

# SERVICE MANUAL

## CRAFT™ and DUO-VAC™

### Oocyte Aspiration Pumps



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## CONTENTS

1. GENERAL ASSEMBLY .....	3
1.1. CRAFT™ DUO-VAC™ SUCTION PUMP .....	3
1.2. CRAFT™ DUO-VAC™ SUCTION PUMP – INTERNAL VIEW .....	4
1.3. CRAFT™ SUCTION PUMP .....	5
1.4. CRAFT™ SUCTION PUMP – INTERNAL VIEW .....	6
2. GENERAL DESCRIPTION: .....	7
2.1. INDICATIONS .....	7
2.2. CONTRAINDICATIONS .....	7
2.3. REFERENCES .....	7
3. GENERAL INFORMATION .....	8
3.1. COPYRIGHT .....	8
3.2. MODEL NUMBERS .....	8
3.3. MANUAL REVISION .....	8
3.4. MANUFACTURER .....	8
3.5. SERVICE AGENTS .....	9
3.6. SUPPLY VOLTAGE SELECTION .....	10
3.7. ELECTROMAGNETIC COMPATIBILITY .....	10
3.8. PACKAGING .....	10
3.9. POSITIONING AND PLACEMENT OF THE DEVICE .....	10
3.10. SYMBOLS USED ON CRAFT™ SUCTION AND CRAFT™ DUO-VAC™ PUMPS .....	11
3.11. SYMBOLS USED ON R57685 WATER TRAP SET FOR CRAFT™ SUCTION PUMPS .....	11
4. ANNUAL SERVICE .....	12
4.1 REPLACING THE FILTER ELEMENT .....	13
4.2 REPLACING THE PUMP VALVE AND DIAPHRAGM SET .....	15
5. REPAIRS AND REPLACEMENTS .....	19
5.1 REPLACING THE CRAFT™ DUO-VAC™ FOOTSWITCH CONNECTORS .....	19
5.2. REPLACING THE GAUGE IN CRAFT™ DUO-VAC AND CRAFT™ SUCTION MODELS .....	20
5.3. BOTTLE BRACKET REPLACEMENT USING SERVICE KIT B02-I90S .....	21
6. FINAL TESTING .....	22
7. FUSE REPLACEMENT .....	23
8. TROUBLESHOOTING .....	24
8.1. DEVICE DOES NOT POWER ON .....	24
8.2. DEVICE DOES NOT PRODUCE SUCTION .....	24
9 . CLEANING THE PUMP CASING .....	25
10. YEAR OF MANUFACTURE .....	25
11. RETURNING THE PUMP FOR REPAIR OR SERVICE .....	25
12. STORAGE .....	26
13. TRANSPORTATION: .....	26
14. WARRANTY .....	27
15. TECHNICAL SPECIFICATIONS .....	28
15.1. CLASSIFICATION .....	28
15.2. SPECIFICATIONS .....	28
16. DRAWINGS .....	29
16.1. GENERAL ASSEMBLY .....	29
16.2. GENERAL ELECTRICAL .....	30
16.3. GENERAL INSTALLATION .....	31

