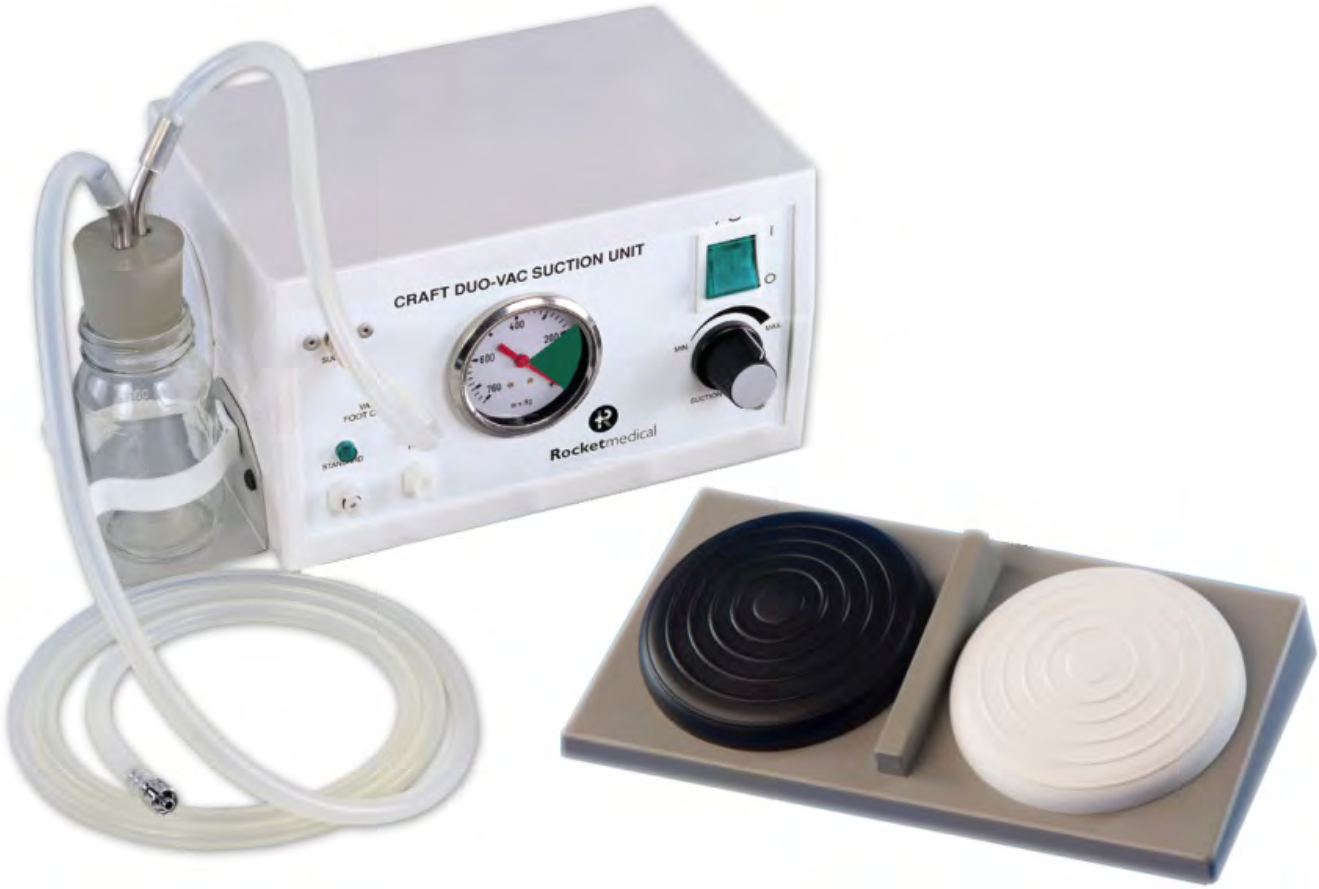
Rocketmedical

SERVICE MANUAL

Rocket CRAFT™
Oocyte Aspiration Pumps



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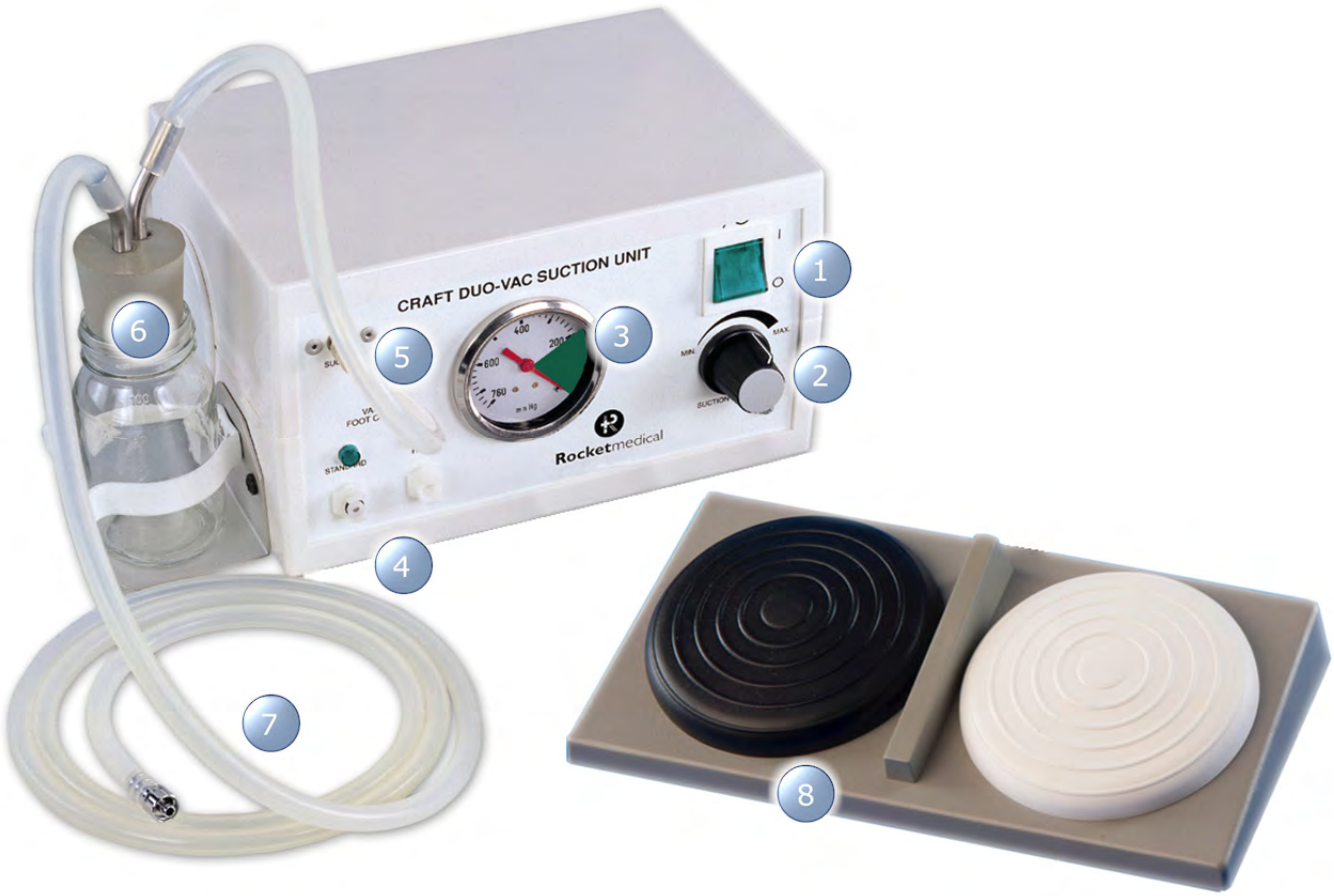
1. CONTENTS

