SURGICAL DIATHERMY UNITS

Review Issue

A review of 9 models

Eschmann TD411-RS
Eschmann TD411-S
Eschmann TD20
Eschmann TDB60
Martin ME400
Olympus PSD-10
Valleylab Force 2
Valleylab Force 40S
Wolf 2175

with appended information on two further models which have not yet been assessed:

Erbe ICC350
Berchtold Elektrotom 540
Surgical Diathermy Units

INTRODUCTION

This issue of 'Evaluation' reviews all Surgical Diathermy Units that have been evaluated and are still available in the UK.

The Overall Comparison and Summary pages are based on the evaluation findings. Whilst these can provide potential buyers with initial guidance on choice, the full report on the equipment should be consulted before making the decision to purchase a particular model. The Summaries include the issue number of 'Evaluation' in which the full report appears.

New information regarding the equipment and suppliers is provided in Appendix 7. Appendix 3 highlights the points to bear in mind when choosing a particular Surgical Diathermy Unit.

A technical glossary is given in Appendix 9 and for a full list of addresses of suppliers the reader should refer to Appendix 10.

ACKNOWLEDGEMENTS

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

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

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

For information on the evaluation of surgical diathermy units, please contact Peter Oddy, Department of Health, Medical Devices Directorate (MDD), 14 Russell Square, London WC1B 5EP (Tel: 071 972 8155).

For advice on surgical diathermy please contact Dr Chris Hacking, Bioengineering Services, Department of Medical Physics and Bioengineering, Cardiff Royal Infirmary, Newport Road, Cardiff, CF2 1SZ (Tel: 0222 492233 ext 5123).

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Overall Comparison

OVERALL COMPARISON

High Power Units (over 200 W)

At present, of the high power diathermy units featured in the Evaluation Summaries in this issue, the Eschmann TD411-RS (£5,820), the Eschmann TD411-S (£4,980), the Martin ME400 (£5,653) and the Valleylab Force 40S (£6,665) have a BSI Certificate of Compliance with the full safety Standard (BS 5724: Part 1 and 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. Martin Medizintechnik have an ISO 9003 quality assurance certificate for final inspection and test of surgical diathermy. Prices do not include VAT.

All of the high power units performed well in a wide range of procedures. Although each model has the conventional monopolar outputs: cut, coagulation and blend, they differ in the facilities they offer.

For loop excisions the Eschmann TD411-RS and the Martin ME400 have a specialist cut facility specifically designed for transurethral resections and colposcopy. All of the units have a low voltage output for desiccation. The Valleylab Force 40S has two dedicated high voltage coagulation outputs, one intended for fulguration, the other for spray coagulation, which are useful in a number of applications including urology; the other units have only a single output for fulguration/spray coagulation.

For procedures requiring two surgeons to work together using monopolar outputs, for example in cardiac surgery, the Martin ME400, the Valleylab Force 2 and the Valleylab Force 40S are worth considering. The Martin ME400 has two monopolar outputs available on a first come, first served basis, with the primary output taking priority. Both the monopolar cut and blend outputs of the Valleylab Force 2 and the Valleylab Force 40S operate on a first come, first served basis, but the monopolar coagulation outputs can be activated simultaneously with the total output power shared between them.

Some models can be operated in dual mode such that the monopolar and bipolar modes can be used together in a single procedure without having to make a selection on the front panel. The Valleylab Force 2 and the Valleylab Force 40S have this facility but only one output is energised at a time on a first come, first served basis. The Martin ME400 extends this by allowing the simultaneous activation of one monopolar and one bipolar output which is useful in plastic, vascular and neurological surgery.

Valleylab has followed previous DH advice and has not fitted an autobipolar facility to their Force 2 and Force 40S units. The bipolar output for these units is operated by handswitching forceps (see Glossary). In this case the output is activated as soon as the forceps are closed together.

However, users who consider that they require an automatic, tissue sensing, forceps switching bipolar output (autobipolar, see Glossary) should consider the Eschmann TD411-RS, the Eschmann 411-S and the Martin ME400. The Martin ME400 energizes the output immediately the forceps have gripped tissue (See Update, Appendix 7). The Eschmann TD411-RS and the Eschmann TD411-S are provided with a start delay control, allowing the user to adjust the time between gripping the tissue and energizing the output. To enable the autobipolar mode on the Eschmann units, the user must first depress the footswitch, a good safety feature.

Medium Power Units (under 200 W)

The Olympus PSD-10 (£5,700, includes SP cord, re-usable neutral plate, 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.

Bipolar Units

The Wolf 2175 (£1,081 including footswitch) is a good choice for laparoscopy, its primary application. It is simple to use, having a single bipolar output.

