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NHS Breast Screening Programme Practical Equipment Report

Practical Evaluation of the Siemens Mammomat Revelation

August 2020

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Executive summary

The purpose of this evaluation was to assess the practical performance of the Siemens Mammomat Revelation system for use within the National Health Service Breast Screening Programme (NHSBSP).

The evaluation was performed between February and August 2019.

Overall the radiographers, advanced practitioners and radiologists found the Revelation easy to use. The majority felt that image quality was excellent and that the time for the image to appear on the acquisition workstation was much faster than previous equipment, as well as the readiness for the next projection, improving on the overall time for a standard mammogram and stereotactic procedures.
The quality control (QC) was felt to be easy and quick to carry out.

Everyone was in favour of the paddles and paddle designs. Clients have commented on comfort of the equipment and the mood lighting was well received. No negative comments were received from clients. A recurring comment from the radiographers was the lack of a handle for clients to hold on to steady themselves during MLO views which resulted in some clients gripping onto the rotating tube arm.

All radiologists were impressed with the sharpness and contrast of the tomosynthesis images and valued tomosynthesis highly as an assessment tool. Tomosynthesis increased the confidence in diagnosis of benign lesions and projectional changes and often alleviated the need for biopsies. It was felt that Tomosynthesis was superior in the assessment of dense breasts and in the assessment of distortion and sizing of an abnormality. Tomosynthesis guided biopsy was felt to be faster in comparison to 2D stereo biopsies and more accurate in the biopsy of densities and subtle distortion.

The Revelation allows for core biopsy specimens to be x-rayed in the room using a small basket that is attached to the side of the mammography unit while the procedure is on-going. This obviates the need to leave the room and client during the procedure. Although not part of the formal evaluation it was felt that this was a useful adjunct.

The system comfortably meets the 2.5mGy national diagnostic reference level in both 2D and Tomosynthesis modes.
In conclusion the equipment evaluated is deemed acceptable for use in the NHSBSP.

1. Introduction

Following a previous technical evaluation, a practical evaluation was undertaken to assess the suitability for the equipment to be used within the NHSBSP.
The practical evaluation was undertaken at the Southampton and Salisbury Breast Screening Unit in Southampton (SSBSU) as outlined in the NHSBSP Guidance Notes for Equipment Evaluation. The evaluation took place between February and August 2019.
The objectives for evaluation included the performance and reliability of the Siemens Mammomat Revelation system, 2D and tomosynthesis image dose, image quality and diagnostic value of tomosynthesis as well as evaluation of the practical experiences of radiographers and radiologist during tomosynthesis and 2D biopsy procedures. Micro calcifications were primarily assessed with magnification views.
The unit was already familiar with an earlier version of a Siemens tomosynthesis system, albeit without biopsy capabilities. The SSBSU invites approximately 36,500 women for screening per annum of which 28,500 were screened, resulting in 1,250 assessments. As part of the evaluation over 700 screening mammograms were performed on the system and 247 tomosynthesis (DBT) examinations. 90 magnification views and 54 paddle views were obtained, 67 stereo and 43 tomosynthesis guided biopsies were undertaken.
The centre meets relevant national quality standards for breast screening and meets the criteria for evaluation centres outlined in the Guidance Notes for Equipment Evaluation.

2. Equipment evaluated

The practical performance of the Siemens Mammomat Revelation with a 50° wide angle tomosynthesis system was evaluated. The Revelation was used for the acquisition of 2D FFDM and tomosynthesis (DBT) images, stereotactic 2D and tomosynthesis guided biopsy, as well as magnification and paddle views.
Images were viewed and reported on SECTRA PACS workstations. The acquisition of tomosynthesis images automatically generated a DBT stack, synthetic 2D mammogram (Insight 2D) and 3D maximum image projection (MIP) images (Insight 3D).

- Reliability: see appendix 4
- Dose assessment: see 4.1

3. Routine Quality Control

The system was tested to NHSBSP standards in both 2D and tomosynthesis modes. Test methods followed the guidance given in NHSBSP reports 1303 and 1406, with an additional daily 2D automatic exposure control (AEC) test as recommended by Siemens using the tube mounted Perspex block provided with the system. The radiographer quality assurance team using the Revelation system were confident in the use of the Siemens Inspiration, which performs in a similar manner for QC testing in 2D mode.

