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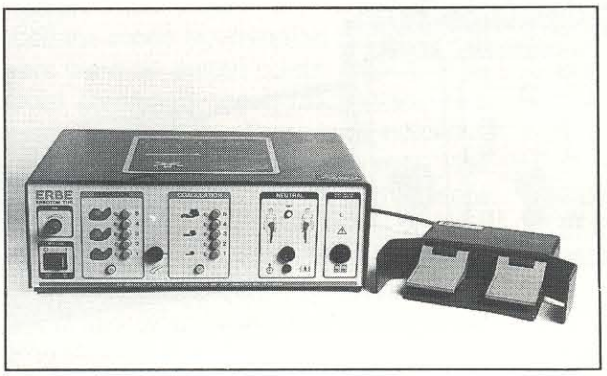


SURGICAL DIATHERMY UNITS

ERBE Erbotom TUR

BRIEF DESCRIPTION

The Erbe TUR is a solid-state, table-top surgical diathermy unit intended exclusively for TUR (Trans-Urethral Resection) procedures. The cut and coagulation power outputs are automatically controlled and the maximum power is 400 W. The outputs are activated by twin electrical 'piano-pedal' footswitches. The auditory output indicator has a volume control. A neutral plate continuity monitor and an automatic systems self-check, with auditory and visual alarms, are incorporated. The unit does not have any carrying handles and weighs 17.3 kg.

MAIN FEATURES

facilities	
monopolar	cut, coag, blend
power output controls	none
alarms	
neutral plate continuity monitor	yes
neutral plate voltage monitor	no
monopolar footswitches	twin electrical
monopolar handswitch	none
output indicators	
visual	yes
auditory	yes
volume control	yes
electrical	
generator type	solid-state
output configuration	earth referred
maximum output power	400 W

SUMMARY

Advantages: None

Disadvantages: Poor documentation; supplier and manufacturer unable or unwilling to provide information; minimum output power too high; poor serviceability; serious non-compliances with BS 5724. No carrying handles.

Overall: It is recommended that no further purchases of this equipment be made until the manufacturer is able to demonstrate compliance with BS 5724: Part 1 and Section 2.2. Existing users of this equipment should withdraw it from service until further notice.

