OPERATORS GUIDE

Rocket R54569 PSU

Portable low vacuum/low flow Suction Pump
1. GENERAL ASSEMBLY

1. Carry Handle
2. On/Off Button
3. Control/Decision interface
4. Back Lit LCD Screen
5. Rotating lock for connection to chest drainage bottle.
6. Single use filter cavity & filter detection

7. USB port & reset button indicated by

8. Power Supply Unit
   Connection port indicated by

Not Shown
9. Power Supply Unit
   Model: R54569-PSU-UK

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

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.
2. GENERAL INFORMATION

2.1. COPYRIGHT

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2.2. MODEL NUMBERS:

Suction Unit R54569.
Power Supply R54569-PSU-UK
Single Use Filter R54571

2.3. MANUAL REVISION:

Revision 1: New Document
Revision 2: Text update
Revision 3: Addition of CE Mark and information for end user
Revision 4: Text update
Revision 5: Alarm & Software Update
Revision 6: Text update
Revision 7: Cleaning materials update

2.4. MANUFACTURER:

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NE38 9BZ
UK.

SERVICE AGENTS:

Customer Services:
Rocket Medical plc.
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Email: customerservices@rocketmedical.com
2.5. GENERAL DESCRIPTION:

The Rocket Digital low vacuum/low flow Suction unit (Known as the PSU, and referred to as the PSU for the purposes of this instruction manual) has been developed to provide low volume/low pressure suction via the Rocket Medical R54500, R54509 and R54517 Chest drain units.

The system provides regulated negative pressure via the R54500, R54509 or R54517 (1800ml volume) chest drain bottles and R54502 or R54539 (12mm x 1500mm) connector tubing. Before and during use inspect the chest drainage bottle and connector tubing to ensure no damage has occurred. The R54500, R54509 and R54517 chest drainage bottles and R54502 or R54539 connector tubing are single use only.

There is a gravity drainage setting, and the range of suction is variable from -0.5 KPa / -3.7mmHg/-5cmH2O to -5 KPa / -37.5mmHg/-50 cmH2O*.

*cmH2O is not a SI unit according to EU Directive 80/181/EEC.

Treatment information is displayed graphically on the LCD screen in real time and when treatment has concluded, this information can be downloaded to a PC, using Rocket Medical software.

Suction is applied to the chest drain unit, not directly to the pleural space. This is due to the underwater seal within the chest drainage unit. Adjustment may be required to levels of suction

The PSU requires a disposable filter to be fitted to the chest drainage bottle and the suction unit before use. If no filter is fitted then the suction unit will not operate.

The filter is supplied separately, sterile and for single use.

The order code for the filter is R54571.

The device is portable and can be operated independently of the mains supply. This is due to the rechargeable battery and thus this also allows patients to have suction applied to their chest drain unit even whilst they are mobile.

2.6. INTENDED USE

To act as a device for the aspiration and removal of surgical fluids, tissue, gases, bodily fluids or infectious materials. PSU is indicated for drainage from the pleural and mediastinal cavity; which may include: post-operative management following cardiac surgery, pneumothorax, pleural effusion, empyema and other related conditions.

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 only be used with a R54571 single use filter and R54500, R54509, R54517 chest drain units and tubing set (R54502, R54539).

2.7. CONTRAINDICATIONS:

Not intended for use where a suction (vacuum) value of over 5 KPa or a flow of over 5L/min is required.

Not intended for use where the application of suction/vacuum to the pleural space is contraindicated or would place the patient at risk.

