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2. GENERAL ASSEMBLY

2.1. Rocket CRAFT™ DUO-VAC Suction Pump

1. Illuminated O/I Mains Power On/Off
2. Vacuum Control Dial – clockwise to increase, anticlockwise to decrease the set value
3. Vacuum Display mmHg⁻¹
4. Footswitch connection ports
5. Water trap connection port for use with R57685 Rocket Craft Pump Water Trap Sets
6. R57685 Rocket Craft Pump Water Trap Set
7. Medium Vacuum (Standard) 50-250mmHg⁻¹ & High Vacuum 440mmHg⁻¹ foot-switch
2.2. Rocket CRAFT™ Suction Pump

1. Illuminated O/I Mains Power On/Off
2. Vacuum Display mmHg⁻¹
3. High Vacuum (440mmHg-1) control button
4. Vacuum Control – clockwise to increase, anticlockwise to decrease the set value
5. Patient Connection Port, for use with R57685 or R57686 Disposable Rocket Craft Pump Water Trap Sets or Filter Connection Sets
6. R57685 Disposable Rocket Craft Pump Water Trap Sets
7. Medium Vacuum (Standard) 50-250mmHg⁻¹ footswitch connection port
8. Single foot switch
3. GENERAL INSTRUCTIONS

3.1. COPYRIGHT
This manual contains information that is subject to copyright. All rights reserved. This manual should not be photocopied, duplicated or distributed completely or in part without the approval of Rocket Medical plc.

3.2. MODEL NUMBERS:
- Rocket Craft™ Suction Pump Complete (110v) R29654
- Rocket Craft™ Suction Pump Complete (240v) R29655
- Rocket Craft™ Duo Vac™ Suction Pump (240v) R29660
- Rocket Craft™ Duo Vac™ Suction Pump (110v) R29661

3.3. MANUAL REVISION:
Revision 8: New specification based on Rev 7 25/05/10
Revision 9: Updated CSD address graphics 07/06/10
Revision 10: Symbol tables & storage/transport 28/10/11
Revision 11: CE Mark, manufacturer data 21/11/11
Revision 12: Update to consumables info, voltage 01/12/11
Revision 13: Terminology change Low-Medium 05/12/11
Revision 14: Amend voltage statement in Section 4 07/12/11
Revision 15: CE mark amendment 07/12/11
Revision 16: Symbol correction 30/05/12
Revision 17: Correction to annotated images 29/06/12
Revision 18: Update images with new footswitch 30/09/13
Revision 19: Update to latex statement and symbol 06/11/13
Revision 20: Image to clarify footswitch controls 14/11/13
Revision 21: Amend EMC revision 15/04/14
Revision 22: Update to: YOM, consumption, footer 16/07/14
Revision 23: Update to LRQA CE mark 27/08/14
Revision 24: Gauge images, water trap cleaning ins. 17/12/14
Revision 25: Addition of Portuguese language version 01/08/16
Revision 26: Added EMC Tables, Procedure IFU, Labelling and additional warnings 09/05/17
Revision 27: Standards references 23/05/17
Revision 28: Update to Warnings, duty cycle 10/11/17
Revision 29: Update to Warnings, duty cycle 19/12/17
Revision 30: Amend rating specifications 05/01/18
Revision 31: Amend Warranty period & US address 25/02/19

WARNING: READ THIS MANUAL CAREFULLY: Please familiarise yourself with the contents of this manual before attempting to use the device.
Failure to observe these instructions may result in damage to the pump or cause injury to the patient or user.
This device should only be used by suitably qualified personnel.

WARNING: ELECTRIC SHOCK HAZARD.
The equipment is to be used only with electrical systems complying with all IEC, CEC and NEC requirements.

CAUTION: Any adjustment, modification or repairs to the equipment should be carried out by authorised service agents.

Disposal of this device must be undertaken with regard to the WEEE directive (2002/96/EC).
3.4. MANUFACTURER:

Rocket Medical plc
Sedling Road
WASHINGTON
Tyne & Wear
NE38 9BZUK.

3.5. SERVICE AGENTS:

Rocket Craft™ Pumps typically require little routine maintenance; however they must be serviced and calibrated annually at a Rocket Medical plc approved service facility.

Failure to service the pump at the indicated intervals may invalidate the Warranty.

