



Public Health
England

Protecting and improving the nation's health

NHS Breast Screening Programme practical evaluation report

Practical evaluation of the Fujifilm
Amulet Innovality digital breast
tomosynthesis system

December 2019

Available from the National Co-ordinating Centre
for the Physics of Mammography (NCCPM)

About Public Health England

Public Health England (PHE) exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-leading science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health and Social Care, and a distinct delivery organisation with operational autonomy. We provide government, local government, the NHS, Parliament, industry and the public with evidence-based professional, scientific and delivery expertise and support.

Public Health England, Wellington House, 133-155 Waterloo Road, London SE1 8UG

Tel: 020 7654 8000 www.gov.uk/phe

Twitter: [@PHE_uk](https://twitter.com/PHE_uk) Facebook: www.facebook.com/PublicHealthEngland

About PHE screening

Screening identifies apparently healthy people who may be at increased risk of a disease or condition, enabling earlier treatment or informed decisions. National population screening programmes are implemented in the NHS on the advice of the UK National Screening Committee (UK NSC), which makes independent, evidence-based recommendations to ministers in the 4 UK countries. PHE advises the government and the NHS so England has safe, high quality screening programmes that reflect the best available evidence and the UK NSC recommendations. PHE also develops standards and provides specific services that help the local NHS implement and run screening services consistently across the country.

www.gov.uk/phe/screening Twitter: [@PHE_Screening](https://twitter.com/PHE_Screening) Blog: phescreening.blog.gov.uk

For queries relating to this document, please contact: phe.screeninghelpdesk@nhs.net

OGL

© Crown copyright 2019

You may re-use this information (excluding logos) free of charge in any format or medium, under the terms of the Open Government Licence v3.0. To view this licence, visit [OGL](http://www.ogil.io). Where we have identified any third party copyright information you will need to obtain permission from the copyright holders concerned.

Published December 2019

PHE publications

gateway number: GW-935

PHE supports the UN

Sustainable Development Goals



Contents

About Public Health England	2
About PHE screening	2
Executive summary	4
1. Introduction	5
2. Equipment evaluated	5
Objectives	8
3. Routine quality control	8
4. Data on images evaluated	9
4.1 Dose data	9
4.2 Clinic workflow	11
4.3 Reader assessment of diagnostic value of tomosynthesis images	11
5. Conclusions and recommendations	12
References	14
Appendix 1: NHS BSP equipment evaluation form 4 (reliability of equipment evaluated)	15
Appendix 2: NHS BSP equipment evaluation form 5 (overall comments)	16
Appendix 3: Manufacturer's comments	17

Available from the National Co-ordinating Centre
for the Physics of Mammography (NCCPM)

Executive summary

The purpose of this practical evaluation was to assess the performance of the Fujifilm Amulet Innovality tomosynthesis system for use within the NHS Breast Screening Programme (BSP) in the assessment of recalled women in a clinical environment.

The evaluation was carried out from January 2018 to December 2018.

The workflow for the evaluation was slightly restricted as all women recruited had both standard 2D assessment views and tomosynthesis using the Fujifilm Amulet Innovality machine. All the radiographers did online Good Clinical Practice (GCP) training to enable them all to be able to consent the women. This helped the workflow within the assessment clinics.

The radiologists were very positive about the diagnostic value of tomosynthesis. The visualisation of various lesion types was overall felt to be the same as or better than standard 2D assessment views. Radiologists frequently reported added value with tomosynthesis in the assessment of asymmetric densities, when tomosynthesis added confidence to a normal result. This relates to the ability of tomosynthesis to demonstrate the composite nature of an apparent soft tissue density. It thus improves the specificity of the assessment process and reduces the need for unnecessary biopsies of benign or normal tissue.

Overall the women being assessed felt the tomosynthesis system with the fit-sweet paddle was more comfortable than their previous mammogram.

A dose survey was carried out for 2-view tomosynthesis images of the breast being assessed. The average mean glandular dose for the 50 to 60mm breast was 1.71mGy, well within the dose limits for 3D mammography.

1. Introduction

The system passed the technical evaluation so a practical evaluation was undertaken to assess suitability for the equipment to be used within the NHS BSP.

