# NHS Breast Screening Programme Equipment Report: Practical Evaluation of Siemens Healthineers Mammomat B.brilliant

June 2025

# Contents

# Executive Summary

The purpose of this evaluation was to assess the practical performance of the Siemens Mammomat B.brilliant system for use within the NHS Breast Screening Programme (NHSBSP). The main evaluation was performed between 1 May 2024 and 31 August 2024 with an extended evaluation period for 2D implant imaging until January 2025.

The 2D full field digital mammography (FFDM) imaging, Digital breast tomosynthesis (DBT) in perspective mode, stereotactic biopsy, and tomosynthesis guided biopsy were tested as part of the evaluation. The evaluation did not include PRIME, Contrast enhanced mammography, InSpect or DBT in 'Perspective' mode. The system was evaluated at the default dose of 100%, but there is an option to operate at a different dose level if required.

The Siemens B.brilliant has some distinct new design and safety features. Radiographers, Advanced Practitioners, Medical Physicists and Radiologists found the B.brilliant easy to use once training was completed. The Radiographers would have preferred a longer on-site training period to become more familiar with the differences and safety features of the B.brilliant machine. The Radiographers felt that the training on manufacturer recommended calibrations and manufacturer recommended QA testing of the equipment was limited as it was assumed there was prior knowledge from other equipment. However, there are notable differences in the testing of this equipment compared to previous models.

All Radiologists, Advanced Practitioners and image readers felt that image quality for 2D FFDM and DBT was excellent and that the time for DBT images to be acquired and to appear on the acquisition workstation was much faster compared with previous equipment. All Radiologists were impressed with the sharpness and contrast of the tomosynthesis images, the enhanced visibility of microcalcifications and the reduced metal artefact.

The image quality of 2D implant images was initially suboptimal in a small subset of implant images (breasts with an increased thickness, greater than 7cm compressed thickness), which resulted in the extension of the evaluation period whilst imaging was optimised by the Medical Physics teams from both Siemens Healthineers and the Trust. Some of the acquired images showed fraying at the skin line. A stepwise optimisation process of the implant exposure table in close collaboration with Siemens and Medical Physics led to a satisfactory solution and fraying of the skin line is no

longer apparent. For Southampton, a bespoke Manual OpDose table was created. It is recommended that systems in the NHSBSP use this updated Manual OpDose table in the first instance. The table can be found in Appendix 3.

The stationary headrest with the attached face shield was perceived by some operators to be a hindrance for mediolateral oblique (MLO) positioning depending on client size and stature. It was felt to be difficult to get the required pectoralis muscle coverage without the need for the client to overstretch the neck and back. These issues were largely mitigated through minor adaptations in technique. The face shield is frequently removed between craniocaudal (CC) and MLO image acquisition to aid MLO positioning and client comfort which may slow down the procedure.

The user must be careful when manually aligning the gantry and stationary headrest as fingers can get trapped between the two fixtures.

The mood lighting was well received.

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

In conclusion, the equipment as evaluated is deemed acceptable for use in the NHSBSP. As with all equipment procurement processes, screening services should not rely on this report alone and must ensure that it meets their needs for their department.

# Disclaimer

Mammographic equipment approved for use in the NHS Breast Screening Programme ("NHSBSP") is subject to evaluation commissioned by NHS England and carried out by a number of breast screening services in England who undertake the practical evaluation of equipment using protocols provided by the NHSBSP. These evaluations comprise a staged process as follows:

A technical evaluation by the National Coordinating Centre for the Physics of Mammography ("NCCPM") (the "Technical Evaluation").

If the Technical Evaluation meets requirements, a subsequent practical evaluation is conducted by one of the breast screening services involved in the NHSBSP (the "Practical Evaluation").

Technical and Practical Evaluations are undertaken to assess the use of equipment in a practical, clinical setting and are not intended to be clinical trials. Further information about the limitations of the Technical Evaluation and Practical Evaluations are set out below.