In 2D mode the Siemens and NHSBSP daily 4cm thick Perspex system checks were consistent with the mAs and signal-to-noise ratio (SNR) set at baseline. The weekly full field contrast-to-noise ratio (CNR) and magnification SNR test results also show good consistency. Daily QC was repeated seven times during the period, with repeat tests indicating no equipment error. The mAs was the most stable measure, with both SNR and CNR values falling across the permitted ±10% range.

Weekly uniformity tests showed almost no variation at all and it was noted that this is a quicker test than on other systems (as only one target-filter combination is available) leaving more time for other tests. The results of the weekly image quality tests using the TOR(MAM) test object in 2D mode showed only small variations in performance during the period. Total scores for TOR (MAM) were all within 20% of baseline, and with a smaller variance when observer variation is accounted for.

The monthly 2D AEC tests at 2cm, 4cm and 7cm Perspex thicknesses showed good consistency, well within tolerance.

The tomosynthesis quality assurance testing included a daily 4cm thick Perspex system check, weekly image quality assessment and monthly AEC thickness check. The daily 4cm system check demonstrated consistent results, with the mAs and SNR remaining within the NHSBSP specified tolerance for the duration of the evaluation. Weekly CNR was stable and within the required tolerance. There were no repeats required for any of these tests.

Total scores for the tomosynthesis TOR(MAM) were within a 20% tolerance of the baseline with one outlier. It was noted that some variation in mAs, as selected by the AEC, occurred for the weekly tomosynthesis TOR(MAM) exposure. This variation was not generally seen in AEC tests and it is suspected that differences in exposure mode may be the cause. The TOR(MAM) test protocol replicated a clinical exposure with Segmentation turned on, whereas AEC tests use a non-clinical mode with Segmentation turned off. Variation in Segmented AEC performance with TORMAM position has previously been noted and with small variations in mAs duplicated for each projection, the mAs stability appears to be worse for tomosynthesis compared to 2D, despite no noticeable loss of image quality.

Monthly tomosynthesis AEC checks showed consistent mAs, SNR and CNR for 2cm,4cm, 6cm and 7cm thicknesses. There was some variation in the mAs selected by the AEC for the 6cm and 7cm thicknesses which could have been due to the measurements being carried out at different time points and thus different detector temperatures. There was some variation in CNR for the 2cm thickness but the 6cm and the 7cm were relatively stable.
It has been previously reported that Siemens systems with the same detector technology have variable QC performance within 1hour after powering up the system. Whilst this effect is apparent in the Revelation QC test results, its effect appears to be smaller than that seen on the Inspiration systems within this Breast Unit and affected higher mAs monthly AEC tests only.

4. Data on images evaluated and interventional procedures performed

4.1 Dose data

The system comfortably meets the 2.5mGy national reference level in both 2D and Tomosynthesis modes. The radiation doses for both 2D and tomosynthesis modes on the Siemens Revelation are given below. Mean glandular dose (MGD) data for 100 examinations in 2D mode (Table 2 and Figure 1) and 50 examinations in tomosynthesis mode (Table 3 and Figure 2) are presented.

Table 2 . Average values of MGD and compressed breast thickness (CBT) for different components of exposure (2D Mode)

View	Group of women	Average MGD (mGy) for 2D	Average CBT (mm)
CC	All	1.18	54
MLO	All	1.26	57
MLO	CBT 50 to 60 mm	1.20	55

