SECTION 1

INTRODUCTION

1-1 GENERAL

This manual provides operator information for the SenoScan® Full Field Digital Mammography System (hereafter, referred to as *SenoScan*). The major assemblies that comprise a typical *SenoScan* system are shown in Figure 1-1.

Only information relating to the *SenoScan* system and SenoScan-related procedures is described in this manual. Information pertaining to other equipment and procedures which may be referenced in this manual must be obtained from documentation supplied with the specific equipment.

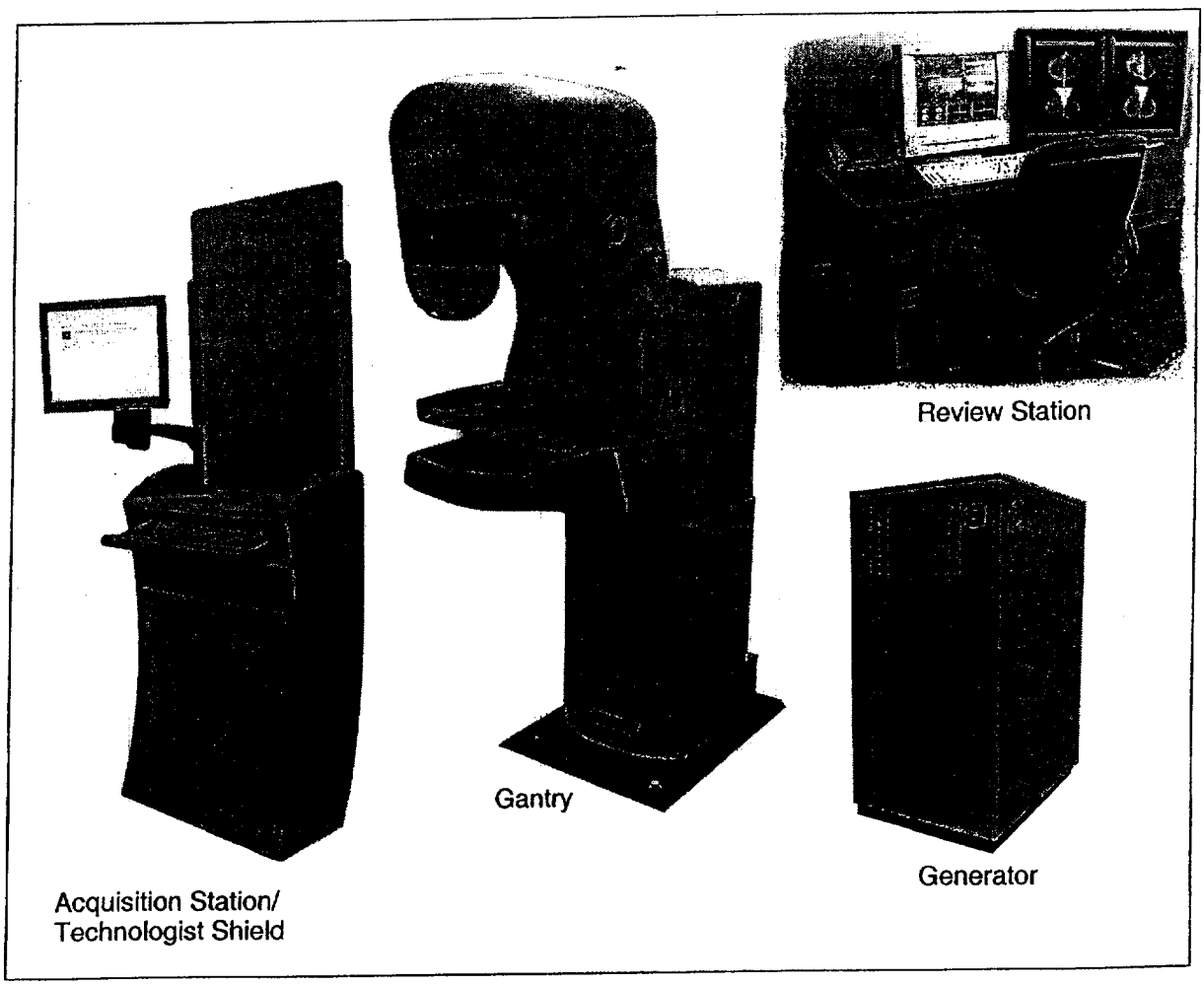

Figure 1-1. SenoScan Full Field Digital Mammography System (typical)

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1-2 OVERVIEW OF THIS MANUAL

This manual consists of 6 Sections and 3 Appendices:

Section 1 – Introduction, contains an overview of this manual, a general description of the *SenoScan* system, symbols, key features and specifications, general information about safety, cleaning and disinfecting, and compliance with regulatory requirements.

Section 2 – Features, Controls, and Indicators, describes the locations and functions of all operator-relevant components, controls, and indicators.

Section 3 – Operating Instructions for the Technologist, describes how to use the Acquisition Station and Gantry to image the patient. It describes how to startup and shut down the system, prepare the patient for imaging, acquire an image, optimize and evaluate the acquired image, and save the image into the Review Station's data storage system for subsequent retrieval and study.

Section 4 – Operating Instructions for the Radiologist and Physician, describes how to use the Review Station to retrieve patient image records from the data storage system then optimize and manipulate them for detailed study. It also provides instructions for archiving images and printing hard copies of patient images.

Section 5 – Quality Control, describes a program of periodic tests accomplished by the technologist, radiologist, and physicist, that verifies system functionality and suitability for use on patients.

Section 6 – Operator Maintenance, describes operator-level maintenance procedures: cleaning, disinfecting, and servicing.

Appendix A – Records, Worksheets, and Checklists, contains examples of the recommended records, worksheets, and checklists used to support and record *SenoScan* operations, QC, and service.

Appendix B – Error Messages and Codes, describes the system conditions that cause various error messages to be displayed.

Appendix C – Technique Charts, contains the default *SenoScan* technique chart (baseline) and provides instructions for creating and customizing technique charts.

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1-3 DESCRIPTION OF SENOSCAN

The *SenoScan* is a full field digital mammography system that produces high-resolution on-screen x-ray images of the breast for detection and diagnosis of disease. The *SenoScan* system consists of the following major assemblies and component groups:

- Gantry
- Generator
- Acquisition Station/Technologist Shield
- Review Station

1-3-1 Gantry

The patient is imaged at the gantry.

The gantry consists of the components required to position and image the patient. The gantry contains the diagnostic source (x-ray tube, filter, and collimator), image detector, breast support, and compression assembly. The gantry can be raised, lowered, and rotated, under motorized control, to accommodate patients of all statures, standing and/or sitting, to produce images in all standard views. All gantry motions are controllable by means of motion switches located at multiple locations on the gantry where they are readily accessible to the operator regardless of gantry position.

The breast compression system works in conjunction with the breast support to position the patient and uniformly compress the breast for x-ray imaging. The compression system provides both motorized and manually operated controls. Manual control allows for fine adjustment of the compression force and also provides a means to release the compression device in the event of power failure. Manual control is via a knob on either side of the compression assembly. Motorized control is activated by foot switches located on either side of the patient. Use of motorized control frees the operator's hands to assist in patient positioning during compression.

A display at the base of the gantry housing shows gantry rotation, compression force, and compression thickness.

Inside the gantry housing, the x-ray source and the detector are aligned to each other from the opposite ends of an internal C-shaped swing arm assembly. This puts the x-ray source and the detector on opposite sides of the breast support/compression assembly which is located in the open part of the C-shaped swing arm. During image

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acquisition, the internal swing arm is motor driven to pivot at the x-ray source, causing the detector (at the other end of the swing arm and on the far side of the breast support) to swing in an arc under the breast support from one edge of the breast support to the other. The x-ray, which is shaped into a flat fan-shaped beam (slice) by the collimator, passes through the compressed breast tissue as it sweeps across the breast support and falls on the image detector underneath. The detector and its associated electronics convert the acquired x-ray into a digital data signal which is sent to the acquisition station computer for processing into the actual image.

1-3-2 Generator

The generator converts the facility line power into the high-voltages required to operate the x-ray tube and the voltages required by the gantry for motion control, image acquisition, and data conditioning.

The generator contains a dedicated microprocessor control system to assure fail-safe operation of actual x-ray exposure. An x-ray exposure is not possible when an out-of-limit condition exists because of incomplete patient setup, inappropriate technique values, or system malfunction.

1-3-3 Acquisition Station/Technologist Shield

The technologist uses the acquisition station to image the patient.

The acquisition station consists of a Unix-based workstation to run the acquisition station software; a flat-panel color display monitor, keyboard, and mouse through which the technologist can control the operation of the workstation; and the x-ray switch. All acquisition station equipment is incorporated into the technologist shield enclosure which includes a leaded-glass shield.

All setup, patient information, and exam requirements are entered into the system at the acquisition station via the icon-driven graphical user interface (GUI). After the patient and exam information is entered, the patient is positioned and compressed, and the technique is set by the technologist. When all requirements are met, the system is ready for the technologist to take the exposure. To acquire the image, the technologist presses and holds the x-ray button while the image is being acquired (approximately 6 seconds).

Digital image data is received by the acquisition station computer from the gantry. The acquisition station computer processes and displays the acquired image for review by the technologist. Each acquired image must be either accepted or rejected by the technologist.

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If necessary, the contrast and brightness (window width and level) of the image can be temporarily altered by the technologist to aid in determining if the image should be accepted. Accepted images are automatically transferred (via a dedicated ethernet network) to the review station equipment for storage in the system database. Rejected images are cleared.

Acquisition station operating instructions are detailed in Section 3.

1-3-4 Review Station

Patient images are reviewed by the physician at the review station.

Image data acquired by the acquisition station is passed to the review station where it can be retrieved, displayed, printed, and archived.

The review station consists of a Unix-based workstation to run the review station software; a color display monitor, keyboard, and mouse to provide control of the review station; and two high-resolution black and white display monitors on which patient images are displayed. A RAID data storage unit and a film-screen laser printer complete the review station. Some installations may also include a magneto-optical drive for permanent archive, and/or a connection to PACs (Picture Archive Communications System), if available.

Patient images may be retrieved from an on-screen listing in the patient database, or review list. Patient images are displayed in soft copy for diagnosis on two high-resolution black and white monitors. The use of two monitors allows the physician to display two different studies from the same patient simultaneously as an aid in diagnosis (study review).

