

ACCE News

Vol. 8, No. 6 – November 1998

ACCE Partners with Telemetry Manufacturers

The technology shift to digital television and the subsequent allocation of broadcast frequencies by the U.S. government severely impact the safety, cost and availability of medical telemetry, effecting hospitals, patients, and telemetry manufacturers. ACCE Representatives Caroline Campbell, Yadin David and Joe McClain are leading efforts of working groups to define the telemetry issues, determine current and projected needs, and develop educational material. ACCE is working closely with the four actively participating manufacturers Spacelabs Medical, Marquette Medical, Hewlett Packard and VitalCom. See page 11 for the Sept. 17th Medical Telemetry Task Force meeting summary and the Nov. 2nd Working Group presentation to the FCC.

ACCE ACEW in Hartford June '99

Management Issues, Business Practices and Team Building are focus of ACEW in June '99. Trinity College, Hartford, Connecticut. See page 9.

Ballasts Bug Beaumont

Read how clinical engineers solve telemetry interference caused by light ballasts -- page 12

Hughes Reports on Down Under, see p.4

Health Tech '99 Features ACCE Track

Binseng Wang has assembled a star-studded cast of ACCE members to run a strong ACCE Track at **Health Tech '99**. You won't want to miss it. See details, p. 14.

Hold Those Regs!

Tom Bauld, ACCE Representative, covered the recent AAMI / FDA meeting on FDA attempts to regulate Medical Device Servicers, Remarketers, and Refurbishers. See page 6 for a full report.

A Practical Lesson on Y2K

Your colleague's experience can help you. Details on page 13.

American College of Clinical Engineering

ACCE News

21 Bob's Lane

Setauket, NY 11733

ACCE News

ACCE Mission

1. To establish a standard of competence and to promote excellence in Clinical Engineering Practice.
2. To promote safe and effective application of Science and Technology to patient care.
3. To define the body of knowledge on which the profession is based.
4. To represent the professional interests of Clinical Engineers.

ACCE on the Web
[http:// accenet.org](http://accenet.org)

President's Message

Robert L. Morris, PE, CCE, morris@ohsu.edu

Continuing in the vein of my last ACCE newsletter article, I would like to continue to point out efforts of ACCE members to improve the lot of clinical engineering and demonstrate their dedication to the profession.

Dave Francoeur (dave.francoeur@bhs.org) through perseverance and by using his knowledge of laboratories convinced the College of American Pathologists to make substantial changes to the CAP Accreditation requirements that significantly reduce the effort required to safety test and PM laboratory equipment. We all have or will benefit from Dave's efforts every time the CAP comes to our hospital laboratory.

Carolyn Campbell (cac1@mhg.edu), Yadin David (ydavid@msmail.his.tch.tmc.edu), and Joe McLain (mcclain@ix.netcom.com) are working with ASHE, FDA and the FCC to establish designation frequencies for medical telemetry applications. This involves a lot of extra work helping to reconcile multiple demands for frequency allocations while effectively representing the medical community.

Al Jackniunus (agj@cldc.howard.edu), Tom Judd (tom.judd@kp.org), Joe Dyro (jfdyro@aol.com), Frank Painter (frpainter@aol.com) and myself volunteered to assist our clinical engineering colleagues in Mexico by contributing to an Advanced Clinical Engineering Workshop in Mexico City and to the First Latin American Congress on Biomedical Engineering. The

organizer of the activities, Adriana Velásquez (adrianavb@compuserve.com), ensured the success of the effort by her customary diligence and warmth. Attendees included clinical engineers from Mexico, Central and South America.

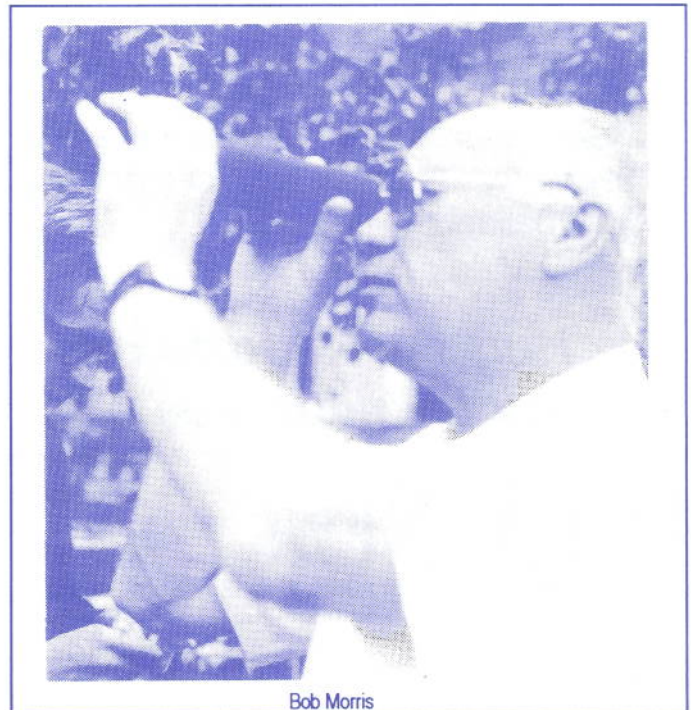
Antonio Hernandez (1hernana@paho.org), Tom Judd (tom.judd@kp.org), Kevin Taylor (ktaylor1@partners.org), and myself are participating in a WHO sponsored consultation in an attempt to improve the strategies used to establish physical infrastructure, technology and sustainable systems in developing countries.

Siim Aid (siim@cut.ee) from Estonia is responsible for performing a complete survey of x-ray equipment, its condition, calibration and performance throughout the entire country of Estonia. It is the first such comprehensive survey of medical technology to be done in his country.

Lúcio Flavio Brito, of São Paulo, Brazil works tirelessly to improve and promote clinical engineering in Brazil.

Binseng Wang (binseng@voicenet.com) is organizing the Clinical Engineering program for the Health Tech'99 meeting to be held in Baltimore, 25 -28 April 1999. ACCE and Health Tech have signed an agreement that provides registration discounts for ACCE members among other mutual benefits.

I have only mentioned those activities I know about. I am certain that many of you know of efforts by you or your colleagues that improve, promote, and enhance the profession of clinical engineering. Please drop me an e-mail to tell me of their efforts. It is important that our members know what an active membership we have.



Bob Morris

ACCE News

ACCE News

ACCE News is the official newsletter of the American College of Clinical Engineering (ACCE).

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proposing the revocation of Compliance Policy Guide on Reconditioners and Rebuilders of Medical Devices:

<http://www.fda.gov/ohrms/dockets/98fr/120498c.txt>

Please, however, do not feel that we have won the war yet. Some regulatory actions (even if voluntary) may still be taken (read the last paragraph). But this is a good first step, I believe.

Hope you and yours have a wonderful holiday season!

Dr. Binseng Wang
Cherry Hill, NJ
binseng@voicenet.com

Ed. Note: Last year Binseng wrote the following message:

Dear Colleagues:

Great news! Your holiday gift just arrived! The CDRH/FDA's Office of Compliance just published the Advance Notice of Proposed Rulemaking (ANPR) concerning medical device refurbishers and servicers. You can get a copy from the Federal Register's website or from CDRH/FDA's website.

