From the Global Harmonization Task Force…

FDA Official: Expect "Explosive Growth" in Nanotech Products

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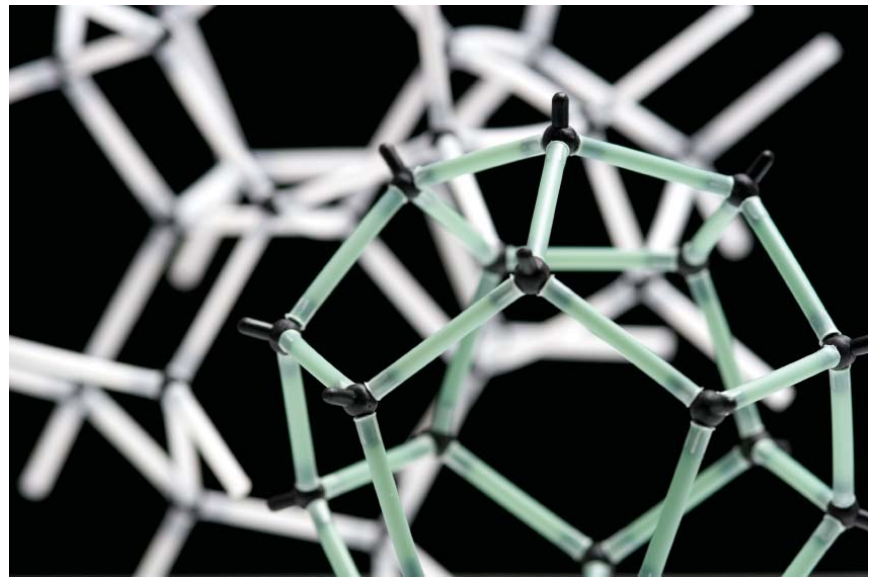
Nanotechnology-based medical innovations that would seem to be science fiction will be here "much sooner than we think," Subhas Malghan, PhD, a member of FDA's Nanotechnology Task Force, said during a recent session of the recent Global Harmonization Task Force (GHTF) in Washington, DC.

Malghan, deputy director for the Office of Science and Engineering Laboratories in FDA's Center for Devices and Radiological Health (CDRH), noted that the demand for nanotechnology-based medical products will continue to increase exponentially and that the nanotech-based medical product business is expected to be a $53 billion industry in 2011, and a $110 billion industry in 2016.

Medical technology advancements incorporating nanotechnology include implants and prosthetics. For example, "nanomaterials" may allow for the creation of artificial organs or prosthetics that are more similar to their original counterparts, making a body's rejection of these products less likely.

Meanwhile, "nanoshells"—miniscule particles composed of a metallic shell surrounding a semiconductor—appear to be components of a promising cancer treatment. According to the National Cancer Institute, when nanoshells reach a targeted cancer cell, they can be irradiated with near-infrared light, causing the nanoshell to become very hot, killing the cancer cell. This technology has the potential to provide more effective treatments with fewer side effects that current radiation or drug treatments.

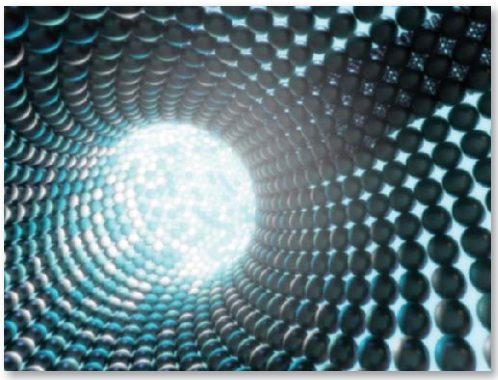


Researchers are developing tiny, magnetic nanoparticles like these that can be used for killing tumors and for imaging them. Nanoparticles can also be applied to devices, such as prosthetics, to make them more biocompatible.

As with any medical device, Malghan suggested that it will be critical to develop standards that address such nanotech-based medical products. "All indications are pointing to explosive growth. Standards development and international harmonization are major challenges, because standards don't currently exist. Standards need to be developed so that when a product is created in one part of the world, it can move to other parts of the world without difficulty."

