Proven clinical effectiveness at low radiation dose

Philips MicroDose Mammography

Summary

Several studies provide evidence that Philips MicroDose Mammography* can provide outstanding image quality at 18% to 50% lower radiation dose than used on other digital mammography systems, with an average dose reduction of approximately 40%.[1,**]

Author and study title	Publication year	Key findings
Oduko, et al., "A survey of patient doses from digital mammography systems in the UK in 2007 to 2009."[2]	2010	Philips MicroDose Mammography* had 18% to 53% lower mean glandular dose (MGD) compared to mammography systems from Hologic, GE, Siemens, and Giotto.
Baldelli, et al., "Comprehensive dose survey of breast screening in Ireland."[3]	2010	Philips MicroDose Mammography* has the lowest MGD for both CC and MLO views. The average examination dose for the MicroDose Mammography was 36% lower than Hologic Selenia, and 39% lower than GE Senographe Essential.
Leitz W., Almén A., "Patient doses from X-ray examinations in Sweden – trends from 2005 to 2008."[4]	2010	The average MGD for Philips MicroDose Mammography* was about half that of the other FFDM systems in the survey.
Cole, et al., "Comparison of radiologist performance with photon counting full-field digital mammography to conventional full-field digital mammography."[5]	2012	Radiologist performance with Philips MicroDose Mammography* was equal to that of GE Senographe DS at an average 40% lower MGD.
Keavey, et al., "Comparison of the clinical performance of three digital mammography systems in a breast cancer screening programme."[6]	2011	The cancer detection rate with the Philips MicroDose Mammography * was at least equal to that of GE Senographe Essential and Hologic Selenia.

Table 1: Summary of scientific papers.

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sense and simplicity

Introduction

Because breast tissue is sensitive to radiation, it is crucial that the radiation dose used in mammography is as low as possible,[7] particularly in mammography screening, in which a large number of healthy women are examined on a regular basis. Recently, the scientific guidance from the International Commission on Radiological Protection (ICRP) concluded breast tissue is more than two times more radiosensitive than thought earlier.[8,9]

Doctors should always strive towards exposing patients to the lowest dose possible when performing X-ray scans. Authorities such as the American College of Radiology (ACR) and the Radiological Society of North America (RSNA),[10] as well as the U.S. Food and Drug Administration's Center for Devices and Radiological Health (CDRH), have all launched initiatives intended to reduce unnecessary radiation exposure from medical imaging.[11]

Given the value of mammography screening, as well as the exposure to radiation it involves, it is very important for mammography system manufacturers to provide systems that enable low radiation dose exams without sacrificing clinical image quality.

This white paper summarizes data from scientific publications, and shows that the MicroDose Mammography can provide outstanding image quality with 18% to 50% lower radiation dose than used on other digital mammography systems, with an average dose reduction of approximately 40%.[1,**]

Figure 1: Philips MicroDose Mammography system.

Review of scientific papers comparing MicroDose Mammography with other FFDM systems

Oduko, et al.: A survey of patient doses from digital mammography systems in England in 2007 to 2009

Oduko, et al. analyzed patient dose data collected as part of the quality system for the United Kingdom's nationwide breast screening program (NHSBSP) run by the National Health Service (NHS).[2] Data was collected for a sample of fifty or more women for each mammography system used from 2007 to 2009. Dose data from more than 28 digital mammography systems and more than 4,100 images were analyzed. Radiographers who performed the mammography examinations supplied the exposure parameters for individual patients to the physicists working with the NHSBSP for the calculation of mean glandular dose (MGD). All physicists used the same program to calculate the MGD, according to Dance, et al.[12]

Results:
The average MGD levels of the MicroDose Mammography system ranged from 18% to 53% lower than other digital mammography systems, with a comparable average breast thickness (Table 2, Figure 2).

