BOSCAROL MEDICAL SUCTION UNIT

OB MINI AVIO 500
OB MINI AVIO FA
OB MINI AVIO LINER

USER MANUAL

CE 0123

MANUFACTURED BY:

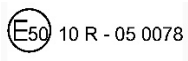
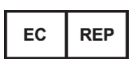
BOSCAROL®

Emergency Medical Systems

CONTENTS

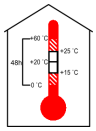
SYMBOLS

S.1 Symbols used on the suction unit and accessories, and indicated in the user manual

	Double insulation symbol. The suction unit has dual electrical insulation to protect user and work environment, providing two means of protection (there is no ground conductor or equipotential connection point).
	Type BF applied part
	Use suction unit only within indicated temperature range. Using the OB MINI AVIO outside these limits may compromise its operation, reduce battery life and cause internal safety devices to trip.
	Read the User Manual
	Suction unit accessories and/or consumables bearing this symbol are single use, disposable items. After use, they must be discarded and replaced with new ones.
	Specific warnings regarding the suction unit, which must always be taken into consideration.
	CE marking compliant with It. Leg. Decree 46/97 for medical devices rated class I or higher (European Directive MDD 93/42/EEC)
	Device homologated under the ECE-R10 International Regulation
	Manufacturer
	Date of manufacture
	The OB MINI AVIO suction unit contains electrical and/or electronic equipment that must be recycled per European Directive 2012/19/UE – Waste Electrical and Electronic Equipment (WEEE).
	Electric and magnetic fields generated by radiographic or tomographic equipment, portable radio equipment, RF radio and devices bearing this symbol could affect suction unit operation. In these cases, the suction unit should not be used or a proper distance should be kept from such equipment.
	The materials composing the suction unit can be recycled following specific procedures outlined in national laws and local regulations.
	The suction unit complies with European Directive 2011/65/EU (RoHS)
	Authorized Representative in the European Community, if the manufacturer is not resident therein.
	Expiration date
	Do not use if the packaging is not intact.
	Catalogue ID code.

STERILE EO	Sterile device. Sterilization method: ethylene oxide.
STERILE R	Sterile device. Sterilisation method: ionizing radiation.
LOT	Production batch number
SN	Serial number

S.2 Symbols used on battery and indicated in the User Manual

BATTERY	The battery is enclosed in a rigid plastic case and has a special internal electronic circuit to prevent the risk of damage. The battery cannot be opened, disassembled or repaired.
LiPo	Lithium polymer battery (solid-inorganic), 500 charge cycles
	Never short-circuit the battery and its contacts
	Do not incinerate or dispose of in a fire
	Do not cut the battery or its plastic case. Do not pierce or puncture the battery (risk of explosion, fire, or short circuit)
	Do not crush the battery or apply strong deforming pressures. Do not pierce the battery with tools, drills or other mechanisms.
	Battery storage (battery pack only): - Temperature (optimal): 0–25°C - Humidity (optimal): 60±25% RH
	Do not dispose of the battery along with household waste. Follow the national and local regulations for proper disposal.
	Read the User Manual
	Battery expiration date

S.3 Symbols used in the User Manual to draw the reader's attention

	Important safety information on proper use of the unit to prevent injuring operator or patient and/or damaging the suction unit
	Warning: information requiring special attention
	Notes or information on correct use of the unit

WARNINGS, PRECAUTIONS AND IMPORTANT INFORMATION

Read carefully

This User Manual has been prepared using simple, easy-to-understand language. If you have difficulty interpreting the above, contact the manufacturer for further clarification.

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- Read all instructions carefully before using the unit. Careful, proper use will ensure smooth operation and protect both patients and operators alike.
- The unit is designed exclusively to remove non-flammable organic fluids (secretions) during medical procedures. For this reason, it should only be used by duly trained personnel.
- Never use the suction unit in the presence of flammable and/or explosive liquids, gases and mixtures as this could lead to explosion and/or fire.
- Using the suction unit under environmental conditions other than those indicated herein can seriously compromise function and modify its technical parameters (e.g. the maximum suction value or battery life).
- If suction is performed without the collection jar and/or filter in place, or if you suspect that substances may have entered the suction circuit (i.e. inside the OB MINI AVIO unit), immediately contact the nearest service centre or the manufacturer to have the unit serviced.
- Before cleaning the unit or proceeding with any maintenance, unplug the unit from the external power supply. Do not submerge in liquids as this could damage the suction unit and cause the safety devices to cut in.
- The unit does not require any maintenance on the operator's part. The only operations authorized are those listed herein. For technical support, periodic overhaul and any repairs that may be needed, contact your authorized service centre.
- The manufacturer provides authorized personnel — who have taken a specific technical assistance training course — with the documentation necessary to carry out the work (service manual).
- To ensure patient safety, precision of the displayed values and proper unit function, use only original spare parts. By failing to comply with this warning, the operator assumes responsibility for any patient injury or property damage.
- Do not use any batteries except those approved by the manufacturer. The battery is contained in a protective plastic casing that cannot, and must not, be removed.
- The battery cannot be replaced by the operator. Contact an authorized service centre.
- The OB MINI AVIO suction unit does not perform any clinical diagnostics on the patient.
- The OB MINI AVIO suction unit must be used with its carrying/storage bag.

LiPo BATTERY

- Before using the suction unit for the first time (and/or upon receiving it), charge the internal battery for at least 16 consecutive hours.
- The suction unit is equipped with a special test feature that shows the remaining battery charge.
- Recharge the suction unit immediately if only 1 or fewer LEDs light up.
- Remaining plugged into the vehicle power supply (11÷25 Vdc) does not damage the suction unit.
- The internal battery cannot be replaced by the operator. Contact Oscar Boscarol srl for a list of authorized service centres.

WARNING ON REUSE OF DISPOSABLE PARTS

- Reuse of disposable parts may compromise the suction unit function and be direct or indirect source of operator and patient contamination.
- Sterilization and/or cleaning of disposable parts (antibacterial filters, suction tubes, Yankauer suction catheters, etc.) can cause structural damage leading to the risks of lost mechanical integrity.

IMPORTANT INFORMATION ON THE OB MINI AVIO SUCTION UNIT

The suction unit was designed and tested according to the latest regulatory standards. If the suction unit is hooked up to a non-compliant electrical system and/or if the work is not performed by professional installer, both the suction unit and the electrical system could be damaged. Always consult a qualified technician with knowledge of the latest requirements!

Preventive maintenance and safety inspection:

The suction unit must be checked at least once a day (function check). It has a special feature that notifies the operator when maintenance/safety inspection is required, at least once every 24 months. If the suction unit is subject to intensive use, the circuit automatically reduces this time interval, adapting it to real need. An indicator light on the front warns you when this is needed. Even if no indication is present, the suction unit must be checked by the service centre or manufacturer 24 months after the date of manufacture (see label).

Contamination:

Sending a contaminated suction unit to the manufacturer, installer or service centre is strictly forbidden. Any device received in such condition will be rejected and health authorities notified of possible contamination. Here the term contaminated means a suction unit that has not been cleaned of the secretions aspirated from the patient. If the substances aspirated have entered the suction unit, it must be discarded. For Oscar Boscarol srl, the safety of its employees and authorized service centre staff is important. The suction units will not be demolished according to the WEEE Directive (Waste Electrical and Electronic Equipment) if the suction unit is contaminated and there is the risk of infection (application of It. Legislative Decree 81).

