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 17,1992

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 Intensive Care Unit Mini-PACS (ICU Mini-PACS)**. 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 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This submission generally follows the format of FDA's February 1991 draft Guidance For the Content and Review of 510(k) Notifications for Picture Archiving and Communications Systems (PACS) and Related Devices.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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One Cambridge Center, Suite 905
Cambridge, MA 02142

Primary Contact
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RSTAR, Inc.
One Cambridge Center, Suite 905
Cambridge, MA 02142
Phone: (617) 726-8381

1.2. Establishment registration number

Registration No. ######## (Not yet applied for)

1.3. Common and proprietary names of the device

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

Proprietary Names:

RSTAR Intensive Care Unit Mini-PACS (ICU Mini-PACS)

ICU Mini-PACS Components:

- **ICU Image Server (ICU-IS)**
- **Image Review Station (IRS)**
- **Patient Census Station (PCS)**
- **Film Digitizer Station (FDS)**
- **Computed Radiography Station (CRS)**

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 images devices. Accordingly, RSTAR, Inc. intends to market the ICU Mini-PACS product 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. buys off-the-shelf monitors for use in its ICU Mini-PACS, and to be best of its knowledge, believes that such monitors comply with all applicable 21 CFR 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; 510(k) no. K901423/A] and a 510(k)-cleared laser film printer [the 3M Laser Imager XL; 510(k) no. K910092/A] for use in its ICU Mini-PACS. RSTAR, Inc., to the best of its knowledge, believes that these devices/components comply with all applicable 21 CFR 1040.10 standards.

1.5.3. Voluntary Standards

SMPTE

RSTAR, Inc. uses the SMPTE test pattern standard to test the display monitors in the Image Review Station.

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 ICU Mini-PACS.

Underwriters Laboratories

RSTAR, Inc. plans on complying with the UL Standard No. 1950. The ICU Mini-PACS will be submitted to UL testing during the first quarter of 1993.

RSTAR, Inc. plans on further complying with the following standards:

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

The ICU Mini-PACS will be submitted for compliance testing for the above standards during the first half of 1993.

RSTAR, Inc. does not intend to market the ICU Mini-PACS product in the United States. until UL and FCC compliance testing has been satisfactorily completed.

RSTAR, Inc. does not intend to market the ICU Mini-PACS product in Canada until CSA compliance testing has been satisfactorily completed.

RSTAR, Inc. does not intent to mark the ICU Mini-PACS product in Europe until TUV or VDE compliance testing has been satisfactorily completed.

2. Device Description: Summary of Functions

2.1. The RSTAR Intensive Care Unit Mini-PACS

The RSTAR ICU Mini-PACS is a computer based image management system that is intended to provide intensive care units (ICU's) faster access to patient radiographic data. The system offers a solution to the common problem facing most radiology departments: how patient radiographic data in the form of conventional x-rays or films can be available in multiple places at the same time. In this case, the clinicians in the ICU's need constant availability to patient radiographic data for ongoing patient care. The radiologists in the radiology department need access to patient radiographic data for interpretation.

The RSTAR ICU Mini-PACS solves this problem by acquiring the information on conventional x-rays, converting it to digital image data and transferring it to a computer-based image management system. In this way, the radiographic data is no longer tied to the physical film; instead, the image data is accessible through the ICU Mini-PACS. For example, the Image Review Stations will allow two clinicians in two separate ICU's and a radiologist in the radiology department to view the same image data simultaneously.

Specifically, the RSTAR ICU Mini-PACS will:

- Collect and manage patient demographics, study information, image information 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

- Store radiographic images in a short-term image cache for the duration of a patient's stay in the hospital intensive care unit

- Offer simple-to-use membrane switch operation at the viewing stations with no need for keyboard or mouse interaction

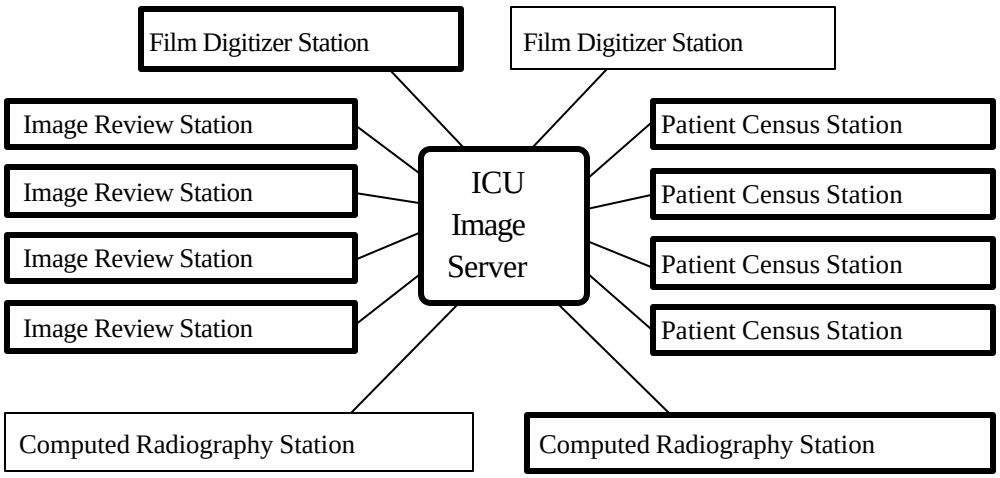
- Perform soft copy image viewing on high-performance high-resolution (2K) viewing stations with real-time window and center (the window and center manipulation is described in Exhibit A)

- Perform soft copy image viewing on medium-resolution (1K) viewing stations with real-time window and center, and magnification

- Perform soft copy image viewing and simultaneous image comparison on dual screen viewing stations
- Offer digitized voice notations on a per study basis
- Offer text notations on a per study basis
- Offer simple admissions/discharge/transfer functionality for patients in the system
- Print image data on a 12 bit high-resolution laser film printer
  [using the 510(k)-cleared 3M Laser Imager XL; K910092/A]
- Distribute information over a dual network with:
  - Command and control information, database information and image acquisition data transmission over an IEEE 802.3 Local Area Network (also referred to as Ethernet)
  - Image data transmission from the short-term image cache to the viewing stations over a 100 megabit/second fiber optic star network
- Generate system usage, audits, events and error logs
- Generate patient, study and image reports
- Offer built-in remote diagnostics for software updates and system support

The RSTAR ICU Mini-PACS consists of various components which acquire, transfer, store, display and print patient demographics, study information and radiographic image data.

RSTAR ICU Mini-PACS



Listed below are short descriptions of the components which make up the RSTAR ICU Mini-PACS:

- **Intensive Care Unit Image Server (ICU-IS)**
  The ICU-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 ICU Mini-PACS. Additionally, it controls the overall functions of the ICU Mini-PACS. It contains the ICU database with patient demographic records and study information records. It also contains the short-term image cache which stores the radiographic image data for patients currently in the system. The attached laser film printer will print images queued from the Image Review Stations and the Patient Census Stations. Using the monochrome monitor, a System Administrator may configure, monitor, and track usage of the ICU Mini-PACS.

- **Image Review Station (IRS)**
  The IRS 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. Additionally, patient images may be queued to print to the laser film printer. The ICU Mini-PACS will support a maximum of four Image Review Stations in either dual or single screen configurations with either 2K or 1K

resolution monitors. Membrane switches control user interaction with the viewing station. There is no need for a keyboard or mouse.

- **Patient Census Station (PCS)**
  The PCS is an Admissions Discharge Transfer (A/D/T) System designed specifically for the ICU Mini-PACS. The Patient Census Station manages patient information in the ICU Mini-PACS. The PCS admits new patients into and discharges patients from the ICU Mini-PACS. It checks patients' locations, transfers patients from one ICU to another. Voice and text notations can be added to a patient's studies at the PCS. Patient images may be queued to print on the laser film printer. The Patient Census Station is the main control center for patient information. The ICU Mini-PACS will support a maximum of four Patient Census Stations

- **Film Digitizer Station (FDS)**
  The FDS acquires information from conventional x-rays and converts it to digital image data. The image data are then transferred to and stored in the ICU-IS. The ICU Mini-PACS will support up to two Film Digitizer Stations or one FDS and one Computed Radiography Station (discussed further below).

- **Computed Radiography Station (CRS)**
  The CRS acquires image data from computed radiography phosphor plates. The image data are then transferred to and stored in the ICU-IS. The ICU Mini-PACS will support up to two Computed Radiography Stations or one CRS and one FDS.

ICU Mini-PACS usage within the hospital environment

When processing films from the ICU's, a radiology technician will use the Film Digitizer Station to digitize the films or the Computed Radiography Station to acquire phosphor plate images into the ICU Mini-PACS. The FDS will scan existing films and translate them into a digital images made up of thousands of dots, or pixels. After the technician acquires a set of films, the FDS or CRS will send the images to the ICU Image Server over a IEEE 802.3 local area network. The display monitors on the FDS and the CRS will allow the technician to preview the images before transmission for verification of proper image orientation and acquisition.

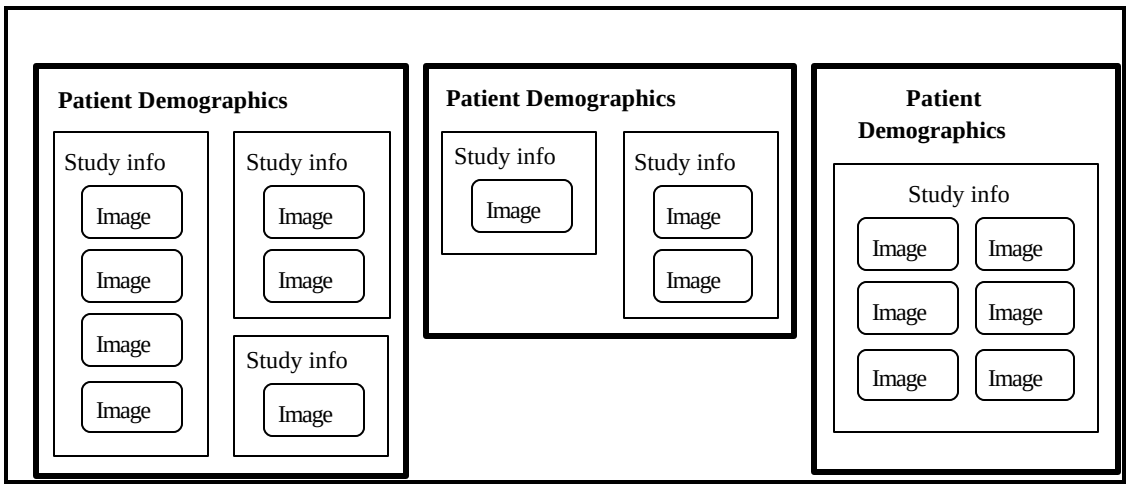
Images transmitted from the FDS or CRS will be stored in the ICU Image Server. The ICU-IS emulates a film library. It organizes images so a radiologist or a clinician can request them later. However, unlike films, several clinicians in different locations can request and look at the same image at the same time. Any Image Review Station linked to the ICU-IS can access any of the stored images. The ICU-IS also maintains the ICU database with patient demographic records and study information records.

The Image Review Station will allow a radiologist or a clinician to examine the images stored in the ICU Image Server. The radiologist may request images for a particular patient. The image server will transmit the selected images to the Image Review Station where they will be displayed on a high-resolution (1792 x 2250) or medium-resolution (1152 x 882) gray-scale monitors. Image Review Stations with dual monitors can display images from two studies at the same time for comparison. A control at the workstation will allow the radiologist or clinician to adjust the window and center of the image displayed.

The Patient Census Station located in the ICU will allow nurses to review and maintain patient information and to track patient location and patient radiographic studies. Images can be queued to the laser film printer for printing from the Patient Census Station.

The RSTAR ICU Mini-PACS organizes images into studies. Every study in the ICU Mini-PACS belongs to a particular patient. Every image in the ICU Mini-PACS belongs to a particular study. The ICU Mini-PACS 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 FDS or the CRS, or it can be entered at a Patient Census Station.

As represented in the examples shown in the figure below, every patient has a standard set of demographics and one or more studies that may contain one or more images.



Each study contains a standard set of study information and may contain text and/or voice notations. In the ICU, there are usually two new studies for a patient each day. Typically, only images from only one study are viewed at a time. On Image Review Stations with dual monitors, images from two different studies for one patient can be viewed simultaneously.

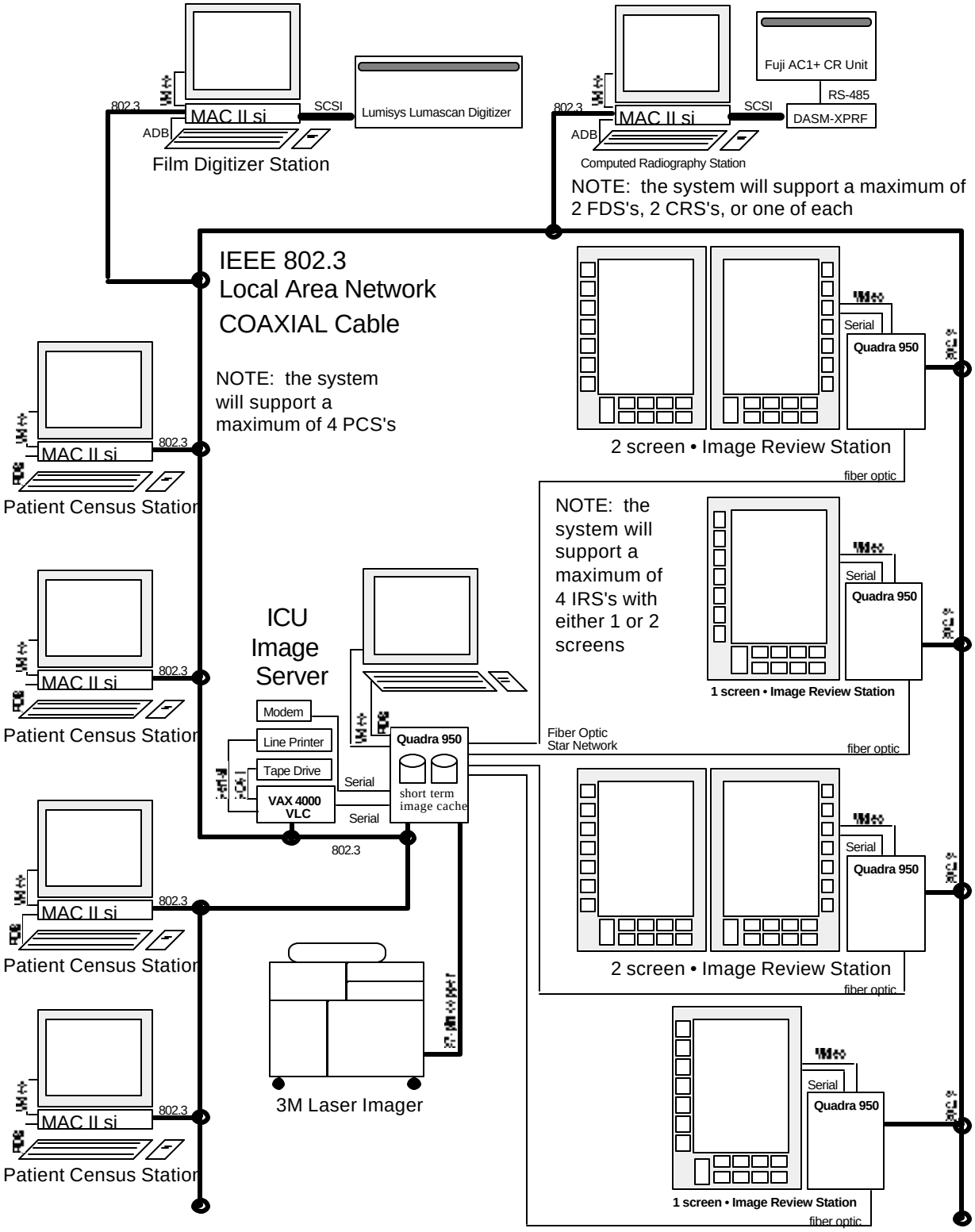
The RSTAR Intensive Care Unit Mini-PACS follows the client/server model where the ICU Image Server contains the servers that the clients (IRS, PCS, FDS, and CRS) can access. The clients access the ICU server for information regarding the patient, patient location, study, image data, system audit logs, system event logs, system usage logs, and system error logs. Patient image data is stored in the short-term 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 three second access to any image stored in the ICU-IS. The ICU-IS also contains the ICU Database with Patient Demographic records and the Study Information Records. Additionally, the ICU-IS contains the overall system control software that manages the ICU Mini-PACS. Patient demographics and study information gathered at the Patient Census Stations (PCS) or at the image input stations (FDS or CRS) are collected and stored in the ICU-IS in the ICU Database. Patient radiographic image data is stored in a short-term image cache for the duration of the patient stay in the hospital intensive care unit.

The IRS, PCS, FDS, CRS and the ICU-IS Administrator's Console are Apple Computer based and conform to the Apple Computer Inc., Macintosh human interface guidelines, which means that 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 contains a system diagram illustrating the RSTAR Intensive Care Unit Mini-PACS. Shown are the interconnections of the components with interfaces and physical media specifically labeled. The ICU Mini-PACS does not employ data compression and therefore no compression ratios are indicated.

Sections 2.3 through 2.7 fully describe the individual RSTAR ICU Mini-PACS Components detailing their characteristics, means of operation and specifications.

2.2. System Diagram: RSTAR ICU Mini-PACS



2.3. Intensive Care Unit Image Server (ICU-IS)

The **ICU-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 ICU-IS is the hub of the ICU Mini-PACS; all other components are connected to it. The list below is a summary of the functions provided by the ICU-IS.

1. The **ICU-IS** will coordinate overall system activity.
2. The **ICU-IS** will maintain and store the ICU database.
3. The **ICU-IS** will maintain and store patient demographic records.
4. The **ICU-IS** will maintain and store study information records.
5. The **ICU-IS** will maintain and store radiographic image data in the short-term image cache (for the duration of the patient's stay in the hospital ICU).
6. The **ICU-IS** will maintain and store the voice notations on a per study basis.
7. The **ICU-IS** will maintain and store the text notations on a per study basis.
8. The **ICU-IS** will support up to four **IRS**'s of 2K or 1K resolution with single or dual monitors.
9. The **ICU-IS** will support up to four **PCS**'s.
10. The **ICU-IS** will support up either two **FDS**'s or two **CRS**'s or one of each.
11. The **ICU-IS** will support one laser film printer capable of 12 bit image printing.
12. The **ICU-IS** will manage its storage assets and will optionally purge unwanted images and patient records of discharged patients.
13. The **ICU-IS** will compile, and optionally print system audit, usage, event and error logs.
14. The **ICU-IS** will compile, and optionally print database reports of images stored, images recalled, images printed, and total patients in system.
15. The **ICU-IS** will support a System Administrator's Console for periodic maintenance and status investigation.
16. The **ICU-IS** will contain system level diagnostic and consistency software.
17. The **ICU-IS** will store images transmitted from a **FDS**, and/or a **CRS**.

18. The **ICU-IS** will transmit images to the **IRS**'s over the 100 megabit/sec fiber optic star network.

19. The **ICU-IS** will manage queued printing to the laser film printer.

20. The **ICU-IS** will manage transaction event logging to record image digitizing, printing, and deletions.

21. The **ICU-IS** will manage internal system integrity checking and logging.

22. The **ICU-IS** will manage system error logging for corrective maintenance.

23. The **ICU-IS** will maintain System security entries for controlled access to the image server and for voice entry.

24. The **ICU-IS** will support a magnetic tape system for initial installation of system and RSTAR application software; installation of major software maintenance releases and system software upgrades as applicable; and for VMS backups.

25. The **ICU-IS** will support a set of maintenance functions to allow initial configuration of ICU types and bed numbers.

26. 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 ICU Image Server is based on a Digital Equipment Corporation (DEC) VAX 4000 VLC computer, with patient, study and image information stored in RDB, the DEC standard relational database. The VAX 4000 VLC 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 and transmits the image data to requesting stations over a 100 megabit/sec fiber optic star network. All the ICU Mini-PACS components are networked together using an IEEE 802.3 LAN.

List of operator controls

The ICU Image Server has a Apple Macintosh-based, menu driven executive utility that allows the System Administrator to monitor the RSTAR ICU Mini-PACS. 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 Manual is included as Exhibit B.

Storage

Standard general purpose equipment

The RSTAR ICU Image Server uses standard magnetic disk drives to store image data, patient demographics and study information. The DEC VAX 4000 VLC has one 245 megabyte hard drive containing the system software and the ICU Database. The Apple, Inc. Quadra 950 has one 230 megabyte hard drive containing system software and two 1.02 gigabyte hard drives which comprise the short-term image cache.

Image formats

The radiographic image data is stored in row-column format in the short-term image cache on the Apple, Inc. Quadra 950. The DEC VAX 4000 VLC contains the ICU Database with patient demographics records and study information records stored with ACR/NEMA tags.

Data Compression

Not applicable - the base performance of the RSTAR Intensive Care Unit Mini-PACS is such that data compression is not employed for either communications or storage of data.

Software

See sections 6.3 and 6.5 for descriptions of the ICU Image Server software.

2.3.2. Specifications

Computer Specifications:

Digital Equipment Corporation • VAX 4000 VLC

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 16 megabytes	
Disk Drives	
floppy disk drive	1.4MB Apple SuperDrive
hard disk drive	230MB Apple SCSI
Interfaces	
Serial	VAX 4000 VLC
Serial	Modem
ADB (Apple Desktop Bus)	keyboard
Video port	12" monochrome monitor
NuBus slot	Laser Film Printer Interface Board
NuBus slot	High-Speed DMA (Direct Memory Access) Board
NuBus slot	Fiber Transmitter Board (4-outputs)
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. • 12" Monochrome Display

Picture tube	
Diagonal	12"
CRT	P104 & P193 phosphor
Screen Resolution	
Horizontal pixels	640 pixels
Vertical lines	480 pixels
Dots Per Inch	76 dpi
Active video display area	
Horizontal	8.35 inches
Vertical	6.26 inches
Input signals	RS-343 standard, TTL (Transistor
Transistor Logic) 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 (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

Line Printer:

Panasonic • Dot Matrix Printer Model# KX-P1180i

Interface

RS-232C Serial	VAX 4000

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.

Digital Storage Devices:

Hewlett Packard • HP C2247 3.5-inch Disk Drive

Characteristics

Interface	SCSI
Capacity	1.05 gigabyte
Disks	7
Data heads	13
Rotational Speed	5,400
Recording Density	52,000 bits per inch

Performance

Transfer rate Async	2.5 megabytes/s to 5 megabytes/s
Transfer rate Sync	up to 20 megabytes/sec

Reliability

MTBF (Mean Time Between Failure)	300,000
Service Life	> 5 years

Electrical requirements

Power	15.3 watts max

Operating environment

Temperature	5° to 50° C
Humidity	80% max
Altitude	10,000 ft. max

Size and Weight

Height	1.625 in.
Width	4.0 in.
Depth	5.75 in.
Weight	2.2 lb.

Tandberg Data • TDC 3800 Tape Drive

Characteristics

Interface	SCSI-2
Capacity	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	80,000 hours
MTTR (Mean Time To Repair)	30 minutes

Electrical requirements

Power	15 watts max

Operating environment

Temperature	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

Modem:

Practical Peripherals • Pratical Modem 2400 SA

Laser Film Printer:

3M • Laser Imager XL See technical specifications in Exhibit C

2.4. Image Review Station (IRS)

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

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

Medium-resolution			
Single monitor	1,152	by	882 landscape (1K)
Dual monitors	1,152	by	882 landscape (1K)
High-resolution			
Single monitor	1,792	by	2,250 portrait (2K)
Dual monitors	1,792	by	2,250 portrait (2K)

2. The **IRS** will provide radiologists and clinicians with a membrane switch user interface for ease of use; no keyboard or mouse is interaction is necessary.

3. The **IRS** will display by default the list of patients located in the hospital intensive care unit where viewing station is deployed.

4. The **IRS** will allow for selection of a different hospital intensive care unit.

5. The **IRS** user interface will allow for selection of the patient, the patient study, and individual radiographic image.

6. The **IRS** will allow the pixel intensity mapping (image window & center) to be rapidly changed by the user.

7. The medium-resolution 1K **IRS**, will provide for image zooming on a 5 quadrant basis (upper left, upper right, lower left, lower right, and center).

