Rocketmedical

SERVICE MANUAL

R29700 Oocyte Aspiration Pump

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1. GENERAL ASSEMBLY

1.1 OOCYTE ASPIRATION PUMP

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

Not shown:

11. Power Supply Unit (PSU) Model: MPU30
12. Power Cords, IEC UK & EC types

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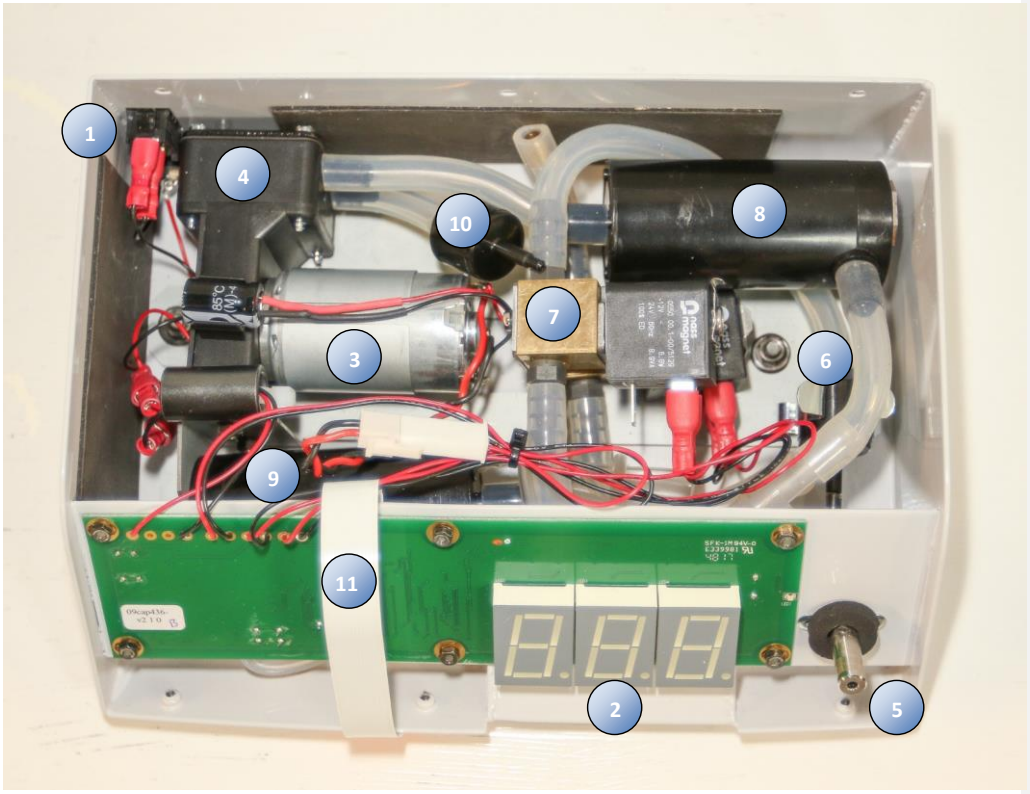
1.2 OOCYTE ASPIRATION PUMP – INTERNAL VIEW



1. O/I Mains Power On/Off
2. Vacuum Display 0 to -500 mmHg – normal range -50 to -300 mmHg
3. 12V Motor
4. Pump Head including Valve Housing
5. Vacuum Outlet Port
6. Vacuum Inlet Filter
7. Vacuum Control Solenoid
8. Internal Silencer with Filter Chamber (A)
9. Internal Silencer with Filter Chamber (B)
10. Internal Exhaust Vent and Filter
11. Control PCB with ribbon cable to vacuum control touch wheel

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2. GENERAL DESCRIPTION

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

The range of suction is variable, from -50 to -300 mmHg and at a preset -500 mmHg in 'Max' suction mode.

The Oocyte Aspiration Pump requires a disposable filter set, R57686, for attachment of the pump to the oocyte collection needle. The filter set is supplied separately, sterile and for single patient use.

You will also require:

- A suitable oocyte aspiration needle such as 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

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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 or under the supervision of suitably qualified personnel.

