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NHS Breast Screening Programme Equipment Report

Practical evaluation of IMS Giotto Class NHSBSP Equipment Report

August 2020

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Executive Summary

The purpose of this evaluation was to assess the practical performance of IMS Giotto Class Full Field Digital Mammography (FFDM), Digital Breast Tomosynthesis (DBT) and the biopsy facility for use within the National Health Breast Screening Programme (NHSBSP).

The evaluation was performed between June 2018 and June 2019.

Overall the radiographers, advanced practitioners and radiologists found the Giotto Class easy to use with a good provision of accessory equipment.

The IMS Giotto Class was found to be fit for purpose in terms of image quality, serviceability and breast dose. The performance of the biopsy unit was easy to use and found to be acceptable when used with either stereotactic or DBT guidance.

The quality control (QC) was felt to be easy and quick to carry out.

It was felt that Tomosynthesis was superior in the assessment of persistant abnormalities in the majority of cases.

Performing procedures with patient in the upright position was the preferred option for ease of manual handling of the equipment and client comfort. The average reconstruction time of 1 minute 55 seconds is a little long when performing DBT guided interventional procedures.

Feedback on the prone table and reconstruction time has been relayed to the manufacturers. The manufacturer has considered the feedback and made changes but this has not been evaluated.

In conclusion the equipment evaluated is deemed acceptable for use in the NHSBSP.

1. Introduction

This evaluation was carried out at the Thirlestaine Breast Unit, Cheltenham. This centre meets the relevant national quality standards for breast screening and also meets the criteria for evaluation centres outlined in the NHS Breast Screening Programme (NHSBSP) guidelines for equipment evaluation[1]
The Thirlestaine Breast Unit is an NHSBSP unit that invites approximately 37,000 women per year for screening of whom 29,000 are screened. Approximately 1000 assessments are carried out per year.

The evaluation took place between June 2018 and June 2019. Due to a change in requirement of documents produced following evaluation, the information provided details examinations performed over a 4 month period between January 2019 and April 2019.

As per the technical evaluation the equipment can be used in several modes. In the technical evaluation it was shown that dose was acceptable in all modes. For the practical evaluation the breast unit was advised to use the “contrast 2D high dose” mode as it was felt that this would give image quality better than achievable.

The primary objectives of the evaluation were to establish the performance and serviceability of the full field digital mammography (FFDM) component of the IMS Giotto Class, to evaluate the digital breast tomosynthesis system for women who have been recalled for further examination following mammographic screening and to assess the biopsy unit.

2. Equipment evaluated

2.1 Equipment under evaluation

The main components of the Giotto Class function as a full field digital mammography unit and a tomosynthesis unit. Other equipment is as listed below.

Paddles

The GIOTTO Class Mammography unit has several compression paddles. There is:

- a 24 cm x 30 cm compression paddle for standard mammography
- a 15 cm x 30 cm compression paddle for standard mammography
- a shifting 18 cm x 24 cm compression paddle for standard mammography
- a 24 cm x 30 cm TOMO paddle for Digital Breast Tomosynthesis
- a 10 cm x 10 cm spot paddle and Biopsy spacer for lateral approach biopsies

- a 10 cm x 10 cm spot and mag paddle and Geometrical Magnification device provides a 1.8 magnification factor for magnification purposes
- a shifting 17 cm x 22 cm biopsy paddle for upright and prone biopsies

The paddles lock in to place and can be removed easily for cleaning.

Face Shield

The Giotto unit comes with two face shields. A face shield for mammograms and a face shield for tomosynthesis. The mammography face shield slots in to a groove on to the top of the head of the machine. The tomosynthesis face shield locks in to place on the gantry by turning the fixing levers and has three height positions that can easily be moved on the console. The tomosynthesis face shield can also be used for standard mammography.
The face protectors must be removed when using the magnification device.

GIOTTO FLEXITABLE Biopsy Table

The Flexi Table is a patient support table used to position the patient in the prone position during breast biopsy examinations. It is designed to be used in conjunction with the Giotto Class system to perform stereotactic (or tomosynthesis) biopsy examinations with patients in the prone position.
The table needs to be moved into position using two people and has independent mechanical brakes on each couple of wheels. The brakes are controlled by the manual step position. The table has vertical movement with an up and down hand control and the Flexi table has lighting underneath.
The table has an aperture at the head of the table for a breast to be positioned through. The table does not have a floating top but the aperture has a movable ring which has more of an arc on one side which enables the breast to be moved to either a left or right laterality. The bed comes with a thin cushion that the patient lies on and a strap/belt that holds the patient in position. The bed can be charged in between patients to maintain vertical movement as the battery maximum operating cycles (up/down) with patients are approximately 20.

