CLEMENTS

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# HiFlo2 Max
# High Vacuum High Flow
# Mobile Suction Pump
# SUC 84604
# 220-240 V 50/60 Hz


## User Manual

Manual No. SUC84604008
Issue 3

## Safety

Thank you for purchasing this Clements HiFlo2 Max High Suction Pump.

For your safety it is imperative that this unit only be operated by authorised personnel in accordance with the instructions as described in this manual. Operated in this way, the HiFlo2 Max High Suction Pump will provide the standard of service specified.

Due to continual improvements in product design, the HiFlo2 Max High Suction Pump may vary in detail from the descriptions in this manual. In the event of further questions please contact your local distributor or ICU Medical Australia direct.

Familiarise yourself with these *Directions for Use* before operating this device.

User Manual
HiFlo2 Max High Suction Pump
Manual Number SUC84604008 MDR Revision 0
Issue 3 2022-07-12



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## Contents

## Description

The Clements HiFlo2 Max High Suction Pump is a mobile unit designed to suit the needs of hospitals, doctors' surgeries and paramedics in providing a strong source of suction for use in indoor environments where mains power is available.

## Identification

SUC84604 HiFlo2 Max High Vacuum / High Flow Mobile Suction Pump

## Intended Use

To provide a continuous vacuum source, within the stated operating vacuum range, for the aspiration of fluids and particulate matter in medical procedures carried out by clinically trained and authorized personnel.

## Contraindications

Before using the HiFlo2 Max, consult the instructions for use.
Failure to follow instructions in this manual could cause harm.
Do not use the HiFlo2 Max for thoracic or low vacuum drainage.
Do not use the HiFlo2 Max for suctioning of explosive, corrosive or easily flammable fluids.
HiFlo2 Max is not suitable for MRI. Do not place in MRI environments.

## Pump Classifications

| | |
|---|---|
| GMDN | 63642 |
| GMDN Term | Surgical suction pump |
| GMDN Synonym | Aspirator |
| Device Class<br>Typology (Regulation EU 2017/745) | Medical Device Class IIa |
| Electrical Protection | Class II |
| Protection | Type B Applied Part |
| Sterilisation | Not supplied in sterile state |
| Anaesthetic Rating | NOT Category AP<br>NOT Category APG |
| ISO 10079-1 Designation | High Vacuum / High Flow |
| Operation Mode | Continuous operation |

## Specifications

| | |
|---|---|
| Maximum Vacuum | -90 kPa [-675 mmHg] |
| Maximum Flow | 80 L/min (through jar) 90 L/min (free air) |
| Mains Power Requirement | 220 - 240 V 50/60 Hz 385 VA |
| Pump | Piston type |
| Motor | PSC AC motor |
| Fuse | F4A L 250V |
| Filter | Disposable hydrophobic and bacterial filter<br>BFE 99.9999%, VFE 0.027 micron |
| Collection Container | 2x 2 litre autoclavable, reusable jar<br>Optional 5 litre autoclavable, reusable jar<br>Optional 2 litre disposable liner jar<br>Optional 3 litre disposable liner jar |
| Overfill Protection | Float valve mechanism in external trap jar |
| Vacuum Control | Needle valve |
| Gauge | Bourdon tube type. Dual scale. CL 2.5 |
| Gauge Range | 0 to -100 kPa graduated at 5 kPa<br>0 to -760 mmHg graduated at 50 mmHg |
| Weight | 17.5kg |
| Dimensions | 460W x 850H x 420D mm |
| Packed Weight | 23 kg |
| Packed Dimensions | 500W x 910H x 500D mm |
| Standard Conditions | 25 °C, Sea level, 100 kPa |

## Package Contents

The Clements HiFlo2 Max package contains:

- HiFlo2 Max mobile suction pump
- 2 x 2 litre reusable collection jar with lid assembly
- External trap jar x2
- Silicone 8 x 14 mm medical suction tubing 1.5m x2, 0.34m x4
- 2-Pin AU plug to IEC 320 power lead
- Disposable antibacterial/hydrophobic filter x2
- Stepped conical tubing connector x2

## Environmental Conditions

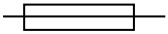
Environmental conditions for operation, transportation and storage are shown in the following table. In addition, for vehicular transportation, the unit should be kept upright.

| State | Parameter | Minimum | Maximum |
|---|---|---|---|
| Operating | Temperature | 5 ºC | 35 ºC |
| | Humidity | 30% RH | 75% RH |
| | Barometric Pressure | 800 hPa | 1060 hPa |
| | Altitude | 0 m | 2000 m |
| Transport and Storage | Temperature | -40 ºC | 70 ºC |
| | Humidity | 10% RH | 100% RH |
| | Barometric Pressure | 500 hPa | 1060 hPa |

## Symbols

| | |
|---|---|
|  | General warning |
|  | Consult user manual |
|  | Type B Applied Part (suction cannula) |
|  | Insulation Class II (double insulation) |
| Hz | Mains power frequency |
| ~ | Alternating current |
|  | On / Off |
| CE 0123 | CE Mark in conformity with Regulation EU 2017/745 |
|  | Manufacturer |
| REF | Model / Reference Number |
| LOT | Lot / Batch Number |
|  | Consult user manual before use |
| MD | Medical Device |