8. The **IRS** will allow for the recording of voice notations on a per study basis.

9. The **IRS** will allow for the playback of voice notations associated with the current patient study.

10. The **IRS** will allow for the display of text notations associated with the current patient study.

11. At an **IRS** with dual 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 Image Review Station 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 noted above, the Image Review Station 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. Pressing this button will turn on the IRS. 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 help 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 undoes 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 Image Review Station: 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 Image Review Station supports the following four configurations of CRT displays:

Medium-resolution

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

High-resolution

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

Available image display formats

The Image Review Station 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 Image Review Station. It can be displayed in two ways:

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

2. It is also stored as a study on the main RSTAR ICU Image Server to allow for server to workstation testing of the workstation and 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 Image Review 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 workstation. All data is stored on the RSTAR ICU Image Server and downloaded to the workstations over the 100 megabit fiber optic star network when requested by a user. The image data is however cached to RAM (random access memory) for display and image processing by the 68040 processor. The workstations can be configured to hold from eight to sixteen megabytes of RAM. That translates to enough memory to cache between one and two full resolution 11" by 14" plane films that have been digitized at 200 microns at 12 bits of resolution. The IRS has an 80 megabyte hard drive the contains the Macintosh Operating System and the RSTAR Image Review Station Application Code. Additionally, the SMPTE test pattern is stored on the hard disk for stand-alone testing of the workstation.

Operator Interfaces

The Image Review Station 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 Image Review Station Manual is included as Exhibit D.

Software

See section 6.2 and 6.4.1 for descriptions of the Image Review Station software.

2.4.2. Specifications

Computer Specifications:

Apple Computer, Inc. • Quadra 950

Processor	
Chip	MC68040 32-bit architecture
Clock speed	33-megahertz
CO processor	68882 IEEE standard
Memory	8 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 (8MB or 16MB)
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.
Input devices	Vertical Selection Membrane Switch
	Menu Selection Membrane Switch

Monitor Specifications:

Tektronix, Inc. • GMA212 High Bright Display

Picture tube	
Diagonal	19"
CRT	P45 Phosphor
Screen Resolution	
Horizontal pixels	1792 pixels
Vertical lines	2250 pixels
Dots Per Inch	163 dpi
Active video display area	
Horizontal	11.000 inches
Vertical	13.750 inches
Input signals	video using BNC (BayoNet Connector),
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 pixels
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 (Radio Frequency Interference)	FCC Class A (part 15 of FCC rules)
Safety	UL listed CSA certified TUV approved

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. Patient Census Station (PCS)

The Patient Census Station is a free-standing computer station to be used by clerical and nursing staff for text entry and for maintaining the ICU Mini-PACS databases. It allows the entry of patient demographics, patient location, and patient discharge information into the system. Images cannot be viewed on a PCS. The PCS will most likely be located at the nursing station on a floor with several hospital intensive care units or within an individual intensive care unit. The list below is a summary of the functions provided by the PCS.

1. The **ICU Mini-PACS** will support up to four **PCS**'s.

2. The **PCS** will allow basic patient demographics (name, medical record number, etc.) to be entered or modified.

3. The **PCS** will allow study information (study descriptor, study date, etc.) to be modified.

4. The **PCS** will allow for patient location (ICU name and bed identification) to be specified and/or modified.

5. The **PCS** will queue for printing to a laser film printer all radiographic images for a selected patient.

6. The **PCS** will queue for printing to a laser film printer all radiographic images for a selected patient study.

7. The **PCS** will allow for the automatic printing of all images to a laser film printer upon patient discharge from the hospital intensive care unit.

8. The **PCS** will allow for the addition of a voice notations to a particular patient study.

9. The **PCS** will allow for the addition of a text notations to a particular patient study.

2.5.1. Technical characteristics and means of operation

Means utilized by each component to function

The Patient Census 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). A preliminary draft of the Patient Census Station Manual is included as Exhibit E.

List of operator controls

The Patient Census Station allows for database searches of specific patients by name and patient medical record number. 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 Patient Census Station are 12" monochrome monitors with 640 pixels by 480 lines. The station is for text entry only. Images can not be viewed on this station.

Processors and storage

Basic function of each device

The Patient Census Station is a text entry device for maintaining the RSTAR Intensive Care Unit Mini-PACS databases.

Image storage media listed

There is no local storage of patient information on the Patient Census Station. All data is stored on the RSTAR ICU Image Server and transmitted to the station for viewing upon request. New and modified data are transmitted back to the RSTAR ICU Image Server and stored in the appropriate database records. The station has nine megabytes of memory and an 80 megabyte hard drive which contains the Macintosh Operating System and the RSTAR Patient Census Station Application Code.

Operator Interfaces

The Patient Census Station is keyboard and mouse driven.

Software

See section 6.1.3 and 6.4.2 for a description of the Patient Census Station software.

Computer 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

ADB (Apple Desktop Bus)	keyboard
Video port	12" monochrome monitor
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. • 12" Monochrome Display

Picture tube	
Diagonal	12"
CRT	P104 & P193 phosphor
Screen Resolution	
Horizontal pixels	640 pixels
Vertical lines	480 pixels
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

2.6. Film Digitizer Station (FDS)

This is one of the two types of image input stations supported by the ICU Mini-PACS. This component allows for the electronic digitization of conventional radiographs and the entry of these data into the ICU Image Server. The list below is a summary of the functions provided by the FDS.

1. The **FDS** will digitize ICU patient plane films via a laser film digitizer.
2. The **FDS** will collect image information via keyboard and mouse input.
3. The **FDS** will collect study information via keyboard and mouse input.
4. The **FDS** will collect patient demographics for new patients via keyboard and mouse input.
5. The **FDS** will, with the entry of a medical record number, pull patient demographics from the ICU database for existing patients.
6. The **FDS** will allow for review of digitized films prior to acceptance into the clinical image database.
7. The **FDS** will allow for digitized images to be flipped and/or rotated into standard orientation (as defined by the institution) prior to entry in to the clinical image database.
8. The **FDS** will support multiple images per study.
9. The **ICU Mini-PACS** may be configured with up to two image input modalities: two **FDS**'s, or two **CRS**'s, or one **FDS** and one **CRS**.

2.6.1. Technical characteristics and means of operation

Means utilized by each component to function

The Film Digitizer 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 Film Digitizer/Computed Radiography Station Manual is included as Exhibit F.

List of operator controls

The Film Digitizer Station allows for the entry of patient demographics, study information, image information and image data into the RSTAR Intensive Care Unit Mini-PACS. The above data are collected at the Film Digitizer Station and transmitted over the IEEE 802.3 LAN to the RSTAR ICU Image Server.

Monitors

The monitors used for the Film Digitizer Station are 12" monochrome 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 Film Digitizer Station is a text and image entry device for entering data into the RSTAR Intensive Care Unit Mini-PACS.

Image storage media listed

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

Operator Interfaces

The Film Digitizer Station is keyboard and mouse driven.

Software

See section 6.1.1 for a description of the Film Digitizer Station software.

2.6.2. Specifications

Computer Specifications:

Apple Computer, Inc. • Macintosh IIsi

Processor

Chip	MC68030 32-bit architecture
Clock speed	20-megahertz

Memory 17 megabytes

Disk Drives

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

Interfaces

Apple Desktop Bus (ADB)	keyboard
Video port	12" monochrome monitor
Internal Expansion slot	IEEE 802.3 Interface Board
SCSI	LUMASCAN Digitizer
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. • 12" Monochrome Display

Picture tube	
Diagonal	12"
CRT	P104 & P193 phosphor
Screen Resolution	
Horizontal pixels	640 pixels
Vertical lines	480 pixels
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

Laser Film Digitizer

Lumisys LUMASCAN See technical specifications in Exhibit G

2.7. Computed Radiography Station (CRS)

This is one of the two types of image input modalities supported by the ICU Mini-PACS. This component allows for the entry of radiographic images into the ICU-IS from a Fuji AC-1 Plus CR unit via an ANALOGIC DASM™-XPRF SCSI Interface. The list below is a summary of the functions provided by the CRS.

1. The **CRS** will acquire phosphor plate images from ICU patients via an ANALOGIC DASM™-XPRF SCSI Interface to the Fuji FCR AC-1 Plus.

2. The **CRS** will collect image information via keyboard and mouse input.

3. The **CRS** will collect study information via keyboard and mouse input.

4. The **CRS** will collect patient demographics for new patients via keyboard input.

5. The **CRS** will, with the entry of a medical record number, pull patient demographics from the ICU database for existing patients.

6. The **CRS** will allow for review of acquired images prior to acceptance into the clinical image database.

7. The **CRS** will allow for acquired images to be flipped and/or rotated into standard orientation (as defined by the institution) prior to entry in to the clinical image database.

8. The **CRS** will support multiple images per study.

9. The **ICU Mini-PACS** may be configured with up to two image input modalities: two **CRS**'s , or two **FDS**'s, or one **CRS** and one **FDS**.

2.7.1. Technical characteristics and means of operation

Means utilized by each component to function

The Computed Radiography 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 Film Digitizer/Computed Radiography Station Manual is included as Exhibit F.

List of operator controls

The Computed Radiography Station allows for the entry of patient demographics, study information, image information and image data into the RSTAR Intensive Care Unit Mini-PACS. The above data are collected at the Computed Radiography Station and transmitted over the IEEE 802.3 LAN to the RSTAR ICU Image Server.

Monitors

The monitors used for the Computed Radiography Station are 12" monochrome 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 Computed Radiography Station is a text and image entry device for entering data into the RSTAR Intensive Care Unit Mini-PACS.

Image storage media listed

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

Operator Interfaces

The Computed Radiography Station is keyboard and mouse driven.

Software

See section 6.1.2 for a description of the Computed Radiography Station software.

2.7.2. Specifications

Computer Specifications:

Apple Computer, Inc. • Macintosh IIsi

Processor

Chip	MC68030 32-bit architecture
Clock speed	20-megahertz

Memory 17 megabytes

Disk Drives

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

Interfaces

Apple Desktop Bus (ADB)	keyboard
Video port	12" monochrome monitor
Internal Expansion slot	IEEE 802.3 Interface Board
SCSI	Fuji AC-1 Plus
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. • 12" Monochrome Display

Picture tube	
Diagonal	12"
CRT	P104 & P193 phosphor
Screen Resolution	
Horizontal pixels	640 pixels
Vertical lines	480 pixels
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

SCSI Interface to Computed Radiography Unit

ANALOGIC DASM™-XPRF See technical specifications in Exhibit H

2.8. Indications for use

2.8.1. Brochure

A draft copy of the RSTAR Intensive Care Unit Mini-PACS Brochure which gives an overview of the ICU Mini-PACS is included as Exhibit I.

2.8.2. User's Manuals

Preliminary draft copies of User's Manuals for the ICU Mini-PACS are included as the following exhibits.

- ICU Image Server System Administrator Manual — Exhibit B
- Image Review Station User's Manual — Exhibit D
- Patient Census Station User's Manual — Exhibit E
- Film Digitizer / Computed Radiography Station User's Manual — Exhibit F

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 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 3.5 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 2.7 above is validated.

3.1. ICU Image Server (ICU-IS)

3.1.1. Functional Testing

1. Monitor System Activity via the Status Screen
2. Monitor available Image Cache disk space
3. Monitor available Database disk space
4. Monitor available Voice Cache disk space
5. Generate System Configuration Report
6. Generate Patients Report
7. Generate Studies Report
8. Generate Data Files Report
9. Generate Audits Log
10. Generate Errors Log
11. Generate Usage Log
12. Generate Events Log
13. Clear Audits Log
14. Clear Errors Log
15. Clear Usage Log
16. Clear Events Log
17. Configure System
18. Restart Servers
19. Display System Event log
20. Verify Database
21. Backup Database
22. Restore Database
23. Run Database Consistency Check
24. Remove Selected Job from the laser film printer queue
25. Clear the laser film printer queue
26. Reset the laser film printer

3.1.2. Simulated Error Testing

1. Disrupt IEEE 802.3 LAN connection
2. Disrupt RSTAR Fiber Optic Network connection
3. Stop each individual server in turn and attempt access from the each of the RSTAR Display and Acquisition Stations
4. Disrupt the IEEE 802.3 LAN connection
5. Disrupt the optical LAN connection
6. Remove the film cassette from the Laser Imager
7. Place empty film cassette in the Laser Imager
8. Turn off the Laser Imager
9. Disrupt Optical LAN connection
10. Generate transmission errors

3.1.3. Data Compression (Not Applicable)

The February 1991 draft FDA PACS 510(k) guidance document requires the submission of specified test results for devices that employ data compression. This requirement is not applicable to this notification - the base performance of the RSTAR Intensive Care Unit Mini-PACS is such that data compression is not employed for either communications or storage of data.

3.2. Image Review Station (IRS)

3.2.1. Functional Testing for all IRS's

1. Start work session
2. Select Intensive 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. Print image on screen to Laser Imager
9. Display textual notation for a study
9. Play back voice notation for a study
9. Record voice notation for a study

3.2.2. Functional Testing for IRS's with 2 Screens

1. Selection a comparison study
2. Select an image from the comparison study

3.2.3. Functional Testing for IRS's with 1K monitors

1. Magnify the image

3.2.4. Simulated Error Testing

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

3.3. Patient Census Station (PCS)

3.3.1. Functional Testing

1. Start work session
2. Select work queue preference
3. Select **New Study** button
4. Enter patient demographics
5. Enter study 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 study information
14. Modify patient history
15. Select **Study Complete** button
16. End work session

3.3.2. Simulated Error Testing

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

3.4. Film Digitizer Station (FDS)

3.4.1. Functional Testing

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

3.4.2. Simulated Error Testing

1. Disrupt the IEEE 802.3 LAN connection
2. Turn off the scanner
3. Enter inappropriate data
4. Leave required fields blank
5. Scan film with wrong orientation
6. Jam a film in the scanner

3.5. Computed Radiography Station (CRS)

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 study information
6. Enter patient history
7. Place phosphor plate in CR unit
8. Select **Acquire** button
9. Preview sub-sampled image
10. Set to proper orientation if necessary
11. Select **Save Image** button
12. Enter image title
13. Repeat steps 9-12 several times
14. Select **Study Complete** button
15. Repeat steps 2-14 while station is transmitting first study to the ICU Image Server
16. Repeat steps 2-13 and select **Cancel Study** button
17. End work session

3.5.2. Simulated Error Testing

1. Disrupt the IEEE 802.3 LAN connection
2. Turn off the CR unit
3. Enter inappropriate data
4. Leave required fields blank
5. Enter phosphor plate with wrong orientation

4. Substantially Equivalent (SE) Devices

4.1. Manufacturer and tradename of SE devices

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

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

4.2. Promotional material and specifications

Included are brochures for the AVP and Kodak/Vortech systems as Exhibits J and K respectively.

4.3. Tabular comparison of features and specifications

The next three pages compare the RSTAR ICU Mini-PACS 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 none of these affect the safety and efficacy of the RSTAR ICU Mini-PACS.

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 a RSTAR brochure intended as an overview to the RSTAR Intensive Care Unit Mini-PACS is included as Exhibit I.

5.2. User's manuals

Draft copies of User's Manuals for the ICU Mini-PACS are included as the following exhibits.

- Image Server System Administrator's Manual — Exhibit B
- Image Review Station User's Manual — Exhibit D
- Patient Census Station User's Manual — Exhibit E
- Film Digitizer / Computed Radiography Station User's Manual — Exhibit F

6. Software Information

The following sections 6.1 through 6.5 list and briefly describe the software functions performed by each of the RSTAR components.

6.1. Data Acquisition

6.1.1. Film Digitizer Station (FDS)

- Collect new patient demographic information
- Collect study information
- Collect image information
- Collect image data
- Transmit above data to the ICU Image Server

6.1.2. Computed Radiography Station (CRS)

- Collect new patient demographic information
- Collect study information
- Collect image information
- Collect image data
- Transmit above data to the ICU Image Server

6.1.3. Patient Census Station (PCS)

- Enter patient demographic information
- Modify patient demographic information
- Enter study information
- Modify study information
- Enter image information
- Modify image information
- Enter textual notation for a particular study
- Modify textual notation for a particular study
- Enter voice notation for a particular study
- Modify voice notation for a particular study
- Queue print request to Laser Imager for all images of a particular study

6.2. Data Display

6.2.1. Image Review Station: 2K 1-Screen (IRS - 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 workstation
- Display textual notation for a particular study
- Play back voice notation for a particular study
- Enter voice notation for a particular study

6.2.2. Image Review Station: 2K 2-Screen (IRS - 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 workstation
- Display textual notation for a particular study
- Play back voice notation for a particular study
- Enter voice notation for a particular study

6.2.3. Image Review Station: 1K 1-Screen (IRS - 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 workstation

6.2.4. Image Review Station: 1K 2-Screen (IRS - 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 workstation

6.3. Data Storage

6.3.1. ICU Image Server (ICU-IS)

- Coordinate overall system activity
- Support a System Administrator's Console for maintenance and system status investigation
- Maintain the ICU database
- Maintain the patient demographic records
- Maintain the study information records
- Maintain the image information records
- Maintain the radiographic image data
- 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 Review Station (IRS)

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

6.4.2. Patient Census Station (PCS)

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

6.5. Data Transmission

6.5.1. ICU Image Server (ICU-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 ICU Mini-PACS 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.

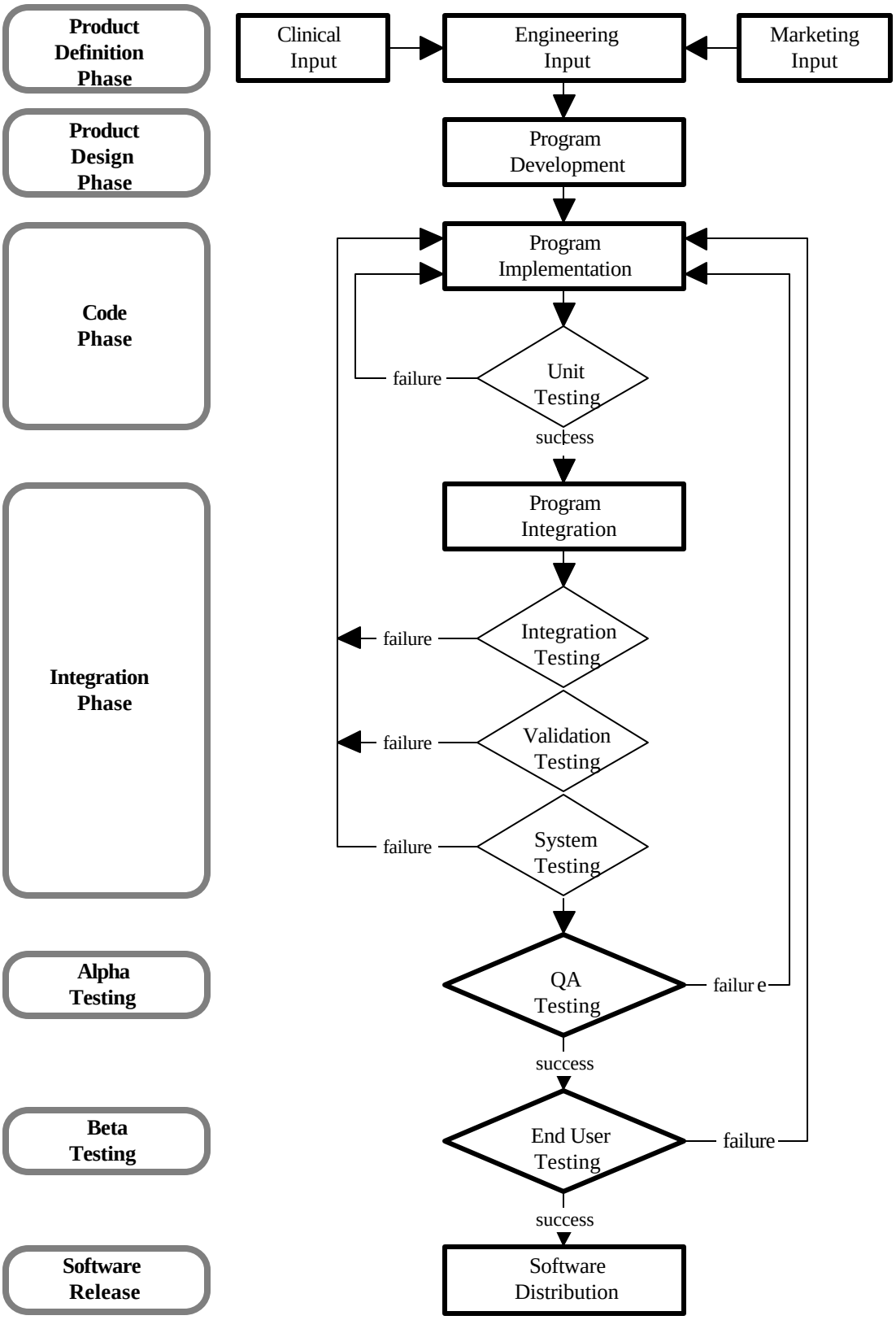
Integration Phase: Software is validated through three levels of testing. Integration testing assembles all the individual software modules and tests their individual functions and interfaces. Validation testing verifies that all software requirements have been met. System testing verifies the proper 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 3.6 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 MPW (Macintosh Programmer's Workshop). Projector provides the same functionality as 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 Intensive Care Unit Mini-PACS, 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 a 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, and so on)
  - Tracing the execution path of the program
  - Monitoring the changes in variables and other program entities
  - Monitoring events (for example, 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 whole 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 and effectiveness of the system as it is described in

this document. Such changes 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 Intensive Care Unit Mini-PACS.

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 Intensive Care Unit Mini-PACS. The three phases of hardware engineering and the basic functions and deliverables of the phases are listed below.

1. Planning and Specification

Hardware Functions	Hardware Deliverables
Development Planning (DP)	Costs Schedule
Review (failure to DP)	
Detailed Requirements Analysis (DRA)	Hardware Specification
Review (failure to DRA)	

2. Design and Prototype Implementation

Hardware Functions	Hardware Deliverables
Design Analysis (DA)	Design Drawings
Manufacturing Analysis (MA)	Manufacturing Specification
Build prototype and test	Prototype
Review (failure to DA)	

3. Manufacturing, Distribution and Field Service

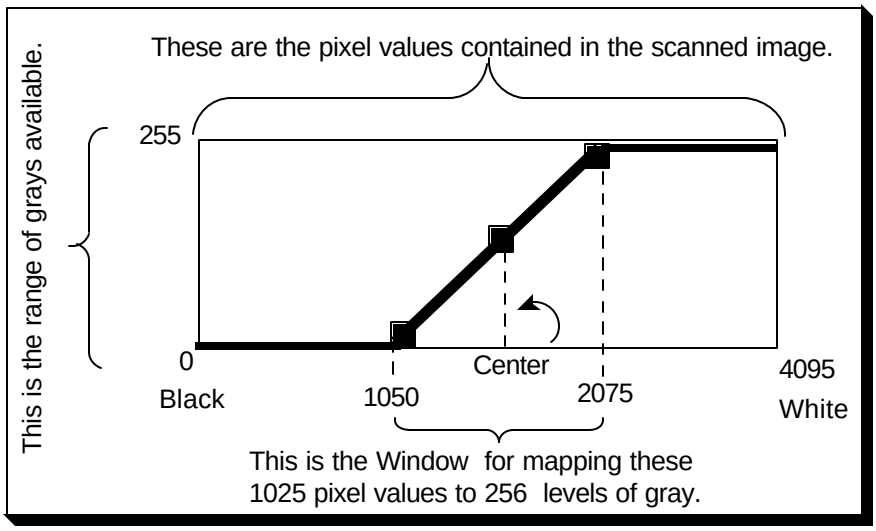
Hardware Functions	Hardware Deliverables
Manufacture	Products
Quality Assurance	
Error Cause Removal (ECR)	
Review (failure to ECR)	
Distribution	

8. Listing of Exhibits

Exhibit A	Window and Center Description
Exhibit B	**ICU Mini-PACS** • System Administrator Manual
Exhibit C	**3M** Laser Imager XL Brochure
Exhibit D	**ICU Mini-PACS** • Image Review Station Manual
Exhibit E	**ICU Mini-PACS** • Patient Census Station Manual
Exhibit F	**ICU Mini-PACS** • Film Digitizer/Computed Radiography Station Manual
Exhibit G	**Lumisys** Lumascan 150 Laser Film Digitizer Brochure
Exhibit H	**ANALOGIC** DASM™-XPRF Brochure
Exhibit I	**RSTAR** Intensive Care Unit Mini-PACS Overview Brochure
Exhibit J	**Advanced Video Products** (AVP) TELEPRO Brochures
Exhibit K	**Kodak/Vortech** IMAGELINK Brochures
Exhibit L	**Product Comparison System** (PCS) on Picture Archiving and Communication Systems (PACS)

WINDOW AND CENTER

When an image is digitized, the ICU Mini-PACS system records 4096 shades of gray from completely black (0) to completely white (4095). The monitors can only display 256 shades of gray, so the ICU Mini-PACS maps each of the 4096 shades stored in the image to one of the 256 shades it can display on the screen. To control brightness and darkness, you control how ICU Mini-PACS maps 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 fewer image shades map to the display shades. For instance, 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 doesn't 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.