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

3.GENERAL INFORMATION

3.1 COPYRIGHT

3.2 MODEL NUMBER

Oocyte Aspiration Pump	R29700
Power Supply	MPU30

3.3 MANUFACTURER

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

EC REP

ROCKET MEDICAL GmbH
Am Rosengarten 48.
15566 Schöneiche.
Germany

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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 SERVICE AGENTS

Oocyte Aspiration Pumps require servicing when indicated by the Service Indicator.

It is recommended they are serviced and calibrated at an approved **Rocket Medical plc.** service facility.

Failure to service the pump at the indicated intervals and with an authorised service agent may invalidate the Warranty.

UK & European Service Agents:
IVF Synergy Ltd.,
Old School,
Tresillian,
Cornwall
TR2 4BA
United Kingdom.
Tel: +44 (0) 1872 487224
E: service@ivfsynergy.com
W: www.ivfsynergy.co.uk

Australian Service Agent :
Rocket Medical Pty Ltd
Suite 6,
157 Gordon Street,
Port Macquarie NSW 2444
Australia
Email: aus@rocketmedical.com

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

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

3.5 SUPPLY VOLTAGE SELECTION

The device is only for use with power supply Model Number: MPU30 with 12V DC output. Attachment of any other power supply may severely damage the device.

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

The device operates at a voltage 100V to 240V AC @ 50 / 60Hz. 0.15A.

3.6 ELECTROMAGNETIC COMPATIBILITY

Rocket Medical CRAFT™ Suction Pumps comply with the electromagnetic compatibility (EMC) limits for medical devices as specified by EN 60601-1-2:2015. These limits are designed to provide a reasonable degree of protection against harmful interference found in typical medical installations.

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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.

3.7 PACKAGING

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

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.

3.8 POSITIONING AND PLACEMENT OF THE DEVICE

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

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 to +40°C

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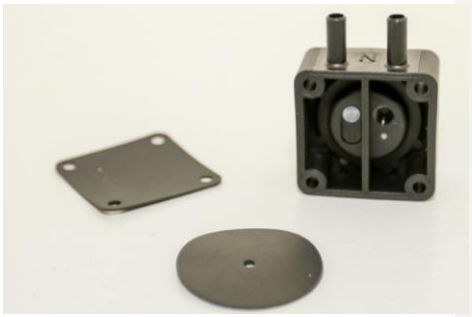
4. ANNUAL SERVICE

Service Kits:

Filter Service Kit: F04-081S

Pump Service Kit: S02-072



Tools required:

a) Pozidriv 1 Screwdriver
b) 8mm Nut Runner
c) 2mm Hex Key

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4.1 REPLACING THE INLET FILTER (F04-081S)

WARNING: Observe precautions for handling electrostatic discharge sensitive devices

Lay the pump on a clean surface, protecting the casing from scratches.

Remove the 3 screws and washers from the rear casing and retain.

Turn the pump over and remove the 3 screws and washers from the front lower casing and retain.

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

Remove the white silicone retaining 'O' ring from the vacuum inlet port.

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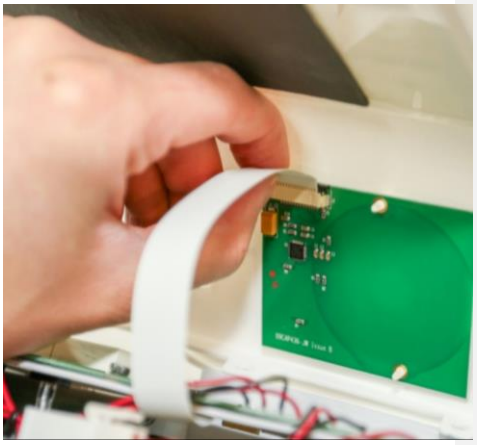
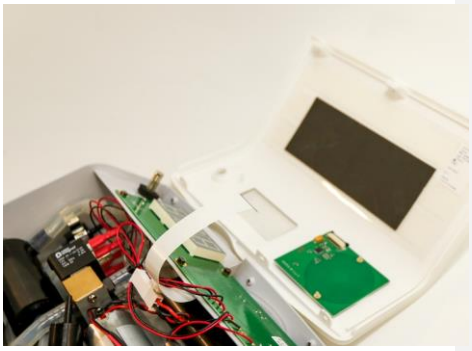
Detach the ribbon cable from the front panel vacuum controller PCB by lifting the tab.



