## UNCLASSIFIED

## AD NUMBER

### ADB246947

## NEW LIMITATION CHANGE

#### TO

Approved for public release, distribution unlimited

## FROM

Distribution authorized to U.S. Gov't. agencies only; Proprietary Info.; Jan 99. Other requests shall be referred to US Army Medical Research and Materiel Comd., 504 Scott St., Fort Detrick, MD 21702-5012.

## AUTHORITY

U.S. Army Medical Research and Materiel Command and Fort Detrick ltr., dtd October 17, 2001.

AD

#### CONTRACT NUMBER DAMD17-96-C-6104

TITLE: Clinical and Technical Evaluation of Full-Field Digital Mammography

PRINCIPAL INVESTIGATOR: R. Edward Hendrick, Ph.D.

CONTRACTING ORGANIZATION: University of Colorado Health Science Center Denver, Colorado 80262

REPORT DATE: January 1999

TYPE OF REPORT: Annual

PREPARED FOR: Commander U.S. Army Medical Research and Materiel Command Fort Detrick, Frederick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Distribution authorized to U.S. Government agencies only (proprietary information, Jan 99). Other requests for this document shall be referred to U.S. Army Medical Research and Materiel Command, 504 Scott Street, Fort Detrick, Maryland 21702-5012.

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

#### DTIC QUALITY INSPECTED 4

19990902 089

USING GOVERNMENT DRAWINGS, SPECIFICATIONS, OR OTHER DATA INCLUDED IN THIS DOCUMENT FOR ANY PURPOSE OTHER THAN GOVERNMENT PROCUREMENT DOES NOT ΤN ANY WAY U.S. OBLIGATE THE GOVERNMENT. THE FACT THAT THE GOVERNMENT FORMULATED OR SUPPLIED THE DRAWINGS, SPECIFICATIONS, OR OTHER DATA DOES NOT LICENSE THE HOLDER OR ANY OTHER PERSON OR CORPORATION; OR CONVEY ANY RIGHTS OR PERMISSION TO MANUFACTURE, USE, OR SELL ANY PATENTED INVENTION THAT MAY RELATE TO THEM.

#### LIMITED RIGHTS LEGEND

Award Number: DAMD17-96-C-6104 Organization: University of Colorado Health Science Center Location of Limited Rights Data (Pages):

Those portions of the technical data contained in this report marked as limited rights data shall not, without the written permission of the above contractor, be (a) released or disclosed outside the government, (b) used by the Government for manufacture or, in the case of computer software documentation, for preparing the same or similar computer software, or (c) used by a party other than the Government, except that the Government may release or disclose technical data to persons outside the Government, or permit the use of technical data by such persons, if (i) such release, disclosure, or use is necessary for emergency repair or overhaul or (ii) is a release or disclosure of technical data (other than detailed manufacturing or process data) to, or use of such data by, a foreign government that is in the interest of the Government and is required for evaluational or informational purposes, provided in either case that such release, disclosure or use is made subject to a prohibition that the person to whom the data is released or disclosed may not further use, release or disclose such data, and the contractor or subcontractor or subcontractor asserting the restriction is notified of such release, disclosure or use. This legend, together with the indications of the portions of this data which are subject to such limitations, shall be included on any reproduction hereof which includes any part of the portions subject to such limitations.

THIS TECHNICAL REPORT HAS BEEN REVIEWED AND IS APPROVED FOR PUBLICATION.

Noungha aboren Minha 8/3/99

|   | REPORT DO  | CUMENTATION P  | AGE  | Form Approved<br>OMB No. 0704-0188  |
|---|--|--|--|---|
|   | Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503. |  |  |   |
| 1 | 1. AGENCY USE ONLY (Leave blank)   | <b>2. REPORT DATE</b><br>January 1999  | 3. REPORT TYPE AND<br>Annual (30 Dec   | <b>D DATES COVERED</b><br>ac 97 - 29 Dec 98)  |
| 4 | <ol> <li>TITLE AND SUBTITLE</li> <li>Clinical and Technical E</li> <li>Mammography</li> </ol>  | valuation of Full-F  | ield Digital   | 5. FUNDING NUMBERS<br>DAMD17-96-C-6104  |
| e | 6. AUTHOR(S)<br>R. Edward Hendrick, Ph.  | D.   |  |   |
| 7 | 7. PERFORMING ORGANIZATION NAM<br>University of Colorado H<br>Denver, Colorado 80262   | <b>IE(S) AND ADDRESS(ES)</b><br>Wealth Science Cente   | r  | 8. PERFORMING ORGANIZATION<br>REPORT NUMBER   |
|   | 9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)<br>Commander<br>U.S. Army Medical Research and Materiel Command<br>Fort Detrick, Frederick, Maryland 21702-5012  |  |  | 10. SPONSORING/MONITORING<br>AGENCY REPORT NUMBER   |
| - | <ul> <li>11. SUPPLEMENTARY NOTES</li> <li>12a. DISTRIBUTION / AVAILABILITY S</li> <li>Distribution authorized<br/>information, Jan 99). (U.S. Army Modical Posco)</li> </ul>   | TATEMENT<br>to U.S. Government<br>Other requests for t   | agencies only (p<br>this document sha  | <b>12b. DISTRIBUTION CODE</b><br>proprietary<br>all be referred to  |
|   | Maryland 21702-5012.   |  |  | Street, Fort Detrick,   |
|   | This report summarized<br>field digital mammogra<br>Accomplishments duri<br>technique factors to m<br>performance of FFDM<br>volunteers over the pa<br>women at the two scre<br>statistically significant  | es the work performed<br>aphy (FFDM) as a scr<br>ng year two include 1<br>aximize low-contrast<br>in addition to screen-<br>ast year, bringing the t | in Year 2 of a three<br>eening tool for bree<br>further progress to<br>esion detection wi<br>film mammograph<br>otal number of stu-  | ee-year study to evaluate ful<br>east cancer.<br>toward optimization of<br>vith FFDM, and 2)<br>ny on over 3,000 women<br>udy participants to 3,961<br>wim clinical results include a |
|   | indistinguishable sens<br>limited number of can<br>volunteer accrual will<br>addition of new study   | lower false positive ra<br>itivities to breast cano<br>cer cases (22) include<br>be higher due to incre<br>sites at Bethesda Nav                     | and OMMC). Inter<br>te with FFDM than<br>er with the two mo<br>d among study vo<br>ased accrual at U0<br>ral Hospital and the  | on with SFM and statistically<br>odalities, in part due to the<br>plunteers to date. In Year 3,<br>CHSC and UMMC, plus the<br>ne University of South Florida                          |
|   | indistinguishable sens<br>limited number of can<br>volunteer accrual will<br>addition of new study   | lower false positive ra<br>itivities to breast cano<br>cer cases (22) include<br>be higher due to incre<br>sites at Bethesda Nav                     | and OMMC). The<br>te with FFDM than<br>er with the two mo<br>d among study vo<br>ased accrual at U0<br>ral Hospital and the  | on with SFM and statistically<br>odalities, in part due to the<br>plunteers to date. In Year 3,<br>CHSC and UMMC, plus the<br>ne University of South Florida                          |
| - | indistinguishable sens<br>limited number of can<br>volunteer accrual will<br>addition of new study<br>14. SUBJECT TERMS Breast Car<br>Breast cance<br>Mammogra   | lower false positive ra<br>itivities to breast cano<br>cer cases (22) include<br>be higher due to incre<br>sites at Bethesda Nav                     | and OWINC). The<br>te with FFDM than<br>er with the two mo<br>d among study vo<br>ased accrual at UC<br>ral Hospital and the<br>mography, image qua<br>mography, radiation d | ality<br>dose   |
|   | indistinguishable sens<br>limited number of can<br>volunteer accrual will<br>addition of new study<br>14. SUBJECT TERMS Breast Car<br>Breast cance<br>Mammograj<br>17. SECURITY CLASSIFICATION 18.<br>OF REPORT  | lower false positive ra<br>itivities to breast cance<br>cer cases (22) include<br>be higher due to incre<br>sites at Bethesda Nav                    | mography, image qual<br>mography, radiation d<br>mography, radiation d<br>mography, radiation d  | ality<br>dose<br>FICATION<br>20. LIMITATION OF ABSTRA   |

