THE DOSE AND IMAGE QUALITY IN MAMMOGRAPHY PRACTICE IN FINLAND

Asko Miettinen, Markku Pirinen
Patient doses, image quality and some technical parameters of mammography X-ray equipment in Finland were studied in 2000–2002. The study was conducted to review the overall condition of mammography equipment and image quality in actual mammography practices in Finland. The purpose was to find out the weak points in the mammography practices in order to suggest improvements in the practices and their quality control procedures. The ESD distribution obtained was fairly consistent with the current diagnostic reference level and suggests that the current level is reasonable. The results for the testing of image quality indicated that the major sources for a sub-optimal image quality are related to shortcomings in the film processing (53% of all cases) and in the adjustments of the automatic exposure control systems. Relatively simple improvements of the techniques and maintenance procedures together with increased training of the users are needed to overcome these problems. A system of regularly monitoring patient dose and image quality is proposed as a possible solution in order to ensure continuously a high quality of mammography examinations.
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1 Introduction

There are approximately 200 mammography X-ray units in Finland. In the year 2000, about 236,000 screening examinations and 97,000 other clinical examinations for mammography were carried out [1]. The quality assurance procedures are generally the responsibility of the health care units carrying out mammography examinations (the license holders), while the mammography practices in Finland are routinely inspected every three to five years by the regulatory authority Radiation and Nuclear Safety Authority (STUK).

Against this background, it was considered useful to review the overall condition of mammography equipment and image quality in actual mammography practices in Finland, by focusing the inspections of practices and conducting a special study for a representative number of mammography equipment and practices. In this study concerning years 2000–2002, the patient doses, image quality and some technical parameters of the equipment were evaluated. The purpose was to find out what are the weak points of the mammography practices in order to improve the practices and their quality control procedures.
2 Material and Methods

2.1 Mammography Units
For this study, a total of 144 units were randomly selected from the total of about 200 mammography units used in Finland. The sample included most models in use during the study time, and accounted for about two thirds of the mammography examinations in Finland. Twelve different models of mammography X-ray units were included in the study (Table I). The film/screen combinations are in the Table II. No digital mammography devices were included. A total of 52 of the evaluated units were used for mammography screening.

Table I. The types of mammography devices used in Finland included in this study.

<table>
<thead>
<tr>
<th>Device</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Senograph</td>
<td>(General Electric)</td>
</tr>
<tr>
<td>Alpha III</td>
<td>(Instrumentarium Corp.)</td>
</tr>
<tr>
<td>Alpha RT</td>
<td>(Instrumentarium Corp.)</td>
</tr>
<tr>
<td>Diamond</td>
<td>(Instrumentarium Corp.)</td>
</tr>
<tr>
<td>Performa</td>
<td>(Instrumentarium Corp.)</td>
</tr>
<tr>
<td>Vision One</td>
<td>(Instrumentarium Corp.)</td>
</tr>
<tr>
<td>Mamex DC</td>
<td>(Orion Corp. Soredex)</td>
</tr>
<tr>
<td>Mamex DC Ami</td>
<td>(Orion Corp. Soredex)</td>
</tr>
<tr>
<td>Mamex DC MAG</td>
<td>(Orion Corp. Soredex)</td>
</tr>
<tr>
<td>Sophie</td>
<td>(Planmed Oy)</td>
</tr>
<tr>
<td>Mammomat 2, B, C</td>
<td>(Siemens AG)</td>
</tr>
<tr>
<td>Mammomat 3000</td>
<td>(Siemens AG)</td>
</tr>
</tbody>
</table>

