

## I-Flow gains clearance for oxygenated topical dressing

I-Flow's wholly-owned subsidiary, AcryMed, has received 510(k) clearance from the FDA for its oxygen enriched topical hydrophilic closed cell foam wound dressing. Receiving the 510(k) enables I-Flow to start on the path to clinical studies on the dressing in keeping with a plan to make the product commercially available in the second half of 2009. This homogenous oxygenated dressing will likely be the first used for topical oxygen enrichment specifically at the site of tissue damage, which may improve healing.

I-Flow's oxygen enriched topical dressing was developed to be intuitive and straightforward for health care professionals treating wounds. Oxygen is a required nutrient for wound healing. This oxygen enriched dressing is intended to supply this nutrient as well as manage wound moisture in difficult to heal wounds. The product is composed of a proprietary material that is treated chemically to generate and capture the oxygen. Supplemental oxygen, delivered by hyperbaric chambers, has been shown to accelerate wound healing for burns and chronic wounds. The I-Flow dressing is indicated for topical application to burns and acute and chronic wounds and may be ideal for many patients that may benefit from supplemental oxygen but that do not have access to hyperbaric oxygen or where that treatment may be contraindicated.

"We are excited about this new product, which we believe will drive a paradigm shift toward the use of oxygen enrichment for wound care," said Donald M Earhart, I-Flow's chairman and CEO. "We believe that this product, like our ON-Q Pain Relief System, which treats a local area with therapy versus treating the body systemically, will provide significant patient benefits and improve outcomes."

Patents for the product have been issued in the US and Europe and others are pending.

## Philips launches CX50 portable ultrasound system

Philips has announced that its new portable ultrasound system, the CX50, the first mobile system that can be used with the company's proprietary PureWave transducers, has been launched. These transducers are powered by a technology based on a new class of piezoelectric crystals, that exhibit "a quantum improvement in electromechanical coupling and strain levels. Compared to PZT ceramics, PureWave crystals are purer, more uniform, have lower losses, and are able to transfer energy with greater precision and efficiency."

Previously available only on the company's premium iE33 system, PureWave on the CX50 system allows clinicians to get the clear images you need for confident diagnoses on a wide variety of patients, including the difficult-to-image. The CX50 system was designed for critical study requirements. In addition to PureWave, its premium imaging and Doppler performance are possible because of its digital broadband beamformer and XRES technology. Easily perform advanced echo analysis with integrated QLAB and stress echo capability.

The CX50 is designed to make portable exams easy and efficient. One-button iSCAN automatically optimizes 2D and Doppler data for new levels of clarity for portable examinations. On-board QLAB provides advanced analysis capabilities during and after exams.



Portable exams are a challenge, and getting clear diagnostic data is complicated by many factors. Now clinicians have the opportunity to have the image quality required for the diagnostic confidence wherever it is needed.

The CX50 system can be used on a specially designed cart, hand carried to your patients, or packed in its special travel case for easy transport to remote destinations.



## Inverness Medical releases prothrombin time monitoring system

Inverness Medical Physician Diagnostics Group, a division of Inverness Medical Innovations, has released the INRatio 2 PT/INR Monitoring System, a portable device that prothrombin time, using one drop of blood from a patient's finger. The INRatio2 is used by healthcare professionals and their patients in the management of warfarin, a blood-thinning drug, to monitor the effectiveness of the drug and warn of potential blood clots and other bleeding risks.

Warfarin (brand name Coumadin) is the second most common cause of emergency room visits related to adverse drug events, trailing only insulin. The FDA estimates that two million Americans start taking warfarin every year, and many will take the drug for the rest of their lives. Due to the serious bleeding risks associated with warfarin, the FDA has labelled it with a "black box" warning, informing consumers of the major and potentially fatal risks, and indicating that patients should have their PT/INR monitored regularly.

The INRatio2 PT/INR Monitoring System has been cleared by the FDA for warfarin patients to test themselves at home, offering patients quick access to their PT/INR results. The test results are then transmitted to their treating physician by telephone or internet. The results provide important data that helps physicians make informed warfarin dosing adjustments to ensure that patients stay within their recommended therapeutic range. Warfarin is known to be a difficult drug to manage due to the wide variance in each patient's response to the drug, in addition to factors such as diet, age, illness, and interaction with other drugs. Research has demonstrated that more frequent PT/INR testing can help improve a patient's time in therapeutic range.