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

FOREWORD

\_\_\_\_\_ Where copyrighted material is quoted, permission has been obtained to use such material.

\_\_\_\_\_ Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

 $R^{t}\underline{A} \times Citations$  of commercial organizations and trade names in this report do not constitute an official Department of Army endorsement or approval of the products or services of these organizations.

<u>NA</u> In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and use of Laboratory Animals of the Institute of Laboratory Resources, national Research Council (NIE Publication No. 86-23, Revised 1985).

 $\mu M \times$  For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

<u>NA</u> In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

 $\underline{NH}$  In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

 $\underline{NH}$  In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

REMEnduck 2/3/99

PI - Signature

Date

## TABLE OF CONTENTS

## Page Number

| FRONT COVER                        | 1     |
|------------------------------------|-------|
| REPORT DOCUMENTATION PAGE (SF 298) | 2     |
| FOREWORD                           | 3     |
| TABLE OF CONTENTS                  | 4     |
| INTRODUCTION                       | 5     |
| BODY OF REPORT                     | 6-15  |
| CONCLUSIONS                        | 16    |
| REFERENCES                         | 17-18 |
| APPENDIX:                          | 19-26 |
| Figures 1-8                        | 19-26 |
| Figure Captions                    | 27-28 |

. .≯ ₩ .≯

4

#### INTRODUCTION

This report summarizes the work performed in year two of a three-year study to evaluate full-field digital mammography (FFDM) as a screening tool for breast cancer. The goal of this project is to evaluate FFDM as a screening tool for breast cancer. The study began December 30, 1996, and is being conducted at two institutions: the University of Colorado Health Sciences Center (UCHSC) and University of Massachusetts Medical Center (UMMC).

The first year's work on this project was devoted to acquisition and technical evaluation of two prototype full-field digital mammography systems, comparison of low-contrast lesion detection using FFDM with that of screen-film mammography (SFM), and implementation of a clinical study comparing screen-film and FFDM in screening for breast cancer. Year 1 technical evaluation results indicated that with the current GE- FFDM prototype systems, 100 micron mode had superior low-contrast detection to 50 the micron mode. In addition, we found that for compressed breasts greater than 2-4 cm thickness, grid use gave superior low-contrast detection to non-grid systems using the same technique factors. We also found that FFDM using 100 micron pixels with a grid, and with techniques matched to those of SFM, demonstrated slightly better detection of simulated low-contrast lesions than SFM with optimized optical densities (also with a grid) across the entire spectrum of breast thicknesses and compositions.

The work performed during year two of this project included: 1) additional technical evaluation directed toward optimizing clinical technique factors on the GE full-field digital detector system, and 2) continued progress on the clinical comparison of full-field digital mammography to screen-film mammography.

#### BODY OF REPORT

The body of this report contains Methods and Results of the second year's progress in this project on full-field digital mammography. The Methods for each experiment are listed first, then the corresponding Results.

#### I. Methods

4

#### **Technical Evaluation of FFDM**

To optimize technique factors for FFDM, we began by studying the relationship among low-contrast lesion detection, signal-to-noise ratios (SNR), compressed breast thickness, and digital technique factors. First, for a range of simulated breast thicknesses (2-6 cm) we varied mAs at a fixed target-filter and kVp using a contrast detail phantom that allowed quantitation of low-contrast detection and signal-to-noise ratios under each imaging condition. The contrast-detail (CD) phantom was developed previously at UCHSC and consists of a 9 by 9 array of low-contrast circular test objects milled into a Dshaped 1 cm thick section of breast equivalent material, to which additional 1 cm thick sections of D-shaped breast materials are added to give the total thicknesses of 2, 4, and 6 cm. Each row of the CD pattern contained 9 low-contrast targets at a fixed level of contrast with different object diameters ranging from 0.25 mm to 4 mm. Each column contained a fixed size object, with subject contrast ranging from 0.29% to 3.95%. In the first experiment, digital images were acquired for 2, 4, and 6 cm breast thicknesses at fixed target-filter (Mo/Mo) and kVp (25) over the full allowable range of mAs values (4 mAs to 600 mAs). Signal-to-noise ratios were measured using ROI software on a uniform portion of the phantom for each exposure. CD scores were independently determined for each exposure by four medical physicists assessing detected low-contrast objects in each image under standardized viewing conditions using a standardized scoring method previously developed. CD scores represent the area of detected objects in contrast-detail space from zero (no objects detected) to 17.34 (all 81 objects detected). Signal, SNR, and CD scores were plotted versus mAs for each breast thickness to display results. CD scores also were plotted versus SNR for all breast thicknesses.

