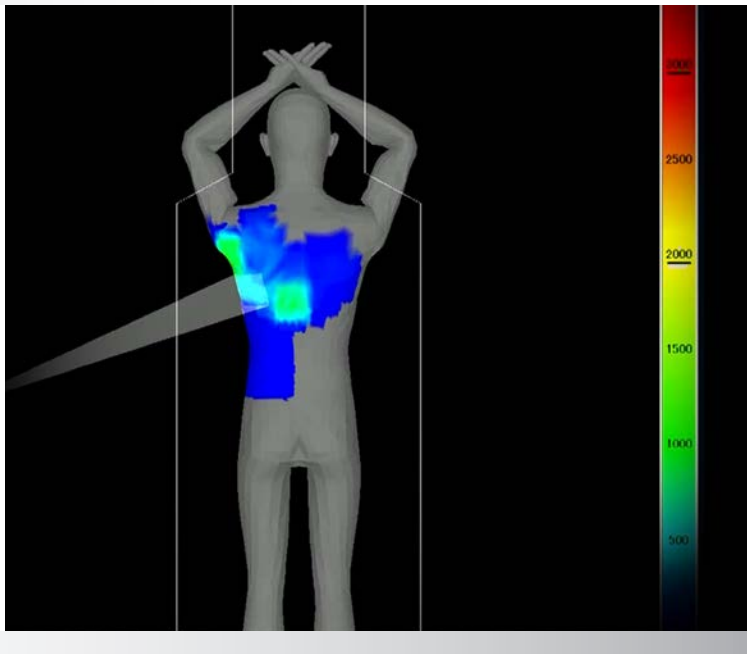
TOSHIBA
Leading Innovation

Dose Tracking System:

A Paradigm Shift in Patient Dose Monitoring



Andrew Kuhls-Gilcrist, Ph.D.

XRVL Clinical Science Manager
Toshiba America Medical Systems, Inc.

Millions of fluoroscopically guided interventional (FGI) procedures are performed annually, offering tremendous benefit over alternative invasive surgical procedures, faster recovery times and resulting in improved patient outcomes and quality of life[1]. As both technology and clinical practice continue to rapidly advance, more and more diagnostic and curative procedures leverage and rely upon fluoroscopic imaging. The growing use and increasing complexity of FGI procedures have been accompanied by a renewed focus on the management and administration of ionizing radiation in order to ensure the highest safety for both patients and staff.

Classifying the Risks of Radiation Exposure

Radiation risk can be classified as either stochastic (probability-based) or deterministic (threshold-based). Stochastic risk refers to the belief that any amount of exposure to ionizing radiation may lead to an increased probability of cancer incidence. The exact magnitude of this risk remains under active debate for the relatively lower levels of radiation typically administered in medical imaging procedures[2]. Deterministic risk refers to the skin injury or "radiation burn" that can occur if the single-site acute skin dose exceeds a high enough threshold.

The National Council on Radiation Protection and Measurements (NCRP) suggests a substantial radiation dose level (SRDL) be defined at a peak skin dose of 3 Gy or a reference air kerma of 5 Gy, recommended to trigger additional dose management and patient follow-up actions to monitor for possible deterministic skin injury[3]. In order to minimize these potential risks as much as practicable, the ALARA (As Low As Reasonably Achievable) principle should be followed whenever possible.

A New Age of Regulatory Requirements

New technologies bring new capabilities. Today's state-of-the-art interventional fluoroscopy equipment provides a multitude of dosimetric indications and reporting capabilities that were not widely available just a decade ago. In an effort to increase transparency, awareness, understanding and safety, a growing number of organizations are recommending or even requiring the

Figure 1: Infinix™-i bi-plane system.

monitoring and recording of patient radiation dose metrics and the establishment of reference levels to facilitate quality improvement[4-7].

