

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

Re: 510(k) Submission
Picture Archiving and Communication System (PACS)

Date: November 25, 1992

Attention: Document Mail Clerk

Enclosed is our submission under 510(k) of the Food, Drug, and Cosmetics Act for a Picture Archiving and Communication System (PACS) - commercial name **RSTAR Image Management System (RSTAR-IMS)**. We propose that this system be categorized as Class II (Special Controls).

We trust you have no problems with our intent. If you have any questions, please contact me at (617) 726-8381. I look forward to receipt of your acknowledgment letter and your technical review.

Sincerely yours,

Maria Kaldis
VP Administration
RSTAR, Inc.

Enclosure

510(k) Statement

I certify that I, Maria Kaldis, will make available all information included in this premarket notification, for the RSTAR Image Management System, on safety and effectiveness that supports a finding of substantial equivalence within 30 days of request by any person. The information I agree to make available does not include confidential patient identifiers.

Maria Kaldis
Vice President Administration

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This submission generally follows the format of FDA's February 1991 draft Guidance For the Content and Review of 510(k) Notifications for Picture Archiving and Communications Systems (PACS) and Related Devices.

1. General Information

1.1. Name and address of manufacturer

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Primary Contact

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RSTAR, Inc.

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1.2. Establishment registration number

The company has not yet submitted an establishment registration form to FDA's Device Registration and Listing Branch but will do so within 30 days of engaging in an activity which requires registration.

1.3. Common and proprietary names of the device

Common Names: **PACS Equipment, PACS Components**

Proprietary Names:

RSTAR Image Management System (RSTAR-IMS)

RSTAR Components:

- **RSTAR Image Server (RSTAR-IS)**
- **Diagnostic Workstation (DWS)**
- **Clinical Review Station (CRS)**
- **TouchPanel Viewstation (TPV)**
- **Demographic Entry Station (DES)**
- **Image Acquisition Station (IAS)**
- **Image Printing Station (IPS)**

1.4. Class

No formal classifications have been issued by FDA for PACS or PACS components. For purposes of determining substantial equivalence, they have been considered by FDA to be accessories to medical imaging devices. Accordingly, RSTAR, Inc. intends to market the RSTAR Image Management System as if it has been classified into: Class II (Special Controls).

1.5. Applicable Standards

1.5.1. Food Drug and Cosmetic Act (FDCA)

No performance standards for PACS systems or components have been issued under the authority of section 514.

1.5.2. Radiation Control for Health and Safety Act

Video Monitors (21 CFR 1020.10)

RSTAR, Inc. is not a manufacturer of video monitors.

RSTAR, Inc. purchases off-the-shelf monitors for use in its RSTAR Image Management System product, and to the best of its knowledge, believes that such monitors comply with all applicable 21 C.F.R. 1020.10 standards.

Fiber optic communications, Laser digitizers, laser printers, optical disc storage devices (21 CFR 1040.10)

RSTAR, Inc. is not a manufacturer of laser fiber optic communications equipment, laser digitizers, laser printers or optical disc storage devices. RSTAR, Inc. has incorporated a 510(k)-cleared laser film digitizer [the Lumisys Lumascan Digitizer (K901423/A)] and a 510(k)-cleared laser film printer [the 3M Laser Imager XL (K910092/A)] for use in its RSTAR Image Management System. RSTAR, Inc., to the best of its knowledge, believes that these devices/components comply with all applicable 21 C.F.R. 1040.10 standards.

1.5.3. Voluntary Standards

SMPTE

RSTAR, Inc. uses the SMPTE test pattern standard to test the display monitors in the Diagnostic Workstation, Clinical Review Station and the TouchPanel Viewstation.

ACR/NEMA • Data Exchange Standard

RSTAR, Inc. complies with the draft ACR/NEMA Data Exchange Standard (also referred to as DICOM-3) and uses it as part of the internal data structures for patient demographics, study information, image information and image data.

ACR/NEMA • Data Compression Standard

RSTAR, Inc. does not use any data compression in its RSTAR-IMS.

HL-7 • Hospital Level Seven • Information Systems Data Exchange Standard

RSTAR, Inc. complies with the HL-7 Standard for information systems and will interface to HL-7 compliant Hospital Information Systems (HIS) or Radiology Information Systems (RIS).

Underwriters Laboratories

RSTAR, Inc. plans to comply with the UL Standard No. 1950. The RSTAR-IMS will be submitted to UL testing during the second quarter of 1993.

RSTAR, Inc. further plans to comply with the following standards:

- FCC part 15
- CSA 220-1950
- TUV or VDE EN950

The RSTAR Image Management System will be submitted for compliance testing for the above standards during the second half of 1993.

RSTAR, Inc. does not intend to market the RSTAR Image Management System product in the United States until UL and FCC compliance testing has been satisfactorily completed.

RSTAR, Inc. does not intend to market the RSTAR Image Management System product in Canada until CSA compliance testing has been satisfactorily completed.

RSTAR, Inc. does not intent to mark the RSTAR Image Management System product in Europe until TUV or VDE compliance testing has been satisfactorily completed.

2. Device Description: Summary of Functions

2.1. The RSTAR Image Management System

The RSTAR Image Management System is a Picture Archiving and Communication System (PACS) that is intended to provide rapid access to radiographic data (specifically, high-resolution images) throughout the Radiology Department as well as the entire hospital. The system offers solutions to many common operational problems facing most radiology departments. The most notable being:

- Radiographic films can be in only one place at a time.
- Radiographic films must be transported physically throughout the hospital complex.
- Radiographic films are easily lost or misplaced in their travels within the hospital complex.
- Radiographic films are difficult to file and archive.
- At the time of interpretation, it is difficult to make available all prior radiographic studies for comparison.
- Imaging clinics/centers are becoming geographically separated from the Radiologists who are responsible for the interpretations.

The RSTAR Image Management System strives to solve these problems by 1) providing multiple means for inputting radiographic data (images, text reports, graphics, and digital voice) into the RSTAR-IMS from a multiplicity of sources, 2) providing a hierarchical digital image and demographic storage architecture utilizing both magnetic disk storage and optical disk storage, 3) providing networked data communications between the sub-systems of the RSTAR-IMS utilizing high-speed optical networks as well as public switched telecommunication networks, 4) providing multiple means for the display of radiographic images and related data using both high-resolution and medium-resolution image viewing stations, 5) providing means for laser-film printing to generate hard-copy images, and 6) providing means for the coordination and validation of all the functions of the RSTAR-IMS.

Specifically, the RSTAR-IMS will:

- Collect and manage patient demographics, study demographics, image demographics, and radiographic image data
- Acquire radiographic image data from:
 - Conventional film radiographs via a laser film digitizer
[using the 510(k)-cleared Lumisys Lumascan Digitizer (K901423/A)]

- Phosphor plate radiographs from a Computed Radiography Unit via the ANALOGIC DASM™-XPRF SCSI Interface
- Computed Tomography Scanners via the industry standard DICOM-3 (formerly ACR/NEMA)
- Magnetic Resonance Imaging Scanners via the industry standard DICOM-3 (formerly ACR/NEMA)

- Store radiographic images in a high-speed image cache, consisting of magnetic disk drives, for active patients

- Store radiographic images in an optical disk jukebox archive (described in Exhibit A) for inactive patients

- Perform softcopy display on high-resolution (2K) viewing stations

- Perform softcopy display on medium-resolution (1K) viewing stations

- Perform softcopy display on high-resolution and medium-resolution viewing stations with simple to use membrane switch operation with no need for keyboard or mouse interaction

- Perform soft copy image viewing with real-time window and center (described in Exhibit A)

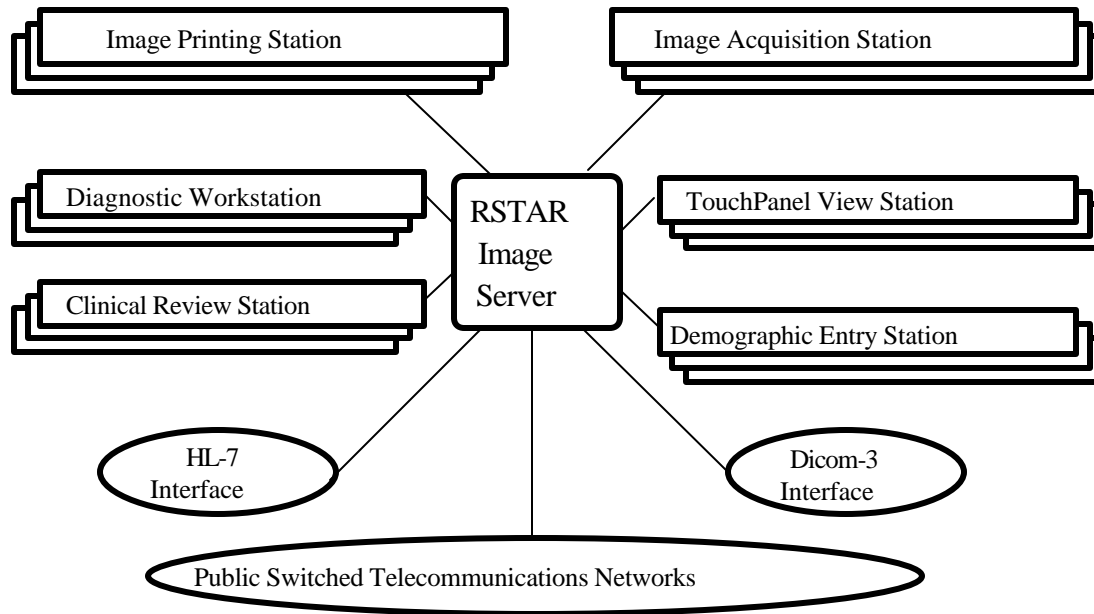
- Perform soft copy image viewing with 2x and 4x magnification using bi-linear interpolation

- Perform soft copy image viewing and simultaneous image comparison on viewing stations with two or more display monitors

- Interface to high-resolution laser film printers capable of a 4000 x 5000 pixel image of 12 bit depth
[using the 510(k)-cleared 3M Laser Imager XL (K910092/A)]
- Offer digitized voice notations on a per study basis
- Offer text notations on a per study basis
- Offer simple demographic entry functionality for patient demographics and scheduling information via keyboard and mouse interaction
- Offer automatic entry of patient demographics and scheduling information from Hospital Information Systems (HIS) or Radiology Information Systems (RIS) using the industry standard Hospital-Level-7 interface (HL-7)
- Distribute information over a dual network with:
 - Command and control information, database information and image acquisition data transmission over the industry standard International Electrical and Electronic Engineers (IEEE) 802.3 Local Area Network (sometimes referred to as Ethernet)
 - Image data transmission from the short-term image cache to the viewing stations and printing station over a 100 megabit/second fiber optic network configured in a star topology
- Generate system usage, audits, events and error logs
- Generate patient, study and image reports
- Offer built-in remote diagnostics for system monitoring, software updates, and system support

The RSTAR-IMS consists of various components that acquire, transfer, store, display and print patient demographics, study information and radiographic image data.

RSTAR Image Management System



Listed below are brief descriptions of the components that form the RSTAR-IMS:

- RSTAR Image Server (RSTAR-IS)**
 The RSTAR-IS is the electronic equivalent of a film library and a medical records department. It is the central depository for all the information acquired by the RSTAR-IMS. Additionally, it controls the overall functions of the RSTAR-IMS. It contains the RSTAR database with patient demographic records and study information records and manages the high-speed image cache which stores the radiographic image data for active patients and the optical disk jukebox archive for inactive patients. Using the monochrome monitor, a System Administrator may configure, monitor, and track usage of the RSTAR-IMS.
- Diagnostic Workstation (DWS)**
 The DWS is the electronic equivalent of a "light box," a back lit frame where radiographic films are hung for review. It displays patient demographics, study information and image data on high-resolution (2K) monitors. On stations with two or more screens, a current image can be viewed simultaneously with a comparison image. A clinician or radiologist may add voice notations to the study being viewed or listen to previously recorded voice notations. A clinician or radiologist may also add text notations to the study being viewed or read previously saved text notations.

Additionally, patient images may be queued to print to the Image Printing Station. The DWS offers a variety of image processing and manipulation tools.

- **Clinical Review Station (CRS)**

The CRS is the electronic equivalent of a "light box." It displays patient demographics, study information and image data on medium-resolution (1K) monitors. On dual screen stations, a current image can be viewed simultaneously with a comparison image. A clinician or radiologist may add voice notations to the study being viewed or listen to previously recorded voice notations. A clinician or radiologist may also add text notations to the study being viewed or read previously saved text notations. Additionally, patient images may be queued to print to the Image Printing Station. The CRS offers a variety of image processing and manipulation tools.

- **TouchPanel Viewstation (TPV)**

The TPV is the electronic equivalent of a "light box." It displays patient demographics, study information and image data on high-resolution (2K) or medium-resolution (1K) monitors. On dual screen stations, a current image can be viewed simultaneously with a comparison image. A clinician or radiologist may add voice notations to the study being viewed or listen to previously recorded voice notations. A clinician or radiologist may read previously save text notations. Additionally, patient images may be queued to print to the Image Printing Station. Membrane switches control user interaction with the TPV. There is no need for a keyboard or mouse.

- **Demographic Entry Station (DES)**

The DES is a demographic entry station designed specifically for the RSTAR-IMS. The DES manages patient text and voice information. Demographics for new patients may be added at the DES. Additionally, patient demographics, patient location and study information may be modified as necessary. Voice and text notations for particular studies may be added or modified and patient images may be queued to print on the Image Printing Station.

- **Image Acquisition Station (IAS)**

The IAS acquires radiographic data and associated patient and study information from a variety of modalities. Using a laser film digitizer, it scans conventional x-rays and converts them to digital image data. Using the ANALOGIC SCSI Interface, it collects phosphor plate image data. Once acquired, the image data is transferred to and stored in the RSTAR-IS.

- **Image Printing Station (IPS)**

The IPS is a stand-alone networked printing station that interfaces to a laser film printer. Images can be queued to print from the DWS, CRS, TPV, and DES.

- **DICOM-3 Interface**

The RSTAR Image Server supports a DICOM-3 interface to compliant imaging devices (i.e. CT scanners, MRI scanners, etc.). The interface allows for the acquisition of direct digital data and patient information from the imaging scanners.

- **HL-7 Interface**

The RSTAR Image Server supports an HL-7 interface to compliant RIS/HIS. The interface allows for automatic acquisition of demographic and scheduling information for patients in the system.

- **Public Switched Telecommunication Network**

The components of the RSTAR Image Management System, such as the Image Acquisition Station, the Image Printing Station and the viewing stations, will operate over the public switched telecommunications networks (i.e. 19.2K, 56KB, switched 56KB, T1, switched T1 and DS3).

RSTAR-IMS usage within the hospital environment

The Image Acquisition Station (IAS) digitizes plain films or acquires phosphor plate images into the RSTAR-IMS. Existing films are digitized by the IAS and translated into a digital image data comprised of thousands of dots, or pixels. When a series of images is acquired, the IAS sends the image data to the RSTAR Image Server over an IEEE 802.3 Local Area Network. The display monitors on the IAS will allow for preview of images before transmission for verification of proper image orientation and acquisition. CT and MRI images are collected automatically over the DICOM-3 interface and stored in the RSTAR Image Server.

Images transmitted from the IAS will be stored in the RSTAR Image Server. The RSTAR-IS emulates a film library. It organizes images so that a radiologist or a clinician can request them later. However, unlike films, several clinicians in different locations can request and review the same image simultaneously. Any image viewing station linked to the RSTAR-IS can access any of the stored images. The RSTAR-IS also maintains the RSTAR database with patient demographic records and study information records.

The Diagnostic Workstation, Clinical Review Station, and the TouchPanel Viewstation will allow a radiologist or a clinician to examine the images stored in the RSTAR Image Server. The radiologist may request images for a particular patient. The image server will transmit the selected images to the image viewing station where they will be displayed on a high-resolution (1792 x 2250) or medium resolution (1152 x 882) gray-scale monitor. Viewing stations with two or more monitors can display images from two studies simultaneously for comparison. A set of knobs at the viewing stations will allow the radiologist or clinician to adjust the window and center of the image displayed.

The Demographic Entry Station located in the radiology department will allow the system administrator to review and maintain patient information, and to track patient activity and patient radiographic studies. The set of films generated from a single radiological examination form a study.

The RSTAR-IMS organizes information into work queues, which are a collection of related studies. Every study in the RSTAR-IMS belongs to a particular patient. Every image in the RSTAR-IMS belongs to a particular study. Work queue organization is hospital specific and follows the operations of the radiology department. Some radiology departments group work according to modalities (i.e. CT, MRI, US, etc.), others group work according to body systems (i.e. head, heart, abdomen, extremities, etc.). The RSTAR-IMS stores standard demographic information about a patient as well as the patient's clinical history. This patient information can be entered when the first study for the patient is acquired into the system through the IAS, or it can be entered at a Demographic Entry Station. Additionally, patients in the system can be assigned to a specific location, usually an intensive care unit. As represented in the table below, every patient has a standard set of demographics and one or more studies that may contain one or more images. Additionally, patients may be assigned a location.

RSTAR-IMS

Organization of Medical Information

Location		Work Queue-1	Work Queue-2	Work Queue-3	● ● ●	Work Queue-xx
ICU-1	Patient-1 Demographics	Study 4 Images ...		Study 2 Images		Study 1 Image ...
ICU-2	Patient-2 Demographics		Study 2 Images ...	Study 1 Image		
	Patient-3 Demographics	Study 1 Image	Study 4 Images ...	Study 10 Images		Study 2 Images
ICU-2	Patient-4 Demographics		Study 2 Images ...	Study 1 Image		
	Patient-5 Demographics	Study 3 Images	Study 4 Images ...	Study 2 Images		Study 2 Images
	● ● ●					
ICU-XX	Patient-xx Demographics	Study 5 Images	Study 10 Images ...	Study 4 Images ...		Study 10 Images

Each study contains a standard set of study information and may contain text and/or voice notations. Additionally, patients may or may not be assigned to a location. Typically, images from only one study are viewed at a time. On image viewing stations with two or more display monitors, images from two different studies for one patient can be viewed simultaneously.

The RSTAR Image Management System follows the client/server model where the RSTAR Image Server contains the servers that the clients (DWS, CRS, TPV, DES, IAS and IPS) can access. The clients access the servers for information regarding the patient, study, image data, system audit logs, system event logs, system usage logs, and system error logs. Image data for active patients is stored in the high-speed image cache composed of magnetic disk drives that are tightly-coupled to the 100 megabit optical start network. This network gives the IRS's approximately two second access to any image stored in the RSTAR-IS. Image data for inactive patients is stored in optical disk jukebox archive. The RSTAR-IS also contains the RSTAR Database with patient demographic records and the study information records. Additionally, the RSTAR-IS contains the overall system control software that manages the RSTAR-IMS. Patient demographics and study information gathered at the Demographic Entry Stations (DES) or at the Image Acquisition Station (IAS) are collected and stored in the RSTAR-IS in the RSTAR database.

The DWS, CRS, TPV, DES, IAS, IPS and the RSTAR-IS Administrator's Console are Apple Computer-based and conform to the Apple Computer Inc., Macintosh human interface guidelines, meaning the system components are highly intuitive for radiologists, clinicians, and other users. The software has a consistent user interface between all components.

Section 2.2 below contains a system diagram illustrating the RSTAR Image Management System. The interconnections of the components with interfaces and physical media specifically labeled are shown. The RSTAR-IMS does not employ data compression and, therefore, no compression ratios are indicated.

Sections 2.3 through 2.9 below fully describe the individual RSTAR Image Management System Components and detail their characteristics, means of operation and specifications.

2.2. System Diagram: RSTAR Image Management System

2.3. RSTAR Image Server (RSTAR-IS)

The **RSTAR-IS** will control the overall activity of the system as well as be the repository for the diagnostic and usage data. As shown on the diagram in section 2.2, the RSTAR Image Server is the hub of the RSTAR-IMS; all other components are connected to it. The list below is a summary of the functions provided by the RSTAR-IS.

1. The **RSTAR-IS** will coordinate overall system activity.
2. The **RSTAR-IS** will maintain and store the RSTAR Database.
3. The **RSTAR-IS** will maintain and store patient demographic records.
4. The **RSTAR-IS** will maintain and store study information records.
5. The **RSTAR-IS** will maintain and store radiographic image data for active patients in the image cache.
6. The **RSTAR-IS** will maintain and store radiographic image data for inactive patients in the optical jukebox archive.
7. The **RSTAR-IS** will manage its storage assets and will move image data for inactive patients from the image cache to the optical jukebox archive.
8. The **RSTAR-IS** will maintain and store the voice notations on a per study basis.
9. The **RSTAR-IS** will maintain and store the text notations on a per study basis.
10. The **RSTAR-IS** will compile, and optionally print, system audit, usage, event and error logs.
11. The **RSTAR-IS** will compile, and optionally print, reports of images stored, images recalled, images printed, and total patients in system.
12. The **RSTAR-IS** will support a System Administrator's Console for periodic maintenance and status investigation.
13. The **RSTAR-IS** will contain system level diagnostic and consistency software.
14. The **RSTAR-IS** will store images transmitted from an **IAS**.
15. The **RSTAR-IS** will contain the DICOM-3 interface for acquiring data from compliant CT and MRI Scanners.
16. The **RSTAR-IS** will contain the HL-7 interface for acquiring data from compliant RIS's and HIS's.

RSTAR Image Management System (RSTAR-IMS)

RSTAR, Inc.

510(k) Notification

17. The **RSTAR-IS** will transmit images to the **DWS, CRS, TPV, and IPS** over the 100 megabit/sec fiber optic network in a star topology.
18. The **RSTAR-IS** will manage queued printing to the Image Printing Station.
19. The **RSTAR-IS** will manage transaction event logging to record image digitizing, printing, and transfer to archive.
20. The **RSTAR-IS** will manage internal system integrity checking and logging.
21. The **RSTAR-IS** will maintain System security entries for controlled access to the image server and for voice entry.
22. The **RSTAR-IS** will support a magnetic tape system for initial installation of system and RSTAR application software; for installation of major software maintenance releases and system software upgrades as applicable; and for VMS backups.
23. The **ICU-IS** will support a modem for remote diagnostics, software updates, troubleshooting and minor system adjustments.

2.3.1. Technical characteristics and means of operation

Means utilized by each component to function

The RSTAR Image Server is based on a Digital Equipment Corporation (DEC) VAX 4000 Model 60 computer, with patient, study and image information stored in RDB, the DEC standard relational database. The VAX 4000 Model 60 also coordinates overall system activity and monitors transaction processing, system usage and error logging. The image data cache is maintained on a Quadra 950 computer from Apple Computer, Inc. The Quadra 950 stores all image data for active patients and transmits the image data to requesting viewing stations and printing stations over a 100 megabit/sec fiber optic star network. Also connected to the Quadra 950 is the optical jukebox archive which contains inactive patient data. All of the RSTAR-IMS components are networked together using an IEEE 802.3 LAN.

List of operator controls

The RSTAR Image Server has an Apple Macintosh-based, menu driven executive utility that allows the System Administrator to monitor the RSTAR-IMS. The user interface follows the Apple Human Interface guidelines and has on-line help for ease-of-use. Most commands can be executed using the point and click facilities of the mouse and all other input is explicitly requested through the use of dialog boxes (small pop-up windows that demand action before allowing the system to continue). A preliminary draft of the System Administrator Guide is included as Exhibit C.

