SCATTER MATTERS

Everyone Deserves Protection

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System Overview and Clinical Data

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Challenges Facing Hospital and Interventional Labs

Hospital Challenges

- Staffing shortages
- Staff recruitment
- Staff retention
- Tight capital budgets
- Staff safety

Cath & IR Lab Challenges

- Lost time due to overexposure (cataracts, lesions, cancer)
- Overcrowded procedure rooms
- Workflow efficiency

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The Entire Interventional Team is at Risk from Scatter Radiation

Interventional Cardiologist Career Exposures

- 50 mSv-200mSv
  (equivalent to 2,500-10,000 chest x-rays)
- Head exposure: 1,000 mSv
  (equivalent to 50,000 chest x-rays)

Longer, more complex procedures (TAVR, CTOs, Multi-Vessel), lead to more exposure for Interventional Teams

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3 Cs of Scatter Radiation

The Health Risks From Scatter Radiation are Real

HEALTH EFFECT	ODDS RATIO (95% CI)
CATARACTS	6X RISK
CANCER SKIN CARCINOMA, THYROID, BRAIN	3X RISK
CARDIOVASCULAR INCREASED CVD	2X RISK

*The Odds ratio is the multiple or the normal occurrence of each condition in healthcare personnel not working in x-rays labs. Reference: Andreassi MG, Piccaluga E, Guagliumi G, et al. Occupational health risks in cardiac catheterization laboratory workers. Circ Cardiovasc Interv. 2016,9:003273.

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Feature | Radiation Dose Management | October 06, 2015

Study Shows Radiation Exposure for Interventionalists Greater on Left Side of Head

Published study reveals exposure at 16 times the ambient radiation level during invasive cardiovascular procedures

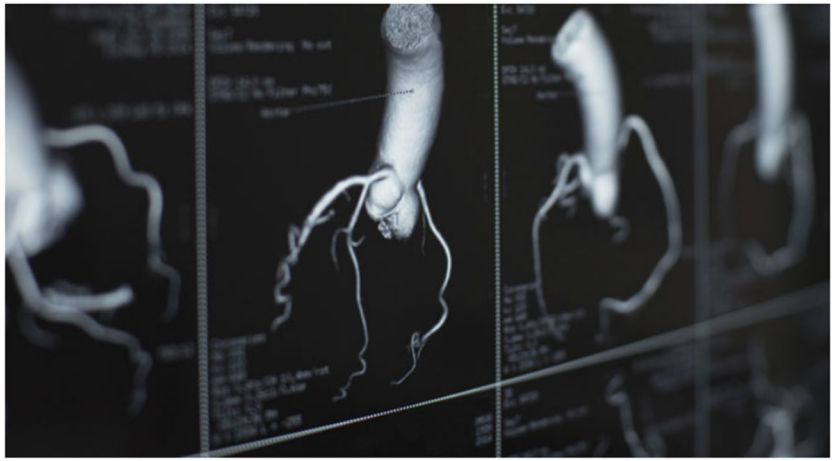
the RADIATION PROBLEM

Cardiology fellows-in-training are exposed to relatively high levels of radiation in the cath lab compared with staff interventional cardiologists—insights from the RECAP trial

W. Vlastra · B. E. Claessen · M. A. Beijk · K. D. Sjauw · G. J. Streekstra · J. J. Wykrzykowska · M. M. Vis · K. T. Koch · R. J. de Winter · J. J. Piek · J. P. S. Henriques · R. Delewi

Radiation a Danger to Patients and Physicians Alike

Exposure can be lowered without affecting test results



By Samir Kapadia, MD, Director, Cardiac Catheterization Laboratory

Cleveland Clinic

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US Nuclear Commission's Guide: As Low As Reasonably Achievable

Other Radiation Safety Practices

Provide radiation safety training to all workers who operate or are exposed to radiation-generating equipment, radiation sources, or radioactive materials.

Keep radiation exposures **A**s **L**ow **A**s **R**easonably **A**chievable **(ALARA)**, and certainly below regulatory limits.

The three basic concepts of radiation protection are: (1) minimize the time of exposure, (2) maximize the distance from the source of radiation, and (3) use shielding. Applying these concepts will help to keep radiation exposures ALARA.

Some examples of radiation protective practices include:

- Using the shortest practical irradiation times
- Using radiation-absorbing shields to protect against X-Ray exposure when procedures are in close proximity to the patient

ALARA goalposts have moved:
> 91% reduction is achievable!

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Radiation Exposure Is Costly to Hospitals

The **annual economic cost** of radiation exposure associated with Interventional Fluoroscopy is estimated to be **$60M** in the US alone*

- Costs associated with treatment of cancer and orthopedic injuries
- Does not factor in treatment of non-acute conditions such as precursors to cataracts, cognitive decline, and risks to reproductive health

"This economic study draws attention to the alarming annual costs resulting from the adverse health effects associated with long-term exposure to interventional fluoroscopy in the United States"

- Michael Seymour MS, MPH, CIH, ORSIF Director of Advocacy Programs

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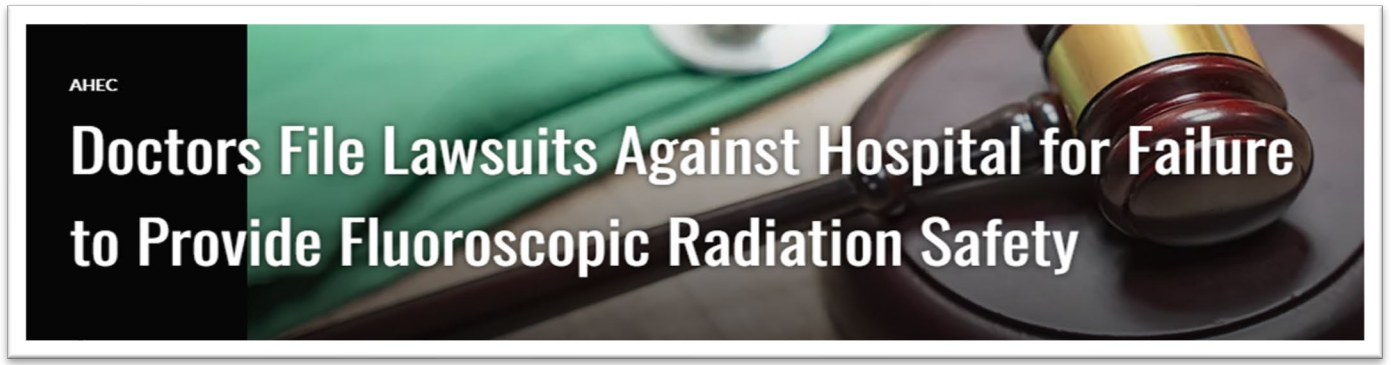
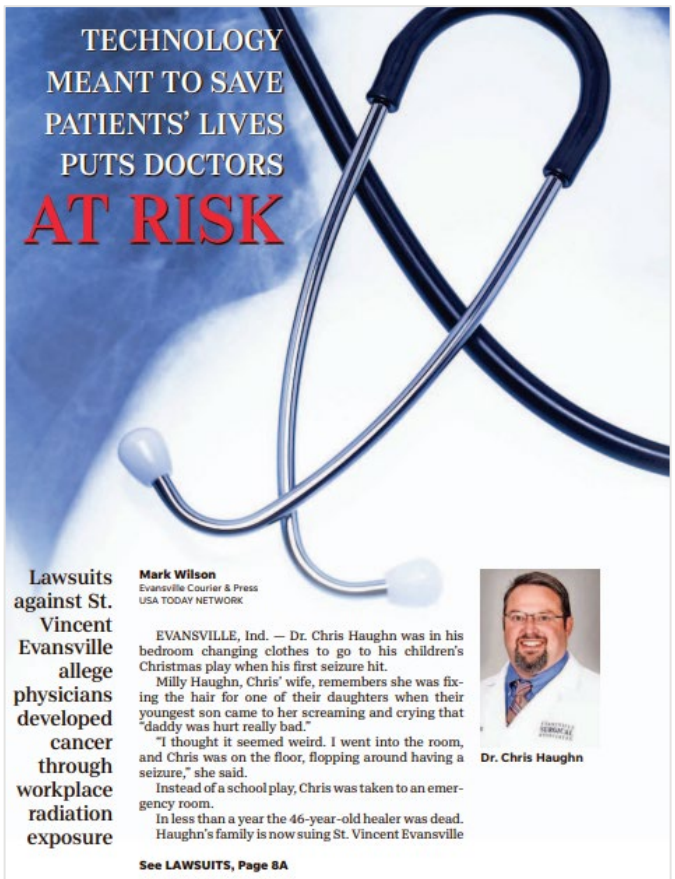
*ORSIF; Economic Impacts of Radiation Exposures Associated with interventional Fluoroscopy. Dec 2018. Figures adjusted for inflation.

Hospital workers sue over excessive radiation exposure

Five Methodist Medical Center employees say the walls of the CT Scan room did not include required radiation protection.




TECHNOLOGY MEANT TO SAVE PATIENTS' LIVES PUTS DOCTORS AT RISK

Lawsuits against St. Vincent Evansville allege physicians developed cancer through workplace radiation exposure

Mark Wilson
Evansville Courier & Press
USA TODAY NETWORK

EVANSVILLE, Ind. — Dr. Chris Haughn was in his bedroom changing clothes to go to his children's Christmas play when his first seizure hit.

Milly Haughn, Chris' wife, remembers she was fixing the hair for one of their daughters when their youngest son came to her screaming and crying that "daddy was hurt really bad."

"I thought it seemed weird. I went into the room, and Chris was on the floor, flopping around having a seizure," she said.

Instead of a school play, Chris was taken to an emergency room.

In less than a year the 46-year-old healer was dead.

Haughn's family is now suing St. Vincent Evansville

Dr. Chris Haughn

See LAWSUITS, Page 8A

Radiation Exposure

Boston Attorneys Advocating for Workers' Compensation Claimants

Doctors File Lawsuits Against Hospital for Failure to Provide Fluoroscopic Radiation Safety

In what may be the first lawsuits of their kind, 3 surgeons have filed lawsuits allegi a hospital's radiation safety practices were inadequate and that radiation exposure caused their cancers. The first of the lawsuits will take place early in 2020.

