MEC

MEDICAL LIMITED

Medical Gas Equipment

Purair 130

ACTIVE ANAESTHETIC GAS SCAVENGING SYSTEM

Operator and Maintenance Manual

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CE 0120

P130UM/R001
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Read this manual before operating the machine.

The user must be familiar with the machine and its various functions before using it on a patient.

Recommended operating environment Temperature: 15°C-25°C Humidity: Max relative humidity 90% (up to 31°C) decreasing linearly to 50% relative humidity at 40°C Altitude: Max 2,000m.

Storage/transport temperature -20°C to 45°C (-4°F to 113°F).

Store all components in a cool, dry place when not in use.

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1. Introduction

Foreword

This manual is intended for users of the Purair 130 AGSS (Anaesthetic Gas Scavenging System) and contains detailed information and operating instructions. It also includes cleaning and sterilisation methods, basic trouble-shooting and maintenance procedures.

Personnel operating the Purair 130 AGSS must become thoroughly familiar with the instructions contained in this handbook *prior* to using the device with patients.

The Purair 130 AGSS is intended for use by a qualified practitioner under the direction of a qualified anaesthetist. When the unit is connected to a patient, it is recommended that a licensed medical practitioner be in attendance at all times.

The Purair 130 AGSS is classified as a Class 1 electrical item which includes an electrical earth.

Notices

Product Improvement

MEC has a policy of continued product improvement and therefore reserves the right to make changes which may affect the information contained in this manual without giving prior notice.

Responsibilities of the Manufacturer

The Manufacturer accepts responsibility for the effects on safety, reliability and performance of the equipment only if:

- assembly operations, extensions, adjustments, modifications and repairs are carried out by persons with written authorisation from the manufacturer and,
- the equipment is used in accordance with the instructions contained in this manual.

Disclaimer

Assembly operations, extensions, adjustments, modifications and repairs to the Purair 130 AGSS unit made by unauthorised personnel automatically void all warranties and specifications. The prevention of tampering is solely the responsibility of the user.

Conventions

The terms left, right, clockwise and anti-clockwise refer to the Purair 130 AGSS when viewed from the front.

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Valve System

Patent No: 2228419A

CE Marking

The product is labelled with the CE mark.

Note to Service Personnel

The contents of this manual are not binding. If any significant difference is found between the product and this manual, please contact MEC for further information at the address on the front cover.

It is recommended that the equipment is serviced at regular intervals (eg. every 6 months) by qualified service personnel using genuine spare parts for all servicing and repairs.

The power cable is only to be replaced by qualified persons with parts supplied by MEC Medical Ltd.

Contact MEC sales and they will advise of a suitable engineer.

Hazard Notices

This manual contains important information. Statements preceded with the following symbols are of special significance.

Warning Notices Denote a potential hazard to the health and safety of users and/or patients. These notices clearly state the nature of the respective hazard and the means by which it can be avoided.

Warning notices appear in full in the preliminary pages and are highlighted at their point of application in the manual.

Cautionary Notices denote a potential hazard to the physical integrity of equipment but NOT a danger to personnel. These notices clearly state the nature of the hazard and the means by which it can be avoided.

Cautionary notices appear in full in the preliminary pages and are highlighted at their point of application in the manual.

Relevant or helpful information.

Additional copies of this O & M manual can be obtained from MEC (Quote Part number P130UM/R001 - Purair 130 AGSS Manual).

It is recommended that all relevant documentation, including the Operator and Maintenance Manual, accompanying labels and/or inserts, is immediately available to all prospective users of the equipment.

User Responsibility

The performance of this product conforms with the description thereof contained in this manual and accompanying labels and/or inserts when the product is set up, operated, maintained and serviced in accordance with the instructions provided.

The product must be checked periodically.

A defective product must not be used.

Parts that are broken, missing, plainly worn, distorted or contaminated must be replaced immediately. Should such repair or replacement become necessary, the manufacturer recommends that a verbal or written request for service advice is communicated either to MEC or to an authorised distributor.

It is recommended that this product, including any of its parts, is repaired only by trained personnel in accordance with written instructions provided by MEC.

The product must not be altered without the prior written approval of MEC.

