Senographe 2000D Full Field Digital Mammography System
Information for Use

CAUTION: United States Federal law restricts this device to use by or on the order of a physician.

DEVICE DESCRIPTION

The Senographe 2000D has been designed to perform screening examinations as well as diagnostic views (including spot compression, magnified, and/or coned views). It is a modular system that eliminates the need for film cassettes and takes advantage of digital technology, including on-screen image display, networking, filming, and archiving.

The Senographe 2000D is equipped with a dual track X-ray tube (molybdenum/rhodium) and a digital detector. The digital detector is a flat panel of amorphous silicon on which cesium iodide is deposited to maximize detection of X-rays. Positioning operations and X-ray exposure are controlled by the Control Panel which also controls power to all parts of the Senographe 2000D system. The Senographe 2000D includes an acquisition work station ("AWS") monitor, keyboard and mouse, computer, electronics, accessory storage, and uninterruptible power supply. The AWS is used for image acquisition, processing, and display. The AWS can also be used for database management, and can send images to archive, review, or filming.

Several options are available for use with the Senographe 2000D system. These options include a Senographe 2000D review workstation (not to be used for final interpretation of examinations), a mass archiving system, a laser camera, networking capabilities, and CD-ROM interchange media. The Senographe 2000D review workstation is a stand-alone workstation with its own dedicated computer and image database. The review workstation supports image display, and manipulation.

INDICATIONS FOR USE

The Senographe 2000D system generates digital mammographic images that can be used for screening and in the diagnosis of breast cancer. The Senographe 2000D is intended to be used in the same clinical applications as traditional mammographic screen-film systems.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS and PRECAUTIONS

For User

Senographe 2000D

- For U.S. only, until such time as an FDA approved accreditation process for full-field digital mammography has been developed, the Senographe 2000D Full Field Digital Mammography System must only be used in MQSA screen-film accredited/certified facilities.

- The light box (on the AWS cart) must *not* be used for final interpretation of examinations. The ambient light conditions in the examination room, and the resulting light level of the light box, are incompatible with its use for final interpretations.

- The (AWS) workstation monitor must *not* be used for final interpretation of examinations. It is set up for optimum visualization with an ambient light level of 50 lux. Leaving the AWS light box illuminated without a film in place may degrade reviewing quality of images displayed on the monitor.

- Only images produced by GE-recommended laser cameras can be used for final interpretation of examinations. For compatible printers, see the latest product data sheets for this system, which you can obtain from your local sales representative.

- The three-section table is not designed to hold items in excess of 20 kg weight.

- Never make a clinical examination without either the Bucky or the Breast Holder or the Magnification stand fitted; the unprotected edge of the Digital Detector may damage sensitive skin when compression is applied.

- Breast compression of at least 3 daN (30 Newtons or 6.7 pounds) is essential in AOP mode.

- The AWS Cart is mounted on wheels so that it can be easily positioned for maximum convenience in the examination room. It should NOT be considered a "mobile" unit. Take great care if you must move it in the vicinity of any person or equipment. Do not move it during an examination.

- The monitor should be used in a suitably dark environment when reviewing a digital image. The optimum ambient light level is 50 lux.

- NEVER switch off at the Uninterruptible Power Supply (UPS) except in emergency (risk of data loss).

- To assure continued high level operation of the Senographe 2000D, the recommended quality control procedures should be followed.

- All measurement values refer to measurements made at the image plane. When magnification mode is used, the zoom factor is NOT taken into account. All processed images in Medical Application are in log format. All raw images in RWS are in linear format. The displayed measurements represent the lengths and areas of the graphic annotations made by the user, not the real length or surface area of the pathologies displayed on the screen.

- Annotations added by the operator on the Acquisition Workstation will be lost during image transfer to the Review Workstation.

- In AOP mode, only use a 19 x 23 cm paddle. The use of all other paddles is only permitted in Manual mode. In AOP mode, the automatic calculation of administered dose will only be accurate if the 19 x 23 cm paddle (specific to the Senographe 2000D) is used. Paddles that are NOT to be used in AOP mode are labeled with the following symbols:

- Markers larger than 2 mm^2 should not be present in the ROI. Large markers will affect the calculation of tissue density, which may lead to a degraded image.

- After exposure press  (located on the right of the Control Console) for decompression if the automatic decompression is not set in the program.

- In the absence of the compression paddle, leave the space free between the bottom of the paddle arm and the top of the image receptor assembly.

- To avoid image loss, never touch the recordable surface of a recordable CD (CD-R). Handle the disk only by the outer edge. Do not place it face down on a hard surface. Fingerprints or scratches will make the disk unusable. Before usage, verify that CD-R surface has no visible scratches. If there are any scratches, do NOT use the CD-R.

Senographe 2000D Review Workstation

- The Senographe 2000D Review Workstation has not been cleared by the FDA for final interpretation of examinations. Final interpretations should be done from hard copy films only.

- The monitor should be used in a sufficiently dark environment (optimum ambient light level of 50 lux) when reading a digital image.

