

ACCE News

Vol. 8, No. 5 – September 1998

Y2K Bugs Slow ACCE Presses

Your Editor, who up until this time has faithfully and reliably fulfilled his commitment to produce and mail the *ACCE News* on time, succumbed to the fearsome threat of Y2K phantasms. Lured into managing Y2K projects in two major New York and New Jersey university teaching hospitals, he found the fun part of his responsibilities slipping further and further into the background. His Y2K work successfully completed, he can direct all attention this fine fall weekend to the *News*. This is the September issue. Shortly after you read this issue, you will receive November's issue featuring the work ACCE is doing with the Federal Communications Commission, FCC, and the FDA on the vexing digital TV dilemma.

Morris Hits the Ground Running

Newly elected ACCE President, Bob Morris, pleased your Editor by promptly sending his President's Message to the *News*. See also Bob's Mongolia Report on page 5.

India's TGK Keeps Rolling Along
See Inside p. 14

Calcutta Survives Harrington & Morris, see p.10

FCC & FDA TACKLE DIGITAL TV

FDA and FCC have joined forces to address the problem of interference with medical devices caused by digital TV transmissions. See inside page 6.



International Clinical Engineering

This issue of *ACCE News* features reports from around the world concerning clinical engineering. Sam Miller, ACCE International Committee Chairman, has galvanized the Committee to action. Future ACEWs are planned. Opportunities for travel abound. The need is great. Read more see page 6 inside the *News*.

ACCE Board of Directors unanimously approves clinical engineering track for HealthTech '99.
Baltimore, MD April 25-28
Mark Your Calendars!

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

The First Report

The ACCE like any organization must evolve and change to meet member desires and needs and to respond to external economic, political and regulatory forces. To remain static is become less and less relevant to our members and community. As the President of ACCE, I will do my best to ensure the vitality and utility of the College.

We must expand the membership. No organization can survive without members. To that end, we (The Board of Directors) are developing new initiatives. Renewal policies are being reviewed to assist in retaining current members. Active efforts to recruit new members are being initiated. There is an impression among some of our colleagues that only Certified Clinical Engineers are eligible for membership in ACCE. This is not so.

A survey of the members to determine desires and priorities is being prepared and should be presented to the Members this fall. Kelly Galanopoulos, galanopoulos@msvax.mssm.edu, Membership Chair, Jim Wear, Wear.James@forum.va.gov, Education Chair, Bryanne Patail, bpatail@beaumont.edu, Treasurer, and Frank Painter, fpainter@novamedcorp.com, Past President, are leading the effort; but all members are encouraged to contribute.

ACCE needs ACTIVE members, members who will provide the personal time, effort and resources to move us forward. To this end, efforts will be made over the coming year to get more members involved in ACCE activities.

Brian Porras has been appointed Second Vice President. One of his responsibilities is to organize the Second Clinical Engineering Symposium to be held in conjunction with the 1999 AAMI meeting in Boston. Members are encouraged to contact Brian with ideas and suggestions for the Symposium, Brian_Porras@premierinc.com.

ACCE is involved in local, national and international education initiatives. To maintain and improve on our efforts, topics,

instructors and curricula are necessary. Jim Wear, Wear.James@forum.va.gov, Education Committee Chair, is currently soliciting potential topics and presenters for the 1999 audio teleconference series.

There is an Advanced Clinical Engineering Workshop (ACEW) planned for Hartford, Connecticut immediately following the 1999 AAMI meeting. If you wish to participate or attend, contact Joe Bronzino or Frank Painter, fpainter@novamedcorp.com. An ACEW will be held in Mexico City in November 1998. Contact Joe Dyro, jfdyro@aol.com.

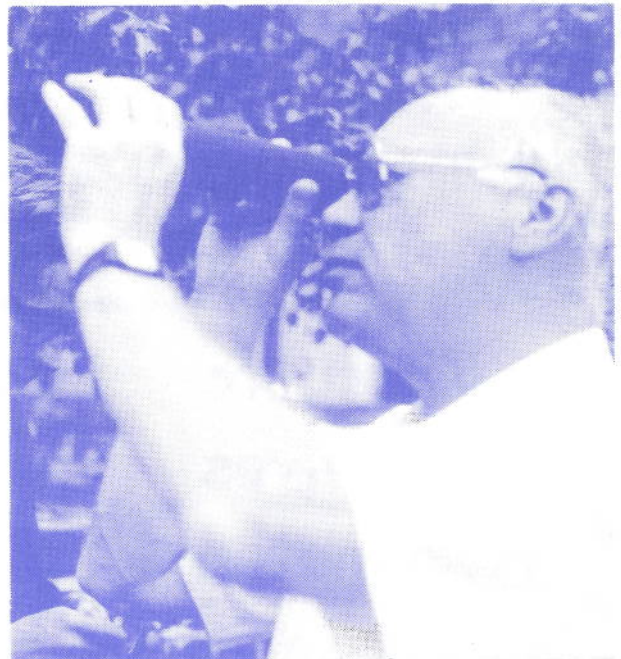
ACCE currently has requests to develop, participate or provide faculty for Advanced Clinical Engineering Workshops in Moscow, Moldova, Kyrgistan, Africa, Chicago and Kyrgistan. Speakers and faculty are required. Interested persons should contact Tom Judd, tom.judd@kp.org. Sam Miller is the International Chair, samiller@localnet.com.

In short, there are many opportunities for members to become involved in ACCE activities. The planned member survey will no doubt identify others than those mentioned here.

The ACCE website has a new look. Check it out at www.accenet.org. Bruce Morgan, jmorgan@ibm.net, is the webmaster.

This issue of the *ACCE News* continues the practice of having one issue each year that focuses on international activities. Joe Dyro, jfdyro@aol.com, is doing an excellent job of putting the newsletter together. A significant number of ACCE members are not resident in the USA. Our international members are active in ACCE. In the recent election, a large majority of international members voted as opposed to less than 40% of American members.

I encourage your comments, pro or con. Send them to Bob Morris, morris@ohsu.edu.



Bob Morris looks to the future

ACCE News

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

ACCE News is a benefit of ACCE membership; nonmembers may subscribe for \$50. To subscribe call (516) 751-7244.

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Letters

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Hungary hospital loses fine clinical engineer

Dear Joe -- I am very happy to have direct contact with you by E-mail. Excuse me my silence, but in the last two years many things have changed in my life. First of all I have changed my job and left

the hospital. The story is not too simple. If I try summarizing my decision I must write 3 things:

1. Clinical engineers do not have such a good reputation in the Hungarian healthcare system.
2. The facilities in which clinical engineers typically work are rather poor and not conducive for building careers.
3. The clinical engineer's salary is very low.

Any hope to change the situation was dealt a severe blow in 1997 with the "rationalization" in healthcare. "Rationalization" means the cut back of technical staff in the hospitals.

In May of 1997, I accepted the offer of SGS Hungary Ltd. to work on ISO 9000 issues as Medical Device Auditor. Fortunately, we have many medical firms among our clients and auditing hospitals will be part of my work.

On a personal note, I am pleased to announce the birth of my second child. My son Flórián was born on the 26th of March, 1998.

György Balázs
Hungary

Gyorgy_Balazs @sgsgroup.com

Clinical Engineering Advocate in India

Manya, Sanpadak, Nirdeshak Prof. Dyro -- For you and your ACCE colleagues I enclose the following information. TGK carries on with his income (monthly) never exceeding 30 dollars a month!!! I completed 67 years on September 5, 1998 and feel younger and younger to carry on. Hope we meet soon.

Dr. T.G. Krishnamurthy
Bangalore, India
Clinic@aicteb.emet.in

Ed. Note: One of TGK's articles is reprinted on page 15 of this issue.

