INTENDED PURPOSE

The intended purpose of the devices described herein, (when connected in the approved manner and used by suitably trained personnel), are to convert, conduct and switch electrical energy from the 230V mains power supply through a step down transformer, cord and switchable holding device, to a range of cautery burners which, when activated are used to perform cutting and sealing operations on body tissue by the application of incandescent heat.

The devices have been designed to work in harmony with each other and RB Medical will not guarantee satisfactory performance if used with non RB devices.

DEVICE CLASSIFICATION

The above devices, when connected in the approved manner and used for their intended purpose, are classified as transient, active, invasive devices, and will be Class IIb in respect of Annex IX of EC Directive 93/42/EEC plus revision 2007/47/EC.

APPLICABLE STANDARDS

The devices have been designed and tested to conform to:

BS EN 60601-1 : 2006 (Medical Electrical Equipment - Part 1. General Requirements for Safety)

The devices are manufactured in line with the requirements of:

- **EN ISO 13485 Quality** management System as approved by **Lloyds Register Quality Assurance** (Notified Body Number 0088).

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions</td>
<td>Group 1</td>
<td>The JA750 is intended for use in the electromagnetic environment specified below. The user of the equipment should assure that it is used in such an environment. The JA750 uses RF only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions</td>
<td>Class B</td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>Class B</td>
<td>The JA750 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Voltage fluctuations/flicker</td>
<td>Complies</td>
<td></td>
</tr>
<tr>
<td>emissions IEC 61000-3-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Guidance and manufacturer’s declaration – Electromagnetic emissions
INDIVIDUAL DEVICE AND ACCESSORY REFERENCE DOCUMENTS

The details on individual Cautery Devices and accessories, including operating instructions, safety and cleaning requirements can be found on the following reference documents:

- Cautery Transformers JM016
- Cautery Handles & Cords JM017/S10002
- Cautery Burners JM018/S10002

WARRANTY

These Devices are guaranteed against all faults which can be traced to faulty material or poor workmanship for a period of ONE YEAR from the date of invoice. This service will be provided free of charge except for insurance, handling, transportation and incidental charges, provided the devices have been used strictly in accordance with the intended purpose of the devices. Any unauthorised modification to, or work on these devices, invalidates this warranty.

Note: Cautery Burners are NOT covered by warranty.
Instructions for Use
Heavy Duty Cautery Transformer JA750

GENERAL DESCRIPTION

The Cautery Transformer is a heavy duty model suitable for cautery burners rated up to 40amps.

- JA750: 230V~ Heavy duty model

INSTRUCTIONS FOR USE

Mains Connection

Before connecting to the mains supply, ensure that the voltage indicated on the specification label on the back of the unit corresponds with the mains supply voltage.

The power switch on the front of the unit is illuminated ‘green’ when the power is switched on.

Cautery Operation

Connect up all applied parts (cord, handle and burner) BEFORE switching on the unit and ensure that all connections are tight.

Before energising a burner, turn the cautery control knob to setting ‘1’, then whilst pressing the switch on the handle, turn up the control knob slowly to produce the required operating temperature. (The graduations on the cautery control are for reference only).

Turn the control knob to setting ‘1’ and switch off the unit before disconnecting any applied parts.

ATTENTION

- These units are not anaesthetic proof and should not be used within the zone of risk of flammable medical gases.
- These units should not be stored in damp conditions.
- These units are designed for use with cautery cords, handles and burners manufactured by RB Medical to which these instructions apply. Other makes of equipment may be used, however their safety, reliability and performance cannot be guaranteed.

MODE OF OPERATION

This equipment is designed for use on an intermittent mode of operation with a single cycle of a maximum operating time of 30 seconds followed by a minimum resting time of 30 seconds repeated continuously for 2½ hours. The equipment may however be used safely for other intermittent cycles over a lesser overall time.

CLASSIFICATION

These units are type BF devices as defined in BS EN 60601-1: 2006 and BS EN 60601-1-2 : 2007 (ERA Report nos: 98-0287 and R/2004/D167/A refer). The applied parts (cord, handles and burners) are fully floating, being isolated from all other parts of the equipment (i.e. from mains and earth).