Advantages and Limitations of Dose Monitoring Techniques

Fluoroscopy Time [unit: minutes (min)] is the total amount of time that fluoroscopy is utilized during an imaging or interventional procedure. Historically, fluoroscopy time has been used as a dose surrogate for clinical radiation dose management, often in conjunction with a count of the number of digital acquisitions or cine recordings. Modern interventional imaging equipment includes a five-minute fluoroscopy timer that emits an audible alert until manually reset with the goal of increasing awareness to the amount of fluoroscopy used during the course of a procedure. **What's missing?** Fluoroscopy time is a poor indicator of patient dose (**Figure 2**) and is considered an inadequate indication of skin-dose estimation for many reasons, including the lack of information regarding fluoroscopic dose rate, exclusion of cine radiographic recording contributions, patient size, beam size or beam position[8]. Because fluoroscopy time is such a poor indictor of radiation dose, its use is generally discouraged in favor of the dose metrics now available on today's systems.

Cumulative Air Kerma, a.k.a., Reference Air Kerma, Cumulative Dose, Reference Point Dose [unit: milligray (mGy)] is the total amount of radiation dose absorbed by air at a specific point in space relative to the X-ray source, measured free-in-air, during an imaging or interventional procedure. The interventional or patient entrance reference point is most commonly utilized and is located 15 cm from the isocenter toward the X-ray source. Displays of cumulative air kerma are required on all fluoroscopic equipment manufactured on or after June 10, 2006[9]. Cumulative air kerma represents a significant improvement over fluoroscopy time, as it is an actual indication of the radiation output from the X-ray tube. **What's missing?** Cumulative air kerma may be a poor indicator of patient skin dose among individual instances due to a number of insufficiencies[8,10] (**Figure 3**). Cumulative air kerma sums all of the radiation dose as

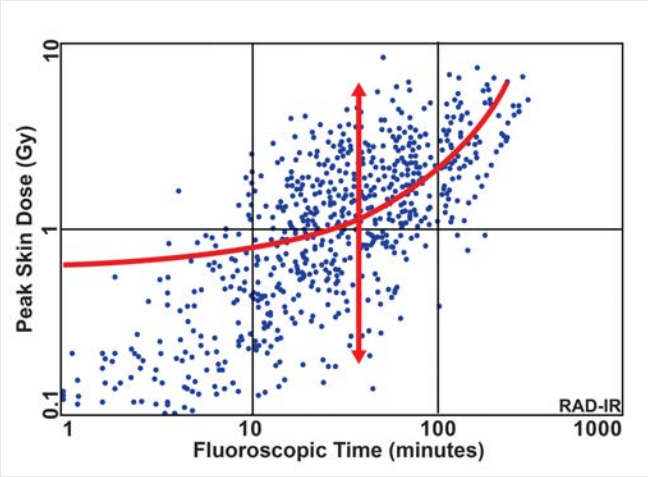


Figure 2. Fluoroscopy time was shown to correlate very poorly with other patient dose metrics. More than an order of magnitude variation was measured between fluoroscopy time and peak skin dose as demonstrated by the wide variability in this illustrative plot based on the RAD-IR study[10].

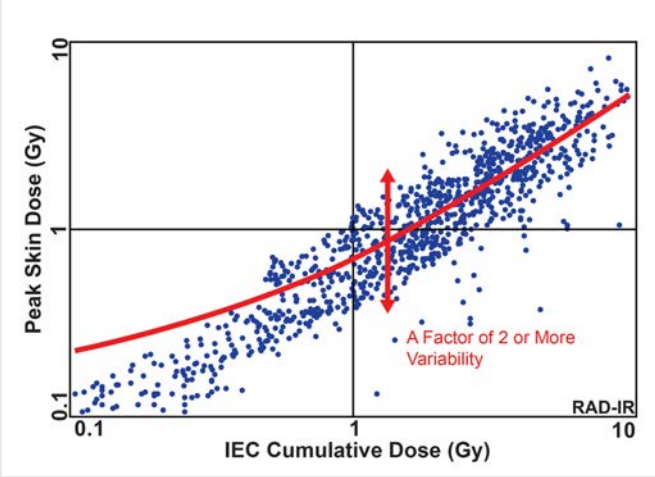


Figure 3: Cumulative air kerma (referred to here as "IEC Cumulative Dose") shows an improved correlation with peak skin dose, as illustrated in the above plot adapted from the RAD-IR study[10]. However, a variability of more than a factor of two is still observed between the cumulative air kerma and peak skin dose.

if it occurred at a single point in space. However, clinical procedures may involve movement of the X-ray beam through the varying of the table position and C-arm angulation, which tends to distribute the dose to many different points across the patient skin surface. Further, air kerma depends upon the reference point location as described by the inverse-square law. The patient entrance reference point may not correspond to the actual position of the patient's skin, which introduces further uncertainty. Lastly, cumulative air kerma is measured free-in-air, meaning it does not take into account attenuation and scattering effects of the patient table and mattress nor tissue absorption and backscatter characteristics.

