



A broad variety of hazards are associated with the over 5,000 different medical devices in use today. Physicians, nurses and administrators are expressing increasing concern over both the safety and the efficacy of clinical equipment. The Emergency Care Research Institute of Philadelphia, a nonprofit agency, is undertaking a comprehensive study of this problem with the support of the Office of Medical Devices of the Food and Drug Administration.

A detailed index will be compiled of injuries, complications and deaths associated with the improper design, manufacture, maintenance or use of all types of medical instruments, devices and systems. Hazards or inadequate performance in diagnostic and therapeutic devices found in hospitals, clinics, nursing homes, private medical offices, aid stations, ambulances and homes and used by health professionals, paramedical personnel or lay people, are being investigated.

Health professional and paramedical personnel are urged to contribute information in support of this continuing program to improve safety. All contributors may be assured that each problem will be investigated and resolved and will receive a complimentary copy of the final report. If you have ever encountered or do ever encounter a medical device which you feel is directly or indirectly responsible for injury or death to either a patient or the user, please notify ECRI by letter or

Medical Device Hazards

telephone. Only information related to the device is necessary. Identification of your institution is not necessary unless you or your institution wish technical assistance in resolving a current problem or recognition for your assistance. The needed information includes:

1. Type of device (e.g. electrocardiograph, oxygen-powered resuscitator, heart valve, wheel chair, surgical dressing, etc.)
2. Mode of injury and effect on patient or user (e.g. laceration of hand by sharp-edged equipment housing, tissue reaction to implanted pacemaker, ventricular fibrillation and death due to electric shock by patient monitor, thrombosis and infection due to venous catheter, perforation of the uterus by IUD, etc.)
3. Cause of problem if identified with reasonable certainty (e.g. operator error in using defibrillator, broken plug and frayed electrical cord, micro-wave oven, inhibition of pacemaker, uncalibrated spectrophotometer) or indicate if cause is unknown.
4. Name of manufacturer, model number and serial number of the device, if possible.
5. What action, if any, was taken to correct the problem or prevent future injuries (e.g. replaced with new equipment, rewired electric cord and plug, unknown).

The more details you can provide, the more valuable your contribution will be. A standard short reporting form is available on request.

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In Vivo

Dear Editor:

After having discussed perfusion techniques with various Technologists at the 10th Annual Convention, a question of much concern has arisen in my mind. This question has to do with maintenance of optimal PH at Hypothermia. I have observed that many technologists believe that at 30° C for instance, a PCO₂ of 30-35 MM Hg. and PH of 7.30-7.35 is acceptable. This in my opinion is far from correct.

According to Carson et al "The essence of management on by pass is maintenance of optimal PH but, since optimal PH is changing as the temperature is altered, it is necessary to vary the percentage of carbon dioxide in the pump oxygenator gas mixture to maintain the desired PH." It is not possible to maintain good acid-

base balance by administering a pre-determined fixed percentage of CO₂ into the pump oxygenator through out by pass.

At our institution we are using the above principle to maintain normal blood gas physiology. For example, at 30° C, optimal PH reading when uncorrected for temperature with the electrode maintained at 37° C should be 7.20 with a PCO₂ of approximately 60-65 MM Hg.

If we were to drop the blood temperature lower, then the PCO₂ should be raised until optimal PH is reached for that lowered temperature. When rewarming, the CO₂ percentage has to be greatly reduced.

We are employing the aforementioned techniques for acid-base management at Hypothermia with great success. We walk the patient through cardio-pulmonary by pass with virtually no acid-base imbalance.

I welcome any comments from my colleagues and the medical profession.

Herbert M. Schwartz
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