AUDIT TRAIL			
Version	**Change Description**	**Date**	**Approved By**
A	Initial version		Dave Harvey
B	Further details	April 6, 2010	Roni Zenvirt
C	Updated Tables	April 19, 2010	Roni Zenvirt
D	Update company name to Brainlab Ltd. Added TraumaCad Mobile (TCM)	Feb 12, 2016	Yifat Mushkin
E	Separate TCM from doc	Feb 18, 2016	Yifat Mushkin
F	Periodic Review – Valid according to DICOM Standard 2019C	July 2019	Yifat Mushkin
G	Periodic Review – Valid according to DICOM Standard 2020E	Feb 2021	Yifat Mushkin

Remarks:

	Name	**Position**	**Date**	**Signature**
Prepared By:	Roni Zenvirt	Software Specialist		
Reviewed By:	Yael Guttentag	QM & RA Sr. Manager		
Approved By:	Yifat Mushkin	General Manager		

TraumaCad™

Table of Contents

1. Introduction

1.1. Overview

TraumaCad is a Pre-Operative Templating and Planning Software for Orthopaedic Procedures.

TraumaCad has the following basic functions:

1.1.1. Import and Calibrate

TraumaCad enables import and export of any PACS file (X-ray, CT) from the local workstation or central PACS system. JPG, scanner and digital camera images also can be imported. Automatic or manual calibration must be done on the image.

1.1.2. Measure

In manual, semi-automatic or automatic mode, TraumaCad provides a series of accurate anatomical measurements. In addition to length, width and diameter, it measures leg length discrepancy, Cobb angle, mal-alignment tests, and more.

1.1.3. Apply Templates

By automatically providing calibrated on-screen implant images, TraumaCad dramatically expedites the important evaluation and selection process. Several scenarios can be recorded and compared, to find the optimal implant. Once a template is chosen, it can be easily scaled and manipulated.

1.1.4. Save and Archive

Once the planning of a procedure is completed, a full report is saved and sent to the patient's PACS file, ensuring convenient access.

1.2. Intended Audience

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

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

TraumaCad™

TCP/IP	Transmission Control Protocol/Internet Protocol
UID	Unique Identifier

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 TraumaCad with other devices. Interoperability does not lie within the scope of the DICOM standard.

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.
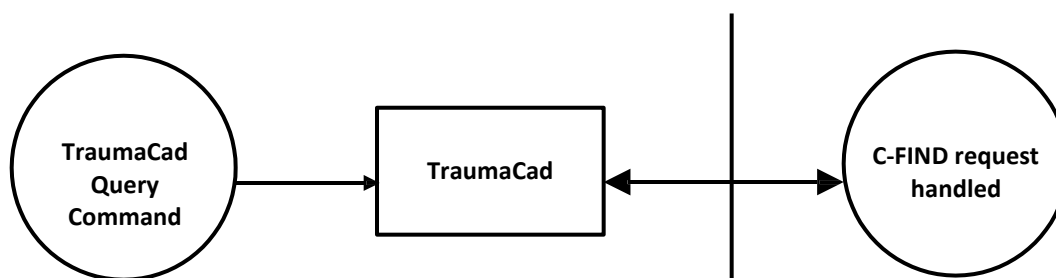

Figure 2.1-1

2.1.2. Retrieve

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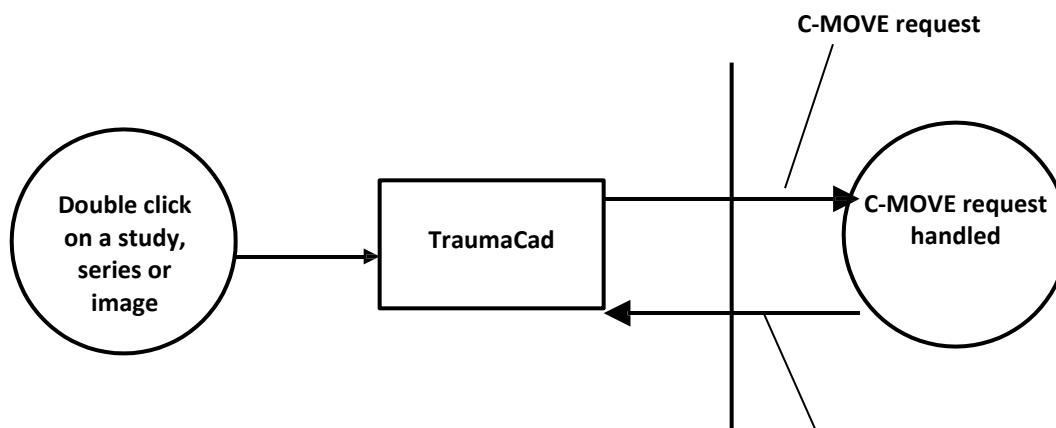