ICU Mini-PACS

System Administrator Manual

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Welcome
1

Welcome to the ICU Mini-PACS, an electronic imaging system makes radiographic images available to ICU physicians and to radiologists at the same time. Radiographic images start in radiology, where they are digitized and stored in the ICU Mini-PACS system. These digitized images are immediately available in both the radiology department an in the ICU.

This manual shows you how to use the System Administrator Station. The System Administrator Station lets you keep an eye on the status of the ICU Mini-PACS system, print reports and diagnostics, perform backups, and configure the system.

Do you need to read this chapter?

You should read this chapter if you have never worked with ICU Mini-PACS before. This chapter gives you an overview of the ICU Mini-PACS system and teaches you essential terms and concepts that ICU Mini-PACS uses to store images. Understanding these concepts will make it easy for you to find the images you want to display quickly.

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.

Topics covered in this chapter

- What is the System Administration Software?
- What is ICU Mini-PACS?
- How ICU Mini-PACS stores information

What is the System Administration Station

The System Administration Station lets you manage the ICU Mini-PACS system. You use this station to make sure that the system is running smoothly, to print reports, and to configure the system for the other stations. The System Administration Station isn't part of the day-to-day

operation of the ICU Mini-PACS, but it is important to make sure that all the components of the system are working correctly.

What is ICU Mini-PACS?

The ICU Mini-PACS system is a computer system that makes it easier for Intensive Care Units and radiology departments to work together. One of the problems that the system solves is the ICU physician's requirement that radiographic images be available in the ICU at all times and the radiologist's requirement to do radiographic interpretation in the radiology department. Usually, the radiologist has to travel to the ICU to interpret films, which is not the best use of a radiologist's skill and time. Another problem is that in many hospitals, the film is processed in the radiology department, which means that the film needs to be removed from the ICU.

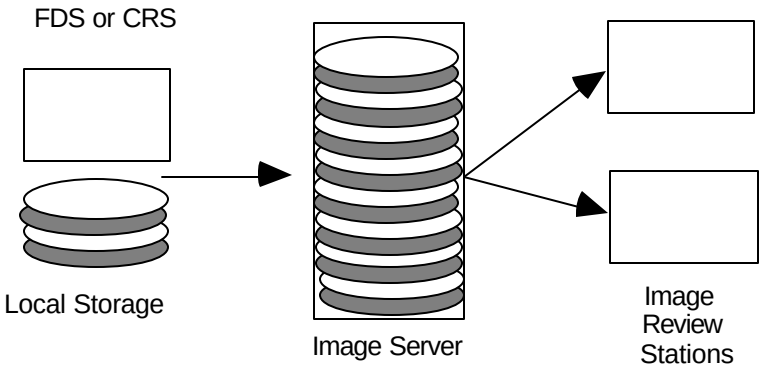
The ICU Mini-PACS system solves these problems. A complete ICU Mini-PACS system has several components, called stations, each with a specific function:

Station	**Function**
Film Digitizer Station	Scans radiographic films into the system.
Computed Radiography Station	Scans computed radiography images into the system.
Image Review Station	Used in the ICU or in the radiology department to view and annotate radiographic images.
Patient Census Station	Used in the ICU to maintain patient information, track patient location, annotate studies, and print images.

When the radiology department processes images, technicians use a Film Digitizer Station (FDS) or a Computed Radiography Station (CRS) to digitize the images into the ICU Mini-PACS system. 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 station sends the image to the image server over a high speed network. The display on the station lets the technician preview the images before sending them to make sure they were scanned correctly.

The images from the FDS or CRS are stored in the ICU Mini-PACS Image Server. 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 Image Review Station linked to the image server can access any of the images stored there. The image server also holds patient information and voice and text annotations for the images.

When you scan an image, the FDS or CRS stores it temporarily in its local storage. When you finish scanning images, the scanning station sends them to the image server. Once the images are there, they're available for viewing at an image review.



How ICU Mini-PACS stores information

The Image Review Station is where a radiologist examines the images stored in the image server. The radiologist requests images from the image server for a particular patient. The image server transmits the selected images to the workstation where they're displayed on a large high-resolution or medium resolution gray-scale monitor. The monitor shows images at 200 pixels per inch, and each pixel can be one of 256 shades of gray, from completely black to completely white. On Image Review Stations with two monitors can display two images for comparison. A special control in the workstation lets the radiologist adjust the brightness and contrast of the image display.

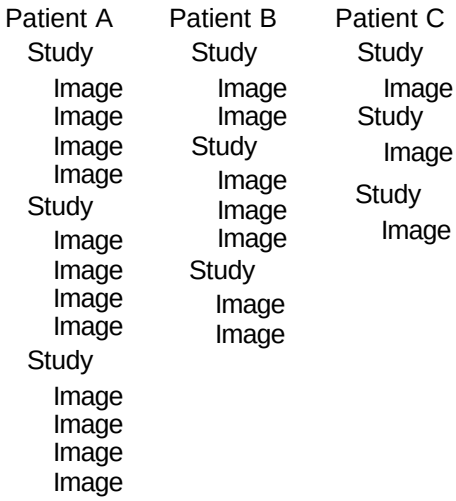
The Patient Census Station located in the ICU lets nurses maintain patient information, keep track of patients and any radiographic studies. Images can be printed to a Laser Imager from the Patient Census Station.

How ICU Mini-PACS Stores 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. ICU Mini-PACS organizes images into studies. No matter what kind of ICU Mini-PACS station you use, you should know how the system organizes images, so you can get at them quickly.

Every image in the ICU Mini-PACS system belongs to a particular patient. The ICU Mini-PACS system stores standard demographic information about a patient as well as the patient's clinical history. This patient information can be entered when the first image for the patient in scanned into the system, or it can be entered or modified at a Patience Census Station.

Every patient has at least one study that contains one or more images. Some studies contain only one image, and other studies contain several images. Every study can have text annotations or voice annotations. In the ICU, there may be a new study for a patient every day. Usually, you can see images from only one study at a time. On Image Review Stations with two monitors, you can compare images from two different studies.



How ICU Mini-PACS organizes images

Understanding how ICU Mini-PACS stores images will make it easier and faster for you to get to the information you need..

Using the System Administration Station 2

This chapter shows you how to use the ICU Mini-PACS System Administration Station. You'll learn how to check the status of the ICU Mini-PACS system, how to print reports, how to run diagnostics, how to back up the system, and how to configure the system.

What you should know

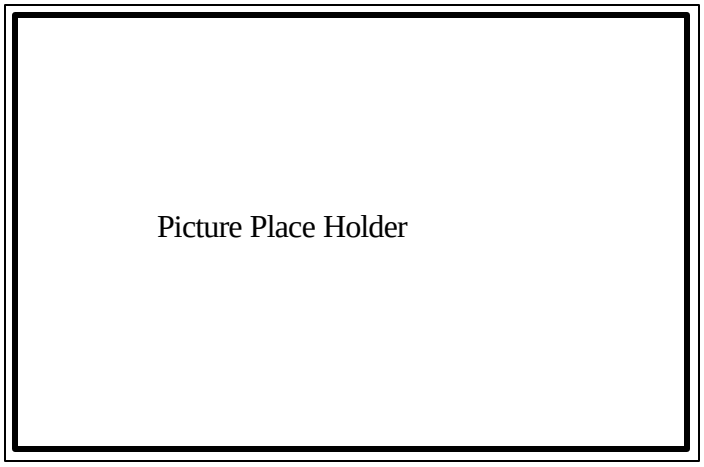
You should be familiar with the way ICU Mini-PACS stores information. You should be familiar with each of the ICU Mini-PACS stations. You should know about studies, and images. If you do not know what these things are, read "How ICU Mini-PACS Stores Information" in Chapter 1.

Topics covered in this chapter

- About the System Administration Station
- Adding a new patient
- Changing patient information
- Changing the patient location
- Changing study information
- Annotating information
- Printing images
- Discharging patients
- Troubleshooting

About the System Administration Station

The System Administration Station consists of a Macintosh computer with a black and white monitor.



System Administration Station

Turning the System Administration Station on

To turn the System Administration Station on, press the power button on the keyboard. This is a button on the top right of the keyboard with a triangle etched in it. You will hear a chime, and you will see a box that says "Welcome to Macintosh" on the screen.

After a few seconds, the System Administration Station software starts up, and you are ready to use the System Administration Station.

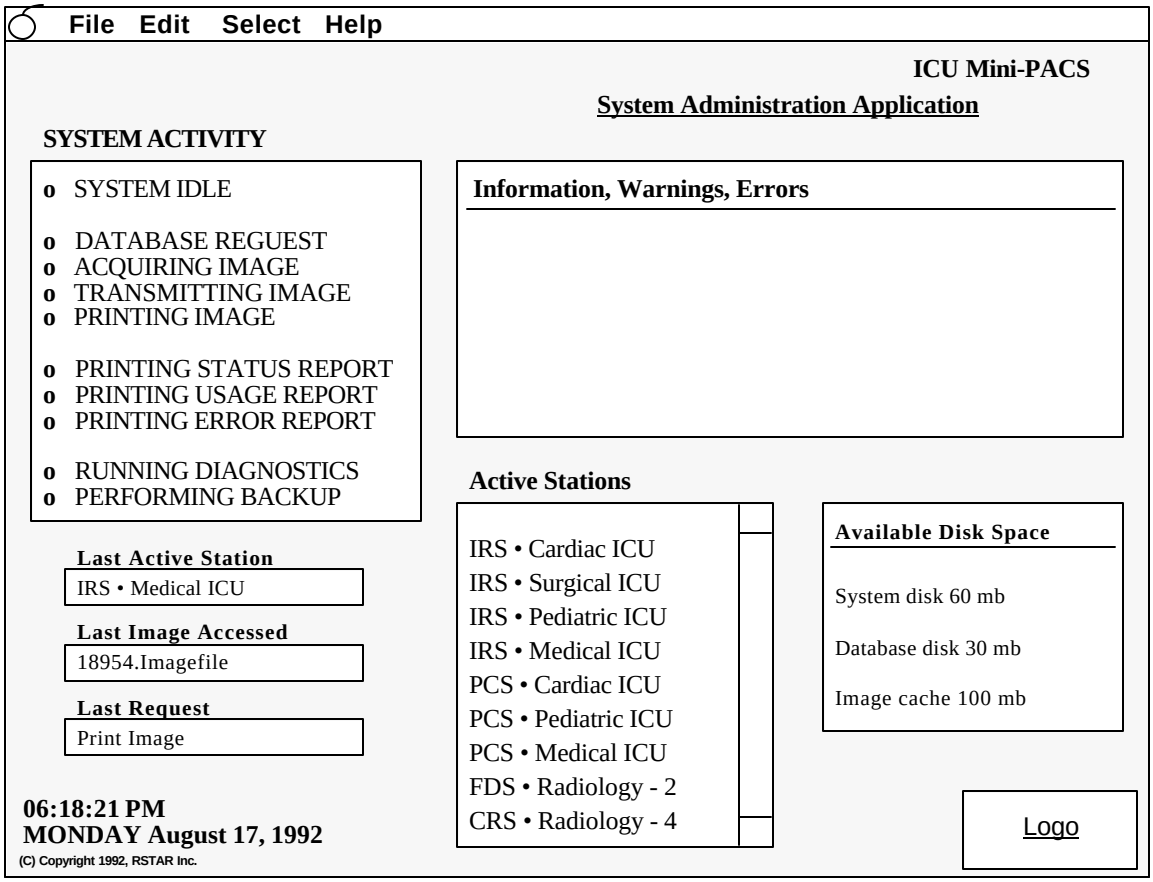
Turning the System Administration Station off

To turn the System Administration Station off, choose the **Quit** command from the **File** menu. After the System Administration Station software quits, you will see the Finder menu bar. Choose the **Shut Down** command from the **Special** menu.

Note: If you don't see the **Shut Down** command in the **Special** menu, you probably didn't choose the **Quit** command from the **File** menu.

The System Administration Station Application

When you start the System Administration Station, the first thing you see is the System Status window. This window shows you the state of the entire ICU Mini-PACS system.



The System Status Window

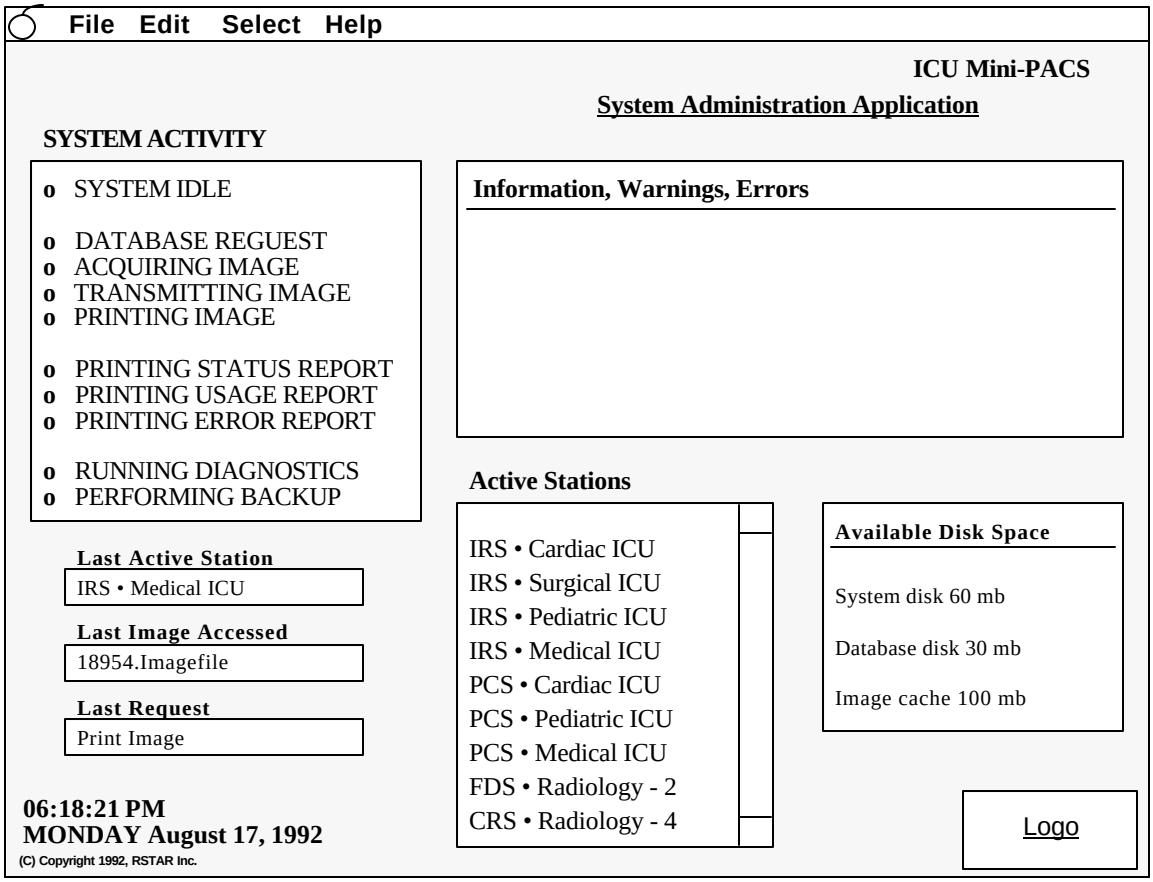
The next section describes the System Status Window in more detail.

The menus at the top of the screen let you choose the different tasks you can do from the System Administration Station.

Menu	Function
Apple	The standard Macintosh Apple menu, not generally used with the System Administration Station
File	Contains the Quit command
Edit	Used for editing text.
Select	Lets you choose the different tasks you can perform from the System Administration Station.
Help	Contains help information for each of the tasks you can perform.

Checking System Status

The first window you see at the System Administration Station is the System Status Window. This window is divided into several panes that look like this:



The System Status Window

The field on the left shows you the system activity. When one of the items is highlighted, the ICU Mini-PACS is performing that action. In general, you'll use this field just to make sure that the system is working. If none of the items is highlighted, or if the highlighting doesn't change, it may mean that the system is not working.

The larger pane on the top left of the window shows you information, warning, and error messages coming from the VAX image server. One message might be to tell you that the disk space is running low. Another message might warn you of an upcoming backup.

The three small fields in the lower left part of the window show you the last request or command, the last image that was accessed from the image server, and the name of the ICU Mini-PACS station that issued the last request.

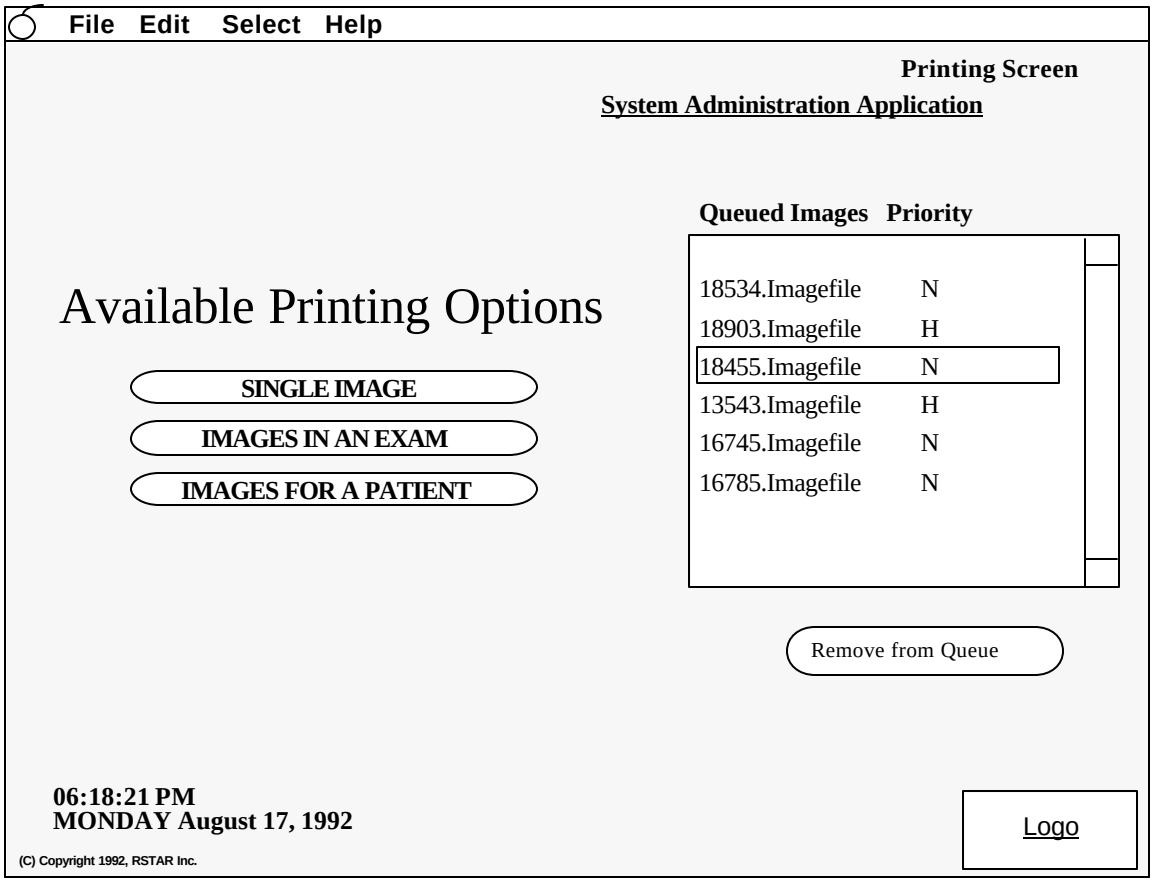
In the middle of the window, you will see a list of active stations. You can use this list to check if all the stations are on the network.

The field in the lower right shows you how much free disk space is left on your system. You'll use this information to decide when it's time to purge discharged patients from the system.

Printing Images

You can use the System Administration Station to print one image, all the images for a patient or all the images in a particular study. You can also remove print requests from the print queue.

To print images or to control the print queue, choose the **Printing** command from the **Select** menu. You will see the Printing Window that looks like this:



Print Window

Any time you print images, the ICU Mini-PACS system asks you for an ID number. This ID number helps your institution keep track of costs.

To print a specific image, click on the **Single Image** button. You will see a list of patient names. Choose the name of the patient whose image you want to print. Next, you will see a list of studies. Choose the study that contains the image you want to print. Finally, when you see a list of images, choose the image you want to print, and click on the **Print** button.

To print all the images in an exam, click on the **Images in a Study** button. You will see a list of patient names. Choose the name of the patient whose study you want to print. Next, you will see a list of studies. Choose the study that you want to print, and click on the **Print** button.

To print all the images for a particular patient, click on the **Images for a Patient** button. You will see a list of patient names. Choose the name of the patient whose images you want to print

Whenever you or anyone else in the ICU Mini-PACS system asks to print an image, the request goes to the print queue. If an image can't be printed right away because an image is being printed in the laser imager, ICU Mini-PACS stores the request in the print queue until the imager is ready to print.

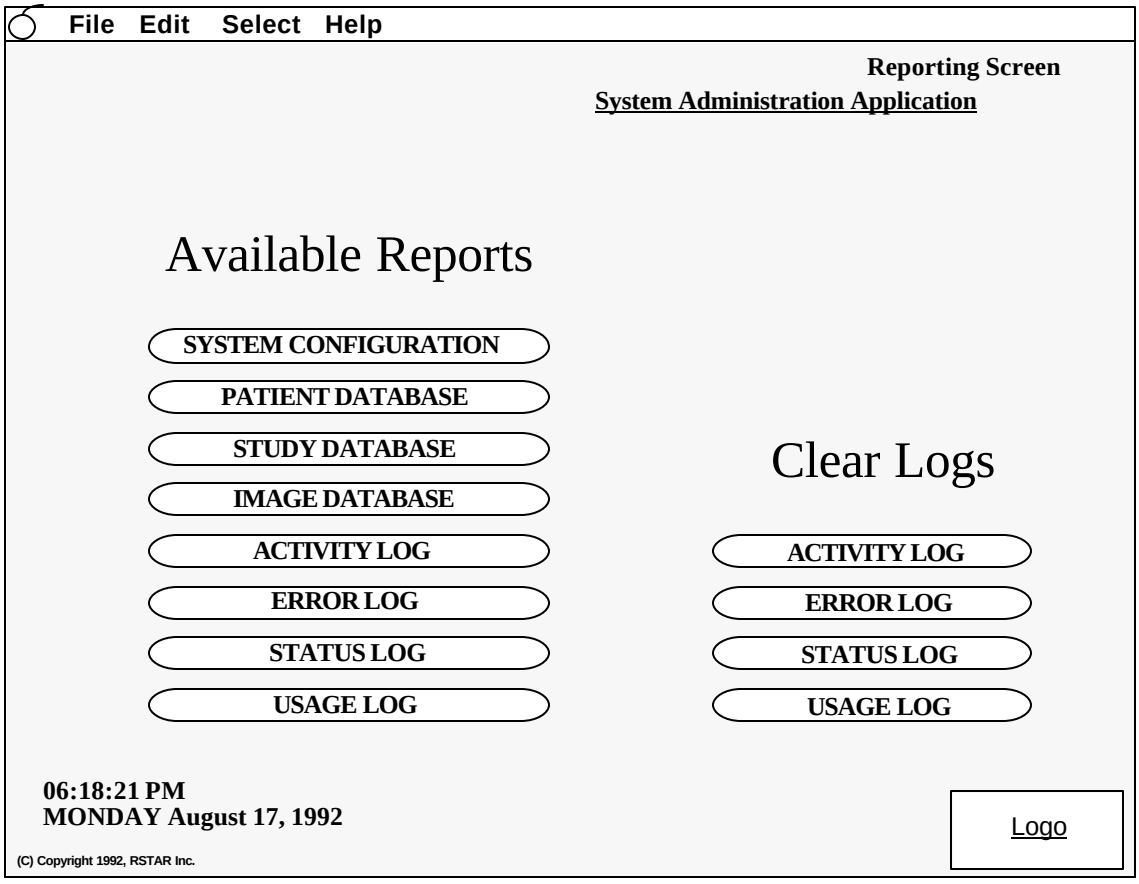
If you need to, you can remove images from the print queue. Choose the name of the image from the print queue list, and then click on the **Remove from Queue.**

Important: Once you remove an image from the print queue, the only way to print the image again is to send a brand new request.

