GUIDANCE NOTES ON ELECTRICAL SAFETY IN ROOMS USED FOR COLPOSCOPY AND THE SAFE USE OF ELECTROSURGERY FOR LLETZ PROCEDURES

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Enquiries

Enquiries in connection with this report should be addressed to:

Colin W Hancock
Consultant Engineer
Tel. 01920 465780

Further copies

Requests for further copies should be made to:

National Cancer Screening Programmes
260 Ecclesall Road South
Sheffield S11 9PS
Tel: 0114 271 1060
Fax: 0114 271 1089
e-mail: nhs.screening@sheffield-ha.nhs.uk

The document is available in PDF format on the NHS Cancer Screening Programmes website
www.cancerscreening.nhs.uk

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(MHRA) can be obtained from:

Business Services
MHRA
Hannibal House
Elephant & Castle
London SE1 6TQ
Tel: 020 7972 8272
Fax: 020 7972 8124
e-mail: dts@mhra.gsi.gov.uk

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# Guidance Notes on Electrical Safety in Rooms Used for Colposcopy

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INTRODUCTION

Part I of this publication contains details of the changes necessary to enable existing rooms for colposcopy to comply with International Standard IEC60364-7-710 for medical locations classified for group 1 procedures (see section 2.1) and is for implementation by competent electrical personnel. However, all users of colposcopy rooms are advised to read Part I Electrical Safety in order to be aware of the limitations of use of a group 1 rated room and the importance of the checks to be made to confirm compliance with these recommendations for the safety of themselves and their patients.

Part II of this publication provides updated guidance on the safe use of electrosurgery for the treatment of cervical intraepithelial neoplasia. The guidance was previously published as Guidance Notes on the Safe Use of Diathermy Loop Excision for the Treatment of Cervical Intraepithelial Neoplasia and was intended for clinicians to explain why the high frequency current used for electrosurgery required special precautions in its use. These precautions are quite different from those to be taken when using mains frequency powered equipment and require a basic knowledge about the effects of high frequency on electrical conductivity that users of electrosurgery equipment should be aware of. This revised guidance contains additional advice, particularly in relation to preparation of the patient.
PART I. ELECTRICAL SAFETY

1. BACKGROUND

Surveys carried out by the Medicines and Healthcare products Regulatory Agency (MHRA) have shown that some colposcopy rooms currently in service do not meet the electrical safety requirements for medical locations now required in International Standard IEC 60364-7-7101 and Chapter 56 of BS 7671 IEE Wiring Regulations.3 This guidance, which is advisory, has been provided to enable existing rooms to be brought up to the requirements of these standards. Other sensible precautions to remove potential hazards to patients and staff have been added.

Measures to check that existing colposcopy rooms comply with the requirements of IEC 60364-7-710 and BS 7671 IEE Wiring Regulations will have to be undertaken by a competent person appointed by the authorised person for the hospital. Providing that the original electrical wiring installation was carried out in compliance with the IEE Wiring Regulations applicable at the time, any rectification work necessary to comply with the requirements of BS 7671 IEE Wiring Regulations will not be major.

Note: Guidance on permanent electrical installations in new buildings and refurbished rooms in healthcare establishments is contained in the Medical Electrical Installation Guidance Notes (MEIGaN), which is available on the MHRA website (www.mhra.gov.uk).

2. LIMITATIONS OF USE OF ROOMS USED FOR COLPOSCOPY

2.1 Room ratings

Rooms used for colposcopy fall within group 1 of IEC 60364-7-710, namely medical locations where applied parts are intended to be used as follows:

1 externally
2 invasively to any part of the body, except where group 2* applications are intended.

*Group 2 covers operating theatres and intracardiac procedures.

2.2 Anaesthesia

It follows from section 2.1 that only local analgesia may be administered in a group 1 rated room. If and when general anaesthesia is required, it must be administered in a group 2 rated operating theatre. Guidance on the use of general anaesthesia is given in Colposcopy and Programme Management (NHSCSP Publication No 20, section 8.8).4
3. GENERAL RULES FOR ELECTRICAL SAFETY

- Room earth connected to one authentic earth source.
- Only one phase per room.
- No multiway mains sockets or trailing leads.
- Check non-CE marked devices.

3.1 Room earth

The regulations require that the room earth must be the TN-S system; this means that it is connected directly to the centre point of the transformer in the hospital substation, as illustrated in Figure 1.