Storage

Standard general purpose equipment

The RSTAR Image Server uses standard magnetic disk drives to store image data, patient demographics and study information. The DEC VAX 4000 Model 60 has one 245 megabyte hard drive which contains the system software and the RSTAR Database. The Apple, Inc. Quadra 950 has one 230 megabyte hard drive containing system software and from two to eight 1.02 gigabyte hard drives which comprise the image cache. For long term archiving, the data is written to optical platters and stored in a jukebox.

Image formats

The radiographic image data is stored in row-column format. The DEC VAX 4000 Model 60 contains the RSTAR Database with patient demographics records and study information records stored with ACR/NEMA tags.

Data Compression

The base performance of the RSTAR Image Management System is such that data compression is not employed for either communications or storage of data.

Software

See sections 6.3.1 and 6.5.1 for description of the RSTAR Image Server software.

2.3.2. SpecificationsComputer Specifications:**Digital Equipment Corporation • VAX 4000 Model 60****Processor**

Chip	CMOS three-chipset
Clock speed	18-nanoseconds
rating	12.0 SPECmarks

Memory 16 megabytes**Cache Memory** 256 megabytes**Disk Drives** 245 megabytes**Interfaces**

Serial	Macintosh 950
Serial	Line Printer
SCSI (Small Computer System Interface)	Tape Drive
IEEE 802.3 connector	Local Area Network

Electrical requirements

Voltage	120 to 240 volts AC
Frequency	50 to 60 hertz
Power	465 watts max

Operating environment

Temperature	50° to 104° F
Humidity	80% max
Altitude	8,000 ft. max

Size and Weight

Height	4.4 in.
Width	19.0 in.
Depth	15.5 in.
Weight	10 lb.

Computer Specifications:**Apple Computer, Inc. • Quadra 950****Processor**

Chip	MC68040 32-bit architecture
Clock speed	33-megahertz

Co-processor

68882 IEEE standard

Memory 20 megabytes**Disk Drives**

floppy disk drive	1.4MB Apple SuperDrive
hard disk drive	230MB Apple SCSI

Interfaces

Serial	VAX 4000 Model 60
Serial	modem
ADB (Apple Desktop Bus)	keyboard
Video port	13" RGB (Red Green Blue) Display
NuBus slot	High Speed DMA (Direct Memory Access)

Board

NuBus slot	Fiber Transmitter Board
NuBus slot	SCSI Controller Board
Stereo sound output	Speaker
Sound input	Microphone
IEEE 802.3 connector	Local Area Network

Electrical requirements

Voltage	100 to 240 volts AC
Frequency	50 to 60 hertz
Power	303 watts max

Operating environment

Temperature	50° to 104° F
Humidity	80% max
Altitude	10,000 ft. max

Size and Weight

Height	18.6 in.
Width	8.9 in.
Depth	20.6 in.
Weight	36 lb.

Monitor Specifications:**Apple Computer, Inc. • 13" RGB (Red Green Blue) Display****Picture tube**

Diagonal	13"
CRT	Trinitron

Screen Resolution

Horizontal pixels (picture elements)	640 pixels
Vertical lines	480 lines
Dots Per Inch	69 dpi

Active video display area

Horizontal	9.3 inches
Vertical	6.9 inches

Input signals

Transistor Logic) composite sync	RGB using RS-343, TTL (Transistor
----------------------------------	-----------------------------------

Horizontal scan

55.0 kilohertz

Vertical refresh

66.7 hertz

Dot clock

30.24 megahertz

User Controls

Power, brightness and contrast

Electrical requirements

Voltage	85 to 270 volts AC
Frequency	47 to 63 hertz
Power	90 watts max

Fuse Protection

internal power line fuse

Operating environment

Temperature	50° to 104° C
Humidity	90% max
Altitude	10,000 ft. max

Size and Weight

Height	11.0 in.
Width	13.5 in.
Depth	15.2 in.
Weight	34 lb.

Input Devices:

Apple Computer, Inc. • Standard Keyboard II

Apple Computer, Inc. • Apple Desktop Bus Mouse

Communications Equipment

IEEE 802.3 LAN

transport speed	10 megabits/sec
media	coaxial cable
topology	bus
protocol	IEEE 802.3/AppleTalk
error checking	16 bit CRC (Cycle Redundancy Check)

RSTAR Fiber Optic Network

transport speed	100 megabits/sec
media	fiber optic cable
topology	star
protocol	proprietary
error checking	16 bit CRC

High-Speed Image Cache (Active Patients):

Hewlett Packard • HP C2247 3.5-inch Disk Drive

User specified from two to sixteen disk drives.

See technical specifications in Exhibit D

Optical Jukebox (Inactive Patients):

Hewlett Packard • Optical Disk Library System

User specified Model 10, 20, 60, 100.

See technical specifications in Exhibit D

Tape Drive:**Tandberg Data • TDC 3800 Tape Drive****Interface**

SCSI-2 VAX 4000

CharacteristicsCapacity 525 megabytes
Buffer size 256 kilobytes**Performance**Transfer rate Async 2.4 megabytes/sec
Transfer rate Sync 4.8 megabytes/sec
Transfer rate Sustained 200 kilobytes/sec**Reliability**MTBF (Mean Time
Between Failure) 80,000 hours
MTTR (Mean Time To Repair) 30 minutes**Electrical requirements**

Power 15 watts max

Operating environmentTemperature 5° to 45° C
Humidity 20 - 80% max
Altitude 13,000 ft. max**Size and Weight**Drive format 5 1/4" half height
Height 1.69 in.
Width 5.87 in.
Depth 8.51 in.**Media**

Cartridge type DC 6320/DC 6525 or equivalent

Paper Line Printer:

Panasonic • Dot Matrix Printer Model# KX-P1180i

Interface

RS-232C Serial VAX 4000 Model 60

Electrical requirements

Voltage 120 volts AC
Frequency 60 hertz
Power 144 watts max

Operating environment

Temperature 10° to 35° C
Humidity 30-80% max
Altitude 10,000 ft. max

Size and Weight

Height 5.2 in.
Width 16.7 in.
Depth 13.4 in.
Weight 15.7 lb.

Modem:

Practical Peripherals • Practical Modem 2400 SA

2.4. Diagnostic Workstation (DWS)

The RSTAR Diagnostic Workstation will display previously acquired radiographic image data upon high resolution monochrome monitors. These stations will be deployed throughout the radiology department and the hospital, allowing radiologists and clinicians continuous access to patient images and information. The list below is a summary of the functions provided by the DWS.

1. The **DWS** will support the following five configurations of monochrome monitors:

High-Resolution

Single monitor	1,792 by	2,250 portrait (2K)
Dual monitors	1,792 by	2,250 portrait (2K)
Four monitors	1,792 by	2,250 portrait (2K)
Six monitors	1,792 by	2,250 portrait (2K)
Eight monitors	1,792 by	2,250 portrait (2K)

Thus, there is no difference in the high resolution quality of the image, regardless how many monitors are part of the configuration.

2. The **DWS** user interface will allow for selection of the patient, the patient study, and individual radiographic image with searches available on patient name, patient medical record number, work queue and location.
3. The **DWS** will allow the pixel intensity mapping (image window & center) to be rapidly changed by the user via a set of knobs.
4. The **DWS** will allow for 2x and 4x magnification of image data by bilinear interpolation.
5. The **DWS** will allow for the recording of voice notations on a per study basis.
6. The **DWS** will allow for the playback of voice notations associated with the current patient study.
7. The **DWS** will allow for the entry of text notations on a per study basis.
8. The **DWS** will allow for the display of text notations associated with the current patient study.
9. At an **DWS** with two or more screens, more than one study can be displayed simultaneously, thus allowing for the display of comparison images.

2.4.1. Technical characteristics and means of operation

Means utilized by each component to function

The Diagnostic Workstation is Apple Macintosh-based and menu driven. The user interface follows the Apple Human Interface guidelines and has on-line help for ease of use. Most commands can be executed using the point and click facilities of the mouse and all other input is explicitly requested through the use of dialog boxes (small pop-up windows that demand action before allowing the system to continue). A preliminary draft of the Diagnostic Workstation User's Manual is included as Exhibit E.

List of operator controls

The Diagnostic Workstation allows for database searches by work queue (a collection of related studies) and location, and of specific patients by patient name and patient medical record number.

Monitors**Type**

The monitors used for the Diagnostic Workstations are high resolution gray scale monitors with 1792 pixels by 2250 lines. A single workstation can have up to eight monitors.

As noted above, the Diagnostic Workstation supports the following five configurations of CRT displays:

High-Resolution

- Single monitor 1,792 by 2,250 portrait (2K)
- Dual monitors 1,792 by 2,250 portrait (2K)
- Four monitors 1,792 by 2,250 portrait (2K)
- Six monitors 1,792 by 2,250 portrait (2K)
- Eight monitors 1,792 by 2,250 portrait (2K)

Available image display formats

The available screen real estate may be formatted into any number of non-overlapping rectangular tiles, where an image is displayed in a tile.

Video monitor diagnostics provided by software (SMPTE test pattern)

The SMPTE test pattern is provided as a quality assurance check for the Diagnostic Workstation. It can be displayed in two ways:

1. It is stored locally on the hard disk to allow for stand-alone testing of the viewing station and the monitors.
2. It is also stored as a study on the main RSTAR Image Server to allow for server-to-viewing station testing of the viewing station, the monitor and the local area network.

Processors and storage**Image processing hardware**

All image processing is executed using the facilities of the Quadra 950 CPU and the Motorola 68040 processor chip.

Basic function of each device

The Diagnostic Workstation is a display device that allows users to view at full resolution patient images stored in the RSTAR Image Server.

Image storage media listed

There is no local disk caching of image data on the workstation. All data are stored on the RSTAR Image Server and downloaded to the workstations over 100 megabit RSTAR optical star network when requested by a user. The image data are, however, cached to Random Access Memory (RAM) in the viewing station for display and image processing by the 68040 processor. The workstations can be configured to hold from eight to 64 megabytes of RAM. That translates to enough memory to cache between one and eight full resolution 11" by 14" plane films that have been digitized at 200 microns at 12 bits of resolution. The workstation also has a 230 megabyte hard drive containing the Macintosh Operating System and the RSTAR Diagnostic Workstation Application Code. Additionally, the SMPTE test pattern is stored on disk for stand alone testing of the workstation.

Operator Interfaces

The Diagnostic Workstation is keyboard and mouse driven with a set of knobs for window and center manipulation.

Software

See section 6.2.1 for description of the Diagnostic Workstation software.

2.4.2. SpecificationsComputer Specifications:**Apple Computer, Inc. • Quadra 950****Processor**

Chip	MC68040 32-bit architecture
Clock speed	33-megahertz

Co-processor

68882 IEEE standard

Memory 20 megabytes**Disk Drives**

floppy disk drive	1.4MB Apple SuperDrive
hard disk drive	80MB Apple SCSI

Interfaces

Apple Desktop Bus (ADB)	Keyboard
Serial	Knobs
NuBus slot	Display Interface Board
NuBus slot	High Speed DMA Board
NuBus slot	Optical Fiber Receiver Board
NuBus slot	Memory Board (8, 16 32, or 64MB)
Stereo sound output	Speaker
Sound input	Microphone
IEEE 802.3 connector	Local Area Network

Electrical requirements

Voltage	100 to 240 volts AC
Frequency	50 to 60 hertz
Power	303 watts max

Operating environment

Temperature	50° to 104° F
Humidity	80% max
Altitude	10,000 ft. max

Size and Weight

Height	18.6 in.
Width	8.9 in.
Depth	20.6 in.
Weight	36 lb.

Monitor Specifications:**Tektronix, Inc. • GMA212 High Bright Display****Picture tube**

Diagonal	19"
CRT	P45 Phosphor

Screen Resolution

Horizontal pixels	1792 pixels
Vertical lines	2250 lines
Dots Per Inch	163 dpi

Active video display area

Horizontal	11.000 inches
Vertical	13.750 inches

Input signals

separate sync	video using BNC (Bayonet Connector),
---------------	--------------------------------------

Horizontal scan

160 kilohertz

Vertical refresh

70 hertz

Dot clock

400 megahertz

User Controls

Power, brightness, contrast

Electrical requirements

Voltage	85 to 256 volts AC
Frequency	48 to 63 hertz
Power	130 watts max

Fuse Protection

internal power line fuse

Operating environment

Temperature	0° to 40° C
Humidity	95% max
Altitude	15,000 ft. max

Size and Weight

Height	19.6 in.
Width	14.0 in.
Depth	19.8 in.
Weight	82 lb.

Input Devices:

- | | |
|----------------------|---------------------------|
| Apple Computer, Inc. | • Standard Keyboard II |
| Apple Computer, Inc. | • Apple Desktop Bus Mouse |
| RSTAR, Inc. | • Knobs |

Communications Equipment:

IEEE 802.3 LAN

transport speed	10 megabits/sec
media	coaxial cable
topology	bus
protocol	IEEE 802.3/AppleTalk
error checking	16 bit CRC

RSTAR Fiber Optic Network

transport speed	100 megabits/sec
media	fiber optic cable
topology	star
protocol	proprietary
error checking	16 bit CRC

2.5. Clinical Review Station (CRS)

The Clinical Review Station will display previously acquired radiographic image data upon medium-resolution monochrome monitors. These stations will be deployed throughout the hospital, allowing clinicians on-going access to patient images and information. The list below is a summary of the functions provided by the CRS.

1. The **CRS** will support the following two configurations of monochrome monitors:

<u>Medium-Resolution</u>		
Single monitor	1,152 by	882 landscape (1K)
Dual monitors	1,152 by	882 landscape (1K)
2. The **CRS** user interface will allow for selection of the patient, the patient study, and individual radiographic image with searches available on patient name, patient medical record number, work queue and location.
3. The **CRS** will allow the pixel intensity mapping (image window & center) to be rapidly changed by the user via a set of knobs.
4. The **CRS** will allow for 2x and 4x magnification of image data by bilinear interpolation.
5. The **CRS** will allow for the recording of voice notations on a per study basis.
6. The **CRS** will allow for the playback of voice notations associated with the current patient study.
7. The **CRS** will allow for the entry of text notations on a per study basis.
8. The **CRS** will allow for the display of text notations associated with the current patient study.
9. At a **CRS** with dual screens, more than one study may be displayed simultaneously, thus, allowing for the display of comparison images.

2.5.1. Technical characteristics and means of operation

Means utilized by each component to function

The Clinical Review Station is Apple Macintosh-based and menu driven. The user interface follows the Apple Human Interface guidelines and has on-line help for ease-of-use. Most commands can be executed using the point and click facilities of the mouse and all other input is explicitly requested through the use of dialog boxes (small pop-up windows that demand action before allowing the system to continue).

List of operator controls

The Clinical Review Station allows for database searches by work queue or patient location, and of specific patients by patient name and patient medical record number.

Monitors

Type

The monitors used for the Clinical Review Stations are medium-resolution gray scale monitors with 1152 pixels by 870 lines. A single display station can have one or two monitors.

As noted above, the Clinical Review Station supports the following two configurations of CRT displays:

Medium Resolution

- Single monitor 1,152 by 882 landscape (1K)
- Dual monitors 1,152 by 882 landscape (1K)

Available image display formats

The available screen real estate may be formatted into any number of non-overlapping rectangular tiles, where a image is displayed in a tile.

Video monitor diagnostics provided by software

The SMPTE test pattern is provided as a quality assurance check for the Clinical Review Station. It can be displayed in two ways:

1. It is stored locally on the hard disk to allow for stand-alone testing of the viewing station and the monitors.
2. It is also stored as a study on the main RSTAR Image Server to allow for server-to-viewing station testing of the viewing station, the monitor and the local area network.

Processors and storage

Image processing hardware

All image processing is executed using the facilities of the Quadra 950 CPU and the Motorola 68040 processor chip.

Basic function of each device

The Clinical Review Station is a display device that allows users to view at full resolution patient images stored in the RSTAR Image Server.

Image storage media listed

There is no local disk caching of image data on the viewing station. All data are stored on the RSTAR Image Server and downloaded to the viewing stations over the 100 megabit RSTAR optical star network when requested by a user. The image data are, however, cached to RAM for display and image processing by the 68040 processor. The viewing stations can be configured to hold from eight to 64 megabytes of RAM which translates to enough memory to cache between one and eight full resolution 11" by 14" plane films that have been digitized at 200 microns at 12 bits of resolution. The viewing station also has a 230 megabyte hard drive that contains the Macintosh Operating System and the RSTAR Clinical Review Station Application Code. Additionally, the SMPTE test pattern is stored on disk for stand alone testing of the viewing station.

Operator Interfaces

The Clinical Review Station is keyboard and mouse driven with a set of knobs for window and center.

Software

See section 6.2.2 for description of the Clinical Review Station software.

2.5.2. SpecificationsComputer Specifications:**Apple Computer, Inc. • Quadra 950****Processor**

Chip	MC68040 32-bit architecture
Clock speed	33-megahertz

Co-processor

68882 IEEE standard

Memory 20 megabytes**Disk Drives**

floppy disk drive	1.4MB Apple SuperDrive
hard disk drive	80MB Apple SCSI

Interfaces

ADB (Apple Desktop Bus)	Keyboard
Serial	Knobs
NuBus slot	Display Interface Board
NuBus slot	High Speed DMA Board
NuBus slot	Optical Fiber Receiver Board
NuBus slot	Memory Board (8, 16, 32, 64MB)
Stereo sound output	Speaker
Sound input	Microphone
IEEE 802.3 connector	Local Area Network

Electrical requirements

Voltage	100 to 240 volts AC
Frequency	50 to 60 hertz
Power	303 watts max

Operating environment

Temperature	50° to 104° F
Humidity	80% max
Altitude	10,000 ft. max

Size and Weight

Height	18.6 in.
Width	8.9 in.
Depth	20.6 in.
Weight	36 lb.

Monitor Specifications:**Radius Inc. • Two Page Display 19"****Picture tube**

Diagonal 19"

Screen ResolutionHorizontal pixels 1152 pixels
Vertical lines 882 lines
Dots Per Inch 82 dpi**Active video display area**Horizontal 14.0 inches
Vertical 10.8 inches**Input signals**

RS-343

Horizontal scan

64.8 kilohertz

Vertical refresh

70.4 hertz

User Controls

Brightness and contrast

Electrical requirementsVoltage 100 to 240 volts AC
Frequency 50 to 60 hertz
Power 135 watts max**Fuse Protection**

internal power line fuse

Operating environmentTemperature 10° to 35° C
Humidity 20% to 80%
Altitude 10,000 ft. max**Size and Weight**Height 15.5 in.
Width 18.0 in.
Depth 16.5 in.
Weight 55 lb.**Regulatory Approvals**RFI (Radio Frequency Interference) FCC Class A (part 15 of FCC rules)
Safety UL listed
CSA certified
TUV approved

Input Devices:

- | | |
|----------------------|--------------------------------------|
| Apple Computer, Inc. | • Standard Keyboard II |
| Apple Computer, Inc. | • Apple Desktop Bus Mouse |
| RSTAR, Inc. | • Knobs (Window and Center Controls) |

Communications Equipment

IEEE 802.3 LAN

transport speed	10 megabits/sec
media	coaxial cable
topology	bus
protocol	IEEE 802.3/AppleTalk
error checking	16 bit CRC

RSTAR Fiber Optic Network

transport speed	100 megabits/sec
media	fiber optic cable
topology	star
protocol	proprietary
error checking	16 bit CRC

2.6. TouchPanel Viewstation (TPV)

The TouchPanel Viewstation will display previously acquired radiographic image data upon high-resolution and medium-resolution monochrome monitors. These stations will be deployed in hospital intensive care units and other critical care areas, allowing clinicians continuous access to patient images and information. Listed below is a summary of the functions provided by the TPV.

1. The **TPV** will support the following four configurations of monochrome monitors:

<u>High Resolution</u>		
Single monitor	1,792 by	2,250 portrait (2K)
Dual monitors	1,792 by	2,250 portrait (2K)
<u>Medium Resolution</u>		
Single monitor	1,152 by	882 landscape (1K)
Dual monitors	1,152 by	882 landscape (1K)
2. The **TPV** will provide radiologists and clinicians with a membrane switch user interface for ease of use, with no keyboard or mouse interaction.
3. The **TPV** will display by default the list of patients located in the hospital intensive care unit where viewing station is deployed.
4. The **TPV** will allow for selection of a different hospital intensive care unit.
5. The **TPV** user interface will allow for selection of the patient, the patient study, and individual radiographic image.
6. The **TPV** will allow the pixel intensity mapping (image window & center) to be rapidly changed by the user.
7. The medium resolution 1K **TPV** will provide for image zooming on a 5 quadrant basis (upper left, upper right, lower left, lower right, and center).
8. The **TPV** will allow for the recording of voice notations on a per study basis.
9. The **TPV** will allow for the playback of voice notations associated with the current patient study.
10. The **TPV** will allow for the display of text notations associated with the current patient study.
11. At a **TPV** with dual screens more than one study can be displayed simultaneously, thus allowing for the display of comparison images.

2.6.1. Technical characteristics and means of operation

Means utilized by each component to function

The TouchPanel Viewstation is Apple Macintosh-based and membrane switch driven. The user interface follows the Apple Human Interface guidelines and has on-line help for ease-of-use. Commands are executed using the membrane switches on the sides and along the bottom of the monitor.

List of operator controls

As mentioned above, the TouchPanel Viewstation is membrane switch driven. The membrane switch along the right or left hand side of the monitor contains buttons that allow for selection of items in a list. The membrane switch along the bottom of the monitor contains four types of buttons. The first is the Power button which turns on the TPV. The top six buttons to the right of the Power button are soft keys. Their functions change depending on the state of the application. The bottom six buttons are static commands keys. The Start button brings the application back to the Patient Listing Screen. The Help button displays information to help the user as appropriate for the state of the application. The Menu button displays the list of functions shown on the screen to the left. The Undo button reverses the last command. The Yes and No buttons allow the user to answer questions. The four triangle buttons on the far right control the window and center setting for viewing images.

Monitors**Type**

Two types of monitors are used for the TouchPanel Viewstation: high resolution gray scale monitors with 1792 pixels by 2250 lines and medium resolution gray scale monitors with 1152 pixels by 870 lines. A single display station can have either single or dual monitors.

The TouchPanel Viewstation supports the following four configurations of CRT displays:

High Resolution

- Single monitor 1,792 by 2,250 portrait (2K)
- Dual monitors 1,792 by 2,250 portrait (2K)

Medium Resolution

- Single monitor 1,152 by 882 landscape (1K)
- Dual monitors 1,152 by 882 landscape (1K)

Available image display formats

The TouchPanel Viewstation will display one radiographic image at a time per monitor.

Video monitor diagnostics provided by software

The SMPTE test pattern is provided as a quality assurance check for the TouchPanel Viewstation. It can be displayed in two ways:

1. It is stored locally on hard disk to allow for stand-alone testing of the viewing station and the monitors.

2. It is also stored as a study on the main RSTAR Image Server to allow for server-to-viewing station testing of the viewing station, the monitor and the local area network.

Processors and storage

Image processing hardware

All image processing is executed using the facilities of the Quadra 950 CPU and the Motorola 68040 processor chip.

Basic function of each device

The Touch Panel View Station is a display device that allows users to view radiographic image data.