Appalled by Ignorance and Arrogance

Sir -- Mark Bruley's "20-20" presentation on oxygen fires in surgeries highlights a problem in the education and training of medical professionals which clinical engineers can AND SHOULD address. Medical professionals, doctors and nurses alike, receive necessary scientific grounding in the life sciences but usually inadequate education and training in the physical or "hard" sciences. This produces situations such as the one Mark addressed where a doctor failed to anticipate the three basic ingredients necessary for a fire: fuel, oxygen and heat (the fire triangle taught by safety professionals to groups ranging on down to school children). Furthermore Mark raised the question as to whether 100% oxygen was even necessary. Apparently instead of reviewing the need on a case by case basis, 100% oxygen is simply routinely provided. Were there clinical engineering involvement, these questions would have been raised before the fact; and were such involvement ROUTINE this lack of physical science awareness on the part of medical professionals and the potential consequences would have been detected and training and other measures taken to improve the safety and efficacy of the health care delivery to the patient (the first-listed goal stated in the ACCE Code of Ethics).

This problem has grown concurrent with the ever-increasing application of technology in health care delivery. Nurses I have

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talked to recognize the need for more education in physics and electronics as part of their education, in order to prepare them better to operate the proliferation of high tech devices routine in their daily work. Yet at the same time I have encountered resistance from nursing school academicians to introduce course work that would provide that training. Is anyone aware of a nursing curriculum that includes such courses? I would love to hear from them.

Doctors can be even less prepared technically and grossly lacking in safety awareness and safety precautions. Some years ago I testified in an electro-surgical burn suit. The deposition of the doctor being sued was an incredible illustration of gross technical ignorance coupled with arrogance. I can best illustrate this with a few responses to questions put to him. And I leave it to ACCE and its readers as to how best address this problem.

Q. What was the Bard Power Plus 5000 being used for at the time the Plaintiff was injured?

A. Is that what the machine is called. I didn't know it was 5000. It is a Bovie machine we use routinely when we do surgery.

Q. Prior to Ms. _____'s surgery, had you ever read any manuals regarding the use of a Bovie machine?

A. No.

Q. Did you read any literature regarding the use of a Bovie machine prior to Ms. _____'s surgery?

A. No.

Q. Did you ever read any of the warnings on any of the Bovie machines

that you used prior to Ms. _____'s surgery?

A. No.

Q. Did you ever receive any verbal instructions in regards to the use of a Bovie machine.

A. No verbal instructions, no specific verbal instructions.

Q. Did you have an understanding of how the Bovie machine was to be used?

A. My understanding is that you get the pen. If there is a bleeding, you push the button and it should coagulate.

Q. Was this something you observed during surgery?

A. Yes.

Q. So your complete understanding of the use of the Bovie machine was your observation of its use during surgery?

A. Yes. Throughout residency a lot of things are done routinely and that is how you get training. You get the Bovie and you use it.

Q. Do you know if there is any direct contact between any part of the machine and the accessories, such as the pen that directly contacts the patient during surgery?

A. The only thing I know of is a pad which they usually attach to another surface of the patient's body.

Q. Does the pad have electrical energy going into it?

A. I don't know. The only thing I know is they usually say it is grounded, and that is the terminology being used in the operating room many times. But I don't know what it means.

Q. Is it your understanding that the use of the Bovie results in electricity being run through the patient's body?

A. I don't know and I didn't know.

A. _____ (response to a question and then this addition). I forgot to mention something. That it was not written in my progress notes and this was the last day of Ms. _____'s visit before she left. She hugged me.

Q. I am sorry.

A. she hugged me, she kissed me and she said she loved me, she loves me.

George Johnston
Portland, Oregon
Johnstog@oshu.edu

Status of Y2K Programs

Joe McClain

The following is a list of questions developed by the GAO to check status of Y2K programs. They might be helpful in developing your program.

1. Has the agency developed and documented a year 2000 strategy?
2. Has the potential impact of Y2K failures been documented?
3. Have IT management capabilities been assessed and documented?
4. Is the strategy supported by executive management? (not just CIO & IT professionals)
5. Has the agency identified and secured required resources?
 - a. Is there a documented cost estimate for all systems?
 - b. Have all costs been funded?
6. Does the agency have a program management structure in place?
 - a. Have roles and responsibilities of POCs and Year 2000 managers been defined and documented?
 - b. Is there a documented process for making resource tradeoff decisions?
7. Has the agency developed a detailed program plan?
 - a. Is there a master schedule for all phases and tasks?
 - b. Have common definitions of terms and processes been documented?
8. Does the agency have a comprehensive, documented enterprise-wide systems inventory?
9. Does the agency have a documented process for prioritizing systems?
 - a. Have business process (functional area) risk assessments been completed?
 - b. Have individual system risk assessments been completed?
 - c. Have agency-wide priorities been assigned to each system?
 - d. Is there a decision mechanism in place for resolving priority conflicts?
10. Is there a decision mechanism in place for resolving priority conflicts?
 - a. Have interface policies and responsibilities been defined and documented?
 - b. Have internal/external interfaces been documented?
 - c. Is there a mechanism for system managers to track interface resolution status?

- d. Have interface-testing procedures been developed and documented?
- 11. Has the agency developed test plans and identified needed testing resources?
 - a. Has a validation strategy been developed?
 - b. Have test plans been developed?
 - c. Has a standard definition of compliance been documented for testing purposes?
- 12. Has the agency developed and documented contingency plans for mission critical systems and activities?
 - a. System contingency plans?
 - b. Interface contingency plans?
 - c. Operational contingency plans?
- 13. What is the current program status and schedule?
 - a. Percent total systems in Assessment
 - b. Percent in Renovation
 - c. Percent in Validation
 - d. Percent in Implementation
- 14. Does the agency have a mechanism in place to validate reported status?



SENSITIVE DATES

David Bailey, Mayo Clinic

Here is a list of 35 dates (in YYYY-MM-DD format). Pick the ones applicable to your application. There will be others dependent upon unique application logic.

BEWARE: Problems can occur when running these types of tests on machines that have time-stamp sensitized programs such as scheduling programs (date activated file purges), demo programs, and shareware.

- 1899-12-31 => Verification of age and date of birth calculations test
- 1970-01-01 => Bank 30 Mortgages Overflow Test
- 1996-01-01 => Overflow Unisys Mainframe Test
- 1998-01-01 => Flag year 98 or 2 year horizon test
- 1999-01-01 => Flag year 99 or 1 year horizon test
- 1999-02-29 => Invalid Leap Year Test
- 1999-08-22 => Overflow GPS Week Counter Test
- 1999-09-09 => Special value: could be *test date* or *no expiration date*

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- 1999-12-31 => End of century rollover to 2000 not 1900 Test
- 2000-01-01 => Overflow 2-digit years test
- 2000-01-01 => First calendar day of new year Test
- 2000-01-03 => First working day of new year Test
- 2000-01-03 => Verify day of week roll over is Wednesday Test
- 2000-01-10 => First 9 character date Test
- 2000-01-14 => Backdated 5, 15, and 30 day calculations Tests
- 2000-01-31 => Last business day and calendar day of the month Test
- 2000-02-28 => Last month day in 2000 before first leap day of new century
- 2000-02-29 => Leap Year Test
- 2000-02-29 => Backdate 45, 60, and 90 day ranges Test
- 2000-02-30 => Non-existent day in 2000
- 2000-03-31 => Verify last business and calendar day for quarter end Test
- 2000-07-01 => Last business day of week Test
- 2000-08-01 => End of week processing Saturday Test
- 2000-09-01 => End of week processing Sunday Test
- 2000-10-10 => First 10 character date test
- 2000-12-31 => 366th day of the year Test
- 2001-01-01 => Twenty First Century Test
- 2001-01-01 => Overflow Tandem systems Test
- 2001-02-29 => Invalid Leap Year Test
- 2010-01-01 => Overflow ANSI C Library Test
- 2034-09-30 => Overflow UNIX time function Test
- 2038-01-19 => Overflow UNIX systems Test
- 2042-09-18 => Overflow IBM System/360 Test
- 2100-02-29 => Invalid Leap Year Test
- 0000-00-00 => Special value



CE NOTES FROM MONGOLIA

Robert Morris, morris@oshu.edu

Mongolia is a poor country, further affected by the current Asian economic crisis. The Asian Development Bank has provided several millions of dollars to purchase new medical equipment for the hospitals of Mongolia. The tender, issued about 1 July 98, for medical equipment had very poor over all specifications and no specifications at all concerning technical support or technical documentation. Since there is currently no organized support for medical equipment available in Mongolia, this will create predictable serious equipment maintenance problems in the future. The place is over run with NGOs all trying to do good deeds with no coordination, lots of overlap and concomitant waste of resources. Volunteer English teachers are taking jobs from Mongolians who did work for pay teaching English. In summary, everything seems normal for a developing country.

