MEDCommons

May 17, 2004

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard,
Rockville, Maryland 20850

RE: **ABBREVIATED 510(k)**
          for MedCommons™ Open Radiology™ Gateway

Dear Sir:

MedCommons, Inc. intends to market the Open Radiology™ Gateway, a medical image
viewer.

The enclosed material is submitted consistent with:
- 21 CFR 807
- FDA's guidance, How to Prepare an Abbreviated 510(k)'s, and
- FDA's Guidance for the Submission of Premarket Notifications for Medical
  Image Management Devices

If there are questions about this submittal, please contact Chas Burr of SoftwareCPR, Inc.

Chas Burr
SoftwareCPR, Inc.
11 Mystic Avenue
Winchester, MA 01890-2920

email: cburr@softwarecpr.com
cell phone: 781-789-1646
efax: 781-723-2422

Respectfully yours,

Chas Burr

cc:
MedCommons, Inc.
William Donner, President
Adrian Gropper, M.D., Chief Medical Officer
Susan Belanich, Quality Manager

Enclosure:
Two copies of the User Fee Cover Sheet
Two copies of the Abbreviated 510(k) for MedCommons Open Radiology™ Gateway

Table of Contents

The organization of this 510(k) is consistent with FDA's Guidance for the Submission of Premarket Notifications for Medical Image Management Devices.

A. General Information

1. Name and address of manufacturer

MedCommons, Inc.
52 Marshall Street
Watertown, MA 02472

2. Establishment registration number

Pending

3. Name, title, and phone number of contact

For review questions regarding this 510(k) submittal:
Chas Burr
Consultant
SoftwareCPR, Inc.
11 Mystic Avenue
Winchester, MA 01890-2920

781-789-1646
cburr@softwarecpr.com

For ongoing questions:
Adrian Gropper, MD
Chief Medical Officer
MedCommons, Inc.
52 Marshall Street
Watertown, MA 02472

617-571-3857
agropper@medcommons.org

4. Trade name and common name of device

Trade Name: MedCommons Open Radiology™ Gateway
Common Name: Medical image viewer software

5. Classification of the device

Classification Name: Picture Archiving and Communications System
Classification Panel: Radiology
CFR Section: 21 CFR 892.2050
Class: II
Product Code: LLZ

6. Intended use

MedCommons Open Radiology™ Gateway (MedCommons Gateway™) is a software application for viewing medical images. Typical MedCommons Gateway™ users are healthcare professionals, such as, clinicians, radiologists, and technologists.

MedCommons Gateway™ receives, communicates, and displays digital images and data from various types of imaging and image processing system, such CT, MR, US, RF units, computed and direct radiographic devices, scanners, imaging gateways and image processing sources). MedCommons Gateway™ can be integrated with an institution's HIS or RIS, linking or transferring images and data into electronic patient records.

7. Substantially equivalent device

The MedCommons Open Radiology™ Gateway is substantially equivalent to the eFilm Workstation, which was cleared in 510(k)'s K020995 and K012211.

8. Applicable mandatory and voluntary standards

DICOM (Digital Imaging and Communications in Medicine)
JPEG (Joint Photographic Experts Group)

B. Administrative Information

The following pages contain three FDA forms:
- 510(k) Summary
- Indication for Use Statement
- Truthful and Accurate Statement

510(k) Summary for the MedCommons Open Radiology™ Gateway

This 510(k) summary of safety and effectiveness information complies with 21 CFR 807.92.

Submittal information:

Manufacturer:
MedCommons, Inc.
52 Marshall Street
Watertown, MA 02472

Contact person:
Adrian Gropper, M.D.
Chief Medical Officer
MedCommons, Inc.
52 Marshall Street
Watertown, MA 02472

(617) 571-3857

Device name and classification

Proprietary Name: MedCommons Open Radiology™ Gateway
Classification Name: Picture Archiving and Communications System
Classification Panel: Radiology
CFR Section: 21 CFR 892.2050
Class: II
Product Code: LLZ

Substantial Equivalence

The MedCommons Open Radiology™ Gateway is substantially equivalent to the eFilm Workstation, which was cleared in 510(k)'s K020995 and K012211.

Device Description

MedCommons Open Radiology™ Gateway (MedCommons Gateway™) is a component of a Picture Archiving and Communications System (PACS). MedCommons Gateway™ is a software application that provides image viewing and manipulation in a diagnostic imaging setting. The functions of this application are applied to medical images that are acquired and stored on an image server in DICOM and/or other proprietary formats. MedCommons Gateway™ can also transfer DICOM 3.0 images over a medical imaging network, as well as export images to applications in JPEG and/or proprietary formats.

Intended Use

MedCommons Open Radiology™ Gateway (MedCommons Gateway™ is a software application for viewing medical images. Typical MedCommons Gateway™ users are healthcare professionals, such as, clinicians, radiologists, and technologists.

MedCommons Gateway™ receives, communicates, and displays digital images and data from various types of imaging and image processing system, such CT, MR, US, RF units, computed and direct radiographic devices, scanners, imaging gateways and image processing sources). MedCommons Gateway™ can be integrated with an institution's HIS or RIS, linking or transferring images and data into electronic patient records.

Comparison to the predicate device

The MedCommons Open Radiology™ Gateway and the eFilm Workstation are both software applications intended for viewing medical images stored in PACS systems. They have similar features and are substantially equivalent in safety and effectiveness.

Indications for Use

510(k) Number (if known): _____

Device Name: _ MedCommons Open Radiology™ Gateway _____

Indications for Use:

MedCommons Open Radiology™ Gateway (MedCommons Gateway™) is a software application for viewing medical images. Typical MedCommons Gateway™ users are healthcare professionals, such as, clinicians, radiologists, and technologists.

MedCommons Gateway™ receives, communicates, and displays digital images and data from various types of imaging and image processing system, such CT, MR, US, RF units, computed and direct radiographic devices, scanners, imaging gateways and image processing sources). MedCommons Gateway™ can be integrated with an institution's HIS or RIS, linking or transferring images and data into electronic patient records.

Prescription Use ___X____   AND/OR   Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)   (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Truthful and Accurate Statement

I certify in my capacity as Quality Manager and Official Correspondent of MedCommons, Inc., I believe to the best of my knowledge that all data and information submitted in this premarket notification are accurate and that no material fact has been omitted.

