Insight. Delivered.

White paper

Technology advances
in
CR digital mammography
using
needle crystalline detectors

AGFA HealthCare

1. Executive summary

Agfa HealthCare always strictly follows all current regulations for digital mammography. In the past years, we have obtained FDA Clearance and EUREF (European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services) Certification for our computed radiography (CR) digital mammography solutions, based on equivalence with well-established technical standards and clinical tests.

In this white paper, our goal is to provide full visibility and details on the evolution over time of the image quality of our CR digital mammography solutions, due to the technology advancement from powder (phosphor) imaging plates (CR-PIP) to crystalline needle (phosphor) imaging plates (CR-NIP). Equally, in parallel, the evolution of medical technical and clinical standards are gradually moving away from using analog Screen/Film (S/F) as a reference standard; direct radiography (DR) is instead becoming the common reference for clinical and technical image quality and corresponding X-ray dose.

2. Introduction

Scope

This white paper illustrates the technology advances in CR digital mammography that have been realized over the past few years. The technology has achieved significant improvements by moving from powder (phosphor) imaging plates (CR-PIP) to needle (phosphor) imaging plates (CR-NIP), offering a cost-efficient digital mammography solution with performance close to DR.

The paper provides comprehensive facts and figures on the technical and clinical image quality of Agfa HealthCare's CR-NIP-based digital mammography system. It will demonstrate (1) the superiority of CR-NIP systems compared to CR-PIP systems (single- and double-sided) and (2) their competitiveness with DR technology, both for screening and diagnostic mammography.

Needle technology

The CR-NIP plates highlighted in this paper were introduced by Agfa HealthCare in 2010 as a new technology existing alongside S/F, CR-PIP and DR.
With CR-NIP plates, photostimulable phosphor is deposited in a needle structure on a rigid base plate. CR-NIP technology has a 90% fill rate, compared to 75% for CR-PIP. Both CR-NIP and CR-PIP plates are read with a flying spot laser digitizer at a pixel size of 50 µm.

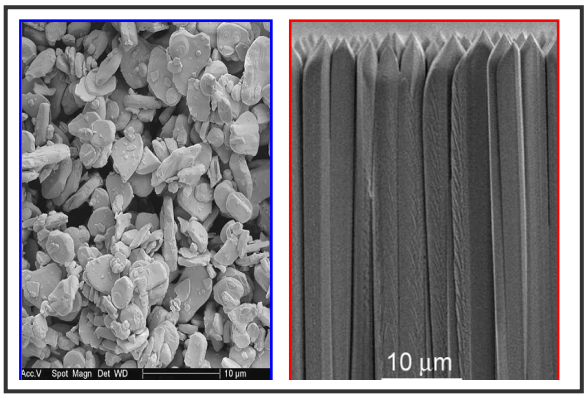


Figure 1: microscopic view (10µm) of powder phosphor (left) & needle phosphor (right) technology

CR-NIP (HM5.0) has the ability to provide a number of performance improvements over CR-PIP (MM3.0). These include increased image sharpness for the same screen thickness, due to the reduced lateral light spread of the photo stimulated light signal promoted by the needle structure.
CR-NIP also offers increased gain and reduced structure noise, due to greater absorption and homogeneity of the evaporated CsBr:Eu^{2+} layers across the plate. Furthermore, CR-NIP has higher photon transmission to the CR scanner optical module, due to the higher light transparency of the needles. Both the higher X-ray absorption and the higher photon collection efficiency lead to an improved signal-to-noise ratio.
Agfa HealthCare has developed a unique technique to correct residual image plate structure noise for the CR-NIP (HM5.0), in a similar way to the role of the “Gain Image Correction” procedure for DR systems. By providing a smoother image background, this Image Plate Gain Image Correction slightly improves the image quality and reading comfort.

3. Agfa HealthCare's CR-NIP digital mammography system

Agfa HealthCare's CR-NIP digital mammography system comprises of the DX-M reader, HM5.0 needle crystalline detectors and MUSICA² for Mammography image processing.

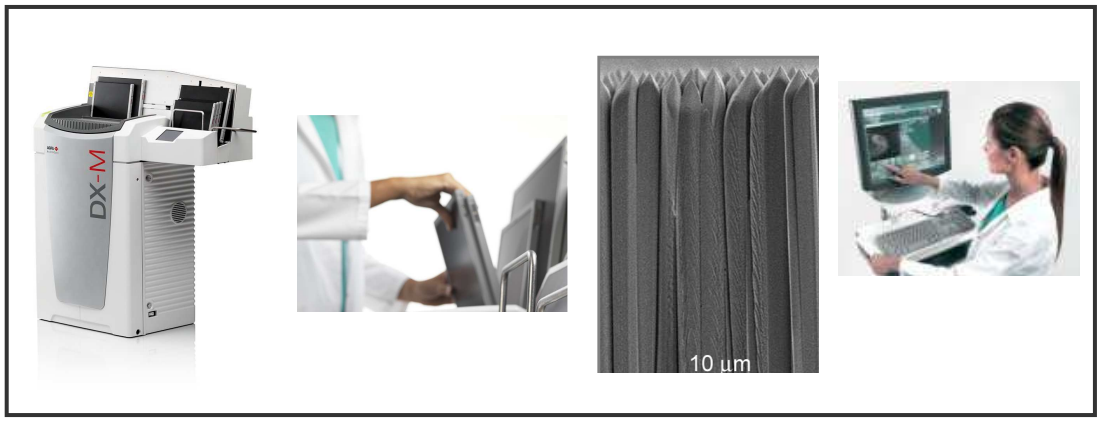


Figure 2: Agfa HealthCare's DX-M with HM5.0 and MUSICA² for Mammography

The solution unites the DX-M, which scans at the high resolution of 10 line-pairs per millimeter, with the mammography-dedicated HM5.0 needle crystalline detectors, for optimal image quality. With its user-friendly drop-and-go buffer, the DX-M offers a smooth and highly productive workflow. As HM5.0 needle crystalline detectors are compatible with existing mammography modalities, there are no additional, costly expenditures, making this an affordable transition from analog to digital mammography.