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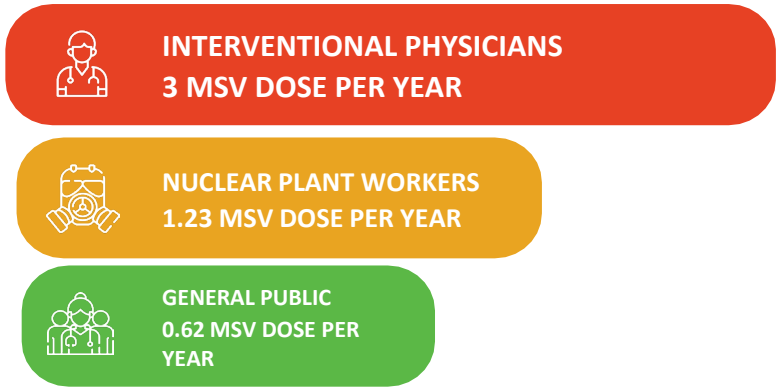
Interventional Teams are at Risk for High Exposure and Occupational Risk

INTERVENTIONAL TEAMS HAVE THE HIGHEST RADIATION EXPOSURE OF ALL PROFESSIONS



OCCUPATIONAL RISK FROM HIGH DOSE SCATTER RADIATION

- RADIATION CAUSED CANCER **1 IN 25**
- RADIATION CAUSED DEATH **1 IN 50**
- REPRODUCTIVE HEALTH RISKS **SIGNIFICANTLY HIGHER**

* International Atomic Energy Agency: Occup Med (Lond). 2010;60(6):464-9. Zakeri F, Hirobe T, Akbari Noghabi K. Biological effects of low-dose ionizing radiation exposure on interventional cardiologists.

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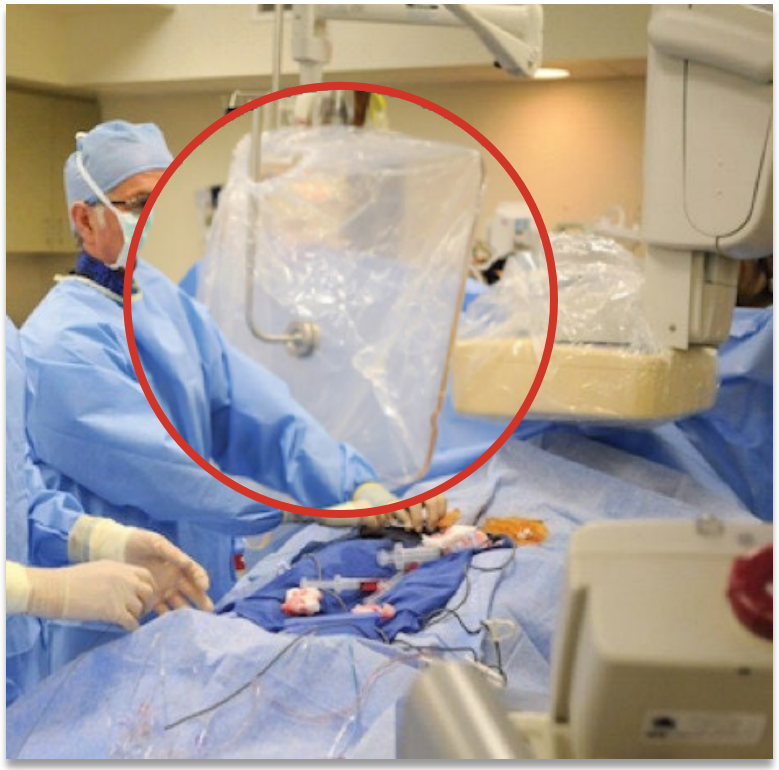
Standard Shielding is Insufficient



Hanging Shield

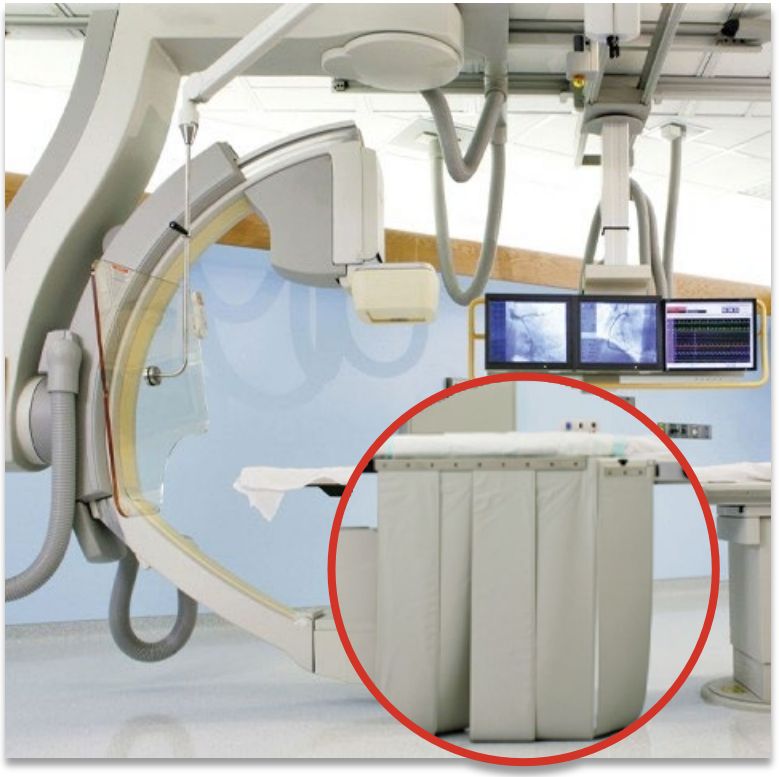


Table Skirt (Shield)

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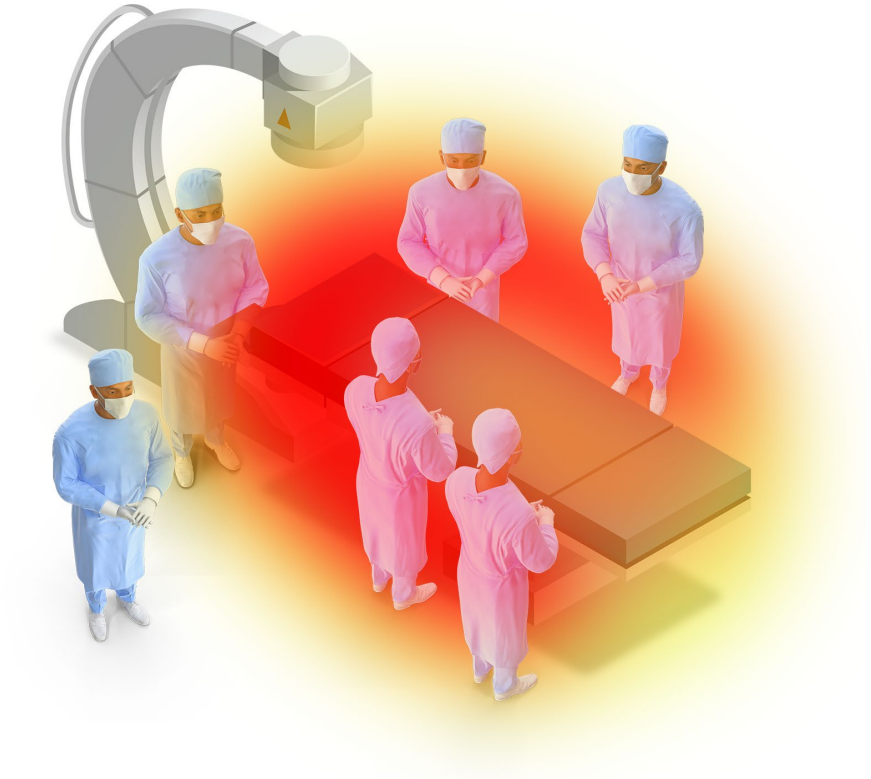
Other Shielding Not Designed to Reduce Exposure for Entire Team



Shortcomings of other solutions:

- Provide protection for limited staff (doctor and technician only)
- Require additional equipment (booms, affix to expensive C-arms)
- Compromise workflow
- Only address radiation scatter problem for a few members of the team
- Costly and cumbersome

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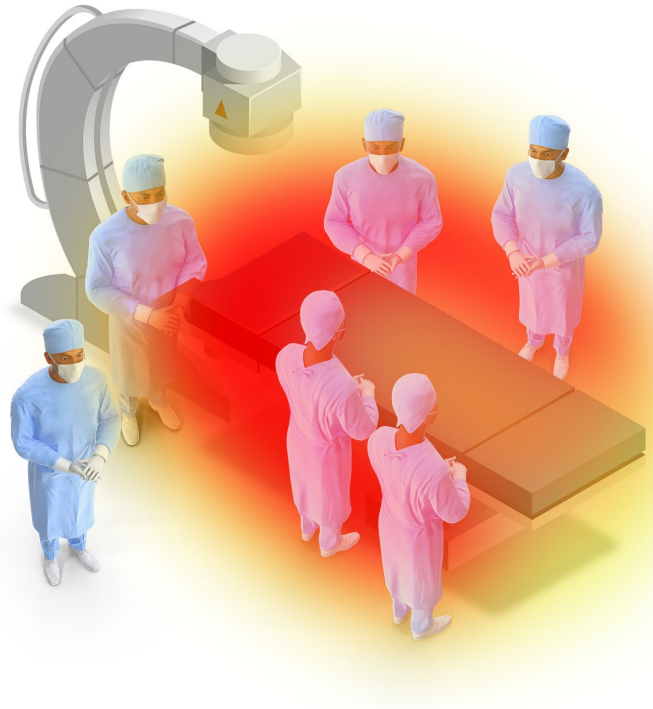
Don’t Compromise on Radiation

Radiation protection needs to block scatter radiation at the head, side and below the table

- Scatter radiation does not distribute uniformly and is dependent on several factors
  - Patient size or thickness
  - Projection angle
- The dose received by the physician can vary 20-fold depending on projection angle
- The more complicated the procedure, the higher the radiation dose
- Protection needs to be developed for the additional staff locations around the table for:
  - TAVR, Echo, Right Heart procedures, Biopsies, Device implants



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Effective + Easy + Economical + Everyone

Ideal Characteristics of a Radiation Protection Solution

Effective

- Works to get radiation As Low As Reasonably Achievable

Easy to Use

- Easy access to patient for urgent needs (i.e. chest compressions)
- Does not impact workflow
- Versatile for use and protection in multiple procedures (TAVR, EP, IR, Cardiology)

Economical

- Affordable
- May eliminate the need for other products (disposables and capital)
- Does not require major room or C-arm equipment modifications that can be costly

Everyone

- Protects everyone in the procedural area

Effective + Easy + Economical + Everyone

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Clinical Data

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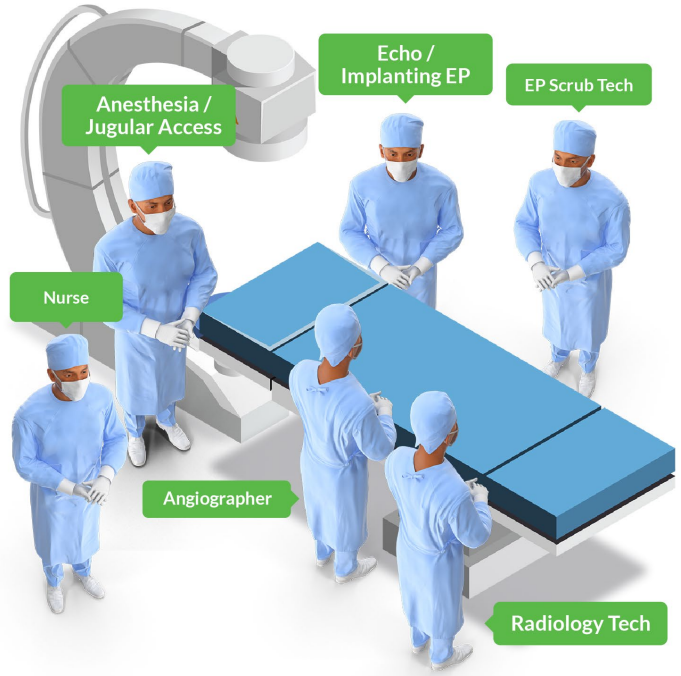
Radiation Cloud in the Cath Lab