# 1. GENERAL ASSEMBLY

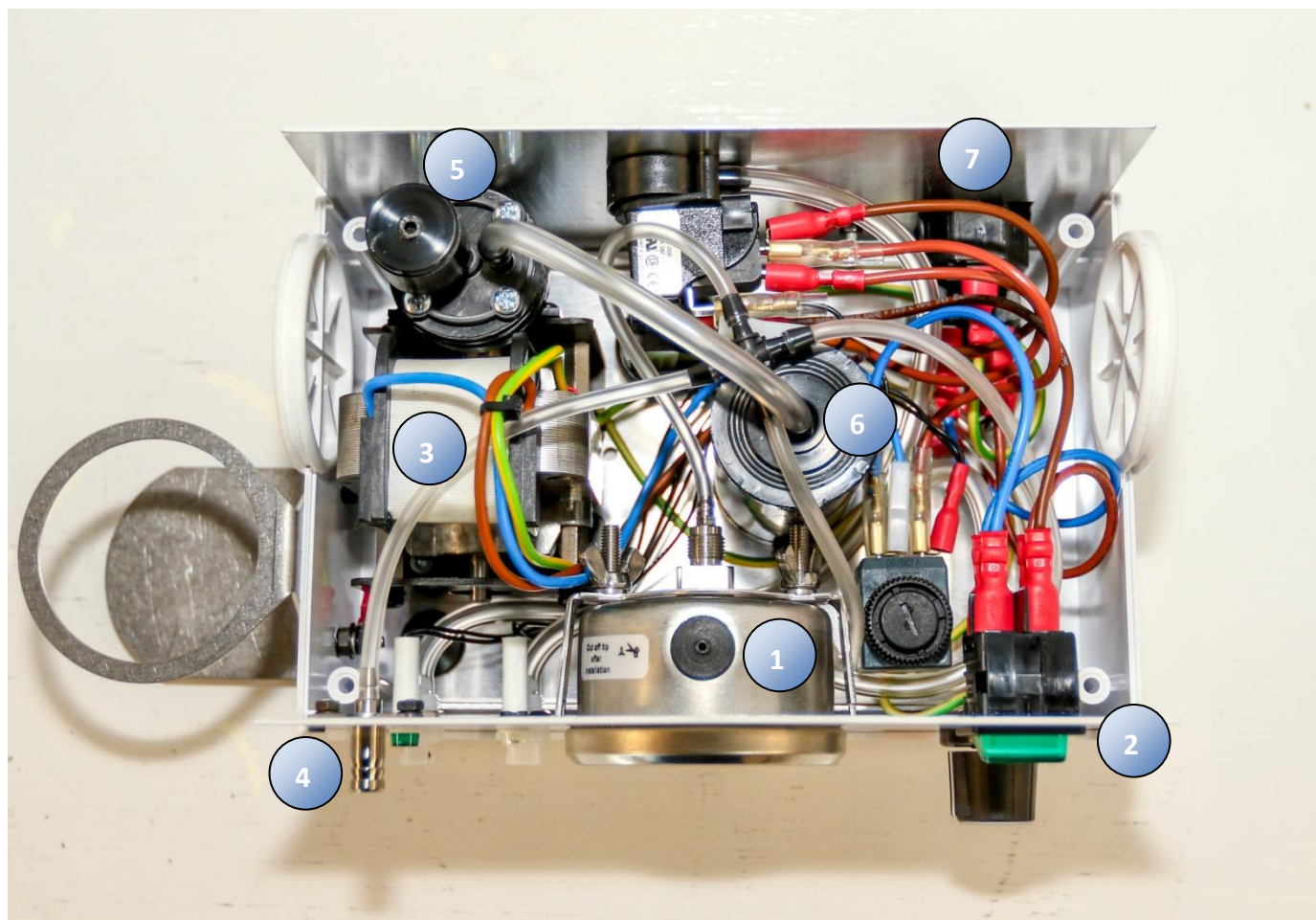
## 1.1. CRAFT™ DUO-VAC™ SUCTION PUMP



CRAFT™ DUO-VAC™ Pump with footswitch supplied after 2018

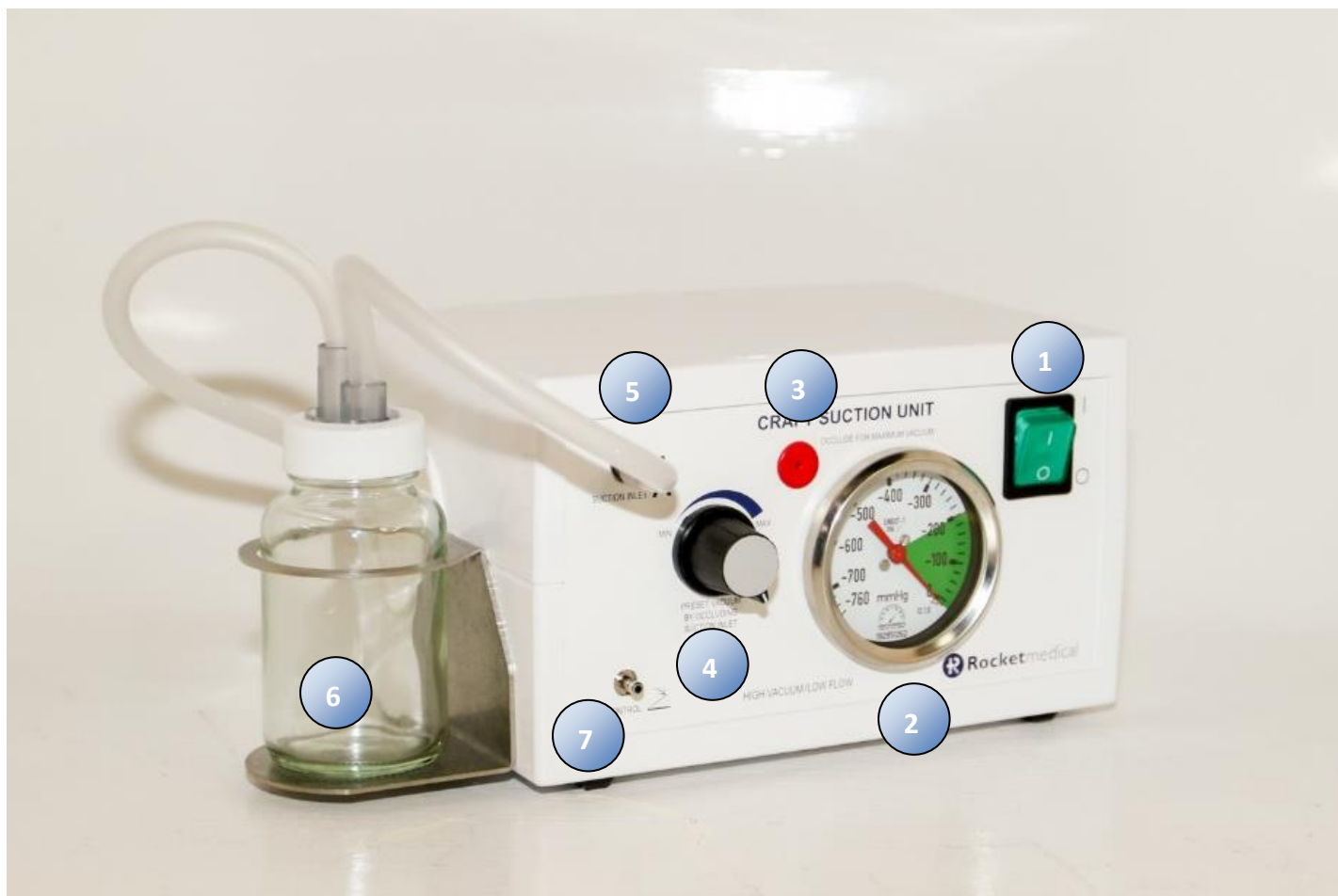
1. Illuminated O/I Mains Power On/Off
2. Vacuum Control Dial – clockwise to increase the set value and anticlockwise to decrease
3. Vacuum Display mmHg<sup>-1</sup>
4. Footswitch Connection Ports
5. Water Trap Connection Port – recommended for use with R57685 Water Trap Sets for CRAFT™ Suction Pumps
6. Disposable Water Trap Set
7. Dual Footswitch: BLACK: Standard: 0-200mmHg<sup>-1</sup> and WHITE: High Vacuum 440mmHg<sup>-1</sup> footswitch

## 1.2.CRAFT™ DUO-VAC™ SUCTION PUMP – INTERNAL VIEW



1. Vacuum Gauge 0-700mmHg – normal range 50-440mmHg<sup>-1</sup>
2. Illuminated O/I Mains Power On/Off
3. Motor 220VAC 50Hz OR 110VAC 60Hz – model dependent
4. Vacuum Outlet Port
5. Pump Head including Valve Housing
6. Internal Silencer with Filter Chamber
7. Mains Power Input

### 1.3.CRAFT™ SUCTION PUMP



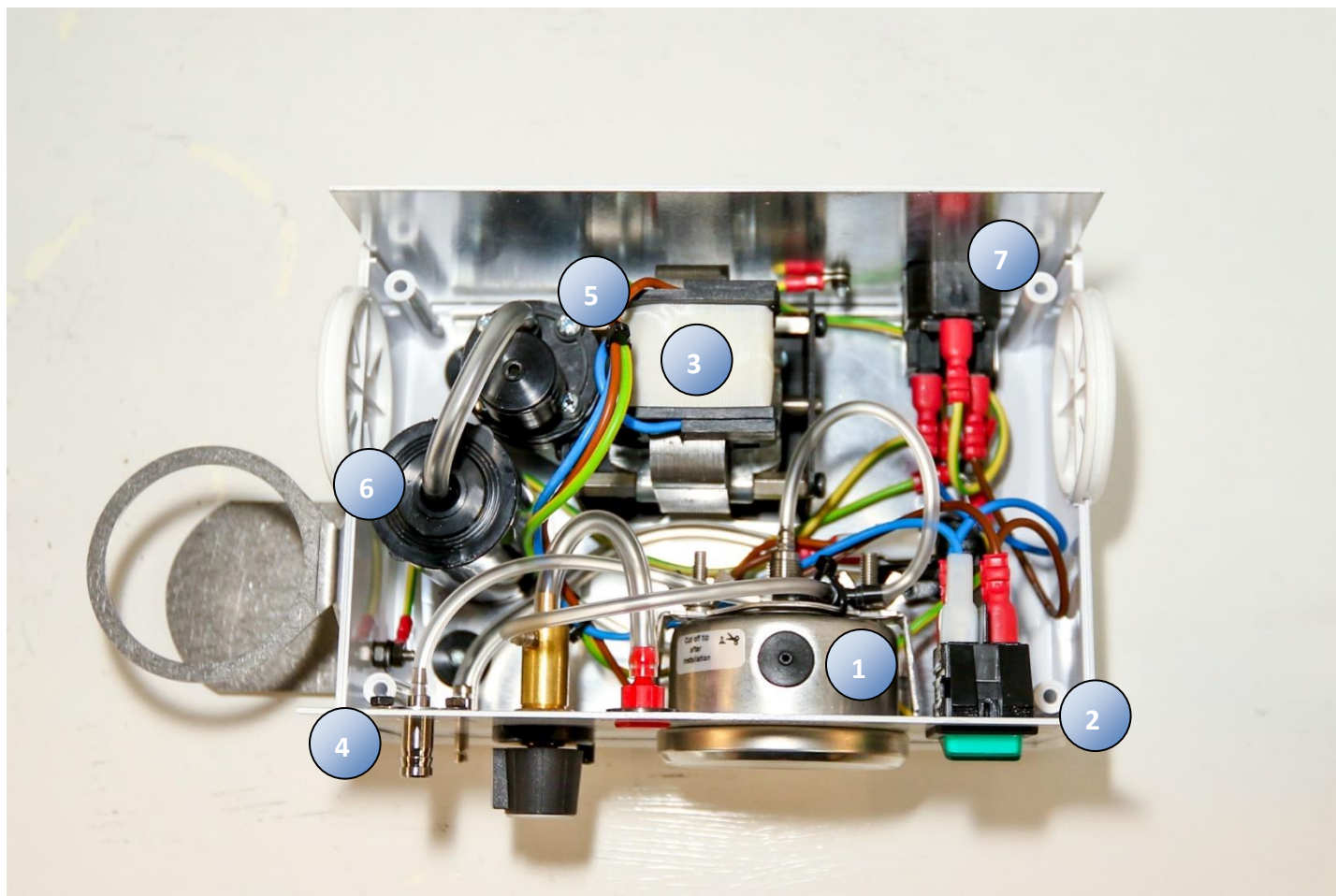
1. Illuminated O/I Mains Power On/Off
2. Vacuum Display mmHg<sup>-1</sup>
3. High Vacuum (440mmHg-1) Control Button
4. Vacuum Control – clockwise to increase the set value and anticlockwise to decrease
5. Water Trap Connection Port – recommended for use with R57685 Water Trap Sets for CRAFT™ Suction Pumps
6. Disposable Water Trap Set
7. Footswitch Connection Port
8. Medium Vacuum 0-200mmHg<sup>-1</sup> footswitch



