Low / Medium Power Electrosurgery

*Review 2002*

- Cutting
- Contact Coagulation
- Loop Excision
- Spray Coagulation
INTRODUCTION

Electrosurgery (surgical diathermy) is a commonly used surgical tool but the method is poorly understood. Electrosurgery is increasingly being used for a variety of outpatient and minimal invasive surgical procedures. In addition, some low powered units are purchased for performing minor surgical procedures in the GP surgery.

Low and medium power output monopolar electrosurgical units (ESUs) are reviewed in this evaluation report. Bipolar mode is available on twelve of these models but there are also a number of dedicated bipolar ESUs on the market which were reported on in evaluation report 01022 (see the back page for how you can obtain a copy). A further review will be published next year covering high powered ESUs available in the UK.

Most low/medium powered ESUs have been developed for specific specialties and operative procedures. In addition, electronic design improvements have enabled three manufacturers to produce ESUs suitable for general surgery applications, including urology, without requiring high power output settings (over 200 Watts).

This report includes a brief introduction to the electrosurgical technique, a guide to some technical and procurement issues in addition to the product data pages. Fifteen electrosurgery units having power outputs up to 200 Watts are briefly summarised. Brief technical assessments were conducted on fourteen devices specifically for this evaluation report. A summary of manufacturer’s data on the Ellman Surgitron Dual Frequency is included for completeness.

A glossary of electrosurgery terminology is contained in the Appendix at the back of the report.

ELECTROSURGICAL TECHNIQUE

Tissue Heating: Using heat to stop bleeding (cautery) is an ancient technique which traditionally used hot metal objects. If the applicator is heated electrically this is called electrocautery. Tissue damage is largely dependent on the temperature achieved (Table 1) and heat transfer by conduction. Cautery is hindered by unpredictable tissue damage.

<table>
<thead>
<tr>
<th>Temperature (°C)</th>
<th>Surgical Effect</th>
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<tbody>
<tr>
<td>&gt;40°C</td>
<td>Reversible cell damage</td>
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<tr>
<td>&gt;49°C</td>
<td>Denaturation (irreversible cell damage)</td>
</tr>
<tr>
<td>&gt;70°C</td>
<td>Coagulation (collagens convert to gelatin)</td>
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<tr>
<td>&gt;100°C</td>
<td>Desiccation (cells dry as water vaporises, gelatin becomes ‘sticky’)</td>
</tr>
<tr>
<td>&gt;200°C</td>
<td>Carbonisation, eschar formation (pathological 4th degree burns)</td>
</tr>
</tbody>
</table>

In electrosurgery / surgical diathermy the electric current (I) is designed to travel through tissue between metal electrodes, producing heat in the tissue while the applicators remain relatively cool. The resistance (R) or impedance of tissue to the flow of electricity generates heat within cells, intracellular fluid and blood. Mathematically, local heating (Watts) is proportional to \( I \times I \times R \).

Electrosurgery uses high frequency oscillations, usually between 200kHz and 5MHz, to achieve tissue heating. High frequencies avoid muscle spasms and cardiac fibrillation that is caused by inadvertent contact with frequencies below 100kHz, for example mains electricity at 50 Hz.
Introduction and Modalities

Bipolar Circuit: In bipolar electrosurgery two electrodes are combined into a single applicator, usually forming forceps. Only the tissue grasped between the two tines of the forceps are included in the electrical circuit (see Figure 1).

Monopolar Circuit: The monopolar circuit only uses one electrode (active) at the surgical site and a separate electrode (return) is placed somewhere else on the patient’s body. The electrical current must pass through much of the patient’s body to complete the circuit (see Figure 2). Monopolar is the more commonly used electrosurgical modality, due to its versatility and established clinical effectiveness, but it is known to involve greater risks to patients and staff than bipolar coagulation.

Controlling the surgical effect: High frequency current has either a coagulating or cutting effect according to the shape and dimensions of the active electrodes, the chosen electrosurgical mode (voltage waveform) and the output power. Tissue changes as a result of this energy deposition primarily depend on the current density. If the current is highly concentrated, for example when a thin wire barely touches the tissue surface, then all the energy is deposited in a very few cells, producing very high temperatures so they vaporise. This causes the tissue to split as though it had been cut with a razor sharp knife, as shown in the top left figure on the front cover. As a result a fine electrosurgical cut can be produced by stroking a fine wire along the tissue surface in monopolar mode. Using a larger electrode produces a lower current density and a lower rise in temperature so contact coagulation of the tissue is more likely, as shown in the top right figure on the front cover.

There is a wide range of types, shapes and sizes of active electrodes. The nature of tissue modification is heavily dependant on the type of electrode used, with a fine needle electrode producing a cut using the same current that would produce contact coagulation from a large area ball electrode. For example, when the Korpo Timed TD50A is in the Coag Micro Elect mode a fine needle will cut tissue if the power exceeds 14 Watts. Conversely a large electrode and low power can produce coagulation even when the cut mode has been selected, but the surgical result is unpredictable.

To complicate matters the actual power output is rarely constant. Characteristics vary between different designs of ESU, as illustrated by the power curves on pages 8&9, which are also published in User Manuals. The actual power output is affected by the load impedance, primarily determined by the tissue type at the surgical site. However other factors (eg poor skin adhesion and electrical contact of the return electrode, excessive distance between the surgical site and the return plate electrode, damaged accessories) also increase the overall impedance to electrosurgical current flow and may reduce the surgical effect.

Power curves of many ESUs show a peak in the power output at specific impedance values. Frequent adjustment of the power setting will be required to achieve a consistent surgical effect for different tissues. Power curves of some ESUs can maintain almost constant power output regardless of the local tissue impedance, whether it is muscle (500-1800Ω) or fat and scar tissue (above 3000Ω).

Fatty tissue, air and bone have low water content so are highly resistant to the flow of electrons. Consequently a high voltage is required to ‘push’ electrons through these tissues or across an air gap. When an active electrode is held over muscle the
Introduction and Modalities

electrosurgical current flows easily, as blood is a good conductor and a low voltage is required. It is good practice to experiment on samples of different meats from a butcher until the user is familiar with the characteristics of each ESU and activation mode.

Ideally the electrodes should remain cool and separable from the tissue while they deliver the electrosurgical current. However this requires careful selection of the power setting and surgical technique to ensure the power is switched off immediately the tissue is blanched. Further heating converts collagen into gelatin, which at higher temperatures becomes sticky and then a blackened eschar (see Table 1 on page 2). Tissue may then remain attached to the active electrode and cause rebleeding following its removal.

MODALITIES

Each manufacturer uses their own terms to describe the activation modes of their generator. The most common terms are: cut, blend, contact coagulation (or desiccation) and spray coagulation (or fulguration).

**CUTTING:** Cut waveforms are continuous AC, but the shape varies between manufacturer and model, some using sinusoidal, square wave, etc. Cutting voltages must be above a few hundred volts to develop the arc (or spark) required for cutting but must be low enough to avoid unwanted charring. When electrosurgical cutting is performed with the correct technique it is atraumatic and reduces post-operative problems such as tissue swelling, post-surgical shock and contractile scar tissue.

**Bipolar Cutting & Ablation:** New types of accessories and specialised bipolar electrosurgical units have been developed to make cutting and ablation possible. This issue is covered in more detail in the Bipolar Review (evaluation report 01022). Bipolar electrosurgery cutting may be considered for operating on a tissue pedicle, such as a penis, but it is important to consult the ESU user manual and/or manufacturer for guidance.

**Monopolar Cutting:** The monopolar modality is more versatile and widely used. Effective surgical cutting is best achieved with a fine wire, ensuring the tip hovers above the incision site with a smooth brush-stroke, so it does not adhere to the tissue. Cells close to the tip of the active electrode burst when the cellular water is heated rapidly and boils. (see top left figure on the front page)

Monopolar cutting should not be used when a constriction in soft tissue can occur between the operative site and return electrode. A concentration of electrosurgical current in the return path through the tissue constriction (pedicle) can cause unwanted damage from tissue heating.

Yellow colour coding is usual on dials, switches and indicators for activating monopolar cut.

**BLEND:** Monopolar blend waveforms have a continuous waveform that is modulated to give resting periods. This allows heat to spread into adjacent tissues causing cutting with some coagulation of the cut surface. Some devices offer several blend modes giving variable coagulation depths. The degree of haemostatis is regulated by the blend waveform shape not the ratio of cut to coag power output settings. Blend may be called CUT/COAG by some ESU manufacturers.

When electrosurgical cutting is performed with minimal but sufficient haemostatis of the cut surface it reduces post-operative problems such as post-surgical shock from excessive blood loss, and post operative adhesions.

Yellow colour coded dials, switches and indicators are usual for functions associated with blend.

**COAGULATION:** Spray coagulation waveforms are short duration, high voltage pulses, that typically require a few thousand Volts, to spark across the air gap between the active electrode and tissue surface. By contrast, contact coagulation waveforms have variable characteristics. Depending on ESU manufacturer and model the waveform may be pulsed or continuous but it will have a higher crest factor than the cutting waveform.

Blue colour coding is usually used for functions associated with coagulation.

**Bipolar Forceps Coagulation:** Small tissue bundles and blood vessels can be coagulated with bipolar electrosurgery. The blood vessel or tissue is grasped between the forceps tines, each of which acts as an active electrode, and current passes to desiccate and coagulate the tissue. Power requirements must be matched to the size and shape of the accessories and impedance of the tissue volume held between the forceps tines.

