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THIS ISSUE

Council For The Society for Medical and Biological Engineering (SA) Inc. 1996/1997

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In this newsletter I have given my summary of the annual conference in Canberra. I have only covered a small number of the presentations but for those who would like more information , the abstract book will soon be in the SMBE library. I will also be attempting to publish some of the abstracts as well as some of the papers from the conference in future newsletters , assuming I can get permission.

The electrical safety scare , which initiated the development of standards for medical equipment etc , started back in the early seventies and the article reprinted here from the April 1971 Popular Mechanics discussed issues that were of concern then. Dr Nobel , ECRI , makes several comments throughout the article. I thought this article was appropriate given the current discussions on AS3551 and several discussions that took place at the conference.

I had hoped to have a summary of the recent AS3551 seminar held here but this will have to wait until the next newsletter in January.

The newsletter is a major cost to the society and we are always looking at ways to reduce the cost of production while keeping you informed. One suggestion discussed at the last council meeting was the possibility of distributing the newsletter by email where possible. Your thoughts and comments on this would be appreciated. They can be made to any council member of faxed or emailed to me .

Don't forget the Christmas dinner on December 10. Come along and join in the celebrations as another successful year for the SMBE draws to a close.

I hope you all have a merry Christmas and a safe and happy New Year.

Editor.

ENGINEERING & THE PHYSICAL SCIENCES IN MEDICINE & HEALTH CONFERENCE

Warm days , balmy nights. Sound like Cairns? No , this is Canberra 21-24 October 1996 , the venue for our national conference. Canberra turned on the weather and Martin Dwyer and his team turned on an excellent conference. Some 200-250 delegates gathered at Rydges Hotel on the shores of Lake Burley Griffen on the Monday morning to start a hectic week of technical programs , workshops and the all important mixing and socialising with fellow technicians and engineers.

The program was very full with three sessions running in parallel on most occasions. This catered easily for the mixed background of the delegates , Biomedical Engineering , Medical Physics and Radiation Protection.

My comments and summary will only cover the Biomedical aspects of the conference.

Dr Joel Nobel , President of ECRI , was the main keynote speaker for biomedical engineering. Dr Nobel presented a number of keynote addresses throughout the conference.

His first paper , **Improving Medical Device Safety : Lessons from the Past** , discussed safety problems that ECRI have investigated and the lessons learnt from these investigations. While the causes of injury and death range from design errors, manufacturing and quality problems , software problems and many others the predominating factors where found to be design defects and user errors. While regulatory efforts reduce many of the problems , many design errors go undetected during the clinical trials and pre-market clearance procedures. Dr Nobel stated that "undoubtedly, the most common single cause of device related harm is user-error, not the intrinsic characteristics of a device ." Basic causes of device related accidents include device failure , multiple device interaction , user error , maintenance error , packaging error , tampering and sabotage , support system failure , environmental factors and idiosyncratic patient regulations.

Dr Nobel concluded by saying that while the substantial global regulatory efforts will have a positive impact on safety the fact remains that ignorance , ego , fatigue , carelessness, and the often chaotic clinical environment will defeat engineering , regulatory , and standards based efforts.

A session on physiological measurement followed and included the measurement of tracking performance on 1-D and 2-D tasks in normal and parkinsonian subjects , using Labview virtual instrumentation software for 3-D kinematic recordings of human shoulder movement , and measuring changes in body composition in sport. This paper highlighted the need for equipment designers to be aware of the issues in using the equipment in the clinical setting. The most reliable method of measuring body fat changes is using simple skinfold calipers.

Another keynote speaker , Dr John Russell from the Royal Adelaide Hospital , commenced the session on Anaesthesia and Respiratory Medicine by discussing the various techniques for measuring volatile anaesthetic agents.

Martin Dwyer presented the Woden Valley Hospital's system for the delivery of nitric oxide in intensive care. When delivered as a gas nitric oxide appears to be a specific pulmonary vasodilator , allowing greater oxygen transport to the blood for some patients with pulmonary hypertension of a temporary nature due to infection.

