Innova X-ray Dose Efficiency: Objective Evidence and Rationale

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ABSTRACT
This document presents objective scientific evidences for the fluoroscopic x-ray dose (from here on a.k.a. dose) efficiency advantages of GE Healthcare’s Innova and Image Guided System (IGS) products by an extensive literature review. The review includes the importance of dose minimization and related factors, desirable characteristics of objective scientific studies on dose utilization, summary of relevant objective evidence for patient dose utilization by manufacturer, and the rationale for better dose performance of Innova systems. In analyzing these studies it was considered that some systems operated with image intensifiers (II) and others with flat panel detectors (FPD), therefore several studies were assessed to review the validity of including this data, the results showed that IIs could be compared on a similar dose/image quality basis with FPDs. Additionally, phantom studies were analyzed as an adjunct to patient studies. The DAP (alternately KAP) values, where reported, compared quite favorably to current and proposed reference standards for procedural doses. It is important to note that many factors affect the total exam doses able to be achieved by a clinician during a patient exam. Variation is expected due to user preferences, facility practices, patient population and other factors.

As a conclusion, data analysis in 4 out of the 5 studies reviewed indicates clinicians using one or more GE Innova systems achieved lower patient case doses than they or their peer groups achieved using other manufacturers’ equipment. Also, the DAP (alternately KAP) values, where reported, compared quite favorably to current and proposed reference standards for procedural doses performed on Innova systems. In analyzing potential reasons for these results, it has been shown that GE Innova systems may have quantifiable advantages in detector DQE. Additionally, other factors in the Innova design such as: automatic exposure regulation, flexibility in dose settings, ease/automation of procedure protocol selection, dose monitoring, dose reporting and other special features play a pivotal role in the clinicians ability to optimize the dose to the clinical task and patient at hand, potentially contributing to the favorable Innova performance in the cases presented.
Radiation risks are usually categorized as stochastic versus deterministic (non-stochastic). Stochastic risk is generally associated with an assessment of the increase in likelihood of the occurrence of cancers resulting from exposure to radiation. For any procedure involving the use of x-rays, the potential benefits of the procedure must be weighed against the stochastic risk. For interventional procedures, the risk/benefit balance is different from screening procedures, because the patient is known to have a serious medical condition that will very likely benefit from treatment. As an example, (Lickfett 2004) have reported that the estimated additional lifetime risk for a fatal malignancy associated with performing an ablation procedure for atrial fibrillation was 0.15% for female patients and 0.21% for male patients in their study. The average age of the patients in the study was 56 +/- 11 (39-78). This modest risk is judged acceptable against the risks of not performing the procedure, which include the possibility of stroke, complications of decreased heart function, and decreased quality of life.

Pediatric interventions are an important case of stochastic risk, since the likelihood of cancer expression may increase with lifetime following exposure, and the young are generally considered more sensitive to radiation exposure. Stochastic risk is also an important consideration for the physicians and staff working within the procedure room on a regular basis. Occupational x-ray exposure limits, shielding and monitoring systems have been put in place to address this issue.

The main radiation concern for patients in interventional procedures is usually deterministic risk, which is the tissue damage that will occur if radiation exposure exceeds certain thresholds. The tissue at greatest risk is usually the skin at the entrance location of the incident x-ray beam, where the intensity is greatest. Table 1 provides a list of the deterministic skin injuries that can be caused by the amounts of radiation used in interventional procedures, and the entrance skin dose (ESD) thresholds at which they can be expected to occur. In the US, the Joint Commission (TJC), formerly the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), has set a level of 15 Gy exposure to a single area of skin as a threshold of a sentinel event. (A sentinel event is defined as an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.) To retain TJC accreditation, a medical facility must respond to the occurrence of a Sentinel event with a thorough investigation and implementation of an effective remediation plan, including ongoing monitoring.

Table 1: Deterministic radiation risks, threshold doses and times of onset.

<table>
<thead>
<tr>
<th>Effect</th>
<th>Approximate Threshold Dose (Gy)</th>
<th>Time of onset</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early transient erythema</td>
<td>2</td>
<td>2-24 hours</td>
</tr>
<tr>
<td>Temporary epilation</td>
<td>3</td>
<td>~3 weeks</td>
</tr>
<tr>
<td>Main erythema reaction</td>
<td>6</td>
<td>~1.5 weeks</td>
</tr>
<tr>
<td>Permanent epilation</td>
<td>7</td>
<td>~3 weeks</td>
</tr>
<tr>
<td>Moist desquamation</td>
<td>18</td>
<td>~4 weeks</td>
</tr>
<tr>
<td>Secondary Ulceration</td>
<td>24</td>
<td>&gt;6 weeks</td>
</tr>
</tbody>
</table>

Although the occurrence rate of reported deterministic radiation injuries is low, it is not zero, and the reported data on total case doses in various interventional procedures show that there is significant variation in total dose (ICRP Report 168). This is likely due to a combination of factors including patient obesity, duration of the procedure, imaging equipment performance and operator skill. In some of the more involved procedures, typical case doses may not be far below the threshold at which deterministic effects can be expected to occur. This is particularly evident in those procedures where the x-ray viewing angle is not varied significantly during the procedure, as seen with neuro-radiologic and cardiac electrophysiologic interventions. A study of patients undergoing RF ablation procedures demonstrated that, even with careful attention to radiation exposure, including use of low-dose fluoroscopy techniques, the maximum skin doses accurately measured on a cohort of 15 patients was 1.48 ± 0.37 (0.8 – 2.05) Gy versus a threshold of 2.0 Gy for deterministic skin injuries (Lickfett et al 2004). (Data are given as mean ± standard deviation (min – max)). The weights and body mass indexes (BMI) of the patients were 82 ± 12 (64-108) kg and 26 +/- 2 (23-32) respectively, which does not indicate a bias toward obesity in this patient population. So it is not difficult to imagine how factors including case difficulty and patient obesity could enhance the overall risks of such effects.

The presence of deterministic risks and the increased awareness of potential stochastic risks have driven dose minimization efforts, summarized in the ALARA (As Low As Reasonably Achievable) principle, widely accepted in all fields of radiation protection. A key premise is that the physician is in charge of balancing all the risks to the patient, including both that from radiation and that of not performing the procedure or aborting it.

To effectively balance the risks, the physician must be aware of radiation risks, how to control the radiation levels of the equipment, and have feedback from the x-ray system about dose rates and cumulative case doses while performing a procedure. The last of these is particularly important, since interventional procedures are open-ended, unlike a diagnostic imaging procedure with a specified set of views. A clinician may need to perform many angiographic imaging series to assess the progress of a multi-lesion angioplasty/stenting intervention, for example. Similarly, fluoroscopic imaging time can be quite variable and long, depending on case difficulty and the number of procedure steps. Thus, even though national regulatory agencies have set upper limits on patient entrance dose rates in fluoroscopy, for example, 88 milliGy/min in the US, skin injuries can still occur due to long fluoroscopic procedure times in complex procedures lasting hours.

Equipment manufacturers have a role in helping to achieve ALARA. This includes optimizing the dose efficiency of their imaging systems, providing flexible settings in imaging modes so dose (and consequently image quality) can be adjusted to meet clinical imaging needs, providing patient case dose data for the physician during procedures, and meeting regulatory requirements. These aspects will be discussed in more detail in a later section.

