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October 2018

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## Letter from the Editor

# Does radiation oncology need a better 'brand'?

In addition to our focus this month on CT innovations, this is the issue where we turn out attention to radiation oncology and cutting-edge cancer therapies. What a coincidence that we are covering these topics as the annual American Society for Radiation Oncology (ASTRO) meeting gets underway in San Antonio, Texas!

OK, not a coincidence at all. ASTRO is the biggest event of the year for stakeholders in radiation oncology, and it's the perfect time to get experts discussing how the specialty is advancing.

It also happens to be a good time for non-experts to discuss it. During my annual check-up last week, my physician and I got on the subject. I was surprised that he (an excellent doctor, I should stress) had never heard of a linear accelerator. Maybe I shouldn't have been surprised, but for some reason I assumed they were generally well-known technology in the medical field.

It reminded me of the conversation I had with John Adler, CEO of Zap-X and inventor of the CyberKnife (pg. 40). To paraphrase, Adler suggested radiation is misunderstood in the general public and may unfairly suffer from an outdated reputation. He attributes this to the fact that radiation has advanced considerably over several decades, but has done so from within heavily shielded bunkers, secluded from everyone except the individuals who require these sophisticated services.

You'll have to read our interview to find out how Adler intends to improve that state of affairs, but I find that analysis very interesting and I wonder if others in radiation oncology feel the same way.

In our little bubble of HealthCare Business News we spend so much time writing about the incredible capabilities of the latest and greatest medical equipment that we sometimes forget there's a whole world of people out there (including medical professionals) who might have no idea how much better the technology is today than it was ten, twenty, thirty or even sixty years ago.

If you work in radiation oncology then I'd love to hear from you on the subject. Is your work a mystery to general practitioners and primary care providers?

Thanks for reading,

Gus Iversen
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# Misread scans at Illinois VA led to visit from concerned Congress member

**Posted online August 28, 2018 by Thomas Dworetzky**

**Reports of misread radiology scans are the latest problem to hit the Marion VA Hospital in Illinois – and the issue has led Illinois U.S. Rep. Mike Bost to pay a visit to the facility.**

He hosted House Veterans' Affairs Committee Chairman Phil Roe for a "listening tour" of the Marion facility – and to hold a press conference later, according to The Southern Illinoisan.

"We met with the radiology group today," Bost said, according to WPSD news. "We listened. They are working to improve that. We believe that they are. We believe they are meeting the goals and criteria that were set forth by the report to make sure that what happened here, as far as the reading of the X-rays [is concerned], does not happen again."

But neither representative brushed off the problems.

"They've got a lot of work to do," Roe said at the press conference, according to the station.

Veterans who had raised the alarms were less philosophical. "Shocked, shocked that something like this could happen," said Vietnam veteran Rocky Morris, who was there with a group of veterans, according to WPSD.

The matter is personal to Morris. "We had a friend from Benton that was one of them. It's going to cost him his life," he told the station, noting that even though he, personally, has gotten good care from the VA, "the complaints come from when we can get it better and nobody listens."

The Marion center had issues that hit the news in July, when Bost called on U.S. Department of Veterans Affairs Secretary David Shulkin to investigate allegations of mismanagement at the facility that might have hurt care and safety, according to a statement at the time.

Bost, along with Jack Bergman, R-Michigan, sent Shulkin a letter referencing a memorandum dated May 31, 2017, written by the VA National Center for Patient Safety program manager, that reported on the problem.

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15. **Israeli startup Alpha Tau Medical raises $29 million for novel radiotherapy**
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# iCAD shares soar following FDA nod for PowerLook Density

**Posted online August 13, 2018 by John R. Fischer**

**Shares for iCA Inc. soared last Wednesday in premarket trade following the FDA's thumbs up for the sale of PowerLook Density Assessment Version 3.4 in the U.S.**

The cancer detection and therapy solution enterprise experienced over 30 percent growth upon receiving FDA clearance for its artificial intelligence software, which is compatible with its digital breast tomosynthesis platform on GE and Hologic systems.

"Version 3.4 now supports assessing density using 2D synthetic images from GE and Hologic systems," Ken Ferry, CEO of iCAD, told HCB News. "With the updated version, the product can be used for GE and Hologic breast tomosynthesis cases where no 2D FFDM images are acquired."

Between 40-50 percent of women in the U.S. alone have dense breasts, which pose the risk of increasing the aggressiveness of tumors and masking their presence in mammograms. When used to evaluate dense breast tissue, the sensitivity of mammography decreases from an average of 98 percent to approximately 48 percent.

Using PowerLook Density Assessment Version 3.4 reduces the risk of reader variability, allowing radiologists to more easily determine if a woman may benefit from additional screening by delivering automated, rapid and reproducible assessments of breast density.

The solution utilizes a machine learning technique to categorize a patient's breast density, based on the American College of Radiology's Breast Imaging Reporting and Data system (BI-RADS).

While efficient, Ferry says that more action must be taken on the state level to educate patients about breast density and the associated risks, as well as laws in every state that mandate notifying women of their breast density following a mammogram.

"Ideally, patients should be educated about their density and the associated risks, but that's not always the case," he said. "Many U.S. states require healthcare providers to notify women – typically via a letter. However, not every state has laws in place that require women to receive some level of notification about breast density following a mammogram."

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# Philips unveils new ultrasounds for general and interventional cardiology

**Posted online August 23, 2018 by John R. Fischer**

**Royal Philips is unveiling two new cardiology ultrasound systems, tailored to meet the unique needs of general practitioners and interventionalists in the cath lab.**

Equipped with anatomical intelligence, the EPIQ CVx cardiovascular system provides clinicians with sharper images for greater diagnostic confidence and simplified workflow, reducing the need for repeat scans and increasing the time they spend with patients. The EPIQ CVxi solution combines live ultrasound and X-ray information into one intuitive view, enabling interventional cardiologists to oversee both procedures and the location of key anatomical structures simultaneously.

"By using advanced 3D organ modeling, image slicing, and proven quantification, anatomical intelligence is helping make ultrasound exams easier to perform and more reproducible," David Handler, general manager of cardiac ultrasound at Philips, said in a statement.

When evaluated, ninety-five percent in a group of clinicians claimed to see sharper and clearer images with the use of EPIQ CVx. The EPIQ CVxi platform is designed specifically for cath labs and utilizes Philips' EchoNavigator system.

The systems are CE marked and FDA cleared.

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# Boston Scientific to buy VENITI for $160 million

**Posted online August 13, 2018 by Thomas Dworetzky**

**Boston Scientific has signed a deal to acquire all of VENITI, privately-held maker of the Vici Venous Stent, upfront in cash for $108 million, with an added sum of up to $52 million contingent on FDA clearance for the Vici stent system.**

The east coast-based manufacturer initially invested in the Fremont, California firm in 2016, building up a 25 percent share of ownership in the company.

"This stent system was designed with the distinctive demands of the venous system in mind, and built to provide physicians with a high-quality lumen across a variety of venous anatomies and disease states," Jeff Elkins, president and chief executive officer of VENITI, said in a statement. "We are excited to see this stent technology become even more accessible to physicians and the patients they treat under the leadership of Boston Scientific."

Venous obstructive disease strikes over 1.1 million people in the U.S. and Western Europe each year. The self-expanding, nitinol VICI system addresses the specific challenges posed by venous anatomy, maintaining integrity for the life of the patient.

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# Image resolution three times higher with new MR coil

**Posted online August 09, 2018 by John R. Fischer**

**Researchers at ITMO University in Saint Petersburg have developed a new MR coil that produces images at three times the resolution of standard commercial volume MR coils.**

Using inexpensive materials and manufacturing technology, scientists created the component and conducted preclinical testing to capture high-resolution, whole-body imagery of a mouse.

"The primary goal of this work is the demonstration of the superiority of the proposed small-animal coil design for whole-body imaging, which opens new perspectives for preclinical imaging experiments that require high-quality imaging of large anatomical structures," Mikhail Zubkov, a postdoctoral researcher at ITMO University, told HCB News. "This may improve the sensitivity of other preclinical research if such coils are used, particularly for drug delivery, systemic diseases and other studies on animal models."

Obtaining high-quality, whole-body images with standard coils is often difficult, with clinicians combining images produced by several small receiving coils or using a big one to emit and receive signals to produce images that possess poorer quality.

The ITMO coil is adapted specifically for scanning the size of a mouse, enabling it to avoid extra noise in its imagery, and is composed of materials that can be adjusted for various projects. Scientists reduced its size using a metastructure with a disturbed capacity.

Researchers constructed a prototype based on numerical modeling used to optimize its geometry and determine which materials were needed. They then measured the signal-to-noise ratio in different parts of images at different distances between the object and coil, comparing their findings to the mathematical simulation and experimental parameters of standard volume coils. They eventually found an optimal distance in which the coil provides image quality three times higher than a standard one.

The reason is due to the higher alternating magnetic field intensity of the coil, compared to a standard one, providing it with high sensitivity in the entire field of view for improved image quality. It also requires no capacitors due to its self-resonant nature and can be tuned by changing the geometric parameters.

The design optimizes how the coil works as well as its sensitivity level and image quality, while offering faster prototyping and easier production of coils designated for very specific clinical tasks.

In addition, the coil can potentially possess higher lifetime expectancy than standard ones, and decreases scan preparation time due to the absence of wires needed to connect to the coil.

The findings were published in NMR in Biomedicine.

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# CureMetrix teams with University of Florida on CAD development

**Posted online August 01, 2018 by John R. Fischer**

**Computer-aided detection developer CureMetrix is teaming up with the University of Florida to produce the next generation of CAD tools for mammographers.**

The California-based enterprise will provide the radiology department of the sunshine state university access to its physics-based AI and deep-learning software solutions as part of an educational and investigational endeavor that aims to evaluate its efficiency and impact in producing accurate readings of breast imagery.

"I believe that University of Florida is always looking to stay at the forefront of innovation. CureMetrix and more broadly Artificial Intelligence represent a paradigm shift in radiology," Kevin Harris, CEO of CureMetrix, told HCB News. "There is an opportunity, through use of AI-based tools, to improve clinical effectiveness and efficiency. Building products that help improve the sensitivity and specificity of doctors is good for the patient, the doctor, the hospital, and healthcare in general."

Under the terms of the agreements, UF radiologists will evaluate the use of two of CureMetrix's investigational products, one being cmAssist. The physics-based CAD software is designed to identify and quantify regions of interest.

They will also be equipped with cmTriage, a worklist organizer and optimization tool for prioritizing studies based on regions of interest that are found to have suspicious findings. Clinical trials for both products are currently underway in preparation for their submission to the FDA in the coming months.

The agreement provides radiology residents with the opportunity to learn about AI in imaging while enabling the university to explore ways for improving clinical efficiency and patient outcomes.

In exchange, CureMetrix will utilize clinical data and anonymized images collected by the university over the last five years to further develop its CAD software for 3D tomosynthesis.

"By working closely with University of Florida, we will expand our firsthand knowledge of what doctors need to deliver better care," said Harris. "Combining that with access to their deep and rich data sets will help us continue to develop a CAD that works in all areas of radiology."

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# Varian to acquire motion management company, humediQ Global

**Posted online August 07, 2018 by Thomas Dworetzky**

**Varian has announced plans to acquire humediQ Global GmbH, maker of IDENTIFY, which handles patient identification, positioning and motion management for radiation therapy.**

"We are pleased to welcome the humediQ Global employees to the expanding Varian family in the region and add the comprehensive IDENTIFY solution to our portfolio," said Kolleen Kennedy, president of Varian's Oncology Systems business, in a statement accompanying the announcement.

IDENTIFY's automated workflow solution for surface-guided radiation therapy (SGRT) uses a palm reader to identify patients, and an RFID reader to ensure correct accessory verification and placement on the treatment couch. It automatically syncs with the oncology information system and SGRT cameras to verify proper patient positioning and motion monitoring during treatment.

"The IDENTIFY solution combines improved patient safety, an enhanced clinical workflow and surface-guided imaging for high-quality radiation therapy treatments," said Christian Hieronimi, CEO of humediQ Global in a statement, "we are excited to join Varian and bring this solution to as many patients as possible worldwide."

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# GE Healthcare joins AdvaMed

**Posted online August 15, 2018 by John R. Fischer**

**GE Healthcare has joined the ranks of the Advanced Medical Technology Association in an effort to advance policies in support of medical progress and improved patient care.**

The induction of the $19 billion healthcare business as an AdvaMed member provides it access to global thought leadership as well as policy area expertise.

"Just as GE will benefit from being part of AdvaMed and the extensive experience the association has in regulatory, reimbursement, legal and international issues, so AdvaMed will benefit from the resources and expertise GE has built up over decades," Andrew Steiner, vice president of membership and business development for AdvaMed, told HCB News.

In addition, its president and CEO of imaging, Tom McGuinness, will join AdvaMed as a member of its board of directors.

The decision of the multinational conglomerate to join AdvaMed follows a difficult year for the company, which has experienced a loss of $100 billion in wealth and was removed from the Dow Jones Industrial Average, a place it held steady on continuously since November 7, 1907.

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# NYU and Facebook collab to make MR 10x faster with AI

**Posted online August 22, 2018 by John R. Fischer**

**Completing an MR scan in a fraction of the time may soon be possible thanks to a new collaboration underway between the NYU School of Medicine and ubiquitous social media giant, Facebook.**

The New York-based med school's department of radiology has tapped Facebook Artificial Intelligence Research – a group dedicated to advancing the state of artificial intelligence – to support an NYU project called FastMRI that aims to reduce the time associated with MR scans without compromising image quality.

"MR is the gold standard imaging technology for soft tissues of the human body. However, its main limitation is the amount of time an exam takes," Yvonne Lui, associate professor and associate chair of artificial intelligence in the department of radiology at NYU School of Medicine, told HCB News. "Using AI, our aim is to acquire significantly less data than typically needed for a high-quality medical image, allowing the examination to be completed in a significantly shorter period of time while maintaining diagnostic imaging quality."

MR scans range from 15 minutes to over an hour and require patients to remain very still within a narrow bore which can sometimes induce claustrophobia. The exams can be uncomfortable experiences for young children and patients suffering from chronic illness and pain, requiring holding one's breath for a length of time when imaging certain organs.

Speeding up the process may alleviate some of these discomforts while also yielding practical benefits to providers, particularly in regions where MR access is limited and scheduling backlogs prevent patients from undergoing needed diagnostics.

The length of time associated with MR scans is due largely to the collection and transformation of raw numerical data into cross-sectional images of internal body structures for evaluating patient health, with larger data sets tacking on more time to exams.

Researchers in the NYU radiology department's Center for Advanced Imaging Innovation and Research (CAI²R) are planning to use artificial intelligence networks to recognize the underlying structure of images, filling in views omitted from accelerated scans, similar to how humans process sensory information.

Although reconstructing images from smaller amounts of information is difficult due to the risk of a few missing or incorrectly modeled pixels leading to inaccurate diagnoses, previous work at the medical center has found that artificial neural networks are capable of generating high-quality images from far less data, and may be able to capture previously inaccessible information that could help save lives.

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# Investors raise over $14 million for disruptive, low cost X-ray startup

**Posted online August 31, 2018 by John R. Fischer**

**Swiss and African investors have pledged more than $14.4 million (14 million CHF) to startup Pristem SA in the development of lower-cost X-ray scanners capable of operating in any location.**

Initiated by the EssentialMed foundation, a Swiss nonprofit, a project called GlobalDiagnostiX aims to bring imaging to low-income countries that generally lack the necessary infrastructure.

"I'm delighted to see the great enthusiasm for this project among the scientific, student and now investor communities," Klaus Schönenberger, the director of the EssentialTech program, which is heading the project, said in a statement. "This shows that we share the same vision of universal access to essential technologies, particularly in the medical field."

Two-thirds of the world's population lacks any access to medical imaging, according to the World Health Organization, preventing diagnosis and treatment for a range of conditions. Further burdening this issue is the surge in healthcare costs, of which medical imaging procedures make up a significant portion. The purpose of the project is to change this by introducing a high-quality system that provides services to markets worldwide at a lower cost.

The machine will be designed with a robust and economic design, constructed of mechanical, solid and stainless constituents and capable of resisting harsh tropical climates as well as high temperatures, humidity and dust.

It will also utilize a radiographic image sensor based on an array of twelve CMOS sensors that are available at moderate costs, are easy to replace, and the images from which are composed by the scanner's software. It will provide services to markets worldwide at lower total cost, which includes both the machine itself and all aspects of its life cycle such as commissioning, maintenance and training.

In addition, the machine will be equipped with a power module that will provide up to 150,000 volts for operating an X-ray emitter without overloading the hospital's network, the total consumption of which is often lower in developing countries than a single X-ray machine.

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# Alphabet-backed One Medical in talks to raise over $200 million

**Posted online August 22, 2018 by Thomas Dworetzky**

**One Medical is "in late-stage conversation" with The Carlyle group about raising $200 million in growth capital, sources have told CNBC.**

The company, which launched in 2007, had already raised about $180 million from backers including JPMorgan, Alphabet's GV, Benchmark and Maverick.

Concierge-care-focused One Medical is hoping to "disrupt" the doctor's office primary care market.

Carlyle, with over $200 billion in assets, also is intending to buy $100 million in shares from investors on top of the funds, sources told CNBC.

One Medical has offices in cities around the nation, including in San Francisco, New York, and Seattle, and takes most insurance – as well as taking payments without insurance. At present, it is in-network with all major PPO and HMO health plans, according to its website – with copays, coinsurance and deductibles just as with a regular doctor visit. Insurers already accepting One Medical include: Aetna, Anthem, Blue Cross Blue Shield, Cigna, Health Net, UnitedHealthCare, Blue Shield of CA, Oscar, Arizona Care Network, PacifiCare, Empire, Tufts, and Harvard Pilgrim.

One Medical's latest reported value is over $1 billion.

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# Siemens Healthineers to adjust supply networks to minimize tariff hits

**Posted online August 01, 2018 by Thomas Dworetzky**

**Siemens Healthineers is looking to ease its tariff costs by altering supply routes to ship more of its U.S.-destined goods from European factories rather than Chinese ones, chief financial officer Jochen Schmitz told reporters Monday, according to Reuters.**

"This won't happen without leaving some trace on our results because we have to change logistic chains ... depending on how the situation develops," he said, following the company's conference call on Q3 results.

He advised the tariff impact would be low – "a low single digit million euro impact on Healthineers' results this year," said the wire service.

"When it stays in this range it won't be a catastrophe but of course the topic is very, very regrettable because it significantly impairs global trade," he said.

Adjusting to the tariff landscape was not the least of the Healthineers' economic picture, as it announced results for its fiscal third quarter, which came in at an adjusted operating property margin of about 16 percent, down from 17.1 percent in the year-ago quarter.

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# FDA greenlights focused ultrasound trial for Alzheimer's treatment

**Posted online August 03, 2018 by John R. Fischer**

**The FDA has cleared the way for researchers to initiate a clinical study that will utilize MR-guided focused ultrasound to noninvasively open the blood-brain barrier (BBB) for enhancing the treatment of Alzheimer's disease.**

The multicenter, single-arm phase 2a trial follows a smaller one conducted by researchers in Toronto to evaluate the efficiency and safety of INSIGHTEC's Exablate Neuro low-frequency ultrasound for temporarily opening the BBB of five AD patients repeatedly, to enable better delivery of drugs for Alzheimer's and other neurodegenerative diseases. The phase 2a trial will evaluate the approach in a larger set of patients.

"The most common way through the blood-brain barrier is to inject hypertonic mannitol in the arteries going to the brain," Dr. Neal Kassell, chairman of the Focused Ultrasound Foundation, told HCB News. "It opens the blood-brain barrier in the territory in which the arteries are feeding the brain. It's sort of an indiscriminate approach and invasive and incredibly awkward to do. Focused ultrasound can be done in a very highly targeted manner and can be done to open the blood-brain barrier temporarily and reversibly; and it can be done repetitively."

More than 6.4 million people in North America and 44 million worldwide are afflicted by dementia, with Alzheimer's being the most common form. While efficient at protecting the brain from toxins and infectious agents, the BBB blocks the entry of drugs treating diseases such as AD, with many unable to breach it due to their large sizes.

Utilizing low frequency ultrasound waves, Canadian researchers at Sunnybrook Health Sciences Centre in the phase one trial were able to noninvasively open the BBB in a small area of the frontal lobe in patients between 50 and 85 in the beginning stages of AD. They previously applied this approach in 2015 to evaluate the delivery of chemotherapy to brain tumors.

The trial was conducted to evaluate safety and feasibility in the repeated opening of the BBB with focused ultrasound, taking part in two stages. The first involved opening a small area of the brain to temporarily open the BBB, followed approximately one month later by the second, which involved opening a larger area. No drugs were administered in this study.

The phase 2a trial is expected to begin this fall.

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# North Carolina surgeon fights to overturn state law on MR

**Posted online August 03, 2018 by John R. Fischer**

**An MR scan for as low as $500 would be a dream for many patients. Dr. Gajendra Singh, a surgeon based in Winston-Salem, North Carolina, set out to make that dream a reality last August when he set up his own imaging center.**

Immediately, he encountered trouble in the form of North Carolina's Certificate of Need (CON) law, which prohibits him from purchasing his own MR system and has forced him to rely on the assistance of a mobile rental unit, costing him more than a permanent machine would, and leaving his office without the ability to perform MR scans five days a week.

This week, Singh had enough, filing a lawsuit Monday in North Carolina Superior Court to overturn the law.

"CON laws require government permission in order to offer a new medical service or buy new equipment such as an MR scanner," Renée Flaherty, an attorney at the Institute of Justice and the lead lawyer for Singh in his case, told HCB News. "The process to obtain a CON is extremely expensive and burdensome. In North Carolina, it can cost up to half a million dollars and take years to get through the process. Smaller medical providers simply can't afford to fight for a CON, but big hospitals can."

Only 14 of 49 states that retained CON laws at one time have rescinded them in the last 40 years on the basis that they only serve to protect hospitals from competition. In North Carolina, state officials decide each year if different places require certain services. If it is decided that an area does not need a specific service, then providers seeking a CON are barred from applying for even a permit.

This was the case for Singh, who argues that along with expenses of applying for CONs, the use of this law creates monopolies dominated by big providers that restrict the ability of others to compete in the market and raise the costs for exams.

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# Hologic acquires Faxitron Bioptics for $85 million

**Posted online August 01, 2018 by John R. Fischer**

**Hologic has acquired Faxitron Bioptics for approximately $85 million, expanding its product portfolio within the breast conservation surgical market.**

The purchase of the privately held enterprise gives Hologic access to Faxitron solutions, designed for breast lesion localization and sentinel lymph node biopsy, as well as digital specimen radiography.

"With the expanding range of Hologic's breast health portfolio, this acquisition further strengthens our ability to positively impact patient lives by enabling us to play a larger role in breast conserving surgery, an adjacent growth market for the company's interventional breast business," Pete Valenti, division president of Hologic's breast and skeletal health solutions, told HCB News.

The agreement equips Hologic with a variety of solutions including Faxitron's VisionCT, the first 3D breast specimen-designated CT systems designed and FDA approved to offer 360-degree images of excised lesions, and its VersaVision digital specimen radiography system, cleared in October by the FDA for imaging core biopsy and surgically excised specimen samples.

Primarily a provider for breast surgeons and pathologists, Faxitron racked up approximately $27 million in revenue in its last fiscal year.

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# FDA clears Aidoc AI solution for triaging head CT scans

**Posted online August 08, 2018 by Lisa Chamoff**

**Aidoc has received FDA clearance for its first AI-based workflow optimization solution, which assists radiologists by flagging acute intracranial hemorrhage (ICH) cases in head CTs and integrates with existing PACS.**

The deep learning product is the first to focus on acute care for radiologists, where time is of the essence, according to Elad Walach, Aidoc's chief executive officer.

"We're excited about this specific clearance as it has a unique place in the market," Walach told HCB News.

Walach said the deep learning algorithm runs in the background and focuses on abnormal regions and not a specific pathology, lending itself to triage and prioritization of certain cases, at a time when radiologists are challenged by more data and higher read volumes.

"We believe the biggest component of AI is the workflow integration," Walach said. "It has to be intuitive to the radiologist."

Cedars-Sinai Medical Center in Los Angeles recently conducted a study of the Aidoc brain package and found that using it decreased report turnaround time by more than 60 percent and also increased the radiologist's confidence in their findings.

"Seeing the software in action emphasized the key aspects an AI solution needs to possess to have an impact on the radiologist day to day – seamless integration into the workflow and broad applicability," said Dr. Barry Pressman, chairman of imaging at Cedars-Sinai Medical Center and former president of the American College of Radiology, in a statement. "With the evidence I've seen, in the not so distant future, it will almost be unthinkable to practice radiology without the assistance of solutions like Aidoc."

Walach said the latest clearance is part of a company strategy to focus on AI solutions for acute care across the entire body. They are currently developing and investigating algorithms for the head, spine, abdomen and chest.

"We want to make sure whenever there is a CT exam, we will be applicable to it," Walach said.