If the earth is connected to the neutral at any point along its route to the substation (as shown in Figure 2, the TN-CS system), the earth wire will acquire a voltage generated by the resistance of the neutral wire from the point the earth is connected to it multiplied by the value of the return current from all three phases.

It is essential that the incoming earth connection to the room is from a valid TN-S system source and is terminated in the room at the earth reference bar (ERB) connection (Figure 3).

All earth wires from the mains sockets or other supply points as well as accessible conductive surfaces within the room must also be connected at the ERB. Conductive surfaces include water taps, radiators, conduits, room lighting boxes and structural metal such as false ceiling supports etc.

Figure 1 The TN-S system.
The ERB should be housed in a dedicated enclosure located close to the point at which the mains supply is brought in to the room. It should be between 1.0 and 1.8 metres from the floor and have a lockable cover marked earth reference bar or ERB. The copper busbar should have sufficient terminals to accommodate the earth conductors and the incoming earth. Each earth lead should be correctly terminated and clearly identified with its origin. All screws and washers should be brass. Where possible, the ERB should be located near to the reference socket (see section 3.2). Further information about the requirements for an ERB is contained in MEIGaN sections 6.4 and 6.7.

**Figure 2** The TN-CS system.

**Figure 3** Typical earth reference bar (ERB).
Each earth wire from the socket or other earth point should be run separately to the ERB in 6 mm² cable. This is radial earthing, as shown in Figure 4. Existing ring main installations will be considered satisfactory if both ends of the ring earth, which must be at least 2.5 mm² cable, are connected to the ERB, as shown in the example of ring main earthing (Figure 5). Here, since the water tap, structural metal and the metal case of the light fitting are not part of the ring, they are radially earthed.

The bonding resistance of all the earthed devices should be checked. The resistance from the ERB to the earth connection of each mains outlet should not exceed 100 milliohms. The resistance from the earth pin of the plug on any mains powered device to any accessible conductive point should not exceed 100 milliohms. Bonding resistance should be measured using a standard earth bonding tester, not an earth loop tester as this can damage sensitive equipment.

3.1.1 Earthing of conductive metal surfaces
The MHRA survey found that the conductive metal surfaces of equipment used in colposcopy rooms were often improperly earthed. These are listed below, and the earth conductivity of each should be checked.

Patient couch
The metal frame of electrically driven patient couches must be earthed. Earth continuity should be checked from the metal frame to the earth pin of the plug of the electric supply lead to the couch. If modifications are necessary to the lead or its termination at the couch to ensure proper earth continuity of the couch frame, the couch supplier should be contacted because the mains lead of a piece of equipment is an essential part of it and should only be replaced by a part provided by the supplier.

Figure 4 Radial earthing.
GUIDANCE NOTES ON ELECTRICAL SAFETY IN ROOMS USED FOR COLPOSCOPY

Metal equipment cabinet

When a metal cabinet or rack is used to house mains operated equipment, it should be earthed using a link connected from the earth terminal of each piece of equipment to an adjacent terminal on the surface. Earth continuity of the cabinet or rack should be checked to the earth pin of the supply lead connecting each piece of equipment on the cabinet.

Colposcope

The metal base of the colposcope is earthed by the mains supply lead, and earth continuity should be checked from the earth pin of the plug to the point where the earth lead is connected to the base. Any problem with the earth continuity caused by the mains lead should be referred to the supplier if replacement is required. Earth continuity from the base to the microscope support often depends on a number of adjustable elbows; the clamps of these must be tightened to achieve good connection and the contact surfaces must be kept bright and clean.

Proper earthing of the microscope eyepiece assembly is dependent on sliding connections and can be a problem. Earth continuity should be checked to confirm that all accessible conductive surfaces have a resistance to earth of 100 milliohms or less. Should it not be possible to achieve a consistent low value of bonding resistance to the microscope, a 6 mm² external (yellow/green) flexible earth lead should be connected from the earth at the base of the colposcope to the microscope head.

3.1.2 Checking the touch voltage of all accessible earthed surfaces

The integrity of the earth conductivity of all accessible earthed surfaces in the room should be checked by measuring the touch voltage (AC and DC) between the earthed surface and the ERB. The touch

Figure 5  Ring main earthing.