Regulatory agencies and professional organizations play an important role in managing radiation exposure by setting standards for x-ray system performance, generating guidelines for training and equipment usage and periodically verifying compliance with occupational exposure limits and with other regulations.
DESIRABLE CHARACTERISTICS OF OBJECTIVE SCIENTIFIC STUDIES ON DOSE UTILIZATION

In evaluating any scientific study of a complex subject, it is important to assess the clarity of the objectives and metrics, the methods for managing confounding factors, and the strength of the objective evidence to support the conclusions. In the case of studies of patient dose in interventional x-ray procedures, these considerations may be summarized as follows:

**Clinically relevant objectives and metrics:** It is clear that, particularly for physicians, patient case doses for common interventional procedures under real-life conditions provide the most compelling evidence. Staff doses are also of interest. Phantom doses and image quality metrics provide supporting data, but are generally not considered definitive evidence. And in considering the results of phantom studies, it is important to judge whether the characteristics of the phantom(s), e.g., range of attenuation given by thickness of acrylic, are similar to those of patients in commonly performed procedures. It is also important to consider whether the critical settings, e.g., dose rate, frame rate, field of view, collimation, and patient-receptor distance are those commonly used by clinicians in performing interventional procedures on a given system.

**Methods and Controls:** Studies must be scientific, evidence-based, and preferably peer-reviewed. Given all the sources of variability in interventional procedures, adequate controls for a number of factors should be in place, including, but not necessarily limited to the following: typical patient populations, matched patient populations (e.g., height, weight/BMI), well-defined type of interventional procedure, adequate number of cases for meaningful statistics, typical ranges of case type and difficulty (e.g., single lesion, multiple lesions), physician/staff skill, and practice habits.

**Minimization of Bias:** Ideally, studies should be free of potential conflicts of interest. In this regard, more weight should be given to studies performed by independent clinicians and/or medical physicists, particularly if their primary objective was not to compare the performance of individual manufacturers’ systems.

**Weighing all the evidence:** In evaluating multiple studies on a subject, fairness demands that all the relevant data be weighed, and summary judgment be balanced by an assessment of the quality and constraints of each study. Physicians are quite familiar with the ambiguities that often arise in clinical studies and have learned to deal with them.

In light of the previous discussion, it is fair to say that the ideal study comparing the dose performance of different manufacturers’ systems to the satisfaction of all interested parties has not yet been performed, and probably never will be. However, a number of studies have been performed which do in fact meet many of the criteria described above, thereby providing valuable insights into the comparative dose performance of various equipment manufacturers.

**SUMMARY OF RELEVANT OBJECTIVE EVIDENCE FOR PATIENT DOSE MINIMIZATION.**

The following studies were identified in scientific literature searches performed up to the time of this writing. No filtering was performed to remove results unfavorable to the GE Innova and IGS products. The results are organized in three categories: patient dose studies (the most relevant), impact of digital detectors (relevant to understanding patient and test phantom dose studies), and test phantom dose studies (supporting data).

Patient Dose Studies:

- **Zontar 2009:** The authors are medical physicists who reported on “a country-wide study to determine patient exposure from interventional cardiology procedures”. They chose “five cardiology rooms in four public hospitals” that had modern interventional x-ray systems: Siemens Axiom Artis FC (II), Siemens Coroscop (II), GE Innova 2100 (FP), Philips Allura XPER FD20 (FP), and Philips Allura XPER FD10 (FP). (II = image intensifier, FP = flat panel detector) They deliberately blinded the results by manufacturer by reporting results by room number rather than system type. Only by recognizing that the image receptor field of view sizes are unique to each image detector is it possible to sort the data out by manufacturer in Tables 1 and 2 of the study. This was confirmed through correspondence with a contributing author. The following is a restatement of the data from Table 4, for PTCA procedures, with system identification added.

```
<table>
<thead>
<tr>
<th>System</th>
<th>Room</th>
<th>Patients</th>
<th>FL Time 3rd Q (min)</th>
<th>No. Frames 3rd Q</th>
<th>KAP avg (Gy•cm²)</th>
<th>KAP 3rd Q (Gy•cm²)</th>
<th>CDirp 3rd Q (Gy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GE Innova 2100</td>
<td>2</td>
<td>97</td>
<td>14.1</td>
<td>1139</td>
<td>43.0</td>
<td>46.7</td>
<td>0.8</td>
</tr>
<tr>
<td>Siemens Coroscop</td>
<td>1</td>
<td>64</td>
<td>12.1</td>
<td>n/a</td>
<td>92.7</td>
<td>117.8</td>
<td>n/a</td>
</tr>
<tr>
<td>Siemens Artis FC</td>
<td>3</td>
<td>225</td>
<td>10.6</td>
<td>n/a</td>
<td>54.3</td>
<td>67.7</td>
<td>n/a</td>
</tr>
<tr>
<td>Philips FD 20</td>
<td>4</td>
<td>37</td>
<td>11.8</td>
<td>1042</td>
<td>66.4</td>
<td>84.2</td>
<td>1.37</td>
</tr>
<tr>
<td>Philips FD 10</td>
<td>5</td>
<td>21</td>
<td>11.0</td>
<td>720</td>
<td>55.8</td>
<td>61.3</td>
<td>1.04</td>
</tr>
</tbody>
</table>
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Note: The GE Innova 2100 is legally marketed under the brand name Innova 2100-IQ.

Note that the patient doses included in this study, both skin dose at the interventional reference point (CDirp) and Kerma-Area Product (KAP), where available, are lowest for the Innova 2100 system, even though the third quartile fluoro time and number of frames are slightly higher. Specifically, for the cases reported in this study the clinicians using the Innova 2100 achieved exam doses in the range of 20 to 60% lower than the clinicians using Siemens systems, and 22 to 44% lower than the clinicians using Philips systems. Note also that the number of patients in each group is quite large, suggesting fairly robust statistical significance. Similar results were reported for diagnostic-only coronary procedures. The authors also measured doses using a standard 20 cm thick water phantom. At the protocols selected in these phantom measurements the Innova 2100 had the lowest reported doses in 11 out of 12 measurements performed.

It is also of interest to compare the results from the Innova 2100 to reference doses which have been established by various medical physics and regulatory groups. The 3rd Quartile (75%) KAP (also known as DAP) for the GE Innova was 47.9 Gy•cm², which compares quite favorably to the following:

**Recommended or Mandatory Reference Levels for IC procedures (DAP 75% percentile in Gy•cm² units):**

- **UK reference levels:** Hart et al 2010/2012 40 (PTCA single stent)
- **German regulation:** Nobke 2010 60 (PTCA)
- **USA Initial Reference Values:** Miller et al 2012 199 (PCI+diagnostic)
• Zontar 2010: This study, published in the peer-reviewed journal Radiation Protection Dosimetry, conducted by four of the five authors of the 2009 study above, extends the previous work and provides more data on the skin dose (CDirp) results from the three procedure sites that provided them; the ones using the GE Innova 2100, the Philips Allura XPER FD20 and Philips Allura XPER FD10. As in the 2009 study, the results are blinded by manufacturer. However, by comparing the phantom data in Table 1 of this study to the identical data in Table 1 of the 2009 study, it can be seen that Room 1 is the GE Innova 2100, Room 2 the Philips FD10, and Room 3 the Philips FD20. Figure 1 in the 2010 study presents the entire histogram of procedure doses by room/system. It is evident that the patient dose histogram for each system shows roughly the same shape, with a cluster about the mean but a long tail out to considerably higher doses, which is typical for interventional procedures with a range of complexity and patient size. However, the histogram data for the Innova 2100 are shifted toward the left, toward lower doses. Analyzing the data in Figure 1, the median dose achieved by the clinicians using the Innova 2100 was 0.58 Gy, 23% lower than the Philips FD10, and 34% lower than the Philips FD20. The corresponding third quartile dose for the Innova 2100 was 0.94 Gy. Using the authors’ average conversion factor for CD\textsubscript{IRP} to KAP (ESD to DAP) of 17 +/-2 mGy/Gy\textsuperscript{2} cm\textsuperscript{2} yields an estimated third quartile DAP of 49.4 Gy\textsuperscript{2} cm\textsuperscript{2}, which also compares favorably with the above Recommended/Mandatory reference dose levels for IC procedures.

• Kien 2011: The purpose of this peer-reviewed multicenter study, conducted by medical physicists claiming no conflicts of interest, was to determine the doses received by patients during interventional neuroradiology procedures with the goal of establishing reference standards. Comparing the performance of different manufacturers’ systems was of interest only in assessing overall variability in procedure doses and in having a large database, which covered nine neuroradiology departments, fifteen x-ray systems and contained over 4600 procedures, divided into seven categories: three diagnostic and four interventional. The authors measured case dose as dose area product (DAP), total fluoroscopic time and total number of images acquired. Among the findings was that the group of clinicians using a GE Innova 2121 biplane and an older GE Advantx biplane had lower patient doses for diagnostic and interventional neuro procedures than eight other peer groups using a mix of Philips II, Philips DFP, Siemens DFP systems and a GE Advantx single plane system, despite similar fluoroscopy times and numbers of recorded images (for diagnostic studies). For interventional studies, the number of recorded images was the lowest for the group using the GE Innova + GE Advantx. Specifically, using the dose data presented in Table 3 of the study, the average patient dose (DAP) for aneurysm embolization procedures performed in the site with the two GE systems was 65% lower than the average of all the systems (85 vs. 241 Gy\textsuperscript{2} cm\textsuperscript{2}), 63% lower than the average of sites using only Siemens equipment (85 vs. 233 Gy\textsuperscript{2} cm\textsuperscript{2}), and 68% lower than the average of sites using only Philips equipment (85 vs. 266 Gy\textsuperscript{2} cm\textsuperscript{2}). The results for diagnostic cerebral angiography average patient doses were similar, with clinicians achieving patient doses 34 to 61% lower on the Innova systems as compared to the other groupings of systems. For example, compared to the average of all systems, the mean DAP in the site with the two GE systems was 56% lower (57 vs. 129 Gy\textsuperscript{2} cm\textsuperscript{2}) than the average of all the systems. It is possible to draw some comparisons with proposed patient dose reference levels for two procedures, diagnostic cerebral angiography, and cerebral aneurysm embolization, based on the data provided. Reference levels are typically stated at the 75%ile level, whereas data for the systems is provided at the 50%ile level. However, combined data covering all systems are provided at both the 50 and 75%ile levels, which allows an estimation of the ratio of the two levels, which can then be applied to the GE system-specific data. Doing this gives a 75%ile estimate of 76 Gy\textsuperscript{2} cm\textsuperscript{2} for diagnostic cerebral angiography in the site with the two GE systems, which can be compared with proposed reference values reported by the author (Table 5) which range from 75 to 230 Gy\textsuperscript{2} cm\textsuperscript{2}, the latter value being proposed by the author. In the case of aneurysm embolization, the values are 107 Gy\textsuperscript{2} cm\textsuperscript{2} versus a range of 338 to 360 Gy\textsuperscript{2} cm\textsuperscript{2}, with 350 Gy\textsuperscript{2} cm\textsuperscript{2} being proposed by the author. So the values for the site with two GE systems fall at or significantly below the reference values being proposed.

• Jensen 2011: This peer-reviewed study compared the performance of a GE Innova 4100 and a Siemens Multistar (III) in cardiovascular interventional procedures. Patient doses as measured by both dose-area product (DAP) and entrance surface dose (ESD) were significantly lower with the GE Innova 4100, particularly in dense anatomy, even though there was no significant difference in patient weights and fluoroscopy times, and case types were essentially the same. Specifically, the mean DAP over all procedures was 24 Gy\textsuperscript{2} cm\textsuperscript{2} for the Innova, versus 49 Gy\textsuperscript{2} cm\textsuperscript{2} for the Siemens Multistar. The corresponding comparison of ESD was 167 versus 368 mGy. Broken down by individual procedure type, which included PTA lower extremities, PTA/stenting pelvis, Nephroscopy and varicocele, the differential achieved by the Innova users ranged from 31 to 70% less for mean DAP, and from 33 to 60% less for mean ESD.