Michael Flood , Medical Devices Section , TGA , presented their investigation into anaesthesia incidents where patient awareness occurred. The anaesthetic agent vapouriser or its connection to the anaesthetic machine was found to be the cause in the majority of cases.

Dr Russell presented a very interesting paper titled "The Engineering Aspects of Warming During Fluid Replacement". He discussed the various techniques used and their pros and cons. He mentioned several blood warmers that are routinely used that fail to deliver fluid at the required temperature at the required flow rate. The widely accepted minimum benchmark is to deliver fluid at 32 degrees centigrade at a flow rate of 150 ml/min , often starting at a temperature close to 0 degrees C. The choice of material for the container is also important with PVC being a good insulator , denser materials such as the polythenes giving better heating.

The tympanic thermometer is finding increasing popularity in hospitals. But ,as Stan Scahill from Concord Hospital found during a study of their accuracy , they should be used with care otherwise accurate readings will not be obtained. Key issues included regular calibration and damaged or dirty sensor windows.

A very interesting session looked at the "Harmonisation of Healthcare Devices." This session was kicked off by Dr. Nobel. He discussed three levels of global harmonisation efforts to improve device design , efforts by some 20 national medical device regulatory agencies in countries like USA , Australia , Europe and Japan , efforts by IEC and ISO , and the drive from manufacturers. The push from manufacturers is by far the greatest as they try to increase exports by operating across national boundaries. They need to simplify the complex variations in standards between countries to minimise the variations in models and thus reduce their costs.

Bren Milson from the Conformity Assessment Branch of TGA discussed the effects of global harmonisation on Australia. Australia started some 4 years ago moving towards global harmonisation and it is now starting to have effect. A Mutual Recognition Agreement on conformity assessment has been signed which will eventually allow free access of medical devices between Europe , Australia and New Zealand. Australia is starting to change its legislation to harmonise with the requirements being adopted by the European Union and other countries. The "CE" mark , which will become more prominent , will indicate conformance with European Medical Device Directives . These Directives will embody various standards like IEC 601 and its various parts. This is an area we should keep an eye on as it will effect our work and how will meet the requirements of AS3551.

Authur Brandwood , TGA , discussed the National Implant Tracking System which is currently under development. Basically this will allow the recording of implant details at time and place of implant so that followup is easier if problems occur. There needs to be international consensus on such things as the minimum data set and the labelling of the devices. The system is currently being piloted so expect to see more of this in the near future.

Dr John Russell discussed some of the findings from incidents reported to the Australian Incident Monitoring System since 1987. Some 4000 incidents have been reported with over 1/3 of them involving equipment. Dr Russell believes that biomedical engineers and technicians can play an important role in the selection of the safest and most appropriate equipment , in Standards advice , and in training anaesthetists. Dr Russell believes that many users of medical devices do not fully understand the correct use and operation of the devices , which has the potential to lead to hazardous situations.

There where many other very good papers on the future of biomedical engineering as we know it , risk management , management software , benchmarking and UV radiation.

One paper I must mention was by Alex Watson , Prince Henry Hospital , titled "How to Nurture a White Elephant" , in which he challenges the electrical safety standards as we know them , in particular the requirement for equipotential earthing. Australia led the world in the seventies in the creation of practical electromedical safety standards . Alex discussed some of his early research and questioned whether the standards are cost effective and actually save lives. Dr Nobel agreed that the whole electrical safety scare had little basis with there being no conclusive proof that any patient was ever killed by microshock.

Equipotential earthing , which is not used in the USA , has little benefit according to Alex and he would like to see AS3003 reviewed. As many of you know , trying to achieve the low earthing resistances required can be a difficult and costly exercise , and I agree with Alex that EP systems are not generally required. In fact in our hospital the only claim to fame for EP systems came from two workers compensation claims from staff who injured their back and elbow on the stud type EP terminals.

Another promising aspect of this conference was the large number of high quality papers and posters from students in biomedical engineering. With the conference in Adelaide next year coinciding with the final year for our first BME degree students we should see this aspect continue.

