MGE

SAM 2 & SAM 2 IU

Medical Suction Collection Containers

Operating and Maintenance Manual

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Dear Customer,
We take this opportunity to thank you for purchasing a **SAM** Medical Suction Unit. Please read the operating instructions and listed precautions thoroughly before attempting to operate the unit. MG Electric manufactures its range in accordance with the requirements of BS EN ISO 9001 and BS EN ISO 13485

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Return of Medical Equipment
Should you wish to return any equipment to MG Electric (Colchester) Limited (MGE), or one of our designated distributors, Health Service Guideline HSG (93) 26 Decontamination of equipment prior to inspection, service or repair) must be adhered to. Failure to follow this guideline will invalidate any warranty claims and result in the equipment being destroyed.

bsi ISO 9001 Quality Management Systems CERTIFIED FM15051 ISO 13485 Quality Management for Medical Devices CERTIFIED MD599004

CE 2797

EC REP Advena Ltd. Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013 Malta

Definition of symbols used in these instructions:


The Instruction for use must be referred to!


Disposal in accordance with directive 2012/19/EU

Manufacturers' details and date of manufacture


Temperature Limits


Safety Warning

Humidity Limits

1. SAFETY INSTRUCTIONS

The safety of the patient and **SAM** suction unit operator are the first priorities. It is therefore vital that the following precautions are strictly observed:

WARNING!!!

- No modification of this equipment is allowed.
- Only original and approved spare parts and collection container systems must be used with MG Electric products – failure to use original or approved spares will invalidate the warranty and may cause injury or damage the **SAM 2**/**SAM IU**.
- Other than for routine daily procedures, any maintenance or repairs to MG Electric products must be carried out by fully trained and qualified Electro-Biomedical engineer/technician (EBME) or an authorised MG Electric dealer. Such persons are to be familiar with the relevant standards, rules, accident prevention regulations, and operating conditions as a result of their training, experience, and instruction. They are qualified to carry out the required activities and in doing so recognize and avoid potential hazards. All testing on **SAM** suction units should be in accordance with ISO 10079-1
- Contamination may be present on any components. When cleaning or replacing any part of the **SAM** suction unit appropriate protective clothing and gloves MUST be worn to avoid contamination. Disposal of contaminated parts must be according to local protocols.
- Store the manual in a safe place, so that it is available to the trained personnel at all times.
- All **SAM 2** and **SAM IU** collection containers must be securely mounted when in use.
- **SAM 2** and **SAM IU** collection containers are NOT suitable for use in an MRI environment.
- The overflow valve may not operate fully against frothing. To prevent frothing anti-foam agent maybe used.
- When replacing a full **SAM 2**, be aware of its weight and ensure handling the container is comfortable to avoid the possibility of spillage.
- Transport of the suction unit with a full **SAM 2** or **SAM IU** collection container attached is not advised.

2. GENERAL DESCRIPTION

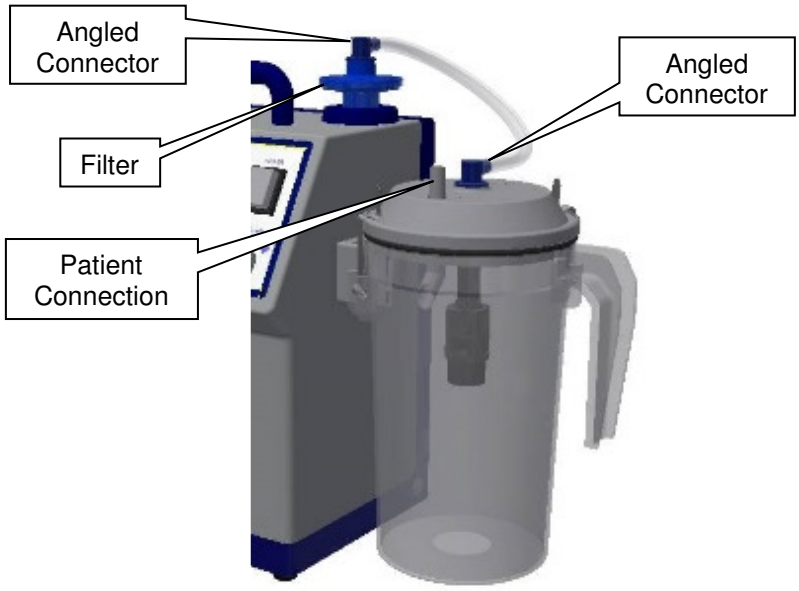
SAM 2 - Reusable collection container with a nominal capacity of 2 litres, used for the collection of body fluids during suction therapy.