The Eschmann TDB60 (£1,145 including pneumatic footswitch) is a good choice for low power applications. It is very easy to use having a single bipolar output with two power ranges, 8 W (micro) and 60 W (macro). The 8 W power range allows very fine control of the power setting, a particularly useful feature in ophthalmic and neurological surgery. The Eschmann TDB60 is activated by either a single footswitch (pneumatic or electrical) or by automatic, tissue sensing, forceps switching (autobipolar). To enable the autobipolar mode of operation, the user must first depress the footswitch, a good safety feature. If the autobipolar mode is employed a variable start delay of up to two seconds may be set, in advance, by screwdriver adjustment on the rear panel.

3 evaluation no 211, May 1994
Overall Comparison

Chiropody Unit

The Eschmann TD20 (£1,550 including pneumatic footswitch, accessories and instruction video) is worth considering for chiropody applications. This low power monopolar surgical diathermy is specifically designed for the removal of vascular and neurovascular corns. The TD20 produces two different effects, coagulation and desiccation, dependent on the setting of the power control. Low power settings are selected for coagulation, high power settings for desiccation.
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 is activated from an electrical or pneumatic footswitch or by automatic forceps switching (autobipolar).

The Eschmann TD411-RS has a continuously variable volume control, a neutral plate continuity monitor, a patient earth monitor and a patient voltage monitor.

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

Disadvantages: None.

Overall: Good all round performance, particularly for bipolar work — has autobipolar mode with start delay; complies fully with BS 5724: Part 1 and Section 2.2.

See Update, Appendix 7.

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, 300/300 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 is activated from an electrical or pneumatic footswitch or by automatic forceps switching (autobipolar).

The Eschmann TD411-S has a continuously variable volume control, a neutral plate continuity monitor, a patient earth monitor and a patient voltage monitor.

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

Disadvantages: None.

Overall: Good all round performance, particularly for bipolar work — has autobipolar mode with start delay. Complies fully with BS 5724: Part 1 and Section 2.2.
The Eschmann TD20 is a solid-state, table-top, monopolar surgical diathermy unit with an isolated RF output rated at 20 W. Its primary application is for the removal of vascular and neurovascular corns.

The TD20 has a single continuously variable rotary power control. The unit produces two different effects, coagulation and desiccation dependent on the setting of the power control. Low power settings are selected for coagulation, high settings for desiccation. The output is activated by a pneumatic footswitch.

The Eschmann TD20 has an audible output indicator with a two position volume control.

The Eschmann TDB60 is a solid-state, table-top, bipolar surgical diathermy unit with an isolated RF output rated at 60 W.

A touch button allows the user to select one of two power ranges (8 W or 60 W). Power output is set using a continuously variable rotary control and is activated by a pneumatic or electrical footswitch or by automatic forceps switching (autobipolar). In autobipolar mode, a delay of between 0 and 2 seconds may be introduced between gripping tissue and activation of the output.

The Eschmann TDB60 has an audible output indicator with a two position volume control.

Advantages: Good performance; high success rates for complete removal of digital and plantar corns; easy to use; good serviceability and manuals; compact.

Disadvantages: Does not comply fully with BS 5724: Part 1 and Section 2.2.

Overall: Good performance; good results; liked by users. This equipment is being employed in a new area of application, so additional training/supervision, beyond that available from the company, will normally be required.

See Update, Appendix 7.
Martin ME400

The Martin ME400 is a solid-state, table-top, surgical diathermy unit with an isolated RF output rated at 330 W cut, 300/300/270 W blend, 250/100 W coag monopolar, and 70 W bipolar.

The unit has a dual mode operational facility with continuously variable rotary power controls and digital displays. The primary monopolar output is activated by twin electrical footswitches or a finger-switching active pencil; the secondary monopolar output is activated by fingerswitching active pencil. The primary bipolar output is activated by an electrical footswitch or automatic forceps switching (autobipolar); the secondary bipolar output is activated by automatic forceps switching. The Martin ME400 has a continuously variable volume control, a neutral plate continuity monitor and a carrying handle.

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<td>No</td>
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<td>Manufacturer?</td>
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**Advantages:** Very good footswitches; excellent cutting facility; easy to use.

**Disadvantages:** Unable to switch out 'Uro-cut' facility when using footswitches; activation alarm irritating.

**Overall:** Good all round unit; well liked by users. Changes to future production, See Update, Appendix 7.

Olympus PSD-10

The Olympus PSD-10 is a solid-state, table-top monopolar surgical diathermy unit with an isolated monopolar RF output rated at 80 W cut, 60 W blend and 40 W coag.

The unit is designed exclusively for endoscopic procedures. The power level is set by one of ten push buttons and the output is activated by a single electrical footswitch.

The Olympus PSD-10 has a neutral plate continuity monitor, a Safety-Patient cord continuity monitor and a current imbalance monitor. Additionally, there is a pre-procedural check facility. This compact unit is fitted with a carrying handle.

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<td>Yes, R0257/ME/SP</td>
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**Advantages:** Good performance; easy to set up and use for endoscopic procedures; pre-procedural check facility; compact.