2.2 Patient Doses
For patient doses, entrance surface doses (ESD, or more precisely, entrance air kermas, including backscatter from the phantom) were measured using PMMA (polymethylmethacrylate) phantoms with three different thicknesses: 2 cm, 4.5 cm and 6 cm. The 4.5 cm-phantom is a phantom specified for patient dose measurements for comparison with the diagnostic reference levels as given in Finland. Radcal 9015 and Radcal 3036 radiation monitors (Radcal Corporation, Monrovia, CA, USA), with type 10X5-6 ionization chambers, were used as the measuring instruments. The measuring instruments were calibrated at the national standards laboratory at STUK at a soft X-ray energy simulating a mammography beam quality (mean photon energy 20 keV).
In the first step, the exposure settings used by the radiographers in normal mammography practices were asked for, and the phantoms were exposed with these settings directly under the compressing paddle, thus simulating the normal exposure conditions. The actual kV- and mAs-values from these exposures were recorded. In the next step, further exposures were made with the ionization chamber on top of the phantoms, under the compressing paddle, and by manual setting of the same kV-value and, as close as possible, also the same mAs-value. The ESD for each phantom thickness was then measured from these exposures, and corrected for the possible difference in the mAs-values.

2.3 Image Quality
A standardized RMI 156 Accreditation Phantom [2] (Gammex RMI, Middleton, WI, USA) was used to generate the x-ray images. This phantom is composed of a wax block containing 16 various sets of test objects, a 3.3 cm thick acrylic base, a tray for placement of the wax box and a 0.3 cm thick acrylic cover. All of this together approximates a 4.2 cm thick compressed breast. The test objects in the wax insert include five groups of simulated micro-calcifications of different size, six nylon fibers of different size to simulate fibrous structures, and five tumor-like masses of different size.

The image of the phantom was taken using the same settings (X-ray tube voltage, filtration, automatic exposure control etc.) as were used during normal mammography practices. The same cassettes, screens and X-ray films were used as in normal practice in the facility, and the films were processed according to their normal method for mammograms. This approach was chosen because the results depend not only on the X-ray equipment, but also on the accessories, film processing and the user’s choices.

The test phantom images were delivered for assessment to a mammography specialist of Helsinki University Hospital Mammography Center, without information about the X-ray facility or the type of equipment used in producing the images. The radiologist provided a written report of the analysis of each image. Each image was rated by “quality points” according to the number of test patterns visible, as specified by the manufacturer of the phantom [2] and also in accordance with the requirements adopted by the ACR [7]. A separate rating was given for the visibility of fibers (maximum 6 points, acceptability limit 4 points), micro-calcification (maximum 5, acceptability limit 3) and tumor-like masses (maximum 5, acceptability limit 3). Half value numbers were also allowed to be used for cases where only a part of the object pattern was visible. The mammography specialist also checked the film density and provided comments about suspected equipment failures (such as defects in grids), defects in the film processing (roller marks, dirt in chemicals), dirt and dust in film cassettes and some other factors that affect image quality. According to the test phantom specifications, and also in accordance with the Finnish guidelines [3], the optical density (OD) of the mammogram (total density including film base and fog) should be above 1.2.

2.4 Other Tests of Mammography Equipment
The other tests of the mammography equipment comprised measurements of spatial resolution, contrast, the accuracy of the X-ray tube voltage and the functioning of the automatic exposure control. All the test films were analyzed by one observer only.

Limiting spatial resolution was measured using two line pair test plates of 0.025 mm Pb, one for vertical and another for horizontal resolution, located on the surface of the 4.5 cm thick PMMA phantom. The resolution values provided in this report are the mean values of both vertical and horizontal resolution measurements. As a limit for the lowest acceptable resolution, 12 lp/mm was applied in accordance with the Finnish guidelines (Guide ST 3.2 [3]).

Contrast was measured by placing the contrast piece (4 mm thick PMMA disk) of the above mentioned RMI Accreditation Phantom on the surface of the phantom. The limit of 0.35 for the minimum acceptable contrast was applied in accordance with the specifications by the manufacturer of the Accreditation Phantom [2] and by the ACR [7].

The accuracy of the indicated X-ray tube voltage was measured using kV-meters of type RMI Model 232 or Radcal Model 9015 with the
Model 4081 sensor. According to the Finnish guidelines [3], the tube voltage should not deviate from its nominal value by more than ±5 per cent.