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ACCE International Committee

Sam Miller, Chairman

The core members of the committee are Al Levenson Frank Painter George Johnston Tom Judd and myself. Any who have an interest in serving as advisors to this committee please send your comments to me. The next meeting will be via telephone conference call on October 2nd. The agenda follows:

1. Opening remarks..... Sam's personal goals for the committee
2. Everyone else's quickie thoughts
3. Do we need to update the Committee's 1996 Mission Statement?
4. Which of the following tasks can/should we take on for this year:
 - continue work on George's brochure about ACCE's international activities,
 - explore funding for another workshop in China,
 - explore dues offset methods for CE's in economically depressed countries,
 - look at collaboration with CE organizations in other countries,
 - look at ways to share printed technical information with other countries,
 - and/or start a lending library of technical info.

Comments on the above:

Work on the brochure was essentially finished and it was ready for printing at ECRI. It would need the ACCE Board's approval first. The committee should review it first since it could stand minor updating.

I feel that the committee should only promote and encourage the workshops, but not take on the role of organizing and conducting them.

I myself am committed to setting up an email information list of ACCE members and CE's in other countries for the purpose of exchanging information about international CE projects, grant opportunities, CE seminars/workshops/meetings, regulations, equipment donations, visits, problems, needs, etc. Suggestions welcomed.

We should try to decide now on one or two of these tasks, and then explore methods, costs, timetable, and details over the next month or so, and meet again in early November to firm up the planning needed and see who can work on what aspects of it. I think that any task we take on should be one that can be essentially completed before the next ACCE Annual Meeting (June 1999).

5. Old/New business
6. Set a tentative date and time for the next meeting
7. Adjourn

BMET Brouard Off Base

Be aware of the latest efforts by BMET Alan Brouard of the Hermann Hospital in Texas to redefine clinical engineering. See his survey posted on the Internet. The latest version of his petition to Congress and the President regarding a Biomedical Week DID NOT include changes suggested by ACCE, changes that he indicated he would incorporate. Remarkably, his definitions for a clinical engineer and biomedical technician are identical.

Perhaps a few ACCE members may wish to enlighten Mr. Brouard who is clearly out of step with ASHE, IFMBE, EMBS, CEMBS, VA and ICC just to name a few organizations that have accepted the ACCE Definition of Clinical Engineer. You may find his efforts at the following:

<http://www.flash.net/~addman/bmet/petition/bmetweeksurvey.html>

Nordic Guidelines on Web

Ulf Bostroem, Ulf.Bostrom@lio.se

Nordic Guidelines for Good Clinical Engineering Practice can be accessed on the Internet. To find these recommendations go to the following address:

<http://www.uas.se/nmt>

Interference from Digital TV

When digital TV comes to your neighborhood it will definitely have an impact on any hospitals close to the transmitter.

Joint Statement of the Federal Communications Commission and the Food and Drug Administration Regarding Avoidance of Interference Between Digital Television and Medical Telemetry Devices -- March 25, 1998

Certain medical telemetry devices, such as cardiac monitors, are allowed to use TV broadcast channels that are unoccupied in their geographic area. However, television stations are now beginning to use these formerly unoccupied TV channels as they transition to digital television service. When this occurs, the digital signal may interfere with medical telemetry systems. Such cases of interference have occurred recently and fortunately no patients were significantly affected. The Federal Communications Commission and the Food and Drug Administration are taking steps to avert such cases of interference in the future.

Medical telemetry devices have long shared the TV broadcast spectrum on a secondary basis. This sharing can continue during the implementation of digital television. However, it is important to ensure that broadcasters, the health care community and manufacturers of medical devices have adequate information and take appropriate steps to avoid radio frequency interference.

The FCC and the FDA are taking the following actions to address interference to medical telemetry devices:

Federal Communications Commission:

□

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- * The FCC will ensure that TV broadcasters communicate with area hospital and other health care facilities to avoid interference to medical telemetry devices.
- * The FCC is contacting manufacturers of medical telemetry devices to ask that they assist their customers in determining whether they may be affected by new DTV operations and, if appropriate, assist them in finding vacant channels.
- * The FCC will provide easy access to information on spectrum sharing between DTV and medical telemetry devices on the FCC Internet web site. This will include a Fact Sheet and a listing of the channels that will be used for digital television service in each area.

Food and Drug Administration:

- * The FDA is sending a Public Health Advisory to all U.S. hospitals and nursing homes, alerting them to the potential problem and providing advice on how to avoid future incidents.
- * The FDA will work with medical device manufacturers to assure that medical devices are adequately labeled to alert users about the need to take steps to avoid interference.

Joint FCC & FDA:

- * The FCC and FDA will explore the long-term spectrum needs of medical devices so as to avoid future interference problems.
- The two agencies will work with equipment manufacturers and the health care community to consider various long-term technology improvements that might ameliorate the interference problem.

MEETINGS

Clinical Engineering in Bangalore

The Society for Biomedical Technology in collaboration with the Clinical Engineering Society organized a National seminar on Technology Management in Healthcare Systems, July 18-19, 1998 at Defense Bioengineering and Electromedical Laboratory, Bangalore. Dr. APJ Abdul Kalam, Scientific Adviser to Raksha Mantri, Secretary of the Department of Defense Research and Development, inaugurated the seminar. Over 100 participants came from hospitals, R&D institutions, medical and engineering colleges. The Seminar addressed the following areas: Healthcare delivery systems; Technology Management in hospitals; Hospital waste management; Energy management in hospitals; Safety-standardization-calibration of medical equipment; Information technology on healthcare management; Technology for basic hygiene and awareness; Technology for dental care; Technology education for healthcare professionals; Alternate systems of medicine in healthcare.

People on the Move and in the News

ACCE Board Election Results

Election results are in.

- **Bob Morris**, President,
- **Bryanne Patail**, Treasurer,
- **Jennifer Ott**, Secretary
- **Joseph McClain**, member-at-large
- **Caroline Campbell**, member-at-large

Congratulations!

Dr. Telemedicine Spans the Globe

Dr. Yadin David continues to promote the deployment of telemedicine systems around the world when he traveled on behalf of Texas Children's Hospital and Baylor College of Medicine to Venezuela, Mexico, Brazil, and Israel. Following the trip to Venezuela, the Venezuelan Consul General, Ambassador Mr. Gerardo E. Wills received a tour of Texas Children's Hospital lead by YD. While in Venezuela, he visited the Universidad Simon Bolivar in Caracas,

biomedical Engineering department and was the guest of DR. Lara Estrella, and Carabobo medical center and children's hospital. In Israel, he met with members of the Peres Peace Institute and discussed plans for using telemedicine to promote peace in the Middle East.

Dr. David, president of the Center for Telemedicine Law (CTL), will offer the welcoming and opening remarks at the first National Telemedicine Conference on Legal and Policy Developments. This is a joint conference between the American Telemedicine Association (ATA) and the Center for Telemedicine Law (CTL) is

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scheduled for October 8, 1998 at the Carlton Hotel in Washington, D.C. For more information call 1-202-857-6395. Among other issues the conference will cover are the telehealth device regulation and Federal policy update.

