



BMETS Newsletter

May 2010

<http://www.BMETS.org>

SEP 2010—Aug 2011
BMETS Officers

President:

Rob Bain, Sinai Hospital

Vice President:

Lola Lyttle-Hill, Sinai Hospital

Treasurer:

James Bissett, ENDOPLUS Corp.

Secretary:

Roy Leake, Retired BMET

THE PRESIDENT'S THOUGHTS

I would like to thank all the members who have attended meetings and offered suggestions for their support. We have, in the last 4 years, made the following improvements:

1. Fixed the confusion in dealing with the RSVP's, thanks Roy.
2. Gotten the scholarship off the ground and had students and faculty attend a meeting and show support (Dan, Neil and Patty kudos on that).
3. Gotten some national press on Tech nation.
4. Pushed forward with training, thanks GMI, Robi and the leadership team.
5. Maintained a sound budget and kept a lid on extras that are wasteful (not having a lot of leadership meetings with food unless necessary, only 2 last year.)
6. Reaching out to vendors, this year we will have GE added as a sponsor and our trip to Northfield went very well, thanks Sara.
7. Given well deserved awards to those that were forgotten in the past. (Brian Ethan, Vester Rick Schrenker.....)
8. A multi vendor kick off meeting and good member turnout.
9. Continued investments in BMETS future by giving free membership to students.
10. Getting the BMETS newsletter to the students, instead of a few messages by word of mouth.

BMETS is getting involved in the scholarship program and being accountable to the membership, and



Rob Bain

because of that students are interested and attending at least a meeting.

Some of my concerns are 1) not to get too top heavy, I have resisted the idea of a board appointing the leaders as I feel it is the Membership that should decide. 2) I don't feel we need to be part of a larger Maryland BMETS and thus create a bureaucracy with people just touting they are on the board and that we become less interested in the work and more interested in the show and power of an office.

I do listen and have heard that the parking for the May bash and the noise was not to everyone's liking, we will do something

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different next year, but not waste money on something just to look good and put on a show. I am concerned that though the Cruise was a good idea, it was just not cost effective at this time unless we can get some sponsorship.

With all this said I am making this year my last as I want to leave the leadership to another member who will hopefully see what we have accomplished as worthy and continue in that direction. My belief that past officers should not interfere with the new ones is that I will not object is the direction changes with new leadership; rather it is one person one vote so I will be back to a regular member.

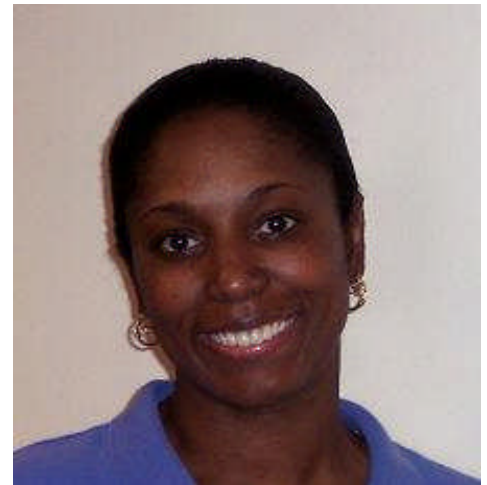
Thank you for the opportunity to serve one more year,
have a great summer

Robert Bain ,MS CBET
BMETS President

THE VICE PRESIDENT'S SHOUT OUT

Good Day,
We would like to thank the membership for a wonderful year. An organization is as good as its membership. Thanks to all the sponsors i.e., Pilot, Conquest Imaging, and GMI for being apart of BMETS this year. We welcome next year's sponsors.. See you all in September.

Lola Lytle-Hill, Vice President



Lola Lytle-Hill, Vice President

National Biomedical/Clinical Engineering Appreciation Week

May 23-29, 2010

Sponsored by AAMI's Technology Management Council (TMC)

This annual celebration is specifically designed to promote the awareness of—and appreciation for—biomedical and clinical engineering professionals. So how did you celebrate?