MUSICA² for Mammography dedicated digital image processing for mammography is designed to provide the best possible diagnostic information. The Multi Scale Image Contrast Amplification (MUSICA) algorithm decomposes the digital image in a number of different frequency ranges, modulating the signal amplitudes or contrast within each of these ranges. It automatically optimizes processing parameters and minimizes the need for re- or post-processing, regardless of the variations in input or dose. These features make MUSICA² for Mammography less time-consuming.

4. Dose aspects

Needle technology and dose

In digital mammography, 'dose consumption' can be expressed by the average dose required for a given contrast-detail detection. It is based on the analysis (whether from a human reading or from an automated analysis) of contrast-detail phantoms specifically designed for mammography (CDMAM, Nijmegen). Contrast-detail visibility is an important predictor of a system's capability to faithfully represent micro calcifications - amongst other pathologies - in a mammography image. Limiting or remedial dose values for the required contrast-detail visibility are defined by national guidelines or standards for digital mammography in screening and diagnosis.

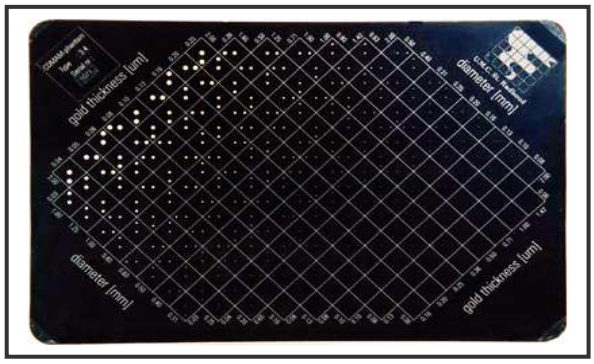


Figure 3: CDMAM: contrast-detail phantom consisting of pure gold discs of various thickness and diameter.

In this method for presenting performance data, the lower the dose required to reach a specific (here: minimum) contrast-visibility, the better the system.

1.
The National Health Service Breast Screening Programme (NHSBSP), in its "Technical Evaluation of Agfa DX-M Mammography CR Reader With HM5.0 Needle Image Plate", NHSBSP Equipment Report No. 0905 (NHSBSP Publications, Sheffield, 2009), provides a comprehensive overview:

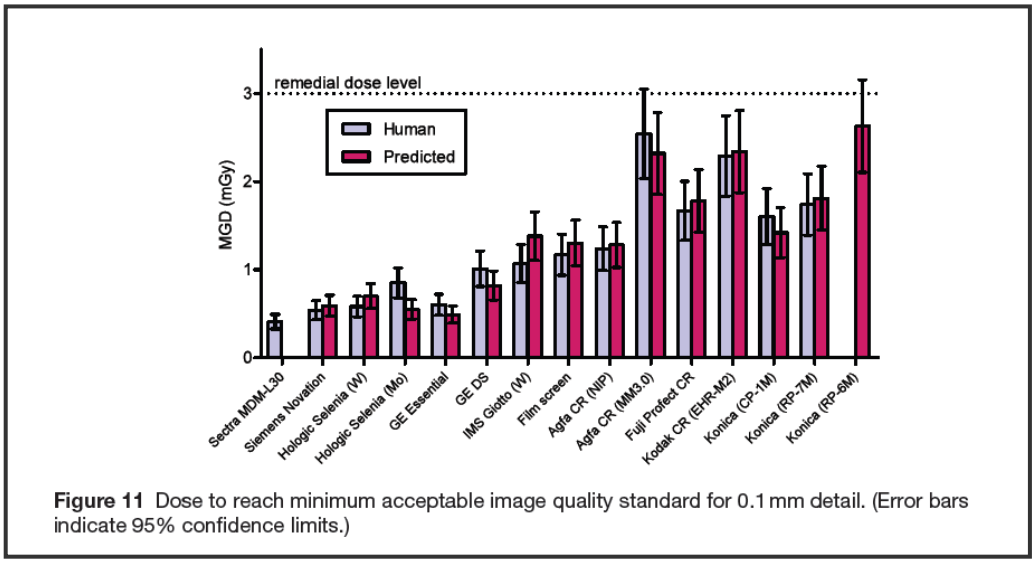


Figure 11 Dose to reach minimum acceptable image quality standard for 0.1 mm detail. (Error bars indicate 95% confidence limits.)

Figure 4: Figure 11 from "Technical Evaluation of Agfa DX-M Mammography CR Reader With HM5.0 Needle Image Plate", NHSBSP Equipment Report No. 0905 (NHSBSP Publications, Sheffield, 2009)

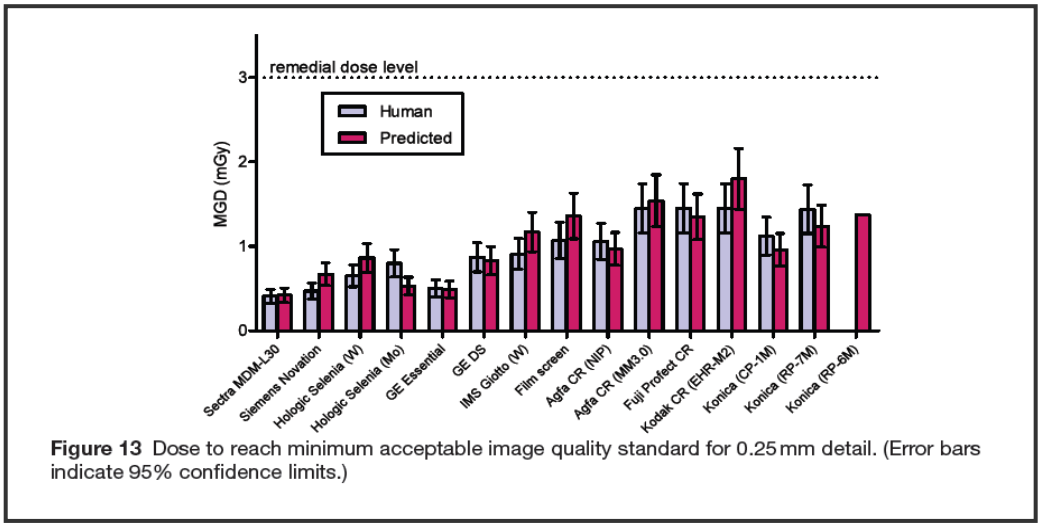


Figure 13 Dose to reach minimum acceptable image quality standard for 0.25 mm detail. (Error bars indicate 95% confidence limits.)