Table 1. Evaluation site information

Site/location	East Lancashire Breast Screening Service Burnley
Eligible population	Approx. 90,000
Period of evaluation	January to December 2018
Commissioning date	July 2016
Additional equipment/software tested	None
Any specialised features	Dual Swing Tomosynthesis

2. Equipment evaluated

The Fujifilm Amulet Innovality digital breast tomosynthesis (DBT) system has a tungsten target, with a 50µm thick rhodium filter for 2Dimensional (2D) imaging and a 700µm thick aluminium filter for tomosynthesis imaging. It has a flat panel amorphous selenium detector, manufactured by Fujifilm. The Amulet Innovality has 2 tomosynthesis modes, the Standard (ST) mode which uses a narrow angular range of projections (15°), and the High Resolution (HR) mode which uses a wider angular range of projections (40°).

There is a facility available to carry out a combination exposure, in which a 2D and a tomosynthesis exposure are performed within a single compression. In addition, the Amulet Innovality automatically produces a synthesised 2D image in both ST and HR modes, which is displayed at the end of the tomosynthesis series. The tomosynthesis images are reconstructed planes spaced at 1mm intervals, with the total number of planes equal to the compressed breast thickness in mm. This thickness can be user configured and is supplied with a default value of plus 10mm (the system was configured to plus 5 for the evaluation). The maximum compressed thickness for a tomosynthesis scan is 149mm. The projection images and the reconstructed planes appear on the acquisition workstation after each acquisition. Figures 1, 2 and 3 below show the Fujifilm Amulet Innovality breast tomosynthesis system.

The provided acquisition workstation (AWS) consists of two 3MP monitors mounted on swing arms, with a keyboard and a separate control pad (note the quantity and size of displays is configurable). It has an integrated radiation shield within the console. A footswitch for exposure at workstation was provided. This operated satisfactorily. Software version 7.0.0017 was in use during the period of the evaluation.

A practical evaluation of the Amulet Innovality in normal 2D operation was published in February 2017.¹ The technical evaluation of the Amulet Innovality digital breast tomosynthesis system was published in February 2018.²

For the purpose of the evaluation all tomosynthesis imaging was undertaken in the ST mode only.



Figure 1: The Fujifilm AMULET Innovality digital breast tomosynthesis system (front view)



Figure 2: The Fujifilm AMULET Innovality digital breast tomosynthesis system (side view)



Figure 3: Tomosynthesis face guard

Objectives

The primary objective of the evaluation was to establish the performance and serviceability of the Fujifilm Amulet Innovality digital breast tomosynthesis system for women who have been recalled for further assessment following mammographic screening:

- to evaluate the function and reliability of the equipment when used for tomosynthesis
- to assess the practical aspects of the equipment in an assessment clinic setting
- to report the experiences and comments of radiographers and radiologists on the use and value of the system during assessment, including image quality and practical aspects of image review
- to report the radiation dose to the breast for the women imaged during the evaluation

3. Routine quality control

Routine quality control (QC) was undertaken daily, weekly and monthly as detailed in the NHSBSP guidelines relevant to both 2D and tomosynthesis exposures. Different radiographers carried out these tests from day to day. All test results were recorded on the QA spreadsheet supplied by Integrated Radiological Services (IRS), the local physics provider.

The daily calibration of the Innovality takes place automatically when the system is not in use. The system was ready for quality control testing within 2 and a half minutes of start-up.

A 4.5 cm thick block of Perspex was imaged under AEC control for the daily QC tests. The exposure factors were recorded. The mean pixel value and SNR were determined in a central region of the image. The images were examined for artefacts and a log was kept.

The results for mAs, signal-to-noise ratio (SNR) and pixel value for 2D imaging, and mAs for tomosynthesis were all recorded daily. All values remained within the NHS BSP remedial limits ($\pm 10\%$ of the baseline). No artefacts were seen or logged.

Both contrast-to-noise ratios (CNR) and image quality were recorded weekly throughout the evaluation. The results were within the remedial levels showing that CNR was stable throughout the evaluation. CNR is one indication of image quality.

Monthly tests included the mechanical safety checks and the changing thickness Perspex blocks of thickness 2cm and 7cm were exposed under AEC control and the mAs recorded for both 2D imaging and tomosynthesis. The SNR and CNR were also determined for both thicknesses of Perspex for 2D imaging. The Amulet Innovality does not have a region of interest measurement facility in tomosynthesis mode therefore clinically for QC purposes the SNR and CNR cannot be evaluated. All results for 2D lie within the remedial limits of $\pm 10\%$ for mAs and $\pm 20\%$ for SNR and CNR.