Manufacturer and model	Number of systems	Number of main images	Average and range of Mean MGD+ to breast (mGy)	Mean thickness (mm) ± 2 SEM	Percent difference
Philips MicroDose Mammography*	4	316	0.95 (0.93 - 0.97)	63.5 ± 0.6	–
GE Senographe 2000D	2	200	1.3 (1.26 - 1.34)	57.0 ± 0.8	27%
GE Senographe DS	7	1139	1.59 (1.56 - 1.62)	53.9 ± 0.3	40%
GE Senographe Essential	4	805	1.44 (1.41 – 1.47)	58.1 ± 0.4	34%
Hologic Selenia	3	356	2.00 (1.93 - 2.07)	53.1 ± 0.5	53%
Hologic Selenia W	3	616	1.44 (1.40 – 1.48	52.2 ± 0.8	34%
Siemens Inspiration	1	128	1.21 (1.14 – 1.28)	58.8 ± 1.1	21%
Siemens Novation	3	483	1.16 (1.11 – 1.21)	56.9 ± 0.6	18%
IMS Giotto	1	118	1.78 (1.68 - 1.88)	55.5 ± 0.9	47%

Table 2: MGD and thickness for oblique views, for all breasts, for different types of digital mammography systems.

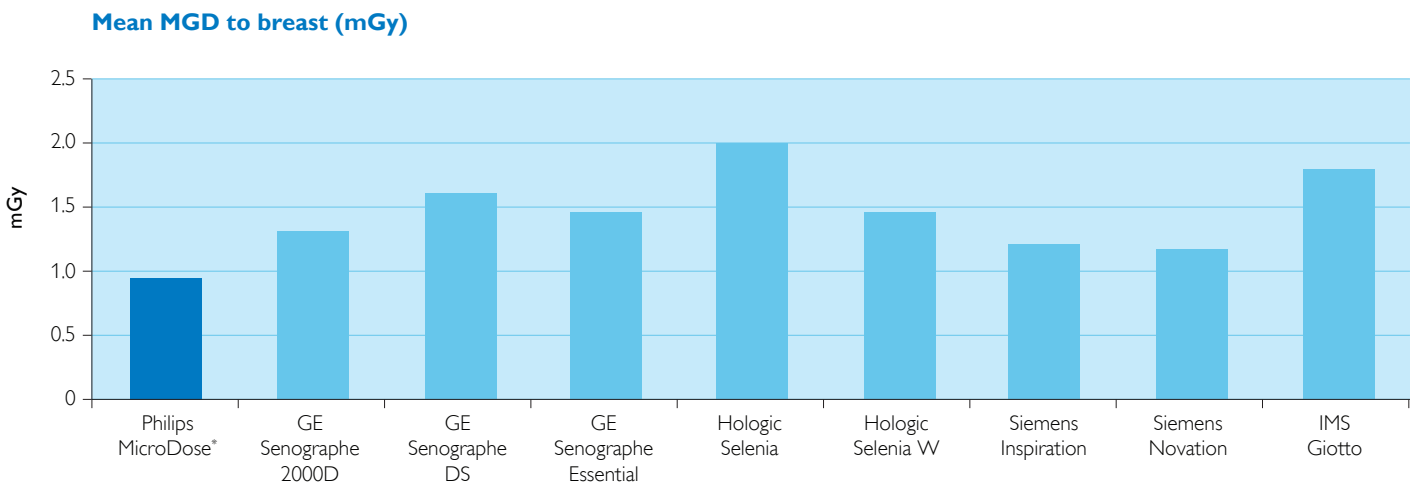

Figure 2: Comparison of Mean MGD to breast for Oblique Views for different mammography systems.

Baldelli, et al.: Comprehensive dose survey of breast screening in Ireland

Baldelli, et al. examined the dose impact of breast screening by digital mammography systems by analyzing BreastCheck (Ireland's national breast screening program) clinical dose survey results.[3] Data acquired over a one-month period in 2009 included 2,910 examinations compromising 12,110 images from three different FFDM models: GE Senographe Essential, Hologic Selenia, and Philips MicroDose Mammography* systems.

Results:
The study found that the MicroDose Mammography system demonstrated the lowest average MGD. The average examination dose for the MicroDose Mammography was 39% lower than that of GE Senographe Essential and 36% lower than that of Hologic Selenia.

	Philips MicroDose Mammography*	GE Senographe Essential	Hologic Selenia
Average MGD for an exam	1.86 mGy	3.03 mGy	2.91 mGy
Average MGD in the CC view	0.90 mGy	1.39 mGy	1.36 mGy
Average MGD in the MLO view	0.88 mGy	1.52 mGy.	1.44 mGy
Average MGD	(0.90+0.88+)/2=0.89	(1.39+1.52)/2=1.455	(1.36+1.44)/2=1.4

Table 3: Radiation dose comparison based on BreastCheck 2009 data.