Printing System Reports

The ICU Mini-PACS can generate several kinds of reports. Some reports let you know about the integrity and size of the image database. Other reports are activity logs that you may need to generate for your institution. For instance, you might need to print a report that shows all the people who printed radiographic images to the laser imager.

To go to the reports window, choose the **Reporting** command from the **Select** menu. You will see the Reporting Window that looks like this.



Reporting window

Each of the buttons prints a report of the contents of a log. To print a report or a log, click on the button for the report you're interested in.

Logs are records of periodic activity. From time to time you may want to clear the logs. For instance, you may want to print the Usage Log once a month to keep track of printing expenses. Once you print it, you might want to clear the log to start fresh the following month.

These are the reports and logs you can print:

Report	Contents
System Configuration	Prints the kinds of stations and the number of stations that are in your network.
Patient Database	Prints a report on the size and integrity of the patient database.
Study Database	Prints a report on the size and integrity of the study database.
Image Database	Prints a report on the size and integrity of the image database.
Activity Log	Print a report of the all the activity on all the stations on the ICU Mini-PACS system.
Error Log	Print a list of all the error messages generated while the system is working.
Status Log	Print a summary report of the entire system.
Usage Log	Print a list of people who used ICU Mini-PACS for printing.

Running Diagnostics

The ICU Mini-PACS system has built-in diagnostics that let you know whether the internal state of the system is in a consistent check. You should run each of these checks at least once a month. You will probably want to stage them so you perform on diagnostic per month.

To run the diagnostics, choose the **Diagnostics** command from the **Select** menu. These are the available diagnostics:

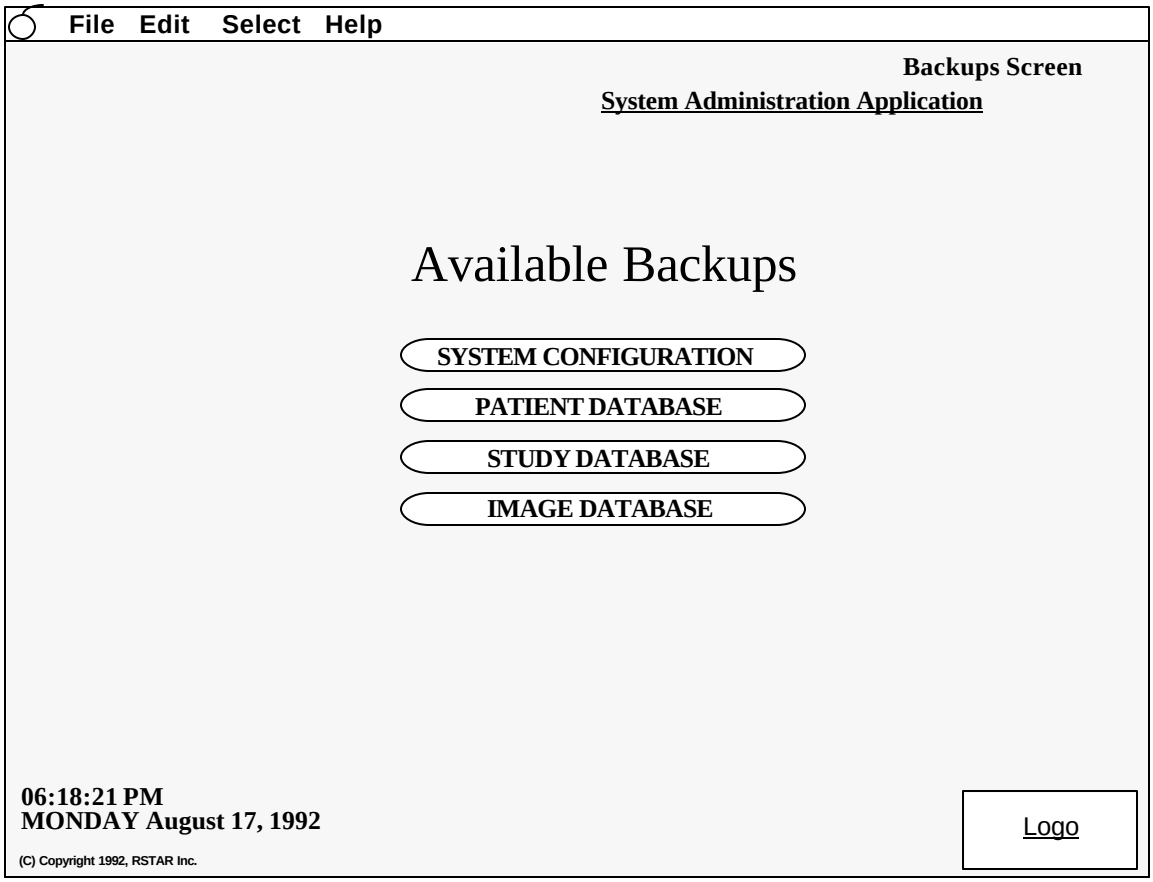
Diagnostic	Function
System Consistency	Checks the integrity of the entire system. This is a rather long test.
Patient DB Consistency	Makes sure that the patient database, which contains the patient information and history, is working correctly.
Study DB Consistency	Makes sure that the studies database is working correctly, and linked correctly to the patient database.
Image DB Consistency	Checks that every image in the ICU Mini-PACS belongs to a study.

on either button, you will be back at the patient status window.

Backing Up and Restoring

One of the best ways to protect any kind of computer data is to back it up. To start backing up the images in the ICU Mini-PACS system, choose **Backups** from the **Select** menu.

You will see a Backup / Restore window that looks like this:

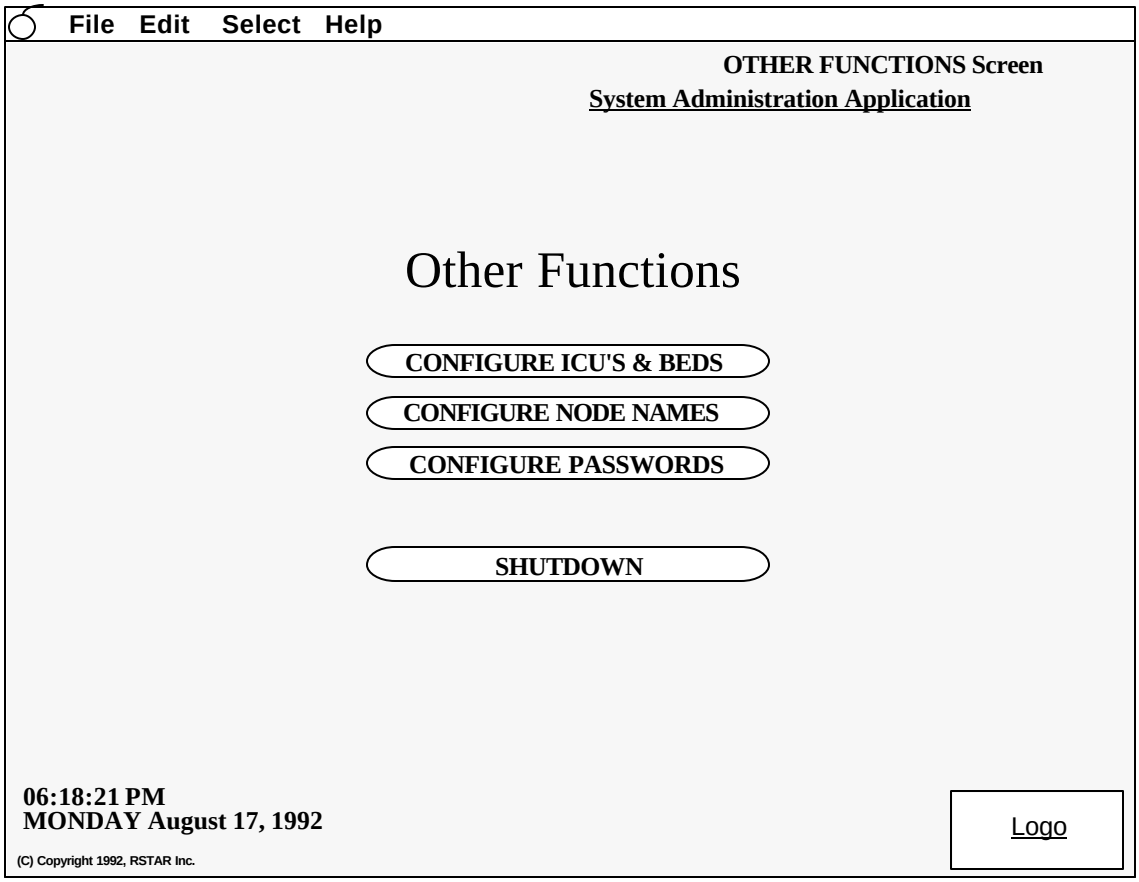


Backup/Restore window

You can choose to back up the entire system or just the patient, study, or image database. You can restore from the same kinds of backups as well.

Configuring the System

The System Administrator Station lets you configure the ICU Mini-PACS system. You can name the ICUs and stations, and you can assign user IDs to the people who will be using the system. To configure the system, choose **Other Functions** from the **Select** menu. You will see a window that looks like this:



Other Functions Window

To name the ICUs, click on the **Configure ICUs and Beds** button. $$WHAT DOES THIS LOOK LIKE$$

To name the stations, click on the **Configure Node Names** button.

To assign passwords to user, click on the **Configure Passwords** button.

To shut down the ICU Mini-PACS systemclick on the **Shutdown** button. This command stops all of the software on all of stations, so you can update ICU names, node names, and passwords.

Troubleshooting

This section gives you tips on how to deal with some questions you might have as you use the System Administration Station.

ICU Mini-PACS

Image Review Station Manual

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Welcome
1

Welcome to the ICU Mini-PACS, an electronic imaging system makes radiographic images available to ICU physicians and to radiologists at the same time. Radiographic images start in radiology, where they are digitized and stored in the ICU Mini-PACS system. These digitized images are immediately available in both the radiology department an in the ICU.

This manual shows you how to use the Image Review Station. The Image Review Station works like an electronic light box to display radiographic images on a computer display. Depending on your system, your Image Review Station may have one or two screens. This manual shows you how to call up images for different patients. The Image Review Station lets you record and listen to voice annotations. If you have a two display system, you can compare two images.

Do you need to read this chapter?

You should read this chapter if you have never worked with ICU Mini-PACS before. This chapter gives you an overview of the ICU Mini-PACS system and tells you where the Image Review Station fits into the whole system. You'll learn where images are stored, how they got there, and how they get to the Image Review Station.

You'll also learn essential terms and concepts that ICU Mini-PACS uses to store images. Understanding these concepts will make it easy for you to find the images you want to display quickly.

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.

Topics covered in this chapter

- What is the Image Review Station
- What is ICU Mini-PACS?
- How ICU Mini-PACS Stores Images

What is the Image Review Station

You can think of the Image Review Station as an electronic light box. But instead of clipping films to this light box, you display images that have been stored electronically. The advantage of this system is that the "film" does not have to be in the same room as the "light box."

What is ICU Mini-PACS?

The ICU Mini-PACS system is a computer system that makes it easier for Intensive Care Units and radiology departments to work together. One of the problems that the system solves is the ICU physician's requirement that radiographic images be available in the ICU at all times and the radiologist's requirement to do radiographic interpretation in the radiology department. Usually, the radiologist has to travel to the ICU to interpret films, which is not the best use of a radiologist's skill and time. Another problem is that in many hospitals, the film is processed in the radiology department, which means that the film needs to be removed from the ICU.

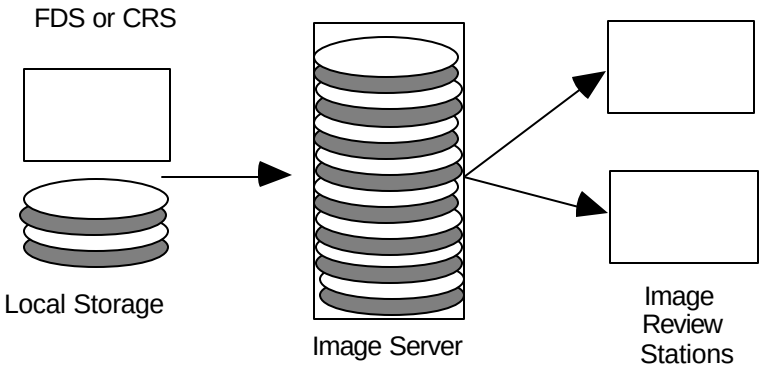
The ICU Mini-PACS system solves these problems. A complete ICU Mini-PACS system has several components, called stations, each with a specific function:

Station	Function
Film Digitizer Station	Scans radiographic films into the system.
Computed Radiography Station	Scans computed radiography images into the system.
Image Review Station	Used in the ICU or in the radiology department to view and annotate radiographic images.
Patient Census Station	Used in the ICU to maintain patient information, track patient location, annotate studies, and print images.

When the radiology department processes images, technicians use a Film Digitizer Station (FDS) or a Computed Radiography Station (CRS) to digitize the images into the ICU Mini-PACS system. 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 station sends the image to the image server over a high speed network. The display on the station lets the technician preview the images before sending them to make sure they were scanned correctly.

The images from the FDS or CRS are stored in the ICU Mini-PACS Image Server. 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 Image Review Station linked to the image server can access any of the images stored there. The image server also holds patient information and voice and text annotations for the images.

When you scan an image, the FDS or CRS stores it temporarily in its local storage. When you finish scanning images, the scanning station sends them to the image server. Once the images are there, they're available for viewing at an image review.



How ICU Mini-PACS stores information

The Image Review Station is where a radiologist examines the images stored in the image server. The radiologist requests images from the image server for a particular patient. The image server transmits the selected images to the workstation where they're displayed on a large high-resolution or medium resolution gray-scale monitor. The monitor shows images at 200 pixels per inch, and each pixel can be one of 256 shades of gray, from completely black to completely white. On Image Review Stations with two monitors can display two images for comparison. A special control in the workstation lets the radiologist adjust the brightness and contrast of the image display.

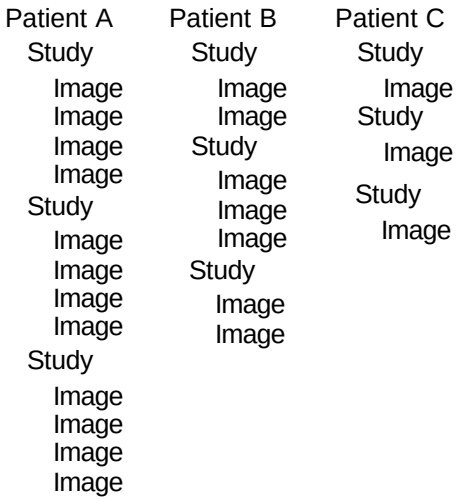
The Patient Census Station located in the ICU lets nurses maintain patient information, keep track of patients and any radiographic studies. Images can be printed to a Laser Imager from the Patient Census Station.

How ICU Mini-PACS Stores 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. ICU Mini-PACS organizes images into studies. No matter what kind of ICU Mini-PACS station you use, you should know how the system organizes images, so you can get at them quickly.

Every image in the ICU Mini-PACS system belongs to a particular patient. The ICU Mini-PACS system stores standard demographic information about a patient as well as the patient's clinical history. This patient information can be entered when the first image for the patient in scanned into the system, or it can be entered or modified at a Patience Census Station.

Every patient has at least one study that contains one or more images. Some studies contain only one image, and other studies contain several images. Every study can have text annotations or voice annotations. In the ICU, there may be a new study for a patient every day. Usually, you can see images from only one study at a time. On Image Review Stations with two monitors, you can compare images from two different studies.



How ICU Mini-PACS organizes images

Understanding how ICU Mini-PACS stores images will make it easier and faster for you to get to the information you need..

Using the Image Review Station 2

This chapter shows you how to use the ICU Mini-PACS Image Review Station. You'll learn how to use the controls on the Image Review Station, how to select the image you want to display, how to compare images, and how to change the display to lighten and darken images.

What you should know

You should be familiar with the way ICU Mini-PACS stores information in patient studies. If you need to find out how this works, read "How ICU Mini-PACS Stores Information" in Chapter 1.

Topics covered in this chapter

- About the Image Review Station
- Turning the Image Review Station on and off
- Choosing a patient
- Choosing a study
- Displaying images
- Adjusting brightness and contrast
- Working with annotations
- Comparing images
- Printing images
- Choosing a different ICU
- Troubleshooting

About the Image Review Station

The Image Review Station consists of one or two monitors with a row of buttons running along the bottom and side edges of the screen. On one-monitor systems, the buttons run along the left edge of the screen. On two-monitor systems, the buttons run along the outside edges of the monitors. Depending on your system, the monitors are either medium-resolution monitors or high-resolution monitors.

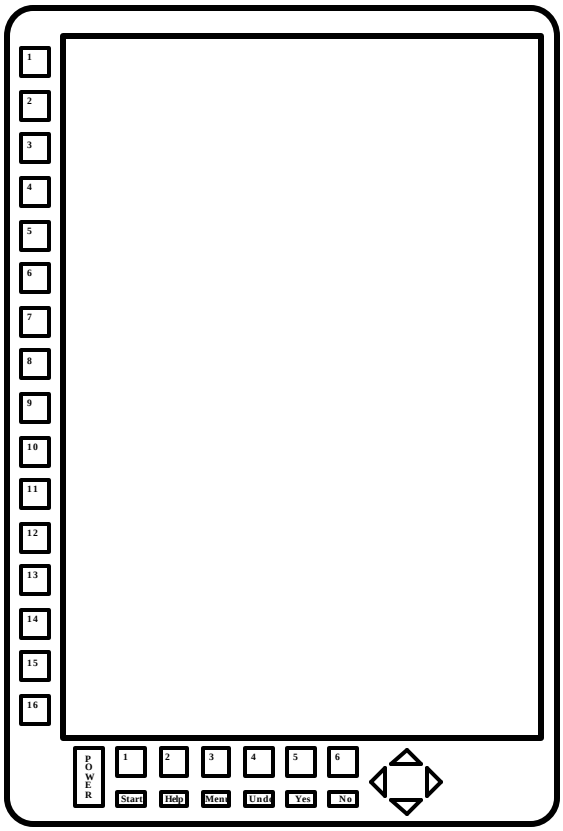


Image Review Station with one monitor

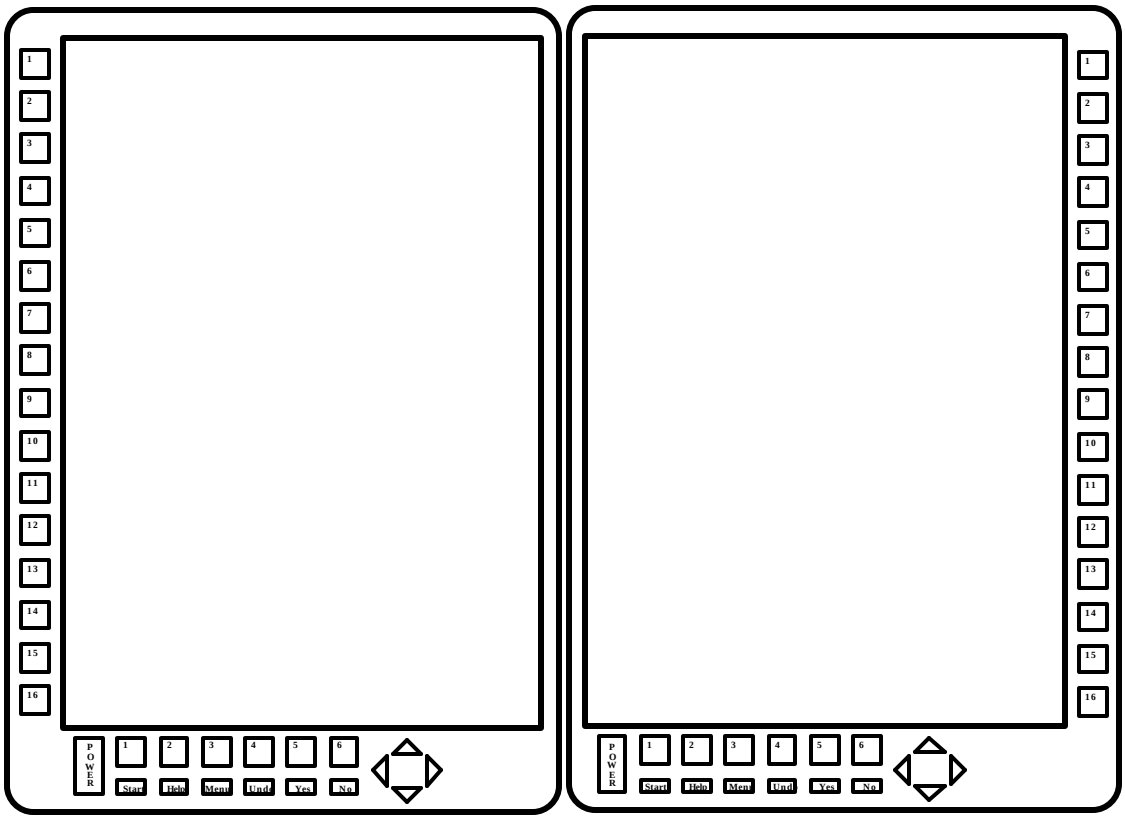


Image Review Station with two monitors

The buttons running along the sides of the screen are labeled with numbers. You'll use these buttons to select items from a list of patients, studies, or images.

Along the bottom of the screen, you'll see the power button, two rows of buttons, and a set of arrow buttons. The top row of buttons is unlabeled. These are **soft buttons**. Labels that describe the function of these buttons appear at the bottom of the screen.

The buttons along the bottom row have labels that describe their function. The button labeled Help, for example, always displays directions on the screen.

Button	**Function**
Start	Always returns you to the initial patient list
Help	Displays a window that gives you help with the current state of the Image Review Station
Menu	Displays a list of commands that let you print images, run a self test on the Image Review Station, choose a different ICU, and turn off the Image Review Station.
Undo	Undoes the effect of the last command
Yes / No	These buttons let you give answers to questions

The arrow buttons let you adjust the brightness and contrast on the display. On low-resolution monitors, these buttons also magnify parts of the screen so you can see the images in more detail.

Turning the Image Review Station On and Off

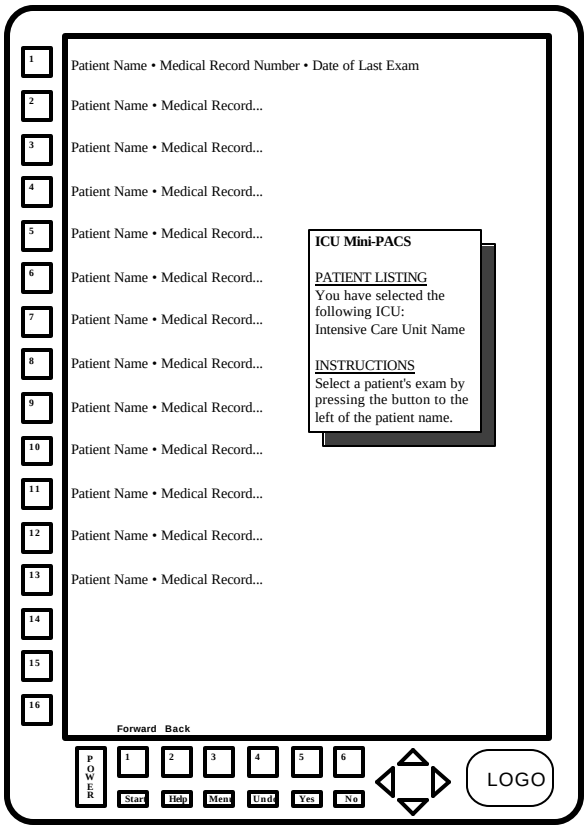
To turn the Image Review Station on, press the Power button. After a few seconds, the screen shows you the patient list for the current ICU.

You can leave the Image Review Station on when you're not using it. If you don't touch any button on the Image Review Station for more that $$15$$ minutes, a "screen saver" starts up to protect the screen. The screen saver stops when you press the **Start** button.

To turn the Image Review Station off, press the **Menu** button. You will see a list of commands on the screen. Press the soft button next to the Shut Down command, and the Image Review Station turns itself off.

Choosing a Patient

When the Image Review Station first starts up, it displays the patient list. This is a list of all the patients in the current ICU. The patient list shows you the patient name, the patient's medical record number, and the date of the last study. If no one has viewed the last study, the date of the last study appears highlighted.



