SURGICAL DIATHERMY UNIT

MARTIN ME80

MAIN FEATURES

Facilities
- monopolar
- bipolar
- power output controls
  - cut, coag, blend
  - macrobipolar, microbipolar
  - rotary, continuously variable

Alarms
- neutral plate continuity monitor
- patient contact monitor
- patient earth monitor
- patient voltage monitor
  - yes
  - no
  - no
  - no

Operating switches
- footswitches
  - monopolar, twin electrical; bipolar
  - single electrical
  - monopolar, single; bipolar, forceps
- handswitches

Output indicators
- visual
- auditory
- volume control
  - yes
  - yes
  - no

Electrical
- generator type
- output configuration
- maximum output power
  - solid-state
  - rf-isolated
  - 80 W

Price ex VAT
£1,805.40

Made in
Germany

Weight
4.6 kg

Manufacturer
Martin Medizin-Technik
Tuttlingen
Germany

Size H x W x D
97 x 256 x 320 mm

Does product comply with BS 5724/IEC 601?
Yes, BS 5724 Pt 1 & Section 2.2

DH Registered Manufacturer?
No

Note: Manufacturers may be registered, de-registered or re-registered at any time. Consult the latest issue of the DH Register of Manufacturers to check current status.

SUMMARY

Advantages: good bipolar performance; useful autobipolar facility; easy to use; compact and transportable.

Disadvantages: early version unsuitable for cutting in dermatology, later version satisfactory.

Overall: compact monopolar/bipolar unit; complies fully with BS 5724:Section 2.2.

BRIEF DESCRIPTION

The Martin ME80 is a solid-state, table-top, surgical diathermy unit, with an rf-isolated output rated at 80 W cut, 30 W spray coag, 80 W blend and 70 W bipolar.

The unit has a dual mode operational facility with discrete touch controls. The monopolar output is activated by the twin electrical footswitches or a fingerswitching active pencil; the bipolar output is activated by a single electrical footswitch, or by automatic forceps switching (autobipolar).

The ME80 has an audible output indicator and a neutral plate continuity monitor.
DESCRIPTION

The Martin ME80 is a solid-state, table top, surgical diathermy unit with an rf-isolated monopolar output rated by the manufacturer at 80 W maximum and a bipolar output rated at 70 W maximum.

All modes of operation are selected by illuminated touch switch controls. Output power levels for cut/blend, spray coagulation and bipolar are adjusted by separate, continuously variable, rotary controls. The selected power levels are indicated by simple numeric settings (1-10) printed around the control knobs. A single 'micro' touch switch reduces the maximum power available from all outputs to about one third of that normally available.

One pure cut and one blend output is available. A single touch switch allows the user to switch between pure cut and blend, then the power level is set using the cut control.

Two types of monopolar coagulation are provided: contact coagulation intended for desiccation and spray coagulation intended for fulguration. Contact coagulation is available by simply using the cut output with a large area active electrode, for example a ball electrode.

The monopolar output is activated by the twin electrical footswitches or a fingerswitching active pencil; the bipolar output is activated by a single electrical footswitch or by automatic forceps switching (autobipolar).

The unit has a dual mode operational facility, allowing the user to switch between monopolar and bipolar without having to select a switch on the control panel. Simply depressing the appropriate footswitch activates the selected output. Only one output can be energized at a time, on a 'first come, first served' basis.

The auditory output indicator produces three tones to distinguish between the cut/blend, and coag and bipolar outputs.

The unit weighs 4.6 kg.

Since the start of the evaluation of the ME80, Martin have released a revised unit for the UK market. The updated unit is the ME81, which is similar to the ME80. The ME81 was included in the User Evaluation and the results are summarised in Appendix 4.

USER EVALUATION

The users were asked to score the facilities and attributes of the surgical diathermy on a five point scale.

The Martin ME80 was used in dermatological and plastic surgery. After initial instruction, all users found the unit very easy to operate.
The unit was considered to be particularly compact and transportable, despite not having a carrying handle. Our users would have preferred smaller footswitches for easier transportation to clinics in other hospitals.

Apart from their large size, the footswitches were well liked by our users. They had a positive action and good sensitivity, both at the edge and centre of the switch. They were very easy to clean, either by wiping the smooth surfaces, or by total immersion.

The auditory output indicator had an unobtrusive tonal quality.

Our users found the unit very easy to clean because of the smooth front panel and recessed rotary controls.

The touch switches and display were considered to be generally good, although the illumination of some of the touch switches was very dim (see Update, Appendix 4).

For many procedures, only the bipolar output was required and, therefore, a neutral plate was not connected. Our users would have preferred to have been able to disable the monopolar output/neutral plate alarm, because they did not like having to ignore the neutral plate alarm (a flashing red warning light) during these procedures.

In dermatological surgery, the microbipolar output was primarily used and gave consistently good results, with minimal adhesion to the forceps. Forceps switching was good, although some users commented that a brief delay between touching the tissue and activation of the output would have been useful.