RaySafe Radiation Meter



- Used a state-of-the-art radiation meter
- Collected measurements in 6 most common positions around the table
- At each position 10 measurements were recorded from 20cm to 200cm

*This test allowed us to understand the highest exposure areas for scatter radiation in the cath lab using a human phantom and measuring scatter at 6 positions around the cath lab table

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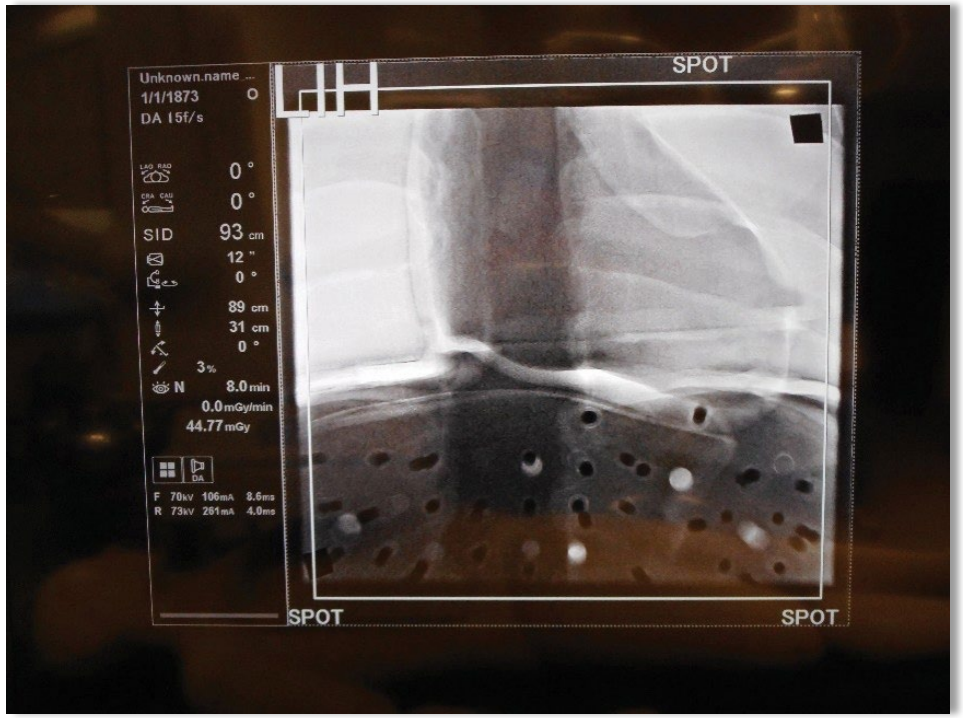
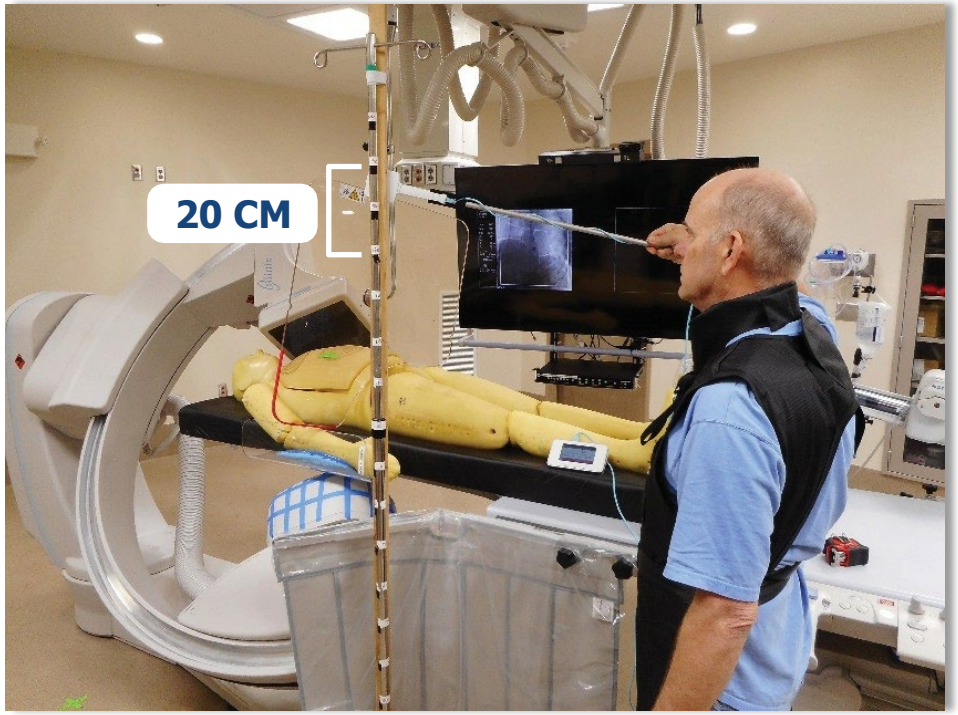
Measurement Methodology



US Department of Energy
Anthropomorphic Human Phantom



RaySafe X2 Scatter Radiation Meter Measurements
20-200 cm from the floor in 20 cm Intervals

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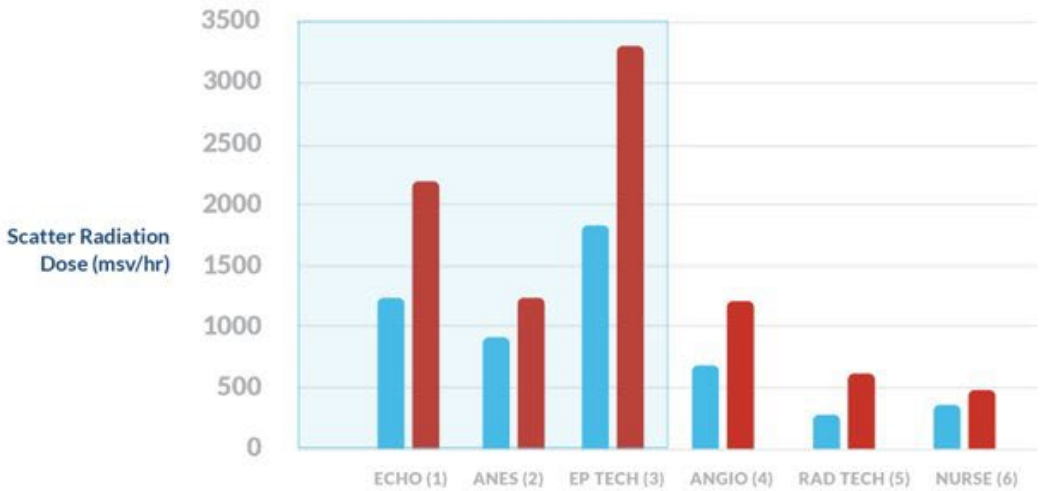
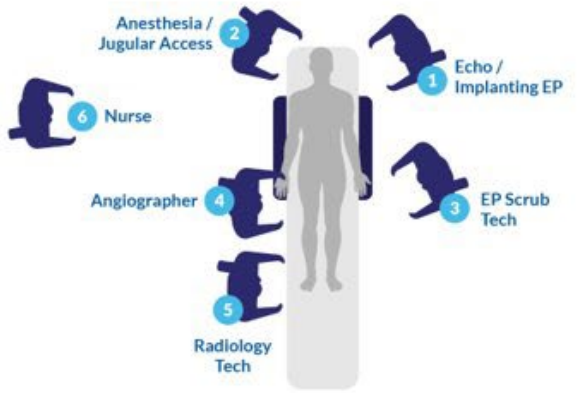
Scatter Radiation Around the Cath Lab Table



	ECHO (1)	ANES (2)	EP TECH (3)	ANGIO (4)	RAD TECH (5)	NURSE (6)
Average Dose	1327	859	1774	644	296	389
Peak Dose	2060	1180	3310	1210	560	483

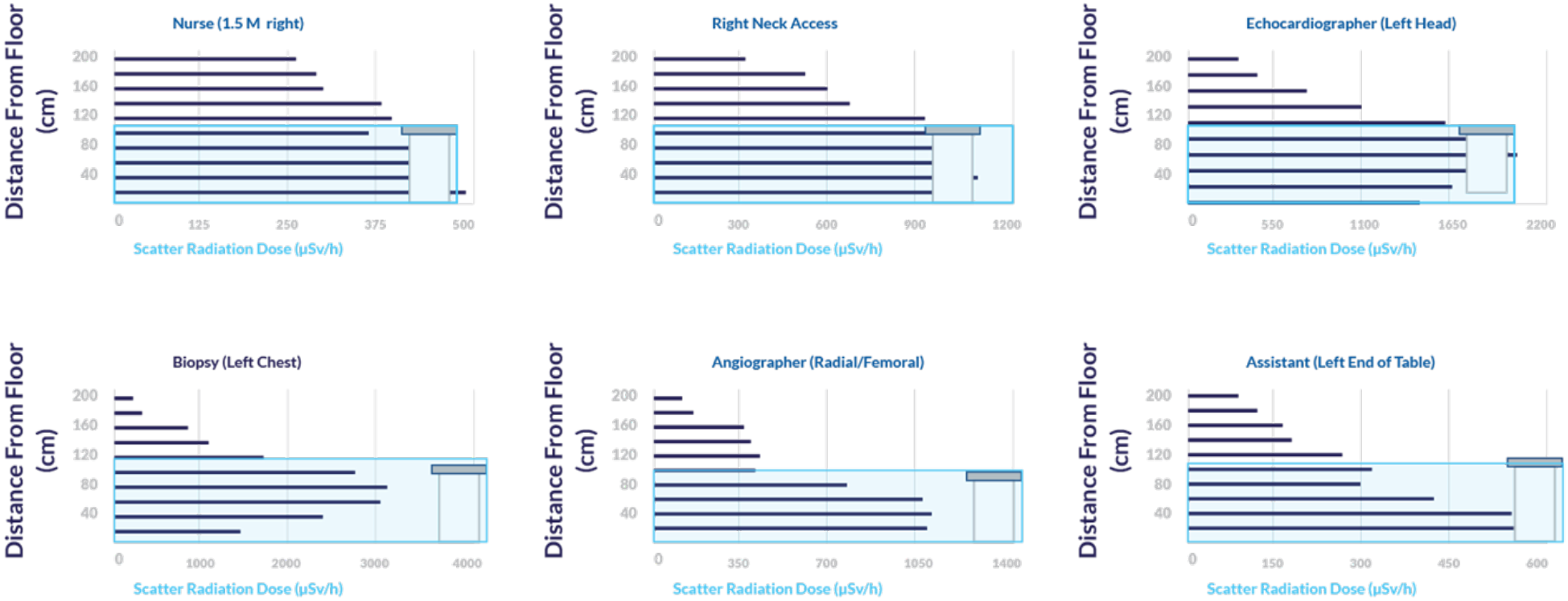


- The positions near the head and chest receive the most scatter radiation.
- The nurse position 1.5 M from the table receives more radiation on average than the assistant position at the table pedestal.