Figure 5: Figure 13 from "Technical Evaluation of Agfa DX-M Mammography CR Reader With HM5.0 Needle Image Plate", NHSBSP Equipment Report No. 0905 (NHSBSP Publications, Sheffield, 2009)

Conclusions from the NHSBSP report:

> "For the NIP system a dose of about 1.3 ± 0.26 mGy was calculated to be necessary to reach the minimum image quality level for this equivalent breast thickness. That is comparable with the dose required for film-screen systems."
>
> "The NIP system is capable of producing good image quality for a relatively low radiation dose. The system met the main standards in the NHSBSP and European protocols and demonstrated a substantial improvement over previous models from the same manufacturer in terms of image quality and/or dose efficiency."

Other conclusions:

- The figures suggest that all of the systems (including CR-PIP) meet the minimum requirements for contrast-detail visibility, but each requires a different dose level to do so. All dose levels are within the prescribed limiting dose value of 3 mGy.

- CR-NIP technology forms one group of dose levels, together with S/F and DR systems such as GE DS and IMS Giotto. This group overlaps with DR in dose and therefore in performance. CR-NIP needle technology outperforms the double-sided Fuji Profect CR-PIP system.

- CR-NIP and DR dose levels are well below the remedial values set by the EUREF guidelines for breast screening.

2.
Similar findings are published in: N.W. Marshall, K. Lemmens, H. Bosmans, "Physical evaluation of a needle photostimulable phosphor based CR mammography system," Med. Phys. 39 (2) (2012). The contrast-detail curves below compare the four existing digital technologies (single- and double-sided CR, needle technology and DR) and confirm the above conclusions.

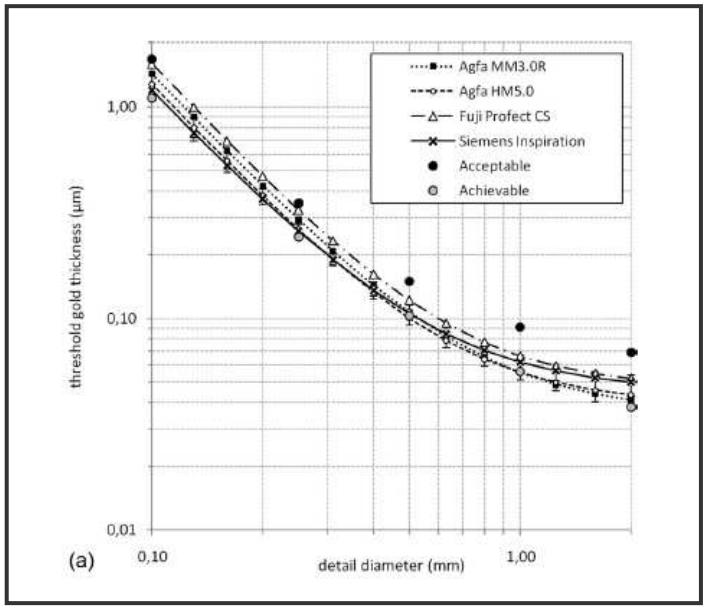


Figure 6: Figure 8(a) from "Physical evaluation of a needle photostimulable phosphor based CR mammography system", Med. Phys. 39 (2) (2012)

Conclusion from the article:

> "The needle CR detector reached the Acceptable limit for 0.1 mm details in the European Guidelines at a mean glandular dose (MGD) of approximately 1.31 mGy imaged at 28 kV Mo/Rh, compared to figures of 2.19 and 1.43 mGy for the single-sided and dual-sided readout powder CR systems."

Other conclusions:

- In practice, digital mammography systems use a somewhat higher dose in order to build in margin for the limiting contrast-detail performance or to further optimize image quality (the DX-M & HM5.0 digital mammography system uses 1.8 mGy for 50 mm PMMA, while DR typically ranges between 0.8 and 2 mGy).

- Accurate dose adjustment of the system's AEC is crucial to obtain optimal and consistent image quality across all breast thicknesses and densities. Agfa HealthCare has developed an accurate, dosimetry-based adjustment procedure for all its digital mammography systems. This procedure is compliant with all commonly available X-ray units.

Dose optimization

Using more specialized (although commonly available) anode/filter combinations like W/Rh or Rh/Rh further optimizes needle technology dose consumption. This is particularly the case for larger breast thicknesses.

The following two studies, both published in 2012, provide further details:

1. F. Semturs, P. Peloschek, G. Zwettler, J. Hummel, P. Homolka, "Needle Crystal Detector Technology in Mammography - Relationship Between Image Quality and Dose Depending on Beam Quality", Fortschr Röntgenstr 2012; 184: 905–910

   Conclusion:

   "Die Umstellung von Mo/Rh auf W/Rh erlaubt bei 50mm PMMA um 20 % geringere AGD bei gleichbleibender CDMAM-Bildqualität und bei 70mm PMMA eine Reduzierung von bis zu 40 %."
   ("The change from Mo/Rh to W/Rh allows for 20% less dose at 50 mm PMMA at the same CDMAM-image quality and a reduction of up to 40% at 70 mm PMMA.")