_____   _____
Susan Belanich   Date of signature

C. Device Description

1. Summary of Functions
- Import and export of medical imaging studies from modalities, PACS and workstations
- Selection, grouping, and editing of medical imaging study contents
- Viewing of medical images for both review and diagnostic indications
- Annotation and characterization of images and imaging studies for clinical referral
- Communication of medical imaging studies
- Storage of medical imaging studies
- Tracking and status display of referral activities
- Authentication and authorization of users and enforcement of security policies

2. Diagram of Major Components
See Figure 1 – Major Components and Architecture on next page.

DICOM LAN

ROUTER

**MedCommons
INSTALL**

IAD

2 - DICOM Import and Export

1 - DICOM Configuration Screen

3 - Local Database and File System

13 - Router Monitor Screen

4 - Selection List Query / Report

7 - Selection Screen

5 - Web Services Interface

6 - Web Services Interface

10 -Web Access to DICOM Objects

8 - Order Form Screen

11 - Order Payload Encryption

9 - Image View Screen

FIREWALL
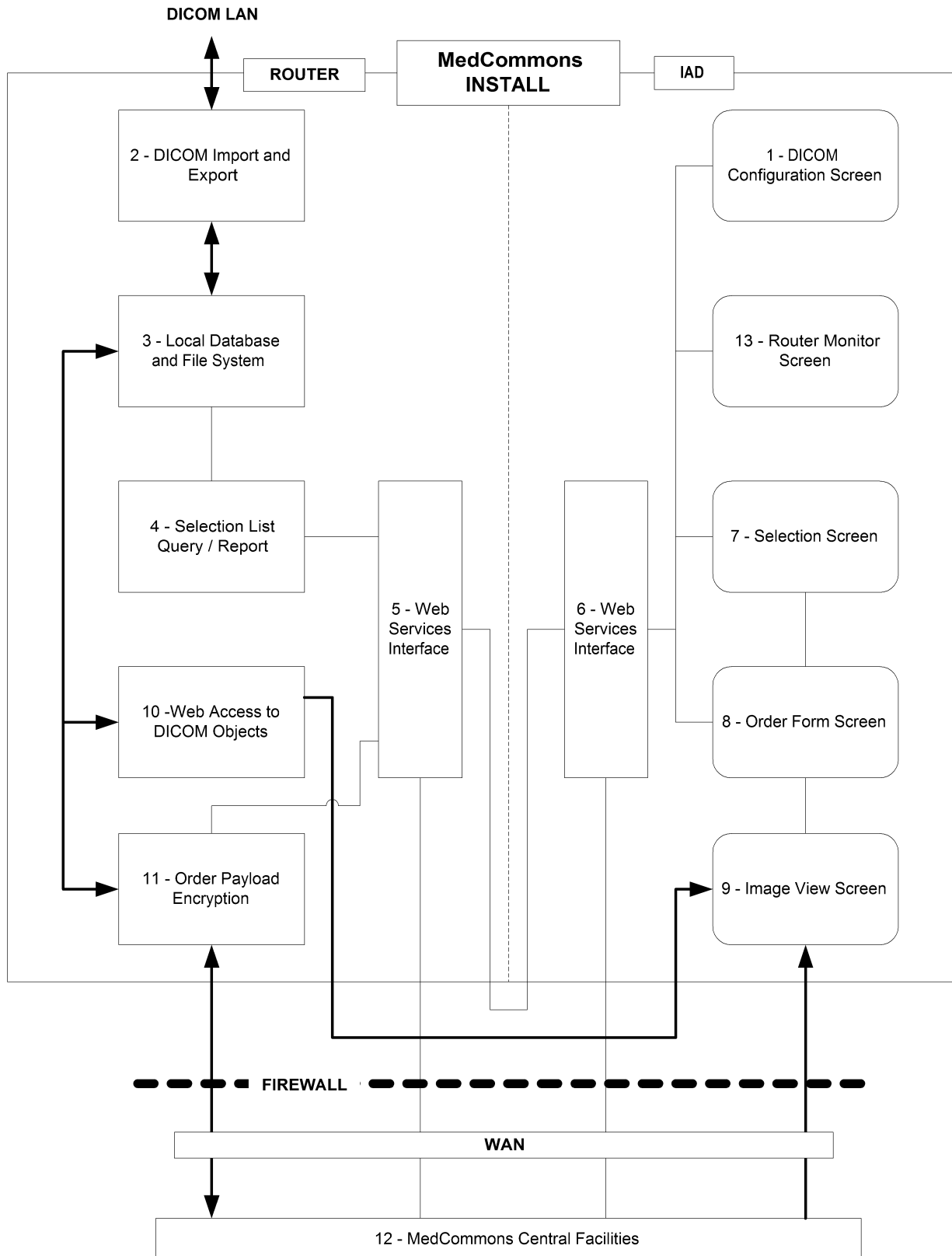
WAN

12 - MedCommons Central Facilities

Figure 1 – Major Components and Architecture

3. Technical Characteristics and Principles of Operation

Technical Characteristics

MedCommons Gateway™ (Gateway) is a stand-alone software package which can be used on more than one hardware platform. As long as minimum hardware requirements are met, the user is free to choose his own hardware platform. It is the user's responsibility to choose image display hardware that is of adequate quality and properly calibrated for the specific clinical application and protocol.

Gateway allows digital image processing and measurement capability. It can transmit to remote viewing stations over a medical imaging network.

Gateway does not contact the patient, nor does it control any life-sustaining devices. A physician providing ample opportunity for competent human intervention interprets images and information being displayed.

Principles of Operation

Numbers refer to Figure 1 – Major Components and Architecture

The pre-requisite is a computer on the institutional DICOM LAN under the control of a user that has DICOM PACS access privileges.

Upon satisfactory Registration with the MedCommons Central Facilities [12], the user is allowed to download a MedCommons Installer to his computer. The Installer installs two distinct components – the Router and the Intelligent Access Device (IAD) on the computer. In alternate hardware configurations, the Router is installed on a separate computer; the IAD is replaced by a Web browser; or the User orders a MedCommons Tablet with software installed.

1   A DICOM Configuration Screen [1] configures the Router to join the DICOM network.

2   DICOM Query, Move, etc. to the DICOM Engine [2] are used to populate and update a Local Database [3] of imaging studies in accordance to the user's privileges and role relative to the PACS.

3   The Local Database and File System [3] provides temporary storage of imaging studies and items such as pending Orders that might be the subject of a transfer.

4   A Selection List Query [4] responds to parameters entered by the User on Selection Screen [7] with a Report that populates a list on Selection Screen [7] with items from Database [3]. Alternative embodiments would build a Selection Report by a Query to the PACS directly.

5   Web Services Interface [5] and [6] relay messages between the Router and
        IAD using standard protocols.

6   The Router can be located on a different computer from the IAD and
        multiple IADs can communicate with multiple Routers.

7   The User picks one or more items from the Selection Screen [7]. Each
        item typically represents a DICOM Study.

8   The item(s) selected populates the payload field of an instance of an Order
        as displayed on the Order Form Screen [8].   Information such as the
        Patient's Name and Referring Physician are derived from the DICOM
        Study metadata and can be used to populate other fields of the Order
        Form. Furthermore, the Order Form Screen can use the Web Services
        Interface [6] to fetch additional information from MedCommons Central
        [12] by using Patient, Physician and other information such as Procedure
        that is available in the DICOM metadata.

9   An Image View Screen [9] is available to the User for quality control
        purposes during the Order creation process.

10   A Web Access to DICOM Objects (WADO) [10] module supports the
        View Screen [9]. Alternative embodiments would have DICOM access to
        the Router by a Diagnostic or 3D Workstation (e.g.: eFilm, Voxar) or
        could access images directly from the local Database and File System [3].

11   Finalization of the Order, as communicated via the Web Services
        Interface, triggers the Order Payload Encryption [11] to package the
        payload and Order information for transport over the WAN to the
        MedCommons Central Facilities [12].

