IMSURE QA™ SOFTWARE

DICOM Router 3.4

User Manual

STANDARD IMAGING

General Precautions

Warnings and Cautions alert users to dangerous conditions that can occur if instructions in the manual are not obeyed. Warnings are conditions that can cause injury to the operator, while Cautions can cause damage to the equipment.

⚠️ **WARNING:**
Federal law in the U.S.A., and Canadian law, restricts the sale distribution, or use of this product to, by, or on the order of a licensed medical practitioner. This product should be used under the guidance of a medical physicist.

⚠️ **WARNING:**
Where applicable, Standard Imaging products are designed to be used with the versions of common radiation delivery devices, treatment planning systems and other common computer software products or systems used in the delivery of ionizing radiation, available at the time the Standard Imaging product is released. Standard Imaging does not assume responsibility, liability and/or warrant against, problems with the use, reliability, safety or effectiveness that arise due to the evolution, updates or changes to these products or systems in the future. It is the responsibility of the customer or user to determine if the Standard Imaging product can be properly used with these products or systems.

⚠️ **WARNING:**
Should IMSure QA results differ from the treatment planning results, further review of each is needed to determine which results are most appropriate.

⚠️ **WARNING:**
Enter complete and correct data. Ensure that complete and correct data has been entered by viewing the data on the screen before proceeding.

⚠️ **WARNING:**
Poor quality Imported Fluence Maps and/or Maps with an incorrect resolution may reduce correlation of the Difference Map and increase the Maximum Difference. It is the responsibility of the user to visually verify Imported Fluence Maps, and to ensure that Fluence Map resolutions are correctly defined in User Preferences.

⚠️ **WARNING:**
Conduct Acceptance and routine QA Testing. It is the responsibility of the user to conduct Acceptance Testing on the machine specified for treatment, and to conduct routine QA Testing at appropriate intervals. Algorithm information is provided in this IMSure QA User Manual.

⚠️ **WARNING:**
Verify file selection before import, and verify imported data. It is the user's responsibility to select the correct Plan and Fluence Map Files for import. Patient name and selected plan data is displayed prior to Plan import to assist in this process. After import, verify plan data before proceeding.

⚠️ **WARNING:**
Machines must be commissioned before use. Verify physics data prior to commissioning. Only machines commissioned prior to the initiation of a treatment plan may be used to complete that plan. If a machine is recommissioned while a plan is in progress, the new data will be used starting with the next new plan.

⚠️ **WARNING:**
Verify all printed data. Verify that printed data matches the screen display. All pages need to be accounted for and correctly collated. Correct paper size and printer conditions need to be verified for all print jobs.

⚠️ **WARNING:**
Verify exported reports. After exporting a report for electronic storage, users are advised to verify the file before closing the plan.

⚠️ **WARNING:**
Verify all physics data. Ensure that physics data is complete and correct after entering or importing data by viewing the data screens in the Physics Data Module.

⚠️ **WARNING:**
The use of IMSure QA does not preclude the need for routine machine QA.

⚠️ **CAUTION:**
Active plans are deleted when Preferences are modified. When any Preference is modified in the User Preferences Module, all existing plan data is cleared out and reset to default. Users are cautioned not to change Preferences when plans are in progress.

⚠️ **CAUTION:**
Assign unique names to each machine. Do not attempt to assign the same name to more than one machine.

⚠️ **CAUTION:**
Verify precision levels when importing tables. Precision levels on imported tables may affect calculations, due to rounding.

⚠️ **CAUTION:**
Only one user may access the Physics Data Module concurrently. On networked machines with a shared Physics Data file, only one user may access the Physics Data Module at any one time.

⚠️ **CAUTION:**
Machine changes are effective when the next plan is initiated. The machine that is commissioned at the initiation of a plan is used to complete that plan. If machine parameters are changed while a plan is in progress, the change does not take effect until the current plan is closed.

⚠️ **CAUTION:**
Back up data files. Data files should be backed up on a regular basis.

⚠️ **CAUTION:**
Protect the CD-ROM surface from fingerprints, scratches and other damage. Do not store the CD-ROM in direct sunlight or warm and humid places.

