



# BMETS Newsletter

February 2009

<http://www.BMETS.org>

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## THE PRESIDENT'S THOUGHTS

I would again like to thank the membership for supporting the organization and attending the meetings. I spoke with Sara at Northfield Instruments many times to get feedback on how the meeting at her facility affected business. She stated that she had at least one new customer based on the positive experience of touring her facility and seeing first hand how the scopes were repaired. That is exactly what we were hoping for and we will, I hope, be able to do more of that. It is imperative that we give a good "bang for the buck" for our sponsor. I found Northfield Instruments to be an excellent host and would enjoy doing that again in the future. Thanks to all the members that went and to those that gave me feedback it was a quickly put together event and Sara and her company deserve much credit.

I have requested a Treasury report from Vicki so we can have an overview of spending and receipts taken in. Vicki is attending classes on Thursday so I will present the report once it is ready. I have an open door policy and will answer any questions at any time on any issue, please feel free to e mail, call or talk to me during the meetings.

We started a new section on the BMETS webpage, an education page, we hope to get information from our vendors and links to technical references. Any suggestions would be helpful. I would like to thank Mark from Steris for taking the time to look at IT training among our membership, Mark has stepped up to plate many times, not asked, but on his own and that is why I gave him an award for outstanding service. I am humbled at the members that want to do more and am thankful of those like Mark that both attend and go the extra mile. I hope to see all at the February



**Rob Bain**

meeting. We are working on the May bash and as I stated, we will NOT be spending a fortune on this but rather doing what is best for the members. Any suggestions are welcome,

thanks again ,  
Rob Bain MS, CBET  
President BMETS

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

**Peter Van Berg**  
**Alan Hoffman**  
**Rick Schrenker**  
**Strickler Medical**

## THE VICE PRESIDENT'S QUILL

The officer's had a meeting this evening, February 4, 2009. In that meeting I found out that of all the members that came to last months meeting a question was asked; "Are you going to attend the AAMI Conference?" What amazed me was the response from all the members attending the meeting; "No". This was a shocker to me. What is it that drives us to these meetings? The Food? The Sponsor's? The Networking and companionship of other in our field? So, I pose a question to all the members; I hope I get a response from all, I pray that some will answer this call to assist and help the BMETS to continue running and keeping it's tradition going well past my time on this earth.

What drives you to be a Biomed? What drives you to be working in this field? What possesses some if not all of us to work where we do not get recognized for doing the job we trained for with our sweat, toils and frustrations? How can you best serve the B.M.E.T.S.? I can tell you right now that if was not for a few dedicated individuals with in the organization B.M.E.T.S. would not be around. Many a time has Sylvester Knox, Wayne Jenkins, Victor Dobbs, Roy Leake, and others have performed all the jobs when no one else would do them to keep B.M.E.T.S. running.



Chris Jones, Sr.

What is wrong with devoting some time to the organization that has been providing – I hope – a valuable venue of educational material and opportunities thru out the last couple of years I have been the Vice President. As President John F. Kennedy once said "Ask not what your country can do for you, but what can you do for your country!" I ask the same, but only for the Society. We are trying to put together what we hope will be a great opportunity for the Baltimore Medical Engineers and Technicians Society to be recognized as a valuable entity with in the Biomedical and Clinical Engineering Industry. Many of you are members of the Biomed List Serve Talk list and have been reading about the First Biomedical Congress happening in Atlanta, GA sometime in July. This is for our benefit to be recognized as a viable profession with all sorts of benefits, opportunities both in education and financial resources. But what I see with our own members is a lack of caring to enhance the organization to put forth an effort to continue making valuable contribution to the Biomedical and Clinical Engineering field. I see many faces that continue to come to the meetings agree with what the officer's say yet in the back of the room a full conversation totally disrespecting the Sponsor or an officers when they are talking about an important issue that requires the memberships full attention. We have negotiated the "Lady Baltimore" on June 5, 2009 for our Before AAMI conference fun dinner cruise. We will provide this "Free" to all paying members of the B.M.E.T.S., but there is a "Catch 22"; I do have the total ship ready to sign and deliver for the AAMI and the societies around the country at a reduce price for non- members. What I hear that "No One" in BMETS besides myself, the President, Secretary, and Treasure plan on going to the conference. When BMETS is one of the sponsoring organizations and only four members out of 110 are going, really shows me the lack of care for the industry and community involvement from our members. It upsets me, it hurts me, and personally just makes me feel – Is this really worth all the head aches of putting on a monthly meeting, providing a Dinner Cruise and other venues when the membership really honestly "does not care" one way or the other. I have put my family, myself and others on the back burner, my wife had a stroke and I still continued supporting her, my family and the B.M.E.T.S. during that time and I still will until I can no longer breathe.

