Bipolar Electrosurgery

Review 2001

Coagulation

Cutting

Ablation
INTRODUCTION

Electrosurgery or surgical diathermy, is a commonly used, though sometimes not well understood, surgical tool. Bipolar electrosurgery can offer a safer alternative to monopolar electrosurgery in some applications.

Bipolar power requirements are lower than monopolar since almost all the current is limited to the small piece of tissue between the active electrodes. This results in more predictable tissue modification with less risk of neuromuscular stimulation. Return electrode burns are eliminated and the potential for alternative site burns or interference with electronic devices is reduced. Adverse incidents are, however, still possible due to poor user understanding of the action of high frequency electricity or inappropriate accessory selection.

Bipolar is preferred for procedures such as forceps coagulation where risks are reduced and there is no loss of clinical performance. However, extreme care is needed when using new types of bipolar instruments or developing new surgical techniques. For example, the use of open-surgery bipolar scissors in a confined space, such as the mouth or pharynx, is contra-indicated due to the risk of accidental burns.

This report briefly introduces the principal modalities of bipolar electrosurgery, with a guide to some technical and procurement issues. Two further reviews will be published in the coming year covering the different types of electrosurgical devices currently available in the UK.

Eight bipolar-only units are briefly summarised here; seven summaries are based on previously published evaluation reports or unpublished brief, technical assessments. The full evaluation reports contain additional technical information and users’ comments. Technical assessment of the Arthrocare System 2000 was not possible, as the manufacturer was unable to provide a necessary adapter in time for evaluation. The summary is therefore based solely on manufacturer’s data.

BIPOLAR MODALITIES

The application of bipolar electrosurgery has traditionally been limited to forceps coagulation. Recently, new types of accessories and bipolar electrosurgical units have been developed to make cutting and ablation possible.

Forceps Coagulation of small tissue clusters and blood vessels, as shown by the first figure on the front cover, is still the most common application of 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.

This technique may be used in microsurgery or for coagulation of blood vessels up to several millimetres in diameter. The power requirements of a particular application must therefore be matched to the appropriate electrosurgical unit and accessories.

Bipolar Cutting is a relatively recent innovation. Although a range of cutting accessories is available, the technique remains unproven for many procedures. One type of cutting accessory is shown by the second figure on the front cover. It incorporates a central needle electrode surrounded by a second electrode with a larger area. When electrosurgical current flows through any tissue or conducting fluid between the two electrodes, the cutting effect tends to be restricted to the needle electrode. Tissue damage is therefore limited to this small region and an incision is made.

Bipolar scissors are also available in both laparoscopic and open-surgery configurations. These instruments combine the mechanical cutting of sharp blades with electrosurgical coagulation. The active electrodes are isolated from each other by a thin layer of insulation on one or both of the blades, as shown in Figure 1. As tissue is mechanically cut and the scissors are activated, current flows between the active electrodes via the intervening tissue.

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MDA evaluation 01022, March 2001
Coagulation without cutting can be achieved by touching both blades to the tissue and activating without closing the scissors. The laparoscopic configuration is also particularly suited for adhesions.

**Ablation in a Conductive Medium:** The bipolar probes used for ablation are constructed with the active electrodes in close proximity at the distal end of a probe, as shown by the final figure on the front cover. The electrosurgical current passes through and heats a conductive irrigant to establish a vapour pocket. Any tissue entering the vapour pocket provides a current path between the two electrodes, giving rise to desiccation or arcing and tissue destruction.

Normal saline or Ringer’s Lactate may be used as a conductive irrigant; both have the advantage of avoiding electrolyte imbalance. A continuous flow of irrigant improves visualisation by removing bubbles and ablation by-products. There is a small risk of sudden ignition if there is a build up of flammable gases; this may be reduced by increased irrigant flow or suction.

When using bipolar ablation techniques, the electrode tip must be completely immersed in irrigant before activation. As well as being essential for producing the vapour pocket, the irrigant cools the ceramic insulation at the electrode tip.

**Bipolar vs Monopolar Cutting:** Cutting of tissue has been traditionally achieved using monopolar current. The monopolar modality is still more versatile and more widely used but the development of new bipolar generators and accessories has expanded the potential applications of bipolar electrosurgery.

For many procedures it is difficult to achieve the same quality of cutting using bipolar as may be achieved using monopolar. There are, however, some applications where bipolar has proved a useful cutting tool and a few where it may even enhance the procedure.

