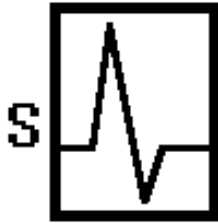


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M.B.E. April 1998 Newsletter

As you can see our visit to Cooper's Brewery has been cancelled for the moment but I hope some arrangement can be made for a future meeting. A visit to Adelaide Airport to hear about aeroplane maintenance is also in the wind .

The council is still keen to distribute as many newsletters as possible over the EMAIL system. A number of you have indicated a willingness to receive the newsletter this way and I hope this is working ok. **If you are on the EMAIL system and wish to receive the newsletter this way please let me know.** With the ever increasing costs in producing the newsletter any savings can be put into meeting arrangements.

AS3003 Update

As many of you are aware AS3003 is about to appear in it's 3rd edition. Adrian Richards is the BEAG representative on Standard Australia committee HT/21 which has been working on the

revisions. This edition sees no major changes but does address some outstanding issues in the current version. A rather significant call to remove the equipotential earthing requirement for cardiac protected areas has been discussed in several previous forums and HT/21 will be seriously looking at this for the next edition.

We should see this standard in 3-4 months as well as an associated standard **"Isolated Electrical Supply Systems for Medical Use"**.

Adrian will be making a presentation to BEAG in June where he will detail changes and some work that is required of state BEAG groups for the next edition.

I will publish a more detailed report from Adrian then.

The testing of electrosurgery accessories has had some discussion recently on the BME list . The following document has been developed to provide some guidance in this area.

Electrosurgery accessories - the need for high voltage testing.

This document is the outcome of extensive discussions which arose in the BEAG(NSW) forum about appropriate testing of electrosurgical accessories and leads for insulation breakdown. During the development of this process, the NSW Health Department released Information Bulletin (Circular No 97/20) to which BEAG(NSW) had provided a major input. Subsequent deliberations of the IEAust National Panel on Clinical Engineering (NPCE) then resulted in this document. The NPCE invites comment on this test protocol, or any other matters associated with insulation testing of surgical instruments. - Contact Bruce Morrison, Chairman of NPCE, at the Hunter Area Biomedical Engineering Service, John Hunter Hospital, Locked Bag 1, Hunter Region Mail Centre, 2310.

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The N.S.W. Health Department has recently published advice on the high voltage electrical testing of leads and accessories attached to electrosurgical generators. In short, the N.S.W. Health Department advice can be summed up as stating that visual inspection of electrosurgical accessories is not adequate to guarantee the integrity of insulation, and therefore high voltage testing should be undertaken. This document gives advice on appropriate testing of electrosurgical leads and accessories.

With the advent of "key hole" surgery, the proliferation of instruments and accessories for use on electrosurgical units has been profound. While the manufacture of electrosurgical generators is subject to extensive regulation by Australian and overseas Standards, there is little available in the form of good guidance on the continuing maintenance and support of the instruments and accessories attached to these generators.

The primary hazard associated with electrosurgical procedures is attributable to the high voltage used and the potential for insulation failure of leads or accessories, resulting in burns to the patient or the operator. However the nature of laparoscopic surgical procedures means that such burns may not be readily detected, and may result in undetected internal injuries to the patient. Alternately, damaged leads can cause skin burns to the patient as they are laid out between the generator and the operating site. Burns can also occur where the trochar enters the body. These tend to be of lesser concern, being readily visible after the case, so that faulty leads or accessories are withdrawn from service. It must be emphasised that the hazard to the patient is what is driving this test protocol. Clearly electrical shocks can occur from uninsulated handles of many surgical instruments. However this is not regarded as a serious hazard since firstly the surgeon or operator should take appropriate precautions against such burns, and secondly the surgeon or operator is awake and able to sense the burns and take defensive action if shocked. The patient is anaesthetised and unable to respond. The internal burns associated with laparoscopic procedures can be clinically undetectable. The result can be that equipment with compromised insulation can

be used repeatedly, burning many patients while the internal burns go undetected - certainly not good medical practice!