**Disadvantages:** Does not comply fully with BS 5724.

**Overall:** Expensive, but a good unit for endoscopy. See Update, Appendix 7.
Summaries

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 a dual mode operational facility with discrete touch controls and digital displays. One monopolar output is activated by the twin electrical footswitches or a fingerswitching active pencil; the other monopolar output is activated by a fingerswitching active pencil. The bipolar output is activated by a single bipolar footswitch; or by using monopolar footswitches or handswitching forceps.

Advantages: Easy to use; good performance especially for 'wet field' work; good access for servicing; well constructed.

Disadvantages: Current version does not comply fully with BS 5724: Part 1 and Section 2.2.

Overall: Good performance.

See Update, Appendix 7.

Valleylab Force 40S

The Valleylab Force 40S is fitted with a continuously variable volume control, a patient contact monitor, a neutral plate continuity monitor, an output error monitor and a carrying handle.

Advantages: Very easy to use; very good serviceability and manuals; simultaneous coag option useful in cardiac procedures.

Disadvantages: Tissue adhesion to forceps can be a problem in 'wet field' work.

Overall: Well liked by most users, complies fully with BS 5724: Part 1 and Section 2.2.
Wolf 2175

The Wolf 2175 is a solid-state, table-top, bipolar unit with an isolated RF output rated at 50 W. Its primary application is laparoscopic surgery.

The unit has a single continuously variable rotary power control. The output is activated by a single electrical footswitch.

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

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**Advantages:**
very good performance; well made; easy to service.

**Disadvantages:**
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 7.
APPENDIX 1

Erbe ICC350

BRIEF DESCRIPTION

The Erbe ICC350 is a microprocessor controlled, solid-state, table-top surgical diathermy unit with an isolated RF (or optional RF-earthed) output rated at 300/300 W cut, 120/120/120 W coag, 300/300/300 W blend and 100/120 W bipolar.

The unit has a dual mode operational facility with discrete touch controls and digital displays. One monopolar output is activated by the twin electrical footswitches or a fingerswitching active pencil; the other monopolar output is activated by a fingerswitching active pencil. The bipolar output is activated by a single electrical footswitch or by using the monopolar footswitches.

The ICC350 has a continuously variable volume control, a patient contact monitor, a neutral plate continuity monitor, an output error monitor and a carrying handle.

INFORMATION TABLE

- Full report: Currently under evaluation.
- Price: £6,950, set of 3 footswitches £250
- BS 5724/IEC 601? Yes, IEC 601-1 and IEC 601-2-2, TUV Stuttgart. Currently under type testing at TUV Bayern and BSI testing.
- DH Registered Manufacturer? No
- Made in: Germany

APPENDIX 2

Berchtold Elektrotom 540

Atherodax Surgical Ltd, Ross-on-Wye, Herefordshire, the distributor, was approached by the Department on two occasions in the last 12 months with a view to carrying out a brief assessment of the Berchtold Elektrotom 540 which is a preliminary requirement before we consider a full evaluation.

Disappointingly they were reluctant to provide a unit for a brief assessment and have not returned MLQ1 and MLQ2 forms. We were, therefore, unable to assess this unit.

APPENDIX 3

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. There 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 Manufacturers 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 such equipment complies with DH requirements. 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 manufacturer's claims of compliance with product standards. When selecting equipment you are strongly recommended to take into account the manufacturer's registered status.

**Electrical safety**

Whether to choose a monopolar or 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 Appendix 5, Safety of Surgical Diathermy Units. 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 5. 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 important therefore, 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.

An increasing number of surgical diathermy units have a dual mode facility which allows the monopolar and bipolar modes to be used together, in a surgical procedure, without having to make the selection at the control panel. This can be very useful for two surgeons working together or when one surgeon needs to switch repeatedly between monopolar and bipolar outputs.

Most monopolar surgical diathermy have two coagulation modes; a low voltage output for soft coagulation and desiccation and a high voltage output for fulguration and spray coagulation. Some units extend the coagulation options by having two dedicated high voltage outputs; one for fulguration, the other for spray coagulation. This facility often allows the user to simply switch modes rather than adjust the power control up or down to achieve the desired effect.

Units with bipolar outputs have footswitch control of at least one bipolar output. The footswitch may be electrical or pneumatic but there might not be a choice. Bipolar outputs may also have automatic, tissue sensing, forceps switching (autobipolar), with or without a start delay.

Risk of inadvertent operation in autobipolar mode may be minimised by requiring concurrent operation of a footswitch, or by pre-selection of "autobipolar" forceps. The relative merits of these different aids to safety should be considered before a unit, with an autobipolar facility, is purchased or used for any particular range of procedures.

Many models now have digital displays of power settings — but see Special Note in Appendix 6 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 4

**PRODUCT CERTIFICATION TO MEDICAL ELECTRICAL SAFETY STANDARDS**

First issued in 1979, BS 5724: Part 1 is the UK equivalent of the International Standard IEC 601-1, covering the general requirements for the safety of medical electrical equipment. In its 1979 edition, the differences from IEC 601-1 are slight, and normally of no significance. The second edition, BS 5724: Part 1: 1989 is identical to the revised IEC 601-1: 1988. A number of test houses issue certificates relating to these standards. However, any certificate of compliance with BS 5724 or IEC 601-1 comes with a set of assumptions, the validity of which is discussed below.

