SUMMARY
- two independent monopolar outputs
- simultaneous activation of all outputs
- flexible endoscopy and arthroscopy modes
- video interface to reduce camera interference
- bipolar cut mode
- specialist cut mode

Advantages: good performance; well constructed; two independent monopolar outputs; simultaneous activation - power on demand for up to three surgeons; bipolar cut facility; some excellent safety features, e.g. output from fingerswitching pencil cannot be footswitch activated.

Disadvantages: poor explanation of endoscopic and bipolar cut modes; inadequate description of over-temperature alarm; no switch to recall previously used settings.

Overall: well specified versatile unit, widely liked by our users; good performance, excellent simultaneous activation facility, complies fully with BS 5724:Section 2.2/IEC 601-2-2.

BRIEF DESCRIPTION
The Eschmann TD850 is a microprocessor-controlled, high-power surgical diathermy unit. The unit has two independent rf-isolated monopolar outputs each rated at 210 W maximum and one bipolar output rated at 50 W maximum.

The unit has two independent monopolar outputs and one bipolar output which can be activated simultaneously, so that up to three surgeons can operate at the same time with each output available on demand.

Each output mode has a 'normal' setting and a 'parameter change' setting. The normal modes are primarily intended for open surgery and laparoscopic procedures. The parameter change modes are intended for flexible endoscopy and arthroscopy applications.

SURGICAL DIATHERMY

Eschmann TD850

MAIN FEATURES
Main facilities
- monopolar
- bipolar
- power output control
- cut, coag, blend
- cut, coag
- single rotary

Alarms
- neutral plate continuity monitor
- patient contact monitor
- patient earth monitor
- patient voltage monitor
- yes
- yes
- yes

Operating switches
- footswitches
- handswitches
- monopolar, two per output
- bipolar, two
- monopolar, twin
- fingerswitch per
- output; bipolar, forceps

Output indicators
- visual
- auditory
- volume control
- yes
- yes
- yes

Electrical
- generator type
- output configuration
- maximum output power
- solid-state
- rf-isolated
- 210 W single output
- 400 W total, multiple outputs

Price ex VAT
£7,950

Made in
UK

Weight
18.1 kg

Manufacturer
Eschmann Bros. & Welsh Ltd
Lancing
West Sussex

DH registered manufacturer?
Yes, R0008/ME/SP

CE Marking on product?
No

How is safety demonstrated?

£20

© crown copyright
DESCRIPTION

The Eschmann TD850 is a microprocessor-controlled, high-power surgical diathermy unit (see Photograph 1). The unit has two independent rf-isolated monopolar outputs each rated at 210 W maximum and one bipolar output rated at 50 W maximum.

Unusually, the TD850 has just one power control. To adjust the set power the user must select the mode required, then adjust the power setting. The set power for each output mode can be set separately.

Each monopolar output is activated by twin electrical footswitches or a fingerswitching active pencil. The bipolar coagulation output is activated by an electrical footswitch or a pneumatic footswitch, or by forceps switching. The bipolar cut output is activated by an electrical footswitch.

At the bottom of the control panel there are three pull-out information cards (see Photograph 2). Two cards are to help the user set up the unit, the third card summarises the alarm codes.

The TD850 has a continuously variable volume control. The unit weighs 18.1 kg and has two carrying handles.

User facilities

Each output mode has a 'normal' setting and a 'parameter change' setting. Normal modes are primarily intended for open surgery and laparoscopic procedures. Parameter change modes are intended for flexible endoscopy and arthroscopy applications. The TD850 has a safety 'S' scope connection for flexible endoscopes.

For normal modes of operation, the accompanying documentation provides specific guidance on the choice of output and suggested power setting.

In addition to the normal cut (160 W), pinpoint coag (90 W), spray coag (80 W), blend (130 W) and bipolar coagulation (50 W) outputs intended for most surgical applications, the TD850 has a number of special features which are listed below:

Two independent monopolar outputs: The TD850 has two independently controlled monopolar outputs. Two surgeons requiring a monopolar output can each choose their preferred mode, power setting and method of activation (footswitch or fingerswitch).

