NHS England

NHS Breast Screening Programme Equipment Report: Technical Evaluation of GE Healthcare Senographe Pristina update Enhanced Automatic Optimisation of Parameters (AOP)

December 2024

Contents

Executive Summary

Full evaluation reports on the GE Healthcare Pristina were previously published. GE Healthcare have introduced a new exposure curve for the automatic exposure control (AEC) for the GE Senographe Pristina. This is called the Enhanced Automatic Optimisation of Parameters (AOP).

Changes were made to the Standard and Standard+ AOPs for 2D mode, but no changes were made to the Dose- AOP. There were also changes for the tomosynthesis mode, the doses were raised for the Mo/Mo anode/filter combination used for compressed breast thicknesses of less than 35mm. The purpose of the evaluation was to determine whether the updated equipment meets the main standards in the NHS Breast Screening Programme (NHSBSP) and European protocols.

The mean glandular dose (MGD) was found to be well below the remedial level for all automatic exposure control (AEC) dose modes. For a 53mm equivalent standard breast, the Dance MGD was 1.52mGy and 1.85mGy for Standard and Standard+ respectfively, this compares to 1.34mGy and 2.07mGy for the original Standard and Standard+ respectively, which are well below the remedial level of 2.5mGy. The image quality, measured by threshold gold thickness using the CDMAM 3.4 test object, is better than the achievable level for both Enhanced Standard and Standard+.

The new Enhanced AOP of the GE Senographe Pristina meets the requirements of the NHSBSP standards for digital mammography systems operating in 2D and tomosynthesis modes.

A practical evaluation for this change is not recommended. However, it would be sensible for departments to audit the image quality and dose of the Enhanced AOP, if it is installed.

Background

Mammographic equipment approved for use in the 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:

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

2. 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
- 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
- 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 Technical 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 Technical Evaluation is undertaken over a short time and so will not assess if image quality may change over time. The equipment tested is generally selected by the equipment supplier and has been set up by them. It should be noted that individual centres may be set up differently for example to meet the requirements of the screening service.

The technical image quality as measured on this system must be acceptable. The image quality of the final displayed image will be affected by the image processing and display and this is separately evaluated qualitatively in the Practical Evaluation.

This 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.

1. Introduction

1.1 Testing procedures and performance standards for digital mammography

This report is an update to a series evaluating commercially available direct digital radiography (DR) systems for mammography on behalf of the NHS Breast Screening Programme (NHSBSP). In particular, this is an update to the Evaluation of the GE Pristina [1] [2]. The testing methods and standards applied are mainly derived from NHSBSP Equipment Report 0604 [3] which is referred to in this document as 'the NHSBSP protocol'. The standards for image quality and dose are the same as those provided in the European protocol, [4] [5] but the latter has been followed where it provides a more detailed standard, for example, for the automatic exposure control (AEC) system.

Some additional tests were carried out according to the UK recommendations for testing mammography X-ray equipment as described in IPEM Report 89 [6].

1.2 Objectives

The aims of the evaluation were to:

- determine whether the GE Pristina digital mammography system, operating in the new AOP mode, meets the main standards in the NHSBSP and European protocols
- provide values for contrast-to-noise ratio (CNR) for tomosynthesis planes with 1mm separation

2. Methods

2.1 System tested

The tests were conducted at the Helen Garrod Centre in Nottingham, on a GE Senographe Pristina system as described in Table 1. The Pristina is shown in Figure 1.

Table 1. System description

Manufacturer	GE Healthcare
Model	Senographe Pristina
System serial number	000048089018194177
Target material	Molybdenum (Mo), rhodium (Rh)
Added filtration	30µm molybdenum, 30µm silver (Ag)
Detector type	Caesium iodide with amorphous silicon
Detector ID	PXA0500_02
Pixel size	100µm
Detector size	240mm x 286mm
Pixel array	2294 x 1914, 2850 x 2394
Typical image sizes	9MB (small field size), 13MB (large field size)
Source to detector distance	660mm
Source to table distance	637mm
Pre-exposure mAs	Thickness < 38mm : 26kV Mo/Mo 2mAs Thickness 38-65mm: 34kV Rh/Ag, 2mAs Thickness > 65mm: 34kV Rh/Ag, 4mAs
Automatic exposure control (AEC) modes	Standard, Dose-, Standard+, Implant
Software version	8.2.10

Four AEC modes are available for use with the Pristina, as listed in table 1. The AEC is referred to GE as Automatic Optimisation of Parameters (AOP). GE Healthcare have produced an enhanced AOP to replace the Standard and Standard+. The 2D modes were changed alongside fewer changes for the tomosynthesis mode. In tomosynthesis, the doses were raised for the Mo/Mo anode/filter combination used for compressed breast thicknesses of less than 38mm. In the DICOM header, ‘Exposure Control Mode Description’

(0018x,7062x) shows the AEC mode used and states ‘Enhanced’ if the AOP has been updated.

Exposure factors 26kV Mo/Mo are used for small breasts, for exposures up to 38mm radiological thickness. For thicker breasts the factors used are 34kV Rh/Ag. The mAs is selected as appropriate for the most dense part of the breast. 29kV Mo/Mo is used for exposures of smaller thicknesses when the magnification table is in use.

There has been another change in the set up of the Pristina since the original evaluation of tomosynthesis [2], the default plane separation has been changed from 0.5mm to 1mm.

Figure 1. GE Healthcare Pristina system

The following tests were undertaken in 2D and tomosynthesis modes for the original AOP and the Enhanced AOP.

2.2 Output and HVL

The output and half-value-layer (HVL) were measured as described in the NHSBSP protocol, at intervals of 3kV.

2.3 Dose estimation

Doses were measured by exposing different thicknesses of PMMA under AEC with segmentation turned off. Each PMMA block had an area of 180mm x 240mm. Spacers were used to adjust the paddle height to be equal to the equivalent breast thickness, as shown in Table 3. The exposure factors were noted and mean glandular doses (MGDs) were calculated for breasts of equivalent thicknesses using the Dance dosimetry model [7] [8] [9].

