WHAT IF YOU COULD MINIMIZE RADIATION EXPOSURE WHILE ACHIEVING CLINICAL AND QUALITY SUCCESS?1-4

The reduction of live X-ray in medical procedures performed in Europe is a clear goal set by the EU institutions, as well as among physicians and other health care professionals. This poses no greater challenge (or opportunity) than in the area of cardiovascular medicine.

By working with industry partners that can provide innovative technology solutions to the health care provider community, our X-ray occupational, public and medical exposure may be minimized.
CVD BURDEN

Each year cardiovascular disease (CVD) causes more than 4 million deaths in Europe representing 47% of all deaths. The prevalence of CVD is increasing, presenting substantial health and economic burdens. Treatment for CVD often involves medical imaging-assisted interventions, such as cardiac ablation and rhythm management.

The increased use of medical imaging for CVD management has resulted in increased medical radiation exposure for both health care providers and patients. Along with this increased exposure comes higher risk for radiation-related illnesses, such as cancer, and ocular cataracts/lens opacities.

Though rare in Europe, mandatory regulations exist for recording or reporting radiation dosing; clinical measures and guidance that regulatory agencies endorse suggest a societal need for facilities and care providers to minimize radiation exposure as much as reasonably possible.
CURRENTLY, 47% OF ALL DEATHS IN EUROPE are caused by some form of CVD\(^5\)

The costs associated with treatment are estimated TO COST THE EU ECONOMY ALMOST €196 BILLION A YEAR.\(^5\)

The high burden of CVD in Europe has led to the use of a substantial number of imaging-assisted interventions for disease treatment. However, radiation exposure from medical imaging procedures and tests has become the largest man-made source of human radiation exposure,\(^2\) and it is expected that the use of medical imaging for CVD management will continue to rise.\(^11\) This will create work-related risks for interventional cardiologists and electrophysiologists, as well as other health care professionals.
Interventional radiology imaging uses ionizing radiation, such as X-ray and fluoroscopy.

**Figure 1.** In the United States, interventional radiology is responsible for only 12% of cardiology exams, but represents 48% of the total radiation exposure related to medical imaging, more than any other single source of medical radiation.\(^2\)
RADIATION RISKS

While patients and providers are both exposed to radiation due to medical imaging procedures, medical personnel may be at the greatest risk because of the high number of procedures performed each year.\(^\text{13}\)

Unlike many other mutagens, X-ray beams can access all internal organs, meaning that even a single electron set into motion by an X-ray photon may cause permanent molecular damage.\(^\text{14}\) This radiation causes DNA damage to human cells.\(^\text{15}\) Research shows that even low levels of radiation exposure from X-ray examinations can lead to chromosomal damage.\(^\text{16,17}\)
HEALTH CARE PROFESSIONAL RISK

Research supports the hypothesis that increased brain cancer in practitioners who perform fluoroscopic procedures may be linked to radiation exposure.7,15,18 Other radiation-associated conditions observed in interventional cardiologists include lens opacity and posterior subcapsular cataract.9,10

These risks are compounded by the added risk of chronic orthopedic injury from traditional lead aprons, aggravated by conditions common to the EP lab (e.g., improper table height, fluoroscopy monitor height and position, and on-table control panel position). Traditional lead aprons weigh approximately 15 pounds, and can place up to 300 pounds of pressure per square inch on a physician’s intervertebral discs.19,20

Interventional cardiologists and electrophysiologists, in particular, are at the highest risk for radiation exposure.17,21 Invasive and interventional cardiologists often receive radiation through fluoroscopy (Figure 2),22 which can cumulatively cause a non-negligible lifetime attributable risk of cancer.13 Specifically, high radiation exposure, and associated increased risk for cancer, has been identified in clinicians who regularly perform interventional procedures involving fluoroscopy.23-26

PATIENT RISK

Patient risk for radiation exposure is highest for individuals who require multiple imaging tests.4 Although exposure guidelines are in place for patients,28,29 individual patient differences may lead to differences in risk related to exposure. Specifically, the cumulative effective dose of radiation administered increases with age, and is higher in children, women and obese patients.