## Symbols

| | |
|---|---|
|  | Serial Number |
|  | Fragile |
|  | Relative Humidity Range |
|  | Keep Cool / Keep out of direct sunlight |
|  | Temperature Range |
|  | Atmospheric Pressure Range |
|  | Fuse |
|  | C-Tick Mark |
|  | Dispose of electrical product according to requirements of WEEE directive |
| IPX1<br>(On footswitch control label) | Degree of protection against intrusion by body parts or objects and against ingress by water. |
| | 1st Digit - Penetration of Solids<br>X = No Protection |
| | 2nd Digit - Penetration of Liquids<br>1 = Protection against vertical dripping water |

## Cautions

**Usage**

1. Use only for the specified *Intended Use*.
2. Only suitably trained and authorised personnel may operate.
3. Keep out of reach of children or non-competent persons.
4. Do not use near flammable substances such as oxygen or anaesthetic gases.

**Fluids**

1. Keep device clear of water and other fluids. Do not handle pump with wet hands.
2. Handle full containers very carefully when transferring to disposal area, observing local protocols.

**Electrical**

1. Use only the supplied power cord.
2. Confirm that electrical rating of rating label matches that of the mains power.
3. Avoid the use of power boards and extensions.
4. Maintain clear access to the mains power outlet to facilitate disconnection.
5. Place pump clear of patient and other electronic equipment.
6. When not in use, disconnect pump from power supply.
7. Do not pull cable to remove plug from mains power outlet.

**General**

1. Check the pump and fittings for damage before each use.
2. Do not use without the bacteria/hydrophobic filter correctly fitted.
3. Switch off pump *immediately* if overflow float valve is actuated.
4. After use, clean and store away from heat, dust and sunlight.

**Repair**

1. Refer all service to suitably trained technicians.
2. Use only original spare parts and accessories.
3. No modifications are permitted.

## Important Safety Rules

1. Check the condition of the unit before each use. The surface of the unit should carefully inspected for visual damage. Check the mains cable and do not connect to power if damage is apparent.
2. Before connecting the appliance always check that the electric data indicated on the data label and the type of plug used, correspond to those of the mains electricity to which it's to be connected.
3. Respect the safety regulations indicated for electrical appliances and particularly:
   - Use original components and accessories provided by the manufacturer to guarantee the highest efficiency and safety of the device.
   - The device can be used only with the bacteriological filter.
   - Never immerge the appliance into water.
   - Position the device on stable and flat surfaces in a way that the air inlets on the back aren't obstructed.
   - To avoid incidents, do not place the aspirator on unstable surfaces, which may cause it to accidentally fall and lead to a malfunction and/or breakage. Should there be signs of damage to the plastic parts, which may expose inner parts of the energised device, do not connect the plug to the electrical socket. Do not attempt to make the device work before it has been thoroughly checked by qualified personnel.
   - Don't use in the presence of inflammable substances such as anaesthetic, oxygen or nitrous oxide.
   - Don't touch the device with wet hands and always prevent the appliance coming into contact with liquids.
   - Don't leave the appliance connected to the power supply socket when not in use.
   - Don't pull the power supply cable to disconnect the plug remove the plug from the mains socket correctly.
   - Store and use the device in places protected against the weather and far from any sources of heat. After each use, it is recommended to store the device in its own box away from dust and sunlight.
   - In general, it is inadvisable to use single or multiple adapters and/or extensions. Should their use be necessary, you must use ones that are in compliance with safety regulations, however, taking care not to exceed the maximum power

- supply tolerated, which is indicated on the adapters and extensions.

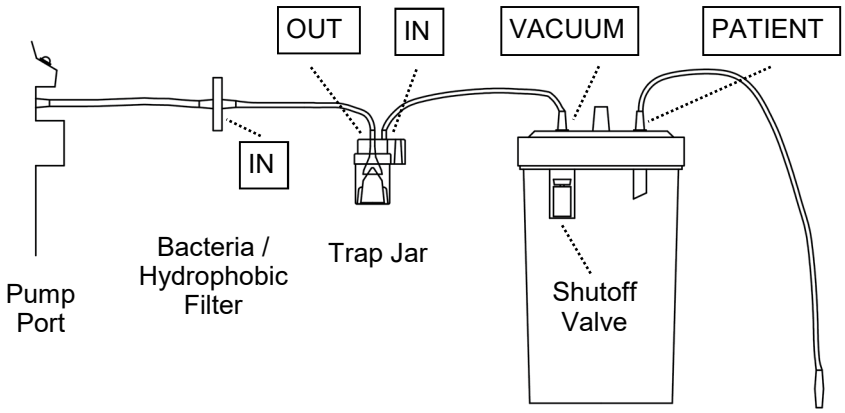
4. For repairs, exclusively contact technical service and request the use of original spare parts. Failure to comply with the above can jeopardise the safety of the device.
5. Use only for the purpose intended. Don't use for anything other than the use defined by the manufacturer.
   The manufacturer will not be responsible for damage due to improper use or connection to an electrical system not complying with current regulation.
6. Instrument and accessory disposal must be done according to current regulations in the country of use.
7. WARNING: Do not change this equipment without the permission of the manufacturer. None of electric or mechanical parts have been designed to be repaired by customers or end-users. Don't open the device, do not mishandle the electric / mechanical parts. Always contact technical assistance
8. Using the device in environmental conditions different than those indicated in this manual may harm seriously the safety and the technical characteristics of the same.
9. The medical device is in contact with the patient by means of a disposable probe (not supplied with the device). If this device must be used with a specific suction probe, the end user is responsible for making sure it complies with the ISO 10993-1 rule.
10. The product and its parts are biocompatible in accordance with the requirements of regulation EN 60601-1.
11. Operation of the device is very simple and therefore no further explanations are required other than those indicated in the following user manual.
12. The medical device requires special precautions regarding electromagnetic compatibility and must be installed and used in accordance with the information provided with the accompanying documents. The HiFlo2 Max device must be installed and used away from mobile and portable RF communication devices (mobile phones, transceivers, etc.) that may interference with the said device.