2. N.W. Marshall, K. Lemmens, H. Bosmans, "Physical evaluation of a needle photostimulable phosphor based CR mammography system", Med. Phys. 39 (2) (2012)

   Conclusion:

   "Examining the performance of the Agfa needle detector at 28 kV W/Rh, we find that the needle CR system can meet the Acceptable level at 1.09 mGy, a result that is ≈15% lower than that of the Mo/Rh A/F combination, although still ≈35% higher than the Siemens Inspiration result of 0.65 mGy."

5. Technical image quality

In addition to contrast-detail visibility, other technical data is also used to judge the performance of digital mammography systems. The detective quantum efficiency (DQE), which incorporates noise and spatial resolution properties, is the most important for characterizing a system in standard exposure conditions. In addition to the complex relationship between machine-related statistics (like DQE) and task-related statistics (contrast-detail visibility), needle technology DQE statistics outperform double-sided reading CR, and approach those of DR systems (SIEMENS Inspiration).

DR detectors are always subject to electronic noise, which affects the signal to noise ratio, especially at low exposure levels. As a result, the DQE for DR systems drops at low exposure levels. In most CR systems, however, there is negligible electronic noise, so the technical image quality of the DX-M HM5.0 system outperforms that of the DR systems for the clinically relevant exposure levels.

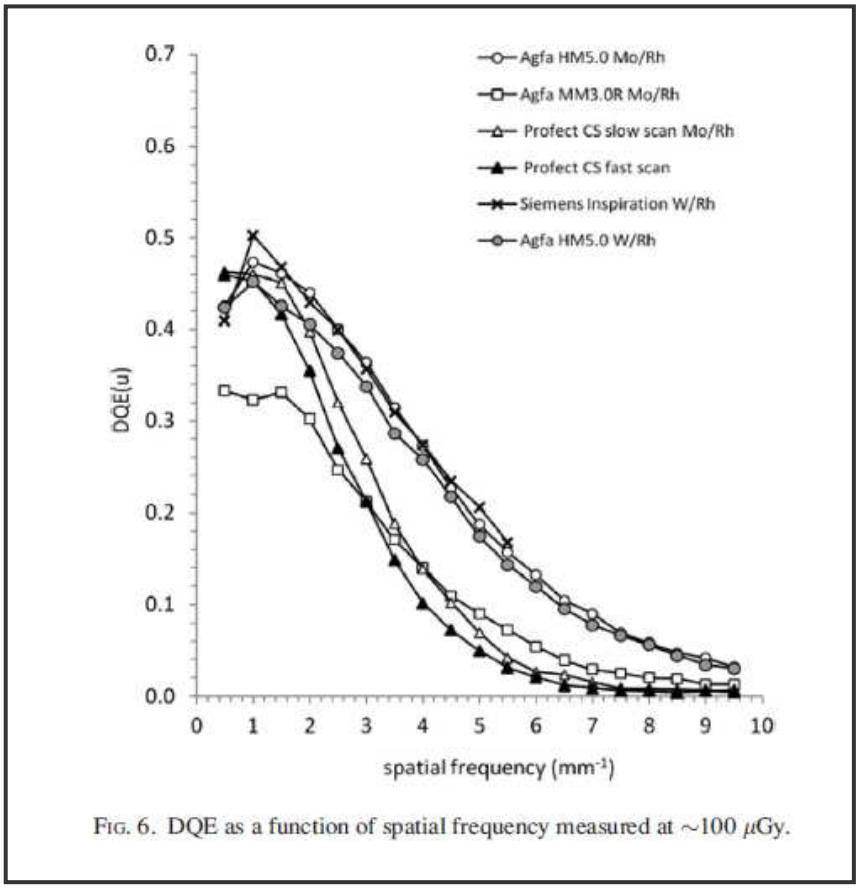


FIG. 6. DQE as a function of spatial frequency measured at ~100 μGy.

Figure 7: Figure 6 from "Physical evaluation of a needle photostimulable phosphor based CR mammography system", Med. Phys. 39 (2) (2012

Further details are outlined in: N.W. Marshall, K. Lemmens, H. Bosmans, "Physical evaluation of a needle photostimulable phosphor based CR mammography system", Med. Phys. 39 (2) (2012).

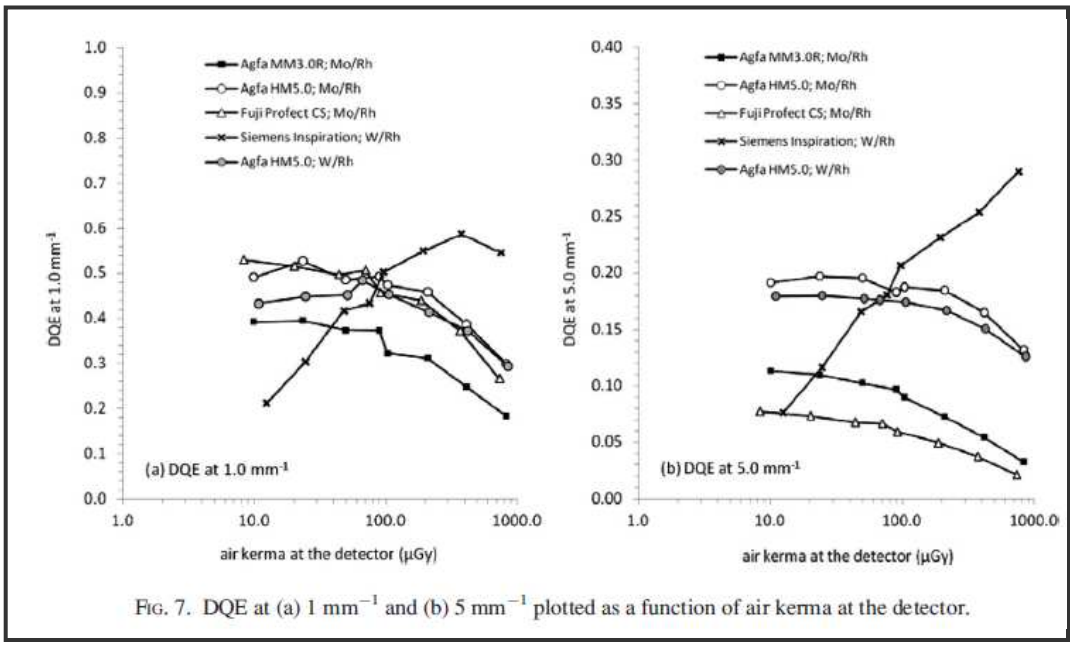


FIG. 7. DQE at (a) 1 mm^{-1} and (b) 5 mm^{-1} plotted as a function of air kerma at the detector.