The purpose of the Technical and Practical Evaluations together are intended to:

- determine the suitability of the equipment for use within the NHSBSP;
- assist potential purchasers in making their choice of equipment;
- provide potential users with performance data about equipment;
- provide potential users with a record of the practical experience of using the equipment in the NHSBSP; and
- enable comparisons to be made with other pieces of tested equipment

**Disclaimer**

Whilst NHS England commissions testing for the purposes outlined above, in order to provide further information and support to providers of screening services within the NHSBSP, it is for informational purposes only and such testing is subject to the limitations described below. No representation is made by NHS England in relation to the reports generated from the Technical Evaluation or the Practical Evaluation and, insofar as the law allows, NHS England accepts no liability arising from purchase or use of equipment by providers of screening services within the NHSBSP subjected to them.

Providers of screening services within the NHSBSP must ensure that all equipment purchased and used within the NHSBSP complies with all relevant requirements of the

NHSBSP, the terms of their contracts in respect of the NHSBSP, and all other relevant obligations including but not limited to ensuring that such equipment:

- complies with national equipment standards;
- has been approved for use in the programme and is tested by appropriately trained staff and medical physics services, in accordance with NHSBSP guidelines;
- is accredited for use within the NHSBSP and that image quality and radiation dose meet acceptable standards; and
- is suitable for the usage intended in the breast screening unit.

Providers are reminded that they should carry out their own due diligence in respect of the above.

Testing undertaken during the Practical Evaluation is a balance between time, evaluation costs and depth. There are therefore limitations to the scope of the Evaluations undertaken on the behalf of the NHSBSP.

The Practical Evaluation is undertaken over a short time and does not include long term reliability or any subsequent updates to the system.

Evaluations are undertaken on systems in an assessment unit to test the full range of uses of a system. The usage may not reflect the usage required in other services or providers, in particular of a unit system solely used in a screening van or room. The technical image quality is shown in a separate report and must be acceptable before a Practical Evaluation is undertaken. The image quality of the final displayed image will be affected by the image processing and display. These are evaluated qualitatively in this evaluation, but it is not practical to evaluate clinical outcomes for the system.

The evaluation report does not absolve the provider of their responsibility during the procurement process to ensure the equipment is suitable for the usage intended by the provider. It is particularly advised that providers see example clinical images to ensure that they are satisfied with the image processing.

# 1. Introduction

A practical evaluation was undertaken to assess the suitability of the Mammomat B.brilliant 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 equipment was installed and commissioned in April 2024. The evaluation took place between 1 May 2024 and 31 August 2024 with an extended evaluation period for implant imaging until January 2025. Technical evaluation reports for the B.brilliant was carried out by the National Co-ordinating Centre for the Physics of Mammography (NCCPM) have also been published.

The SSBSU currently provides breast screening for over 100,000 clients registered across 60 GP practices. The SSBSU invites over 41,000 clients for screening per annum, resulting in over 1,300 assessments. 429 vacuum assisted biopsies/vacuum assisted excisions were performed last year. The unit performed more than 7,000 symptomatic mammograms last year in addition to the screening workload.

The objectives for evaluation included the performance and reliability of the Siemens Mammomat B.brilliant system, 2D and tomosynthesis client dose, image quality and diagnostic value of tomosynthesis as well as evaluation of the practical experiences of Radiographers and Radiologists during tomosynthesis and 2D biopsy procedures. Micro calcifications were primarily assessed with magnification views during assessment.

The screening unit is familiar with the Siemens Mammomat Revelation and Inspiration models which are both used for screening and assessment within the unit. As part of the evaluation, over 524 2D mammograms were performed on the system and over 173 tomosynthesis (DBT) examinations. 21 magnification views were obtained and over 53 stereotactic and 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.

Appendices 1 – 4 contain the template evaluation forms which were used to evaluate the equipment. Appendix 5 details the reliability of the equipment evaluated. Appendix 6 contains overall comments on the system. Appendix 7 is an exposure chart to guide implant exposure settings.

## 2. Equipment evaluated

The practical performance of the Siemens Mammomat B.brilliant was evaluated. The B.brilliant has a 50 degree wide angle tomosynthesis system and is enabled for Contrast Enhanced Mammography (CEM). The B.brilliant was used in the breast imaging department for the acquisition of 2D FFDM including breast implant imaging, tomosynthesis (DBT), stereotactic 2D and tomosynthesis guided biopsy and localisations, as well as magnification and paddle views. CEM is not part of the evaluation. Images were viewed and reported on Sectra IDS7 PACS workstations. The acquisition of tomosynthesis images automatically generated a DBT stack and synthetic 2D mammogram.

