

648- B51009

DESCRIPTION License(s)

ClearRead Bone Suppression™ is an innovative image enhancement technology that is designed to increase the clarity of chest x-rays by suppressing bone on the digital image. ClearRead Bone Suppression automatically processes appropriately tagged AP/PA chest x-rays and sends the resulting derived images to the PACS system. The resulting bone suppressed image can be displayed within the existing patient file and viewed on any PACS viewer.

Enterprise Site License: Permitted use at a single hospital site. *(Standard is 10 acquisition devices)*
ClearRead Bone Suppression is installed as a software only installation in your current IT environment and allows additional add-on modules as defined below. For technical specifications see **Exhibit A. If a server is required, a Dell rack mount server may be included, Part #25-0130**

ClearRead +Confirm emphasizes lines and tubes on portable chest x-ray images. With diagnostic quality preserved, a radiologist can minimize imaging adjustments and decrease reading time. The resulting ClearRead +Confirm image and/or enhanced PA image is placed within the existing patient file and viewed on any PACS viewer.

Enterprise Site License: Permitted use at a single hospital site.
This will work with existing installation of ClearRead Bone Suppression - Model #25-0370-VA

ClearRead +Detect is a computer-aided detection (CAD) system that processes AP/PA chest x-rays and identifies regions of interest that may warrant further examination by a radiologist. A scalable marker is placed on a copy, or as an overlay, of the original chest x-ray. The system is designed to identify nodules that may be early stage lung cancer. ClearRead +Detect automatically processes appropriately tagged AP/PA chest x-rays and sends derived content to the PACS system. The resulting CAD image can be displayed within the existing patient file and viewed on any PACS viewer.

Enterprise Site License: Permitted use on a single hospital site.
This will work with existing installation of ClearRead Bone Suppression - Model #25-0370-VA

ClearRead +Compare is an image registration and enhancement application that accentuates changes between patient x-ray images taken at different times by forming a third, subtraction image and/or registered prior between the current and prior chest x-ray. ClearRead +Compare automatically processes appropriately tagged AP/PA chest x-rays and sends the resulting derived images to the PACS system. The resulting image can then be displayed within the existing patient file and viewed on any PACS viewer.

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This will work with existing installation of ClearRead Bone Suppression - Model #25-0370-VA

- If a physical server is required, a fully installed and tested Dell premium rack mount server will be included. For technical specifications see **Exhibit A** for details.
- Riverain Technologies will provide remote assistance for installation and configuration.
Customer is responsible for Installation Tasks A. Riverain Technologies will provide remote assistance to customer with Installation Tasks B and C as outlined in Exhibit B.

DESCRIPTION License(s)
1 Year Warranty - per Exhibit D , attached hereto and incorporated herein.

DESCRIPTION Professional Services
<p>Installation and Implementation (2 business days) - Includes installation tasks A, B, and C as outlined in Exhibit B. 8am-5pm. Travel to site included. Requires customer fulfillment of installation requirements outlined in Exhibit C.</p> <p>Once scheduled visit <u>cannot</u> be rescheduled, no refund will be offered. Requires local support as outlined in Exhibit C <u>during on-site visit</u>. If local support is unavailable during on-site visit, visit will <u>not</u> be rescheduled and no refund will be offered. Additional visit or day may be purchased.</p>
<p>In-service Training (1 Day) 1 day, from 8am-5pm, Travel included. Up to 5 radiologists maximum. Requires that installation and implementation is complete. Must be purchased in whole units. Additional applications must be used within 12 months of purchase date.</p>
<p>1 Day Additional Onsite Professional Services – Customers choice of Installation, Implementation, or Training. Includes Travel Costs</p>

Optional Add-Ons

<u>Fixed Rate Service Contract</u>
<p>Yearly Service Contract – 15% of License Subtotal To commence at end of first year of warranty. Requires execution of “Service Contract”. Rate will be <u>locked in</u> and will not rise during the term of the contract. Quantity indicates number of years (Choose between 1 and 5) up to five (5) years maximum. Payment due 30 days before expiration of each warranty year.</p>
<u>Up Front Extended Service Contract</u>
<p>1 Year Service Contract - (15% of License Subtotal) - 5% Discount To commence at end of first year warranty. Requires execution of “Service Contract” - available upon request. Payment to be made with initial purchase</p>
OR
<p>3 Year Service Contract - (3 X 15% of License Subtotal) - 10% Discount To commence at end of first year warranty. Requires execution of “Service Contract” Requires execution of “Service Contract” - available upon request. Payment to be made with initial purchase</p>
OR
<p>5 Year Service Contract - (5 X 15% of License Subtotal) - 15% Discount To commence at end of first year warranty. Requires execution of “Service Contract” - available upon request. Payment to be made with initial purchase</p>

Exhibit A - Technical Specifications

The Dell Premium server option is one of the following packages:

- The PowerEdge R710 19" rackmount server (Height 2U) with 10/100/1000 Base-T Ethernet and Windows Server 2008 SP2
- The PowerEdge T110 free standing server with 10/100/1000 Base-T Ethernet and Windows Server 2008 SP2

Input and output interfaces are DICOM 3 compliant

- The input images may be derived from the modalities and acquisition systems outlined below and output images are sent to one or more DICOM storage devices. All image transfer protocols are compliant with the DICOM 3.0 standards.

Supported Input Image Devices:

- Digital X-ray -- DX
- Computed Radiography -- CR
- Secondary Capture digitized chest X-ray films – SC

Supported Destination Device Storage Formats

Output images are in DICOM Secondary Capture Image Storage format.

Typical performance

Typical processing time for one image is 20 seconds.

