



SAM 35, SAM 36

Medical Suction Unit Operating and Maintenance Manual



M.G. Electric (Colchester) Ltd
Altbarn Close, Colchester, Essex, CO4 9HY, United Kingdom
Tel: +44 (0) 1206 842244, Fax: +44 (0) 1206 845849
e-mail: sales@mgelectric.co.uk www.mgeworldwide.com

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. MGE manufactures its range in accordance with the requirements of BS EN ISO 9001 and BS EN ISO 13485

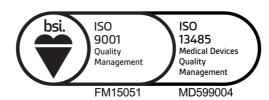
INDEX

1.	SAFETY INSTRUCTION	S	4
2.	GENERAL DESCRIPTION	DN	6
3.	INSTRUCTIONS FOR U	SE	7
	3.3 3.4 3.5 3.6 3.7 3.8 3.9 3.10 3.11 3.12 3.13 3.14	Unit Set Up Handling Operating Environment Gauge (Manometer) - Indicated Vacuum External Filter Internal Filter Fluid Collection Containers Disposable Liner Systems Effect of altitude Cleaning Procedure Transport Storage Long Term Storage Instructions by Medical Staff to Patients	
4.	MAINTENANCE	<u> </u>	13
	4.2 4.3 4.4 4.5 4.6 4.7	, , ,	
5.	OPTIONS AND RECOM	MENDED SPARES	19
	5.1 5.2	Options Recommended spares	
6.	TECHNICAL SPECIFICA	ATION	21
	6.1 6.2 6.3	General Dimensions End of life Electromagnetic Compatibility (EMC)	
7.	NOTES		26
8.	OTHER PRODUCTS IN	THE SAM RANGE	28

Manual 118 Issue 15 Page 2 of 28

Return of Medical Equipment

Should you wish to return any equipment to MGE (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.





Definition of symbols used in these instructions:



The Instruction for use must be referred to!



Manufacturers' details and date of manufacture



Electricity Warning



Safety Warning



Disposal in accordance with directive 2012/19/EU



Temperature Limits



Humidity Limits



Type B applied part

Ingress Protection



X - Ingress Protection against particulates

2 - Ingress Protection against water.



Equipotential earth point

Manual 118 Issue 15 Page 3 of 28

1. SAFETY INSTRUCTIONS

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



Never operate a **SAM** suction unit without an MGE filter capsule.

The filter capsules are single patient use and cannot be reused. Reuse of such devices can be dangerous for both patient and operator.

A hydrophobic filter must be fitted internally to prevent liquid passing through to the pump. Hydrophobic filters only work once and should be replaced immediately it becomes wetted.

No modification of this equipment is allowed.

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

No liability can be accepted by MGE for units affected by the occurrence of overflow when Disposable Liner Systems are being used.

Other than for routine daily procedures, any maintenance or repairs to MGE products must be carried out by fully trained and qualified Electro-Biomedical engineer/technician (EBME) or an authorized MGE dealer. Such persons must 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** 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 collection containers must be securely mounted when in use.

The overflow valve may not operate fully against frothing. To prevent frothing anti-foam agent maybe used.

When replacing a full collection container, be aware of its weight and ensure handling the container is comfortable to avoid the possibility of spillage.

Transport of the **SAM** suction unit with a full jar attached is not advised.

Solvent-based cleaning agents or abrasive cleaners must not be used on any **SAM** suction units. Do not wash any **SAM** suction units under running water or submerge in water.

Any dismantling and re-assembly of this equipment - for whatever purpose - must be followed by testing in accordance with the manufacturers' recommendations as specified for monthly maintenance.

Manual 118 Issue 15 Page 4 of 28



ELECTRICAL WARNING

Always electrically isolate the **SAM** suction unit from the mains power supply before carrying out any cleaning, maintenance or repairs. Electrical isolation of the **SAM** suction unit is by removal of the mains power cable from the mains power supply.

Never operate a **SAM** suction unit in the presence of flammable gas such as anaesthetic agents.

This is an Explosion hazard!

Ensure the power cable does not create a trip hazard or is subject to damage.

The suction pumps may only be opened by qualified technical personnel. Electric shock hazard!



Equipotential bonding may be required in some critical treatment areas. This is intended to minimize any voltage differences between earthed parts of equipment and any other exposed metal in the room. All conductive metal in an equipotential area is connected to a common equipotential earth (reference) point.

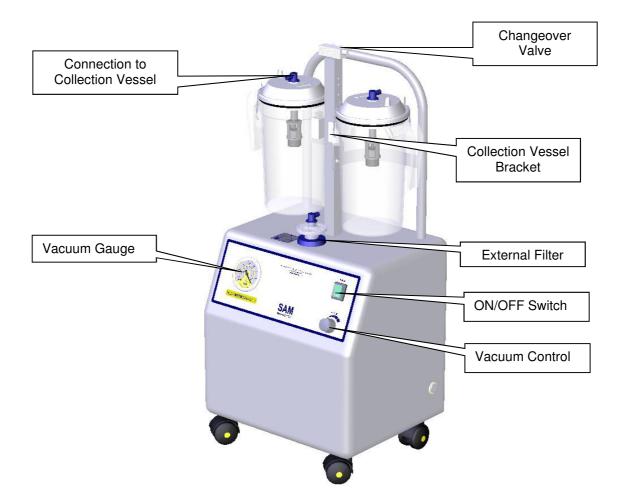
The **SAM** suction unit has on its back panel (adjacent to the mains power cable) an equipotential earth point to allow connection to an earth reference point when required. Installation of this connection must be carried out by a fully qualified engineer. Ref: BS EN 60601-1