Clinton Signs Y2K Act

Jim Berger, jberger@PENN.COM

It would behoove everybody involved in a Y2K project to check out the new law that Clinton signed on October 18th of this year called the Year 2000 Information and Readiness Disclosure Act. You can get a copy along with a "lawyerly" interpretation of it at the following site: <http://www.y2k.com/legalpage.htm> (about 18 pages in MS Word format).

Among other things, this act protects manufacturers by making it harder to sue them if they provide erroneous Y2K Compliance Statements. The rationale of the lawmakers seems to be that fear of lawsuits has impeded many companies from releasing Y2K compliance information...so they seemed to have let them off the hook in hopes of encouraging them to be more forthcoming with info. Go figure!

The act also does a couple of good things, in my opinion, such as protecting entities that re-publish Year 2000 statements of others and lets information from a legitimate Y2K web site "qualify as legally sufficient notice of that information." Therefore, according to the Act, a compliance status page from a manufacturer's web site presumably is as good as the signed or faxed document from the company.

I'd be interested in others' reaction to this legislation. I'm especially interested in hearing if this Act has in any way affected the way your hospitals are approaching the Y2K projects. For example, does it make you more likely to test equipment for compliance since now there's less protection to be had by the manufacturer's statement?

All opinions expressed are my own, and do not necessarily reflect those of my employer.

Ed. Note: Jim Berger is a Service Manager for ISS in Western Pennsylvania. The above was sent to the Editor by Frank Painter. Frank read Berger's report in BIOMEDTALK-L Digest - 20 Dec 1998 to 21 Dec 1998 (#1998-132)

Letters

ACCE News, 21 Bob's Lane, Setauket, NY
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Christmas gift from the FDA

Dear Colleagues --Last year I sent you a holiday gift and heard many complaints about it. So this year I am being nicer and sending you something that, hopefully, will be more to your liking. Below please find an Action Notice just published by the FDA/CDRH on 12/4/98

ACCE News

Commentary

Frank R. Painter, fpainter@novamedcorp.com

So now the lawyers can't go after the manufacturers when things go wrong. That leaves the ISOs. Good thing we're out of the business. There are going to be thousands of lawyers that have switched careers to jump on the Y2K bandwagon just looking for someone to sue. If this e-mail is true, it just took all the "deep pockets" out of the ring.



Clinical Engineering News From "Down Under"

John Hughes

I and my family (wife Karen, children Kevin age 8, Colleen age 6, Patrick and Matthew, age 4) recently returned from a month in Australia and New Zealand where I was invited to be a Keynote Speaker at the **Annual Australasian Conference on Engineering and the Physical Sciences in Medicine** held in Hobart, Tasmania, Australia. The venue for the conference was the Wrest Point Casino and Convention Center, a stunning setting right on the harbor. Tasmania is Australia's smallest and only island state. Hobart is a city of approximately 185,000 people with one of the world's most beautiful harbors. (My latest dream (scheme?) is to open a Starbucks in Hobart, buy a sailboat, and retire on the job).

I was also invited to speak at a joint meeting of The Society for Medical and Biological Engineering and The Institution of Engineers College of Biomedical Engineers in Adelaide and at a meeting of The Institute of Engineers of Australia in Sydney.

I had the opportunity to interact with clinical engineering colleagues from Australia and New Zealand and was pleased to meet so many dedicated, committed, and talented professionals. The theme of the Conference was *Relevance Beyond Rationalism: Charting a Course for the Future*. I found it both eloquent and appropriate. They face many of the same challenges and opportunities that we in the U.S. face such as downsizing, rightsizing, reengineering and outsourcing, funding issues for public vs. private hospitals, and competition between hospitals. GE recently bought the largest ISO in Australia. Other concerns were voiced over regulatory issues, the need to structure organizations to run as businesses, education and training, certification, and Y2K. Sound familiar? The good news is that there are many bright and talented people who are dedicated to their profession and to the improvement of patient care in their communities and countries.

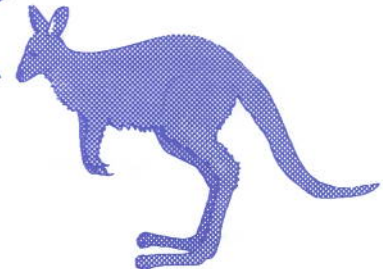
On a personal note, my family and I had a wonderful adventure.

The Aussies are an extremely open and friendly people. Adults and children alike had a tremendous time in Australia and New Zealand and enjoyed both immensely. The children exceeded our best expectations as travelers; twelve plane flights and eight hotels later they are indeed veterans. Our youngest twin, Matthew endeared himself to the "fear of flying" passengers by shouting "One, two, three, Blast-Off!!!" during every takeoff. I wouldn't have thought it possible that we could do and see so much in such a short time. It's impossible to pick a favorite; each leg of the trip was unique and exciting in its own right. Hobart is stunningly beautiful, as was the rest of Tasmania that we saw. Adelaide was so diverse, but for a large city (approximately 1,000,000 population) it had a small town feel to it. Hamilton Island is in such a beautiful setting in the Whitsunday Islands. The entire family enjoyed snorkeling on the Great Barrier Reef, which is truly the 8th wonder of the world. We enjoyed Sydney very much. It's hard to believe we experienced as much of it as we did. Our hotel was quite close to the harbor, so we toured the Rocks, the Circular Quay, the Sydney Opera House, the Botanical Gardens, took a cruise of the entire Harbor, and visited the Olympic site. Lots of tired feet at the end of the days.

And not to forget the kiwis. Wellington is quite beautiful and houses the national museum, Te Papa, which was enjoyed equally by the children and us. Rotorua was very interesting with many geothermal springs and the like. We drove from Rotorua to Auckland along the seacoast and saw some stunning scenery. Unfortunately, we didn't have enough time to really see and experience Auckland.

Everyone calls it a once in a lifetime trip, but we sincerely hope it was just the first of many. We recommend it highly.

G'Day, Mates!



ACCE International Committee News

Sam Miller, Chairman, samiller@localnet.com

Al Levenson stepped down as Chairman last June and I am picking up where he left off. Thanks for all the hard work, Al. The committee work will continue as before and I plan to keep ACCE members aware of committee activities and international news with a column like this in each issue of the *ACCE News*. The core committee members this year are Al Levenson, George Johnston, Tom Judd and Frank Painter. In addition, there are about twenty other ACCE members who have offered to assist the committee in an advisory capacity, and they are routinely asked to review and comment on the committee's activities.

ACCE News

The role of the committee is defined by the following mission and goals statement developed in May of 1997:

Mission: To promote the advancement of clinical engineering worldwide in the belief that improved management of healthcare technology will contribute to the betterment of health care for all people, regardless of national origin, color or creed.