⚠️ WARNING: Ensure the suction level is appropriate. Patients may experience discomfort when higher levels of suction are applied.
2.8. CLASSIFICATION

EN 60601-1:2006

Type of protection against electric shock: Class II
Degree of protection against electric shock: Type B
Vacuum type: low vacuum/low flow

Suitable for continuous operation.
Not suitable for use in the presence of flammable gases.
Not suitable for use in conditions which expose the device to the ingress of fluids.
Not suitable for sterilisation

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

2.9. SPECIFICATIONS

Power Input to Pump: 18VDC
Power Supply: 100 - 240VAC 50/60Hz
Consumption: 0.096 KW/h
Frequency: 50/60 Hz
Maximum current: 2.5A @ 18V

Environmental conditions: +5°C to +35°C
Service interval: 500 Battery charges

Dimensions:
- W - 190mm
- H - 118mm
- D - 140mm

Weight:
- Unit - 0.96Kg

Suction Ranges:
- User Set: -0.5KPa to -5KPa

Suction Range Accuracy: ±10% at 2.5KPa.
3. SAFETY INSTRUCTIONS

This manual describes the operation and intended use of the device and the associated consumables and it is essential that you use this document to familiarise yourself with the correct function and operation of the device before use.

This device should only be used by, or under the supervision of, appropriately trained personnel and in conjunction with current local clinical practice guidelines.

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.

The Rocket R54569 Digital low vacuum/low flow Suction Unit is EMC tested in conformity with the requirements of EN 60601-1-2:2007 and can be used in the vicinity of other EMC tested devices that fulfil the requirements outlined in the EN 60601-1-2:2007 standard.

Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards. Furthermore all configurations shall comply with the requirements for medical electrical systems. Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems.

Local laws take priority over the above requirements. If in doubt consult your local representative or the service agents.

Please note these instructions for use are a general guide for the use of the product, clinical matters must be addressed by qualified personnel.

3.1. POWER SUPPLY AND BATTERY OPERATION:

The PSU can be operated from the mains power supply or with the inbuilt battery (Rechargeable Lithium-ion 14.4V nominal, capacity approx. 2250mAh – Type 4SP1 4 cell 34Wh).

The battery is charged on mains operation. Battery duration is dependent on the run time of the PSU. This is influenced by the extent of the parenchymal leakage and the set suction level. PSU does not run continuously but only switches on when the actual and nominal values differ.

During continuous battery operation, Rocket Medical guarantees a minimum run time of 4 hours, after the battery has been fully charged.

In practical operation the battery operating time is > 10 hours.

⚠️ WARNING: The device is only for use with supplied power supply unit: Model Number: R54569-PSU-UK.

⚠️ CAUTION: Disconnection from the mains supply can be achieved with the removal of the mains power lead from the power supply connection port of the device itself or from the wall socket.
3.2. CONSUMABLES:

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

The device must only be used with a R54571 single use filter and only be used in conjunction with R54500, R54509 and R54517 chest drain units (capacity 1800ml) and tubing set (R54502, R54539).

The suction unit will not operate if a filter set is not in situ.

The filter sets are designed to prevent fluid contamination of the suction pump.

If there is any evidence that the pump may have become contaminated with fluid or a solid during use or the filter has failed in any other way, it must be removed from service and returned for examination immediately.

Please contact your nearest service centre for advice.

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3.3. TERMINOLOGY:

Throughout this manual the term “suction” is used to denote *the application of vacuum or negative pressure*. The use of the term ‘suction’ is in observance of the requirements of the ISO6061-1 Standard as amended.
3.4. WARNINGS:

- Users should be familiar with and adhere to all warnings, cautions and instructions for use that are labelled on the PSU device and included in the PSU 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.
- Not intended for use where a suction (vacuum) value of over -5 KPa or a flow of over 5L/min is required.
- Not intended for use where the application of suction/vacuum to the pleural space is contraindicated or would place the patient at risk.
- Data transfer is not allowed during therapy.
- The PSU device is not approved for connection to any other device except the Rocket Medical R54571 single use filter and R54500, R54509 and R54517 chest drain unit and tubing set (R54502, R54539).
- The R54500 chest drain unit and tubing set (R54502, R54539) are single use parts and their instructions for use must be followed at all times.
- The PSU device has not been tested for compatibility with Magnetic Resonance Imaging (MRI) equipment and should not be introduced to an MRI scanning room.
- The device is not suitable for use during bathing or showering.
- Do not use in an area where flammable gases are present.
- If a persistent air leak is shown, check the filter is positioned correctly on the chest drain unit and that the suction unit is securely attached to the chest drain unit.
- Regular periodic maintenance of the PSU device is recommended and as a minimum should be undertaken annually.
- Precautions for EMC safety should be observed. The PSU complies with IEC60601-1-2:2007, however:
  - Electronic equipment in the vicinity of the PSU device may affect its operation and potentially cause unpredictable operation of the device.
  - Wherever possible the PSU device should be distanced from surrounding electromagnetic equipment and cables to this equipment in order to reduce possible electromagnetic interference.
  - The PSU device power cable should only be connected to a correctly wired grounding receptacle in order to avoid the risk of electrical shock.
- When positioning the unit, ensure that access is available to the DC power cable located on the rear of the unit.
- To avoid damage to the unit only use the approved mains power adaptor supplied with the unit, Model Number: R54569-PSU-UK.
- The PSU contains a Li-ion battery and that is not user replaceable and that unauthorised attempts to repair could lead to damage to the unit, environment and/or human health if incorrectly fitted, handled or disposed of improperly.
- The Li-ion battery must only be replaced by a suitably trained and Rocket Medical approved service centre.
- 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 unit cabinet should not be opened except by these personnel due to the risk of hazardous electrical shock. All service requirements should be referred to a PSU authorised representative.
- All equipment should be thoroughly cleaned after each use (refer to section 7 Cleaning Guidelines).

WARNING: Do not modify this equipment without written authorization of the manufacturer.
3.5. SUPPLY VOLTAGE SELECTION

The device operates at a voltage of 18VDC supplied via a medical grade power supply unit (PSU). Rocket Model Number: R54569-PSU-UK

Input voltage: 18VDC

Power supply range 100 - 240VAC 50/60Hz. Ensure that only the supplied power supply cord is connected.

**WARNING:** ELECTRIC SHOCK HAZARD.

This device is only for use with electrical systems complying with the appropriate IEC, CEC and NEC requirements.

3.6. ELECTROMAGNETIC COMPATIBILITY

The PSU complies with the electromagnetic compatibility (EMC) limits for medical devices as specified by EN 60601-1-2:2007. These limits are designed to provide a reasonable degree of protection against harmful interference found in typical medical installations.

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

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

Evidence of EMC interference may include erratic digital displays, an inability to correctly set the desired suction, the device failing to operate, or other incorrect functioning.

If this occurs, stop using the aspiration pump and contact Customer Services or Rocket Medical authorised distributor.

3.7. PACKAGING

The packaging has been carefully designed to allow secure transportation of the PSU 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

The PSU must be placed securely on a R54500, R54509 or R54517 Chest drainage bottle, away from sources of heat, water splashes, mists or cooling vents and with due regard to EMC protection (Section 4.6)

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

Do not expose to direct sunlight.
Do not expose to flammable gases.
Operating temperature Range: +5°C to +40°C

**WARNING:** Device can cause explosion in the presence of flammable gases.
### 3.9. Symbols used on the PSU Unit.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Power Icon" /></td>
<td>On/Off</td>
</tr>
<tr>
<td><img src="image" alt="Warning Icon" /></td>
<td>Read the manual before connection and use</td>
</tr>
<tr>
<td><img src="image" alt="Person Icon" /></td>
<td>This device is Type B</td>
</tr>
<tr>
<td><img src="image" alt="USB Icon" /></td>
<td>USB Port</td>
</tr>
<tr>
<td><img src="image" alt="Battery Icon" /></td>
<td>DC power connection point. This device operates on 18V DC power provided by a separate power supply module supplied with the device. Disconnection from the mains supply can be achieved with the removal of the mains power lead from the power supply connection port of the device itself or from the wall socket</td>
</tr>
<tr>
<td><img src="image" alt="Disposal Icon" /></td>
<td>Dispose of this device in accordance with WEEE directive (2002/96/EC)</td>
</tr>
<tr>
<td><img src="image" alt="CE Mark" /></td>
<td>CE Mark</td>
</tr>
<tr>
<td><img src="image" alt="Class II Icon" /></td>
<td>Class II Device</td>
</tr>
<tr>
<td><img src="image" alt="Battery Icon" /></td>
<td>Li-ion Battery used in the device</td>
</tr>
<tr>
<td><img src="image" alt="Reset Icon" /></td>
<td>RESET Reset button</td>
</tr>
</tbody>
</table>
3.10. Symbols used on the PSU Screen