Carefully detach the ribbon from the front cover and store securely.



Detach the patient outlet filter from the tube.

Unclip the filter from the spring clip; discard and replace the filter.

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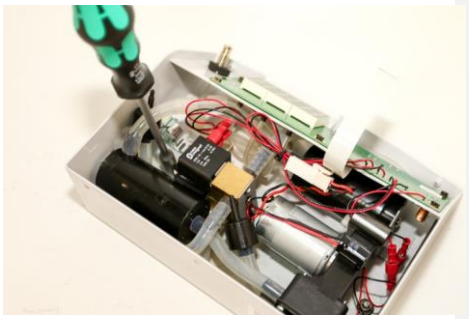
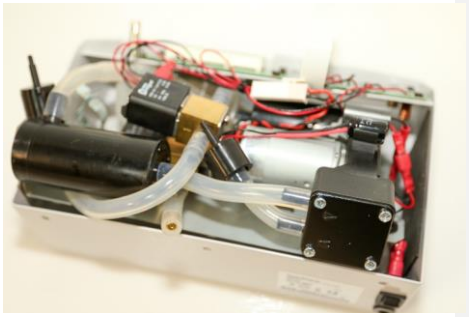
4.2 REPLACING THE PUMP VALVE AND DIAPHRAGM SET: S02-072

Unscrew the two securing nuts and lift out the chassis to gain access to the pump head.

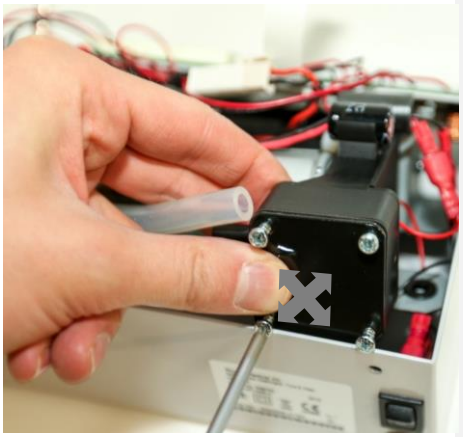


Angle the chassis to support it on the casing.



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

Disconnect the pipe connected to the inlet, and the filter connected to the outlet.



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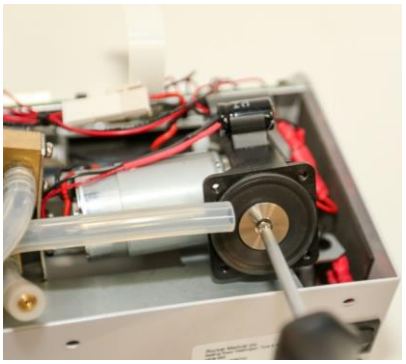
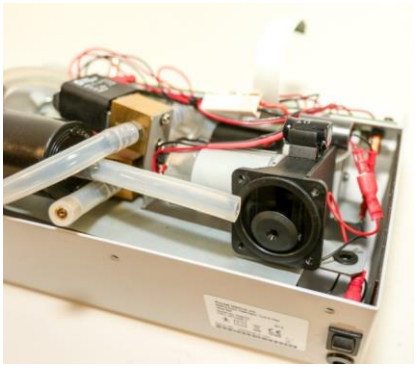
Unscrew the center diaphragm screw.



Remove the diaphragm to reveal the piston head.

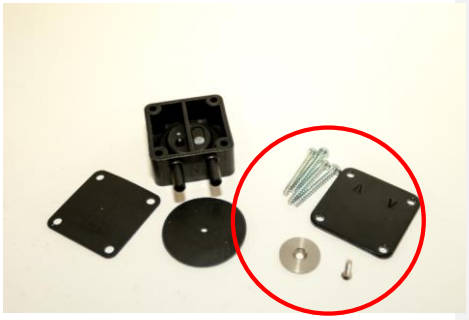
Retain the metal plate and screw and discard the diaphragm.

Ensure the piston is free to move and that there is no contamination or corrosion present.