Bipolar electrosurgery is preferred over monopolar if operating on a pedicle such as the penis. If monopolar electrosurgery were used, the current could be concentrated at any constriction in the path to the return electrode, causing unwanted tissue damage. Bipolar electrosurgery reduces this risk by limiting current to the tissue between the bipolar electrodes.

**GUIDE TO PRODUCT DATA PAGES**

There are several technical issues to consider when deciding which particular electrosurgical unit to purchase. Some devices are more specialised, designed for particular procedures, whilst others offer a more comprehensive range of outputs. All devices should be matched to the intended application in terms of output power, rated load and peak voltage.

Some units offer features such as automatic coagulation or constant voltage output, which automatically control the electrosurgical output to enhance the surgical effect. These features, and other issues, are discussed below.

**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 from the Medical Devices Agency in England and other government offices throughout the UK, (see back page for contact details).

**CE Marking:** Medical devices sold in the European Union are required to comply with the European Union Medical Devices Directive. Suppliers must display the CE mark on the devices as a sign of conformity.
**Notified Body:** This is a laboratory or test house authorised by the Competent Authority of a European Union country to certify CE marking by a supplier. The Competent Authority in the UK, is the Medical Devices Agency.

**Compliance with Safety Standards:** The International Electrotechnical Commission (IEC) safety standard which covers all general medical electrical equipment is IEC 601-1, (equivalent to the European harmonised standard EN 60601-1). The particular standard for electrosurgery equipment is IEC 601-2-2, (EN 60601-2-2). If a device complies with the particular harmonised standard this will be accepted as evidence that the device meets the Essential Requirements of the Medical Devices Directive. It is not however necessary for a device to comply with a standard in order to meet the Essential Requirements and carry the CE mark.

All devices included in this report are either certified to or claim compliance with these harmonised standards. Further details can be obtained from the manufacturer, hospital Clinical Engineering Departments or the British Standards Institute (www.bsi.org.uk).

**Facilities:** Bipolar units may have a single coagulation output or several different output modes available 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 technical manuals for each device.

**Maximum Power:** Power requirements vary according to the desired surgical effect and the size and type of tissue to be treated. The tissue in the current path determines the electrical load, which can change as current alters the tissue’s properties. The power output depends on this load, with the selected output level usually indicating the nominal maximum power that may be delivered. The declared maximum power is delivered into a specific load called the rated load; these values are given on the product data pages for each mode of each device.

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.

**Peak Voltage:** The large range of peak voltages reflects the various intended applications of each device. 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 or direct arcing between active electrodes.

Peak coagulation voltages of the devices included in this review range from 90 V to 800 V; this reflects the range of intended applications from microsurgery to sealing large blood vessels. The maximum open-circuit peak voltage is given for each mode of each device.

**Constant Voltage / Dynamic Power Regulation:** The usual relationship between power output and the load on an electrosurgical generator results in an optimum output for a specific load. In such a system, as the load changes during activation, the power delivered also changes, resulting in a variable surgical effect.

Some electrosurgical generators have systems designed to counteract this variation in voltage and power output to keep the surgical effect efficient throughout the activation. These systems have various descriptions including constant voltage and dynamic power regulation.

**Autocoag:** Coagulation should continue long enough to ensure that vessels will not rebleed but should not cause excessive tissue damage. Tissue is coagulated by the passage of current causing heating and desiccation. As water is driven out of cells the ability of tissue to transport current is reduced and the tissue impedance (load) rises. The CoaComp/M and the Ligasure™ Vessel Sealing Generator monitor this changing impedance and automatically terminate output when coagulation is estimated to be complete.

**Autobipolar:** Autobipolar, also known as impedance sensing, is available with the Eschmann TDB60 and the CoaComp/M. With such a system, the electrosurgical output may be activated automatically when the forceps grasp conductive tissue. This feature enables the surgeon to coagulate a large number of small bleeder without having to simultaneously activate the footswitch each time.

Some devices introduce a pause of a few seconds between contact of the forceps with the tissue and activation. This is to enable the surgeon to briefly manipulate tissue with the inactive forceps.
Procurement Issues

Table 1 Manufacturers’ Principal Intended Applications

<table>
<thead>
<tr>
<th>Applications</th>
<th>Arthrocare System 2000</th>
<th>Erbe</th>
<th>ICC Bipolar</th>
<th>Eschmann TDB60</th>
<th>Gynecare Versapoint</th>
<th>IBBAB CoaCompm</th>
<th>Mitek VAPR</th>
<th>Valleylab</th>
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Matching the Device to the Surgical Task: Some bipolar devices 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 and the frequency of use, see Table 1.