SAFETY

A sample of these units has been tested to BS EN 60601-1: 2006 and BS EN 60601-1-2 : 2007 (ERA Report nos: 98-0287 and R/2004/0167/A refer). All devices have been safety tested: a print out of the test performed is enclosed in the document wallet.

CLEANING

Disconnect unit from power supply BEFORE cleaning. DO NOT AUTOCLAVE. DO NOT SOAK

All parts can be cleaned with a damp cloth: a mild detergent may be used if required. Care should be taken to avoid liquid getting into the contact points.

Note: The units are supplied non-sterile and are not designed for sterilisation. Should use in a sterile environment be required, the unit may be placed in a sterile bag.

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Important - disconnect the unit from the mains before removing the lid.

The following spares are available from the manufacturers:

- TJ102/3  Control Knob and Cap
- TJ309   Spare Fuse for 230V ~ Heavy Duty model – T0.63A
- TJ401   3m Mains Cable
- ZJ008   Chrome Handle

Further technical details and spare parts, if necessary, can be provided by the manufacturer for repairs suitable for being carried out by the user's appropriately qualified technical personnel. When ordering spare parts or seeking advice from the manufacturer, always quote the model and serial number.

A full repair service is available from the manufacturer.

TECHNICAL INFORMATION

Input Voltage: 230V ~ 50-60Hz
Fuses: See Parts List below
Total Output Power: 70W (Heavy Duty)
Cautery Output (open circuit) 70W (Heavy Duty) variable

TRANSFORMER CIRCUIT DIAGRAM

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
<th>RB Part No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tr</td>
<td>Transformer: Primary 0 - 115V, 0 - 115V. Secondary 0 - 4V</td>
<td>JJ025</td>
</tr>
<tr>
<td>Sw</td>
<td>Mains Switch (Green Illuminated)</td>
<td>TJ120</td>
</tr>
<tr>
<td>F1, F2</td>
<td>Fuses: Heavy Duty Model = T0.63A</td>
<td>TJ309</td>
</tr>
<tr>
<td>VR</td>
<td>Variable Resistor, single turn linear, conductive plastic, 1w 100k</td>
<td>TJ328</td>
</tr>
<tr>
<td>PCB</td>
<td>Complete PCB sub-assembly (Issue 3)</td>
<td>TJ210</td>
</tr>
</tbody>
</table>

Manufacturer
RB Medical Engineering Ltd, 2 Alton Road Ind. Est. Ross-on-Wye, Herefordshire. HR9 5NS.
Tel: +44 (0) 1989 563958 Fax: +44 (0) 1989768267

WARRANTY

These Devices are guaranteed against all faults which can be traced to faulty material or poor workmanship for a period of ONE YEAR from the date of invoice. This service will be provided free of charge except for insurance, handling, transportation and incidental charges, provided the devices have been used strictly in accordance with their intended purpose. Any unauthorised modification to, or work on these devices, invalidates this warranty.
Cautery Handles and Cables
Instructions for Use

GENERAL DESCRIPTION
The following Cautery Handles and associated cords are covered in this leaflet:

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
<th>Part No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye</td>
<td>Pencil style handle with rocker switch and fixed cord.</td>
<td>JA113</td>
</tr>
<tr>
<td>Light Duty</td>
<td>Push button handle with fixed cord.</td>
<td>JA103</td>
</tr>
<tr>
<td>Light Duty</td>
<td>“Mark Hovell” handle *, *(Separate cord required - see below)</td>
<td>JA101</td>
</tr>
<tr>
<td>Light Duty</td>
<td>Pen Grip Handle with fixed cord.</td>
<td>JA124</td>
</tr>
<tr>
<td>Light Duty</td>
<td>Pistol Style handle with fixed cord.</td>
<td>JA142</td>
</tr>
<tr>
<td>Light Duty</td>
<td>2.0 metre double insulated cord with Pins and Nipples for Mark Hovell *</td>
<td>JB106 *</td>
</tr>
<tr>
<td>Light Duty</td>
<td>2.0 metre double insulated cord for Mark Hovell handle</td>
<td>JB107</td>
</tr>
</tbody>
</table>

These are designed for use with cautery burners rated between 15 and 20 amps.

Heavy Duty | Pistol Style handle with fixed cord.                                        | JA141    |

These are designed for use with cautery burners rated up to 40 amps.