Images can be viewed in a variety of formats and with various imaging tools. The image display parameters are highly adjustable by means of the review station's graphical user interface program, allowing the physician to selectively adjust contrast, magnify, invert, and measure pathology on-screen. The ability to edit and add comments to the current study is also provided.

Images with accompanying patient examination information are stored in the RAID (redundant array of independent disks) storage system and may be permanently archived to a magneto-optical drive or PACs (if available), and may be printed in hard copy via a laser-film printer.

Review station operating instructions are detailed in Section 4.

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1-4 SYMBOLS

The following symbols are affixed to the exterior of the *SenoScan* system to alert operators and service personnel to potential hazards and operational functions:

Dangerous Voltage

Dangerous voltages are present.
(This symbol may also appear without the triangle border.)

Danger X-Rays

This equipment produces ionizing radiation when energized.

Warning

This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide.

Warning

This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed.

Attention

A potential hazard to operator, service personnel, or equipment exists. Refer to the technical manual for instructions before proceeding.

Attention

This equipment contains no user serviceable parts. DO NOT remove covers.

Power Off

Disconnection from the mains. Used on power switches.

Power On

Connection to the mains. Used on power switches.

Type B Applied Part

This equipment meets the requirements of EN60601-1 for protection against electric shock.

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Ionizing Radiation

This symbol (red) is used as the x-ray indicator on both sides of the gantry column. X-ray emission is taking place when this symbol is displayed.

Standby

This symbol (green) is paired with the ionizing radiation symbol on the sides of the gantry column. The system is energized when this symbol is displayed.

< No Symbol>

Mode of Operation

SenoScan is designed for continuous operation with short time loading. Short time loading is defined as: one 10 second (max) x-ray exposure every 2.5 minutes or 4 x-ray exposures in 10 minutes.

1-5 KEY FEATURES AND SPECIFICATIONS

- **Equipment Class**

  Class I

- **Degree of Protection Against Ingress of Water:**

  Ordinary

- **SID** (Source-to-Imager Distance)

  64.18 cm (fixed)

- **X-ray Field Dimensions** (see Figures 1-2 and 1-3)

  21 cm x 29 cm (Normal mode)
  10.5 cm x 14.5 cm (Mag/High-Res mode)

- **X-ray Beam Cross-sectional Dimensions** (see Figure 1-2)

  slice-shaped beam
  1.1 cm x 22.5 cm (Normal mode)
  1.1 cm x 11 cm (High-Res mode)

- **Scan Speed and Direction**

  5 cm/sec (duration ≤6 sec); patient's left to patient's right

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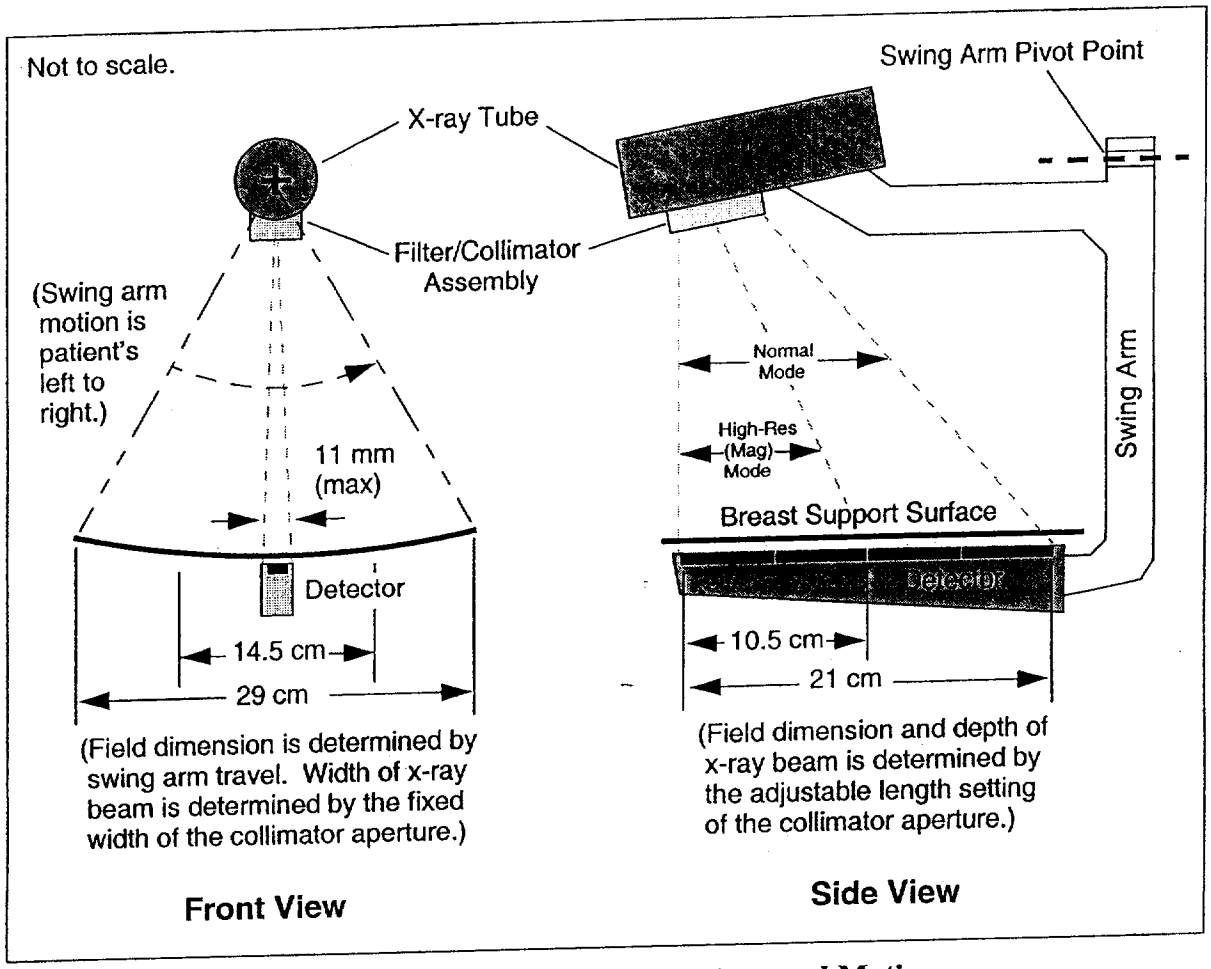

Figure 1-2. X-ray Beam Dimensions and Motion

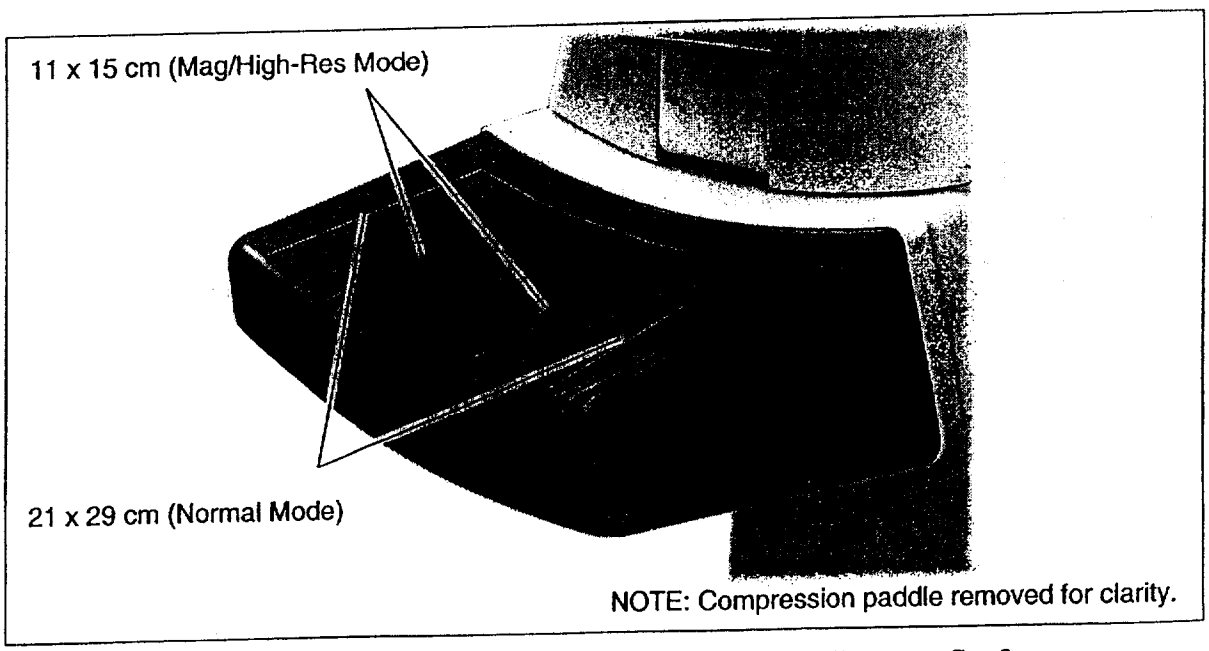

Figure 1-3. X-ray Field Size Markings on Breast Support Surface

- **Collimator Adjustment Method**

  Motorized – Automatically resets when Normal and High Res modes are selected.

- **Collimator Reset Time**

  15 sec (max)

- **Focal Spot Size**

  0.3 mm @ 25 kV, 150 mA (0.45 x 0.65 mm maximum)

- **Permanent Filtration of RAD71F X-ray Tube**

  0.76 mm (beryllium)

- **Additional Equivalent Filtration in X-ray Beam**

  0.5 mm (aluminum) for normal operation

  2.0 mm (aluminum) for calibration – automatically selected

- **Equivalent Attenuation of Carbon Fiber Breast Support**

  Maximum attenuation is less than 0.15 mm (aluminum).

- **Rated Load Capacity of Breast Support**

  300 newtons

- **Generator Rating and Duty Cycle**

  12 kW

  Duty Cycle is limited by the x-ray tube thermal characteristics.

- **kV Range**

  20 - 45 kVp (in increments of 1 kVp)

  Accuracy is ±3% +1 kV of the indicated kV

- **mA Selection Range**

  80 - 220 mA (in increments of 10 mA)

  Accuracy is ±5% +5 mA of the indicated mA

- **Connectivity**

  SenoScan provides DICOM 3.0 TCP/IP Network Communication Support as defined in Part 8 of the DICOM Standard.