#### Matching Breast Doses Between SFM and FFDM for Various Techniques

A second phase of the optimization of FFDM technique factors is to determine the constraints under which low-contrast detection capabilities will be compared experimentally. For this task, we have chosen to match digital techniques to screen-film techniques for a given breast thickness and to compare different digital techniques under the constraint of equal breast doses for a given breast thickness. All SFM image acquisition was done on a GE-DMR mammography unit using automatic optimization of parameters (AOP) mode. Kodak Min R-2000 film was used Kodak Min R- 2000 cassettes. Films were processed on a Kodak M8 processor with Kodak chemistry and autoloading. SFM phantom images were obtained with a narrow range of background film

optical densities yielding maximum low-contrast detection (1.60-1.70). To equalize breast dose to SFM techniques, we measured half-value layers (HVLs) and X-ray output values at each target-filter and kVp setting on both the screen-film DMR and the FFDM system. This, along with the accepted method of calculating average glandular breast dose [1-3], allowed us to determine the FFDM techniques (in particular, mAs values) that matched breast dose to SFM for each breast thickness (2-8 cm). In addition, we have constructed an Excel software program that automatically calculates the mAs needed at each target-filter and kVp available on the FFDM system to precisely match the average glandular dose of FFDM to that of SFM. We used the parametrization of normalized average glandular dose tables by Sobol and Wu to determine technique factors that provide equal average glandular doses for different digital techniques. [4].

#### **Clinical Evaluation of FFDM**

The project is designed to compare FFDM to SFM in a large group of women being screened for breast cancer. The study population for the clinical comparison of FFDM and SFM is defined as all women who enter a participating facility (UCHSC or UMMC) for 2-view mammography of both breasts. Women excluded from the study include women under the age of 40 years, women with breast implants, and women with breasts too large to be adequately positioned on the 24x30 cm screen-film image receptor. To eliminate entry bias, all women meeting entry criteria at each participating facility are asked to participate in the study and are informed of the study design and potential risks. Those women who meet entry criteria, who sign an informed consent form, and who successfully undergo both SFM and FFDM of both breasts at the study site are included in the study population.

For women consenting to the study, cranio-caudal (CC) view and mediolateral oblique (MLO) view FFDM images are acquired of each breast at the same technique factors and breast radiation doses as for SFM. Images from each modality are read independently by board certified, MQSA-qualified radiologists with the same information (patient history and prior mammograms when available) for interpretation of each modality. To avoid reader bias, each radiologist reads an equal number of screen-film and digital mammograms. Any discrepancies between outcome recommendations are resolved by two radiologists reviewing both the images and interpretations from FFDM and SFM simultaneously and jointly making a single recommendation for follow-up. To eliminate bias due to follow-up on one modality over another, findings suggestive of malignancy seen on either modality are worked up. Interpretation results are entered on computer and maintained at each facility. Results have been merged between facilities and analyzed collectively in an interim analysis for this report.

Women participating in the study are examined by screen-film mammography using phototimed techniques (AOP Mode on a GE-DMR) prior to examination by FFDM. Technique factors (target material, filtration material, kVp, and mAs), compression force, and compressed breast thickness are recorded for each view of each breast in screen-film mammography. FFDM is then performed using technique factors that produce the same or slightly lower average glandular breast doses for each view of each breast. Technique factors for FFDM, including compression force and compressed breast thickness, are also recorded for each view of each breast. All FFDM image acquisitions employ a grid (as do all screenfilm images) and 100 micron pixel sizes.

For each case, screen-film and digital mammograms are independently interpreted by different MQSA-qualified radiologists. Each interpreting physician has the same prior knowledge of the case, which includes a patient history form and any prior mammograms available for the woman. To minimize reader bias, each interpreting physician reads an approximately equal number of screen-film mammograms and digital mammograms.

ACR BIRADS categories are used to assess findings for each modality. These ACR BIRADS categories are:

| ACR BIRADS Category | <u>Finding</u>               |  |  |
|---------------------|------------------------------|--|--|
| 0                   | Additional evaluation needed |  |  |
| 1                   | Normal                       |  |  |
| 2                   | Abnormal - benign            |  |  |
| 3                   | Abnormal - probably benign   |  |  |
| 4                   | Suspicious for cancer        |  |  |
| 5                   | Highly suspicious for cancer |  |  |

Digital mammograms are interpreted using soft-copy display on a GE-FFDM Advantage Workstation with two high resolution, high luminance monitors, controlled by a SUN UltraSPARC computer. This is done to take advantage of the ability to manipulate digital data in a manner that permits visualization of the entire breast or enhanced visualization of possible suspicious findings within a region of the breast.

An interim analysis of all women screened with the two modalities between the start of the clinical study (August 1997) and December 31, 1998, was performed. In cases where there was a discrepancy between SFM and FFDM, the discrepancies were also analyzed to gain greater insight into the causes of discrepancies between the two modalities.

Results were based on the evaluation of radiologist's follow-up recommendations. Radiologist's results in ACR BIRADS categories 0 (needs further diagnostic evaluation), 4 (suspicious for malignancy), and 5 (highly suspicious for malignancy) were considered positive. Radiologist's results in ACR categories 1 (normal), 2 (benign), or 3 (probably benign) were considered negative.

Agreement between FFDM and SFM was assessed in a two-by-two table of positive and negative outcomes, as shown below:



Truth about positivity and negativity of breast cancer, and therefore truth about FFDM and SFM assessment is established through follow-up data. Relatively immediate follow-up results are available for cases that are SFM positive, FFDM positive, or both (categories **a**, **b**, or **c** in the chart above). The truth about cases assessed to be negative by both modalities is determined only by long-term follow-up and by linkage with cancer registries in Colorado and Massachusetts to determine false negative results. A more detailed analysis is presented on cases where disagreement exists between FFDM and SFM (categories **a** and **b** above).

9

#### II. Results

#### **Technical Evaluation of FFDM**

**Figure 1** shows the behavior of measured mean detector signal as a function of mAs for 2, 4, and 6 cm thick simulated compressed breasts of 50% glandular/50% fatty composition. The figure shows that for each breast thickness, measured signal is linearly proportional to mAs and that for a given mAs, signal is attenuated by approximately a factor of 4 for each 2 cm increase in simulated breast thickness.

**Figure 2** shows the behavior of measured SNR as a function of mAs for 2, 4, and 6 cm thick simulated compressed breasts. The figure shows that for each breast thickness, measured SNR increases approximately as the square root of mAs, as expected for a quantum-noise limited system. For a given mAs, SNR is approximately a factor of 2 lower for each 2 cm increase in simulated breast thickness.

Figure 3 shows the behavior of contrast-detail (CD) scores as a function of mAs for each breast thickness. Error bars on CD scores extend plus and minus one standard deviation about the mean, based on four independent reader's CD scores. These results demonstrate the consistency of CD scores among the four readers. They also demonstrate the clear trend of CD scores to increase rapidly for low mAs, to display decreasing improvement as mAs is increased, and to reach a plateau at high mAs. While breast dose increases linearly with mAs, these results indicate that gains in low-contrast detection are minimal above a certain mAs value, which depends critically on breast thickness. For example, little improvement is achieved at this target-filter and kVp for mAs values beyond 50 for 2 cm breasts, 100 for 4 cm breasts, and 160 for 6 cm breasts. Moreover, these results indicate that increasing technique (in this case increasing mAs) cannot be used to overcome some of the fundamental limitations of increased breast thickness, in particular the increase in scatter-to-primary ratio, unless the system is operated at very low CD score levels. That is, for reasonable mAs settings, lesion detection in 2 cm thick breasts is going to superior to lesion detection in 4 cm thick breasts, and , lesion detection in 4 cm thick breasts is going to superior to lesion detection in 6 cm thick breasts.