12   The MedCommons Central Facilities [12] provide temporary buffering
        and routing for studies on the way to Routers at other facilities. Payload
        elements are typically decrypted and re-encrypted with keys that are
        specific to the destination Router. Payload metadata may be examined to
        assist in routing if the Order Form itself does not have sufficient
        information. Payload images and reports are made available directly to
        Web browsers using a WADO module at the Central Facility that uses
        technology similar to that used in the Router. The Central Facility keeps a
        HIPAA Log of transfers that is accessible to the Patient and to other
        authorized Users. The Central Facility provides long-term archiving.

4. Specifications

MedCommons Gateway™ (Gateway) is a software application. It has no equipment specifications consistent with the intent of section C.4 of FDA's Guidance for the Submission of Premarket Notifications for Medical Device Image Management Devices.

Gateway is specified to operate on:
- Hardware:
  - Pentium III or compatible processor
  - 512 MB RAM
  - 100 MB Hard Drive Space
  - Minimum Display Resolution 1024x768 pixels
  - Color Table Resolution 24 or 32bits per pixel
- Operating System
  - Windows XP
  - Microsoft IE 5 or higher

D. Testing

MedCommons Gateway™ (Gateway) requires no testing consistent with the intent of section D of FDA's Guidance for the Submission of Premarket Notifications for Medical Device Image Management Devices.

Gateway uses JPEG compression, a standard irreversible compression technique.

E. Comparison to Legally Marketed Device

Category	eFilm Workstation	MedCommons Gateway™
PACS Functionality	Yes	Yes
Diagnostic Image Display	Yes	Yes
Image Manipulation and Annotation	Yes	Yes
Image Interpolation and Processing	Yes	Yes
Software Only	Yes	Yes
Install from the Web	Yes	Yes
Documentation Online	Yes	Yes
Centralized Management	Optional	Optional
Software Source Code Online	No	Yes

The MedCommons Gateway™ (Gateway) is similar to the predicate device in function, labeling and intended use.

The principal difference between the devices is in production and quality management procedures due to the extensive use of Open Source Software in the Gateway. MedCommons, Inc. expects that availability of source code will enable peer review that will improve quality, safety and effectiveness of the Gateway more effectively as compared to the predicate device and other complex medical devices that enforce secrecy of important and increasingly risky software components.

F. Labeling

1. Promotional Materials

MEDCommons

Open Source Software

The MedCommons Open Radiology™ Gateway is Open Source Software.

Medical images are increasing in resolution and accuracy and are playing an ever more important role in medical care. Improved resolution and accuracy coupled with increasing computer processing capacity enables enhanced diagnosis, treatment planning and evidence-based medicine.

MedCommons, Inc. is founded on the belief that public peer review of software and open access to sophisticated software algorithms are essential to managing the next generation of health care software.

In the MedCommons Gateway™, the processing chain from DICOM modality to the physician's eye is based on Open Source Software and is intended for clinical use.

High-resolution data sets such as multi-detector CT and modern MR increasingly benefit from sophisticated processing to display data quickly and efficiently. Whether as simple as interpolation between pixels or as complex as tracking the location of an aortic stent, image manipulation methods—from the acquisition protocols to the physician's user interface—are becoming too important to keep secret.

Open Source Software architecture, particularly in the image and image interpretation pipelines, enables peer review and incremental extension of functionality. Because Open Source methods allow for public visibility at all stages of the software life cycle, all bugs are public and innovators are less prone to introducing errors when they re-invent or reverse engineer the functionality of critical subsystems.

Open Source Software also provides powerful components for data interchange and archival storage. Open Source Software protects the data by enabling interchange between vendors even when standards compliance is imperfect, or when vendor-provided support is unavailable.

As a complete image acquisition, management and display device in a format accessible to clinicians, MedCommons, Inc. provides an Open Source Software alternative to physicians as they take increasing responsibility for understanding and using ever more sophisticated software-based tools.

2. Users Manuals

The following is a draft.

Product Identification

MedCommons Open Radiology™ Gateway User Guide

V 0.5
Part Number 01-0001
May 14, 2004

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This user guide has been produced to assist in providing instruction for the MedCommons Open Radiology™ Gateway product. Every effort has been made to make the information in this guide as accurate as possible. The authors of this guide shall have neither liability nor responsibility to any person or entity with respect to any loss or damages in connection with or arising from the information contained in this guide.

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Contact Information

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www.medcommons.net
mailto: support@medcommons.net

Before you begin…

This software is intended for use by licensed clinical practitioners who are trained appropriately in the software's functions and applications and are aware of its limitations. Poor ambient conditions (e.g.: excessive room light), improper display calibration (e.g.: excessive contrast), careless application of image manipulation tools (e.g.: window and level adjustment) and inadequate familiarity with the user interface (e.g.: not reviewing all available information) can all result in incorrect interpretations of an imaging study.

You should also be aware that the image information being processed by MedCommons Gateway™ is potentially incomplete or does not adequately conform to the standards as implemented by the device. To mitigate the impact of these problems, you should take into account the underlying imaging protocols and recognize the potential absence or gross corruption of information.

This device is designed, manufactured and tested to reduce the risk of subtle and serious corruption of labels and image contents. Internal checks and redundant external labels are used to reduce the likelihood of misinterpretation due to internal software errors but these are not foolproof and cannot compensate for bad information coming into the device.

On occasion, interpolated (magnified) data may introduce image artifacts which should not be interpreted as real pathology. When artifacts are suspected, you should be able to change the magnification ratio or window/level setting to help differentiate artifacts from pathology.

System Requirements

Hardware:
> Pentium III or compatible processor
> 512 MB RAM
> 100 MB Hard Drive Space
> Minimum Display Resolution 1024x768 pixels
> Color Table Resolution 24 or 32bits per pixel

Operating System
> Windows XP
> Microsoft IE 5 or higher

Please check the support and help files at www.medcommons.net for the most up-to-date system requirements.

Software License

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MedCommons Open Radiology™ Gateway Overview

The MedCommons™ Open Radiology™ Gateway is Open Source Software.

Medical images are increasing in resolution and accuracy and are playing an ever more important role in medical care. Improved resolution and accuracy coupled with increasing computer processing capacity enables enhanced diagnosis, treatment planning and evidence-based medicine.

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Registration and Installation

MEDCOMMONS - Microsoft Internet Explorer

File   Edit   View   Favorites   Tools   Help

Back ▼ | ✖ 🔄 🏠 | 🔍 Search ⭐ Favorites 🌐 Media 🔮 | 🔷▼ 🖨 🗐 📒

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Please fill in the form below. A valid email address and name are required. An email will be sent to you with your password.

email*: [   ]

name*: [   ]

age*: [   ] [required]

gender*:   male   female
              ⦿   ○

phone
number*: [   ]

are you a   yes   no
healthcare   ○   ⦿
professional*?

are you   yes   no
licensed*?   ○   ⦿

if yes, in what   [AL ▼]
state are you
licensed*?

company: [   ]

comments: [   ]

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The WADO Viewer

Using the Tools

Image display is controlled primarily by gestures made with a mouse or equivalent pointing tool such as the "pen" of a tablet PC. Some actions have keyboard alternatives.

The two principal gestures are click and drag. A click is typically used to select or activate. Drag is the gesture that draws an imaginary line or rectangle across the screen. Drag gestures are used to indicate a region or to achieve proportional control.