The system integrated well with our Encore, Hologic and Mammotome biopsy equipment. No problems were recorded with NBSS and PACS integration.

The B.brilliant has an integrated specimen scanner (InSpect) that allows for core biopsy specimens to be scanned immediately in the exam room. This obviates the need to leave the room and client during the procedure. The InSpect (Integrated specimen scanner) was not evaluated as the unit has a free-standing core specimen radiography system.

## 3. Routine Quality Control

The system was tested to NHSBSP standards in 2D, magnification, biopsy, stereo and digital breast tomosynthesis (DBT) modes. Test methods followed the NHSBSP guidance given in reports 1303 and 1406. The manufacturer recommends no additional tests to those recommended in Report 1303. The limited target filter combinations and rapid processing time enables the tests to be performed relatively quickly, once the users are familiar with the system. The system has two target filter combinations, one for 2D (Tungsten/ 1.0mm Aluminium) and one for tomosynthesis (Tungsten/ 0.7mm Aluminium).

In 2D mode the Siemens and NHSBSP daily 4cm Perspex system checks were consistent with the mAs, CNR and SNR set at baseline. The weekly full field and magnification test results also show good consistency. The supplied square Perspex blocks were used for all 2D and tomosynthesis tests, with the addition of an in-house aluminium square for CNR measurements. Later versions of the Mammomat Revelation changed the detector calibration methods. The B.brilliant uses the same method; the detector calibration is performed with an unfiltered beam rather than using a tube head suspended Perspex block. Weekly uniformity tests were carried out with an unattenuated beam as per the calibration conditions. These showed very little variation during the evaluation. It was noted that this is a very quick test as there is only one 2D target filter combination.

Weekly image quality tests using the TOR MAM in 2D mode did not display any significant variation in performance during the period. Total scores for TOR MAM were all within 20% of baseline, and with a smaller variance when observer subjectivity is accounted for.

The monthly 2D AEC tests at 2cm, 6cm and 7cm thicknesses showed good consistency, with results well within tolerance.

The tomosynthesis quality assurance testing included a daily 4cm 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.

The total scores for images of TOR MAM acquired using tomosynthesis were within a 20% tolerance of the baseline. 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 tomosynthesis AEC tests and it is suspected this is because of differences in exposure mode for these tests. 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, for both 2D and DBT tests. Variation in segmented AEC performance with TOR

MAM position has previously been noted.  With small variations in mAs between scans, the TOR MAM mAs stability appears to be worse for tomosynthesis compared to 2D despite no noticeable loss of image quality.

Monthly tomosynthesis AEC checks acquired with segmentation turned off, showed consistent mAs and SNR for 2cm, 6cm and 7cm thicknesses. The CNR was relatively stable for the 2cm thickness but showed more variation for the 6cm and 7cm thicknesses.

There are several configuration options available on the system that may affect user quality control tests, depending on local arrangements.

Unlike previous Siemens systems, tomosynthesis images can only be processed in BTO form, as opposed to CT. This means that individual ‘slices’ cannot be exported for performance testing and that the full BTO image must be exported. The local PACS configuration had to be changed to be able to receive BTO images.

The configuration of biopsy needles took a significant amount of time with the radiographers and applications specialists. It is thought that this is due to the novelty of the system to the installation team and the local holder selection, and that this should be more efficient for future installations. All subsequent biopsy calibration checks have passed in both 2D and tomosynthesis modes.

The routine physics geometric distortion test in tomosynthesis mode indicates a non-uniformity of scaling between slices in 'perspective' reconstruction modes of up to 8%. Siemens altered the tomosynthesis reconstruction processing of the evaluation unit to the ‘Cartesian’ mode used on previous Mammomat systems which uses a rectilinear reconstruction method and passes the geometric distortion test. There is no inconsistency in scaling for biopsy modes as the default reconstruction is ‘Cartesian’. The system default is ‘Perspective’ and users are advised to review the suitability of this reconstruction during commissioning. To ensure consistency with other systems in the unit, it was decided to not use the “Perspective” mode clinically during the evaluation period.