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# Henry Ford Health System and GM enter 'Direct to Employer' healthcare contract

**Posted online August 08, 2018 by Thomas Dworetzky**

**Henry Ford Health System and General Motors have signed a "Direct to Employer" healthcare contract – a first-of-its-kind arrangement for both organizations.**

The deal means that GM will deliver both healthcare management and wellness services to salaried GM workers and families in Southeast Michigan. The option will cover a seven-country area and roughly 24,000 individuals.

"We are very committed to addressing the affordability of healthcare – offering exceptional care while bending the cost curve for consumers in the communities we serve. Given our experience in delivering value-based care, and our extensive physician network, we are uniquely poised to create a truly innovative solution for GM, their employees and families," said Wright L. Lassiter III, president and CEO, Henry Ford Health System, in a statement.

The arrangement takes the form of GM's ConnectedCare plan option, to go live in 2019, which will give access to a 3,000 provider network of both primary care physicians and specialists. The option offers primary care, over 40 specialties, behavioral health services, hospitalization and emergency care, plus other services, including a pharmacy feature.

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# Philips relocating 280 jobs out of Andover, Massachusetts

**Posted online August 29, 2018 by Thomas Dworetzky**

**Philips has announced it is moving another 280 of its remaining Andover, Massachusetts positions to new locations.**

Plans currently slate the departure for 2020, Silvie Casanova, Philips director of communications, told the Eagle Tribune.

About 120 of the positions are heading for the firm's Reedsville, Pennsylvania location, where workers "will have the opportunity to transition with their role," she noted. About 160 of the slots are heading to Philips' new Cambridge headquarters.

Alex Vispoli, chairman of the Andover board of selectmen, called the decision to relocate the jobs to Cambridge "disappointing." It was particularly hard, he added, as they "were told that the ultrasound division would stay in Andover."

Despite numerous meetings between town manager Andrew Flanagan, Paul Materazzo, the town's director of planning, and Philips executives, Vispoli noted, that was not to be.

"Ultrasound employees whose roles require closer collaboration and proximity to customers, partners, academic institutions and technology leaders so that we can truly partner and co-create solutions for the future of healthcare will transfer to Philips' new location at Cambridge Crossing," Casanova said.

The company had already said in January that it would transfer 1,900 positions from Andover. At that time, it announced that it was moving its U.S. headquarters from Andover to Cambridge, as well, according to the Boston Globe.

Plans call for the new Cambridge location to become the world hub for the firm's healthcare efforts, pulling together R&D, already in the Boston area, and innovation and commercialization groups into one place.

CEO Frans van Houten told the paper at the time that this was part of the transformation of the conglomerate into a healthcare-focused company.

"This is all about location and proximity to innovation," he said. "We need to be in the hot spots of healthcare innovation, close to universities, where you can find the talent for the next generation of innovation."

In the last few years Philips has purchased roughly 14 healthcare firms.

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# IBM pushes back against Watson Health critics

**Posted online August 21, 2018 by Thomas Dworetzky**

**Big Blue has a big problem with media coverage of Watson Heath.**

After a number of negative stories about the progress of IBM's AI efforts – notably including one in Stat News and another in the August 11th Wall Street Journal – Dr. John Kelly, IBM senior vice president, Cognitive Solutions and IBM Research, is pushing back.

"We at IBM have a lot to be proud of, including our pioneering work with Watson Health," he writes in his August 11th blog post. "Unfortunately, some media reports, including an August 11th story published by The Wall Street Journal, distort and ignore facts when suggesting IBM has not made 'enough' progress on bringing the benefits of AI to healthcare."

The Wall Street Journal piece noted that «more than a dozen IBM partners and clients have halted or shrunk Watson's oncology-related projects.»

Kelly acknowledged that the company had made "a big bet" on healthcare, and that although there have been some dropouts, the systems are in 230 hospitals. They've also doubled the number of patients reached to 84,000 in the first half of 2018.

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# Richardson Healthcare obtains ISO 13485:2016 certification

**Posted online August 14, 2018 by John R. Fischer**

**Richardson Healthcare is stepping up its reputation as a quality manufacturer by obtaining ISO 13485:2016 certification.**

To hold the international standard provides greater confidence to customers by validating the ability of the healthcare division of Richardson Electronics Ltd. to design, develop, produce and distribute medical devices that are safe for use, particularly in its manufacturing of CT solutions and power grid tubes.

"Obtaining certification to ISO13485 demonstrates to our customers and to regulatory bodies that we have an organization that is committed to the Medical Device Industry and we have the discipline to maintain the structure we have created to run an efficient business with a focus on quality, regulatory compliance and customer expectations," Pat Fitzgerald, executive vice president and general manager at Richardson Healthcare, told HCB News.

Certification required demonstrating that Richardson could develop and distribute medical solutions and related services that continually meet customer and regulatory requirements by participating in a thorough audit of its quality system processes and product quality requirements.

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# Upcoming Events

## ASTRO 2018 Annual Meeting - American Society for Radiation Oncology

**Location:** Henry B. Gonzalez Convention Center, San Antonio, TX
**Dates:** October 21 – 24
**Years in existence:** 60
**Average attendance:** 11,000
**Who should attend:** Radiation and medical oncologists, surgeons, researchers, oncology nurses and medical physicists.

## TractManager User Group Conference

**(Incorporating MD Buyline, MediTract, Hayes, Newport Credentialing and more)**
**Location:** Omni Frisco Hotel, Frisco, TX
**Dates:** October 30 - November 1
**Years in Existence:** 1
**Who should attend:** Healthcare professionals who use or would like to learn about TractManager solutions and services.

## MEDICA 2018

**Location:** Düsseldorf Fairgrounds Dusseldorf, Germany
**Dates:** November 12 – 15
**Years in Existence:** 49
**Average attendance:** +130,000
Who should attend: GPOs, integrated delivery networks, HME/DME providers, physician private practice, medical laboratories, HER/EMS/PHR/PACS/RIS, medical services providers.

## RSNA 2018 - Radiological Society of North America

**Location:** McCormick Place Chicago, IL
**Dates:** November 25 – 30
**Years in Existence:** 104
**Average attendance:** +55,000
**Who should attend:** Physicians, radiologists, physicists, medical professionals in all fields of medicine.

## Oklahoma Hospital Association

**Location:** Cox Convention Center & Renaissance Hotel, Oklahoma City, OK
**Dates:** December 5 - 7
**Years in Existence:** 99
**Average attendance:** 600+
**Who should attend:** Anyone employed at an Oklahoma hospital.

## FBA 2018 - Florida Biomedical Association

**Location:** Disney's Yacht Club Resort, Lake Buena Vista, FL
**Dates:** December 6 - 8
**Years in Existence:** 33 years
**Average attendance:** 550
**Who should attend:** FBS offers educational offerings for Biomeds, Clinical Engineers & CE Managers that want to continue their career growth. Our exhibit hall has over 110 Exhibitors showing off their products and services.


## Arkansas Children's Northwest

**Location:** Springdale, Arizona
**Year founded:** Opened Feb. 27, 2018
**Number of beds:** 24 inpatient beds and 30 clinic rooms
**Number of employees**: 350+
**Senior Vice President and Chief Administrator:**
Trisha Montague, MSN, RN, NEA-BC


**Noteworthy distinctions:**
As the region's only comprehensive pediatric health center, Arkansas Children's Northwest offers families:

- 233,613 square feet of wellness space designed to maximize children's discovery & delight
- A state-of-the-art pediatric surgery center with 5 operating rooms
- A full range of ancillary and diagnostic services, child-life, social work and pastoral care programs
- Outdoor gardens, nature trails and interactive features designed specifically for children
- A helipad and refueling station supporting Angel One, one of the nation's leading pediatric intensive care transport services

**Specialties:**

- Region's only pediatric emergency room
- Pediatric cardiology
- Pediatric neurology
- Pediatric hematology/oncology
- Pediatric pulmonology

**Recent developments:**

Arkansas Children's Northwest offers families the first and only children's hospital and pediatric emergency department in the region. The health system moved existing outpatient clinics from Lowell, Arkansas to the new facility in January.

In late February, Arkansas Children's Northwest opened to inpatient care, offering 24 beds. ACNW was built on 37 acres in Springdale donated by Robin and Gary George, Cathy and David Evans and their families, a $7.5 million investment in the region's children. The new campus joins a flagship hospital in Little Rock, a statewide transport system dedicated to delivering children in critical condition to lifesaving care, and a range of outreach programs that includes telemedicine, mobile health and school-based health solutions.




1. *The nation's newest children's hospital is built on 37 acres of land donated by Robin and Gary George, Cathy and David Evans and their families, a $7.5 million investment in the region's children.*
2. *Natural light and an open, airy design makes Arkansas Children's Northwest an inviting place where children are less intimidated by the sometimes frightening medical procedures ahead of them.*
3. *Arkansas Children's Northwest offers families lifesaving diagnostic services in its imaging center, complete with child-savvy designs and lighting that distracts young patients.*
4. *A colorful infusion center is already in use by several children who are for the first time able to take chemotherapy near their homes at Arkansas Children's Northwest. They have previously driven three hours to Little Rock for each treatment.*
5. *Sculptures across the new hospital were strategically created to inspire "discovery and delight" for visitors of all ages. Photo credit Ken West.*

# Q&A with Trisha Montague

## chief administrator for Arkansas Children's Northwest

*By Sean Ruck*

**Arkansas Children's Northwest is the nation's newest stand-alone children's hospital. Its campus opened in early spring, hosting 24 inpatient beds and the region's only pediatric emergency room.** HCB News spoke with the hospital's chief administrator, Trisha Montague to learn more about her background and about the new hospital.

**HCB News: What inspired you to follow a career in healthcare?**

**Trisha Montague:** Honestly, I am one of those people, even as a small child, I was very interested in nursing as a career. I just always loved being with people and I was the little girl going around finding animals to take care of. As I got through high school and thinking about college, nursing was all I was interested in. My first rotation in pediatrics – that was it for me – I knew it was my calling. I've been a pediatric nurse ever since.

**HCB News: What attracted you to Arkansas Children's Northwest?**

**TM:** I actually worked at Arkansas Children's Hospital in Little Rock a number of years ago. So I was very familiar with the healthcare system in Little Rock and their reputation, and the level of care they provided. When the opportunity came up to build a greenfield small children's hospital and to create something really transformative for a community, it was certainly something I was going to consider. To add to that, there's the president and CEO of Arkansas Children's hospital, **Marcy Doderer**. I worked with her in San Antonio at a children's hospital there previously, so I knew her very well and certainly considered her a person I'd love to work with again. It was really a combination primarily of the uniqueness of the opportunity and the chance to make a difference in a community that didn't have a children's hospital nearby, and knowing I was going to be working with a visionary leader.

**HCB News: What kind of population does Arkansas Children's serve?**

**TM:** Northwest Arkansas is an interesting community. The world's largest company is headquartered here and there are a couple of Forbes 500 companies too, so there's wealth and growth and high-level executives. There are also parts of Northwest Arkansas that have some of the most underserved communities in the state. So it's really a combination. When we look at who our patients and payors are, we're looking at probably about 63 percent of our population as Medicaid, then private pay and about 4 percent self-pay.

**HCB News: What challenges does the hospital face that are specific to treating children?**

**TM:** Pediatric healthcare is unique, with its own standards of care and body of evidence of what's best for children that might be differentiated from adults. So that's one challenge right out of the gate.

There are about 200 children's hospitals in the country, so legislation, recognition, research, funding, all of those things – children's hospitals are not always at the top-of-mind. Children don't vote, so when you're working with the politicians you have a different level of conversation as far as advocacy goes. It makes it uniquely challenging to have a level playing field.

The other thing about children's hospitals is that our expertise is from the smallest of neonates up to someone like a 20-year-old linebacker for the Razorbacks. So you have to have the knowledge and ability to deal with that spectrum of people and to also have the equipment and supplies. You don't have one set of adult oxygen masks, you have five sets of different sizes. That just repeats throughout all your medical supplies and equipment. That's one of the reasons children's hospitals are more challenging from a financial standpoint, because you need to have everything available for any size patient that may come through the door.

Another thing is that your patient isn't just the child, but the family as well. It's about taking care of the family as a whole.

**HCB News: What kind of accommodations or children-specific attributes does your hospital have?**

**TM:** That experience really starts as soon as they walk through the door. That was a very intentional part of our design process throughout the hospital. We wanted there

to be an experience from the moment they walked through the door where they say, "It's a warm, inviting, interesting place that engages me and doesn't frighten me at all." I think it's really important for kids and parents to be able to enter and have that experience right from the beginning. We did that here with a design concept we call "discovery and delight" that has different little things like a little bird or squirrel that children can find throughout the hospital. Another example would be our MR scanner. We installed this newer kind of pediatric scanner in a room that's set up with a whole lighting system and video system. Before the child goes into the MR, they sit with the tech to pick out the colors and videos. It's a cool digital process for choosing things. That was something we invested in and it turned out to be super popular for all ages. We also have a child-life specialist program which is a standard of care. It's really an important part of effectively taking care of families.

**HCB News: Do you believe the appropriate levels of investment are being made in children's healthcare today?**

**TM:** I want to be clear that this is speaking from my perspective. I think what's challenging about pediatric and reimbursement these days is that Medicaid is federally funded, but state-regulated. So one state may be reimbursing hospitals in a reasonable manner for their Medicaid populations and another state may be really difficult. That really varies. In the last few years, all the workarounds and how things are reimbursed make it challenging. I think the big challenge for children's healthcare, as I mentioned earlier, is getting the attention of legislators. And the way Medicaid is regulated right now is a little challenging.

> As I got through high school and thinking about college, nursing was all I was interested in. My first rotation in pediatrics – that was it for me – I knew it was my calling. I've been a pediatric nurse ever since.

**HCB News: With hospitals being a place for ill individuals and children undergoing treatment sometimes having compromised immune systems, is there a concern with the growth of non-vaccinated children arriving for treatment?**

**TM:** As a pediatric healthcare provider, I would say we absolutely have a concern about that and that is a little bit of an issue specifically in this community. The concern is partly ensuring that we're keeping everyone safe within our hospital. That's why we have a lot of different screenings in place to make sure we understand who's coming in through the door. Moreover, we know from the science that vaccinations can prevent what can be deadly diseases. So it's not just about preventing the spread of disease within a community, but also about the individual child avoiding a disease that could cause long-term complications or even death. For instance, there was an outbreak of mumps in this community a couple of years ago.

> Before the child goes into the MR, they sit with the tech to pick out the colors and videos. It's a cool digital process for choosing things. That was something we invested in and it turned out to be super popular for all ages.

**HCB News: What are your predictions on how child-focused healthcare should change and how it might change over the next five to 10 years?**

**TM:** I think in pediatric healthcare we have the advantage of a relatively small community, compared to the rest of healthcare. It allows us to come together and learn best practices from each other, do focused research on children, and gain knowledge about patient safety and outcomes in a much more nimble way. There's an international association called the Children's Hospital Association. In the past 10 years or so it's become much more comprehensive, and this group has developed what they call "solutions for patient safety." They're bringing experts from children's hospitals around the world and pooling knowledge and resources around understanding what the safety risks are for children in hospitals and clinics, what the pediatric healthcare outcomes are that we believe we want to make an impact on but haven't yet, and working toward comprehensive solutions. I see pediatric healthcare really setting a high bar in relation to the rest of healthcare as to how we can come together and benefit the patients we serve.

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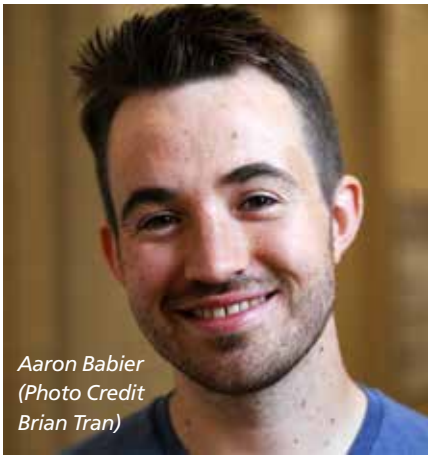
# Optimizing radiation therapy plans with AI

*By Sean Ruck*



*Aaron Babier (Photo Credit Brian Tran)*

**Aaron Babier, a Ph.D. candidate at University of Toronto, and his team have developed a new method for AI to optimize radiation therapy plans.** While AI has been used for optimization previously, Babier is taking a new approach.

The inspiration struck nearly two years ago. Babier said there was an optimization method that provided an output a clinician could use in their current treatment planning pipeline. "We knew that we could get those parameters if we had dose volume histogram curves, which are basically high-level representations of a treatment plan," he said. "We did a bit more digging in the literature and found there were a lot of methods that would predict these high-level treatment plan features."

After the team modified the features, they were able to get predictions for the target as well as the healthy tissues. Combining that information with their optimization method allowed for the creation of an optimization pipeline. "So the things we developed were based on the bag and query method and this generalized PCA (principal components analysis) approach, which was based on previous work," Babier explained.

Babier was inspired to get into the field of cancer treatment after his stepmother passed away from cancer when he was 12. His interest in optimization and machine learning developed later, but ultimately led him to the idea of automated treatment planning.

Studying the field of automated planning, Babier realized that many of the current automated pipelines overhaul current planning paradigms. He realized there was an opportunity for a new method to be adopted if a higher level of control could be given back to clinicians since, he said, the current programs don't allow clinicians to change the plans in an intuitive manner. "Our program can almost work like a black box behind the scenes of the current planning method and it can basically be a plug-in to a framework that clinicians are familiar with," he said.

Essentially, Babier's method isn't looking to reinvent the wheel. Instead, it's looking to add some rubber to the treads to help clinicians get more control of their plans in a way that provides support, but isn't overbearing.

The team focused on throat cancer for their research because, as Babier explained, they wanted to study a cancer treatment plan that would be relatively complex, while having a heterogeneous patient population – or a cohort which looked very different from each other. The complexity comes in part from healthy tissue often overlapping the target area, "so it's not as intuitive on how you should be planning for certain cases. We wanted to pick a site where the patients are very different so we could use the machine learning to predict the trade-off the clinician would normally make before the clinician looked at the plan. We chose head and neck because the trade-offs are quite variable between the patients," Babier said.

Babier believes that by perfecting the software by focusing on head and neck, it should translate well to other sites like prostate and breast. The evidence backs him on this, as there have been successful implementations from head and neck to simpler sites in the past. He says the hard part is getting the data to do it.

Regarding the optimization, Babier says the work the software does takes about 20 minutes. For a human to do the same work – to go in and tweak optimization programs and then review – takes 15 to 20 minutes. However, it's typically not a one-time tweak of a program. Babier says the process of adjusting, reviewing and revising might take a couple of hours to a couple of business days. So if it was "one and done" for a human to do the work, it would be one story, but due to repeat revisions the AI optimization earns its keep.

Babier believes there's work to be done not just on the software and technical side, but also on the personnel side where the people working on machine learning and those in clinical practice aren't necessarily speaking the same language, but both sides are starting to understand each other more as the work evolves.

One of the big takeaways from the work the team did was learning how messy hospital data is. Even within the treatment plans, Babier said there was a lot of information that wasn't clear on how they were developed. "Even the simplest things, like how certain structures are named, can vary dramatically. Dealing with that weird naming culture is a challenge. The data cleaning work you do upfront is really important to these AI optimization processes. I will say that, apparently, hospitals are getting better with their labeling – I think they're starting to use scripts or AI more to make it more uniform. When humans are in charge, variation happens very quickly," Babier said.

The next step for the technology is to get it out to a hospital in Canada to further refine it, with the plan to grow it to other hospitals and other treatment planning software.

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# The price of peace of mind and patient safety

*By Sean Ruck*

*Michael McNeil*

**There's been a constant hum of news about cybersecurity in recent years.** That hum became more of a roar around late 2016, when hacks of campaign emails became front page news during the presidential election. But in healthcare, the constant balancing act of keeping legacy systems safe and fending off attacks that continue to increase in sophistication keeps professionals like **Michael McNeil** busy.

McNeil was a member of the Healthcare Industry Cybersecurity Task Force, a government-sponsored group that was instrumental in the creation of the Cybersecurity Act of 2015. He is also the global product security and services officer for Royal Philips, and has held the position for over a decade. He and his team are responsible for deploying and installing security by design for any customer-facing offerings the company has in the marketplace. "As we identify threats and vulnerabilities, we put the process into place to make sure they're managed appropriately. So I have a team that has that responsibility globally across Philips," he said.

While there have been a number of high-profile attacks on the healthcare sector recently – like the WannaCry ransomware attack last year that hit hospitals in the U.K. particularly hard – McNeil said that in order to understand events like that, it's important to take a step back to look at the landscape of the healthcare industry and marketplace. "That particular landscape allows us to know where we stand in regard to other industries. So for example, the healthcare industry, with how it's designed to maintain solutions in the marketplace, has clearly been a laggard compared to the financial services industry, even though healthcare is considered by most countries to be a critical infrastructure," he explained.

McNeil said healthcare has the tendency to maintain and elongate the life cycle of the technology the sector uses. That wasn't necessarily a problem for some solutions when the technology was introduced 15 or 20 years ago because they may have been operating in a contained environment. It wasn't until connectivity and the need for connectivity increased that the vulnerabilities in those systems became obvious. "What a number of organizations from manufacturers to health delivery organizations have tried to do is to bolt on protocols and abilities to make that communication and connectivity of solutions much more ubiquitous," McNeil said.

But the problem was that they put a bandage on something that potentially had a deeper wound. As those protocols were added, the possibility that they could hide but not necessarily fix other flaws increased. That means the industry had to continue playing catch-up to keep legacy devices safe and adhere to the appropriate level of performance to head off vulnerabilities, even as the revenue stream for those devices slowed.

That information lead to the question that probably causes sleepless nights for hospital administrators – at what point does it become more financially responsible to buy new technology instead of patching legacy equipment?

It could be argued that the WannaCry attack that wreaked havoc in U.K. hospitals last year had the potential to physically harm patients due to it blocking access to medical records and causing the rescheduling of non-critical medical operations, the harm wasn't direct. While some experts have warned that it's possible we could see hacks to pacemakers or other devices that would cause direct harm to people, so far it's been ransomware attacks and theft of patient information, which all seems targeted at a direct for-profit focus. Regardless of the rationale behind the attacks, the potential financial impact for a compromised hospital or healthcare system is enormous. Consider the cost of a few days' downtime on one of your heavily-used pieces of imaging equipment. Now multiply that by however many different modalities you have in use every day and consider that financial impact. That's not even taking into account the hit to your organization's reputation. So that's why McNeil urges people to understand where their vulnerabilities are. "So the very first task is that you take an inventory of the equipment and see where you have systems that are still being supported, because you need to know where your exposure is in that particular environment," he said.

By support, McNeil means you need to know which devices are still being monitored by the OEM or software provider, how often patches are introduced, and what kind of access you have to customer support in case something seems strange. After you've done your assessment, he advises you weigh your financial decisions and focus on the higher-risk areas to replace equipment if possible. "Now, for those that can't be replaced, we need to understand what other isolations and hardening of the systems can be done," he said.

Still, his main advice when using connected technology is to go with what is supported. "The notion of patches will always be attractive because malware will continue to evolve," he said.

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# Navigating the CT market

*By Cris Bennett R.T. (R) (MR)*

**When considering the purchase of a new scanner, a facility must focus not only on today's needs, but on needs over the next 10 years.** We are seeing purchasing departments take this exact approach more and more these days. As reimbursement is falling across the radiology space year by year, many facilities are making their capital equipment purchases for the long haul.

Don't be afraid to let the prospective vendor know you're looking into other vendors; this can add to deeper discounting to get your business.

We are seeing very few system purchases in the 16-32-slice count categories due to scalability and dose. Such systems are purchased mainly for clinics or as a secondary system to back up the primary, higher-slice-count system. We have seen a big increase over the past year in interest in the 64-slice and above market. Many facilities are taking advantage of end-of-quarter/end-of-year savings and multiple promotions offered by the quoting vendor that can help offset the cost of the overall system.

The end of the fiscal year can often yield the best prices of the year from a vendor. Also, don't be afraid to let the prospective vendor know you're looking into other vendors; this can add to deeper discounting to get your business. We have seen many facilities previously known to buy their CT systems from only one vendor leave that relationship for a better price and sometimes a better system. Also make sure the vendor identifies the price for the trade-in. With this information it is easier to know the true purchase price of the system. Often an included trade-in can falsely increase the discount by 10 percent.

Your knowledge of the market and your negotiation skills are key to getting the best discount. Market research can be done through benchmarking companies or through a Request for Information (RFI) or Request for Quotes (RFQ). The information from these documents can help to educate your purchasing and/or departmental staff about the offerings of multiple vendors, thereby guiding the team to the right system to purchase.

It is important to know the scalability of the systems of interest, as this will aid in determining if the system you are interested in is right for your facility over the long term. Another important factor is the availability of advanced scanning applications for cardiac, vessel, and metal artifact reduction. These applications are some of the most common items on quotes we see from various vendors.

As always, when purchasing capital equipment, you will need service for that system. Some years back, there was a trend toward entrusting service to the in-house BioMedical Service Engineer (BME) department. In today's market, we are seeing more hospitals opt for full-service contracts from the vendor instead. When looking at service contracts, make sure that your tube metrics are within range of the patient volume that you are currently processing and that the metrics represent what your usage will be with an improved workflow with the new system.