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Guidance Notes on Electrical Safety in Rooms Used for Colposcopy

voltage should not exceed 100 millivolts. One terminal of a digital multimeter should be connected to the ERB and a sharp pointed probe used on the other lead. Switch the meter to auto-ranging mode and touch the probe to every accessible conductive surface using the sharp point to pierce any surface finish. If the touch voltage is excessive, the earth bonding must be checked.

3.2 One phase per room

The electrical supply to all the single phase supply points in the room should all be connected to a common phase. The use of a single phase 230 volt supply in a room means that the maximum voltage between the live and neutral or earth wires in the room is 230 RMS or 325 volts peak. If a different phase has been used to supply any other single phase supply point, the maximum voltage accessible in the room between the live wires of the two different phases increases to 400 RMS or 565 volts peak. This represents an unnecessary hazard that having only one common phase in the room will remove.

When using a three phase supply in a building, it is necessary to balance the loading on each phase as far as is possible. This should be achieved by distributing the load of the three phases between different rooms and not within the same room. To check that the room is supplied from one phase, one socket outlet should be designated the reference socket; this should be the socket nearest to the point at which the mains supply is brought into the room. Confirm that the supply is from one phase by measuring the voltage between the live terminal of the reference socket and the live terminals of all the other supply points in the room, including the supply to the room lighting. The voltage should not be more than 1 or 2 volts.

3.3 Multiway sockets and trailing leads

A random check of multiway extension sockets in use on the floor in two hospitals revealed that a quarter of those in use were faulty despite carrying certification by PAT 1000 tests. Use of such devices in a colposcopy room represents an electrical safety and trip hazard. These sockets are susceptible to damage by people walking on or over them, by objects falling into them as well as damage to the sockets caused by the difficulty of aligning the plug to the socket at the correct angle when inserting the plug into the socket on the floor.

3.3.1 Electrical sockets on the room wall
The safest place for an electrical socket is on the room wall. Multiway sockets are invariably used when there is an insufficient number of sockets available in the room for the number of electrical devices used. This will be a continuing problem that must be addressed by increasing the number of sockets on the room walls so that there are always spare sockets available. A safe and inexpensive alternative to wiring additional sockets is to replace the existing one and two way wall sockets with two and three way sockets that are wired flush with the wall in the box for the original socket. These sockets are now available from electrical wiring component suppliers.

3.3.2 Mains leads
Trailing mains leads going from the wall to a piece of equipment also represent a major trip hazard.
Mains leads fitted with moulded plugs must not be shortened because they are an integral part of the equipment that they supply and are only to be replaced with a like part from the equipment supplier. Any surplus lead from a mains cable should be neatly stowed, but not coiled, near to the wall under the mains socket that it is connected to.

Mains leads are not designed to be walked on and should be covered with a tread strip from the wall to the point of use. This will reduce the trip hazard and protect the lead from damage.

3.4 CE marked devices

The requirement for medical devices to be CE marked became mandatory in 1998, and only CE marked devices must now be purchased. Manufacturers of medical devices for use in colposcopy rooms are not bound to apply particular standards to their products if they can demonstrate by other means that they meet the essential requirements of the EC medical devices directive. Nowadays, the manufacture of goods from a European company may well have been outsourced to some other country not covered by European regulations. The most effective safeguard for a UK purchaser to check that a product conforms to the relevant British Standard (BS 60601-1 Medical Electrical Equipment: General Requirements for Safety) is to confirm that it is CE marked. CE marking does not necessarily mean compliance with safety standards but that the essential requirements are in line with current good practice.

Safety standards do not necessarily cover equipment performance, and the supplier will usually provide a demonstration unit for a prospective customer to evaluate if requested before a commitment to purchase is made. The national office of the NHS Cancer Screening Programmes should be informed of the results of such new equipment trials so that other centres can benefit from your experience.
4. COLLPOSCOPY ROOM CHECK LIST

**Room earth TN-S format**

Check: Incoming room earth is directly connected to centre point of hospital supply transformer

Method: Visual check

**Room earths connected to ERB**

Check: The incoming earth and all earth wires from all supply points and conductive surfaces are connected to the ERB

Method: Use earth bonding tester

Resistance \( \leq *100 \text{ milliohms} \)

**Check earth bonding conductivity to all conductive metal surfaces to earth socket of supply cable or ERB**

Method: Use earth bonding tester; include patient couch, colposcope, metal equipment cabinet or rack, lighting fittings, radiators