Goals:

- To facilitate the exchange of information and ideas among members of the international clinical engineering community through bulletin boards, newsletters, e-mail and other media as available and appropriate;
- To assist clinical engineers in developing countries in their search for information on technical issues, training programs, management techniques, and special needs;
- To provide educational opportunities for clinical engineers in developing countries through workshops, publications, internships, and visits to well-established clinical engineering programs;
- To educate healthcare decision- and policy-makers in developing countries on the advantages of incorporating clinical engineers in the management of healthcare technology;
- To promote certification of clinical engineers in the international community as a means to verify professional competency and advancement of professional standards;
- To assist the ACCE Inter-Society Committee in establishing and maintaining communications with non U.S.-based clinical engineering associations and societies.

In keeping with the first goal... *to facilitate the exchange of information....*, we are developing an e-mail list of ACCE members and international CE's who wish to be kept abreast of international CE activities (projects, events, grants, travels, etc.) on a frequent basis. This e-mail list will function as a moderated listserv and will contain excerpts of pertinent information from many sources. Please contact me at the above e-mail address if you wish to be added to this e-mail list, or have some information that should be shared with the list. The intent is not to clutter your mailbox with more Spam, but to pass on useful information and requests for information every few weeks as needed.

At the committee meeting on 10/2/98 we reviewed possible projects to undertake. We decided to finish the ACCE brochure on offering the services of members to assist developing nations with workshops, consultations and/or acquiring equipment. Also considered were suggestions for establishing a library for international use and for encouraging ACCE membership from developing countries. At our next meeting, 12/4/98, we focused on the content of the brochure, more ideas about the library, and membership projects. If anyone is interested in joining the core committee as an advisor, please e-mail me at the above address. More about progress in the next issue of the *ACCE News*.

Auf Wiedersehen!

AIHA Opportunities

Sam Miller, samiller@localnet.com

I came across an announcement that should be of interest to all ACCE members. The announcement (see below) was released by The American International Health Alliance (AIHA). AIHA is the agency that started my involvement with the former Soviet Union hospitals as they funded the partnership program linking my hospitals here in Buffalo with two similar hospitals in Ukraine six years ago. That partnership is still being funded by AIHA and covers some staffing costs. Most importantly, however, the partnership covers travel costs and expenses for two-way people exchanges and shipping costs for equipment, books and supplies.

The importance of this new announcement is that partnerships now extend beyond simply those between hospitals. Partnerships could conceivably now include university-university partners for clinical engineering program exchanges and industry-industry partners for service organizations or manufacturers.

For more information, visit their website and then contact them directly via e-mail or telephone.

ANNOUNCEMENT

FOR IMMEDIATE RELEASE - October, 5, 1998 - Washington, DC -

The American International Health Alliance (AIHA) has signed a five-year agreement with the US Agency for International Development (USAID) to continue managing voluntary health partnerships between institutions and communities in the United States and their counterparts in the New Independent States of the former Soviet Union (NIS). Under the agreement, effective September 30, 1998, AIHA will establish and promote sustainable US/NIS partnerships to foster more effective and efficient delivery of health services in the NIS. USAID intends to provide \$53 million over the first three years of the agreement, with a total estimated award of \$75 million over five years.

The new agreement continues to expand the range of possible partnerships beyond the hospital-to-hospital model that AIHA and USAID first initiated in 1992, allowing, for example, further development of partnerships between schools of public health and other health professions, non-governmental organizations, citizens health advocacy groups, medical group practices, professional associations, and healthy communities. The partnership program's regional component will support AIHA's efforts to similarly expand the sharing of experience and lessons learned and promote the replication of successful partnership-initiated programs within and among regions in the NIS.

Health-related organizations, including health care providers, schools of health professions, city, county and state health departments, non-governmental organizations, and professional associations interested in the possibility of becoming involved in the AIHA partnership program should check the AIHA World Wide Web Site: <http://www.aiha.com> for further information and to register their interest. E-mail inquiries may be addressed to Lara Moninghoff at lara@aiha.com. For those without Web or e-mail access, please address your inquiries to Lara Moninghoff at (202) 789-1136.

Meetings

AAMI / FDA Servicers & Remarketers Regulation Meeting

Thomas J. Bauld, Ph.D.

The AAMI / FDA Conference on **Medical Device Servicing, Remarketing and Refurbishing: Is Regulation Needed?** was held in Reston, Virginia on September 17 and 18, 1998. The public meeting spanned one and a half days. That was followed by a half day Working Group meeting attended by representatives of each of the sponsoring organizations.

ACCE was a co-sponsor of the meeting as was ECRI, Health Industry Manufacturers Association, Independent Service Network International, American Society of Healthcare Engineering, International Association of Medical Equipment Remarketers, National Electrical Manufacturers Association, Medical Device Manufacturers Association, and the American Society of Healthcare Central Service Professionals.

In general, the meeting was very collegial with few instances of overt discord. The scheduled presenters had reasonable material although not much was strikingly new since the last presentations in June of 1997. Many of the participants in the audience participated actively, proposing questions to the various panel members. The FDA was well represented on the panels and in the audience as general registrants. FDA staff provided key presentations as well as queried the other panelists.

Last year at the AAMI Annual Meeting in Philadelphia, the FDA staff indicated that there were three possible options to consider:

1. A modification of the current Quality System Regulations developed for manufacturers applied to servicers and remarketers,
2. A voluntary system devised by the industry, and
3. Do nothing at all.

FDA staff clearly stated that the third option was not acceptable

Based on the presentations and discussion during the meeting, it appears that the FDA now realizes that there is no evidence of a problem involving patient safety due to the activities of services or remarketers. Mark Bruley of ECRI presented a comprehensive analysis of the records from the FDA's Device Product Reporting system. His detailed search of 750,000 records showed 241 incidents over the last twenty years where servicer error may have been implicated in an injury. There was significant discussion of the data and no challenge to its validity. Clearly it represents a very tiny percentage. Tom Bauld presented the ACCE's version of definitions for Servicers and Remarketers during that session of the program. Mike Carver of Premier and Elliot Sloane of MEDIQ/PRN provided succinct summaries of the compelling arguments against more regulations, focusing on the cost/benefit factors and the lack of any credible evidence of a risk to patient safety.

The Original Equipment Manufacturers (OEMs) have not been able to substantiate their claims of serious injuries or death due to the lack of regulation of ISOs. The HIMA spokesman presented a few anecdotes of device problems and a couple of staff injuries and attributed them as "due to ISO work", but there was no attempt to show a comprehensive study or analysis of manufacturer data to support an allegation of risk to patient safety. This was surprising in light of the fact that the OEMs have had three years to develop such data. Wes Morganstern, Deputy Director, Office of Compliance FDA / CDRH immediately questioned the HIMA representative about the lack of real data. The silence was impressive.

The OEMs do not appear willing to make any statements concerning the quality, reliability, or need for regulation of in-house service organizations since they are portrayed as the OEMs' customers.

The Working Group made up of a representative from each of the sponsoring organizations met Friday afternoon in an atmosphere that was cooperative and productive. The discussion was lead by an independent facilitator. The Working Group came up with a variety of methods to move forward in a voluntary environment. Details will be available later, but in general, the following was proposed:

1. Develop a Registry or Listing process for servicers and remarketers, with ECRI providing that service at no cost to the FDA;
2. Develop a glossary of terms used in remarketing and servicing;
3. Define levels of reconditioning;
4. Develop a method of labeling remarketed equipment;
5. Work to significantly improve the availability of OEM service documentation to owners and ISOs at a reasonable cost; and
6. Develop a Compliance Guideline to assist servicers and remarketers, as well as customers.