**Control over test procedures**

Test authorities may differ in the degree to which they exercise control over staff and procedures used in testing. The Department has ensured that adequate control is provided for tests to BS 5724 or IEC 601 done at BSI testing, Hemel Hempstead, or by certain test authorities in other countries where the tests are requested to be carried out under the terms of a Joint Agreement between BSI and these test authorities.

At present, these are limited to TÜV (Bayern, Germany), IMQ (Italy), SEMKO (Sweden) and GLE (France).

**Control over interpretation of standards**

Testing by BSI or under a Joint Agreement also means that agreed interpretations of certain clauses of BS 5724 are applied. These are established by the
Appendices

BSI Committee which represents all UK interests and which acts as the UK input to the continuing process of revising the International Standard IEC 601-1, and are published to UK manufacturers associations as BS 5724 Advisory Notices.

Control over test voltages used

Testing to BS 5724 by BSI or under a Joint Agreement also ensures that the tests on the mains section are carried out at the UK’s nominal mains supply voltage of 240 volts. Certificates of compliance obtained under other circumstances may ‘conceal’ the fact that tests were done at 220 or 115 volts: components suitable for these lower voltages may not be adequate for UK applications.

Control over content of testing

GS (Gepüfte Sicherheit) certificates issued by test houses in the Federal Republic of Germany may not cover all the requirements of IEC 601, but may include additional tests. This is because the German Ministry of Labour requires the country’s test houses to ensure the safety of medical electrical equipment, and leaves the test house to apply what tests it thinks necessary.

TÜV (Bayern) – Technischer Überwachungsverein, Bayern e.V., Munich
IMQ = Instituto Italiano del Marchio di Qualita, Milan
SEMKO = Svenska Elektriska Materialkontrollanstalten
GLEM = Groupement des Laboratoires d’Essais des Matériels de Technique Medicale LCIELNE

APPENDIX 5

SAFETY OF SURGICAL DIATHERMY UNITS

MONOPOLAR DIATHERMY

(1) Isolated or RF earthed?

It has generally been accepted for many years that during diathermy procedures the patient connected to other equipment (which might be faulty) is at risk of receiving an electric shock. Direct connection of the patient to earth should be avoided in order to minimise this risk. Moreover, even a circuit with no connection to earth may allow sufficient leakage current at diathermy frequency, to flow to earth, exposing the patient to localised burns where they 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 lower 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.
Appendices

(3) The neutral plate

In a monopolar surgical diathermy unit, power from the mains is converted into r.f. 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 r.f. (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 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.

It is important that the neutral plate of an isolated surgical diathermy does not attain a high r.f. 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 lower power level 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 transurethral resections) for which monopolar diathermy is still essential.
APPENDIX 6

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 (e.g. fallopian tube, or penis) the surgical effect of the diathermy can extend along the tissue path 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 diathermy, there is no neutral plate, and the surgical effect is made to occur at both tips of a pair of special forceps held by the surgeon. The two arms of the forceps constitute the two diathermy electrodes, and only the tissue between the tips is surgically affected.)

However, if in monopolar surgical diathermy the intervening tissues and organs contain an implanted pacemaker and its leads, it is possible under certain conditions that the diathermy current will have unwanted effects. The following notes offer guidance on the risks, and on possible precautions.

The risks

Operating with surgical diathermy equipment on patients who have an implanted pacemaker incurs the risks of affecting the pacemaker’s operation, either by direct contact or by radiated interference, and of inducing burns at the pacemaker electrode implantation site. Clearly the risks are very much lower with bipolar than with monopolar diathermy, because of the highly localised current path.

Precautions

Recommendations published in the USA suggest that an implanted pacemaker should be unaffected, or at least merely revert to fixed-rate operation, if the diathermy active electrode and neutral plate are kept ‘a few inches’ away from the pacemaker pulse generator and its electrode leads; while to avoid burns to the myocardium at the electrode site, or possible ventricular fibrillation, it should remain ‘at least 15 cm away from the heart’. (It will also of course be sensible to choose a neutral plate location which puts the path of the diathermy current through the body as far as possible from the heart and from the pacemaker and its leads.) If the pacemaker is of the programmable type, it is suggested that it be set to either the VVT (ventricular sensing and triggering) or the VOO (fixed rate) mode — preferably the latter if the patient is not at particular risk from a competitive rhythm — so that it functions as a fixed rate pacemaker during the surgical procedure.

It is further recommended that the peripheral pulse is monitored during the course of surgical diathermy, and that precautions are taken to ensure that the patient’s well-being is maintained in the event of interference with pacemaker operation. By using the diathermy in ‘short bursts’ it is suggested that, at most, only one or two beats will be affected.

