

C.M.I.A. NEWSLETTER

Central Coastal Chapter

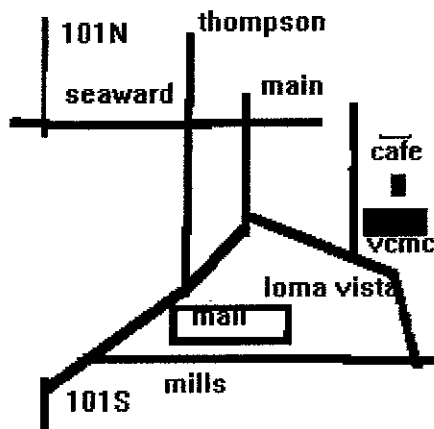
P.O. Box 360

Camarillo, Ca 93011

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The February meeting will be held at Ventura County Medical Center on Thursday the 18th in the small cafeteria conference room. Dinner is at 6:30 pm with the monthly meeting to follow. Please RSVP to Randy Cook at 805 652-6676.



Directions: From the North, exit at Seaward Ave, go left and cross over the freeway on Seaward Ave. Take Seaward to Main St (four stoplights) Make a right on Main and go to Loma Vista. Left on Loma Vista. Pass CMH hospital on right, VCMC is on the left. Parking is behind the Medical Center. Cafeteria conference room is downstairs in the cafeteria addition behind the hospital. From Ventura South, Exit on Main St. Make an immediate right on Mills Rd (before the Mall) Take Mills to Loma Vista (4 lights) Make a left, VCMC is on the right as you head downtown.

Russ Ayers and Shane Criddle from **SpaceLabs** will be presenting on **IT** for Biomed.

Individual \$25.00 membership renewals to Central Coast CMIA are due. A reminder will be sent via mail to follow.

San Diego seminars and annual banquet, held January 29th and 30th, were educational and a great meeting place of vendors. Next year the meeting will be held in Northern California. Plan now to attend.

News off the Net: Biomedtalk Change I want to let you know of an exciting change related to Biomedtalk. After 13 years of running the service, I will be passing the baton to ECRI Institute as the new owner. ECRI Institute plans to basically leave things the way they are and potentially tweak things after obtaining input from us, the members.

Nothing should change from your perspective. You will send and receive exactly as you are doing now. We will have better IT assistance (they are already helping me with errors)!

As a Biomed for over 30 years, I have used ECRI Institute many times. They have provided the same product over and over - an extremely independent, professional, and high quality service with timely response. I know this will also be the case with Biomedtalk. Mike Kauffman

I would like to thank Mike Kauffman for providing ECRI Institute with the opportunity to take on his longstanding stewardship of Biomedtalk. Mike has done an excellent job of providing the biomedical and clinical engineering community with a forum for sharing information and ideas. The long list of notes of gratitude that have been posted on Biomedtalk since your transition announcement last week are a testament to how valued your efforts have been. We look forward to working with the Biomedtalk membership to continue with more of the great service you have provided and to find ways to make BiomedTalk an even more effective tool for the biomedical and clinical engineering community.

Once we formally take on ownership of Biomedtalk on **March 1, 2010** we will provide the membership with Biomedtalk-related contact information at ECRI Institute and other logistics. In the meantime, we encourage you to continue to provide ideas on ways that we can work together to make Biomedtalk better.

Jim Keller Vice President Health Technology Evaluation and Safety ECRI Institute

Need tips for removing broken screws:

Not very glamorous, but what are you using to loosen stainless screws that are stuck in aluminum? Liquid wrench kind of works (sometimes), but that white oxide is really tough.

I've searched and found some alternative commercial products. I just wanted some recommendations before buying. Cliff Shelby, Castle Rock, Colorado

This is what I used to remove SS screws from the aluminum cases on my motorcycle engines. <http://www.kk.org/cooltools/archives/000723.php> They are available from most tool suppliers. Michael J. Murphy University of Washington Medical Center Clinical Engineering

Try using a left and twist drill in a hand held electric drill. The drill will catch the screw and turn it out on its own threads. This is assuming the screw is a right hand thread to begin with.