Image storage media listed

There is no local disk caching of image data on the viewing station. All data are stored on the RSTAR Image Server and downloaded to the viewing stations over the 100 megabit RSTAR optical star network when requested by a user. The image data are, however, cached to RAM for display and image processing by the 68040 processor. The viewing stations can be configured to hold from eight to 64 megabytes of RAM. That translates to enough memory to cache between one and eight full resolution 11" by 14" plane films that have been digitized at 200 microns at 12 bits of resolution. The viewing station also has a 80 megabyte hard drive the contains the Macintosh Operating System and the RSTAR Image View Station Application Code. Additionally, the SMPTE test pattern is stored on hard disk for stand-alone testing of the viewing station.

Operator Interfaces

The TouchPanel Viewstation is driven off the two membrane switches: the Vertical Selection Membrane Switch located on the side of the monitor, and the Menu Selection Membrane Switch located on the bottom of the monitor. There is no keyboard or mouse. A preliminary draft of the TouchPanel Viewstation User's Manual is included as Exhibit F.

Software

See sections 6.2.3, 6.2.4, 6.2.5 and 6.2.6 for description of the TouchPanel Viewstation software.

2.6.2. SpecificationsComputer Specifications:**Apple Computer, Inc. • Quadra 950****Processor**

Chip	MC68040 32-bit architecture
Clock speed	33-megahertz

Co-processor

68882 IEEE standard

Memory 20 megabytes**Disk Drives**

floppy disk drive	1.4MB Apple SuperDrive
hard disk drive	80MB Apple SCSI

Interfaces

Serial	Membrane Switches
NuBus slot	Display Interface Board
NuBus slot	High Speed DMA Board
NuBus slot	Optical Fiber Receiver Board
NuBus slot	Memory Board (8, 16,32, 64MB)
Stereo sound output	Speaker
Sound input	Microphone
IEEE 802.3 connector	Local Area Network

Electrical requirements

Voltage	100 to 240 volts AC
Frequency	50 to 60 hertz
Power	303 watts max

Operating environment

Temperature	50° to 104° F
Humidity	80% max
Altitude	10,000 ft. max

Size and Weight

Height	18.6 in.
Width	8.9 in.
Depth	20.6 in.
Weight	36 lb.

Monitor Specifications:**Tektronix, Inc. • GMA212 High Bright Display****Picture tube**

Diagonal	19"
CRT	P45 Phosphor

Screen Resolution

Horizontal pixels	1800 pixels
Vertical lines	2250 lines
Dots Per Inch	163 dpi

Active video display area

Horizontal	11.000 inches
Vertical	13.750 inches

Input signals

video using BNC, separate sync

Horizontal scan

160 kilohertz

Vertical refresh

70 hertz

Dot clock

400 megahertz

User Controls

Power, brightness, contrast

Electrical requirements

Voltage	85 to 256 volts AC
Frequency	48 to 63 hertz
Power	130 watts max

Fuse Protection

internal power line fuse

Operating environment

Temperature	0° to 40° C
Humidity	95% max
Altitude	15,000 ft. max

Size and Weight

Height	19.6 in.
Width	14.0 in.
Depth	19.8 in.
Weight	82 lb.

Monitor Specifications:**Radius Inc. • Two Page Display 19"****Picture tube**

Diagonal 19"

Screen Resolution

Horizontal pixels 1152 pixels

Vertical lines 882 lines

Dots Per Inch 82 dpi

Active video display area

Horizontal 14.0 inches

Vertical 10.8 inches

Input signals

RS-343

Horizontal scan

64.8 kilohertz

Vertical refresh

70.4 hertz

User Controls

Brightness and contrast

Electrical requirements

Voltage 100 to 240 volts AC

Frequency 50 to 60 hertz

Power 135 watts max

Fuse Protection

internal power line fuse

Operating environment

Temperature 10° to 35° C

Humidity 20% to 80%

Altitude 10,000 ft. max

Size and Weight

Height 15.5 in.

Width 18.0 in.

Depth 16.5 in.

Weight 55 lb.

Regulatory Approvals

RFI FCC Class A (part 15 of FCC rules)

Safety UL listed

CSA certified

TUV approved

Input Devices:

- RSTAR, Inc.** • **Vertical Selection Membrane Switch**
- RSTAR, Inc.** • **Menu Selection Membrane Switch**

Communications Equipment:

IEEE 802.3 LAN

transport speed	10 megabits/sec
media	coaxial cable
topology	bus
protocol	IEEE 802.3/AppleTalk
error checking	16 bit CRC

RSTAR Fiber Optic Network

transport speed	100 megabits/sec
media	fiber optic cable
topology	star
protocol	proprietary
error checking	16 bit CRC

2.7. Demographic Entry Station (DES)

The Demographic Entry Station is a free-standing computer station to be used primarily by clerical and nursing staff for text entry and for maintaining the RSTAR database. It permits patient demographics, and patient location and discharge information (in the case of an ICU patient) to be entered into the system. Images cannot be viewed on a DES. In most facilities, the DES will most likely be located in the radiology department or at the nursing station within an individual intensive care unit. Listed below is a summary of the functions provided by the DES.

1. The **DES** will allow basic patient demographics (name, medical record number, etc.) to be entered or modified.
2. The **DES** will allow for patient assignment to and discharge from a particular location (typically an ICU).
3. The **DES** will allow study information (study descriptor, study date, etc.) to be modified.
4. The **DES** will queue for printing to a Image Printing Station all radiographic images for a selected patient.
5. The **DES** will queue for printing to a Image Printing Station all radiographic images for a selected patient study.
6. The **DES** will allow for the automatic printing of all images to a Image Printing Station upon patient discharge from the hospital intensive care unit.
7. The **DES** will allow for the addition of voice notations to a particular patient study.
8. The **DES** will allow for the addition of text notations to a particular patient study.

2.7.1. Technical characteristics and means of operation

Means utilized by each component to function

The Demographic Entry Station is Apple Macintosh-based and menu driven. The user interfaces follows the Apple Human Interface guidelines and has on-line help for ease-of-use. Most commands can be executed using the point and click facilities of the mouse. All other input is explicitly requested through the use of dialog boxes (small pop-up windows that demand action before allowing the system to continue). Preliminary draft copies user interface screens for the Demographic Entry Station are included as Exhibit G.

List of operator controls

The Demographic Entry Station allows for database searches of specific patients by name and patient medical record number. It allows for database searches by work queue and location. With the use of a password, the station allows for entry of new patients into the system and for modification of existing patient information.

Monitors

The monitors used for the Demographic Entry Station are 13" color monitors with 640 pixels by 480 lines. The station is for text entry only. Images cannot be viewed on this station.

Processors and storage

Basic function of each device

The Demographic Entry Station is a text entry device for maintaining the RSTAR database.

Image storage media listed

There is no local storage of patient information on the Demographic Entry Station. All text and voice data are stored on the RSTAR Image Server and transmitted to the station for display or play-back upon request. New and modified data are transmitted back to the RSTAR Image Server and stored in the appropriate database records. The station has nine megabytes of memory and a 80 megabyte hard-drive which contains the Macintosh Operating System and the RSTAR Demographic Entry Station Application Code.

Operator Interfaces

The Demographic Entry Station is keyboard and mouse driven.

Software

See section 6.1.2 for a description of the Demographic Entry Station software.

2.7.2. SpecificationsComputer Specifications:**Apple Computer, Inc. • Macintosh IIsi****Processor**

Chip	MC68030 32-bit architecture
Clock speed	20-megahertz

Memory 9 megabytes**Disk Drives**

floppy disk drive	1.4MB Apple SuperDrive
hard disk drive	80MB Apple SCSI

Interfaces

Apple Desktop Bus (ADB)	keyboard
Video port	13" RGB color display
Internal Expansion slot	IEEE 802.3 Interface Board
Stereo sound output	Speaker
Sound input	Microphone

Electrical requirements

Voltage	100 to 240 volts AC
Frequency	47 to 63 hertz
Power	100 watts max

Operating environment

Temperature	50° to 104° F
Humidity	95% max
Altitude	10,000 ft. max

Size and Weight

Height	4.0 in.
Width	12.4 in.
Depth	14.9 in.
Weight	10 lb.

Monitor Specifications:**Apple Computer, Inc. • 13" Color Display****Picture tube**

Diagonal	13"
CRT	Trinitron

Screen Resolution

Horizontal pixels	640 pixels
Vertical lines	480 lines
Dots Per Inch	69 dpi

Active video display area

Horizontal	9.3 inches
Vertical	6.9 inches

Input signals

RGB using RS-343, TTL composite sync

Horizontal scan

55.0 kilohertz

Vertical refresh

66.7 hertz

Dot clock

30.24 megahertz

User Controls

Power, brightness, and contrast

Electrical requirements

Voltage	85 to 270 volts AC
Frequency	47 to 63 hertz
Power	90 watts max

Fuse Protection

internal power line fuse

Operating environment

Temperature	50° to 104° C
Humidity	90% max
Altitude	10,000 ft. max

Size and Weight

Height	11.0 in.
Width	13.5 in.
Depth	15.2 in.
Weight	34 lb.

Input Devices:

- Apple Computer, Inc. • Standard Keyboard II
- Apple Computer, Inc. • Apple Desktop Bus Mouse

Communications Equipment

Ethernet

transport speed	10 megabits/sec
media	coaxial cable
topology	bus
protocol	IEEE 802.3/AppleTalk
error checking	16 bit CRC

2.8. Image Acquisition Station (IAS)

The RSTAR Image Acquisition Station is used for capturing images from various imaging devices and transferring those images to the Image Server for subsequent review at the viewing stations. Patient and study demographics as well as clinical history and hypothesis are entered at the acquisition station. Listed below is a summary of the functions provided by the IAS.

1. The **IAS** will digitize plane films via a laser film digitizer.
2. The **IAS** will acquire phosphor plate images via an ANALOGIC DASMTM-XPRF SCSI Interface to the Fuji FCR AC-1 Plus.
3. The **IAS** will collect image information via keyboard and mouse input.
4. The **IAS** will collect study information via keyboard and mouse input.
5. The **IAS** will collect patient demographics for new patients via keyboard and mouse input.
6. The **IAS** will, with the entry of a medical record number, pull patient demographics from the RSTAR database for existing patients.
7. The **IAS** will allow for review of acquired images prior to acceptance into the image database.
8. The **IAS** will allow for acquired images to be flipped and/or rotated into standard orientation (as defined by the institution) prior to entry into the clinical image database.
9. The **IAS** will support multiple images per study.

2.8.1. Technical characteristics and means of operation

Means utilized by each component to function

The Image Acquisition Station is Apple Macintosh-based and menu driven. The user interface follows the Apple Human Interface guidelines and has on-line help for ease-of-use. Most commands can be executed using the point and click facilities of the mouse. All other input is explicitly requested through the use of dialog boxes (small pop-up windows that demand action before allowing the system to continue). A preliminary draft of the Image Acquisition Station Manual is included as Exhibit H.

List of operator controls

The Image Acquisition Station allows for the entry of patient demographics, exam information, image information and image data into the RSTAR Image Management System. The above data are collected at the Image Acquisition Station and transmitted over the optical star network to the RSTAR Image Server.

Monitors

The monitors used for the Image Acquisition Station are monochrome portrait monitors with 640 pixels by 480 lines. The station is intended primarily for text and image entry. Image viewing on this station is only for quality assurance.

Processors and storage

Basic function of each device

The Image Acquisition Station is a text and image entry device for entering data into the RSTAR Image Management System.

Image storage media listed

Patient information and image data are collected on the Image Acquisition Station. There is no long-term storage of patient information on the Image Acquisition Station. All data are transmitted and stored on the RSTAR Image Server. The station has twenty megabytes of memory and a 230 megabyte hard drive which contains the Macintosh Operating System and the RSTAR Image Acquisition Station Application Code.

Operator Interfaces

The Image Acquisition Station is keyboard and mouse driven.

Software

See section 6.1.1 for a description of the Image Acquisition Station software.

2.8.2. SpecificationsComputer Specifications:**Apple Computer, Inc. • Quadra 700****Processor**

Chip	MC68040 32-bit architecture
Clock speed	25-megahertz

Memory 20 megabytes**Drives**

floppy disk drive	1.4MB Apple SuperDrive
hard disk drive	230MB Apple SCSI

Interfaces

Apple Desktop Bus (ADB)	keyboard
Video port	portrait monochrome monitor
SCSI	LUMASCAN Digitizer or ANALOGIC INTERFACE
Stereo sound output	Speaker
Sound input	Microphone
IEEE 802.3 connector	Local Area Network

Electrical requirements

Voltage	100 to 240 volts AC
Frequency	50 to 60 hertz
Power	50 watts max

Operating environment

Temperature	50° to 104° F
Humidity	80% max
Altitude	10,000 ft. max

Size and Weight

Height	11.9 in.
Width	5.5 in.
Depth	14.4 in.
Weight	13 lb.

Monitor Specifications:**Apple Computer, Inc. • Monochrome Portrait Display****Picture tube**

Diagonal	15"
CRT	"full square flat" screen

Screen Resolution

Horizontal pixels	640 pixels
Vertical lines	870 lines
Dots Per Inch	80 dpi

Active video display area

Horizontal	203.2 mm
Vertical	271.1 mm

Input signals

Video	Analog RS-343
Sync	separate sync, negative going, TTL

Horizontal scan

68.85 kilohertz

Vertical refresh

75 hertz

Dot clock

57.2832 megahertz

User Controls

Power, brightness, contrast

Electrical requirements

Voltage	90 to 270 volts AC
Frequency	47 to 63 hertz
Power	75 watts max

Fuse Protection

internal power line fuse

Operating environment

Temperature	10° to 35° C
Humidity	90% max
Altitude	10,000 ft. max

Size and Weight

Height	14.5 in.
Width	11.5 in.
Depth	14.5 in.
Weight	35 lb.

Input Devices:

- Apple Computer, Inc. • **Standard Keyboard II**
- Apple Computer, Inc. • **Apple Desktop Bus Mouse**

Communications Equipment

IEEE 802.3 LAN

transport speed	10 megabits/sec
media	coaxial cable
topology	bus
protocol	IEEE 802.3/AppleTalk
error checking	16 bit CRC

Laser Film Digitizer

Lumisys LUMASCAN See technical specifications in Exhibit G

SCSI Interface to Computed Radiography Unit

ANALOGIC DASM™ -XPRF See technical specifications in Exhibit H

2.9. Image Printing Station (IPS)

The need for hard-copy films will exist for years to come. RSTAR has created an Image Printing Station that allows laser film printers to be interfaced to the RSTAR Image Management System. This offers radiologists, clinicians, and referring physicians the ability to print on film any image in the RSTAR Image Management System. Images can be queued to print from any of the viewing stations or from the Demographic Entry Station. The list below is a summary of the functions provided by the IPS.

1. The **IPS** will print images queued by the Diagnostic Workstation.
2. The **IPS** will print images queued by the Clinical Review Station.
3. The **IPS** will print images queued by the TouchPanel Viewstation.
4. The **IPS** will print images queued by the Demographic Entry Station.
5. The **IPS** will display the last image printed.
6. The **IPS** will display the current status of the station.
7. The **IPS** will display related information, warning and error messages.
8. The **IPS** will allow for the resetting of the laser film printer.
9. The **IPS** will allow for the direct entry of commands to drive the laser film printer.

2.9.1. Technical characteristics and means of operation

Means utilized by each component to function

The Image Printing Station is Apple Macintosh-based and menu driven. The user interface follows the Apple Human Interface guidelines and has on-line help for ease-of-use. Most commands can be executed using the point and click facilities of the mouse. All other input is explicitly requested through the use of dialog boxes (small pop-up windows that demand action before allowing the system to continue). A preliminary draft copy of the user interface screen for the Image Printing Station is included as Exhibit K.

List of operator controls

The Image Printing Station allows for printing of queued images by the attached laser film printer.

Monitors

The display used for the Image Printing Station is a 12" monochrome monitor with 640 pixels by 480 lines. Image viewing on this station is only for quality assurance.

Processors and storage

Basic function of each device

The Image Printing Station is an image printing device that interfaces to a laser film printer. Image printing requests are queued to the Image Printing Station from the viewing stations and the DES through the Image Server.

Image storage media listed

There is no local storage of patient information on the Image Printing Station. All data are stored on the RSTAR Image Server and transmitted to the station over the 100 megabit/sec fiber optic star network for printing upon request. The station has twenty megabytes of memory and a 80 megabyte hard drive which contains the Macintosh Operating System and the RSTAR Image Printing Station Application Code.

Operator Interfaces

The Image Printing Station is keyboard and mouse driven.

Software

See section 6.4.1 for a description of the Image Printing Station software.

2.9.2. SpecificationsComputer Specifications:**Apple Computer, Inc. • Quadra 700****Processor**

Chip	MC68040 32-bit architecture
Clock speed	25-megahertz

Memory 20 megabytes

Drives

floppy disk drive	1.4MB Apple SuperDrive
hard disk drive	80MB Apple SCSI

Interfaces

Apple Desktop Bus (ADB)	keyboard
Video port	12" monochrome monitor
NuBus slot	High Speed DMA Board
NuBus slot	Optical Fiber Receiver Board
NuBus slot	Laser Film Printer Interface Board
IEEE 802.3 connector	Local Area Network

Electrical requirements

Voltage	100 to 240 volts AC
Frequency	50 to 60 hertz
Power	50 watts max

Operating environment

Temperature	50° to 104° F
Humidity	80% max
Altitude	10,000 ft. max

Size and Weight

Height	11.9 in.
Width	5.5 in.
Depth	14.4 in.
Weight	13 lb.

Monitor Specifications:**Apple Computer, Inc. • 12" Monochrome Display****Picture tube**

Diagonal	12"
CRT	P104 & P193 phosphor

Screen Resolution

Horizontal pixels	640 pixels
Vertical lines	480 lines
Dots Per Inch	76 dpi

Active video display area

Horizontal	8.35 inches
Vertical	6.26 inches

Input signals

RS-343 standard, TTL composite sync

Horizontal scan

35.0 kilohertz

Vertical refresh

66.7 hertz

Rise and fall time

16 nanoseconds max

User Controls

Power, brightness, contrast

Electrical requirements

Voltage	90 to 270 volts AC
Frequency	47 to 63 hertz
Power	30 watts max

Fuse Protection

internal power line fuse

Operating environment

Temperature	50° to 104° C
Humidity	95% max
Altitude	10,000 ft. max

Size and Weight

Height	12.2 in.
Width	14.4 in.
Depth	10.2 in.
Weight	16 lb.

Input Devices:

- Apple Computer, Inc. • **Standard Keyboard II**
- Apple Computer, Inc. • **Apple Desktop Bus Mouse**

Communications Equipment:

IEEE 802.3 LAN

transport speed	10 megabits/sec
media	coaxial cable
topology	bus
protocol	IEEE 802.3/AppleTalk
error checking	16 bit CRC

RSTAR Fiber Optic Network

transport speed	100 megabits/sec
media	fiber optic cable
topology	star
protocol	proprietary
error checking	16 bit CRC

Laser Film Printer:

- 3M • Laser Imager XL** See technical specifications in Exhibit L.

2.10. Indications for use

2.10.1. Brochure

A draft copy of the RSTAR Image Management System Brochure which gives an overview of the RSTAR-IMS is included as Exhibit M.

2.10.2. User's Manuals

Preliminary draft copies of User's Manuals for the RSTAR-IMS are included as the following exhibits.

- System Administrator's Guide Exhibit C
- Diagnostic Workstation User's Manual Exhibit E
- TouchPanel Viewstation User's Manual Exhibit F

2.10.3. Screens

The following RSTAR Components do not, as of yet, have draft copies of user manuals completed. Copies of the user interface screens are included as indication for use for this components.

- Demographic Entry Station Exhibit G
- Image Printing Station Exhibit K

2.10.3. User's Manuals with updated Screens

The following RSTAR Component has a preliminary draft copy of a User's Manual plus updated user interface screens which have not as yet been incorporated into the manual.

- Image Acquisition Station User's Manual Exhibit I

3. Laboratory Tests

During the Alpha Phase, conducted under the management of the Quality Assurance department, each RSTAR component is subjected to two types of Quality Assurance (QA) testing.

Functional Testing: The component is tested against a series of functional requirements under normal operating conditions. The testing sequence is laid out in a Functional Test Plan. The results of the test are recorded in the operational section of the plan.

Simulated Error Testing: The component is tested against a series of simulated error conditions. The error conditions also are laid out in the Functional Test Plan. This process validates the error tracking and handling of the component for each of the elements in the Functional Test Plan. The results of the testing are recorded in the simulated error section of the plan.

Sections 3.1 through 3.7 on the following pages briefly describe the functional testing sequence and simulated error conditions for which each of the RSTAR components described in sections 2.3 through 2.9 above is validated.

3.1. RSTAR Image Server (RSTAR-IS)

3.1.1. Functional Testing

1. Start all system servers
2. Query patient demographic database
3. Query exam information database
4. Query image information database
5. Query station preferences database
6. Display System Audit log
7. Display System Error log
8. Display System Event log
9. Execute the Executive Utility

3.1.2. Simulated Error Testing

1. Disrupt IEEE 802.3 connection
2. Disrupt RSTAR optical star network connection
3. Stop each individual server in turn and attempt access from each of the RSTAR Viewing and Acquisition Stations

3.1.3. Data Compression (Not Applicable)

The February 1991 draft Guidance for the Content and Review of 510(k) Notifications for Picture Archiving and Communications Systems and Related Devices requires the submission of specified test results for devices that employ data compression. This requirement is not applicable to this notification because the base performance of the RSTAR Image Management System is such that data compression is not employed for either communications or storage of data.

3.2. Diagnostic Workstation (DWS)

3.2.1. Functional Testing

1. Start work session
2. Select work queue preference
3. Search database by work queue
4. Search database by patient name
5. Search database by patient medical record number
6. Select study from patient studies list
7. Select image from presentation pane
8. Select all images from presentation pane
9. Adjust window & center control
10. Choose window & center presets
11. Use linear measurement on image
12. Use area measurement on image
13. Magnify image by 2x
14. Magnify image by 4x.
15. Rotate image by 180°
16. Flip image horizontally
17. Flip image vertically
18. Print image on screen to Laser Imager
19. End work session

3.2.2. Simulated Error Testing

1. Disrupt the IEEE 802.3 network connection
2. Disrupt the optical LAN connection
3. Delete a known patient
4. Delete a known exam
5. Delete a known image

3.3. Clinical Review Station (CRS)

3.3.1. Functional Testing

1. Start work session
2. Select work queue preference
3. Search database by work queue
4. Search database by patient name
5. Search database by patient medical record number
6. Select study from patient studies list
7. Select image from presentation pane
8. Select all images from presentation pane
9. Adjust window & center control
10. Choose window & center presets
11. Use linear measurement on image
12. Use area measurement on image
13. Magnify image by 2x
14. Magnify image by 4x.
15. Rotate image by 180°
16. Flip image horizontally
17. Flip image vertically
18. Print image on screen to Laser Imager
19. End work session

3.3.2. Simulated Error Testing

1. Disrupt the IEEE 802.3 network connection
2. Disrupt the optical LAN connection
3. Delete a known patient
4. Delete a known exam
5. Delete a known image

3.4. TouchPanel Viewstation (TPV)

3.4.1. Functional Testing

1. Start work session
2. Select Critical Care Area preference
3. Select patient from patient list
4. Select study from patient studies list
5. Select image from image list
6. Adjust window & center control
7. Choose window & center presets
8. Magnify image by 2x
9. Print image on screen to Laser Imager
10. End work session

3.4.2. Simulated Error Testing

1. Disrupt the IEEE 802.3 network connection
2. Disrupt the optical LAN connection
3. Delete a known patient
4. Delete a known exam
5. Delete a known image

3.5. Demographic Entry Station (DES)

3.5.1. Functional Testing

1. Start work session
2. Select work queue preference
3. Select **New Study** button
4. Enter patient demographics
5. Enter exam information
6. Enter patient history
7. Select **Study Complete** button
8. Select **Existing Study** button
9. Choose Patient
10. Choose Exam
11. Enter password
12. Modify patient demographics
13. Modify exam information
14. Modify patient history
15. Select **Study Complete** button
16. End work session

3.5.2. Simulated Error Testing

1. Disrupt the IEEE 802.3 network connection
2. Enter inappropriate data
3. Leave required fields blank

3.6. Image Acquisition Station (IAS)

3.6.1. Functional Testing

1. Start work session
2. Select work queue preference
3. Select **New Study** button
4. Enter patient demographics
5. Enter exam information
6. Enter patient history
7. Place film in scanner
8. Select **Scan** button
9. Preview subsampled image
10. Select **Save Image** button
11. Enter image title
12. Repeat steps 9-12 several times
13. Select **Study Complete** button
14. Repeat steps 2-14 while station is transmitting first study to the Image Server
15. Repeat steps 2-13 and select **Cancel Study** button
16. End work session

3.6.2. Simulated Error Testing

1. Disrupt the IEEE 802.3 network connection
2. Turn off the scanner
3. Enter inappropriate data
4. Leave required fields blank
5. Jam a film in the scanner

3.7. Image Printing Station (IPS)

3.7.1. Functional Testing

1. Queue an image to be printed
2. Queue many images to be printed

3.7.2. Simulated Error Testing

1. Disrupt the IEEE 802.3 network connection
2. Disrupt the optical LAN connection
3. Remove the film cassette from the Laser Imager
4. Place empty film cassette in the Laser Imager
5. Turn off the Laser Imager

4. Substantially Equivalent (SE) Devices

4.1. Manufacturer and tradename of SE devices

The RSTAR Image Management System is substantially equivalent in design, composition and function to the following predicate 510(k)-cleared products that are currently on the market.

