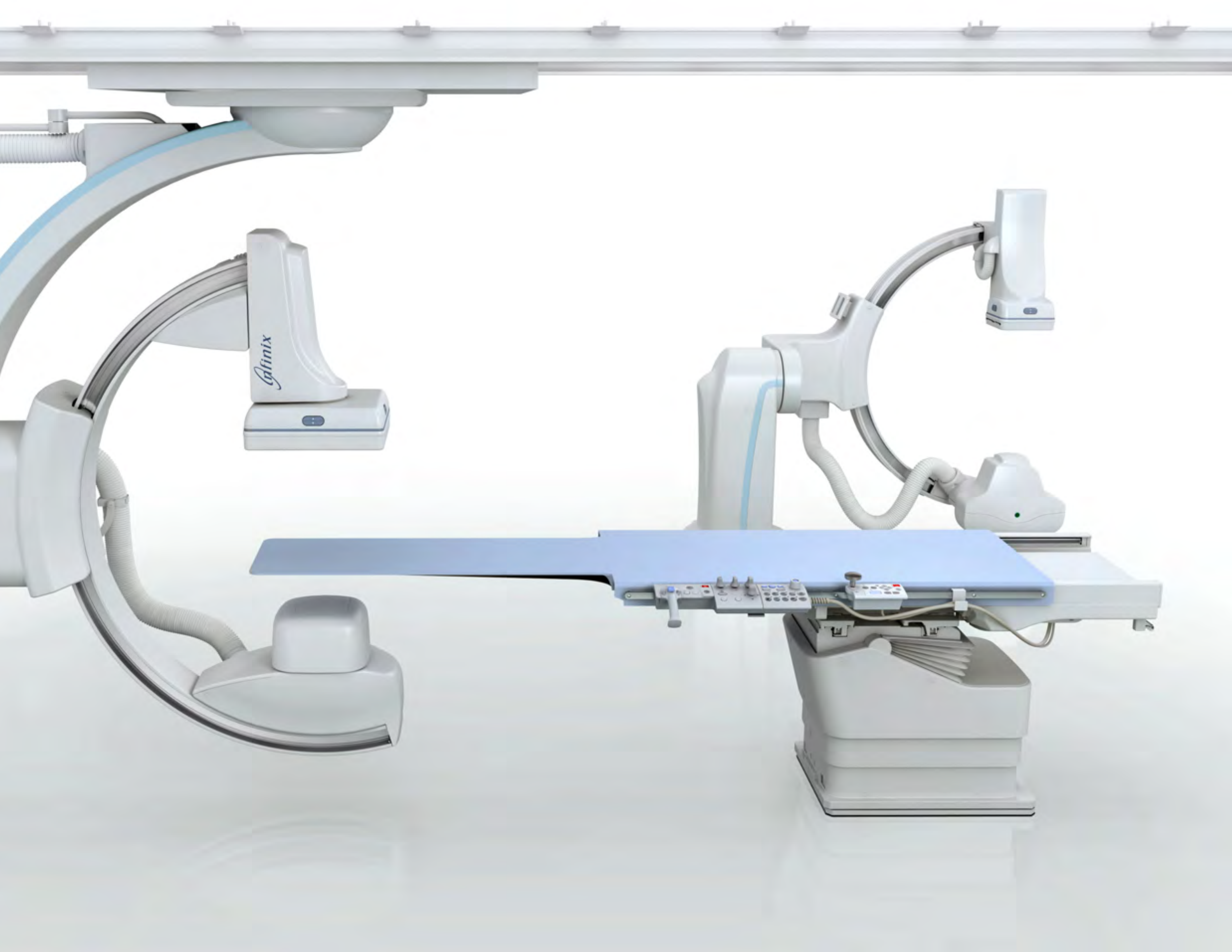
Canon

White Paper

Infinix™-i Dual plane

The Low-Dose, Multi-Procedural Interventional System



INTRODUCTION

Infinix™-i Dual plane is the first and only imaging system that's been built to keep pace with the expanding landscape of interventional cardiology by allowing cardiac and peripheral procedures to be done in one space at significantly reduced dose. Infinix-i Dual plane achieves unmatched versatility for cardiac and vascular procedures with two dedicated C-arms in the same room without sacrificing dose, image quality, peripheral coverage and efficiency.

