

CMIA/Los Angeles

June 2010

K.Kalusa, CBET; Editor
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Our Company

BMEYE is a technology-based, market driven company which was established in April 2005, bringing over 30 years of research and development experience to our customers, focused on finger arterial pressure and cardiac output technologies. Our technologies have been validated extensively and are used in groundbreaking products for the space agencies and experimental market launches. Our products are considered as thoroughly evaluated, and have been documented in over 800 publications.

Achieving miniaturization and increased user-accessibility, required for broad adoption, were the most important challenges BMEYE faced when developing the next generation product: Nexfin.

Building on the experience we are convinced that, with the introduction of Nexfin, we offer cardiovascular monitors that will be used in every hospital and for many indications. We will continue to improve our products in close cooperation with physicians, through research, development and clinical evaluations.

The Nexfin, BMEYE's first product, obtained CE and FDA clearance in 2007, is a unique non invasive blood pressure and cardiac output monitor, offering a precise hemodynamic profile with real-time data posted within a minute.

Global Business

BMEYE is a Dutch company based in Amsterdam, The Netherlands. We have a close cooperation in joint research projects with many medical centers and universities all over the globe. Our technology is used in the practice of many clinicians and researchers worldwide, in several application areas.

With the launch of Nexfin we are building a network of strong distributors, to open new horizons, to make it possible that physicians will be able to use our equipment to diagnose their patients.

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FROM THE PRESIDENT

Larry Burton; President CMIA/LA



Fellow BMETS and Colleagues:

The Board of Directors conducted their first meeting last month utilizing a webinar service. I think we had a winning forum for us to participate in the comfort of our surroundings of choice. I was glad some of us didn't partake in the meeting with their webcams while in pajamas! What was discussed was the seminar for next year. We will be trying the services and direction of M/D Expo next March. It will be held in Napa at the Meritage Resort. Mark your calendars March 24-28, 2011. Of course there will be more to come. We also discussed the website content, continuing upgrades, chapter status and membership (the Central California Chapter has been closed). It is befitting that we continue to utilize our e-mails as a forum for chapter communication.

It brings up the point of chapter participation. We have the oldest chapter in the state with the second highest membership count. There is a high concentration of biomedical professionals in our region yet, we haven't seen many of them at meetings. This year we are trying new venues to spark an interest for membership participation. Expect a survey in the coming weeks to participate in. All but one of us in the association as officers and board members participate voluntarily to keep the CMIA a viable professional organization.

I've had a pleasurable few months meeting or talking with current members or potential new members in person, on the phone or via e-mail. There have also been some interesting posts on the Biomedtalk Listserve recently that I recommend you at least give a look. There is a lot of information, opinions and tips to aide us in our individual professional decision making. If you have an interest in sharing a thought, send it to my e-mail address because we are still open to meeting topics.

I look forward to seeing many of you at our meeting in June at the San Antonio Winery. If not, drop me a line periodically to let us know how you are doing.

Larry Burton, President

LA Chapter, CMIA

If your not happy with your results, change your methods.

CMIA - Los Angeles Chapter Members,

You are invited to attend our Chapter meeting on Tuesday June 8th. The meeting will be hosted by Jeff Stayberg West Region sales representative from Bmeye. Jeff will be presenting the Nexfin continuous beat-to-beat non-invasive blood pressure and cardiac output monitor through a finger pressure cuff.

Here are some of the planned learning objectives:

- 1) Technology Overview: 30 years of technology and development with unparalleled validation, for the only continuous beat-to-beat non-invasive blood pressure monitoring waveform with systolic, diastolic and mean values from a finger pressure cuff that can be wore on the same finger for up to 8-hours. Technology documented to be more accurate than oscillometric BP, and within 5% of an invasive radial arterial pressure, and cardiac output absolute values within 8 - 10% of thermal dilution cardiac output. I will discuss the physiology, mechanics and algorithms.
- 2) Literature and tech / white paper review.
- 3) Equipment Hospital Usage: EP Lab- ICD placement and testing. CRT (Cardiac Resynchronization Therapy), Syncope Evaluation- Tilt Table and Autonomic Dysfunction testing. Exercise Stress Testing, CHF clinics, ER- chest pain clinic, toxic shock, sepsis. etc.
- 4) Equipment Demonstration: Touch Screen Monitor, Wrist Unit, Finger Cuffs, HRS unit (corrects for the height of the finger in relation to the heart). Adequate time to attach and demonstrate on volunteer chapter members for blood pressure and cardiac output values.

Check the link to the Bmeye Nexfin product info: <http://www.bmeye.com/>



Quality System and Standards-Related Training Programs

Helping you to make medical devices safer and more effective.

