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A novel robotic radiation shielding device for interventional cardiology procedures

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Introduction

Fluoroscopy-guided interventional procedures are the leading source of occupational ionising radiation exposure for medical personnel[1]. The prevailing radiation protection measures for interventional personnel include: reduced radiation imaging systems, personal protective clothing, ceiling-mounted shields and table-skirts. However, interventional personnel continue to be exposed to high cumulative doses of X-ray radiation, which may increase the risk for malignancies[1], early development of cataracts[2], and orthopaedic problems due to the heavy weight of lead aprons[3].

Newer dedicated solutions, such as suspended radiation protection systems[4] and a remote-controlled robotic system[5,6], provide protection only to the main operator, limit free movement (zero-gravity) and require a significant learning curve (CorPath). The application of a lead-attenuator across the patient's abdomen/pelvis reduces radiation exposure[6-8], but this is limited during femoral access procedures.

The Radiaction Shielding System (RSS; Radiaction Ltd.) was developed to provide full-body protection from scattered radiation to all medical personnel in the interventional suites by encapsulating the imaging beam and blocking the scattered radiation at its origin. It comprises an upper shield around the image detector and a lower shield around the X-ray source, thereby creating a barrier around the imaging beam **(Supplementary Figure 1)**.

The aim of the study was to test the efficacy of the RSS using a phantom for measurements in a clinical laboratory, and to evaluate the feasibility and initial user experience during real-time coronary catheterisation procedures, electrophysiological (EP) procedures and implantations of cardiovascular implantable electronic devices (CIED).

Methods

THE SHIELD SYSTEM

The RSS comprises four main components **(Supplementary Figure 1)**: 1) two robotic extendable shields, upper and lower, composed of discrete overlapping lead-free radiation-blocking segments, assembled on the C-arm around the X-ray tube and image receptor. The device utilises sensors and controls to deploy and retract its attenuating segments and to accommodate C-arm angulation and table movement; 2) a table-mount control panel; 3) indication lights that show the system's state; and 4) a patient face guard (physical barrier).

Prior to C-arm rotation, the operator retracts the shields to allow undisturbed C-arm motion. Once the C-arm reaches the desired orientation, the shields quickly deploy by extending the telescopic segments and their flexible edges **(Supplementary Figure 1)**. During table panning the RSS can be operated in hover mode, where the segments are partially deployed, thus allowing the table to be freely moved.

BENCH TESTS

The RSS was tested using a phantom for measurements in a clinical laboratory (RANDO anthropomorphic phantom; The Phantom Laboratory). Radiation rates were measured at different locations around the C-arm at two heights (waist and head), at all relevant C-arm angles, and according to X-ray energy levels (nominal and worst-case kV levels). Scattered radiation dose rate measurements were compared in two different setups: without the RSS versus with the RSS deployed **(Supplementary Figure 2)**. In both setups, no additional external shielding was used (no table-mounted drapes, suspended shields etc.).

The scattered radiation was measured by eight sensors: four ion chambers (model 10X6, 1800; Radcal Inc.) and four dose diodes (DDX6-WL solid state low dose sensor; Radcal Inc.). The accuracy for dose and dose rate measurement using the ion chamber or the dose diode is ±5%. The sensors used were designed to work in the range of diagnostic energy levels and low-level radiation doses **(Supplementary Appendix 1)**. The minimum sensitivities of the sensors for bench tests were: ion chamber: 0.01 nSv and solid-state sensor: 0.2 nSv.

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PERFORMANCE ASSESSMENT IN REAL CLINICAL ENVIRONMENT

The RSS was installed for one week in the coronary catheterisation laboratory (CL) and for one week in the electrophysiology (EP) laboratory at Assuta Ashdod University MC. During these two weeks, all procedures were performed with the RSS, except for emergent coronary catheterisations **(Supplementary Table 1)**. This was a non-randomised, non-controlled performance assessment in a real clinical environment. Radiation measurements while using the RSS were compared retrospectively to radiation measurements during a prior week without the RSS. In both setups, standard protection measures were used (i.e., table-mounted drapes and a ceiling-suspended shield). Training was provided for all the staff. Three types of procedures were studied: 1) non-emergent coronary catheterisations; 2) EP procedures; and 3) left-sided CIED implantations.

The sensors' locations in the coronary and EP laboratory and technical details are described in **Supplementary Appendix 2** and **Figure 1**. Sensors #4 (chest height) and #5 (pelvis height) in the CL were placed on the physicians, outside the lead aprons; therefore, they reflect the combined protection of the RSS plus the suspended and table shields. Thermo-luminescent dosimeters (TLD; Soreq Nuclear Research Center) were used for radiation dose measurements **(Supplementary Appendix 3)**. The minimum sensitivity of the TLD sensor for a clinical environment was 0.1 mSv.

Average dose rates were calculated by dividing total dose (in mSv) by the total radiation time (sec). Detailed feedback from the users regarding system operation, workflow and safety was obtained.

