K980213

Addendum to 510(k) for DICOM Client
K955708

510(k) Summary

MAR 17 1998

1. Identification

Date: January 7, 1998

Submitter: Lumisys, Inc.
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Tucson, AZ 85715

Contact: Trindy LeForge
(520) 751-6842
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2. Device Name

Trade Name: DI-2000
Common Name: DICOM Client

3. Registration Number

2029024

4. Classification

No formal classifications have been issued for PACS or PACS components. For purposes of determining substantial equivalence they have been considered to be accessories to medical imaging devices. A stationary x-ray system is a permanently installed diagnostic system intended to generate and control x-rays for examination of various anatomical regions. Accessories to a stationary x-ray system, such as digitizing application software, have been classified as Class II Radiology Devices under 21 CFR 892.1680.

5. Standards

Performance: None established.
Voluntary: ACR/NEMA DICOM 3.0

Requirements of 21 CFR 1020.10.

CCITT (Consultative Committee on International Telephone and Telegraph) and ISO/IEC 10918-1 for compression.

6. Labeling

See Appendix A.

7. Safety and Effectiveness Information

Hazard Analysis

Formal analysis of the design for potential and existing hazards takes place during the requirements phase, the design phase, and during the testing phase. All potential existing hazards are analyzed using the following steps:

- Hazard Identification — Determine if hazard exists in the product.
- Level of Concern — Determine whether the hazard is of minor, moderate, or major concern.
- Possible Causes — Determine all possible causes through analysis or testing.
- Methods of Control — Identify possible methods of controlling or eliminating the hazard.
- Corrective Action — Decide upon corrective action to mitigate the hazard.

The DI-2000 software was analyzed for potential hazards. A summary of hazards that were considered and found not to be exposures in the design of DI-2000 are included in Appendix E.

Level of Concern

The level of concern for the DI-2000 software is considered low for the following reasons:

1. If the transfer of data cannot be completed without compromising the image quality, the transaction cannot be completed, and therefore, the image quality cannot be lost.
2. The system provides checks and balances for potential user errors, such as failing to save images, or assigning duplicate IDs. The system will not allow users to proceed until images are cleared or saved appropriately.
3. These checks and balances are re-validated with each release of the product. Separate test plans exercise these specific points within the system. Products are not released until all checks and balances are fully validated.

8. Photographs

See Appendix B.

9. Device Description

A detailed description of each of all functions is contained in the Functional Requirements Specification, included as Appendix B. The following feature comparison provides an easy way to identify the changes between the initial 510(k) for DICOM Client submitted December 1995, and this addendum for DI-2000.

Features	DICOM Client	DI-2000
Patient Information Modification	Y	Y
Delete Patient Information	Y	Y
Fax Report	Y	N
Print DICOM Image	Y	Y
Export DICOM images to TIFF	Y	N
Annotate DICOM Images	Y	N
Window/Level Preset Settings	Y	N
Image Flip	Y	Y
90 degree Image Rotation	Y	Y

Features	DICOM Client	DI-2000
180 degree Image Rotation	Y	Y
Black/White Inversion	Y	Y
Multiple Image Display	Y	N
Token/Iconic Display	Y	Y
DICOM Send	Y	Y
DICOM Receive	Y	Y
DICOM Query User	Y	N
DICOM Query Provider	Y	Y
DICOM Retrieve User	Y	N
DICOM Retrieve Provider	Y	Y
DICOM Echo	Y	Y
LAN/WAN Communication	Y	Y
Zoom/Unzoom	Y	N
Copy to Clipboard	Y	N
JPEG Compression lossy/lossless	Y	Y
*i*JPEG Compression	Y	Y
Analog modem support	Y	Y
Lumisys Film Digitizers connection capability	Y	Y
Industry Standard Digital Communication Support	Y	Y
Display Resolution	Up to 2K	Up to 2K
Communication Media Supported	ATM, ISDN, Analog modems, Ethernet, FDDI, Token Ring, Analog Phone Lines	ADSL, Cable Modem, Routers, Brouters, Internet, ATM, ISDN, Analog modems, Fast Ethernet, Gigabit Ethernet, Ethernet, FDDI, Token Ring, Analog Phone Lines
DICOM Print	N	Y
Images Displayed	CT, MR, US, CR, NM, Plain Films	CT, MR, US, CR, NM, Plain Films
Color Images	Y	Y
Cine Loop Viewing	Y	Y
Measurement Tools	Y	Y
DICOM Removable Media Support	N	Y
Wavelet Compression	N	Y

DI-2000 Components

The following is a list of the minimum recommended requirements for the DI-2000 software:

1. Pentium 200MHz CPU or equivalent.
2. 64MB of RAM
3. 2MB video board capable of 1024-by-760 screen resolution at 16K colors.
4. 14-inch monitor capable of displaying a 1024-by-760 screen.
5. 2GB local hard drive
6. Iomega Corp JAZ drive for local archive and redundancy capabilities.
7. Network connection of 10/100 Base-T Ethernet card.

