

# The Whole Truth: The science behind Fujifilm CR for digital mammography.

FUJIFILM Medical Systems USA, April 2009

It is ironic that the world's most widely used<sup>1</sup> and heavily peer-reviewed digital mammography system would come under question as to its technological adequacy for mammographic imaging. Such is the situation Fujifilm finds itself in to adequately address the negative marketing that has been widely broadcast by Hologic Corporation.

In a marketing paper titled *Image Quality of CR Mammography*, authored by Andrew Smith, Ph.D., several aspersions are made against CR FFDM technology that are misleading, poorly documented and indeed inaccurate. The purpose of this paper is to correct said inaccuracies and false claims, and provide ample references of well-respected researchers around the world who have come to trust Fujifilm's CR technology for this most important and challenging imaging application.

## Resolution Performance

With respect to resolution performance, Hologic claims because CR uses an indirect conversion method of a phosphor scintillator, there is light diffusion through that phosphor that limits the resolution characteristics of the detector. Relative to Modulation Transfer Functions (MTF) Hologic concludes: "Using 50 micron pixels is not optimal. The system could use much coarser pixels without affecting observable image quality because resolution is determined by the broad point spread of the laser beam during readout" and "The CR system has all the disadvantages associated with small pixels, with none of the gain in image resolution."

**MTF.** The MTF curves shown in Hologic's paper are misleading in that they selectively use *unprocessed data* to apparently show an inferior MTF for Fujifilm CR. However, unprocessed images are not used for interpretation, nor are they even available to the radiologist for interpretation. Hologic is well aware of this; arguing the point with unprocessed data is deceptive at best. In fact, using processed image information, the MTF curve for Fujifilm CR would show superiority between 0 and 4 lp/mm Spatial Frequency (Figure 1.) This would correspond to offering greater contrast resolution in anatomical structures critical to diagnosis.

Also note that the MTF curve for Hologic's Selenia stops at 7 lp/mm. Beyond that point there is no useful information since it is limited by its physical architecture of 70 micron resolution. Similar to film screen performance, Fujifilm is able to acquire useful data beyond 7 lp/mm because of our 50 micron pixel pitch. This area of the MTF curve is associated with greater detail resolution.

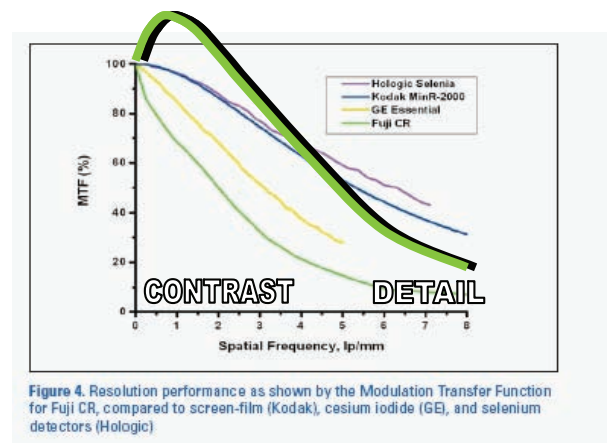


Figure 1 Fujifilm CR Mammography processed image data (bold green) superimposed on Hologic MTF graph. The portion of the spectrum representing contrast vs. detail is also highlighted.

**Images Say it All.** Mammographers, however, do not diagnose from MTF curves but from diagnostic images. Because the use of phantoms for quality control is such an integral part of mammography, the following phantom and clinical images clearly demonstrate why a processed image needs to be evaluated and why a 50 micron image sampling is superior to 100 micron sampling.

The following (page 2) are not artificially created images. Because Fujifilm's technology provides a choice of both 50 micron and 100 micron sampling within the system, each of the following pairs of comparisons are from the same equipment, same positioning and same exposure parameters. Also, for the phantoms each pair was processed using the same algorithms so that the sole remaining variable of comparison is the sampling pitch of the pixels.

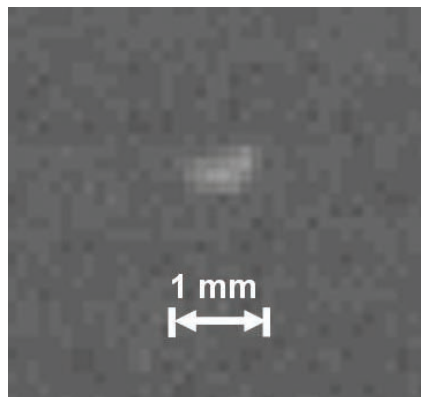


Figure 2. RMI ACR phantom Model 156 acquired with 100 micron pixel sampling.

