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Agfa DR image quality and patient care

The impact of 30 years of experience in image processing and dose management

White paper

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Introduction

In recent years, several studies have been carried out to evaluate the effect of image processing on the visibility of important anatomical structures in X-ray images or, more generally, for quantifying diagnostic or clinical image quality.

While image quality undoubtedly depends on the clinical question, there are methods and objective criteria for standardizing and quantifying image quality to obtain a measure of quality and diagnostic confidence that a radiologist can expect when using digital X-ray systems. These are provided through the guidelines on quality criteria for diagnostic radiographs in adult[1] and pediatrics[2] published by the Commission of the European Communities (CEC).

Agfa has a long-term history as well as worldwide leadership in X-ray image processing. It was therefore considered appropriate to carry out a study on a larger clinical scale in order to obtain reliable clinical data and to re-confirm and quantify real-world image quality.

The study was organized by Agfa's headquarters; it involved five individual hospitals in Germany, six independent readers (radiologists), and data collected over more than two years. All relevant body parts and exam types, both for adult and pediatric X-ray imaging, were included.

The study covered the complete range of standard DR systems: from full-sized, ceiling mounted systems; to floor mounted systems; to DR retrofit setups. In addition, it provided for the first time detailed information on clinical dose levels applied with digital X-ray detectors.

Study facts & figures

- Data collected from 5 hospitals in Germany
- 6 readers for Visual Grading Analysis
- Image criteria from CEC guidelines or literature
- 151 images read, for a total of 856 scores
- Statistical sample size calculation and result analysis
- Additional survey questions

The following white paper highlights and illustrates the methods and most relevant outcomes of this study.

Study scope and design

As a basis of the study, an absolute Visual Grading Analysis (VGA) on a continuous scale from 0 to 5 was used to judge the image quality of defined anatomical structures and key features. Clinical images were randomly collected from five sites, including Agfa DR 400 and DR 600 systems with CsI-based DR detectors. The images were anonymized and pooled for reading by six qualified radiologists.

The mid-point of the VGA scale (2.5) was equalized to represent 'diagnostic image quality'; a VGA score (VGAS) above 2.5 thus represents 'diagnostic quality' in this study [3]. Per body part or exam type (excepting lumbar spine), 16 images were randomly sampled prior to the readings. For lumbar spine, 26 images were used. From every site, the same number of images were used. The figures regarding appropriate sample sizes were based on a statistical power calculation with a limited dry run upfront to serve as input on effect sizes and confidence levels. The study aimed for 80% statistical power and 95% confidence.

Body parts and exam types

Projection radiography (adult)
- Chest PA/AP and LAT
- Lumbar spine AP/PA and LAT
- Pelvis AP
- Knee AP

Projection radiography (pediatric)
- Chest PA/AP (children)
- Pelvis AP (infants and older children > 12 years)

Per exam type and patient group (adult and pediatric), the following were included in the study:
- MUSICA-processed images with Agfa CsI-based DR panels
- pathologies or clinical indications (high-level description) in more than 30% of the cases
- implants (where applicable)

Chest and lumbar spine were handled as paired images (same patient).

The anatomical structures and image criteria were taken from the CEC guidelines[1][2] (all body parts except knee) or literature (knee)[3]. The criteria were furthermore confirmed by clinical experts. Purely radiographic criteria (for example, positioning) were excluded.

As complementary information, dose and exposure index (EI) were recorded and extracted from the DICOM headers of the individual images.

A continuous 5-point scale was used for evaluating each criterion:

- left edge = criterion definitely not fulfilled
- middle = indecisive
- right edge = criterion definitely fulfilled

In addition, checkboxes for the following options were included:

- approved for diagnosis
- limited, but still acceptable
- not approved
- adipositas (yes/no)

A total VGAS per body part or exam type was calculated following reference[3] from all readers and scores.

To evaluate intra-reader reliability, 26 additional, mixed images from the original data pool were also read.

Six experienced radiologists from the different sites scored the datasets on the continuous scale defined above, in a controlled environment, using standard diagnostic monitors and reading stations.

All data used in the study originated from quality-controlled DR equipment complying with the German DIN standard 6868-150 (acceptance and periodic quality control) and set up according to the Agfa service standards.

Results: Image quality (adult and pediatric)

Approval of images

The results did not contain a single score representing 'not approved' status. From the 856 total scores given, 19 (2.2%) were scored as 'limited but still diagnostically acceptable'. The 'limited' scores were mainly given for spine and pelvis exams. 14 individual scores were missing (1.6%).