Footswitch supplied on CRAFT™ Suction Pumps from 2013 onwards



## 1.4.CRAFT™ SUCTION PUMP – INTERNAL VIEW



1. Vacuum Gauge 0-700mmHg – normal range 50-440mmHg<sup>1</sup>
2. Illuminated O/I Mains Power On/Off
3. Motor 220VAC 50Hz OR 110VAC 60Hz – model dependent
4. Vacuum Outlet Port
5. Pump Head including Valve Housing
6. Internal Silencer with Filter Chamber
7. Main Power Input

## 2. GENERAL DESCRIPTION:

The CRAFT™ Suction 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 0-200mmHg<sup>-1</sup> in medium vacuum mode and at a pre-set 440mmHg<sup>-1</sup> in high vacuum mode.

CRAFT™ Oocyte Aspiration Pumps require R57685 Water Trap Sets for CRAFT™ Suction Pumps, supplied separately, sterile and for single patient use.

You will also require:

- A suitable oocyte aspiration needle such as Rocket Medical SX Single Lumen Oocyte Aspiration Set (R57603-SX-90)
- Suitable collection tubes for use with oocyte needle sets such as a Falcon® test tube, 17 x 100mm
- Flushing media

### 2.1. INDICATIONS

For the generation of high vacuum/low volume suction between 0 and 440 mmHg<sup>-1</sup> 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.

### 2.2. 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.

### 2.3. 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.



**WARNING:  
ELECTRIC SHOCK  
HAZARD.**

The equipment is to only be used 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. GENERAL INFORMATION

### 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 written approval of Rocket Medical plc.

### 3.2. MODEL NUMBERS

CRAFT™ Suction Pump (110v)	<b>R29654</b>
CRAFT™ Suction Pump (240v)	<b>R29655</b>
CRAFT™ DUO-VAC™ Suction Pump (240v)	<b>R29660</b>
CRAFT™ DUO-VAC™ Suction Pump (110v)	<b>R29661</b>

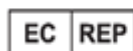
### 3.3. MANUAL REVISION

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
Revision 5	Update to latex statement, symbol	06/11/13
Revision 6	Update to YOM, consumption, footer	16/07/14
Revision 7	Update to LRQA CE mark	27/08/14
Revision 8	Update US address	17/01/19
Revision 9	Update Warranty and service addresses & EU Representative	25/02/19
Revision 10	Update Service Agents & CE mark	19/08/20
Revision 11	Update Photographs & Add Troubleshooting	16/11/20
Revision 12	Update to Product Names	08/03/21
Revision 13	Addition of hyphen in DUO-VAC	25/03/21
Revision 14	Update to Vacuum values and phthalate symbol in Water Trap symbol table	21/05/21
Revision 15	Accuracy Settings. Modification and addition of Drawings in section 16.3	05/11/21

### 3.4. MANUFACTURER

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**CE**  
**1639**



**Rocket Medical GmbH**  
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15566 Schöneiche.



### 3.5. SERVICE AGENTS

CRAFT™ Pumps typically require annual maintenance; however, it is recommended that they are serviced and calibrated annually at an approved **Rocket Medical plc** service facility.

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

#### **UK & European Service Agents:**

IVFSynergy Ltd.,  
Old School,  
Tresillian,  
Cornwall  
TR2 4BA  
Tel: +44 (0) 1872 487224  
Email: [service@ivfsynergy.com](mailto:service@ivfsynergy.com)  
Website: [www.ivfsynergy.co.uk](http://www.ivfsynergy.co.uk)

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Tel: +1 781 749 6223



**WARNING:  
ELECTRIC SHOCK  
HAZARD.**

*The equipment is to be used only with electrical systems complying with all IEC, CEC and NEC requirements.*

### 3.6. SUPPLY VOLTAGE SELECTION

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

Ensure that the correct power cord is connected.

### 3.7. ELECTROMAGNETIC COMPATIBILITY

CRAFT™ Suction Pumps comply with the electromagnetic compatibility (EMC) limits for medical devices, as specified by IEC 60601-1-2:2015. 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.

### 3.8. 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.

### 3.9. POSITIONING AND PLACEMENT OF THE DEVICE

CRAFT™ Suction 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 to +35°C**



**WARNING:  
ELECTRIC SHOCK  
HAZARD.**

*Do not immerse the device.*











**WARNING:**







*Device can cause explosion in the presence of flammable gases.*

### 3.10. SYMBOLS USED ON CRAFT™ SUCTION AND CRAFT™ DUO-VAC™ PUMPS

These tables describe their respective meanings.