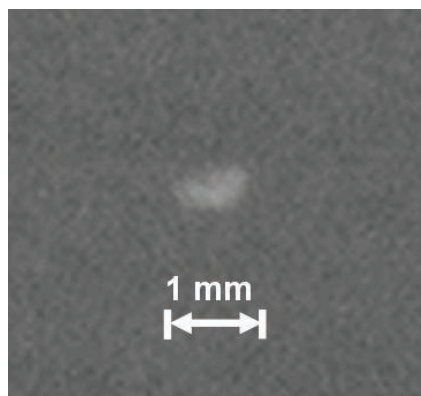
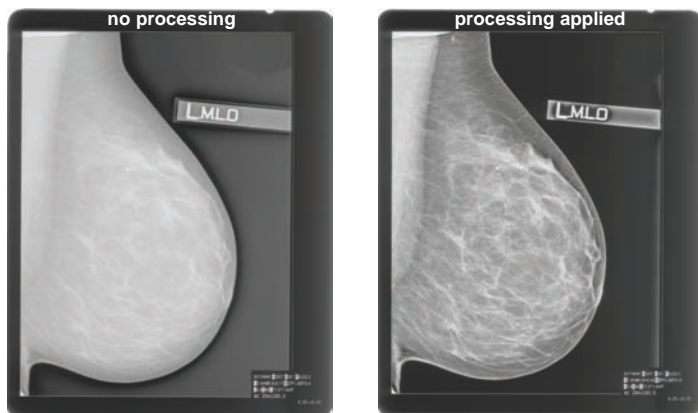


Figure 3. RMI ACR phantom Model 156 acquired with 50 micron pixel sampling, with all other parameters, exposure, positioning and image processing remaining the same as the 100 micron image.

Above, you will immediately see that there are noticeable differences in phantom speckle shape reproduction (Figures 2, 3) and line pair visibility (Figure 6), above right. The clinical images below (Figures 4, 5) show how important image processing is to rendering accurate diagnoses.



Figures 4, 5. The left image demonstrates a Fujifilm CR clinical acquisition with no image processing applied. This is never seen by the interpreting physician. The right image demonstrates optimized Fujifilm CR processing on the same image.

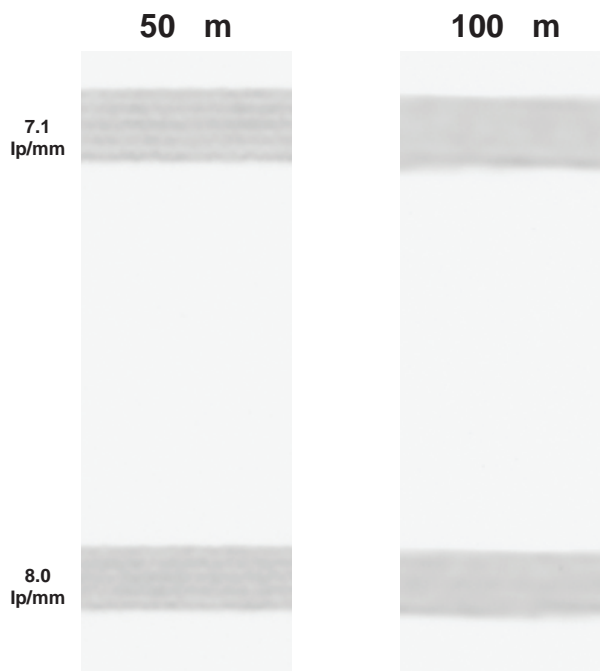


Figure 6. Nuclear Associates, Carle Place, NY, line pair phantom model 07-521 acquired with 50 micron sampling vs 100 micron sampling. It is visibly obvious that 50 micron sampling has far better resolving power than 100 micron. The 8.0 line pairs/mm capability of the 50 micron which Fuji routinely resolves is also beyond the theoretical Nyquist limit of the 70 micron Hologic Selenia which – at its theoretical best – could only resolve 7.1 line pairs/mm.

### FDA 510(k) Cleared Printers for Mammography.

Hologic claims 70 micron pixels are optimal for FFDM. To follow Hologic’s argument to a logical conclusion would indicate that other ancillary components of a mammographic image delivery system would also be better matched at their larger pixel size. Unfortunately this is not played out in reality and the best example is that of FDA 510(k) cleared printers for mammography. Table 1 below demonstrates that manufacturers of imagers offer both non-cleared and cleared devices for mammography. If the 70 micron pixel size was indeed optimal as Hologic claims, why would the FDA only clear those printers that are 50 micron and below?