Also keep in mind that the vendor has an overage fee if you exceed the tube metrics. This fee needs to be outlined in all documentation that accompanies your CT system. This will help you avoid costly overage fees. You also need to make sure all equipment – not just the tube – is covered: for example, ECG cables, injectors, and UPS systems that are attached to the scanner.

### Product/Technology

32–40 Slice CT Systems

| Low | High | Average Price |
|---|---|---|
| $290,000 | $390,000 | $340,000 |

### 64–80 Slice CT Systems

| Low | High | Average Price |
|---|---|---|
| $600,000 | $950,000 | $700,000 |

### 128–160 Slice CT Systems

| Low | High | Average Price |
|---|---|---|
| $530,000 | $1,200,000 | $815,000 |

### 256–512 Slice CT Systems

| Low | High | Average Price |
|---|---|---|
| $1,200,000 | $3,200,000 | $1,650,000 |

*Source: MD Buyline, mdbuyline.com*

Please note that these numbers have been adjusted to exclude special deals, outliers, and unique circumstances.

*About the author: Cris Bennett is a clinical analyst at MD Buyline.*

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# Q&A with Horst Giesen

## global portfolio director for Health & Medical Technologies at Messe Düsseldorf

## What to expect at MEDICA 2018

*By Gus Iversen*

**Fall is almost here and that means the annual MEDICA trade fair is just around the corner.** As it does every year, the event will take place at the Messe Düsseldorf fair grounds in Germany. From November 12 - 15, medical equipment stakeholders from around the world will convene for the massive event to network, make deals and catch up with old colleagues.

HealthCare Business News checked in with Horst Giesen, global portfolio director, Health & Medical Technologies at Messe Düsseldorf, to find out what he's most excited about for this year's event, how the show has evolved over the years, and what role global affairs have in the actual experience of MEDICA.

**HCB News: Can you tell us about your role within MEDICA and how long you have been involved in the event?**

**Horst Giesen:** For over 25 years I have been the project manager responsible for MEDICA. In addition to managing the work of the project team, key aspects include the ongoing content alignment of MEDICA with current trends and its worldwide marketing.

This requires close cooperation and coordination with many partners. At MEDICA 2017 we introduced our new umbrella brand MEDICAlliance. This includes all healthcare events organized by the Messe Düsseldorf Group globally. As global director, Health & Medical Technologies, I am also responsible for the strategic alignment and uniform marketing of these events.

**HCB News: In retrospect, which memories or topics made the biggest impression at last year's event?**

**HG:** At MEDICA, visitors are always offered the entire spectrum of innovations for outpatient and inpatient care, with a variety that has no equal and is unique worldwide. And yet there is one subject in particular that fascinates the industry, has already had a strong influence on the last MEDICA, and will once again provide much to talk about in November 2018 – digital transformation! It shapes the healthcare industry worldwide, has changed processes and business models, in some cases radically. We're staying on top of this hot topic and are examining it from different perspectives in our forums as well as the accompanying conferences.

**HCB News: Is there anything you are particularly looking forward to at MEDICA 2018?**

**HG:** I look forward to the appearance of our new Federal Minister of Health, Jens Spahn. He has only been in office for a few months and has already made it clear that he wants to "step up the pace" with regard to the digitalization of the healthcare industry in Germany. Jens Spahn will open MEDICA 2018 and the 41st German Hospital Day on the opening day (November 12).

**HCB News: In what way is MEDICA influenced by the global economic crisis and political climate? Do political conversations make up a large part of the event?**

**HG:** The market for medical technology and medical products is, and always has been, a growth market. However, in many sectors the current tendencies toward more restrictions in trade policies, certain political tensions or exchange rate fluctuations are not beneficial for business. This is also true of the medical technology sector. The increasingly strict regulations for product approvals on a transnational level present a challenge. This affects manufacturers and their suppliers equally. Particularly, small and midsized companies struggle intensely with the obligations of increasingly extensive documentation and reports as a result of a multitude of EU regulations and guidelines, for example the Medical Device Regulation or REACH (Registration Evaluation, Authorization and Restriction of Chemicals).

Due to such market characteristics, visitors and exhibitors to our MEDICAlliance trade fairs, which are organized worldwide, are faced with many questions in order to put their own business on the right track internationally and to get together with the right partners. We offer them the communication and information platforms tailored to their specific needs. For example, the MEDICA TECH FORUM provides

information on legal aspects of product approval, interesting export markets – including the consideration of political developments or, among other aspects, current issues in connection with data protection and cybersecurity.

**HCB News: What percentage of visitors and exhibitors came from the USA last year and what feedback did they give you?**

**HG:** Of the total 5,115 exhibitors at MEDICA 2017, over 400 came from the U.S. This is one of the nations that traditionally count among those with the most registrations, behind Germany. This year we are expecting a comparable amount of registrations. The rate of returning exhibitors is very high, which indicates how satisfied the American exhibitors are with MEDICA. Last year, just over 4,000 of the total 123,000 visitors came from North America.

**HCB News: Do you have any tips for new exhibitors at the trade fair?**

**HG:** Every exhibitor, whether he has been at MEDICA for years or for the first time, should «drum up advertising» for his MEDICA participation. We offer a wide range of services to support exhibitor promotion and inform all participating companies well in advance of the start of MEDICA.

**HCB News: In all the years you've been involved in the MEDICA, how has the show changed and developed over the course of the years?**

**HG:** In the earlier years of its more than 40-year history, MEDICA was a trade fair and congress event that focused primarily on physicians from the private practice sector and, incidentally, was more nationally oriented. Over the years, MEDICA became more and more popular on a transnational level and through conceptual changes, for example the integration of INTERHOSPITAL, it also expanded its target group spectrum on both the visitor and exhibitor side. In addition to medical specialists, the clinic management, the specialized medical dealers and the medical technology industry itself are now also strongly represented among the visitors. The latter is mainly due to the fact that since its launch in 1992, the concurrently held supplier trade fair COMPAMED has developed into the leading international platform and thus, a visitor magnet for industrial audiences.

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# Q&A with Dr. Paul Harari

## ASTRO president

ASTRO
TARGETING CANCER CARE

*By Sean Ruck*

**ASTRO's annual meeting is scheduled for Oct. 21-24 at the Henry B. Gonzalez Convention Center in San Antonio.** In advance of the show, HealthCare Business News spoke with ASTRO president Dr. Paul Harari to get some insight on his background, what's going on with the association and oncology, and what to expect at this year's show.

**HCB News: What inspired you to get involved in healthcare?**

**Dr. Paul Harari:** Dreams of being a professional baseball player as a kid faded away after tearing my rotator cuff while pitching in college and realizing a baseball career was not going to happen. Medicine seemed a natural fit, as I greatly enjoyed biology and physics in college. Medical school opened up my passion to care for patients with significant illnesses. Early in residency, recognizing that we could provide cancer patients a chance for cure or meaningful palliation to improve their quality of life attracted me to oncology.

**HCB News: How long have you been a member of ASTRO and why did you join?**

**PH:** I joined ASTRO as a first-year resident in radiation oncology training and have not missed an annual meeting in 32 years since then. ASTRO serves as a cornerstone of activity and information for clinical advances, cancer research, education and health policy. ASTRO also provides a remarkable network for professionals interested in the field of radiation oncology around the world to connect.

**HCB News: What initiatives do you plan to champion as president of the association?**

**PH:** It is vitally important for us to illuminate the tremendous power and precision of radiation to heal, cure, image and improve human health and quality of life. With the 60th anniversary of ASTRO in 2018, the October annual meeting highlights the enormous capability of radiation oncology to deliver cancer cure and palliation now and into the future. Translating cutting edge research discoveries into opportunities for cure is a theme to be highlighted this year.

**HCB News: What are the biggest uncertainties or challenges in radiation oncology today?**

**PH:** A significant challenge, as well as opportunity, for disciplines like radiation oncology is that the body of knowledge changes very rapidly. New cancer treatments and techniques are emerging at a record pace and practitioners are always searching for the best way to stay abreast of the latest developments that may be beneficial to their cancer patients.

**HCB News: Is radiation oncology facing any difficulty with having enough professionals entering the field?**

**PH:** Radiation oncology has been among the most competitive specialties for medical students to enter over the last decade. We have plenty of young professionals highly interested in entering radiation oncology. The challenge involves the optimal geographic distribution with urban and suburban centers being very well served, whereas many rural regions have significant challenges attracting radiation oncology practitioners.

**HCB News: Are there any recent developments in the field you're particularly excited about?**

**PH:** The field of radiation oncology continues to become more precise and increasingly team-oriented. Advances in the technological precision of radiation delivery are allowing higher doses to be delivered to tumors with reduced dose to surrounding normal tissues. Cancer specialists are increasingly working more effectively as teams, where minimally-invasive surgery, radiation and drugs are often combined to increase cure rates. Multidisciplinary care that aligns the expertise of dedicated specialists together is very powerful to help shape the most effective cancer treatment approach for each individual patient.

**HCB News: How much discussion is there about the role or potential of AI in oncology?**

**PH:** AI is squarely on the radar in virtually every medical specialty. There are fantastic opportunities emerging with AI to further enhance the field of radiation oncology. We have many brilliant medical physicists highly engaged in this space currently. For example, how might we more efficiently and precisely contour all the normal tissue structures adjacent to tumors on hundreds of diagnostic images for each patient? This can be a time-

consuming process at radiation treatment centers around the world. New opportunities for advancing these and other AI efforts are increasingly on display at our meetings, including the October 2018 ASTRO Annual Meeting in San Antonio.

**HCB News: Can you talk about some of the things you feel are the highlights of the upcoming ASTRO conference?**

**PH:** Discovery Science takes center stage at the 2018 ASTRO Annual Meeting, as highlighted by the Presidential Symposium, where we will explore four major themes that have the potential to dramatically impact cancer care and radiation oncology in the future. These game-changers include Immunotherapy/Radiotherapy Interactions, Viral-Induced Cancers, Artificial Intelligence and Liquid Biopsies. A powerful lineup of exceptionally talented speakers will illuminate the science and potential clinical applications in each of these exciting areas.

The 60th annual ASTRO meeting will highlight several practice-changing clinical trials that will impact cancer care around the world almost immediately. Look in particular for powerful new clinical trial results that will come forth in head and neck cancer, breast cancer, lung cancer and prostate cancer.

The Director of the National Cancer Institute (NCI), Dr. Ned Sharpless will provide a high profile Keynote Address that will illuminate current and future visions for the NCI.

Community oncologists will find a valuable new program at the 2018 ASTRO meeting that provides valuable tips and practice approaches to assist in their daily cancer practice.

And these highlights only scratch the surface for ASTRO's 60th Annual Meeting in San Antonio this October. We encourage HCB News readers to follow the meeting online using the hashtag #ASTRO18.

**HCB News: Is there any advice you can offer for someone looking to join ASTRO?**

**PH:** Join now, even while you are a medical student with a developing interest in the field of oncology. This early glimpse into the world of cancer research and clinical care will capture your enthusiasm and engage your professional interest for a lifetime.

**HCB News: Can you give your prediction as to how you think radiation oncology will change over the next 10 years?**

**PH:** During the next 10 years, radiation oncology will be characterized by even greater precision, increased cure rates, diminished side effects, more effective and durable palliation, increased cost effectiveness and an expanding role in the multidisciplinary world of cancer care.

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# Radiation oncology stakeholders flock to San Antonio for ASTRO



**The American Society for Radiation Oncology (ASTRO) will host its 60th Annual Meeting at the Henry B. Gonzalez Convention Center in San Antonio, Texas, October 21-24, 2018.** The event is expected to attract approximately 11,000 oncologists, researchers and other industry stakeholders from around the world.

Researchers will present peer-reviewed abstracts on advances in clinical care for cancer patients, panels and case discussions will feature leading experts and underscore the meeting's theme, "Translating Discovery to Cure," and the exhibit hall will be filled with leading manufacturers showcasing their latest offerings.

As always, the meeting will feature updates from clinical trials and cancer research involving radiation therapy. At last year's ASTRO meeting, our reporters noticed four themes at the show, which conveniently all began with the letter P: planning, precision, protons and the patient.

While those topics are sure to continue dominating conversations at this year's meeting, it will be interesting to see how the focus has shifted. Whether you're down on the front lines in the Lone Star State or keeping up with the news remotely: be sure to check out our Daily News online at www.dotmed.com/news for updates throughout the event.

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# ASTRO Exhibitors 2018

## Cold Shot Chillers
## Booth 2008

Cold Shot Chillers manufactures medical chillers for cancer care facilities and hospitals. Our chillers are configured to provide correct heat removal, using proper flow and pressure requirements. We work directly with contractors, physicists, OEMs, distributors, rebuilders, and resellers. Please stop by booth 2008 to discuss your next chiller project.

## Hitachi Booth
## Booth 3349

Hitachi provides flexible particle therapy solutions from single compact room to multi-room solution. Hitachi also offers proton, heavy-ion particles and hybrid (proton + carbon) solutions. Hitachi is a pioneer in the spot scanning technology for particle therapy. Our state of the art system have been selected and demonstrated by prestigious users worldwide. For more information, please visit Hitachi booth at ASTRO 2018.

## IBA
## Booths 2033, 2226 and 2233

IBA is the worldwide technology leader in proton therapy. From truly compact single rooms to fully customized multiple room systems, IBA's Proteus Class portfolio offers the solution you need. With IBA, you will secure your investment, secure your performance and secure your future by establishing a world-class radiation oncology department.

## Mevion Medical Systems
## Booth 2844

The MEVION S250 Series is elegantly designed to deliver high-powered, efficient proton therapy treatments. Built upon the world's only gantry-mounted proton accelerator and benefitting from Mevion's patented direct beam technology, the MEVION S250 Series delivers on the therapeutic promise of proton therapy while enhancing beam quality, stability and uptime. The result is reduced system complexity, higher reliability and throughput, and lower capital and operating costs—making the MEVION S250 Series a compelling, financially viable solution for all cancer centers. **MEVION S250i with HYPERSCAN technology**, overcoming pencil beam scanning uncertainties by delivering robust Intensity Modulated Proton Therapy treatment at hyper-speed.

## Sun Nuclear & Gammex
## Booths 1302 & 733

Sun Nuclear, the worldwide leader in Patient Safety solutions for Radiation Oncology, is pleased to participate in the 2018 ASTRO Annual Meeting, exhibiting in booths #1302 and #733.

Booth #1302 will display the latest in Patient-Specific and Machine-based quality assurance (QA) and Dosimetry. Demo the SunCHECK™ workflow automation platform for fully integrated and independent QA, and view Stereotactic Solutions, including SRS MapCHECK™ and StereoPHAN™.

Diagnostic QA solutions featured will include comprehensive CT QA tools, Mammography, Ultrasound, and Solid Water® HE.

Booth #733 will highlight Patient Marking and Alignment solutions, including CT SIM+™ Moveable Laser and MICRO+™ Remote Adjustable Fixed Lasers Systems.

## Varian Medical Systems
## Booth 1403

Imagine a world free from the fear of cancer. We do, every day. That's why at Varian, we're obsessed with creating simpler, more efficient, and more effective technologies to power new victories in cancer care. Our goal: enable clinical teams to spend less time managing technology and more time caring for patients. Varian provides comprehensive solutions for radiotherapy, radiosurgery, proton therapy and brachytherapy, as well as software systems for managing comprehensive cancer clinics, planning treatments, and analyzing data to support knowledge sharing and evidence-based medicine. Visit our booth #1403 to learn more about what's new this year.

# ASTRO
## PRODUCT SHOWCASE

The following are just some of the products and services on display at ASTRO 2018. To view these products online or to share the article with colleagues, visit dotmed.com and enter the code DM 44492 in the search window or enter the address www.dotmed.com/news/44492 in your browser.

### MEVION S250i™
### Mevion Medical Systems
### Booth 2844

Mevion is the leader in compact proton therapy. The MEVION S250i™ with HYPERSCAN™ technology is a radically different pencil beam scanning solution, built to eliminate the shortcomings of first generation PBS systems. HYPERSCAN technology utilizes a unique combination of optimum spot sizes, hyper-fast layer switching and a novel multi-layer proton MLC.



### Comprehensive Radiation Oncology Tools
### Sun Nuclear & Gammex
### Booths 1302 & 733

Gammex, a Sun Nuclear company, develops solutions for your evolving diagnostic QA needs. Visit Booths #1302 and #733 to learn about the latest solutions.

Comprehensive QA solutions shown in Booth #1302 will include Patient-Specific and Machine-based quality assurance (QA), Dosimetry, CT, Mammography, Ultrasound, and Solid Water® HE.

Booth #733 will highlight our laser focus on Patient Safety. Our Patient Marking and Alignment solutions - CT SIM+™ Moveable Lasers and MICRO+™ Remote Adjustable Fixed Lasers - ensure accurate patient marking with a simplified approach for effective CT simulation workflows.

### ACWC-90-DM Air-Cooled Water Chiller
### Cold Shot Chillers
### Booth 2008

Our model ACWC-90-DM is an air-cooled water chiller. Two pumps are used with this chiller. A chiller pump is used to recirculate the fluid through the tank and evaporator to provide a consistent chilled fluid for your linear accelerator. A process pump is used to provide the proper flow and pressure needed, based on the piping layout and the model of linear accelerator used. An onboard PLC monitors the operation of the chiller and will report any errors in a numeric code to the temperature controller LED display. This feature has proven to reduce downtime.

### Proteus®PLUS
### IBA
### Booths 2033, 2226 and 2233

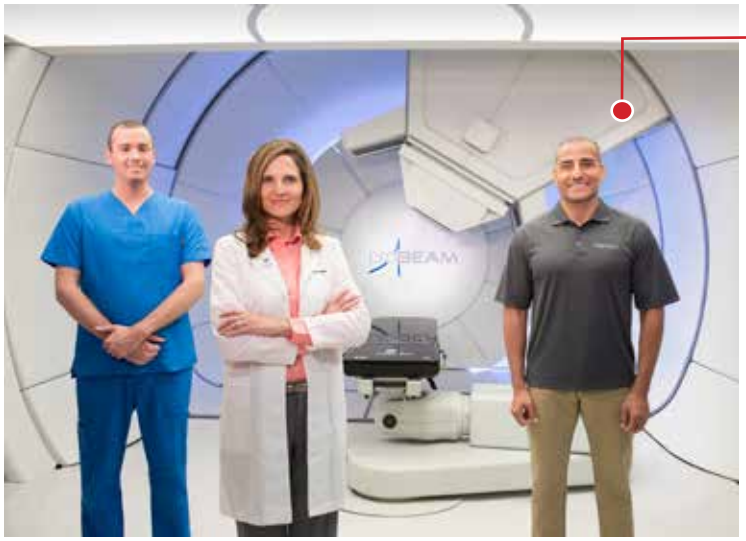
Proteus®PLUS is a multi-room proton therapy solution with the latest advances in precise, image-guided and intensity modulated proton beam delivery. It enables you to offer new treatment options to patients and investigate new protocols and retreatment opportunities.

### Proteus®ONE
### IBA
### Booths 2033, 2226 and 2233

Proteus®ONE is a compact single-room proton therapy solution with PBS and CBCT, allowing easy integration into a variety of healthcare settings. Smaller and more affordable than conventional multi-room proton systems, but with the same clinical applications.


### GammaPod™
### Xcision Medical Systems
### Booth 739

GammaPod™ is the world's first stereotactic radiotherapy system optimized for treating breast cancer. With GammaPod, radiation oncologists will be at the forefront of a new era in cancer care by providing stereotactic body radiotherapy (SBRT) for breast cancer. The delivery of higher doses in one or several fractions differentiates stereotactic radiotherapy from conventional techniques. The system combines a dynamic treatment delivery system that conforms the dose to the target with sharp falloff to limit dose to healthy tissue, a first-of-its-kind breast immobilization system for stereotactic precision and automated prone positioning systems for quick and comfortable patient setup.

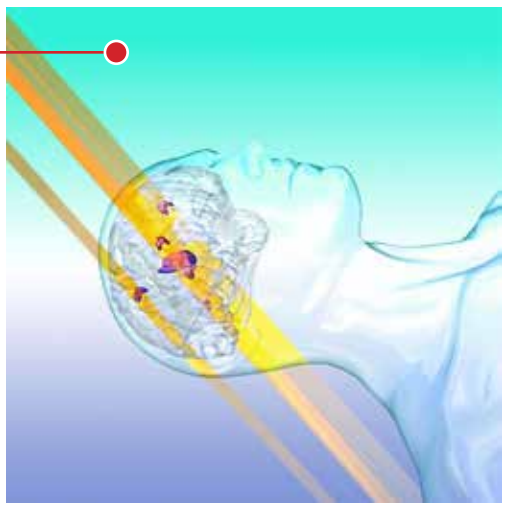


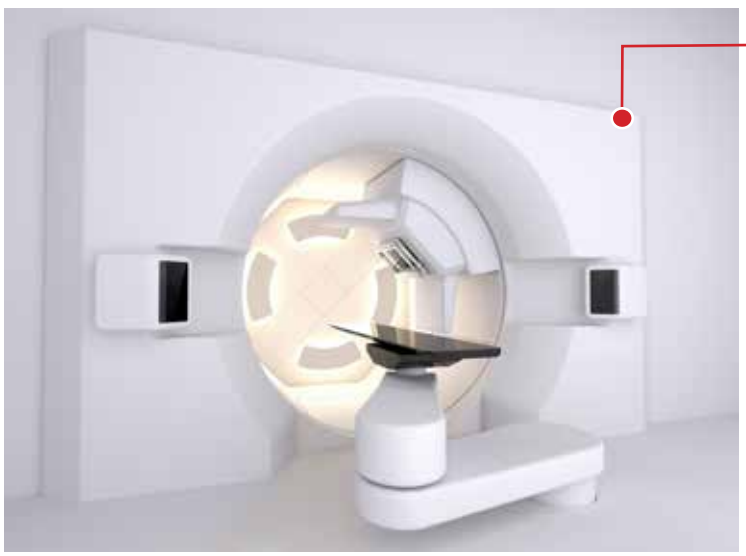
### ProBeam® proton therapy system
### Varian Medical Systems
### Booth #1403

Varian's ProBeam® proton therapy system is available in single-room and multi-room configuration. The system consists of one proton accelerator, and up to five fully rotational 360° gantry treatment rooms, or a variety of room configurations. Gain confidence that you're on target with the integrated 360° CBCT technology that is utilized on over 5000 Varian Linear Accelerators. Linac-like treatment flexibility with the full 360° rotational gantry and ad-hoc KV-Xray imaging enables you to image anytime during treatment at your current gantry angle. Highly efficient Pencil Beam Scanning and automated workflow enables patient throughput that is similar in efficiency to modern linear accelerators.

### HyperArc™ high-definition radiotherapy
### Varian Medical Systems
### Booth 1403

Varian's HyperArc™ high-definition radiotherapy is an end-to-end solution for frameless, linear accelerator-based intracranial radiosurgery. It automates and simplifies the planning and delivery of sophisticated treatments such as stereotactic radiosurgery (SRS) to make them available to more cancer patients around the world. Virtually all elements needed for treatment of both simple and complex cases are incorporated, including simulation guidelines, patient immobilization, treatment planning, patient setup, intra-fraction imaging and a predetermined delivery sequence. HyperArc addresses concerns about complexity, patient safety, cost, and human resources that can make SRS inaccessible for many patients and unfeasible for many institutions. It capitalizes on the unique capabilities of Varian's TrueBeam® and EDGE™ treatment platforms and is designed to enable consistent, high quality planning and seamless one-click delivery.





### Hitachi
### Booth 3349

The world's only synchrotron-based single room solution, the synchrotron accelerator technology allows for less shielding thus minimizing the overall size of the layout and the concrete cost to the building. Compared with our past layout, Hitachi has minimized and optimized the configuration yet utilized the identical gantry and accelerator technology which has been proven with our multi-room solution.

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# Radiation shielding: ways to save and things to consider

*By Lauren Dubinsky*


*Workers lower high-density concrete blocks into assembled framework on site (courtesy MarShield)*

**Requiring as much as 1.5 million pounds of concrete, a radiation shielding project is not a construction job that should be taken lightly.**

These expensive and time-consuming endeavors call for a team effort and the leadership of a specialist. HealthCare Business News went around the industry to get tips and insights from some of the experts in the field.

"The first thing I always advise is to get the physicist involved as early as possible in the planning process," said **Adam Evearitt**, co-owner of Atom Physics, a company that specializes in X-ray equipment and radiation safety consulting. "I often can help in the design of a room or project to minimize the shielding or the cost that's going to be involved with the shielding just by the way the machines are oriented in the room."

He says that too often he receives calls from facilities seeking help at the last minute when a project is almost complete. Usually this happens when the vendor is about to install the machines and, when asked for the shielding design specifications, the administrators aren't prepared.

**Robert J. Farrell**, CEO of Veritas Medical Solutions, stresses that there is a big difference between general construction and a specialty company that focuses on radiation protection.