4. Data on images evaluated

4.1 Dose data

For the purposes of the evaluation, only the affected breast was imaged, normally with both a cranio-caudal (CC) and medio-lateral oblique (MLO) tomosynthesis projection. In addition, 2D focal compression views were acquired of the affected breast at the same time as the tomosynthesis exposure. Ethical approval for this additional dose was gained and all women assessed were given risk and benefit information so they could make an informed choice.

The exposure data from 53 women (25 imaged within the first month of the evaluation and 28 at the end of the evaluation) was recorded. This data was entered into a modified version of the NHS BSP dose calculation database.

The detailed results of the dose survey are presented in Appendix 2. The average mean glandular dose (MGD) and compressed breast thickness (CBT) are summarised in Table 2 below. MGDs were calculated using data published by Dance et al.³

Table 2. Average values of MGD and CBT for different components of exposure

View	Group of women	Average MGD (mGy) for 2D	Average MGD (mGy) for tomosynthesis	Average CBT (mm)
CC	All	1.61	1.60	53
MLO	All	1.71	1.64	53
MLO	CBT 50-60 mm	1.59	1.71	55

The national diagnostic reference level (DRL) for mammography is 3.5mGy for an MLO view of a 55mm compressed breast. There are currently no limiting values for tomosynthesis, but the Fujifilm Amulet Innovality with average MGD of 1.71mGy for a

compressed breast thickness of 50 to 60mm compares favourably with other manufacturers tomosynthesis systems. The national DRL figure for 2D exposures may be used for comparison. The dose survey results for the Fujifilm Amulet Innovality tomosynthesis system is well below the national DRL.

The most recent dose audit for 2D imaging on the Fujifilm Amulet Innovality system found that the average MGD for 50 to 60mm breasts was 1.59mGy. The tomosynthesis exposures are therefore approximately 8% higher than 2D. Whilst the 2D dose audit data was not obtained from women who were involved in the tomosynthesis study, the calculated doses compare favourably with data from other manufacturers' systems.

Comparison of displayed dose with calculated MGD

The calculated MGDs were compared with the doses displayed on the acquisition workstation and stored in the DICOM header of each image as 'organ dose'. These are plotted against each other in Figure 4 (below). The gradient of each graph is close to 1.0 for tomosynthesis exposures. These displayed and stored values could therefore be used for dose surveys (or if required for any individual woman) without the usual need for extensive calculation based on exposure parameters and X-ray tube output.