While nanotechnology holds great promise for new medical advancements, it poses questions about FDA's current regulatory authority.

During the nanotechnology session at the GHTF meeting, Norris Alderson, PhD, associate commissioner for science of FDA's Office of the Commissioner and a member of its Nanotechnology Task Force, stated that "nanotechnology is a major issue at FDA." He indicated that the Nanotechnology Task Force has been charged with three main tasks—assessing the current state of nanotech science, communicating with the public about nanotechnology, and submitting a report on nanotechnology to the FDA commissioner. That report was submitted in July 2007.



Nanotubes are tiny devices that may be used in a variety of medical applications, including cancer detection.

Some of the recommendations outlined in the July report include:

- Promoting efforts and participating in collaborative efforts to further the understanding of biological interactions of nanoscale materials.
- Promoting and participating in collaborative efforts to further the understanding of measurement and detection methods for nanoscale materials.
- Collecting/collating/interpreting scientific information for specific product review categories.
- Building in-house FDA expertise regarding nanotechnology.
- Building infrastructure to share and leverage knowledge internally and externally, seeking to collect, synthesize, and build upon information from individual studies of nanoscale materials.
- Ensuring consistent transfer and application of relevant knowledge through the establishment of an agency-wide regulatory science coordination function for products containing nanoscale materials.

According to Alderson, current knowledge does not support the conclusion that products that include nanoscale materials present a greater safety risk than do products without nanoscale materials. Thus, "there is no need for new regulations at this time."

Alderson concluded by saying that "FDA will continue to review products on a case-by-case basis and continues to stress the importance of early communication with industry" when new products are being conceived. ■

Considering Certification?

The ICC/USCC exams to become a Certified Biomedical Equipment Technician (CBET), Certified Laboratory Equipment Specialist (CLES), and Certified Radiology Equipment Specialist (CRES) will be held in locations throughout the United States three times in 2008: **May 3, June 3 (San Jose, CA, only), and November 1.** Study guides and resources are available on the AAMI website, but some of the best tips come from those who have successfully taken the exam.

First, think back to high school. The same common-sense tips that helped you with tests then can help you with the certification exam:

- Don't cram, but prepare a little each day.
- Get a good night's sleep the night before and eat breakfast the morning of the test.
- Each question carries the same weight, so don't spend too much time on any one question.
- If you skip a question, be sure you skip the corresponding answer line as well.
- There's no penalty for wrong answers, so if you're stumped or out of time, make educated guesses.

Obviously, though, the CBET exam isn't a high school test (you probably weren't required to know much about the Joint Commission's Environment of Care at age 16!). Below are some tips from biomeds who have prepared for—and passed—the exam.

- Study prefixes and suffixes. (That can help to make an educated guess on an answer.) Study the heart electrical conduction system. Memorize basic body parameters such as average cardiac output (4 to 5 lpm).

  —Mike Kauffman

- Don't become obsessed with formulas. They will give you a two-page sheet with all the formulas you need. Have enough familiarity so you can recognize them. Be careful of your decimal places when doing calculations or conversions.

  —Brian R. Morey

- The test is on the basics—a basic understanding of electronics is all that is really needed. I don't believe there were any questions beyond what would be covered in an Electronics 101 course. Make sure you know transistor theory.

  —Chris Poulsen

AAMI serves as secretariat of the ICC/USCC exams. For more information on certification, visit **www.aami.org/certification.** ■

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INSIDE LOOK

It's "All About the Kids" at Cincinnati Children's Hospital

When Kevin Yelton joined the clinical engineering department at Cincinnati Children's Hospital three years ago, he was saddened to see young children and babies suffering. But he soon realized he had a chance to make a real difference every time he came to work.

"I recall seeing a baby no bigger than my arm hooked up to all kinds of tubes and equipment, and I mentioned to a colleague how sad it looked," says Yelton. "But when he responded by saying, '10 years ago we couldn't have saved that kid,' it hit me that we have a chance to do a lot of good."