❖ Dose calculated using 10 measurements in each position to highlight average dose and peak dose.

Distribution of Scatter Radiation by Position

PA Projection, No Shielding



~70% of scatter radiation originates at and below the table surface

Effective protection must protect below the table and at the head

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System Overview

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The EGGNEST™ System

EggNest is a comprehensive passive radiation protection platform fully integrated into the modern Cath Lab workflow

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The Science Behind EGGNEST™

- **GOAL: Attenuate majority of radiation down to an energy where it does less to no damage to those exposed**
- Shields attenuate the radiation by slowing down the photons and absorbing energy through interactions

<u>Xenolite Non-lead Equivalent Material</u>

- NL stands for non-lead and is made up of antimony, tungsten, and bismuth to attenuate radiation
  - Made for energies of 35-100 keV
  - Antimony and bismuth are good attenuators for lower energy photons and tungsten is a good attenuator for high energy photons
  - Combination of different materials results in a better overall shield
- Lead can be a dangerous material, so limiting the amount used is a good practice in design

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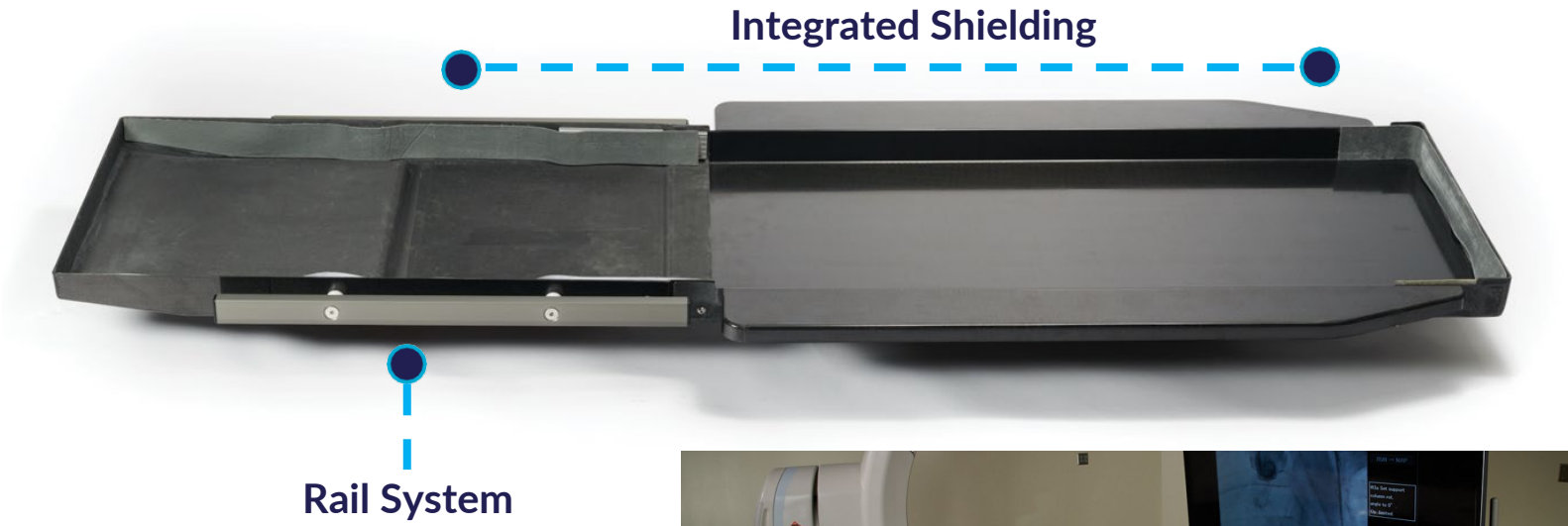
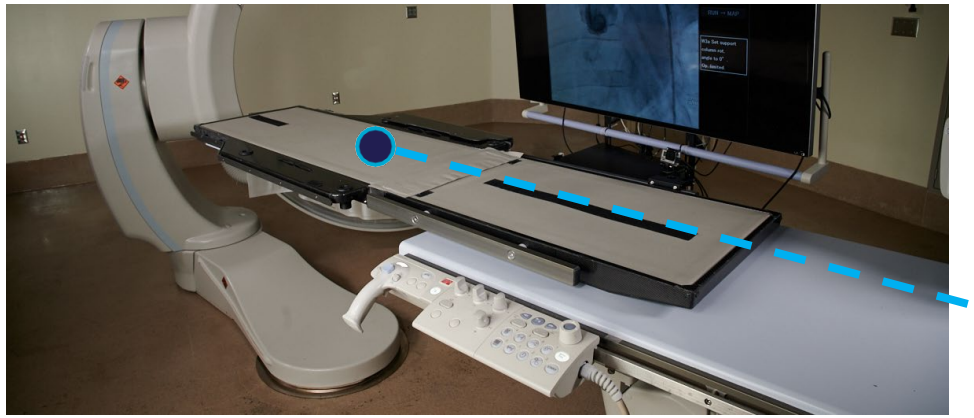
EGGNEST™ XR Base Platform



Carbon fiber frame with patient mattress and shielding inside:

- Strong
- Light
- Radiolucent



Prevents radiation leak from the mattress

Built in CPR board

The foundation of the EggNest™ XR is a carbon fiber “sled” that replaces that patient mattress and becomes the platform to attach and support all the radiation protection components

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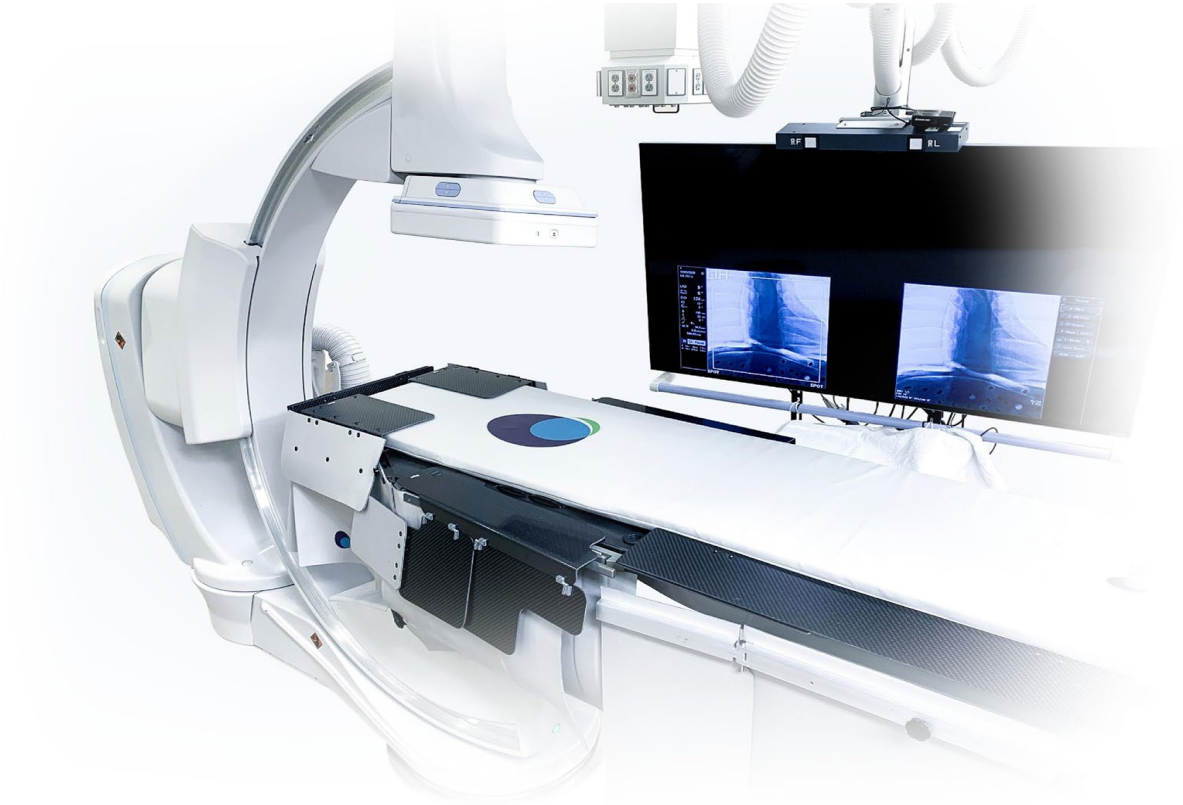
EGGNEST™ Patient Loading



Easy Patient Loading

- Patient loading requires arm and femoral shields to be lowered
- Once patient is loaded, “Flip” up shields
- Easy to clean by following standard protocol