PROCUREMENT ISSUES

Price: All prices in this report exclude VAT. For some units a carriage charge may also be added. Suppliers should be contacted for 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.

User manuals, accessories and active leads may be included in the price of the electrosurgical unit. Suppliers should be contacted for details of the system under consideration.

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

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.

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

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.
**BRIEF DESCRIPTION**

The Arthrocare® System 2000 is a solid-state, specialised, ablation electrosurgical unit. The device is rated Type BF and is capable of continuous operation.

The unit is designed for use with normal saline or Ringer’s Lactate as an irrigant. Current flows from the active electrode to the integrated return electrode, generating a vapour pocket in the irrigant. Any tissue entering this pocket offers a lower impedance return path and current flow causes ablation, coagulation or thermal modification.

An LED display indicates the selected output level between 0 and 9. Each level corresponds to an output voltage range up to a maximum range of 270 to 330 V (rms).

The footswitch incorporates pedals for ablation, coagulation and adjustment of output level.

**Dimensions** 133 × 305 × 400 mm

**Weight** 8.2 kg

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**MAIN FEATURES**

**Facilities**

- Ablation 23 to 284 W
- Coagulation 10 to 16 W

**Specifications** (see Guide to Product Data Pages)

<table>
<thead>
<tr>
<th>Facility</th>
<th>Maximum Power</th>
<th>Rated Load</th>
<th>Peak Voltage</th>
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<tr>
<td>Ablation</td>
<td>284 W</td>
<td>317 Ω</td>
<td>469 V</td>
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<tr>
<td>Coag</td>
<td>16 W</td>
<td>317 Ω</td>
<td>68.2 V</td>
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**Safety Features**

- Excessive current alarm
- Connection fault alarm
- Automatic electrode detection

**Operating Switches**

- Footswitch: electrical
- Handswitch: none

**Output Indicators**

- Visual
- Auditory
- Volume control

**SERVICING**

The Arthrocare System 2000 is not intended to be serviced by the user. It is intended that the unit be returned to the manufacturer for service and repair. A service manual is available on request.

**Typical Servicing Costs**

Information not supplied.
**BRIEF DESCRIPTION**

The ERBE ICC Bipolar is a solid–state electrosurgical unit. The device is rated Type CF and is capable of continuous operation.

Cut Effect 1 is designed for very precise cutting, whilst Cut Effect 2 causes a greater degree of coagulation. Coag Effect 1 is intended for very precise procedures using low power, whilst Coag Effect 2 provides a more standard coagulation output.

The ICC Bipolar is designed to provide dynamic regulation of the power output for both cut effects, within the limit of the output power setting. This is achieved by automatic adjustments to the output voltage as the load changes.

Bipolar Cut requires ERBE accessories. ERBE supply a range of electrodes and forceps for minimal access and open surgery.

**Dimensions** 275 × 105 × 255 mm  
**Weight** 2.8 kg

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**SUMMARY**

- 50 W output
- Cut and coagulation modes
- Complies with IEC 601-2-2

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

**Price** £2,350

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**MAIN FEATURES**

**Facilities**
- Cut Effect 1  
- Cut Effect 2  
- Coag Effect 1  
- Coag Effect 2

**Specifications** (see Guide to Product Data Pages)

<table>
<thead>
<tr>
<th>Facility</th>
<th>Maximum Power</th>
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<td>50 W</td>
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<td>Cut Effect 2</td>
<td>50 W</td>
<td>500 Ω</td>
<td>600 V</td>
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<td>Coag Effect 1</td>
<td>50 W</td>
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<td>190 V</td>
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<tr>
<td>Coag Effect 2</td>
<td>50 W</td>
<td>500 Ω</td>
<td>800 V</td>
</tr>
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</table>

**Safety Features**
- Output error monitor  
- Activation time limit

**Operating Switches**
- Footswitch twin electrical  
- Handswitch none

**Output Indicators**
- Visual  
- Auditory

**SERVICING**

The Erbe ICC Bipolar can be serviced by the user, by service contract with the supplier or by returning the unit to the supplier. The supplier provides various levels of service contract, which are detailed below.