STATISTICAL ANALYSIS

Scatter dose measurements in the bench studies were taken at 38 different C-arm angles. Radiation doses were normalised to exposure time (radiation dose rates). Radiation reduction was calculated in relation to the dose-rate calculations without the shields **(Supplementary Appendix 1)**. In addition, the median reduction for all C-arm angles measured was calculated with a 95% confidence interval (CI).

A non-parametric, Wilcoxon signed-rank test was used for comparison of radiation dose rates, with and without radiation shields, using GraphPad Prism version 9.0.0 (GraphPad Software). Values were paired according to C-arm angulation.

Results

BENCH TESTS

The RSS CL bench tests showed significant radiation reduction performance under full usage of the system, compared to no shielding at all, both in the absence of conventional shielding (93% for main physician – position 1, 94% for second physician – position 4, and an average of 91.5% in all locations) **(Table 1, Figure 2, Central illustration, Supplementary Figure 3)**.

CLINICAL ENVIRONMENT

Radiation sensors measured total accumulated daily and weekly doses. Average dose rates were calculated according to actual

Table 1. Median radiation rates using phantom with and without Radiaction radiation shields (RSS).

	80 kV		
	Without RSS	With RSS	n
	Radiation rate-median [uSv/h] (IQR)		*p*-value*
Main physician			38
Head	246 (155-898)	28 (11-79)	*p*<0.0001
Body	1,165 (865-1,585)	103 (84-213)	*p*<0.0001
Echo operator			38
Head	271 (203-503)	31 (18-62)	*p*<0.0001
Body	556 (405-849)	48 (38-83)	*p*<0.0001
Nurse/technician			38
Head	46 (35-89)	6 (3-24)	*p*<0.0001
Body	72 (53-105)	16 (11-24)	*p*<0.0001
Second physician			38
Head	136 (109-362)	22 (8-67)	*p*<0.0001
Body	314 (225-402)	50 (32-68)	*p*<0.0001
	120 kV		
	Without RSS	With RSS	
Main physician			10
Head	1,951 (1,401-4,741)	248 (126-730)	*p*=0.002
Body	4,928 (4,384-6,127)	700 (587-1,085)	*p*=0.002
Echo operator			10
Head	1407 (997-1,732)	187 (145-345)	*p*=0.002
Body	2359 (2,036-2,719)	365 (292-476)	*p*=0.002
Nurse/technician			10
Head	234 (156-295)	56 (30-99)	*p*=0.002
Body	332 (292-346)	94 (82-121)	*p*=0.002
Second physician			10
Head	876 (608-1,814)	183 (77-777)	*p*=0.002
Body	1,237 (1,154-1,510)	261 (232-358)	*p*=0.002
*Wilcoxon matched-pairs test			

X-ray time, as recorded by the fluoroscopy system **(Supplementary Table 2, Supplementary Table 3, Supplementary Figure 4, Supplementary Figure 5)**. Despite the low procedure sample size, average scatter radiation dose rates were significantly lower with the RSS versus without the RSS in both the EP and the CL at different locations around the C-arm **(Figure 1)**. In the CL, for both upper and lower body sensors of the primary operator (sensors #4,5, **Figure 1**, **Supplementary Table 2**, **Supplementary Figure 4**) with the RSS, the average radiation dose rates were below the detection threshold, compared to 0.13 mSv/h without the RSS. The total weekly radiation time was similar (358.4 minutes without and 384.2 minutes with the RSS). For two ablation procedures, the average radiation rate in all three upper body sensors (sensors #1,2,6, **Figure 1**, **Supplementary Table 3**, **Supplementary Figure 5**) with the RSS was below the detection threshold, and was not available for control ablation procedures (these data were not included in the average calculation). The average dose rate below the table (sensor #3, **Figure 1**, **Supplementary Table 3**, **Supplementary Figure 5**) was 0.232 mSv/h with