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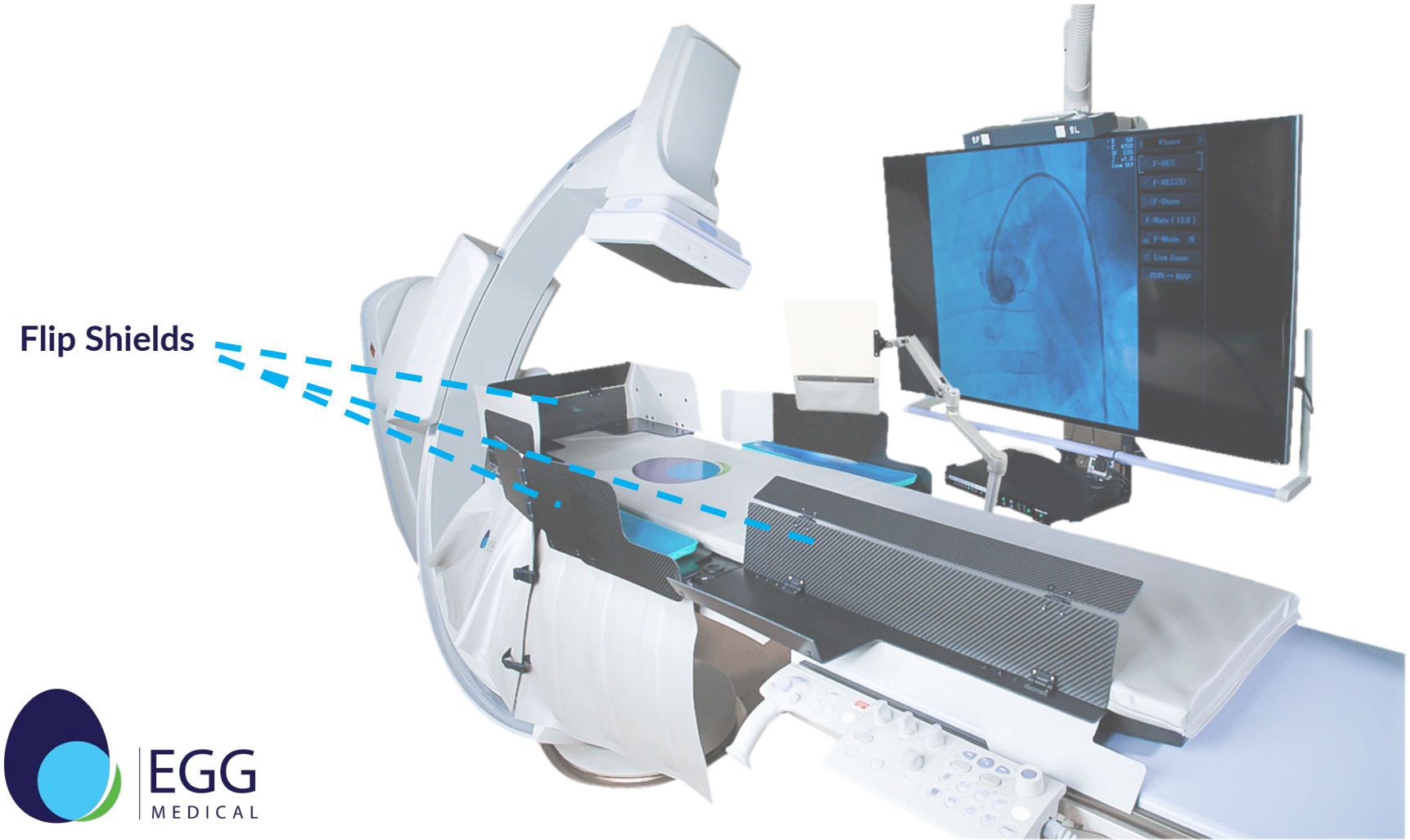
EGGNEST™ Above Table “Flip Shields”



Carbon Fiber “Flip Shields” are adjustable and conform to patient's body to provide protection above the table

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EGGNEST™ Below Table “Flex Shields”

“Flex Shield” Radiation Protection System provide comprehensive protection below the table and at the head of the table

Moves, bends and flexes to allow full
X-ray gantry motion

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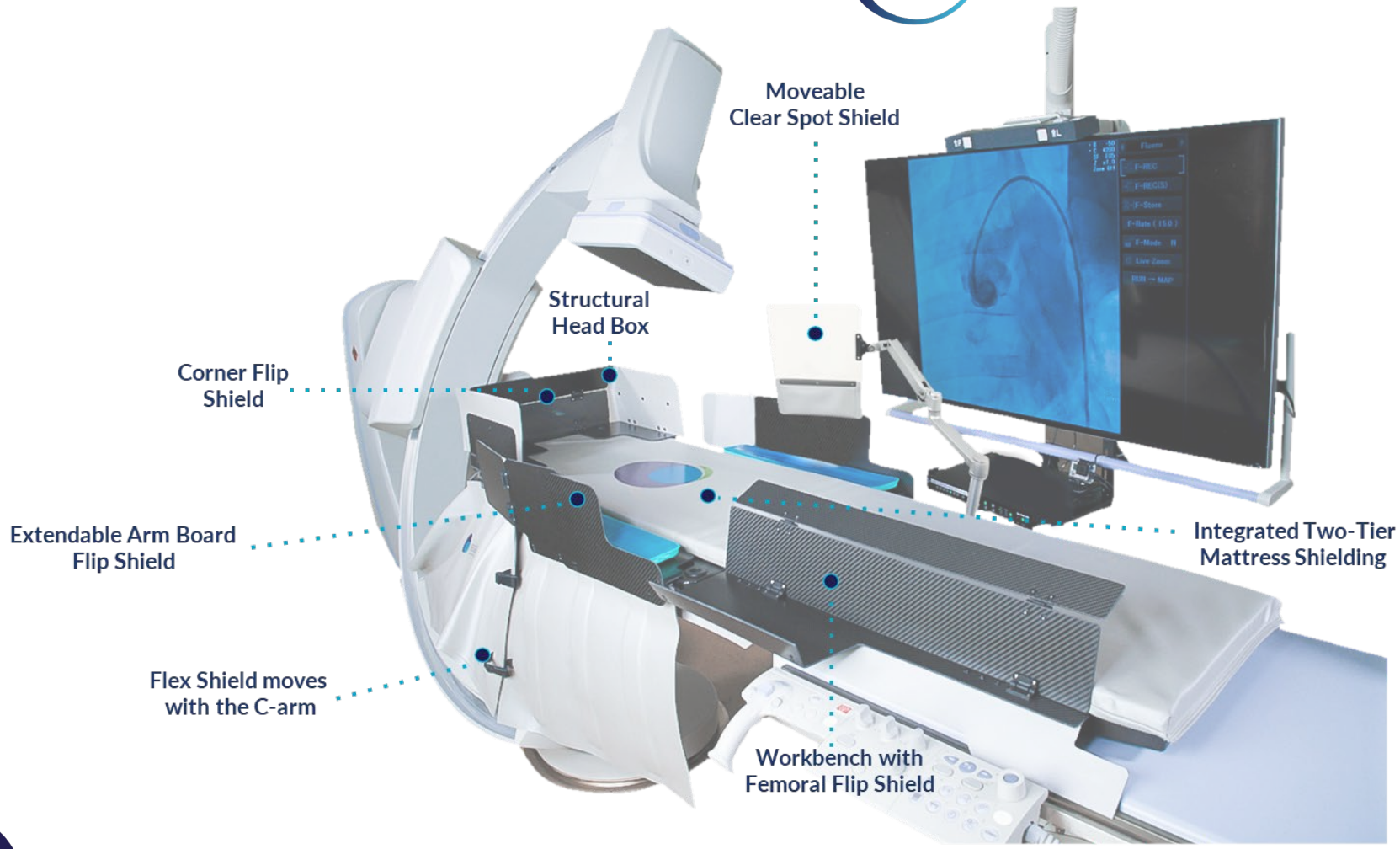
The EGGNEST™ XR



- Reduces Scatter Radiation >91%
- Protects Everyone Working in the Lab
- Fits seamlessly into Cath Lab environment

Carbon Fiber Base Platform with modular shielding components designed for optimal imaging and C-arm Motion

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The EGGNEST™ XR

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EGGNEST™ Fits Seamlessly into the Cath Lab

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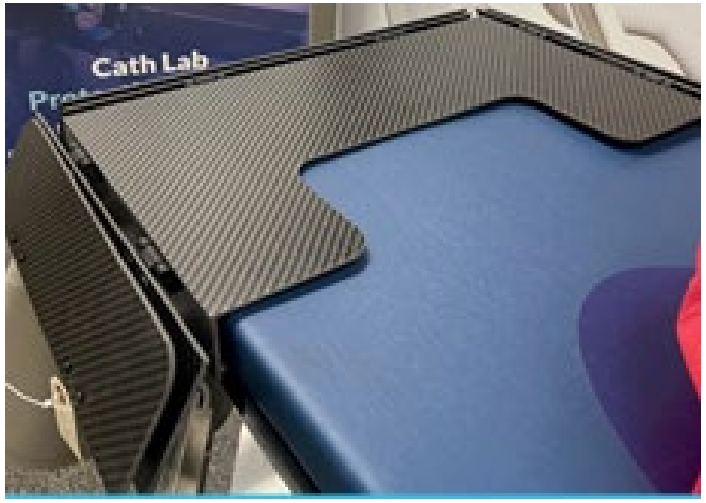
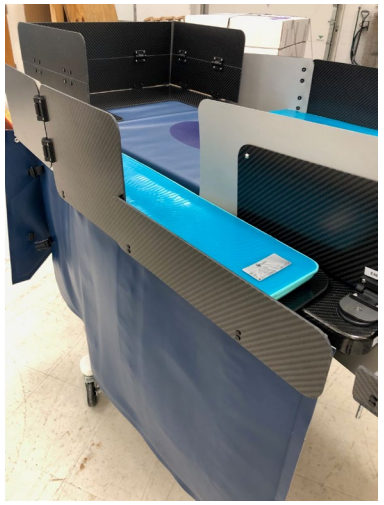
Scatter Radiation Protection without Compromise

EGGNEST™ Versatility for Every Case





Scatter Radiation Protection without Compromise

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EggNest™ Efficacy

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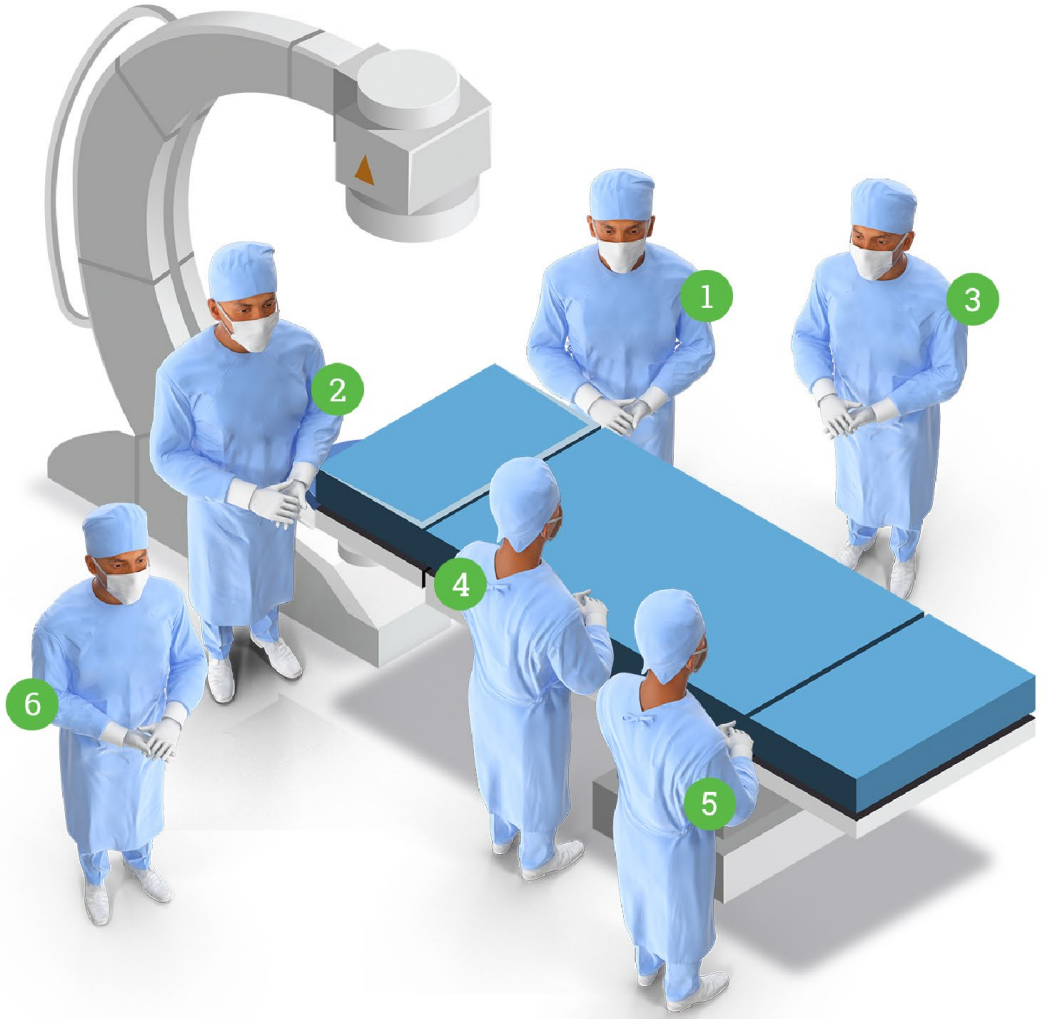
Effect of EggNest XR™ on Scatter Radiation Around the Table