Wear Teaches in Hong Kong & Scotland

In November last year, ACCE Education Committee Chairman, **Dr. James O. Wear**, taught a graduate course entitled *Clinical Engineering* at Hong Kong Polytechnic University, Hong Kong. The 16 students Jim taught are on their way to the MS in Biomedical Engineering. In June of this year Dr. Wear attended the International Healthcare Engineering Congress in Edinburgh, Scotland, presenting a paper entitled *Future Maintenance of Medical Equipment and Technology*. He is off to the IEEE EMBS 1998 Conference in Hong Kong, October 29- November 1, 1998 to present Audioteleconferencing for Clinical Engineering Continuing Education, a part of which paper describes the ACCE audioteleconference series.

Porras ACCE Second VP

Brian Porras accepted the position of Second Vice President of ACCE. Among his many responsibilities, he is chief organizer of the Second ACCE Clinical Engineering Symposium to be held in Boston in June of 1999.

Mo Kasti Visits Editor

On a sultry summer day Mr. and Mrs. **Mo Kasti** honored the editor of the *News* with their presence. We had tea while catching up on the news then took an extensive tour of Setauket and surrounding hamlets. See photo on page 17.

Mo left STERIS and joined GE Medical Systems as an Account Manager for Service

responsible for the West Coast of Florida. He is responsible for the growth of GE service offerings including service on GE equipment, multivendor service, and clinical engineering services. So far, he has had great success in establishing high level partnerships with multihospital systems. His new phone is 813- 286-5500.

In Memoriam Michael J. Shaffer

Michael J. Shaffer, a founder and long-time member of ACCE, died this summer in Florida. A leader in clinical engineering throughout his long and illustrious career, Shaffer was Professor Emeritus of Anesthesiology, Department of Health Services Management and Policy, and had served for many years as Director of Clinical Engineering at George Washington University Hospital. He was widely published on all aspects of clinical engineering professionalism and was a tireless advocate for strong educational and experiential credentials. He championed the concept of exclusivity in engineering practice, *i.e.*, clinical engineering establishing a niche which only the clinical engineer can fill by virtue of his and her special qualifications. He shaped the Advocacy Committee and helped ACCE establish its philosophy with regard to the strict engineering qualifications he espoused. Shaffer was a frequent contributor to the *Newsletter*. His insightful, thought-provoking commentary will be sorely missed by his many friends and colleagues.

Wang Woos Brazil

Returning to his old stomping ground, **Dr. Binseng Wang** presented a three-day workshop on Technology Assessment and Strategic Planning in São Paulo, Brazil, August 14-16. The Workshop is the first 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.

Wang's program covered the principles and methods of strategic planning as applied to the implementation of healthcare services. He emphasized the need to define objectives; to utilize SWOT (strength, weakness, opportunity and threats); to collect competitive information; and to position oneself competitively in the market. He applied models to large, small, private and public hospitals. He described the essential elements of a health technology assessment program. The Workshop, punctuated by interactive assignments, was well received.

Participants look forward to the next workshop covering the methods for selection and acquisition of healthcare technology. **Dr. Joseph F. Dyro** will present these topics in October 2-4, 1998.

Recollections of Otto Schmitt

George Johnston

Otto Schmitt died last winter. In my efforts to get video interviews with our pioneering historical biomed/CE people, I had asked **Tom O'Dea** to interview Otto. That was almost two years ago. Tom was personally acquainted with Otto but said he had not seen him for a while. Turns out Otto had developed Alzheimer's, but Tom was still optimistic as Otto had good lucid moments. We never got the video; Otto worsened and died last winter. Considering Otto's pioneering contributions to our field as well as electronics in general, it would seem appropriate to put something about him in the newsletter. For in-stance, we all know he developed the Schmitt trigger, but how many know he also created most of the other wave generating circuits including the multivibrator, phantastron, one-shot, and the dc amplifier? Then there is all the work he did on vector cardiography with his "cupie doll" as his illustrating mechanism. Tom attended Otto's funeral and heard a lot interesting tributes to Otto citing his early work.

Advocacy Award Update

We announced the winners of the Advocacy Awards last issue but failed to mention the achievements that prompted the awards. **Marvin Shepherd** won the Professional Achievement Award for his presentation, *Investigating Equipment-Related Incidents and an SMDA Update Risk Managers and Clinical Engineers-Working as a Team*, presented at the CHIC/TDC Risk Forum on June 11, 1997 in Pomona, Ca., sponsored by the California Hospitals Affiliated Insurance Services Inc. (CHAIS). In this presentation, Marv builds upon the groundwork of his classic 1992 article in *BIT* and presents the methodology of equipment related accident investigation common in clinical engineering practice to

an entirely new group of health care professionals. Marv's diligence and expertise in this area over the years show clearly in this presentation and significantly advance the profession.

The Professional Development Award went to **Michael J. Shaffer**, Professor Emeritus of Anesthesiology, Department of Health Services Management and Policy, George Washington University, Washington, D.C., for his article, *Clinical engineers: A vanishing hospital resource*, published in *Hospital Topics*, Vol. 75, No.2 Spring 1997 by bringing the consequences of the perceived decline in clinical engineering and thus the exodus of clinical engineers from the hospital sector to the attention of the hospital administrative community, Dr. Shaffer performed a valuable service to not only the clinical engineering community but to the healthcare system as a whole. Dr.

Shaffer's dedication and experience shines brightly in this publication. Dr. Shaffer's article shed light on a startling fact derived from the AAMI records that only 40% of all certified clinical engineers have maintained their certification.

Dickey Delights Dysko

Dave Dickey describes the success of Medical Technology Management in the August issue of *Health Facilities Management*. Client Advocate Health Care's technology manager, Joe Dysko says MTM helps hospitals save money and improve equipment quality by establishing in-sourced clinical engineering programs.



The View from the Penalty Box

David Harrington, davesbt@kersur.net

Most of us have completed our vacations and are getting ready for a new capital purchase cycle starting in October. We have had the meetings with the users, gotten budgetary quotes and started to plan the installation schedule of the new equipment. On top of this, many administrators have learned a new term, Y2K, and they seem to think that devices will fail on January 1, 2000. Even in many of our publications we are reading about all the "potential" problems that will occur on that date. Infusion pumps, ventilators, and other life support items will fail. Diagnostic equipment will not power up, the medical record systems will crash and most importantly billing for patient services will be stopped. Administrators are getting close to panic but they still, generally, have not provided the budget for additional personnel to handle the new equipment installations, investigate if Y2K will actually be a problem and to keep up with our normal workload.

In following the Y2K stories it is surprising, at least to me, that some companies will only correct the Y2K problem in their equipment if you purchase a full service contract from them. I have seen several that are offering flat rate "upgrades" to the software but never say what the upgrades involve. If they are anything like Windows 98 we can all look forward to numerous problems with older data that may be stored in the system. Several of our members have published articles saying that the Y2K problem is very much over stated and others have published saying it is understated. All I know for sure is that on December 31, 1999 I will not be on a plane or hopefully in a hospital but sitting back watching what happens. It is probably good planning to avoid areas that could be affected but until we have some better information all we can do is to try to avoid the potential problem areas.

Presently I am involved with the development of "turn key" manufacturing facilities for the developing countries. The products that are being manufactured are simple products, IV solutions, tubing, needles, syringes, etc. The main push has been to take existing commercial equipment and modify it for the manufacture of medical devices. In doing the preliminary work it was an eye opener to learn of all the good commercial equipment that can be used in medical areas with little or no modification. The quality of the final product often exceeds the standards set by various agencies but the manufacturers simply do not want to have to file all the reports, maintain additional records and do tracking so they avoid medical applications for their products. Also many of the manufacturers will not use many of the common items that are used in medicine, such as PVC, because they are dangerous both in the manufacturing and in disposing of them. With cost escalating ever higher maybe it is time to reassess how medical equipment is manufactured and move toward the technology used in other areas. Are the regulations adding to costs and impeding innovations in our field? Maybe once the pressure of Y2K is over we can all look at our simple products that we use every day and start coming up with better products. The push should come from the users not industry or it will be like the early 1980's in the automotive industry where imports captured more of the market while the big three all were saying "you like this product in the past."