It was noted during commissioning that the 'deadman' functions correctly when the exposure button is released during an exposure by terminating the beam. However, the operator can continue with the next exposure with the error message still visible on the screen. This is unlikely to be an issue in clinical use as the system would have decompressed and thus operators would need to compress before the next exposure. Nevertheless, users should be aware of this.

The system was installed with factory default image processing (“Flavor 5”) which led to a different image appearance compared to other Siemens systems at the centre. After a trial of

the different processing flavours with a Radiologist and Siemens Applications Specialists, the processing was altered to “Flavor 0” which has a much more comparable image appearance to the other Siemens systems in the unit.

A stationary tomosynthesis feature is available for testing the tomosynthesis target/filter combination in routine physics tests, as the alternative filter is not available in 2D mode.

# 4. Data on images evaluated and interventional procedures performed

## 4.1 Dose survey

As the image quality results from physics testing were deemed acceptable during commissioning, the manufacturer recommended dose setting of 'Normal 100%' was used for the full duration of the evaluation. There is the option to set different dose levels.

The dose results below are presented using both the Dance dose model and the TG282 dose model in Tables 1 and 2 respectively. Data was exported from the Trust's Dose Management System, Sectra DoseTrack. The system also communicates effectively with the Dose Management System, OpenRem.

The system meets the 2.5mGy national reference level in both 2D and tomosynthesis modes. The CC and MLO 2D data was made up of approximately 2,500 images. The 2D MLO data for 50-60mm compressed breast thickness (CBT) had a sample size of 540 images. For tomosynthesis, the sample size was 158, 154 and 26 images for CC, MLO and 50-60mm CBT CC respectively.

**Table 1. Mean values of MGD and CBT for different components of exposure using the Dance dose model**

| View | Group of clients | Average MGD (mGy) | | Average 2D CBT (mm) |
|---|---|---|---|---|
| | | 2D | Tomosynthesis | |
| CC | all | 1.29 | 2.09 | 54 |
| MLO | all | 1.44 | 2.16 | 59 |
| MLO | CBT 50 to 60mm | 1.21 | 1.90 | 55 |

**Table 2. Mean values of MGD and CBT for different components of exposure using the TG282 dose model**

| View | Group of clients | Average MGD (mGy) | | Average 2D CBT (mm) |
|---|---|---|---|---|
| | | 2D | Tomosynthesis | |
| CC | all | 1.05 | 1.61 | 54 |
| MLO | all | 1.15 | 1.66 | 59 |
| MLO | CBT 50 to 60mm | 1.09 | 1.59 | 55 |

## 4.2 Clinic workflow

The SSBSU has three mammogram rooms, two of which have biopsy capabilities, including the Siemens Mammomat Revelation and the Siemens B.brilliant under evaluation. Most of the assessment clients receive DBT as further views. Having an additional Mammomat with DBT and 2D stereo capability was an advantage and aided efficiency and workflow. Calcifications were largely assessed with magnification views.

There were no specific issues impacting negatively on clinic workflow.

Image acquisition and reconstruction time was felt to be much faster for DBT imaging than previous systems. The transfer time for DBT images to our Sectra PACS workstation was slower at times, however likely related to our network system capability.

## 4.3 Ergonomics

The SSBSU is already familiar with the Siemens Mammomat Revelation which has similar operating features to the B.brilliant under evaluation.

A major design difference of the B.brilliant to the previous Siemens Mammomat versions is the independent movement of the tube unit from the table and gantry (ComfortMove) during set up. The independent tube movement from the detector was felt to be a good feature for MLO positioning by some Radiographers.

The stationary headrest was felt to be suboptimal for biopsy procedures. Our clients undergo biopsy predominantly in a supine position and the stationary headrest was felt to be in the way when attaching the biopsy equipment. This was less of an issue after the users became more familiar with the machine and did not affect the success of the procedure.

The user must be careful when manually aligning the gantry and stationary headrest as fingers can get trapped between the two fixtures. There is a rubber sensor along the top

edge of the gantry with an automated movement stop but this does not extend down the front edges of the gantry. Although this was specifically mentioned in the Applications training, a radiographer did trap her fingers between the gantries during the trial period. Fortunately, she only sustained a minor injury that did not require any treatment.