Figure 8: Figure 7 from "Physical evaluation of a needle photostimulable phosphor based CR mammography system", Med. Phys. 39 (2) (2012)

TABLE IV. Peak DQE and DQE at 5 mm^{-1} at reference air kerma with 2 mm Al added beam filtration.

	Tube potential (kV)	Anode/ filter	Mean energy (keV)	Peak DQE	DQE at 5 mm^{-1}
Detector name					
Agfa HM5.0	28	Mo/Rh	20.2	0.47	0.19
Agfa HM5.0	28	W/Rh	20.8	0.45	0.17
Agfa MM3.0R	28	Mo/Rh	20.2	0.33	0.09
Fuji profect CS (left–right)	28	Mo/Rh	20.2	0.46	0.05
Fuji profect CS (chest wall-nipple)				0.46	0.07
Siemens inspiration	28	W/Rh	20.8	0.50	0.21

Figure 9: Table IV from "Physical evaluation of a needle photostimulable phosphor based CR mammography system", Med. Phys. 39 (2) (2012)

Results and conclusions of this study:

> "Peak DQE at 100 µGy was 0.47 for the needle system compared to peak DQE figures of 0.33 and 0.46 for the single-sided readout powder plates and dual-sided readout plates."
>
> "The high frequency DQE (at 5 mm^{-1}) was 0.19 for the needle CR plates, a factor of approximately 3 greater than for the powder CR plates. At 28 kV W/Rh, 2 mm Al, peak DQE for the needle CR system was 0.45 against a value of 0.50 for the α-Se detector."
>
> "Imaging performance for the needle CR phosphor technology, characterized using MTF and DQE and threshold gold thickness demonstrated a clear improvement compared to both single- and dual-sided reading powder phosphor based CR systems."

6. Clinical image quality

Agfa HealthCare has successfully passed EUREF-type testing routines introduced in 2010. "EUREF type testing is defined as a test (1) to verify whether a type of system is able to pass the acceptability criteria of the European protocol (European Guidelines for Breast Cancer Screening), (2) to provide guidelines about the best practice in terms of dose and (clinical) image quality (EUREF 'Type Test Equipment')."

For the testing, an excessive technical assessment of the tested unit - installed at two independent sites - is carried out. The results must meet all EUREF criteria and demonstrate consistency in all relevant parameters (AGD, CNR and CDMAM contrast-detail performance).

A subsequent assessment of the clinical image quality is performed on a representative set of studies collected over a period of at least three months in a screening environment. The reading is done by experts in European screening with "ample experience in digital mammography and in the assessment of image quality." (EUREF 'Type Test Equipment') This includes both CR and DR clinical image quality.

The final scores shown below are based on a relative 9-point scale (9 being 'best possible').

Needle technology (CR-NIP) and clinical image quality

All scores were achieved using an optimized image processing setting (MUSICA^2 for Mammography) and the low-dose setting of the DX-M & HM5.0 digital mammography system (1.8 mGy at 50 mm PMMA).

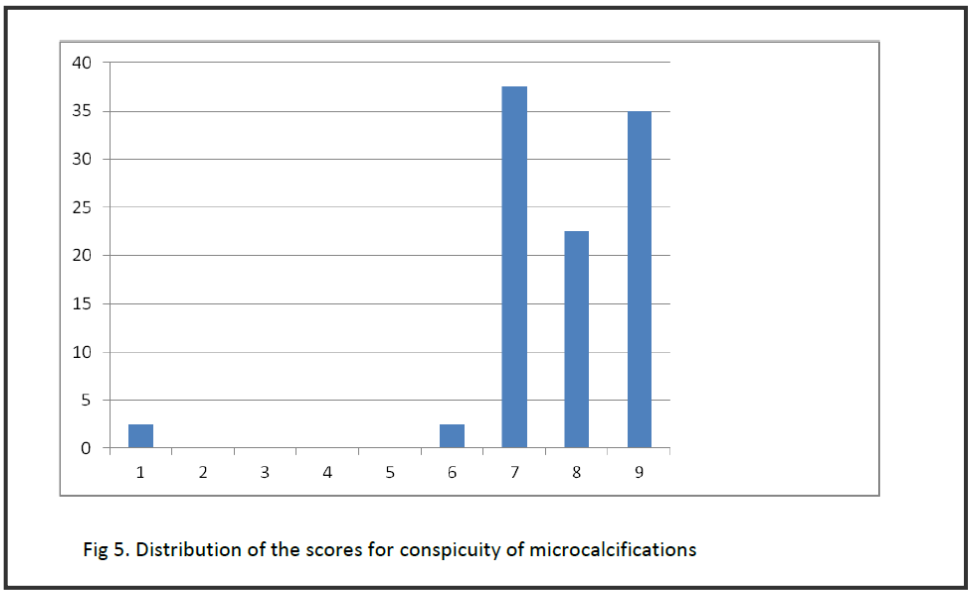


Fig 5. Distribution of the scores for conspicuity of microcalcifications

Figure 10: Figure 12 from EUREF report (microcalcifications)