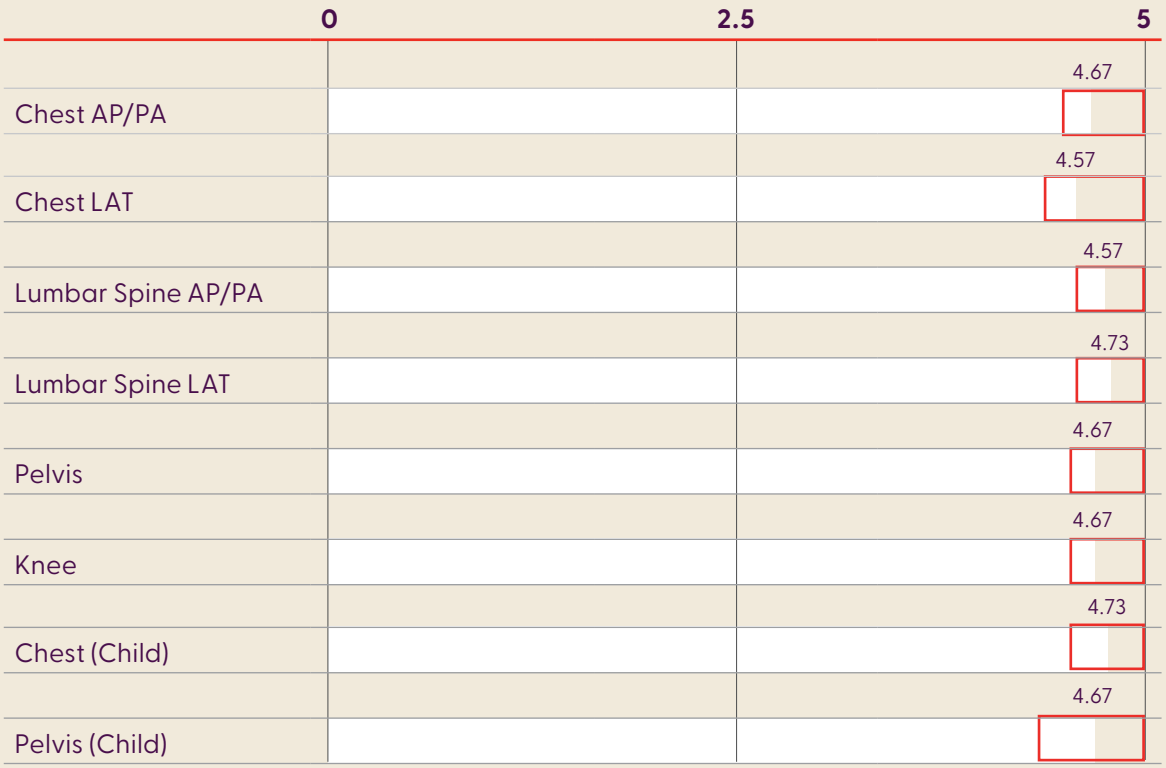
Visual Grading Analysis

From the total of 856 scores, 2 individual VGA image scores ranked below 2.5, from one reader on Chest PA/AP (2.43 and 2.39): no reasons were provided for these scores.

The statistical analysis shows that all of the radiographic images (represented by VGAS) are above the acceptance criteria score of 2.5 (mid-point of scale), and are therefore of diagnostic quality.

The following plot shows the summary results, including statistical confidence intervals:

VGAS (adult and pediatric imaging) on a scale from 0 to 5



White frame = VGAS, red frame = VGAS 95% confidence interval

The numerical results (VGAS) show a consistently close-to-optimal clinical confidence (5 equals maximum confidence) across all exam types and body parts. The statistical results indicate that diagnostic image quality is proven with 80% power and a 95% confidence interval.

With a 95% confidence interval, the inter-reader reliability is considered poor. However, the applied ICC2 standard scale is extremely sensitive with respect to variations of reader scores on the applied 0 to 5 continuous scale. One reader in particular delivered lower scores than the other five readers. The label 'poor' should therefore be considered as statistically understating the real reliability of the clinical readers.

The most likely explanation for the lower scoring by the one reader is their unfamiliarity with the look *&* feel of the MUSICA image processing. The other readers are all frequent users of MUSICA 3 and Agfa equipment.

With a 95% confidence interval, the intra-reader reliability (ICC3 standard scale) is moderate for all body parts. The less favorable 95% confidence interval of an intra-reader reliability between 'poor' and 'moderate' for body part Spine AP/PA might be attributed to the larger variation in generic image quality for that exam type.

28 pathologies (high-level) were reported and documented from a total of 109 patients (25.6%). Approximately 55% of the patients (all adult) were indicated with 'adipositas' (in reference to the X-ray images). Implants mainly appeared in pelvis and knee exams.