  Communication is via Ethernet to PACs and printers which support DICOM 3.0 Print Services.

  SenoScan acts as a SCU (service class user) to store images to a remote DICOM SCP (service class provider).

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For complete information on DICOM connectivity for *SenoScan*, refer to *SenoScan* DICOM Conformance Statement, Fischer document number 98550.

1-6 CERTIFIED COMPONENTS

The following components are certified for use with SenoScan Full Field Mammography System 94001G-3. Certification is applicable when components are installed, calibrated, and serviced in accordance with all applicable instructions. Unauthorized modifications will invalidate certification.

- *SenoScan* Gantry 94500G-2
- X-ray Tube 94518-2
- Collimator/Filter Assembly 94710M-2
- Detector 94767-1
- *SenoScan* Generator 94100G-2
- HF/HV Transformer Assembly 94060M-2
- Inverter Assembly 94030M-2
- *SenoScan* Acquisition Station 94830G-1
- *SenoScan* Acquisition Station Computer 94502-1

1-7 QUALIFIED COMPONENTS (LASER IMAGERS)

The following laser film imaging systems have been qualified for use with *SenoScan* Full Field Mammography System 94001G-3. These hard copy film printers have been tested and found to be fully compatible with the *SenoScan* system when installed, maintained, and operated in accordance with the manufacturer's instructions.

- Kodak Dry View 8610 Laser Imaging System/for Mammography
- Agfa Scopix LR 5200 Laser Imager

Note: **Although a printer is listed as an option, facilities must have the ability to transfer usable images to other facilities and to patients. At this time, the indicated laser imagers are the only devices qualified for this task.**

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1-8 SYSTEM ACCESSORIES

Descriptions and part numbers for *SenoScan* system accessories are provided below.

1-8-1 Compression Paddles

- Compression Paddle, 24 x 30 cm (9.4 x 11.8 in) – 94295M-2
- Compression Paddle, 18 x 24 cm (7.1 x 9.4 in) – 94770M-1
- Compression Paddle, 4 x 6 in (10.2 x 15.2 cm) – 94321M-2
- Compression Paddle, Spot, Round, 3 in (7.6 cm) – 104344M-1

Caution

DO NOT use any accessories or other items not specifically intended for use with this x-ray system. Adverse effects may occur from foreign material located in the x-ray beam.

1-8-2 Optional Accessories

1-8-2-1 Archive Devices

- Magneto-Optical Drive 94330-1

1-8-2-2 Laser-Film Printer/Imager

- Kodak 8610 Laser Imaging System 94852-1
- Agfa Scopix LR5200 Laser Imager 77249-1

1-9 INDICATIONS FOR USE

The SenoScan Full-Field Digital Mammography System is a dedicated mammography system intended to produce radiographic images of the human breast for the purpose of diagnostic and screen mammography. The *SenoScan* Full-Field Digital Mammography System is intended to be used in the same clinical applications as traditional film-based mammographic systems.

1-10 CONTRAINDICATIONS

None known.

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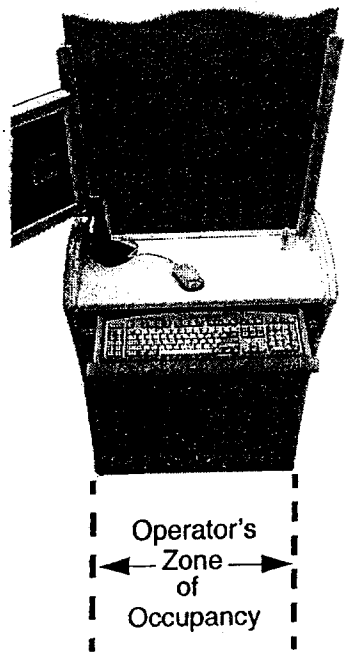
1-11 WARNINGS AND PRECAUTIONS

The following warnings and precautions must be observed by the operator:



- WARNING: This equipment is not suitable for use in the presence of a flammable anethestic mixture with air or oxygen or nitrous oxide.
- Operators must remain behind the provided leaded-glass shielding during an x-ray exposure. To prevent exposure to x-ray, the operator must remain behind the technologist shield, in the zone of occupancy shown at the left, during the entire exposure.
- For U.S. only, until further direction is available from the FDA, the SenoScan Full Field Digital Mammography System must only be used in MQSA film-screen accredited/certified facilities. The facility must maintain accreditation on at least one film-screen mammography system. The facility is subject to an annual on-site MQSA inspection of the *SenoScan* system at the same time its film-screen systems are inspected. The facility must follow the quality assurance program recommended by the manufacturer, employee personnel must meet all applicable requirements including 8 hours of digital training, and provide an FFDM equipment evaluation performed by a qualified medical physicist within six months before submitting material to FDA. Additionally, the facility may not use the *SenoScan* FFDM system for the imaging of patients until a letter is received from the FDA stating specifically that the facility's certification has been extended to their digital unit.
- The acquisition workstation cannot be used for final interpretation of patient studies.
- For compatible laser printers, see the Qualified Components listing in this section of the the manual and the latest product data sheets. These sheets are available from your local sales representative.
- Operators should be trained to properly operate the user interface and review workstation. Only authorized trained personnel may operate this equipment. It is the responsibility of the site to ensure that proper operating techniques and procedures are followed when using mammographic x-ray equipment.

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- Operators must ensure maximum radiological protection is provided to all persons present during x-ray operations. No unauthorized/unprotected persons should be allowed in the room during x-ray operation.
- Quality control procedures must be followed to ensure continued high levels of operation and be in compliance with the MQSA regulations.
- Compression paddles must be carefully handled to prevent damage. Before use, compression paddles must be examined for the presence of cracks, sharp edges, roughness, and foreign matter, which may cause discomfort or injury to the patient. When not in use, compression paddles should be carefully stored in a manner that protects the paddles from damage.
- The provided on-screen ruler tool assumes that all measurements are made on a virtual surface located 2 cm above the breast support. Therefore, objects in the image which are above the virtual plane may be slightly larger than measured and those below the plane may be slightly smaller than measured.
- The review station should be located in a suitably dark environment to enhance image visibility during review. The ambient light level, measured at the surface of the monitor screen (with the monitor turned off), must not exceed 50 lux.
- This system contains no user serviceable parts. DO NOT remove any covers.
- Covers should be removed by qualified service personnel only. Installation and service should be performed only by qualified service personnel. Installation and Service manuals are available for use by these personnel and should be consulted.
- Avoid touching the recording surface of magnetic or optical storage media. Store recording media in an approved manner and do not allow recording media to be exposed to any potentially harmful environment. Before use, verify that there are no visible scratches or other imperfections that may affect the media performance.
- Unauthorized (third-party) software should not be added to the acquisition or review station computers. Addition of unauthorized software has the potential to affect system performance or cause conflicts with system operation.

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- DO NOT attempt to operate a system that has not been properly installed. The gantry, acquisition station/technologist shield, and generator must be properly anchored to the floor and all shielding and wiring must conform to the installation specifications.
- DO NOT use any accessories or other items not specifically intended for use with this x-ray system. Adverse effects may occur from foreign materials located in the x-ray beam.
- Before removing any component or assembly to be sent out for servicing:
  1. Determine if the component has been exposed to any body fluids. If so, wear proper personal protective equipment (gloves, gown, mask, goggles, etc.) when accomplishing steps 2 through 4.
  2. Clean and disinfect the component as described in the Cleaning and Disinfecting section of this manual.
  3. Remove the component from the system and inspect any previously inaccessible surfaces for possible contamination. Clean and disinfect these surfaces as necessary.
  4. Place the component in a standard Red Biohazard bag, bearing the proper biohazard symbols, and seal.
  5. Carefully package the component for shipping.

1-12 POTENTIAL ADVERSE EVENTS

The following list of potential adverse events apply to mammography and are also applicable to digital mammography using the *SenoScan* Full Field Digital Mammography System.

- Excessive breast compression
- Excessive x-ray exposure
- Electric shock
- Infection
- Skin irritation, abrasions, or puncture wounds.

Note: **No adverse events were observed during clinical trials.**

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1-13 NON-CLINICAL LABORATORY STUDIES

Results from non-clincal laboratory studies and the methodology used for those studies is detailed in the following paragraphs.

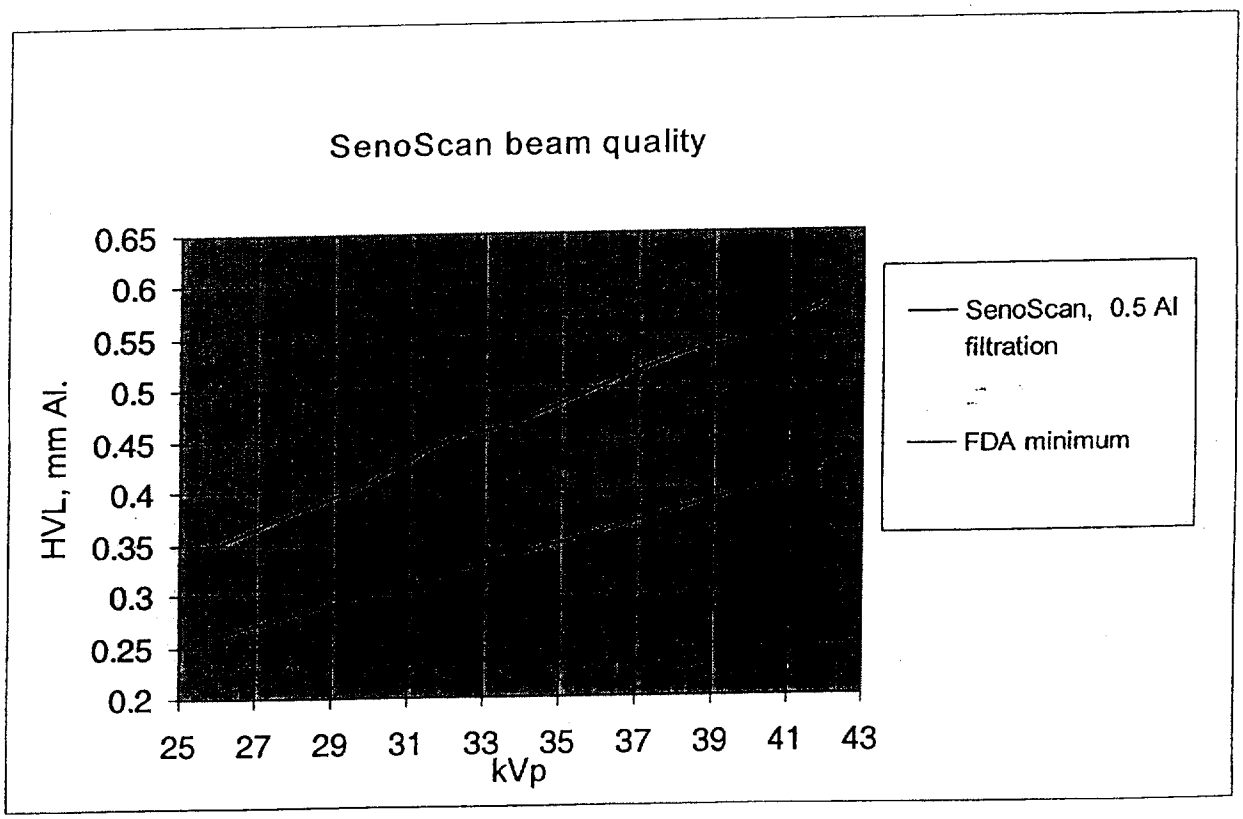
This section contains a description of acquired data and image quality, and patient dose.