**Typical Servicing Costs**
- Contracted repair and preventative maintenance charge per year £415.80  
- As above but excluding parts £303.50  
- Non-contract emergency call-out rate, labour/travelling/waiting per hour £68.25  
- Return to supplier, labour per hour £50.93

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**Full Report** Brief Assessment  
**CE Marking?** Yes, MD Directive  
**Notified Body** DEKRA (0124)  
**BRIEF DESCRIPTION**

The Eschmann TDB60 is a compact, solid-state surgical diathermy. The device is rated Type BF and has a duty cycle of 10 seconds on full power followed by 30 seconds off.

Two coagulation modes are available, 8 W (micro) or 60 W (macro). The micro range is intended for ophthalmic, neuro and plastic surgery, whilst the macro range is intended for more general and open procedures such as laparoscopic sterilization and vasectomy.

Power output is activated by footswitch or automatic forceps switching (autobipolar). To avoid accidental activation under forceps control, a delay can be set between gripping tissue and activation of the output; this delay is adjustable to between 0 and 2 seconds. The maximum activation time is limited to 8 seconds before the output is automatically switched off.

**Dimensions**  
155 × 233 × 273 mm

**Weight**  
4 kg

**MAIN FEATURES**

**Facilities**
- Coagulation  
  - Micro (0 to 8 W)  
  - Macro (0 to 60 W)

**Specifications**  
*(see Guide to Product Data Pages)*

<table>
<thead>
<tr>
<th>Facility</th>
<th>Maximum Power</th>
<th>Rated Load</th>
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<tr>
<td>Micro</td>
<td>8 W</td>
<td>100 Ω</td>
<td>200 V</td>
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<tr>
<td>Macro</td>
<td>60 W</td>
<td>100 Ω</td>
<td>400 V</td>
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**Safety Features**
- Activation time limit 8 seconds

**Operating Switches**
- Footswitch pneumatic or electrical (extra)
- Handswitch autobipolar

**Output Indicators**
- Visual
- Auditory 2 levels

**SERVICING**

The Eschmann TDB60 can be serviced by the user, by service contract with the manufacturer or by returning the unit to the manufacturer. The user/service manual was well written, containing a complete circuit diagram and a comprehensive parts list.

**Typical Servicing Costs**
- Contracted preventative maintenance charge (1 visit) £23
- Emergency call-out rates, labour/waiting time per hour £43
- Emergency call-out, fixed fee, travelling charge £73
- Return to manufacturer, labour per hour £41
**SUMMARY**

- 200 W gynaecological electrosurgery unit
- Vaporisation, blend and desiccation modes
- Complies with IEC 601-2-2

**Supplier**
Gynecare
A Division of Ethicon Ltd
PO Box 408
Bankhead Avenue
Edinburgh, EH11 4HE
Tel: 0131 453 5555
Fax: 0131 453 6011
Web: www.gynecare.com

**Price**
£4,000

**BRIEF DESCRIPTION**

The Gynecare Versapoint is a solid-state, specialised gynaecological, 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 device is designed for use with normal saline or Ringer’s Lactate as the continuous flow distension medium. On activation, electrosurgical current heats the saline to establish a vapour pocket. Current passes through any tissue entering the vapour pocket causing ablation or coagulation.

The active electrode is introduced into the endometrial cavity of the uterus via the working channel of a hysteroscope inserted through the cervical canal.

There are three VaporCut (VC) modes, two Blend modes (BL) and one Desiccation mode (DES), providing varying degrees of tissue removal and desiccation.

The VersaPoint automatically detects the accessory type as it is inserted and adjusts output settings to suit.

**Dimensions**
90 × 410 × 368 mm

**Weight**
5.6 kg

**Facilities**
- VaporCut VC1, VC2, VC3
- Blend BL1, BL2
- Desiccation DES

**Specifications** (see Guide to Product Data Pages)

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<th>Facility</th>
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<td>VC2</td>
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<td>DES</td>
<td>120 W</td>
<td>160 Ω</td>
<td>168 V</td>
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**Safety Features**
- Excessive current alarm
- Automatic electrode detection

**Operating Switches**
- Footswitches twin electrical
- Handswitches none

**Output Indicators**
- Visual
- Auditory
- Volume control

**SERVICING**

The Gynecare VersaPoint is not intended to be serviced by the user. It is intended that the unit be returned to the supplier for service and repair. Loan units are available.