2. GENERAL ASSEMBLY

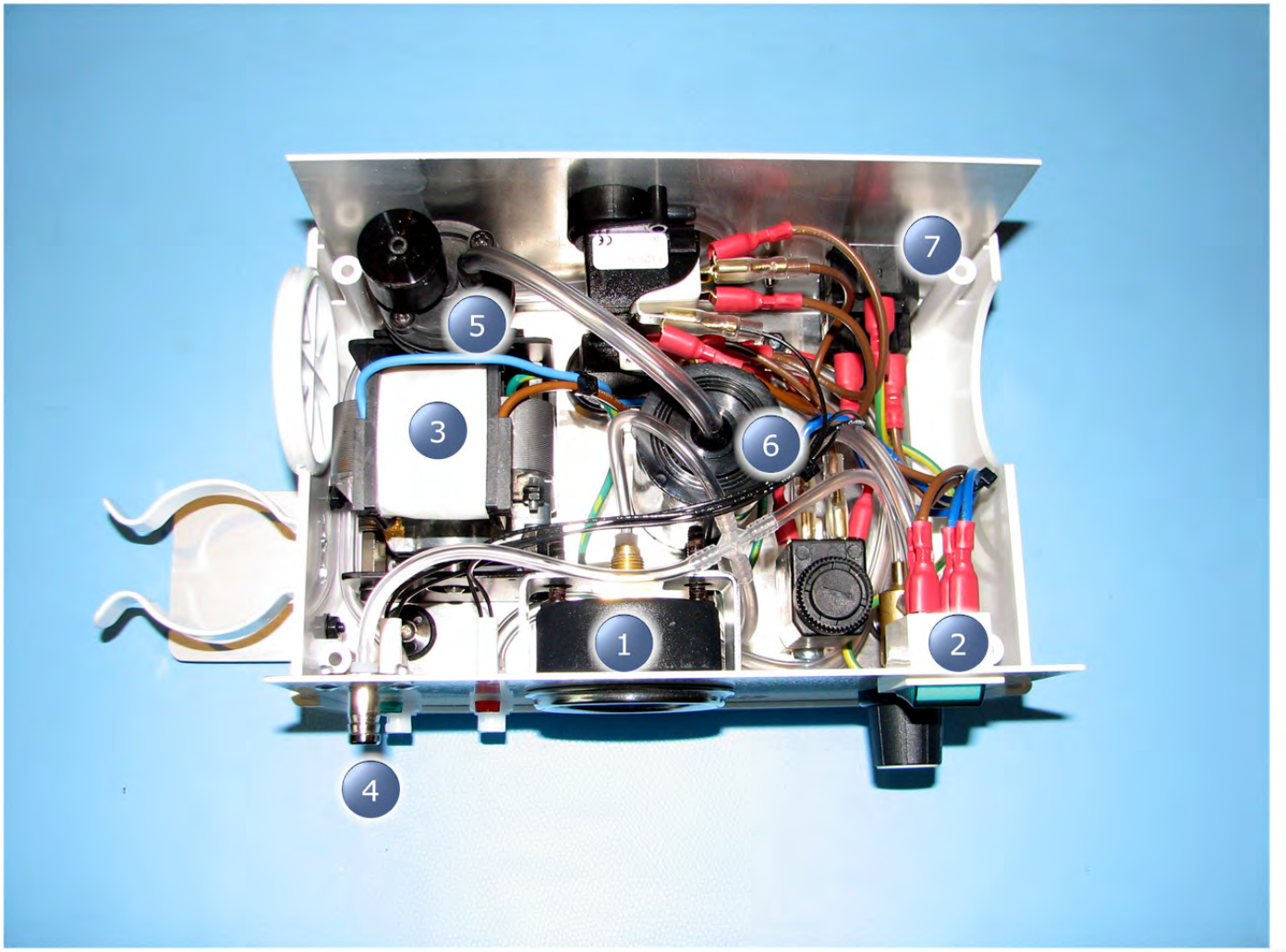
2.1.Rocket CRAFT™ DUO-VAC Suction Pump



Rocket Craft DUOVAC Pump with footswitch supplied after 2013

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 – recommended for use with R57685 Rocket Craft Pump Water Trap Sets
6. Water Trap Set comprising glass bottle, bung, angled connectors, silicone tube set.
   Recommended for use with R57685 Rocket Craft Pump Water Trap Sets
7. Silicone tube set with metal luer connector
8. Footswitch: BLACK: Standard: 50-250$mmHg^{-1}$ and WHITE: High Vacuum 440$mmHg^{-1}$ foot-switch

2.2.Rocket CRAFT™ DUO-VAC Suction Pump – Internal View



1. Vacuum gauge 0-700mmHg – normal range 50-440mmHg^{-1}
2. Illuminated O/I Mains Power On/Off
3. Motor 220VAC 50Hz, 110VAC 60Hz – model dependant
4. Vacuum outlet port
5. Pump head including valve housing
6. Internal silencer with filter chamber
7. Main power input