Monopolar spray coagulation was used for minor lesions with a small ball electrode and gave good results.

Small skin tags could not be removed using the cut output at any power setting, even with a fine needle electrode (see Update, Appendix 4). The effect of the electrosurgical current was to coagulate, rather than cut, the tissue.

In plastic surgery, the microbipolar output gave good results and was well liked by our users. Monopolar spray coagulation sometimes lacked sufficient power to be effective.

Contact coagulation performance was good, with little adhesion to the active electrode, though power settings close to the maximum available were required for large area coagulating forceps (see Update, Appendix 4).

**TECHNICAL EVALUATION**

**Safety and performance:** The ME80 met all of the safety and performance requirements. A sample of the ME80 submitted by Martin to TÜV, Bayern Munich and BSI testing independently of the evaluation, has recently been granted Certificates of Compliance. TÜV Certificate No. 91 04 9628 005 (April 1991) and BSI Certificate No. 189098 (January 1992) apply.

Test results are summarised in the Table of Results on page 6.

**Reliability:** The equipment was well made and reliability should be high.

**Serviceability and manuals:** The User Manual was well written and gave clear instructions for use. It also contained photographs of accessories for use with this unit. The Service Manual supplied with the ME80 gave good technical descriptions of circuit design, but failed to provide any circuit diagrams. However, circuit diagrams are available from the supplier.

Access for servicing was good, and repair of printed circuit boards could be carried out by printed circuit board exchange with the supplier/manufacturer. The supplier does not offer a service contract, but faulty units can be returned.
to him for repair, with the option of temporary equipment replacement.

COMPLIANCE WITH STANDARDS

For products without a CE mark, the UK Health Departments recommend that purchasers specify compliance with BS 5724, IEC 601 or EN 60601.

Independently of the evaluation, a sample of the Martin ME80 has been submitted by Martin to the TÜV Test House under the joint agreement with BSI. The Martin ME80 has been granted a Certificate of Compliance with IEC 601-1 and IEC 601-2-2 (1982) by TÜV and a Certificate of Compliance with BS 5724:Part 1 and Section 2.2 (1983). TÜV Certificate No. 91 04 9628 005 (April 1991) and BSI Certificate No. 189098 (January 1992) apply.

MANUFACTURER'S COMMENTS

The findings of the report were sent to the UK supplier but no written reply had been received, at the time of going to press, even though we were assured that they would respond and were given extra time to do so.
## Manufacturer's Information

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<td>Tuttlingen</td>
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<tr>
<td><strong>DH Manufacturer Registration</strong></td>
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<td><strong>Certificated product</strong></td>
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### Physical data
- **size (H x W x D)**: 97 x 256 x 320 mm
- **weight**: 4.6 kg

### Facilities

### Outputs
- **monopolar**
- **bipolar**
- **output controls**
- **cut, coag, blend**
- **2 (macrobipolar, microbipolar)**
- **rotary, continuously variable**

### Operating switches available
- **footswitches**
  - monopolar
  - bipolar
- **handswitching**
  - monopolar
  - bipolar
- **twin electrical**
- **single electrical**
- **single fingerswitch**
- **forceps switching (autobipolar)**

### Output indicators
- **visual**: yes
- **auditory**: yes
- **volume control**: no

### Electrical
- **generator type**: solid-state
- **output configuration**: rf-isolated
- **maximum output power**: 80 W
- **output connection**
  - monopolar: 4 mm coaxial plug
  - bipolar: small coaxial plug
  - cooling: convection

### Notes
1. Manufacturers may be registered, de-registered or re-registered at any time. Consult the latest issue of the DH Register of Manufacturers to check the current status.
2. Prices typically include footswitch, active cable and plate assembly, but do not include P&P or VAT.
3. Manufacturer's rating.
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<td>- patient leakage current³</td>
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<td>- diathermy leakage current⁴</td>
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<td>- earthling of exposed conductive parts</td>
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<td>- controls and front panel</td>
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**NOTES**

1. Worst case, single fault conditions: PASS ≤ 1000 μA.
2. Worst case, single fault conditions: PASS ≤ 500 μA.
3. With mains on the active electrode or neutral plate: PASS ≤ 5000 μA.
4. PASS ≤ 150 mA.
5. PASS ≤ 400 W.
7. See Update Appendix 4.
APPENDIX 1: HOW TO BUY WITH CONFIDENCE

Current production

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

Compliance with standards

For products without a CE mark, you should normally give preference to those which comply with BS 5724, IEC 601 or EN 60601. If the product we tested failed to comply with BS 5724, we will have listed the points of non-compliance in the Compliance with Standards section of this report. To find out whether any have been rectified in current production, you should refer to the Manufacturer's Comments section, or contact the manufacturer or supplier.