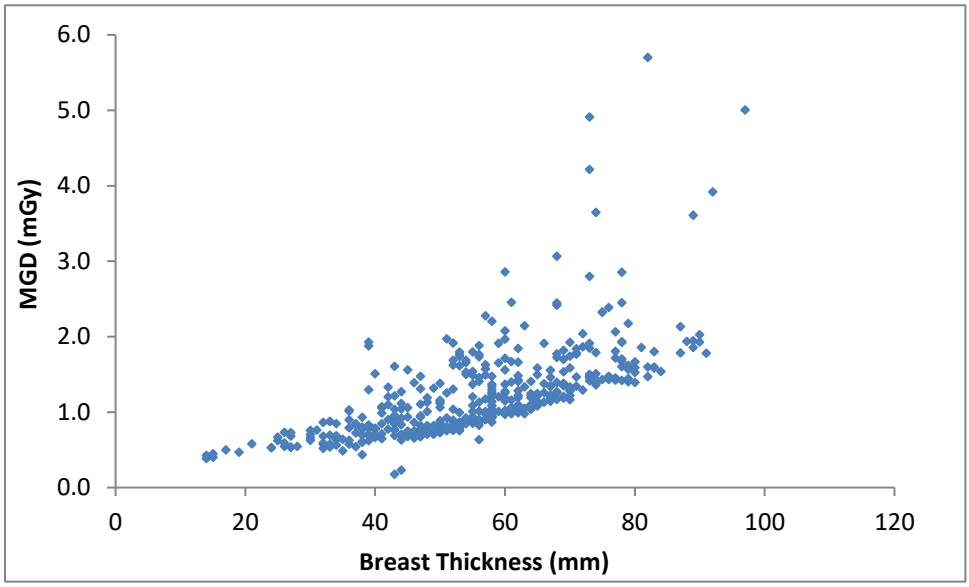

Figure 1. Calculated MGD (mGy) against compressed breast thickness (mm) for 2D

Table 3 . Average values of MGD and CBT for different components of exposure (Tomosynthesis Mode)

View	Group of women	Average MGD (mGy) for tomosynthesis	Average CBT (mm)
CC	All	2.39	57
MLO	All	2.43	58
MLO	CBT 50 to 60 mm	2.05	53

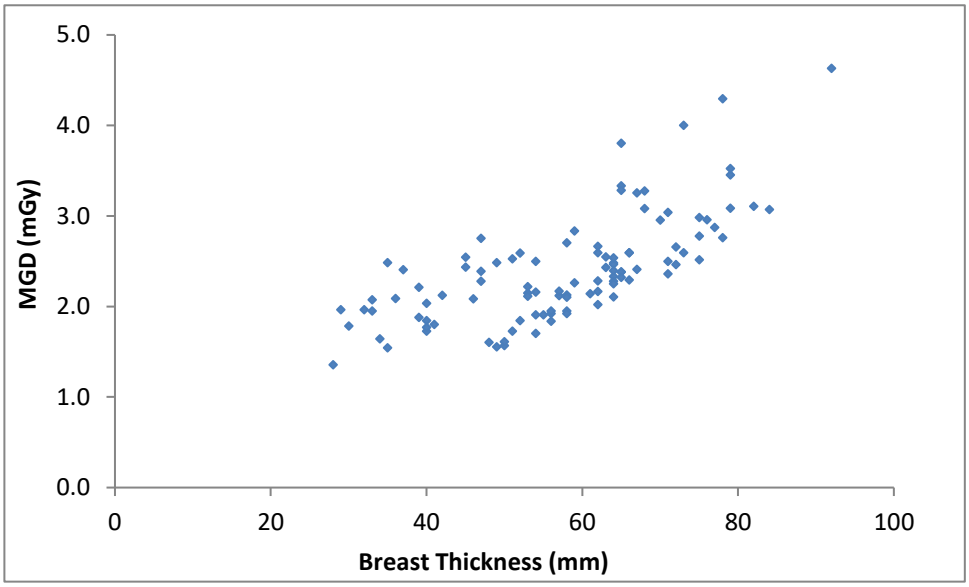

Figure 2 . Calculated MGD (mGy) against compressed breast thickness (mm) for tomosynthesis

4.2 Clinic workflow

The Southampton and Salisbury Breast Imaging unit has three mammography rooms, two of which have biopsy capabilities (including the Siemens Mammomat Revelation under evaluation). Tomosynthesis imaging and biopsy was not possible for every eligible woman in assessment clinics and some women underwent conventional further view 2D FFDM imaging or a 2D biopsy procedure instead to ensure a timely throughput. There were no other specific issues impacting on clinic workflow.
Image reconstruction time was appropriate.

4.3 Reader assessment of diagnostic value of FFDM images

The equipment is acceptable for use in clinical practice.

Overall the diagnostic value of 2D images was excellent and similar to earlier models of the Siemens Mammomat. The image quality was felt to be excellent throughout.

As expected 2D FFDM performed well in the detection of spiculated and well defined masses. Distortion and asymmetry was less well seen on FFDM images in comparison to DBT images. Calcification with and without masses was well seen on 2D FFDM images. There was no reported difference in the detection of associated micro calcifications between 2D and tomosynthesis images.