In tomosynthesis mode, exposures of a range of thicknesses of polymethyl methacrylate (PMMA) were made using AEC. For each measurement the height of the paddle was set to the equivalent breast thickness for that thickness of PMMA. Spacers were positioned at the nipple edge of the field, so as not to affect the operation of the AEC.

The method of measuring tomosynthesis doses described in the NHSBSP protocol differs slightly from the method described by Dance et al [10]. The incident air kerma is measured with the compression paddle well above, instead of in contact with, the dosimeter. Measurements on other systems show that this variation reduces the air kerma and thus the mean glandular dose (MGD) measurement by 3% to 5%. Otherwise the MGDs in tomosynthesis mode were calculated using the method described by Dance et al [10]. This is an extension of the established 2D method, using the equation:

$$D = KgcsT \qquad (1)$$

where D is the MGD (mGy), K is the incident air kerma (mGy) at the top surface of the PMMA blocks, and g, c and s are conversion factors. The additional factor, T, is derived by summing weighted correction factors for each of the tomosynthesis projections. Values of T are tabulated [11] for the GE systems for different CBTs.

Although not yet adopted in UK breast screening programmes, a joint AAPM TG282 and EFOMP report on breast dosimetry was published recently [12]. The model proposed in this collaboration is intended by the authors as a future international standard. Mean glandular

doses were therefore also estimated and tabulated using the TG282 model for Cranio-caudal (CC) views applying TG282 median percentile glandularities.

An aluminium square, 10mm x 10mm and 0.2mm thick, was used with the PMMA during these exposures, so that the images produced could be used for the calculation of the contrast-to-noise ratio (CNR), described in Section 2.5. The aluminium square was placed between two 10mm thick slabs of 180mm x 240mm PMMA, on the midline, with its centre 60mm from the chest wall edge (CWE). Additional layers of PMMA were placed on top to vary the total thickness.

2.4 Contrast-to-noise ratio

2.4.1 CNR (2D)

Unprocessed images acquired during the dose measurement were analysed to obtain the CNRs. Thirty-six small square ROIs (approximately 2.5mm x 2.5mm) were used to determine the average signal and the standard deviation in the signal within the image of the aluminium square (4 ROIs) and the surrounding background (32 ROIs), as shown in Figure 2. Small ROIs are used to minimise distortions due to the heel effect and other causes of non-uniformity [13]. The CNR was calculated for each image, as defined in the NHSBSP and European Protocols.

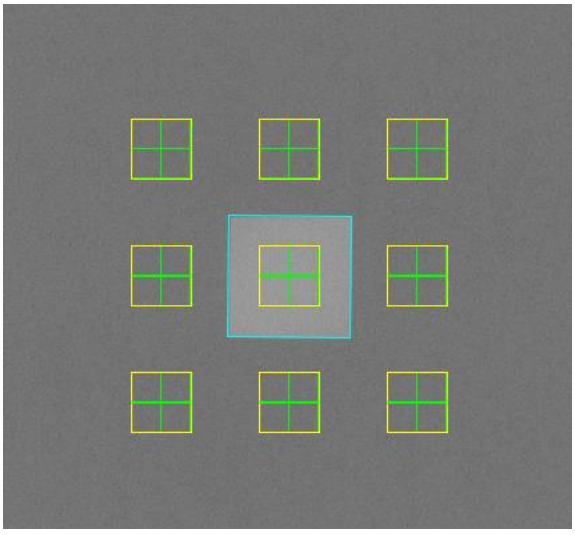

Figure 2: Location and size of ROI used to determine the CNR

To apply the standards in the European protocol, it is necessary to relate the image quality measured using the CDMAM (Section 2.5) for an equivalent breast thickness of 60mm, to that for other breast thicknesses. The European protocol [5] gives the relationship between threshold contrast and CNR measurements, enabling the calculation of a target CNR value

for a particular level of image quality. This can be compared to CNR measurements made at other breast thicknesses. Contrast for a particular gold thickness is calculated using Equation 2, and target CNR is calculated using Equation 3.

$$\text{Contrast} = 1 - e^{-\mu t} \quad (2)$$

where μ is the effective attenuation coefficient for gold, and t is the gold thickness.

$$CNR_{target} = \frac{CNR_{measured} \times TC_{measured}}{TC_{target}} \quad (3)$$

where $CNR_{measured}$ is the CNR for a 60mm equivalent breast, $TC_{measured}$ is the threshold contrast calculated using the threshold gold thickness for a 0.1mm diameter detail, (measured using the CDMAM at the same dose as used for $CNR_{measured}$), and TC_{target} is the calculated threshold contrast corresponding to the threshold gold thickness required to meet either the minimum acceptable or achievable level of image quality as defined in the NHSBSP protocol.

The threshold gold thickness for the 0.1mm diameter detail is used here because it is generally regarded as the most critical of the detail diameters for which performance standards are set.

The effective attenuation coefficient for gold used in Equation 1 depends on the beam quality used for the exposure, and the value used is in Table 2. This value was calculated with 3mm PMMA representing the compression paddle, using spectra from Hernandez et al [14] and attenuation coefficients for materials in the test objects (aluminium, gold, PMMA) from Berger et al [15].

The European protocol also defines a limiting value for CNR, which is calculated as a percentage of the threshold contrast for minimum acceptable image quality for each thickness. This limiting value varies with thickness, as shown in Table 3.

Table 2. Effective attenuation coefficient for gold contrast details in the CDMAM

kVp	Target/filter	Effective attenuation coefficient (μm^{-1})
34	Rh/Ag	0.110

Table 3. Limiting values for relative CNR

Thickness of PMMA (mm)	Equivalent breast thickness (mm)	Limiting values for relative CNR (%) in European protocol
20	21	> 115
30	32	> 110
40	45	> 105
45	53	> 103
50	60	> 100
60	75	> 95
70	90	> 90

The target CNR values for minimum acceptable and achievable levels of image quality and European limiting values for CNR were calculated. These were compared with the measured CNR results for all breast thicknesses.