Manual 118 Issue 15 Page 5 of 28

2. GENERAL DESCRIPTION

- **SAM 35** General-purpose high vacuum medical suction unit, normally incorporating two collection containers of 2L capacity. Other types of collection container are allowed. Designed specifically for use in medical and healthcare facilities, primarily in operating theatres where high vacuum and high flow are required. These units are not intended for field and transport use.
- **SAM 36** General-purpose high vacuum medical suction unit, incorporating two collection containers of 2L capacity. Other types of collection container are allowed. Designed specifically for use in intra-uterine procedures where high vacuum and high flow are required and is fitted with a wide bore collection container top complete with specimen filter. These units are not intended for field and transport use.

There are no contra-indications.



Manual 118 Issue 15 Page 6 of 28

3. INSTRUCTIONS FOR USE

3.1 Before Operating Unit

BEFORE operating your new SAM suction unit please read the following instructions carefully.

Become thoroughly familiar with the operation and maintenance of the unit before using and note the information on the control panel and rear of the unit. Only persons trained in its use should operate the unit.

Check that the voltage supply is as printed on the rating plate fitted to the back of the **SAM** suction unit.

Unscrew and remove the transport screws located on the underside of the unit.



Warning! Always electrically isolate the **SAM** suction unit from the mains power supply before carrying out any cleaning, maintenance or repairs. Electrical isolation of the **SAM** suction unit is by removal of the mains power plug from the mains power supply.

3.2 Unit Set Up

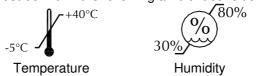
- Connect the desired collection system securely in place on the bracket fitted to the top of the unit. More detail can be found later in this section.
- Connect the desired equipment to the patient inlet tube on the collection container top.
 Multi-fit bubble tubing (If supplied) has an I/D Ø7mm. Recommended length of tubing
 used is 2 meters.
- Connect the unit to the power supply, check label on rear of unit for correct ratings. Do
 not obstruct access to the mains power supply, and ensure the power cable does not
 create a trip hazard or is subject to damage. Ensure the exhaust outlet on the side of the
 unit is kept clear of any restriction.
- Switch the **SAM** suction unit on by pressing the green rocker switch so that it illuminates. The lamp indicates the **SAM** suction unit is operating and ready for use.

3.3 Handling

The larger **SAM** suction unit are not normally intended for lifting or carrying. They will either be designed to installed on a trolley or fitted with lockable wheels. This mobility allows the larger **SAM** suction unit to be moved during use and easily transported between locations.

3.4 Operating Environment

Operation of this equipment must be within the following ambient condition





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

3.5 Gauge (Manometer) - Indicated Vacuum

The unit has a gauge fitted to allow the vacuum to be set at a pre-determined level and monitored during use. To achieve the desired degree of vacuum, occlude the tubing fitted to the patient inlet on the collection container top, and read the indicated vacuum on the gauge. Adjust the vacuum control until the required degree of vacuum is achieved. (Turning the knob clockwise \mho increases the vacuum). The **SAM** suction unit is now set to operate at the selected vacuum.

Manual 118 Issue 15 Page 7 of 28

3.6 External Filter



Warning! Never operate a SAM suction unit without a MGE filter capsule.

The filter capsules are a sealed disposable bacterial or hydrophobic filter capsule. Both the bacterial and hydrophobic filters have bacterial retention of 99.9999% ensuring safety and hygiene for patient and operator. The 0.3 micron particle retention of the filter medium also gives not less than 99.985% Dispersed Oil Particulate (D.O.P.) and so provides an effective barrier against possible aerosol contamination. The hydrophobic filter also has an integrated micro porous membrane on the rear of the filter medium which allows a clear flow of air through one way and an excellent block against any accidental back flow the other. The external filters are fitted between the vacuum connector and the filter capsule mount, and can be either a bacterial or hydrophobic filter. The connector, mount, and 'O' rings are autoclavable. However, the filter capsules are 'Single Patient Use' and must not be autoclaved. The external filter must be changed with every patient and renewed in accordance with the recommendations detailed in the 'Daily Procedures'.



Warning! The filter capsules are single patient use and cannot be reused. Reuse of such devices can be dangerous for both patient and operator.

3.7 Internal Filter

The **SAM** suction unit must have fitted internally a hydrophobic filter capsule to prevent ingress of foreign material into the pump. The hydrophobic filter prevents costly pump damage as well as additional protection against contamination from liquids being sucked through due to jar overfill. Liquid sucked through to the pump motor will cause damage and invalidate the warranty. The filter is disposable and must not be autoclaved, but renewed in accordance with the recommended maintenance program.



Warning! A hydrophobic filter must be fitted internally to prevent liquid passing through to the pump. Hydrophobic filters only work once and should be replaced immediately it becomes wetted.