8. Microsoft Windows NT Workstation 3.51 or 4.0 operating system with Service Pack 3 or later.
9. Sybase SQL Anywhere installed as the local database.
10. Symantec Corp. pcANYWHERE version 8.0.

10. Comparison with Equivalent Devices

Lumisys, Inc., believes that DI-2000 is substantially equivalent to the following medical devices in commercial distribution:

Manufacturer	Product (Trade Name)	510(k)#	Decision Date
Howtek, Inc.	Digitizer Director ™	K972191	9/8/97
DeJarnette Research Systems	ImageShare Film Digitizer 1000™	K963628	11/7/96
DeJarnette Research Systems	ImageShare Secondary Capture Acquisition Station; ImageShare Computed Radiography Acquisition Station	K963594	11/7/96
Mitra Imaging, Inc.	Film Express	K970652	5/2/97

Feature Comparison

Feature	DI-2000	Digitizer Director™	ImageShare™	Film Express
Bulk Transfer	Y	N	N	N
DICOM 3.0 Compliance	Y	Y	Y	Y
Windows NT 4.0	Y	Y	N	Y
Internet Connectivity	Y	Y	Y	N
Variable Compression	Y	N	Y	N
Wavelet Compression	Y	N	N	N
JPEG Lossless, Lossy, Enhanced Compression	Y	N	N	Y
Remote Administration and Management Support	Y	N	N	N
Image Processing Algorithm	Y	N	MANUAL	N
Automatic Disk Maintenance	Y	N	N	N
Auto-Transmit	Y	N	N	Y
Supports Lumisys, Inc., digitizers and Computed Radiography	Y	N	Y	Y
Quality Assurance Function	Y	Y	Y	Y
Patient Identification on the Plate	Y	N	N	N
Local Archive Functionality	Y	Y	N	N
Batch Mode Scanning	Y	Y	N	N
Network Printing Support	Y	N	Y	N
Confirmed Delivery	Y	N	N	Y

11. Image Compression Technology

DI-2000 supports the following compression methodologies:

Compression Type	Algorithms
Lossless	In hardware, via network
	JPEG
	Wavelet
Lossy	JPEG
	Wavelet

In general, the software conforms to the image formats described in the DICOM standard.

Wavelet compression description.

DI-2000 supports the use of wavelet compression in addition to JPEG (described in detail in the original submission of the 510(k), K955708, December 5, 1995.) Images that have been compressed using the wavelet technique are included in Appendix B.

Wavelet transform based compression involves the representation of an image at a variety of scales of resolution. The wavelet transform itself is performed by repeatedly filtering the image with a pair of high and low pass digital filters which obey strict mathematical constraints. Often referred to as a multi-resolution decomposition, the wavelet transform allows fine details in an image (otherwise known as "contrast" information) to be separated from larger scale trends. In this implementation, the requested compression ratio controls the degree of contrast identified. After an image has undergone a wavelet transform, an effort is made to detect those regions of the transform which have little or no contrast. Once such a region has been identified, it is quantized (stored with fewer bits of precision than those parts of the transform which appear important). It is in the quantization steps that all loss occurs. Once quantization is performed, it is not possible to retrieve the original, higher precision representation. Following quantization, standard lossless compression techniques are used which includes run-length encoding. These techniques perform quite well as they are generally operating on data which contains large runs of zero with no appreciable effect on image quality.

As the rows of the image are sent to the compressor, the lengths are padded to a multiple of 16 and then the row transform is performed. After all of the lines have been sent, the last line is copied as many times as needed to pad the height to a multiple of 16. The image is then sent off to have its columns transformed; this completes the first-level decomposition

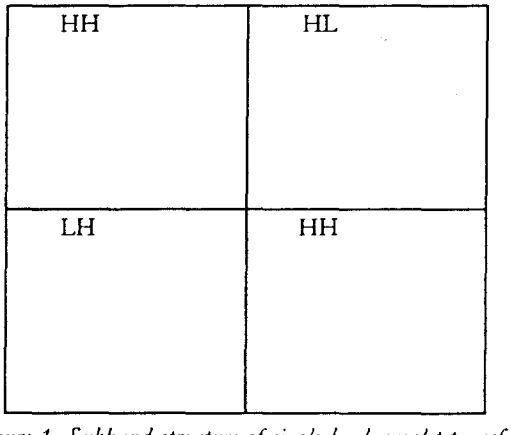

Figure 1 Subband structure of single-level wavelet transform

For each of the three high-frequency quadrants, an energy mapping is computed. Each quadrant is broken up into 8x8 sub-blocks and the energy of each sub-block is computed.