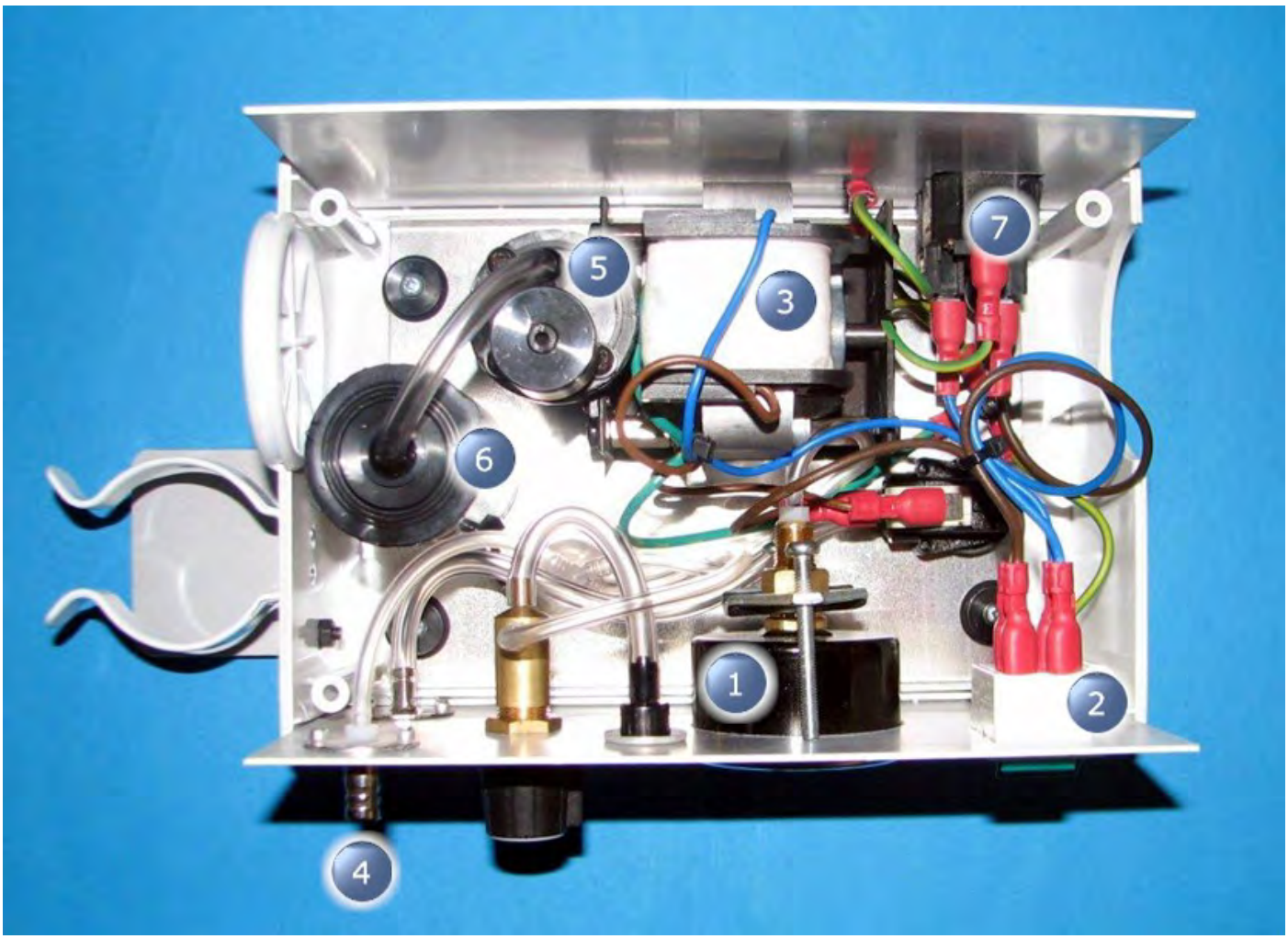
2.3.Rocket CRAFT™ Suction Pump

Rocket Craft Suction Pump with earlier metal footswitch.

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. Water trap connection port – recommended for use with R57685 Rocket Craft Pump Water Trap Sets
6. Water Trap Set comprising glass bottle, bung, angled connectors, silicone tube set.
7. Footswitch connection port
8. Medium Vacuum (Standard) 50-250$mmHg^{-1}$ footswitch
9. Silicone tube set with metal luer connector

Footswitch supplied on Rocket Craft Suction Pumps 2013 onwards

2.4.Rocket CRAFT™ Suction Pump – Internal View



1. Vacuum gauge 0-700mmHg – normal range 50-440mmHg^{-1}
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3. Motor 220VAC 50Hz, 110VAC 60Hz – model dependant
4. Vacuum outlet port
5. Pump head including valve housing
6. Internal silencer with filter chamber
7. Main power input

3. 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 10-200mmHg^{-1} in medium vacuum mode and at a pre-set 400mmHg^{-1} in high vacuum mode.

Rocket CRAFT™ Oocyte Aspiration Pumps require either a water trap set (supplied) or R57685 Disposable Rocket CRAFT™ Water Trap Sets, supplied separately, sterile and for single patient use.

A suitable collection test tube for use with oocyte needle sets is B.D. Falcon test tube No. 2001F, 17 x 100mm.

3.1. INDICATIONS:

For the generation of high vacuum/low volume suction between 10-400 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.

3.2. CONTRAINDICATIONS:

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

3.3. 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

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.

4. GENERAL INFORMATION

4.1. COPYRIGHT

4.2.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**

4.3. MANUAL REVISION:

Revision 1	First Publication	15/02/12
Revision 2	Addition of drawings	29/06/12
Revision 3	Update of tolerance specifications	23/09/13
Revision 4	Update images with new footswitch	30/09/13

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

4.4. MANUFACTURER:

Rocket Medical plc Sedling Road WASHINGTON Tyne & Wear NE38 9BZ UK.	CE 0120

4.5. SERVICE AGENTS:

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

Rocket Craft™ Pumps typically require only annual maintenance; however it is recommended they are serviced and calibrated annually at a **Rocket Medical plc** service facility.

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

Customer Services:
Rocket Medical plc.
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Email: usa@rocketmedical.com

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

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

4.6. SUPPLY VOLTAGE SELECTION

The device operates at a voltage 110V 60Hz or 220-240 VAC @ 50Hz. 0.12A depending on model.

Ensure that the correct power cord is connected.

4.7.ELECTROMAGNETIC COMPATIBILITY

Rocket Craft Suction Pumps comply 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.

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

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

4.9. 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 direct sunlight.

Do not expose to flammable gases.

Operating temperature Range: +5°C and +35°C

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

4.10. SYMBOLS USED ON CRAFT SUCTION & DUO-VAC PUMPS.

These tables describe their respective meanings.

	**Mains Power ON/OFF**
	**This device is Type B**
	**CE Mark**

4.11. SYMBOLS USED ON R57685 PATIENT CONNECTION SET.

	**Read the Instruction for Use before connection and use**
	**Device is for Single Use Only**
	**Device is sterilised by Ethylene Oxide**
	**The device is Latex Free**
	**CE Mark**

5. GENERAL INFORMATION:

5.1. General Description:

The Rocket CRAFT™ Oocyte Aspiration Pumps have been developed to provide smooth, low volume/high 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 10-200mmHg^{-1} in medium vacuum mode and at a pre-set 440mmHg^{-1} in high vacuum mode.

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

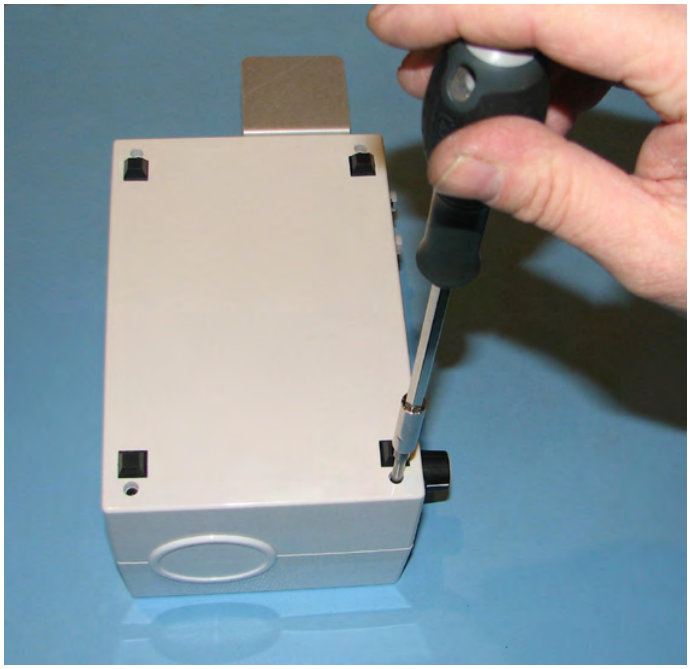
Reeves G, Scott R T, et al (1989) Journal of Assisted Reproduction and Genetics Volume 6, Number 6 / December, 1989

6. ANNUAL SERVICE

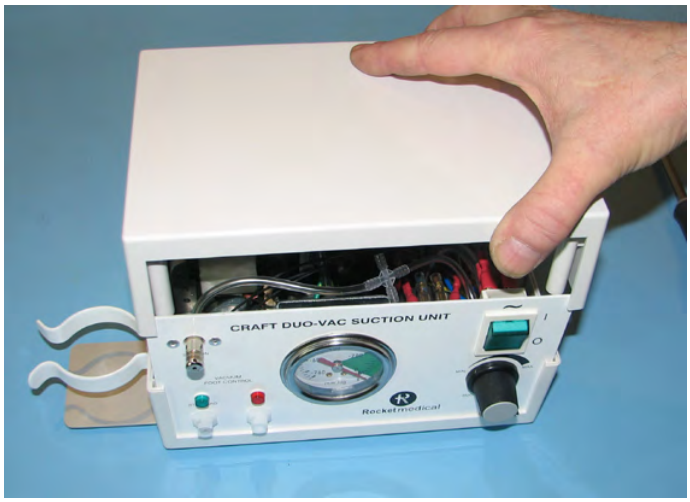
6.1 Replacing the filter element

WARNING: ELECTRIC SHOCK HAZARD.