3.8 Fluid Collection Containers

The silicon service tube (Ø6mm I/D with 3mm minimum wall thickness) must be connected between the filter and the changeover valve. The changeover valve must then be connected to the vacuum port on the collection container. These tubes have an elbow connector on one end for fitting to the filter and for fitting to the 'VACUUM' port of the SAM 2 collection container. 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.



Warning! All collection containers must be securely mounted when in use.

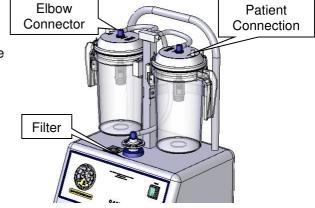
An anti-foam agent may be put into the fluid collection container, without disinfectant solution, before use to reduce the possibility of frothing. It should not however, be placed into the container for extended storage periods.

Manual 118 Issue 15 Page 8 of 28

3.8.1 SAM 2 Collection System

The **SAM** 2 collection container is fitted as standard to all **SAM** suction units. They are fully autoclavable Polyester Carbonate (P.E.C.) collection containers, with integral handle and for IU applications, with a wide bore. The collection containers are connected to the **SAM** suction unit via a changeover valve.

- Place the collection containers in the brackets. Connect the tubing from the changeover valve to the angle connector in the centre of the lid.
- Connect the patient tube to the patient connection.
- Turn on the SAM suction unit.
- Check the desired vacuum is established.
- After the suction procedure disconnect the patient tube.



The **SAM 2** is fitted with an overflow valve designed to shut off the vacuum to the **SAM 2** collection container when the fluid level reaches 1750ml. When the valve operates, the **SAM** suction unit must be switched off and the full container replaced by an empty one.

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



Warning! The overflow valve may not operate fully against frothing. To reduce frothing an anti-foam agent may be used.



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

3.8.2 SAM 4 Collection System

The **SAM** 4 collection container is fitted as standard to all **SAM** suction units. They are fully autoclavable Polyester Carbonate (P.E.C.) collection containers. The collection containers are connected to the **SAM** suction unit via a changeover valve.

 Place the collection containers in the cradle. Connect the tubing from the changeover valve to the connector on top of the lid (marked 'VACUUM').



- Connect the patient tube to the 'PATIENT' connection.
- Turn on the SAM suction unit.
- Check the desired vacuum is established.
- After the suction procedure disconnect the patient tube

The **SAM 4** is fitted with an integral shut off for overflow protection.



Warning! The overflow valve may not operate fully against frothing. To reduce frothing an anti-foam agent may be used.

Manual 118 Issue 15 Page 9 of 28



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

3.9 Disposable Liner Systems

The **SAM** suction units have been designed to accept various disposable liner systems. When fitted, protection of the unit against overflow is entirely dependent upon the correct use of the appropriate liner in accordance with the manufacturers' instructions.



Warning! No liability can be accepted by MGE for units affected by the occurrence of overflow when Disposable Liner Systems are being used.

3.9.1 VacSax suction system

- Place liner into collection container and push firmly.
- Push the taper connector on the vacuum tubing from the suction controller into the vacuum port with a twisting motion.
- Connect the patient tubing firmly to the patient port to ensure a good fit.
- Turn on the SAM suction unit.
- Confirm suction is present at the patient tube by occluding the patient tube end.
- After the suction procedure disconnect the patient tube and fit stopper located on rim into the port.
- Turn OFF the **SAM** suction unit and remove the liner for disposal.

The collection container may be sterilised by autoclaving at 121°C or by washing with water based disinfectants. Before autoclaving, rinse the collection container well to remove any detergent.

3.9.2 Abbott Receptal Disposable Suction System

- Place the collection container in the bracket making sure that the tee connection on the collection container is tight. Fully extend the liner, and place it into the collection container. Make sure that the liner is tightly secured in the collection container.
- The liner incorporates an internal shut off valve, which protects the vacuum source from contamination. Connect the vacuum source tubing (from the filter) to one side of the tee connection and the lid to the other side using the 'yellow to yellow' coding.
- Tee Connection
 Yellow to Yellow
 e liner is
 oing
 on and
 ow'

Patient

- Connect the patient tube to the patient connection, either directly or by using the optional elbow piece, which prevents kinking of the patient tubing.
- Turn on the SAM suction unit to inflate the liner and the collection container is now ready for use.
- For maximum safety and to minimise the risk of contamination when dismantling, the fluid level must not rise above the 'DO NOT FILL ABOVE THIS LINE' mark on the collection container.
- At the end of the procedure, the SAM suction unit should remain switched on while the
 patient suction tubing is removed from the patient port and discarded.
- Disconnect the liner lid tubing from the tee connection and immediately reconnect the yellow connector to the patient port with a push and twist motion.

Manual 118 Issue 15 Page 10 of 28



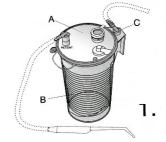
Turn the vacuum off and use the thumb tab to remove the liner for disposal.



Warning! The liner lid tubing must not be used as a carry handle.

Serres Suction Bag System 3.9.3

- The system comprises the suction bag (A), the collection container (B), and the angle connector (C).
- Place the collection container (B) in the bracket. Connect the tubing from the **SAM** filter to the angle connector (C).
- Place the suction bag into the collection container ensuring bag tail is not trapped between the lid and collection container.