1-13-1 Studies on Quality of Acquired Data

This subsection provides an overview of the *SenoScan* physics performance characterization. Aspects of beam quality, detector response, signal-to-noise ratio (SNR), and SNR transfer through the imaging chain (detective quantum efficiency, DQE) are quantitatively described.

1-13-1-1 Beam Quality

A typical measurement of the beam half-value layer (HVL) as a function of peak kilo-voltage (kVp) is presented in Figure 1-4. The *SenoScan* beam quality exceeds the FDA minimum at all relevant values for kVp.



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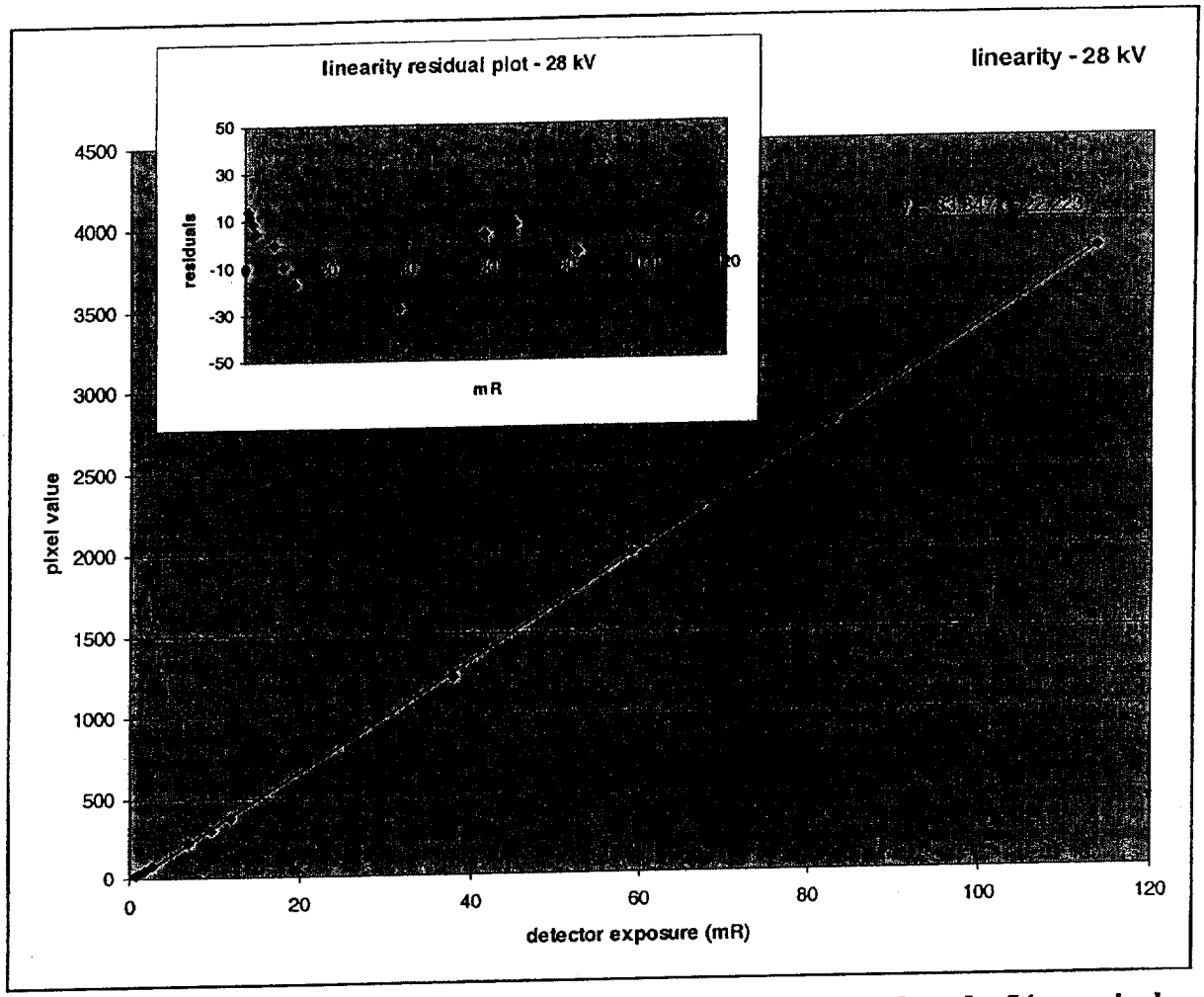

Figure 1-5. Detector system sensitometric response in the Standard mode, 54-µm pixels, obtained after offset correction at 28 kVp, gain #1.

1-13-1-2 Sensitometric Response

X-rays attenuated by the detector scintillator are converted into light energy. The CCD transforms the light energy into an electric charge. The electric charge forms an analog voltage that is then converted into digital values by the data acquisition system. That system offers a number of gain settings that provide various sensitometric responses (i.e. digital value vs. radiation exposure curve). Gain settings are selected for optimal imaging characteristics and allow for optimal exposure. The benefit of multiple gain settings can be seen particularly in the high-resolution mode of operation. Figure 1-5 shows a typical detector sensitometric response curve as a function of incident exposure, in the Standard mode.

The curves demonstrate linear response over the system practical dynamic ranges.

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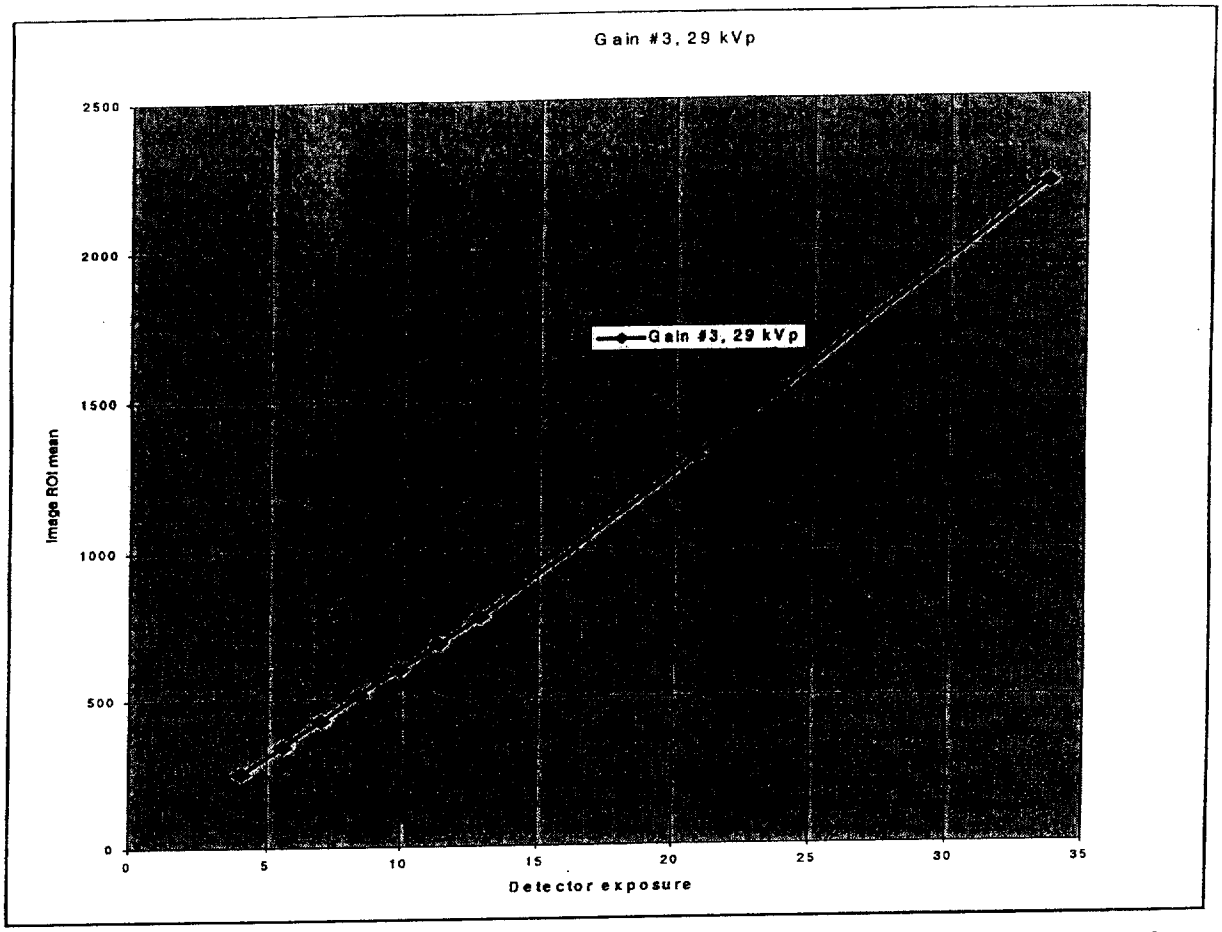

Figure 1-6. Detector system sensitometric response with gain number 3, obtained after offset correction, at 29 kVP. Gain 3 is used in high-resolution mode.