Printer Mfr.	FDA-Cleared for Mammography	Not FDA-Cleared for Mammography
Agfa	DryStar™ 4500M, 5500, 5503: <b>50 microns</b>	DryStar 3000, 5300, 5302: <b>79 microns</b>
Fujifilm	DryPix™ FM-DP L, 4000, 5000, 7000: <b>50 microns</b>	DryPix 1000, 2000, 3000: <b>84.7 microns</b>
Carestream	DryView™ 8900, 8600, 8610: <b>40 microns</b>	DryView 8700, 8100, 8150, 8200: <b>78 microns</b>

Table 1. Those printers 510(k) cleared by the FDA for mammography are 50 micron printing or below. No vendor has a printer >50 microns cleared for mammography despite Hologic’s assertion that 70 micron is the optimal pixel size.

## Clinical Research Supports Fujifilm CR FFDM.

There are numerous papers that have been published demonstrating the equivalence of Fujifilm CR to screen film imaging including an exhaustive review by the FDA in granting a stringent PMA to the technology.<sup>1</sup> Additionally, researchers including those at the Mayo Clinic<sup>2</sup> have found benefits in screening dense breast patients that were later verified by the large scale ACRIN-DMIST trial.<sup>3</sup> What many mammography professionals in the U.S. have not been informed of, though, is that a large number of cases in the DMIST study population were contributed by sites using Fuji CR technology. Figure 7 shows the number of DMIST patients imaged by Fujifilm compared to the population imaged with the Hologic Selenia. Clearly the benchmark study in digital mammography today supports the efficacies of Fujifilm CR mammography.

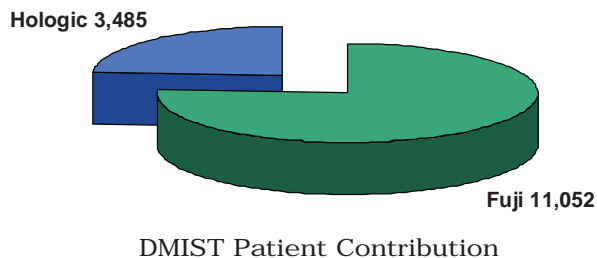


Figure 7. Patient populations contributed to DMIST by Fujifilm and Hologic Mammography Systems that are still marketed in the US today.

In fact, during a presentation of additional analysis of DMIST results<sup>4</sup> at RSNA 2006, it was disclosed by principal investigators that an insufficient number of patients with cancers were contributed by the Hologic Selenia in looking at machine-specific results.

## CR FFDM Dose Efficiency

Although it is a basic tenet of imaging physics that, all other things being equal, a higher DQE is preferred, the way this plays out in perceivable image quality is dependent upon a number of factors. Fujifilm's FDA-approved CR for mammography is actually a very specialized version of our CR technology that uses a patented, dual side reading technology (the Smith paper showed a graphic of single side reading on its front page). The Fujifilm digital mammography systems read image data from both sides of the imaging plate.<sup>5</sup> This increases the DQE by as much as 47% over the single side CR reading method used for conventional radiographic applications.<sup>6</sup> Fujifilm believes this large DQE increase is necessary for mammography and is also cause for

skepticism that single side CR reading technologies will be sufficiently adequate to meet the rigorous needs of the mammography application.

However the issue at hand is comparing Fujifilm's technology on the basis of DQE to either an amorphous silicon/cesium iodide (a-Si/CsI) system or a system based on amorphous selenium (a-Se). Instead of avoiding the issue and trying to stick with documented clinical performance on patients such as those from DMIST, recently published physics research actually demonstrates that factors other than DQE must be in play as the Fuji CR solution performed better than an a-Se system. Researchers in Italy found the following: "*However, the IMS system showed a statistically significant different response for details smaller than 0.3 mm. In this case, the poor response of the a-Se detector could be attributed to its high-frequency noise characteristics, since its MTF, NEQ, and DQE are not inferior to those of the other systems.*"<sup>7</sup>

So, in practical conditions, and using contrast-detail analysis which takes into consideration human observers, it is clear that DQE and even MTF alone do not deliver superior observed image quality. The overwhelming usage of Fujifilm CR FFDM worldwide as well as the extensive patient contributions made by Fujifilm CR FFDM within DMIST is ample evidence that confident diagnoses are being made with this technology. To suggest that resolution or DQE is clinically deficient in CR mammography is patently false.