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Checkmark]</td>
<td>Confirm choice</td>
</tr>
<tr>
<td>![X]</td>
<td>Cancel Choice</td>
</tr>
<tr>
<td>![Up Arrow]</td>
<td>Increase</td>
</tr>
<tr>
<td>![Down Arrow]</td>
<td>Decrease</td>
</tr>
<tr>
<td>![Exclamation Mark]</td>
<td>Warning</td>
</tr>
<tr>
<td>![Battery]</td>
<td>Battery Charging</td>
</tr>
<tr>
<td>![Battery Charge Low]</td>
<td>Battery level of charge indication</td>
</tr>
<tr>
<td>![Screen Number]</td>
<td>Screen number (from 1-4)</td>
</tr>
<tr>
<td>![KPa]</td>
<td>Unit of measurement</td>
</tr>
</tbody>
</table>

Can also be cmH₂O and mmHg
### 3.11. Symbols used on the Power Supply Unit.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>⚠️</td>
<td>Read the manual before connection and use</td>
</tr>
<tr>
<td>⚡</td>
<td>WARNING: Risk of electric shock. The PSU should not be opened</td>
</tr>
<tr>
<td>🏡</td>
<td>Device is only for use indoors</td>
</tr>
<tr>
<td>☐</td>
<td>Class II Power Supply Unit</td>
</tr>
<tr>
<td>- - +</td>
<td>18V DC connection polarity</td>
</tr>
<tr>
<td>🗑️</td>
<td>Dispose of this device in accordance with WEEE directive (2002/96/EC)</td>
</tr>
<tr>
<td><img src="image" alt="EN60601-1 IEC60601-1" /></td>
<td>PSU conforms to EN60601-1 &amp; IEC60601-1:2006</td>
</tr>
<tr>
<td>CE</td>
<td>CE Mark</td>
</tr>
</tbody>
</table>

### 3.12. Other Symbols used in the manual

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>🌧️</td>
<td>This symbol indicates to keep the device dry</td>
</tr>
<tr>
<td>🌡️</td>
<td>This symbol indicates the temperature limitations for operation, transport and storage</td>
</tr>
<tr>
<td>🌡️</td>
<td>This symbol indicates the humidity limitations for operation, transport and storage</td>
</tr>
<tr>
<td>🌡️</td>
<td>This symbol indicates the atmospheric pressure limitations for operation, transport and storage</td>
</tr>
</tbody>
</table>
4. INITIAL SET UP OF THE PUMP

4.1. Charge the Battery

IMPORTANT: The suction unit battery is not charged.

DO NOT CONNECT TO A PATIENT IMMEDIATELY UPON OPENING.

1. Remove all packaging for the device and the power supply.

2. Connect the correct mains lead to the 18V power supply module and connect to an electrical supply 100 - 240VAC 50/60Hz. The power supply module is self-regulating to generate 18VDC.

3. Connect the power supply to the PSU, the power supply connection port is on the back of the device. It is protected, and is behind the door marked

4. Charge the device for approximately 3 hrs until the battery display is full.

IMPORTANT: The PSU may be connected to the power supply unit and remain in use while the battery is charging.

If the PSU is switched on and in use, the power supply unit may be disconnected at any time and the PSU will remain in use.

If the PSU is turned off while still connected to the power supply, the power supply MUST be disconnected before the PSU is switched on again.
4.2. When the battery is charged.
Press and hold \( \bigcirc \) for longer than 2 seconds (s) to switch on the device.

A self-test will commence.

When the self-test has completed, follow the software instructions to set the time and date.