IMPORTANT

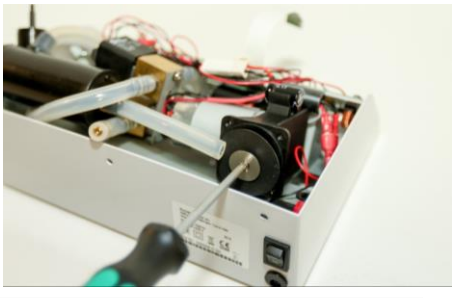
The service kit contains only the parts on the left. Retain the parts circled, on the right, from the unit.



IMPORTANT

Centralise the piston into the housing and re-attach the diaphragm, plate and screw.

DO NOT OVERTIGHTEN THE SCREW



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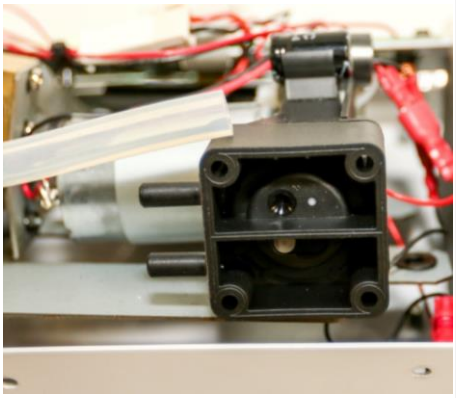
IMPORTANT

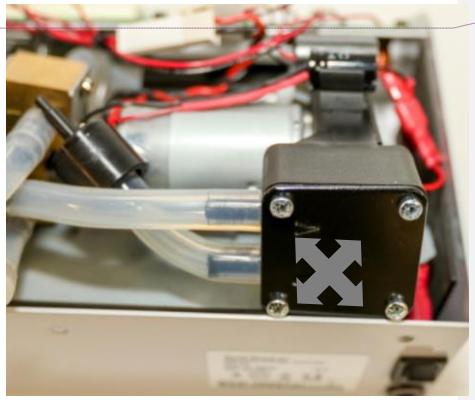
Push the diaphragm plate and screw so they are in their lowest position.

Refit the head to the pump.



IMPORTANT: Note valve and head orientation

Discard the old gasket and use a new replacement with the existing metal plate and 4 screws.



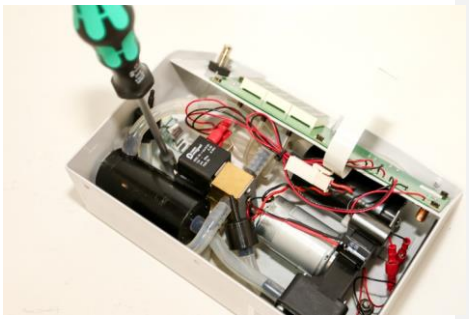
IMPORTANT

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

DO NOT OVERTIGHTEN THE SCREWS

Re-attach the inlet vacuum tubing to the inlet.

Re-attach the exhaust filter to the bottom port and relocate between the motor and the inlet tubing.



Return the chassis to the casing, locating it onto the threaded bosses within the case.

Refit the washers and nuts and tighten the securing nuts.

4.3 REASSEMBLING THE CHASSIS INTO THE CASING

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Pass the inlet filter underneath the tubing and refit it in the clip.

Re-attach the filter to the patient connection port tube.

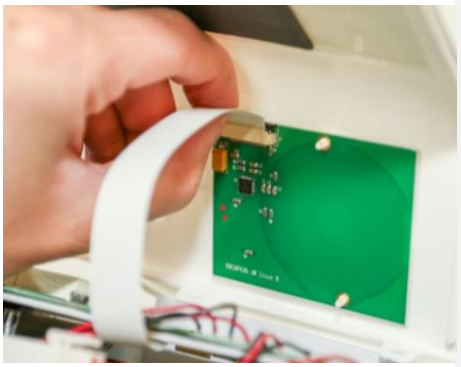
VERY IMPORTANT

Ensure that the tubing is not trapped by the spring clip and is correctly routed to avoid occlusion.

Ensure that the filter tubing is not kinked.

Re-attach the ribbon cable from the PCB to the front panel vacuum controller PCB by lifting the tab.

Carefully insert the ribbon and close the tab securely.