**Typical Servicing Costs**
Information not supplied.
IBBAB CoaComp/M

SUMMARY
- 40 W output
- One coagulation mode
- Compliance with IEC 601-2-2 claimed

Supplier
Mediplus Ltd
37-39 Baker Street
High Wycombe
Buckinghamshire, HP11 2RX
Tel: 01494 551 200
Fax: 01494 536 333
Web: www.mediplus.co.uk

Price £2,500

BRIEF DESCRIPTION
The IBBAB Coa-Comp®/M is a compact, solid-state surgical diathermy. The device is rated Type CF and is capable of continuous operation.

Auto-start The normal mode of operation is Auto-start; in this mode the device generates short pulses of very low power to measure the impedance of the tissue between the forceps tines. The set power will be activated if the measured impedance is below a certain value. The CoaComp/M continues to monitor the resistance and output is automatically turned off when coagulation is estimated to be complete. If a successful coagulation is not detected, output is automatically turned off after 3.5 seconds.

Dimensions 155 × 200 × 150 mm including handle

Weight 2.6 kg

MAIN FEATURES

Facilities
- Coagulation 2, 4, 8, 16, and 38 W

Specifications (see Guide to Product Data Pages)

Safety Features
- Activation time limit

Operating Switches
- Footswitch\(^1\) electrical (optional extra, £225)
- Handswitch autobipolar autocoag

Note 1: The electrical footswitch is only recommended for microsurgery and laparoscopy.

Output Indicators
- Visual
- Auditory
- Volume control

SERVICING
The IBBAB CoaComp/M can be serviced by the user or by returning the unit to the supplier. The user / technical manual contains circuit diagrams and a comprehensive parts list.

Typical Servicing Costs
- Return to supplier, labour per hour £35

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</tr>
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</table>

Full Report Brief Evaluation
CE Marking? Yes, MD Directive
Notified Body Nemko (0470)
Manufactured to Standard? Type tested by Nemko and certified as conforming with the relevant provisions of the Medical Device Directive

Supplier
Mediplus Ltd
37-39 Baker Street
High Wycombe
Buckinghamshire, HP11 2RX
Tel: 01494 551 200
Fax: 01494 536 333
Web: www.mediplus.co.uk

Price £2,500

Facility Maximum Power Rated Load Peak Voltage
Coag 40 W 100 Ω 90 V

Safety Features
- Activation time limit

Operating Switches
- Footswitch\(^1\) electrical (optional extra, £225)
- Handswitch autobipolar autocoag

Note 1: The electrical footswitch is only recommended for microsurgery and laparoscopy.

Output Indicators
- Visual
- Auditory
- Volume control

SUMMARY
- 40 W output
- One coagulation mode
- Compliance with IEC 601-2-2 claimed

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BRIEF DESCRIPTION
The IBBAB Coa-Comp®/M is a compact, solid-state surgical diathermy. The device is rated Type CF and is capable of continuous operation.

Auto-start The normal mode of operation is Auto-start; in this mode the device generates short pulses of very low power to measure the impedance of the tissue between the forceps tines. The set power will be activated if the measured impedance is below a certain value. The CoaComp/M continues to monitor the resistance and output is automatically turned off when coagulation is estimated to be complete. If a successful coagulation is not detected, output is automatically turned off after 3.5 seconds.

Dimensions 155 × 200 × 150 mm including handle

Weight 2.6 kg

MAIN FEATURES

Facilities
- Coagulation 2, 4, 8, 16, and 38 W

Specifications (see Guide to Product Data Pages)

Safety Features
- Activation time limit

Operating Switches
- Footswitch\(^1\) electrical (optional extra, £225)
- Handswitch autobipolar autocoag

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Output Indicators
- Visual
- Auditory
- Volume control

SERVICING
The IBBAB CoaComp/M can be serviced by the user or by returning the unit to the supplier. The user / technical manual contains circuit diagrams and a comprehensive parts list.

Typical Servicing Costs
- Return to supplier, labour per hour £35

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<td>Coag</td>
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<td>100 Ω</td>
<td>90 V</td>
</tr>
</tbody>
</table>
BRIEF DESCRIPTION

The Mitek® VAPR™ is a solid-state, specialised arthroscopic 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 device is designed for use with normal saline or Ringer’s Lactate as the continuous flow distension medium. On activation, electrosurgical current heats the saline to establish a vapour pocket. Current passes through any tissue entering the vapour pocket causing ablation or coagulation.

There are three Vaporisation (V) modes, two Blended Vaporisation (BV) modes and one Desiccation (DES) mode; providing varying degrees of tissue removal, desiccation and thermal modification.