13. Any serious incident occurrence in relation to the device should be reported to the manufacturer and the competent authority in your country/area. If you have no contact information of such authority, please contact the manufacturer or distributor whose contact information is indicated in this instruction manual.

Under certain failure conditions, the temperature of the casing (HiFlo2 Max) may become hot and there may be a risk of burns if you touch those parts.
In any case, the temperatures do not exceed the limit of 105°C (ref. Interpretation Sheet IEC 60601-1 / ISH May 2013)

The manufacturer cannot be held liable for accidental or indirect damages should the device be modified, repaired without authorization or should any of its components be damaged due to accident or misuse.
Any minimal modification / repair on the device voids the warranty and does not guarantee the compliance with the technical requirements provided by the Regulation 2017/745 and its normatives

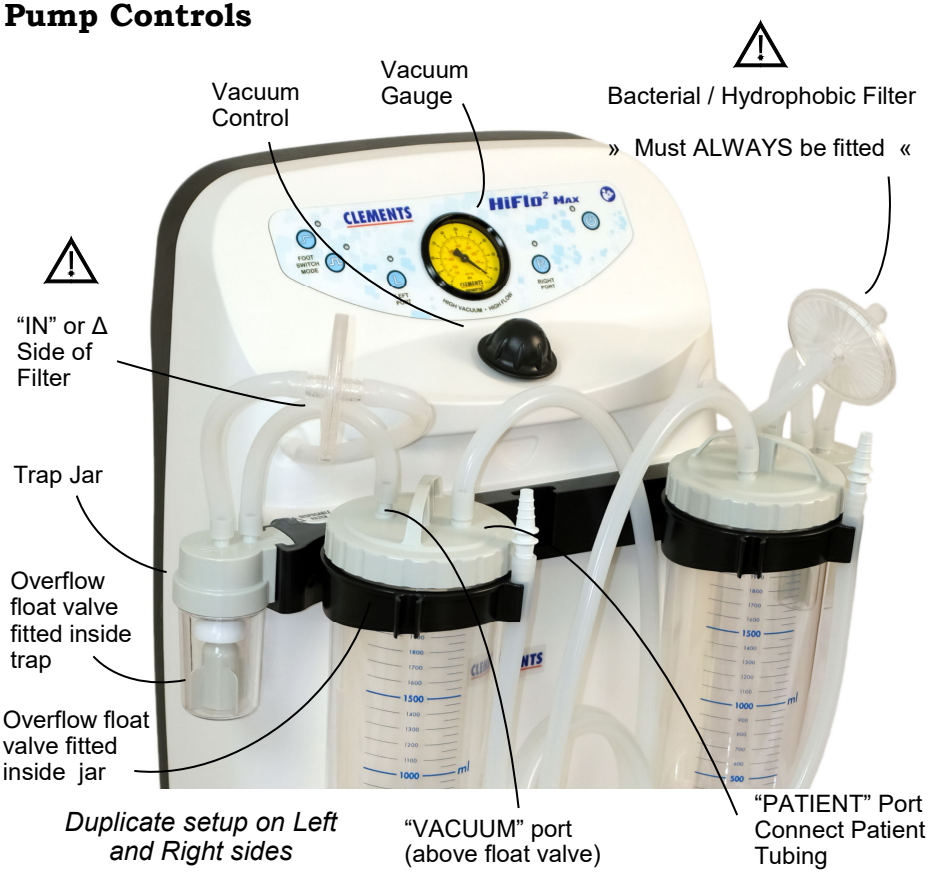
## Connection Diagram



## Control Panel

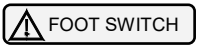

| Item | Button | Function |
|---|---|---|
| Gauge | | Display vacuum level in both kPa and mm Hg |
| Foot Switch Maintained Mode | | Select *Maintained* mode for foot switch operation. In *Maintained* mode press and release footswitch to switch pump on. Press and release again to switch pump off. |
| Foot Switch Instantaneous Mode | | Select *Instantaneous* mode for foot switch operation. In *Instantaneous* mode press and hold footswitch to switch pump on. Release footswitch to switch pump off. |
| Left Port | | Select the *Left Port* as the vacuum source. The previously selected port is restored at power-on. |
| Right Port | | Select the *Right Port* as the vacuum source. The previously selected port is restored at power-on. |
| On/Off | | When pump is first connected to mains power all LEDS are off. Pressing On/Off initiates a 1 second LED self-test. On/Off LED flashes to indicate pump is ready. Press and release to switch pump on. Press and release again to switch pump off. |
| Status LEDs | | The LED adjacent to each button indicates the state is active when lit. If neither *Foot Switch Mode* LED is lit, it indicates that the foot switch is not plugged into the rear socket. |