My sense of the attitude of the FDA staff members is that they will participate in continuing discussions of the Working Group and will evaluate the final proposals before taking any other actions. If they are satisfied that the voluntary course proposed is reasonable, they will probably support that process until some evidence of a real problem comes to light.

There is no definite timeline yet established. FDA staff indicated that they would assess the results of the meeting and in particular, the future activities and documents of the Working Group. Another meeting of the Working Group is likely in November. Any determination or decision by the FDA would appear to be months away.

All the participants supported AAMI's leadership in coordinating future meetings of the Working Group and uniformly expressed appreciation for the work done by Kathy Warye and other AAMI staff members in making this meeting a success.

New York City Metropolitan Area Clinical Engineering Directors Group

Ira Soller

Deborah Zane, Marketing Manager for Datascope, lectured to the Group on *Challenges of Monitoring in an MRI Environment* on October 27, 1998. ACCE Member Mike Mirsky of St. Luke's - Roosevelt Hospital Center hosted the meeting. After the presentation, the group discussed aspects of the Y2K issue, pitfalls of Y2K testing by hospitals, HDTV developments, and the latest JCAHO Environment of Care Standards. For information contact Ira Soller at 718-270-3192; 718-270-3194 fax.

People on the Move and in the News

ACCE Members Aid WHO

Of a group of 30 worldwide experts invited to Geneva, Switzerland by the World Health Organization, six were members of the ACCE. The group was created to participate in an informal consultation on creating sustainable physical infrastructure and technology support systems in developing countries and countries in transition. The consultation was held from 8 - 11 December 1998 in Geneva, Switzerland.

The result of the consultation will be a position paper and set of recommendations published by WHO and distributed to member countries. The position paper and recommendations will be used by public and private donor agencies, financial institutions, and Ministries of Health to establish policy and assist in creating sustainable physical infrastructure to support buildings, utilities, systems and equipment in health care.

Another meeting is tentatively planned for next year to monitor progress and refine the recommendations.

ACCE members who participated were Yadin David, Ph.D, Texas Children's Hospital, Houston, TX;

Antonio Hernandez, PAHO, Washington, DC;

Andrei Issakov, WHO, Geneva, Switzerland;

Thomas Judd, Kaiser Permanente, Atlanta, GA;

Robert Morris, Oregon Health Sciences University, Portland, OR; and

Kevin Taylor, Brigham & Women's Hospital, Boston, MA.

Dyro in Brazil

Dr. Joseph F. Dyro presented a three-day workshop covering the methods for selection and acquisition of healthcare technology in São Paulo, Brazil, October 4-6, 1998. The Workshop was the second in a series of workshop organized by Lúcio Flavio Brito of Engenharia Clinica, Ltd. In cooperation with SENAC, a countrywide organization dedicated to health education. Evanisa Arone, SENAC representative, provided kind and efficient support for the Workshop.

Dyro's program covered technology acquisition process; cost of ownership, utilization analysis and life-cycle cost analysis. Procurement steps included the bidding process and the development of purchasing documents such as requests for information, bid specifications, general and technical specifications, and requests for

proposals. Techniques for evaluation of vendor, equipment and technical support and for conducting clinical trials were taught. Negotiation, contract award, installation, acceptance testing, and user and maintainer training concluded the program. Detailed examples were drawn from Dyro's work in the acquisition of a physiological monitoring and clinical information system for a major university teaching hospital. The Workshop, punctuated by interactive assignments, was well received. Dyro included a discussion of the Year 2000 and the impact the date change might have on medical devices.



Dyro, Arone and Brito

The View from the Penalty Box

David Harrington, davesbt@kersur.net

While getting the equipment ready for this new hockey season I have had to replace several items in the equipment bag. At the sports store I compared the new equipment with my old equipment and found that there have been major changes in such basic items as shin guards and elbow pads. They are about half the weight and have better padding. This brought me to think about the changes that have occurred in medical instrumentation since I got involved some 34 years ago.

I recently came across a listing of equipment that some experts consider as top priority in the Y2K testing arena. More than 30% of those items were not invented when I started, about another 20% were still not in wide use. In looking at the list I thought about the conflict that is present in many hospitals relating to emergency power. Over 40% of the Y2K "hot list" of devices are generally not on emergency power in most hospitals. If these devices are not considered as "essential" to these hospitals why are they so designated by the Y2K experts? I believe that the Y2K "hot list" was put together by people who do not work in hospitals but are advisors to the "healthcare industry". I believe that they looked at capital costs and determined that if it is expensive it probably has a Y2K problem.

In one hospital group the outside consulting group reported that they would have to replace equipment valued at \$78,000,000.00 to be sure that they would have no Y2K problems. The clinical engineering group was asked to confirm the consultants' numbers and put a plan in place to get the new equipment purchased. The engineering groups dug their heels in and stated that the number was much too high. They started looking into the devices that were "selected" for Y2K replacement and found that most that had problems could be updated easily with software changes from the companies involved. Less than 1% would have to be replaced. The clinical engineers saved this group over \$77 M and were

rewarded by having their budget cut. Now the administration has come back and given the department funding to do the testing and upgrading needed. It should be pointed out that one part of administration that cut the budget was not aware that another part of administration was giving the department more work. The budget cut was reversed to level funding with the extra funding for testing and upgrading being put into a special budget. At least no jobs were lost.

The moral of this is very simple and can be expressed in the following truths:

- *Consultants are not always right;*
- *One part of administration does not always know what the other part is doing;*
- *Equipment has changed, both in medicine and hockey and we have to change with it; and*
- *Clinical engineers, not accountants, should be making the Y2K equipment decisions.*

Now it is time to lace up the skates and see how bad the knees got over the summer.

Happy Holidays!



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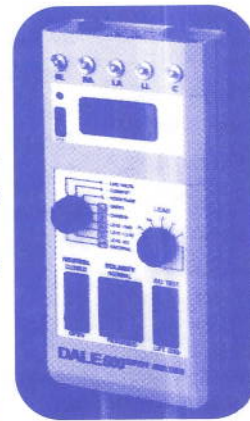


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ADVANCED CLINICAL ENGINEERING WORKSHOP

The American College of Clinical Engineers (ACCE)
The Biomedical Engineering Alliance for Connecticut (BEACON)

Hartford, Connecticut

June 10-12, 1999

Trinity College

A three-day workshop providing detailed presentations on management and business practices needed by all clinical engineering managers in today's healthcare environment.

Designed for current clinical engineering managers, technology managers, BMET supervisors and those interested in healthcare technology management.