The VAPR unit automatically detects the accessory type as it is inserted and adjusts output settings to suit.

Dimensions: 90 x 410 x 368 mm
Weight: 5.6 kg

MAIN FEATURES

Facilities
- Vaporisation: V1, V2, V3
- Blended Vaporisation: BV1, BV2
- Desiccation: DES

Specifications (see Guide to Product Data Pages)

<table>
<thead>
<tr>
<th>Mode</th>
<th>Maximum Power</th>
<th>Rated Load</th>
<th>Peak Voltage</th>
</tr>
</thead>
<tbody>
<tr>
<td>V1</td>
<td>200 W</td>
<td>160 Ω</td>
<td>368 V</td>
</tr>
<tr>
<td>V2</td>
<td>200 W</td>
<td>160 Ω</td>
<td>465 V</td>
</tr>
<tr>
<td>V3</td>
<td>200 W</td>
<td>160 Ω</td>
<td>525 V</td>
</tr>
<tr>
<td>BV1</td>
<td>200 W</td>
<td>160 Ω</td>
<td>465 V</td>
</tr>
<tr>
<td>BV2</td>
<td>200 W</td>
<td>160 Ω</td>
<td>525 V</td>
</tr>
<tr>
<td>DES</td>
<td>120 W</td>
<td>160 Ω</td>
<td>185 V</td>
</tr>
</tbody>
</table>

Safety Features
- Excessive current alarm
- Automatic electrode detection

Operating Switches
- Footswitch: twin electrical
- Handswitch: none

Output Indicators
- Visual
- Auditory
- Volume control

SERVICING

The Mitek VAPR is not intended to be serviced by the user. It is intended that the unit be returned to the supplier for service and repair.

Typical Servicing Costs
Loan units and repair are included in the purchase price.

Supplier: Mitek
A Division of Ethicon Ltd
PO Box 408
Bankhead Avenue
Edinburgh, EH11 4HE
Tel: 0131 453 5555
Fax: 0131 453 6011
Web: www.vapr.com

Price: £5,600
Valleylab Ligasure

**SUMMARY**
- 150 W output
- 3 modes, one of which allows bipolar cutting
- Complies with IEC 601-2-2

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

**Price**
£12,500

**BRIEF DESCRIPTION**
The Valleylab LigaSure™ Vessel Sealing Generator is a solid-state electrosurgical unit intended for vessel sealing and bipolar surgery. The device is rated Type CF and has a duty cycle of 10 seconds on full power followed by 30 seconds off.

The device is designed to regulate output voltage to maintain a consistent effect across a range of loads. The accessory type is automatically detected and output settings adjusted to suit.

**Bipolar**: intended for most applications; the output voltage is low to prevent arcing.

**Macro Bipolar**: intended for bipolar cutting or rapid coagulation. This output provides higher voltages and greater power than the Bipolar mode.

**Vessel Sealing**: intended for sealing arteries and veins up to 7mm in diameter. Once activated, output continues until the resistance has increased to a cut-off level and sealing is complete or until a time limit is reached.

**Dimensions**
386 × 406 × 127 mm

**Weight**
5.9 kg

**MAIN FEATURES**

**Facilities**
- Bipolar coagulation
- Macro Bipolar cut and coagulation
- Seal vessel sealing

**Specifications (see Guide to Product Data)**

<table>
<thead>
<tr>
<th>Facility</th>
<th>Maximum Power</th>
<th>Rated Load</th>
<th>Peak Voltage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bipolar</td>
<td>95 W</td>
<td>100 Ω</td>
<td>168 V</td>
</tr>
<tr>
<td>Macro Bipolar</td>
<td>95 W</td>
<td>100 Ω</td>
<td>380 V</td>
</tr>
<tr>
<td>Seal</td>
<td>150 W</td>
<td>100 Ω</td>
<td>288 V</td>
</tr>
</tbody>
</table>

**Power Adjustment**
- Bipolar 1 W or 5 W increments
- Macro Bipolar 1 W or 5 W increments
- Seal 5 discrete settings

**Safety Features**
- Regrasp indicator monitors sealing
- Automatic electrode detection
- Activation time limit

**Operating Switches**
- Handswitches bipolar forceps
- Footswitches Seal / Bipolar or (electrical) Bipolar / Macro Bipolar

**Output Indicators**
- Visual
- Auditory adjustable

**SERVICING**
The Ligasure can be serviced by the user or by return to the supplier / service centre.

**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

Note 1: Add £25 for non-contract rates.