For the second year in a row, Cincinnati Children's Hospital was recognized by *U.S. News and World Report* as one of the 10 best hospitals in the United States for pediatric care in 2007. And earlier in the year, *Child* magazine named Cincinnati Children's among the top five children's hospitals in the country—all of which makes Yelton and his clinical engineering staff very proud to work there.

"It's all about the kids here," Yelton says. "We're not over here producing widgets. We're creating a safer environment in which kids can get better. We all know that we're making a difference, and it really is a thrill to come to work every day."

Yelton notes that when he tells people that he works at the facility, he invariably gets positive responses. "I always have people telling me, 'hey, my kid went there when he was sick,' or 'my cousin was there.' It's always heart-warming, and that pumps me up."

Yelton and his team stay busy. "We've got 21 technicians—24 employees in the department overall—and each of us works hard," he says. "We're a patient care facility and a teaching hospital, so in addition to the 20,000 pieces of patient care equipment, we've got another 10,000 pieces of equipment devoted to research.

"We're a 24/7 shop, because we have to be. The doctors and nurses need the coverage."

According to Yelton, servicing equipment for a children's hospital is for the most part similar to servicing equipment at any other facility. But there are some subtle differences.

Facility: Cincinnati Children's Hospital
Location: Cincinnati, OH—www.cincinnatichildrens.org
Facility Size: 400 beds
Department Size: 24 employees, including 21 technicians
About the Facility: As Greater Cincinnati's only pediatric hospital, Cincinnati Children's Hospital incorporates the "family-centered care" philosophy into every aspect of its clinical and research practice. Cincinnati Children's ranks second nationally among all pediatric centers in research grants from the National Institutes of Health and is a teaching affiliate of the University of Cincinnati College of Medicine.

"When you're dealing with children, you need beds of all different sizes, you need pumps that are sensitive to dispensing smaller amounts of medication, you need defibrillators that are safe for children. These are things you have to think about.

"But at the end of the day, we're a lot like any other clinical engineering department. We take our responsibility to serving the needs of our nurses very seriously, because they are our customers. And they serve the ultimate customers—the children."

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BIOMED ROUNDUP

TMC Takes IT Integration Issue to Colorado

Biomeds in the Colorado region received in-depth guidance on information technology (IT) convergence issues recently, resulting from an outreach training session developed by AAMI's Technology Management Council (TMC).

Jeff Kabachinski, technical training manager with TomoTherapy, and David Braeutigam, director of biomedical engineering for the Baylor Health Care System, conducted the training on AAMI's behalf at a meeting held by the Colorado Association of Biomedical Equipment Technicians (CABMET) in Denver.

As a case study, Braeutigam discussed how the Baylor Health Care System integrated biomedical engineering into the information systems (IS) department, and the results of that integration. The integration "has given our department a better understanding of information systems operations, provided us with earlier notification of upcoming projects and increased our participation in significant projects, made our department part of a larger group and increased our influence, and has not negatively impacted the organization's perception of us as a department," says Braeutigam.

Discussing technological change, Kabachinski demonstrated how rapidly technology advances by pointing to Moore's Law, which states that information processing doubles every 18 months and halves in cost at the same time. Moore's Law was developed in 1965 by Gordon Moore, co-founder of Intel.

David Braeutigam discusses the critical issue of IT integration at the CABMET Symposium.

The CABMET meeting attracted about 150 attendees. "We've had tremendously positive feedback from our members regarding Jeff and Dave's presentations," says David Scott, president of CABMET. "The topic was timely and well-received."

To view the presentations made by Kabachinski and Braeutigam, visit **www.aami.org/cabmet.** For more information about the TMC, visit **www.aami.org/tmcconnect.**

At CMIA: Biomeds Urged to Take Greater Role in Patient Safety

Bruce Hyndman and Marvin Shepherd encouraged BMETs and clinical engineers attending a recent meeting of the Capital Chapter of the California Medical Instrumentation Association (CMIA) to look at their profession with a new eye toward patient safety.

Hyndman, director of engineering services for California's Community Hospital of the Monterey Peninsula, told audience members to "look at your profession and the product you deliver, and see how you can contribute to a greater level of patient safety."