This document is only concerned with the burns associated with insulation breakdown. It is not aiming to address the capacitive coupling associated with trochars or similar devices. The motivation for this protocol is the clear evidence that visual inspection of the insulation on laparoscopic instruments is not adequate. It is relatively easy to find instruments on which insulation deterioration allows high voltage arcing through points which do not appear damaged when inspected with the naked eye or even the microscope. Such points are easily detected with a high voltage testing routine, and are sites for potential patient burns if not detected in a routine inspection and preventative maintenance schedule. Typically, imperfections in insulation can be associated with bubbles which form in the insulation, chips and damage which have occurred during use or handling, thin insulation or even moisture uptake. Many of the insulating plastics are somewhat hygroscopic and the resulting water uptake can result in insulation breakdown. Prolonged low temperature drying to remove the water can be temporarily beneficial, though re-hydration during use and sterilising is almost inevitable.

Parts of the instrument

Most surgical instruments used with electrosurgical generators can readily be divided into distinct zones - those which make patient contact and those which do not make patient contact - the handle end or the operator handle etc. Within the areas of the instrument which make patient contact, there is a further distinction into conductive parts and non conductive parts. It is the integrity of the insulation of the non conductive parts which make patient contact that this document aims to address.

Patient safety

The safety of the patient (or indeed the operator) depends on the satisfactory operation of several components which are inter-related. The electrosurgical generator must be functional and appropriately adjusted. The return electrode must be appropriately connected to the patient. Lead integrity to the electrodes is of course essential. The instruments must be suitably insulated on surfaces which are not meant to conduct current to the patient. The surgical practice must be consistent with the equipment and the procedure. It is proposed that all electrosurgical instruments and accessories should be tested for insulation integrity with a high voltage source rated at 3kV rms 50Hz (or 4.2kV dc to achieve the same peak voltage). The reasons for this are as follows:

All reinsulated instruments can withstand this test voltage.

Newly manufactured or reinsulated instruments typically withstand voltages greater than 8kV rms. (At least one manufacturer is currently testing all accessories and leads to 8kV before dispatch to the customer).

3kV is probably a higher voltage than needed, but leaves some margin for deterioration of insulating properties during the use of the instrument.

There should be a current limit of 0.5mA or less on the test device used for 3kV testing of electrosurgical leads and accessories. This is to give an appropriate level of protection to the user. An electrosurgical unit could also be used as a tester but does not have any safety features in the form of a current limit. An **electrosurgical unit is therefore not recommended** for the testing of leads and accessories. It can also be difficult to know the voltage output of an electrosurgical generator at any particular power setting.

Although some generators can develop particularly high voltages in excess of 12kV in spray coagulation mode, such voltages are never attempted or attained in laparoscopic procedures. It is not recommended that such high voltages be used as no coating currently used on laparoscopic instruments can withstand these high voltages. For in-service testing to be non-destructive the testing voltage must be chosen appropriately. It must be high enough to ensure discovery of breaks in the insulation but not so high as to cause such ruptures.

The choice of 3kV rms 50Hz as the testing voltage, represents a compromise between safety, operational voltages used in actual laparoscopic procedures and advice from AS-3894.1 □ 1991, relating to minimum voltages for different coating materials and their thickness.

Regularity of testing

The regularity of testing required for any particular healthcare establishment will depend on the type of equipment used, the age of the accessories and the level of usage to which they are subjected. It is recommended that initial testing be established on a monthly basis as proposed in the N.S.W. Health Department Information Bulletin. Within a few months, enough local data will be amassed in order to justify continued monthly testing, or to drop back the regularity of testing. Initially it could be expected that a service which has not previously embarked on high voltage testing of accessories will find a high rate of failure. (Several experienced operators have variously estimated a typical yield of 20-40% of instruments failing high voltage testing on first implementation of a testing program.) As the instruments with compromised insulation are progressively identified and removed from service for replacement or reinsulation, the regularity of instruments failing high voltage testing should drop dramatically. The regularity of testing should then be adjusted appropriately. In general, if no failures are

being detected, then testing is probably being performed too often. Conversely, if many instruments are failing high voltage testing, then the testing is not being performed regularly enough, and should be increased. **The overall perspective should be one of minimising the clinical use of surgical instruments and accessories with compromised insulation resistance and thereby minimising the possibility of inflicting patient burns.**

Attention is drawn to clause 4.4 of AS3551-1996 which states that "the maximum interval between tests shall not exceed 12 months" for medical equipment. While this is not specifically directed towards electrosurgical accessories, it is probably good advice.