The functioning of automatic exposure control (AEC) systems was tested by film exposures using the three different PMMA phantoms of 2 cm, 4.5 cm and 6 cm thicknesses. In case the AEC system was not fully automatic, i.e., when the high voltage and mAs-values were not automatically selected to account for the variations in the thickness of the breast, the settings were made according to user's normal mammography practice. According to the Finnish guidelines [3], the optical density obtained with the 2 cm and 6 cm phantoms must not deviate more than ±0.3 from the basic density obtained with the 4.5 cm phantom.

The film optical densities were measured using the X-Rite densitometer 331 (X-Rite Incorporated, Grandville, MI, USA). The measuring point on the film was at the center, at a distance of 6 cm from the long (mediastinum) side of the film.
3 Results and Discussion

3.1 ESD measurements
The distribution of the measured ESD values for the 4.5 cm thick PMMA phantom is illustrated in Figure 1. The range of ESD is from 2 to 18.3 mGy with the average of 7.2 mGy. The average dose for screening units was 6.6 mGy, and the average dose of the units used solely for clinical application was 7.5 mGy. The average ESD for imaging the 2 cm thick PMMA phantom (Figure 2) was 1.1 mGy (range 0.32–2.9 mGy), and the average ESD for imaging the 6 cm thick PMMA phantom (Figure 3) was 18.1 mGy (range 4.4–48.5 mGy).

Figure 1. The ESD distribution in imaging the 4.5 cm thick PMMA phantom.

Figure 2. The ESD distribution in imaging the 2 cm thick PMMA phantom.
The diagnostic reference level for mammography in Finland is given as an ESD value of 10 mGy (corresponding to the measurements with a 4.5 cm PMMA phantom). The reference level was exceeded in 20 facilities, or in 14% of all facilities included in the study, two of which were involved in mammography screening. The results suggest that the current reference level for mammography is reasonable. On the average, the screening facilities complied better with the diagnostic reference level than the clinical facilities.

When analyzing the possible reasons for ESD values higher than the reference level, the following observations can be made:

- It seems that the problems in film processing, ineffective film/screen combination and the examination technique choices of the users are the major factors resulting to the high ESD. The users’ choices of manual adjustments for AEC and kV-values are of particular importance.
- The X-ray tube voltage, filtration and geometrical factors of the various X-ray systems are relatively similar in the various equipment models (at least in the newer models) so that the ESD is not strongly X-ray system model-dependent. Differences of ESD values between models may be mainly attributable to the properties of the antiscatter grid in the systems. The average ESD of devices without a grid (13 units) was 4.8 mGy, and 7.6 mGy for those with a grid.
- Theoretically, in film-based imaging, a low tube voltage should result in a high ESD, but this was not clearly seen in the results due to the narrow range of high-voltages used and many other variables influencing dose. No clear correlation between dose and film density could be seen either.
- The cases where the ESD exceeded the reference level were typically units where a relatively small number of yearly examinations (100–800; only one exception with 4700 examinations/year) was carried out. These included small clinics, where the equipment can sometimes be kept as a spare unit. The minor use of the equipment may lead to less attention paid to appropriate film processing, quality control as well as training of the staff for optimum use of the equipment.

3.2 Image Quality

The distribution of devices with respect to the quality points (number of the visible groups of each of the three different object types in the test phantom) is shown in Figure 4. Twenty-five facilities (17%) did not achieve the minimum of three points for the tumor-like masses. Eighteen facilities (13%) did not achieve the minimum of four points for fiber details. All facilities fulfilled the minimum requirement of three quality points.

