Rocketmedical

OPERATORS GUIDE

Rocket® CRAFT™
and
DUOVAC™

Oocyte Aspiration Pumps

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1. CONTENTS

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) 50-250$mmHg^{-1}$ & High Vacuum 440$mmHg^{-1}$ 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) 50-250$mmHg^{-1}$ footswitch connection port
8. Single foot switch

3. GENERAL INSTRUCTIONS

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.

3.1. COPYRIGHT

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 images, patient profile, training	19/12/17
Revision 30	Amend rating specifications	05/01/18
Revision 31	Amend Warranty period & US address & EU Rep	25/02/19
Revision 32	Update to Service Agents & CE marks	19/08/20

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.	CE 1639

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:

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TR2 4BA
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EC REP

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Am Rosengarten 48,
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Germany

4. SAFETY INSTRUCTIONS

***WARNING**:*

This manual contains important information. Please familiarise yourself with these safety instructions before using the device.

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.

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

WARNING:
This device should only be operated by appropriately qualified personnel.

WARNING:
This device must only be operated with approved consumables.

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

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.

***WARNING**:*
Ensure the set vacuum level is appropriate.

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.

WARNING:
No user serviceable parts inside.

Do not use in an area where flammable gases are present.

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WARNING:
Device can cause explosion in the presence of flammable gases.

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

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.

WARNING: ELECTRIC SHOCK HAZARD.
Do not immerse the device.

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.

WARNING:
Device can cause explosion in the presence of flammable gases.

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:

WARNING:
This device must only be operated with approved consumables.

WARNING:
Device can cause explosion in the presence of flammable gases.

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

***WARNING**:*
Ensure the suction level is appropriate.

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).

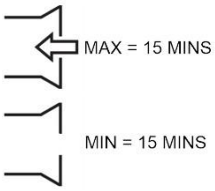
WARNING: Do not modify this equipment without written authorisation of the manufacturer.

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.

	**Mains Power ON/OFF**
	**This device is Type B**
	**Footswitch connection port**
	**Dispose of this device in accordance with WEEE directive (2002/96/EC)**
	**Earthed**
	**Read the manual before connection and use**
	**Consult the Instructions for Use**
	**Usage Duty cycle: 15 minutes ON followed by 15 minutes OFF**
	**CE Mark**

4.10. SYMBOLS USED ON R57685 SINGE USE WATER TRAP

	**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 rube 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, McLeod F. Edmonds K, 'Human embryo transfer technique'. Lancet 1961 ii 1104-5

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

Craft I, (1984) 'Clinical Methodology' British Journal of Hospital Medicine 90-102

Reeves G, Scott R T, et al (1989) Journal of Assisted Reproduction and Genetics Volume 6, Number 6 / December, 1989

6. OPERATING THE PUMP

WARNING:
This device must only be operated with approved consumables.

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.

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.

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

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

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.

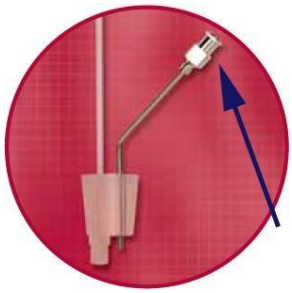
WARNING:
Ensure the set vacuum level is appropriate to the patient's needs taking into consideration the needle and tube set configuration

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

6.1. TABLE 1 RECOMMENDED VACUUM SETTINGS

	Single Lumen		Double Lumen	
	16G	17G	16G	17G
Tube Set Length	**Recommended Vacuum -mmHg**			
55cm	80	110	130	150
70cm	90	130	150	170
90cm	100	150	170	190

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

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.*

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.

WARNING:
This device must only be operated with approved consumables which are specifically designed to provide the correct flow rates and vacuum characteristics

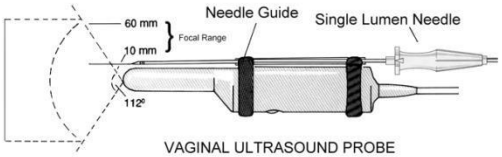
Should any liquid enter the device, discontinue use immediately and refer to an authorised service agent

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.