"We are pleased to announce the launch of the INRatio2, as it exemplifies our continuing focus on patient-centred care, and the growing movement toward patient self-monitoring in the home," said David Phillips, vice president of marketing for Inverness Medical's coagulation division. "Due to Medicare's expanded coverage of home INR monitoring for atrial fibrillation and venous thromboembolism earlier this year, the INRatio2 is now accessible to more patients who wish to monitor their own coagulation."

The INRatio2 offers many patient-friendly features, including a one-minute test time, easy single button interface, and 200 test battery life. Its simple fingerstick test procedure, light weight (9.3 oz), and individually-sealed test strip packaging enables patients to easily test themselves at home or when travelling.

Available to patients by prescription and to healthcare professionals for in-office or laboratory testing, the INRatio2 was developed by HemoSense, a point-of-care diagnostics manufacturer acquired by Inverness Medical in November of 2007.

## GE Healthcare introduces LOGIQ E9

GE Healthcare has launched a new ultrasound system for radiology and vascular applications that fuses ultrasound images with images from other imaging modalities like CT and MR. The new LOGIQ E9 includes Volume Navigation, an innovative tool which incorporates two key components to maximize the system's new agile ultrasound architecture: 'Fusion' to combine the advantages of real-time ultrasound imaging with the high spatial and contrast resolution of CT, MR or PET; and a 'GPS-like technology' to track and mark a patient's anatomy during the ultrasound exam, bringing confidence and productivity to both diagnostic and interventional studies.

This new GE architecture, called Agile Ultrasound, replaces old assumptions of conventional ultrasound systems with new, modular mathematical models that provide more accurate measurements of how sound interacts with different body tissue types. The result of the LOGIQ E9 architecture is an improved, more life-like image without a lot of manual adjustments to view specific anatomy.

Another key feature for the LOGIQ E9 is Scan Assistant, which aids clinicians to put the emphasis on diagnosis rather than on keystrokes. This tool allows a clinician to pre-program the actions most often performed, and then let the system do the detailed manipulations as the patient is scanned. It improves exam time up to 54%, automatically inserts comments, completes measurements, steers Colour Doppler, sets up imaging controls and modes, and improves ergonomics.

"GE's new LOGIQ E9 helps address the biggest challenge in ultrasound radiology and vascular care, how to leverage clinical images from previous diagnostic imaging studies for interventional or diagnostic ultrasound procedures," said Terri Bresenham, GE's Vice President of Diagnostic Ultrasound and Information Technology. "We worked closely with a global team of radiologists and sonographers to develop this new ultrasound architecture, giving clinicians the advantages of imaging modalities - MR, CT and PET - and it is already reigniting the imagination of the ultrasound industry."

## EKOS launches the EkoSonic ES with RPM

EKOS recently launched the EkoSonic Endovascular System (EkoSonic ES) with Rapid Pulse Modulation (RPM) for the dissolution of vascular blood clots. According to the company, EkoSonic ES is the only endovascular system that can deliver microsonic energy and thrombolytic drugs simultaneously, providing a safer, faster and more complete way to remove clots by accelerating dissolution.

Intermittent bursts of microsonic energy effectively increase the permeability of the clot to the thrombolytic, four times faster than conventional catheter-directed thrombolysis with no evidence of thrombus breakage or hemolysis. In addition to its unique RPM technology, EkoSonic ES design features include an advanced control unit with an easier, more intuitive user interface, making set up and operation simple. EkoSonic ES is also compatible with a new line of endovascular devices, EkoSonic Mach 4 Endovascular Device, (Mach4). The Mach 4 was specifically created to be compatible with the RPM technology.

The Mach 4 offers a variety of treatment zone options and consists of a MicroSonic Core within an Intelligent Drug Delivery Catheter. This combination device enables the system to deliver microsonic energy and drugs simultaneously to accelerate clot dissolution. The reduction in time translates to fewer drugs, lowering the risk profile of the procedure while the convergence of technologies results in a safer, faster, more complete outcome in the treatment of Deep Vein Thrombosis (DVT) and Peripheral Arterial Occlusions (PAO).

"Unlike mechanical devices, EKOS technology does not fracture the thrombus or damage red blood cells. Faster clot dissolution means a lower lytic drug dosage, resulting in fewer complications. Physicians can treat patients in less time, with even greater clinical confidence," said Robert Hubert, EKOS president and CEO. "We predict that the EkoSonic will become the new gold standard to treat patients with vascular thrombosis."

Over the past three years, physicians have responded favourably after performing nearly 6,000 cases utilising the EKOS technology.