UK & European Service Agents:
Hunter Scientific Limited
Unit 1, Priors Hall
Widdington
Saffron Walden
Essex
CB11 3SB
Tel: +44 (0)1799 541 688
Fax +44 (0)1799 541 703
E: service@hunterscientific.com
W: www.hunterscientific.com

UK Customer Services:
Rocket Medical plc. Sedling Road. WASHINGTON. NE38 9BZ. ENGLAND
Tel: +44 (0) 191 419 6988. Fax: +44 (0) 191 419 6989
Email: customerservices@rocketmedical.com

US Office:
Email: usa@rocketmedical.com
Rocket Medical
50 Corporate Park Drive.
Suite 890.
PEMBROKE.
MA. 02359. USA
Tel: +1 781 749 6223
4. SAFETY INSTRUCTIONS

This manual describes the operation and intended use of the device and the associated consumables and it is essential that you use this document to familiarise yourself with the correct function and operation of the device before use.

Failure to follow these instructions may result in serious injury to the patient or operator and can lead to damage or breakdown of the device. In case the device fails during an operation, a replacement device and replacement disposables should be kept within reach so that the operation may be completed.

4.1. PATIENT PROFILE

The expected patient profile is:

- Age: Adult, typically between 18-46 years.
- Sex: Female
- Weight: Not relevant
- Health: Not relevant
- Nationality: Multiple
- PATIENT state: – Sedated or under GA. PATIENT is not USER: not relevant

4.2. MANUAL USAGE:

This manual does not provide a detailed description of the oocyte harvesting procedure and is not intended as a training guide for users inexperienced in the technique.

The device must be used with R57685 Rocket CRAFT™ Water Trap (Patient Connection) Sets. The usage of non-approved tubing or filter sets may impair pump performance, lead to increased risk to patients and harvested oocytes and will invalidate the Warranty.

The water trap sets are designed to prevent fluid contamination of the vacuum pump. If the device has been used with a non-approved filter set or there is any evidence or suspicion that the pump may have been contaminated with fluid during use, it must be removed from service and returned for examination immediately. Please contact your nearest Service Centre for advice.

The use of high vacuum levels may lead excessive fluid flow rates which may result in damage to the oocyte and reduced fertilisation rates. Damage to oocytes in harvesting systems is principally caused by turbulent flow which can lead to physical shearing stresses on the cumulus sufficient to denude or damage the fragile zona (Reeves et al 1989). Flow rate is a function needle set configuration and vacuum applied.

HIGH vacuum setting must only be used to clear blockages from a needle set.

Refer to Table 1 for recommended vacuum setting for given needle set configurations.

Refer all servicing to the manufacturer’s authorised service agent.

Do not use in an area where flammable gases are present.
4.3. USER TRAINING:

Rocket Medical or its authorised distributors and agents can provide end-user training on the preparation, connection, operation and cleaning of the device.

Initial end-user training is recommended on installation with refresher training every 3 years thereafter as required.

Training may include on-site visits, teleconferences, webinars and the provision of training support materials including this manual.

Contact your local Rocket Medical sales office or distributor for further training support. See our website www.rocketmedical.com for details of your local office

End User Training includes:

1. Introduction to the product
   a. Components
   b. Symbols used

2. Setup
   a. Mains supply
   b. Attachment of footswitches and patient connection sets

3. Operation
   a. Vacuum Settings
   b. Footswitch control/operation

4. Contamination control
   a. Cleaning
   b. Use of approved patient connection sets

4.4. SUPPLY VOLTAGE SELECTION

The device operates at a voltage 220-240 VAC @ 50Hz. 40VA or 110VAC @ 60Hz as appropriate to the model.

Ensure that the correct power cord is connected.

4.5. ELECTROMAGNETIC COMPATIBILITY

Rocket CRAFT™ Oocyte Aspiration Pumps comply with the electromagnetic compatibility (EMC) limits for medical devices as specified by BS EN 60601-1-2:2015.

The device must be operated according to the instructions contained in this manual to ensure continued electromagnetic compatibility.

4.6. PACKAGING

The packaging has been designed to allow secure transportation of the pump and its accessories.

After unpacking, re-assemble and retain the packaging for transport for servicing when required.

4.7. POSITIONING and PLACEMENT of the DEVICE

Rocket CRAFT™ Oocyte Aspiration Pumps must be placed on a secure, level surface, away from sources of heat, water splashes, mists or cooling vents. Do not expose to direct sunlight.