Purchase Price
£4000

Weight
17.3 kg

Size H x W x D
175 x 480 x 360 mm

Made in
West Germany

Product certificated? No

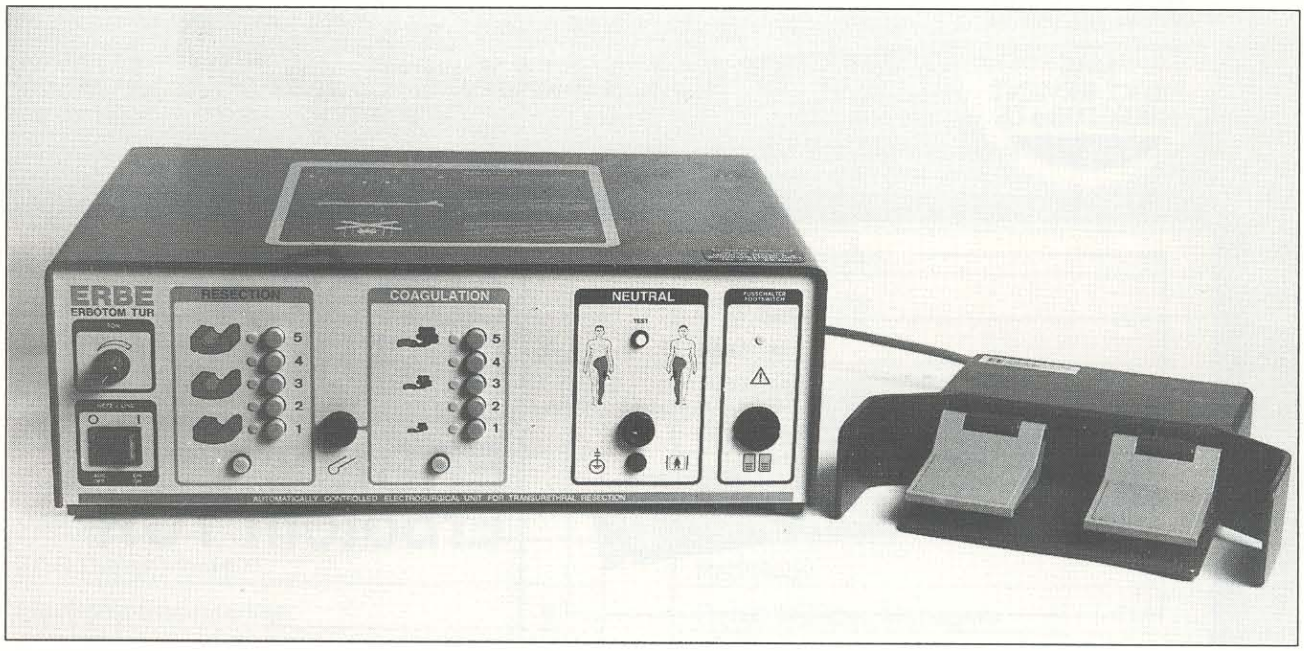
DH Registered Manufacturer? No

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

Manufacturer
Erbe Electromedizin GmbH, Tubingen, West Germany

Free to the NHS £5

ERBE Erbotom TUR



DESCRIPTION

The Erbe TUR is a solid-state, table-top surgical diathermy unit with an earth referred output, rated by the manufacturer at 400 W maximum. It is a specialised unit that is intended solely for performing TUR procedures.

The unit has cut and coagulation outputs but **NO** power controls. The manufacturer states that the output power is controlled automatically for optimum effect (see Technical evaluation). In addition to a pure cut output, four levels of haemostasis may be set. These outputs are selected by push button on the front panel. Similarly five degrees of coagulation may be set by push-button.

The outputs are activated by a twin electrical 'piano-pedal' type footswitch. The auditory output indicator produces two tones to distinguish between cut and coag outputs and there is a volume control. The unit has a neutral plate continuity monitor and an automatic systems self-check with auditory and visual alarms.

The unit does not have any carrying handles and weighs 17.3 kg.

USER EVALUATION

Laboratory tests showed that the user would have **NO** control over the power delivered by this unit (see Technical evaluation below). In the light of this and because we could obtain no satisfactory information on the mode of operation from either the manufacturer or supplier we were unable to allow a user evaluation.

TECHNICAL EVALUATION

Safety and performance:

The manufacturer described the unit in the operating instructions as an "automatically controlled HF surgical unit for transurethral resections (TURs)". The cut output was described as maintaining a constant "intensity" of sparks. Other cut settings were said to introduce different amounts of haemostasis. It was found that the cut output power was unaffected by the control setting.

The operating instructions stated that "The intensity of coagulation can be set to five different levels by pressing the respective button". However, the measurements into the matched load showed that there was no alteration of coagulation power output.

These are serious shortcomings. Not only was it impossible to adjust the output power, but the minimum achievable output power of 358 W, measured on the unit tested at BSI, far exceeded the minimum output power of 10 W required by clause 50.1 of BS 5724: Section 2.2: 1983.

The evaluators, BSI Testing and the Department of Health asked the supplier and the manufacturer on a number of occasions for detailed information on the operation of this machine, to enable a judgement to be made as to whether or not it was safe for clinical use. Unfortunately, this information could not be obtained and indeed the supplier never acknowleged letters from the evaluators, and was tardy in responses to the Department of Health. **In the light of the incomplete knowledge of the mode of operation of this equipment it is strongly recommended that under no circumstances should it be used.**

Reliability: There were no faults on delivery but the equipment was never used clinically. Basic mechanical and electrical construction appeared to be of a satisfactory standard.

Serviceability and manuals: Both the user instruction manual and the service manual were photocopies. The user manual was poor, it omitted most of the required safety information and inadequately described the mode of operation of the unit. In particular there were no output power graphs. The service manual contained circuit diagrams and a parts list that was in German. There were no circuit descriptions and no fault finding procedures - the supplier promised to send us these when they were available, but these were never received.

There was poor access for servicing because of the relative positions of the circuit boards and this together with the lack of servicing information would make servicing difficult.

COMPLIANCE WITH STANDARDS

BS 5724 is the current British Standard for the safety of medical electrical equipment. Part 1 applies to all types, while Section 2.2 adapts it specifically for this category of equipment. The UK Health Departments recommend that purchasers specify compliance with both Part 1 and Section 2.2

The supplier, Rimmer Brothers, claimed on the EMQ1 form submitted with this equipment that it complied with BS 5724 Part 1. However, on the Erbe TUR examined at BSI the following points of non-compliance were found against BS 5724: Part 1 and Section 2.2:

BS 5724: Part 1.

