

# Terarecon Aorta.CT DICOM Conformance Statement

Version 1.0.0

English





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### **General Description**

TeraRecon Aorta.CT is a software as a medical device (SaMD) deployed as a containerized application (e.g., a Docker container) that may run on off-the-shelf hardware or on a cloud platform. The device inputs are CT Angiography images acquired via DICOM compliant imaging devices. The device outputs are DICOM result files which may be exported for use by other DICOM-compliant systems. The device does not alter the original input data and does not provide a diagnosis.

TeraRecon Aorta.CT provides an automatic segmentation result of the aorta which allows visualization of the lumen and outer wall. Additionally, the device identifies important landmarks from Aorta such as important branches of aorta.

The results of TeraRecon Aorta.CT are intended to be used in conjunction with other patient information by trained professionals who are responsible for making all patient management decisions per the standard of care.

TeraRecon Aorta.CT v1.0.0 is intended to be a containerized standalone medical device that runs on a standard off-the-shelf computer or a virtual platform, including VMware, and can be used to perform processing of images. Data and images are acquired through DICOM compliant imaging devices. DICOM results may be exported, combined with and/or utilized by other DICOM- compliant systems and results.

The results of the TeraRecon Aorta.CT Algorithm can be delivered to the end-user through image viewers such as TeraRecon's Intuition system, TeraRecon's Eureka Clinical AI, or other image viewing systems like PACS that can support DICOM results generated by TeraRecon Aorta.CT.

As such, TeraRecon Aorta.CT communicates with other machines with file-based communication using DICOM 3.0 The purpose of this document is to describe the conformance of the device to the DICOM 3.0 Standard as described by the NEMA in the edition 2022d. Thus, this DICOM conformance statement is applicable to TeraRecon Aorta.CT.

TeraRecon Aorta.CT supports following listed SOP class:

SOP Class Name	SOP Class UID
CT Image Storage	1.2.840.10008.5.1.4.1.1.2
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7
Segmentation Storage	1.2.840.10008.5.1.4.1.1.66.4

### How to Use this Guide

It is recommended that you read all content to gain a complete understanding of how the Platform communicates with other 3rd party hospital systems, such as PACS, on the network using DICOM 3.0. Use the table of contents to navigate to the desired information.

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# **Chapter 1 Introduction**

#### **Revision History**

Following table provides revision history of this DICOM conformance statement:

Revision #	Description	Date of Release
1	Initial version for TeraRecon Aorta.CT	01-Mar-2023

#### **Intended Audience**

This DICOM conformance statement is intended for following audiences:

- Hospital staff or Customer
- System integrator of medical equipment
- DICOM Software engineer or designer
- Marketing or Sales personal with DICOM knowledge

#### **First-level Validation**

DICOM, by itself, does not guarantee interoperability. However, the Conformance Statement facilitates a first-level validation for interoperability between different applications supporting the same DICOM functionality.

This Conformance Statement is not intended to replace validation with other DICOM equipment to ensure proper exchange of information intended.

The scope of this Conformance Statement is to facilitate communication with other vendors' Medical equipment. The Conformance Statement should be read and understood in conjunction with the DICOM Standard [DICOM]. However, by itself it is not guaranteed to ensure the desired interoperability and a successful interconnectivity.

The user should be aware of the following issues:

- Test procedures should be defined to validate the desired level of connectivity.
- The DICOM standard will evolve to meet the users' future requirements.

### Abbreviations, Terms, and Definitions

Table 1.2 lists the definitions, terms, and abbreviations for the DICOM standard.

Table 1.2: Abbreviations,	<b>Terms, and Definitions</b>
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Abbreviations, Terms	Definition
FSC	File-Set Creator
IOD	Information Object Definition
ISO	International Standard Organization
SOP	Service-Object Pair
UID	Unique Key Attribute

Note: Reference: [DICOM] Digital Imaging and Communications in Medicine (DICOM), NEMA PS 3.1-3.20, 2022d

# **Chapter 2 Networking**

TeraRecon Aorta.CT does not provide any network base communication. This section does not apply to TeraRecon Aorta.CT.

## **Chapter 3 Media Interchange**

The following diagram provides information about TeraRecon Aorta.CT operation:



For application profile class STD-GEN, the following storage SOP classes are supported:

SOP Class Name	SOP Class UID	Function
CT Image Storage	1.2.840.10008.5.1.4.1.1.2	Read Images
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7	Write Images
Segmentation Storage	1.2.840.10008.5.1.4.1.1.66.4	Write Images

The following transfer syntaxes listed below are supported for inputs reading:

Transfer Syntax Table		
Syntax List Name	Transfer Syntax	
Uncompressed Syntax List	Implicit VR Little Endian Explicit VR Little Endian	1.2.840.10008.1.2 1.2.840.10008.1.2.1

The following transfer syntax is supported for outputs writing:

Transfer Syntax Table		
Syntax List Name	Transfer Syntax	
Uncompressed Syntax List	Implicit VR Little Endian	1.2.840.10008.1.2

### **Chapter 4 Printing**

TeraRecon Aorta.CT does not provide any printing functions. This section does not apply to TeraRecon Aorta.CT.

# **Chapter 5 Support of Character Sets**

All TeraRecon Aorta.CT DICOM applications support following character sets:

Character Set Description	Defined Term
Latin alphabet No. 1	ISO_IR 100

### **Chapter 6 Security**

TeraRecon Aorta.CT does not support any specific security measures.

It is assumed that TeraRecon Aorta.CT is used within a secured environment. It is assumed that a secured environment includes at a minimum:

- 1. Firewall or router protections to ensure that only approved external hosts have network access to TeraRecon Aorta.CT.
- 2. Firewall or router protections to ensure that TeraRecon Aorta.CT only has network access to approved external hosts and services.
- 3. Any communication with external hosts and services outside the locally secured environment use appropriate secure network channels (for example, 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.