2.4.2 CNR (tomosynthesis)

The set up above was also imaged using tomosynthesis. The CNR was measured in the focal plane in which the aluminium square was brought into focus. The 5mm x 5mm regions of interests (ROI) were subdivided into 1mm x 1mm elements and the background ROIs were positioned adjacent to the aluminium square, as shown in Figure 3. The mean pixel values and their standard deviations were averaged over all the 1mm x 1mm elements, and the CNR was calculated from these averages.

CNR was also assessed in the unprocessed tomosynthesis projections acquired for these images. The variation in central projection CNR with PMMA thickness was also assessed.

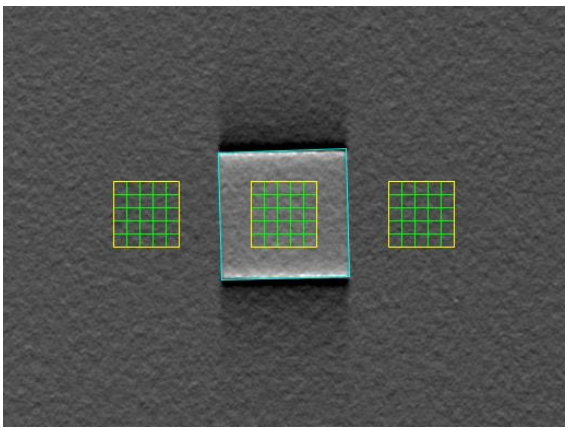

Figure 3: The position of 5mm x 5mm ROIs for assessment of CNR. (The CWE is to the right)

2.5 Image quality measurements

Contrast detail measurements were made using a CDMAM phantom (serial number 1022, version 3.4, UMC St. Radboud, Nijmegen University, Netherlands). The phantom was positioned with a 20mm thickness of PMMA above and below, to give a total attenuation approximately equivalent to 50mm of PMMA or 60mm thickness of typical breast tissue. The exposure factors were chosen to match as closely as possible those selected by the AEC, at the standard dose setting, when imaging a 50mm thickness of PMMA. This procedure was repeated to obtain a representative sample of 16 images at this dose level. Further sets of 16 images of the test phantom were then obtained at other dose levels by manually selecting higher and lower mAs values with the same beam quality.

The CDMAM images were read and analysed automatically using Version 1.6 of CDCOM [16] [17]. and Version 2.1.0 of CDMAM Analysis https://medphys.royalsurrey.nhs.uk/nccpm/). The threshold gold thickness for a typical human observer was predicted using Equation 4.

$$TC_{predicted} = rTC_{auto} \quad (4)$$

where $TC_{predicted}$ is the predicted threshold contrast for a typical observer, TC_{auto} is the threshold contrast measured using an automated procedure with CDMAM images. r is the average ratio between human and automatic threshold contrast determined experimentally with the values shown in Table 4.

Table 4. Values or r used to predict threshold contrast

Diameter of gold disc (mm)	Average ratio of human to automatically measured threshold contrast (r)
0.08	1.40
0.10	1.50
0.13	1.60
0.16	1.68
0.20	1.75
0.25	1.82
0.31	1.88
0.40	1.94
0.50	1.98
0.63	2.01
0.80	2.06
1.00	2.11

The predicted threshold gold thickness for each detail diameter in the range 0.1mm to 1.0mm was fitted with a curve for each dose level, using the relationship shown in Equation 5.

$$\text{Threshold gold thickness} = a + bx^{-1} + cx^{-2} + dx^{-3} \quad (5)$$

where x is the detail diameter, and a, b, c and d are coefficients adjusted to obtain a least squares fit.

The confidence limits for the predicted threshold gold thicknesses have been previously determined by a sampling method using a large set of images. The threshold contrasts quoted in the tables of results are derived from the fitted curves.

The expected relationship between threshold contrast and MGD is shown in Equation 6.

$$\text{Threshold contrast} = \lambda D^{-n} \quad (6)$$

where D is the MGD for a 60mm thick standard breast (equivalent to the test phantom configuration used for the image quality measurement), and λ is a constant to be fitted.

It is assumed that a similar equation applies when using threshold gold thickness instead of contrast. This equation was plotted with the experimental data for detail diameters of 0.1 and 0.25mm. The value of n resulting in the best fit to the experimental data was determined, and the doses required for target CNR values were calculated for data relating to these detail diameters.

3. Results

3.1 Output and HVL

The output and HVL measurements are shown in Table 5. The results are very similar to the previous reports [1] [2].

Table 5. Output and HVL

kVp	Target/filter	Modality	Output (μGy/mAs at 1m)	HVL (mm Al)
26	Mo/Mo	2D	26.3	0.35
34	Rh/Ag	2D	44.9	0.55
26	Mo/Mo	Tomosynthesis	26.3	0.35
34	Rh/Ag	Tomosynthesis	44.9	0.55

3.2 AEC performance

3.2.1 Dose (2D)

The MGDs for breasts simulated with PMMA exposed under AEC control are shown in Table 6 and Table 7 for exposures made in Standard and Standard+ Enhanced respectively. The mAs values include the pre-exposure. The MGDs were calculated from the total mAs, including the pre-exposure. The results presented in Tables 6 to 10 are also presented graphically in Figure 4. The results for Dose- (Table 8) is only shown once, as there was no difference between the original and Enhanced setting.