Do not expose to flammable gases.

Operating temperature Range: +5°C and +35°C
4.8. **WARNINGS:**

Users should be familiar with and adhere to all warnings, cautions and instructions for use that are labelled on the device and included in the User Manual.

- This device should only be used by, or under the supervision of, appropriately trained personnel and in conjunction with current local clinical practice guidelines.
- To avoid the risk of electric shock this equipment must only be connected to a supply mains with a protective earth.
- The device can be isolated from the mains supply by removal of the mains supply cord from the rear of the equipment.
- The device is not approved for connection to any other device except the Rocket R57685 or R57686 Water Trap/Filter Sets.
- The Rocket R57685/686 set is single use and its instructions for use must be followed at all times.
- Do NOT use the Rocket R57685/686 Aspiration set if the packaging is broken.
- **DUTY CYCLE:** The pump should be operated for 15 minutes ON with a 15 minute period OFF prior to re-operation.
- Do not use in an area where flammable gases are present.
- Regular periodic maintenance of the device is recommended annually.
- Precautions for EMC safety should be observed. The device complies with EN60601-1-2:2015 for use in a Professional healthcare facility however:
  - Electronic equipment in the vicinity of the device may affect its operation and potentially cause unpredictable operation of the device.
  - Wherever possible the device should be distanced from surrounding electromagnetic equipment and cables to this equipment in order to reduce possible electromagnetic interference.
  - The Rocket Craft Pump device power cable should only be connected to a correctly wired receptacle in order to avoid the risk of electrical shock and ONLY use the cable supplied by Rocket Medical.
- When positioning the unit, ensure that access is available to the AC power cable located on the rear of the unit.
- Fluids should not be allowed to enter the device as this may result in damage to the system.
- User should be aware of the status of unit at all times during the procedure.
- Only qualified personnel should service the device and the device must not be opened except by these personnel due to the risk of hazardous electrical shock and premature damage to the device. All service requirements should be referred to a Rocket Medical authorised representative.
- All equipment should be thoroughly cleaned after each use (refer to section 6 Cleaning Guidelines).

**WARNING:** Do not modify this equipment without written authorisation of the manufacturer.

The use of high suction levels may lead excessive fluid flow rates which may result in damage to the oocyte and reduced fertilisation rates. Damage to oocytes in harvesting systems is principally caused by turbulent flow which can lead to physical shearing stresses on the cumulus sufficient to denude or damage the fragile zona ([Reeves et al 1989](#)). Flow rate is a function needle set configuration and the suction applied.

Therefore, the 400mmHg⁻¹ (Max) suction setting must only be used to clear blockages from a needle set and must NOT be used in contact with the patient. Refer to Section 6 for recommended suction setting for given needle set configurations.
### 4.9. SYMBOLS USED ON CRAFT SUCTION & DUO-VAC PUMPS.
These tables describe their respective meanings.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Mains Power ON/OFF" /></td>
<td>Mains Power ON/OFF</td>
</tr>
<tr>
<td><img src="image" alt="This device is Type B" /></td>
<td>This device is Type B</td>
</tr>
<tr>
<td><img src="image" alt="Footswitch connection port" /></td>
<td>Footswitch connection port</td>
</tr>
<tr>
<td><img src="image" alt="Dispose of this device in accordance with WEEE directive (2002/96/EC)" /></td>
<td>Dispose of this device in accordance with WEEE directive (2002/96/EC)</td>
</tr>
<tr>
<td><img src="image" alt="Earthed" /></td>
<td>Earthed</td>
</tr>
<tr>
<td><img src="image" alt="Read the manual before connection and use" /></td>
<td>Read the manual before connection and use</td>
</tr>
<tr>
<td><img src="image" alt="Consult the Instructions for Use" /></td>
<td>Consult the Instructions for Use</td>
</tr>
<tr>
<td><img src="image" alt="Usage Duty cycle: 15 minutes ON followed by 15 minutes OFF" /></td>
<td>Usage Duty cycle: 15 minutes ON followed by 15 minutes OFF</td>
</tr>
<tr>
<td><img src="image" alt="CE Mark" /></td>
<td>CE Mark</td>
</tr>
</tbody>
</table>
4.10. SYMBOLS USED ON R57685 SINGLE USE WATER TRAP

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>⚠️</td>
<td>Read the Instruction for Use before connection and use</td>
</tr>
<tr>
<td>☓️</td>
<td>Device is for Single Use Only</td>
</tr>
<tr>
<td>✂️</td>
<td>Device is sterilised by Ethylene Oxide</td>
</tr>
<tr>
<td>🔴</td>
<td>The device is not manufactured with natural rubber latex</td>
</tr>
<tr>
<td>🔴</td>
<td>Do not use if pack is opened or damaged</td>
</tr>
<tr>
<td>☑️</td>
<td>CE Mark</td>
</tr>
</tbody>
</table>

Read the Instruction for Use before connection and use

Device is for Single Use Only

Device is sterilised by Ethylene Oxide

The device is not manufactured with natural rubber latex

Do not use if pack is opened or damaged

CE Mark
5. GENERAL INFORMATION:

5.1. GENERAL DESCRIPTION:

The Rocket CRAFT™ Oocyte Aspiration Pumps have been developed to provide smooth, low volume vacuum at a pre-determined negative pressure. Vacuum is activated by a foot operated toggle air switch controlled by the surgeon performing the oocyte collection.

The range of vacuum is infinitely variable from 10-250mmHg⁻¹ in medium vacuum mode and at a pre-set 440mmHg⁻¹ in high vacuum mode.

Rocket CRAFT™ Oocyte Aspiration Pumps either a R57685 Disposable Rocket CRAFT™ Water Trap Sets supplied separately, sterile and for single use.

5.2. INDICATIONS:

For the generation of medium vacuum between 10-250 mmHg⁻¹ to permit the aspiration of follicular fluid, oocytes and ovarian fluid as part of the treatment of infertility relating to IVF and other gynaecological procedures.

This device may only be used by, or under the supervision of, appropriately trained personnel in conjunction with clinical practice guidelines such as those published by the National Institute of Clinical Excellence (NICE 2004) and the Human Fertilisation & Embryology Authority. (HFEA April 2010 – as amended).

5.3. CONTRAINDICATIONS:

Not intended for use where ovarian aspiration or the aspiration of ovarian fluid is contraindicated. For short term operation only. NOT for continuous drainage.

5.4. REFERENCES:

Craft I, Diahanbakch O. McLeod F et al ‘Human pregnancy following oocyte and sperm transfer to the uterus.’ Lancet 1992 i 1031-3
6. OPERATING THE PUMP

Rocket CRAFT™ Suction Pump:

1. Unwrap the footswitch and attach the air tubing to the ports on the front of the pump casing. The footswitch is normally left attached to unit in daily use unless removal for storage is required.

WARNING: Protect the device from ingress of liquid. Should any liquid enter the device, discontinue use immediately and refer to an authorised service agent.

Rocket CRAFT™ Suction Pump:

2. Unwrap the footswitch and attach the air tubing to the male/female ports on the front of the pump casing. The footswitch is normally left attached to unit in daily use unless removal for storage is required.
1. Connect the correct mains lead to an electrical supply 110-240VAC 50-60Hz. Model dependant

2. Turn the power switch 0-I (front panel) to on. The green light illuminate.

3. Using aseptic technique, un-pack the R57685 Rocket CRAFT™ Water Trap Set and attach the short tubing length to the water trap connection point

4. Pass the longer patient connection tube into the operative field. The R57685 water trap set is for single patient use and must be replaced for each patient.

5. Refer to Table 1 for recommend vacuum values for various needle and tube set combinations

6. Occlude the patient tube set, distal to the water trap.

7. Activate the foot switch

8. Rotate the control knob clockwise to increase to the desired value on the gauge

9. To decrease the set value: rotate anticlockwise.

10. When the desired value is reached, release the footswitch and tubing set occlusion.

11. Repeat from Step 8 to ensure stable value.
6.1. TABLE 1 RECOMMENDED VACUUM SETTINGS

<table>
<thead>
<tr>
<th>Tube Set Length</th>
<th>Single Lumen</th>
<th>Double Lumen</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>16G</td>
<td>17G</td>
</tr>
<tr>
<td>55cm</td>
<td>80</td>
<td>110</td>
</tr>
<tr>
<td>70cm</td>
<td>90</td>
<td>130</td>
</tr>
<tr>
<td>90cm</td>
<td>100</td>
<td>150</td>
</tr>
</tbody>
</table>

WARNING: Ensure the set vacuum level is appropriate to the patient's needs taking into consideration the needle and tube set configuration.

WARNING: HIGH VACUUM MODE must NOT be used to aspirate oocytes as this may result in damage to the oocyte and lead to reduced fertilisation rates.

12. Connect the patient filter set to a suitable luer fitting (indicated) such as that found on the Rocket Oxford Tube Set found on Rocket Single and Double Lumen Oocyte Aspiration Needles and attach a collection tube to the bung.

If vacuum lines become blocked due to debris or viscous fluids, a temporary high vacuum (440mmHg-1) can be obtained to unblock the needle and tubing set by following the procedures below:

**Rocket CRAFT™ DUO-VAC**

13. To activate the HIGH vacuum, depress the WHITE HIGH VACUUM Pedal – the pump will immediately deliver a vacuum of 440mmHg-1.

**Rocket CRAFT™ Suction Pump**

14. To activate the HIGH vacuum, occlude the RED button and depress the footswitch – the pump will immediately deliver a vacuum of 440mmHg-1.

15. Removing the occlusion will cause the vacuum to revert to its previously set level.
1. If water, media or any other material is allowed to enter the water trap chamber, the pump must be stopped immediately.

2. Replace with a R57685 Rocket Water Trap Set

3. The pump must NOT be operated if fluid is present in the water trap.

4. Should the water trap become full and there is a risk that fluid has entered the pump, it must be withdrawn from service and returned to an authorised service agent for inspection and repair.
6.2. PROCEDURE

Preparation: ROCKET MEDICAL PLC strongly recommend that the position of the uterus and pelvic organs are confirmed by ultrasonography prior to the procedure. Similarly, the presence of developed follicles should have been confirmed by serial ultrasound during the 10 days prior to the procedure. The procedure is normally be carried out under local analgesia and/or supplemented light sedation. General anaesthesia may be necessary in very anxious patients.

Follicular Aspiration: It is essential for a successful outcome that oocytes are harvested with the least possible trauma to both patient and ova.

Using aseptic technique:

1. Following the manufacturers guidelines, cover the transvaginal ultrasound probe with a sterile sheath. A small amount of ultrasound gel may be added to improve picture definition.
2. Select a sterile needle guide approved for use with the vaginal ultrasound probe and assemble following the manufacturers instructions.
3. Open the needle pack carefully, taking care not to touch or damage the needle bevel. The use of damaged needles will cause increased discomfort to the patient and may result in loss of the oocyte.
4. Prior to inserting the needle into the needle guide, attach a syringe of flushing media to the flushing port, open the tap and flush the channel with 2ml of media. Close the 2 way tap.
5. Locate the bung/stopper and attach to a sterile sample tube.
6. Connect the tubing connector to patient connection port (see Section 4)
7. Aspire 2-5ml of flushing media into the tube and discard.
8. Assemble the needle into the needle guide following the manufacturers instructions. The diagram above shows a common probe and needle assembly.
9. Set the vacuum level to your personal preference using the values in Table 1 as a guide.
10. Ensure all connections are air tight and the tube set is free from any constrictions as these cause turbulence which greatly increases the risk of oocyte damage.
11. With the patient in lithotomy, introduce the needle/probe assembly into the vagina, advancing into the anterior fornix to visualise each ovary. Once the ovaries have been identified, introduced the needle and advance through the vaginal wall and ovarian stroma into the target follicle.
12. Activate the vacuum pump and aspirate the follicular fluid into the sampling tube. Check microscopically for the presence of an oocyte. If desired, 2-5ml of media can be injected via a flushing limb if fitted to distend the follicle prior to subsequent aspiration. Complete the harvesting from one ovary before commencing the other.
7. CONSUMABLES

WARNING: This device must only be operated with approved consumables which are specifically designed to provide the correct flow rates and vacuum characteristics. Should any liquid enter the device, discontinue use immediately and refer to an authorised service agent.

R57685 Rocket CRAFT™ Water Trap (Patient Connection) Set
glass water trap bottle 2.5m patient connection tube with male luer connector. Supplied sterile, for single use in cartons 10 units.
8. CLEANING THE PUMP CASING

At the end of each clinical session, turn off the device at the front panel and disconnect the device from mains power supply.