The user of this product shall have sole responsibility for any malfunction which results either from alteration by anyone other than authorised, fully trained personnel or from improper use, faulty maintenance, improper repair or damage.

Specification

Equipment specification	Class 1.
The system is for use in an environment	<25oc and 90% RH.
Voltage	230V 50Hz.
Operating Current	0.4amps.
Power	100VA.

Servicing Policy

Warning: Only Engineers trained to repair and/or service this type of equipment should attempt to repair and/or service the Purair 130 AGSS. It must only be repaired and/or serviced in accordance with written instructions provided by MEC. An improper repair and/or service could result in patient injury.

Requests for servicing facilities, advice or assistance must be addressed either to MEC or an authorised distributor.
Contact MEC sales or an authorised distributor and they will advise of a suitable installer.

Warranty repairs must only be performed by MEC or authorised distributors.

Do not use malfunctioning equipment. Parts listed in this manual can be replaced only by Engineers trained to repair and/or service this type of equipment.

After repair, the equipment must be tested to verify that it operates correctly. If assistance is required, contact MEC or the nearest authorised distributor.

In the event that the Purair 130 AGSS is to be transported to MEC or an authorised distributor, it should be securely packed with suitable protection for transit, in the original packaging if possible, and shipped pre-paid.

Enclose the following items as applicable:

- A letter describing in detail any difficulties experienced with the equipment.
- Warranty information, such as a copy of the invoice or other applicable documentation.
- Purchase Order number to cover repair of equipment not under warranty.
- Serial number (located on the label at the base of the receiver unit: part number (2)).
- Contact name and telephone number.

Warnings and Cautions

Warning Notices

1. **This manual and all its associated documents must be studied thoroughly before any attempt is made to set up, operate or service any part of the Purair 130 AGSS. Failure to do so may result in patient injury.**

2. **Only Engineers trained to repair and/or service this type of equipment should attempt to repair and/or service the Purair 130 AGSS and it must be repaired and/or serviced only in accordance with written instructions provided by MEC. An improper repair and/or service could result in patient injury.**

3. **Check all components for damage. Any damaged components must be replaced before reassembly with MEC approved parts.**

4. **WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with a protective earth.**

Cautionary Notices

4. **Ensure that the Purair 130 AGSS system is securely supported before connecting the hoses.**

5. **The installation shall not be positioned in such a way where it is difficult to operate the disconnection device (mains plug).**

Symbols and Abbreviations

APL	Airway Pressure Limiting
bpm BPM	Breaths per minute
cmH_2O	Gauge pressure expressed in centimetres of water
CPAP	Continuous positive airway pressure
PEEP	Positive end expiratory pressure
IE Ratio	A ratio of inspiratory to expiratory time
	IEC symbol to consult the instructions for use
	WARNING: There is danger of personal injury to the user or patient
	Further relevant or helpful information
○	Power off
|	Power on
	Dangerous voltage
l/m lpm	Litres per minute
ml	Millilitres
O_2	Oxygen
psi	Pounds per square inch
psig	Pounds per square inch gauge
l	Litres
	IEC symbol for alternating current
CE	Confers approval under the European Medical Device Directive
CE 0120	Each medical device's notified body has an identification number, the identification number for SGS is '0120', as SGS is the Notified body for MEC Medical Ltd therefore MEC Medical Ltd needs to put the number '0120' below its CE logo.
	This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorised representative of the manufacturer for information concerning the decommissioning of your equipment.

