WARNINGS AND IMPORTANT NOTES

- This device should only be installed, commissioned and maintained by technicians who are suitably trained with medical gas systems, such as Competent or Authorised Persons as defined in UK Department of Health HTM 02-01. Any work involving alteration, extension or maintenance work to an existing system should be subject to the 'Permit to Work' procedure.
- Only appropriately trained practitioners should use the device under the direction of a qualified anaesthetist. When the device is connected to a breathing circuit, it is recommended that a licensed medical practitioner be in attendance at all times to react to an alarm or other indication of a problem. The effectiveness of medical gases can only be determined by continuous monitoring by the user.
- Do not autoclave or submerge the device in any fluid and ensure that no fluid is allowed to enter the device.
- Do not subject the device to pressures greater than as identified in the specification section.
- This device complies with the international standard BS EN ISO 80601-2-13 Clause 201.103 Requirement for an Anaesthetic Gas Scavenging System.

INTRODUCTION

- This document provides instructions for the safe use and maintenance of the device.
- Read through this entire instruction guide before using.
- Personnel handling and operating the device must be authorised and appropriately trained.
- Do not use the device if you do not understand the information provided.
- Attempting to use the device without a thorough understanding may result in patient or user injury.
- Before use, verify the device is compatible with the devices connected, especially if supplied by different manufacturers.

INTENDED USE AND DESCRIPTION

- The device is used to provide the extraction of waste and excess gases from the patient breathing system to atmosphere. The device operates as a portable anaesthetic gas scavenging disposal system where a fixed install is not possible.
- The device comprises the PurAir 500 unit and includes the supplied accessories of an exhaust line and a transfer hose assembly which includes a 10cm H2O pressure relief valve (PRV).
- The transfer hose assembly supplied is a single-use item which must be replaced for each new patient.
- The 10cm H2O pressure relief valve (PRV) can be reused if cleaned in accordance with these instructions.

INSTALLATION AND OPERATING INSTRUCTIONS

- Installation should be completed and tested in accordance with HTM 02-01 and ISO 80601-2-13.
- Remove the device from the packaging and inspect for damage. If the device is damaged on receipt, do not use.
- Place the device in a stable position on a horizontal surface (i.e. floor or table). Do not obstruct the ports.
- Ensure that the AGSS System is securely supported before connecting the hoses.
- Open the case to see the motor (1), power lead (2), exhaust line (3) and transfer hose (4).
- Remove the exhaust line (3) from the case and connect to the exit pipe connector on the end of the motor (1). To do this, align the slots in the exit pipe connector (3) with the two lugs on the flange of the motor and push on squarely.
- Once pushed on, twist the adaptor until it stops. Pull back on the adaptor to make sure it is secure to the motor.
- Connect the power lead plug (2) to a power outlet and kettle lead into the IEC power filter (6).
- Switch on the unit using the power switch (7) and check the pump is running by feeling the end of the exhaust line (3).
- Place the other end of the exhaust line (3) out to atmopshere (i.e. vent or through an open window).
- If the pump is not running check the mains power supply, check fuses on your power circuit or contact MEC Medical.
- Pass the 30mm green conical fitting (8) through the grommet in the side wall (9) and connect to the 'Patient Inlet' port (10)
- Connect the pressure relief valve (11) to either the patient breathing system APL valve or the breathing circuit expiratory valve.

DIAGRAMS

Figure 1: Top View

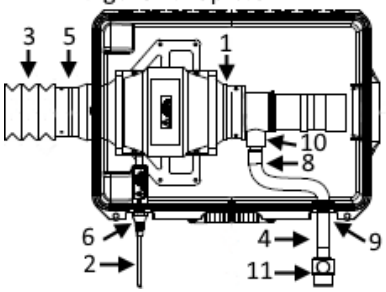
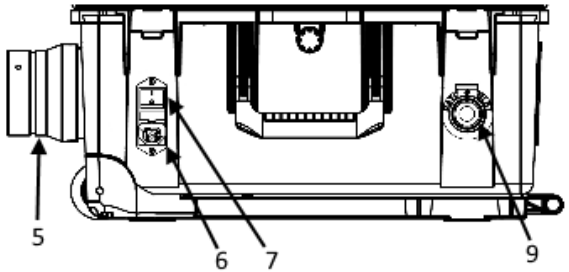