Simultaneous activation: The two monopolar outputs and the bipolar output can be activated simultaneously, so that up to three surgeons can
Eschmann TD850

PRODUCT SUPPORT

Supplier
Eschmann Bros. & Walsh Ltd
Peter Road
Lancing
West Sussex
BN15 8TJ
Tel: 01903 753322
Fax: 01903 766793

Guarantee
1 year

Maintenance provisions
- service contract? yes
- will service engineer call? yes
- maximum response time quoted? 48 hours
- temporary equipment replacement? yes

Spare parts
- spares availability 7 years

Cost of spares (ex VAT + P&P)
- neutral plate lead £37.00
- adhesive neutral plate, single area, pack 200 £260.00
- adhesive neutral plate, divided area, pack 200 £320.00
- monopolar lead £31.90
- bipolar lead £42.20
- monopolar footswitch £35.00
- bipolar footswitch £95.00
- video synchronisation lead £25.00
- remote control unit £35.00
- ‘S’ scope lead £69.00

Service charges (ex VAT)
- contracted preventative maintenance charge (two required per year) £81.00
- emergency call-out rates 1, labour/waiting time per hour £36.00
- travelling per hour £41.00
- return to manufacturer, labour per hour £36.00

NOTE
1. Add £10.00 + VAT per hour for users not on a preventative maintenance contract.

Characteristics specifically intended for flexible endoscopy and arthroscopy applications. These modes are intended to provide a higher level of safety than normal modes of operation, primarily by limiting the maximum power setting available to avoid damage to the endoscope. In common with surgical diathermy specifically designed for endoscopy applications, the TD850 has a safety ‘S’ scope connection. Eschmann manufacture a lead for connection of a flexible endoscope to the TD850.

Video synchronisation: The TD850 has a video interface to reduce the level of interference on medical camera images during urological and minimal access surgery. This system is intended to produce a rectangle in the centre of the video picture, free from any interference generated by the high frequency electrosurgical output.

Bipolar cut: The TD850 has a bipolar cut output rated at 40 W. Both the bipolar cut and coagulation footswitches are white, as required by the standard. However, the user can identify the cut and coag footswitches by the colour of the lead; blue for coag, yellow for cut.

Specialist cut mode: The TD850 has a specialist cut mode for some (for example TURP and DEXC), though not all, loop excisions. Guidance on the suitability and recommended power setting of this output mode is provided in the accompanying documentation.

Output connectors: Each monopolar output has a spring-loaded sliding door to ensure that only one active electrode lead is connected to each output. In its central position a 4 mm active electrode socket can be used. Moving the door to the left allows an 8 mm socket to be used and moving it to the right allows a fingerswitching active pencil to be connected and disables the footswitches for that output.

Remote control unit: An optional remote control handset is available (see Photograph 3). The user can adjust the set power of the previously used monopolar output mode. The handset can be sterilised and re-used.

Alarms: The TD850 has a number of monitoring systems including:
- a patient contact monitor.
- a neutral plate continuity monitor.
- a patient earth monitor.
- a patient voltage monitor.
- an over-temperature alarm.

Most major error conditions have auditory and visual alarms and are identified by a red error number on the control panel.
USER EVALUATION

Users in a number of hospitals (see Acknowledgements) with varying experience in the use of the Eschmann TD850 helped us in our evaluation. Several surgeons already routinely used the TD850, the rest used the unit for the first time during the user evaluation. The users were asked to score the facilities of the TD850 on a five point scale. These were aggregated and are depicted in Fig. 1.

The TD850 was used in paediatric, urological, neurological, general and endoscopic surgery. After initial instruction, all users found the unit fairly easy to operate, with a clear control layout and useful information cards. Our users were happy with the level of training and support provided by the manufacturer.

The specific guidance on the choice of mode and control settings required for particular procedures, included in the accompanying documentation, was helpful.

The stand-by switch was useful, but the lack of a switch to recall previously used settings was considered a disadvantage.

The monopolar footswitches were liked by our users. They had a positive action and good sensitivity both at the edge and centre of the switch. They were very easy to clean, either by wiping the smooth surfaces or by total immersion. Some users found that the footswitches were rather lightweight and tended to slide around the theatre floor.

In all theatres, the auditory output indicator was set to a low level but was still audible. All users found the auditory output indicator unobtrusive, even during intensive periods of use.