	<b>Mains Power ON/OFF</b>
	<b>This device is Type B</b>
	<b>CE Mark</b>
	<b>Footswitch connection</b>
	<b>CAUTION: consult accompanying documents</b>
	<b>Consult the Instructions for Use</b>
	<b>Dispose of this device in accordance with WEEE directive (2002/96/EC)</b>
	<b>Indicates manufacturer</b>

### 3.11. SYMBOLS USED ON R57685 WATER TRAP SET FOR CRAFT™ SUCTION PUMPS

	<b>Read the Instruction for Use before connection and use</b>
	<b>Device is for Single Use Only</b>
	<b>Device is sterilised by Ethylene Oxide</b>
	<b>This device is not manufactured with natural rubber latex</b>
	<b>CE Mark</b>
	<b>CONTAINS or PRESENCE of PHTHALATES</b>

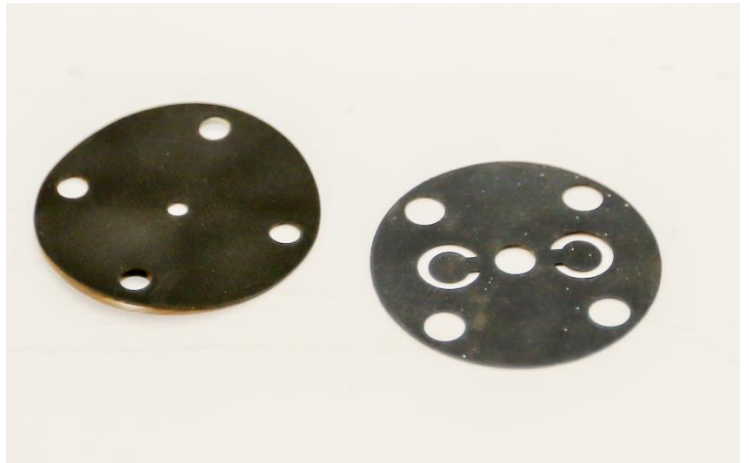
## 4. ANNUAL SERVICE

### Service Kits:

a. Filter Element:



b. Pump Service Kit:



### Tools Required:

a. Pozidriv I Screwdriver

b. ½" Spanner

c. 7mm Spanner

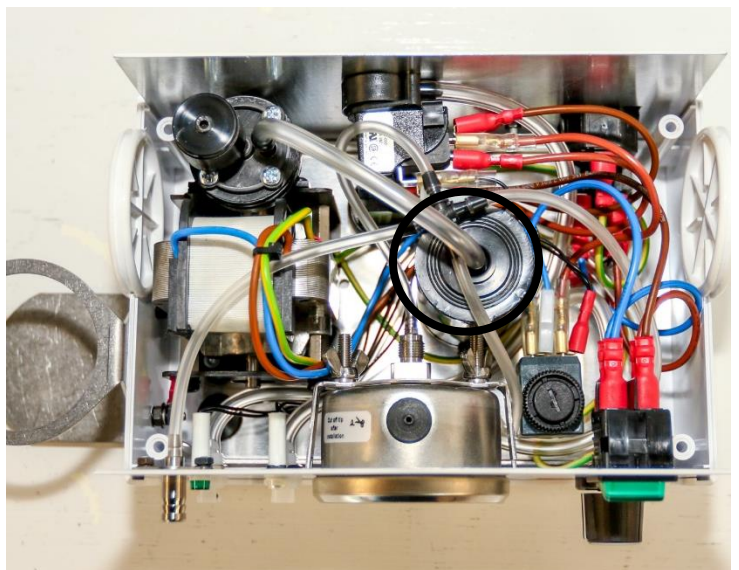
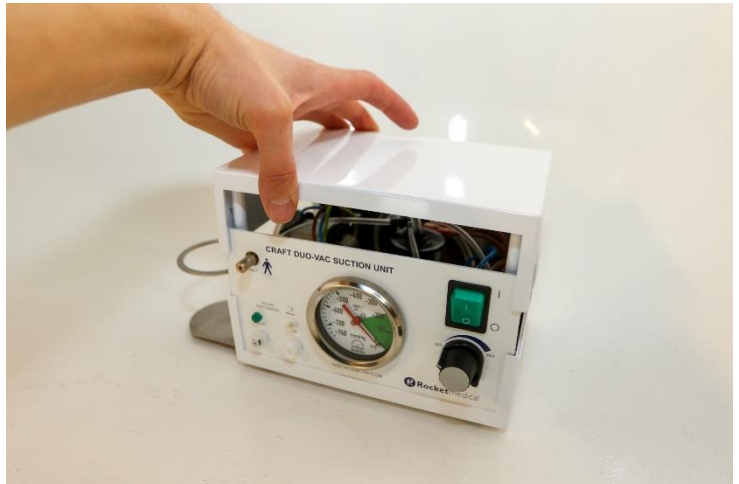
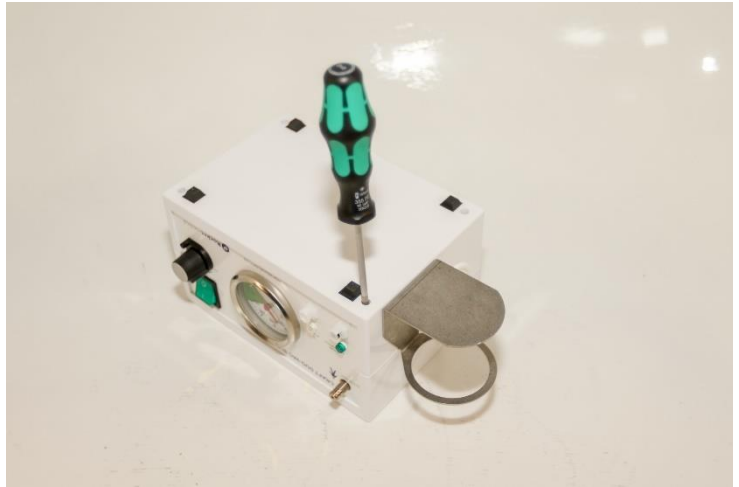




**WARNING:  
ELECTRIC  
SHOCK HAZARD.**

## 4.1 REPLACING THE FILTER ELEMENT

1. Lay the pump on a clean surface, protecting the casing from scratches.
2. Remove the 4 screws from the casing underside and retain.
3. Carefully separate the case halves, ensuring that the front and rear fascia plates remain located in the lower shell.
4. Locate the filter housing (outlined in black in the right-hand image). Note that the location differs in the CRAFT™ Suction Unit.





5. Using fingers, lift the top of the filter away from the chamber.

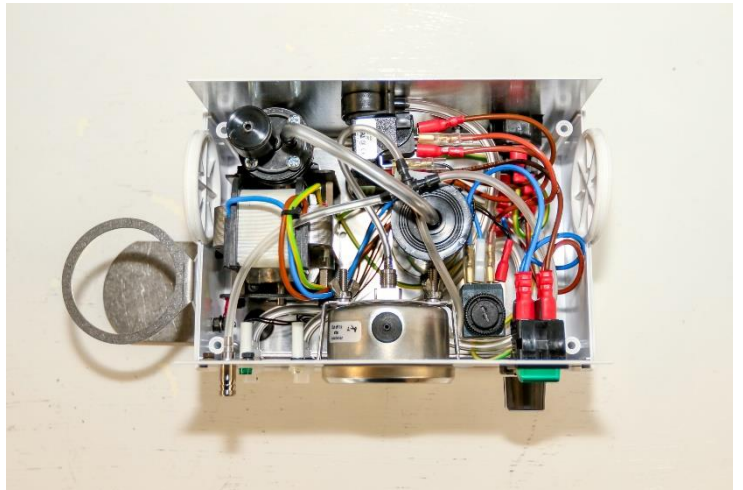


6. Remove the filter element from the cap. Replace with the new item from the service kit.



7. Replace the top of the filter in the housing, ensuring that the lid seats securely.

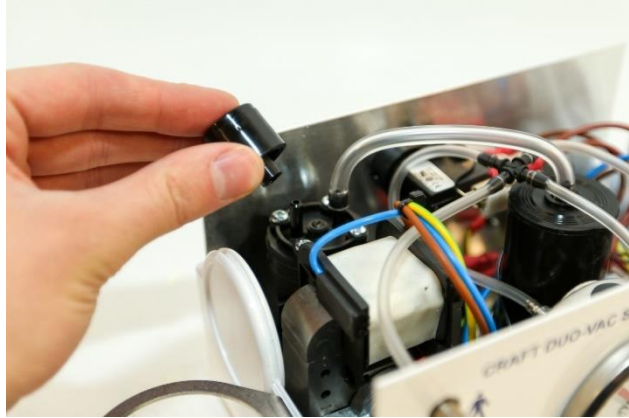
Take care to avoid trapping or pinching the 'o'-ring.