Dose Area Product (DAP), a.k.a., Kerma Area Product (KAP) [unit: gray centimeter squared (Gy.cm²) or other SI prefixes] is the product of the area irradiated and the air kerma. Dose area product is a surrogate measurement for the entire amount of energy delivered to the patient by the X-ray beam and is most often utilized in estimating stochastic risk. Similar to air kerma, DAP is an improvement over fluoroscopy time, as it is an actual indication of the radiation output from the X-ray tube. Unlike air kerma, DAP is constant regardless of the distance from the X-ray source. **What's missing?** DAP is generally considered a poorer indication of patient skin dose as compared to cumulative air kerma[11]. In addition to several similar limitations discussed previously, dose area product also suffers from the inability to distinguish between large fields with low skin doses and small fields with high skin doses, which could result in the same dose area product.

Skin Dose [unit: milligray (mGy)] is the absorbed dose to soft tissue, including the contribution from any backscattering, at a specified point of the skin. *Skin Dose Distribution* refers to the distribution of skin dose across the skin surface. *Peak Skin Dose* refers to the highest skin dose occurring at any point on the skin surface, while *Field-of-View (FOV) Peak Skin Dose* refers to the highest skin dose occurring at any point on the skin surface that is within the area of irradiation of the present FOV. Because skin dose depends upon a large number of factors, including gantry angle and position, field size and shape, and patient size and position, it cannot be calculated directly from overall measures of dose described previously, such as cumulative air kerma and dose area product[12] (**Figure 4**). **Why skin dose?** In order to accurately predict the likelihood and severity of deterministic skin effects and to better assess

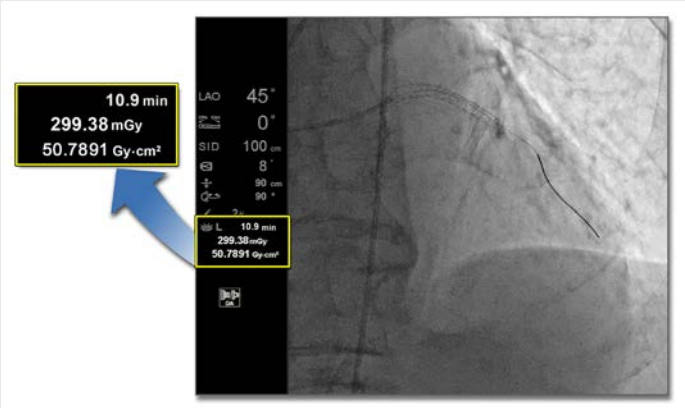


Figure 4: An example display of standard dosimetric indications, including fluoroscopy time and cumulative air kerma.

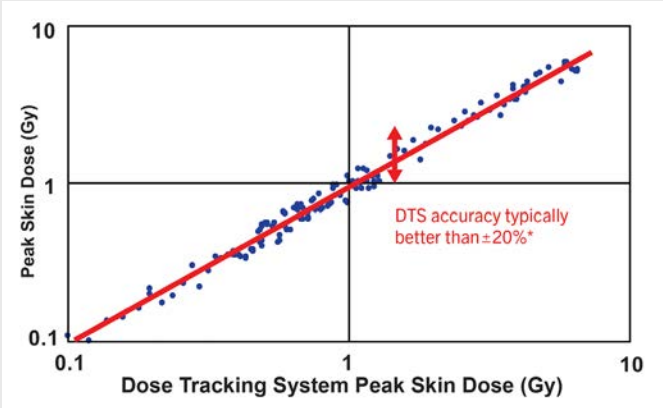


Figure 5: Illustrative plot demonstrating typical accuracies of the estimation of peak skin dose provided by the DTS to within ±20%, with appropriate patient graphic selection and positioning. Presently, no alternatively reliable methodology exists.

which patients might require follow-up for detection of possible skin injuries. The International Commission on Radiological Protection (ICRP), the National Council on Radiation Protection and Measurements (NCRP), and professional societies have emphasized the importance of estimating skin dose during and after FGI procedures[3,13]. Furthermore, The Joint Commission considers a skin dose that exceeds 15 Gy to be a sentinel event[14]. Hence, accurate estimation of peak skin dose and the skin dose distribution is important both during and after FGI procedures in order to efficiently and effectively manage deterministic radiation risk.