"I met with a contractor today," he said. "The group is very well qualified as a general contractor, but they have not designed


Adam Evearitt


Robert J. Farrell


Frank Heinz


Kevin Milne

or constructed a project requiring radiation shielding in over seven years."

Making sure you have the right team members involved in a shielding job is the best way to ensure costly problems don't arise along the way or in the aftermath of installation. Trying to go it alone, or cutting corners as a way to keep costs down, is one of the surest ways to wind up paying more in the long run.

## Things to consider

Regardless of the specific project, the most common advice **Frank Heinz**, owner of H&H Design-Build, provides to his clients is to focus on safety.

"It's important for them to understand the impact of the project on their facility," he said. "Radiation shielding is a function of patient, staff and public health and safety. Depending on the type of project — diagnostic, cancer treatment, cyclotron or hybrid operating room — the requirements can be all over the board."

Farrell recalled a facility Veritas worked with in the past that gave no consideration in the design phase to the occupied space below the proposed treatment room. The design team was well-versed in construction but since they didn't understand shielding, they didn't plan how they were going to shield the public in the area below the room.

"They also did not consider the massive weights as well as the logistics involved in a shielding project," said Farrell. "This lack of familiarity led to a failure to take precautions for adequate support of the treatment level floors, where material deliveries and future service requirements would be required."

The purpose of radiation shielding is twofold, and what's going to happen in the room itself is no less important than what's going to be happening in the neighboring rooms.

*The H&H Design-Build team added 14" of lead shielding for the ceiling of a new radiation therapy to protect occupants above.*

"It really matters if the other side of the wall is a parking lot, where you don't need to shield as much, rather than if you are next to a daycare center or an administrative office," said Evearitt.

For an interventional suite or a CT room, the workload is key to determining how much shielding is required. Therefore, it's advisable to also plan for a potential increase in workload.

"If you are building a new X-ray room and you are not a very busy center, you shield based on 25 exams per week. But five years from then, business could quadruple and you're doing hundreds of exams per week," said Evearitt. "With that increased workload, you may then need to go back and add shielding in, and that is always extremely expensive."

Paying for extra shielding during the initial construction job is a way to save money down the line, while also banking on the success of your new facility and a heightened demand for services.

As with anything, it may be tempting to go for the cheapest option, but Farrell warns that the least expensive solution is rarely going to save money in the long run.

"A project we were asked to provide pricing for decided to save money by choosing a different method than we offered. It was the least expensive option that was presented them," said Farrell. "They called us nearly 11 months later, having just completed their project because they had problems. The shielding they constructed did not work."

The facility had to spend over $150,000 on shielding remediation in order to be safe and compliant, and the project took an additional eight months, according to Farrell.

According to **Kevin Milne**, president and CEO of MarShield, the best thing a radiation shielding client can do is bring as much logistical information as possible to the chosen shielding company. This preparation, even before the project begins, will help ensure a smoother job.

That means figuring out how much protection they need, what lead shielding equivalency they require, the dimensions and application of the room, the availability of off-loading, handling of the weight and demographics of the install.

## Lead or no lead?

Even though people equate lead to shielding, shielding today does not necessarily have to be made of lead. This is a good thing, considering the Department of Health and Human Services, Environmental Protection Agency and the International Agency for Research on Cancer have determined that lead is "probably cancer-causing" in humans.

"Lead is a hazardous material so the cost of shipping it, installing it and ripping it out can get pretty expensive," said Evearitt.

Several companies now offer non-lead-based materials for shielding. For Atom Physics projects, Evearitt uses Artemis Shielding's patented, nontoxic lead placement, which is a tungsten-based material that is embedded into a rubbery substance.

"It's more flexible and can be applied straight onto things," he said. "With my company, we use that in particular when we don't want to rip out a wall and have those construction costs. We get this Artemis Shielding material and slap it on the back of some paneling and then we can place that onto the wall."

He added that it may cost a little more upfront to purchase this material, but in the long-run it will save money.

MarShield offers a non-lead alternative called T-Flex, which is made of a bismuth tungsten base. Milne said it's ideal for applications that require custom moldable shapes such as small-bore pipes, elbows and valves, but it's also available as blankets, ribbon wrap, pipe shields, floor tiles and magnetic tiles.

Still, not everyone agrees that it's time to abandon lead for radiation shielding. Companies like Calder Industrial Metals, for example, assert that it offers advantages that continue to make it the best option.

"Lead is very quick and easy to install and the room is ready to use straight away," said **Andy Carr**, head of external sales at Calder. "You don't have to wait for the lead to harden or set."

In the case of a room being relocated, Carr said lead offers unique advantages in that it can be quickly disassembled. It is also recyclable and can be melted and reused.

## Radiation therapy rooms

In early 2010, Mount Vernon Cancer Centre in the U.K. began a project to install its first Accuray CyberKnife. For Calder, it was a particularly demanding radiation shielding project.

The architects determined that in order to construct a safe room, while minimizing the impact on the existing hospital structure, lead radiation shielding was the most effective material to use. Calder's Chevron Rail System was installed and depending on the location within the room, the thickness of the lead varied between 30 millimeters to 300 millimeters.

In total, 102 tons of lead was installed. The overall budget was £3.8 million and the project was completed in eight months.

Designing a vault for a radiation therapy system was also one of the biggest projects Evearitt has worked on. The design process took Atom Physics about a month, but the entire install project took approximately a year.

He explained that the difference with radiation therapy machines is that once you get above 10 megavolts, you are producing neutrons.

"Not only do you have to protect from the X-rays that are a thousand times higher than a typical X-ray machine, but they create neutrons, which are much harder to stop," he said. "So you have to have several feet of concrete in place in each of the walls and ceiling."

MarShield's biggest project was supplying over 245,000 pounds of high-density concrete shielding blocks to Princess Margret Hospital in Toronto for its cancer treatment therapy room expansion project.

These high-density concrete blocks are dry-stacked and require half the space of concrete vaults. According to the company, the blocks interlock to form a tight, leak-free therapy room of any size or shape.

This option is also suitable for proton therapy facilities because they can cut months off of the average construction schedule.

"The high density block systems have replaced concrete as we all know it," said Milne. "For assessable locations and large projects for high-dose therapy rooms, this is the way to go."

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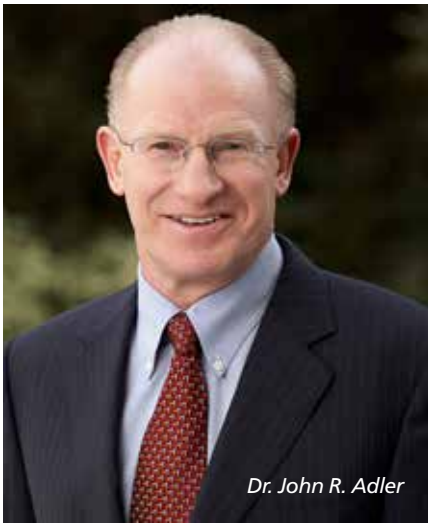
# With Zap-X, the creator of CyberKnife aims to give radiation a better image

*By Gus Iversen*



*Dr. John R. Adler*

**Best known as the creator of the CyberKnife and a pioneer in image-guided radiation targeting, Dr. John R. Adler Jr. is a familiar name to most people involved in radiation oncology.** What many people may not know, however, is that he is currently in the process of bringing a new radiosurgical tool to head and neck cancer treatment that aims to bring lower cost to providers.

In early July, HealthCare Business News sat down with Dr. Adler to learn about his new company, Zap Surgical Systems, and why the Zap-X radiosurgical solution could fill an important gap in the existing radiosurgical landscape.

**HCB News: Is it fair to say the Zap-X surgical solution is like a Gamma Knife combined with a CyberKnife?**

**Dr. John R. Adler:** Technologically, and kind of in its primary design specifications, but it's like neither one exactly. It does things slightly different from both of them but the primary objectives and some of the major design specifications are quite similar.

It uses a linear accelerator, which makes it like a CyberKnife, CyberKnife uses image guidance to target and it also uses a linac. The defining feature of the Gamma Knife, I might argue, is that it specializes on the brain and goes after a specific subset of the anatomy, which makes it like the Zap-X machine – but in the end Zap-X is its own unique animal.

**HCB News: What sets it apart from other linear accelerators?**

**JA:** It focuses on radiosurgery not radiotherapy… I would argue that there is value to focusing on specific anatomy because you can optimize performance for the specific anatomy and also simplify the process of treating specific anatomy, and also focus on cost. You can strip out a lot of useless function that people don't want.

Think about a linear accelerator that is designed to treat all parts of the anatomy. Intrinsically, that's good, but along with that comes a lot of complexity and a lot of cost, and so our design here was to break down what we think are the cost and procedural complexity barriers that prevent the wider availability of brain radiosurgery, specifically.

A Siemens MR scanner can do head and kidney and ankles, for example, but now more and more we see more people who just want an extremity MR scanner. We are like that extremity MR scanner. We are the first ever to segment the overall radiotherapy marketplace with a linac. Zap-X is used for brain and head and neck; it goes down to the base of the neck.

**HCB News: Are there any currently installed? Does it have regulatory clearance?**

**JA:** We have FDA clearance as of last year, but not yet in clinical use. First machine is installed in Barrow Brain and Spine in Phoenix, Arizona, a partner of Barrow Neurological Institute. That is a 40-person neurosurgery practice and they installed it in the last couple months. They're planning to treat the first patient next month.

**HCB News: In June we heard about Foxconn opening up a manufacturing plant in Wisconsin. What role is Foxconn playing in the efforts to ramp up awareness and access to Zap-X?**

**JA:** My investor, my primary investor is Foxconn. They are led by Terry Gou, the chairman, who is a major industrial figure well-known in Silicon Valley, sort of like an Elon Musk or Jeff Bezos figure in Taiwan. Foxconn makes iPhones, and they have 1.5 million employees. Four percent of all Chinese exports are exported by them and [they represent] 20 percent of the GNP of Taiwan. It is the 30th biggest company in the world by revenue, but they are always behind the scenes so they don't have such a big profile.

That may be changing, which relates to what was going on in Wisconsin, where they are investing $10 billion into building a manufacturing city that is close to four square miles. They plan to hire 20,000 to 30,000 new employees and they want to focus on manufacturing American technologies.

One of the primary focuses that has gotten a lot of publicity is making displays for TVs, they bought Sharp Electronics – so Sharp's next generation TV will be made in Wisconsin using what's called a micro LCD.

There will be a few other products manufactured there as well, including ours.

**HCB News: How was the Zap-X technology developed?**

**JA:** It was developed by me. After inventing the CyberKnife and creating Accuray, I went back to Stanford 10 years ago, wanting to make a next generation product because I was kind of disappointed that radiosurgery didn't have a bigger footprint. I thought the technology warranted even greater usage, even in developed countries like the U.S. but especially around the developing world.

A survey we did suggested more than 2 million patients every year in the wealthiest part of the world should undergo SRS (stereotactic radiosurgery) for brain tumors but only 150,000 patients do. So we were driven by the opportunity to address an unmet need, and wanting to make something that overcame the limitations, the limitations boil down to cost and complexity.

If one backs up for a second and looks at the landscape of medical procedures and devices, it's pretty clear that radiosurgical technology specifically, not just radiotherapy, is the most expensive technology in the healthcare landscape, and the most complex. So with Zap-X we're trying to address that problem.

Ideally this would be a handheld consumer device, so give me a thousand years on that one, but right now we're trying to strip away to the best of our abilities, the complexity and cost. One of the striking features of the Zap-X is that it does not require a radiotherapy vault. It the first therapeutic radiation device ever made that does not require a vault, because we find that the vault itself is a major impediment to the wider dissemination and availability of radiosurgery.

It is entirely self-shielding, which is a bit of a breakthrough, and is only possible by virtue of the fact that we are focusing on a specific set of anatomy.

**HCB News: How is Zap-X different from Gamma Knife?**

**JA:** Gamma Knife uses radioactive cobalt to generate its radiation, and that in itself is a big problem. Cobalt is magical stuff in some respects and makes optimally-tuned energetic particles, but it's such a dangerous thing and poses lots of complexity in the way access to cobalt is regulated. For instance, a terrorist incident with a Gamma Knife could be very destructive.

*The Zap-X radiosurgical system*

Gamma Knife also requires a vault and stereotactic frame to immobilize the patient's head, whereas we use image guidance, which is nicer for the patients and also allows us to spread treatment out over a few days more easily. We have a potential to be much faster and perform higher-quality treatments, but a lot of that isn't fully baked into the product yet, so that's coming.

**HCB News: In terms of cost, what kind of savings are we looking at?**

**JA:** One of the objectives is to sell a Zap-X with the facility in which it goes, for approximately half to one-third of the cost a competing device might have. It really depends on what kind of facility you're trying to build, but since we don't require a vault, which can be a $1-2 million proposition, that's a big part of our savings – and the machine itself costs much less as well.

**HCB News: Is the footprint comparable to CyberKnife and Gamma Knife?**

**JA:** Yes, the square feet required to install the system is the same, although an alternative system would have five to six feet of concrete taking up a lot of that space.

**HCB News: What's next for Zap-X?**

**JA:** We need to start patient treatments and we will learn a lot as we treat our first few patients. We expect to install two or three in the next year in the U.S., and a system is going to a prestigious hospital in China called Beijing 301, but we won't grow substantially until the following year, and after that we have significant plans for growth. This year we're still doing our initial clinical shakedown.

I would argue that therapeutic radiation is among the worst brands in healthcare. Patients would rather undergo just about anything else other than radiation, and this harkens back to a time when radiation was incredibly primitive, 30 or 40 years ago and beyond… Image guidance and accurate targeting and stereotactic techniques have transformed what's possible with modern radiation, but the world doesn't know about it.

Part of the reason is because most equipment has been hidden away in basements, entombed in concrete, so now that we don't need vaults anymore we intend to be much more in your face with what new modern equipment looks like, so it is rather dramatic looking.

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# Theranostics – Nuclear medicine's fountain of youth

*By: Ken Herrmann and Wolfgang P. Fendler*

*Combining therapy with diagnostics in nuclear medicine*

**The term "theranostics" reigns among medicine´s hottest buzz words, being almost as popular as "artificial intelligence" and "immunoncology".** According to PubMed, the term was introduced in an abstract in 2002. Today more than 3800 hits are reported for "theranostic" or "theragnostic". In short, theranostics is defined as "diagnostic testing employed for selecting targeted therapy."

Interestingly, Nuclear Medicine has long applied the theranostic concept by using radioactive iodine for diagnostic imaging and therapy of thyroid cancer. In 1943 Seidlin, et al. used a Geiger counter to localize sites of metastases under $^{131}$I treatment. Whereas radioactive iodine-based theranostics are established worldwide, it took more than 70 years to successfully translate a new generation of theranostics into the clinic. Similar to radioiodine treatment, Lutathera and other theranostic probes are highly efficacious, with few serious adverse events. It was only earlier this year that Lutathera, a $^{177}$Lu-labelled somatostatin receptor agonist, was approved for clinical use in patients with rare neuroendocrine tumors (NET) by the FDA and a bit earlier by the EMA. The medical and economic excitement associated with

the introduction of Lutathera represents just a small glimpse of what can be expected when new theranostic pairs are made available to diagnose and treat more prevalent malignancies such as prostate, breast, lung and/or pancreatic cancer. For prostate cancer the target of interest is the prostate specific membrane antigen (PSMA). PSMA is over-expressed by the majority of prostate cancers and was also described to have prognostic value. The introduction of specific PSMA ligands conjugable with diagnostic ($^{68}$Ga-, $^{18}$F-) or therapeutic ($^{177}$Lu-, $^{90}$Y-, $^{225}$Ac-) radionuclides resulted in an overwhelming demand by referring physicians and patients.

Recent developments have triggered a lot of industry interest in theranostics. The acquisition of Advanced Accelerator Applications by Big Pharma (Novartis) for $3.9 billion, the recent surge of the Endocyte Inc. stock after licensing a theranostic to be applied to prostate cancer, as well as the reimbursement level of around $47,500 per dose of Lutathera highlight the emerging economic relevance of theranostics and therefore nuclear medicine. However, opportunities are associated with challenges such as setting up the required infrastructure, training the healthcare professionals, establishing the appropriate position of a new therapeutic within established treatment algorithms and many more. There are approximately 40 dedicated theranostic centers in Germany supplying a population of 80 million citizens. Translating this number to a population of 320 million in the U.S. suggests a need of around 160 theranostic centers. Few early adopters, such as UCLA, UCSF and MSKCC, among others, are currently setting up dedicated theranostic centers in the U.S. Others are hesitant due to unknown regulatory (FDA approval) and reimbursement status, which renders development of solid business plans difficult. In addition, only few in the U.S. have been appropriately trained in theranostics. There is, therefore, an unmet need to train a wide spectrum of healthcare professionals, including nurses, technologists, physicists, radiation safety officers, and medical doctors. At the same time this also provides an opportunity to attract young, motivated people, including specialists from other fields, such as medical oncology, gastroenterology, endocrinology, and urology to nuclear medicine.

Supply of theranostic compounds remains another significant roadblock to widespread adoption. Some experts, using conservative models, predicted an annual need of around 30,000 doses of Lutathera for NET and around 160,000 doses of $^{177}$Lu-PSMA for prostate cancer patients. Based on 250 work days per year this results in an average of 760 doses per day and, including a safety margin, the need to produce 800-1000 doses per day. However, the current production infrastructure as well as the $^{177}$Lu-supply are far from ready to meet this demand. This crisis provides an opportunity for industry, insurances, health care providers and health care professionals to come up with mutually beneficial solutions.

As outlined above, the demand for theranostics will be high. However, with the development and emergence of additional novel theranostics the demand is likely to become even higher. These new compounds will be applicable to NET and other somatostatin receptor expressing tumors ($^{177}$Lu-Satoreotide), neurotensin-1 receptor ligands, possibly for pancreactic cancer among others ($^{177}$Lu-3BP-227), CD37-binding antibodies for hematological malignancies (Betalutin) and the recently approved $^{131}$MIBG (Azedra) for neuroblastoma and pheochromocytoma. More recently introduced ligands targeting tumor stroma (Fibroblast Activation Protein (FAPI)) may find even wider application in various cancers.

In summary, theranostics provides unique new opportunities and challenges for nuclear medicine and industry regulators, insurances and healthcare systems. But there is no time to hesitate – the future is now!

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**Whereas radioactive iodine based theranostics are established worldwide, it took more than 70 years to successfully translate a new generation of theranostics into the clinic.**

**The acquisition of Advanced Accelerator Applications by Big Pharma (Novartis) for $3.9 billion, the recent surge of the Endocyte Inc. stock after licensing a theranostic to be applied to prostate cancer, as well as the reimbursement level of around $47,500 per dose of Lutathera highlight the emerging economic relevance of theranostics.**

# Stereotactic ablative radiotherapy (SAbR) is ushering radiotherapy into a new (and better) era

*By Dr. Robert D. Timmerman*

*Harold C. Simmons Comprehensive Cancer Center, Radiation Oncology Building at UT Southwestern*

**Radiotherapy is a common and effective cancer therapy.** Nearly all cancers can be treated with radiation. In fact, according to the American Cancer Society, about 60 percent of all cancer patients will receive radiotherapy at some point in their overall treatment. Curative intent radiotherapy is used as the initial, primary therapy in 20-50 percent of patients, depending on the diagnosis.

Radiotherapy delivery is painless, and can be tolerated in more frail patients as compared to surgery. Yet radiotherapy has been inconvenient and costly, generally being delivered in multiple daily treatments over many weeks (e.g., 30 or more separate, daily treatments). Implementation of this protracted form of radiation was first introduced in the 1920s in a response to problems related to archaic treatment technology of the time.

Today, with improvements in technology, small fraction daily dosing is no longer an absolute requirement. It remains common, however, because of two important barriers to change: 1. Most doctors providing radiation therapy were trained to give protracted radiotherapy and have comfort with its management, and 2. Hospitals and doctors get paid effectively by the number of treatments delivered. So giving inconvenient, costly, protracted courses of therapy leads to comfortable doctors and higher revenues for radiotherapy cost centers – not exactly patient-centered care.

But the climate is changing – quickly. Pressures include both data and dollars. The opposite of protracted radiation is called hypofractionation. The most pure form of hypofractionation completes a course of therapy in five or fewer treatments and is called stereotactic ablative radiotherapy or

SAbR. Some have also called this therapy stereotactic body radiation therapy or SBRT, but SAbR is a better descriptor of the potent treatment. SAbR requires the most advanced technologies to deliver large daily dosing including image guidance, intensity modulation, and rotational therapy capability. Therefore startup costs are higher.

SAbR was first introduced in the 1990s and initially used at larger academic centers having such equipment. But now these capabilities are widespread. Particularly, younger doctors, fresh from residency, have been trained to use SAbR and are comfortable with its requirements and management issues. SAbR is more potent than historical, protracted radiotherapy with local control of targeted tumors on par with best surgery. Also as with surgery, misguiding this potent therapy can lead to severe normal tissue injury. Hence, competency and training in conjunction with modern technology is essential for safe, effective treatment.

Outcomes have been impressive. For example, early stage lung cancer patients treated with three painless outpatient SAbR treatments on an NIH-sponsored multicenter trial were shown in a recent JAMA Oncology article to have 90+ percent targeted tumor eradication with few side effects after long term follow-up.

While SAbR is not cheap, it is generally less costly than protracted courses of conventional radiotherapy. This fact led to its being approved by CMS for treating prostate cancer, a disease with many, generally expensive, treatment options. And SAbR is more effectively utilized by a Cancer Center. As recently as 2004, the average number of treatments per course of radiotherapy was 28, or nearly 6 weeks of daily treatments. Protracted fractionation is inconvenient for patients who have other things to do, but also limits the capacity of the treatment center.

At the University of Texas Southwestern Medical Center in Dallas, Texas, where I practice, we heavily employ SAbR for our patients. Our current number of treatments per course of radiotherapy is 15, about half the national average. That means that with the same capital acquisition costs for radiotherapy equipment and the same cost of labor, we can treat twice as many patients as our competitors. Our capacity is double!

But SAbR wasn't first conceived to be just a more cost-effective cancer therapy. It was developed amid a desire to improve cancer outcomes. It was first used in the brain (e.g., treatments like the Gamma Knife and the Cyberknife), moved to the lung, then liver, and beyond. Pancreas cancer, kidney cancer and sarcomas have been tested successfully with SAbR.

SAbR is the fastest growing treatment for prostate cancer and is being tested in trials aimed at improving potency preservation compared to surgery or conventional radiation. SAbR is being used in breast cancer where a machine specifically designed for breast SAbR called the Gamma Pod was recently FDA approved. All of these sites were treated with conventional, protracted radiation prior to SAbR. But SAbR is clearly expanding radiotherapy indications.

While radiotherapy has been mostly a palliative treatment in metastatic cancer, SAbR is being tested as part of hopefully curative or life-lengthening treatments for a variety of metastatic cancers. Trials are underway that could transform the field, including randomized trials. When the number of tumors is limited (i.e., oligometastases), SAbR is used to eliminate them all. When systemic therapy is mostly working but a few tumors progress, SAbR is used to consolidate the bad actors. When immunotherapy is indicated, SAbR might be used to "immunize" one or more tumors to accentuate the response. In all cases, SAbR is used with systemic therapy in a collaborative way, playing to the strengths of each therapy while dramatically expanding the indications for radiotherapy.

SAbR is changing radiotherapy, rapidly. Centers without SAbR-trained physicians and equipment are facing considerable competitive disadvantage. SAbR is high-tech and not cheap. But short course, ablative therapy is cost-effective. Fortunately, this is one of the first medical technology innovations that "grew up" during an era where clinical trials were both feasible and expected. Data from these trials is clear. First, SAbR is very potent, yielding exceptional tumor control. The potency also means the therapy can injure normal tissues. Training to properly use SAbR and avoid toxicity is available for guiding physicians, physicists, and care givers. Trials in new indications, including metastatic cancer, are ongoing, which could dramatically increase the number of patients who might benefit. SAbR is transforming radiotherapy, just in time.

**Giving inconvenient, costly, protracted courses of therapy leads to comfortable doctors and higher revenues for radiotherapy cost centers – not exactly patient-centered care.**

*About the author: Dr. Robert D. Timmerman is a professor of radiation oncology and neurosurgery and Effie Marie Cain Distinguished Chair in Cancer Therapy Research at the University of Texas Southwestern Medical Center in Dallas, TX.*

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# Precision cancer care with proton and radiation oncology

*By Lisa Chamoff*

**In cancer treatment, time is of the essence. For the best outcomes, precision is also a key component. Whether it be proton therapy or conventional radiation oncology, those goals are at the heart of the new treatment systems and oncology software entering the market.**

## The rise of proton therapy

Proton therapy has had a slow adoption due to the high price tag, but as evidence accrues for its benefits and insurers begin to take notice, access is coming within reach for more of the patients who stand to benefit most from it.

