SURGICAL DIATHERMY UNITS

Review Issue

A review of 5 models

ESCHMANN TD411—RS
ESCHMANN TD411—S
OLYMPUS PSD—10
VALLEYLAB FORCE 10
WOLF 2175

including a brief assessment of

MIRA MD1000
INTRODUCTION

In this issue of 'Evaluation' we review all infant transport incubators which have been evaluated and which are still available in the UK.

The Overall Comparison and Summary pages which follow are based on the evaluation findings and aim to provide guidance on choice. Please consult the full report on any model you are interested in before making a purchasing decision (issue numbers of full reports are given in the Summaries).

The Appendices provide more general background advice: in particular, Appendix 1 repeats DH advice that purchasers should give preference to equipment which complies with the safety standard, and to manufacturers who are listed in the DH Register of Manufacturers of Medical Equipment.

ACKNOWLEDGEMENTS

This report was prepared by Dr C J Hacking of the Bioengineering Unit, South Glamorgan Health Authority. The DH thanks the following members of the Bioengineering Unit for their work on this evaluation:

Dr D G Spendley
Dr C J Hacking
Mr J McCarthy.

We also thank the consultants and all the medical, nursing and theatre staff who helped in the evaluations; and the Department of Medical Photography, Cardiff Royal Infirmary for the photographic work.
OVERALL COMPARISON

At present, of the diathermy units featured in the Evaluation Summaries in this issue, only the Eschmann TD411-S (£4,660, set of 3 footswitches £310), the Eschmann TD411-RS (£5,280, set of 3 footswitches £310) and the Valleylab Force 2 (£4,475, set of 3 footswitches £480) have a BSI Certificate of Compliance with the full safety standard (BS 5724: Section 2.2). Eschmann Bros and Walsh Ltd also have a BS 5750: Part 1 quality assurance certificate for surgical diathermy design, production and servicing.

Mira is not a DH Registered Manufacturer of surgical diathermy equipment; manufacturers of all other models in this issue are.

Facilities
All of the high power units (over 200 W) performed well in a wide range of procedures. However, they differ in the facilities they offer. Each model has the conventional monopolar outputs: cut, coagulation and blend. The Eschmann TD411-RS also has a specialist cut facility specifically designed for trans-urethral resections and colposcopy. All units provide two types of monopolar coagulation: a low voltage coagulation output, intended for desiccation and a high voltage output, intended for fulguration (spray coagulation).

They all have a bipolar output. The Eschmann TD411-S and the Eschmann TD411-RS both have two bipolar output ranges: macrobipolar (50 W) and microbipolar (15 W). The output can be operated by tissue-sensing forceps with a ‘start’ delay: the output is energized automatically, a short time after the forceps have gripped tissue. The Valleylab Force 2 has a single 70 W bipolar output. Under forceps switching control the output is activated as soon as the forceps are closed together.

The Valleylab Force 2 is designed to allow two surgeons to work in parallel with up to two monopolar (one footswitched, the other fingerswitched) outputs and one bipolar output. Except for the monopolar coagulation output, only one output can be energised at a time on a ‘first come, first served’ basis. Two monopolar coagulation outputs can be activated simultaneously with the total output shared between them.

The Olympus PSD-10 (£4,390, includes S-P cord, test cable and footswitch) performed well in endoscopic procedures, for which it was designed. It is very expensive for a monopolar-only machine, but does have a number of safety features particularly related to its use with an endoscope. (For example, the unit cannot be operated unless the body of the endoscope is connected to it and until the active electrode and neutral plate are both in good contact with the patient.) It was easy to set up and use and, despite the price, represents a good choice for this specialist application.

The Wolf 2175 (£1,120 including footswitch) is a good choice for laparoscopy, and comes complete with laparoscopic forceps. It is simple to use, having a single bipolar output. Note, however, that the manufacturer does not supply standard or microsurgery forceps.
ESCHMANN TD411—RS

The Eschmann TD411—RS is a solid-state, table-top, surgical diathermy unit with an isolated RF output rated at 400/350 W cut, 150/80 W coag, 300 W blend monopolar and 15/50 W bipolar.

The unit has continuously variable rotary controls. The monopolar outputs are activated from the single electrical footswitches or a fingerswitching active pencil; the bipolar output from an electrical or pneumatic footswitch or by forceps switching.

The Eschmann TD411—RS is fitted with a volume control, a neutral plate continuity monitor, a patient earth monitor and a patient voltage monitor.

ESCHMANN TD411—S

The Eschmann TD411—S is a solid-state, table-top, surgical diathermy unit with an isolated RF output rated at 400 W cut, 150/80 W coag, 300 W blend monopolar and 15/50 W bipolar.