Is It Possible and Practical to Estimate Patient Skin Dose Today?

Yes, with Toshiba America Medical Systems, Inc.'s revolutionary Dose Tracking System (DTS), a real-time color-coded estimate of skin dose distribution is displayed. Numerical displays of the peak skin dose and FOV peak skin dose are also provided in complement to the skin dose distribution map. **How is this possible?** For the first time ever, peak skin dose is displayed in real time on an intuitive and easy-to-interpret patient graphic, minimizing the guesswork required for patient dose monitoring. The DTS estimation of skin dose goes beyond cumulative air kerma and other dosimetric indications by offering the following advancements:

1. It tracks and incorporates movement of the X-ray beam relative to the patient graphic, providing a distribution of dose rather than a single cumulative number.

2. Inclusion of realistic patient models that can be selected to closely match the actual patient undergoing the procedure for specific source-to-skin distance corrections.

3. Addition of other real-world influences, such as the patient support and tissue absorption and backscatter characteristics.

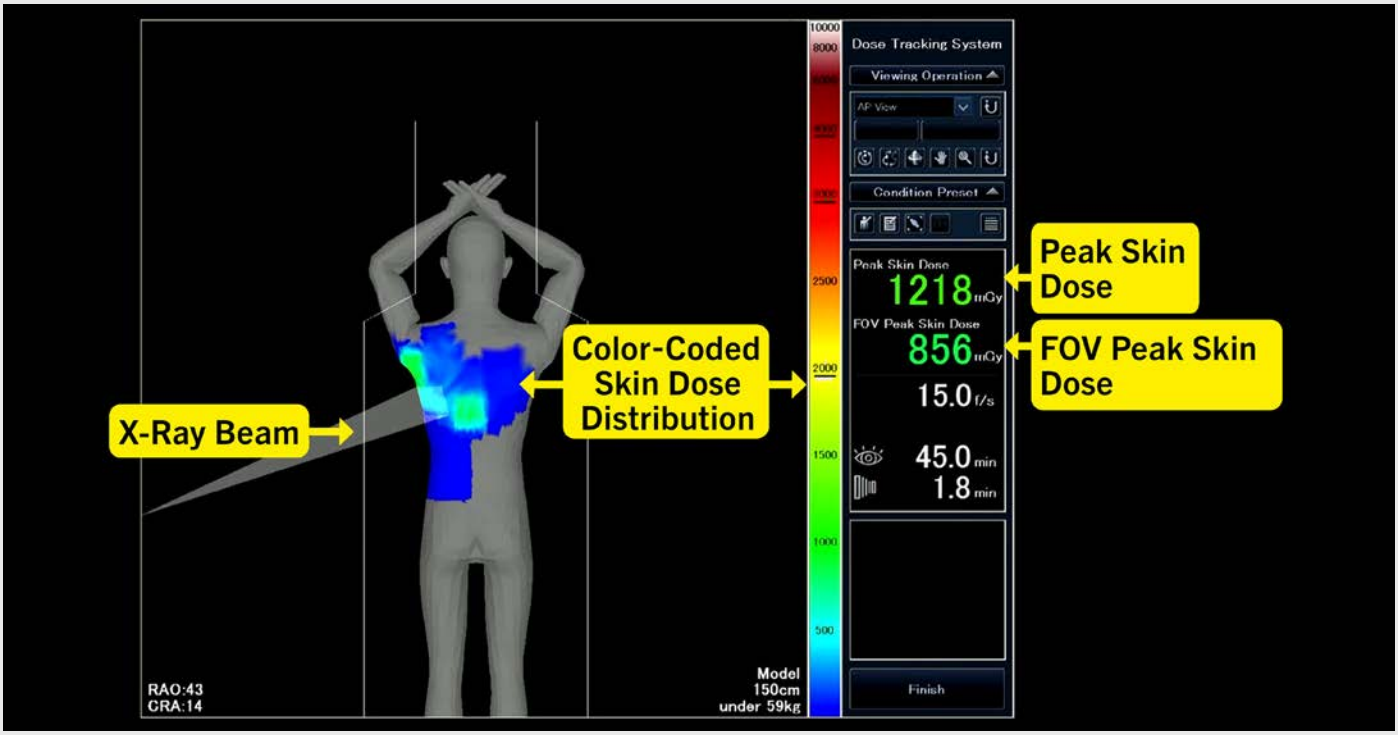


Figure 6: The operation screen of the Dose Tracking System, illustrating the color-coded skin dose distribution display area and the dose information display area that includes numerical peak skin dose and FOV peak skin dose estimates.

Leading Innovation with Toshiba's Dose Tracking System: How It Works