- Turn on the SAM suction unit.
- Install the suction bag by using the vacuum Occlude the patient connection and simultaneously press lightly from the middle of the lid.
- Establish the desired vacuum and ensure the bag is fully inflated.
- Connect the patient tube to the patient connection.
- After the suction procedure disconnect the patient tube and close the connection with the plug provided on the lid.
- Turn OFF the **SAM** suction unit and remove the liner for disposal.

If necessary, the collection container only, may be washed (85°C) and autoclaved (121°C). Before washing, disconnect the angle connector. If autoclaving, rinse the collection container well to remove any detergent.

3.10 Effect of altitude

Altitude effects all vacuum pumps and it should be noted that there will be a reduction in the maximum achievable vacuum / negative pressure level equivalent to approximately 3.5% per 300m (approximately 1000ft) rise in altitude.

3.11 Cleaning Procedure



Warning! 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.



Warning! Always electrically isolate the SAM suction unit from the mains power supply before carrying out any cleaning, maintenance or repairs. Electrical isolation of the SAM suction unit is by removal of the mains power cable from the mains power supply.



Warning! Solvent-based cleaning agents or abrasive cleaners must not be used on any SAM suction units. Do not wash any SAM suction units under running water or submerge in water.

To clean the outside case of the **SAM** suction unit, disconnect the unit from the power supply, wipe over with a clean damp cloth or use an appropriate mild disinfectant solution. Following the manufacturers' instructions on cleaning product, and avoiding excessive moisture.

3.12 Transport

The SAM suction unit 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%

Manual 118 Issue 15 Page 11 of 28



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

3.13 Storage

SAM suction units 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.



3.14 Long Term Storage

When the units are held in storage, or used very infrequently, the three-monthly maintenance period may be extended to twelve months. Particular care must be taken when inspecting flexible components, such as valves, diaphragms, to ensure embrittlement has not occurred.

SAM suction units should be stored in a cool, dry environment, as stated above.

3.15 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 unit and contact the authority from which the unit is loaned.

3.16 Troubleshooting

Problem:	Cause:	Solution:	
	Unit not turned on	Turn Main Switch "ON/OFF" ON	
	Wrong operating voltage	Check mains voltage output	
No power to unit	Mains not connected	Connect mains cable	
	Defective Fuse	Check fuse and replace if indicated	
Dumpo foil to rup	Leak in vacuum system	Check all connection and tubing.	
Pumps fail to run	Collection Jar is full	Replace Jar	
	Vacuum leaks	Check all seals and hoses. Make sure Lid is securely on Jar.	
	Vacuum not to required setting	Turn vacuum control clockwise until the desired suction power is reached	
Pump suction power too weak	Tubing is plugged, bent and/or disconnected	Replace tubing if plugged and eliminate any bends	
	Internal hydrophobic filter is blocked or wet	Replace internal hydrophobic filter. – Must be done by EBME	
	External filter is blocked	Replace External filter.	

If a problem cannot be solved, contact a fully trained and qualified engineer (EBME), authorized MGE dealer or MGE (sales@mgelectric.co.uk).

Manual 118 Issue 15 Page 12 of 28

4. MAINTENANCE



Warning! Other than for routine daily procedures, any maintenance or repairs to MGE products must be carried out by fully trained and qualified engineers (EBME) or an authorized MGE dealer. Such persons must 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 so doing recognize and avoid potential hazards. All testing on SAM suction units should be in accordance with ISO 10079-1



Warning! No modification of this equipment is allowed.



Warning! 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.



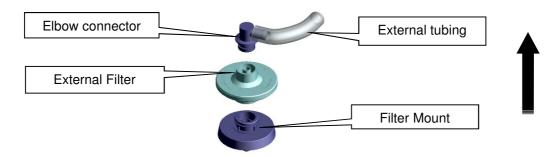
Warning! Any dismantling and re-assembly of this equipment - for whatever purpose must be followed by testing in accordance with the manufacturers' recommendations as specified for Monthly maintenance.



Warning! Isolate the SAM suction unit from the mains power supply before carrying out any maintenance or repairs. Electrical isolation of the SAM suction unit is by removal of the mains power cable from the mains power supply.

4.1 **Daily Procedures**

- The external filter capsule should be changed after any of the following:
 - Each day's use.
 - If it becomes wetted by froth.
 - After aspiration of any infective material.
 - Before being used on a new patient.



- Examine the collection container for damage. Replace if necessary.
- Examine the external tubing for ageing, damage, or contamination. Replace if necessary using equivalent tubing (Ø6mm I/D with 3mm minimum wall thickness).

Manual 118 Issue 15 Page 13 of 28

4.2 Monthly Maintenance

- Carry out the daily maintenance procedure.
- Check the vacuum and the flow at the collection container top.
- With the collection container empty and the vacuum control valve set to maximum, switch
 on the unit and read the indicated vacuum on the gauge. Occlude the suction inlet
 (Patient connection) on the collection container top and note the time taken for the gauge
 to indicate an increase to 450mm Hg (60 kPa) vacuum. This time should not exceed 10
 seconds.
- The gauge should continue to rise and stabilise to indicate the maximum vacuum available, and this should be not less than 590mm Hg (78.7 kPa).
- Replace the exhaust filters in the exhaust outlet housing located on the side of the casing and marked 'Exhaust Outlet'.