Gestures cause different actions depending on the region (e.g.: image display, thumbnail display, tool palette, menu) of the screen where they are begun. Most gestures provide the user with visual feedback as they are performed.

- **Display Menu**
  A Display Menu at the bottom of the WADO Viewer lists all of the available series for the current patient / study. A check mark next to an item indicates that the thumbnail for that series is currently displayed.

  By default (un-clicked) the Display Menu label shows the total number of series available for the current patient and the patient's identifying information. This feature allows the patient's name to be displayed in two places in the viewer for safety reasons. Although the WADO Viewer is designed to operate without scroll bars to ensure that critical information is always on-screen, some browser / screen configurations can automatically introduce scroll bars. Operation of the WADO Viewer on a screen with less than 1024 x 768 pixels is not recommended.

  Select **About…** on the Display Menu to display the portion of the SMPTE test pattern that will allow you to check the settings of your monitor.

  Clinical applications require a monitor capable of adequate gray-scale range. The test pattern contains 12 discernible squares including two small squares of 95% and 5% density. If, in your viewing environment, your monitor is not adjusted to display all 12 squares, then it is inadequate for clinical use. Adjust the brightness and contrast controls per the monitor manufacturer instructions until all 12 squares are visible at the same time.

- **Scroll Wheel**
  The Scroll Wheel of the mouse controls the displayed image number in all modes. Keyboard arrow keys can also be used to step through images and series.

- **Left Mouse Function**

  The primary mouse button (typically the left button) toggles between two modes of control for Window / Level or Zoom. Clicking the tool icon toggles the mode and changes the icon to match. The Window / Level settings and Zoom / Pan settings apply to the display of all images in a series.

  Window / Level

  In Window / Level mode, a drag across the image defines a region. On mouse-up, the image will be replaced by a matrix of 9 versions of the region. Each version of the region will be a different Window / Level option automatically selected by the software. For reference, the middle image of the matrix (cell # 5) will be rendered with no change in the Window / Level. The options presented in the other 8 cells may depend on the modality of the originated the image and other information derived from the DICOM image header.

  A click on a cell of the Window / Level matrix redraws the entire previous image using the selected Window / Level option. A click on a thumbnail in Window / Level mode selects the new series, replaces the image in the display frame, and applies the current settings to the image series.

  A drag on a cell of the Window / Level matrix causes the entire matrix to be redrawn as variations from the selected cell. The region itself is unchanged. The extent of the drag gesture indicates how large a change is desired.

  Zoom

  In Zoom mode, a drag across the image defines a region. On mouse-up, the image is replaced by a magnified version of the selected region. A frame appears over the corresponding thumbnail to indicate the location of the magnified region. Enabling image overlay displays the magnification factor.

  A click on the image window toggles the image between full display and magnified display.

  A drag across a thumbnail showing the Zoom region frame pans the frame to adjust the region on display.

  Reset

  A click on the Reset tool restores the image display for the currently selected series to the initial defaults. This includes Window / Level and Zoom.

Two consecutive clicks on the Reset Tool restores the entire study (all series) and other display modes (e.g.: Overlays) to the initial defaults.

Rotate / Flip
Successive clicks on the Rotate / Flip Tool changes the displayed image in sequence. The sequence is 0–, 90–, 180–, 270–, Flip Horizontal, Flip Vertical and back to 0–. Rotations apply to all images in a series.

Overlay Show / Hide
This tool toggles the display of information as an overlay on the image. Patient identifying information (Name, ID, Age, Sex) cannot be hidden. The information displayed depends on the modality, the information received and the current display state.

Examples of display state information include: Image #, Window / Level, Lossy Compression Ratio and Magnification Ratio. Scale Bars, if displayed on the Overlay, reflect the current Magnification Ratio.

Compare
This tool launches another instance of the WADO Viewer and automatically selects the most likely series from the same patient and study for initial display. Depending on screen size, screen configuration and user login preferences, the new WADO Viewer instance can be running on the same computer or another computer.

WADO Viewers launched using the Compare tool are automatically linked with respect to the actions of the Mouse Scroll Wheel for image selection.

Annotation Tools
The Annotation tool changes state in sequence to enable Text, Regions, Arrows and Dimensions to add Annotation Objects to the Annotation Overlay. The Annotation Overlay is associated with a particular image and is not saved once the WADO Viewer is closed or a new Patient is selected.

The behavior of each Annotation Object may depend on the particular browser in use and some tools may not be available in your browser.

Caution: The position of Annotation Objects is automatically adjusted to reflect Zoom and Pan of an image. This action can cause some annotations to be obscured or to change position relative to each other. If

the image Magnification and Pan states are changed, it is the user's responsibility to verify that the annotations still reflect the user's clinical intent.

A   **Annotations Show / Hide**
This tool toggles the visibility of all of the Annotation Overlays in a study.

_i_   **View HIPAA Log**
This tool displays a page of information including security, transfer and warning notices that apply to the current study.

X   **Exit**
This tool always removes the current patient from display. Depending on configuration, the WADO Viewer window may stay open with no patient or the next patient and study in a sequence is displayed.

User Feedback

The MedCommons Gateway™ is Open Source Software. Please refer to the Support section of our Web site for an up to date listing of user forums and directions on how to give feedback directly to MedCommons.

MedCommons values your input. Bug reports, feature requests, clinical notes and, yes, even software are welcome submissions. Under the terms of the Open Source licenses associated with this distribution, source code is available at MedCommons.net for most of the functional components. Users with the skill and support to modify and enhance the software are free to do so. However, modification of the Gateway software invalidates the performance, test and labeling protections that apply to the software as distributed from MedCommons. Modification may also impact your ability to get support from the community of users.

MedCommons Gateway™ software is designed, produced and tested in a formal and documented manner consistent with the legal and regulatory requirements that apply to medical devices in this product category. Our procedures include controlled documentation, risk analyses, traceability processes, automated and manual tests and other controls that will not be available to clinicians and engineers in the community. Regulatory approval of MedCommons Gateway™ software applies only to software issued to MedCommons, Inc. Redistribution of MedCommons software, whether commercial or not, without regulatory approval is illegal in the US, Canada and most other countries. Please contact MedCommons for additional information on how to meet regulatory requirements or to discuss the inclusion of your software in future versions of the MedCommons Open Radiology Gateway.

3. Images

The MedCommons Gateway™ software does not know the extent to which an image has been processed before it is received. On-image labeling about processing may be misleading. For example, MedCommons Gateway™ could indicate that an image has not been processed, when in fact it had been processed extensively prior to its receipt. The following labeling is in the Users Guide:

> The user should also be aware that the image information being processed by the device is potentially incomplete on does not adequately conform to the standards as implemented by the device. To mitigate the impact of these problems, a qualified user is expected to take into account the underlying imaging protocols and to recognize the absence or gross corruption of information.

> This device is designed, manufactured and tested to reduce the risk of subtle and serious corruption of labels and image contents. Internal checks and redundant external labels are used to reduce the likelihood of misinterpretation due to internal software errors but these are not foolproof and cannot compensate for bad information coming into the device.

