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.
- The AGSS Receiving System is designed to be connected to a compliant anaesthetic gas scavenging system. However it may also be used with a BS6834:1987 system. Connecting it to any other vacuum system could results in injury.
- This device is suitable for use with high flow-rate disposal systems only.
- The minimum exhaust flow-rate is 50 l/min and the maximum exhaust flow-rate is 130l/min.

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.

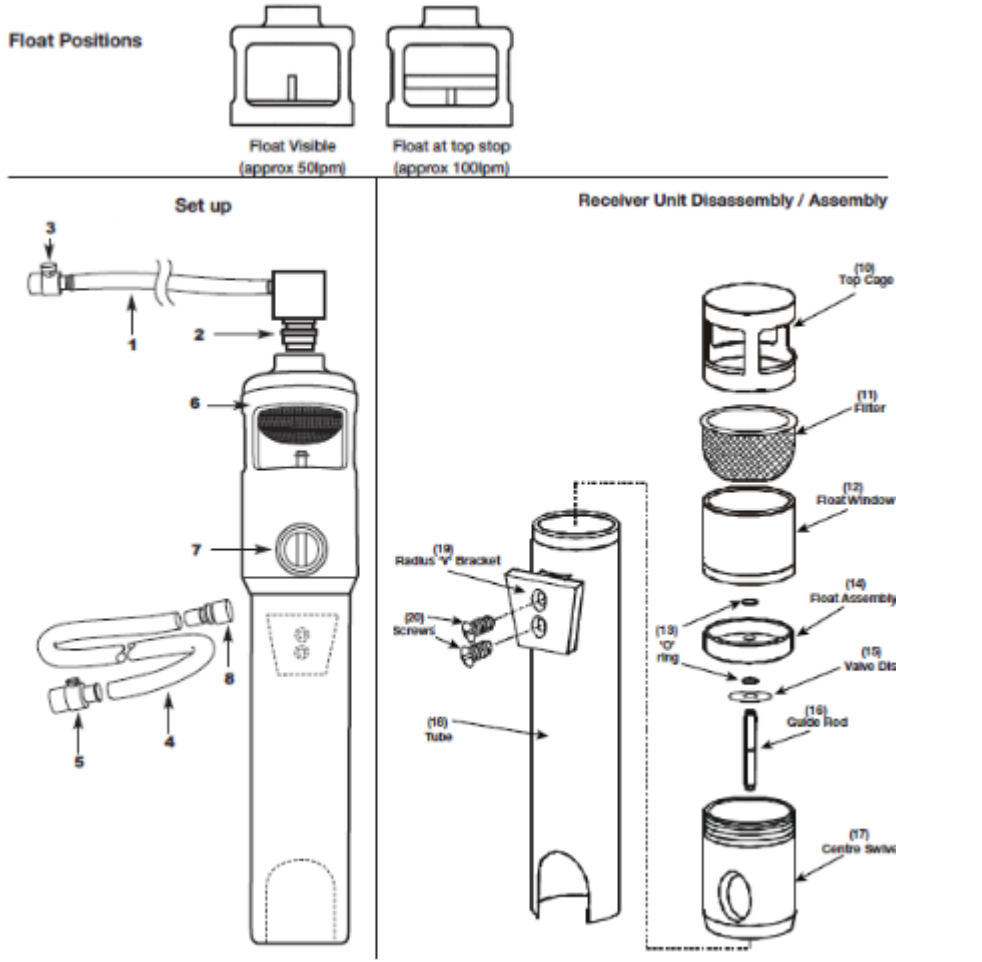
INTENDED USE AND DESCRIPTION

- The device is used to provide the extraction of waste and excess gases from the patient breathing system into an anaesthetic gas scavenging disposal system.
- The device comprises the receiver unit (air brake) and includes the supplied accessories of a disposal hose assembly 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. Replacement transfer hose and male connector are shown in the Spares and Accessories section overleaf.
- The 10cm H2O pressure relief valve (PRV) can be reused if cleaned in accordance with these instructions.
- It is the responsibility of the end user to ensure that the correct device with correct fittings has been selected. MEC Medical Limited accepts no responsibility for the selection of an incorrect device.

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.
- Mount the receiving system in a vertical position.
- Ensure that the AGSS Receiving System is securely supported before connecting the hoses.
- Connect the pressure relief valve (5) to either the patient breathing system APL valve or the breathing circuit expiratory valve.
- Connect the male adaptor (8) to the patient inlet (7) on the receiving system.
- Ensure that 'O' rings (2 & 3) are fitted to the probe and swivel on the disposal hose assembly (1).
- Connect end of (1) the disposal hose assembly to the receiving system top cage (6) and then connect the other end (1) to the anaesthetic gas scavenging disposal system.
- Check that the float is visible in the float window, as illustrated in Figure 2. If the float is not visible, refer to the Troubleshooting section.
- Do not obstruct the ports.
- The receiver unit incorporates a transparent window so that the position of the float and the condition of the filter can be observed. Typical positions of the float are illustrated in Figure 2.
- The filter should be kept visibly clean to prevent flow restriction through it.
- The disposal hose assembly is used to connect the receiving system to the anaesthetic gas scavenging disposal system.
- The transfer hose assembly is used to connect the receiving system to the patient breathing system. It consists of a 22mm corrugated tube, 30mm male adaptor and a pressure relief valve (PRV).
- The male adaptor is used to connect the transfer hose to the receiving system patient inlet assembly.
- The pressure relief valve (PRV) is used to connect the AGSS to the patient breathing system.
- The receiver unit should be operated with an extract flow of between 50 lpm and 130 lpm. The top of the float becomes visible at approximately 50 lpm. The float reaches its top stop at approximately 100 lpm.