Table of Contents

IMSURE QA™ SOFTWARE

STANDARD IMAGING®

3120 DEMING WAY
MIDDLETON, WI 53562-1461 USA
WWW.STANDARDIMAGING.COM

Minimum System Requirements

Operating System	Windows® XP SP1
	Windows Vista®
	Windows® 7
Processor	Intel® or AMD® 600 MHz or greater
Memory	1 GB or greater
Hard Drive	250 MB or greater
Screen Resolution	1024 x 768 or higher recommended
CD-ROM Drive	2X speed or greater

Windows® and Windows Vista® are registered trademarks of Microsoft Corporation.

Product Standards: Designed to meet IEC 60601-1-4   C E

DICOM Router

Purpose

To allow for network transport of DICOM plan files for import into IMSure QA.

Function

The DICOM Router Module is an option to receive and, optionally, forward streams of DICOM data.

This module is not normally required for DICOM imports from most TPS systems.

However, it is useful for unix-based (ADAC and CMS) users who have purchased the DICOM option, and who wish to avoid 'ftp' file transfer, or who require this option because their TPS cannot send to more than one DICOM location. It is particularly useful for CMS users with Elekta systems that have limited options for DICOM export.

IMSURE QA™ SOFTWARE

Registering DICOM Router

An automated software-licensing algorithm is embedded into each Standard Imaging software application. Its intended use is to prevent piracy and unauthorized use of Standard Imaging software products. Standard Imaging utilizes a multi-layered encryption algorithm to ensure that only legally licensed end-users may access the protected software applications based on electronic security keys. Through an automated key creation and distribution process, Standard Imaging is able to provide a quick and completely automated means of licensing a software product.

Software Keys

Each Standard Imaging software application is issued a software key. The key is a series of numbers attached to the CD-ROM packaging. Each key is capable of registering a set number of computers. In the case of a computer failure it will be necessary to contact Standard Imaging to release the license that was used on the computer before another computer can be licensed using the supplied key. **NOTE: in the case of a computer requiring repairs, any changes to the computer hardware could result in the failure of the license for that computer.**

Upon running the software for the first time you will be shown the DICOM Registration form.
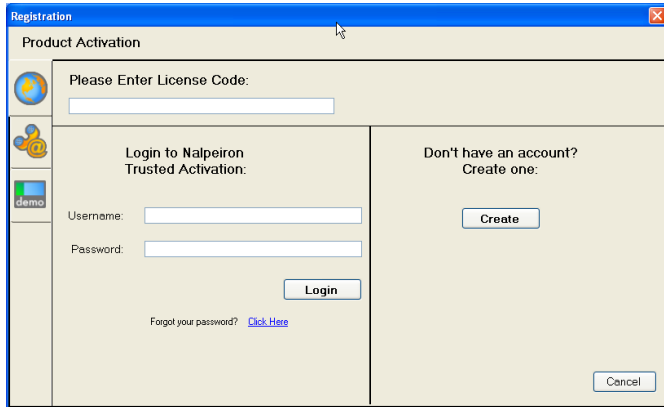
Authorization of a computer with internet access-Enter the License Code provided on the CD-ROM packaging.

If you have previously licensed a Standard Imaging product using the Nalpeiron licensing system enter the Username and Password previously created. If you do not remember your password click on the 'Forgot Your Password' link and you will be directed to the Nalpeiron website where you can retrieve it. If you continue to have problems please contact Standard Imaging support. NOTE: Please do not create a second account.