The unit has continuously variable rotary controls. The monopolar outputs are activated from the single electrical footswitches or a fingerswitching active pencil; the bipolar output from an electrical or pneumatic footswitch or by forceps switching.

The Eschmann TD411—S is fitted with a volume control, a neutral plate continuity monitor, a patient earth monitor and a patient voltage monitor.

**Full report:** Evaluation No 97
**Price:** £5,280
**Product Certificated?** Yes, BS 5724: Section 2.2
**DH Registered Manufacturer?** Yes, R0008/ME
**Made in:** UK

**Advantages:** good performance, especially bipolar; clear controls and easy to use; well constructed; good serviceability and manuals.

**Disadvantages:** none.

**Overall:** a good all round performance, particularly for bipolar work — has forceps switching with start delay. Complies with BS 5724: Part 1 and Section 2.2.

**Full report:** Evaluation No 96
**Price:** £4,660
**Product Certificated?** Yes, BS 5724: Section 2.2
**DH Registered Manufacturer?** Yes, R0008/ME
**Made in:** UK

**Advantages:** good performance, especially bipolar; clear controls and easy to use; well constructed; good serviceability and manuals.

**Disadvantages:** none.

**Overall:** a good all round performance, particularly for bipolar work — has forceps switching with start delay. Complies fully with BS 5724: Part 1 and Section 2.2.
OLYMPUS PSD – 10

The Olympus PSD—10 is a solid-state, table-top monopolar surgical diathermy unit with an isolated RF output rated at 80 W. It is designed exclusively for endoscopic procedures.

There are cut, coagulation and blend outputs. The output is activated by a single pedal electrical footswitch. There is a neutral plate continuity monitor, a Safety-Patient cord continuity monitor and a current imbalance monitor with auditory and visual alarms. Additionally, there is a pre-procedural check facility.

VALLEYLAB Force 2

The Valleylab Force 2 is a solid state, table-top, surgical diathermy unit with an isolated RF output rated at 300 W cut, 150/200/250 W blend, 99/120 W coag monopolar and 70 W bipolar.

The unit has dual mode operational facility with discrete touch controls and digital displays. The outputs are activated from the twin electrical footswitches, a fingerswitching active pencil, and a single bipolar footswitch; or can use monopolar footswitches or handswitching forceps.

The Force 2 is fitted with a volume control, a diathermy current continuity monitor and a patient plate contact monitor.
WOLF 2175

The Wolf 2175 is a solid state, table-top, bipolar unit with an isolated output rated at 50 W.

The output is activated by a single electrical foot-switch.

A test facility is provided to check that the leads and forceps are functional.

<table>
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<tr>
<th>Full report:</th>
<th>HEI 139</th>
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<tr>
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Advantages: very good performance; well made; easy to service.

Disadvantages: standard and microsurgery forceps not available; output indicator too loud and harsh; did not comply fully with BS 5724.

Overall: a good unit for laparoscopy. Test facility a welcome feature.

See Update Appendix 5
Appendices

APPENDIX 1

BRIEF ASSESSMENT OF THE MIRA MD1000

The Mira MD1000 (£1,185) is a low power, solid state, table-top, unit with a bipolar output rated at 12 watts by the manufacturer. The unit is specifically intended for ophthalmic applications. The output frequency is crystal controlled at 13.56 MHz. A continuously variable rotary control is used to set the output power. The unit incorporates electronic feedback to maintain a constant RF output voltage. Although a bipolar instrument, this unit can be used in a monopolar mode using one of the special probes available from the supplier. In this mode the return diathermy current path is via leakage to the probe support held by the surgeon.

The output is activated by a single footswitch. The MD1000 weighs 3.2 kg, is 165 mm high by 133 mm wide and is 279 mm deep.

Existing users should note two particular points:-

First, the unit supplied for the brief assessment had been repaired by the manufacturer. As part of the repair, one of the active electrodes had been directly connected to the protective earth terminal of the instrument. In use, the patient would be directly connected to earth, so presenting a potential hazard. Two similar units in local hospitals have been checked but do not exhibit this fault. Existing users should have their units checked by their medical physics department, especially if the unit has been repaired by the manufacturer.

Second, the use of electronic feedback raises the maximum output power available. Although rated at 12 W by the manufacturer, this unit can deliver more than 100 W into a 50 ohm load. Sub-clause 101.4.1 of BS 5724: Section 2.2 requires the use of a neutral electrode for equipment having a rated output in excess of 50 W when used in a monopolar mode.

APPENDIX 2

POINTS TO BEAR IN MIND BEFORE DECIDING WHAT TO BUY

During the evaluations several points emerged which should be considered before buying a surgical diathermy unit. These are the obvious ones of electrical and mechanical safety, performance characteristics, likely reliability and ease of servicing. The evaluations assess all these points by testing against British and International standards and by subjecting each diathermy to several months use in hospitals.