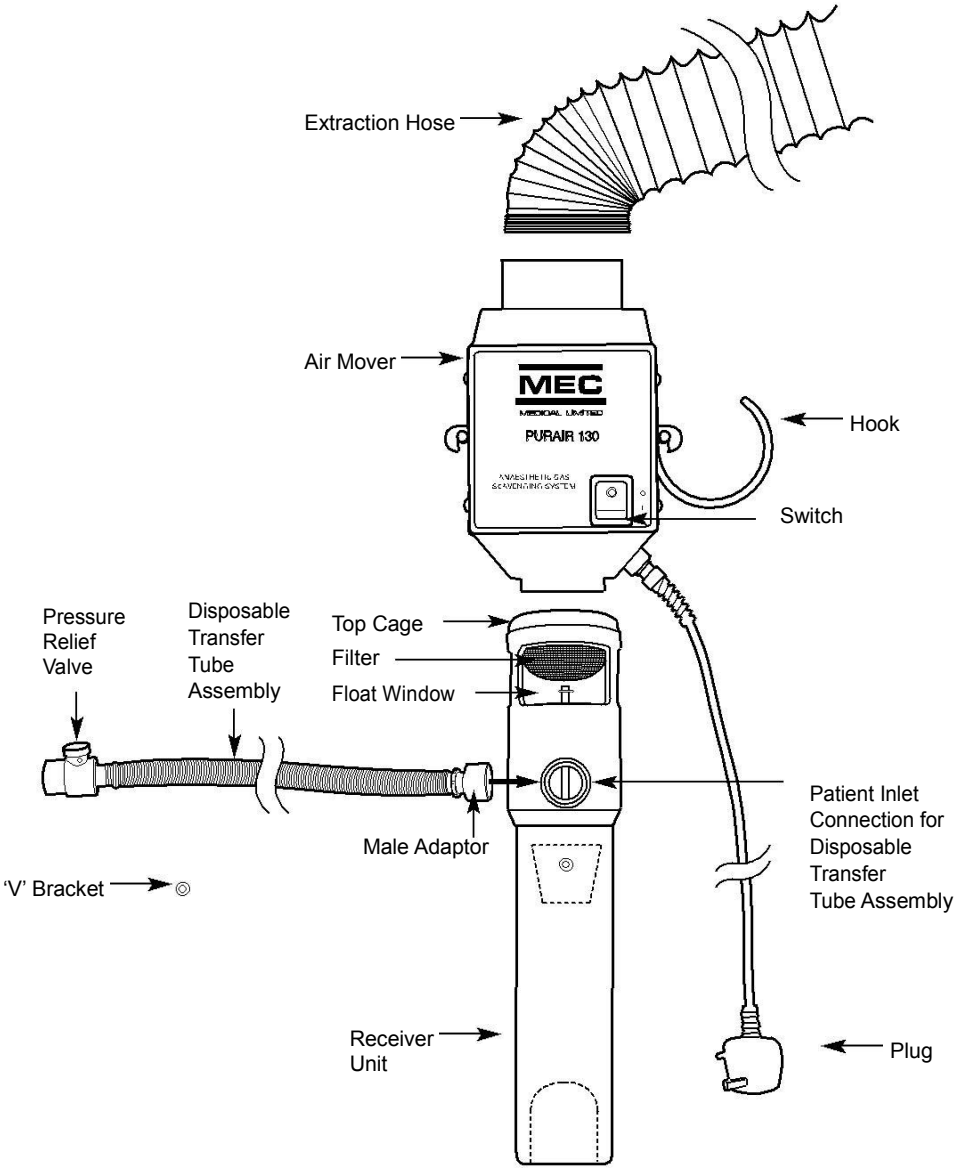


Figure 1
The Purair 130 AGSS

2. Description

Warning: This manual and all its associated documents must be studied thoroughly before any attempt is made to set up, operate or service any part of the Purair 130 AGSS. Failure to do so may result in patient injury.

Refer to Figure 1.

The Purair 130 is a high flow system with > 75 l/min, high flow rate which is used for the extraction to atmosphere of waste anaesthetic gases exhaled from the patient breathing system during anaesthesia.

The Purair 130 is a stand-alone system that is either ON or OFF. The float is purely a go/no-go indicator and as such MUST ALWAYS be in the 'MAX' position, as described in this manual. Any deviation from the 'MAX' position must be investigated following the troubleshooting guide as in section 5.

The receiver unit incorporates a transparent window so that the position of the float and the condition of the filter can be observed. Typical position of the float is illustrated in Figure 2.

The filter should be kept visibly clean to prevent flow restriction through it.The mesh size is 150µm.

The disposable transfer hose assembly is used to connect the receiver unit to the patient breathing system. The disposable transfer hose compromises a 30mm male adaptor (single patient use), a 22mm corrugated transfer tube (single patient use and a pressure relief valve.

