



# BMETS Newsletter

April 2009

<http://www.BMETS.org>

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## THE PRESIDENT'S THOUGHTS

The AAMI Conference and Expo are getting close. I hope any BMETS member, who does not otherwise have an opportunity to go to the Exhibit hall, will sign up to work the BMETS booth and get to see what AAMI has to offer. It is a great opportunity to network and meet fellow professionals in our field.

I want to take a minute to discuss some new ideas for meetings. I want to do a BMETS sponsored meeting with a purely technical lecture, a class or topic that we can learn from, something like Radiology or an organization to aid our profession. Maybe a nursing topic or do you have some suggestions. This could be at a Hospital or service facility and involve a piece of equipment or event, i.e. Omeda, FDA, Physician. We would sponsor and thus have it as a learning session on something to enhance our technical growth.

At the April 16 monthly meeting we need to discuss 1) the "May Bash" it is coming up soon and we need a topic and place. 2) What will BMETS do at the AAMI Conference and Expo to welcome BMETS and AAMI members



**Rob Bain**

to Baltimore? Thanks for your support and time. See you at the April meeting.

Rob Bain MS, CBET  
President, BMETS  
(w) 410-601-6745

List of Members that Donated to the BMETS Scholarship Fund This Month

**None**

## THE VICE PRESIDENT'S QUILL

Wow, April it just seems like yesterday that we were in January. How time flies when you have so much fun. I would just like to remind all of you that nomination for the officers are still open, this will be the last time anyone can be nominated before the vote at the May Bash. It has indeed been a pleasure working with and for the Baltimore Medical Engineers and Technicians Society these last three years. I look forward to providing a great venue for the September 2010 MD Expo that we will be hosting. The place and other items have not been announced yet, however we will be discussing with MD Publishing some of things over the next couple of months. Look for news in the next month or so about the MD Expo and BMETS kick off celebration for the MD Expo in 2010 at AAMI.

Speaking of AAMI, if you have not signed up for the booth please see John Sears so that he can provide you with a schedule to assist in manning our booth (#712) at AAMI at the Baltimore Convention Center starting on June 6, 2009. More information about that at Thursday's meeting. Please make sure that when you come to the Meeting on Thursday that you thank MEDRAD MVS for sponsoring.

That is all from the Vice President – See you Thursday.

Chris Jones, Sr. MCP CPACS Assoc.



Chris Jones, Sr.

## THE SECRETARY'S SPIEL

Due to the many requests that we have received from our membership, the BMETS officers have been researching the cost of the set up to use "credit cards" or "PayPal". After gathering all the information, we found out that there was going to be an additional cost to BMETS no matter which way we went. We discussed the raising of membership dues, the raising of membership dues for those that wanted to use credit cards or PayPal, and what would be the added benefits to the BMETS association. The additional cost would be for every month all year long. We have our membership drive between September and December. At the last officer's meeting it was decided to keep things the way they are considering the financial climate. BMETS will not be using credit cards or PayPal in the near future.

The officers are always open to membership input, so let us know if you feel differently about it.

Roy Leake, CBET , FASHE  
 BMETS Secretary  
 (c) 410-802-7652



Roy Leake

## F.D.A. to Check Safety of Old Devices

By GARDINER HARRIS

The New York Times Published: April 8, 2009

WASHINGTON — Federal regulators said Wednesday that they would ask makers of some of the riskiest medical devices to prove that their products were safe and effective — a step that critics have said was long overdue.

In January, the Government Accountability Office issued a report scolding the Food and Drug Administration for failing for decades to fix its system for reviewing categories of devices that have been on the market since before the enactment of the medical device law in 1976.

Such legacy devices, as they are known, were originally allowed on the market with minimal testing. But in the 1976 law Congress told the F.D.A. to gradually reclassify these older devices and decide which ones needed extensive testing before approval of new versions and which ones did not.

The agency never finished that process, leaving 27 different types of devices unexamined — products that include artificial lung membranes, external defibrillators and various pacemaker components.

For decades, the F.D.A. has approved devices in these categories for sale without demanding rigorous tests showing that they work safely. Investigators for the accountability office stated that “it is imperative that F.D.A. take immediate steps” to fix its system for approving such devices, and the agency agreed.

The agency has already undertaken a review of two of these older device types, and it announced Wednesday that it was requiring makers of the other 25 types of devices to submit information to the agency within 120 days, detailing the products’ safety and

effectiveness.

Mary Long, an F.D.A. spokeswoman, said she could not predict how long the reclassification process for the older devices would take.