### Hitachi

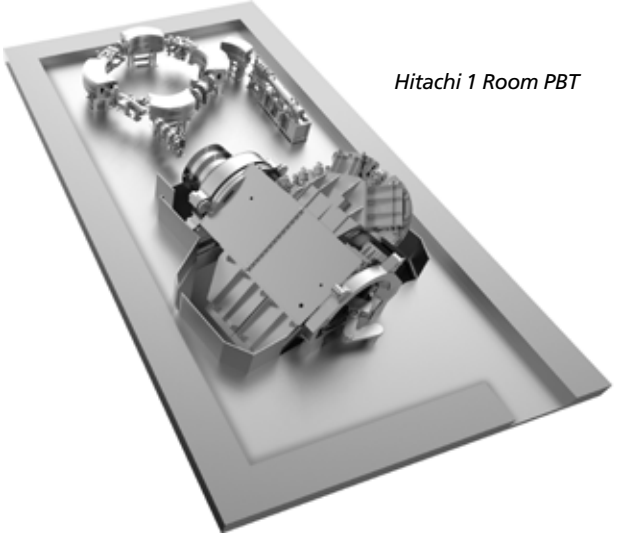
The company has been moving ahead with installations of its Hitachi Proton Beam system since receiving FDA clearance in 2008.

The system is equipped with a compact synchrotron accelerator, which the company says allows for beam delivery at selected energy levels, with significantly less neutron generation, and is used by facilities including the MD Anderson Cancer Center and Mayo Clinic sites in Minnesota and Arizona.

The company is currently working on an installation at Sibley Memorial Hospital, a member of Johns Hopkins Medicine, in Washington, D.C., and hopes to start treating sometime in late 2019, said **Sash Matsumoto**, general manager at Hitachi America.

The company also announced late last year that it will install a system at Clinica Universidad de Navarra (CUN) in Madrid, Spain.

Matsumoto noted that the lead time for constructing proton therapy facilities is getting shorter and the overall cost is coming down, though facilities are mainly focusing on one- or two-room centers instead of multiple rooms because of the investment.



*Hitachi 1 Room PBT*

"Not every hospital can afford a multi-room proton system," Matsumoto said. "I think every vendor is doing everything we can to lower the cost and, hopefully, it will allow more hospitals to have the technology. With more clinical trials providing evidence, it's become more and more clear that for certain tumors proton is the best treatment and it's something that every patient deserves to have access to."

### IBA

Since the company's ProteusPLUS treated its first patient in 2001 and its smaller ProteusONE was first used in 2014, IBA has been rapidly deploying its technology. In the last six months, IBA completed four installations of the ProteusONE – which has pencil beam scanning and cone beam CT – around the world.

The company's goal is to make the system such that it could be used for a wide variety of indications, with the ability to treat complex tumors, including moving ones, using respiratory gating systems and better imaging, said **Nicolas Denef**, IBA's product management director.

Denef said the ProteusONE, which has a smaller footprint and offers an affordable solution for a one-room proton therapy system, has become the preferred technology as fewer facilities have built multi-room facilities.

Several years ago, developers thought that having four to five rooms would be more financially beneficial, but patient recruiting was more difficult for more remote Proton Therapy Centers.

"There was an idea that if you build it they would come," Denef said. "Which happened for some, but not for the ones that were far away from city centers."

The company's IBA Dosimetry solution decreases the time needed for beam data commissioning and accelerator QA, Denef said.

In the future, IBA is looking to continue to improve imaging and introduce improved workflows, Denef said. The ultimate goal is to do adaptive treatment, using the cone beam CT to replan quickly just before treatment starts.

### Mevion Medical Systems

Earlier this year, Mevion received FDA clearance for HYPERSCAN pencil beam scanning for its compact MEVION S250i Proton Therapy System. Shortly afterward, MedStar Georgetown University Hospital in Washington, D.C., became the first to treat a patient with the system, which combines pencil beam scanning with a single-room machine.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The system features what Mevion calls the Adaptive Aperture proton MLC, which the company says generates layer-by-layer specific beam collimation and blocking with beam sharpening performance identical to conventional proton therapy apertures.

"The combination of HYPERSCAN and Adaptive Aperture moves the science of proton therapy ahead to even sharper dose distributions," said **Skip Rosenthal**, vice president of clinical systems for Mevion Medical Systems.

The company has two more systems in deployment, one in Europe and another system being installed in the U.S. in the fall.

An important aspect of the HYPERSCAN is the ability to have support from advanced treatment planning, and the company has a collaboration with RaySearch. Currently, centers will be using RayStation, the RaySearch treatment planning system to provide clinicians with Monte Carlo-based planning for HYPERSCAN. Rosenthal said that by the end of the year, RaySearch will release the ability to plan and treat using the full multilayer collimation capabilities of Adaptive Aperture.

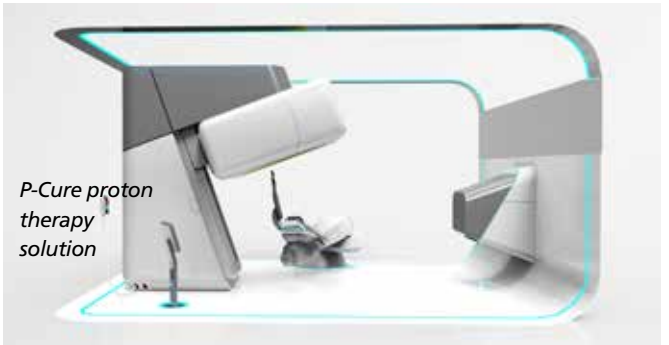
Rosenthal said Mevion also is integrating cone beam CT and CT on rails with the system sometime this year.

"The ability to use that in a proton room has been slow to materialize," Rosenthal said.

## P-Cure

P-Cure has marketed its gantry-less solution, and the company is planning to soon publicize results from use of the P-Cure system on patients being treated for lung, brain, eye and other types of cancer at the Northwestern Medicine Chicago Proton Center.

"The objective is to show … that patients can be treated even better without a gantry, in the seated position," said **Michael Marash**, P-Cure's chief executive officer. "When a patient is seated, the magnitude of the inner organ motion is minimized, enabling it to direct the beam to the tumor with much greater precision. There are also fewer equipment and construction costs, as a gantry needs three floors."


*P-Cure proton therapy solution*

At the Chicago center, P-Cure enabled treating in their open registry study. Next year, the company will look to show the effects of the system on treating several other tumor sites including, head and neck, breast, and liver cancers.

The company is also starting to explore international markets and has received a positive response from facilities in India and China, Marash said. The company is building a new facility in the center of Israel to ship both west and east.

## ProTom International Holding Corporation

ProTom has made moves into the Asia Pacific market and was recently awarded the contract for the Australian Bragg Centre for Proton Therapy, the first proton therapy center in Australia, to be housed in a massive new health complex expected to break ground in the second quarter of next year in Adelaide.

"The U.S. market is more mature," said **Stephen Spotts**, chief executive officer of ProTom International. "As cancer providers are looking at adding proton therapy, more providers are looking at single room systems."

ProTom's Radiance 330 Proton Therapy System – which received FDA clearance in March 2014 – uses one synchrotron accelerator for multiple rooms, which is different from the company's competitors, except for Hitachi, Spotts said. The center in South Australia is using renewable energy, which is one of the reasons they chose ProTom, which uses a synchrotron, with varied acceleration levels, as opposed to a cyclotron, where the acceleration is constant.

"Our energy consumption is about 30 percent of a multiple-room cyclotron," Spotts said.

# Radiation oncology

Like proton therapy, radiation oncology companies have shown greater interest in simplifying their systems while also providing greater specificity. What follows is a look at some of the newest software and hardware solutions from companies in the conventional radiation oncology space.

## Accuray

At this month's ASTRO annual meeting, Accuray will be introducing the CyberKnife VOLO optimizer for the CyberKnife robotic radiation therapy system. The system simplifies the process of creating treatment plans using a new next-generation optimization algorithm, said **Corey Lawson**, vice president of product strategy at Accuray.

"It's a state-of-the-art optimizer that resets the bar for user experience," Lawson said.

Lawson said VOLO should reduce optimization time, or the time to do calculations, by 95 percent. So, a lung cancer case that may have taken close to an hour with the previous optimizer will now take a few minutes. It will also reduce delivery time by more than 20 percent.

Faster treatment planning means clinicians can try different ways of planning a case with much greater efficiency, Lawson said.

"With the ability to push a plan harder than ever before, will likely come the ability to get better plans than previously thought possible with the CyberKnife System," Lawson said. "We expect our clinical partners to readily adopt this new technology because of the clinical workflow and plan quality benefits that will be quickly realized."

*Accuray CyberKnife*

Accuray also recently introduced CTrue IR imaging on its Radixact Treatment Delivery System. CTrue IR integrates a new iterative reconstruction algorithm which improves soft tissue contrast, while also reducing noise in scanned image sets.

"It does all of this with the same low-dose imaging and fast scan time we've always had," Lawson said. "Furthermore, it is not affected by metal artifacts, nor in larger patients, the obscuring effects of electron starvation. We are truly improving user experience and clinical utility with this new release for our Radixact System."

The company is also planning to show Synchrony motion compensation on the Radixact Treatment Delivery System.

Lawson stressed that the new feature is very different than conventional gating solutions. It will use an algorithm to adjust the beam to follow a moving target throughout its motion cycle, in real-time.

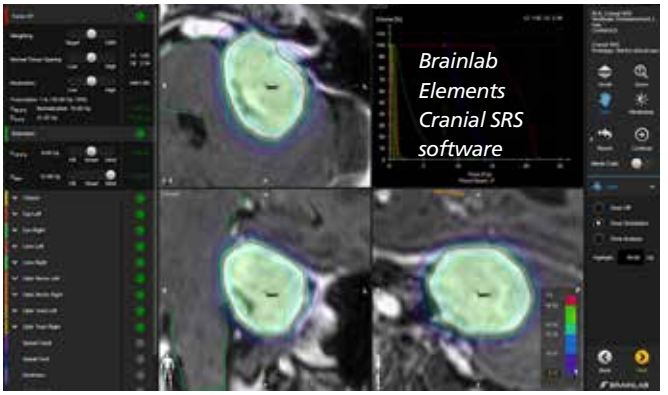
## Brainlab

Brainlab released a newer version of its Elements Multiple Brain Mets SRS treatment planning software for focused stereotactic radiosurgery. The updated software provides new treatment strategies to treat brain metastases and adds new contouring and response assessment tools to increase utilization, said **Bogdan Valcu**, director of clinical research at Brainlab.

The previous version of Elements Multiple Brain Mets SRS was only planning for a single fraction radiosurgery, or the treating oncologist would have to specify one fractionation strategy, Valcu explained. With the new version of the software, you can combine multiple strategies, with one tumor receiving a single fraction and one receiving multiple fractions.

"We just want to provide more flexibility within this application, enabling everything from single fraction radiosurgery to fractionated SRS prescriptions customized to the individual patient disease and irrespective of tumor size," Valcu said. "Using Elements Contrast Clearance Analysis, we can now detect earlier whether or not patients are failing therapy and require re-treatment. Timely re-treatment is critical for maximizing survival profiles for brain metastasis patients and so is the ability to distinguish between tumor and radiation effect."

The spine is another key target for Brainlab, and in March 2017 the company released Elements Spine SRS. First patient


Brainlab Elements Cranial SRS software


Elekta Unity

treatments began in Argentina, Germany and Italy followed by the first patient treatment in the U.S. in August of 2018.

Elements Spine SRS works with CT and MR scans to calculate the clinical target volume using international spine radiosurgery consortium consensus guidelines, and takes less time using Monte Carlo simulations.

"The software offers automatic treatment planning, which helps raise overall plan quality with consistent adherence to desired treatment protocol. In a half hour clinicians can go from zero to treatment plan," Valcu said. "Planning steps that would have taken clinicians two to three hours to perform in the past are now performed in under 10 minutes and physician involvement time is reduced to just a few minutes."

Brainlab specializes in customized algorithms for the treatment site, working around the challenges of the spinal column.

In March 2017 Brainlab also released Elements Cranial SRS for treating primary tumors in the brain. The software corrects the cranial distortion from MR scans, Valcu said.

"Planning automation is paramount for this software, starting with tools to correct MR distortions and improve co-registration, to planning CT and continuing with a comprehensive risk organ definition based on a tissue-class universal atlas," Valcu said.

The company plans to continue developing indication-specific solutions and plans to focus on metastases in the lung and liver and other body sites.

## Elekta

Elekta has mainly been promoting its Elekta Unity MR-linac, which received a CE mark in June 2018 (the company submitted for FDA 510(k) clearance in beginning of August).

In August, the first treatment of a cancer patient with a recurrence in a pelvic lymph node with the Unity was completed in the Netherlands. The concentrated high-dose treatment took 10 days, significantly less than typical radiation therapy treatments that require up to 30 fractions, said **Ioannis Panagiotelis**, the chief marketing and sales officer for Elekta.

On the software side, Elekta released a product called AQUA, which standardizes and automates clinical quality assurance tests.

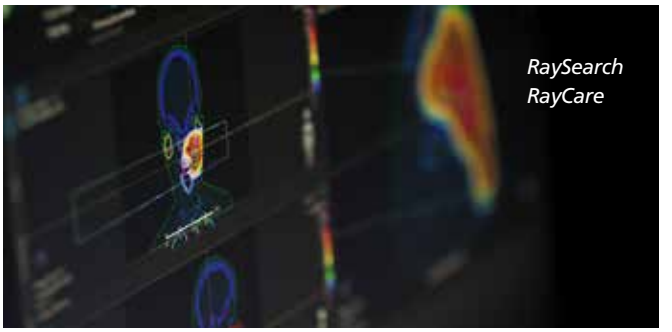
The company also entered into two agreements. One is with IBM, to allow its Watson for Oncology to pair with Elekta's MOSAIQ, oncology information system and personalize treatment with artificial intelligence (AI). Elekta also partnered with Palabra to allow clinicians to use voice commands for MOSAIQ to expedite clinical operations and reduce the time needed for data entry.

"Our customers have access to the latest and greatest when it comes to software solutions that have been developed by other parties," Panagiotelis said.

## RaySearch Laboratories

Late last year, RaySearch Laboratories released RayCare, its new oncology information system (OIS).

**Johan Löf**, president and chief executive officer of RaySearch Laboratories, said RayCare is a "completely new take on" the OIS, with an "advanced architecture that is extremely resilient and scalable."


RaySearch RayCare

Users have full access to the system through Android or iOS devices and the company introduced a structured way of handling workflows. If a user is logged on in a certain role, they will only see the tasks relevant to that role. The company has been updating RayCare to add functionality, including billing.

In June, the company released a new version of its RayStation treatment planning system that includes full planning capabilities for the TomoTherapy and Radixact systems from Accuray, and support for Accuray's TomoDirect and TomoHelical delivery modes.

Later this year, RaySearch Laboratories plans to release an auto-contouring product that applies deep learning, with a database of "well-contoured" patients that will allow the process to be completely automated.

## Varian

Varian recently released version 2.0 of its Halcyon radiotherapy system, which debuted at last year's ESTRO meeting in Vienna.

The new version adds additional imaging modalities – kV cone beam

CT and iterative cone beam CT, which **Tracey Fisher**, director of marketing for the Americas oncology division at Varian, said brings a "diagnostic-like" quality to the images.

"What is unique about Halcyon is the speed," Fisher said. "You can get kV volumetric images in as few as 17 seconds. It's better soft-tissue imaging and target delineation. The more you can see, the better is the potential treatment."

*Varian Halcyon*

The Halcyon is field upgradable, and since the launch Varian has taken 98 orders for the system worldwide.

The new version of Varian's Eclipse treatment planning system, Eclipse 15.5, enables many of the features of the Halcyon 2.0 and a feature that allows clinicians to more easily adapt a treatment plan from one machine to another. Additionally, Eclipse 15.5 features Multicriteria Optimization (MCO), which allows clinicians to explore what happens when different clinical criteria are varied, such as the degree to which particular organs are spared versus coverage of the targeted tumor.

In April, Varian announced a new version of its Velocity cancer imaging software. Called Velocity 4.0, it has several new capabilities, including RapidSphere image-guided Y90 dosimetry, which offers an image-guided dosimetry solution for Y90 Selective Internal Radiation Therapy (SIRT) and is a method for tracking absorbed dose, confirming that the treatment was delivered as planned.

The software also offers new features including Velocity M3i, which allows clinicians to use images from multiple modalities – CT, MR, PET, SPECT and ultrasound – for contouring, and Velocity ARIA Sync, which automatically synchs with Varian's ARIA oncology information system and Eclipse treatment planning system.

A feature called Velocity Tumor & Dose Tracking, which can track radiation dose of multiple treatments and different types of therapies, allows clinicians to verify volumetric tumor changes and a patient's cumulative dose history.

"This allows them to more easily account for prior treatments and their impact on current or future treatments," Fisher said.

## ViewRay

Last year, ViewRay's big release was the MRIdian Linac, which combines a linear accelerator with an MR scanner and was cleared by the FDA in February 2017. The company later announced imaging improvements under development that double the signal-to-noise ratio, frame rate and resolution without raising the field strength, said **Jim Dempsey**, ViewRay's chief scientific officer.

The device uses what Dempsey called a "proprietary approach" to compressed sensing.

"We think there are some very impressive imaging improvements, under development," Dempsey said. "Speed, resolution and SNR are potentially improved by a factor of three."

*ViewRay MRIdian Linac*

Elekta, which released a similar MR-linac, called the Elekta Unity, uses an MR scanner with a higher field strength

The second generation is available via an upgrade, and Dempsey said some customers with service agreements have already purchased upgrades.

"Their argument has been you need high field strength," Dempsey said. "Elekta and Philips made a decision to sacrifice dose quality for a better image. As a small team, we work on impossible problems, such as how to make a low-field MR work like a high-field MR."

Dempsey notes that the clinical data shows that the MRIdian can treat cancer with lower toxicity.

"The biggest headlines for us are the clinical data," Dempsey said.

## Xstrahl

In December 2017, Xstrahl launched the new RADiant X-ray radiation therapy system with an FDA 510(k) clearance, which was followed by a CE mark in March 2018.

The RADiant system offers two types of treatment – electronic brachytherapy (eBX) and superficial radiotherapy (SRT), which is different from conventional radiotherapy systems currently on the market, according to **Adrian Treverton**, chief operating officer of Xstrahl Inc. This allows customers to increase their throughput and allows for adoption by the American dermatological market, which cannot use the high-powered radiotherapy systems currently on the market.

*Xstrahl RADiant*

"The radiotherapy industry current has two main trends – a significant increase in skin cancers and skin conditions worldwide, and increased pressures on departments and clinics to treat patients in cost- and time-effective ways," said Treverton. "The RADiant offers a cost-effective treatment platform treating not only skin cancers, but also non-malignant skin conditions, keloids and dermatological conditions, allowing for reduced pressure on oncology departments, and an increase of client base for dermatological clinics."

RADiant is currently installed at four sites across the continental U.S., both in radiotherapy oncology departments and dermatology clinics. The RADiant will also soon be released in Europe, South America and China, before a full worldwide rollout.

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# Proton therapy comes to New York City: behind the scenes at the NYPC

*By John R. Fischer*

*The newly constructed New York Proton Center on 126th St. in Harlem.*

**At 10 p.m. on Halloween night in 2017, a 150 foot-long truck inched its way through the dark congested streets of midtown Manhattan.** Most of the trick-or-treaters had already gone to bed, but a construction crew was waiting outside 126th St. between 2nd Ave. and 3rd Ave. for a treat of their own: a ProBeam proton therapy system from Varian Medical Systems.

The following morning, the crew pried the large blue cargo box open to reveal a cyclotron, fresh off the boat from Germany. The team fastened the particle accelerator to a crane, which lifted it high into the air before bringing it down through an opening in the roof of an unfinished building.

Fast forward to almost one year later and the cyclotron is fully installed in the now complete, three-story building in Harlem that in the coming months will make its debut as the New York Proton Center, the first proton therapy facility in New York State.

"Our goal is to really serve the greater New York marketplace," **Jonathan Weinbach**, chief financial officer of New York Proton Center, told HCB News. "We envision that the majority will come from the New York metro area. We're going to treat the patients who need proton therapy the most and who get the most from it."

The opening is planned for sometime in February or March of 2019. Meanwhile, Weinbach and his team continue to work through the last few hurdles in what amounts to a nearly decade-long endeavor.

The idea for the NYPC goes back to 2009. Within a year the Department of Health put out a request for proposal in New York, catching the attention of Mount Sinai Health System, Montefiore Medical Center, and Memorial Sloan Kettering Cancer Center. The three subsequently signed on as partners, bringing with them the financial support, clinical expertise and patient populations that are necessary for a successful proton facility.

But how do you find space for a proton therapy facility in Manhattan?

> "The building is as centrally located as it could be because their physicians would be going back and forth on a daily basis from the different hospitals."

"You essentially need half a city block," said Weinbach. "The center is 256 feet long but we only needed three stories. Trying to find a piece of real estate where you don't have to use all of the air rights, which is a key factor for a lot of the real estate decisions in New York, was extremely challenging. We looked at a number of options for building residential units on top of parts of the building."

After four or five years of looking around, they acquired the 126th Street site from the New York City Economic Development Corporation. In 2015, construction began on the four treatment room facility, comprising three gantries and a fixed beam room.

Entering the building, patients will find themselves in a large waiting room with lots of natural light and simple ornamental decor hanging from the ceiling. Conjoined is another waiting room for pediatric patients and a set of consultation rooms for patient-physician discussions.

Upon being called, the patient can take an elevator to the second floor and head into one of the changing rooms. Personal belongings are stored in lockers across from the changing area and patients continue to either a diagnostic room or one of the center's four treatment rooms.

In the treatment rooms, patients are laid out on a table under a dome-like sphere, facing upward at the proton beam. What the patient doesn't see is the three-story delivery system behind the gantry, the installation of which took 18 months to complete. Within it lies the beam line, from which the protons are transferred, with a 70,000 pound magnet curving the beam as it rotates, enabling treatment to be delivered from the bottom of the patient to the sides.

"It's all done by magnets," said **Allan W. Freeman**, the senior vice president of project development for the New York Proton Center. "We have four different treatment rooms. The majority of time is spent positioning the patient and making sure they're in the right place. Then the actual delivery of protons for the patient is only a couple of minutes."

Accelerating these protons to two-thirds the speed of light is the cyclotron. Functionality is monitored 24/7 in a control room using software that is also provided by Varian. It also monitors and offers users the ability to make adjustments to a number of cabinets and equipment on the third floor that supply electrical power.

In addition, a mechanical room provides air conditioning and chilled water for the equipment. Systems are equipped with a number of redundancies as backup in case one goes down.

Comprising the third floor is a series of work stations, a staff training room, a lounge area, and a conference room with a view of the entire street outside the front of the center, where everyday life can be seen down below and a medley of restaurants, shops and hardware stores can be found just around the corner.

Being located in the heart of the city is a benefit for physicians from Montefiore, Sloan Kettering and Mount Sinai.

*The regulatory climate for proton therapy in New York presents challenges because the technology is so new.*

"The building is as centrally located as it could be because their physicians would be going back and forth on a daily basis from the different hospitals, so it actually works out very well for all three partners," said Freeman. "It's actually very convenient for patients as well to get to, because you have the highway a block away and a bridge right there."

In addition to the three provider partners, the project has accumulated a number of banks as investors including JPMorgan Chase & Co., Deutsche Bank AG and the Goldman Sachs Group Inc., along with Long Island-based multi-specialty physician practice, ProHEALTH Care Associates LLP, which serves as the manager of the project.

Also lending expertise and resources is **Dr. Thomas Petrone**, who runs Petrone Associates LLC, a medical consulting practice with expertise in all areas of medical physics including diagnostics, nuclear medicine, MR and radiation oncology. The firm carries extensive experience on the regulatory requirements that govern the specific use of radiation, particularly within New York.

"They need to know how to write the regulations, how to enforce the regulations, what the technical aspects of the program are," said Petrone. "We're trying our best in making some inroads at creating a bridge between the regulators because this is the first of its kind in New York State, so my role is to bring these parties together."

Petrone said the main objective at the moment is obtaining a permit for the particle accelerator.

"Because of the newness of this, the New York City Department of Health and Mental Hygiene (DOHMH) Office of Radiological Health (ORH) has established a very detailed scope of what they want accomplished for them to feel comfortable issuing a registration permit to operate the accelerator," he explained. "That's the biggest job we have to work on and we are well on our way to doing so, having brought in numerous third-party consultants to help."

Other less monumental approvals to be completed include radioactive materials licenses for PET/CT scanners and X-ray registration for CT systems, many of which were provided to the center by Siemens Healthineers.

The NYPC is also in the midst of acquiring a permit to occupy the building, which is expected to come through next month. Once completed, it can then apply to the Department of Health for its actual license. In addition, a nationwide search is underway to recruit experts in the field and build up an entire staff of 115-120 individuals to help in the running of the facility.

The center is in line to become the 27th or 28th proton therapy facility in the U.S., and while the aim is to serve the greater New York area, referrals from any hospital will be evaluated and accepted on a medical needs basis.

"It's the preferred therapy for certain tumors," said Freeman. "The main objective is to kill the tumor by all means but minimize the damage that you do to tissues in the surrounding areas or other clinical organs that are nearby. Protons have that specific ability to be very focused and not cause damage outside of the area that you are trying to treat."