"When we're called upon, it's typically because a piece of equipment has failed. We need to stop looking at that repair in a vacuum, or as an individual repair,"says Hyndman. "We need to look at the system, and determine why things are failing to reduce risks. Learn to do root-cause analysis.

"Our perspective is different from that of a clinician, and we need to offer our perspectives. If you want to elevate your self-image, and the image others have of you, you can't just sit in the basement and do preventive maintenance. It's not good enough to sit there and say 'No Problem Found' over and over. You've got to make the extra effort."

With the presentation, Hyndman hopes to "spark people to get out of the feeling that they are rechecking the same equipment over and over, and that nobody cares about them. Become a part of the medical team. Stop, look around, and see the bigger picture."

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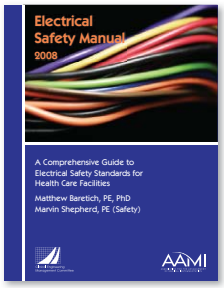
Inside AAMI

Coming Soon: Updated Electrical Safety Manual

A new edition of AAMI's popular *Electrical Safety Manual* will be published by the end of 2007. Updated for the first time in more than three years, this valuable resource for healthcare facilities includes an overview of electrical safety programs; requirements for healthcare facilities; routine tests; guidance for the safe operation of medical devices; and sources for codes, standards, and regulations.



Written and updated by Matt Baretich of Baretich Engineering and Marvin Shepherd, an expert in the field, the 2008 edition will include additional information on isolated power systems; updated guidelines created or revised since 2004, including NFPA 99 and ANSI/AAMI/ISO 60601; electromagnetic interference and human error involving devices; and new regulations from the Joint Commission and other regulatory agencies.

The *Electrical Safety Manual* is just one of many new and revised resources that AAMI has released this year. Visit **http://marketplace.aami.org** to see other offerings and stock your library with valuable resources.

To order your advanced copy, visit **http://marketplace.aami.org** or call 877-249-8226.

Annual Conference Takes Shape

AAMI's 2008 Annual Conference & Expo—which will be held in San Jose, CA, May 31–June 2, 2008—will include up-to-date and practical guidance on issues ranging from asset tracking and staff development practices to imaging radiation issues and risk assessment and management.

Highlights include educational sessions on preventing tubing and catheter misconnections (the subject of a Joint Commission Sentinel Event Alert last year), demystifying IT, radiation safety, codes and standards compliance in clinical engineering, and organizing your biomed department.

Visit **www.aami.org/ac** for more information.

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Major attention will be directed to the **Joint Commission requirements** for medical equipment management, to prepare attendees to meet the requirements and prepare for an accreditation site visit.

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TMC Corner

Connecting with Future Leaders

As part of the Technology Management Council's (TMC) efforts to increase access to the medical technology field for students and new professionals, AAMI has partnered with Stephens International Recruiting to donate AAMI memberships to students studying medical technology.

Stephens has purchased 50 student memberships, which the company will distribute to students at selected schools around the country. "We feel strongly about the 'professionalization' of the field and helping people learn about their trade association," says Cindy Stephens, president and CEO of Stephens International Recruiting. "The memberships will help those just learning the field to understand newer technologies, and to associate with other professionals."

For more information on how to sponsor the student membership program or other educational outreach efforts, contact Steve Campbell at scampbell@aami.org.

Online Resource Center

AAMI's Greatest Hits for 2007

Whether you're looking for a new job, searching for the latest standards and guidelines, or considering certification, the AAMI website has what you're looking for. The most-visited pages in 2007 include:

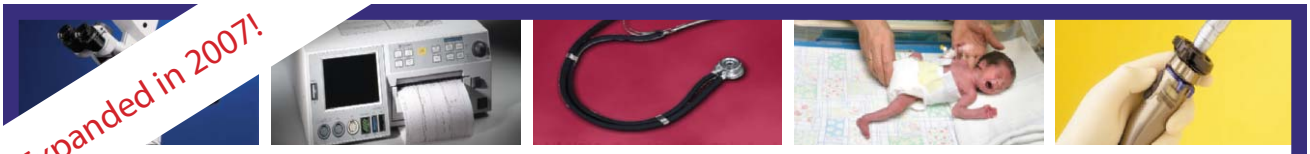
Career Center (www.aami.org/career). With new jobs and resumes posted daily, AAMI's Career Center can help you land the perfect job or find the perfect employee.