• Trianni 2005: This peer-reviewed study compared the performance of a GE Innova 2000 and a Philips Integris 3000 (III) in coronary angiography and PTCA procedures. Although phantom entrance doses were comparable in fluoro and lower in digital cine mode on the GE Innova 2000, mean diagnostic patient case doses were slightly lower for the Philips system although not significantly different (GE: 33.4+/-19.2 vs. Philips: 31.2+/-30.2 Gy\textsuperscript{2} cm\textsuperscript{2}, GE 7% higher), and interventional patient case doses on the Innova were higher (GE: 66.9+54.4 vs. Philips: 52.1+/-45.0 Gy\textsuperscript{2} cm\textsuperscript{2}, GE 29% higher). Fluoro times were not significantly different. It should be noted that the Innova 2000 was GE’s first generation flat panel detector product (the first of any manufacturer), and was subsequently replaced in 2006 by the second-generation Innova 2100, which has several dose efficiency improvements over the Innova 2000, that will be described in more detail below.

Summary:
The data reported in four out of the five independent studies described above indicates that clinicians using one or more GE Innova systems achieved lower patient case doses than they or peer groups achieved using other manufacturers’ equipment. Over 7000 procedures are represented in these five studies, covering coronary angiography, PTA, cerebral angiography, embolization of cerebral aneurysms, arterio-venous malformations and fistulas, vertebroplasty, PTA with or without stenting in the pelvis and lower extremities, nephroscopy and varicocele. It is important to note that many factors affect the total exam doses able to be achieved by a clinician during a patient exam. Variation is expected due to user preferences, facility practices, patient population and other factors. However, given the number of studies and breadth of the data reported (including number of different sites/users & patient population groups) the data supports the summary statements above. And although it may be argued that the image intensifier (II)-based systems being compared to may not be as dose efficient as their more modern flat-panel (FP) counterparts, evidence was not found indicating such claims are being made by the other manufacturers represented regarding increased dose efficiency due to the replacement of their image intensifiers with flat panel detectors. To support this, the following two studies were evaluated and found to report the contrary: an increase in patient doses in transitioning from II to FP in some cases.
Impact of Digital Flat Panel Detectors:

- **Prieto 2010:** The authors analyzed the patient doses, fluoro times and number of recorded images in coronary angiography (CA) and PTCA procedures in two Siemens II-based labs that were upgraded with FP detectors. Data from 698 CA and 376 PTCA procedures were acquired in the II phase, and 342 CA and 709 PTCA procedures in the FP phase. They found statistically significant increases in patient DAP in both diagnostic CA (median dose +32%) and interventional PTCA (median dose +57%) procedures following the change from II to FP, without significant changes in fluoro time or number of recorded images.

- **Prasan 2008:** The authors analyzed the patient doses, patient demographics, fluoro times, number of recorded images, and contrast volumes used in PTCA procedures in a Toshiba II-based lab that was upgraded to FP. Data from 69 PTCA procedures were acquired in the II phase, and 68 PTCA in the FP phase. They found a significant increase in mean patient DAP after upgrading to the FP (99.129 vs 71.77 Gy•cm²), with no significant change in fluoro screening time, number of exposures and total contrast volume. There was no significant difference in patient weight or age between the two groups. Image quality measurements were better on the DFP system.

**Summary:**

Data from manufacturers other than GE or other sources was not found to support improvements in dose efficiency in migrating from II-based to FP-based imaging systems. In fact, there is some evidence to the contrary. Based on the data analyzed and published by manufacturers, it can be deduced that replacing an II with a Trixel-manufactured FP detector (used by both Siemens and Philips) or Varian-manufactured FP detector (used by Toshiba), does not bring apparent advantages in dose efficiency. Considering these results, it is fair to include patient dose data from modern II-based systems in comparison studies, as was done above in the Patient Dose Studies.

**Patient Dose Reports on Specific Product Features:**

- **Soderman Jan 2012 & Soderman June 2012:** The authors, from Karolinska University Hospital in Stockholm, Sweden and Philips Medical, report on the reduction in patient exposure from the DSA (Digital Subtraction Angiography) portion of the x-ray imaging performed in the course of biplane cerebral angiography procedures, with and without a set of improvements made to the DSA imaging mode by Philips. As a baseline, they determined that the DSA portion of conventional cerebral neuroangiography procedures at their institution comprised 80% of the total patient exposure, on average. (The remaining exposure is 19% fluoroscopy and 1% rotational angiography.) The DSA improvements resulted in an average reduction of 73% in the DSA dose, which would translate to a 58% reduction in the total patient dose, assuming that the fluoro and rotational angiography portions of the procedures were unaffected. According to the authors, this dose reduction was achieved without degrading the qualitative clinical image quality of the DSA images. The improvements to the DSA mode were increased x-ray spectral beam filtration, an auto-mask alignment function, a new ‘reconstruction’ algorithm, and noise reduction techniques. These results would seem to be beneficial for any user of a similar Philips system. But no conclusions can be drawn in comparison to other manufacturers’ systems, since no such data are presented, and each manufacturer has the ability to apply spectral filtration and image processing algorithms they have found appropriate. No information is given regarding the relative scientific advancement of different manufacturers in this regard. Second, the Karolinska group’s experience that 80% of exposure comes from the DSA imaging portions of the procedure may not align with other institutions’ experience. For example, there have been reports of some DSA series being supplanted by greater use of rotational angiography for its improved 3D visualization, with attendant reductions in overall patient dose. So individual group/site procedural preferences will impact the amount of total patient dose reduction to be expected from improvements in DSA function.

**Summary:**

Clinicians working with manufacturers occasionally report on dose reduction improvements at scientific meetings. Typically the abstracts are screened but the content is not peer-reviewed. Usually the comparisons are with respect to the current product offerings of the manufacturer and involve limited numbers of patients. So while they provide potentially useful information on the progress of an individual manufacturer, they may not provide inter-manufacturer comparisons in a rigorous scientific framework.

**Phantom Dose Studies:**

- **Chida 2009 and Inaba 2010:** The authors measured and compared entrance surface dose rates into a 20 cm thick acrylic block on 20 systems in 15 sites (Chida 2009) and 11 systems in 7 sites (Inaba 2010). It appears that many of the systems and data are common to the two studies. The systems tested included: GE Innova 2100 & Adventa, Toshiba DFP and II, Siemens II and DFP, Philips II and DFP and Shimadsu DFP. The authors used the same system settings typically used by operators performing PCI procedures at each site. The two GE Innova 2100’s had the lowest fluoro dose per pulse (frame dose) and dose rates tested (5.7 and 6.0 mGy/min at 15 f/s versus 6.5 mGy/min for the next higher measured system: Siemens Bicor operating at 7.5 f/s), the lowest digital cine dose per pulse tested (0.064 and 0.067 mGy/fr versus 0.089 mGy/fr for the next higher measured system: Siemens Axiom Artis), and the second-lowest digital cine dose rates tested. (A Siemens Axiom Artis had the lowest digital cine dose rate, however it was operating at 10 f/s, versus 15 f/s for the Innova 2100). All the data can be found in Tables 1 and 2 in Chida 2009 and Table 1 in Inaba 2010.

- **Padovani 2008:** This is another dose survey study of cardiac angiography imaging equipment. The authors measured phantom entrance surface air kerma (ESAK) and two image quality metrics on 13 different systems. Among these were a GE Innova 2000 and units manufactured by Philips and Siemens, some with II and others with FP detectors. The GE Innova 2000 fluoro and digital cine doses were among the lower values recorded for all systems (see Figures 1 and 2). However, one Philips-II and several Siemens systems, both II and DFP, demonstrated lower fluoro dose rates, and two Siemens systems, one II, one DFP, demonstrated lower digital cine dose/image. The Innova 2000 product has been superseded by the more dose efficient Innova 2100, as described below.