Due to the design, the transparent face shield attached to the stationary headrest comes down lower in comparison to other Siemens Mammomat machines. This was optimal for CC imaging and felt to be an advantage for DBT imaging in protecting the client from the fast movement of the tube head. Although the transparent face shield is angled inwards and the client could be more easily accessed during MLO positioning, the stationary headrest and face shield come down very low, touching the client's shoulder and some clients must bend further backwards risking neck strain injury or images with suboptimal pectoralis muscle coverage. Therefore, the face shield is frequently removed in between MLO and CC image acquisitions to aid more comfortable MLO positioning to the detriment of workflow speed, patient ergonomics and equipment longevity.

For safety reasons, automatic movements are disabled if the object table is below 95cm. If the 'Ready' button is pressed continuously, the system will move to the desired position.

A positioning laser light was felt to be unnecessary and too bright for clients' eyes and was subsequently disabled. The integrated mood lighting creates a welcoming and soothing atmosphere, especially with adjustable colours and intensity levels. The Radiographers were advised not to use the integrated mood lighting on the full intensity, white light setting as this can cause the circuit to overload and thus blow a fuse. It is understood that this has subsequently been resolved in a software update.

The screen displaying the system position and angles differs from other Siemens systems as it has been moved from the base of the column at floor level to eye height under the gantry. This has benefits and limitations, the main benefit being that the operator does not have to look down to the screen and the main limitation being that the operator cannot see the screen from behind the control panel as easily. The manufacturer highlights this is due to the layout of that room. Clients were reported to be interested in the values on the screen, which is now directly in front of them.

# 5. Reader assessment of images

## 5.1 Reader assessment of diagnostic value of routine 2D images

The equipment is acceptable for use in clinical practice. All images acquired during the evaluation period were assessed as part of the evaluation.

PRIME was not currently used in the centre and so was not included in this evaluation.

The diagnostic value of standard 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 in dense breasts and asymmetry was less well seen on FFDM images in comparison to DBT images as expected.

Calcifications with and without masses were well seen on 2D FFDM images. There was a reported difference in the detection of associated micro calcifications between 2D and tomosynthesis images. There was enhanced visibility of microcalcifications on the DBT images in comparison to earlier versions of the Mammomat. Artefacts from surgical clips was markedly reduced.

We had a problem with the image display of 2D implant imaging. Some of the acquired images showed fraying at the skin line.  The image quality of 2D implant images was initially suboptimal in a small subset of implant images (breasts with an increased thickness, greater than 7cmcompressed thickness). It was initially felt by Siemens that this was related to overexposure and low compression force and could not be corrected in image processing.

The radiography team initially used the pre-installed manual OpDose tables for implants, integrated on the system, with a standardised compression force above 35N as advised by Siemens.

The implant exposure table was optimised for Southampton needs in close collaboration with Siemens engineers and the Medical Physics department to provide a local solution. Careful, stepwise adjustments of mAs and kV were implemented and fraying of the skin line has not been observed subsequently. The recommended implant exposure chart can be found in Appendix 7, it is recommended that this is used as a starting point for NHSBSP systems. Individual centres must ensure that this exposure chart is suitable for their local requirements.

## 5.2 Reader assessment of diagnostic value of magnification images

The equipment is acceptable for use in clinical practice.

Magnification views were primarily used for the assessment of micro calcifications and paddle views at the preference of the assessing Radiologist for other lesions. Image quality was excellent and no measurable difference in image quality was highlighted in comparison to the earlier versions 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 very good.

## 5.3 Reader assessment of diagnostic value of biopsy examinations

The equipment is acceptable for use in clinical practice.

Both conventional 2D and tomosynthesis core and vacuum biopsies and wire localisations were performed using the B.brilliant. The time to acquire and for images to be displayed was clearly shorter for DBT than on our older Mammomat Revelation system. Image quality was rated as excellent. The usability of the controls was rated good but not as intuitive as with the Mammomat Revelation as additional button presses are required in certain situations. It is understood that this has been resolved in a subsequent software update.