Performing these procedures with the same C-arm requires a compromise among coverage, image quality (IQ) and radiation exposure. Peripheral procedures require detectors with wide coverage, and cardiac interventions require high spatial resolution. Wider X-ray cone beams necessitate a larger anode target angle, which in turn has a negative impact on available focal spot sizes and subsequently, the spatial resolution of the system.

Therefore, selecting a system with a wider detector to accommodate both aforementioned interventions inherently reduces the IQ of cardiac images. In addition, large flat panel detectors (FPD) cannot achieve steep viewing angles used routinely in cardiac procedures. To achieve certain steep angles, the larger FPD has to be positioned farther away from the patient anatomy increasing the source to image distance (SID) and thus the dose to the patient, per the inverse-square law. The positioning of the larger FPD to approximate steeper angles is another source of compromise between IQ and radiation exposure.

SYSTEM DESIGN AND PERFORMANCE

Based on a design commitment to delivering optimum image quality at reduced dose, Infinix-i Dual plane systems incorporate industry-leading dose management tools including:

1. Dedicated C-arms

Depending on the procedure, either the cardiac or the peripheral C-arm can be selected for optimal performance with zero compromises in the same room. The dedicated cardiac C-arm has a small FPD (8" x 8") and a cardiac X-ray tube. The peripheral C-arm has a larger FPD (12" x 16") and a dedicated peripheral X-ray tube. Using the cardiac C-arm for cardiac procedures, instead of a peripheral C-arm, results in significant Air Kerma Rate (AKR) reductions without image quality compromises as demonstrated in bench and clinical studies.

A. Bench Studies

A torso phantom was imaged with both FPDs of an Infinix-i Dual plane system. Results were generated under typical use conditions and projection views that provide optimal visualization of the coronary segments and are typically used as working views for coronary interventions.[1] Acquisitions with both C-arms were performed with an 8" field-of-view (FOV).

The cardiac C-arm offered greater flexibility for imaging at steeper angles and reduced SID compared to the peripheral C-arm. Differences in SID, detector size, magnification mode, scattered radiation impingent upon the FPD, X-ray tube and collimator/beam filtration were all contributing factors that resulted in AKR reductions up to 57 percent in digital acquisition (DA) and 68 percent in fluoroscopic modes without image quality compromises that would be observed by simply reducing AKRs for the peripheral system below optimum levels (Table 1). Table 2 provides AKR reduction comparisons at typical projection views at minimum achievable SID for the two C-arms. Minimum achievable SIDs were, in general, smaller for the cardiac panel. In addition, there was a limitation in the maximum angle that could be achieved by the peripheral C-arm (12" x 16" FPD) in one of the tested projection views (RAO: 7°, and CRA: 32°).

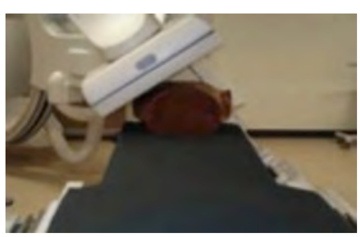
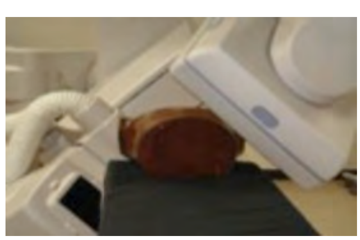
Table 3 shows the average AKR reduction from all seven projection views achieved by the 8" x 8" FPD when compared with the 12" x 16" FPD operated in the 8" FOV mode.