Providing there is no loss of surgical performance the bipolar mode may be preferred for forceps coagulation where risks are significantly reduced,
Design Features

DESIGN FEATURES

This section provides a brief description of design features mentioned in the product data pages. Some of these are specific to a single manufacturer. Please note inclusion in this section should not be interpreted as endorsement of the design feature.

Low and Medium Power Electrosurgery units included in this review vary considerably in their sophistication. The simplest provide only monopolar output with single cut and coagulation mode. However, many ESUs provide bipolar and monopolar outputs and a wide range of different modes to achieve various tissue effects. The required tissue effect is obtained by a careful selection of appropriate accessories, output mode, power level and surgical technique. These factors vary from device to device and more detailed information may be found in the user and service manuals for each device. Some manufacturers also offer supplementary written, audio-visual or CD-ROM training information prepared by clinical users familiar with the specific unit.

Electric Shock Protection: Careful ESU design must limit the leakage of mains frequency (50Hz) electric current to electrodes touching the patient. All ESUs in this report are mains powered and constructed to Class II requirements, ie they have double or reinforced insulation for wires carrying mains frequency current. Medical equipment is classified by the level of patient protection from mains leakage current. Applied parts electrically isolated from earth and with low leakage currents are classed as F-type (F for floating). Leakage current protection is further classified as type B or C. ESUs in this report are either classified as BF, indicating they are suitable for direct patient contact providing cardiac tissue is avoided, or type CF, ie suitable for direct cardiac application.

RF-Isolated: Many ESUs are also electrically isolated at high frequencies. RF-isolation reduces the risk of current leakage to earth or alternate site burns, should the patient touch an earthed metal object or if the return electrode connection should fail. Patient safety can be compromised when a mixture of isolated and earthed equipment is attached. It is also important to be aware that some mains isolated patient monitoring equipment may not be well isolated at high frequencies.

Earth Referenced: Four lower powered units (up to 50 Watts) included in the review are earth
Design Features

referenced at high frequencies. Manufacturers may suggest using capacitive coupling of the ESU current to earthed metal objects, such as a dentist’s chair, to return monopolar electrosurgical current to the ESU. However, great care should be taken when a conductive patient return plate is not attached.

Duty Cycle: All low/medium powered ESUs specify the type of activation tolerated for an hour without overheating of electronic circuitry and adversely affecting the power output levels. On each Product Data Page the duty cycle is stated, specifying the activation time, ‘on time’, and pause required between surgical activation, ‘off time’. The design of some ESUs enables continuous activation at full power without the unit overheating.

Programmable Cut/Blend Waveforms: Two ESUs developed for specialist applications provide the option of pre-programmed delivery of pulses of specified duration and/or separation on activation

Fractionated delivery for cutting ‘underwater’ in glycine solutions has been called ENDOCUT™. A moderately high voltage cutting waveform is generated to heat the solution and produce an arc in the water vapour. When this moment is detected a pure cut waveform continues for a short pre-defined period before being turned off, to permit the heat to dissipate and coagulate the tissue. Extending the ‘off time’ increases the depth of coagulation.

Another ESU permits activation time to be pre-programmed in fractions of a second and initiated each time the foot switch is depressed. In addition, special waveforms are programmed with the ‘on time’ and ‘off time’ specified in hundredths of a second. Both are designed for delicate cutting.

Specialised Contact Coagulation Modes: Some ESUs provide a monopolar coagulation mode which produces very low power output for high load impedances. This is called ‘soft coagulation’ on several ESUs included in this review. These units also provide a second coagulation mode with a more conventional power curve which is called ‘forced coagulation’.

Some ESUs in bipolar coagulation mode have power curves with a shape similar to that of ‘soft coag’, eg Aaron Bovie 2100, Erbe and Martin ME102 & 200. Other models maintain high power output levels at relatively high tissue impedances, ie Aaron Bovie 1250, Conmed Hyfrecator, Korpo Timed TD50 and Valleylab Surgistat II.

Argon Beam Coagulation: Argon is an inert, non-combustible gas more easily ionised by an electrosurgical current than air. In spray coagulation mode a stream of argon gas flowing over the active electrode is reported to improve the surgical effectiveness of surface coagulation. Erbe ICC200 offers argon beam coagulation as an option but this facility was not available on the device tested for this review.

Power Control: All ESUs provide the surgeon with a rotating dial or digital buttons to vary power output levels. Some manufacturers display the power setting in Watts. Other manufacturers provide a dial position setting, usually 0 - 10, roughly dividing the maximum ESU power output in that mode, eg 50 Watts. The user manual will provide details of the maximum power if there is no display or label on the ESU.

Great care should be taken when using different models of ESU as the same dial settings may not produce equivalent power outputs. For example a power setting of ‘5’ could produce major differences in surgical effect as it can mean 5 Watts or, perhaps, 50 Watts (if the ESU maximum power is 100W).

Active power/voltage management: Careful control of voltage and power output parameters will achieve smooth cutting in most surgical procedures. Some electrosurgical generators have monitoring and control systems designed to maintain output power and/or voltage to within pre-set limits, dependent on the mode and power setting. These systems have various descriptions including constant voltage, dynamic power regulation, CUT CONTROL™, Optisense™, etc.

Active output control is particularly useful in procedures such as loop excision in colposcopy (see bottom left figure on the front page). In this procedure a section of tissue is removed in one continuous movement of the loop; but the tissue impedance changes as the area in contact with the electrode starts small, increases to a maximum, then falls again.

In cut or blend modes a burst of higher voltage may help to initiate ionisation between the active electrode and tissue surface. This type of active output control has been called Power Peak System™.
Capacitive return electrodes: Some ESU manufacturers supply capacitive return electrodes for use with specific models. This design of reusable return electrode provides an inexpensive alternative to the conductive, adhesive pads and may be convenient in an outpatient clinic. However, some may be difficult to position in close contact with the skin surface over a well vascularised region. Because there can be no contact quality monitoring there is an increased risk of alternate site burns when using capacitive plates, particularly with earth-referenced ESUs. Users must verify with the manufacturer that capacitive return electrodes supplied separately are compatible for use with each specific ESU model.

Activation Switches: All electrosurgical units included in this review can be supplied with a footswitch(s) to activate ESU power output. However care must be taken if using more than one ESU model as there is no standard footswitch configuration. The Ellman Surgitron Radiolase, Korpo Timed 50A and Martin MD62 require the mode (cut or coag) to be selected on the ESU front panel and a single footswitch is supplied for activation.

Some ESUs in this review (from Aaron Bovie, Erbe, Olympus, Utah Medical & Valleylab) have separate pedal switches for activating cut and coagulation modes which are colour coded, yellow for cut and blend modes and blue for coagulation modes (both monopolar and bipolar). Although Martin ESUs also supply twin blue and yellow foot switches and a separate white foot switch is provided for activation of bipolar coagulation. Conventionally in the operating theatre the coagulation (blue) pedal is placed to the right of the cut/blend (yellow) pedal. Erbe units and the Olympus PSD-30 are supplied with pedals fixed in this orientation and also have a central footrest. This design may avoid inadvertent selection of the wrong activation mode. Please note some footswitch designs are prone to inadvertent activation, eg. if they are moved or become physically wedged during the surgical procedure, eg under the operating table support.

Finger-switching pencil electrodes are available for many ESU models in this review series. Most provide yellow and blue buttons to active the cut/blend and coagulation respectively. The Conmed Hyfrecator permits control of the power output level and an activation button on the monopolar finger-switching pencil but the mode must be selected on the ESU front panel.

Automatic Start: In bipolar mode electrical impedance across the ESU output suddenly drops as tissue is grasped between the forceps tines. In some ESUs electrosurgical output may be activated automatically when the forceps grasp conductive tissue. This feature can enable coagulation of a large number of small vessels without simultaneous activation of the footswitch each time. Some devices introduce a pause of a few seconds between tissue contact and activation to enable the surgeon to briefly manipulate tissue with the inactive forceps.

Automatic Switch Off: Contact coagulation should continue long enough to ensure that vessels will not re-bleed but should not cause excessive tissue damage (Table 1 on page 2). Heating drives water out of cells reducing the ability of tissue to transport current and so tissue impedance rises. Auto Stop™ monitors the rise in impedance and turns off activation once it reaches a pre-set value.

SAFETY FEATURES

Start-up Self Check: Some low and medium powered ESUs perform an internal check on start up and prior to activation being permitted.

Return Electrode Continuity Monitor: An isolated ESU will not work unless a patient return electrode is connected to the generator input socket. This is a requirement of the latest version of the international standard for electrosurgical units (EN60601-2-2:2001).

Contact Quality Monitoring (CQM): Using a split plate return electrode with two wires a small monitoring signal can be 'injected' into one electrode half, flow through the skin and tissue and return to the generator via the other electrode half. Measuring the total impedance monitors electrical conductivity across the pad-skin surface. If this exceeds a pre-set range, eg 0-150Ω, ESU power output is stopped and an alarm sounds. Return electrode contact quality monitoring (RECQM or CQM) reduces the risk of patient return electrode burns. However, those units that need a larger impedance value to trigger the alarm may be less effective in detecting poor pad-skin contact.

Return Current Feedback Monitor: Monitoring current flow to the active electrode and comparing it with that from return electrode can detect current division and prevent alternate site burns.
High Frequency Leakage Monitor: Monitoring the high frequency current flowing to the ESU from earth can detect earth leakage. If it exceeds a pre-set limit ESU power output is disabled and an alarm sounds. High levels of electrical coupling to earth can occur for many reasons eg. insulation failure and poor return electrode contact.