Figure 2: Front View



1	Motor	750007
2	Power Lead UK plug	161917
3	Exhaust Line	161900EXHO
4	Transfer Hose Assembly	181934

5	Exit Pipe Connector	161906
6	IEC Power Filter	161915
7	Power Switch	161915
8	30mm Conical Fitting	181932

9	Grommet	GR3035
10	Patient Inlet port	181909
11	Pressure Relief Valve	181931

INSPECTION AND PREVENTATIVE MAINTENANCE:

- Inspection and maintenance should be carried out in accordance with HTM 02-01 and ISO 80601-2-13.
- The device is designed to operate with the minimum of maintenance but it is recommended that the entire device is visually inspected at regular intervals, at least every 6 months, to check for any signs of damage or wear and tear.
- Any visible damage would necessitate the device being replaced.
- The device should be checked regularly for dirt and obstructions, and can be cleaned using a vacuum cleaner.
- The in-line flow fan should be professionally serviced to ensure no build up of dirt or deposits on the impeller or motor.
- It is recommended that all Purair Systems are replaced 5 years' after the date of manufacture regardless of condition. A manufacture date is printed on the device label.

CLEANING AND DISINFECTION

- Generally clean the device and components using only a dry lint-free cloth, distilled water or detergent wipe.
- Where a detergent wipe proves insufficient an isopropyl alcohol wipe may be used.
- Do not use any solvents as this may cause damage to the device.
- Clean the PRV (5) with isopropyl alcohol. Do not autoclave.
- It is not practical or economical to internally clean or disinfect due to the nature and complexity of the internal components.

DECONTAMINATION

- Decontamination of the device should be managed in accordance with national or local legislation, UK Department of Health Guideline HTM 01-01 Part A and/or other policies applicable to your organisation.
- Devices suspected of bio-contamination should be removed from service and destroyed by incineration according to proper medical and environmental protocols.

DISPOSAL

- To be disposed as per user's country disposal regulations and hospital/clinic protocol.

RETURN OF EQUIPMENT

- If for any reason it is necessary to return equipment to MEC Medical Limited, either directly or through a distributor, the equipment must be decontaminated first and a Decontamination Certificate signed by a Competent Person enclosed.

STORAGE:

- Storage temperature between -20ºC and 60ºC with operational temperatures between -10ºC and 40ºC
- Protect from contamination and deterioration, including protection from excessive heat or undue exposure to direct sunlight.
- Take adequate precautions against spillage or breakage, attack by micro-organisms, contamination and cross-contamination.
- Store off the ground and suitably spaced to permit cleaning and inspection. Should not be stacked when stored.
- Ensure that identification is not lost.
- Packaging should be maintained until used and stored with identification visible.

SPECIFICATIONS

Information	AGSS maximum flow rate: 500l/min Dimensions: 555mm (l) x 417mm (w) x 296mm (h) Weight: 13kg (approximate) Temperatures between -10ºC and 40ºC	Electrical	Voltage: 230V, Frequency: 50/60 Hz, Power: AC 20W Class 1 Equipment

REGULATORY

- This is a medical device built to comply with MDD 93/42/EEC, MDR 2017/745, UKMDR 2002/618 and BS EN ISO 80601-2-13.
- Any serious incident in relation to the device that might lead to death or serious deterioration in the health of a patient should be reported to the manufacturer and competent authority in the country.
- Supplied transfer hose and male connector are single use only as indicated on the product labelling.
- Is neither for single use, nor sterile.
- Does not incorporate medicinal substances, nor biological or animal tissues, nor human blood, nor phthalates.
- The biocompatibility risk assessment indicates that the likelihood of adverse effects from the device is considered low but the device is a conduit for the gas pathway and connected devices must consider the combined biocompatibility effect.

WARRANTY

- The medical device is guaranteed free from manufacturing defects for 12 months from the date of delivery. The replacement or repair of the parts covered by this warranty does not extend the validity of the warranty itself.

PRODUCT IDENTIFICATION

This IFU is applicable to the following stock series	161900N		

SYMBOLS

CE	UK CA	EC REP				LOT	SN	REF			
CE mark	UKCA mark	Authorised representative in the EU	Manufacturer	Date of manufacture	Use-by date	Batch code	Serial Number	Catalogue number	Caution, consult accompanying documents	Alternating Current	Operating Instructions

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IL161900N R04/2022
INSTRUCTIONS FOR USE (IFU) – PURAIR 500 ACTIVE ANAESTHETIC GAS SCAVENGING SYSTEM (AGSS)