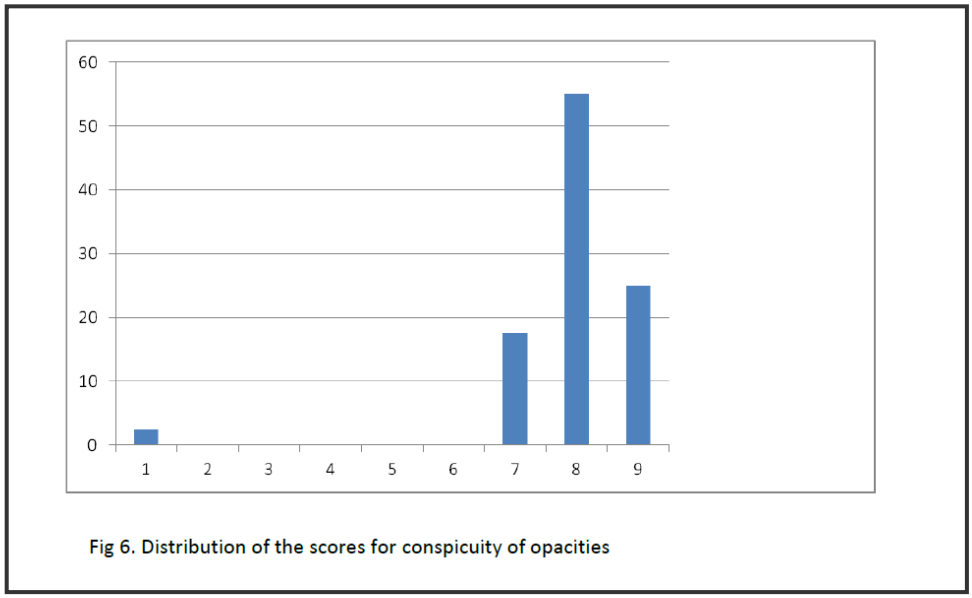


Figure 11: Figure 6 from EUREF report (opacities)

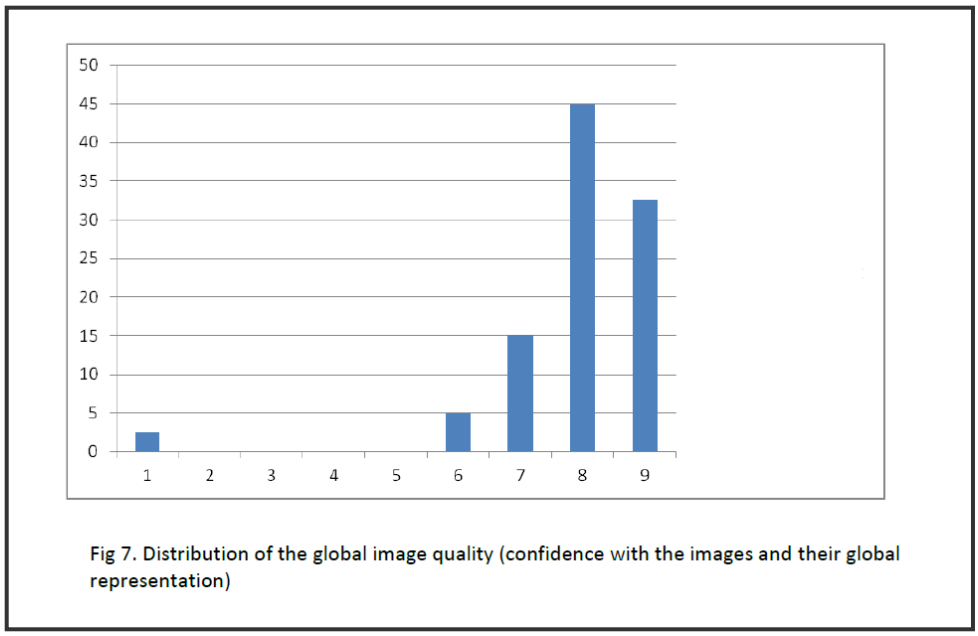


Figure 12: Figure 7 from EUREF report (Global quality and confidence with the images and their representation)

-> The 2.5% score in the lowest scale (one single image) was not due to equipment failure (confirmed by EUREF).

The overall conclusion of the EUREF type test for CR-NIP:

> "The mammographic images of the Agfa DX-M reader in combination with CR HM 5.0 plates, and using the image processing settings described in table 5, meet the demands of the EUREF type test for the observer study. Overall the radiologists were positive about the image quality."

CR-PIP and clinical image quality

All scores refer to the CR 85-X/CR 35-X & MM3.0 digital mammography system (2.6 mGy at 50 mm PMMA).

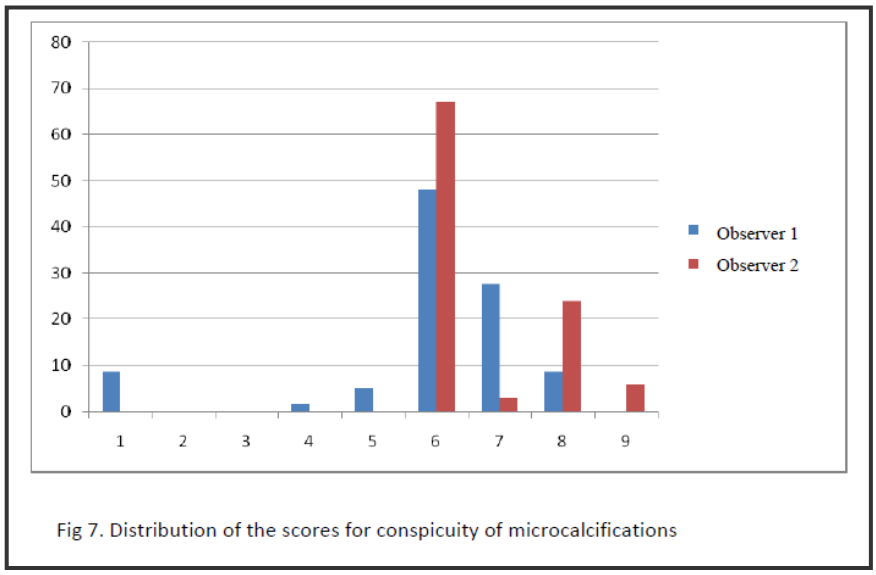


Figure 13: Figure 7 from EUREF (CR 35-X/CR 85-X) report (microcalcifications)