When this has been completed turn the device off by pressing and holding \( \bigcirc \) for longer than 2s.

Press \( \checkmark \) to shut down device.
**WARNING:** This device should only be used by, or under the supervision of, appropriately trained personnel and in conjunction with current local clinical practice guidelines.

Sterile accessories (Filter Unit R54751) packaging must be checked for integrity before use.

The filter unit (R54571) is a single use device. This can be used for a maximum of 7 days.

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

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

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

**Operation without the correct filter set will invalidate the Warranty.**

Suction is applied to the chest drain unit, not directly to the pleural space. This is due to the underwater seal within the chest drainage unit. If the levels of fluid within the chest drain unit increase, adjustment may be required to increase levels of suction during treatment.

The suction unit must be cleaned and disinfected between patient use, according to the Rocket cleaning guidelines.

**The device is for use with and connection to the R54500, R54509 and R54517 chest drainage units only.**

The chest drain unit must already be connected to the patient and checked to be in complete working order before the suction unit is attached.
4.3. Attaching the filter

1. Remove the R54500, R54509 and R54517 chest drain bottle from its packaging.

2. Fill bottle with fluid to prime level noted on label.

3. Open tubing package (R54502, R54539) and attach tubing set to bottle by inserting straw and cap into aperture and twisting clockwise until clicked shut. Take care not to touch the straw.

4. Once underwater seal has been established, place bottle on the floor and connect drainage catheter to tubing connector.

5. Then remove the Blue handle and the Green venting cap from the chest drain.

6. Unwrap the filter from packaging.

7. Place filter on to the suction port of the R54500, R54509 and R54517 Chest Drainage bottle.

8. Ensure when placing the filter the location peg is placed in the aperture which the green venting cap was in.

The PSU can now be attached to the chest drain bottle.

9. Rocket Electronic Suction Unit Filters are for single patient use for up to a maximum of 7 days.

⚠️ **CAUTION:** If the filter is contaminated by fluid, the level of suction could be compromised. The filter is designed to protect the pump mechanism from fluid ingress.
If contaminated, the filter set MUST be replaced immediately.

4.4. Attaching the suction unit to the chest drain bottle

Place the PSU over the filter unit, so the filter will fit in to the filter recess under the suction unit.

Place the PSU on to the chest drain unit. With slight downward pressure rotate the locking ring Anti-clockwise so that it locks into position.

4.5 Disconnecting the suction unit from the chest drain bottle

With slight downward pressure rotate the locking ring clockwise.

To dispose of the R54500 Chest Drain Bottle

1. Remove tubing set for disposal in the usual manner by turning the clear plastic bayonet closure cap anti-clockwise from "close" position to "open" position.

2. Remove the filter, tear/pull the red seal cap located on the bottle lid and marked seal, from its tether.

3. Push the red sealing cap firmly with a twisting action into the suction port on the lid of the bottle to seal.

4. Remove the red bayonet cap from its bracket on the side of the lid and replace in hole vacated by the tubing set.

5. Seal cap in place by rotating the cap clockwise from "open" to "close".

6. Should the red bayonet cap be mislaid, do not remove tubing set, but cut through the tubing and place the end of the tubing over the suction port on the lid of the bottle to create a seal.

7. Bottle is now ready for disposal.
5. OPERATING INSTRUCTIONS

1. Press for longer than 2s to turn the device on.

   The unit will begin a self-test

   If the self-test is unsuccessful see the trouble shooting instructions on page 24.

   During the set you can confirm or cancel your decisions using the three buttons at the side of the screen.

2. Verify if the PSU is connected to a new patient.

   This information is important for the data reading & recording.

   Yes – New patient number is issued. – Follow column A.
   No – Patient number is unchanged: Recommended for continued treatment of the same patient.
   Data recording is continued. – Follow column B.
If you press you will progress to the next screen.

Please verify that you have changed the filter by pressing or to confirm your decision.

If you press you will be taken to the next set up screen.

If you press you will be asked to change the filter and the unit will shut down.