In paediatric surgery, the TD850 performed extremely well. Previously, our user was using a bipolar coagulation output for both dissection and coagulation, so the incorporation of a bipolar cutting output was considered an advantage. Using fine bipolar forceps, coagulation was good and dissection excellent. Although there was some build-up of coagulum on the tines of the forceps, this was less than our user was used to and was easier to clean off.

In urological surgery, the TD850 was used for TURP and bladder tumours. For TURPs, our users found the specialist cut output good, with minimal mechanical drag on the resection loop. One user was particularly pleased with the low level of adhesion of resected tissue to the resection loop. A number of users noted that the resected tissue appeared more grey and less pink than they had expected, which they thought might adversely affect histological examination. To maintain effective coagulation performance, our surgeons found that it was necessary to switch between spray coag and pinpoint coag when they switched between using a resection loop and a roller ball electrode. Power settings up to the maximum available were required for the spray coagulation mode. For bladder tumours, normal cut was used and was good.

In neurosurgery, the TD850 was well liked. Our users required the option of simultaneous activation and had purchased the TD850 to replace the separate monopolar and bipolar units they had previously used. Primarily, normal monopolar cut or blend and macrobipolar coag were employed and were very effective, allowing two surgeons to work together with each having power available on demand.

In general surgery, the TD850 gave good results using pinpoint coag with monopolar forceps. For some procedures, for example abdominoperineal resection, the twin independent monopolar outputs with simultaneous activation were very useful. The two surgeons were able to work very quickly and effectively, each using their preferred mode and power setting for both cut and coagulation.

In colonoscopy, the TD850 endoscopy blend mode was very effective for polyp removal. Our users were happy with the smoothness and speed of the cutting effect and the degree of haemostasis. The over-temperature alarm was often activated during intense periods of electrosurgery and was indicated by a red number 06 on the control panel, at the end of a burst of electrosurgical output. There was no auditory alarm. The diathermy output was not affected and activating the output again cancelled the alarm.

TECHNICAL EVALUATION

The TD850 met all of the safety requirements and has a certificate of compliance with the appropriate standards. We looked at some of the performance aspects of the unit.

Over-temperature alarm: Having noted the over-temperature alarm during the user trials we investigated its performance and reviewed the information provided with the unit. Both the instruction book and the information card fitted to the unit warned the user of possible damage to the equipment with continued use after the over-temperature alarm had been activated.

The manufacturer has informed the evaluation centre that the over-temperature alarm is really a duty cycle (activation time/rest time) alarm that takes no account of the power setting. In common
with many surgical diathermy units, the TD850 is rated at 10 s on/30 s off. We operated the unit repeatedly at high power settings within the rated duty cycle and did not activate this alarm. Furthermore, at a power setting of 1 watt, using a much higher duty cycle (30 s on/15 s off) the unit alarmed in under 3 minutes, which appears to confirm the manufacturer’s comments.

**Video synchronisation**: The TD850 uses a standard PAL composite video synchronisation signal from a camera to automatically switch off the diathermy output during brief periods of the video signal. A compensating circuit boosts the power during the on periods to maintain the output close to the set power.

In our tests we measured the power output of the specialist cut mode both with and without a video signal input to the TD850. Figure 2 compares the power curves at a typical power setting of 150 and shows the change in the shape of the power curve when this facility was activated. Users may notice either a small increase in the power output or a small reduction, depending on the load impedance of the patient. Below 600 ohms the unit delivered more power, above 600 ohms it delivered less power.

**Nominal frequency**: In our tests, all outputs had a nominal frequency of 490 kHz. The rating plate and the accompanying documentation incorrectly stated the nominal frequency of the bipolar output as 525 kHz.

**Bipolar output characteristics**: As part of the evaluation we compared the bipolar cut, microbipolar and macrobipolar modes. The three bipolar modes were found to have different waveform characteristics. Figures 3, 4 and 5 show the different measured voltage waveforms of each mode at the same power setting and load impedance.
We compared the bipolar parameter change modes with the normal modes of operation. In our tests, we could find no difference between the normal and parameter change bipolar coagulation outputs. For bipolar cutting the only difference was that the maximum power setting available was 20 instead of 40. Up to 20, these outputs were the same.