Fluoroscopic imaging is a fixture in modern electrophysiology and catheterization labs, and may expose both patients and practitioners to radiation due to scatter from the incident beam.7,30 These doses are rarely measured,14 and it is difficult to determine how much radiation internal organs absorb.31 Complex procedures generally require longer fluoroscopy times, resulting in increased radiation exposure.10,30,32 Besides cancer risks related to radiation exposure, other risks associated with fluoroscopic imaging include radiation-induced cataracts and skin burns.33
LONG-TERM FINANCIAL IMPACT

In the long-term, illness related to radiation exposure may jeopardize cardiologists’ ability to maintain a full workload, and the hospital may be responsible for treatment costs, as well as insurance or other liability associated with key staff developing radiation-induced illness.

An international survey conducted by the Society of Cardiovascular Angiography and Interventions (SCAI) revealed that nearly 1 in 5 cardiologists have purposely not worn a dosimeter to avoid exceeding a radiation limit.34

As cardiologists increasingly move from contract positions toward full-time hospital employment, hospitals will be responsible for their benefits and Workers’ Compensation claims. Efforts taken now to reduce radiation exposure and develop a radiation-safe hospital environment can help preserve both hospital revenue and the safety of staff members.
REGULATORY RESPONSES

The current core European principle now governing the use of ionizing medical radiation is known as ALARA – As Low As Reasonably Achievable. Additionally, the EU developed a regulatory framework specifically related to medical radiation exposure.

Regulatory measures have been proposed by the European Commission to help protect health care professionals and patients from excess medical radiation exposure. The EU institutions agree that radiation exposure from medical imaging is potentially dangerous and should be minimized.
LIVE X-RAY REDUCTION

MediGuide™ Technology is the first and only solution to enable navigation of devices on pre-recorded X-ray images allowing the physician to reduce the duration of live X-ray during a procedure. MediGuide Technology applies 3-D visualization and precise navigation to pre-recorded 2-D X-ray images; the physician can use these images to perform complex electrophysiology procedures and CRT implants.
MEDIGUIDE™ TECHNOLOGY

MediGuide™ Technology is analogous to a global positioning system (GPS) in that it uses a low-powered electromagnetic field to locate device-based sensors in three-dimensional space. The system uses this location information to overlay MediGuide Enabled™ devices on the corresponding pre-recorded X-ray image, which allows the physician to reduce the duration of live X-ray during a procedure (Figure 3).

With the use of pre-recorded X-ray images, MediGuide Technology creates a real-time clinical environment that:

- adjusts automatically for changes in heart rate, respiratory motion and patient movement;
- accurately tracks catheter position and orientation within 1 mm and 1 degree;
- provides biplane visualization with uniplane equipment; and
- adds additional perspective and improves workflow during catheter navigation.

CLINICAL RESEARCH

Animal and human data consistently show that MediGuide Technology can accurately track diagnostic and ablation catheters with decreased fluoroscopic exposure and procedure time.\textsuperscript{1,39-42} Animal (swine) data have confirmed the accuracy of the technology during pacing, radiofrequency energy delivery and subject movement.\textsuperscript{39} Human data on the use of MediGuide Technology have shown consistent, positive outcomes in both tracking accuracy and reduction in duration of live X-ray.\textsuperscript{1,40-42}

Figure 3. Live X-ray (left) and pre-recorded X-ray (right) using MediGuide™ Technology
MEDIGUIDE ENABLED™ DEVICES FOR EP AND CRT PROCEDURES

The system consists of hardware and software elements that can be installed in conjunction with existing fluoroscopy imaging systems in catheterization or EP laboratories (Figure 4).