Air Kerma Rate Reduction		
	Cardiac (8" x 8" FPD)	Peripheral (12" x 16" FPD)
DA	**Up to 57%**	Reference
Fluoroscopic	**Up to 68%**	Reference

Table 1. Bench Data: AKR reduction comparison between the cardiac and peripheral C-arm for DA and fluoroscopic acquisitions.

Average Air Kerma Rate Reduction		
	Cardiac (8" x 8" FPD)	Peripheral (12" x 16" FPD)
DA	**37%**	Reference
Fluoroscopic	**45%**	Reference

Table 3. Comparison of average AKR reductions in 8" FOV.

Ideal Projection View †	Coronary Artery Segment	12" x 16" (Peripheral)	8" x 8" (Cardiac)	Percent AKR Difference 8" x 8" (Cardiac) vs. 12" x 16" (Peripheral)
RAO: 5-10° CRA: 35-45° Test Angle: RAO: 7° CRA: 32°**	LM Ostium LAD Mid LCX Distal RCA Distal/ Crux PDA PLV	 Min. Achievable SID: 103 cm	 Min. Achievable SID: 98 cm	Fluoroscopic: -65% Digital Acquisition: -36%
Lateral CAU/ CRA: 10-30° Test Angle: Lateral CRA: 20°	LAD Distal RCA Mid LIMA Anastomosis	 Min. Achievable SID: 105 cm	 Min. Achievable SID: 105 cm	Fluoroscopic: -38% Digital Acquisition: -27%
RAO: 30-45° Test Angle: RAO: 37°	LAD Distal RCA Mid LIMA Anastomosis	 Min. Achievable SID: 101 cm	 Min. Achievable SID: 99 cm	Fluoroscopic: -68% Digital Acquisition: -45%
LAO: 40-50° CAU: 25-40° Test Angle: LAO: 45° CAU: 32°	LM Bifurcation	 Min. Achievable SID: 112 cm	 Min. Achievable SID: 104 cm	Fluoroscopic: -51% Digital Acquisition: -57%

***Maximum Angle Achievable with the 12" x 16" FPD (Peripheral System)*

Table 2. AKR reduction comparison between the cardiac and peripheral C-Arm for DA and fluoroscopic acquisitions at different projection views.

B. Clinical Studies

Clinical data from 687 procedures with a total of 38,648 irradiation events were collected at Carle Foundation Hospital. The cardiac FPD (8" x 8") was used in 287 procedures, and the peripheral FPD (12" x 16") in 400 procedures.

i. Patient Profile

BMI distributions between the two groups (8" x 8" and 12" x 16") were well matched as indicated by the mean values and standard deviations (SD) in Table 4. Figure 1 depicts the BMI of the patients in group one (8" x 8") in light blue and in group two (12" x 16") in gray.

ii. Procedure Profile

Procedures performed with the cardiac and peripheral C-arms included coronary angiograms, percutaneous coronary interventions (PCI) (also including FFR & IVUS), STEMI work, staged PCI, right heart catheterizations, left ventriculograms, and complex PCI (involving laser, rotablator, balloon pump insertion, and Impella assisted PCI). Chronic total occlusion cases and procedures on severely obese populations were preferentially performed with the peripheral

	Mean ± SD (kg/m^2)
8" x 8"	**32.0 ± 7.8**
12" x 16"	**32.2 ± 8.6**

Table 4. Mean + SD values of BMI of the patients belonging in the two groups. 32.2 ± 9.0 kg/m2 (8x8) versus 32.2 ± 7.2 kg/m2 (12x16)

	Fluoro Time (min.)	Acquisition Frames
8" x 8"	**8.7 ± 9.5**	**710 ± 476**
12" x 16"	**8.2 ± 7.9**	**665 ± 426**
p-value	**0.43**	**0.20**

Table 5. Procedural mean and SD values for fluoroscopic time and acquisition frames.

