I. GENERAL ASSEMBLY

1. Touch sensitive Suction Control Dial – clockwise to increase, anticlockwise to decrease the set value
2. Suction Display in mmHg⁻¹
3. Patient connection port – only for use with R57686 Rocket Oocyte Aspiration Pump Patient Connection Sets
4. Power On Indicator LED (Green, 12VDC)
5. Footswitch connection ports
6. User Set Suction Indicator LED (Blue, 50-300mmHg⁻¹)
7. Pre-set (Max) Suction Indicator LED (Orange, 500mmHg⁻¹)
8. Service Indicator LED (Yellow)
9. O/I 12V Power On/Off switch
10. Dual footswitch – air controlled

Not shown:
11. Power Supply Unit (PSU) Model: MPU30B-3
2. GENERAL INFORMATION

2.1. 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.

2.2. MODEL NUMBERS:
Pump: R29700. Power Supply: MPU30B-3

2.3. MANUAL REVISION:
Revision 1: First Release 11/12/09
Revision 2: Update to Tube Set image 15/03/10
Revision 3: Pre-evaluation corrections & update 11/08/10
Revision 4: Correction to pedal designations 16/08/10
Revision 5: Addition of set-up schematic 09/05/11
Revision 6: Update to accuracy statement 19/05/11
Revision 7: Addition of ZDOCK code and © statement 15/06/11
Revision 8: Service intervals 14/07/11
Revision 9: Symbol tables and storage conditions 27/10/11
Revision 10: CE mark, year of manufacture statement 21/11/11
Revision 11: PSU markings, EMC statement added 08/12/11
Revision 12: Addition of Classification statements 20/12/11
Revision 13: Amendment to vacuum type 13/02/12
Revision 14: Amendment to control increments 08/03/12
Revision 15: Updated cover images 07/01/13
Revision 16: Standardisation of accuracy limits 13/08/13
Revision 17: Update to images and latex statement, symbol. 06/11/13
Revision 18: Update: power consumption, YOM, footer 16/07/14
Revision 19: Amend CE mark 27/08/14

2.4. MANUFACTURER:
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2.5. SERVICE AGENTS:
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2.6. GENERAL DESCRIPTION:

The Rocket Oocyte Aspiration Pump has been developed to provide smooth, low volume/high suction (vacuum) at a pre-determined negative pressure. Suction is activated by a foot operated toggle air switch controlled by the surgeon performing the oocyte collection.

The range of suction is variable from 50-300 mmHg\(^{-1}\) and at a pre-set 500 mmHg\(^{-1}\) in ‘Max’ suction mode.

The Rocket Oocyte Aspiration Pump requires a disposable filter set for attachment of the pump to the oocyte collection needle. The filter set is supplied separately, sterile and for single patient use.

You will also require:

- A suitable oocyte aspiration needle such as Rocket SX Single Lumen Oocyte Aspiration Set (R57602-00-90)
- Suitable collection tubes for use with oocyte needle sets such as B.D. Falcon test tube No. 2001F, 17 x 100mm.
- Flushing media

2.7. INTENDED USE

Device for the generation of low volume/high (vacuum) suction of between 50-300 mmHg\(^{-1}\) to permit the aspiration of follicular fluid, oocytes and ovarian fluid as part of the treatment for infertility relating to IVF and other related procedures.

2.8. CONTRAINDICATIONS:

Not intended for use where ovarian aspiration or the aspiration of ovarian fluid is contraindicated. Not intended for surgical suction or other applications.

2.9. CLASSIFICATION

IEC 60601-1

Type of protection against electric shock: Class II

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 fluids.

Not suitable for sterilisation

2.10. REFERENCES:


Craft I, Diahankbch O, McLeod F et al 'Human pregnancy following oocyte and sperm transfer to the uterus.' *Lancet* 1992 i 1031-3


3. 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 maybe completed.

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.

4.1. POWER SUPPLY:

The device is only for use with power supply Model Number: MPU30B-3. Attachment of any other power supply may severely damage the device.