Figure 4. Main Components of the MediGuide™ System
ADDRESSING MEDICAL IMAGING CONCERNS

The use of medical imaging has increased substantially over the past 20 years, leading to concerns that physicians and patients are being exposed to increased and possibly excessive levels of radiation. Fluoroscopy, used for interventional radiology, is associated with the highest levels of radiation exposure. Current fluoroscopic navigational systems that interventional cardiology departments now deploy may lead to substantial radiation exposure for physicians, patients and hospital staff.

The use of MediGuide™ Technology in the electrophysiology lab improves procedure planning and guidance, while reducing the duration of live X-ray. The use of MediGuide Technology has been shown to reduce the duration of live X-ray by 50% to 86%. MediGuide Technology is the only 3-D cardiovascular navigation and visualization platform available to reduce live X-ray usage in the EP lab. This technology offers the potential to increase EP lab capacity and safety, as well as provide institutions with substantial benefit that may improve a hospital’s competitive marketplace position.
## Reduction of Medical Radiation Exposure

86% reduction of medical radiation exposure. 

## Procedure Time Reduction

40% reduction of procedure time.

### Comparison of Typical Effective Doses (mSv) from Medical Imaging Modalities and Body Area examined

<table>
<thead>
<tr>
<th>Procedure Description</th>
<th>Effective Dose (mSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental X-ray (Intraoral)</td>
<td>0.01</td>
</tr>
<tr>
<td>Chest X-ray (posteroanterior)</td>
<td>0.02</td>
</tr>
<tr>
<td>Chest X-ray (posteroanterior and lateral)</td>
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<tr>
<td>Breast X-ray (mammography)</td>
<td>0.4</td>
</tr>
<tr>
<td>Head CT scan</td>
<td>2</td>
</tr>
<tr>
<td>Coronary angiography CT scan (prospectively gated)</td>
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</tr>
<tr>
<td>Diagnostic coronary angiography (Invasive Imaging)</td>
<td>7</td>
</tr>
<tr>
<td>Coronary angiography CT scan (tube current modulation)</td>
<td>13</td>
</tr>
<tr>
<td>Coronary angiography CT scan (helical)</td>
<td>19</td>
</tr>
<tr>
<td>201TI-99mTc dual isotope (130/1000 MBq) (Cardiac Nuclear Stress test)</td>
<td>24</td>
</tr>
</tbody>
</table>

### Reported Values of Effective Dose Estimates (mSv)

<table>
<thead>
<tr>
<th>Procedure Description</th>
<th>Effective Dose (mSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Round trip flight, New York to New Orleans</td>
<td>0.02</td>
</tr>
<tr>
<td>Posteroanterior and Lateral Study of Chest</td>
<td>0.1</td>
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<tr>
<td>Annual Background Radiation to Public</td>
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<tr>
<td>CT Calcium Scoring</td>
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<tr>
<td>Myocardial Perfusion Imaging: Rubidium- 82</td>
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<tr>
<td>Diagnostic Coronary Angiography</td>
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<tr>
<td>Myocardial Perfusion Imaging: Sestamibi stress/rest (single day)</td>
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<tr>
<td>CT Chest for Pulmonary Embolism</td>
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<tr>
<td>PCI or RF Ablation</td>
<td>15</td>
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<tr>
<td>CT Coronary Angiography</td>
<td>16</td>
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<tr>
<td>Average Annual Occupation Dose Limit*</td>
<td>20</td>
</tr>
<tr>
<td>Myocardial Perfusion Imaging: Thallium stress/rest</td>
<td>41</td>
</tr>
</tbody>
</table>

*Average over 5 years. Maximal permissible in a year =50mSv.
References


5. European Cardiovascular Disease Statistics 2012.


Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

MediGuide™ Technology is intended for the evaluation of vascular and cardiac anatomy. It is intended to enable real time tip positioning and navigation of a MediGuide Enabled™ diagnostic or therapeutic invasive devices used in vascular or cardiac interventions in the Cath Lab environment, on both live and pre-recorded fluoroscopy. The System is indicated for use as an adjunct to fluoroscopy.

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