Yes, this job; Vice President is not an easy one, Life is not easy. God never told us he would provide us with a rose garden; he did promise us eternal life. I ramble on, I ramble when I am upset about something that is truly in my heart, is my passion and enjoy for these many 32 years; I have been proud to say "I am a Biomedical Equipment Technician."

So, I hope to see most of you Thursday, February 19<sup>th</sup> at the Town and Country Caterers for our monthly meeting sponsored by Sonora Medical Systems, Inc.

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

## FDA Shoots Down Handgun as Approved Medical Device

ROCKVILLE, Md., Dec. 11 -- Faster than a speeding bullet, the FDA disapproved a tentative registration of a handgun as a medical device.

An embarrassed FDA conceded the handgun was given an automatic temporary designation as a medical device via an Internet registration. But the label was immediately revoked after a review. FDA marketing approval was never issued.

The agency said in a terse statement that it had "determined that the Palm Pistol, manufactured by Constitution Arms, is not a medical device under the Federal Food, Drug, and Cosmetic Act."

According to the Palm Pistol Web site, the gun is "ideal for seniors, disabled, or others who may have dexterity limitations or difficulty sighting and controlling a traditional revolver or semi-automatic pistol."

The gun maker submitted an Establishment Registration on Dec. 2, listing the product as a "recreational adaptor" using the online registration system of the FDA's Center for Devices and Radiological Health.

Upon review, the agency canceled the registration and returned the fee to Constitution Arms.

"Registration and listing does not constitute an admission, agreement, or determination that a product is a device with the meaning of section 201 (h) of the Act," the statement said. "The FDA has determined that the company's listing was in error."

Some media outlets interpreted the original registration as evidence that the Palm Pistol was approved as a medical device and that it might become covered by Medicare.

However, according to an FDA spokesperson, manufacturers that list their products as Class I devices -- as Constitution Arms did -- do not necessarily have agency approval or clearance for marketing.

The registrations are not automatically reviewed before acceptance, the spokesperson said.

The weapon -- which holds a single 9-mm round -- is gripped in the palm of the hand and held in a fist

with the barrel extending between the middle and ring fingers. Two safeties, one each on the top and bottom of the gun, must be pressed before the gun can be fired using the thumb.

Additional medical indications included on the Palm Pistol Web site are "arthritis; peripheral neuropathy caused by chemotherapy, infection, traumatic injury or diabetes; phalangeal amputations-fusions-fractures; distal muscular dystrophy; multiple sclerosis, carpal tunnel syndrome, Raynaud's syndrome; ganglion cysts; side effects of certain medications; and inclusion body myositis."

The FDA spokesperson would not comment directly on the medical usefulness of the Palm Pistol but said, "According to federal regulation, a daily assist device is a product that has been modified or adapted to help a medical patient perform a specific function. The FDA has several product groups for these devices -- examples include certain medication reminders, eating utensils, and recreational adaptors. There are no firearms in this category."

Palm Pistol said it is exploring an appeal of the FDA's decision.

### Palm pistol: A gun for the elderly



Will Gran confuse this with her inhaler?

Arms manufacturers have developed a gun which is specially designed for use by disabled people and OAPs.

The Palm Pistol is a single-shot 9mm weapon which is grasped in the palm and fired by pressing a button with your thumb.



# 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

February 19, 2009—Monthly Meeting—Sponsored by Sonora Medical Systems, Inc. @  
Town-Country Caterers

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

**Sonora Medical Systems, Inc.**

February 19, 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 [RSVP@bmets.org](mailto:RSVP@bmets.org) No later than February 16, 2008.

**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

## Top Hospital Medical Device Hazards For 2008 Revealed

Date Published: Tuesday, December 23rd, 2008

The ECRI Institute just released its annual list of top ten hospital medical device hazards for this year. The Institute is a nonprofit organization that “researches the best approaches to improving patient care” and is a designated Collaborating Center of the World Health Organization (WHO) as well as an Evidence-based Practice by the U.S. Agency for Healthcare Research and Quality. The 2008 list was published in a recent Health Devices guidance article.