Remove the suction unit and change the filter as per the instructions, re-fit the PSU to the chest drain bottle and switch on the unit again to restart the set up process.

If you have changed the filter press and you will be taken to the next set up screen.

If the filter requires replacing press you will be asked to change the filter and the unit will be shut down.

Remove the suction unit and change the filter as per the instructions, re-fit the PSU to the chest drain bottle and switch on the unit again to restart the set up process.
3. Confirm your unit of measurement. The PSU can measure – ve pressure in KPa, cmH₂O and mmHg.

4. You will be asked to confirm your decision.

5. Set the amount of suction required. Using increase or decrease buttons until you are at a level you deem satisfactory.
   The levels suction applied increase in -0.5KPa, -5cmH₂O and 3.75mmHg increments.
   There is also a gravity drainage option.

   When you are happy with the set level of suction press

6. You will be asked to confirm your decision.

   If you press you will be taken back to the previous screen where you can confirm your preferred unit of measurement.
Pressing **AND** holding unit and to the patient. for over 2 seconds will commence the application of suction to the chest drain unit and to the patient.

5.1 Changing suction levels

If at any time the level of suction required needs changing, then press buttons 2 & 3 **together** for longer than 2s. This will return you to the suction level setting screen.

Repeat instruction number 5 to change the level of suction required and instruction 6 to confirm.

When the suction unit is in situ and suction is applied 4 different display modes are available to view.

Scroll through the 4 screens by pressing button number 1.
Screen 1

Suction level and flow rate

The flow rate, is the volume of air being removed by the pump in L/min.

Screen 2

Suction level and time of suction applied.

Screen 3

Flow vs Time Graph.
The graph shows the flow and pressure progression as a function of time. The screen shows 24 hours of use and is updated every 12 minutes. Flow is measured from 5L/Min. 4 hours are necessary to have a representative graph.

(Image is a representation)

Screen 4

Air leak indicator, if the patient has a 4-hour period where the suction pump is not engaged, this is classed as the patient having no air leak, the indicator will change colour. This will scroll through as each 4-hour block passes. This is an indication only, further clinical checks should be performed; such as an x-ray prior to chest drain removal.
5.2 Changing the clock time

The clock time can be changed in 2 ways:
1. On the new patient screen press button 1 and while holding button 1 press button 3.
2. By using the software program – see section 8.

5.3 Switching the unit off

When this has been completed turn the device off by pressing and holding for longer than 2 seconds.

Press to shut down device.
6. Alarm codes

The PSU distinguishes between warnings, alarms and internal errors. If PSU detects any of these situations, an acoustic warning signal sounds and an error number will be displayed.

The error number corresponds to the problem as shown below.

<table>
<thead>
<tr>
<th>Error</th>
<th>Problem Description</th>
<th>Trouble Shooting</th>
<th>Source of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>501</td>
<td>Self-test failed</td>
<td>Switch off unit and restart. If self-test fails again, rest the unit, by pressing the reset button on the rear of the device next to the USB port.</td>
<td>Filter may not have been recognised, problem with sensor.</td>
</tr>
<tr>
<td></td>
<td>Sensor defect</td>
<td>If you have switched the unit off and then immediately switched it back on again, the suction unit may not be able to detect a zero pressure point. Remove the pump and filter to allow the pressure in the chest drain bottle to stabilise and then reattach.</td>
<td>Pump cannot detect a zero pressure in the chest drain bottle.</td>
</tr>
<tr>
<td>502</td>
<td>Battery low</td>
<td>Plug in Power Supply to recharge battery</td>
<td>Battery low on charge, approximately 30 mins of power remaining</td>
</tr>
<tr>
<td></td>
<td>Connect power supply</td>
<td></td>
<td></td>
</tr>
<tr>
<td>504</td>
<td>No filter</td>
<td>Check to see if filter is in place. Remove pump from bottle to check filter in in position.</td>
<td>Unit may have been turned on without filter in place.</td>
</tr>
<tr>
<td></td>
<td>Please insert filter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>506</td>
<td>Data storage error</td>
<td>Turn unit off and back on. If error occurs please contact manufacturer for service.</td>
<td>Memory malfunction, failure in storage access</td>
</tr>
</tbody>
</table>
If the PSU has been switched off when still attached to a patient, if the PSU is turned immediately back on, the pump will perform a self-check and then calibrate to the suction level set, this takes approx. 10 seconds.