<u>Manufacturer</u>	<u>Product</u>	<u>510(k) No.</u>
Advanced Video Products (AVP)	TELEPRO	K862158/D
Kodak/Vortech	IMAGELINK	K915094

4.2. Promotional material and specifications

Brochures for the AVP and Kodak/Vortech systems are included as Exhibits J and K respectively.

4.3. Tabular comparison of features and specifications

The following three pages compare the RSTAR Image Management System to the Advanced Video Products TELEPRO System and the Kodak/Vortech IMAGELINK System. Although technical differences can be noted on the following comparison chart, RSTAR, Inc. believes that these differences are minor and that none of them affect the safety and efficacy of the RSTAR Image Management System.

Additionally, the Product Comparison System (PCS) for Picture Archiving and Communication Systems (PACS) as of August 1992 is included as Exhibit L.

5. Labeling

5.1. Promotional material

A draft copy of an RSTAR brochure intended as an overview to the RSTAR Image Management System is included as exhibit M.

5.2. User's manuals

Draft copies of User's Manuals for the RSTAR-IMS are included as the following exhibits.

- System Administrator's Guide Exhibit C
- Diagnostic Workstation User's Manual Exhibit E
- TouchPanel Viewstation User's Manual Exhibit F
- Image Acquisition Station User's Manual Exhibit H

5.3. Screens

Copies of screens for the IPS, DES, and IAS are included as the following exhibits.

- Image Printing Station Exhibit K
- Demographic Entry Station Exhibit G
- Image Acquisition Station Exhibit H

6. Software Information

The following sections list and briefly describe the software functions performed by each of the RSTAR components.

6.1. Data Acquisition

6.1.1. Image Acquisition Station (IAS)

- Collect patient demographic information
- Collect exam information
- Collect image information
- Collect image data
- Transmit above data to the Image Server

6.1.2. Demographic Entry Station (DES)

- Enter patient demographic information
- Modify patient demographic information
- Enter exam information
- Modify exam information
- Enter image information
- Modify image information
- Enter text note for a particular study
- Queue print request to Image Printing Station for all images of a particular study

6.2. Data Display

6.2.1. Diagnostic Workstation (DWS)

- Display patient demographic information
- Display exam information
- Display image information
- Display image data up to full resolution for a 14"x17" plane film digitized at 200 microns and 12 bits of resolution.
- Real-time window and center of image data allowing for display of the full 12 bit data set.
- Image Measurement (linear and area measurement)
- Image Data Isolation (rectangular and irregular isolation)
- Text annotation
- Bilinear image zoom by 2x or 4x
- Queue printing of image displayed on workstation

6.2.2. Clinical Review Station (CRS)

- Display patient demographic information
- Display exam information
- Display image information
- Display image data up to 1k by 1k by 12 bits of resolution
- Subsampled display of 14"x17" plane film image data digitized at 200 microns and 12 bits of resolution.
- Real-time window and center of image data allowing for display of the full 12 bit data set.
- Image Measurement (linear and area measurement)
- Image Data Isolation (rectangular and irregular isolation)
- Text annotation
- Bilinear image zoom by 2x or 4x
- Queue printing of image displayed on viewing station

6.2.3. TouchPanel Viewstation: 2K 1-Screen (TPV - 2K 1S)

- Display patient demographic information
- Display study information
- Display image information
- Display image data
- Real-time window and center of image data allowing for display of the full 12 bit data set.
- Queue printing of image displayed on viewing station
- Display textual notation for a particular study
- Play back voice notation for a particular study
- Enter voice notation for a particular study

6.2.4. TouchPanel Viewstation: 2K 2-Screen (TPV - 2K 2S)

- Display patient demographic information
- Display study information
- Display image information
- Display image data
- Real-time window and center of image data allowing for display of the full 12 bit data set.
- Simultaneous viewing of images from comparison study.
- Queue printing of image displayed on viewing station
- Display textual notation for a particular study
- Play back voice notation for a particular study
- Enter voice notation for a particular study

6.2.5. TouchPanel Viewstation: 1K 1-Screen (TPV - 1K 1S)

- Display patient demographic information
- Display study information
- Display image information
- Display image data
- Real-time window and center of image data allowing for display of the full 12 bit data set.
- Bilinear zoom at 2x at each of the four corners plus the center
- Display textual notation for a particular study
- Play back voice notation for a particular study
- Enter voice notation for a particular study
- Queue printing of image displayed on viewing station

6.2.6. TouchPanel Viewstation: 1K 2-Screen (TPV - 1K 2S)

- Display patient demographic information
- Display study information
- Display image information
- Display image data
- Real-time window and center of image data allowing for display of the full 12 bit data set.
- Bilinear zoom at 2x at each of the four corners plus the center
- Simultaneous viewing of images from comparison study.
- Display textual notation for a particular study
- Play back voice notation for a particular study
- Enter voice notation for a particular study
- Queue printing of image displayed on viewing station

6.3. Data Storage

6.3.1. RSTAR Image Server (RSTAR-IS)

- Coordinate overall system activity
- Support a System Administrator's Console for maintenance and system status investigation
- Maintain the patient demographic database
- Maintain the exam information database
- Maintain the image information database
- Maintain the radiographic image database
- Collect system audit information
- Collect system event information
- Collect system error information
- Store information transmitted from the Image Acquisition Station
- Manage queued requests to the Image Printing Station
- Retrieve and transmit images to the various display stations.

6.4. Data Printing

6.4.1. Image Printing Station (IPS-5000)

- Print image data to film
- Print patient demographic information with image data
- Print exam information with image data
- Print image information with image data

6.5. Data Transmission

6.5.1. RSTAR Image Server (RSTAR-IS)

- Transmit patient demographic information via IEEE 802.3
- Transmit study information via IEEE 802.3
- Transmit image information via IEEE 802.3
- Transmit image data via fiber optic star network

6.6. Description of software development methods

6.6.1. List or Diagram of steps in process

A flow diagram of the steps in the software development process used for the RSTAR Image Management System is included at the end of this section. The product development cycle is listed on the left with the associated software development activities on the right.

Included below are short descriptions on each of the phases.

Product Definition Phase: Joint effort between Software Engineering and the End-User (Marketing, Sales, Clinical User) to specify the requirements of the software to be generated.

Product Design Phase: Software Engineering effort to establish design guidelines (code modules, structures, interfaces, etc.) that meet the requirements established during the Product Definition Phase.

Code Phase: Generation of modular software units under the design guidelines that meet the specifications for a particular software module or unit of the overall software design. Individual unit testing validates the module code.

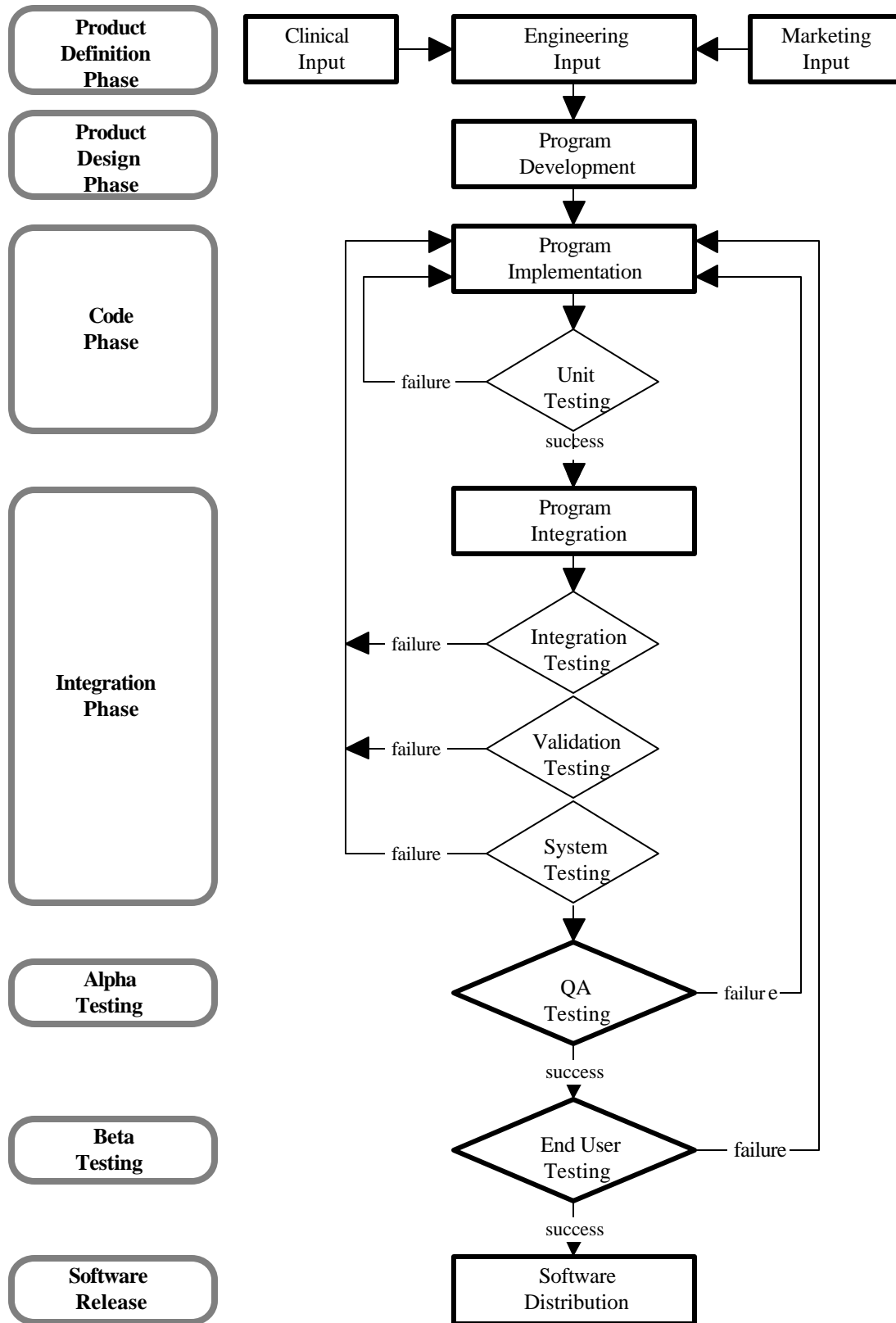
Integration Phase: Software is validated through three levels of testing. Integration testing assembles all the individual software modules and tests their individual functions and interfaces. Validation testing verifies that all software requirements have been met. System testing verifies the proper integration and functioning of the software with the hardware components in the system.

Alpha Testing: Quality Assurance testing on the complete system checks that the requirements generated during the Product Definition Phase have been met. For detailed testing information on each RSTAR component, see the Laboratory Testing sections 3.0 through 3.7 of this document. For an overview description of the software test procedures see section 6.8 of this document.

Beta Testing: End-user testing verifies the proper operation of the software at a customer site.

Software Release and Maintenance Phase: Once the software is released, the Maintenance Phase, under the management of Customer Support and Service, is initiated to track, monitor, diagnose and correct problems in the software. Section 6.8 of this document contains further detailed descriptions of software maintenance procedures.

Flow Diagram of Software Development Process



6.6.2. List of the departments responsible**• Software Engineering**

Product Definition Phase	- Engineering Input
Product Design Phase	- Program Development
Code Phase	- Program Implementation
Integration Phase	- Program Integration
Alpha Phase	- QA Testing

• Quality Assurance

Integration Phase	- Program Integration
Alpha Phase	- QA Testing
Beta Phase	- End User Testing

• Customer Service and Support

Alpha Phase	- QA Testing
Beta Phase	- End User Testing
Software Release	- Software Distribution
Software Maintenance	- Software Revision

6.6.3. Source control methods

Source code generated on the Digital Equipment Corp. (DEC) VAX series of computers is managed utilizing functionality from a number of different software facilities offered by VMS, a standard DEC operating system. The rest of this section describes these facilities and how each contributes to the RSTAR Code Control System.

Code Management System (CMS)

CMS, the VAX/VMS Code Management System, is a commonly used source code control system. It synchronizes programmers' modifications to software elements to prevent simultaneous modifications to the same piece of source code by two different programmers. In addition, it provides logging of modifications to software elements, and permits old versions of software to be recovered as necessary. Complete information on CMS is available in *Guide to VAX DEC/Code Management System*.

Module Management System (MMS)

MMS, the VAX/VMS Module Management System, is the VAX/VMS version of the UNIX "make" utility. It helps programmers and system administrators keep large software subsystems up-to-date as they evolve. MMS is able to rebuild an entire software subsystem from a concise description of the dependencies among the various parts of the subsystem, called a "description file". The description tells MMS which targets depend on which sources in the subsystem and what commands must be executed to reconstruct a given target from a given set of sources. Complete information on MMS is available in *Guide to VAX DEC/Module Management System*.

Projector Project Management Facility (Projector)

Source code generated on Apple Inc. Macintosh Computers is managed and tracked using Apple's **Projector**, a build-in Project Management facility of Macintosh Programmer's Workshop (MPW). Projector provides the same functionality that CMS and MMS provide on the VAX Computer. Complete information on Projector is available in *MPW: Macintosh Programmer's Workshop Development Environment, Volume 1*.

6.7. List of hazards related to the functions performed by the software and means taken to mitigate these hazards

The loss or corruption of patient demographics, study information and image data is the basic hazard related to any PACS. In the development of the RSTAR Image Management System, the following means have been taken to mitigate this potential problem.

Digital Equipment Corporation (DEC) VAX series computers are used as the main system controllers. Patient demographics, study information, and image information are stored in the DEC standard RDB relational databases running under the DEC standard VMS operating system. VAX computers also feature self-correcting magnetic storage devices which preclude data corruption in the databases. Additionally, nightly backups of the databases are initiated to safeguard against catastrophic failures.

Each entry in the databases is given a unique class and incidence number. Three system level tracking servers monitor the RSTAR Intensive Care Unit Mini-PACS.

1. **System Audit:** Tracks all transactions and notifies the appropriate resources of the transaction's completion, success or failure.
2. **System Event:** Tracks all events and notifies the appropriate resources of the event.
3. **System Error:** Tracks all errors and notifies the appropriate resources of the problem.

To prevent the display of incorrect image data, the patient name, medical record number, unique study number and unique image number are stored in the upper part of the image data as an ASCII text header. The software automatically checks the medical record number, the unique study number and the unique image number against the numbers requested by the display station, before displaying the image on the monitor. If the numbers do not match, no image is displayed, an error message appears on the screen and a message is sent to the System Administrator's account detailing the error. The system will not display the wrong image data for a patient.

6.8. Description of software test procedures

- **All source code** written by RSTAR programmers follows the **Coding Standards for RSTAR** document which outlines coding standards for code modules including documentation standards, headers and naming conventions.
- **Programs, sub-systems, subroutines, libraries, procedures and functions** each have standard boiler-plate headers which include:
 - source file name
 - release date
 - version number
 - author
 - purpose
 - audit trail (dates and revision number of the last 3 revs)
 - titles of companion RSTAR documents
 - calling conventions
 - input and output parameters
 - external procedures used
 - library functions used
 - external functions used
 - global variables accessed
 - titles of relevant reference documents
- **Program development** is executed under the full debugging facilities offered by the software compilers utilized to generate the source code. These facilities include:
 - Controlling the software program's execution (starting the program, stopping at points of interest, resuming execution, etc.)
 - Tracing the execution path of the program
 - Monitoring the changes in variables and other program entities
 - Monitoring events (e.g., exception conditions)
 - Examining and modifying the contents of variables, or forcing events to occur
 - Testing the effect of modifications without having to edit the source code, recompile and relink
- **Separate test programs** are generated for each sub-system and all sub-systems are thoroughly tested before integration into the system.

- **Integration testing** is conducted under the management of Quality Assurance. Each system component is stress-tested before the code is released for Alpha Phase QA Testing.
- **QA testing** is conducted under the management of Quality Assurance. For more detailed information, see the Laboratory Testing section (3.0) of this document. The entire system is stress-tested before the code is released for Beta Phase Testing.
- **End-user testing** is conducted under the management of Customer Service. The system is tested for proper operation in a customer environment.
- **Software Release** is managed by Customer Service and Support. Revision levels at all customer sites are tracked and monitored. Software upgrades are performed as deemed necessary by Customer Service and Support in collaboration with each individual customer site.
- **Software Maintenance** is managed by Customer Service and Support. There are four types of software maintenance that require software upgrades. These are as follows:
 1. Corrective Maintenance - diagnosis and correction of software errors found by end-users.
 2. Adaptive Maintenance - modification of software to maintain compatibility with the changing hardware environment.
 3. Prefective Maintenance - requests from users for new capabilities, modifications and general enhancements.
 4. Preventive Maintenance - modifications to improve future maintainability and reliability or to provide a better basis for future enhancements.

As software maintenance is accessed, the management of RSTAR, Inc. will evaluate the changes and will decide if they could significantly affect the safety or effectiveness of the system as it is described in this document. Changes that could significantly affect the safety or effectiveness of the devices in the system will result in the submission of a new 510(k).

6.9. Certification of a responsible company official that the software information is correct

I certify that the software information provided in this notification is correct, and that RSTAR, Inc. follows and will continue to follow the above Software Development Methods for the design, development, testing, and validation of the software for the RSTAR Image Management System.

Maria Kaldis
Vice President Administration

7. Hardware Information

RSTAR, Inc. follows the basic principles of electronic design in the development of custom hardware for the RSTAR Image Management System. The three phases of hardware engineering and the basic functions and deliverables of the phases are listed below.

1. Planning and Specification

Hardware Functions

Development Planning (DP)
 Review (failure to DP)
 Detailed Requirements Analysis (DRA)
 Review (failure to DRA)

Hardware Deliverables

Costs Schedule
 Hardware Specification

2. Design and Prototype Implementation

Hardware Functions

Design Analysis (DA)
 Manufacturing Analysis (MA)
 Build prototype and test
 Review (failure to DA)

Hardware Deliverables

Design Drawings
 Manufacturing Specification
 Prototype

3. Manufacturing, Distribution and Field Service

Hardware Functions

Manufacture
 Quality Assurance
 Error Cause Removal (ECR)
 Review (failure to ECR)
 Distribution

Hardware Deliverables

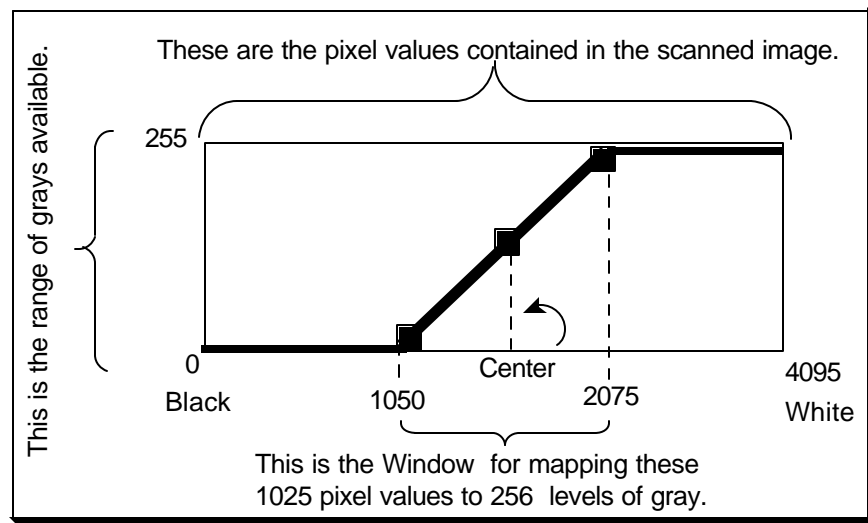
Products

8. Listing of Exhibits

Exhibit A	HP • Optical Disk Library Systems Technical Specifications
Exhibit B	Window and Center
Exhibit C	RSTAR-IMS • System Administrator's Guide
Exhibit D	HP • C2247 3.5-inch Disk Drive Technical Specifications
Exhibit E	RSTAR-IMS • Diagnostic Workstation User's Manual
Exhibit F	RSTAR-IMS • TouchPanel Viewstation User's Manual
Exhibit G	RSTAR-IMS • Demographic Entry Station • Screens
Exhibit H	RSTAR-IMS • Image Acquisition Station User's Manual and Screens
Exhibit I	Lumisys Lumascan 150 Laser Film Digitizer Technical Specifications
Exhibit J	ANALOGIC DASM™-XPRF Brochure
Exhibit K	RSTAR-IMS • Image Printing Station • Screen
Exhibit L	3M Laser Imager XL Technical Specifications
Exhibit M	RSTAR • RSTAR Image Management System Overview Brochure
Exhibit N	Advanced Video Products (AVP) TELEPRO Brochures
Exhibit O	Kodak/Vortech IMAGELINK Brochures
Exhibit P	Product Comparison System (PCS) on Picture Archiving and Communication Systems (PACS)

WINDOW AND CENTER

When an image is digitized, the Image Acquisition Station component of the RSTAR Image Management System, records 4096 shades of gray from completely black (0) to completely white (4095). Monitors can only display 256 shades of gray, so the viewing stations map each of the 4096 shades stored in the image to one of the 256 shades that can be displayed on the screen. To control brightness and darkness, you control how viewing stations map "image gray shades" to "display gray shades." This mapping is shown in the figure below.



Initially, the 4096 image shades are spread out evenly over the 256 display shades. This spread is called the **window**. To increase contrast, you narrow the window so that fewer image shades map to the display shades. For example, image shades 1293 to 3872 might map to the 256 display shades. Any gray darker than 1293 would show up on the display as black, and any shade lighter than 3872 would show up on the display as white.

Note: In this usage, the term window does not have anything to do with "windows" as they're used on Macintosh and PC computers.