The future is ours, if we want to get involved with pushing the technology envelope instead of being pushed by the envelope.

Wandering Clinical Engineers

David Harrington & Bob Morris

On the last weekend of June, two teams left the United States for Calcutta with a plan of action to install a cardiac cath lab, a 10-bed ICU, and an operating microscope in 10 working days. What we didn't know at the time was that the dedication ceremony was set for the 8th working day. The team from the left coast arrived first on a Monday afternoon after over 30 hours in transit to find the cath lab in pieces scattered over several rooms in the basement of the hospital. They set about getting it a little organized. Bob Pagett, President of Assist International who organized the trip, headed this team. He was made an Honorary Biomed several trips back, Bob Morris from Oregon, Mike Persaud from Washington and Ruben Valdez, a nurse from Salinas Valley Hospital in California. On Tuesday morning the team from the right coast arrived, Bill Kelleher and Dave Harrington and the work started at a frantic pace. What was a little scary is that the team had no pre-trip meetings, just phone conversations. Bill Kelleher and I had worked together at the New England Medical Center 20 years ago, Bob Pagett and Bob Morris had done several projects together in the past, as had Bob Pagett and I.

Bill and Mike being the radiology experts attacked the cath lab, as illustrated in the photo, this is no small unit and everything was on the floor. In addition there were no power lifts available to pick up the units and put them in place. So with block and tackle, bamboo levers and a lot of muscle power the L arm was put in place, about 3,500 pounds. Next the C arm had to be mounted to the L arm, again using the same methods. It was a wonder that someone was not hurt in the process. There was at least two dialects plus English being spoken in the room, often at a considerable volume. But everything got into place.

Since the ICU installation was so simple we delayed starting that for a few days so we all could be in the cath lab working. Once we started on the ICU and physical labor was required, one well-known engineer went down with a bad back that got him a day in bed while the rest of us struggled on.

The microscope went in with no problems and Ruben was asked to look at several other units that they were having problems with. On one the optics were so dirty the surgeon had the light source turned to maximum. Once the optics were cleaned the surgeon could not believe that it was the same unit. We trained the hospital staff on how to clean the optics.

With Bill and Mike doing most of the wiring in the cath lab, along with two of the hospital engineers Bob Morris and I worked other parts of the lab and repaired other items that were brought to us, along with completing the ICU installation.

At the end of the first week the cath lab was standing and most of the power was in place and the rest of the equipment was installed and being used.

On Monday an old friend, Ken Wade, late of Spacelabs, came out of the hills of India, where he is living and working with a group of hospitals to join the team for a few days. We were at a critical point in that the dedication of the Cath Lab was Wednesday afternoon and the unit had to look good and the room had to be painted, new floor put down and all the wiring covered. So it was two long days of getting as far along as possible before the covers went on.

On Wednesday afternoon the dignitaries descended on the hospital for the dedication of the cath lab in honor of Mother Teresa. Many of them had participated in her funeral, last year and

it was a great feeling to know that we had accomplished something in her honor.

On Thursday the covers came off and the final wiring, startup and calibration began. Everything was going well until a missing 12-volt power supply was discovered. For two days we tried to work around the missing power supply and were somewhat successful, but the final calibration could not be completed until the missing supply was installed.

On Friday afternoon we went over what was left to be done with the local service organization, organized the documentation and cleaned up as many loose ends as possible. The two engineers at the hospital were left with a list of items to be done and everything is being supported by e-mail. The first patient into the cath lab will be about the first of August. The ICU is fully operational and the nursing staff was comfortable with the equipment. The microscopes were all working so we left the hospital in better condition than when we arrived.

As the team said their good-byes we talked about where we all were heading. Bob Morris headed directly to China and from there on to Mongolia. Mike Persaud learned that the job he applied for in Germany came through which meant he had to pack up his family and move. Bob Pagett is scheduled to do projects in Albania in August, plus several others later in the year. Ruben used all his vacation time so he had to return to work. Bill returned to retirement and I have projects in Romania, Hungary, Egypt and Russia to keep the frequent fliers piling up.

Two semi-retired clinical engineers, a retired radiology engineer, a working radiology expert, a nurse, and the President of a Foundation joined forces with dozens of in-house engineers and technicians (see page 16 for pictures of the lab and the team) to complete a project that will help thousands over the next 10 years. Clinical engineers have again made a difference in the world, but like a tree falling in the forest nobody heard. It is time to spread the word that clinical engineers do make a difference in health care.



Bob Pagett, Bob Morris, and Dave Harrington

STATE OF THE CLINICAL ENGINEERING PROFESSION

The CE profession is an active national and international force that partners with other healthcare professionals to introduce efficiencies, introduce and manage a wide range of technologies, and provide the unique expertise that assures safety and performance of patient care technologies. Clinical engineers have vast technical talents that promote efficiencies in health care and improve the conditions that assure the safety of patient and staff.

CEs evolved from bioengineers working in university labs, to BMEs, to CEs managing maintenance programs, and to technology managers. That all of these groups still exist in lesser or greater numbers bespeaks of the complex health care environment that requires diverse talents and abilities.

Divisions exist within the ranks. Since 53% of all clinical equipment maintenance and 67% of all biomedical engineering is now performed by outsource groups, ACCE must identify itself as the recognized leader of all. In-house groups and outsource groups must picture themselves as promoting a competitive product but with customer satisfaction and bottom lines as the final arbiter of an acceptable product. Changes will continue to occur in the entities providing maintenance to health care such as partnerships, outsourcing and co-sourcing.

CEs are not just responding to the changes in managed care, they are leading the charge! CEs frequently develop new paradigms for effectively and efficiently merging new technologies into healthcare such as streamlining in-house programs (Tackel, Hertzler, Bauld), developing partnerships (Dahl, Hertz, Ridgway), developing asset management teams (COHR, NationalMD, ServiceScope). Where do shared engineering groups fit into this...perhaps a bit of each?

CEs play a vital role on the international scene. Harmonization and the Internet are breaking down barriers that allow us to interact with and learn from activities and models in other countries.

Where should we going in the future? What steps do we need to take? Permit me to blue sky a bit! Ponder the following!

- What are we going to do to help support technology in homecare?
- Patient "self-care" is emerging; how can ACCE help this new market? Should ACCE reserve a section of the webpage to answer technical questions related to pacemakers, monitors, infusion pumps, and the like, for interested lay persons. Can we offer this as a public service?
- What additional effects will telemedicine have on healthcare?
- What new technology support entities are on the horizon such as co-sourcing?
- What other measures of the influences of CE s on health care should be developed?

REFLECTIONS

George Johnston, johnstog@oshu.edu

At the AAMI 1998 Awards Luncheon I heard Adrian Kantrowitz, in his Dwight Harkin Memorial Lecture, credit Dwight Harkin and Arthur Bell as pioneers in artificial heart valve development. While I do not disagree with their contributions, it occurred to me that much history in medical technology development is being lost in antiquity. For instance, one of the earliest pioneers in artificial heart valve development of whom I am aware, was Stan Sarnoff at NIH in the early 1950's. Wendell Stainsby and I both graduated from Johns Hopkins in 1955, he with his Ph.D. in cardiac physiology and I with my B.S. in electrical engineering. We both

went to work that summer at NIH; he in Stan Sarnoff's laboratory and I in what was then known as the Instrument Section, now the Biomedical Engineering Instrument and Development Branch. Stan and his group had developed an artificial aortic ball valve, employing an acrylic ball, and had been implanting them in research dogs. Wendell took one of the dogs, a collie named Sissie, home as a pet while following her progress. She survived well, having two litters of pups. On Friday evenings I often played bridge at Wendell's house and used to listen to Sissie "clicking" away on the living room floor.