Compliance with safety standards

BS 5724: Part 1 (IEC 601-1) and BS 5724: Section 2.2 (IEC 601-2-2) is officially recognised by the DH, and when purchasing equipment preference should be given to products which comply with these standards. (See The Technical Evaluation and Manufacturer's Comments sections of each report.)

Manufacturer's quality control

The Manufacturer's Information table in the individual reports show which manufacturers have registered, or applied for registration under the DH Registration Scheme for Manufacturer's of certain medical products, including electro-medical equipment. The scheme has been in operation since 1985. A manufacturer seeking registration for a specific category of equipment is required to declare that the quality system used to control the manufacture of that category is in compliance with the requirements of the DH 'Quality Systems for Medical Equipment 1990 (Good Manufacturing Practice)'. This 'green' Quality Systems Document includes the Design Control Specific Requirement, in clause 4.4.1, which states that this requirement shall be based on harmonised European Standards, where applicable and available, otherwise on applicable International or British Standards.

The quality system subsequently becomes subject to audit, by the Medical Devices Directorate, in order to assess its compliance. (In general, Registration does not imply that all products offered by the manufacturer are from registered sources; you should ask the supplier whether the particular product you want is manufactured under the DH Registration Scheme.) One of the aims of the DH Manufacturer Registration Scheme is to give NHS buyers confidence in manufacturers' claims of compliance with product standards. When selecting equipment you are strongly recommended to take into account the manufacturers' registered status.

Electrical safety

Whether to choose a monopolar unit, a bipolar unit, or one with both facilities, will depend on the use for which it is intended. However, the use of a bipolar unit will give greatly increased safety advantages - see
Appendices

Appendix 3. If monopolar diathermy is necessary or preferred, there is a choice of isolated or rf earthed type of unit; this, and the application and advantages of various monitoring provisions, are also discussed in Appendix 3. On balance, the isolated system appears to offer some advantages, although these may not always be realised in practice.

Maximum power requirement

The standards set an upper limit of 400 W on the output of any surgical diathermy machine. However, the power available from some units, though less than this value, may still be greater than that necessary for particular procedures. Clearly, to use a machine which is able to deliver significantly higher power than is required for the procedure is to introduce a potential safety hazard. It is, therefore, important to relate the maximum power of the machine to the type of work to be undertaken.

Facilities

It is important to check that the outputs and controls provided suit your working conditions. For example, not all models which combine monopolar and bipolar units have a separate control for the bipolar output, and some have no blend facility. Diathermy units are now available which enable both the monopolar and bipolar outputs to be used together on a 'first-come, first served' basis, and this can be very useful for two surgeons working together. Increasingly, monopolar units have the option for the use of fingerswitching electrodes. A unit with a bipolar output may have forceps switching (with or without a start delay); all have a footswitch control, it may be electrical or pneumatic but there might not be a choice. On some models, supplied with a single footswitch, the selection between cut and coagulation outputs has to be made on the front panel: this was not popular with our users. Many models now have digital displays of power settings - but see Special Note in Appendix 3 about what the display actually means. Some units can only be used with the manufacturer's own accessories and it is important to determine that these are suitable for your application.

APPENDIX 3

SAFETY OF SURGICAL DIATHERMY UNITS

MONOPOLAR DIATHERMY

(1) Isolated or rf earthed?

It has been generally accepted for many years that direct connection of the patient to earth should be avoided in order to eliminate the risk of the patient receiving an electric shock if he were to be connected to other equipment which might be faulty. However, even a circuit with no connection to earth may allow sufficient leakage current at diathermy frequency to flow to earth for the patient to be exposed to the risk of burns at sites where he may be inadvertently in contact with earthed objects.

In recent years methods of dealing with both these risks have been developed. In the rf earthed type of monopolar surgical diathermy unit the neutral plate is connected to earth, not directly, but through a capacitor of such value that it presents little resistance to the diathermy current but a high resistance to mains currents. In contrast, an isolated unit is one with no connection or components whatsoever between the diathermy circuit and earth. Although 'leakage' of energy from the diathermy circuits cannot be entirely prevented even in the isolated type of unit, the use of modern electronic components and design techniques can ensure that the leakage currents which result are very small indeed. The standards define strict limits within which they are required to be kept.

(2) Safety differences between the two types

Electric shock

The electric shock risk is primarily from the 50 Hz mains supplies. At this low frequency it should always be possible to obtain a greater separation from earth with an isolated diathermy than with an rf earthed type. The isolated diathermy should, therefore, offer a lower risk of electric shock.