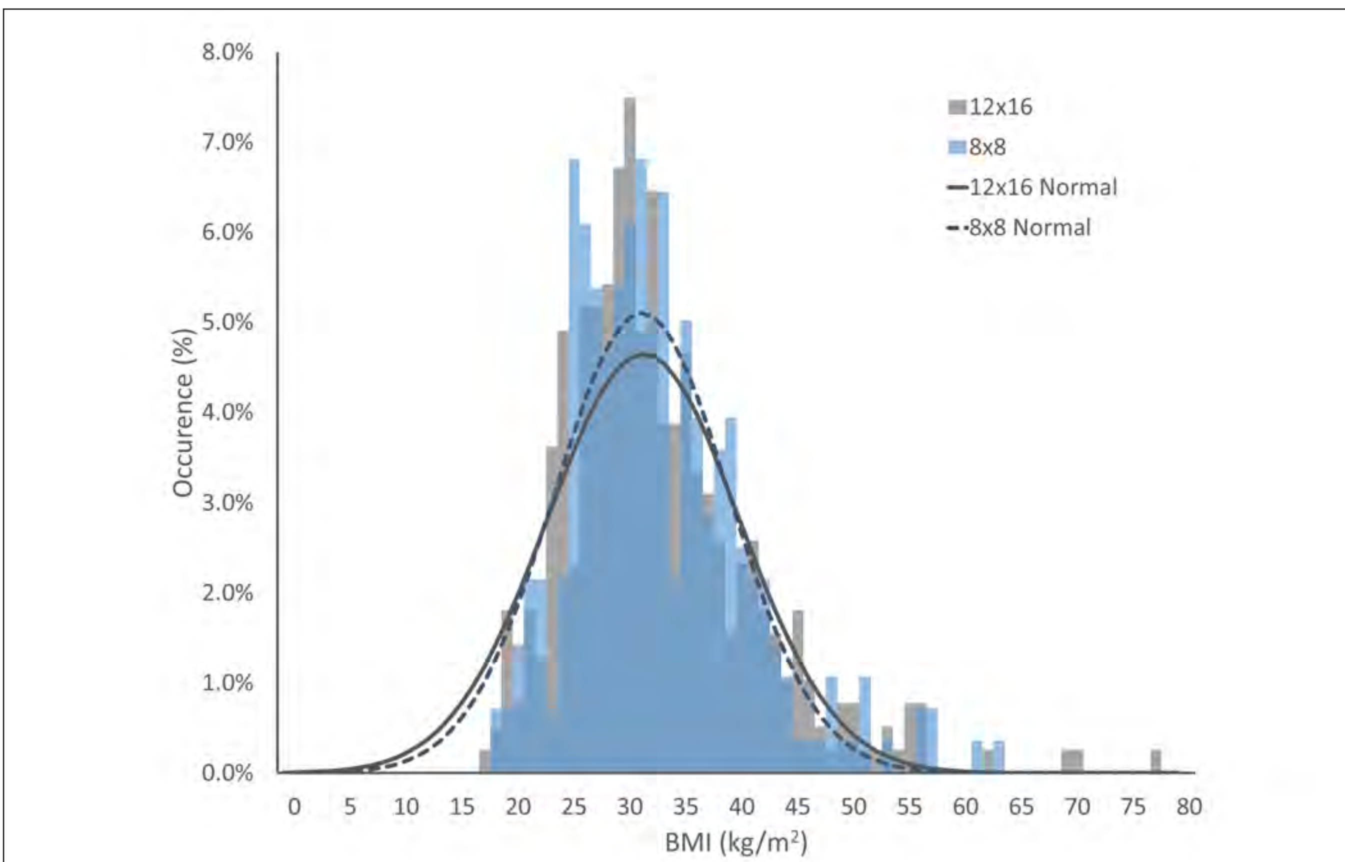


Figure 1. BMI depicted in light blue for group one and gray for group two. Both groups had an approximately normal distribution, as illustrated by the normal distribution fits.