Day One, June 10: Management Issues

- Performance Indicators for Clinical Engineering
- Improving Utilization of Service Resources
- Measuring and Improving Client Satisfaction
- Performance Improvement

Day Two, June 11: Business Practices

- Responding to Consolidations and Mergers
- Taking In-house Programs on the Road: Pricing Marketing and Support Strategies
- New Ideas in Vendor Management
- Developing and Administering Strategic Internships

Day Three, June 12: Team Building

- Motivation and Morale When Dealing with Change
- Art of Negotiation
- Accessing Competencies
- Career Development
- Leveraging the Intra/Internet (Supplementary Session)

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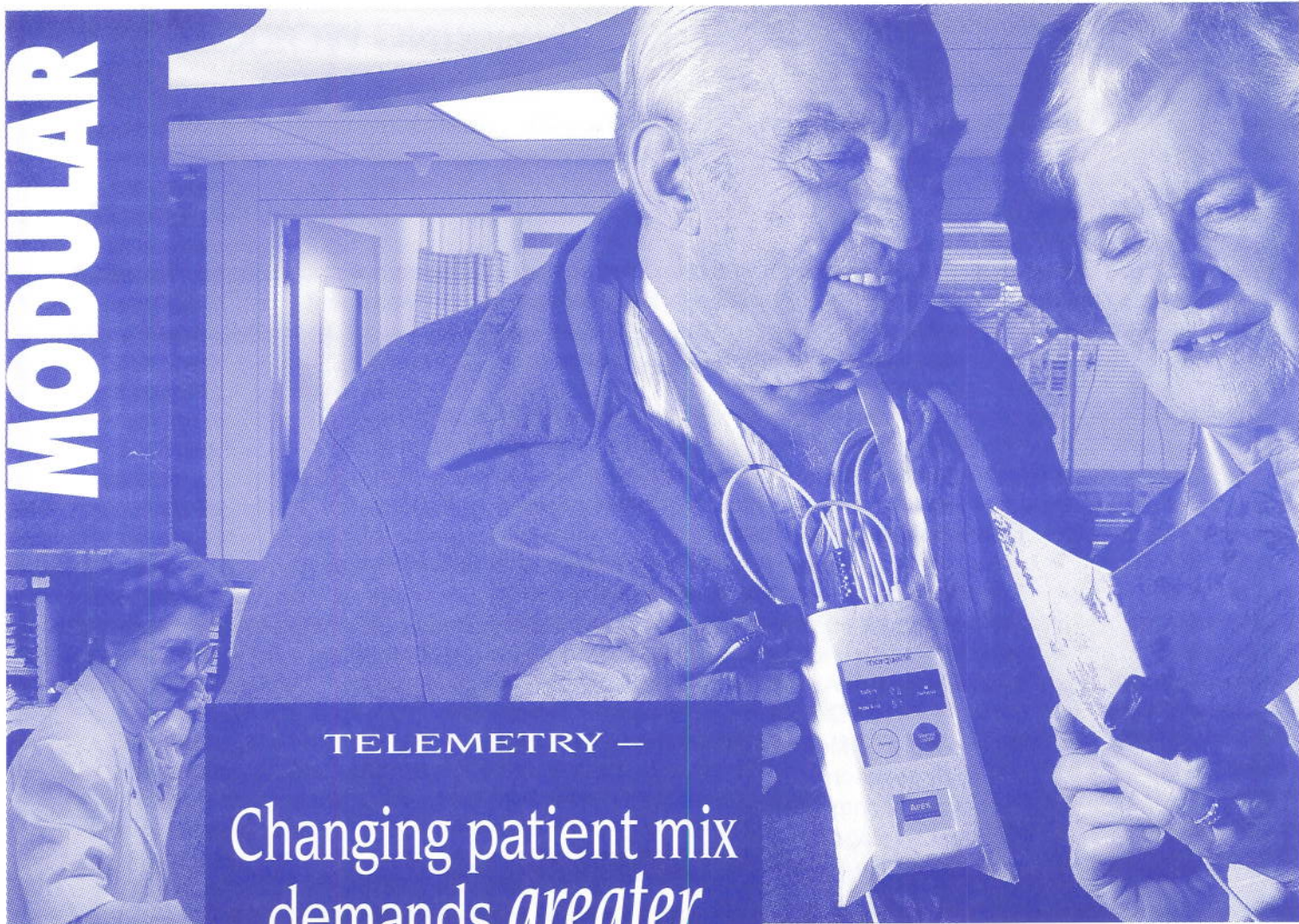
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ACCE News

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ACCE Partners with Telemetry Manufacturers, AAMI, ASHE, and the AHA to Recommend Spectrum Allocation to the FCC

Given the mandate of Congress to transition television services to digital technology over a period of several years, television broadcasters have begun receiving an additional frequency allocation from the Federal Communications Commission (FCC) to begin the transition to digital television (DTV). This additional allocation and use of spectrum has directly impacted the remaining frequencies available for use by medical telemetry. This shrinkage of available frequencies is particularly critical in certain geographical areas. As secondary unlicensed users of the spectrum, hospitals that utilize medical telemetry must endure any interference resulting from the primary licensed user's broadcasts. In an effort to alleviate the resultant shortage of spectrum, the FCC granted the medical community permission to utilize the 470-668 MHz bandwidth for medical telemetry. Unfortunately, there are no products available on the market which utilize this band and hence allocation of the additional bandwidth has no practical impact on the medical community's immediate ability to avoid interference. Additionally, telemetry manufacturers may be slow to introduce technology that utilizes this bandwidth given the impending expansion and redistribution of bandwidth for use by private land mobile communications.

Due to an incident at the Baylor University Medical Center in March 1998 where a large number of patient telemetry channels became nonfunctional due to interference from local DTV and the potential for other instances of major interference with medical telemetry from DTV and other sources, the FCC has developed both short and long term strategies for preventing a repeat occurrence of this interference. In the short term, the FCC has put a freeze on private land mobile radio spectrum changes due to the potential to cause interference with medical telemetry equipment in the 470-668 MHz band. The FCC also strongly recommended that broadcasters to voluntarily contact local healthcare facilities to inform them of plans to initiate TV services. In the long term, the FCC is making plans for investigating the possibility of medical telemetry equipment being given primary user status in a portion of the spectrum. In other words, some quantity of the frequency spectrum would be dedicated to medical telemetry, thereby eliminating the potential for interference from sources other than medical telemetry. In response to the FCC's request, the American Hospital Association (AHA) has established a Medical Telemetry Task Force to gather more information on the present and future requirements of medical telemetry equipment as it relates to spectrum allocation. Joseph P. McClain, Yadin David, and Caroline Campbell represent ACCE on this Task Force. Actively participating manufacturers include Spacelabs Medical, Marquette Medical, Hewlett Packard, and VitalCom.

The Medical Telemetry Task Force met in Washington D.C. on September 17th to devise a strategy for developing the requested recommendation. At this meeting, four areas of need were identified and working groups were formed to address each area of need. These identified needs were education of the healthcare community regarding electromagnetic interference, telemetry definition, parameters driving bandwidth requirements, and spectrum allocation. Three of these four working groups are under the leadership of the ACCE representatives.