1. Lay the pump on a clean surface, protecting the casing from scratches.
2. Remove 4 screws from the casing underside and retain

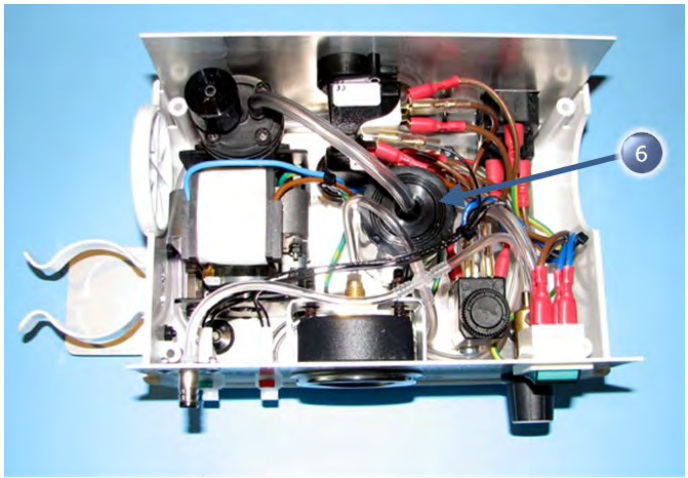


3. Carefully separate the case halves, ensuring the front and rear fascia plates remain located in the lower shell.

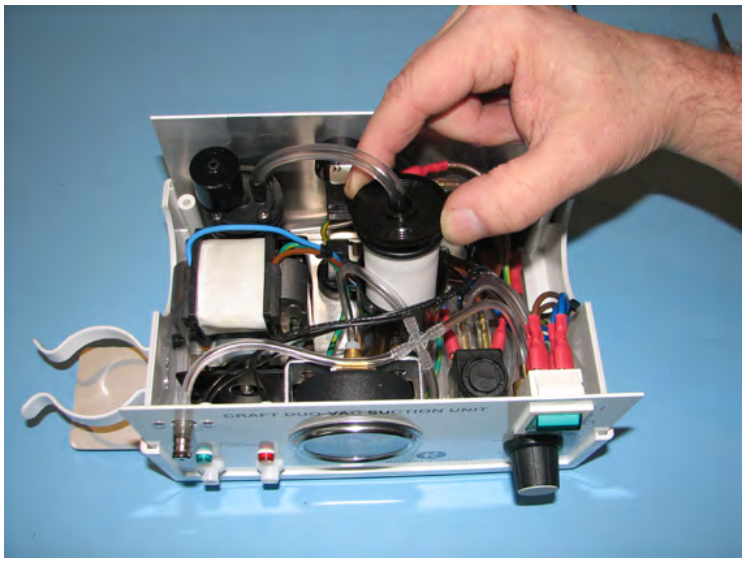


4. Locate filter housing ❻
5. Using fingers, lift the top away from filter chamber.

CAUTION: Avoid the use of sharp tools as these may damage the O' ring.



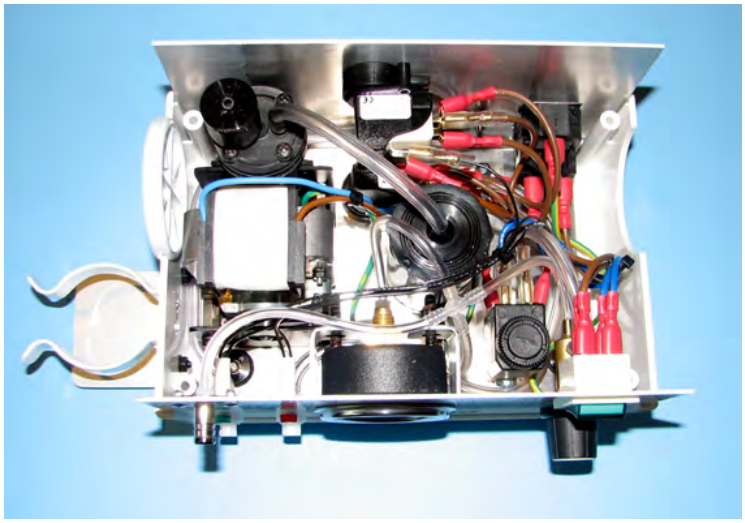
6. Life out the filter assembly and remove the filter.



7. Fit new replacement filter

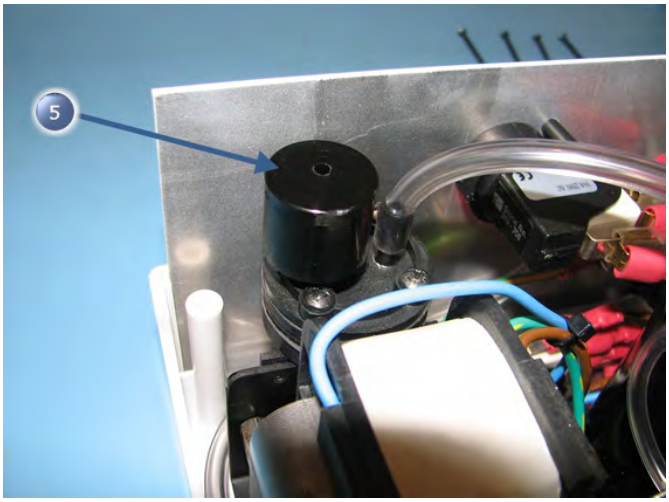
   P/N: E05-000

8. Replace filter, ensuring the top seats securely into the chamber.
9. Avoid trapping or pinching the ‘O’ ring.
10. Check the top is correctly seated.