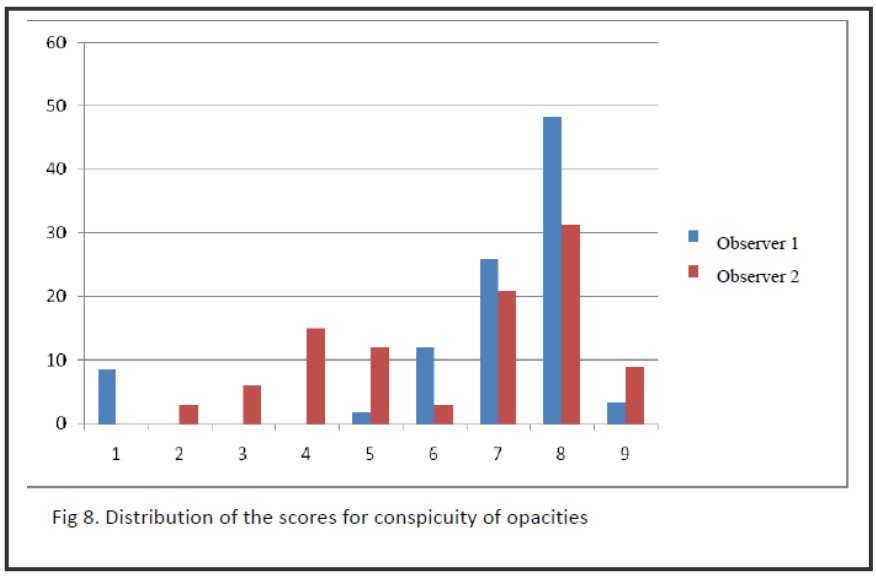


Figure 14: Figure 8 from EUREF (CR 35-X/CR 85-X) report (opacities)

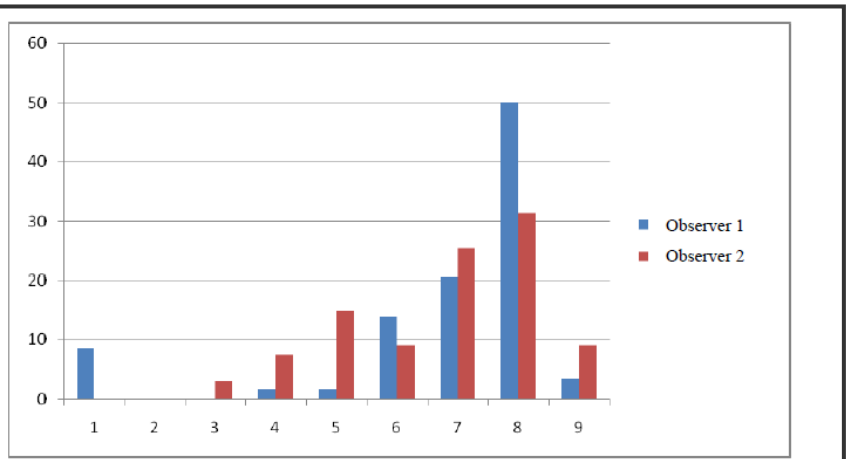


Fig 9. Distribution of the global image quality (confidence with the images and their global representation)

Figure 15: Figure 9 from EUREF (CR 35-X/CR 85-X) report (global quality and confidence with the images and their representation)

The overall conclusion of the EUREF type test for CR-PIP:

> "The mammographic images of the Agfa CR 35-X/CR 85-X reader meet the demands of the EUREF type test for the observer study.
> Overall the radiologists were positive about the image quality. They were satisfied with the representation of microcalcifications and the representation of opacities was good."

Further optimization of CR-NIP and clinical image quality:

Similarly to technical image quality, needle technology dose consumption can be further reduced without loss of diagnostic performance by using more specific beam qualities. (10)

This was studied in: P. Peloschek, E. Kalinowski, G. Langs, G. Zwettler, F. Semturs, "Needle Crystal Detector Technology in Mammography - Further dose reduction and clinical image quality with different beam qualities (W/Rh vs. Mo/Rh)", European Society of Radiology, ECR Congress, Vienna (2013).

The main conclusions from this study:

> "To compare diagnostic image quality of CR needle crystal technology used in mammography acquired with anode/filter combination of Tungsten/Rhodium

versus Molybdenum/Rhodium. This showed equivalent technical image quality (EUREF, CDMAM) with further dose reduction of 15-20% in earlier studies."

"Application of W/Rh instead of Mo/Rh has shown to allow for a further dose reduction without loss of diagnostic image quality."

7. Clinical studies related to CR-PIP (no CR-NIP)

Several studies describe performance of digital mammography. They do not contain CR-NIP as this is a relative new technology on the market.

Hilde Bosmans, Hubert Thierens et al,, “Technical and clinical breast cancer screening performance indicators for computed radiography versus direct digital radiography”, Eur Rad, May 21, 2013

Anna M. Chiarelli, et al., “Digital Compared with Screen-Film Mammography: Performance Measures in Concurrent Cohorts within an Organized Breast Screening Program.”, Radiology 122567; 2013

Seppo Lipasti, Ahti Anttila, Martti Pamilo, “Mammographic findings of women recalled for diagnostic work-up in digital versus screen-film mammography in a population-based screening program”, Finland Acta Radiol 2010 51: 491

Boel Heddson, Katarina Rönnowa, Magnus Olsson, David Miller, “Digital versus screen-film mammography: A retrospective comparison in a population-based screening program”, European Journal of Radiology 64 (2007)

Pisano ED, et al., “Diagnostic performance of digital versus film mammography for breast-cancer screening”, NEJM 2005;353:1773–83 (DMIST study)
The DMIST study concludes that double-sided reading CR is safe and effective for diagnosis and screening in the United States, which is known as the most regulated country worldwide for quality in conventional and digital mammography.