4.3 Three Monthly Maintenance

• Carry out the monthly procedure. Poor performance of the unit would indicate the internal pump requires maintenance

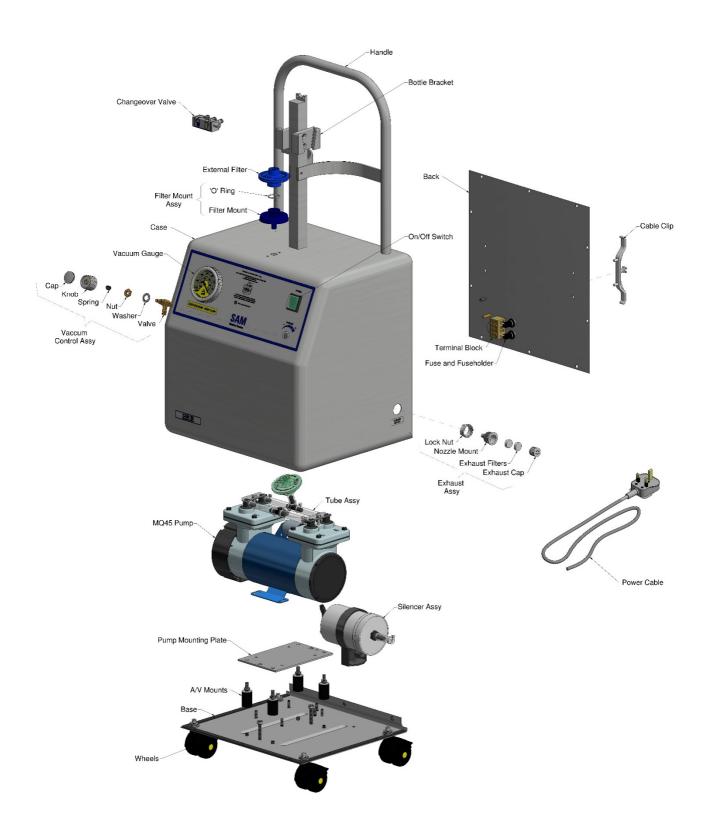


Warning! Always electrically isolate the **SAM** suction unit from the mains power supply before carrying out any cleaning, maintenance or repairs. Electrical isolation of the **SAM** suction unit is by removal of the mains power cable from the mains power supply.

- Remove the back cover.
- Check the internal and external tubing for ageing or wear. Replace with equivalent tubing where necessary. Tubing to gauge Ø5mm I/D, wall thickness min 2mm, all other tubing on the **SAM** suction unit Ø6mm I/D, wall thickness min 3mm.
- Replace the internal hydrophobic filter. Details in section 4.6 Replacing the Internal Hydrophobic Filter
- Check the internal wiring for ageing or wear. Replace with equivalent material and terminations where necessary.
- Examine the mains cable for wear or damage and replace if necessary using equivalent cable.
- Replace the back cover. Do not overtighten the rear cover fixings. (Recommended torque 20 cNm)
- Examine the overflow valve float mechanism (SAM 2) to ensure that this has free movement.
- Check the vacuum and flow performance at the collection container as previously described

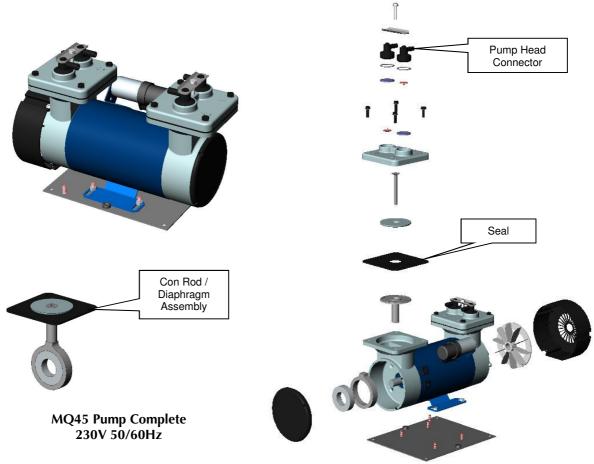
Manual 118 Issue 15 Page 14 of 28

4.4 General Layout



Manual 118 Issue 15 Page 15 of 28

4.5 Pump (If Required)



- Remove the pump from the SAM suction unit.
- Remove the pump head from the pump casing and examine the diaphragm for signs of wear
- Check the balance within the connecting rod for excessive movement. Replace the connecting rod and balance if necessary.
- Remove both pump head nozzles from the pump head.
- Remove the transfer valves.
- Clean the valve seats and check the valves for signs of wear.
- Replace any worn or damaged components as necessary and re-assemble.
- Replace the pump back into the SAM suction unit and re-connect the internal tubing.

Note: Replacement kits are available to change an old LQ45 Pump with a new MQ24 Pump. Details found in Options and Recommended Spares section.

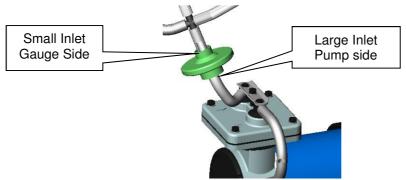
Manual 118 Issue 15 Page 16 of 28

4.6 Replacing the Internal Hydrophobic Filter



Warning! A hydrophobic filter must be fitted internally to prevent liquid passing through to the pump. Hydrophobic filters only work once and should be replaced immediately it becomes wetted.