SAM 2 IU - A specialist version of the **SAM 2** collection container with a wide bore patient connection for Intra-Uterine procedures.

All further references of **SAM 2** in this manual refer to both **SAM 2** and **SAM 2 IU** connection containers.

The **SAM 2** includes a sealed top with integral shut-off valve, an integral handle and tube connections. The shut-off valve provides prevent from contamination of the **SAM** suction unit. The **SAM 2** is connected to the **SAM** suction unit via a moulded 'V' bracket and has graduations at intervals of 250 millilitres for volume indication.

The collection container does not come into contact with the patient under normal use – there are no contra-indications.



The **SAM 2** collection container is fitted as standard to all **SAM** suction units, and are connected to the **SAM** suction unit via a moulded vacuum connector of the same type as that fitted to the filters.

- Place the **SAM 2** in the bracket. Connect the tubing from the filter to the angle connector in the centre of the lid.
- Connect the patient tube to the patient connection.
- Turn on the aspiration unit.
- Check the desired vacuum is established.
- After the suction procedure – disconnect the patient tube.

3. INSTRUCTIONS FOR USE

3.1 Before Operating Unit

BEFORE operating your new SAM 2 collection container, please read the following instructions carefully.

Become thoroughly familiar with the operation and maintenance of the **SAM 2** before use. Only persons trained in its use should operate the suction unit.

3.2 SAM 2 Set Up

Warning! When replacing a full **SAM 2** collection container, be aware of its weight and ensure handling the container is comfortable to avoid the possibility of spillage. Transport of the suction unit with a full **SAM 2** attached is not advised.

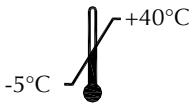
Warning! The **SAM 2** must be securely mounted when in use.

The **SAM 2** collection container is fitted as standard to all **SAM** suction units, and are connected to the **SAM** suction unit via a moulded vacuum connector of the same type as that fitted to the filters.

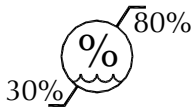
- Place the **SAM 2** in the bracket. Connect the tubing from the filter to the angle connector in the centre of the lid.
- Connect the patient tube to the patient connection.
- Turn on the aspiration unit.
- Check the desired vacuum is established.
- After the suction procedure – disconnect the patient tube.

3.3 Operating Environment

Operation of the **SAM 2** must be within the following ambient condition.



Temperature



Humidity

Warning! Never operate a **SAM** suction unit in the presence of flammable gas such as anaesthetic agents. This is an Explosion hazard!

An anti-foam agent may be put into the **SAM 2**, without disinfectant solution, before use to reduce the possibility of frothing. It should not however, be placed into the **SAM 2** for extended storage periods.

3.4 Connection

The silicon service tube (∅6mm I/D with 3mm minimum wall thickness) must be connected between the filter and the vacuum port on the **SAM 2** lid. The tube has an elbow connector on each end for fitting to the filter and for fitting to the 'VACUUM' port of the **SAM 2**. The silicon tubing used in conjunction with this equipment is a replaceable item. It should be changed regularly according to the level of usage and where it has become in any way contaminated or damaged.

3.5 SAM 2 Overflow Protection Valve

The **SAM 2** is fitted with an overflow valve designed to shut off the vacuum when the fluid level reaches 1750ml, this will stop suction from the suction unit. When the valve operates, the suction unit must be switched off and the full **SAM 2** replaced by an empty one. For **SAM** suction units with two collection containers and where appropriate the full **SAM 2** collection container may be replaced by the second **SAM 2** through operation of the changeover valve located on the top of the unit.

It should be noted that even after the overflow valve has shut off, fluid might continue to be drawn into the **SAM 2** to an extent dependent upon the level of vacuum in the **SAM 2** at the time when the valve closed.

Warning! The overflow valve may not operate fully against frothing. To reduce frothing anti-foam agent may be used. Liquid sucked through to the pump will cause damage - As a precaution, a hydrophobic filter should be fitted to prevent liquid passing through.

3.6 Cleaning Procedure

Warning! Contamination may be present on any components. When cleaning or replacing any part of the **SAM 2** appropriate protective clothing and gloves MUST be worn to avoid contamination. Disposal of contaminated parts must be according to local protocols.

Warning! Solvent-based cleaning agents or abrasive cleaners must not be used on any **SAM 2**. Minimise contact with cleaning solution and rinse well immediately with warm water. Prolonged immersion of parts in water above 60°C causes loss of material properties and must be avoided. Do not soak in dilute or neat disinfectant, as this will cause damage.