Integration with our current Encore, Hologic, Mammotome and Achieve biopsy equipment was good.

The InSpect (Integrated specimen scanner) was not evaluated as the Breast Imaging Unit has a free-standing core specimen radiography system.

## 5.4 Reader assessment of diagnostic value of tomosynthesis images

The equipment is acceptable for use in clinical practice.

The evaluation of the Siemens Mammomat B.brilliant showed that the diagnostic value in assessment clinics for DBT was rated as excellent. The acquisition of tomosynthesis images automatically generated a DBT stack and a synthetic 2D mammogram. The synthetic 2D mammogram was felt to be of excellent quality and valued for instant comparison. All Radiologists were impressed with the sharpness and contrast of the tomosynthesis images.

Clients recalled for assessment of microcalcifications underwent magnification views in the first instance.

It was noted that microcalcifications showed enhanced visibility on the DBT images in comparison to earlier versions of the Mammomat. Artefacts in the planes from surgical clips was markedly reduced.

In clients with a compressed breast thickness over 8cm (11 out of 173 DBT examinations) some artefacts such as blurring-ripple, lines in the axilla and truncation of the skin surface were noted. This mainly affected the MLO views. The artefacts did not obscure important findings and had no negative impact on reporting. No clients with compressed breast thickness over 10cm were imaged using tomosynthesis during the trial.

Whilst previous Siemens mammography systems with wide angle tomosynthesis have displayed a warning message to the operator regarding limited image quality between 80 and 100mm compressed breast thickness, the B.brilliant does not. It is however stated in the Operator Manual (VA10). Operators should be aware of this. There is a warning message for compressed breast thicknesses greater than 100mm, that only the slices from 0-100 will be generated, this is consistent with previous models

Mammographers found that for clients with thicker breast tissue under automatic exposure control operate more effectively for the B.brilliant than the Siemens Revelation. For the B.brilliant there was less need to adjust the exposure settings. Mammographers also noted the increased speed of tomosynthesis image acquisition and processing, compared to previous Siemens Mammomat systems. Scan and reconstruction timings can be found in the NHSBSP Technical Evaluation.

Tomosynthesis increases the confidence in diagnosis of benign lesions and projectional changes and often alleviates the need for biopsies. Tomosynthesis was superior in the assessment of dense breasts and in the assessment of distortion and calculating the size of abnormality. Tomosynthesis was better in detecting multifocal cancers and incidental lesions and calcifications.

## 5.5 Reader assessment of diagnostic value of contrast enhanced digital mammography

CEM is currently not approved by the NHSBSP and was therefore not part of the evaluation. There are ongoing trials of CEM.

## 5.6 Reliability of equipment

The equipment was found to be reliable during the period of evaluation with a few technical and operational glitches. The overall support from the engineering team and application specialists was good. See Appendix 1 for details.

The previously mentioned CQC incident relating to a motion block being enabled when the gantry was below a safety threshold of 95cm was resolved by disabling the motion block function. On the day of the incident the machine was below 95cm, the scout images were carried out but when the operator attempted to progress to the two stereo views the system would not move to its first exposure position. The system was taken out of clinical use and thoroughly tested, though notably at above 95cm. The system was put back into clinical use as the fault could not be recreated but occurred again on the next patient. Upon investigation by the manufacturer, the motion block was disabled and it has not been an issue since.

A software reinstall was required when the system would not switch on. This resolved the fault.

## 6. Confidentiality

The evaluation of the B.brilliant Mammomat was undertaken on behalf of the NHS Breast Screening Programme. The evaluation fully complied with the local and NHS information governance requirements relating to confidentiality and disclosure of patient information and system security.

Patient data were not shared with the company. Limited data were visible to the company where necessary to resolve technical problems and improve system reliability. Any data exported from the unit was done so anonymously.

# 7. Training

The SSBSU is already familiar with the Siemens Mammomat Revelation which has similar operating features to the B.brilliant under evaluation.

Some differences in design and operation are detailed in section 4.3 Ergonomics.

The B.brilliant application training was scheduled for one week after installation. Radiographers felt that the B.brilliant training could have been more efficient if the configuration of the system and needles had been planned separately from the training of Superusers to gain more dedicated time for one-to-one training.