Burns

Burns are generally caused by diathermy currents passing from the patient to earth at contact points of small area. Monitoring electrodes are always possible sites of burns. Theoretically, an isolated monopolar diathermy will not show any rf potential to earth at the sites of monitoring electrodes. With an rf earthed diathermy, however, one side of the generator is intentionally connected to earth and there is, therefore, a gradient on the patient's body from the high potential of the active electrode down to earth (the neutral plate). Monitoring electrodes placed near the active electrode will be at a higher potential to earth than electrodes placed near the neutral plate. This comparison suggests that, during actual operation, an isolated diathermy should offer a smaller risk of burns.

However, in some circumstances, the reverse may be true. In particular, if the diathermy is operated when the active electrode is not in contact with the patient, the neutral plate of an isolated diathermy may rise to an rf potential, with the possibility of burns at the monitoring sites. This does not happen with the rf earthed diathermy where the neutral plate, and hence also the patient, are held at rf earth potential.

On balance, the isolated diathermy appears to offer some advantages but, because of the variability in design and construction of surgical diathermy equipment, it is impossible to say that these advantages will always be realised in practice. At the moment, therefore, whether to choose an isolated or an rf earthed unit need not be the first consideration.
(3) The neutral plate

In a monopolar surgical diathermy unit, power from the mains is converted into rf power in the generator and is then delivered to the surgical site along the active lead to the active electrode. This, because of its small area, causes a high concentration of rf (diathermy) current at the surgical site, resulting in the disintegration and vapourisation of tissue. From this site, the diathermy current disperses through the patient’s body. The neutral plate (or ‘dispersive electrode’) provides a return path through which the current can travel back to the generator, thus completing the circuit. The neutral plate should be large enough to avoid concentrations of diathermy current and so prevent burns at the site where it is applied. Adequate area alone, however, is not sufficient for acceptable neutral plate performance. A combination of adequate area, good contact between plate and patient, secure connection between plate and cable, and correct location of the neutral plate is necessary. See Safety Information Bulletin SIB(87)66, September 1987 for more details.

(4) Contact/continuity monitoring circuits

The standards require that rf earthed surgical diathermy units of over 50 W rated output power have a circuit to monitor the continuity of the neutral plate and its cable which will give an audible alarm and switch off the diathermy power if a break should occur. (Older units may not have such a system - see Safety Information Bulletin SIB(86)54, September 1986.) Moreover, this is a minimum requirement, and such a neutral plate continuity monitor does not monitor the contact between the patient and the neutral plate.

This is achieved by a patient contact monitor, which uses a two-part neutral plate to monitor continuity between one part, the patient and the other part.

Monopolar diathermy units of the isolated type do not require a neutral plate continuity alarm. It is nevertheless important that the neutral plate of such a unit does not attain a high rf potential. This could happen if, for example, the contact between neutral plate and patient were poor, or if the active electrode were to touch any earthed metal, while the diathermy unit was being operated. Although not required by the standards, a neutral plate voltage monitor circuit is provided on some isolated diathermy units. This is designed to detect any rise in voltage of the neutral plate and to switch off the diathermy output should this voltage reach a preset level (usually about 100 volts). An alternative method, the diathermy current continuity monitor is to compare the current leaving the generator along the active lead with the current returning through the neutral plate lead. Most of any difference between these two currents will be flowing from the patient and the wiring to earth: when this exceeds a certain level the diathermy output is switched off. A similar system, but one which operates even when the diathermy unit is not being activated, is the patient earth monitor. While not totally infallible, these various detector circuits do offer an increased level of safety.

BIPOLAR DIATHERMY

A technique of increasing importance and having considerable safety advantages over monopolar techniques is bipolar diathermy. In this arrangement there is no neutral plate to complete the circuit to the generator. Instead, specially designed forceps having each blade insulated from the other are used. The high frequency current is passed down one blade, through the small volume of tissue gripped between the tips of the forceps, and returned via the other blade. Bipolar generators must be of the isolated type and have all the advantages outlined in the discussion of isolated monopolar generators above. Further, since the two tips of the forceps blades are very close to each other, there is little chance of current flowing away to monitoring electrodes. Therefore, the risk of accidental diathermy burns is very much reduced. In addition, because all the diathermy current passes through a small volume of tissue, a much smaller power may be employed to cause the same surgical effect as that achieved by a monopolar diathermy and this is intrinsically safer.

This would suggest that bipolar diathermy should be used in preference to monopolar diathermy, and this is indeed the case for coagulation. Unfortunately, although cutting tools for use with bipolar units are being developed, the cutting effect achieved with a bipolar diathermy unit is not yet as good as that achieved by monopolar diathermy and there are certain other procedures (for example trans-urethral resections) for which monopolar diathermy is still essential.