Figure 1-6 presents the sensitometric response associated with gain number 3. Higher gain in this mode makes more efficient use of the available quantum energy. In High-resolution mode, the pixel size is ¼ of the available pixel area in the standard imaging mode.

Finally, figure 1-7 presents an image noise-variance versus exposure plot for gain #2 at 29 kVp. The linearity of the graph demonstrates that the *SenoScan* operates in a quantum-limited mode over a wide range of detector exposures, including exposures well below those expected in routine clinical imaging.

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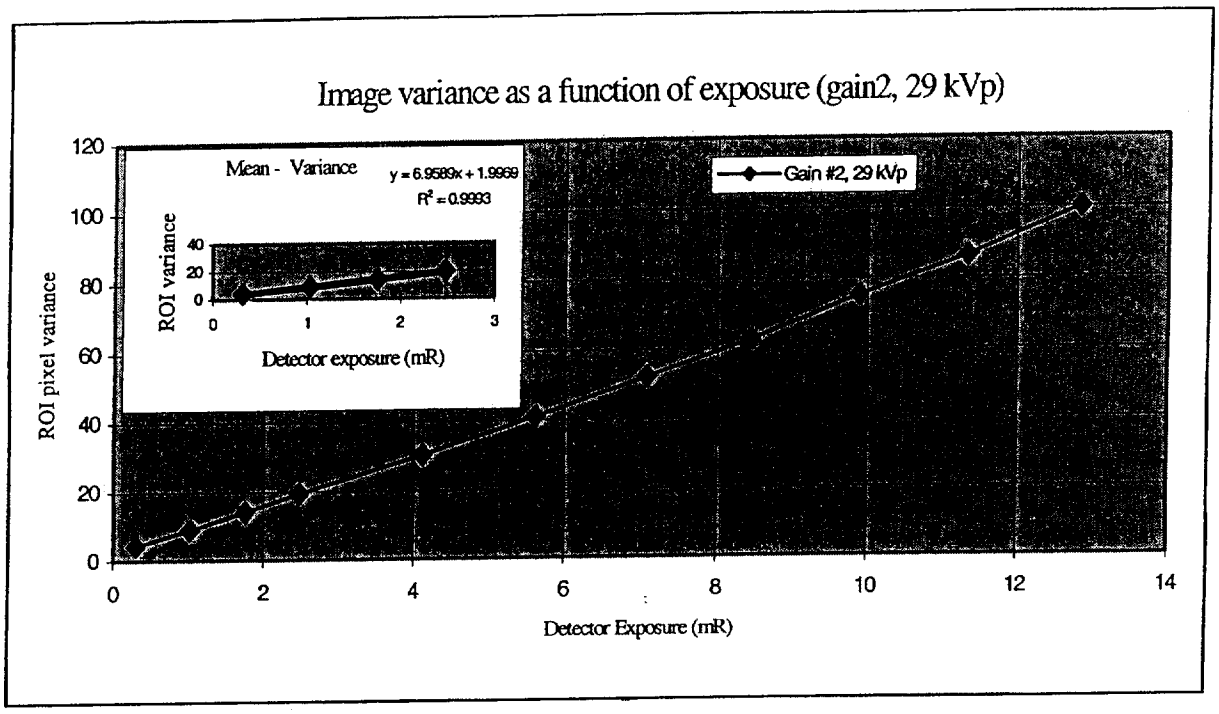

Figure 1-7. Image noise variance as a function of detector exposure, gain #2, 29 kVp

1-13-1-3 Detective Quantum Efficiency

The detective quantum efficiency (DQE) provides a quantitative measure of the efficiency of SNR transfer of the image acquisition system. While the radiologist is the ultimate judge of diagnostic content of medical images, the detective quantum efficiency (DQE) is widely accepted as the most relevant figure of merit to quantitatively characterize the image quality of medical x-ray systems. Medical imaging system performance can often be evaluated in terms of detection performance characteristics. The DQE characterizes a detection system, and can be interpreted as the efficiency of such system in transmitting the information it receives. Specifically, the DQE can be described as the fraction of incident photons that would have to be detected without additional (detector) noise to yield the same signal-to-noise (SNR) ratio as is actually observed.[1] Therefore, it is a measure of detection performance (SNR) as a function of frequency that accounts for dose. The noise factor derived from the DQE, NF=1/(DQE)1/2 is the decrease in SNR that accompanies the detection process.

1. H.H. Barrett, W. Swindell, *Radiological Imaging*, Academic Press, New York, 1981

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Accordingly, the DQE, defined as:

$$\left[SNR_{out}(v) / SNR_{in}(v)\right]^2$$

- Includes combined effects of the modulation transfer function (MTF) and all relevant noise.
- Remains stable under spatial filtering that affects the MTF.
- Facilitates the comparison of different imaging systems.

The DQE as measured on an imaging system will always be less than the DQE of the detector alone. Indeed, the system measurement necessarily includes MTF reducing factors such as the finite focal spot aperture, off-focal radiation, and other components such as grids that reduce scattered radiation but require increased patient dose.

It should be noted that this evaluation was conducted using a complete imaging system. Readers should use caution in comparing DQE measurements. Other published DQE measurements may represent 'detector only' calculations. 'Detector only' calculations may not include important contributing factors to resolution or dose degradation. Further DQE exposure measurements obtained on a laboratory system demonstrate DQE as a function of exposure.

1-13-1-4 Methodology

1-13-1-4-1 Sensitometry and Mean-Variance

X-ray sensitometry was evaluated by performing a series of imaging exposures under a variety of conditions of kilovoltage (kV) and tube current settings. To extend the range of measurement, observations were also recorded with different thicknesses of poly-methyl methacrylate (PMMA) attenuating slabs placed in the beam. The exposure time was fixed by the scanning time of the system. A region of interest is selected in the image and the mean image digital signal pixel value (referred to hereafter as P) is recorded as well as the variance of signal within the region. In addition, the tube current (mA) and the exposure in mR incident on the detector were recorded.

The variance of the digital signal is also plotted vs the mean value to assess the contribution to the image noise from quantum and non-quantum sources and to estimate the dynamic range.

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1-13-1-4-2 X-ray Spectrum

The purpose of this measurement is to estimate the shape of the spectrum so that the number of input quanta to the detector can be used in the calculation of DQE. A CdZnTe room temperature spectrometer, with a 100 :m pinhole at its entrance, was located at a distance of approximately 20 cm from the detector and aligned with the central ray of the x-ray beam. Spectra were measured to estimate the shape of the spectrum. At least 500 counts were acquired at the peak of the spectrum.

Exposure was measured with a Keithley mammographic ionization chamber, corrected for temperature and pressure. The measured exposure was used to obtain an absolute calibration of the spectrum.

1-13-1-4-3 MTF

Modulation transfer function was evaluated by imaging a slanted edge composed of a sheet of niobium foil with ground edges mounted on a larger sheet of aluminum. This was placed at a location 4 cm from the detector. This provided a moderate contrast transition. The slanted edge ~1:16, provided approximately 10x oversampling.

MTF was determined in both the direction along the slot detector and in the scanning direction at several kilovoltages. In addition, to assess possible hysteresis effects, MTF was measured in both the rising and falling directions of signal.

1-13-1-4-4 NPS

The noise power spectra were measured from images of a uniformly attenuating PMMA phantom. After standard flat-fielding, the image is segmented into multiple sections, each of size 32x32 pixels. These are integrated in one dimension (x or y) to synthesize "slit"images. A standard, one-dimensional Fourier-transform based noise power spectrum is calculated in both x and y directions. The spectra from each region are then averaged to reduce the uncertainty in the final nps. NPS data were acquired at four kilovoltages and at several intensity levels obtained by varying tube current (mA) and the thickness of PMMA attenuator in the x-ray beam.

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1-13-1-4-5 DQE

The spatial frequency dependent DQE was calculated from the x-ray spectrum, MTF and nps using the definition:

$$DQE(f) = \frac{P^2 \cdot MTF^2 \cdot (f)}{(n / a)nps(f)}$$

where a is the area of the detector element, and n is the number of x-ray quanta incident on the detector element. Therefore (n/a) is the entrance x-ray quantum fluence to the detector (obtained from the exposure and the spectral measurement).

DQE(0) was estimated by extrapolating the mean of the DQE values in the slot and scan directions from the two lowest frequency points measured.

1-13-1-5 DQE Performance Characterization

The smaller pixel size of the *SenoScan* system extends the effective detection capability for this system well beyond a frequency of 5 cycles per mm. Measurable DQE between 5 and 10 cycles per mm means that *SenoScan* is capable of distinguishing much smaller objects. Also, the *SenoScan* system exhibited a zero spatial frequency DQE of 32% for 28 kVp. This is shown in Figure 1-8.