- Should it ever be necessary to remove all power from the workstation (for maintenance, or to move the workstation), workstation database corruption may occur if the following procedure is not used: You MUST first bring the workstation to the **Shutdown** state as

described in Section 3 of the Operator's Manual. Once the system is completely shut down, switch off the equipment in this order: workstation computer unit; monitors; external CD-ROM device; external hard disk unit (option); filming interface unit (option); and keypad.

- When saving images on a CD, it is strongly recommended that no other operation should be performed. For a full CD-R the save operation can take up to 45 minutes.

For Device

Senographe 2000D

- If the digital detector casing is punctured, it must be removed by authorized GE Service personnel wearing protective gloves and dust masks; send the protective items for disposal along with the defective detector.

- Only Senographe 2000D recommended accessories should be used with this equipment. Failure to heed this warning may cause unexpected functions and possible data loss.

- Software programs other than those supplied by General Electric Medical Systems specifically for use with this system must NOT be loaded onto the system.

- The Interchange Media option is NOT recommended for permanent archiving. GE does not guarantee the suitability of the media for such purposes.

Senographe 2000D Review Workstation

- The Interchange Media option is NOT recommended for permanent archiving. GE does not guarantee the suitability of the media for such purposes.

- The Review Workstation monitors are unshielded. Placing them in a high magnetic field (e.g., near an MR system magnet) can cause permanent damage, and may void the warranty.

For Cleaning And Disinfection

Senographe 2000D

- CIDEX (a cleaning solution) contains glutaraldehyde. Direct contact is corrosive to exposed tissue, causing eye damage and skin irritation/damage. Do not get into eyes, on skin or on clothing. Use in well ventilated area and store in closed containers.

- Adequate cleaning and disinfection is necessary to prevent disease transmission. Be sure to thoroughly clean and disinfect equipment surfaces that contact the patient and all equipment surfaces likely to become soiled during use.

- Improper cleaning methods or the use of certain cleaning and disinfecting agents can damage the equipment, cause poor imaging performance or increase the risk of electric shock. To avoid possible injury or equipment damage:

  - Do not use harsh detergents, abrasive cleaners, high alcohol concentration or Methanol at any concentration. If skin preparations contain high alcohol concentrations, allow sufficient drying time before applying compression;

  - Do not expose equipment parts to steam or high temperature sterilization;

  - Never allow liquids to enter the internal parts of the equipment. Do not apply cleaning sprays or liquids directly to the equipment; always use a clean cloth dampened with the spray or liquid. If you become aware of liquid entry, disconnect the electrical supply and have the equipment checked by qualified service personnel before returning it to use.

- Always follow the germicide manufacturer's instructions and precautions for mixing, storage, method of application, contact time, rinsing requirements, protective clothing, shelf life and disposal to help assure effective and safe use of the product.

Potential Adverse Effects

The following is a list of potential adverse effects that apply to mammography and are also applicable to digital mammography using the Senographe 2000D system.

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

SUMMARY OF CLINICAL STUDIES

A. Study Design and Objectives

A multi-center clinical trial of the Senographe 2000D full field digital mammography (FFDM) device was conducted in the United States comparing results obtained with the Senographe 2000 D to results obtained with screen-film mammography (SFM) systems.

The objective of the study was to test the non-inferiority of Senographe 2000D compared to SFM in a mixed diagnostic and screening population. Sensitivity, receiver operating characteristics (ROC), and specificity analyses were performed. A side-by-side feature comparison was also performed.

B. Study Population

- Cancer cases were identified from a diagnostic cohort and a screening cohort. The diagnostic cohort consisted of 605 women presenting for diagnostic mammography.

- Six hundred twenty-five (625) women (44 cancer cases and 581 non-cancer cases) were included in the combined study cohort.

- Fifty-five percent (55%) (24/44) of the cancer cases in the study cohort were derived from a diagnostic population and forty-five percent (45%) (20/44) were derived from a screening population. The study population provided adequate information about use of the device in a diagnostic population and provided some additional information about use of the device in a screening population. While this study cohort was a mixture of diagnostic patients and screening cancers, the distribution of cancer stages and sizes was not statistically different from that of a screening population.

- Sixty-one percent (61%) of the cancers in the study were Stage 0 or I. Thirty-nine percent (39%) were Stages II, III, and IV. Forty-three percent (43%) of the cancers were less than or equal to 1 cm; fifty-seven percent (57%) of the cancers were larger than 1 cm.

C. Results

- Receiver Operating Characteristic (ROC) curve area was 0.722 for Senographe 2000D versus 0.723 for SFM. Based on the 95% confidence interval for the difference between ROC curve areas, the ROC curve area of Senographe 2000D could be as much as 0.073 below, to as much as 0.055 above, that of SFM. Thus the null hypothesis that the ROC curve area of Senographe 2000D was lower than that of SFM by more than 0.10 was rejected ($p<0.0001$).