**Output connectors**: Although not required by the standard and unlike some other surgical diathermy units, the Eschmann TD850 had two excellent safety features; simultaneous connection of two active leads to one output was prevented by a sliding door and the delivery of power to a fingerswitching pencil was prevented when a footswitch was inadvertently depressed.

**Auxiliary socket**: The TD850 has an additional BNC connector, marked ‘Aux’ on the rear panel. There is no internal connection to this socket and its intended purpose is not noted in the accompanying documentation.

**‘S’ (scope) connection**: In common with surgical diathermy specifically intended for flexible endoscopy, the TD850 has a socket for connec of a safety ‘S’ scope lead to a flexible endoscope. The socket provides a capacitive connection to the neutral plate. An ‘S’ scope lead is available from the manufacturer.

The results of our evaluation are summarised in the Table of Results on page 11.

**Reliability**: The manufacturer is registered under the DH Manufacturer Registration Scheme for the supply of this equipment. In addition, the manufacturer has been assessed by BSI QA and has been found to comply with BS5750:Part 1:1987 (Certificate Number FM 12513). There were no faults on delivery and there were no faults in use. The equipment was well made and reliability should be high.

The Eschmann TD850 has a 1 year guarantee.

**Serviceability and manuals**: Overall, the instruction manual was satisfactory. Most
instructions and features were clearly explained. There was good safety advice and instructions for cleaning the unit and the electrosurgical accessories. Further advice was also provided for the sterilization of active accessories, electrodes and cables.

A very useful list of suggested output settings for different procedures for normal monopolar modes of operation was included. However, there was only limited information on the parameter change and bipolar output modes. The description of the over-temperature alarm was inadequate. There was no description of the forceps switching facility for the bipolar coagulation output and no comment in the manual that the required accessories for this facility cannot be obtained from Eschmann, even though the manual strongly recommended Eschmann bipolar forceps.

The Eschmann TD850 is not user serviceable. It is intended that the equipment is serviced either by service contract with the manufacturer or by returning the unit to the manufacturer. The user can choose to have repairs undertaken using repair/exchange or new printed circuit boards, though the latter option is more expensive.

COMPLIANCE WITH STANDARDS

For products without CE Marking, you should normally give preference to those which comply with EN 60601 (formerly BS 5724 or IEC 601), the current European Standard for the safety of medical electrical equipment. Part 1 of the Standard applies to all categories, while Section 2.2 adapts it specifically for surgical diathermy equipment (see Appendix 2). Independently of the evaluation, a sample of the Eschmann TD850 has been submitted by Eschmann to TÜV, Essen, Germany. The Eschmann TD850 was granted a Certificate of Compliance 1151/95 (March 1995) with IEC 601-1 (1988) and IEC 601-2-2 (1991) by TÜV.

MANUFACTURER'S COMMENTS

We would like to thank the MDA for evaluating and commenting upon the TD850.

We are currently affixing the CE Mark to claim compliance with EMC directive 89/336/EEC, and, in the future, compliance with medical directive 93/42/EEC. We accept the criticism of the standby switch - a revised version of software will be available to enable the user to recall previously used settings, and also to de-select user 2. The rating plate and accompanying documentation will state the nominal frequency of bipolar output as 490 kHz. We plan to enlarge on the information in the instruction manual giving a pertinent description of the 06 alarm, with more detailed information on bipolar and parameter change modes. Should a current user require such knowledge, we would be delighted to provide them with appropriate information.
Figure 2: Power Curves for Specialist Cut, Power Setting 150

Figure 3: Microbipolar, 80 ohm load, 6 W Power Setting
Figure 4: Macrobipolar, 80 ohm load, 6 W Power Setting

Figure 5: Bipolar cut, 80 ohm load, 6 W Power Setting
**MANUFACTURER’S INFORMATION**

<table>
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<tr>
<th>Manufacturer/supplier</th>
<th>Eschmann Bros. &amp; Walsh Ltd, Lancing</th>
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<td>DH manufacturer registration?¹</td>
<td>yes, R0008/ME/SP</td>
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<td>Certificated product</td>
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<td>CE Marked?</td>
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**Facilities**