Smart Finder Biopsy Unit

The Smart Finder Biopsy Unit comes with its own accessories. There is a:

- Fine Needle Support
- Guide for fine needles or guns with a lateral approach
- 90 mm test needle
- Green Grid Phantom
- Compressor Grid Adaptor
- Needle Phantom
- 24 cm x 30 cm Plastic Compressor with 7 cm x 7 cm window

- A shifting 17 cm X 22 cm Plastic Compressor with 7 cm x 7 cm window
- 10 cm x 10 cm Plastic compressor without window
- Mammotome support
- Vacora support
- Core Biopsy (BIP) support
- Mammotome guide for a vertical approach
- Mammotome guide for a lateral approach
- 10 cm x 10 cm biopsy compressor without window
- Spacer
- Needle spacer for guns with a lateral approach

The Smart Finder consists of a motorised support and movement unit for commercial biopsy guns and needles.

At Thirlestaine Breast Centre the following biopsy devices and needles were used during the evaluation.

- Bard 14G x 10.0 cm Biopsy needle
- Bard 14G x16.0 cm Biopsy needle
- Hawkins lll 20G x 10.0 cm Localisation wire
- Hawkins ll 20G x 12.5 cm Localisation wire
- 17G x 10 cm Ultraclip Marker Coil
- Achieve 14G x11 cm Disposable Biopsy needle
- Achieve 14G x15 cm Disposable Biopsy needle
- 10G X 118 cm Vacora Vacuum Assisted Biospy needle
- Bard Encore Espire 10G Vacuum Assisted Biopsy needle
- Bard Encore Espire 7G Vacuum Assisted Excision needle

It operates in conjunction with the use of the X-ray source and digital sensor of the Giotto Class device. The Smart Finder is operated through the Acquisition Work Station (AWS) and manually motored to target on the Smart Finder Unit by the Clinician/Operator.

The Smart Finder Biopsy Unit allows X-rays to be taken under biopsy exposures consisting of Scout, tilt left 15° and tilt right 15° for stereo paired pictures for paired targeting. Two images, tilt left 15° and tilt right 15° are sufficient to identify (target) a lesion in both images. A single tomosynthesis image is required for one point targeting. The user is able to view the latest images acquired in the three different perspectives or in tomosynthesis with biopsy on the AWS.

At Thirlestaine Breast Centre the following image techniques were used:

- Scout with Stereotactic pair biopsy targeting and Stereotactic pair check images
- Scout with Tomosynthesis biopsy targeting and Stereotactic pair check images
- Scout with Tomosynthesis lateral approach targeting and Tomosynthesis check image

After a target has been selected and the clinician/operator has chosen a needle to perform the procedure the data is sent to the Smart Finder Biopsy Unit. This enables the calculation of the co-ordinates of the lesion identified on the three Cartesian axes X-Y-Z. The clinician manually moves the Smart Finder Biopsy Unit to target by pressing an enable button on the Smart Finder Biopsy Unit. The button is continually pressed until the Smart Finder Biopsy Unit beeps when it has reached target. At target the X-Y-Z co-ordinates read 0.

At target the unit is ready to perform the procedure by inserting the needle in to the breast. If the procedure has been performed properly, the tip of the needle (or the centre of the sampling chamber) will reach the centre of the identified lesion. Further fine adjustment can be made of the needle position or for taking a sample from the areas around the lesion using the AWS or the gantry mounted display.

The Smart Finder Biopsy Unit has a series of safety devices to prevent improper movements or procedural errors by the clinician/operator. The equipment has been designed to minimise the risk of inserting the needle in an area other than the targeted area.

3. Routine Quality Control

Routine QA was undertaken and evaluated during the process & found to be acceptable.

4. Data on images evaluated and interventional procedures performed

As recommended in the guidance notes for evaluation we collected information on exposure and image quality for FFDM, tomosynthesis images, magnification views and interventional procedures. Any issues were also documented. 3 readers then retrospectively reviewed documentation and images to provide objective summaries of 100 FFDMs, 100 DBTs, 50 magnification views and 100 interventional procedures.