Lay the pump on a clean surface, protecting the casing from scratches.

IMPORTANT DO NOT OVER TIGHTEN THE SCREWS

Re-fit the casing taking care of the ribbon cable.

After re-fitting the upper casing to the lower frame, re-install the 3 screws and washers to the rear casing.

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IMPORTANT DO NOT OVER TIGHTEN THE SCREWS

Turn the unit over and re-install the 3 screws and washers to the front lower casing.

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

Re-install the white silicone retaining 'O' ring to the vacuum inlet port.

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5. 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 to -500mmHg in 1mmHg increments.
3. Attach the vacuum test gauge as indicated in the image below to the external vacuum port.
4. Attach the footswitch as for normal operation.
5. Power the device on.
6. On Start-Up, the pump is pre-set to -100mmHg suction. To increase this value, use a circular motion, lightly drawing a finger *clockwise* over the outer zone of the control dial in the direction of the arrows.
7. The active dial zone will sense the motion and increase the display in -5mmHg increments.
8. To decrease the set value, use an *anticlockwise* circular motion.
9. When the desired value is reached, hold the finger still for 2 seconds when an audible 'beep' will confirm the new setting.
10. Activate the Standard Vacuum footswitch – observe that the suction indicator is illuminated.
11. Record the vacuum registered for each of the test values.

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

Test Value mmHg	Acceptance Criteria / mmHg	Indicated Vacuum	Test Gauge
-100	-85 to -115		
-140	-125 to -155		
-300	-285 to -315		
-500	-475 to -525		

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6. TROUBLESHOOTING

6.1 DEVICE DOES NOT POWER ON

- Check device is plugged in.
- Check device is switched on at main supply.
- Check device is switched on at rear of unit.
- Check power supply green led is illuminated.
- Check plug fuse (if fitted).
- Check DC connector is not damaged.
    - Do not use the power supply if the connector is damaged. Replace immediately.

6.2 DEVICE DOES NOT PRODUCE SUCTION

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

- Check device is powered on.
- Check footswitch is correctly connected.
- Check both high suction and standard mode (black and white footswitch).
- Check indicator LEDs flash when the footswitch is pressed.
    - If the LEDs do not flash the device is not receiving the signal to start from the footswitch.
    - If the LEDs do flash the device is receiving the signal to start but the device is not functioning correctly.
- Check pump plumbing is connected correctly (see section 4.2).
- Check pump is producing suction within unit.
- Check inlet pipe is not kinked (see section 4.2).
- Check inlet pipe is connected (see section 4.2).
- Check footswitch pipes are connected to PCB.
- Check footswitch pipes are not kinked.
- Check all the wiring plugs are connected (see section 1.2).
- Check the control PCB ribbon cable is connected (see section 4.3).
    - This can cause erratic behaviour if disconnected.

6.3 DEVICE DISPLAY VARIES WHEN UNIT OPERATING.

- Change device from Service Mode (see section 12.3).
    - Device should display the target vacuum when operating.

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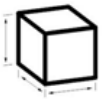
7. STORAGE AND TRANSPORTATION

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

8. OPERATING CONDITIONS

	The device's operating temperature range is +5°C to + 40°C	
	The device must be operated at relative humidity levels between 15% and 93%	
	The device must be operated at ambient pressure levels between 70kPa and 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 - 248mm H - 86mm D - 194mm	**Weight:** Unit – 2.56Kg Footswitch – 0.51Kg
	Protect the device from ingress of liquid. Should any liquid enter the device, discontinue use immediately and refer to an authorised service agent	
Altitude	This device is intended for use below 2000 meters.	

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9. WARRANTY

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 the 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.

10. 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.

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11. TECHNICAL SPECIFICATIONS

11.1 CLASSIFICATION

IEC 60601-1

Type of protection against electric shock: Class II

Degree of protection against electric shock: Type B

Vacuum type: high vacuum/low volume

Suitable for continuous operation.

Not suitable for use in the presence of flammable gases.

Not suitable for use in conditions which expose the device to the ingress of water.