The male adaptor is used to connect the transfer hose to the receiver unit patient inlet.
The pressure relief valve issued to connect the Purair 130 to the patient breathing system. The pressure relief valve is not autoclaveable.

A complete Purair 130 comprises of a receiver unit/air break (designed to conform to BS EN ISO 80601-2-13-2012), air mover , disposable (single patient use only) transfer tube assembly with a 10cm H^2O pressure relief valve, extraction / venting hose and wall venting kit.

Pre Use Checkout Procedure

Checkout procedure to be followed daily before each use

The anaesthetic gas scavenging system should be switched on and functioning. Ensure that the tubing is attached to the appropriate expiratory port of the breathing system or ventilator. The top of the float becomes visible at approximately 50 l/min and reaches the top at approximately 100 l/min

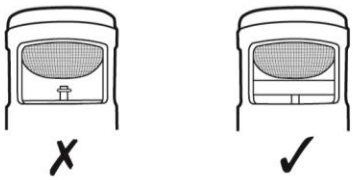


Figure 2
Float Positions

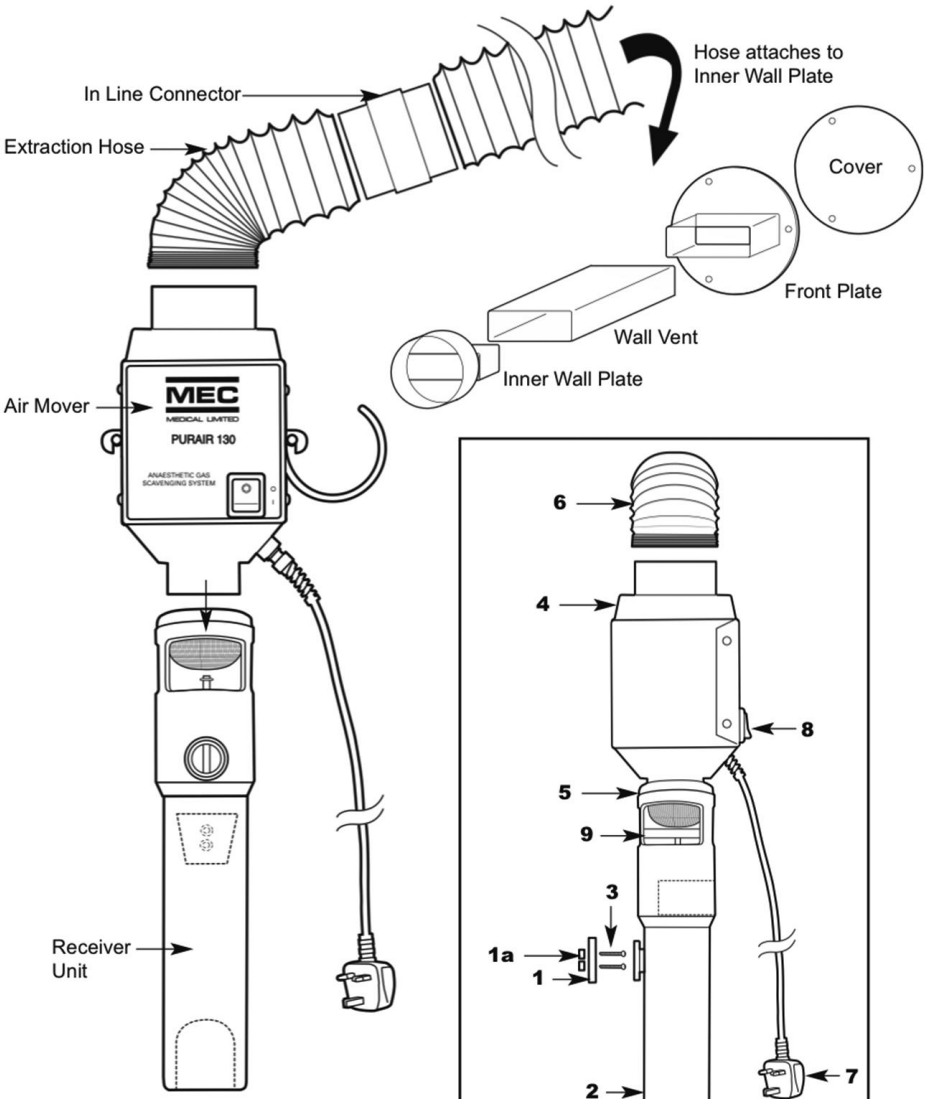


Figure 3
Installing the Purair 130 AGSS

3. Installing and Operating the Purair 130 AGSS

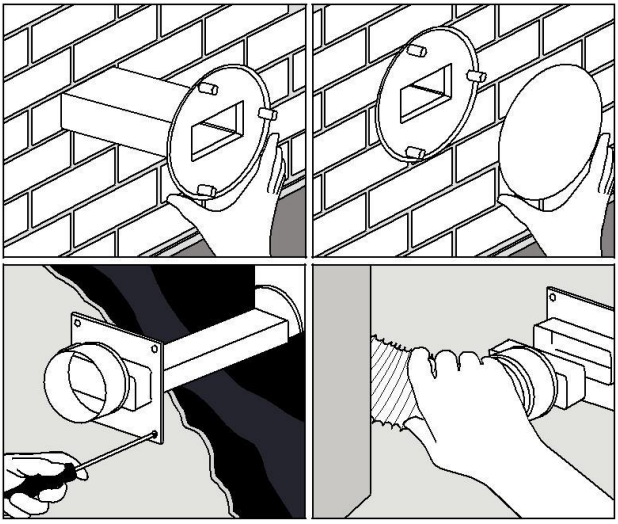
Installing the Purair 130 AGSS

1. Determine a location for installing the Purair 130 AGSS where the unit will be free from any obstructions and can be safely used.

Ensure that the system is securely supported before connecting the hoses.

2. Install the Purair 130 AGSS referring to Figure 3 and Figure 3A.
    a. With packing pieces **(1A)** (x4) located between **(1)** and wall, screw item **(1)** with item **(3)** onto vertical flat wall at required position, approximately 1.25m above floor level.
    b. Carefully push fit **(4)** fully onto **(2)** through 'O'-ring seal **(5)** and place complete assembly onto item (1).
    c. Mark item **(4)** fixing hole locations (x 2) on wall ensuring that the complete assembly is both horizontal and vertical. Contact MEC sales or an authorised distributor and they will advise of a suitable installer.

Figure 3A Installation



d. When marked, remove complete assembly from **(1)**, then drill and plug wall accordingly.