> On occasion, interpolated (magnified) data may introduce image artifacts which should not be interpreted as real pathology. When artifacts are suspected, the trained user may be able change the magnification ratio or window/level setting to help differentiate artifacts from pathology.

G. Software Information

1. Functions Performed by the Software

MedCommons Gateway™ is a software application. All functions are performed by software. See Section C.1 for the list of functions.

2. Software Development Methods

MedCommons uses a standard iterative development process. Project management, issues, and defect tracking are performed with the software system, Mantis. Each stage of the design process is documented.

Design Input

Design input to the process arrives from four sources:

1. Customer requirements based on market research
2. The open source software process
    The MedCommons Gateway™ source code will become available on a public internet site after the 510(k) clearance from the FDA. This permits peer review of the software design and implementation by third parties.)
3. Customer feedback from existing products
    The Corrective and Preventive Action (CAPA) process evaluates software defects and enhancement requests found in released products.
4. Hazard analysis

Team design reviews are held to determine what new or modified requirements will be added to the product.

Design Output

Software developers develop software architecture and code to meet the requirements. They create or modify MedCommons code or incorporate third-party software.

MedCommons maintains a paperless environment. Documents (specifications, requirements, and source code) are managed using the source control program, Subversion. Access to the source control repository is available only to authenticated users. Document generation, distribution, and changes are controlled by the user's permissions. The repository creates snapshots of the software and audit trails of changes.

The build procedure for products is completely automated from code in the repository. The build procedure is used for product development as well as the completed product.

Design Verification/Validation

There are two separate procedures:

1. Requirements are numbered; test plans must address each numbered requirement.
2. Requirements claim adherence to standards but may not specify attributes of these standards. Test plans measure compliance using standard image and data sets. Any deviation from compliance must be documented and justified if it is to be included in our product.

Design Review

A cross-functional team reviews the results of major design phases and approves each product release.

Control of Design Changes

Design changes that require a change to the product (as opposed to a change to clarify an ambiguity in the requirements or specifications) are subject to review by a change control team. Defect corrections require retesting of potentially affected software functions. Major design changes are subject to the entire design control process.

MedCommons firmly believes that making source code available to the open source community will encourage peer review, and ultimately improve the quality and safety of the product. Open source input is treated as design input. It proceeds through the same MedCommons design control and quality assurance processes as other software. Defects found in open source components and their fixes are published in the open source community.

3. Hazard Analysis

MedCommons reviewed the experience of its software and clinical personnel with medical imaging applications and with PACS and other software. In addition, the MAUDE database was examined for reports in recent years. The table below describes hazards identified and the associated mitigation strategies or product requirements.

Hazard Analysis

MedCommons quality assurance processes will be used to confirm successful implementation of strategies and requirements.

Hazard	Mitigation Strategy / Requirement
Primary hazards	None identified. Pure software has no means of causing direct harm. Potential harm results from the application, i.e., from secondary hazards.
Delay of treatment	None identified. The use of the Gateway PACS for viewing images is not intended for time-critical medical applications.
Misinformation leading to misdiagnosis and mistherapy.	
- Incorrect patient ID's	- Display the correct patient ID with each image/screen. - Clear patient demographic data after each transaction to prevent carry-over of previous patient's data. - Whenever possible have redundant demographic info on-screen, e.g., name and birth date.
- Image data lost or damaged by processing	- Processing not intended to alter patient data may not alter patient data fields.
- Wrong image retrieved from database	- Gateway erases pointers to previous data when retrieving new files. - Gateway retrieves files requested or shows error message.
- Information associated with image is corrupted	- DICOM information is correctly represented. - Test scenarios include multiple image series viewed out of order.
- Miscalculation, mismeasurement	- All calculations reviewed and thoroughly validated. - Registration will be accurate before and after zooms.
Corrupted image leading to misdiagnosis and mistherapy	- Gateway presents images correctly per original file and user-requested zoom, etc. - Gateway provides user labeling explaining to view images through multiples zooms (or other image manipulations) to confirm if an anomaly is real patient image or artifact.

4. Software Test Procedures

Testing for conformity with requirements and specification is conducted as described in section G.2.

Testing includes acceptance, integration, regression, platform, upgrade, stress, performance, and system tests.

Testing for DICOM conformance is performed by third party products designed for this purpose.

- Image presentation and Part 10 media interchange formats verified by DICOMScope. The DICOMScope viewer was commissioned by the DICOM committee to enforce consistent image presentation on DICOM Devices. The image presentation test procedure requires that the WADO rendering process yield images which are visually identical to DICOMScope images with the same parameters.
- Network protocols tested by OT-DICE from OTech.

The full set of tests is performed before each software release.

At the end of testing, results are studies against the initial risk management plan. The goal is to determine:
- Did the testing address all identified risk requirements?
- Has further risk management been performed to address issues discovered in testing?
- Is the overall residual risk of the release acceptable?

5. Software Certification

I certify in my capacity as Quality Manager of MedCommons, Inc., I believe to the best of my knowledge that the software information in this premarket notification is correct. The testing procedures described in Section G. 4. Software Test Procedures will be used to retest and revalidate the software when it is revised.

_____   _____
Susan Belanich   Date of signature

H. Declaration of Conformity to Recognized Standards

Summary Report of Reliance on Standards

The MedCommons Open Radiology™ Gateway complies with these FDA Recognized Standards:

ISO 10918-1 (1994-02), Information Technology--Digital Compression and Coding of Continuous-Tone Still Images: Requirements and Guidelines

NEMA PS3.1 through PS 3.14 2000, Digital Imaging and Communications in Medicine (DICOM)

Declaration of Conformity to JPEG

ISO 10918-1 (1994-02), Information Technology--Digital Compression and Coding of Continuous-Tone Still Images: Requirements and Guidelines

All requirements of this standard were met.

This standard was adapted for application to the Gateway™ by: Not applicable
These requirements of the standard are inapplicable to the Gateway™:   Not applicable
Deviations from the standards and their rationale: Not applicable
Differences between the tested device and the device to be marketed and a justification of the test results in these area of differences: Not applicable
Name and address of any test laboratory or certification body involved in determining the conformance of the device to this standard and a reference to any accreditations: Not applicable

Declaration of Conformity to DICOM

NEMA PS3.1 through PS 3.14 2000, Digital Imaging and Communications in Medicine (DICOM)

All requirements of this standard were met. See the following DICOM Conformance Statement.

This standard was adapted for application to the Gateway™ by: Not applicable
These requirements of the standard are inapplicable to the Gateway™:   Not applicable
Deviations from the standards and their rationale: Not applicable
Differences between the tested device and the device to be marketed and a justification of the test results in these area of differences: Not applicable
Name and address of any test laboratory or certification body involved in determining the conformance of the device to this standard and a reference to any accreditations: Not applicable

MedCommons™ Router 0.5

DICOM Conformance Statement

[MedCommons, Inc](#).

May 12, 2004

Overview

The MedCommons™ Router is a system that provides services for safe, secure storage and retrieve of DICOM evidence object such Images, Key Image Notes, Presentation States, Structured Reports and others.