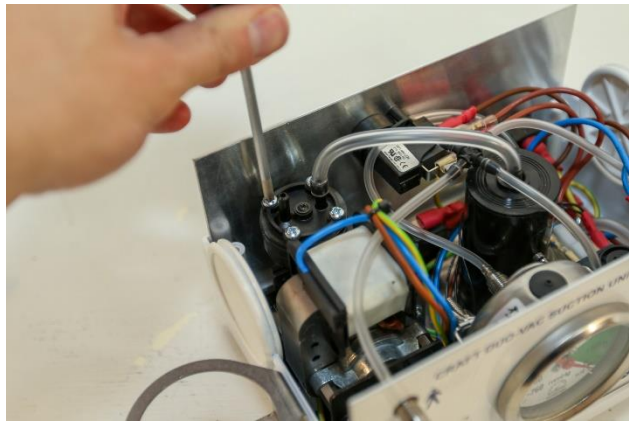
**IMPORTANT**

## 4.2 REPLACING THE PUMP VALVE AND DIAPHRAGM SET

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

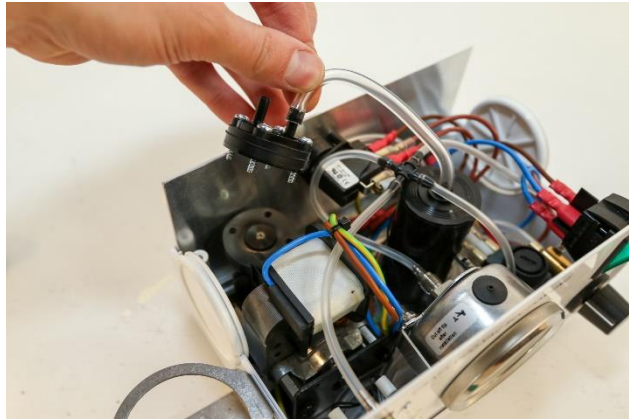


2. Unscrew the 4 screws from the pump head in a crosswise manner to prevent distortion of the pump head

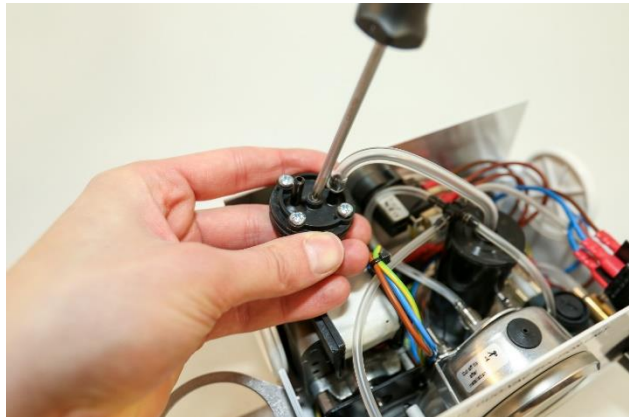


3. Lift the head assembly away from the pump body to reveal the diaphragm assembly.

**Note:** if a plastic spacer ring is located on the diaphragm this must be retained and reused.



4. Undo and remove the centre screw to release the head assembly.
5. Remove the pipe from the inlet and separate the two head halves with a gentle twisting motion.





6. Note the valve and head orientation.

Replace the valve element with the item from the service kit. Note the orientation of the valve cut outs to the head. This must be maintained.



7. Fit the valve to head lower, noting the orientation.



8. Maintaining the valve and head orientation, refit the head upper.

When the head is assembled, refit and tighten the screw to secure the head assembly.



9. Undo the centre screw to remove the diaphragm and top plate and thereby, to expose the piston.



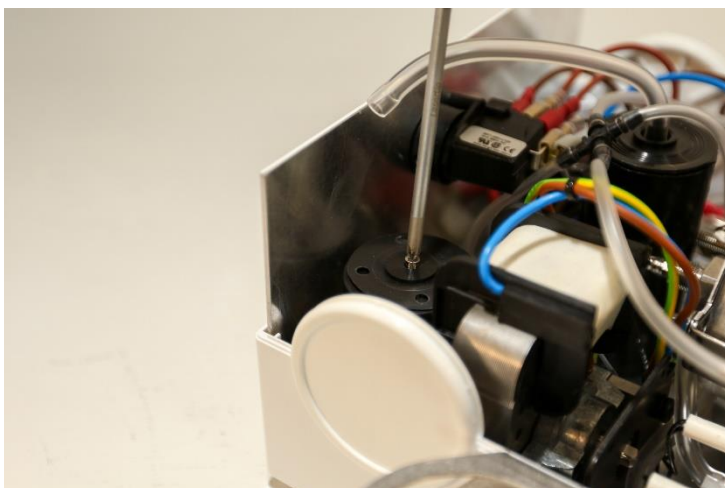
10. Discard the old diaphragm. Retain the screw and plastic washer.



11. Refit the new diaphragm, reusing the old washer and screw. Ensure that the outer holes align with the crankcase.

**DO NOT OVERTIGHTEN THE SCREW**

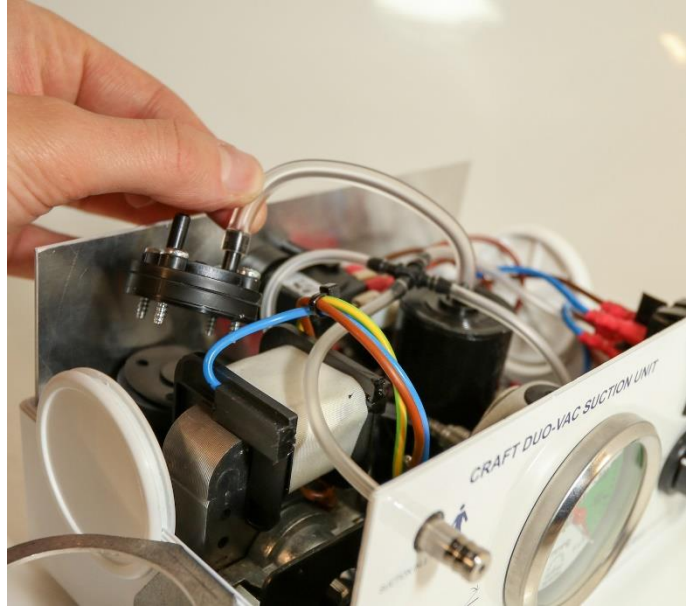
Refit the spacer if fitted originally.