SPECIAL NOTES

1. SURGICAL DIATHERMY AND IMPLANTED CARDIAC PACE-MAKERS

In monopolar diathermy, the surgeon uses a single-point electrode to concentrate high frequency electric current in the body tissues close to its tip. If the operating site is linked to the bulk of the body only by a tissue path of small cross-sectional area (eg: fallopian tube, or penis) the surgical effect of the diathermy can extend along it from the electrode, with devastating results. Normally, of course, the surgeon will have ensured that the operating site is bounded by a bulk of tissue into which the current can disperse, so that the cutting or coagulating effect is limited to the tissues close to the electrode. The current then disperses into the body and leaves it by way of the relatively large neutral plate return electrode, having passed harmlessly through any intervening tissues and organs. (In contrast, in modern bipolar
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Heart Association in their journal 'Circulation', (1983), 68(1):232A-233A

2. 'POWER' DISPLAYS IN WATTS

Some units now display the selected output setting in watts (frequently in digital form) either as well as, or instead of, a simple numeric setting (eg 1-10) on the control knob. Care should be taken when interpreting this, as the actual output is heavily dependent on how the diathermy output varies with the load placed on the equipment by the procedure being undertaken. The setting is frequently only accurate for the matched load. It is safer to regard the displays as an indication of the maximum power available at this setting.

It must be appreciated that the actual power being applied to the diathermy by the diathermy unit may be much lower than that indicated. As a result, a 'watts' setting used successfully on one instrument should not be transferred directly to a different model, as a higher output than anticipated may be produced by it.

The latest draft version of IEC 601-2-2 has taken account of this potential problem and does not allow output controls/displays to represent power in watts unless the equipment does give the power stated within ±20% over the whole range of procedures, i.e. between 100 Ohms and 1000 Ohms load.

APPENDIX 5

UPDATE

Olympus PSD-10
A number of changes have been made to the Olympus PSD-10 which are listed in Evaluation 42 under 'Manufacturer’s Comments'.

Valleylab Force 2
The documentation is now up to date.

Wolf 2175
A new footswitch is now provided with this unit: we have inspected one and can confirm that it is now waterproof.

References:
A. ‘Optimal resources for implantable cardiac PACE-MAKERS’ (section on electromagnetic interference) - a report by the Into-Society Commission for Heart Disease Resources, published by the American
APPENDIX 6

Health Circulars (HAZARD), Safety Information Bulletins and Safety Action Bulletins.

Since the last Health Equipment Information on Surgical Diathermy (HEI 184) the Department of Health has issued a number of Hazard Warnings and Safety Action Bulletins (formerly Safety Information Bulletins) concerning surgical diathermy equipment and its safe use. The following are summaries of these items. For further information, the user should refer to the full document indicated by the Department of Health document number and date which refers to the document issued in England. Readers in Wales, Scotland and Northern Ireland must refer to local numbering.

Hazard No and date
HC(HAZARD)(90)25, 19 June 1990

IGNITION OF SPIRIT-BASED SKIN CLEANING FLUID BY SURGICAL DIATHERMY SETTING FIRE TO DISPOSABLE SURGICAL DRAPES RESULTING IN PATIENT BURNS

Nature of Problem
An incident has been reported in which surgical diathermy ignited remaining traces of a spirit-based fluid used for skin cleaning. This also set light to the patient’s disposable surgical drapes.

Resolution
It is recommended that spirit-based fluids should not be used for skin cleaning, disinfection or preparation of patients for operations using surgical diathermy. It is particularly important to avoid spirit based fluids when other, easily ignited, materials such as disposable drapes are used in conjunction.

Where the use of spirit-based fluids is unavoidable, it is important to ensure that pooling does not occur and that the drapes do not become soaked. The fluid should be used sparingly and adequate time be allowed for the fluid to evaporate and the skin to become dry before diathermy commences.

SIB No and date
SIB(87)66, September 1987

SURGICAL DIATHERMY: AVOIDING PATIENT BURNS

Nature of Problem
Poor contact between the patient’s body and the return electrode, damage to the electrode, incorrect connection between electrode and cable or contact between the active electrode and conductive objects can lead to patient burns in surgical diathermy.

Resolution
Care should be taken to avoid bringing the active electrode near to conductive materials as these can act as extensions of the active electrode. Before commencing a surgical diathermy procedure, users should ensure that they are familiar with the manufacturer’s instructions for the attachment and use of the return electrodes. When a suitable place on the patient’s body has been chosen for the return electrode, any excessive body hair should be removed and the skin carefully cleaned. Dry return electrodes, or those with adhesive around the edge only, may need some additional means (eg crepe bandage) of ensuring that the whole area of the electrode is in contact with the skin. Electrodes completely covered with adhesive may lose contact over part of their surface if they become nudged up during use and care should be taken to prevent this. Care should also be taken to ensure that the return electrode is correctly inserted into its cable connector before use. Do not rely solely on the cable continuity alarm. If it is necessary to use higher than usual power settings for cutting and coagulation it may be an indication of a poor connection in the patient return circuit and this should be investigated.