6.1 A number of external markings were missing
6.2 No internal 'high voltage' symbol
6.3 The mains on/off switch was not identified with its function
20 Failed the dielectric strength test at a number of points on the printed circuit boards
56.1 No documentary evidence of compliance of mains parts
57.5 One component inadequately secured
57.10 Creepage distances less than the minimum required at a number of points

BS 5724: Part 2: Section 2.2.

6.7 The cut and coag visual output indicators were white. They must be yellow and blue respectively
6.8.2bb Many safety statements were missing from the instructions for use
6.8.3 There were no output power diagrams in the instructions for use
50.1 The output power could not be adjusted
50.1 The minimum output power measured was 358 W. A minimum setting of 10 W must be possible
101.2 Auditory output sound level could be reduced to zero

MANUFACTURER'S COMMENTS

The findings of the report were sent to Rimmer Brothers Ltd (the supplier), who responded that they had copied the report to ERBE Elektromedizinische GmbH asking them to reply direct to the Department of Health. Also that as from the beginning of 1990 they were no longer the exclusive UK agent for ERBE, as ERBE had approached Messrs Spembly Products to sell ACC products.

A telefax reply was recieved from ERBE Elektromedizinische GmbH as follows:

"The most serious non-compliance with BS 5724 (IEC 601 Part 2.2) in your report is the high level of the minimum output power. But this must be a misunderstanding.

The ERBOTOM TUR is a specialized equipment for trans urethral resections only. The quality of the cut during trans urethral resections depends on many parameters, such as for example the shape and diameter of the resection loop, the cutting rate, the depth of cut, the electrical conductivity of the irrigation agent, the type of tissue, the type of high frequency current, etc. In order to achieve a reproducible and good cutting quality in spite of the fairly wide variations in these paramenters, a diathermal surgery unit is required which monitors the above mentioned parameters sufficiently quickly and also adjusts the intensity of the HF current sufficiently quickly so that an extensively even and reproducible cutting quality is always achieved.

Due to the realization that a cut is almost only possible with high frequency current if there is an arc between the resection loop and the tissue, and that the quality of the cut depends extensively on the intensity of the arc. K. FASTENMEIER and G. FLACHENECKER (1) developed an electronic control circuit, which adjusts the intensity of the high frequency current sufficiently quickly so that the intensity of the arc between the resection loop and the tissue is kept largely constant, thus achieving a quality of cut which is reproducible and regular.

This electronic circuitry was incorporated in the ERBOTOM TUR diathermal surgery unit. ERBE tests showed that, compared with conventional diathermal surgery units, this unit possesses the following characteristics:

(1) Prof. Dr-Ing. K FASTENMEIER,
Prof. Dr-Ing. G FLACHENECKER -- High frequency generator with automatic control for optimum cutting.
Proceedings of the 32nd Conference of the German Urological Society.

1. Quality of the cut

Three separate cutting qualities can be set by pushing the button on the control panel of the ERBOTOM TUR. This sets the intensity of the arc which must be present between the resection loop and the tissue. The higher the intensity of the arc, the greater will be the coagulation of the cut surfaces during the cut, and this will take place largely independently of the above mentioned variable parameters. The latter is used as required for closing small blood vessels unavoidably perforated during the cut.

If the resection loop is drawn quickly and / or deeply through the tissue, then the ERBOTOM TUR will automatically deliver a correspondingly high cutting current. Also, if the cut is fast and deep but very flat, as with so called smoothing cut, the ERBOTOM TUR regulates the intensity of the cutting current very quickly to a value which guarantees an even cut.

With conventional diathermal surgery units the intensity of the cutting current is usually set so high that it is adequate to cope with the most disadvantagous conditions.

This, however, has the disadvantage that the intensity is too high for most situations, particularly for the smoothing cut. Since with conventional diathermal units the intensity of the cutting current can be adjusted manually, which in practice is not possible to carry out, as manual adjustments take too long and are inaccurate, there are great variations in the cutting quality.