e. With wall drilled and plugged, refit complete assembly back onto **(1)** and screw **(4)** (x2) onto wall.
f. Fit extraction vent **(6)** as shown in Figure 3A.
g. Push **(6)** onto **(4)** and connect other end of **(6)** onto extraction exit.

The extraction hose (6) is not to exceed 6.5 metres length overall. Ensure there are no kinks in the minimum length.

h. Plug **(7)** into 13 amp 220/240V electrical socket and switch ON control item **(8)**.
i. With system in operation, check that the float level **(9)** rises above the minimum level indicator as marked on assembly (See Figure 2).

Ensure hoses are fully extended and the float indication is at the top.

Operating the Puair 130 AGSS

1. Connect the pressure relief valve on the disposable transfer hose to either the patient breathing system APL valve or the breathing circuit expiratory valve.
2. Connect the male adaptor on the disposable transfer hose to the patient inlet on the receiving system.
3. Check that the float is visible in the float window, as illustrated in Figure 2. If the float is not visible, refer to Section 5 – Troubleshooting.
4. Switch the Purair 130 AGSS on using the on/off switch on the air mover enclosure.

The power cable is only to replaced by qualified persons with parts supplied by MEC Medical Ltd. Contact MEC sales and they will advise of a suitable engineer.

The equipment must be isolated from the mains supply by removing the plug from the mains source.

4. Servicing Procedure

Servicing procedures are confined to a visual inspection, cleaning and replacement of worn or damaged components.

Warning: Only Engineers trained to repair and/or service this type of equipment should attempt to repair and/or service the AGSS and it must be repaired and/or serviced only in accordance with written instructions provided by MEC. An improper repair and/or service can result in patient injury. The power cable is only to replaced by qualified persons with parts supplied by MEC Medical Ltd.

The System can be partly disassembled in order to replace an individual component. It is not always necessary to complete a full Servicing procedure.