**IMPORTANT**



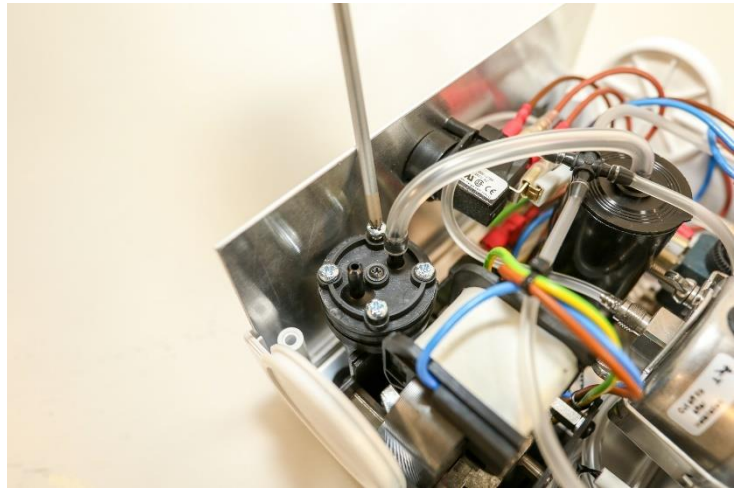
12. Replace the valve head assembly onto the gasket. Ensure that the holes are correctly aligned and the gasket seated correctly.



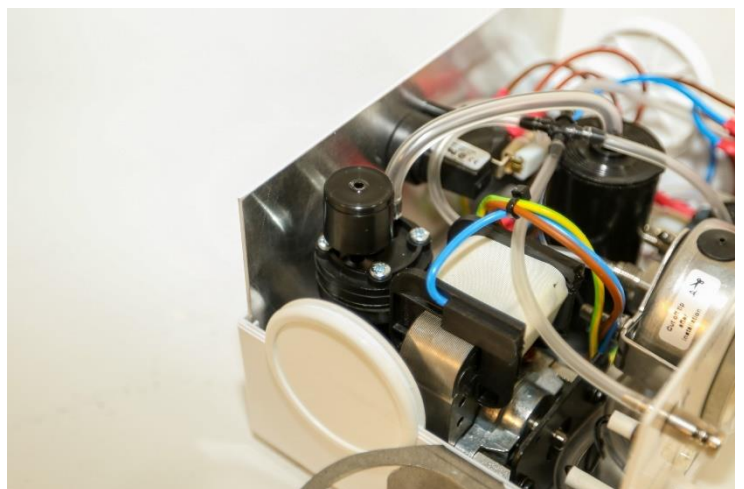
13. Tighten the head screws in crosswise fashion to avoid distorting the head.

**DO NOT OVERTIGHTEN THE SCREWS**

Note the head alignment – connect the tube to the inlet.



14. Refit the pump silencer to the head outlet.



**IMPORTANT**



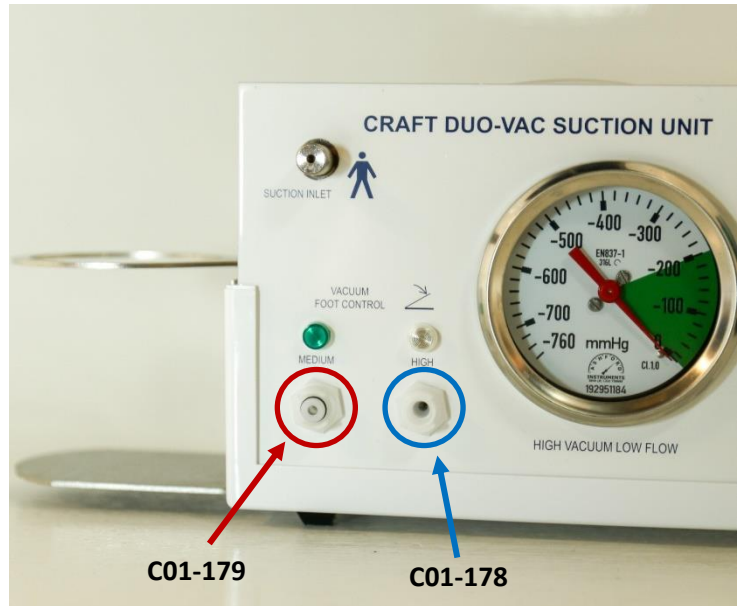
## 5. REPAIRS AND REPLACEMENTS

### 5.1 REPLACING THE CRAFT™ DUO-VAC™ FOOTSWITCH CONNECTORS

Should they become damaged, the two front panel connectors can be replaced.

The 'Medium' (or 'Standard') connector part number is: **C01-179**.

The 'High' connector part number is: **C01-178**.



1. Remove the upper casing (see section 6).
2. Lift the front panel out of the retaining groove in the lower case.



3. Remove the tubing from the rear of the connector.
4. Loosen and remove the securing nut.
5. Replace the connector and tighten the securing nut.
6. Re-fit the tubing by pushing over the connector barb.



## 5.2. REPLACING THE GAUGE IN CRAFT™ DUO-VAC AND CRAFT™ SUCTION MODELS

1. Remove the upper casing (see section 6).
2. Lift the front panel out of the retaining groove in the lower case.



3. Loosen and remove the screws / nuts (as applicable).
4. Remove the bracket from the rear of the gauge and draw the gauge through the panel.
5. Detach the gauge from the tube by carefully pulling the tube.
6. Replace the gauge, reconnect tubing and insert through the panel.
7. Replace the gauge mounting plate, refit the sprung washers and tighten the wingnuts.

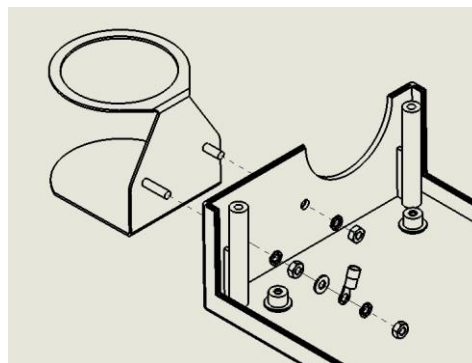
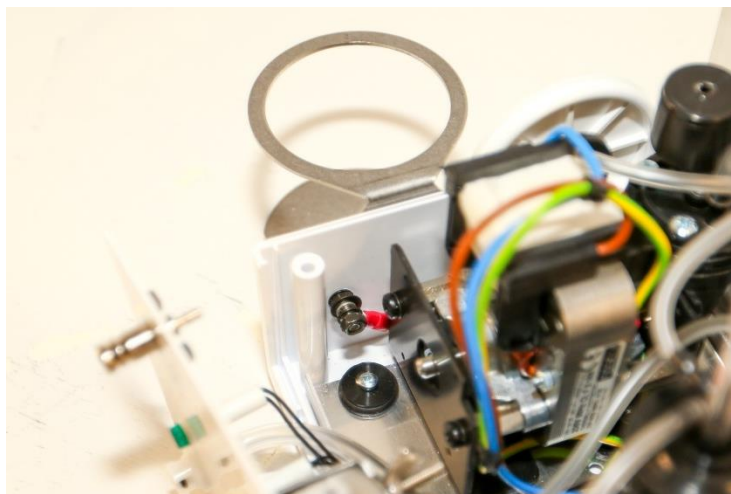