Before I left NIH in 1958 to set up a biomedical instrument support facility in Oregon, I had heard that Hufnagel, then at Walter Reed, had performed some aortic valve replacements in patients with cardiac disease. I was not aware until recently that the "Hufnagel Aortic Valve" was an outgrowth of Sarnoff's earlier ball valve development work. Consequently when Al Star, another pioneer credited by Kantrowitz in his Awards Luncheon speech, came to Oregon in 1959, also from Johns Hopkins, and was having difficulty developing an artificial mitral valve employing silastic leaves or flaps, I suggested he abandon the leaf approach and employ a caged ball similar to the "Hufnagel" valve. He suggested I make him one, which we did, in my shop. The next day after implanting that valve in a dog, he came to my shop ecstatic - the dog had survived eight hours, four times longer than any previous leaf valve implant. From then on he and Edwards concentrated on ball valve technology in their very successful pursuit of an artificial mitral valve.

The 1950's saw the evolution of a number of biomedical instrument development and support centers throughout the country, mostly in medical research centers, some with affiliated hospitals and a few in major hospitals without direct medical center affiliation. Most of the instrument and technology development work was research based with an eventual trickle down to clinical usefulness, but occasionally there were requests for immediate clinical support. As example in my own experience, shortly after I opened my Oregon University shop, a local obstetrician approached me with a pregnant diabetic patient. Because of her diabetes she had twice previously miscarried and was currently in the sixth month of a third pregnancy. So far the fetus was fine, but as Dr. Marshal explained, he needed a means of continuously monitoring the baby's EKG. As soon as it developed signs of distress he intended to take it by Cesarean. The hope was to get the mother past the seventh month. But how to effectively monitor? The fetal EKG was clearly evident mixed with the maternal but one could not run the EKG continuously. Could I rig a timer to take a short EKG sample periodically? This was easily done with the addition of two Microflex timers cascaded to allow a short strip to be run every hour or so on a portable Sanborne ECG machine. Dr. Marshal was able to follow his patient well into the seventh month before signs of distress appeared at which point he delivered a healthy baby by Cesarean.

One success often leads to additional requests. A member of our obstetrics faculty decided a "fetal tachometer" would be a highly desirable clinical instrument. Using early vacuum tube pulse height analysis circuitry I was able to construct a window that could be adjusted to recognize the fetal EKG distinct from the maternal, integrate those pulses into a DC signal which we displayed on a large meter as beats per minute. The major problem was how to verify the instrument's performance and calibrate it without a biological signal source or a simulated signal. Enter Exact Electronics, a company often thought of as a Tektronix spin-off, having been started by some ex Tektronix engineers. They had just introduced their new 50-point (build your own signal waveform) signal simulator to the electronic instrument market and loaned me one to test and calibrate my fetal tachometer. In return I wrote an article for *MEN* (*Medical Electronic News*) which included a picture of their instrument on my test bench. I suppose this could be considered a forerunner of today's

biological signal simulators.

It is interesting that occasionally biomedical research needs impact the electronics test equipment business. Exact Electronics in Hillsboro, Oregon, along with Wavetek, were two major manufacturers of function generators, sine/square/triangle waveform producers. At that time only continuous waveform generators were marketed. One of our neurophysiological researchers, studying cat auditory systems, wanted to present short tone bursts to the animal, but without the "click" which would randomly occur according to what part of the sine wave signal it started from. Could I provide a tone burst that always started at zero degrees/zero volts and ended the same? I took this problem to George Evelsizer, Exact's chief engineer, and we mulled it over for a while at the blackboard in his office. Finally he said, "Yes, we can do that," and to my knowledge thus was born the first gateable/triggerable function generator, which was introduced as part of Exact's product line the following year.

The University of Oregon Medical School faculty was very enthusiastic about having an instrument design and development group at their disposal. One of the most enthusiastic was Dr. Charles Dotter, professor and chairman of the radiology department. Charlie asked to meet me shortly after I arrived and impressed me as the most hyper individual I had ever met, but also the most imaginative. He is considered the father of cardiac catheterization and eventually was so recognized on the cover of Radiology Magazine. One of his earliest requests, and what started him down the catheterization road, was for what we later called his "rotorooter," a small augur welded onto the end of a Volkswagen speedometer cable (and I have no idea why a Volkswagen as opposed to any other as I don't believe there is a significant difference in diameter). With this he was able to unblock a lower limb artery in a patient and save the leg. And this started him on his way although we made no more catheters for him as he considered our services too expensive (an almost universal complaint of instrument service departments of the time).

During the late '50's and early '60's I was able to meet a number of biomedical engineering service department colleagues around the country through the IRE's (Institute of Radio Engineers) annual fall "Medical Electronics Group" meeting - later through merger with AIEE (American Institute of Electrical Engineers) to become the IEEE's (Institute of Electrical and Electronics Engineers) Engineering in Medicine and Biology Society. We would share our experiences, our triumphs and our problems. It also helped to know who was working on what for possible future help. Often the triumphs of a particular group resulted in, or contributed to, a marketable product. Don Baker was the engineer working in Dr. Rushmer's laboratory at the University of Washington in Seattle on the development of Doppler flow technology. I'm sure there are many similar stories of small laboratory research developments as sources of major commercial products during this period, which I refer to as the "golden years" of NIH funded research. Baker had his group in Rushmer's laboratory in Seattle, Carter Collins, replaced by Emil Barrish had the R&D laboratory at the University of California Medical Center in San Francisco, Mat Petrovick had a group at Northwestern in Chicago, Jim Bray had a group at Baptist Medical in Memphis, Larry Mills had his "Biomedical Physics Department" at Good Samaritan Hospital in Portland, Oregon; other engineer design/developer individuals left to go with specific researchers, like Tom Arnold went with Elliott Neuman from Johns Hopkins to Vanderbilt and Bob Bosler left Hopkins to accompany Steve Kuffler to Harvard. George Webb, who did so much design work on early VCG's and BCG's under Sam Talbot at Johns Hopkins, stayed on after Talbot died and ultimately became "Mr. Clinical Engineer," remaining there until his retirement. At this point it is hard to know the magnitude of the contributions of all these pioneers. This was a time when few commercial biomedical and clinical products existed and often one

laboratory or laboratory individual moonlighting would manufacture a product for others. Again as example I remember Earl Sandbeck and Johnny Armant at Johns Hopkins in the '40's and 50's supplying most of the country with hand-crafted "ear oximeters," forerunner of today's pulse oximeters; my glassblower in Oregon was a major supplier of glass tear duct tubes. Tony Bak at NIH had a thriving sideline in his negative capacitance microelectrode amplifiers. My grandfather at Johns Hopkins, as a sideline, used to make tangent screen targets for ophthalmologists (long before today's computerized visual field test equipment). Also certain commercial products such as General Radio's 611B bridge transformers became the standard as isolation transformers for electrophysiological research. Tektronix's 160 series pulse and waveform generators along with its 360 indicator oscilloscopes and 110 low-level amplifiers also became standard equipment for electrophysiological research throughout the world.

Biomedical engineers of this period also investigated any new technologies introduced as possible useful solutions. I remember Tony Bak showing me a "beam capadyne" device as a potential microelectrode manipulator. This was a small rectangular sandwich of piezoelectric material that could be distorted in very precise micron increments by the application of high voltage. Apparently it could not be made reliable, as I am unaware of further development. Bob Morris, in my department, was always purchasing new gadgets for investigation, often to provide beneficial future solutions to problems.

Today's researchers and clinicians have an abundance of commercially available products and no longer require as much support in the design and development arena, although there is still a frequent need for custom modification or integration of multiple units. The major growth for engineering input is the technical evaluation and choice of systems to be exploited in the most efficacious, economical and safe manner for the health care provider.