SIB No and date
SIB(88)19, January 1988

ELECTROSURGERY UNIT FOOTSWITCH TYPE DAVOL 13-0135 USED WITH BARD AND VALLEY-LAB ELECTROSURGERY UNITS

Manufacturer
C R Bard

Nature of Problem
The ‘cut’ footswitch of a Bard Model 5000 electrosurgery unit jammed in the ON position during use. Investigation of the footswitch revealed corrosion of the cast aluminium body of the switch around the footpedal shaft.

Resolution
Users of these footswitches should ensure that the required maintenance is carried out as specified by the manufacturer. Footswitches of this type should be checked for stiffness of operation on a regular basis. When released slowly the footpedals should return to the ’off’ position without any tendency to stick at any point of their travel. Any showing a tendency to stick should be removed from service and repaired or replaced.

SIB No and date
SIB(88)59, September 1988

INSULATION OF BIPOLAR DIATHERMY DISSECTING FORCEPS

Nature of Problem
Users are advised of the necessity of using only those bipolar diathermy dissecting forceps which
Appendices

have been insulated to prevent inadvertent damage to the patient.
Resolution
All bipolar diathermy instruments should be insulated to protect the patient from accidental damage and forces without insulation should be replaced.

SAB No and date
SAB(90)36, April 1990

ERBE ERBOTOM TUR: SERIOUS NON-COMPLIANCE WITH BS 5724: PART II: ADVICE AGAINST PURCHASE OR CONTINUED USE
Manufacturer
Erbe Elektromedizin GmbH
Nature of Problem
During a recent evaluation of the ERBE Erbotom TUR it was found that the minimum output power setting was greatly in excess of that permitted by BS 5724: Part II, standard for surgical diathermy.
Resolution
Hospitals are advised not to purchase this equipment until further notice. Any existing users should remove their machines from service.

SAB No and date
SAB(90)37, April 1990

CONDUCTIVE ADHESIVE DIATHERMY NEUTRAL RETURN PLATES: AVOIDANCE OF PATIENT BURNS
Nature of Problem
An increased number of patient burns, almost exclusively involving self-adhesive diathermy neutral return plates, has been reported during the past year. It is not clear whether this is due to some faulty neutral plates, poor application or better reporting.
Resolution
The quality of self-adhesive neutral plates can be adversely affected by poor storage conditions resulting from extremes of temperature or moisture. Neutral plates should be correctly stored and used in the order in which they were purchased. The area of attachment should be a fleshy, well vascularised one such as the thigh, close to the operating site. Underlying bony areas should be avoided. The package should be examined before opening to ensure it is sealed. The manufacturer’s ‘use by’ date should also be checked and any neutral plates past this date discarded.

SAB No and date
SAB(90)50, July 1990

GU SURGICAL DIATHERMY MACHINES: RISK OF SPURIOUS OUTPUT

Nature of Problem
Several models of surgical diathermy machine manufactured by GU Manufacturing co Ltd., serial numbers in the model range 27- and 28- have been shown to be capable of producing a spurious output sufficient to injure a patient.
Resolution
All machines in the 27- and 28- model ranges manufactured by GU Manufacturing Co Ltd should be examined to ensure that both of the following modifications have been incorporated:
1. a relay to connect base to emitter on both output transistors when the footpedal is released;
2. a capacitor from collector to emitter on each output transistor.
If either modification is not present, arrangements should be made for it to be added either in house or by the manufacturer.

SAB No and Date
SAB(91)16, March 1991

BOVIE ELECTRO-SURGICAL UNITS, MODEL CSV, MADE BETWEEN JANUARY 1989 AND AUGUST 1990: MANUFACTURER’S RECALL
Nature of problem
The manufacturer, MDT Diagnostic Company, USA, has initiated a recall of all Bovie Model CSV Electrosurgical Units made between January 1989 and August 1990 because the neutral plate monitor may not operate when there is a break in the neutral return electrode.
Resolution
It is possible that no affected units are present in the UK. However, should any hospital have a Bovie Model CSV, of any serial number, made by the MDT Diagnostic Company between January 1989 and August 1990, then they should withdraw the equipment from use, contact the manufacturer and inform their Health Department.

