



BMETS Newsletter

January 2009

<http://www.BMETS.org>

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THE PRESIDENT'S THOUGHTS

I hope everybody had a nice holiday. I spent time working on the model train house at the Ellicott City Fire Station #2. We raised over \$8,000 for the fire dept. I think it is important to do something for others, not just for money during these difficult times. There are so many takers that the givers may just want to give up. Let's not sell ourselves short if we believe in our causes and dreams. It is important that we continue to strive to be the best we can be and help those less fortunate than ourselves.

Chris and I are working to reduce the cost to our vendors for the monthly meetings, we are very aware that times are tough and that we all must do our part to maintain the best and cost effective venue that we can have. We have the AAMI convention in Baltimore this Spring and the Scholarship in May at our May Bash. I am hoping that we express our support by attending the meetings and showing the sponsors we are listening and expanding our product knowledge. Happy New Year to all and lets make this year even better.

Sincerely,
Rob Bain MS, CBET
President BMETS



Rob Bain

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

None

AAMI2009
CONFERENCE & EXPO

June 6 - 8, 2009 | Baltimore, MD

CONFERENCE LOCATION

Baltimore Convention Center
One West Pratt Street
Baltimore, Maryland 21201

THE VICE PRESIDENT'S QUILL

Wow!! It is a New Year already. Man how time flies when you're having so much fun. Learning, creating, and hopefully just enjoying yourself and your job. I for one have been enjoying the fruits of my labors with my job. As with all New Year's come new responsibilities, projects and other things to take the time away from the things you would like to continue. With that in mind, I will not accept a nomination as the Vice President or any other officer position for the coming year. Too many things in my life have changed over this last year that warrants my leaving this position. It is a personal decision that has weighed very heavily on my mind over the last several months. I will continue to provide sponsors, schedule the May Bash and coordinate the AAMI conference in June here in Baltimore. I have agreed with the President to remain the point of Contact with the MD Expo for September 2010, that we will be co-sponsoring with the Virginia Biomedical Association. Other than those two things I must bow out of this office. If anyone would like to take on this position – it has been very fulfilling and rewarding – I will gladly assist in doing my utmost in providing the necessary information and materials. It has been a fun 4 years serving as the Vice President of the Baltimore Medical Engineers and Technicians Society.



Chris Jones, Sr.

Our Sponsor this month is Ampronix being held at the Town & Country Carters (where we had the 25th Anniversary Party) on January 15, 2009 starting at 6:00 PM. See you all there. I look forward to networking and talking to all.

Chris Jones, Sr. MCP CPACS Assoc.
Vice President B.M.E.T.S.

THE SECRETARY'S SPIEL



Roy Leake

The AAMI Conference will be in Baltimore, June 6—8, 2009. BMETS will be an exhibitor at this conference and we will need help from the membership to man the exhibit booth.

By the way, if your membership is not paid up, you will have to pay the full registration for a non-member (\$825) however if you are a paid up member for 2009, then you can register at the discounted rates or \$695.00 by April 24, 2009 /or/ \$750.00 after April 24. BMETS is checking to see if there will be a special discount for those that work at the exhibit booth.

Hope to see you at the January 15 monthly meeting.

Roy E. Leake, CBET, SASHE, Secretary, BMETS

FDA Announces Class I Recalls of Two Unapproved Devices

FOR IMMEDIATE RELEASE

December 15, 2008

Media Inquiries:

Siobhan DeLancey, 301-796-4668

Consumer Inquiries: 888-INFO-FDA

The U.S. Food and Drug Administration (FDA) announced a Class 1 recall today for two unapproved and uncleared devices whose manufacturers claimed could treat various medical conditions. A Class 1 recall means that there is a reasonable probability that the use of a device will cause adverse health consequences or death.

The manufacturers, VIBE Technologies of Greeley, Colo., and Nebion LLC of Los Angeles, Calif., claimed their devices treated conditions ranging from cancer to migraines. The FDA is concerned that based upon the original health claims made by the company, patients may forgo approved therapies, and that this could result in more severe illness or death.

"These recalls underscore the importance of taking action against manufacturers who make false medical claims for their devices," said Daniel G. Schultz, M.D., director of the FDA's Center for Devices and Radiological Health. "One of the FDA's primary responsibilities is protecting consumers from harm that can be caused by manufacturers who try to sidestep the approval and clearance process."

Vibrational Integrated Bio-photonic Energizer device
On April 11, 2008, the FDA issued a warning letter to VIBE Technologies stating that the agency's November 2007 inspection of the facility showed that the company had not obtained FDA marketing approval or clearance for the Vibrational Integrated Bio-photonic Energizer (VIBE device), which claims to treat cancer, infections, and depression. The FDA also cited the company for substantial deviations from the current Good Manufacturing Practice/Quality System regulation.