Standards (www.aami.org/standards). Everything you wanted to know about AAMI's standards program, including new and upcoming documents, our standards philosophy, and how to join a committee or workgroup.

Meetings (www.aami.org/meetings). AAMI offers courses and webinars throughout the year for medical technology professionals, quality assurance specialists, and others in the healthcare field. Find a course that's right for you.

Certification (www.aami.org/certification). Whether you're considering certification for the first time or need to renew, AAMI's website has everything you need.

Visit **www.aami.org** for more!



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Company News

Society Names Philips "Pioneer in Technology"

Philips Medical Systems has been recognized by the International Brain Mapping and Intraoperative Surgical Planning Society (IBMISPS) as a "Pioneer in Technology" for the company's leading role in developing and commercializing image-guided procedures.

Philips was recognized for its early development and long history of innovations in interactive magnetic resonance imaging (MRI), as well as interventional and intraoperative MRI. The company's involvement in developing the "Operating Room of the Future" suites that include multiple imaging systems to help physicians simplify diagnosis and improve patient care also helped garner it this honor.

Working closely with customers to drive innovation, Philips teamed with the University of California San Francisco to develop the XMR suite, combining MRI and cardiovascular x-ray; and with Tokai University Japan to develop a MRXO suite, combining MRI, catheterization lab, computed tomography, and operating room.

CAS Awarded $2.8 Million Grant

CAS Medical Systems, Inc., has been awarded a Phase IIb Small Business Innovative Research Grant by the National Institute of Neurological Disorders and Stroke (NINDS), a component of the National Institutes of Health (NIH).

The three-year grant totaling $2.8 million will be used primarily to support advanced clinical outcome studies that focus on the company's proprietary LASER-SIGHTR technology. This technology is incorporated into the FORE-SIGHTR Cerebral Oximeter. Further clinical studies funded by this grant will be used to expand the clinical applications for FORE-SIGHT outside of the initial target market of high risk cardiovascular surgery.

Submit your company news to sgillespie@aami.org.

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AAMI's
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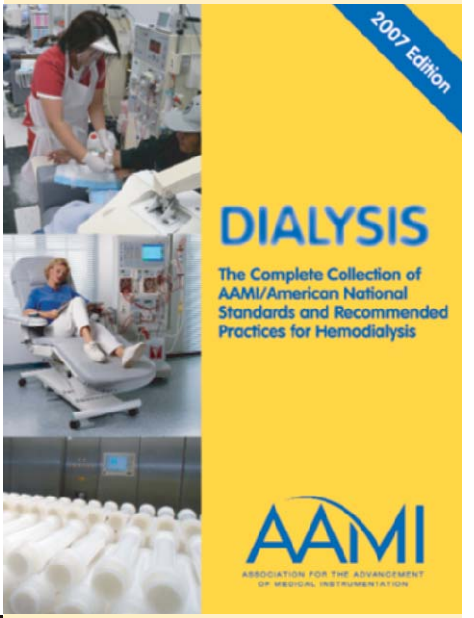
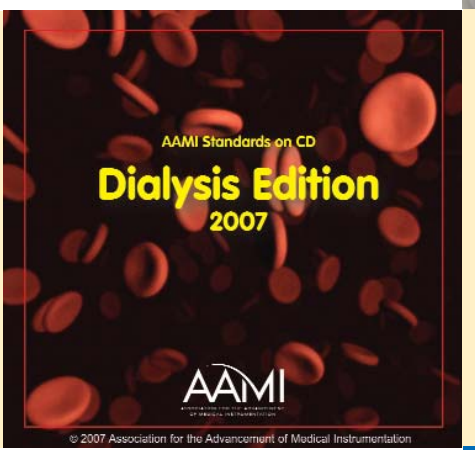
This comprehensive dialysis collection includes EVERY CURRENT AAMI standard and guidance document covering hemodialysis, including these four UPDATED standards, plus three other current AAMI standards:

- Water treatment equipment for hemodialysis applications (RD62:2006)
- Concentrates for hemodialysis (RD61:2006)
- Cardiovascular implants and artificial organs—Hemodialyzers, hemodiafilters, hemofilters, and hemoconcentrators (RD16:2007)
- Cardiovascular implants and artificial organs—Extracorporeal blood circuit for hemodialyzers, hemodiafilters, and hemofilters (RD17:2007)





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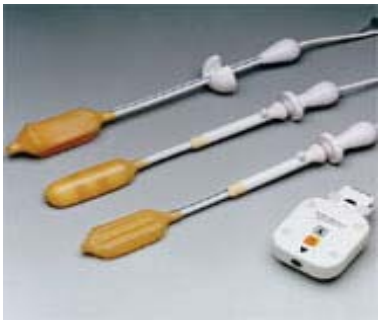
MR Coil



The **MEDRAD** 3.0T Prostate eCoil™ MR Endorectal Coil is now available for magnetic resonance scanners made by Philips and Siemens. MEDRAD introduced the 3.0T prostate eCoil for GE scanners in 2006. The eCoil conforms to the size and shape of the prostate for consistent contact between the gland and the signal-amplifying elements of the coil. The result is small field of view and high spatial resolution, sensitivity, and specificity that yield clearer pictures of the prostate. These pictures provide information needed by clinicians to diagnose and stage cancer, and also to plan and deliver targeted treatment, such as radiation therapy.

For more information, go to www.medrad.com.

Brushless Motor

Pittman has released a brushless DC motor that can perform with minimal noise or vibration at the highest speeds. The patented "Parallex" coil-winding geometry generates more power using less energy for maximized operation and efficiency. The motor can accommodate a wide range of applications, including medical instruments and dental drills. Features include 2-pole rotor, 3-phase stator, and neodymium magnets promoting optimized reliability and life; stainless steel housings that offer corrosion resistance; and precision shielded ball bearings and balanced rotors contributing to smooth and quiet operation.

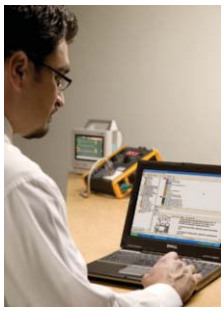
For more information, go to www.ametektechnicalproducts.com.

Autoclavable Temperature Probe

Measurement Specialties introduces a new MEAS 400 Series Autoclavable Temperature Probe for use in clinical environments. This probe allows steam autoclave sterilization up to 134°C (273°F) for a maximum of 20 minutes. The probe uses a stable pressed ceramic (thermistor) sensing element and offers a molded transition between a C-Flex cable, 10 feet long, and a two-pin plug with molded Santoprene housing, ensuring the reliability of the probe after the autoclave process. The probe is compliant with FDA regulations, 93/42/EEC CE-Medical Device Directives, and EN12470.

For more information, go to www.meas-spec.com.

Automation Software Platform



Fluke Biomedical has released the Ansur plug-in for all models of its QED 6 Defibrillator/Transcutaneous Pacer Analyzer. Ansur improves testing quality, repeatability, and productivity using a single human interface no matter how many different mainframe testers are used. The Ansur Test Automation System plug-ins are used as an adjunct and interface to Fluke Biomedical and Metron analyzers and simulators for the purpose of more quickly and easily performing medical device inspections, whether for preventive maintenance or post-repair testing. The software design ensures a consistent user interface for every test device used.

For more information, go to www.fluke.com.

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Platelet Centrifuge

Bio/Data Corporation announces the new PDQ™ platelet function centrifuge, which standardizes platelet sample preparation and reduces processing time. The PDQ accepts evacuated specimen collection and aliquot tubes, and may be used as a companion to any light transmission aggregometer engaged in platelet function testing. The primary purpose of the PDQ is to centralize the sample preparation process adjacent to the platelet aggregometer for specimen control and greater time efficiency.