Figure 2.1-2   **C-STORE operation**

2.1.3. Commit

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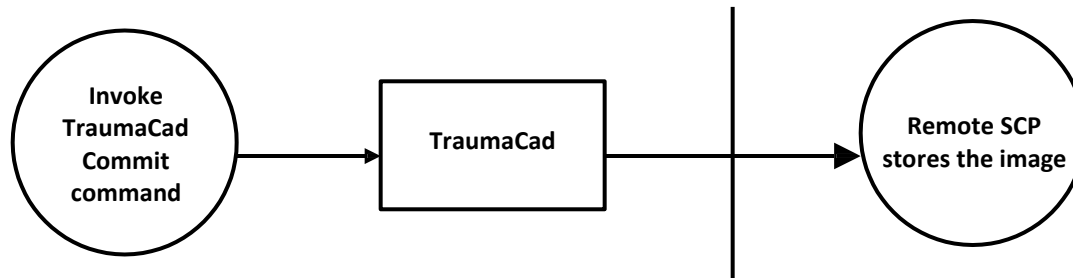

Figure 2.1-3

2.2. Invocation

TraumaCad is a stand-alone Windows application and is started explicitly by the user

2.3. Functional Definitions of AE's

TraumaCad is capable of receiving images through standard DICOM Query/Retrieve services, and can also create new DICOM instances by importing external non-DICOM formats such as JPEG or directly from image acquisition devices such as scanners or cameras. 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.

2.4. Sequencing of Real-World Activities

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

3. AE Specifications

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

3.1. TraumaCad Specification

TraumaCad 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
CT Image Storage	1.2.840.10008.5.1.4.1.1.2

TraumaCad™

Enhanced CT Image Storage	1.2.840.10008.5.1.4.1.1.2.1
MR Image Storage	1.2.840.10008.5.1.4.1.1.4
Enhanced MR Image Storage	1.2.840.10008.5.1.4.1.1.4.1

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

SOP Class Name	SOP Class UID
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
CT Image Storage	1.2.840.10008.5.1.4.1.1.2
Enhanced CT Image Storage	1.2.840.10008.5.1.4.1.1.2.1
MR Image Storage	1.2.840.10008.5.1.4.1.1.4
Enhanced MR Image Storage	1.2.840.10008.5.1.4.1.1.4.1

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

TraumaCad listen for incoming associations when a C-MOVE operation is initiated, and responds as described elsewhere in this document.

The maximum PDU size which TraumaCad 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 can maintain.

3.1.1.3. Asynchronous Nature

TraumaCad will not perform asynchronous operations window negotiation.

3.1.1.4. Implementation Identifying Information

TraumaCad will provide an Implementation Class UID of "1.2.826.0.1.3680043.1.2.100.xxx".

TraumaCad will provide an implementation version name of "DicomObjects.NET".

The 3 digit component represented by xxx in the above identifying strings may change in different
versions of the program, to reflect the current version number.

3.1.2. Association Initiation by Real-World Activity

TraumaCad attempts to initiate new associations as documented in section 2.1 above

3.1.2.1.　Query

3.1.2.1.1.　Associated Real-World Activity

The User initiates the Query Command

3.1.2.1.2.　Proposed Presentation Contexts

TraumaCad 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

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

Abstract Syntax		Transfer Syntax		Role	Extended
Name	UID	Name List	UID	List	Negotiation
Study Root Query/Retrieve Information Model – FIND	1.2.840.10008.5.1.4.1.2.2.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCU	None
		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 double-clicks on a study, series or image in the query results.

3.1.2.2.2.　Proposed Presentation Contexts

TraumaCad will only propose a single Presentation Context in each association, and the proposed Transfer Syntaxes will be as shown in Table 3.1.2-2

Table 3.1.2-2: Proposed Presentation Contexts for Application Entity TraumaCad and Real-World Activity Retrieve

Abstract Syntax		Transfer Syntax		Role	Extended
Name	UID	Name List	UID	List	Negotiation
Study Root Query/Retrieve Information Model – MOVE	1.2.840.10008.5.1.4.1.2.2.2	Implicit VR Little Endian	1.2.840.10008.1.2	SCU	None
		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 will only propose a single Presentation Context in each association, and the proposed Transfer Syntaxes will be as shown in Table 3.1.2-3

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

Abstract Syntax		Transfer Syntax		Role	Extended
Name	UID	Name List	UID	List	Negotiation
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7	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 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

TraumaCad™

Table 3.1.3-1: Acceptable Presentation Contexts for Application Entity TraumaCad and Real-World Activity Retrieve

Abstract Syntax		Transfer Syntax		Role	Extended
Name	UID	Name List	UID	List	Negotiation
See Note 1 and Table 3.1.3-2	See Note 1 and Table 3.1.3-2	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 and Real-World Activity Retrieve

Abstract Syntax Name	Abstract Syntax UID
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

3.1.3.1.3. SOP Specific Conformance

All SOP classes are handled the same in TraumaCad, except 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 Contexts using an abstract syntax listed in Table 3.1.3-2 above

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 provides DICOM V3.0 TCP/IP Network Communication Support as defined in PS 3.8.

4.2. TCP/IP Stack

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

4.3. Physical Media Support

TraumaCad 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 writes the following private:

Private creator code	(7f05,0010)	Set to <company name>
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 TraumaCad's graphical User Interface.

7. Support of Extended Character Sets

TraumaCad preserves any present extended character sets in any DICOM instances received.

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

8. Codes and Controlled Terminology

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

▶TraumaCad™