Earth leakage connector: Some manufacturers of minimally invasive equipment incorporate an earth leakage connector (safety cord or S-cord) to provide a direct return pathway to the ESU generator for rf leakage currents in the metal endoscope / laparoscope. This equipment should be used with split plate electrodes and a contact quality monitoring system to prevent this lead being inadvertently used as the primary current return path to the ESU. An S-cord continuity monitor can ensure the S-cord is not inadvertently disconnected.

Output Error Monitoring: Equipment malfunction, overheating or incompatibility with ESU accessories can cause excessive power output and adversely affect surgical outcome. Some units monitor actual power output, comparing this with selected power setting. If output exceeds pre-set limits above the intended dosage the ESU output is disabled and an alarm enacted. This feature may be called output error monitoring by some manufacturers.

This feature is mandatory for ESUs over 50 Watts designed in compliance with the latest version of the international standard (EN60601-2-2:2001). This document specifies the maximum allowed output power in single fault conditions.

Smoke Filtration: There is some evidence that toxic and carcinogenic by-products are contained in the smoke plume and aerosol generated by electrosurgery. Use of high filtration smoke evacuation units, simultaneously activated by the ESU, is now an option for several models in this review. The Utah Medical Finnesse has an integrated smoke evacuation and filter unit but this facility was not tested for this review.

Activation Time Limit Alarm: ESU power output is automatically turned off after a pre-set period. This would reduce deleterious effects caused by inadvertent prolonged activation, eg ESU overheating.

SPECIFICATIONS

Power output should be sufficient to achieve the desired surgical effect but should not be too high since this increases the risk of unwanted tissue damage. Power requirements vary according to the desired surgical effect, the active electrode size and type of tissue to be treated. Tissue in the current path determines the electrical load, but this can change as the current alters the tissue’s properties. The power output depends on this load, with the selected power level usually indicating the maximum power that may be delivered.

A useful characteristic of electrosurgical power delivery is the variability of power output as the tissue impedance changes for a fixed power setting. This is called the power curve and every ESU user manual must include power curves for maximum and half power settings in each mode. Knowledge of tissue impedance values typical for a specific operation can help in the selection of the most appropriate electrosurgical device and mode.

To illustrate this concept we could consider bipolar tubal sterilisation. This surgical procedure may fail if the combination of bipolar forceps and ESU output parameters do not achieve complete coagulation of the inner core. Power curves can help to predict the tissue effect. For example two hypothetical ESUs with different characteristics are illustrated. The power curve in Figure 3a suggests that high power output is only possible for a tissue volume of very low impedance. Tissue heating could stop immediately once superficial layers are dessicated, as this will slightly increase tissue impedance between the bipolar tines and the power output will drop. By using an ESU mode...

Figure 3a Power curve: rated load of 50 Ω
with a power curve having a broader peak, as in Figure 3b, tissue heating can continue until the total impedance of tissue grasped between the tines is well over 600\(\Omega\), as the power output remains high above this value. Providing an appropriate selection of forceps size and power setting is made, the second ESU is more likely to coagulate the inner core of the fallopian tube.

In this review there is insufficient space for reproducing power curves for each device and mode. A key feature summarising the power curve is the Maximum Power at the Rated Load. The Maximum Power and Rated Load are both tabulated for each mode on the product data pages.

GUIDE TO PRODUCT DATA PAGES

There are a number of issues to consider when considering which particular electrosurgical unit to purchase including clinical, technical, financial and legal. Each product summary page is designed to provide an overview of these issues for each device to assist in procurement decisions. You are advised to obtain information on the cost of reusable / ‘single use’ accessories compatible with the ESU you are planning to purchase as these can add significantly to the lifetime cost of the device. Limited space prevents inclusion of accessory data in these product summaries.

Price: All prices in this report exclude VAT. For some units a carriage charge may also be added. User manuals, accessories and active leads may be included in the price of the electrosurgical unit. Suppliers should be contacted for the current prices of accessories. 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.

Dimensions & Weight: Dimensions are listed consistently for all units (width \(\times\) height \(\times\) depth, in mm). The weight (given in kg) coupled with the size could significantly affect the procurement decision if the ESU must be stored in a cupboard or transported between surgical sessions.

Full Evaluation Report: Where available, the full evaluation report should be consulted before making a decision to purchase. These reports contain user assessments, technical evaluations, and safety issues. Locally, they may be archived in the Clinical Engineering or EBME Department. Alternatively, these are free to NHS staff (see back page for contact details).

CE Marking: Manufacturers of medical devices placed on the market in Europe are required to meet the relevant European Union Medical Devices Directive. A classification of medical devices has been established denoting the risk of the device type for the patient, Class III having the highest risk. The electrosurgical units listed in this review have been classified by the manufacturers as IIb. The routes to CE marking chosen by these manufacturers were through full quality assurance (ie the manufacturer’s design and manufacturing processes) audited and certified by a Notified Body.

Notified Body: This is an organisation authorised by their national Competent Authority. In the UK this is the Medical Devices Agency. The same system operates in all EC countries and a number of Notified Bodies have branches in the USA, Japan, etc.

Manufactured to Standard: Certificate copies received from the manufacturer or an independent test house stating conformance with international standards are summarised in this section.

EN 60601 is the European standard for electrical medical devices, which is harmonised to the international standard. Special requirements for ESUs are detailed in EN 60601-2-2. Please note CE marking does not automatically mean that all ESUs conform to the current, relevant international safety standards.

Where the only certification received is related to the manufacturer’s quality assurance system (eg EN ISO13485 or EN 46001) this information is detailed in this section. For these devices compliance is only with the Essential Requirements, the legal minimum.
Guide to Product Data Pages

Main Features: This section summarises the ESU modes, special features, such as automatic coagulation, and power control labelling. These features are briefly described on pages 5 to 8.

Specifications: All devices should be matched to the intended surgical application(s) in terms of output power, rated load and peak voltage. Values listed are from the user manual. CEDAR measured values were within permitted tolerances.

Maximum Power: The current flow delivered into a specific load impedance, called the ‘rated load’, at the maximum power output setting is used to calculate the maximum power output.

Rated Load: For each mode the rated load is usually the total impedance between the active and return electrode for which the ESU generator delivers the highest power output.

Peak Voltage: The maximum open-circuit peak voltage is listed for each mode. This is the highest voltage away from zero, either in a positive or negative direction measured between the active and return electrodes when no tissue / load is connected between them. Peak voltage is useful for giving an idea how far an electric spark from an active electrode can jump through the air. Different voltages reflect the intended applications of each device. Cutting voltages must be above a few hundred volts, to develop the arc required for cutting, but low enough to avoid unwanted charring or direct arcing between active electrodes. Contact coagulation peak voltages of the devices in this review range from 190 V to 3.5 kV. Spray coagulation peak voltages may vary from 1.6 kV to 9 kV.

Matching the Device to the Surgical Task: Some ESUs are specialised, intended for one particular surgical field, whilst others provide a range of outputs and modes for a more general range of applications. The cost of a device should be weighed against the range of applications (see Table 2) and the frequency of use.

Maintenance: During its lifetime an ESU will need routine preventative maintenance and possibly repair. Any purchasing decision should include careful consideration of the servicing and maintenance required and the cost and availability of technical training. Most suppliers offer service or maintenance contracts, though they may differ in the level of cover they offer. Service manuals should be available, though there may be a charge.

PROCUREMENT ISSUES

Controls Assurance Standard: Trust boards must take responsibility for ensuring there are safe systems in place to minimise the risks associated with the acquisition and use of medical devices (www.casu.org.uk ➔ standards ➔ medical devices).

Current Production: Manufacturers may continue to modify products after this report is published. Please note that the version you buy may differ from the one evaluated.

Compliance with Safety Standards: If a device complies with the relevant harmonised international standard (see page 9) this will be accepted as evidence that the device meets the Essential Requirements of the Medical Devices Directive. Devices included in this report may be certified to, or the manufacturer claims compliance with, these standards. Further advice about these issues can be obtained from the manufacturer, hospital Clinical Engineering, EBME or Medical Physics Departments or the British Standards Institute (www.bsi-global.com).

Purchasing Assessment: It is intended that this review and other full evaluations should assist purchasers in carrying out a rigorous specification and assessment process. Suppliers should be contacted for the latest product information and prices. Product demonstrations and trials may also be arranged prior to purchasing. Thought should be given to the lifetime cost of a unit, including accessories and maintenance.

Indemnity Insurance: Loan-unit indemnity arrangements between the suppliers and NHS Supplies in England, Wales, Scotland and Northern Ireland have not been verified for devices in this review.

Training: User knowledge and skills have major implications for safety. Instructions, both the user manual and local protocols, must be clear, concise and readily available. Training of staff in the use of equipment needs to be timely and effective. Users and technicians need to understand the basic principles on which the ESU works (generic training) as well as how to use a particular model (specific training). Training programmes should, where possible, include input from manufacturers and independent experts. Procurement of a new medical device should include a resource allocation for user training. Strategic procurement policies will reduce training time if the number of different models is limited.
<table>
<thead>
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<th>Surgical Applications</th>
<th>Aaron Bovie 1250</th>
<th>Aaron Bovie 2100</th>
<th>ConMed Hyfrecator 2000</th>
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Table 2 Manufacturers’ Principal Intended Applications
Aaron Bovie 1250

**SUMMARY**
- 120 W monopolar, 30 W bipolar
- Cut, blend and coagulation modes

**Supplier**
Avail Medical Europe Ltd  
The Coach House  
Dosthill Hall  
Dosthill  
Tamworth  
Staffordshire, B77 1JB  
availmedic@aol.com  
Tel: 01827 288 883  
Fax: 01827 288 334  
Web: www.aaronmed.com

**Price** £3,500

**BRIEF DESCRIPTION**
The Aaron 1250 is a compact, rf-isolated, solid-state electrosurgical unit. The device is rated Type BF and has a duty cycle of 10 seconds on full power followed by 30 seconds off.