The Superusers also felt that it would have been useful to have the training syllabus / checklist on hand for the initial training to guide learning and make it more efficient. The training checklist was made available however for the cascade of training thereafter.

Support was always available on demand after the initial training period but couldn’t be fully utilised because of clinical pressures.

## 8. Conclusion and recommendations

The practical performance of the Siemens Mammomat B.brilliant is good. Radiographers, Advanced Practitioners and Radiologists found the B.brilliant user friendly once familiar with all new features. More intense training was required to get to know the machine and its limitations.

The integrated mood lighting creates a welcoming and soothing atmosphere.

All readers felt that image quality was excellent following local adjustment for implants.

The overall acquisition and reconstruction time for DBT was reduced. The system impressed with the sharpness and contrast of the tomosynthesis images and the increased visibility of microcalcifications and reduced metal artefacts.

The equipment was found to be reliable during the period of evaluation with a few technical glitches at the start of the evaluation period. The support from the application specialist and the company was good.

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

In conclusion, the equipment as evaluated is deemed acceptable for use in the NHSBSP. As with all systems, screening units must ensure that the mammography unit meets their needs during the procurement process.

## 9. Acknowledgements

The authors (Dr Michaela Stahnke, Fiona Wall, Ben Johnson) would like to acknowledge the contribution of all staff at the Southampton and Salisbury Breast Screening Service and the Medical Physics department. Their feedback was instrumental in preparing this report. Thank you also to John Loveland and his colleagues at the NCCPM for assistance in calculating patient dose information.

## Appendix 1: Reliability of equipment evaluated

Screening service: Southampton and Salisbury Breast Screening

Evaluation centre (mobile/static): Princess Anne Hospital, Southampton

Start of evaluation: 01 May 2024 End of evaluation: 31 August 2024

Images from 100 women minimum to ensure as much natural variation is captured within the 6-week evaluation period

| Questions | Comments |
|---|---|
| Have any equipment faults been reported to NCCPM and the manufacturer during the evaluation?<br><br>If yes, please detail | 02.05.24 Error 61 & 68 with height below 95cm would not allow the scout pair to be taken for biopsy and localisation procedure. Reported to NCCPM.<br><br>02.05.24 BIOS password box appears on start up/reboot, could not start the system. Resolved by Engineer, keyboard replaced. Reported to NCCPM.<br><br>02.05.24 Failed tomosynthesis geometric distortion tests. Siemens informed who adapted configuration of Premia0_Bio to Premia0_C which performs a cartesian reconstructs. Tests subsequently passed. Reported to NCCPM.<br><br>02.05.24 There was a problem with the table height during a biopsy procedure at the beginning of the evaluation. The system would not allow the scout pair to be taken for biopsy and localisation procedures with the table height below 95cm. The table height needed to be lower with the patient in a supine position to allow comfortable access to the biopsy field by the performing Advanced Practitioner/Radiologist. A fault caused gantry movement to be blocked below this height. The unexpected behaviour of the system resulted in overexposure of two patients. This was reported to the Care Quality Commission (CQC) and NCCPM as a multiple patient unintended exposure. Siemens promptly |

| | |
|---|---|
| | resolved the problem which was caused by a motion block being incorrectly enabled.<br><br>23.05.24 Warning message on machine console if below 95cm, users unaware if it was a fault hence contacted Siemens, they reassured it was a warning message to inform user that machine will not automatically move to MLO or ML position for safety reasons. Users can move to desired position using their hand on the button or raise the height to allow MLO imaging. Reported to NCCPM<br><br>11.06.24 Multiple error messages on the machine when performing stereo procedure. Engineer remotely dialled in and explained that compression force was below 15N for biopsy phase hence error MU 60 ID 38. Apps advised staff to apply minimum compression of 35N. Reported to NCCPM.<br><br>26.06.24 System not switching on one morning at 8am, PC kept going into shutdown mode. Engineer called to reload the system software and system backed up with user settings. Reported to NCCPM<br><br>28.06.24 Casing damaged after a biopsy procedure when tube head hit the back of the biopsy chair. Replacement casing to left side cover fitted by Siemens. Reported to NCCPM.<br><br>28.06.24 First Implant taken since reload of software, images showed frayed skin edges on CCs , the examination was completed in other room as images taken in he room were not to the standard expected. Apps specialist visited on 3.7.24 and advised us to use Manual OpDose with minimum 35 Newtons compression for Implants in B.brilliant machine. Reported to NCCPM.<br><br>29.07.24 Replacement of glass lead screen as it had ripples when it was first installed in April, noticed by Siemens engineer and he ordered a new glass screen. Also, the PC was swapped over to other side of the |