Disassembly (refer to Figure 3, page 14)

1. Disconnect the Purair 130 AGSS from the mains power supply.
2. Disconnect the Extraction Hose **(6)** from the Air Mover **(4)**.
3. Remove the Air Mover **(4)** from the Receiving Unit **(2)** by loosening the mounting screws and lifting off.
4. Disconnect the Transfer Hose Assembly from the patient breathing system and the male adaptor from the patient inlet connection.
5. Remove the Receiving Unit **(2)** from its mounting.

Under normal circumstances, the unit should not need to be disassembled further than this.

Disassembly (refer to Figure 4, page 18)

1. Stand the Receiver Unit on a clean, flat surface. Hold the Centre Swivel **(21)** to prevent it from rotating and unscrew the Top Cage **(10)**. Remove the Float Window **(12)** and the Filter **(11)** from inside the Top Cage **(10)**. Remove the top ‘O’ Ring **(13)** from the Guide Rod **(16)** followed by the Float Assembly **(14)**, the lower ‘O’ Ring **(13)** and the Valve Disc **(15)**.

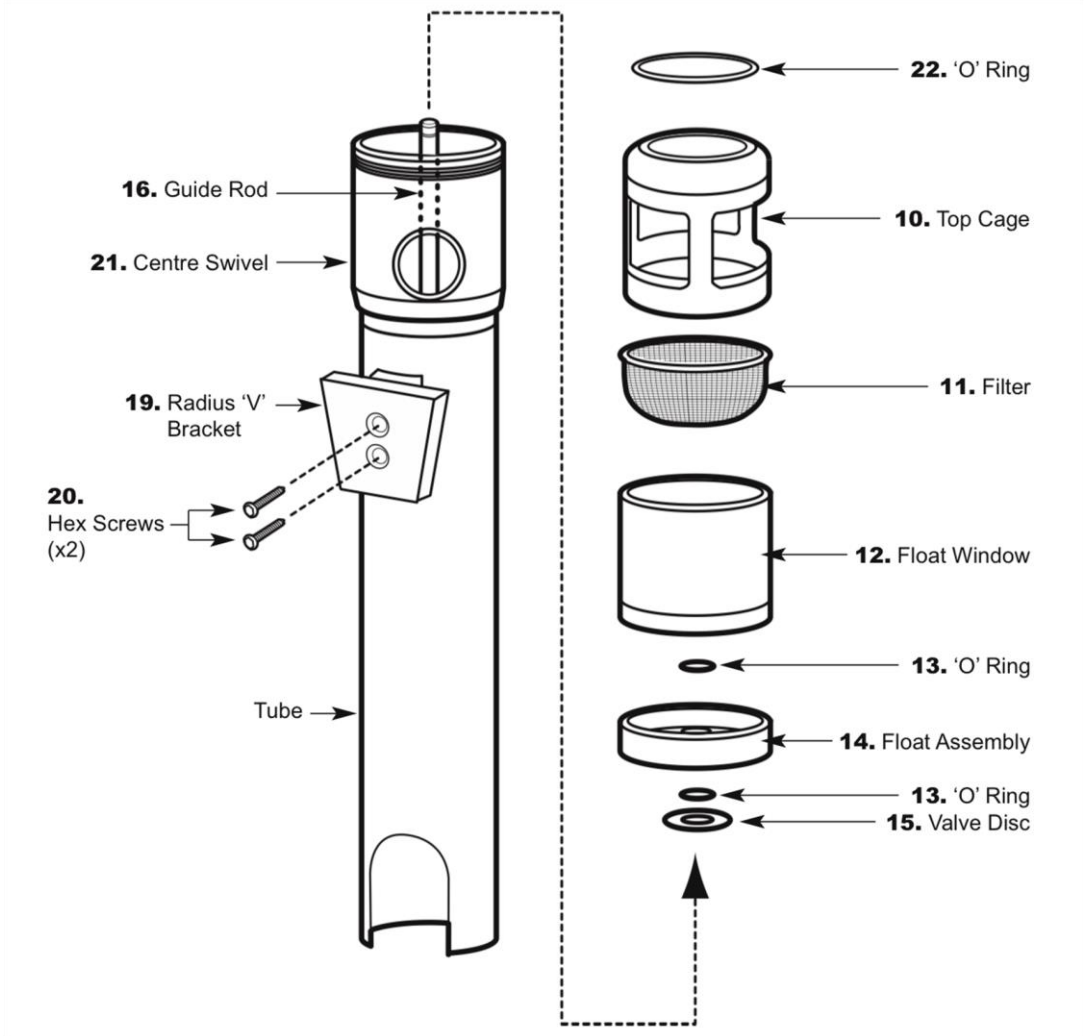


Figure 4 – Disassembly

1. The filter **(11)** should be rinsed with water from the concave (hollow) side, to remove lint and debris, and may then be steam autoclaved as required (recommendation once every week).
2. Wash all other receiver components in a mild detergent (such as Turbex Ltd USF-4) The Mild Cleaning detergent should not contain acid, ammonia or ammonium must be used. Do not use any cleaning solutions that contain chlorine, aromatics, moisturisers, or scented oils. Use a lint-free cloth to dry.
3. No PPE is required for these operations as no dangerous or irritating substances are used.
4. Check the air mover assembly. (See page 20 for Servicing).
5. Clean the PRV with isopropyl alcohol. DO NOT AUTOCLAVE.

Ensure that isopropyl alcohol complies with Regulation EC No 1907/2006 Art.31

WARNING: It is possible the system may eventually fail if cleaning is not carried out as and when instructed.

Re-assembly of the Receiver Unit.