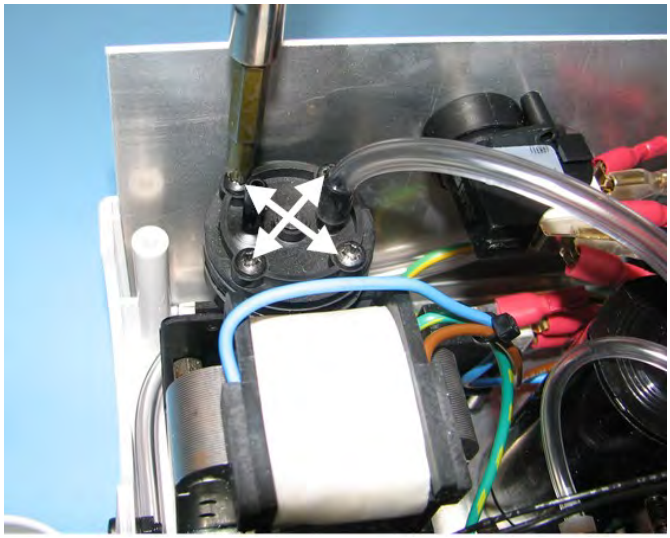


6.2 Replacing the pump valve & diaphragm set

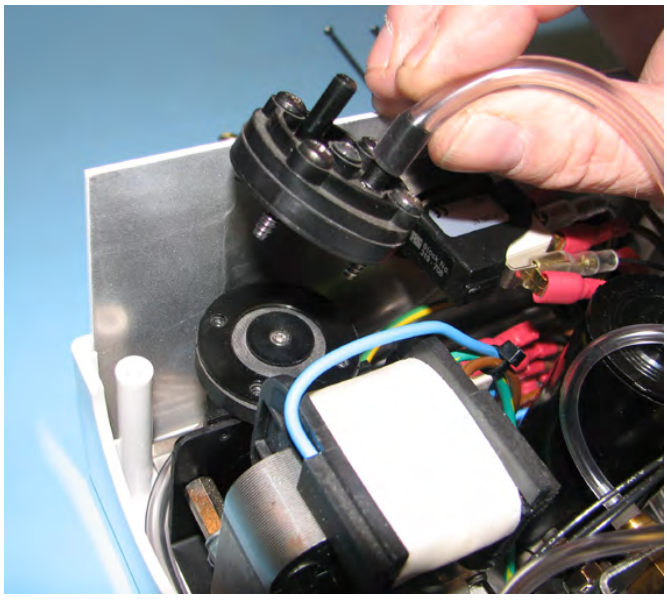
1. Locate the pump silencer housing ❺ and carefully remove with a gentle twisting movement.



2. Using a diagonal method, remove the 4 screws securing the pump valve head.



3. Lift the valve head away from the pump body to reveal the pump head gasket and diaphragm assembly.



4. Undo and remove the centre Pozi drive screw to release the valve plate.

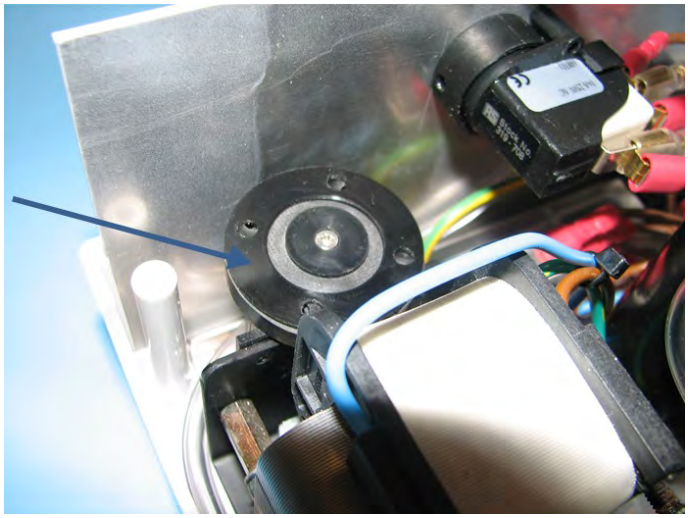
5. Carefully remove valve plate from head moulding with a twisting motion to separate the two halves

6. Valve gasket and valve plate.

Note the orientation of the cut-outs on the valve gasket in relation to the valve plate.

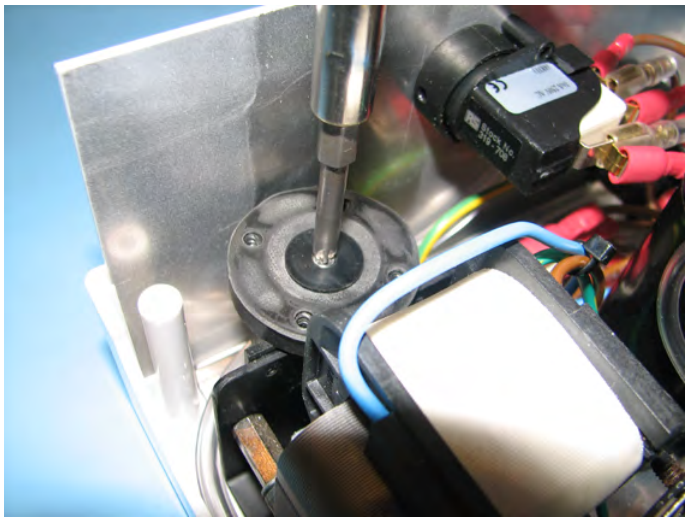
IMPORTANT

7. Lift off pump head gasket and retain safely.



8. Undo and remove the centre Pozi drive screw from the pump diaphragm retaining plate

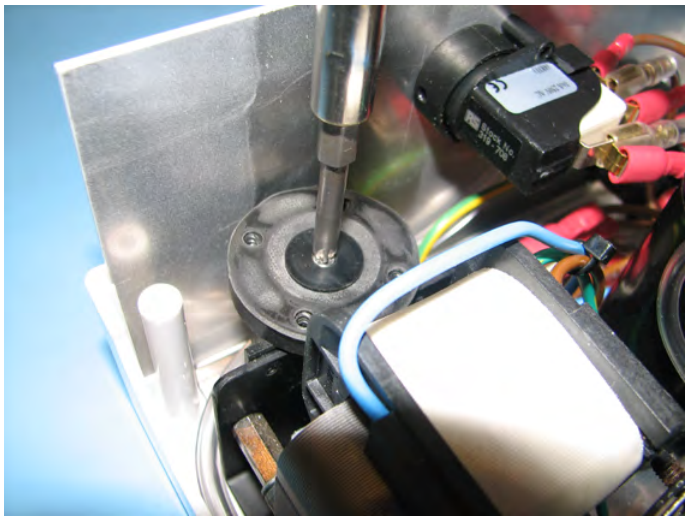
9. Retain retaining plate and screw, discard old diaphragm