C-arm. The mean values and SD of the fluoroscopic time and acquisition frames per procedure were not statistically different between the two groups (Table 5).

iii. Dose Profiles

Average AKR, mean cumulative and median cumulative values were calculated and compared.

Table 6 shows the average AKR reductions on the cardiac 8" x 8" FPD acquisitions compared with the peripheral 12" x 16" FPD for both fluoroscopic and DA, confirming significant reductions with the cardiac panel.

Specifically, average AKR reductions for fluoroscopic acquisitions were 42 percent and 18 percent for DA.

Mean and median Cumulative Air Kerma (CAK) values were 30 percent and 29 percent lower on the cardiac panel (8" x 8") respectively (Table 7). P-values for the mean CAK values indicate significant statistical difference (p<0.001).

Mean and median CAK values were also compared for reference to the mean and median CAK Advisory Data Set (ADS) based on the Nationwide Evaluation of X-ray Trends (NEXT) survey, which includes data from over 150 facilities across 30 states (Tables 8 and 9).[2] The comparison

Average Air Kerma Rate Reduction			
	Cardiac (8" x 8" FPD)	Peripheral (12" x 16" FPD)	p-value
DA	**18%**	Reference	p<0.001
Fluoroscopy	**42%**	Reference	p<0.001

Table 6. Comparison of average AKR reduction.

Cummulative Air Kerma Reduction		
	Cardiac (8" x 8" FPD)	Peripheral (12" x 16" FPD)
Mean CAK	**30%**	Reference
Median CAK	**29%**	Reference

Table 7. Mean and median CAK for the two groups.

Cummulative Air Kerma Reduction		
	Cardiac (8" x 8" FPD)	ADS (171 facilities, 30 States)
Mean CAK	**75%**	Reference
Median CAK	**73%**	Reference

Table 8. Mean and median CAK reduction values on the cardiac panel compared with the ADS [2].

Cummulative Air Kerma Reduction		
	Peripheral (12" x 16" FPD)	ADS (171 facilities, 30 States)
Mean CAK	**64%**	Reference
Median CAK	**62%**	Reference

Table 9. Mean and median CAK reduction values on the peripheral panel compared with the ADS [2].

demonstrates CAK reductions exceeding 70 percent with the cardiac FPD and 60 percent with the peripheral FPD. Figure 2 shows a box plot of the mean and median CAK values for the cardiac, peripheral panels as a fraction of the respective values from the ADS.

Table 10 summarizes the differences in geometric factors including average FOV, focal spot size, fluoroscopy beam filter, and absolute primary/secondary angles. Utilization of the cardiac C-arm resulted in shorter SIDs. A shorter SID provides dual benefit in reducing AKR by the inverse square law and also in having less geometric unsharpness, which improves image quality. Additionally, the average focal spot size was approximately 20 percent lower on the cardiac C-arm, which further improves resolution due to less geometric unsharpness. The cardiac C-arm also resulted in smaller FOVs. Smaller FOVs result in less tissue irradiated. Fluoro beam filtration was greater by 20 percent, which generally results in lower skin dose. Lastly, the cardiac C-arm enabled a small, but statistically significant increase in average C-arm angulations, as expected based on the smaller profile housing.