Operator responsibilities

- The OB MINI AVIO suction unit is designed for emergency health services and must therefore be ready for use at any time and in any situation. The suction unit is portable and cannot be wall mounted or secured with specific restraint systems. Given that it is light weight, it can be stored in bags, backpacks and specific first aid kits.
- Always make certain that the internal battery is sufficiently charged (press the test button).
- Immediately replace any components/parts that are damaged, altered or missing, and/or for which a unit malfunction is suspected. Always replace such parts with original spares. The suction unit should be stored in a place inaccessible to children.
- Dispose of packaging in accordance with current regulations and make certain that it is out of the reach of children.
- Read these instructions carefully before using the suction unit. Careful, proper use will ensure smooth operation and protect both patients and operators alike.
- Operate the suction unit only in compliance with the technical specifications laid out by the manufacturer in this manual.

Intended Use

- The suction unit can be used on all types of patients following the correct medical technique.
- The suction unit is designed to clear the upper airways. Clearing the lower respiratory tract is to be performed by medical and/or health care professionals trained and authorized to perform this function.
- In some countries, this information must be verified according to the protocols implemented by the local emergency medical services.

OB MINI AVIO MEDICAL SUCTION UNIT

INSPECT THE SUCTION UNIT AND ALL OF ITS PARTS BEFORE USING.

DO NOT USE THE DEVICE IF IT HAS DAMAGED OR MISSING PARTS

The OB MINI AVIO is a medical secretion suction device that complies with all envisaged reference standards. It can be used in motor vehicles, in the field, in hospitals, clinics and for home treatment. The suction unit has an internal battery which does not contain any dangerous substances; it is an inorganic, solid battery with an internal circuit to protect against short circuiting or other failures that could make the unit dangerous. The battery has undergone IATA tests (UN/DOT-38.3) for aircraft and helicopter transport.

Model BSU370 (EU):

1. Suction unit
2. Autoclavable 500 ml collection jar
3. Antibacterial filter
4. Conical connector
5. Charging cable

Model BSU374 (EU):

1. Suction unit
2. Autoclavable OB-J FA collection jar
3. Antibacterial filter
4. Yellow elbow connector
5. Red elbow connector
6. Power supply EU
7. Charging cable

Model BSU378 (EU):

1. Suction unit
2. Autoclavable OB-J collection jar
3. Elbow connector for OB-J jar
4. Disposbale bag SERRES
5. Red elbow connector
6. Power supply EU
7. Charging cable

For accessories and options available, see the catalogue at www.boscarol.it or send an email to info@boscarol.it.

Description and intended use

The OB MINI AVIO is a portable electrical medical suction device designed to remove fluids and substances obstructing the upper airways and restore spontaneous and/or assisted respiration. High vacuum is normally used for oropharyngeal tract suction while low vacuum values are used for tracheal suction and/or applications in children and infants. The device can be used in emergency health services, first aid, home care and in hospitals and/or mobile medical units. The device comes with a carrying/storage bag. The unit is designed to meet the classification for “HIGH VACUUM – HIGH FLOW” medical suction equipment (see ISO10079-1).

Contraindications for use

Do not use the OB MINI AVIO for thorax drainage.

Controls, operations and control panel

All controls are on the front of the suction unit. To activate the device, press the switch (3), which is protected against infiltration of moisture, splashing of water and other cleansers. Vacuum can be adjusted by turning the knob (2) located beside the switch. Turning the control knob clockwise increases the vacuum. The vacuum produced by the internal pump can be read on the analogue vacuum gauge (1) and is expressed in millibars (mbar) and kilo-pascals (kPa) or millimetres of mercury (mmHg). The vacuum gauge is fluorescent and can be seen in the dark. Above the LEDs displaying battery charge (5) a socket is arranged to plug the unit into the mains or 11÷25 Vdc power supply (4). The charging socket is air-tight and fit with two electric poles.

Fig.1

1. Fluorescent analogue vacuum gauge with dual scale
2. Vacuum regulation knob
3. On/off switch
4. Suction unit charging socket (11 to 25 Vdc)
5. Charge indicator panel and charge TEST button

Indicator lights

The front of the unit holds the lights (LEDs) and battery charge test button (see figure to the side). The indicator lights perform different functions including indicating: battery charge (4 green LEDs indicate battery full), charging in progress and charging completed (the two-tone LED marked with the triangle containing an exclamation mark). In addition, there is a "TEST" button that can be activated when the power is off and the unit is disconnected from the external supply (with adapter or vehicle 12 Vdc power supply). Pressing the test button activates the LED display for about 20 seconds. While charging — which starts automatically when the unit is plugged into an external power supply or to the mains with the adapter — the LED below the triangle starts flashing yellow and continues flashing until charging has been completed. Once battery charging is complete, the yellow LED remains on steady, indicating that the battery is fully charged. This LED remains on until the suction unit is disconnected from the external power supply (confirming not only that the battery is charged but that the unit is powered by an external 11÷25 Vdc power supply). Under such conditions, LED status cannot be viewed, not even by pressing the TEST button or starting up the suction unit, because the unit is not being powered by the internal battery.
If the test button is pressed during charging or when charging has been completed, the LEDs display the current battery charge. The table below summarizes the battery charge according to the number of green LEDs that are on.

LEDS STATUS	BATTERY POWER LEVEL
4 LEDS on	>80% – maximum power
3 LEDS on	50-79% – medium power
2 LEDS on	20-49% – low power
1 LED on	**<20% Battery low – the suction unit will shut down soon**

The suction unit will cut out within two minutes of the moment the last green LED starts flashing because the battery is completely discharged.
Always check that the plug is inserted correctly into the cigarette lighter: vehicle vibration could cause it to come out. To ensure this, check the yellow LED: it should be on, both during charging and once charging has been completed!
To view the battery charge, press the TEST button: to do so, the suction unit must be disconnected from the adapter or charging cable. A steady yellow light indicates that the battery is fully charged (maximum battery life).

WARNING!

A low battery compromises suction unit function, and thus its use. The TEST button has been inserted precisely to provide indication of battery status and ensure that it can be charged when necessary. It takes approximately 10 hours to fully charge the battery. The suction unit can be left steadily plugged into the charge. The battery has a 2-year life and is automatically replaced during the safety inspection. The battery cannot be replaced by the user (contact your authorized service centre).

Periodic unit testing

To ensure correct suction unit operation, two types of periodic tests are provided: the first should be performed daily to ensure that the suction unit is in good working order, there are no anomalies and/or casing breakage and that the unit is functioning properly; the second is a semi-annual/annual check of full suction unit functionality and therefore its compliance. These times should be decreased in the case of intensive use, or when the unit is used under harsh conditions, outside the recommended limits.

DAILY TEST

This test lets you quickly check whether the suction unit is fit for use in the field; it involves functional tests that take no more than 5 minutes.

- Set the unit on a stable surface in the upright position so the front is facing you. Do not withdraw the unit from its carrying/storage bag.
- Press the test button located near the battery charge LEDs. If all 4 green LEDs are on, the battery is full (running time: approximately 70 minutes). If not, remember to charge the unit.
- Turn on the unit with the switch on the front panel (0 = off, 1 = on). The suction unit should run smoothly and you should not note any fluctuation in the external pump rpm. You should not hear any unusual noise and/or sharp vibrations.
- Completely close the vacuum regulator (turning it clockwise) and, with your finger, plug the transparent silicone tubing running from the filter or disposable bag to the container. The sound of the pump should change and the reading on the vacuum gauge should reach maximum value (about 800 mbar, 80 kPa, 600 mmHg) in a few seconds.
- While keeping your finger over the silicone tubing, turn the vacuum regulator counter-clockwise and check the reading on the instrument to ensure that suction drops to nearly 0 (40-50 mbar).
- Turn off the suction unit and turn it 180° to check the dataplate on the back and the condition of the carrying/storage bag.
- Plug the external power supply cable into the cigarette lighter or optional adapter and check that the charging process starts (yellow LED flashing).
- Check that the filter is clean and is not contaminated. If the filter is not white, it must be replaced. A dirty filter prevents the suction unit from functioning properly and decreases performance.