Original Tap Magic will also penetrate to help loosen the screw. Howard Gorin

Break Free and/or **Kroil** are just wonderful products, give them time to soak in. The left hand drill bit works very well also, just be sure to stay exactly in the middle of the screw/bolt. Heat also helps makes the oxide let go. No guarantees, but the combo has never failed me. Tom Hoehler

Another little trick is to use Freeze spray or use a spray duster can upside down and spray the bolt head, trying to just spray the head. This sometimes will shrink the bolt enough to break it loose for removal. If you have drilled a hole in the bolt it even works better. Terry Doukas CBEI

TapMagic is not such a good idea on aluminum. It will eventually erode it. Several companies make a set of three screw removers (I know Sears sells them as do a number of the woodworking catalogs. These screw removers are left handed and have a cutter on one end and an "easy-out" on the other end. They work really well. A drill press you can reverse is really best for this, however, you can do it with a hand drill. Sometimes though it is best just to drill out to the tap drill size and re-tap the threads. Jerry Messina

Okay, for this situation. In the past as a mechanic, here is what I have done: Use a very thin cut-off wheel (dremel or dye grinder), small enough to place a flat blade screwdriver in it. Match up your cut with a good screwdriver, not a **techni-tool** screwdriver. Place the screwdriver in a freezer, within the coldest section, you want the screwdriver to get very cold. Start to heat up the screw and the surrounding metal, no it does not have to glow red, but enough to burn out the corrosion between the two types of metal. The following step is very important,, as soon as you remove heat from the metals, you want that frozen screwdriver handy so you can place it into the broken screw or bolt. The trick is, from the metals being heated up and the frozen screwdriver being placed on the bolt or screw, there will be a dramatic change in temperature. The heated screw and surrounding metal has expanded from the heat, when you apply the frozen screwdriver, allow it to set in the screw 5 - 10 seconds before you try to remove the broken screw. The frozen screwdriver will rapidly cool, this will "shrink" the broken screw. The heat will help burn the corrosion and expands the metal from the screw and the frozen screwdriver cools the screw causing it to return to the original size, leaving the surrounding metal still swollen and finally breaking the bolt loose. Sometimes when I have done this, you will actually hear a popping noise as the screw shrinks away from the surrounding metal. Hope this helps. Albert Hardy

Updated FDA Notice Concerning the Steris System 1:

Dear Healthcare Facility Administrators and Infection Control Practitioners:

The purpose of this document is to inform you that **FDA is extending to 18 months from the date of this notice the total recommended time period** for transitioning from Steris Corporation's modified System 1 processor (SS1) to legally-marketed alternative devices. As FDA announced in its December 3, 2009, notice, the Agency has not approved or cleared the SS1 for its labeled claims. Steris Corporation has chosen not to seek FDA clearance of this device and, therefore, **its use should be discontinued as soon as practicable.**

During a December 10, 2009, stakeholder conference call, FDA stated its view that healthcare facilities should be able to transition from the SS1 to legally-marketed alternative devices in three to six months. That recommendation was based on discussions with a number of outside constituents. Since then, Agency staff has heard from many other healthcare providers and professional organizations. FDA now understands that a three to six month transition period may present significant difficulties for some healthcare facilities, which could, in turn, adversely affect patient care.

FDA's primary objective is that safe and effective alternative reprocessing devices be identified and placed into use as soon as practicable, without compromising either patient care or employee health. Therefore, FDA is extending to 18 months the recommended period for transitioning from the SS1 to legally-marketed alternative devices. At this time, FDA expects that Steris Corporation will continue to support existing SS1 units throughout the extended transition period, e.g., through provision of currently-marketed components, accessories, and sterilant. During this period, FDA will monitor the availability and supply of legally- marketed replacement products.