These energy values are sent off to a clustering algorithm which partitions them into 4 levels. Each 8x8 sub-block in the quadrant is labeled with one of the four levels. The resulting three mappings are stored to be used later in partitioning of the subbands.

1	1	2	4
3	3	2	2
1	4	3	3
1	2	2	1

Figure 2 Example of energy partitioning map of a high-frequency quadrant.

The decomposition is finished by doing one more level in the high frequency quadrants and then performing the standard decomposition in the LL quadrant until the lowest resolution subband image dimensions are at some specified level.

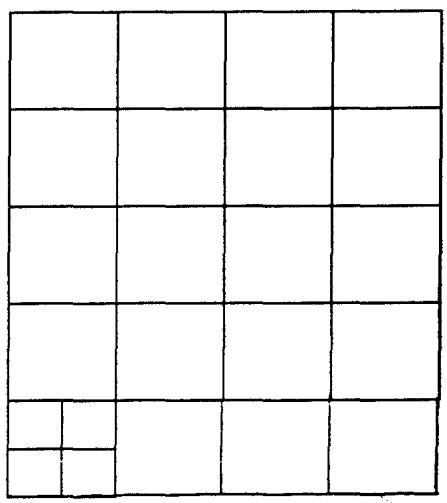

Table 3 Subband structure of a full wavelet decomposition.

After the decomposition, the 2^{nd} , 3^{rd}, and 4^{th} level subbands are each partitioned into 4 sequences by the mapping constructed in step 2. The 2^{nd} level subbands are subdivided into 4x4 subblocks and one of the mappings is superposed on this subdivision. The 3^{rd} level subbands are subdivided into 2x2 subblocks and, again, one of the mappings are superposed on this subdivision. Finally, one of the mappings is superposed onto the 4^{th} level subbands. Recall that in step 2, three mappings were constructed. The particular mappings applied to each of the 2^{nd}-4^{th} level subbands can be obtained by referring to figure 3. These mappings partition each of the 2^{nd}-4^{th} level subbands into 4 sequences which constitute one part of the bands making up the transfomed data Each of the remaining higher level subbands form the other set of transform bands. For each transform band, we calculate the normalized kurtosis, the 4^{th} moment divided by the squared variance, and then matched to a generalized Gaussian distribution. The normalized kurtosis of a generalized Gaussian distribution with exponent α and variance σ^2 is given by

$$\frac{E[x^4]}{\sigma^2} = \frac{\Gamma(\frac{5}{\alpha})}{\Gamma(\frac{3}{\alpha})\Gamma(\frac{1}{\alpha})},$$

where Γ is the ordinary Gamma function. The kurtosis is then matched to one of the predetermined generalized Gaussian exponents .5, .75, 1.0, 1.5, 2.0. This exponent, along with the variance, is used to supply the generalized Gaussian pdf model for the given transform band.

The transform bands, along with there model parameters α and σ^2 and the length of the band, are sent to a bit-allocator which then returns the step sizes to be used in the quantization of each transform band.

12. Test Data and Conclusions

See Appendix B.

13. Software Information

For a list and brief description of software functions, a description of the software development methods, and a description of software test procedures, see Appendix C.

14. Truthful and Accurate Statement

As required by 21 CFR 807.87(j) a Truthful and Accurate Statement is contained in Appendix D.

15. Confidentiality

Portions of the attached enclosure are confidential.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Trindy LeForge
Director, Quality Assurance
Lumisys, Inc.
1350 North Kalb Road
Tucson, Arizona 85715

Re: K980213
DI-2000 (Digital Interface)
Dated: January 7, 1998
Received: January 9, 1998
Regulatory class: Unclassified
Procode: 90 LMA

MAR 17 1998

Dear Mr. LeForge:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Addendum to 510(k) for DICOM Client (K955708)
510(k) Summary
Lumisys, Inc.

510(k) Number: ~~K955708~~ K980213

Device Name: DICOM Client
DI-2000

Indications for Use:

DI-2000 is intended to utilize a scanner and software interface to digitize either radiology film or computed radiography exposed phosphor plates.

DI-2000 is a DICOM 3.0 compliant radiological digitization application.

DI-2000 enables the user to autoarchive lossless or lossy compressed images locally or at a remote archive site. Supports DICOM 3.0 Query and Retrieve Service Class.

Supports scanning of films or phosphor plates in batch mode prior to entering patient information. Once scanned, images can be sent to multiple destinations.

Users:

The DI-2000 will be located in a radiology department or clinic, or in a mobile radiology van. DI-2000 will support reading and digitizing exposed CR plates or radiology film. The expected users are as follows:

Radiologists
Radiology Technologists
System Administrator within the radiology department

David L. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K980213

Prescription Use ✓
(Per 21 CFR 801.109)