Report from Estonia

Siiim Aid

The current comprehensive technical assessment Survey of Estonian Hospitals and Clinics provides the following preliminary results:

- There are 98 locations, where X-ray diagnostics is performed. Of these 80 are hospitals and 18 outpatient centers (polyclinics). Most of the institutions are municipal, some 10 are state owned, and 5-7 are private.
- The total number of stationary big X-ray machines (mainly R&F Rooms) is about 140.
- The total number of X-ray tubes (on stationary and portable devices) in Medical Imaging is approximately 450-550.
NOTE: The exact number depends greatly, what to consider as an X-ray device in working order. Some of them are making very low quality pictures, but are considered to be working devices.
- Out of the X-ray machine total number, some 25 % (23 units of stationery equipment) are new (less than 4 years). Manufacturers are Siemens, Philips, GMM, Shimadzu, GE, and Toshiba.
- Approximately 20 % of equipment were obtained as used or humanitarian aid (age: 8-30 years). Manufacturers are Siemens, CGR, Shimadzu, Picker etc.
- Approximately 55 % of equipment are from previous Eastern Block: Russia, Hungary, GDR, and Czechoslovakia (age: 7-25 years).

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- Condition of the Eastern Block equipment (55%) and Western used and humanitarian aid equipment (20%) is poor. Most of this equipment surveyed have a lot of quality problems (on the average, some 7-10 problems on every device). These problems are described in a separate paper¹. Most of the defects are minor problems with grids, scales, pointers, one phase of power line absent, unregulated kV and mA, etc. A number of devices have more difficult problems: unstable kV, sparks in the tube, excessive radiation, etc. Proper functioning of these machines is important, as they provide countrywide geographic coverage and handle approximately 40% of the total imaging workload.
- Condition of the recently purchased Western technology equipment (25% of total) is generally in much better condition. Nevertheless about 30% of devices in this group are in process of degrading because of weak or non-existent manufacturer's support. The remainder of new equipment (about 15-17 stationary X-ray devices) enjoy well-qualified manufacturer's service support and are, therefore maintained at a level that is close to specified performance.
- The overall situation in the hospitals and clinics is also aggravated by the lack of quality control processes to ensure adequate feedback about the safety and quality issues.

Current situation – medical equipment infrastructure

- After Estonia regained independence in 1992, the centralized government organization that provided servicing of Eastern Block medical equipment was abandoned. There are currently some 6-7 engineers in Estonia, specialized on X-ray equipment and capable of solving major problems. They are mainly supporting the new devices. These engineers are overburdened, tired and frequently not fully qualified. Companies that are selling the equipment employ most of them.
- There are approximately 35 engineers and technicians currently employed or on contract by the hospitals and laboratories. Their education, training and qualifications, in general, are not adequate to support and maintain the installed equipment, as well as to institutionalize the required clinical and quality control processes.
- There are some 20 firms in Estonia that sell medical equipment. They employ a small number of technicians, who are generally self-trained or factory trained only on one specific piece of equipment.
- The biomedical technology programs in Estonia are coordinated through a national framework program "Eesti Biomeditsiintechnika Teadusprogramm 1996-1999". The major program participants are the Tallinn Technical University, the Tartu University, and the Estonian Academy of Sciences Cybernetics Institute. The program objectives include the coordination and strategic direction of research, education, problem solution applications, and international cooperation. The primary areas of focus are biotechnology, medical technology and clinical technology.
- A long-term solution to the equipment maintenance infrastructure problem is evolving. As part of national strategy, Estonia is in process of establishing the Medical Equipment Training Center (METC) at the Tartu University. The METC will serve as an educational and training institution for medical equipment service engineers, technicians and users for Estonia and potentially other transition countries in the region. A working relationship and technology transfer agreement with the RSTI (Radiology Service Technology Institute, Solon, Ohio, USA) has been in effect since 1994. Visiting lecturers from the Emory University and the Oregon University also support METC educational and training programs. Limited facilities during the start-up and problems related to the development of a well-trained staff will delay the availability of fully trained X-ray engineers and technicians for some 3-5 years.
- A short-term solution is necessary to repair the older equipment, as far as practical, and to reverse the degradation of new equipment. If this is not accomplished, much of the older equipment needs to be shut down for safety and performance reasons during the next 2 years as quality and safety awareness increases and medical equipment safety regulations are introduced. The acquisition of replacement equipment is highly constrained by country's budgetary limitations. This can result in severe economic and social impacts at the regional level, the results of which are difficult to project. The problem is acute and cannot be allowed to continue for the next 3-5 years to wait until qualified people from the Training Center are available to service the equipment.

Tips for MedWatch Partners

The summer 1998 issue of the User Facility Reporting Bulletin contains the following 6 articles. The issue is posted on the Internet (www.fda.gov/cdrh/fusenews/fuse24.pdf) and Facts-On-Demand (1-800-899-0381).

- *What to Expect During an FDA User Facility Inspection*, by Jacqueline Eghan, OC, explains what happens during an FDA inspection and how user facilities should prepare for the inspection.
- *Public Health Message: Electrode Lead Wires and Patient Cables*, summarizes the safety standard that became effective on May 9, 1999 for manufacturers and will be phased in for user facilities from January 1, 1999 through May 9, 2000.
- *Future of Bulletin Uncertain* chronicles the circulation history of the Bulletin, which is now available only through the Internet and Facts-On-Demand. The article raises the question of whether there is sufficient readership to justify the resources needed to produce a quarterly bulletin.
- *FDA Cautions Users of Vacuum Assisted Delivery Devices* by Sheila Murdock, Ph.D., OSB, summarizes the recent Public Health Advisory.
- *Safeguarding Cardiac Guide Wires: Follow These Tips to Avoid Breakage* by Cathleen Michaloski, B.S.N., M.P.H., OSB, discusses precautions for nurses to take to minimize the risk of breakage before the procedure.

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- *Implanted Pacemakers: Avoiding Electromagnetic Interference* by Diane Dwyer, R.N., B.S.N., OSB, discusses precautions to take if a person has a pacemaker implant and is using a cellular telephone or near anti-theft systems in stores.

Info from India

T. G. Krishnamurthy, L.V. Muralikrishna Reddy, S. Sriranga

Impact of Infotech on Health Rehab Care Systems

It is well known that two thirds of the global people live in the so-called third world nations with the affluence in these nations ranging from ten to fifteen percent of the population. About eighty percent live in the rural areas. India happens to be the largest democratic nation in the world with 930 million people with nearly 93 million handicapped and 50 million elderly. India is also unique for its integrating a wide range of traditions, cultures, religious, languages; perhaps the only other democratic nation similar is the USA whose affluence equals the non-affluence level in India. The health rehab care of 930 million with 93 million people handicapped and 50 million elderly poses a really formidable technobiopsychosociomedical challenge to committed interdisciplinary intellectuals who obviously have to provide the innovative initiative and dynamic leadership so essential. Also HRC involves integration of CME, CEP, QIP to optimize the utilization of the large manpower (trained and untrained), reasonable material and the rather limited monetary resources available for HRC programs. Cost effective techniques have to be conceived, initiated, planned, coordinated, promoted, propagated to benefit the socioeconomically backward who form eighty percent of the population. Sadly and unfortunately, it is a matter of fact that due to various reasons the knowledge gap between the urban-rural areas appears to be widening instead of narrowing. Though the third largest techno manpower nation in the world, various bottlenecks, barriers, hurdles, have been responsible for this very wide urban-rural gap.

Advancements in the fields of engineering, medicine, science, technology have no doubt made phenomenal impact on the urban elite. Electronic media is continuing to make its impact. A lot needs to be done regarding planned utilization of Infotech explosion to benefit humanity on a need-based, realistic, feasible, time-bound plan to reach the rural millions. Lack of accountability at various levels has to a very large extent come in the way of improving the quality of life and technologies in the rural scenario. Infotech revolution in the last decade has virtually eradicated national-global barriers due to distance and other reasons. Advent of Internet and e-mail has made instant reception and transmission possible, however. Accessibility is still restricted to selected institutions even in the urban areas. With the operational and initial investment costs on a downward trend, one can be optimistic and look forward to an eventful decade to benefit wider section of the society in India and other developing and under developed nations of the world.