![Figure 3. The ESD distribution in imaging the 6 cm thick PMMA phantom.](image-url)
for micro-calciﬁcations. Altogether there were 28 units (20%) which did not fulﬁl the minimum requirements for the visibility of either tumor-like masses or ﬁbres of the test phantom. In addition, there were 22 units which had the ﬁlm density lower than the requirement of 1.2 although they complied with the test object visibility criteria. Altogether there were 50 units (35%) which did not fulﬁl the criteria of the test phantom.

The average sum of all the three classes of quality points was 12.3 for the screening units and 11.3 for the other units. According to the test phantom criteria, 33% of the screening devices and 36% of the mammography devices used for clinical purposes did not produce satisfactory images.

The radiologist provided additional comments on shortcomings in four out of ﬁve devices (112 equipment or 78%). In 55% of the comments the reason was related to ﬁlm processing, in 25% to equipment, and in 40% to ﬁlms and screens (the sum exceeding 100% due to multiple comments in some cases).

3.3 Other Tests

For spatial resolution, thirty devices (21%) fell below the threshold of 12 lp/mm and most of these (83%) were old devices, about ten years or more old, supplied by just one manufacturer. For the “new” generation of equipment, the mean value of spatial resolution was about 14 lp/mm.

The contrast disk measurement resulted to thirteen devices (9%) being below the lower limit of 0.35. The contrast of sixty-nine devices (49%) was above 0.45. Most of the devices (113 devices, 80%) were between the contrast values 0.35 and 0.54.

Figure 4. Number of units as a function of quality points, classiﬁed in accordance with the visibility of the three test objects.
The X-ray tube voltages were correct within the \( \pm 5\% \) criterion in most cases. The measured X-ray tube voltage of only ten units deviated more than 5% from the indicated value, and these deviations were all less than 10%.

For the test of optical density, a total of 33 units (23%) fell below the threshold of 1.2. For the test of the AEC with the three phantoms, a total of 51 units (35%) exceeded the given limit of \( \pm 0.3 \), and the maximum deviation was 0.98. Sixteen of the units failing to comply with the AEC requirement were devices that had a fully automatic AEC. In about one third of all devices, the operators performed manual +/- adjustments in order to achieve a satisfactory density. The results for the AEC tests suggest that more attention should be paid to the operator's adjustments, but also the automatic exposure controls in many devices require further adjustment.

3.4 Image Quality Versus Technical Characteristics

Analysis of image quality (quality point rating by the radiologist) versus different technical parameters might reveal some correlation which could help to identify the sources of the main problems and, accordingly, point out where improvements would be needed. However, the analysis is complicated due to the interplay of the effects of various characteristics, and it may be difficult to draw unambiguous conclusions about the importance of a given technical parameter.

3.4.1 Image Quality Versus Dose

The quality points related to the visibility of the various detail object types have been plotted against the ESD in the 4.5 cm thick PMMA phantom in Figures 5–7. A similar plot for the sum of the quality points is shown in Figure 8. The trend curve shown in these figures is a polynomial of 3rd order fitted to the points (created by Microsoft Excel programme). A histogram of quality point distribution for ESD values is shown in Figure 9. The dependence of quality points between the visibility of tumor-like masses and fibres is shown in Figure 10.

The reason for the two zero values in Figures 5 and 10 was in both cases the notable processing artifacts.

It can be concluded from Figures 5 to 8 that there is not a clear correlation between quality points and ESD, and any threshold for the minimum ESD producing good quality points cannot be set. Good quality points can be obtained within a large range of ESD, and with much lower values than the diagnostic reference level of 10 mGy. Closer examination of the results (Figure 9) would suggest that the best quality points are obtained, on the average, with ESD values from 4 to 8 mGy. However, below 4 mGy there were only seven units, and six of them were very old, low-power devices from one manufacturer; five of them without a grid. This could explain the low quality points for the results with the lowest ESD: the low quality is not necessarily directly due to the low ESD.

![Figure 5](image-url). Quality points for the visibility of tumor-like masses in the RMI 156 phantom, plotted against the ESD.
Figure 6. Quality points for the visibility of fibers in the RMI 156 phantom, plotted against the ESD.