CAUTION: Disconnection from the mains supply can only be achieved with the removal of the mains power lead from the wall socket.

4.2. CONSUMABLES:

The device must only be used with R57686 Rocket Oocyte Aspiration Pump Patient Connection Sets. The use 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 hydrophobic filter sets are designed to prevent fluid contamination of the suction 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.

4.3. TERMINOLOGY:

Throughout this manual the term "suction" is used to denote aspiration of fluid with vacuum or negative pressure. The use of the term ‘suction’ is in observance of the requirements of the ISO6061-1 Standard as amended.

4.4. WARNINGS:

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 500mmHg\(^1\) (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.

Do not use in an area where flammable gases are present.
4.5. SUPPLY VOLTAGE SELECTION
The device operates at a voltage of 12VDC supplied via a universal medical grade power supply unit (PSU).

Input voltage: 12VDC
Universal power supply range 100–240VAC, 50/60Hz. 0/8-0.4W. 0.096KW/h
Ensure that the correct power cord is connected.

4.6. ELECTROMAGNETIC COMPATIBILITY
The Rocket Oocyte Aspiration Pump complies with the electromagnetic compatibility (EMC) limits for medical devices as specified by IEC 60601-1-2:2001. These limits are designed to provide a reasonable degree of protection against harmful interference found in typical medical installations.

Medical electrical equipment requires special precautions regarding EMC and the device must be installed, positioned and operated according to the instructions contained in this manual to ensure continued electromagnetic compatibility.

It is possible that high levels of radiated or conducted radio-frequency electromagnetic interference (EMI) from portable and mobile RF communications equipment or other strong or nearby radio-frequency sources could result in performance disruption of the suction pump.

Evidence of EMC interference may include erratic digital displays, an inability to correctly set the desired suction, the device failing to operate, or other incorrect functioning.
If this occurs, stop using the aspiration pump and contact Customer Services or Rocket Medical authorised distributor.

4.7. PACKAGING
The packaging has been carefully 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.

4.8. POSITIONING and PLACEMENT of the DEVICE
The Rocket Oocyte Aspiration Pump must be placed on a secure, level surface, away from sources of heat, water splashes, mists or cooling vents and with due regard to EMC protection (Section 4.6)

Do not expose to direct sunlight.
Do not expose to flammable gases.
Operating temperature Range: +5°C and +35°C
### 4.9. SYMBOLS USED ON OOCTYE ASPIRATION PUMP.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Image](12 V DC Power ON/OFF.)</td>
<td>This device operates on 12V DC power provided by a separate power supply module supplied with the device. Disconnection from the mains supply can only be achieved with the removal of the mains power lead from the wall socket.</td>
</tr>
<tr>
<td>![Image](This device is Type B)</td>
<td>This device is Type B</td>
</tr>
<tr>
<td>![Image](Connection point for filter set)</td>
<td>Connection point for filter set</td>
</tr>
<tr>
<td>![Image](This device is powered by a Class II power supply unit.)</td>
<td>This device is powered by a Class II power supply unit.</td>
</tr>
<tr>
<td>![Image](Indicates the Service Interval Indicator)</td>
<td>Indicates the Service Interval Indicator</td>
</tr>
<tr>
<td>![Image](Suction Display Touch control symbol.)</td>
<td>Suction Display Touch control symbol.</td>
</tr>
<tr>
<td>![Image](Indicates activation of the pre-set (Max) 500mmHg⁻¹ mode)</td>
<td>Indicates activation of the pre-set (Max) 500mmHg⁻¹ mode</td>
</tr>
<tr>
<td>![Image](Indicates activation of the user set 50-300mmHg⁻¹ mode)</td>
<td>Indicates activation of the user set 50-300mmHg⁻¹ mode</td>
</tr>
<tr>
<td>![Image](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>![Image](CE Mark)</td>
<td>CE Mark</td>
</tr>
</tbody>
</table>
### 4.10. SYMBOLS USED ON POWER SUPPLY UNIT.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>!</td>
<td>Read the manual before connection and use</td>
</tr>
<tr>
<td>⚡</td>
<td>WARNING: Risk of electric shock. The PSU should not be opened</td>
</tr>
<tr>
<td>🏡</td>
<td>Device is only for use indoors</td>
</tr>
<tr>
<td>☐</td>
<td>Class II Power Supply Unit</td>
</tr>
<tr>
<td>➡️ ➤️</td>
<td>12V DC connection polarity</td>
</tr>
<tr>
<td>🗑️</td>
<td>Dispose of this device in accordance with WEEE directive (2002/96/EC)</td>
</tr>
<tr>
<td>🟢</td>
<td>PSU conforms to EN60601-1 &amp; IEC60601-1</td>
</tr>
<tr>
<td>CE</td>
<td>CE Mark</td>
</tr>
</tbody>
</table>