Remote Service - Riverain Requirement

Port 443 outbound (HTTPS) is required for remote service and support

Regulatory Specifications:

All hardware devices have conformance for computing equipment to the following standards or regulating bodies:

- US FDA 510K Clearance (ClearRead Bone Suppression) and US FDA Pre-Market Approval (ClearRead +Detect)
- FCC (Class A) – Federal Communications Commission
- UL – Underwriters Laboratory
- Canadian Device License
- CE – Conformité Européenne – (Marking statement of CE safety and emissions compliance)
- CSA – Canadian Standards Association
- Australian TGA Certificate

Environmental Requirements:

- Temperature: 10° C to 35° C (50° F to 95° F)
- Humidity: 8% to 80%

Exhibit B – Installation Tasks

Installation Tasks A

- If utilizing a virtual machine environment, ensure VMWare ESXi version 5.x or higher is used.
- Build a server with the following recommended machine specification:

Server	<ul style="list-style-type: none">• 4 CPU cores - Intel Core 2 or later, at least 2.0 GHz• 6 GB RAM• 100 GB free hard disk space• 1 Gbit/sec Ethernet controller• DVD-ROM drive• USB 2.0 port for HASP license device
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Operating System	Microsoft Windows [®] 64-bit 2008 SP2 or Windows 64-bit 2008 R2 Server or Windows 7 Professional/Enterprise/Ultimate 64-bit SP1
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- Ensure the system has access to the Internet via port 443 outbound to allow remote support. If remote access cannot be granted then only phone support can be provided and system uptime as outlined in section 5 of the "Service Contract" cannot be guaranteed.
- Identify a suitable environmentally controlled location to install the system
- Mount the system in a standard 19 inch server rack (2U of rack space required)
- Connect the system to suitable power supplies
- Connect the system to a facility KVM
- Connect the system to the local area network
- Power up the system and configure the network interface card with a unique IP address, subnet mask and gateway (DNS is not required)

Installation Tasks B

- Configure the Riverain device on the site's DICOM network to accept and store DICOM images with all intended DICOM modalities and PACS
- Test that the Riverain device can accept images from all modalities configured to send images to the Riverain device
- Test that the Riverain device can deliver ClearRead derived images to all intended PACS
- Assist site's onsite resources with configuring the PACS/modalities to automatically send all Chest Radiograph studies to the Riverain device

Installation Tasks C

- Configure the Riverain device's image filters to discard all non-chest and lateral images
- Assist customer's onsite resources with configuring the PACS workstation hanging protocols to display images according to the needs of the Radiologists.
- Monitor the throughput of images to assure that the filters are working correctly.
- As required, create site specific image filtering or configuration to achieve seamless workflow integration
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Exhibit C - Onsite Installation Requirements

- In advance of the on- site visit, customer shall provide Riverain Technologies with a completed Pre-Installation Questionnaire (PIQ)
- In advance of the on-site visit, customer shall provide Riverain Technologies with guidance from the onsite Radiologist or Radiology group on desired preferences for displaying images as part of the hanging protocol.
- During the on-site visit, customer shall provide Riverain Technologies with an IT or PACS administrator with access to the location where the server will be installed, ability to assign an IP address to the server and knowledge of the configuration of the PACS system and modalities.
- During the onsite visit, customer shall provide Riverain Technologies with onsite or remote assistance for the configuration of the PACS system via customer's personnel or 3rd party PACS vendor personnel.
- Note failure to provide on-site resources during the on-site visit may prevent completion of system installation during allocated time. No refund will be offered.

Exhibit D

WARRANTY DETAILS

Unlimited technical support: Email – 24 Hour answering service.
Direct remote technical support via secure connection 8:30AM – 8:30PM EST
Provision of system software updates
Provision & installation of all spare parts and systems necessary to maintain proper operations.
On Site support when necessary

1. For a period of twelve (12) months beginning upon completion of the installation in a test environment or first clinical use of the system, (the “Warranty Period”), the System shall meet the requirements and specifications set forth in the Licensor Sales Quote, Equipment Specifications and applicable Installation & Service Manual defined features and functions.
2. During the Warranty Period, for any non-conformities of which Licensor receives notice from the Customer, Licensor shall work directly or through its approved agents, to correct these non-conformities.
3. During the Warranty Period, Licensor or its approved agent shall provide to the Customer, free of additional costs and charges, support necessary to ensure that the System is maintained and/or modified to meet the requirements of the Licensor Sales Quote, Equipment Specifications and applicable Installation & Service Manual defined features and functions.
4. During the Warranty Period, Licensor will furnish, or cause to be furnished, at no additional cost or charge to the Customer, all software Updates, parts and replacements necessary to maintain the System in good working condition. During the Warranty Period, Licensor or its approved agent shall be responsible for 1st line technical support, and to engage in any remedial maintenance at the Customer site as necessary, including any periodic inspections as outlined in Licensor’s Device Service & Installation manuals.
5. *Uptime* – During the Warranty Period, in its standard configuration, the system shall be 99.5% available for clinical use during agreed operational time. Operational up-time calculations do not include downtime incurred due to scheduled maintenance, system upgrades, customer configuration change requests, and losses in power, network or any other external cause. The uptime guarantee is conditional upon the Customer complying with all aspects of this contract and allowing full access via remote support tools at all times. Downtime is calculated from the instant that Licensor technical services is notified that a system is down, until the time that the particular unit is reported to the customer as being available for clinical use.

Riverain Technologies will comply with the current DOD/Army information Assurance and HIPAA Information Assurance requirements as listed in the following documents:

1. Military Health System DOD Business Associate Agreement (TMA TPS BAA)
2. MEDCOM IA and HIPAA Standard Contract Language (MEDCOM Required IA and HIPAA Contract Language)
3. Memorandum of Agreement for Business Gateway (B2B memo of Agreement Template)