**Figure 4** shows the dependence of measured CD scores on measured SNR in each image. This figure demonstrates that the underlying reason for lower CD scores is lower SNR, independent of compressed breast thickness. This is an important result, as it indicates that the underlying basis for low-contrast lesion detection is simply SNR, independent of breast thickness. This result has a number of ramifications. It indicates that SNR in digital images (at least with this detector system) can be used as a surrogate to low-contrast lesions detection.

That is, to have adequate detection of low-contrast lesions in digital mammograms, adequate SNR is required throughout the image. A simple way to assess the adequacy of FFDM technique factors is to measure the SNR in a clinical image. If that technique achieves a certain minimum SNR, one can be assured of a given level of low-contrast detection capability. For example, optimization of technique factors may be as simple as ensuring that an adequate minimum threshold of SNR (> 40-60) is achieved. It remains to be seen if this result holds up across variations in beam quality (target-filtration and kVp) and breast composition, which will be one of the tasks in Year 3 of this project.

#### Matching Breast Doses Between SFM and FFDM for Various Techniques

Figures 5-8 present the results of matching breast average glandular doses between screen-film techniques and digital techniques for 2, 4, 6, and 8 cm thick compressed breasts, respectively. For example, in Figure 5, the techniques listed under DMR - Initial Technique are the technique factors selected by the screenfilm DMR under AOP – Contrast Mode for a 2 cm thick 50% glandular-50% fatty breast. These techniques have been set to yield a film optical density of 1.6-1.7 for a uniform 2 cm thick tissue-equivalent breast phantom. The technique factors in the lower box are FFDM techniques that exactly match the breast dose in FFDM to that in SFM. Note that target-filtration and kVp are identical between FFDM and SFM; mAs is slightly different (17 versus 16 mAs) to compensate for the differences in HVL and output of the two units. Note that the same average gladular dose is obtained on the two modalities (38.9 mrad). The table at the right indicates the mAs values that would be required at different target-filter and kVp values on the digital system to yield the same breast dose as the screen-film system. Figures 6-8 are similar results for the digital techniques that would exactly match breast doses from SFM at 4, 6, and 8 cm breasts, respectively.

We are currently in the process of acquiring FFDM images at different techniques (varying target-filter, kVp, and mAs in a manner that matches breast dose) to those of SFM at each breast thickness and determining SNR and CD scores for each of those techniques. This task will be completed during Year 3 of this project.

#### **Clinical Evaluation of FFDM**

From August 1997 through December 31, 1998, the two study sites combined to perform 3,961 exams, 2,183 at UCHSC (55%) and 1,778 at UMMC (45%), on 3,475 patients with both screen-film and full-field digital mammography. The 486 women who participated twice did so with at least one year between their exams. Of these 3,961 exams, 25 are awaiting completion of follow-up; 3,936 exams were read as negative on both modalities or have completed follow-up for positive assessment by one or both modalities. 3,913 of the exams (99%) were performed on asymptomatic women; 23 of the exams (1%) were performed on women with breast symptoms.



The following two-by-two table of outcomes compares the independent assessment of FFDM and SFM (by different interpreting physicians) for these exams:

#### All cases as of 12/31/98:

|            |        | Screen-film A  | ssessment<br>-  |                     |  |
|------------|--------|--|---|---------------------|--|
| •          |        | ور و هم الم الم الم الم الم الم الم الم الم ال   |   | Digital Totals      |  |
| Digital    | +      | 215  | 310   | ND+ = 525           |  |
| Assessment |        | نیک بینا که این می ها بین اینا کا بیان کی این این این واب بین می این بین می بین می بین بین | وبا جراعيا جا بي اير اير اير اي غلال الله الله الله الله الله الله الله |                     |  |
|            | -      | 404  | 3,032   | ND- = 3,436         |  |
| Screen-Fi  | <br>Im | NSF+   | NSF-  | $N_{total} = 3,961$ |  |
| Totals     |        | = 619  | = 3,342   |                     |  |

Note: ND+ = number of studies interpreted as digital positive
 ND- = number of studies interpreted as digital negative
 NSF+ = number of studies interpreted as screen-film positive
 NSF- = number of studies interpreted as screen-film negative
 N<sub>total</sub> = total number of study cases

A major concern about FFDM is the concern that it may generate an excessive number of false positive mammograms (recalls for biopsy or other procedures). This concern does not appear to supported by the preliminary statistics. The recall rate for screen-film mammography was 619 of 3,961 cases (15.6%) and for digital mammography was 525 of 3,961 cases (13.3%). This represents a statistically significant difference in recall rate (p<0.001), with digital having lower recall rates that screen-film in the study results to date.

Of the 215 cases interpreted as positive using both SFM and FFDM, 8 were true positives and 207 were false positives. Of the 404 cases interpreted as positive by SFM and negative by FFDM, 7 were found to be positive at follow-up. Of the 310 cases interpreted as positive using FFDM and negative using SFM, 5 were found to be positive at follow-up. Of the 3,032 cases interpreted as negative using both modalities, 2 presented with palpable cancers within the following year and are considered false negatives on both modalities. Other possible double false negative cases will be investigated by re-contacting each patient one year after her enrollment.

Recasting these preliminary data in terms of 2 by 2 truth tables separately for SFM and FFDM yields the following results.