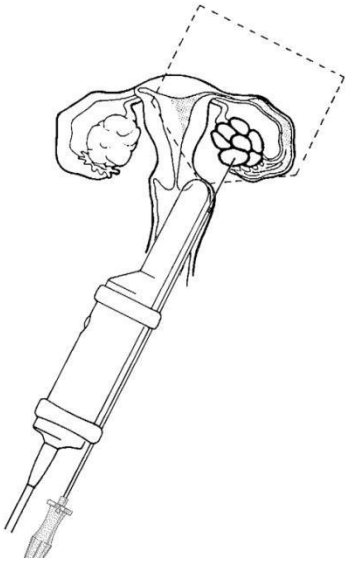
6.2. PROCEDURE

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.



VAGINAL ULTRASOUND PROBE



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 pateint connection port (see Section 4)
7. Aspirate 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

WARNING: ELECTRIC SHOCK HAZARD.
Do not immerse the device.

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.

WARNING:
Do NOT attempt to sterilise the device

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

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 **11**180776 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.

WARNING:
No user serviceable parts inside.

HAZARD:
Do NOT include used consumables as these pose a significant contamination risk

10. RETURNING THE PUMP FOR SERVICE:

IMPORTANT
A decontamination certificate MUST be included with every returned pump.

Repair or servicing cannot be commenced unless the service agent is in possession of this certificate

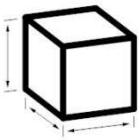
All devices to be returned must be prepared as described below for the protection of the servicing team and for safety during transport.

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

11. STORAGE & TRANSPORTATION:

	The device must be transported/stored at temperatures between -10°C to + 50°C
	The device must be transported/stored at relative humidity levels between 20% to 95%
	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:

	The device must be transported in temperatures +5°C to +35°C	
	The device must be operated at relative humidity levels between 15% to 93%	
	The device must be operated at ambient pressure levels between 70kPa to 106kPa.	
	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 - 264mm • H - 124mm • D - 164mm	**Weight:** • Unit – 1.9Kg • Foot Switch: ○ 0.57Kg – DUOVAC (plastic) ○ 0.34kg – Craft Suction (plastic) ○ 0.51Kg – DUOVAC (metal) ○ 0.38kg – Craft Suction (metal)
	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

Emissions Test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	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.
RF CISPR 11	Class A	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.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

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.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6kV contact +/- 8kV air	+/- 6kV contact +/- 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient burst IEC 61000-4-4	+/- 2kV for power supply lines	+/- 2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1kV differential mode +/- 2kV common mode	+/- 1kV differential mode +/- 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 610004-11	<5% Ut (>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 <5% UT (>95% dip in Ut) for 5 seconds	<5% Ut (>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 <5% UT (>95% dip in Ut) for 5 seconds	Mains power quality should be that 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.

Note: Ut is the a.c. mains voltage prior to application of the test level.

Table 3: Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The device is intended for use within the electromagnetic environment specified below. The customer or the operator of a should ensure that it is used within such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment Guidance
.			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
			Recommended Separation Distance
Conducted Rf	3 Vrms	3Vrms	D=1.2√P
IEC 61000-4-6	150 kHz to 80MHz		
Radiated RF	3V/m	3V/m	D=1.2√P 80 MHz to 800 MHz
IEC 61000-4-3	80 MHz to 2.5 GHz		D=1.2√P 800 MHz to 300 GHz
			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 my occur in the vicinity of equipment marked with the following symbol
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note2: 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.

	Separation Distance According to Frequency of Transmitter m		
Read Maximum Output Power of Transmitter	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
W	d = 1.2 √ P	d = 1.2 √ P	d = 2.3 √ P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	3.8	3.8	7.3
10	3.8	3.8	7.3
100	12	12	23

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.