## Pump Controls




## Operation

1. Place the pump on a flat stable horizontal surface.
2. Connect a short length of silicone tubing from the trap jar centre port to the "IN" (or directional arrow symbol) side of the bacterial/ hydrophobic filter. Connect a short length of silicone tubing from the other side of the filter to the pump port.
   Connect a short length of silicone tubing from the trap jar peripheral port to the "VACUUM" port of the collection jar.
3. Connect the long silicone tubing to the collection jar "PATIENT" port.
4. Connect supplied power cord to power socket at rear of pump. Connect power cord to compatible mains outlet.
5. If using the footswitch plug it into the rear socket.




6. Select left or right port to match tubing connection setup.
7. Press switch button or footswitch to turn on pump. (Press again to turn off. See footswitch modes in control panel section.)
8. Occlude tubing and adjust vacuum control to the required vacuum level. (Clockwise = increase)

*Always reduce the vacuum level for paediatric and neonatal patients.*

9. Apply suction to patient with a compatible suction cannula fitted to the patient tubing.
10. When finished, switch off pump.

*Ensure that the mains power plug is accessible at all times when pump is in use, in case a positive disconnection from the mains power supply is required.*

## Suction Accessories

The device and its accessories are biocompatible in accordance with EN 60601-1.

### Suction Cannulae

Suction cannulae or suction probes for contact with the human body should comply with ISO 10993-1 requirements for biocompatibility.

### Collection Jar (Canister)

The mechanical strength of the reusable collection jar (canister) is guaranteed for 30 cycles of cleaning and sterilization. Beyond this, the there may be signs of decay and replacement is recommended.

### Silicone Tubing

The number of cleaning and sterilization cycles of the silicone tubing is dependent on the actual usage. Tubing should be checked for cracking and other visible signs of wear before re-use.

**Using FLOVAC Disposable Liners**


1. Fit FLOVAC ring bracket to multipurpose rail.
2. Insert liner bag [1] into the matching size support jar [2].
   Press edge of lid firmly all around edge to ensure seal.
3. Close the TANDEM inlet [3] with the attached cap [4].
4. Fit jar assembly into FLOVAC ring bracket.
5. Press short side of yellow connector firmly into matching yellow port [5] on the lid.
6. Using a short length of tubing connect the yellow connector to centre port of the trap jar.
7. Connect patient tubing to white inlet elbow[7]. Connect patient tubing to suitable suction cannula.
8. Follow steps in Operation section.

If fluid reaches the maximum level the hydrophobic filter in the lid will operate to prevent further fluid flow. When this happens switch off pump and replace liner.

**Disposal**

1. Switch off pump.
2. Disconnect tubing from jar.
3. Remove the white elbow [7] and close the inlet port with the cap [9] attached to lid.
4. Using the lid handle remove the liner [1] from the support jar and dispose of liner according to hospital protocol.
5. Retain support jar [2] for reuse.

**Support Jar Cleaning**

The reusable support jar may be cleaned either with water and neutral detergents or autoclaved at 121°C for 15 minutes.
Do not use solvents or alcohol for cleaning and disinfection. These may damage the support jar.
The mechanical integrity of the support jar is guaranteed for 30 cleaning cycles under the specified conditions.
After this, the jar may show signs of wear and replacement is recommended.

# Cleaning

## After Each Operation

### Empty Collection Jar

The contents of the collection jars, trap jars, suction tubing and bacteria filter, may contain biohazard wastes. Handle using safe handling procedures, which may include the use of rubber gloves, clothing and eye protection, and dispose of according to local protocols for biohazardous materials.

To empty collection jar disconnect tubing and remove jar from pump. Remove lid from jar and dispose of aspirated fluid according to local protocols for potentially biohazardous waste. Dispose of single use suction cannula according to local protocols for potentially biohazardous waste.

## Clean

**Housing**

Wipe clean with a damp soapy cloth. Do not immerse or allow liquid to enter the housing. Do not use abrasive cleaning agents.

**Accessories**

Before using the device, the manufacturer advises you to clean or sterilize the accessories.

*The filter must not be cleaned or autoclaved.*

*Wear rubber gloves, apron and eye or face protection to avoid contact with contaminated substances.*

**Collection Jars**

Separate all parts of the lid. Unlock bayonet on float cage by rotating cage *clockwise*. Disconnect float cage and float from lid (bung) and separate seal from lid (bung).

Wash each part of the jar under cold running water and then clean every part in hot water (temperature not exceeding 60°C).

Once again, carefully wash each part using, if necessary, a non-abrasive brush to remove any deposits.

Rinse with hot running water and dry all parts with a soft non-abrasive cloth. It is possible to wash with commercial disinfectants by carefully following the instructions and dilution values supplied by the manufacturer. Do not use phenolic solutions as disinfecting agents in polycarbonate jars.
After cleaning, leave the parts to dry in an open, clean environment.

**Suction Tubing**

The silicone aspiration tubes and the conical fitting may be carefully washed in hot water (temperature must not exceed 60°C). After cleaning, leave the parts to dry in an open, clean environment. Suction Tubing may be sterilised with sterilants determined by local protocols and compatible with silicone tubing. Suction tubing may be autoclaved to a maximum of 121°C for 15 minutes. At higher temperatures the suction tubing will discolour and lose shape.