CALENDAR OF EVENTS
CHECK THE WEB PAGE FOR UPDATES

May 23-29, 2010—Biomedical/Clinical Engineering Week
June 26-28, 2010—AAMI Conference & Expo, Tampa, FL
July & August, 2010—Summer Break

THE SECRETARY'S PEN



Roy Leake, Secretary

Thank you for letting me serve another year as secretary of BMETS. I have enjoyed my last two years, but I have had some surprises.

I am surprised at how many RSVPs do not show up. I am surprised at how many non members RSVP for the monthly meetings. I am surprised at how many non members want BMETS to allow them to come to BMETS sponsored training. I am surprised at how many non members say they will join BMETS at the next meeting but never do. I am surprised at how many members feel that it is OK not to join BMETS. They bring non member BMETS as guests to BMETS sponsored events.

I would like to encourage all BMETS to become members and I would like to encourage all members to take advantage of any training that BMETS sponsor's. BMETS will need to make some changes in the future if we are going to survive in these economic times.

We have 144 members that paid up for year 2009-2010. In September it will be time to renew our membership and sign up new members to BMETS for year 2010-2011. Invite your fellow BMETS to become members. We have a good society and they will enjoy being a member.

It has become more costly to operate BMETS, we now have three BMETS sponsored events each year. Some sponsors are hesitant to spend the money, if the numbers that RSVP do not show up. Rob, Lola and I have discussed this situation and believe a \$10.00 increase in membership dues are necessary to maintain the quality of our meetings and continued improvements in our training each meeting. Each meeting cost the sponsor \$30.00 for each person that RSVP's. Remember BMETS sponsors three meetings each year.

Please help us by paying your membership dues, becoming a member and encouraging your fellow BMETS to become a member of BMETS. If you feel \$55.00 for membership dues is too much, and you have another suggestion, let the BMETS leadership know about it.

Roy Leake, Secretary

FDA to Formally Recognize Electrical Equipment Standard

The U.S. Food and Drug Administration (FDA) will formally recognize the electrical equipment standard IEC 60601-1/Ed.3:2006.

Carol Herman, director of standards at the FDA's Center for Devices and Radiological Health (CDRH), made the announcement during the Association for the Advancement of Medical Instrumentation (AAMI)/FDA International Conference on Medical Device Standards and Regulation, which took place in Reston, VA, March 9-10.

"We will not only recognize the third edition of the standard, but we will also recognize all collaterals and all particulars," Herman told attendees.

The third edition of 60601-1 offers general requirements for basic safety and essential performance of medical electrical equipment. It also contains requirements for reliable operation to ensure safety.

CDRH hopes to publish notice of the recognition in the Federal Register by June, Herman said. Once the notice is published, users will have three years to transition to the third edition and the related collaterals and particulars, Herman added.

The standard already has been recognized and harmonized in Europe for the last several years, said Charles Sidebottom, director of corporate standards for Medtronic and secretary of IEC/Sub Committee 62A, which developed the standard.

Sidebottom, who is chair of AAMI's Board of Directors, says that the subcommittee has been working with CDRH staff to get the standard recognized since well before it was even published. "For us that is a real big deal

that the agency formally announced recognition of the whole collection of standards," he said.

AAMI had adopted its own version of the standard with national deviations called ANSI/AAMI ES60601-1:2005 (IEC 60601-1:2005, MOD), which includes original IEC text where U.S. modifications are introduced for easy comparison of requirements, as well as a number of the collateral and particular standards.

Changes on the Horizon

The CDRH recognition comes as a new amendment to 60601-1 is under development, which includes some changes to the original standard.

One of the proposed changes focuses on extending the scope of 60601-1 to include medical software systems. The amendment includes a definition of medical software systems and associated technical requirements.

The amendment also aims to streamline the application of risk management. It clarifies how a manufacturer should apply the standard's requirements when evaluating residual risk, Sidebottom said during a presentation at the conference. When there are specific requirements with specific acceptance criteria, compliance is "presumed to establish acceptable risk," Sidebottom added. The amendment also revises how to establish alternative risk controls or test methods.

The amendment is expected to be published in August 2013.

Physio-Control Inc., LIFEPAK 15 Monitor/ Defibrillator

Recall Class: Class I

Date Recall Initiated: March 4, 2010

Product(s): LIFEPAK 15 Monitor/Defibrillator

Search for affected devices by serial number.