**CE Marking?** Yes, MD Directive

**Notified Body** BSI (086)

BRIEF DESCRIPTION

The Wolf 2352 is a 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 device is primarily intended for use in minimal invasive surgery; it also has applications in ORL/ENT, spinal surgery, and neurosurgery.

The device has auditory and visual indicators of electrosurgical current. The auditory tone and the number of LED bars lit on a segment display vary with the current. These indicators can give the surgeon an impression of how the coagulation is proceeding.

Dimensions: $320 \times 120.5 \times 255$ mm
Weight: 5 kg

<table>
<thead>
<tr>
<th>Facility</th>
<th>Maximum Power</th>
<th>Rated Load</th>
<th>Peak Voltage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coag</td>
<td>50 W</td>
<td>75 $\Omega$</td>
<td>190 V</td>
</tr>
</tbody>
</table>

Safety Features

- Activation time limit
- Incorrect dosage monitor
- Integrated test facility

Operating Switches

- Footswitch: electrical
- Handswitch: none

Output Indicators

- Visual
- Auditory
- Volume control

SERVICING

The Wolf 2352 is not intended to be serviced by the user. It is intended that servicing is carried out by returning the unit to the supplier.

Typical Service Costs

- Preventative maintenance excluding parts and carriage: £200
- Labour per hour: £60

Supplier

Richard Wolf UK Ltd
Waterside Way
Wimbledon
SW17 OHB
Tel: 0208 944 7447
Fax: 0208 944 1311
Web: www.richard-wolf.com

Price

£1,261
GLOSSARY OF TERMS

Ablation
Removal or excision of tissue by electrosurgical thermal disruption or by laser treatment.

AC (Alternating Current)
Current direction and voltage polarity vary with time, often in a sinusoidal manner. The rate of variation is referred to as the frequency.

Active Electrode
Metallic probe used to deliver high density current to the surgical site. The current is returned to the electrosurgical unit by a second active electrode or by another, large area electrode.

Alternative 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.

Applied Part
Any part of the equipment that may come into contact with the patient; more specifically active and return electrodes or bipolar instruments.

Arc
Sparking across an ionised air gap, resulting in very high concentrations of current in the target tissue.

BF
Isolated (not earth referenced) applied part providing a degree of protection against electric shock, but which is not suitable for direct cardiac application.

Bipolar
Application of electrosurgical current using two electrodes in close proximity. Current is limited to the small piece of tissue between the electrodes.

Capacitive Coupling
Transfer of electric current across an insulator or air gap via an electric field, this transfer increases as frequency and voltage increase.

CF
Isolated (not earth referenced) applied part providing a higher degree of protection against electric shock than a Type BF applied part. This category is intended for direct cardiac application.

Coagulation
The denaturing of tissue by the application of heating current to cause tissue destruction, haemostasis or vessel closure. The active electrode is in contact with the tissue so no arcing occurs.

Current
The electric charge flowing through a region in one second; measured in amps (A). Electrosurgical current is AC and alternates at very high frequencies to avoid neuromuscular stimulation.

Current Density
The amount of current passing through an area; measured in amps per square metre (A/m²). The current density or concentration determines the amount of heat generated in the tissue. Current density is high where the active electrode is applied, giving the surgical effect. As current spreads through a larger volume of tissue, the density falls.

Cutting
Local arcing causes the vaporisation of cells with heat being dissipated by steam. As the electrode moves an incision is made. Cut waveforms are often, though not always, pure sine waves.

Desiccation
Heating of tissue causes water to be expelled from cells resulting in dehydration and considerable shrinkage of the tissue.

Duty Cycle
The manufacturer’s recommended ratio of time-on to time-off, where the unit is intermittently activated at full power over a period of one hour.

Earth Referenced
A connection to earth at high frequencies by components such as a capacitor that greatly reduce the mains frequency current allowed to pass to earth.

Electrically Insulated
No direct conductive path exists between two electrical conductors; leakage currents may occur at electrosurgical frequencies due to capacitance or inductance.

Electrode
Metal instrument or accessory used to conduct electrosurgical current to tissue or another conducting medium, eg saline. The size and shape of the electrode influences the current density and surgical effect.