If the PSU cannot calibrate the pressure setting, alarm 501 may sound. If this happens, remove the PSU from the chest drain bottle, reattach, turn on and set up the unit as required.

When error number 508 is displayed, any button can be pressed to clear the screen or the screen itself will clear after 10 seconds.
7. Cleaning Guidelines

⚠️ **Warning** after each use the PSU should cleaned and disinfected and single use items such as the filter should be disposed of.

At the end of each patient use, turn off the device and disconnect from the Power Supply Unit. Using an aqueous 70% alcohol solution (eg. IMS or isopropyl BP) solution, moisten a cloth and wipe all external surfaces of the device.

If the surface has become contaminated, remove with a light detergent solution before cleaning with an alcohol solution.

1000pm and 10,000pm Chlorine, and Hydrogen Peroxide based disinfectants can also be used on the PSU.

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.

Never place electrical devices in water or other liquids, specifically the PSU. The Rocket Medical PSU cannot be sterilized. Immersion disinfection, thermal disinfection and ultrasound cleaning for the PSU is not permitted.

Clean all surfaces immediately after use to avoid residues from drying and to prevent growth of microorganisms.
Do not use cleaning agent/detergent based on phenol.
Do not use steel brushes or steel wool for cleaning.
Store medical products dry and dust free.

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

⚠️ **WARNING:** Do NOT attempt to sterilise the device
8. Data Retrieval

To retrieve the data from the device, disconnect from the patient.

1. Download and install the free Rocket PSU Data Retrieval Application from www.rocketmedical.com.

2. Disconnect the PSU from the patient - data cannot be accessed while the device is in use.

3. Connect a Mini USB cable, using the port on the rear of the suction unit and connect the device to your computer.

5. Open the application and power on the PSU.

6. Once the data recorded is downloaded, click on the patient data you wish to retrieve and graphical display of the recorded data will be displayed. You will be able to retrieve data from up to 10 patients – identifiable by date and time.

7. You will be able to save patient data into an identifiable record using the save as function.

Click on - Connect Device
Choose which patients information you choose to examine.

The patients are identified by the date and time that the treatment started.
The device will store the information of up to 10 patients.
When the storage is full, then the oldest patient record or information is automatically deleted.
You will be provided with an initial view of the data.

Click on the data to be taken to a larger format screen.

You can also change the unit of measurement.

The blue line indicates flow (size of air leak).

The green line indicates pressure applied (suction).

From this page the information can be printed out and the scale of the time axis can be changed.
The software can be used to change the time display on the suction unit if required.

Device Stats provides information for use during servicing.

⚠️ **WARNING**: Data retrieval should not take place while the PSU is in use.
9. Service

Service of the PSU can only be undertaken by suitably trained and approved service engineers, there are no parts that are user changeable within the unit.

The PSU contains a replaceable lithium rechargeable battery that can only be accessed by using a tool and only by a service engineer.

The PSU contains a Li-ion battery and that is not user replaceable and that unauthorised attempts to repair could lead to damage to the unit, such as excessive temperature, fire, risk to the environment and/or human health if incorrectly fitted, handled or disposed of improperly.

In the unlikely event that the lithium battery is showing signs of leakage the PSU must be immediately taken out of service, the battery must be disconnected from the main PCB and the service engineer must contact Rocket Medical for advice as to how to proceed.

Only replace with an approved lithium battery supplied from Rocket Medical Type 4SP1 4 cell 34Wh.

To avoid damage to the unit only use the approved mains power adaptor supplied with the unit, Model Number: R54569-PSU-UK.