WARNING: Check all components for damage. Any damaged components must be replaced before reassembly.

1. Place the Valve Disc **(15)** on the Guide Rod **(16)** then slide ‘O’ Ring **(13)** down to locate in the lower groove.
2. Place the Float Assembly **(14)** on the Guide Rod **(16)** – note orientation of the Float Assembly **(14)** with the concave side upwards. Slide ‘O’ Ring **(13)** down Guide Rod **(16)** to locate in upper groove.
3. Position the Float Window **(12)** on the Centre Swivel **(21)** with the recess downwards, locating on shoulder. Place the Filter **(11)** in the top of the Float Window **(12)** and screw the Top Cage **(10)** onto the Centre Swivel **(21)** until hand tight.
4. Fit the Air Mover **(4)** Assembly into the Receiver Unit **(2)**.
5. Verify that all components are assembled correctly.

Servicing the Air Mover Assembly (refer to figure 5 below)

1. Unplug the Main Housing **(4)** from the mains supply.
2. Remove Extraction Hose **(6)** from top of Main Housing **(4)**.
3. Loosen 2 wall screws retaining Main Housing **(4)** and lift whole unit from wall.
4. Separate Reciever Unit **(2)** from Main Housing **(4)**.
5. Loosen the Gland/Lock ring **(22)**.
6. Undo 4 screws **(23)**.
7. Whilst feeding the Cable **(24)** through the Gland/Lockring **(22)**, slide the Motor Housing **(25)** out of the Main Housing **(4)**.
8. Clean the fan blades either with air or using a dry/damp cloth.
9. Place the Motor Housing **(25)** back in the Main Housing **(4)**, feeding the Cable **(24)** back through the Gland/Lock ring **(22)**, and tighten.
10. Replace Screws (x4) **(23)** and tighten.
11. Refit the Main Housing **(4)** to the top of the Reciever Unit **(2)**.
12. Having serviced the complete unit, reposition the Purair 130 back on to the wall plate. Re-fasten in position.
13. Refit the Extraction Hose **(6)** to top of Main Housing **(4)**.
    Unit is now ready for use.
14. Verify that all components are correctly assembled.