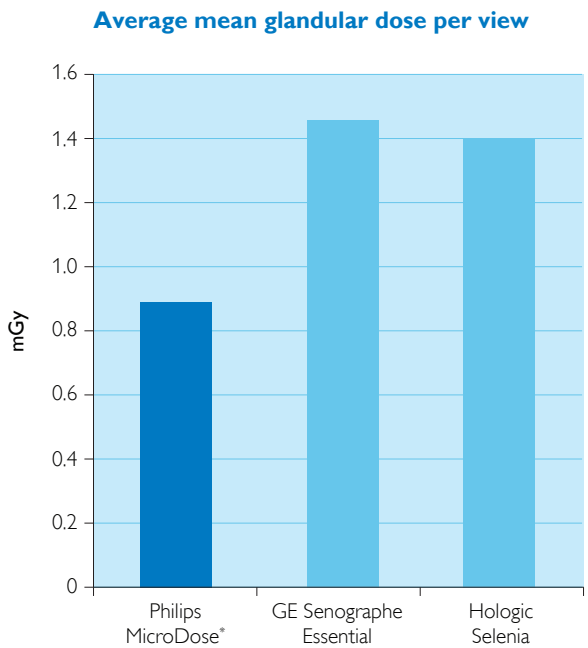

Figure 3: Comparison of overall MGD for Philips MicroDose, GE Senographe Essential, and Hologic Selenia, based on BreastCheck 2009 data.

The Swedish Radiation Safety Authority report on patient doses from X-ray examinations in Sweden – trends from 2005 to 2008

The Swedish Radiation Safety Authority (SSM) controls the screening program, sets the standards for permitted X-ray doses, and controls the quality of the mammography systems used in Sweden. The report issued from SSM contains data from 150 mammography systems used in clinics from 2006 to 2008.[4, ++]

Because many new FFDM units have been installed since 2008, a follow-up analysis of SSM data was conducted in 2010.13 Dose data was collected from 62 clinics with a total of 175 mammography units. Figure 4 notes the variation in average MGD among different FFDM systems. As in the earlier study, the average radiation dose for MicroDose systems was about half that of the other FFDM systems in the survey (Figure 4).

Results:

- MicroDose Mammography systems used approximately half of the radiation dose of the other FFDM systems and less than half the dose of screen-film mammography systems.
- Between 2006 and 2008, the patient-related standard dose for mammography in Sweden decreased by 12% on average. The report notes that a significant part of this reduction can be attributed to the introduction of MicroDose systems.