The ERBOTOM TUR with automatic arc control offers the operating surgeon the following advantages regarding the cutting quality:

1.1 A regular and reproducible quality of the cut surfaces at all cutting rates.

1.2 Both deep as well as shallow cuts can be optimally performed with the unit set to the same value.

1.3 The resected tissue is not unnecessarily highly coagulated, which is advantageous for histological investigations on the tissue.

1.4 The cut surfaces are not unnecessarily highly coagulated, so that the operating surgeon can better differentiate the various types of tissue during the resection.

The following advantadeous characteristics, resulting from the automatic arc control, were observed (by ERBE) in addition to the improved cutting quality during tests on the ERBOTOM TUR.

2. Stimulation of nerves and muscles

The sparks and arcs which occur between resection loop and tissue during cutting, give rise to low frequency electrical currents which can stimulate nerve and muscle cells. The risk of this happening increases with the intensity of the sparks and arcs. Because with conventional diathermal surgery units the formation of sparks and arcs is uncontrolled and the intensity is usually set too high, the risk of unintentional nerve and muscle stimulation is considerably greater with these units than with the ERBOTOM TUR. This is important, for example, during endovesicular resections in the region of the obturator nerve.

3. Risk of burning

3.1 The automatic control of the HF output avoids the application of an excessive HF current and thus reduces proportionally the risk of burns for the patient.

3.2 The ERBOTOM TUR has a high quality HF filter in the output stage, which suppresses all harmonics, which contributes to determining the so-called HF leakage currents. The HF leakage currents with this unit are distinctly smaller than with conventional diathermal surgery units. This also reduces the risk of burns.

4. Less interference to other electronic equipment

The high quality HF filter in the ERBOTOM TUR clearly reduces the risk of causing interference to other electronic equipment, such as for example television transmission equipment, ECG units, radios, and two way telephone systems, etc.

5. Preservation of the resection loops

5.1 Due to the automatically controlled and relatively small spark formation between resection loop and tissue, the resection loop is spared and thus has a longer life.

5.2 The resection loop remains clean longer.

6. Reduced dissociation of water

The automatically controlled HF output reduces both the formation of steam bubbles as well as the dissociation of water caused by the formation of sparks. Fewer bubbles and foam in front of the optical system. Less oxyhyrdogen gas in the bladder.

7. Easy operation of the ERBOTOM TUR

The ERBOTOM TUR has been specially designed around the requirements for performing TURsd. Functions not required for TURs have been omitted. The control panel is very clearly arranged.

The comments regarding the operating instructions and service documentation are of course right. On the other hand the operation of this unit is so easy and clearly for a urologist that this deficiency hasn't been an object of complaint until now. But, of course, the technical service demands a thorough knowledge. This is why the technical service is carried out practically only by our own or distributor's service technicians.

Since 1983 more than 1000 ERBOTOM TUR units have been sold world-wide and used without considerable problems.

The model tested is no longer on the market, ie since 1987 and the newer model with 5 push buttons for cutting and coagulation will be replaced by a completely new model, the ERBOTOM ACC 450, during this year.

With respect to the fact that the functioning of the ERBOTOM TUR is based on other principles than with conventional units and it has been in use since 1983 without causing considerable problems, we want to ask for the report to be corrected regarding the comment of a too high a level of the minimum output power. The HF output power is automatically controlled by the intensity of the arcs between the resection loop and tissue as described before. But if no arc is present, the unit regularly generates the maximum HF output voltage, but, unfortunately, this characteristic is not measurable with conventional HF power meters."

ERBE Erbotom TUR

RESULTS TABLE

Safety

earth leakage current[1]	PASS
patient leakage current[2]	PASS
patient leakage current[3]	PASS
diathermy leakage current[4]	PASS

Output power

maximum output power and load used[5]	PASS
Cut:	358 W/500
Coag:	358 W/500
Blend:	358 W/500
output power on minimum setting	FAIL

Output waveform

basic frequency	425 kHz
waveform	Sinusoidal

Construction[6]

quality of assembly	Satisfactory
mechanical construction	Satisfactory
serviceability	Poor

Reliability

faults on delivery	None
breakdowns in service	Never used

Manuals[6]

user instructions	Unacceptable
servicing information	Poor

CLINICAL OBSERVATIONS

Performance[6]

applications	
TUR:	Never used
muscle stimulation	Never used

Controls[6]

footswitches	Never used
controls and front panel	Never used

NOTE
1 - Worst case, single fault condition PASS ≤1000 µA
2 - Worst case, single fault condition PASS ≤500 µA
3 - With mains on active electrode or neutral plate PASS ≤5000 µA
4 - PASS ≤150 mA
5 - PASS ≤400 W
6 - Scale used: excellent/ good/ satisfactory/ poor/ unacceptable