For more information, go to www.biodatacorp.com.

Respiratory Trainer

Ingmar Medical's QuickLung RespiTrainer provides training and feedback in proper manual ventilation technique. Feedback is transmitted via a wireless connection to a portable digital assistant or pocket PC, from which the user can see ventilation patterns, volume, flow, and pressure delivery. Other features include intuitive graphics, training and test modes, and performance data storage and export. An adjustable QuickLung test component can simulate a range of clinical scenarios.

For more information, go to www.ingmarmed.com.

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Micro-Needle Drug Patch Uses Inkjet Technology

Researchers at Hewlett Packard (HP) Labs have used their inkjet-printer technology to create a drug patch that painlessly delivers medications through the skin via tiny micro-needles. A single patch outfitted with hundreds of micro-needles could potentially deliver multiple drugs at preprogrammed intervals, without the pain of conventional needles.

"There are a few patches out there for drugs like nicotine and fentanyl, very small and potent molecules that go across the skin on their own," says Samir Mitragotri, a researcher at the University of California, Santa Barbara, who specializes in new drug-delivery devices. "They don't need any help. For these molecules, you can buy a patch and it can last up to a week. The problem comes when you try to deliver drugs that are large in size, or water-soluble. And those are the kinds of molecules for which we need to break the skin barrier."

A single micro-needle measures a couple hundred micrometers, a length that could penetrate the outer layer of skin, delivering a drug directly to the underlying capillary bed without triggering nerve endings located deeper in the skin.

Researchers explored several methods of using such micro-needles for drug delivery; strategies ranged from coating the micro-needles with drugs to pumping tiny amounts through micro-needles in controlled doses. Scientists at HP Labs realized that this latter approach resembled the inner workings of an inkjet printer—hundreds of tiny nozzles spraying small amounts of ink at specific times and in preprogrammed patterns.

Janice Nickel, principal scientist at HP Labs, worked to reengineer the inkjet technology as a drug-delivery system, using HP's thermal inkjet printer, or bubble jet, as a model. The bubble jet gets its name from its ink-pumping mechanism: each ink reservoir contains a tiny resistor that heats the area, creating a bubble that displaces the ink, pushing a small amount through the nozzle and onto the paper. Nickel and colleagues designed the drug-dispensing patch in a similar manner, using heat to pump a fluid through tiny, 150-micrometer needles.

The prototype patch, which is about one inch square, contains 400 cylindrical reservoirs, each less than one cubic millimeter. Each reservoir is connected to a micro-needle, and the whole array is fueled by a low-power battery and controlled by an embedded microchip programmed to heat up any given reservoir to deliver a specific drug. The design challenge was in localizing the thermal energy to a specific reservoir. The array is also scalable, and it can be designed to contain tens or even hundreds of reservoirs, depending on its intended therapeutic use.

The prototype skin patch reveals the micro-needles (the sparkling dots on the top of the black square platform) that dispense medicine from tiny reservoirs. A microprocessor (gold square) is programmed to control dosage timing, size, and history. Photo credit: Brett Bausk, Hewlett Packard.

Down the line, the patch may be customized to the patient. For example, tiny sensors embedded in a patch could detect when medication is needed and treat an asthma attack in the middle of the night. Or a patch could automatically deliver insulin when it detects that glucose levels are low.

Says Nickel, "I even had ideas in terms of military applications. You could put sensors on the device to detect chemical or biological weapons, and develop the appropriate antidote for the pathogen dependent on what was detected by the sensors. So there are a myriad of applications for this technology." ■

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Detecting Signs of Glaucoma

Researchers at Purdue University have engineered a wireless eye implant that monitors glaucoma by continuously measuring intraocular pressure—a primary risk factor for the disease. The implant could potentially help ophthalmologists catch and treat problematic spikes in pressure that would otherwise go unnoticed.