FDA does not expect to take regulatory action against healthcare facilities for failing to replace SS1 units within the 18-month transition period. But these facilities should be aware that the current SS1 is a misbranded and adulterated medical device because it has not been cleared by FDA as safe and effective for its labeled claims. Healthcare facilities should therefore transition to alternative reprocessing devices as soon as practicable.

Additional information on this issue may be found at:

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm194411.htm>

and questions can be directed to Candace McManus, DrPH, at the Office of Compliance, CDRH, 10903 New Hampshire Avenue, WO 66, Silver Spring, Maryland 20993, by email at candace.mcmanus@fda.hhs.gov, or by telephone message at 1-877-260-3731.

Sincerely, Timothy A. Ulatowski Director, Office of Compliance
Center for Devices and Radiological Health Food and Drug Administration

Steris Part:

One of our Steris System 1 Processors has a crack in the lid and needs to be replaced. Apparently, the FDA has given healthcare facilities an 18-month extension to transition to alternative devices or sterilization methods. The replacement lid is expensive. Does anyone know where I could find Steris parts perhaps through a second source supplier? Thanks.
Tom Citak Clinical Eng. St. Joseph Health

RPI sells a replacement lid for the System 1 - please call me at my desk (8:00 to 4:30 PST) and we can discuss your situation.

Neil Blagman Product Development Engineer 800-221-9723 (818-882-8611) Ext. 127

Replacement for the Solar 8000M Display:

Anyone have a second source for replacing a GE Solar 8000M, 15" display with touch screen?
Rick Sell

Try ELO medical grade touch screen displays with SAW (Sound AcousticWave)technology. You can get them at Techdepot or CDW Healthcare or any other distributor.
Lester Zybura, CBET Clinical Engineering Elkhart General Healthcare System

We do not recommend Touch screen, anywhere, as we feel they could be a vector for patient to equipment, equipment to patient sources of cross infection. If proper cleaning is not performed between patients or sterile workflow techniques are not used when touching the patients and then the screens, this a problem. To compound the issue, most of the screens I have reviewed are very sensitive to the harsh cleaning agents that are now required in a medical environment. Look at their recommended cleaning solutions then cross index that to what your infection control committee is recommending for cleaning of contact surfaces. For the additional cost of touch-screen..... - cost verses benefits verses reduction in the risk for hospital acquired infections... It never seems to pencil out for me. Oh sure the "Glamour" factor is great. Personally, I'm waiting for infrared holographic interfaces- stick your hand in an open donut to control it all, then we are on to something. Mark Granger

If a touch screen application is desirable for clinical practice, you can always install antimicrobial LCD protectors (<http://www.nushield.com/>) to remedy the damage from chemicals and provide a layer of protection for staff. While I understand Mark's point of view, and it is completely accurate, I don't think flat panel physiological monitors are devices that are high on the list for infection transmission. I am more concerned with hand held peripheral devices that nurses use to chart with, especially since some have permeable elastic hand straps. Mindy Gonzales, CBET Biomedical Instrumentation, SWMC

Changing PM frequencies:

At the CMIA Symposium this past weekend George Mills from the Joint Commission requested our assistance. In short, CMS is interpreting maintenance as being "according to manufacturer's recommendations." (Remember TJC has deeming authority from CMS.) He (George) is fighting this to keep the options open for us. He is formulating a reply, and would like input from the field with hard data as to why we should not be locked into the Mfg recommendations. He has less than 2 weeks to reply! I think we can all see what will happen if CMS maintains this interpretation. Paul Kelley, CBET

Paul: I've been taught manufacturers "recommended" maintenance procedures and intervals. Once purchased the equipment is the property of the purchaser. The manufacturer cannot control the risk assumed, the staffing levels, or the monetary allowance for equipment cost of ownership. This is all done by established programs in the institutions and individual departments such as Biomedical. The manufacturers can advise and supply proper documentation to insure their designs maintenance plans are addressed. I hope George wins this one or we all will have to double our staffing levels. Sanpedrodave