Updated annually, the list is based on problems reported to and investigated by ECRI and includes detailed descriptions and information on how to avoid such hazards. “Our list is based on serious technology safety concerns that can be prevented with appropriate attention and planning,” says James P. Keller, Jr., vice president, health technology evaluation and safety, ECRI Institute.

The ECRI Institute’s 2008 list of the 10 most dangerous medical device hazards include:

- **Alarm Hazards.** In which alarm conditions are not effectively communicated, placing patients at risk for injury or death and includes reports involving patient monitoring equipment, ventilators, and dialysis units, among others.
- **Needlesticks and Other Sharps Injuries.** In which intravenous and other device administration can cause injuries to clinicians, patients, laboratory personnel, pharmacy staff, housekeeping personnel, and waste handlers by an exposed needle or other sharp. Consequences include serious cuts and exposure to blood borne pathogens such as HIV or the hepatitis B or C virus.
- **Air Embolism from Contrast Media Injectors.** In which X-ray imaging of blood vessels where contrast media is injected into the patient’s vasculature and can create the risk of injecting air, potentially resulting in a fatal embolism.
- **Retained Devices and Un-retrieved Fragments Left in Patients:** In which an entire device is left behind in surgery or a portion of a device breaks away within the patient. Sometimes, surgical items are intentionally placed in the patient, but can pose the risk of infection or burn hazards when the patient undergoes MRI examination.
- **Surgical Fires:** In which medical devices or other components ignite, such as electrosurgical units; electrocautery devices; lasers and related disposable components; oxygen, which can ignite easily and burn intensely; and fuel, such as from fenestration towels and gowns.
- **Anesthesia Hazards due to Inadequate Pre-Use Inspection:** In which staff discovers serious problems such as misconnected breathing circuits, ventilator leaks, and empty gas cylinders.
- **Misleading Displays:** In which ambiguous or counterintuitive displays create misinterpretation.
- **CT Radiation Dose:** In which high doses can present an increased risk of cancer, possibly linked to 6,000 additional cancers a year, roughly half being fatal.
- **MR Imaging Burns:** In which patients become burned from the Magnetic Resonance Imaging technology.
- **Fiberoptic Light-Source Burns:** In which light sources used in endoscopes, retractors, and headlamps cause burns to staff and patients from the light itself or from its heated cable connections.

**Last year’s top five reported hazards were: Burns during electrosurgery, caster failures, infusion pump programming errors, misconnection of blood pressure monitors to IV lines, and radiation therapy errors.**

## TOOLS OF THE TRADE

**FLUKE****Biomedical**

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



**The ESA620 Electrical Safety Analyzer** represents the next generation in portable, manual electrical-safety testers for the biomedical technician and clinical engineer that are performing tests on medical equipment. With selections of three test loads, two protective earth test currents, and two insulation test voltages this versatile product can be used worldwide to test to their standard of choice: IEC60601, ANSI/AAMI ES60601, IEC62353, VDE 751, ANSI/AAMI ES1:1993, NFPA-99, AN/NZS 3551, IEC61010.

It comes standard with test leads for 2-wire protective earth measurements, and with optional leads offers the time-saving 4-wire technique. Additionally, the 20-A-device receptacle allows for testing of those devices that need it, so the technician is not limited to only test 15-A equipment. (US only)

Equipped with ten ECG posts, the ESA620 offers simulation of ECG and performance waveforms so both electrical safety and basic tests on patient monitors can be performed with a single connection. The unit is equipped with standard USB interface for computer control and data transfer. The ESA620 Electrical Safety Analyzer represents the next generation in portable, manual electrical-safety testers for the biomedical technician and clinical engineer that are performing tests on medical equipment.

## BMETS Web Site Statistics

**January 2009 = 19517 Total Hits**

**December 2008 = 1926 Total Hits**

**November 2008 = 18856 Total Hits**

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## BMETS Monthly Meeting Sponsors for 2008

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

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**Northfield Instrument Services**

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

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## BMETS Monthly Meeting Sponsors for 2009

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

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 **Ampronix Incorporated**



<http://www.ampronix.com>

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