Purchasing Controls and Supply Chain Management

June 7-9, 2010

This new 2½ day course provides extensive information on effective implementation of supplier selection and controls. Course content focuses on the key aspects of supplier controls, from planning for supplier assessment/selection, to defining acceptance activities, to monitoring supplier performance. Each topic is presented from a practical perspective, with links to the requirements of the Quality System regulation, the ANSI/AAMI/ISO 13485 standard, risk management considerations, and pertinent Global Harmonization Task Force guidances. The course also covers life-cycle management approaches for a medical device manufacturing organization's supply chain. Through "hands-on" exercises and specific industry examples, attendees will be able to apply concepts and interact with colleagues. Upon completion of the course, participants will be able to evaluate their organization's compliance with FDA's requirements for purchasing controls and acceptance activities, and consider appropriate risk mitigation

Integrating Risk Management into the Quality System

June 21-23, 2010

This 3 day course provides intensive coverage of integrating risk management practices and principles into a medical device manufacturer's quality system. Upon completion of the course, participants will have learned the basic terms of risk management, the appropriate tools for risk evaluation, FDA's expectations for submissions and compliance, as well as how to apply risk management principles to various aspects of a quality system. Instruction is targeted to quality assurance and regulatory affairs personnel, design and process engineers, manufacturing and operations managers, and members of research and development or new product development teams. For participants to gain the maximum benefit from this course, it is recommended for those who have a working knowledge of the Quality System regulation and design control or who have already attended AAMI's Quality System and Design Control courses.

Association for the Advancement of Medical Instrumentation

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California Bill Would Require Recording of Radiation Dose



The California Senate is considering a bill (SB 1237) that would require healthcare facilities and clinics that use CT Scanners for diagnostic purpose to—if technologically feasible—record the radiation dose administered in the patient’s medical record.

If passed, the bill would go into effect Jan. 1, 2012, but wouldn’t be applicable to small and rural hospitals, or hospitals and clinics located in an area that is designated as medically underserved until Jan. 1, 2013.

The legislation also would require physicians or other practitioners, facilities or other entities that provided diagnostics MRI, CT and nuclear medicine services to be accredited by an organization approved by the Centers for Medicare & Medicaid Services.

The bill is sponsored by Sen. Alex Padilla, D-Pacoima. During a hearing last month on the legislation, Padilla referred to the situation at Cedars-Sinai Medical Center in Los Angeles, in which over the course of 18 months more than 250 patients received excess doses of radiation while undergoing CT Perfusion scans.

“The fact that these overdoses continued for 18 months speaks to the genuine need for protocols and safeguards to prevent overdoses in the future,” said Padilla during the hearing. “SB 1237 will establish those protocols and safeguards and require that radiation dosages be recorded on the scanned images and in a patient’s records. This will provide physicians the information they need to track dosage levels and prevent patients from receiving overdoses of radiation.”



Jay Mathis

A colleague, friend, and industry pioneer has passed away. Jay Mathis trained a very large number of imaging service professionals over many years. His rare talent for presentation, motivation and humor which ensured that students enjoyed learning. Although he has been out of the industry due to illness for a few years, those of you who benefitted from his instruction will never forget him.

Life's Truths for Mature Adults

1. I think part of a best friend's job should be to immediately clear your computer history if you die.
2. Nothing is worse than that moment during an argument when you realize you're wrong.
3. I totally take back all those times I didn't want to nap when I was younger.
4. There is great need for a sarcasm font.
5. Really, how ARE you supposed to fold a fitted sheet?
6. Was learning cursive really necessary?
7. Map Quest really needs to start their directions on # 5. I'm pretty sure I know how to get out of my neighborhood.
8. Obituaries would be a lot more interesting if they told you how the person died.
9. I can't remember the last time I wasn't at least kind of tired.
10. Bad decisions make good stories.
11. You never know when it will strike, but there comes a moment at work when you know that you just aren't going to do anything productive for the rest of the day.
12. Can we all just agree to ignore whatever comes after Blue Ray? I don't want to have to restart my collection...again.
13. I'm always slightly terrified when I exit out of Word and it asks me if I want to save any changes to my ten-page technical report that I swear I did not make any changes to.
14. "Do not machine wash or tumble dry" means I will never wash this - ever.
15. I hate when I just miss a call by the last ring, but when I immediately call back, it rings nine times and goes to voice mail. What did you do after I didn't answer? Drop the phone and run away?
16. I hate leaving my house confident and looking good and then not seeing anyone of importance the entire day. What a waste.
17. I keep some people's phone numbers in my phone just so I know not to answer when they call.
18. I think the freezer deserves a light as well.
19. I disagree with Kay Jewelers. I would bet on any given Friday or Saturday night more kisses begin with Tequila than Kay.
20. I wish Google Maps had an "Avoid Ghetto" routing option.
21. Sometimes, I'll watch a movie that I watched when I was younger and suddenly realize I had no idea what the heck was going on when I first saw it.
22. I would rather try to carry 10 over-loaded plastic bags in each hand than take 2 trips to bring my groceries in.
23. The only time I look forward to a red light is when I'm trying to finish a text.
24. I have a hard time deciphering the fine line between boredom and hunger.
25. How many times is it appropriate to say "What?" before you just nod and smile because you still didn't hear or understand a word they said?
26. I love the sense of camaraderie when an entire line of cars team up to prevent a jerk from cutting in at the front. Stay strong, brothers and sisters!
27. Shirts get dirty. Underwear gets dirty. Pants? Pants never get dirty, and you can wear them forever.
28. Is it just me or do high school kids get dumber & dumber every year?
29. There's no worse feeling than that millisecond you're sure you are going to die after leaning your chair back a little too far.
30. As a driver I hate pedestrians, and as a pedestrian I hate drivers, but no matter what the mode of transportation, I always hate bicyclists.
31. Sometimes I'll look down at my watch 3 consecutive times and still not know what time it is.
32. Even under ideal conditions people have trouble locating their car keys in a pocket, finding their cell phone, and Pinning the Tail on the Donkey - but I'll bet everyone can find and push the snooze button from 3 feet away, in about 1.7 seconds, eyes closed, first time, every time!