### 4.11. SYMBOLS USED ON R57686 PATIENT CONNECTION SET.

<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>LOT</td>
<td>Batch number for sterile device</td>
</tr>
<tr>
<td>STERILE EO</td>
<td>Device is sterilised by Ethylene Oxide</td>
</tr>
<tr>
<td>✅</td>
<td>The device is not manufactured with natural latex</td>
</tr>
<tr>
<td>CE</td>
<td>CE Mark</td>
</tr>
<tr>
<td>0088</td>
<td></td>
</tr>
</tbody>
</table>
4. OPERATING THE PUMP

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

2. Connect the correct mains lead to the 12V power supply module - Model number: MPU30B-3 and connect to an electrical supply 110-240VAC 50/60Hz. The power supply module is self-regulating to generate 12VDC.

3. Turn the power switch 0-I (rear panel) to on. The green LED (indicated) on the front panel will illuminate.

4. The main display will display an initial value of 100mmHg.

5. Using aseptic technique, un-pack the R57686 Rocket Oocyte Aspiration Pump Filter Set and attach the short length of silicone tubing to the spigot (indicated). The tubing should be a light push-on fit.

6. Pass the longer patient connection tube into the operative field. The filter set is for single patient use and must be replaced for each patient.

NOTE: The hydrophobic filter set is specially designed to prevent ingress of fluid to the pump.

If the filter material becomes contaminated with fluid it will occlude thereby protecting the pump mechanism. Immediately replace the filter set if it becomes contaminated and between every patient.

The pump must NOT be operated without the correct filter set attached.

Operation without the correct filter set will invalidate the Warranty.
7. On Start-Up, the pump is pre-set to 100mmHg⁻¹ suction. To increase this value, use a circular motion, lightly drawing a finger clockwise over the outer zone of the control dial in the direction of the arrows.

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

9. The active dial zone will sense the motion and increase the display in 5mmHg⁻¹ increments.

10. To decrease the set value, use an anticlockwise circular motion.

11. When the desired value is reached, hold the finger still for 2 seconds when an audible ‘beep’ will confirm the new setting.

12. If the new setting is not correctly saved, the value will return to its previous set value in 10 seconds.

13. If the new value has not been stored, repeat from #7.

### 4.1. TABLE 1 Recommended Suction Settings

<table>
<thead>
<tr>
<th>Tube Set Length</th>
<th>Single Lumen 16G</th>
<th>Single Lumen 17G</th>
<th>Double Lumen 16G</th>
<th>Double Lumen 17G</th>
</tr>
</thead>
<tbody>
<tr>
<td>55cm</td>
<td>80</td>
<td>110</td>
<td>130</td>
<td>150</td>
</tr>
<tr>
<td>70cm</td>
<td>90</td>
<td>130</td>
<td>150</td>
<td>170</td>
</tr>
<tr>
<td>90cm</td>
<td>100</td>
<td>150</td>
<td>170</td>
<td>190</td>
</tr>
</tbody>
</table>

14. 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.

15. The luer connection is also suitable for connection to other standard ISO 6% luer taper adaptors and fittings.
16. The footswitch control operates on a toggle switch. Depress a pedal once for ON and depress again for OFF. A tone will sound to indicate activation of the footswitch.