To create a new account click the 'Create' button and the following screen will be shown.
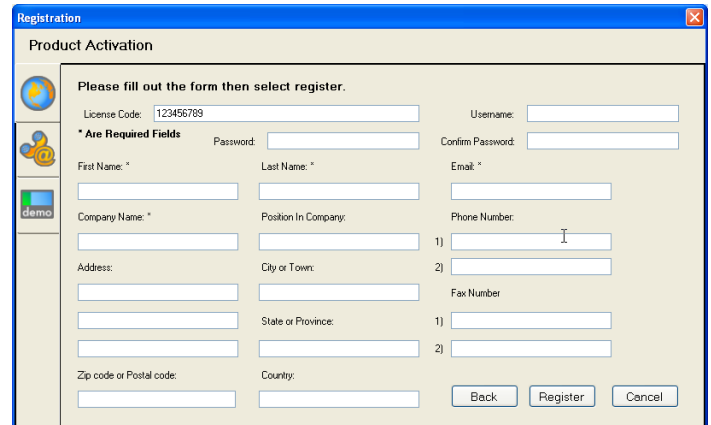
Create a Username and Password for the licensing system. Having an account set up will make it easier in the future if licensing issues need to be resolved. Fill in the requested information. NOTE: First Name, Last Name, Email Address, and Company Name are also required to be filled in.

Click the Register button to complete the registration process.

Authorization of a computer without internet access – If your computer is not connected to the internet or firewall issues prevent you from utilizing the web based registration click on the manual registration [ ] button. You will be shown the following screen:
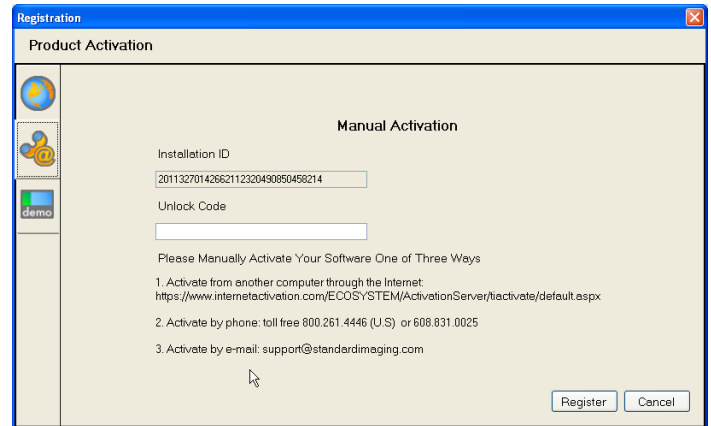
Copy the Installation ID number shown on your screen and follow the directions to either:

1. Activate from another computer that is connected to the internet
2. Call Standard Imaging for an unlock code
3. E-mail your ID to Standard Imaging and a unlock code will be returned to you within 1 working day.

Run the software in DEMO mode – If you are evaluating the software before purchase click on the demo button and the following screen will be shown:
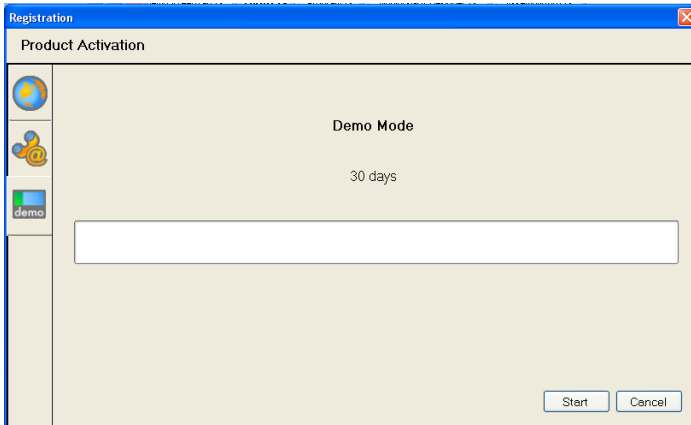
Clicking the 'Start' button will allow you to use the software application for a period of 30 days. Once this period has expired and you have not purchased a perpetual key, the registration software will disable the use of the software.

Transferring a license

All Standard Imaging software licenses are tied to the specific ID of the computer the software is installed and registered on. If your software is going to be removed from a computer, or if the computer that the software is installed on is no longer going to be utilized it is necessary to release the license that is in use for the installation.