- **NHS Report (UK) 2010:** This is one in a series of reports from the Centre for Evidence-based Purchasing, part of the Policy and Innovation Directorate of the National Health Service Purchasing and Supply Agency of the UK. It is supported by the Department of Medical Engineering and Physics, King’s College Hospital, London. The objective of this report was the evaluation of cardiovascular x-ray imaging systems with flat panel detectors over a range of attributes including dose, image quality and usability. The systems evaluated are the GE Innova 2100, Philips Allura Xper FD10, Siemens Artis zee and Toshiba Infinix CC-i. Eight particular modes of operation were tested in the dose section along three axes: fluoro versus acquisition, 7.5 and 15 f/sec image acquisition rate, and coronary artery versus electrophysiology setting. The typical settings preferred by the operators at each site were used. All of
the systems tested were judged acceptable. No manufacturer was consistently better on dose performance. The Toshiba system had the lowest coronary acquisition dose rates (Figs. 4 & 5). Electrophysiology acquisition dose rates were roughly similar (Figs. 6 & 7), as were coronary fluoroscopy dose rates (Figs. 8 & 9). The GE Innova 2100 and Philips system had the lowest dose rates in EP fluoroscopy (Figs 10 & 11).

- **Belanger 2006:** This study, conducted by engineers and scientists at GE Healthcare, compared the performance of the GE Innova 2100 to the preceding product, the Innova 2000, and to a Siemens and a Philips digital flat panel cardiac interventional system. Two methods were used to measure dose and imaging performance. The first employed an industry standard test phantom (NEMA/SCAI). The second employed an anthropomorphic chest phantom equipped with a moving coronary artery stent to simulate the actual conditions of clinical use (MCAS). Skilled observers blinded to the identity of each image sequence evaluated them in randomized order for sensitivity on a Likert scale (0 = stent not visible, 1 = stent barely visible, 2 = stent plus hint of strut structure visible, 3 = stent and strut structure visible). The NEMA/SCAI phantom measurements showed the Innova 2100 to be better than or comparable to the Innova 2000 in all image quality measurements, and lower in phantom entrance dose in all cases. The NEMA/SCAI comparisons of the Innova 2100 to the Siemens and Philips systems were more mixed, but overall favorable to the Innova 2100. The Innova 2100 measured better or equal in Dynamic Range, Stationary Wire visibility, and Moving Wire visibility; and results on Lag, Iodine Disk visibility, Spatial Resolution limit and Dose were mixed. The tests performed with the moving coronary artery stent (MCAS) phantom showed that the Innova 2100 performed significantly better than the Philips system in fluoroscopy operating at the same dose (+0.5 on Likert scale, p =0.001) and in digital cine (+0.6 on Likert scale, p = 0.000) with the Innova 2100 operating at half the phantom entrance dose of the Philips unit. The performance advantage of the Innova 2100 over the Siemens unit was not as large in fluoro (+0.0 on Likert scale, p = .243) operating at the same dose, but was significant in digital cine (+0.7 on Likert scale, p = 0.000). The smaller difference in fluoro performance was attributed to the use of stronger temporal filtering on the Siemens unit (verified in part by testing higher temporal filtering on the Innova 2100).

**Summary:**

Innova system doses are among the lower values reported, although not the lowest in every case. When compared to other manufacturers’ units, the GE Innova 2100 demonstrates lower doses than the Innova 2000, which was superseded by the Innova 2100.

**RATIONALE FOR THE INNOVA SYSTEMS DOSE PERFORMANCE**

Practicing the ALARA principle in the midst of demanding clinical procedures can be challenging, particularly when the primary focus in any interventional procedure must be the condition of the patient and performing the percutaneous intervention with image guidance. Equipment manufacturers have responded to this need in different ways and to varying degrees.

From an equipment standpoint, we can summarize our key design objectives for dose efficiency in four principles.

1. Maximize the Imaging Dose Efficiency, so as to deliver the best clinical image quality possible for any dose level the clinician chooses to use.
2. Provide a range of dose/Image quality selections, so that the operator can select the appropriate level for the procedural task at hand.
3. Provide dose readout to the clinician, so he/she is aware of the rate at which dose is being delivered as well as the total dose for the study, and can therefore make informed decisions.
4. Automate the process of dose/IQ selection and adjustment as much as possible, so the clinician can focus on the patient and still operate in the spirit of ALARA.

Expanding on item 1, consider the x-ray system components that are critical for Imaging Dose Efficiency.

**X-Ray Tube:** Although it may at first appear to be counter-intuitive, a high power and high heat dissipation x-ray tube is preferred for dose minimization. This is due to two facts. First, x-ray production is inefficient; most of the applied energy, more than 99%, ends up as heat that must be dissipated. Second, the x-ray beam spectrum is broad, containing a wide range of x-ray photon energies that have different absorption characteristics when interacting with anatomy. The lower-energy, or “soft” x-rays are preferentially absorbed in the anatomy and few reach the detector to form a useful image. Therefore there is a dose advantage to filtering the x-ray beam with thin sheets of materials like copper to preferentially remove these “softer” or low-energy photons in favor of the higher energy x-rays. These filters are not sharply discriminating on the basis of photon energy, so some high energy photons are removed from the beam as well, lowering overall x-ray production efficiency. So x-ray tube power and heat dissipation capability are important. A 3000 watt continuous fluoro input power dissipation capability is reasonable for an interventional x-ray lab, based on clinical needs and current technological capabilities.

X-ray tubes will typically have two or three different focal spot sizes, which is usually achieved by having at least two different filaments, and sometimes by applying a bias voltage to the cathode cup to control the size of the electron distribution. A 0.3 mm focal spot size is typical for neuro and some pediatric applications, 0.5-0.6 mm for normal fluoroscopy and low-power record modes, and 0.8-1.0 mm for higher-power record modes, like digital cine and DSA (Digital Subtraction Angiography) in the adult thorax and abdomen. The value of having several focal spot sizes is to be able to balance spatial resolution loss due to focal spot size or penumbra, against having sufficient x-ray tube output to create an image with adequate x-ray photon statistics in a sufficiently short exposure time to avoid motion blurring.

Fluoroscopy can typically be performed on the adult thorax and abdomen using a 0.5-0.6mm focal spot, whereas digital cine or DSA in these body sections typically requires use of a 0.8-1.0mm focal spot, with attendant loss in spatial resolution, but overall gain in visibility due to significantly better photon statistics with the elevated dose/image. This example illustrates the importance of not confusing “spatial resolution limit” with “image resolution” in general. “Spatial resolution limit” is an imaging physics term that is defined as the finest periodic grating of lead bars that can be visualized in an image. “Image resolution” is a less-scientific term used by clinicians to describe their ability to see the features that they care about in an image. The two concepts are related but not equivalent, as the above example illustrates. Clinical image resolution depends on many factors, including DQE and dose.

**Beam Filters:** The x-ray beam-hardening filters are usually located in the collimator, just above the exit port of the x-ray tube. The optimal filter thickness for a given application is dependent on the power capability of the x-ray tube, the attenuation of the patient, and the dose per image required at the detector. So it is preferred to have several filter selections available. A range of copper filtration from 0.1 to 0.9 or 1.0 mm copper, in increments ranging from 0.1 to 0.3 mm, is typical. Higher values of filtration, above 0.4-0.5 mm copper, are mainly...
useful in pediatric and thin body section imaging. In adult thoracic and abdominal imaging, x-ray tube power limitations typically limit the useful range of filter thickness to 0.05-0.4mm copper.

**X-Ray Detector:** The detector is a key component in terms of dose efficiency. Since the industry has largely converted over to the use of digital flat panel detectors, we will focus mainly on this technology.

The medical imaging physics and detector manufacturing communities have developed a standard measure of detector imaging performance which captures the effects of x-ray detection efficiency, spatial dispersion of signal, and noise contamination in a single function called Detective Quantum Efficiency (DQE), defined as follows.

\[
DQE(x, f) = \frac{\langle S(x) \cdot MTF(f) \rangle^2}{\langle NPS(x) \cdot X \cdot C \rangle}
\]

where:

- \( S(x) \) = input signal (a function of dose) (counts)
- \( MTF(f) \) = Detector modulation transfer function (dimensionless)