The MedCommons™ Router supports the following network services:

Table 1. NETWORK SERVICES

Networking SOP Classes	User of Service (SCU)	Provider of Service (SCP)
Transfer		
US Image Storage	Yes	Yes
US Multi-frame Storage	Yes	Yes
Computed Radiography Image Storage	Yes	Yes
Digital X-Ray Image Storage - For Presentation	Yes	Yes
Digital X-Ray Image Storage - For Processing	Yes	Yes
Digital Mammography X-Ray Image Storage - For Presentation	Yes	Yes
Digital Mammography X-Ray Image Storage - For Preocessing	Yes	Yes
Digital Intra-oral X-Ray Image Storage - For Presentation	Yes	Yes
Digital Intra-oral X-Ray Image Storage - For Processing	Yes	Yes
CT Image Storage	Yes	Yes
MR Image Storage	Yes	Yes
Secondary Capture Image Storage	Yes	Yes
X-Ray Angiographic Image Storage	Yes	Yes
X-Ray Radiofluoroscopic Image Storage	Yes	Yes
Nuclear Medicine Image Storage	Yes	Yes
VL Endoscopic Image Storage	Yes	Yes
VL Microscopic Image Storage	Yes	Yes
VL Slide-Coordinates Microscopic Image Storage	Yes	Yes
VL Photographic Image Storage	Yes	Yes
Positron Emission Tomography Image Storage	Yes	Yes
RT Image Storage	Yes	Yes

Networking SOP Classes	User of Service (SCU)	Provider of Service (SCP)
Grayscale Softcopy Presentation State Storage	Yes	Yes
Basic Text SR	Yes	Yes
Enhanced SR	Yes	Yes
Comprehensive SR	Yes	Yes
Key Object Selection Document	Yes	Yes
Query/Retrieve		
Study Root Q/R - FIND	No	Yes
Study Root Q/R - MOVE	No	Yes
Connectivity Verification		
Verification	Yes	Yes

NOTE: Relational Queries are not supported either as an SCU or SCP.

1. Introduction

1.1. Revision History

Revision History

Revision 0.1   March 15 2004; SWD; Initial Draft

Revision History

Revision 0.5 May 12 2004; SWD

1.2. Audience

This document is intended for hospital staff, health system integrators, software designers or implementers. It is assumed that the reader has a working understanding of DICOM.

1.3. Remarks

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 MedCommons and 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 successful interconnectivity with existing DICOM systems.

The user should be aware of the following important issues:

- The comparison of different conformance statements is the first step towards assessing interconnectivity between MedCommons and non-MedCommons software.
- Test procedures should be defined to validate the desired level of connectivity.
- The DICOM standard will evolve to meet the users' future requirements. MedCommons is actively involved in developing the standard further and therefore reserves the right to make changes to its products or to discontinue its delivery.

1.4. Definitions, Terms and Abbreviations

Definitions, terms and abbreviations used in this document are defined within the different parts of the DICOM standard.

Abbreviations and terms are as follows:

AE

Application Entity

AET

AE Title

DICOM

Digital Imaging and Communications in Medicine

DIMSE

DICOM Message Service Element

GSDF

Grayscale Standard Display Function

HIS/RIS

Hospital Information System / Radiology Information System.

IHE

Integrating the Healthcare Enterprise

IHE-TF

Integrating the Healthcare Enterprise Technical Framework

IOD

Information Object Definition

ISO

International Standard Organization

PDU

DICOM Protocol Data Unit

LUT

Look-up Table

P-LUT

Presentation Look-up Table

SCP

Service Class Provider

SCU

Service Class User

SOP

DICOM Service-Object Pair

TCP/IP

Transmission Control Protocol/Internet Protocol

TLS

Transport Layer Security

UID

Unique Identifier

VR

Value Representation

1.5. References
[DICOM]

Digital Imaging and Communications in Medicine (DICOM), NEMA PS 3.1-3.16, 2001

2. Networking

2.1. Implementation Model
2.1.1. Application Data Flow

The MedCommons™ Router is logically divided in two different DICOM Application Entities: Storage Server and Query/Retrieve Server.

The Application Entities detailed in the Application Data Flow Diagram are all Java Enterprise Application and are designed to run in a J2EE compliant container (i.e. JBoss) on any Java Virtual Machine 1.4 capable Operating System.

The Storage Server AE implements the DICOM Storage Service Class, the Verification Service Class.

The Query/Retrieve Server AE implements Query/Retrieve Services.

2.1.2. Functional Definition of AEs
2.1.2.1. Functional Definition of MedCommons™ Router Storage Server Application Entity

The MedCommons™ Storage Server Application Entity waits for another application to connect at the presentation address configured for its Application Entity Title. When another application connects, the STORAGE-SCP AE expects it to be a DICOM application. The STORAGE-SCP AE will accept Associations with Presentation Contexts for SOPClasses of the Verification and Storage Service Classes. Any images received on such Presentation Contexts will be added to the Image Repository.

2.1.2.2. Functional Definition of MedCommons™ Router Query/Retrieve Server Application Entity

The MedCommons™ Query/Retrieve Server Application Entity

2.1.3. Sequencing of Real-World Activities

2.2. AE Specifications

2.2.1. MedCommons™ Router DICOM Server Application Entity Specification
2.2.1.1. SOP Classes

The MedCommons™ Router DICOM Server Application Entity provides Standard Conformance to the following SOP Classes:

SOP Class Name	SOP Class UID	SCU	SCP
Verification SOP Class	1.2.840.10008.1.1	No	Yes
Computed Radiography Image Storage	1.2.840.10008.5.1.4.1.1.1	No	Yes
Digital X-Ray Image Storage - For Presentation	1.2.840.10008.5.1.4.1.1.1.1	No	Yes
Digital X-Ray Image Storage - For Processing	1.2.840.10008.5.1.4.1.1.1.1.1	No	Yes
Digital Mammography X-Ray Image Storage - For Presentation	1.2.840.10008.5.1.4.1.1.1.2	No	Yes
Digital Mammography X-Ray Image Storage - For Processing	1.2.840.10008.5.1.4.1.1.1.2.1	No	Yes
Digital Intra-oral X-Ray Image Storage - For Presentation	1.2.840.10008.5.1.4.1.1.1.3	No	Yes
Digital Intra-oral X-Ray Image Storage - For Processing	1.2.840.10008.5.1.4.1.1.1.3.1	No	Yes
CT Image Storage	1.2.840.10008.5.1.4.1.1.2	No	Yes
Ultrasound Multi-frame Image Storage	1.2.840.10008.5.1.4.1.1.3.1	No	Yes
MR Image Storage	1.2.840.10008.5.1.4.1.1.4	No	Yes
Ultrasound Image Storage	1.2.840.10008.5.1.4.1.1.6.1	No	Yes
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7	No	Yes
X-Ray Angiographic Image Storage	1.2.840.10008.5.1.4.1.1.12.1	No	Yes
X-Ray Radiofluoroscopic Image Storage	1.2.840.10008.5.1.4.1.1.12.2	No	Yes
Nuclear Medicine Image Storage	1.2.840.10008.5.1.4.1.1.20	No	Yes
VL Endoscopic Image Storage	1.2.840.10008.5.1.4.1.1.77.1.1	No	Yes
VL Microscopic Image Storage	1.2.840.10008.5.1.4.1.1.77.1.2	No	Yes
VL Slide-Coordinates Microscopic Image Storage	1.2.840.10008.5.1.4.1.1.77.1.3	No	Yes