Removing a license – Click on Help/License and the following screen will be shown:
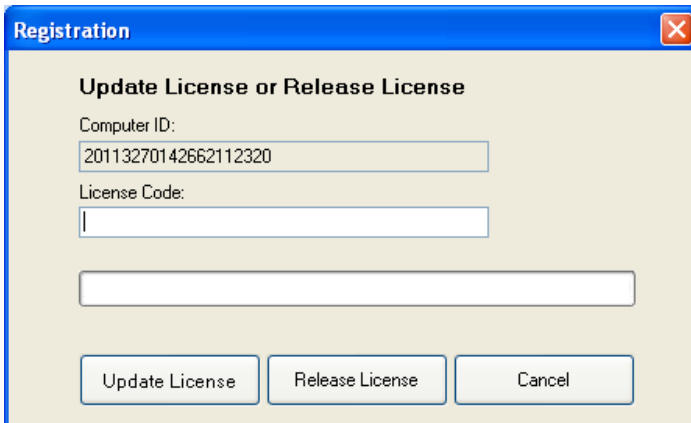
To remove the license from the computer enter your License Code and click the 'Release License Button'. If your computer is not connected to the internet, please contact Standard Imaging support for assistance.

Update License – Certain Standard Imaging software products are offered with optional modules that are activated based on a license code. If a product is purchased and in the future a new module is desired an update can be made to the license automatically. Standard Imaging support services will contact you and you will be asked to click on the 'Update License' button at the appropriate time.

DICOM Conformance Statement

This document is the DICOM Conformance Statement for DICOM Router included with IMSure QA Software. Contained in this statement are detailed descriptions of how the DICOM Router collaborates with other medical imaging devices and applications that conform to the DICOM 3.0 standard. The intended user of this document is involved with software design and system integration. It is understood that this individual is familiar with the concepts and terms used throughout this document. Readers unfamiliar with the DICOM 3.0 standard should consult the documentation prior to examining this conformance statement.

All necessary references and definitions have been taken from the Digital Imaging and Communications in Medicine (DICOM) standard, parts 1 through 13 (NEMA PS 3.1-13). All symbols and abbreviations used herein are described in the Digital Imaging and Communications in Medicine (DICOM) standard, parts 1 through 13 (NEMA PS 3.1-13).

Readers should note the following points:

- This document should not be interpreted as a guarantee of connectivity between the DICOM Router and any equipment and/or applications offered by other vendors.

- Integration of the DICOM Router with the equipment and/or applications of different vendors are outside the scope of the DICOM 3.0 standard and product conformance statements. Integration and interoperability of different equipment/applications are the sole responsibility of the user.

- In the case of any possible connectivity inferred by a user to exist between the DICOM Router and another product, the user is responsible for testing and verifying the inferred connectivity.

- Future changes to the DICOM 3.0 standard may require alterations to be made to the DICOM Router. Standard Imaging, Inc. reserves the right to modify the DICOM Router architecture as needed, in order to meet changing standards.

- The user should ensure that any existing DICOM equipment also changes with the future developments of the DICOM standards. Failure to keep pace with any alterations in the DICOM standards may result in decreased or lost connectivity.

Implementation Model

The DICOM Router runs as a program on all specified operating systems.

Functional Definitions of Application Entities

All communications and file transfer with the remote application is accomplished utilizing the DICOM protocol over a network using the TCP/IP protocol stack.

DICOM Router supports the following functions:

SCP
- Verification
- Storage

Application Entity Specifications

The DICOM Router services provide support for the following DICOM 3.0 SOP Classes as an SCP:

SOP Classes as SCP	
SOP Class UID	SOP Class Name
Verification	
1.2.840.10008.1.1	Verification
Storage	
1.2.840.10008.5.1.4.1.1.481.3	RTStructureSetStorage
1.2.840.10008.5.1.4.1.1.481.5	RTPlanStorage

Number of Associations

The DICOM Router can support multiple associations simultaneously as an SCP. The DICOM Router will listen for incoming associations and spawn a new process to manage each request. This ability means it is possible for the DICOM Router to receive files and from multiple SCUs simultaneously.

Asynchronous Nature

The DICOM Router does not support asynchronous operations. All operations will be performed synchronously.

Association Acceptance Policy

The DICOM Router accepts associations for the activities listed below:

- DICOM communication verification between the DICOM Router and a remote system.
- File transfer from a remote system to the DICOM Router.
- Processing remote system queries.