**Autoclaving**

Separate the jar and lid items as detailed in the cleaning section above.

The following items may be autoclaved in a single steam sterilisation cycle at 121°C and 1 bar for 15 minutes:

- Jar - position jar upside down in autoclave
- Lid - position lid upside down in autoclave
- Silicone tubing
- Conical connector
- Trap jar - position jar upside down in autoclave

**Re-Assembly**

Place float valve into overflow cage with the seal facing up. Connect overflow cage to lid and lock bayonet on float cage by rotating cage *anticlockwise*. Place lid seal carefully into groove in lid. Fit lid to jar and lock securely into place by engaging bayonet and rotating lid firmly clockwise.

### Check Bacteria Filter

The bacterial/hydrophobic filter is an important device to help protect the pump and environment from moisture and bacteria from the patient. It is recommended that the filter be changed every month or when damp or discoloured. Do not clean, sterilise or disassemble filter.

*Change filter after every use when used on infectious patients or patients whose infection status is unknown.*

## After Every 100 Hours or 2 Months of Operation

- Check all suction tubing and replace if it is perished, soft or discoloured.
- Check the seal ring on the lid and replace if hard, cracked or perished. Check the fit of the lid in the collection jar (canister).
- Check the overflow cut off valve seal and replace if perished or damaged.

### Waste Materials

The contents of the collection jars, trap jars, suction tubing and bacteria filter may contain biohazard wastes. Handle using safe handling procedures, which may include the use of rubber gloves and eye protection, and dispose of according to local protocols for biohazard materials.

### Recycling

At the end of their service life, the pump and accessories should be dismantled if necessary, and disposed of according to the WEEE directive.

## Spare Parts

| | |
|---|---|
| SUC81030009 | Kit, Seal, Lid, 1L/2L Reusable Jar (Pack 2) |
| SUC81030010 | Kit, Lid Assembly for 1L/2L Reusable Jar |
| SUC81030034 | Kit, Float and Cage for 1L Reusable Jar (Pack 2) |
| SUC81030042 | Kit, 2L Reusable Collection Jar |
| SUC84500013 | Jar, Support for FLOVAC 3L Disposable Liner |
| SUC84500112 | Kit, Liner Connect Nipple (Pack 5) |
| SUC84500123 | Kit, Disposable 3L Liner (Pack 50) |
| SUC84600120 | Jar, Trap, 220mL for Multipurpose Rail |
| SUC84600122 | Jar, Suction, Reusable, 2L, Complete |
| SUC84600125 | Jar, Suction, Reusable, 5L, Complete |
| SUC84600135 | Jar, Suction, Reusable, 5L, Jar Only |
| SUC84600145 | Lid, Assembly with Shutoff Valve and Seal for 5L Reusable Jar |
| SUC84600155 | Seal, Lid for 5L Reusable Jar. |
| SUC84600171 | Silicone Tubing Set for HiFlo2 (1.5m x1, 0.34m x2, Conical Joiner) |
| SUC84600176 | Filter, Hydrophobic/Antibacterial for HiFlo2 |
| SUC84600100 | Rail, Multipurpose, 5-Position |

## Spare Parts

| | |
|---|---|
| SUC84600101 | Hook, RH for Multipurpose Rail |
| SUC84600102 | Hook, LH for Multipurpose Rail |
| SUC84600103 | Cap, for Multipurpose Rail |
| SUC84600110 | Bracket, Ring for 2L Reusable Jar |
| SUC84600111 | Bracket, Ring for 5L Reusable Jar |
| SUC84600112 | Bracket, Ring for 2L/3L FLOVAC Jar |
| SUC84600113 | Bracket, Ring for Catheter Holder |
| SUC84600114 | Catheter Holder |
| SUC84600115 | Footswitch for HiFlo2 Max |
| SUC84600160 | Rail, Stainless Steel Standard Medical, 30 x 10 |
| SUC84600201 | Motor/Pump for HiFlo2, 200-240V 50/60Hz |
| SUC84600202 | Kit, Piston, Rings for HiFlo2 Pump |
| SUC84600203 | Vacuum Controller + Black Knob for HiFlo2 Pump |
| SUC84600205 | Fuse, F4A L 250V for HiFlo2 Pump |
| SUC84600206 | Gauge, -100 kPa, for HiFlo2 Pump |
| SUC84604008 | User Manual for HiFlo2 Max Mobile Suction Pump |
| SUC84604219 | PCBA, Control for HiFlo2 Max Pump |
| SUC84604220 | Solenoid,  for HiFlo2 Max Pump |

# Troubleshooting

## 1. The Pump Fails To Operate

- Check that the mains power supply lead is firmly connected and that the power is on at the mains power supply outlet.
- Check fuse as detailed below.
- Ensure that the Vacuum Gauge on the Control Panel indicates zero. If not, release vacuum and switch pump off and on.

## 2. Pump Running But No Vacuum

- Check that all fittings are connected tightly.
- Turn the vacuum controller knob on the control panel and watch the indicator on the vacuum gauge.
- Ensure that the silicone medical suction tubing is in good condition and not old and cracked.
- Check the type of handpiece in use as some handpieces require finger occlusion to assist suction.
- Check trap jar.
- Check bacteria/hydrophobic shut off valve filter.