- \( NPS(x) \) = Detector output power spectrum (a function of spatial frequency and dose) (counts\(^2\)/mm\(^2\))
- \( f \) = spatial frequency (cycles/mm)
- \( X \) = detector exposure (Gy)
- \( C \) = X-ray fluence per exposure ( photons/gy/mm\(^2\))

As evident in the above definition, DQE is a function of both spatial frequency and input radiation dose to the detector. As such, it can be used to assess imaging performance with regard to image content in both fluoroscopic and radiographic operation.

DQE is a very useful characterization of detector performance because it incorporates the fundamental imaging performance measurements of signal conversion, modulation transfer function and noise as a function of spatial frequency and input dose. As such, DQE effectively captures the combined effects of the underlying detector design parameters such as pixel spacing, fill factor, scintillator type, readout electronics design, etc., over the operating range of dose levels used in clinical practice (Figure 4).

A performance standard established by the International Electrotechnical Commission for assessing detectors for use in interventional imaging systems (IEC 2008) has been widely accepted. The introduction to this standard states “Since in X-ray imaging, the noise in the radiation field is intimately coupled to the AIR KERMA level, DQE values can also be considered to describe the dose efficiency of a given digital x-ray imaging device”. In simplest terms, DQE is a measure of the fraction of the x-ray information or latent image incident on the detector that is captured in its output. The higher the DQE, the greater the fraction of information detected. The highest that DQE can be is one, or 100%. X-ray information that is undetected or lost at the level of the detector cannot be regained later in image processing. Because of the dose to the patient associated with imaging, it is in the best interests of the patient and clinical staff to maximize DQE, i.e., dose efficiency, in all imaging situations.

In Figure 1, DQE is shown as a function of spatial frequency (a) and dose (b) for two generations of detector designed for cardiovascular interventional applications (GE Innova 2000 and 2100).

There is a gradual but significant decrease in DQE with decrease in detector dose in (b). This is shown at two fixed spatial frequencies for simplicity. As dose to the detector is reduced, the relative importance of the electronic noise increases. The DQE performance at lower doses is important for fluoroscopy, which typically operates at average detector doses in the neighborhood of 10 – 20 mGy (~1 – 2 uR) per image. From a clinical perspective, however, one should also be concerned about several situations encountered in practice in which too little radiation may reach the image receptor. One is where there is dense anatomy in the field, such that the corresponding dark areas of the image are produced by local detector doses much lower than the average. Another occurs in imaging large patients in oblique views, where the regulated fluoroscopic maximum patient entrance dose rate has been reached and the detector is operating dose-starved at levels well below target values. In both cases there is a clinical need to be able to see, for example, a guidewire positioned over the spine or mediastinum, but at very low radiation levels. In addition, trends toward increasing obesity are potentially making these occurrences more frequent. Taking these facts into account, it is reasonable to consider DQE performance at doses as low as 2.5 mGy per image, and to consider DQE at fluoroscopic dose levels to be a critical performance parameter of interventional fluoroscopic systems.

In Figure 1 graphs (a) and (b), the DQE of the 2100 version detector is uniformly and significantly better than that of the 2000, over both spatial frequency and dose. This is due to design and manufacturing improvements in the scintillator, amorphous silicon panel, and readout electronics; and not major design changes (Belanger et al 2006). So it is possible for DQE performance to differ significantly between detectors of the same general design and pixel spacing. This is evident in comparing the performance reported for detectors of different manufacturing origin and size. The variations in DQE at the significantly higher doses used for radiography are less than those at fluoroscopic dose levels. Most manufacturers quote DQE at zero spatial frequency and at radiographic dose in their product data. The DQE (if = 0) value is extrapolated from a series of measurements made at non-zero spatial frequencies, at doses in the neighborhood of 1000 nGy, and the values typically range from 70% – 79%.

[Belanger et al 2006] performed a study that provides insight into the relationship between DQE and clinical imaging performance. The imaging performance of two similar systems having digital detectors with different DQE, graphs (a) and (b) above, and different spectral beam filtration, were compared on a phantom that mimicked the cardiac motion of real stents in a thorax. The spatial frequency content of a cardiac stent was produced by performing Fourier transforms on several axial lines across a high resolution image of the stent, shown in the Figure 2. The set of lobes of intensity declines with

![Figure 1: DQE as a function of spatial frequency (a) and dose (b) for two generations of detector designed for cardiovascular interventional applications (GE Innova 2000 and 2100)](image-url)
spatial frequency from 0 to 2.5 cycles/mm, the same spatial frequency range as in the DQE curves in Figure 1 above. The lobe at zero spatial frequency represents the coarse structure of the stent, that is, a box or rectangle without features, while the series of lobes continuing from 0.25 to 2.3 cycles/mm correspond to progressively finer periodic structures, that is, the struts in various orientations.

Figure 2: The spatial frequency content of a cardiac stent produced by performing Fourier transforms on several axial lines across a high resolution image of the stent. The stent is characterized here by signals over a wide range of spatial frequencies, and the largest of them are at low frequencies. This correlates with the clinical observation that it is easier to see the “box” of the stent than it is to see the fine strut structure, particularly in fluoroscopy, where quantum noise is high and obscures the smaller, higher-frequency lobes. At the higher doses provided by digital cine and DSA recording, the quantum noise is reduced relative to the signal, such that the higher-frequency lobes representing the detailed cell structure of the stent can be appreciated. This happens notwithstanding the fact that the overall system spatial resolution limit is reduced by the use of the large focal spot for these imaging modes. Also, for stent visualization, one should be concerned about the detector DQE over the range of spatial frequencies where the stent has significant signal strength, which in this case would be 0 to 2.3 cyc/mm. And the 2100-version detector should perform better than the 2000-version in stent visualization because of its higher DQE over the entire spatial frequency range of interest, and over the dose range as well.

See the adjacent images of the moving stent phantom from the two generations of detector used in the study. Observers blinded to the detector type viewed randomized recorded fluoroscopy sequences and rated stent visibility on a continuous scale. It was found that the stent visibility was significantly better (p < 0.005) with the higher DQE detector. The phantom dose with the 2100 system was also about 19% lower, but the improved spectral filtration used in the 2100 system accounted for most of this dose decrease. So it is reasonable to conclude that the improved stent visibility by itself can be attributed to the improvement in DQE.

Despite the clinical importance of DQE data at fluoroscopic dose levels, these values are not frequently provided in manufacturers’ product data. However, some data that allow valid comparisons have been reported in the scientific literature by manufacturers and external scientific partners. Innova products have the highest DQE values, particularly at fluoroscopic dose levels, according to available published literature that will be reviewed here.

**Cardiac: GE 2100 versus Trixell 4800 (used by Philips and Siemens)**

Data for the Trixell Pixium 4800 cardiac detector come from Trixell’s product data sheet, referenced below. DQE at low doses was calculated from data sheet values for high dose DQE, electronic noise, and MTF using a model for DQE as a function of dose (Granfors 2003). GE Innova 2100 cardiac panel data come from (Belanger 2006) and GE Manufacturing data, as referenced below. The results are summarized in the accompanying table.

<table>
<thead>
<tr>
<th>Imaging Mode</th>
<th>Dose (nGy/Img)</th>
<th>freq (cyc/mm)</th>
<th>DQE (%) GE2100</th>
<th>DQE (%) Trixell 4800</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoro</td>
<td>5</td>
<td>1</td>
<td>50^3</td>
<td>43^2,6</td>
</tr>
<tr>
<td>Fluoro</td>
<td>5</td>
<td>0.5</td>
<td>62^4</td>
<td>53^2,6</td>
</tr>
<tr>
<td>Rad</td>
<td>1000</td>
<td>0</td>
<td>79^1</td>
<td>75^2</td>
</tr>
</tbody>
</table>

Note that the DQE values for the GE Detector are consistently higher, in the range of 5 to 17%, with greater differences at fluoroscopic dose levels. (Superscripts identify the data source in the references below.)