The Aaron 1250 is intended for all low to medium power range specialties, this includes; general surgery, both open and laparoscopic, gynaecology, dermatology, ENT, maxillofacial, orthopaedics, plastic surgery, neurosurgery, paediatric, cardiac and thoracic surgery and endoscopy. The 1250 is not suitable for urology.

**Dimensions**
- 260 x 152 x 305 mm (W) (H) (D)
**Weight**
- 6.5 kg

**MAIN FEATURES**
**Facilities**
- Cut
- Coagulation
- Power control

**Specifications**

<table>
<thead>
<tr>
<th>Facility</th>
<th>Maximum Power</th>
<th>Rated Load</th>
<th>Peak Voltage</th>
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<td>1.4 kV</td>
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<td>2.0 kV</td>
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<td>3.3 kV</td>
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<td>1.25 kV</td>
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**Safety Features**
- Return electrode continuity monitor
- Patient contact monitor
- Connection for simultaneous activation of smoke filtration

**Operating Switches**
- Footswitches twin electrical
- Handswitches fingerswitching pencil (monopolar)

**SERVICING**
A loan service is provided when units are returned for servicing OR hospital visits may be arranged.

**Typical Servicing Costs**
- Annual comprehensive repair/preventative maintenance contract (inc. parts) **£ 375**
- **Reductions available depending on location**
- Service Training *Price on Application*
- Service Manual £ 70
**BRIEF DESCRIPTION**

The Aaron 2100 is a compact, rf-isolated, solid-state electrosurgical unit. The device is rated Type CF and has a duty cycle of 10 seconds on full power followed by 30 seconds off.

The Aaron 2100 is a multipurpose electrosurgical generator for use in surgical operating theatres and centres for day case surgery. This includes; general surgery (including laparoscopic surgery), cardiovascular, gynaecology, dermatology, ENT, neurosurgery, orthopaedics, plastic surgery, endoscopy, paediatrics and maxillofacial surgery. The 2100 is not recommended for urology.

The 2100 provides nine blend settings, for differing haemostatic effect, in addition to pure cut, coagulation, fulguration and bipolar modes.

**Dimensions**  
380 × 152 × 460 mm

**Weight**  
7.2 kg

**Supplier**  
Avail Medical Europe Ltd  
The Coach House  
Dosthill Hall  
Dosthill  
Tunworth  
Staffordshire, B77 1JB  
availmedic@aol.com  
Tel: 01827 288 883  
Fax: 01827 288 334  
Web: www.aaronmed.com

**Price**  
£4,450

**SUMMARY**

- 200 W monopolar, 80 W bipolar
- Cut and variable blend (9 settings)
- Contact and spray coagulation modes
- Impedance sensing

**MAIN FEATURES**

**Facilities**
- Cut: Cut, Blend (10% -100%)
- Coagulation: Forced Coagulation, Fulguration, Bipolar
- Power control: Digital, display in Watts
- Active output control: Optisense™
- Memory of last setting for each mode
- PC interface for ease of servicing

**Specifications**

<table>
<thead>
<tr>
<th>Facility</th>
<th>Maximum Power</th>
<th>Rated Load</th>
<th>Peak Voltage</th>
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</thead>
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**Safety Features**
- Return electrode continuity & patient contact monitor
- Connection for simultaneous activation of smoke filtration

**Operating Switches**
- Footswitches: twin electrical
- Handswitches: fingerswitching pencil (monopolar)

**SERVICING**

A loan service is provided when units are returned for servicing OR hospital visits may be arranged.

**Typical Servicing Costs**
- Annual comprehensive repair/preventative maintenance contract (inc. parts) **£ 375**  
  **Reductions available depending on location**
- Service Training: Price on Application
- Service Manual: FREE

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**Aaron Bovie 2100**

**Full Report**  
Brief Assessment

**CE Marking?**  
Yes, MD Directive  
Quality System Audit

**Notified Body**  
ITS SEMKO-AB (0413)

**Manufactured to Standard?**  
Manufactured under EN46001:1996

---

**Supplier**  
Avail Medical Europe Ltd  
The Coach House  
Dosthill Hall  
Dosthill  
Tamworth  
Staffordshire, B77 1JB  
availmedic@aol.com  
Tel: 01827 288 883  
Fax: 01827 288 334  
Web: www.aaronmed.com

**Price**  
£4,450

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**Facility**  
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<th>Maximum Power</th>
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**ConMed Hyfrecator 2000**

**BRIEF DESCRIPTION**

The ConMed Hyfrecator 2000 is a low power, earth-referenced electrosurgical unit. The device is rated type BF and has a duty cycle of 30 seconds on full power, followed by 30 seconds off. Spray coagulation and contact coagulation may be achieved using the HI or LO output modes, respectively. Bipolar coagulation requires the use of a footswitch and provides precise coagulation or haemostasis.

No patient return electrode is required in monopolar modes as the low powers involved mean that sufficient current can be returned to the Hyfrecator unit by environmental capacitive coupling. More effective coagulation can be achieved when using the optional return electrode with either the HI or LO outputs. The return electrode provides a more efficient path for the electrosurgical current and increased coagulation results. Power settings may need to be reduced to compensate for the increased surgical effect.

**Dimensions** 222 × 102 × 190 mm

**Weight** 2.7 kg

| Full Report | Brief Assessment |
| CE Marking? | Yes, MD Directive |
| Quality System Audit | |
| Notified Body | TÜV München (0123) |

**Manufactured to Standard?**

Manufacturer claims compliance with EN60601-1, EN60601-1-2, EN60601-1-4 and EN 60601-2-2

**MAIN FEATURES**

**Outputs**
- Monopolar Coagulation: LO (contact coag), HI (spray coag)
- Bipolar Coagulation: BI
- Power control: Rotary, display in Watts

**Specifications**

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**Operating Switches**

- Footswitches: mono/bipolar, single electrical
- Handswitches: monopolar, fingerswitching with pencil with power control
- bipolar, none

**SERVICING**

The ConMed Hyfrecator 2000 can be serviced in-house or returned to the UK agent. It is intended that the unit be returned to the supplier for repair. A comprehensive service manual is available including full circuit diagrams.

**Typical Servicing Costs**

- Full service: £ 52 (exc. materials & carriage)
- Inspection and testing: £ 29 (exc. carriage)
- Service Manual: £ 15

**Price**

- Basic ESU: £ 715
- plus footswitch: £ 830
- plus bipolar & footswitch: £ 962

**Supplier**

Schuco International London Ltd
Lyndhurst Avenue
London N12 ONE
Tel: 0208 368 1642
Fax: 0208 361 3761
Web: www.schuco.co.uk
Ellman Surgitron Dual Frequency

**SUMMARY**
- 100 W monopolar, 38 W bipolar
- Cut and coagulation modes
- 4 MHz rf output in monopolar modes
- 1.71 MHz rf output in bipolar mode

**Supplier**
Ellman International (UK) Ltd
16 Ryehill Court
Lodge Farm
Northampton, NN5 7EU
Tel: 01604 589928
Fax: 01604 759098
Web: www.ellman.com

**Price**
£8,750

**BRIEF DESCRIPTION**
The Ellman Surgitron Dual Frequency is a compact, solid state, earth-referenced electrosurgical unit. The device is rated Type BF and has a duty cycle of 10 seconds on full power followed by 30 seconds off.

The Surgitron IEC is primarily intended for outpatient procedures in dermatology, plastic surgery, ENT, maxillofacial and ophthalmology. This is similar to the Surgitron IEC ([evaluation report 402](https://www.ellman.com)). Principal upgrades: high frequency (4MHz) now used for all monopolar modes; a three-button fingerswitch hand-piece, for activating power on and selecting the activation mode.

The patient contact monitor permits a maximum impedance of 1000 Ω; this is higher than similar monitoring systems and less effective for detecting partial detachment of the return electrode.

**Dimensions**
229 × 127 × 337 mm

**Weight**
8.16 kg

**MAIN FEATURES**
- Cut
  - Cut
  - Cut/Coag (blend)
- Coagulation
  - Hemo (contact coag)
  - Fulgurate (spray coag)
  - Bipolar
- Power control
  - Digital, display in Watts

**Specifications**

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<tr>
<td>Bipolar</td>
<td>38 W</td>
<td>500 Ω</td>
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**Safety Features**
- Return electrode continuity monitor
- Contact quality monitor (see Brief Description)

**Operating Switches**
- Footswitches  dual electrical
  (mono & bipolar)
- Handswitches  fingerswitching
  pencil (3 buttons)

**SERVICING**
As required and contract servicing arrangements are available.

**Typical Servicing Costs**
The Ellman Surgitron Dual Frequency can be serviced by the user or a service contract with the supplier, which includes the cost of carriage and any parts used in the annual service and calibration check. If repairs to the ESU are required this charge covers labour costs only.

**Typical Servicing costs**
- Service Contract (per year) £150
- Service Manual 2 copies supplied FREE
BRIEF DESCRIPTION

The Ellman Radiolase is a compact, low power, solid-state, earth referenced electrosurgical unit. The device is rated Type BF and has a duty cycle of 10 seconds on full power followed by 30 seconds off.