Warning! The black 'O' seal is a re-usable item but must not be autoclaved.

The **SAM 2** collection container is made from Medical Grade Polycarbonate and is autoclavable up to 138°C. The **SAM 2** must be cleaned and sterilised between uses. The **SAM 2** is connected to the aspiration unit via silicon tube and two vacuum connectors. The tubing and connectors are replaceable items and should be changed regularly according to the level and type of usage and when it has become in any way contaminated or damaged. The black 'O' seal is a re-usable item but must not be autoclaved.

The **SAM 2** can be cleaned, disinfected and sterilised by most of the well-known methods employed in practice. Under certain conditions, however, contact with cleaning, disinfecting and sterilising media may cause some damage, which manifests itself in the form of stress cracking. This usually leads to a reduction in mechanical strength. This manual contains no specific recommendations as to suitable cleaning agents and disinfectants for the **SAM 2**, because the choice is many, and the composition of such products can change.

In order to avoid mechanical stress to the **SAM 2**, it is advisable not to clamp or stack them during cleaning, disinfection or sterilization.

3.6.1 Cleaning of Jar and Lid

In many cases it is sufficient to clean with warm or hot water to which some weakly acidic, neutral or weakly alkaline cleaning agent has been added.

- Cleaning is a pre-requisite for all types of decontamination. Sterilisation will not be effective on a jar that is still soiled. In addition, proteinaceous matter may become baked onto the surface.
- Gloves, apron and eye protection must be worn when cleaning by hand.
- The jar, lid and other parts must be separated before cleaning to ensure all surfaces that may be contaminated are cleaned.
- Special attention should be paid to the overflow valve assembly and passageway attached to the lid.
- Always pre-clean **SAM 2** parts under water and in a deep sink using detergent and hot water to remove visible contamination - A soft brush may be used.
- Items must be examined after the cleaning process, to ensure that all visible soiling is removed.
- Rinse well to remove any cleaning agent and avoid surface damage.

3.6.2 Cleaning of the 'O' Ring Seal

In many cases it is sufficient to clean the 'O' seal with warm or hot water to which some weakly acidic, neutral or weakly alkaline cleaning agent has been added. The 'O' ring seal is a re-usable item but must not be autoclaved. Thoroughly dry the 'O' seal after cleaning. Inspect the 'O' ring seal after cleaning to ensure it is not cracked or damaged in any way. Replace if necessary.

3.6.3 Sterilisation

Sterilising by steam autoclaving -

- Ensure removal of all visible soiling.
- The **SAM 2** must be dried prior to sterilisation. This reduces the likelihood of lime scale build up and ensures adequate steam penetration.
- The **SAM 2** jar should be inverted on the tray.
- Sterilise in a high temperature Autoclave at 138°C for a minimum of 3 minutes.

In contrast to standard autoclaving conditions, i.e., 121°C for 15 to 30 minutes, the **SAM 2** may be subjected to temperatures up to 138°C, thus reducing the amount of time needed for sterilisation. When sterilising with steam, germicides and detergents must be rinsed thoroughly from parts prior to autoclaving. Failure to thoroughly remove germicides and detergents from the parts prior to autoclaving may cause accelerated degradation. Permanent immersion of parts in steam causes loss of material properties and must be avoided.

Care must be taken to ensure that the **SAM 2** parts are not damaged by substances added to the boiler feed water, such as alkaline corrosion inhibitors, and that the **SAM 2** jar is positioned in such a way that no condensation can accumulate inside it as this may also cause damage.

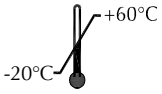
The **SAM 2** complies with ISO 10079-1 and will undergo 30 sterilisation cycles before deformation may become visible. Stress cracking and fracture may occur after further autoclave cycles. As a rule, it is possible to sterilize the **SAM 2** many times before gradual chemical decomposition reduces the mechanical strength to a level where it is no longer adequate for its application. Sterilization tests have shown that even after 100 cycles of 30 minutes each at 120 to 125°C, the material still retains comparatively good impact strength.

Service UK Health and Safety Act – The unit must be decontaminated internally and externally and certified as such before returning for service. Help Line 01932 355277

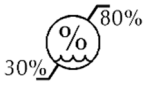
3.7 Transport

The **SAM 2** will be adequately boxed and protected to ensure no damage occurs during normal transportation of goods, providing the ambient conditions are within the following parameters:

Temperature max +60°C min -20°C



Humidity max +80% min +30%

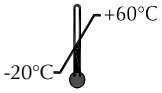


There are no restrictions for land, air, or sea transport.