SAB No and Date
SAB(91)24, April 1991

DIATHERMY BURNS DUE TO SOLE RELIANCE ON THE INSULATION OF SURGICAL GLOVES.
Nature of problem
Surgical gloves alone cannot adequately protect users from surgical diathermy burns. Higher output voltages have made the chance of such injuries more likely.
Resolution
Metal instruments used directly or indirectly in conjunction with surgical diathermy should be insulated to provide the principal means of isolating the operator from high frequency current.

evaluation no 117, February 1992

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In procedures where the size of the surgical instrument is limited by the medical application (e.g., endoscopes, resectoscopes, Palmer's forceps), the amount of insulation is similarly restricted. In these procedures it may be necessary to avoid electro-surgical generators with high maximum output voltages or operate the equipment at reduced power settings.

**APPENDIX 7**

**GLOSSARY**

Short, largely non-technical, notes are given about some characteristics and features mentioned in this report which effect the performance and safety of transport incubators. They are not meant to be precise definitions.

**ACTIVE ELECTRODE**

This is the active or live end of the diathermy through which the cutting or coagulation current is applied. The electrode itself is usually a sharp needle point for fine, controlled cutting or ball-shape for coagulation. Cutting results from the intense heating caused by a very localised high current density. Coagulation occurs in a similar manner, but at lower current densities causing charring of the tissue.

**APPLIED PART**

All parts of equipment which are intentionally brought into contact with a patient.

**BIPOLAR OUTPUT**

An output from a surgical diathermy unit arranged so as to apply a current to tissue held by a pair of bipolar forceps. The current actually flows between the tips of the forceps, so a neutral plate is not used to return current to the diathermy. Maximum power outputs are not usually greater than 75 watts.

**CLASS AND TYPE**

The CLASS of the equipment refers to its construction and its connection to the mains while the TYPE refers to the connection to the patient and the safety and isolation of that connection.

**CLASS 1:** Equipment in which protection against electric shock depends upon a reliable earth connection. The mains lead of such equipment has three wires - one being the earth wire, which is usually connected to external metalwork.

**CLASS II:** Equipment in which protection against electric shock depends on double, or reinforced insulation between live parts and the user. This equipment does not rely on an earth connection for safety, and the mains lead, therefore, usually has two cores only. Typically there is little or no accessible metalwork on the equipment.

**TYPE B:** Equipment having no electrical patient connection or one where the patient connection may not be isolated from earth. This equipment offers a degree of safety better than household electrical equipment by improved insulation and reduced leakage currents.

**TYPE BF:** In this equipment patient safety is improved over TYPE B equipment by having a fully electrically isolated ('floating') patient connection.

**TYPE CF:** This is the highest safety category of patient connection, being fully isolated and having very low leakage currents indeed. This category is intended particularly for direct cardiac connection.

**DH Manufacturer Registration Scheme**

A Registration Scheme for Manufacturers of certain medical products set up by the DH in 1986, intended to help the NHS when it purchases medical electrical equipment and which offers certificated quality status. Surgical diathermy units made by a registered manufacturer are produced using a quality system which meets the requirements of 'Quality Systems for Medical Equipment 1990' (Good Manufacturing Practice).

**DIATHERMY FREQUENCY**

Often referred to as radio frequency (rf) or simply high frequency. In order to allow electric currents to be applied to the body without causing physiological effects other than those desired, diathermy operates at very high frequency, typically about 500 kHz to 1 MHz (megahertz). Lower frequency electric currents, well below 100 kHz (kilohertz) can cause muscle stimulation and represent a shock hazard.

**DIATHERMY CURRENT CONTINUITY MONITOR**

A circuit which compares the diathermy current being passed into the patient from the active electrode with that leaving the patient through the neutral plate. If the difference between the two is sufficiently great - perhaps because a proportion of the diathermy current is taking an alternative path to earth, with the risk of burning the patient at its exit point - the diathermy output is disabled.

**EMQ1 Form**

see MLQ1 FORM

**ISOLATED**

The arrangement of the diathermy output in which neither the active nor neutral outputs are referred to earth. See Appendix 3.

**LEAKAGE CURRENTS**

Diathermy frequency leakage current:

This refers to the amount of current at diathermy frequencies 'leaking' or flowing from a patient to earth rather than back to the generator via the neutral plate. To keep these leakage currents to a minimum and so reduce the risk of burns, the neutral plate must be securely attached to the patient and diathermy unit. A maximum value for this current is specified.

**Earth leakage current:**

This is the current which leaks from the mains supply part of the equipment and flows harmlessly to earth via
the earth conductor in the mains lead of the unit. However, if the earth wire breaks or becomes detached, the current normally flowing to earth must now find an alternative path which may be provided by a person touching the (normally earthed) case of the unit. If the current flowing is sufficient, an electric shock may be felt. Hence, maximum permissible values of leakage current are specified in various standards.