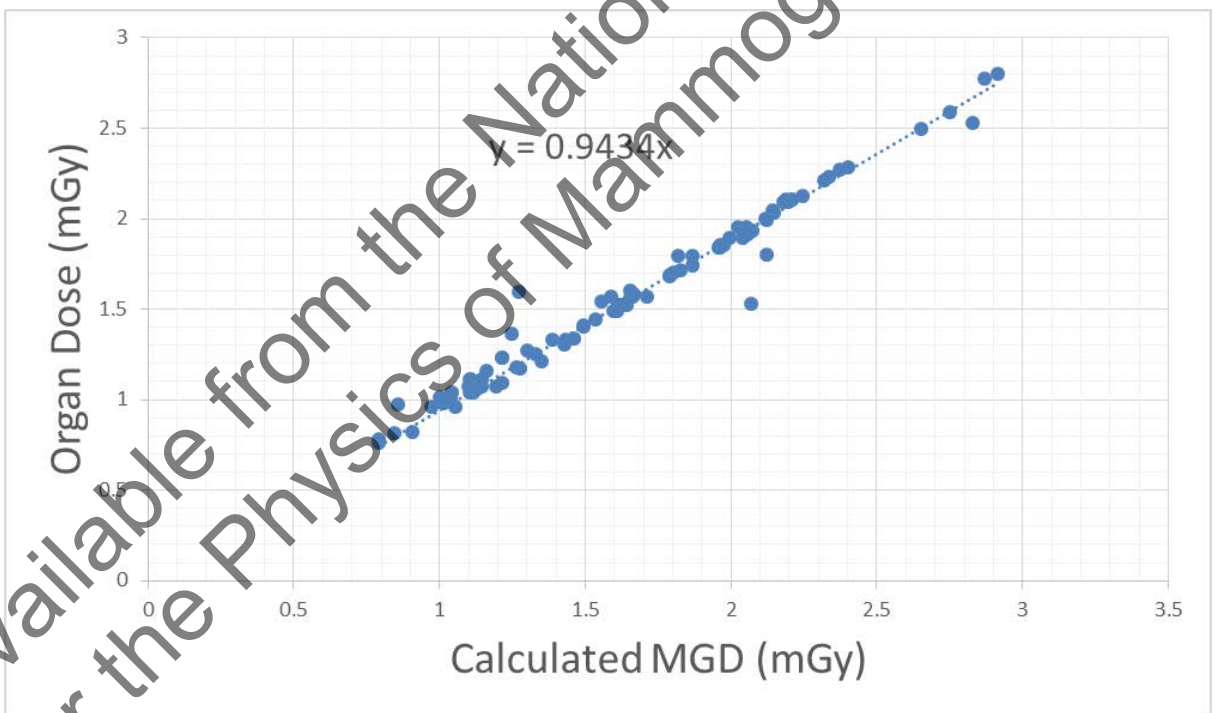


Figure 4. Calculated MGD against compressed breast thickness (mm)

4.2 Clinic workflow

There were minor issues impacting on clinic workflow, the clinical trial required that the women be consented. Appointments were booked 15 minutes earlier than usual to allow for completion of consent forms and to answer any questions. All the radiographers completed online Good Clinic Practice Training (GCP), so they could all consent the women.

The radiologists reported each case as it became available and manipulated the images and display settings on an individual case basis. The time taken to review each case varied according to the complexity of the case. An informal discussion with the radiologists revealed that the total reviewing time was between 6 to 10 minutes per woman, including reviewing the case with the other radiologist present in clinic.

4.3 Reader assessment of diagnostic value of tomosynthesis images

The equipment is acceptable for use in clinical practice. Asymmetries and well-defined masses were all clearly seen on tomosynthesis. Distortions also had better visualisation on tomosynthesis. Some distortions were only visible on one view on standard 2D mammograms and could be seen on both views on tomosynthesis, allowing improved technical planning for stereo-core biopsies. There is no difference in the visibility of ill-defined masses with 2D imaging and tomosynthesis (see figure 5).

A total of 360 patients were evaluated in the trial. There were 138 lesions identified in 131 patients. Four patients had an additional lesion on the same side and four patients had a lesion on the contralateral side. For all 138 lesions the readers felt that evaluation with tomosynthesis was as good as 2D spot compression views. Overall the readers found tomosynthesis better than 2D imaging in the majority of the lesions.

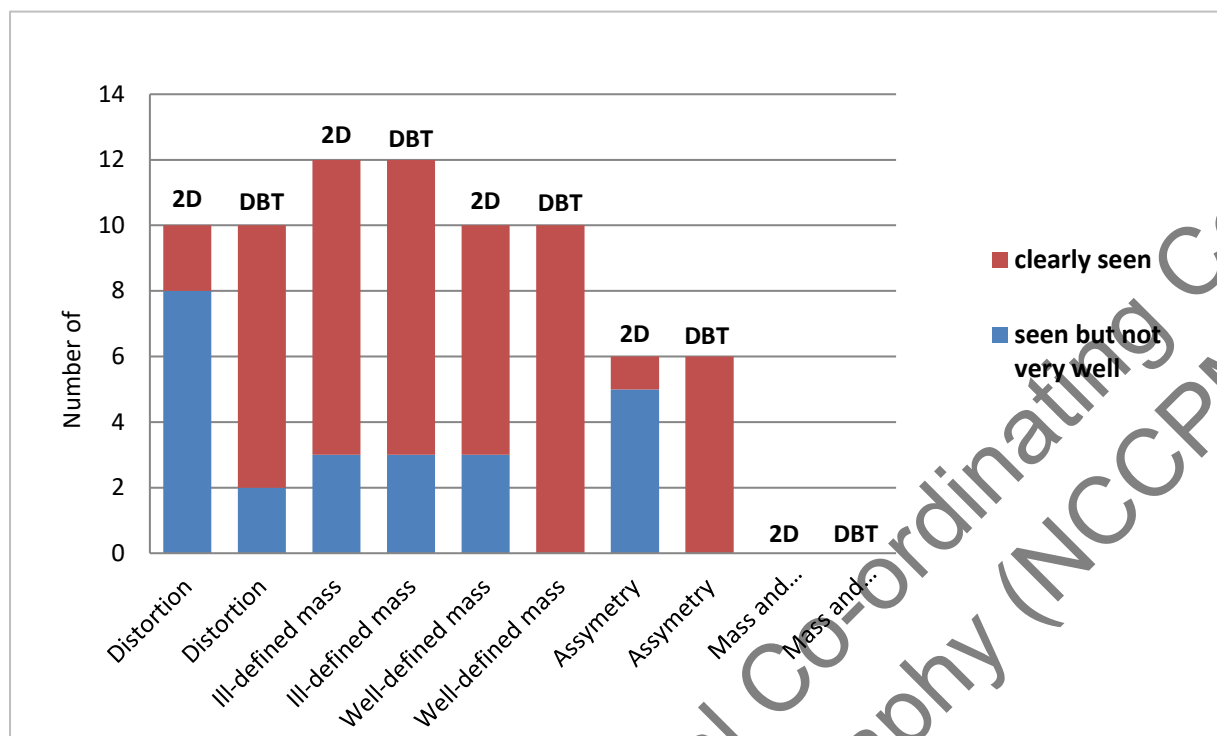


Figure 5: Visibility with tomosynthesis and with 2D imaging

5. Conclusions and recommendations

The overall assessment of the practicality and usefulness of the Fujifilm Amulet tomosynthesis system for assessment is positive. The Fujifilm Amulet tomosynthesis was found to be at least equivalent to standard supplementary mammographic views for the diagnosis of screen detected soft tissue breast lesions.

The readers were satisfied with the tomosynthesis images. In particular, architectural distortions, margin delineation of masses and composite densities are demonstrated very well.

As expected in the first instance of using new equipment, the radiographers had to adapt their technique to produce diagnostic images. They are now all very familiar with the use of the Fujifilm Amulet Innovality.

The equipment was found to be reliable during the period of the evaluation. Mean glandular doses for both 2D and tomosynthesis imaging were found to be well below the national DRL.

The acquisition workstation could be changed to make it user friendly by making the icons easier to find. The new improved fixed 3D faceguard supplied by Fujifilm has now been in use for 1 month and has proved much more acceptable for both women and the radiographers alike.

The Fujifilm Amulet Innovality tomosynthesis was found to be suitable for use in assessments in the NHS BSP.

Available from the National Co-ordinating Centre
for the Physics of Mammography (NCCPM)

References

1. Clark J, Mungutroy EHL. Practical evaluation of Fujifilm AMULET Innovality digital mammography system. (NHS Breast Screening Programme Equipment Report 1602) 2017.
2. Studley CJ, Hadjipanteli A, Oduko JM, Yong KC. Technical evaluation of Fujifilm AMULET Innovality digital breast tomosynthesis system. (NHS Breast Screening Programme Equipment Report) 2018.
3. Dance DR, Young KC, van Engen RE. Estimation of mean glandular dose for breast tomosynthesis: factors for use with the UK, European and IAEA breast dosimetry protocols. *Physics in Medicine and Biology*, 2011, 56(2): 453-471.

Available from the National Co-ordinating Centre
for the Physics of Mammography (NCCPM)

Appendix 1: NHS BSP 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 15/05/18: machine would not turn on 15/08/18: cracked faceguard 24/10/18: software issue
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?	1-2 days
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: NHS BSP 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	Evaluation was over a 12 month period as assessment clinics only held twice a week.
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	NO

Available from the National Co-ordinating Centre for the Physics of Mammography (NCCPM)

Appendix 3: Manufacturer's comments

Fujifilm are delighted that the Amulet Innovality has now been evaluated and passed as acceptable for use with 3D Tomosynthesis imaging in Symptomatic use and Screening (should Tomosynthesis be approved by NHSBSP for use in screening in the future).

Fujifilm are pleased to see that the system demonstrated excellent image quality at low dose and that patients commented on how much more comfortable the system was than previous mammograms. Image quality and patient experience are two areas that Fujifilm has invested heavily to improve. From our unique Hexagonal Close Packed Pixel detector delivering 50 micron pixel image and iterative reconstruction techniques, to our Fit-Sweet compression paddles and Comfort Comp hysteresis compression.

We would like to make note that the system was tested using software version 7.0.0017. The latest software available for the system is 9.2. Version 9.2 contains iterative reconstruction of tomosynthesis images in to our S-View synthetic 2D image, and hysteresis based compression for our Comfort Comp compression as the most significant additions.

Fujifilm would like to highlight the reliability of the system which, despite some early teething problems listed in the report, remained operational throughout the trial and subsequent to its completion. Our UK install base delivered uptime of 99.99% during the evaluation period.

We would like to conclude our comments by thanking PHE, NHS BSP and the National Co-ordinating Centre for the Physics of Mammography (NCCPM) for their support and co-operation during the evaluation and not least East Lancashire Breast Screening Trust for completion of the trial.