When replacing filters, particularly the hydrophobic filter, it is important to ensure the filter is connected correctly to suit the direction of flow. The filters will only operate efficiently in one direction. The flow diagram indicates the correct orientation installed in the pipework.



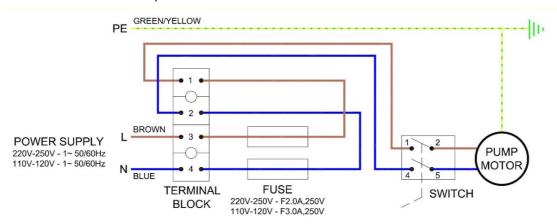
Hydrophobic Filter Installation

4.7 Replacing the Main Cable



Warning! Always electrically isolate the **SAM** suction unit from the mains power supply before carrying out any cleaning, maintenance or repairs. Electrical isolation of the **SAM** suction unit is by removal of the mains power cable from the mains power supply.

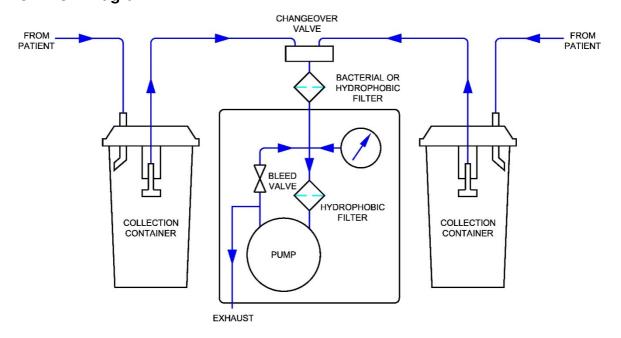
- Isolate the **SAM** suction unit from the mains power supply!
- Detach the back panel to access the internal terminal block.



- Disconnect the brown and blue conductors of the cable from the terminal block, and withdraw the cable.
- Fit the replacement cable through the access hole.
- Connect the conductors to their respective terminals (Blue to Blue and Brown to Brown) in the terminal block. Provide sufficient length of cable between the gland and terminal block.
- Fit the cable into the labyrinth.
- Ensure all conductors are fitted as the original.
- Check continuity of each circuit.
- If reconnection is correct replace the back panel.

Manual 118 Issue 15 Page 17 of 28

4.8 Flow Diagram



SAM 35 and SAM 36

Manual 118 Issue 15 Page 18 of 28

5. OPTIONS AND RECOMMENDED SPARES

5.1 Options

User Instruction Manuals are offered in English. Other languages are available on request.

	Model	Elec	trical Specification	Collection Jars		ars Power Cable		Version	
	35	01	230Vac 50/60Hz	00	No Jar	01	UK	01	Static
	36	02	110Vac 50/60Hz	01	SAM 2 (2Ltr)	05	European	02	Mobile
				03	Abbott	06	Aus/NZ		
				04	Pennine				
				05	SAM 4 (ltr)				
SAM				06	VacSax				
				07	Serres				
				08	Cardinal Medline				
				09	Cardinal CRD				
				10	SAM 2 Holder				
				11	МТР				
				13	Flowmeter Flovac				

Example: SAM 35 / 01 01 01 02

5.2 Recommended spares

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

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

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

5.2.1 Collection Container Components

Disposable bacterial filters – 24pk	MSP1002
SAM 2 bottle	
SAM 2 IU bottle	SAM 2 IU
SAM 4 bottle	MSP1290
SAM 4 It Jar Conversion	MSP1317
SAM 2 bottle top assembly	MSP1047
SAM 2 IU plastic bottle top assembly	MSP1071
SAM 2 overflow valve – 10pk	
Silicone tube (O/D Ø12mm) − 25M	MSP1156
SAM patient multi-fit bubble tubing (I/D Ø7mm) − 30M	MSP1155

Manual 118 Issue 15 Page 19 of 28

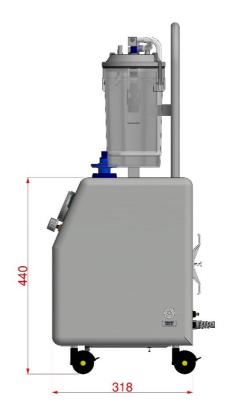
5.2.2 Unit Components	
Disposable hydrophobic filters – 24pk	MSP1003
Elbow connector and 'o rings – 10pk	MSP1004
Exhaust filter – 10pk	MSP1015
Filter capsule mounts with 'o' rings and fixings – 10pk	MSP1017
2amp 20mm fuses – 10pk	MSP1225
Power cable – 2M	MSP1567
5.2.3 Pump Components	
MQ45 pump (Pump & motor 230V 50/60Hz)	MSP1226
Motor 230V 50/60Hz	MSP1227
MQ45 pump head connector set	MSP1230
MQ45 pump head service kit	MSP1229
MQ45 consumable spares service kit	MSP1231
Con rod/diaphragm assembly	MSP1210
SAM 35 MQ45 replacement for LQ45	MSP1236
SAM 36 MQ45 replacement for LQ45	MSP1240
5.2.4 Accessories	
Foot-switch conversion kit	MSP1151

