little Endian | 1.2.840.10008.1.2 | SCU | None |
| | | JPEG Lossless | 1.2.840.10008.1.2.4.57 | SCU | None |
| | | JPEG Lossless First Order | 1.2.840.10008.1.2.4.70 | SCU | None |
| | | JPEG 2000 Image Compression (Lossless Only) | 1.2.840.10008.1.2.4.90 | SCU | None |
| | RLE Lossless | 1.2.840.10008.1.2.5 | SCU | None | |
| | | JPEG Extended | 1.2.840.10008.1.2.4.51 | SCU | None |
| | | JPEG 2000 Image Compression | 1.2.840.10008.1.2.4.91 | SCU | None |

3.1.3. Association Acceptance Policy

TraumaCad Mobile using Quentry Gateway accepts any associations which are directed to it during the course of an outgoing C-MOVE operation, as initiated via the Retrieve real-world activity

3.1.3.1. Retrieve

Images are accepted when they have been requested using C-MOVE.

| 3.1.3.1.1. | Associated Real-World Activity |
|------------|--|
| | The User double-clicks on a study, series or image in the query results. |
| 3.1.3.1.2. | Presentation Context Table |

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| Table 3.1.3-1: Acceptable Presentation Contexts for Application Entity TraumaCad Mobile and Real-World Activ | ity |
|--|-----|
| Retrieve | |

| Abstract Syntax Name | UID | Transfer Syntax Name List | UID | Role List | Extended Negotiation |
|---|------------------------------|--|------------------------|--------------|-------------------------|
| See Note 1See Note 1 andand TableTable 3.1.3-23.1.3-2 | Explicit VR Little Endian | 1.2.840.10008.1.2.1 | SCP | None | |
| | | Implicit VR Little Endian | 1.2.840.10008.1.2 | SCP | None |
| | | JPEG Lossless | 1.2.840.10008.1.2.4.57 | SCP | None |
| | | JPEG Lossless First Order | 1.2.840.10008.1.2.4.70 | SCP | None |
| | | JPEG 2000 Image Compression (Lossless Only) | 1.2.840.10008.1.2.4.90 | SCP | None |
| | RLE Lossless | 1.2.840.10008.1.2.5 | SCP | None | |
| | | JPEG Extended | 1.2.840.10008.1.2.4.51 | SCP | None |
| | | JPEG 2000 Image Compression | 1.2.840.10008.1.2.4.91 | SCP | None |

Note 1: The same transfer syntaxes are acceptable for all acceptable Abstract Syntaxes, which are as follows:

 Table 3.1.3-2: Acceptable Abstract Syntaxes for Application Entity TraumaCad Mobile and Real-World Activity

 Retrieve

| Abstract Syntax Name | | Abstract Syntax UID | |
|--------------------------------------|---|--|-------------------|
| Verification SOP class | | 1.2.840.10008.1.1 | |
| Computed Radiography Image Stora | ige | 1.2.840.10008.5.1.4.1.1.1 | |
| Digital X-Ray Image Storage – For Pr | esentation | 1.2.840.10008.5.1.4.1.1.1.1 | |
| Secondary Capture Image Storage | | 1.2.840.10008.5.1.4.1.1.7 | |
| 3.1.3.1.3. | SOP Specific Conformation | ance | |
| | All SOP classes are ha | ndled the same in TraumaCad Mobile, e | xcept that, |
| | unlike the other SOP classes, the Verification SOP class does not cause | | |
| | images to be acquired and displayed to the user. | | |
| 3.1.3.1.4. | Presentation Context | Acceptance Criteria | |
| | All Presentation Conte | exts using an abstract syntax listed in Ta | ble 3.1.3-2 above |

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shall be accepted, provided that one or more transfer syntaxes are acceptable. There is no limit to the number of presentation contexts accepted, either in total or for a single abstract syntax.

3.1.3.1.5. Transfer Syntax Selection Policies

For each presentation context with an acceptable abstract syntax, the transfer syntax selected shall be the first listed in Table 3.1.3-1 which is also present in the offered list. Note that the order in which the Transfer Syntaxes are offered is therefore irrelevant to the selection process.

4. Communication Profiles

4.1. Supported Communications Stacks (Part 8)

TraumaCad Mobile using Quentry Gateway provides DICOM V3.0 TCP/IP Network Communication Support as defined in PS 3.8.

4.2. TCP/IP Stack

TraumaCad Mobile using Quentry Gateway inherits its TCP/IP stack from the Windows system upon which it executes.

4.3. Physical Media Support

TraumaCad Mobile using Quentry Gateway is indifferent to the physical medium over which TCP/IP executes; it inherits this from the Windows system upon which it executes.

5. Extensions/Specializations/Privatizations

5.1. Standard Extended/Specialized/Private SOPs

TraumaCad Mobile writes the following private:

| Private creator code | (7f05,0010) | Set to <company name=""></company> |
|----------------------|-------------|------------------------------------|
| Various private tags | (7f05,10xx) | |

6. Configuration

The list of Remote Applications from which the user may initiate Query and retrieve operations is configured through Gateway.

It does not allow configuration of C-MOVE destinations. A C-MOVE request will always return the response to the IP of the caller and to the same port that Quentry Gateway is listening on.

7. Support of Extended Character Sets

TraumaCad Mobile using Quentry Gateway preserves any present extended character sets in any DICOM instances received.

DICOM Instances created by TraumaCad Mobile may contain the extended character set ISO_IR 192 (UTF8).

8. Codes and Controlled Terminology

No codes or controlled terminology are used by TraumaCad Mobile itself, though such codes present in any DICOM instances received are preserved.