This page contains proprietary data

Screen-Film Mammography Results:

. 1 .<sup>1</sup>\* 3 .X

| Truth (pending additional follow-up) |          |            |                    |                                  |
|--------------------------------------|----------|------------|--------------------|----------------------------------|
|                                      |          | T<br>      | -                  | Screen-Film Totals               |
| Screen-Film                          | + 15     |            | 604                | NSF+ = 619                       |
| Assessment                           | -        | 7          | 3,335              | NSF- = 3,342                     |
| Totals                               |          | N+ = 22    | N- = 3,939         | N <sub>total</sub> = 3,961 cases |
| Digital Mammography Results:         |          |            |                    |                                  |
|                                      | Truth (p | ending add | itional follow-up) |                                  |
|                                      |          | +          |                    | Digital Totals                   |
| Digital                              | +        | 13         | 512                | ND+ = 525                        |
| Assessment                           | -        | 9          | 3427               | ND- = 3,436                      |
| Totals                               |          | N+= 22     | N- = 3,939         | N <sub>total</sub> = 3,961 cases |

These results yield the following 2x2 table for the 22 cancers occurring in our study to date:

#### Cancer Cases Only:

|                   |      | Screen-film A | ssessment   |                         |  |
|-------------------|------|---------------|-------------|-------------------------|--|
|                   |      | +             | -           |                         |  |
|                   |      |               |             | Digital Totals          |  |
| Digital           | +    | 8             | 5           | CD+ = 13                |  |
| Assessme          | ent  |               |             |                         |  |
|                   | -    | 7             | 2           | CD-= 9                  |  |
| Screen-<br>Totals | Film | CSF+<br>= 15  | CSF-<br>= 7 | C <sub>total</sub> = 22 |  |

Note: CD+ = number of studies interpreted as digital positive
 CD- = number of studies interpreted as digital negative
 CSF+ = number of studies interpreted as screen-film positive
 CSF- = number of studies interpreted as screen-film negative
 C<sub>total</sub> = total number of study cases

These results translate to the following comparative statistics between FFDM and SFM:

| Effectiveness | Results |       |  |
|---------------|---------|-------|--|
| Parameter     | SFM     | FFDM  |  |
| Sensitivity   | 68%     | 59%   |  |
| Specificity   | 85%     | 87%   |  |
| PPV           | 2.4%    | 2.5%  |  |
| NPV           | 99.8%   | 99.7% |  |

Sensitivity to breast cancer is somewhat lower with FFDM than with SFM (59% versus 68%), but the difference is not statistically significant due to the small number of cancers among study participants to date (22). No significant difference has been found between FFDM and SFM in terms of specificity, positive predictive value (PPV), or negative predictive value (NPV).

After independent readings by different radiologists, all discrepancies between screen-film and digital mammography interpretations were resolved by discrepancy evaluations by both radiologists, with completion of a discrepancy evaluation form. There have been 1034 discrepant interpretations among the 3,961 cases (26%) to date. Major reasons for discepancies fell into the following categories: visibility/conspicuity (548 or

53%), interpretation (388 or 38%) and appearance (98 or 9%).

The results of a slightly earlier interim analysis (as of September 15, 1998) were presented in a Scientific Session at the 1998 Annual Meeting of the Radiological Society of North America [5]. These results are also being written up for submission to <u>Radiology</u>.

Accrual of volunteers during the first 17 months of this clinical project has been lower than that estimated in our original proposal. This has been due to a number of factors, including difficulty in scheduling an adequately high number of digital slots due to the time required to perform SFM and FFDM and complete all required paperwork for the protocol, and due to cancellations and no-show examinees. The project Executive Committee (Dr. Hendrick, Dr. Lewin, and Dr. D'Orsi) have met concerning this issue and have developed a plan to increase the numbers of volunteers participating in the protocol. These include altering the daily schedule to open up more digital mammography slots at each site, including information about the digital mammography project in patient reminder letters and mentioning it in reminder telephone calls. Staffing is being increased at UCHSC to support these additional activities and we are attempting to get similar staffing increases at UMMC. Throughput of examinees will be monitored carefully on a month-by-month basis to evaluate the effect of these changes on the number of examinees at each site. We have arranged for two other sites where clinical prototype GE-FFDM units have been installed (Bethesda Naval Hospital) or soon will be installed (University of South Florida) to participate in this study through funding separate from this grant.

#### CONCLUSIONS

Our technical evaluation of FFDM indicates that image SNR is a good surrogate of the ability of the system to detect low-contrast lesions. This suggests that each FFDM image should meet minimum SNR requirements to ensure adequate lesion detection. Further testing is being conducted to confirm that this simple surrogate for lesion detection applies across the entire spectrum of beam quality and breast compositions.

Our clinical evaluation of FFDM on nearly 4,000 women as of December 31, 1998, indicates that FFDM has fewer false positive readings than SFM, but a somewhat lower sensitivity than SFM, although the difference lacks statistical significance due to the small number of cancer cases included in the study to date. Both modalities had similar specificities, positive predictive values, and negative predictive values. Our clinical evaluation will continue with an increased accrual rate during Year 3.

#### REFERENCES

#### **Cited References:**

1. Rothenberg LN, ed. <u>NCRP Report No. 85: Mammography: A User's Guide</u>, Bethesda, MD: National Council on Radiation Protection and Measurement, 1986.

2. Wu X, Barnes GT, Tucker DM. Spectral dependence of glandular tissue dose in screen-film mammography. Radiology 1991; 179:143-148.

3. Wu X, Gingold EL, Barnes GT, Tucker DM. Normalized average glandular dose in molybdenum target-rhodium filter and molybdenum target-rhodium filter mammography. Radiology 1994; 193:83-89.

4. Sobol WT, Wu X. Parametrization of mammography normalized average glandular dose tables. Med. Phys. 1997; 24: 547-554.

5. Lewin JM, Hendrick RE, D'Orsi CJ, Moss LJ, Sisney GA, Karellas A. Clinical evaluation of a full-field digital mammography prototype for cancer detection in a screening setting – work in progress. Radiology 209(P): 238, 1998.

#### Additional References (not cited by number in this report):

Feig SA, Yaffe MJ. Current status of digital mammography. Semin. Ultrasound, CT, MR 1996; 17: 424-443.

Schmidt RA, Nishikawa RM. Clinical use of digital mammography: the present and the prospects. J. Digit. Imaging 1995; 8 (Supplement 1): 74-79.

Fletcher SW, Black W, Harris R, Rimer BK, Shapiro S. Report of the International Workshop on Screening for Breast Cancer. JNCI 1993; 85: 1644-56.

Elwood JM, Cox B, Richardson AK . The effectiveness of breast cancer screening by mammography in younger women. Online Journal Curr. Clin. Trials 1993; 1: 32-227.

Bird RE, Wallace TW, Yankaskas BC. Analysis of cancers missed at screening mammography. Radiology 1992; 184: 613-617.

Jackson VP, Hendrick RE, Feig SA, Kopans DB. Imaging of the radiographically dense breast. Radiology 1993; 188: 297-301.

Bassett LW, Gold RH, Kimme-Smith C. History of the technical development of mammography, in Syllabus: A Categorical Course in Physics: Technical Aspects of Breast Imaging, 3rd Edition, Eds. AG Haus and MJ Yaffe, 1994: 9-20.

Johns PC, Yaffe MJ. X-ray characterization of normal and neoplastic breast tissues. Phys. Med. Biol. 1987; 32: 675-695.

Cohen G, McDaniel DL, Wagner LK. Analysis of variations in contrast-detail experiments. Medical Physics 1984; 11: 469- 473.