He's quick to add that it isn't right for all cancer cases – but for certain indications it can mean the difference between life and death. For New Yorkers, who are already accustomed to having everything at their fingertips, proton therapy should be a welcome addition to the neighborhood.

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# Why randomized trials for proton therapy are difficult to complete (and what we can do about it)

*By Dr. Justin E. Bekelman*

*Coverage policy is an important tool that can reduce inappropriate use of medical technologies, but it can also creates barriers to evidence development.*

**Randomized, controlled clinical trials are the gold standard of cancer research and can shed light on whether innovative, new therapies with great potential actually have clear benefits over usual care for patients.** However, the seven randomized trials funded by the National Cancer Institute (NCI) and the Patient Centered Outcomes Research Institute (PCORI) to test proton therapy are enrolling more slowly than expected. Commercial insurance medical policies that do not cover treatment with proton therapy can make it difficult for patients to participate in randomized clinical trials funded by the NCI, part of the National Institutes of Health, that are evaluating the therapy. This is the biggest barrier these trials face, but as my colleagues and I recently laid out in a commentary in the *Journal of Clinical Oncology*, there are concrete steps we can take to improve this situation.

It's important to note at the outset that most commercial insurers and state Medicaid plans do not cover proton therapy for the cancers under study in these seven trials, though Medicare typically does through local coverage determinations. While coverage policy is an important tool that can reduce inappropriate use of medical technologies, it can also create barriers to evidence development: in the case of proton therapy, coverage policies on proton therapy prevent patients from participating in the seven randomized clinical trials sponsored by the NCI and PCORI and specifically designed to answer crucial questions about the treatment's benefits and harms.

We need evidence from these seven trials to determine whether proton therapy is better than usual care at reducing side effects, extending survival, or both. The evidence to date includes studies that have shown benefits to proton therapy as well as studies that have demonstrated expected or sometimes unexpected toxicities in certain cancers.

Currently, six of these randomized trials comparing proton therapy to photon (X-ray) therapy are funded by the NCI, with the seventh funded by PCORI. All of these trials have faced enrollment challenges. For example, in the RadComp trial for breast cancer, nearly two-thirds of eligible patients have insurance coverage policies that do not cover proton therapy for breast cancer; thus, the majority of eligible patients for RadComp cannot actually enroll and participate in the clinical study. While it is true that Medicare typically does cover proton therapy, thus allowing patients to participate in trials, inclusion of only Medicare-eligible patients over 65 significantly limits the number of patients who can participate in the trials and may reduce the generalizability of the results.

These seven trials have been specifically designed to provide evidence comparing proton and photon therapies, and future patients will benefit directly from the knowledge we stand to gain. The sooner we complete these trials, the sooner patients, hospitals, and insurers will be able to use the results to make more informed decisions.

All three groups of stakeholders – patients, hospitals, and insurers – are aware of the dilemma and are attempting to find solutions. Some commercial insurers and some proton centers and hospitals have made arrangements to cover proton therapy for selected cancers under study. For example, some insurers have established coverage with trial participation policies. We propose an approach that leverages the lessons learned from these successful experiences. The goal is to bring together public and private insurers, proton therapy centers, hospitals, radiation therapy equipment vendors, and patient advocates to establish a program of coverage that includes participation in one of the seven trials. If this effort is successful, it can serve as a model to evaluate new advanced technologies in the future.

*About the author: Dr. Justin E. Bekelman is an associate professor of Radiation Oncology and Medical Ethics and Health Policy and senior fellow in the Leonard Davis Institute for Health Economics at the University of Pennsylvania's Perelman School of Medicine.*

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HCB Daily News (www.dotmed.com/news) covers the biggest events in the proton therapy industry throughout the year. In this section you will find a small sampling of the most read articles we've published on this cutting-edge cancer treating technology over the last several months. These are the current events impacting the proton therapy market today and the research emerging to improve patient access and define the treatment's value for tomorrow.

For more stories like these, visit out news site and click "Proton Therapy" in the red navigation bar at the top of the screen.


## Proton therapy arrives in the Netherlands

**Posted online January 25, 2018 by John R. Fischer**

**Proton therapy has officially launched in the Netherlands, following its use this week in treating a cancer patient for the first time.**

Radiologists at the University Medical Center Groningen (UMCG) Proton Therapy Center treated the patient Monday, January 24, using IBA's Proteus Plus system within 13 months of its installation.

"We are proud that the UMCG is now the first to deliver proton therapy treatment to patients," Prof. Dr. J.A. Hans Langendijk, the chair of the department of radiation oncology at UMCG Proton Therapy Center, said in a statement. "IBA has one of the most advanced proton therapy technologies on the market and has demonstrated its market-leading speed by delivering a state-of-art proton therapy facility within this time frame."

The system consists of two gantry rooms equipped with IBA's pencil-beam scanning (PBS) and cone-beam computed tomography (CBCT) large field-of-view image guidance, for enhanced precision and adaptive treatment.

Rooms also include IBA's wireless hand pendant, the only wireless patient remote control in the radiotherapy industry, along with a new generation, high-accuracy and -precision Patient Positioning System.

## ProCure Proton Therapy Center NJ completes 3,000th patient treatment

**Posted online by Gus Iversen**

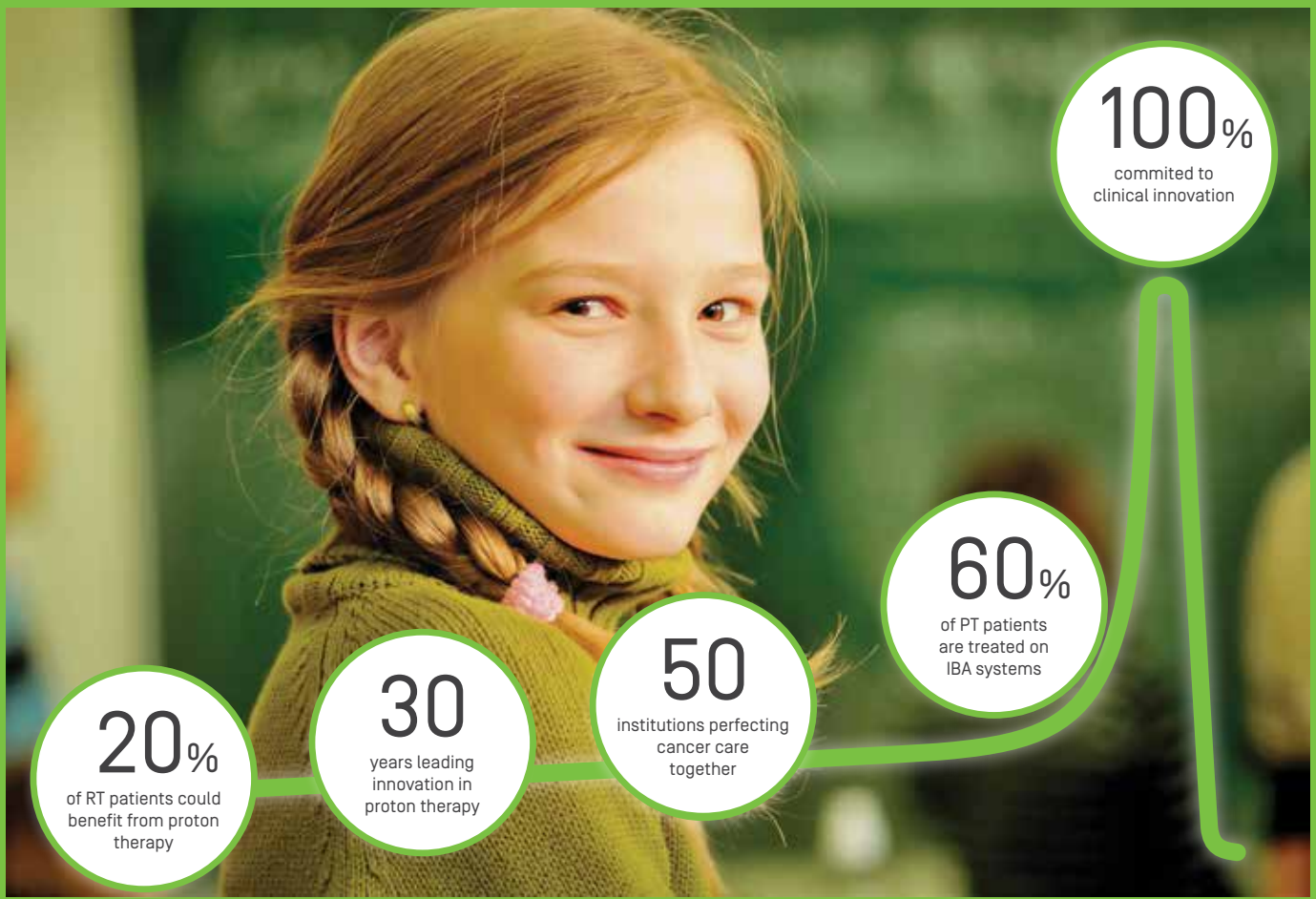
**The ProCure proton facility in Somerset, New Jersey has announced the successful completion of its 3,000th proton therapy treatment.** The patient, Victoria Croft, was part of a special graduation ceremony celebrating all of the individuals who had been cared for at the facility using the cutting edge cancer therapy.

"I've been a Hodgkin's survivor for the past twenty years, so I've had my fair share of treatments. Living in the Cayman Islands, I was fearful that I would have difficulty with accessibility to the right treatment," said Croft in a statement. "However, when my father told me about proton therapy and I further researched it, I was thrilled to learn that ProCure NJ was only twenty short minutes away from my hometown in New Jersey."

Croft was treated for breast cancer, which the American Cancer Society says is the most commonly diagnosed cancer among American women beside skin cancer.

"It's an amazing feeling to know our dedication to advancing cancer care and improving our human-care element has helped us reach this significant milestone," said Dr. Henry Tsai, radiation oncologist at ProCure NJ.

# WHEN ONLY ONE THING MATTERS

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PROTECT + ENHANCE + SAVE LIVES

# Tennessee governor vetoes state employee proton therapy coverage

**Posted online May 09, 2018 by John R. Fischer**

**Tennessee Governor Bill Haslam (R.) has vetoed a bill that would make coverage for proton therapy mandatory under state employee insurance plans.**

Haslam asserted that the bill, passed by both the Tennessee House and Senate, would burden patients with excessive charges from out-of-network providers and put them at risk. The bill was sponsored by physician and senator Mark Green (R.) and representative Bob Ramsey (R.).

"The provider advocating this bill rejected a medically appropriate plan for expanded coverage to instead pursue a political mandate," Haslam said in a statement. "The state is committed to high-quality care that is medically appropriate and fiscally responsible for patients and taxpayers, but this mandate could put patients at risk and expose them to excessive charges from out-of-network providers."

If passed, the bill would require the state group insurance program to cover physician prescribed hypofractionated proton therapy under the same aggregate amount as intensity-modulated radiation therapy.

Coverage would extend to patients in a clinical trial or registry and prescribed by a board certified radiation oncologist. Aggregate cost would be required to equal the average cost paid by the state for an entire course of IMRT treatment for the delivery of the same biologically effective dose.

Green and Ramsey have called for a special meeting to consider overriding the veto, a move supported by executive director Scott Warwick of The National Association for Proton Therapy.

"His statement that the bill could 'put patients at risk and expose them to excessive charges from out-of-network providers' is incorrect and misguided," Warwick told HCB News. "The bill's language, which improves access for cancer patients on the state health plan who would benefit from hypofractionated proton therapy, explicitly states that there will be no additional cost over standard IMRT to the patient, the state, or its insurers. We hope that the Tennessee legislature will reconvene for a special session to override the veto."

Haslam's office did not return calls for comment.

# FDA gives thumbs up to Hitachi's tumor tracking proton solution

**Posted online January 29, 2018 by John R. Fischer**

**Hitachi Ltd. will soon be marketing its Real-Time Image Gating System for Proton Beam Therapy Systems (RGPT), offering motion management capabilities and advanced spot scanning irradiation technology to U.S. consumers.**

The solution, derived from collaboration with Hokkaido University, will enable radiologists to treat moving targets with proton therapy.

"This can be beneficial for moving tumors such as lung and liver, but can be used for other sites such as prostate," Hiroyuki Itami, executive general manager of Hitachi's Healthcare Business Unit Particle Beam Therapy Division, told HCB News. "Other tumors that can be affected from the movement of the diaphragm can also benefit from this feature."

Conventional motion management only tracks the surface of a patient's body and requires a predetermined time as a basis for irradiating tumors.

RGPT tracks the location of the tumor with X-rays, irradiating it while in motion and with greater accuracy.

Hitachi plans to install RGPT at U.S. facilities under construction. The company is also in the process of obtaining CE approval for use of RGPT in EU countries.

# MedStar Georgetown treats first patients with MEVION S250i proton therapy

**Posted online April 05, 2018 by Lauren Dubinsky**

**MedStar Georgetown University Hospital in Washington, D.C. recently become the first to treat a patient with the MEVION S250i Proton Therapy System.**

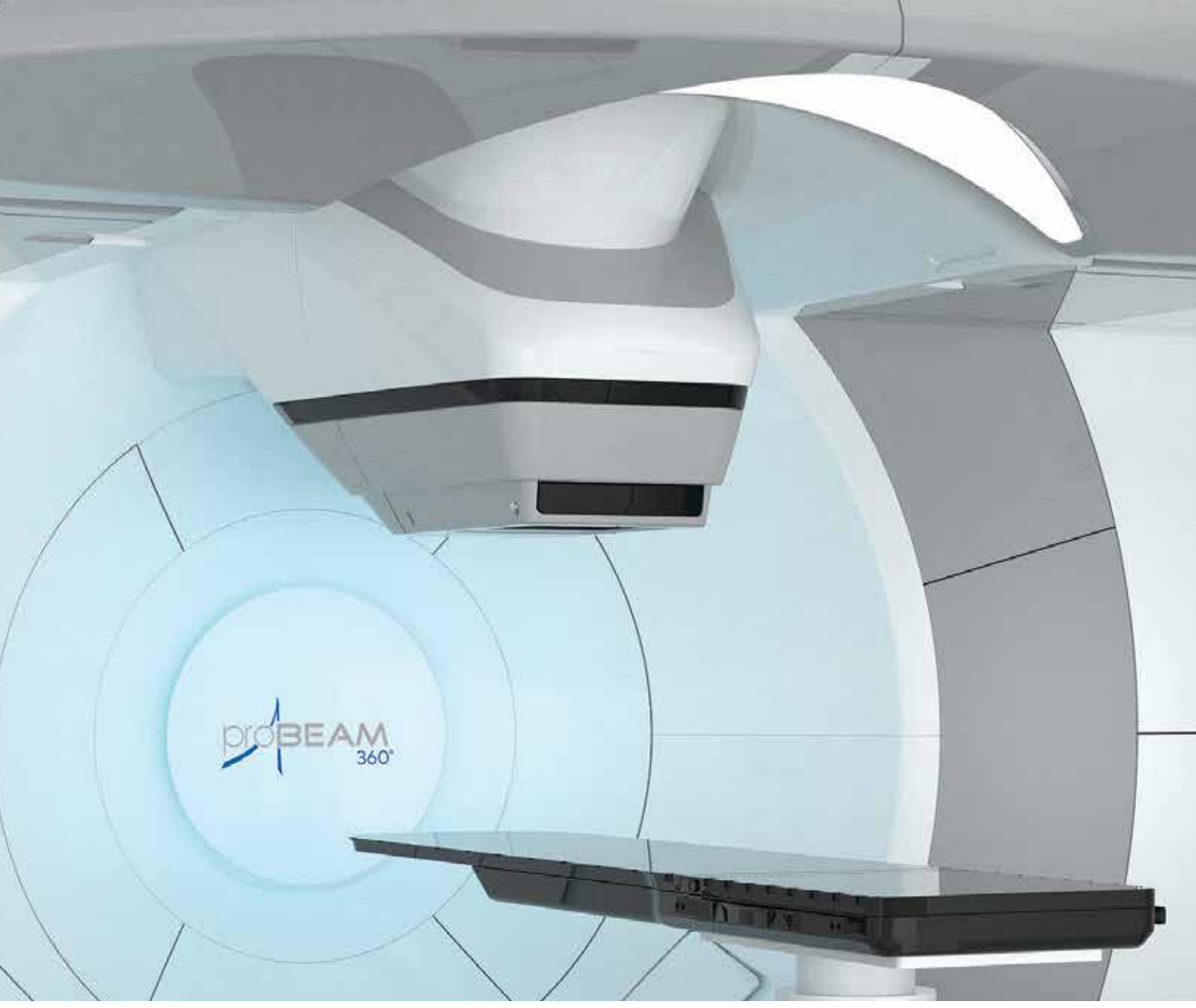
The system at MedStar Georgetown is equipped with the company's cutting edge HYPERSCAN pencil beam scanning technology.

"The system can be used for a wide variety of complex tumors, such as central nervous system, base of skull, lung, GI, GU, breast and liver to name a few," Skip Rosenthal, vice president of clinical systems at Mevion, told HCB News.

The MEVION S250i also features the Adaptive Aperture proton multi-leaf collimator, which sharpens lateral dose gradients.

"HYPERSCAN Pencil Beam Scanning is a type of conformal proton therapy which is ideal for treating solid cancer tumors in close proximity to critical organs including indications where motion creates additional challenges," said Rosenthal.

At MedStar Georgetown, the system was integrated into the hospital as part of a renovation to the existing cancer entrance. Other proton centers have typically constructed stand-alone facilities, but this system is small enough to fit into existing radiation oncology departments.

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**Safety information: Radiation may cause side effects and may not be appropriate for all cancers. Product may not be available in all markets.**



varian

# Proton therapy arrives in the UK

**Posted online April 13, 2018 by John R. Fischer**

**The Rutherford Cancer Centre South Wales has delivered the first bout of proton therapy treatment in the U.K. to a cancer patient, providing Brits with the option to pursue the cutting edge treatment domestically rather than travel abroad for it.**

"After many years being behind the game, the U.K. can now deliver a transformational change for cancer patients over the next five years with Rutherford Cancer Centres," Professor Karol Sikora, chief medical officer of the center's parent company, Proton Partners International (PPI), told HCB News. "Proton Partners International's aim is to have a Rutherford Cancer Centre within 90 minutes of 75 percent of the U.K. population by 2021. There is a growing demand for proton beam therapy, and we, as a country, need to be fully equipped to meet that demand."

More than 150,000 U.K. cancer patients undergo radiation therapy annually. PPI argues that ten percent who receive radical radiotherapy would benefit more from PT, ushering in a need for at least 15 more such facilities.

The Welsh-based enterprise itself plans to open eight more PT cancer centers across the U.K., eliminating long-distance travel for patients to countries such as the U.S. and Switzerland, where costs for such treatments add up to around £114,000 (over $140,000).

The Rutherford Cancer Centre South Wales utilizes a single-room Proteus One proton beam therapy system, designed by Ion Beam Applications (IBA) Group and approved for use there in February.

The system, installed in May 2017, is more compact than large multi-room systems, and is equipped with pencil beam scanning, enabling precise targeting of tumors while minimizing exposure to healthy tissues.

IBA plans to supply and provide maintenance for Proteus One systems at PPI's eight other centers in development, agreeing to do so for the last three in March.

The Rutherford Cancer Centres treats self-paying patients and those with health insurance. Treatment is also available to patients referred by an NHS Trust.

# Russia's first proton therapy facility up and running in St. Petersburg

**Posted online March 21, 2018 by John R. Fischer**

**With the first patient having successfully completed treatment at a new facility in St. Petersburg, proton therapy is officially available to treat cancer patients in Russia.**

PTC St. Petersburg Center of Nuclear Medicine of the Sergey Berzin Medical Institute administered treatment this month to a pediatric patient afflicted with a brain tumor in its two-treatment room facility using Varian's ProBeam system.

"This is a new possibility for oncology patients, especially pediatric patients," Dr. Arkadi Stolpner, president of the Sergey Berezin Medical Institute, told HCB News, adding that the majority of patients currently undergoing treatment at the facility are children.

Varian's ProBeam system provides patients fully integrated intensity-modulated proton therapy (IMPT), enabling greater adaptive proton therapy.

The advent of operations at Russia's first proton therapy center has major implications, according to Bill Hansen, director of marketing for Varian's particle therapy division.

"St. Petersburg is a major metropolitan location in Russia with a large population, and is a well-known destination for visitors to Russia," he told HCB News. "Its location on the western coast of Russia lends itself to easy access for northern Europe."

# RaySearch to supply RayStation to first proton therapy center in India

**Posted online February 08, 2018 by John R. Fischer**

**An Indian-based health care provider has selected the RayStation platform as the treatment planning system for the first proton therapy center in the Southeast Asian country.**

Apollo Hospitals will incorporate the RaySearch solution at the facility, which is set to begin treating patients in September 2018 in Chennai.

"We are delighted to have been chosen by Apollo Hospitals for their groundbreaking introduction of proton therapy in India," Johan Löf, CEO of RaySearch, said in a statement. "Apollo shares our view of the many benefits in having a single treatment planning system for all treatment machines, and our partnership will result in high efficiency and outstanding patient care. This installation reinforces our strong and growing presence in the APAC region and our commitment to supporting the widest possible range of treatment machines."

The center will be comprised as a multi-room configuration that consists of two gantry treatment rooms and one fixed-beam treatment room, and equipped with IBA's Proteus Plus treatment delivery system.

The agreement also includes modules for deformable registration, dose tracking, adaptive therapy and multi-criteria optimization.

# Is low-cost Proton-to-Carbon Heavy Ion radiotherapy coming soon?

**Posted online May 25, 2018 by John R. Fischer**

**Best Particle Therapy, a division of TeamBest Companies, has announced plans to introduce a Proton-to-Carbon Heavy Ion system for highly precise, conformal and hypofractionated radiation therapy.**

The 400 MeV ion Rapid Cycling Medical Synchrotron (iRCMS) will be equipped with variable energy and heavy ion treatment technologies to offer a more advanced form of radiotherapy, compared to current options available to patients.

"Carbon Heavy Ion can only be produced with at least a 400 MeV Synchrotron," Krishnan Suthanthiran, founder and president of TeamBest Companies and the Best Cure Foundation, told HCB News. "Our technology is the most sophisticated and yet the simplest solution, providing the most precise, conformal and hypofractionated radiation therapy of five fractions, compared to the range of 30 to 40 fractions found in proton, X-ray, and gamma external-beam radiation therapies."

Carbon ion therapy targets cancer cells while minimizing damage to surrounding tissue. Beams are accelerated up to 70 percent of the speed of light and treatment time is shorter than other forms of radiotherapy.

BPT's 400 MeV iRCMS is designed with intrinsically small beams that enable precise delivery of the most conformal radiation therapy. Its small beam sizes enable it to utilize small magnets and light gantries, creating a reduced footprint.

The system also offers hypofractionated therapy and requires less shielding, due to its highly efficient single turn extraction. It is flexible enough to provide heavy ion beam therapies using protons and/or carbon.

Along with BPT are Best Theratronics Ltd. (BTL), Best Cyclotron Systems (BCS) and Best Medical International (BMI), the other enterprises that make up TeamBest Medical Companies.

BCS currently offers New Advanced Technology Cyclotrons that range from 15 to 70 MeV with as high as 1000 micro Amp current for each device. BCS is developing a Multi-Particle 35 MeV Cyclotron that will utilize alpha, deuteron and proton power as forms of therapy.

BPT plans to release its 400 MeV iRCMS in two to three years' time.

# California Proton Therapy Center re-launches California Protons

**Posted online December 12, 2017 by John R. Fischer**

**California Proton Therapy Center LLC officially re-launched California Protons, a cancer treatment center in San Diego, on Thursday, December 7, under new management and leadership and with an expanded group of physicians.**

The relaunch follows a year of hardship for the center, which filed for chapter 11 bankruptcy protection in March and parted ways with its management, Scripps Health, in September. Loughlin Management Partners, a specialist in business and health care turnaround, is working with the facility on a transition plan as it welcomes Orix, JP Morgan and Varian as its new owners and investors, and Proton Doctors Professional Corporation (PDPC) as its clinical manager.

"The center has been recapitalized, the investor group has provided additional financial resources to support the center's future growth, and we have taken a number of steps to improve short- and long-term financial performance," James J. Loughlin, Jr., managing partner at Loughlin Management Partners + Co., told HCB News. "The center is well positioned to truly become a regional resource that is available to treat patients from all over the state of California and abroad."

Changes include a reduction in cost structure and an alignment with a group of experienced proton physicians, three of whom are from the University of California at San Diego. Certain functions, such as insurance authorizations, will be brought in-house to decrease delays and enhance the efficiency of processes.

The center also aims to continue building on its clinical affiliations with its partners, including UC San Diego and Rady Children's Hospital, while forging new partnerships and alliances throughout California.

Though Scripps Health no longer maintains day-to-day operations, patients of the network are still welcome to the center to seek treatment.

"As more proton treatment centers open throughout the U.S., the overall awareness of the benefits of proton therapy will increase," Loughlin said. "And as new research results support the benefits of proton therapy, demand will increase, which will benefit the California Protons Cancer Therapy Center."