The patient list

> **Note:** You can always press the **Start** button to get back to the patient list.

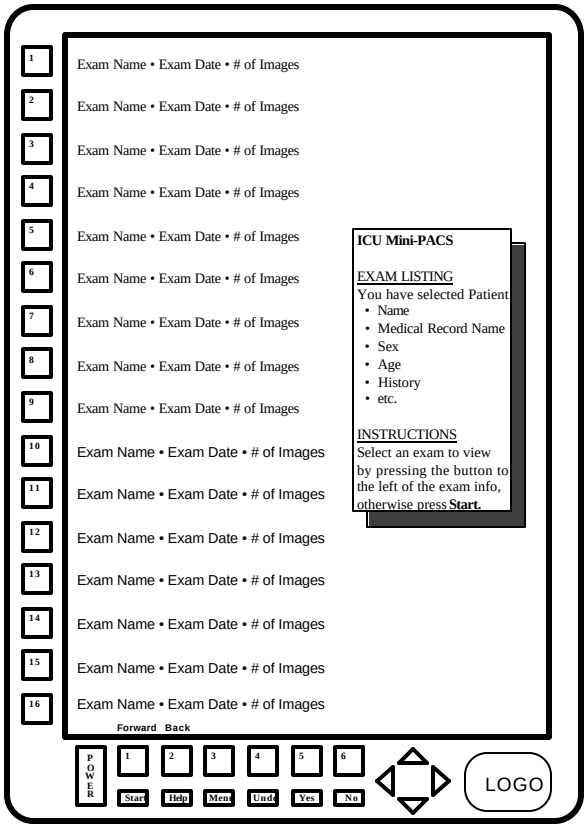
To choose a patient from the list, press on of the soft buttons next to the patient name.

If there are more patients than would fit on the screen, two soft buttons at the bottom of the screen are marked Forward and Back. Press the Forward button to see names toward the end of the list, and press the Back button to see names toward the beginning of the list.

A small window to the right of the patient names tells you the name of current ICU. To learn how to see patients in another ICU see the section “Choosing an ICU” below.

Choosing a study

Once you choose a patient, ICU Mini-PACS displays a list of all the studies for that patient. The study list shows you the name of each study, its date, and the number of images the study has.



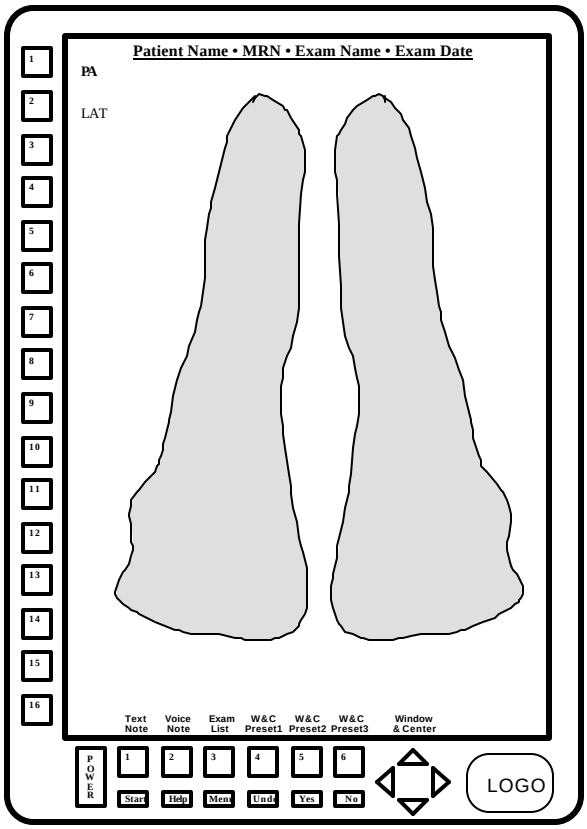
The study list

The window to the right of the study list shows you demographic information about the patient.

To choose a study from the study list, press the buttons next to the study you want to see. If there are more studies for this patient than would fit on the screen, two soft buttons at the bottom of the screen will be labeled **Forward** and **Back**. Use the **Forward** button to see more studies to wards the end of the list, and use the **Back** button to see studies toward the beginning of the list.

Displaying Images

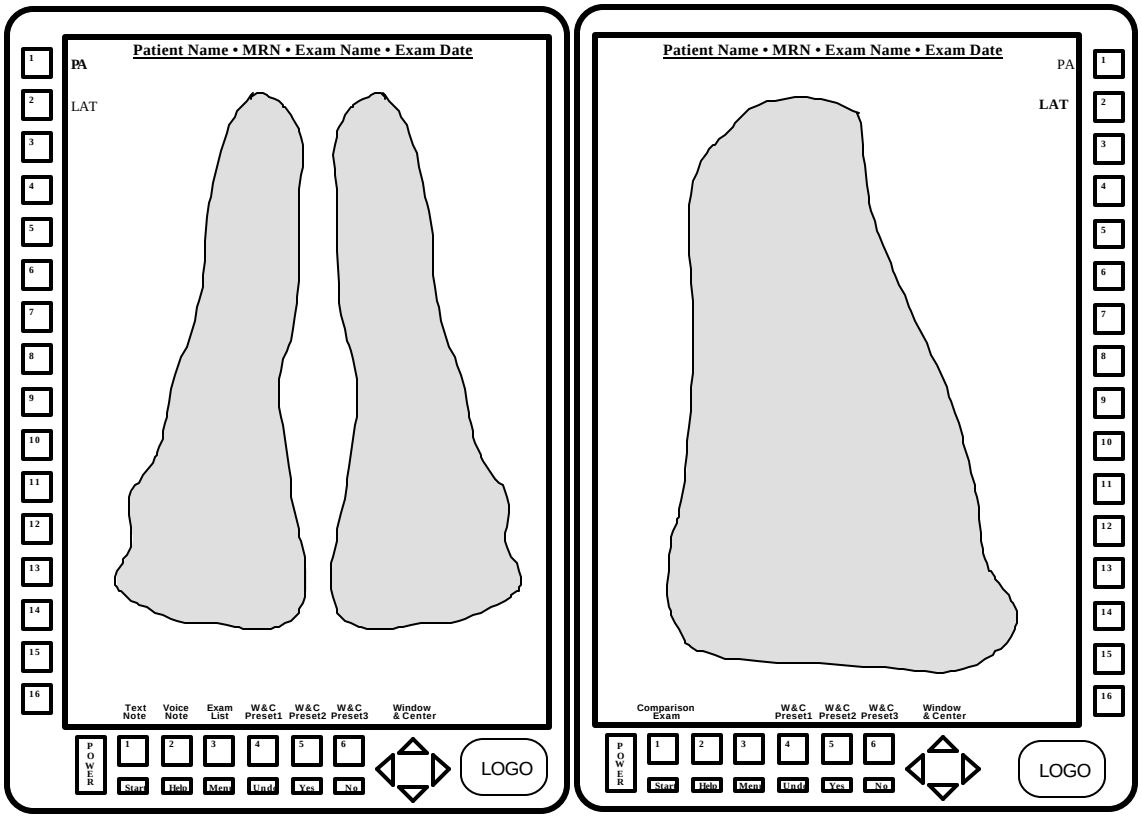
After you choose a study, ICU Mini-PACS displays the first image in the study. If your system has two monitors, you’ll see the first image on the left monitor and the second image on the left monitor. The name of the patient, the patient medical record number, the name of the study, and the date of the study appear along the top of the screen.



Displaying an image on the screen

A list of images in the study appears next to the buttons on the side of the screen, and the current image appears highlighted. To look at a different image, press the button next to its name.

On two-monitor systems, the first image in the study appears on the left monitor, and the second image appears in the right monitor.



Images on a two-monitor system

Returning to the study list

When you are looking at an image, you can press the soft button labeled **Study List** to return to the study list. $$WHAT HAPPENS TO THE IMAGE ON THE RIGHT MONITOR IN THIS CASE?$$ From there, you can choose to look at a different study.

Note: If your system has two monitors, and you want to compare images from two studies, read the section "Comparing Images" below.

While you are looking at images, you can listen to voice annotations, read text annotations, and controls the brightness and contrast. If your system has two monitors, you can also compare images from different studies. The following sections tell you how to do these things.

Adjusting Brightness and Contrast

As you view an image, you may want to adjust the brightness and contrast to accentuate different tissue densities. Three soft buttons and the arrow buttons on the bottom of the display let you adjust the brightness and contrast.

The preset buttons

The easiest way to set the brightness and contrast is to use the built-in presets. When ICU Mini-PACS displays an image on one of the monitors, three soft buttons will be labeled **Preset1**, **Preset2**, and **Preset3**. $$THESE MAY ACTUALLY BE LABELED "BONE" "SOFT TISSUE" ETC.$$

Button	Function
Preset1	$$FULL RANGE$$
Preset2	$$NARROW DARK$$
Preset3	$$NARROW LIGHT$$

Using the arrow buttons

In general, the up arrow and down arrow buttons control brightness, and the left arrow and right arrow buttons control contrast. But to make full use of these buttons, you need to know how ICU Mini-PACS displays grays.

When an image is digitized, the ICU Mini-PACS system records 4096 shades of gray from completely black (0) to completely white (4095). The monitors can only display 256 shades of gray, so the ICU Mini-PACS maps each of the 4096 shades stored in the image to one of the 256 shades it can display on the screen. To control brightness and darkness, you control how ICU Mini-PACS maps image gray shades to display gray shades.

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 fewer image shades map to the display shades. For instance, 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 doesn't 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.

The up arrow and down arrow buttons control the center, and the right and left arrows control the width of the window.

Button	Function
Up Arrow	Maps the center to lighter image shades (brighter)
Down Arrow	Maps the center to darker image shades (darker)
Right Arrow	Makes the window wider (less contrast)
Left Arrow	Makes the window narrower (more contrast)

The best way to understand these concepts is to experiment with the arrow buttons. After a few minutes, their functions will become intuitive, and you won't have to refer to this description.

Working with annotations

Every study may have voice annotations and text annotations. While you are looking at images, you can view text annotations and you can listen to and record voice annotations at the Image Review Station. Text annotations are usually recorded at the Patient Census Station.

Viewing text annotations

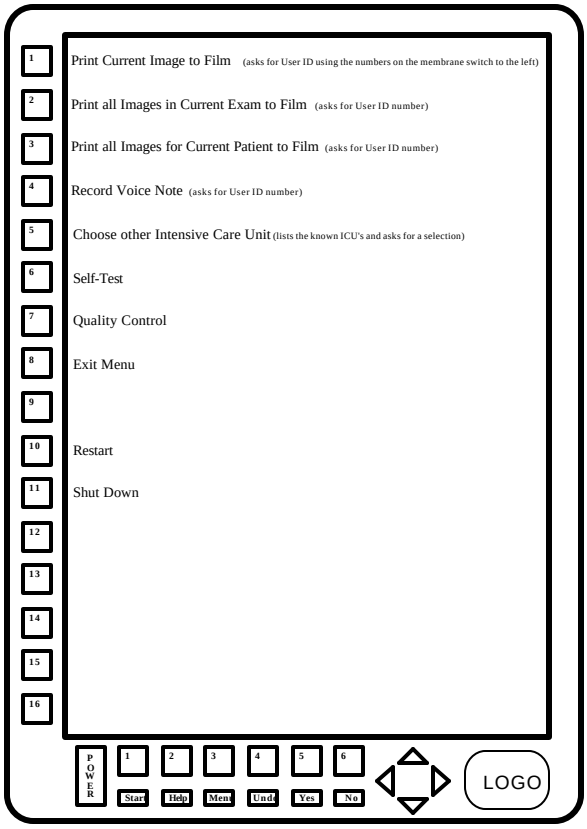
To view a text annotation, press the soft button labeled **Text Note**. A window that contains the text note will appear on the screen. $$HOW DO YOU GET RID OF IT? THE UNDO BUTTON!?!$$

Listening to voice annotations

To listen to a voice annotation, press the soft button labeled **Voice Note**. The voice annotation associated with this study plays through the Image Review Station's built-in speaker. $$CAN YOU STOP THE NOTE WHILE IT'S PLAYING? CAN YOU CONTROL THE VOLUME?$$

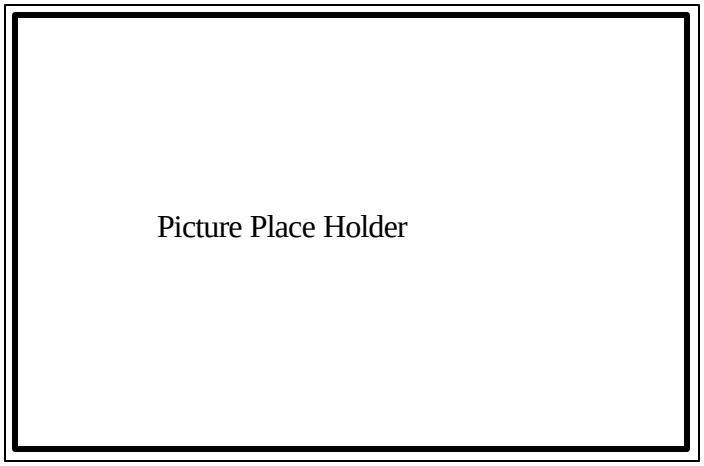
Recording voice annotations

To record a voice annotation, press the button labeled Menu in the bottom row of buttons on the lower keypad. The image will be replaced with a list of several choices. Press the button next to the choice labeled **Record Voice Note**.



Menu

The Image Review Station will ask you for your ID number. Use the buttons on the left edge of the screen to enter your number.



Asking for ID

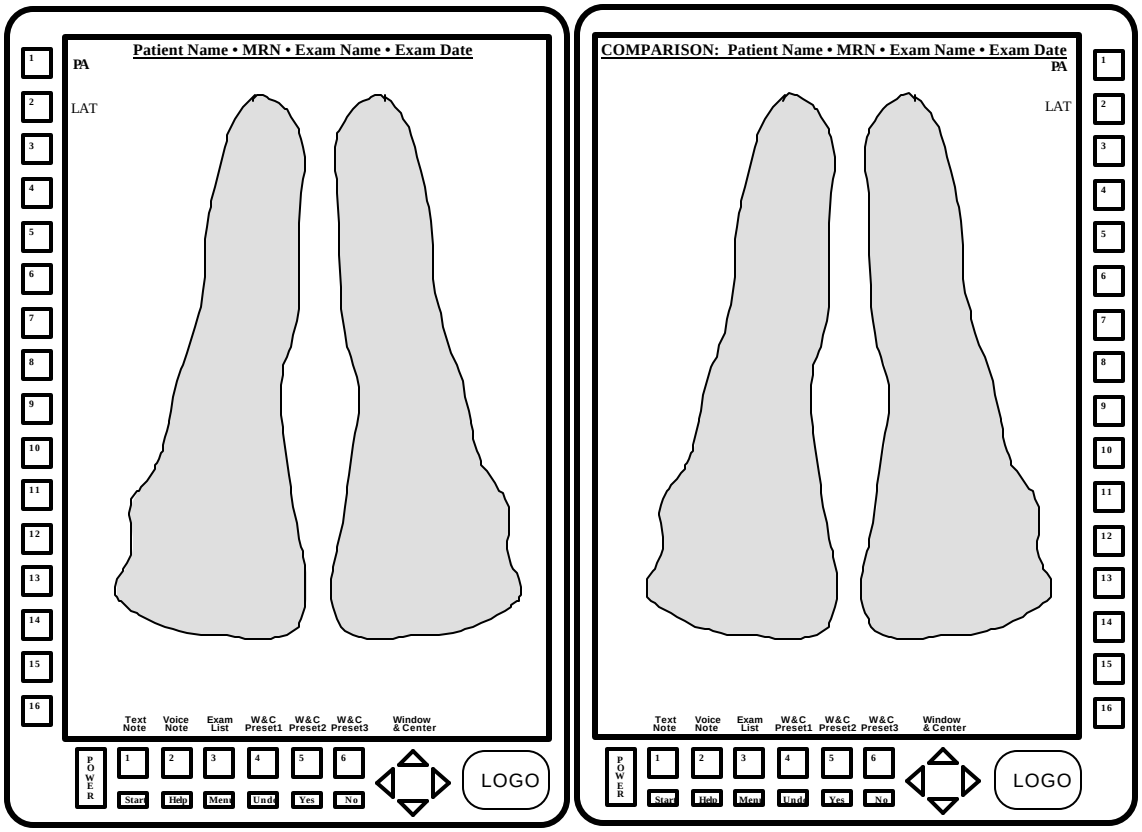
If a voice note already exists for this study, Image Review Station will ask you if you want to replace the existing note. Use the **Yes** and **No** buttons at the bottom of the screen to answer.

$$HOW DO YOU START? HOW DO YOU STOP?$$

Comparing images

On a two monitor Image Review Station, the right monitor usually displays additional images in the study. But you can use that monitor to display images from a different study so you can compare them. For instance, you can compare yesterday's image with today's image to see how treatment is progressing. $$I MADE THIS SENTENCE UP. CAN WE GET A DOCTOR TO DO SOME DOCTOR TALK?$$

While you are looking at an image, press the soft button labeled **Comparison Study** on the right monitor. You will see a study list for the current patient appear on the right monitor. Use the buttons to the right of the list. $$IS THE CURRENT STUDY EXCLUDED FROM THE LIST OR SHOULD I WARN THEM NOT TO COMPARE TO THE CURRENT STUDY?$$



Comparing images

Once you choose a study, you'll see the first image in that study. This display is just like the one on the left monitor, but in addition to the patient name, patient medical record number, study name, and study date, you'll also see the word COMPARISON on the top of the screen so you know you're looking at images from two different studies.

All the images in the comparison study appear in the list to the right of the screen. To display one of those images, press the button next to the image name.

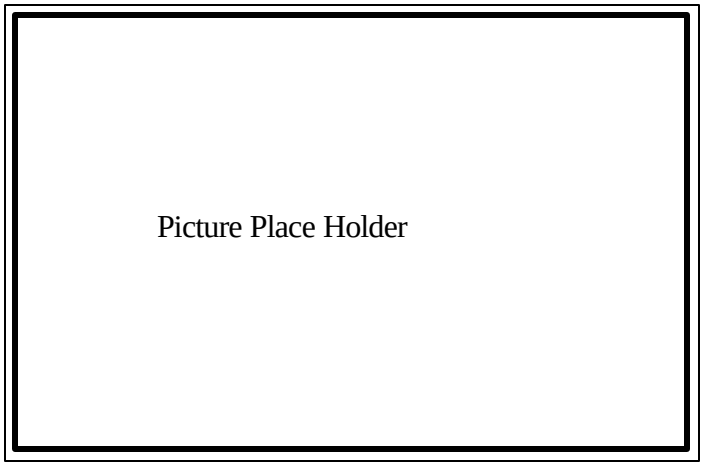
$$HOW DO YOU GET OUT OF COMPARE MODE?$$

Printing Images

You can print the current image, all the images for the current study, and all the images for the current patient from the Image Review Station. Your print request goes to the ICU Mini-PACS laser images where the images will be printed on film.

To print an image, press the **Menu** button on the bottom row of buttons at the bottom of the screen. You will see a list of commands. Some of these commands let you print the current image, all the images in the current study, and all the images for the current patient. Press the button next to the option you want.

The Image Review Station will ask you for your ID number. Use the buttons on the left edge of the screen to enter your number.



Asking for ID

After you enter your ID number, the Image Review Station displays a message asking you to confirm your print request. Use the **Yes** and **No** buttons to answer. $$I MADE THIS UP$$

Choosing a Different ICU

Usually, you will be looking at studies for patients in a particular ICU. You can choose the ICU that you want to pick patient studies from. To choose another ICU, press the **Menu** button in the bottom row of buttons at the bottom of the screen. You will see a list of commands. Press the button next to the Choose Other Intensive Care Unit.

The list of commands changes to a list of intensive care units. Press the button next to ICU that you want to see. The display will show the patient list for the ICU you just chose.

Troubleshooting

This section gives you tips on how to deal with some questions you might have as you use your Image Review Station.

ICU Mini-PACS

Patient Census Station Manual

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Welcome
1

Welcome to the ICU Mini-PACS, an electronic imaging system makes radiographic images available to ICU physicians and to radiologists at the same time. Radiographic images start in radiology, where they are digitized and stored in the ICU Mini-PACS system. These digitized images are immediately available in both the radiology department an in the ICU.

This manual shows you how to use the Patient Census Station. The Patient Census Station lets you keep track of radiological images for patients in an intensive care unit. This manual will show you how to add new patients to the ICU Mini-PACS system, how to add annotations to studies, how to print images, and how to discharge patients from the system.

Do you need to read this chapter?

You should read this chapter if you have never worked with ICU Mini-PACS before. This chapter gives you an overview of the ICU Mini-PACS system and tells you where the Patient Census Station fits into the whole system. You'll learn where images are stored, how they got there, and how to keep track of them with the Patient Census Station.

You'll also learn essential terms and concepts that ICU Mini-PACS uses to store images. Understanding these concepts will make it easy for you to find the images you want to display quickly.

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.

Topics covered in this chapter

- What is the Patient Census Station
- What is ICU Mini-PACS?
- How ICU Mini-PACS Stores Information

What is the Patient Census Station

The Patient Census Station lets you manage patients in the ICU Mini-PACS system. You can use the Patient Census Station to see which ICU a particular patient is in, to see whether the last study entered into the ICU Mini-PACS system has been read, to make annotations on a particular study. The Patient Census Station is the main control center for the ICU Mini-PACS.

What is ICU Mini-PACS?

The ICU Mini-PACS system is a computer system that makes it easier for Intensive Care Units and radiology departments to work together. One of the problems that the system solves is the ICU physician's requirement that radiographic images be available in the ICU at all times and the radiologist's requirement to do radiographic interpretation in the radiology department. Usually, the radiologist has to travel to the ICU to interpret films, which is not the best use of a radiologist's skill and time. Another problem is that in many hospitals, the film is processed in the radiology department, which means that the film needs to be removed from the ICU.

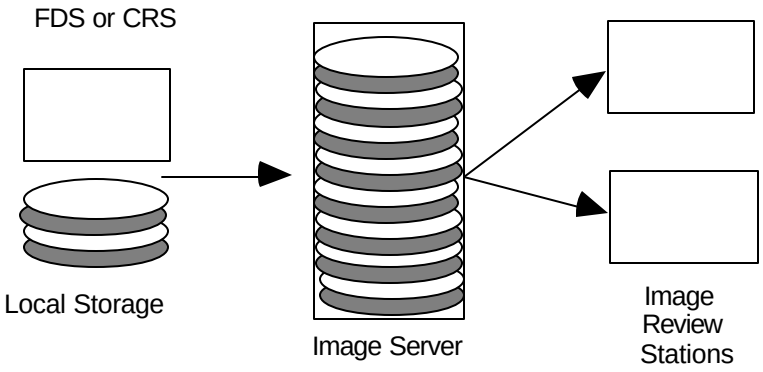
The ICU Mini-PACS system solves these problems. A complete ICU Mini-PACS system has several components, called stations, each with a specific function:

Station	Function
Film Digitizer Station	Scans radiographic films into the system.
Computed Radiography Station	Scans computed radiography images into the system.
Image Review Station	Used in the ICU or in the radiology department to view and annotate radiographic images.
Patient Census Station	Used in the ICU to maintain patient information, track patient location, annotate studies, and print images.

When the radiology department processes images, technicians use a Film Digitizer Station (FDS) or a Computed Radiography Station (CRS) to digitize the images into the ICU Mini-PACS system. 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 station sends the image to the image server over a high speed network. The display on the station lets the technician preview the images before sending them to make sure they were scanned correctly.

The images from the FDS or CRS are stored in the ICU Mini-PACS Image Server. 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 Image Review Station linked to the image server can access any of the images stored there. The image server also holds patient information and voice and text annotations for the images.

When you scan an image, the FDS or CRS stores it temporarily in its local storage. When you finish scanning images, the scanning station sends them to the image server. Once the images are there, they're available for viewing at an image review.



How ICU Mini-PACS stores information

The Image Review Station is where a radiologist examines the images stored in the image server. The radiologist requests images from the image server for a particular patient. The image server transmits the selected images to the workstation where they're displayed on a large high-resolution or medium resolution gray-scale monitor. The monitor shows images at 200 pixels per inch, and each pixel can be one of 256 shades of gray, from completely black to completely white. On Image Review Stations with two monitors can display two images for comparison. A special control in the workstation lets the radiologist adjust the brightness and contrast of the image display.