Figure 7. Quality points for the visibility of micro-calcifications in the RMI 156 phantom, plotted against the ESD.

Figure 8. Quality point sum for the three object groups, plotted against the ESD.
From Figure 10 a trend can be seen, that the visibility of tumor-like masses is related to the visibility of fibres. Therefore, the sum of the quality points for the visibility of these two objects could also be used as an indicator for the possible correlation between quality points and the given characteristics. For convenience of the study, the sum of these two components will be used in the following. The sum of all the three components would be less useful for this purpose, because the quality points for the visibility of microcalcifications are fairly constant and always acceptable (Figure 7).

### 3.4.2 Image Quality Versus Film Density

The dependence of the quality points (the sum for masses and fibres) on the film density is shown in Figure 11. It can be seen that below the optical density of 1.2, the relative number of low values of quality points (quality points less than seven) is significantly higher than above this density (33% below 1.2 compared with 14% above it). Below the density of 1.2, the quality points for masses (average 2.9 points) are less than the acceptance limit of 3 points while that for fibres just around the limit of 4.0 points. Above the density of 1.2, the average quality points for masses are 3.3 and for fibers 4.4. However, low quality points also occur in many cases above the density of 1.2; 14%
of this group was below seven points. The underexposure of the film is obviously one reason for the poor image quality but cannot explain most of the cases.

3.4.3 Image Quality Versus Spatial Resolution
The dependence of the quality points for tumorlike masses and fibers on spatial resolution is shown in Figure 12. The quality points tend to decrease significantly when the resolution falls below the minimum requirement of 12 lp/mm (mainly old devices). In other words, poor visibility of masses and fibers seems to be connected with poor resolution. As the quality points for the visibility the micro-calculifications were always acceptable (4–5 points), all tested devices produced sufficient resolution to meet the minimum threshold for identifying micro-calculifications.

On the basis of the results, the minimum resolution of 12 lp/mm seems a reasonable requirement as one criterion for acceptable image quality, although this requirement alone will certainly not provide sufficient guarantee for good visibility of all types of interesting objects.

3.4.4 Image Quality Versus Contrast
The dependence of the quality points on contrast is shown in Figure 13. The quality points tend to decrease noticeably below the minimum acceptable contrast of 0.35. The average quality points (the sum for masses and fibers) for the contrast below 0.35 was 6.6 points.

In Figure 14, contrast is plotted versus film density. There is a clear trend that a low film density, or under-exposure of the film, yields also a low contrast.

3.5 Image Quality Versus Number of Examinations Per Year
The number of examinations per year is not a good predictor of image quality, as can be seen from Figure 15. Although there is an apparent peak of quality points in the trend curve above about 1000 examinations per year, the scatter of quality points is very high throughout the scale. There are several facilities with a high number of examinations per year that produced sub-optimal quality images and vice versa. For example, the lowest score (4 quality points for the sum for masses and fibres) was attained by a facility that performed approximately 4000 examinations a year, while one of the highest scores (9.5 quality points) was achieved by a facility that performed only 150 examinations a year. Nevertheless, facilities with the lowest number of examinations seem not to perform too well generally.

3.6 Importance of the film/screen combination
Selected characteristics of the film/screen combinations in the mammography facilities of this study are summarized in Table III. For types 1 to 4, the cassette, film and screen are from one manufacturer, while “mixed” means a combination of them from different manufacturers. The measured values are the average values of a given type.

Similarly to the other technical factors discussed above, the film/screen combination alone does not seem to have a clear correlation with ESD or image quality. However, it could be expected that a single manufacturer would have a better chance to optimize the combined effectiveness of the various parts in the system; it is more likely to make a mistake when combining several products. The results in Table III roughly support this expectation, as the combinations of films and screens from different manufacturers (type “Mixed” in the table) yields the lowest values of quality points, film density and resolution, while the ESD was a little higher than the average for all facilities.