The Radiolase is intended for use in minor surgical outpatient based procedures such as dermatology, plastic surgery, ophthalmology, and dental surgery.

The manufacturer claims that using a higher frequency (4 MHz) can be beneficial in terms of lessening tissue damage, reduced scarring and more rapid healing.

Due to the higher than usual radio frequency (4.0MHz) used by the Radiolase, a small area capacitive return electrode is available as an option to the more usual conductive, adhesive return plates.

Dimensions: 178 × 108 × 216 mm
Weight: 3.35 kg

Supplier: Ellman International (UK) Ltd
16 Ryehill Court
Lodge Farm
Northampton, NN5 7EU
Tel: 01604 589928
Fax: 01604 759098
Web: www.ellman.com

Price: £ 2,095

SERVICING

The Ellman Surgitron Radiolase can be serviced by the user or a service contract with the supplier, which includes the cost of carriage and any parts used in the annual service and calibration check. If repairs to the ESU are required this charge covers labour costs only.

Typical Servicing costs
- Service Contract (per year) £150
- Service Manual 2 copies supplied FREE

MAIN FEATURES

Outputs
- Cut
- Coagulation Hemo (contact coag)
- Power control rotary, continuous labelled 0 - 10

Specifications

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<td>300 V</td>
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* CEDAR measurements, not stated in the user manual

Operating Switches
- Footswitch single electrical
- Handswitch single fingerswitch

CE Marking?
Yes, MD Directive
Quality system audit

Notified Body
ITS-SEMKO AB (0413)

Manufacturer to Standard?
**Erbe ICC 50**

**BRIEF DESCRIPTION**

Erbe ICC50 is a compact, low powered microprocessor controlled electrosurgical unit. The unit is rf isolated, rated Type CF and is capable of continuous operation. Nominal frequency is 350kHz in all modes.

Erbe ICC50 is appropriate for minor surgical procedures and use in outpatient clinics, such as dermatology and oral surgery.

Two pre-programmed default settings for monopolar cutting are provided called Auto Cut Effect modes. Auto Cut Effect 1 provides a pure sinusoidal cut (Crest factor = 2). Auto Cut Effect 2 is a blended waveform providing coagulation at the cut surface (Crest factor = 4 ).

Soft and Forced monopolar coagulation can be activated by footswitch or pedal. Bipolar coagulation is only activated by footswitch.

**SUMMARY**

- 50 W monopolar, 50W bipolar
- Auto Cut – providing initial power surge
- Soft Coag – voltage limited
- Pre-set voltage response to tissue load

**Supplier**

ERBE Medical UK Ltd  
The Antler Complex  
2 Bruntcliffe Way, Morley  
Leeds, LS27 0JG

Tel: 0113 253 0333  
Fax: 0113 253 2733  
Web: www.erbe-med.com

**Price**  
£ 1,700

**MAIN FEATURES**

- Automatic voltage control – CUT CONTROL™
- Coagulation forced soft (voltage limited at high Ω)  
  bipolar (voltage ltd at high Ω)
- Power control Digital, display in Watts

**Specifications**

<table>
<thead>
<tr>
<th>Mode</th>
<th>Maximum Power</th>
<th>Rated Load</th>
<th>Peak Voltage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auto Cut (1)</td>
<td>50 W</td>
<td>500 Ω</td>
<td>500 V</td>
</tr>
<tr>
<td>Auto Cut (2)</td>
<td>50 W</td>
<td>500 Ω</td>
<td>800 V</td>
</tr>
<tr>
<td>Soft Coag</td>
<td>50 W</td>
<td>200 Ω</td>
<td>190 V</td>
</tr>
<tr>
<td>Forced Coag</td>
<td>50 W</td>
<td>500 Ω</td>
<td>900 V</td>
</tr>
<tr>
<td>Bipolar Coag</td>
<td>50 W</td>
<td>200 Ω</td>
<td>190 V</td>
</tr>
</tbody>
</table>

**Safety Features**

- Switch on safety check includes accessories
- Return electrode continuity monitor
- Activation Time Limit (adjustable 1 - 99 secs)
- Start-up self-check & Output Error Monitor

**Operation Switches**

- Footswitches monopolar bipolar twin electrical coag mono pedal
- Handswitches monopolar bipolar fingerswitching none

**SERVICING**

The ERBE ICC50 can be serviced by the user, a service contract with the supplier or returning the unit to the supplier. The supplier provides various levels of service contract, some are listed below:

**Typical Servicing Costs**

- Contracted repair & preventative maintenance (per year) £ 450.45
- as above but excluding parts £ 343.35
- Non-contract emergency call-out rate labour/travelling/waiting per hour £ 68.25
- Return to supplier, labour per hour £ 50.93
- Service Manual £ 35.00
Erbe ICC80

BRIEF DESCRIPTION

SUMMARY
- 80 W monopolar, 50W bipolar
- Auto Cut – providing initial power surge
- Soft Coag – voltage limited
- Pre-set voltage response to tissue load

Supplier
ERBE Medical UK Ltd
The Antler Complex
2 Bruntcliffe Way, Morley
Leeds, LS27 0JG
Tel: 0113 253 0333
Fax: 0113 253 2733
Web: www.erbe-med.com

Price
£ 1,800

Erbe ICC80 is a micro-processor controlled electrosurgical unit designed for minor surgery procedures. Appropriate for use in outpatient clinics and specialised medical practices such as oral surgery and dermatology.

The unit is rf isolated, rated Type CF and is capable of continuous operation. Nominal frequency is 330kHz in all modes.

Two Auto Cut Effect modes are provided: Auto Cut Effect 1 is a pure sinusoidal cut (Crest factor = 2), Auto Cut Effect 2 is a blended waveform providing coagulation at the cut surface (Crest factor = 4 ). Both Auto Cut modes incorporate the CUT CONTROL™ to facilitate a smoother cutting action.

Soft and Forced monopolar coagulation and Bipolar coagulation are available on this unit.

Fingerswitch activation is available for monopolar modes. The foot switch will activate all modes.

Dimensions
275 × 105 × 255 mm

Weight
2.8 kg

MAIN FEATURES
- Automatic voltage control – CUT CONTROL™
- Coagulation
  - soft (voltage limited at high Ω)
  - bipolar (voltage ltd at high Ω)
- Power control Digital, display in Watts

Specifications

<table>
<thead>
<tr>
<th>Mode</th>
<th>Maximum Power</th>
<th>Rated Load</th>
<th>Peak Voltage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auto Cut (1)</td>
<td>80 W</td>
<td>500 Ω</td>
<td>500 V</td>
</tr>
<tr>
<td>Auto Cut (2)</td>
<td>80 W</td>
<td>500 Ω</td>
<td>500 V</td>
</tr>
<tr>
<td>Soft Coag</td>
<td>50 W</td>
<td>200 Ω</td>
<td>190 V</td>
</tr>
<tr>
<td>Forced Coag</td>
<td>50 W</td>
<td>500 Ω</td>
<td>900 V</td>
</tr>
<tr>
<td>Bipolar Coag</td>
<td>50 W</td>
<td>200 Ω</td>
<td>190 V</td>
</tr>
</tbody>
</table>

Safety Features
- Switch on safety check includes accessories
- Return electrode continuity and contact quality monitor (dual plate electrodes only)
- Activation Time Limit (adjustable 1 - 99 secs)
- Start-up self-check & Output Error Monitor

SERVICING

The ERBE ICC80 can be serviced by the user, a service contract with the supplier or returning the unit to the supplier. The supplier provides various levels of service contract, some are detailed below:

Typical Servicing Costs
- Contracted repair & preventative maintenance (per year) £ 450.45
- as above but excluding parts £ 343.35
- Non-contract emergency call-out rate labour/travelling/waiting per hour £ 68.25
- Return to supplier, labour per hour £ 50.93
- Service Manual £ 35.00

Full Report
Brief Assessment

CE Marking?
Yes, MD Directive

Notified Body
DEKRA (0124)

Manufactured to Standard?
Manufactured under EN 46001

Quality System Audit
DEKRA (0124)

Manufactured
under
EN 46001

Mode
Auto Cut (1)
Auto Cut (2)
Soft Coag
Forced Coag
Bipolar Coag

Maximum
Power
80 W
80 W
50 W
50 W
50 W

Rated
Load
500 Ω
500 Ω
200 Ω
500 Ω
200 Ω

Peak
Voltage
500 V
500 V
190 V
900 V
190 V

Supplier
ERBE Medical UK Ltd
2 Bruntcliffe Way, Morley
Leeds, LS27 0JG
Tel: 0113 253 0333
Fax: 0113 253 2733
Web: www.erbe-med.com

Price
£ 1,800

Mode
Auto Cut (1)
Auto Cut (2)
Soft Coag
Forced Coag
Bipolar Coag

Maximum
Power
80 W
80 W
50 W
50 W
50 W

Rated
Load
500 Ω
500 Ω
200 Ω
500 Ω
200 Ω

Peak
Voltage
500 V
500 V
190 V
900 V
190 V

Safety Features
- Switch on safety check includes accessories
- Return electrode continuity and contact quality monitor (dual plate electrodes only)
- Activation Time Limit (adjustable 1 - 99 secs)
- Start-up self-check & Output Error Monitor

SERVICING

The ERBE ICC80 can be serviced by the user, a service contract with the supplier or returning the unit to the supplier. The supplier provides various levels of service contract, some are detailed below:

Typical Servicing Costs
- Contracted repair & preventative maintenance (per year) £ 450.45
- as above but excluding parts £ 343.35
- Non-contract emergency call-out rate labour/travelling/waiting per hour £ 68.25
- Return to supplier, labour per hour £ 50.93
- Service Manual £ 35.00

