MAINTENANCE OF ELECTROSURGICAL ACCESSORIES

1.0 BACKGROUND

The N.S.W. Health Department has published advice on the high voltage electrical testing of leads and instruments attached to electrosurgical generators (Information Bulletins 98/17 & 97/20). The advice was developed during consultation with Biomedical Engineering Advisory Group (BEAG), NSW, following incidents involving undetected burns to some patients during laparoscopic surgery.

The Department’s 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 more detailed advice on appropriate testing of electrosurgical leads and instruments and includes recent technological developments in testers since the publication of the NSW Information Bulletins.

2.0 RATIONALE FOR TESTING ELECTROSURGICAL ACCESSORIES

With the advent of endoscopic electrosurgery, the proliferation of specialised electrosurgical instruments, accessories and leads for use with electrosurgical generators has been profound. While the manufacture of electrosurgical generators is well covered by International Standards, there is little available in the form of good guidance on the continuing maintenance and support of the instruments and accessories used with these generators.

The hazard common to all electrosurgical procedures is the high voltage output of the generator and the potential for resultant insulation failure of leads or accessories, resulting in burns to the patient or the operator. The internal burns associated with laparoscopic procedures can be clinically undetectable and may result in injuries to the patient, which may show up days after surgery. This can mean that equipment with compromised insulation may be used repeatedly, burning many patients while the internal burns go undetected. The test protocol suggested in this document, seeks to reduce the hazards thus outlined.

2.1 Insulation breakdown in electrosurgical instruments

Instruments used with electrosurgical generators are commonly insulated at the operator end, whilst uninsulated where contact is made with the tissues. Instruments designed for laparoscopic use will always be insulated along the body of the instrument, ie where it is necessary for it to pass through the skin. Of concern is the electrical integrity of this insulation. If it is compromised by cracking, even microscopic insulation failures can allow unwanted electrosurgical currents to traverse this path. The outcome may well be an unwanted site burn.
Electrical shocks or burns can also occur from uninsulated handles of many surgical instruments. However this is not regarded as a serious hazard for the following reasons:

a. the surgeon or operator should take appropriate precautions against such burns,
b. the surgeon or operator is awake and able to sense the current and take defensive action if shocked,
c. the surgeon will not normally be part of the electrical circuit.

Burns to the patient from the handles, while possible, can not occur if correct operating procedures are followed.

2.2 Insulation breakdown in leads

Damaged leads can cause skin burns to the patient as they are laid out between the electrosurgical generator and the operating site. Burns can also occur where a trochar enters the body. These tend to be of lesser concern, being readily visible after the procedure, so that faulty leads or accessories may be withdrawn from service.

2.2 Mechanism of insulation breakdown

Insulation failure may result from:

Poor manufacturing technique, in the case of deposited insulation material;
Microscopic imperfections in the insulation;
Wear and tear in normal use;
Damage due to abnormal use;
Incorrect sterilization technique; and
Overuse of single-use or limited use instruments

In all cases, insulation failure occurs because of a degradation in the insulation, from whatever cause.

*Detection of insulation failure must result in the repair or replacement of the instrument in question.*

3.0 MANAGEMENT OF INSULATION INTEGRITY TESTING

3.1 Test parameters

It is recommended that all electrosurgical instruments and accessories should be tested for insulation integrity with a high voltage source rated at 3kV rms ± 10%, 50Hz (or 4.2kV dc to achieve the same peak voltage). The rationale for this is as follows:

a. Newly manufactured or reinsulated instruments typically will withstand voltages greater than 8kV rms. (At least one manufacturer is currently testing all accessories and leads to 8kV before dispatch to the customer).
b. 3kV is probably a higher voltage than needed, but leaves some margin for deterioration of insulating properties during the use of the instrument.
c. 3kV is considered an appropriate voltage for ‘in-service’ testing of electrosurgical accessories.

There should be a current limit of 0.5mA or less on the test device used for 3kV testing of electrosurgical leads and instruments. This is to give an appropriate level of protection to the user.

An electrosurgical generator could also be used as a tester, but does not have any current limiting features, and is therefore not recommended for the testing of accessories. It can also be difficult to know the voltage output of an electrosurgical generator at any particular power setting.

The choice of 3kV rms at 50Hz as the testing voltage represents a compromise between safety and the operational voltages used in actual laparoscopic procedures and advice from AS-3894.1 – 1991 “Site testing of protective coatings, Method 1: Non-conductive coatings – continuity testing – high voltage (‘brush’) method”. This standard relates to minimum voltages for different coating materials at different thickness.