VIBE Technologies initiated a recall of 840 VIBE devices in an April 3, 2008, letter sent to users. VIBE Technologies agreed to stop promoting and marketing the VIBE device, and will contact all those who had purchased it to ensure no other unsubstantiated medical claims are being made. The FDA has requested that the company update its recall notices to state that the VIBE device is not intended for the treatment of any diseases or medical conditions.

The FDA is aware of information that suggests that the VIBE device has been used in cancer patients. There is one death that occurred in a patient who used this device. However, FDA has not verified that there is any association between the death and the VIBE device.

HLX8 device

In June 2008 FDA inspected Nebion, LLC, which revealed that the company had not obtained FDA marketing approval or clearance for the HLX8 device, which claims to treat cancer, migraines, arthritis, and ruptured discs. The inspection also uncovered substantial deviations from the Current Good Manufacturing Practice/Quality System regulation.

Nebion recalled eight HLX8 devices on July 2, 2008, and notified their customers to stop using the devices immediately and to contact Nebion for their retrieval.

Nebion's first recall letter did not address the potential risks associated with the HLX8 device, but the company has recently notified FDA that they will issue a second letter that identifies potential health hazards. The FDA has not received any reports of injuries or deaths linked with the HLX8 device.

Under federal law, products that claim to diagnose a disease or condition, cure, mitigate, treat or prevent disease, or that are intended to affect the structure or function of the body are devices subject to FDA jurisdiction and may require FDA approval or clearance prior to marketing. Premarket approval is the most stringent type of FDA device review and is for devices with a high level of risk, such as those that support or sustain human life. FDA clearance is for lower risk devices that are shown to be as safe and effective as a similar device already on the market.

Neither VIBE Technologies nor Nebion has demonstrated to the FDA that their device is safe and effective at curing or treating diseases as claimed.

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.



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

There has been NO replies to this Article, so there will NOT be an article on
highlights of BMETS that have passed

BMETS would like to highlight BMETS that have passed. To do this in an article in one of the future newsletters, we will need some background information on the following BMETS: Craig Case, John McKinnon, and Victor Dobbs. We would like to have as much information as possible including hobbies, awards, recognitions, organizations that they belonged to, etc. One of the titles suggested for this article was "Tribute", do you have any suggestions? Do you know of a BMET that has passed recently that we have not listed?

You can send any information to webmaster@bmets.org Make sure you include enough information about who the information is for. If we get no information, then it will be a short lived proposal for a newsletter article.

CALENDAR OF EVENTS
CHECK THE WEB PAGE FOR UPDATES

January 15, 2009—Monthly Meeting—Sponsored by Ampronix, @ Town-Country Caterers

February 18, 2009—Monthly Meeting—Topic, Speaker, Place to be announced later

March 18, 2009—Monthly Meeting—Topic, Speaker, Place to be announced later

April 15, 2009—Monthly Meeting—Topic, Speaker, Place to be announced later

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

Plan to attend our next meeting sponsored by

Ampronix

January 15, 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.
3. Healthy appetite
4. Relative mind set for conversation and enjoyment.

Please send your RSVP's to RSVP@bmets.org No later than January 12, 2008.

Thank you for your cooperation in this matter.

Sincerely,
Rob Bain MS, CBET
President BMETS

TOOLS OF THE TRADE



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



The **HHC3 HAND HELD CONTROLLER** is used to remotely operate medSim 300B, MPS450 and Marq III simulators in an easy and efficient manner. The HHC3 has all the output controls for these simulators and enables current simulator users, including hospital biomedical technicians and manufacturers, to simplify and standardize their testing, training, and preventive maintenance protocols. In addition, the HHC3 is an excellent device for biomedical training and demonstration use.

The HHC3 facilitates the direct selection of parameters for the Fluke Biomedical medSim 300B, MPS450, and Marq III simulators. The HHC3 uses flexible coiled cable to connect to a simulator. The HHC3 provides single-key commands, dual-key commands, factory-defined sequences and easy programming of user-defined sequences. Customers can use the HHC-Utility software to upload user-defined sequences from a PC and download the sequences

BMETS Web Site Statistics

December 2008 = 1926 Total Hits

November 2008 = 18856 Total Hits

October 2008 = 22078 Total Hits

BMETS Monthly Meeting Sponsors for 2008



For ultrasound parts, probes, or service, call 1-800-248-4153.

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www.northfieldinfo.com

BMETS Monthly Meeting Sponsors for 2009



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