Web Trappings

B.J. Morgan, Webmaster, jmorgan@ibm.net

After a short furlough to move, work on the ACCE web site has resumed. The newest addition is the ability to send e-mail to ACCE Board members by using title@accenet.org. The following have been implemented:

- president@accenet.org → Bob Morris
- firstvp@accenet.org → Jeff Secunda
- secretary@accenet.org → Jennifer Ott
- treasurer@accenet.org → Bryanne Patail
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- editor@accenet.org → Joe Dyro
- webmaster@accenet.org → B. J. Morgan

This has been accomplished by e-mail forwarding so that any e-mail sent to one of the above addresses will automatically be forwarded to the appropriate individual. As the officers change, the system will be updated to send the mail to the correct person.



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October 15, 1998	Consulting Services	David Simmons, Sc.D. Health Care Engineering, Inc. 3114 Elmendorf Drive Oakton, VA 22124
November 19, 1998	Financial Management of a Biomedical Service Business	Brian A. Porras, MSBE Premier 4601 Charlotte Park Drive, Suite 300 Charlotte, NC 28217
December 17, 1998	Non-profit to Profit	Dave Dickey Medical Technology Management PO Box 808 Clarkston, MI 48346

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Calendar of Events

- Advanced Clinical Engineering Workshop, Nov. 4-10, 1998, Mexico City. Joe Dyro 516-751-7244; jfdyro@aol.com.
- XXI National Biomedical Engineering Conference, Nov. 11-14, Mazatlán, Mexico. Info: Roberto Ayala at cmt@DNS.dsinet.com.
- 18th Annual Northeastern Biomedical Symposium, Nov. 9-11, 1998 Albany, NY. Info: Ronald Hulin 518-525-1799; lbs978@aol.com.
- WSC '98, 1998 Winter Simulation Conference, Dec. 13-16, 1998, Washington, DC. <http://www.wintersim.org>.
- XXVIth General Assembly of the International Union of Radio Science, Aug. 13-21, 1999, Toronto, Canada, 613-993-7271; ursi99@nrc.ca.
- AIMBE Annual Event, March 12-14, 1999, Washington, DC.
- 19th Annual Northeastern Biomedical Symposium, Nov. 8-10, 1999 Manchester, NH. Info: www.nnesbt.org.
- 1999 Northeast Bioengineering Conference, April 8-9, 1999, Hartford, CT. Michael D. Nowak, 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>.
- BUDAMED '99, September 13-15, 1999, Budapest, Hungary. <http://www.fsz.bme.hu>; arato@fsz.bme.hu; (+361) 463 2699 phone; 2204 fax.

ACCE News

Board Minutes (continued from page 20)

Committee Reports:

Education (J Wear)

- 1998 Telconference is on schedule. There are those who have paid have not attended. Jim and Jeff to develop preliminary topics and speakers for next year.
- While ACCE has several ACEW curriculum requests from WHO's Andrei Issakov financing remains problematic. ACCE will not commit to ACEW participation without advanced funding from external agencies.

Advocacy T O'Dea Plan for 1998-1999 year

International (JS Miller) Committee in place

Other Activities:

HealthTech 99 (B Wang)

- List of topics and speakers has been developed for an ACCE Management track. Response has been good.
- Lisa Narcisso has been in contact with Frank. We would have a booth and co-sponsorship of the conference.
- No financial obligation but we will obtain recognition.
- Binseng Wang will chair the program with assistance from Painter and Wear.

ACCE Board of Directors unanimously approved developing track for HealthTech 99.

Symposium (B Morris)

- We will also develop a symposium in conjunction with AAMI

FDA Update (F Painter)

- The ACCE response to the ANPR has been submitted
- Tom Bauld is attending and speaking at the program to discuss ANPR.

ACEW (J Dyro)

- Mexico - November 4-10, 1998 - Adriana Velázquez is working on finalizing the program. Funding is being worked with PAHO and other organizations.
- Hartford, CT - June 1999: In the works
- Africa - Spring 1999 and Moscow - Fall 1999 depends upon Andrei Issakov's funding

Newsletter (J Dyro)

- Running smoothly and on time. Advertisement renewals are due and Caroline is working on contacting. The mailing list needs to be modified so that there is separation between membership and marketing. The membership list should be current and include the paid members only. Those that did not renew should not receive the Newsletter except with the marketing list as a teaser once a year.

Website Update (J Dyro for Bruce Morgan)

- Availability to have mail forwarding for the Board Members and Bruce Morgan will be sending out faxes to work the details
- AAMI will not link with any other sites

New Business:

- AAMI Mid-year will be in Michigan in 2000. We should work with AAMI on co-sponsorship.

The next Board Meeting will take place October 29, 1998.



Mo and Giana Kasti visit
Betsy and Joe Dyro
in Setauket

Mr. Antonio Hernandez
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USA

ACCE Board Highlights

Jennifer C. Ott, Ottj@slucare1.sluh.edu

Wednesday, August 26, 1998, 2:00 - 4:00pm EST

Present: J Ott, B Morris, B Patail, D Minsent, F Painter, C Campbell, J Secunda, T Bauld, K Taylor, J Wear, J Dyro, B Wang

Excused: K Galanopoulos, JS Miller, B Morgan, J McClain

Minutes of the last Board Meeting (J Ott) ACTION: T Bauld to send minutes from Annual Meeting to Jennifer.

Officer Reports:

Past President (F Painter)

- Election results are as follows: We had 46 of 90 paid members vote with a large International contingency. All those listed were unanimously approved: President - Bob Morris, Secretary - Jennifer Ott, Treasurer - Bryanne Patail, Board Member at Large - Caroline Campbell, Board Member at Large - Joseph McClain

ACCE Board of Directors unanimously approved the installation of the new Board Members. Welcome to Bob, Caroline, and Joe!

- A summary of the Annual Meeting is available in the July issue of *ACCE News*.

President (B Morris) Plan for 1998-1999 year:

- We need to continue to work to expand our membership. Frank has volunteered to lead publicity campaign about ACCE
- We must introduce new blood into ranks of chair and officers to get other ACCE members involved and broaden the participation.
- We should create a speaker list and database of ACCE members. Jim Wear and Jeff Secunda will develop a survey to establish a speakers list.
- Brian Porras was recommended to fill the open VP position. **ACCE Board unanimously voted that if Brian would agree we would love to have him!**
- As of August 27, 1998 he has accepted. Welcome Brian.

First Vice President (J Secunda) Plan for 1998-1999 year:

- We have excellent education efforts but we need to collect input for continuation and development of future programs.
- Teleconference evaluation form should be simplified as part of the attendee sign-up sheet. The handout and promotion material should encourage the attending institution to invite other non-clinical engineering personnel. We currently have 10 or more sites per conference.

Secretary (J Ott)

- We need better control over the production of the Directory because once all the renewals are received the year is almost over. It would be best to send the first renewal around November 15 with a due date of January 30; a second notice February 1 with a close of February 28; and the Directory available March 1.

ACCE Board of Directors unanimously approved the membership renewal time line.

- The Board Meetings and Executive Committee meeting schedule will be sent to all members.
- Jennifer will research the development of Fellow plaques.
- Pins were ordered. Bryanne received them and will forward them to Jennifer.
- E-mail was received regarding women in engineering. Jennifer will contact Cynthia Fowler and offer the ACCE Directory for purchase.

Treasurer (B Patail)

- The budget through 8/19/98 shows a comfortable surplus.
- Membership renewal will follow the schedule above (see Secretary's Report). They will be mailed separately. Assistance can be provided. Jennifer maintains the current master database.
- The finance committee consists of the Past President and the 2 VPs.
- We will not reimburse for calls at this time; however, those Board Members who would like assistance can contact Jennifer. Those Board Members who can conference others in should notify Jennifer and she can pair those members together.

Continued on page 19