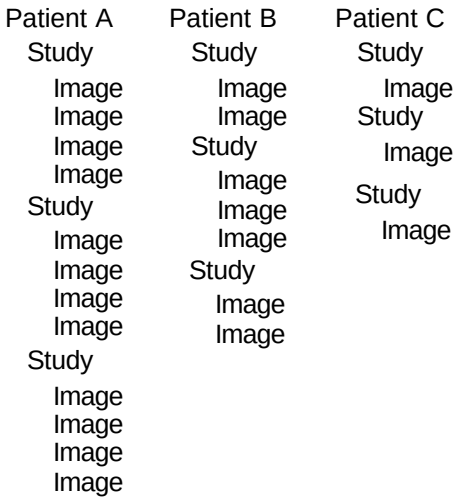
The Patient Census Station located in the ICU lets nurses maintain patient information, keep track of patients and any radiographic studies. Images can be printed to a Laser Imager from the Patient Census Station.

How ICU Mini-PACS Stores 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. ICU Mini-PACS organizes images into studies. No matter what kind of ICU Mini-PACS station you use, you should know how the system organizes images, so you can get at them quickly.

Every image in the ICU Mini-PACS system belongs to a particular patient. The ICU Mini-PACS system stores standard demographic information about a patient as well as the patient's clinical history. This patient information can be entered when the first image for the patient in scanned into the system, or it can be entered or modified at a Patience Census Station.

Every patient has at least one study that contains one or more images. Some studies contain only one image, and other studies contain several images. Every study can have text annotations or voice annotations. In the ICU, there may be a new study for a patient every day. Usually, you can see images from only one study at a time. On Image Review Stations with two monitors, you can compare images from two different studies.



How ICU Mini-PACS organizes images

Understanding how ICU Mini-PACS stores images will make it easier and faster for you to get to the information you need.

Using the Patient Census Station 2

This chapter shows you how to use the ICU Mini-PACS Patient Census Station. You'll learn how to enroll new patients into the ICU Mini-PACS, how to modify their demographic information, how to add annotations, how to print images, and how to discharge them from the system.

What you should know

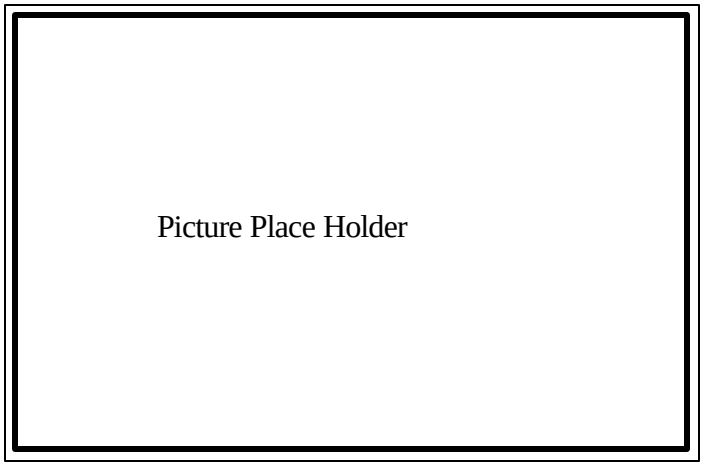
You should be familiar with the way ICU Mini-PACS stores information in patient studies. If you need to find out how this works, read "How ICU Mini-PACS Stores Information" in Chapter 1.

Topics covered in this chapter

- About the Patient Census Station
- Adding a new patient
- Changing patient information
- Changing the patient location
- Changing study information
- Annotating information
- Printing images
- Discharging patients
- Troubleshooting

About the Patient Census Station

The Patient Census Station consists of a Macintosh computer with a black and white monitor.



Patient Census Station

Turning the Patient Census Station on

To turn the Patient Census Station on, press the power button on the keyboard. This is a button on the top right of the keyboard with a triangle etched in it. You will hear a chime, and you will see a box that says “Welcome to Macintosh” on the screen.

After a few seconds, the Patient Census Station software starts up, and you are ready to use the Patient Census Station.

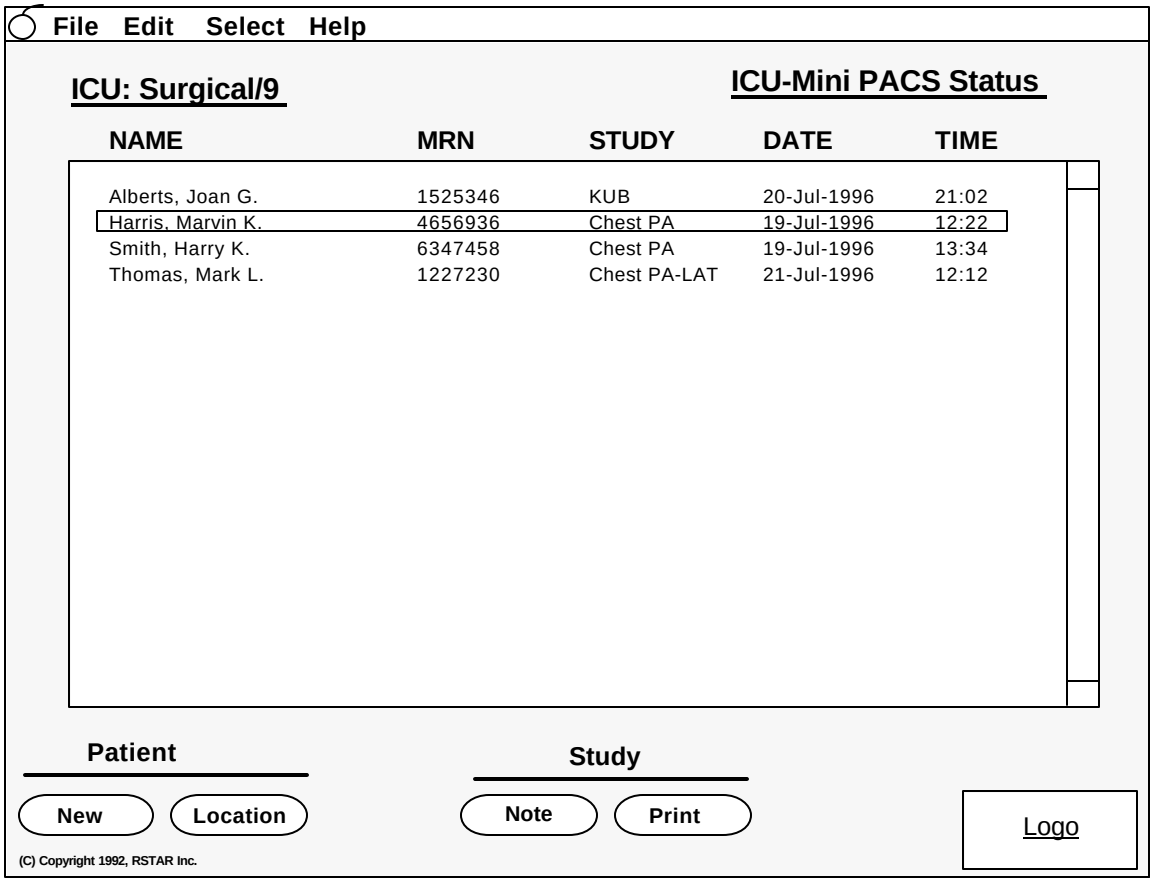
Turning the Patient Census Station off

To turn the Patient Census Station off, choose the Quit command from the File menu. After the Patient Census Station software quits, you will see the Finder menu bar. Choose the **Shut Down** command from the Special menu.

Note: If you don’t see the **Shut Down** command in the **Special** menu, you probably didn’t choose the **Quit** command from the **File** menu.

The Patient Census Station Application

When you start the Patient Census Station, the first thing you see is the patient status window. The patient status window is the main control for performing most of the tasks at the Patient Census Station.



The patient status window

This window shows you a list of all the patients in the current ICU. The list shows the patient name and the date of the last study. If a radiologist has not viewed the study on an Image Review Station, the date of the study appears highlighted. If there are more patient names than fit in the window, you can use the scroll bars on the right side of the window.

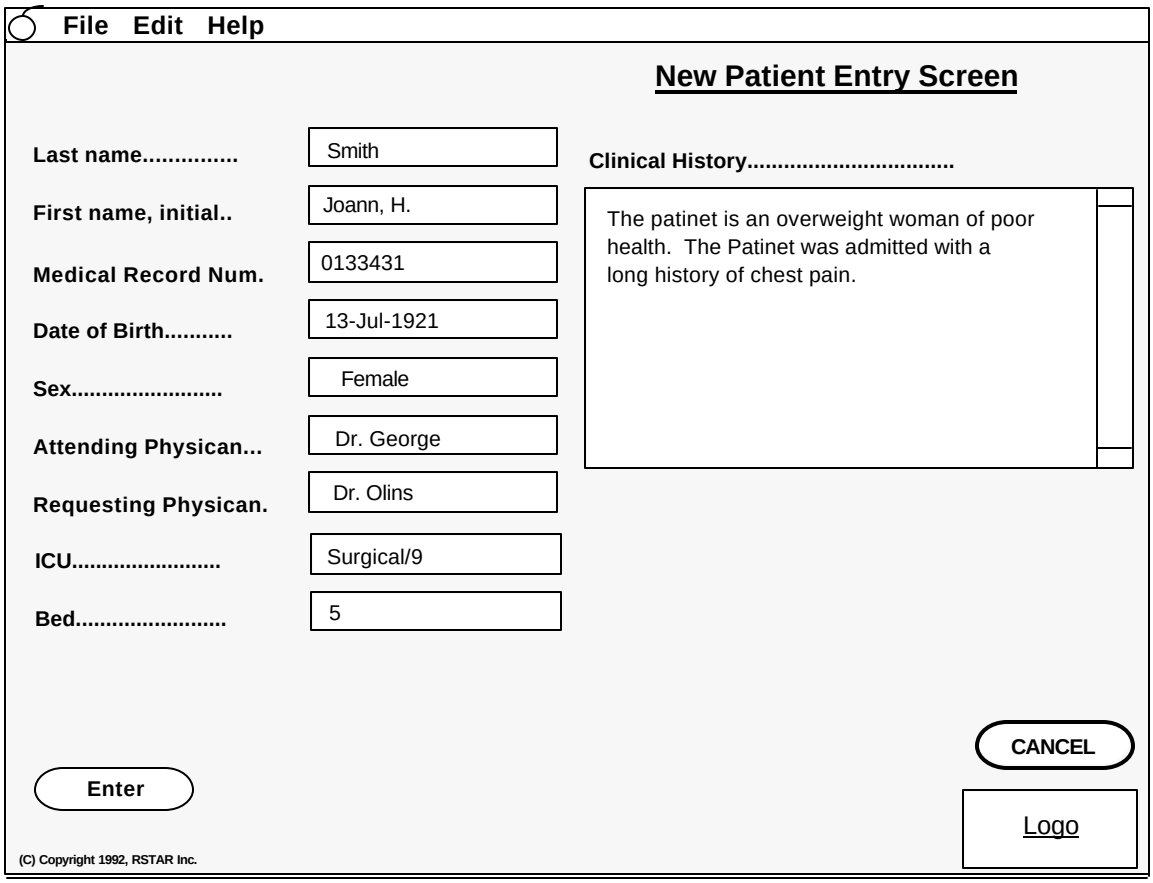
The buttons at the bottom of the window let you perform most of the Patient Census Station tasks. The menus at the top of the screen let you perform other tasks.

Menu	Function
Apple	The standard Macintosh Apple menu, not generally used with the Patient Census Station
File	Contains the Quit command
Edit	Used for editing text, patient information, and study information Contains Undo, Cut, Copy, Paste, and Clear commands as well as commands to edit patient information and study information
Select	Contains commands to select all the items in a list and to choose specific ICUs

The name of the current ICU appears in the upper left part of the patient status window. To display a list of patients in another ICU, choose the ICU name from the **Select** menu. To see all the patients in all the ICUs, choose **All** from the **Select** menu.

Adding a New Patient

To add a new patient to the ICU Mini-PACS system, click on the **New** button at the bottom of the patient status window. You will see a new patient window that looks like this.



The new patient window

Fill in the fields for the patient demographic information and location. Some of the fields, the patient name, sex, date of birth, medical record number, ICU, and bed are required. The others are optional.

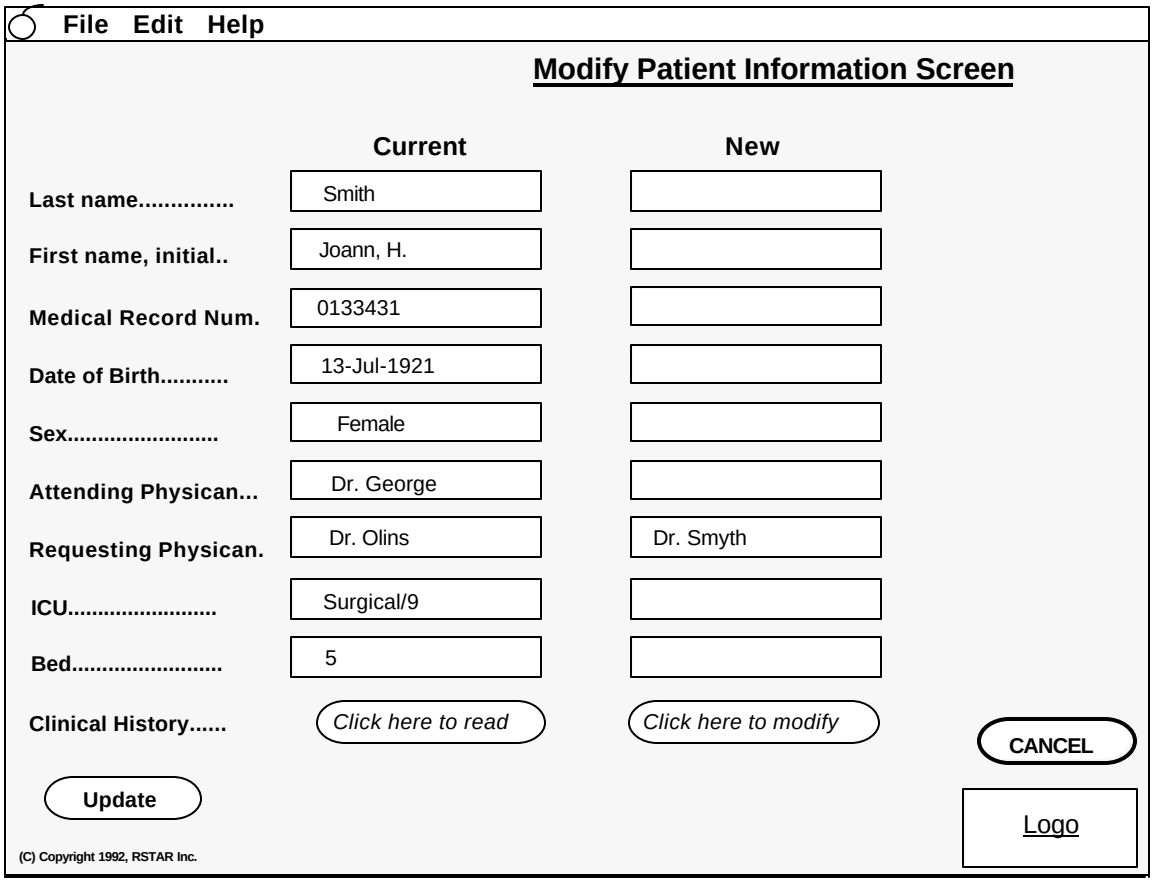
> **Note:** The sex, ICU and Bed fields are pop-up menus. Click the mouse in one of those fields and you will see a list that you can choose from.

Use the large field on the right of the window to type in the patient's clinical history.

When you have entered all the information, click on the **Enter** button. If you forgot to type information for a required field, the Patient Census Station will ask you to fill it in. If you decide that you do not want to enter the patient into the ICU Mini-PACS system, click on the **Cancel** button. After you click on either the **Enter** or **Cancel** button, you will be back at the patient status window.

Changing Patient Information

If you need to change information about a patient, click on the patient name in the patient status window. Then choose the **Patient Info** command from the **Edit** to change information about the patient. You will see a window that looks like this.



Modify patient information window

The information is organized into two columns. In the left column, you'll see the current information. You can type changes in the fields in the right column.

> **Note:** You cannot change the ICU and bed location in this screen. To do that, use the **Location** button described below.

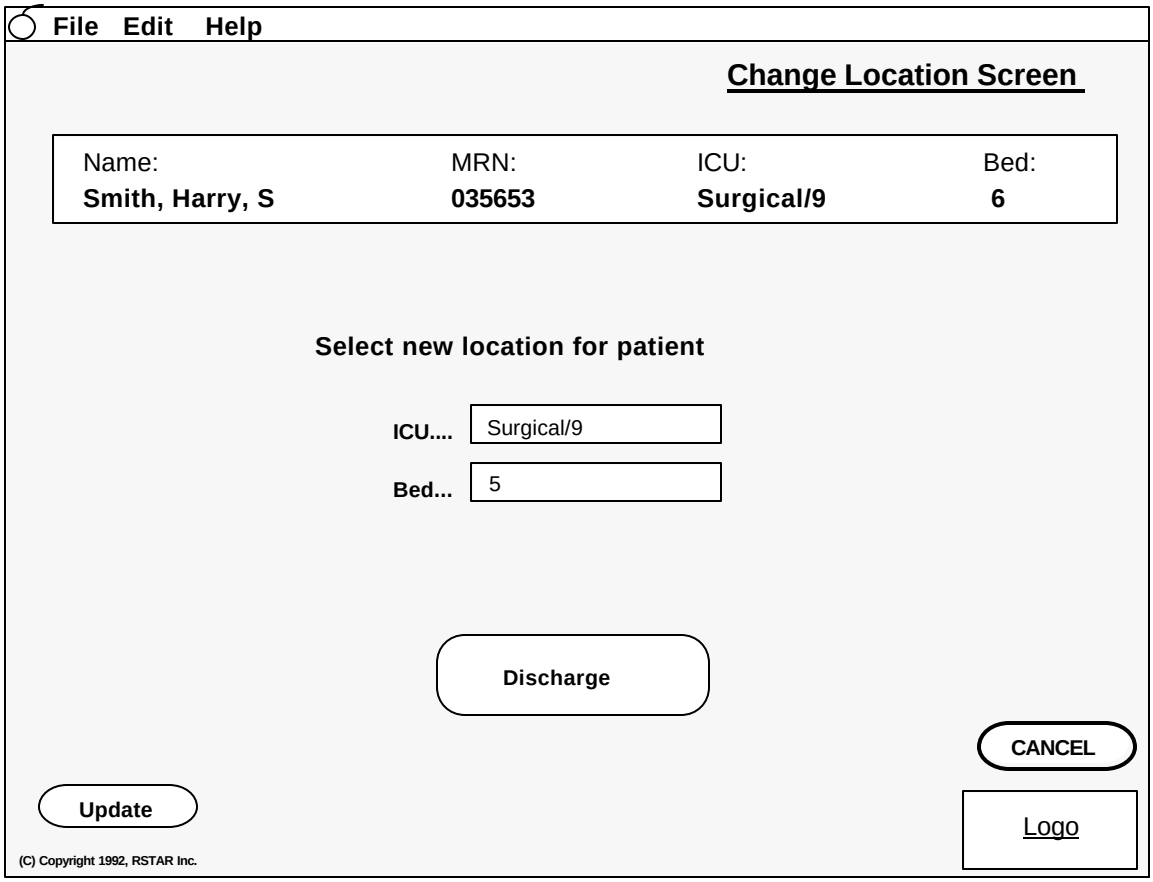
Click on the buttons at the bottom of each column to read and to modify the clinical history.

If you are satisfied with the changes you have made, click on the **Update** button. If you change your mind and decide not to make changes, click on the **Cancel** button. After you click on either button, you will be back at the patient status window.

Changing the Patient Location

If the patient is moved to a different ICU or to a different bed, use the **Location** button at the bottom of the patient status window to let the ICU Mini-PACS know about the change.

To change a patient location click on a patient name in the patient status window, then click on the **Location** button. You will see a window that looks like this:



Change location window

The patient name, medical record number, and current location appear at the top of the window. To change the ICU or bed, click on the pop-up menus in the middle of this window. When you click on one of these fields, you will see a list of options that you can choose from.

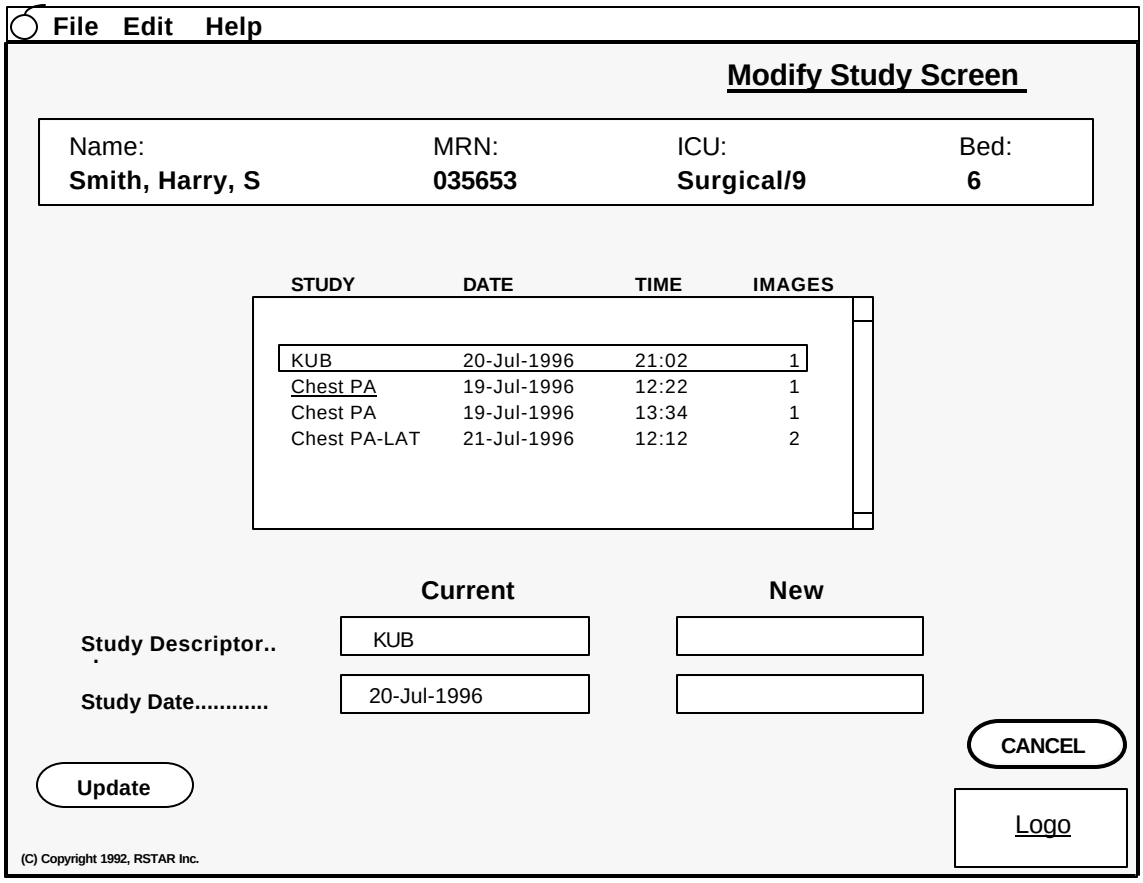
If the patient is being discharged, click on the **Discharge** button. When you discharge a patient, you will have several options. Be sure to read the section "Discharging a Patient" for more information about discharging patients.

If you are satisfied with the changes you have made, click on the **Update** button. If you change your mind and decide not to make changes, click on the **Cancel** button. After you click on either button, you will be back at the patient status window.

Changing Study Information

From time to time, you may want to change information about a particular study. To do that, choose the patient name from the patient list in the patient status window, then choose the **Study Info** command from the **Edit** menu.