INSTRUCTIONS FOR USE
Connection - fixed cord handles (JA113, JA103, JA124, JA141 and JA142).

Ensure any power supply units are switched off and disconnected from the mains before connecting the handle.

- The power supply cord is terminated at the power supply end by standard 4mm Lantern type pin fittings. These should be introduced into the holes in the red and black transformer terminals on the front panel and pressed home firmly.
- Cautery burner connection is by “friction” fit, and should be pushed fully home when inserted.

Connection - Mark Hovell handle and separate cord with pins and nipples (JA101 and JB106) (708 Transformer only) *

- The power supply cord is terminated at the power supply end by pins and nipple fitting. Unscrew terminal fully until hole on the shaft can be seen, introduce pin through the hole and screw terminal down firmly using hand pressure only.
- The power supply cord is terminated at the handle end with thumbscrew bosses and should be connected to the handle legs by placing over the leg as far as they will go, and the thumbscrews tightened firmly using hand pressure only.
- Cautery burner connection is by clamping pressure of the handle thumbscrews. The burner should be introduced into the handle bosses to approximately half way along the exposed leg portions and the thumbscrews tightened firmly using hand pressure only.

Connection - Mark Hovell handle and separate cord (JA101 and JB107) (CE Transformer only)

- The power supply cord, (JB107), is terminated at the power supply end by standard 4mm Lantern type pin fittings. These should be pushed into the holes in the red and black transformer terminals on the front panel and pressed home firmly.
- The power supply cord is terminated at the handle end with thumbscrew bosses and should be connected to the handle legs by placing over the leg as far as they will go, and the thumbscrews tightened firmly using hand pressure only.
- Cautery burner connection is by clamping pressure of the handle thumbscrews. The burner should be introduced into the handle bosses to approximately half way along the exposed leg portions and the thumbscrews tightened firmly using hand pressure only.
- WARNING! Never allow a connected, energised handle to be placed on a metal object as a short circuit may occur.

The handle and cord may become warm during use. This is normal due to their natural electrical resistance, and it will not rise in temperature to a level that will pose any risk to user or patient. UNDER NO CIRCUMSTANCES HOWEVER, MUST THE CORD BE CHANGED FOR A NON APPROVED TYPE OR SHORTENED AS THIS WILL ADVERSELY AFFECT THE OVERALL PERFORMANCE OF THE DEVICE. NEVER use light duty accessories with a heavy duty transformer.

R.B.Medical recommends the use of a Sterile Cover JB104 to cover Cautery Handle. This avoids the need to wash handle prior to autoclaving.

MODE OF OPERATION
This equipment has been designed for use in an intermittent mode of operation with a single cycle of a maximum operating time of 30 seconds followed by a minimum resting time of 30 seconds repeated continuously for 2½ hours. The equipment may however be used safely for other intermittent cycles over a lesser overall time.

CLEANING AND STERILISATION (all types)
Refer to document: - S10002

Manufacturer -
RB Medical Engineering Ltd, 2 Alton Road Ind. Est. Ross-on-Wye, Herefordshire. HR9 5NS.
Tel: +44 (0) 1989 563958 Fax: +44 (0) 1989 768267

WARRANTY
These Devices are guaranteed against all faults which can be traced to faulty material or poor workmanship for a period of ONE YEAR from the date of invoice. This service will be provided free of charge except for insurance, handling, transportation and incidental charges, provided the devices have been used strictly in accordance with the intended purpose of the devices. Any unauthorised modification to, or work on these devices, invalidates this warranty.

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DESCRIPTION

Cautery burners are available with the tips shown (not to scale) in the table below:

Burners are available in sizes: 1” (Eye), 2”, 3”, 5” and 7”; the measurement being the length of the legs, excluding the tip. To order a burner, add the tip letter code to the order code of the burner size, which are as follows:

<table>
<thead>
<tr>
<th>Type</th>
<th>Leg Length</th>
<th>Shape</th>
<th>Order Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye</td>
<td>1”</td>
<td>Straight</td>
<td>JA211</td>
</tr>
<tr>
<td>Light Duty</td>
<td>2”</td>
<td>Straight</td>
<td>JA321</td>
</tr>
<tr>
<td>Light Duty</td>
<td>3”</td>
<td>Straight</td>
<td>JA331</td>
</tr>
<tr>
<td>Light Duty</td>
<td>5”</td>
<td>Straight</td>
<td>JA351</td>
</tr>
<tr>
<td>Light Duty</td>
<td>5”</td>
<td>Angled</td>
<td>JA357</td>
</tr>
<tr>
<td>Light Duty</td>
<td>7”</td>
<td>Straight</td>
<td>JA371</td>
</tr>
<tr>
<td>Light Duty</td>
<td>7”</td>
<td>Curved</td>
<td>JA376</td>
</tr>
<tr>
<td>Heavy Duty</td>
<td>5”</td>
<td>Straight</td>
<td>JA451</td>
</tr>
<tr>
<td>Heavy Duty</td>
<td>7”</td>
<td>Straight</td>
<td>JA471</td>
</tr>
</tbody>
</table>

CARE OF BURNERS

If used properly, and with care, your burners will last a considerable time. Observance of the following guidelines will preserve the life of your burner.

- Before use inspect burners for damage or distortion. In particular the legs should not touch.
- Whenever possible use the burner in short bursts rather than continuous operation.
- Do not bend the tips of burners or use burners with damaged tips as this can lead to disintegration of the burner tip whilst in use.

ATTENTION

- CAUTERY BURNERS BECOME HOT DURING USE. To avoid burning, remove from holder when cool, and hold plastic block when removing.
- The different sizes and shapes of burners require different levels of current to heat them, only heat burners to the minimum useable level. OVERHEATING WILL SEVERELY SHORTEN THE LIFE OF A BURNER AND MAY CAUSE THE TIP TO MELT ONTO THE PATIENT OR USER.
- NEVER use light duty burners with a heavy duty transformer or vice versa.
- R.B.Medical recommends the use of Sterile Pads JB105 to remove biological residue from the tips when in use.

CLEANING AND STERILISATION

Refer to document: - SI00024

Manufacturer -
RB Medical Engineering Ltd, 2 Alton Road Ind. Est. Ross-on-Wye, Herefordshire. HR9 5NS.
Tel: +44 (0) 1989 563958 Fax: +44 (0) 1989768267

WARRANTY

There is NO warranty with Cautery Burners.
Reprocessing guidelines for RB Medical reusable medical devices

Manufacturer: RB Medical Engineering Ltd
Method: Autoclave

Device: Cautery Burners

| WARNINGS: | UTRASONIC CLEANING IS NOT RECOMMENDED FOR ANY OF THESE PRODUCTS. DO NOT IMMERSE OR SOAK THESE PRODUCTS. |
| Limitations on reprocessing: | Do not exceed 70 cycles of autoclave for these products. |
| **INSTRUCTIONS:** | |
| Point of use: | We recommend the use of RB Medical cages with silicone support strips. Immediate removal of all biological residues from cautery burners. |
| Preparation for decontamination: | - Wipe all surfaces to remove biological residue
- Non abrasive cleaning pads should be used (except on Burner Tips)
- Brushes should not be used to clean surfaces
- No special tools are required |
| Cleaning: Automated | These instruments can be cleaned/disinfected in approved washers (guidelines are available in CFPP01-01 and Welsh 01-01) 90° - 95°C for 1 minute and should reach Aₒ Value of 600. A PH neutral detergent is recommended but the device can withstand a pH of ≤ 10. |
| Cleaning: Manual | Only for preparation for autoclaving |
| Disinfection: | Chemical Soaking is not recommended. |
| Drying: | Care must be taken to ensure that the instrument is dried thoroughly before storage. When drying do not exceed 120°C. |
| Maintenance, Inspection and Testing: | Before autoclaving
- remove all biological residue
Before re-assembling
- check for damage
- check mechanical function of burners |
| Packaging: | Burners can be sterilised in wrapped cycle to local protocol. |
| Sterilisation: | Autoclave in approved autoclaves. 134°C - 137°C for three and half minutes 2.25 bar. Do not exceed a temperature of 137°C. Cleaning and sterilising guidelines are available in CFPP01-01 and Welsh HTM 01-01. |
| Storage: | There are no manufacturer’s limitations on storage. |
| Additional Information: | When sterilising multiple instruments in one autoclave cycle ensure that the sterilizer’s maximum load is not exceeded. |
| Contact: | RB Medical Engineering Ltd, Alton Road Industrial Estate, Ross-on-Wye, Herefordshire, HR9 5NS, Tel: 01989 563958 Fax: 01989 768267 E: mail sales@rbmedical.co.uk |