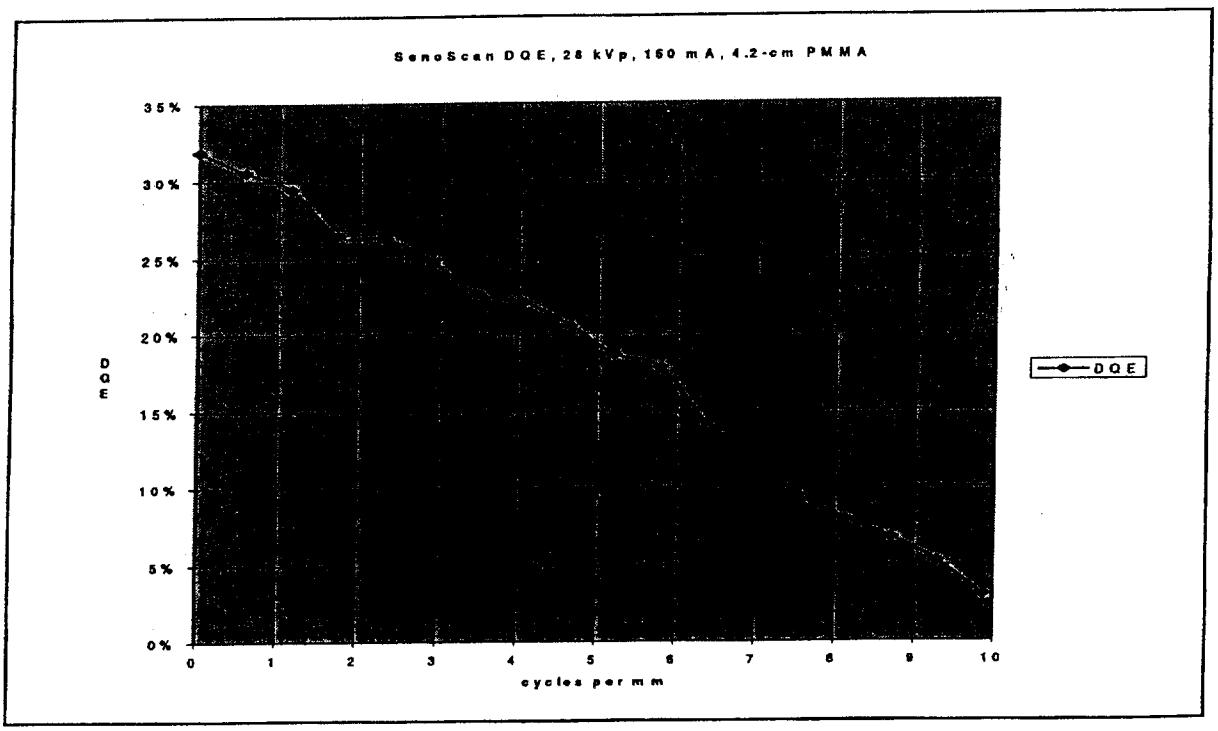

Figure 1-8. SenoScan DQE at 28 kVp, 150 mA, and 4.2 cm PMMA in the beam.

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These DQE data indicate clearly the detection efficiency achieved by a combination of slot scanning (and associated scatter rejection) and digital detector, over a range of frequencies that extend out through 10 LP/mm. The true *system* performance indicated by these measurements should translate into improved conspicuity of minute lesions requiring non-vanishing DQE at relatively high frequencies. Published DQE measurements are often "detector only", that is do not include the effect of a scatter-rejection grid. Generally speaking, DQE measurements with a grid will be about 50% of those obtained without a grid, although the actual variation will depend on the amount of scattered radiation generated by the object being imaged and rejected by the grid. The SenoScan System DQE measurement supports the claim that *SenoScan* could significantly reduce dose in a patient population.

Figure 1-9 presents system *SenoScan* DQE measurements as a function of detector exposure, for four different spatial frequencies.

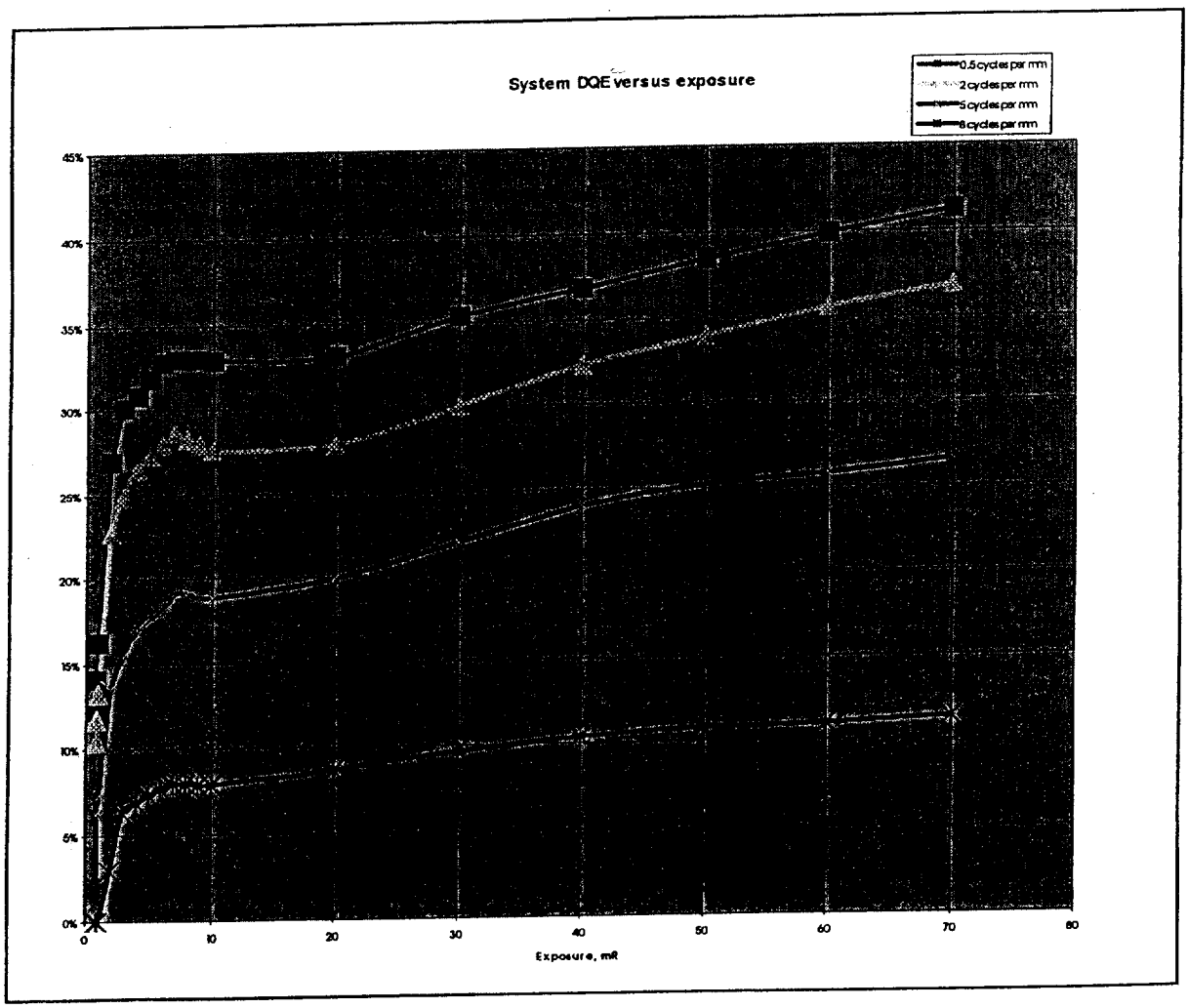

Figure 1-9. DQE data for the SenoScan system as a function of exposure.

1-13-2 Studies of Patient Radiation Dose

Table 1-1 shows the calculated mean glandular dose for the production *SenoScan* system based on the technique chart for a 50/50 adipose/fibroglandular breast composition. The technique chart is derived by setting technique factors to achieve a constant ADU response. A constant ADU response assures that the exposure is adequate across a complete range of compressed thicknesses. The 4.2-cm SenoScan dose was interpolated from the available data for direct comparison with the data given in Tesic et al.[2], Suleiman et al.[3], and Rothenberg[4]. Figure 1-10 presents the same information in a graphical form.

Table 1-1. Mean glandular dose for the recommended exposure techniques for 50/50 breast composition.

Breast thickness, cm	kVp	mA	*SenoScan* MGD, mRad	FSM MGD, mRad
2	26	110	72	
3	27	140	80	
4	29	160	94	140
4.2			96	160
5	31	170	106	
6	33	180	119	237
7	35	200	139	
8	37	200	152	465

From Table 1-1, it is apparent that for the techniques recommended in the operator manual, the *SenoScan* system provides dose savings that varies from 33% for a 4-cm compressed breast to more than 67% for an 8-cm compressed breast. At 4.2-cm, the dose savings is 40%.

2. M.M. Tesic, M. Fisher Piccaro, and B. Munier, "Full Field Digital Mammography Scanner," European Journal of Radiology, *Vol.* 31, *No.* 1, *pp.* 2-17, 1999.
3. O.H. Suleiman, D.C. Spelic, J.L McCrohan, G.R. Symonds, F. Hond, "Mammography in the 1990s: the United States and Canada," Radiology 1999, 210:345-51.
4. L.N. Rothenberg, "Exposures and Doses in Mammography," in Categorical Course in Diagnostic Radiology Physics: Physical Aspects of Breast Imaging – Current and Future Considerations, A.G. Haus and M.J. Yaffe, Eds. RSNA 1999, pp. 91-7.

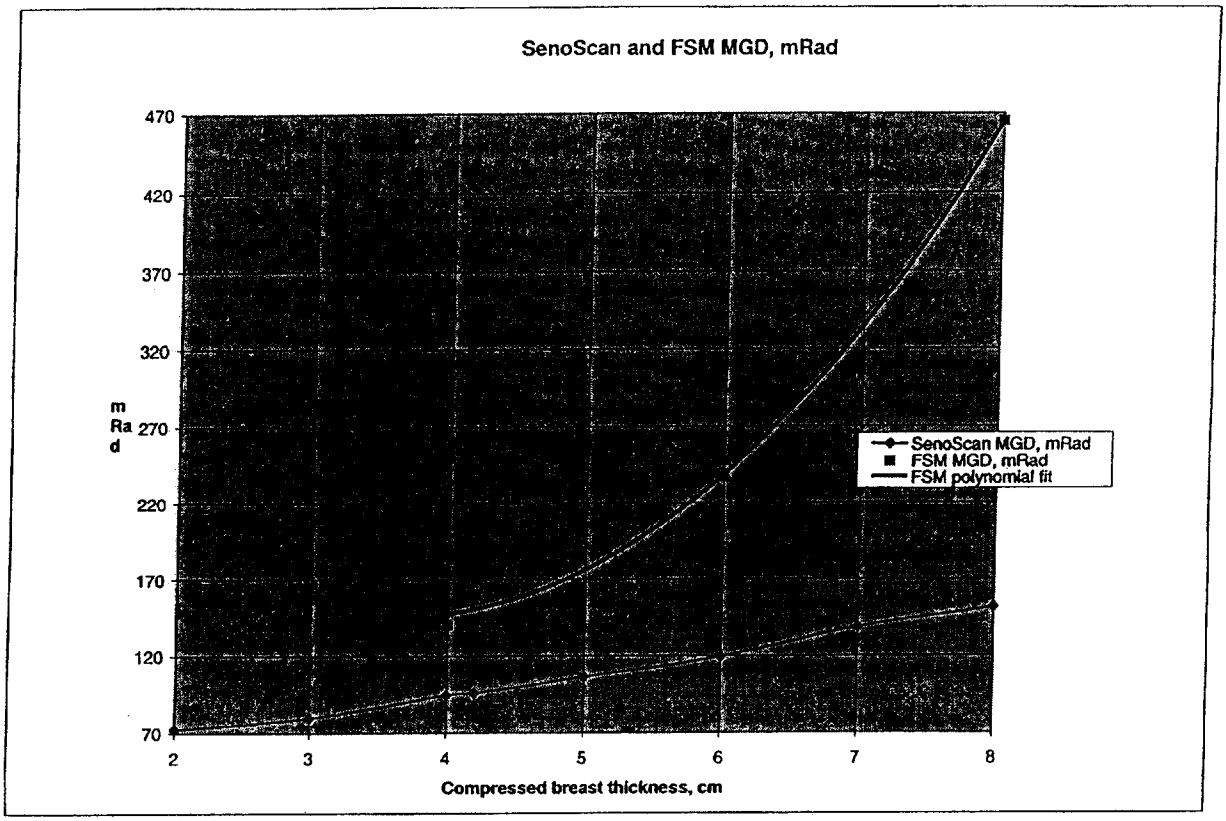

Figure 1-10. SenoScan and Film-Screen mean glandular dose as a function of compressed breast thickness

The *SenoScan* dose was also calculated from the *SenoScan* technique chart provided with prototype systems used during the clinical trial. Table 1-2 presents the corresponding *SenoScan* dose data.