Service intervals are based on 500 charges of the battery. If the battery was charged every day this would give over 500 days of use before the pump requires servicing. After 500 charges Service Indicator screen will appear indicating servicing is now overdue.

Appearance of the service indicator screen does not inhibit pump function. From 500 charges onwards the battery may be reduced. Once illuminated, the pump must be returned for servicing as soon as possible.

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: No user serviceable parts inside.

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

1. Surface clean the pump as described in Section 8 above
2. Seal in a plastic bag and seal within a second plastic bag.
3. Place in the original packaging.
4. Enclose the following information:
   - Contact name
   - Centre address
   - Decontamination Certificate
   - Description of the fault or service required
   - Accompanying Order to authorise servicing – contact your local Customer Services Team for details

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

Contact your local service agent for further information.

Customer Services:
Rocket Medical plc.
Sedling Road. WASHINGTON. NE38 9BZ. ENGLAND
Tel: +44(0)191 419 6988. Fax: +44(0)191 419 6989
Email: customerservices@rocketmedical.com
10. Environmental Requirements for Transport and Storage

| ![Symbol] | The device must be transported/stored at temperatures between -20°C to +50°C |
| ![Symbol] | The device must be transported/stored at relative humidity levels between 20% to 95% |
| ![Symbol] | The device must be stored in a clean, dry condition, ideally in its original packaging which should be retained to return the unit for servicing. Protect the device from ingress of liquid. Should any liquid enter the device, discontinue use immediately and refer to an authorised service agent |

11. Environmental Requirements for Operation

| ![Symbol] | The device must be operated at temperatures between +5°C to +40°C |
| ![Symbol] | The device must be operated at relative humidity levels between 15% to 93% |
| ![Symbol] | 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. |
| ![Symbol] | Dimensions: W - 190mm H - 118mm D - 140mm Weight: Unit – 0.96Kg |
| ![Symbol] | Protect the device from ingress of liquid. Should any liquid enter the device, discontinue use immediately and refer to an authorised service agent |
12. EMC Tables:

Table 1: Guidance and Manufacturer’s Declaration – Electromagnetic Emissions

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions CISPR 11</td>
<td>Group 1</td>
<td>The Rocket Medical Electronic Suction Device generates RF signals for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF CISPR 11</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Harmonic Emissions IEC 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations / flicker emissions IEC 61000-3-3</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>
The Rocket Medical Digital low vacuum/low flow Suction device is intended for use within the electromagnetic environment specified below. The customer or operator of a PSU should ensure that it is used within such an environment.

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

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 PSU device is intended for use within the electromagnetic environment specified below. The customer or the operator of a PSU should be ensured that it is used within such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic environment Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted Rf</td>
<td>3 Vrms</td>
<td>3 Vrms</td>
<td>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.</td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td>150 kHz to 80 MHz</td>
<td></td>
<td>D=1.2√P 80 MHz to 800 MHz</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V/m</td>
<td>3 V/m</td>
<td>Recommended Separation Distance</td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td>80 MHz to 2.5 GHz</td>
<td></td>
<td>D=1.2√P 800 MHz to 300 GHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Interference may occur in the vicinity of equipment marked with the following symbol</td>
</tr>
</tbody>
</table>

Note 1: At 80 MHz and 800 MHz, 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.

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 PSU device is used exceeds the applicable RF compliance level above, the PSU 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 PSU 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 Medical PSU low vacuum/low suction device.

The PSU device is intended for use in the electromagnetic environment specified below. The customer or the user of the PSU device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PSU device as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Read Maximum Output Power of Transmitter</th>
<th>Separation Distance According to Frequency of Transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td>W</td>
<td>d = 1.2 \sqrt{P}</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>3.8</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

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.
13. Warranty

Rocket PSU 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.

14. Disposal

At the end of the service life of the equipment, this device should be handled and disposed of in accordance with local hospital policy and with regard to all applicable regulations, including but without limitation to, those pertaining to human health & safety and care of the environment.

Where applicable, disposal of this device must be undertaken with regard to the WEEE directive (2002/96/EC).