10. Replace diaphragm with **P/N: DO1-053**

11. Re-assemble and tighten sufficient to secure the retaining plate.

    DO NOT OVERTIGHTEN or use excessive force



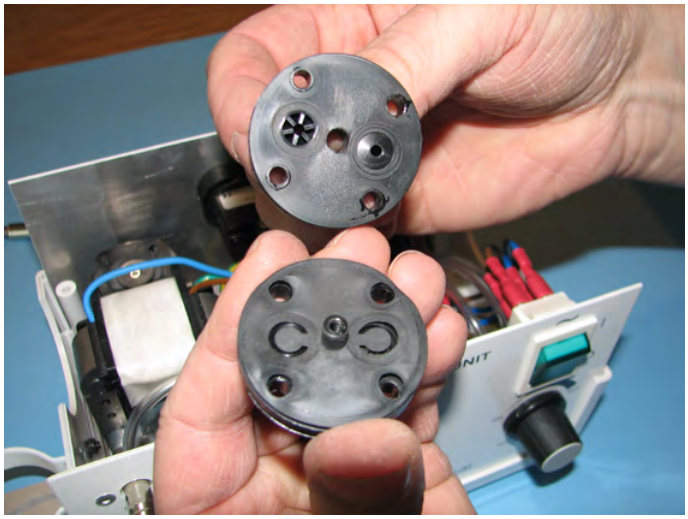
IMPORTANT

6.3 Reassembling the valve set

1. **Ensure the valve plates are orientated as in the image (right).**

VERY IMPORTANT

IF THIS ORIENTATION IS REVERSED, THE VALVE AND PUMP WILL FAIL TO OPERATE



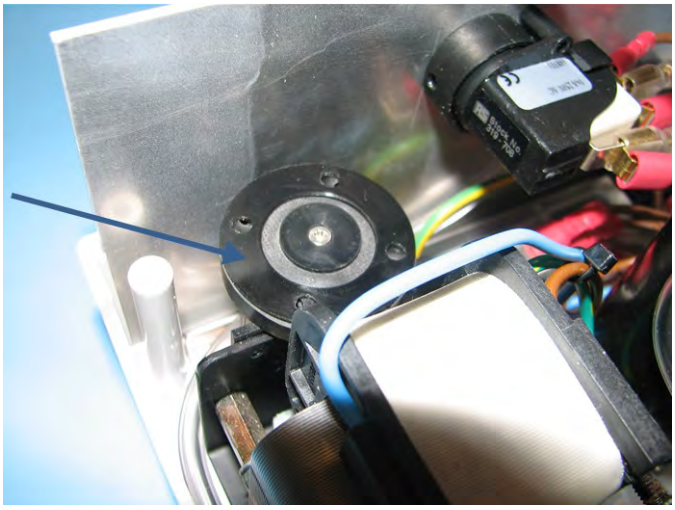
2. Replace the valve gasket with **P/N: VO1-002**

IMPORTANT

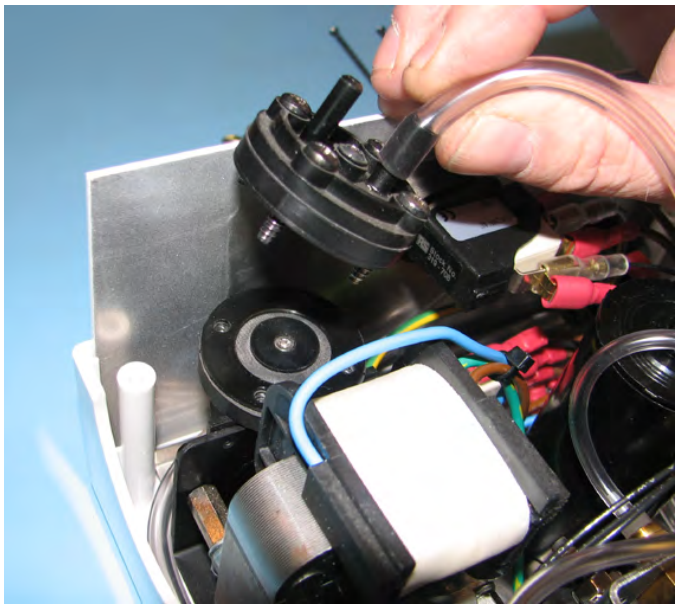
Note the orientation of the cut-outs on the valve gasket in relation to the valve plate

3. Reassemble the valve head and tighten the centre screw

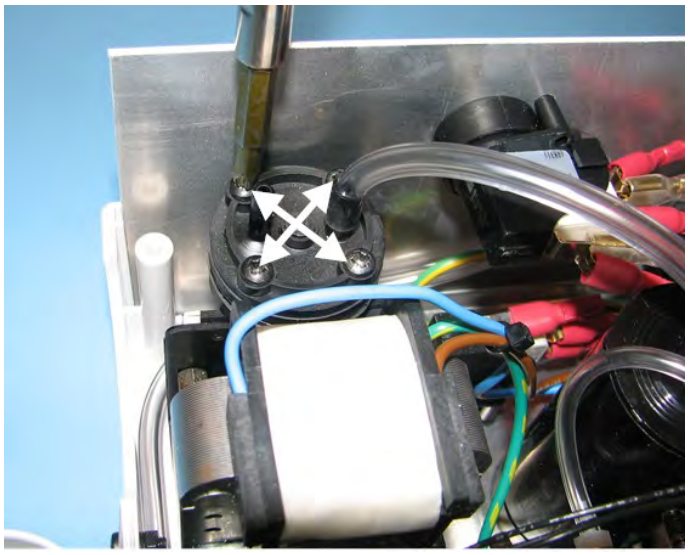
4. Reseat the pump head gasket
   P/N: GO1-001



5. Replace the valve head assembly onto the gasket, ensure the holes are correctly aligned and the gasket with seated correctly.



6. Tighten the valve head screws in a diagonal pattern to ensure the pump head is correctly seated without distortion.



7. Re-fit the pump silencer to the head module.

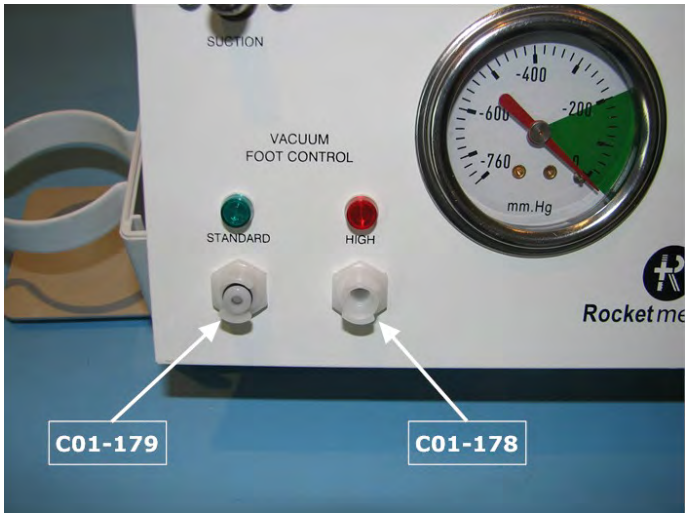
IMPORTANT

7.REPAIRS & REPLACEMENTS

7.1 Replacing the DUO-VAC Footswitch Connectors

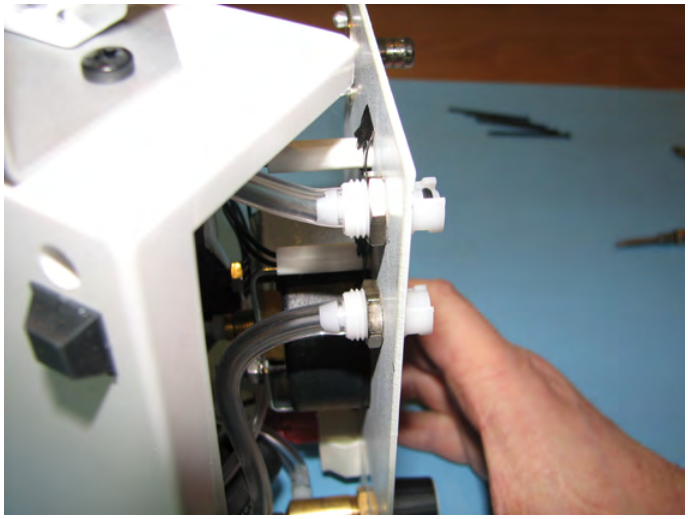
The front panel connectors of the DUO-VAC can be subject to damage through misuse or repeated over-stressing of the retaining clips on connection of the footswitch.