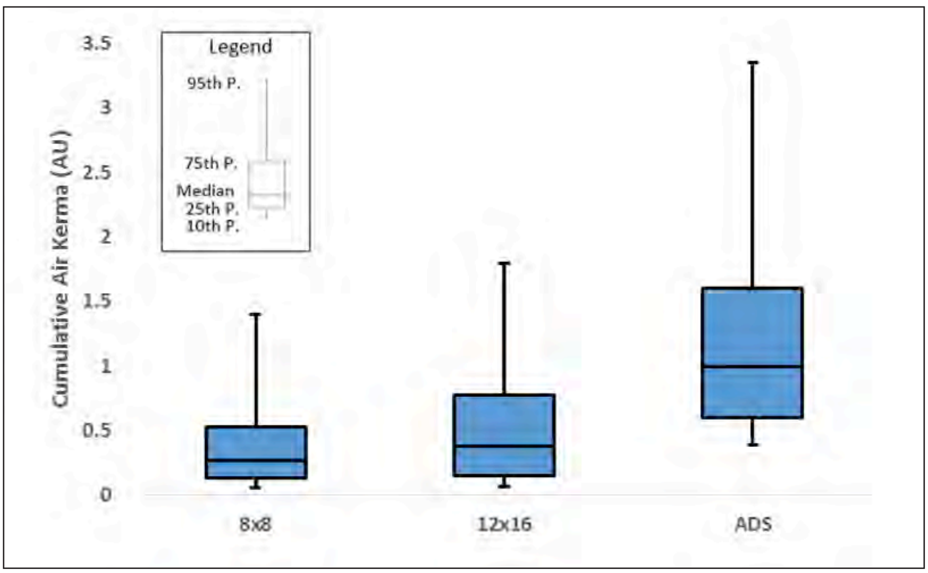


Figure 2. Box plot of the mean and median CAK values for the cardiac and peripheral panels as a fraction of the respective values from the ADS.

Geometry Factors			
	Cardiac (8" x 8" FPD)	Peripheral (12" x 16" FPD)	p-value
SID	**101.2 ± 4.3 cm**	**105.4 ± 5.5 cm**	**p<0.001**
Average FOV	**17.3 x 17.3 cm**	**19.8 x 19.8 cm**	**p<0.001**
Average Focal Spot Size	**0.51 mm**	**0.63 mm**	**p<0.001**
Average Fluoro Beam Filter	**0.35 (mm Cu)**	**0.29 (mm Cu)**	**p<0.001**
Average Absolute Primary/ Secondary Angles	**17.8/11.9**	**16.8/10.7**	**p<0.04**

Table 10. Average values of geometry factors for the different groups and associated p values.

2. Dose Tracking System (DTS)

Canon Medical Systems is offering DoseRite™, a comprehensive and unique suite of dose management tools. One of these tools is DTS, the world's first and only real-time dose tracking system. DTS estimates dose delivered to the skin in real time and displays it on a color-coded map (Figure 3) during procedures, allowing physicians to continuously monitor exposure and make adjustments.

3. Next Generation Technology

Next generation detector technology, which was not utilized in the data presented herein, provides high-quality fluoroscopic and fluorographic images with detective quantum efficiency at 77± 5 percent and redesigned lower-noise electronics. The new Detector Technology along with next generation DoseRite dose management tools including Advanced Image Processing (AIP) with Super Noise Reduction Filter (SNRF), Spot Fluoroscopy, ROI fluoroscopy, Live Zoom, and many others, are expected to drive even further improvements in dose reduction while maintaining IQ.

CONCLUSION

Infinix-i Dual plane is a versatile imaging system offering exceptional performance for every application. Bench and clinical data acquired on dedicated cardiac and peripheral C-arms were compared to demonstrate its benefits. Utilization of the cardiac C-arm with the smaller FPD (8" x 8") resulted in 42-45 percent and 18-37 percent reduction in average AKR in fluoroscopic and DA modes respectively. Mean and median CAK reductions approached 30 percent in a clinical comparison of 687 patients. Shorter SIDs achieved with the cardiac C-arm, its smaller focal spot size, and greater beam filtration are factors that contributed to the dose reductions while providing better sharpness.

Finally, the acquired data on the Canon Medical Systems technology were also compared for reference to the CAK ADS, demonstrating CAK reductions exceeding 70 percent with the cardiac FPD and 60 percent with the peripheral one.