Verify Communication with a Remote System

The DICOM Router will send an echo response to verification requests made by remote systems.

Accepted Presentation Contexts

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name	UID		
Verification	1.2.840.10008.1.1	Implicit VR, Little Endian	1.2.840.10008.1.2	SCP	None

SOP Specific Conformance Statement for SOP Verification Class

The DICOM Router provides standard conformance for DICOM communication verification.

Receive files from a Remote System

A remote system pushes (i.e. sends) files to the DICOM Server. Upon completion of the transfer, the images are available locally and can be selected for display.

Accepted Presentation Contexts

Presentation Context Table for Receive from a Remote System					
Abstract Syntax		Transfer Syntax	UID	Role	Ext.Neg.
Name	UID				
RTStructureSetStorage	1.2.840.10008.5.1.4.1.1.481.3	Implicit VR, Little Endian	1.2.840.10008.1.2	SCP	None
RTPlanStorage	1.2.840.10008.5.1.4.1.1.481.5	Implicit VR, Little Endian	1.2.840.10008.1.2	SCP	None

SOP Specific Conformance Statement for SOP Storage Class

The DICOM Router conforms to the SOP's of the Storage SOP Class at Level 2 (full). No elements are discarded or coerced by the DICOM Router. In the case of a successful CSTORE operation the object has successfully been written to disk in the chosen directory. If a file is sent with the same SOP Instance UID (0008, 0018) as one that already exists on the chosen directory, the new file will replace the old file.

COMMUNICATION PROFILE

Supported Communication Stacks
DICOM Part 8 is supported by the DICOM Router through TCP/IP.
TCP/IP Stack
The TCP/IP stack supported by the DICOM Router is inherited from the host operating system (Microsoft® Windows®).

CONFIGURATION

Configuration Parameters
The following fields are configurable for the local application entity:
• Listening TCP/IP Port
• AE Title
• Storage Directory

SUPPORT OF EXTENDED CHARACTER SETS

No support of extended character sets is offered by the DICOM Router at this time.

COPYRIGHT

The DICOM Router was developed with the Leadtools DICOM SDK from Lead Technologies Incorporated

IMSURE QA™ SOFTWARE

Notes

IMSURE QA™ SOFTWARE

Notes

IMSURE QA™ SOFTWARE

Notes

IMSURE QA™ SOFTWARE

Customer Responsibility

This product and its components will perform properly and reliably only when operated and maintained in accordance with the instructions contained in this manual and accompanying labels. A defective device should not be used. Parts which may be broken or missing or are clearly worn, distorted or contaminated should be replaced immediately with genuine replacement parts manufactured by or made available from Standard Imaging Inc.

⚠ **CAUTION: Federal law in the U.S.A. and Canadian law restrict the sale, distribution, or use of this product to, by, or on the order of a licensed medical practitioner. The use of this product should be restricted to the supervision of a qualified medical physicist. Measurement of high activity radioactive sources is potentially hazardous and should be performed by qualified personnel.**

⚠ **WARNING: Proper use of this device depends on careful reading of all instructions and labels.**

⚠ **WARNING: Where applicable, Standard Imaging products are designed to be used with the versions of common radiation delivery devices, treatment planning systems and other products or systems used in the delivery of ionizing radiation, available at the time the Standard Imaging product is released. Standard Imaging does not assume responsibility, liability and/or warrant against, problems with the use, reliability, safety or effectiveness that arise due to the evolution, updates or changes to these products or systems in the future. It is the responsibility of the customer or user to determine if the Standard Imaging product can be properly used with these products or systems.**

Should repair or replacement of this product become necessary after the warranty period, the customer should seek advice from Standard Imaging Inc. prior to such repair or replacement. If this product is in need of repair, it should not be used until all repairs have been made and the product is functioning properly and ready for use. After repair, the product may need to be calibrated. The owner of this product has sole responsibility for any malfunction resulting from abuse, improper use or maintenance, or repair by anyone other than Standard Imaging Inc.

The information in this manual is subject to change without notice. No part of this manual may be copied or reproduced in any form or by any means without prior written consent of Standard Imaging Inc.