Replacement is a straight forward operation



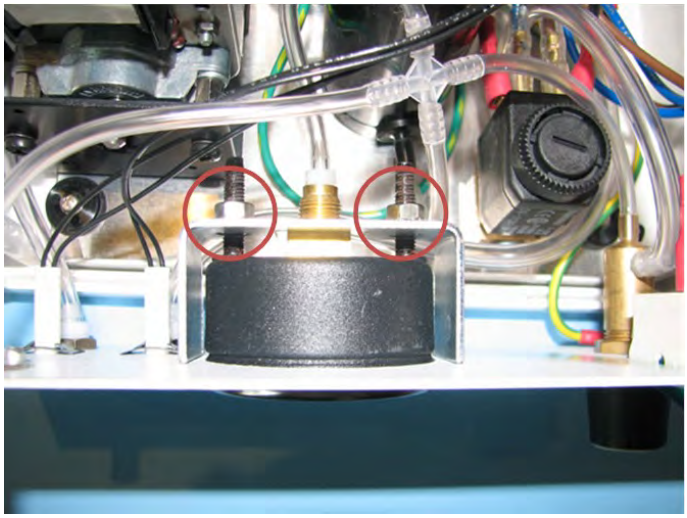
1. Remove the upper casing. (See Section 6)
2. Lift the front panel out of the retaining grooves on the lower case

3. Remove tubing by carefully pulling from connector.
4. Loosen and remove securing nut.
5. Replace connector, locate and tighten securing nut.
6. Re-fit tubing by pushing over connector inlet.



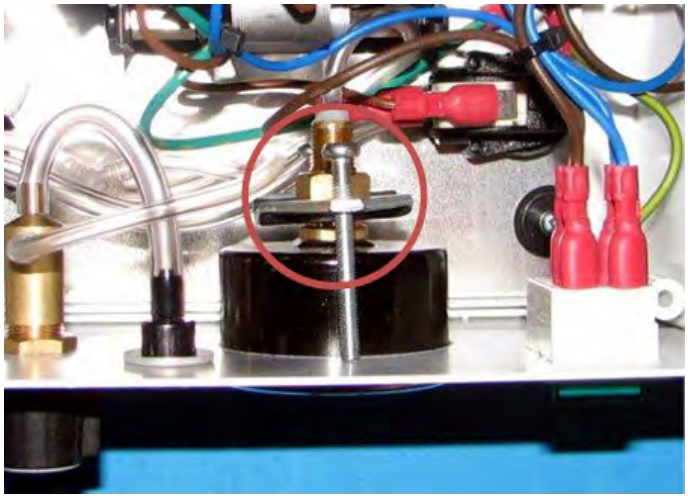
7.2 Replacing the gauge in DUO-VAC & Suction Pump models:

1. Remove the upper casing. (See Section 6)
2. Lift the front panel out of the retaining grooves on the lower case



3. Loosen and remove the securing nuts or screws (ringed right).
4. Draw the gauge through the front panel whilst supporting the mounting plate.
5. Detach the gauge from the centre tube by carefully pulling the tubing from the rear connection.
6. Replace the gauge, reconnect the centre tubing and insert through the front panel.
7. Replace gauge mounting plate and tighten securing nuts or screws.

Rocket Craft DUO-VAC gauge assembly

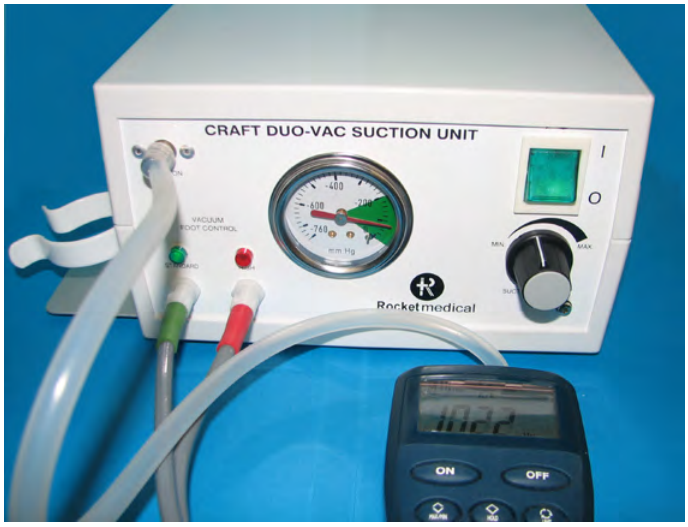


Rocket Craft Suction Pump gauge assembly

8.FINAL TESTING:

1. Final testing should be completed with a validated and independently calibrated electronic vacuum gauge or similar device.
2. Required operating scale: 10-500mmHg in 1mmHg increments
3. Attach the vacuum test gauge as indicated in the image below to the external vacuum port ❹
4. Attach the footswitch as for normal operation.

5. Power device on.
6. Occlude the tube to the test gauge.
7. Activate the Standard Vacuum footswitch – observe the green light is illuminated.
8. Rotate the control knob *clockwise* to increase to the desired value on the gauge. (See table below)
9. To decrease the value: rotate anticlockwise.
10. When the desired value is reached, release the footswitch and tubing set occlusion.
11. Activate the Standard Vacuum footswitch.
12. Record the vacuum registered.
13. Repeat from #6 for each of the test values indicated in the table (right).



***WARNING**: Ensure the vacuum levels are within the specified accuracy tolerance before returning the pump to clinical service.*

Test Value	Indicated vacuum	Test Gauge
50mmHg		
100mmHg		
200mmHg		

Specified accuracy: ±10% of test value

9.FUSE REPLACEMENT:

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

1. Two 0.5A fuses are located in the main power socket mounted on the rear panel	
2. Using a small screwdriver, carefully ease out the fuse carrier to reveal the fuses 3. To ensure continued protection : **REPLACE WITH FUSES OF IDENTICAL RATING**	

IMPORTANT

10. 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 ❶ 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.

WARNING: *Do NOT attempt to sterilise the device*

Prevent any fluid from entering 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*

11. YEAR OF MANUFACTURE:

	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

WARNING: *No user serviceable parts inside.*

12. RETURNING THE PUMP FOR FACTORY REPAIR OR SERVICE:

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

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

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

13. 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

14. TRANSPORTATION:

<table>
<tr><td>  </td><td colspan="2">The device must be transported in temperatures +5°C to +35°C</td></tr>
<tr><td>  </td><td colspan="2">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>
<tr><td></td><td>Dimensions:
W - 264mm
H - 124mm
D - 164mm</td><td>Weight:
Unit – 1.9Kg
Foot Switch:
0.57Kg – DUOVAC (plastic)
0.34kg – Craft Suction (plastic)
0.51Kg – DUOVAC (metal)
0.38kg – Craft Suction (metal)</td></tr>
<tr><td>  </td><td colspan="2">Protect the device from ingress of liquid. Should any liquid enter the device, discontinue use immediately and refer to an authorised service agent</td></tr>
</table>

15. 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 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.