Not suitable for sterilisation

11.2 SPECIFICATIONS

Power Input to Pump: 12VDC

Universal Power Supply: 100 - 240VAC

Frequency: 50/60 Hz

Maximum current: 2.5A @ 12V

Environmental conditions: +5°C to +40°C

Service interval: 1000hrs of pump operation

Dimensions:

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

Weight:

- Unit - 2.56Kg
- Foot Switch 0.51Kg

Suction Ranges:

- User Set: - 50 to - 300mmHg in 5mmHg increments
- Pre-set: -500mmHg - nominal

Accurate to ±5% full scale:

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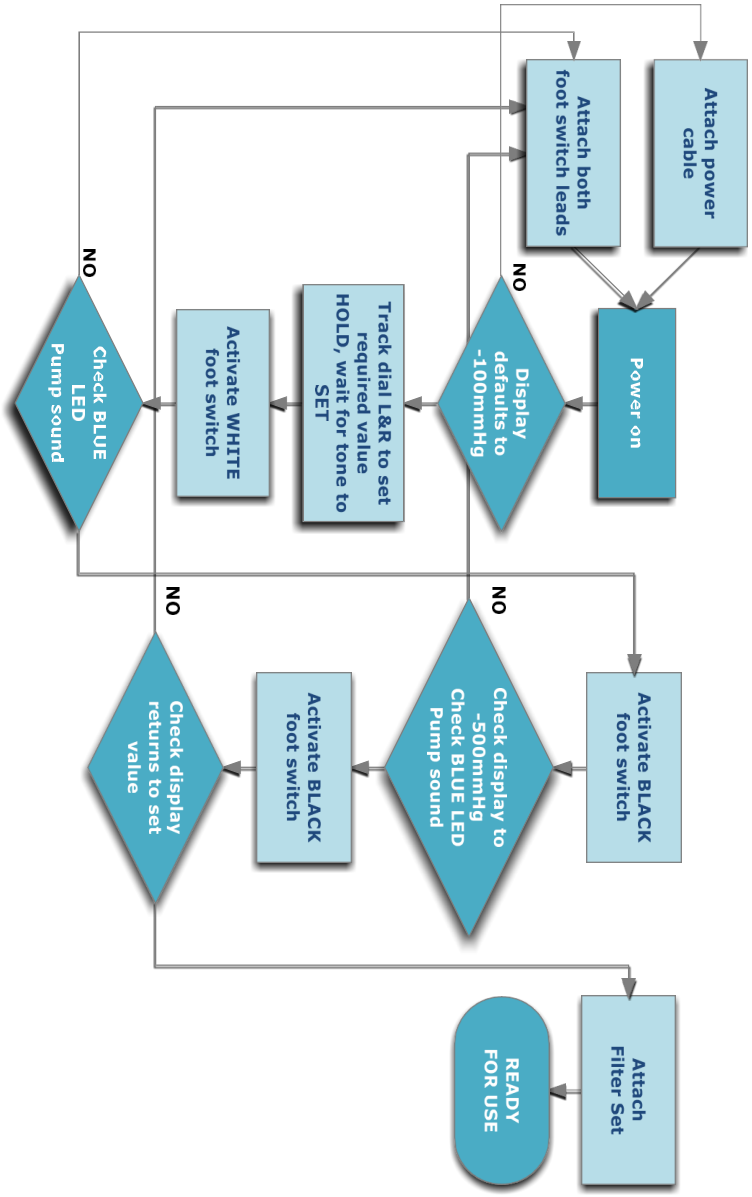
12. DRAWINGS