4.4 Reader assessment of diagnostic value of magnification

The equipment is acceptable for use in clinical practice.

Magnification views were primarily used for the assessment of micro calcifications and at the preference of the assessing radiologist for other lesions. No measurable difference in image quality was highlighted in comparison to the earlier version of the Siemens Mammomat.

Respondents felt that magnification paddles were easy to attach and remove and rated the ease of use of the magnification breast support table good to excellent.

4.5 Reader assessment of diagnostic value of stereotactic examinations

The equipment is acceptable for use in clinical practice.

Both conventional 2D and tomosynthesis core and vacuum biopsies were performed on the Siemens Mammomat Revelation. Acquisition and appearance of the scout images on the viewer was clearly faster in comparison to our older system. Although the acquisition of multiple tomosynthesis images took slightly longer than acquiring a conventional 2D 30-degree view, this was offset by requiring one view only for localisation. Image quality was rated as excellent. The use of the controls was rated as good to excellent.

Tomosynthesis guided biopsy accuracy outperformed 2D when biopsying densities and subtle distortion and in cases where the abnormality was seen on one view only. Tomosynthesis guided biopsy was felt to be a great adjunct to 2D biopsy in our department and was generally preferred over 2D by all biopsy performing radiologists and advanced practitioners. The entire biopsy procedure was felt to be faster and targeting was felt to be easier in comparison to 2D imaging.

We did experience a problem with the biopsy compression paddle on a couple of occasions. A bit of plastic broke off unexpectedly at the joint where the paddle slots into the machine during the biopsy procedure. Although it was felt to be safe to continue the procedure, it weakened the stability of the paddle under compression. This could have resulted in inaccuracies and might have posed a danger to the client. The fault was reported to the manufacturer immediately and adjustments to the joint

interface were made by the manufacturer to minimise the risk of this occurring in the future.

4.6 Reader assessment of diagnostic value of tomosynthesis images

The equipment is acceptable for use in clinical practice.

The evaluation of the Siemens Mammomat Revelation showed that the diagnostic value in assessment clinics for DBT was rated better compared to 2D FFDM in the majority of cases. The acquisition of tomosynthesis images automatically generated a DBT stack, synthetic 2D mammogram (Insight 2D) and 3D MIP images.
The synthetic 2D mammogram was felt to be of excellent quality and valued for instant comparison. The majority of radiologists felt that the rotating 3D MIP did not add any additional diagnostic value.

All radiologists were impressed with the sharpness and contrast of the tomosynthesis images. Tomosynthesis increased the confidence in diagnosis of benign lesions and projectional changes and often alleviated the need for biopsies. It was felt that Tomosynthesis was superior in the assessment of dense breasts and in the assessment of distortion and calculating the size of abnormality. (see Chart 1) Tomosynthesis was better in detecting multifocal cancers and incidental lesions.

Women recalled for assessment of micro calcifications were not assessed with tomosynthesis and underwent magnification views in the first instance.

Positive comments were made about the slider at the side of the image which easily indicated the position of a lesion in the breast.

An acceptable downside was the time for tomosynthesis images to appear on the PACS workstation, typically 2 to 3 minutes. This was largely related to network/PACS connections rather than to the Siemens Mammomat Revelation system.

5. Conclusion and recommendations

The practical performance of the Siemens Mammomat Revelation was very good. Overall the radiographers, advanced practitioners and radiologists found the Revelation easy to use and pleasing in design. The majority felt that image quality was excellent and that the overall time for a standard mammogram and stereotactic biopsy procedures was reduced.

The system impressed with the sharpness and contrast of the tomosynthesis images and tomosynthesis was highly valued as an assessment tool. Tomosynthesis increased the confidence in diagnosis of benign lesions and projectional changes and often alleviated the need for biopsies. It was felt that tomosynthesis was superior in the assessment of dense breasts and in the assessment of distortion and sizing of an abnormality. Tomosynthesis

guided biopsy was felt to be faster in comparison to 2D stereo biopsies and more accurate in the biopsy of densities and subtle distortion.
The equipment was found to be fairly reliable during the period of evaluation with a few technical glitches, in particular at the start of the evaluation period. The support from the application specialist and the company was exemplary.

The system comfortably meets the 2.5mGy national reference level in both 2D and Tomosynthesis modes.

In conclusion the Siemens Mammomat Revelation Tomosynthesis system is recommended for use in the NHSBSP.