You will see a Modify Study window that looks like this:



Modify study window

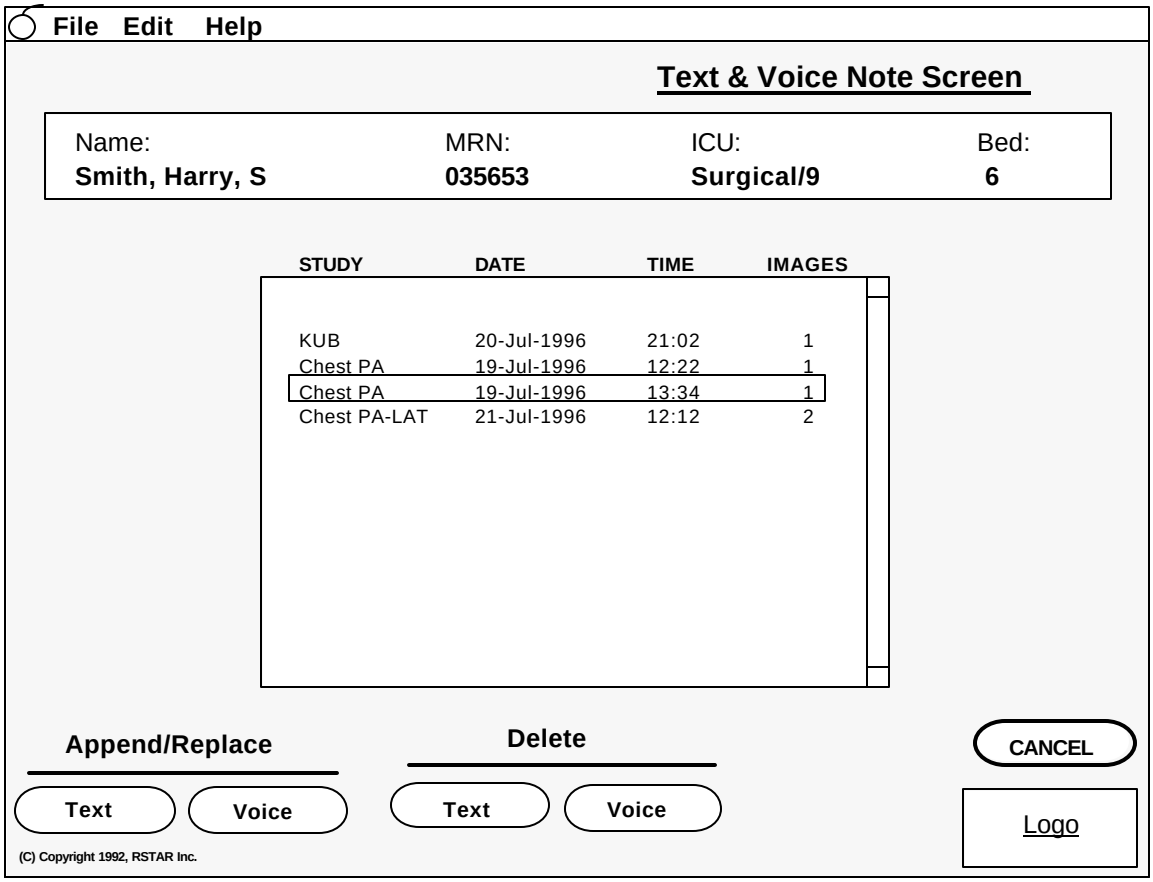
The patient name, medical record number and location appear at the top of the screen. The list in the middle of the window contains a list of all the studies for that patient. The list gives the study descriptor, the date and time, and the number of images in the study.

You can change the study descriptor and the study date in this window. To do that, click on the study that you want to change. The current study descriptor and study date appear in the left column. You make the changes in the right column.

Note: The study descriptor field is a pop-up menu. Click the mouse on this field to see a list of study descriptor that you can choose from.

Annotating Studies

The Patient Census Station lets you add text or voice annotations to any study. To add either kind of note, click on a patient name to select a patient from the patient status window. Then click on the **Note** command at the bottom of the patient status window. You will see a Text & Voice Note window like this:



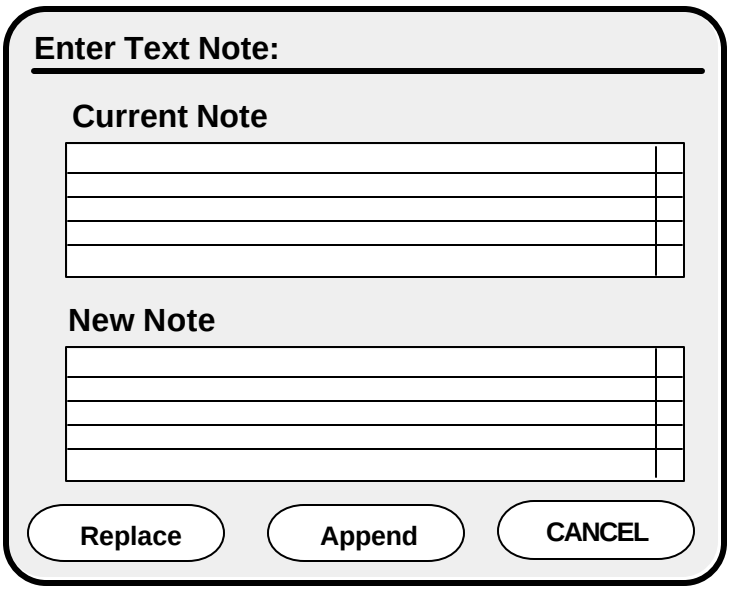
Text & Voice Note Window

The patient name, medical record number and location appear at the top of the screen. The list in the middle of the window contains a list of all the studies for that patient. The list gives the study descriptor, the date and time, and the number of images in the study. You will use this study list to choose the study that you want to work with as you add or delete notes.

The buttons at the bottom of this window let append / replace notes and delete notes. If you decide that you don't want to add, replace, or delete notes, click on the **Cancel** button to go back to the Patient Status Window.

Making text notes

To add or replace a text note, click on the study that you want to work with. Then click on the **Append/Replace Text** button. You will see a window that shows you the current note and gives you a place to type in your new note.



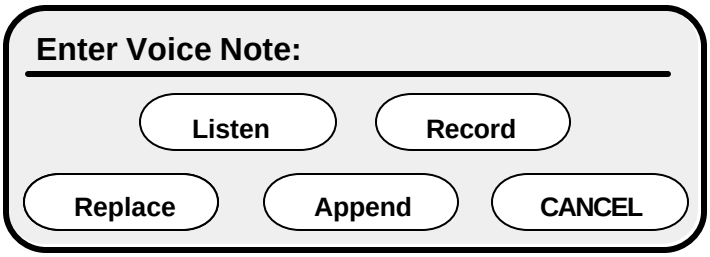
Text Note Window

Type in your new note in the New Note field. When you are done, click on one of the buttons:

Button	Function
Replace	Replaces the current note with the new note. The old note is no longer available.
Append	Appends the new note to the current note.
Cancel	Does not change the note. You will be back at the Text & Voice Note window.

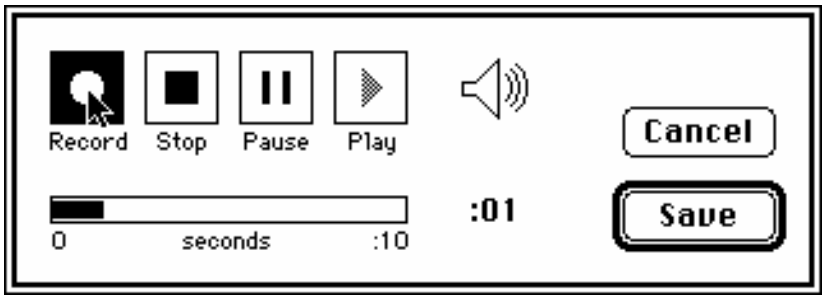
Making voice notes

To add or replace a voice note, click on the study that you want to add or replace the note to. Then click on the **Append/Replace Voice** button. You will see a window that lets you control the recording.



Enter Voice Note controls

If there is a voice note already associated with this study, click on the **Listen** button to hear it. To record a voice annotation, click on the **Record** button. You will see the standard Macintosh recording dialog:



Standard Macintosh recording dialog

To start recording, click on the **Record** button, and speak clearly into the microphone. The black bar and the counter show you how much time you have left to record. To stop recording click on the **Stop** button. To hear what you've recorded, click on the **Play** button. Use the **Pause** button to pause during playing or recording. If you're satisfied with the note you have recorded, click on the **Save** button. If you change your mind about recording a voice note, click on the **Cancel** button.

When you are finished recording, click on one of these buttons:

Button	Function
Replace	Replaces any existing voice note with the voice note you just recorded.
Append	Appends the new voice note to the current note.
Cancel	Does not change the voice note. You will be back at the Text & Voice Note window.

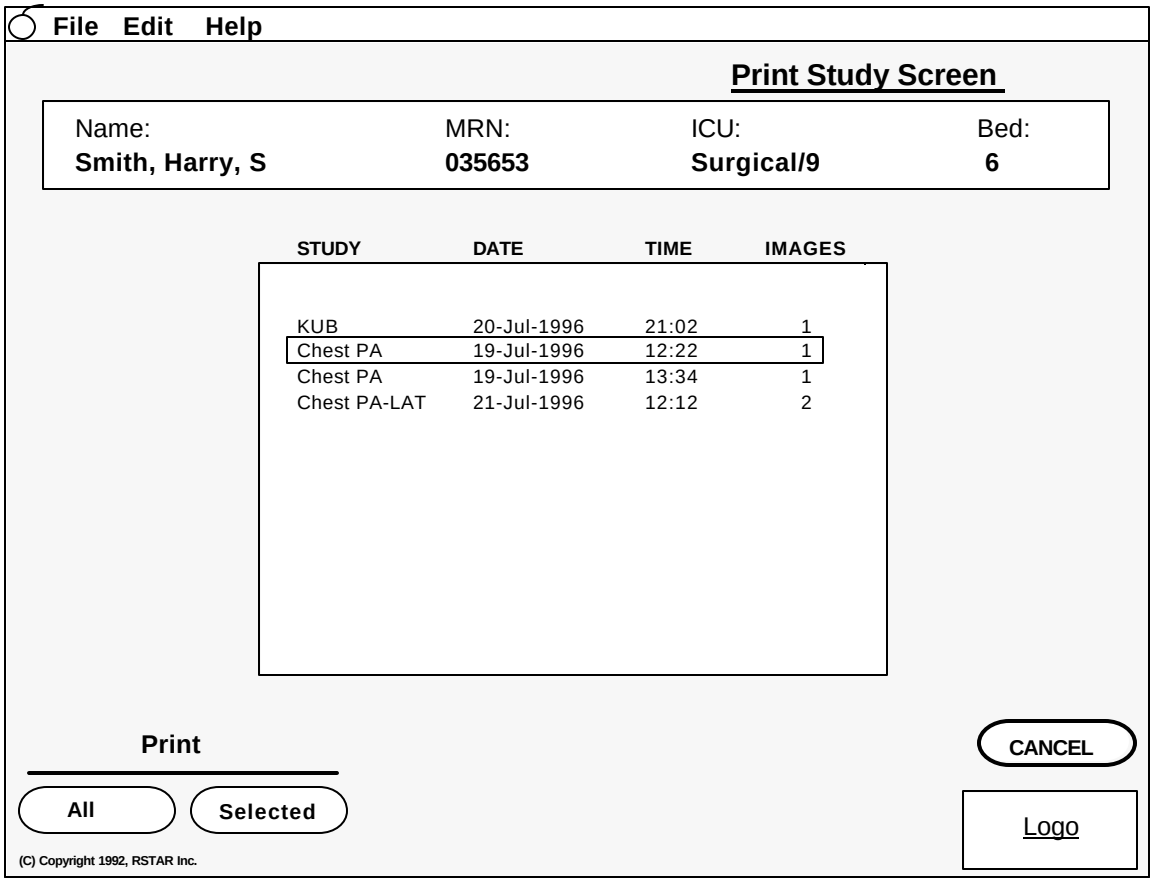
Deleting notes

To delete a note, click on the study that you want to delete the note from. Then click on the **Delete Text** button to delete the text note associated with that study, or click on the **Delete Voice** button to delete the voice note associated with that study. When you click on either of these buttons, the Patient Census Station will ask you to make sure that you really want to delete the note.

Printing Images

You can use the Patient Census Station to print all the images for a patient or all the images in a particular study. Any time you print images, the ICU Mini-PACS system asks you for an ID number. This ID number helps your institution keep track of costs.

To print an image, click on a patient name to select a patient from the patient status window. Then click on the **Print** command at the bottom of the patient status window. You will see a Printing Window like this:



Print Study Window

The patient name, medical record number and location appear at the top of the screen. The list in the middle of the window contains a list of all the studies for that patient. The list gives the study descriptor, the date and time, and the number of images in the study. You will use this study list to choose the study that you want to print.

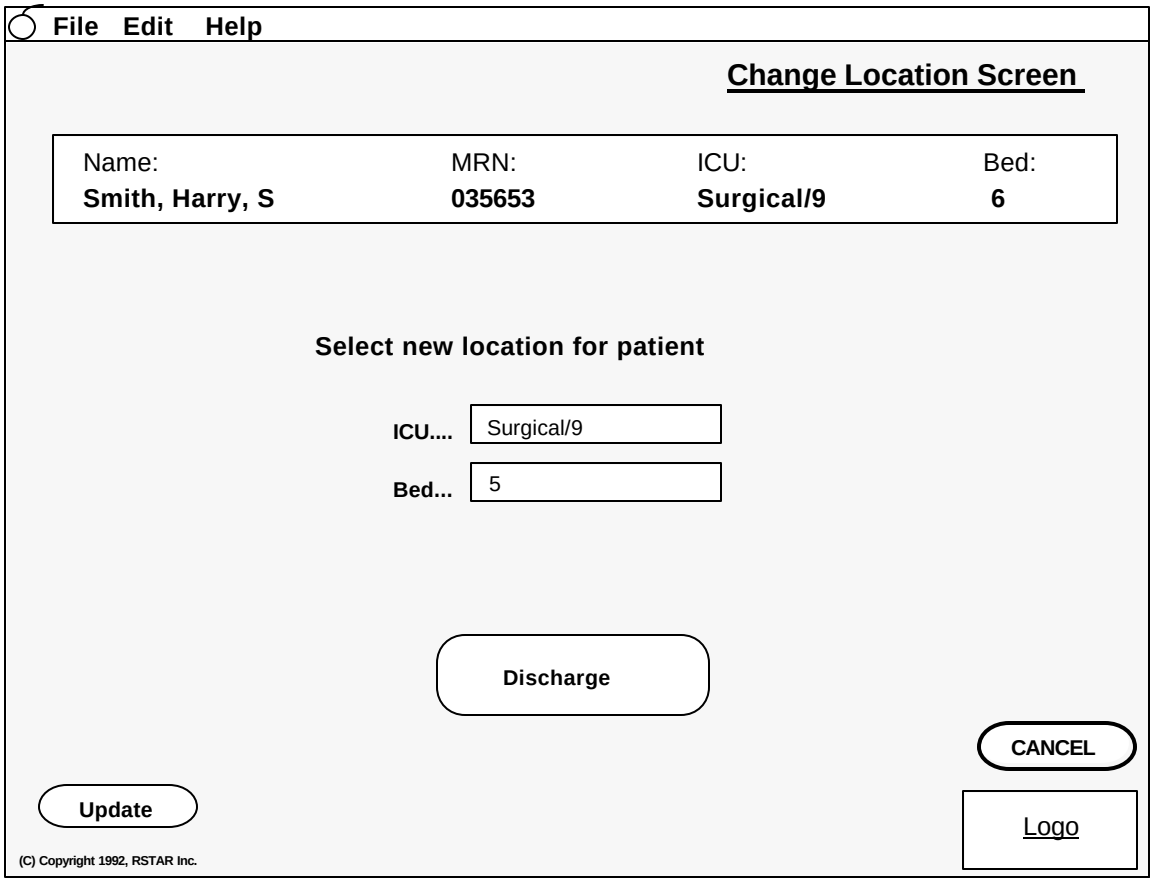
To print all the images for this patient, click on the **Print All** button. The Patient Census Station will ask you if you're sure you want to print all the images in all the studies for this patient.

To print the images for a particular study, click on the study in the studies list. To select more than one study, hold down the Shift key $$YES?$$ as you click on additional studies. Then click on the **Print Selected** button to print the images in these studies.

If you change your mind about printing, click on the Cancel button to go back to the Patient Status Window.

Discharging Patients

When a patient leaves the ICU, and you want to remove the patient from the ICU Mini-PACS, you can discharge the patient from the system. To discharge a patient, click on the patient name in the patient status window, then click on the **Location** button. You will see a window that looks like this:



Change location window

Click on the **Discharge** button to discharge the patient. When you click on this button, the Patient Census Station asks you if you are sure that you want to discharge this patient. If you answer No, you will go back to the Change Location Window. If you click yes, the Patient Census Station asks you if you want to print all the images for that patient.

Important: Be sure that you really mean to discharge a patient. Once a patient is discharged, ICU Mini-PACS removes the patient's records from the system.

Troubleshooting

This section gives you tips on how to deal with some questions you might have as you use your Patient Census Station.

ICU Mini-PACS

Film Digitizer /
Computed Radiography
Station Manual

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Welcome
1

Welcome to the ICU Mini-PACS, an electronic imaging system makes radiographic images available to ICU physicians and to radiologists at the same time. Radiographic images start in radiology, where they are digitized and stored in the ICU Mini-PACS system. These digitized images are immediately available in both the radiology department an in the ICU.

This manual shows you how to use the Film Digitizer Station (FDS) and the Computed Radiography Station (CRS). Both of these stations let you store radiological images in the ICU Mini-PACS system. The Film Digitizer Station scans images from film, and the Computed Radiography Station gets its images from a CR unit.

Do you need to read this chapter?

You should read this chapter if you have never worked with ICU Mini-PACS before. This chapter gives you an overview of the ICU Mini-PACS system and tells you where the Film Digitizer Station and the Computed Radiography Station fits into the whole system. You'll learn how to acquire images, how to store them in patient studies, and how to enter patient demographics..

You'll also learn essential terms and concepts that ICU Mini-PACS uses to store images. Understanding these concepts will make it easy for you to find the images you want to display quickly.

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.

Topics covered in this chapter

- What are the Film Digitizer and Computed Radiography Stations
- What is ICU Mini-PACS?
- How ICU Mini-PACS Stores Images

What are the Film Digitizer and Computed Radiography Stations

The Film Digitizer Station and the Computed Radiography Station store images into the ICU Mini-PACS system. Your system may have up to two Film Digitizer Stations, or two Computed Radiography Stations, or one of each. Both kinds of stations work the same way. The only difference is that in the Film Digitizer Station, the images start out on film, and on the Computed Radiography Station, the images start out on a CR unit.

What is ICU Mini-PACS?

The ICU Mini-PACS system is a computer system that makes it easier for Intensive Care Units and radiology departments to work together. One of the problems that the system solves is the ICU physician's requirement that radiographic images be available in the ICU at all times and the radiologist's requirement to do radiographic interpretation in the radiology department. Usually, the radiologist has to travel to the ICU to interpret films, which is not the best use of a radiologist's skill and time. Another problem is that in many hospitals, the film is processed in the radiology department, which means that the film needs to be removed from the ICU.

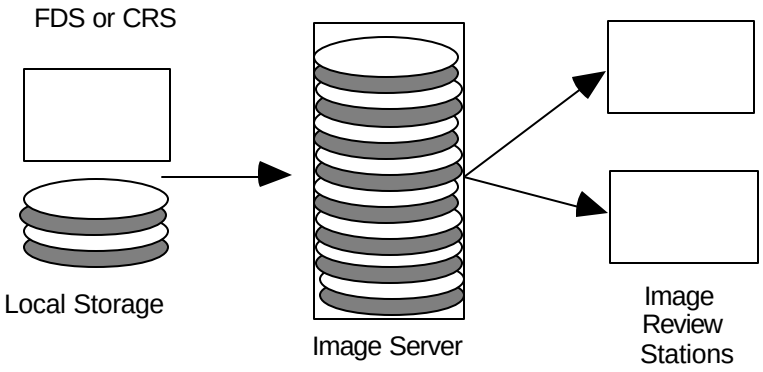
The ICU Mini-PACS system solves these problems. A complete ICU Mini-PACS system has several components, called stations, each with a specific function:

Station	Function
Film Digitizer Station	Scans radiographic films into the system.
Computed Radiography Station	Scans computed radiography images into the system.
Image Review Station	Used in the ICU or in the radiology department to view and annotate radiographic images.
Patient Census Station	Used in the ICU to maintain patient information, track patient location, annotate studies, and print images.

When the radiology department processes images, technicians use a Film Digitizer Station (FDS) or a Computed Radiography Station (CRS) to digitize the images into the ICU Mini-PACS system. 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 station sends the image to the image server over a high speed network. The display on the station lets the technician preview the images before sending them to make sure they were scanned correctly.

The images from the FDS or CRS are stored in the ICU Mini-PACS Image Server. 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 Image Review Station linked to the image server can access any of the images stored there. The image server also holds patient information and voice and text annotations for the images.

When you scan an image, the FDS or CRS stores it temporarily in its local storage. When you finish scanning images, the scanning station sends them to the image server. Once the images are there, they're available for viewing at an image review.



How ICU Mini-PACS stores information

The Image Review Station is where a radiologist examines the images stored in the image server. The radiologist requests images from the image server for a particular patient. The image server transmits the selected images to the workstation where they're displayed on a large high-resolution or medium resolution gray-scale monitor. The monitor shows images at 200 pixels per inch, and each pixel can be one of 256 shades of gray, from completely black to completely white. On Image Review Stations with two monitors can display two images for comparison. A special control in the workstation lets the radiologist adjust the brightness and contrast of the image display.

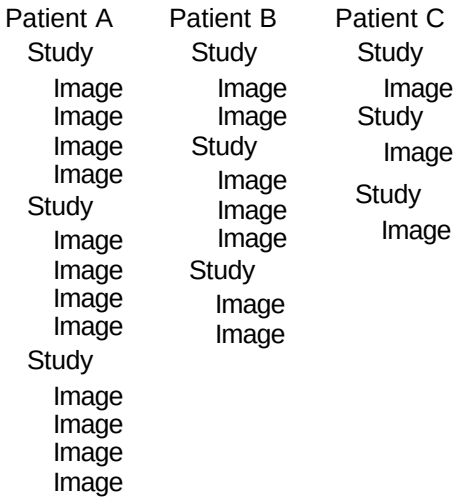
The Patient Census Station located in the ICU lets nurses maintain patient information, keep track of patients and any radiographic studies. Images can be printed to a Laser Imager from the Patient Census Station.

How ICU Mini-PACS Stores 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. ICU Mini-PACS organizes images into studies. No matter what kind of ICU Mini-PACS station you use, you should know how the system organizes images, so you can get at them quickly.

Every image in the ICU Mini-PACS system belongs to a particular patient. The ICU Mini-PACS system stores standard demographic information about a patient as well as the patient's clinical history. This patient information can be entered when the first image for the patient in scanned into the system, or it can be entered or modified at a Patience Census Station.

Every patient has at least one study that contains one or more images. Some studies contain only one image, and other studies contain several images. Every study can have text annotations or voice annotations. In the ICU, there may be a new study for a patient every day. Usually, you can see images from only one study at a time. On Image Review Stations with two monitors, you can compare images from two different studies.



How ICU Mini-PACS organizes images

Understanding how ICU Mini-PACS stores images will make it easier and faster for you to get to the information you need..

Using the Film Digitizer Station and the Computed Radiography Station 2

This chapter shows you how to use the ICU Mini-PACS Film Digitizer Station and the Computed Radiography Station. You'll learn how to store images into the ICU Mini-PACS, and how to enter patient information.

What you should know

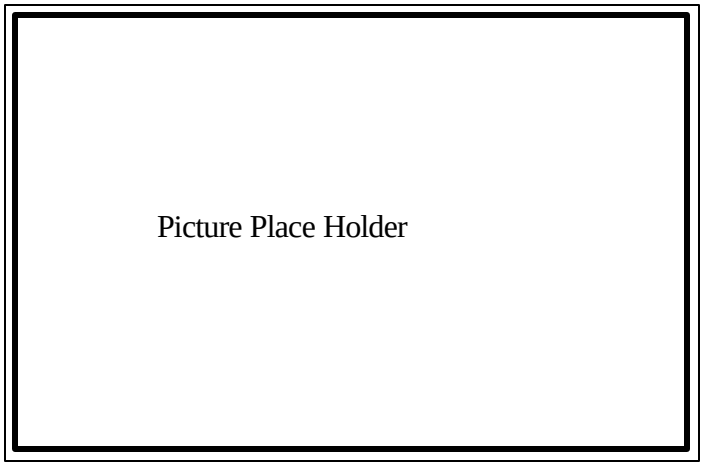
You should be familiar with the way ICU Mini-PACS stores information in patient studies. If you need to find out how this works, read "How ICU Mini-PACS Stores Information" in Chapter 1.