MEETING AGENDA

MESSAGE WELCOME....CALIFORNIA MEDICAL INSTRUMENTAL ASSOCIATION

HERITAGE CELLAR BUFFET SETUP OUT SIDE OF ROOM

FULL TABLE SETUP
WHITE TABLE LINEN AND BURGUNDY NAPKINS
WATER GLASS
SILVERWARE

4:00 TO 5:00

GUEST ARRIVE

4:30

SCHEDULED TASTING IN THE HERITAGE CELLAR

5:00

PRESENTATION

6:00

DINNER: MADDALENA LINE...LIMITED MENU

HOT MEALS INCLUDED BREAD AND SALAD

CARAFES OF WATER ON
TABLE

MADDALENA MEAT LASAGNE
SPAGHETTI WITH MEATBALLS OR SAUSAGES
HOMEMADE RAVIOLI
CHICKEN OF THE DAY
FISH OF THE DAY

GUEST PURCHASE OWN WINE/BEER AND DESSERT

CMIA/LA Dinner & Meeting

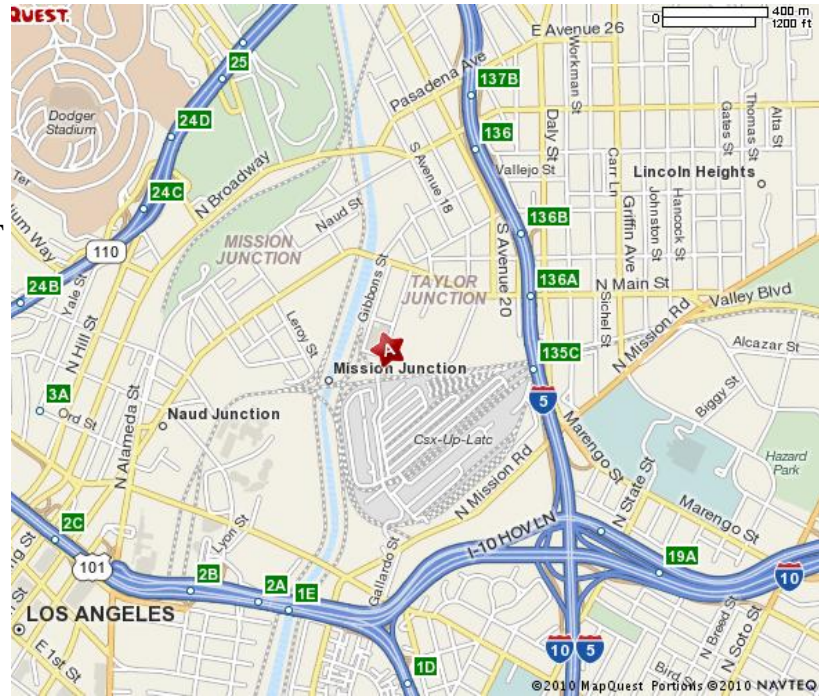
DATE: Tuesday June 8th, 2010

TIME: 4:00-7:00 pm

PLACE: San Antonio Winery
MADDALENA RESTAURANT
737 Lamar Street
Los Angeles, CA 90031
323-223-1401

TOPIC: Automated Vitals Signs Data

HOSTED: Jeff Stayberg
West Region Sales Representative
BMEYE



**California Medical
Instrumentation Association**



www.cmia.org

Attention Biomedical Engineering