## Signal Loss After Exposure

The final inaccurate claim in the Hologic white paper is one stating that "if only ten minutes transpire from exposure to readout, approximately 10% of the signal will have been lost." Hologic does not reference the source of their graph but it is completely inaccurate. On the next page is Fujifilm's submission to the FDA of image fading data as a function of both time and temperature (figure 8).<sup>8</sup> Note that this data on photostimulable luminescence (PSL) is acquired in a worst case temperature environment of 32° C (which is ~90° F). The typically lower ambient room temperatures in a mammography environment would make these miniscule degradations even more insignificant.

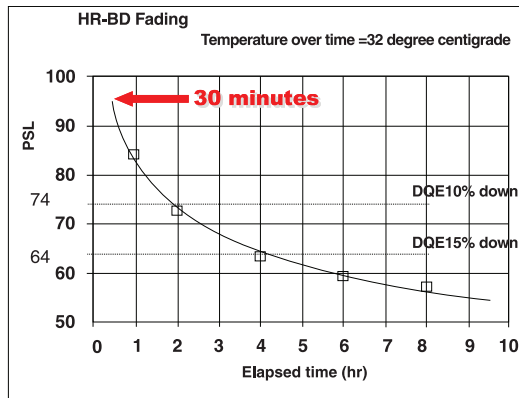


Figure 8. Signal loss from mammography imaging plate as a function of time and temperature. Note that noticeable DQE loss is not apparent for two hours after exposure.

With simple interpolation of the data provided and approved by the FDA, approximately 95% of the PSL signal is still present a full 30 minutes after exposure. Also, it is important to note that there is not a direct relationship between PSL and DQE. In other words if 5% of PSL is degraded due to delayed readout, this would equate to less than 2% of DQE reduction which is commonly agreed by all imaging physicists to be imperceptible in any aspect of image presentation. Fujifilm’s reasonable estimate is that a just noticeable increase in perceptible image impact would not occur until two hours after exposure. Again, that estimate is based upon worst case temperature conditions and not by room temperature standards.

## Summary

Hologic’s marketing paper, which tries to present itself as technically accurate information, contains baseless and false claims against the well-recognized technology of CR FFDM. Those professionals involved in making purchase decisions, fortunately, are careful in considering any technology that is used for mission critical diagnostic studies and do so based upon peer-reviewed literature and accurate experience from other clinical users.

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- 1 Fujifilm Computed Radiography Mammography Suite, “Summary of Safety and Effectiveness Data”, U.S Food and Drug Administration Pre-Market Approval Application P050014, Approved July 2006
- 2 J.P. Quam, S.J. Ackerman, M.M. Mordin, L.J. Bassett, “Conspicuity and Characterization of Findings on Computed Radiography for Mammography vs Screen-film Mammography: Results from a Prospective Clinical Trial.” Paper presented at the Radiological Society of North America annual meeting, Chicago, IL, November 2003.
- 3 E. Pisano, C. Gastonis, E. Hendrick, M. Yaffe, J. Baum, S. Acharyya, E. Conant, L. Fajardo, L. Bassett, C. D’Orsi, R. Jong, M. Rebner, “Diagnostic Performance of Digital versus Film Mammography for Breast-Cancer Screening,” New England Journal of Medicine 2005;353
- 4 E. Pisano, E. Hendrick, “New ACRIN DMIST Results.” Papers presented at the Radiological Society of North America annual meeting, Chicago, IL, November 2006.
- 5 S. Arakawa, H. Yasuda, K. Kohda, and T. Suzuki, “Improvement of image quality in CR mammography by detection of emissions from dual sides of an imaging plate,” Physics of Medical Imaging [Proc. SPIE 3977, 590-600 (2000)]
- 6 K. A. Fetterly and B. A. Schueler, “Performance evaluation of a computed radiography imaging device using a typical ‘front side’ and novel ‘dual side’ readout storage phosphors,” Medical Physics. 33 (2), February 2006
- 7 S. Rivetti, N. Lanconelli, R. Campanini, M. Bertolinin, G. Borasi, A. Nitrosi, C. Danielli, L. Angelini and S. Maggi, “Comparison of different commercial FFDM units by means of physical characterization and contrast-detail analysis,” Medical Physics. 33(11), November 2006
- 8 Fujifilm Computed Radiography Mammography Suite, “Non-Clinical Laboratory Studies/General Information and Device Description,” U.S Food and Drug Administration Pre-Market Approval Application P050014, Approved July 2006

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† 6,000 units worldwide as of 12/2008