**outputs**

- monopolar, two
  - normal modes:
    - normal cut
    - specialist cut
    - pinpoint coag
    - spray coag
    - blend
  - parameter change modes:
    - endoscopy cut
    - arthroscopy cut
    - MIS pinpoint coag
    - soft spray coag
    - endoscopy blend
    - microbipolar coag
    - macrobipolar coag
    - bipolar cutting
    - bipolar cutting parameter change
    - digital switches, single rotary power control

- bipolar

- output controls

**Operating switches available**

- footswitches
  - monopolar
  - bipolar
- handswitching
  - monopolar
  - bipolar

- two electrical per output
- two electrical (optional one electrical, one pneumatic)

**Electrical**

- output configuration
- maximum output power²
  - rf-isolated
  - 210 W single output
  - 400 W total, multiple outputs

**NOTES**

1. Manufacturers may be registered, de-registered or re-registered at any time. Consult the latest issue of the DH Register of Manufacturers to check the current status.
2. Manufacturer’s rating.
<table>
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<td>• bipolar forceps switching</td>
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</tr>
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<td>• controls and front panel</td>
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</table>

NOTE
1. Scale used: excellent/good/satisfactory/poor/unacceptable.
APPENDIX 1: HOW TO BUY WITH CONFIDENCE

Current production
Please note that, because a manufacturer or supplier might continue to modify a product after commenting on our report, the version you buy might differ from the one we evaluated. You are strongly advised to check this with your supplier.

Compliance with standards
You should give preference to products which either carry CE Marking or comply with the standards covering the safety of medical electrical equipment (BS 5724, IEC 601 or EN 60601).

For products without CE Marking, you should give preference to those from sources covered by the DH Registration Scheme for Manufacturers.

Under this scheme, a manufacturer declares that the quality system used to manufacture the product meets the MDA requirements, and the system becomes subject to audit by the Medical Devices Agency.

APPENDIX 2: STANDARDS USED FOR TESTING

The technical performance and safety assessments in this issue were carried out for the manufacturer by TÜV, Essen, Germany and for the Medical Devices Agency by the evaluation centre at the University Hospital of Wales, Cardiff. Supplementary testing was also carried out at the Cardiff evaluation centre.

For this evaluation, two samples were assessed: one at TÜV, the other at Cardiff. The conclusions are, therefore, based on the assumption that the samples tested were typical of normal production.

Safety
TÜV, Technischer Überwachungsverein, Essen, is one of a number of notified bodies in Europe capable of type testing medical devices to the appropriate safety standards. TÜV tested a unit at 240 V, for compliance with the following standards, to assess the general and particular safety aspects of the equipment: IEC 601-1: 1988 and IEC 601-2-2: 1991.


IEC 601-1: 1988 and BS 5724:Part 1: 1989 have been accepted as European Standards and have been renamed EN 60601-1: 1990. IEC 601-2-2: 1991 and BS 5724:Section 2.2: 1992 have also been accepted as European Standards and have been renamed EN 60601-2-2: 1993.

User evaluation
The protocol used for the evaluations was devised in cooperation between the surgeons and nursing staff involved in the trials, the medical physicists of the evaluation centre and the Medical Devices Agency.
APPENDIX 3: THE MEDICAL DEVICES DIRECTIVE

UK regulations implementing this Directive (93/42/EEC) came into force on 1 January 1995 through Statutory Instrument No 3017. The regulations allow for a transition period until 13 June 1998, during which time either the controls existing on 31 December 1994 or the new regulations may be followed. From 14 June 1998 all medical devices (apart from active implantable and in vitro diagnostic medical devices, for which separate regulations apply) marketed in the European Union must comply with the new regulations for medical devices.

CE Marking

Manufacturers indicate that medical devices are in compliance with the regulations by affixing the “CE” Marking to either the device itself or the packaging. For many types of devices the CE Marking can be affixed only after approval has been given by an independent certification organisation (Notified Body).

Essential Requirements

The regulations set out “Essential Requirements” which medical devices must meet in order not to compromise the health or safety of the patient, user or any other person, taking into account any associated risks. It is the duty of the manufacturer to ensure that these Essential Requirements are met, and this may be achieved by manufacturing under a quality system, by type testing, by sampling, or by using a mixture of these manufacturing controls.