Topics covered in this chapter

- About the Film Digitizer Station and Computed Radiography Station
- Starting a New Study
- Digitizing Images
- Ending a Study
- Troubleshooting

About the Film Digitizer Station and Computed Radiography Station

The Film Digitizer Station and the Computed Radiography Station consist of a Macintosh computer with a gray scale monitor. The Film Digitizer Station acquires images through a Lumisys scanner, and the Computed Radiography Station acquires images through a Fuji AC1+CR unit.



FDS and CRS

Turning the stations on

To turn a station on, press the power button on the keyboard. This is a button on the top right of the keyboard with a triangle etched in it. You will hear a chime, and you will see a box that says "Welcome to Macintosh" on the screen.

After a few seconds, the software starts up, and you are ready to use the station.

$$HOW ABOUT TURNING THE SCANNERS ON?$$

Turning the stations off

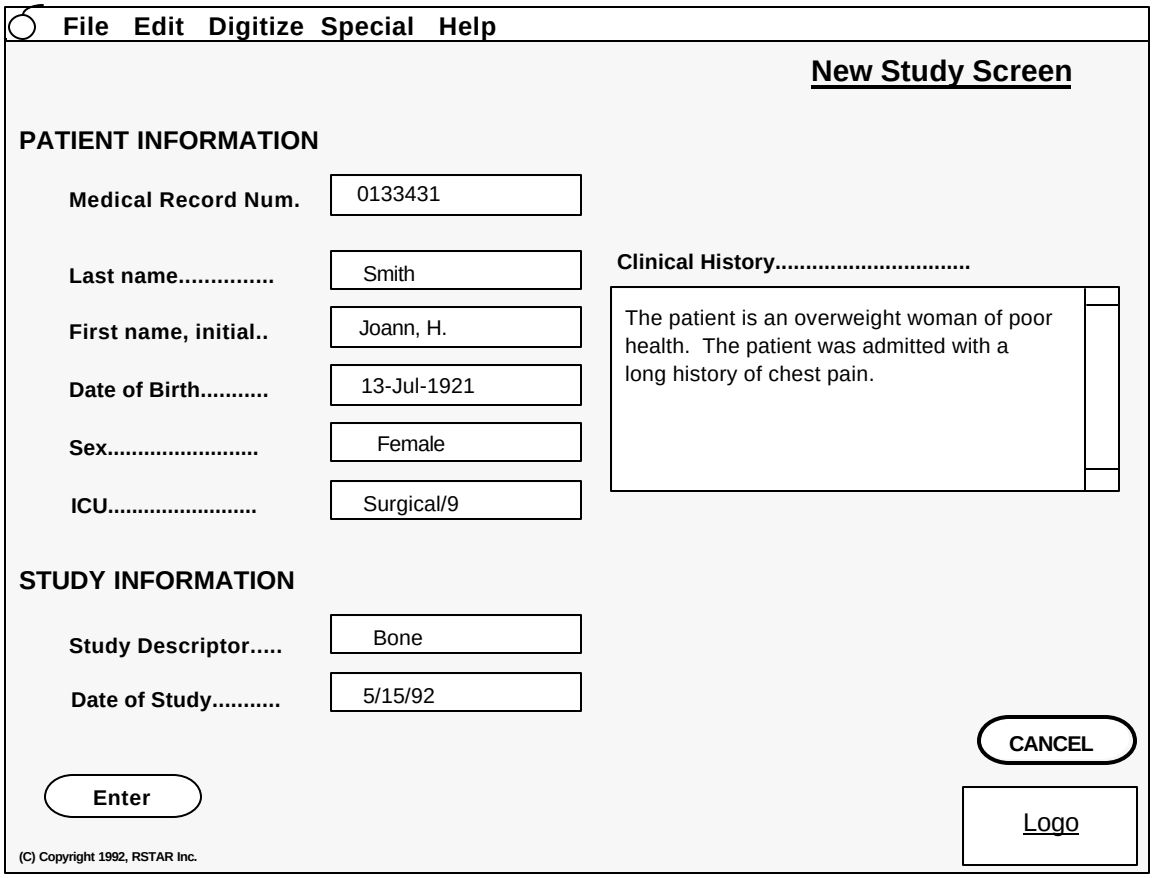
To turn the station off, choose the **Quit** command from the **File** menu. After the software quits, you will see the Finder menu bar. Choose the **Shut Down** command from the Special menu.

Note: If you don't see the **Shut Down** command in the **Special** menu, you probably didn't choose the **Quit** command from the **File** menu.

$$HOW ABOUT TURNING THE SCANNERS OFF?$$

The FDS and CRS Software

When you start either the Film Digitizer Station or the Computed Radiography Station, you will see the New Study window.



The new study window

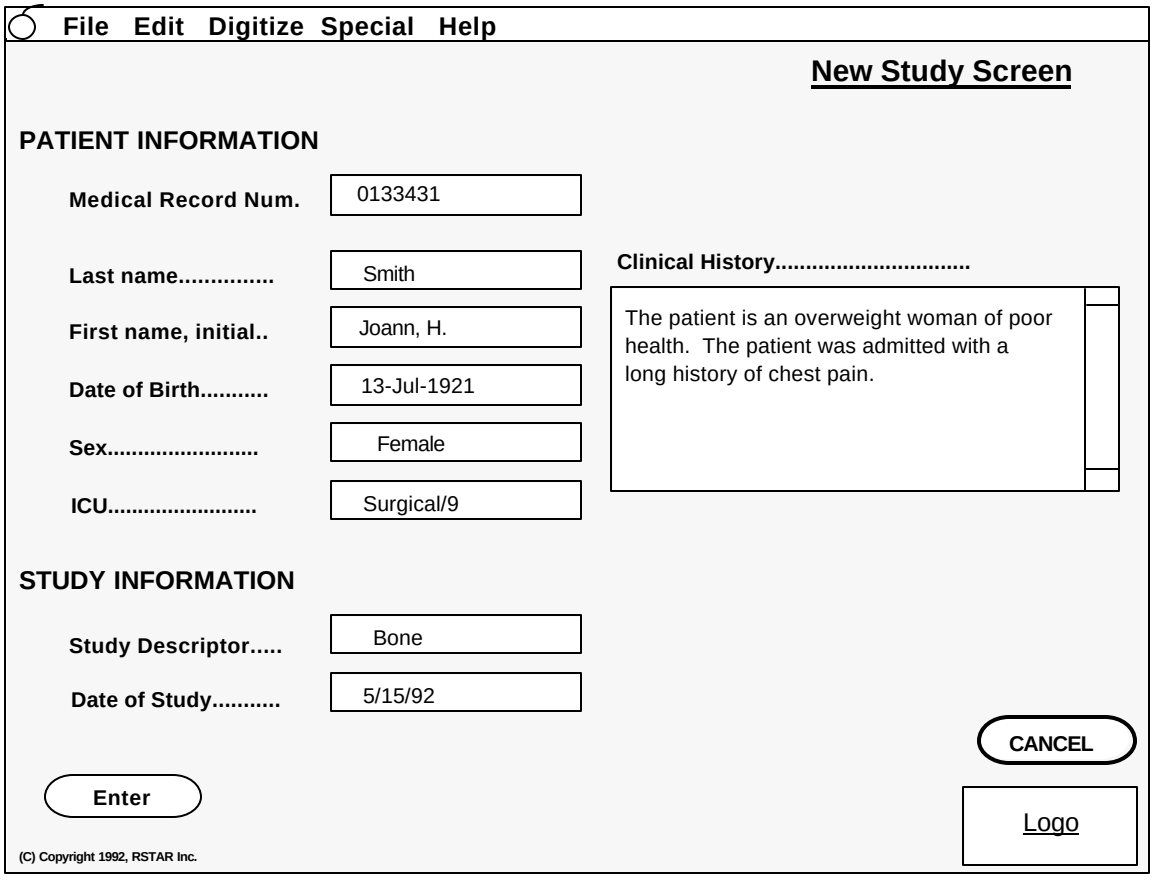
The New Study window has fields where you can type the patient information and information about the study. The section "Creating a New Study" tells you how to use this window to begin a new study.

Across the top of the screen, you will see a list of menus.

Menu	Function
Apple	The standard Macintosh Apple menu, not generally used in the FDS or CRS
File	Contains the Quit command
Edit	Used for editing text. Contains Undo, Cut, Copy, Paste, and Clear commands
Digitize	Contains commands to scan images. On FDS includes a command to eject film from the scanner.
Special	Contains commands to test and calibrate the scanners
Help	Contains commands that give you help about the FDS/CRS application

Starting a New Study

To start a new study, type the patient's medical record in the MRN field. If the patient information is already in the ICU Mini-PACS system, the patient's demographic information appears in the patient information fields. If the patient is a new patient, you should type the patient information now.



New study with patient information

Note: If the patient is already in the ICU Mini-PACS system, you will be able to see the patient information, but you cannot change the information. Once patient information is in the system, it can be only be changed on a Patient Census Station.

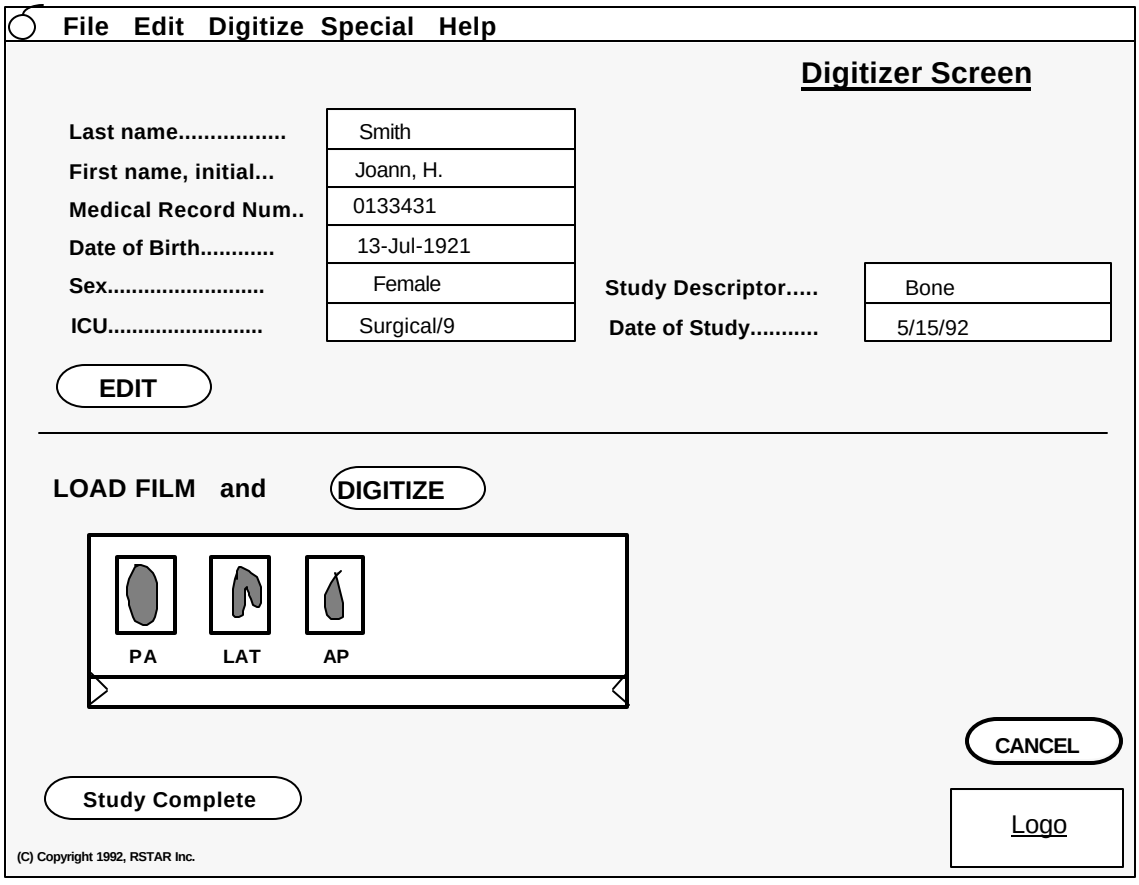
Next fill in the information about the study. The study descriptor is a pop-up menu that contains a list of common study types. If the type of study you are entering is not in the pop-up menu choose Other. A text entry box appears that lets you type in the name of the study. $$I MADE THIS PART UP$$ The date of the study should be the date that the image was taken.

When you have entered all the information, click on the **Enter** button. If you were entering information for a new patient, and you forgot to type information for a required field, the application will ask you to fill it in. When you click on the **Enter** button, you will go to the Digitizer Window described in the next section.

If you decide that you do not want to go ahead with the study, click on the **Cancel** button. When you click on the **Cancel** button, you return to the New Study window.

Digitizing Images

After you enter the study information, you will see a Digitizer Window that looks like this:



The Digitizer Window

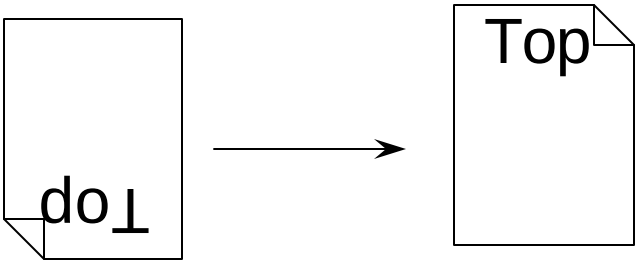
The top part of the Digitizer Window displays the patient information and the study information. If you need to edit the study information, click on the **Edit** button to go back to the New Study window temporarily. $$WHY NOT EDIT IN PLACE?$$

> **Note:** Remember that if the patient was already in the ICU Mini-PACS system when you started the study, you will only be able to edit the study information. If the patient was not in the system, and you entered the patient information, you will be able to edit it.

Now you are ready to load the film or the CR unit. $$HOW DO YOU LOAD THE CR UNIT$$

Digitizing film in the Film Digitizer Station

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.

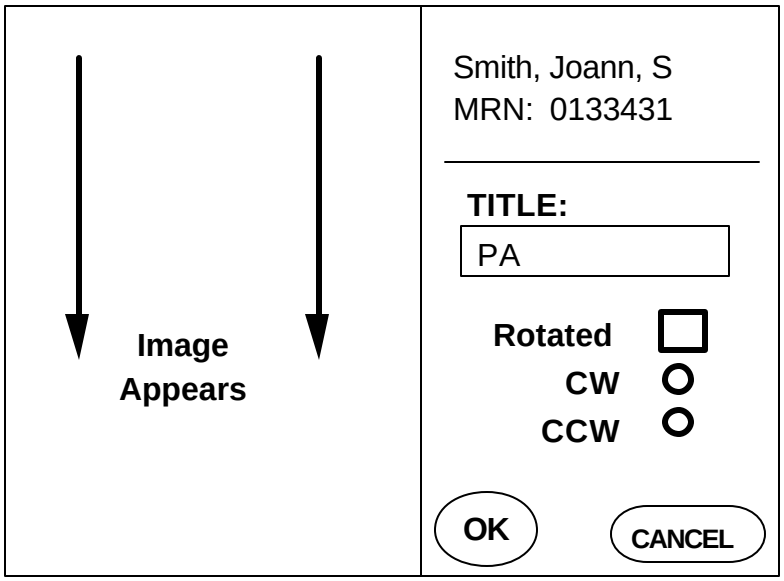
To scan the image, click on the **Digitize** button. The Lumiscan scanner takes about 45 seconds to scan an image.

Digitizing from a CR unit in the Computed Radiography Station

Load the phosphor plate into the Fuji AC1+CR unit. To scan the image, click on the **Digitize** button. The Fuji AC1+CR unit takes about $$HOW LONG$$ seconds to scan an image.

Previewing images

After you press the Digitize button, another window appears on the screen. You will see the image appear in this window as it is being scanned.



The preview window

The preview window shows you the image and the patient name and medical record. Type the name of the image in the text entry box. Be sure to give the image a descriptive name. A radiologist using a Image Review Station to look at a study will use the image name to choose which image to display.

If the image in the preview window is rotated or flipped, click on the rotation and flipping buttons to change the image. This table shows you the effect of the flipping and rotating buttons. Note that the order that you flip and rotate makes a difference.

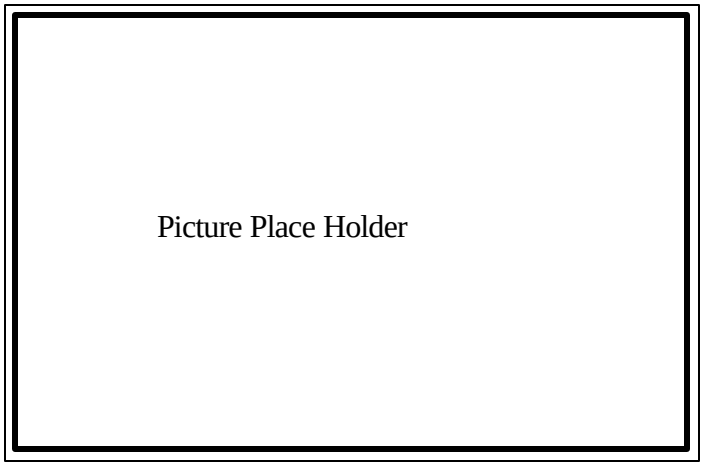
To get this…	a	ɒ	ɐ	ɑ	a	ɑ	ɐ	ɒ
Do this…	nothing	CW	180°	CCW	Vertical	Vertical CW	Vertical 180°	Vertical CCW

If you are satisfied with the way the image looks, click on the **OK** button. To discard the image, click on the **Cancel** button. You will be back in the Digitizer Window.

Important: Before you click **OK**, be sure that you are satisfied with the name of the image and the settings of the rotation buttons. Once you click **OK**, you cannot change any of these settings.

If you are using a CRS, you be aware that film images, you can only read phosphor plates once. The process of reading the information from it erases what is on the plate, so if you choose not to save the image, you will not be able to rescan the phosphor plate.

As you digitize images, you will see miniature images appear in a box in the Digitizer Window.



Miniature Images

These image miniatures let you keep track of the work you've done.

Ending a Study

When you have scanned all the images for a study, click on the **Study Complete** button in the Digitizer Window. If you are not satisfied with the study, you can click on the Cancel button to cancel the study.

Important:	When you click on the Cancel button, any images that you have scanned for the study disappear.

When you click on the Study Complete button, the Film Digitizer Station or the Computed Radiography Station sends the images (and any patient demographic information you entered) to the ICU Mini-PACS Image Server where it will be available to Image Review Stations and to Patient Census Stations.

Troubleshooting

This section gives you tips on how to deal with some questions you might have as you use your Patient Census Station.

The film in the Lumiscan scanner is jammed

To unjam the film in the Lumiscan scanner, choose the **Eject Film** command from the **Digitize** 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.

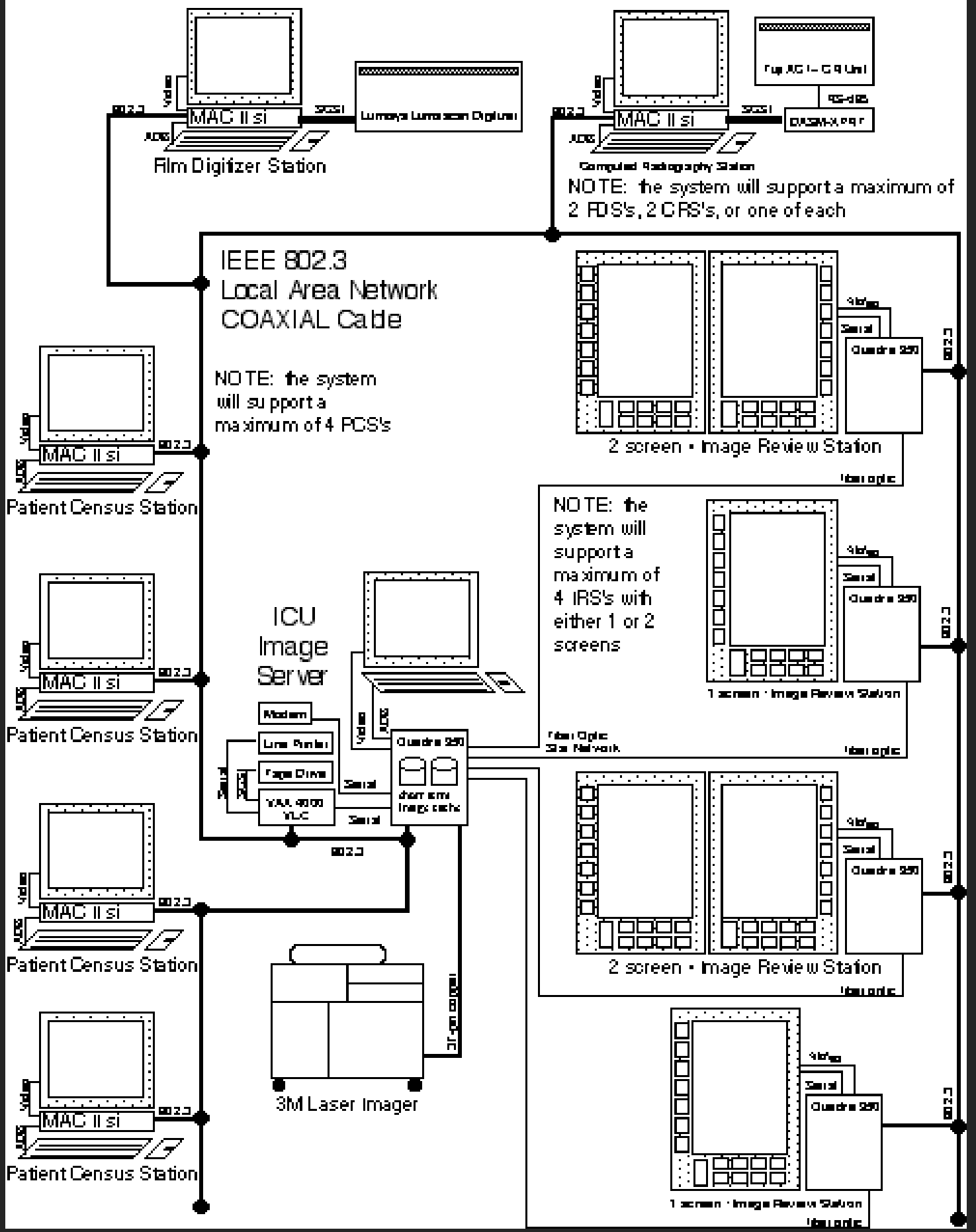
- Open the two black latches.
- Rotate the latches 90°
- Pull out the panel

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.

MANUFACTURER	**RSTAR, INC.**	**Advanced Video Products (AVP)**	**Kodak/Vortech** #
MODEL	RSTAR Intensive Care Unit Mini-PACS	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	No	Yes	Yes
DISTRIBUTED PROECESSING	Yes	Yes	Yes
OPERATING SYSTEM	VAX VMS / Mac OS	MS-DOS	Unix
IMAGE DISPLAY			
Matrix size, pixels	1800 x 2250 1152 x 882	640 x 480 1280 x 1280 2560 x 2048	1600 x 1200
ROI resolution	1800 x 2250	Up to 2560 x 2048	2048 x 2048
Multiformat display	Yes	Yes	Yes
Number of display stations supported	4 Image Review Stations	500 Workstations	Unlimited depend on network loading
Number of monitors per station	1 or 2	1 to 8	1 to 6
Color Display	No	Yes	No

IMAGE STORAGE			
Online, MB	Up to 8 gigabytes	Up to 80,000	Up to 45,000
Archival, MB	Not an option	Up to 80,000	10,200/14" : 680/5.25" platter
Floppy disk	for software distribution	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 Film Printers	All options	Laser printers
IMAGE TRANSMISSION			
Communications protocol	Ethernet, Proprietary Optical	Proprietary	Ethernet-TCP/IP
Time per image,sec	>2 sec for a 2k x 2k image	2 sec	2 sec
Interconnection			
Coaxial cable	Ethernet	Broadband or twisted	Ethernet
Fiber optics	Ethernet, Proprietary Optical	Yes	Ethernet
Telephone lines	No	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

IMAGE INPUT			
Multimodality	No	Yes	Yes, digital and analog interfaces
Vendor-supplied softare, hardware interfaces	No	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, membrane switch	Keyboard, trackball, mouse	Keyboard, trackball, mouse
Image access time			
From online stoarge, sec	< 3 sec for a 2k x 2k image	2 sec	5-7 sec for 2k image
From archive storage, sec	Not an option	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	Not an option	Optional	Under development
SYSTEM SECURITY	User password	User password	Optional password

2.2. System Diagram: RSTAR ICU Mini-PACS