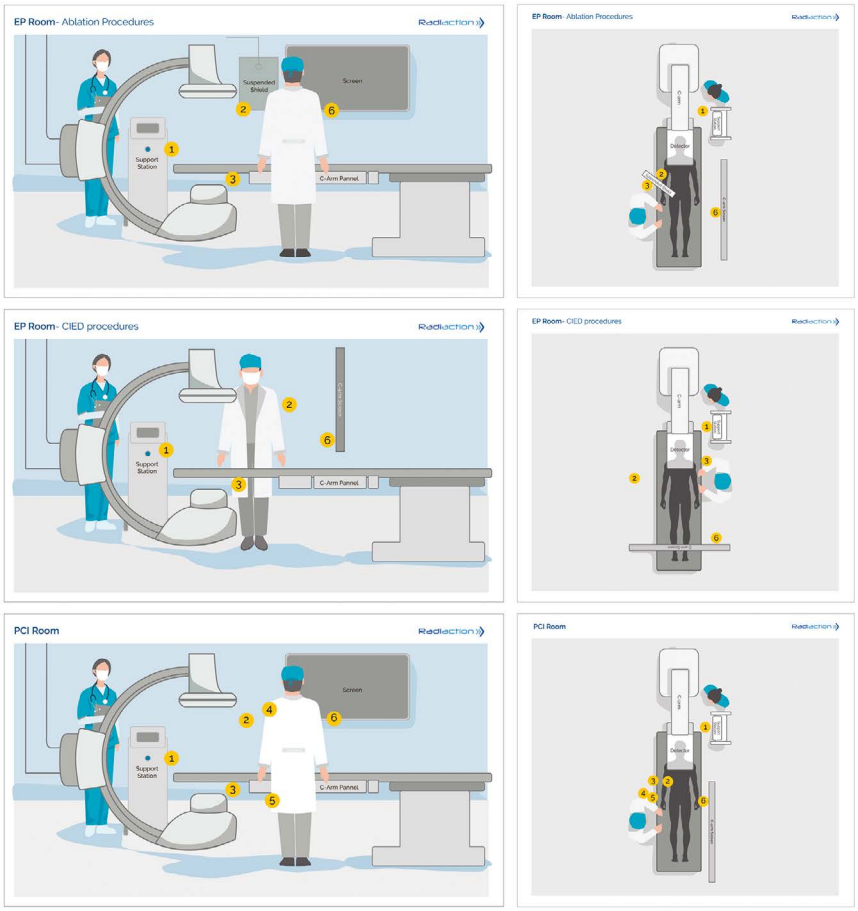

Figure 1. *RSS sensor locations. Side view (left) and top view (right) with placement of the six sensors. EP room/ablation procedures: sensor #1: on support system/nurse station, #2: inner side of clear suspended shield (facing C-arm), #3: under the table (inner side of the table mounted drape), #6: on the viewing monitor (chest height); EP room/CIED implantations procedures: sensor #1: on support system/nurse station, #2: inner side of clear suspended shield (facing C-arm, right side of patient), #3: under the table (inner side of the table mounted drape), #6: on the viewing monitor (chest height); PCI room (coronary interventions): Sensor #1: on support system/nurse station, #2: inner side of clear suspended shield (facing Carm), #3: under the table (inner side of the table mounted drape), #4: on physician chest height outside lead apron, #5: on physician pelvis height outside lead apron, #6: on the viewing monitor (chest height). CIED: cardiovascular implantable electronic devices; EP: emergency procedure; PCI: percutaneous coronary intervention; RSS: Radiaction Shielding System*

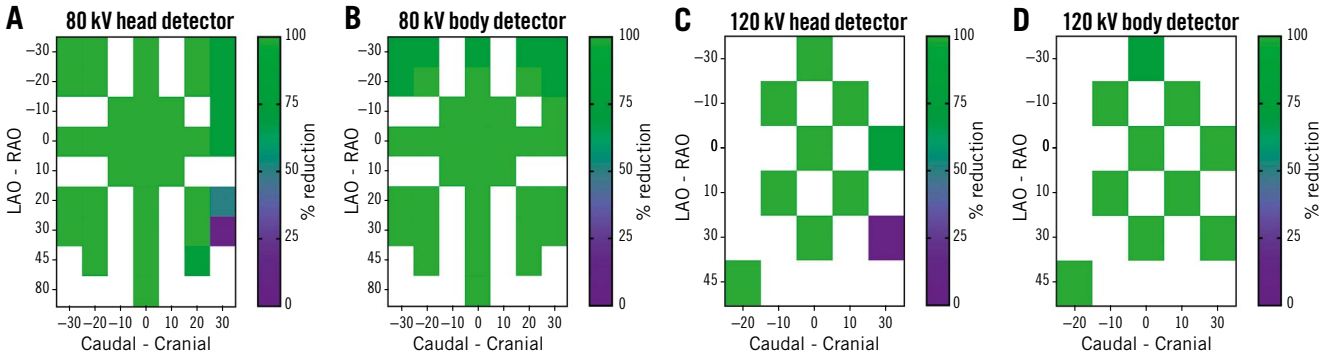

Figure 2. *Scattered radiation reduction performance at different CL personnel positions (bench tests). The X-axis represents the C-arm angle in the caudal-cranial plane, the Y-axis represents the C-arm angle in the LAO-RAO plane. A, B) Percentage of radiation reduction (averaged) while using the radiation shields at 80 kV as depicted by the primary operator head detector (height of 155 cm from the floor) and body detector (height of 75 cm from the floor). The colour scale represents the percentage of radiation reduction in 0-25%, 25-50%, 50-75% and 75-100% categories. C, D) Percentage of radiation reduction while using the radiation shields at 120 kV as depicted by the primary operator head detector (height of 155 cm from the floor) and body detector (height of 75 cm from the floor). LAO: left anterior oblique; RAO: right anterior oblique*

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CENTRAL ILLUSTRATION Mean radiation rate reduction of the robotic Radiaction Shielding System (RSS).

