



CT Cardiomegaly
DOC-0047 SOUP (OTS) Report

1. PURPOSE

The purpose of this document is to provide the Off-the-shelf (OTS) Software documentation for the CT Cardiomegaly per the 2023 FDA Guidance “Off-The-Shelf Software Use in Medical Devices”.

2. SCOPE

This document applies to CT Cardiomegaly.

3. DEFINITIONS

Terms and abbreviations used within this document:

Term	Definition
Function	An FDA term for a distinct purpose of the product, which could be the intended use or a subset of the intended use of the product. For example, a product with an intended use to analyze data has one function: analysis. A product with an intended use to store, transfer, and analyze data has three functions.
OTS Software	A generally available software component, used by a medical device manufacturer for which the manufacturer cannot claim complete software life cycle control.
Requirement	A statement about something the design must accomplish. Good requirements are verifiable, necessary, irreducible, and don't prescribe a design.
Risk Assessment	overall process comprising risk analysis and risk evaluation
Risk Management	Systematic application of management policies, procedures (3.13) and practices to the tasks of analyzing, evaluating, controlling and monitoring risk
Software Item	Any identifiable part of a computer program, i.e., source code, object code, control code, control data, or a collection of these items.



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Term	Definition
System	Integrated composite consisting of one or more of the processes, hardware, software, facilities, and people that provides a capability to satisfy a stated need or objective.
System Image	An individual file which can be used to completely reproduce the state of a software system. E.g., including the operating system, system-dependencies, DLLs, configuration files, etc
User	Person who interacts with (i.e., operates or handles) the device.
Verification	Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled (i.e., the requirements are met).

4. REFERENCES

References made within this document:

4.1. Guidance

- 2023 FDA Guidance “Off-The-Shelf Software Use in Medical Devices”

4.2. Internal

- DOC-0003 Product Development Plan (Software Development Environment Description)
- DOC-0006 Software Requirements Specification
- DOC-0033 Documentation Level Evaluation
- DOC-0045 Software Verification Report
- DOC-0039 Software Bill of Materials
- DOC-0048 Traceability Analysis
- DOC-0040 Software Description
- DOC-0007 Risk Assessment
- DOC-0013 User Manual



5. OTS SOFTWARE RISK MANAGEMENT

Risk Management of OTS Software Items was performed as part of the medical device risk management. See the DOC-0007 Risk Assessment.

Additionally, as described in DOC-0033 Documentation Level Evaluation, CT Cardiomegaly has been found to require a Basic Level of Documentation.

6. OTS SOFTWARE ITEMS

The CT Cardiomegaly contains a few OTS Software Items. To see the full list of titles, manufacturers (when available), and versions of the individual OTS software dependencies, see the DOC-0039 Software Bill of Materials.

The OTS Software Items were deemed appropriate for the medical device.

7. OTS SOFTWARE DESIGN CONTROLS

The functions that the OTS Software Items serve, and the verification of these functions, are described in the DOC-0006 Software Requirements Specification and DOC-0048 Traceability Analysis.

8. COMPUTER SYSTEM SPECIFICATIONS FOR OTS SOFTWARE

The CT Cardiomegaly was designed and verified with pre-set computer hardware. See the DOC-0040 Software Description.

9. INSTRUCTIONS FOR USE RELATED TO OTS SOFTWARE

The end users do not install any OTS Software Items.

The OTS Software may be updated during CT Cardiomegaly software updates.

Most end users are prevented from directly interacting with any OTS Software Items. Admins may access the underlying operating system.

10. CONFIGURATION MANAGEMENT OF OTS SOFTWARE

See the DOC-0003 Product Development Plan (Software Development Environment Description) for details about how the OTS Software Item versions are tracked and controlled.



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The proper installation of OTS Software will be ensured as part of the System Verification.

11. OTS SOFTWARE DOCUMENTATION

OTS Software	Docker
Manufacturer	Docker, Inc. (open source)
Version	23.0.1 (2023-02-09)
OTS Software Documentation Provided to End User	Instructions related to starting the device using Docker is provided in the User Manual.
Why this OTS Software appropriate for this medical device?	The OTS software is widely used. Docker allows for a consistent virtualization of the operating system (containerization) that is running the device functions. Deploying different builds of the software device for each operating system would be more error prone than using this OTS software.
What are the expected design limitations of the OTS Software?	None
What are the Computer System Specifications for the OTS Software?	Recommended >30 GB of storage to accommodate the Docker container associated with the device.
How will you assure appropriate actions are taken by the End User?	Instructions related to starting the device using Docker is provided in DOC-0013 User Manual.
What does the OTS Software do?	Docker allows for a consistent virtualization of the operating system (containerization) that is running the device functions.
How do you know it works?	The OTS software was tested indirectly by the system verification. See the system-level verification records in DOC-0045 Software Verification Report.



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How will you keep track of (control) the OTS Software?	The building of the Docker container and its deployment is within our control. The device is intended to be installed by a qualified Body Check engineer.
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OTS Software	MONAI
Manufacturer	MONAI (open source)
Version	1.2.0 (2023-06-08)
OTS Software Documentation Provided to End User	N/A, the user does not have access.
Why this OTS Software appropriate for this medical device?	The OTS software is commonly used for medical image processing.
What are the expected design limitations of the OTS Software?	None
What are the Computer System Specifications for the OTS Software?	Recommended >8 GB of RAM to accommodate the reading of large image data into memory.
How will you assure appropriate actions are taken by the End User?	N/A, the user does not have access.
What does the OTS Software do?	The OTS software allows for the reading and preprocessing of medical images into memory for use by the device.
How do you know it works?	The OTS software was tested indirectly by the system verification. See the unit- and system-level verification records in DOC-0045 Software Verification Report.
How will you keep track of (control) the OTS Software?	The OTS software is fully contained within the deployed system image.



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OTS Software	DCMTK
Manufacturer	OFFIS (open source)
Version	3.6.4 (2018-11-29)
OTS Software Documentation Provided to End User	N/A, the user does not have access.
Why this OTS Software appropriate for this medical device?	The OTS software is commonly used for the sending, receiving, and storing of DICOM files.
What are the expected design limitations of the OTS Software?	None
What are the Computer System Specifications for the OTS Software?	Recommended >8 GB of RAM to accommodate the reading of large image data into memory.
How will you assure appropriate actions are taken by the End User?	N/A, the user does not have access.
What does the OTS Software do?	The OTS software allows for the receiving of DICOM images to a specified directory for use by the device.
How do you know it works?	The OTS software was tested directly by the system verification. See the unit-level verification records in DOC-0045 Software Verification Report.
How will you keep track of (control) the OTS Software?	The OTS software is fully contained within the deployed system image.

OTS Software	fpdf2
Manufacturer	open source software



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Version	2.7.4 (2023-04-28)
OTS Software Documentation Provided to End User	N/A, the user does not have access.
Why this OTS Software appropriate for this medical device?	The OTS software converts machine-readable inputs into a human-readable PDF report.
What are the expected design limitations of the OTS Software?	None
What are the Computer System Specifications for the OTS Software?	Recommended >8 GB of RAM to accommodate the reading of large image data into memory.
How will you assure appropriate actions are taken by the End User?	N/A, the user does not have access.
What does the OTS Software do?	Generate the PDF report
How do you know it works?	The OTS software was tested indirectly by the system verification. See the system-level verification records in DOC-0045 Software Verification Report.
How will you keep track of (control) the OTS Software?	The OTS software is fully contained within the deployed system image.