Additional survey

On a scale of 1 to 5, for questions regarding the absence of artefacts and conclusions on overall diagnostic image quality and confidence, all reader scores were equal to 5 (full agreement with the statement).

Results: Dose, DRLs and EI

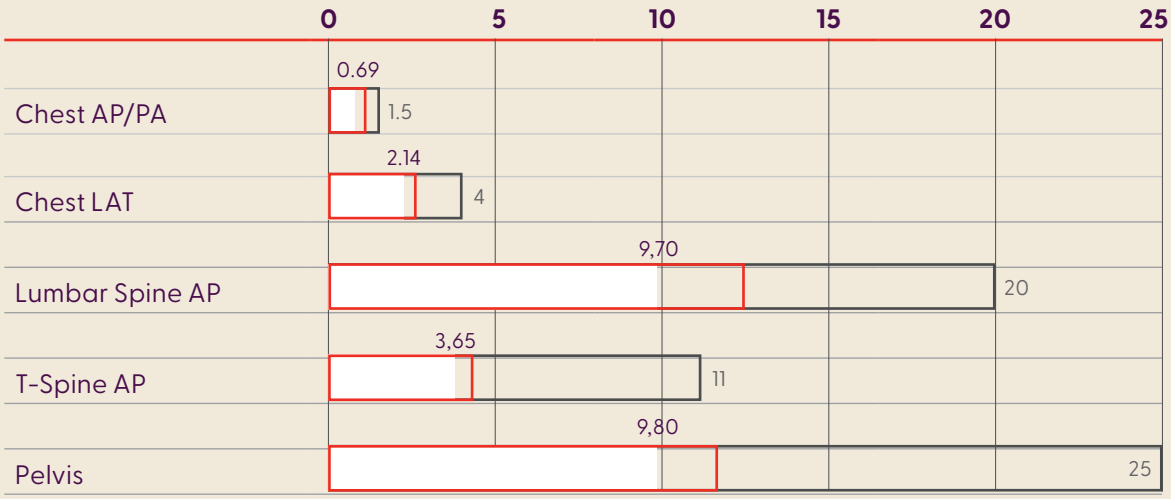
Complementary dose monitoring data were obtained for a similar list of body parts and exam types, from the same five hospital sites engaged in image collection.

Dose Reference Levels (DRLs)

In total, 200 entries per site were collected and merged into one data set. A one-tailed Wilcoxon signed-rank test was performed on each data subset. Dose reference levels (DRLs) were calculated and compared to national DRLs (NDRLs), using the German NDRLs as reference[4].

The following plot shows the corresponding results, including statistical confidence intervals:

Summarized DRLs relative to the NDRLs (Germany, right side)



White frame = DRL, red frame = DRL 95% confidence interval, all numbers in [dGy*cm²]

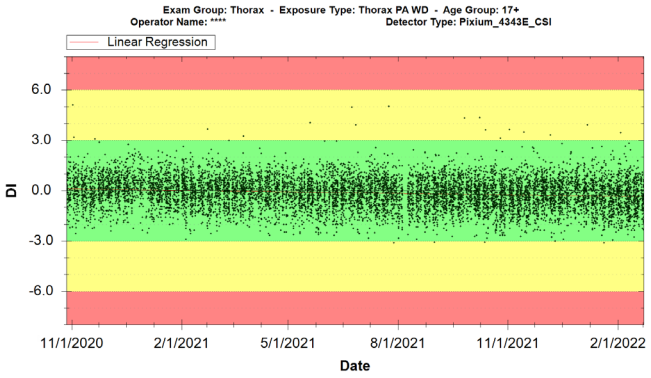
In all cases, the acceptance criteria (DRLs) were met. All DRLs recorded from the field were significantly lower than the NDRLs. In fact, for the equipment involved in the study, doses used were approximately half of the NDRL dose levels.

Exposure Index (EI)

Image quality is the result of a number of elements, including detector performance, image processing, radiographer skill level, etc. Besides the radiographer's skills, it is key to have a system that can perform consistently in real-world situations. The reality for radiology is that patients are quite different, which impacts the potential dose and thus creates a spread in the doses applied to the detector.

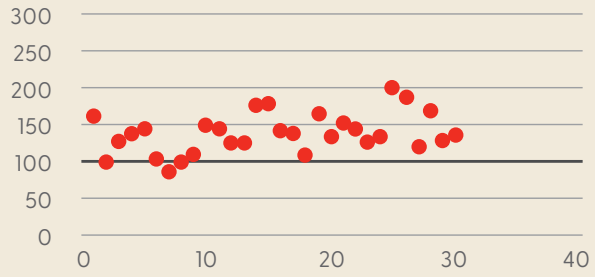
Even with good performance by the radiographers, there is still a deviation of a factor of +/- 2 on the detector dose to target for. That can be easily traced by monitoring the Deviation Index (as part of IEC 62494-1 on Exposure Index).