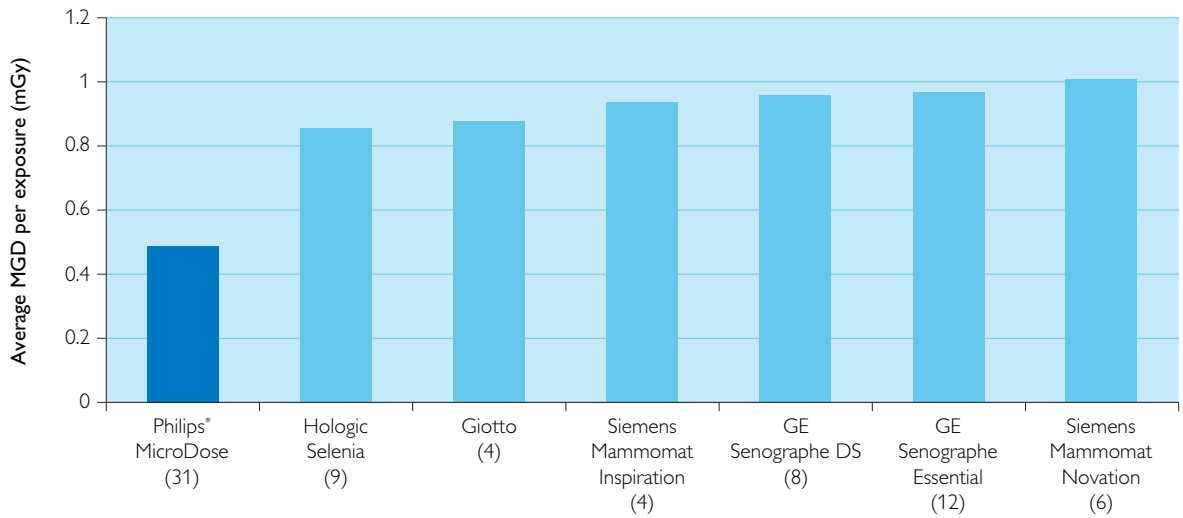

Figure 4: The average MGD per exposure for different FFDM systems, including both screening and clinical mammography. (The number of units for each model is shown in parentheses.)

Cole, et al.: Comparison of radiologist performance with photon-counting full-field digital mammography to conventional full-field digital mammography

Dr. Pisano, and colleagues of this study, assessed the performance of the MicroDose Mammography system in comparison to another FFDM system (GE Senographe DS) for women presenting for screening mammography, diagnostic mammography, or breast biopsy.[5] A total of 133 women were enrolled in this study at two European medical centers. Sixty-seven women who were tested using a conventional FFDM 10 to 36 months earlier were tested using MicroDose Mammography. Another 66 women had screening tests with MicroDose Mammography and within 90 days after that underwent diagnostic tests with a conventional FFDM. Mean glandular dose was recorded for all cases. Sixteen U.S. radiologists were recruited to participate in the reader study, which took place at the American College of Radiology Image Metrix Core Laboratory in Philadelphia.

Results:
Radiologist performance with MicroDose Mammography was equal to that of conventional FFDM, at an average 40% lower MGD.

	Philips MicroDose Mammography*	GE Senographe DS
Average AUC	0.947	0.931
Sensitivity per case	0.936	0.908
Specificity per case	0.764	0.749
The average MGD	0.74 mGy	1.23 mGy

Table 4: Radiologist performance with MicroDose Mammography system compared to a conventional FFDM.

Keavey, et al.: Comparison of the clinical performance of three digital mammography systems in a breast cancer screening program

Keavey, et al. conducted a study that compares the clinical performance of three digital mammography systems used in BreastCheck, Ireland's national breast screening program, from April 2007 to April 2010.[6] (BreastCheck data on dose had been investigated by Baldelli,[3] as described earlier in this white paper.)

Twenty-eight digital mammography systems from three different vendors were included in the study: GE Senographe Essential, Hologic Selenia, and Philips MicroDose Mammography* systems. The retrospective analysis included 238,182 screening examinations of women aged between 50 and 64 years. Cancer detection rates were calculated separately for the initial and subsequent screening cohorts, and a total of 1,632 cancers were diagnosed. All images were double-read and assigned a result according to a five-point rating scale (R1-R5) to indicate the probability of cancer. Women with a positive result (R3-R5) were recalled for further assessment workup.

Results:

- The cancer detection rate with the Philips MicroDose Mammography was at least equal to that of GE Senographe Essential and Hologic Selenia.
- In all the comparisons, there was a trend in favor of MicroDose for invasive cancer detection rate and ductal carcinoma in situ (DCIS), both for prevalent and subsequent screening **however there was not a statistically significant difference** (Figures 5 and 6).

Cancer detection rate performance result – Prevalent screening (n=119556)