In development over the last decade in partnership with researchers at the University at Buffalo's Toshiba Stroke and Vascular Research Center, the DTS exemplifies innovation[15-17]. With recent advancements in computational power and real-time data streams, the DTS has finally become a reality.

To achieve the highest accuracy possible, skin dose calculations take into consideration a wide range of system parameters, including exposure parameters such as the kV, tube current, pulse width, frame rate, field of view, beam filter and acquisition mode along with imaging-system geometry information such as gantry angulation, table position and source-to-image distance. Furthermore, patient table/support attenuation and scatter influences are taken into consideration along with soft tissue absorption and backscatter characteristics. Each DTS implementation is calibrated on site for inclusion of site-specific variations that may occur. The skin dose estimation under typical clinical conditions is estimated to be within a range of plus or minus 20 percent with careful matching of the patient graphic to

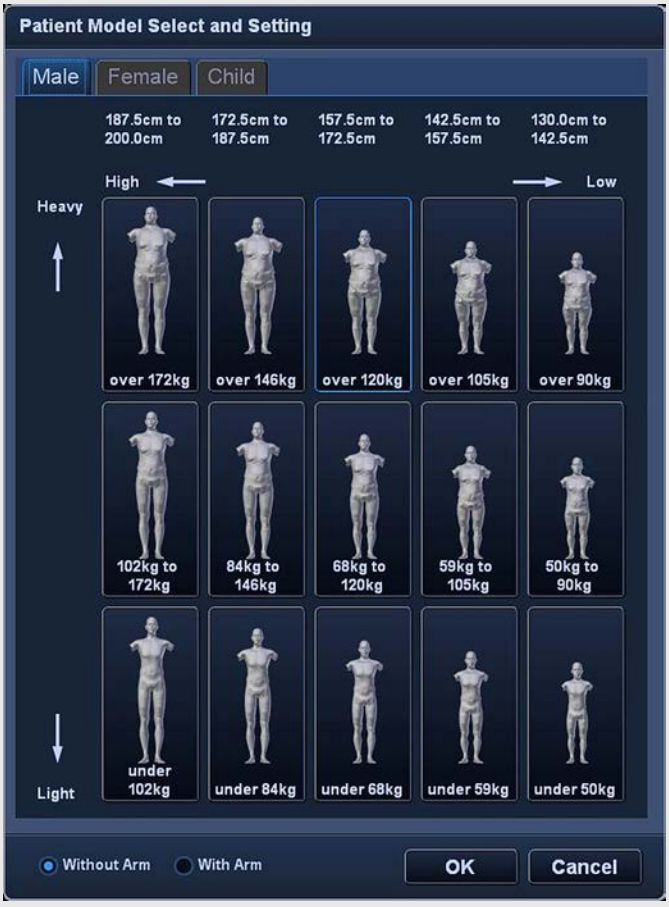


Figure 7: The appropriate patient model can be selected according to the patient sex, height and physique to be examined. Male, female and child models can be selected with standard/underweight, overweight, and obese physiques ranging in weight from 3 to 260 kg and height from 50 to 200 cm. The position of the patient graphic relative to the tabletop can be adjusted in order to closely match the actual position of the patient.