The social program for the conference was equally stimulating. The welcome reception was held at The National Science and Technology Centre , which is a bigger version of our Investigator Centre. We had free range of all the exhibits which included demonstrations of such devices as Jacob's Ladder and the lightning generator as well as many hands on activities. Coupled with this was a non ending supply of food , beer and red and white wine.

Needless to say reaction times and success on the displays severely diminished as the night progressed.

The conference dinner was held in The Great Hall of New Parliament House and while I did not attend , reports indicated that it was a very enjoyable night with some stayers going on to the casino.

In summary a very enjoyable week was had by all and full credit must go to Martin Dwyer and his team for organising what I believe to be one of the best conferences I have been to.

Until next year!
Robin Woolford

DANGER IN THE HOSPITAL

In the growing field of medical devices, there are no standards of safety or performance. Until they are established, hospitals will have no guarantee that equipment will operate properly - or even that it won't kill you.

The man was in his mid-forties and the doctors were fighting his cancer with radiation. Now he lay on the table awaiting a treatment. The massive X-ray machine was ponderously lowered over his chest - only this time the unit didn't stop when the switch was thrown. Before the technician could get across the room to the circuit breaker, the patient had been crushed to death.

A woman in her mid-sixties was in the operating room of a hospital in the Washington, D. C., metropolitan area. Her routine thyroid surgery had been successfully completed and the surgeon was sewing up the wound. The doctor turned off the anaesthesia machine. But there was an electrical spark - and a explosion whose full force hit the woman. Four and a half hours later she was dead.

On the West Coast, a whole series of broken hips was repaired with a ball-pin device in which the ball was nylon. The plastic reacted with body tissues to form abscesses that failed to heal. Additional surgery was required.

A patient in a large East Coast hospital was operated on with an electrocautery while an electrocardiograph leads removed, deep third-degree burns were discovered underneath one of the leads. It was even difficult to tell the extent of the burn at first because these tend to mushroom out and form a cone whose broad base is deep inside the tissues while the opening on the skin remains small - slow and hard to heal.

A large operating-room monitoring oscilloscope was recently returned from a factory-authorised service station. When first turned on, it caught fire.

There have been artificial kidney machines which poured distilled water into the veins of patients, artificial heart valves with surface defects so that blood clots formed in these faults, metal implants - bone plates and screws - that broke or corroded in the body tissues, mechanical hip-joint replacements of such poor quality that additional corrective surgery was required. The plastics doctors use - both inside and outside you - are only commercial-grade - none are specially made for medical purposes. Dr. Joseph Davis, director of Div. of Clinical Medical Devices of the Food and Drug Administration, told me he believes this is definitely dangerous and the reason patients get toxic reactions from plastic implants.

Even hospitals in major medical centers have admitted they have no central surveillance and testing by trained engineering personnel of medical equipment when it is delivered to the hospital. So it's not surprising that the experts speak of accidents in terms of 5000 patients being electrocuted annually - others of 10,000, 25,000 - pick your own figure, no one can really dispute it. As Dr. Davis explained to me: "We know there are at least 5000 different medical devices, perhaps as many as 25,000. So out of 25,000 different type devices with X number of each in use, I think you would be hard put to say an occurrence couldn't occur with each device."

Yet in only a very few hospitals across the country (some say in only one) is there a department with trained personnel who routinely check every piece of medical equipment when it arrives and before use, then follow up with proper, regular maintenance. In this one hospital's department, for example, technicians obtain the operating-room schedule for the coming day and go over every unit of sophisticated surgical equipment to be used.

This unusual department is located at New York's Downstate Medical Center where Seymour Ben-Zvi is director of scientific and medical instrumentation. His department of two dozen people, including five engineers, tests every piece of equipment, when it arrives, to make certain it meets manufacturer's specifications and is safe and in good working condition. His precautions have repeatedly paid off.