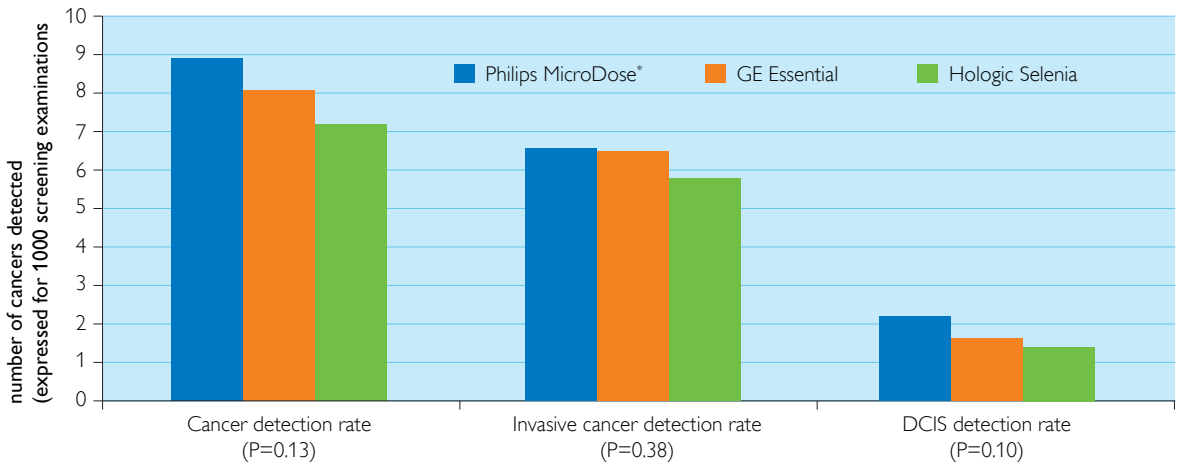

Figure 5: Comparison of cancer detection rate for prevalent screening for three FFDM systems (Confidence Interval 95%).

Cancer detection rate performance result – Subsequent screening (n=118626)

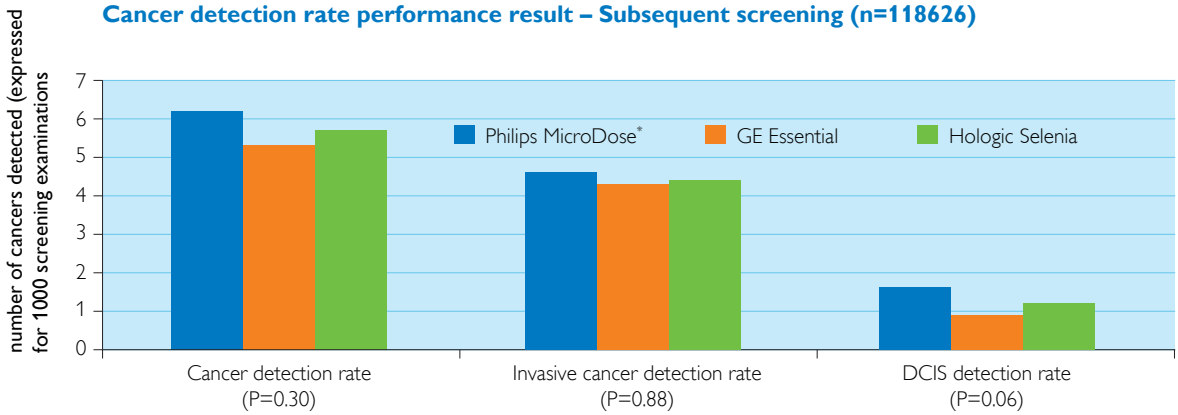

Figure 6: Comparison of cancer detection rate for subsequent screening for three FFDM systems (Confidence Interval 95%).

Conclusion

The scientific studies reviewed in this paper demonstrate the significant dose efficiency of Philips photon counting detector technology in comparison to other FFDM systems used in the studies.[2,3,4,5,13]

Keavey's comparison of the clinical performance in terms of overall cancer detection rate shows that no statistically significant difference was found among the three different mammography systems employed in the study.[6] Earlier study from the same Irish BreastCheck by Baldelli reported the examination dose for MicroDose to be 36% to 39% lower than that for the other models in the survey.[3]

In addition, Philips calculated an average weighted dose reduction using the data from the UK nation-wide breast screening program published by Oduko, et al.[2] Using the range of mean MGD for each system, dose was weighted by the number of images per FFDM model using the data summarized in Table 2.[2] The weighted average dose reduction is approximately 40%.[1]

These studies showed that we can conclude that cancer detection rate using the MicroDose Mammography was equal to that of other FFDM systems while using 18% to 50% lower radiation dose, with an average dose reduction of approximately 40%.**[1,2,3,4,5,6,13]

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* MicroDose Mammography was developed by Sectra, whose mammography operation was acquired by Philips Healthcare in September 2011.

** The actual result of the average dose reduction will vary based on variations of digital mammography systems.

\+ Mean MGD is the same as the Average MGD.

++ Data for mammography systems in the report were collected between 2006 and 2008.

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