Supplier
ERBE Medical UK Ltd
2 Bruntcliffe Way, Morley
Leeds, LS27 0JG
Tel: 0113 253 0333
Fax: 0113 253 2733
Web: www.erbe-med.com

Price
£ 1,800

Mode
Auto Cut (1)
Auto Cut (2)
Soft Coag
Forced Coag
Bipolar Coag

Maximum
Power
80 W
80 W
50 W
50 W
50 W

Rated
Load
500 Ω
500 Ω
200 Ω
500 Ω
200 Ω

Peak
Voltage
500 V
500 V
190 V
900 V
190 V

Safety Features
- Switch on safety check includes accessories
- Return electrode continuity and contact quality monitor (dual plate electrodes only)
- Activation Time Limit (adjustable 1 - 99 secs)
- Start-up self-check & Output Error Monitor

SERVICING

The ERBE ICC80 can be serviced by the user, a service contract with the supplier or returning the unit to the supplier. The supplier provides various levels of service contract, some are detailed below:

Typical Servicing Costs
- Contracted repair & preventative maintenance (per year) £ 450.45
- as above but excluding parts £ 343.35
- Non-contract emergency call-out rate labour/travelling/waiting per hour £ 68.25
- Return to supplier, labour per hour £ 50.93
- Service Manual £ 35.00

Supplier
ERBE Medical UK Ltd
2 Bruntcliffe Way, Morley
Leeds, LS27 0JG
Tel: 0113 253 0333
Fax: 0113 253 2733
Web: www.erbe-med.com

Price
£ 1,800
**BRIEF DESCRIPTION**

Erbe ICC200 is a micro-processor controlled electrosurgical unit for general application and includes specific features designed for minimally invasive surgery. The unit is rf isolated, rated Type CF and is capable of continuous operation. The nominal frequency is 350kHz in most modes. Spray and forced coagulation operate at 1MHz.

Four Auto Cut Effect modes are standard, all incorporating the Power Peak System to facilitate a smoother cutting action. Auto Cut Effect 1 is a pure sinusoidal cut, with Auto Cut Effects 2 to 4 being blended waveforms increasing the coagulation of the cut surface. Endo Cut (option) is a fractionated cut for delicate cutting.

Soft & Forced monopolar coagulation and bipolar coagulation are standard. Auto Start for bipolar coagulation (either immediate or delayed) is disabled for the UK market. Spray & Argon plasma coagulation is available as an optional extra.

**Dimensions** 280 × 152 × 368 mm

**Weight** 8.0 kg

**Price** £3,200

**Options**
- endoscopic cut: £800
- spray and argon beam coagulation: £1,400

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**SUMMARY**

- 200 W monopolar, 120 W bipolar
- Auto Cut – providing initial power surge
- Soft Coag – voltage limited
- Programmable settings memory (single)

**Supplier**

ERBE Medical UK Ltd
The Antler Complex
2 Bruntcliffe Way, Morley
Leeds, LS27 0JG
Tel: 0113 253 0333
Fax: 0113 253 2733
Web: www.erbe-med.com

**Full Report** Brief Assessment

**CE Marking?** Yes, MD Directive

**Notified Body** DEKRA (0124)

**Manufactured to Standard?** Certified by DEKRA as complying with: EN 60601-2-2: 1991

**MAIN FEATURES**

- Power Peak System – burst of power (higher voltage) to initiate cutting action
- Automatic voltage control – CUT CONTROL™
- Coagulation allowed
  - soft (voltage limited at high Ω)
  - bipolar (voltage limited at high Ω)
- Power control Digital, display in Watts

**Specifications**

<table>
<thead>
<tr>
<th>Mode</th>
<th>Maximum Power</th>
<th>Rated Load</th>
<th>Peak Voltage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auto Cut</td>
<td>200 W</td>
<td>500 Ω</td>
<td>650 V</td>
</tr>
<tr>
<td>Endo Cut</td>
<td>200 W</td>
<td>500 Ω</td>
<td>650 V</td>
</tr>
<tr>
<td>Soft Coag</td>
<td>120 W</td>
<td>125 Ω</td>
<td>190 V</td>
</tr>
<tr>
<td>Forced Coag</td>
<td>120 W</td>
<td>350 Ω</td>
<td>2300 V</td>
</tr>
<tr>
<td>Spray Coag</td>
<td>120 W</td>
<td>500 Ω</td>
<td>4000 V</td>
</tr>
<tr>
<td>Bipolar Coag</td>
<td>120 W</td>
<td>125 Ω</td>
<td>190 V</td>
</tr>
</tbody>
</table>

**Safety Features**

- Return electrode continuity and contact quality control monitor also checks on return electrode orientation (NESSY™)
- Activation Time Limit (adjustable 3 - 960 secs)
- Output Error Monitor

**SERVICING**

The ERBE ICC200 can be serviced by the user, a service contract with the supplier or by returning the unit to the supplier.

**Typical Servicing Costs**

- Contracted repair & preventative maintenance (per year) £611.10
- as above but excluding parts £406.35
- Non-contract emergency call-out rate labour/travelling/waiting per hour £68.25
- Return to supplier, labour per hour £50.93
- Service Manual £35.00

---

**Price** £3,200

**Options**
- endoscopic cut: £800
- spray and argon beam coagulation: £1,400
BRIEF DESCRIPTION

The Korpo TD 50 A Micropulse is a rf-isolated, low power, solid-state electrosurgical unit. The device is rated Type CF and is capable of continuous operation.

Two modes are available, ‘cut’ and ‘coag micro elect’, the monopolar outputs are each rated at 49.5 W. Both these outputs are available in a bipolar configuration with slightly reduced powers and peak voltages. The bipolar power outputs and configurations are poorly explained in the manual. The manufacturer will resolve this in future copies.

A compact disk is also supplied detailing many dermatological and other minor procedures, recommended electrodes, outputs and timed functions.

The TD 50 A has a specialist timed function, where the output is activated for a programmable fraction of a second each time the footswitch is depressed. Five pre-programmed pulsed functions enable continuous pulsed operation with a range of frequencies and active periods.

The device is designed to be used with specialised active electrodes supplied by the manufacturer. The return electrode supplied with the ESU is rigid so care must be taken to ensure adequate patient contact. Disposable electrodes can also be used.

Dimensions: 117 × 416 × 350 mm
Weight: 8 kg

Price: £2,310
BRIEF DESCRIPTION

The Martin MD 62 is a low power, earth referenced electrosurgical unit. The device is rated Type BF and has a duty cycle of 10 seconds on full power, followed by 30 seconds off.

The primary intended application is in dental surgery where the device may be used without a return electrode in the monoterminal mode. In this mode, the patient must be seated in an earthed dental chair or hold a hand cylinder (return electrode) to ensure safe operation. Since the device is earth referenced it is especially important that the patient does not touch any earthed metal objects.

The device is supplied with either, a rubber coated capacitive return electrode or a metal cylinder conductive return electrode to be gripped by the patient’s hand. The usual considerations on the safe placement of return electrode apply in this mode of operation.

Dimensions  
78 × 200 × 185 mm

Weight  
2.8 kg

SUMMARY

- 50 W monopolar
- Cut and coagulation
- Intended for dentistry, dermatology and minor cosmetic surgery

Supplier  
Albert Waeschle Ltd  
123/125 Old Christchurch Road  
Bournemouth  
Dorset, BH1 1EX  
Tel: 01202 204803  
Fax: 01202 204800  
Web: www.martinmedizintechnik.de

Price £ 750

MAIN FEATURES

- Monopolar  
  Cut  
  Coag
- Power control  
  rotary, continuous  
  labelled 0 - 10

Specifications

<table>
<thead>
<tr>
<th>Facility</th>
<th>Maximum Power</th>
<th>Rated Load</th>
<th>Peak Voltage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cut</td>
<td>50 W</td>
<td>600 Ω</td>
<td>600 V</td>
</tr>
<tr>
<td>Coag</td>
<td>30 W</td>
<td>1200 Ω</td>
<td>1300 V</td>
</tr>
</tbody>
</table>

Operating Switches

- Footswitches  
  single pneumatic
- Handswitches  
  fingerswitching pencil

SERVICING

It is intended that the Martin MD 62 be returned to the supplier in the event of a fault. Routine preventative maintenance can be carried out in-house or by returning the unit to the supplier.

Typical Servicing Costs

- Return to supplier labour per hour £ 35
- Service Manual FREE
Martin ME 102

**SUMMARY**
- 100 W monopolar, 80 W bipolar
- Cut, blend and coagulation modes
- Automatic bipolar switching
- MICRO control for low power outputs

**Supplier**
Albert Waeschle Ltd.
123/125 Old Christchurch Road
Bournemouth
Dorset, BH1 1EX
Tel: 01202 204803
Fax: 01202 204800
Web: www.martinmedizintechnik.de

**Price** £1,795

**BRIEF DESCRIPTION**
The Martin ME 102 is a rf-isolated, solid-state, electrosurgical unit. The device is rated Type CF and has a duty cycle of 10 seconds on full power followed by 30 seconds off.

All outputs have a micro option that reduces the power to a third of normal values, allowing enhanced precision in the selection of lower powers.

The device may also used with a large area capacitive return electrode. This electrode should only be used in procedures that allow for safe siting of the plate with regard to current concentrations and tissue pressure.

The ME 102 has a dual mode operational facility, allowing the user to switch between monopolar and bipolar without the need to select a switch on the control panel. Only one output can be energised at any one time, on a first come first served basis.