SOP Class Name	SOP Class UID	SCU	SCP
VL Photographic Image Storage	1.2.840.10008.5.1.4.1.1.77.1.4	No	Yes
Positron Emission Tomography Image Storage	1.2.840.10008.5.1.4.1.1.128	No	Yes
RT Image Storage	1.2.840.10008.5.1.4.1.1.481.1	No	Yes
Grayscale Softcopy Presentation State Storage SOP Class	1.2.840.10008.5.1.4.1.1.11.1	No	Yes
Basic Text SR	1.2.840.10008.5.1.4.1.1.88.11	No	Yes
Enhanced SR	1.2.840.10008.5.1.4.1.1.88.22	No	Yes
Comprehensive SR	1.2.840.10008.5.1.4.1.1.88.33	No	Yes
Key Object Selection Document	1.2.840.10008.5.1.4.1.1.88.59	No	Yes

2.2.1.2. Association Establishment Policy

2.2.1.2.1. General

The MedCommons™ Router DICOM Server AE can both accept and propose Association Requests. The MedCommons™ Router DICOM Server AE will accept Association Requests for the Verification, and Storage.

The DICOM standard application context name for DICOM 3.0 is always accepted and proposed:

Table 3. DICOM application context name for The MedCommons™ Router DICOM Server AE

Application Context Name	1.2.840.10008.3.1.1.1

2.2.1.2.2. Number of Associations

The MedCommons™ Router DICOM Server can support multiple simultaneous Associations requested by peer AEs. Default is 10. This value can be configured through the attribute "MaxClients" in the config.xml file.

Table 4. Number of Associations accepted for the MedCommons™ Router DICOM Server AE

Maximum number of simultaneous Associations	10 (Configurable)

2.2.1.2.3. Asynchronous Nature

The MedCommons™ Router DICOM Server does not support asynchronous communication. Multiple outstanding transactions are not supported. It allows up to one invoked and one performed operation on an Association (it is synchronous).Asynchronous mode of operation is not supported.

Table 5. Asynchronous Nature as SCP for the MedCommons™ Router DICOM Server AE

Maximum number of outstanding asynchronous transactions	1 (Not Configurable)

2.2.1.2.4. Implementation Identifying Information

The implementation information for this Application Entity is:

Table 6. DICOM Implementation Class and Version for the MedCommons™ Router DICOM Server AE

Implementation Class UID	1.2.40.0.13.1.1
Implementation Version Name	medcommons-05

2.2.1.3. Association Initiation Policy
2.2.1.3.1.1. Description and Sequencing of Activities
2.2.1.3.1.1.1. Proposed Presentation Contexts

The MedCommons™ Router DICOM Server will propose Presentation Contexts as shown in the following table:

Table 7. Proposed Presentation Contexts by the MedCommons™ Router DICOM Server AE

Abstract Syntax		Transfer Syntax		Role	Ext. Neg.
Name	UID	Name List	UID List		
Verification	1.2.840.10008.1.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCU	None

2.2.1.3.1.1.1.1. SOP Specific Conformance
2.2.1.3.1.1.1.1.1. Specific Conformance for Verification SOP Class

Standard conformance is provided to the DICOM Verification Service Class as an SCU. The Verification Service as an SCU is actually only supported as a diagnostic service tool for network communication issues.

2.2.1.4. Association Acceptance Policy
2.2.1.4.1.1. Description and Sequencing of Activities

A remote peer DICOM Application Entity, acting as an Storage SCU, establishes an association with the MedCommons™ Router DICOM Server that accepts these Associations for the purpose of receiving supported SOP Class Instances.

In the default configuration any Calling and Called AET will be accepted. But the Called AET does not correspond to the actual Storage Server AET, only a Presentation Context

for the Verification SOP Class will be accepted and the SCU can only verify the DICOM Association, but cannot invoke any other related DICOM service.

Association requests can be rejected with the following status codes and reasons:

Table 8. Association Rejection Reasons

Result	Source	Reason	Description
rejected transient	provider	local-limit exceeded	The (configurable) maximum number of simultaneous associations has been reached. An association request with the same parameters may succeed at a later time.
rejected permanent	user	app. context name not supported	Incorrect application context name

2.2.1.4.1.2. Accepted Presentation Contexts

The accepted Presentation Contexts depends on the configuration for the paper printer associated with the Called AET in the association Request:

Table 9. Accepted Presentation Contexts for the MedCommons™ Router DICOM Server AE

Abstract Syntax		Transfer Syntax		Role	Ext. Neg.
Name	UID	Name List	UID List		
Verification	1.2.840.10008.1.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
Computed Radiography Image Storage	1.2.840.10008.5.1.4.1.1.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
Digital X-Ray Image Storage - For Presentation	1.2.840.10008.5.1.4.1.1.1.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
Digital X-Ray Image Storage - For Processing	1.2.840.10008.5.1.4.1.1.1.1.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
Digital	1.2.840.10008.5.1.4.1.1.1.2	Implicit	1.2.840.10008.1.2	SCP	None

Abstract Syntax		Transfer Syntax		Role	Ext. Neg.
Name	**UID**	**Name List**	**UID List**		
Mammography X-Ray Image Storage - For Presentation		VR Little Endian			
Digital Mammography X-Ray Image Storage - For Processing	1.2.840.10008.5.1.4.1.1.1.2.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
Digital Intra-oral X-Ray Image Storage - For Presentation	1.2.840.10008.5.1.4.1.1.1.3	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
Digital Intra-oral X-Ray Image Storage - For Processing	1.2.840.10008.5.1.4.1.1.1.3.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
CT Image Storage	1.2.840.10008.5.1.4.1.1.2	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
Ultrasound Multi-frame Image Storage	1.2.840.10008.5.1.4.1.1.3.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
MR Image Storage	1.2.840.10008.5.1.4.1.1.4	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
Ultrasound Image Storage	1.2.840.10008.5.1.4.1.1.6.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
X-Ray Angiographic	1.2.840.10008.5.1.4.1.1.12.1	Implicit VR	1.2.840.10008.1.2	SCP	None

| Abstract Syntax | | Transfer Syntax | | Role | Ext. Neg. |
Name	UID	Name List	UID List		
Image Storage		Little Endian			
X-Ray Radiofluoroscopic Image Storage	1.2.840.10008.5.1.4.1.1.12.2	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
Nuclear Medicine Image Storage	1.2.840.10008.5.1.4.1.1.20	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
VL Endoscopic Image Storage	1.2.840.10008.5.1.4.1.1.77.1.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
VL Microscopic Image Storage	1.2.840.10008.5.1.4.1.1.77.1.2	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
VL Slide-Coordinates Microscopic Image Storage	1.2.840.10008.5.1.4.1.1.77.1.3	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
VL Photographic Image Storage	1.2.840.10008.5.1.4.1.1.77.1.4	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
Positron Emission Tomography Image Storage	1.2.840.10008.5.1.4.1.1.128	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
RT Image Storage	1.2.840.10008.5.1.4.1.1.481.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
Grayscale Softcopy Presentation State Storage SOP Class	1.2.840.10008.5.1.4.1.1.11.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None

| Abstract Syntax | | Transfer Syntax | | Role | Ext. Neg. |
Name	UID	Name List	UID List		
Basic Text SR	1.2.840.10008.5.1.4.1.1.88.11	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
Enhanced SR	1.2.840.10008.5.1.4.1.1.88.22	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
Comprehensive SR	1.2.840.10008.5.1.4.1.1.88.33	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
Key Object Selection Document	1.2.840.10008.5.1.4.1.1.88.59	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None

If the Called AET is not corresponding to the actual Storage Server AET, it only will be accepted the Presentation Context for the Verification SOP Class.