When testing has been completed, compare the results of this test with the values in the table below:

Test phase	Result	Recommended action in case of test failure
Start battery life test	The green LEDs go on according to the battery charge (1 to four LEDs).	If the LEDs do not go on, the battery is fully discharged or faulty. Try charging the battery with the external cable or adapter. During these operations, bypass active suction unit operation

Check pump operation	Noise emitted by the motor is smooth, rpm does not drop and there are no abnormal vibrations	Uneven noise means that the pump is not operating normally. A drop in rpm indicates that the current is inadequate and the motor cannot run properly. Contact an authorized service centre or the manufacturer
Check maximum suction by plugging the tubing running from the filter or disposable liner to suction unit with your finger	The maximum vacuum reading on the vacuum gauge should be around 800 mbar (± 10%).	If this value is not reached, close the vacuum regulator all the way by turning the knob counter-clockwise. Make certain that your finger completely closes the tubing. If not, do not use the suction unit and contact an authorized service centre
Maximum vacuum adjustment	Value from around 0 to maximum by turning the knob	If you cannot adjust the vacuum value, contact an authorized service centre. Do not use the suction unit in the field

If any of the tests are not passed, even after taking the steps outlined above, send the suction unit to an authorised service centre or consult the manufacturer.

SEMI-ANNUAL/ANNUAL TEST

This test carefully checks whether the suction unit is fully compliant with the original design characteristics and therefore suitable for use in the field. The checks and controls should be performed by persons and/or companies specializing in this type of work. Once the checks have been performed, the company performing this service must run an electrical safety test according to IEC60601-1 and issue a test summary document.

List of tests to be performed on the suction unit

- Full suction unit function check: battery life, charging function, full function check of LEDs (from maximum to minimum while battery is discharging). Check that, during charging, the LEDs function as shown on page 10.
- Check internal pump operation by pressing the switch. Maximum vacuum value must be between a minimum of 730 mbar and 880 mbar. Use a precision vacuum gauge to measure this value. There should be no operating abnormalities such as unusual noise, fluctuations in rpm, excessive vibration of overall suction unit: while running, it must be placed on a stable surface to check that vibrations do not cause it to move.
- Check the vacuum regulator which must operate over full range — from minimum to maximum. This is done by turning it counter-clockwise. Rotation should not be hindered in any way. When the regulator is fully open, a small vacuum value is permitted (drop in vacuum due to antibacterial filter).
- Check minimum suction unit life: turn on the suction unit and let it run for at least 20 minutes. The suction unit must run using only the internal battery. If this test fails, the internal battery needs to be replaced.
- Check for cracks and fissures on the unit container. Penetration of liquids or solids can damage the unit and render it unsafe for operators (mechanical parts running).
- Check that the dataplates are present and legible.
- Do not open the suction unit for any reason whatsoever. For technical service, contact only one of the authorized service centres listed at the end of this manual.
- Check vacuum gauge function. When the suction unit is off, the needle should be on "0".
- Make certain that the carrying/storage bag and its strap are stable, intact and not torn. Slipping of the strap (in nylon) is not permitted; if this occurs, the bag must be replaced.
- Check that the collection jars are intact and that there are no cracks that could compromise suction.
- If necessary, replace the disposable bag or antibacterial filter, which are disposable components.
- Before declaring the suction unit compliant with the manufacturer's dataplate, run an electrical safety test as per IEC60601-1. Contact the manufacturer or authorized service centre for information on running this test.

Use only consumables or parts provided by the manufacturer. Do not use components that are similar or seem the same. Only the manufacturer can confirm component conformity.
Keep on file a document certifying that all checks were performed and, if possible, keep a photograph recording the state of the suction unit at the time of control. Always keep a copy of the report on the safety test performed with an appropriate, calibrated instrument.

If you have any doubts or concerns regarding how this test is performed, always contact the suction unit manufacturer or an authorized service centre.
For any information, call +39 0471 932893 or send an email to info@boscarol.it or raq@boscarol.it.

Special automatic functions

The OB MINI AVIO secretion suction unit has some automatic features that are controlled by an internal microprocessor. This component does not affect suction unit operation and, even if it is blocked or fails, this does not compromise the suction produced by the unit. The microprocessor serves a particular function: it notifies the operator when it is time for the suction unit safety inspection. Normally, such inspection is required after 24 months of operation, however, the operator must check the product expiration date on the label. Not only does the suction unit's internal processor provide this information, it also saves the unit serial number, date of manufacture, name of the service centre that performed maintenance and date on which the work was performed. The operator cannot perform any programming operations.

Periodic safety maintenance

Depending on how the suction unit is used, the internal microprocessor uses flashing of the third LED (3 consecutive flashes alternated with a 5-second pause) to indicate that the unit needs to be taken to the authorized service centre for the scheduled maintenance. If the suction unit is not used, this LED goes on 730 days after it was first started up. This time decreases if the unit is used frequently, thus ensuring that the suction unit is always functioning properly. If internal components are worn, this LED can go on, for example, after 700 days and this is absolutely normal.
The life of the suction unit is 10 years from date of manufacture.

The operator cannot access processor programming. The software is password protected and only those holding the reader software can download the data. The processor is not accessible from the outside and is of no use to the operator.

OB MINI AVIO COLLECTION JARS

The suction unit is marketed with three different jars:

1. Suction unit with 500 ml autoclavable collection jar (OB MINI AVIO 500).
2. Suction unit with 1000 ml autoclavable OB-J FA collection jar (OB MINI AVIO FA)
3. Suction unit with 1000 ml autoclavable OB-J collection jar and SERRES disposable liner (OB MINI AVIO LINER)

Autoclavable 500 ml collection jar

The 500 ml collection jar is made of polycarbonate and can resist up to a maximum of 30 autoclave sterilization cycles, after which it must be replaced. The jar is made up of the following parts:

1. Connector to the OB filter
2. Overflow valve
3. Polycarbonate jar - 500 ml
4. Outlet to patient catheter
5. Silicone cap

Fig. 2

Sterilization is possible with conventional methods and autoclaves: temperature 121° C and pressure 2 bar. The jar should be taken apart before sterilization. The jar must be replaced if it shows any deformation, breaks or cracks. The jar must always be used in the upright position to prevent activating the overflow valve. If this safety device cuts in, turn off the suction unit and disconnect the tubing.
When used in a home environment, the jar can be cleaned using a special cleanser able to guarantee medical device disinfection. The aspirated secretions must be disposed of in compliance with medical doctrine, i.e. as prescribed by the physician according to the patient's medical condition.

Autoclavable OB-J FA collection jar

Fig.3

The jar is made of specific transparent plastic. It includes canister (1), snap-on lid (2), overflow valve (3) and 90° plastic connector (4). The lid allows direct insertion of the filter.
The jar can be sterilized in a conventional steam autoclave at a maximum temperature of 121 °C and pressure of 2 bar (200kPa). The jar must be replaced if it shows any deformation, breaks or cracks.
The jar must always be used in the upright position to prevent activating the overflow valve. Should this occur, switch the suction unit off and disconnect the patient catheter.

When used in a home environment, the jar can be cleaned using a special cleanser able to guarantee medical device disinfection. The aspirated secretions must be disposed of in compliance with medical doctrine, i.e. as prescribed by the physician according to the patient's medical condition.

Anti-bacterial filter

The filter protects the suction circuit against contaminants aspirated during use. It is made of a hydrophobic material and prevents the passage of any atomized fluids and aerosols, thus preventing their uptake (complete absence of patient side suction).
In case of possible contamination, discolouration and increased resistance to suction replace the filter.

If the suction unit is used on a patient whose medical condition is not known, **always replace the filter after use**. This will prevent contamination, even serious contamination, of the operating environment, operator and patient. If, instead, the patient's medical condition is known and/or there is no danger of cross contamination, we recommend replacing the filter after each shift or when the filter turns dark.

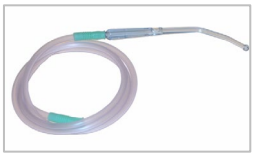
If the suction unit remains unused, it is advisable to replace the filter once a month. The material used in its construction could even be damaged by particular environmental conditions (humidity, heat, cold).
Do not use the suction unit without the protection filter or jar!

OB J collection jar with SERRES disposable liner

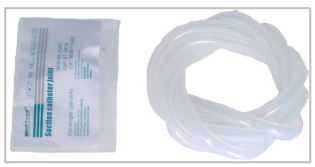
Fig. 4

The OB-J jar for SERRES disposable liners (see Fig. 4) is made of a specific transparent plastic. It includes a canister (1), adaptor for SERRES disposable liners (2), "L" connector (3) and disposable liner (4). The filter integrated into the liner prevents aspirated fluids from flowing back into the suction unit when it is completely full.
The jar can be sterilized in a conventional steam autoclave at a maximum temperature of 121 °C and pressure of 2 bar (200kPa). The disposable liner must be replaced after use on a given patient.
When used in a home environment, the jar can be cleaned using a special cleanser able to guarantee medical device disinfection. The disposable liner can never be emptied and reused. The liner containing the aspirated secretions must be disposed of in compliance with medical doctrine, i.e. as prescribed by the physician according to the patient's medical condition.

Yankauer suction catheter and end-piece with finger-tip control



The suction unit is sold complete with a sterile, Yankauer-type suction catheter and tubing for connection to the jar. The suction tip and catheter are disposable and must be changed after each use. To facilitate correct operation, the rigid suction tip is angled so it can reach all parts of the mouth and upper airways.



Upon request, the suction unit can be outfit with a silicone patient tubing (length: 130 cm) and one sterile Finger-tip joint so that sterile suction tips of varying size can be connected. The finger-tip joint allows the user to control vacuum directly with a finger, without requiring any commands. The silicone tubing can be sterilised while the finger-tip joint is, instead, disposable.
The disposable devices supplied with the medical suction unit bear labels providing all information needed for proper use.
Warning! Do not use sterile medical devices beyond their expiration date or if the package is damaged.

WARNING ON REUSE OF DISPOSABLE MEDICAL DEVICES

The suction unit comes with some sterile accessories that facilitate patient suction. Such devices are "DISPOSABLE" and therefore cannot be used on different patients.

The disposable medical devices are made to withstand limited use and cannot be reused. Therefore, once used on a patient, the operator must properly discard them and reset the suction unit with new accessories. Reuse of such devices can be dangerous for both patient and operator.

The disposable liner ***cannot and must not be emptied***. The upper cap is arranged so that secretion samples can be taken for laboratory tests. Each time the filter comes into contact with fluids (of any nature), it is blocked and must be replaced!

ACCESSORIES & OPTIONAL

The suction unit has a rechargeable internal battery (which cannot be replaced by the operator). The maximum battery charging time (depending on residual charge) is between 10 and 12 consecutive hours. A fully charged battery will provide approximately 60 minutes of continuous operation (at open flow). This time may also vary, even considerably, if the suction unit is used outside of the parameters recommended by the manufacturer (e.g. when used in the presence of very high or very low temperatures).
When properly charged, average battery life is 24 months. After this period, we recommend replacing the battery.
If the unit is not used for a long time, run a complete check and fully charge the battery every 15 days.
The suction unit can be charged using the cable (supplied) or power adapter (100–230 Vac).
The charging cable must be connected to a 12–15 Vdc power supply.
To be used while being charged, the suction unit must be connected to an external power supply (11÷25 Vdc) that can provide at least 6A.

Charging cable
BSU855

Power supply
BSU895EU – BSU895UK – BSU895JP

CAUTION

Check that the external 11÷25 Vdc power supply is protected by a fuse rated at least 15A (time-delay). Request such protection from the manufacturer if necessary.

The adapter is an exclusive accessory, available only from the manufacturer. It is approved for such function and cannot be replaced with other brands. It can only be used indoors and on a power supply compliant with the law. The medical suction unit can only be used with this adapter. The OB MINI AVIO secretion suction unit has passed compliance testing only with this type of adapter (see IEC 60601-1 and related standards).

WARNING

Never tamper with and/or open the adapter. Danger of death. The adapter contains internal electronics subject to line voltages that can be fatal.

REUSE, SCHEDULED MAINTENANCE AND DISPOSAL

After each use

After each use, unplug the suction unit, disconnect the disposable parts and discard them. Check that the suction unit is intact, check the connection tubing and check for any structural anomalies. Clean and disinfect the suction unit as described below. Replace all single-use, disposable parts with new components and recharge the battery.
Run the daily function test as described under "Periodic unit testing".

Occupational safety and health and PPE (It. Legislative Decree no. 81)

The decontamination process is always a delicate process, which implies specific training, especially in the emergency field where the patient's medical condition and degree of contamination are mostly unknown. For this reason, the operator must always wear personal protective equipment (PPE) to protect himself and others.
If proper PPE is not available, please contact your safety representative.

The organic secretions collected by the suction unit can cause severe operator infection. For this reason, always use suitable PPE and disinfection products as established by the competent authorities.

Cleaning of jars

Cleaning of autoclavable 500 ml jar

The steps required to separate the jar from the suction unit, dismantle the jar and, after cleaning and disinfection, reassemble it are described below. Before starting, put on all personal protective gloves, also covering the forearms.

1. Remove the patient tubing, withdrawing it from the jar. If the tube is equipped with a Yankauer suction tip, it must be disposed of together with the curved tip (disposable device).
2. Disconnect the conical connection from the suction unit connector.
3. Disconnect the filter from the lid and discard it.
4. Loose canister fixing belt.
5. Pull the jar vertically out of the unit.
6. Remove the lid (paying attention to possible contamination with the contents of the jar!). Empty the contents of the jar. Separate all parts of lid.

After having disposed of the disposable filter and Yankauer suction catheter, complete with tubing, set the reusable parts in cold running water and rinse thoroughly. Then dip the same parts in hot water (temperature not higher than 60°C) containing a mild, non-alcoholic detergent. Rinse thoroughly and, if necessary, use a non-abrasive brush to remove any deposits. After washing, rinse all parts with hot running water (30-40°C max.) and then dry with a soft, non-abrasive cloth. Before reassembling, check that all parts are clean, dry and intact. If the suction unit is equipped with silicone tubing and "finger-tip" connection, dispose of the connector and clean the silicone tubing. The tubing can be autoclave sterilized.

Replacing the filter

Carefully disconnect the silicone tubing from the contaminated filter and dispose of it in accordance with current laws and regulations. Install a new filter ensuring that the part marked "IN" is connected to the jar. Failure to heed this detail can cause filter failure and contamination of the suction unit intake circuit.

Cleaning of autoclavable OB-J FA jar

The steps required to separate the jar from the suction unit, dismantle the jar and, after cleaning and disinfection, reassemble it are described below. Before starting, put on all personal protective gloves, also covering the forearms.

1. Remove the patient tubing together with yellow elbow connector. If the tube is equipped with a Yankauer suction tip, it must be disposed of together with the curved tip (disposable devices). The angular connector can be sterilized.
2. Disconnect the filter from the lid by turning it slightly in its housing.
3. Carefully pull the jar vertically out of the unit.
4. Disconnect the red elbow connection from the suction unit. Disconnect the filter from the tubing and discard it.
5. Remove the lid (being careful not to contaminate it with the contents of the jar!) by prying on the tab. Empty the contents of the jar.
6. Remove the overflow valve from the lid.
7. Separate all parts of overflow valve.
8. Parts composing the lid.

After having disposed of the disposable filter and Yankauer suction catheter, complete with tubing, set the reusable parts in cold running water and rinse thoroughly. Then dip the same parts in hot water (temperature not higher than 60°C) containing a mild, non-alcoholic detergent. Rinse thoroughly and, if necessary, use a non-abrasive brush to remove any deposits. After washing, rinse all parts with hot running water (30-40°C max.) and then dry with a soft, non-abrasive cloth. Before reassembling, check that all parts are clean, dry and intact. If the suction unit is equipped with silicone tubing and “finger-tip” connection, dispose of the connector and clean the silicone tubing. The tubing can be autoclave sterilized.

Replacing the filter

Carefully disconnect the silicone tubing from the contaminated filter and dispose of it in accordance with current laws and regulations. Remove the filter from the lid by screwing or unscrewing it from its housing. This operation facilitates withdrawal and prevents it from breaking inside the lid! Install a new filter ensuring that the part marked “IN” is connected to the jar inlet marked VACUUM. Failure to heed this detail can cause filter failure and contamination of the suction unit intake circuit.

NOTE

The filter must be inserted with the side marked “IN” facing toward the jar. Using the suction unit with filter inserted incorrectly can lead to contamination of the suction circuit.

Place all components of the jar on a flat, secure surface. During assembly and disassembly, always check all parts for damage. The overflow valve has a float that slides on a plastic guide. Make certain that it slides easily and unhindered and that the silicone seal is intact.

OB-J LINER collection jar with SERRES disposable liner

The jar OB-J Liner is equipped with a specific disposable liner, approved for this type of use. Unlike the OB-J FA version, the disposable filter is located inside the liner.

1. Holding the suction unit securely, disconnect the connection tubing.

2. Pull the jar vertically out of the unit.
3. Disconnect the patient tubing together with the white angular connector for the disposable liner and discard it.
4. Close the “PATIENT” connector with the cap provided on the liner cover.
5. Remove the liner from the jar and dispose of it in compliance with current laws and regulations.
6. Disconnect the tubing from red angular connector.
7. Remove adapter for disposable bag.
8. Unscrew the plastic elbow connector while keeping the screw pressed inside the jar. Be careful with the seal ring.

Dispose of the single-use parts and, after disassembling the collection jar, set the reusable parts under cold running water and rinse thoroughly. Then dip the same parts in hot water (temperature not higher than 60°C) containing a mild, non-alcoholic detergent. Rinse thoroughly and, if necessary, use a non-abrasive brush to remove any deposits. After washing, rinse all parts with hot running water (30-40°C max.) and then dry with a soft, non-abrasive cloth. Before reassembling, check that all parts are clean, dry and intact.
If the jar needs to be sterilised, proceed as described under “Decontamination/sterilisation of the collection jar”..

Reassembling the jar

Draw a new disposable liner from the package, stretch it out (Fig. 1) and insert it into the jar (Fig. 2). Connect the completed jar to the suction unit. Activate the suction unit. With a finger, close the “PATIENT” connector and, at the same time, press lightly on the liner from the centre of the lid (Fig. 3). Make certain that the liner is completely extended in the jar. Connect the disposable patient catheter (Yankauer) to the “PATIENT” connector.

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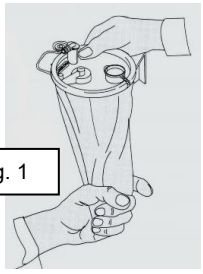
Fig. 1

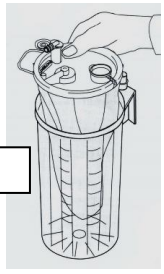
Fig. 2

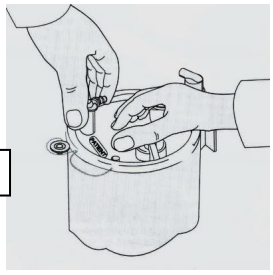
Fig. 3

The disposable liner must be replaced after each use!

Decontamination/sterilisation of the collection jar and silicone tubing

The collection jar and silicone tubing can be disinfected with any mild, non-abrasive chemical cleanser. Alcohol or solvent-based detergents cannot be used. Do not use any coloured disinfectants as these may damage the plastic of the

jar and stain the silicone tubing, reducing its transparency (e.g. Betadine). Never use disinfectants undiluted. Sterilize with a steam autoclave at a maximum temperature of 121°C for max. 15 minutes. Do not use pressures above 2 bar (200 kPa). The jar should be placed in the autoclave upside-down (bottom facing upward). At the end of the autoclave cycle, leave to cool to ambient temperature, check that it is intact and then reassemble the jar following the operations used to dismantle it in inverse order.

WARNING

- **Do not put weight on the parts during the sterilisation cycle.**
- **Observe the maximum limits for temperature, pressure and duration during the autoclave cycle.**
- **Never exceed the value of 60°C for washing or disinfection operations (with the exception of sterilization in a steam autoclave).**
- **Cleaning and/or and sterilisation operations should only be performed by trained personnel.**
- **Replace the collection jar if it presents fissures, cracks or even partial breakage.**
- **After reassembling the jar, always check that the lid is properly fitted so as to prevent loss of vacuum and carryover of fluids.**

Place all components of the jar on a flat, secure surface. During assembly and disassembly, always check all parts for damage. The overflow valve has a float that slides on a plastic guide. Make certain that it slides easily and unhindered and that the silicone seal is intact.

Disposal of contaminated parts

Always follow local regulations or hospital practices when dealing with contaminated materials. Never store contaminated parts with new or sterile parts.

Cleaning the suction unit

Disconnect the suction unit from any external power supply. To clean the chassis of the suction unit, use a damp cloth with mild detergent (type used for dishes and/or delicate clothing). When finished, dry the surface with a dry cloth or paper towel.

WARNING

- **Never submerge the suction unit in water or other liquids.**
- **Do not clean the unit with abrasive substances, alcohol or solvents that could deteriorate plastics or remove printing/labels.**

To correctly disinfect and decontaminate the suction unit, we recommend using specific, approved products. These disinfectants must be free of alcoholic and/or abrasive substances. Oscar Boscarol srl can provide specific materials for disinfection of medical equipment, including our suction units. These disinfectants, available in different formats (wipes, spray, liquids), have been laboratory tested and guaranteed to deactivate viruses, bacteria and microorganisms. When used periodically, they destroy and prevent the formation of dangerous biofilms (superficial layers that easily host bacteria, moulds, viruses and microorganisms). Our disinfectants do not contain alcohol, chlorine, phenols, aldehydes and halogens.

NOTE

For more detailed information, contact us at info@boscarol.it visit our website www.boscarol.it .

Suction unit safety

All electrical suction unit guards are set on the inside and cannot be accessed by the operator.
The suction unit also has thermal switches and safety devices for the internal battery. If the above safety devices trip, if they do not reset automatically, contact your authorized service centre or Oscar Boscarol srl.

Internal battery

The OB MINI AVIO suction unit has an internal battery that ensures long operating life. The lithium-polymer (LiPo) battery is located on the inside and cannot be removed by the user. The battery does not normally have to be replaced but, in case of failure or if the maximum number of charge cycles has been exceeded, contact a service centre. The old or faulty battery must be disposed of according to the regulations in force in the country where the suction unit is used

and only after all residual charge has been completely drained. Please consult a recycling centre for the location of the collection centres. Do not dispose of batteries if they are charged or partially charged. To know the procedure for discharging a battery completely, contact the manufacturer Oscar Boscarol srl (info@boscarol.it).

RISKS ASSOCIATED WITH THE BATTERY AND BATTERY REPLACEMENT

The suction unit has a battery produced exclusively for this purpose; it is not sold on the open market. The battery is enclosed in an airtight, rigid plastic container that cannot be opened. If the battery is perforated, cut or sawn it can easily explode or catch fire.

Battery Function Tests

The steps required to check that the battery is fully functional and efficient are given below.

- Recharge the suction unit by plugging it into an external direct current power supply rated between 11 and 25 V (using the charging cable provided). Wait until the yellow LED is on steady;
- Disconnect the suction unit from charging and set the vacuum regulator to maximum suction (turning the knob clockwise);
- Turn the suction unit on and let it run (without closing the patient tubing). Note the operating time which must be at least 30 minutes of consecutive operation;
- If this time is not reached and the suction unit shuts down before 20 minutes has elapsed, the battery is damaged and must be replaced.

NOTE

When battery life decreases significantly, it should be replaced. Contact the manufacturer or an authorized service centre.

Activation of internal safety devices

The suction unit does not have electrical and mechanical safety devices that can be accessed by the operator. Temperatures that are too high or too low can cause some of the internal safety devices to cut in, blocking unit operation. For this reason, the suction unit should never be exposed to extreme conditions (temperature, humidity and pressure). If the suction unit needs to be used under limit conditions, check the following:

- Operate the suction unit for the time strictly necessary. Once it has been used, set the suction unit in a place exposed to less critical operating conditions.
- If the suction unit ceases to function, set it in an area where the temperature is between 0 and 25° C. Wait for about 30 minutes for the machine to cool down.
- In the presence of high humidity, condensation may form on the outside and front of the suction unit. When you have finished using the unit, remove the condensation with a soft cloth. Such condensation can also be caused by sudden changes in temperature and humidity associated, for example, with rapid changes in altitude (e.g. use in a helicopter).

Disposing of the suction unit

The unit contains electrical and/or electronic equipment that must be recycled according to EC Directive 2012/19/EU – Waste Electrical and Electronic Equipment (WEEE) enacted in Italy with Leg. Decree 49/2014. The suction unit is also compliant with Directive 2011/65/EC which restricts and prohibits the use of certain hazardous substances in electrical and electronic equipment. Harmful substances that violate the above Directive are not used in the production and assembly of electronic boards or in the wiring and connection of electric cables.

ACCESSORIES, CONSUMABLES AND SPARE PARTS

Manufacturer code	Description
	Accessories
BSU895EU	Adapter 100/240 Vac LYD 14V - 2 poles and Euro-plug
BSU895UK	Adapter 100/240 Vac LYD 14V - 2 poles and UK-plug
BSU895JP	Adapter 100/240 Vac LYD 14V - 2 poles and Japan/USA-plug
	Consumables
BSU730	Filter for autoclavable jar – 5 pcs
BSU732	Filter for autoclavable jar – 15 pcs
BSU734	Filter for autoclavable jar – 40 pcs
BSU705	SERRES disposable liner – 6 pcs
BSU706	SERRES disposable liner – 12 pcs
BSU707	SERRES disposable liner – 36 pcs
BSU504	Collection jar in autoclavable polycarbonate - 500 ml
BSU500	Autoclavable OB-J FA jar, without filter
BSU506	OB-J LINER jar, without disposable liner
126140107191	Yankauer suction catheter
126140105021	Yankauer suction catheter without tubing
BSU750	End-piece with fingertip control – 5 pcs
BSU752	End-piece with fingertip control – 15 pcs
BSU754	End-piece with fingertip control – 50 pcs
11214101003	Suction tip Finger Ch 10 black
11214101104	Suction tip Finger Ch 12 white
11214101005	Suction tip Finger Ch 14 green
11214101006	Suction tip Finger Ch 16 orange
11214101007	Suction tip Finger Ch 18 red
11214101008	Suction tip Finger Ch 20 yellow
	Spare parts
BSU855	External charging cable with cigarette lighter fitting and 2-pole plug
BSU902	Silicone patient tubing - length 130cm
SPS6000	Overflow valve – 3 pcs
SPS6002	90° plastic connector for OB-J FA jar – 3 pcs
SPS6004	Lid for OB-J FA jar complete with overflow valve and 90° plastic connector
SPS6006	OB-J FA jar without lid
SPS6011	Red angular connector – 3 pcs
SPS6014	Conical connector – 5 pcs
SPS6019	Silicone tubing 18 cm with angular connector for OB-J LINER jar
SPS5092	Elbow connector for OB-J jar – 3 pcs
SPS6050	Straight connector for 500ml jar
SPS6052	Elbow connector for 500ml jar
SPS6029	Silicone tubing with conical connector for 500ml jar
---	User Manual (available on the Boscarol website www.boscarol.it)

NOTE

To make technical improvements, the parts listed may be changed by the manufacturer without prior notice. Contact the manufacturer for additional information (info@boscarol.it).

TECHNICAL SERVICES

No electrical and/or mechanical part of the suction unit OB MINI AVIO is designed to be repaired by the dealer, customer and/or operator. Do not open the suction unit and do not tamper with the electrical and/or mechanical parts. Always contact your authorized service centre or the manufacturer. Performing even the ***most minor*** operation on the suction unit ***voids the warranty***. Unauthorized access to the suction unit can jeopardize its conformity with the applicable laws and reduce safety for both operators and patients. Contact Oscar Boscarol srl for a list of authorized service centres by sending an e-mail to info@boscarol.it.

TROUBLESHOOTING

Malfunction	Possible cause(s)	Solution
The suction unit does not work	• Battery low • Battery failure • Internal electronic circuit failure	• Charge the suction unit with the charging cable or power supply adapter • Contact an authorized service centre to have the battery replaced • Contact an authorized service centre
The suction unit does not work when connected to the external charging cable.	• Power supply voltage is outside the required range (11 to 25 Vdc) • Current insufficient to power the suction unit (must be at least 8 A) • Suction unit internal circuit failure	• Power supply voltage must be between 11 and 25 Vdc • The current rating must be at least 8 A • Contact an authorized service centre
The suction unit works ***only*** when connected to the mains or external power cable.	• Internal battery damaged • Internal electronic circuit failure	• Contact an authorized service centre • Contact an authorized service centre
Suction unit does not charge and/or does not work when connected to the mains power supply	• Power supply failure	• Replace the adapter • Contact an authorized service centre
Battery charge indicator does not function when the TEST button is pressed	• Suction unit is charging • Internal battery is very low or damaged • LED display or internal electronic circuit failure	• Disconnect the suction unit from the charging cable or adapter • Recharge internal battery (yellow LED flashing) • Contact an authorized service centre
Suction unit battery life is significantly reduced	• Battery is dead • Internal charge circuit failure	• Contact an authorized service centre • Contact an authorized service centre
Vacuum power on patient side is low or absent	• Vacuum regulator completely open. • Filter plugged • Tubing connecting filter with device is plugged, bent and/or disconnected • Overflow valve for 500 ml • Pump damaged	• Close vacuum regulator completely and check vacuum on both instrument and patient sides (by turning the knob clockwise) • Replace filter • Connect tubing to filter and/or jar; replace if plugged and eliminate any bends • Disconnect the tubing running to the suction unit, empty the jar and check that the valve moves properly (the silicon gasket must be facing upwards). The jar can only be used in the upright position • Contact an authorised service centre
The third green LED on the front flashes periodically	• It is time for the suction unit to undergo scheduled safety maintenance	• Contact an authorised service centre
High noise, low suction, high vibration.	• Internal pump is damaged	• Contact an authorized service centre

NOTE

In the case of anomalies or malfunctions other than those indicated above, always contact only an authorized service centre and/or the manufacturer.

TECHNICAL DATA AND REFERENCES TO LEGAL REQUIREMENTS

Classification according to European Directive 93/42/EEC

The secretion suction unit is a medical device suitable for fixed and portable use. Compliant with ISO 10079-1:2009.

Medical Device classification:	**IIa**
Vacuum degree:	HIGH VACUUM-HIGH FLOW
Mode of operation (duration):	TEMPORARY (45 minutes “ON”, 10 minutes “OFF”)
Electrical requirements:	SELV (11÷25 Vdc)
Use of the device in the home environment:	complying to IEC60601-1-11
Use of the device in the health emergency:	complying to IEC60601-1-12
Applied part per IEC 60601-1:	TYPE BF
Insulation rating:	CLASS II
Protection against ingress of liquids and solids (IEC 529):	IP43
Compliant with general rules in IEC 60601-1:	Compliant with 3rd Edition
Device risk assessment:	UNI CEI EN ISO 14971:2012
Device usability analysis:	CEI EN 62366-1:2015

Other directives or regulations the device is subject to

Aeronautical sector EMC	**RTCA/DO-160 Section 21 (curve M)**
ECE R10 (automotive) type-approved	**E50 10 R - 05 0078**
Dimensions	
Maximum dimensions:	290 mm (l) x 240 mm (h) x 95 mm (d)
Weight:	1,8 Kg max. complete with all accessories
Tolerance on all values:	±5%
Technical data	
Nominal suction power:	850 mbar (85 kPa, 637.5 mmHg) ±10%
Vacuum regulation:	Linear with integrated mechanical regulator
Vacuum range regulation:	30–850 mbar (3–85 kPa)
Nominal flow rate:	25 LPM (litres per minute) at open flow ±10%
Max running time with the maximum current-load:	>70 minutes ±10% run time
Approximate maximum noise:	70 dBA
Vacuum gauge precision:	±5%
Battery power indicator precision:	±5%
Power supply	
Running/charging:	11÷25 Vdc (Direct Current)
Max current load:	80 W (max. current 8 A)

Battery:	Internal, LiPo, 11.1 V – 5 A
Max charge time:	10–15 hours consecutive
Electrical safety devices:	Internal, not accessible to operator

NOTE

The external direct current power supply must provide at least 8A to enable correct unit operation or charging. If the suction unit is plugged into the mains or an external DC power supply, the internal battery is not used.

Special storage and operating conditions	
Charging temperature range:	0–50 °C
Operating temperature range:	-10–45 °C
Storage and transport temperature range (packaged unit):	-20–60 °C
Storage and transport temperature range (without packaging):	-10–45 °C
Relative humidity for storage, operation and transport (unit without battery):	15–95%, not condensed
Ideal battery storage parameters (for less than 1 year)	0–25 °C (relative humidity 60±25%)
Atmospheric pressure for storage and transport:	70–1060 kPa (700–106 mbar)

Operating in the rain

The OB MINI AVIO suction unit is protected against ingress of liquids and solids. However, it is always best to protect the unit from heavy rains. During operation and storage, the unit must be kept in its carrying/storage bag and kept dry. If the suction unit is completely wet, move it to a dry area, dry the outside and wait at least 30 minutes before attempting to restart.

High altitude operation

The operator must take into account the altitude when using the unit. Under such conditions, the vacuum produced by the internal pump may drop, even considerably, as a result of the reduced atmospheric pressure.

Technical filter specifications

The antibacterial/antiviral filter consists of a PTFE filter support and an air-tight polypropylene container.
Max pressure applicable: 1bar (100kPa)
Retention capacity: for aqueous solutions - up to 0.9 bar (90 kPa); for airborne particles - 0.1 µm 99.99%

SERRES® disposable liners

SERRES® products are factory disinfected and should be stored in warm, indoor locations. Protect the package from humidity, dirt and dust. The SERRES® disposable liners are manufactured in Europe and bear CE marking. This device is a Class I medical device.

Power supply adapter specifications

Input: 100–240 Vac 50/60Hz, 1.5 A max.
Output: 14 Vdc 4,25 A
Manufacturer: LYD
Technical and product conformity specifications available from Oscar Boscarol srl

NOTE
The adapter can be used while operating on patients. The adapter cannot be used outdoors.

Terms and symbols

Vac Voltage (alternating current)
Vdc Voltage (direct current)
°C Unit of measure for temperature (°C = degrees Celsius)

bar unit of measure for pressure
kPa unit of measure for pressure (kilopascal)

mmHg unit of measure for pressure (millimetres of mercury)
Conversion formula: 1bar = 100kPa = 750mmHg

RISKS OF MUTUAL INTERFERENCE WITH OTHER DEVICES

The OB MINI AVIO suction unit does not create interference for other medical devices performing tests and clinical treatments in the same area. The unit must not be connected to other equipment for its operation and has an internal power supply.

RISK OF ELECTROMAGNETIC INTERFERENCE AND POSSIBLE SOLUTIONS

Electro-medical equipment requires special precautions regarding electromagnetic compatibility. For this reason, they must be installed and/or used according to the information specified in the accompanying documents (in this case in the tables below).
Portable and mobile radio communication devices may affect operation of the medical device.
Electro-medical equipment and systems should not be used in proximity with, adjacent to or overlapping with other electrical or radio communication equipment. If such use is necessary and unavoidable, special precautions must be taken to ensure that the electro-medical device functions properly in the envisaged configuration (for example, constantly and visually checking that there are no anomalies or failures). The following tables provide information on the EMC (electromagnetic compatibility) of this electro-medical unit. Full unit functionality is considered an "essential service" for the purposes of electromagnetic immunity. The suction unit is a CISPR 11 Group 1 electro-medical unit and complies with Class B requirements.

METHODS FOR PREVENTING ELECTROMAGNETIC INTERFERENCE

When there may be interference between the medical device and other electrical equipment in the vicinity, try to change operating position or remove sources if radiofrequency (cell phones, radio transceivers, mobile antennas). Try to move to another position (if possible) or turn off all non-essential equipment in the vicinity (including electrical appliances) and follow the directions given below.

MANUFACTURER'S GUIDELINES AND DECLARATION – ELECTROMAGNETIC EMISSIONS

The BSU family of suction units is intended for use in the electromagnetic environment specified below. The customer or operator should ensure that the unit is used in such an environment.

Emissions tests	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The OB MINI AVIO suction unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The OB MINI AVIO suction unit is suitable for use in all buildings, including residential buildings and those connected directly to the public low-voltage power supply powering buildings designated for domestic purposes.
Harmonic current emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker IEC 61000-3-3	Compliant	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The OB MINI AVIO suction unit is designed for use in the electromagnetic environment specified below. The customer or operator of the OB MINI AVIO suction unit should ensure that it is used in such an environment.