Serialization Information

Standard Imaging products that are serialized contain coded logic in the serial number which indicates the product, day and year of manufacture, and a sequential unit number for identification:

A YY DDD X

A   Unique product ID
YY   Last two digits of the year (e.g. 1999 = 99, 2000 = 00)
DDD Day of the year (1$\leq$ DDD $\leq$ 365)
X   Unique unit ID Number (1 $\leq$ X $\leq$ 9)

Warranty

Standard Imaging, Inc. sells this product under the warranty herein set forth. The warranty is extended only to the buyer purchasing the product directly from Standard Imaging, Inc. or as a new product from an authorized dealer or distributor of Standard Imaging, Inc.

For a period provided in the table below from the date of original delivery to the purchaser or a distributor, this Standard Imaging, Inc. product, provided in the table, is warranted against functional defects in design, materials and workmanship, provided it is properly operated under conditions of normal use, and that repairs and replacements are made in accordance herewith. The foregoing warranty shall not apply to normal wear and tear, or if the product has been altered, disassembled or repaired other than by Standard Imaging, Inc. or if the product has been subject to abuse, misuse, negligence or accident.

Product	Warranty Period
Standard Imaging Ionization Chambers	2 years
Standard Imaging Well Chambers	2 years
Standard Imaging Electrometers	5 years
Standard Imaging Software Products	1 year
All Other Standard Imaging Products	1 year
Standard Imaging Custom Product	90 days
Consumables	90 days
Serviced Product	90 days
Resale Products	As defined by the Original Equipment Manufacturer
ADCL Product Calibration (Standard Imaging uses the UW-ADCL for recalibrations required under warranty)	0 - 90 days = 100% of ADCL Calibration Costs 91 - 182 days = 75% of ADCL Calibration Costs 183 – 365 days = 50% of ADCL Calibration Costs 366 – 639 days = 25% of ADCL Calibration Costs (days from date of shipment to customer)

Standard Imaging's sole and exclusive obligation and the purchaser's sole and exclusive remedy under the above warranties are, at Standard Imaging's option, limited to repairing, replacing free of charge or revising labeling and manual content on, a product: (1) which contains a defect covered by the above warranties; (2) which are reported to Standard Imaging, Inc. not later than seven (7) days after the expiration date of the warranty period in the table; (3) which are returned to Standard Imaging, Inc. promptly after discovery of the defect; and (4) which are found to be defective upon examination by Standard Imaging Inc. All transportation charges (including customs, tariffs, duties and brokerage fees) are the buyer's responsibility. This warranty extends to every part of the product excluding consumables (fuses, batteries, or glass breakage) or material reactions. Standard Imaging, Inc. shall not be otherwise liable for any damages, including but not limited to, incidental damages, consequential damages, or special damages. Repaired or replaced products are warranted for the balance of the original warranty period, or at least 90 days.

This warranty is in lieu of all other warranties, express or implied, whether statutory or otherwise, including any implied warranty of fitness for a particular purpose. In no event shall Standard Imaging, Inc. be liable for any incidental or consequential damages resulting from the use, misuse or abuse of the product or caused by any defect, failure, malfunction or material reactions of the product, whether a claim of such damages is based upon the warranty, contract, negligence, or otherwise.

This warranty represents the current standard warranty of Standard Imaging, Inc. Please refer to the labeling or instruction manual of your Standard Imaging, Inc. product or the Standard Imaging, Inc. web page for any warranty conditions unique to the product.

Software License Agreement

Contains licensed program materials of Standard Imaging, Inc.
Copyright © Standard Imaging, Inc., Middleton, Wisconsin, USA

This software is protected by U.S. copyright laws, international treaties, FDA regulations, and other intellectual property laws and treaties.

This is a software license agreement to use the software product or products ("the product") enclosed in this package and described in the applicable purchase order or other ordering document. Standard Imaging, Inc., a Wisconsin corporation (Standard Imaging) hereby grants to the purchaser of the product ("Licensee") the right to use the product, together with its documentation and other related materials, only in connection the computers or computer network system located at the site of use ("the site") previously designated as such by Licensee and only if in strict compliance with the terms and conditions set forth below. Any purchase and installation or use of the product shall constitute acceptance of and agreement by Licensee to be bound by the terms and conditions hereof. Licensee also agrees that the agreement terms and conditions will prevail in the event of any conflict between the agreement applicable purchase order or other ordering document.