3.2 Frequency 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. The overall perspective should be one of eliminating the clinical use of surgical instruments and accessories that are demonstrated to have compromised insulation resistance.

It was previously 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 would be amassed to justify continued monthly testing, or to drop back the regularity of testing. However this approach is really only tenable if all instruments are individually marked and a tracking system is in place. Some instruments and accessories are inherently difficult to mark, thus and tracking is difficult and may be expensive to achieve. Depending on the regularity of testing, this approach can allow instruments to be used clinically for some time before scheduled testing detects insulation breakdowns.

With the advent of modern testers which are intrinsically safe, some hospitals have embarked on testing of instruments after every usage, and made this a part of the cleaning and sterilising cycle. This is certainly the best means of ensuring that a safe instrument is presented to every patient, and is readily achievable.

Such testing is being routinely performed by sterilising staff and does not differ significantly from their inspection of surgical instruments to identify their suitability for clinical use, or their need for repair or sharpening.

High voltage testing should not take any more time to perform than the visual inspections currently undertaken. The other major advantage of such a testing routine is that it alleviates the need to identify and to track individual instruments and accessories.
Attention is drawn to clause 4.4 of AS3551-1996, which states that “the maximum interval between tests shall not exceed 12 months”.

### 3.3 Personnel implementing testing

Testing of electrosurgical leads and accessories can be a hazardous procedure using traditional high voltage testers. *Testing with older style high voltage testers should only be performed by personnel who have had training and experience in the use of high voltage test equipment.*

However the recent development of intrinsically safe high voltage testers specifically for testing of electrosurgical instrument insulation has greatly reduced the risk. With these devices, it is almost impossible for the operator to receive a discernible electric shock. Deployment of such devices is essential for operator safety. Advice on the availability of these devices should be sought from your hospital’s Biomedical Engineering Service.

In order for insulation testing to be performed effectively, it must be done during the ‘clean-sterilise’ cycle. This is best facilitated by the testing being performed by sterilising staff (after appropriate instruction).

### 3.4 Operator safety

While most of the precautions associated with traditional high voltage testing are now unnecessary with modern units, it remains essential that testing be performed well away from combustible or flammable material, since the high voltage tester will produce sparks when it detects an insulation failure.

### 3.5 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 should 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 universal precautions should be observed as the instruments are not yet sterilised.

Test instrument manufacturer’s guidelines should be closely observed.

#### 3.5.1 Leads

Testing insulated cables which connect from the electrosurgery unit to the surgical instrument will typically involve a channel of some type 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. Some Sterilising Departments which have dispensed with jigs, run the leads through the wire brush on an insulated bench surface.

One terminal of the voltage source is connected to the central conductor of the lead under test and the other terminal to the channel or brush. When the test voltage is applied, any insulation failure will produce a discharge current which will be indicated by the test apparatus.

Some hospitals have abandoned the use of high voltage insulation testing for leads, as the insulation is often thicker than that on the instruments. Damage is easily visualised during packaging.

Electrical resistance tests on leads are sometimes performed to lead continuity. These tests are safe and easy to preform. As such they are recommended.

### 3.5.2 Instruments/accessories

Instruments will be tested by connecting the metal of the instrument or accessory to one terminal on the high voltage tester while a probe or wire brush (suitably insulated on the handle to protect the operator), connected to the other terminal, 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 test instrument.

### 3.5.3 Test equipment

The equipment used for high voltage insulation resistance testing should conform to the voltage and current specification outlined in section 3.1 “Test parameters” and should be simple and safe to use. It should have a high output impedance to limit current flow and provide audible and visual indications of breaks in the insulation.

### 3.5.4 Test documentation

Documentation is essential if testing is conducted by a batch-mode process. Problems in identifying instruments and leads should not be underestimated as tagging and tracking of accessories is very difficult. Hence it is difficult to assure all accessories have been tested. 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. However, the problem remains that the safety of the instrument or lead can only be assured as often as it is tested.

The testing of leads and instruments in the Sterilising Department during the cleaning/sterilisation cycle after each use ensures a safe instrument is always presented to the patient. In this process documentation is minimal and there is no need for complex and costly tracking processes.
4. FURTHER ADVICE.

Further advice may be sought from your local provider of biomedical engineering testing services. Clarification of issues arising from this publication may be sought from any member of BEAG (NSW) or the National panel on Clinical Engineering (Institution of Engineers, Australia.).