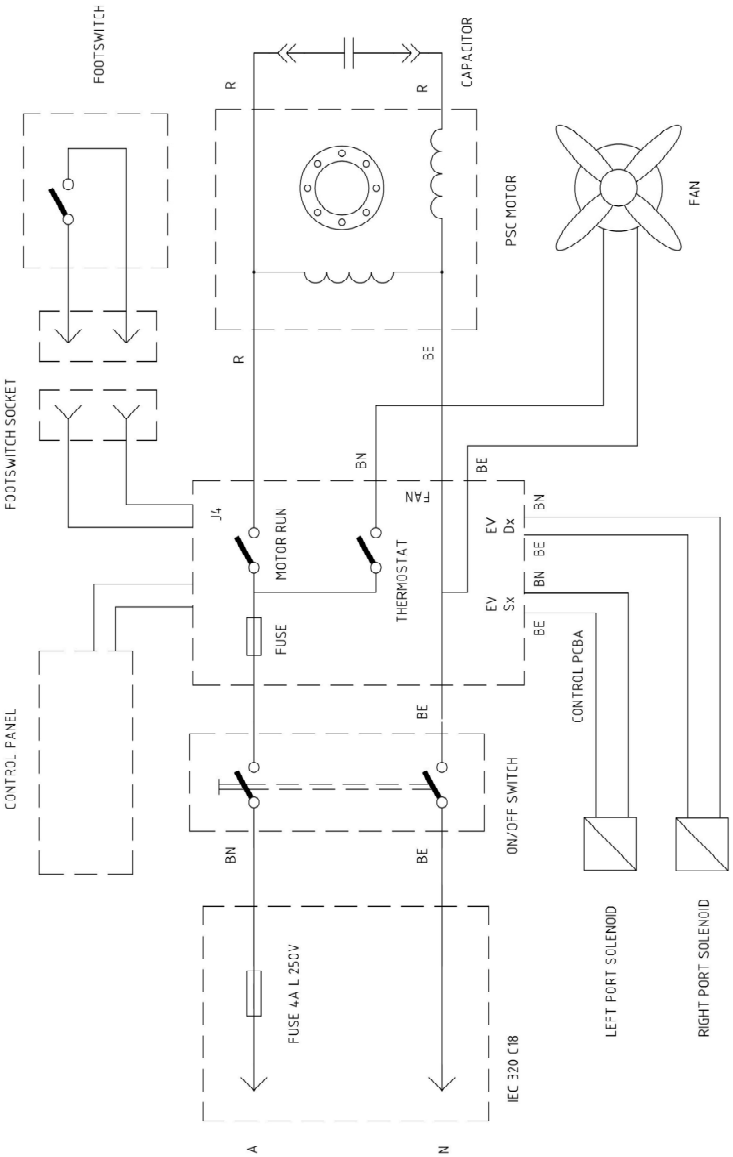
If the pump fails to work and you are unsure why, please contact your service department or return unit to your distributor.

## Fuse Replacement

The HiFlo2 Max is fitted with a fuse located in a fuse holder that is externally accessible

1. Disconnect the pump from the mains power supply.
2. Locate the fuse holder which is mounted on the rear side of the unit at the lower right-hand side.
3. Pull out the fuse holder.
4. Remove the old fuse and inspect. If blown, replace it with a new fuse of the same rating.
5. Replace the fuse holder cover.

# Wiring Diagram

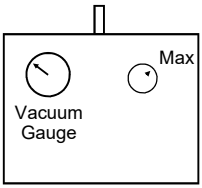


## Setup for Diagnostic and Performance Testing

Note that the following arrangements are not used for actual suctioning applications. They are specified to remove unnecessary variations when diagnosing faults and as a standard setup for performance measurement.

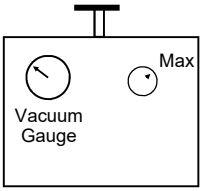
### Vacuum Check

**1. Unoccluded - zero check**



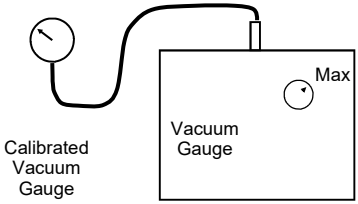

Disconnect all items from inlet and with pump switched off, confirm that gauge reads zero. A non-zero reading indicates a faulty gauge.
Set vacuum control knob to maximum, switch on pump and confirm that gauge reads zero. A non-zero reading indicates obstruction in internal tubing or connections.

**2. Occluded - vacuum check** **2.**




Switch on pump and occlude inlet. Note maximum vacuum reading.

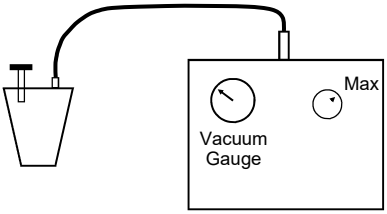
**3. Occluded - gauge check**




Connect a calibrated vacuum gauge directly to inlet and repeat maximum vacuum reading.
Confirm that pump gauge reads within the specified tolerance.