# C-RAD to integrate Catalyst PT system with Mevion S250i in Netherlands

**Posted online April 4, 2018 by Gus Iversen**

**A proton therapy facility under construction in the Netherlands, The Zuid-Oost Nederland Protonen Therapie Centrum (ZON-PTC), will combine the latest Mevion proton therapy technology with a specialized version of C-RAD's Catalyst technology and software.**

The facility, located at and largely owned by MAASTRO clinic, will integrate Catalyst PT with the compact Mevion S250i accelerator. As part of the collaboration MAASTRO has ordered the Sentinel 4DCT and Catalyst PT system.

"In Maastricht we want to become a world leader in proton therapy with a special focus on moving targets (lung cancer and breast cancer). Therefore, the Catalyst PT in combination with the Sentinel system on the CT scanner plays a crucial role in establishing this goal," said Geert Bosmans, head of proton physics at ZON-PTC, in a statement.

In a first step the Catalyst system will be installed on a Varian TrueBeam linac at MAASTRO clinic to train future proton therapy staff in the clinical application of surface tracking.

Proton treatments are expected to begin by the end of the year.

# RayStation reports strong uptake of Monte Carlo Dose Engine among proton therapy centers

**Posted online May 22, 2018 by Gus Iversen**

**Within a year of its release, RayStation has announced that 13 of its 18 clinically operational proton therapy sites are utilizing the Monte Carlo dose engine in RayStation 6.**

Several clinics report that they use the MC dose engine for all patients, while others use it for selected cases where high accuracy is important, such as lung, brain, breast or head and neck.

"The implementation of the RayStation Monte Carlo dose engine has expanded our capability to serve more and a wider range of patients," said Chang Chang, director of physics, Texas Center for Proton Therapy. "For example, it enabled us to use larger range shifter to patient air gaps, which streamlined our process in the treatment rooms."

Peer reviewed research papers, like one published in the International Journal of Radiation Oncology, Biology, Physics, entitled "Pencil Beam Algorithms Are Unsuitable for Proton Dose Calculations in Lung" are showing that Monte Carlo is now considered key for certain cancer types, which has prompted rapid implementation and acceptance.

The utilization information was collected in a survey conducted by RayStation.

# Proton therapy trumps IMRT for prostate cancer: study

**Posted online October 27, 2017 by John R. Fischer**

**Proton therapy may ensure higher survival rates and a decline in complications among prostate cancer patients, compared to intensity-modulated radiation therapy (IMRT).**

That is according to a new study presented by researchers from the Northwestern Medical Chicago Proton Center at the 4th Annual PTCOG Conference on October 25, in Chicago. The authors of the study hope their findings will prompt insurance companies to enroll patients in PARTIQoL, a randomized trial for evaluating quality of life in both sets of patients.

"A lot of the insurance companies have said they won't pay for the treatment of prostate cancer at all with proton therapy," Dr. William Hartsell, the lead author of the study and medical director of the Northwestern Medicine Chicago Proton Center, told HCB News. "Some of the reasons they said have been because it's experimental, even though there are thousands and thousands of men who have received proton therapy for cancer, and that there is no evidence that it's better. Well, this is some evidence that there's a possibility that this is better, and I think that should spur the completion of PARTIQoL."

Proton therapy administers the energy of protons into the tumor and then stops the dose, compared to conventional radiation which deposits dose beyond the tumor.

The researchers examined records from the Medicare and Surveillance, Epidemiology and End Results (SEER) national databases of more than 28,000 IMRT patients and 851 proton patients who underwent treatment between 2006 and 2012.

The five-year overall survival rate was 93.25 percent for proton patients and 88.43 percent for IMRT patients. The rate was slightly greater for the matched group of intermediate risk patients, with proton recipients at 93.65 percent and IMRT at 88.27 percent.

Incidents of complications in the bladder, endocrine and other areas were also found to be fewer in proton therapy patients, along with the occurrence of secondary malignancies, with a rate of 10.5 percent for IMRT patients and 6.1 percent for proton therapy at five years.

# IBA and Raysearch showcase the first Online Adaptive Proton Therapy workflow at ESTRO

**Posted online April 16, 2018 by Gus Iversen**

**At the ESTRO congress, IBA and RaySearch will demonstrate how they can optimize patient treatment by offering the first online adaptive proton therapy workflow.**

The two companies will present their full size demonstration including the RayCare oncology information system, the RayTreatment workflow and treatment planning system, the AdaPT Insight imaging platform and the AdaPT Deliver treatment delivery. In an online adaptive workflow, daily cone beam CT images are used and matched to the planning CT of an individual patient.

"The combination of IBA's cutting-edge Cone Beam Imaging solutions with the treatment planning and treatment workflow solutions from RaySearch enables our future clinical partners to make online adaptive proton therapy a reality," said Frederic Genin, head of product management at IBA, in a statement. "We are very excited to see how these advanced functionalities can be beneficial to the patients around the world."

The technology will automatically suggest an adapted treatment plan to the care team which takes into account the patient's most up-to-date anatomy, allowing for more accurate treatment plans as well as faster plan adaptation.

# After water damage, Florida proton provider back in business

**Posted online August 14, 2018 by Gus Iversen**

**American Shared Hospital Services, a leading provider of turnkey technology solutions for advanced radiosurgical and radiation therapy services, said that proton treatments have resumed, following water damage to its proton therapy system at Orlando Health – UF Health Cancer Center that occurred on July 28, 2018.**

Certain components of the system were compromised by the facility's water evacuation system about two weeks earlier, according to a prior statement from the organization.

"We expect repairs to the system to be covered under existing insurance and any interruption in service also to be an insurable event after a five-day waiting period," said Dr Ernest A. Bates, chairman and CEO, at the time. "Accordingly, we do not currently anticipate that this interruption in service will have a significant impact on our financial performance. This is a temporary interruption and will not impact the expected long-term growth of the program."

The facility has been treating patients since April of 2016 using its Mevion S250 accelerator.

# A dose of sophistication comes to CT protocols

*By John R. Fischer*

*Dr. Donald Frush says along with technology, techniques for preparing patients for scans are essential for dose optimization. (Credit: DukeHealth)*

**Over the last several years, Duke University Medical Center's monitoring program for CT performance has undergone some big advancements.** These included incorporating CT study image quality metrics to augment the more standard radiation dose profile of each examination, with monitoring of performance by a multidisciplinary team on a regular basis. From creating a set schedule for dose monitoring reviews to organizing accounting and database protocols, the North Carolina institution has taken steps to enhance its program.

"Several years ago, discussions on dose monitoring practices were on a random basis. It would be primarily through protocol review, which we tried to do regularly to see that the doses we were delivering were reasonable, but the benchmarks weren't well developed," **Dr. Donald Frush**, a professor of radiology and pediatrics in Duke's department of radiology, told HCB News. "The development of that formal program has allowed us better data to begin to address what we do and how to improve our service."

Today, staff members meet quarterly for reviews, searching for outliers to identify areas in need of improvement and formulating approaches to make those fixes. Accounting and database protocols are also in check thanks to the introduction of a server.

Experts like Frush have witnessed similar transformations across

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*Part of dose optimization means knowing when a CT scan is truly advisable versus when other diagnostics might be better.*

the country in radiation dose management through the introduction of updated guidelines, assessment programs, accreditation, and technological innovations to ensure patients remain safe and receive appropriate amounts of radiation to address their individual imaging needs.

But dose optimization goes deeper than just understanding how radiation management works. It requires a broader knowledge of CT and its usage, from technique to scan prep time, to knowing when a CT scan is or is not the right thing to do.

## Dose rates are safe? Prove it.

Almost every facility with a CT scanner today requires some form of accreditation in order to gain reimbursement for exams. In addition to most, if not all, payors, even states are now demanding some form of credentials from providers to demonstrate the safety of their environment and practices.

Obtaining certification varies by accrediting organization, with each requiring facilities to meet certain criteria. The Intersocietal Accreditation Commission (IAC) for instance requires facilities to have a consistent quality assessment program to ensure that periodic random checks of patient radiation exposure rates take place and to review and compare actual patient radiation dose to predetermined doses to avoid overexposure or assess what factors led to it taking place.

"Maybe the patient was very large, or needed to have a repeat exam because they moved, or perhaps your staff members inadvertently selected the wrong technical factors. That's what you need to check periodically to make sure your patients aren't becoming erroneously irradiated," said **Nancy Merrill**, director of accreditation for MRI/CT/carotid stenting at the IAC.

Further guidance can be found through programs such as Image Wisely, which provides resources and information on ionizing radiation exposure from medical equipment to radiologists, medical physicists, other imaging practitioners and patients; or Image Gently, which supplies guidance for effective and safe imaging of pediatric patients.

Tools such as the American College of Radiology's Dose Index Registry are also available. Using the ACR registry, clinicians can compare the range and output of their dose index data to that of their peers and similar facilities throughout the country and in their individual regions, and learn and adopt measures to meet quality and safety requirements.

"The latest technology always comes with a great cost, one that not all facilities can afford," **Debapriya Sengupta**, manager of national radiology data registry analytics at the ACR, said. "Dose Index Registry provides high-value but low-cost tools so that all facilities can provide high-quality patient care and meet their Leapfrog reporting requirements."

While important, dose management and safety is just one area that must be assessed when exposing patients to radiation from CT and other imaging modalities. Clinicians must ask themselves if CT is the correct modality of choice or if there is another that exposes a patient to less or no radiation at all. Furthermore, they must question their own practices in utilizing CT and how those influence the outcomes of procedures and the overall health of patients.

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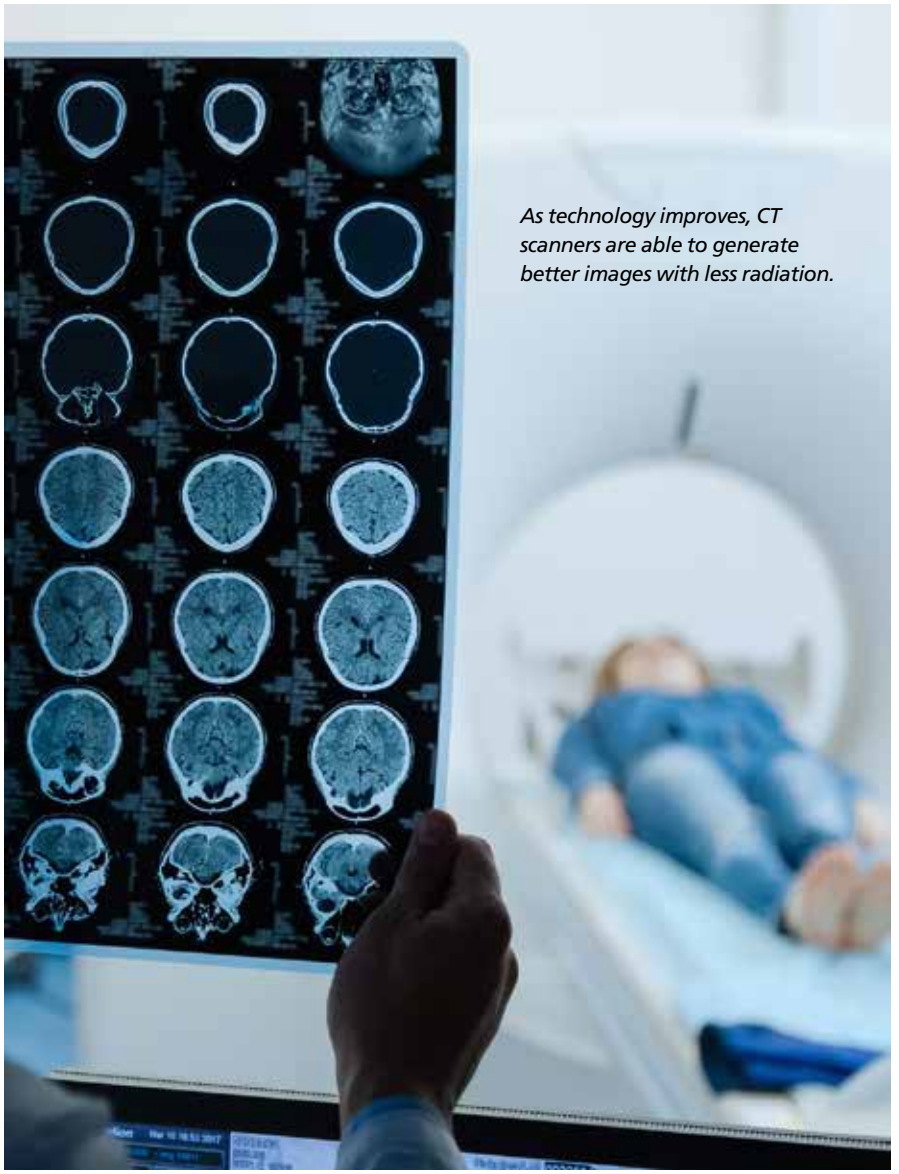

*As technology improves, CT scanners are able to generate better images with less radiation.*

## To scan or not to scan

CT utilization has dropped in the past ten years by roughly 20 percent for Medicare beneficiaries, with heightened attention to dose practices playing an integral role. This change in attitude toward dosage is derived from greater emphasis on the appropriate use of CT with clinicians questioning and communicating with one another more often on whether CT is the right option or if another diagnostic tool would be a better option.

"Maybe a physician thinks that performing a CT is appropriate but then the order goes to the diagnostic imaging group that says, 'This really would be better if it were an MR,'" said Merrill. "They'll call the physician who may usually agree and send a different script. Or he or she might say, 'No, my patient has a pacemaker so you need to give them a CT.'"

Image Wisely, Image Gently and RadiologyInfo.org have made information on imaging exams that do not utilize ionizing radiation more accessible. The ACR Appropriateness Criteria, which offers guidance on the most appropriate tests for specific clinical conditions, is another powerful tool for choosing the right exam for the right patient.

It's important that providers understand such tools are merely guides and not tell-all instructions. "The Appropriateness Criteria isn't meant to be a cookbook of medicine but to help the ordering physician have the most current information and promote those conversations addressing what the experts have said about this condition," said **David Kurth**, senior director of the ACR Practice Parameters and Appropriateness Criteria.

In addition to clinicians, the responsibility of knowing the risks of CT use falls on patients themselves and is on the rise as more engage in consultations and shared decision-making with their physicians on which exam is the right choice based on their condition and individual needs.

But while the drop in CT exams among Medicare beneficiaries may appear positive due to the decrease in ionizing radiation exposure, statistics on total utilization are limited due to a lack of any reliable source of information on non-Medicare patients. At the same time, the extent to which each factor has contributed to this decline is uncertain.

"With CMS mandating the use of Appropriate Use Criteria in 2020, it should become less of an issue," **Jason H. Launders**, director of operations for Health Devices Group at the ECRI Institute, said. "However, it isn't clear how much of that is being driven by financial concerns or dose concerns."

## Technique and technology

The actions of the patient before and during the exam make all the difference. For example, movement during a CT scan can lead to repeats of procedures, exposing patients to more ionizing radiation.

"Patients, especially children, can be somewhat anxious about the scan or outwardly frightened," said Duke's Frush. "To have parents in the room, some preparatory information available, child specialists or anticipatory training for patients and parents, can allow the scan to happen more efficiently, with less chance for movement-affected scan quality."

Ensuring patients are calm and prepared is part of scan preparation, one of two components (scan preparation and scan performance) according to Frush that determine the success of a CT scan. Movement and improper positioning can degrade quality and diagnostic information, and if extreme, may necessitate re-scanning with additional radiation exposure.

Errors such as incorrect positioning in the gantry, improper arm or leg positioning, or not immobilizing a young patient (when

needed) can contribute to overexposure and stress the need for providers to develop and implement comprehensive protocols that are mindful of preparation for children throughout their practices.

"Without adequate preparation, you may have detriments to scan quality and that means the dose you use is connected to a scan of reduced quality, less 'bang for the buck'," said Frush. "In pediatric radiology, and I think likewise for adult radiology, it is important to look at the fundamental basics of scanning, such as preparation, because this increases study quality, potentially reducing patient dose while providing better diagnostic yield."

In conjunction with correct technique is the other component, technology, which continues to evolve through research and development, such as with the release of a new detector or the discovery of a faster scanning method for decreasing motion. One example is the wider availability over the last few years of dual energy CT technology, which enables clinicians to gather information from a single phase alone and to preclude pre-contrast and post-contrast study.

Another is the incorporation of automated technical factors in scanners that enable radiologic technologists to prep for exams more accurately and avoid exposing the patient to excessive amounts of dose.

Many payors require that such features be assessed as part of the accreditation process to ensure their use equates to safe dose rate applications. "That includes specific technical factors such as your kV, mA or mA range, rotation speed, and pitch – that are very specific items to ensure they are appropriate, with an acceptable radiation dose," said Merrill.

One approach to ensure such standards are met has been the introduction of XR-29, requiring CT facilities to implement processes to record and assess the exposure of their doses to keep them within reasonable ranges. In effect, its use has raised accountability among providers in their administration of radiation and efforts to optmize dose delivery.

Understanding the full functions and uses of current developing technologies such as AI, as well as technique, is crucial says Frush, who sees them as integral parts in the calibration and delivery of correct dosage in the coming years.

"We need to promote the fact that CT has saved countless lives by continuing to question how we are going to make sure dose is right for the examination. I think we can look at advances with AI and how we are beginning to leverage that in terms of being able to assess image quality. We're also evolving to have organ dose estimations now supplant what we typically have had, which is CT dose index volume ($CTDI_{vol}$) and size-specific dose estimation (SSDE). Having this more granular, organ-based dose information for each patient's scan can also enhance the dose component of a comprehensive CT performance monitoring program."

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# Low-dose, mobile CT technology powers the future of lung care

*By Mellisa Wheeler, BSW, MHA*


*With BodyTom, the lung screening process takes about twelve minutes. Patients receive results within 24-48 hours.*

**When the first mobile stroke unit dispatched in Houston four years ago, it motivated a wave of hospitals adopting the technology for their own facilities.** At Atrium Health's Levine Cancer Institute (LCI) in Charlotte, North Carolina, we were inspired to establish a different kind of mobile unit – one that could address rural North and South Carolina's deadly combination of high smoking rates and lack of access to lung cancer screenings.

It was a tall order that required a CT scanner with mobile capabilities. Moreover, the scanner needed to have low-dose screening capabilities in order to adhere to the American College of Radiology's guidelines set forth in 2011 to establish low-dose lung screenings as the standard of care. Our team moved forward and proposed the idea to the Bristol-Myers Squibb Foundation, which provided a grant to make the dream of a mobile lung unit and comprehensive screening program come true.

Since its launch in April 2017, LCI's mobile lung unit has provided care to many people who might not otherwise have


*Levine Cancer Institute's Mobile Lung Unit, equipped with Samsung NeuroLogica's BodyTom, can be parked virtually anywhere and deliver high-quality, low-dose CT images to patients in underserved populations.*

had access. Additionally, the lung screenings have located incidental findings outside of the lungs. Our team has been able to refer these affected patients to other LCI programs for care options.

## Covering new ground

In selecting a scanner, our team considered several factors that were crucial to ensuring the mobile lung unit's functionality, such as low-dose lung scanning, durability to withstand transit, and its safety in providing patient screenings. Ultimately, the 32-slice mobile CT scanner BodyTom by Samsung NeuroLogica fulfilled all of our requirements.

The system's resistance to being affected by its environment ensured that the device would deliver high-quality images despite high temperatures, humidity, or the rough road conditions faced on the journeys into rural areas. In our extensive research of CT scanners for the unit, Samsung NeuroLogica's commitment to understanding mobile technology was evident from their experience introducing Mobile Stroke Units to the world. We knew that we were selecting a partner that thoroughly understood the complicated nuances of bringing a mobile unit on the road.

BodyTom's ability to deliver high-quality low-dose lung images in real time was also paramount to our decision. Given the time that the unit spends in remote areas that may not have immediate access to emergency services, it was important for us to prioritize safety as well. BodyTom's shielded workstation delivers 0.5mm of protection for our staff, and internal lead shielding provides another 0.75mm to reduce radiation scatter in the vehicle.

## Point of care dose management

Since its first site visit, the mobile lung unit has been providing critical screenings to underserved populations in North Carolina that have some of the highest lung cancer rates nationwide.

Many people within this area do not have access to reliable transportation, so bringing the screenings to them was one way to bridge the access gap. The mobile lung unit also offers the unique opportunity to educate rural healthcare providers about the importance of lung screenings, encouraging collaborative partnerships that will continue to grow in the future.

Having a device with protocols for dose management helps us to resolve patient concerns about the safety of the screening process. As providers, we face challenges due to health literacy and strive to keep our answers as simple as possible, reminding patients that the risk of a late-diagnosed lung disease and/or cancer is much greater than risks from very minimal exposure to radiation during the procedure.

Additionally, the mobile lung unit is equipped with a tablet where we store shared decision-making information that provides patients with helpful information. Prior to the procedure, patients view a short video that reinforces key risks and benefits associated with lung screening, along with information on smoking cessation and healthy lifestyle habits. The tablets also allow our staff to collect vital patient information, such as smoking history, occupation, and occupational exposure on a short survey. We're using this information to research how we can better serve the communities and people that we touch.

## Mobile lung units: Future of patient care

Given the success rate of our mobile lung unit, we expect to see programs like ours expanding across the country. Already, we've received inquiries from facilities beginning the process of incorporating a mobile lung unit into their programs. Questions range from technological – how to make particular equipment and technology work on the road – to logistical – how we determine which locations to serve first.

At LCI, we believe mobile lung units are a model for the future of patient care. Mobile lung units have the potential to save the lives of not only underserved populations, but also the lives of patients with insurance who may not otherwise seek out lung cancer screenings. Convenient, safe, simple, quick, and most importantly, lifesaving, mobile lung units have the potential to change the way caregivers and patients experience lung screenings for years to come.

*About the author: Mellisa Wheeler is the director of the Disparities & Outreach program at Levine Cancer Institute, a department dedicated to eradicating the burden of cancer in underserved communities through prevention education, screening and early detection of the disease. She has over 20 years of experience in healthcare with a specialized focus in oncology.*

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# Spectral CT, workflow and dose reduction drive new CT scanner and software releases

*By Lisa Chamoff*

*Canon Aquilion Prime SP*

**Though the technology has been around for more than a decade, spectral CT is starting to gain ground in the CT market.** Many of the new releases over the last year tout spectral imaging capabilities, meant for cancer detection and cardiovascular applications.

At the same time, manufacturers are improving workflow and software companies are helping providers get critical reimbursements while lowering radiation dose.

Here's what's new from the major CT players.

## Canon Medical Systems USA

In April 2018, Canon Medical Systems USA received FDA clearance for its Aquilion Precision CT system. The scanner has an ultra-high-resolution detector with more than twice the resolution that is able to detect much smaller abnormalities – as small as 150 microns – and is part of a trend toward using CT for cancer detection and management, said **Dominic Smith**, senior director of the CT, MR and PET/CT business units for Canon Medical Systems USA Inc.

At last year's RSNA, the company released the Aquilion Prime SP, a 160-slice all-purpose CT scanner that can be used for advanced cardiac care.

Last fall the company also released an updated version of its Aquilion ONE GENESIS, with a technology that improves image quality in brain scans and for cardiac imaging.

Smith said the changes were prompted by new guidelines for the management of patients with stroke from the American Heart Association and American Stroke Association, which recommended CT over MR when triaging such cases.

The scanner's Neuro FIRST MBIR application improves high-contrast spatial resolution and low contrast detectability in the brain, which allows physicians to possibly see early signs of stroke.

Aside from the buzz around the rise of spectral CT, a technology that has been around for the last decade, artificial intelligence is the next frontier for CT, and the company plans to release more information related to AI initiatives at this year's RSNA.

"Our technology is built so that it's AI ready," Smith said. "AI is the next big trend that will impact all diagnostic imaging technology."

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## CurveBeam

CurveBeam, which specializes in cone beam CT diagnostic imaging for the orthopedic market, received FDA clearance in May 2018 for its LineUP scanner, which provides weight-bearing imaging of the knee and lower extremities.

The scanners are specially designed for orthopedic practices, as they can plug into a regular wall outlet and don't need a fully lead-lined room.

"Extremity scanners don't require as much power as a full body CT," said **Vinti Singh**, the marketing manager for CurveBeam. "It's also convenient for patients, since they don't have to travel to a separate imaging center or hospital for a scan."

Some major medical centers have also purchased the scanner for their radiology departments because of the clinical advantage of standing exams.

"In a lot of lower extremity conditions, alignment is a very important aspect of understanding the condition," Singh said.

CurveBeam has also created a scanner for hand specialists, the InReach, which was FDA-cleared in May 2017. To use the scanner, the patient steps up to the scanner and places his or her hand inside a small gantry opening that is raised or lowered according to the patient's height.

CurveBeam's products provide an advantage, as X-ray has limitations when imaging the extremities, Singh said.

"The foot and the hand are really complicated parts of the body," Singh said. "It's hard to see overlapping bone structures clearly on an X-ray. Incorrect tube head positioning can distort the anatomy. With CT, you have an exact three-dimensional view, with no distortions or overlaps."