1	Echo / Implanting EP	97%
2	Anesthesia / Jugular Access	89%
3	EP Scrub Tech	90%
4	Angiographer	92%
5	Radiology Tech	82%
6	Nurse	92%

Compared to Standard Shielding

Wilson R et al: TCT 2018

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Effect of EggNest XR™ on Scatter Radiation Around the Table

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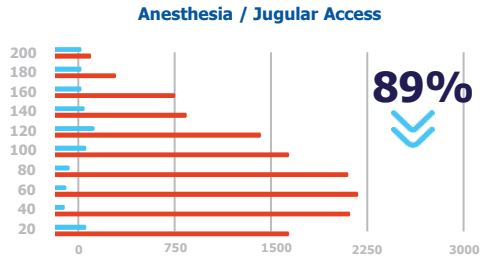
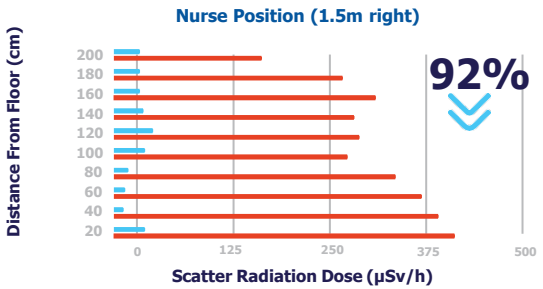
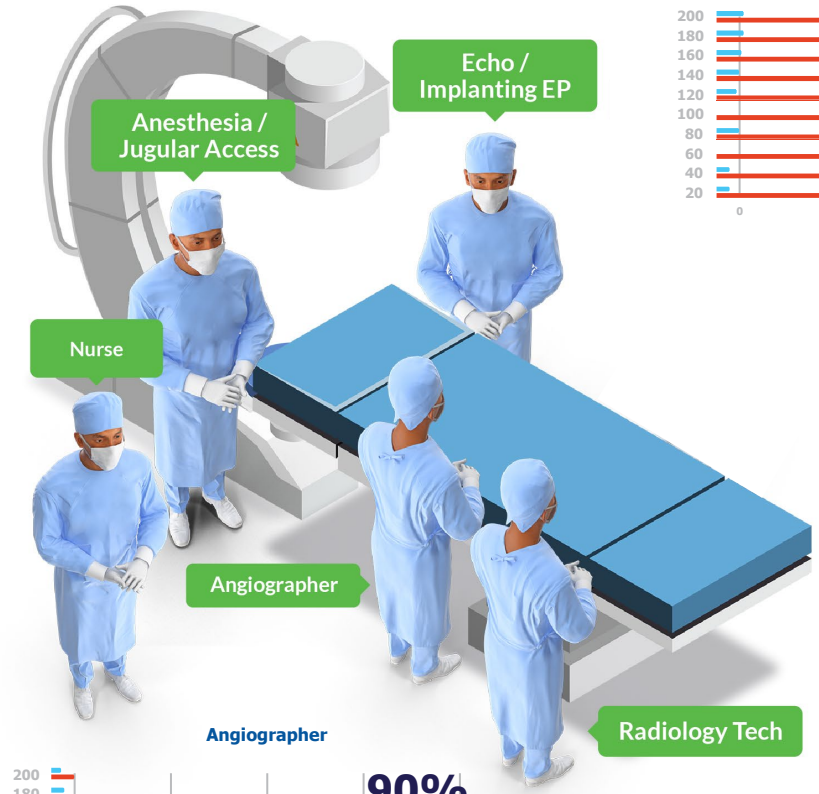
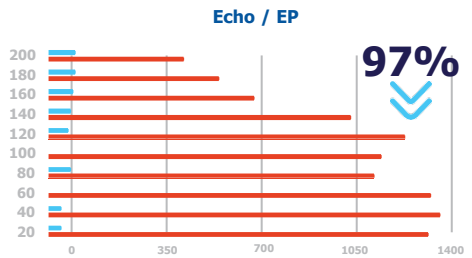
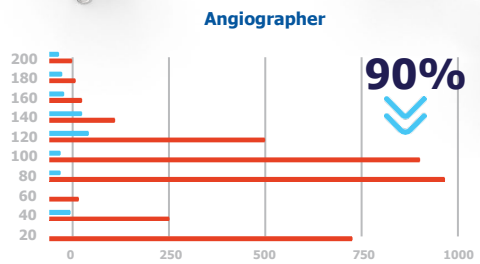
STANDARD SHIELDING

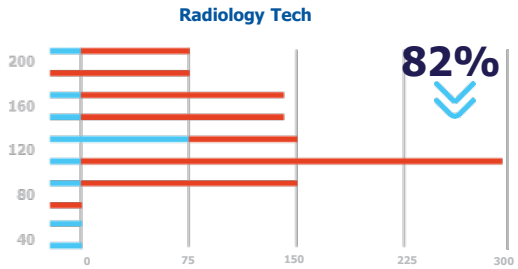












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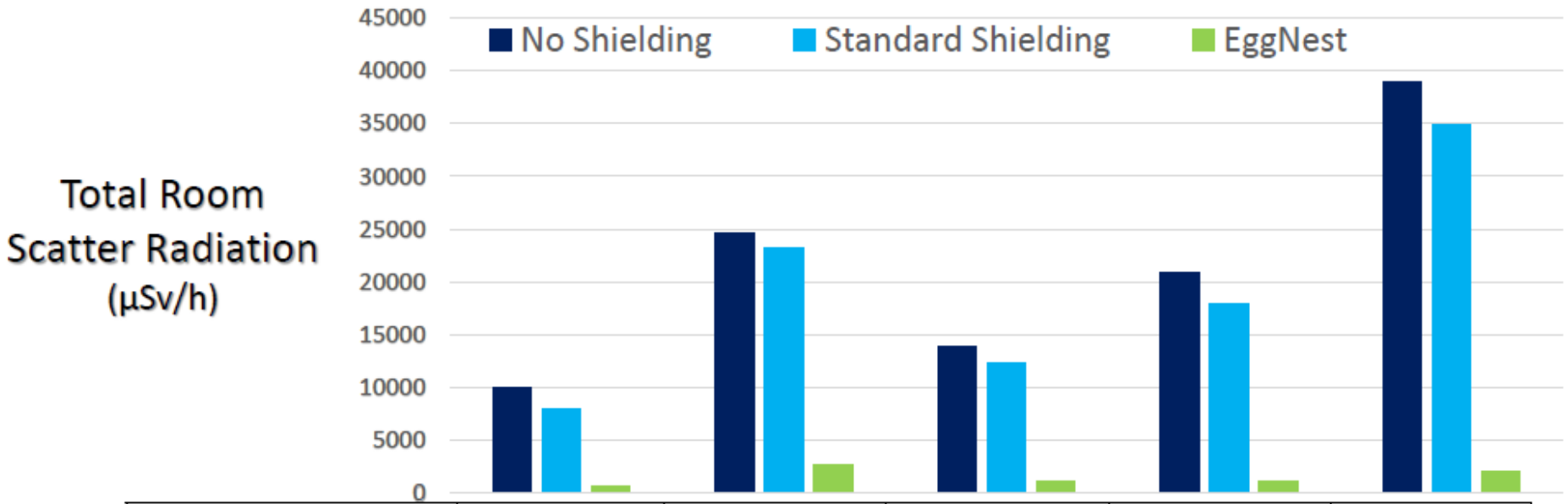
Wilson R et al: TCT 2018

Effect of Shielding on Total Room Scatter Radiation in Complex Cases



Total Room SR (µSv/h)	PA	RAO30 Caud20	RAO 30 Cran30	LAO40 Cran30	LAO40 Caud30
No Shielding	10010	24540	13910	20850	38910
Standard Shielding	7910	23230	12330	17960	34870
EggNest	640	2670	1210	1110	2040

*Average scatter radiation dose for all heights and positions around the table

Wilson R et al: TCT 2018

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EggNest™ Avg Scatter X-ray Dose Reduction

EggNest v. Standard Shielding	All Heights Sum Dose Averaged (1-(EN/STD))				
	PA	**RAO30/Cuad20**	**RAO30/Cran20**	**LAO40/Cran30**	**LA040/Caud30**
Echocardiographer	97%	87%	91%	94%	90%
Right Heart Cath	89%	81%	87%	94%	95%
Right/Left Chest	92%	94%	93%	97%	95%
Angiographer	90%	98%	90%	73%	94%
Assistant	82%	80%	72%	48%	95%
Nurse	92%	91%	93%	95%	98%
Projection Average	**92%**	**88%**	**90%**	**94%**	**94%**

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Articles & Publications

Cath Lab Digest

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CLINICAL EDITOR'S CORNER: KERN

Novel Radiation Protection Devices: An Update on Radiation Safety in the Cath Lab

Volume 26 - Issue 1 - January 2018

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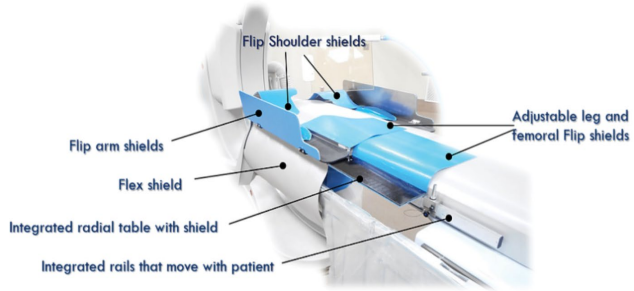
DAIC Diagnostic and Interventional Cardiology — Dicardiolog Anytime. Anywhere.