This graphic shows the Chest PA/AP exposures carried out with 1-point technique using AEC and a Target Exposure Index of 150:

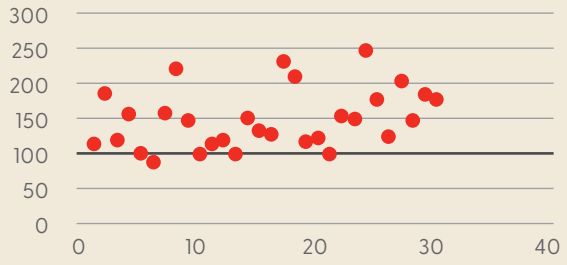


The plots below provide two examples of Exposure Indices from the study (Chest PA/AP exams):

EL SITE 1



EL SITE 2



Exposure indices for Chest PA/AP exposures taken from two of the test sites (an EI of 100 indicates a detector dose of 1 µGy).

It is paramount to try to use the lowest dose possible that enables diagnostic image quality. The required dose level is based firstly on the sensitivity of the detector, to ensure that the body part to be diagnosed is fully within the range of the panel's detectability (i.e., skin line to the thickest bone).

Secondly, but just as important, the dose level must result in an image quality that is sufficient to enable diagnosis: proper noise level, resolution and low contrast visibility in all zones of the body part.

In this respect, the study proved that the Agfa technology – DR panel and MUSICA image processing – performs at a very high level. Image quality is rated very high, even, as stated in the previous chapter, at a very low dose level (much lower than the NDRLs).

This is thanks to the technology and the unique strength of the MUSICA algorithm. Every image is analyzed; based upon the real content, processing parameters are automatically optimized for that particular image. By avoiding the use of default parameters that must serve the full range of variations in an exposure type, an image can be better optimized regardless of variations, which are always present.

How low one can go with the target, is determined as well by the minimal dose needed to achieve diagnostic image quality. Besides the sensitivity of the detector, this is largely determined by the performance of the image processing. MUSICA makes a very low target feasible, while avoiding unnecessary retakes due to suboptimal or insufficient image quality.

The study shows that individual images with a dose level that compares with a system speed-class of up to 1000 (equals a detector dose of 1 µGy) are still evaluated as diagnostic.

Further discussion

The quality of the MUSICA3 images used in this study ranges between the older MUSICA2 version and the newer, optimized MUSICA3+ packages for skeleton, chest and abdomen. They thus represent Agfa's standard image quality level. The same holds true for the comparably low 2.5 µGy AEC cut-off dose used for the systems' CsI DR detector technology.

Since image quality is primarily defined by radiographic technique, DR panel and image processing, these results are representative for all DR devices in Agfa's portfolio, except mobile and dynamic imaging. GOS panels exhibit the same image quality at a 30% higher dose level.

This study did not use data from different geographical regions within Europe or from outside Europe. As the study design was based on European guidelines for image criteria, and the system configuration (AEC cut-off dose) is pre-defined and configured by Agfa service personnel, the outcome can be considered as representative for all countries and regions, in Europe and worldwide.

Conclusions

The results of this large-scale study on Agfa's image quality and the associated dose levels impressively demonstrate the optimal level of clinical image quality that a standard X-ray technology can achieve. To reach close-to-maximum image quality and diagnostic confidence, only half of the dose prescribed by Germany's NDRLs is required.

Moreover, the study (re-)confirms with high statistical confidence (95% confidence level, 80% power) the diagnostic usability and quality of images created by Agfa DR systems using MUSICA and CsI DR detector technology.

For dose, in exposure techniques where AEC cannot be used, the unique strength of the MUSICA image processing proves its value. By nature, 2-point-techniques (without AEC) yield even more spread. A system that can deal with such a wide dose spread on the DR detector, while still providing good image quality, is key to enable fewer retakes, faster diagnosis and lower patient dose. In essence, better patient care.

The conclusions of the study can be summarized as follows:

Study conclusions

- Optimal image quality and highest diagnostic confidence at half the prescribed dose (NDRLs)
- Consistent high image quality, including difficult body parts and adipositas patients (with high amount of scatter)
- Acceptable image quality on individual images done with a dose as low as speed-class 1000 (1 µGy detector dose)

The striking outcomes of this study are the result of an in-depth understanding of imaging technology and image processing techniques, paired with close follow-up of new and long-standing Agfa customers over the past three decades.

References

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