Bench tests (left); coronary catheterisation procedures (middle); electrophysiology and CIED procedures (right) CIED: cardiovascular implantable electronic devices; EP: emergency procedure.

the RSS and 1.546 mSv/h without the RSS – an 85% reduction. For 10 CIED implantation procedures, the average radiation dose rate in the upper body sensors (sensors #1,2,6, **Figure 1**, **Supplementary Table 3**, **Supplementary Figure 5**) was 0.0055 mSv/h with the RSS and 0.23 mSv/h without the RSS – a 97% reduction. A 77% reduction in average dose rate was measured in the lower body sensor (0.289 mSv/h with the RSS vs 1.257 mSv/h without the RSS). In all CIED implantation procedures, the upper skirts of the RSS above the incision area had to remain retracted to enable the physician's optimised visualisation of the operation field. The total weekly radiation time for all EP procedures was similar (231.9 minutes without shields vs 181.5 with the RSS). The mean radiation rate reduction over all sensor locations was 91.2±8.9% (range 78.4-100%) in the CL, and 93.3±12.3% (range 77-100%) in the EP laboratory, including CIED implantations **(Central illustration, Supplementary Table 2, Supplementary Table 3, Supplementary Figure 4, Supplementary Figure 5)**.

USER EXPERIENCE

Supplementary Table 4 presents the ranking given to a seven-question survey. The feedback showed good satisfaction levels for RSS integration into the procedure workflow and the short learning curve. The satisfaction was less pronounced for the CL team due to limitations and alarms in steep cranial angulations which delayed work flow for a few seconds (with no safety issues).

The feedback showed that the operation of the device is intuitive and simple and does not add significant time to the procedure; the users felt that the RSS was safe, with no perceived changes in image quality. The operators did not notice signs of anxiety or stress in patients concerning the face guard and shields.

Discussion

The RSS is a novel robotic radiation shielding system that provides full-body protection to all medical personnel during fluoroscopy-guided procedures. This is the first study to test the efficacy of this system on a phantom model and to evaluate its feasibility during live interventional cardiology procedures.

Our bench tests showed significant radiation reduction performance under full usage of the system in the absence of conventional shielding, potentially providing 93-94% exposure reduction to physicians in coronary procedures and 87-93% to all medical team members. For the real-world first-in-man use of the RSS, the mean radiation rate reduction was above 90% for all sensor locations in both CL and EP procedures.

User feedback proved the feasibility and ease of use of the system within a short learning curve, with no apparent disturbance to the patient's well-being. The higher ranking in the survey by the EP team may be due to fewer C-arm rotations and the steep cranial angulations required in the CL.

Reducing high radiation exposure during medical procedures has been the principal task of many professional societies and advisory groups[9,10].

The RSS, therefore, has the potential to improve medical team safety by offering radiation reduction to all interventional staff. It provides radiation reduction to the entire body, at all angulations, and appears to integrate smoothly into the clinical workflow. It

is recommended, however, to maintain existing standard shielding until additional clinical data are available.

Limitations

Firstly, the first-in-man data were limited and not from a randomised controlled study. Secondly, operators were given the discretion to choose whether to use the RSS or not, and to what degree (fully or partially). This variability may have attenuated the potential benefit from the system. Thirdly, the RSS was not used for emergent coronary procedures, and finally, current sensors might not be sensitive enough in this dose range.

Future studies should measure radiation exposure per specific procedures using more sensitive sensors, employ a controlled randomised design, and a large number of procedures should be performed beyond the operator's learning curve. Further studies and improvements of the system may potentially lead to a reduction in the need for personal protective clothing.

Conclusions

This first report of the RSS bench testing and performance in a live clinical environment shows a significant reduction (but not elimination) of radiation and a high level of integration in the clinical workflow, as well as a good safety profile for both coronary and EP procedures. Thus, the RSS may have an important role in both full-body and whole team protection from scattered radiation during interventional cardiology procedures. Until more data are available to show elimination of radiation by the RSS, it is recommended to maintain existing standard shielding.

Impact on daily practice

Current standard radiation protection fails to fully protect interventional cardiology personnel from scattered radiation, leaving the head, hands and feet exposed. A novel robotic radiation protection device was developed to provide full-body protection to all medical personnel by encapsulating the imaging beam and blocking scattered radiation. Bench tests show significant radiation reduction, and preliminary clinical evaluation shows the system is safe and highly integrated into the clinical workflow.

Conflict of interest statement

E. I. Lev and A. Finkelstein received payments as clinical advisors for Radiaction Ltd.. A. Finkelstein serves as a proctor and consultant for Medtronic and for Edwards Lifesciences. The other authors have no conflicts of interest to declare.

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Supplementary data

Supplementary Appendix 1. Calculation of dose rate and radiation reduction.

Supplementary Appendix 2. Procedure characteristics.

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Supplementary Table 1. Procedures done during performance assessment in real clinical environment.

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Supplementary Figure 3. Scattered radiation reduction performance at different catheterisation laboratory (CL) personnel positions (bench tests).

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The supplementary data are published online at: https://eurointervention.pcronline.com/doi/10.4244/EIJ-D-21-00577

Supplementary data

Supplementary Appendix 1. Calculation of dose rate and radiation reduction.