3.8 Storage

SAM 2 must be stored in a dry, dust-free, well-ventilated environment. The storage environment should not exceed the temperature and humidity conditions stated below. Avoid direct sun or UV exposure and shield nearby sources of heat. The equipment should be stored in its original packaging providing no damage is evident. Protect against ground moisture by storing on a shelf or wooden pallet.

Temperature max +60°C min -20°C



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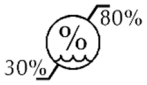


3.9 Instructions by Medical Staff to Patients

When the equipment is required by a patient for home use, Medical Staff must fully instruct the patient on the safe operation of the equipment. In the event of equipment contamination or failure, the patient must be advised to switch off the suction unit and contact the authority who loaned the equipment.

4. MAINTENANCE

With the need for hospitals to be able to ensure **SAM 2** collection containers are compatible with their Sterile Services Department prior to purchase - the following information is provided for guidance and the procedure outlined may be adapted to suit current practise.

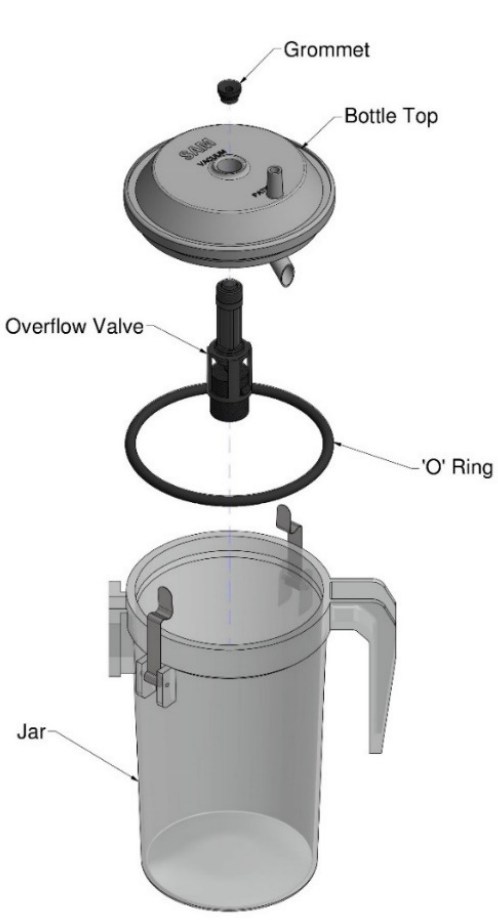
Warning! Contamination may be present on any components. When cleaning or replacing any part of the SAM unit appropriate protective clothing and gloves MUST be worn to avoid contamination. Disposal of contaminated parts must be according to local protocols.

Warning! No modification of this equipment is allowed.

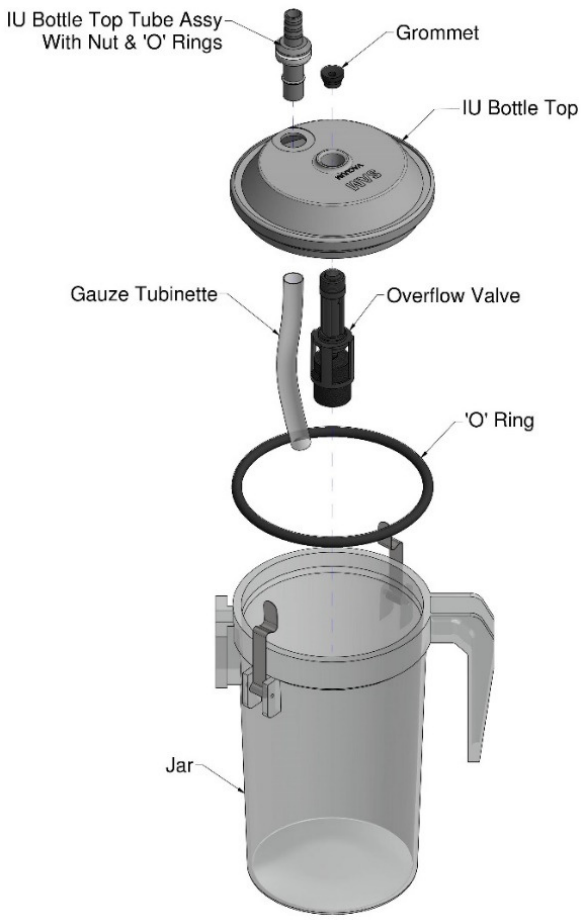
4.1 Daily Procedures

- An anti-foam agent may be put into the **SAM 2**, without disinfectant solution, before use to prevent the possibility of frothing. It should not however, be placed into the container for extended storage periods.
- Examine the collection container for damage. Replace if necessary.
- Examine the external tubing for ageing, damage, or contamination and replace if necessary, using equivalent tubing.