IMAGING CATH LAB EP LAB STRUCTURAL HEART HEART FAILURE DIAGNOSTIC

TECHNOLOGY | RADIATION DOSE MANAGEMENT | MAY 10, 2018

Patient Table Reduces Scatter Radiation in the Cath Lab



We started our design from the ground up, tested many prototypes, did not want to compromise on radiation protection for any staff in the room no matter where they stood.

TRENDING NOW
Study Finds Effective

Medscape Business of Medicine

B Allen

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Cath Lab Radiation Shielding Protects Whole Team

Neil Osterweil
May 29, 2018

Read Comment ADD TO EMAIL ALERTS

PARIS — A radiation shielding system reduces the amount of scatter radiation exposure to cath lab personnel by more than 80% compared with no shielding and better protects every position around the table than do conventional shielding systems.

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Recommendations

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Below-the-Table System May Protect Against Scatter Radiation in the Cath Lab

By replacing the patient mat with a carbon fiber platform, the "EggNest" protects better against the 69% of radiation that comes from below the table

By Yael L. Maxwell | May 25, 2018

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Cath Lab Digest Articles

Cath Lab Digest

A product, news & clinical update for the cardiac catheterization laboratory specialist

Cath Lab Spotlight

MetroWest Medical Center

Ashley Margossian, NP; Jean Decourcey, RN; James Alderman, MD; Christopher Gange, MD; Kimberly Kelley, DNP; Framingham, Massachusetts

Tell us about your hospital and cath lab.
We are a community hospital located in Framingham, Massachusetts, a small city located in the Boston suburbs. Our lab performs cardiac catheterization, elective and primary percutaneous coronary interventions (PCIs), as well as a full array of electrophysiology (EP) procedures. Being located in the suburbs, just outside of Boston's major academic medical centers, has created a unique niche for us to deliver high quality, personalized interventional cardiovascular care. We have received the American Heart Association Mission: Lifeline STEMI Gold award and the American Heart Association Mission: NSTEMI Silver award.

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In This Issue

Case Report

Management of an Ascending Aortic Aneurysm Diagnosed in an Outpatient Setting

Radhika-Alicia Patel, RA[a], Joseph Ibrahim, MD[a,b], Aditya Kulkarni, MD[a,c], Angela Awad, MSII[a], Pratik B. Patel, MD, FACC[a,b]

An ascending aortic aneurysm is an uncommon, incidental finding for patients undergoing transthoracic echocardiography (TTE) during an outpatient visit.[1] An aortic aneurysm is defined as an abnormal enlargement of the walls of the aorta that is variable to the size and gender of a patient.[1] The official measure of an aortic aneurysm has not been defined due to inter-patient variability, but it is generally agreed upon that the aortic index should factor in body surface area.[1]

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RADIATION SAFETY

For the Cath Lab Team, Up to a >90% Reduction in Scatter Radiation With Use of the EggNest

Can you tell us about the cath lab at The Minneapolis Heart Institute at Abbott Northwestern Hospital?
We are a combined lab and including peripheral vascular, we have 6 labs total. We are a fairly high volume lab, doing about 2000 percutaneous coronary interventions (PCIs) a year, including complex chronic total occlusion (CTO) PCI. We are one of the leading centers nationally, both in terms of CTO and intravascular brachytherapy (VBT). Our structural program is also quite large and we are easily one of the leading structural groups in the country. I do not do structural work, but some of my partners are national principal investigators on TRILUMINATE and other structural studies.

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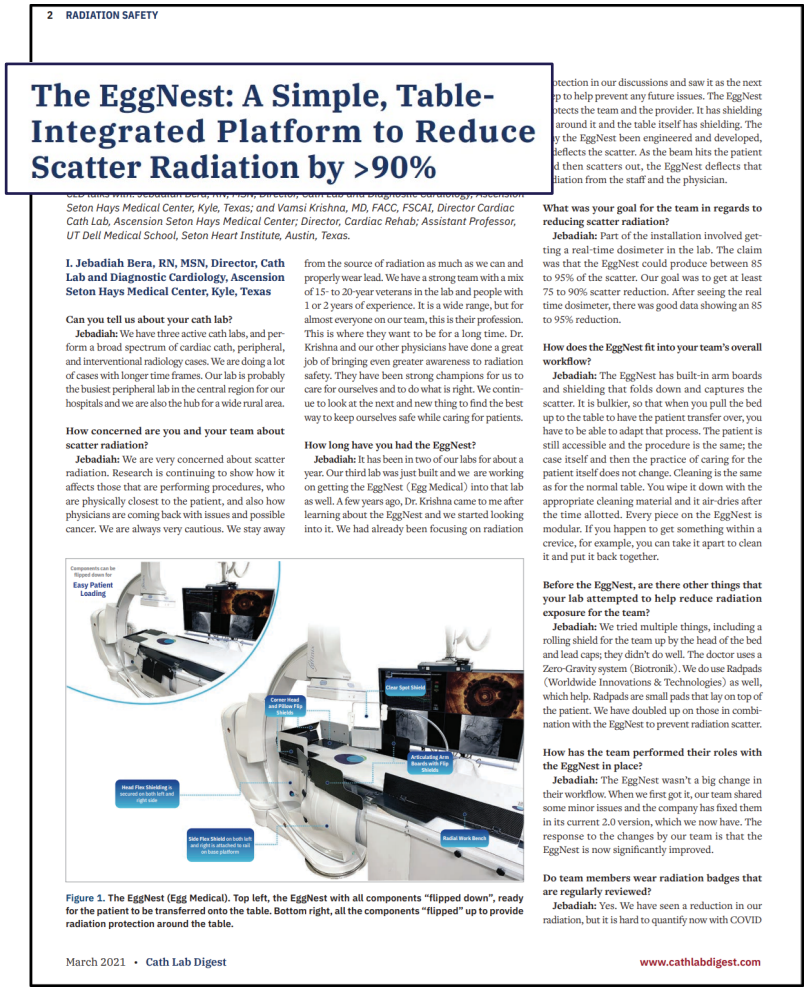
HAPPY CARDIOVASCULAR PROFESSIONALS WEEK (FEB 9-15)!

Dr. Nick Burke, Abbott Northwestern, Hospital, Minneapolis MN

FEBRUARY 2020



The EggNest: A Simple, Table-Integrated Platform to Reduce Scatter Radiation by >90%

Seton Hays Medical Center, Kyle, Texas; and Vamsi Krishna, MD, FACC, FSCAI, Director Cardiac Cath Lab, Ascension Seton Hays Medical Center; Director, Cardiac Rehab; Assistant Professor, UT Dell Medical School, Seton Heart Institute, Austin, Texas.

I. Jebadiah Bera, RN, MSN, Director, Cath Lab and Diagnostic Cardiology, Ascension Seton Hays Medical Center, Kyle, Texas

Can you tell us about your cath lab?
Jebadiah: We have three active cath labs, and perform a broad spectrum of cardiac cath, peripheral, and interventional radiology cases. We are doing a lot of cases with longer time frames. Our lab is probably the busiest peripheral lab in the central region for our hospitals and we are also the hub for a wide rural area.

How concerned are you and your team about scatter radiation?
Jebadiah: We are very concerned about scatter radiation. Research is continuing to show how it affects those that are performing procedures, who are physically closest to the patient, and also how physicians are coming back with issues and possible cancer. We are always very cautious. We stay away from the source of radiation as much as we can and properly wear lead. We have a strong team with a mix of 15- to 20-year veterans in the lab and people with 1 or 2 years of experience. It is a wide range, but for almost everyone on our team, this is their profession. This is where they want to be for a long time. Dr. Krishna and our other physicians have done a great job of bringing even greater awareness to radiation safety. They have been strong champions for us to care for ourselves and to do what is right. We continue to look at the next and new thing to find the best way to keep ourselves safe while caring for patients.

How long have you had the EggNest?
Jebadiah: It has been in two of our labs for about a year. Our third lab was just built and we are working on getting the EggNest (Egg Medical) into that lab as well. A few years ago, Dr. Krishna came to me after learning about the EggNest and we started looking into it. We had already been focusing on radiation protection in our discussions and saw it as the next step to help prevent any future issues. The EggNest protects the team and the provider. It has shielding around it and the table itself has shielding. The way the EggNest been engineered and developed, deflects the scatter. As the beam hits the patient and then scatters out, the EggNest deflects that radiation from the staff and the physician.

What was your goal for the team in regards to reducing scatter radiation?
Jebadiah: Part of the installation involved getting a real-time dosimeter in the lab. The claim was that the EggNest could produce between 85 to 95% of the scatter. Our goal was to get at least 75 to 90% scatter reduction. After seeing the real time dosimeter, there was good data showing an 85 to 95% reduction.

How does the EggNest fit into your team's overall workflow?
Jebadiah: The EggNest has built-in arm boards and shielding that folds down and captures the scatter. It is bulkier, so that when you pull the bed up to the table to have the patient transfer over, you have to be able to adapt that process. The patient is still accessible and the procedure is the same; the case itself and then the practice of caring for the patient itself does not change. Cleaning is the same as for the normal table. You wipe it down with the appropriate cleaning material and it air-dries after the time allotted. Every piece on the EggNest is modular. If you happen to get something within a crevice, for example, you can take it apart to clean it and put it back together.

Before the EggNest, are there other things that your lab attempted to help reduce radiation exposure for the team?
Jebadiah: We tried multiple things, including a rolling shield for the team up by the head of the bed and lead caps; they didn't do well. The doctor uses a Zero-Gravity system (Biotronik). We do use Radpads (Worldwide Innovations & Technologies) as well, which help. Radpads are small pads that lay on top of the patient. We have doubled up on those in combination with the EggNest to prevent radiation scatter.

How has the team performed their roles with the EggNest in place?
Jebadiah: The EggNest wasn't a big change in their workflow. When we first got it, our team shared some minor issues and the company has fixed them in its current 2.0 version, which we now have. The response to the changes by our team is that the EggNest is now significantly improved.

Do team members wear radiation badges that are regularly reviewed?
Jebadiah: Yes. We have seen a reduction in our radiation, but it is hard to quantify now with COVID

Figure 1. The EggNest (Egg Medical). Top left, the EggNest with all components "flipped down", ready for the patient to be transferred onto the table. Bottom right, all the components "flipped" up to provide radiation protection around the table.