3.7 Importance of the Age of the Equipment
The specific age distribution of the mammography units was not part of the evaluation. However, some distinction between old and new designs (generations) could be made. The “new” design typically had the fully automatic AEC, while the “old” one (typically older than about 10 years) did not. The old design typically had a large focal spot size and low electrical power, and they are not more in production. The use of such equipment is also typically related to a low annual number of examinations (often used in small clinics, sometimes as spare units). As seen from Table IV, the new design tends to receive higher number of quality points, a little lower ESD and, in particular, remarkably better spatial resolution.
Figure 11. Quality point dependence on film density.

Figure 12. Quality point dependence on spatial resolution.

Figure 13. Quality point dependence on contrast.
Figure 14. Contrast versus film density.

Figure 15. Quality point dependence on the number of examinations per year.

Table III. Film/screen combinations in the mammography facilities studied (* the sum for the visibility of masses and fibers). Resolution data obtained from measurements with the test plates on the 4.5 cm phantom. (The type numbers are not in the order of the Table II.)

<table>
<thead>
<tr>
<th>Cassette/film/screen</th>
<th>pc</th>
<th>ESD mGy</th>
<th>Film density (OD)</th>
<th>Quality points (sum*)</th>
<th>Resolution lp/mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>93</td>
<td>6.9</td>
<td>1.43</td>
<td>7.5</td>
<td>13.4</td>
</tr>
<tr>
<td>2</td>
<td>14</td>
<td>8.5</td>
<td>1.38</td>
<td>7.5</td>
<td>12.9</td>
</tr>
<tr>
<td>3</td>
<td>13</td>
<td>5.7</td>
<td>1.42</td>
<td>7.9</td>
<td>13.7</td>
</tr>
<tr>
<td>4</td>
<td>8</td>
<td>9.1</td>
<td>1.51</td>
<td>7.6</td>
<td>13.8</td>
</tr>
<tr>
<td>Mixed</td>
<td>16</td>
<td>8.3</td>
<td>1.32</td>
<td>7.1</td>
<td>12.4</td>
</tr>
</tbody>
</table>
Table IV. Summary of selected characteristics for old and new designs of mammography units (averages).

<table>
<thead>
<tr>
<th></th>
<th>Old design</th>
<th>New design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sum of quality points (for masses and fibers)</td>
<td>7.1</td>
<td>8.0</td>
</tr>
<tr>
<td>Number of examinations per year</td>
<td>800</td>
<td>2600</td>
</tr>
<tr>
<td>ESD, mGy</td>
<td>7.6</td>
<td>6.8</td>
</tr>
<tr>
<td>Focal spot size (marked on unit)</td>
<td>0.45</td>
<td>0.31</td>
</tr>
<tr>
<td>Spatial resolution, lp/mm</td>
<td>11.8</td>
<td>14.9</td>
</tr>
</tbody>
</table>
4 Conclusions

A summary of the results for all tests is shown in Table V.

For the ESD, the reference level for mammography X-ray examinations in Finland was exceeded in about 14% of all facilities of this study, which was to be expected and actually suggests that the present reference level is reasonable.

For the image quality, a third of all equipment studied (50 devices out of 144) did not fulfil the minimum image quality requirements. Twenty-eight units failed due to non-acceptable visibility of masses or fibres in the accreditation phantom test, and additionally 22 units due to an inadequate film density. Considering the number of examinations taken by each facility per year, the devices that failed to reach the acceptable image quality criteria covered about 36% of the mammography images in the facilities studied, i.e., about 80 000 examinations out of the total of 220 000 annual examinations were taken by facilities which failed to comply with the image quality standard. Only 20% of the equipment passed the evaluation without any critical comments.

Devices used for screening purposes had a slightly higher image quality than non-screening devices. This could partly be related to the higher number of images taken at screening facilities and by more experienced users of the equipment.