The AHA and working group chairs made a presentation to the FCC on November 2nd to describe their progress on developing recommendations. Other interested groups present at that Forum included the National Association of Broadcasters (NAB), Industrial Telecommunications Association (ITA), Land Mobile Communications Council (LMCC), the FDA, and the National Telecommunication Information Administration. Although NAB, ITA, and LMCC were supportive of a dedicated allocation of the spectrum for medical telemetry, they conveyed some anxiety about the timeframes in which that allocation will be designated as well as the transition timeframes to utilize the newly allocated spectrum. Although they are complying with the FCC's short term measures taken to prevent interference with medical telemetry in support of patient safety, each of these industries have their own spectrum issues that need to be addressed and hence these industries are anxious to have the medical telemetry issue resolved.

Through November, the work groups have been busy gathering and analyzing information for use in developing their recommendations. Under the leadership of Yadin David, a definition for telemetry has been developed that is specific enough to eliminate use of the spectrum that is not related to measurement and recording of physiologic parameters and other patient-related information, yet broad enough to include technology to

accommodate a variety of telemetry service models. Under the leadership of Caroline Campbell, the physiologic parameters work group surveyed hospitals and professional organizations to determine their current and projected future telemetry needs. The spectrum work group, under the leadership of Stan Wiley, Spacelabs Medical, evaluated potential spectrum bands for accommodation of the required bandwidth. The education work group, under the leadership of Joseph P. McClain and Joe Martori of ASHE, is developing standardized educational material for use in a variety of forums.

The FCC desires to finalize its investigation within a few months and has requested the AHA to assist in that investigation and submit recommendations to the FCC by early 1999. The AHA plans to finalize its recommendations based on the outcomes of the work groups at a meeting in Washington D.C. on December 17th.

Telemetry System Interference Traced to Lighting Ballasts

Jay Hall and Bryanne Patail

In an attempt to save energy Beaumont Hospital, Royal Oak, Michigan inadvertently introduced a source of electromagnetic interference that caused a large telemetry system to fail. The hazard, its investigation, and successful resolution are described herein.

Beginning in May of 1998, a single telemetry system of 62 monitors on one floor had up to 60% of its channels simultaneously "dropping out." These drop out episodes continued to occur for as short a time as 8 seconds to as long as 6 hours. Dropout episodes would then cease with normal monitoring resuming. A total of 41 episodes were recorded. A central telemetry system with a separate and independent antenna system experienced three dropouts, two of which coincided with the 41 episodes. Such dropouts are hazardous to patients because clinical staff suddenly loses for an unpredictable duration the capability of EKG monitoring and alarms. Upon resumption of monitoring, unexpected and unpredictable as it is, the nursing staff does not immediately recognize that alarms are valid.

Using a Tektronix 2712 spectrum analyzer, the source of interference was localized to a section of the monitored floor. A directional Yagi antenna confirmed that the broad band noise, 100 MHz to 1.3 GHz, emanated from arcing contacts in several Touch-Plate Model 2500B relays in Hill-Rom fixtures and in several Hubbell 277/120 VAC 20A Spec. Grade light switches. Some of these switches were found on both the floor above and the floor below the monitored floor. At our request, Motorola tested their electronic ballasts, Models G2-RL-T8-ILL-277 and M1-RN-T8-ILL-D-277. Motorola stated that the ballasts operated normally and that they did not create the radio frequency noise. They did acknowledge, however, that their "rapid start" ballasts with "<10% Total Harmonic Distortion" have higher inrush currents than their "instant start" ballasts, i.e., the older and original style magnetic type ballasts. They stated that the "rapid start" ballasts with this higher inrush current might not be compatible with 20-year switching contacts. This insidious hazard began shortly after the installation of energy saving ballast for 277-volt lighting circuits. No failures have been detected on the 120-volt lighting circuits.

The switching contacts in both the relay and the wall switch create a faint buzzing sound as the electric arc jumps the gap. The area occupant is not likely to notice this. With the old magnetic ballasts, the light did not partially light. With the electronic ballast

the lights flicker or come on just enough for the occupant to finish the work at hand. While flickering lights are, technically, incidents that ought to be reported, in reality this is rarely done. The user typically considers such flickering too minor to worry about. Moreover the switch might subsequently work perfectly well confirming in the mind of the user that the problem was nothing to worry about. In the above case, such a "minor" incident points to a serious hazard.

PRESS RELEASE

(Effective 11/15/98)

From: Marvin Shepherd, PE
DEVTEQ Publishing Company
2977 Ygnacio Valley road, Suite 407
Walnut Creek, CA 94598

DEVTEQ Publishing is pleased to announce the transfer of ownership of the "Shepherd's System™ for Medical Device Incident Investigation & Reporting" publication from Lippincott, Williams & Wilkins Publishing to Marvin Shepherd and DEVTEQ Publishing Company in Walnut Creek, California. Shepherd's System is a practical guide to investigating device-related accidents, determining their "cause(s)", and preventing similar events in the future. It includes a guideline for implementing and reporting under the SMDA-90 and will incorporate JCAHO Sentinel Event investigation and reporting in early 1999. The Shepherd's System™ has been published since 1991 and has been used as a technical reference and educational resource by more than 750 healthcare organizations, ISOs, educators, manufacturers and distributors.

- For additional information on the manual, manual updates, and future plans, contact: Marv. Shepherd, at (925) 945-0137 or e-mail: marvins523@aol.com.

A Y2K Story

William Buckley, WILLIAM.BUCKLEY@NEBH.ORG

In the early years of biomedical engineering claims were made that many people were being electrocuted or shocked. The ensuing panic gave birth to the clinical/biomedical profession. Electrical safety became a major component in the healthcare industry and complex inspection programs featuring frequent testing intervals were created. The years went by without the alleged problems ever materializing. The programs established did, however, make the hospital safer. Later, it was empirically determined that the testing frequency exceeded the needs of the hospital. Safety testing shifted to more intensive preventive maintenance programs. An increase in the amount of equipment and technological improvements necessitated this.

Today's version of the electrical safety scare is the Y2K Problem. We need to show where our expertise can be applied in this area. It might not be easy with our resources and budgets strained as they are, but rise to the challenge we must. It is more than a challenge. It's a once in a lifetime opportunity for us to excel.

New England Baptist Hospital established a program to address this problem in December 1997. The designed program incorporated many of the ECRI guidelines on Y2K. Training for 52 managers/administrators was the first phase of the process. These managers and administrators included all departments at all levels including the president of the hospital. The second phase of the program was the creation of a Y2K Task Force to gain support and develop strategies. Phase 3 included developing an inventory of equipment in all departments. Phase 4 developed a Y2K risk inventory of devices. The next phase entailed letters to manufacturers that might have Y2K Problems. To maximize credibility this document was signed by the CEO of the hospital. While the letter writing is not difficult, the time delay for response can be exasperating. Letters should be sent to all manufacturers about whom you have concerns.

NEBH is part of CareGroup, a network of hospitals in the New England area. CareGroup hired a consulting agency to address the problem. Prior to this, the existing clinical engineering program had been studying the Y2K Problem. The consulting agency initially estimated that 80 million dollars would be required to bring the entire CareGroup into compliance. The initial figure was felt to be rather on the high end of the scale. Further analysis, deliberation and discussion saw the figure drop to approximately 27 million dollars. The estimate includes biomedical, HIS and facilities.