The midpoint between the lightest image shade and the darkest image shade in the window is called the **center**. The center determines which image shade corresponds to a 50% gray on the display. Initially, image shade 2048 corresponds to display shade 128. Both values represent 50% grays. To increase the brightness, you map the center to lighter image shades. To make the image darker, you map the center to darker image shades.

RSTAR

System Administrator's Guide

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Using the System Administration Utilities 1

When RSTAR, Inc. installs the RSTAR Image Management System, the manager in charge of the installation will make sure that the image server, the diagnostic workstations, and image acquisition stations are set up correctly. As the on-site system administrator, you may need to perform some maintenance tasks from time to time. Or if a problem develops in the system's computers, your RSTAR liaison may ask you to use the utilities described in this chapter to do some preliminary diagnosis.

Do you need to read this chapter?

This chapter assumes that you are the on-site system administrator—the person designated by your institution to be the key contact between your institution and RSTAR. You should understand how the RSTAR system is organized and how it works. You should also be familiar with both the RSTAR Diagnostic Workstation and the RSTAR Image Acquisition Workstation.

Topics covered in this chapter

- About the System Administrator Utilities
- The Workstation Preferences Utility
- The Executive Utility

About the System Administrator Utilities

The System Administrator utilities are HyperCard stacks that let you examine the state of any workstation in your RSTAR Image Management System and that let you monitor the servers (auxiliary programs) running on the VAX.

In this chapter, you will see many references to servers. In this case, a server is a program running either on the VAX (or some other computer) that provides a service to an RSTAR IMS workstation. For instance, there is a server whose only purpose is to send images from the main storage to an RSTAR Diagnostic Workstation. There is another server that gets patient information from the

patient database. When a radiologist opens a study, the workstation sends a request to the database server for the patient information and a request to the image server for the image.

Each server offers its clients a set of remote procedure calls (RPCs). You can think of RPCs as the kinds of requests that a server can satisfy.

This is a list of some servers that make up your RTSR Image Management System:

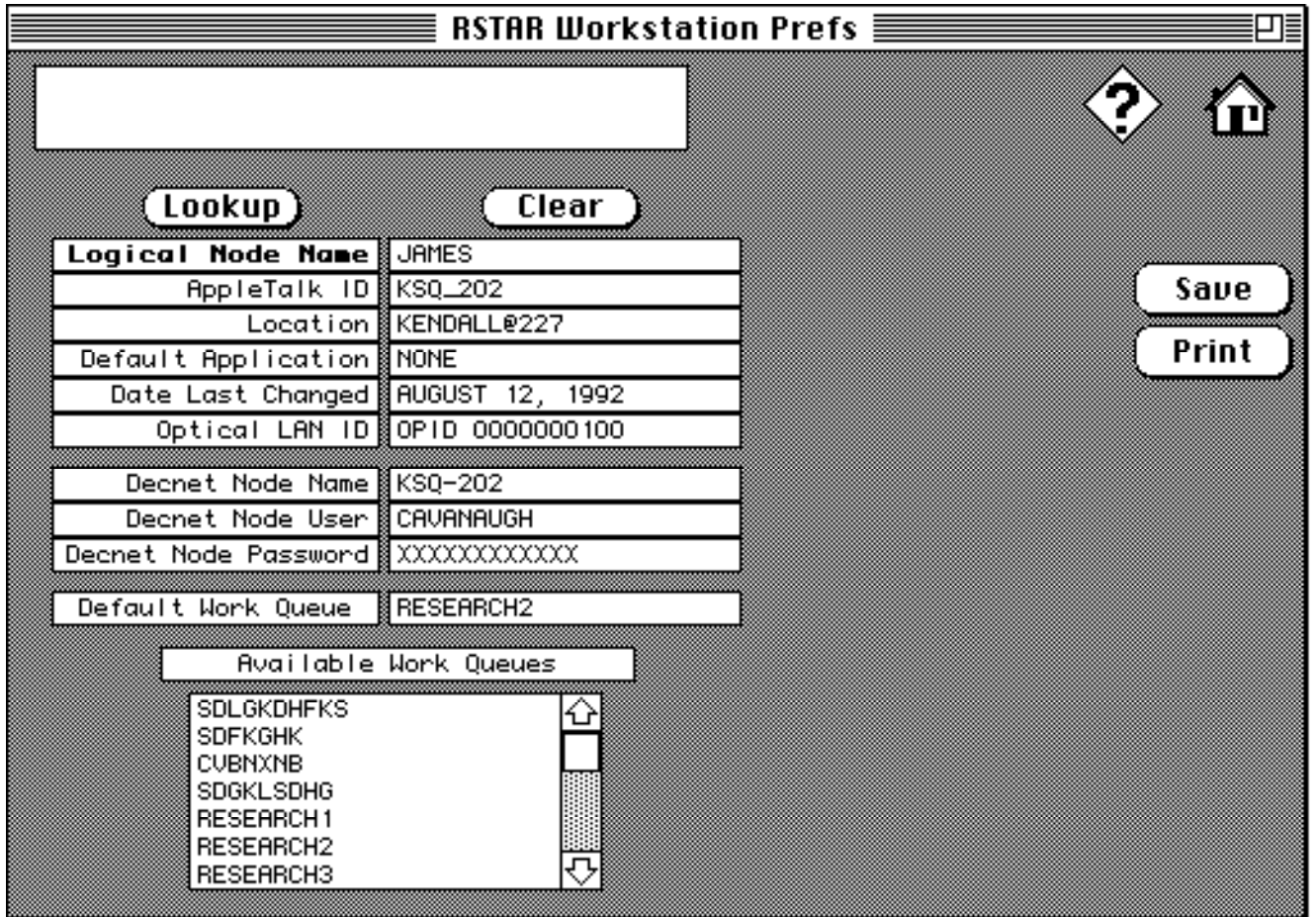
Server	Function
DBV2	Transfers patient information from the patient database.
IMAGESUBSTRATE	Transfers images to workstations
NAMESERVER	Directs traffic between workstations and servers
NEW_EXEC	Monitors servers and starts them again if they have stopped.
PREF_DB	Maintains workstation preferences.

Because there are many complex parts, a problem in the RSTAR Image Management System might be physical (a loose networks connection), hardware-related (an unplugged computer), or software-related (a malfunctioning sever or RPC). The System Administrator utilities can help you and your RSTAR liasion diagnose some of these problems quickly.

Not all of the information that the System Administrator utilities provide will be meaningful to you. Most of the information is designed to help you help your RSTAR liasion diagnose and correct any problems in your RSTAR IMS.

The Workstation Preferences Utility

The RSTAR Workstation Preferences Utility lets you examine and modify information about any workstation in your RSTAR Image Management System.



Logical Node Name	JAMES
AppleTalk ID	KSQ_202
Location	KENDALL@227
Default Application	NONE
Date Last Changed	AUGUST 12, 1992
Optical LAN ID	OPID 0000000100

Decnet Node Name	KSQ-202
Decnet Node User	CAVANAUGH
Decnet Node Password	XXXXXXXXXXXX

Default Work Queue: RESEARCH2

Available Work Queues

- SDLGKDHFKS
- SDFKGHK
- CUBNXNB
- SDGKLSDHG
- RESEARCH1
- RESEARCH2
- RESEARCH3

The Workstation Preferences Utilities

When you click on the Lookup button, you'll see a window that lists all of the workstations in your RSTAR IMS system. Select the workstation whose preferences you want to examine from that list.

The fields in this card give you information about how the workstation is set up. You can edit some of these fields, but not other. Some of the information in this card is useful when you are talking with your RSTAR liaison to track down a problem.

Field	Meaning	Editable
Logical Node Name	This is the name of the workstation that you chose from the list of workstations. Node names are assigned when your RSTAR Image Management System is installed.	No
AppleTalk ID	This is the name of the Macintosh computer at the workstation you chose. This name is not normally used in RSTAR IMS operations.	No
Default Application	This field tells you what kind of workstation you are looking at.	No
Date Last Changed	This is the date of the last time changes were made to this workstation's preferences. This field updates automatically.	No
Optical Lan ID	This is the ID of the workstation on the RSTAR Optical LAN that transfers images from the image server to the workstation.	No
Decnet Node Name	This is the name of the workstation on the Decnet network. This is the network that transfers patient information from the VAX to the workstation.	No
Decnet Node User	This is the user name of the workstation on the Decnet network	No
Decnet Node Password	This is the password of the workstation on the Decnet network	No
Default Work Queue	This is the selected work queue when the workstation is turned on. You can change this field.	Yes
Available Work Queues	This is the list of work queues that appears in the pop-up menu in the Work Queue Preferences dialog. You can type in this list to add or remove the names of work queues.	Yes

Note: You can't use the Available Work Queues list to create or delete work queues. This list just controls which queues are available to a particular workstation.

If you have the information in this card, click on the **Update** button to save it. To print the information, press the **Print** button.

To delete the workstation preferences for the selected workstation, click on the **Delete** button.

Important: If you delete a workstation's preferences, that workstation will not be able to communicate with the image server to get images or patient information. You will have to create a new workstation preferences for that workstation.

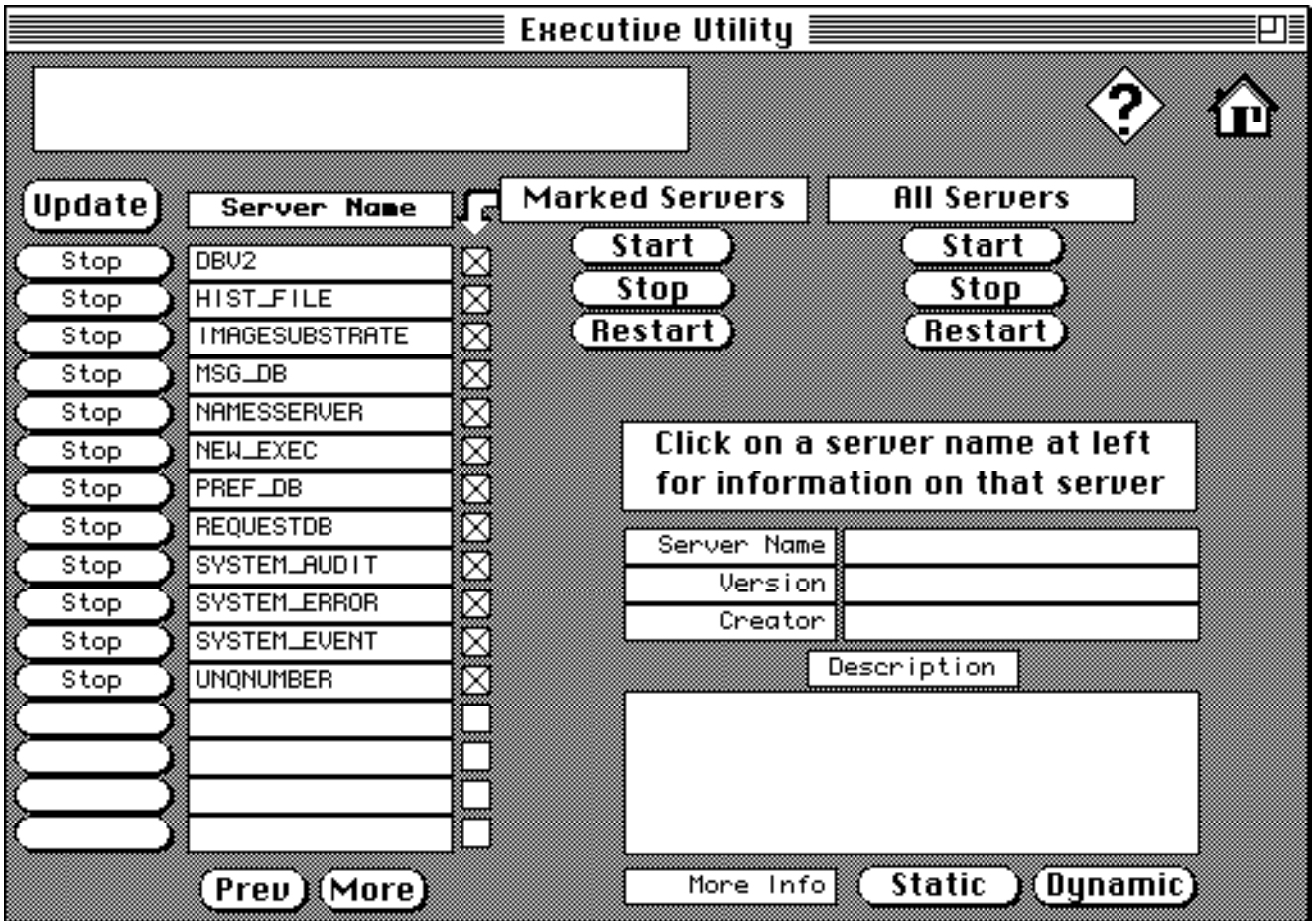
To create a new set of workstation preferences, click on the **Clear** button. The card will contain empty fields, and you will be able to type in values in each field. When you have typed in all the appropriate values, click on the **Save** button.

Note: The **Save** button is in the same place as the **Update** button. When you are working with existing information, the button says **Update**. When you are working with new information, the button says **Save**.

The Executive Utility

The Executive Utility lets you monitor the servers that are running on the VAX image server. To use the Executive Utility, click on the `$$EXECUTIL$$` button in the `$$HOME$$` Card `$$JAMES, HOW ABOUT A "GO TO EXEC" BUTTON IN THE WS PREFS CARD?$$`

You'll see a card that looks like this:



The Executive Utility

The names of all the RSTAR IMS **servers**, appear in the list in the left side of the card. If a process is running, the button to the left of the list says Stop, otherwise it says Start. If there are more servers than fit in the list, use the Prev and More buttons to move forward and backward through the list.

Note: In most cases, you'll use this utility to make sure that all the servers are running. In general, a stopped server— that you didn't stop yourself— is a sign of trouble.

When you click on a server name in the list, you'll see information about the server in the fields to the right of the server list.

Field	Meaning
Server Name	This is the name of the server that you clicked on from the list at the left.
Host Name	This is the name of the computer that the server is on.
Version	This is the version number of the server. Use this number to make sure that your servers are up to date.
Programmer	This is the name of the programmer who wrote the server.
Decription	This is a short description that tells you what the server does.

To start, stop, or restart a group of processes, click in the check boxes to the right of the list, and use the buttons under the Marked Servers label. To start, stop, or restart all the servers, use the buttons under the All Servers label.

Important: Be sure you know what you're doing when you stop or restart a server. Stopping a server while others are using image acquisition workstations or diagnostic workstations may interfere with their ability to retrieve images or to scan images.

You can get more information about the sever through the **Static** and **Dynamic** buttons. The **Dynamic** button gives you information that changes as the server runs. The **Static** button gives you additional information about the server.

The Dynamic information display

This is what that Dynamic informatino display looks like:

The screenshot shows a window titled "Executive Utility" with a home icon in the top right. The interface is divided into several sections:

- Top Left:** A large empty rectangular box.
- Top Right:** A home icon.
- Left Side:** Two input fields labeled "Server Name" and "Host Name".
- Center:** A vertical list titled "RPCs" with ten empty rows.
- Right Side:** An input field labeled "RPC", and three stacked input fields labeled "Times Exec.", "Debug Level", and "Hard Errors".
- Bottom Left:** A section titled "ERRORS" containing a table with three rows: "Transport" with value "0", "Value" with value "0", and "SWIB" with value "0".
- Bottom Center:** Two buttons labeled "Prev" and "More".

The Executive Utility Dynamic View

The two fields in the upper right part of the card have the same information as the summary card you just came from.

Field	Meaning
Server Name	This is the name of the server that you clicked on from the list at the left.
Host Name	This is the name of the computer that the server is on.

The Errors list gives information about communication errors on the server. The information in these fields is useful when you are trying to track down a problem with your RSTAR liasion.

Field	Meaning
Transport	This is a count of transport errors. Transport errors are network errors like failed requests or failed responses.
Validation	This is a count of validation errors. A validation error is a bad authorization code or an out-of-date parameter block.
SWIB	This is a count of software interface bus errors. These errors involve the mechanism that lets a workstation communicate with servers.

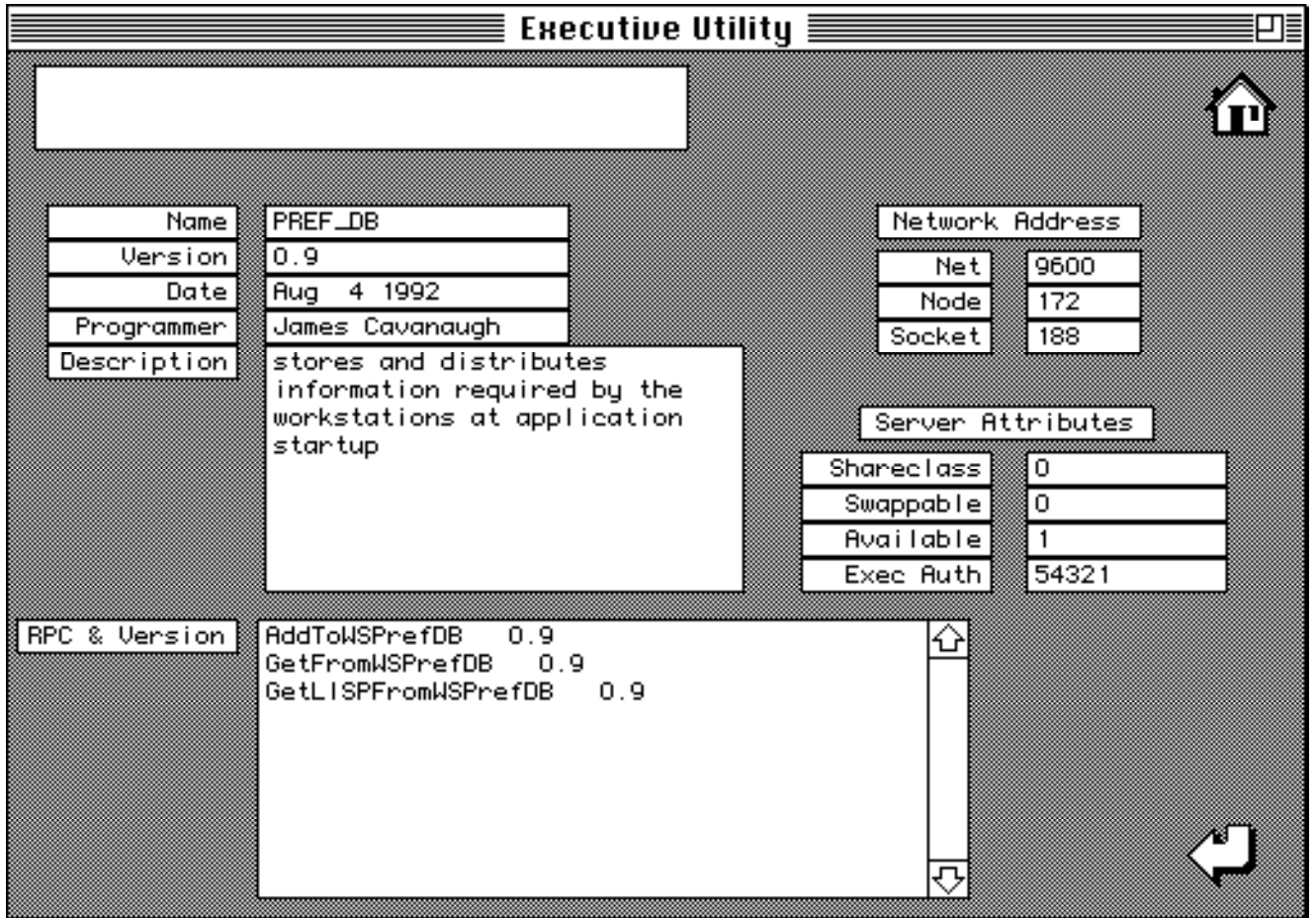
The list in the center of the display lists all the **remote procedure calls** (RPCs) that the server supports. If there are more RPCs than fit in the list, use the **Prev** and **More** buttons to move back and forth in the list.

When you select an RPC from the list, you'll see information about that RPC in the fields to the right of the list.

Field	Meaning
Times Exec	This is the number of times the RPC has been called.
Debug Level	This is an indication of how much diagnostic information the RPC is generating.
Soft Errors Hard Errors	These two fields log programmer-defined errors. The values in these fields are useful when you are tracking down a problem with your RSTAR liaison.

The Static information display

This is what the Static information display looks like.



The Executive Utility Static View

The information in the top left part of the display is the same as in the main Executive Utility display.

Field	Meaning
Server Name	This is the name of the server that you clicked on from the list at the left.
Host Name	This is the name of the computer that the server is on.
Version	This is the version number of the server. Use this number to make sure that your servers are up to date.
Date	This is the date the server was built.
Programmer	This is the name of the programmer who wrote the server.
Description	This is a short description that tells you what the server does.

The RPC & Version field shows you all the remote procedure calls (RPCs) that the server provides and their version numbers. You can get more information about each RPC in the Dynamic display.

The Network Address fields tell you the AppleTalk network address of the server. The information in these fields is useful when you are tracking down a problem with your RSTAR liasion.

The Server Attributes give you additional information about some of the properties of the server.

Field	Meaning
Shareclass	If the value in this field is not zero, the server can be use by more than one client at the same time.
Swappable	If the value in this field is not zero, this server must be available before a new server can be installed in its place.
Available	If the value in this field is not zero, the server is available to clients. Some servers can be used by a limited number of clients, and if the server is busy, this field will read zero.
Exec Auth	This is the athorization code needed to stop or start the server.

RSTAR System Administrator

System Activity

- System Idle
- Status Request
- Acquiring Image
- Transmitting Image
- Printing Image
- Running Diagnostics

Information, Warnings, Errors

Image server ready
Request copying "SteveM:RSTAR:65761:65712.RIFF" from
Copied "65712.RIFF"
Request copying "DIGITIZER1:RSTAR:65763:65713.RIFF"
Copied "65713.RIFF"

Last Active Station

Workstation 4

Last Image

65946.RIFF

Last Request

Transmit Image

Active Stations

Digitizer - DIGITIZER3
Workstation 4
Digitizer - DIGITIZER1

Available Disk Space

System Disk
60 megabytes

Database Disk
30 megabytes

Image Cache
100 megabytes



RSTAR System Administrator

Image Printing Options

Remove Selected Job

Clear Print Queue

Reset Laser Imager

DAK Report Printing Options

Clear Print Queue

Image Print Queue

Queued Image	Priority
18534.IMAGEFILE	N
19339.IMAGEFILE	H
18760.IMAGEFILE	N
13065.IMAGEFILE	N
12864.IMAGEFILE	H

Goto Status Screen

RSTAR



RSTAR System Administrator

Available Reports

System Configuration

Patients Report

Studies Report

Data Files Report

Audits Log

Errors Log

Usage Log

Events Log

Clear Logs

Audits Log

Errors Log

Usage Log

Events Log

DataBase Functions

Verify Databases

Backup Databases

Restore Databases

Databases Consistency

Other Functions

Configure System

Restart VAX Servers

Goto Status Screen

RSTAR

Diagnostic Workstation User Manual

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Welcome

1

Welcome to the RSTAR Image Management System. This manual shows you how to use the RSTAR Diagnostic Workstation to work with images stored on the RSTAR Image Server.

This chapter gives you an overview of the RSTAR Image Management System (IMS) and introduces you to some basic RSTAR IMS concepts that you need to know to use the RSTAR Diagnostic Workstation.

Do you need to read this chapter?

If you're already familiar with RSTAR IMS and with work queues and studies, you can skip ahead to the next chapter to learn how to use the RSTAR Diagnostic Workstation.