“We have to review each device type separately,” she said. “It will take some time.”

Industry groups predict that the F.D.A. will conclude that most of the products are not risky enough to warrant greater scrutiny. “The device types subject to the F.D.A. notice have already been thoroughly reviewed by the agency,” said Janet Trunzo, executive vice president of the Advanced Medical Technology Association.

But consumer advocates argue that the agency’s entire process for approving medical devices needs overhauling.

“It’s great that F.D.A. is finally going to look at pre-1976 devices, but the bigger problem is the low standards for approving any and all devices without clinical trials or any proof of safety or effectiveness,” said Diana Zuckerman, president of the National Research Center for Women and Families.

A group of F.D.A. scientists complained to the Obama transition team — and before that to Congress and to the agency’s commissioner — that during the Bush years, managers in charge of medical device reviews had corrupted and distorted the process in ways that put the public at risk.



# AAMI 2009

## CONFERENCE & EXPO

Association for the  
Advancement of  
Medical Instrumentation

June 6 - 8, 2009 | Baltimore, MD



### Some CONFERENCE HIGHLIGHTS

#### Educational Sessions

AAMI 2009 offers a full schedule of educational sessions that will expand your knowledge and help you to provide better healthcare delivery for your facility. Sessions are organized into six concurrent tracks: Technical Operations & Support, Imaging, Patient Safety, Information Technology, Business and Management, and The Big Picture. [Click here for the full schedule.](#)

#### The Expo

Saturday, June 6, 4:30 pm - 7:00 pm

Sunday, June 7, 3:45 pm - 7:00 pm

Monday, June 8, 11:00 am - 2:30 pm

The AAMI 2009 Expo is where you'll get a first-hand look at the latest medical technologies, and learn how those technologies can help improve your facility's healthcare delivery. Meet with representatives of leading manufacturers and service providers, get answers to your device-specific questions, and discover services that can enhance your productivity. [Click here for full information about current exhibitors,](#) or [click here to search for exhibitors for by product category.](#)

#### BMET Evaluation & Review Course

Part I, Saturday, June 6, 8:30 am - 5:30 pm

Part II, Sunday, June 7, 8:30 am - 5:30 pm

This two-day course is designed to provide you with an understanding of basic principles, and to help you identify areas in which you need further review and study to prepare for the CBET Certification Exam.

#### Breakfast Symposia

Symposium #1, Sunday, June 7, 7:00 am - 8:15 am

Symposium #2, Monday, June 8, 7:00 am - 8:15 am

Come and learn about new technologies, techniques, and industry trends from representatives of companies working on the cutting edge of medical technology. These two full-length symposia, which focus on broad educational topics, are organized and presented by AAMI 2009 exhibitors. Breakfast will be served.

Sunday's symposium will be presented by GE Healthcare.

Monday's symposium will be presented by Covidien

#### Dwight E. Harken, MD, Memorial Lecture and AAMI Awards Luncheon

Sunday, June 7, 11:15 am - 12:45 pm

Join your colleagues for lunch, honor the achievements of your peers, and hear a stimulating lecture by a distinguished industry leader. The Dwight E. Harken, MD, Lecture and AAMI Awards Luncheon provides a forum to honor Dr. Harken's substantial contributions to medical science and technology.

#### Career Center

Saturday, June 6, 9:00 am - 5:00 pm

Sunday, June 7, 8:00 am - 5:00 pm

Monday, June 8, 8:00 am - 12:00 noon

The onsite Career Center is where you can meet face to face with potential employers, scan through a list of the most up-to-date job opportunities, get a critique of your resume, receive career guidance, and discuss interviewing techniques with our resident employment experts. [Click here for more information.](#)

#### Product Showcases

These informative 20-minute demonstrations will help you stay on top of the latest medical products and services. Showcases are presented by AAMI 2009 exhibitors and are scheduled in the exhibit hall throughout the exhibit hours.

CALENDAR OF EVENTS  
CHECK THE WEB PAGE FOR UPDATES

April 16, 2009—Monthly Meeting—Medrad, Town-Country Caterers

May 20, 2009—Monthly Meeting—Topic, Speaker, Place to be announced later

June 6-8, 2009—AAMI Conference & Expo, Baltimore Convention Center, Plan now to attend  
AAMI 2009, the premier conference for healthcare

July & August 2009—Summer Break

September 2009—Membership renewal,

Monthly Meeting— Topic, Speaker, Place to be announced later

Plan to attend our next meeting sponsored by

**Medrad**

**April 16, 2009**

**Town & Country Caterers, 2319 Hammonds Ferry Road, Baltimore, MD 21227,**

**Phone: (410) 247-5100**

RSVP's ONLY Emails will be accepted - Place RSVP in the Subject line

What must be included in the RSVP's is:

1. Place RSVP in the Subject line
2. Name of ALL individuals coming to the Meeting.

Please send your RSVP's to [bmets.rsvp@gmail.com](mailto:bmets.rsvp@gmail.com) No later than March 15, 2009.