I felt that even this figure was high. The figure had been derived in part from the application of industrial standards to the Y2K Problem. Because the Y2K Problem is an unknown entity, such application of typical standards to Y2K is fraught with considerable uncertainty. Replacement cost estimates were an additional source of uncertainty. These figures were based on biomedical inventories and replacement of high end critical care equipment using ECRI "high costs" estimates of equipment. Up to this point the process was relatively easy. Now the difficult challenge begins!

What is a Y2K Problem?, I ask. While discussion of problems with microprocessor, dates and software abounded, no clearly defined instructions or guidelines existed. In fact a lot of

hyperbole had been expressed over the past several years. Clearly some of this hype was being used to generate the new Y2K Problem Industry. This was a combination of reality, fantasy and science fiction. You may as well call the Psychic Connection. This intentional inflation of the problem causes an organization and especially the CEO to worry enough about this problem that the resulting fear can be relieved only by spending large amounts of money to protect their institutions.

Y2K is not just about the year 2000 but is an examination of engineering practices used over the last twenty years or so. Problems come from software and hardware. Here are some examples of the problems we uncovered. A HP defibrillator defaults to the year 1985 when going into the year 1999. This has nothing to do with the year 2000 but was detected during the Y2K Problem process. An ultrasound machine handles year 2000 properly but does not have the leap year capability. To replace this device will cost \$123,000. A recorder does not display the date correctly but the print head is removable and eliminates that function. While all these are examples of Y2K Problems, it begs the question of significance. The question is one of cost versus risk. Does the hospital invest \$123 thousand for a new ultrasound machine or educate the staff that the existing machine does not display leap year properly in the next millennium? Does removing the print head cause any risk to the patient because there is to human intervention to record the date on the strip? But is additional risk taken by a facility that decides to do so instead of spending many thousands to replace the recorder?

These problems become more complex as you look at more complex devices such as x-ray and laboratory equipment. I don't have any clear-cut answers because we are still examining our own practices and methodologies. This entire process is being developed as we go through this process. I do have some advice, however. There is no right or wrong way to handle the Y2K Problem. Develop your strategy and stick to it. Don't spend inordinate resources on developing extremely accurate inventories when many of these devices will drop off of the inventory. Eliminate devices that don't pertain such as cast cutters, flowmeters, wheelchairs or any other device that does not have electronic capabilities. Prioritize to insure that critical items are handled properly first and then concentrate on lower priorities.

Don't hesitate to challenge cost estimates that appear outrageously high. Always remember that patient safety is the primary reason for addressing this problem. We test to insure that Y2K information from the manufacturers is accurate. Such testing can establish replacement needs and, perhaps more importantly and more often, alternate solutions. Strategies developed have involved modify clinical engineering practices by setting dates appropriately or modifying devices. The Y2K Problem is really about identifying problems and training appropriate personnel on what to expect and how to handle problems that will occur.

This problem dictates leadership by technical personnel because of its technical nature. Because the process should include risk management, safety and administrative input, it affords an excellent opportunity for team work and bridge building. Clinical/Biomedical Engineers have an opportunity and responsibility to make their facilities Y2K safe for the year 2000.

Carpe Diem!

ACCE News

HealthTech '99 Features ACCE Track

ACCE is pleased to announce that an ACCE Track will be featured at HealthTech '99 at the Baltimore Convention Center, Baltimore, MD, April 25-28, 1999. ACCE members will chair 12 sessions (see below). Speakers in these sessions are listed below and include many ACCE members. For registration call Lisa Narciso at 401-434-1270 Ext. 207.

- *Indicators of service quality* --- Greg Davis Mo Kasti, Wayne Morse, Dave Dickey **Monday, April 26**
- *Risk reduction and sharing* --- George Johnston, Marv Shepherd
- *Asset management/Outsourcing* --- Malcolm Ridgway, Frank Painter, Mark Brody, Tom Legacy, Mike Carver, Larry Hertzler
- *FDA's proposed regulation of servicers. The Sequel* --- Binseng Wang, Tom Bauld, Casper Uldriks, Elliot Sloane, Ed Kimmelman, Malcolm Ridgway
- *Servicer training* --- Manny Roman, Jim Wear **Tuesday, April 27**
- *Telemedicine & Wireless Telemetry* --- Yadin David, David Natale
- *Year 2000: Is now too late?* --- Tobey Clark, Bob Larkin, Thomas Shope, Jim Keller, Binseng Wang
- *JCAHO EC Standards: Interpretation challenges and improvements needed* --- Al Levenson Manny Furst, Larry Hetzler, Britt Beret, Ode Keil
- *International training* --- Elliot Sloane, Bob Morris, Antonio Hernandez, Tom Judd, Sam Miller
- *ISO-9002: Is it really applicable to CE Departments?* --- Dave Simmons, Tim Ritter, John O'Donnell **Wed., April 28**
- *Incident investigations* --- Mark Bruley, Marv Shepherd, Bob Morris, Joe Dyro
- *Manuals in CD-ROM* --- Al Jakniunas, Don Trambatore, John Reich, Ray Seblock, Dave Harrington, Gerald Zion, Dave Kaputa, Carl Dimario

Advanced Clinical Engineering Workshops in 1999

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ACCE / WHO / Association of
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Chair: Yadin David 713-770-1817

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Chair: Tom Judd 404-364-7140



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- Code of Ethics Plaque\$40
- Lapel Pin\$8

- Teleconference Audio Tapes (incl. handouts)\$30
 - Business Planning Simplified, Tom Zdon
 - Implementing CQI in a Cost-Conscious Environment - Lana Berry
 - Perspectives from a CE in Managed Care: Where is our Role in Healthcare Headed? - Tom Judd
 - Breakthrough Management - Gailord Gordon
 - Incident and Accident Investigations - Marvin Shepard
 - Benchmarking - Robert Stiefel
 - Cost of Ownership/Cost Effectiveness of Service Support - Denise M. Axelrod-Kahn
 - Tools for Technology Managers: Strategic Technology Planning - Yadin David, Ph.D.
 - Medical Equipment Service Contract Management - David Simmons

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Second ACCE Symposium

The Future of Clinical Engineering: Clinical Engineering & Information Systems

On Saturday, June 5, 1999, a panel of visionaries from a variety of backgrounds will lead a discussion of the future relationships between clinical engineers and hospital information systems departments. Methods used to develop partnerships between Clinical Engineering and HIS to improve the clinical engineer's position going into the future will be discussed. Adequate time is planned to maximize audience participation for questions and answers, brainstorming, and alternate points of view. The formal program will run from 9 AM to 12:30.

*This symposium is being held as part of the AAMI annual meeting
Sheraton Hynes Convention Center, Boston MA
When registering for AAMI, indicate that you wish to attend the ACCE Symposium*

For information contact Symposium Committee Chairman Brian Porras:
704-679-5056 phone; 704-527-5223 fax; brian_porras@premierinc.com

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Centralizing Monitoring Proves to be a 'Best Practice' at UAB

The University of Alabama Medical Center is an 812-bed academic medical center that encompasses five city blocks in downtown Birmingham, AL. In 1994, UAB was using a distributed approach to monitoring. Scattered in six designated areas throughout the facility were 122 critical care beds with some telemetry monitoring capability.