Table 6. MGD for simulated breasts (Standard Enhanced)

PMMA thick-ness (mm)	Equivalent breast thickness (mm)	kVp	Target/ filter	mAs	Dance MGD (mGy)	Remedial dose level (mGy)	Displ-ayed dose (mGy)	TG282 MGD (mGy)
20	21	26	Mo/Mo	24.2	0.66	1.0	0.68	0.67
30	32	26	Mo/Mo	43.5	0.88	1.5	0.89	0.85
40	45	34	Rh/Ag	25.4	1.19	2.0	1.21	1.13
45	53	34	Rh/Ag	36.2	1.52	2.5	1.56	1.37
50	60	34	Rh/Ag	47.9	1.87	3.0	1.89	1.58
60	75	34	Rh/Ag	66.6	2.33	4.5	2.34	1.71
70	90	34	Rh/Ag	85.2	2.57	6.5	2.68	1.65
80	103	34	Rh/Ag	108	2.89	-	3.06	1.68

Table 7. MGD for simulated breasts (Standard+ Enhanced)

PMMA thick-ness (mm)	Equivalent breast thickness (mm)	kVp	Target/ filter	mAs	Dance MGD (mGy)	Remedial dose level (mGy)	Displ-ayed dose (mGy)	TG282 MGD (mGy)
20	21	26	Mo/Mo	24.2	0.66	1.0	0.67	0.67
30	32	26	Mo/Mo	44.6	0.90	1.5	0.92	0.87
40	45	34	Rh/Ag	31.6	1.46	2.0	1.45	1.39
45	53	34	Rh/Ag	44.3	1.85	2.5	1.89	1.66
50	60	34	Rh/Ag	56.2	2.18	3.0	2.20	1.85
60	75	34	Rh/Ag	79.1	2.75	4.5	2.75	2.01
70	90	34	Rh/Ag	98.2	2.95	6.5	3.04	1.89
80	103	34	Rh/Ag	106	2.84	-	3.02	1.65

Table 8. MGD for simulated breasts (Dose- Enhanced/Original)

PMMA thick-ness (mm)	Equivalent breast thickness (mm)	kVp	Target/ filter	mAs	Dance MGD (mGy)	Remedial dose level (mGy)	Displ-ayed dose (mGy)	TG282 MGD (mGy)
20	21	26	Mo/Mo	12.2	0.36	1.0	0.36	0.36
30	32	26	Mo/Mo	28.6	0.59	1.5	0.60	0.57
40	45	34	Rh/Ag	18.6	0.90	2.0	0.90	0.85
45	53	34	Rh/Ag	22.2	0.97	2.5	0.96	0.87
50	60	34	Rh/Ag	26.7	1.08	3.0	1.08	0.91
60	75	34	Rh/Ag	39.7	1.45	4.5	1.45	1.06
70	90	34	Rh/Ag	62.9	1.93	6.5	1.99	1.24
80	103	34	Rh/Ag	60.6	1.67	-	1.76	0.97

Table 9. MGD for simulated breasts (Standard Original)

PMMA thick-ness (mm)	Equivalent breast thickness (mm)	kVp	Target/ filter	mAs	Dance MGD (mGy)	Remedial dose level (mGy)	Displ-ayed dose (mGy)	TG282 MGD (mGy)
20	21	26	Mo/Mo	17.5	0.49	1.0	0.50	0.50
30	32	26	Mo/Mo	40.7	0.83	1.5	0.84	0.80
40	45	34	Rh/Ag	24.9	1.12	2.0	1.16	1.11
45	53	34	Rh/Ag	31.5	1.34	2.5	1.29	1.20
50	60	34	Rh/Ag	37.9	1.50	3.0	1.44	1.27
60	75	34	Rh/Ag	58.4	2.01	4.5	2.00	1.51
70	90	34	Rh/Ag	82.3	2.51	6.5	2.59	1.59
80	103	34	Rh/Ag	85.9	2.33	-	2.45	1.34

Table 10. MGD for simulated breasts (Standard+ Original)

PMMA thick-ness (mm)	Equivalent breast thickness (mm)	kVp	Target/ filter	mAs	Dance MGD (mGy)	Remedial dose level (mGy)	Displ-ayed dose (mGy)	TG282 MGD (mGy)
20	21	26	Mo/Mo	17.5	0.49	1.0	0.5	0.50
30	32	26	Mo/Mo	43.9	0.90	1.5	0.9	0.85
40	45	34	Rh/Ag	34.1	1.52	2.0	1.55	1.49
45	53	34	Rh/Ag	49.7	2.07	2.5	2	1.85
50	60	34	Rh/Ag	58.3	2.27	3.0	2.26	1.91
60	75	34	Rh/Ag	87.2	2.96	4.5	2.92	2.20
70	90	34	Rh/Ag	98.9	2.99	6.5	3.07	1.90
80	103	34	Rh/Ag	107	2.88	-	3.04	1.66

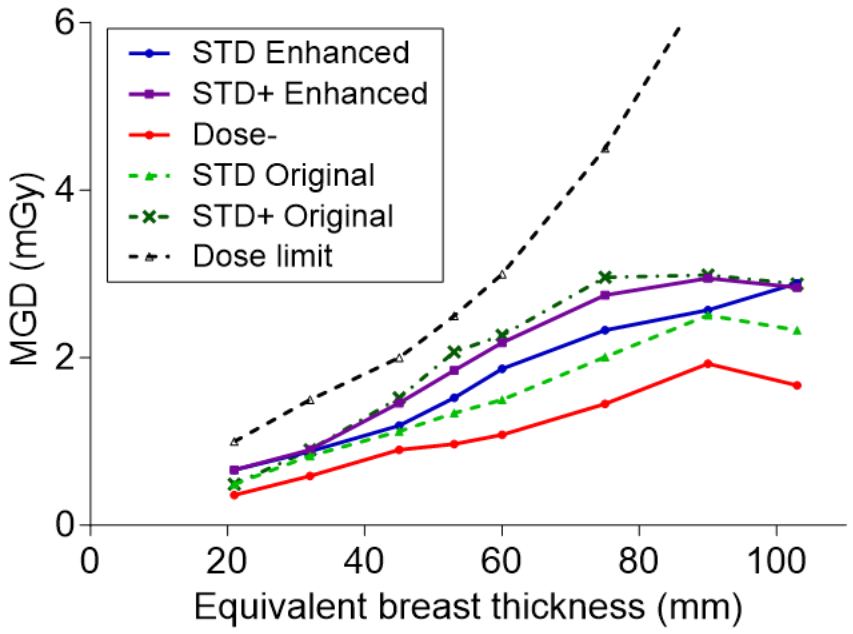

Figure 4. Dance MGD for different thicknesses of simulated breasts using AEC normal dose mode for 2D. (Error bars indicate 95% confidence limits.)