**Dimensions** 256 × 97 × 320 mm
**Weight** 4.6 kg

**MAIN FEATURES**
- Monopolar
- Cut 1
- Cut 2 (blend)
- Contact coagulation
- Bipolar
- Coagulation
- Power output
- Rotary, continuous
- labelled 0 – 10
- MICRO power
- ~ third of normal o/p

**Specifications (Macro modes)**

<table>
<thead>
<tr>
<th>Facility</th>
<th>Maximum Power</th>
<th>Rated Load</th>
<th>Peak Voltage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cut 1</td>
<td>100 W</td>
<td>600 Ω</td>
<td>600 V</td>
</tr>
<tr>
<td>Cut 2 (blend)</td>
<td>90 W</td>
<td>600 Ω</td>
<td>800 V</td>
</tr>
<tr>
<td>Contact coag</td>
<td>70 W</td>
<td>600 Ω</td>
<td>1000 V</td>
</tr>
<tr>
<td>Bipolar</td>
<td>80 W</td>
<td>100 Ω</td>
<td>220 V</td>
</tr>
</tbody>
</table>

**Safety Features**
- Return electrode continuity monitor
- Contact quality monitor (if split plate is used)

**Operating Switches**
- Footswitches
  - Monopolar (twin electrical)
  - Bipolar (single electrical)
- Handswitches
  - Fingerswitching pencil
- Automatic start
  - Bipolar mode only

**SERVICING**
It is intended that the Martin ME 102 be returned to the supplier in the event of a fault. Routine preventative maintenance can be carried out in-house or by returning the unit to the supplier.

**Typical Servicing Costs**
- Return to supplier, labour per hour £35
- Service Manual FREE
BRIEF DESCRIPTION

The Martin ME 200 is a rf-isolated, solid state, electrosurgical unit. The device is rated Type CF and has a duty cycle of 10 seconds on full power followed by 30 seconds off.

Cut 1 mode has a pure sinusoidal cutting waveform. Other Cut modes are blend waveforms with an increasing depth of coagulation. All outputs have a micro option, reducing the power to a third of normal values, allowing enhanced precision in the selection of lower powers.

The ME 200 may also be used with a large area capacitive return electrode supplied by Martin. This return electrode should only be used in procedures that ensure safe siting, minimising current concentrations and tissue pressure.

The device allows simultaneous activation of bipolar and one monopolar output. The footswitch activated monopolar output takes priority over the handswitched output.

Dimensions  135 × 405 × 380 mm
Weight       9.6 kg

SUMMARY

- 175 W monopolar, 70 W bipolar
- Cut, blend, dessication & spray coagulation
- Automatic bipolar switching
- MICRO control for low power outputs
- Intended for general surgery applications

Supplier  Albert Waeschle Ltd.
123/125 Old Christchurch Road
Bournemouth
Dorset, BH1 1EX
Tel: 01202 204803
Fax: 01202 204800
Web: www.martinmedizintechnik.de

Price  £ 3,440

MAIN FEATURES

- Monopolar  Cut1 (pure) & 2-4 (blend) Coag: spray & contact
- Bipolar  Coagulation
- Power control  Rotary, continuous labelled 0 – 10
- MICRO power  ~ third of normal o/p peak voltage is halved

Specifications

<table>
<thead>
<tr>
<th>Facility</th>
<th>Maximum Power</th>
<th>Rated Load</th>
<th>Peak Voltage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cut 1</td>
<td>175 W</td>
<td>500 Ω</td>
<td>700 V</td>
</tr>
<tr>
<td>Cut 2</td>
<td>175 W</td>
<td>500 Ω</td>
<td>1100 V</td>
</tr>
<tr>
<td>Cut 3</td>
<td>175 W</td>
<td>500 Ω</td>
<td>1300 V</td>
</tr>
<tr>
<td>Cut 4</td>
<td>175 W</td>
<td>500 Ω</td>
<td>1500 V</td>
</tr>
<tr>
<td>Spray coag</td>
<td>100 W</td>
<td>500 Ω</td>
<td>1600 V</td>
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<tr>
<td>Contact coag</td>
<td>175 W</td>
<td>300 Ω</td>
<td>1100 V</td>
</tr>
<tr>
<td>Bipolar coag</td>
<td>70 W</td>
<td>100 Ω</td>
<td>200 V</td>
</tr>
</tbody>
</table>

Safety Features

- Return electrode continuity monitor
- Contact quality monitor (if split plate is used)
- Activation time limit alarm

Operating Switches

- Footswitches  Monopolar (twin electrical)
- Bipolar (single electrical)
- Handswitches  Fingerswitching pencil
- Automatic start  Bipolar mode only

SERVICING

It is intended that the Martin ME 200 be returned to the supplier in the event of a fault. Routine preventative maintenance can be carried out in-house or by returning the unit to the supplier.

Typical Servicing Costs

- Return to supplier, labour per hour  £ 35
- Service Manual  FREE
Olympus PSD-30

BRIEF DESCRIPTION
The Olympus PSD-30 is a solid state, rf-isolated monopolar electrosurgical unit rated Type CF replacing the PSD-20 (evaluation Report 343). It has a duty cycle of 10 seconds on full power followed by 30 seconds off.

The PSD-30 is a specialist unit, designed for use exclusively with the Olympus flexible endoscope system. This incorporates the S-cord system so high frequency surgical current leaked to the endoscope is returned directly to the ESU generator. Operation can only be activated by a twin electrical footswitch.

The device is intended for low-power gastrointestinal and broncho-endoscopic procedures such as polypectomies & sphincterotomies.

Dimensions 295 x 160 x 420 mm
Weight 7.9 kg

SUMMARY
- 50 W monopolar
- Cut, blend and coagulation modes
- Endoscope safety connection and monitoring
- Intended for use with the Olympus flexible endoscope system

Supplier KeyMed Ltd
KeyMed House
Stock Road
Southend-on-Sea
Essex, SS2 5QH
Tel: 01702 616333
Fax: 01702 465677
www.keymed.co.uk

Price £6,610

MAIN FEATURES
• Monopolar Cut : Pure, Blend 1 & 2,
  Coag : Forced, Soft & AutoStop
• Monitoring tissue impedance (Auto Stop only)
• Footswitch two pedal electrical
• Programme Memory
• Power control Digital, display in Watts

Specifications

<table>
<thead>
<tr>
<th>Facility</th>
<th>Maximum Power</th>
<th>Rated Load</th>
<th>Peak Voltage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pure cut</td>
<td>50 W</td>
<td>300 Ω</td>
<td>480 V</td>
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<tr>
<td>Blend 1</td>
<td>50 W</td>
<td>300 Ω</td>
<td>380 V</td>
</tr>
<tr>
<td>Blend 2</td>
<td>50 W</td>
<td>300 Ω</td>
<td>420 V</td>
</tr>
<tr>
<td>Soft Coag</td>
<td>50 W</td>
<td>100 Ω</td>
<td>160 V</td>
</tr>
<tr>
<td>Forced Coag</td>
<td>50 W</td>
<td>300 Ω</td>
<td>550 V</td>
</tr>
<tr>
<td>AutoStop</td>
<td>50 W</td>
<td>100 Ω</td>
<td>240 V</td>
</tr>
</tbody>
</table>

Safety Features
- S-cord returns leakage current in endoscope
- Contact quality monitor if split-plate used
- Return electrode & S-cord continuity monitor
- Return current feedback ratio monitor
- Activation time limit
- Output error monitor

SERVICING
The Olympus PSD-30 can be serviced in-house but annual return of units to the supplier for preventative maintenance is recommended. Two levels of service contract are available, standard and comprehensive.

Typical Servicing Costs
- Standard repair/preventative maintenance contract (excluding parts) per year £ 330
- Annual comprehensive repair/preventative maintenance contract (inc. parts) £ 665
- Return to manufacturer labour per hour £ 60
- Service Manual £ 110

Full Report Brief Assessment
CE Marking? Yes, MD Directive Quality System Audit
Notified Body TÜV Rheinland (0197)
Manufactured to Standard? Manufacturer claims compliance with EN 60601-2-2

CEDAR measurements, not stated in the user manual
BRIEF DESCRIPTION
The Utah Medical Finesse is a rf-isolated, solid-state electrosurgical unit. The device is rated Type CF and has a duty cycle of 10 seconds on full power followed by 30 seconds off.

The Finesse is designed to automatically adjust the voltage of cut and blend outputs to maintain a constant effect through different tissue depths. The coagulation mode provides sufficient voltage and power for spray coagulation.

The Finesse system has been developed to be particularly suitable for loop excisions of the cervical transformation zone and other gynaecological procedures. It also has applications in other outpatient procedures including dermatology and plastic surgery.

The primary HEPA filter should be changed on a daily basis; the internal ULPA filter should be renewed annually. The device has a carrying handle at the rear.