Resistance \( \leq *100 \text{ milliohms} \)

**Check touch voltage of all accessible earthed surfaces**

Method: Use digital multimeter

Voltage \( \leq *100 \text{ millivolts} \)

**Check that room supplied from only one phase**

Method: Use digital multimeter; check voltage between reference socket and all other supply points

Voltage \( \leq *2.0 \text{ volts} \)

**Check all electrical sockets and mains supply leads**

Method: Visual check that all equipment supply points are wall mounted or above floor level and that any trailing leads are protected with tread strip

**Check all equipment in use is manufactured to a safety standard**

Method: Look for CE mark on rating plate and check that the standards for the equipment meet the essential requirements of the EC medical devices directive

*Less than or equal to
PART II. THE SAFE USE OF ELECTROSURGERY FOR LLETZ PROCEDURES

5. BACKGROUND

Colposcopy and treatment of the cervix is most commonly performed in hospitals, either in the general gynaecology departments or in a specific colposcopy unit. Departments of genitourinary medicine often run their own colposcopy service. It is usually an outpatient procedure. However, it may also be carried out in general practice or in community clinics. For this reason, because the use of electrosurgery can cause burns to patients and those using or assisting in its use, the NHS Cervical Screening Programme has considered it advisable to provide guidance on the safe use of electrosurgery equipment. These new guidance notes, which replace Guidance Notes on the Safe Use of Diathermy Loop Excision for the Treatment of Cervical Intraepithelial Neoplasia, have provided an opportunity to update the advice given, particularly in respect of preparation of the patient. Their object is to point out simple safety procedures and to explain why they are necessary. If they are followed they will reduce the risks, which most certainly exist, in this form of treatment.

Many clinics have been using large loop excision of the transformation zone (LLETZ) without any adverse consequences to users or patients, and the author is grateful for the help freely given by medical consultants, equipment manufacturers and service engineers in providing information on the techniques and equipment used which has achieved the end result.

These guidance notes are concerned wholly with aspects of safe working with diathermy equipment and are not concerned with power levels for cutting and coagulation or any other matters concerning surgical technique.

6. USE OF HIGH FREQUENCY IN ELECTROSURGERY

Electrosurgery is performed using alternating electric current at frequencies in the order of 500000 cycles per second. High frequency is used because it does not cause ventricular fibrillation but has a cutting or coagulating effect due to the generation of heat. However, the use of high frequency current creates problems not present with mains frequency current. It is for this reason that special precautions quite different from those to be taken when using mains frequency powered equipment, and consequently not obvious, must be taken.
7. **EFFECT OF HIGH FREQUENCY ON CURRENT FLOW**

Current in all alternating current circuits is controlled by the impedance offered to it by three sources.

1. **Resistance**

   This, as the name implies, is the resisting power of the circuit components and conductors to flow of current. Current flow is governed by a simple relationship:

   \[
   \text{Current} = \frac{\text{Voltage}}{\text{Resistance}}
   \]

   The effect is independent of frequency.

2. **Inductance**

   This is the effect on current flow of the magnetic field set up by a coil of wire in the circuit. Current flow through an inductance is governed by a relationship involving frequency:

   \[
   \text{Current} = \frac{\text{Voltage}}{k f L}
   \]

   where \( k \) is a constant, \( f \) the frequency and \( L \) the inductance.

   It can be seen that the blocking effect on the current of a single loop of wire, which at the mains frequency of 50 cycles per second is insignificant, would be 10 000 times greater when using electrosurgery at 500 000 cycles per second.

3. **Capacitance**

   This is a measure of the ability of the circuit to store and discharge or leak a charge of energy. Again, this is an effect that is governed by a relationship involving frequency:

   \[
   \text{Current} = \text{Voltage} \times \frac{k f}{C}
   \]

   where \( k \) is a constant, \( f \) the frequency and \( C \) is the capacitance.

   Again, it can be seen that the leakage current available to discharge and cause burns is 10 000 times greater than with equipment operating at mains frequency.
8. SAFE WORKING PROCEDURES FOR LLETZ

8.1 Electrosurgery equipment manufacturers’ operating instructions and literature

Manufacturers’ operating instructions, educational booklets and video programmes should be read or viewed and thoroughly understood by all personnel, before use of the equipment.