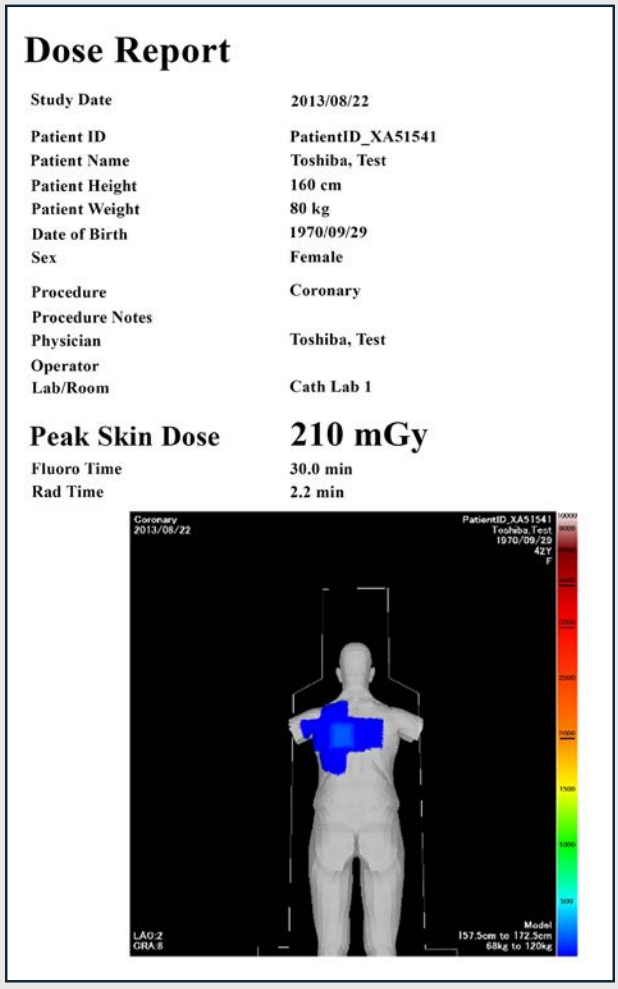


Figure 8: A summary dose report can be automatically generated at the end of the examination, providing both numerical and graphical indications of skin dose estimates.

that of the actual patient being imaged (**Figure 5**). Validation tests have utilized a wide variety of water-equivalent plastic, PMMA and anthropomorphic phantoms under the gamut of system utilization conditions[15-17]. Gafchromic film testing was utilized to provide further insights into the spatial correlation between the dose distributions displayed by the DTS compared to the actual distribution of dose to the phantom to within approximately 10 percent under test conditions[16,18].

In order to maintain a high degree of accuracy, it is necessary to choose the appropriate patient graphic and position. Because the DTS uses detailed source-to-skin distance values between the X-ray source and the individual elements of the patient graphic, appropriate selection and matching of the patient graphic to most closely match the patient being imaged is a critical step in maintaining the accuracy of the skin dose estimates provided by the DTS. The appropriate patient model can be selected according to the height, weight/physique and sex of the patient from a library of more than 40 realistic patient models based on 3D digital scanning technology (**Figure 7**). Greater differences in height or body size between the actual patient and the selected patient model results in greater errors in the estimated skin dose distribution. For example, a surface mismatch of 1 inch can introduce additional errors of approximately 10 percent, following the inverse-square law[15]. The position of the patient graphic can be further fine-tuned using longitudinal, lateral and vertical adjustments relative to the table top. The skin dose distribution to extremities is less reliable due to the potentially wide variability in their exact position or potential movement during a procedure, thus requiring careful considerations outside of the DTS capabilities.

Real-time feedback provides skin dose information when it is needed most—during the procedure. Physicians can quickly and easily visualize the administration of radiation exposure at a glance, while using the skin dose distribution map on the realistic patient graphic and the displayed X-ray beam location to further facilitate the management of peak skin dose and the reduction of risk of deterministic injury by avoiding areas approaching skin dose thresholds or further leveraging the many dose reduction technologies available.

Summary dose reports record peak skin dose and other pertinent information, including snapshots of the skin dose distribution (**Figure 8**). Dose reports for up to 500 patients can be automatically stored on the DTS system. Archival and backup of dose reports can be accomplished through export to a USB memory device or a Windows-networked drive.