- Sensitivity was 68% for Senographe 2000D versus 70% for SFM, for all cancer stages and sizes. Based on the 95% confidence interval for the difference in sensitivities, the sensitivity of Senographe 2000D could be as much as 9.96% below, to as much as 7.24% above, that of SFM. Thus the null hypothesis that the sensitivity of Senographe 2000D was lower than that of SFM by more than 10% was rejected ($p=0.0245$).

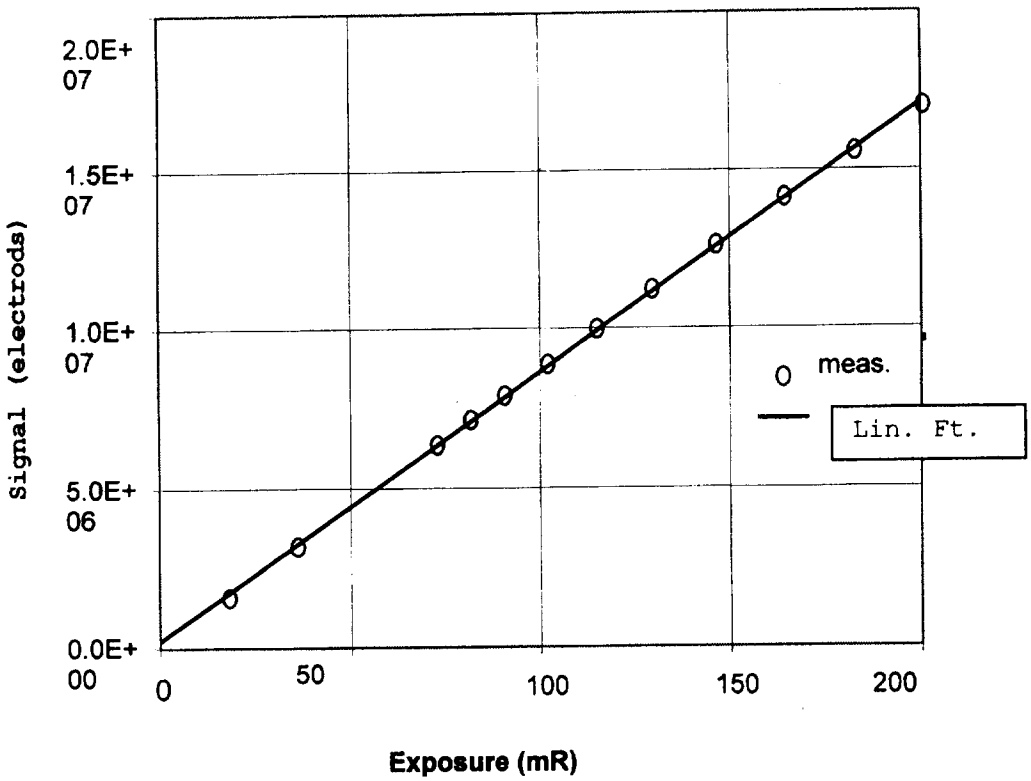
- Specificity was 55% for Senographe 2000D versus 53% for SFM, for all cancer stages and sizes. Thus the recall rate in this study for lesions that turned out to be benign was 45% for Senographe 2000D versus 47% for SFM. Based on the 95% confidence interval for the difference in specificities, the specificity of Senographe 2000D could be as much as 0.58% below, to as much as 4.36% above, that of SFM. Thus the null hypothesis that the specificity of Senographe 2000D was lower than that of SFM by more than 5% was rejected ($p<0.001$).

- Side-by-side feature comparison data demonstrated that Senographe 2000D allows better visibility of tissue at the skin line than SFM and that Senographe 2000D is equivalent to SFM for lesion conspicuity and visibility of tissue at the chest wall.

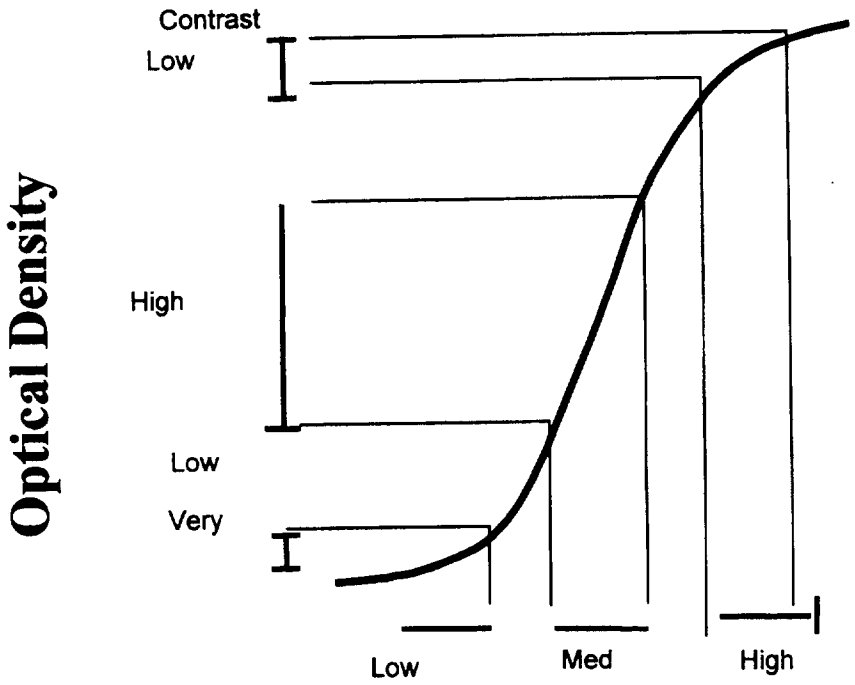
NONCLINICAL STUDIES

A. Dynamic Range and Sensitometric Response

The detector exhibits a response that is linear over a range of 0 to 153 mR at the breast support surface. The range of exposure over which linear response is achieved is at least 3 times larger than the linear portion of a SFM sensitometric curve.



Digital Detector Response



Film / Screen Response

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B. Detective Quantum Efficiency (DQE)

DQE measures the efficiency by which a system transfers signal and noise. It is defined as the ratio of the square of input signal-to-noise ratio (SNR) to the square of input SNR. Since the output SNR is a measure of the displayed image quality and the input SNR can be related to patient dose, DQE can be considered as a ratio of image quality to patient dose. Doubling DQE means that one gets the same image quality at half the dose or a 40% improvement in image quality for the same dose.

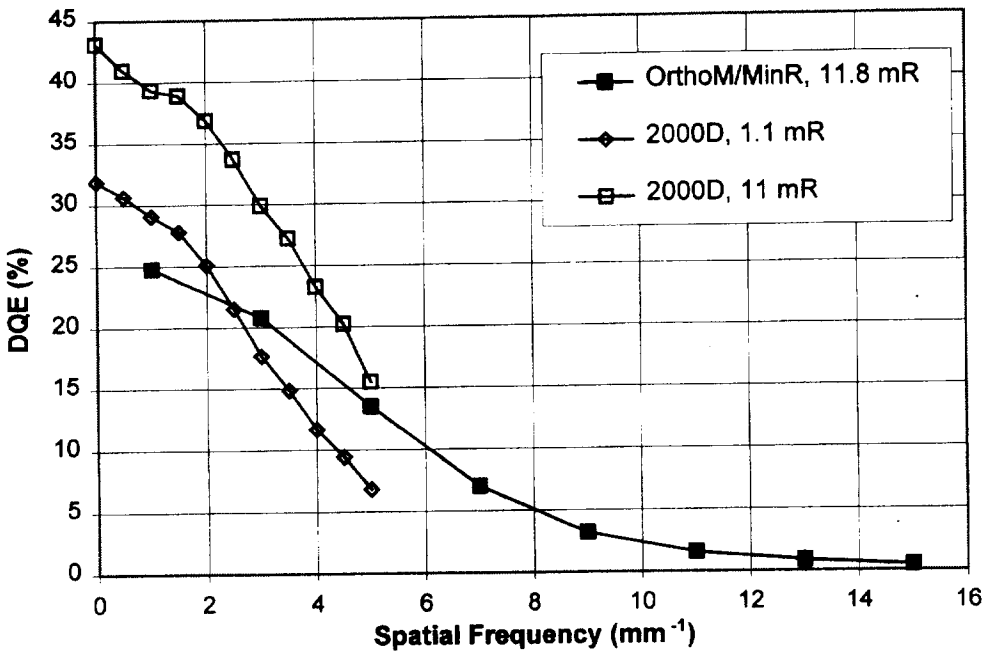
$$DQE = \frac{SNR^2 \text{ at detector output}}{SNR^2 \text{ at detector input}} \propto \frac{\text{Image Quality}}{\text{Patient Dose}}$$

where SNR = signal-to-noise ratio

C. Comparison of Senographe 2000D and SFM DQE

At detector exposure levels characteristic of those used in screen-film mammography (10 to 15 mR), the DQE of the Senographe 2000D exceeds that of common screen-film systems throughout the 0 to 5 cycle/mm range. Even at 1 mR, the low-frequency DQE of the Senographe 2000D exceeds that of screen-film systems when used at ten times the exposure level. While the DQE of screen-film systems extends to higher spatial frequencies, the output SNR is often dominated by film-grain noise and not quantum noise. Because of the essentially linear response of the Senographe 2000D detector, quantum-limited performance and substantially constant DQE are achieved over a wide range of exposure levels. DQE of Senographe 2000D exceeds that of SFM up to the 5 lp/mm Nyquist frequency.

DQE of the Senographe 2000D and a Screen-Film System

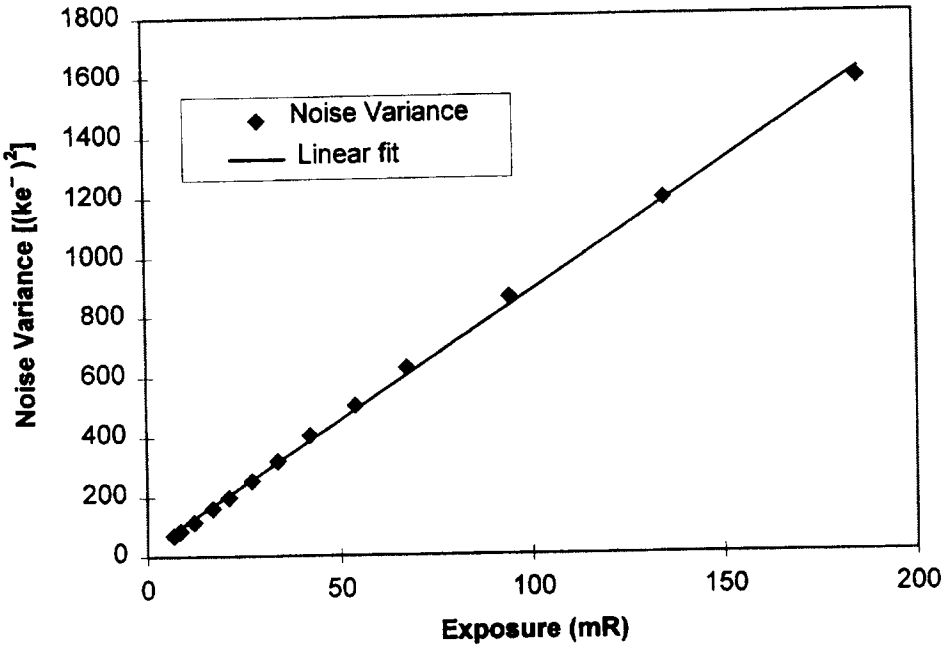


All Senographe 2000D DQE measurements shown here were made using 30 kVp, Rh anode track, Rh filter, and added filtration of 1.5 cm acrylic plus 3 mm Al. Exposures at the detector entrance plane are included with the data.

D. DQE versus Exposure Level - Quantum-Limited Performance

The detector of the Senographe 2000D not only exhibits a linear signal response over a wide exposure range, it also exhibits a quantum-limited noise response. Quantum-limited response is evidenced by image noise variance (the square of the standard deviation of the pixel values within a region of interest) that increases linearly with the exposure to the detector.

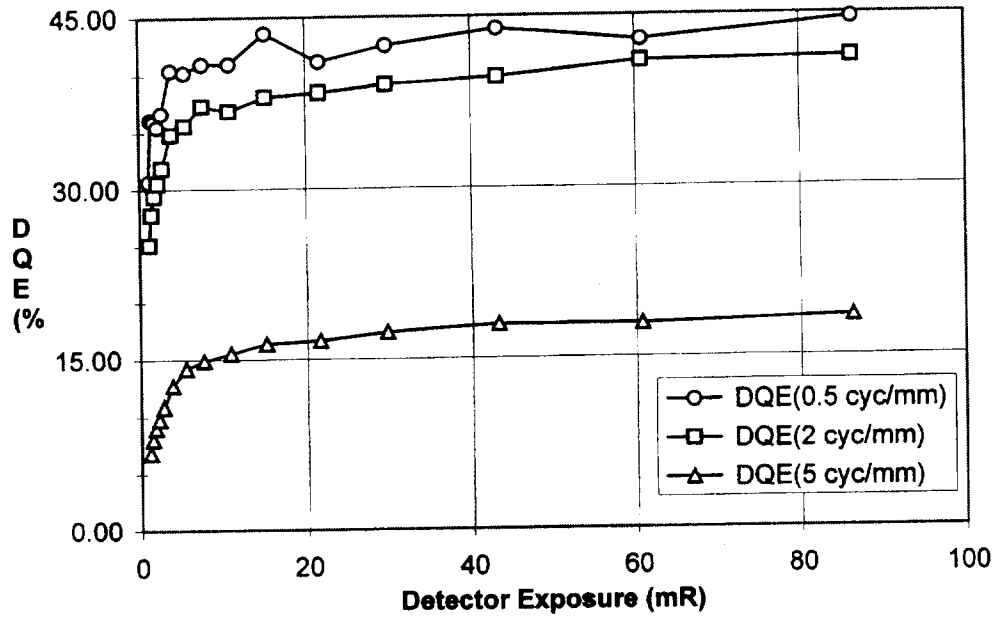
Image Noise vs. Exposure for the Senographe 2000D



At low exposure levels, the plot of image noise variance vs. exposure commonly deviates from a straight line due to the influence of noise in the imaging system. For the Senographe 2000D, this deviation is not evident until the exposure at the detector is less than about 3 mR.

The combination of linear signal response and quantum-limited noise response leads to a DQE that is independent of exposure level over a broad range of exposures. Unlike screen-film systems, which tend to have low DQE at high film densities (near the skin line) and at low film densities (in the image of glandular tissue or near the chest wall), the Senographe 2000D provides uniformly high DQE throughout the mammogram. This provides a probability of detection of an abnormality that is less dependent on its location than is the case for screen-film detectors.

DQE vs. Exposure at Three Spatial Frequencies



DQE is essentially independent of exposure for exposures at the detector plane greater than about 3 mR. Therefore, the Senographe 2000D DQE has little dependence on the exposure level for the clinical exposure range.

E. Conclusions

The range of linear signal response for the Senographe 2000D is significantly better than that of screen film.

The detective quantum efficiency (DQE) for the Senographe 2000D is comparable to or higher than screen film up to its Nyquist frequency (5 lp/mm), though beyond that frequency the Senographe 2000D gives no meaningful information.

Below the Nyquist frequency, for exposures that are typical near the skin line or in a dense area of the breast, the Senographe 2000D has a DQE that is higher than that of screen-film by a factor of 2 to10. Furthermore, at these spatial frequencies the Senographe 2000D has nearly constant DQE over the range of exposures commonly found in a mammogram, while that of screen-film varies by a factor of 3 to 5 between the mid- and high-density regions

While the higher DQE for the Senographe 2000D at spatial frequencies less than or equal to the Nyquist frequency suggests the possibility that mammograms may be taken at a lower radiation dose, particularly in dense breasted women, the accuracy of mammographic interpretation at lower doses has not been studied to determine whether the absence of information above the Nyquist frequency is clinically important.

The combination of linear signal response and quantum-limited noise response leads to a DQE that is independent of exposure level over a broad range of exposures. Unlike

screen-film systems, which tend to have low DQE at high film densities (near the skin line) and at low film densities (in the image of glandular tissue or near the chest wall), the Senographe 2000D provides uniformly high DQE throughout the mammogram. This provides a probability of detection of an abnormality that is less dependent on its location than is the case for screen-film detectors. This was shown to be true by the side-by-side feature comparison (see section I of CLINICAL STUDIES).

The Senographe 2000D has wider exposure latitudes, higher DQE, allows for electronic archival transmission and image manipulation, and involves shorter examination time. The ability to manipulate images has the potential to eliminate the need for additional magnification of views. Similarly, windowing and leveling can compensate for exposure variations eliminating the need for repeated exposures or exposures adjusted to specifically view the skin line or the chest wall.

CLINICAL STUDIES

A. Study Design and Objectives

A multi-center clinical trial of the Senographe 2000D full field digital mammography (FFDM) device was conducted in the United States comparing results obtained with the Senographe 2000D to results obtained with screen-film mammography (SFM) systems.

The objective of the study was to test the non-inferiority of the Senographe 2000D compared to SFM in a mixed diagnostic and screening population. Sensitivity, receiver operating characteristics (ROC), and specificity analyses were performed. A side-by-side feature comparison was also performed.

B. Study Population

Women aged 40 or older attending for diagnostic mammography were included in the study. Women were excluded from the study if they were pregnant or suspicious of being pregnant; had breast implants; had breasts too large to be adequately positioned on a 24 x 30 cm screen -film receptor; had non-focal or bilateral breast pain; or who were unable or unwilling to execute the consent form.

Six hundred twenty-five (625) women (44 cancer cases and 581 non-cancer cases) were included in the study cohort. Cancer cases were identified from a diagnostic cohort and a screening cohort. The diagnostic cohort consisted of 605 women presenting for diagnostic mammography at four sites [the University of Colorado Health Sciences Center (UCHSC), the University of Massachusetts Medical Center (UMMC), Hospital of the University of Pennsylvania (HUP), and Massachusetts General Hospital (MGH)]. This population included 24 diagnostic cancer cases. The screening cohort consisted of 20 consecutive cancer cases generated from a screening population of over 4,000 women. The screening cohort was conducted at UCHSC and UMMC.

Fifty-five percent (55%) (24/44) of the cancer cases in the study cohort were derived from a diagnostic population and forty-five percent (45%) (20/44) were derived from a screening population. The study population provided adequate information about use of the device in a diagnostic population and provides additional information about use of the device in a screening population. While this study cohort was a mixture of diagnostic patients and screening cancers, the distribution of cancer stages and sizes was not statistically different from that of a screening population.

C. Demographics

The average age for the women in the study was 55 years with a range from 40-86 years. Eighty-five percent (85%) of the women were white, 8% were African-American, 2% Hispanic, 1% Asian, and 4% unknown. Thirty-four percent (34%) of the women reported a history of breast-related medical diseases or conditions and 33% reported a history of hormone replacement therapy.

D. Image Acquisition and Interpretation

Two views, craniocaudal (CC) and mediolateral (MLO), of each breast were acquired by each modality using GE Medical Systems' (GEMS) Senographe 2000D system with equal or slightly lower breast doses than SFM. Equivalent target-filter, kVp, and equal or slightly lower mA values were used on the Senographe 2000D. The same technologist performed both the Senographe 2000D and SFM imaging with similar positioning and compression forces. Fifty-nine percent (59%) were bilateral exams and 41% were unilateral exams.

Five MQSA-qualified radiologists independently interpreted each SFM and Senographe 2000D image. The radiologists had no prior knowledge of the cases. Senographe 2000D images were stored digitally and printed at UCHSC and UMMC to provide comparability to SFM. Each radiologist interpreted half the SFM cases first and half the Senographe 2000D cases first, with at least 30 days between interpretations of the same case from each of the two modalities. For each case, the radiologist provided BIRADS categories (0, 1, 2, 3, 4, or 5) and a probability of cancer on a 0-100% scale for BIRADS 0, 3, 4, and 5 breasts.

E. Cancer Stage and Size Distribution

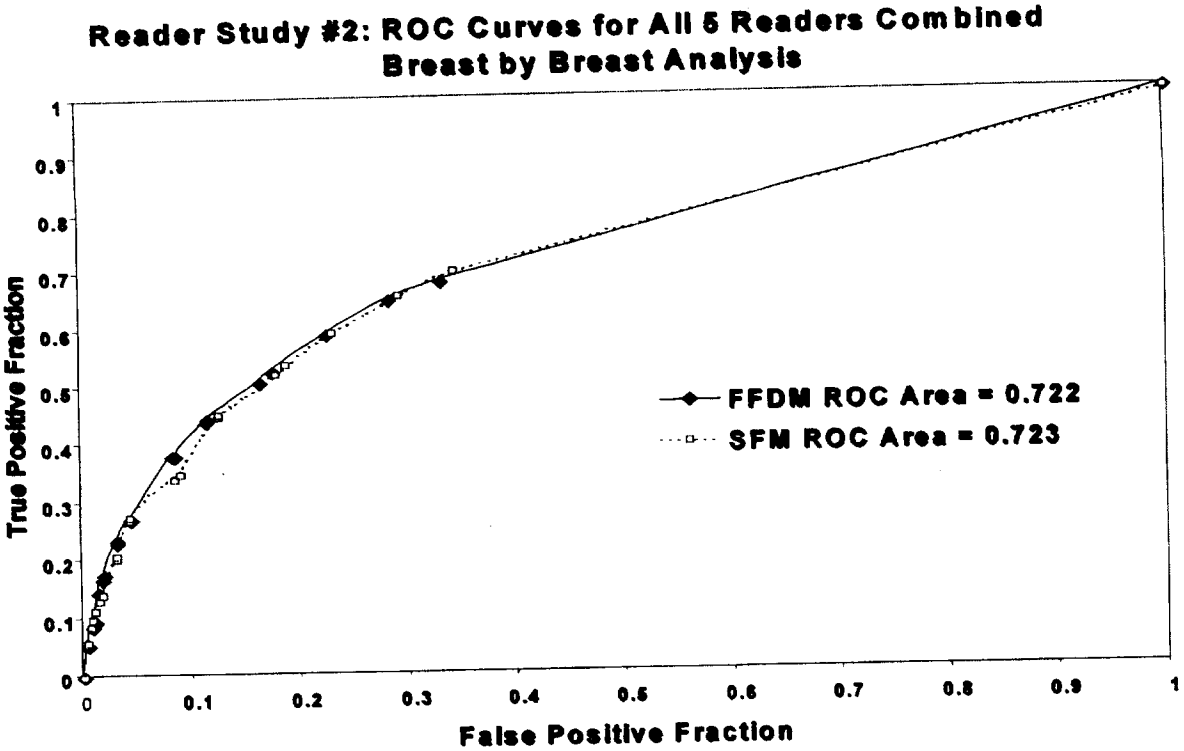
Sixty-one percent (61%) of the cancers in the study were Stage 0 or I. Thirty-nine percent (39%) were Stages II, III, and IV. Forty-three percent (43%) of the cancers were less than or equal to 1 cm; fifty-seven percent (57%) of the cancers larger than 1 cm.

The Agency for Health Care Policy and Research (AHCPR) Clinical Practice Guidelines recommend that in a good mammography program at least 50% of detected cancers should be Stage 0 or I and at least 30% of detected cancers should be less than or equal to 1 cm in size. The percentage of Stage 0 and I cancers in this study exceeded the AHCPR guideline for Stage 0 and I cancers by 11% and exceeded the AHCPR guideline for small cancers by 13%.

F. ROC Curve Results

ROC curves were constructed from all cases assigned a BIRADS code of 0, 3, 4, or 5, using independent interpretations of Senographe 2000D and SFM based on the probabilities of cancer (on a 0-100% scale). ROC curve areas were 0.722 for Senographe 2000D versus 0.723 for SFM.

Based on the 95% confidence interval for the difference between ROC curve areas, the ROC curve area of Senographe 2000D could be as much as 0.073 below, to as much as 0.055 above, that of SFM. Thus the null hypothesis that the ROC curve area of Senographe 2000D was lower than that of SFM by more than 0.10 was rejected ($p<0.0001$).


Reader Study #2: ROC Curves for All 5 Readers Combined
Breast by Breast Analysis
True Positive Fraction
False Positive Fraction
FFDM ROC Area = 0.722
SFM ROC Area = 0.723
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1

G. Sensitivity Results

A comparison was made of the fraction of total cancers among the study cohort that were detected by Senographe 2000D and SFM, giving an estimated sensitivity for each modality. For all cancer stages and sizes, the sensitivity was 68% for Senographe 2000D compared to 70% for SFM, for all cancer stages and sizes.

Based on the 95% confidence interval for the difference in sensitivities, the sensitivity of Senographe 2000D could be as much as 9.96% below, to as much as 7.24% above, that of SFM. Thus the null hypothesis that the sensitivity of Senographe 2000D was lower than that of SFM by more than 10% was rejected ($p=0.0245$).

H. Specificity Results

Specificity was 55% for Senographe 2000D versus 53% for SFM, for all cancer stages and sizes. Thus the recall rate in this study for lesions that turned out to be benign was 45% for Senographe 2000D versus 47% for SFM.

Based on the 95% confidence interval for the difference in specificities, the specificity of Senographe 2000D could be as much as 0.58% below, to as much as 4.36% above, that of SFM. Thus the null hypothesis that the specificity of Senographe 2000D was lower than that of SFM by more than 5% was rejected ($p<0.001$).

I. Side-by-Side Feature Comparison

The side-by-side feature analysis comparison included 40 cancer cases. All 40 cases had MLO comparisons and 39 had CC comparisons for a total of 79 views. Both Senographe 2000D and SFM images were placed on the same mammography alternator or bank of viewboxes. Five (5) independent MQSA-qualified radiologists evaluated lesion conspicuity, inclusion of tissue along the chest wall, and visibility of tissue at, or near, the skin line of the breast using an 11-point Likert scale (0-4 favoring Senographe 2000D, 5 equally visible on Senographe 2000D and SFM, 6-10 favoring SFM). An overall mean value was calculated across all readers and views.

For visibility near the skin line, readers could see tissue at the skin line better with Senographe 2000D than with SFM (mean value of 2.95). Lesion conspicuity and tissue at the chest wall were equally visible with mean values of 5.17 and 5.21, respectively. Readers could, on average, discriminate calcifications, masses, architectural distortions, and focal asymmetry equally well on Senographe 2000D and SFM.

J. Safety

No adverse consequences (serious or otherwise) were reported for patients enrolled during the study.

K. Conclusions

- Data derived from clinical trials, in conjunction with preclinical data on the physical parameters of the system, provide reasonable assurance that the Senographe 2000D system is safe and effective for use in screening and diagnosis of breast cancer.

- The ROC curve areas for the Senographe 2000D and SFM systems are virtually identical.

- The sensitivity analysis demonstrated that the Senographe 2000D has a sensitivity comparable to that of SFM in the screening and detection of breast cancer.

- The specificity analysis demonstrated that the Senographe 2000D system results in fewer women being recalled than SFM.

- The side-by-side feature comparison data demonstrated that the Senographe 2000D system allows better visibility of tissue at the skin line than SFM and that the Senographe 2000D system is comparable to SFM for lesion conspicuity and visibility of tissue at the chest wall.

CONFORMANCE TO STANDARDS

The GE Medical Systems Senographe 2000D system meets the following standards:

- IEC 601-1: Medical electrical equipment - General requirements for safety (cert. N° 0004/601.1/15 for Senographe 2000D and cert. N° 0004/601.1/13 for Acquisition WorkStation in Annex).
- IEC 601-1-1: Medical electrical equipment — Collateral standard: Safety requirements for medical electrical systems (cert. N° 0004/601.1.1/27 in Annex).
- IEC 601-1-2: Medical electrical equipment — Collateral standard: Electromagnetic compatibility for medical electric systems (AC N° 032/AF-99-40137 for Senographe 2000D and AC N° 033/AF-99-40138 for Review WorkStation in Annex).
- IEC 601-1-3: Medical electrical equipment — Collateral standard: Requirements for radiation protection in diagnostic X-ray equipment (cert. N° 004/601.1.3/5 in Annex).
- IEC 601-2-32: Medical electrical equipment — General requirements for Safety (cert. N° 0004/601.2.32/8 in Annex).
- IEC 601-2-45: Medical electrical equipment — Particular requirements for the safety of mammography X-ray equipment (cert. N° 0004/601.2.45/1 in Annex).
- IEC 601-1-4: Medical electrical equipment — Collateral Standard: programmable electrical medical systems.
- IEC 905: Safety of information technology equipment (Review Workstation)

TRAINING PROGRAM

Users must ensure that they receive training on the Senographe 2000D with GE Medical Systems training programs prior to use on patients. GE Medical System training programs will address the new MQSA training regulations in product labeling to ensure that prospective users are aware of the required eight hours of training for any medical physicist, technologist, or interpreting physician. *The recommended training program is documented in the Operator's Manual.*

OPERATOR MANUAL/DIRECTIONS FOR USE

A copy of the table of contents from the Senographe 2000D and Senographe 2000D Review Workstation Operator Manuals are provided on the following pages. The user should refer to the Operator Manuals for directions on how to use the Senographe 2000D system.

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PRODUCT COMPLAINTS

Any health care professional (e.g., customer or user of this system of products) who has any complaints or has experienced any dissatisfaction in the quality, durability, reliability, safety effectiveness and/or performance of this product, should notify GEMS. If the device malfunctions and may have caused or contributed to a serious injury of a patient, GEMS should be notified immediately by telephone, fax, or written correspondence.