8. Certifications

A number of certifications and clearances have been granted to Agfa HealthCare's DX-M & HM5.0 digital mammography system, as well as its CR-PIP based system (EUREF certificate).

European Reference Organisation
for Quality Assured Breast Screening
and Diagnostic Services

EUREF *Mammographic Type Test*

EUREF
certifies that the

AGFA
DX-M
in combination with CR HM 5.0 imaging plates
(needle based technology)

has successfully passed the EUREF Type test

The demands are described in the EUREF Type Test Protocol version 1.11,
based on chapter 2B of the European guidelines for quality assurance in breast cancer screening and diagnosis (4th ed.).
The system tested passed both the physico-technical and clinical tests.

Prof. Dr. R. Holland
Chairman EUREF

Dr. M. Thijssen
Board EUREF

Nijmegen. November 20, 2011

The specifications of the systems tested and the image processing settings are summarised on the back side of this document

Figure 16: EUREF certification (HM5.0)

European Reference Organisation
for Quality Assured Breast Screening
and Diagnostic Services

EUREF *Mammographic Type Test*

EUREF
certifies that the

AGFA
CR35-X/CR85-X
in combination with CRMM 3.0 plates

has successfully passed the EUREF Type Test

The demands are described in the EUREF Type Test Protocol version 1.11,
based on chapter 2B of the European Guidelines for quality assurance in breast cancer screening and diagnosis (4th ed.).
The system tested passed both the physico-technical and clinical tests.

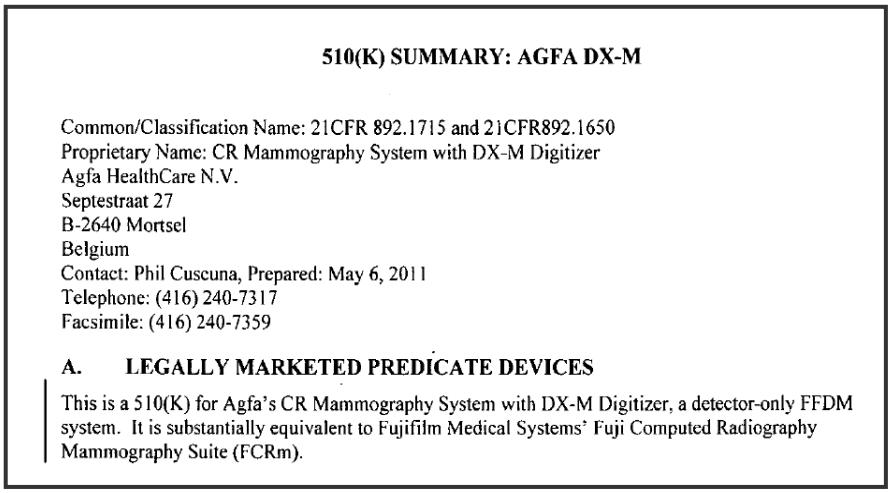
Prof. Dr. R. Holland
Chairman EUREF

Dr. M. Thijssen
Board EUREF

Nijmegen. November 02, 2010

The specifications of the system tested are summarised on the back side of this document

Figure 17: EUREF certification (MM3.0)



510(K) SUMMARY: AGFA DX-M

Common/Classification Name: 21CFR 892.1715 and 21CFR892.1650
Proprietary Name: CR Mammography System with DX-M Digitizer
Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Phil Cuscuna, Prepared: May 6, 2011
Telephone: (416) 240-7317
Facsimile: (416) 240-7359

A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(K) for Agfa's CR Mammography System with DX-M Digitizer, a detector-only FFDM system. It is substantially equivalent to Fujifilm Medical Systems' Fuji Computed Radiography Mammography Suite (FCRm).

Figure 18: FDA Clearance (HM5.0)

Summary & outlook

Agfa HealthCare's CR digital mammography systems have been implemented and used worldwide since 2005. The huge installed base clearly illustrates the confidence of customers throughout the medical world for their use in screening and diagnostic mammography.

A large number of scientific studies, clinical investigations and type-testing activities have demonstrated that the newer needle technology, introduced in 2010, significantly outperforms single- and double-sided CR-PIP technology (as acknowledged by Agfa HealthCare's FDA 510(k) clearance obtained in 2011).

Agfa HealthCare's technology allows to comply fully with the current regulations and guidelines worldwide. It has obtained FDA Clearance and EUREF (European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services) Certification for its CR digital mammography solutions, based on equivalence with well-established technical standards and clinical tests.

Agfa HealthCare's CR-NIP digital mammography system, based on the DX-M digitizer using HM5.0 needle crystalline detectors and MUSICA² for Mammography image processing, offers consistent and very high image quality and enhanced details. Further enhancement of details is possible with a unique option on MUSICA² for Mammography: Micro Calcification Enhancement (MCE). This intelligent algorithm detects potential microcalcifications and microcalcification clusters, and facilitates reading by subtly enhancing potential microcalcifications while preserving their shape, all without disturbing the overall visual context. The original image and the MCE image are stacked, so the radiologist can easily switch between the two.

Needle technology has proven to be competitive in technical/clinical performance, as well as in price and total cost-of-ownership. CR-NIP systems are very robust, which further reduces the total cost of ownership and allows them to be used in more physically demanding environments, such as mobile screening vans.

Agfa HealthCare's CR digital mammography systems also include the IMPAX for Breast Imaging diagnostic workstation, the mammography CAD and dedicated DRYSTAR imagers. It offers a true, fully integrated solution designed for the specific needs of breast imaging departments.

References

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Abbreviations

S/F: screen/film
CR: computed radiography
CR-PIP: computed radiography based on powder phosphor imaging plates
CR-NIP: computed radiography based on needle crystalline phosphor imaging plates
DR: direct radiography
FDA: food and drug administration (US)
EUREF: European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services
NHSBSP: National Health Service Breast Screening Programme (UK)
DQE: detective quantum efficiency
CNR: contrast-to-noise ratio
AGD: average glandular dose
MCE: micro calcification enhancement
CAD: computed aided detection

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