Manufacturer's Quality Control

The summary box on page 1 shows whether the manufacturer has registered, or applied for registration, under the DH Registration Scheme for Manufacturers of this category of medical equipment. The Scheme has been in operation since April 1985. A manufacturer seeking registration for a specific category of equipment is required to declare that the quality system used to control the manufacture of that category is in compliance with DH requirements. The quality system at a specific manufacturing site is subject to audit by the Medical Devices Agency, to assess its compliance. In general, registration does not imply that all products offered by the manufacturer are from registered sources; you should ask the supplier whether the relevant product is manufactured at a DH Registered Site.

NOTE

1. See HEI 145 Item 18/85.

APPENDIX 2: STANDARDS USED FOR TESTING

The technical performance and safety assessments in this issue were carried out for Martin by TÜV, Bayern Munich and BSI testing, Hemel Hempstead and in the evaluation centre at Cardiff. Supplementary testing was also carried out at the Cardiff evaluation centre.

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

Safety

An Electromedical laboratory of TÜV tested a unit at 240 V under the joint agreement with BSI, for compliance with the following standards to assess the general and particular safety aspects of the equipment: IEC 601-1:1977 and IEC 601-2-2:1982 Medical Electrical Equipment: Specification for high frequency surgical diathermy units.

BS 5724:Part 1 and IEC 601-1 cover the general requirements for safety of medical electrical equipment. These are amended by the second editions of the Particular requirements for safety: Specification for high frequency surgical equipment, BS 5724:Section 2.2 and IEC 601-2-2, respectively. BS 5724:Section 2.2:1983 is identical to IEC 601-2-2:1982.

User evaluation

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

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

CE marking

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

Essential Requirements

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

Standards

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

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

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

European standards, mandated by the European Commission, that are accepted as addressing identified Essential Requirements in a Directive are listed in the Official Journal of the European Communities and are known as harmonised standards. Products manufactured in line with such standards will be presumed to comply with the relevant Essential Requirements.

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

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

Directives Bulletins

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

Mr Richard M Gutowski
Medical Devices Agency
14 Russell Square
London, WC1B 5EP
Tel: 0171 972 8253/8256/8300
Fax: 0171 972 8112
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**ACKNOWLEDGEMENTS**

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

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

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

Dr R J Motley, Department of Dermatology, University Hospital of Wales Healthcare NHS Trust, Cardiff  
Mr P J Sykes, Burns and Plastic Surgery Directorate, Morriston Hospital, Ysbyty Treforys Trust, Swansea

together with all the medical, nursing and theatre staff who helped in the evaluation; and Mrs J Rowles of the Department of Medical Photography, University Hospital of Wales, Healthcare NHS Trust for the photographic work.
Since the start of the evaluation of the ME80, Martin have released a revised unit for the UK market. The updated unit is the Martin ME81, which is similar to the ME80. A sample of the ME81 submitted by Martin to TÜV, Bayern Munich independently of the evaluation, has recently been granted a Certificate of Compliance with IEC 601-1 and IEC 601-2-2 (1982). Certificate number APL 94 05 10916 010, November 1994 applies.

The supplier loaned a unit to the evaluation centre for inclusion in the evaluation programme. Key changes to the unit are as follows:

The ME81 had an updated control panel which included an illuminated on/off switch and brighter illumination behind the touch switch controls.

The shape of the power curve for the cut and spray coagulation outputs has been changed and the rated load impedance has been increased from 300 ohms to 1000 ohms for cut/blend and from 1000 ohms to 1500 ohms for spray coagulation.

User evaluation
Our users considered that the control panel on the ME81 was an improvement on the ME80. All users preferred the illuminated on/off switch and the brighter illumination behind the touch switch controls.

The cut performance was improved. In dermatological surgery, skin tags could now be removed so that the users rated the cut performance as satisfactory for the ME81, rather than unacceptable for the ME80.
OTHER REPORTS ON SURGICAL DIATHERMY UNITS

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

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COMING NEXT

Other surgical diathermy units now being evaluated:

- Valleylab
- Precision

ENQUIRIES

For information on the evaluation of surgical diathermy units, please contact Peter Oddy, Department of Health, Medical Devices Agency, Hannibal House, Elephant and Castle, London, SE1 6TQ (direct tel: 0171 972 8155) or via the switchboard on 0171 972 2000.

Customers not employed by the NHS can order individual reports by sending a cheque with their order to Orders Department, Room 1207, Medical Devices Agency, Hannibal House, Elephant and Castle, London, SE1 6TQ (Fax: 0171 972 8105). Price information is available from the general enquiry point on 0171 972 8158.

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- Estate Services Directorate
- Deed Centre, Stoney Road
- Dundonald
- Belfast BT16 0US
- Tel: 01232 523714

**Scotland:**
- Scottish Healthcare Supplies
- Trinity Park House
- South Trinity Road
- Edinburgh EH5 3HS
- Tel: 0131 552 8256 ext 2206

**Wales:**
- Welsh Office
- Health Management Division
- Cathays Park
- Cardiff CF1 3NP
- Tel: 01222 823278

If you are not an NHS employee, you can purchase 'Evaluation'.

Further information can be obtained by calling 0171 972 8181.