3.2.2 Dose (tomosynthesis)

The MGDs to the standard breast model are shown in Figure 5. All MGDs include the preliminary exposure, which is not included in the image. The dose limiting value from the EUREF protocol [18] is shown. The MGDs for tomosynthesis are shown in Table 11 and Table 12 for Standard+ and Standard respectively. Figure 5 shows a comparison of the Standard and Standard+ for both the Enhanced and Original modes. The exposure levels have not changed with the introduction of the Enhanced mode for tomosynthesis, apart from an increase for the thinnest breasts.

Table 11. DBT MGD for simulated breasts (Standard Enhanced)

PMMA thick-ness (mm)	Equivalent breast thickness (mm)	kVp	Target/ filter	mAs	Dance MGD (mGy)	Dose limiting value (mGy)	Displ-ayed dose (mGy)	TG282 MGD (mGy)
20	21	26	Mo/Mo	25.2	0.68	1.0	0.63	0.69
30	32	26	Mo/Mo	44.9	0.90	1.5	0.9	0.87
40	45	34	Rh/Ag	26.7	1.24	2.0	1.08	1.18
45	53	34	Rh/Ag	29.9	1.26	2.5	1.17	1.14
50	60	34	Rh/Ag	35.6	1.39	3.0	1.35	1.18
60	75	34	Rh/Ag	51.2	1.80	4.5	1.71	1.32
70	90	34	Rh/Ag	81.2	2.42	6.5	2.43	1.56
80	103	34	Rh/Ag	90.1	2.39	-	2.43	1.39

Table 12. DBT MGD for simulated breasts (Standard+ Enhanced)

PMMA thick-ness (mm)	Equivalent breast thickness (mm)	kVp	Target/ filter	mAs	Dance MGD (mGy)	Dose limiting value (mGy)	Displ-ayed dose (mGy)	TG282 MGD (mGy)
20	21	26	Mo/Mo	25.2	0.68	1.0	0.63	0.69
30	32	26	Mo/Mo	45.1	0.90	1.5	0.9	0.87
40	45	34	Rh/Ag	37.8	1.71	2.0	1.53	1.64
45	53	34	Rh/Ag	46.1	1.90	2.5	1.8	1.71
50	60	34	Rh/Ag	56.7	2.18	3.0	2.16	1.85
60	75	34	Rh/Ag	81.9	2.81	4.5	2.7	2.06
70	90	34	Rh/Ag	100	2.96	6.5	2.97	1.90
80	103	34	Rh/Ag	110	2.90	-	2.97	1.69

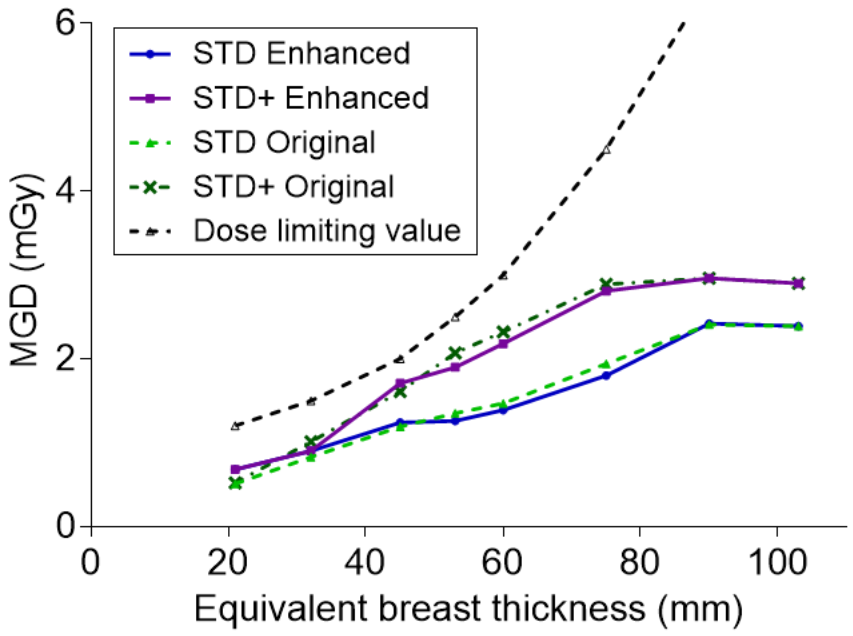

Figure 5. Dance MGD for different thicknesses of simulated breasts using AEC normal dose mode for tomosynthesis. (Error bars indicate 95% confidence limits.)

3.2.3 Contrast-to-Noise ratio (2D)

The results of the CNR measurements for images acquired in 2D for the Enhanced and Original AEC settings are shown in Table 13 and 14 respectively. Figure 6 shows the CNR for the Enhanced AEC mode. The following calculated values are also shown for the 2D mode (Enhanced):

- CNR to meet the minimum acceptable image quality standard
- CNR to meet the achievable image quality standard
- CNRs at each thickness to meet the limiting value in the European protocol

Figure 7 shows a comparison of the Original and Enhanced modes.