The dose rate was calculated as follows:

$$Dose\ rate\ \left[\frac{\mu Sv}{h}\right] = Dose\ [nSv]\ /time[sec]\ \text{x}\ 3.6$$

The radiation reduction was calculated in relation to the dose rate calculations without the shields as follows:

$$Radiation\ reduction\ [\%] = \left(1 - \left(\frac{AVG\ Dose\ rate_{with\ Shields}}{AVG\ Dose\ rate_{without\ Shields}}\right)\right) \text{x}\ 100$$

Supplementary Appendix 2. Procedure characteristics.

Sensor locations

Sensor 1 was located on the support station (nurses, tech); Sensor 2 was located on the suspended clear shield, facing the C-arm (direction of main physician's head, but much closer to the radiation field); Sensor 3 was placed at the top of the table's lead drape, facing the C-arm (direction of main physician's pelvis, but much closer to the radiation field); Sensor 6 was located on the screen, opposite side of the table, in front of main physician's face (similar to the main physician's location due to symmetry).

Supplementary Appendix 3. Sensor data sheets.

a) Bench tests:

Ion chamber:
Manufacturer: Radcal Inc., USA

10X6-1800
The Radiation Protection Chamber

For very low-level radiation measurements such as shielding, leakage, irradiators and environmental. Superior to typical survey meters for accuracy.

Specifications[1]

Rate Specifications	0.1 mR/hr - 18 mR/s 0.1 µGy/hr - 200 µGy/s
Exposure Specifications	1 nR - 196 R 0.01 nGy - 1.7 Gy
Auto Dose Threshold	7 µR/s 63 pGy/s
Cine Specifications:	N/A
Calibration Accuracy:	±4% using X-rays @ 150 kVp & 10.2 mm Al HVL
Exposure Rate Dependence:	±0%,-5%, 0.1 mR/hr to 20 R/hr, -10% to 65 R/hr
Energy Dependence	±5%, 30 keV to 1.33 MeV (with build up material)

Solid state sensors:
Manufacturer: Radcal Inc., USA

SENSORS:	DDX6-WL	
Min Rate:	50 nR/s	500 pGy/s
Max Rate:	0.65 R/s	5.7mGy/s
Min Dose:	200 nR	2 nGy
Max Dose:	1.8 kR	15 Gy
Accuracy:	±5% using X-rays @ 80kVp with 2.5 mm Al total filtration (IEC 61267 RQR-6)	
Energy dependence:	± 5% from 50 kVp to 120 kVp at 2.5 mm Al	
Filtration dependence:	+10% to -5% from 2.5 mm Al to 23 mm Al	

b) Assuta clinical data – TLD (personal dosimeter badges):

Manufacturer: SNRC, Israel
Min detection threshold: 0.1 mSv
Measurement error:
<0.1 mSv=25%
0.1-0.5 mSv=10%
>0.5 mSv=7%
Angular performance=+/-45% with negligible angular dependency within this range and when X-ray energy >20 kV

Supplementary Table 1. **Procedures done during performance assessment in real clinical environment.**

https://youtu.be/q0rFWBaIxng

	Coronary lab	EP lab	Total
Days (n)	5	4	9
Procedures with shield (n)	23	12	35
Types of procedures	Diagnostic PCI, CTO, STEMI	EPS, ablation, CIED implantation	
Physicians using shield (n)	6	3	9
Procedures without shield (n)	22	12	34

CIED: cardiovascular implanted electronic devices; CTO: chronic total occlusion; EP: electrophysiology; PCI: percutaneous coronary intervention; STEMI: ST-elevation myocardial infarction

Supplementary Table 2. Radiation data for PCI – clinical use.

Procedure	Total X-ray time (min)	Total patient DAP (Gy*cm^2)	Sensor position	Accumulated radiation dose with RSS (mSv)	Dose rate with RSS (mSv/h)	Average dose rate without RSS (mSv/h)	Dose reduction (%)	Average dose reduction
PCI #1	5.3	26	1. Nurse station	0.002	0.026	0.206	87.2%	82.8%
			2. On suspended shield	0.071	0.799	3.694	78.4%	78.1%
			3. Below table	0.003	0.033	0.824	96%	98%
			4. Physician's chest	0.000	0.000	0.143	100%	100%
			5. Physician's pelvis	0.000	0.000	0.114	100%	100%
			6. On screen	0.004	0.046	0.475	90.3%	88%
PCI #2	15.8	65	1. Nurse Station	0.012	0.044	0.206	78.5%	
			2. On suspended shield	0.216	0.818	3.694	77.9%	
			3. Below table	0.000	0.000	0.824	100%	
			4. Physician's chest	0.000	0.000	0.143	100%	
			5-.Physician's pelvis	0.000	0.000	0.114	100%	
			6. On screen	0.018	0.067	0.475	85.8%	