Dr. Vishna Krishna, Ascension Seton Hayes Hospital, Kyle, TX

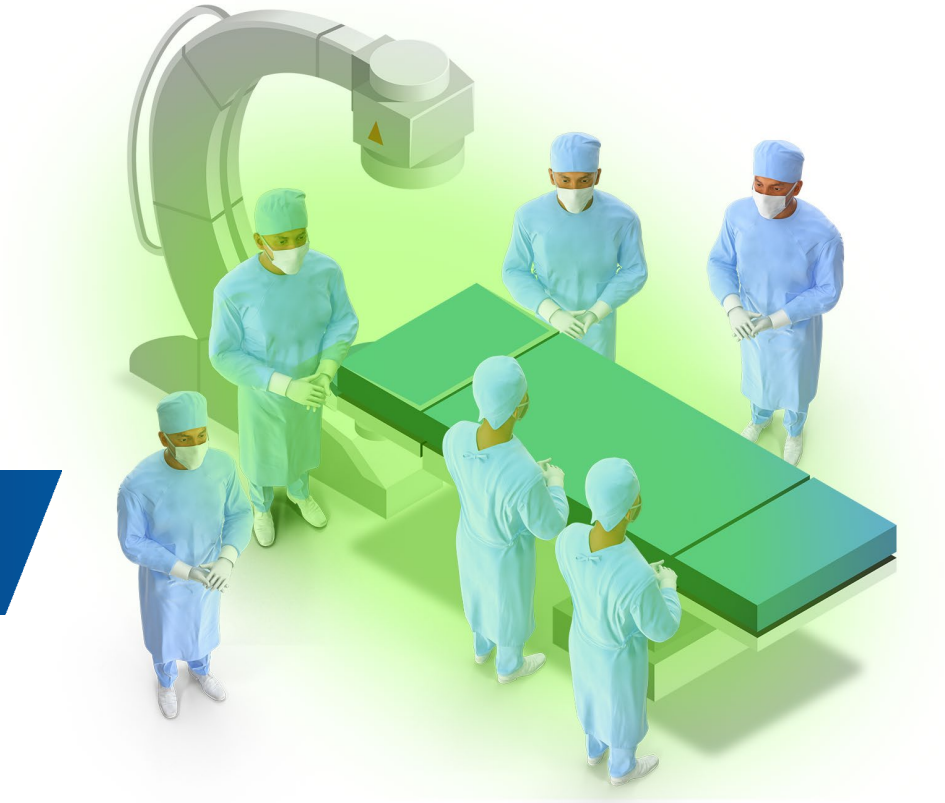
MARCH 2021

EGG MEDICAL

Why EggNest™?

Effective + Easy + Economical + Everyone = EggNest XR

Every Nurse Matters
Every Tech Matters
Every Doctor Matters



SCATTER MATTERS

For Everyone

EGG MEDICAL

Next Steps

- Personalized Scatter Score for Your Hospital Labs
- Partnership with market-leading Fluke Medical for ongoing radiation monitoring for EVERYONE
- Comprehensive assessment before and after EggNest installation
- Option to bundle with EggNest

Comprehensive Scatter Score Report

EGG MEDICAL

EggNest™ Evaluation Data

Prepared For:

Your Hospital

Between the Dates of:
1/31/23 - 2/2/23

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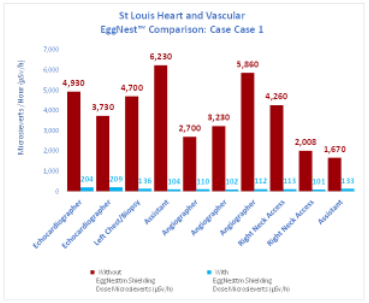
Heart and Vascular

Case 6

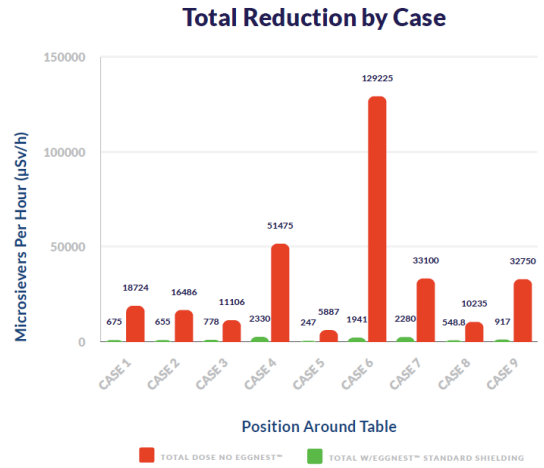
Room Number	Cath lab/Structural lab
Physician Name	Doctor Smith
Imaging System	Alphanetix
Procedure	Left and Cor #3
Date	20-Apr-2023

Meas.	Camera Angle	Flooro or Cine	Height of Meas. (cm)	Pos	Position Around Cath Table	Without EggNest™ Shielding Dose Microsieverts (µSv/h)	With EggNest™ Shielding Dose Microsieverts (µSv/h)	% Reduction
1			60	1	Echocardiographer	4,930	204	96%
2			90	1	Echocardiographer	3,730	209	94%
3			60	3	Left Chest/Biopsy	4,700	136	97%
4			60	5	Assistant	6,230	104	98%
5			90	4	Angiographer	2,700	110	96%
6			120	4	Angiographer	3,230	102	97%
7			60	4	Angiographer	5,860	112	98%
8			90	2	Right Neck Access	4,260	113	97%
9			120	2	Right Neck Access	2,008	101	95%
10			90	5	Assistant	1,670	133	92%
St Louis Heart and Vascular - Case 1						39,318	1,324	96.6%



Total Reduction by Case

	TOTAL W/EGGNEST™ STANDARD SHIELDING	TOTAL DOSE NO EGGNEST™	AVERAGE	FLORO TIMES
CASE 1	675	18,724	96%	1.2
CASE 2	655	16,486	96%	21.1
CASE 3	778	11,106	92%	6.18
CASE 4	2,330	51,475	95%	8.4
CASE 5	247	5,887	95%	35.6
CASE 6	1,941	129,225	98%	6.7
CASE 7	2,280	33,100	93%	3.8
CASE 8	548.8	10,235	94%	14.7
CASE 9	917	32,750	97%	10.7
TOTAL	10,371.8	310,488	95%	108.38 MINS



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Purchase Options

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Purchase Options

1

Cash or Capital

2

Philanthropy or Foundation Funding

3

Lease or Lease to Own

4

Bridge to Budget

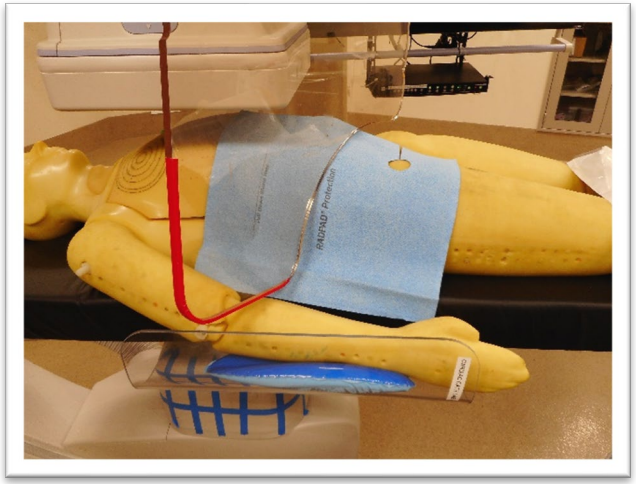
(No payments for 3 months) Able to payoff when budget arrives with no penalty.

5

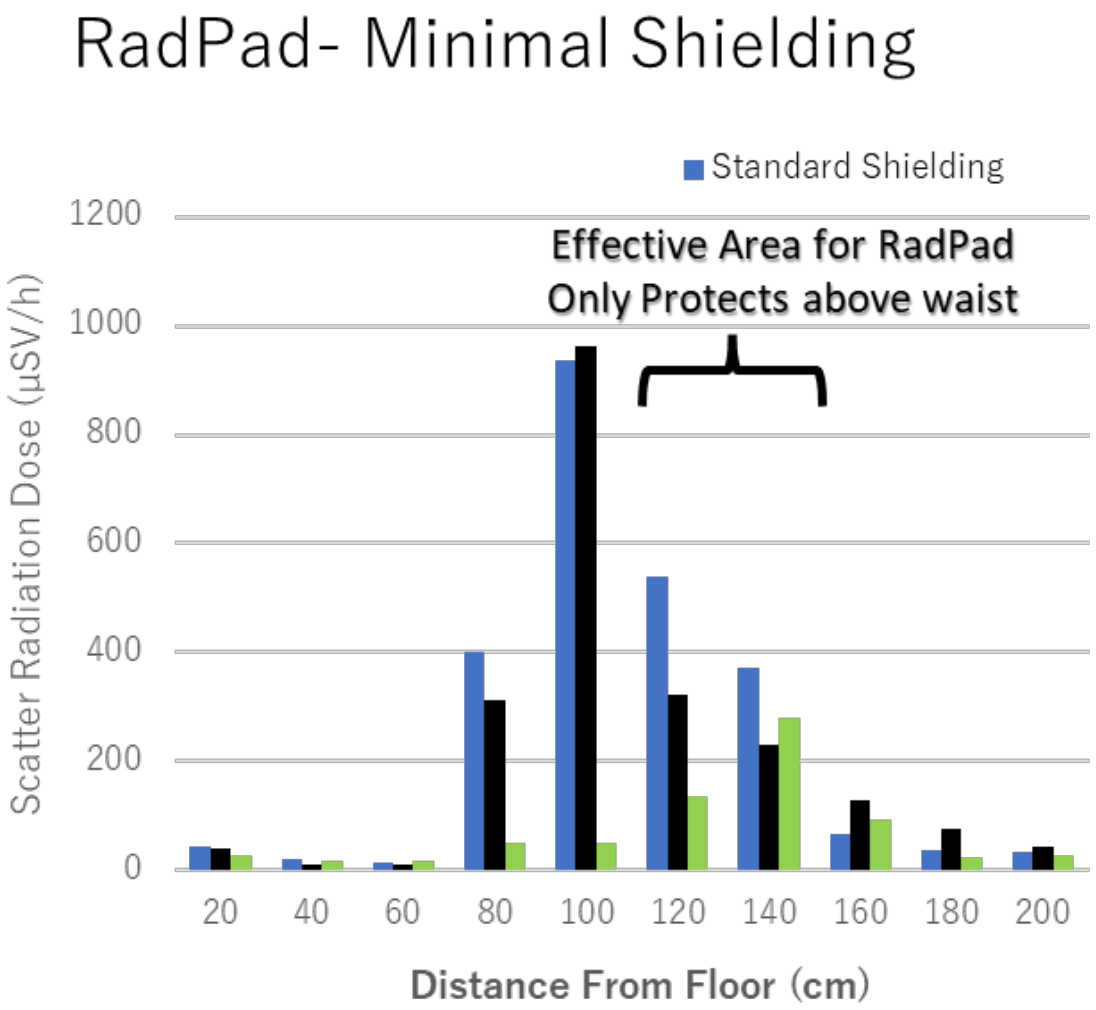
Rent via Operational Budget

EGG MEDICAL

Effect of RadPad Compared to Standard Shielding Alone



Scatter Reduction	Overall	Above Table
RadPad	-13%	-12%
EggNest	-76%	-78%



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