4.2 General Layout



SAM 2



SAM 2 IU

5. RECOMMENDED SPARES

5.1 Recommended Spares

Only original and approved spare parts must be used with all **SAM 2** collection containers – failure to use original spares will invalidate the warranty and may cause injury and/or damage to suction unit.

All spares can be purchased by the user from MG Electric directly. Not all available spares are listed below. Please contact the MG Electric sales team for a full list. (sales@mgelectric.co.uk)

It is recommended that only competent persons should undertake the replacement of spare parts.

5.1.1 Collection Container Components

SAM 2 2 litre autoclavable collection container	**SAM 2**
SAM 2 IU 2 litre autoclavable Intra-Uterine collection container	**SAM 2 IU**
SAM 2 bottle top assembly	MSP1047
SAM 2 IU bottle top assembly	MSP1071
SAM 2 overflow valve – 10pk	MSP1048
SAM 2 top grommets – 10pk	MSP1049
SAM 2 jar (No bottle top included) – 4pk	MSP1050
SAM 2 'O' ring – 10pk	MSP1051

5.1.2 Associated Components

Disposable bacterial filters – 24pk	MSP1002
Disposable hydrophobic filters – 24pk	MSP1003
Elbow connector and 'O' rings – 10pk	MSP1004
Silicone tube (OD ∅12mm) – 25M	MSP1156
SAM patient tubing – 2M	MSP1351

6. TECHNICAL SPECIFICATION

6.1 General Dimensions

Free air-flow (litres/minute):	50 lt/min nominal*
Vacuum:	700mmHg*
Performance classification:	High vacuum High flow (ISO 10079-1)
Nominal collection container capacity:	2 Litres
Patient Connection:	∅6mm I/D bore – **SAM 2** ∅9mm I/D bore – **SAM 2 IU**

*Measurements are quoted at sea level

6.2 End of Life

IMPORTANT INFORMATION
Correct disposal of the product in accordance with EC directive 2012/19/EU

At the end of its life, the product must not be disposed of as urban waste.
It must be taken to a special local authority differentiated waste collection centre or to a dealer providing this service.

7. NOTES

8. OTHER PRODUCTS IN THE SAM RANGE

Mains Powered Suction

SAM 12 - General ward high vacuum suction unit
SAM 14 – Twin jar minor operating theatre high vacuum suction unit
SAM 15 - Intra-uterine aspirator suction unit
SAM 16 – Twin jar intra-uterine aspirator suction unit
SAM 17T - Thoracic Theatre suction unit
SAM 17W - Thoracic Ward suction unit
SAM 18 - Intensive care low vacuum suction unit
SAM 19 - Twin jar Intensive care low vacuum suction unit
SAM 35 - Major operating theatre high vacuum suction unit
SAM 36 - Twin jar intra-uterine aspirator unit
SAM MS – Micro suction unit

Portable Suction

SAM HOSPY - General high vacuum suction unit
SAM EPS - Battery powered portable suction unit (Neonatal Option available)
SAM MANUVAC - Portable foot operated suction unit
SAM TVAC - Disposable, hand operated suction unit

Oxygen Flowmeters

SAM OXYFLOW - Oxygen flowmeter
SAM OXYHUM - Oxygen humidifier

Pipeline Regulators

SAM 50 - High vacuum pipeline regulator with remote probe
SAM 51 - High vacuum pipeline regulator with direct probe
SAM 52 - Low vacuum pipeline regulator with remote probe
SAM 53 - Low vacuum pipeline regulator with direct probe
SAM 54 - High vacuum pipeline regulator - remote probe & mobile trolley

Research and Development
Since 1954, when MGE produced their first surgical suction units, the **SAM** range has become accepted as the industry standard, both in the U.K. and throughout the world.
In recent years, the **SAM** range has been greatly extended, with models now available for portable, electrical suction and central suction requirements. They have been completely re-designed, using lightweight, robust materials, achieving greater efficiency, and making them easier to clean and operate. All MGE equipment is manufactured and assembled to very high standards of quality at the modern factory in Colchester in accordance with BS EN ISO 9001 Quality Management System, BS EN ISO 13485 and the Medical Device Directive 93/42/EEC.

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