Table 1-2. *SenoScan* dose as calculated from the technique chart used on clinical evaluation systems.

Breast Thickness, cm	kVp	mA	*SenoScan* Dose, mRad
2	26	160	105
3	29	170	128
4	31	190	142
4.2			144
5	33	200	151
6	35	200	163
7	38	200	184
8	40	190	183

The significantly reduced dose values for the production *SenoScan* system as compared to the dose values of the prototype systems used in the clinical trials result from design changes that enabled imaging at lower techniques with a somewhat softer beam. Dose calculations and comparisons in Table 1 are based solely on the recommended technique chart, and do not necessarily imply equal image quality relative to film-screen mammography at large breast thicknesses. However, recent research on beam optimization in digital mammography indicates that dose-constrained image quality should not decrease significantly as the kVp is increased. Williams et al.[5] suggest that for digital mammography a figure of merit appropriate for beam optimization is related to SNR per unit radiation dose. Using SNR^2/MGD as indicative of image quality constrained by dose, the authors find that the performance of all three referenced digital mammography systems (including *SenoScan*) remains fairly flat as a function of kVp.

1-14 CLINICAL STUDIES

Two reader studies were conducted using images acquired with the *SenoScan* system. Study A compared reader performance of digital mammography exams printed on laser film with film-screen mammography for the same patient. Study B compared reader performance with softcopy diagnosis with hard copy diagnosis (laser printed film) of digitally acquired mammograms.

Reports detailing the methodology and results of the two clinical studies are provided in the following paragraphs.

1-14-1 Study Comparing Full Field Digital Mammography to Film-Screen Mammography

This report describes a multicenter clinical study designed to determine the diagnostic accuracy of the Fischer *SenoScan* digital mammography system compared to standard film-screen mammography in the population of women presenting for screening and diagnostic mammography, using ROC methodology.

The first two phases involved the enrollment of patients at participating institutions. Informed consent was obtained from all patients enrolled in phases 1 and 2. The third phase involved the collection of additional digital mammograms from institutions running other research protocols using the Fischer *SenoScan* equipment. In total,

5. M.B. Williams et al., *Beam Optimization for Digital Mammography*, in Digital Mammography IWMD 2000, 5th International Workshop on Digital Mammography, M. Yaffe editor, Medical Physics Publishing, Madison Wisconsin, 2001.

case acquisition was driven by the desire to obtain a representative sample from both a screening and diagnostic population.

The first phase of case acquisition involved the enrollment of women who had been recommended for breast biopsy, who had abnormal film-screen mammograms, or who had symptoms which led to their referral for diagnostic mammography at 4 of the participating institutions. The second phase of case acquisition involved the enrollment of women who were scheduled to undergo breast biopsy, either percutaneous or open surgical biopsy, at 2 of the participating institutions.

In addition, in the third phase of case acquisition, cases were drawn from the files of cases of two additional institutions. These mammograms were obtained on women who were not recruited to the Fischer *SenoScan* FDA approval trial per se, but to other clinical trials that had the same eligibility criteria as this study at 2 participating institutions. All of the women whose mammograms were included in Phase 3 of case acquisition had signed consent forms that allowed the use of their images in additional research, as needed.

The digital mammograms of the women enrolled in all phases of case acquisition were included in the reader study reported here. The design of the reader study was selected to meet the new requirements for digital mammography FDA approval for *SenoScan*.

1-14-1-1 Clinical Site

The institutions and the phase of recruitment and case acquisition in which they participated are listed in Table 1-3.

Table 1-3. Institutions and The Phase of Case Acquisition in which they participated

Institution	Phase(s)
University of North Carolina	1 and 2
Sally Jobe Clinic	1 and 2
Brooke Army Hospital	1
Thomas Jefferson University	1
University of California at San Francisco	3
University of Toronto	3

1-14-1-2 Eligibility and Exclusion Criteria

During Phase 1 of case acquisition, women presenting to the 4 participating institutions were considered eligible for recruitment for imaging if they had been assigned a BIRADS score of 3, 4 or 5 after a film-screen mammogram (FM) (Cohort 1), or, who had been referred for diagnostic mammography by virtue of breast symptoms or clinical findings (Cohort 2). Cohort 1 enrollees represent the more challenging cases from a screening population. Cohort 2 is a representative sample from a diagnostic population.

During Phase 2 of case acquisition, women presenting to the 2 participating institutions were considered eligible for recruitment for imaging if they presented for problem-solving mammography and were subsequently recommended to undergo open or percutaneous breast biopsy within the 12 weeks after their film mammogram. This group of patients included patients in Cohorts 1 and 2, as described above.

During Phase 3 of case acquisition, digital mammograms of women were collected from the 2 participating institutions based on the same patient eligibility criteria as for Phase 2 of case acquisition.

Case acquisition in Phase 1 was terminated when a total of 560 women had been enrolled. The goal of case acquisition in Phase 2 and 3 was to enroll subjects until a total of 100 biopsy-proven breast cancer cases were available for inclusion in the planned reader study.

A woman who otherwise met the eligibility criteria was excluded from the trial if she was under age 21, if she was pregnant or thought she might be pregnant, or if she was unable to give informed consent for any reason (e.g. psychiatric or neurological, disability or language barriers.)

All patients in both cohorts underwent both digital and film-screen mammography to participate in this trial. All eligibility film-screen mammograms were obtained within 30 days of the digital mammograms for all patients.

1-14-1-3 Recruitment of Patients During Phases 1 and 2

At each of the four participating institutions, the recruiting radiologist, or his or her designee, determined the eligibility of the women presenting for problem-solving mammography. Attempts were made to recruit all consecutive eligible women at the participating institutions. Research assistants at each institution approached eli-

gible women regarding participation in the clinical trial when they presented for problem-solving mammography. Informed consent for participation in the trial was obtained at the time of recruitment to the study. An IRB-approved consent form was discussed with the patients, who signed them prior to imaging. After consent was obtained, the patient underwent digital mammography using the Fischer *SenoScan* digital mammography unit. All women underwent two-view mammograms (both cranio-caudal and medio-lateral oblique views) of one or both breasts using the digital system. For large-breasted women, as many cranio-caudal and medio-lateral oblique views as were deemed necessary by the technologist to include each breast in its entirety were performed. This is in accordance with standard clinical practice for the performance of film-screen mammography. All medio-lateral oblique and cranio-caudal mammograms obtained on the enrolled patients were considered the digital mammogram for the experimental reading study.

The original eligibility film-screen mammogram was stored at each site for use in the reader study. These original studies were copied for patient care purposes at the clinical sites and the originals were transmitted to the University of North Carolina for use in the reader study.

1-14-1-4 Determination of Breast Cancer Status for Patients

The truth about breast cancer status for each patient whose mammograms were included in the reader study was determined by either biopsy or follow-up. A single expert breast imaging radiologist at the University of North Carolina (UNC) reviewed the pathology reports on all patients and coded the available histopathologic diagnosis. The local radiologists who interpreted the patient's film-screen studies coded lesion locations. For missing forms, the breast imaging radiologist at UNC coded lesion location using needle localization and imaging-guided core biopsy clinical reports and patient records.

All patients who did not undergo biopsy were classified as normal or benign for this study. These patients underwent follow-up mammography one year after they received their digital mammogram. None of these patients showed evidence of malignancy by mammography or clinically for a minimum of one year after their Fischer *Senoscan* mammogram. Research assistants at each of the participating sites coded the results of the follow-up mammogram.

The distribution of cancer stages is listed in Table 1-4. The AHCPR guidelines suggest that 50% of detected cancers should be Stage 0 or

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1. With 75% of cancers being stage 0 or 1, this study population falls well within this guideline.

Table 1-4. T Stage

Size	Frequency Count	Percent	Cumulative Frequency	Cumulative Percent
Tis	15	20.83	15	20.83
T1	11	15.28	26	36.11
T1a	4	5.56	30	41.67
T1b	11	15.28	41	56.94
T1c	13	18.06	54	75.00
T2	11	15.28	65	90.28
T3	4	5.56	69	95.83
T4	2	2.78	71	98.61
TX	1	1.39	72	100.00

Size and stage of cancer is consistent with expected values from a screening and diagnostic population. The median cancer size was 13mm and staged as T1a or T1b. Missing data is the result of some cancers being confirmed by FNA as is standard practice at some of the participating institutions.

1-14-1-5 Reader Study

All cases of patients with cancer were included in the reader study. Noncancer cases were selected by taking a stratified random sample from the remaining cases. The stratification was by institution, so that cases would be included in proportion to the number of cases recruited to the protocol at each institution.

There were a total of 248 cases selected for inclusion in the reader study. All 248 cases consisted of both a unilateral or bilateral digital and film-screen mammogram of the same patient. The 248 digital mammograms and the 248 film-screen mammograms were randomly assigned to one of two groups, A and B, so that each group contained 248 mammograms, a mixture of digital and film-screen examinations, and so that each group had only one version, digital or film-screen, of each patient. All readers read group A cases first, followed by a minimum of a 24 day "washout" period, and then the readers read group B cases.