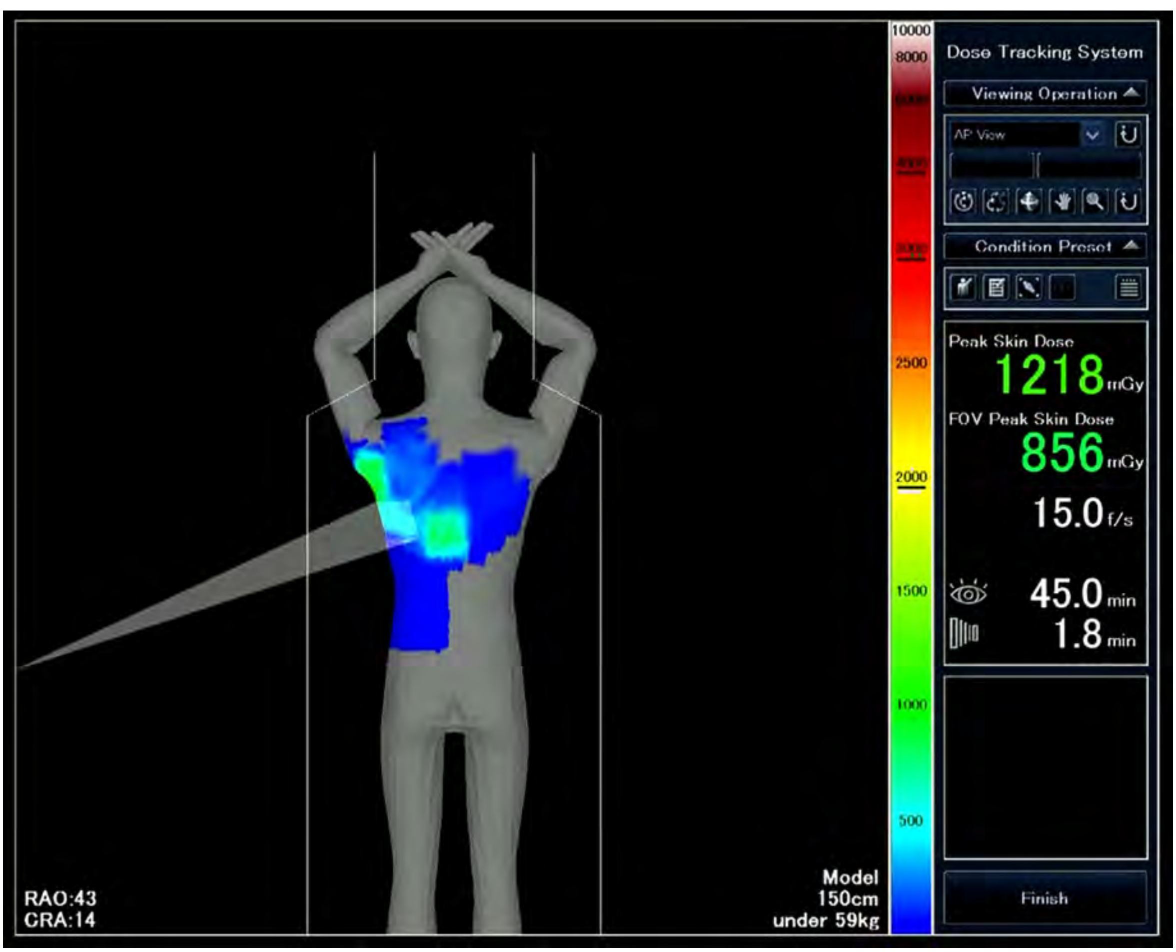


Figure 3. World's first and only real-time dose tracking system.

REFERENCES

1. *C.D. Mario and N. Sutaria, "Coronary angiography in the angioplasty era: Projections with a meaning", Heart, 91, 968-976, 2005*

2. *D.L. Miller, C.M. Hilohi, and D.C. Spelic, "Patient radiation doses in interventional cardiology in the U.S.: Advisory data sets and possible initial values for U.S. reference levels," Medical Physics, 39, 10, 6276-6286, 2012*

Canon

CANON MEDICAL SYSTEMS USA, INC.

https://us.medical.canon

2441 Michelle Drive, Tustin CA 92780 | 800.421.1968

VLWP12859US MCAXR0302EBA

Made For life