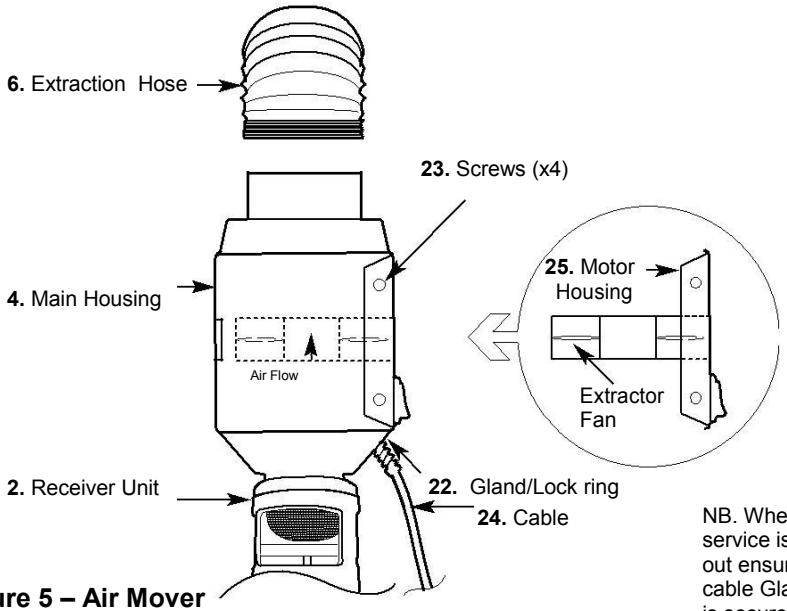


Figure 5 – Air Mover

5. Troubleshooting

1. Verify that all components are correctly assembled, the filter is clean and all connections are properly made. Rectify if necessary.
2. If the float is not visible, check that there is a power supply and/or check the fuses in the plug and switch box. Replace fuse if necessary.

Use of the incorrect Fuse may cause a hazard.

3. If the float is still not visible, contact the nearest Authorised Distributor for advice.

6. Appendix

Spares and Consumables List

The components in the following table are available as replacement parts.

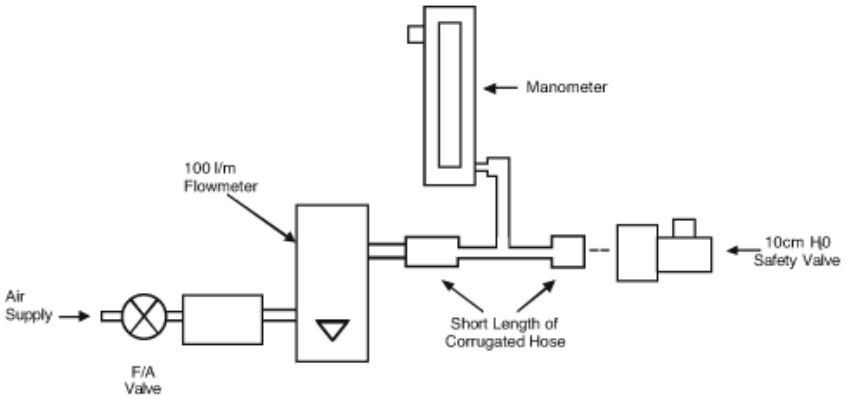
Description	Part Number
Transfer Hose Assembly	181934
22mm Transfer Hose (50m Roll)	181933R
Pressure Relief Valve	181931
30mm Male Connector (10 pack)	181932P
O-ring (10 pack)	51610600P
Filter (10 pack)	12800034P
Float Window	12800035
‘O’ Ring (20 pack)	51010041P
Float Assembly	12800010
Valve Disc	12800029
Radius ‘V’ Bracket	12800036
Screw (20 pack)	SM0635P

10 cm H2O Pressure Relief Valve (PRV) Specification

Test Procedure

Note: 1 kPa = 10 cm H2O

1. The PRV is a pre-set system (no adjustment possible).
2. Ensure that the PRV is clean and in good condition, paying particular attention to the 30mm inlet taper. If any damage is noted or any of the following tests failed, the PRV must be replaced.
3. Connect up an air supply via a fine adjustment valve and a flowmeter to a 30mm male connector using 22mm bore corrugated tube. Place a manometer at the 30mm connector end.
4. Push the valve onto the 30mm connector and set the flow to 30 lpm. Set the manometer to zero.
5. Occlude the valve outlet and check the pressure rise is not more than 1.0 kPa (10cm H2O). If the rise is above this limit, the valve must be replaced.
6. Increase the flow to 90 l/min and zero the manometer. Occlude the exit and ensure the pressure rise is less than 2 kPa (20.4cm H2O). If the valve is outside this limit, it must be replaced.



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