The serial number is located on the underside of the device.

These devices were manufactured between March 26, 2009 and December 15, 2009 and distributed between March 27, 2009 and December 15, 2009.

Use: The LIFEPAK 15 monitor/defibrillator is designed for use by trained medical personnel in out-of-doors and indoor emergency care settings to monitor patient heart rhythms and to treat patients experiencing cardiac arrest.

Recalling Firm:

Physio-Control, Inc.

11811 Willows Road NE

Redmond, Washington 98052-2003

Reason for Recall: There is a potential for the device to unexpectedly:

- Power Off then On by itself.
- Power Off then NOT turn On.
- Power Off by itself requiring the operator to turn it back On.

Stay powered On and not allow itself to be turned Off.

Public Contact: Physio-Control Technical Support at

1-800-442-1142 – option 5, Monday – Friday between 6:00 A.M. and 4:00 P.M. (Pacific Time).

More information available at <http://www.physio-control-notice.com/LP15pcba>

FDA District: Seattle

FDA Comments: On March 4, 2010, the company informed customers by letter advising them to keep the device in service and to test their devices according to the operating instructions. The company stated that local service representatives are scheduling service visits within 60 days. Customers were asked to forward the Physio-Control notice to all their responsible parties.

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

TOOLS OF THE TRADE

FLUKE**Biomedical**

The 199XRAY Medical ScopeMeter has all of the normal oscilloscope functions, as well as the speed, performance, and analysis power for the more demanding applications. This high-performance oscilloscope offers specifications found on top-end bench instruments. With up to 200 MHz bandwidth, 2.5 GS/s real-time sampling, and a deep memory of 27,500 points per input, the 199XRAY is ideal for engineers who need the full capabilities of a high-performance oscilloscope in a handheld, battery-powered instrument.

In addition, the 199XRAY is especially designed for use with x-ray systems. This ScopeMeter displays kVp waveforms and direct kVp values simultaneously on an easy-to-read screen. Now you no longer have to waste time calculating scope traces to derive the kVp values.

Field Applications :

- * Dual input – 200, 100 or 60 MHz bandwidth
- * Up to 2.5 GS/s real-time sampling per input
- * Connect-and-View™ automatic triggering and a full range of manual trigger modes
- * Digital Persistence for analyzing complex dynamic waveforms, similar to an analog scope
- * Fast-display update rate for seeing dynamic behavior instantaneously
- * Automatic capture and replay of 100 screens
- * 27,500 points-per-input record length using ScopeRecord mode

BMETS Web Site Statistics

April 2010 = 18820

March 2010 = 17793

February 2010 = 14236

BMETS Monthly Meeting Sponsors



FLUKE

Biomedical

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

September 2009



Northfield Instrument Services

www.northfieldinfo.com

September 2009

STERIS



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

September 2009



Pilot Medical Products

<http://www.pilotmedicalproducts.com/Products.htm>

November 2009



Advantage Medical Cables

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

November 2009



Official Leader in Used Ultrasound Parts, Probes, Systems, Service & Repair

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

February 2010

BMETS Monthly Meeting Sponsors



Global Medical Imaging

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

March & April 2010

AAMI News

Interactive Educational Programs Direct to the Office!

AAMI is now offering webinars as a companion to its comprehensive and interactive training programs. To date, over 11,000 attendees have taken the opportunity to enhance their skills and knowledge through these cost-effective events.

A webinar is a learning event that can be attended from the comfort and convenience of one's office. The savings are significant — completely eliminate travel time, hassle, and expense. Invite staff members to listen and participate all for one low fee. It's easy; you only need a telephone and access to the Internet.

WEBINAR FEES

Webinar — *Invite your staff and co-workers to listen in for one low price!*

\$315 per registrant (AAMI Member) - unlimited registrants per site

\$415 per registrant (Non-member) - unlimited registrants per site

Please check back on web page <http://www.aami.org/>

for webinars as they are added throughout the year. For webinars you may have missed, check out the [Webinars on CD](#) area.

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