Manual 118 Issue 15 Page 20 of 28

6. TECHNICAL SPECIFICATION

6.1 General Dimensions





Free air-flow (litres/minute): *50 lt/min** nominal *25 lt/min* nominal

Vacuum: *675mmHg** *730mmHg*

Performance classification: High vacuum High flow (ISO 10079-1)

Nominal collection container capacity: 2 Litres or 4 Litre**

Power input (watts): 100W

Standard supply voltages available: 220V-240V 50/60 Hz, 1Ph 110V-120V 50/60 Hz, 1Ph

Capacitor: 220V-250V 4uF 110V-120V 12uF

Fuse type: 5 x 20mm 220V-250V: F2.0A, 250V 110V-120V F 3.0A, 250V

Electrical protection: Type B, Applied part to EN60601-1

Class I insulated (Earth Required) to EN60601-1

Electric motor classification: BS2757 Class B (insulated). Auto reset thermal cut out

Basic Weight: 21Kg

Maximum allowable weight: 30kg all units.

Maximum Noise level: 55 dB (a)

*Vacuum measurements are quoted at sea level, and flow rates are taken at the filter point.

Manual 118 Issue 15 Page 21 of 28

^{**} SAM 35 Options

^{*} SAM 36 Options

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.

6.3 Electromagnetic Compatibility (EMC)

Special Instructions / Notes regarding the **SAM** suction unit and Electromagnetic compatibility (EMC) testing to EN60601-1-2: 2014

The **SAM** suction unit has been tested regarding its ability to operate in an environment containing other electrical/electronic equipment (including other medical devices).

The purpose of this testing is to ensure the **SAM** suction unit is not likely to adversely affect the normal operation of other such equipment and that other such equipment is not likely to adversely affect the normal operation of the **SAM** suction unit.

Despite the testing of the **SAM** suction unit that has been undertaken, normal operation of the **SAM** suction unit can be affected by other electrical/electronic equipment and portable and mobile RF communications equipment.

As the **SAM** suction unit is medical equipment, special precautions are needed regarding EMC (electromagnetic compatibility).

It is important that the **SAM** suction unit is configured and installed/put into service, in accordance with the instructions/guidance provided herein and is used only in the configuration as supplied.

If the **SAM** suction unit is used with cables / accessories other than those supplied, this may result in increased emissions or decreased immunity of the **SAM** suction unit in relation to EMC performance.

It should be noted that cables / accessories provided with the **SAM** suction unit should not be used on other equipment. To do so may result in increased emissions or decreased immunity of the other equipment in relation to EMC performance.

The **SAM** suction unit should not be used adjacent to or stacked with other equipment. If adjacent or stacked use with other equipment is necessary, the **SAM** suction unit and the other equipment should be observed/monitored, to verify normal operation in the configuration in which it will be used.

For the purposes of EN60601-1-2, the SAM suction unit has no essential performance.

The user should be aware that if the **SAM** suction unit is subject to electromagnetic interference in the form of electrical fast transients/bursts (IEC61000-4-4), electrostatic discharges (IEC61000-4-2) or conducted / radiated RF interference (IEC 61000-4-6 / IEC61000-4-3), incorrect operation of the **SAM** suction unit may occur. This could cause the vacuum to stop

Manual 118 Issue 15 Page 22 of 28

Guidance and manufacturer's declaration – electromagnetic emissions

It is important that the **SAM** *35/36* is configured and installed/put into service, in accordance with the instructions/guidance provided herein and is used only in the configuration as supplied. For the purposes of EN60601-1-2:2014, the **SAM** *35/36* has no essential performance.

It should be noted that cables / accessories provided with the **SAM** *35/36* should not be used on other equipment. To do so may result in increased emissions or decreased immunity of the other equipment in relation to EMC performance.

Emission test	Compliance	Electromagnetic environment - guidance		
RF emissions CISPR 11	Group 1	The SAM 35/36 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.		
		If the SAM 35/36 is used with cables / accessories other than those supplied, this may result in increased emissions or decreased immunity of the SAM 35/36 in relation to EMC performance.		
		The SAM 35/36 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use with other equipment is necessary, the SAM 35/36 and the other equipment should be observed/monitored, to verify normal operation in the configuration in which it will be used.		
RF emissions CISPR 11	Class B	The SAM 35/36 is suitable for use in all establishments, included domestic establishments and those directly connected to the propose low-voltage power supply network that supplies buildings used domestic purposes.		
Harmonic emissions IEC61000-3-2	Class A	If the SAM <i>35/36</i> is used with cables / accessories other than those supplied, this may result in increased emissions or decreased		
Voltage fluctuations / flicker emissions IEC61000-3-3	Complies	immunity of the SAM <i>35/36</i> in relation to EMC performance. The SAM <i>35/36</i> should not be used adjacent to or stacked with other equipment. If adjacent or stacked use with other equipment is necessary, the SAM <i>35/36</i> and the other equipment should be observed/monitored, to verify normal operation in the configuration in which it will be used.		

Guidance and manufacturer's declaration – electromagnetic immunity

The purpose of this testing is to ensure the SAM *35/36* is not likely to adversely affect the normal operation of other such equipment and that other such equipment is not likely to adversely affect the normal operation of the **SAM** *35/36*.