Where is the data to support "manufacturer's recommendations"? A long time ago, I called a vendor because the checkout procedure did not make sense. I actually got the person that wrote the procedure on the phone and asked why they were having us do some things. He didn't have clear answers and basically asked "isn't that what you would do?" I believe many (not all) "manufacturer's recommendations" are written from a design and manufacturing perspective with little regard for real world practicality. Inspection intervals are assigned because "that is how we have always did it" and legal CYA versus true need. Some are there as barriers to non-oem service and revenue generation. If CMS is going to mandate this, mandate complete service documentation for everything and cut through the legal 21CFR nuances that give us all headaches. Brad Motes CBET

I spoke to this subject at the 2000 AAMI session on department improvements in San Jose. My results on scheduling maintenance based on risk allowed for improved results in lowering corrective maintenance and overall costs. Scheduling based on manufacturer's recommendations is artificial and detrimental to patient safety. Some firms will say that their equipment needs no service to boost sales, while some firms will require onerous maintenance schedules in an attempt to deflect potential liability. I can hear it in the courtroom now.... "Your staff didn't check the full functionality and calibration of this alternating pressure pump every day as specified by the service manual, so we cannot accept any liability in that the attached pad did not prevent a deep vein thrombo. You say you have 300 of these and each one takes half an hour to find and check, you should have hired adequate staff."

Please forward my comments to Mr. Mills so he can fight to have common sense dictate the scheduling of medical equipment service to the staff most aware of the risk and the costs associated with said service. Let outcomes decide on our competence, hold our feet to the fire if we don't get it right. But please don't micromanage a site that is maximizing safety and minimizing patient and financial risk. Jeff Shaffer

PM frequency for diagnostic ultrasound systems, the medical devices with which I am most familiar, is often not specified by the OEM. Having been an OEM QA and tech support manager, I know one reason the manufacturers do this is to avoid having their own service personnel committed to performing these service calls for warranty and contract customers. In most cases, the frequency and type of maintenance required is directly related to the amount and type of use

the unit gets, which the manufacturer is unable to predict. For example, a system in the OR is a much higher risk than one in L&D due to the environment and the clinical application

Whatever the reasoning, the fact is that the manufacturer often does not specify the frequency of periodic maintenance. This leaves it to the user to determine the frequency and often the methods of preventive maintenance and QA testing based on their specific equipment use and risks. Many manufacturers have adopted language that says the user is responsible for determining what to do and when to do it. There is a standard that was developed to guide in the development of an equipment maintenance program based on risk assessment: ANSI+AAMI EQ56 2004.

As an example of my point, here is what GE says about PM frequency in Chapter 10 of 5180263-100, Rev2 of the Logiq E9 service manual: "It has been determined by engineering that your LOGIQ E9 system does not have any high wear components that fail with use, therefore no Periodic Maintenance inspections are mandatory. Some Customers Quality Assurance Programs may require additional tasks and or inspections at a different frequency than listed in this manual."

With all due respect to GE, anyone who repairs medical equipment and is familiar with these systems knows that it has several high wear components that fail with use. The probes age and fail even with normal use, if they don't suffer from SDT first (sudden deceleration trauma). In fact, in a seemingly self-contradictory manner Chapter 10 goes on to describe various maintenance tasks and gives time frames of daily, weekly, monthly and annually for them. For example, on page 10-3 of the aforementioned manual, it calls for weekly inspection of the cables and main AC power cord.

The Philips iU22 ultrasound system provides another example of how the responsibility for determining preventive maintenance has been put on the user. A search of the service (453561281504) and user (453561170891 Rev A) manuals for a timeframe for PMs and what to do turns up empty, except for comments such as the one about cleaning the air filters every 6 months or that the recommended interval for brake and swivel-lock assembly maintenance is every 12 months. (Don't wait that long on either one, in my experience!) Page 329 of the service manual makes it clear whose responsibility Philips thinks it is: "Preventive maintenance inspections are part of the Customer Service Quality Assurance (QA) Program. The "Preventive Maintenance Checklist" on page 346 included at the end of this section can be used to ensure that all preventive maintenance is performed." James D. (Jim) Carr Unisyn Medical Technologies, Inc

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