Standards

Application of Standards will help manufacturers and Notified Bodies to judge whether the Essential Requirements have been met. Since the Directives cover a wide range of products, involving many levels and types of technology, the Essential Requirements can only provide a broad approach in setting the targets that manufacturers must meet. The European Commission, therefore, has mandated the European Standards Organisations to prepare European standards to address the Essential Requirements. These standards will assist manufacturers by setting out objective definitions of what the necessary requirements are for particular products, and practical means for manufacturers to show that their products comply with the Essential Requirements.

They will, therefore, help to eliminate potential difficulties which otherwise may be experienced by industry when asked to provide justification for claims of compliance with the Essential Requirements.

Manufacturers may need to refer to more than one Standard in order to address the relevant Essential Requirements pertinent to a given medical device.

European Standards, mandated by the European Commission, that are accepted as addressing identified Essential Requirements in a Directive are listed in the Official Journal of the European Communities and are known as Harmonised Standards.

Products manufactured in line with such Standards will be presumed to comply with the relevant Essential Requirements.

Manufacturers may choose whether or not to apply relevant harmonised standards. In practice, however, compliance with these standards will be the easiest way of showing that their products meet the Essential Requirements.

Since the application of harmonised standards will be voluntary, manufacturers may choose alternative methods of demonstrating compliance with the Essential Requirements. For example, manufacturers may use international, national or in-house standards. These alternative routes may also be used where harmonised standards do not exist for a particular product or Essential Requirement(s).

Directives Bulletins

The Medical Devices Agency has produced a number of Directives Bulletins which provide guidance on various aspects of the new regulations. Copies can be obtained from:

Mr Richard M Gutowski
Medical Devices Agency
Hannibal House
Elephant & Castle
London
SE1 6TQ
Tel: 0171 972 8253/8256/6300
Fax: 0171 972 8112

No. 2 The CE Mark
No. 3 The Vigilance System and Update on the Directives
No. 4 Conformity Assessment Procedures
No. 5 Pre-clinical Assessment Procedures and the Product Registration Scheme
No. 6 The Notified Body
No. 7 The Competent Authority
APPENDIX 3: THE MEDICAL DEVICES DIRECTIVE (cont'd.)

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ACKNOWLEDGEMENTS

This report was prepared by Dr C J Hacking of the Medical Physics and Bioengineering Group, University Hospital of Wales Healthcare NHS Trust. The MDA thanks the following members of the Medical Physics and Bioengineering Group, University Hospital of Wales, Cardiff, for their work on this evaluation:

Dr C J Hacking, BSc PhD, Senior Physicist  
Dr D G Spendley, BSc MSc PhD CPhys MInstP, Principal Physicist  
Mr J P McCarthy, BSc MSc CEng MIEEE FIPEMB, Consultant Physicist.

We also thank the following consultants for their cooperation and assistance in carrying out the user evaluations:

Mr S N Huddart and Mr D Carey, University Hospital of Wales, Cardiff  
Mr R L Gower, Mr A Thomas, Mr D G Clarke and Mr B Stephenson, Royal Gwent Hospital, Newport  
Mr K El-Shunnae and Mr L Pobereskin, Derriford Hospital, Plymouth  
Mr M C Mason and Mr J Beynon, Singleton Hospital, Swansea.

and all the medical, nursing and theatre staff who helped in the evaluation; and the Media Resources Centre, University Hospital of Wales, for the photographic work.

Dr Hacking is the representative of the Institution of Physics and Engineering in Medicine and Biology on the national BSI Standards committee CH/97 for High Frequency Surgical Equipment.

Mr McCarthy is the chairman of the national BSI Standards committee CH/97 for High Frequency Surgical Equipment.
## OTHER REPORTS ON SURGICAL DIATHERMY UNITS

This is the seventeenth issue of 'Evaluation' on this category of electro-medical equipment. In Evaluation number order these are:

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## ENQUIRIES

For information on the evaluation of surgical diathermy units, please contact Peter Oddy, Medical Devices Agency, Hannibal House, Elephant and Castle, London SE1 6TQ (direct tel: 0171 972 8155) or via the switchboard on 0171 972 8000.

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