If you're eager to get started, but you've never worked with RSTAR before, be sure to scan the section called "How RSTAR IMS Organizes Information" later in this chapter.

About this manual

In this manual the names of menu commands and buttons appear in **bold face**. When a new term appears for this first time, it appears in bold face, too.

Note: Useful information that makes it easier to work with your RSTAR Image Management System or that you might want to know appears in a "note box" like this.

Important: Be sure to read the information in an "important box" like this one. It alerts you to steps that you can't undo or that might affect the operation of your workstation.

What is the RSTAR Image Management System?

The RSTAR Image Management System is a Picture Archiving and Communication System (PACS) that lets you store, look at, and manipulate radiological images on a high-resolution display. The main purpose for any PACS is to store images electronically and to make these images accessible for interpretation to remote sites.

As physicians rely more and more on radiology for effective and accurate diagnoses, radiology departments need to deal with the overwhelming amount of radiological information. Currently, most radiological information is stored on photographic film. Although film has been useful and effective for years, it has significant drawbacks. It is bulky. It is fragile. It is easily misplaced.

Electronic images have substantial advantages over film images. Electronic images take up less space. Electronic images are easily transmitted over networks without affecting the original image. The same image can be transmitted to several interpretation sites at the same time. But perhaps the most important advantage of electronic images over film images is that electronic images can be manipulated. The RSTAR Diagnostic Workstation, for instance, lets radiologists enlarge images, isolate parts of images, and change the display to highlight different characteristics.

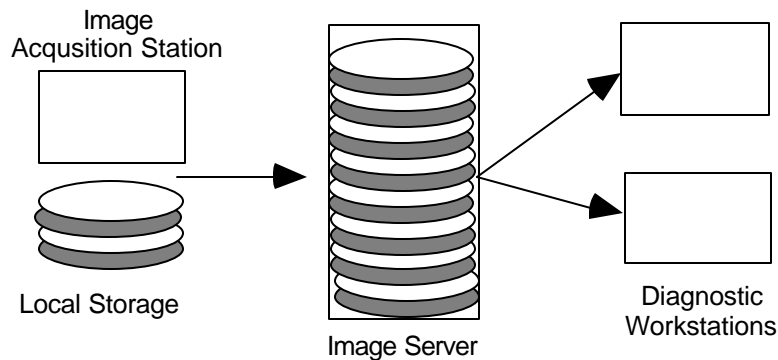
How RSTAR IMS Works

The RSTAR Image Management System is made up of three main parts: the image acquisition station, the image server, and the diagnostic workstation. These three components don't have to be in the same room— or even in the same building.

A radiology technician uses the **image acquisition station** to scan existing film images into the RSTAR Image Management System. The RSTAR Image Acquisition Station has a **scanner** and a Macintosh computer. The scanner reads existing film images and translates them into a digital image made up of thousands of dots, or **pixels**. There are 200 pixels per inch, and each pixel can be one of 4096 shades from completely white to completely black. After the technician scans a set of images, the workstation sends the image to the image server over a high speed network. The display on the Macintosh lets the technician preview the images before sending the images to make sure they were scanned correctly.

The **image server** is a high-capacity computer that stores the images. The image server works like a file cabinet to organize images so a radiologist can request them later. Unlike film images, several radiologists can request and look at the same image at the same time. Any diagnostic workstation linked to the image server can access any of the images stored there. The RSTAR image server can be configured to work with as many images as your institution requires.

When you scan an image, the image acquisition station stores it temporarily in its local storage. When you finish scanning images, the image acquisition station sends them to the image server. Once the images are there, they're available for viewing at a diagnostic workstation. Depending on the speed of the network between the image acquisition station and the image server, it could take a few minutes for images to actually get from the image acquisition station to the image server. The RSTAR system has a mechanism to make sure that important clinical images get to the image server faster than low priority research images. The next section describes this mechanism.



How RSTAR stores information

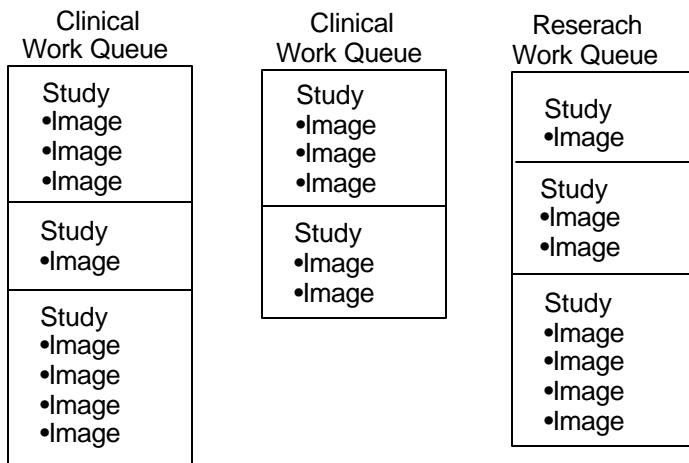
The diagnostic **workstation** is the computer where a radiologist examines the images stored in the image server. The radiologist requests images from the image server from a list of images or by patient name or medical record number. The image server transmits the selected images to the workstation where they're displayed on a large (10 x 12 inch) high-resolution gray-scale display. The display shows images at 200 pixels per inch, and each pixel can be one of 256 shades of gray, from completely black to completely white. Using the workstation controls, the radiologist can enlarge or isolate parts of the image. A special control in the workstation lets the radiologist adjust the image display to highlight soft tissues or bone or even to turn the whole image from a film negative to a film positive.

How RSTAR IMS Organizes Information

If all the images were stored at the image server without some organization, it would be very difficult to find the particular set of images you want to work with. The RSTAR Image Management System uses the concept of studies and work queues to organize images. Whether you use the image acquisition station or the diagnostic workstation, it is important that you become familiar with studies and work queues.

Every image in the RSTAR system belongs to a **study**. Some studies contain only one image, and other studies contain several images. Studies also hold demographic information about the patient and the patient history. Usually, whoever scans the images into the RSTAR Image Management System adds the patient information to the study.

Every study is part of a **work queue**, which is a collection of related studies. For example, your system might have several clinical work queues for different departments as well as several work queues for research projects. Work queues are like a file cabinets to keep images about specific patients or about a particular research project together.



How RSTAR IMS organizes images

Work queues have another purpose. They prioritize how quickly images get from an image acquisition station to the image server. Suppose that a technician is scanning historical images for a research project. These images go into a research work queue. In the middle of scanning the research images, the technician is asked to scan a clinical image that a radiologist needs to examine immediately. That image should go into a clinical work queue. Because it takes time for a study to get from the image acquisition station to the image server, there may be several research studies waiting to go to the image server when the technician scans the important clinical study.

Instead of transmitting the waiting research images, the image acquisition station sends the clinical study first. That's because clinical queues have a higher priority than research queues. Once the image server receives the clinical study, the image acquisition station continues with the research studies.

Note: A control in the image acquisition station can give a higher priority to any study so the station transmits ahead of any pending study.

Understanding studies and work queues is important whether you use the RSTAR Image Acquisition Workstation or the RSTAR Diagnostic Workstation. When you digitize images, the image acquisition station asks you to choose a work queue where you'll create studies to receive the images you're scanning. When you use the diagnostic workstation, the first thing you'll need to do is choose a work queue from which you'll pick the studies that contain the images you want to examine.

Where To Go Next

The next chapter shows you how to use the RSTAR Diagnostic Workstation to look at images stored in the RSTAR Image Server. If you want to learn how to use the image acquisition workstation, see the RSTAR Image Acquisition Workstation User Manual.

Using the Diagnostic Workstation 2

This chapter shows you how to use the RSTAR Diagnostic Workstation. You will learn how to select the images you want to display, how to rotate images, how to enlarge images, and how to change the display to lighten and darken images.

What you should know

You should be familiar with the way the RSTAR Image Management System stores information. You should know about work queues, studies, and images. If you do not know what these things are, read “How RSTAR IMS Organizes Information” in Chapter 1.

Topics covered in this chapter

- About the Diagnostic Workstation
- Choosing a Study
- Working with Images
- Using the Tool Palette
- Rotating and Flipping Images
- Adjusting Contrast and Brightness
- Printing Images
- Ending a Work Session
- Troubleshooting

About the Diagnostic Workstation

The RSTAR Diagnostic Workstation consists of Macintosh Quadra 950, and one to eight high resolution display monitors.

Turning the workstation on

To turn the RSTAR Diagnostic Workstation on, press the power-on key on the Macintosh keyboard. This is the key marked with a triangle in the upper right part of the keyboard.

You will hear a chime, and the display will show a “Welcome to Macintosh” dialog. After a minute or so, the RSTAR Diagnostic Workstation program will start, and you will see a large RSTAR logo in the middle of the display area, some buttons and controls on the right side of the display, and a row of menus across the top of the screen.

Diagnostic workstation menus

Across the top of the display you will see the RSTAR Diagnostic Workstation menus. These menus contain commands that let you choose the images you want to look at and commands that manipulate the image being displayed.

Menu	Function
Apple	Standard Macintosh Apple menu. Contains Macintosh-related commands not used with the RSTAR Diagnostic Workstation.
File	Contains the Quit command
Work Flow	Contains commands that let you choose the images you want to display.
RSTAR	Contains the Clear Overlays command
Image Processing	Contains commands that let you rotate and flip images and set the magnification factor.

Diagnostic workstation panes

The RSTAR Diagnostic Workstation display is divided into several sections or panes. The main part of the screen shows the radiological images of a particular study. The right side and bottom of the screen has several buttons and controls that let you work with the radiological images.



The RSTAR Diagnostic Workstation display

This table shows you what the controls in each of the panes are for.

Pane	Function
Tool Palette	Contains several tools that let you measure, isolate, and enlarge the image being displayed.
Window/Center	Controls the intensity and contrast of the image being displayed.
Presentation	Contains a list of all the images associated with the study.
Work Flow	Contains buttons that let you mark a study as being read, and scan the current work queue.
Study Information	Information about the study.
Patient Demographics	Displays patient information about the current study

Choosing a Study

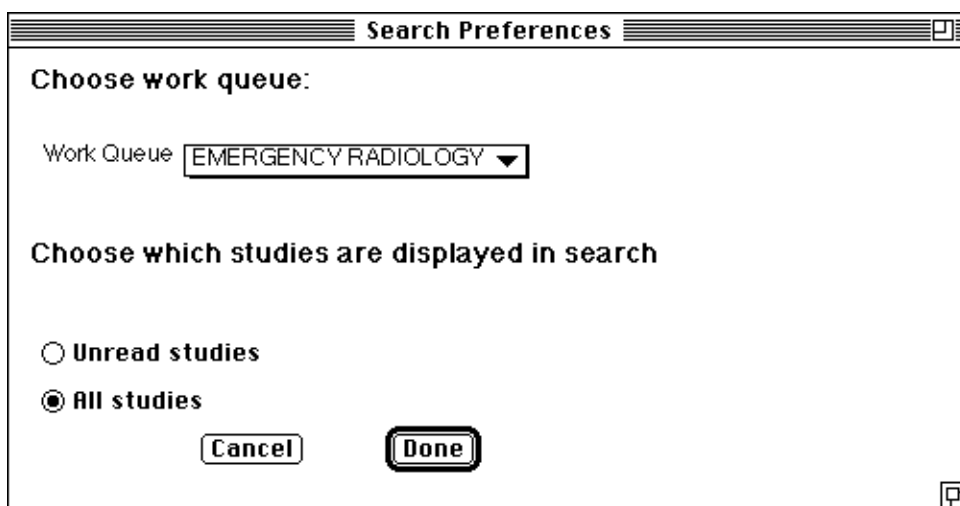
As you learned in Chapter 1, RSTAR IMS groups all images into studies and all studies into work queues. The first thing you need to do to work with images is to choose a study. RSTAR IMS lets you choose studies three ways:

- from a list of all or unread studies in a work queue
- by patient name
- by medical record number

If you want to work with a set of related studies, or if you know that the study you want to look at is in a particular work queue, then choosing it from a list of all the studies in that queue is easiest and fastest. If you are looking for studies that belong to a specific patient, then looking for it by patient name or medical record number is fastest.

Searching by Work Queue

To choose the work queue, choose the **Work Queue Preferences** command from the **Work Flow** menu. A dialog box that looks like this appears:



The Work Queue Preferences Dialog Box

If you want to see only the studies that have not been read, click on the **Unread studies** button. If you are interested in all the studies in the work queue, click on the **All studies** button.

Click and hold the pointer on the **Work Queue** pop-up menu, and choose the work queue you want to use.

Once you have selected a work queue, you can select the study you want to examine from the studies list. The studies list shows the patient name, medical record number, date, and study type for each study.

Select studies by double-clicking			
Patient Name	MRN	Date	Exam Description
Harrison, Mikhail	018779856	1992-08-19	Chest
Roberts, Melanie	279087614	1992-08-17	Bone
Papadopoulos, Andreas	135420846	1992-07-15	Bone
Smithson, Cornelia	106689543	1992-07-15	KUB
Torres, Ricardo	491961840	1992-07-15	Chest
Christiansen, David	985177627	1992-07-15	Chest
Davidson, Christina	541003326	1992-08-19	Spine
Leverett, Ahmed	341175392	1992-08-18	Bone
	163060992	1992-08-14	KUB

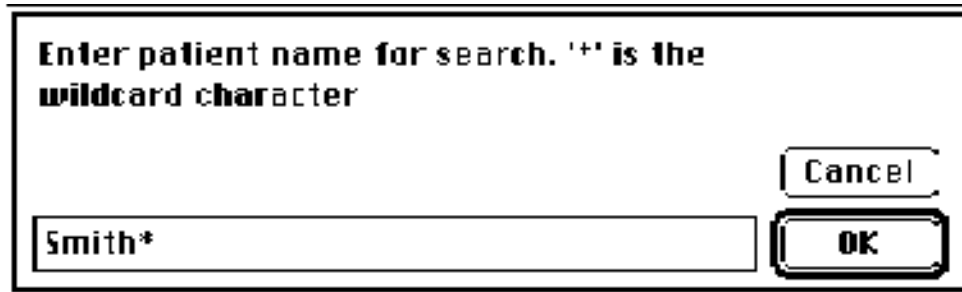
The Patient Studies list

Double-click on the study that you want to look at. In a few seconds the first image in the study appears on the screen.

To go back to the studies list for the work queue you chose, click on the **Search** button in the Work Flow pane or choose the **Search by Work Queue** command from the **Work Flow** menu. You do not have to choose the same work queue again.

Searching by patient name or medical record number

If you know the patient name or the medical record number of the study you want to look at, choose the **Search by Patient Name** or the **Search by Patient MRN** command from the **Work Flow** menu. You will see a dialog box that looks like this:



Search by Patient Name Dialog Box

Although you can type the entire patient name or medical record number, it is more convenient to type only part of the name or number and use the **wildcard character** (*). For instance, to find all the patients named “Smith” you might type:

Smith, *

RSTAR IMS stores patient names in the form Last Name, First Name. So to find all the patients whose last name begins with Smith (Smith and Smithson, for instance), you would type this instead:

Smith*

You can use the (*) character anywhere in the search. To find all the patients whose first name Mikhail, you would type:

* , Mikhail

The same principles apply to searching by medical record number. Here are some examples:

Typing this...	finds this...
1961*	all records that start with 1961
*1776	all records that end with 1776
1066	all records that contain 1066 anywhere in the number

Note: An important thing to keep in mind, particularly when searching by patient name, is that RSTAR IMS distinguishes between upper case and lower case.

Getting new studies

If you need to look at an image that is being scanned in, it will not appear in the studies list automatically. You need to rescan the work queue. To do this, click on the **Search** button or choose the **Search by Work Queue** command from the **Work Flow** menu.

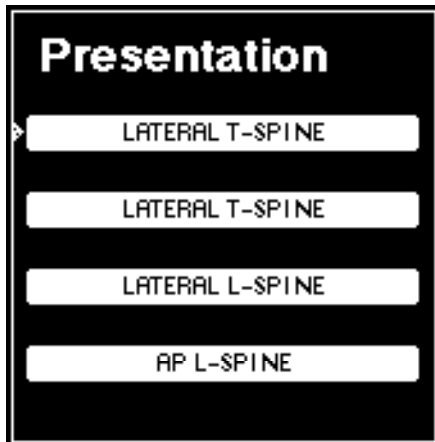
Working with Images

The RSTAR Diagnostic Workstation has many tools that let you manipulate images. You can isolate, enlarge, and rotate images, and you can change the contrast in the image to accentuate different features.

For operations that enlarge, isolate, measure, and annotate, use the tools in the tool palette. For operations that flip and rotate images, use the commands in the **Image Processing** menu. To control the contrast of the image, use the Window/Center control. To choose from the several images in a study, use the buttons in the presentation panel. This section shows you how to use each of these tools and controls.

Displaying images

When you choose a study, the RSTAR diagnostic workstation automatically displays the first image in the study. If the study has more than one image, the presentation pane will have one button for each image.

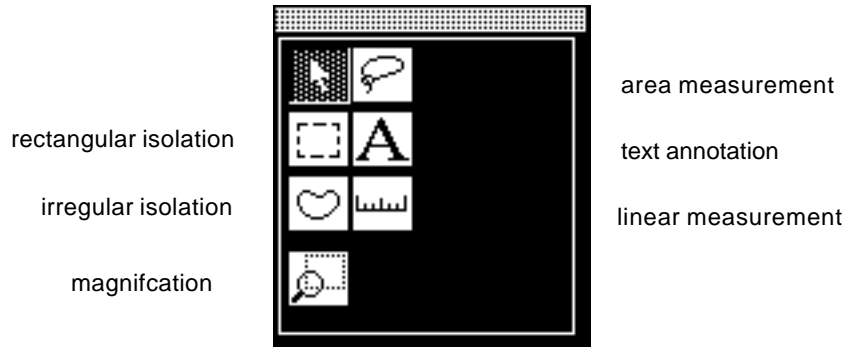


Presentation Pane with several images

To display a different image, just click on the button of the image you are interested in.

Using the Tool Palette



The Tool Palette in the upper right part of the RSTAR Diagnostic Workstation display has several tools that let you isolate parts of the image, enlarge parts of the image, measure distances and areas.




The Tool Palette

Isolating parts of images


The two isolation tools in the tool palette let you isolate rectangular and irregularly shaped areas of the image being displayed.

To isolate a rectangular area, click on the tool that looks like a dotted rectangle: . The pointer turns into cross-hairs: . Move the pointer into the image. Hold down the mouse button, and drag the mouse to form a rectangle. When you let go of the mouse button, RSTAR IMS blacks out everything in the image except the rectangle you just drew. To go back to the full view of the image, click the mouse anywhere in the display area.

To isolate an irregularly shaped area, click on the tool that looks like a kidney: . The pointer turns into cross-hairs. Hold down the mouse button and use the mouse to draw any shape you like. You do not need to complete the shape exactly. When you let go of the mouse button, RSTAR IMS connects the two endpoints and blacks out everything in the image except the shape you just drew. To go back to the full view of the image, click the mouse anywhere in the display area.


Enlarging parts of images

The magnification tool in the tool palette gives you a 2x or 4x enlargement of a portion of the displayed image. To change the magnification factor, choose it from the **Image Processing** menu.

When you click on the magnification tool, the pointer changes to a magnifying glass . Move the pointer into the image and hold down the mouse button. The place where you click the mouse button becomes the top left corner of the enlargement. A dotted rectangle shows you which part of the image will be enlarged. As long as you hold down the mouse button, you can move this rectangle to select the part of the image to enlarge.

When you let go of the mouse button, RSTAR IMS takes several seconds to enlarge the image. To make it easy for you to come back to the enlarged image, RSTAR IMS adds it to the list of images in the presentation pane. The name of the enlarged image is the same as the original image, but it has an icon next to it to show that it is enlarged.

Annotating images


Use the annotation tool to add text to the images you are looking at. Click on the text tool, . Move the pointer to the place you want the text to appear, and click the mouse. RSTAR IMS displays a dialog box where you can type anything you like. If you are satisfied with what you have typed, click on the **Save** button, otherwise click on the **Cancel** button.


The annotation appears on top of the image where you clicked the mouse. If you want to remove the text, choose the **Clear Overlays** command from the **RSTAR** menu.

Note: The annotations are not saved with the image.

Measuring images

The two measurement tools in the tool palette let you measure straight lines or areas.

Use the tool that looks like a ruler to measure straight lines: . When you click on this measurement tool, the pointer turns into cross-hairs. In the image area, click on the point you want to start measuring. Drag the mouse and release the mouse button at the point that you want to stop measuring. A measurement window appears in the upper right part of the screen, and reports the length of the line in centimeters.

Use the tool that looks like a lasso to measure areas: . When you choose this measurement tool, the pointer turns into cross-hairs. Hold down the mouse button and use the mouse to draw any shape you like. You do not need to complete the shape exactly. When you let go of the mouse button, RSTAR IMS connects the two endpoints and reports the area of the region in pixels in a window in the upper left part of the screen.

The measurement tools leave lines on the image while you are viewing it, so you can continue to use them for reference. To clear these lines, use the **Clear Overlays** command in the **RSTAR** menu.

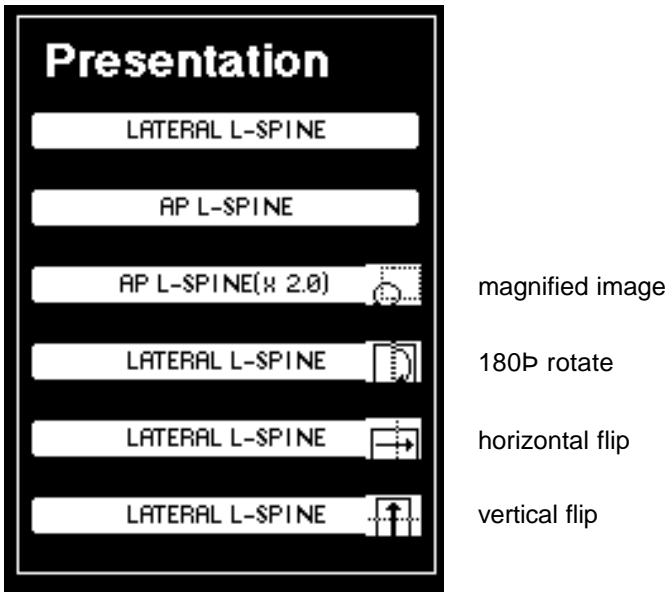
Rotating and Flipping Images

Use the commands in the **Image Processing** menu to rotate and flip the image on the screen and to set the magnification factor.

Command	Effect
Rotate 180°	Rotates the image so the top is at the bottom of the screen
Flip Vertical	Flips the image from top to bottom (upside-down mirror image)
Flip Horizontal	Flips the image from left to right (mirror image)

Note: The two other commands in this menu control the magnification factor when you use the magnification tool in the tool palette. See “Enlarging parts of images” above to learn how to magnify images.