2.2.1.4.1.3. SOP Specific Conformance
2.2.1.4.1.3.1. Specific Conformance for Verification SOP Class

The MedCommons™ Router Storage Server provides standard conformance to the DICOM Verification Service Class as a SCP. The status code for the C-ECHO is described in the following table:

Table 10. C-Echo Response Status Handling Behavior

Service Status	Further Meaning	Error Code	Behavior
Success	Success	0000	The C-ECHO request is accepted

2.2.1.4.1.3.2. Specific Conformance for Storage SOP Classes

The associated Activity with the Storage service is the storage of medical DICOM data received over the network on a designated storage repository. The MedCommons™ Router Storage Server AE will return a failure status if it is unable to store the received instance(s).

The MedCommons™ Router Storage Server AE does not have any dependencies on the number of Associations used to send images to it. Images belonging to more than one

Study or Series can be sent over a single or multiple Associations. Images belonging to a single Study or Series can also be sent over different Associations. There is no limit on either the number of SOP Instances or the maximum amount of total SOP Instance data that can be transferred over a single Association.

The MedCommons™ Router Storage Server AE is configured to retain the original DICOM data in DICOM Part 10 compliant file format. The MedCommons™ Router Storage Server AE is Level 2 (Full) conformant as a Storage SCP. In addition, all Private and SOP Class Extended Elements are maintained in the DICOM format files. In addition to saving all Elements in files, a subset of the Elements are stored in the MedCommons™ Router Query/Retrieve Server database to support query and retrieval requests and also allow updating of Patient, Study, and Series information by user input, or demographic and Study related messages.

The Behavior for handling duplicate SOP Instances (as identified by SOPInstanceUID) it to permit them to overwrite earlier instances.

For the purposes of image display the system supports the following photometric interpretations: MONOCHROME1, MONOCHROME2, RGB, PALETTE COLOR, YBR FULL 422, and YBR FULL.

2.2.1.4.1.3.2.1. Storage Server AE C-STORE Response

Table 11. The MedCommons Router Storage Server C-STORE Response Status

Service Status	Further Meaning	Error Code	Error Comment	Behavior
Success	Success	0000H		The Composite SOP Instance was successfully received, verified, and stored in the system repository.
Error	Rejected Permanent	0001H	No Reason Given	Unknown error; examine log of sending device.
Error	Rejected Permanent	0001H	Application Context Name Not Supported	The Application context name must be "1.2.840.10008.3.1.1.1"
Error	Rejected Permanent	0001H	Calling AE title not recognized	Calling AE title in transaction is unknown to system. The default configuration of the device is to permit all calling AE titles.
Error	Rejected Permanent	0001H	Called AE title not recognized	Called AE title in transaction is unknown to system. The default configuration of the system is to permit all Called AE titles.

2.2.1.4.1.3.2.2. Storage Server AE Storage Service Communication Failure Reasons

Table 12. The MedCommons™ Router Storage Server Service Communication Failure Reasons

Exception	Reason
Timeout expiry for an expected DICOM Message Request (DIMSE level timeout). I.e. The STORAGE-SCP AE is waiting for the next C-STORE Request on an open Association but the timer expires.	The Association is aborted by issuing a DICOM A-ABORT. Error message is output to the Service Log. If some Composite SOP Instances have already been successfully received then they are maintained in the database. They are not automatically discarded because of a later failure.
Timeout expiry for an expected DICOM PDU or TCP/IP packet (Low-level timeout). I.e. The STORAGE-SCP AE is waiting for the next C-STORE Data Set PDU but the timer expires.	The Association is aborted by issuing a DICOM A-ABORT. Error message is output to the Service Log. If a C-STORE Data Set has not been fully received then the data already received is discarded. If some Composite SOP Instances have already been successfully received over the Association then they are maintained in the database.
Association aborted by the SCU or the network layers indicate communication loss (i.e. low-level TCP/IP socket closure)	Error message is output to the Service Log. If some Composite SOP Instances have already been successfully received then they are maintained in the database. They are not automatically discarded because of a later failure.

2.3. Physical Network Interfaces

2.3.1. Supported Communication Stacks

DICOM Upper Layer over TCP/IP is supported.

2.3.1.1. TCP/IP Stack

The MedCommons™ Router inherits their TCP/IP stack from the installed Java Runtime Environment.

2.3.2. Physical Network Interface

The MedCommons™ Router is indifferent to the physical medium over which TCP/IP executes; it inherits this from the Java Runtime Environment.

2.4. Configuration

2.4.1. AE Title/Presentation Address Mapping

2.4.1.1. Local AE Titles

The mapping from AE Title to TCP/IP addresses and ports is configurable through web interface.

Table 13. AE Title Configuration Table

Application Entity	Default AE Title	Default TCP/IP Port
The MedCommons™ Router Storage Server	STORE_SCP	2351
The MedCommons™ Router Query/Retrieve Server	QR_SCP	2351

2.4.1.2. Remote AE Title

In the default configuration, Association Requests with any Calling AET will be accepted.

2.4.2. Parameters

The following table shows the MedCommons™ Router configuration parameters relevant to DICOM communication.

DICOM Configuration Table

Attribute	Default Value
cstore-scp-port	3002
max-clients	10
resp-delay	0
ac-timeout	5000
rq-timeout	5000
rsp-delay	0
dimse-timeout 0	0
so-close-delay 500	500
pack-pdvs false	false
trunc-post-pixeldata false	false

prior 0	0
max-pdu-len 16352	16352
max-op-invoked 0	0
buf-len 2048	2048

3. Media Interchange

The MedCommons™ Router does not currently support Media Storage.

4. Support of Extended Character Sets

Supports ISO_IR 100 (ISO 8859-1 Latin 1) as an extended character set.

5. Security

5.1. Security Profiles

The MedCommons™ Router supports secure DICOM communication in conformance with the Basic TLS Secure Transport Connection Profile. At default configuration, the TLS option is deactivated.

5.2. Association Level Security

The MedCommons™ Router can be configured to accept Association Requests from only a limited list of Calling AE Titles and to check that the Association requester specifies the correct Called AE Title.

In the default configuration, Association requests with any Calling AET and any Called AET will be accepted. However, if the Called AET is not correspondent to any of the actual DICOM server AETs, only acceptance of the Presentation Context for Verification SOP Class will be returned in the Association Acceptance Response (A-ASSOCIATE AC).

5.3. Application Level Security

The MedCommons™ Router web module can be configured to require user authentication in order to access to the user interface functionalities. Different level of user authorization and profiling can also be specified through the web module configuration file(s).