**Patient leakage current in worst case single-fault condition:**

The patient leakage current is the current flowing to earth from the active electrode and neutral plate through the patient. In diathermy equipment, where a deliberate electrical connection to the patient is made, the risk of a severe electric shock to the patient must be eliminated. Therefore, stringent requirements are placed on the maximum value of this current.

**Patient leakage current with mains on the active electrode or neutral plate:**

This current gives a measure of the protection afforded by the equipment when either the diathermy unit is grossly faulty, or where additional faulty equipment such as an ecg monitor places mains voltages on the patient. Stringent limits are placed on the maximum permitted value of this current.

**MAINS FREQUENCY**

This is the frequency of the electrical power supply to the equipment, and in the United Kingdom is 50 Hz.

**MICROBIPOLAR OUTPUT**

A bipolar output, usually limited to 20 watts, particularly useful in microsurgery.

**MLQ1 FORM**

This form has superseded the EMQ1 form and should be sent by the potential purchaser to the supplier, prior to purchase, to confirm that the equipment they intend to buy complies with the required standards for that equipment. All medical electrical equipment should conform to BS 5724: Part 1, applicable Part 2s and any further relevant standards.

**MONOPOLAR OUTPUT**

The usual arrangement for a surgical diathermy, in which the output current passes from a single active electrode through the patient to a neutral plate. No significant heat is generated at the neutral plate because its large area causes a low current density.

**NEUTRAL PLATE**

Sometimes also called patient plate, indifferent plate, dispersive plate, or earthing plate. This is always large in area (typically 150 sq cm) compared with the active electrode, so as to keep current densities low and enable the diathermy current to be safely returned to the diathermy generator. Should the current return inadvertently via paths of small surface area, eg needle-type monitoring electrodes, high current densities could arise possibly causing burns.

**NEUTRAL PLATE CONTINUITY MONITOR**

In order to avoid burns, the neutral plate must always fulfill its function of returning the diathermy current safely to the generator. To ensure that the neutral plate and its lead are connected to each other and to the diathermy unit, these connections are continually checked by a monitoring device. Should these connections fail, the monitor activates an alarm and switches off the diathermy output. The neutral plate monitor does NOT check the contact between the plate and patient. Proper application of the plate is still absolutely essential.

**NEUTRAL PLATE VOLTAGE MONITOR**

In fully isolated diathermy units it is important that the neutral plate does not attain a high rf potential. This can happen if, for example, the active electrode touches any earthed metal or the contact between neutral plate and patient is poor. A neutral plate voltage monitor detects any rise in voltage of the neutral plate and switches off the output should this voltage reach a preset level (usually about 100 volts).

**PATIENT CONTACT MONITOR**

More than a neutral plate continuity monitor, this uses a special two-part neutral plate to check continuity between both parts of the plate and the patient, as well as between plate, cable and diathermy unit.

**PATIENT EARTH MONITOR**

This circuit disables the diathermy output if the patient is intentionally or unintentionally in contact with an earthed object (for example, an earthed operating table or fibre light guide), so further reducing the risk of diathermy burns due to contact with the earthed object and of electric shock caused by leakage currents to earth through the patient.

**RF**

Radio frequency - same as diathermy frequency.

**RF-EARTHED**

The arrangement of the diathermy output in which the neutral output is held at earth potential for diathermy frequencies while remaining isolated from earth at low (ie mains) frequencies.

**SOLID STATE**

Terminology used to indicate that most of the control circuitry and the power output circuit uses transistors and integrated circuits.

**TYPE**

see CLASS AND TYPE

**VALVE/SPARK GAP**

Traditionally, diathermy units have used either valves alone or a combination of valves and spark gaps to produce cutting and coagulating waveforms. Because valves and spark gaps are physically bulky, diathermy units using these components tend to be large.
SUPPLIERS’ ADDRESSES
Suppliers of the equipment mentioned in this report are:

Eschmann TD411S
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   Eschmann Bros & Walsh Ltd
   Equipment Division
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   John Weiss & Son Ltd
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   Bradwell Abbey
   Milton Keynes
   MK13 9HF
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   Unit 5, Royal London Estate
   29-35 North Acton Road
   London NW10 6PE
   Tel: 081 961 9955

Wolf 2175
   Richard Wolf UK Ltd
   PO Box 47
   Mitcham
   Surrey
   CR4 4TT
   Tel: 081 640 3054

Service Addresses
Existing users of Bard System 3000, Bard System 5000 and Concept 9900E should note that maintenance and servicing is available from:

   GU Manufacturing Co Ltd
   841 Coronation Rd
   Park Royal
   London NW10 7QJ
   Tel: 081 961 9000
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ISSN 0960-5843

evaluation no 117, February 1992