| | |
|---|---|
| | workstation for easier access to switch on and off the machine. Reported to NCCPM.<br><br>15.08.24 Head rest/face shield loose. Replaced by Engineer. Reported to NCCPM. |
| Have any faults led to screening downtime? (if yes, please give details of what the fault was and how long it persisted) | We had 2 other rooms so screening was not affected as such but the room was hard down on couple of occasions.<br><br>2 days machine not in use till Error 61 and 68 - height issue.<br><br>1 day for system not booting up. Software upload was completed the next day, only 1 engineer trained in B.brilliant and he was available the next day.<br><br>1 day for replacing the damaged casing. |
| If faults were reported, what was the response time from the manufacturer? | Response time was good, usually within 24 hours. |
| Were there any problems with connectivity? | No |
| Were these resolved in a timely manner? | Yes |
| Have you had any electrical or mechanical safety issues? | No |

## Appendix 2: Overall comments

| Questions | Comments |
|---|---|
| Is the equipment fit for use in the NHSBSP?<br><br>If no, please comment | Yes) |
| Was the equipment used at full capacity over the period of the evaluation (6/9/12 weeks)<br><br>If no, please comment | Yes<br><br>Contrast Enhanced Mammography not commissioned. |
| Were there any concerns identified regarding repetitive strain injury for the future?<br><br>If yes, please comment | No |
| Any additional comments on general or imaging performance | Beware of finger trapping between the gantry and tube head when moving the tube head back to neutral position. |

## Appendix 3: Proposed implant exposure chart

| Implant in Situ | | | | | Push back implant |
|---|---|---|---|---|---|
| Use 'Implant' Manual exposure | | | | | Use 'Bilateral Mammogram' (OpDose mode) |
| mm | kVp | mAs | Target /filter | | |
| 0 – 19 | 24 | 45 | W/Al1.0 | | |
| 20 – 29 | 25 | 45 | W/Al1.0 | | |
| 30 – 39 | 26 | 56 | W/Al1.0 | | |
| 40 – 49 | 26 | 90 | W/Al1.0 | | |
| 50 – 59 | 26 | 110 | W/Al1.0 | | |
| 60 – 69 | 26 | 125 | W/Al1.0 | | |
| 70 – 79 | 27 | 125 | W/Al1.0 | | |
| 80 – 89 | 28 | 125 | W/Al1.0 | | |
| 90 – 99 | 29 | 110 | W/Al1.0 | | |
| 100 - 109 | 30 | 110 | W/Al1.0 | | |
| 110 + | 31 | 110 | W/Al1.0 | | |

## Appendix 4: Manufacturer's comments

Siemens Healthineers extends its sincere thanks to the Southampton and Salisbury Breast Screening Unit (SSBSU) for their commitment, time, and effort during the NHS Breast Screening Programme (BSP) practical evaluation of the MAMMOMAT B.brilliant system.

We greatly appreciated the close collaboration with Southampton and Salisbury Breast Screening Unit (SSBSU), particularly in addressing implant imaging concerns. This partnership proved invaluable in deepening our understanding of the unit's specific requirements. While the extended evaluation period for implant imaging may appear lengthy, it is important to note that such cases are infrequent and were assessed consistently throughout the process.

In response to the evaluation, we have implemented updates to improve training for future MAMMOMAT system installations. Application training materials have been revised to ensure accurate and consistent communication, including highlighting subtle differences from previous models to help prevent avoidable errors. Additional warning labels have also been added to the tube head as a visual reminder for users during system movement.

We also recognise that a few software-related idiosyncrasies were encountered during the evaluation. These issues have been addressed and resolved in the latest software release which is now already supplied with all systems and installed systems are currently being upgraded to the latest software.