**Cardiac Detector DQE References:**

3. GE Engineering & Manufacturing data. (The same database from which data were reported in reference #1 above.) All data conform to IEC 62220-1-3 “Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1-3: Determination of the detective quantum efficiency – Detectors used in dynamic imaging”. International Electrotechnical Commission, 2008-6.
4. GE Engineering & Manufacturing data. (The same database from which data were reported in reference #1 above.) All data conform to IEC 62220-1-3 “Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1-3: Determination of the detective quantum efficiency – Detectors used in dynamic imaging”. International Electrotechnical Commission, 2008-6.
Cardiac: GE 2100 versus Varian (used by Toshiba)
Data for the Varian 2020 cardiac panel come from (Tognina 2004), referenced above. GE Innovia 2100 cardiac panel data come from (Belanger 2006) and GE Manufacturing data, as referenced above. The results are summarized in the accompanying table.

<table>
<thead>
<tr>
<th>Cardiac Detectors: GE vs Varian</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Imaging Mode</td>
<td>Dose (nGy/mg)</td>
<td>freq (cyc/mm)</td>
<td>DQE (%) GE 2100</td>
<td>DQE (%) Varian 2020</td>
</tr>
<tr>
<td>Fluoro</td>
<td>5</td>
<td>1</td>
<td>50^5</td>
<td>35^5</td>
</tr>
<tr>
<td>Fluoro</td>
<td>5</td>
<td>0.5</td>
<td>62^4</td>
<td>50^5</td>
</tr>
<tr>
<td>Fluoro</td>
<td>13</td>
<td>1</td>
<td>61^1</td>
<td>47^5</td>
</tr>
<tr>
<td>Fluoro</td>
<td>13</td>
<td>0.5</td>
<td>68^4</td>
<td>59^5</td>
</tr>
<tr>
<td>Rad</td>
<td>150</td>
<td>1</td>
<td>72^1</td>
<td>57^5</td>
</tr>
<tr>
<td>Rad</td>
<td>150</td>
<td>0.5</td>
<td>63^1</td>
<td>65^5</td>
</tr>
</tbody>
</table>

Note that the DQE values for the GE Detector are consistently higher in all but one case, by as much as 15 to 43% in the fluoro dose ranges. (Superscripts identify the data source in the references below.)

Angio: GE 4100 versus Trixell (used by Philips and Siemens)
Data for the Trixell Pixium 4700 cardiac panel come from (Bruijns 2002) and Trixell’s product data sheet, both referenced below. GE Innovia 4100 cardiac panel data come from (Granfors 2003) and GE Manufacturing data, as referenced below. The results are summarized in the accompanying table. (Bruijns 2002) do not clearly specify whether the readout mode used for the DQE data is single pixel (full resolution) or binned. Single pixel readout mode typically leads to lower DQE at low dose levels. The GE data are for single pixel readout mode. If the (Bruijns 2002) data were taken in binned operating mode (as is suggested by the fact that the supporting figures 11 and 12 only run out to 1.5 lp/mm spatial frequency), the DQE difference would be greater that what is shown in the table.

<table>
<thead>
<tr>
<th>Angio Detectors: GE vs Trixell</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Imaging Mode</td>
<td>Dose (nGy/mg)</td>
<td>freq (cyc/mm)</td>
<td>DQE (%) GE4100</td>
<td>DQE (%) Trixell 4700</td>
</tr>
<tr>
<td>Fluoro</td>
<td>5</td>
<td>0.25</td>
<td>63^6</td>
<td>55^8</td>
</tr>
<tr>
<td>Fluoro</td>
<td>100</td>
<td>0.25</td>
<td>71^6</td>
<td>68^8</td>
</tr>
<tr>
<td>Rad</td>
<td>1000</td>
<td>0</td>
<td>77^7</td>
<td>73^9</td>
</tr>
</tbody>
</table>

Note that the DQE values for the GE Detector are consistently higher, by 4 to 15%, with greater differences in the fluoro dose ranges. (Superscripts identify the data source in the references below.)

Angio detector DQE references:
6. Granfors, P. R., G. E. Possin, B. W. Giambatista, Z. S. Huang, J. Liu, and B. Ma. “Performance of a 41x41cm2 amorphous silicon flat panel x-ray detector designed for angiographic and R&E imaging applications” In: Medical Physics 30 (10), pp. 2715-2726, October 2003. Figure 7, pg. 2722.

Angio: GE 4100 versus Varian (used by Toshiba)
Few data are available describing the DQE performance of the Varian 4030 panel. The product data sheet, Reference #10 above, states that DQE(0) > 60%, without specifying dose level. By comparison, the radiographic dose level DQE of the GE 4100 is 77%, or 28% higher. Even the GE detector DQE at the lowest reported fluoro dose in the table above, at f = 0.25 lp/mm, is 63%.

It would be useful to clinicians and imaging scientists if all manufacturers provided clear data on the performance of their detectors at fluoroscopic dose levels, in addition to radiographic dose levels, using the international DQE measurement standard IEC 62220-1-3. GE Healthcare currently provides DQE(0) values at three dose levels: 175, 8.8 and 2.2 nGy/image, corresponding to radiographic, average fluoroscopic, and low fluoroscopic dose levels, respectively.

<table>
<thead>
<tr>
<th>DQE (0) Values at Indicated Average Fluoro and Record Dose Operating Levels</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mode @ Dose/ Frame</td>
<td>Innova 2100IQ 20 x 20 cm</td>
<td>Innova 3100 30 x 30 cm</td>
<td>Innova 4100 40 x 40 cm</td>
</tr>
<tr>
<td>Record 175 nGy</td>
<td>77</td>
<td>77</td>
<td>77</td>
</tr>
<tr>
<td>Fluoro 8.8 nGy</td>
<td>74</td>
<td>71</td>
<td>70</td>
</tr>
<tr>
<td>Low dose fluoro 2.2 nGy</td>
<td>62</td>
<td>58</td>
<td>54</td>
</tr>
</tbody>
</table>

Note: The low dose fluoro value of 2.2 nGy/fr is estimated to be the lowest dose level incident on the detector in fluoroscopy, which would typically occur in (the image of) a dense area of anatomy of a large patient.

X-RAY AUTOMATIC EXPOSURE CONTROL
Now let’s turn from components to imaging system design and features, starting with automatic exposure control (AutoEx). The GE Innovia AutoEx design is shown in Figure 3. It monitors image and dose parameters and controls kVp, mA, exposure time (pulse width), focal spot selection and beam filter selection automatically. The advantage is that the clinician can focus on the patient while the control system manages IQ/Dose efficiently according to pre-determined rules. The control system operates in a continuous loop. Using the x-ray technique, spectral filter, average brightness signal from the detector and other information from a given exposure, the AutoEx system computes the effective patient thickness (EPT) after every exposure. This is critical for two reasons. First, the selection of the optimal x-ray technique in terms of maximizing IQ for a given dose depends on EPT. Second, keeping running track of EPT allows the system to rapidly transition from one imaging mode to another, e.g. from fluoro to digital cine or DSA, without the need for test exposures or unnecessary control loop settling time, both of which would represent additional dose to patient and staff.

Next, the AutoEx uses each updated measurement of EPT and associated x-ray technique and detector signal to set the x-ray technique for the next exposure. The AutoEx makes this new technique selection intelligently, usually based on optimization rules that are embedded in lookup tables for computational speed. Thus, the AutoEx can perform these actions easily in real-time, running at 30 images/second or more; correcting for differences between actual and desired signal to the detector due to patient motion, panning, rotation of gantry, etc. The “rules” embodied in these tables conform to certain strict design criteria. An example might be “maintain Image Quality as defined by iodine contrast to background noise ratio of 5:1 at minimum patient entrance dose for effective patient thicknesses up to 30cm equivalent cm of PMMA, thereafter lock patient entrance dose, allowing IQ to drop because present patient dose limits have been reached.” Because of the flexibility of this approach, enabled by...
advances in cost-effective processing power and storage, it is possible to have multiple sets of these “design rules” to fit different imaging modes, different IQ/Dose objectives, detector fields of view, imaging rates, etc. Thus, the imaging chain can be designed to perform optimally under a wide variety of conditions and for different clinical objectives.

Selection of fluoroscopic image rate or frame rate can be used to balance image quality needs against dose delivered to patient and staff. From an image quality standpoint, frame rate must be high enough to adequately demonstrate anatomic motions of interest and to enable image-guided manipulations, particularly in moving or sensitive structures. On the other hand, it has been shown by (Aufrichtig et al 1994) that there are dose saving advantages to using the lowest practical frame rate while maintaining image quality objectives. Figure 4 illustrates two different, common schemes for changing dose rate with fluoroscopic frame rate. The top diagram in Figure 4 illustrates a scheme whereby dose rate drops proportionally with frame rate. The advantage is that large dose reductions are achieved with reducing frame rate. The disadvantage is that the resulting image quality loss may prohibit the use of the lower rates for clinical reasons. The lower diagram in Figure 4 illustrates a scheme inspired by Aufrichtig’s work in which the dose rate is reduced more gradually with frame rate. Due to the behavior of the human visual system, the apparent background noise remains constant as frame rate is reduced, making the lower frame rates more acceptable clinically, and therefore more likely to be used. The GE Innova AutoEx system allows selection of either of these schemes, by protocol, as desired for clinical purposes.