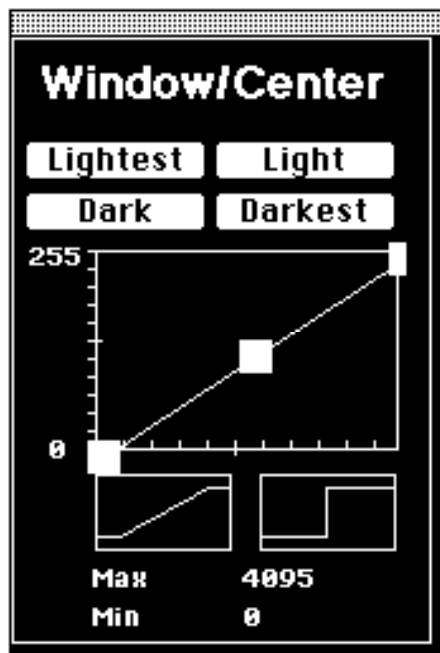
All of these commands take a few seconds to finish. To make it easy for you to come back to the flipped or enlarged image, RSTAR IMS adds it to the list of images in the presentation pane. The name of the enlarged image is the same as the original image, but it has an icon next to it to show how it has been transformed.



Buttons for rotated and flipped images in the presentation pane

Adjusting Contrast and Brightness

The controls in the Window/Center panel let you adjust the contrast of the image you are looking at. You may recall that when images are scanned in, each pixel can take on one of 4096 shades of gray from completely black (0) to completely white (4095). The RSTAR Diagnostic Workstation can display only 256 shades of gray. The Window/Center control determines how RSTAR IMS maps the 4096 gray values stored in the image to the 256 gray values the display screen can show.

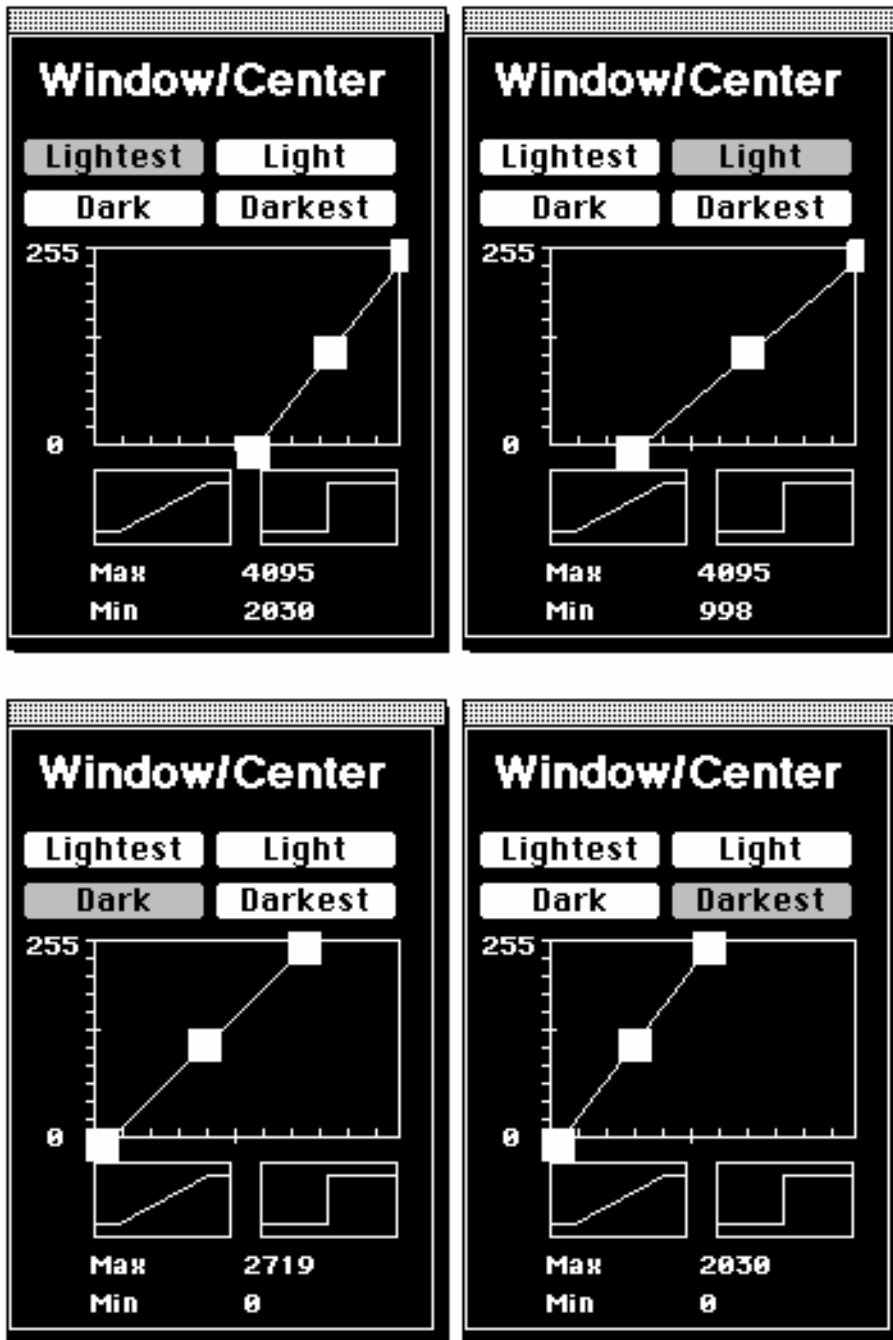


The Window/Center control

The graph shows the mapping between the gray shades stored in the image and the gray shades that the RSTAR IMS display can show. The Max and Min values that appear below the graph show

the range of grays that are being mapped to the monitor's grays. In the picture above, you see that all 4096 shades of gray in the image map evenly to the 256 shades of gray in the display.

The four buttons above the graph change the mapping to preset points to make the entire image lighter or darker. When you click on one of these buttons, notice that they narrow the range to the lighter or darker shades.



Using the preset points

The two icons below the graph also change the mapping to preset points. The first icon changes the mapping to the initial state with all 4096 shades in the image mapped to the 256 shades of the monitor. The other icon changes the mapping so the lighter grays map to all white and the darker grays map to all black.

If none of the preset buttons display the image the way you want to see it, you can drag the handles— the white squares— in the graph to get the effect you want. The top and bottom handles control the range (or **window**) of gray shades of the original image that map to the 256 gray shades of the display. The handle in the middle (the **center**) controls which shade of gray of the original image maps to 50% gray in the display.

Note: All shades of gray of the original image to the right of the upper handle map to black, and all shades of gray of the original image to the left of the lower handle map to white.

Click on the top handle and drag it to the left. As you drag, you will see the contrast change. Notice that the lower handle moves at the same time when you move. Now click and drag on the center handle and move it to the right or left. The entire image lightens or darkens.

If the upper handle is to the right of the lower handle, the image appears as a photographic negative. If the upper handle is to the left of the lower handle, the image appears as a photographic positive.

Printing Images

To print any image displayed on the RSTAR Diagnostic Workstation, click on the **Print** button in the Work Flow pane. When you click on the **Print** button, RSTAR IMS sends the image to the RSTAR Image Printing Station.

The Image Printing Station prints the image to film. If your printing workstation has a docked processor, it will develop the film automatically. Otherwise, you will need to develop the film in a darkroom.

Ending a Work Session

When you are through using the RSTAR Diagnostic Workstation, click on the Done button in the Work Flow panel in the lower right part of the screen. This button returns the workstation to the same state as if it had just been turned on.

Turning the workstation off

If no one is going to use the workstation for the rest of the day, you may want to turn it off.

Important: Do not turn the power off or unplug your workstation. Always use this procedure to turn the workstation off.

Choose the **Quit** command from the **File** menu. RSTAR IMS asks you if you really want to quit.



Confirm Quit Dialog

Click on the **Yes** button. If you made a mistake, and you do not want to quit RSTAR IMS, click on the **No** button.

In a few moments, you will see the Macintosh Finder. Choose the **Shut Down** command from the **Special** menu. Within a few seconds, the Macintosh will shut itself off.

Troubleshooting

As you work with the RSTAR Diagnostic Workstation, you may run into problems. Read this section to see if it describes your problem. If it doesn't, please call RSTAR, Inc. at (800) 888-XRAY.

I know a study has just been scanned, but I don't see it in the studies list.

If you do not see a study that has just been scanned, click on the **Search** button in the Work Flow pane or choose the **Search by Work Queue** command from the **Work Flow** menu. This command forces the Diagnostic Workstation to retrieve a fresh studies list from the image server.

I typed a patient name or MRN I know is in the system, but RSTAR IMS can't find it.

When you type a name into the Search by Patient Name or Search by Patient MRN dialog box, it must match the full name exactly. Most of the time, you won't want to type in the entire name. That's why you should use the wildcard character (*). For instance it is much easier to type Popa* or *Andreas* instead of Popadopoulos, Andreas.

I click and drag in the center handle of the Window/Center control, but it won't move.

When you click and drag in the center handle of the Window/Center control, you need to have room on either side of the right or left handles. If the right and left handles are all the way at the edges, move one of them in to give it more room.



ICU-Mini PACS Status

ICU: Cardiac

Name	MRN	Bed	Most Recent Study	Date	Time
p one, one	1	1	Unknown	11/18/1992	3:54:12
test four, test four	3231132	Unknown	Unknown	11/17/1992	22:26:26
test, patient	1234567	2	Unknown	11/18/1992	9:12:54
testone, testtwo	321123	Unknown	test1	11/17/1992	21:48:02



Patient

New Location

Study

Note Print

New Patient Entry Screen

MRN

Last Name

First Name

Date of Birth

Sex

Unknown ▼

Attending Physician

Requesting Physician

ICU

Unknown ▼

Bed

Unknown ▼

Clinical History





RSTAR

Cancel

Enter

Change Location Screen

MRN	321123
Name	testone, testtwo
ICU	Cardiac
Bed	Unknown

New Location	New ICU	Cardiac	New Bed	Unknown
---------------------	----------------	---------	----------------	---------



Discharge	
Cancel	Update

Modify Patient Information Screen

Current	New
MRN 321123	<input type="text" value="321123"/>
Last Name testone	<input type="text" value="testone"/>
First Name testtwo	<input type="text" value="testtwo"/>
Date of Birth 1/1/95	<input type="text" value="1/1/95"/>
Sex Female	<input type="text" value="Female"/>
Attending Physician	<input type="text"/>
Requesting Physician	<input type="text"/>
ICU Cardiac	<input type="text" value="Cardiac"/>
Bed Unknown	<input type="text" value="Unknown"/>
Clinical History	<input type="button" value="Click Here to Modify Clinical History"/>


RSTAR

Cancel

Update

Text & Voice Note Screen

MRN 321123
Name testone, testtwo
ICU Cardiac
Bed Unknown

Study	Date	Time	Images
• test1	11/17/1992	21:48:02	1 



Study Note

Print Study Screen

MRN 321123
Name testone, testtwo
ICU Cardiac
Bed Unknown

Study	Date	Time	Images
• test1	11/17/1992	21:48:02	1



Print

Cancel All Selected

Modify Study Screen

MRN	321123
Name	testone, testtwo
ICU	Cardiac
Bed	Unknown

Study	Date	Time	Images
• test1	11/17/1992	21:48:02	1

Current	New
Study Descriptor	Unknown
Study Date	



Cancel Update

RSTAR

Image Acquisition Station User Manual

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Welcome

1

Welcome to the RSTAR Image Management System. This manual shows you how to use the RSTAR Image Acquisition Station to scan existing images and store them on the RSTAR Image Server.

This chapter gives you an overview of the RSTAR Image Management System (IMS) and introduces you to some basic RSTAR IMS concepts that you need to know to use the RSTAR Image Acquisition Station.

Do you need to read this chapter?

If you're already familiar with RSTAR IMS and with work queues and studies, you can skip ahead to the next chapter to learn how to use the RSTAR Image Acquisition Station.

If you're eager to get started, but you've never worked with RSTAR before, be sure to scan the section called "How RSTAR IMS Organizes Information" later in this chapter.

About this manual

In this manual the names of menu commands and buttons appear in **bold face**. When a new term appears for this first time, it appears in bold face, too.

Note: Useful information that makes it easier to work with your RSTAR Image Management System or that you might want to know appears in a "note box" like this.

Important: Be sure to read the information in an "important box" like this one. It alerts you to steps that you can't undo or that might affect the operation of your workstation.

What is the RSTAR Image Management System?

The RSTAR Image Management System is a Picture Archiving and Communication System (PACS) that lets you store, look at, and manipulate radiological images on a high-resolution display. The main purpose for any PACS is to store images electronically and to make these images accessible for interpretation to remote sites.

As physicians rely more and more on radiology for effective and accurate diagnoses, radiology departments need to deal with the overwhelming amount of radiological information. Currently, most radiological information is stored on photographic film. Although film has been useful and effective for years, it has significant drawbacks. It is bulky. It is fragile. It is easily misplaced.

Electronic images have substantial advantages over film images. Electronic images take up less space. Electronic images are easily transmitted over networks without affecting the original image. The same image can be transmitted to several interpretation sites at the same time. But perhaps the most important advantage of electronic images over film images is that electronic images can be manipulated. The RSTAR Diagnostic Workstation, for instance, lets radiologists enlarge images, isolate parts of images, and change the display to highlight different characteristics.

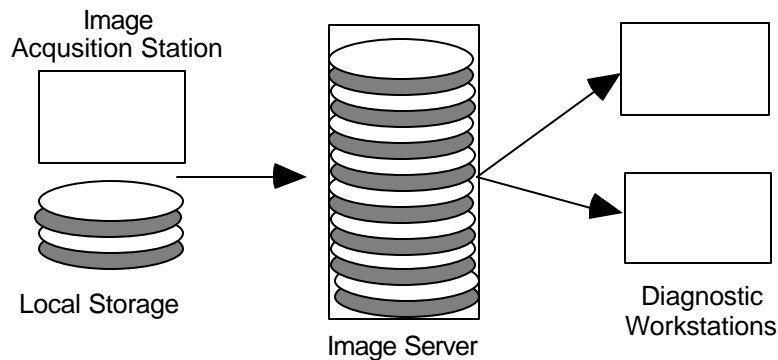
How RSTAR IMS Works

The RSTAR Image Management System is made up of three main parts: the image acquisition station, the image server, and the diagnostic workstation. These three components don't have to be in the same room— or even in the same building.

A radiology technician uses the **image acquisition station** to scan existing film images into the RSTAR Image Management System. The RSTAR Image Acquisition Station has a **scanner** and a Macintosh computer. The scanner reads existing film images and translates them into a digital image made up of thousands of dots, or **pixels**. There are 200 pixels per inch, and each pixel can be one of 4096 shades from completely white to completely black. After the technician scans a set of images, the workstation sends the image to the image server over a high speed network. The display on the Macintosh lets the technician preview the images before sending the images to make sure they were scanned correctly.

The **image server** is a high-capacity computer that stores the images. The image server works like a file cabinet to organize images so a radiologist can request them later. Unlike film images, several radiologists can request and look at the same image at the same time. Any diagnostic workstation linked to the image server can access any of the images stored there. The RSTAR image server can be configured to work with as many images as your institution requires.

When you scan an image, the image acquisition station stores it temporarily in its local storage. When you finish scanning images, the image acquisition station sends them to the image server. Once the images are there, they're available for viewing at a diagnostic workstation. Depending on the speed of the network between the image acquisition station and the image server, it could take a few minutes for images to actually get from the image acquisition station to the image server. The RSTAR system has a mechanism to make sure that important clinical images get to the image server faster than low priority research images. The next section describes this mechanism.



How RSTAR stores information

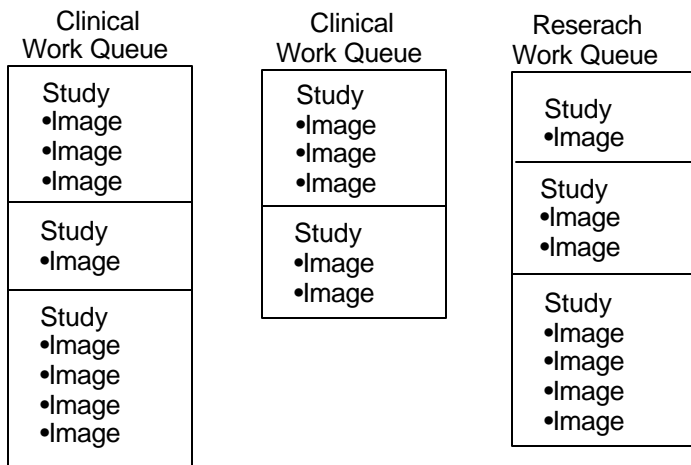
The diagnostic **workstation** is the computer where a radiologist examines the images stored in the image server. The radiologist requests images from the image server from a list of images or by patient name or medical record number. The image server transmits the selected images to the workstation where they're displayed on a large (10 x 12 inch) high-resolution gray-scale display. The display shows images at 200 pixels per inch, and each pixel can be one of 256 shades of gray, from completely black to completely white. Using the workstation controls, the radiologist can enlarge or isolate parts of the image. A special control in the workstation lets the radiologist adjust the image display to highlight soft tissues or bone or even to turn the whole image from a film negative to a film positive.

How RSTAR IMS Organizes Information

If all the images were stored at the image server without some organization, it would be very difficult to find the particular set of images you want to work with. The RSTAR Image Management System uses the concept of studies and work queues to organize images. Whether you use the image acquisition station or the diagnostic workstation, it is important that you become familiar with studies and work queues.

Every image in the RSTAR system belongs to a **study**. Some studies contain only one image, and other studies contain several images. Studies also hold demographic information about the patient and the patient history. Usually, whoever scans the images into the RSTAR Image Management System adds the patient information to the study.

Every study is part of a **work queue**, which is a collection of related studies. For example, your system might have several clinical work queues for different departments as well as several work queues for research projects. Work queues are like a file cabinets to keep images about specific patients or about a particular research project together.



How RSTAR IMS organizes images

Work queues have another purpose. They prioritize how quickly images get from a image acquisition station to the image server. Suppose that a technician is scanning historical images for a research project. These images go into a research work queue. In the middle of scanning the research images, the technician is asked to scan a clinical image that a radiologist needs to examine immediately. That image should go into a clinical work queue. Because it takes time for a study to get from the image acquisition station to the image server, there may be several research studies waiting to go to the image server when the technician scans the important clinical study.

Instead of transmitting the waiting research images, the image acquisition station sends the clinical study first. That's because clinical queues have a higher priority than research queues. Once the image server receives the clinical study, the image acquisition station continues with the research studies.

Note: A control in the image acquisition station can give a higher priority to any study so the station transmits ahead of any pending study.

Understanding studies and work queues is important whether you use the RSTAR Image Acquisition Workstation or the RSTAR Diagnostic Workstation. When you digitize images, the image acquisition station asks you to choose a work queue where you'll create studies to receive the images you're scanning. When you use the diagnostic workstation, the first thing you'll need to do is choose a work queue from which you'll pick the studies that contain the images you want to examine.

Where To Go Next

The next chapter shows you how to use the RSTAR Image Acquisition Workstation to scan existing images into the RSTAR Image Management System. If you want to learn how to use the diagnostic workstation, see the RSTAR Diagnostic Workstation User Manual.

Using the Image Acquisition Station 2

This chapter shows you how to use the RSTAR Image Acquisition Station. The Image Acquisition Station is connected to the RSTAR Image Server directly through an Ethernet local area network or over high-speed telephone lines. You will learn how to create studies, how to scan film, and how to transfer the studies the RSTAR Image Server.

What you should know

You should be familiar with the way RSTAR IMS stores information. You should know about work queues, studies, and images. If you don't know what these things are, read "How RSTAR IMS Organizes Information" in Chapter 1.

Topics covered in this chapter

- About the Image Acquisition Station
- Choosing a Work Queue
- Starting a Study
- Scanning Images
- Ending the Study
- Ending the Session
- Troubleshooting

About the Image Acquisition Station

The RSTAR Image Acquisition Station consists of

- A Macintosh IIfx computer
- A Macintosh monitor
- A Dupont or Lumiscan scanner

Turning the station on

The RSTAR Image Acquisition Station should always be on. If it is not on, press the power-on key on the Macintosh keyboard. This is the key marked with a triangle in the upper right part of the keyboard.

You will hear a chime, and the display will show a “Welcome to Macintosh” dialog. After a minute or so, the RSTAR Image Acquisition Station program starts, and you’ll see the Image Acquisition Station control panel with some buttons and controls on the left side of the window, and a row of menus across the top of the screen.

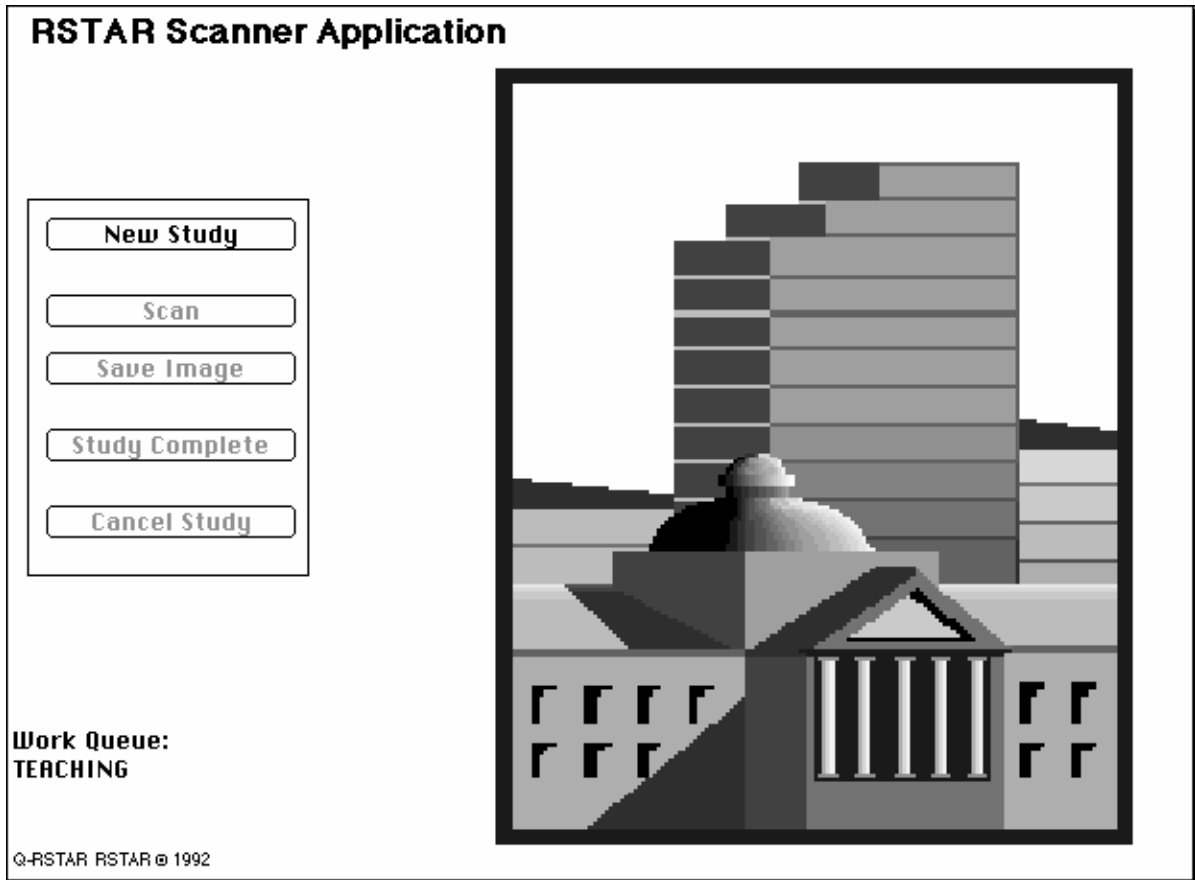
Image Acquisition Station menus

Across the top of the display you will see the RSTAR Image Acquisition menus. These menus contain commands that let you choose the images you want to look at and commands that manipulate the image being displayed.