8.2 Patient electrical isolation

When the active electrode is energised in contact with the patient, the whole of the patient’s body is available to serve as a return path. Electrical isolation of the patient from the earthed metal parts of the couch and leg supports by means of insulating mattresses is essential. The patient’s hands must not be allowed to touch any earthed metal when diathermy is in progress and contact with the patient by touching should be avoided. Special care should be taken to safeguard patients who are subject to involuntary movement. A burn occurs when the energy cannot be safely dissipated over a large area. If staff have to touch the patient, contact with the patient using the whole hand may be harmless but finger tip contact could result in a painful burn.

8.3 Connection of the electrosurgery unit to the mains supply

The standard mains lead provided with the unit must be connected with a 13 amp plug, fused at the value specified by the manufacturer, and connected directly to a mains socket.

8.4 Preparation of the patient

Colposcopy procedures carried out in a group 1 medical location (see section 2 of Part I) generally involve removal of only the patient’s undergarments below the waist. The patient’s brassiere, jewellery, glasses, earrings or necklace may be left in situ. Body piercings, particularly around the operating site, and any metal item nearer than the return electrode should be removed where possible; if this is impracticable, they should be covered with adhesive tape in cross form. Items of large metal jewellery which may prejudice the electrical isolation of the patient by making contact with an earthed object should also be removed.

When general anaesthesia is administered in a group 2 operating theatre (see section 2.2 of Part I), the usual procedures for removal of clothing and jewellery in theatre will apply.

8.4.1 Pacemakers, defibrillators and neurostimulators

Where a patient has an implanted pacemaker, defibrillator or neurostimulator, an appropriate risk/benefit assessment will need to be undertaken prior to surgical diathermy taking place. Manufacturers of these devices generally advise against the use of monopolar surgical diathermy normally used for LLETZ procedures. This is because implanted lead electrodes can form an alternative path for high frequency current that may adversely affect operation of the device or cause localised heating in lead electrodes resulting in tissue damage.
The decision as to whether a patient can safely receive diathermy is a clinical one and should therefore take into consideration the position of the implant and location of lead electrodes in relation to the current path formed between the excision loop and the position of the return electrode. The majority of pacemakers and defibrillators are implanted in the upper pectoral region but some may be implanted in the abdominal region. Some neurostimulators are also implanted in the abdominal region (anterior or posterior) whereas others are implanted in the pacemaker position, but with lead electrodes implanted in deep brain tissue. Under no circumstances should the return electrode be positioned so that the implanted device is within the diathermy current path. It is particularly important that implanted pacemakers are prevented, as far as possible, from responding inappropriately to ‘noise’ generated by high frequency electric and magnetic fields from diathermy equipment that may change operation of the device and potentially compromise patient health.

Where risk/benefit analysis indicates surgical diathermy to be appropriate for a pacemaker/defibrillator patient, it is advisable to first arrange for the operational status of the device to be checked by cardiac department technical staff (eg sufficient battery energy remaining and soundness of leads). For pacemaker/defibrillator dependent patients, consideration should be given to reprogramming the device to avoid sensing of noise and subsequent delivery of inappropriate therapy. Operational status should also be verified on completion of the diathermy procedure.

This advice has been provided by the Medicines and Healthcare products Regulatory Agency (MHRA), which recommends a poster The Electrosurgery Team that highlights particular problems associated with surgical diathermy and how to avoid them. This is available on their website (www.mhra.gov.uk).

8.5 Attachment of return electrode

Diathermy equipment manufacturers’ instructions on attachment and positioning of the return electrode must be followed. The return electrode collects the current delivered to the patient and conducts it back to the diathermy generator. To reduce the risk of heat being generated at the point of contact with the patient, the pad should provide a large low impedance contact area on conductive tissue that is close to the operative site. Consequently, the whole area of the return electrode must be in contact with the patient without wrinkles. Surface area impedance can be compromised by excessive hair, adipose tissue and scar tissue. The return electrode should not be attached in the area of prosthetic inserts. If the alternative limb is also not available, use an area nearer to the excision site. Single use plates must not be reused since the conducting gel which is used to coat the contact surface may not be intact and may impair conduction of the return current.