Cardiology procedures were used as a primary example here. But the same logic and capabilities apply to interventional radiology and image-guided surgical procedures as well. In interventional radiology, for example, PICC (Peripherally Inserted Central Catheter) line placements and biopsy needle guidance may typically be performed at lower fluoro frame rates with lower dose/IQ AutoEx selections. Neuro guidewire manipulations, on the other hand, would require a higher IQ/Dose AutoEx selection and 15 frame/sec fluoro imaging. In image-guided surgical procedures, devices like abdominal aortic stents would be well visualized using lower dose/IQ AutoEx selections operating at lower frame rates. However, precise placement of a renal stent relative to the ostium of the vessel might call for a higher IQ/dose selection operating at 15 frames/second.

Figure 4: Illustration of two different strategies for reduction of dose rate with imaging frame rate.
The clinician can select the appropriate procedure protocol at tableside, using a touchscreen interface that can be operated while wearing gloves, through a transparent sterile drape. The clinician selects by clinical procedure type, and the system responds with the underlying selections that have been programmed in the initial setup of the system using clinicians’ input, including the naming of the protocols in the clinicians’ preferred terms. During operation, the clinician still has the option to modify his pre-programmed selections by changing fluoro imaging rate and dose rate from the default values associated with the particular protocol.

**RADIATION MONITORING AND FEEDBACK**

A clinician has immediate feedback and intuitive assessment of image quality, but the same is not true of radiation dose. Interventional systems should have a monitoring system with a display convenient to the clinician, and the clinician needs to understand the units of measure, the related thresholds of risk, and develop the habit of awareness of the accumulation of dose to the patient during each procedure. There are two main types of dose measurement in an interventional lab, Patient Entrance Dose and Dose-Area Product. Patient Entrance Dose is known technically as Entrance Skin Air Kerma (ESAK). It is a measure of the radiation energy per unit area incident upon the patient, and is most useful for estimating the risk of deterministic skin injury. Dose-Area Product (DAP) is a measure of the total amount of radiation incident upon the patient, without regard to local intensity, and therefore may be most useful in correlating to stochastic risk estimates. (However, in systems providing only DAP, it may be possible to estimate ESAK through knowledge of or making reasonable assumptions about the fields of view employed in a given procedure.)

GE Innova systems provide in-room display of ESAK rate, total ESAK and DAP, immediately adjacent to the fluoroscopic image for ready availability.

**Dose Reports:** Beyond providing dose rate and accumulation data during interventional procedures, GE offers an optional reporting system that provides summaries post-procedure. The intent is to provide statistical data which may be used to understand overall equipment utilization by procedure type, to identify trends, to analyze cases of high patient exposure, and to identify best practices and modify behaviors accordingly, thereby helping clinicians “close the loop” on radiation practices.

Figures 6 and 7 provide examples of two summary charts showing dose distribution by procedure type, with totaled data on imaging duration, DAP, dose (ESAK) and corresponding percentages broken down by fluoroscopy and individual radiography modes. Such information might be used in a departmental effort on minimizing dose by first identifying the procedures that, by their number or complexity, contribute the highest dose to patients and staff.

Figure 8 is an example of a “Dose Incidence Map” which provides the estimated maximum skin exposure versus position on the patient, in 30 x 30 degree angular increments. This is an effort to break down the total patient entrance dose by region of skin incidence to better estimate the maximum dose received by any one area. In this example, the maximum dose was delivered in an RAO/Caudal angulation.

These reporting tools provide more detailed and graphic information about the effects of a clinician’s behaviors and may thereby provide guidance for minimizing radiation effects to patients and staff.

**Figure 6 and 7:**

**Figure 6:** A summary chart showing frequency of procedures and dose distribution by procedure type.

**Figure 7:** A summary chart showing totaled data on imaging duration, DAP, dose (ESAK) and corresponding percentages broken down by fluoroscopy and individual radiography modes.

**Figure 8:** An example of a dose incidence map. The maximum skin exposure was in the RAO/Caudal incidence.

**Figure 9:** A sample monthly summary report on dose utilization as a function of source-image receptor (detector) distance (SID). Data for the individual lab can be compared with a database of other operators of similar equipment. In this case the individual lab shows greater use of longer SID than the average behavior of similar users. Since adoption of a longer SID may be due to failure to routinely minimize the gap between the patient and detector following each repositioning of the imaging gantry or patient, these data may provide insight into lapses in good imaging practice that lead to higher than necessary doses.
The GE Innova Dose Reporting feature provides relevant statistical data on dose utilization that can be used in departmental dose monitoring and management programs.

OTHER X-RAY SYSTEM FEATURES TO MINIMIZE & OPTIMIZE DOSE

Many other system-level features have been developed to minimize/optimize radiation exposure in interventional procedures.

Automatic Detector Positioning: Most clinicians and technicians understand that positioning the detector close to the patient is optimal in terms of dose minimization and image quality. However, performing this action after repositioning the gantry can be forgotten in the midst of a busy procedure. To address this issue, GE Healthcare has developed a feature whereby the detector is automatically repositioned close to the patient following each gantry maneuver, thereby improving dose efficiency and image quality. The feature also works in the opposite sense at the start of a gantry motion, automatically backing the detector away from the patient to provide clearance for repositioning. So it is designed to assist the user and thereby be utilized regularly in a busy lab.

Dynamic Range Management: This term describes a class of image processing techniques which is used to minimize apparent overexposure and underexposure in a displayed image, such that anatomic and device details are not lost in the very bright and dark areas of an image. These image processing techniques tend to provide a useful image in difficult situations, without the additional time and radiation exposure associated with adjusting collimation or wedge filters until the image is adequate. GE pioneered these techniques, which has led to its Innova products employing a very refined and effective dynamic range management system.

Virtual Collimation: GE Innova products feature a technology whereby the clinician can preview collimator, and in some cases wedge filter, repositioning on the last fluoro image, in lieu of requiring radiation to visualize.

Fluoro Image Storage: Most modern systems provide for fluoro image storage. Storing a fluoro image sequence for the patient record allows taking an additional higher-dose record sequence represents a dose savings. However, the quality of the fluoro image must be adequate for clinical needs, which brings us back to the importance of the fluoroscopic DQE of the detector.

CONCLUSION:

In the first section of this document, data analysis in 4 out of the 5 studies reviewed indicates clinicians using one or more GE Innova systems achieved lower patient case doses than their or their peer groups achieved using other manufacturers’ equipment. Also, the DAP (alternately KAP) values, where reported, compared quite favorably to current and proposed reference standards for procedural doses performed on Innova systems. In analyzing potential reasons for these results, it has been shown that GE Innova systems may have quantifiable advantages in detector DQE. Additionally, other factors in the Innova design such as: automatic exposure regulation, flexibility in dose settings, ease/automation of procedure protocol selection, dose monitoring, dose reporting and other special features play a pivotal role in the clinicians ability to optimize the dose to the clinical task and patient at hand, potentially contributing to the favorable Innova performance in the cases presented.

REFERENCES:


Table VII.


About GE Healthcare
GE Healthcare provides transformational medical technologies and services to meet the demand for increased access, enhanced quality and more affordable healthcare around the world. GE (NYSE: GE) works on things that matter - great people and technologies taking on tough challenges. From medical imaging, software & IT, patient monitoring and diagnostics to drug discovery, biopharmaceutical manufacturing technologies and performance improvement solutions, GE Healthcare helps medical professionals deliver great healthcare to their patients.

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