4.1 Clinical dose audit and comparison of displayed dose with mean glandular dose

Clinical dose audits were undertaken for FFDM and Digital Breast tomosynthesis (DBT) Mean Glandular Dose (MGD) data using the NHSBSP dose calculation database. The 2D audit included 1930 views (980 cranio-caudal and 950 medio-lateral oblique) from 501 patients and the DBT audit included 1142 views from 566 patients.

Detailed results of the dose surveys are presented in Appendix 1. A summary is shown in Table 1 below for cranio-caudal (CC) and medio-lateral oblique (MLO) views.. The national diagnostic reference level (NDRL) for mammography is 2.5 mGy for a 53mm

standard breast. There are currently no limiting values for tomosynthesis. The dose survey results for screening are shown to be below the NDRL. The DBT doses are seen to be 30% higher than 2D imaging views & above the DRL for 2D.

Table 1. Mean values of MGD and compressed breast thickness (CBT) for 2D and DBT modes.

	Mean MGD (mGy)	Mean CBT (mm)
CC – 2D all scans	1.93	57
MLO – 2D all scans	2.38	59
MLO – 2D CBT 50-60mm	1.97	55
CC - DBT all scans	2.57	57
MLO – DBT all scans	3.04	58
MLO – DBT CBT 50-60mm	2.58	55

Agreement between the displayed and measured MGD was seen to be between 11 to 16% for 2D and 6 to 17% for DBT during the evaluation period which is well within the expected tolerance of a 30% difference.

4.2 Clinic workflow

Digital mammography:

In terms of client throughput in a screening clinic the machine functioned similarly to other mammography units within the department.

Digital Breast tomosynthesis (DBT) in screening assessment:

Staff involved in screening assessment clinics all felt that workflow was improved with use of DBT compared with spot compression views. DBT images were reviewed on PACS in 2 formats. Planes (1mm thickness) or thicker slices (slabs). A 2D synthetic image was also automatically generated for viewing on PACS but this has not been formally evaluated as part of the assessment purpose.

4.3 Reader assessment of diagnostic value of FFDM images

Digital image quality was assessed by 3 film readers for 100 sets of mammograms acquired during the evaluation period. For this group of patients density was assessed as dense, mixed or fatty in line with previous evaluation documents. In this patient cohort breast density was evaluated as dense in 24%, mixed in 53% and fatty in 23%.Contrast was evaluated as being either high or satisfactory. There were no problems with image sharpness or image noise. Diagnostic value was graded as either good or satisfactory in the majority of patients. Value of the zoom function was more variable and whilst satisfactory overall, in dense breasts this function was more variable.

4.4 Reader assessment of diagnostic value of magnification views

Digital image quality was assessed by 3 film readers for 50 sets of physical magnification views acquired during the evaluation period. Diagnostic image quality was rated as good in 41 and satisfactory in 9. A rating of satisfactory was generally attributed to a degree of blurring which occurred in either very dense or large breasts. Contrast was generally good. As expected physical magnification produced higher quality images than optical magnification.

4.5 Reader assessment of diagnostic value of tomosynthesis images

The same 3 readers retrospectively reviewed DBT images from 100 patients who had undergone DBT as part of their screening assessment process. If an abnormality persisted we assessed whether it was better visualised on DBT compared with original screening mammograms. We also evaluated whether the DBT had provided additional diagnostic information in terms of size and multifocality in those cases that proved to be malignant. Although we did not use DBT to assess microcalcification if it was the predominant mammographic abnormality, in 22 of the cases we reviewed there was associated microcalcification. Of the abnormalities that persisted the reviewers felt that the abnormality was better visualised on DBT in the majority of cases (85%) including the visibility of the microcalcification. In those cases that proved to be malignant additional useful information was demonstrated in 7 of 34 cases (21%).

4.6 Clinician and radiographic assessment of biopsy device

100 consecutive cases undergoing image guided interventional procedures were reviewed. These were 56 core biopsies, 10 vacuum assisted biopsies and 34 localisations.