17. To activate the suction pump to deliver the set value – depress the WHITE pedal once.

18. Once activated, the pump will commence to deliver the suction level previously set. The display indicates the actual suction set by the user.

19. The blue LED will illuminate and flash rapidly to confirm suction (50-300mmHg) is active.

20. To stop suction, depress the pedal once again. The pump will immediately stop and vent to air and the user set suction LED will go out.

21. To activate the pre-set Max suction, depress the BLACK Pedal once – the pump will immediately deliver a nominal suction of 500mmHg.

22. Both suction indicator LED’s will illuminate.

23. To stop max suction, depress the BLACK pedal once or depress the WHITE pedal to continue to evacuate at the previously set suction level.
4.2. Pump Set-Up Procedure Schematic

- Check BLUE Pump LED (NO)
  - Activate WHITE foot switch
  - Track dial L&R to set required value
  - Display HLD, wait for tone to SET

- Check display returns to set value (NO)
  - Activate BLACK foot switch
  - Check BLUE LED Pump sound
  - Check display to -50mmHg
  - Attach foot switch leads

- Attach both foot switch leads (NO)
  - Attach power cable
  - Power on

- READY FOR USE (Attach Filter Set)
5. CONSUMABLES

<table>
<thead>
<tr>
<th>Description</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rocket Oocyte Aspiration Pump Patient Connection Set</td>
<td>R57686</td>
</tr>
<tr>
<td>5µm filter set, 2.5m patient connection tube with male luer connector. Supplied sterile, for single use in cartons 10 units.</td>
<td></td>
</tr>
</tbody>
</table>

5.1. Disposal:

This device should be handled and disposed of 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.

WARNING: This device must only be operated with approved consumables which are specifically designed to provide the correct flow rates and protect the device from ingress of liquid.

Should any liquid enter the device, discontinue use immediately and refer to an authorised service agent.
6. CLEANING THE PUMP CASING

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

Using an aqueous 70% alcohol solution (eg. IMS or isopropyl BP) solution, 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 an alcohol solution.

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.

7. SERVICE INDICATOR

Service intervals are based on 1000 hours of pump operating time measured when the unit is providing suction. This equates to approximately 3000 aspiration cycles before the pump requires servicing.

The Service Indicator LED (arrowed) will remain illuminated indicating the pump now requires servicing. After 50 hours of usage without servicing, the Service Indicator will flash continuously indicating servicing is now overdue.

Illumination of the service indicator does not inhibit pump function.

Once illuminated, the pump must be returned for servicing as soon as possible.

8. 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 Section 8 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
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. STORAGE:

The device must be stored and operated in temperatures +5°C to +35°C.

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.

11. TRANSPORTATION:

The device must be transported in temperatures +5°C to +35°C.

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.

Dimensions:

- W - 248mm
- H - 86mm
- D - 194mm

Weight:

- Unit - 2.56Kg
- Foot Switch 0.51Kg

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

Rocket 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 twelve (12) 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.

13. DISPOSAL:

At the end of the service life of the equipment, this device should be handled and disposed of 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.
14. TECHNICAL SPECIFICATIONS

14.1. CLASSIFICATION

IEC 60601-1

Type of protection against electric shock: Class II
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

14.2. SPECIFICATIONS

Power Input to Pump: 12VDC
Universal Power Supply: 100 - 240VAC @ 0.8-0.4W
Consumption: 0.096 KW/h
Frequency: 50/60 Hz
Maximum current: 2.5A @ 12V
Environmental conditions: +5°C to +35°C
Service interval: 1000hrs of pump operation.

Dimensions:
- W - 248mm
- H - 86mm
- D - 194mm

Weight:
- Unit - 2.56Kg
- Foot Switch 0.51Kg

Suction Ranges:
- User Set: -50mmHg to -300mmHg \(^1\) in 5mmHg increments
- Pre-set: -500mmHg - nominal

Suction Range Accuracy: ±10% at operating range: 100-500mmHg \(^1\)