Using an aqueous solution of 70% alcohol (IMS or isopropyl BP), moisten a cloth and wipe all external surfaces of the device. If the surface has become contaminated with proteinaceous material, remove with a light detergent solution before surfacing cleaning with alcohol.

Do NOT use a 100% alcohol or any other solvent to clean the device as this may cause damage to the casing surface and display.

Prevent any fluid from entering the device.

9. YEAR OF MANUFACTURE:

Units manufactured before 2014: The year in which the device was manufactured is indicated by the first 2 numbers of the serial number. For example: a serial number starting 11180776 indicates the device was manufactured in 2011.

For units manufactured after 01/04/14, the year of manufacture is shown on the rear rating plate label opposite the model number.

10. RETURNING THE PUMP FOR SERVICE:

All devices to be returned must be prepared as described below for the protection of the servicing team and for safety during transport.

1. Surface clean the pump as described in the Section above.
2. Seal in a plastic bag and seal within a second plastic bag.
3. Place in the original packaging.
4. Enclose the following information:
   - Contact name
   - Centre address
   - Decontamination Certificate
   - Description of the fault or service required
   - Accompanying Order to authorise servicing – contact your local Customer Services Team for details.
### II. STORAGE & TRANSPORTATION:

<table>
<thead>
<tr>
<th><strong>The device must be transported/stored at temperatures between -10°C to +50°C</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The device must be transported/stored at relative humidity levels between 20% to 95%</strong></td>
</tr>
</tbody>
</table>
| **The device must be stored in a clean, dry condition, ideally in its original packaging which should be retained to return the unit for servicing**  
Protect the device from ingress of liquid. Should any liquid enter the device, discontinue use immediately and refer to an authorised service agent |
## 12. OPERATING ENVIRONMENT:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Temperature</strong></td>
<td>The device must be transported in temperatures +5°C to +35°C</td>
</tr>
<tr>
<td><strong>Humidity</strong></td>
<td>The device must be operated at relative humidity levels between 15% to 93%</td>
</tr>
<tr>
<td><strong>Pressure</strong></td>
<td>The device must be operated at ambient pressure levels between 70kPa to 106kPa.</td>
</tr>
<tr>
<td><strong>Fragility</strong></td>
<td>The device is FRAGILE and must be transported in its original packaging to ensure protection. If the original packaging is not available please contact your local Customer Services Agent who will provide replacement packaging.</td>
</tr>
</tbody>
</table>
| **Dimensions** | Weight:  
  - Unit – 1.9Kg  
  - Foot Switch:  
    - 0.57Kg – DUOVAC (plastic)  
    - 0.34Kg – Craft Suction (plastic)  
    - 0.51Kg – DUOVAC (metal)  
    - 0.38Kg – Craft Suction (metal)  

  |  
| **Protection** | Protect the device from ingress of liquid. Should any liquid enter the device, discontinue use immediately and refer to an authorised service agent |
| **Altitude** | This device is intended for use below 2000 meters. |
13. WARRANTY

Rocket CRAFT™ Oocyte Aspiration Pumps are sold by Rocket Medical plc under the warranties set forth in the following paragraphs. Such warranties are extended only with respect to the purchase of the Products directly from Rocket Medical plc as new merchandise and are extended to the first Buyer thereof, other than for resale.

For a period of TWENTY FOUR (24) months from the date of shipment the Products are warranted to be free from functional defects in materials and workmanship and to conform to the description of the Products contained in the operating manual and accompanying labels, provided the same is properly operated under conditions of normal use, that annual maintenance and service is performed at an authorised Rocket Medical plc service facility.

Removal of any QC seal voids the warranty.

The foregoing warranties shall not apply if the Products have been repaired other than by Rocket Medical plc or other than in accordance with written instructions provided by Rocket Medical plc, or altered by anyone other than Rocket Medical plc, or if the Products have been subject to misuse, negligence, or accident.

Rocket Medical plc’s sole and exclusive obligation and Buyer’s sole and exclusive remedy under the above warranties is limited to repairing or replacing, free of charge, at Rocket Medical plc’s option, Products, which are reported to Rocket Medical plc by mail, telephone or email and which, if so advised by Rocket Medical plc, is thereafter returned with a statement of the observed deficiency, not later than seven (7) days after the expiration date of the warranty, to Rocket Medical plc during normal business address, transport charges prepaid and which, upon Rocket Medical plc’s examination, is not found to conform with the above warranties.