Electrosurgery
Also known as surgical diathermy. Application of high frequency electrical current to achieve a variety of surgical effects including cutting, coagulation and desiccation. The surgical effect is obtained via the heat produced as a result of the passage of current.
GLOSSARY OF TERMS

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

Excessive Current Alarm
This alarm is triggered when a monitoring circuit in the electrosurgical unit detects that a higher than usual level of current is being delivered.

Frequency
The number of times a periodic cycle repeats in one second; measured in hertz (Hz). The fundamental frequency of electrosurgical current usually lies between 200kHz and 5MHz and is often referred to as radio frequency (rf) or high frequency (hf). Such high frequencies avoid the neuromuscular stimulation caused by lower frequencies.

Forceps Switching
Bipolar forceps that contain a switch. As the forceps are closed together the output is activated.

Fulguration
Very high voltages are used in monopolar procedures to give random arcing over a wide area. This mode is used to staunch areas of light bleeding and results in a superficial eschar. Also known as spray coagulation.

Impedance
Also referred to as load. The opposition to the flow of electric current; measured in ohms (Ω). Bone and adipose tissue have high impedances: blood, and highly vascular tissues have lower impedances.

Inductive Coupling
Transfer of electric current across an insulator or air gap via a changing magnetic field.

Leakage Currents
Currents that arise via capacative 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.

Load
Another term for impedance. The size of the load affects the power delivered by the electrosurgical unit.

Monopolar Electrosurgery
Current is applied by an active electrode and, after passing through the bulk tissue, returns to the electrosurgical unit by the much larger return electrode.

Output Error Alarm
This alarm is triggered when a monitoring circuit in the electrosurgical unit detects that the measured power output exceeds the set output level.

Peak Voltage
The highest possible voltage for a given output mode. This maximum voltage is generated for the highest load, i.e. open circuit, where power is activated with the active electrode remote from the tissue. A high peak voltage increases the potential for arcs and leakage currents.

Pedicle
A narrow stalk or tube of tissue attached to a larger tissue mass, such as the penis. Monopolar electrosurgery should not be applied to a pedicle in case current concentration at a tissue constriction causes unwanted damage.

Power
The energy per second delivered by an electrosurgical unit; measured in watts (W). The power delivered is heavily dependent on the load placed on the equipment and the power setting is often only accurate at the rated load. It is therefore safer to regard the power setting as an indication of the maximum power available. Power should be set at the minimum level capable of achieving the desired surgical effect.

Rated Load
The load at which the electrosurgical unit delivers its maximum power. The rated load should be matched to the intended procedure with sufficient, but not excessive, power available at the expected load.

Return Electrode
Also known as the neutral electrode or dispersive electrode. In monopolar electrosurgery it provides a very large area for current to pass to bulk tissue, resulting in low current density. When applied correctly, this results in a small skin-temperature rise under the return electrode.

Surgical Diathermy
Also known as electrosurgery. Application of high frequency electrical current to achieve a variety of surgical effects including cutting, coagulation and desiccation.

Voltage
The potential difference between two points giving rise to a proportional current in a conductor; measured in volts (V).
Appendix

ACKNOWLEDGEMENTS

This report was prepared by Dr Nicholas Cook, Dr Diane Crawford 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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  e-mail: nicholas.cook@cardiffandvale.wales.nhs.uk
  www.imaging.uwcm.ac.uk/mpce/sctns/cedar/index

- Or: Mr Arthur Goodman, Evaluation Manager, Medical Devices Agency, Hannibal House, Elephant and Castle, London SE1 6TQ, Tel: 0207 972 8156, Fax: 0207 972 8105
  e-mail: Arthur.Goodman@doh.gsi.gov.uk
  www.medical-devices.gov.uk

We would like to thank all the medical, nursing and theatre staff who have taken part in the evaluations on which this report is, in part, based. We would also like to thank Dr Chris Hacking for his work on this report, prior to taking up a new position in the NHS.

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MDA evaluation reports are available, free of charge, to NHS Trusts and Clinics

In England
Medical Devices Agency
Room 1207
Hannibal House
Elephant and Castle
London, SE1 6TQ
Tel: 0207 7972 8181

In Scotland
Mr S Eales
Health Care Policy Division
Scottish Executive
Health Department
St Andrew's House
Edinburgh, EH1 3DG
Tel: 0131 244 3077

In Wales
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National Assembly for Wales
Health Services 3 Division
Cathays Park
Cardiff, CF10 3NQ
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In Northern Ireland
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Health Estates
Stoney Road
Dundonald
Belfast, BT16 OUS
Tel: 028 9052 0025

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