*Curvebeam LineUP*

Singh said the next frontier for Curvebeam is a scanner that scans from the feet up to the hips, and the company's engineers are already at work on a design.

## GE Healthcare

GE Healthcare's latest CT release is the Revolution Frontier, a 128-slice scanner designed to provide spectral imaging at a more affordable price, according to the company.

The Frontier, FDA-cleared before last year's RSNA, comes with a new tube and detector technology that improves overall image quality of spectral CT, said **Scott Schubert**, general manager of premium CT for GE Healthcare.

*GE Revolution Frontier*

Peer-reviewed papers looking at the Frontier technology show a 17 percent improvement in liver lesion characterization.

"That particular advantage means that 17 percent of your patients would not have to go to invasive follow-up testing," Schubert said.

The company also doubled the overall workflow and speed of reconstruction, utilizing a partnership with AI computing company NVIDIA, allowing for the completion of post processing in five minutes, according to Schubert.

The company also recently released the CardioGraphe, a dedicated cardiovascular CT system. The scanner images the heart, coronary arteries and vascular structures and it can be used for structural heart procedures like transcatheter aortic valve replacement (TAVR).

"Facilities might not be able to afford top-of-the-line general purpose scanners," Schubert said. "It is more of a middle price point with top-of-the-line performance for cardiovascular applications."

The CardioGraphe is aimed at radiology practices with a high number of cardiac cases or imaging centers that want to set up chest pain management clinics, as well as for cardiology practices and in the cath lab.

"This is taking CT for the first time in a point-of-care setting, which is, of course, more comfortable for patients who have minor chest pain," Schubert said. "Making the system more affordable in an outpatient setting is really the goal."

Since RSNA, GE has also released three new advanced clinical applications to improve diagnosis and accelerate workflow for CT.

The first, GSI Fat, is a fat quantification tool to determine whether a patient is susceptible to fatty liver disease, which is a precursor to liver cancer.

"Fat has been demonstrated to be very useful to show patients who may be pre-symptomatic," Schubert said. "The gold standard has been MR in the past, but that is not for a broad population of patients."

GE also released a physician visualization tool for 4D myocardial perfusion scans that Schubert said can "image the heart in one heartbeat, but also scan the heart over time and see perfusion of the myocardia."

The third new application is for planning minimally-invasive mitral valve replacement procedures. The application is similar to GE's aortic valve replacement planning tool, which evaluates the insertion point, makes sure the valve won't dislodge any plaque and ensures that the size of the valve is adequate.

In the last year, GE also began offering what it calls Smart Subscription, which provides access in the cloud to the latest software updates for a facility's entire fleet of CT scanners.

"This keeps all your scanners and software applications up to date with the latest upgrade subscription for the applications," Schubert said.

## Hitachi

At last year's RSNA, Hitachi released a compact, economical CT scanner for the value-oriented market of community hospitals called the Supria True64.

The scanner is an upgrade from the Supria 16-slice model and it's called the True64 because "it is a CT that really has 64 discrete detector channels," said **Mark Silverman**, manager of CT marketing for Hitachi. "Being a true 64 gives it some speed of scanning and resolution advantages."

For the premium market, many manufacturers design a true 64-slice scanner, but for the economy market, they create a 32-slice CT that uses software upgrades to get the 64 slices, Silverman said.


*Hitachi Supria True64*

"The 16-slice market is beginning to fade away," Silverman said. "The true 64 is becoming the new 16."

Supria True64 also comes with a new environmental efficiency feature called Eco-Mode that reduces power consumption by up to 55 percent when the scanner is idle.

## MedicVision

Back in early 2015, the Centers for Medicare and Medicaid Services (CMS) announced reimbursement for low-dose CT lung cancer screenings for certain Medicare beneficiaries.

The screening presents a new potential source of income for imaging centers, but the scans cannot exceed radiation levels of 1.5 mSv in order to be eligible for reimbursement, which can be hard to achieve with older or lower-level CT scanners, said **Eyal Aharon**, the chief executive officer of MedicVision.

"In many places where they use older machines, they cannot get reimbursement," Aharon said.

Last year, the company released SafeCT LS, a cloud-based solution – there is no hardware or on-site software installation – that reprocesses the low-dose scans to help facilities get under the 1.5 mSv threshold while retaining image quality. A cloud-based solution eliminates the investment in equipment and facilities pay for SafeCT LS per scan.

While lung cancer screening programs have been slow to adoption, Aharon said the company has noticed an increase in the market in the last year or so, and thus the need for such a solution.

## Neusoft

Around last year's RSNA, Neusoft received FDA clearance for its NeuViz Prime 128-slice dual energy CT scanner with spectral imaging capabilities.

What makes the system unique is a newly designed X-ray tube that removes heat faster than it's introduced, said **Keith Mildenberger**, the CT product manager for Neusoft.

The NeuViz Prime offers a 0.259 second rotation speed, allowing for motion suppression that is ideal for pediatric imaging, as well as trauma and cardiac cases.

"In pediatrics, motion is the enemy," Mildenberger said. "It will be a really great pediatric system and should have the potential to do very good cardiac imaging as well."

The system also has the ability to upgrade to perform spectral imaging, which Mildenberger said has a big future in cardiac imaging and virtual colonoscopy.

"The market we're in is very dynamic and changing very rapidly," Mildenberger said. "We have all the tools in place to support the clinical applications for spectral CT."

## PACSHealth LLC

In the last year, PACSHealth LLC, a radiology informatics software company, added new features to version 2.5.4 of its DoseMonitor software. The software can now perform organ dose modeling both pre- and post-scan, using phantom sets from National Cancer Institute.

In July, the company added Modality Utilization reporting, which monitors the time that the CT scanner is actually utilized based on scan time, not time the room is blocked. This information automatically gets sent to all customers for better planning of exams.

"Now we can retrospectively analyze how long the exam took versus what it was scheduled for," said **Mike Battin**, chief operating officer of PACSHealth.

PACSHealth also recently introduced its Global Dose Registry, a feature that is integrated into DoseMonitor and that allows clinicians to compare the radiation dose of an exam to a global database of millions of similar studies done at healthcare facilities around the world.

Battin said that this is a big improvement over existing data aggregation sources that require separate data collection and manual reporting.

## Philips Healthcare

At last year's RSNA, Philips introduced its IQon Elite Spectral CT scanner, a premium product that is ideal for oncology applications, as well as for cardiology and trauma settings.

The scanner can detect different levels of tissue composition, distinguishing between healthy and unhealthy cells, allowing for doc-

*Neusoft NeuViz Prime*

*Philips IQon Spectral CT*

tors to be more confident in their diagnoses, said **Karim Boussebaa**, head of CT and AMI for Philips.

"The advantage is in the ability to look at tissue composition at various levels of chemistry," Boussebaa said.

The scanner also provides faster reconstruction and image quality improvements, decreasing the need to reimage patients, according to Boussebaa.

The IQon Elite is the world's first and only spectral detector-based CT scanner, according to the company, and is part of a shift toward the technology.

"As price goes down, spectral will become new normal," Boussebaa said.

## Siemens Healthineers

It's been a busy year for the Siemens Healthineers CT segment. In April 2018, the company received FDA clearance for the SOMATOM go.All and SOMATOM go.Top systems, the latest addition to its SOMATOM family of CT scanners.

The scanners include a redesigned tablet workflow that allows technologists to spend more time with patients, a development that came after the company engaged with more than 500 customers from around the world in co-creation sessions.

"We believe this is a major enhancement," said Matthew Dedman, U.S. marketing director for CT for Siemens Healthineers North America.

*Siemens SOMATOM Edge Plus CT system*

Along with the tablet workflow comes intelligent automation, including the ability to set up the scan range and the reconstruction field of view automatically, for greater standardization and consistency of results, Dedman said.

The scanners also come with a larger 75-kilowatt generator, for busier and more complex environments.

"We enhanced the horsepower of those systems to enable more advanced exams, such as emergency department patients and cardiac," Dedman said.

Both systems utilize the new Athlon X-ray tube, which Dedman said offers its highest mA output of 825 mA at its lowest kV settings, allowing radiation dose to be tailored to each patient.

"The industry as a whole has done a good job in investing in iterative reconstruction," Dedman said. "Additionally, we have invested heavily into hardware-based dose reduction technologies as well. If we can optimize our hardware, so that prior to any iterative reconstruction we are delivering the lowest dose, high-quality image, that means we're less reliant on IR algorithms and can maintain a more natural image impression for the radiologist."

In April, the company also received FDA clearance for its SOMATOM Edge Plus and SOMATOM Force CT systems. Both scanners feature Fully Assisting Scanner Technologies (FAST) Integrated Workflow with what the company calls the FAST 3D Camera, a patient positioning system that uses artificial intelligence.

Historically, patient positioning has been a manual task, with the height of the technologist impacting the patient position, Dedman explained.

"A six-four tech versus a five-six tech will have a different visual perception of what the ISO center is," Dedman said.

The FAST 3D camera, mounted above the table, uses an AI algorithm to do correct positioning for the exam, reducing variability among exams.

"When we looked at areas to develop new technologies, we're always looking for ways to improve standardization and increase consistency for our customers," Dedman said.

## Xoran Technologies LLC

Xoran specializes in point-of-care CT scanners that are utilized in doctor's offices as well as the operating room. The company's flagship product is the MiniCAT, which is primarily used in ENT and allergy offices for CT scans of the ears and sinuses.

In April 2018, the company released the MiniCAT 2020, a scanner that is further optimized for CT imaging within the workflow of the ENT clinic.

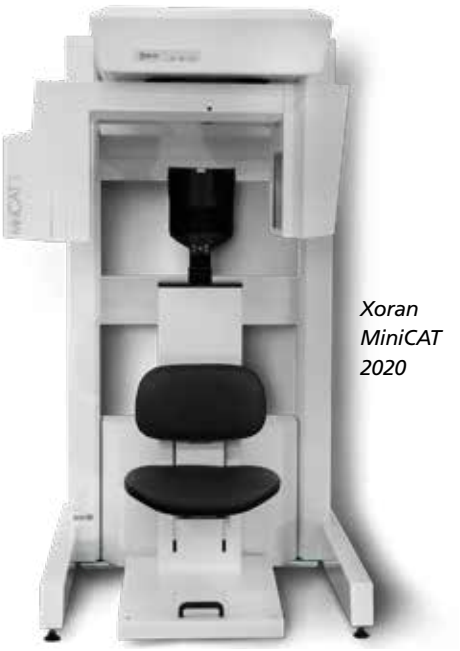
The scanner can differentiate between bone, liquid and air, giving clinicians the ability to detect disease, infection, obstruction and other ailments, said **Russell Jahnke**, director of product management for Xoran Technologies.

"We really looked at what patients are expecting," Jahnke said. "When they go see their ENT, they really want to see things taken care of in as few visits as possible. The point-of-care imaging the MiniCAT offers in the ENT office is exactly that."

In the middle of last year, the company introduced the xCAT, a portable head CT scanner for use in the OR, allowing surgeons access to CT imaging during surgery. This year, Xoran also released the xCAT IQ, a portable intraoperative CT designed for neurosurgeons to use in both the OR and the ICU.

"If a neurosurgery patient is in the ICU, the current standard-of-care is to pack them up and take them to the CT suite," Jahnke said. "With the xCAT IQ, you can bring the device to the bedside."

Earlier in 2018, Xoran debuted what it calls "Ace Mode" on its MiniCAT IQ sinus and temporal bone scanner used in the doctor's office. When MiniCAT is in ACE Mode, it uses patient-specific data obtained during the pre-scan setup to automatically present a patient profile that helps the clinician select the just-right patient CT scan.



*Xoran MiniCAT 2020*

## Zetta Medical Technologies

In July 2017, Zetta Medical Technologies, a third-party service provider that also develops CT software, released Z-DOSE RP, a dose reporting platform. The software connects with the ACR dose registry and also allows facilities to track dose data by study type over multiple scanners and locations.


*Zetta Medical Z-DOSERP*

"A lot of the legacy systems don't have those capabilities," said **Mike Ghazal**, the chief executive officer of Zetta Medical Technologies. "Even the new scanners will generate a structured report, but don't generate a dose report for the director of radiology to view and track data. Ours is more of a dashboard comparison to analyze dose data over time using multiple criteria. In addition to CTDi and DLP values, it also includes comparisons by exam type, scanner type, referring physician, etc."

The product is designed for large university hospitals and imaging centers, and is designed to work with the scanners from the major manufacturers, including Canon, GE, Philips and Siemens.

"Once they see the reports, they don't want to go back to not using it," Ghazal said. "They like the ability to see all this data and have it at their fingertips."

The company has designed custom templates for its customers to allow them to view more data to their own specifications.

"Every place has its own set of protocols," Ghazal said.

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# Chronos Imaging sells 100th CT X-ray tube in under three months

**Posted online June 13, 2018 by John R. Fischer**

**Chronos Imaging has secured the sale and shipment of 100 CT X-ray tubes from the Dunlee CT tube facility in Aurora, Illinois.**

The diagnostics imaging manufacturer rang up its 100th milestone in late May, less than three months after acquiring the CT tube manufacturing plant from Philips.

"There is high demand for high-quality CT replacement tubes that our facility has a reputation for bringing to the marketplace," Rudy Piskule, Chronos sales operation and marketing manager, told HCB News. "We will continue to move quickly to address the needs of market. We have a strong order book and a healthy pipeline."

Focusing on operational efficiency and yield optimization, Chronos began ramping up production at the Aurora location within weeks of the acquisition, while also implementing a new framework for the quality and regulatory systems within the organization.

As part of negotiations with Philips, Chronos agreed to continue to provide the Dutch-based OEM with CT tubes on a long-term supply basis while developing other tubes to serve the entire OEM and replacement CT tube marketplace.

# GE plans to integrate MedyMatch's AI platform with CT systems

**Posted online November 29, 2017 by Lauren Dubinsky**

**CHICAGO — MedyMatch Technology announced a collaboration with GE Healthcare on Tuesday to integrate its 510(k)-pending artificial intelligence platform with the company's CT systems.**

"GE has 20,000 to 25,000 CTs in its install base, so it's a wonderful opportunity for us to reach many customers and it's also an opportunity for them to add value to their imaging platforms," Gene Saragnese, chairman and CEO of MedyMatch, told HCB News at the RSNA annual meeting.

The first available application for the AI platform is for intracranial hemorrhage detection. It's designed to be a decision support tool that helps clinicians assess patients with suspected acute head trauma or stroke.

"Many times a patient will come into the ER who bumped their head, have a headache or have some paralysis, and the question that has to be answered is whether they have blood in their brain," said Saragnese. "Our tool is designed to provide the second read or prioritize a case."

The platform was trained using data from Massachusetts General Hospital, Cleveland Clinic and Capital Health in New Jersey.

# Coalition urges CMS clarification on low dose CT guidance

**Posted online May 24, 2018 by Thomas Dworetzky**

**The ACR and other partner groups sent a formal letter to CMS requesting that it confirm that Medicare will reimburse for CT lung cancer screening at Independent Diagnostic Testing Facilities (IDTF).**

"We believe that Medicare Administrative Contractors (MACs) are not correctly adhering to the lung cancer screening NCD 210.14. In accordance with the June 12, 2017 Medicare Learning Network Matters article (MM9246), CMS clarified that IDTFs are, in fact, eligible facilities capable of performing low-dose computed tomography (LDCT) lung cancer screening. Nevertheless, MACs regularly exclude LDCT lung cancer screening coverage when performed in the IDTF setting, including at sites that meet the NCD criteria. We hope CMS can clarify these outstanding issues contributing to the MACs' decision to deny coverage of LDCT lung screening at IDTFs," the letter stated.

ACR noted in a May 18th statement that physician ignorance of screening guidelines, lack of patient and physician education about screening and "drastically low Medicare reimbursement for low-dose computed tomography (LDCT) lung cancer screening exams" may be resulting in thousands of unnecessary deaths each year.



# Richardson unveils replacement tube for Toshiba CT systems

**Posted online May 30, 2018 by Gus Iversen**

**Richardson Healthcare has just introduced a new replacement CT tube compatible with a range of Toshiba (Canon Medical Systems) CT scanners.**

The ALTA750 is the first new CT replacement tube manufactured by parent company Richardson Electronics, and is designed as a replacement for the CXB-750D/4A tube, (also known as the Varex Imaging MCS-7078).

The new tubes, which will come packaged with a Heat Exchanger and HV Cable Kit, will include a prorated 12-month (or 200,000 rotations) limited warranty.

"We expect to see a good response to the product launch, as many customers have told us they would like to be able to buy a new tube with a new tube warranty at a reasonable price," Pat Fitzgerald, executive vice president and general manager of Richardson Healthcare, told HCB News.

For a limited time, the company is also offering a 90-day satisfaction guarantee, during which customers can return the tubes for a full refund of the purchase price.

Richardson is now one of a few global companies with the design and manufacturing capabilities necessary to produce CT tubes.

# Canon's ultra high-res CT system gets FDA nod

**Posted online April 10, 2018 by Lauren Dubinsky**

**Canon Medical Systems USA Inc. announced on Monday that the FDA cleared its Aquilion Precision CT system.**

According to the company, this is the world's first ultra-high resolution (UHR) CT system.

Its UHR detector has been designed to provide more than double the image resolution of conventional CT technology. The system can also image anatomy as small as 150 microns.

"The increased amount of information delivered by the Aquilion Precision opens new doors for healthcare providers," said Dominic Smith, senior director, CT, PET/CT, and MR Business Units, Canon Medical Systems USA. "The system delivers higher resolution images than other systems on the market, enabling customers to deliver better patient care."

The detector channels are only 0.25 millimeters thick and significant improvements have been made to scintillator quantum efficiency, detector circuitry and other data acquisition system components. All of those factors provide better dose efficiency.

The Aquilion Precision is also equipped with the company's new automated Model-Based Iterative Reconstruction (MBIR) technology, which reduces noise and maintains resolution. This is the first MBIR optimized for UHR CT.

# Largest multi-lesion CT imaging dataset, DeepLesion, available to public

**Posted online July 23, 2018 by Thomas Dworetzky**

The new publicly-accessible medical imaging database, DeepLesion, is a "critical step forward in computer-aided radiology detection, diagnosis, and deep learning," according to the paper announcing its availability in the Journal of Medical Imaging.

It is the largest CT lesion-image database ever made available to the public, with over 32,000 annotated lesions from over 10,000 cases, according to the team from the National Institutes of Health Clinical Center that developed it. Such huge, annotated radiological datasets are essential in the creation of deep learning approaches to medical data.

"We hope the data set will benefit the medical imaging area just as ImageNet benefited the computer vision area," said Ke Yan, the lead author on the paper and a postdoctoral fellow with senior author Dr. Ronald Summers, senior investigator and staff radiologist at the center.

DeepLesion was creating by "mining" historical medical data from the Institute's own Picture Archiving and Communication System (PACS).

DeepLesion differs from most other medical image data sets now available, which are only able to spot one type of lesion, according to the NIH in a statement.

# New Siemens CT scanner uses AI to improve patient positioning

**Posted online April 04, 2018 by John R. Fischer**

**The FDA has greenlit the SOMATOM Edge Plus CT system from Siemens Healthineers.**

The solution incorporates Fully Assisting Scanner Technologies (FAST) Integrated Workflow with the FAST 3D Camera, the first system to utilize AI for the correct positioning of patients, enabling high-quality images while minimizing dose exposure and repeat scans.

"If a patient were not properly positioned, it could result in a CT study that has a less than desirable or less than optimal image quality," Matthew Dedman, CT marketing director for Siemens Healthineers, told HCB News. "With new FAST 3D Camera and automated patient positioning, we can improve the consistency of the image quality delivered to the radiologist so they are more confident in their diagnosis and more consistent in the workflow because they're getting high-quality images every time."

The task of positioning patients inside a CT gantry at isocenter has traditionally fallen on the technologist, whose visual interpretation and depth perception is crucial in the matter. If incorrect, positioning can lead to noisy images and unnecessary radiation exposure.

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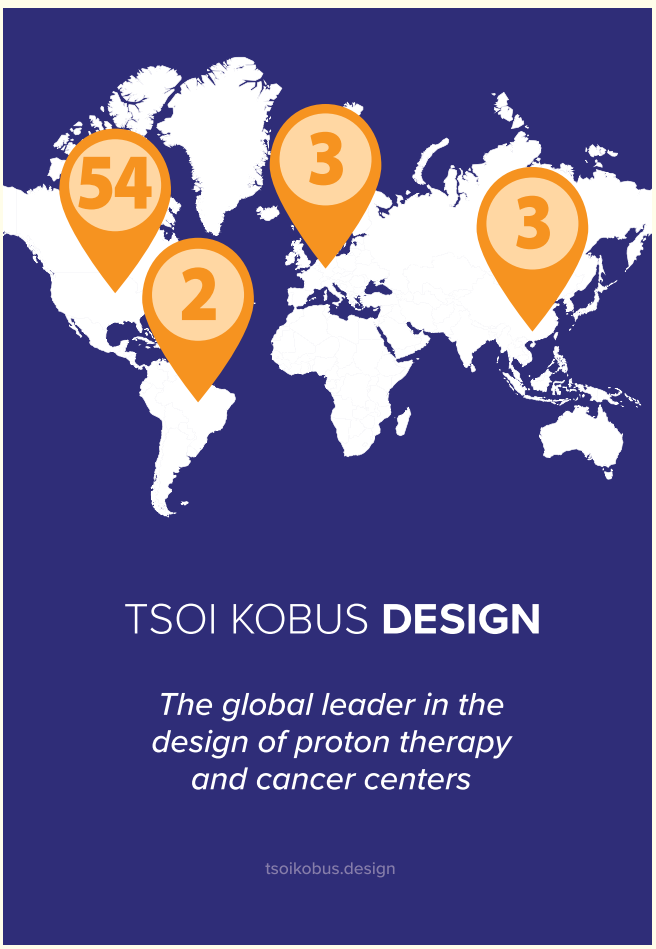

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# The present and future of spectral imaging

*By Christian Eusemann, Ph.D.*

**Decades before it debuted in the clinical setting, the concept of spectral imaging – the acquisition of two or more different X-ray spectra – intrigued the scientific community. Sir Godfrey Hounsfield first mentioned spectral imaging in the scientific literature in 1973, a year after he invented CT.** But while the first clinical CT system capable of spectral imaging – also known as dual energy CT – became available in 1987, clinical adoption didn't occur until 2005. That's when the first generation of dual-source CT systems emerged, enabling fast, simultaneous acquisition of spectral data at radiation dose levels similar to conventional CT.

After 30 years of gradual momentum, spectral imaging has thrived over the past decade. Published papers proliferated from less than 50 in 2006 to nearly 350 in 2015, according to PubMed, and spectral imaging's presence has expanded far beyond the academic institutions that once used it exclusively. In the past two years, adoption has increased rapidly in large, nonacademic hospitals – specifically, in their emergency departments (EDs), where up to 60 percent of all CT scans are conducted in spectral mode. Over the next three years, midsized (200- to 400-bed) hospitals are similarly expected to acquire more CT systems with spectral imaging capabilities.

The value of data obtained from two different energy spectra is multifold. In ED and trauma departments, where speed is critical, spectral imaging can rapidly visualize subtle fractures and bone marrow edema in patients who don't have time for – or easy access to – a magnetic resonance imaging (MR) scan. Additionally, spectral imaging can improve iodine visualization in the GI and GU tracts for better visualization of solid organ injury or ischemia (i.e., ischemic bowel). Spectral imaging also enables easier, more accurate identification and visualization of pulmonary embolisms, especially at suboptimal contrast enhancement. Finally, it can help clinicians characterize incidental lesions as non-enhancing (i.e., cysts) or enhancing (i.e., requiring additional workup). Outside of the ED, spectral imaging has been widely adopted for multiple applications in radiology and oncology (e.g., improving lesion visualization and characterization).

Despite these benefits, spectral imaging was not widely adopted for many years due to workflow issues. Fortunately, medical device manufacturers have invested heavily in automating the postprocessing of spectral data. These companies are also migrating spectral imaging to more accessibly priced CT systems.

But for all its inherent appeal and increasing accessibility, today's spectral imaging technology is still limited to the acquisition of only two different sets of image data. The next logical extension of spectral imaging is photon counting, a technology being developed and installed by multiple manufacturers as a prototype in a select few academic institutions. Photon-counting detectors not only register (or count) each photon in an X-ray beam, but they also measure its energy, enabling the sorting of photons into different energy bins.

That ability to gauge each photon's energy output represents true multi-energy imaging, and it could have profound implications. While current spectral imaging technology is sufficient to characterize some materials in the human body and to quantify iodine enhancement, new contrast materials with additional absorption peaks could one day enable simultaneous imaging of multiple contrast agents. For example, clinicians could highlight and tag a specific lesion with one agent and enhance the vasculature feeding it with another agent.

Exactly when this next iteration of spectral imaging will advance beyond the prototype stage is unclear. But this much is certain: Spectral imaging will one day become THE imaging standard for CT, delivering significant added value in terms of quantitative and functional information beyond the advanced structural imaging of today – all to improve patient outcomes.

*About the author: Christian Eusemann, Ph.D., is vice president of collaborations at Siemens Healthineers North America.*

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