Dimensions 356 x 361 x 180 mm
Weight 10 kg

PRICE £ 5,620

SUMMARY
- sold as 100 W monopolar (max. at 500 Ω) but maximum output is 150 Watts at 200 Ω.
- Cut, blend and coagulation modes
- Integral smoke evacuation and filter unit
- Active power/voltage management

Supplier Euro Surgical Ltd
Merrow Business Centre
Guildford
GU 4 7WA
Tel: 01483 456007
Fax: 01438 456008
Web: www.eurosurgical.co.uk

Main Features

Facilities
- Monopolar cut, blend 1, 2, 3 coagulation
- Impedance sensing for controlling power o/p
- Power control Rotary, display labelled 0 - 99

Specifications

<table>
<thead>
<tr>
<th>Facility</th>
<th>Maximum Power</th>
<th>Rated Load</th>
<th>Peak Voltage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cut</td>
<td>150 W</td>
<td>200 Ω</td>
<td>490 V</td>
</tr>
<tr>
<td>Blend 1</td>
<td>150 W</td>
<td>200 Ω</td>
<td>1000 V</td>
</tr>
<tr>
<td>Blend 2</td>
<td>150 W</td>
<td>200 Ω</td>
<td>1000 V</td>
</tr>
<tr>
<td>Blend 3</td>
<td>150 W</td>
<td>200 Ω</td>
<td>1000 V</td>
</tr>
<tr>
<td>Coag</td>
<td>75 W</td>
<td>500 Ω</td>
<td>1800 V</td>
</tr>
</tbody>
</table>

* CEDAR measurements, not stated in the user manual

Safety Features
- Output power error monitor
- Integral smoke extraction and filtration system turned on during ESU activation if selected

Operating Switches
- Footswitches twin electrical
- Handswitches fingerswitching pencil

Servicing
The Finesse can be serviced by the qualified technical personnel in the user’s hospital or by returning the unit to the manufacturer’s servicing facility in Ireland. Annual service contracts are also available.

Typical Servicing Costs
- Annual service contract: repair & preventative maintenance (inc. parts and carriage) £ 350
- Non-contract repair per hour £ 60
- Return to supplier, labour per hour £ 60
- Service Manual FREE

Price £ 5,620

Full Report Brief Assessment
CE Marking? Yes, MD Directive Quality System Audit
Notified Body NSAI (0050)
Manufactured to Standard? Certified by G-MED as complying with EN 60601-2-2: 1993

Supplier
Euro Surgical Ltd
Merrow Business Centre
Guildford
GU 4 7WA
Tel: 01483 456007
Fax: 01438 456008
Web: www.eurosurgical.co.uk

Price £ 5,620
BRIEF DESCRIPTION

The Valleylab Surgistat II is a compact, rf-isolated, solid-state electrosurgical unit. The device is rated Type CF and has a duty cycle of 10 seconds on full power followed by 30 seconds off.

The Surgistat II is intended for lower-powered electrosurgical applications, eg in outpatient clinics. The device is recommended for procedures such as colposcopy, endoscopy, and dermatology.

Handswitiching bipolar forceps are available on request.

On power up a self-test is automatically performed and then the last power setting for each mode is loaded from memory.

Dimensions 260 × 140 × 254 mm
Weight 6.5 kg

SUMMARY

- 120 W monopolar, 30 W bipolar
- Cut, blend and coagulation modes
- Intended for general low power applications

Supplier
Tyco Healthcare
154 Fareham Road
Gosport
Hampshire, PO13 OAS
Tel: 01329 224114
Fax: 01329 224260
Web: www.valleylab.com

Price £3,500

MAIN FEATURES

- Cut Pure Cut & Blend
- Coagulation Desiccate, Fulgurate & Bipolar
- Power control Rotary, display in Watts

Specifications

<table>
<thead>
<tr>
<th>Facility</th>
<th>Maximum Power</th>
<th>Rated Load</th>
<th>Peak Voltage</th>
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<td>Pure Cut</td>
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<td>500 Ω</td>
<td>1400 V</td>
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<tr>
<td>Blend</td>
<td>90 W</td>
<td>800 Ω</td>
<td>2000 V</td>
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<td>Desiccate</td>
<td>80 W</td>
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<td>3300 V</td>
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<td>Fulgurate</td>
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<tr>
<td>Bipolar</td>
<td>30 W</td>
<td>200 Ω</td>
<td>1250 V</td>
</tr>
</tbody>
</table>

CEDAR measurements, not stated in the user manual

Safety Features

- Return electrode continuity monitor
- Contact quality monitor (if split plate used)
- Connection for simultaneous activation of smoke filtration

Operating Switches

- Footswitches twin electrical (mono and bipolar)
- Handswitches fingerswitching pencil (monopolar)

SERVICING

Routine safety and function testing can be carried out in house. The Surgistat II can be serviced by return to the supplier / service centre. Loan service available.

Typical Servicing Costs

- Contracted preventative maintenance for 1, 2 or 3 units, per year (2 visits) £620
- Emergency call-out rates, labour/travelling/waiting per hour £60
- Return to service dept (labour/hour) £60
- Service Manual £60

Add £25 for non-contract rates.
GLOSSARY OF TERMS used in ELECTROSURGERY

**AC (Alternating Current)**  
Current direction and voltage polarity vary with time. The rate of variation is called frequency.

**Alternate Site Burns**  
Unwanted tissue damage due to concentrated current at a location remote from the surgical site. Such burns may be caused by contact between the patient and another conductive object, unintended activation, or carelessness with a hot electrode after activation has stopped.

**Arc**  
Sparking across an ionised air gap, resulting in very high concentrations of current where the spark makes contact with the target tissue.

**Capacitive Coupling**  
Transfer of electric current across an insulator or air gap by generating a changing electric field. This effect increases at high frequencies, high voltages and small separation distances.

**Conductive (Direct) Coupling**  
Transfer of electric current through a conducting medium, such as metal, saline or blood.

**Crest Factor**  
The peak voltage divided by the average voltage (rms) is an indicator of the voltage waveform. Typical values are 1.5 for a cutting waveform and approximately 8 for spray coagulation.

**Current (I)**  
The electric charge flowing through a region in one second; measured in amps (A). Batteries produce direct current (DC). Electrosurgical current is AC.

**Current Density**  
The amount of current passing through an area; measured in amps per square metre (Am⁻²). The current density or concentration determines the amount of heat generated in the tissue.

**Current Division**  
Electrical current leaving the intended electrosurgical circuit, between the active and return electrodes, and following an alternate path of least resistance, through metal objects or fluids, to earth. A frequent cause of alternate site burns.

**Diathermy**  
Heating of body tissues caused by an impedance to the flow of high frequency electric current. It has numerous surgical and physiotherapy applications.

**Desiccation**  
Removal of water from cells resulting in dehydration and considerable tissue shrinkage.

**Earth Referenced**  
A connection to earth (ground) at high frequencies by components such as a capacitor, so mains frequency current is not allowed to pass to earth.

**Insulated / Isolated**  
No conductive path between electrical conductors or with earth. At high frequencies capacitive and inductive coupling may produce current flow.

**Eschar**  
A charred crust resulting from high temperature destruction of the cell structure, eg by arcing.

**Frequency**  
The number of times a periodic cycle repeats in one second; measured in hertz (Hz). Frequencies above 100kHz are denoted rf as they are in the same range used for radio-transmission.

**Impedance (called Resistance if direct current)**  
Opposition to the flow of a high frequency electric current; measured in ohms (Ω).

**Inductive Coupling**  
Transfer of electric current across an insulator or air gap by a changing magnetic field. Coiled leads and high frequencies increases this effect.

**Leakage Currents**  
Currents that arise by capacitive and inductive coupling between conductors that are electrically insulated from one another. The human body is a large and efficient conductor and currents may be induced at electrosurgical frequencies.

**Power**  
Rate at which energy is produced or consumed, measured in watts (W). Power is directly related to Voltage×Current or Impedance×Current×Current.

**Return Electrode**  
Also known as neutral electrode, dispersive electrode, return plate, neutral plate or dispersive plate. The large area of the return electrode results in a low current density in the underlying tissue and a small skin-temperature rise.

**Surgical Diathermy**  
Another term for electrosurgery. Application of high frequency electrical current to achieve a variety of surgical effects including cutting, coagulation and desiccation.

**Voltage (V)**  
The force that drives electrons (electric current) through a circuit, wires, tissue, air gap, etc. It is measured in volts (V).

**Waveform**  
The pattern of electrical activity generated. Usually a graphical display of changing voltage over time.
ACKNOWLEDGEMENTS

This report was prepared by Dr Diane Crawford, Dr Nicholas Cook and Dr Stephanie Wentworth of CEDAR (Clinical Engineering Device Assessment and Reporting), Medical Physics and Clinical Engineering Directorate, Cardiff and Vale NHS Trust, under contract to the Medical Devices Agency.

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  INTERNET: www.imaging.uwcm.ac.uk/mpce/sctns/cedar/index

- Or: Mr Robert Allen, Programme Manager, Medical Devices Agency, Hannibal House, Elephant and Castle, London SE1 6TQ, Tel: 0207 972 8156, Fax: 0207 972 8105 e-mail: robert.allen@medical-devices.gov.uk
  INTERNET: www.medical-devices.gov.uk

We would like to thank all the manufacturers for loaning a sample free of charge for technical assessment. We would also like to thank Dr Nicholas Cook and Dr Chris Hacking for their work on this report, prior to taking up their new positions.

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<tr>
<th>In England</th>
<th>In Scotland</th>
<th>In Wales</th>
<th>In Northern Ireland</th>
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<tbody>
<tr>
<td>Medical Devices Agency Room 1207, Hannibal House Elephant &amp; Castle, London SE1 6TQ Tel: 020 7972 8181</td>
<td>Mr R Stock Health Planning &amp; Quality Division Scottish Executive, Health Department, St Andrew's House, Edinburgh, EH1 3DG Tel: 0131 244 6913</td>
<td>Mr J Lewis National Assembly for Wales, HIMTE 3, Cathays Park Cardiff, CF10 3NQ Tel: 029 2082 3987</td>
<td>Mr D Calfolla Health Estates, Stoney Road, Dunonald, Belfast, BT16 OUS Tel: 028 9052 3745</td>
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