Finally, more severe consequences — local heating, and destruction of the circuit — would result if the diathermy electrode were actually to touch the pacemaker.

References:

1. ‘Optimal resources for implantable cardiac pacemakers’ (section on electromagnetic interference) — a report by the Inter-Society Commission for Heart Disease Resources, published by the American 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) on the control knob either as well as, or instead of, a simple numeric setting (e.g. 1-10). 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 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 version of BS 5724: Section 2.2: 1992 (IEC 60122: 1991) has taken account of this potential problem and does not allow output controls/displays to represent power in watts unless the equipment
Appendices

APPENDIX 7

UPDATE

Eschmann TD411RS
The current version of the TD411RS is the series 2, which has a modified patient interface board.

Eschmann TD20
An instruction video is now included with the Eschmann TD20.

Eschmann has addressed the points of non-compliance listed in Evaluation 165. The three remaining points of non-compliance noted by Eschmann are as follows:

1. A white light on the front panel is used to show that the output circuit is energised.

2. The patient plate electrode connector is not constructed so that there is adequate protection against accidental contact with accessible conductive parts of the 4 mm socket.

3. 4 mm connectors are used for both plate electrode and active electrode sockets.

Martin ME400
Units manufactured after August 1993 (from S/N 4093-5000) will have a modification to the monopolar Cut IV (ie Blend 3) output, reducing the maximum power output from 270 W to 250 W.

The DH has been informed that future production models will incorporate auto foot operated bipolar output operation as the default mode and that impedance sensing forceps operation will be by operator selection. Also that an abrasive patch will be fitted to the underside of the footswitches to minimise 'skating' on damp surfaces.

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

Since the evaluation report was published, additions have been made to the Instruction Book to indicate the symbol for the type of supply current, intermittent operation, with information concerning high frequency cables including diagrams showing the output power at full and half setting of the output control over the range of load resistance 50 to 2000 ohms for all three operating modes.

Approved fuses are now being used and the wiring is now secured at TB1.

Valleylab Force 2
The current version of the Force 2 is version 8-PCH which has TUV Rheinland certification to IEC 601-1 and IEC 601-2-2 (see Appendix 4). Valleylab UK note two major points of deviation from BS 5724. They are as follows:-

1. Creepage and clearance distances on interface pcb do not comply with BS 5724.

2. Front panel output jacks do not comply with the BS 5724 finger test.

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

Since the last review issue on Surgical Diathermy (Evaluation 117) the Department of Health has issued two Safety Action Bulletins concerning surgical diathermy equipment and its safe use. They are summarised below.

SAB(92)40, June 1992

PATIENTS IN CONTACT WITH THE ENGSTROM ARIDUS GAS SAMPLING TUBE (WITH THE METAL SPIRAL): RISK OF DIATHERMY BURNS

SUMMARY

The external metal spiral of the Engstrom Aridus gas sampling tube, distributed by Gambro Ltd, can become an alternative grounding path for patients undergoing surgery with electrosurgical diathermy. This can lead to burns at the points where the spiral comes in contact with the patient.

Similarly, any other items which can act as conductive pathways, could cause the same risk to patients.

ACTION

Consider discontinuing the use of the Aridus tube, which has an external protective metal spiral, in conjunction with surgical diathermy and to replace it with an alternative non-conductive sampling tube.

Check that there are no alternative conductive pathways between the patient and any other object in their vicinity.

BACKGROUND

1. In two incidents reported to the Department, patients received burn marks where the Aridus tube spiral was in contact with them.

2. At the high frequencies used by surgical diathermy any large metallic object, such as an equipment trolley, even if not directly earthed, can form a path to ground. If the metal spiral of the Aridus tube touches the patient and any such object, diathermy current can pass to ground along this alternative path. This can lead to the patient receiving a diathermy burn where the Aridus tube contacts their body.

3. The same risk can exist with any other object which could act as an alternative diathermy path. For example, conductive sheaths and metal cladding of fibre optic light guides.

4. The manufacturer has informed the Department, and also through a published Application Note sent directly to users, that they are discontinuing the manufacture of this type of tube and that they are replacing it with an all-plastic disposable Aridus tube.

5. The majority of users have replaced the metal spiral tube with the plastic type, but there is at present a small number of users who are still using the metal spiral pipe.

SAB(92)41, June 1992

DIATHERMY FOOTSWITCHES: INCIDENTS OF FAILURE

SUMMARY

A number of problems have been reported with footswitches used on diathermy equipment. Regular electrical and mechanical checks on equipment footswitches can help to prevent failure during use.

ACTION

Footswitches and their cables should be checked regularly and a record should be kept for each footswitch assembly.

For sealed types of footswitch check:

a) For any cuts and holes in the footswitch and cable casing due to mechanical damage or perishing, particularly at cable junctions and at points where the cable enters the foot pedal enclosure;

b) For open or short circuits in the footswitch wiring while the footswitch is in operation;

c) For any damaged or loose end connectors.