16. TECHNICAL SPECIFICATIONS

16.1.CLASSIFICATION

IEC 60601-1

Degree of protection against electric shock: Type B

16.2. SPECIFICATIONS

Power Input to Pump: 220-240 VAC @ 50Hz. 0.12A

Maximum current: 2.5A

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

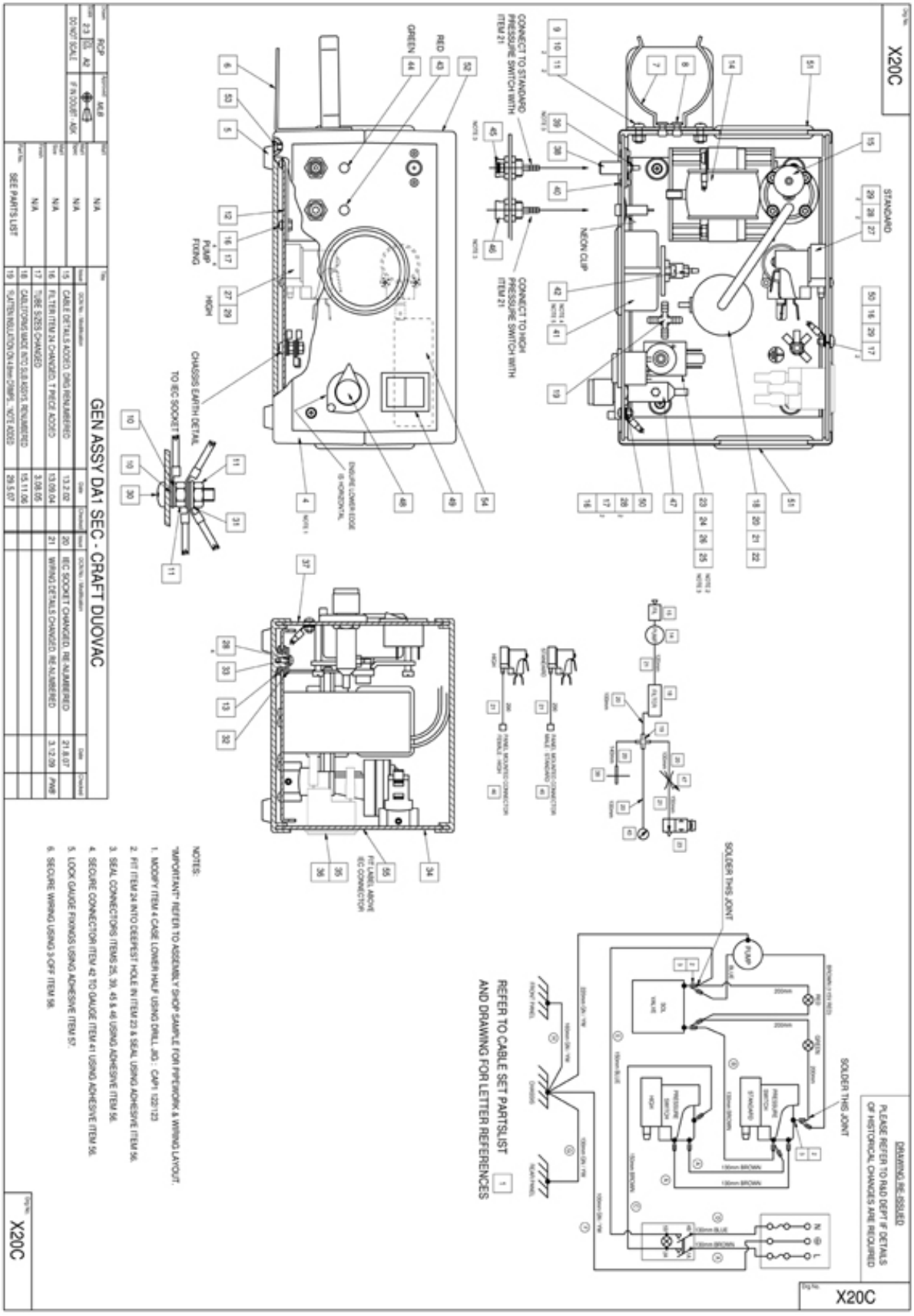
Vacuum Ranges:

- Medium vacuum: -20mmHg to -200mmHg in 20mmHg increments
- High vacuum: -400mmHg

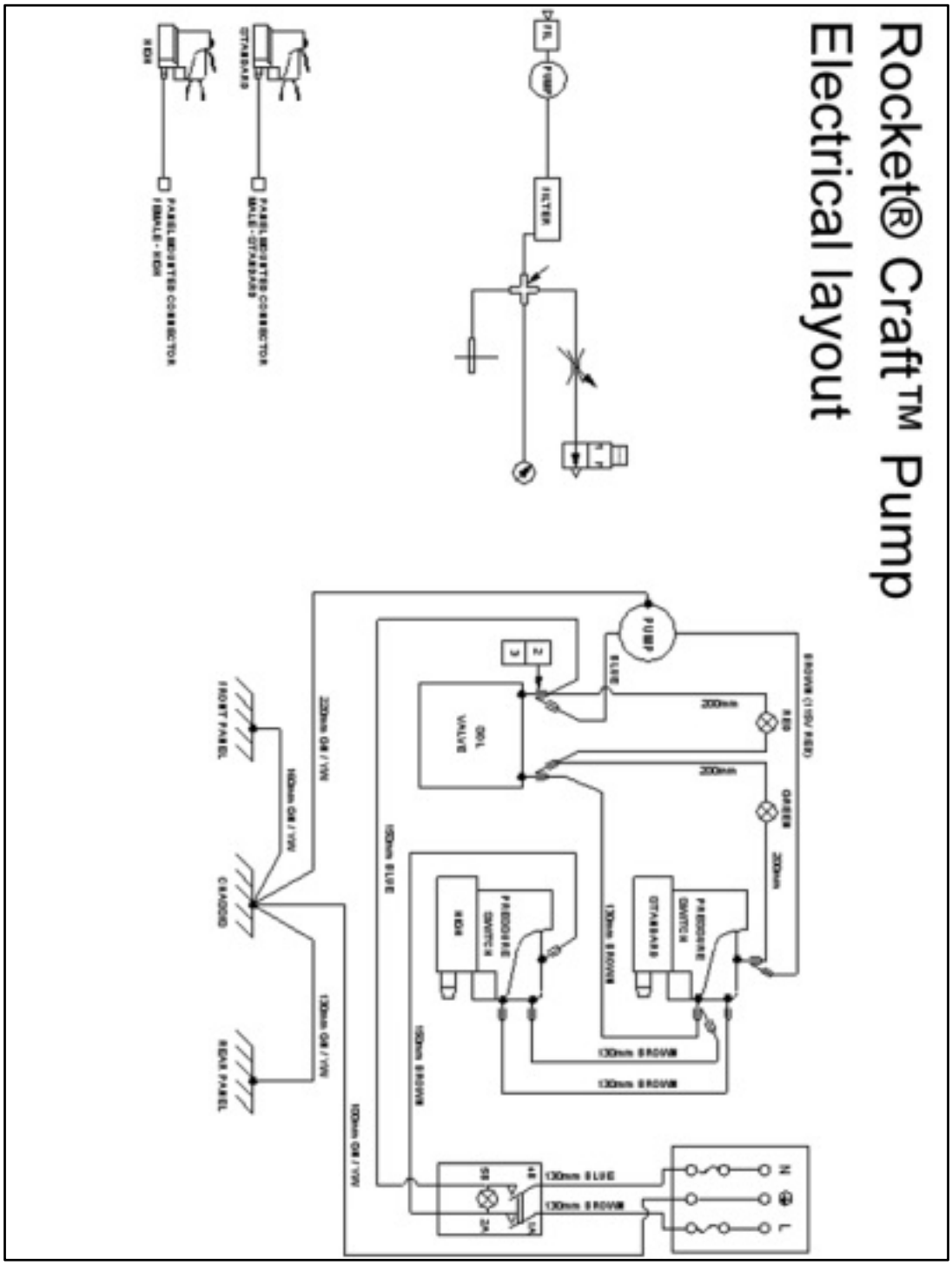
Vacuum Range Accuracy: ±10% of value

17. DRAWINGS

17.1.GENERAL ASSEMBLY:



17.2. GENERAL ELECTRICAL:



17.3.GENERAL INSTALLATION: