INSTRUCTIONS MANUAL

MAK 300 - MAK 500
MAK 300 Antibacteria - MAK 500 Antibacteria
COLLECTING JARS FOR SMALL VOLUMES

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⚠ CAUTION
THIS DOCUMENT IS INTENDED FOR THE INSTALLER AND THE SERVICE ENGINEER. IT IS INTEGRATED WITH THE INSTRUCTIONS CONTAINED IN THE INSTRUCTIONS FOR USE IU 014 THAT MUST ACCOMPANY THE EQUIPMENT THROUGH TO THE FINAL USER.

Contents

⚠ Important

CAUTION: INDICATION OF DANGER

Attention: Important indication

General information

- **THE INFORMATION IN THIS DOCUMENT MUST BE READ CAREFULLY BEFORE USING THE MAK SERIES LIQUID COLLECTING JARS FOR SMALL VOLUMES.**
- **AFTER UNPACKING AND CONNECTION, CHECK THE DEVICE IS INTACT AND CARRY OUT THE FUNCTIONAL TEST AS DESCRIBED IN THE CHAPTERS "INSTALLATION" AND "START-UP PROCEDURE".**
- **EACH TIME BEFORE USING THE DEVICE CARRY OUT THE OPERATIONS DESCRIBED IN THE CHAPTER "START-UP PROCEDURE".**
- **INSTALLATIONS THAT ARE NOT ENVISAGED BY THIS MANUAL MAY REDUCE THE SAFETY LEVEL OF THE APPLIANCE.**
- **The company will not accept any responsibility if the instructions in this manual are not observed, if original spare parts and/or authorized technicians are not used.**
- **The device and its components or accessories do not include parts in natural rubber latex.**

Connections

- **MAKE THE CONNECTIONS AND CHECK THE SEALS BETWEEN THE COMPONENTS AS DESCRIBED IN "INSTRUCTIONS FOR USE" SECTION. FAILURE TO MAKE THESE CONTROLS MAY COMPROMISE THE SAFETY AND FUNCTIONING OF THE DEVICE.**
- **ANY SUCTION ADJUSTMENT DEVICES CONNECTED AND THE CONNECTION HOSES MUST COMPLY WITH EN ISO 10079-3 STANDARDS.**
- **INADVERTENT INVERSION OF THE CONNECTIONS COULD LEAD TO CONTAMINATION OF THE OPERATOR AND/OR OF THE VACUUM GENERATING SYSTEM.**

Operation

- **THE MAK SERIES COLLECTING JARS FOR SMALL VOLUMES MUST ALWAYS BE USED WITH CARE AND ONLY BY PERSONNEL WHO ARE AWARE OF THE CONSEQUENCES OF THE ONGOING THERAPY.**
- **FULL CONTAINERS MUST BE HANDLED WITH GREAT CARE DURING TRANSFER TO THE DISPOSAL AREAS, FOLLOWING THE LOCAL PROCEDURES AND REGULATIONS.**

Service

- **All the modifications and repairs must only be performed by personnel authorized by FLOW METER S.p.A., or by hospital technicians approved by the same company.**
- **Original spare parts must always be used for the maintenance operations.**
- **Check the MAK collection containers every three years in accordance with the chapter "Periodic controls".**
- **For periodical updating reasons, the device configuration can be subjected to changes. Therefore, FLOW METER guarantees spare parts to be available for at least 5 years from the manufacturing date.**
- **Any modifications to the device must be approved by FLOW METER S.p.A., and carried out in accordance with the procedures prescribed.**

The device has been designed and manufactured to satisfy the safety requirements of the following standards:
- EN ISO 10079-3

Your local dealer and service center

Your local dealer and service centre for FLOW METER S.p.A. products is:

Sponsor:
ICU Medical Australia Pty Ltd
Unit U, 10 – 16 South St, Rydalmere
NSW 2116, Australia
Tel: +61 2 9466 5300
www.clements.net.au

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The equipment described in this publication is designed and manufactured by:

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Applications

The MAK/300 and MAK/500 series of collecting jars for small volumes of suctioned liquids are used to collect suctioned organic fluids and have been designed and constructed for "High flow and high vacuum" applications (classification reference EN ISO 10079-3: Medical suction equipment - Part 3: Suction equipment powered from a vacuum or positive pressure gas source point 8.1). The range consists of models with standard capacities of 300 ml. and 500 ml. or with a lid designed for the fitting of an antibacterial filter (Antibacteria). These devices are generally used, apart from containing small volumes of liquids collected by suction, as security containers to protect equipment upstream, if the overflow valve in the main container is not functioning correctly. Made with a polycarbonate structure and couplings in chrome-plated brass, the MAK series collection containers can be sterilized in in a steam autoclave (recommended cycle: 121 °C - 15 min) thus guaranteeing that, together with the EASYVAC – EASYVAC Plus series vacuum regulators, or the AV – EASYAIR® series of Venturi vacuum regulators, they are simple to use, versatile and extremely economical to run. The jars have also a mechanical overflow valve with float, threaded or hose connector to the suction supply and hose connector to the patient. The extremely rational and essential design, together with the sophisticated technical execution, makes it possible to work under the maximum safety conditions for both the operators and the patients.

MAK COLLECTING JARS FOR SMALL VOLUMES

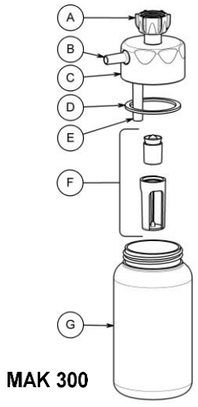
MAK 300

MAK 500
Antibacteria

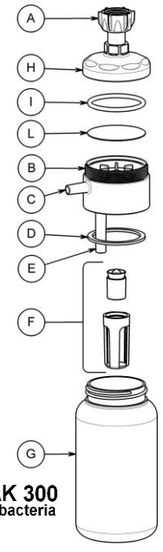
Controls and connections

LEGEND

A – Suction supply connector
B – Patient port
C – Lid
D – Container sealing gasket
E – Dip tube for antifoaming agents
F – Overflow valve
G – Vessel
H – Antibacterial upper lid
I – Sealing gasket for antibacterial filter
L – Antibacterial filter



MAK 300



MAK 300
Antibacteria

Working principle

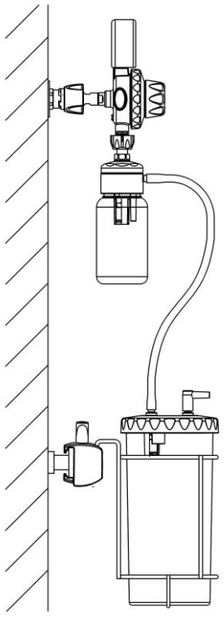
MAK 500
Antibacteria

⚠ CAUTION

THE MAK SERIES COLLECTING JARS FOR SMALL VOLUMES CAN WORK CORRECTLY WHEN SUPPLIED WITH A MAXIMUM DEPRESSION OF -95 kPa. THE DEVICE OFFERS MAXIMUM EFFICIENCY BELOW THIS DEPRESSION RANGE.

After connecting the "patient port (B)" to the suction hose and "the suction supply connector (A)" to the vacuum regulator, the MAK series container can be used for the safe and aseptic collection of organic fluids.
The jar has an overflow valve with float, that can be disable the vacuum system if the maximum filling level is reached.
The "Antibacteria" version can also be used to house an antibacterial filter to protect the vacuum supply system against any contamination by particulate.

Installation



Check the functioning of the unit every day or in accordance with the hospital routine. A description is given below of some of the most commonly used methods for connecting the collecting jar for small volumes MAK.

- Screw the lid, with connections, to the jar (G), making sure that the lid is closed home firmly.
- For Antibacteria version: open the upper transparent lid (H) and position the antibacterial filter (L) in its housing, positioning it as described in the instructions supplied by the manufacturer; then place the sealing gasket (I) over the filter and screw down the upper lid tightly (H), checking that it is positioned correctly.
- Connect the vacuum supply connector to the vacuum regulator, making sure that the system is vertical and firmly secured. In the version with a double hose connection, position the device in its support (e.g. a wall basket) and connect the vacuum supply connector to the vacuum regulator, fitted with a hose connection, using an appropriate hose with suitable dimensions.
- ⚠ **CONNECT THE SUITABLE PATIENT TUBE OF APPROPRIATE DIMENSIONS AND, IF NECESSARY, FITTED WITH A CANNULA, TO THE CONNECTOR TO PATIENT (B) OF THE LID (C).**
- If the MAK container is used as a security system to protect the upstream equipment, it is necessary to connect a jar for suction liquid to the Patient port, using a suitable hose of the correct dimensions (see diagram alongside).
- Before use, check that there are no leaks by turning ON the suction and blocking the connector to Patient. There are no leaks in the system if the set vacuum level has been reached: check this on the control vacuum gauge of the regulator.

Start-up procedure

To start-up the MAK series suction jar for small volumes, proceed as follows:

- Make sure that the overflow valve float moves freely in its container;
- After connecting the MAK collection container for small volumes to the regulator, connect the vacuum source of the unit to the quick coupling of the centralized hospital distribution system;
- Set the necessary suction level with a vacuum regulation device and check it on the control vacuum gauge.

The system is then ready for use.

- ⚠ **DO NOT USE A SOURCE OF VACUUM OF LESS THAN -95 kPa (-722 mm Hg) WITH THIS JAR.**
- Turn ON the suction and check regularly the level inside the jar. The overflow valve shuts down suction when the level reached exceeds the maximum level established for the device.

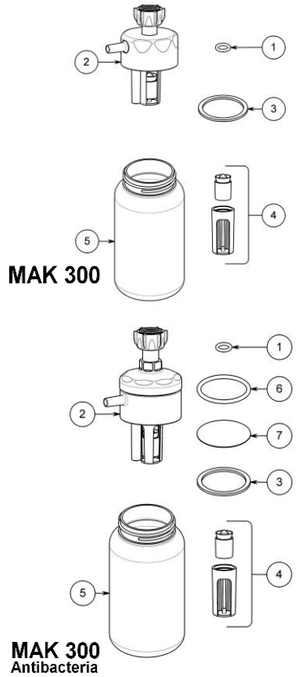
After using the device, it is essential to proceed as follows:

- ⚠ **WHEN THE OVERFLOW VALVE INTERVENES, IT IS NECESSARY TO DISCONNECT THE VACUUM WITHIN A MAXIMUM OF 5 MIN.**
- Disconnect the vacuum supply from the hospital system supply quick coupling or acting on the I-0 switch of the suction regulation device.
- The collection container must now be removed by first disconnecting the hose for connection to the collection vessel and then disconnecting it from the suction regulation unit.
- Proceed for disposal as described in the instructions given beside.

⚠ **CAUTION**

- **BEFORE USING, MAKE SURE THAT THE SUCTION JAR IS SECURELY FIXED AND IN A VERTICAL POSITION (THIS IS FUNDAMENTAL FOR THE CORRECT FUNCTIONING OF THE OVERFLOW VALVE).**
- **FOR THE ANTIBACTERIA VERSION: TO ENSURE ADEQUATE PROTECTION OF THE VACUUM REGULATION SYSTEM AND OF THE SYSTEM UPSTREAM, AN ANTIBACTERIAL FILTER WITH SUITABLE SPECIFICATIONS (Ø 50 – MAXIMUM POROSITY 1.7µm) MUST HAVE BEEN POSITIONED IN THE SPECIFIC HOUSING PROVIDED IN THE LID.**
- **THE LIQUIDS COLLECTED MUST ONLY BE DRAINED OUT IN AREAS ASSIGNED TO THE DISPOSAL OF HOSPITAL WASTE AND/OR STRICTLY FOLLOWING THE INSTRUCTIONS OF THE AUTHORITIES FOR THE TREATMENT OF THESE PRODUCTS.**
- **BEFORE USING THE SUCTION JAR AGAIN, IT MUST BE CLEANED AND DISINFECTED AS DESCRIBED IN THE CHAPTER "CLEANING AND DISINFECTION".**
- **TAKE PARTICULAR CARE NOT TO SPILL LIQUIDS FROM THE HOSE COUPLING FOR CONNECTION TO THE PATIENT WHILE TRANSPORTING THE MAK CONTAINER TO THE DISPOSAL AREA.**

Maintenance



Maintenance operations

The MAK series collecting jars for small volumes are designed and manufactured using materials that ensure a long working period without requiring maintenance.
However, when the periodic controls made by the user indicate the need for repairs (e.g. replacement of components), this must be done by FLOW METER authorized technicians and according with following instructions.
Whatever the circumstances, to ensure a prolonged efficiency of the system described in this publication it is necessary to:

- Clean the unit regularly and accurately as described in the chapter "Cleaning and disinfection".
- Replace any damaged or faulty parts always using original spare parts (see codes shown in the following table).
- ⚠ **BEFORE USING THE DEVICE AGAIN, MAKE SURE THAT THE DEVICE IS APPROPRIATELY ASSEMBLED, FOLLOWING THE DIAGRAM AT SIDE. FAILURE OF ANY COMPONENTS MAY COMPROMISE THE PRODUCT SAFETY.**

Pos.	Article	MAK 300	MAK 500	MAK 300 Antibacteria	MAK 500 Antibacteria
1	Supply connector gasket	900010021	900010021	900010021	900010021
2	Lid	000161011	000161011	000161012	000161012
3	Lower sealing gasket for container	900080011	900080011	900080011	900080011
4	Overflow valve	000000613	000000613	000000613	000000613
5	Jar	970010031	970010032	970010031	970010032
6	Sealing gasket for antibacterial filter			900010031	900010031
7	Antibacterial filter			000000009	000000009

Cleaning and disinfection

Before using the suction jar again, it must be cleaned and sterilized according with following instructions.

- Separate the basic components of the jar: the container (G), the seal (D), the lid (C) (H) with the connections and overflow valve (F).
- Carefully clean all the surfaces of the device using hot water at temperature not exceeding 60 °C.
- Carefully dry the components using a soft damp cotton cloth.
- Place the parts in an autoclave and run a sterilization cycle with a steam temperature of 121 °C for a maximum of 15 minutes (relative pressure 1 bar), placing the container upside-down (with container bottom-up).
- After sterilization and cooling the components to ambient temperature, check that they are not damaged; then reassemble the MAK suction jar carrying out the dismantling operations in reverse.
- The device is now ready to be used again.

⚠ **CAUTION**

SOLVENTS, DISINFECTANTS OR ABRASIVE PRODUCTS MUST NOT BE USED FOR CLEANING: THESE CAN CAUSE IRREPARABLE DAMAGE TO THE PLASTIC COMPONENTS IN THE DEVICE.

- **DO NOT IMMERSE THE UNIT IN DISINFECTANT;**
- **DO NOT USE INFLAMMABLE PRODUCTS.**

DO NOT PLACE WEIGHTS ON THE PARTS DURING THE STERILISATION IN THE AUTOCLAVE.

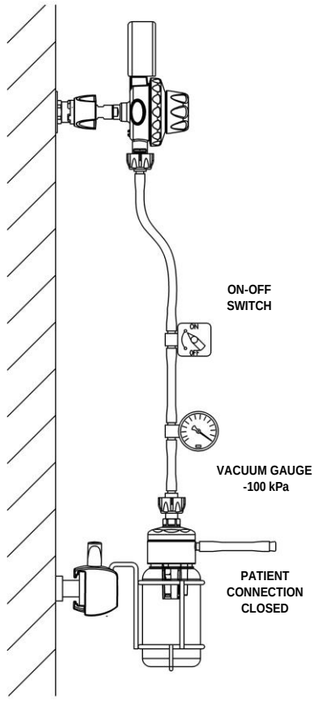
POLYCARBONATE, THE MATERIAL FROM WHICH THE PLASTIC PARTS OF THE MAK SUCTION JAR ARE PRODUCED, OFFERS A GOOD SEAL AGAINST MOISTURE AND WATER BUT DESPITE THIS, PROLONGED IMMERSION IN HOT WATER AT TEMPERATURES OF MORE THAN 60 °C CAN LEAD TO A PROGRESSIVE CHEMICAL DECOMPOSITION THAT RESULTS IN A MINOR RESISTANCE OF THE COMPONENTS TO KNOCKS.

QUALIFIED HOSPITAL PERSONNEL MUST CARRY OUT THE NECESSARY CLEANING AND DISINFECTING OPERATIONS.

THE MECHANICAL RESISTANCE OF THE PRODUCT IS GUARANTEED UP TO 30 CLEANING AND STERILISATION CYCLES UNDER THE SPECIFIED CONDITIONS. BEYOND THIS LIMIT, THERE MAY BE A DEGRADATION IN THE PHYSICAL-MECHANICAL CHARACTERISTICS OF THE PLASTIC MATERIALS AND THEREFORE IT IS ADVISABLE TO REPLACE THE FOLLOWING COMPONENTS:

- **CONTAINER;**
- **LID;**
- **OVERFLOW VALVE.**

Periodic controls



Check the device at least every three years or in accordance with hospital procedures to guarantee adequate operation and perfect efficiency of the collection container for small volumes of aspirated liquids MAK.

1. Functioning control

Check functioning following the instructions in the chapter "Start-up procedure".

2. Hermetic control

- Assembly the device according with instructions described in "Installation" chapter.
- Connect the jar following the diagram shown at side (ISO 10079-3).
- Bring the pressure inside the device at a value of -40 kPa, close the ON-OFF switch and check with the controlling vacuum gauge the pressure increase within 10 seconds. The maximum acceptable leak, in kPa, corresponds to 3,33/Volume of container, in L, in a time of 10 seconds (e.g.: for a MAK 500 container, the maximum acceptable leak is 3.33/0.5=6.66 kPa in 10 s).

3. Overflow valve control

- Assembly the device according with instructions described in "Installation" chapter.
- Connect the jar following the diagram shown at side (ISO 10079-3) but opening PATIENT connection.
- Bring the pressure inside the device at a value of -40 kPa and suck distillated water at environmental temperature until overflow device intervenes. At this mark the reached water level.
- Continue the suction for further 2 minutes and check if the reached level still stands. If there is a leak in float seal, the level increases. In this case, it is necessary to replace the overflow valve (pos. 4 of diagram of page 9) and to perform the test again.

Technical features

Sales description	MAK COLLECTING JARS FOR SMALL VOLUMES
Dimensions	Height: 180 mm (MAK 300) 215 mm (MAK 500) 210 mm (MAK 300 Antibacteria) 245 mm (MAK 500 Antibacteria) Width: 98 mm Depth: 70 mm
Weight	Kg. 0.20 (MAK 300) Kg. 0.24 (MAK 500) Kg. 0.21 (MAK 300 Antibacteria) Kg. 0.25 (MAK 500 Antibacteria)
Connector to vacuum supply	ISO G. ½" F. or Ø8.5 mm
Connector to Patient	Ø8.5 mm
Maximum applicable vacuum value	-95 kPa / 5 min.
Maximum flow value	60 L/min. ± 10 L/min. to -95 kPa (without antibacterial filter)
Dimensions of hose to vacuum supply (for double hose connector version)	Min. Ø6x9 mm (recommended Ø8x11 mm L=1.8m max)
Patient hose dimensions	Min. Ø6x9 mm (recommended Ø8x11 mm L=2.5m max)
Environmental storage conditions	-40 °C ± 2 °C / +60 °C ± 5 °C and 40%÷70% relative humidity
Environmental working conditions	-18 °C ± 2 °C / +50 °C ± 5 °C