The instructions provided above have been validated by the manufacturer of the medical device as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieve the desired result. This normally requires validation and routine monitoring of the process. Mr. C. Harris, Managing Director, RB Medical Engineering Ltd

REF: SI00024
Issue 5
Date issued: 2.10.14
Reprocessing guidelines for RB Medical reusable medical devices

Manufacturer: RB Medical Engineering Ltd
Method: Autoclave

Product: Cautery Handles and Cables - various materials.

| WARNINGS: | ULTRASONIC CLEANING IS NOT RECOMMENDED FOR ANY OF THESE PRODUCTS. DO NOT IMMERSE OR SOAK THESE PRODUCTS. |
| Limitations on reprocessing: | Do not exceed 70 cycles of autoclave for these products. |

INSTRUCTIONS:

Point of use: We recommend the use of RB Medical cages with silicone support strips. Immediate removal of all biological residues from handles and cables is essential to prevent them becoming encrusted. Do not immerse handles only wipe with damp cloth.

Preparation for decontamination:

- Wipe all surfaces to remove biological residue
- Non abrasive cleaning pads should be used
- Brushes should not be used to clean surfaces
- No special tools are required

Cleaning: Automated
These instruments can be cleaned/disinfected in approved washers (guidelines are available in CFPP01-01 and Welsh 01-01) 90° - 95°C for 1 minute and should reach AₒValue of 600. A PH neutral detergent is recommended but the device can withstand a pH of ≤ 10.

Cleaning: Manual
Not recommended

Disinfection:
Chemical Soaking is not a preferred method.

Drying:
Care must be taken to ensure that the instrument is dried thoroughly before storage. When drying is achieved as part of a washer disinfector cycle do not exceed 120°C.

Maintenance, Inspection and Testing:
Before autoclaving
- remove all biological residue
Before re-assembling
- check for damage
- check mechanical function of handles/cables

Packaging: Handles/cables can be sterilised in wrapped cycle to local protocol.

Sterilisation:
Autoclave in approved autoclaves. 134°C - 137°C for three and half minutes 2.25 bar. Do not exceed a temperature of 137°C. Cleaning and sterilising guidelines are available in CFPP01-01 and Welsh HTM 2010 01-01. WARNING: The product must be allowed to return room temperature before use.

Storage:
There are no manufacturer’s limitations on storage.

Additional Information:
When sterilising multiple instruments in one autoclave cycle ensure that the sterilizer’s maximum load is not exceeded.

Manufacturer Contact:
RB Medical Engineering Ltd, Alton Road Industrial Estate, Ross-on-Wye, Herefordshire, HR9 5NS, Tel: 01989 563958 Fax: 01989 768267 E: mail sales@rbmedical.co.uk

The instructions provided above have been validated by the manufacturer of the medical device as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieve the desired result. This normally requires validation and routine monitoring of the process. Mr. C. Harris, Managing Director, RB Medical Engineering Ltd

REF: SI0002
Issue 11
Date Issued 2.10.14
ANNUAL SERVICE CONTRACT: Cautery Sets

Annual Service:  
RB Medical will carry out a Safety Test  
Re-calibrate  
Worn or broken parts will be replaced at an additional cost

Report:  
A full service report will be enclosed with each service

Terms:  
RB Medical will undertake to advise customer of annual service due date approximately one month in advance. It will be the responsibility of the customer to arrange for the unit to be returned to RB Medical for service.

Where additional labour and parts are required RB Medical will issue a quotation that must be authorised/ signed by appropriate persons before the work can be undertaken.

Service Charge:  
Please call 01989 563958 to establish a contract/ request a current price.

*RB Medical retains the right to increase the Annual Service Price at any time; in this instance the customer will be advised accordingly but is not bound to accept the amended contract.

IMPORTANT INFORMATION:

*Please note: RB Medical request that all accessories used in conjunction with the cautery machine, are also enclosed & returned for inspection (including handle, leads, cautery burners etc.) All products must be in a sterile/ clean condition. It is the responsibility of the customer to ensure that cautery equipment is sufficiently packaged ready for transport. Insufficient packaging may result in damage to your equipment.