Procedures were performed either with patient in upright position or on Prone table using 14 gauge core needle biopsy, 10 gauge Vacuum Assisted Biopsy or Hawkins 3 localisation needles.
The approach for procedures varied:

- CC compression, CC approach
- Latero-medial compression, lateral approach
- Medio-lateral compression, medial approach
- CC compression, lateral approach with angled lateral arm
- CC compression, medial approach with angled lateral arm

For reasons of both patient comfort and manual handling it soon became apparent that most staff preferred performing procedures with patient in the upright position. Feedback re the prone table has been relayed to the manufacturers with the main issues being discomfort for patient and the lack of a floating top.
Radiographers found positioning of the patient and obtaining a scout view straight forward in the upright position. A compression of 6kG or greater is necessary to enable exposure which some patients found too fierce. Targeting of the lesion is as described in section 2. We found that the compression often reduced to less than 6kG therefore not allowing automatic exposure. We overrode this by setting manual exposures which worked well.
Re-construction of the DBT image takes some time (see section 4.7) particularly in patients with large breasts, compared with an almost instant image using 15° stereo pair. Despite this most clinicians/radiologists favoured the DBT for initial targeting of both soft tissue abnormalities and calcifications mainly because they felt very confident in its accuracy and abnormalities were often more clearly visualised on the DBT image.
Target and needle are selected easily from drop down lists. A traffic light colour system indicates which needles can be used and if the target is achievable which helps with decision making. The pictorial image gives useful 2D information of the position of the selected needle to lesion when at target. The gantry mounted display unit is used by operators to achieve fine movements of the X, Y, Z coordinates when performing 14 gauge core needle biopsy (CNB) and wire localisation. Some operators commented that they preferred the hand held unit of the previous GIOTTO model.
Operators found deployment of tissue markers straightforward although when enabling, the unit moves almost back to home before moving to target which is time consuming at the end of a procedure.
The lateral approach was used primarily for Vacuum assisted procedures. Fitting the lateral approach paddle and spacer launches the software for a lateral approach procedure. Once the patient is in position and an acceptable scout image has been obtained, targeting and needle

selection are achieved in the same way as described for 14 gauge biopsy and wire localisation. Needle angle is simulated on the acquisition station with 2D image guidance helping with decision making to achieve optimal angulation for sampling. The biopsy arm is manually adjusted to the correct angle for the procedure and locked into place. Most operators initially found use of the lateral arm more complicated than the vertical approach. However with training ease of use has improved.
Most biopsy procedures successfully obtained representative histology specimens and failure to obtain was usually due to patient factors eg movement. All localisation wires were accurately placed.
Overall we have been satisfied with performance.

4.7 Image reconstruction time

Image reconstruction times were measured as in the guidance provided in the technical evaluation. Times were found to be the same as in the technical report with an average time to viewing reconstructed images from decompression of 1minute 55secs. Whilst this is not a problem in screening assessment it is rather long when performing DBT guided interventional procedures.

5. Conclusions

We found the IMS Giotto Class to be fit for purpose in terms of image quality, serviceability and breast dose. We also found the performance of the biopsy unit to be acceptable when used with either stereotactic or DBT guidance.

For reasons of both patient comfort and manual handling it became apparent that most staff preferred performing procedures with patient in the upright position. As stated above the average reconstruction time of 1 minute 55secs is a little long when performing DBT guided interventional procedures.

Feedback re the prone table and reconstruction time has been relayed to the manufacturers. The manufacturer has considered the feedback and made changes but this has not been evaluated.

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 -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)	Initials
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

MIS would like to thank colleagues within Thirlestaine Breast Unit for the time taken to assess the Giotto Class. The feedback has been very valuable and we have implemented a few changes to further improve new units that are currently being delivered. Please see a list of changes and improvements below:

- New Prone Table (lighter and with better maneuverability, can withstand load up to 200 kg)
- New radiolucent needle guide to reduce artifact during tomo-guided biopsy
- New sliding biopsy paddle 17x22 cm for frontal approach and 10x10 cm (without hole) for lateral approach
- Completely new Raffaello Software interface speeding up Tomosynthesis reconstruction times and allows imaging whilst the system is reconstructing the prior image. The new iterative reconstruction time (50mm CBT) is less than 27seconds.
- Real Time SLAB – allows users to select slice thickness direct from the software with a visual vertical bar to scroll
- SMARTCHECKER accessory device for real time biopsy core imaging on the mammography unit