**If you are not a member, then bring a membership application and \$45.00 for 2009 membership dues.**

Thank you for your cooperation in this matter.

Sincerely,

Rob Bain MS, CBET

President BMETS

## Class 1 Recall: ZOLL Medical Corporation, ZOLL AED Plus Defibrillator

[February 12, 2009]

This product was manufactured from May, 2004 through February, 2009 and distributed from May, 2004 through February 9, 2009.

Use: This device is used by emergency or medical personnel, by others who have completed CPR AED training courses, or the public at large. It is intended to treat patients having a heart attack (cardiac arrest). The device analyzes an unconscious patient's heart rhythm and instructs the user to press a button that delivers an electrical shock to the heart to restore a normal heart rhythm.

Recalling Firm: ZOLL Medical Corporation, 269 Mill Road, Chelmsford, Massachusetts 01824

Reason for Recall: The AED failed to deliver the defibrillation energy.

Public Contact: The company may be contacted at 1-978-421-9655.

FDA District: New England

FDA Comments: The company sent their distributors and customers an initial recall letter on February 12, 2009 by certified mail. This letter instructed customers to replace their batteries every three years. The company then sent their distributors and customers a follow-up recall letter on March 31, 2009 by certified mail. This letter instructed customers to download new software for their devices and to remove any battery replacement reminder labels.

ZOLL will send an email notice to all customers who included their email address as part of their contact information. ZOLL will also publish information about the recall in industry magazines.

For more information about this recall, please see the company's website at:  
<http://www.ZOLLAEDPlusbatteryhelp.com>

Class 1 recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious injury or death.

Health care professionals and consumers may report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by FAX.

Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)

Regular Mail: use postage-paid FDA form 3500 available at:

[www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm)

Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787

FAX: 1-800-FDA-0178

## TOOLS OF THE TRADE

<http://global.flukebiomedical.com/busen/products/Impulse+6000D+and+7000DP.htm>



The Impulse 6000D Defibrillator Analyzer and Impulse 7000DP Defibrillator/Transcutaneous Pacer Analyzer Test Systems are rugged, portable precision test instruments that ensure proper operation and ultimate performance of critical life-support cardiac-resuscitation equipment.

The Impulse 6000D and Impulse 7000DP test capabilities encompass the spectrum of world wide established pulse shapes, showcase breakthrough AED technology compatibility, and outperform in accuracy and standards. Additionally, the Impulse 7000DP incorporates the tests and the extensive range of test loads and measurement algorithms needed to test external transcutaneous pacemakers.

In conjunction with an Impulse 7000DP, the Impulse 7010 Defibrillator Selectable Load Accessory provides multiple loads of 25  $\Omega$ , 50  $\Omega$ , 75  $\Omega$ , 100  $\Omega$ , 125  $\Omega$ , 150  $\Omega$ , and 200  $\Omega$  for defibrillator performance testing.\* A standard USB interface enables computer control and data transfer, and optional Ansur PC-based automation software increases productivity by outfitting users with an easy-to-use method to standardize testing procedures and capture, print and document data.

\*Impulse 7010 Defibrillator Selectable Load Accessory not intended to be used for calibration of medical equipment.

## BMETS Web Site Statistics

**March 2009 = 19405 Total Hits**

**February 2009 = 24742 Total Hits**

**January 2009 = 19517 Total Hits**

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## BMETS Monthly Meeting Sponsors

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<http://www.skytron.us/>

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The logo for FLUKE, consisting of the word 'FLUKE' in a bold, black, sans-serif font on a yellow rectangular background.

<http://global.flukebiomedical.com/busen/home/default.htm>

**Biomedical**



<http://www.echoserve.com>



**Northfield Instrument Services**

[www.northfieldinfo.com](http://www.northfieldinfo.com)



**Global Medical Imaging**

<http://www.gmi3.com/>

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The logo for Ampronix Incorporated, featuring a stylized blue 'A' icon followed by the word 'Ampronix Incorporated' in a bold, black, sans-serif font.

<http://www.ampronix.com>



<http://www.4sonora.com>



<http://www.steris.com/index.cfm>

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