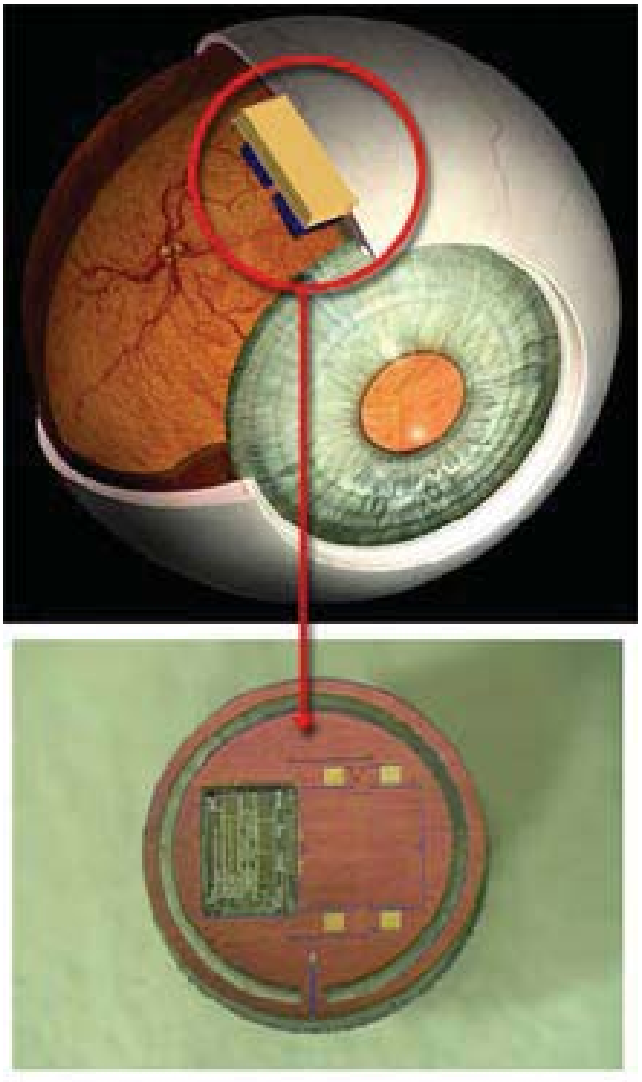
Glaucoma is the second leading cause of blindness in the world after cataracts. There are no outward symptoms other than perhaps a gradual loss of peripheral vision. The disease is caused by a buildup of intraocular fluid that drains from the pupil through a system of canals. The elevated pressure, if left untreated, can permanently damage the optic nerve, leading to compromised vision and, in some cases, blindness.

If the disease is caught early enough, ophthalmologists can give patients drugs to relieve the pressure and stave off further damage. But regular examinations in a doctor's office are inadequate for charting a glaucoma patient's progress.

"People with glaucoma go to the doctor every six months to check their eye pressure," says Pedro Irazoqui, an assistant professor of biomedical engineering at Purdue, who is leading the research. "But the problem is that pressure doesn't spike within months: it spikes within hours, sometimes minutes. Once there's a spike, there's a limited amount of time you have to act before it does permanent damage to the optic nerve. We wanted to design a device that monitors pressure continuously, so that if there is a spike, we'd be guaranteed to catch it."

Toward that end, Irazoqui and his colleagues have designed a tiny microchip, to be implanted between two layers of the eye. The sensor is designed to measure intraocular pressure and wirelessly transmit the data to a nearby computer. A doctor can then access the data and review it for possible warning signs. At present, Irazoqui's team has engineered a prototype of the sensor, although they have yet to test it on animals; that testing is expected to begin by the end of 2007.

One of the major obstacles in creating this type of device is designing a tiny but highly functional chip that uses very little power. Irazoqui's group has overcome this problem in part by designing the sensor to run on nanowatts rather than on microwatts. Such a sensor, once available to patients and doctors, will not only provide better diagnosis for glaucoma, but it may also hold patients accountable for keeping track of their health. ■



A nanosize wireless sensor (top image, highlighted by the red circle) implanted in the eye will provide 24-hour monitoring of intraocular pressure, a key risk factor for glaucoma. The bottom image shows a prototype of the device. Photo credit: Babak Ziaie, Purdue University.

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