Menu	Function
Apple	Standard Macintosh Apple menu. Contains Macintosh-related commands not usually used with RSTAR IMS
File	Contains the Quit command
Work Flow	Contains commands that let you choose the work queue that will receive the images
RSTAR	Contains a command that lets you send a message to RSTAR
Digitizer	Contains a command that lets you fix digitizer jams

Image Acquisition Station panes

The main window of the RSTAR Image Acquisition Station is divided into two sections. On the left side of the window is a set of buttons that you’ll use to start new studies, scan images, and transmit studies to the RSTAR Image Server.



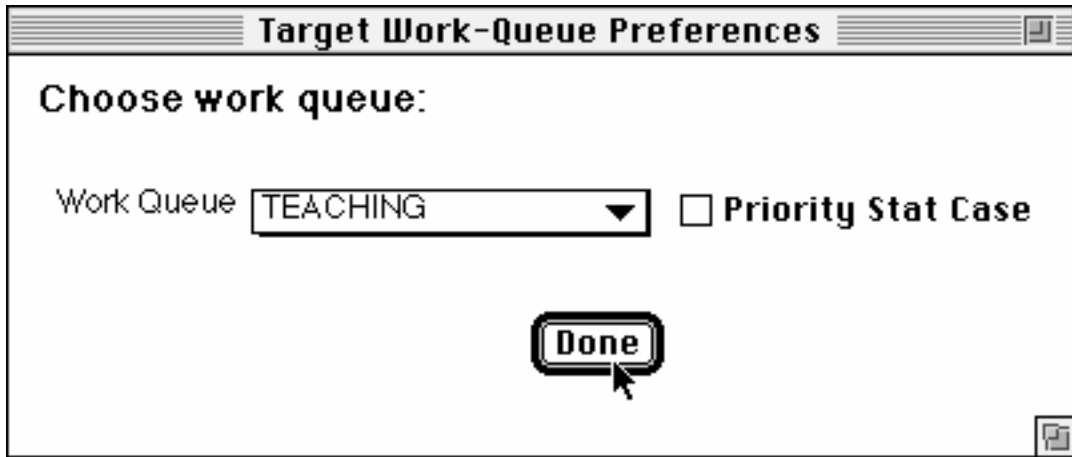
The RSTAR Image Acquisition Station

Choosing a Work Queue

As you learned in Chapter 1, RSTAR IMS organizes images into studies, and each study is part of a work queue. Before you start scanning images, you need to choose a work queue.

The RSTAR Image Acquisition Station shows the current work queue in the lower left part of the initial display. If the work queue is set to the one you want to work with, you can go ahead and start scanning images. If it's not set to the right queue, you'll need to set it up before you start scanning.

To choose the work queue, choose the **Work Queue Preferences** command from the **Work Flow** menu. You will see a dialog box that looks like this:



The Work Queue Preferences dialog box

Click and hold the pointer on the Work Queue pop-up menu, and choose the work queue you want to use. Click on the **Done** button to confirm the work queue.

Important: Be sure that you choose the right work queue at the start of a scanning session. Once you have saved a study in a work queue, you can't move it to another work queue. If you save studies to the wrong queue, you'll need to rescan the studies to the right queue.

If you click on the **Priority Stat Case** check box, the study that you are scanning will have priority over any other study being sent to the RSTAR Image Server.

Note: The Priority Stat Case button applies only to one study at a time. If you need to send more than one study with high priority, you need to check this check box again for each study.

Starting a Study

When you have all the images for a study, click on the **New Study** button. RSTAR IMS asks you to enter the patient information.

The screenshot shows the 'RSTAR Scanner Application' window with a 'Please enter information' dialog box. The dialog box contains the following fields and options:

- Patient Last Name:** Harrison
- Patient First Name:** Mikhail
- Medical Record #:** 018779856
- Date of Birth:** 12 / 8 / 56. Note: Use numeric format: 12/1/1942
- Sex: (M,F, or O):** M
- Study Date:** 8 / 25 / 1992. Note: Use numeric format: 12/1/1942
- Exam Descriptor:** A dropdown menu is open showing options: Bone, Chest (selected), KUB, and Other. The text 'KUB' is visible to the right of the dropdown.
- Referring physician:** [Empty text box]
- Physician telephone #:** [Empty text box]
- Attn to:** [Empty text box]
- Buttons:** Cancel and OK

On the left side of the dialog box, the text 'Work Queue: TEACHING' is displayed. At the bottom left, the copyright notice '© RSTAR RSTAR © 1992' is visible.

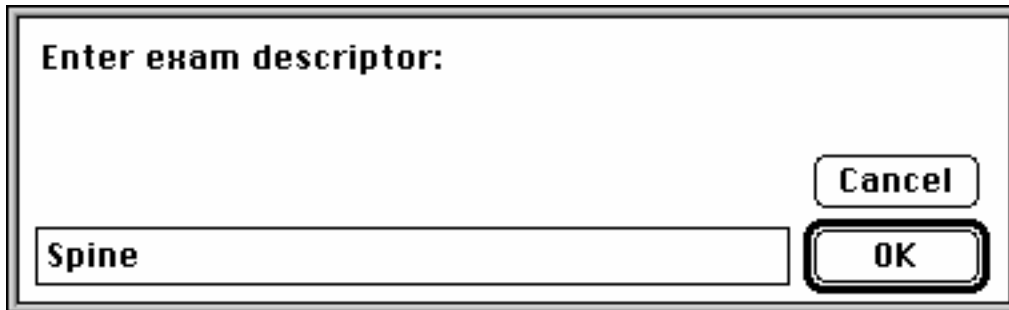
The Patient Information dialog

The following fields are required fields. If you don't type anything in those fields, or if you type the information in the wrong format, you'll see a dialog box asking you to fix what you've typed or fill in the missing information.

- last name
- first name
- medical record number
- date of birth
- sex

The station automatically uses today's date for the study date. You can change this date if you're scanning a study that was done earlier.

To choose the exam descriptor, click the mouse on the Exam Descriptor pop-up menu. If the exam you're scanning isn't on the list, you can choose Other from the pop-up menu. If you choose Other instead of one of the preset exam descriptors, RSTAR IMS displays a small dialog where you can type in your own descriptor.



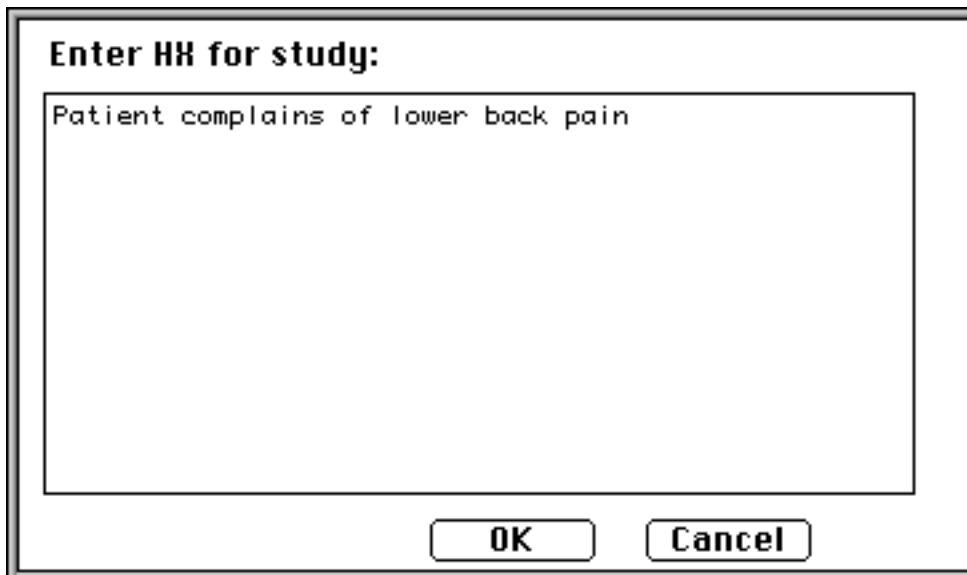
The Other Exam Descriptor text entry dialog box

The last three fields let you type in information about the referring physician. These three fields are optional.

When you've filled in all the information, click on the OK button. If you decide that you don't want to continue with this study, click on the Cancel button.

Important: Before you click on the OK, be sure that you're satisfied with everything you typed in the patient information fields. Once you click on the OK button, it's not possible go back to the patient information form to fix any mistakes.

After you click on the OK button in the patient information form, RSTAR IMS asks you for the patient history. This is a free-form text dialog box where you can type any information about the patient study you're about to scan.



The Patient History dialog box

When you've finished typing in the patient history, click on the **OK** button.

Note: If you click on the Cancel button, you can continue with the study, but it won't have any patient history information.

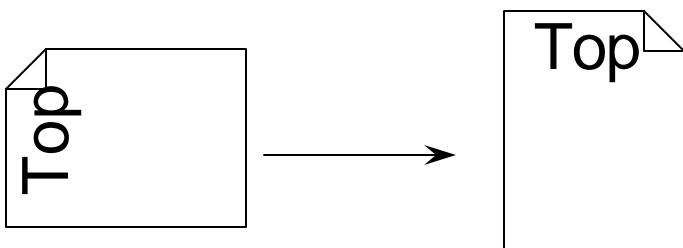
Scanning Images

After you've entered the study information, you're ready to scan the images that belong to that study. The RSTAR Image Acquisition Station is equipped with either a Dupont scanner or a Lumiscan scanner. While the way you load the film into each scanner is different, the general procedure is the same for both:

- Load the film into the scanner
- Click on the Scan button to start the scan
- Wait as the scanner digitizes the image
- Preview the image before saving it as part of the study

Loading the Dupont scanner

The Dupont scanner looks a little like a roll-top desk. Load the film into the slot at the top of the Dupont scanner, and let it drop in. For a normal vertical orientation, insert the film lengthwise. The left edge of the image will appear at the top when it's scanned. This picture shows you how the Dupont scanner scans the image.



How the Dupont scanner scans

Your institution may have specific requirements whether the emulsion side should be up or down. You will be able to see the image on the station after you scan it to make sure that it follows your institution's guidelines.

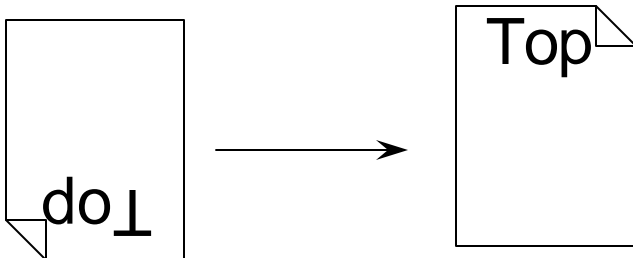
From time to time, a film may jam in the digitizer. To clear film jams, follow the instructions in the "Troubleshooting" section at the end of the chapter.

Important: Do not try to open the scanner to clear film jams.

To scan the image, click on the **Scan** button. The Dupont scanner takes about 10 seconds to scan an image.

Loading the Lumiscan scanner

The Lumiscan scanner is a rectangular box with a slot at the top and a tray on one end. For a normal vertical orientation, load the film “head” first. If the film you are scanning is smaller than 14x17 inches, load the film to the far right in the tray. You’ll see a metal guide for smaller images. This picture shows you how the Lumiscan scanner scans the image.



How the Lumiscan scanner scans

Your institution may have specific requirements whether the emulsion side should be up or down. You will be able to see the image on the station after you scan it to make sure that it follows your institution’s guidelines.

From time to time, a film may jam in the digitizer. To clear film jams, follow the instructions in the “Troubleshooting” section at the end of the chapter.

Important: Do not try to open the scanner to clear film jams.

To scan the image, click on the **Scan** button. The Lumiscan scanner takes about 45 seconds to scan an image.

Previewing the image

As the scanner scans the image, it appears on the monitor, so you can make sure it was scanned correctly. You can check to make that you loaded the film right-side-up and with the correct emulsion side up.

Important: This image appears at one-fifth its actual size, and it is not appropriate for interpretation.

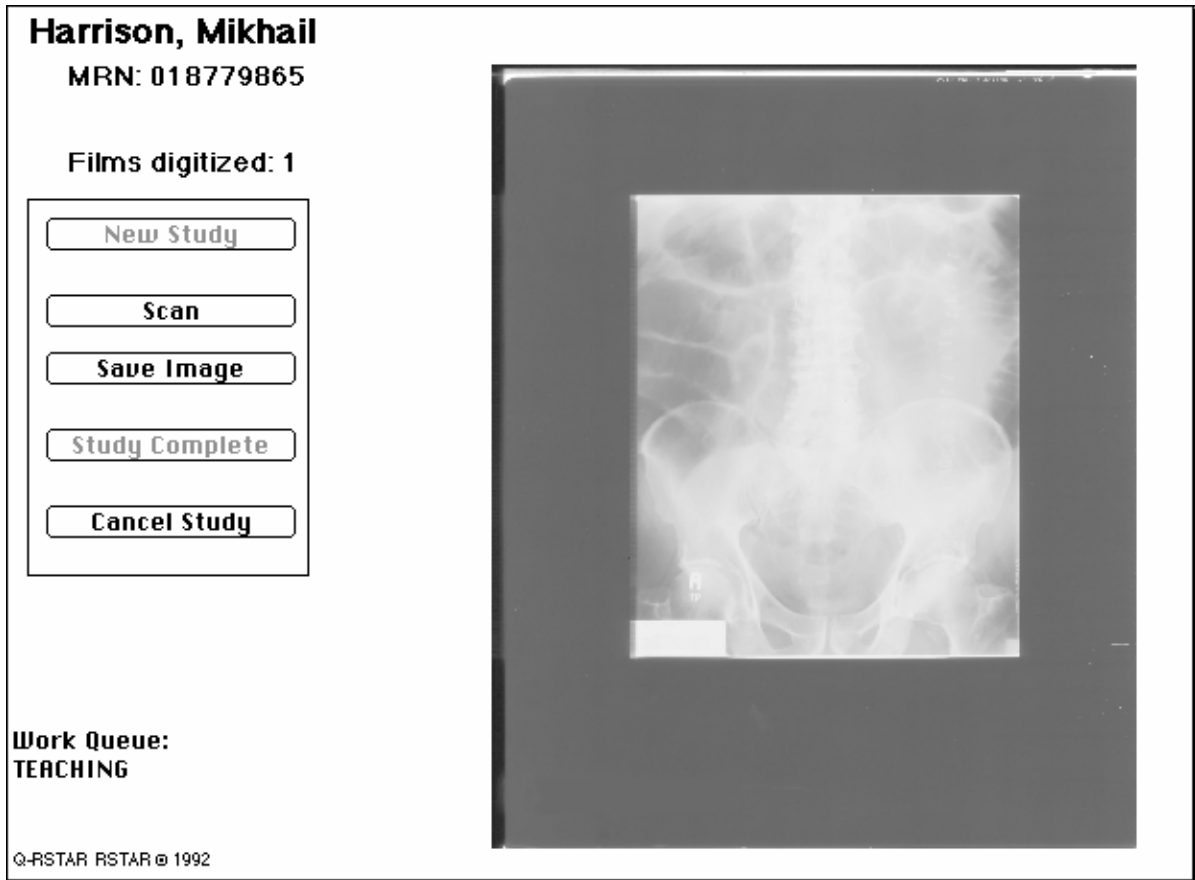
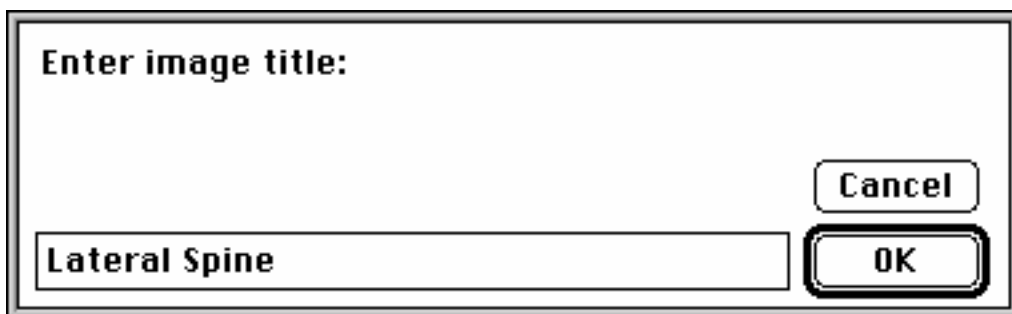


Image preview after scanning

To see the image at full size, move the pointer into the image area, and hold down the mouse button. The image around the pointer appears at full size. When you release the mouse button, the image appears at the standard one-fifth size.

Saving or rejecting the scanned image

If you're satisfied with the scanned image, click on the **Save Image** button. RSTAR IMS asks you to name the image in a text-entry dialog box.



The Image Title dialog

Give the image a name and click on the **OK** button. The image is now part of the study.

Be sure that you give each image a unique and descriptive name. The only way a radiologist using the RSTAR Diagnostic Workstation can distinguish among images within a study is by their

names. For instance, if every image in a study is called “Spine,” the radiologist would have to examine each image to see how they’re different.

If you are not satisfied with the scanned image, and you want to scan it again, reload the film and scan the image again.

Scanning additional images into a study

It’s likely that the study you’re working on has more than one image. To scan additional images into a study, follow the same procedure you did for the first image. Load the film into the scanner, press the **Scan** button, and press the **Save Image** button to add the image to the study.

Ending the Study

After you’ve scanned and saved the last image for a study, click on the **Study Complete** button. The RSTAR Image Acquisition Station starts transferring the study to the image server, but you can continue to scan additional studies.

If you decide not to finish the study, click on the **Cancel Study** button.

Important: If you choose to cancel a study, remember that all the images you have scanned for the study will be lost. If you are not happy with a specific image, don’t click on the **Cancel Study** button. Instead, reload the film and scan it again before saving the image.

To start another study, click on the **New Study** button, and start the process all over.

Ending the Session

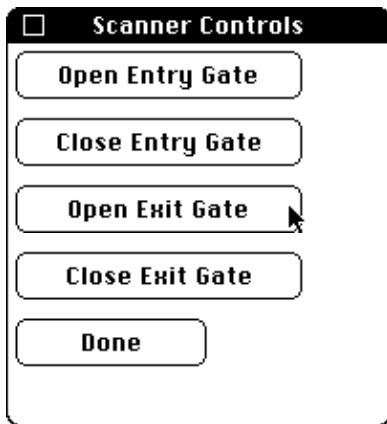
When you finish scanning your last study, just leave the machine, so it’s ready for the next person. You should not quit the application, and you should never shut down the RSTAR Image Acquisition Station. It’s OK to leave it on all the time.

Troubleshooting

This section tells you what to do if you have problems while you use the RSTAR Image Acquisition Station. If your problem isn’t listed here, please call RSTAR, Inc. at (800) 888-XRAY.

The film in the Dupont scanner is jammed

To unjam a film in the Dupont scanner, you need to open the exit gate of the scanner. Choose the **Scanner Controls** command from the **Digitizer** menu, and you'll see a window that looks like this:



The Scanner Controls window

Click on the **Open Exit Gate** button. The jammed film should drop out. If it doesn't, please call RSTAR, Inc. at (800) 888-XRAY. Do not try to open the scanner.

Be sure to reset the gates before you continue working:

- Click on the **Close Exit Gate** button in the Scanner Controls window
- Click on the **Open Entry Gate** button in the Scanner Controls window
- Click on the **Done** button in the Scanner Controls window

The film in the Lumiscan scanner is jammed

To unjam the film in the Lumiscan scanner, choose the **Eject Film** command from the **Digitizer** menu. The film should fall into the tray.

If a foreign object falls into the scanner, or if a film tears and you need to get it out, open the pane in the side of the scanner.

- Open the two black latches.
- Rotate the latches 90°
- Pull out the panel

Look inside and clear out anything that might be in the film path.

Note: The scanner will not operate with this panel off, but the **Eject Film** command will still work.

If you can't clear the film path or jam, please call RSTAR, Inc. at (800) 888-XRAY.

Tabular Comparison Chart of Features and Specifications

MANUFACTURER	RSTAR, INC.	Advanced Video Products (AVP)	Kodak/Vortech
MODEL	RSTAR IMAGE MANAGEMENT SYSTEM	TELEPRO	IMAGELINK
DESIGN	Client/Server	Combination	Distributed
PRIMARY COMPUTER SYSTEM	DEC VAX System	286 386 486	SUN
NETWORK CONFIGURATION	Bus/Star	Star/ring	Bus
DISTRIBUATED STORAGE	Yes	Yes	Yes
DISTRIBUTED PROECSSING	Yes	Yes	Yes
OPERATING SYSTEM	VMS, Mac OS	MS-DOS	Unix
IMAGE DISPLAY			
Matrix size, pixels	1792 x 2250 1152 x 882	640 x 480 1280 x 1280 2560 x 2048	1600 x 1200
ROI resolution	Up to 1792 x 2250	Up to 2560 x 2048	2048 x 2048
Multiformat display	Yes	Yes	Yes
Number of display stations supported	unlimited depend on network loading	500 Workstations	Unlimited depend on network loading
Number of monitors per station	1 to 8	1 to 8	1 to 6
Color Display	Yes	Yes	No

Tabular Comparison Chart of Features and Specifications

IMAGE STORAGE			
Online, MB	Up to 19 Gigabytes	Up to 80,000	Up to 45,000
Archival, MB	Up to 93.6 Gigabytes	Up to 80,000	10,200/14" : 680/5.25" platter
Floppy disk	for software	Standard	for software
Optical disk	not available	50-platter (320 GB)	Single drive or jukebox
Magnetic tape	for system backups	Optional	No
HARD-COPY DEVICE		Laser Printers	All options
IMAGE TRANSMISSION			
Communications protocol	Ethernet, Proprietary Optical	Proprietary	Ethernet-TCP/IP
Time per image,sec	>2 sec for a 2kx2k image	2 sec	2 sec
Interconnection			
Coaxial cable	Ethernet	Broadband or twisted	Ethernet
Fiber optics	Ethernet, Proprietary Fiber Optic Star Network	Yes	Ethernet
Telephone lines	Yes (19.2, 56Kb, T1, DS3)	Yes	Yes, several options
DATA COMPRESSION			
Ratio			
Lossless	Not an option	3:1 lossless	Under development
Lossy	Not an option	user selectable lossy	
Processing time for compression, sec	Not an option	2 sec	NA

Tabular Comparison Chart of Features and Specifications

IMAGE INPUT			
Multimodality	Digital Interfaces DICOM-3, Analog Interfaces	Yes	Yes, digital and analog interfaces
Vendor-supplied software, hardware interfaces	Yes	Yes	Yes
Analog film input	Yes	Yes	Yes
Processing time	variable according to resolution and spot size	0.033 sec/film	NA
Matrix size, pixels	variable upto 3584 pixels over 14"	512 x 512 1280 x 1024	Up to 2048 x 2048
Image depth, bits	12 bits (4096 levels)	8 or 12 bits	12 bits
SYSTEM OPERATION			
System interaction	Keyboard, mouse, trackball, membrane	Keyboard, trackball, mouse	Keyboard, trackball, mouse
Image access time			
From online storage, sec	< 2 sec for a 2k x 2k image	2 sec	5-7 sec for 2k image
From archive storage, sec	<10 sec for a 2k x 2k image	7 sec	150 sec
Dial-in telephone access	Yes	Yes	Yes
Integrated database manager	Yes	Yes	Yes
Clinical reports autolink to images	Yes	Yes	Yes
Hospital management system interface	Yes - HL7 compatible	Optional	Under development
SYSTEM SECURITY			
	User password	User password	Optional password