Personnel implementing testing

Testing of electrosurgical leads and accessories is a hazardous procedure and as such should only be performed by personnel who have had training and experience in the use of high voltage test equipment. This would preclude the testing being performed by operating theatre or sterilising department staff unless they had the necessary training and experience.

Operator Safety

With the high voltages used in the testing apparatus, some general safety precautions should be implemented. These may include

- a) the wearing of rubber gloves while testing the accessories,
- b) testing only when an assistant is present,
- c) testing in an area clear of other personnel and obstructions such that the surprise of a shock does not cause a related or secondary hazard and
- d) testing well away from combustible or flammable material.

Test Methods

Methods of testing vary from hospital to hospital but all involve some form of connection between the high voltage source and the inner conductor of a lead or instrument on one terminal and a wire/probe/brush/channel surrounding or rubbing on the insulated surface of the lead or instrument on the other terminal. Testing can be conducted at the point in the usage cycle where the accessories have been cleaned but not yet sterilised. This may present damp accessories for testing, replicating actual operating conditions. However the infection control implications of testing un-sterilised instruments should not be overlooked. More commonly, testing is performed on sterilised instruments which then require re-

sterilisation prior to use. The additional cost of additional sterilising is generally accepted as a better approach than testing un-sterilised instrument.

Leads

Testing insulated cables which connect from the electrosurgery unit to the surgical instrument will typically involve a channel into which the lead is placed. The channel needs to provide intimate contact with the lead over as much of the surface as possible such that testing can be accomplished in a single pass. The channel may be as crude as a length of aluminium section in a U-shape with a moveable fence to accommodate different lead sizes and a terminal at the end to facilitate easy connection to the test apparatus.

One terminal of the voltage source is connected to the central conductor of the lead under test and the other terminal to the channel. The voltage is set and current limit adjusted to 0.5 mA or less, and the test voltage is applied. Breaks in the insulation will produce a discharge current which will be indicated by the current meter and visual/audible indicators on the test apparatus.

Instruments/accessories

Instruments will be tested by connecting the terminal of the instrument or accessory to one terminal on the test apparatus while the other terminal is connected to a probe or wire brush (suitably insulated on the handle to protect the operator). The probe is rubbed over the surface of the instrument or accessory. Once again, breaks in the insulation will produce a discharge current which will be indicated by the current meter and visual/audible indicators on the test apparatus.

Management of testing

The management of the testing cycle can be difficult because of the problems identifying instruments and leads. Tagging is very difficult and hence testing is usually conducted in a single pass in which all of the instruments and leads used in an operating theatre are tested together. Future developments in mandatory instrument tracking may improve this process when markings such as laser etched bar-codes are put on to instruments and then read at all points in the cleaning/sterilising/usage cycle.

Equipment

Test equipment typically consists of a current limited high voltage tester and an array of test jigs suited to the purpose.

High voltage testers are manufactured by such companies as AVO of the UK and some Australian manufacturers are currently producing prototype testers for use

in this field. Because of the large number of shapes and sizes of instruments and accessories standard testing jigs are not readily available. Biomedical Engineers will manufacture jigs to suit the range of instruments within their area of operation.

A program of routine testing will be organised by the hospitals □ Biomedical Engineering service provider.

MEETING CALENDAR

Please mark the following dates in your diary. Technical meetings will be held in the 3rd week of the month. Where no date is set , this will be advised as soon as possible as will the topic of the meeting.

Tuesday 21st April 6pm Medico Legal Issues and Risk Management,

Women's and Children's Hospital, Samuel Way Building (ground floor)

May

June

July

Tuesday 18th August 1998 Annual General Meeting

Tuesday 1st December 1998 Christmas Dinner

CONFERENCE CALENDAR

2nd -8th August 1998 Third World Congress on Biomechanics , Hokkaido University , Japan

29th October -1st November 1998 20th Annual International Conference of the IEEE Engineering in Medicine and Biology Conference-Biomedical Engineering Towards Year 2000 and Beyond , Hongkong. <http://www.ee.cuhk.edu.hk/embs98.html>

15th - 19th November 1998 EPSM98 "Relevance Beyond Rationalism" Hobart , Tasmania

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

E.& O.E.

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