Table 13. CNR measurements (Enhanced)

PMMA (mm)	Equivalent breast thickness (mm)	Measured CNR			CNR for minimum acceptable IQ	CNR for achievable IQ	European limiting CNR value
		Dose-	Standard	Standard+			
20	21	15.2	22.7	22.5	8.84	13.1	10.2
30	32	15.1	19.0	19.5	8.84	13.1	9.7
40	45	13.5	15.8	17.8	8.84	13.1	9.3
45	53	12.4	16.0	17.6	8.84	13.1	9.1
50	60	11.5	15.3	16.5	8.84	13.1	8.8
60	75	10.2	13.2	14.7	8.84	13.1	8.4
70	90	9.4	10.9	11.9	8.84	13.1	8
80	103	6.7	9.1	9.0	8.84	13.1	8

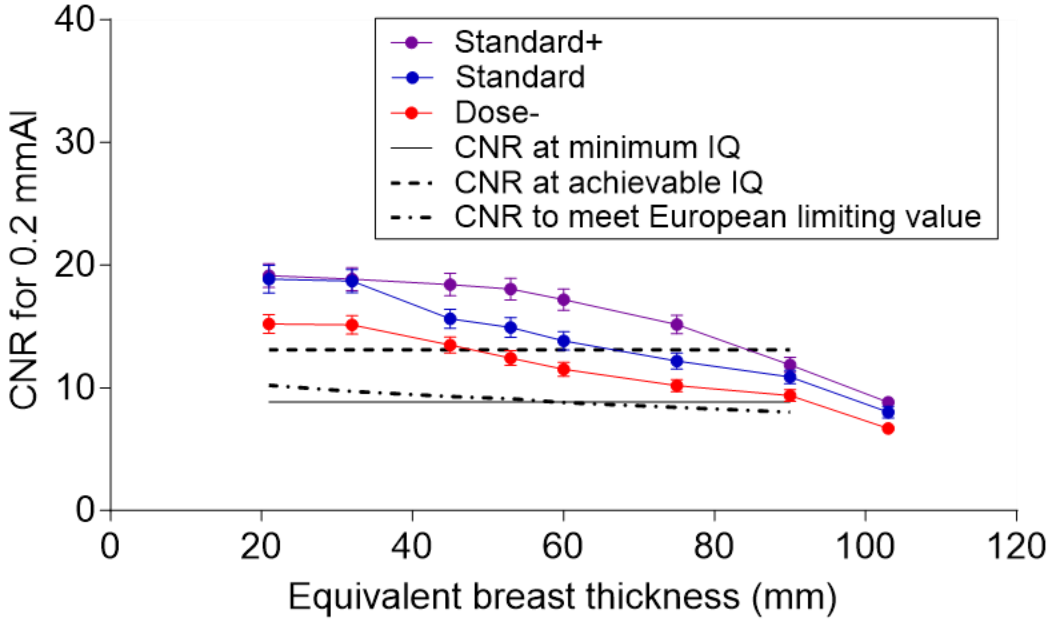

Figure 6. Measured CNR (2D) compared with the limiting values in the European protocol for Enhanced AOP. (Error bars indicate 95% confidence limits.)

Table 14. CNR measurements (Original)

PMMA (mm)	Equivalent breast thickness (mm)	Measured CNR			CNR for minimum acceptable IQ	CNR for achievable IQ	European limiting CNR value
		Dose-	Standard	Standard+			
20	21	15.2	18.8	19.1	8.84	13.09	10.2
30	32	15.1	18.7	18.8	8.84	13.09	9.7
40	45	13.5	15.6	18.4	8.84	13.09	9.3
45	53	12.4	14.9	18.0	8.84	13.09	9.1
50	60	11.5	13.8	17.2	8.84	13.09	8.8
60	75	10.2	12.2	15.2	8.84	13.09	8.4
70	90	9.4	10.9	11.9	8.84	13.09	8
80	103	6.7	8.01	8.82	8.84	13.09	8

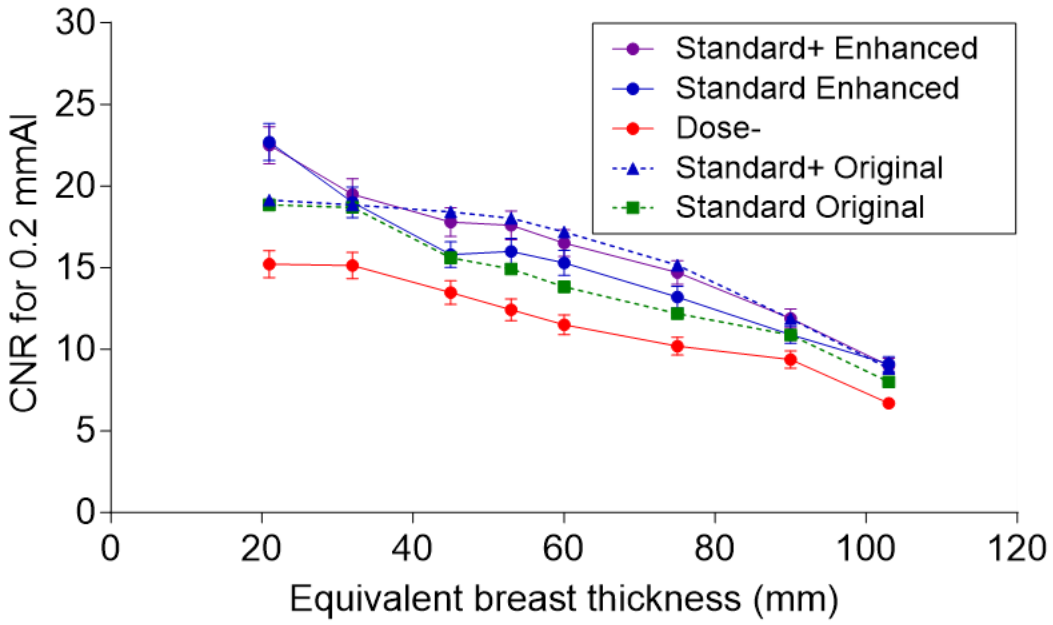

Figure 7. Measured CNR (2D) comparison of enhanced and original AOPs

3.2.4 Contrast-to-Noise ratio (tomosynthesis)

Figure 8 shows the CNRs measured in focal planes, central projection images and slabs for Standard and Standard+. The values of the CNRs are shown in Table 15 and Table 16 for Standard and Standard+ respectively. The 16th plane and 4th slab were selected as best in focus for the measurements. The results for the slabs and projections were very similar to the results previously measured [2], the CNR for the planes were reduced compared to

previous evaluation report [2], this would appear to be due to differences between the evaluation systems.