All rights not specifically granted to licensee under this software license agreement are reserved by Standard Imaging. The Standard Imaging documented Warranty and Customer Responsibility statements shall be considered to be part of this agreement. The term of this agreement and the licenses granted hereunder will continue in perpetuity, unless sooner terminated by Standard Imaging.

Licensee may:
a. Use the product only on a single computer or single network system at the site of use; and
b. Make backup copies of the product only for back-up, recovery and archival purposes.

Licensee may not and shall not:
a. Make copies of the product, except as otherwise permitted herein;
b. Rent, lease, sub-lease or otherwise permit any third party to use the product;
c. Redistribute any portion of the product, its software programs, documentation, or other related materials;
d. Other than as set forth in section 1.b. above, copy the product, any of its software programs, documentation or other related materials, without the express written permission of Standard Imaging;
e. Remove or obscure copyright and/or trademark notices appearing on the product;
f. Reverse engineer the product in order to derive or appropriate for any reason or purpose the source code or any other trade secret or other proprietary information; or
g. Transfer the software program of the product to another site or to a third party purchaser without the express written permission of Standard Imaging and agreement to all the terms and conditions of the then current software license agreement utilized by Standard Imaging by the authorized representative of the new site or such third party.

The Licensee shall be solely responsible for the installation of the product and any updates provided by Standard Imaging. Standard Imaging shall provide telephone technical support for the product for a period of (1) one year from the date of shipment. Any updates, upgrades and new releases to the product within the period of (1) year from date of shipment will be provided at no additional costs. After the expiration of the period of (1) year from the date of shipment, Standard Imaging will provide technical support, and updates, upgrades and new releases for an additional fee.

Standard Imaging shall not be liable for any amount in excess of the product costs actually paid by the Licensee giving rise to any claims hereunder. In no event shall Standard Imaging be liable, whether in contract, tort or otherwise for any indirect, incidental or consequential damages arising out of the subject matter of this agreement.

In the event of breach by Licensee of any of the terms and conditions of this software license agreement, Standard Imaging shall be entitled to enforce all legal rights and remedies conferred upon it by State of Wisconsin, federal, and/or international law. Standard Imaging and Licensee acknowledge that because breach by Licensee of any of the terms or conditions of this agreement will likely cause irreparable harm to Standard Imaging, injunctive relief would be an appropriate remedy for Standard Imaging resulting from any such breach by Licensee. In the event that action, suit, or legal proceedings are initiated or brought to enforce any or all of the provisions of this agreement, the prevailing party shall be entitled to such attorney's fees, costs, and disbursements as are deemed reasonable and proper by a court of law or an arbitrator. In the event of an appeal of an initial decision of a court or of an arbitrator, the prevailing party shall be entitled to such attorney's fees, costs, and disbursements as are deemed reasonable and proper by such appellate court.

Notwithstanding the foregoing, in the event of any breach by Licensee of the terms and conditions of this agreement, Standard Imaging may, upon reasonable advance written notice to Licensee (which in no event shall be less than thirty days), terminate this license. Upon such termination by Standard Imaging, Licensee shall furnish Standard Imaging with a sworn affidavit stating that all of the product, including, without limitation, its software program(s), documentation and other related material and any copies thereof, have been returned by certified mail, return receipt requested to Standard Imaging or destroyed by Licensee.

This agreement shall be deemed executed in the State of Wisconsin and shall be interpreted and construed in accordance with the laws of the State of Wisconsin. If any provision of this agreement is judicially declared to be invalid, unenforceable, or void by a court of competent jurisdiction, such decision shall not have the effect of invalidating or voiding the remainder of this agreement and the part or parts of this agreement so held to be invalid, unenforceable, or void shall be deemed to be deleted from this agreement and the remainder of this agreement shall have the same force and effect as if such part or parts had never been included.

IMSURE QA™ SOFTWARE