IMMUNITY test	**Test level IEC 60601**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV in air	±6 kV contact ±8 kV in air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	The quality of the mains supply voltage should be that of a typical commercial or hospital environment.
Overvoltages IEC 61000-4-5	± 1 kV between phases ± 2 kV between phase and ground	± 1 kV differential mode ± 2 kV common mode	The quality of the mains supply voltage should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on the inlet power supply lines IEC 61000-4-11	<5 % U_T (>95% dip in U_T) for 0.5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	The quality of the mains supply voltage should be that of a typical commercial or hospital environment. If the operator needs to run the OB MINI AVIO suction unit continuously even when power from the mains is out, we recommend powering the OB MINI AVIO suction unit with an uninterruptible power supply or battery.
Magnetic field at grid frequency (50/60 Hz) IEC 61000-4-8	3 A/m	0.3 A/m	If abnormal suction unit performance is observed, it may be necessary to move the OB MINI AVIO suction unit away from sources of magnetic fields at grid frequency or install magnetic shielding. The magnetic field at grid frequency should be measured in the room where the unit is to be installed to ensure that it is low enough.

NOTE: U_T is the network voltage prior to application of the type test.

GUIDELINES AND COMPLIANCE OF THE ELECTRO-MEDICAL DEVICES
CONDUCTED AND RADIATED IMMUNITY TESTS

For testing purposes, the tests are performed using IEC 60601 test levels, ***V_1*=3 and *E_1*=10**

The OB MINI AVIO suction unit is designed for use in the electromagnetic environment specified below. The customer or operator should ensure that the suction unit is used in such an environment.

IMMUNITY test	**TEST LEVEL IEC 60601**	**CONFORMITY LEVEL**	**Electromagnetic environment - guidance**
Induced RF as per IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used at a distance from the OB MINI AVIO suction unit, including the cables; recommended distance is calculated using the following equation applied to transmitter frequency: Recommended distance d= 1,2√P d= [3.5/E1] x √P = 0.35√P 80MHz to 800MHz d= [7/E1] x √P = 0.7√P 800MHz to 2.5GHz where *P* is the maximum transmitter output power rating, in watts (W), according to the transmitter manufacturer, and *d* is the recommended distance of separation in meters (m). [a] The strength of the fields generated by RF transmitters, as determined by an electromagnetic site survey [b], should be less than the compliance level in each frequency range [c] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF as per IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency 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] The levels of conformity of the ISM frequency band between 150 kHz and 80 MHz and in the 80 MHz to 2.5 GHz frequency interval are required to decrease the likelihood that a mobile or portable communications unit could produce interference if it is inadvertently brought into the patient area. For this reason, an additional factor of 10/3 is used to calculate the distance of separation recommended for transmitters operating within that frequency range.

[b] The strength of the fields generated by fixed transmitters, such as radio base stations for telephones (cellular and cordless) and for land mobile radios, amateur radio transmitters, AM and FM radios and TV transmitters cannot be accurately predicted on the basis of theory. To assess the electromagnetic environment created by fixed RF transmitters, an electromagnetic site survey should be considered. If the field strength, measured in the site where the Model 005 is used, exceeds the above applicable RF compliance level, normal functioning of the Model 005 should be kept under observation. In the case of performance anomalies, additional measures may be necessary, such as reorienting or repositioning the Model 005.

[c] Over the 150 kHz–80 MHz frequency range, the field strengths should be less than 1 V/m.

WARRANTY

Oscar Boscarol guarantees the OB MINI AVIO suction unit for a period of 36 months from the date of purchase by the original operator. The company guarantees that the suction unit is free of material and manufacturing defects.

The warranty does not cover: the collection jar, external battery charging cable, internal battery, normal wear and tear of the unit, discolouration and any other cosmetic irregularities that do not affect unit operation.

If, during the 36-month warranty period, the product is found defective, it should be sent to Oscar Boscarol srl with a note describing the defect. Oscar Boscarol srl will, at its own discretion, repair or replace the defective parts and/or the entire unit. All shipping costs are borne by the customer.

Warranty conditions:

To benefit from the warranty, the product registration form below must be filled out and returned by mail, fax or e-mail, to the following address:

OSCAR BOSCAROL SRL V. E. Ferrari, 29 – 39100 BOLZANO, ITALY

Fax: +39 0257760142 – E-mail: production.manager@boscarol.it

To validate the warranty, the customer shall provide the following documentation:

- copy of the invoice and/or purchase statement containing the device serial number and date of purchase;
- service department recognition of a failure and/or material or manufacturing defect;
- absence of tampering, changes and/or anything not conforming to the original product.

In terms of safety, reliability and suction unit function, Oscar Boscarol srl can only be held liable if:

- all technical operations, repairs, modifications and preventive maintenance actions are performed by Oscar Boscarol srl or by an authorised service centre;
- the suction unit is used correctly, strictly following the indications given in this User Manual;
- the electrical system to which the suction unit is connected has been built according to the reference national and European regulations and rules.

With reference to what was described in these warranty conditions, Oscar Boscarol Company cannot be held responsible for accidental or indirect damage resulting from unauthorised modification or repair, unauthorised technical interventions or when any parts of the unit are damaged in instances of accidental, improper use or misuse. The secretion suction unit is not subject to any other warranties, expressed or limited, regarding product marketability, suitability other than that described in this manual.

DECLARATION OF CONFORMITY

We, the manufacturer: *Il produttore:*		**OSCAR BOSCAROL srl** Via E. Ferrari , 29 – 39100 BOLZANO – ITALY Tel. +39 0471 932893 – Fax. +39 0257760140 Web: www.boscarol.it - Email: info@boscarol.it Certifies EN ISO 13485:2016 Certificate N° Q5 042208 0031 Certifies UNI EN ISO 9001:2015 Emission: TÜV–SÜD Product service (CE0123) EC Certificate N° G1 042208 0032 rev.00
We declare under our sole responsibility that the device (name):		**MEDICAL SUCTION UNIT**
Dichiariamo sotto nostra responsabilità che il dispositivo (nome):		**ASPIRATORE MEDICALE DI SECRETI**
	Type: **Tipo:**	**OB MINI AVIO**
	UMDNS code: **GMDN code**	**15-016** **63643**
	Boscarol code:	**BSU370 – BSU370JP – BSU370UK** **BSU372 – BSU372JP – BSU372UK** **BSU374 – BSU374JP – BSU374UK**
Device classification (MDD 93/42/EEC – Annex IX): *Classificazione dispositivo (MDD93/42/CEE – Allegato IX):*		**Class IIa**
Meets all provisions in MDD directive 93/42/EEC and subsequent amendments which apply. *Soddisfa tutte le disposizioni della direttiva MDD 93/42/CEE e successivi emendamenti che lo riguardano.*		
Harmonised standards, national standards or other regulatory documents applied: *Norme armonizzate o nazionali applicate, altri documenti normative applicate:*		**ISO 10079-1** **UNI EN 1789** **IEC 60601-1** **IEC 60601-1-12** **ECE-R10** **RTCA DO 160G**
Conformity assessment procedure: *Procedimento di valutazione della conformità:*		**MDD 93/42/EEC, Annex II**
Notified body: *Organismo di notifica incaric. della valut. della conformità:*		**TÜV SÜD PRODUCT SERVICE GmbH** **CE 0123** **Ridlerstrasse 65 – 80339 München – Germany**

Bolzano, 25.08.2020

DIR/RAQ – Quality Manager
Dr. MARCHETTI BENEDETTA

DIR/CEO
BRAZZO DANIELE

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