Appendix 1

NHSBSP equipment evaluation form 1: Exposure and image quality record – screening & assessment

Images from 100 women minimum should be captured within the 6 to 12 week evaluation period

	Exposure factors											Comments from mammographers, r/radiographer/radiologist image readers
Image no.	Date	Patient ID	View	Field Size	Operation mode (AEC, autokV)	Dose indication or dose	Target/filter combination	kV	mAs	Compression thickness (cm)	Compression force (N)	Comments on technical image quality at the acquisition workstation (blurring, contrast, noisy, artefacts, for example)
1												
5												

Chart 1: Comparative performance by radiological abnormality:

Appendix 2

NHSBSP equipment evaluation form 2: Exposure and image quality record – magnification mammograms in assessment

Images from 100 women minimum should be captured within the 6 -12 week evaluation period

Exposure factors													Radiographer's comments	Image reader/radiologist's comments		
Date	Patient ID	View	Type of mag*	Mag factor	Field Size	Operation mode (AEC, autokV)	Dose indicator or dose	Target/filter combi-nation	kV	mAs	Comp thick (cm)	Comp force (N)	Comments on image quality (blurring, contrast, noisy, repeats, for example)	Clinical quality** E/G/S P	Comments	Initials

* Physical magnification (with mag platform) or high resolution mode ** Grade as excellent (E), good (G), satisfactory (S), poor (P)
Note: you may wish to collect further exposure data with different settings such as mA value
Images should also be viewed in optical magnification mode and compared with physical magnification.

Appendix 3

NHSBSP equipment evaluation form 3: Exposure and image quality record – stereo examinations (use one line for each exposure) for assessment

Images from 100 women minimum should be captured within the 6 -12 week evaluation period

Exposure factors											Radiographer's/radiologist's comments			
Date	Patient ID	Projection	Operation mode (AEC, autokV)	Dose indication or dose	Target/filter combi-nation	kV	mAs	Calibration checked before use Yes/no	2D or Tomo	Diagnostic quality** E/G/S/P	Was the lesion seen best in the 2D image	Was the lesion seen best in the 3D image	Was any additional information detected on either view	Initials

* This should include a check of the measurement tool ** Grade as excellent (E), good (G), satisfactory (S), poor (P)

Appendix 4

NHSBSP equipment evaluation form 4: Reliability of equipment evaluated

Questions	**Comments**
Have any equipment faults been reported to NCCPM and the manufacturer during the evaluation? If yes, please detail	Yes Noise was reported during tomo/stereo acquisitions; this was resolved by replacing the foam inserts in the tube arm with nylon inserts. The biopsy paddle was replaced twice during the trial period due to damage. The password store was corrupted twice and there was a biopsy needle error message. An interface error message led to a replacement external hard drive and monitor. A rattling was heard inside the stand which was found to be a small screw which was removed. The tower and hard drive had to be replaced at a later date when the computer would not power on.
Have any faults led to screening downtime? (if yes, please give details of what the fault was and how long it persisted)	No
All faults must be reported to the fault reporting system. Confirm this has been done.	Yes
What was the response time from the manufacturer for faults reported?	Within 24 hours
Were there any problems with connectivity?	No
Were these resolved in a timely manner?	N/A
Have you had any electrical or mechanical safety issues?	No

Appendix 5

NHSBSP equipment evaluation form 5: Overall comments

Questions	**Comments**
Is the equipment fit for use in the NHSBSP? If no, please comment	Yes
Was the equipment used at full capacity over the period of the evaluation (6/9/12 weeks) If no, please comment	Yes
Were there any concerns identified regarding repetitive strain injury for the future? If yes, please comment	No
Any additional comments on general or imaging performance	

Appendix 6 Manufacturer's comments

The Mammomat Revelation allows for cancer detection with tomosynthesis and Tomo biopsy procedures whilst ensuring the dose to the breast tissue is as low as possible. We were delighted to hear that the system produced excellent image quality as well as no reported difference in the detection of associated micro calcifications between 2D and tomo images.

We acknowledge that there was an issue with the biopsy paddle and due to the system being used clinically rather than a testing environment, we have now changed the design of this. We have had no further complaints about this.

Siemens Healthineers pride ourselves on the positive comments regarding training and support with technical issues and knowing that our wider network is working to the best of its ability.