Table 15. CNR measurements Tomosynthesis (Standard Enhanced)

PMMA (mm)	Equivalent breast thickness (mm)	kV	Target/ filter	mAs	Measured CNR		
					Focal planes	Slabs	Central projections
20	21	26	Mo/Mo	25.2	5.2	4.9	7.7
30	32	26	Mo/Mo	44.9	5.2	4.9	6.4
40	45	34	Rh/Ag	26.7	4.5	4.3	5.3
45	53	34	Rh/Ag	29.9	4.6	4.4	4.8
50	60	34	Rh/Ag	35.6	4.7	4.4	4.6
60	75	34	Rh/Ag	51.2	4.8	4.5	3.9
70	90	34	Rh/Ag	81.2	4.7	4.5	3.6
80	103	34	Rh/Ag	90.1	4.4	4.2	2.7

Table 16. CNR measurements Tomosynthesis (Standard+ Enhanced)

PMMA (mm)	Equivalent breast thickness (mm)	kV	Target/ filter	mAs	Measured CNR		
					Focal planes	Slabs	Central projections
20	21	26	Mo/Mo	25.2	5.1	4.8	7.6
30	32	26	Mo/Mo	45.1	5.1	4.8	6.4
40	45	34	Rh/Ag	37.8	5.4	5.2	6.6
45	53	34	Rh/Ag	46.1	5.2	5.1	6.1
50	60	34	Rh/Ag	56.7	5.3	5.0	5.8
60	75	34	Rh/Ag	81.9	5.5	5.3	4.9
70	90	34	Rh/Ag	100	5.2	5.0	4.0
80	103	34	Rh/Ag	110	4.6	4.4	3.0

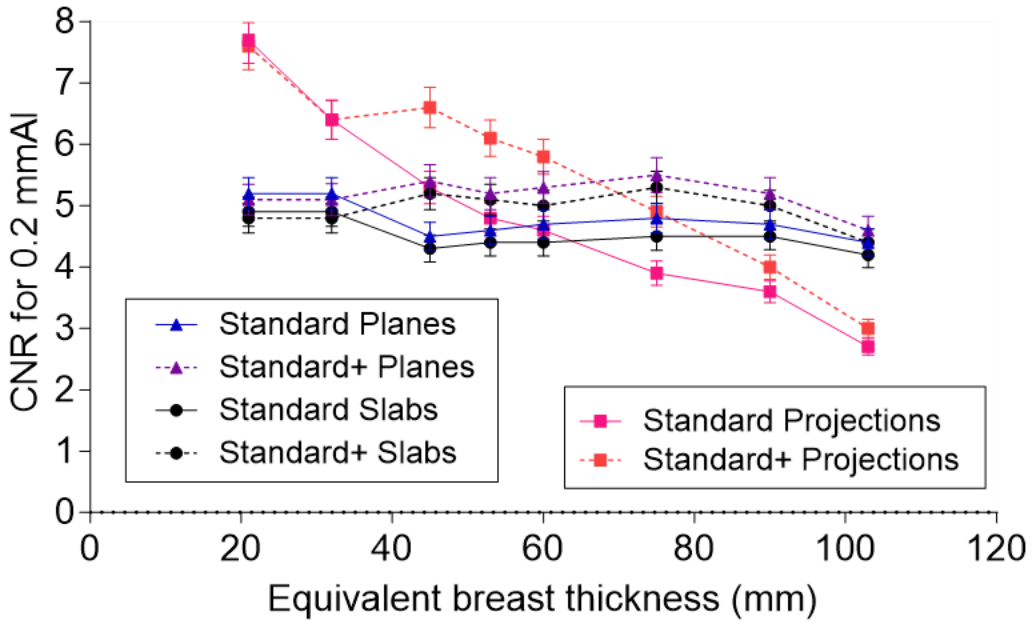

Figure 8. Measured CNR (Tomosynthesis) comparison of Image Presentation for enhanced AOPs

3.3 Image quality measurements

The exposure factors used for each set of 16 CDMAM images are shown in Table 17. The mAs were selected was close to that selected for the equivalent breast of 60mm thick in AEC mode for the different dose modes of the system (Dose-, Original Standard, Enhanced Standard and Enhanced Standard+).

Table 17. Images acquired for image quality measurement

kVp	Target/filter	Tube loading in mAs (closest AEC mode)	Mean glandular dose to equivalent breasts 60mm thick (mGy)
34	Rh/Ag	28.0 (Dose-)	1.05
34	Rh/Ag	36.0 (Standard Original)	1.35
34	Rh/Ag	50.0 (Enhanced Standard)	1.88
34	Rh/Ag	56.0 (Enhanced Standard+)	2.10

The contrast detail curves (determined by automatic reading of the images) at the different dose levels are shown in Figure 9. The threshold gold thicknesses measured for different

detail diameters at the 4 selected dose levels are shown in Table 18. The NHSBSP minimum acceptable and achievable limits are also shown.