SAIN 33/30.						
Immunity test IEC 60601 tes		Compliance level	Electromagnetic environment - guidance			
Electrostatic discharge (ESD) IEC60601-1-2:2014 IEC61000-4-2:2008	±2Kv, ±4kV, ±6kV and ±15kV air discharge ±6kV contact discharge	±2Kv, ±4kV, ±6kV and ±15kV air discharge ±6kV contact discharge	The SAM 35/36 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use with other equipment is necessary, the SAM 35/36 and the other equipment should be observed/monitored, to verify normal operation in the configuration in which it will be used.			
Electrical fast transient / burst IEC60601-1-2:2014 IEC61000-4-4:2012	± 2 kV for power supply lines ± 2 kV for power supply lines Input / output line tests not ± 2 kV for power supply lines Mains power quality sho commercial or hospital expressions.		Mains power quality should be that of a typical commercial or hospital environment.			
Surge IEC60601-1-2:2014 IEC61000-4-5:2005	output lines Test level 1 ±0.5kV, ±1.0kV Test level 2	applicable. Test level 1 ±0.5kV, ±1.0kV Test level 2	Mains power quality should be that of a typical commercial or hospital environment.			
Voltage dips, short interruptions and voltage variations on power supply input lines	±2 kV Test level 1 Reduction of the supply voltage of 100% for a half and 1 periods	±2 kV Test level 1 Reduction of the supply voltage of 100% for a	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SAM 35/36 requires continued operation during power mains interruptions, it is			

Manual 118 Issue 15 Page 23 of 28

rest level 2 Reduction of the upply voltage of 0% for 25 eriods rest level 3	periods Test level 2 Reduction of the supply voltage of 70% for 25 periods	recommended that the SAM 35/36 be powered from an uninterruptible power supply or a battery.
Reduction of the upply voltage of 00% for 250 eriods	Test level 3 Reduction of the supply voltage of 100% for 250 periods	
0 A /m	30 A/m	The SAM 35/36 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use with other equipment is necessary, the SAM 35/36 and the other equipment should be observed/monitored, to verify normal operation in the configuration in which it will be used.
		If incorrect operation occurs, it may be necessary to position the SAM 35/36 further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
Reu O e	eduction of the pply voltage of 1% for 25 eriods est level 3 eduction of the pply voltage of 10% for 250 eriods	eduction of the pply voltage of 1% for 25 rest level 3 reduction of the supply voltage of 70% for 25 reduction of the pply voltage of 10% for 250 reduction of the supply voltage of 100% for 250 reduction of the supply voltage of 100% for 250 reduction of the supply voltage of 100% for 250 reduction of the supply voltage of 100% for 250 reduction of the supply voltage of 100% for 250 reduction of the supply voltage of 100% for 250 reduction of the supply voltage of 100% for 250 reduction of the supply voltage of 100% for 250 reduction of the supply voltage of 100% for 250 reduction of the supply voltage of 100% for 250 reduction of the supply voltage of 100% for 250 reduction of the supply voltage of 100% for 250 reduction of the supply voltage of 100% for 250 reduction of the supply voltage of 100% for 250 reduction of the supply voltage of 100% for 250 reduction of the supply voltage of 100% for 250 reduction of the supply voltage of 100% for 250 reduction of the supply voltage of 100% for 250

Guidance and manufacturer's declaration – electromagnetic immunity

Guidance and mandiacturer's declaration – electromagnetic infiniting					
The SAM 35/36 is intended for use in the electromagnetic environment specified below. The customer or the					
user of the SAM 35/36 should assure that it is used in such an environment.					
Immunity to RF test	Electromagnetic environment - guidance				
Basic standard IEC60601-1-2:2014 (table 9) Test setup	If the SAM <i>35/36</i> is used with cables / accessories other than those supplied, this may result in increased emissions or decreased immunity of the SAM <i>35/36</i> in relation to EMC performance.				
IEC61000-4-3:2006; Amd, 1:2007 and Amd, 2:2010	The SAM 35/36 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use with other equipment is necessary, the SAM 35/36 and the other equipment should be observed/monitored, to verify normal operation in the configuration in which it will be used.				
	Despite the testing of the SAM 35/36 that has been undertaken, normal operation of the SAM 35/36 can be affected by other electrical/electronic equipment and portable and mobile RF communications equipment.				
	Interference may occur in the vicinity of equipment marked with the following symbol:				

Manual 118 Issue 15 Page 24 of 28

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- ^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **SAM** 35/36 is used exceeds the applicable RF compliance level above, the **SAM** 35/36 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the **SAM** 35/36.
- ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between Portable and mobile RF communications equipment and the SAM 35/36

The **SAM** 35/36 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **SAM** 35/36 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **SAM** 35/36 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output	Separation distance according to frequency of transmitter m			
power of transmitter W	150 KHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz	
	d = 1.2√√P	$d = 1.2\sqrt{\sqrt{P}}$	d = 2.3√√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	23.3	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures objects and people.

Manual 118 Issue 15 Page 25 of 28

7. NOTES

Manual 118 Issue 15 Page 26 of 28

Manual 118 Issue 15 Page 27 of 28

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 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.

© Copyright M.G. Electric (Colchester) Limited

All Rights Reserved.

Reproduction, adaptation, or translation without prior written permission is prohibited, except as allowed under the copyright laws.

Manual 118 Issue 15 September 2019

Manual 118 Issue 15 Page 28 of 28