**BRIEF DESCRIPTION**

The Ellman Surgitron IEC is a compact, microprocessor-controlled, medium power, surgical diathermy with an earth-referenced rf output rated at 100W.

The system is primarily intended for outpatient use with applications in dermatology, gynaecology, plastic surgery, ophthalmology, podiatry and ENT.

The maximum power output for each facility is:
- **Cut** 100W
- **Cut/coag** 75W
- **Hemo** 35W
- **Fulguration** 32W
- **Bipolar** 38W

**Note:** Some units may have been supplied with a capacitive neutral electrode, which, in our tests, failed the rf leakage current requirements of the BS EN 60601-2-2 standard. Although we are not aware of any related adverse incidents, our recommendation is not to use this capacitive plate with this device because of the increased risk of an unintended patient burn.

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**SUMMARY**

**Advantages:**
- good range of electrode tips;
- good monopolar cutting performance;
- compact; easy to set up and transport.

**Disadvantages:**
- lack of tactile feedback when cutting; average bipolar performance.

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**Surgical Diathermy**

**Ellman Surgitron IEC**

**MAIN FEATURES**

**Facilities**
- Cutting mode **cut**
- Coagulation mode **cut/coag**
- Hemo **hemo**
- Fulguration **fulgurate**
- Bipolar **bipolar**

**Alarms**
- Neutral electrode **continuity monitor**
- Neutral electrode patient **connection monitor**

**Operating Switches**
- Footswitch **single electrical**
- Handswitches
  - Monopolar **one fingerswitching pencil**
  - Bipolar **forceps, activated by footswitch**

**Output Indicators**
- Visual and auditory **yes**
- Volume control **yes, rotary**

**Price ex VAT** £4,495 including a range of tips, handpiece, forceps, manuals and neutral electrodes.

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

**CE Marking?** Yes, MD Directive

**Applied Standards**
Ellman Surgitron IEC

DESCRIPTION

**Indicated Pathologies:** The Surgitron IEC is designed for a wide range of procedures including: treatment of skin tags, papilloma keloids, basal cell carcinomas, nevi, blepharoplasty, epilation, uvulopalatoplasty and myringotomy.

**Active Accessories:** Various autoclaveable and disposable, active electrodes are available. These include loops for excision, broad needles for fulguration, ball electrodes for coagulation, and needle tips for cutting. The fine needle electrode enables the surgeon to control the depth of cut by adjusting the length of exposed, active electrode. Electrodes also come in a choice of fine or regular gauge wire, the fine wire causing less coagulation than the regular.

Active electrodes are available in a range of styles, see Figures 1 and 2, some may be bent to provide easier access. A variety of bipolar forceps is also available from Ellman, see Figure 2.

![Figure 1: Active Electrode Types](image)

**User Facilities:** The Surgitron has five output facilities, which are selected using touch switch controls on the front panel.

- **cut:** pure cut waveform with the least amount of lateral heat and tissue destruction.
- **cut/coag:** cutting with superficial coagulation of adjacent tissue.
- **hemo:** for coagulation (haemostasis) of small blood vessels, up to 1.6mm in diameter.
- **fulguration:** sparking to produce desiccation and eschar.
- **bipolar:** a similar waveform to hemo with lower voltages, intended for more precise coagulation.

The output facilities are accessed via two modes of operation: **cutting mode** and **coagulation mode**.

**Footswitch Operation:** For footswitch activation, a single mode of operation is selected via the front panel.

**Fingerswitch Operation:** For fingerswitching control, the user can select one cutting and one coagulation output on the front panel. Both outputs may then be activated by the fingerswitching pencil.

The particular output facility for each mode is selected using the incremental touch-switch in the appropriate mode-panel of the device. The active mode is indicated by yellow and blue LEDs for the cutting and coagulation modes respectively.

![Figure 2: Bipolar Forceps and Monopolar Pencil with Bent Electrode.](image)

USER ASSESSMENT

**User Assessment Method:** The supplier was asked to provide several names of existing users who could be approached to take part in the user evaluation. The supplier provided the names of two surgeons. One other, new user also took part in the user evaluation. The users came from three different hospitals.

We also sought the opinion of theatre staff who were experienced in setting up the Surgitron. Surgeons and theatre staff completed questionnaires on various aspects including performance and ergonomics, using the rating options: excellent, good, satisfactory, poor, and unacceptable.

**Surgical Assessment:** The existing users, one oral surgeon and one ophthalmic surgeon, each had over two years experience with the device. The new user is an experienced consultant dermatologist who routinely uses a range of electrosurgical equipment. All three users received training from the supplier.
The surgeons were asked to rate the Surgitron’s performance in a number of procedures. Each questionnaire also gave the users an opportunity to comment on any particular advantages and disadvantages of the device.