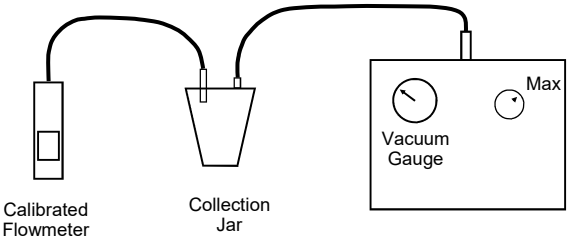
## Flow Check

### 1. Occluded - leak check




Connect pump as shown in diagram. Set vacuum control knob to maximum, and switch on pump. Occlude jar inlet and confirm that pump achieves the same maximum vacuum as in the previous vacuum check setup . Any difference indicates leaks in jar or connections.

### 2. Unoccluded - flow check




Connect pump as shown in diagram. Set vacuum control knob to maximum, and switch on pump. Connect jar inlet to calibrated flow meter and note flow reading.
If flow is significantly below specification, check internal tubing and pump itself.

**IMPORTANT**

**There are no user-serviceable components inside. Maintenance must be carried out by qualified personnel only.**

## Periodic Safety Check

*The following safety checks should be performed at least every 12 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.*

** Inspect the equipment and accessories for mechanical and functional damage.*

** Inspect the safety relevant labels for legibility.*

** Verify that the device functions properly as described in the instructions for use.*

** Perform electrical safety check.*

## EMC Information Tables per EN60601-1-2:2015.

In accordance with EN 60601-1-2 (2015) + A1 (2021) Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
1) “Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Accompanying Documents” (the following tables).
2) “Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.”
3) “The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it is used.”
The following tables provide information regarding the EMC characteristics of this Medical Electrical Equipment.
The performance of all functions of the HiFlo2 Max suction pump are considered essential performance for the purpose of electromagnetic immunity.

| **Guidance and manufacturer’s declaration - Electromagnetic emissions** | | |
|---|---|---|
| The HiFlo2 Max suction pump is intended for use in the electromagnetic environment specified below. The customer or user of the HiFlo2 Max suction pump should assure that it is used in such an environment. | | |
| **Emissions Test** | **Compliance** | **Electromagnetic environment - guidance** |
| Irradiated / Conducted Emissions CISPR11 | Group 1 | The HiFlo2 Max suction pump uses RF energy only for its internal functioning. Its RF emissions are very low and will not cause interference in nearby electronic equipment. |
| Irradiated / Conducted Emissions CISPR11 | Class B | The HiFlo2 Max suction pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic Emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations / flicker emissions IEC 61000-3-3 | Complies | |

**Guidance and manufacturer's declaration – Electromagnetic Immunity**

The HiFlo2 Max suction pump is intended for use in the electromagnetic environment specified below. The customer or the user of the HiFlo2 Max suction pump should ensure that it is used in such an environment.

| Immunity Test | Level indicated by EN 60601-1-2 | Compliance Level | Electromagnetic environment - guidance |
|---|---|---|---|
| Electrostatic discharge (ESD) EN 61000-4-2 | ± 8 kV on contact<br>± 15 kV in air | The device doesn't change its state | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient / burst EN 61000-4-4 | ± 2 kV power supply lines<br>± 1 kV for input / output lines | The device doesn't change its state | Mains power quality should be that of a typical commercial environment or hospital. |
| Surge EN 61000-4-5 | ± 1 kV differential mode | The device doesn't change its state | Mains power quality should be that of a typical commercial environment or hospital. |
| Loss of voltage, brief voltage interruptions and variations EN 61000-4-11 | 5%$U_T$ (>95% dip $U_T$) for 0.5 cycle<br>40%$U_T$ (>60% dip $U_T$) for 5 cycle<br>70%$U_T$ (>30% dip $U_T$) for 25 cycle<br><5%$U_T$ (>95% dip $U_T$) for 5 sec | - | Mains power quality should be that of a typical commercial environment or hospital. If the user of the HiFlo2 Max suction pump requires that the appliance operates continuously, the use of a backup supply is recommended. |
| Magnetic field EN 61000-4-8 | 30 A/m | The device doesn't change its state | The power frequency magnetic field should be measured in the intended installation location to assure that it's sufficiently low. |

Note $U_T$ is the nominal value of the power supply voltage

**Guidance and manufacturer's declaration – Electromagnetic Immunity**

The HiFlo2 Max suction pump is intended for use in the electromagnetic environment specified below. The customer or user of the HiFlo2 Max suction pump should assure that it is used in such an environment.

| Immunity Test | Level indicated by EN 60601-1-2 | Compliance Level | Electromagnetic environment - guidance |
|---|---|---|---|
| Conducted Immunity EN 61000-4-6 | 3 Vrms 150 kHz to 80 MHz (for non life-supporting devices) | $V_1$ = 3 Vrms | The portable and mobile RF communication devices, including cables, must not be used closer to the HiFlo2 Max suction pump, than the separation distance calculated by the equation applicable to the transmitter frequency.<br><br>$d = [3.5/V_1]\sqrt{P}$ from 150 kHz to 80 MHz<br>$d = [12/E_1]\sqrt{P}$ from 80 MHz to 800 MHz<br>$d = [23/E_1]\sqrt{P}$ from 800 MHz to 2.7 GHz<br><br>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.<br>Interference may occur in the vicinity of equipment marked with the following symbol.  |
| Radiated Immunity EN 61000-4-3 | 3 V/m 80 MHz to 2.7 GHz (for non life-supporting devices) | $E_1$ = 3 V/m | |

Note 1: At 80 MHz and 800 MHz the interval with the highest frequency is applied.
Note 2: These guide lines may not be applicable in all situations. The electro-magnetic propagation is influenced by the absorption and by reflection from buildings, objects and people.