Rocket Medical plc shall not be otherwise liable for any damages including but not limited to incidental damages, consequential damages or special damages.

There are no express or implied warranties which extend beyond the warranties herein above set forth. Rocket Medical plc makes no warranty of merchantability or fitness for a particular purpose with respect to the Products or parts thereof.

14. DISPOSAL:

At the end of the service life of the equipment, this device should be disposed of in accordance with WEEE directive (2002/96/EC as amended) and in accordance with local hospital policy and with regard to all applicable regulations, including but without limitation to, those pertaining to human health & safety and care of the environment.
15. TECHNICAL SPECIFICATIONS

15.1. CLASSIFICATION

IEC 60601-1
Type of protection against electric shock: Class I
Degree of protection against electric shock: Type B
Vacuum type: high vacuum/low volume
Suitable for continuous operation.
Not suitable for use in the presence of flammable gases.
Not suitable for use in conditions which expose the device to the ingress of water.
Not suitable for sterilisation

15.2. SPECIFICATIONS

Power Input to Pump: 220-240 VAC @ 50Hz. 40VA
Maximum current: 2.5A
Consumption: 0.6KW/h

Environmental conditions:
- Temperature +5°C to +35°C
- Atmospheric Pressure Range: 700-1060hPA

Dimensions:
- W - 264mm
- H - 124mm
- D - 164mm

Weight:
- Unit – 1.9Kg
- Foot Switch 0.51Kg

Suction Ranges:
- Medium vacuum: -20mmHg to -250mmHg in 20mmHg increments
- High vacuum: -440mmHg

Suction Range Accuracy: ±10%
15.3. EMC Tables:

**Table 1: Guidance and Manufacturer’s Declaration – Electromagnetic Emissions**

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions CISPR 11</td>
<td>Group 1</td>
<td>The Rocket Craft Aspiration Pumps generate RF signals for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF CISPR 11</td>
<td>Class A</td>
<td>Rocket Craft Aspiration Pumps are suitable for use in all establishments, other than domestic and those connected directly to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Harmonic Emissions IEC 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations / flicker emissions IEC 61000-3-3</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>

**Table 2: Guidance and Manufacturer’s Declaration - Electromagnetic Immunity:**

Rocket Craft Aspiration Pumps (the device) is intended for use within the electromagnetic environment specified below. The operator of a device should ensure that it is used within such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic environment Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>+/- 6kV contact +/- 8kV air</td>
<td>+/- 6kV contact +/- 8kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical fast transient burst IEC 61000-4-4</td>
<td>+/- 2kV for power supply lines</td>
<td>+/- 2kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>+/- 1kV differential mode +/- 2kV common mode</td>
<td>+/- 1kV differential mode +/- 2kV common mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>3 A/m</td>
<td>3A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 610004-11</td>
<td>&lt;5% Ut (&gt;95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles &lt;5% UT (&gt;95% dip in Ut) for 5 seconds</td>
<td>&lt;5% Ut (&gt;95% dip in Ut) for 0.5 cycles 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles &lt;5% UT (&gt;95% dip in Ut) for 5 seconds</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the operator of the device requires continued operation during mains interruptions, it is recommended that the device be powered from an uninterruptable power supply.</td>
</tr>
</tbody>
</table>

Note: Ut is the a.c. mains voltage prior to application of the test level.
Table 3: Guidance and Manufacturer’s Declaration - Electromagnetic Immunity

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic environment Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Portable and mobile RF communications equipment should be no closer to any part of the PSU device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conducted Rf</td>
<td>3 Vrms</td>
<td>3Vrms</td>
<td>D=1.2√P</td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td>150 kHz to 80MHz</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3V/m</td>
<td>3V/m</td>
<td>D=1.2√P 80 MHz to 800 MHz</td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td>80 MHz to 2.5 GHz</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Where P is the maximum power output [power rating of the transmitter in watts (W)] according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and/or people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
Table 4: Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Rocket Oocyte Aspiration Pump.

The device is intended for use in the electromagnetic environment specified below. The operator of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Read Maximum Output Power of Transmitter</th>
<th>Separation Distance According to Frequency of Transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td>W</td>
<td>d = 1.2 √ P</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>3.8</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distances d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and/or people.