For other types of footswitch with accessible mechanical or electrical parts check for correct operation and that no fixings or connections have become loose. Microswitches should be firmly secured. Care should be taken, however, to ensure that they are not overtightened.

Footswitches which fail inspections should be clearly marked and repaired or replaced.

BACKGROUND

1. A number of incidents of footswitch failure have been reported to the Department.

2. In some of these incidents the footswitch enclosure developed a fault and the contacts remained permanently closed. In one incident the securing screws of the contact plates loosened and the plates were making a permanent electrical contact.

3. In other reported incidents the outside cable insulation had perished allowing moisture to enter the cable assembly. In one of these incidents with a twin type footswitch, one for coagulation, the other for cut, moisture had accumulated inside the insulation and it was shorting the cable connections at the "Y" junction.

4. If the assembly does not remain intact and sealed then it is very likely that moisture would enter into the insulation and cause a short across the cables. Shorts because of moisture, are more likely
Appendices

to occur after the assembly has been washed in a disinfectant fluid.

5. In other reported incidents the moisture had entered the footswitch pedal enclosure causing a short across the operating contact plates of the foot pedal.

6. In one incident, as a result of incorrect assembly, either during manufacture or after maintenance, the switching mechanism of the footswitch had fractured, during use, making the footswitch inoperative.

**APPENDIX 9**

**GLOSSARY**

Short, largely non-technical, notes are given about some characteristics and features mentioned in this report which effect the performance and safety of surgical diathermy. 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.

**AUTOBIPOLAR**

An automatic bipolar mode of operation. The bipolar output is activated automatically when the tines of the forceps touch tissue. (see also Handswitching Forceps)

**BIPOLAR**

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.

**BLEND**

A monopolar Cut output giving a higher level of haemostasis than the pure cut output. Blend waveforms are often, though not always, bursts of cut waveform occurring many times per second.

**CLASS AND TYPE**

The CLASS of the equipment refers to its
collection 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 wires 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.

**CUT**

An output (usually monopolar) giving maximum cutting effect with minimum haemostasis. Cut waveforms are often, though not always, A pure sine wave. The peak to peak voltage must be high enough to initiate an arc because the arc produces the cutting effect. Narrow active electrodes give the best results and should be held slightly away from tissue to initiate an arc before starting to cut.

**DESICCATION**

A coagulation output similar to soft coagulation but by extending the time the current passes through the tissue a drying effect is achieved. The tissue becomes white.

**DH MANUFACTURER REGISTRATION SCHEME**

A Registration Scheme for Manufacturers of certain medical products set up by the DH in 1985, 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)'.
Appendices

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 (kiloherz). Lower frequency electric currents, well below 100 kHz 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.

DUAL MODE

A facility which allows the monopolar and bipolar modes to be used together in a surgical procedure without having to make the selection at the control panel.

FULGURATION

Fulguration (sometimes called forced coagulation) is a high voltage monopolar coagulation output, up to several kilovolts, so that from a fine active electrode an arc can be initiated across the gap from the electrode to the tissue. The tissue is often coated with a black eschar.

HANDSWITCHING FORCEPS

Bipolar forceps which contain a switch. As the forceps are closed together the output is activated. (see also Autobipolar)

ISOLATED

The arrangement of the diathermy output in which neither the active nor neutral outputs are referred to earth. See Appendix 5, Safety of Surgical Diathermy Units.

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 (both physically and electrically) to both 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

Completion of this form by the supplier will indicate to the potential purchaser whether 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 (for example, IEC 601-1).

MONOPOLAR OUTPUT

This is 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 fulfil 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 continuity 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 pre-set level (usually about 100 volts).

OUTPUT ERROR MONITOR

An output error monitor is a system which compares the measured power output with the set power level. If the measured power output exceeds the set power level by a significant amount, the output error alarm is activated.

PATIENT CONTACT MONITOR

Is more than a neutral plate continuity monitor. It 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), 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 plate is held at earth potential for diathermy frequencies while remaining isolated from earth at low (ie mains) frequencies.

SOFT COAGULATION

A low voltage monopolar coagulation output used to arrest bleeding. Soft coagulation waveforms often look similar to blend waveforms but the peak to peak voltage is too low to initiate an arc. The coagulation effect is achieved with the active electrode (eg arterial forceps) in direct contact with the tissue.

SOLID-STATE

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

SPRAY COAGULATION

Spray coagulation is similar to fulguration but the voltages are higher, giving a stronger arc and the capacity to jump a wider gap between the active electrode and tissue.

TYPE

see CLASS AND TYPE.