12.1 SET-UP FLOW CHART



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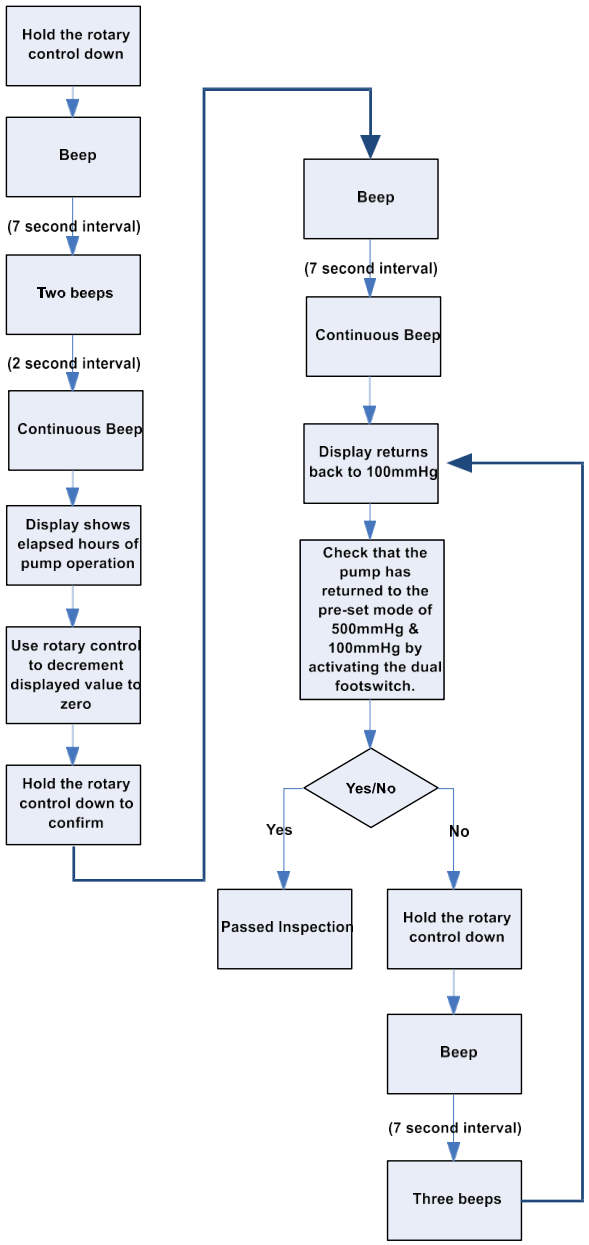
12.2 PUMP TIMER RESET FLOWCHART



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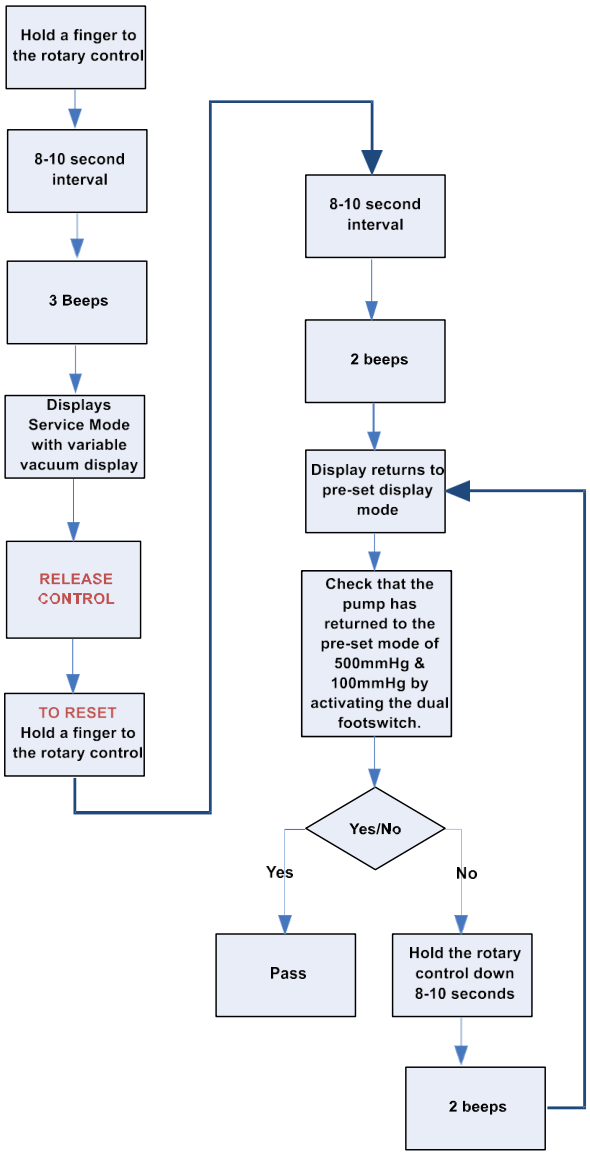
12.3 SERVICE MODE RESET FLOWCHART



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