8.6 Connection of the active electrode

Where a choice of length of active electrode lead is available from the supplier, choose the shortest length that will allow the lead to run from the diathermy electrode to the connection on the generator. Any surplus lead must NOT be coiled, neither should the lead be looped to clip it to the patient’s couch or the generator trolley. Unlooped attachment to support the lead to prevent undue strain on the surgeon’s hand and generator connection plug is acceptable. Particular care should be taken to keep the lead away from the colposcope and in no case should it be looped around the surgeon’s arm to support it.
8.7 Inspection and storage of the cutting loop

Before use, the cutting loop should be carefully inspected and not used if the insulation is impaired. A holster of non-conducting material placed within easy reach of the surgeon should be used to house the active electrode when not in use. It should be kept clean and dry.

The voltage of the loop in the cutting mode is in the order of 1900 volts and in the coagulation mode 3500 volts. Under no circumstances should the diathermy loop or coagulation ball be energised away from the excision site.

Where cutting or coagulation modes can be switched from the electrode shaft, the non-active setting should be set to its minimum value until required for use so that inadvertent operation of the switch does not cause harm.

8.8 Supply lead safety

8.8.1 Trailing leads
Care must be taken not to allow an additional hazard to arise from the presence of the trailing leads on the floor of the treatment room, particularly when the patient is being brought in and taken from the room. This can be best ensured by storing the active and return electrode leads on the generator trolley when the equipment is not in use.

8.8.2 Use of lead adaptors
The use of adaptors which allow smaller lead connectors to be connected to a larger size socket inlet must be avoided because most have accessible bare metal parts and do not conform with basic safety standards for medical devices. Consequently, their use gives rise to the risk of electrosurgical burns. The risk is increased when using spade or hook connectors. Only leads and connectors designed for direct connection to the equipment must be used and the manufacturers’ recommendations about use, storing, cleaning and checking followed.

For further information, read MDA Safety Notice SN9609 Risk of Skin Burns from Lead Adaptors Used with Electrosurgical Equipment.8

8.9 Electrical isolation of the nursing staff and clinician when the electrode is energised

8.9.1 Nursing staff
As a general rule, nursing staff should avoid touching the patient when the electrode is energised. If contact is essential, this should be by firm whole hands not tips of fingers. Care must be taken not to allow contact with the earthed couch frame while touching the patient.

8.9.2 Clinicians
The wearing of surgical gloves does not provide an effective means of isolation for the clinician during electrosurgery. Consequently, clinicians should isolate their arms, head and feet from the earthed couch and base and supporting column of the colposcope.
A range of insulated electrosurgical accessories is available from appliance manufacturers to assist in providing effective isolation.

The unused hand should not touch the patient when at rest. Although the eyepiece of the colposcope is plastic, the metal supporting tube should not be touched. If a teaching arm is fitted to the colposcope, the observer must take similar isolation measures to the clinician.

8.10 Smoke evacuation

A dedicated filtered evacuation system should be used to remove surgical smoke in order to allow clear observation of the excision site and removal of the potential health risk to personnel. The hospital vacuum system should not be used for this purpose. Recent research quoted in the Archives of Dermatology claims that viral transmission via surgical smoke had been demonstrated.

8.11 Precautions in the use of swabs and solutions

During electrosurgery it is normal for sparking to occur at the active electrode. These sparks are easily able to ignite fluids which have low ignition temperatures, and dry swabs and drapes. It is therefore important that spirit based fluids are not used for skin cleaning, disinfection or preparation of patients, particularly when other easily ignited materials such as dry swabs or drapes are used. When lubrication is required, use lubricants that are water based. Consideration should be given to labelling containers of spirit based cleaning and preparation materials and non-water based lubricants, such as petroleum jelly, with a cautionary note about the danger of their use in conjunction with diathermy. Queries about suitability of fluids and lubricants from any source for use in surgical diathermy should be addressed to the hospital pharmacy department.

Do not use electrosurgery in an oxygen enriched environment.

For further information, read MDA Safety Notice SN 2000(17) Use of Spirit-based Solutions During Surgical Procedures Requiring the Use of Electrosurgical Equipment.

8.12 Other safety measures

Routine maintenance of all equipment should be carried out at the intervals recommended by the manufacturer. A contract schedule listing all checks to be carried out should be drawn up, and a dated and signed report on the tests made and results obtained, where appropriate, should be provided by the service engineer at the conclusion of each visit.

For further information, see Health Equipment Information HEI 98 Management of Medical Equipment Devices.
REFERENCES