VALVE/SPARK GAP

Traditionally, diathermy units 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. Valve/Spark gap surgical diathermy have been almost completely superseded by solid-state units.
SUPPLIERS' ADDRESSES

Suppliers of the equipment mentioned in this report are:

Erbe ICC350
   The Surgical Technology Group
   Newbury Rd
   Andover
   Hampshire
   SP10 4DR
   Tel: 0264 365741

Eschmann TD411-S
Eschmann TD411-RS
Eschmann TDB60
Eschmann TD20
   Eschmann Bros & Walsh Ltd
   Equipment Division
   Peter Road
   Lancing
   West Sussex BN15 8TJ
   Tel: 0903 753322

Martin ME400
   Albert Waeschle
   PO Box 19
   123-125 Old Christchurch Rd
   Bournemouth
   BH1 1EX
   Tel: 0202 290502/557513

Olympus PSD-10
   KeyMed (Medical & Industrial Equipment) Ltd
   KeyMed House
   Stock Road
   Southend-on-Sea
   Essex SS2 5QH
   Tel: 0702 616333

Valleylab Force 2
Valleylab Force 40S
   Valleylab UK
   Pfizer Hospital Products Group
   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 Address
   Existing users of Bard System 3000 and Bard System 5000 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
NATIONAL REPORTING & INVESTIGATION CENTRE (NATRIC)

All staff working in a healthcare environment have a responsibility to report any incident that occurs at work that could put either themselves or patients at risk. The National Reporting and Investigation Centre (NATRIC) exists to coordinate investigations into all faulty products/materials and ensure that the NHS is aware when any product has been deemed unsafe.

Incident reports are a vital source of product feedback, that enables the DH to advise the health care sector of potentially hazardous or safety related situations by the publication of hazard notices and safety action bulletins, as well as enabling manufacturers to make improvements to product design, manufacturing processes, labelling and user instructions.

NATRIC's computer database currently holds over 20,000 incident records dating back to 1983. During 1993, 3,500 incidents were reported of which 32 per cent were the subject of a full investigation, and current trends indicate that over 4,000 will be reported this year. The kind of incidents staff should report include:

- any safety related incident or potentially harmful product/material whether identified as such prior to use, during use, or as the result of an accident;
- problems arising through incorrect use of or inappropriate modification, adjustment or maintenance of equipment, products or materials;
- minor incidents or anomalies which may be indicators of inadequate quality assurance on the part of the manufacturer or supplier.

It is important to bear in mind that apparently minor local incidents might, when added to other reports, indicate a wider problem. If staff are in any doubt, they should contact their line management or NATRIC direct for advice.

Experience shows us that an incident in a local unit will often have implications for the rest of the health care sector. The purpose of reporting procedures allows nationally coordinated action to be taken to safeguard patients and staff. That is why all those involved in care have a responsibility, if they come across a product that might be faulty, to let us know about it.

HOW TO CONTACT NATRIC

NATRIC

'HOT LINE' during normal office hours is: 071 972 8080
24 hour answering machine service: 071 972 8080

FAX facility number: 071 972 8109 + BT Gold computer link: NHS217

The information about NATRIC given on this page is here for your guidance purely in connection with medical devices generally, and the importance of reporting incidents. It is not intended to imply that there are any problems associated with the particular equipment evaluated in this publication.

HOW TO REPORT ADVERSE INCIDENTS (DEFECTS)

All staff working in a healthcare environment have a responsibility to report any incident that occurs at work involving medical devices, equipment or materials to the Department of Health. Guidance for reporting such incidents is contained in Health Service Guidelines (93)13. If you are in any doubt about the reporting procedures please seek advice from your line manager or from the Department of Health.

NOTE: The UK Territorial Health Boards of N Ireland, Scotland and Wales equivalents to HSG(93)13 are:
N Ireland: DHSS Circular HSS(ESD)3/90,
Scotland: NHS Circular 1991 (Gen) 24, issued in September 1991,
Wales: WHC(89)26 issued in August 1989.
Other Evaluation Reports

A complete list of 'Evaluation' reports published to date is set out below (see back page for ordering information)