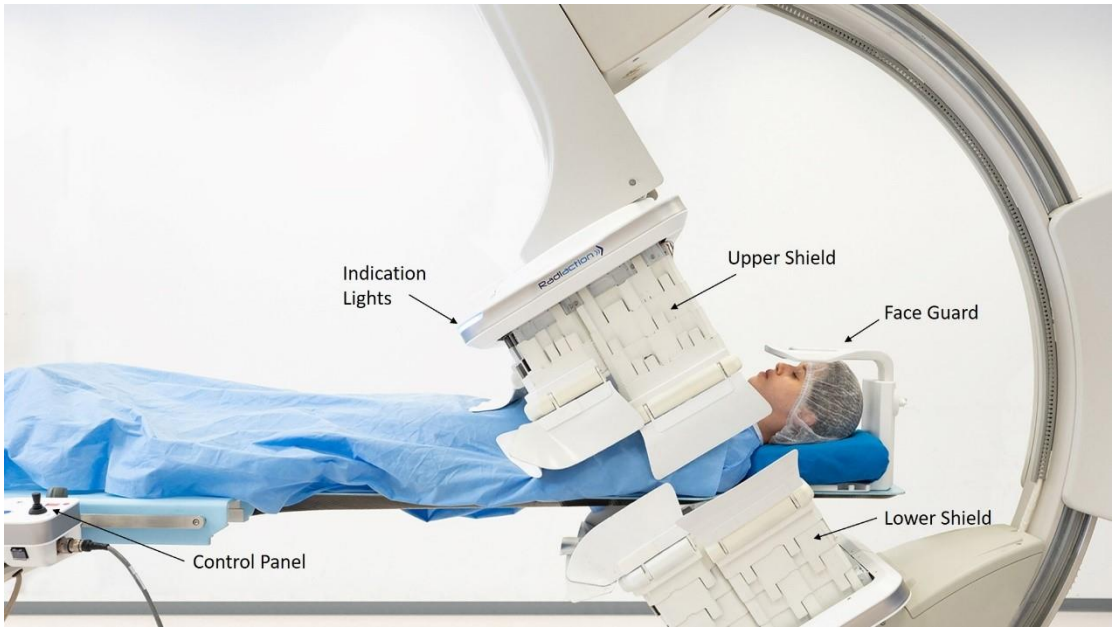
Supplementary Table 3. Radiation data for EP – clinical use.

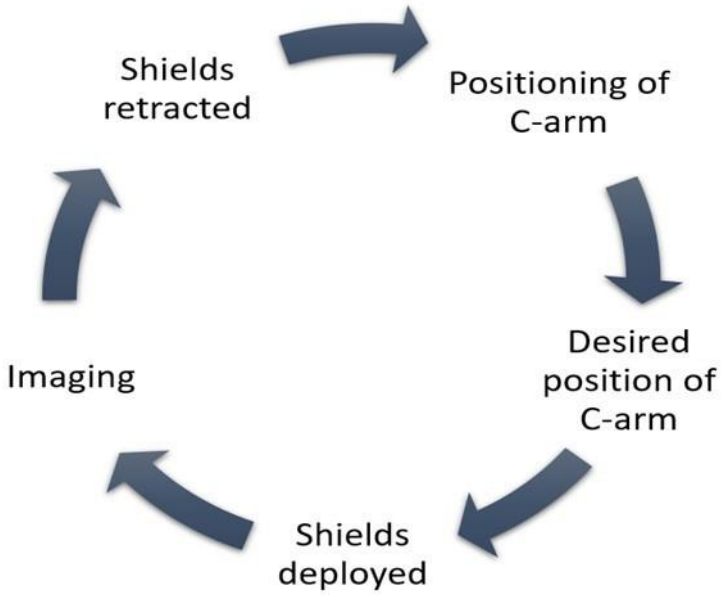
	Sensor position	Accumulated radiation dose with shields (mSv)	Accumulated radiation dose without shields (mSv)	Dose rate with shield (mSv/h)	Dose rate without shields (mSv/h)
Ablations	1. Nurse station	0	N/A	0	N/A
	2. On suspended shield	0	N/A	0	N/A
	3. Below table	0.215	8.44	0.232	1.546
	6. On screen	0	N/A	0	N/A
CIED	1. Nurse station	0	0.2	0	0.05045
	2. On suspended shield	0.05	1.84	0.01653	0.47476
	3. Below table	0.87	4.86	0.289	1.25741
	6. On screen	0	0.64	0	0.16558

Supplementary Table 4. RSS user experience questionnaire.

	Question	**CL physicians**, n=12 Mean (SD)	**EP physicians**, n=12 Mean (SD)	**Medical personnel**, (non-physicians) n=4 Mean (SD)
Q1	The operation of the shield does not interfere with procedure workflow (1-6)	4.01 (0.86)	4.33 (0.75)	4 (1.33)
Q2	The device's operation logic is intuitive and simple (1-6)	3.92 (0.67)	5.5 (0.5)	5.25 (0.43)
Q3	The operation of the shields does not add significant time to the procedure (1-6)	5.83 (0.38)	5.3 (0.47)	5.5 (0.65)
Q4	The shield system feels safe to use	6 (0)	5.5 (0.5)	NA
Q5	Was there a change in image quality while using the shield system? (1-6)	1 (0)	1 (0)	NA
Q6	Did you notice signs of anxiety/stress of patient concerning the face guard?	1 (0)	1 (0)	NA
Q7	How many working days will it take to get fully used to the system? (range)	1-5	2	1-10

Grade 1-6; 1: strongly disagree; 6: completely agree





Supplementary Figure 1. Radiaction Shield System – components and method of use.