DIAGRAMS



Diagrams of AGSS Receiving System, part number 12800000

1	Disposal Hose Assembly	
2	Swivel 'O' Ring	
3	Probe 'O' Ring	
4	Transfer Hose	
5	Pressure Relief Valve (PRV)	
6	Top Cage	
7	Patient Inlet Port (30mm)	
8	Male Adaptor	

10	Top Cage	
11	Filter	
12	Float Window	
13	'O' Ring	
14	Float Assembly	
15	Valve Disc	
16	Guide Rod	
17	Centre Swivel	
18	Tube	
19	Radis 'V' Bracket	
20	Screws	

Items 16, 17 & 18 shown here disassembled for clarity only. They must not be disassembled by the user.

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INSTRUCTIONS FOR USE (IFU) –AGSS RECEIVING SYSTEM

INSPECTION AND PREVENTATIVE MAINTENANCE:

- 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.
- Where the device is in environments where it could be damaged, for example by having heavy equipment knocked into them, a full examination of the device should be made every week.
- Any visible damage would necessitate the device being replaced.
- The device contains rubber seals which may deteriorate over time. Because of the wide variation of usage and probe condition MEC cannot recommend a period to cover all circumstances but O rings should be replaced at least every 5 years.
- It is recommended that all AGSS Receiving Systems are replaced 12 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.
- Clean the PRV (5) with isopropyl alcohol. Do not autoclave.
- The filter (11) should be rinsed with water from the concave side, to remove lint and debris and may then be steam autoclaved as required (recommendation once a week).

MAINTENANCE

- Maintenance engineers must fully understand the device and be familiar with these instructions.
- Sub-standard or inappropriate parts and materials may damage the device and invalidate the warranty. Only use genuine MEC Medical spare parts.
- Obtain a work permit before commencing any work on medical gas equipment.
- All hand tools used must be clean, completely free of oil and grease and checked for serviceability before use.

DISASSEMBLY

- Warning: Only Engineers trained to repair and/or service this type of equipment should attempt to repair and/or service the device and it must be repaired and/or serviced only in accordance with written instructions provided by MEC Medical Ltd. An improper repair and/or service can result in patient injury.
- Refer to Diagrams of AGSS Receiving System overleaf.
  1. Disconnect the disposal hose probe end (1) from the central anaesthetic gas scavenging disposal system.
  2. Unplug the disposal hose assembly (1) from the receiver system top cage (6).
  3. Remove the 'O' rings (2 & 3) from the probe and swivel of the disposal hose assembly (1).
  4. Disconnect the 10cm H2O pressure relief valve (5) from the patient breathing system and the male adaptor (8) from the patient inlet (7).
  5. Remove the 10cm H2O pressure relief valve (5) and the male adaptor (8) from the transfer hose (4).
  6. Remove the receiver unit from its mounting.
  7. Refer to Figure 4. Stand the receiving unit on a clean, flat surface. Hold the centre swivel (17) 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. 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). Remove the two screws (20) to release the radius 'V' bracket (19).

SPARES AND ACCESSORIES

- For all service spares and accessories please check the latest catalogue or contact MEC Medical.

Disposal Hose Assembly 3m	12800011	Filter (single)	12800034
Disposal Hose Assembly 5m	12800013	Float window	12800035
'O' Ring (pk 20)	231743P	'O' Ring (pk 20)	51010041P
'O' Ring (pk 20)	231744P	Float Assembly	12800010
Transfer Hose Assembly	181934	Valve Disc	12800029
Pressure Relief Valve (PRV)	181931	Radius 'V' Bracket	12800036
30mm Male Connector (pk 10)	181923P	Screw (pk 10)	SM0635P

LEAKAGE TESTING

- The device has been designed to ensure that leakage of gas from the receiving system is less than 100 ml/min at a gas flow rate of 10 +- 0.5 l/min.
- To measure the leakage from the receiving system involves specialist testing equipment and cannot be completed by the end user. Return to MEC or your supplier for validation if required.

TROUBLESHOOTING

- Verify that all components are correctly assembled, the filter is clean and all connections are properly made. Rectify if necessary.
- If the float is not visible, check that the gas scavenging disposal system supply is correct. Rectify if necessary.
- If the float is still not visible, contact the manufacturer for advice.

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.
- Adequate precautions should be taken against spillage or breakage, attack by micro-organisms, contamination and cross-contamination.
- Store off the ground and suitably spaced to permit cleaning and inspection.
- Ensure that identification is not lost.
- Packaging should be maintained until used and stored with identification visible.
- Should not be stacked.

SPECIFICATIONS

Gas Compatibility		
AGSS	**Intended range of use**	AGSS: 20 kPa absolute Minimum flow rate 50l/min Maximum flow rate 130l/min
	Materials	Receiving Unit: Aluminium Float Window: Polycarbonate Filter: Stainless Steel Float Assembly: LPDE Valve Disc: Acetal Guide Rod: Stainless Steel Seals: Nitrile and Viton Hoses: Plastic connectors: Brass and Stainless Steel V Bracket: Acetal Screws: Stainless Steel

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:

1280000*	132200*				

SYMBOLS

CE 1639	UK CA 0120	EC REP				LOT	SN	REF	
CE mark with Notified Body number	UKCA mark with Approved Body number	Authorised representative in the EU	Manufacturer	Date of manufacture	Use-by date	Batch code	Serial Number	Catalogue number	Caution, consult accompanying documents

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INSTRUCTIONS FOR USE (IFU) –AGSS RECEIVING SYSTEM