<table>
<thead>
<tr>
<th>EQUIPMENT TYPE</th>
<th>REPORT NUMBERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>audiometers</td>
<td>169, 193</td>
</tr>
<tr>
<td>cardiococographs:</td>
<td></td>
</tr>
<tr>
<td>intrapartum</td>
<td>45, 71, 78, 138, 181</td>
</tr>
<tr>
<td>antenatal</td>
<td>1, 53, 184</td>
</tr>
<tr>
<td>review issue</td>
<td>147, 166</td>
</tr>
<tr>
<td>defibrillators:</td>
<td>61, 88, 112, 125, 131, 143, 145, 174, 178, 201, 203</td>
</tr>
<tr>
<td>review</td>
<td>132, 209</td>
</tr>
<tr>
<td>ecg monitors</td>
<td>5, 20, 21, 22, 25, 98, 133</td>
</tr>
<tr>
<td>review issue</td>
<td>75, 204</td>
</tr>
<tr>
<td>ecg recorders:</td>
<td></td>
</tr>
<tr>
<td>conventional</td>
<td>2, 3, 18, 19, 64, 65, 91, 92, 124, 140, 144, 150, 156, 167, 177, 192, 194, 196, 197, 210</td>
</tr>
<tr>
<td>ambulatory</td>
<td>4, 116, 118, 146, 159, 185</td>
</tr>
<tr>
<td>review issue</td>
<td>54, 168, 206</td>
</tr>
<tr>
<td>enteral feeding pumps</td>
<td>73, 74, 76, 77, 79, 81, 82, 83, 84, 85, 86, 87, 195</td>
</tr>
<tr>
<td>fetal heart detector</td>
<td>99, 100, 114, 122, 123, 137, 170</td>
</tr>
<tr>
<td>review issue</td>
<td>200</td>
</tr>
<tr>
<td>haemodialysis equipment</td>
<td>30, 31, 32, 33, 34, 46, 47, 66, 68, 69, 119, 136, 154, 183</td>
</tr>
<tr>
<td>review issue</td>
<td>115</td>
</tr>
<tr>
<td>heat and moisture exchanger (HME)</td>
<td>63, 93, 102, 103, 109, 110, 111, 113, 141, 142, 148, 151, 152, 155, 189, 190</td>
</tr>
<tr>
<td>incubators:</td>
<td></td>
</tr>
<tr>
<td>nursing</td>
<td>39, 70, 129, 164, 172</td>
</tr>
<tr>
<td>transport</td>
<td>9, 10, 11</td>
</tr>
<tr>
<td>review issue</td>
<td>95 (transport), 135 (nursing)</td>
</tr>
<tr>
<td>infusion pumps:</td>
<td></td>
</tr>
<tr>
<td>syringe</td>
<td>90, 101, 120, 121, 149, 158, 162</td>
</tr>
<tr>
<td>volumetric</td>
<td>57, 58, 60, 126, 127, 163</td>
</tr>
<tr>
<td>lung ventilators and alarms:</td>
<td></td>
</tr>
<tr>
<td>alarms</td>
<td>51, 105, 130</td>
</tr>
<tr>
<td>ventilators</td>
<td>40, 41, 43, 44, 173, 175, 176</td>
</tr>
<tr>
<td>review issue</td>
<td>139 (alarms and ventilators)</td>
</tr>
<tr>
<td>medical humidifiers:</td>
<td>106, 107, 108, 198</td>
</tr>
<tr>
<td>patient monitors:</td>
<td>23, 29, 35, 49, 50, 55, 59, 62, 89, 128, 161, 171, 179, 180, 186, 72, 202, 205</td>
</tr>
<tr>
<td>review issue</td>
<td></td>
</tr>
<tr>
<td>peritoneal dialysis equipment</td>
<td>48, 67, 80, 207, 208</td>
</tr>
<tr>
<td>review issue</td>
<td>94</td>
</tr>
<tr>
<td>radiant warmers:</td>
<td></td>
</tr>
<tr>
<td>infant</td>
<td>6, 7, 8, 28, 104, 160</td>
</tr>
<tr>
<td>review</td>
<td>134</td>
</tr>
</tbody>
</table>
## Other Evaluation Reports (continued)

A complete list of *Evaluation* reports published to date is set out below (see back page for ordering information)

<table>
<thead>
<tr>
<th>EQUIPMENT TYPE</th>
<th>REPORT NUMBERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>resuscitators:</td>
<td></td>
</tr>
<tr>
<td>gas-powered</td>
<td>13, 14, 15, 16, 17, 182, 191</td>
</tr>
<tr>
<td>surgical diathermy units</td>
<td>12, 26, 42, 56, 96, 97, 157, 165, 187, 199,</td>
</tr>
<tr>
<td>review issue</td>
<td>117, 211</td>
</tr>
<tr>
<td>UV treatment lamps</td>
<td>24, 27, 36, 37, 38, 52</td>
</tr>
<tr>
<td>water treatment equipment:</td>
<td></td>
</tr>
<tr>
<td>review issue</td>
<td>153</td>
</tr>
</tbody>
</table>
## DISTRIBUTION

This report could improve safety and reduce costs

A copy should be placed in all hospital and health authority libraries. In addition, all major users of this type of equipment, and all staff involved in its selection, maintenance and purchase, including the departments and professions marked below, should be made aware of this issue.

<table>
<thead>
<tr>
<th>Accident &amp; Emergency</th>
<th>Maternity/Midwifery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambulance Officers</td>
<td>Medical</td>
</tr>
<tr>
<td>Anaesthetics</td>
<td>Medical Physics</td>
</tr>
<tr>
<td>Audiology</td>
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<td>Supplies Officers</td>
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<td>Home Dialysis Administrators</td>
<td>Surgical</td>
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<td>Theatre Staff</td>
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<td>HOSPITAL LIBRARIES</td>
<td>Transplant Units</td>
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<tr>
<td>HEALTH AUTHORITY LIBRARIES</td>
<td>Works Officers</td>
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<tr>
<td>Intensive Care/Therapy</td>
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