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A research assistant loaded the cases onto a multiviewer 50 to 100 cases at a time, utilizing appropriate masking for extraneous light. Readers were required to take 5 minute breaks every 50 minutes, or more often as necessary.

There were a total 8 radiologists who participated in this reader study. Of those, 6 had extensive experience in interpreting digital mammograms through direct clinical practice or through participation in other reader studies. The remaining two readers were trained in interpreting *Senoscan* digital mammograms by reading 10 printed digital mammograms that were not part of this study, and receiving immediate instructive feedback regarding pathologically proven lesions present in the images. All readers also trained in the use of the forms used in the study just before interpreting examinations.

The research assistant recorded reader data onto paper forms as the examinations were interpreted by the readers. If findings were found, the research assistant recorded the data regarding specific to the lesion type mass, calcifications, architectural distortion, or asymmetric density, and the probability of malignancy.

1-14-1-6 Statistical Analysis/Methods

Number of cancers and readers in the study represent a substantial effort to detect any differences in film-screen and digital mammography. The 95% confidence interval for the difference of the mean area under the curve (AUC) (digital-film) was determined by applying the approach described by Obuchowski[6].

As noted in Diagnostic Imaging 9/99, Lewin[7], AUC, sensitivity and specificity can be affected by using suspicion of cancer on the initial screen film mammogram, as an enrollment criteria. Using recruitment criteria such as a BIRADS score of 3, 4, or 5, results in a bias towards higher sensitivity for screen film mammography and a higher specificity for digital mammography. The amount of bias cannot be easily quantified.

6. N.A. Obuchowski, Academic Radiology, 1995, 2:S22-S29.
7. "Full-Field Digital Mammography: A Candid Assessment," Diagnostic Imaging, September 1999, pg 40.

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The calculation of sensitivity and specificity are based on a cut in the 1-5 scale used to classify the likelihood of cancer in each case. The cut used for calculating sensitivity and specificity was 1-2, 3-5. The scale is:

1 – definitely not malignant
2 – probably not malignant
3 – possibly malignant
4 – probably malignant
5 – definitely malignant

The BIRADs standard scale for classifying was not used because of the confounding of likelihood of cancer with "abnormality".

1-14-2 Results

There is no statistically significant difference in the average AUC for *SenoScan* full field digital mammography and screen/film mammography. The standard error and size of the confidence interval confirms that the study achieved the predicted power based on the choice of number of readers and number of cases to be included.

The true, but unknown mean difference between digital and film AUC includes zero.

	Digital	**Film**	**95% CI for difference in AUC's**
Average AUC	.715	.765	(-.101, .002)

The average specificity of *SenoScan* full field digital mammography is somewhat higher than the specificity of screen/film mammography. Difference in sensitivity and specificity are consistent with selection bias as noted by Lewin[8] et al.

	Film	**Digital**
Average Sensitivity	0.74	0.66
Average Specificity	0.60	0.67

8. "Full-Field Digital Mammography: A Candid Assessment," Diagnostic Imaging, September 1999, pg 40.

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1-14-3 Performance with Softcopy and Hardcopy Images

1-14-3-1 Specific Aim

This study compared the speed and accuracy of interpretations by radiologists of Fischer *SenoScan* digital mammograms displayed using two different media, laser-printed on film and on a softcopy workstation.

1-14-3-2 Materials and Methods

1-14-3-2-1 Digital Mammogram Case Selection

A total of 63 *Senoscan* digital mammograms were identified for use in the study. These cases contained 7 biopsy proven cancers and 13 biopsy-proven benign lesions. The remaining cases were of 23 patients who underwent six-month follow-up for probably benign findings and 20 cases without apparent findings. Of the 43 patients whose mammograms were included in the study who did not undergo biopsy, 42 had normal follow-up mammograms at one year after their study digital mammogram. The remaining patient had an unchanged mammogram at six months after her study digital mammogram.

SenoScan digital mammograms were selected from UNC case files. Digital mammograms were deemed suitable for inclusion in this study if the patient had had at least one prior screen-film mammogram available for comparison between 10 and 65 months previously and there were a total of four standard digital mammograms (two craniocaudal views and two mediolateral oblique views) that included all portions of both breasts. If more than one such eligible comparison mammogram existed, only the most recent comparison screen-film mammogram was used in the study. Otherwise suitable digital mammograms were excluded if they had been used in another digital mammography reader study that was occurring at the same time as this study, involving many of the same readers.

1-14-3-2-2 Reader Study

Participants and Prior Digital Mammography Experience

A total of 8 other radiologist readers participated in the reader study. Seven of the 8 readers had been trained in the interpretation of digital mammography through participation in prior reader studies at the University of North Carolina. This prior experience consisted of the interpretation of 200 printed digital mammograms.

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Reader Study Methodology

The 63 cases were divided into two sets of cases, set A and set B, for each of the two modalities, softcopy display and printed film, so that there were 4 sets of cases altogether (softcopy A, printed A, softcopy B, printed B). Four readers read all 63 cases in softcopy first, two readers starting with the cases in softcopy A, two readers starting with softcopy B. Similarly, the remaining four readers read all 63 cases on printed film first, two readers beginning with printed A, two readers beginning with printed B.

At least one month passed before each of the two groups of four readers read the cases in the other display condition. Again, half the readers were randomly assigned to begin with the cases in Block A first. The other half began with Block B. This counterbalancing of case display was intended to mitigate for the effects of learning and fatigue.

Statistical Analysis Methods

The same statistical analysis was conducted for all four outcome variables: area under the ROC curve (AUC), Sensitivity, Specificity, and Time. Nonparametric ROC analysis was conducted separately for each reader in each display (Film and Softcopy). This analysis created 16 values each of AUC, sensitivity, and specificity. Exploratory analysis of residuals was used to choose an appropriate transformation of time values to insure Gaussian errors. The reading time, t, for each case was transformed to log10(t). All such values were then averaged separately for each reader in each display (giving 16 observations).

The analysis data consisted of outcome means for each reader on each display medium. For each outcome, paired data t-tests and confidence intervals for the difference were computed.

Because there were four outcomes of interest, Bonferroni corrections were applied. AUC was tested at $\alpha = 0.02$, Sensitivity at $\alpha = 0.01$, Specificity at $\alpha = 0.01$, and Time at $\alpha = 0.01$. Retrospective power analysis was done to describe the power of the study against a range of interesting alternatives.

1-14-3-3 Results

A summary of the results of this study is shown in Table 1-5. As can be seen in the table, there was a tendency for interpretations on softcopy to be slightly faster than film interpretations. In addition, Area

under the ROC curve (0.67 film, 0.65 softcopy) and sensitivity (0.71 film, 0.69 softcopy) were slightly better for film than softcopy. Specificity was slightly better for softcopy than for film. None of these results was statistically significant.

The results of the study, after the interpretations of the mammogram of the one patient with only 6 months follow-up was excluded from the analysis, did not change in any substantial way. All differences between film and softcopy were in the same direction, and the values for time, AUC, sensitivity and specificity, as well as the still nonsignificant p values changed only very slightly.

Results for each individual reader in the study are shown in Table 1-6.

Table 1-5. Summary Results

	Film	Softcopy	Difference	Bonferroni Corrected 95% Confidence Intervals	P Value
AUC	0.673	0.647	0.026	-0.060 – 0.112	0.393
Sensitivity	0.708	0.687	0.021	-0.111 – 0.153	0.598
Specificity	0.528	0.563	-0.035	-0.243 – 0.172	0.572
Time	1.607	1.532	0.076	-0.058 – 0.209	0.088

In this table, Time is reported in log base 10 units. The mean film time is equivalent to 40.5 seconds. The mean Softcopy time is equivalent to 34 seconds. The differences reported correspond to Film – Softcopy. None of the p-values are significant.

Table 1-6. Reader Results

Reader	AUC		Sensitivity		Specificity		Time	
	Softcopy	Film	Softcopy	Film	Softcopy	Film	Softcopy	Film
A	0.52	0.50	0.50	0.50	0.42	0.47	2.01	1.93
B	0.60	0.50	0.67	0.50	0.28	0.26	1.71	1.85
C	0.58	0.67	0.67	0.67	0.43	0.61	0.88	1.16
D	0.77	0.73	0.83	0.83	0.75	0.42	1.37	1.35
E	0.60	0.73	0.67	0.83	0.74	0.53	1.63	1.67
F	0.72	0.73	0.67	0.67	0.84	0.82	1.56	1.64
G	0.63	0.72	0.67	0.83	0.39	0.50	1.40	1.53
H	0.76	0.79	0.83	0.83	0.65	0.60	1.69	1.73

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Table 1-6 lists the means within display medium for each reader. Time is reported in units of log10(seconds).

1-14-3-4 Conclusion

The results of this study are consistent with the hypothesis of equivalence of softcopy and film interpretation of digital mammograms. It seems unlikely that reading time is slower for softcopy systems. Less certainty surrounds the diagnostic accuracy estimates, although the data exclude very large differences.

1-15 PERSONNEL SAFETY

Everyone engaged in operating or using x-ray equipment must be familiar with the recommendations of the Center for Devices and Radiological Health (CDRH), National Bureau of Standards, the National Council on Radiation Protection (NCRP), and the International Committee on Radiation Protection (ICRP). The regulation of diagnostic medical x-ray equipment varies slightly from state to state. In general, all states adhere to the established recommendations of the NCRP.

Facility management must ensure that all personnel authorized to operate the x-ray system are familiar with the established regulations of the authorities named above.

Current sources of information include:

- National Council on Radiation Protection Report No. 102 ("Medical X-ray, Electron Beam, and Gamma-Ray Protection for Energies up to 50 MEV – Equipment Design, Performance, and Use – 1989"). (Internet URL is www.ncrp.com.)
- National Bureau of Standards Handbook No. 76 ("Medical X-ray Protection up to Three Million Volts"); Refer to NCRP Report No. 102. (Internet URL is www.ncrp.com.)
- Current recommendations of the International Committee on Radiation Protection.

Be certain all service and operating personnel are properly educated concerning the hazards of radiation. Persons responsible for the system must understand the safety requirements and special warnings for x-ray operation. Review this manual to become aware of all safety and operation requirements.

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