PRODUCT SUPPORT

supplier	Rimmer Brothers Aylesbury House Clerkenwell Green London EC1R 0DD Tel: 01 251 6494
guarantee	12 months
maintenance provisions	
service contract	On request
will service engineer call?	Yes
maximum response time quoted	No
temporary equipment re-placement?	No
spare parts	
spares availability	5 years

MANUFACTURER'S INFORMATION

Facilities

monopolar output	Cut,coag,blend
bipolar output	No
power output controls	None
separate bipolar control	Not applicable

Alarms

neutral plate continuity monitor	Yes
neutral plate voltage monitor	No

Operating switches available

footswitches:	
monopolar	Twin, electrical
bipolar	Not applicable
handswitching:	
monopolar	No
bipolar	Not applicable

Output indicators

visual	Yes
auditory	Yes
volume control	Yes, external

Electrical

generator type	Solid-state
output configuration	Earth referred
maximum output power	400 W
output connection	4 mm Erbe type
cooling	Convection

ACKNOWLEDGEMENTS

This report was prepared by Dr D G Spendley of the Bioengineering Unit in the Department of Medical Physics and Bioengineering at Cardiff Royal Infirmary. The Department of Health thanks the following personnel for their work on this evaluation.

Dr D G Spendley
Mr R Vine
Mr J McCarthy

APPENDIX 1: HOW TO BUY WITH CONFIDENCE

Compliance with standards

BS 5724: Part 1 is officially recognised by the Department of Health[1] (DH): when purchasing equipment preference should be given to products which comply with this standard. (For this product, see the Technical Evaluation and Manufacturer's Comments on pages 2 to 4.)

Manufacturer's Quality Control

The summary table 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 electrical equipment. The Scheme has been in operation since April 1985. A manufacturer seeking registration for a specific category of medical equipment is required to declare that the quality system used to control the manufacture of that category is in compliance with the requirements of the DH Guide to Good Manufacturing Practice for Medical Equipment (the "Green Guide").

The quality system subsequently becomes subject to inspection by the Supplies Technology Division of the Department's, NHS Procurement Directorate, in order to assess its compliance. [In general, Registration does not imply that all products offered by the manufacturer are from registered manufacturing sources: you should ask the supplier whether the particular product you want is manufactured under the DH Registration Scheme.]

NOTE
1. See HEI 145 Item 18/85.

APPENDIX 2: STANDARDS USED FOR TESTING

TECHNICAL STANDARDS

The technical performance and safety assessment in this issue were carried out at BSI Testing Services at Hemel Hempstead, and by the Bioengineering Unit at Cardiff Royal Infirmary, South Glamorgan Health Authority.

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

SAFETY

The Electro-medical Laboratory of BSI Testing Services at Hemel Hempstead tested a unit for compliance with the following current British Standard to assess the technical safety aspects of the equipment:

BS 5724 Part1: 1979 Medical electrical equipment: specification for general safety requirements.

BS 5724 Part 1 is the UK equivalent of the international standard IEC 601-1. A revised edition of IEC 601-1 has been published; a similarly revised BS 5724: Part 1 was published during October 1989.

The unit was also tested against the Particular Safety standard for Medical electrical equipment: specification for high frequency surgical equipment, BS 5724: Part 2: Section 2.22: 1983.

THE USER EVALUATIONS

User assessments were carried out in hospitals within the South Glamorgan and Ogwr Health Authorities (see Acknowledgements). The protocol used for the user trials was devised in co-operation between the evaluators, the surgeons involved in the user trials and DH.

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Other surgical diathermy units now being evaluated:

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Valleylab Force 2;
Eschmann TD 411S;
Martin Electrotom 390

ENQUIRIES

For information on the evaluation of transport incubators, please contact Peter Oddy, Department of Health, NHS Procurement Directorate, 14 Russell Square, London WC1B 5EP (Tel: 071 636 6811 ext 3023).

'Evaluation' series editor is Charles Herrington, Department of Health, NHS Procurement Directorate, 14 Russell Square, London WC1B 5EP (Tel: 071 636 6811 ext 3053).

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