Conclusion

Dose management continues to be an important focus, assuring that fluoroscopically guided interventional procedures are providing the maximum benefit under the safest of conditions for both patients and staff. An appropriate understanding of the administration of radiation exposure, in terms of skin dose, during the course of an intervention is a crucial element in effectively managing risks while maximizing benefits. Toshiba's Dose Tracking System represents a unique real-time solution that facilitates effective management of peak skin dose and subsequently the further reduction and mitigation of radiation risks. The DTS, in combination with an industry-leading set of dose management and reduction technologies, such as Spot Fluoroscopy, Advanced Image Processing, variable isocenter, C-arm flip and other exclusive Toshiba technologies, provides clinicians with the necessary tools to succeed in today's healthcare environment and to ensure the highest safety standards.

Actual radiation output should be monitored using the dose display information, due to dynamic factors that can vary and affect total dose output, such as different patient sizes, anatomical structure, user application and system techniques. Estimated values cannot be guaranteed under all conditions.

www.medical.toshiba.com

References

1. NIH, Interventional Fluoroscopy Reducing Radiation Risks for Patients and Staff, NIH Publication No. 05-5286 (2005)

2. W.R. Hendee and M.K. O'Connor, Radiation Risks of Medical Imaging: Separating Fact from Fantasy, Radiology. 264(2) 312-321 (2012)

3. NCRP, Report 168: Radiation dose management for fluoroscopically-guided interventional procedures, NCRP Report No. 168 (2010)

4. Texas Administrative Code, Use of Radiation Machines in the Healing Arts, Section 289.227 (2013)

5. Accreditation for Cardiovascular Excellence, ACE Standards for Catheterization Laboratory Accreditation (2013)

6. D. L. Miller et al, Patient radiation doses in interventional cardiology in the U.S.: Advisory data sets and possible initial values for U.S. reference levels, Med. Phys. 39(10): 6276-6286 (2012)

7. D.L. Miller et al, Reference Levels for Patient Radiation Doses in Interventional Radiology: Proposed Initial Values for U.S. Practice, Radiology. 253(3): 753-764 (2009)

8. D.L. Miller et al, Radiation Doses in Interventional Radiology Procedures: The RAD-IR Study Part II – Skin Dose, J Vasc Interv Radiol, 14:977-990 (2003)

9. FDA, Performance Standards for Ionizing Radiation Emitting Products, 21CFR1020.32 (2013)

10. S. Balter, Methods for measuring fluoroscopic skin dose, Pediatr Radiol. 36(2): 136-140 (2006)

11. D.L. Miller et al, Radiation Doses in Interventional Radiology Procedures: The RAD-IR Study Part I – Overall Measures of Dose, J Vasc Interv Radiol, 14:711-727 (2003)

12. D. Kwon et al, Reference air kerma and kerma-area product as estimators of peak skin dose for fluoroscopically guided interventions, Med Phys 38(7): 4196-4204 (2011)

13. ICRP, Avoidance of radiation injuries from medical interventional procedures, ICRP Publication 85, Ann ICRP 30: 7-67 (2000)

14. The Joint Commission, Radiation Overdose as a Reviewable Sentinel Event, Update March 7, 2006

15. V.K. Rana et al, Updates in the real-time Dose Tracking System (DTS) to improve the accuracy in calculating the radiation dose to the patients skin during fluoroscopic procedures, Proc of SPIE, 8668:86683Z-1-13 (2013)

16. D.R. Bednarek et al, Verification of the performance accuracy of a real-time skin-dose tracking system for interventional fluoroscopic procedures, Proc of SPIE, 7961: 796127-1-8 (2011)

17. K Chugh et al, A computer-graphic display for real-time operator feedback during interventional X-ray procedures, Proc of SPIE, 5367 (2004)

18. V.K. Rana et al, Comparison of skin-dose distributions calculated by a real-time dose-tracking system with that measured by gafchromic film for a fluoroscopic c-arm unit, Med Phys 38:3702 (2011)

Made for Life

TOSHIBA AMERICA MEDICAL SYSTEMS, INC.

2441 Michelle Drive, Tustin CA 92780 / 800.421.1968

VLWP12220US