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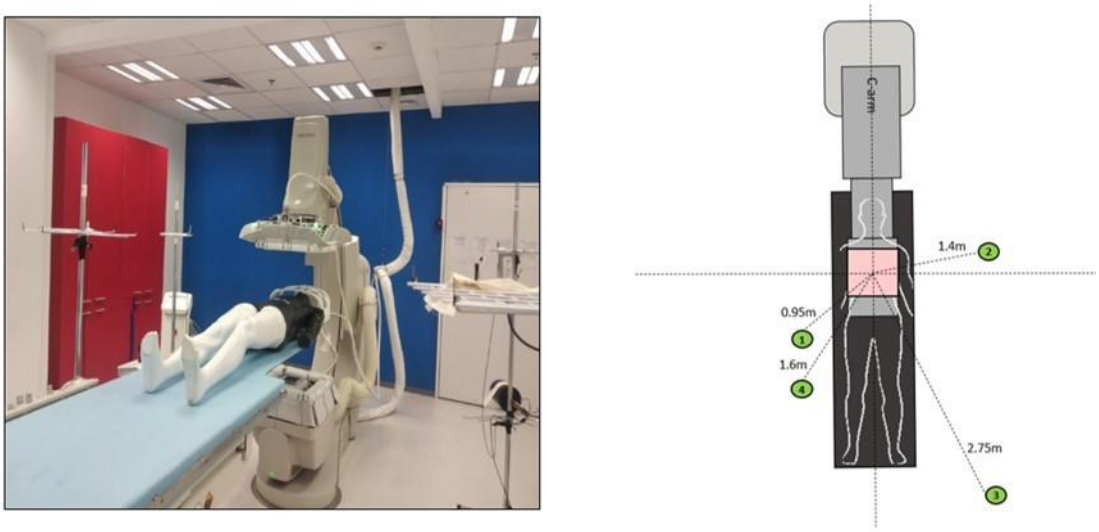
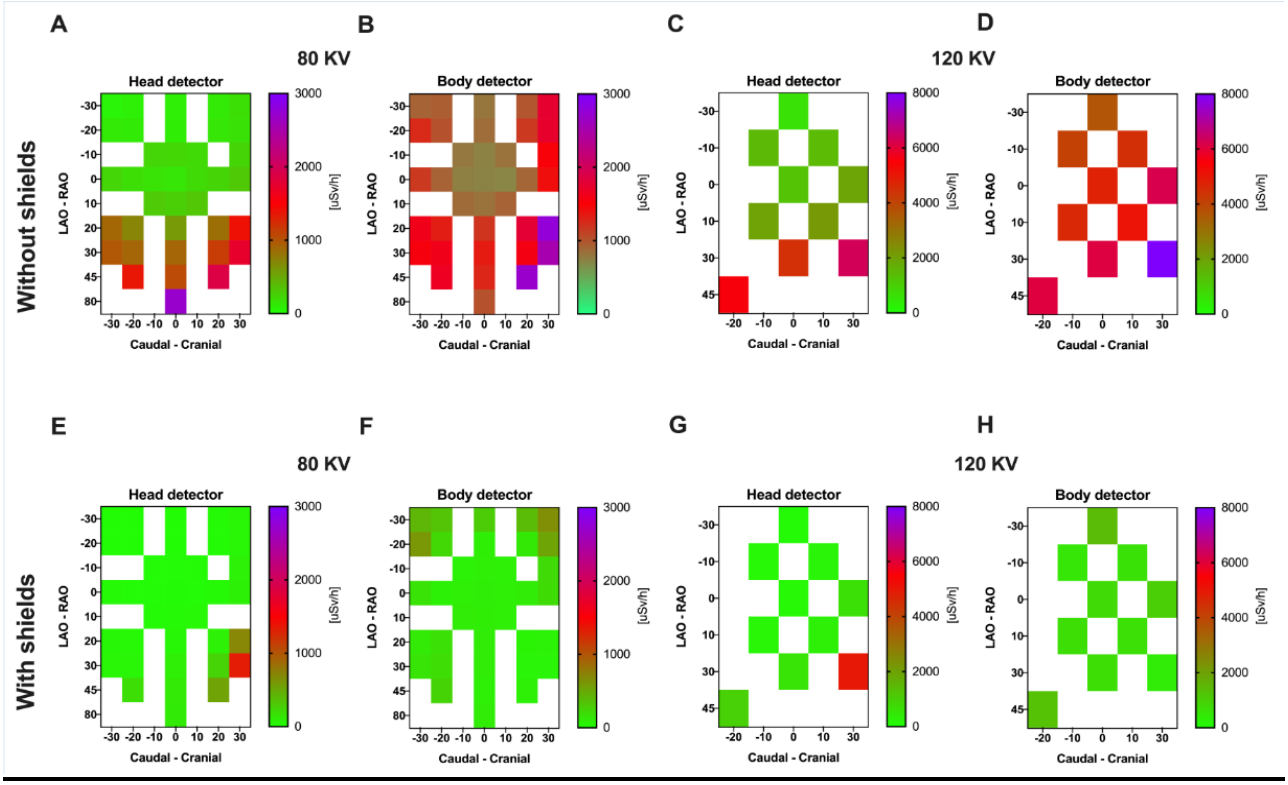