**Surgical Assessment:** The following table shows the averaged ratings given for a selection of procedures. ‘Users’ refers to the number of consultants who rated each procedure.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Users</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor skin lesions/tags</td>
<td>3</td>
<td>●</td>
</tr>
<tr>
<td>Bipolar coagulation</td>
<td>2</td>
<td>○</td>
</tr>
<tr>
<td>Gingivectomy</td>
<td>1</td>
<td>●</td>
</tr>
<tr>
<td>Intra-oral biopsies</td>
<td>1</td>
<td>●</td>
</tr>
<tr>
<td>Rhinophyma</td>
<td>1</td>
<td>●</td>
</tr>
<tr>
<td>Blepharoplasty</td>
<td>1</td>
<td>●</td>
</tr>
<tr>
<td>Ptosis</td>
<td>1</td>
<td>●</td>
</tr>
<tr>
<td>Dacrycophtorhinostomy</td>
<td>1</td>
<td>○</td>
</tr>
</tbody>
</table>

○ - Unacceptable, ● - Excellent

**Table 1: Surgical Assessment**

Our users all thought that the Surgitron provided good cutting and excision performance with reduced bleeding when the cut/coag facility was used. One surgeon commented that the lack of tactile feedback caused problems with identifying tissue planes and could result in too deep a cut. Our new user, a dermatologist, commented that the bipolar coagulation function was disappointing.

**Surgical Technique:** During this evaluation the device was most commonly operated at between 20 and 30W, using the cut, cut/coag and bipolar coagulation modes.

**Theatre Staff Assessment:** Six theatre staff from two hospitals completed a questionnaire. Four staff completed the questionnaire individually and two staff completed it jointly. The questionnaire rated 17 features, which were grouped under controls, indicators and alarms, connectors, ease of cleaning, and instructions and training.

All features received an average rating of satisfactory or higher. The highest ratings, between good and excellent, were given to the power settings display and the auditory output indicator, while the lowest rating of satisfactory was given to the footswitch connection and supplier training and backup.

**TECHNICAL EVALUATION**

**Neutral Electrode:** The Surgitron was initially supplied for evaluation with a plastic-coated, capacitive neutral electrode. Use of this electrode may lead to leakage currents above the limits set by the BS EN 60601-2-2 standard and an increased risk of alternate site burns.

A disposable split neutral electrode, which reduces leakage currents to below the standard limits and enables the patient contact monitor is available from Ellman. The user manual states that the maximum resistance allowed by the patient contact monitor is 1000 Ω. This is higher than other, similar monitoring systems (typically less than 150 Ω) and the monitor may be less effective in detecting partially removed neutral plates.

**Power Output:** The maximum powers available from each output facility are noted on the backplate of the device. The digital display of power setting is a scale of 1 to 100 and is described in the user manual as representing a percentage of the power available from that output. However, the power output does not increase linearly with power setting, for example: the device tested gave approximately 80% of the maximum cutting output power when the control was set to 50. This may lead to inappropriate power selection whilst users familiarise themselves with the device.

**Other Safety Issues:** The rf output is earth-referenced and, compared to rf isolated diathermy, there is a slightly increased risk of alternate site burns. It is therefore especially important to avoid patient or user contact with earthed objects whilst the unit is activated.

Both disposable and reusable electrodes are available. Ellman recommend the use of disposable electrodes to guard against cross contamination. Steam autoclavable handpieces, cables, plugs and reusable electrodes are available.

There is a continuous, auditory tone when output is activated. This tone changes after 25 seconds and the output will automatically turn off 5 seconds later.

**Accompanying Documents:** The user and technical manuals are comprehensive, providing circuit diagrams, a component parts list, and instructions for the use and testing of the device. Calibration instructions are available on request from Ellman International.
COMPLIANCE WITH STANDARDS

Ellman International Inc manufacture the Surgitron IEC and corresponding accessories under an ISO 9001/EN 46001 system for quality assurance, audited by ITS-SEMKO AB. Ellman have declared that the device meets the provisions of the Medical Devices Directive (93/42/EEC) based upon application of the following standards:

- EN 60601-2-2:1991
- EN 60601-1-1:1992
- BS 5724: section 2.2:1992

MANUFACTURER’S DATA

Manufacturer: Ellman International Inc
1135 Railroad Avenue
Hewlett, NY 11557, USA

Repairs: As required or by contract, through Ellman UK Ltd

Spare parts: Available for 10 years after final manufacture.

Dimensions (H×W×D): 12.7 × 22.9 × 33.7 cm

Weight: 8.16 kg

MANUFACTURER’S COMMENTS

The latest Ellman diathermy models are designed to be used with a more substantial, dual footswitch. This allows activation of cutting and coagulation modes without the need to select the required mode on the front panel.

ACKNOWLEDGEMENTS

This report was prepared by Dr N Cook, Dr D Crawford and Dr S 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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ENQUIRIES

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