Based on the detailed observations on the different cases, the reasons for high ESD and the failures in image quality can be related to film processing in 53% of the cases, to X-ray equipment in 34% of the cases, and to accessories (cassettes, screens) in 13% of the cases. The main source of problem clearly is in the film processing, while the second largest problem is the functioning of the automatic exposure controls. Observations of dirt and dust in cassettes and screens were also common. Thus, particular attention should be paid to the quality of film handling, film processing and the adjustments of the automatic exposure controls. The increase of digital imaging systems in the future will gradually reduce the problems related to film processing, but this development will bring about other considerations, including the fundamental question on the suitability of digital systems in mammography.

Compared with earlier studies in Finland, the patient doses have decreased significantly. For example, in a study by STUK in 1979 [4] the measured patient doses (ESD values) were on the average 11 mGy with a 4 cm thick phantom (cf. Table V) and 6 mGy with a 2 cm thick phantom.

Similar observations with this study have been obtained in the USA. MQSA's (Mammography Quality Standards Act) quality standards and the related accreditation process have had a substantial effect on improving quality assurance activities. When MQSA initially took effect, many mammography units did not meet the standards. For example, between October 1, 1994, and August 1, 1995, about 35 percent of the mammography units that sought ACR accreditation initially failed to meet accreditation requirements. In 2002, 87% of units applying for (or renewing) accreditation passed on their first attempt. Currently, over 98% of all mammography facilities pass the phantom image test during their facility inspection [5].

Taking into account the above sources of problems, the level of image quality in mammography in Finland can be improved by relatively simple improvements in the techniques and maintenance procedures of equipment, together with increased training of the users.
Many such improvements have already been carried out or initiated as a result of the observations in this study. For the worst cases, requirements on repair or improvements have been set in the inspection protocols (Table V).

The results of this study also suggest that re-checking of the image quality in mammography should be carried out on a regular basis. This would be of high importance due to the continuous rapid development of the technology as well as frequent changes of the staff that operates and carries out the maintenance of the equipment. One possibility is to improve the quality assurance programmes conducted by the users themselves. Another possibility would be to establish a system of user-independent checks through a suitable accreditation programme (like that by the MQSA in the USA [5]) or other programmes for external image quality audits.

### Table V. Summary of the results for all tests (* the sum of quality points for masses and fibers). (The type numbers are not in the order of the Table I).

<table>
<thead>
<tr>
<th>Type no</th>
<th>Number of devices studied</th>
<th>Average ESD mGy</th>
<th>Exceeding ref level (&gt; 10 mGy) number%</th>
<th>Average quality points</th>
<th>Fulfills quality criteria of test phantom</th>
<th>Additional comments given by the radiologist</th>
<th>Average film density (OD)</th>
<th>Performance of AEC: Exceeding ± 0.3 number%</th>
<th>Req. for repair set by inspection</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>19</td>
<td>9.0</td>
<td>6/32%</td>
<td>7.4</td>
<td>11/58%</td>
<td>3/16%</td>
<td>1.46</td>
<td>2/11%</td>
<td>4/21%</td>
</tr>
<tr>
<td>2</td>
<td>35</td>
<td>7.2</td>
<td>4/11%</td>
<td>8.1</td>
<td>29/83%</td>
<td>1/3%</td>
<td>1.47</td>
<td>10/29%</td>
<td>13/37%</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>7.3</td>
<td>1/33%</td>
<td>8.5</td>
<td>3/100%</td>
<td>-</td>
<td>1.45</td>
<td>1/33%</td>
<td>1/33%</td>
</tr>
<tr>
<td>4</td>
<td>8</td>
<td>5.4</td>
<td>-</td>
<td>6.5</td>
<td>5/63%</td>
<td>-</td>
<td>1.55</td>
<td>2/25%</td>
<td>2/25%</td>
</tr>
<tr>
<td>5</td>
<td>3</td>
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Acknowledgements

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5. FDA's mammography web-pages: www.fda.gov/cdrh/mammography


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