Not long ago a shipment of 10 defibrillators arrived. These are electrical devices which literally "shock" a wildly beating heart back into its normal rhythm by delivering a 7500-volt short-duration pulse. Actually a simple instrument, it consists of a circuit which charges an oil-filled capacitor. The physician or nurse presses two paddles against the patient's chest. Pressing the discharge button causes a relay to switch the capacitor from the charging circuit and pour its full voltage into the patient. All 10 devices were defective - and dangerous! They had improperly degassed

vacuum relays and their capacitors discharged without having the discharge button depressed. The devices could have been fatal to both the operator and patient. One manufacturer's representative assured Ben-Zvi that the company stood behind these machines and would be happy to replace any defective ones.

"But how will they replace the dead patient, or physician, or nurse?" asked Ben-Zvi.

Dr. Joel J. Nobel- scientific director of Philadelphia's Emergency Care Research Institute, also an authority in this field - points out that every one of the estimated 50-million people who annually enter U.S. hospitals has contact with medical instrumentation. If you have a heart attack you will be in close contact with nearly 400 different medical devices during your three or four-week hospitalisation. If you are an average adult and enter a hospital for gall bladder surgery, you will be directly involved with over 600 devices, and if your child has his tonsils out he will be in contact with almost 200.

Dr. Nobel says that 30 to 40 percent of device failures are operator errors. There are more problems than just accidents - electrocardiographs which, in private offices, don't provide correct tracings because they're not calibrated, and instrumentation which gives incorrect diagnostic information. But Nobel believes it is possible "to set up failure systems so that when things do fail they fail in a safe position rather than in a dangerous position" and "to do many things to make instrumentation much safer, both on the part of industry and on the part of the hospitals and designers."

Ben-Zvi's unit at Downstate Medical Center checked several thousand pieces of incoming scientific and medical equipment in the past two years. About 40 percent of all those delivered were defective. These ranged from simple, but dangerous, inadequacies, such as lamps on extendable arms whose strut mechanism eventually severed its own electrical cord, to defective flow meters which delivered 36 times more oxygen than the meter indicated - enough to explode a patient's lungs or do other damage, depending on the use to which this versatile equipment is put. Mechanical failures included devices not properly assembled, castings not checked before delivery, and other problems due to inadequate quality control - the same slipshod quality we find in our every day lives, except that in medical devices this becomes a matter of life and death.

As Ben-Zvi explained it, there are two types of electrical hazards - the macro and the micro-electrical shock. The macro-shock is the big jolt you get when you touch an exposed power line in you house. It electrocutes by actual tissue damage and heart fibrillation - an uncontrolled wild runaway beating which is so in efficient that the body cannot be adequately supplied with blood. In a minute or so, permanent brain damage can result and in about three, death. Micro-shock, predominant in the medical environment, is a newer hazard. It has been proven that as little as 20 microamps. (millionths of an amp., really a microscopic amount of current) of leakage current flowing through the heart is enough to produce fibrillation even though it takes a thousand times this current to light the smallest incandescent bulb.

Ben-Zvi describes micro-shock as "an evasive sort of shock-evasive to the medical person who is not knowledgeable about the technical causes." But a patient may die if fibrillation is not detected in time, as often happens. Most scientists working in this field agree that this internal electric shock is a subtle hazard that escapes recognition by most physicians. Accurate statistics on the accidents caused by medical devices will not be available until the law requires reporting of these deaths and injuries in every instance.

Responsibility for the lack of medical instrumentation safety is said by those in the field to be shared equally by government, manufacturers and medical profession. There is general agreement that federal legislation is essential but many are pessimistic about the chances for passage of current legislation. As Ben-Zvi puts it "It always gets bogged down somehow." In the

last analysis it will be the public's demand for protection that will determine the fate of any effective legislation to insure the safety of medical devices and equipment. Until passage of such laws, you are in danger nearly every time you enter a hospital.

Reprinted from Popular Mechanics , April 1971.

Useful Internet Sites

1. TGA
2. IEC
3. Healthtechnet
4. Medical Equipment Management
5. Healthnet Australia
6. Medinet Australia
7. Standards Australia
8. Hospital Web

CONFERENCE CALENDAR

Sept 8th 1997 Annual Biomedical Engineering Conference, Adelaide, SA

Sept 14-19 1997 World Congress on Medical Physics and Biomedical Engineering, Nice, France

Information on the above are available from the editor or president.

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