The field intensity for fixed transmitters such as the base stations for radiotelephones (mobile and cordless) and terrestrial mobile radio, amateur radio devices, radio AM and FM transmitters and TV transmitters cannot be theoretically and accurately foreseen. To establish an electro-magnetic environment generated by fixed RF transmitters, an electro-magnetic study of the site should be considered. If the field intensity measured in the place where the device will be used surpasses the above mentioned applicable level of conformity, the normal functioning of the device should be monitored. If abnormal performance arises, additional measures such as changing the device's direction or positioning may be necessary.

The field intensity on an interval frequency of 150 kHz to 80 MHz should be less than 3 V/m.

## Separation Guidance Table

**Recommended separation distances between portable and mobile RF communications equipment and the device**

The HiFlo2 Max device is intended to operate in an electromagnetic environment where RF irradiated interferences are under control. The client or operator of the HiFlo2 Max device can help prevent electromagnetic interference by keeping a minimum distance between portable and mobile RF communication devices (transmitters) and the HiFlo2 Max device, as recommended below, according to the maximum output power of the communications equipment.

| | **Separation distance from the frequency transmitter (m)** | | |
|---|---|---|---|
| **Maximum nominal output power of the transmitter W** | 150 kHz to 80 MHz $d = [3.5/V1] \sqrt{P}$ | 80 MHz to 800 MHz $d = [12/E1] \sqrt{P}$ | 800 MHz to 2.7 GHz $d = [23/E1] \sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters with a maximum nominal output power not shown above, the recommended separation distance in metres (m) can be calculated using the equation applicable to the transmitter frequency, where P is the maximum nominal output power of the transmitter in Watt (W) depending on the transmitter's manufacturer.
Note 1: At 80 MHz and 800 MHz the interval with the highest frequency is applied.
Note 2: These guide lines may not be applicable in all situations. The electromagnetic propagation is influenced by the absorption and by the reflection from buildings, objects and people.

# Warranty

ICU Medical Australia Pty Limited ("ICU Medical Australia") warrants that this product is free from defects in workmanship and materials for a period of 24 months (3 months for batteries) from the date of shipment by ICU Medical Australia or its authorised agent to the purchaser. Subject to the conditions of this warranty, if the product fails to operate for any reason within the warranty period and the product is returned to the place of purchase at the purchaser's expense, ICU Medical Australia will repair or replace the product free of charge.

If a valid warranty claim is made within 30 days from the date of shipment, then ICU Medical Australia will also reimburse the purchaser for reasonable freight costs in returning the product to the place of purchase.

## Conditions of Warranty

1. The product must be returned to the place of purchase with proof of purchase.
2. This warranty is only available to the original purchaser of the product.
3. The product must not have had its serial number removed, defaced or changed, its casing opened, its power supply altered or have been tampered with in any other way.
4. This warranty does not cover :
   - inadequate or incorrect site preparation;
   - improper installation;
   - connection to the wrong voltage;
   - failure of the product due to misuse;
   - the use or operation of the product outside of the physical, electrical or environmental specifications of the product;
   - use in a manner or environment in which the product is not designed to be used;
   - improper adjustment, calibration or operation by the purchaser;
   - the use of accessories including consumables, hardware or software which were not manufactured or approved in writing by ICU Medical Australia;
   - any modifications of the product which were not authorised in writing by ICU Medical Australia;
   - any contamination or leakages caused or induced by the purchaser; and
   - inadequate or improper maintenance of the product.
5. This warranty does not cover normal wear and tear.
6. ICU Medical Australia will not be responsible for damage or loss caused during shipping.

7. In Australia, apart from any warranties implied by the Trade Practices Act 1974 all other warranties expressed or implied and whether arising by virtue of statute or otherwise are hereby excluded.
8. Outside Australia, all other warranties expressed or implied and whether arising by virtue of statute or otherwise (including any warranties implied by the Vienna Convention) are hereby excluded.
9. ICU Medical Australia's obligations under this warranty are limited to the repair or replacement of the product, within the terms of this warranty and the total liability of ICU Medical Australia for loss or damage of every kind whether arising pursuant to the terms of the sale of the product or otherwise in connection with the product is limited to the amount paid by the purchaser to ICU Medical Australia for the product.
10. Apart from any liability imposed by Part VA of the Trade Practices Act, ICU Medical Australia accepts no other liability for any loss or damage occasioned (including consequential loss or damages) in any way as a result of the use of the product.
11. The warranty does not extend to cover damage to the following parts as they are inherently prone to wear :

    • motor brushes

12. This warranty does not extend to cover corrosion due to any cause nor to any damage to painted or anodised surfaces.
13. ICU Medical Australia will give the purchaser the benefit of any manufacturer's warranty in respect of any components in the product which were not manufactured by ICU Medical Australia, if such a manufacturer's warranty is available.

## Notes

## Notes

## Notes