The problems

Each unit operated as an island and needed 75 full time employees to provide oversight for the distributed monitors. Internal patient transfers averaged five per patient stay. Doctors logged countless miles a day going from site-to-site to check a patient's status. Managing patient census to monitoring bed availability was a logistical nightmare.

UAB searches for a new approach

Working together, UAB and **VitalCom** took these steps to address the issues:

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- ***Existing monitors were connected to a single monitoring network.*** UAB can now view monitored information from nearly any manufacturer on the same PC. This created freedom of choice. Now all monitored information is integrated into the single PC network, regardless of the brand or manufacturer.

Visit **VitalCom** at www.vitalcom.com for other informative case studies and product information.

Calendar of Events

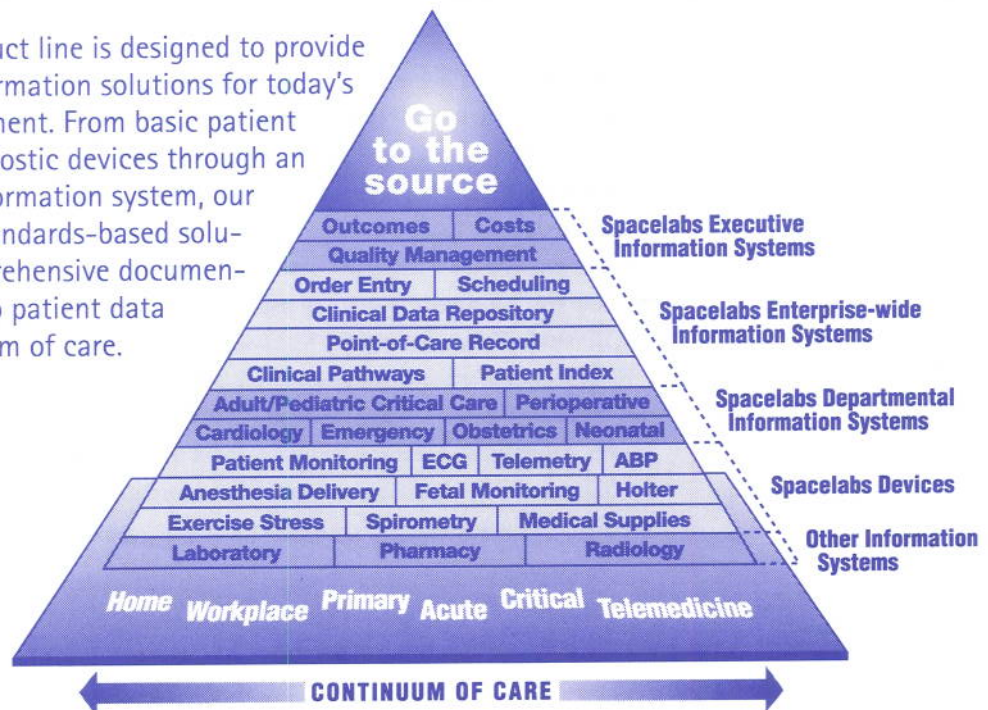
- AIMBE Annual Event, March 12-14, 1999, Washington, DC.
- 1999 Northeast Bioengineering Conference, April 8-9, 1999, Hartford, CT., 860-768-5079; nowak@mail.hartford.edu.
- 18th Southern Biomedical Engineering Conference and the 2nd International Conference on Ethical Issues in Biomedical Engineering, May 20-23, 1999, Clemson University, Clemson, SC. Subrata Saha 864-656-7603; ssaha@clemson.edu; www.techexpo.com/
- ESEM '99, The Fifth Conference of the European Society for Engineering and Medicine, May 29-June 2, 1999. <http://www.esem.org/esem.html>.
- 2nd ACCE Symposium The Future of Clinical Engineering, June 5, 1999, Boston, MA. Brian Porras 704-679-5056, 704-527-5223 fax.
- ACCE Annual Meeting, June 8, 1999, Boston, MA. Frank Painter 203-384-3388.
- AAMI Annual Meeting, June 5-9, 1999, Boston, MA.
- The 3rd International Workshop on Biosignal Interpretation (BSI99), June 12-14, 1999, Chicago, IL. 312-996-3422, (312) 413-0024 fax, bsi99@eecs.uic.edu.
- Eighth Annual National Expert Witness and Litigation Seminar, June 17-18, 1999, Hyannis, MA. SEAK, Inc. 508-457-1111; 508-540-8304 fax; www.seak.com.
- XXVth General Assembly of the IURS, Aug. 13-21, 1999, Toronto, Canada, 613-993-7271; ursi99@nrc.ca.
- BUDAMED '99, Sept. 13-15, 1999, Budapest, Hungary. <http://www.fsz.bme.hu>; arato@fsz.bme.hu; (+361) 463 2699; 2204 fax.
- 19th Annual Northeastern Biomedical Symposium, Nov. 8-10, 1999 Manchester, NH. Info: www.nnesbt.org.

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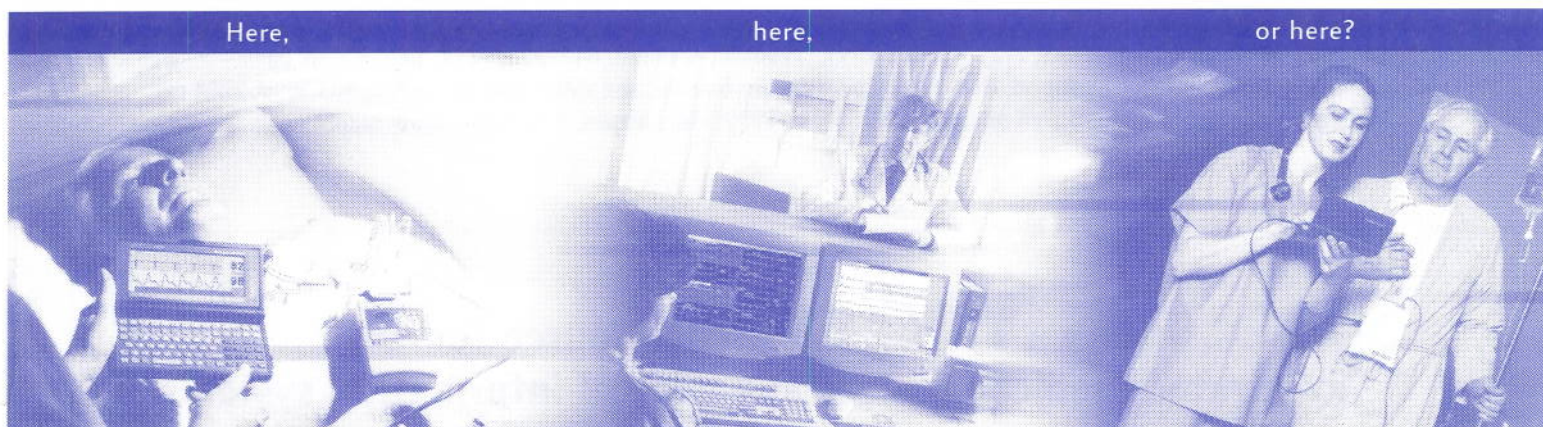


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