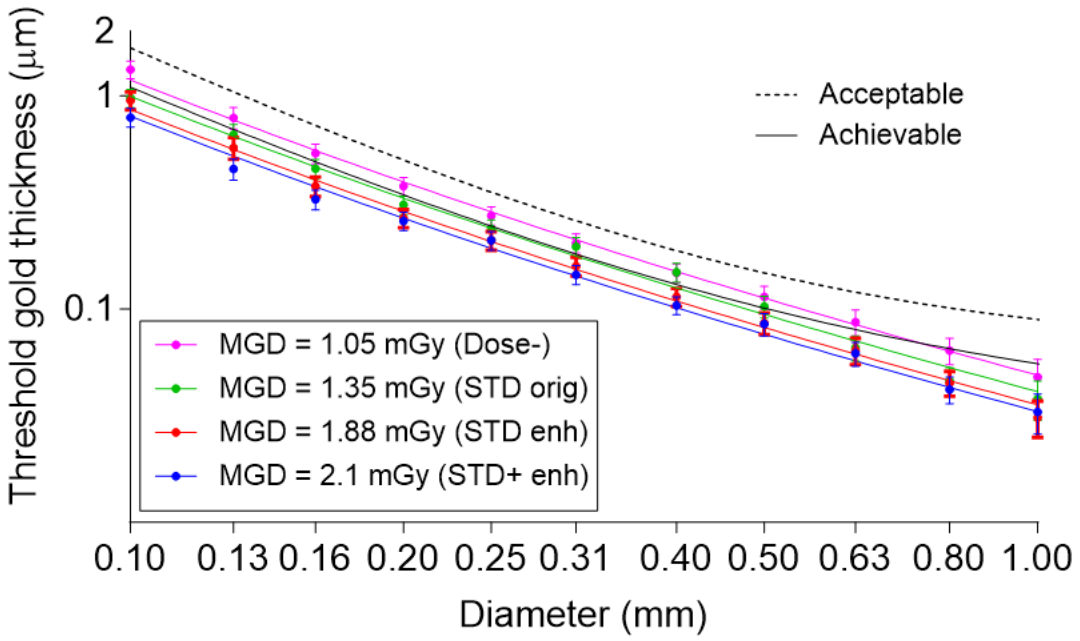

Figure 9. Threshold gold thickness detection curves for 4 doses at 34kV Rh/Ag. (Error bars indicate 95% confidence limits.)

Table 18. Average threshold gold thicknesses for different detail diameters for 4 doses using 34kVp Rh/Ag, and automatically predicted data

Diam-eter (mm)	Accept-able value	Achiev-able value	Threshold gold thickness (µm) Mean Glandular Dose to equivalent breast 60mm thick (mGy) 1.05	1.35	1.88	2.10
0.1	1.680	1.100	1.33 ± 0.13	0.976 ± 0.096	0.952 ± 0.093	0.793 ± 0.078
0.25	0.352	0.244	0.274 ± 0.027	0.238 ± 0.024	0.21 ± 0.021	0.21 ± 0.021
0.5	0.150	0.103	0.114 ± 0.014	0.103 ± 0.012	0.086 ± 0.01	0.085 ± 0.01
1	0.091	0.056	0.048 ± 0.01	0.038 ± 0.008	0.031 ± 0.006	0.033 ± 0.007

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4. Discussion

4.1 Dose

The new Enhanced AOP are different from the AOP from the original evaluation report [1] for the 2D Standard and Standard+. The enhanced Standard+ is set to be lower than the original Standard+. The Enhanced Standard AOP is generally higher than original Standard. There was an exception for the thinnest compression thicknesses where the exposure level was increased for both Standard and Standard+ for the enhanced compared to the original AOPs. GE made this change to improve the contrast to noise ratio for these breasts.

Dance MGDs measured using PMMA were well within the NHSBSP remedial dose levels for all equivalent breast thicknesses when using all AEC Enhanced dose modes. In the Enhanced Standard and Standard+ AEC dose modes the Dance MGD to the 53mm thick standard breast model were 1.52mGy (Table 6) and 1.85mGy (Table 7) respectively, this compares to the original AOP of 1.34mGy (Table 9) and 2.07mGy (Table 10) respectively.

GE state that the enhanced Standard+ is set to be identical to the original Standard+ on the Rh/Ag thickness range (>38mm), but measurements showed slightly lower dose on the enhanced mode.

The Enhanced AOP did not change the exposure levels for both the ‘Dose-‘ in 2D and tomosynthesis.

4.2 Contrast-to-noise ratio

CNR measurements made with plain PMMA showed a steady decrease with increasing equivalent breast thickness (Figure 6) for Enhanced AOP. Target CNR values of 8.84 and 13.1, for minimum acceptable and achievable image quality respectively, were calculated for 2D. All CNR values exceeded the European limiting values for CNR in Enhanced mode (Table 13). The Enhanced Standard and Standard+ AEC modes exceeded the CNR target for minimum image quality from 20 to 90mm equivalent breast thicknesses. In the Enhanced Standard mode the CNR target for achievable image quality was equalled or exceeded up to 60mm equivalent breast thickness. In Enhanced Standard+ mode this target was exceeded up to 75mm equivalent breast thickness. The Dose- mode is not recommended for routine use because of the resulting reduction in image quality. A recent survey of GE systems in the UK [19] showed that Dose- is not used as default, while the majority of systems were set up to Standard.

Although, the dose levels were the same for the Original and the Enhanced AOP for tomosynthesis. There was a change in the measured CNR for the reconstructed planes, between this evaluation and the previous evaluation [2], this is likely due to differences between the evaluation systems rather than any difference in plane separation. This CNR for the planes was lower for this system, while the CNR measured for the slabs and central projection images were similar to those previously measured.

4.3 Image quality

Threshold gold thicknesses for a range of detail diameters are shown in Figure 9. At an MGD of 1.88mGy (close to that selected for the equivalent thickness of PMMA in Standard mode), the image quality was better than the achievable level for all contrast detail diameters.

5. Conclusions

The Enhanced AOP for the GE Pristina in 2D mode meets the minimum requirements of the NHSBSP standards for digital mammography systems when operating in the normal dose AEC mode.

The MGD calculated using Dance's factors is well below the remedial level in all of the AOP AEC modes. The image quality, as measured by threshold gold thickness for both Standard and Standard+, is at the achievable level.

There is no need for a practical evaluation for this change. However, it would be sensible for departments to audit the image quality and dose of the Enhanced AOP, if it is installed.

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