### 5.3. BOTTLE BRACKET REPLACEMENT USING SERVICE KIT B02-190S

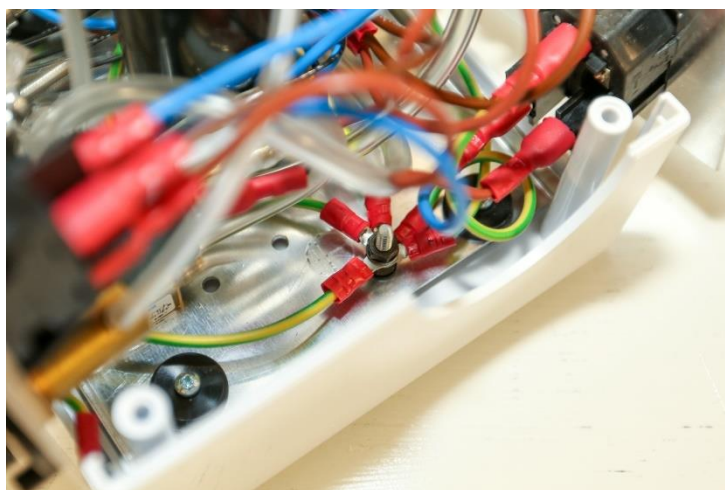
1. Undo the nuts securing the bracket. The design may differ depending on the model.
2. Take care to remove the earth lead if fitted.
3. Refit the new bracket with the fitted shakeproof washers.

See exploded view for nut and washer order.

Ensure that the earth lead is reattached where fitted.



4. When fitting the bracket, ensure that the earth lead is secured to the stud using the arrangement shown below.



## 6. 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 to the external vacuum port, as indicated in the image below.
- 4. Attach the footswitch as for normal operation.



- 5. Power the 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).

Test Value mmHg <sup>-1</sup>	Indicated Vacuum	Test Gauge
100		
150		
200		

Specified accuracy: ±5% full scale (±10 mmHg<sup>-1</sup>)



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





**WARNING:  
ELECTRIC  
SHOCK  
HAZARD.**

*The equipment is only to be used with electrical systems complying with all IEC, CEC and NEC requirements.*

## 7.FUSE REPLACEMENT

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**



## 8. TROUBLESHOOTING

### 8.1. DEVICE DOES NOT POWER ON

- Check device is plugged in.
- Check device is switched on at main supply.
- Check I/O Switch is illuminated.
- Check plug fuse.
- Check device fuses (see section 9).
- Check kettle connector is not damaged.
  - Do not use the power supply if the connector is damaged. Replace immediately.

### 8.2. DEVICE DOES NOT PRODUCE SUCTION

- Check device is powered on.
- Check footswitch is correctly connected.
- Check both high suction and standard mode (black and white footswitch) (CRAFT™ DUO-VAC™ only).
- Check High Vacuum Control (Suction only).
- Check pump plumbing is connected correctly (see section 5.2).
- Check pump is producing suction within unit.
- Check inlet pipe is not kinked (see section 5.2).
- Check inlet pipe is connected (see section 5.2).
- Check footswitch pipes are not kinked.
- Check all the wiring plugs are connected (see section 2.2).
- Check vacuum control dial is fully open.
- Check gauge when Vacuum Control dial is fully closed – needle should read at least 400mmHg.



**WARNING: ELECTRIC  
SHOCK HAZARD.**  
*Take care when working  
on the unit with the lid  
removed.*



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



**WARNING:**  
Do NOT attempt to sterilise the device



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



**WARNING:** No user serviceable parts inside.



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



## 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

## 9. CLEANING THE PUMP CASING

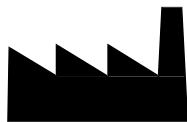
At the end of each clinical session, turn off the device at the front panel and disconnect the device from the mains power supply.

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.

## 10. 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.

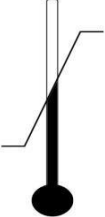

## 11. RETURNING THE PUMP FOR REPAIR OR SERVICE

Except under warranty, all service and/or repair should be organized via an authorized service provider. For warranty repairs, please contact Rocket Medical customer services.




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

- Surface clean the pump as described in the Section 11 above
- Seal in a plastic bag and then seal within a second plastic bag.
- Place in the original packaging.
- Enclose the following information:
  - Contact name
  - Centre address
  - Decontamination Certificate (can be obtained from Rocket Medical Customer Services)
  - Description of the fault or service required

## 12. STORAGE

	The device must be stored within the temperature range +5°C to +35°C
	<p>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</p> <p>Protect the device from ingress of liquid. Should any liquid enter the device, discontinue use immediately and refer to an authorised service agent</p>

## 13. TRANSPORTATION:

	The device must be transported in temperatures +5°C to +35°C	
	<p>The device is FRAGILE and must be transported in its original packaging to ensure protection.</p> <p>If the original packaging is not available please contact your local Customer Services Agent who will provide replacement packaging.</p>	
	<p>Dimensions:</p> <ul style="list-style-type: none"> <li>W - 264mm</li> <li>H - 124mm</li> <li>D - 164mm</li> </ul>	<p>Weight:</p> <ul style="list-style-type: none"> <li>Unit – 1.9Kg</li> <li>Foot Switch:               <ul style="list-style-type: none"> <li>0.57Kg – CRAFT™ DUO-VAC™ (plastic)</li> <li>0.34kg – CRAFT™ Suction (plastic)</li> <li>0.51Kg – CRAFT™ DUO-VAC™ (metal)</li> <li>0.38kg – CRAFT™ Suction (metal)</li> </ul> </li> </ul>
	Protect the device from ingress of liquid. Should any liquid enter the device, discontinue use immediately and refer to an authorised service agent	

## 14. WARRANTY

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.

## 15. TECHNICAL SPECIFICATIONS

### 15.1.CLASSIFICATION

#### IEC 60601-1

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. 0.12A

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

Vacuum Ranges:

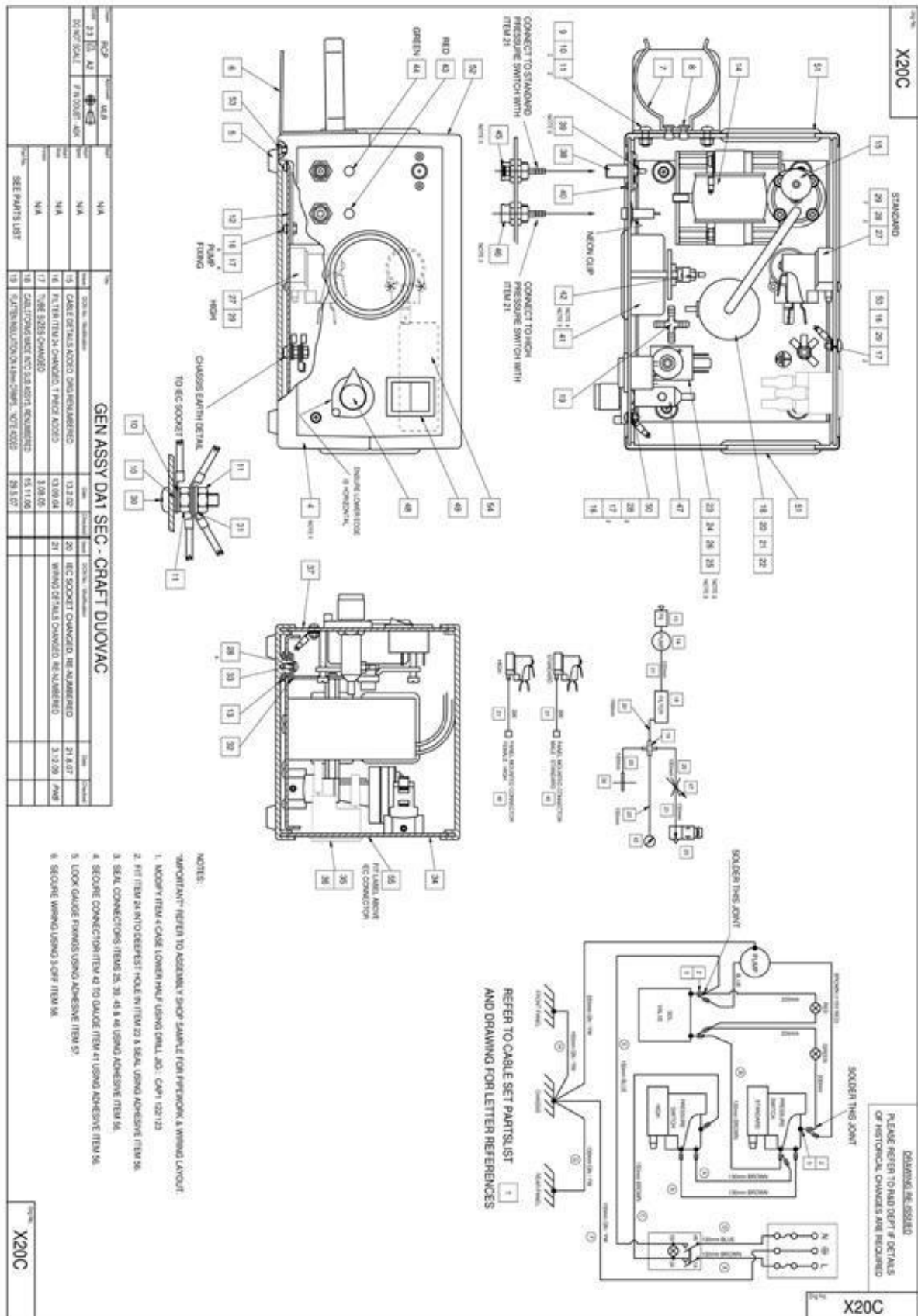
- Medium vacuum: 0-200mmHg<sup>-1</sup> in 20mmHg increments
- High vacuum: 440mmHg<sup>-1</sup>

Accurate to ±5% full scale

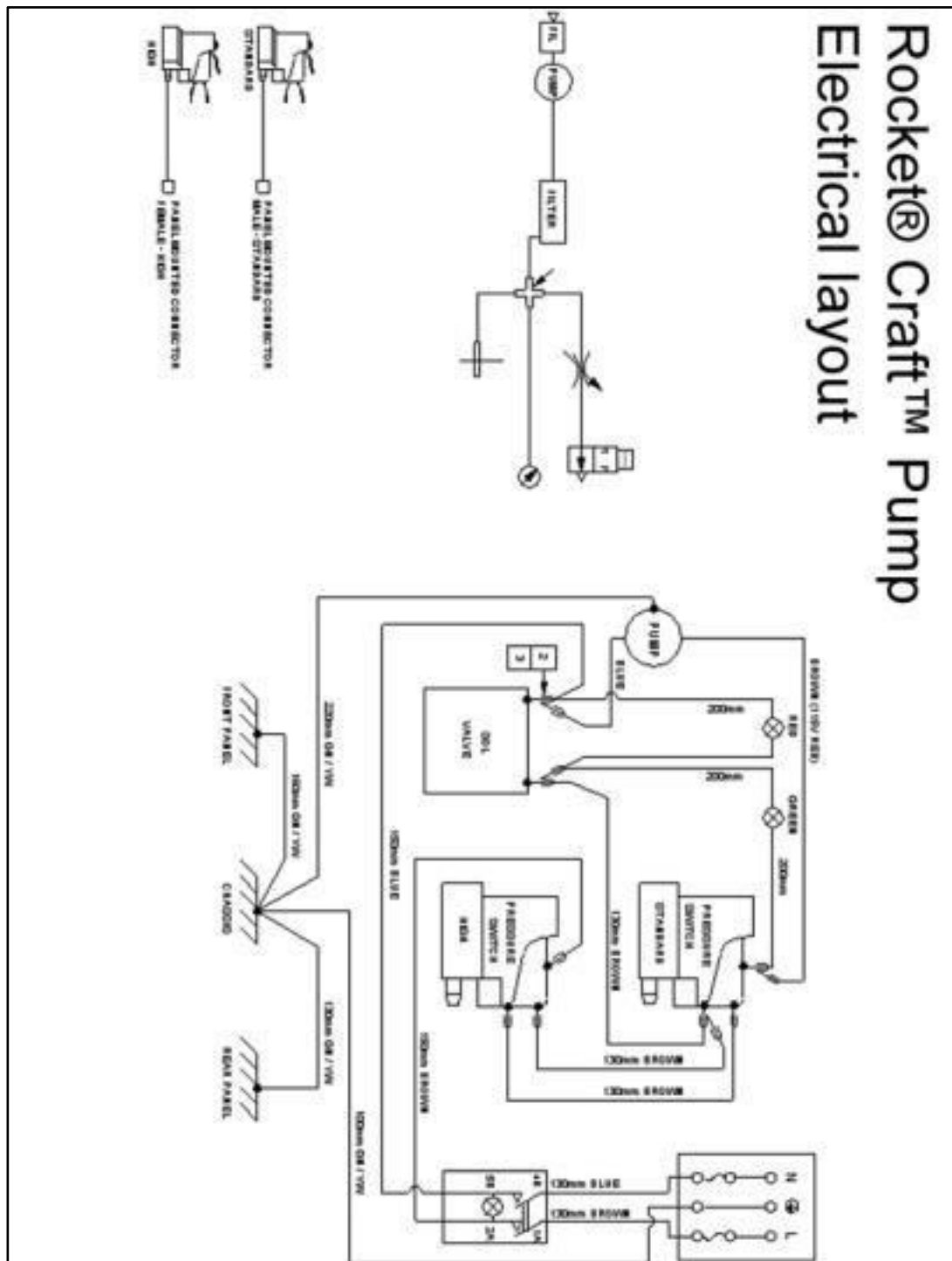


# 16. DRAWINGS

## 16.1.GENERAL ASSEMBLY



## 16.2. GENERAL ELECTRICAL



16.3.GENERAL INSTALLATION