Robson KJ, Kotre CJ, Faulkner K. The use of a contrast-detail test object in the optimization of optical density in mammography. The British Journal of Radiology 1995; 68: 277-282.

Law J. Improved image quality for dense breasts in mammography. The British Journal of Radiology 1992; 65: 50-55.

Hendrick RE, Bassett LW, Butler PA, et. al., Mammography Quality Control: Radiologist's Manual, Radiologic Technologist's Manual, Medical Physicist's Manual, American College of Radiology, Revised Edition, 1994.

# APPENDIX



**Figure 1:** Detector signal measured on the GE-FFDM system versus mAs for 2, 4, and 6 cm thicknesses of 50% glandular/50% fatty compressed breasts.

19





**Figure 2**: Signal-to-noise ratios (SNR) measured on the GE-FFDM system versus mAs for 2, 4, and 6 cm thicknesses of 50% glandular/50% fatty compressed breasts.

20

١.



error bars represent  $\pm$  one standard deviation among the four independent readers. mAs for 2, 4, and 6 cm thicknesses of 50% glandular/50% fatty compressed breasts. Point values represent mean CD scores from 4 independent readers;

21

CD Scores vs. SNR



**Figure 4:** CD scores versus SNR for 2, 4, and 6 cm thicknesses of 50% glandular/50% fatty compressed breasts.

22

₹~~s • • • •



| Patient:     | 2 cm    |
|--------------|---------|
| Patient ID#: | 2       |
| Date:        | 1/29/99 |

DIVIRE UNITED TO GINGING

| Thickness (cm)                | 2      |
|-------------------------------|--------|
| T/F (Mo/Mo, Mo/Rh, Rh/Rh)     | Mo/Mo  |
| kVp                           | 25     |
| Comp.(100F, 50/50, 100G)      | 50/50  |
| Entrance X (mR)               | 124.5  |
| HVL (mm Al)                   | 0.3429 |
| Average Glandular Dose (mrad) | 38.90  |
| Density Setting               | 0      |
| mAs                           | 16     |
| mR/mAs                        | 7.78   |
| mA                            | 100    |
| Exposure Time (sec.)          | 0.16   |
| D <sub>gN</sub> (mrad/R)      | 312.3  |

| and the second se  | and the second se | ANNO A ADDRESS OF ANY | And a compared on the company and the | Mentanity of the provident of a company          |
|--|---|---|---------------------------------------|--|
|  | a the state of the state of the street of   | as Color and Barry and                                    | 12 Mar 199 4 16 Sugar                 | 3 1 M. W. M. |
| [1] M. S. S. S. Ganger, 198, 199, 199, 199, 199, 199   | 1.8. K . K . S . S . W . V  | 2 8 8 8 M 81  | 5                                     | 12 million (1997)                                |
| 그는 동네가 좀 잘 듣는 것을 많이 못 하나? 이번 것을 가장했다. 가까지,   |   | A 6.32 88 A 1 A.  |                                       | - 💥 🖉 🏟 K. K. L. 🗉 🖓 K. S.                       |
|  | · ?   | 22 8 3 3 82 meth 87                                       |                                       | Stand Street                                     |
| and the state of the second state of the secon | 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1   |   |                                       |  |
| A 0115 . 2111 . AU   | 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1   | C. C  |                                       | 14070000204001 c                                 |

| D <sub>gN</sub> (mrad/R)      | 309.9   |
|-------------------------------|---------|
| Exposure Time (sec.)          | i, 0.17 |
| mA                            | 100     |
| mR/mAs                        | 7.38    |
|                               | 17.049  |
| Density Setting               | 0       |
| Average Glandular Dose (mrad) | 38,90   |
| HVL (mm Al)                   | 0.3397  |
| Entrance X (mR)               | 125.5   |
| Comp (100F, 50/50, 100G)      | 50/50   |
| kVp                           | 25      |
| T/F (Mo/Mo, Mo/Rh, Rh/Rh)     | Mo/Mo   |
| Thickness (cm)                | 2       |

#### Digite DMR Metalies Terminours

|     | Mo/Mo | Mo/Rh | Rh/Rh |
|-----|-------|-------|-------|
| kVp | mAs   | mAs   | mAs   |
| 22  | 30.3  | 35.7  |       |
| 23  | 24.8  | 28.0  |       |
| 24  | 20.3  | 22.6  |       |
| 25  | 17.0  | 18.6  | 18.3  |
| 26  | 14.4  | 15.8  | 15.6  |
| 27  | 12.5  | 13.5  | 13.3  |
| 28  | 10.9  | 11.8  | 11.6  |
| 29  | 9.5   | 10.3  | 10.1  |
| 30  | 8.4   | 9.2   | 8.9   |
| 31  | 7.6   | 8.1   | 7.8   |
| 32  | 6.8   | 7.3   | 7.0   |
| 33  | 6.2   | 6.7   | 6.3   |
| 34  | 5.7   | 6.1   | 5.8   |
| 35  | 5.2   | 5.6   | 5.3   |
| 36  |       | 5.2   | 4.9   |
| 37  |       | 4.8   | 4.5   |
| 38  |       | 4.5   | 4.2   |
| 39  |       | 4.2   | 3.9   |
| 40  |       | 3.9   | 3.6   |
| 41  |       |       | 3.4   |
| 42  |       |       | 3.2   |
| 43  |       |       | 2.9   |
| 44  |       |       | 2.7   |
| 45  |       |       | 2.5   |
| 46  |       |       | 2.3   |
| 47  |       |       | 2.1   |
| 48  |       |       | 1.9   |
| 49  |       |       | 1.7   |

**Figure 5:** The upper left-hand box shows technique factors selected by the GE-DMR screen-film unit under AOP mode for a 2 cm thick 50% glandular/50% fatty compressed breast and resultant entrance exposure, half-value layer (HVL), and average glandular dose. The lower left-hand box shows technique factors for the FFDM system that match FFDM dose to SFM dose using the same target-filter and kVp. The right hand table shows mAs values that match FFDM dose to the SFM dose using different target-filter and kVp settings on the FFDM system.

#### Mammography Technique and Dose Matching Program

| Patient:     | 4 cm   |
|--------------|--|
| Patient ID#: | 4  |
| Date:        | 1/29/99  |
|              | ورمري <u>محمد المحمد من </u> |

Average Glandula

DICEDAL

Average Glandula

| Thickness (cm)           | 4                                       |
|--------------------------|---|
| /F (Mo/Mo, Mo/Rh, Rh/Rh) | Mo/Mo                                   |
| kVp                      | 25                                      |
| Comp.(100F, 50/50, 100G) | 50/50                                   |
| Entrance X (mR           | 705.0                                   |
| HVL (mm Al               | 0,3429                                  |
| age Glandular Dose (mrad | 126.38                                  |
| Density Setting          | 0                                       |
| mAs                      | 85                                      |
| mR/mAs                   | 8.29                                    |
| mA                       | 100                                     |
| Exposure Time (sec.      | 0.85                                    |
| D <sub>gN</sub> (mrad/R  | 179.3                                   |
|                          |   |
|                          |   |
| Netelia: Teahni          |   |
|                          |   |
| Thickness (cm            | 4                                       |
| T/F (Mo/Mo, Mo/Rh, Rh/Rh | ) Mo/Mo-                                |
| KVI                      | 25                                      |
| Comp.(100F, 50/50, 100G  | ) 50/50                                 |
| Entrance X (mR           | 711.0                                   |
| HVL (mm Al               | 0.3397                                  |
| age Glandular Dose (mrad | ) 126.38                                |
| Density Setting          | 0                                       |
|                          | 1 · 》 · · · · · · · · · · · · · · · · · |
| mR/mA                    | 7,86                                    |
| m                        | 100.                                    |
| Exposure Time (sec.      | 0.90                                    |
| D <sub>gN</sub> (mrad/R  | ) 177.8                                 |

Figure 6: The upper left-hand box shows technique factors selected by the GE-DMR screen-film unit under AOP mode for a 4 cm thick 50% glandular/50% fatty compressed breast and resultant entrance exposure, half-value layer (HVL), and average glandular dose. The lower left-hand box shows technique factors for the FFDM system that match FFDM dose to SFM dose using the same target-filter and kVp. The right hand table shows mAs values that match FFDM dose to the SFM dose using different target-filter and kVp settings on the FFDM system.

#### Mammography Technique and Dose Matching Program



|              |     | Mo/Mo | Mo/Rh | Rh/Rh |
|--------------|-----|-------|-------|-------|
| ו            | kVp | mAs   | mAs   | mAs   |
|              | 22  | 444.7 | 508.7 |       |
| )            | 23  | 360.8 | 389.5 |       |
| 2            | 24  | 290.6 | 308.7 |       |
| 30           | 25  | 240.6 | 251.6 | 243.4 |
| 7            | 26  | 201.8 | 210.9 | 202.9 |
|              | 27  | 172.7 | 178.4 | 170.2 |
|              | 28  | 149.4 | 155.5 | 144.9 |
| 117<br>142   | 29  | 128.4 | 135.5 | 124.8 |
|              | 30  | 113.6 | 120.1 | 107.9 |
|              | 31  | 101.7 | 105.2 | 93.4  |
|              | 32  | 90.9  | 95.1  | 83.0  |
|              | 33  | 81.9  | 86.3  | 74.3  |
|              | 34  | 74.4  | 78.0  | 67.6  |
| 1            | 35  | 67.7  | 71.7  | 61.5  |
|              | 36  |       | 65.9  | 56.9  |
| бй»          | 37  |       | 59.9  | 53.0  |
| D.           | 38  |       | 55.2  | 49.1  |
|              | 39  |       | 50.7  | 46.2  |
|              | 40  |       | 46.7  | 43.2  |
| 5            | 41  |       |       | 40.6  |
| ing)<br>Mari | 42  |       |       | 37.8  |
| 7            | 43  |       |       | 35.1  |
|              | 44  |       |       | 33.2  |
|              | 45  |       |       | 30.5  |
|              | 46  |       |       | 28.5  |
|              | 47  |       |       | 26.3  |
|              | 48  |       |       | 24.4  |

48 49

22.7

Denten DMR MERGINEMBERMICHES

| 6      | Thickness (cm)                |
|--------|-------------------------------|
| Mo/Rh  | T/F (Mo/Mo, Mo/Rh, Rh/Rh)     |
| 27     | kVp                           |
| 50/50  | Comp.(100F, 50/50, 100G)      |
| 1576.2 | Entrance X (mR)               |
| 0.4213 | HVL (mm·Al)                   |
| 234.97 | Äverage Glandular Dose (mrad) |
| 0      | Density Setting               |
| 168    | mAs                           |
| 9.38   | mR/mAs                        |
| 100    | mA                            |
| 1.68   | Exposure Time (sec.)          |
| 149.1  | D <sub>pN</sub> (mrad/R)      |

#### DICEPAL ----- ELGEREI REGIMELLE.

| Thickness (cm)                | 6      |
|-------------------------------|--------|
| T/F. (Mo/Mo/Mo/Rh, Rh/Rh)     | Mo/Rh  |
| kVp                           | 27     |
| Comp.(100F, 50/50, 100G)      | 50/50  |
| Entrance X (mR)               | 1580.5 |
| HVL (mm Al)                   | 0.42   |
| Average Glandular Dose (mrad) | 234.97 |
| Density Setting               | 0      |
|                               |        |
| mR/mAs                        | 8:86   |
| mA                            | 100    |
| Exposure Time (sec.)          | 1.78   |
| D <sub>gN</sub> (mrad/R)      | 148.7  |

**Figure 7:** The upper left-hand box shows technique factors selected by the GE-DMR screen-film unit under AOP mode for a 6 cm thick 50% glandular/50% fatty compressed breast and resultant entrance exposure, half-value layer (HVL), and average glandular dose. The lower left-hand box shows technique factors for the FFDM system that match FFDM dose to SFM dose using the same target-filter and kVp. The right hand table shows mAs values that match FFDM dose to the SFM dose using different target-filter and kVp settings on the FFDM system.

#### Mammography Technique and Dose Matching Program

| Patient:  | `8 cm                                    |                                       |           |        |        |        |
|---|--|---------------------------------------|-----------|--------|--------|--------|
| Patient ID#:  | 8  |                                       |           |        |        |        |
| Date:   | 1/29/99                                  | _                                     |           |        |        |        |
| ONE INTRA PARTICIPA   | <u>, 10 (10)</u>                         |                                       | ile (jane | MRAMAG |        | nigues |
| Thickness (cm)  | 8  |                                       |           | Mo/Mo  | Mo/Rh  | Rh/Rh  |
| T/F (Mo/Mo, Mo/Rh, Rh/Rh)   | Rh/Rh                                    |                                       | kVp       | mAs    | mAs    | mAs    |
| kVp   | 28                                       |                                       | 22        | 920.8  | 1062.0 |        |
| Comp.(100F, 50/50, 100G)  | 50/50                                    |                                       | 23        | 745.5  | 807.5  |        |
| Entrance X (mR)   | 3140.5                                   |                                       | 24        | 599.9  | 636.9  |        |
| · HVL (mm Al)   | 0 4315                                   |                                       | 25        | 496.5  | 517.5  | 500.3  |
| Average Glandular Dose (mrad)   | 384.77                                   |                                       | 26        | 416.1  | 432.8  | 414.9  |
| Density Setting   | 0  |                                       | 27        | 355.7  | 365.9  | 347.0  |
| mAs   | 283                                      |                                       | 28        | 307.3  | 318.7  | 294.9  |
| mR/mAs  | 11.10                                    |                                       | 29        | 263.8  | 277.8  | 253.8  |
| mA  | 80                                       |                                       | 30        | 233.0  | 246.3  | 219.1  |
| Exposure Time (sec.)  | 3.5375                                   | · · · · · · · · · · · · · · · · · · · | 31        | 208.4  | 215.8  | 189.6  |
| D <sub>oN</sub> (mrad/R)  | 122.5                                    |                                       | 32        | 186.0  | 195.1  | 168.3  |
|   |  |                                       | 33        | 167.3  | 177.0  | 150.4  |
|   |  |                                       | 34        | 151.9  | 159.8  | 136.4  |
| TRATAL WEIGHEN TEAMING  | U.C                                      |                                       | 35        | 138.1  | 146.6  | 123.7  |
| 1. South on the intervention comparison of the second s<br>Second second s<br>Second second se | an a |                                       | 36        |        | 134.5  | 114.1  |
| Thickness (cm)  | 8  |                                       | 37        |        | 121.6  | 105.8  |
| T/F (Mo/Mo, Mo/Rh, Rh/Rh)   | Rh/Rh                                    |                                       | 38        | •      | 111.6  | 97.8   |
| kVp   | 28                                       |                                       | 39        |        | 101.6  | 91.5   |
| Comp (100F, 50/50, 100G)  | 50/50                                    |                                       | 40        |        | 92.7   | 85.3   |
| Entrance X (mR)   | 3166.8                                   |                                       | 41        |        |        | 79.9   |
| HVL (mm Al)   | 0.4274                                   |                                       | 42        |        |        | 74.3   |
| Average Glandular Dose (mrad)   | 384.77                                   |                                       | 43        |        |        | 69.0   |
| Density Setting   | <u>,</u> 0                               | ] [                                   | 44        |        |        | 65.3   |
|   | - M. S. S.                               |                                       | 45        |        |        | 60.1   |

**Figure 8:** The upper left-hand box shows technique factors selected by the GE-DMR screen-film unit under AOP mode for a 8 cm thick 50% glandular/50% fatty compressed breast and resultant entrance exposure, half-value layer (HVL), and average glandular dose. The lower left-hand box shows technique factors for the FFDM system that match FFDM dose to SFM dose using the same target-filter and kVp. The right hand table shows mAs values that match FFDM dose to the SFM dose using different target-filter and kVp settings on the FFDM system.

mR/mAs

(mrad/R)

Exposure Time (sec.)

D<sub>gN</sub>

33

mΑ

10.74

80

3.69

121.5

46

47

48

49

56.2

52.1

48.4

45.1

#### **Figure Captions**

**Figure 1:** Detector signal measured on the GE-FFDM system versus mAs for 2, 4, and 6 cm thicknesses of 50% glandular/50% fatty compressed breasts.

**Figure 2:** Signal-to-noise ratios (SNR) measured on the GE-FFDM system versus mAs for 2, 4, and 6 cm thicknesses of 50% glandular/50% fatty compressed breasts.

**Figure 3:** Contrast-detail (CD) scores measured on the GE-FFDM system versus mAs for 2, 4, and 6 cm thicknesses of 50% glandular/50% fatty compressed breasts. Point values represent mean CD scores from 4 independent readers; error bars represent <u>+</u> one standard deviation among the four independent readers.

**Figure 4:** CD scores versus SNR for 2, 4, and 6 cm thicknesses of 50% glandular/50% fatty compressed breasts.

**Figure 5:** The upper left-hand box shows technique factors selected by the GE-DMR screen-film unit under AOP mode for a 2 cm thick 50% glandular/50% fatty compressed breast and resultant entrance exposure, half-value layer (HVL), and average glandular dose. The lower left-hand box shows technique factors for the FFDM system that match FFDM dose to SFM dose using the same target-filter and kVp. The right hand table shows mAs values that match FFDM dose to the SFM dose using different target-filter and kVp settings on the FFDM system.

**Figure 6:** The upper left-hand box shows technique factors selected by the GE-DMR screen-film unit under AOP mode for a 4 cm thick 50% glandular/50% fatty compressed breast and resultant entrance exposure, half-value layer (HVL), and average glandular dose. The lower left-hand box shows technique factors for the FFDM system that match FFDM dose to SFM dose using the same target-filter and kVp. The right hand table shows mAs values that match FFDM dose to the SFM dose using different target-filter and kVp settings on the FFDM system. **Figure 7:** The upper left-hand box shows technique factors selected by the GE-DMR screen-film unit under AOP mode for a 6 cm thick 50% glandular/50% fatty compressed breast and resultant entrance exposure, half-value layer (HVL), and average glandular dose. The lower left-hand box shows technique factors for the FFDM system that match FFDM dose to SFM dose using the same target-filter and kVp. The right hand table shows mAs values that match FFDM dose to the SFM dose using different target-filter and kVp settings on the FFDM system.

**Figure 8:** The upper left-hand box shows technique factors selected by the GE-DMR screen-film unit under AOP mode for a 8 cm thick 50% glandular/50% fatty compressed breast and resultant entrance exposure, half-value layer (HVL), and average glandular dose. The lower left-hand box shows technique factors for the FFDM system that match FFDM dose to SFM dose using the same target-filter and kVp. The right hand table shows mAs values that match FFDM dose to the SFM dose using different target-filter and kVp settings on the FFDM system.





#### DEPARTMENT OF THE ARMY

US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND AND FORT DETRICK 810 SCHRIEDER STREET, SUITE 218 FORT DETRICK, MARYLAND 21702-5000

REPLY TO ATTENTION OF:

MCMR-RMI-S (70-1y)

17 Oct 01

MEMORANDUM FOR Administrator, Defense Technical Information Center (DTIC-OCA), 8725 John J. Kingman Road, Fort Belvoir, VA 22060-6218

SUBJECT: Request Change in Distribution Statement

1. The U.S. Army Medical Research and Materiel Command has reexamined the need for the limitation assigned to technical reports written for grants. Request the limited distribution statements for the Accession Document Numbers listed at enclosure be changed to "Approved for public release; distribution unlimited." These reports should be released to the National Technical Information Service.

2. Point of contact for this request is Ms. Judy Pawlus at DSN 343-7322 or by e-mail at judy.pawlus@det.amedd.army.mil.

FOR THE COMMANDER:

Deputy Chief of Staff for Information Management

Enclosure