Supplementary Figure 2. Bench test setup.



Supplementary Figure 3. Scattered radiation reduction performance at different catheterisation laboratory (CL) personnel positions (bench tests).

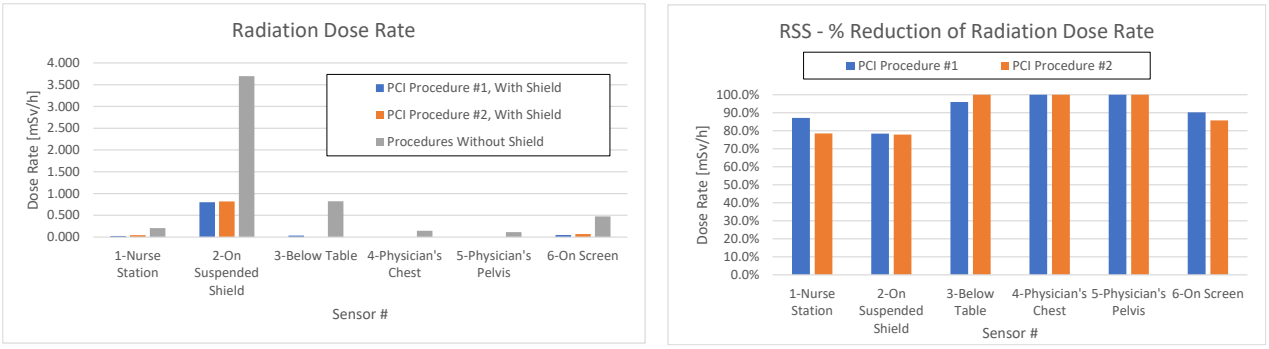
The X-axis represents the C-arm angle in the caudal-cranial plane, the Y-axis represents the C-arm angle in the LAO-RAO plane, either without RSS (A-D) or with RSS (E-H). The colour scale represents the averaged radiation rate. The averaged percentage of radiation reduction (the difference) is shown in the main manuscript.

A, E. Averaged radiation rate at 80 KV without and with radiation Shields as depicted by the primary operator head detector (height of 155 cm from the floor).

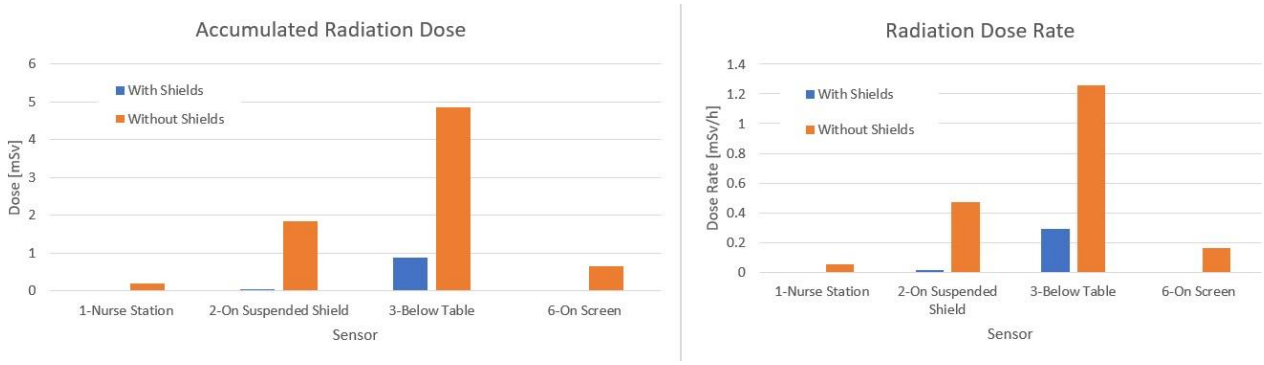
B, F. Radiation rate at 80 KV depicted from the body detector (height of 75 cm from the floor).

C, G. Averaged radiation rate at 120 KV without and with radiation shields as depicted by the primary operator head detector.

D, H. Radiation rate at 120 KV depicted from the body detector (height of 75 cm from the floor).



Supplementary Figure 4. Radiation data for PCI – clinical use.



Supplementary Figure 5. Radiation data for EP – clinical use.